

OPIS LUCRARI DIN PORTOFOLIU

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Incisional Hernias with Loss of Abdominal Domain: A New Look to an Older Issue or the Elephant in the Living Room. Literature Review

Mihai Toma^{1,2}, Valentin Oprea¹, Ovidiu Nicolae Grad^{1,3}, Adrian Pavel⁴, Hunor Kovacs⁵, Călin Molnar^{2,3}

¹Department of Surgery, "Dr. Constantin Papilian" Military Emergency Clinical Hospital, Cluj-Napoca, Romania

^{2a}"George Emil Palade" University of Medicine, Pharmacy, Sciences and Technology, Târgu Mureș, Romania

^{2b}Iuliu Hațieganu" University of Medicine and Pharmacy, Cluj-Napoca, Romania

⁴"Dr. Constantin Papilian" Department of Radiology, Military Emergency Clinical Hospital, Cluj-Napoca, Romania

⁵¹Department of Surgery, County Emergency Clinical Hospital Târgu Mureș, Romania

*Corresponding author:

Valentin Oprea, MD
Department of Surgery
Military Emergency Clinical Hospital
"Dr. Constantin Papilian" Cluj-Napoca
22 General Traian Mosolu street
Cluj-Napoca, Cluj County, Romania
Zip code 400132
E-mail: opreav31@gmail.com

Abbreviations:

IH: Incisional Hernia,
LOD: Loss of Abdominal Domain,
IHV: Incisional Hernia Volume,
ACV: Abdominal Cavity Volume,
IAP: Intra – Abdominal Pressure,
IAH: Intra – Abdominal Hypertension,
ACS: Abdominal Compartment
Syndrome,
PPP: Preoperative Progressive
Pneumoperitoneum,
BTX: Toxine Botulinica (Botox, Dysport),
PP: Plateau Pressure,
PEEP: Positive End Expiratory
Pressure,
Cab: Abdominal Compliance.

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Rezumat

Herniile incizionale cu pierderea dreptului la domiciliu: o nouă abordare a unei vechi probleme sau elefantul din sufragerie. Revizuire a literaturii

Hernia incizională (HI) este un defect postoperator la nivelul peretelui abdominal prin care conținutul cavității peritoneale, acoperit de seroasa peritoneală, se exteriorizează sub piele. HI sunt entități clinice unice datorită diferențelor de complexitate anatomică dar și datorită comorbidităților asociate și istoricului chirurgical. Pe măsură ce cresc în dimensiuni, evoluția naturală spre complicații este aproape regula. Obiectivul acestui studiu este de a reevalua impactul formelor de hernie incizională cu pierderea dreptului la domiciliu asupra peretelui abdominal înainte dar și după reconstrucția acestuia. Absența anatomică și funcțională a liniei albe conduce la o serie de alterări musculare, patologice cronice respiratorii și digestive precum și la probleme psihosociale. Asocierea scăderii presiunii intra-abdominale (PIA) este un factor agravant al acestor tulburări. În timpul și după reconstrucția peretelui abdominal, reintroducerea forțată a viscerelor într-o cavitate peritoneală nepregătită conduce la creșterea brutală a volumului cavității și implicit a PIA cu implicații fiziopatologice severe, uneori mortale. Pentru o reconstrucție parietală optimală și sigură peretele abdominal trebuie augmentat prin atingerea următoarelor obiective: reducerea volumului conținutului sacular, îmbunătățirea complianței, lărgirea volumului conținătorului. Mai

mult, sunt necesare cunoștințe privind managementul local și sistemic al ansamblului de modificări, evaluarea pacientului prin examen computer tomografic, monitorizarea PIA, a presiunii de platou și a presiunii expiratorii pozitive. Obiectivele pot fi atinse prin optimizarea sistemică cu ajutorul unei echipe multidisciplinare, prin utilizarea pneumoperitoneului progresiv preoperator (PPP) și /sau a toxinei Botulinice la care se adaugă reconstrucția peretelui abdominal prin tehnici de separare a componentelor întărite de material protetice adecvate situație clinice și anatomice.

Cuvinte cheie: hernie incizională, pierderea dreptului la domiciliu, insuficiență respiratorie, presiune intra-abdominală, hipertensiune intra-abdominală, sindrom de compartiment abdominal

Abstract

Incisional hernia (IH) is a postoperative defect of the abdominal wall through which the contents of the peritoneal cavity are externalized beneath the skin in a peritoneal sac. IH differs in anatomic complexity, but also in its associated comorbidities and surgical history. As IH enlarges, complications occur and these become part of its natural history. The goal of the study is to review the impact of loss of domain upon abdominal wall before and after abdominal wall reconstruction. The absence of anatomical and functional linea alba leads to a combination of muscular disturbances, chronic respiratory and gastrointestinal conditions, and psychosocial issues. The pathophysiological changes are also due to the decrease of the intra-abdominal pressure (IAP). During repair, the sudden reintroduction of the viscera into an unprepared cavity leads to a sudden increase in cavity volume and an increase in IAP with fatal pathophysiological implications. For an optimal repair, preoperatively, the abdominal wall must be augmented by achieving the following objectives: reducing the volume of the sac contents, optimizing compliance, enlargement of the container. At the same time, for the optimal repair, the following must be taken into account: increased knowledge about this condition to manage systemic and local changes, CT scan evaluation, monitoring IAP, plateau pressure (PP), and Positive End Expiratory Pressure (PEEP). In conclusion, the goals can be achieved by systemic optimization with a multidisciplinary team, using Preoperative Progressive Pneumoperitoneum (PPP) and/or Botox (BTX), and abdominal wall reconstruction through a mesh with augmented component separation technique.

Key words: incisional hernia, loss of abdominal domain, respiratory failure, intra-abdominal pressure, intra-abdominal hypertension, abdominal compartment syndrome

Introduction

An incisional hernia (IH) is defined as a post-operative, abnormal weakness or orifice in the abdominal wall, through which, normally contained viscera, always enveloped by a serous sac, protrude beneath the skin (1,2). Despite the considerable improvements in surgical know-how (innovations, suture materials, suturing techniques, mesh, and laparoscopy), the incidence of incisional hernia, recurrences, and complications remains

high. The frequency of these appears to be on the rise due to more complex, extensive surgeries in an older, higher risk patient group, an increasing population, and longer life expectancy. All these factors emphasize the fact that the topic is one of major medical and economic importance (3,4). We propose in this study to review recent literature in order to update some important concepts regarding definition of loss of domain, physiopathology of the anatomical disturbances, and the consequences of the un-prepared

abdominal wall reconstruction upon respiratory function and intra-abdominal pressure.

Materials and Method

The authors conducted a research through electronic databases: PubMed, Scopus and Web of Science using the following search formula: "(incisional hernia OR ventral hernia) AND (loss of domain)". Three inclusion criteria were applied: the articles must be available full text, written in English and published no more than 10 years ago. The references of the selected papers were also checked for other relevant material. The resulting references were included in the current review, focusing on loss of abdominal domain in incisional hernia. In the end, a total number of 28 articles were included in this research.

Discussion

Concept of Loss of Domain

Hernia defects are not all the same. They differ in their anatomic complexity but also in their associated co-morbidities and surgical history. Recently, Slater et al defined the concept of "complex hernia" by introducing four criteria: 1. defect size and location, 2. patient history and risk factors, 3. contamination and soft tissue condition, and 4. clinical scenario (5). The size of the defect is the outmost variable in hernia repair being an important risk factor for 30-day readmission due to severe local and systemic complications and recurrence.

The same group included IH with loss of abdominal domain (LOD) as being a complex hernia but without clearly specifying the defining criteria. LOD is a term used commonly in the literature to describe the distribution of abdominal content between the hernia and residual abdominopelvic cavity. Its repair is fraught by severe complications and even death (6). However, the definition has only prognostic value for failure or success prediction of the repair. The utility of LOD as a morphological predictor of peri- and postopera-

tive outcomes is limited.

Recently, an International Delphi Consensus of Expert Surgeons has developed a standardized definition of LOD; this is to be used for comparable pre-operative assessment and trial comparison. According to this consensus, LOD is a ventral hernia large enough such that simple reduction in its contents and primary fascial closure cannot be achieved without additional reconstructive techniques, without significant risk of complications due to raised intra-abdominal pressure (7). Regarding the volumetric method, the Consensus Group decided that the Sabbagh formula should be used to determine the index of LOD. This formula is the ratio, expressed as percentage, between incisional hernia volume (IHV), and the sum of the abdominal cavity volume (ACV), and IHV (8). All these volumes can be easily determined on a native abdominopelvic CT scan, using Tanaka method (9). Unfortunately, no consensus was reached in relation to the cutoff point the Group leaving the decision to the surgeon's choice. A value larger than 20% represents, in our opinion a minimum cutoff to consider an incisional hernia as being with LOD (10).

Evolution to a functional dynamic abdominal wall reconstruction (AWR) rather than simply patching a hole put these frail patients, with multiple co-morbidities and LOD to increased risk for developing intra-abdominal hypertension (IAH) or abdominal compartment syndrome (ACS) (11). Efforts to reconstruct this failed abdominal wall in association with the reduction of herniated viscera within an unyielding stiff abdominal wall, without evaluation of the physiology of the abdominal compartment raises the specter of ACS (12,13).

Anatomy, Physiology, and Physiopathology of Loss of Domain

The abdominal wall is considered as a semi rigid cylinder that contains intra-abdominal viscera. It is delineated anteriorly by the rectus abdominis muscles enclosed in its sheaths and by the linea alba; laterally by the trilaminar complex composed of external,

internal oblique, and transversus abdominis muscles; posteriorly, the abdominal wall is limited by the lumbar vertebrae and erector spinal muscles (14). Due to this structure, it is flexible in its antero-lateral dimension and has potential cephalad distensibility (11).

The linea alba is the central tendon that fixes rectus abdominis muscles through its sheets, external oblique, internal oblique and transversus muscles through their large aponeuroses and ensures their coupling activity to stabilize torso, to allow coordinated movements (flexion of the abdomen, rotation and lateral flexion of the spine) and weight shifts. Individually, lateral abdominal muscles have different vectors of movement according to the direction of their fibers, but, when synergistic movements are employed, the overall direction of pull is to distract from the midline (14).

The top of the cylinder is the diaphragm and the bottom the pelvic floor; when they simultaneously contract, increase intra-abdominal pressure, and contribute to expiration, micturition, defecation, and parturition.

The natural history of IH is a gradual increase in size according to Laplace's law (simply stated the Law of Laplace says that the tension in the walls of a container is dependent on both the pressure of the container and its radius). As IH enlarges, complications occur and these become part of its natural history.

When an IH develops the structural and functional integrity of this cylinder is broken. The main problem of these patients is the absence of the anatomical and functional linea alba which leads to a combination of muscular disturbances, chronic respiratory and gastrointestinal pathology, and psychosocial issues.

In the absence of the linea alba, disinserted lateral abdominal muscles, are no longer mechanically coupled, lose their function, and become shortened. Because of the absence of activity and purpose, the muscle fiber loses its contractile ability and becomes shorter (2). A defect as large as $\frac{1}{4}$ of the abdominal circumference leads to retraction of the composite layer of the abdominal wall (internal oblique muscle and transversus abdominis muscle) by

20% on each side (15). The internal oblique muscle significantly reduces its elasticity and extensibility by 27%; stiffness is increased nearly 60% and tensile strength is increased too (16). The absence of strain results in decreased cell proliferation and modification of orientation angle of the fibroblasts. The lack of activity of the anterolateral abdominal group of muscles is a major hindrance to the back muscles that are not counterbalanced by the abdomen. Therefore, the spine is strained into a dorsal kyphotic accentuation and postural reflex contraction of the vertebral musculature. The rectus abdominis muscles and erector spinae muscles maintain torso stability also. Due to the disruption of the linea alba, rectus muscles became dysfunctional, and the columns are uncoupled which increases the pressure on the lumbar column. Back pain becomes a major symptom for which no statistics on prevalence are supplied in the literature (17,18). Upper and lower activities of the torso are also affected: decreased stabilization during physical activity, decreased coordination of movements, and inability to weight shifts. These modifications are reversible after abdominal wall reconstruction as stated by Dubay et al. (15).

In patients with LOD, chronic respiratory insufficiency is a major feature. The altered respiratory function is a summation of pathological factors related to extreme obesity, smoking and cardiovascular comorbidities connected to factors induced by the loss of domain: loss of the contribution of the abdominal muscles, decreased IAP and diaphragmatic impairment. Secondary dorsal kyphosis is another contributing factor for respiratory disturbances. In 1973, Rives emphasized the therapeutic problems and respiratory implications of large abdominal IH introducing the term "thoracic-abdominal compartment" to describe the link between the chest and the abdomen (19). These complex alterations were named "volet abdominal" or "abdominal shutter". This leads to a four phases "paradoxical respiration" (19). Briefly, abdominal wall moves in and out during both inspiration and expiration being unable (together with the diaphragm) to contract

against the viscera. During inspiration, the bowels are forced out. The result is a major chronic respiratory insufficiency through reduced respiratory compliance (both pulmonary and thoraco-abdominal), increased resistance of the airways, decreased functional residual capacity, and decreased oxygenation. The entire mechanical work of breathing is altered. In obese patients, the presence of LOD can mask all these disturbances with an increased vital capacity and increased residual volume/total lung capacity ratio (19). These disorders underline the inefficiency of the diaphragm and abdominal muscles when their contraction acts on an open, extended, extra-abdominal cavity. The diaphragm does not contract against the abdominal viscera, which are no longer retained by the muscular abdominal wall. The decreased intra-abdominal pressure (IAP) alters the balance between intra-thoracic and IAP leading to the modifications of the diaphragm shapes which became flattened (20).

A decreased IAP induces disturbances in pressure within hollow viscera with chronic distension and chronic edema of the mesentery and visceral wall. Chronic traction of the outside viscera extends the mesentery, which thickens. The continued obstructed venous and lymphatic return add a new dimension to the increased global volume of the viscera. This leads to chronic bowel dilatation and the loss of the balance between the visceral and parietal tonus (20). The viscera chronically outside the abdomen suffer gravitational chronic stretching and elongation, which worsens the edema. Portal circulation is also affected and it is a contributing factor in venous mesenteric stasis. In association with visceral adhesions and incompetent abdominal wall, all the above-mentioned mechanisms lead to a poor bowel function, chronic micturition disorders, chronic abdominal pain, and discomfort.

The skin also suffers important changes. Usually, secondary to the pressure of the viscera, the covering skin becomes extremely thin due to an absence of the subcutaneous fat. Disorders of the subcutaneous circulation

induce local ischemia at the top of the bulge with skin ulcers. These ulcers are always infected, and microorganisms are always found at the edges of these ulcerations. The treatment is usually conservative with topical antibacterial agents rather than systemic antibiotics (21). Another dermatological problem is intertrigo, more frequently seen in diabetic patients. Unlike trophic ulcers, which cannot be eliminated, intertrigo is easy to treat and eradicated before surgery.

Physiopathology of Abdominal Wall Reconstruction

Closure of large defects is fraught with possible and severe complications. During repair, the sudden reintroduction of viscera into an unprepared abdominal wall cavity leads to sudden increase of the cavity volume and increase of the IAP. The abdominal cavity can accommodate modest increases in its volumes through reshaping and stretching; this explains why IAP does not exceed critical values with the most "modest" hernia repairs (16). When compensatory mechanisms are exceeded, IAP rises greatly and exponentially exposes the patient to intra-abdominal hypertension syndrome (IAHT) or, even worse, to abdominal compartment syndrome (ACS) with respiratory compromise, renal failure, mesenteric ischemia, pro-inflammatory status, and multi-system organ dysfunction. Obesity can exacerbate the increase of IAP (12).

Because AWR becomes more common, we shortly review the risks and implications of IAHT/ACS in the light of the potentially serious issues regarding IAP. Measuring the IAP before, during, and after AWR is often ignored and this represents a serious drawback because it is responsible for most respiratory shortcomings. Increased IAP elevates the diaphragm, reduces pulmonary and chest wall compliance, use of respiratory accessory muscles with increased effort of breathing for equal respiratory volumes, reduces airway clearance, and increases airway resistance. In association with the patient's comorbid condition, this multifactorial

event trigger respiratory complications/failure.

In LOD patients, respiratory events have been reported in one of five subjects (22,23) and are associated with significantly increased surgical morbidity and mortality (18-fold greater death rate), prolonged hospital stay (four-fold greater), and additional cost burden. Incidence of postoperative pulmonary complications is unfortunately unclear given the lack of consensus on definitions and reporting in the literature (22). It is difficult to identify risk factors for postoperative respiratory morbidity, but it is important to do so in order to associate impact on resource mobilization and open the opportunity for the optimization of treatment strategies and interventions. Older age, male sex, congestive heart failure, lung disease, obesity, and sleep apnea are some of the risk factors independently associated with increased risk of respiratory failure (24). Fischer et al, recently identified that intraoperative blood transfusion, ASA score higher than 2, and fascial closure are surgical factors associated with respiratory morbidity (23). In a retrospective analysis, Mommers et al showed that hernia sac volume was highly associated in univariate and multivariate analysis with respiratory events ($p= 0.045$; 95% CI: 1.008-1.910) (25). Oprea et al, recently demonstrated, in a retrospective study, that all patients developed IAHT in various degrees after transversus abdominis release abdominal wall reconstruction in patients with defects larger than 10 cm, and 24 of them (23.7%) had pulmonary involvement in their outcomes (26). The main factors involved in respiratory compromise were postoperative elevated IAP and hernia sac volume.

In patients with risk factors for IAHT, it is necessary to measure IAP with simultaneous evaluation of the respiratory function (27). No clear algorithm for monitoring these patients has yet been developed, but two main pressures values must be registered:

1. Peak inspiratory pressure – is the pressure required to push the air through the ventilator circuit and into the lung; it is measured at the end of the inspiration.

2. Plateau pressure – is the pressure required to maintain the air space open after breath delivery. This value is not a function of flow resistance in the airway and is directly related to the recoil force of the lung and chest wall. Increased plateau pressure is closely related to a decreased compliance caused by abdominal hypertension. The difference between the values recorded at the opening of the abdominal wall and at the end of the anterior fascia closure is the delta plateau. If the value is larger or equal to 6 cm H₂O, there is a nine-fold risk to develop respiratory complications; the risk increases to 12-fold if the value is larger than 9 cm (20).

The increase of IAP during surgical repair and the early postoperative period is accompanied by deterioration of CO₂ elimination (increased PaCO₂) followed by a decrease in arterial oxygenation (decreased oxygenation index - PaO₂/FiO₂); this suggests an impairment of the respiratory function after procedure.

One factor that can be involved in the outcomes of LOD patients is the abdominal compliance (C_{ab}) which reflects the ability of the abdomen to accommodate the reduction of large hernia volume. It plays a very important role in understanding the deleterious effects of misfit intra-abdominal volumes on IAP and organ dysfunction. Unfortunately, measurements of C_{ab} are difficult at the bedside. Some indirect measures are available in mechanically ventilated patients: the ΔIAP (= IAP at the end of inspiration minus the IAP at the end of expiration) and the abdominal pressure variation (APV= ΔIAP divided by mean IAP) are such parameters, and they are negatively correlated with C_{ab}, i.e., the higher ΔIAP or APV, the lower C_{ab} (10). Therefore, if we could identify patients with a low C_{ab}, we could anticipate and select the most appropriate surgical treatment in order to avoid possible complications related to IAHT/ACS (26-28).

Strategies to Avoid IAHT/ACS

LOD patients are not emergency cases in

Table 1. Factors associated with decreased abdominal compliance

A. Related to anthropomorphy and demographics
• Male gender
• Old age (loss of elastic recoil)
• Obesity (weight, BMI)
• Android composition (sphere, apple shape)
• Increased visceral fat
• Waist-to-hip ratio > 1
• Short stature
B. Related to comorbidities and/or increased non-compressible IAV
• Fluid overload
• Bowels filled with fluid
• Stomach filled with fluid
• Tense ascites
• Hepatomegaly
• Splenomegaly
• Abdominal fluid collections, pseudocyst, abscess
• Diabetes
• COPD
C. Related to abdominal wall and diaphragm
• Muscle contractions (pain)
• Body builders (six-pack)
• Abdominal burn eschars (circular)
• Thoracic burn eschars (circular)
• Rectus sheath hematoma
• Multiple previous abdominal operations
• Mechanical ventilation (positive pressure)
• Fighting the ventilator
• Use of accessory muscles
• Use of positive end expiratory pressure (PEEP)
• COPD emphysema (diaphragm flattening)

almost all instances but a challenge to restore the anatomic and functional integrity of the cylinder without severe complications. Therefore, the goal is to maximally optimize the patient with adequate preoperative preparation. Leaving aside systemic optimization (smoking cessation, albumin > 3.5 g/L, blood glucose level around 150 mg% and HbA1c less

or equal with 6.5%, compensated cardiovascular function) the semi-rigid container will require modifications: increasing capacitance (compliance), reducing the volume of the contents, physical enlargement of the container. For an optimal repair, all of these goals have to be fulfilled.

Reducing the volume of the contents – weight loss will decrease the volume of the abdominal viscera (central obesity) which is an important part contributing to IAHT. Although visceral content can be reduced assuming omentectomy, right hemicolectomy or enlarged small bowel resection. There are no large studies to confirm the benefits of such procedures and in general they are encumbered by serious risks and complications such as fistulas, mesh infections, etc.

Optimizing compliance – use preoperative injections of the abdominal wall with Botox 4 to 6 weeks before surgery.

Enlargement of the container – use preoperative progressive pneumoperitoneum alone or associated with Botox. The container can be enlarged using unilateral or bilateral anterior (Ramirez) or posterior (transversus abdominis muscle release – TAR) component separation techniques. In a recent study, TAR show an increase of the peritoneal volumes almost identical to the preoperative calculated value ($11,015.82 \pm 2,184.44 \text{ cm}^3$ versus $12,171.8 \pm 2079.07 \text{ cm}^3$; (Student's t test: $P = 0.076$; F test: $P = 0.739$) (10).

In a recent review, primary closure was achieved after PPP in 84% of the patients after PPP and in 100% in Botox patients (13). The recurrence rate ranged between 6 and 7.2%.

Table 2. Advantages of the PPP and BTX for optimization of the abdominal wall

Progressive preoperative pneumoperitoneum	Botox injections
1. Increasing of the ACV with 49 to 53% within 15 to 21 days of insufflation	1. lateral muscle relaxation – increase visceral reduction
2. Increasing of the abdominal wall muscle length up to 9 cm	2. reduce lateral physiological forces – decrease defect
3. Pneumatic adhesiolysis: reduce the amount of dissection and operative time	3. reduce tension at closure – decrease IAP
4. Improves diaphragmatic function	4. ensure suture line protection – low recurrence rate
5. Reduces the chronic edema of the mesentery	5. increase muscle length, decrease lateral m thickness
6. Unmasked additional defects	6. increase transversal length of the AW
7. Spontaneous reduction of the viscera	7. primary fascial closure in up to 85%
8. Fewer analgesic requirements	8. decrease pain

Lessons to Be Learned

1. LOD is a morbid condition with a poor quality of life for the patient.
2. Abdominal CT scan is mandatory for defining LOD and for assessing the nature of the contents, volume of the contents of the sac, the percentage of the contents in the sac, and the size of the defect.
3. It is necessary to know the anatomical and physiological changes in the abdominal wall and abdominal wall cavity, which develop during the evolution of a giant hernia.
4. Systemic optimization by a multidisciplinary team (pneumologist, cardiologist, anesthetist, nutritionist, bariatric surgeon) is essential for a good quality surgery and optimal results.
5. Abdominal optimization alone or in combination with PPP and/or BTX is the cornerstone in avoiding IAHT/ACS and severe respiratory complications.
6. Always use an abdominal wall reconstruction through a mesh augmented component separation technique, which increases intra-abdominal volume and restores domain through myofascial advancement and medialization of the rectus complex.
7. Monitoring of IAP, plateau pressure, and PEEP are easily quantifiable parameters for determining high-risk patients. If delta plateau values are higher than 6 cm H₂O, keep the patient intubated and ventilated for 24 hours in order to prevent respiratory failure induced by IAHT. Postoperative respiratory morbidity is a relatively understudied area in AWR and warrants significant attention as postoperative risks can be significant.
8. Open communication between surgical and anesthesia teams can improve patient care.

Author's Contribution

All authors equally contributed to literature search, drafting the manuscript, and revising the final form.

Conflict of Interest

The authors declare no conflicts of interests.

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Chronic Mesh Infection after Incisional Hernia Repair. Factors Influencing Negative Outcomes of Complete Mesh Removal

Valentin Oprea¹, Florin Buia¹, Dan Gheorghescu¹, Dan Leuca¹, Mihai Toma¹, Ovidiu Grad^{1,2}

¹Department of Surgery, "Constantin Papilian" Emergency Clinical Military Hospital, Cluj-Napoca, Romania

²Department of Surgery, "Iuliu Hatieganu" University of Medicine and Pharmacy, Cluj-Napoca, Romania

*Corresponding author:
Valentin Oprea MD, PhD
Department of Surgery
"Constantin Papilian" Emergency
Clinical Military Hospital
22 Gral Traian Mosoiu Street
Cluj-Napoca, Cluj County, Romania
E-mail: opreacv31@gmail.com

Rezumat

Introducere: tratamentul herniilor incizionale s-a schimbat radical în ultimii 50 de ani odată cu introducerea materialelor protetice sintetice care au scăzut incidența ratei de recidivă. Reconstrucțiile peretelui abdominal cu materiale protetice sunt însă grevate de o incidență mare de complicații severe cum ar fi infecția bacteriană, fistulele intestinale și sindroamele aderențiale. Acestea impun sancțiuni terapeutice care reprezintă o mare provocare pentru chirurg și pentru pacient.

Material și metode: din ianuarie 2009 până în decembrie 2018 au fost colectate și analizate retrospective datele pacienților operați pentru infecții cronice după protezarea peretelui abdominal pentru herniile incizionale. Comorbiditățile, localizarea protezei, indicele prognostic nutrițional (IPN), datele demografice și rezultatele exciziei complete a protezei au fost introduse într-o bază de date SPSS.

Rezultate: au fost identificați 89 de pacienți (29 de sex masculin) care au îndeplinit criteriile de includere. Timpul mediu de la intervenție până la debutul infecției protezei a fost de 15.04 ± 0.95 luni. Factorul determinant pentru infecția protezei a fost infecția plăgii după intervenția primară. După excizie, în 43% din culturile bacteriene, protezele extrase s-au pozitivat pentru *St. aureus*, MRSA și *Enterobacter spp*. Au fost utilizate mai multe tehnici de excizie protetică și de reconstrucție a peretelui abdominal. După

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inchiderea reconstrucției peretelui abdominal, 54% din pacienți au dezvoltat complicații cu o mortalitate de 12%.

Concluzii: riscul de infecție după reconstrucția protețică este mai ridicat decât pentru alte intervenții curate. Excizia protezei este obligatorie când evoluția infecției este mai mare de 3 luni. Procedura este asociată cu o rată ridicată de mortalitate, morbiditate și calitate scăzută a vieții mai ales când abdomenul nu poate fi închis. Prevenția pare singura metodă validă de tratament.

Cuvinte cheie: hernie incizională, infecția protezei, fistula entero-cutanată, excizia protezei, evoluție negativă

Abstract

Background: The treatment of incisional hernias has radically changed over the last 50 years due to the introduction of mesh repair, which has been proven to be superior to tissue repairs in terms of recurrence. Severe complications such as bacterial contamination, enteral fistulas and severe visceral adhesions are the bane of mesh repair and lead to great challenges as far as treatment is concerned.

Methods: From January 2009 to December 2018, we retrospectively collected operative and outcome data on reoperation following septic complications of incisional hernias (IH) mesh repair in 89 patients. For adjustment, comorbidities, mesh location, prognostic nutritional index (PNI) and operative time were included in a SPSS data analyzer.

Results: in the referred interval 89 patients (29 males) met the inclusion criteria. The mean time for the infections onset was 15.04±0.95 months and the number of previous abdominal interventions varied from 1 to 5. Wound infections were reported to be the primary factor for mesh infection. Following removal only 43% of meshes were found to be positive for bacterial infections; the most common species detected being *St. aureus*, MRSA and *Enterobacter spp.* Different techniques of mesh removal and abdominal wall closure were used. After abdominal wall closure, 54% of patients developed post-operative complications with a mortality of 12%.

Conclusion: The risk of infection after abdominal wall reconstruction (AWR) appears to be higher than other clean abdominal procedures. Mesh removal is mandatory when the infection prolonged over 3 months. The procedure is associated with a high rate of morbidity and mortality and with low quality of life if the abdomen can't be closed. Prevention is the best treatment option.

Key words: incisional hernia, chronic mesh infection, entero-cutaneous fistula, mesh removal, negative outcomes

Introduction

With the introduction of synthetic prosthetic materials the treatment of incisional hernias (IH) has been radically changed over the last 50 years. Although controversy still exists concerning mesh type, positioning and approach (open or laparoscopic), mesh repair was demonstrated to be superior in terms of recurrence in randomized trials (1-3).

Far from being harmless, the burden of these materials is given by bacterial contamination and subsequent infections, intestinal fistulas and severe visceral adhesions. These unexpected surgical site occurrences (SSO), although infrequent frequent, often require arduous surgical interventions and re-interventions resulting in severe sequelae (loss of domain, open abdomen, intestinal stomas) and, sometimes, death.

In this retrospective study our main goal was to assess the outcomes and factors that negatively influence these outcomes following complete removal of chronically infected mesh and entero-cutaneous fistula (ECF) in patients with previous mesh incisional hernia repair.

Material and Methods

The study was conducted between January 2009 and December 2018. Following institutional review board approval, all files of the patients with mesh infection who underwent mesh removal in the referred interval were retrospectively reviewed. Only patients with signs of abdominal wall infections or intestinal fistulas lasting a minimum 3 months after a prosthetic repair of a primary or recurrent incisional hernia have been included. Demographic variables including patient's age and gender were collected. Medical co-morbidities such as Body Mass Index (BMI), Chronic Obstructive Pulmonary Disease (COPD), diabetes, smoking and alcohol habits, American Society of Anesthesia Score (ASA) score were also reported. The preoperative Onodera's Prognostic Nutritional Index ($10 \times \text{serum albumin (g/dl)} + 0.005 \times \text{total lymphocyte count/mm}^3$) was calculated to evaluate the preoperative nutritional and immunological condition (4). Types and size of mesh were identified using previous operative notes whenever was possible. We further classified mesh location into on-lay, inlay (bridging), sub-lay (retro-rectus) and under-lay (intra-peritoneal) (5 – 7). All admitted patients were investigated with standard abdominal ultrasound and contrast enhanced CT scan, in order to establish: location and status (folded, wrinkled) of the prosthetic material, the presence of the peri-prosthetic fluid collections, fistula location and bowel involvement, and to evaluate the abdominal wall musculature status and quality. Microbiology data were preoperatively collected on all patients by swab technique. For negative results the test was repeated and combined with an ultrasound guided puncture. All positive samples

were tested with 15 antibiotics for sensitivity. The Multiple Antibiotic Resistance Index (MAR Index) was calculated using the ratio between number of antibiotics to which an isolate is resistant and the total number of antibiotics to which it was tested (8).

Additional variables including previous surgical site infections (SSI) or a history of previous surgical debridement were also included.

Surgical Technique

Patients were admitted for the night before surgery and received an osmotic bowel preparation and the prophylaxis of deep vein thrombosis with low weight heparins according to the anesthesiologist preference. When a skin orifice was present it was injected with 2 ml of methylene blue, in order to evaluate the extent of mesh infection. Skin incision encompassed scar and open wounds. The abdominal cavity was entered above or below the supposed location of the mesh, along the medial border of the rectus muscle. All the viscera were sharply dissected from the abdominal wall inner surface while the infected mesh, scar and inflamed tissues were removed in bloc. When the mesh was extremely adherent to the bowel this was also resected. In the same way it was proceeded for intestinal fistulas which were "en bloc" removed with the mesh and abdominal wall. Any mesh remnants were removed. Mesh samples were sent to the microbiologist in order to identify the germs and when it was positive MAR Index was also determined. Also the whole mesh specimen was sent to the pathologist for examination. The duration of surgery and intraoperative complications were recorded.

The resulting abdominal wall defect was closed whenever was possible with the Ramirez anterior component separation technique. In some instances, the defect was allowed to remain, the skin was closed and a planned ventral hernia was proposed. The Bogota bag and Negative Wound Pressure Therapy (NPWT), followed by skin closure were the next options for the abdominal wall closure.

Outcome measures included: postoperative wound morbidity (superficial and profound SSI, hematoma, seroma, wound dehiscence), general morbidity, general mortality and hernia recurrence. Duration of hospital stay and Intensive Care Unit (ICU) stay were also noted.

Statistical Analysis

Data were tabulated as mean \pm standard deviation (sd). Continuous variables were analyzed by ANOVA variance test followed by unpaired 2 tail Student's t test assuming unequal variance and the binary outcomes with the χ^2 test. Pearson correlation (r) was used with the regression equation. A Receiver Operating Characteristics (ROC) curve was designed to determine the specificity and sensitivity of the PNI in relation with total amount of complications, with specific complications and also with the mortality rate. Youden index was determined to calculate the optimal cut-off value of PNI. Multivariate logistic regression models were built with all the variables as the outcomes of interest of severe postoperative complications, adjusting for identified confounders. In addition to the variables of interest the following were included for adjustment: comorbidities, mesh location, PNI, operative time. Multivariate models were calculated with the linear logistic regression and the results were shown with the Odd's ratio (OR) and the 95% confidence interval (CI). Probabilities smaller than 0.05 were considered as statistically significant. SPSS statistic version 22.0, 2018 (IBM Chicago, IL, USA) was used to perform the statistical analysis.

Results

Over the study period, 89 patients (29 males) with a mean age of 63.34 ± 0.67 (37-77) years were identified; 6 patients (7%) were initially operated in our hospital by 3 different staff surgeons, using a light weight macro-porous monofilament polypropylene mesh in sub-layer position. The mean time from the hernia

repair to the onset of infection was 15.04 ± 0.95 (3 – 39) months. All patients had a mean number of previous abdominal operations of 1.6 ± 0.1 , varying from 1 to 5. Presence of previous wound infections was reported in 33 patients (37%) and documented with isolated germs in 16, to which *Staphylococcus aureus* and MRSA were the main strains identified. In 63 patients the previously repaired incisional hernia was a primary one. The main clinical sign for admission was a chronic sinus in 55 patients, exposed mesh in 18 patients, and wound cellulitis with exteriorization of digestive liquids in 16 patients. Comorbidities and the results of the preoperative bacteriologic samples are listed in Table 1.

Mesh was identified as an on-layer in 31 patients (35%), in-layer in 28 (31%), sub-layer in 13 (15%) and under-layer in 16 patients (18%). The main polymeric compound has been identified as polypropylene in 80 patients, polyester in 6 and a PTFE in 3 patients. The

Table 1. Comorbidities and bacteriologic results of the preoperative samples

BMI (kg/m ²)	31.9 ± 0.48 (25 – 51)
	Under 30 – 31 patients
	Over 30 – 58 patients
COPD	– 16 patients
Diabetes	– 15 patients
Smoking	– 15 patients
Alcohol	– 13 patients
ASA score	
	1 – 6 patients
	2 – 78 patients
	3 – 5 patients
Preoperative albumin (g/dl)	3.21 ± 0.04 (2.1 – 4)
Preoperative lymphocytes/mm ³	2966 ± 116.9 (748 – 6120)
Prognostic Nutritional Index (PNI)	47.14 ± 0.89 (30.51 – 70.6)
Positive samples before surgery	– 21 patients (24%)
Isolated bacterial strains before surgery	
<i>Staphylococcus aureus</i>	– 16 patients
	MRSA – 5 patients
<i>Enterococcus spp</i>	– 3
MAR index	
<i>Staphylococcus aureus</i>	– 0.6
	MRSA – 0.66
<i>Enterococcus spp</i>	– 0.28
BMI – Body Mass Index; COPD – Chronic Obstructive Pulmonary Disease; ASA – American Society of Anesthesiologists score; MRSA – Methicilino - Resistant <i>Staphylococcus Aureus</i> ; MAR Index – Multiple Antibiotic Resistance Index Normal range values for albumin 3.2 – 5g/dl; Normal range values for lymphocytes is 21.8 – 53.1% from the count of leucocytes; Normal range leucocytes values 4.200 – 9.000/mm	

exact type of mesh (regarding weight, filament structure and porosity) could not be identified because almost all previous operative notes did not contain such details except for patients discharged from our department. Mesh was completely/almost completely removed in all patients. Mesh removal, as a unique procedure, was possible only in 20% of the patients. In 30 patients, visceral resections were necessary. No stoma was performed at the index (mesh removal) procedure. The abdominal wall was closed in 63 patients (71%), left open with temporary abdominal closure (TAC) in 10 (11%) and, with a direct planned ventral hernia by skin closure in the last 16 patients (18%). For 3 patients, who survived with the abdomen left open, the defect was closed with a skin graft after secondary healing (2 patients) and with anterior component separation (1 patient). The mean time from

temporary abdominal closure to definitive closure was 7.8 ± 0.73 days (6-17). Intra-operative details are listed in *Table 2*.

After the explanted prosthesis were sent for bacteriological examination, postoperative positive samples and germ identification increased to 43% of the patients. In 11 samples only one germ was identified (*St. aureus* in 4, MRSA in 4 and *Enterobacter* spp in 3 patients) while in the final samples, 2 different strains were isolated. The postoperative MAR Index ranged between 0.26 and 0.86.

Mean duration of surgery was 165.35 ± 8.19 minutes with limits ranging from 45 minutes to 382 minutes. Overall, 48 patients (54%) developed postoperative local and general complications. Wound events were reported in 38 patients and included: SSI in 18 (out of which 12 were noted as superficial), seroma - in 12 and hematoma - in 8 patients. Except

Table 2. Details of the surgical procedures and outcomes related to every type of mesh location

Variable	Number (%)	On-lay	Inlay	Sub-lay	Under-lay
Mesh removal only	18/89 (20%)	18/32 (56%)	0/28	0/13	0/16
Abdominal wall resection	24/89 (27%)	14/32 (44%)	0/28	10/13 (77%)	0/16
Small bowel resection	19/89 (21%)	0/32	9/28 (32%)	1/13 (8%)	9/16 (56%)
Large bowel resection	5/89 (6%)	0/32	2/28 (7%)	0/13	3/16 (19%)
Combined bowel resections	6/89 (7%)	0/32	2/28 (7%)	0/13	4/16 (25%)
Simple fascial closure	35/89 (39%)	22/32 (69%)	13/28 (46%)	0/13	0/13
Anterior Component Separation (ACS)	28/89 (31%)	10/32 (31%)	15/28 (54%)	2/13 (15%)	1/16 (6%)
Bogota bag + ACS	1/89 (1%)	0/32	0/28	1/13 (8%)	3/16 (19%)
NPWT + skin graft	2/89 (2%)	0/32	0/28	1/13 (8%)	5/16 (31%)
Simple skin closure	16/89 (18%)	0/32	0/28	9/13 (69%)	7/16 (44%)
Duration of surgery (minutes) (mean and sd) (45 – 382)	165.35 ± 8.19 (45 – 90)	73.16 ± 6.9 (58 – 125)	92.14 ± 9.7 (75 – 150)	101.7 ± 12.4 (125 – 382)	139.3 ± 18.5
Hospital stay (days) (mean and sd) (5 – 65)	15.21 ± 1.5 (5 – 16)	11.5 ± 1.6 (9 – 21)	14.7 ± 3.1 (11 – 17)	15.1 ± 2.1 (17 – 65)	18.2 ± 3.6
ICU stay (days) (mean and sd) (7 – 61)	36.53 ± 4.38 (1 – 2)	1.3 ± 0.1 (6 – 19)	11.7 ± 2.9 (3 – 12)	4.2 ± 0.8 (22 – 65)	39.5 ± 9.3
Number of procedures/patient (1 – 8)	1.85 ± 0.14 (1 – 2)	1.3 ± 0.1 (1 – 4)	1.6 ± 0.3 (1 – 2)	1.3 ± 0.1 (1 – 8)	2.6 ± 0.6
Superficial SSI	12 patients (13%)	5	4	1	2
Profound SSI	6 patients (7%)	0	2	1	3
Seroma	12 patients (13%)	10	0	1	1
Hematoma	8 patients (9%)	6	1	1	0
Anastomotic leakage	6 patients (7%)	0	2	0	4
Mortality	11 patients (12%)	1	4	1	5
Anastomotic leakage	4 patients	0	1	0	3
Sepsis	3 patients	0	1	0	2
Pulmonary embolism	2 patients	0	1	1	0
Myocardial infarction	1 patient	0	1	0	0
Abdominal Compartment Syndrome	1 patient	1	0	0	0

NPWT – Negative Pressure Wound Therapy; ICU – Intensive Care Unit; SSI – Surgical Site Infection

seroma, all wound events imposed re-intervention for debridement or hemostasis. Anastomotic leakage was noted in 6 patients (20% of all patients with visceral resections), all of them requiring surgical exploration for signs of peritonitis. In all patients a stoma was created and the abdomen was left open on a Bogota bag (4 patients) or on NWPT. Hospital stay ranged from 5 to 65 days with a mean of 15.21 ± 1.5 . For the severe complicated patients, the mean stay in the Intensive Care Unit was 36.53 ± 4.38 (Table 2).

The mean number of surgical procedures/

patient for the whole cohort was 1.85 ± 0.14 but when we analyzed only patients with local complications the number increased, becoming almost doubled, with a mean of 3.3 ± 0.24 (2-8).

Mortality was recorded in 12% of the patients. 4 patients died after complicated anastomotic leakages with multiple organ failure, 3 - from wound sepsis and open abdomen, and 1, with multiple organ failure due to an abdominal compartment syndrome after an anterior component separation. The rest of the causes of mortality are detailed in

Table 3

Table 3. Factors that independently influence the postoperative outcomes in both uni- and multivariate analysis

Variables	Complications		Anastomotic leaks		Mortality	
	univariate	multivariate	univariate	multivariate	univariate	multivariate
Age	$r = -.158$ $p = .138$	$p > .05$	$r = -.027$ $p = .801$	$p > .05$	$r = -.032$ $p = .763$	$p > .05$
Gender	$r = .019$ $p = .863$	$p > .05$	$r = -.004$ $p = .968$	$p > .05$	$r = .115$ $p = .282$	$p > .05$
Onset	$r = .013$ $p = .901$	$p > .05$	$r = .034$ $p = .754$	$p > .05$	$r = .090$ $p = .404$	$p > .05$
Abdominal operations	$r = -.139$ $p = .194$	$p > .05$	$r = .005$ $p = .894$	$p > .05$	$r = .149$ $p = .163$	$p > .05$
Recurrences	$r = -.122$ $p = .253$	$p > .05$	$r = .103$ $p = .339$	$p > .05$	$r = .137$ $p = .201$	$p > .05$
BMI	$r = -.163$ $p = .126$	$p > .05$	$r = .130$ $p = .225$	$p > .05$	$r = .130$ $p = .224$	$p > .05$
COPD	$r = -.108$ $p = .312$	$p > .05$	$r = .341$ $p = .001$	OR = 0.0360 95%CI 0.0039 - 0.328 $p = .034$	$r = .269$ $p = .011$	OR = .048; 95% CI = .0096 - .247 $p = .0003$
Diabetes	$r = .036$ $p = .737$	$p > .05$	$r = .118$ $p = .269$	$p > .05$	$r = .013$ $p = .901$	$p > .05$
Smoking	$r = .157$ $p = .140$	$p > .05$	$r = .01$ $p = .99$	$p > .05$	$r = .105$ $p = .330$	$p > .05$
ASA	$r = -.102$ $p = .343$	$p > .05$	$r = .007$ $p = .813$	$p > .05$	$r = .112$ $p = .214$	$p > .05$
Mesh location	$r = -.239$ $p = .024$	OR = 3.36; 95%CI 1.87 - 6.02;	$r = .291$ $p = .006$	OR = 4.88 95%CI .54 - 43.54; $p = .015$	$r = .323$ $p = .002$	OR = .21; 95%CI = .044 - 1.06; $p = .05$
Operative time	$r = -.032$ $p = .769$	OR = 23.5; 95%CI 2.97 - 186.6; $p = .0028$	$r = .332$ $p = .001$	OR = .037; 95%CI = .001 - .67; $p = .02$	$r = .304$ $p = .004$	$p > .05$
Albumin	$r = .182$ $p = .088$	$p > .05$	$r = -.328$ $p = .002$	$p > .05$	$r = .392$ $p = .000$	$p > .05$
Leucocytes	$r = .081$ $p = .453$	$p > .05$	$r = .07$ $p = .0776$	$p > .05$	$r = .07$ $p = .0886$	$p > .05$
Lymphocytes	$r = -.158$	$p > .05$	$r = -.394$ $p = .000$	$p > .05$	$r = -.291$ $p = .006$	$p > .05$
PNI	$r = .301$ $p = .004$	OR = 0.336; 95%CI 0.15 - 0.71; $p = .0047$	$r = -.394$ $p = .000$	OR = .073; 95% CI = .008 - .66; $p = .021$	$r = -.427$ $p = .000$	OR = .0821; 95% CI .016 - .407; $p = .0022$
Anastomotic leak				$p > .05$	$r = .307$ $p = .03$	$p > .05$
ICU stay				$p > .05$	$r = .802$ $p = .001$	$p > .05$

BMI - Body Mass Index (kg/m²); COPD - Chronic Obstructive Pulmonary Disease; PNI - Prognostic Nutritional Index; ICU - Intensive Care Unit

The mean time of follow-up was 41.5 ± 9.4 months (11 – 71 months). At 1 year 63 patients from the survival group were clinically examined (48 of them with abdomen closed after mesh excision). In the group of patients with closed abdomen, more than half (26 patients) developed incisional hernias. From the rest of the patients, 18 were with stable abdomen and 19 with the planned ventral enlarging. All of the patients with IH declined surgical repair.

Complications rate was highly correlated with mesh location, and preoperative PNI in a univariate analysis. Logistic regression with adjustment for positive variable showed that mesh location (for inlay and underlay) and PNI are the only independent risk factors for development of postoperative complications (OR 3.36; 95%CI 1.87 – 6.02, $p < .0001$ respective OR 0.337, 95% CI 0.15 – 0.71, $p = .0047$). The increased incidence of anastomotic leaks was correlated with: the presence of COPD, mesh location, duration of surgery, PNI, lymphocytes count and albumin. In logistic regression the only independent factors for fistula were: COPD, duration of surgery, mesh location for inlay and underlay position and PNI. The same factors were directly involved in the incidence of postoperative deaths (Table 3).

To determine the sensitivity and specificity of the factors involved in postoperative morbidity and mortality, individual and multi-

ple ROC curves were created for: PNI, duration of surgery, mesh location and presence of comorbidities. Duration of surgery was highly specific for predicting mortality and anastomotic leakage (98% specificity), but not a valid model for the overall rate of complications. The cutoff time for duration of surgery, which predicted unfavorable outcomes and deaths was 125 minutes ($J \text{ max} = 0.81$)

PNI was highly specific for overall rate of complications (area under curve 0.867; 98% specificity for a cutoff of 37; $J \text{ max} = 0.76$), but not a valid predictor for fistula formation and postoperative mortality (Fig. 1).

Mesh location for inlay and under – lay position demonstrated a high specificity in relation with fistula formation (area under curve 0.799, 88%) along with postoperative death (area under curve 0.753; 88%) (Fig. 2).

Regarding co-morbidities, COPD and obesity were the only specific factors predicting complications, anastomotic leakage and mortality (data not shown).

Discussion

Natural history of IH is prone to complications: pain, increasing size, poor cosmetics, poor abdominal wall function, low quality of life and increasing risk of strangulation and incarceration (9). An optimal approach has to be identified, but there is one consensus: mesh repair is mandatory (1-3). Mesh repair refined

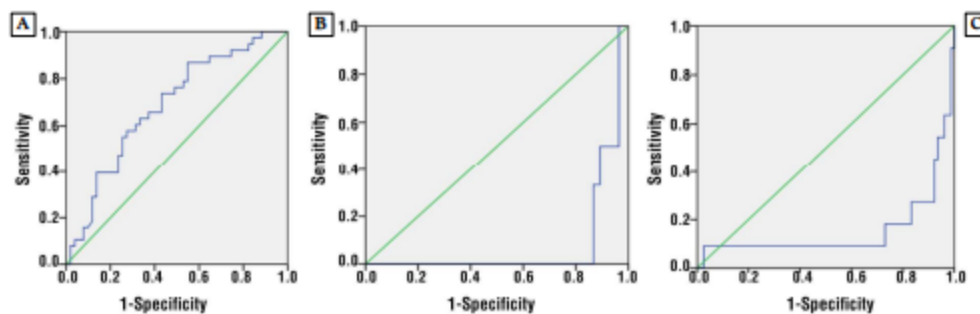


Figure 1. Individual Receiver Operating Curve (ROC) curve for "Prognostic Nutritional Index" in relation with overall complications rate (A), fistula presence (B), and postoperative mortality (C). Model is valid only for the complications rate (area under curve 0.897) but highly nonspecific for the presence of anastomotic fistula (B) and for mortality (C)

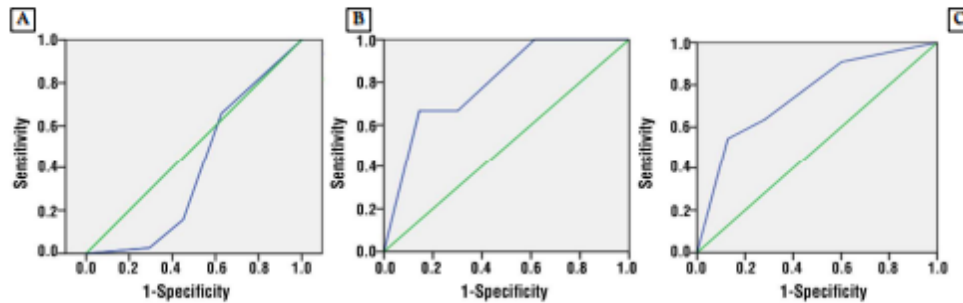


Figure 2. Individual Receiver Operating Curve (ROC) curve for “Mesh location inlay and under-lay” in relation with overall complications rate (A), fistula presence (B), and postoperative mortality (C). Model is not valid for complications rate (area under curve 0.397) but highly specific for the presence of anastomotic fistula (B) (area under curve 0.799) and for mortality (C) (area under curve 0.753)

the existent surgical techniques allowing complex cases to be solved and offering a real chance of social reinsertion with better healthcare outcomes for patients.

Even though the quality of the prosthetic materials has undergone successive improvements over time, their use is still associated with severe complications: intestinal obstruction, mesh infection, entero-cutaneous fistula (ECF). Infection plays the number one role in major device - related complications. It can lead to severe and costly consequences, severe impact on patients life (disability, suffering, economic loss), prolonged hospitalization and multiple re-interventions (10 -12).

The risk of infection after abdominal wall mesh reconstruction appears to be higher than other clean cases. A study from Schumpelink et al, emphasizes that patients with mesh repair have a 3 times higher risk ratio for infection than non-mesh repairs (13).

Some would advocate that mesh infection is a complication frequently observed only in the early postoperative period; although the first year may be important for the majority of mesh infections, in some studies, there is a large body of evidence showing that the complication occurs later (10). In our study, 44% of the patients reported the infection onset after more than 12 months from the last mesh repair. Infection occurred without a history of outbreak of infections or unknown sepsis outstanding from previous intervention in 53 patients.

Chronic mesh infection is unique because bacteria adhere to the mesh surface and create a microenvironment called “biofilm” (Bi) (12-16). By its tridimensional structure, Bi provides mechanical stability to the bacteria and physical protection from outside stressors (immune cells and therapeutic compounds including antibiotics), making ineffective any measure of conservative treatment (12).

If there is an agreement that infected mesh must be removed, controversy remains regarding complete or partial mesh removal. Complete mesh removal is usually associated with increased complication rates, hernia recurrence and increased associated morbidity and even mortality. Intestinal resection was needed in 30 patients (34%) due to dense adhesions between prosthetic surface and bowel or migration of the mesh into the small or large bowel. As a consequence, anastomotic leakage was the most serious complication and reason for re-intervention. Same results were obtained by Bueno-Lledò et al, who reported 13.1% intestinal resections after complete mesh removal with 7,8% intestinal fistula and 10.5% re-intervention (10).

An alternative to total removal of the mesh is the partial removal of the prosthesis. In Sabbagh series partial removal of the mesh was associated with healing in every case and the postoperative morbidity was nil but the patients still required up to five operations for healing to take place (17). In another study,

Bueno-Lledo found that 50% of the patients with partial mesh removal continue with a discharging sinus needing complete mesh removal for healing (18).

The goals of surgery are not only to remove the infected mesh, or control the infection, and achieve wound healing, but also to address the abdominal wall defect and to prevent hernia recurrence. This is a thorny issue and until now, no satisfactory standard treatment has been developed. The recommended treatments include primary closure with suture or mesh repair or staged operations with a 6 months minimum gap between procedures (19).

We don't use any mesh for the abdominal wall repair after mesh explantation. Closure of the abdomen with simple suture or anterior component separation was associated, in our series, with high rates of SSO, SSI and increased rates of recurrences. Multi-staged approach was tailored in our study for the patients with prolonged operative time, associated comorbidities, large intestinal resections and more than one anastomosis, and for the patients with a compromised immune and nutritional status. When PNI was under the cut-off value of 37 the abdomen was closed by skin suture or was left open with various TAC methods and a planned ventral hernia was preferred.

Several factors have been identified to be associated with poor outcomes after mesh removal. Mesh location for inlay and underlay and PNI are the only independent risk factors for development of postoperative complications. The incidence of fistula was independently related to the presence of COPD, duration of surgery, mesh location for inlay and underlay position and PNI. The same factors were directly involved in the incidence of postoperative deaths. An operative time longer than 125 minutes was found highly specific in predicting mortality and anastomotic leakage. PNI was highly specific for overall rate of complications. A high specificity demonstrated mesh location for inlay and underlay position in relation with fistula formation (area under curve 0.799, 88%) and for postoperative deaths

(area under curve 0.753; 88%). Regarding morbidities, COPD and obesity were the only specific factors predicting complications, anastomotic leakage and mortality. All of them are correctable factors before surgery in the patient's optimization process.

To our knowledge this study seems to be the first large series of mesh infections reported in our surgical literature. Though not new, the results of our research are in accordance with previously published western literature and confirm once again the difficulties induced by the presence of the mesh in contact with the bowels. Our contribution could be important due to the large number of operated cases with unexpected, challenging intra-operative situations in a series of complex patients.

Our study is not without limitations. Retrospective chart review was limited by the incomplete medical information collected from the patient's files as well as the bias of the reviewers. Our patient population was almost exclusively referred to resolve a severe complication. Also it spans a long period of time, but given the relatively low incidence of the cases and long-time lapse manifestation, it is not possible to construct a randomized trial in a reasonable time frame. The degree of contamination cannot be predicted or anticipated preoperatively so, intraoperative findings can alter the risk of mesh explantation. Finally, the entire cohort was heterogeneous and also surgical therapy included various procedures both involving a serious bias. The applicability of this data to other patient population should be approached cautiously.

Conclusions

Mesh infection after IH repair is a severe and debilitating condition. Complete mesh removal seems to be the only valid therapeutic option but generates a high early and late severe complication rates with increased morbidity (in terms of SSO and SSI) and mortality. Factors that negatively influenced the outcomes of complete mesh removal are: mesh location as in-lay and under-lay, decreased PNI (under 37), prolonged operative time (over 120 minutes)

and co-morbidities especially COPD. Abdominal wall closure after mesh removal is challenging and no satisfactory standard treatment till now has been developed. The rate of incisional hernia after closure of the abdominal wall remains high. Multi – staged approach for abdominal wall closure is an inconvenient long – term solution, but could be a valid option in selected cases with obese, co-morbid patients and increased risk of fistulas. Patient's optimization is mandatory and aims correction of the nutritional status in patients with PNI under 37, correction of the respiratory status and sometimes staged repair when these targets can't be achieved. Practically, patient referral to a specialized center or to an experienced dedicated surgeon could be a valid option to avoid major complications.

Authors Contribution

OV – design concept, data collecting and interpretation, writing the manuscript, revising and final approval; FB, DG, DL, MT, and OG – reading, revising and approval of the final form

Conflict of Interest

The authors declare no conflicts of interests.

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Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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Why Should Be Removed Chronic Infected Abdominal Synthetic Meshes? A Review

V. OPREA^{1,*}, D. MOGA²

¹Department of Surgery, Emergency Military Hospital "Constantin Papilian" Cluj-Napoca

²Department of Surgery, Emergency Military Hospital "Alexandru Augustin" Sibiu

*Corresponding author: opreacv@yahoo.com

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Abstract Incisional hernia is the most common late complication of laparotomy. Prosthetic treatment resulted in a remarkable improvement in surgical outcomes by reducing drastically the rate of recurrence and increasing quality of life. Insertion of synthetic prostheses is encumbered by a relatively high rate of complications of which the most common is infection. Chronic infection requires removal of mesh as radical therapeutic measure. Based on the literature review, the article presents, the main mechanisms of chronic infection and the main reasons for removal of prosthesis. Specially are analyzed mechanisms in gaining the antibiotic resistance of bacteria in biofilm. Following the analysis it can be concluded that once infected prosthesis can not be saved by conservative means.

Keywords: incisional hernia, biofilm, chronic mesh infection, antibiotic resistance

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1. Introduction

Despite the development of minimally invasive surgery a large number of diseases (especially traumatic and visceral neoplasia) can be solved only by large incisions. The most common complication with an incidence ranging between 11 and 20% is incisional hernia (IH) and also it is the most common cause of reoperation due to direct complications, discomfort or low quality of life [1-6].

Incisional hernia treatment changed radically with the introduction of prosthetic materials. Although there is still controversy about the type of prosthesis, its positioning and methods of implantation (open or laparoscopic) prosthetic reconstruction of the abdominal wall proved to be superior in randomized trials compared with other repairs [7,8,9,10].

Far from being harmless, the burden of such materials is bacterial contamination and consecutive infection, visceral adhesions and intestinal fistulas. The most common complication and the most feared at the same time by the devastating consequences it produces (increasing the number of hospitalization days, increased direct and indirect costs for diagnosis and treatment, multiplying physical and mental suffering of the patient, recurrence or even death) is **infection** [11,12,13].

2. Incidence

If postinguinal herniorrhaphy infections are usually circumscribed to the groin, IH infections constitute a major surgical complication that poses a serious challenge

to both the surgeon and the patient and may end in the patient's death but the real incidence of infection including the mesh is quite rare and difficult to establish in clinical series.

Dates are sparing and inaccurate because the incidence is changing depending on the personal interpretation of the surgeon, by hospital and even with the patient population. For the moment there is no valid and accepted classification of mesh infection, clinical facts are subjectively interpreted and the surgeons tend to underestimate infections rates. In a 36 years literature study (1966-2002), Sanchez-Montes et al, found 386 studies reporting incisional hernias series [14]. Of these studies, 43.8% were prospective and 34.4% retrospective. However, in 22% of these publications, those variables were not specified. If it was to talk about mesh infection only 32 articles (8,29%) report this. The authors of articles on ventral herniorrhaphy did not define or classify the infections encountered. Most of the studies (81%) were reported between 1990 and 2000.

In another review of the literature from 2003 to 2008, on series larger than 100 cases, Lammers et al found a wound infection rate ranging from 0,3% to 21,5% [13]. This large variation make data impossible to adjust to a clinical conclusion. In the same study the rate of mesh infection is mentioned only in 4 of the 8 studies with a rate of 0,3 to 2%; mesh removal is noted in only 1 study.

Mesh infection can follow either open or laparoscopic IH repair. The reported incidence after open repair ranges from 6%-10% [15,16,17], whereas that after laparoscopic repairs is lower, from 0-3.6% (18). A mesh infection rate as low as 0.78% (45/6,266) after laparoscopic IH repair was published in a systematic review by Carlson et al. Twenty-eight of the 45 patients (56%) with mesh infection

required re-operation, and such infections were the third leading cause of re-operation [20].

Initial evolution of the prosthetic infections is acute onset being 9-12 days after surgery and apparently is the most well known and studied. It is caused by free floating bacteria (planktonic form) that grow like individual organism that can be easily isolated and identified in culture. The answer to the antibiotic and host defense mechanisms is extremely favorable [14].

Untreated acute infections and / or incomplete / incorrect treated with antibiotics, percutaneous drainage or dressing become chronic infection with a specific pattern generated by phenotypic change of bacteria lifestyle to sessile growth which is the predominant form of life on surfaces [22]. Sometimes chronic infection reactivation occurs without a history of outbreaks of infectious or unknown septic outstanding from previous interventions. Clinically, chronic infection occurs late after discharge (months even years) and is slowly corrugated evolving. In variable proportions wound dehiscence is present but there is no tissue necrosis because sessile bacterial phenotype do not secrete increased amounts of proteases and lysine. Antibiotic therapy is ineffective due to the presence of biofilm on the surface of the wound [23]. Jezupovs and Cobb, on open IH repairs with polypropylene mesh, reported presentations of infection at an average of 11.3 months (range 2.5–18 months) and 10.9 months, respectively (15,24). This has been substantiated by a recent VA study of 55 mesh removals,

revealing a median time to explantation of 224 days. Klosterhalfen and Klinge, on a large series of 623 explanted meshes reported that in case of infection, the meshes have been explanted after 241/214 month (class 1) or 211/219 month (class 2) [25].

3. Risk Factors for Mesh Infection

Despite major advances in the management of patients undergoing surgery—including aseptic technique, prophylactic antibiotics, and advances in surgical approaches such as laparoscopic surgery—surgical wound infection remains among the most common complications of surgery. A growing body of literature supports the concept that patient factors are a major determinant of wound outcome following surgery. Comorbidities such as diabetes and cardiac disease clearly contribute, but environmental stressors as well as the individual's response to stress are equally important. Recently, Fischer et al, report a validated risk model of surgical site occurrence (SSO) in open repair of IH [26]. Breakdown of risk factors for wound complications is represented in Table 1. Applying the SSO score the total risk ranges from 0 to 28 and the associated rate of wound morbidity varied from < 1 to 44,4%. From the study, patient related factors, aside from morbid obesity were uniformly low or intermediate predictors while operative factors predominated as moderate and severe.

Table 1

Risk grouping	Risk factor	Risk score
Mild (+1)	diabetes	1
	COPD	1
	Class 1 obesity	1
	Age 45-64	1
	Intraabdominal procedure	1
Intermediate (+2)	Smoking	2
	ASA>2	2
	Panniculectomy	2
	Clean-contaminated wound	2
	Low albumin	2
	Age<45	2
	Partially dependent functional status	2
Operative time 43-71 min	2	
Moderate (+3)	Totally dependent functional status	3
	Inpatient operation	3
	Class 3 obesity	3
	Component separation	3
Severe (+4 or more)	Contaminated wound	4
	Operative time (71-117min)	4
	Dirty/infected wound	5
	Operative time > 118 min	6

Using new techniques and new materials it is quite impossible to define detailed risk factors for wound and mesh infection that are related to each procedure and each material. In an analysis of mesh infection lighter meshes carry a lower risk of infection than heavier meshes (from 119 extruded meshes for infection only 21 were light meshes) [25]. Meshes overall surface is a risk factor for infection, meshes larger than 200cm² are 3 times more exposed to infection than smaller ones [27]. A greater total surface area of mesh, such as in multi-filament-based

products, carries a theoretically higher risk of bacterial adherence than does monofilament-based mesh, as suggested by studies comparing multi-filament with monofilament sutures [27].

Need for removal of PP mesh is infrequent after infection. This could be attributed to the fact that a PP mesh becomes incorporated into the anterior abdominal wall with neovascularization within two weeks of implantation, allowing leukocytes and macrophages to gain access to the local microenvironment [28].

4. Bacterial biofilm

The pathogenesis of biomaterial-associated infections is a complex process involving interactions between variable factors: bacterial virulence, surface physicochemical properties of prosthetic and alterations in host defense mechanisms. The result of this interaction is the formation of bacterial biofilm, a developmental switching on abiotic surface genetically conditioned as close to the surface bacteria meets environmental conditions different from those in the liquid phase leading to altered gene expression [29,30,31]. Structurally 15% of the biofilm is cells and 85% the matrix [32,33,34,35,36]. The cells form microcolonies which is the structural unit of the biofilm that develops within physiological interactions. From the clinical point of view this structural feature has great impact on the evolution of chronic infection as individual microcolonies tend to break and / or detach presenting a serious risk of remote embolization or colonization with increased resistance sessile cells [34].

Mucopolysaccharides matrix (gel, slime) is secreted by microorganisms after attaching the substrate. Glicocalix is made up of water and a compound consisting predominantly of anionic polysaccharides, nucleic acids, proteins and lipids [37]. Each constituent has specific functions in maintaining the integrity of bacterial physiology and anatomy. Its structure depends on the location, nature of constituent organisms, nutrient concentration and physico-chemical factors. The structure formed by a bacterial species can have various shapes and sizes depending on the processes regulated by bacteria and processes regulated by natural forces [38]. Once formed, the structure of the biofilm is highly visco-elastic allowing bacteria to survive mechanical stress. The biofilm is a special ecological structure in which there is a high biological and chemical heterogeneity. This is related to the nutrients, oxygen and metabolic products concentration gradients as well as microorganisms with different rates of metabolic activity and growth. Cells localized in the surface layers have access to nutrients and oxygen while bacteria in depth face a hostile environment in which the concentration of metabolites is higher than that of nutrients [39]. In the deeper layers bacteria are in a dormant state with an extremely low growth rate and metabolism [40].

Protein synthesis occurs in the corresponding layer of aerobic biofilm a relatively narrow area measuring approximately 30-60 μ . Heterogeneous protein synthesis activity is the result of oxygen limitation in the biofilm, the penetration of which is similar to the activity of the protein as demonstrated by staining with fluorescein green [39].

At this moment there are no clinical and biological data to identify the relative risk of biofilm formation on the mesh surface. It is to believe that biofilm is a consequence of a long contact of meshes with low infected bacteria in the presence of some patient risk factors.

5. Pathogens

Generally, in the biofilm bacterial population is single species. Recent studies have shown, however, both *in vivo* and *in vitro* that there is a mixture of bacteria and / or

fungi [32,41]. Bacteria that shows biofilm growth strategy present molecular mechanisms for the recruitment of other bacteria of the same species or other species probably in order to increase their survival [41]. Moreover in *Pseudomonas aeruginosa* and *Staphylococcus aureus* monospecies biofilms selection of sub-population variants with increased virulence and resistance is promoted by genetic plasticity mechanisms (mutability and recombination). Sometimes, microorganisms do not have all the genes necessary so that the effect of recombination occurs with the formation of groups of pathogenic functional gene equivalent

The most common bacterial strains are the *Staphylococcus aureus* and *epidermidis*, group B Streptococcus and Gram-negative bacteria (Enterobacteriaceae) [42,44]. Rarely fungi (*Candida* spp) or mycobacteria can colonize prosthetic wound. A particular form that raises special problems of treatment is methicillin-resistant staph infection (MRSA). Generally they are low virulence germs but rapidly adhere to prosthetic surface, producing colonies and biofilms difficult to eradicate without removing the prosthesis. Both *St. aureus* and *epidermidis* are cutaneous commensals having a large and fast gateway for prosthetic contamination. *St aureus* produce adhesive components (Polysaccharide Intercellular Adhesin - PIA; Biofilm Associated Protein - BAP and others) that allow bacteria to rapidly bind prosthetic conditioned surface [44]. Undisputed leader in the production of prosthetic infections is *St. epidermidis*. Due to the ability to form stable biofilms its eradication is difficult. It has high adhesion because of the synthesis of Associated Accumulation Proteins (AAP) localized on the bacterial wall and of a giant Extracellular Matrix Binding- Protein (EMBP) [45].

Pseudomonas aeruginosa preferentially increase as biofilm. Manifests high gene expression characterized by increasing gene activity up to 300 times [29]. Biofilm contains alginates whose production is controlled by gene *algC* but also by environmental factors (limiting nitrogen intake, increased osmolarity, high blood pressure oxygen).

An important role in *E. coli* biofilm formation it is the developing of cell surface appendages: flagella, pili and other adherent outer membrane [35]. One third of the bacterial genome is involved in biofilm maturation and more than half of these genes are specific. 15% of the genes identified as overexpressed or repressed in biofilms exponential growth phase are involved in carbohydrate metabolism and energy processes. There are genes expressed by 2 to 8 times compared with planktonic forms [35].

6. Substrate

The concept of using synthetic meshes began with the introduction into clinical practice of polypropylene in 1958 [45]. Since then reconstruction of abdominal wall defects using synthetic mesh became standard especially for incisional hernia and was imposed due to the drastic reduction in the recurrence rate. The number of synthetic meshes has grown exponentially by time and includes a variety of shapes, sizes and structural types. From the multitude of materials used the concept of ideal mesh has not found yet because each has advantages and

disadvantages. All these varieties continue to use one of three basic materials, alone or in combination: polypropylene (PP), polyester (PE) or poly-tetrafluoroethylene (PTFE).

The most commonly used prostheses are those of PP with significant changes in recent years, most with small pores. PP is a stable, non-degradable with acceptable biocompatibility polymer. PE shows excellent biocompatibility but histologically marked physical instability, resulting in degradation and fracture years after implantation. PTFE shows a good biocompatibility but tissue integration is difficult because ultramicroporous structure [47].

Whatever the nature of the polymer, the method of manufacturing (braided or woven), or surface porosity prosthetic meshes are inevitably subjected to the risk of infection. But everything according to these parameters, the behavior before the infection is different and this has practical importance in the management of this complication. Bacterial adhesion is directly proportional to the surface of the prosthesis, hydrophobicity, pores size. Add to address those physical configuration (flat or rough) and electric charge [12,48,49]. Adherence is low on surfaces with negative electric charge (poly-tetrafluoroethylene) and those with high positive charge. Porous materials have a high affinity for bacteria as opposed to dense plaques of poly-tetrafluoro-ethylene. Adhesion increases to woven materials, (polypropylene, polyester) due to increased contact surface. Despite flat PTFE plates it can be colonized if the surface presents grooves or striations with similar size with bacteria. These conditions increase the contact area and exploiting the full binding potential [50]. This mechanism of infection is more common in composite meshes (PTFE + PP) where due to contraction of the two different layers they tend to be susceptible to misalignment forming a dead space susceptible to infection [12].

Prosthetic pore size is an objective factor for protection against infection. When the pores or interstices between the filaments are less than 10 μ in each of the three dimensions, bacteria with a diameter of 1 μ are easily enclosed at this level. Neutrophils and macrophages that have 10-15 μ in size can not penetrate the mesh network and therefore bacterial growth is favored [51]. Hydrophobic surfaces (PP, PE) prevent colonization because germs, mostly hydrophobic tend to have poor adherence in these circumstances [52]. Prolonged exposure to bacteria increases adherence. Stranded meshes (PP, PE) are more frequently exposed to biofilm formation due to larger surface compared to monofilament ones because of the interfibrillar niches that can be adaptive zone of bacterial diameter and increase the degree of germs adhesion.

7. Body Reaction to Prosthetic Infection

Pathogenesis of biomaterial-associated infections is a complex process involving variable factors: bacterial virulence, physico-chemical properties of the material and alterations in host defense mechanisms [53]. Although bacterial inoculum is reduced these infections have high infective power, have long evolution and persist until the removal of the prosthesis. When do not distal

embolization, they are limited to tissues immediately in contact with prosthesis [54]. The implant itself induces a decrease in the reactivity of the organism evidenced by the lack of local and systemic response. One of the factors that lead to mesh infection is an acquired polymorphonuclear phagocytic defect. It involves decreased phagocytosis by cell wall modifications to withstand low endosomal pH and enzymatic degradation of endosomes. Polymorphonuclear (PMN) in this case have low granules content, low duration of life and oxidative metabolism is deficient, as suggested by its intracellular persistence of bacteria in macrophages [42]. Due to persistent intracellular germs, tissue macrophages can be survival niches for germs (especially for *St. epidermidis*) around the implant which probably explain the late clinic onset of chronic infection.

8. Antibiotic Resistance

The mechanisms by which this resistance of 100 to 1000 times greater is installed in sessile forms are incompletely known [55]. Theoretically, gaining antibiotics and disinfectant resistance is controlled by two main mechanisms: biofilm structure and genetic and metabolic status of biofilm associated bacteria. These mechanisms work synergistically and with maximum probability are mediated by the quorum sensing path which may represent the third mechanism of action. Type of antibiotic used may itself be a mechanism of installing resistance.

1. Biofilm structure: the polysaccharidic extracellular matrix by its multilayered structure, is a molecular filter and a barrier that prevents and delay infusion of biocides to target cells. Ito et al have shown that Ampicillin do not inhibit bacterial growth in *E. coli* biofilm when the thickness is approximately $42.59 \pm 10.48 \mu$ so that it recovers after 72 hours of incubation [55]. Reducing the thickness and the biofilm bio-volume to $1.48 \pm 1.08 \mu$ by blowing air cause complete inhibition of its formation by Kanamycin and Ofloxacin which proves that a biofilm can be easily penetrated when is thinner [55].

Limitation of penetration can be achieved by possible interactions between biocides and matrix organic components (proteins, nucleic acids, carbohydrates) so at their structural level occur changes that make impossible their mechanism of antibacterial action. Polysaccharides of *Staphylococcus epidermidis* mature glyco-calix interfere with the action of glycopeptide increasing 5 times the minimum inhibitory concentration (MIC) of Vancomycin and Teicoplanin [32]. The gel is physically coupled with glycopeptides and inactivate them. In mature biofilm of *Pseudomonas aeruginosa*, Coquet et al showed 15 times increases the MIC of Tobramycin and 20 times for Imipipem compared with planktonic strains [56].

Resistance to biocides is different and depending on the different stages of evolution and biofilm formation [55]. Bacteria in the state of attachment (at 2 hours) and the colony-forming stage (24 hours after exposure) do not form mature biofilms after 24 hours of treatment with Ampicillin. Maturation phase cells formed biofilm in the first 72 hours of discontinuing antibiotic. The finding has double meaning: clinical and therapeutic. Early antibiotic administration during surgery can prevent contamination and biofilm formation on prosthetic material if it acts to

suppress bacteria in optimal range of 2-24 hours. Once formed and matured biofilm antibiotic treatment becomes inefficient due to selection of resistant strains, even in a favorable initial response.

Other mechanisms in which biofilm structure acts as a mechanical barrier refers to inadequate exposure to antimicrobial agents at all loci relevant to infection [57] or matrix sequestration of bacteriostatics that acts in synergy with profoundly altered host defense mechanisms in the presence of prosthetic material. Alkaline substances penetrate biofilm weaker due to their ability to react with matrix constituents. Biofilms rich in glucose lead to increased antibiotic sensitivity [55].

Glycocalyx extracellular enzymes are able to alter a structurally similar antibiotic metabolite and so on they can intervene on biocides with known structures. 2'N acetyltransferase, which may inactivate bacterial peptidoglycans is able to inactivate Gentamicin it has a structure similar to the original action of the enzyme substrate. Penicillins and β -lactams derivatives covalently binds a specific set of bacterial proteins - Penicillin-Binding-Proteins (PBP) that are involved in cell wall synthesis and formation. β -lactamases which have the structure similar to the PBP, specifically binds the antibiotic preventing the destruction of the cell wall. Hydrogen peroxide is inactivated by mature *Pseudomonas aeruginosa* biofilm catalase.

2. Metabolic and genetic cellular status: genomic changes are the basis of any evolutionary process; likelihood of these events represent the first step in the development of resistance control. Due to the preservation of genome and avoiding lethal gene mutations bacteria tend to have low mutational rates. Modulation frequency of mutations is done by gene amplification or by regulated increasing of mutational rates [58]. In stress conditions imposed by the biofilm lifestyle (basic morphological condition of chronic infection) or repeated exposure to sublethal doses of antibiotic, bacteria occur frequently hypermutation. The phenomenon begins immediately when the cell reaches the surface: genes that encode flagellar proteins are repressed and are activated the genes encoding the synthesis of matrix structures and adhesive proteins. Overall the cells occurs repression of genes that control the biosynthesis of cofactors, central intermediary metabolism, energy metabolism and that of nucleotides. This way explains the decrease in metabolic activity and growth during biofilm formation [55]. The response to decreasing nutrients and growing stress factors of the Gram-negative bacteria is characterized by the synthesis of sigma factors. Sigma factors are controlled by *rpoS* gene that regulates the transcription of genes whose byproducts diminishes the effects of stress [59]. *E. coli* biofilms positive for *rpoS* have an increased number of germs and in particular an increased number of viable germs. *rpoS* system represses 33 genes that control energy metabolism and flagella system. The level of expression of these genes decreases with increasing *rpoS* level expression [60].

In parallel with genetic suppression of metabolic pathways are selectively overexpressed others, controlling carbon compounds catabolism, regulation of protective protein or transport proteins, the synthesis of heat shock proteins (HSP), energy metabolism with anaerobic respiration and multidrug resistance [55].

There are also upregulated genes involved in oxidative stress response (catalase and superoxidedismutase) thus providing protection against internal and external oxidizing agents [61]. This explains its high resistance to hydrogen peroxide.

Another genetically controlled resistance mechanism is the multidrug resistance efflux pumps. The pump has a tripartite composition: a membrane protein whose activity is linked to the membrane proton motive force, an external membrane protein and a periplasmic protein [58]. Efflux pump main function is to allow the bacteria to release toxic molecules and survive in their presence. In addition controls virulence and maintain cell homeostasis. Resistance is obtained by mutations leading to constitutive expression of these transporters change.

In multispecies biofilms interactions between species can lead to the appearance of specific phenotypes. The combination leads to a more viscous secreted matrix that is associated with synergistic enzymatic mechanisms acting against biological agents (a phenomenon described as a complementary enzyme)

3. Quorum sensing system: it is a form of communication by which bacteria monitor their population density cell [62]. This is achieved by producing, releasing, detection and response to low concentrations of auto-secreting signal molecules that are called autoinducers. Controlled quorum sensing behaviors only occur when there is a critical mass of bacteria and extracellular concentration of autoinducers is correlated with population density cell [62]. Quorum sensing system allows filling substrate niches, intercellular communication and regulation of virulence and colonization factors [63]. It also coordinates the entire activity of biofilm resistance and what is important to synchronize the alteration of gene expression for the entire population cell [36].

Quorum sensing systems are different for Gram positive in comparison with the Gram negative germs.

For Gram negative auto-induction signal molecules are lactones more precisely acetylhomoserinlactone (AHL) [36]. It consists of a homoserinlactonic ring attached to a acyl chain. Secretion is controlled by an enzyme *Lux*.

9. Treatment Options

there is no evidence in the literature that chronic infected abdominal meshes benefits of adequate and optimal therapeutic measures. The most effective surgical treatment is prevention. First of all it is important to identify and stratify all patient-related risks and compensate them in order to have good outcomes. Antibio prophylaxy seems to reduce the rate of infected abdominal wall after IH repair but there are not enough clinical randomized trials in order to support the assumption. Adequate prevention of a biomaterial-centered infection is therefore aimed at the first contact of a microorganism with a biomaterial. Bacterial adhesions on the biomaterial depend on the material surface. Mesh coated with different precious metals, such as titanium, silver, or gold, can successfully reduce bacterial attachment

If the abdomen became infected after IH repair, strategy of monotherapy with intravenous antibiotics in cases of mesh-related infections has a poor outcome and

consequently has no indication because of poor bacterial susceptibility to antimicrobial agents [21]. The next step is to open the wound as soon as possible and to aggressively debride the wound in order to avoid prosthetic infection. After necrosectomy, wound debridement and irrigation the best therapeutic option is to manage the wound with negative wound pressure therapy. The dressing foam will be changed every 2-5 days depending on the quantity and aspect of the liquids discharged. The results of the therapy is a progressive debridement and a soft granulation tissue which can lead to wound closure over the mesh [63].

Because ultrasound reduces biofilm formation, several studies on the effect of ultrasound on bacterial cell growth and on the treatment of biomaterial-centered infections have been performed. A positive effect of ultrasound in addition to treatment with antibiotics has been shown. Theoretically, a phenomenon called the bioacoustic effect enhances the transportation and penetration of antibiotics within the biofilms. The contribution of low-frequency and high-intensity ultrasound in the presence of an antibiotic agent removes and kills microorganisms [64].

A recent study show that Diclofenac and Ibuprofen limit the biofilm formation by the strains of *S. aureus* and *E. coli* on the surface of monofilament polypropylene mesh [65]. The mechanism of NSAIDs impact on biofilm formation has not been fully explained. It is considered that it shall be connected with inhibition of bacterial adhesion. Decrease of adhesion and biofilm formation may be the result of the inhibiting impact of NSAIDs on production of agents which play essential roles in the processes and the modification of the surface properties of the bacterial cell (reduction of extracellular polysaccharide, teichoic acids and proteins by *S. epidermidis*, change their hydrophobicity and inhibit the production of fimbriae by *E. coli*). Another possible explanation for inhibition of bacteria biofilm formation by NSAIDs is their impact on the process by quorum sensing system of *P. aeruginosa* by means of inhibition of quorum sensing *las* system.

10. Conclusions

Multiple mechanisms by which bacteria from the prosthetic surfaces develop antibiotic therapy resistance make this treatment ineffective from the beginning. More with no means of chemical and / or physical breaking of the biofilm, the topical treatment of prosthetic infection can 't lead to good results. Currently the only way seems to solve the problem is to remove the whole infected material. The procedure is accompanied by a full suite of technical difficulties, risks and postoperative complications. The safest measure but therapy is prevention. Which unfortunately can not be absolute and overrated!

Disclosures

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Contribution

Both authors equally contributed to the manuscript editing and correction.

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Necessary duration of follow-up to assess complications of mesh in hernia surgery: a time-lapse study based on 460 explants

K. Petersen¹ · J. Morrison² · V. Oprea³ · D. Grischkan⁴ · A. Koch⁵ · R. Lorenz⁶ · R. Bendavid⁷ · V. Iakovlev⁸

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Abstract

Purpose Risk of complications following hernia repair is the key parameter to assess risk/benefit ratio of a technique. As mesh devices are permanent, their risks are life-long. Too many reports in the past assessed mesh safety prematurely after short follow-ups. We aimed to explore what length of follow up would reveal the full extent of complications.

Methods Time lapses between implantation and excision were analyzed in 460 cases of meshes excised for complications after hernia repair. Patterns of percentage growth and time lapses at 50th and 95th percentiles were used to compare groups of different hernia type, age, gender and reason for excision.

Results The 50th and 95th case percentiles in the dataset were at 3.75 and 15.0 years between mesh implantation and excision. For hernia types, the longest time lapses were for groin hernias (4.0 and 16.11 years at 50th and 95th percentiles). The shortest were for umbilical hernias (2.16 and 9.68 years). Males had later excisions than females (4.11 and 16.1 vs. 2.47 and 9.79 years). Younger patients (<45 y.o.) had later excisions than older patients (4.12 and 17.68 vs. 3.37 and 10.0 years). Out of all subgroups, the longest time lapses were for groin hernias in younger males (4.77 and 18.89 years) and for mesh erosion into organs (4.67 and 17.0 years).

Conclusions Follow-up of more than 15 years is needed to fully assess complications after mesh hernia repair. Especially longer periods are needed to detect mesh erosion into organs and complications in younger males. Presently, short observations and lack of reporting standard in the literature prohibit accurate assessment of complication risks. We propose to use cumulative incidence for standardized risk reporting (*y% risk at x years*). This will show time-dependent patterns and allow comparisons between different techniques and studies of variable duration. Standardization will also help to predict long-term risks beyond shorter (practical) follow-ups and facilitate real-time monitoring during surveillance.

Keywords Hernia · Repair · Mesh · Complications · Rate · Follow-up · Standardization · Incidence · Risk

R. Bendavid and V. Iakovlev are equally senior contributors to this work.

✉ V. Iakovlev
iakovlev.v@gmail.com

¹ Private Practice, Las Vegas, NV, USA

² Chatham Kent Health Alliance, Chatham, Ontario, Canada

³ Military Hospital of Cluj, Cluj-Napoca, Romania, Romania

⁴ Hernia Center of Ohio, Cleveland, OH, USA

⁵ Day Surgery and Hernia Center, Cottbus, Germany

⁶ Hernia Center 3+CHIRURGEN, Berlin, Germany

⁷ Department of Surgery, Shouldice Hospital, Thornhill, University of Toronto, Toronto, ON, Canada

⁸ Department of Laboratory Medicine, St. Michael's Hospital, Keenan Research Centre of the Li Ka Shing Knowledge Institute, University of Toronto, Toronto, ON, Canada

Introduction

In memory of senior author Dr. Robert Bendavid.

There can be no doubt that the surgery of abdominal wall hernias has undergone a vital and consequential transformation since the discovery of synthetic materials. The first report of a synthetic mesh repair came from Eugène Acquaviva of Marseille (France) in 1944. He used nylon which had been discovered in 1935 in what he described as a tension free repair [1]. A series of 300 successful cases was presented by Bourret and Sordinas to the French Congress of Surgery of 1949 but the new concept never caught on [2]. The next meaningful attempts came from Francis Usher in 1957 who introduced polypropylene and Irving Lichtenstein in 1989 who promoted polypropylene as an ideal material

[3, 4]. Both emulated the very technique described by Acquaviva 13 and 45 years earlier, respectively. From Acquaviva to the surge in the mid-1990s in the use of synthetic materials there was a period of dormancy of 50 years. Such a delay may well have been due to an ingrained aversion to foreign bodies in humans as a principle but also, to the fear of dreaded infections at a time when antibiotics were just being discovered and suture materials consisted of cotton and silk [5, 6].

The sudden and ready adoption of polypropylene mesh in the mid-1990s is unique in surgery. Have we suddenly embraced implantable mesh in a casual, uncritical and indiscriminate way? It may seem so! According to the recommendations of HerniaSurge through its EHS-International Guidelines for the Treatment of Hernias in the Adult, mesh is recommended for all adult hernias in men and women [7]. Do we have enough information to adapt such a blanket approach? We need to consider quality of available data and factors related to the commercial nature of the implants. Competition and shareholder pressures for the companies and conflicts of interest for scientists are distinct possible factors that can influence the original research and later, its analysis and application [8, 9]. Also, quality of data is affected by the methodological factors: specifically length of follow-up and sensitivity of studies to detect complications. As implants are permanent and stay in the body for life, the risks of associated complications should be considered lifelong. Most of the early published reports were small series and case reports, which were sporadic and did not allow prediction of any realistic timing for these events [10–18]. As surgeons become more aware of the fact that implantable mesh devices can present with complications severe enough to consider mesh removal, we are beginning to see reports of larger series [19–22]. Among the more common of these complications are pain, infection, erosion into adjacent organs and bowel obstruction. When do they occur during a patient's lifetime? How long does it take for them to accumulate in a cohort and what would be an acceptable follow-up time for studies? How do we standardize reporting of the complication rates for studies of different duration, different techniques and during surveillance?

Methods

Explant data were merged into a single dataset from several sources: academic tertiary center St. Michael's Hospital (Canada), a specialized hernia center Shouldice Hospital (Canada) and clinics of six specialized hernia surgeons from USA (KP, DG), Canada (JM), Germany (AK, RL), and Romania (VO). Clinical data from St. Michael's Hospital, an institution with a formal Ethics board, were retrieved after approval of the Research Ethics Board. Contributors from other hospitals and

clinics without formal ethics boards retrieved data following standard patient consents allowing anonymous data use. The data were recorded prospectively, of consecutive mesh excisions with a variable starting point between the sources. The earliest and the latest points of data collection were 2007 and 2017. All data were analyzed in an anonymous format and treated to the same ethical standards as per the Research Ethics Board approval of St. Michael's Hospital.

The inclusion criterion was partial or complete mesh excision. The exclusion criterion was unavailability of the key clinical information: hernia type, reason for mesh explantation, gender, and time lapse between mesh implantation and excision. We used mesh excision as an inclusion criterion and a timing milestone for several reasons. This approach limited analysis to the cases in which severity and certainty of the cause of complications justified a revision surgery. Also, this high severity threshold was chosen with the aim to reduce cases of clinically insignificant complications and cases of spontaneous pain improvement that can occur over time [23]. Additionally, date of excision surgery is reliably recorded and a reproducible time-point. In contrast, onset of symptoms is frequently based on subjective recollections.

Microsoft Excel (www.microsoft.com) and XLSTAT (www.xlstat.com) applications were used for data analysis. The data were analyzed combining all cases together and as groups separated by hernia type, reason for excision, gender, and age. For age comparison, the median age of 45 years at implantation in the dataset was used to separate patients into the younger and older groups. Non-parametric two-tailed Mann-Whitney test was used for continuous data. Chi-square test was used for categorical data. Percentiles were calculated for each case in the entire dataset and each group separately. Graphs were generated to visualize accumulation of percentages over time since implantation. Time lapses between mesh implantation and excision at 50th and 95th case percentiles were used as numerical comparators. We used time-points at these percentiles to compare the groups as well as to provide analogies for studies of full cohorts. The lapse at 50th percentile would reflect an estimated time-point when an "ideal" cohort of simultaneous implantations would accumulate 50% of all possible complications, while the 95th percentile would reflect an estimated time-point when complication risk assessment would reach 95% accuracy.

Results

There were a total of 460 cases in the dataset after amalgamation of the data from the described sources. The numbers from each source/co-author were: KP-215, JM-63, VI-46, VO-42, DG-33, AK-29, RB-20, RL-12. Out of all cases, nine cases were subject to known past medico-legal assessments.

The dataset included excisions of mesh from four hernia types: groin, umbilical, ventral and incisional (Table 1). All explants were of synthetic meshes, mostly of knitted monofilament polypropylene type, with a smaller proportion of multifilament and composite devices. For this study we did not aim to separate cases by mesh type or type of surgical approach, but rather studied general patterns of timing of complications. The only exception was mesh plugs as they are known to behave differently. There were 40 identified plug devices: all were for groin hernia.

Several reasons for revision, either single or multiple for each case were identified: pain, hernia recurrence, mesh infection, mesh erosion into organs (bladder, bowel), and bowel obstruction without mesh penetration into the bowel wall. The overlaps between stated reasons for excision occurred between recurrence and pain, and recurrence and infection. The larger overlap was between recurrence and pain. It was seen in 20 cases all of which were groin hernias. These 20 cases represented 40% of groin cases with recorded recurrence and 6.7% of those with recorded pain. The other overlap was in four cases in which both recurrence and infection were stated. We considered recurrence data coincidental but kept them in the dataset for completeness and because some cases had another concurrent reason for mesh excision.

All cases combined

In the entire dataset, the time lapses between mesh implantation and excision were 3.75 and 15.0 years at 50th and 95th case percentiles, respectively (range 0.08–31.9 years). Figure 1 graphically shows growth of cumulative case percentage over time since implantation. This curve would be similar to a pattern of accumulation of complications in an “ideal” cohort where all implantations occur at the same time. In full cohorts, this curve represents cumulative incidence.

As frequently seen in biological processes, there was an initial peak of events followed by a gradual decline in the annual event frequency (Fig. 1, lower panel). The peak was

around one year after mesh implantation. This resulted in a more rapid initial rise in the number of complication cases and would correspond to higher annual incidences and a more rapid rise in the cumulative incidence (complication rate) in a full cohort. Then, the number of excisions per year gradually declined which would correspond to a slowing growth of cumulative incidence over the 2–3 decades after implantation, to a point when the curves would plateau at their saturation level (Fig. 1). At that point, in full cohorts all patients who could develop complications either developed them or dropped out.

Hernia types

The groin hernia group showed the longest time lapses with 50th and 95th case percentiles registering at 4.0 and 16.1 years (Table 2). The umbilical hernias had the shortest time lapses (2.16 and 9.68 years at 50th and 95th case percentiles). The difference was significant for umbilical vs. groin (Mann–Whitney $p=0.005$) and umbilical vs. incisional ($p=0.03$) groups. There was a somewhat different dynamic of case percentage accumulation between the three major hernia types (groin, incisional, umbilical) (Fig. 2). The fastest initial rise was observed in the umbilical hernias, while groin and incisional hernias kept a slower increment up to the 50th percentile; then the two curves diverged. The groin hernia cases reached 95th percentile at 16.1 years after mesh implantation while incisional and umbilical reached 95th percentile at 10.0 and 9.68 years respectively.

Plugs

All 40 cases of excised plugs were from the groin. Out of these, 39 were removed for pain and 1 for recurrence. The time lapse for plugs was longer than for flat meshes but it was not statistically significant (4.88 vs. 3.75 years respectively for 50th and 16.01 vs. 14.65 for 95th percentiles, groin hernias). Almost all (98%) plugs were removed for pain in

Table 1 Cases of mesh excision included in the study

	Median age ^a (years)	Gender		Reasons for revision ^b						
		M	F	All reasons	Pain	Recurrence	Infection	Erosion into organs	Bowel obstruction	
All hernia types	45	334	126	460	337	85	43	13	4	
Hernia types	Groin	42	271	62	333	300	50	3	0	0
	Incisional	58	44	52	96	16	32	33	13	4
	Umbilical	42	11	17	28	21	3	4	0	0
	Ventral	43	2	1	3	0	0	3	0	0

^aMedian age at implantation. ^bSome cases had more than one reason for revision surgery

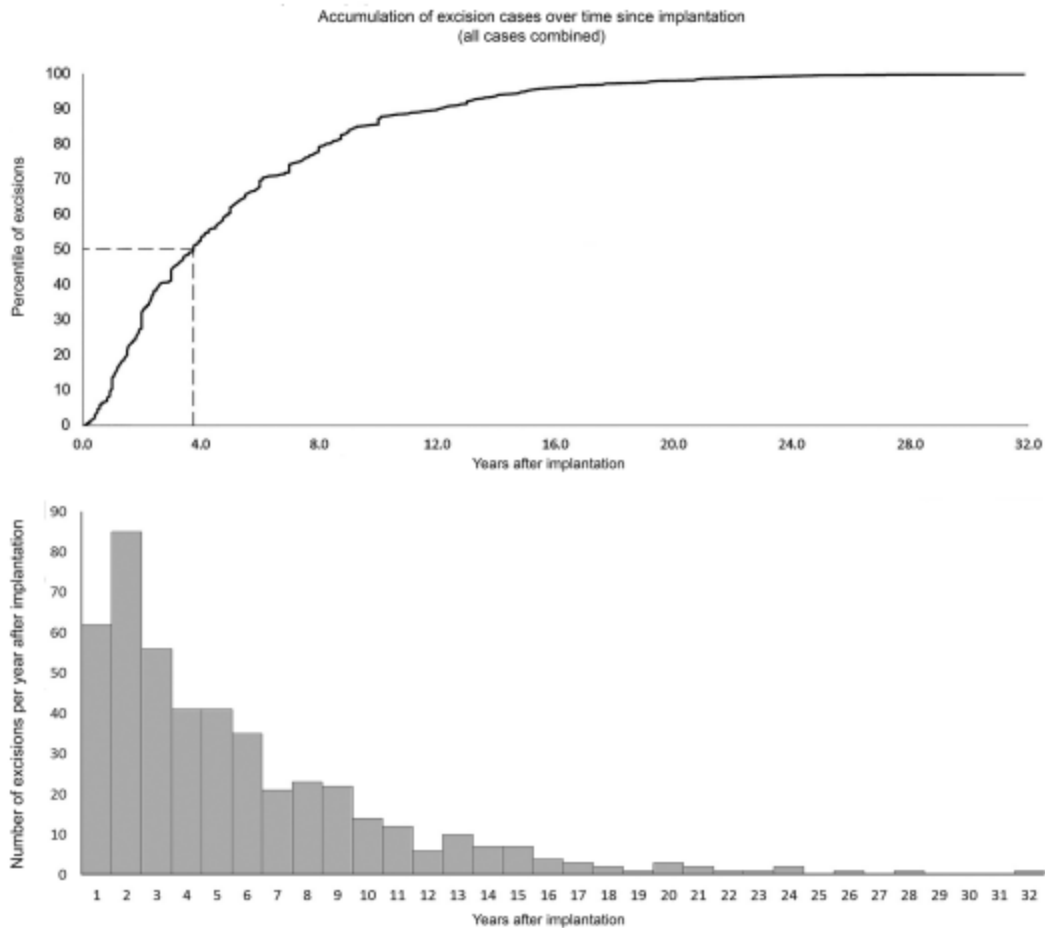


Fig. 1 Rise of case percentage over time since implantation (upper) with numbers of excisions per year after implantation (lower). In the upper graph, 50th percentile is marked by interrupted lines

Table 2 Time lapse (years) between mesh implantation and excision at 50th and 95th case percentiles

	All reasons	Pain	Infection	Erosion into organs
All hernia types	50%–3.75	50%–3.75	50%–3.41	50%–4.67
	95%–15.00	95%–15.38	95%–10.90	95%–17.00
Groin	50%–4.00	50%–3.96	< 10 cases	No cases
	95%–16.11	95%–16.01		
Incisional	50%–3.75	50%–2.41	50%–3.75	50%–4.67
	95%–10.00	95%–9.35	95%–10.40	95%–17.00
Umbilical	50%–2.16	50%–2.05	< 10 cases	No cases
	95%–9.68	95%–8.47		

Groups with < 10 cases are excluded from the table to avoid noise of low numbers

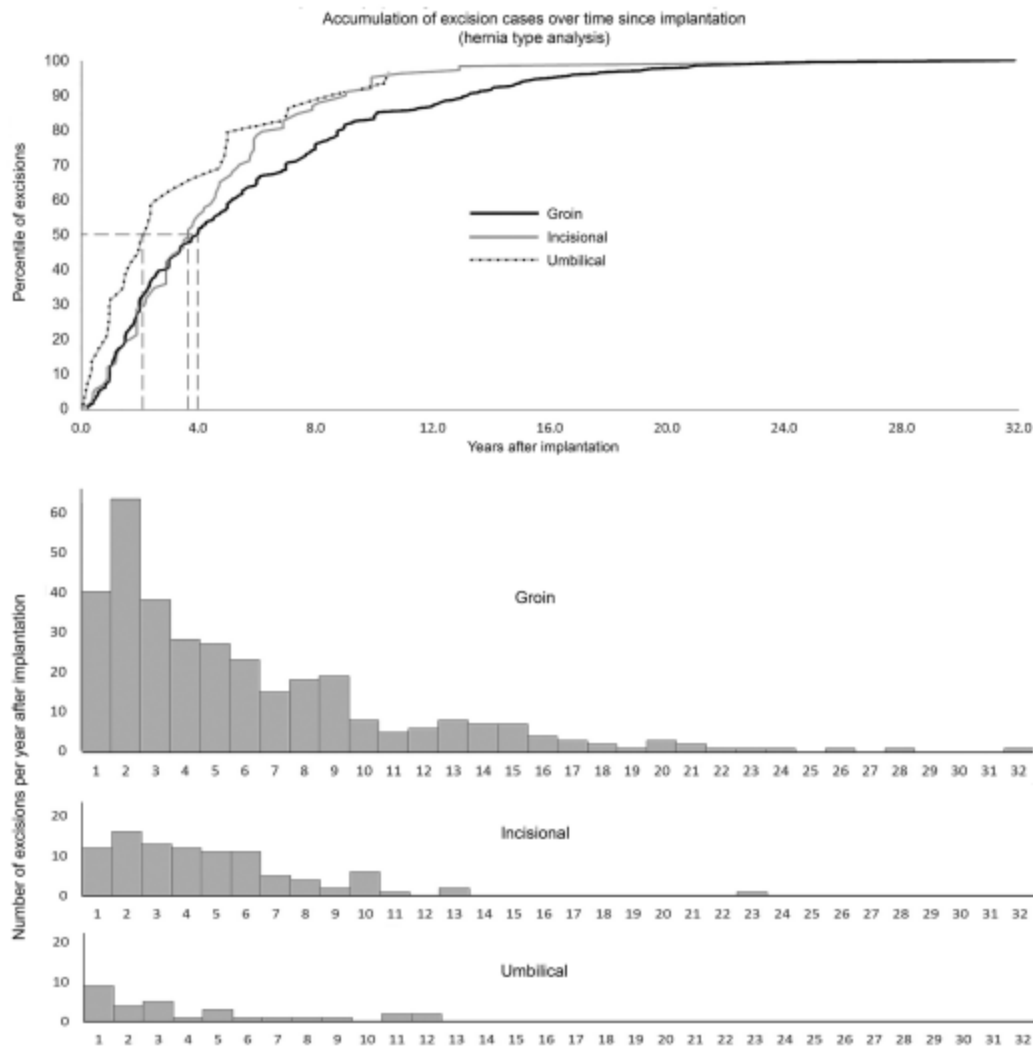


Fig. 2 Percentage (upper) and annual numbers (lower) of excision cases in three major hernia types: groin, incisional and umbilical. Although similar in shape, the patterns are different enough to result

in a two-fold difference in timing of the 50th percentile between the groin and umbilical groups (see Table 2 for numerical values)

comparison with 89% of flat meshes in the groin. This difference was borderline significant ($p = 0.053$).

Reason for excision

By reason for excision, the longest time lapse was for mesh erosion into the organs (4.73 and 17.0 years at 50th and 95th percentiles). The shortest time lapses were for infection

(3.41 and 10.9 years). Differences between the groups were not statistically significant.

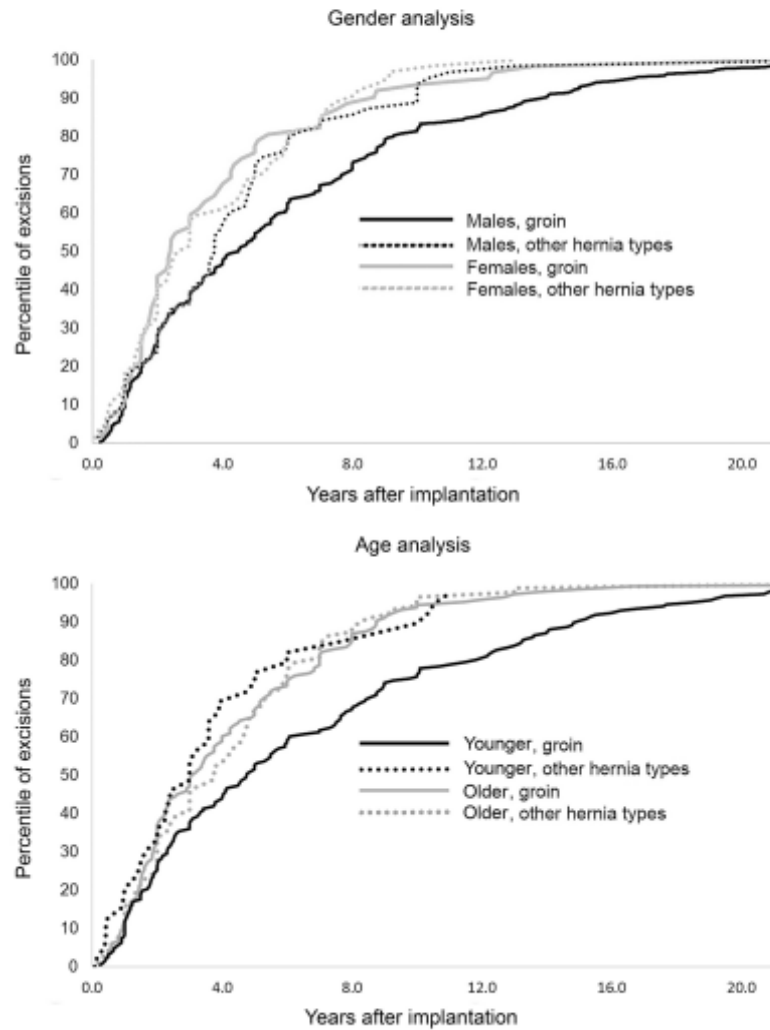
Gender groups

Gender analysis showed that there were more male patients in the dataset (Table 1). This was expected due to the known gender asymmetry in groin hernias (81% of all groin cases

Table 3 Time lapse (years) at 50th and 95th percentiles in gender and age comparisons

	Males	Females	Younger	Older
All reasons, all hernia types	50%—4.11	50%—2.46	50%—4.12	50%—3.37
	95%—16.09	95%—9.79	95%—17.68	95%—10.00
Pain, all hernia types	50%—4.50	50%—2.37	50%—4.52	50%—3.03
	95%—16.38	95%—10.62	95%—17.95	95%—9.49
All reasons, groin	50%—4.50	50%—2.41	50%—4.77	50%—3.11
	95%—16.72	95%—12.06	95%—18.89	95%—11.07

Separation into younger and older groups through median age of 45 years

Fig. 3 Analysis by gender (upper) and age (lower). There was near two-fold difference in the steepness of case percentage accumulation between the groups (see Table 3 for numerical values)

were males). Male patients had mesh excisions later than female patients (Table 3, Fig. 3). The difference was significant for all cases together and in the groin hernia group ($p < 0.001$ and $p = 0.003$ respectively). This trend was also observed in other hernia types, but it did not reach a level of statistical significance ($p > 0.05$).

Age groups

To analyze data by age, we separated cases through the median age of 45 years at mesh implantation. There were 225 patients in the “younger” and 234 in the “older” group (one patient was excluded due to unconfirmed age). The younger patients had predominantly groin mesh excisions (83% of younger vs. 62% of older, $p < 0.0001$). Pain was the most frequent cause for mesh excision in the younger patients for all hernia types (86% of younger vs. 61% older, $p < 0.0001$). Younger patients had significantly longer time lapses for groin hernias (Table 3, Fig. 3, $p = 0.001$) and meshes removed for chronic pain ($p = 0.004$). Explantations of mesh from the groin in younger patients had the slowest incremental rise of case percentage out of all tested groups (4.77 and 18.89 years at 50th and 95th case percentiles). Another asymmetry in age comparison was for mesh erosion into organs. There were only 2 erosion cases in the younger patients compared to 11 in the older group ($p = 0.022$). There was no difference in time lapse between younger vs. older patients for mesh erosion, however the numbers of cases were low.

Discussion

One of the main parameters to assess safety of an implantable device is its risk/benefit ratio. Assessment accuracy of risks and recurrences directly affect assessment of this ratio. For a specific accuracy (e.g. 95%) follow-up needs to be at least as long as it takes to accumulate that percentage of all possible complications and recurrences in a cohort. In prospective studies of full cohorts data are affected by new recruitment and patient dropout. Continuous new recruitment will delay accumulation of complication cases and skew data inherent to a procedure. Therefore, analysis of the cumulative incidence (complication/recurrence rate) should be timed by implantation and follow-up, not beginning and length of a study. We aimed to estimate the length of follow-up needed for accurate assessment of complications after mesh hernia repair and analyzed the lapse of time between mesh implantation and excision. We did not aim to answer questions of which device or a technique poses higher risks. Instead, we studied general timing patterns of complications. Our aim was to help other researchers to better design their studies of full cohorts, assess the risks with

acceptable accuracy and report them in a standardized format. Accumulation of higher quality data will enable valid comparisons between techniques and identification of superior approaches.

Our observation was that complications can occur years and decades after implantation. Their frequency was higher in the first 2 years, then the frequency gradually declined over a decade or longer, depending on the group. This would correspond to an initial faster rise of cumulative incidence (rates) of complications in a cohort, then a slow plateauing until all patients who can develop complications either develop them or drop out. The rates, or prevalence of some complications, for example chronic pain, can also decline over time due to spontaneous resolutions [23]. However, the symptoms can recur after a temporary period of improvement which would result in a bimodal pattern. In our dataset, the inclusion criterion was excision surgery which excluded cases of sustained spontaneous resolution. We observed only unimodal patterns based on mesh excision as a timing point and an inclusion criterion.

The 50th case percentile in our dataset was reached at 3.75 years after mesh implantation. This indicated that studies of comparable median follow-up time may have a large, up to 50% underestimation of the complication risks. The curves plateaued around 15 years after implantation for all cases together and over 17 years in some individual groups. In an earlier report, Klosterhalfen et al. reported median and maximum time lapses of 23 and 180 months [24]. Our data were collected approximately 7 years after that study which gave us more time after the rise of mesh use in the 1990's. It is likely that, after another decade a similar project can yield time lapses longer than in our dataset. This trend was observed in pelvic mesh devices which had sharper timing of device introduction into practice. Miklos et al. collected data between 2011–2013 and reported median and maximum time lapses of 3 and 10 years for devices cleared in 2002 (transvaginal mesh), and 3 and 18 years for devices cleared in 1996 (slings) [25]. Timing difference between device introduction (6 years) appeared to affect the difference between maximum time lapses (8 years).

Our 15-year time lapse at 95th percentile may still be a conservative estimate at this point, as younger patients who underwent implantations in the 1990's will live for several more decades. Based on pure data and not considering financial and practical aspects, follow-up of 15 years or longer is required for studies aiming to assess the full extent of complication risks. Based on our PubMed search, the overwhelming majority of the published studies had follow-up times of less than half of this time. This indicates that there is a large degree of underestimation which is not readily acknowledged in the literature and subsequently not recognized in practice. At this stage, we may not yet have enough data to draw firm conclusions about performance of some

techniques or devices. Let us attempt to review each group of complications:

Pain

Pain has become the most prevalent complication following the use of mesh in hernia surgery. The EHS-HerniaSurge group provided a review indicating 10–12% incidence of clinically significant chronic pain with a range of 0.7–75%, subject to pain definition [7]. Follow up times for the studies referenced in relation to chronic pain were up to 8 years while most were less than 5 years. Another large review provided a range of 0–53% for chronic pain after inguinal herniorrhaphy, where the range was 15–53% when only studies with pain as a primary outcome were considered [26]. Follow-up times in the reviewed studies ranged from 3 months to 6.5 years.

It is also important to understand how the long-term data are collected. For example, the Danish Hernia Database reported 11% of chronic pain at 1 year. Then the patients with pain were surveyed at 6.5 years and showed a reduction in pain intensity. However, based on the described methodology, new incidence appeared not to be studied in the remaining cohort; therefore it was not clear what was the overall prevalence at 6.5 years [23]. Also, lack of follow-up beyond 6.5 years does not exclude recurrence of the symptoms with a bimodal pattern.

Parallel comparisons between different techniques that aim to show difference in the rates, rather than absolute numbers are expected to be less dependent on the length of follow-up. However, we observed different steepness of the percentage rise in different patient groups (Figs. 2, 3). Similarly, differences in curve steepness between different techniques can result in challenges for comparative assessment during the earlier years. A case in point came from the Cochrane review. The reviewed studies had follow-up of up to 5 years but the authors could not reliably compare chronic pain between the mesh and non-mesh groups because of high heterogeneity of follow-up times and definitions in the studies [27]. Unfortunately, this attention to the length of follow-up is not always apparent in publications. For example, a recent review aimed to compare chronic pain after mesh and non-mesh repairs and reviewed 23 randomized controlled trials (RCTs) [28]. They observed no difference between the techniques and concluded: “Mesh may be used without fear of causing a greater rate of chronic pain.” However, the median follow-up in the reviewed studies was only 1.4 years (range 0.5–10 years).

To put the above follow-up times in perspective and estimate the degree of possible underestimation of the risks, our dataset showed that 50% of groin meshes were explanted for pain within the first 4.0 years after implantation. Then, the remaining half had timing of excisions spread over more than

10 additional years with 95th percentile being at 16.11 years. Younger male patients showed even longer intervals between implantation and excision (4.77 and 18.54 years at 50th and 95th percentiles), therefore these patients would need longer follow-up intervals to accurately assess rates of chronic pain after groin repair.

In our dataset, 6.7% of groin meshes removed for pain also had hernia recurrence. In these 6.7%, pain may have been related to the recurrent herniation. Regardless of the mechanisms of pain, the overall situation was assessed as sufficient to justify mesh excision by the treating surgeon. There was no significant difference of the time lapse between these complex and pain only cases (5.0 vs. 3.74 respectively for 50th, and 12.09 vs. 15.43 for 95th percentile, $p=0.51$). Therefore, these complex cases need to be followed for the same duration. Out of 300 groin meshes removed for pain 39 (13%) were plug devices. The frequency of pain in removed plugs was higher than that in flat meshes (98% vs. 89%, $p=0.053$). These findings were in line with the published knowledge that the plugs are higher risk devices [7]. They also showed a trend for longer time lapses, therefore they need to be followed for at least the same duration as the flat devices. Overall, majority (81%) of groin meshes removed for pain were flat devices without recorded recurrence.

Infection

An earlier publication of Mann et al. may have been one of the first to describe infections associated with synthetic mesh “many months from the operation”, but no exact statistics were provided [29]. Delikoukos et al. reported 5 cases of late onset mesh infections out of 1452 repairs (0.35%). The infections occurred between 2 and 4.5 years after implantations [30]. More recently, Filippou et al. reported a case of mesh infected with the rare *Ps. aeruginosa* 14 years after surgery [31]. Chen et al. reported eight cases of such late onset infections occurring from 3 to 60 months after mesh repairs. The cases were of two complicated incisional and six inguinal hernia repairs [32]. The latter were identified as five Lichtenstein and one Rives preperitoneal repair. The incidence was 0.24% for inguinal and 0.78% for incisional hernias.

In the present series, the 50th case percentile registered at 3.41 years while the 95th percentile at 10.9 years after implantation. In agreement with the earlier studies, infections were more prevalent for incisional hernia than for other hernia sites (Tables 1, 2).

Erosion-migration

The word erosion is not a popular term among abdominal wall surgeons yet, it may well be the mechanism whereby many mesh complications may be explained. We recently

showed that slow erosion of mesh into the spermatic cord can cause pain and dysejaculation [33]. What has not been well appreciated is that a foreign object can eventually erode into any tissue and cause damage on its path. Ability of foreign bodies to migrate through human tissues has been continuously described during the previous century [34–38]. It should not be a surprise that mesh, as a foreign object can slowly erode through tissues. Forces such as intraabdominal pressure, mesh shrinkage, muscle contractions, etc. can act to displace the mesh and it is just a matter of time and tissue strength how far mesh can move through the tissues. The process may take years with resultant complications dependent on the involved tissues and organs. Internal erosion and migration have been documented for both, hernia and vaginal mesh devices [17, 18, 39–43].

A special concern has been erosion into the adjacent viscera, especially after laparoscopic repair. One of the earlier reports in 1996 described mesh invasion of the bladder following a laparoscopic inguinal hernia repair [44]. Later reports described mesh migration into the bladder 11 years after the surgery and a composite mesh migration into sigmoid colon after 5 years in the body [45, 46]. Intraperitoneal mesh poses higher risks as it can have a direct contact with the bowel without any anatomical barriers between the mesh and the bowel. However, mesh devices placed deeper in the tissues, especially mesh plugs, can also migrate into the peritoneal cavity and then cause either adhesions or continue their way to erode into the bowel [47–53]. Chronic infection spreading from the bowel lumen can result in a fistula between the bowel and skin [48, 54–57]. This process of internal erosion and fistulisation can take 15 years or longer [55–58].

As time passes since the beginning of widespread use of prosthetics, we see more reports of mesh erosion through tissues and mesh migration. To that end, two recent publications have highlighted the clinical import of this most delayed and challenging of complications. Gossetti et al. have reviewed 101 clinical reports of mesh-related visceral complications following inguinal hernia repair [20]. The discussion noted: “reported complications seem to have tripled in the last decade”. Their conclusion was: “highest incidence is related to laparoscopic repairs, the lowest to Lichtenstein technique”. Time-to-event in the reviewed reports ranged from 2 weeks to 26 years (median 6 years). In another relevant review, Cunningham et al. analyzed data from 84 articles describing mesh migration in 4 hernia types (inguinal, incisional, umbilical and lumbar/obturator) [22]. Their analysis showed that multiple organs were involved in 31.5% of cases, the small bowel in 25.5%, colon and bladder in 16.9% each. Other sites included skin, spermatic cord, scrotum, adnexa, heart, and general abdominal cavity. Median time from mesh placement to definitive diagnosis or treatment was 48 months (interquartile range 24–93).

Our own statistics of the meshes removed for erosion into a viscus revealed 50th case percentile at 4.67 years and 95th percentile at 17 years after index surgery (Table 2). Erosion into organs had the longest time lapse between mesh implantation and excision in comparison with other types of complications. It indicated that accurate assessment of erosion risk would need especially longer follow-up times. We assessed only cases of clinically obvious erosion of mesh into organs. Based on our histological observations, we expect internal erosion through tissues without organ perforation to be much more prevalent. The resultant symptoms, such as pain or organ dysfunction would depend on damaged internal structures. Mesh displacement and deformation can also expose tissues for recurrent herniation. Meshoma formation is another clinically detectable phenomenon caused by mesh movement and deformation.

We observed a smaller number of mesh erosions in younger patients than in older ones. At the same time, younger patients had longer time lapses for other complications. This finding suggests a possible pathophysiological connection. Younger patients may have later presentations because their stronger tissues can delay onset of symptoms related to internal mesh erosion.

Bowel obstruction

This complication could be either due to erosion of mesh into/through the wall of the intestines or due to intraperitoneal adhesions [51, 52, 59]. Such cases of bowel obstruction may defy statistical registration since they are usually emergencies. As surgeons become more aware of this possible complication, significant series are expected to be reported. One such study covered 733 patients who underwent laparoscopic ventral hernia repair and reported 17% reoperations out of which 14.4% or 2.5% of the entire series were for bowel obstruction [21]. The mean follow-up was 19.3 months.

In our dataset we had only four cases of meshes removed for bowel obstruction without mesh erosion into the bowel. The time lapses were 3.65 and 4.61 years 50th and 95th percentiles.

Recurrence

Since mesh excision is not routinely carried out during reoperation for recurrence our data of recurrences was considered mostly coincidental and was not analyzed. The question of how long follow-up should be to accurately assess the recurrence rates was previously raised in the literature. Analysis of the large Herniated database showed that 57.46% of hernia recurrences occurred within 10 years after operation, while the remaining 42.54% occurred much later, some even after 50 years [60]. Incisional hernias showed

faster accumulation of recurrences: 91.87% occurred within 10 years of the last operation. A breakdown of the Herniated data showed that only 77% of groin hernia recurrences presented clinically within 20 years after repair [60]. The follow-up would need to extend well beyond 20 years to assess the long-term recurrence risks with 95% accuracy. Although our data for recurrences were coincidental and the number of cases was only a fraction of the 171,143 cases in the Herniated database, the general patterns were similar: faster accumulation of recurrences for incisional hernia and slower for the groin.

Similarly to complications, failure to implement sufficient follow-up will result in underestimation of recurrence rates and subsequently affect assessment of the risk/benefit ratio. It could be argued that short follow-ups underestimate both the complication and recurrence rates, and therefore may not affect the ratio. However, as we observed in different patient groups, the degree of underestimation between the groups can be very different in the early years after mesh implantation. It can also be different between recurrences and complications in the same group which would affect the ratio.

Risk/benefit ratio

Our aim was not to calculate the risk/benefit ratio but rather to estimate what length of follow-up is needed to accurately assess the risk part of the ratio. The literature analysis above showed that, due to short follow-up intervals most currently available data in the publications do not reveal the full extent of the risks of hernia mesh devices. The available data for recurrences as a measure of the benefit are also affected by follow-up duration. As Herniated data of groin hernias showed, follow-up of over 20 years is needed to assess recurrence risk with accuracy better than 77% [60]. We conducted a separate literature review focusing on recurrences and found that the majority of studies had follow-ups of less than 5 years. Overall, even considering the financial and administrative challenges of long studies, most studies for either complications or recurrences had unacceptably short follow-ups. More studies with longer follow-ups are still needed to accurately assess the risk/benefit ratios and conduct statistically valid comparisons of devices and techniques, including pure tissue repairs. These studies may still not reach the ideal lengths of follow-up; therefore they need to report data in a time-dependent format and inform practicing surgeons of the incomplete nature of the data. In the meantime, we must accept that the ideal implant is yet to be discovered and a judicious approach must be exercised in the use of all current foreign materials. In many instances, the "old ways" may still be valid, safe and rewarding and must not be discarded for the simple notion of being modern, up to date or in sync with one's colleagues. Alexander Pope was never wrong when he penned his aphorism: "Be not the

first by whom the new are tried. Nor yet the last to lay the old aside".

Standardization of risk reporting

Based on information provided in the reviewed studies and definitions of statistical terms we identified at least two methods that were used to calculate complication rates in the studies: cumulative incidence and prevalence. Cumulative incidence represents the proportion of patients who, initially symptom-free started experiencing a disease during a period of time [61, 62]. Prevalence represents the proportion of patients who had a disease either at one point in time (point prevalence) or during a period of time (period prevalence). Cumulative incidence was a more common method as authors counted together all patients who started experiencing a complication at any time during the follow-up. Although cumulative incidence should be reported with a time denominator, most publications reported it as a single number. Median follow-up time, if given would be provided separately. Only few recent studies tracked timing of the risks using different approaches: Kaplan–Meier curves of either recurrence-free survival or risk of reoperation; and cumulative incidence curves of recurrences [63–69]. In relation to complications, one study used cumulative incidence [70]. Prevalence as a method to calculate complication rates was not as common in the reviewed studies. We observed it being used to assess chronic pain. For example, Aasvang et al. reported the final percentage of patients who continued to experience pain at the study end [23]. Studies that used questionnaires asking if patients had pain at the time of answering them would also collect prevalence data.

In other specialties that employ implantable devices there is a trend to assess risks using time-dependent approaches. For example, Kaplan–Meier curves have been used to describe survival of dental implants, risk of reoperation after knee replacements, and risk of capsule contracture around breast implants [71–74]. Cumulative incidence has been used to show risks for knee revisions in articles and publications of the Canadian Joint Replacement Registry [75, 76].

As described, we observed a high heterogeneity of reporting approaches, length of follow-up and quality of methods description in the reviewed hernia publications. This situation makes it difficult to accurately assess the risks and compare different techniques. Our data indicated that follow-up needs to be over 15 years which can be challenging technically and financially. At the same time, usefulness of the more achievable shorter studies is further reduced by non-standardized reporting. The field of hernia surgery needs standardization of reporting to continue its evidence-based development. The question is what would be the most appropriate approach for standardization? The method should track risks in time to enable comparison of

different techniques and studies of different duration. Both cumulative incidence and Kaplan–Meier curves have been used in the literature. The Kaplan–Meier curves were used as a conventional survival of either implant or patient, as well as inverted, to show accumulation of revisions. Graphically, inverted Kaplan–Meier curve is similar to cumulative incidence. As a statistical term, cumulative incidence provides the best fit for the purpose. It defines the risk for an individual patient to contract a disease (complication) within a given period of time (from implantation to follow-up end) [61, 62]. Graphically, cumulative incidence is always shown in one direction. Our graphs reflected cumulative incidence in percentage values. A standard way to report it numerically is together with the time period. Based on our literature review, it is already the most common method to calculate complication rates, although reported without the time denominator. The only additional step would be to record complications together with the lapse time, then use the data to graphically show that relationship and report numbers in the format *Y% risk at X time*.

It could be argued that cumulative incidence does not account for spontaneous resolutions of chronic pain that can be reflected by prevalence. However, serial takes of point prevalence would be needed to show its changes in time. The methodology would be impractical as a standard. Additional studies can be conducted to determine patterns of pain after the overall risk to ever experience chronic pain is determined by the cumulative incidence. An argument against a time-dependent approach could be that risk/benefit ratio is less dependent on time as both parameters are affected simultaneously. An important note is that steepness of the risk rise may be different between the complications and recurrences. Therefore, it will affect the risk/benefit ratio, especially in the early years after implantation.

Standardized reporting cannot replace the need for longer follow-up to minimize underestimation. Longer follow-ups are also needed to compare different techniques and devices as curve steepness can be different, especially in the early years. We observed different steepness of the accumulation curves, depending on patient factors (age, gender) and hernia type. The best balancing factor is still time, time to reach the time-dependent plateau in the risk growth. Therefore, it should be aimed to extend duration of follow-up as much as technically and financially possible and report data together with their timing.

Conclusion

Whereas occasional and rare reports of mesh complications were the rule in the past, the last 10 to 15 years have allowed a better perception of the march of events of synthetics in the

patient population. Regrettably, in their eagerness to report success stories, too many authors have been documenting prematurely what can now be seen as preliminary findings. The technical aspect of any surgery can be mastered in a relatively short time, but assessment of the risk/benefit ratio must depend on the long-term results in patients. Follow-up interval needed to fully assess the risks of mesh hernia repair is estimated to exceed 15 years, yet majority of the published studies had follow-up intervals of less than half of that time. In addition to short follow-ups, lack of reporting standards further complicates the issue. We believe that our patients, practicing surgeons, the scientific community, and regulating bodies are in urgent need of standardization of reporting of complication risks for permanent prosthetic devices. We propose to use cumulative incidence in the format of *Y% rate at X years* and graphically show the relationship between the risks and time since implantation. It would allow statistically valid comparisons between studies of different duration and different techniques; help predicting long-term risks beyond realistic follow-ups; and facilitate early identification of unsafe devices. In the meantime, a judicious approach must be exercised in the use of all current foreign materials.

Author contributions KP contributed the largest dataset; JM, VO, DG, AK, RL contributed datasets; RB coordinated the study, contributed a dataset, collected data from different sources and drafted parts of the manuscript; VI contributed to study design and a dataset, analyzed data, drafted parts and finalized manuscript; all authors critically revised the manuscript and gave final approval.

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Data availability All data submitted with the manuscript in a de-identified format.

Compliance with ethical standards

Conflict of interest JM, DG, RB and VI served as experts for medico-legal cases.

Ethics approval The study was approved by the Research Ethics Board of St. Michael's Hospital, Toronto, Ontario, Canada.

Human and animal rights The study including human participants has been performed in accordance with the ethical standards of the Declaration of Helsinki and its later amendments.

Informed consent Data from all sources were collected after routine institutional consent procedures.

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Transversus Abdominis Muscle Release (TAR) for Large Incisional Hernia Repair

V. Oprea¹, V. Gh Radu², D. Moga³

¹Department of Surgery "Constantin Papilian" Emergency Military Hospital Cluj-Napoca

²Department of Surgery Life Memorial Hospital Bucharest

³Department of Surgery "Alexandru Augustin" Emergency Military Hospital Sibiu

Rezumat

Separarea mușchiului transvers abdominal (TAR) pentru tratamentul herniilor incizionale voluminoase

Introducere: cura herniilor incizionale complex reprezintă un topic provocator și de mare actualitate. Tehnicile, numeroase sunt în majoritatea lor incapabile să atingă obiectivele chirurgiei moderne a peretelui abdominal. Separarea posterioară a componentelor cu eliberarea mușchiului transvers abdominal (TAR) reprezintă un abord nou și inovator care oferă soluția pentru tratamentul herniilor dificile.

Metoda: teaca posterioară a dreptului abdominal este deschisă pentru disecția planului retromuscular. Modificând tehnica Rives-Stoppa se creează un spațiu preperitoneal de mari dimensiuni prin secționarea mușchiului transvers abdominal medial de linia semilunară. Acest spațiu se extinde cranial până la tendonul central al diafragmului, inferior în spațiul Retzius și lateral până la psoas. Meșa este plasată în acest spațiu (sublay). În majoritatea covârșitoare a pacienților linia albă este reconstruită permițând recrearea unui perete abdominal funcțional întărit de proteză.

Rezultate: În intervalul noiembrie 2014 – iulie 2016 am aplicat procedeul la 24 de pacienți (14 de sex masculin) cu hernii

ventrale incizionale de mari dimensiuni. 18 (75%) prezentau defecte recidivate cu grade variabile de recidivă. Dimensiunea medie a lățimii defectului a fost de 18,3 cm (între 12 și 28 cm). La 5 dintre ei s-au instalat complicații ale plăgii care au necesitat reintervenție. Timpul mediu de urmărire a fost de 11,8 luni (2 – 18 luni) fără recidivă.

Concluzii: TAR pare să fie tehnica "ideală" pentru abordarea cu rezultate bune imediate a herniilor complexe.

Cuvinte cheie:

Abstract

Background: complex ventral hernia repair is a frequent and challenging topic. Reconstructive techniques are numerous but most of them are unable to achieve the goals of hernioplasty. Posterior component separation with transverses abdominis muscle release (TAR) is a novel approach that offers a solution for complex ventral hernias.

Method: The posterior rectus sheath is incised and the retro-rectus plane is developed. In a modification of the Rives-Stoppa technique, the transversus abdominis is released medial to the linea semilunaris to expose a broad plane that extends from the central tendon of the diaphragm superiorly, to the space of Retzius inferiorly, and laterally to the retro-peritoneum. This preserves the neurovascular bundles innervating the medial abdominal wall. Mesh is placed in a sublay fashion above the posterior layer. In an overwhelming majority of patients, the linea alba is reconstructed, creating a functional abdominal wall with wide mesh reinforcement.

Corresponding author:

Valentin Oprea MD, PhD
Department of Surgery "Constantin Papilian"
Emergency Military Hospital Cluj-Napoca
No 22 Gral Traian Mosoiu Street, Cluj County
E-mail: opreacv31@gmail.com

Results: Between November 2014 and July 2016 we used this procedure in 24 patients (14 males) with large median ventral incisional hernias. The recurrence in various degrees was present in 18 patients (75%). The average size of the defect was 18,3 cm. in width (12 to 28 cm.). Five patients (21%) developed various wound complications requiring reoperation. Follow-up between 2 and 18 months (11,8 months) without recurrence. **Conclusion:** TAR seems to be the "ideal" approach for complex hernias with good immediate outcomes.

Key words:

Introduction

The ideal surgical approach to the difficult ventral hernia repair is still a matter of debate because of the high peri-operative morbidity (abdominal compartment syndrome, respiratory failure), frequent recurrences and poor quality of life. Recently described by European Hernia Association as a clear entity, difficult complex abdominal wall is a large challenge for both surgeon and patient (1, 2). Closing such defects is a significant problem in obtaining a reliable, durable repair with low morbidity and recurrence rate.

Rives – Stoppa repair evolved as an effective repair with favorable outcomes and low morbidity. The posterior rectus sheath dissection provides release of the rectus muscle and a well vascularised "box" for mesh placement. But the procedure is not appropriate for large defects due to its frequent inability of anterior fascial closure which leads to large surfaces of mesh under the skin (Fig. 1). The immediate result is an increased rate of surgical site events (SSE) and surgical site infections (SSI) as reported recently (3)

The approach of anterior component separation (ACS) as described by Ramirez, despite its wide fascial advancement and improved functional outcomes is encumbered by a significant wound morbidity at rates as high as 50% even in the presence of peri-umbilical perforators sparing (4,5). Minimally invasive surgery modifications reduced SSE but could not improve the recurrence rate which is still up to 30% (6).

As the number of large and complex abdominal wall defects is increasing it is obvious that the procedure is not adequate for such pathology. Some modifications of the technique were reported but the limited advancement of the rectus abdominis muscle (RA) make them inappropriate (7, 8).

In 2012 Novitsky et al reported a novel approach to posterior component separation by transversus abdominis muscle release (TAR) (9). This is a lateral extension of Rives – Stoppa repair with the creation of a wide space between the transversus abdominis muscle (TA) and fascia transversalis-peritoneum complex. The promising results of this initial report determined us to implement the procedure as a daily practice.

The goal of the paper is to present operative technical details of the procedure and our short-term results.

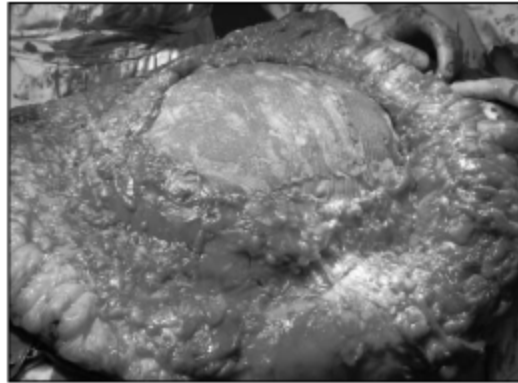


Figure 1. Inability to close the anterior rectus fascia expose to an increased number of SSE with mesh involvement

Step by step procedure for a midline incisional hernia (8 - 15)

1. mid-line large laparotomy with complete excision of the scar if the skin is thin and poorly vascularized only by the contact with the peritoneal sac. The umbilicus is usually excised. Dissection of the sac in the classic fashion.
2. adhesiolysis: completely free all the bowel/omentum adhesions from the undersurface of the abdominal wall (AW) to allow medialization of this layer and to prevent bowel injuries at the reconstruction time. Minimize interloop dissection only to grossly adhesions in order to prevent postoperative obstruction. Protect the viscera with a wide wet soft towel.
3. creation of the retrorectus space is initiated at the level of the umbilicus. An incision is made on the posterior sheath 0,5 – 1 cm. apart of its medial edge (Fig. 2).

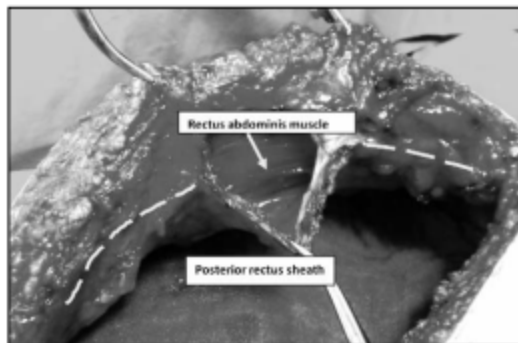


Figure 2. Incision of the rectus sheath with opening and creation of the retromuscular space. The milestone of the procedure is identification of the rectus abdominis muscle (Yellow arrow). The dotted line is the line of incision of the entire rectus sheath

Identify the RA not to enter pre-peritoneal plane !! If the plane is correctly approached the incision is extended cranially and caudally on the entire length of the RA sheath and the retro-rectus space is developed by blunt or sharp dissection. Laterally the dissection is extended to the semilunar line. Care must be taken to prevent damages of the epigastric vessels and of the neurovascular branches of the RA which perforate the posterior sheath just medial to Spiegel line (Fig. 3).

The retro-rectus plane is continued by cranial dissection to the retro-xiphoid plane and caudal in the pre-peritoneal space of Retzius with identification of both Cooper's ligaments and pubic symphysis.

- incision of the posterior rectus sheath in the upper third of the abdomen, 0,5 cm medial to the perforating neurovascular bundles of the thoraco - abdominal nerves the posterior rectus fascia is sharply incised to expose the underlying TA muscle (Fig. 4).

Once the muscle is exposed the fibers are then divided along its entire medial edge. The separation from the pre-peritoneal plane is easily with an "L" curved dissector (Fig. 5).

In the upper third the muscle is well developed and easy to identify; its volume regress in the distal 2 thirds where there is no muscle but only tendinous component.

- creation of the pre-peritoneal plane between the edges of the transected TA a new pre-peritoneal plane is created. Two Allis clamps on the lateral edge of the TA are elevated together with the muscle by the assistant surgeon. Left hand of the surgeon pushes inferiorly the medial edge of the TA so a dihedral angle is created between the muscle and the peritoneum. With a mounted swab the undersurface of the lateral border of the TA is freed from the peritoneum. In 20% or more frequent at the first procedures peritoneal tears are encountered (10). All of them must be carefully closed with an absorbable suture (3-0 Vicryl usually) to avoid protrusions of the small bowel under the mesh. In rare instances (2%) large peritoneal tears cannot be closed and must be buttressed with omentum, local fat or even an absorbable mesh. Laterally the dissection is extended as far as the psoas muscle; it's lateral border can be used as a landmark but usually the posterior axillary line is the main anatomic landmark for the lateral dissection (Fig. 6).

The cranial extend of the dissection depends on the extend of the defect; in upper hernias the space is advanced cranially through the costal margins to view the diaphragm. Inferior the pre-peritoneal plane is contiguous with the space of Retzius in the median line and with the space of Bogros on its lateral part. Trans-section of the medial attachments of the arcuate line of Douglas to the linea alba allow the access to the pre-peritoneal plane. Parietalization of the cord or resection of the round ligament extend the dissection in the space of Bogros and both miopectineal triangles.

- closing of the posterior rectus sheath with a 2-0 slowly absorbable suture (Polydioxanone) recreates the visceral sac excluding the bowel from the large retro-muscular space (Fig. 7).
- placing the mesh this wide pre-peritoneal space is

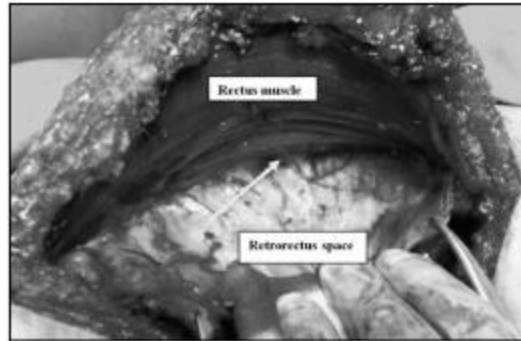


Figure 3. The retrorectus space is created. The dissection is extended lateral as far as linea semilunaris (Spiegel) (yellow arrow) where can be easily identified the neurovascular bundles for the rectus abdominis muscle

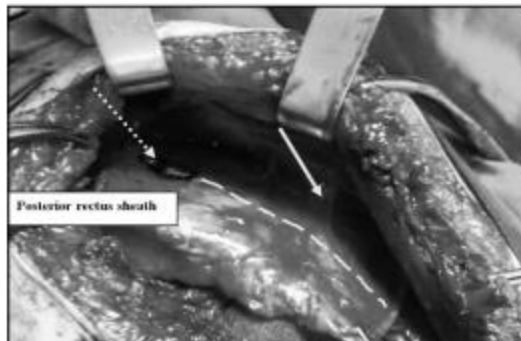


Figure 4. After dissection of the retrorectus space the transversus abdominis muscle is incised at 0,5 cm medial from the semilunar line (dotted arrow). The incision is carried along its entire length (dotted line) medial to the neurovascular bundles (yellow arrow)

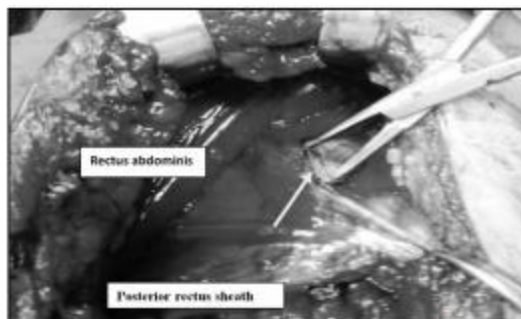


Figure 5. Incision of the transversus abdominis muscle. Arrow-transversus abdominis fibers

measured in length and width for an appropriate mesh adjustment. Usually a mesh larger than 30/30 cm is necessary. A low or mid weight large pores monofilament

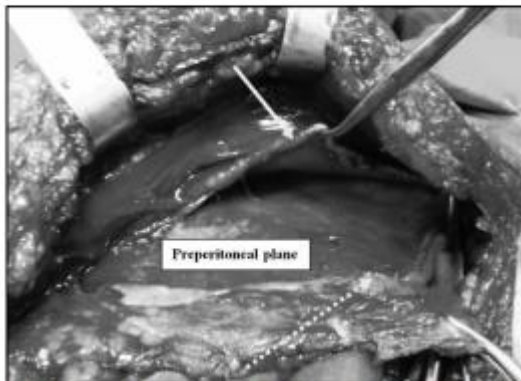


Figure 6. The newly preperitoneal plane is created separating the undersurface of the lateral transected transversus abdominis (arrow) from the peritoneum and fascia transversalis. Dotted arrow- the medial component of the transected transversus abdominis

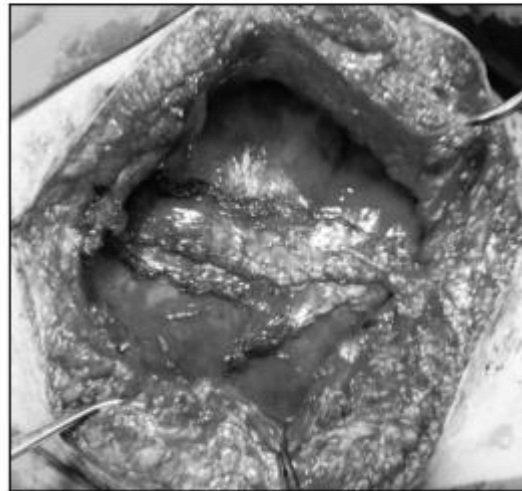


Figure 7. The posterior fascia closed with a running suture. Note the wide preperitoneal space which will be the "ideal" place for the mesh

polypropylene mesh is used (40 to 60 g/m²). For lateral defects or very large defects a heavyweight mesh could be necessary. The mesh must overlap the defect minimally to the anterior axillary line, subxiphoid space and 2-4 cm. below the simphisis.

8. anchoring the mesh first step is to suture the mesh to both Cooper's ligaments and to simphisis with nr 1 slowly absorbable suture. Inferior fixation is essential for the protection of the supra-pubic area because the vectors of the intra-abdominal pressure are directed inferiorly. Cranially 2 stitches fixe the mesh around the xiphoid covering the epigastric area and retrosternal space. Three bilateral stitches below the costal margin, medial to the anterior superior iliac spine and medial to the psoas muscle are passed through the entire abdominal wall with a Reverdin needle and complete mesh fixation. Lateral wide overlap and intra-abdominal pressure maintain the mesh in position without the fear of lateral recurrence. The mesh could be fixed in the retromuscular space by the aid of biologic glue with better outcomes in terms of postoperative pain and recovery. There are no published data yet (Igor Beliansky – personal communication). The space and mesh are irrigated with a saline solution containing 80 mg of Gentamicyne in 250ml. Mechanical and chemical action reduce the risk of mesh infection. Two closed suction drains are placed on the ventral face of the mesh.
9. anterior fascial closure with a running slowly absorbable nr 1 suture recreates the linea alba. A subcutaneous drain is optional only if there are pockets which cannot be closed. Otherwise the subcutaneous tissue is closed with interrupted absorbable sutures. Skin closure. An abdominal binder is recommended in the first post-operative days in order to reduce seroma formation. After that is patient's choice.

Results

Between November 2014 and July 2016 we used this procedure in 24 patients (14 males) with large median ventral incisional hernias. The recurrence in various degrees was present in 18 patients (75%). One patient was with a large median and parastomal left hernia. The average size of the defect was 18,3 cm. in width (12 to 28 cm). The anterior rectus sheath was closed in all patients without one. Five patients (21%) developed various wound complications requiring reoperation (hematoma 3 patients and superficial wound infection without mesh involvement in 2 patients). Follow-up between 2 and 18 months (11,8 months) without recurrence.

Discussions

The benefit of the retro-rectus repair of abdominal wall defects has been well documented over the years by many authors after Rives and Stoppa published their researches. This technique provides many advantages in the reconstruction of complex defects (8-15):

1. the retro-rectus space is an easily dissected potential space;
2. it is a well vascularized compartment with a more efficient collagen deposition and mesh integration;
3. in a recent systematic review and network meta-analysis sublay was associated with lower risk of recurrences and SSI compared to on-lay, inlay and underlay. Sub-lay was ranked the best mesh placement option with a high probability of being the best treatment (94.2% probability of having the lowest odds of recurrence and 77.3% probability of having the lowest odds for SSI) (16).

All this advantages are limited by the frequent impossibility

of closing the anterior fascia in large defects with increasing SSE, recurrence and inability to properly heal.

The goal of any herniorrhaphy is first of all the restoration of a functional abdominal wall by recreating the linea alba reinforced with a large prosthetic mesh overlap and with minimal early and late wound morbidity.

The posterior component separation by transversus abdominis muscle release (simply TAR) is a modification of the Rives-Stoppa procedure which combines it with developing of a large retro-muscular/pre-peritoneal plane and a consistent medial advancement of the abdominal wall musculature and accompanying fascia. Dividing the TA fibers the hoop tension around the abdomen is released and the abdominal cavity is increased. The intra-abdominal pressure (IAP) is also lowered by drawing the abdominal wall upward (11). Also the force vector of the TA directly opposing the medialisation of the fascia is abolished. The result is a fascial advancement of 8 to 12 cm on each side which allows restoration without tension of the linea alba with improved abdominal core muscle function. Fascial closure rates of 91% for defects of 472 cm² with 50% reduction in wound morbidity were obtained in a recent study (17).

Closure of the posterior rectus fascia and the large pre-peritoneal compartment avoids the use of expensive meshes and minimizes mesh-bowel interaction. Bi-laminar closure of the abdominal wall prevents mesh migration and protection against the infection. Working outside the rectus sheath the procedure avoids disruption of the neurovascular bundles that supply the antero-medial abdominal wall.

Unnecessary extensive skin flaps and preservation of a significant portion of the abdominal wall blood supply improves healing and decrease wound morbidity (10).

A wide range of patients benefits from the advantage of the procedure (8-15):

1. any patient with large abdominal wall incisional or ventral hernia (defects larger than 10 cm in width, loss of domain);
2. large subxiphoid, para-iliac, and suprapubic hernias, subcostal/bisubcostal hernias;
3. recurrent incisional hernias after intra-abdominal mesh plasty;
4. recurrences after anterior component separation;
5. parastomal hernias with or without medial incisional hernias;
6. incisional hernias after open abdomen with or without planned ventral hernia.

Difficulties could be encountered for recurrent hernia after Rives-Stoppa repair or after primary or secondary pre-peritoneal fibrosis due to extensive necrotising pancreatitis.

Conclusions

TAR is superior to Rives-Stoppa repair and seems to be the best option for a wide spectrum of complex primary and incisional hernias with low morbidity and good long-term results. Good anatomy knowledge and surgical skills are necessary for valid outcomes.

Disclosures

OV – no conflict of interest to declare; RGhV – no conflict of interest to declare; MD – no conflict of interest to declare. No outside financial contribution to declare.

Authors contribution

All the authors equally contributed in preparing this manuscript.

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Research Article

Tips and Tricks for a Sound Rives - Stoppa Repair

Oprea V¹, Toma M¹, Grad O^{1,2} and Moga D^{3,4}¹Department of Clinical Surgery, Constantin Papilian Emergency Military Clinical Hospital, Romania²Department of Surgery, Iuliu Hatieganu University of Medicine and Pharmacy, Romania³Department of Clinical surgery, Alexandru Augustin Military Hospital, Romania⁴Lucian Blaga University of Sibiu, Romania

Abstract

Background: Incisional and ventral hernia repair is a frequent and challenging topic. Reconstructive techniques are numerous but most of them are unable to achieve the goals of hernioplasty. Rives-Stoppa repair is the gold standard for midline abdominal wall hernias. Our goal is to describe the "step-by-step" procedure for midline incisional hernia repair.

Method: The posterior rectus sheath is incised and the retrorectus plane is developed. For a safe repair the technique, tips and tricks for developing this space are thorough. Mesh is placed in a sublay fashion above the posterior layer. In an overwhelming majority of patients, the Linea Alba is reconstructed, creating a functional abdominal wall with wide mesh reinforcement.

Results: Since 1998, when the procedure was implemented in our Department, 1598 midline incisional hernia patients were operated according to this technique. Mean age was 58.9 years (24-79) with midline defects ranging from 3 cm to 12 cm (mean size 7.9 cm). Major preoperative morbidity present in 17.8% patients. In 178 patients, the anterior fascia cannot be closed, the procedure ending as a retro-rectus bridged repair. Wound complications Surgical Site Events (SSE) encountered in 255 patients (15.95%). Follow-up for 1 to 21 years (mean 8.7 years) with a recurrence rate of 7.8%.

Conclusion: Rives-Stoppa repair is the procedure of choice for all midline incisional hernia being primary or recurrent if the defect is smaller than 8 cm with favorable immediate and long-term outcomes, regardless of age.

"A surgeon can do more for the community by operating on hernia cases and seeing that his recurrence is low than he can by operating on cases of malignant disease" Sir Cecil Wakeley 1948.

Keywords: Surgical site events; Abdominal wall reconstruction; Incisional hernias

Background

The weak abdomen of the human biped has been provided by laparotomy with regrettable iatrogenic "opportunities" for herniation of a complex kind [1]. Indeed, 15%-20% (sometimes more in high-risk group patients) of all laparotomies are complicated by Incisional Hernias (IH), transforming it into the most frequent reason for reoperation [2,3].

The field of Abdominal Wall Reconstruction (AWR) has seen significant advances in the past decades especially due to the understanding of core anatomy and functionality. The revival of the concept of recreating a functional, dynamic, and anatomically sound Abdominal Wall (AW) by reconstruction of the linea alba led to the emergence and promotion of several innovative techniques involving separation of components [4].

The foundation of AWR can be linked by the seminal work

of French surgeons Jean Rives and Renee Stoppa. In 1965, Stoppa developed the preperitoneal space to place a large sheet of polyester mesh (Mersilene®) for the repair of complex and multiply recurrent groin hernias (Giant Preperitoneal Prosthetic Repair) [5]. The forces that act to form hernias became now the factors to protect against recurrence [3]. A year later, Rives revolutionized the technique of repairing IH by placing the same polyester mesh between the Rectus Muscle (RM) (anterior) and posterior rectus sheath (posterior). This reconstructive surgeons brought forth to the concept of posterior component separation to assure complete medialization of the linea alba. Retromuscular Rives-Stoppa repair has gained significant results in the recent surgical era so it was declared "gold standard" for midline IH repair. The goal of this paper is to present step by step operative technical details of the procedure and to promote it for all surgeons.

Methods

Step by step procedure for midline IH [6-9].

Preoperative preparation

When planning an AWR the most important first step is to clarify patients' expectations for a successful outcome. Detailed patients' history, previous operative notes, and physical findings are the foundation of the surgical repair. Assess risk stratification in collaboration with the anesthesiologist, cardiologist, and pneumologist. Assess and correct nutritional status, especially obesity. A Body Mass Index under 35 kg/m² is necessary for a scheduled surgery. Deep vein thrombosis and antibiotic prophylaxis according to local protocols. Abdominal CT scan is mandatory for defining hernia characteristics and for assessing nature of the contents, volume

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*Corresponding author: Valentin Oprea, Department of Clinical Surgery, "Constantin Papilian" Emergency Military Clinical Hospital, Cluj-Napoca nr 22 Gral Traian Mosolu street, Cluj-Napoca, Cluj County, Romania, Tel: +40-745608567; E-mail: opreacv31@gmail.com

of the contents of the sac, the percentage of the contents in the sac, and the size of the defect. Always measure the width of both rectus sheath; if the ratio between width of the defect and the sum of the rectus sheaths is lesser than 2, surely a Rives - Stoppa repair can be performed (Carbonell equation).

Incision

Commonly the procedure begins with a midline laparotomy according to hernia location. Old scars and skin ulcerations are removed at this time or at the end of the operation. The umbilicus, if necessary, is removed to minimize postoperative morbidity (always inform the patient about the possibility and note in the informed consent). The peritoneal cavity is entered through the middle of the sac; the sac is dissected from the subcutaneous adhesions until the medial shift of the RM is reached. Preserve the sac until the posterior rectus fascia is closed.

Adhesiolysis

Is a critical step, as the Abdominal Wall (AW) will be limited in its mobility if it remains fixated to the viscera? Completely free all the bowel/omentum adhesions from the undersurface of the AW taking care to preserve the integrity of the peritoneum and of the posterior rectus sheath. All prior synthetic material, if any, is removed to allow better integration of the new mesh. In addition, it reduces the risk of seroma formation and infections. At the end, protect the peritoneal content with a large wet soft towel.

Creation of the retro-rectus space: begins with the identification of the medial edge of the rectus muscle. Identify visual and by palpation this landmark; if the identification fails, incision of the posterior rectus sheath it is placed improperly, into the hernia sac and the dissection will advance into the subcutaneous plane (Figure 1).

When correctly identified, a horizontal incision is made on the posterior aspect of the sheath, 0.5 cm - 1 cm apart of its medial edge (Figure 2).

The plane is correctly approached if the fibers of the rectus muscle are easy visualized. The incision is carried along the posterior sheath that is open as far to exceed 5 cm to 7 cm the upper and lower limit of the defect. It is not wrong to approach the retro-rectus space placing the incision on the anterior aspect of the rectus sheath, especially when difficulties for identification and dissection are expected (Figure 2). Some surgeons do it deliberately on one size in order to preserve a large peritoneal flap (which usually, in this situation, resides attached on the posterior sheath) for an easier tensionless closure of the posterior fascia. Doing such that we can loss 1 cm to

2 cm of the anterior fascia, which can be paramount for the anterior fascia closure. Once the edge of the posterior rectus sheath is freed from the rectus muscle, constant tension is need to develop the retro-rectus space. Dissection is facilitated by placing two hemostatic clamps on both anterior and posterior sheaths; diverging this upward and medially a constant tension is created to develop the retro-rectus space. A combination between blunt (with a mounted swab) and sharp or electric dissection should be used to advance laterally until the Spiegel line is approached. The perforating neurovascular bundles define the boundary, which looks like the "comb teeth" (Figure 3). Proceed similarly on the contralateral side.

When both sheaths are opened and the retro-rectus space is created, cephalad and caudal extensions are developing according to the location of the defect. Should the hernia defect extend into the upper abdomen, the surgeon may need to develop the dissection up to the costal margin and behind the xiphoid process to the retro-sternal space.

1. For midline hernias with cephalad extension, at least 6 cm below the xiphoid a plane needs to be established to connect bilateral retro-rectus spaces across the midline. Linea alba is maintained in continuity, ventral to the mesh for at least 5 cm by dividing the insertion of each posterior sheath into the linea alba in the cranial direction about 0.5 cm lateral to it.
2. For upper abdominal defects, first divide linea alba to the xiphoid process. Then incise the posterior insertion of the posterior rectus sheath into the xiphoid; the fatty triangle obtained like that assures extension to the substernal plane.
3. For inferior defects, the transition into the pelvis involves the division of the medial attachments of the arcuate line. Following that the pre-peritoneal plane is developed. The inferior epigastric vessels, running along the posterior surface of the rectus muscles need to be identified and preserved. Caudally the dissection extends 2 cm to 3 cm below the pubis symphysis and Cooper's ligaments.

Closure of the posterior fascia

The leafs of the posterior rectus sheaths are re-approximated in the midline for an estimation of tension - closure. If the flaps are unable to be connected, use the peritoneal flaps resulting from the sac dissection or the great omentum to patch the resulting hole. A piece of Vicryl absorbable mesh, if available, could be an excellent option. When the re-approximation is possible without tension a running suture with a 2-0 slowly absorbable stitch (Polydioxanone) is

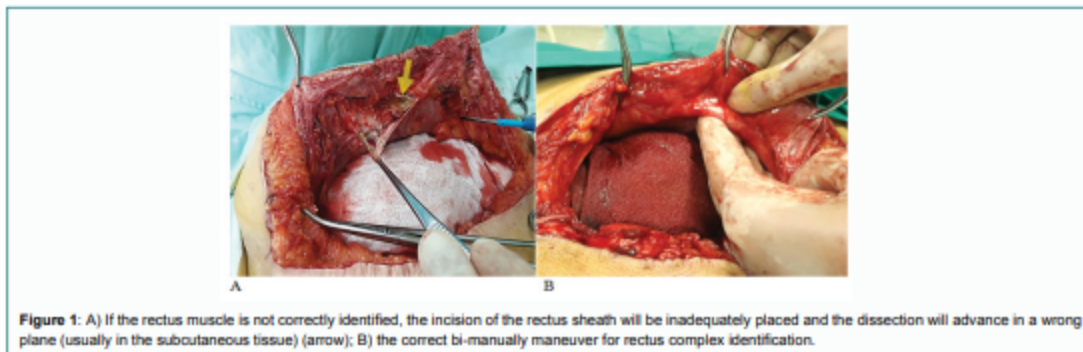


Figure 1: A) If the rectus muscle is not correctly identified, the incision of the rectus sheath will be inadequately placed and the dissection will advance in a wrong plane (usually in the subcutaneous tissue) (arrow); B) the correct bi-manually maneuver for rectus complex identification.

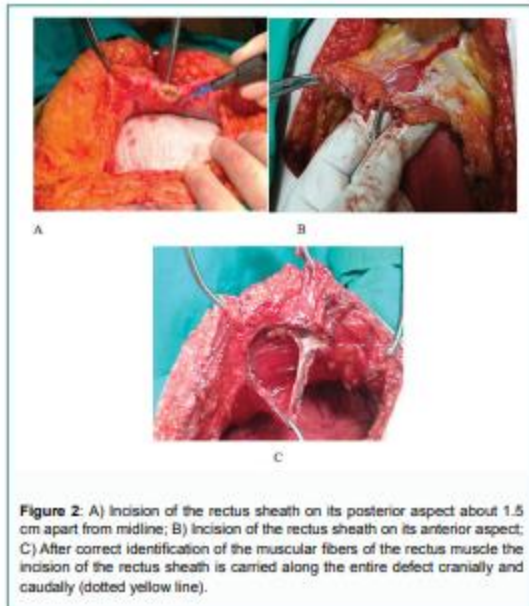


Figure 2: A) Incision of the rectus sheath on its posterior aspect about 1.5 cm apart from midline; B) Incision of the rectus sheath on its anterior aspect; C) After correct identification of the muscular fibers of the rectus muscle the incision of the rectus sheath is carried along the entire defect cranially and caudally (dotted yellow line).

of choice. In our experience, using polypropylene is disadvantageous due to the intense adhesions between bowels and stitches (Figure 4).

This is a crucial step of the procedure because sheath's breakdown exposes to intra-parietal hernia, a challenging complication, difficult to diagnose and to manage. Therefore, the posterior sheath has to be close, has to be close well, and has to be close safely.

Mesh insertion and fixation

The retro-rectus space is variable between patients and it must be measured in its length, and width and the mesh trimmed to adequate size. Usually, a medium or light-weight monofilament large pores polypropylene mesh is the best choice (40 g/m^2 - 60 g/m^2). There is no real consensus regarding if, where, and how to fix the mesh in this retro-rectus plane. We usually suture the mesh to both Cooper's ligaments and to the symphysis with a number 1 slowly absorbable sutures if the mesh is advanced in the pre-vesical space. Cranially, two stitches fix the mesh around the xiphoid covering, the epigastric area, and retro-sternal space. Laterally, two trans-fascial sutures passed with a Reverdin needle are inserted on both sides. At the end, the

mesh should be flat, with some kind of tension, in order to increase mesh - tissue area interface.

The mesh could be fixed with permanent sutures to the posterior rectus sheath but the technique is blind and expose to an increased risk of inadvertent bowel injury. Another option is to fix the mesh with cyanoacrylates (Hystoacril™). It is quick and safe but its efficiency it is not proved yet by prospective studies. Fixation will remain a personal choice. Two suction drains are placed on the mesh surface or in Retzius space (Figure 5).

Anterior fascial closure

With a size 0 or 1 running slowly absorbable suture. A subcutaneous drain is optional; otherwise, the subcutaneous tissue is closed interrupted absorbable sutures. Skin is closed according to preferences. An abdominal binder is recommended in the first postoperative days in order to reduce seroma formation. After that is patient's choice.

Results

We implement the procedure in our Department in 1998, and since then to 2019, 1598 midline incisional hernia patients were operated according to this technique. Mean age was 58.9 years (24-79) with midline defects ranging from 3 cm to 12 cm (mean size 7.9 cm). Major preoperative morbidity present in 17.8% patients. In 178 patients operated until 2014 November, the anterior fascia cannot be closed, the procedure ending as a retro-rectus bridged repair. Wound complications Surgical Site Events (SSE) encountered in 255 patients (15.95%). Follow-up for 1 to 21 years (mean 8.7 years) with a recurrence rate of 7.8%.

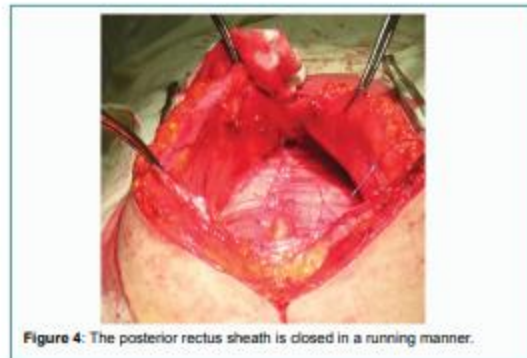


Figure 4: The posterior rectus sheath is closed in a running manner.

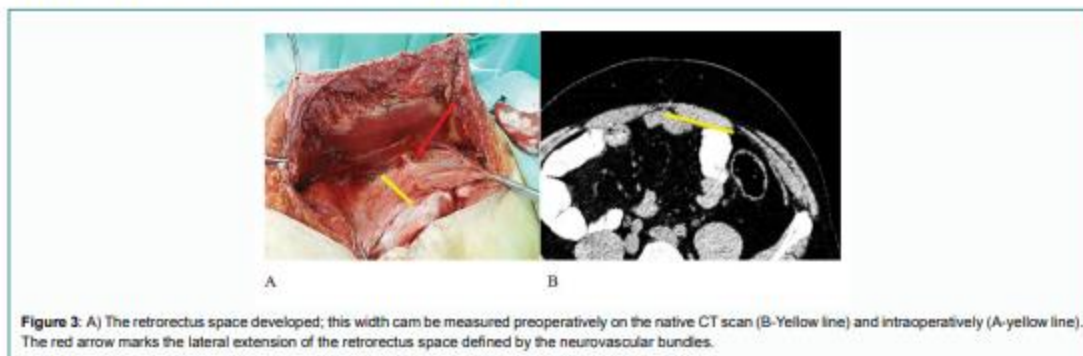


Figure 3: A) The retrorectus space developed; this width can be measured preoperatively on the native CT scan (B-Yellow line) and intraoperatively (A-yellow line). The red arrow marks the lateral extension of the retrorectus space defined by the neurovascular bundles.

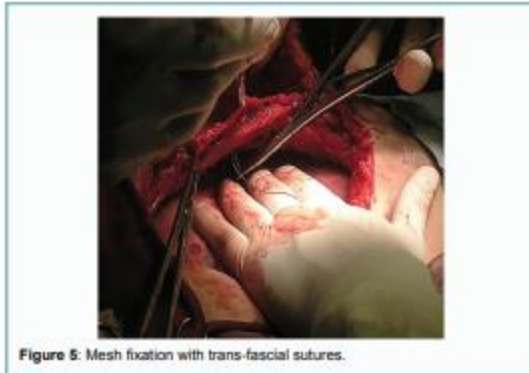


Figure 5. Mesh fixation with trans-fascial sutures.

Discussion

The benefit of the retro-rectus repair of abdominal wall defects has been well documented over the years by many authors after Rives and Stoppa published their researches. This technique provides many advantages in the reconstruction of complex defects [6]:

1. The retro-rectus space is an easily dissected potential space in almost all instances; in our experience the space cannot be attend only twice.
2. It is a well-vascularized compartment with a more efficient collagen deposition and mesh integration
3. In a recent systematic review and network meta-analysis sub-lay was associated with lower risk of recurrences and SSI compared to on-lay, inlay and underlay. Sub-lay was ranked the best mesh placement option with a high probability of being the best treatment (94.2% probability of having the lowest odds of recurrence and 77.3% probability of having the lowest odds for SSI) [10].
4. Fulfills in most instances the goals of modern hernia repair: the restoration of a functional abdominal wall by recreating the linea alba reinforced with a large prosthetic mesh overlap and with minimal early and late wound morbidity.

Frequent impossibility of closing the anterior fascia in large defects, narrow atrophied retrorectus space with limited mesh overlap, and obliterated retromuscular space usually by meshes with fibrosis are the main limitations of the procedure.

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Open Anterior Component Separation for Complex Incisional and Ventral Hernias—When and How? Case Series Analysis

Doru Moga¹ · Valentin Oprea²

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Abstract

Closing the midline in patients with incisional hernias is the cornerstone for a functional reconstruction with low morbidity, low recurrence rates, and good cosmetic results, which is the ideal outcome for every hernia surgeon. However, in patients with large hernias (usually over 10 cm width) or in loss of domain cases, this goal is difficult to achieve. Anterior component separation with or without mesh reinforcement has been the procedure of choice for these patients despite its high rate of wound complications. The goal of our study is to evaluate the opportunity and necessity of the anterior component separation in patients with complex incisional or ventral hernias (defects larger than 10 cm, infected meshes). Data of patients with large incisional/ventral hernia operated using anterior component separation technique in the past 10 years were re-visited and analyzed from hospital records between January 2012 and December 2020. Demographic data (age, gender, body mass index, ASA score) and the main steps of the technique were recorded. Data were reported as mean and standard deviation. We used the anterior component separation in 66 cases, mainly for septic conditions (open abdomen, chronic and extended infections of the abdominal wall, chronic-infected meshes). For large parietal defects with aseptic local condition, we used mesh-reinforced anterior component separation (five patients). Mean age was 68.7 years. Among them, 29 patients developed wound complications (hematoma, seroma, infection). Mean hospital stay was 12.6 days. Recurrence was 18% in patients without mesh and zero in patients with mesh reinforcement after a minimum one-year follow-up. Anterior component separation is still a valid procedure in patients with large abdominal defects especially when a septic wound is to be closed. For large parietal defects, if a wide subcutaneous dissection is required, mesh-reinforced anterior component separation remains a valid alternative in abdominal wall reconstruction in certain cases (mainly aseptic conditions).

Keywords Anterior component separation · Large ventral hernia · Abdominal wall reconstruction · Case series

Introduction

The incidence of hernias following laparotomy ranges between 9 and 50% in high-risk population patients. There also is an increased number of complex incisional hernias (IH) most of them featuring large defects (usually over 10 cm width) or loss of domain, which can lead to a profound alteration of the anatomy and function of the abdominal wall [1]. Once the linea alba has been broken,

the resulting scar tissue is weaker, leading to hernia formation in specific circumstances. In recent years, the concept of abdominal wall reconstruction has been a hot topic in the field of hernia surgery. The goal of this reconstruction is a mesh-reinforced primary fascial closure, with reconstruction of the midline (linea alba) under minimal tension, resulting in minimal complications. Thus, the procedure provides the patient with both a sound and cosmetic result.

Sometimes, due to excessive tension or severe postoperative complications generated by the forced repair (intra-abdominal hypertension, abdominal compartment syndrome, or respiratory failure), large defects or loss of domain hernias cannot be closed without disconnecting some of the components of the lateral abdominal wall. These techniques take advantage of the layered anatomy of the abdominal wall, and, based on which layers are released, they can be categorized as anterior or posterior component separation.

✉ Doru Moga
mogadoru@yahoo.com

¹ Department of Surgery, Military Hospital Sibiu and Lucian Blaga University Sibiu, Sibiu, Romania

² Department of Surgery, Military Clinical Hospital Cluj-Napoca and Iuliu Hatieganu University of Medicine and Pharmacy, Cluj-Napoca-Napoca, Romania

We set out to analyze whether mesh-reinforced anterior component separation (MACS) should remain in the therapeutic arsenal and to exemplify instances in our cases when this procedure may be recommended.

Patients and Methods

Patients We reviewed all the files of the patients with complex incisional hernias (defects larger than 10 cm width, infected abdominal wall meshes, open septic abdomen, extended infections of the abdominal wall) and ACS with and without mesh reinforcement admitted in both departments of surgery during January 2012 and December 2020 after institutional board approval. Demographic variables including patient's age and gender were collected. Medical co-morbidities such as body mass index (BMI), chronic obstructive pulmonary disease (COPD), diabetes, smoking and alcohol habits, and ASA score were also reported. All admitted patients were investigated with standard abdominal ultrasound and native or contrast-enhanced abdomino-pelvic CT scan for size and location of the defect, muscular status, presence or absence of mesh, and infected mesh. The authors, both senior surgeons experienced in open and laparoscopic abdominal wall reconstruction, performed all the procedures.

Surgical Technique Patients were admitted to hospital the night before surgery and received an osmotic bowel preparation and the prophylaxis of deep vein thrombosis with low molecular weight heparins according to the anesthesiologist preference. The exact size and position of the defect relative to the anatomic midline and level of the umbilicus were noted. The surgeon also had to carefully analyze the quality, position, vascularity, and mobility of the skin and muscle structures on both sides of the defect. The procedure began by elevating the skin flaps of the underlying abdominal musculature in a lateral direction towards the anterior axillary line. Next, the linea semilunaris was noted, along with the insertion of the external oblique aponeurosis (EOA). A vertically oriented incision located 2 cm laterally to Spigelian line and in the costal part of the external oblique aponeurosis, of 1 cm length, was made to identify and expand the plane beneath the EOA but superficial to the internal oblique fascia [2].

One must be careful not to dissect too deep into this layer to avoid injuring the internal oblique fascia or muscle. A deep dissection here may damage the segmental innervation of the rectus abdominis muscle or injure the Spigelian fascia, thus predisposing the patient to a Spigelian hernia. Generally, the planes are quite distinct. Once the plane is identified, the incision of the external oblique aponeurosis is extended cranially and caudally in its entire length. The

dissection proceeds in this relatively avascular intermuscular plane and is continued in a lateral direction beyond the area of skin undermining to at least the level of the midaxillary line. At this point, the mobility of the innervated rectus abdominis-internal oblique abdominis-transversus abdominis muscle complex is determined.

If additional mobility of these structures on either side of the midline is desired, then the dissection in the intermuscular plane can be continued to the posterior axillary line [3]. In our experience, each ipsilateral complex can be advanced towards the midline by 4 cm in the upper abdomen, 8 cm at the waist, and 3 cm in the lower abdomen. In the rare instances in which additional advancement is needed, the rectus muscle can be elevated off of the posterior rectus sheath in its entirety. Two centimeters of additional advancement can be obtained at each level by using this maneuver, and a mesh can reinforce the reconstruction, much like in a Rives-Stoppa repair [3]. The muscles are joined together in the midline with an interrupted or continuous closure using a strong non-absorbable suture (our preference is 0 polypropylene) (Fig. 1).

The skin flaps are then also advanced to the midline and approximated in a layered closure. Four suction drains are used routinely, and these are positioned in the plane between the oblique muscles and beneath the skin flaps on each side of the midline. They are brought out through separate stab incisions in the pubic area, lateral abdomen, or both. They are maintained until the drainage decreases to less than 30 cc per 24 h, which is usually at an average of 7 days.

When the peritoneal sac develops much further towards the lateral, for its release, the subcutaneous dissection reaches the vicinity of the linea semilunaris, or even exceeds it (Fig. 2, 3).

As an exception, if the length of the parietal defect is limited (supraumbilical, mesogastric, infraumbilical), the incision may be reduced, if it largely exceeds the defect [4].

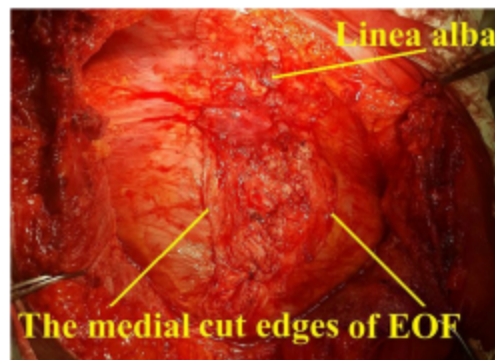


Fig. 1 Bilateral full anterior component separation

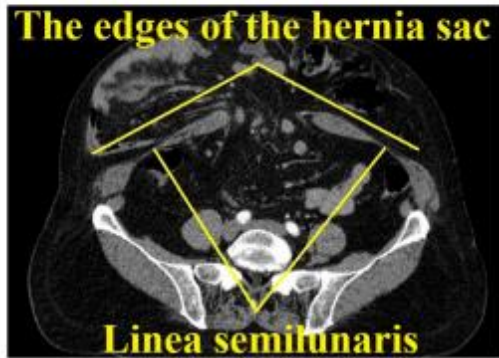


Fig.2 Peritoneal sac developed further to the sides

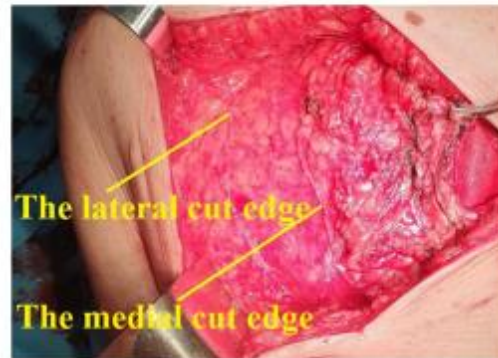


Fig.4 Unilateral limited incision of external oblique fascia (on the right side)



Fig.3 Peritoneal sac developed mainly to the left side

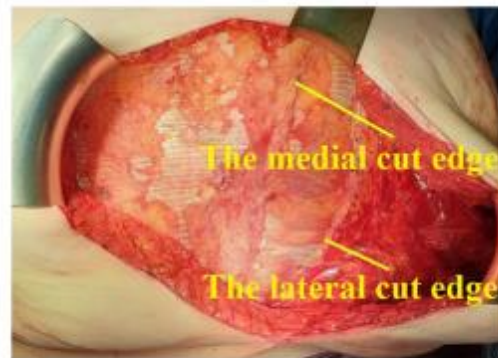


Fig.5 Unilateral limited incision of external oblique fascia (on the left side – mesh in place)

If recreating the linea alba is possible after the unilateral practice of the EOA incision, contralateral anterior component release is not necessary (Fig. 4) [5]. The prosthesis is fixed in the onlay position and must cover the area of the component separation. To do this, the prosthesis is attached to the lateral edge of the EOA (Fig. 5).

Results

During the reference interval, the ACS procedure was used in 66 consecutive patients (41 men) with a mean age of 68.7 ± 8.5 years. All patients presented unique or associated comorbidities; obesity with a BMI over 32 kg/m^2 was reported in 58 patients, diabetes in 38 patients, and COPD in 18 patients. Our indications included:

1. recurrent incisional hernias with chronic infected mesh removal after incisional hernia repair in 28 patients. The onset of mesh infection was over 3 months after primary repair (mean time-lapse 19.8 months, range 3 months–25 years);
2. open septic abdomen treated with negative-pressure wound therapy in 8 patients, open septic abdomen treated with Bogota bag in 10 patients. The main causes for open abdomen were anastomotic fistulas after colorectal surgery in 9 patients, after gastro-intestinal surgery in 3 patients, advanced primary peritonitis in 4 patients, and necrotic pancreatitis in the rest;
3. abdominal primary or secondary tumor resection in 2 patients; and
4. abdominal wall resection for multiple septic granulomas in 13 patients.

Of these, 29 patients (47%) presented postoperative complications. They were represented by skin necrosis in 13 patients, hematoma in 15 patients, and a burst abdomen in 1 patient. The mean hospital stay was 16.7 days (9–56 days); all wounds healed between 48 and 72 days (57.4 days). Recurrence was recorded in 18 patients (29%), all within the first year after the procedure. Of them, seven recurrences were noted in patients with postoperative hematoma, 1 after the burst abdomen, and the rest of them in patients without postoperative complications but with associated co-morbidities (5 in patients with BMI larger than 30 kg/m², 3 in diabetic patients, and 2 in COPD patients). All recurrences were clinically and CT scan documented. All recurrent defects were located in the midline and were probably a healing or technical defect. There was no defect recorded lateral to Spiegel line. Only two of this patients were re-operated; defects smaller than 6 cm were primary closed and the suture was reinforced with a large sheet of light monofilament polypropylene 30 × 30 cm secured with cyanoacrylate blue.

5. large incisional hernias with clean condition. We used MACS in five patient cases in which an extended subcutaneous supra-aponeurotic space was developed after sac dissection. In three patients, we practiced bilateral complete anterior component separation, and for the other 2 cases, unilateral limited anterior component separation. Patients were discharged after an average of 12.6 days (between 7 and 16 days). There were 2 patients with wound complications, represented by seroma, wound limited breakdown, and consecutive superficial infection. Wound healing was obtained after 58 and 94 days, respectively. Recurrence was seen in none of the five patients during postoperative follow-up sessions after at least one year.

Discussion

The closure of the abdominal wall defects using anterior components separation (ACS) was first reported by Albanese in the 50 s, but Ramirez et al. re-described and popularized it in 1990 [6, 7]. This technique is unique in that the functional transfer of the abdominal musculature provides stable and dynamic support to the abdominal wall, without the need for musculofascial flaps.

For 3 decades, ACS was the corner stone of abdominal wall reconstruction in patients with large incisional hernias. Mesh reinforcement, as on lay or underlay, was an important adjunct for improving outcomes due to its low recurrence rate. Many surgeons were reluctant to use it due to the logical sequelae of large myofascial and subcutaneous flap elevation. Some common complications are possible

and these include seroma, hematoma, infection, skin edge necrosis, wound breakdown, and hernia recurrence [5, 8].

Although it has entered clinical use only in a few surgical services, in complex ventral hernia repairs, subcutaneous perfusion mapping with indocyanine green angiography in infrared light offers high sensitivity and facilitates the identification of ischemic tissues, thereby reducing the incidence of delayed wound healing and the risk of surgical site infection. This technique has the potential to reduce costs and improve patients' quality of life by reducing the likelihood of wound complications and reoperation [9].

The complications resulting from ACS can be reduced using minimally invasive ACS, such as perforator sparing or endoscopic techniques [10, 11]. However, it should be noted that, in these procedures, the prosthesis will be placed in the sublay or underlay position, which increases the duration, complexity, and costs of the operation. Furthermore, in these technical variants, the prosthesis will not protect the weak area resulting from the EOA incision, increasing the risk of a lateral bulge or lateral abdominal wall hernia.

With regard to posterior component separation (PCS) and PCS-TAR, we believe it offers superior results to those otherwise obtained using MACS [5]. Most recent innovations have been achieved through the use of the minimally invasive approaches of endoscopic TAR (eTEP TAR) and robot-assisted TAR (rTAR) [8].

The information found in the literature related to incisional hernia is often contradictory. On the one hand, the onlay procedure retains its purpose and role [12, 13]; on the other hand, it is stated that MACS should be no longer performed because it has a high complication rate [14, 15]. Moreover, there are authors who view MACS and PCS-TAR as having comparable outcomes in complex abdominal wall reconstruction of midline ventral incisional hernias [10, 16].

To date, no comparative clinical or animal studies on the efficacy of various component techniques have been published. This is not surprising given that most surgeons prefer one technique over the other and the likelihood of a well-designed prospective randomized trial remains low [17, 18].

A challenging issue, for both patient and surgeon, is the recurrence after ACS without mesh because abdominal wall reconstruction is difficult to perform even for patients with small defects. Posterior component separation via TAR being it open or endoscopic is prohibitive in the first six months because of the important abdominal wall destabilization. After this period, the procedure can be considered with an in-lay mesh reinforcement but remains reserved only for specialized centers or dedicated surgeons with abdominal wall surgery expertise. On-lay mesh reinforcement could be a valid option in patients with small defects but the recurrence rate is not yet estimated.

For large midline hernia defects, if the release of the hernia sac requires extensive subcutaneous dissection, we

consider the incision of the EOA to be a useful and acceptable option to close the midline. The morbidity of the operation does not derive from the EOA incision, but from the subcutaneous dissection, which has already been completed. If the dissection performed can allow for the installation of a sufficiently large mesh to reinforce the abdominal wall, we can proceed to practice MACS. In such situations, PSC-TAR or other technical procedures can be utilized to close the linea alba, although the morbidity following wide subcutaneous dissection will be added to that of wide retromuscular dissection.

MACS is not a complicated procedure compared to other component separations. For surgeons who frequently use onlay mesh placement, with the addition of EOA release, the proportion of cases in which it will be possible to close the medial defect will be higher than after the use of the classic relaxation incisions made in the anterior sheath of the rectus abdominis muscle.

We strongly believe that any hernia surgeon should be well versed in several techniques so they can offer the best technical option to patients with large incisional hernias.

Conclusion

Anterior component separation is still a valid option for reconstruction of the septic abdominal wall despite its high rate of wound complications. If a wide subcutaneous dissection is required, MACS remains a valid alternative in abdominal wall reconstruction in certain cases, but it is an exception due to the benefits of newly introduced posterior component separation via TAR.

Author Contribution Doru Moga and Valentin Oprea wrote the article, which all authors critically revised. All authors agreed to be accountable for all aspects of the work.

Data Availability Statement Data are available at request on the corresponding author.

Declarations

Competing Interests The authors declare competing interests.

Guarantor Doru Moga.

Valentin Oprea.

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Late Results and Quality of Life after Rives-Stoppa Repair for Incisional Hernias: A Prospective Clinical Study

V. Oprea¹, O. Matei¹, D. Leucă¹, D. Gheorghescu¹, A. Mic¹, E. Buia¹, F. Gavrilas²

¹Department of General Surgery, "Constantin Papilian" Emergency Military Hospital, Cluj-Napoca, Romania
²Private Hospital "Sanovil" Bistrita, Romania

Rezumat

Rezultate tardive și calitatea vieții după tratamentul proteic al herniilor incizionale prin tehnica Rives-Stoppa: studiu clinic prospectiv

Introducere: utilizarea protezelor în tratamentul herniei incizionale (HI) a redus drastic rata de recidivă dar a ridicat numărul și incidența complicațiilor asociate. Studiul raportează rezultatele unei serii consecutive de pacienți cu HI operați prin protezare retromusculară și are drept obiectiv evaluarea complicațiilor precoce și tardive asociate tehnicii. **Material și metodă:** au fost evaluați 275 pacienți operați între 2002 și 2006. În 2007 și 2009 au fost reevaluați prin examen direct și chestionar.

Rezultate: 171 pacienți au răspuns în 2007 și 148 în 2009. Au fost examinați direct 143, respectiv 118 pacienți. Rata de recidivă 6,7%. Rata de confort – bună și foarte bună la 58% **Concluzii:** rezultate comparabile cu cele din literatură.

Cuvinte cheie: protezare retromusculară, complicații post-operatorii, calitatea vieții

Abstract

Background: the prosthetic repair of incisional hernias drastically reduced the incidence of recurrence, but increased the associated morbidity. We report a consecutive series of patients with incisional hernias operated by Rives – Stoppa procedure. The aim is to identify the early and late complications associated with the procedure.

Material and methods: 275 patients admitted and operated on between 2002-2006 were prospectively evaluated by direct examination and questionnaire.

Results: 171 responded in 2007 and 148 in 2009; direct examination was obtained 143 and 118 patients respectively. Recurrence rate 6.7%. Good and very good comfort rates in 58%. **Conclusions:** similar results with the expert centre

Key words: retromuscular prosthesis, postoperative complications, quality of life

Background

Incisional hernia still remains an important complication of laparotomies with an estimated incidence between 10% and 15% of cases (1-4). Reported results of surgical treatment are also variable, with high recurrence rates for non-prosthetic repairs (1,5-9). The use of prosthetic materials has improved these results steadily but surely. The placement of the prosthesis is still a matter of debate. In some circumstances it is associated with a high incidence of complications (infections, seromas, intestinal fistulas) (10-14). In the last few years the Rives–Stoppa procedure is associated with the gold standard therapy for incisional hernias (14,15). This

Corresponding author:

Valentin Oprea, MD
Military Hospital Cluj-Napoca
No 22 G-ral Traian Mosoiu Street
Cluj-Napoca 3400, Cluj County
E-mail: opreacv@yahoo.com

study reports the results of a prospective consecutive series of incisional hernias operated by Rives – Stoppa procedure. The primary endpoint was recurrence rate analysis and evaluation of complications rates, and the secondary one – patient assessment of quality of life long term after surgery

Material and Methods

Between January 2002 - December 2006, in the General Surgery Department of The Emergency Military Hospital Cluj-Napoca 302 patients were admitted with primary and recurrent incisional hernias with a relatively constant yearly distribution (Fig. 1).

Surgical technique

After dissection of the peritoneal sac, the rectus abdominis sheath was incised along the defect and the retramuscular space was opened. The abdominal wall defect was evaluated in centimeters in its largest diameter. The posterior rectus sheath and the remaining peritoneum were sutured with Prolene 1™ running suture. Polypropylene prosthesis was fitted in order to exceed the edges of the defect at least 5 cm in all directions. If the defect was too large and the standard prosthesis was not enough, it was customized for the appropriate size. The mesh was fixed with transperitoneal separate nonabsorbable Prolene 1™ stiches all around the defect. The anterior rectus sheath was sutured with Prolene 1™ in a continuous manner. In most cases the relaxing incisions in the sheath were mandatory for closing it without tension. If the suture could not be performed without tension, the edges of the anterior rectus sheath were set in a continuous manner to the prosthesis with a Prolene 1™ thread (Fig. 2-4). As a routine practice we do not perform adjacent gastrointestinal concurrent operations.

Quality of life assessment

The questionnaire was created according to a personal design according to the parameters presented in Table 1.

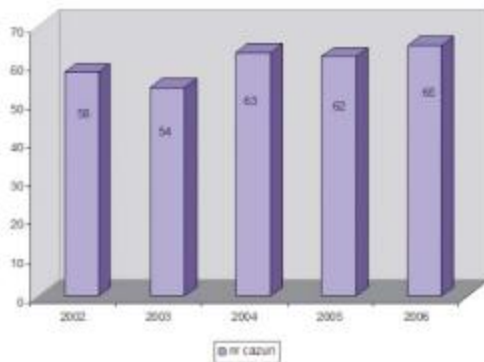


Figure 1. Annual distribution of cases operated



Figure 2. The rectus abdomini muscle sheath open. Muscle mass is observed with the anterior sheath

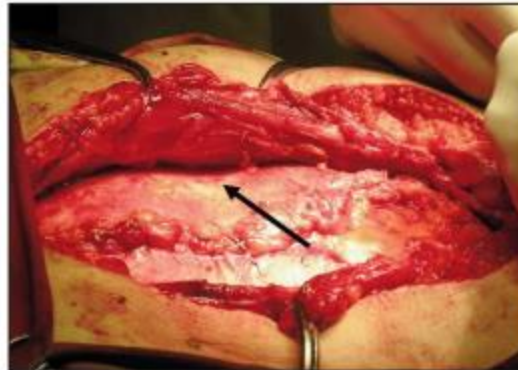


Figure 3. Closure of the posterior sheath and peritoneum with a continuous thread. Note the large surface area, future site of the mesh placement



Figure 4. Transrectus mesh fixation

Table 1. Qualitative and quantitative questionnaire assessment of quality of life after incisional hernia cure

1. How do you feel after your hernia cure?		
1.	Worse than before	- 1
2.	Bad	- 0
3.	The same	- 1
4.	Well	- 2
5.	Very well	- 3
6.	Excellent	- 4
2. Do you have any of the pre-operation symptoms?		
1.	yes	- 0
2.	no	- 1
3.	which one?	
3. Have you developed any symptoms or any complications that you had not had before surgery?		
	yes	- 0
	no	- 1
which of the following - 0		
	- chronic pain	
	- mesh migration	
	- chronic sinus (infection)	
	- limiting abdominal wall movements	
1.	when did it appear (months from surgery)?	
2.	did you fast?	
	yes	- 0
	no	- 1
4. Did your physical activity improve after surgery?		
1.	yes	- 1
2.	no	- 0
5. Are you satisfied with your surgery?		
1.	yes	- 1
2.	no	- 0
3.	why?	
6. Would you recommend the surgery to one of your friends?		
1.	yes	- 1
2.	no	- 0
3.	why?	

The results of the questionnaire were labelled according to the following scale:

- Excellent - 9 to 10 points
- Very good - 6 to 8 points
- Good - 5 to 6 points
- Poor - 3 and 4 points
- Very poor - under 3 points

Only the results of direct examination were recorded.

Results

Demographic data are detailed in Table 2.

275 patients remained in the study (89 male and 186 female) with the following distribution of hernias: vertical median - 202 (73.45%) (54 supraumbilical, 30 umbilical, 84 subumbilical and 34 xyfo-umbilical), superior quadrant - 26 (9.45%), the right inferior quadrant - 34 (12.36%), lumbar - 9 (3.27%), Pfannenstiel - 4 (1.41%) (Fig. 5). The sizes of the abdominal wall defect were over 15 cm in 83 patients (29.67%), between 10 and 15 cm in 168 patients (61.58%), between 5 and 10 cm in 18 patients (6.59%) and less than 5 cm in 6 patients (2.19%). Recurrence rank is shown in Fig. 6.

Table 2. Demographic characteristics of patients in the study group

Number of patients	302
Male: female ratio	98:204
Age (years) (medium and limits)	58,75 (21-78)
BMI (kg/m ²) (medium and limits)	33,5 (22 - 41)
ASA score	2 (1 -4)
Exclusion criteria	BMI > 40 - 17 patients ASA ≥ 3 - 7 patients sever COPD - 3 patients

BMI - Body Mass Index; ASA - American Society of Anesthesia Score; COPD - Chronic Obstructive Pulmonary Disease

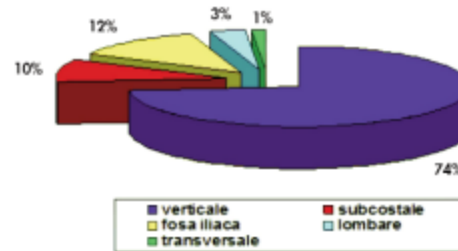


Figure 5. Distribution of parietal defects depending on location

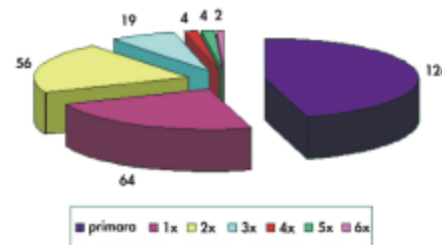


Figure 6. Distribution of patients in relation to recurrence rank

In 5 cases we performed limited enterectomies because of small intestine accidental injuries.

No postoperative mortality was recorded. There have been no major systemic complications (cardiac, pulmonary, neurologic or thromboembolic). Local complications represented the majority and are listed in Table 3.

In 2007 the questionnaires were sent to 237 patients who had undergone surgery at least 18 months previous to that date. Responses came from 171 patients with postoperative follow-up at 18 to 72 months (average 37.8 ± 2). 143 patients were directly examined by the senior operating surgeon and revealed the following complications: recurrence - 6 (4.19%), local abdominal pain related to movement - 18 cases (12.58%), chronic cutaneous fistula - 8 (5.59%) (Fig. 7). It is to be mentioned that 2 of the recurrences and 3 chronic fistulas

Table 3. Immediate postoperative complications

Wound hematoma requiring reintervention	18 (6.59%)
Wound seromas	26 (9.52%)
Superficial infections (2 patients with small bowel resection)	14 (5.12%)
Deep infections with mesh involvement (1 patient with small bowel resection)	4 (1.46%)

were associated with intestinal resection and local postoperative infection (Table 3).

In 2009, 260 questionnaires were again sent. These were filled in by 148 patients who were examined directly and 118 (less than half) with a postoperative follow-up of 49 months. There were two recurrences still raising the overall rate of relapse at 6.7%. Data on quality of life are presented in Table 4.

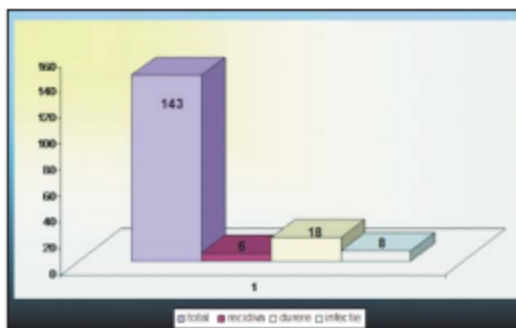
Discussion

Due to the complexity of the registered wall defects but also because of high risk factors present in patients referred for surgery, treatment of incisional hernias is challenging both for the surgeon and the patient. Most of the patients are obese and have multiple other comorbidities such as diabetes and obstructive chronic pulmonary disease. Additionally, many of them present with a history of multiple laparotomies leading to the formation of strong adhesive syndromes or recurrent hernias with large wall defects. Following principles to consistently avoid the gastrointestinal complementary surgeries due to the high risk of prosthetic contamination, we obtained good long lasting results. Relatively low rate of morbidity and absent mortality in this series, demonstrates that intervention can be performed safely. Recurrence rate of 6.7% at 3 to 7 years post-operatively demonstrates that the procedure itself is highly efficient if it is correctly performed. Furthermore, 64% of patients were satisfied with the subsequent development of quality of life.

Despite the good results that we obtained, the study is limited by reduced follow-up and by the recurrence rate based on a small number of patients directly examined. If we assume that the unexamined patients recurrence rate was similar, we record an overall rate of 12%, which correlated with defect complexity seems reasonable and superimposable with literature data (15).

The technique itself provides strategic placement of the mesh so that it covers without tension the entire wall defect and optimizes its tissue ingrowth. Coverage of prosthetic material is ideal, if possible, because it protects against infection. Opening the intestinal tract is a theoretical contraindication to prosthetic repair, but given the complexity of abdominal wall defects the techniques of tissue repair are doomed to failure at a rate of 50% (16).

Aggressive treatment of suppuration in the early days of the event, both locally and systemically, may be useful in preventing the risk of contamination of the prosthesis which can thus be saved (17).

**Figure 7.** Late postoperative complications**Table 4.**

	2007	2009
Excellent	2 (1.39%)	3 (2.54%)
Very good	48 (33.56%)	43 (36.44%)
Good	41 (28.61%)	37 (31.35%)
Poor	46 (32.16%)	27 (22.88%)
Very poor	6 (4.19%)	8 (6.77%)
Total	143 (100%)	118 (100%)

Conclusions

The complex incisional hernia surgical cure Rives-Stoppa technique is a safe procedure, sustainable and efficient, providing a high rate of both patient (by the high degree of comfort) and surgeon satisfaction (by the low rate of complications and recurrence). Postoperative wound infection and especially of the prosthesis are the main causes of relapse and dissatisfaction.

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The outcomes of open anterior component separation versus posterior component separation with transversus abdominis release for complex incisional hernias: a systematic review and meta-analysis

V. Oprea^{1,2} · M. Toma¹ · O. Grad^{1,2} · C. Bucuri^{1,2} · P. Pavel¹ · S. Chiorescu² · D. Moga^{3,4}

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Abstract

Purpose The main objective was to assess the prevalence of hernia recurrence, wound complications (surgical site infections [SSI], seroma and hematoma) and mortality after anterior component separation (ACS) and posterior component separation via transversus abdominis muscle release (PCSTAR) in patients with complex incisional hernias.

Summary background The so-called complex IH is a serious medical and societal challenge due to its direct and indirect costs; it is also hampered by the use of different surgical techniques, different type of meshes, and different results heterogeneously reported and interpreted. According to actual data, the best approach seems to be a mesh reinforcement component separation procedure augmented or not with an adjuvant technique (preoperative progressive pneumoperitoneum and/or Botulin toxin type A infiltration).

Methods A systematic search of four databases (MEDLINE, PubMed, Web of Science, and Google Scholars) was conducted to identify studies reporting on outcomes of component separation techniques and which were published before December 2021. A systematic review and a meta-analysis of postoperative outcomes were performed.

Results Nineteen studies including 3412 patients (1709 with ACS and 1703 with PCSTAR) were selected. Pooled hernia recurrence rate after a minimum 1-year follow-up was evaluated at 5.15% (odds ratio [OR] 0.68; 95% confidence interval [CI] 0.5–0.9; $p=0.0175$). Pooled surgical site infection rate was 10.6% (OR 1.32; 95% CI 1.06–1.65; $p=0.0119$). Seroma and hematoma were estimated at 9.75% (OR 1.93; 95% CI 1.52–2.44; $p=0.0001$) and 3.83% (OR 1.81; 95% CI 1.26–2.61; $p=0.0012$), respectively. ACS was associated with increased wound morbidity, seroma and hematoma. PCSTAR displayed higher recurrence rate (4.27% vs 6.11%).

Conclusions PCSTAR was superior to ACS in terms of wound morbidity, surgical site infections, seroma and hematoma incidence. The procedure should be further evaluated in comparative head-to-head randomized controlled trials.

Keywords Complex incisional hernias · Anterior component separation · Posterior component separation · Transversus abdominis muscle release · Recurrence

Background

Incidence of incisional hernias (IH) remains increased despite modern technologies that have implemented minimally invasive surgery, high-quality synthetic or biologic prosthetic materials and suture materials and techniques. Once developed, IH evolves and may result in progressive enlargement with large defects even loss of domain, or acute life-threatening complications. Furthermore, once repaired the burden of recurrence, mesh infection or migration through a hollow viscus associates pain, impaired quality of life and the risk of subsequent re-intervention [1].

✉ V. Oprea
opreacv31@gmail.com

¹ Clinical Department of Surgery, “Constantin Papilian” Emergency Clinical Military Hospital, No 22 Gral Traian Mosoiu Street, Cluj-Napoca, Cluj County, Romania

² Second Department of Surgery, Iuliu Hatieganu” University of Medicine and Pharmacy, Cluj-Napoca, Romania

³ Department of Surgery, “Alexandru Augustin” Emergency Military Hospital, Sibiu, Romania

⁴ Medicine and Pharmacy Faculty, “Lucian Blaga” University, Sibiu, Romania

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Complex IHs are a serious medical and societal challenge due to their direct and indirect costs; they are also hampered by the use of different surgical techniques, different type of meshes, and different results heterogeneously reported and interpreted [2]. Anatomical restoration of the linea alba, even with the aid of a mesh repair, it is almost impossible to be achieved for such patients without the aid of component separation techniques. Sometimes, the preoperative augmentation of the abdominal wall is necessary and these can be physical (progressive pneumoperitoneum or Fasciotense™ Hernia Dalhausen Medical Technology device) or chemical as type A Botulin toxin in various forms. Currently, only two surgical techniques [the anterior component separation (ACS) as described by Ramirez [3] and the posterior component separation with transversus abdominis release (PCSTAR) as described by Novitsky (4)] address to patients with tissue loss, wide defects, loss of domain, fibrotic/non-compliant abdominal wall are available; each one claims its superiority over each other in terms of effectiveness.

Enthusiastically accepted in the 1990s, ACS soon proved to be burdened by a large number of wound complications (seroma, hematoma, skin necrosis, infections) and a constant recurrence rate ranging between 9 and 18% [5, 6]. Introduction of the endoscopic ACS and periumbilical perforator sparing improved the incidence of complications but without interfering with recurrence rate despite the use of biologic or synthetic prosthetic materials in all locations of the abdominal wall (onlay, inlay, retro-rectus or preperitoneal) [6–8]

PCSTAR is a new myofascial release technique designed as an extension of the Rives-Stoppa repair in which the preperitoneal space is accessed by sectioning the transversus abdominis muscle at the level of the posterior rectus sheath. Thus, an immense retromuscular plane is developed and a large piece of mesh can be inserted into a bilaminar space. Complete fascial closure can be achieved in almost 95% of the patients with a well vascularized and innervated abdominal wall due to the preservation of the neuro-vascular bundles. The incidence of wound complications is variable ranging from two to 30% in different reports [9].

The comparison of the above-mentioned techniques in terms of outcomes, quality of life and recurrence rate represents an important measure for the quality of repair and a possibility to improve the decision-making process and, thus, surgical performance. There is no proof that one technique is superior to the other. A meta-analysis comparing both techniques was recently published but the conclusions were scarce due to the small number of patients and the inclusion of most PCSTAR patients from the same surgical center [10].

The increased use of local augmentation techniques in abdominal wall reconstruction (progressive preoperative pneumoperitoneum—PPP associated or not with Botulinum toxin infiltration) and the newly devised Fasciotense™, were

recently successfully reported as effective adjuvant methods for abdominal wall reconstruction being it open or laparoscopic [11–14].

Given the increased popularity of PCSTAR and its quick adoption for complex abdominal wall IH, our goal was to reevaluate the outcomes of the procedure according to the new literature data with an increased number of included patients. The protocol of the systematic review and the meta-analysis presented here was prospectively registered in the PROSPERO database (http://www.crd.york.ac.uk/PROSPERO/display_record.asp?) with the registration identifier CRD 42021292506.

Methods

Search strategy

Two independent reviewers (OV and MT) performed a structured literature search in MEDLINE, PubMed, Web of Science, and Google Scholars for studies reporting outcomes of component separation techniques. The search strategy was conducted according to Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines [15]. The following index terms “complex incisional hernia” OR “component separation” were used to identify studies from the beginning of 2010 until December 2021. A bibliographic review of selected relevant papers was used as a secondary source for full-length articles.

Eligibility criteria

Relevant studies published in the English language were included if they originated from a unique cohort. In the case of multiple publications from one center, the last publication was considered comprehensive. All single arm and comparative prospective or retrospective studies were included. For open ACS only retromuscular mesh reinforcement with synthetic or biologic meshes was eligible for the analysis. Articles without a clear definition of the outcomes, reporting non-midline hernias at least, pediatric series, non-human studies, less than 25 patient series (to avoid overestimation of the treatment effects), case reports, minimally invasive series, review articles, “How I Do It” reports, discussion papers or meta-analysis were excluded.

Outcome definition

Primary outcome measurements were wound morbidity and hernia recurrence.

Wound morbidity or wound events are described in Table 1 and include Surgical Site Infections (SSI) according to CDC classification [16], Surgical Site Occurrences

Table 1 Description of wound morbidity criteria

Surgical site infections (SSI)	Surgical site occurrences (SSO)	Surgical site occurrences requiring procedural intervention (SSOPI)
Superficial	Any SSI in addition to:	Wound opening
Deep	Wound cellulitis	Suture excision
Organ space	Non-healing incisional wound	Percutaneous drainage
	Fascial disruption	Complete/partial mesh removal
	Skin/soft tissue ischemia	
	Skin/soft tissue necrosis	
	Serous/purulent wound drainage	
	Stitch abscesses	
	Seroma, hematoma	
	Infected/exposed mesh	
	Enterocutaneous fistula	

(SSO), and Surgical Site Occurrences Requiring Procedural Intervention (SSOPI). The recurrence rate was considered only after a minimum of 12 months follow-up and was documented by clinical, radiological (ultrasound, CT scan) or any of the hernia inventory surveys. Other secondary outcomes of interest were mortality, 30-day medical complications, readmission and reoperation rate.

Quality and risk of bias assessment

The included studies were assessed for the risk of bias by two independent raters (OV and MT), with any disagreements resolved by consultation with a third party (MD). The risk of bias assessment was done using the Cochrane Collaboration's tool for assessing the risk of bias in non-randomized trials [17] for each study. Since the risk of bias may not be equal for all outcomes an individual, risk analysis was performed for each outcome assessed. The risk of bias was represented as separate columns in forest plots for individual studies and as stacked bar charts as an overview.

Two independent reviewers (OV and MD) assessed the quality of the studies according to MINORS criteria using 8 items for single arm studies and 12 items for comparative studies [18]. Disagreements were resolved by consensus with a third reviewer (BC). Due to the risk of bias, it was decided that a MINORS score of at least 7 was required to include the study in the meta-analysis.

Data extraction and management

Data were independently extracted and entered into an Excel spreadsheets. From each study, the following data were extracted: first author, study design, sample size, demographic characteristic of the patients (gender, age, body mass index, comorbidities, smoking status, number of prior operations for hernia), intraoperative characteristics of hernia (defect area, type of mesh used, and operative time), and the described outcomes.

Statistical analysis

Data interpretation was performed using Revue Manager (RevMan) Computer Program, version 5.4 The Cochrane Collaboration 2020. Continuous data were summarized by calculating the mean of provided measures included in the study; dichotomous data were represented as absolute numbers and percentages. Pooled proportions of the outcomes were calculated with fixed effects (FE) models in the case of non-significant heterogeneity ($p > 0.1$) and with a random logistic regression when significant heterogeneity was present ($p < 0.1$). The odds ratio (OR) with a 95% confidence interval was assessed for dichotomous outcomes while standard mean difference (SMD) was estimated for continuous outcomes. Corresponding forest plots were constructed for the pooled estimates of the described outcomes and the weight of individual studies is represented by the size of individual squares. Heterogeneity was assessed using chi-square statistics and I^2 measure for inconsistency. Heterogeneity was not considered important when I^2 ranged between 0 and 40%, moderate between 30 and 60%, substantial between 50 and %, and significant between 75 and 100%.

A random effect meta-regression was performed to evaluate possible patient (age, gender, Body Mass Index [BMI], diabetes, and immunosuppression) variables able to influence the outcomes. A network meta-analysis was conducted to compare the different types of mesh on the risk of outcomes using a multivariate regression.

A p value below than 0.05 was considered significant for all outcomes.

Results

Search results

The initial search results identified 1061 references (Fig. 1). After exclusion of duplicates and exclusion of references based on title and abstract, 102 full texts were read. From

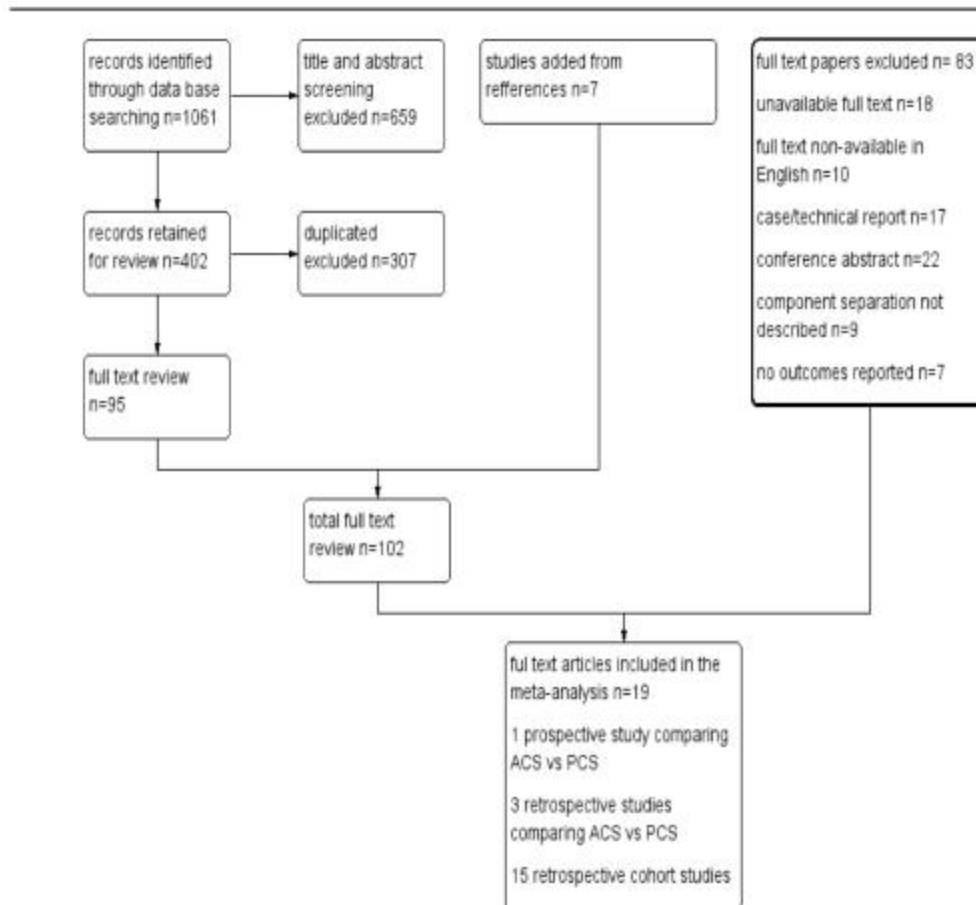


Fig. 1 PRISMA flow chart

the 102 articles, 83 were excluded. The most common reasons for exclusion were the full-text unavailability, and the presence of only conference abstracts. Finally, 19 studies with 3412 patients (1709 with ACS and 1703 with PCSTAR) were included in the meta-analysis [19–37]. Of these 19 studies, one was a prospective non-randomized trial comparing ACS vs PCSTAR [19], three retrospective comparative studies [20–22], and 15 retrospective cohort studies [23–37]. None of the publications included described a randomized control trial. Table 2 shows the characteristics of the studies included.

The risk of bias assessment

The risk of bias assessment is represented globally in Fig. 2. The majority of studies were at risk of random sequence

generation (high risk 75%, critical risk 18%), performance bias (moderate risk 71%, critical risk 24%) and attrition bias (high risk 80%, critical risk 13%).

Quality assessment

Most studies showed good methodological quality; only two of them had 7 points based on MINORS criteria (Table 2).

Baseline characteristics

In total, 3412 patients were included with an almost 1: 1 proportion of male to female ratio (males—1771, females—1641). The median or mean age as reported ranged between 52 and 64 years (aggregated median 57.57 years). Median or mean BMI (as reported) ranged from 27.9 to

Table 2 Characteristics of the included studies

Reference	Study type	MINORS criteria	Year	ACS (N)	PCSTAR (N)	Outcome measures	Recurrence examination	Follow-up (months)	Mesh type
Alkhatib (22)	retrospective	10	2021	–	Bridged PCSTAR 96 patients	Wound morbidity on 30 days follow-up Recurrence rate	Clinical, US CT scan	20 ± 10	
Blair (18)	non-randomized prospective study comparing ACS vs PCSTAR	21	2016	95 patients	33 patients	Wound morbidity, recurrence rate, QoL, self-reported Carolina Comfort Scale	Clinical, US CT scan	16.4 months	
Charzamasovoudis (23)	retrospective	9	2021	–	125 patients	Wound morbidity, associated procedures, recurrence	Clinical, US CT scan	29.8 (12–60)	
Espinosa-de-los-Monteros (24)	retrospective	7	2016	58 patients	–	Wound morbidity, recurrence	Clinical (personal examination)	14	
Fayezizadeh (25)	retrospective	12	2016	–	77 patients	Presence of SSE, SSI, recurrence	CT scan one year or any time for evaluation of clinical symptoms, telephone questionnaire	28.2 (12–60)	Porcine biologic mesh
Gandhi (26)	retrospective	9	2021	–	92 patients	Complications, SSO, recurrence	CT scan performed to look for hernia recurrence and residual collections	–	Synthetic
Garvey (27)	retrospective	13	2012	169 patients	–	Developing of specific wound complications, recurrence rate	Physical examination CT scan evaluation	–	
Krpaia (19)	retrospective comparison ACS vs PCSTAR	11	2012	56 patients	55 patients	Fascial closure, wound morbidity, hernia recurrence	Not specified	ACS—9.1 (3–50.5 months) PCSTAR – 6.8 (3–49, 1)	
Maloney (20)	prospective single institutional	23	2019	25 patients	88 patients	Primary—recurrence rate Secondary—QoL (Carolina Comfort Scale), wound complications	Clinical and CT scan	ACS – 21.3 ± 22.2 PCSTAR – 20.7 ± 23.2	
Montelione (28)	retrospective	13	2021	–	65 patients redo-TAR	30-day wound morbidity, hernia recurrence after more than 1 year	Clinical follow-up and/or CT; patient reported outcomes; Hernia recurrence inventory, Hernia Related quality of life score	12.5	
Novitsky (29)	retrospective	13	2016	–	428 patients	Primary—SSE, SSI Secondary—recurrence rate	Clinical follow-up and/or CT; Telephone questionnaire Clinical examination	31.5 (12–84)	

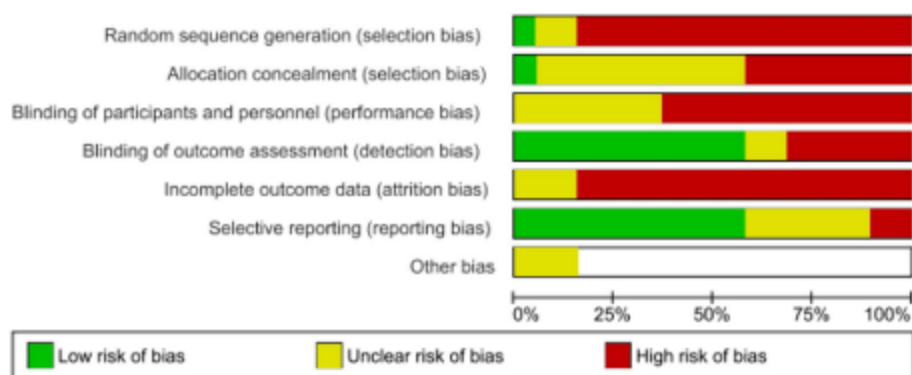


Fig. 2 Evaluation of global risk of bias of searched papers

35.8 kg/m² (aggregated median—32.92 kg/m²). Multiple comorbidities were reported in all studies. Thus, were reported 827 diabetic patients (24.23%), 546 patients with Chronic Obstructive Pulmonary Disease (COPD—16%), and 248 immunosuppressed patients (7.26%). Active or former smoking was reported in 17 studies (14–19, 21, 23–32) and included 665 patients (19.72%). Surgery for recurrent incisional hernia was reported in 18 studies for 1521 of 3340 patients (45.53%) with an aggregated mean of 1.9 previous repair/patient. Comparative pooled data for anterior vs posterior component separation are represented in Table 3.

Intra-operative details

Defect area was reported as mean or median in all studies and varied from 140 to 653 cm² (aggregated median—342.63 cm²). Patients with ACS have a pooled defect area of 278.38 ± 126.82 cm² comparing

with 346.29 ± 160.08 cm² for patients with PCSTAR (SE = 5.18, 95% CI = - 78.07 to - 57.74, *t* test = - 13.27, *p* < 0.001). Operative time as mean or median was documented in 16 studies and ranged from 155 to 377 min (aggregated median 260.32 min). There was no difference between operative time of ACS patients and PCSTAR patients (245.72 ± 94.5 vs 249.92 ± 47.92, SE 1.30, 95% CI 1.48–6.02, *t* test = - 1.30, *p* = 0.192). Overall use of biologic mesh was recorded in 12 studies and included 484 patients (14.18%). In patients with ACS biologic mesh was 3 times more frequently used than in patients with PCSTAR and the difference was significant (366 vs 118 patients; OR 3.66; 95% CI 2.93–4.56; *z* = 12.40; *p* < 0.001). The most frequent biologic mesh used for AWR was Porcine Dermal Graft. A various number of synthetic meshes (in terms of basic polymer, molecular weight, and filament type) were used; of them polypropylene flat mesh was the most frequently reported.

Table 3 Baseline characteristics of the included patients

Variable	ACS	PCSTAR	OR (95% CI)	<i>p</i>
Age (years)	58.35 ± 3.25	57.85 ± 3.59	SE = 0.078 (58.19–58.50)	0.746
Gender (male)	882/1709	889/1703	0.97 (58.19–58.5)	0.728
BMI(kg/m ²)	33.3 ± 2.12	32.49 ± 2.12	SE 0.072 (0.66–0.95)	0.37
Operated recurrences	565/1709	956/1703	0.41 (0.35–0.47)	<0.001
Number of previous repairs	1.6	2.7	-	<0.001
Smokers	446/1668	224/1703	2.4 (2.01–2.87)	<0.001
Diabetics	382/1709	445/1703	0.81 (0.69–0.95)	0.010
COPD	298/1709	248/1703	1.23 (1.03–1.48)	0.0219
Immunosuppressed	198/1709	50/1703	4.43 (3.15–5.95)	<0.001

A statistically significance was relevant when *p* < 0.05

ACS anterior component separation, PCSTAR posterior component separation with transversus abdominis release, OR odds ratio, 95% CI 95% confidence interval, SE standard error, BMI Body mass index, COPD chronic obstructive pulmonary disease

Anterior fascia closure was reported in 15 studies ($n=2612$ patients). A bridged repair was performed in 221 patients (8.46%) and more frequent in patients with PCSTAR (161 patients; OR 0.34; 95% CI 0.25–0.47; $p<0.001$). Only six studies reported concomitant procedures during AWR: small bowel resections and small bowel procedures—222 patients of 1832 (12.11%); other procedures (appendectomy, cholecystectomy, non-specified)—49 of 286 (17.13%) and concomitant mesh removal—62 patients of 1645 (3.76%). Bowel procedures were more frequent encountered in ACS (175 of 1265 patients and the difference was significant comparing to PCSTAR (relative risk [RR])—1.66; 95% CI 1.22–2.26; $p=0.0011$); mesh removal was more frequent in patients with PCSTAR—22 of 380 patients vs 40 of 1265 patients (RR 0.54; 95% CI 0.32–0.90; $p=0.019$).

Postoperative outcomes

Pooled overall wound morbidity was reported in all studies with an incidence of 28.63% (977 events). In ACS group of patients the pooled reported rate of wound occurrences was higher than in the PCSTAR group (565 vs 412 patients; OR 1.54; 95% CI 1.33–1.79; $p<0.001$) (Fig. 3A). Surgical site infection was the most frequent wound occurrence (10.60% of all patients and 37% of all wound morbidity). Pooled data showed that SSI was more frequent in patients with ACS (204 vs 158 events) and the difference was significant (OR 1.32; 95% CI 1.06–1.65; $p=0.0119$) (Fig. 3B). Seroma was encountered in 333 patients (9.75%) and was more frequent reported in ACS patients (215 vs 118 events; OR 1.93; 95% CI 1.52–2.44; $p<0.001$) (Fig. 3C). Only 131 patients developed postoperative hematoma: 84 in the ACS group and 47 in the PCSTAR group (OR 1.81; 95% CI 1.26–2.61; $p=0.0012$) (Fig. 3D). Overall pooled recurrence rate was 5.15% (169 of 3278 patients; in the posterior component separation group were reported only patients who fulfilled a minimum 1-year follow-up). Procedural intervention for wound complication was reported in only five studies ($n=2125$ patients) and consisted in antibiotics, wound opening, dressings and VAC therapy. The pooled overall incidence was 5.08% (78 patients of 2125). There is no description of the number of procedures/patient. The incidence of SSOPI was 2.15% (30 of 1193) ACS patients and 8.36% in the PCSTAR patients (78 of 932); the incidence was statistically significant (OR 1.79; 95% CI 1.48–2.74; $p<0.001$).

Length of hospital stay reported as a mean was identified in 15 studies and varied from six to 14.4 days (aggregated mean 9.7 ± 3.6 days). Patients with ACS had a pooled hospital stay of 8.56 ± 2.06 compared to 7.49 ± 2.39 days for patients with PCSTAR (OR 0.83; 95% CI 0.71–1.02; $p=0.027$).

Follow-up expressed as mean ranged between 6.8 and 32.4 months with an aggregated pooled value of

17.26 ± 7.54 months. It was reported in all studies except one, and included a number of 3291 patients. Patients with ACS had a shorter follow-up (15.61 ± 4.25 months) compared with patients with PCSTAR (19.48 ± 9.48 months) and the difference was significant (SE 0.24; 95% CI – 3.01 to – 2.06; t test = – 10.15; $p<0.001$).

During this follow-up period, overall recurrence rate was recorded in 169 of 3278 patients (5.15%); it was 4.27% in the ACS group (73 of 1709 patients) compared to 6.11% (96 events in 1569 patients) in the PCSTAR group. The difference was statistically significant (OR 0.68; 95% CI 0.5–0.9; $p=0.0175$) (Fig. 3E).

Mortality was reported in only one study for six patients in a report of 96 patients with a bridged PCSTAR and was attributed to medical complications (pulmonary embolism, sepsis and shock).

Factors associated with the outcomes

Logistic regression showed that polypropylene mesh was associated more frequent with seroma formation in ACS patients (OR 0.021, 95% CI 0.067–0.71, $p=0.006$) while biologic mesh with recurrence (OR 0.266, 95% CI 0.123–0.677, $p<0.001$) and infection (OR 0.232, 95% CI 0.12–0.419, $p<0.001$) in ACS patients. Among comorbidities, COPD and obesity were the main factors responsible for SSI and recurrence. The area of the defect and the number of previous hernia repairs were the main factors associated with hematoma and recurrence for both ACS and PCSTAR.

Discussion

This systematic review and meta-analysis is focused on complex hernias that cannot be closed primarily without excessive tension and their management is based on the component separation techniques associated with mesh reinforcement. Component separation techniques with retrorectus mesh reinforcement are effective procedures in complex hernias to reduce recurrence rates and to assure a sound, stable and functional abdominal wall (30). Based on pooled estimates, component separations were associated with relative favorable outcomes in terms of postoperative complications. The overall rate of wound morbidity was 29.3% and was dominated by SSI (380 events—11.1%) and seroma formation (325 events—9.52%). Moreover, severe complications were rarely reported and mortality was extremely low (six events—0.17%) despite the local and systemic complexity of reported incisional hernia patients. After a minimum 1-year follow-up, the recurrence rate, was moderately low and can predict a benefit for these complex hernia patients.

An interesting finding of this meta-analysis is the important proportion of bridged repair in patients with PCSTAR.

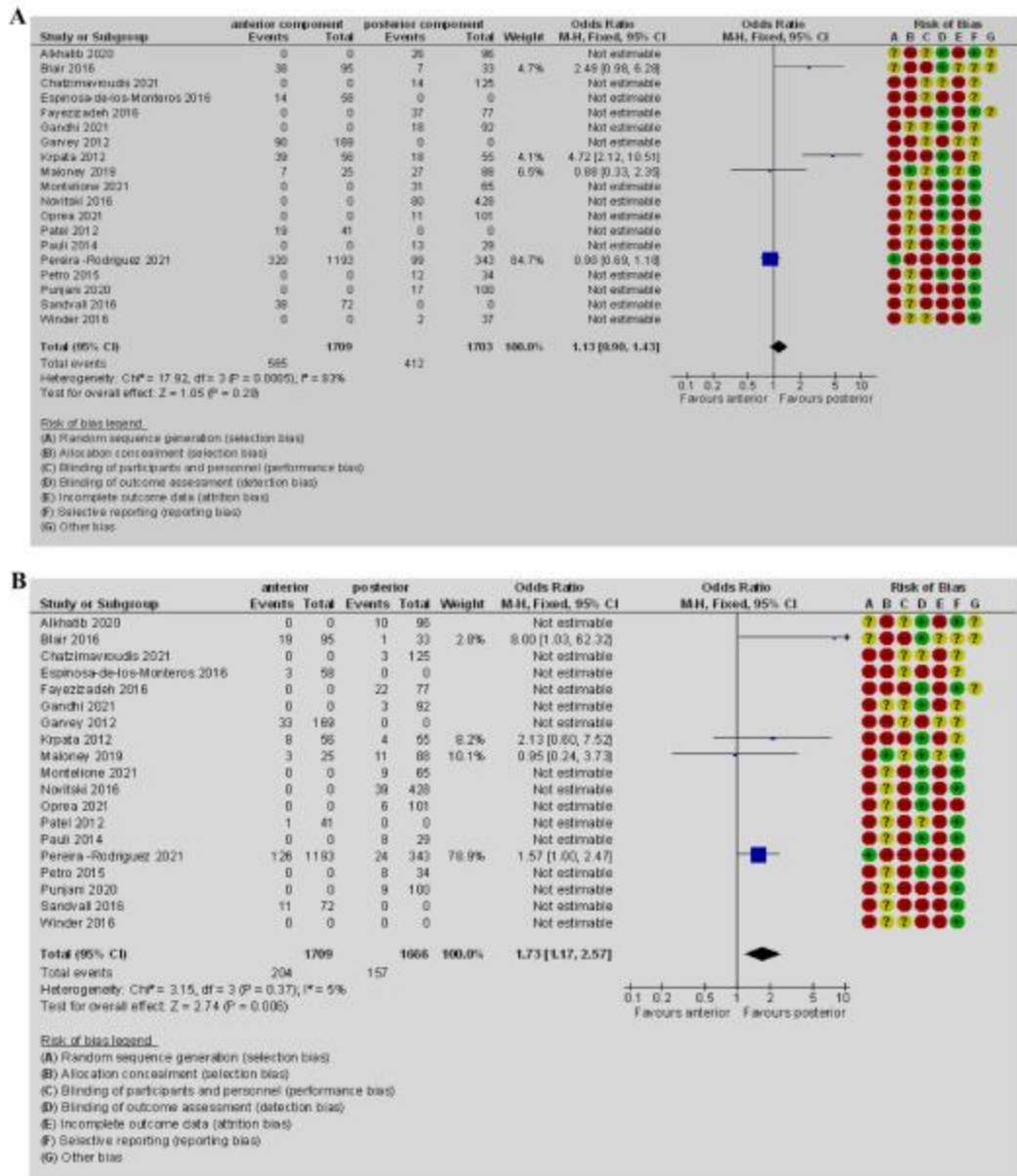


Fig. 3 A Global wound morbidity (favors Posterior Component Separation). **B** Surgical Site Infections (SSI)—Strongly favors Posterior Component Separation **C** Seroma formation (favors Anterior Component Separation).

D Hematoma formation (favors Anterior Component Separation). **E** Recurrence rate (favors Anterior Component Separation). **F** Length of stay (favors Posterior Component Separation)

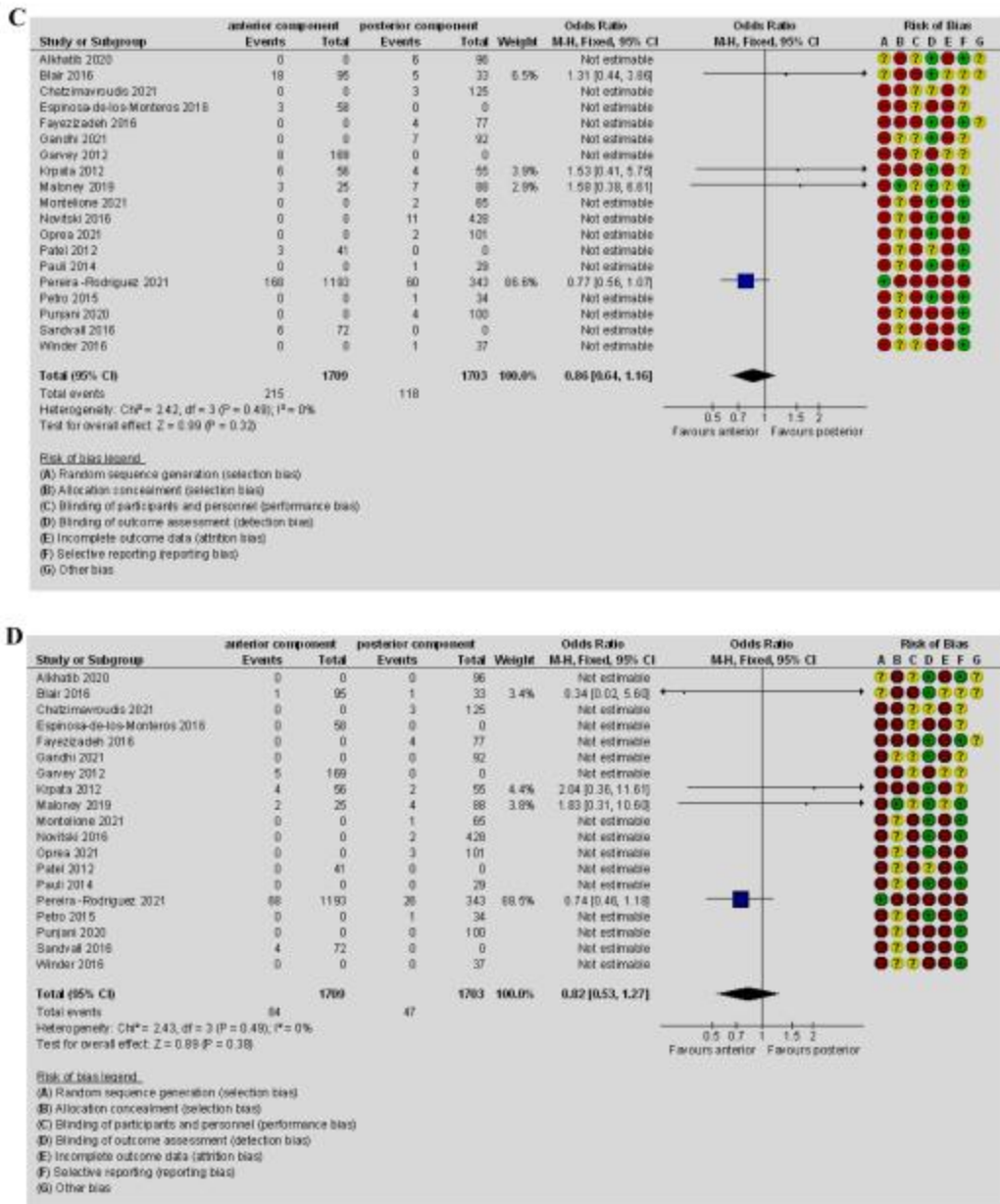


Fig. 3 (continued)

(161 vs 60 patients), missing the advantage of approximated muscles in the midline. The degree of advancement for both techniques has not been adequately described (only in

cadaveric studies); the reported results are still controversial resulting in great uncertainty regarding this issue. A greater degree of abdominal wall advancement is seen in the ACS

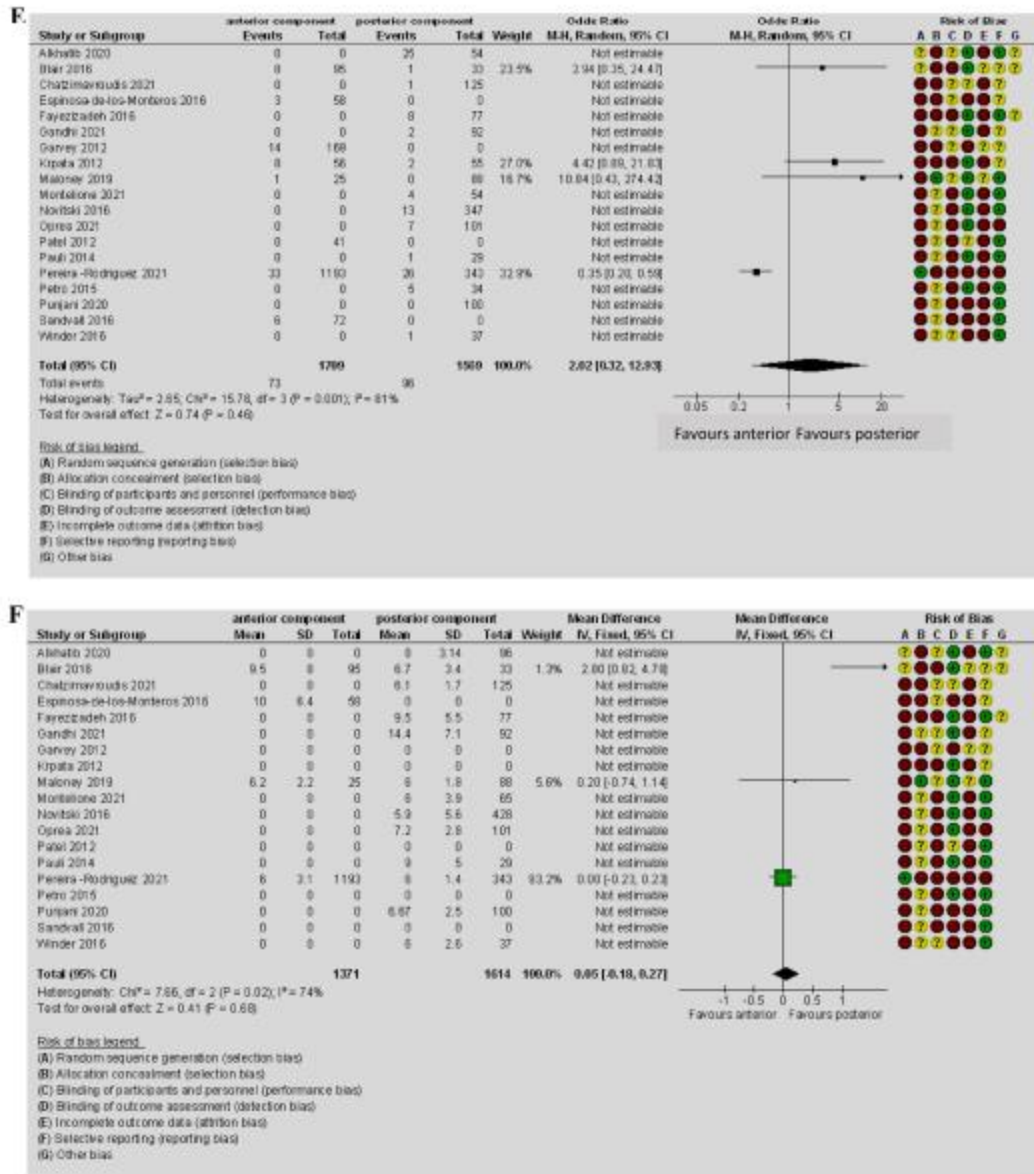


Fig. 3 (continued)

techniques compared with TAR as reported by Loh et al and Moores et al in their cadaveric studies [38, 39]. These results show significant differences of 57% comparing to Majumder et al cadaveric study in which after a complete TAR the medial translation of abdominal wall was 9.9 cm for

each side [40]. A possible contributing factor is the degree of tethering effect of the external oblique muscle insertion compared to the transversus muscle insertion to the rectus sheath [38]. The variation of conditions in the real patient will vary especially with the degree of herniation, abdominal

wall defect, location of the defect, tissue elasticity and resistance, shear modules, and probably the most important factor with the abdominal wall compliance, which is also influenced by a multitude of patient-related factors [41].

Despite large proportion of bridged repairs, benefits are important and resides in the wide pocket for mesh positioning in the retromuscular space compared to ACS; the use of synthetic mesh for the bridged repair is also an essential component as the use of biologics has been found to result in higher infection and recurrence rates. As Alkhatib reported on the largest series of bridged PCSTAR the quality of life was significantly improved [23].

There are promising results with the use of adjuvants for increasing the abdominal wall compliance and volumes but the number of reported patients is still not significant for an extended attitude. The use of preoperative progressive pneumoperitoneum (PPP) and Botulin toxin (BTX) alone but more frequent in combination seems to be useful to provide complete repair and a reduced rate of complication [11–14]. The main drawback of them is that the measurements were difficult, not reliable or reproducible and, therefore, hard to standardize. As a measure of improvement, more studies are necessary [41].

As expected, global wound morbidity was higher in ACS patients and the results are similar to ones reported in other studies. In 2002, Lowe et al. reported on 30 patients with ACS a cumulative incidence of 35 wound events; infection (40%) and wound dehiscence (43%) being the most frequent occurrences [43]. Although the average rates of complications were high, this does not necessarily apply to all patients because of the considerable heterogeneity presented in the pooled analysis ($I^2 = 83\%$). The increased heterogeneity among studies had a high impact on the quality of the meta-analysis for these complications [44]. All other wound events (seroma, hematoma, and SSI) were more frequently encountered in patients with ACS (unimportant heterogeneity for all events). Despite these data, SSOPI were more frequently reported in patients with PCSTAR; probably a better understanding of the mechanisms of wound repair and a more aggressive attitude in controlling healing leads to this attitude.

An important topic to discuss is the follow-up period. Since the follow-up differs significantly between both groups, the shorter follow-up coincides with the lower recurrence rates and this has to be expected since the recurrence rate increase over time; from our pooled data a five percent difference is to be expected within three months between the first and the second year of follow-up. With 5% expected difference due to a longer follow-up, the observed difference may be irrelevant with a 98% likelihood of second-order error [45].

Given the complexity of these patients, the recurrence rate was acceptable despite inadequate follow-up length. The

recurrence rate is probably correct, with a low publication bias, most of the studies (ten of them) reporting adequate recurrence identification by CT scan or ultrasound instead of clinical examination. The recurrence rate for the patients with PCSTAR, despite larger mesh surface, might be also explained by the larger mean defect area, more frequent use of bridged repair, the use of PCSTAR for complex situations (open abdomens, post-transplant patients.), and the higher number of recurrent incisional hernias (including recurrent hernias after ACS) for which the technique was used. Hultman et al. showed that recurrence rate for surgeons using component separation gradually decreases after five years of experience with the technique [46]. No valid correlation was observed between the type of mesh used and the recurrence rate in PCSTAR group.

The increased rate of recurrences in both groups but especially in patients with PCSTAR could be reasonable explained from the point of biomechanical stability against cyclic load and by the complex biomechanical behavior of the abdominal wall after reconstruction [47–51]. According to the authors, biomechanical stability after abdominal reconstruction is dependent by an adequate mesh selection, mesh size and mesh fixation. This is also in relation with the Mesh Defect Area Ratio (MDAR) which is a measure for the static cohesion; this static tension also varies with the surface properties of any mesh touching tissues. The touching surface is loaded by other forces which are influenced by surgical procedure (mesh position), mesh fixation and tissue elasticity keeping the mesh in place until healing occurs. The authors also consider that a tailored approach for each patient is mandatory and the type, shape and mesh surface are important prerequisites of a successful repair. A DIS class A meshes gives the best retention force such that Gained resistance to impacts delivered by pressure (GRIP) to be higher than Critically needed resistance to impact delivered by pressure (CRIP). Increasing hernia size requires higher GRIP values for a biomechanically stable complex hernia repair [48]. Also, application of component separation creates more space for mesh placement as intended in registry data [50].

In the light of these data, component separation applied to achieve a MDAR required for a GRIP above the calculated CRIP was ineffective and in association with an inadequate mesh in terms of surface and fixation (which is not mentioned in no one of the included studies), they lead to increased rate of recurrences and seroma formation. In their studies, the above-mentioned authors report an overall morbidity of 6–10% and no 1-year recurrence which compares favorably with the almost 30% found in the 19 articles considered for analysis.

Based on pooled data, we tried to identify factors involved in negative outcomes after component separation. Among patient-related factors, the presence of obesity and

COPD were the main risk factors for SSI and recurrence. Our results are similar to the ones of Desai et al. and Ko et al. who reported a sixfold increase of SSI when BMI was higher than 40 kg/m² [52, 53]. Also, publication bias on the surgical technique must be considered when analyzing the results; even if one of the inclusion criteria was the description of the procedure, the brief description and unreported differences in technical details cannot be neglected. Suture material, the technique of fascia closure (large or small bites) and mesh fixation were not adequately reported in most of the studies. The biologic mesh negatively influenced the recurrence rate in patients with ACS, while synthetic mesh increased the rate of seroma formation.

Our pooled results outcome data are in accordance with some recent meta-analysis and systematic reviews reported by Hodgkinson et al., Cornette et al., and Wegdam et al. [10, 44, 54]. Our data have the benefit of more comparative studies and more included patients.

The choice of one or the other of the component separation method is still debatable due to limited good quality data confirming the superiority of one over the other. No randomized controlled trials are comparing these procedures and the number of patients is still limited to draw consistent conclusions. Moreover, most of the patients with posterior component separation (TAR)—more than half in our study, are reported by the same surgical center [20, 23, 26, 29, 30, 33, 34]. Despite the increasing number of reports, the decision-making process is still a challenge for the abdominal wall surgeon and depends on several factors. Component separation being anterior or posterior is a difficult repair to perform and there will be a significant learning curve. Surgeons have to rely on their own experience, on the patient's clinical information and on their assistant's help. Monitoring and assessing the situation, taking appropriate actions and monitoring the results is a dynamic stepwise model of surgeon [55]. The influence of published outcomes, mostly on large cohorts and the presence of guidelines and recommendations are also important factors for choosing one or another component separation. Last but not least, a more profound and tailored biomechanical analysis could pave the road to more durable repairs. Unfortunately, we are still far away from this!

This study is not without limitations. Analyzing only cohort and non-randomized comparative studies without any randomized controlled trials can be considered a serious publication bias with a huge impact upon the quality of the results. There is a high heterogeneity among studies regarding patient population, comorbidities, type of used prosthesis and anatomy of the hernia. Also, the lack of head-to-head comparative studies and randomized trials makes a direct comparison between the two groups difficult. The absence of important details regarding the surgical procedure and differences in patients' characteristics undergoing one of the two assessed

surgical techniques can be considered another publication bias and these impact the reported recurrence rate and the rate of wound complications. Furthermore, mortality was not adequately reported in most of the studies and thus, the risk could be underestimated. Functional outcomes (quality of life, daily activities) were also rarely reported and in consequence, these outcomes could not be included in the meta-analysis. Considering these parameters as important for the assessment of treatment effectivity further studies, assessing functional outcomes are mandatory.

Conclusion

In conclusion, considering pooled data, component separation techniques were associated with favorable results in terms of recurrence rates. Differences in terms of outcomes of the two techniques analyzed in this meta-analysis were also observed. ACS is inferior to PCSTAR due to elevated seroma, hematoma, and surgical site infections while PCSTAR was associated with a higher recurrence rate. The increased rate of recurrences after PCSTAR is somehow bothersome as long as the mechanisms of recurrence are not yet clearly elucidated. ACS was associated with an increased amount of complete fascial closure. An interesting finding of this meta-analysis is the increased proportion of bridged repair in patients with PCSTAR; this can be an important "Achille's heel" for recurrence. The topic leaves the door open for further research as long as published studies still not prove a clear correlation between them. Designing hernia repair for durability according to biomechanical principles will bring both complication and recurrence rates below 5%.

Despite higher recurrence rate, PCSTAR could be a more valuable option because it does not require large skin and subcutaneous flaps and a large mesh can be placed as a sublay reducing the odds of SSI.

However, the lack of direct comparison of these techniques limits the interpretability of our results. Future controlled comparative trials with standardized outcome measures, particularly regarding the report of wound morbidity, are recommended to confirm our conclusions. Additionally, given the inherent difficulty in finding comparable patients in the field of abdominal wall reconstruction, Ventral Hernia Working Group grades, range of other operative factors, such as mesh type, and the range of potential comorbidities, an analysis of data available from National and European registries would be recommended.

Data availability All data are available and can be requested to the authors.

Conflict of interest No conflict of interest to declare for all the authors.

Ethical approval No ethical approval was necessary for this study.

Human and animal rights Human and animal rights were not affected in this study.

Informed consent No informed consent was necessary.

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Is transversus abdominis muscle release sustainable for the reconstruction of peritoneal volumes? A retrospective computed tomography study

Valentin Constantin Oprea¹, Marius Rosian¹, Stefan Mardale², Ovidiu Grad^{1,3}

Abstract:

BACKGROUND: Incisional hernia (IH) is the most frequent complication of laparotomy with an increasing incidence over time. A large amount of them present in complex forms with large defects or even loss of domain. There is still no consensus regarding the optimal surgical approach for this IHs. The posterior component separation with transversus abdominis release (TAR) alone or in combination with augmentation of the abdominal wall became the standard of repair in large IHs (LIH). No clear evidence that TAR alone can recreate the normal volume of the peritoneal cavity is available. We assessed if it is possible to reconstruct normal peritoneal volume (PV) by TAR.

MATERIALS AND METHODS: In this retrospective study, data from LIH patients with midline defects equal or larger than 10 cm width, and computed tomography scans available before and 1-week after TAR with complete fascial closure were analyzed. Hernia sac volume (HSV), abdominal cavity volume (ACV), and $(PV = HSV + ACV)$ were evaluated before surgery. Peritoneal index (PI) was calculated as HSV/PV ratio. PV was measured at 7 days post-TAR (PV_{TAR}). The compliance of the abdominal wall (C_{ab}) was calculated as the ratio between the difference of the PV before surgery and after TAR and the difference between preoperative intra-abdominal pressure (IAP) and postoperative IAP.

RESULTS: 23 consecutive patients with a mean age of 64 years were included in the study. The mean value of the HSV was 3,775 cm³ and of the ACV 8377 cm³. PI varied between 0.22 and 0.4. A statistically insignificant difference was recorded between PV and PV_{TAR} ($P = 0.7$). Patients with $PI \geq 0.3$ had the volume of the peritoneal cavity lesser than patients with $PI < 0.3$. The compliance of the abdominal wall was decreased for the patients with defects larger than 15 cm width and PI larger than 0.33. Urine output in the first postoperative day was smaller in the patients with PI larger than 0.3 with a statistically significant ($P = 0.0002$) difference and was highly correlated with the abdominal perfusion pressure (APP) and PI.

CONCLUSIONS: TAR is able to recreate normal PV in LIH patients with $PI < 0.3$. When PI is larger than 0.33, a permissive intraabdominal hypertension develops for 24 h with the reduction of the APP and of the urine output. In this condition, the augmentation of the abdominal wall could be considered as an option by preoperative administration of pneumoperitoneum and/or Botulin toxin.

Keywords:

Abdominal cavity volume, incisional hernia volume, intraabdominal hypertension, large incisional hernias, peritoneal index, transverse abdominal muscle release

Departments of ¹Surgery and ²Radiology, "Constantin Papilian" Emergency Military Hospital, ³Department of Surgery, "Tuliu Hatieganu" University of Medicine and Pharmacy, Cluj-Napoca, Cluj County, Romania

Address for correspondence:
Dr. Valentin Constantin Oprea,
Department of Surgery, "Constantin Papilian" Emergency Military Hospital, No 22 Gral Traian Mosolu Street, Cluj-Napoca, Cluj County, Romania.
E-mail: opreacv31@gmail.com

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Introduction

Despite considerable improvements and innovations in surgery, incisional

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hernia (IH) is still found after 11%–50% of laparotomies. It is one of the most frequent complications and a common indicator for reoperation.^[1,2] The costs involved in caring for this patient population are enormous (over USD

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3 billion only in the USA) and constitute a real public health problem.^[9]

Within this group, a specific subcategory of patients with large or very large IH (LIH) can be identified. Even though LIH incidence is underestimated, up to 40% of patients could be defined as large or with loss of domain (LOD) according to experts.^[4-6] Most of these patients experience severe symptoms, a poor quality of life and surgical repair is commonly needed.^[7]

The surgical management of IH associated with a patient's poor condition results in severe immediate complications (e.g., abdominal hypertension or compartment syndrome, respiratory failure), prolonged hospitalization (including intensive care), high reoperation rates and mortality. An optimized and proper surgical procedure choice is mandatory for a successful outcome.

In the last years, posterior component separation with transversus abdominis muscle release (TAR), alone or in combination with augmentation of the abdominal wall (progressive preoperative pneumoperitoneum (PPP) and/or Botulin toxin) became the standard of repair for LIH and was adopted routinely in several surgical centers.^[8]

The effects of TAR on the abdominal wall muscles and on the abdominal wall function were investigated,^[9,10] but there is no evidence that TAR alone can recreate the normal volume of the peritoneal cavity. The primary objective of our study was to assess, by a computed tomography (CT) volumetric evaluation, if TAR is sustainable in reconstruction of the normal peritoneal volume (PV). The secondary objective was to identify if there is any valuable cut-off based on CT volumes for identification of abdominal wall augmentation indication before the surgery.

Materials and Methods

Patients

All files of the IH patients admitted in the Department of Surgery of the Military Hospital Cluj-Napoca, between November 2014 and November 2018, were retrospectively analyzed. The study was approved by the Ethics Committee of the respective hospital. LIH was defined as a ventral IH with a fascial defect ≥ 10 cm width. The patients were included in the study based on the following pre-defined criteria: Midline IH defects ≥ 10 cm width, CT scan available before surgery and 1-week after the TAR with complete closure of the anterior fascia has been performed. Exclusion criteria were: Patients with preoperative local augmentation by PPP and/or Botulinum toxin, and patients with Class IV

Ventral Hernia Working Group classification.^[11] Patient consent was waived because the medical record review was retrospective and it was not feasible to obtain it.

Computed tomography protocol investigation

All preoperative CT scans were retrospectively re/reviewed by a surgeon and a radiologist. After the cross review, all inconsistencies of the measurements were eliminated. The length and the width of the defects were identified in their maximal dimensions and carefully measured. The width of the both rectus sheath has been also measured. Their sum divided by the width of the defect was the basis for TAR indication. The volume of the abdominal cavity volume (ACV) and of the hernia sac volume (HSV) (expressed in cm^3) were calculated according to Tanaka *et al.* method.^[12] The PV was obtained by adding up ACV and HSV. The peritoneal index (PI) was calculated as the ratio between IHV and PV. All the values were manually collected because there was no computer software; differences larger than $\pm 10\%$ between surgeon's and radiologist's measurements were reassessed until the agreement was obtained. The values were rounded to the nearest hundred or thousand.

Data

Patients' baseline characteristics (age, sex, and onset of symptoms) were recorded in a database. Intraoperative findings (length and width of the defect) were also recorded and compared with the CT scan findings. The defect of most patients was equated with an ellipse, and the defect surface was calculated using the formula $\frac{1}{2} \text{length} \times \frac{1}{2} \text{width} \times \pi$. Intra-abdominal pressure (IAP) was measured by indirect evaluation through a urinary catheter^[13] and was recorded before surgery and 24 h after TAR on the awakened patient. Intraabdominal hypertension (IAH) was defined as an IAP >12 mmHg.

The compliance of the abdominal wall (C_{ab}) was indirectly calculated as the ratio between the difference of PVs before and after surgery ($\Delta V = PV - PV_{TAR}$) and the difference between preoperative IAP and postoperative IAP ($\Delta P = \text{preoperative IAP} - \text{postoperative IAP}$) ($C_{ab} = \Delta V / \Delta P$). As a direct measure of IAH, the abdominal perfusion pressure (APP) was calculated as the difference between mean arterial pressure and IAP preoperatively and in the first postoperative day. Urine output at 24 and 48 h was recorded.

Procedure

The indication for TAR was established preoperatively using the formula 2RW: DW = 2:1, where RW was the rectus sheath width and DW is the defect width measured, both, on CT scan. All the procedures were performed under general anesthesia according to the technique described by Novitsky.^[14,15]

Statistical analysis

Data were tabulated as mean \pm standard deviation (SD). Continuous variables were analyzed by ANOVA variance test followed by unpaired 2 tailed Student's *t*-test assuming unequal variance, and the binary outcomes with the Chi-square test. Pearson correlation[®] was used with the regression equation. Multivariate logistic regression models were built with PI, IAP, PV_{TAR}, C_{ab}, and APP as the outcomes of interest for the major determinants of severe postoperative complications, adjusting for identified confounders. In addition to the variables of interest, the following were included for adjustment: Age, rank of recurrence, severity of comorbidities score, BMI, length, width and area of the defect, ACV, IHV, PV, postoperative IAP, and pain. Probabilities smaller than 0.05 were considered as statistically significant. IBM SPSS Statistics Version 20.0, 2018, Chicago, IL, was used to perform the statistical analysis.

Results

Of 327 IH patients identified during the study period, 98 (27%) underwent TAR and 23 patients (7%) fulfilled the criteria for inclusion in the study. Mean age \pm SD was 64.47 \pm 7.98 years and the onset of symptoms ranged between 12 and 148 months (62.17 \pm 37.4). Demographic characteristics are shown in Table 1.

IAP was low in 6 patients (6 mmHg), moderate in 10 patients (7–8 mmHg), and close to normal values in 7 patients (9–10 mmHg). The mean value was 7.6 \pm 1.24 mmHg.

The dimensions of abdominal wall defect measured on CT scan are listed in Table 2. No statistically significant difference was observed between intraoperative data and CT findings (Student's *t*-test; *P* = 0.83 data not shown). Pre and postoperative values of IAP and of the abdominal volumes are also shown in Table 2.

Univariate analysis of the entire cohort with the PI as a reference, showed no correlation with the dimensions of the defect length, width or surface. A high negative correlation was found with the preoperative IAP at the 0.01 level of significance (Pearson *r* = -0.809 and *r*² linear = 0.654) [Figure 1]. Also PI was negatively correlated with PV_{TAR} (Pearson *r* = -0.512; *r*² linear = 0.654; *P* = 0.006) and with ACV (Pearson *r* = -0.627; *r*² linear = 0.623; *P* < 0.001). When IAP was the reference, a significantly statistical difference between preoperative and postoperative was found *P* = 0.004. A significant negative correlation for 2 tailed at a level of 0.01 was found between postoperative IAP and ACV, preoperative IAP and PV_{TAR} [Table 3].

Table 4 details the results of multivariate logistic regression models. After adjustment, PI and postoperative IAP were shown to be independently associated with

Table 1: Demographic data of the studied patients

Category	n (%)
Sex	
Male	15 (65)
Female	8 (35)
IH location	Median for all patients
Primary IH	11 patients/8 males (48/73)
Recurrent IH	12 patients/7 males (52/58)
1 st recurrence	4 patients/2 males (17/50)
2 nd recurrence	4 patients/3 males (17/75)
3 rd recurrence	3 patients/2 males (13/66)
4 th recurrence	1 patient/1female (4/100)
Comorbidities	
Smoker	6 patients/4 males (26/67)
COPD	5 patients/3 males (22/60)
Hypertension	11 patients/7 males (48/64)
Diabetes	3 patients/males (13/100)
Severity of comorbidities score*	
0	2 patients (9)
1	2 patients (9)
2	7 patients (30)
3	12 patients (52)
4	
ASA score	
II	19 patients (83)
III	4 patients (17)
BMI (kg/m ²) \pm SD (minimum-maximum)	31 \pm 2.97 (25-35)

*The detailed explanation of the evaluation of the severity of comorbidities score: 0: No comorbidities, 1: Asymptomatic no medical consultation in last 12 months, 2: Stable disease, intermittent therapy <4 consultations in last 12 months, 3: Stable disease continuous therapy with regular medication and >4 consultations in last 12 months, 4: Progressive disease changing and intensified therapy and frequent consultations >12/year. IH: Incisional hernia, COPD: Chronic obstructive pulmonary disease, ASA: American society of anesthesiologist, BMI: Body mass index, SD: Standard deviation

Table 2: The values expressed as mean \pm standard deviation for the computed tomography scan evaluation of the abdominal wall defect and for the pre- and post-operative intra-abdominal pressure and volumes of abdomen

Category	Mean \pm SD	Minimum-maximum
Length (cm)	16.13 \pm 3.42	11-23
Width (cm)	17.21 \pm 2.72	12-22
Surface (cm ²)	218.4 \pm 64.7	104-361
ACV (cm ³)	8377 \pm 1721.15	5017-11,028
HSV (cm ³)	3775.3 \pm 745.16	2716-4903
PV (ACV + HSV) (cm ³)*	12,171.8 \pm 2079.07	8498-15,724
PV _{TAR} (cm ³)*	11,015.82 \pm 2233.5	7013-14,211
Preoperative IAP (mmHg)**	7.6 \pm 1.26	6-10
Postoperative IAP (mmHg)**	16.13 \pm 2.37	12-21
PI (IHV/PV)	0.3 \pm 0.05	0.22-0.4

*There is no difference between PV and PV_{TAR} (Student's *Mest*; *P*=0.809). **A significant difference exists between the values of the pre- and post-operative IAP (Student's *Mest*; *P*=0.004). SD: Standard deviation, HSV: Hemia sac volume, ACV: Abdominal cavity volume, PV: Peritoneal volume, TAR: Transversus abdominis release, IAP: Intra-abdominal pressure, PI: Peritoneal index, IHV: Incisional hernia volume

increased odds for higher values of width, area, ACV, HSV, and PV.

Table 3: The univariate analysis shows some significant correlations * for peritoneal index and postoperative intra-abdominal pressure

Parameter	PI (r, P)	Postoperative IAP (r, P)
Age	-0.07, 0.749	0.047, 0.833
Onset	0.033, 0.831	0.302, 0.161
Length	0.366, 0.086	0.388, 0.068
Width	0.072, 0.662	-0.179, 0.413
Area	0.219, 0.316	0.104, 0.637
ACV	-0.627, <0.01*	-0.502, 0.015*
HSV	0.490, 0.018*	0.366, 0.086
PV	-0.326, 0.129	-0.268, 0.216
PI	Reference	0.789, 0.001*
BMI	0.062, 0.779	0.067, 0.076
PV _{TAR}	-0.512, 0.012*	-0.437, 0.037*
Preoperative IAP	-0.809, <0.001*	-0.794, <0.0001*
Postoperative IAP	0.789, <0.001*	Reference

*Statistically significant. HSV: Hernia sac volume, ACV: Abdominal cavity volume, PV: Peritoneal volume, TAR: Transversus abdominis release, IAP: Intra-abdominal pressure, PI: Peritoneal index, BMI: Body mass index

Table 4: Multivariate logistic regression results

Variable	PI			Postoperative IAP		
	OR	95% CI	P	OR	95% CI	P
Age	0.07	0.00-0.01	0.117	1.14	0.49-2.59	0.858
Onset	1.93	1.19-2.80	0.022*	0.50	0.22-1.14	0.714
Length	0.6	0.27-1.70	0.071	1.21	0.49-2.99	0.642
Width	1.07	1.00-1.10	0.052*	1.01	1.00-1.08	0.054*
Area	1.04	0.99-1.07	0.055*	1.07	0.43-1.98	0.946
ACV	0.9	0.27-2.20	0.625	0.98	0.96-1.00	0.035*
HSV	2.81	1.69-3.72	0.004*	0.97	0.95-0.99	0.030*
PV	1.57	0.49-3.61	0.144	1.66	1.07-2.52	0.04*
BMI	1.52	0.56-3.43	0.479	1.11	0.64-1.87	0.201
Postoperative IAP	2.21	1.35-3.45	0.001*			
PV _{TAR}	0.97	0.95-0.99	0.01*	2.47	1.59-3.78	0.01*
PI				2.18	1.37-3.40	0.001*

*Significant difference. 95% CI: 95% confidence interval, OR: Odds ratio, HSV: Hernia sac volume, ACV: Abdominal cavity volume, PV: Peritoneal volume, TAR: Transversus abdominis release, IAP: Intra-abdominal pressure, PI: Peritoneal index, BMI: Body mass index

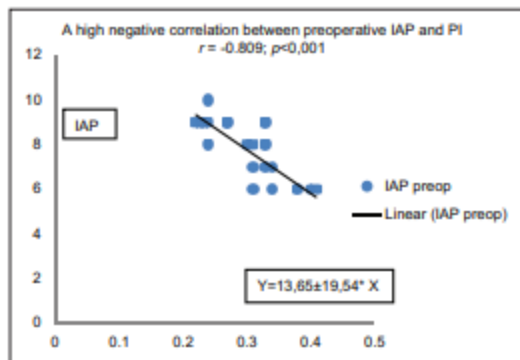


Figure 1: Correlation between preoperative intra-abdominal pressure and peritoneal index (x-axis represents the value of peritoneal index)

The mean postoperative PV increased to 11,015.82 ± 2,184.44 cm³ (ranges: 7,013–14,211 cm³). There was no statistic difference between preoperative PV and PV_{TAR} (Student's *t*-test: *P* = 0.076; *F*-test: *P* = 0.739).

The values of the abdominal wall compliance ranged between -133 and -18 cm³/mmHg with a mean value of -133.51 ± 69.51 cm³/mmHg. It was highly associated with IHV (odds ratio [OR] = 2.7; 95% confidence interval [CI] = 1.35–4.19; *P* = 0.019), and Δ*V* (OR = 4.28; 95% CI = 1.24–14.7; *P* = 0.0001).

Most of the PV_{TAR} values were close to the PI of 0.3. A high negative correlation between PI and PV_{TAR} was observed [Figure 2].

According to histogram distribution of the PI, 57% of the patients had values ranging between 0.3 and 0.34. Related to these values, we considered that a PI equal with 0.3 could be an arbitrary range to compare, so the patients were divided into two groups: Group 1 with PI between 0.2 and 0.29 (7 patients) and Group 2 with PI ≥ 0.3 (16 patients). Demographic characteristics were similar between groups [Table 5].

When the PV and PV_{TAR} were compared, a significant difference was recorded in group 2 (Student's *t*-test *P* = 0.041) and no difference in group 1 (*P* = 0.3). The difference between PV and PV_{TAR} (Δ*P* representing the necessary volume after TAR for completing PV) and the difference between pre- and postoperatively IAP was statistically significant between groups for both values [Table 5].

The compliance in the patients with PI larger than 0.3 was smaller than for the patients with PI < 0.3 and the difference was statistically significant (*P* = 0.0075). In the univariate analysis factors that influenced the compliance in patients with PI larger than 0.3 were postoperative IAP, Δ*V*, and Δ*P*. When multivariate

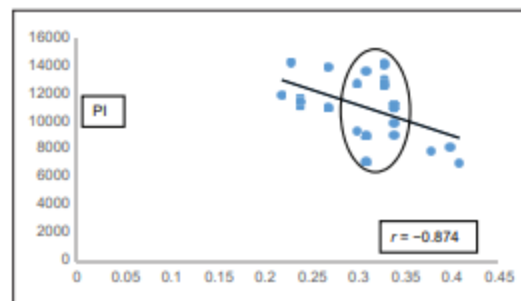


Figure 2: Correlation between PV_{TAR} and the peritoneal index. The critical value for PV_{TAR} is for a peritoneal index of 0.3. The equation of regression confirms the correlation (y = 1.14E + 1.85E3 * x) (x-axis represents the value of peritoneal index and y-axis the peritoneal volume after transversus abdominis release)

Table 5: Comparison of groups characteristics mean±standard deviation

Variable	Group 1 (7 patients) PI <0.3	Group 2 (16 patients) PI >0.3	P
Age (years)	67.0±5.42	63.0±8.76	NS
Occurrence (months)	51.8±28.2	66.6±40.8	NS
Length (cm)	14.57±3.7	16.81±3.16	0.00019
Width (cm)	16.57±2.69	17.5±2.78	NS
Surface (cm ²)	198.2±84.7	227.3±54.8	NS
ACV (cm ³)	9387.0±1057	7935.1±1792.6	NS
HSV (cm ³)	3138.2±401.4	4054.0±691.3	0.0004
PV (ACV + HSV) (cm ³)	12,525.2±1353.8	12,017.2±2350.0	NS
Preoperative IAP (mmHg)	9.0±0.5	7.0±0.9	0.0001
Postoperative IAP (mmHg)	13.5±1.2	17.25±1.8	0.009
ΔIAP (postoperative IAP-preoperative IAP) (cm H ₂ O)	4.71±1.38	10.25±2.51	<0.0001
C _{ab} (cm ³ /mmHg)	-79.64±46.86	-150.69±57.48	0.0075
MAP mmHg	91.85±4.05	87.06±5.96	NS
Preoperative APP (mmHg)	82.85±3.8	80.12±6.02	NS
Postoperative APP (mmHg)	76.85±4.7	69.81±6.42	0.0168
BMI (kg/m ²)	32	30	NS
PV _{TAR} (cm ³)	12,159.1±1322.4	10,516.6±1322.4	0.024
ΔV (PV-PV _{TAR}) (cm ³)	-366.1±242.9	-1485±446.6	<0.0001
24 h postoperative urinary output (ml)	1771.42±372.89	956.25±408.19	0.059
48 h postoperative urinary output (ml)	1836.16±287.3	1721.37±398.29	NS

NS: Statistically insignificant. ACV: Abdominal cavity volume, HSV: Hernia sac volume, PV: Peritoneal volume, IAP: Intra-abdominal pressure, BMI: Body mass index, APP: Abdominal perfusion pressure, MAP: Mean arterial pressure, TAR: Transversus abdominis release, C_{ab}: Abdominal compliance, PI: Peritoneal index

logistic was applied age, onset, length, width, area, ACV, PI, and preoperative IAP were added as risk factors for decreased compliance [Table 6].

The most decreased values of the C_{ab} were encountered in patients with PI >0.33. If the difference of the volumes to replace was larger than 1,000 ml the risk to have a postoperative IAP larger than 16 mmHg is ninefold increased compared with volumes smaller than 1000 ml (OR 9.00; 95% CI = 1.51–53.4; P = 0.0156).

The mean preoperative APP in group 1 was 82.85 ± 3.8 mmHg and in the Group 2, 80.12 ± 6.02 mmHg (P = 0.885). Mean values were decreased postoperatively in both groups and the difference was statistically significant (76.85 ± 4.7 mmHg vs. 69.81 ± 6.42 mmHg, P = 0.0168). APP was negatively highly correlated with the PI in patients of Group 2 for both univariate and multivariate logistic regression (r = -0.724, r² = 0.524, P = 0.002, OR = 4.84, 95% CI = 1.08–21.58, P = 0.038). The value of the PI has no influence on the APP in group 1 (OR = 1.00, 95% CI = 0.017–57.31, P = 1.00). In Group 2, 11 patients with PI larger than 0.33 developed APP lower than 70 mmHg compared with 5 with PI ranging between 0.3 and 0.33 who did not (OR 4.84, 95% CI = 1.08–21.58, P = 0.037) and the difference was statistically significant (χ² = 4.5, P = 0.02).

No difficulties to close the abdominal wall were encountered. The mean urinary output for 24 h from the end of the operation was decreased with an average

Table 6: Risk factors for decreased abdominal compliance

Variable	OR	95% CI	P
Onset	5.11	1.83-13.7	0.014
Age	4.5	1.27-15.9	0.035
Length	8.27	1.68-32.6	0.017
Width	10.93	1.87-63.97	0.013
Area	10.87	1.71-60.83	0.013
ACV	9.0	1.51-53.4	0.029
PI	4.28	1.24-14.7	0.019
Preoperative IAP	2.76	1.16-9.73	0.035

When PI is >0.33, the risk for decreasing of C_{ab} increase by 5 fold (OR=4.78; 95% CI=1.77-12.63; P=0.028). IAP: Intra-abdominal pressure, OR: Odds ratio, CI: Confidence interval, C_{ab}: Abdominal compliance, PI: Peritoneal index, ACV: Abdominal cavity volume

of 815 ml for patients with PI ≥0.3 (P = 0.0002). For the patients of Group 2, the 24-h urinary output was strongly influenced by the PI, postoperative IAP, and postoperative APP in both univariate and multivariate analysis [Table 5]. After 48 h no difference was found between groups (P = 0.813).

Discussion

IH remains an unfortunate event for many patients after laparotomy. With an increasing incidence ranging from 10% to 63% in high-risk patients, IH is the most common complication after abdominal surgery.^{1,2} Despite a large amount of innovation in surgical techniques and technologies, prosthetic materials and more insides into the mechanisms of IH, the short-and long-term

outcomes remain poor. Obesity, smoking, and aging population with multiple associated comorbidities are the main factors contributing to the increased incidence and unsatisfactory results of such repairs.^[11]

A large number of IH are complicated cases, which include large defects or even LOD. The European Hernia society defines LIH as defects with a width >10 cm.^[4] For LOD no acceptable definition exists yet. In a recent systematic review, Parker *et al.* reported six different definitions for "LOD" which vary and are not interchangeable.^[16] They concluded that expert consensus is necessary to standardize this important concept for hernia surgeons, but the best definition is probably a volumetric one. In our study, LOD was considered a chronic large irreducible hernia with a large defect and a large sac in which a significant portion of the abdominal viscera is residing outside the abdominal cavity.

Historically, physical examination was considered acceptable for diagnosing LIH, but nowadays clinical diagnosis alone may result in an inappropriate surgical management. CT is recommended as the standard procedure not only for diagnosis but also for abdominal wall evaluation and for the selection of repair method.^[17,18] This statement is also the conclusion of our study because postoperative IAP is correlated with almost all CT scan evaluated parameters.

However, a recent systematic review suggested that out of 158 studies (31 randomized controlled trials, 32 cohort studies, and 95 retrospective studies with 31,874 patients), only 12% used preoperative imaging for IH characterization.^[19] According to this report, only 511 patients (2%) benefit from a CT scan evaluation. Furthermore, in most studies reporting imaging technique use, not all patients had benefit of it (only 4% used it for all subjects preoperatively).

CT scan is mandatory for labeling protocol of the abdominal wall^[20] but also for the volumetric evaluation of the IH and abdominal cavity, especially when there is a large difference between the abdominal cavity and content (hernia volume that needs to be restored).^[12]

The physiologic function of transversus abdominis muscle is the main target during posterior component separation. It is viewed as the "corset" which maintains the IAP and provides hoop tension through the thoracolumbar fascia.^[14,15,17] The subsequent mobilization of the underlying fascia after its release removes the "tone" of the lateral wall resulting in a larger expansion of the abdominal girth with medial advancement of the rectus complex, especially in patients with wide abdominal defects.^[17]

The impact of TAR has been little studied and only related to core function.^[9,10] To our knowledge, there is no study on the capability of TAR to increase the abdominal capacity without or with minimal consequences upon normal physiology. According to Majumder *et al.*, on a cadaveric study, after a complete TAR with large retro-muscular dissection, an average advancement of 10 cm for the anterior fascia and of 11 cm for the posterior fascia on each side was obtained.^[21] This can provide a significant increase of the abdominal cavity inner diameters and subsequently an increase of the whole visceral sac volume. Our data confirmed these increases since there was no statistical difference between preoperative values of the PV and after TAR volumes (PV_{TAR}) ($P = 0.076$). This mean global increase of the PV_{TAR} compared to PV is strictly dependent on the ACV ($r_{Pearson} = 0.93$) and less on HSV ($r_{Pearson} = 0.654$). These results are in line with the negative correlation between PV_{TAR} and PI ($r_{Pearson} = -0.51$), which indicates that the higher the index the smaller the volume increased. As can be seen from Figure 3, the smallest increase of the volumes occurs at a PI of 0.3. When the patients were divided into two groups according to PI, the increase of the volumes after TAR was smaller and inadequate for patients with $PI \geq 0.3$, and the difference was significant ($P = 0.002$). The necessary volume to reach preoperative PV was larger for patients with $PI \geq 0.3$ [Table 4].

Myofascial release of the transversus abdominis muscle can generate elevated IAP immediately following repair, clearly demonstrated by our results. All our patients developed IAH to varying degrees: Grade 1 (12–15 mmHg) – 8 patients, Grade 2 (16–20 mmHg) – 13 patients and Grade 3 (21–25 mmHg) – 2 patients. No values larger than 15 mmHg were recorded in patients with PI smaller than 0.3. These elevated IAP could be considered permissible due to the fact that no organ dysfunction, except for some reversible decrease of the urinary output, were recorded. Probably maintaining of the APP above the critical value of 60 mmHg was an important contributing factor to the positive outcomes of the patients. In these conditions, it can be suggested that IAH or abdominal compartment syndrome (ACS) immediately after an elective abdominal wall reconstruction creates a clinical aspect that must be distinguished from the settings in which they were originally described. The fact that IAH decreased after 24 h postsurgery and the urinary output returned to physiologic values does not guarantee that this is the normal outcome for all the patients. As there are still no preoperative factors to suggest the irreversible evolution towards ACS, we can consider that $PI \geq 0.33$ may be the threshold from which to associate the preoperative augmentation of the abdominal wall with PPP and/or Botulin Toxin B.

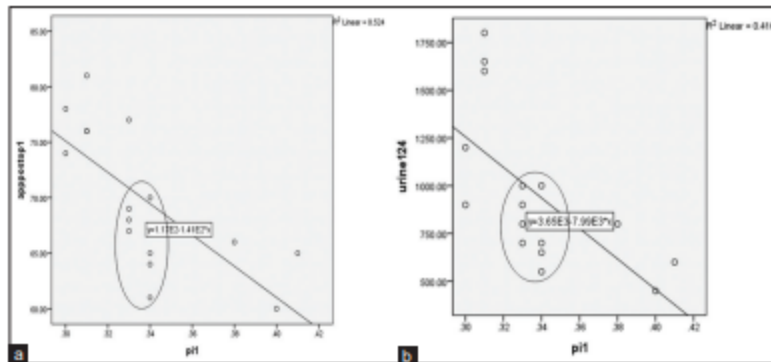


Figure 3: The decrease of the abdominal perfusion pressure (app postop) (a) and of the 24 h postoperative urinary output (urine 124) (b) is strongly correlated with a peritoneal index of 0.34

The assertion is based on the fact that 15 of the patients with PI over 0.3 developed intrabdominal hypertension of grade 2 and 3 compared with those with PI <0.3 where no such values were recorded (OR 155; 95% CI = 5.61–4275.69; $P = 0.0029$). More than that, when PI was larger than 0.33, the most decreased urine output and APP were recorded [Figure 3].

Abdominal compliance (C_{ab}) is a measure of the ease of abdominal expansion and it is determined by the elasticity of the abdominal wall and diaphragm.^[22] It should be expressed as the change in intraabdominal volume per change in IAP. C_{ab} plays a key role in the understanding of deleterious effects of un-adapted IAV on IAP and end-organ perfusion, although at present, it is one of the most neglected parameters in abdominal wall reconstruction. Correct measurement of C_{ab} together with the identification of patients at risk for poor C_{ab} will help avoiding progression from normal IAP to IAH to ACS and its associated complications [Table 7].

There are a lot of ways to determine C_{ab} but no one is perfect.^[23] In our study, we considered that the membrane of the abdomen responds to the linearity of Young.^[22] This means that a variation in the IAV implies a proportional variation in the IAP exerted by the membrane. This can be expressed with the formula $\Delta P = k\Delta V$ where k is a constant of the elastance of the abdomen or the reciprocal of the compliance $k = 1/C_{ab}$. Replacing k in the formula results that C_{ab} is the ratio between ΔV and ΔP .

Factors determining the reshaping properties of the abdominal wall and diaphragm are not well understood, but the mechanical properties are related to C_{ab} . The stretching capacity is influenced by several factors related to demographics and anthropomorphy, comorbidities, and related to the abdominal wall and diaphragm^[22] [Table 7]. In our study demographic factors that influenced C_{ab} were age (decreased in younger

Table 7: Risk factors associated with decreased abdominal compliance (modified after malbrain)

Related to anthropomorphy and demographics

- Male gender
- Old age
- Obesity
- Android composition
- Increased visceral fat
- Waist to hip ratio >1
- Short stature

Related to abdominal wall and diaphragm

- Umbilical IH repair
- Muscle contractions (pain)
- Edema of the abdominal wall
- Abdominal/thoracic circular burns
- COPD emphysema

Related to comorbidities

- Fluid overload
- Tense ascites

Hepato/splemomegaly

IH: Incisional hernia, COPD: Chronic obstructive pulmonary disease

patients), sex (decreased in males), and onset (the longer the evolution the lower compliance). The anatomy of the defect also influenced the values of the compliance which was directly related to the width, length, area, ACV, HSV, PI, and preoperative IAP. This seems logical as the long evolution of LIH leads to lateral retraction of the muscles, with increasing of the defect size and increasing of the HSV. Muscular fibrosis due to suboptimal muscle function and chronic contracture induced by chronic low back pain are factors that influence abdominal wall compliance and must be considered for outcome evaluation.

All these data suggest that TAR is capable to recreate PV without or with minimal disturbances only in patients with $PI \leq 0.33$. We can consider that when PI is >0.33, a local augmentation of the abdominal wall needs to be

evaluated. This is also the conclusion of Sabbagh *et al.* who demonstrated that a PI <0.2 was predictive for tension-free fascia closure; values >0.2 need optimization with PPP.^[23] In Sabbagh's study, no patient was operated by TAR approach. La Meir *et al.* suggest that a high IHV/PV ratio is an indication for PPP, but they did not quantify the parameter.^[24] Tanaka *et al.* reported for the first time the use of PVs to determine the extent of PPP and arbitrarily applied a threshold of 0.25, but no patient was operated by TAR.^[12]

Our data suggest that a PI ranging from 0.3 to 0.35 could be a reasonable threshold for PPP in association with TAR for LIH. Values >0.35 can be optimized by Botulin Toxin B in association with PPP. The PPP has many favorable effects in preventing severe complications after abdominal wall reconstruction. By gradual increase of the IAP, it also increases the tolerance to IHV return during surgery.^[25] Abdominal muscles are gradually expended and have a contribution to the global increase of the visceral sac volume.^[26] Elevation of the diaphragm (even with 10 cm) increases the ACV and contributes in improving the pre and postoperatively respiratory function.^[27] Some studies report a reduction in the postoperative surgical site infections due to a massive input of peritoneal neutrophils, and a reduction of the postoperative hospitalization.^[28] Pneumatic dissection of visceral bands and adhesions, which facilitates the reinsertion of intestinal loops into the abdominal cavity is another benefit of the PPP.^[27]

Regarding the Botulin toxin, this is a patent neuromodulator agent produced by *Clostridium botulinum* which specifically binds the receptors of the neuromuscular plate and inhibits the release of acetylcholine. The result is a flaccid paralysis of the muscle being it smooth or striate.^[29] The toxin requires 24–72 h to take effect, and the maximum paralysis is achieved usually after 4–6 weeks postinjection. The flaccid paralysis is reversible after 4–6 months. All the benefits of Botulin toxin were described in several studies and are listed in Table 8.^[29-32]

The association between PPP and Botulin B toxin is a complementary tool of the surgical procedure and facilitates the integral management of the patients

Table 8: The documented advantages of the Botulin toxin in augmentation of the abdominal wall

Lateral muscle relaxation - mass reduction
Reduce lateral physiologic forces - reduce defect
Reduce tension at closure - decreased IAP
Ensure suture line protection - low recurrence rate
Increase muscle length, decrease lateral muscle thickness
Increase transversal length of the abdominal wall
Primary fascial closure in up to 85%
Decrease pain

IAP: Intra-abdominal pressure

with loss of abdominal domain. Buenno-Lledó *et al.* are the first who reported a large series of LIH and LOD preoperatively prepared with the combination of PPP and Botulinum A toxin after a protocol in which a PI >0.2 (20%) was used in patients enrolled for such optimization.^[32] The reconstruction technique involved an anterior component separation with an on-lay mesh with complete fascial closure in all patients. Some other studies report similar results but further research is still necessary in order to identify the threshold for this indication.^[29-33]

Our study has several limitations. First, it was performed in a single institution and the applicability of these results should be validated. Second, the number of enrolled patients was limited and a high number of exclusion criteria could be a source of bias, but nonparametric analysis shows a modal distribution for almost all variables except for pain. Further multi-centric studies are necessary. Third, a bias can result from the method of calculation, but because it was done in the same conditions and by the same person, this can be excluded. Measuring the volumes with a software could offer more precise data. Another bias can result from the IAP evaluation. The indirect measurement is being not the most precise method of detection. This can be eliminated because the determination has been done by the same investigator and in the same conditions.

Conclusions

To our knowledge, this is the first report examining the efficacy of TAR in recreating the normal PVs. The procedure is strongly effective when the PI (IHV over PV) is <0.3. In these circumstances, the repair increases PV without any disturbances. When the PI is >0.33, the increased IAP resulted from the repair, even it was transient and resilient, can discuss the augmentation of the abdominal wall as an option. Further studies are needed to establish a threshold for PPP and the combination between PPP and Botulinum toxin as a sure indication for abdominal wall augmentation in order to prevent severe outcomes.

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Conflicts of interest

There are no conflicts of interest.

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Truncal function after abdominal wall reconstruction via transversus abdominis muscle release (TAR) for large incisional hernias: a prospective case–control study

V. Oprea¹ · M. Toma¹ · O. Grad^{1,2} · A. Pavel³ · C. Molnar⁴

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Abstract

Background Data about abdominal wall function in patients with incisional hernias (IH) are limited. Abdominal Wall Reconstruction (AWR) could be beneficial for the improvement of this function. The goal of the study was to evaluate if the abdominal wall function was restored after transversus abdominis muscle release (TAR).

Methods We performed a prospective case–control study of 59 patients with IH equal or larger than 10 cm in their width undergoing AWR via TAR with mesh reinforcement and complete linea alba restoration. With two simple physical tests—Trunk Raising (TR) and Double Leg Lowering (DLL), we clinically assessed, preoperatively, 1 month and 1 year postoperatively the functionality of the abdominal wall (flexion). Patients were compared with a control group ($n = 57$) with an intact abdominal wall undergoing visceral surgery through a midline laparotomy.

Results There were no differences between the groups in terms of sex and mean age. In the study group, TR demonstrated an increase from 1.93 preoperatively to 2.44 at 1 month and 4.27, respectively, at 1 year postoperatively ($p < 0.001$). DLL was improved from 2.067 to 4.37 at 1 year postoperatively ($p = 0.016$). In the control group, surgery resulted in a decrease of truncal flexion. At 1 year postoperatively, the abdominal wall function for study group patients was almost identical with that the functionality of the control group featuring an intact abdominal wall (TR 4.26 vs 4.33 $p = 0.532$; DLL 4.42 vs 4.21 $p = 0.193$).

Conclusion AWR via TAR for large IH specifically improved long-term abdominal wall muscular function.

Keywords truncal function · complex incisional hernia · transversus muscle release

Background

Nowadays, we are faced with an increased incidence of incisional hernias (IH) which can range between studies from nine to over 50% in high-risk patients [1]. There is also an increased rate of complex IH most of them featuring large defects or loss of domain, which can lead to a profound alteration of the anatomy and function of the abdominal wall [2]. The absence of linea alba affects the structural integrity and mechanical strength of the trunk secondary to the lateral muscular retraction and outside protrusion of the viscera. One of the goals of the abdominal wall reconstruction (AWR) is to restore the native anatomy by reconstruction of the linea alba at the midline of the abdominal wall. Although restoring the normal anatomy presumably restores its native function, this relationship has not yet been fully elucidated.

The major limitation in studying muscle functionality is finding the optimal method and parameter to represent it.

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✉ V. Oprea
opreacv31@gmail.com

¹ Clinical Department of Surgery, “Constantin Papilian” Emergency Clinical Military Hospital, Nr 22 GralTraianMosoiu street, 3400 Cluj-Napoca, Romania

² Second Department of Surgery, Iuliu Hatieganu” University of Medicine and Pharmacy, Cluj-Napoca, Romania

³ Clinical Department of Imagistic and Radiology, “Constantin Papilian” Emergency Clinical Military Hospital, Cluj-Napoca, Romania

⁴ 1St Clinical Department of Surgery, Targu Mures University of Medicine and Pharmacy, Targu Mures, Romania

Dynamometry has been established as a reliable and effective method for muscle force and power evaluation, but it is expensive, technology dependent, not available in daily practice, and studies are limited by the small number of patients included [3–5]. We believe that for an ideal abdominal wall functional evaluation, the clinical assessment as a routine tool should be considered. The main goal of the study was the prospective, clinical assessment of the level of impairment of the abdominal wall muscle function before and after AWR via a transversus abdominis muscle release (TAR) in patients with large incisional hernias (LIH). Rectus Abdominis Muscle being the main effectors of the abdominal wall function (AWF), especially flexion, we focused the evaluation on this muscle. The second goal was to evaluate the factors influencing the AWF in patients with large incisional hernias.

Patients and methods

Patients

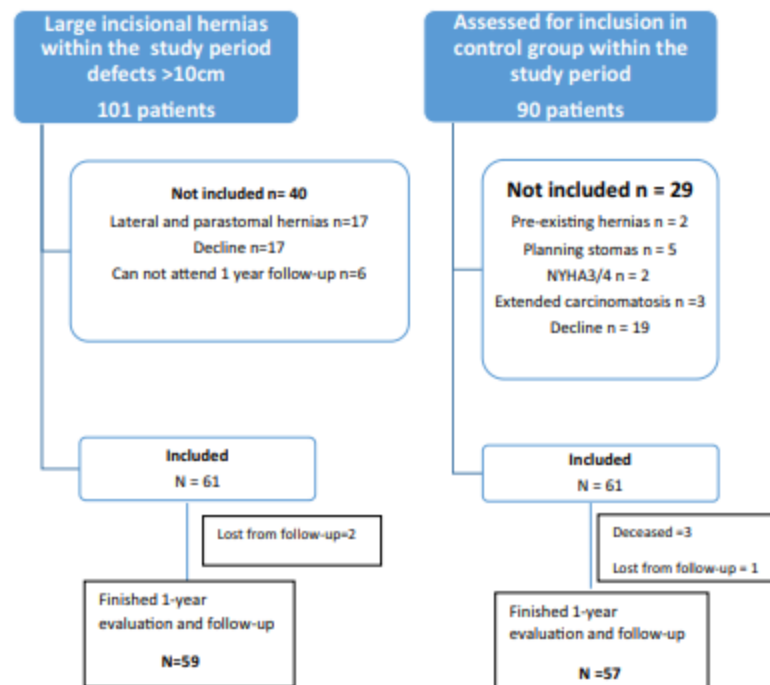
All patients with midline IH with a width of the defect larger than 10 cm admitted in the Clinical Surgery Department of the Military Emergency Clinical “Constantin Papilian”

Hospital were included in this prospective controlled study, registered as the “study group”. Inclusion criteria were age over 18 years, American Society of Anesthesiologist (ASA) score less than four, and complete anterior fascial closure (Fig. 1). To assess the functionality of an intact abdominal wall, a “control group” of patients undergoing colorectal surgery through a midline laparotomy was also included. The Local Ethic Committee under AWF 29/October 13, 2015 approved the study. Baseline demographics (age, gender, Body Mass Index—BMI) and incisional hernia characteristics (evaluated by a native abdomino-pelvic CT scan) were included. The written informed consent from each patient was obtained.

CT protocol investigation

A native abdomino-pelvic CT scan was performed preoperatively in all patients. The surgeon and a radiologist reviewed all preoperative CT scans. We removed all inconsistencies of the measurements after the cross review. Both surgeon and radiologist carefully identified and measured the length and the width of the defects in their maximal dimensions. The defect was equated with an ellipse and the area of the defect was calculated using the formula $\frac{1}{2} \text{length} \times \frac{1}{2} \text{width} \times \pi$. The values were rounded to the nearest hundred or

Fig. 1 Diagram of criteria for inclusion and exclusion from the study



thousand. We also measured the width of both rectus sheath (RW). The ratio between of their sum and the width of the defect (DW) was the basis for TAR indication (Carbonell's equation). According to the Tanaka method, the volume of the abdominal cavity (ACV) and of the incisional hernia sac (IHV) are calculated [6]. By adding up ACV and IHV, we obtained the volume of the peritoneal cavity (PV). The ratio of IHV and PV provide the peritoneal index (Sabbagh Index) as measurement of loos of domain [7]. A 25% cut-off of the Sabbagh index was considered for loss of domain as arbitrary limit in our clinic. All the values were manually collected for lack of computer software; differences of more than $\pm 10\%$ between surgeon and radiologist's measurements were reassessed until the agreement was reached.

Surgical procedure

The indication for TAR was established preoperatively using the formula $2RW: DW = 2:1$, where RW was the width of the rectus sheath and DW is the width of the defect measured, both, on CT scan. All the procedures were performed under general anesthesia according to the technique described by Novitsky [8]. A slowly absorbable monofilament-running suture (2-0 polydioxanone) was used to close the posterior fascia. We fixed the mesh with slowly absorbable transfascial sutures (0 polydioxanone) or with cyanoacrylate (Histocryl® B Braun). A slowly absorbable running suture (1 polydioxanone) closed the anterior fascia. Medium weight macroporous monofilamented polypropylene mesh (with the area five-fold larger than defect area) reinforced the abdominal wall in all circumstances.

AWF evaluation [9]

All measurements were performed by a team of two examiners (OV and MT), each one performing both evaluations. For the purpose of the study, we recorded the mean of the values. A 10-minute break was a regular time interval between each procedure. Subjects wore shorts and took off their shoes to avoid additional external loads.

Double leg lowering (DLL)

The subject lays supine on a firm examination table with arms crossed over the chest and the head resting on the examination table. The examiner places their fingertips under the lower back of the subject. The test began with the examiner assisting the subject to hold their feet upright, with their knees extended to the terminal range until a 90° angle appears between the torso and the thighs. Each subject was instructed to keep the pelvis rotated posteriorly so, that the lumbar spine was held firmly to the table,

while slowly lowering the legs in a horizontal position. The subject aims to support the pressure on the tester's fingers under the lower back by contracting the abdominal muscles as the legs were lowered. The subject slowly lowers both legs until the pressure on the back hand disappears. The lowest angle observed as the pressure is taking off, is the measurement of their abdominal strength. The score is the angle of the legs in degrees to the plane of the table as follows:

- Over 41 degrees—**normal** = 5 points
- Between 31 and 40 degrees—**good** = 4 points
- Between 21 and 30 degrees—**fair** = 3 points
- Between 11 and 20 degrees—**poor** = 2 points
- Between 0 and 10 degrees—**trace** = 1 point

Trunk raising

The subject is lying supine on the table with hip flexion at 45 degrees and 90 degrees for the knee. The patient raises his/her trunk and holds it up for 20". The results depend on the arm position the patient uses to elevate scapulae:

- Hands behind the neck, scapulae clearing the table, 20-s hold—**normal** = 5 points
- Arms crossed over chest, scapulae clearing the table, 20-s hold—**good** = 4 points
- Arms straight, scapulae clearing the table, 10-s hold—**fair** = 3 points
- Arms extended toward knees, top of scapulae lifting from the table—**poor** = 2 points
- Inability to raise more than head off the table—**trace** = 1 point

The obtained scores can be combined and the composite or total score (TS), representing the value of the AWF, is evaluated (Table 1).

The examination was performed preoperatively, then 1 month, and 1 year postoperatively for each patient by the same examiners.

Statistical analysis

According to Bland and Altman, we perform an intra-class coefficient ($ICC_{3,1}$) to estimate intra-tester reliability for repeated measures. Reliability values were 0.99–0.75 as

Table 1 The evaluation of the composite/total score (TS) resulting from the sum of the values of TR and DLL

TRACE	1–2 points
POOR	3–4 points
FAIR	5–6 points
GOOD	7–8 points
NORMAL	9–10 points

excellent, 0.40–0.75 for fair to good, and < 0.40 for poor results. [10].

The data were tabulated as mean \pm standard deviation (SD). Continuous variables were analyzed by ANOVA variance test and followed by unpaired two tails Student's *t* test with unequal variance; the binary outcomes were evaluated with the χ^2 (chi square) test. Pearson correlation (*r*) was used with the regression equation. We set univariate and multivariate logistic regression models with factors of interest that could influence AWF, adjusting for identified confounders. The following variables of interest were included for adjustment: age, rank of recurrence, BMI, length, width and area of the defect, ACV, IHV, PV, length of the rectus sheath. Multivariate models were calculated with the linear logistic regression and the results were displayed with the Odd's ratio (OR) and the 95% confidence interval (CI). Probabilities smaller than 0.05 are considered statistically significant. SPSS statistic version 23.0, 2018 (Chicago, Ill) was used to perform statistical analysis.

Results

Between November 2014 and February 2019, we included in the study and prospectively evaluated the abdominal wall function of 101 patients with large IH (defects larger than 10 cm width). During the same period, they were compared with a control group of 90 patients with healthy abdominal wall operated for colorectal carcinomas. Finally, we enrolled 59 patients as the study group and 57 as the control group

who completed the examination at 1 year postoperatively (Fig. 1). There was no significant difference between the demographics of the groups in terms of age, gender, ASA score, comorbidities, and BMI (Table 2). Details of the CT scan for the study group are also shown in Table 2. There was a significant difference between the width of the rectus sheaths in the study group compared to control (7.61 ± 1.32 vs 11.4 ± 2.07 cm; $p < 0.001$).

In the study group, 10 patients had recurrent incisional hernias in various ranks, ranging from I to 5. The onset of symptoms varied between 12 and 148 months, mean 48.52 ± 24.01 .

There was a very good test–retest correlation for both TR ($ICC_{3,1} = 0.91$, $p < 0.001$) and DLL ($ICC_{3,1} = 0.94$, $p < 0.001$). In control individuals, we observe a similar degree of reliability. Bland and Altman graphs revealed that no systemic bias was present, zero being included in 95% CI (data not shown).

Patients in the study group

DLL: preoperatively the mean value for DLL was 2.1 ± 0.75 (1–3) (Table 3).

In univariate analysis, the main factors correlating with poor abdominal wall function for DLL were the width of the defect, the area of the defect, the RSW and the TAR index. When multivariate logistic regression adjusted for this cofounders was applied the only factor that negatively influenced AWF was the width of the defect (OR 2.90; 95% CI 1.32 – 6.38 $p = 0.008$). At one month after the abdominal

Table 2 No difference between demographic characteristics of the study and control group

Variable	Study group <i>N</i> = 59	Control group <i>N</i> = 57	<i>p</i>
Age (years) ^a	63.0 \pm 6.53 (41–78)	63.8 \pm 7.34 (43–79)	0.469
Gender	M = 32/ F = 27	M = 34/ F = 23	0.5
ASA score	2–49 patients 3–10 patients	2–42 patients 3–15 patients	0.391
BMI (Kg/m ²)	32.0 \pm 4.33 (25–48)	31.8 \pm 4.2 (25–48)	0.5
Global associated comorbidities	29 patients	31 patients	0.5
Length (cm) ^a	18.16 \pm 4.00 (11–28)	–	–
Width (cm) ^a	16.83 \pm 3.48 (11–28)	–	–
Area (cm ²) ^a	242.72 \pm 85.61 (104–528)	–	–
Abdominal Cavity Volume (cm ³) (ACV) ^a	9214.81 \pm 1379.41 (6683–12,138)	–	–
Hernia Sac Volume (cm ³) (HSV) ^a	4151.62 \pm 855.63 (2017–5983)	–	–
Peritoneal Volume (cm ³) (PV = ACV + HSV) ^a	13,345.00 \pm 2039.24 (8700–18,121)	–	–
Sabbagh Index (HSV/PV) ^a	0.3 \pm 0.036 (0.23–0.39)	–	–
TAR index (width/2xRSW sum) ^a	2.23 \pm 0.4 (1.44–3.20)	–	–
Rectus sheaths width sum (RSW) (cm) ^a	7.61 \pm 1.32 (5–10)	11.4 \pm 2.07 (9–15)	< 0.001

ASA score American society of anesthesiologists score; BMI body mass index

^aData of CT scan anatomy of the patients with LIH expressed as mean \pm standard deviation (SD); in brackets minimal and maximal range values

Table 3 Comparable values for DLL and TR according to the moment of clinical functional evaluation

	Double leg lowering (DLL)		Trunk raising (TR)	
	Study group (N=59)	Control group (N=57)	Study group (N=59)	Control group (N=57)
Preoperatively	2.1 ± 0.75 (1–3)	4.33 ± 0.54 (3–5)	1.98 ± 0.7 (1–3)	4.31 ± 0.53 (3–5)
1 month	2.45 ± 0.75 (1–4)	1.85 ± 0.54 (1–3)	2.44 ± 0.81 (1–4)	1.74 ± 0.5 (1–3)
1 year	4.37 ± 0.64 (3–5)	3.9 ± 0.61 (3–5)	4.27 ± 0.66 (3–5)	3.98 ± 0.56 (3–5)

Data expressed as means ± standard deviation (SD). In brackets minimal and maximal values

wall reconstruction, DLL increased to a mean of 2.45 ± 0.75 (range 1–4) (statistically insignificant— $p=0.31$ comparing with the preoperative recorded value). The increase was significantly statistic at 1 year postoperatively when DLL record a value of 4.37 ± 0.64 (range 3–5) ($p=0.0017$ comparing with preoperative value and $p=0.004$ comparing with 1 month value). At the end of the study, 53 patients (out of 59) were recorded with *good* or *normal* abdominal wall functionality; the difference with the preoperative figures is significant ($\chi^2=11.71$; $p=0.0011$).

TR: preoperatively had recorded mean values of 1.98 ± 0.7 (range 1–3) and no patient developed normal range values for this test. Similar to DLL, in univariate analysis, the main factors correlating with poor abdominal function for DLL were the defect width and area, the RSW and the TAR index. When multivariate logistic regression adjusted for this cofounders was applied the only factor that negatively influenced AWF was the width of the defect (OR 13.1; 95%CI 7.76–22.27; $p=0.0007$). There was an insignificant increase of TR values at 1 month postoperatively (mean 2.44 ± 0.81 ; $p=0.071$) and a significant one at 1 year postoperatively (4.27 ± 1.33 ; $p=0.002$) (Table 3).

Preoperative total score (TS) values ranged from 2 to 6, with a mean value of 4.00 ± 1.33 . According to these recorded values, 38 patients (65%) show *trace* and *poor* abdominal function; these values improved significantly one year after abdominal wall reconstruction to 8.73 ± 0.9 ; $p<0.001$) (Fig. 2). At all, after reconstruction, 37 patients regained normal function (63%), 21 patients returned to good function (36%), and one patient was with fair function. There was no correlation of the preoperative total score with age ($r=-0.180$; $p=0.173$); patients younger than 60 years (13–22%) developed the same dysfunctionality of the abdominal wall like the older than 60 (4.11 ± 0.22 vs 3.98 ± 0.4 , $p=0.44$). However, gender, onset of symptoms, and recurrence rate were not correlated with the degree of abdominal functionality.

Patients in the control group

No abdominal wall dysfunction was observed at the preoperative assessment for both DLL and TR (Table 3). Total scores revealed *good* or *normal* function in all patients. At

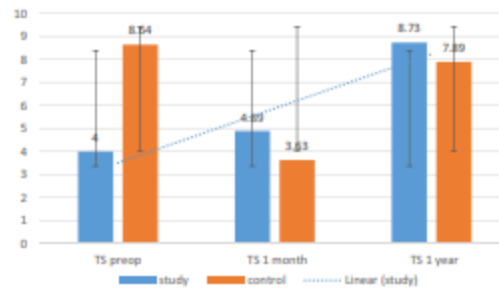


Fig. 2 The evolution of the total score in the study and control group according to the moment of functional evaluation. Data represented as mean and standard deviation (SD). Note the ascendant value of the TS for the study group (dotted line). The difference was significant between values at all moments of evaluation (*t*-Student $p<0.0001$ for preoperatively, 1-month and 1-year comparisons). Despite better preoperative function, patients from control group recovered worse at 1 year postoperatively than study group

1 month evaluation, both DLL and TR registered decreased values that were partially recovered after 1 year postoperatively; the difference was statistically significant for all values and for Total Score (8.64 ± 0.85 vs 7.89 ± 0.95 ; $p<0.001$). After the first postoperative year only 12 patients achieved *normal* abdominal function compared to 29 (51%) before surgery ($\chi^2=14.37$; $p=0.004$); 41 were with *good* function compared to 28 ($\chi^2=19.5$; $p=0.0019$). Four of them remained with a level of *fair* functionality.

Study group vs control group

Preoperatively, patients who underwent abdominal wall reconstruction had lower preoperative abdominal wall functionality compared to patients with oncologic surgery ($p<0.0001$). Both DLL and TR showed statistically significant difference in favor of controls. All patients in the control group showed *normal* or *good* function; while in the study group, no patient recorded values for normal functionality (Table 3).

At 1-month postoperative follow-up, a significant difference for DLL and TR is recorded in favor of the patients from the study group (2.45 ± 0.75 vs 1.85 ± 0.54 $p<0.0001$,

respectively, 2.44 ± 0.81 vs 1.74 ± 0.53 $p < 0.0001$). Mean value for total score (TS) at 1 year postoperatively was significantly increased in patients who underwent IH repair and the difference was significant ($p < 0.001$) (Fig. 2).

A number of 58 patients from the study group developed good or normal function compared to 53 from the study group ($\chi^2 = 6.2$; $p = 0.041$). When the ratio between postoperative and preoperative TS is evaluated, a mean increase of over 200% in AWF is recorded for the study group patients (2.43 ± 0.93); on the other side, patients from the control group recovered only 90% of their initial functionality (24 patients recover or exceeded their initial function) (0.91 ± 0.93). The difference was significant (*t*-Student $p < 0.0001$).

Discussion

Large incisional hernia (LIH) is a complex biological and surgical burden, which can lead to profound alterations in the anatomy and function of the abdominal wall (AW) due to the loss of medial tendinous insertion (linea alba) and lateralization of the rectus abdominis muscle complex [4]. This fascial separation leads to abdominal muscle shortening and relative unloading particularly of the lateral muscles whose insertions are lost and are associated with reversible pathological changes (disuse atrophy, decrease in muscle fiber size, shift in muscle type distribution, and alterations of muscle mechanical properties) [11–13].

Besides causing pain, risk of severe complications (bowel obstruction), and poor cosmesis, LIH negatively affects daily activities and quality of life [14]. One of the important roles of the abdominal wall muscles is to provide the trunk stability and postural support during limb movement.

The evaluation of abdominal wall functionality (AWF) seems to be an important measure for assessment of the outcomes of different techniques of surgical repair but objective measurements are difficult to be obtained for the current practice (expensive, technology dependent, difficult exploration). AWF needs to be proved other way than assessment of recurrence rates, quality of life scores, and/or patient questionnaires. One of the major barriers in studying muscle functionality is choosing the optimal method and parameter to represent it [4, 14].

Dynamometry has been established as a reliable and effective method to evaluate AWF both with static and dynamic work [4, 14]. Validation studies in patients without incisional hernia or loss of domain have been performed but the data from incisional hernia patients are scarce and the number of investigated patients is too small to have sound conclusions. More important, most of the results are from the same centers or investigators [3, 5, 15, 16]. Despite offering an objective approach with less subjective interpretations

bias, the method is highly expensive and has limited flexibility for conducting tests in other locations.

We decide to use clinical tests because they were validated in a recent study [17]. Even so the clinical tests may not be accurate enough and considered inferior, they were also validated in our study (excellent interclass reliability), were mostly without costs, easy to apply, easily accepted and performed by the patients. This is the reason we considered them an adequate instrument for evaluating patients with LIH and not only. We demonstrated a severe alteration of the abdominal wall muscle function in patients with LIH; our regression model indicated that width of the defect was the only significant predictor for poor performance. These results are in accordance with the study of Strigård K et al who demonstrated with dynamometric evaluation a decrease of functionality in patients with hernias larger than 10 cm wide [3]. As the area of the defect increases, there is a proportional decrease in the AWF; patients with defects ranging from 10 to 13 cm width have altered but better AWF comparing to patients with defects larger than 13 cm and the difference was significant. There is such a strong correlation that it seems safe to conclude that the width of the defect is the most important determinant for the degree of lost function.

We also demonstrated an almost full recovery of the AWF after abdominal wall reconstruction (AWR) via posterior component separation with transversus abdominis muscle release (TAR) and this improvement is superior to the control group patients. A greater isokinetic strength was obtained by denHartog et al after re-approximation of the linea alba comparing with IPOM [15]. All these, demonstrates that abdominal wall functions better with the muscles brought together. We do not have a valid explanation as to why we do not find no correlation with age and gender. Even if we split the patients in age and gender related subgroups, the differences in the values of AWF were not statistically significant. The literature has controversial studies, with and without these differences but data cannot be extrapolated because the results were from healthy patients' not IH patients [18–20].

The inferior results in the control group were similar with Jensen's study but there is no explanation for such results [5]. Probably, the presence of mesh is a sound support for an effective collagen deposition. In addition, we can hypothesize that there is an alteration in extracellular matrix formation and/or remodeling during wound healing, induced by the oncologic disease.

The clinical strength tests used in this study rely on resistance provided by the gravitational forces associated with the head, neck, trunk and lower extremities. DLL was superior to the TR, because assesses the ability of abdominal muscles to stabilize the pelvis in a posterior-tilted position against an external load imported by the

lower extremities as they lowered from a standing vertical position [21]. Proper DLL performance requires palpation of a bony landmark to ensure that the abdominal muscles are functioning in a stabilizing role. The measurements can be confounded by two anatomic factors: first, the variation in size of the gluteal mass, which precludes standard positioning of the pelvis and second, the relative distensibility of the hip flexors muscles, which can perform the DLL without a stabilizing contribution from the abdominal wall, muscles (18,21).

Our study is not without limitations. First, the method it is not validated with a gold standard but to our knowledge, there is no gold standard for AWF assessment. Second, we do not investigate for the low back pain, usually present in patients with LIH, so the results can be biased by this component of a poor abdominal wall function. Another limitation is the absence of a group of patients with a bridged repair; in our experience, with only ten patients, a too small sample size was not to be considered. Lastly, no CT scan was performed at the end of the study to evaluate the difference of the compensatory hypertrophic response of the abdominal wall muscles.

Conclusions

This study demonstrates that the width of the defect is the main determinant for a poor AWF before surgery. The significance of midline reconstruction is obvious for AWF improvement after a correct reconstructive procedure with preservation of the neurovascular bundles and large mesh in a retro-muscular position. Finally, clinical studies—DLL and TR—can be used in daily practice—due to their validation—as sound and safe instruments for assessment.

Author contributions VO—study design, measurements, interpretation of data, writing the manuscript, final proof revision; MT—study design, measurements and data interpretation, writing the manuscript, final proof revision; OG—interpretation of data, statistics interpretation, final proof revision; AP—interpretation of CT scans, statistics and final proof revision; CM—supervision of the study, final proof revision and approval. VO and MT can share the first authorship with equal contribution. VO, MT, OG, AP, CM—nothing to disclose in relation with this study.

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Declarations

Conflict of interest VO, MT, OG, AP, and CM have no competing interests to declare.

Ethical approval Local Ethical Committee under AWF 29/October 13, 2015 approved the study.

Human and animal rights No animal used for this study.

Informed consent Every patient was informed about the goals of the study, about each procedure and surgery and signed an informed consent before enrollment in this study.

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The influence of Transversus Abdominis Muscle Release (TAR) for complex incisional hernia repair on the intraabdominal pressure and pulmonary function

V. Oprea¹ · S. Mardale² · F. Buia¹ · D. Gheorghescu¹ · R. Nica³ · S. Zdroba³ · O. Grad^{1,4}

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Abstract

Introduction Among many other techniques for Abdominal Wall Reconstruction (AWR), posterior component separation with Transversus Abdominis Release (TAR), continues to gain popularity and it is increasingly used with promising long-term results. Our goal was to evaluate the influence of TAR with mesh retromuscular reinforcement on the intra-abdominal pressure (IAP) and respiratory function in a series of patients with complex incisional hernias (IH).

Methods Since November 2014 through February 2019, patients with TAR were identified in the Clinical Department of Surgery database and were retrospectively reviewed. Outcome measures include: demographics, pre- and perioperative details, preoperative and postoperative IAP and plateau pressure (PP).

Results One-hundred-and-one consecutive TAR procedures (19.7% from all incisional hernia repairs) were analyzed. Mean age was 63 years with a mean Body Mass Index (BMI) of 31.85 kg/m² (25–51). Diabetes and Chronic Obstructive Pulmonary Disease (COPD) were the main major comorbidities. Mean hernia defect area was 247 cm² (104–528 cm²).

Conclusion TAR is a safe and sound procedure with acceptable modifications of the IAP morbidity and recurrence rate when correctly performed on the right patient.

Keywords Complex incisional hernia · Posterior component separation · Transversus Abdominis Release · Intra-abdominal pressure · Abdominal perfusion pressure · Plateau pressure

Introduction

There is strong evidence that incisional hernias (IH) increased in their incidence despite all modern techniques, technologies and surgical “know-how” [1, 2]. More than that, complex IH as defined some years ago by Slater et al., also increased their incidence [3]. This leads to several

serious challenges: a technical one, because in such patients, it is difficult to achieve the goals of the abdominal wall reconstruction (AWR), and a post-operative one, due to increased wound morbidity (surgical-site occurrences and surgical-site infections), increased intra-abdominal hypertension, respiratory failure, abdominal compartment syndrome and even mortality [4].

There is also strong evidence that mesh repair is compulsory and also that the sub-lay mesh positioning is the golden standard [5, 6]. According to this evidence, the “golden standard” Rives-Stoppa repair is not always a valid option in complex IH due to its limited anatomical and physiological resources for reconstructing the abdominal wall with adequate tension. The recently developed posterior component separation with Transversus Abdominis Muscle Release (TAR) seems to fulfill the goals of the AWR. By its lateral extension towards the semilunar line, TAR ensures a large space in the pre-peritoneal retro-muscular plane for a large, ordinary polypropylene mesh. Due to preservation of the neuro-vascular bundles of the rectus muscle, release of the

✉ V. Oprea
opreacv31@gmail.com

¹ Clinical Department of Surgery, “Constantin Papilian” Emergency Military Clinical Hospital, No. 22 General Traian Mosoiu Street, Cluj-Napoca, Cluj County, Romania

² Department of Radiology, “Constantin Papilian” Emergency Military Clinical Hospital, Cluj-Napoca, Romania

³ Intensive Care Unit, “Constantin Papilian” Emergency Military Clinical Hospital, Cluj-Napoca, Romania

⁴ 2nd Department of Surgery, Iuliu Hatieganu” University of Medicine and Pharmacy, Cluj-Napoca, Romania

“hoop” tension, and closure of the anterior rectus fascia in more than 95–98% of the patients, TAR re-establishes an anatomical and physiological sound abdominal wall [7].

There are few studies on large series of complex incisional hernias so, our goal was to evaluate the impact of the anatomy of the abdominal wall defect and of the abdominal wall reconstruction via TAR on the post-operative abdominal wall physiology in terms of intra-abdominal pressure (IAP) and pulmonary pressure expressed as plateau pressure (PP).

Materials and methods

Patients

After obtaining Institutional Ethics Committee approval, a retrospective review was conducted to analyze relevant variables, which included patient demographics, hernia characteristics, operative details, and postoperative outcomes. The main outcomes of interest were intra-abdominal pressure and plateau pressure. All files of the IH patients admitted between November 2014 and February 2019, were retrospectively analyzed. Complex IH was defined according to Slater et al. criteria [3]. Large IH was defined as a ventral IH with a fascial defect ≥ 10 cm width with or without mesh recurrence; lateral incisional hernias were also included. Patients with class IV Ventral Hernia Working Group (VHWG) classification [8] and emergent presentations were excluded. Patients' written informed consent was obtained before surgery.

CT protocol investigation

All patients were preoperatively evaluated with a native abdomino-pelvic CT scan. All pre-operative CT scans were reviewed by the surgeon and a radiologist. After the cross-review, all inconsistencies of the measurements were eliminated. The length and the width of the defects were identified in their maximal dimensions and carefully measured. In most of the patients, the defect was equated with an ellipse and its surface was calculated using the formula $\frac{1}{2}$ length \times $\frac{1}{2}$ width $\times \pi$. The values were approximated to the nearest hundred or thousand. When multiple associated defects were detected in various position and different dimensions (upper right quadrant and medial), the larger was considered. The width of the both rectus sheath (RW) has been also measured. The ratio of their sum to the width of the defect (DW) was the basis for TAR indication (Carbonell's equation) [9]. The volume of the abdominal cavity (ACV) and of the incisional hernia sac (IHV) was calculated according to Tanaka method [10]. The peritoneal cavity volume (PV) was obtained by adding up ACV and IHV. The peritoneal

index was calculated as the ratio between IHV and PV. All the values were manually collected because there was no computer software; differences larger than $\pm 10\%$ between surgeon's and radiologist's measurements were reassessed until an agreement was reached.

Preoperative optimization

Patient optimization included smoking and tobacco use cessation 1 month prior to elective surgery, glycemic control ensuring an HbA1c level less than 7% and improvement of cardiovascular and ventilatory capacity. Nutritional status was corrected until adequate level of total proteins, albumins and ions were achieved.

Functional evaluation

Respiratory function was evaluated by computerized spirometry (vital capacity—VC in ml, forced expiratory volume—FEV₁ in ml, and the ratio between them—FEV₁/VC) before surgery and 1 month after abdominal wall reconstruction so as to avoid errors and bias induced by incomplete deep breathing as a consequence of an unhealed abdomen. Normal values or predicted values were calculated according to age, sex and height. When FEV₁ was below 88% from the predicted value, an obstructive pulmonary disease was considered and it was stratified as follows: **mild**—when FEV₁ is 80% of the predicted value; **moderate**—FEV₁ ranges between 50 and 79% of the predicted value; and **severe**—with FEV₁ between 30 and 49% of the predicted value. Normal value of FEV₁/VC was considered around 75% or 0.75. When VC was decreased but the ratio was normal, a restrictive lung insufficiency was considered and was attributed to the abdominal wall defect among other pathologies.

Intra-abdominal pressure

The standard method for indirectly measuring IAP is to measure the intra-vesicular pressure [11]. Briefly, the bladder drainage system was clamped just distal to the connection of the urinary catheter to the drainage bag. An 18-gauge needle was then inserted into the sampling port and connected via a sterile tube to the pressure transducer using two three-way stopcocks. A standard infusion bag of normal saline was attached to one stopcock, and a 60-ml syringe was connected to the second stopcock. Sterile saline (50–100 ml) was injected into the bladder. Measurements were taken at end-expiration while patients were in complete supine position and with the transducer zeroed at the symphysis pubis level. Intra-abdominal pressure was recorded before surgery, immediate after the end of the procedure, 24, and 48 h after TAR on the awakened patient. Intra-abdominal hypertension (IAH) is defined by a sustained or repeated elevation

in IAP ≥ 12 mmHg. IAH was graded as follows: Grade I, IAP = 12–15 mmHg; Grade II, IAP = 16–20 mmHg; Grade III, IAP = 21–25 mmHg; and Grade IV, IAP > 25 mmHg [12]. Likewise, abdominal compartment syndrome (ACS) was defined as IAP > 20 mmHg in combination with at least one organ failure. In addition, abdominal perfusion pressure (APP) was calculated by subtracting IAP from mean arterial pressure (MAP) measurements. Mean APP < 60 mmHg was considered abnormal.

Plateau pressure (P_{PLAT}) is the pressure applied to small airways and alveoli during positive-pressure mechanical ventilation. It is measured during an inspiratory pause on the mechanical ventilator and it was recorded after 20 min of the onset of the procedure and 20 min after the anterior fascia was closed. The difference between first and last record of the plateau pressure was noted as Δ plateau pressure. When the difference exceeds 6 mmHg, the patient was kept intubated for 24 h.

Procedure

The indication for TAR was established preoperatively using the formula 2RW: DW = 2:1. All the procedures were performed under general anesthesia according to the technique described by Novitsky [13, 14]. For the posterior fascia closure, a slowly resorbable suture (2-0 polydioxanone) was used as a running suture. Mesh was fixed with transfascial slowly absorbable suture or with cyanoacrylate (Histoacryl® B Braun). Anterior fascia was closed with a running slowly absorbable suture (1 polydioxanone). When repairing a mesh recurrence, the mesh was completely removed whenever possible. Monofilament macroporous medium-weight polypropylene mesh was used for all circumstances when the anterior fascia was completely closed. When the linea alba could not be restored, a heavy weight polypropylene mesh was used.

Follow-up

Patients were followed up 1 month, 6 months and yearly after TAR by direct examination if possible. For the goals of this paper, only 1 month follow-up was considered.

Statistical analysis

Data were tabulated as mean \pm standard deviation (sd). Continuous variables were analyzed by ANOVA variance test followed by unpaired two tails Student's *t* test assuming unequal variance and the binary outcomes with the χ^2 test. Pearson correlation (*r*) was used with the regression equation. Multivariate logistic regression models were built with PI, IAP as the outcomes of interest for major determinants of severe postoperative complications, adjusting for

identified confounders. In addition to the variables of interest, the following were included for adjustment: age, rank of recurrence, severity of comorbidities score, body mass index (BMI), length, width and area of the defect, ACV, IHV, PV, and postoperative intra-abdominal pressure. Multivariate models were calculated with the linear logistic regression and the results were shown with the Odds ratio (OR) and the 95% confidence interval (CI). Probabilities smaller than 0.05 were considered as statistically significant. SPSS statistic version 23.0, 2018 (Chi, Ill) was used to perform the statistical analysis.

Results

All data had a normal distribution (*one-sample Kolmogorov–Smirnov and one-sample Chi-square* tests). In the referral interval, 306 patients with IH were operated in the Department of Surgery. Out of these, 101 (33%) meet the inclusion criteria and were operated by TAR. Demographic data and preoperative hernia characteristics are represented in Table 1.

Table 2 outlines the CT scan characteristics for all IH.

Mean preoperative VC was 2220.94 ± 317.24 (1675–2900) ml. All values were lower than the predicted with 3 to 40%. In 31 patients, the reduction was between 3 and 17%, in 22 patients from 18 and 24%, in 31 from

Table 1 Demographics and preoperative hernia characteristics

Characteristics/variables	Mean \pm standard deviation (min–max)
Number of patients/gender	101/ 45 males
Age (years)	63.78 \pm 6.78 (43–79)
Onset of symptoms (months)	61.49 \pm 35.3 (12–148)
BMI (kg/m ²)	31.85 \pm 4.57 (25–51)
ASA	2–87 patients; 3–14 patients
Co-morbidities (usually more than 1) diabetes	37 patients
COPD	27 patients
Active smoker	27 patients
Retired smokers	18 patients
Cardiac	51 patients
Immune suppression	1 patient
Hernia location	Medial—90 patients Parastomal—4 patients Lateral—7 patients RUQ—4 RLQ—3
Primary IH	74 patients
Recurrent IH	37 (22 mesh recurrences)

BMI body mass index, *ASA* American Society of Anesthesiologists Score, *COPD* chronic obstructive pulmonary disease, *RUQ* right upper quadrant, *RLQ* right lower quadrant, *IH* incisional hernia

Table 2 Computed tomography variables of incisional hernia anatomy

Variables	Mean \pm standard deviation (sd)	Minimum/maximum
Length of the defect (cm)	18.24 \pm 4.11	11–28
Width of the defect (cm)	17.18 \pm 3.29	11–28
Area (cm ²)	247.12 \pm 79.03	104–528
Rectus sheath width (sum) (cm)	7.78 \pm 1.22	5–10
TAR index (DW: RW)	2.25 \pm 0.47	1.37–4
ACV (cm ³)	9297.15 \pm 1452.3	5017–12,138
IHV (cm ³)	4231 \pm 800.96	2017–5983
PV (ACV + IHV) (cm ³)	13,521 \pm 1999.07	8498–18,121
PI (ACV/PV)	0.307 \pm 0.03	0.22–0.41

TAR Transversus Abdominis Release, ACV abdominal cavity volume, IHV incisional hernia volume, PV peritoneal volume, PI Peritoneal Index

25 to 34% and in 17 over 37%. A strongly negative Pearson correlation was found between the length of the defect ($r = -0.103$; $p = 0.305$), width of the defect ($r = -0.321$; $p = 0.001$), and preoperative plateau pressure ($r = -0.201$; $p = 0.044$). Even if the absolute value of r was not highly significant, the distribution of the plots around the regression line argued this statement (data not shown).

Preoperatively, the value of FEV₁ was decreased in all patients with 5–41% than predicted value (mean 1581.92 \pm 267.09 ml; minimum 1055 ml; maximum 2340 ml). According to FEV₁ values, 32 patients were without respiratory insufficiency (reduction of FEV₁ with 9–19%) and 69 patients with respiratory obstructive and restrictive symptoms (reduction of FEV₁ with 21–41%). Width of the defect, area, IHV and preoperative plateau pressure were negatively influenced FEV₁ decrease (width $r = -0.220$; $p = 0.027$, area $r = -0.209$; $p = 0.036$, IHV $r = -0.205$; $p = 0.04$ and plateau pressure $r = -0.247$; $p = 0.013$).

The value of mean preoperatively FEV₁/VC was slightly decreased compared to normal value (0.71 \pm 0.1). In 38 patients with normal ratio, both VC and FEV₁ were equally reduced and all these patients had large volumes of the incisional hernia sac (IHV). This was demonstrated by a significant negative correlation with the IHV ($r = -0.226$; $p = 0.023$). Extreme lower values of the ratio (0.46–0.64) were encountered in 28 patients; 38% were known with COPD and for them, the ratio was decreased due to the extreme decrease of FEV₁. For the rest of them, the ratio was decreased due to the both components.

At 1 month postoperatively, VC increased to a mean of 2785.64 \pm 353.5 (min 2000–max 3600) ml; compared with the preoperative value, the difference was statistically significant (*Student's t test* $p < 0.001$; ANOVA $F = 3.024$,

Table 3 Intra- and post-operative characteristics of the pressure variable

Variables	Mean \pm standard deviation (sd)	Minimum/maximum
Preoperative plateau pressure (mmHg)	14.88 \pm 3.56	10–22
Postoperative plateau pressure (mm Hg)	19.9 \pm 4.16	12–30
Δ plateau (mmHg)	5.03 \pm 1.27	2–9
Postoperative IAP (mmHg)	14.64 \pm 2.83	10–20
POD 1 IAP (mmHg)	18.17 \pm 2.84	12–25
POD 2 IAP (mmHg)	15.87 \pm 1.79	11–20

TAR Transversus Abdominis Release, IAP intra-abdominal pressure, Δ plateau difference between postoperative and preoperative plateau pressure

$p < 0.001$). FEV₁ also recorded increased values ranging from 1300 to 2800 ml and a mean of 2092.3 \pm 335.9 ml. The difference was significant in relation with the preoperative value (*Student's t test* $p < 0.001$; ANOVA $F = 2.58$, $p < 0.001$). Related to the predicted values, the decrease was lower than the preoperative both values with 2–27%. In patients with COPD, the increased of FEV₁ was almost zero; comparing the means of this subgroup of patients, the difference was insignificant (*Student's t test* $p = 0.327$; ANOVA $F = 1.27$; $p = 0.211$). A significant increase of FEV₁ was documented in 52 patients with restrictive respiratory insufficiency in whom this was with over 40% to preoperative values (*Student's t test* $p < 0.001$; ANOVA $F = 4.19$ $p = 0.002$). Mean postoperative FEV₁/VC ratio was 0.74 \pm 0.07 (min 0.54–max 0.9); the difference was significant compared to preoperative mean (*Student's t test* $p < 0.001$; ANOVA $F = 3.19$ $p = 0.006$). Postoperatively, the number of patients with normal ratio (64) was higher than the preoperative one (48) and the difference was significant (Chi-square test $\chi^2 = 23.8$; $p = 0.0017$). There was no modification of the ratio in patients with COPD, postoperative values being almost similar with the preoperative ones.

Preoperative intra-abdominal pressure varied between 4 and 9 mmHg with a mean of 6.15 \pm 1.56 mmHg. In a univariate analysis, preoperative IAP was strongly negative correlated with the width of the defect ($p = 0.029$), area of the defect ($p = 0.019$), IHV ($p < 0.001$), and with PI ($r = -0.803$, r^2 linear = 0.6, $p < 0.001$). When the logistic regression was applied, the only valid correlation of the preoperative IAP was with the PI (OR = 1.82, 95% CI 1.04–3.18, $p = 0.032$).

Intra-operative findings are detailed in Table 3. There was no difference between preoperative and intra-operative values of the defect (data not shown).

In 11 patients with a TAR index between 0.32 and 0.4, the posterior fascia could not be closed, so a peritoneal flap in five patients and an omental patch in the rest of them

was used to separate the mesh from the abdominal content. No biologic or absorbable meshes were available. Anterior fascia was completely closed in 94 patients (93%) and for the rest of them, a bridged repair with mesh fixation to the edges of the defect was performed.

Immediate postoperative IAP ranged between 10 and 20 mmHg with a mean value of 14.64 mmHg and it was significantly higher compared to the preoperative value (Student's *t* test— $p < 0.001$). All patients developed intra-abdominal hypertension in varying degrees: *grade I* (12–15 mmHg)—63 patients, and *grade II* (16–20 mmHg)—38 patients immediately after the end of the procedure.

In the first postoperative day (POD 1), IAP increased to a mean value of 18.17 mmHg (statistically significant compared to the mean value recorded immediately postoperatively; $p = 0.017$ Student's *t* test). The distribution of patients according with the grade of IAH was also changed: *grade I*—22 patients, *grade II*—42 patients and *grade III*—37 patients. No organ dysfunction was recorded, urinary output

being in normal range for all patients. Values of the IAP for the second postoperative day (POD2) and of the urinary out are represented in Fig. 1.

In Table 4 are listed the main variables correlated with the postoperative IAP in the univariate analysis. Because all data were outside confidence interval of the linear regression equation, even if the statistical significance was high, a binary logistic regression was performed. The only variables correlated with the postoperative IAP were IHV, PI, RSW, and preoperative IAP. Data are shown in Table 4.

The mean value for the postoperative plateau pressure was significantly higher than the mean value before abdominal wall reconstruction ($p < 0.01$). For 17 patients, the difference between postoperative and preoperative value of plateau pressure (Δ plateau) was over 6 and they were kept intubated for 24 h. Before extubation, the value of plateau pressure was almost similar with preoperative values (data not shown). The same factors that control IAP are also determinants for plateau pressure in the univariate

Fig. 1 Distribution of patients in relation with the level of intra-abdominal hypertension (IAH). Grade I, IAP = 12–15 mmHg; Grade II, IAP = 16–20 mmHg; Grade III, IAP = 21–25 mmHg; IPO immediate after the end of the procedure, POD 1 postoperative day 1, POD 2 postoperative day 2

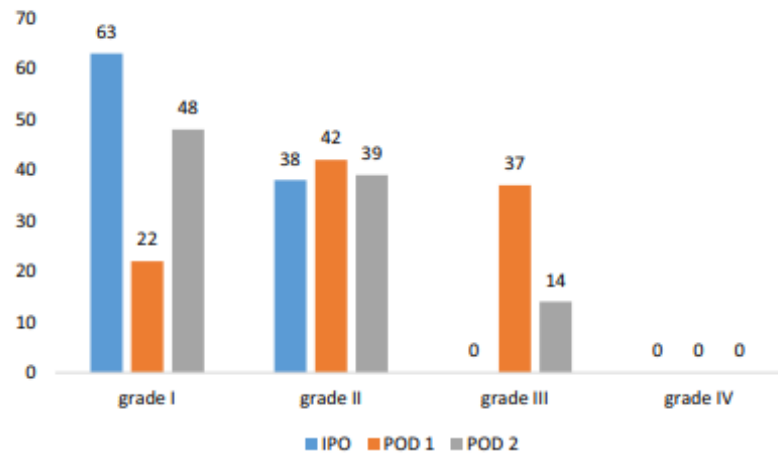


Table 4 Significant factors influencing postoperative intra-abdominal pressure (IAP) (univariate analysis and logistic regression)

Variables	Postoperative IAP (univariate analysis)	Postoperative IAP (logistic regression)
Length of the defect	$r = 0.356; p < 0.001$	OR 0.2; 95% CI = 0.1–0.5; $p = 0.8$
Width of the defect	$r = 0.242; p = 0.015$	OR 0.4; 95% CI = 0.1–0.7; $p = 0.08$
Area of the defect	$r = 0.395; p < 0.001$	OR 0.4; 95% CI = 0.2–0.7; $p = 0.6$
ACV	$r = -0.155; p = 0.122$	OR 0.2; 95% CI = 0.1–0.5; $p = 0.8$
IHV	$r = 0.468; p < 0.001$	OR 1.12; 95% CI = 0.91–2.13; $p = 0.002$
PI	$r = 0.710; p < 0.001$	OR 0.78; 95% CI = 0.45–1.37; $p = 0.011$
Preoperative IAP	$r = -0.634; p < 0.01$	OR 0.85; 95% CI = 0.48–1.49; $p = 0.029$
Rectus sheath width (sum)	$r = 0.096; p = 0.341$	OR 1.09; 95% CI = 0.61–1.93; $p = 0.014$

ACV abdominal cavity volume, IHV incisional hernia volume, PI Peritoneal Index, OR odd ratio, 95% CI confidence interval

Table 5 Significant factors influencing postoperative plateau pressure (univariate analysis and logistic regression)

Variables	Postoperative plateau pressure (univariate analysis)	Postoperative plateau pressure (logistic regression)
Length of the defect	$r=0.197, r^2=0.039, p=0.049$	OR 0.2; 95% CI=0.1–0.5; $p=0.8$
Width of the defect	$r=0.213, r^2=0.043, p=0.041$	OR 0.6; 95% CI=0.1–0.9; $p=0.3$
Area of the defect	$r=0.220, r^2=0.048, p=0.027$	OR 0.2; 95% CI=0.1–0.5; $p=0.8$
ACV	$r=-0.201, r^2=0.04, p=0.044$	OR 0.2; 95% CI=0.57–3.06; $p=0.007$
IHV	$r=0.301, r^2=0.091, p=0.002$	OR 1.19; 95% CI=0.52–2.73; $p=0.019$
PI	$r=0.551, r^2=0.350, p=0.001$	OR 1.64; 95% CI=0.68–3.99; $p=0.001$
Preoperative IAP	$r=-0.608, r^2=0.369, p=0.001$	OR 0.2; 95% CI=0.1–0.5; $p=0.8$
Postoperative IAP	$r=0.658, r^2=0.433, p=0.001$	OR 1.09; 95% CI=0.48–2.45; $p=0.022$
Rectus sheath width (sum)	$r=0.21, 7r^2=0.044, p=0.041$	OR 0.4; 95% CI=0.1–0.8; $p=0.07$

ACV abdominal cavity volume, IHV incisional hernia volume, PI Peritoneal Index, OR odd ratio, 95% CI confidence interval

analysis but after binary logistic regression only, ACV, IHV, PI and postoperative IAP remain as significant (Table 5).

The mean value for APP in POD 1 was 71.99 ± 10.09 (60–93) mmHg. 17 patients with PI higher than 0.3, with grade III IAH, and Δ plateau > 6 mmHg, were kept intubated for the next 24 h, the mean value of APP was 60.2 ± 1.7 mmHg and significantly lower than for the rest of the patients (71.44 ± 9.6 mmHg; $p < 0.001$; Student's *t* test). In POD 2, the mean value of APP increased to 78.2 ± 9.39 mmHg; for the intubated patients, the mean value of the APP increased to a mean of 71.8 ± 8.6 mmHg and was slightly lower than of the other patients (74.6 ± 6.34 ; $p = 0.08$). A negative strong correlation with the PI was recorded for APP (r Pearson = -0.873 ; $p = 0.004$) in a univariate analysis. When logistic regression was applied, ACV (OR 1.19; 95% CI=0.52–2.67; $p = 0.027$), IHV (OR 1.29; 95% CI=0.72–2.87; $p = 0.018$), PI (OR 2.83; 95% CI=1.52–3.84; $p = 0.015$), postoperative plateau pressure (OR 2.19; 95% CI=1.52–3.67; $p = 0.017$) and BMI (OR 0.68; 95% CI=0.67–2.67; $p = 0.021$) were the factors which significantly influence the values of the APP.

No mortality was recorded at 30 days. Systemic morbidity was noted in 38 patients and consisted of: urinary tract infection (two patients), prolonged paralytic ileus—5 to 8 days (11 patients), deep vein thrombosis (one patient), deep vein thrombosis with limited pulmonary embolism (one patient), pneumonia (two patients), and prolonged simple O₂ administration for 21 patients. All pulmonary events occurred in patients with pre-existing lung damage. Paralytic ileus was more frequent in diabetic patients (nine of eleven). Female gender was more frequently exposed to develop systemic morbidity (71 vs 29%). Wound complications were recorded in 11 (29%) of the patients with systemic postoperative morbidity. These surgical-site occurrences (SSOs) were hematomas in three patients, seromas in two patients and surgical-site infections (SSIs) in the rest of them. Re-intervention

was necessary for hematoma patients with an un-eventful recovery and for the half of the patients with SSIs. No mesh debridement was necessary. In all cases of SSIs, the wound was healed by active therapy with negative pressure between 8 and 21 days. Hospital stay ranged between 5 and 38 days (mean of 7.21 ± 2.8 days).

Follow-up varied between 12 and 51 months with mean of 32 months. At 12 months, 91 patients were directly examined and seven recurrences were recorded. Most of them (five patients) were recorded in the first 35 patients between 5 and 11 months after surgery. After the 35th repair, no early recurrence was encountered. There was no established relation between post-operative IAP, respiratory status and recurrence rate. Defect area (OR = 2.81; 95% CI 1.69–3.72; $p = 0.004$), active smoking (OR = 2.21; 95% CI 1.35–3.45; $p = 0.001$), and diabetes (OR = 1.93; 95% CI 1.19–2.83; $p = 0.022$) were the only factors independently associated with recurrence rate.

Discussion

From a mechanical point of view, the IH is an opening in the abdominal wall layers which leads to impossibility of the wall to withstand IAP. An increased number of IH are complicated cases, which include large defects or even loss of domain, lateral incisional hernias, recurrence after mesh repair and /or chronic mesh infection. Surgery of complex IH is a difficult and thorny issue for both surgeon and patient. The main challenge for this surgery is to find the best technique for a complex given equation (patient, hernia, anatomy) which must provide a complete reconstruction of the linea alba augmented by a large and adequately placed prosthetic mesh, with minimal early and late morbidity. The field of herniology offers a large amount of data regarding surgical approach and mesh types but heterogeneity and biases limit standardization [15].

Few options are available but according to the principles and the goals of AWR, they restrict only to component separation techniques. Posterior component separation via-TAR is a relatively new technique which ensures the lateral extension of the retro-rectus space for a wide mesh overlap, release "hoop-tension", allows closure of the anterior fascia in most patients and preserves the AW function by preserving the neurovascular bundles for the rectus abdominis muscle.

According to Majumder et al., on a cadaveric study, after a complete TAR with large retro-muscular dissection, an average advancement of 10 cm for the anterior fascia and 11 cm for the posterior fascia on each side was obtained [16]. This can provide a significant increase of the abdominal cavity inner diameters and, subsequently, an increase of the whole visceral sac volume, without or with minimal consequences upon normal physiology. Indeed, this study reconfirms our previous findings [17]; IAP and postoperative plateau pressure maintained permissive values without altering respiratory function for 90 patients. Peritoneal index and rectus sheath's width are the only factors which influence the negative respiratory outcomes. Myofascial release of the transversus abdominis muscle can generate elevated IAP immediately following repair, clearly demonstrated by our results. All our patients developed intra-abdominal hypertension to varying degrees but no values larger than 15 mmHg

were recorded in patients with PI smaller than 0.3. Analyzing the generalized Log Odds (Fig. 2), one can observe that the main factors for unfavorable prognosis impact the outcomes of IAP from the values over 0.33 of the peritoneal index and are more expressed over the value of 0.37. A total of 37 patients (36.62%) developed increased values of the postoperative IAP and plateau pressure directly related to an increased PI. In nine of them, the values were extreme but without developing abdominal compartment syndrome.

These elevated IAP could be considered permissible due to the fact that no organ dysfunction, except for some reversible decrease of the urinary output, as recorded. Probably, maintaining APP above the critical value of 60 mmHg was an important contributing factor to the positive outcomes of the patients (data not shown). Under these circumstances, one could suggest that intra-abdominal hypertension or abdominal compartment syndrome immediately after an elective abdominal wall reconstruction creates a clinical aspect that must be distinguished from the settings in which they were originally described [18].

One factor that can be involved in the favorable outcomes of our patients is the abdominal compliance (C_{ab}). It plays a very important role in understanding the deleterious effects of un-adapted intra-abdominal volumes on IAP and organ dysfunction. Unfortunately, measurements of C_{ab} are difficult at the bedside. Some indirect measures are available

Fig. 2 Main factors correlated with unfavorable prognosis in relation with peritoneal index

Generalized Log Odds

pindex	Coefficients ^{b,c}					
	IHV ^a	IAPpreop ^a	IAPpostop ^a	IAPD1 ^a	platpreop ^a	platpostop ^a
.22	2893.00	7.00	11.00	15.00	15.00	20.00
.23	2474.33	8.00	12.67	16.33	12.00	17.33
.24	3054.83	7.67	11.50	14.83	11.33	16.00
.27	3869.60	7.80	12.50	16.20	12.20	17.50
.28	4102.67	8.00	12.44	16.22	13.22	18.44
.29	3884.25	7.50	11.50	15.00	12.00	16.75
.30	3954.45	6.82	14.45	18.36	14.36	18.55
.31	4030.50	6.00	14.71	18.36	14.57	19.29
.32	4931.40	5.60	15.20	19.60	13.60	19.00
.33	4971.08	5.42	14.92	18.33	15.83	20.25
.34	4793.85	4.46	17.15	20.46	18.15	23.69
.35	4998.38	4.38	17.25	20.63	17.88	23.38
.37	4933.00	4.00	19.00	22.00	20.00	28.00
.38	3764.00	4.00	19.00	22.00	12.00	17.00
.39	4917.00	4.00	19.00	21.00	21.00	27.00
.40	3902.00	4.00	20.00	21.00	22.00	30.00
.41	3481.00	4.00	20.00	21.00	21.00	30.00

in mechanically ventilated patients: the Δ IAP (= IAP at the end of inspiration minus the IAP at the end of expiration) and the abdominal pressure variation (APV = Δ IAP divided by mean IAP) are such parameters, and they are inversely correlated with C_{ab} , i.e., the higher Δ IAP or APV, the lower C_{ab} [12]. Therefore, if we could identify patients with a low C_{ab} , we could anticipate and select the most appropriate surgical treatment to avoid possible complications related to IAH/ACS.

Preoperative evaluation of the lung function with the aid of spirometry is an easy way to differentiate if the respiratory insufficiency is obstructive or restrictive at origin. Obstructive FEV₁ is reduced, so the ratio will be low. In large IH, this can be no longer the truth due to the fact that the obstruction can be masked by the broken associated abdominal component of the respiration. When the ratio is normal or even increased due to a decrease in magnitude of VC and FEV₁ decrease, the respiratory failure is restrictive as a consequence of the large defect and increased IHV. The surgical procedure itself improves significantly the restrictive respiratory failure by correcting the functionality of the abdominal wall.

Some limitations of the study can be considered. This is a retrospective one even if our database is prospective from a single surgical center; the number of patients is not too high but represents a quarter from all patients with incisional hernias admitted in our Department. Also, the population and hernia characteristics are not homogenous and the results can be biased by the learning curve of a new procedure. Most of the procedures (92 patients) were performed by a single surgeon, so the results cannot be broadly reproducible.

Conclusion

Posterior component separation with TAR is a strongly effective procedure for a stable repair of large and very large defects of the abdominal wall irrespective of their location. TAR is also effective in recreating abdominal wall volumes without severe disturbing of the IAP, plateau pressure and respiratory function when peritoneal index is lower than 0.33. Last but not least, TAR improves restrictive respiratory insufficiency through correction of the abdominal wall functionality. A correct preoperative evaluation (CT scan, respiratory, cardiovascular and metabolic) is the key for minimizing severe complications and achieving superior outcomes. Proper training and profound understanding of the abdominal wall anatomy are the cornerstones for the success.

Authors' contribution VO: study conception and design, acquisition, analysis and interpretation of data, drafting the work and revising, final

approval of the version to be published; SM: acquisition, analysis and interpretation of imagistic data, final approval of the version to be published; FB, DG, RN, ZS: final approval of the version to be published; OG: interpretation of data, drafting the paper, final approval.

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Declarations

Conflict of interest All authors declare no conflict of interest.

Ethical approval All procedures performed in this study involving Human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Human and animal rights No animal was used for this study.

Informed consent Informed written consent was obtained from all patients before surgery.

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Early outcomes of open anterior versus posterior components separation with transversus abdominis release for large median incisional hernias: a retrospective stepwise analysis

Mihai Toma^{1,2} · Valentin Oprea^{1,3} · Ovidiu Grad^{1,3} · Harry Staines⁴ · Carmen E. Bucuri^{1,3} · Octavian Andercou^{3,5} · Mircea Gherghinescu^{2,6} · Calin Molnar^{2,6}

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Abstract

Background Complex incisional hernia is still a debatable topic, with increasing incidence and an increased local and systemic postoperative morbidity and mortality. The size of the defect is a risk factor for both difficult closure and 30-day readmission due to complications. The main option for closure such defect is a mesh augmented component separation technique. The goal was to evaluate 30-day wound events and general complications including 90 days mortality.

Material and methods We present a retrospective study that includes patients from two different university hospitals who underwent open incisional hernia repair with anterior component or posterior component separation between January 2015 and December 2021. Only non-contaminated adult patients (over 18 years old) with postoperative primary or recurrent median abdominal wall defects larger than 6 cm and with complete fascial closure were included. Demographics (age, gender, Body Mass Index—BMI, American Society of Anesthesiologists Classification—ASA score), recurrence rank, and co-morbidities), operative details, patient outcomes complications were collected. A native abdomen/pelvis computerized tomography (CT) scan was performed preoperatively in all patients and the anatomy of the defect and volumetry (abdominal cavity volume, incisional hernia volume and peritoneal volume) were evaluated. One of the component separation technique was performed according to Carbonell's equation.

Results Two hundred and two patients (101 from each group) were included. The patients with posterior component separation were more comorbid and with larger defects. The procedure was longer with 80 min but overall length of hospital stay shorter ($p < 0.001$) for posterior component separation. Seroma, hematoma and skin necrosis were equally distributed for both group of patients and there was no direct relation to surgery (OR 0.887, 95% CI 0.370–2.125, $p = 0.788$; OR 1.50, 95% CI 0.677–3.33, $p = 0.318$ and OR 0.386, 95% CI 0.117–1.276, $p = 0.119$). Surgical Site Infection rate was increased for anterior component separation ($p = 0.004$).

Conclusion Complex incisional hernia repair is a challenge given by a large amount of wound complications. Choosing between anterior and posterior component separation is still a source of significant debate. We were not able to depict significant different rates of complications between the procedures and we couldn't find any specific factor related to complications.

Keywords Large incisional hernias · Anterior component separation · Posterior component separation · Early outcomes

✉ Valentin Oprea
opreav31@gmail.com

¹ Clinical Department of Surgery, "Constantin Papilian" Emergency Clinical Military Hospital, Cluj-Napoca, 22 G-ral Traian Mosoiu, Cluj-Napoca-Napoca, Romania

² "George Emil Palade" University of Medicine, Pharmacy, Science and Technology, Targu-Mures, Romania

³ "Iuliu Hatieganu" University of Medicine and Pharmacy, Cluj-Napoca-Napoca, Romania

⁴ Sigma Statistical Services, Balmullo, UK

⁵ Second Clinical Department of Surgery, Emergency Clinical County Hospital, Cluj-Napoca-Napoca, Romania

⁶ First Clinical Department of Surgery, Emergency Clinical County Hospital, Targu-Mures, Romania

Background

Complex incisional hernia (CIH), despite the seminal paper of Slater et al. [1], is still a debatable topic, which raises many controversies but it is also an active area of surgical innovation and research [1, 2]. Its incidence is increased as older and older patients with multiple associated comorbidities are operated and leads to an increased local and systemic postoperative morbidity and mortality. The size of the defect (especially its width) is a risk factor for both difficult closure and 30-day readmission due to complications [3]. Closure of defects larger than 10 cm width are more likely to need component separation techniques (CST) as Smith et al. recently reported [4].

Following the introduction and popularization of Anterior Component Separation (ACS) by Ramirez et al. in 1990, Novitsky modified component separation is an attempt to minimize and optimize early and late complications [5]. Both CST act as natural tissue expanders but there are little published research especially multi-centric trials comparing the outcomes of anterior versus posterior component separation. The most proper and effective CST remains under active debate despite the new data that suggest the greater effectiveness of posterior compared to anterior component separation in terms of wound morbidity and recurrence [6].

Surgical repair for giant IH is a high-risk procedure with considerable early and late morbidity. Our study is focused mainly on complex hernias (defined by larger defects, difficult locations, etc.) that cannot be primary closed without excessive tension and management based on mesh augmented by CST. As wound morbidity is a measure of early success, we compared the early outcomes of patients undergoing open hernia repair based on the utilization of ACS and Posterior Component Separation with Transversus Abdominis Muscle Release (PCSTAR) with on lay and, respectively, sublay mesh reinforcement in two different tertiary university teaching hospitals. The second goal was to identify if the surgery itself is a major factor inducing wound morbidity and what other patient- and hernia-related factors contribute to poorer outcomes.

Material and methods

Patients

Our retrospective study is from a prospective data base and includes patients from two different university hospitals who underwent open incisional hernia repair with anterior component or posterior component separation

between January 2015 and December 2021. Only non-contaminated adult patients (over 18 years old) with post-operative primary or recurrent median abdominal wall defects larger than 6 cm and with complete fascial closure were included. Emergent patient, lateral, and parastomal hernias were excluded as we believe they present higher complexity with different and specific complications and recurrence rates. Also, patients without a preoperative CT scan, dirty and infected wound class patients, patients in whom anterior fascia could not be closed, and single-sided separation were excluded.

Patients were distributed into two groups depending on the provenience and type of the procedure: group MS with ACS (Clinical County Hospital, Tirgu Mures) and group CJ (Clinical Military Hospital, Cluj-Napoca,) with PCSTAR; will refer to them as ACS group and PCSTAR group (posterior component separation). The Local Ethic Committee under Ad. 10781/19.04.2021 and A4528/25.11.2020 approved the study.

The written informed consent from each patient was obtained. Demographics (age, gender, Body Mass Index—BMI, American Society of Anesthesiologists Classification—ASA score, recurrence rank, and co-morbidities), operative details, patient outcomes and complications were collected. Four surgeons contributed to the database with surgical procedures (VO, MT, MG, and, CM) all of them senior surgeons with extended experience in visceral surgery and abdominal wall reconstruction.

CT protocol investigation

A native abdomen/pelvis computerized tomography (CT) scan was performed preoperatively in all patients. The surgeon and a radiologist reviewed all pre-operative CT scans. We removed all inconsistencies of the measurements after the cross review. Both, the surgeon and the radiologist, carefully identified and measured the length and the width of the defects in their maximal dimensions. The defect was approximated by an ellipse and the area of the defect was calculated using the formula $\frac{1}{2} \text{length} \times \frac{1}{2} \text{width} \times \pi$. The values were rounded to the nearest hundred or thousand. We also measured the width of both rectus sheath (RW). The ratio between their sum and the width of the defect (DW) was the basis for both ACS and Transversus Abdominis Muscle Release (PCSTAR) indication (2RW: DW = 2:1 Carbonell's equation) [7]. The volumes of the abdominal cavity (ACV) and of the incisional hernia sac (IHV) are calculated according to the Tanaka method [8]. By adding up ACV and IHV, we obtained the volume of the peritoneal cavity (PV). The ratio of IHV and PV provides the peritoneal index (Sabbagh Index) as measurement of loss of domain [9]. A 25% cut-off of the Sabbagh index was considered for loss of domain as an arbitrary limit in both clinics. All the values

were manually collected; differences of more than $\pm 10\%$ between surgeon and radiologist's measurements were reassessed until agreement was reached.

Surgical procedure

All the procedures were performed under general anesthesia according to the technique described by Ramirez [10] and Novitsky [11]. All patients had intravenous antimicrobial and antithrombotic prophylaxis according to each hospital protocols. No local adjuvants such as Botox or Progressive Preoperative Pneumoperitoneum were considered for this study.

After adhesiolysis, the peritoneal sac was dissected and the abdominal wall reconstructed according to each clinic and with the original technique [10, 11].

In patients with ACS, a slowly absorbable monofilament-running suture (1 polydioxanone) closed the abdominal wall. Medium weight macroporous monofilament polypropylene mesh was placed on-lay and fixed in place with interrupted monofilament non-absorbable suture (3/0 polypropylene) according to surgeons' preference. The mesh surface was around 900 cm² in almost all patients.

A slowly absorbable monofilament-running suture (2–0 polydioxanone) closed the posterior fascia in patients with PCSTAR. We fixed the mesh with slowly absorbable transfascial sutures (0 polydioxanone) or with cyanoacrylate (Histoacryl® B Braun). Medium weight macroporous monofilament polypropylene mesh (with the area fivefold larger than defect area) reinforced the abdominal wall in all circumstances. A slowly absorbable running suture (1 polydioxanone) closed the anterior fascia. For mesh recurrences the old mesh was completely removed whenever possible.

All PCS patients were drained with more than one suction drainage until the volume of the liquid was less than 30 ml/24 h for two consecutive days. Two drains were placed over the mesh in the retromuscular space and another one in the subcutaneous space. In patients with ACS one or two drains were left in place over the mesh until less than 30 ml were drained for two consecutive days.

In both groups, before skin closure, an elliptic curve of skin and subcutaneous fat was removed on both sides of the incision to eliminate the excess tissue. The amount of scared, fibrotic and de-vascularized skin with its underlying fat varied in relation with the hernia size. Abdominoplasty was not routinely performed.

Functional evaluation

The standard method for indirectly measuring intra-abdominal pressure (IAP) is to measure the intra-vesical pressure [12]. Briefly, the bladder drainage system was clamped just distally to the connection of the urinary catheter to the

drainage bag. An 18-gauge needle was then inserted into the sampling port and connected via a sterile tube to the pressure transducer using two three-way stopcocks. A standard infusion bag of normal saline was attached to one stopcock, and a 60-ml syringe was connected to the second stopcock. Sterile saline (50–100 ml) was injected into the bladder. Measurements were taken at end-expiration while patients were in complete supine position and with the transducer zeroed at the symphysis pubis level. Intra-abdominal pressure was recorded before surgery, immediately after the end of the procedure, 24, and 48 h after TAR on the awakened patient. Intra-abdominal hypertension (IAH) is defined by a sustained or repeated elevation in IAP ≥ 12 mmHg. IAH was graded as follows: Grade I, IAP = 12–15 mmHg; Grade II, IAP = 16–20 mmHg; Grade III, IAP = 21–25 mmHg; and Grade IV, IAP > 25 mmHg [13]. Likewise, abdominal compartment syndrome (AbCS) was defined as IAP > 20 mmHg in combination with at least one organ failure.

Plateau pressure (P_{PLAT}) is the pressure applied to small airways and alveoli during positive-pressure mechanical ventilation. It is measured during an inspiratory pause on the mechanical ventilator and it was recorded after 20 min since the onset of the procedure and 20 min after the anterior fascia was closed. The difference between the first and last record of the plateau pressure was noted as Δ plateau pressure.

The main outcomes of interest were 30-day wound events and general complications including 90 days mortality. Post-operative wound events included Surgical Site Infection (SSI), Surgical Site Occurrence (SSO), and Surgical Site Occurrences Requiring Procedural Intervention (SSOPI). According to the Centre for Disease Control and Prevention (CDC), SSI was defined as superficial, deep or organ space [14]. Surgical Site Occurrence included any SSI, in addition to wound cellulitis, non-healing incisional wound, skin or tissue ischemia, skin or soft tissue necrosis, fascial disruption, serous or purulent wound drainage, stich abscess, seroma, hematoma, infected or exposed mesh, enterocutaneous fistula. Procedural interventions which were considered SSOPI included wound opening and/or debridement, stich removal, percutaneous drainage, partial and/or complete mesh removal [14]. Length of hospital stay, 30-day readmission and mortality were also analyzed. Patients having multiple wound complications such seroma and infection, dehiscence and infection, were classified as were classified as the most severe. The follow-up for this study was short and extended for 90-days for all patients.

Statistical analysis

Descriptive statistics for approximately normally distributed continuous variables are presented as mean \pm standard deviation, otherwise the median and quartiles are displayed. The

numbers and percentages are shown for categorical data. The observed percentage with 95% Clopper–Pearson exact confidence interval are displayed by group.

Baseline and univariate differences between the groups were assessed by the two-sample *t*-test for approximately normally distributed continuous variables, the Kruskal–Wallis test for skewed continuous data and the Chi-squared test for categorical data.

Multivariable logistic regression models were fitted for binary endpoints and the adjusted odds ratio for surgery type (using ACS as the reference level) and adjusted *p*-value displayed. First, type of surgery was forced into the model. Then confounders entered the model, stepwise, if their *p*-value for entry was < 0.05 and remained in the model if their *p*-value for removal < 0.10 . The following potential confounders are considered: sex, environment, diabetes, obesity, COPD, CVD and smoking history, ASA, location, plateau pressure day, age, BMI, recurrence, occurrence, length, width and surface area of the defect, IHV, PV, preoperative IAP, postoperative IAP, day 1 IAP, day 2 IAP, change in plateau pressure, operation time The receiver operated characteristics (ROC) curves and area under ROC (AUROC) were used to assess the model goodness of fit.

Statistics were performed using the statistical package SAS, version 9.4. All tests were two-sided with a significance level displayed without multiplicity adjustment.

Results

Two hundred and two patients (101 from each group) met the inclusion criteria and consented to be included in the research (Fig. 1). The patients undergoing component separation were examined for differences in preoperative factors (Table 1). There was no difference in gender, BMI, and ASA score ($p > 0.05$ for each). Patients in the ACS were younger than in the PCSTAR (mean age 59.13 ± 11.21 years vs. 63.00 ± 6.78 years; $p = 0.021$). There were major differences between the groups in terms of comorbidities, the patients of PCSTAR group being more comorbid (Table 1). Previous hernia repair has been performed in 71 (70.3%) and 27 (26.7%) patients in the ACS and PCSTAR groups, respectively ($p < 0.001$). For the detailed rank of recurrences, see Table 1. No patient had a previous component separation with or without mesh. In 42 patients (29 in ACS group) the recurrence was recorded after a mesh repair. According to pre-operative file reports the mesh was located as an on lay in 27 patients (19 in the ACS group), as a sub-lay in three (all of them in the PCSTAR group) and preperitoneal in the rest of them (all in the PCSTAR group).

Hernia characteristics in terms of length, width, defect surface and volumetry showed larger values for the PCSTAR patients with a significant difference for all of

them (Table 2). Loss of domain (Sabbagh index higher than 0.25) was recorded in 179 patients (78.62%). One hundred and five were with a Sabbagh index between 0.26 and 0.33 (35 in the ACS group and 70 in the PCSTAR group), and 74 (36.63%) with an index larger than 0.33 (48 patients in the ACS vs. 26 in the PCSTAR). The mean preoperative intra-abdominal pressure was 7 mmHg for the ACS group (Q1–Q3 = 5–8) compared to 6 mmHg for the PCSTAR patients (Q1–Q3 = 5–8) ($p = 0.059$).

The median operative time was significantly longer for patients undergoing PCS (110 min vs. 190 min; $p < 0.001$) (Table 3). There was a significant statistical difference in intraoperative complications with more complications occurring in ACS group compared to PCSTAR (15.84% vs. 6.93%; $p < 0.01$). At the end of the procedure, mean IAP was equal for both group of patients but significantly higher after 24 h in patients from the PCS group (16.72 vs. 18.18; $p < 0.001$). The median overall length of hospital stay was longer for ACS patients [9.0 days (Q1–Q3 = 7–11)] compared to PCSTAR patients [7 days (4–10)]; ($p < 0.001$). Post-operative length of stay for each group had median of 6 days, but different distributions ($p = 0.031$). Longer postoperative stays are associated with the ACS group.

There was no difference between groups for Intensive Care Unit (ICU) stay ($p = 0.829$).

Outcomes

1. *Overall length of hospital stays greater than 7 days:* In univariate analysis, 117 events were recorded (72 for patients with ACS; $p = 0.0001$). The final model includes the type of surgery and log (OR time) with high specificity and sensitivity [area under curve (AUROC) = 0.7291; $p < 0.0001$; no outliers]. There was a significant difference between the surgeries adjusting for the confounders (type of surgery OR = 0.070; 95% CI 0.026–0.191; $p < 0.001$ and log (OT in minutes) OR = 7.850; 95% CI 2.901–21.242; $p < 0.001$).
2. *Postoperative hospital stay:* Univariate analysis showed 34 events for patients with ACS and 36 for patients with PCSTAR; there was no significant difference between the groups ($p = 0.7674$). The final model includes surgery, log (OT in minutes) (*p*-value for entry = 0.0028), and BMI (*p*-value for entry = 0.040). There was a reasonable specificity and sensitivity for the model (AUROC = 0.6442; $p = 0.0003$; no outliers). A significant difference between the surgeries adjusting for these confounders was recorded.
3. *Intensive Care Unit stay:* for Intensive Care admission (yes/no) univariate analysis showed no differences between the number of patients included in the ICU (11 patients in ACS group vs. 12 patients for PCSTAR; $p = 0.8247$). The multivariable logistic regression model



Fig. 1 Flowchart of patient selection according to exclusion criteria. ACS, Anterior Component Separation; PCS, Posterior Component Separation

was created for the types of surgery, log (OT in minutes), smoking, and fitted reasonably well (AUROC 0.7236; $p < 0.0001$). There is a significant difference between the surgeries adjusting for the confounders (type of surgery OR—0.287; 95% CI 0.084–0.976; $p = 0.046$ and log (OT) OR—6.093; 95% CI 1.462–25.392; $p = 0.013$). When comparing active smokers with non-smokers a threefold increase in ICU admission was found despite the type of surgery (OR—3.313; 95% CI 1.136–9.663; $p = 0.028$).

4. *Acute respiratory failure (ARDS)*: eleven events were recorded in univariate analysis (5.44% of all patients) equally distributed in both groups (6 patients for ACS group and 5 patients for PCSTAR group). No significant

difference between groups was found ($p = 0.757$). The logistic regression final model includes besides type of surgery, preoperative IAP (p -value for entry 0.0106) and obesity (p -value for entry 0.0133) with a high sensitivity and specificity for confounders (AUROC = 0.822; $p < 0.0001$) and no outliers. There is no significant difference between the surgeries adjusting for the confounders. Adding preoperative IAP quartiles and the transformation of the raw data in the stepwise selection model did not reveal different data for this endpoint (data not shown).

5. *Seroma*: nineteen events (18.81%) were recorded for ACS group of patients and only 15 for PCSTAR (14.85%). There was no significant difference between

Table 1 Demographic characteristics of included patients

Variable	ACS group (N= 101)	PCSTAR group (N= 101)	p-value
Age (years)	59.13 ± 11.21 (23–78)	63.00 ± 6.78 (43–79)	0.003
Gender (M/F)	65/36	56/45	0.196
BMI (kg/m ²)	30.63 ± 5.616 (17–47)	31.73 ± 4.219 (25–48)	0.117
Occurrence (months)	36.0 (17.0–107.0)	52.0 (34–84.0)	0.090
Recurrence	1.00 (0–2)	1.00 (0–1)	0.0001
1st recurrence	35 patients	8 patients	
2nd recurrence	22 patients	8 patients	
3rd recurrence	8 patients	8 patients	
4th or more	6 patients	3 patients	
ASA	1–2 (2.0%)	1–4 (4.0%)	0.858
	2–41 (40.6%)	2–39 (38.6%)	
	3–43 (42.6%)	3–44 (43.6%)	
	4–15 (13.9%)	4–14 (13.9%)	
Comorbidities			
Diabetes	16 (15.8%)	48 (47.5%)	<0.0001
Obesity	36 (36.5%)	67 (66.3%)	<0.0001
CVD	65 (64.4%)	52 (51.5%)	0.087
COPD	7 (6.9%)	18 (17.8%)	0.033
Smokers	6 (5.9%)	25 (24.8%)	<0.0001

BMI, Body Mass Index; ASA, American Society of Anesthesiologists Classification; CVD, Cardiovascular Diseases, COPD, Chronic obstructive Pulmonary Disease

Table 2 Preoperative characteristics of hernias

Variable	ACS group (N= 101)	PCSTAR group (N= 101)	p
Length (cm)	14.0 (11.0–16.00)	18.0 (15.0–21.0)	<0.001
Width (cm)	14.0 (10.0–17.0)	17.0 (15.0–19.0)	<0.001
Surface (cm ²)	130.0 (113.0–173.0)	236.0 (184.0–307.0)	<0.001
ACV (cm ³)	6788.0 (5209.0–8589.0)	9712.0 (8459.0–9914.0)	<0.001
IHV (cm ³)	2867.0 (2198.0–3900.0)	4274 (3763.0–4907.0)	<0.001
PV (cm ³)	9956.0 (7828.0–12,171.0)	13,885.0 (12,315.0–14,827.0)	<0.001
Sabbagh Index (IHV/PV)	0.31 ± 0.066	0.31 ± 0.038	0.345
< 0.250	18 patients	5 patients	
≥ 0.250–≤ 0.330	35 patients	70 patients	
≥ 0.330	48 patients	26 patients	
Preoperative IAP (mmHg)	7 (5–8)	6 (5–8)	0.059

ACV, Abdominal Cavity Volume; IHV, Incisional Hernia Volume; PV, Peritoneal Volume; IHV/PV, Sabbagh Index; IAP, Intra-abdominal Pressure

Table 3 Operative time and postoperative pressure data

Variable	ACS (N= 101)	PCSTAR (N= 101)	p
Or time (minutes)	110.0 (85.0–140.0)	190.0 (177.0–243.0)	<0.001
Postoperative IAP (mmHg)	15.0 (12.0–16.0)	15.0 (12.0–16.0)	0.290
POD 1 IAP	16.72 ± 2.68	18.18 ± 2.84	<0.001
POD 2 IAP	14.04 ± 2.11	14.88 ± 3.56	0.043
Preoperative Plateau pressure	16.0 (14.0–18.0)	14.0 (12.0–17.0)	0.017
Postoperative plateau pressure	20.0 (18.0–23.0)	19.0 (17.0–21.0)	0.133
Delta plateau	4.36 ± 1.46	5.07 ± 1.29	<0.001

OR time, Operative time; IAP, Intra-abdominal Pressure; POD, Postoperative day; Delta plateau, Difference between Postoperative Plateau Pressure and Preoperative Plateau Pressure

- groups ($p=0.452$). For the final model obesity with a BMI over 35 kg/m² (p -value for entry 0.0236), age (entry $p=0.0408$) and diabetes (entry $p=0.0451$) were included. The model fits reasonably well with moderate sensitivity and specificity (AUROC = 0.6857; $p=0.0002$) and no outliers. There is no significant difference between the surgeries adjusting for the confounders.
6. **Hematoma:** overall 29 events were reported (12 patients after ACS and 17 for PCSTAR) without significant difference between groups ($p=0.316$). No confounders were added, the final model including only the type of surgery with a moderate sensitivity and specificity (AUROC = 0.5503). There is no difference in the incidence of hematoma according to the type of abdominal wall reconstruction (OR—1.501, 95% CI 0.677–3.330; $p=0.318$)
 7. **Surgical Site Infection:** In univariate analysis, we record 12 patients with SSI in the ACS group (11.88%) versus 6 for the PCSTAR group (5.94%). The difference between groups was insignificant ($p=0.318$). The main confounder with predictive value included for logistic regression was OT in minutes (p entry value 0.0099). The model fits reasonably well with no outliers (AUROC = 0.6955; $p=0.0058$). There was a significant difference between the surgeries adjusting for the confounders ($p=0.009$) favouring PCSTAR. The analysis was extended to logarithmic transformation in the logistic regression model which included log (OT in minutes $p=0.022$) and the IAP from the second postoperative day. There was an increased sensitivity and specificity for this model (AUROC = 0.7156; $p=0.0014$). An increased statistical difference was found between the surgeries (OR—0.114; 95% CI 0.026–0.492; $p=0.004$). The operative time (OR—6.022; 95% CI 1.370–26.466; $p=0.017$) and the second day IAP (OR—1.196; (95% CI 0.995–1.437; $p=0.056$) were independent predictors for SSI in logistic model.
 8. **Skin necrosis:** there was no significant difference between groups related to this complication in the univariate model (11 events for ACS group vs. four for PCSTAR group— $p=0.060$). The final model includes the types of surgery and the cardiovascular diseases with a higher specificity and sensitivity (AUROC = 0.7098; $p<0.0001$). No significant difference between the surgeries adjusting for the confounders (OR—0.386; 95% CI 0.117–1.276; $p=0.119$) was identified. Cardiovascular diseases were the only independent predictors for skin necrosis.
 9. **Bowel regulation:** Only 43 patients in ACS group and 30 in the PCSTAR group resumed their intestinal movements within the first 48 h. There was no significant difference between groups. The final model includes

log (OT in minutes) (p -value for entry 0.0182) and ASA score ($p=0.0321$). The model fits reasonably well with a good sensitivity and specificity (AUROC 0.677, $p<0.0001$) and no outliers. There was a significant difference between surgeries adjusting for the confounders (OR—0.236; 95% CI 0.099–0.559; $p=0.001$).

A synthesis of all data is represented in Table 4 and Fig. 2.

No mortality was recorded after 90 day-follow-up. Systemic complications included thromboembolic disease (4 patients in ACS group and 3 in PCSTAR group), ileus (12 vs. 21 patients), and prolonged O₂ requirements (11 vs. 7).

Discussion

The component separation techniques both anterior or posterior have gained popularity due to their promising short-and long-term results with acceptable 30-day wound morbidity despite complex and challenging patients. The effectiveness of these techniques was proved by the increased rate of fascial closure so they were quickly accepted as viable options for difficult cases [15]. The proper application of the most effective CST in patients with CIH is still a debate; choosing the optimal surgical procedure and space of mesh implantation for the proper patient and by the proper surgeon are paramount [16]. The open approach is still widely used despite the development of a large variety of minimally invasive (laparoscopic or robotic) approaches that are presumed to limit wound morbidity [5, 17, 18]. Our study, focused on patients with large midline abdominal wall defects, evaluated the early outcomes of patients with lay ACS and PCSTAR and this is probably one of the few multi-centric analyses comparing the procedures.

Demographic data showed that our groups were homogeneous in terms of gender, obesity, and ASA score; patients in the PCSTAR were older and more comorbid but with fewer recurrences than patients in ACS group. The incidence of smoking was higher in PCSTAR patients. Our results are somehow, opposite with Krpata's study in which PCSTAR patients were younger, with a lower mean ASA score, and with more male patients [19]. In 2021, Pereira-Rodriguez et al. in large number of patients from Spanish Registry of Incisional Hernia (EVEREG), reported equal obese patients, equal comorbidities but more high-risk patients with larger defects for ACS patients [20].

Overall, in the univariate analysis there was no significant difference regarding the incidence of local wound complications (54 patients in ACS group vs. 33 in PCSTAR group; $p=0.061$). The same results were obtained comparing groups for specific complications (seroma, hematoma, SSI, and skin necrosis). Our results are similar to

Table 4 Postoperative events as unadjusted and adjusted data

	ACS (N=101)	PCSTAR (N=101)	Unadjusted <i>p</i> -value	AUROC (95% CI)	Adjusted odds ratio (95% CI)	Adjusted <i>p</i> -value
Overall length of hospital stay > 7 days	71.3% (61.4, 79.9)	44.6 (34.7, 54.8)	<0.001	0.7291 (0.660, 0.798)	0.070 (0.026, 0.191)	<0.001
Postoperative hospital stay > 7 days	33.7% (24.6, 43.8)	35.6% (26.4, 45.8)	0.767	0.644 (0.567, 0.721)	0.410 (0.178, 0.945)	0.036
Intensive care unit admission	10.9% (5.6, 18.7)	11.9% (6.3, 19.8)	0.825	0.724 (0.629, 0.818)	0.287 (0.084, 0.976)	0.046
Acute respiratory distress syndrome	5.9% (2.2, 12.5)	5.0% (1.6, 11.2)	0.757	0.822 (0.730, 0.914)	0.398 (0.105, 1.509)	0.176
Seroma	18.8% (11.7, 27.8)	14.9% (8.6, 23.3)	0.452	0.686 (0.589, 0.782)	0.887 (0.370, 2.125)	0.788
Hematoma	11.9% (6.3, 19.8)	16.8% (10.1, 25.6)	0.316	0.550 (0.452, 0.649)	1.501 (0.677, 3.330)	0.318
Surgical site infection	11.9% (6.3, 19.8)	5.9% (2.2, 12.5)	0.138	0.716 (0.584, 0.848)	0.114 (0.026, 0.492)	0.004
Skin necrosis	10.9% (5.6, 18.7)	4.0% (1.1, 9.8)	0.060	0.710 (0.605, 0.815)	0.386 (0.117, 1.276)	0.119
Bowel regulation > 2 days	42.6% (32.8, 52.8)	29.7% (21.0, 39.6)	0.057	0.678 (0.598, 0.757)	0.236 (0.099, 0.559)	0.001

ACS, Anterior Component Separation; PCSTAR, Posterior Component Separation; CI, Confidence interval

Pereira-Rodriguez et al. who found equal distribution of Surgical Site Occurrence, seroma, and hematoma; there were more wound infections and skin necrosis in patients with ACS (10.6% vs. 7.0%, $p=0.05$, respectively 4.4% vs. 0.1%, $p<0.001$) [20]. Krpata reports more complications in ACS group while Blair found that PCSTAR was associated with less infections but without any significant difference ($p=0.07$) [19, 21].

A very interesting and somehow controversial finding of this study was the fact that, contrary to what we expected, no hernia related factors were independently associated predictors with local complications. It was expected that the width of the defect to be highly correlated with local complications but this was not observed with our patients. Franklin et al. showed in 2013 that the patients defect in relation to abdominal wall circumference is a more reliable prediction factor; associated with the dynamic value of the patient specific anatomy and compliance it could better predict the onset of wound complications. The same authors demonstrated that fascial approximation decreased for every incremental increase in defect diameter [22]. In our patients mean width defects of 14 respective 17 cm were completely closed with the aid of medial translation provided only by the component separation technique. PCSTAR medialization effect was larger than for the ACS and is in accordance with Majumder et al. which results from a cadaveric study [23]. After a complete PCSTAR with large retro-muscular dissection, an average advancement of 10 cm for the anterior fascia and 11 cm for the

posterior fascia on each side was obtained. This can provide a significant increase of the abdominal cavity inner diameters and, subsequently, an increase of the whole visceral sac volume, without or with minimal consequences upon normal physiology [24]. The reduced mean value of postoperative plateau pressure in patients with PCSTAR is a valid proof of the effectiveness of this advancement compared to ACS even if in the first postoperative day IAP pressure was higher.

Acute respiratory failure was the main reason for ICU admission but unusually, it was not influenced by hernia related factors. Smoking was the only factor associated with this and increased threefold the probability for ICU admission compared with non-smoking patients. Even if in the PCSTAR there were more active smokers than in the ACS group, the number of respiratory complications was similar. Similarly, smoking was not involved as a potential risk factor for wound complications. This is in accordance with the study of Lindmark et al. who demonstrated that smoking is an influencing factor of poor outcomes after IH repair [25]. On the other hand, recently Gräsbec et al. in a large population study (the sample included 158 638 surgeries) have demonstrated that smokers have increased odds of overall complications (OR = 1.17; 95% CI 1.14–1.20) and critical complications (OR = 1.21; 95% CI 1.14–1.29). Corresponding odds ratios of ex-smokers were 1.09 (95% CI 1.06–1.13) and 1.09 (95% 1.02–1.17). Smokers had increased odds of overall complications in all specialties with over 10 000 surgeries [26].

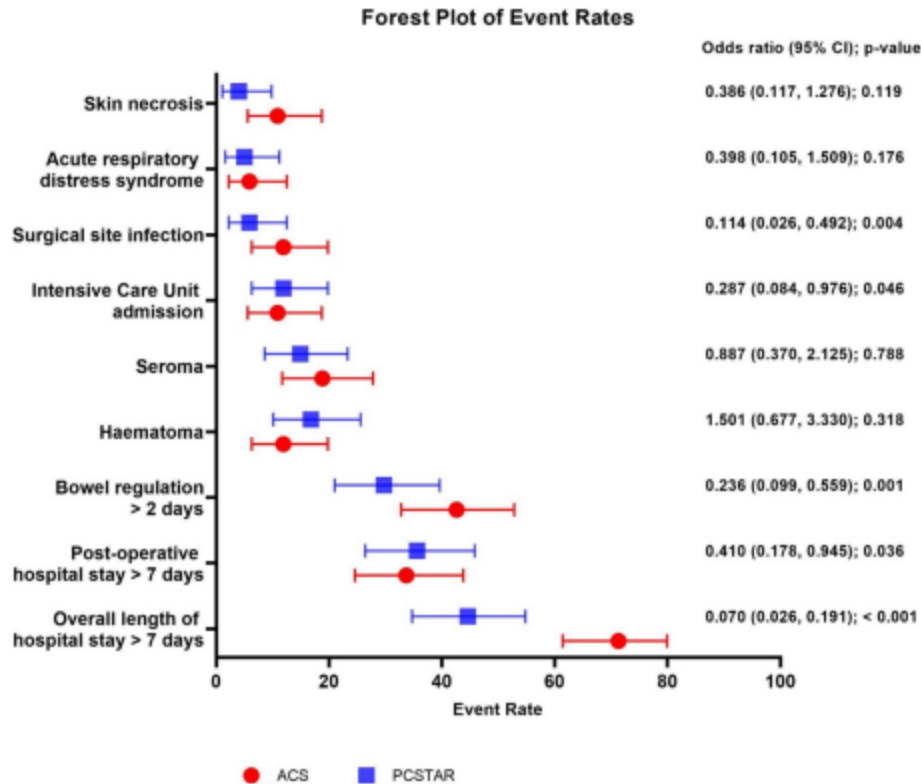


Fig. 2 Forest plot shows event rates with odds ratio results as text. It is currently ordered by increasing event rate in the PCSTAR group

The type of surgery was an independent factor for complications only when it was associated with other confounders (operative time and IAP for SSI); there was no specific statistically significant difference between groups of patients related to the type of the procedure. The results are difficult to explain because we record longer operative time in PCSTAR patients with similar SSI, which is contradictory. Probably the association with a better optimization led to better results.

Obesity, known as a modifiable risk factor which increases rates of SSI, was in our study highly associated only with seroma formation and only when BMI was higher than 35 kg/m².

The operative time was the only variable responsible for more poor outcomes than the traditional well documented risk factors. In a recent meta-analysis and systematic review Cheng et al. examined the relation between operative duration and incidence of SSI across surgical specialties [27]. Without any direct reference to incisional hernia, pooled analyses demonstrated that the likelihood of SSI increased

by close to twofold in surgeries exceeding operative cutoff times of one, two, three, or four hours, and close to threefold in surgeries exceeding five hours. Interestingly, pooled analyses further demonstrated that the odds of developing an SSI increased with increasing operative time increments. This relation typically remained statistically significant across categories of time. For example, the likelihood of SSI was observed to increase by 5% for every 10 min of surgery, 13% for every 15 min of surgery, 17% for every 30 min of surgery, and 37% for every 60 min of surgery. The studies reporting mean operative time for patients with and without SSI, patients who developed an SSI had a mean duration that was, on average, 0.82 h–1.13 (median = 0.5 h) longer than those without SSI. In our study, patients with PCSTAR had a mean longer operative time which demonstrates a more complex procedure. It was interesting that the longer operative time associated with PCSTAR was not associated with an increased rate of SSI and we do not have a valid explication for this. Although operative time is mentioned as a significant predictor in some reviews, there is a poor understanding

of how this risk factor varies across surgery types, the magnitude of the association, and the relation between increasing increments of operative time and SSI [28–30].

Finally, we acknowledge that our study has some limitations. Even if it is the result of the collaboration between two surgical departments, its retrospective nature is always subject to data entry errors and misinterpretation. Another limitation is the selection of the patients; in our study, we only include midline hernias and patients with complete fascial closure which can represent a potential bias for the result. Likewise, a potential bias for inordinate results can be the level of expertise all data being collected from a limited number of surgeons with large patient volume. The accurate comparative analysis of ACS and PCSTAR is difficult to be standardized in terms of preoperative evaluation, defining outcomes, and interpretations. We can also consider as a limitation the risk of over treating, especially in ACS group of patients. Another limitation is the short follow-up period. We considered in our report only immediate outcomes because we cannot evaluate the accuracy of long-term outcomes for the patients with ACS; the protocol of follow-up in patients with PCS was not superimposed with the protocol of ACS. Last, no emergency operation was included and this is a serious bias for the quality of the results being known that the rate of complications and mortality in this particular situation is almost double.

Conclusion

Our study demonstrates once again that complex incisional hernia repair is a challenge given by a large prevalence of wound complications. Choosing between ACS and PCSTAR is still a source of significant debate. We were not able to depict significant different rates of complications between the procedures and we could not find any specific factor related to complications. The operative time and obesity were factors related to more than two wound complications. Future controlled comparative trials with standardized outcome measures, particularly regarding the report of wound morbidity, are recommended to confirm our conclusions.

Author contributions MT, VO, MG, CM: surgical procedures database, study conception and design, acquisition, analysis and interpretation of data, drafting the work and revising, final approval of the version to be published; HS: statistical analysis and interpretation of data, final approval of the version to be published; OA, CEB, and OG: drafting the paper and final approval of the version to be published;

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Data availability Data are available and can be provided by the corresponding author by request.

Declarations

Conflict of interest All authors declare no conflict of interest.

Ethical approval All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Human and animal rights No animal was used for this study.

Informed consent Informed written consent was obtained from all patients before surgery.

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Quality of life and abdominal wall functionality after abdominal wall reconstruction: A prospective single center follow-up study

M Toma^{1,2} · V Oprea^{1,3} · Florentina Scarlat¹ · Carmen Elena Bucuri^{1,3} · O Andercou^{3,4} · F Mihaileanu^{3,4} · O Grad^{1,3} · M Rosianu⁵ · C Molnar^{2,6}

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Abstract

Background Fascial breakdown with the occurrence of an incisional hernia (IH) is an important and challenging complication of any laparotomy. For a long time, the success of the abdominal wall reconstruction (AWR) was measured only from the surgeon's perspective by defining outcome measures such as wound morbidity and recurrence. The understanding that complete recovery is difficult to assess without considering patients has shifted the paradigm of optimal outcomes to Patient Reported Outcome Measures (PROMS) and Quality of Life (QoL), which are pivotal to evaluate the success and efficacy of AWR.

Methods We conducted a prospective follow-up study of 91 patients undergoing mesh-augmented abdominal wall reconstruction for primary or recurrent incisional hernia between January 2021 and December 2023. Demographic data, comorbidities, and hernia characteristics were recorded. All patients were evaluated preoperatively by a native abdomino-pelvic CT scan to assess the characteristics of hernia (length, width, surface, and volume of the incisional hernia sac and of peritoneal cavity), the presence of mesh (if previously inserted), and abdominal wall muscles status. All interventions were performed by the same surgical team according to the techniques described by Rives – Stoppa (RS), Ramirez (ACS), and Novitsky (PCS). Abdominal wall function was assessed using trunk raising (TR) and double leg lowering (DLL) measurements performed preoperatively, 1 month, 6 months, and 1 year postoperatively. At the same time, pre- and post-operative quality of life was analysed using the EQ-5D score.

Results Mean age of 59.42 ± 12.28 years and a male/female ratio of 35/56 were recorded, most of them being obese. There were 36 (42%) patients with defects larger than 10 cm. The distribution of the type of surgical intervention was: RS 35 patients, ACS 13 patients, and PCS 43 patients. The mean value of combined score for the preoperative abdominal wall functionality was 4.41 ± 1.67 (2–8) while the mean value of preoperative EQ-5D index was 0.652 ± 0.026 (-0.32–1.00). QoL was poor and very poor for 48% (44) of the patients who recorded index values less than 0.56 (50% percentile). Preoperative EQ-5D index was highly correlated with Combined AWF score ($r=0.620$; $p<0.0001$) and the correlation was specific (AUC = 0.799; $p<0.0001$; asymptotic 95%CI = 0.711–0.923). At 12 months, the AWF score increased to 8.13 ± 2.58 (1–10) and the QoL total score to 0.979 ± 0.007 (0.71–1). Good and very good total scores for QoL were recorded for 47 patients (84%) compared to 33 (36%) in the preoperative evaluation (χ^2 with Yates continuity correction for two degrees of liberty = 46.04; $p<0.00001$).

Conclusion Our results suggest that patients can expect to see a significant overall improvement in all five components of QoL measured with the help of Eq. 5D questionnaire. This improvement is dependent by hernia size, and some individual patient's factors (diabetes, cardiovascular diseases, and age over 60 years).

Keywords Truncal function · Incisional hernia · EQ-5D score · Rives-Stoppa · ACS · PCS · Quality of life

Extended author information available on the last page of the article

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Background

Fascial breakdown with the occurrence of an incisional hernia (IH) is an important and challenging complication of any laparotomy. Estimated rates may be as high as 40% in high-risk patients 2 years after midline incision [1, 2].

For a long time, the success of the abdominal wall reconstruction (AWR) was measured only from the surgeon's perspective by defining outcome measures such as wound morbidity and recurrence [3]. Beyond this, the results of hernia surgery should be complete recovery with a sound, functional abdominal wall [4]. The understanding that complete recovery is difficult to assess without considering patients has shifted the paradigm of optimal outcomes to Patient Reported Outcome Measures (PROMS) and Quality of Life (QoL), which are pivotal to evaluate the success and efficacy of AWR. QoL and recovery of activities of daily living have rapidly become key outcome measures in the field of hernia surgery over the last decade [1, 5].

Assessing QoL in IH repair is challenging, because not all surveys are equally created and may not provide the same amount of information [6]. Many hernia – specific or non-specific instruments have been developed and are available to assess functional health status; a recent review described 14 tools across 32 studies [7]. Six AWH-specific tools were identified through an extensive literature search [8–12] but none of them has been universally accepted and none become dominant [11]. Acceptability (completion rates), reliability (how will a measure will provide similar values for patients with similar QoLs), and validity (how accurately reflects what is supposed to measure) are influential factors that can jeopardize the accuracy of QoL evaluation.

We hypothesize that patients with IH despite the size and location of the defect demonstrate varying degrees of abdominal wall function (AWF) impairment and decreased QoL because of this. Our study aimed to explore how AWF and QoL are improved after different types of AWR. The second goal was to identify which pre – and postoperative factors are independently related and influence QoL.

Materials and methods

Patients

We conducted a prospective follow-up study of consecutive patients undergoing abdominal wall mesh augmented reconstruction for primary or incisional hernia between January 2021 and December 2023. The paper's senior authors (MT and OV) carried out the follow-up examination. All the included patients were over 18 years old with primary or recurrent incisional hernias and agreed to participate after

the informed consent and if they completed the preoperative and at least one postoperative quality assessment form. Subsets of umbilical, trocar site, emergent cases, and parastomal hernias were excluded. In addition, patients who refused to participate and those in whom a mesh repair could not be performed (VHWG type 4 – infected mesh patients) were excluded.

Written informed consent was obtained for each patient. The study was carried out under approval Ad 4528–9/25.11.2020 of the Local Ethic Committee. Demographic data (age, gender, ASA classification, Body Mass Index-BMI, comorbidities) and hernia characteristics (previous hernia repair, defect location, dimensions and surface, type of procedure) were recorded from the data files. All patients were evaluated preoperatively by a native abdomino-pelvic computerized tomography (CT) to assess the characteristics of hernia (length, width, surface, and volume of the incisional hernia sac and of peritoneal cavity), the presence of mesh (if previously inserted), and abdominal wall muscles status (width of the rectus muscle for retro-rectal space evaluation, the width and length of the lateral muscles). The full investigational protocol has been reported elsewhere [13]. CT scanning was repeated in each patient after Dysport and pneumoperitoneum administration to assess the effectiveness of procedures.

Surgical procedure

All patients had intravenous and antithrombotic prophylaxis according to anesthesiologist protocol. Preoperatively, when Sabbagh index was larger than 0.25, the abdominal wall was optimized with the aid of chemical components separation with Botulin Toxin A (Dysport™ Ipsen Pharma 500 IU) injection according to Ibarra – Hurtado technique [14]. Dysport was administered 4 to 6 weeks preoperatively in order to obtain the maximal effect. When larger defects were associated with irreducibility of the hernia, Progressive Preoperative Pneumoperitoneum (PPP) was performed according to a previously described technique [15]. Duration and volume of insufflated air were variable in accordance with local conditions.

All surgical repairs were performed under general anesthesia by the same surgeons (OV and MT) according to the techniques described by Rives - Stoppa [16], Ramirez [17], and Novitsky [18]. The indication for one of the procedures was consistent with the anatomy of the defect and the anatomy of the abdominal wall. After adhesiolysis, the peritoneal sac was dissected, preserved until the final evaluation of the possibility of fascial closure, and the abdominal wall reconstructed. Whenever encountered, the previous mesh was completely removed when possible.

The abdominal wall was reinforced with a medium weight macroporous monofilament polypropylene placed as sublay or as an on lay. The mesh surface varied between 3-to-5-fold defect area respecting the principles of Mesh Defect Area Ratio (MDAR) [19, 20]. The mesh was held in place with synthetic glue fixation (Histoacryl™ B Braun). All patients were drained with two suction drains on the top of the mesh until the volume of the liquid was less than 30 ml for two consecutive days. Excess skin was removed after anterior fascia closure without routine abdominoplasty. Early mobilization was encouraged postoperatively, and discharge was performed after adequate oral intake and pain control with oral analgesics. The drains were removed when the drainage was less than 30 ml for two consecutive days (usually after discharge if the recovery was uneventful).

Abdominal wall functional (AWF) evaluation

The function of the reconstructed linea alba was evaluated with the aid of previously reported trunk raising (TR) and double leg lowering (DLL) [21]. The test has proven its reliability and we decide to continue using it. A team of two examiners performed all measurements (OV and MT), each performing both assessments. The combined scores (composite or total scores) represent the AWF value and are summarized in Table 1. The AWF measurement was done preoperatively, at 1 month, 6 months, and one –year postoperatively.

Quality of life (QoL) evaluation

The EQ-5D is a concise, generic measure of self-reported health, developed by EuroQol group [22, 23]. Designed as a self-completion questionnaire, it embodies two components, a health state description followed by an evaluation. The '5D' in its name refers to its use of five dimensions to describe health states domains: Mobility (M), Usual Activities (UA), Self-care (SC), Pain & Discomfort (PD) and Anxiety & Depression (AD). A verbal 5-point rating scale that allows the distinction of five levels ('5 L') of severity assesses them: Level 1: no problems; Level 2: slight problems; Level 3: moderate problems; Level 4: severe problems; Level 5: extreme problems per dimension and providing a 1-digit number for each dimension. The descriptive system,

Table 1 Abdominal Wall Functionality Combined score evaluation (the combined score is the sum of the value of trunk raising (TR) and double leg lowering (DLL))

Trace	1–2
Poor	3–4
Fair	5–6
Good	7–8
Normal	9–10

is shown in Fig. 1. Respondents were asked to tick boxes to indicate the level of problem they were experiencing on each of the five dimensions. The combination of these ticks under each dimension describes that person's EQ-5D self-reported health state, often called an 'EQ-5D profile'. Each level of problem experienced is rated from one to 5 points according to self-experienced severity (one – no problem, five - severe problems). Only one case must be completed. The digits for the 5 dimensions health states were directly converted into Romanian-specific single index values (utilities) using country specific value sets [22]. This was the basis for the analysis. The second part of the questionnaire is the EQ VAS, so called because it incorporates a Visual Analogue Scale. This captures the respondent's overall assessment of their health on a scale from zero (worst health imaginable) to 100 (best health imaginable).

The test was translated in Romanian and applied to 38 patients with abdominal wall hernias for internal validation in 2020. Cronbach's α was 0.86 suggesting a shared dimensions of the items. For the test – retest reliability, participants completed the questionnaires after 3.9 ± 0.97 h (mean \pm SD) apart. The ICC was found to be 0.87 (95% CI: 0.85–0.9). Based on these data we considered that the test could meet our QoL assessment needs with minimal risk of bias.

Outcomes

The main outcomes of interest were 30-day wound events and general complications including 90 days mortality. Post-operative wound events included Surgical Site Infection (SSI), Surgical Site Occurrence (SSO), and Surgical Site Occurrences Requiring Procedural Intervention (SSOPI). According to the Centre for Disease Control and Prevention (CDC), SSI was defined as superficial, deep or organ space [24]. Surgical Site Occurrence included any SSI, in addition to wound cellulitis, non-healing incisional wound, skin or tissue ischemia, skin or soft tissue necrosis, fascial disruption, serous or purulent wound drainage, stich abscess, Seroma, hematoma, infected or exposed mesh, enterocutaneous fistula. Procedural interventions which were considered SSOPI included wound opening and/or debridement, stich removal, percutaneous drainage, partial and/or complete mesh removal. Length of hospital stay, 30-day readmission and mortality were also analysed. Patients having multiple wound complications such seroma and infection, dehiscence and infection, were classified as the most severe. The follow – up for this study was performed by personal examination of one of the two senior authors. The patients were examined in the outpatient clinic at 1 month, 6 months, 12 months, and yearly or whenever necessary if clinical complaints were described. A recurrence was defined as a bulge at the operative site at any moment of the follow-up;

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about

I have slight problems in walking about

I have moderate problems in walking about

I have severe problems in walking about

I am unable to walk about

SELF-CARE

I have no problems washing or dressing myself

I have slight problems washing or dressing myself

I have moderate problems washing or dressing myself

I have severe problems washing or dressing myself

I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

I have no problems doing my usual activities

I have slight problems doing my usual activities

I have moderate problems doing my usual activities

I have severe problems doing my usual activities

I am unable to do my usual activities

PAIN / DISCOMFORT

I have no pain or discomfort

I have slight pain or discomfort

I have moderate pain or discomfort

I have severe pain or discomfort

I have extreme pain or discomfort

ANXIETY / DEPRESSION

I am not anxious or depressed

I am slightly anxious or depressed

I am moderately anxious or depressed

I am severely anxious or depressed

I am extremely anxious or depressed

Levels of problems reported by respondents on each dimension are coded as follows:

Level 1 = 1

Level 2 = 2

Level 3 = 3

Level 4 = 4

Level 5 = 5

The responses to the EQ-5D-5L can be summarised as a five number string, representing the levels reported on each dimension in the order in which they appear in the questionnaire. This five number string is an EQ-5D profile.

The EQ-5D-5L describes 3,125 possible profiles.

No problems on any dimension = 11111

Unable to/extreme problems on all dimensions = 55555

Moderate problems on all dimensions = 33333

The profile indicated by the ticked boxes in the example on the left = 21325

Fig. 1 EQ-5D-5 L descriptive system. Source: EuroQol Research Foundation. *EQ-5D-5 L User Guide, 2019*. Latest version available from: <https://euroqol.org/publications/user-guides>

clinical suspicion was confirmed by a native CT abdominal – pelvic CT scan. All postoperative data were collected unblinded.

Statistical analysis

Data were tabulated as mean \pm standard deviation (SD). Continuous variables were analysed by ANOVA variance test followed by unpaired two tails Student's *t* test assuming unequal variance and the binary outcomes with the Chi-square (χ^2) test. Pearson correlation coefficients with the regression equation were used to estimate the correlation between different cofounders. Correlations were considered 'strong' if the coefficient value lied between 0.50 and 1, were said to be 'moderate' if the value lied between 0.30 and 0.49; and were considered 'weak' correlations if the coefficient lied below 0.29. Multivariate logistic regression models were built with all the variables as the outcomes

of interest for QoL and AWF, adjusting for identified cofounders. In addition to the variables of interest, the following were included for adjustment: age, rank of recurrence, severity of comorbidities score, BMI, length, width and area of the defect, and pain. Multivariate models were calculated with the linear logistic regression and the results were shown with the Odd's ratio (OR) and the 95% confidence interval (CI). A Receiver Operating Characteristics (ROC) curve was designed to determine the specificity and sensitivity of the cofounders in relation with the total amount of QoL and AWF. Youden index was determined to calculate the optimal cut-off value for each cofounder. Values of the OoL index were associated with the value of the standard error of mean (SEM) [23]. Probabilities smaller than 0.05 were considered as statistically significant. SPSS statistic version 23.0, 2018 (Ch., III) was used to perform the statistical analysis.

Results

Patient characteristics and clinical outcome

In the referred interval of time, 213 patients with incisional hernias of various types and locations were admitted and operated in the Department of Surgery. Of these, 91 met the inclusion criteria, agreed to participate, signed the informed consent and were included in the study (Fig. 2). Most of the patients were obese, 62 of them having a BMI over 30 kg/m². Demographic data, comorbidities and preoperative characteristics are represented in Table 2.

Intraoperatively, the location and dimensions of the defect were confirmed and compared with the preoperative values; there were no significant differences (data not shown). According to the defect width, Rives–Stoppa repair was performed in 35 patients, Anterior Component Separation with on lay mesh reinforcement in 13 patients, and Posterior Component Separation with Transversus Release in 43 patients. Intraoperative details are depicted in Table 3.

Along this period, local and systemic complications were recorded as follow: wound infection – 4 patients (4%), hematoma – 27 (30%), seroma – 26 (29%), skin necrosis – 7 patients (8%), Acute Respiratory Distress Syndrome in 2 patients, and cardiac arrest also in 2. In the ICU were admitted patients with ASA score higher than 3 and with more than two comorbidities. The mean ICU stay was 1.6 ± 1.72 days (1–10 days). Postoperative hospital stay ranged between 4 and 21 days with a mean of 5.52 ± 3.26 days. Global 30-day mortality was encountered in four patients, and it was due to pulmonary embolism, myocardial infarction, and Clostridial severe infection. Complication rates related to surgical procedure is detailed in Table 4. One-year recurrence was 5% (5 patients).

Abdominal wall function and QoL data

At the end of the first year, only 56 patients completely filled out the Quality-of-Life evaluation form.

The mean value of combined score for the preoperative abdominal wall functionality was 4.41 ± 1.67 (2–8) while the mean value of preoperative EQ-5D index was 0.652 ± 0.026 (-0.32–1.00) (see details for each dimension in Table 5). There were no patients with normal abdominal function recorded preoperatively; most of them (48–53%) recorded trace or poor function while only 11 (12%) were with degrees of good functionality. The preoperative QoL was poor and very poor for 48% (44) of the patients who recorded index values less than 0.56 (50% percentile). Only 7% of the patient are recorded with good QoL scores (index values over 0.87–90% percentile). Preoperative EQ-5D index was highly correlated with Combined AWF score ($r=0.620$;

$p<0.0001$) and the correlation was specific (AUC = 0.799; $p<0.0001$; asymptotic 95%CI = 0.711–0.923). Univariate analysis shows a significant positive correlation with the age ($p=0.004$), diabetes ($p=0.012$), cardiovascular diseases ($p=0.016$) and smoking ($p=0.055$). The preoperative QoL index was negatively significantly correlated with the age ($p=0.002$) but the correlation was not specific except for a Youden index of 62.4 years. Length and width of the defect negatively, significantly, and specifically influenced the value of preoperative index (see Table 6). In multivariate logistic regression, the same factors (except smoking) were identified as independent cofounders directly influencing preoperative QoL (Table 6).

At 1 month postoperatively AWF significantly increased compared to the preoperative values (preoperative total score 4.41 ± 1.67 versus 1-month total score 5.62 ± 2.04; $p<0.0001$). The number of patients with fair, good, and normal AWF increased from 43 preoperatively to 68 in the first postoperative month ($\chi^2=8.36$; $p=0.003$). The index score of QoL was generally rated as good and increased to 0.786 ± 0.02 ($p<0.0001$, 95% CI of difference = -4.35 - -2.88) compared with the preoperative value. Comparing with the preoperative values the difference was statistically significant (χ^2 with Yates correction of continuity = 15.89; $p=0.00067$).

Abdominal wall functionality increased at 6 months postoperatively comparing to 1-month value of total score (7.08 ± 1.99 versus 5.62 ± 2.04) ($p<0.01$). Of 65 responders, 50 were with good and normal AWF comparing to 31 at 1 month postoperatively ($\chi^2=22.048$ with Yates correction of continuity; $p<0.00001$). The mean QoL index score at 6 months postoperatively increased to 0.894 ± 0.011 (range 0.56–1) ($p=0.037$) (Fig. 3).

At 12 months, only 56 patients completed the evaluation of AWF and only 48 filled the QoL questionnaire. The AWF score increased to 8.13 ± 2.58 (1–10) and the QoL total score to 0.979 ± 0.007 (0.71–1) (Table 5). Good and very good total scores for QoL were recorded for 47 patients (84%) compared to 33 (36%) in the preoperative evaluation (χ^2 with Yates continuity correction for two degrees of liberty = 46.04; $p<0.00001$).

In the first postoperative month, the mean percent of increase in the quality of life was 42.34 ± 15.93 (range -16.3 – 527%) with 11 patients in the 75% percentile with increases over 30.9%. A significant increase with mean percent of 88.89 ± 23.78 (9.89 – 770%) was achieved after the first postoperative year with 34 patients in the 50% percentile (increases over 35.13%). The most significant increase in QoL was achieved after the first postoperative month ($p<0.0001$, 95% CI of difference -65.15 - -27.95, $t = -5.03$), and a smaller insignificantly one for the rest of the period.

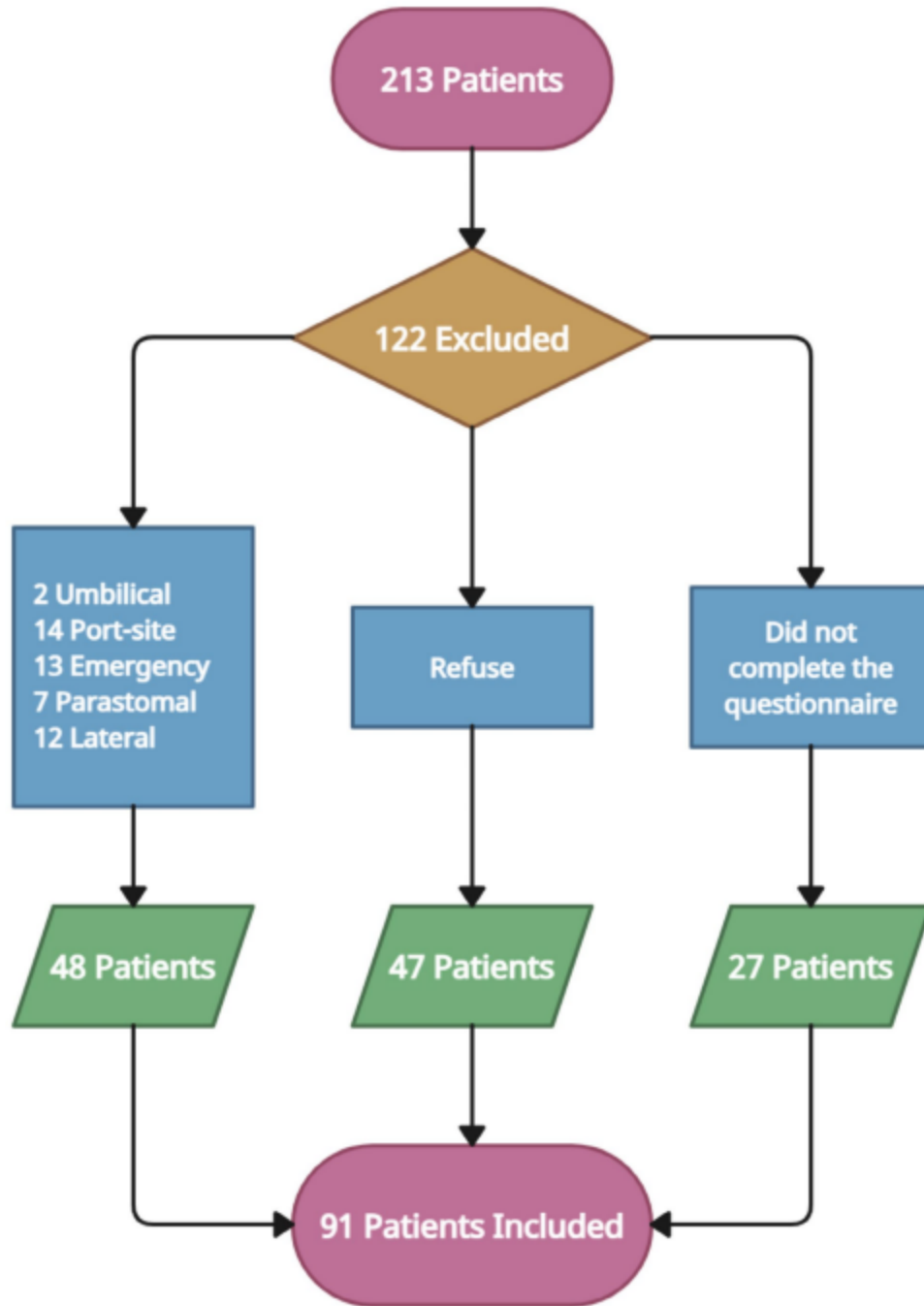


Fig. 2 The flow chart of patient's distribution according to inclusion and exclusion criteria

Table 2 Preoperative demographic characteristics of studied patients. BMI – body Mass Index; COPD – chronic obstructive Pulmonary Disease; CVD – Cardiovascular Disease

Variable	
Age (years) (mean ± SD) (range)	59.42 ± 12.28 (25–80)
Gender (male/female)	35/56
BMI (mean ± SD) (range)	32.02 ± 5.07 (20–47)
Diabetes (%)	27 (30%)
Obesity (BMI > 30 kg/m ²)	62 (68%)
COPD (%)	8 (9%)
CVD (%)	56 (62%)
Smokers (active) (%)	29 (32%)
ASA score (%)	ASA 1–7 (8%) ASA 2–78 (86%) ASA 3–6 (6%)
Recurrence rank	Primary – 21 First – 27 Second – 13 Third – 13 Forth – 12 Fifth – 5
Length of the defect (cm) (mean ± SD) (range)	12.6 ± 6.88 (3–30)
Width of the defect (cm) (mean ± SD)	10.1 ± 5.5 (2–30)

Table 3 Intraoperative details: VHWG (Ventral Hernia Working Group), defect measurement, type of surgery, operative time, estimated blood loss, and intraoperative associated injury rate

Variable	Number (%)
Grade 3 VHWG classification	15 (16%)
Width less/equal than 6 cm	25 (27%)
Width between 6 and 10 cm	28 (31%)
Width over 10 cm	38 (42%)
Rives – Stoppa	35 (38%)
Anterior Component Separation (ACS)	13 (14%)
Posterior Component Separation (TAR)	43 (47%)
Operative time (minutes) (mean ± SD)	150.27 ± 52.99 (60–285)
Rives – Stoppa (R-S)	124.84 ± 34.3 (60–210)
Posterior Component Separation (TAR)	174.37 ± 51.31 (80–285)
Anterior Component Separation (ACS)	148.44 ± 39.43 (80–200)
Estimated Blood loss (ml)	134.5 ± 74.94 (0–350)
Bowel injury	9 (10%)
Urinary bladder injury	2 (2%)

Table 4 Postoperative complication rates related to the procedure

	Wound infection	Hematoma	Seroma	Skin Necrosis	ARDS	Cardiac arrest	Mesh infection	Recurrence
Rives-Stoppa 35 (38%)	0 (0%)	6 (17%)	4 (11%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Anterior Component Separation 13 (15%)	2 (15%)	12 (92%)	13 (100%)	5 (38%)	1 (7%)	1 (8%)	1 (8%)	3 (23%)
Posterior Component Separation 43 (47%)	2 (5%)	9 (21%)	8 (19%)	2 (5%)	1 (2%)	1 (2%)	0 (0%)	2 (5%)
Total: 91	4 (4%)	27 (30%)	26 (29%)	7 (8%)	2 (2%)	2 (2%)	1 (1%)	5 (5%)

Confounders influencing QoL in postoperative period were analysed at 1 and 12 months. At one – month postoperatively QoL was correlated with gender ($p=0.02$ for females), presence of diabetes ($p=0.036$), with the length of the defect ($p=0.05$), presence of wound hematoma ($p=0.05$), ICU stay ($p=0.03$), acute respiratory failure ($p<0.0001$), and preoperative and 1-month total score of AWF (for both $p<0.0001$). Multilogistic regression associated diabetes (OR=0.003, 95% CI=0.004–0.26; $p=0.0012$), length of the defect (OR=0.029; 95% CI=0.003–0.19; $p=0.009$), wound hematoma (OR=0.0821; 95% CI=0.017–0.53; $p=0.0022$), and intensive care unit stay (OR=0.21; 95%CI=0.044–1.07; $p=0.041$) as the only independent predictors for QoL at 1 month postoperatively. No correlates and predictors for QoL were identified during the 12-month evaluation.

According to the surgical procedure, the only difference of QoL between groups was determined by the dimension of the defect, significantly higher for patients with ACS and TAR (Table 2). The preoperative value of QoL index was significantly lower for patients with TAR compared with Rives – Stoppa ($p=0.003$; 95% CI of difference 0.073–0.33). There was no difference between the values in all moments of evaluation despite surgical procedure.

The mean values of the QoL scores according to the surgical procedure are represented in Fig. 4. Preoperatively, we recorded almost equal mean scores for the QoL, but they were lower for the patients with Rives – Stoppa repair and the difference was significant comparing with ACS ($p=0.007$) and TAR ($p=0.00023$). Quality of life was insignificantly different in patients with ACS compared to TAR patients ($p=0.528$). Postoperatively, for all evaluation intervals, the QoL for patients with underlay repair was significantly increased compared to patients with anterior component separation (Fig. 3).

Discussion

Traditionally the success of a surgical procedure was evaluated by measuring short –term outcomes as utilization measures (length of hospital stay, duration of surgery, readmission, and post procedural complications). However, they

Table 5 Postoperative evolution of quality of life dimensions and QoL index EQ-5D. Data are expressed as mean \pm SD and mean \pm SEM for index values

Dimension /time lapse	Preoperatively	1month postoperatively	6months postoperatively	12months postoperatively
Mobility	3.14 \pm 0.99(1-5)	2.08 \pm 1.00 (1-4)	1.54 \pm 0.72 (1-3)	1.07 \pm 0.47 (1-2)
Self-care	3.09 \pm 1.1 (1-5)	2.03 \pm 1.03 (1-4)	1.48 \pm 0.72 (1-3)	1.01 \pm 0.41(1-2)
Usual activities	2.98 \pm 1.1 (1-5)	1.9 \pm 1.00 (1-4)	1.39 \pm 0.67 (1-3)	1.01 \pm 0.41 (1-2)
Pain/discomfort	2.15 \pm 1.01(1-5)	1.53 \pm 0.82 (1-3)	1.13 \pm 0.48 (1-2)	0.94 \pm 0.30(1-2)
Anxiety/depression	1.98 \pm 1.11(1-5)	1.49 \pm 0.99 (1-5)	1.30 \pm 0.86 (1-5)	1.01 \pm 0.51 (1-4)
EQ-5D QoL index	0.6521 \pm 0.24	0.7861 \pm 0.18	0.894 \pm 0.09	0.9795 \pm 0.05

Table 6 Univariate and multivariate analysis related to demographics, comorbidities, defect size, recurrence rate, abdominal wall function, and pain. COPD – chronic obstructive Pulmonary Disease; CVD – Cardiovascular diseases; AWF – abdominal wall function; OR –Odds ratio; 95%CI – confidence interval; AUC – area under curve (was calculated only when the correlation was statistically significant $p < 0.05$)

Variable	Univariate analysis	Logistic regression		
		OR	95% CI	p
Age	$r = -0.324$; $p = 0.002$; AUC = 0.422; $p = 0.649$	0.0681	0.028 – 0.62	0.038
Gender	$r = -0.138$; $p = 0.278$	0.71	0.98– 1.78	0.22
Diabetes	$r = 0.261$; $p = 0.012$; AUC = 0.659; $p = 0.026$	0.059	0.092– 23.45	0.003
Obesity	$r = -0.093$; $p = 0.382$	1.501	0.677– 3.330	0.318
COPD	$r = -0.006$; $p = 0.956$	1.196	0.995– 1.437	0.066
CVD	$r = 0.325$; $p = 0.002$; AUC = 0.573; $p = 0.013$	0.21	0.049– 1.09	0.05
Smoking	$r = -0.273$; $p = 0.055$	0.40	0.074– 2.14	0.28
Length	$r = -0.385$; $p < 0.0001$; AUC = 0.727; $p = 0.035$	0.071	0.07– 0.85	0.027
Width	$r = -0.293$; $p = 0.005$; AUC = 0.767; $p = 0.0117$	0.85	0.017– 0.479	0.021
Recurrent	$r = 0.200$; $p = 0.168$	0.17	0.02– 1.54	0.11
Preoperative AWF	$r = -0.620$; $p < 0.0001$; AUC = 0.799; $p < 0.0001$	0.03	0.004– 0.26	0.0012
Preoperative pain	$r = 0.442$; $p < 0.0001$; AUC = 0.772; $p < 0.0001$	0.029	0.003– 0.19	0.009

do not necessarily capture the effects of health outcomes with significant importance [25].

Abdominal wall hernia patients have different experience both pre and postoperatively compared to the daily lives of the “normal population” and have often suffered a significant surgical history with subsequent physical and psychological

impact [26, 27]. This is the reason why the effects of surgery on health-related quality of life are arguably the most important outcome to measure in evaluating the effectiveness of surgical care. Incorporation of the patient perspective on health and QoL produced in last decade a growing body of literature [28].

Our results reflect the natural progression of postoperative recovery. Baseline patient characteristics showed significant differences between preoperative and postoperative QoL index value along studied intervals of time. Our patients with symptomatic IH were more likely to be female and more likely to have an increased BMI; the results are in accordance with Schlosser et al. [29]. In patients with small defects with high preoperative indexes of QoL, the postoperative QoL records only a small increase. This could be a debatable topic related to the moment for surgery and could consider watch full waiting as an option in patients with modifiable risk factors until the correction. We could not find in the literature such relation.

Our study shows a constant positive impact on QoL despite surgical repair, that is significantly improved when compared to preoperative values for all three studied surgical techniques. Even if the increase was not significant for all patients the rate of improved QoL at the end of the first year was superior to Langbach et al. who reported an overall improved status in only 63%, with SF 36 questionnaire [30]. According to the same authors, an unmodified status was recorded in 20% and a worst one in 17%. A corresponding fraction of satisfied patients was reported in other studies [31, 32]. It is difficult to explain such differences through the terms of hernia characteristics, surgical procedure, or the number of comorbidities because these data are equal. More likely, it is a matter of self-reporting in accordance with cultural differences but apart from these differences, there is a broad array of factors difficult to define. One of them is probably the relation between expectations and experience. Although successful repair was achieved in 84% of the patients, an important ratio report dissatisfaction with physical function, aesthetic results and psychic condition. The results are in accordance with van Venendaal et al. who reports 17% of patients with a worse status compared to before operation [33].

Fig. 3 The evolution of abdominal wall functionality in relation to the EQ-5D QoL index. The difference with the 1-month score was significant ($p < 0.0001$; 95% CI of difference = 2.51–3.51). Data expressed as mean \pm SD for AWF and as mean \pm SEM for QoL index

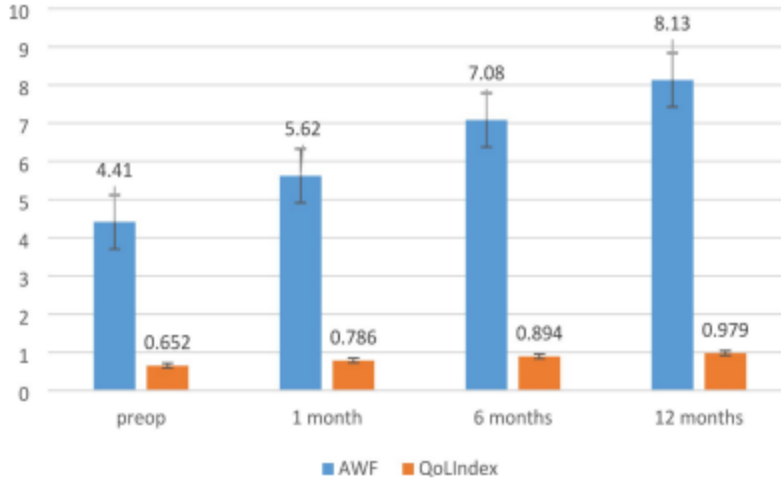
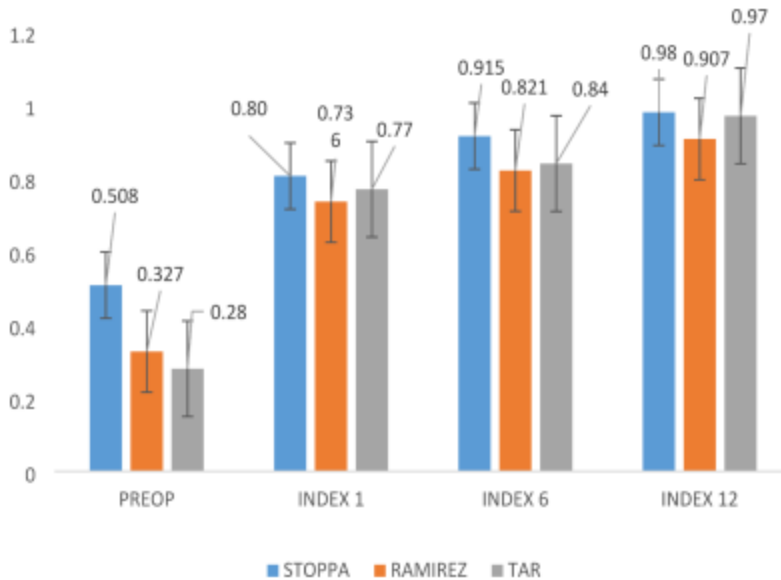


Fig. 4 EQ-5D QoL index in relation to type of surgery; Preop – preoperatively; Index 1–1-month index value; Index 6–6 months index value; Index 12–12 months index value. Preoperatively scores for the QoL were lower for the patients with Rives – Stoppa repair comparing with ACS ($p = 0.007$) and TAR ($p = 0.00023$). Quality of life was insignificantly different in patients with ACS compared to TAR patients ($p = 0.528$). Data expressed as mean \pm SEM



Initially, the mobility function remains quite low with a mean overall increase slightly over 40% but this increase is highly correlated and parallel with the increase of abdominal wall functionality. This, in correlation with the increase of “self-care” and “activity” domains, suggest that the physical component of the QoL is almost completely recovered with more than 80% after the first postoperative year despite the presence of complications. The lower scores on physical domain generally seen among women [29, 34] were not confirmed in our study. The worst improvement was recorded for the “mental” domain and was dominated by the fear of

recurrence, mesh related complications and subsequent surgical intervention (data not shown).

Objective measurements of the abdominal wall functionality are difficult to be obtained for the current practice because of the major barriers in choosing the optimal method for its representation. Dynamometry has been established as a reliable and effective method to evaluate AWF both with static and dynamic work [35, 36]. Despite offering an objective approach with less subjective interpretations bias, the method is highly expensive, has limited flexibility for conducting tests in other locations, and the

number of investigated patients is too small to have sound conclusions [37–39]. Our study, using clinically validated tests [40], demonstrates a profound alteration of the abdominal wall musculature, especially in patients with large incisional hernias and this limitation was highly correlated with the preoperative QoL in the developed regression model. These results are in accordance with the study of Strigård et al. who demonstrated with dynamometric evaluation a decrease of functionality in patients with hernias larger than 10 cm wide [37].

As the area of the defect increases, there is a proportional decrease in the AWF and also in QoL; patients with defects ranging from 6 to 10 cm width have altered but better AWF comparing to patients with defects larger than 10 cm and the difference was significant. There is such a strong correlation that it seems safe to conclude that the width of the defect is the one of the most important determinants for the degree of lost function [21].

Abdominal wall specific surveys have been developed to assess AW – QoL with greater utility than general health surveys [10]. So, why we choose a non-specific questionnaire? The EQ-5D was suitable and adaptable for translation and implementation to Romanian population. In addition, the value sets for Romanian population were available [23] and allow us to easily calculate index QoL. The EQ-5D tailored for the pre and postoperative states provides 5 items quickly and easily completed by the patient. Our preoperative study revealed a good acceptability, reliability, and validity. The design of the questionnaire quantifies generic patient reported outcomes based on all affected incisional hernia domains (mobility, self-care, usual – activities, pain, and anxiety/depression). Even if the response rate after 1 year was only 56%, there are studies that quote response rates in the low 30% range as adequate, with a mean response rate of 50–60% [1]. Results from each symptom can be aggregated to calculate an overall index limitation. Overall, our questionnaire demonstrates a large effect size between pre and postoperative scores and captures the improvement in QoL. QoL scores from EQ-5D have been shown to be comparable to those of Carolinas Comfort Scale [8].

Our study is not without limitations. Although data was collected in a prospective manner, this study remains observational and current data should cautiously interpret. Our data cannot be extrapolated to another population undergoing surgical repair because they are specific to a subset with cultural, ethnic, and educational particularities. Being a single experience team cohort of patients' needs validation in other Romanian population. A team of dedicated surgeons performed all surgical procedures, can represent a selection bias and the results cannot be extrapolated to general surgical population. The follow-up is relatively short (many of the sequels which can severely impact QoL are

reported later) and the small sample size with reduced rates of responses can be considered a selection and collection bias. Last, our cohort consists only of elective patients and this can be considered another selection bias.

Conclusion

A significant overall improvement in all five components of QoL measured with the help of EQ 5D questionnaire was demonstrated.

This improvement is dependent by hernia size, and some individual patient's factors (diabetes, cardiovascular diseases, and age over 60 years).

Further studies should delineate what factors affect EQ-5D scores and to validate the questionnaire to a population level as being an effective tool for hernia assessment.

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Declarations

Disclosures None of the authors has any conflicts of interest to declare related to this research.

Ethical statement All patients sign an informed consent and agreed to be included in the study. The entire research was developed in agreement with the Helsinki Declaration of human rights. Patients agreed to use data in scientific purposes.

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Authors and Affiliations

M Toma^{1,2} · V Oprea^{1,3}  · Florentina Scarlat¹ · Carmen Elena Bucuri^{1,3} · O Andercou^{3,4} · F Mihaileanu^{3,4} · O Grad^{1,3} · M Rosianu⁵ · C Molnar^{2,6}

✉ V Oprea
oprea31@gmail.com

¹ Clinical Department of Surgery, “Constantin Papilian” Emergency Clinical Military Hospital, Cluj-Napoca, 22G-ral Traian Mosoiu, Cluj-Napoca, Romania

² Pharmacy, Science and Technology, “George Emil Palade” University of Medicine, Targu-Mures, Romania

³ “Iuliu Hatieganu” University of Medicine and Pharmacy, Cluj-Napoca, Romania

⁴ Second Clinical Department of Surgery, Emergency Clinical County Hospital, Cluj- Napoca, Romania

⁵ Clinical Department of Radiology - Medical Imaging, Emergency Clinical County Hospital, Sibiu, Romania

⁶ First Clinical Department of Surgery, Emergency Clinical County Hospital, Targu- Mures, Romania

