

Complex abdominal wall hernias

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**COMPLEX
ABDOMINAL
WALL HERNIAS**

optimizing the care pathway

Johannes A. Wegdam

Complex abdominal wall hernias

Optimizing the care pathway

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Optimizing the care pathway

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Table of Contents

Chapter 1	Introduction and outline of the thesis	9
Chapter 2	Abdominal wall hernia surgery in The Netherlands: a national survey	29
PART I. Optimizing the <i>preoperative</i> care pathway: staging and prehabilitation		
Chapter 3	Impact of a multidisciplinary team discussion on planned ICU admissions after complex abdominal wall reconstruction	57
Chapter 4	Impact of hernia volume on pulmonary complications following complex hernia repair	79
Chapter 5	Preoperative exercise therapy preventing postoperative complications following complex abdominal wall reconstruction: a feasibility study	93
Chapter 6	The influence of a multidisciplinary team meeting and prehabilitation on complex abdominal wall hernia repair outcomes	107
Chapter 7	Prehabilitation of complex ventral hernia patients with Botulinum: a systematic review of the quantifiable effects of Botulinum	123

PART II. Optimizing the *operative* care pathway: tailored surgical approach

Chapter 8	eCST: The endoscopic-assisted component separation technique for (complex) abdominal wall reconstruction	157
Chapter 9	Systematic review of transversus abdominis release in complex abdominal wall reconstruction	177

PART III. Optimizing the *postoperative* care pathway: evaluation

Chapter 10	Assessing textbook outcome after implementation of transversus abdominis release in a regional hospital	203
Chapter 11	General discussion and future perspectives	227
	Summary	247
	Samenvatting	255
	Samenvatting Helmonds	263
	Valorisation addendum	267
	Dankwoord	275
	Curriculum Vitae	285
	List of publications	289

Chapter 1

Introduction and outline of the thesis

Starting points

Anatomically, the outer lining of the abdominal wall is formed by skin and subcutaneous fat, and the inner part by muscles and fasciae. Abdominal muscles are covered with a thin fibrous fascia that merge into large aponeurotic sheaths and insert on surrounding bones and other fibrous structures (1). *Physiologically*, the abdominal wall acts as a powerful truncal stabilizer and assists in increasing intra-abdominal pressure, needed for exhalation, defecation, micturition or giving birth (2).

An abdominal wall hernia (Latin: “rupture”) is a defect, or weakening of a pre-existing opening, in the abdominal wall fascia, with protrusion of abdominal content through that opening (evisceration). The hump usually contains preperitoneal fat or abdominal tissues (bowels) vested with the peritoneal sac (3). Primary hernias develop after repetitive stress on naturally weak points of the abdominal wall without muscle coverage, like the linea alba (umbilical and epigastric hernias) or myopectineal orifice (groin hernias). *Incisional hernias* are secondary hernias, developed after an incompletely healed surgical incision, or previously repaired hernia.

The majority of hernias are non-complex, small to moderate hernias (up to orange-size), mostly operated by general surgeons in day-surgery, and with good results (4-6). On the other hand, *complex hernias* lack this ‘benign nature’, and are often large with considerable evisceration (up to pumpkin-size). Repairing these hernias can be hazardous for the patient and a challenge for the surgeon.

A European abdominal wall reconstruction Collaborative defined complex hernias as ‘any hernia, complicated by any negative influencing factors including large defect size (> 10 cm), previous repair, previous mesh, active infection, and patient comorbidities’ (7). Added to these features, hernias that are located near a stoma or bony structure, hernias that contain an entero-atmospheric fistula, hernias that are surrounded by atrophic or absent muscles, and hernias that require a component separation technique for midline closure may also be considered complex (8).

The most cited, modified Ventral Hernia Working Group (mVHWG) classification stratifies hernia patients as grade 1 (clean wounds, low risk of complications), grade 2 (clean wounds, presence of co-morbidity or history of infection), and grade 3 (clean-contaminated to dirty wounds) (9). As the mVHWG does not take hernia size into account, the Dutch guideline on Incisional Hernias (2018) suggested to use the *Hernia Patient Wound* (HPW) classification (9-11). This TNM-like classification was designed to predict postoperative outcome, based on strictly preoperative characteristics.(10) Hernia (H) width is graded 1 (0-9.9 cm), 2 (10-19.9 cm) or 3 (>20.0 cm). Patient (P) comorbidities are noted as absent (0) or present (1) in case of a BMI >35 kg/m², current nicotine abuse, diabetes or use of immunosuppression. The wound (W), or surgical field, is graded as clean (0), or contaminated (1). The three HPW variables are incorporated into a cross table that ordinally ranks four stages by risk of developing wound complications or recurrences (Figure 1). HPW stage II-IV compromise the complex abdominal wall hernias (12). This HPW classification has not been validated yet.

	HERNIA	PATIENT	WOUND	HPW STAGE
STAGE 1	1	0	0	H1, P0, W0
STAGE 2	1 or 2	any	0	H1, P1, W0 H2, any P, W0
STAGE 3	any	any	0 or 1	H1, any P, W1 H2, any P, W1 H3, P0, W0
STAGE 4	3	any	0 or 1	H3, P1, W0 H3, any P, W1

Figure 1. The HPW classification of abdominal wall hernias

Clinical presentation

The Phoenicians described 3.500 years ago the most typical sign of a hernia: an abdominal swelling that comes out during coughing (13). Hernias are perceptible as a bulging mass above a palpable gap in the abdominal wall (Figure 2). Hernias may affect quality of life due to pain and limitations in performing daily activities. Back pain due to a large defect creating truncal instability, with overload of the spinae erector muscles, is much experienced (14). Smells from leaking ostomy appliances or ulcerated skin over infected meshes or fistulae lead to shame and a lowered self-esteem, social deprivation or even incapacitation (15). Life-threatening complications due to incarcerated bowels occur in 3-6% (16-19).



Figure 2. Inguinal hernia (Egyptian statue 1500 BC)

Etiology

Hernias are known to humankind since our predecessors started walking in an erect position and raised pressure on the abdominal wall. Although a complex hernia can originate from a primary hernia, like an inguinal hernia developing into a giant scrotal hernia, almost all complex hernias are secondary hernias. Incisional hernias develop in 13% (0-36%) of all patients after any type of midline abdominal incision and one third (35%) will undergo subsequent repair (20). In particular, gastro-intestinal operations account for over 80% of the incisional hernias (8, 21-24) (Figure 3). Thus, while primary hernias have always been present in humans, incisional hernias became only relevant when surgery evolved in the 19th century, after the introduction of asepsis (Semmelweis) and general anesthesia (Morton).

Incisional hernias develop after impaired wound healing after surgery due to a wound infection or fluid collection (hematoma or seroma). Systemic complications, like a pulmonary infection (coughing) or ileus (distended abdomen) give rise to a raised intra-abdominal pressure with increased tension on the freshly sutured fascia, preventing wound healing (10).

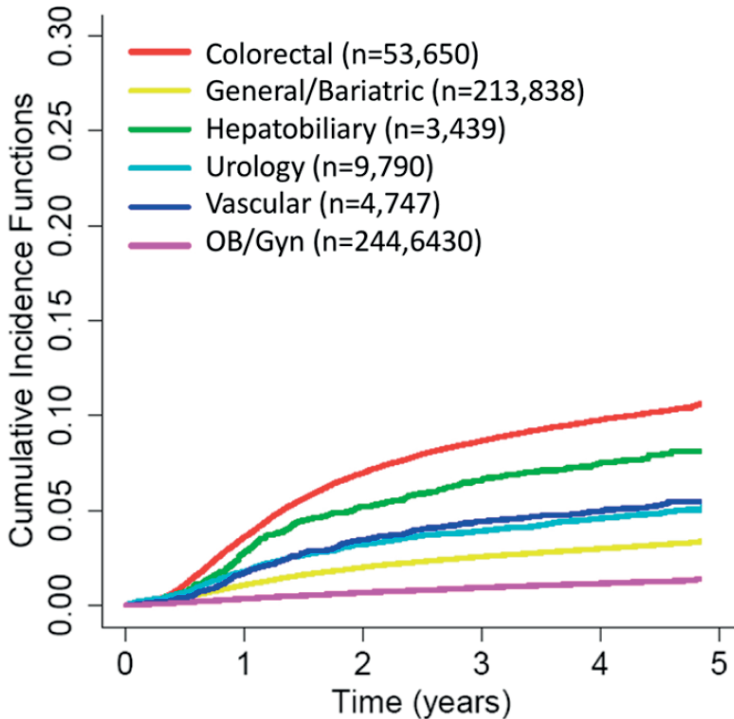


Figure 3. Cumulative incidence of developing incisional hernias by surgical specialty over time (USA data, Rhemtulla 2021)

Hernia factors, like hernia width > 10 cm, evisceration of intra-abdominal contents > 20% (“loss of abdominal domain”), location near a bony structure or the presence of a contaminated wound are independent risk factors for recurrence (25). Also, previous incisions leading to atrophic abdominal wall muscles and previous hernia operations are known risk factors (20, 21).

Patient factors, age, race, gender and smoking behavior are associated with incisional hernia formation, likewise obesity, diabetes, use of immunosuppressants,

cachexia, chronic obstructive pulmonary disease, abdominal aortic aneurysm, anemia, hypo-albuminemia or a low physical condition (21). Congenital connective tissue diseases, like Ehler Danlos or Marfan syndrome, have effect on the strength of fasciae, aponeuroses, and muscles. Klinge postulated that ‘herniosis’ could be the origin of herniation: an unknown genetic disorder which leads to reduced or malformed collagen or increased proteolysis (26). Although some mechanisms of extracellular matrix remodeling and imbalance between connective tissue degrading enzymes and their inhibitors have been described, strong evidence for ‘herniosis’ is lacking (27).

Treatment

Prevention is the best treatment (28). Surgery of an unfit patient, under time pressure, by an inexperienced surgeon, using inadequate suture materials or a poor closing technique, is planning for failure (29, 30). So full attention is also required for the last part of the operation; the closing.

Prophylactic mesh placement during abdominal surgery can effectively diminish the rate of incisional hernias, in patients prone for incisional hernia formation, like obese patients (31). Although the benefits of such a mesh seem to outweigh the risks of seroma and pain, issues with costs, increased length of operation, inexperience with mesh placement, and the ‘primum nil nocere’ principle, prevented widespread implementation in the surgical community (32-35).

Conservative treatment, by a truss or abdominal binder to push the swelling back, may alleviate some of the symptoms (36). Watchful waiting in asymptomatic hernia patients can be a good option with a low-risk of short-term morbidity, but the natural history of hernias lack high-quality data (37). Some surgeons reject the conservative treatment of hernias, due to its natural tendency to increase in size and symptoms (19).

Operative treatment is the only option for curing the hernia, improving quality of life and prevention of future complications. But, repairing a complex hernia has

considerable risks, especially in fragile patients with multiple comorbidities (38, 39). Whether surgery will actually improve the quality of life in a patient, requires careful consideration by the ‘χειρουργός’ (cheir-ourgós = hand-worker) and patient, in which Hippocrates basic goals of medicine must always be remembered: “Cure, care, or comfort. Hurt little and harm never” (40). Most important indication for hernia repair is a relevant and objectified decreased quality of life. Preventing a possible emergent repair is also used as a valid argument, because acute surgery may result into increased morbidity and mortality and has considerable economic impact on society. However, prevention as sole indication, should be put in the perspective of the fact, that only very few patients (3-6%) will ultimately develop a strangulated hernia (21, 41-43).

Surgical techniques developed after the first documented incisional hernia operation in 1836. Pierre Gerdy inverted the hernia sac and closed the defect with sutures (13). Grafting techniques with fascia or muscles were succeeded by iron and silver threads, to reinforce the closed defects. After the second world war, non-absorbable *meshes* made of plastics like polypropylene, polyester, polyvinylidene fluoride or expanded polytetrafluorethylene, became the most important contribution to prevent recurrences, despite chronic pain and infections due to the meshes were also reported (44). Nowadays, all guidelines recommend the use of non-absorbable meshes for elective repair of non-contaminated hernias, > 1 cm (11, 23, 37). In contaminated wounds, recurrences are less with biosynthetic meshes (9%), than with synthetic (13%) or biologic meshes (20%) (45, 46).

The best surgical technique for midline hernias is retrorectus dissection, followed by midline reconstruction and retromuscular mesh implantation, as described by Rives and Stoppa in the early 1970s. This most widely applied technique has superior results, compared to any other open technique (47). In patients, in whom a fascial closure cannot be achieved, numerous techniques have been developed in the past fifty years (48). Initially, ‘relaxing incisions’ were placed in the rectus or

lateral oblique abdominal muscles, to decrease hernia width and facilitate primary fascial closure.

Bridging a defect with a mesh leads to significant more recurrences, than closing the midline with a mesh under it (49). Chevrel developed a technique in which he turned the rectus fascia over, to create an overlapping midline hernioplasty and augmented it with a mesh (50). Some use the hernia sac as an extension of the rectus sheaths, with a mesh placed in between (Sandwich technique), but this is in fact a bridging technique and associated with much wound complications (51, 52).

Gamechangers

In 1996, Oscar Ramirez introduced the (open anterior) component separation technique (CST) (53). Incising the medial aponeurosis of both external oblique muscles, and releasing these muscles from the internal oblique, decreases tension on the midline and creates 5-10 cm medialization per side. In 2000, the 'endoscopic Ramirez' (eCST) emerged, to overcome the wound complications due to the dissection of large subcutaneous flaps, necessary for the open Ramirez (54).

In 2012, Novitsky presented the posterior component separation technique by transversus abdominis release (TAR) (48). This muscle splitting and releasing technique resembles the Ramirez in being a myofascial release, but uses the profound transversus abdominis muscle (Figure 4). Advantages of the TAR over Ramirez are the fact that very large defects and defects near bony structures can be closed and covered with a wide mesh overlap. The safe plane in which the mesh is positioned (retromuscular extraperitoneal) and the lack of an extended subcutaneous dissection are also beneficial.

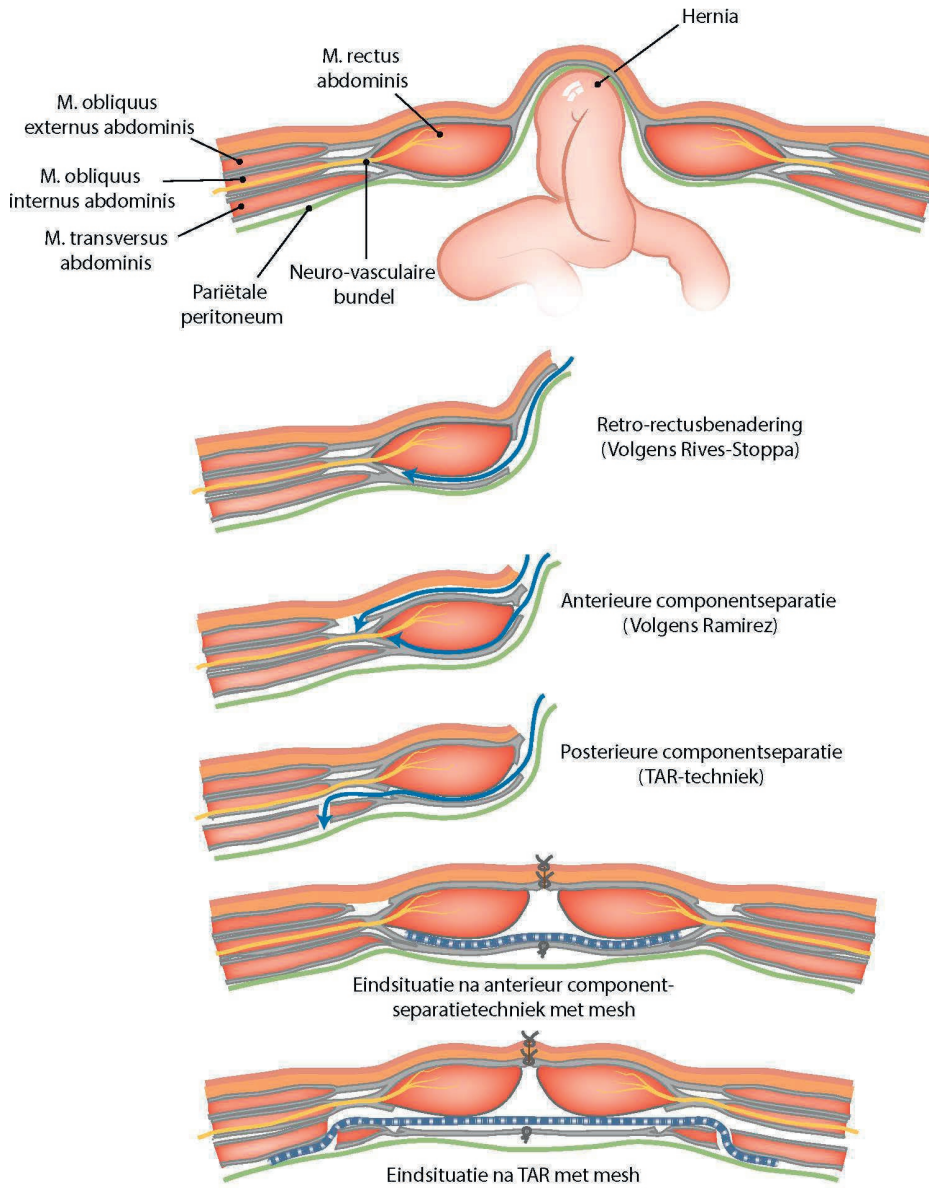


Figure 4. Anatomy of a midline hernia. Surgical approach (blue straight line) according Rives-Stoppa, Ramirez and TAR procedure, and end-situation with mesh (blue dotted line).

Illustration: Ron Slagter. Wegdam J, van der Velde S. Zwelling van de buik. In: van der Velde S, Houwert M, Schepers A, Smit F (red.). Probleemgeoriënteerd denken in de chirurgie. Utrecht: Boom | De Tijdstroom; 2022. p. 568.

While no consensus existed how to treat patients with complex hernias, the Ventral Hernia Working Group proposed five principles in 2010: (1) optimize the patient condition, (2) prepare the wound, (3) reapproximate the midline (primary fascial closure), (4) use a component separation technique when appropriate and (5) use appropriate reinforcement material (a mesh) (23). These five basic principles still apply today and constitute the foundation under any complex hernia repair.

Incidence of complex hernia repairs

Hernia repair is one of the most common procedures performed in surgical practice (3, 20, 41, 42). In the USA, 350.000 hernia repairs are performed annually, and 38.000 in the Netherlands (55, 56). Although incisional hernia repairs decreased from 120.000 (2011) to 100.000 (2018) in the USA, the burden of incisional hernia repairs relative to abdominal procedures effectively increased from 2008 (3.0%) to 2018 (3.3%) (21, 55). Thus, despite increased use of minimal invasive surgical techniques in abdominal surgery, an increasing proportion of patients still develop incisional hernias after abdominal surgery. This phenomenon was described as the ‘unremitting incisional hernia epidemic’, fueled by performing abdominal operations in increasingly older and obese patients with increasingly more comorbidities (21). In the Netherlands, mean 4.200 incisional hernia were repaired between 2012-2014.

The proportion of incisional hernia repairs that are *complex* can only be roughly estimated. The Danish Ventral Hernia Database reported 15% of all repairs were in patients with an incisional hernia > 15 cm (57). In a systematic review by Deerenberg et al., large hernias (> 10 cm) were distinguished between ‘simple’, in 80%, and ‘complex’ (loss of tissue, intra-abdominal infection, infected mesh, parastomal hernia repair) in 20% of the cases (58). If 15-20% of all incisional hernia repairs are complex, at least 600 complex hernia repairs will be performed per year in the Netherlands. This number is probably higher, while the rates only included hernia factors, not patient factors, to define complexity.

From isolation to centers of excellence

During his keynote lecture at the annual European Hernia Society congress in Hamburg, 2019, Todd Heniford, chief surgeon of a large tertiary hernia center, discussed the evolution of hernia surgery. He stated that hernia surgery was initially regarded as *'very low on the surgery cool-and-awesome scale'*. Complex hernia surgery was *'traditionally managed by a single-handed enthusiastic surgeon, developing expertise in splendid isolation'* (59). Long operation times, technical complexity, unsatisfying outcomes and inadequate reimbursement, made surgeons reluctant to perform this type of 'left-over' surgery (19, 60).

In the same time, an international movement towards *'centers of excellence'* developed. High volume orthopedic or bariatric centers demonstrated improved outcomes, compared to low volume hospitals (61, 62). As a consequence, specialized hernia centers also emerged (63). The mix of a high case volume, surgical expertise, interdisciplinary collaboration and improved patient preparation, proved successful, even in increasingly complex hernia patients (61).

Complex hernia program

From the desire to improve the quality of care for the neglected complex hernia patients, a complex hernia program was drafted in our hospital in 2012. The ultimate intention was to become a center of excellence for complex hernias. First, the targeted group was specified: patients with complex hernias, without active entero-atmospheric fistulae. Case volume was increased by making agreements with surrounding hospitals to refer complex hernia patients to our hospital, as well as by advertisements. A business case was drafted, based on cost reduction by increased volume and improved outcome (64). Cooperation with the clinical staff, the institutional board and insurance companies were assured. Then, structural adjustments were implemented by appointing experienced general surgeons as *'dedicated hernia surgeons'*, selecting dedicated scrub nurses for the *'complex hernia team'*, installing a case manager for complex hernia patients, standardizing

operative techniques, installing specific complex hernia consultation hours, planning complex hernia slots in the operating room schedule and developing a hospital-based database for prospective registration of outcome. A multidisciplinary team (MDT) was composed, including hernia surgeons, an intensivist, pulmonologist, anesthesiologist and case manager with scheduled monthly meetings. A quality control cycle was initiated by applying the Plan-Do-Check-Act (PDCA) cycle and outcome evaluation at least once a year during a general meeting (65-67). Finally, a *complex hernia care pathway* was drafted.

Complex hernia care pathway

Care pathways are considered to be one of the best tools hospitals can use to manage the quality in healthcare. Implementation reduces variability in clinical practice and improves outcomes (61). Ten years ago, most Dutch hospitals would have a care pathway for inguinal hernia patients, however, care pathways for complex hernia patients were nonexistent.

In oncological care pathways, the multidisciplinary discussion about tumor staging and treatment options, is pivotal. This integral approach was copied to the local complex hernia care pathway. The comprehensive plan for patient care, from the beginning to the end ('the patient journey') was documented in 2013, after institutional approval of the complex hernia program (68).

Quality of life is surveyed by hernia-specific instruments (EuraHs QOL and EQ-5D-5L) (1, 69). Preoperative care was centralized around the outpatient 'carousel' and multidisciplinary team meeting. In the carousel the patient visits the blood test unit, pulmonary functioning unit, radiology department (CT), surgeon, anesthesiologist, pulmonologist, physical therapist and, on indication, sports physician, all in one-day. During the multidisciplinary team meeting, a tailored approach per patient is pursued. Risk stratification is performed by the staging the patient, the hernia and quality of life. Modifiable risk factors are identified and prehabilitation is effectuated by setting achievable goals and implementing preoperative counseling.

Surgical options are discussed and the final decision is whether a patient is fit for surgery ('green light'), if surgery needs to be postponed until the prehabilitation goals are met ('orange light'), or any surgical intervention is waived due to too many unmodifiable risk factors ('red light'). In case of green light, it is decided whether a postoperative Intensive Care Unit (ICU) bed must be planned. All operative procedures (Rives-Stoppa, Ramirez, eCST or pCST-TAR) and postoperative management of pain, mobility and rehabilitation, were standardized in protocols. Postoperative results were registered at follow-up visits. Yearly evaluations were supported by a hernia dashboard.

This thesis aims to improve the quality of care for patients with complex abdominal wall hernias by analyzing the results of implementing different components of the care pathway.

Outline of this thesis

In 2019, specific evidence-based requirements for accredited hernia centers and hernia surgeons were formulated by the European Hernia Society (62). Based on these requirements, a national survey among all Dutch surgeons was performed to assess the quality of care for complex hernia patients in The Netherlands and *evaluate the relevant components of a complex hernia care pathway*. In **Chapter 2**, an overview of the presence of these components in Dutch hospitals is described.

Optimizing the *preoperative* care pathway: risk stratification

Preoperative risk-stratification of complex hernia patients (staging) during the MDT meeting, leads to plan postoperative ICU beds for high risk patients. In times of limited ICU resources, this often leads to undesired cancellation of elective complex hernia repairs. However, while also many ICU patients are discharged from the ICU without having been submitted to any specific ICU intervention, improving risk-stratification is essential. The *accuracy of the MDT decision and other risk-stratifying tools on justified ICU admissions* is analyzed in **Chapter 3**.

Another part of risk stratification is *predicting the risk of pulmonary complications after complex hernia repair*, especially in patients with large hernias with evisceration. While this correlation was not well defined, the relation between hernia volume, as measured by CT, and pulmonary complication rate is studied in **Chapter 4**.

Optimizing the *preoperative* care pathway: prehabilitation

Prehabilitation by improving a patient's physical capacity by preoperative exercise therapy may lead to a faster recovery after complex hernia repair. However, obese patients with large hernias are reluctant to perform sports, fearing complications of an increased hernia size. A preliminary study was performed surveying the *feasibility of an intense three-month muscle training program, in large hernia patients*. In **Chapter 5** the ability to finish this extensive exercise program is explored.

In general, smokers, obese, or inactive patients demonstrate more complications after complex hernia repair than healthy subjects. *Prehabilitation of modifiable risk factors may prevent postoperative complications*, which is investigated in **Chapter 6**. Outcomes of (green) healthy complex hernia patients without risk factors are compared to (orange) comorbid complex hernia patients with modifiable risk factors, who were operated after prehabilitation.

Primary closure of very large defects increases intraabdominal pressure which may induce systemic and wound complications. The abdominal wall extensibility (compliance) can be modified (prehabilitated) by intramuscular injection of Botulinum, four weeks before the actual surgery. Preoperative paralysis of the abdominal wall leads to an elongated and stretched abdominal wall, which facilitates midline closure and may also reduce surgical trauma by preventing the need to perform a component separation technique. Evidence to use Botulinum in complex hernia patients is scarce. In **Chapter 7** a systematic review is performed to *assess the elongation of the lateral abdominal wall muscles after Botulinum injection* in complex hernia patients.

Optimizing the *perioperative* care pathway: tailored surgery

While Ramirez' anterior component separation technique was the principal technique to repair complex hernias, the endoscopic component separation technique (eCST) was introduced in 2014 in our hospital as an alternative. *Indications, details and results of the eCST* in our series of patients are presented in **Chapter 8**.

The *indication to use the posterior component separation (pCST) with transversus abdominis release (TAR)* within the range of established anterior component separation techniques, was unclear. A systematic literature review of TAR was performed in **Chapter 9**.

Optimizing the *postoperative* care pathway: evaluation

In 2016 the TAR technique was introduced in our hospital. A standardized work up protocol and operative technique based on a Plan-Do-Check-Act cycle was used to implement this new technique. In **Chapter 10**, *the five years results of the TAR are evaluated* in terms of Textbook Outcome and learning curve.

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Chapter 2

Abdominal wall hernia surgery in The Netherlands: a national survey

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Abstract

Purpose In the Netherlands, the quality of abdominal wall hernia surgery is largely unknown due to the lack of a hernia registry. This study was designed to assess the current state of abdominal wall hernia surgery in The Netherlands, to create a starting point for future evaluation of new quality measures.

Methods Dutch hernia management indicators and recently proposed European Hernia Society (EHS) requirements for accredited/certified hernia centers were used. The number of Dutch hospitals that meet the four main EHS requirements (on volume, experience, use of a registry and quality control) was assessed by analyzing governmental information and the results of a survey amongst all 1.554 Dutch general surgeons.

Results The survey was representative with 426 respondents (27%) from all 75 hospitals. Fifty-one percent of the hospitals had a median inguinal repair volume of more than 290 (14-1.238) per year. An open or laparo-endoscopic inguinal repair technique was not related to hospital volume. Experienced hernia surgeons, use of a registry and a structured quality control were reported to be present in, respectively, 97%, 39%, and 15% of the hospitals. Consensus in answers between the respondents per hospital was low (< 20%). Two hospitals (3%) met all four requirements for accreditation.

Conclusion This descriptive analysis demonstrates that hernia surgery in the Netherlands is performed in every hospital, by all types of surgeons, using many different techniques. If the suggested EHS requirements are used as a measuring rod, only 3% of the Dutch hospitals could be accredited as a hernia center.

Introduction

Ever changing operative techniques, continuous new choices in prosthetics and a need for a tailored approach in hernia management make abdominal wall hernia surgery challenging (1). Applying modern principles of value-based health care to hernia surgery, makes it even more challenging (2-4). From this perspective, knowing the outcome of care and developing measures to improve this, adds value to care. The pursuit to know and improve the outcome of hernia surgery led to national hernia registries in at least nine countries (5). Another step in trying to improve the quality of hernia surgery were the implementation of accreditation programs for hernia centers and surgeons in Germany and Italy (6, 7).

A dedicated group of Dutch general surgeons with different backgrounds joined together in the Dutch Hernia Society (DHS) as an official subchapter of the Dutch Association of Surgeons. The DHS aims at improving the quality of care for hernia patients by composing national guidelines and initiating quality measures (8). The quality measure “incisional hernias may only be operated/supervised by a certified Gastro-Intestinal surgeon” was ratified by the Dutch Association of Surgeons and formally implemented in May 2019 (9). This quality measure was supported by the publication of a national guideline on incisional midline hernias in March 2019 (10). There are no other quality measures or official indicators for the management of inguinal and/or primary ventral hernia patients in The Netherlands.

The Netherlands, a country with 17 million inhabitants, lacks a nationwide hernia registry, a quality control protocol for hernia surgery and accredited hernia centers. Despite an excellent healthcare system and extensive contributions to the hernia literature and international guidelines, a comprehensive statement specific on the quality of hernia care in the Netherlands cannot be made (11-16).

This study was designed to assess the current state of abdominal wall hernia surgery in the Netherlands in order to create a starting point to evaluate the effect of future quality measures.

Material and methods

To evaluate the effect of a measure on the quality of care, ideally, a baseline current state of this quality first needs to be assessed. Quality is evaluated by structural attributes of the settings in which the care occurs, results of care processes and, ultimately, clinical outcome (17). As clinical outcome of hernia surgery is largely unknown in The Netherlands, only structural and process related data remain for evaluation. To describe the outcome of structure and care processes accurately and to create a starting point for future evaluation of new quality measures, both a logical framework and a measuring rod were found in the European Hernia Society (EHS) accreditation requirements for hernia centers and hernia surgeons (1).

In 2017, the EHS commissioned a group of hernia experts from across Europe to compile evidence-based requirements for accredited/certified hernia centers. This committee, under the name of the ACCESS Working Group (hernia Accreditation and Certification of Centers and Surgeons) published their scientifically and consensus based accreditation requirements for hernia centers and hernia surgeons in January 2019. The main accreditation requirements were based on a mix of 32 suggestions, recommendations and statements and were deemed implementable by all participating hernia experts in their respective countries.

To determine the current state of abdominal wall hernia surgery in The Netherlands, the number of Dutch hospitals that meet the most important ACCESS requirements (based on volume, experience, use of a database and quality-control cycle) was assessed (Table 1). Additional ACCESS requirements (based on caseload, dedicated consultation hours and a tailored approach for all type of hernias) and requirements that were defined by the authors [presence of a standardized hernia classification system, hernia care pathway, (p)re-habilitation program and referral agreement] were also investigated.

To assess whether a hospital met a specific requirement, all available online information issued by Dutch governmental agencies was analyzed and an electronic survey, concerning many different aspects of abdominal wall hernia surgery and management, was sent to all general surgeons working in The Netherlands.

Table 1. Requirements for accreditation of a hernia center

Main ACCESS requirements for accreditation of a hernia center

- 1 High volume: the center performs a higher case volume in all types of hernia surgery compared to an average general surgery department in their country
- 2 Experienced hernia surgeons: the center is staffed by experienced hernia surgeons who are beyond the learning curve for all types of hernia surgery
- 3 Register: the center documents each case prospectively in a registry or quality assurance database
- 4 Quality-control cycle: the center performs follow-up for comparison of own results with benchmark data for continuous improvement of their treatment results

Additional ACCESS requirements for accreditation of a hernia center

- 5 Caseload: the center has experienced hernia surgeons that perform a minimum caseload per year
- 6 Dedicated consultation hours: the center has availability of dedicated consultation hours for hernia patients
- 7 All hernias: the center treats all types of hernias
- 8 Tailored approach for inguinal hernias: the center is proficient in the open anterior mesh technique (Lichtenstein), the laparo-endoscopic posterior techniques (TEP/TAPP) and the non-mesh technique (Shouldice)
- 9 Tailored approach for ventral/incisional hernias: the center is proficient in generally all open (sublay, onlay, open IPOM, component separation) and laparoscopic (lap. IPOM) hernia repair techniques involving mesh.

Other potential requirements for accreditation of a hernia center (defined by the authors):

- 10 Use of a hernia classification for incisional hernias.
- 11 Use of a standardized care pathway for hernia patients
- 12 Use of a standardized (p)re-habilitation program for hernia patients
- 13 Use of a structured referral pathway for complex hernia patients

ACCESS hernia Accreditation and Certification of Centers and Surgeons Working Group, commissioned by the European Hernia Society

Governmental information

The annual volume of open and endoscopic operations for inguinal, umbilical, epigastric and incisional hernias in the Netherlands is collected by the Dutch Healthcare Authority (DHA) and published online (18). The DHA does not provide outcome data or a specified volume per hospital for reasons of competition-sensitivity. On December 1st, 2018, the DHA data were complete from January 1st, 2012 to December 31st, 2014. The years 2015-2018 were incomplete and not included in this analysis.

All hospitals and private clinics are also obligated to deliver their annual volume of adult patients that have undergone an inguinal hernia operation, as well as the

number of surgeons that provide open and/or endo-laparoscopic inguinal hernia surgery, to the Healthcare Institute Netherlands (HIN) (19). On December 1st 2018, the HIN data were complete from January 1st, 2014 to December 31st, 2017. To calculate the annual volume per hospital and caseload per surgeon, the 4-year results per center were summarized to one annual average number of hernia operations, per hospital and per surgeon.

The HIN is more up-to-date than the DHA, because the DHA only uses data after authorization by the financial department of each hospital, which takes more time. Therefore, the HIN data reflect a period 3 years later, which may result in small differences between HIN and DHA overall annual volume.

Survey

An online survey for all general surgeons in the Netherlands was designed in collaboration with board members of the Dutch Hernia Society. The survey was sent to every active general surgeon in The Netherlands on May 9th, 2018 and available for answering during 2 weeks. The survey was split into a first general section (17 questions) for all 1.554 surgeons and a second specific section (17 questions) designed for surgeons that answered positive on the question if “he/she still practices abdominal wall hernia surgery”. Surgeons that replied positive to this question are defined as ‘hernia surgeons’ throughout this article.

Information on the background of every responding surgeon was collected: years of experience in a surgical practice, type of subspecialty, name and type of hospital he/she worked in.

The survey focused on structural attributes of the settings in which the care occurs and the results of care processes. To maximize the response rate, no data on outcome were asked, as presumably most are not available.

Structural indicators that were evaluated were, for example, the presence of experienced hernia surgeons, use of a hernia registry, availability of a quality control system or dedicated consultation hours for hernia patients. The ACCESS definition of an ‘experienced hernia surgeon’ is ‘a surgeon who is beyond the learning curve for all types of hernia surgery’. Because clear parameters to define the learning curve for each type of hernia surgery are lacking, three other ways to define

'experience' were used in this study: (1) 'experience' indicated by other surgeons. All surgeons were asked in the survey whether the hospital has an 'appointed (group of) surgeon(s)' that operate complex abdominal wall hernias and how many of these surgeons were present in their hospital; (2) 'experience' indicated by mastering both open and laparo-endoscopic inguinal hernia techniques, as provided by the HIN; and (3) 'experience' indicated by the surgeon him/herself. All surgeons were not only asked whether he/she still practices abdominal wall hernia surgery (thus being a 'hernia surgeon'), but more specific whether he/she still practices also complex abdominal wall hernia surgery.

Process indicators are, for example, which types of hernias are treated in the hospital and what type of hernia operations are performed.

The survey categorized abdominal wall hernias in non-complex and complex. Non-complex hernias are all primary inguinal, umbilical, epigastric and incisional hernias without complex features. Complex hernia features are size > 5 cm (incisional hernia) or > 10 cm (any primary hernia), location near a bony structure (xiphoid, costal margin, iliac margin, pubic bone or vertebrae), a recurrent hernia with or without a previous placed mesh, presence of a stoma, evisceration (loss of domain), skin ulceration, enterocutaneous fistula and hernias that need myofascial release for repair.

The survey was calculated to be representative if the following three criteria were met:

1. For the first general section of the survey, in a target population of 1.554 surgeons registered in 2018 (number provided by the Dutch Association of Surgeons in April 2018) with a 5% margin of error and a 95% confidence level, at least 309 (20%) individual surgeons must complete the survey.
2. For the second specific section of the survey, in target population of 654 surgeons that perform inguinal hernia surgery in 2017 (number provided by the HIN in April 2018) with a 5% margin of error and a 95% confidence level, at least 242 surgeons (16%) must complete the survey.
3. To be representative for all hospitals in The Netherlands, it is necessary that at least one surgeon per hospital completes the survey.

The outcome per hospital on a specific question is expressed binary and determined by the majority of equal answers of all responding individual surgeons working in that hospital. To indicate the strength of this outcome per hospital, the rate of consensus in answers between respondents per hospital is also assessed. To calculate consensus at least three respondents per hospital are needed. Consensus for a specific question is present in a hospital if all respondents of that hospital give the same, or a blank, answer.

To sub-analyze whether the type of hospital might play a role in meeting the requirements, a distinction between three types of institutions was made: academic centers, teaching hospitals and general (non-teaching) hospitals. Because every year, private clinics come and go, it was decided that clinics that operated less than 20 inguinal hernias in 2017 and/or were nonexistent the following year (2018), were excluded from this analysis. Surgeons that participate in private clinics are also affiliated to a hospital and their answers represent their hospitals.

Statistical analysis

Data were processed with Excel (Microsoft 2010).

Results

The survey met the three predetermined requirements to be a representative sample. After exclusion of 37 incomplete questionnaires, (1) 426 surgeons (27%) completed the first section; (2) 318 surgeons (20%) reported to perform abdominal wall hernia surgery ('hernia surgeons') and (3) at least one surgeon (range 1-14) from every institute completed the survey. Consensus per hospital could be calculated in 60/75 (80%) of the hospitals that had at least three respondents.

The background of the 426 responding surgeons, in terms of years of experience in a surgical practice, type of subspecialty and the type of hospital, did not differ between the type of hospitals (academic, teaching or general). All six subspecialties were represented: one half (51%) has either a gastrointestinal and/or oncological certificate, the other half (43%) is mainly composed of surgeons with a trauma (27%) or vascular (16%) certificate. Sub-analysis between the 318 'hernia surgeons'

and 108 surgeons that did not perform hernia surgery any more, did also not demonstrate relevant differences in background.

ACCESS main requirement 1: high volume

The DHA demonstrated an annual volume of around 38.000 abdominal wall operations each year compromising 70% inguinal, 19% umbilical/epigastric and 11% incisional hernia repairs (Table 2).

Table 2. Annual volume of abdominal wall hernia operations in unique patients in The Netherlands 2012-2014

Year	Inguinal		Umbilical/epigastric		Incisional		Total	
	Total ^a	Lap-endo	Total	Lap-endo	Total	Lap-endo	Total	Lap-endo
2012	26.871	9.972 (37) ^b	6.926	801 (12) ^b	4.134	1.164 (28) ^b	37.931	11.937 (31) ^b
2013	27.969	11.227 (40)	7.353	820 (11)	4.301	1.281 (30)	39.623	13.328 (34)
2014	24.728	11.492 (46)	6.847	894 (13)	4.237	1.239 (29)	35.812	13.625 (38)
Mean	26.523	10.897 (41)	7.042	838 (12)	4.224	1.228 (29)	37.789	12.963 (34)

Data acquisition Dec 1, 2018 from the Dutch Healthcare Authority website

^aTotal patients with an unilateral or bilateral inguinal operation

^bPercentage laparo-endoscopic operations

The mean annual number of inguinal operations provided by the DHA (26.523 in the years 2012-2014) differed 3%, compared to the mean annual number provided by the HIN in the period three years later (25.731 in the years 2014-2017) (Table 3). The average rate of laparo-endoscopic inguinal operations increased from 41% (2012-2014) to 48% (2014-2017). The HIN demonstrated a median of 290 (14-1.238) inguinal hernia repairs per institute. A total of 38 hospitals (51%), solely teaching and general hospitals, met this requirement and performed a higher case volume in inguinal hernia surgery compared to an average surgical department. A very high volume with a doubled median caseload (> 580 cases per year) is observed in 7 teaching hospitals. A low volume of inguinal hernia repairs, less than 150 inguinal cases (14-145) per year, is present in 13 institutions (16%): seven academic centers, all four private clinics, one teaching and one general hospital.

Table 3. Volume of inguinal hernia surgery and caseload per surgeon in The Netherlands (2014-2017)

	Academic	Teaching	General	Private clinic	Total
Number of institutions	8	42	25	4	79
Mean annual number of inguinal hernia operations (%)	689 (3)	18.495 (72)	6.219 (24)	328 (1)	25.731
Median annual volume per institute (range)	66 (35-239)	409 (136-1238)	230 (142-463)	87 (14-139)	290 (14-1238)
Institutions with annual volume > 150 ^a (%)	1	41	24	0	66 (84)
Institutions with annual volume > 200 ^b (%)	1	39	19	0	59 (76)
Institutions with annual volume > national median (ACCESS) ^c (%)	0	34	4	0	38 (48)
Number of surgeons reported to operate inguinal hernias in 2017 (%)	37 (6)	455 (70)	157 (24)	5 (1)	654
Number of laparo-endoscopic inguinal hernia surgeons (%)	19 (51)	206 (45)	84 (54)	4 (80)	313 (48)
Annual caseload of all inguinal repairs per hernia surgeon ^d (range)	18 (2-50)	38 (11-288)	37 (14-110)	10 (0-153)	38 (4-288)
Annual caseload open repair per hernia surgeon ^d (range)	9 (2-43)	16 (1-166)	16 (3-81)	14 (2-42)	14 (1-166)
Annual caseload lap-endo repair per hernia surgeon ^d (range)	2 (1-29)	45 (0-273)	43 (3-121)	57 (47-93)	41 (1-273)
Institutions with:					
≥ 50 (≥ 25 open and ≥ 25 lap-endo) inguinal repairs per surgeon ^a (%)	0	9	0	1	10 (13)
≥ 50 (open or lap-endo) inguinal repairs per surgeon ^a (%)	0	26	15	1	42 (53)
≥ 30 laparo-endoscopic inguinal hernia repairs per surgeon (%)	0	29	15	3	47 (59)

Data from the Healthcare Institute Netherlands 2014-2017, ACCESS hernia Accreditation and Certification of Centers and Surgeons Working Group as proposed by the European Hernia Society in December 2018

^aItalian accreditation requirement

^bGerman accreditation requirement

^cMedian of 290 inguinal operations per institution in The Netherlands (2014-2017)

^dMedian number per hernia surgeon

ACCESS main requirement 2: experienced hernia surgeons

1. Most (85%) of the 426 respondents, representing almost all hospitals (97%), report that their hospital has an 'appointed group of surgeons' that treat complex hernia patients; 15% report that such a group is not defined or present (Table 4). Summing the mean number of reported 'experienced hernia surgeons' per hospital, as provided by each respondent, generates a total of 228 surgeons that treat complex hernia patients in The Netherlands: 26 in academic; 141 in teaching and 61 in general hospitals. This group forms 35% of all 654 inguinal hernia surgeons (HIN 2017).
2. The HIN data demonstrated that 314 inguinal hernia surgeons also master laparo-endoscopic techniques, who are 48% of all open inguinal hernia surgeons.

3. A total of 160 (50%) of the 318 'hernia surgeons' in the survey answered that they master all types (inguinal, umbilical/epigastric and incisional) of both non-complex, as well as all types of complex hernia surgery.

ACCESS main requirement 3: use of registry

59/426 (14%) survey respondents, representing 29/75 hospitals (37%), reported that they document each complex hernia case in a registry (Table 4). Most (22) hospitals use a local database and in 7 hospitals (2 academic and 5 teaching) the European Hernia Society (EHS) database EuraHS is being used. Consensus between respondents within one hospital whether a form of a registry for complex cases is actually being used, is present in 10/60 hospitals (17%). At least 3 academic, 5 teaching and 2 general hospitals unambiguously use a prospective hernia registry.

ACCESS main requirement 4: use of a structural quality control cycle

The rate in which hospitals perform follow-up for comparison of their own results with benchmark data for continuous improvement of treatment results is unknown. However, 178/426 (42%) survey respondents reported that hernia quality control occurs incidentally in their hospital (Table 4). Structural quality control of hernia surgery, like a thematic evaluation of hernia surgery at least once a year, takes place in 11/75 hospitals (15%). Consensus between the respondents within one hospital, that the quality control cycle is actually structural, demonstrates consensus in only 4/60 (7%) of the hospitals: 3 teaching and 1 general hospital.

In total, two out of 75 hospitals (3%) meet all of the four main ACCESS requirements for accreditation as a hernia center (Table 4).

Table 4. Number of hospitals that meet the ACCESS criteria for hernia center accreditation

	Academic	Teaching	General	Total	Consensus
Number of hospitals	8	42	25	75	60
Main requirements for accreditation (%)					
1 Higher case volume compared to average ^a	0	34 (81)	4 (16)	38 (51)	na
2 Presence of experienced hernia surgeons ^b	8 (100)	41 (98)	24 (96)	73 (97)	(12) ^c
3 Local use of hernia registry ^b	5 (63)	19 (45)	5 (20)	29 (39)	(17)
4 Use of structured quality control cycle ^b	1 (13)	7 (17)	3 (12)	11 (15)	(7)
Hospitals that meet all 4 main requirements	0	2 (5)	0	2 (3)	
Additional requirements for accreditation (%)					
5 Caseload (≥ 50 open and/or lap-endo inguinal repairs) ^a	0	26 (62)	15 (60)	42 (56)	na
6 Dedicated consultation hours	5 (63)	17 (40)	8 (32)	32 (43)	(17)
7 Treat all types of hernias ^d	8 (100)	41 (98)	20 (80)	69 (92)	(60)
8 Tailored approach for inguinal hernias ^{a,e}	6 (75)	29 (69)	17 (68)	52 (69)	
9 Tailored approach for incisional hernias ^f	3 (38)	8 (19)	6 (24)	17 (23)	

ACCESS hernia Accreditation and Certification of Centers and Surgeons Working Group as proposed by the European Hernia Society in December 2018, NA not applicable, *CONSENSUS* Consensus for a specific requirement is present in a hospital if all respondents of that hospital give the same, or a blank, answer

^aBased on Healthcare Institute Netherlands data 2014-2017 on inguinal hernias

^bHospital is positive if the majority of respondents replied positive

^cIn-hospital consensus about the exact number of experienced hernia surgeons

^dBoth non-complex and complex hernias

^eHospital is proficient in both open and laparo-endoscopic techniques

^fHospital is proficient in at least two different types of myofascial release

Additional ACCESS requirement 5: a minimal caseload per surgeon

The median annual caseload of open and endoscopic inguinal hernia repairs per hernia surgeon in the Netherlands is 38 (4-288) (Table 2). The annual caseload of laparo-endoscopic hernia surgeons (41) is three times higher than hernia surgeons that perform open repairs (14), due to the doubled number of open hernia surgeons (654) compared to the number of laparo-endoscopic surgeons (313).

The German Herniated registry data demonstrated that high-volume surgeons, with an annual caseload of minimally 30 laparo-endoscopic inguinal repairs, have a

significantly lower recurrence rate (20). Applying this criterion in the Dutch setting reduces the number of hospitals that have surgeons that can meet this to 41%. Italian annual caseload requirements per surgeon are defined as 50 inguinal hernia repairs (25 open, 25 laparo-endoscopic) (7). It is not clear whether the comma means 'and' or 'and/or'. If the comma means 'and' and this would be applied to the HIN data (including private clinics), only 9 hospitals and 1 private clinic could provide surgeons that meet this requirement. If the comma is changed to 25 open and/or 25 laparo-endoscopic inguinal operations per surgeon, 53% of all hospitals would have surgeons that could meet this requirement.

Additional ACCESS requirement 6: availability of dedicated consultation hours for hernia patients

Specific hernia consultation hours was reported by 83/426 (19%) respondents, representing 30/75 (40%) hospitals. In 10/60 (17%) hospitals (1 academic, 6 teaching and 3 general) consensus between the surgeons concerning the availability was present. Consensus concerning the absence of dedicated consultation hours for hernia patients was much higher: in 26/60 (43%) of the hospitals.

Additional ACCESS requirement 7: the center treats all types of hernias

313 (73%) from 426 survey respondents answered that their hospital treats both non-complex and complex hernias. In 69/75 (92%) Dutch hospitals both non-complex and complex hernia cases are treated with a consensus of 73% (non-complex) and 61% (complex) between the respondents per hospital.

Additional ACCESS requirement 8: a tailored approach for inguinal hernias

A trend towards more laparo-endoscopic repair of all types of hernia surgery is observed: from 31% to 38% (Table 2). Especially in inguinal hernia surgery, the annual rate of laparo-endoscopic repairs steadily increases from 37% to 46% (DHA 2012-2014), up to 55% in the year 2017 (HIN). The rate of laparo-endoscopic inguinal hernia repairs per hospital does not have any relation to the volume of inguinal operations per hospital (Figure 1).

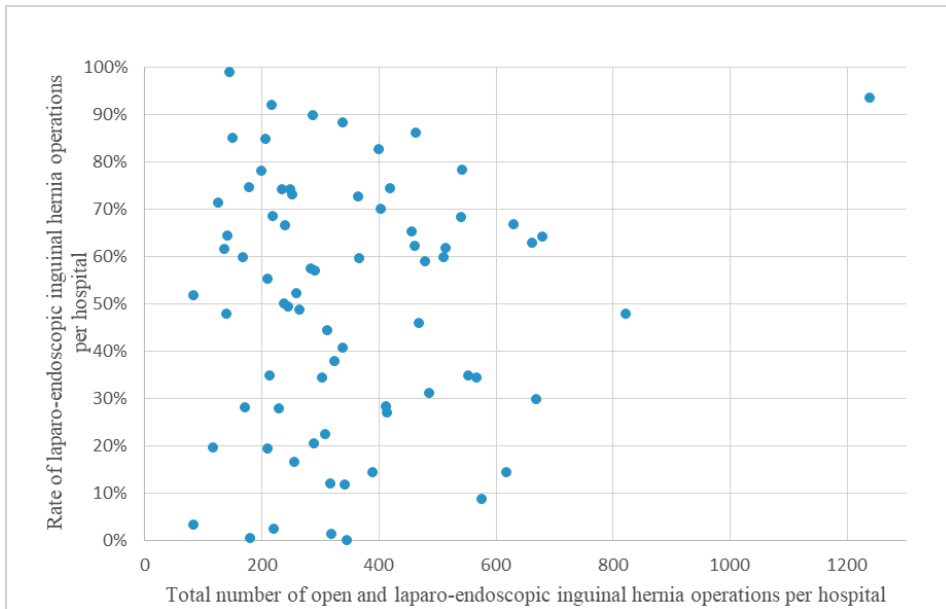


Figure 1. Proportion of laparo-endoscopic inguinal operations versus the total number of inguinal operations per hospital in the Netherlands (median 290 between 2014 and 2016)

The standard technique or techniques (multiple answers were possible) for primary inguinal hernia repair, that expressly has been agreed within the hospital, is reported to be the totally extra-peritoneal approach (TEP) by 80% of the hernia surgeons, Lichtenstein (58%), trans rectal pre-peritoneal (TREPP) (17%), trans inguinal pre-peritoneal (TIPP) (4%) or the bilayer Prolene Hernia System (PHS) technique (3%).

The survey demonstrated whether a hospital is proficient in both the open anterior mesh technique (Lichtenstein) and the laparo-endoscopic posterior techniques (TEP/TAPP).

The most performed endoscopic technique is the TEP, which is performed in all hospitals except one (99%) and far more practiced (88%) than the transabdominal pre-peritoneal (TAPP) technique (12%). The most performed open repair is Lichtenstein, which is performed in all hospitals, followed by TREPP in 27%, TIPP in 4% and PHS in 3% of all hospitals.

One-third of all hospitals (31%) stick to one preferred technique which they apply in over 75% of their inguinal hernia patients: either an open (9) or laparo-

endoscopic approach (14 hospitals). More than half of all hospitals (57%) have two preferred techniques for inguinal hernia surgery: Lichtenstein and TEP. The remaining 8 hospitals (12%) have 3 or more preferred techniques. Which type of operation was used for which indication was not investigated.

Local anesthesia is never offered to patients as an option by 65% of the hernia surgeons, sometimes by 25% and regularly by 10%. Around 4% of all inguinal hernia repairs are performed under local anesthesia and this rate is decreasing between 2014 and 2016 (respectively 5.3%; 3.5%; 3.4%).

Additional ACCESS requirement 9: a tailored approach for ventral/incisional hernias

Whether a hospital is proficient in all open (sublay, onlay, open IPOM, component separation) and laparoscopic (lap. IPOM) hernia repair techniques involving mesh for ventral/incisional hernias was deduced from the survey. Laparoscopic techniques are used in all hospitals, but open techniques still prevail for both small (< 2 cm) and larger umbilical/epigastric hernias (> 2 cm).

In The Netherlands anno 2018, if a myofascial release is warranted, most hernia surgeons (58%) reported to use the classic Ramirez technique, other myofascial releases, like posterior component separation technique with transverse abdominis release (PCS-TAR) (19%) or endoscopic anterior component separation (ECST) technique (10%) are less frequently being used. The preferred mesh location is the sublay position for 221 of the 318 (69%) hernia surgeons. Robotic techniques were reported to be still in an experimental stage.

Other possible requirements for accreditation of a hernia center

10. Use of a hernia classification system for incisional hernias.

70/318 (22%) of the hernia surgeons reported to use one or more hernia classification systems to categorize incisional hernias. The European Hernia Society Classification was used by 22%; the classification by Slater by 5%; the Ventral Hernia Working Group 2010 or 2012 classification by 4%; and the HPW classification of Petro & Novitsky by 3% (21-25).

11. Presence of a standardized hernia care pathway

The HIN data demonstrate that most hospitals (77%) reported to have a standardized protocol for inguinal hernia patients. The one stop shop principle (consultation and operation on one day) is practiced in 7 hospitals (9%).

12. Use of a standardized (p)re-habilitation program

The survey demonstrates that most hernia surgeons (87%) reported to offer active pre-habilitation programs to lose excessive weight, stop smoking and increase physical condition before an complex hernia repair takes place. Only one-third (30%) of respondents also offered a standardized physical therapy program after complex repair.

13. Presence of a referral pathway to a specialized center for complex hernia patients

24% of the 318 hernia surgeons reported to refer complex hernia patients to other specialized hernia hospitals, although with a low (27%) consensus. A total of two formal and four informal networks were mentioned by the hernia surgeons: ‘Dutch-close’ (an expert panel of hernia surgeons from 5 hospitals centered around the Radboud University Medical Centre in the East of the Netherlands; ‘Herniaport’ (4 hospitals around one general hospital that treats high volume complex incisional hernias in the South-East of The Netherlands); and hospitals with informal referral pathways and co-operations with the Amsterdam Medical Centre, the Erasmus Medical University Center (Rotterdam) or the University Hospital in Gent, Belgium.

Discussion

This descriptive study reflects the diversity in management and care for hernia patients in The Netherlands. The state of abdominal wall hernia surgery can be summarized as: ‘hernia surgery is performed everywhere (in all types of hospitals and independent of a minimal annual caseload per hospital), by everybody (independent of a specific surgical certificate or a minimal annual caseload per surgeon) and by every technique (open or endoscopic techniques are being used independent of

hospital volume or tailored approach). This statement is endorsed by the low rate of Dutch hospitals (3%) that can meet with the proposed ACCESS accreditation requirements for hernia centers. This rate can act as a starting point to evaluate the effect of future quality measures in hernia care in The Netherlands. Potential new quality measures are discussed below.

Volume

For any complex surgical procedure, hospital volume is related to outcome (26, 27). This study clearly demonstrated the effect of a lack of formal agreements on centralization of complex hernia cases in The Netherlands. Both high volume centers (teaching and general hospitals) and low volume centers (academic centers and private clinics) perform non-complex and complex hernia surgery.

Since the Dutch financial reimbursement system made no distinction between non-complex or complex hernias, there has never been a real stimulus to centralize, or even treat, complex cases. However, since the 2019 national guideline on midline incisional hernias defined clear terms for hernia complexity, the Dutch Health Authority has subsequently announced to adjust the reimbursement for complex hernias per 2020 (10). This will stimulate the treatment of complex hernia patients in The Netherlands. To prevent a further unrestrained scattering of complex hernia surgical procedures, one may argue that implementation of a minimal hospital volume for complex hernia cases could be the next new quality measure (28).

For procedures that have a short length of stay, like most inguinal or small umbilical/epigastric hernia repairs, surgeon volume, more than hospital volume, is recognized as an important contributing factor related to outcome (29-31). Defining a minimal caseload of hernia operations per surgeon in The Netherlands, which has been effected in Germany and Italy, may also improve the quality of hernia care (31).

However, any quality measure concerning volume will directly lead to centralization of care and will subsequently exclude hospitals and surgeons from hernia care. Although centralization may be beneficial in complex cases, the yield in quality for the large segment of 'normal' hernia cases is debatable.

Experience

Although experienced hernia surgeons were reported to be present in almost every Dutch hospital, it is not clear which percentage of the 654 inguinal hernia surgeons (HIN 2017) are actually 'experienced' hernia surgeons, due to the lack of definitions on experience and inconsistent answers by the respondents. The rate of experienced hernia surgeons varies between 35-48% of all hernia surgeons, depending on the definition used: 'considered as an experienced surgeon by other surgeons' (35%) or 'being experienced in mastering both open and laparo-endoscopic inguinal hernia repairs' (48%). At least 50% of the hernia surgeons that completed the survey could be classified as an experienced hernia surgeon by the fact that they 'masters both open and laparo-endoscopic techniques for all types of non-complex and complex hernias'. Implementation of the quality measure 'incisional hernias may only be operated/supervised by a certified Gastro-Intestinal (GI) surgeon' in 2019 will ultimately lead to a higher consensus in the number of experienced hernia surgeons per hospital (9). In other words: 'this measure leads to better agreements per hospital who operates the complex hernia patients and who does not'.

Registry

To create transparent results for value based healthcare, intelligent use of electronic patient records is needed, especially when registries are lacking (2, 32). However, computerized output from aggregated patients' records is still noticeably insufficient within the current electronic systems. The only possibility to create transparent outcomes is a register, like the EHS-register. But, a widespread reluctance is present in The Netherlands to participate in yet another register, besides the abundant existing mandatory registries for other diseases. The costs and administrative burden are considered too high in relation to potential yield of quality.

A possible solution is the introduction of the implant-register, which has been imposed by the Dutch Health Authority in 2019. Patients in whom a prosthesis or pacemaker is implanted need to be accumulated in this register. This also accounts for patients in whom pelvic meshes are implanted. It is expected that registration of meshes for other hernia indications will also be obligatory in the future. This may ultimately be the first step of a national hernia register in The Netherlands.

Other quality measures

The presence of dedicated hernia consultation hours, standardized preoperative multidisciplinary assessments in complex cases, pre-habilitation programs, standardized postoperative physical therapy programs or the use of a standardized hernia classification, are lacking in general. Also, tailored surgery, defined by offering different surgical techniques to a patient, is more common in inguinal hernia patients (69%) than in incisional hernia patients (23%). These requirements could only be introduced if deciding to implement a hernia accreditation program.

Implementation of a hernia accreditation program

National implementation of a hernia accreditation program is the most potent quality measure. Nevertheless, the question arises whether accredited hernia centers are really needed in The Netherlands.

First, The Netherlands, is “the only country which has consistently been among the top three in the total ranking of any European Index the Health Consumer Powerhouse has published since 2005” (11). Thus, the overall of delivered health care is highly appreciated by independent organizations. If this study subsequently demonstrated that two of the most important requirements, hospital volume and experienced hernia surgeons, are fulfilled by at least 50% of the hospitals in The Netherlands, one may assume that in the other half of the Dutch hospitals the quality of care for the largest part of all hernia patients is at least good.

Second, the results of a recent observational Dutch study about regional and hospital variation in inguinal hernia repair demonstrated that unwarranted variation between academic, private and general hospitals is small and stable over time. Thus, the indication to perform inguinal hernia surgery in a patient, adjusted for patient factors, is more or less the same for all surgeons in The Netherlands and not influenced by unwarranted incentives [Latenstein CSS, de Reuver PR, et al. from the Scientific Institute for Quality of Healthcare, Radboud University Medical Centre, Nijmegen, The Netherlands, manuscript submitted to the British Medical Journal Quality & Safety].

Third, 5 years after the introduction of the German certification program of hernia centers, 90 of 1800 hospitals (5%) have qualified as accredited abdominal wall

surgery center [reviewers' comment]. This is surprisingly comparable with the result of this study (3%). The low Germany rate may be a result of too high accreditation requirements or a reflection of too little enthusiasm.

These arguments make it unlikely that a hernia accreditation program will receive much support within the Dutch surgical community, although this has not been investigated within this study.

Future

Which next quality measure should be implemented in The Netherlands depends of the method that is preferred to improve overall quality of care: an inclusive or exclusive approach. Providing optimal hernia education in combination with a system for monitoring outcomes, with the goal of making all surgeons better, is an inclusive method of improving national hernia care. The exclusive approach focuses mainly on a few surgeons in a centralized setting. Although it is not evident by which approach the hernia patients benefit most, the inclusive approach will likely have more support in the Dutch setting than the exclusive approach, due to the aforementioned arguments. The Dutch surgical society promotes the development and implementation of regional networks in which surgeons from different levels of hospitals with different expertise collaborate, to share knowledge, educate each other and organize protocols for all types of hernia patients within a region. This will lead to a situation in which all patients with non-complex and complex hernias will be managed by the expertise that is required for each special case (tailored treatment).

Therefore, while hard prospective data are needed for future study of the results of abdominal wall hernia surgery and management, the-quality measure in The Netherlands will most likely be inclusive, such as the commencement of a reliable hernia register.

Strength of this study is the truthful representation of the daily practice of the surgical hernia community in The Netherlands anno 2018. The assessed percentage of hospitals that meet the ACCESS requirements is based on a strong fundament of accurate governmental data and a national survey that turned out to be very representative in displaying the state of abdominal wall surgery in The Netherlands.

This study was not designed to validate the ACCESS requirements. Nevertheless, it demonstrated that the ACCESS requirements can be used practically as a measuring rod to define a baseline of the quality of hernia care. The ACCESS requirements give good insight into structural and process related outcomes of care and expose many potential points of improvement.

This study has several limitations due to its method of investigation. A survey has inherent flaws due to the type of questions (closed, open), type of answers (binary, on a scale, multiple answers possible) and unanswered questions. Results must be carefully interpreted as clear definitions on many issues were lacking, which also give rise to some inconsistency in answers. This latter was demonstrated by the generally very low consensus rate between respondents per hospital. The most important limitation to assess the quality of care is that no conclusions could be drawn because complication rates like recurrence, reoperations, chronic pain or infection were lacking.

Conclusion

This descriptive analysis demonstrates that 3% of the Dutch hospitals may be categorized as a hernia center when implementing the EHS proposed requirements for hernia Accreditation and Certification of Centers and Surgeons. This rate forms the starting point for future evaluation of the effect of implementation of new guidelines and quality measures.

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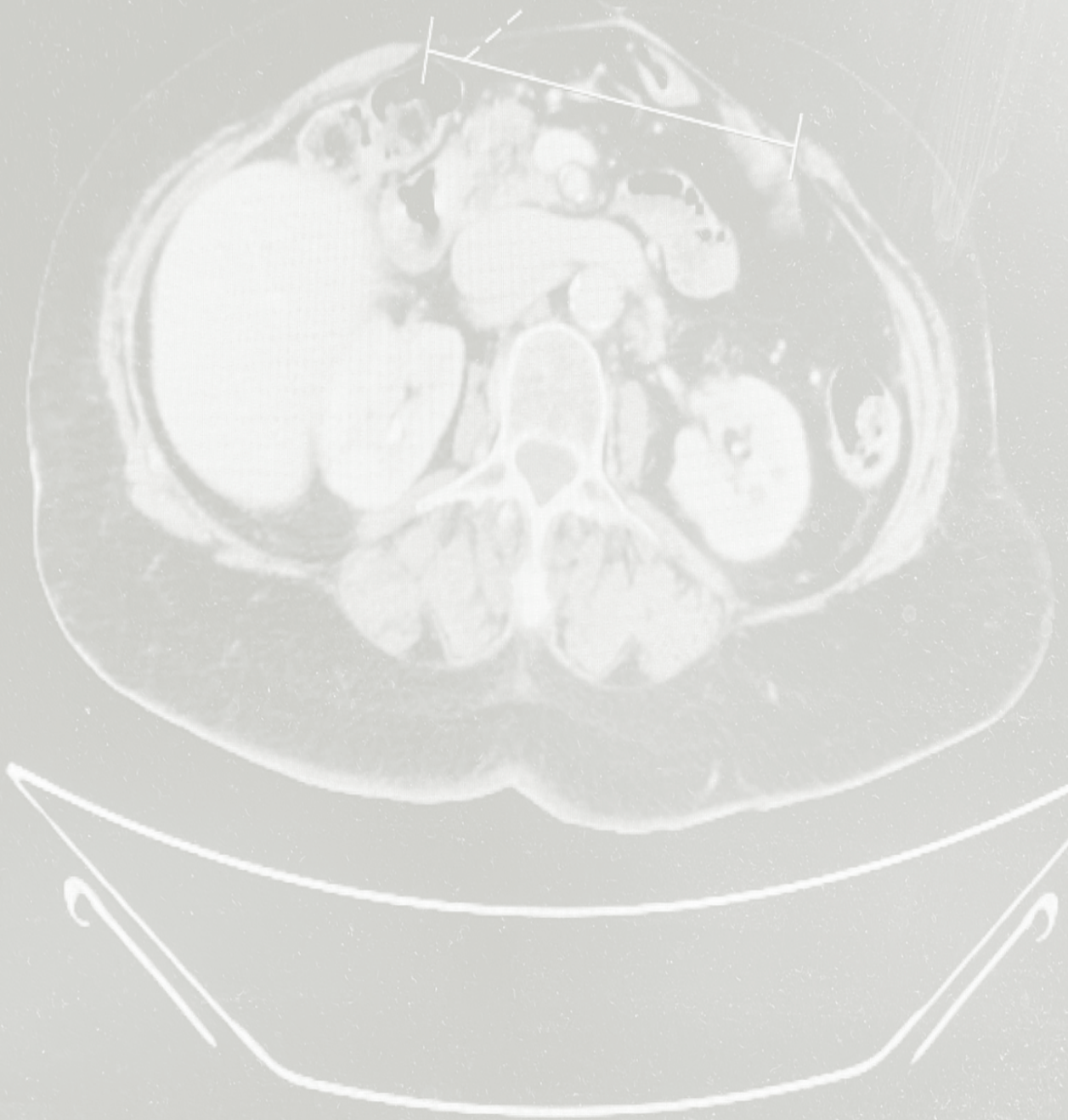
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PART I

Optimizing the *preoperative* care pathway:
staging and prehabilitation

136 mm



Chapter 3

Impact of a multidisciplinary team discussion on planned ICU admissions after complex abdominal wall reconstruction

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Abstract

Background Patients often need admission at an Intensive Care Unit (ICU), immediate after complex abdominal wall reconstruction (CAWR). Lack of ICU resources requires adequate patient selection for a planned postoperative ICU admission. Risk-stratification tools like Fischer score and Hernia Patient Wound (HPW) classification may improve patient selection. This study evaluates the decision-making process in a multidisciplinary team (MDT) on justified ICU admissions for patients after CAWR.

Methods A pre-Covid-19 pandemic cohort of patients, discussed in an MDT and subsequently underwent CAWR between 2016 and 2019, was analyzed. A justified ICU admission was defined by any intervention within the first 24 hours postoperatively, considered not suitable for a nursing ward. The Fischer score predicts postoperative respiratory failure by eight parameters and a high score (> 2) warrants ICU admission. The HPW classification ranks complexity of hernia (size), patient (comorbidities) and wound (infected surgical field) in four stages, with increasing risk for postoperative complications. Stage II-IV point to ICU admission. Accuracy of the MDT decision and (modifications of) risk-stratification tools on justified ICU admissions were analyzed by backward stepwise multivariate logistic regression analysis.

Results Preoperatively, the MDT decided a planned ICU admission in 38% of all 232 CAWR patients. Intra-operative events changed the MDT decision in 15% of all CAWR patients. MDT overestimated ICU need in 45% of ICU planned patients and underestimated in 10% of nursing ward planned patients. Ultimately, 42% went to the ICU and 27% of all 232 CAWR patients were justified ICU patients. MDT accuracy was higher than the Fischer score, HPW classification or any modification of these risk stratification tools.

Conclusion An MDT's decision for a planned ICU admission after complex abdominal wall reconstruction was more accurate than any of the other risk-stratifying tools. Fifteen percent of the patients experienced unexpected operative events that changed the MDT decision. This study demonstrated the added value of an MDT in the care pathway of patients with complex abdominal wall hernias.

Background

Incisional hernias develop in 13% (0-36%) of all patients after any type of midline abdominal incision; one third (35%) will undergo subsequent repair (1-4). Approximately 150,000 incisional hernia repairs are hospitalized each year in the USA and this number is increasing in the past two decades (2, 5, 6). This 'unremitting incisional hernia epidemic' is probably fueled by performing more abdominal operations in the ageing and increasingly obese population with multiple comorbidities, although signs of a stabilized incidence are recently reported (2, 4).

The rate of such hernias that are complex, depends on the definitions used (7, 8). A European Collaborative for abdominal wall reconstruction defined complex hernias as 'any hernia, complicated by any negative factors' (>10 cm, previous repair, previous mesh, infection, and co-morbidities), and complex abdominal wall reconstruction (CAWR) as 'any repair, complicated by large hernia, need for component separation, adhesiolysis or flap reconstruction' (5). The Danish Ventral Hernia Database reported 15% of all repairs were in patients with an incisional hernia > 15 cm (9). In a systematic review by Deerenberg, large hernias (>10 cm) were distinguished between 'simple', in 80%, and 'complex' (loss of tissue, intra-abdominal infection, infected mesh, parastomal hernia repair) in 20% of the cases (10).

CAWR leads to respiratory failure in 6-20% of patients, especially in case of risk factors like a large hernia, loss of domain (LOD), recurrent incarcerations, elderly patient, male, high ASA score, high BMI, COPD, infected wound or a concurrent intra-abdominal procedure (11-18). In absence of any guideline for ICU admission after CAWR, the European Collaborative strongly recommended, that 'intensive care beds must be available for all patients after CAWR' (5). This statement implies cancelation of planned CAWRs, in case of limited Intensive Care Unit capacity, like during the Covid-10 pandemic. While empty critical care beds with adequate personnel staffing will always be a coveted resource, optimal risk-stratifying remains very essential (16).

In our hospital, the multidisciplinary team (MDT) decides whether a postoperative ICU bed needs to be planned for a specific patient. However, many patients were discharged from the ICU within 24 hours after CAWR, without having been

submitted to any specific ICU intervention, like monitoring vital signs by intravascular lines, applying hemodynamic support with vasopressor medication and/or applying pulmonary support by (non) invasive mechanical ventilation (16).

Besides inefficient use of the ICU, unnecessary ICU admissions are undesirable, because frequent diagnostic procedures, sleep interruptions and room transfers lead to anxiety, increased delirium risk, a prolonged hospital stay and higher costs (19-21).

This study was aimed to evaluate the preoperative decision-making process in the MDT to optimize risk-stratification of patients planned for ICU after CAWR and to give recommendations for the future.

Methods

This study is a single-center retrospective review of all consecutive patients with a complex abdominal wall hernia, discussed at the multidisciplinary team meeting and subsequently underwent an open complex abdominal wall reconstruction before the Covid-19 pandemic, between 2016 and 2019. This abdominal wall center is a regional non-teaching hospital and referral center for abdominal wall surgery in the Netherlands, with 50-70 CAWRs performed annually. The hospital is equipped with an ICU department with eight beds for mechanical ventilation, and four beds at the intermediate care unit.

Outcomes of the standardized screening program in every patient, including CT-scan and pulmonary function tests, are discussed at the monthly multidisciplinary team (MDT) meeting. MDT consists of hernia surgeons, an intensive care physician, a pulmonologist, an anesthesiologist, a physical therapist and nurse practitioner (22, 23). The structure and aspects considered in this MDT have been described previously (24). In summary, the process starts with anatomical hernia staging by EHS and risk-stratification by the Hernia Patient Wound (HPW) classification and Fischer score (12, 25, 26). Discussion continues surgical aspects like myofascial release, mesh type, and expected intraoperative difficulties, like enterolysis, mesh explantation and concomitant intra-abdominal procedures. Then, presence of modifiable factors (smoking, weight or mental, physical, cardiopulmonary and

nutritional status) could induce a preconditioning program. In case of agreement to proceed for surgery, the necessity for postoperative intensive care is discussed. The dichotomic decision to plan an ICU bed is made by consensus in the MDT with aid of HPW classification and Fischer score.

HPW classification categorizes size of the hernia (H1: 0-10 cm; H2: > 10-20 cm; H3: > 20 cm), patient comorbidities (P0: absent; P1: diabetes, smoking, BMI>35 or use of immunosuppressants present) and surgical field (W0: clean; W1 infected). These factors are subsequently ordinaly ranked in four stages, with increasing risk for developing postoperative complications (see Table 1). Stage II-IV are considered complex hernia patients, which point to ICU admission. The Fischer score comprises eight risk-factors (ten point maximum) and is a validated clinical risk-stratifying tool that predicts postoperative respiratory failure rates after CAWR: 3% with a score of 0-2, 15% (score 3-4), and 50% (score > 4) (see Table 2) (12). A Fischer score > 2 was used as indicator for postoperative ICU admission by the MDT.

Table 1. HPW staging system of abdominal wall hernias (Petro & Novitsky in *Hernia Surgery: Current Principles: Classification of Hernias*)

	Hernia	Patient	Wound	HPW stage
Stage 1	1	0	0	H1, P0, W0
Stage 2	1 or 2	any	0	H1, P1, W0 H2, any P, W0
Stage 3	any	any	0 or 1	H1, any P, W1 H2, any P, W1 H3, P0, W0
Stage 4	3	any	0 or 1	H3, P1, W0 H3, any P, W1

Included variables were etiology of the hernia, history of wound infection or recurrent incarcerated hernia, LOD (> 20%, calculated according Tanaka) and presence of a parastomal hernia (27). Furthermore, patients demographics, smoking status, dyspnea in rest (score 5, Likert scale) (28), functional status (≥ 4 points at the 10-point Metabolic Equivalent of Task (MET) score was defined as an independent functional status) (29), nutritional status (malnutrition if albuminemia < 30 g/L),

ASA, use of immunosuppressants, anticoagulants, and comorbidities (diabetes, COPD confirmed by pulmonologist) were taken into account.

Altered decisions for (re-)admission to ICU and intervention applied there were noted as well.

Univariate analysis was performed between characteristics of patients with justified ICU admissions and the group that sufficed standard care (all unjustified ICU patients and nursing ward patients). Nominal values and ordinal subcategories are presented as number of cases. Ordinal values are presented as median (IQR). Continuous variables are presented as mean (\pm SD) for parametric data and as median (IQR) for nonparametric data. Significance was set at $p < 0.05$. Nominal data were analyzed by means of crosstabulation with Chi-Square test, whereas Fisher's Exact Test was used in cases of unmet assumptions. Assumptions for continuous data were analyzed via eyeballing, Kolmogorov-Smirnov Test, and Skewness and Kurtosis values. Normally distributed data were analyzed via independent samples student's *T*-Test, whereas non-normally distributed data were analyzed via independent samples Mann-Whitney *U* Test.

Table 2. Fischer score to predict postoperative respiratory failure after complex abdominal wall reconstruction

	Points
Preoperative factors	
COPD	2
Pre-existing dyspnea at rest	2
Dependent functional status	1
ASA score 4	1
Hypoalbuminemia	1
Recurrent incarcerated hernia	1
Intra-operative factors	
Concurrent intra-abdominal procedure	1
Operative time > 240 min	1

Accuracy of the MDT in predicting justified ICU admissions, was calculated by positive and negative predictive values (PPP/NPV) and by Receiver Operative

Characteristic analysis for the Area Under the Curve (AUC) and compared with the AUC of the Fischer score and HPW classification.

In order to optimize the risk-stratifying tools, significant unique and composite variables from the univariate analysis were tested by backward stepwise multivariate logistic regression analysis, with justified ICU admissions as dependent variable. Multiple modifications of the HPW and Fischer score were tested by using different combinations of their mutual risk factors. Also, factors not included in HPW or Fischer score, but reported in similar studies as relevant risk factors (LOD, age and gender) were also tested (11-16). Data were analyzed in RStudio (version 1.2.5001).

Results

The MDT discussed 379 unique patients with a complex abdominal wall hernia and ultimately decided 232 (61%) patients fit for surgery, of whom 44% were prehabilitated. One-third of the discussed patients (39%) was not operated because they were deemed unfit for surgery due to non-modifiable comorbidities or unfinished prehabilitation. Patients with HPW stage I (hernia < 10 cm) still underwent complex reconstructions, due to hernia related factors (LOD, loss of substance need for a CST, mesh explant, concomitant abdominal procedures), co-morbidities not included in original HPW classification (COPD, fragility, age > 70, ASA III) or an expected extensive adhesiolysis. On average, 58 (48-75) CAWRs were performed annually in this selected and optimized group of CAWR patients. The rate of ICU planned patients decreased over the four years (52%, 51%, 40%, 30%) while the rate of justified ICU admissions increased (40%, 61%, 74%, 81%).

Justified ICU admissions

Ninety-eight patients, 42% of all 232 CAWRs, went immediately to the ICU after surgery (see Figure 1). ICU specific interventions were performed in 63 of these 98 patients (64%), compromising 27% of all CAWRs.

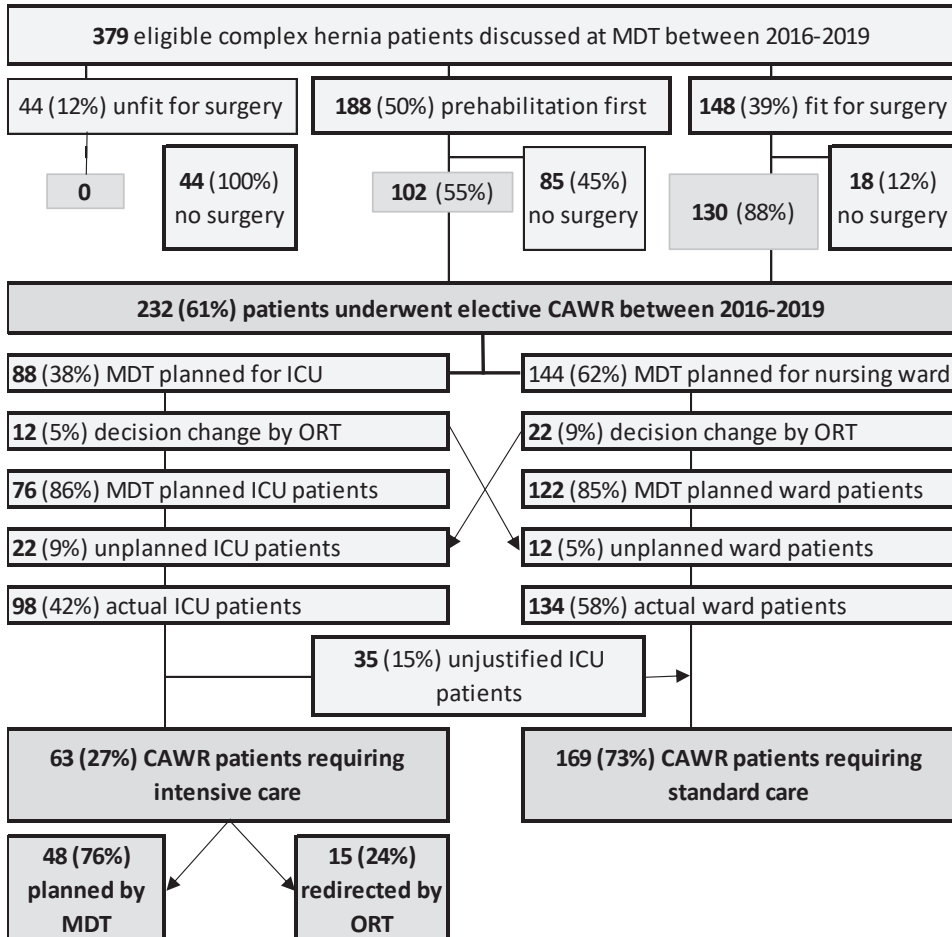


Figure 1. Impact of MDT and ORT on admission at ICU or nursing ward after CAWR. MDT multidisciplinary team, ORT operation room team, CAWR complex abdominal wall reconstruction

Type of ICU specific interventions (n = 63)

- Hemodynamic instability (hypotension, oliguria, tachycardia) requiring fluid resuscitation and invasive monitoring occurred in 56/63 (90%).
- Norepinephrine in 29/63 (46%) and/or prolonged respiratory support with (non) invasive mechanical ventilation occurred in 10/63 (16%) patients.
- One patient required intensified monitoring and medication because a nodal heart rhythm had developed whilst closing the abdomen.

Causes of ICU specific interventions

- Hemodynamic instability and/or signs of a Systemic Inflammatory Response Syndrome (SIRS) were induced by a long operation time (>3 hours), due to complex reconstructions with CST, concurrent abdominal procedures, extensive enterolysis or (un)intended contamination.
- Significant blood loss with anemia requiring transfusion was present in three patients.
- Prolonged pulmonary support was required in six patients after tight midline closure with an imminent abdominal compartment syndrome.
- Pain management issues, due to malfunctioning or absent epidural catheters requiring high doses of intravenous morphine and ketamine, also led to increased monitoring in eleven patients.
- Five (planned and justified) ICU patients developed respiratory failure: three were ventilated >48 hours and two needed a reintubation, one due to exacerbation of COPD, and one due to a peritonitis induced SIRS.

Unplanned ICU admissions (n = 22)

- In 22 of the 144 (15%) nursing ward planned patients, the operation room team changed the initial plan, due to unexpected events intra-operatively.
- Ultimately, 15/144 (10%) of the nursing ward planned patients required ICU specific interventions.

Causes of unplanned ICU admissions

- Surgeons reported midline closure under a non-physiological high tension, contamination during enterolysis and mesh excision, or doubtful vitality of a partially strangulated bowel as reasons for referring a nursing ward planned patient to the ICU.
- Anesthetists reported a need for intensified pain management in case of absent or dysfunctional epidural catheter, a high consumption of parental fluids, increased Positive End Expiratory Pressure during midline closure or a significant anemia.

- Not in every patient a specified reason for the decision-change could be retrieved.

Unjustified ICU admissions

Causes of an unjustified ICU stay (n = 35)

- Thirty-five (36%) from the 98 patients admitted at the ICU were labeled as unjustified ICU admissions, because monitoring of vital signs was the only intervention.
- Six patients with postoperative oliguria, without any other sign of hemodynamic instability, needed extra parental fluids, which is not an ICU specific intervention.
- Another patient was monitored while using a continuous positive airway pressure device for obstructive sleep apnea syndrome. This device is also used at home and does not need specific ICU monitoring.

Follow-up after discharge from ICU

- None of these patients developed a SIRS within the first 24 hours after the operation and all unjustified ICU patients remained at a maximum of 24 hours at the ICU.
- One patient returned after 48 hours from the nursing ward because of a pulmonary infection and needed reintubation.

Nursing ward patients

Causes of unplanned nursing ward admissions (instead of planned ICU admission) (n = 12)

The operation room team decided to monitor twelve ICU planned patients in the recovery room after surgery, instead of planned transfer to the ICU, due to an uneventful operative course. These patients were originally planned for ICU due to the expected complexity of the operation. But if adhesiolysis proved simple, an intended component separation technique was not necessary, or no relevant changes in vital signs occurred, prolonged monitoring in the recovery room was

initiated. While no deterioration occurred, these patients were ultimately referred to the nursing ward. None of these patients returned to the ICU during their admission.

Follow-up of nursing ward patients (n = 134)

None of the 134 patients postoperatively sent to the nursing ward, were transferred back to the ICU within the first 24 hours. One patient, primarily sent to the nursing ward, developed a myocardial infarction three days after CAWR, and was referred to the ICU for resuscitation and unanticipated intubation.

Accuracy of the MDT decision, Fischer score and HPW classification

The PPV of the MDT decision for justified ICU admissions was 55%, the NPV 90%, and the AUC 0.763 (see Figure 2). AUC of the Fischer score was 0.703 and AUC of the HPW classification 0.688.

Univariate analysis of preoperative characteristics, in patients requiring ICU after CAWR, demonstrated nine significant risk factors: six unique variables [hernia width, parastomal hernia in situ, hypoalbuminemia, infected wound, stoma in situ, and a planned concurrent intra-abdominal procedure) and three composed variables (ASA, Fischer score and HPW) (see Table 3 and 4). Age, LOD, recurrent incarcerated hernia, gender, BMI and COPD, were not related to a justified ICU admission.

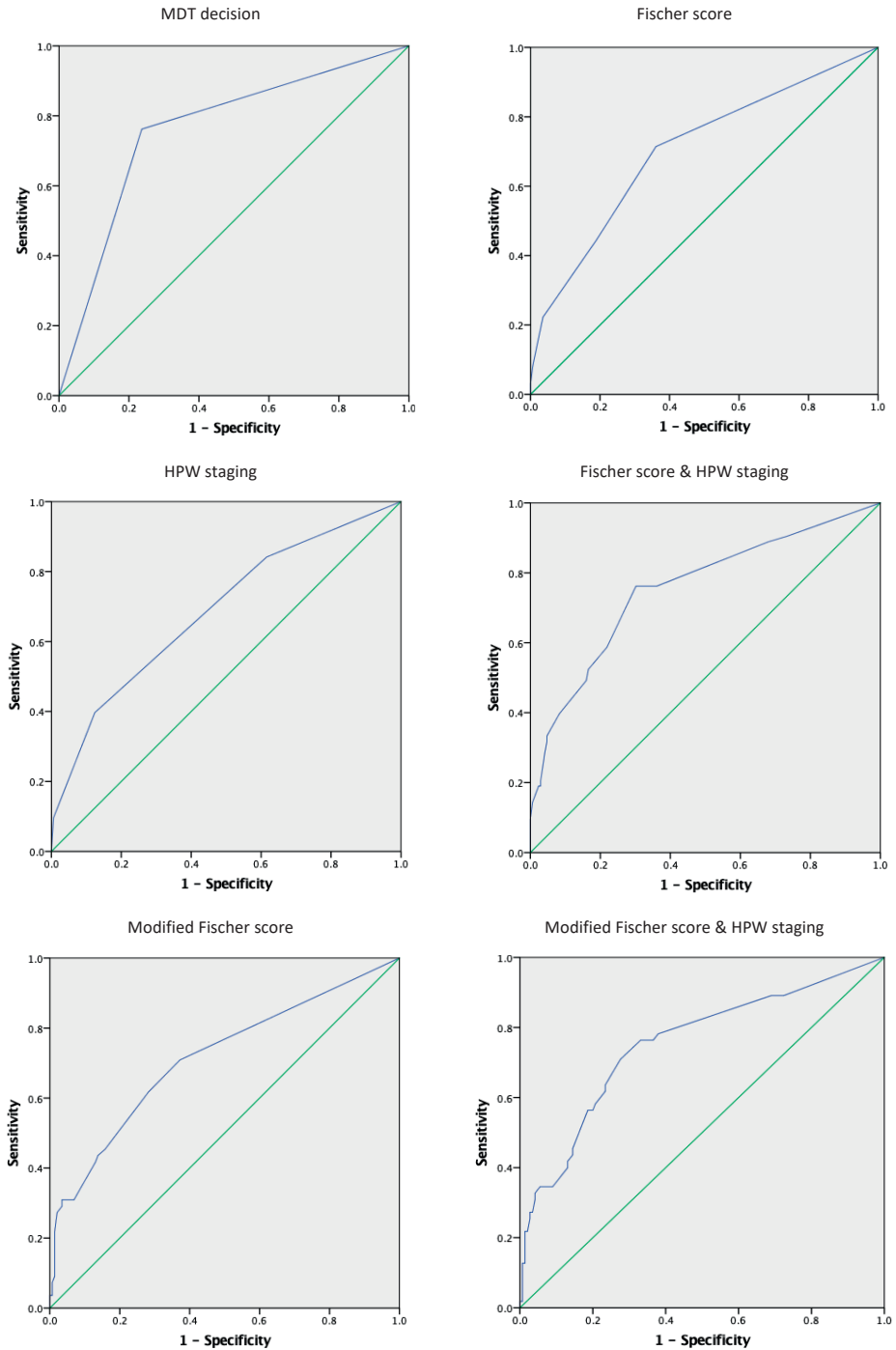


Figure 2. ROC curves on justified ICU admission after CAWR

Table 3. Preoperative characteristics in patients requiring intensive or standard care after CAWR

	All patients	Intensive care ^a	Standard care ^b	<i>p</i> -value
<i>n</i>	232	63 (27.2%)	169 (72.8%)	
Hernia characteristics				
Midline location (EHS M1-5)	188 (81.0%)	53 (84.1%)	135 (79.9%)	
Lateral location (EHS L1-4)	19 (8.2%)	3 (4.8%)	16 (9.5%)	0.509
Mixed location	25 (10.8%)	7 (11.1%)	18 (10.7%)	
Hernia width (cm, median, IQR)	9 (6-12)	11 (7-15)	9 (6-11)	0.004
0-9.9 cm (HPW: H1)	124 (53.4%)	26 (41.3%)	98 (58.0%)	
10-19.9 cm (HPW: H2)	96 (41.4%)	30 (47.6%)	66 (39.1%)	0.009
> 20 cm (HPW: H3)	12 (5.2%)	7 (11.1%)	5 (3.0%)	
Hernia surface (cm ² , median, IQR)	74 (31-154)	120 (50-236)	57 (28-126)	0.000
Loss of substance	64 (27.6%)	19 (30.2%)	45 (26.6%)	0.592
Loss of domain > 20%	36 (15.5%)	13 (20.6%)	23 (13.6%)	0.186
Parastomal hernia	17 (7.3%)	13 (20.6%)	4 (2.4%)	0.000
Patient characteristics				
Age (mean ± SD)	61.3 ± 10.4	64.1 ± 10.8	60.4 ± 10.3	0.072
Female	105 (45.3%)	33 (52.4%)	72 (42.6%)	0.183
History of malignancy	59 (25.4%)	15 (23.8%)	44 (26.0%)	0.931
History of smoking	133 (58.1%)	36 (57.1%)	97 (58.4%)	0.860
History of wound infection	81 (34.9%)	28 (44.4%)	53 (31.4%)	0.063
Anticoagulation use	60 (25.9%)	19 (30.2%)	41 (24.3%)	0.361
BMI (mean ± SD)	28.6 ± 3.8	29.2 ± 4.0	28.6 ± 3.8	0.288
ASA I	24 (10.4%)	2 (3.2%)	22 (13.1%)	
ASA II	160 (69.3%)	38 (60.3%)	122 (72.6%)	0.000
ASA III	47 (20.3%)	23 (36.5%)	24 (14.3%)	
At least one (HPW) P-factor present	64 (27.6%)	20 (31.7%)	44 (26.0%)	0.387
Obese (BMI ≥ 35) (HPW: P1)	14 (6.0%)	6 (9.5%)	8 (4.7%)	0.173
Diabetic (HPW: P1)	25 (10.8%)	10 (15.9%)	15 (8.9%)	0.126
Current smoker (HPW: P1)	24 (10.3%)	5 (7.9%)	19 (11.2%)	0.462
Immunosuppressants (HPW: P1)	12 (5.2%)	5 (7.9%)	7 (4.1%)	0.246
Wound characteristics				
Presence of a stoma	31 (13.4%)	18 (28.6%)	13 (7.7%)	0.000
Wound status CDC II-IV (HPW: W1)	43 (18.5%)	24 (38.1%)	19 (11.2%)	0.000

Bold is *p* < 0.05. ^aJustified ICU admissions, ^bCompromising both unjustified ICU patients and nursing ward patients, *SD* standard deviation, *IQR* interquartile range

Table 4. Fischer score, HPW stage and perioperative characteristics in CAWR patients requiring intensive or standard care

	All patients	Intensive care	Standard care	<i>p</i> -value
	232	63 (27.2%)	169 (72.8%)	
Fischerscore (med., IQR)	0 (0-2)	1 (0-2)	0 (0-1)	0.000
COPD	38 (16.4%)	14 (22.2%)	24 (14.2%)	0.142
Dyspnea at rest	5 (2.2%)	3 (4.8%)	2 (1.2%)	0.095
Dependent functional status	25 (10.7%)	7 (11.1%)	18 (10.6%)	0.129
ASA score > 3	0	0	0	
Hypoalbuminemia	15 (7.3%)	10 (15.8%)	7 (4.1%)	0.003
Recurrent incarcerated hernia	19 (8.2%)	8 (12.7%)	11 (6.5%)	0.126
Planned conc. abdominal procedure	29 (12.5%)	18 (28.6%)	11 (6.5%)	0.000
Operative time > 240 minutes ^a	19 (8.2%)	16 (25.4%)	3 (4.8%)	0.000
Fischer score sum > 2 points	20 (8.6%)	14 (22.2%)	6 (3.6%)	0.000
HPW-stage (median, IQR)	2 (1-2)	2 (2-3)	2 (1-2)	0.000
I (H1P0W0), (non-)complex	75 (32.3%)	10 (15.9%)	65 (38.5%)	
II (H1P1W0;H2P0-1W0), co-morbid	111 (47.8%)	28 (44.4%)	83 (49.1%)	0.000
III (H1-2P0-1W1;H3P0W0), contam.	39 (16.8%)	19 (30.2%)	20 (11.8%)	
IV (H3P1W0;H3P0-1W1), giant	7 (3.0%)	6 (9.5%)	1 (0.6%)	
Intraoperative characteristics				
Operation time (min., med., IQR)	124 (89-167)	163 (125-240)	111 (81-148)	0.000
Extirpation of previous placed mesh	47 (20.3%)	20 (31.7%)	27 (16.0%)	0.008
Extirpation of an infected mesh	19 (8.2%)	9 (14.3%)	10 (5.9%)	0.039
Unintended bowel lesions	16 (6.9%)	11 (17.5%)	5 (3.0%)	0.000
Concurrent abdominal procedure	32 (13.8%)	20 (31.7%)	12 (7.1%)	0.000
Component Separation Technique	109 (47.0%)	43 (68.3%)	66 (39.1%)	0.000
Use of a biosynthetic mesh	35 (15.1%)	20 (31.7%)	15 (8.9%)	0.000
Bridged repair	5 (2.2%)	4 (6.3%)	1 (0.6%)	0.007
Postoperative characteristics				
Hospital stay (days, med., IQR)	6 (5-8)	9 (7-13)	6 (5-7)	0.000
Respiratory failure	7 (3.0%)	5 (7.9%)	2 (1.2%)	0.008
Unanticipated intubation	4 (1.7%)	2 (3.2%)	2 (1.2%)	0.300
Failure to wean < 48 hours	3 (1.3%)	3 (4.8%)	0	0

Bold are values $p < 0.05$

^aJustified ICU admissions, *med.* Median, *IQR* interquartile range, ^aPost operative parameter, contam. contaminated

Table 5 demonstrates different combinations of (composite) variables and summarizes the AUC's after backward stepwise multivariate logistic regression analysis with these variables (see Figure 2). The Fischer score was modified by excluding dyspnea at rest ($p = 0.095$) and dependent functional status ($p = 0.98$). Also, operative time > 240 minutes ($p < 0.01$) was excluded because this is not a preoperative variable. ASA score was limited to ASA III patients, because ASA IV patients were not included in this study. The HPW was adjusted by excluding small hernias (H1) and non-significant p -factors like BMI ($p = 0.288$), diabetes ($p = 0.126$), smoking status ($p = 0.462$) and use of immunosuppressants ($p = 0.246$), as well as including age, LOD and COPD. No (modified) Fischer score, no (modified) HPW classification, or any other variation demonstrated a higher accuracy than the AUC of the MDT decision. Accuracy of the combined HPW and Fischer score (0.755) approached the accuracy of the MDT decision (0.763).

Table 5. Accuracy (ROC AUC) of (modified) risk-stratifying tools for justified ICU admission after CAWR

	Items	Included items	AUC
MDT decision	1	yes/no for ICU admission	76.3 [69.1-83.4]
Fischer score	1	score per patient (0-7)	70.3 [62.5-78.1]
HPW-classification	1	I-IV score per patient	68.8 [60.9-76.6]
Fischer + HPW-classification	2		75.5 [68.1-82.9]
Modified Fischer	5	COPD, ASA III, HypoAlb, HRIH, PCIAP	71.4 [62.9-79.9]
Modified Fischer + HPW	6	COPD, ASA III, HypoAlb, HRIH, PCIAP, HPW	75.2 [67.2-83.2]
Modified HPW 1	3	H2+H3, P1, W1	68.3 [60.4-76.3]
Modified HPW 2	5	H1+H2+H3, W1, ASA III, HypoAlb, Age	74.0 [66.4-81.5]
Modified HPW 2 without age	4	H1+H2+H3, W1, ASA III, HypoAlb	72.0 [63.7-80.2]
Modified HPW 3	6	H2+H3, P1, W1, PSH, LOD, PCIAP	70.9 [63.0-78.7]
Variables from other studies 1	4	LOD, PCIAP, COPD, ASA III	71.3 [63.5-79.2]
Variables from other studies 2	5	H2+H3, W1, ASA III, COPD, PCIAP	74.1 [66.6-81.6]
Modified HPW 4	6	H2+H3, P1, W1, LOD, HRIH, ASA III, PCIAP	71.9 [64.1-79.6]

A maximum of six items could be tested, MDT Multidisciplinary Team, ICU Intensive Care Unit, HPW Hernia Patient Wound, H1 (0-9.9 cm), H2 (10-19.9 cm), H3 (> 20.0 cm), P0 no comorbidities (BMI > 35 kg/m², nicotine abuse, diabetes or use of immunosuppression), P1 at least one comorbidity present, W0 clean surgical field, W1 contaminated field, HypoAlb Hypoalbuminemia (< 30 g/L), PSH Parastomal Hernia, HRIH History of Recurrent Incarcerated Hernia, PCIAP Planned Concurrent Intra-Abdominal Procedure, LOD Loss of domain $> 20\%$

Discussion

Evaluation of the preoperative decision-making process demonstrated that MDT advised ICU admission in 38% of the complex hernia patients. Intra-operative events changed the MDT decision in 15% of all CAWR patients. MDT overestimated ICU need in 45% of ICU planned patients and underestimated in 10% of nursing ward planned patients. Ultimately, 42% went to the ICU. Twenty-seven percent of all 232 CAWR patients were justified ICU patients. Risk-stratification by MDT could not be further optimized by the Fischer score, HPW classification, or any modification of these tools.

Firstly, it was observed that MDT appeared to have a very low threshold for allocation of ICU resources. Almost half (45%) of ICU planned patients did not undergo any intensive care specific intervention. The rate of ICU admissions (38%) was not only higher compared to similar studies (7-29%), patients were also much less complex, in terms of hernia size, LOD, comorbidities, infected wounds and concurrent operations, than reported in other studies (14, 16). This high level of caution by the MDT may be the result of a learning curve. While, during subsequent years, more attention was put on accurate describing of clear and objective arguments for ICU allocation during MDT meetings, planned ICU admissions decreased and justified admission rates increased. Also, awareness of the MDT 'prudency', by its members, may have also calibrated decision-making over the years.

Secondly, overall accuracy was not high, while postoperative change of MDT's initial decision occurred in one of every seven nursing ward planned patient (15%). This high rate of unexpected ICU transfers, due to unintended fecal spillage, significant bleeding or inadequate epidural functioning, is difficult to predict or prevent. Application of a transversus abdominis plane block may diminish systemic complications of intravenous pain medication (30). Unexpected adhesions prolonging operation time could have been predicted by functional cine MRI-studies, but this method has not gained wide acceptance (31). While not all reasons for decision-change could be retrieved, undocumented considerations like 'gut-feeling' may have also played a role. Patients then still may have a justified reason for ICU transfer, despite objective signs of (an imminent) SIRS are lacking (23). In order to

decrease the inaccuracy of preoperative risk-stratification and learn from the unpredictability of intra-operative events, increased end-procedural attention was introduced. During 'sign out', at the end of the operation, the operation room team specifically appoints any unexpected intra-operative event, confirms or rejects presence of (an imminent) SIRS or abdominal compartment syndrome, and evaluates patient's capability to cope with a potential SIRS. Awareness of these findings may improve decision-making.

Thirdly, each (modified) risk-stratifying tool was less accurate than MDT's decision. Fischer score is hampered by not including hernia size and wound contamination as risk factors. Applicability of the Fischer score is also lower in case of a few patients with an increased Fischer score, like in this series (9% versus 19% in the original Fischer study). HPW is limited because it was not primarily designed to stratify for ICU admissions, nor does it include relevant risk factors like LOD, COPD or age. Moreover, effective prehabilitation on BMI, smoking, diabetes and use of immunosuppressants ('P' factors), being present in our series, made these risk factors not significant, which decreased HPW accuracy.

While risk-stratification remains essential to patients, surgeons, health care, and clinical research, most risk models make often more "mathematical sense", than clinical sense, especially when these models are validated externally (32). Predicting a patient's likelihood of developing complications following CAWR remains difficult due to the unpredictability of intra-operative events (32-34). Nevertheless, this study demonstrated that the combination of both tools approached MDT's accuracy, because together they incorporate most of the reported relevant risk factors for respiratory failure or ICU admission, after CAWR. Both tools do not include age and LOD, reported as relevant risk factors by others authors (11-18). Probably, these factors should also be incorporated in any new risk-stratifying tool. Despite their limitations, the combination of Fischer score and HPW classification may still be helpful in selecting patients needing an ICU bed after CAWR.

Last observation by the authors is the added value of non-surgical specialists to the MDT. The capability of a patient to cope with postoperative changes in pulmonary plateau pressures, is a little explored field, in which surgeons can learn from

pulmonologists (11). It has also been noted that intensive care physicians appreciate involvement in the decision-making process before a complex surgical procedure is performed, rather than being presented with an unexpected difficult case in a postoperative acute setting (22, 23, 35, 36).

The conclusion that the MDT is more valuable in predicting ICU after CAWR than any risk-stratification tool, is based on detailed analysis of interventions performed at the ICU and multivariate logistic regression analysis of relevant preoperative risk factors. The retrospective design, relatively small sample size compared with other publications, and the fact that several significant risk factors in this study did not corresponded with previously reported risk factors in other publications, limited predictive risk modelling to further optimize the decision-making process.

The recommendation that for every planned complex abdominal wall reconstruction, an ICU bed must be available, is supported by the high rate of unexpected intra-operative events that led to decision changes in 15% of the nursing ward planned patients. On the other hand, putting this dogma into practice will lead to unnecessary reservation of ICU beds in 73% of all CAWR patients, or in 45% of all ICU planned CAWR patients. The clinical situation of a full ICU in the morning, while a complex hernia patient is waiting for elective repair, will make the surgeon reflect, whether complexity is a dichotomic scale, or if it varies between light white and dark black. If zero risk is pursued, every CAWR patient should be cancelled in such a situation. Further improvement of the risk stratification tools is warranted.

Conclusion

This study was originally initiated to reduce the rate of unnecessary planned ICU beds and improve risk-stratification. Exploring the relationships between the MDT decision, outcome of risk-stratifying tools and the rate of justified ICU admissions, provided a deeper insight in the context and impact of the decisions made by the MDT and in the operation room. Ultimately, the MDT proved more accurate in predicting justified ICU admissions, than the Fischer score and HPW classification, although the combination of both tools approached MDT's accuracy. Overall, MDT's

accuracy was not particularly high, due to the uncertainty of the intra-operative factor. Several options to further optimize risk-stratification are presented.

While in many other specialties, the presence of an MDT improved quality of care, in complex hernia surgery, MDT's are not omnipresent (36). Although the profit of such multidisciplinary teams may be clear, its intrinsic value is difficult to measure (37). This study demonstrated the value of a multidisciplinary team in risk-stratification. This unexpected finding can be an incentive for hernia centers to implement such a multidisciplinary team in their own complex hernia care pathway (23).

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Chapter 4

Impact of hernia volume on pulmonary complications following complex hernia repair

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Abstract

Background Despite a multitude of evidence based prediction models and risk factors for postoperative complications after ventral hernia repair, estimating a patient's risk of postoperative complications after ventral hernia repair remains challenging. In an attempt to improve the preoperative assessment of complex hernia patients, some studies have examined pulmonary changes after hernia repair hypothesizing that large hernias lead to pulmonary changes and increased pulmonary complication rates. Some studies have described a correlation between hernia volume and pulmonary changes, though none provided strong evidence to identify hernia volume as a risk factor for pulmonary complications. This study evaluates the relationship between hernia volume and postoperative pulmonary complications using CT-based volume measurements.

Materials and methods Analysis of a prospectively maintained database of consecutive complex hernia patients from 2011 to 2014 undergoing endoscopic (ECST) or open component separation technique (CST) for a hernia defect with a minimum width of 6 cm and visual protrusion of the hernia sac ventral of the rectus muscles in supine position was performed. Hernia volume was calculated using Multiple Plane Reconstruction of a standard abdominal CT-scan. Noted endpoints were pulmonary complications.

Results 35 Patients underwent ECST ($n = 20$) or CST ($n = 15$) with a median defect volume of 474 cm³ (range 114-2086 cm³). Observed complications were: pneumonia ($n = 4$), pulmonary infiltrate ($n = 3$), aspiration pneumonia ($n = 2$) and acute respiratory distress syndrome ($n = 1$). Uni- and multivariate analysis showed that pulmonary complications were associated with 'hernia volume' ($p = 0.045$; 95% CI [1.008-1.910]).

Conclusions Hernia volume is a promising risk factor for postoperative pulmonary complications and can be calculated using a standard abdominal CT-scan.

Introduction

Reducing large ventral hernias is accompanied with a postoperative complication rate up to 57%, depending on the technique, the patient's comorbidity and complexity of the hernia (2-8). Despite a multitude of evidence based prediction models and risk factors for postoperative complications, estimating a patients' risk of complications following ventral hernia repair remains challenging (9). Hernia repair centres use preoperative multidisciplinary assessments to evaluate patients and estimate their postoperative risk for complications (10). These assessments include variables such as Body Mass Index (BMI), percentage of glycosylated haemoglobin (HbA1C), age, co-morbidity and smoking (10). In an attempt to improve the aforementioned assessment, several studies have analysed pulmonary changes after ventral hernia repair (11-13). These studies hypothesized that when a large ventral hernia is reduced inside the abdominal cavity the intra-abdominal volume will rise. Since the abdominal wall limits the abdomen in expanding outward, the intra-abdominal pressure will increase, causing pulmonary compliance to decline (13). Despite experts agreeing on the validity of this theory none of the previously mentioned studies directly evaluated the correlation between hernia volume and the risk of pulmonary complications (11, 14). This study evaluates the relationship between hernia volume and pulmonary complications using CT-based volume measurements and a prospectively maintained database of pulmonary complications.

Methods

During 2011 and 2014 all patient undergoing complex ventral hernia repair were registered at a hospital specialised in abdominal wall surgery (2, 15). Patient characteristics, pulmonary function and complications were registered prospectively. Thirty-five consecutive patients with ventral hernias were extracted from the aforementioned database if they fulfilled the following criteria. Any patient with a mid-line hernia ≥ 6 cm in width that underwent 'endoscopically assisted' (ECST) or 'open' components separation technique (CST) with evident protrusion of the hernia content ventral of the rectus abdominis muscles in a relaxed supine position.

Exclusion criteria were any patient with rectus diastasis without a true ventral hernia, previous subcutaneous dissection, American Society of Anaesthesiologists (ASA) classification IV or V (16), Body Mass Index (BMI) $> 30 \text{ kg/m}^2$ and patients with a reduced forced expiratory volume ($\leq 80\%$) and/or Vital capacity ($\leq 70\%$) when compared to the predicted value (17, 18).

All patients underwent a standard preoperative abdominal CT-scan without Valsalva manoeuvre. All hernias were classified using the European Hernia Society (EHS) guidelines for hernia classification (19).

The endoscopic component separation technique was performed as described by Mommers et al. (15). All operations were performed by three experienced gastrointestinal surgeons trained in abdominal wall reconstructions (JW, SN and TdVR). Patients were followed at the outpatient clinic (2, and 6 weeks, 3, 6, 12, and 24 months postoperative). Recurrence was assessed during physical examination in standing and supine position, if a clinical recurrence was uncertain an abdominal CT-scan was performed.

Volume measurements

Hernia volume was expressed as a percentage of the total abdominal volume (hernia sac volume (HSV) + abdominal cavity volume (ACV)) that resided inside the hernia sac during standard abdominal CT-scan without Valsalva manoeuvre, and calculated by dividing HSV through the total abdominal volume. HSV was defined as the volume in front of the ACV, demarcated by the parieto-peritoneum of the hernia sac.

All volumes were measured using volume analysis software (ViewForum R6.3V1L3 version 2008) from Philips Healthcare®/Philips Medical System® (Figure). Outlining of the volume was done partially by hand using the 'contour stack' method to calculate volume within a Multiple Plane Reconstruction of a standard abdominal CT-scan. A slice thickness of 2 mm was used, every 4-5 slices a new outlining was made by hand. The software would then interpolate the contours between the outlined areas based on Hounsfield units of the outlined areas. All measurements were performed by the same author (EM) blinded for patient outcome.

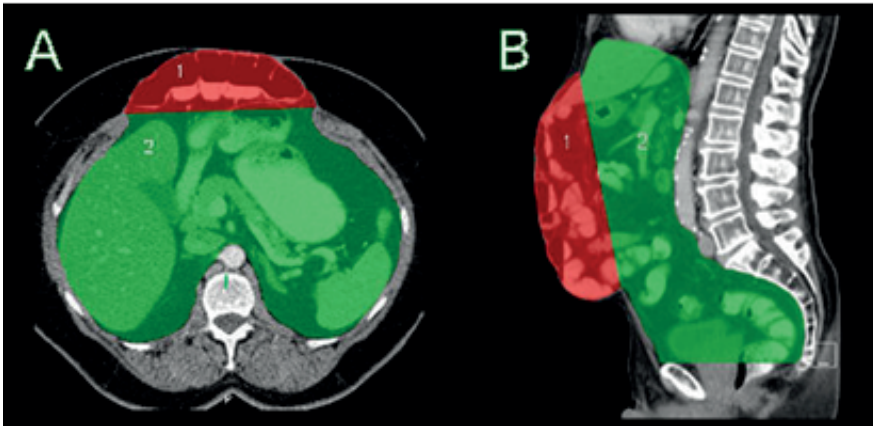


Figure. CT-outlining of hernia sac (HSV) and abdominal cavity volume (ACV). (A) transversal slide showing CT-outlined hernia volume (1/red) and intraperitoneal space (2/green). (B) Sagittal slide showing hernia volume and abdominal cavity volume with caudal limit over the pubic symphysis.

Statistical analysis

Univariate and multivariate analysis were performed to identify statistically significant risk factors for postoperative pulmonary complications. Only known confounders or variables that showed a statistical significance of ≤ 0.06 (approaching alpha of 0.05) in the univariate analysis were included in a multivariate logistic regression analysis to correct for any interactions between the variables.

Statistical analysis was performed with IBM corp. SPSS statistics for windows, version 24, released 2014, Armonk, NY: IBM corp. Correlations were calculated using Pearson's coefficient R. Regression analysis was performed using binomial multivariate logistic regression analysis, standard distribution was tested with the Shapiro-Wilk test, Wilcoxon Signed Rank test or paired two-sided Students t-test was used to compare means depending on the probability distribution of the included variables.

Results

Thirty-five patients (13 female, 22 male) with a median age of 63 years (range 39-77), mean body mass index (BMI) of 27 kg/m^2 ($\text{SD} \pm 6.4 \text{ kg/m}^2$) and median American Society of Anaesthesiologists classification II (range, 1-3) were included (Table

1). All but three patients received mesh augmentation. The median hernia volume was 5.4% (range, 1-25%) with an absolute volume of 474 cm³ (range, 114-2086 cm³). Two patients had COPD gold II and one patient had asthma. All patients fulfilled the criteria for complex hernia as formulated by Slater et al., ‘minor’ ($n = 11$), ‘moderate’ ($n = 18$), ‘major’ ($n = 6$) (20).

Postoperative complications

Seven patients experienced seven mild pulmonary complications, and three patients experienced severe postoperative pulmonary complications. Two of these patients died, one due to sepsis caused by aspiration pneumonia and one due to multiple organ failure and acute respiratory distress syndrome (Table 2). Median hospital stay was 6 days (range, 3-103 d).

Statistical analysis

A univariate analysis was performed to identify the influence of a multitude of risk factors on postoperative pulmonary complications (Table 3). Hernia volume was the only statistically significant predictor ($p = 0.018$) for pulmonary complications. The variable ‘operation Method’ ($p = 0.056$), did not show a statistically significant effect in the univariate model, though since this dataset included two types of component separation techniques (ECST and CST), each associated with different degrees of release and risk of pulmonary complications the ‘operation method’ variable was a confounder in this dataset. Therefore, it was entered in the multivariate model despite the lack of statistical significance (Table 3). Additionally, the risk factor ‘smoking’ showed a near statistical significant result ($p = 0.059$). These three variables were entered in a binomial multivariate logistic regression analysis model to correct for interaction and confounding (Table 3). The logistic regression model explained 44% (Nagelkerke R^2) of the variance in the occurrence in postoperative pulmonary complications and correctly classified 77% of patients with significant goodness of fit (Hosmer and Lemeshow test $\chi^2 = 7.858$; $p = 0.345$). In the multivariate model “hernia volume” was the only statistically significant variable (Table 3). Based on the Wald χ^2 test values in the univariate and multivariate model, “hernia volume” was the most influential variable followed by “smoking” and “operation

method”. A receiver operating characteristic (ROC)-curve analysis (area under the curve 0.772) showed 5.6% evisceration as optimal cutoff value for increased risk of pulmonary complications (sensitivity 0.80, specificity 0.68).

Table 1. Demographic, perioperative, and recurrence details

Demographic characteristics (n = 35)	
Age (yr), median (range)	64 (39-77)
Gender (male/female)	22/13
BMI (kg/m ²) mean (SD)	26.7 (± 3.4)
Smoking	6 (17%)
Ex-smoker	10 (29%)
Diabetes, type 1/type 2	1 (2%) / 6 (17%)
ASA classification III	10 (29%)
Previous repair	11 (31%)
Abnormal Preoperative PFT	5 (14%)
Perioperative details	
Operation, ECST / CST	20 (57%) / 15 (42%)
Concomitant enterostomy take down	7 (20%)
Operating time (min), median (range)	122 (69-239)
Mesh placement	31 (89%)
Contamination	
Clean-contaminated	14 (40%)
Contaminated	0 (0%)
Dirty	2 (6%)
Infected mesh extirpation	4 (11%)
Postoperative details	
Length of stay (days), median (range)	6 (3-103)
Recurrence rate*	
Hernia recurrence*	4 (11%)

Demographic characteristics of all included patients (%) = percentage of total population; PFT = pulmonary function test; (E)CST = (endoscopic components separation technique; contamination = Clavien-Dindo classification for surgical complications; Smoking = occasional smoker; Ex-smoker = stop smoking ≥ 3 months before surgery

* Hernia recurrence after a mean follow-up of 1 year (SD ± 9 months)



Table 2. Pulmonary complications within 30 days postoperative

Complications Class I or II* (<i>n</i> = 7, 46%)	
Pneumonia	4 (11%, ECST <i>n</i> = 2/CST <i>n</i> = 2)
Pulmonary infiltrate	3 (9%, ECST <i>n</i> = 2/CST <i>n</i> = 1)
Complications Class III, IV or V* (<i>n</i> = 3, 14%)	
Aspiration pneumonia	2 (6% ECST <i>n</i> = 1/CST <i>n</i> = 1)
Acute respiratory distress syndrome	1 (3% ECST <i>n</i> = 0/CST <i>n</i> = 1)

Pulmonary complications within 30 days postoperative

*Clavien Dindo classification for surgical complications¹; Pneumonia was defined as the presence of a pulmonary infiltrate on chest radiograph in combination with fever or a positive sputum culture; pulmonary infiltrate was defined as an infiltrate seen on chest radiograph without the presence of fever or a positive sputum culture

Discussion

The concept of a correlation between hernia volume and postoperative pulmonary complications has been suggested previously, though evidence for a correlation between hernia volume and pulmonary complications was not provided up till now (11, 14, 20, 21). Using multivariate analysis, we were able to provide the first statistically significant evidence for a relationship between pulmonary complications and hernia volume. Gaidukov and colleagues proved that the intra-abdominal pressure rises after ventral hernia repair and a subsequent reduction in pulmonary dynamic compliance of 15-20% occurs (13). Sabbagh et al. investigated the relationship between hernia volume and abdominal compartment syndrome in seventeen patients with giant incisional ventral hernia that were treated with preoperative progressive pneumo-peritoneum (11). They divided their population in two groups based on the need for additional interventions to close the abdomen (i.e. colonic resection) and observed that the group with additional interventions had a higher loss-of-domain. They used a cut-off value of 20% as predictor for tension free-closure in a multivariate logistic regression analysis (Odd's 35; 95% CI [1.38-888] $p < 0.05$). Agnew et al. investigated diaphragm height and changes in pulmonary function tests after a component separation technique and found no significant difference (12). In light of the study by Gaidukov et al., diaphragm height may not be the most sensitive tool to assess pulmonary changes after hernia repair. Agnew et al.

measured pulmonary function and diaphragm height three months after hernia repair. Arguably, this period is too long to detect pulmonary changes that occurred due to the operation, since any change in diaphragm height may have been compensated during the first three postoperative months.

Table 3. Univariate and multivariate analysis of predictors for postoperative complication

Variable	Univariate logistic regression analysis			Multivariate logistic regression analysis (R ² = 0.437, correct pred. 77%)		
	Odds ratio (B ^{exp.})	Wald test (P value)	95% CI	Odds ratio (B ^{exp.})	Wald test (P value)	95% CI
Hernia Volume (%)	1.445	5.608 (0.018)	1.066 - 1.960	1.387	4.031 (0.045)	1.008 - 1.910
Age	1.049	2.005 (0.157)	0.982 - 1.122			
BMI	1.082	0.562 (0.454)	0.881 - 1.327			
Smoking	0.105	3.747 (0.053)	0.011 - 1.029	0.188	1.873 (0.171)	0.017 - 2.058
Infected Mesh	1.556	0.120 (0.729)	0.128 - 18.951			
Gender	0.490	1.007 (0.316)	0.121 - 1.975			
Diabetes	2.114	1.517 (0.218)	0.642 - 6.956			
Operation method	4.125	3.656 (0.056)	0.965 - 17.630	1.843	0.485 (0.486)	0.330 - 10.307

R² = Nagelkerke R² represents portion of variance explained by model; correct pred. = correctly predicted percentage of population explained by the model; Odds Ratio = B^(exp) in the logistic regression model; Wald test = test for significance of individual variable corrected for other variables in the model; 95% CI = 95% confidence interval of B^(exp)

Our study uses the observations of Sabbagh et al. and Gaidukov et al. to explore any correlation between hernia volume and pulmonary complications using CT-based volume calculation combined with uni- and multivariate statistical analysis. A statistically significant relationship between hernia size and pulmonary complications was found in both the univariate and multivariate logistic regression models. Based on these models an increase in evisceration of 1% would increase the odds of getting a pulmonary complication with 1.387. The ROC-curve analysis showed 5.6% evisceration as optimal predictive value for pulmonary complications. In our series, with a median abdominal content of 9177cc, this would indicate that any patient with a hernia volume larger than 514cc on standard abdominal CT-scan without Valsalva manoeuvre has an increased risk of pulmonary complications.



However, given the small sample size and the majority of mild complications included in this study this value could be underestimated.

The software used in this study to calculate hernia volume can import any standard abdominal CT-scan, without the need for additional scanning protocols or sequences. Measuring the abdominal and hernia volume will take approximately 15-20 minutes per patient. Therefore, performing this measurement will not lead to additional costs, other than the invested time. The authors would like to stipulate that hernia volume measurement should be performed using exact CT-based measurement software, such as used in this study. Measuring volume with mathematical formulas such as described by Tanaka et al. is deemed unfit since these methods are not validated for exact volume calculation (22).

This study provides the first preliminary evidence for the existence of a direct correlation between hernia volume and pulmonary complications. Though there are limitations that must be accentuated. The sample size is small and therefore the number of events in the multivariate model is low, increasing the risk of bias. Due to the small population ROC-curve analysis only provides a crude estimation of the optimal cut-off value. Therefore, the results of this study must be interpreted with caution. In addition, consecutive patients were derived from a prospectively registered database of complex hernia patients, resulting in a population with pulmonary comorbidities and increased risk for pulmonary events. Ideally a population without pulmonary comorbidity should be used to isolate the effect of hernia volume more accurately. However, patients with large ventral hernias tend to have a high number of comorbidities, making patients without risk factors for pulmonary complication rare. Despite the above mentioned limitations the current study demonstrates the importance of hernia volume as a risk factor for complications in a high risk population, and encourages future research in preoperative risk assessments using hernia volume.

Recommendations for future research

Hernia volume can be expressed in different manners. Measuring the absolute volume will not result in a reliable outcome. Since the total abdominal volume can vary greatly between patients, hernia volume must be expressed as a ratio or

percentage of the total volume in order to create a comparable factor between different patients. Moreover, different limits can be used to define the intra-abdominal volume (i.e. with or without retroperitoneal organs). For future research the authors would recommend the anatomical boundaries of volume measurement stated by Sabbagh et al. which were also applied in this study.

Conclusion

Hernia volume is a promising risk factor for postoperative complications and can be calculated using standard abdominal CT-scans. To evaluate the effect of hernia volume in more detail, we recommend a larger study with more statistical power to isolate the impact of hernia volume on pulmonary complications more accurately.

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Chapter 5

Preoperative exercise therapy preventing postoperative complications following complex abdominal wall reconstruction: A feasibility study

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Abstract

Purpose The population undergoing complex abdominal wall reconstructions (CAWR) tend to have significant associated, multiple comorbidities, complicating the recovery of a reconstruction. Undergoing CAWR exposes these patients to a risk for respiratory complications, which is common after CAWR. These complications are associated with an increased surgical morbidity and mortality, prolonged length of hospital stay (LOHS), an additional cost burden and decrease in health related quality of life (HRQoL). Improving the physical capacity before CAWR, by preoperative exercise therapy (PexT), is likely to give a better recovery and lower complication rate. In this study, we will survey the feasibility of PexT in patients undergoing a CAWR. Outcome measures will be added to demonstrate a possible effect of PexT.

Materials and methods A feasibility study was performed. The intervention consisted of a three month lasting exercise program consisting of cardiovascular-, strength and respiratory muscle training under direct supervision of a physiotherapist. The primary outcome was feasibility, defined as the occurrence of adverse events and the possibility to perform more than 80% of the intervention. Secondary outcome were the physical capacity, HRQoL, the amount of pulmonary complications and the LOHS. Physical capacity was measured with a cardiopulmonary exercise test (CPET) before and after the intervention and after surgery.

Results Nine male and two females were included with a median age of 59 years (95% CI 51-71) and a median BMI of 31.6 kg/m² (95%CI 28.1-36.7). The median width of the ventral hernia was 16.0 cm (95%CI 15.0-23.0). No adverse events occurred and all patients could complete the intervention. Both physical capacity and HRQoL improved after the intervention. All patient had a successful reconstruction with fascial closure.

Conclusion Intensive PExT is feasible in patients waiting for a complex abdominal wall reconstruction. A randomized controlled trial need to be conducted to objective the effect of PExT to prevent pulmonary complications and reduced LOHS in this population.

Introduction

With increasing life expectancies, more comorbidities and progress in operative solutions, Abdominal Wall Reconstruction (AWR) is available for more complex hernias in more complex patients. The technical advancement in AWR is mainly by myofascial releases on several levels and addition of aids like pneumoperitoneum or Botox® (1, 2). This enhances the movement of muscles relative to other muscles in order to overcome the defect. Examples of techniques like Ramirez/CST, eCST or TAR have been introduced (3, 4, 5). However, the population undergoing an AWR tend to have significant associated, multiple comorbidities, complicating the recovery of a repair (6, 7).

Through AWR, diaphragmatic function, use of respiratory accessory muscles and coughing strength are negatively affected (8). Which exposes these patients to a higher risk for respiratory complications. Especially when a myofascial release is used, in which the external oblique muscle or transversus abdominus muscle is released. Patients may have difficulty with coughing and forced expiration since the external oblique muscles and transversus abdominus muscle are accessory respiratory muscle.

Respiratory complications (pneumonia or respiratory insufficiency), following AWR are common, up to 20% (8, 9). These complications are associated with a significant increased surgical morbidity and mortality, prolonged hospital- and ICU-stay, a significant additional cost burden (9,10) and indirectly a decrease in quality of life (11). The occurrence of respiratory complications and the progress of postoperative recovery are influenced by the preoperative physical capacity (12, 13). Impaired physical capacity is associated with all-cause mortality after major elective intra-abdominal surgery. Physical capacity can be tested with a cardiopulmonary exercise test (CPET). One of the outcome measurements is the anaerobic threshold (AT). The AT is the transition of the aerobic exertion (with oxygen) to the anaerobic exertion (with deficiency of oxygen). An AT lower than 11 ml/kg/min is associated with a higher mortality in great abdominal wall surgery (14). Improving the physical capacity before surgery, by preoperative exercise therapy (PexT), is likely to give a better recovery and lower complication rate after surgery. In the last few years

several systematic reviews had been published about prehabilitation in different populations. Recently also for major abdominal surgery (15, 16). These reviews show a positive effect of prehabilitation on postoperative pulmonary complications but not on length of hospital stay (LOHS). All reviews recommended to implement prehabilitation routinely before major abdominal surgery. In these reviews diverse surgical procedures are included but there is no single trial in patients waiting for a complex abdominal wall hernia. Most recent studies about prehabilitation in patients with complex ventral hernia focus on weight loss and not on physical capacity (17, 18). Due to the excessive loss of domain and/or enormous size of the belly patients often are afraid to do exercises.

In this study, we will survey the feasibility of an intensive PexT in patients undergoing a complex AWR. Outcome measures will be added to demonstrate a possible effect of PexT on the physical capacity, health related quality of life (HRQoL), pulmonary complications and LOHS.

Materials and methods

A prospective cohort study was conducted between January and April 2018. Adult patients (age 18-80 years) with a midline ventral hernia of >10 centimetre width were included. Patients were excluded with a body mass index (BMI) $20 \leq$ or ≥ 40 kg/m², ASA ≥ 4 or any comorbidity interfering with the ability to perform exercise (e.d. neuromuscular or orthopedic disabilities). The sample size was set on 11 patients, since this number is within the capability of a single center study and should provide sufficient evidence to evaluate the feasibility of the intervention.

Intervention

The intervention was a three months program consisting of three components. At first patients were given information about the benefits of preoperative exercise therapy (PexT) and encouragement to adhere to the intervention. Second: patients were instructed to use an inspiratory threshold-loading device (IMT) for 15 min daily. The initial load was set at 20% of the maximal inspiratory pressure. Increasing weekly by 10% if the exhaustion score (Borg-score) was <13 (19, 20). Third: three

times a week patients had to do cardiovascular-, and strength training. Two supervised and one unsupervised session at home. The supervised session lasted for 60-90 minutes and consisted of 30-40 minutes aerobic training on 60-80% of the $VO_2\text{max}$ or just below the anaerobe threshold. Resistance training of 6-8 great muscle groups was executed on 80% of 1-repeated maximum (1RM), for 8 repetitions in 4 series (21). Patients were instructed to wear their abdominal binder and to breath out during the exercise. In the unsupervised session the patient had to do a functional activity, according to the capabilities and interest of the patient. The activity had to last for at least 45 min and the exhaustion score (Borg-score) must be between 11-13. The patient receives guides on active cycle of breathing exercise, including coughing and huffing, prior to the operation (22). If necessary, patients were instructed to quit smoking or to lose weight, since this is usual care in the Elkerliek Hospital.

Outcome measurements

The primary outcome was feasibility, defined as the occurrence of adverse events and the possibility to perform more than 80% of the training on the before set intensity. Secondary outcome were the physical capacity, HRQoL, the amount of pulmonary complications and the LOHS. Physical capacity, measured with the cardio-pulmonary exercise test (CPET), was conducted at baseline, after the intervention and 3 months after the operation. The CPET was performed on the cycle ergometer (Lode Corival, Groningen, The Netherlands). The test was conducted by the sports physician and consisted of an anaerobic threshold and maximal oxygen consumption measurement ($VO_2\text{max}$). The test was symptom limited and respiratory gas analysis was conducted.

HRQoL was measured with the RAND-36 (23) at baseline and after intervention. Pulmonary complications were defined as >48 h on the mechanical ventilator after surgery, re-intubation, acute respiratory distress syndrome (ARDS), atelectasis or pneumonia (either pulmonary infiltration on X-ray in combination with clinical symptoms or positive sputum culture). LOHS was noted from day of surgery until day of discharge.

Statistics

Data-analysis was performed using the Statistical Package for the Social Sciences (SPSS) 24.0 (SPSS Inc., Chicago, Illinois). Descriptive statistics will be noted in median and 95% confidence interval (CI). Since the small amount of patients, no normality of data will be reached. Domains of the RAND-36 and physical capacity was analyzed with the non-parametric Wilcoxon signed-rank test. The amount of pulmonary complications and LOHS were noted and compared to all comparable patients in 2018 with respectively the Fisher's exact test and Mann-Whitney *U*-test. For all analysis a significance of $p < 0.05$ was used.

Results

From all the approached patients, one did not want to participate in this study (due to the distance to the training centre). Eleven patients were included between January and April 2018. Nine male and two females were included with a median age of 59 years (51-71) and a BMI of 31.6 kg/m² (28.1-36.7). The median diameter of the width of the ventral hernia was 16.0 cm (15.0-23.0). Demographics can be found in Table 1. During the PexT, no adverse events occurred and all patients could perform the intervention for >80% on the before set intensity. All patients completed the full program.

Table 1. Patient demographics

Characteristic	Median (95% CI)
Sex (m/f)	9/2
Age (years)	59 (51-71)
BMI (kg/m ²)	31.6 (28.1-36.7)
Hernia width (cm)	16.0 (15.0-23.0)

CI = confidence interval, m = male, f = female, BMI = body mass index, kg = kilogram, cm = centimeter

A difference in VO₂max was found between the baseline measurement and after the intervention (Table 2). Also a clinically relevant difference was found in the overall HRQoL between baseline and after the intervention ($p = 0.028$). Evaluating

the different domains of the RAND-36, there was an improvement in most domains (Figure 1/Table 3).

Table 2. Outcome CPET in median (95% CI)

	T0 (n = 11)	T1 (n = 11)	T2 (n = 9)	Sign. TO-T1 (p)	Sign. T1-T2 (p)	Sign. TO-T2 (p)
VO ₂ max (ml/kg/min)	21.2 (18.2-28.3)	22.6 (21.4-30.1)	25.3 (22.3-31.9)	0.003	0.192	0.038
VO ₂ AT (ml/kg/min)	15.5 (11.5-17.0)	15.7 (14.6-18.6)	16.9 (15.10-18.7)	0.213	0.953	0.594

CPET = Cardiopulmonary exercise test, CI = confidence interval, mL = milliliter, kg, kilogram, min = minutes, AT = anaerobe threshold, T0 = baseline, T1 = after 3 months intervention, T2 = 3 months after surgery

Significance tested with the Wilcoxon signed-rank test

Table 3. Quality of life (RAND-36) in median (95% CI)

	T0	T1	Sign. (p)
Overall score	76.5 (60.7-87.9)	88.2 (73.5-96.7)	0.028
Physical functioning	67.5 (47.5-85.0)	87.5 (57.5-95.0)	0.066
Social functioning	93.8 (75.0-100.0)	100.0 (87.5-100.0)	1.000
Physical role functioning	62.5 (0.00-100.0)	100.0 (75.0-100.0)	0.285
Emotional role functioning	100.0 (66.7-100.0)	100.0 (100.0-100.0)	1.000
Mental health	84.0 (60.0-100.0)	98.0 (88.0-100.0)	0.066
Vitality	65.0 (52.5-75.0)	85.0 (77.5-95.0)	0.042
Pain	67.3 (44.9-79.6)	89.8 (67.3-100.0)	0.068
General health	65.0 (50.0-75.0)	77.5 (57.5-92.5)	0.066
General health change	75.0 (50.0-100.0)	100.0 (50.0-100.0)	0.083

T0 = baseline, T1 = after 3 months intervention

Significance tested with the Wilcoxon signed-rank test

All patient had a successful reconstruction with fascial closure. Reconstruction was performed with transversus abdominal release ($n = 6$), endoscopic component separation technique ($n = 2$) or Rives-Stoppa ($n = 3$). Three patients had a pulmonary complication, which is 27% of the total population in the study. This complication rate did not differ from the other likewise patients in our institute ($n = 50$, $p = 0.676$). The median of hospital stay was 6.8 days (range 3–15) and did also not differ from the patients outside this study ($n = 50$, 6.9 days (range 2-19), $p = 0.455$).

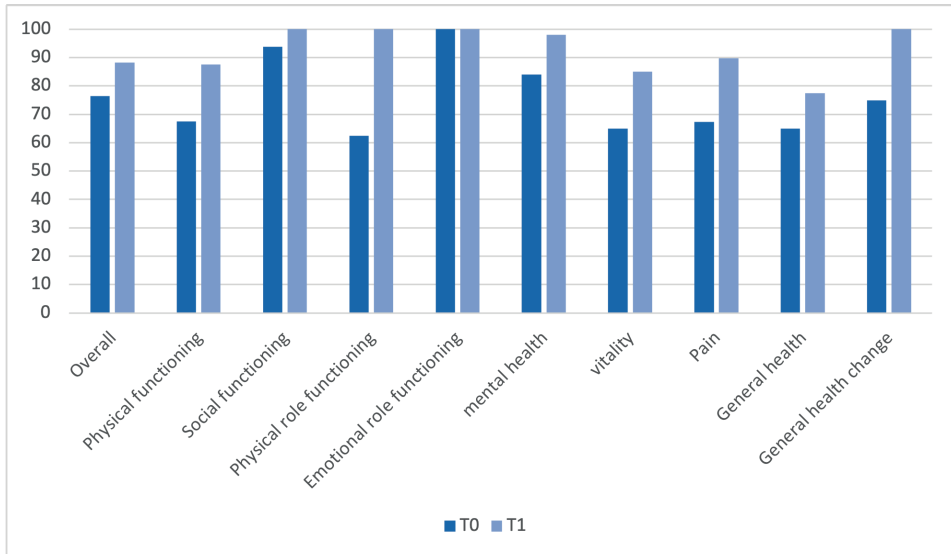


Figure 1. Domains of HRQoL according to the RAND-36. T0 = baseline, T1 = after 3 months' intervention

Discussion

This study shows that intensive PExT is feasible in patients with a complex abdominal ventral hernia. Next to that, we found a relevant difference on the physical capacity and HRQoL after the intervention. No difference was found on pulmonary complication rate or LOHS after surgery.

In the most recent reviews on prehabilitation in major abdominal surgery contradictory evidence was found on the effect of prehabilitation on physical capacity, mainly through the heterogeneous use of outcome measurements (15, 16). Physical condition is mostly measured with the six-minute-walking-test. The six-minute-walking test is an acceptable and cheap alternative to test the physical function in daily practise but it is not as specific as the CPET, which is the golden standard for measuring physical capacity (14). A CPET is more sensitive to identify significant differences in physical capacity. The CPET also provides outcome measures as the VO_2 max and AT. These outcomes are desired to identify the precise intensity of the cardiovascular training.

To achieve the best result of preoperative training not only the intensity is important but also the duration of the training. The interventions in the studies included in the most recent reviews are short (max. 6 weeks) and low intensive with a duration of maximal 60 min. To create a significant and clinical relevant difference on physical capacity it is desired to prolong the time of the intervention program and to intensify the therapy program (Figure 2) (21). This might clarify why the effects of preoperative training that are published, are minimal. In case of a complex abdominal ventral hernia it is in most cases possible to postpone surgery. This time should be taken to achieve a greater result of PExT.



Figure 2. A patient performing the strength training in the leg press

The results of 3 months training in this study show a positive change on physical capacity and also in overall score and most domains of the HRQoL. This can be attributed to the general effects of physical activity on HRQoL (24). Thereby, patients with a great abdominal hernia are often afraid to exercise since they have developed a ventral hernia before. The fear for exercise can contribute to the decrease of HRQoL in patient with a complex abdominal hernia. The positive findings on feasibility might motivate patients with a complex abdominal wall hernia to exercise before surgery. Next to that, patients often feel like they are hand down to the

medical system when they are waiting for surgery. To improve physical performance, they can positively contribute to their own care path. This will increase the autonomy of the patient and, when good instructions are given, it will increase the compliance to the exercise which is proposed to be essential for a potential prehabilitation program's success (16).

Another essential aspect for succeeding of the PExT are the supervised sessions, since these tend to have a greater effect than unsupervised sessions in other diseases (25, 26). The interventions as described in this study includes intensive strength training at 80% of the 1RM. When this amount of strength is conducted, the intra-abdominal pressure (IAP) raises which increases the bulging through the ventral hernia. This is associated with discomfort and pain. It is essential to give instructions during the intervention to prevent increased IAP, through raising the diaphragm by breathing out during the contraction of the strength exercise. This in addition to the counter-pressure of the abdominal binder. Therefore PExT in patients with a complex abdominal wall hernia needs to be guided by an experienced physical therapist.

In contradiction with the other studies we found no effect on the prevention of pulmonary complications or LOHS. Since the population of this study is small, it was not expected to find a significant difference between groups. In the Elkerliek Hospital prehabilitation (quit smoking and to lose weight) and enhanced recovery after surgery are applied for years for all patients after an AWR. As this contributes to improved clinical outcomes and decreased LOHS (27), it is harder to find a significant difference on these outcome, especially in this small number of patients.

Limitations

The greatest limitation of this study was the small sample size and the lack of a control group. Since this is the first initiative for an intensive preoperative training program in patients with great abdominal wall hernias, a greater population should be tested in the future.

Selection bias occurred in this study because the patients who agreed to participate in the study are mainly patients who are motivated to fill the intervention.

Lastly, all patients had an successful AWR but different operation techniques are used. It is not described that whether or not a myofascial release provides more (pulmonary) complications.

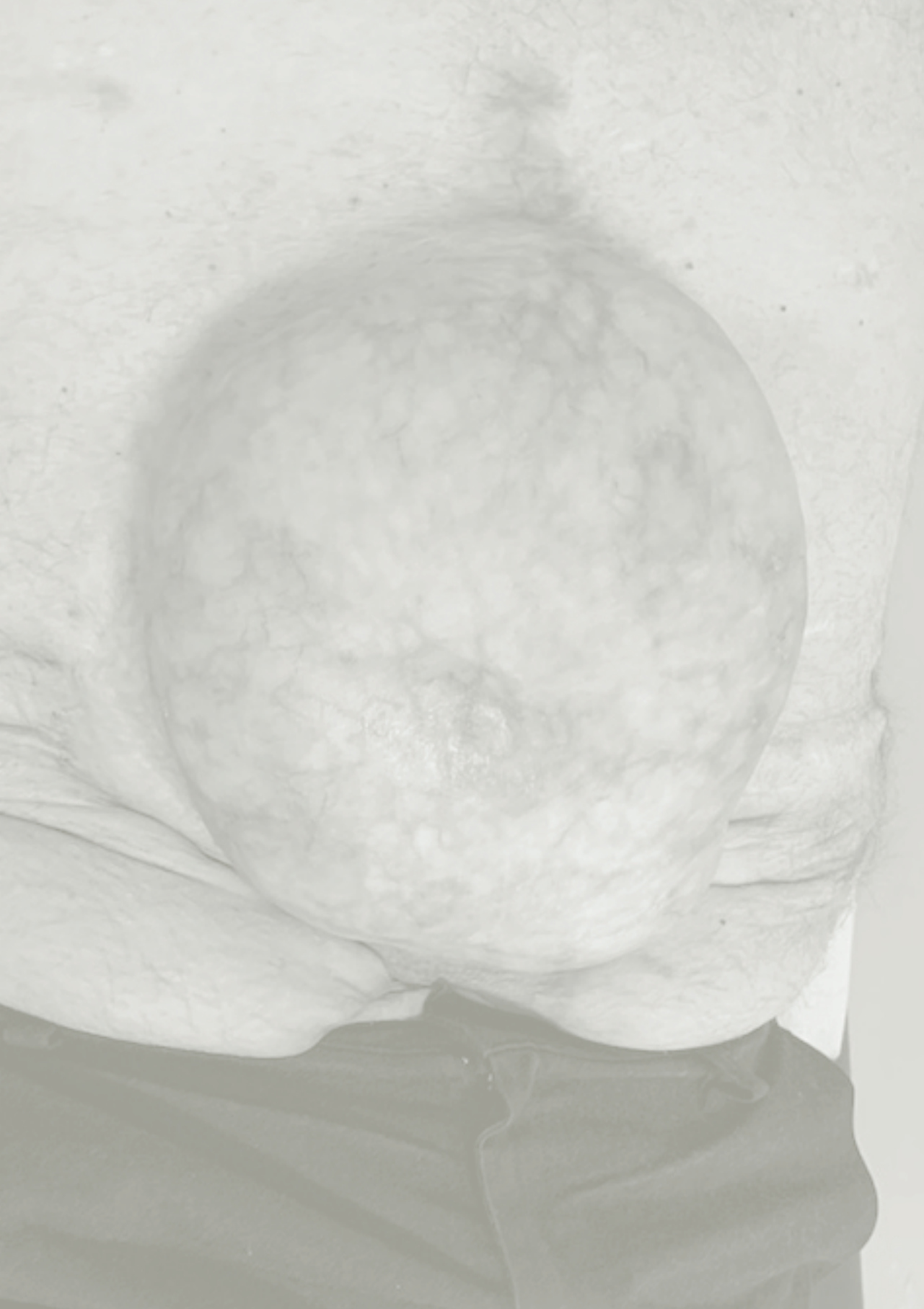
Conclusions

Intensive PExT is feasible in patients waiting for a complex AWR. A randomized controlled trial need to be conducted to objectivate the effect of PExT to prevent pulmonary complications and to reduce LOHS in this population.

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Chapter 6

The influence of a multidisciplinary team meeting and prehabilitation on complex abdominal wall hernia repair outcomes

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Abstract

Purpose Surgical site occurrences after transversus abdominis release in ventral hernia repair are still reported up to 15%. Evidence is rising that preoperative improvement of risk factors might contribute to optimal patient recovery. A reduction of complication rates up to 40% has been reported. The aim of this study was to determine whether prehabilitation has a favorable effect on the risk on wound and medical complications as well as on length of stay.

Methods A retrospective cohort study was performed in a tertiary referral center for abdominal wall surgery. All patients undergoing ventral hernia repair discussed at multidisciplinary team (MDT) meetings between 2015 and 2019 were included. Patients referred for a preconditioning program by the MDT were compared to patients who were deemed fit for operative repair by the MDT, without such a program. Endpoints were patients, hernia, and procedure characteristics as well as length of hospital stay, wound and general complications.

Results A total of 259 patients were included of which 126 received a preconditioning program. Baseline characteristics between the two groups were statistically significantly different as the prehabilitated group had higher median BMI (28 vs 30, $p < 0.001$), higher HbA1c (41 vs 48, $p = 0.014$), more smokers (4% vs 25%, $p < 0.001$) and higher HPW classes due to more patient factors (14% vs 48%, $p < 0.001$). There were no significant differences in intraoperative and postoperative outcome measures.

Conclusions This study showed prehabilitation facilitates patients with relevant comorbidities achieving the same results as patients without those risk factors. The indication of a preconditioning program might be effective at the discretion of an MDT meeting. Further research could focus on the extent of such program to assess its value.

Introduction

Incisional hernias following any kind of abdominal surgery remain an unremitting surgical challenge. This is most applicable in patients with large size (> 10 cm) hernias, recurrent hernias and hernias with a compromised surgical field, like an entero-atmospheric fistulas or an infected prosthetic mesh (1). Recent studies report up to 33% of surgical site occurrences (SSO) after repair with open anterior component separation techniques of these complex abdominal wall hernias (2-5). After posterior component separation techniques with a transversus abdominis release (TAR), SSOs occur still in up to 15% of patients (6).

Previous studies have demonstrated that SSOs occur mainly in patients having a high-risk characteristic at the time of surgery (7-9). Numerous studies have unambiguously reported that preoperative smoking, obesity, or a low physical activity level influence incisional hernia repair negatively, in terms of SSO and recurrence (10-15). Breaking the “vicious circle” of subsequential hernia repairs in a single patient, can be achieved by rigorously addressing these risk factors (3, 13). Evidence is rising that preoperative modification of any of these risk factors, known as prehabilitation, increases patient recovery and deminishes complications (3, 16-21).

In 2018, Liang et al. completed the first randomized controlled trial on prehabilitation in ventral hernia repair. This study demonstrated that prehabilitated patients were more likely to be without complications after one month compared to non-prehabilitated patients (70% vs 48%, $p = 0.015$) (22). Renshaw et al. described that patients prosecuting greater exercise frequency before surgery proved decreased risk of complications and readmission after ventral hernia repair (23, 24). Delaying surgery and optimizing or improving the aforementioned risk factors may reduce complication rates by as much as 40% (15, 23, 25-27).

These results emphasize the potential effect of prehabilitation. It has even been suggested that prehabilitation of high-risk patients is as important as, if not more important than, the surgical technique itself (17, 28, 29).

The aim of this study was to evaluate whether prehabilitation of complex hernia patients with modifiable risk factors has a favorable effect on outcome in patients undergoing complex abdominal wall repair.

Methods

This retrospective cohort study was performed in a referral center for complex abdominal wall surgery. All consecutive patients surgically treated for complex abdominal wall hernias between December 2015 and December 2019 were included. Patients undergoing laparoscopic repair were excluded.

Abdominal wall hernias were defined complex if there was at least one of the following factors present: width > 10 cm, parastomal hernia, infected mesh, presence of a stoma, fistula or abscess, or loss of domain greater than 20% (30, 39). Patients with at least one modifiable risk factor like body mass index (BMI) > 30 kg/m², active nicotine abuses, diabetes mellitus (with HbA1c > 65), COPD (> Gold I), usage of immunosuppressive medication or MET score < 4, were also considered complex hernia patients.

All patients were discussed at least once in a multidisciplinary team meeting (MDT) by a surgeon, pulmonologist, cardiologist, anesthesiologist, and physiotherapist. Assays such as a CT-scan, an EKG, blood tests for hemoglobin, HbA1c and albumin were prosecuted beforehand. Hernias were anatomically graded by the EHS classification and HPW classification (11, 31).

During the MDT, a color code is allocated to each patient. Patients without any risk factors are allocated green and considered fit for surgery. Patients with at least one modifiable risk factor are allocated orange, and are eligible for surgery, only after successful prehabilitation. Patients with too many (or unmodifiable) risk factors are allocated red.

All orange patients were offered a preconditioning program, which was covered by patients' insurance. Such a program comprised weight loss counseling, smoking cessation counseling, glycemic control by a specialized nurse, pulmonary preparation, and physiotherapy (Table 1). After prehabilitation, the patient was discussed again in the MDT. If prehabilitation was deemed successful by the MDT, the allocated color code shifted from orange to green.

Table 1. Modifiable risk factors and prehabilitation interventions

Risk factor	Defined by	Intervention	Achieved if
Smoking	≥ 1 cigarette/day	Nicotine substitute Quit smoking programme	Quitted smoking ≥ 4 weeks prior to surgery
Morbid obesity	BMI ≥ 35	Dietician Physical activity Bariatric surgery	BMI ≤ 35 or ≥ 5% weight loss
Physical condition	MET score ≤ 4	Physiotherapist Sports physician	MET score > 4
Diabetes, glycemic levels	HbA1c ≥ 65	Diabetes nurse Medication optimization	HbA1c < 65
Pulmonary condition	COPD II-IV Other obstructive pulmonary diseases	Consultation of pulmonologist Medication alteration	Optimal pulmonal condition consented by pulomonologist
Cardial condition	EKG abnormalities	Consultation of cardiologist Medication alteration	Optimal cardial condition consented by cardiologist



Outcome after complex hernia repair was compared between two consecutive patient cohorts: green patients (without risk factors nor prehabilitation) versus orange patients (after successful prehabilitation). Endpoints were differences in baseline and intra-operative characteristics, and postoperative outcome (90-day complications such as SSO, SSI, SSE, pulmonary embolism, pneumonia, ileus/gastro paresis, or other systemic complications; length of hospital stay and readmission and reoperation).

Data were retrieved from a database in which every patient with a complex abdominal wall defect was registered prospectively since 2014. Differences between demographic groups of categorical data were tested using the Chi-squared or Fisher’s exact test. The summary statistic was the *p*-value. The patient demographics were judged and continuous variables such as age, BMI and MET score were kept continuous, to prevent loss of data associated with categorizing. These variables were analyzed using an independent unpaired *T* test. A *p*-value < 0.05 was considered statistically significant.

Results

A total of 418 consecutive patients were discussed in the 4-year study period (Figure 1). The MDT allocated 230 patients (55%) orange, 144 patients (34%) green and 44 patients (11%) red. Almost half (45%) of all primarily coded orange patients, did eventually not undergo surgery. Being unable to adequately finish prehabilitation was the most important reason. Other reasons to refrain from surgery were a concomitant disease requiring therapy, decrease of hernia related complaints as a result of prehabilitation, or choosing another hospital. Eventually, 259 operated patients were included in this study: 133 primary green patients (group I), and 126 primarily orange patients after successful prehabilitation (group II).

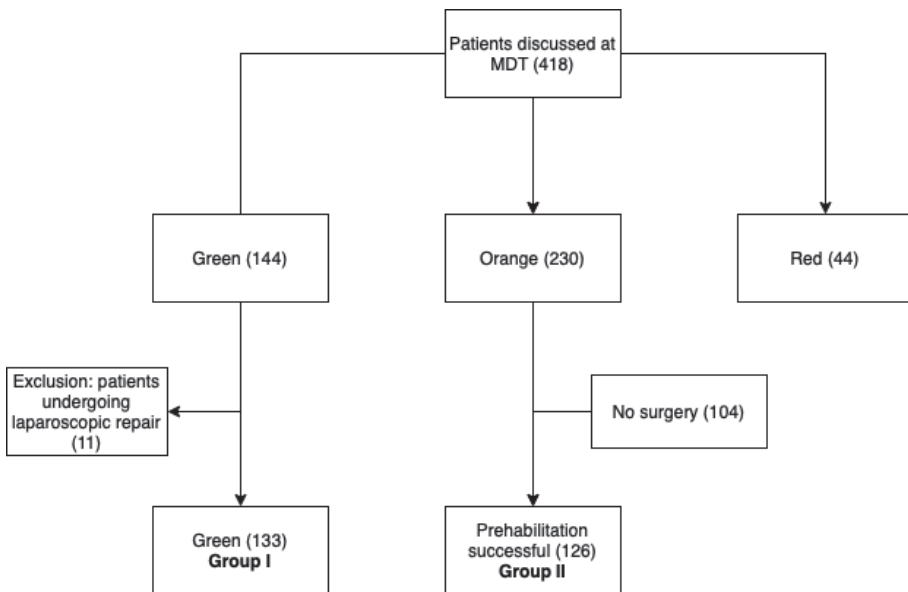


Figure 1. Patient inclusions flowchart

Baseline characteristics between group I and II were different in BMI (median 28 versus 30, $p < 0.001$), HbA1c (mean 41 versus 48, $p = 0.014$) and the rate of active smokers (4% versus 25%, $p < 0.001$) (Table 2). After prehabilitation of orange patients, both BMI and nicotine abuse significantly decreased (Table 3). No

differences in intra-operative conditions, like the rate of component separation techniques, were demonstrated (Table 4).

No significant differences in short term complications were noted between the groups in the convalescence period (Table 5). The length of hospital stay was comparable between the groups: 6 days ($p = 0.908$).

Discussion

This study demonstrated that outcome of complex ventral hernia repair in patients who underwent preoperative prehabilitation of modifiable risk factors was similar to patients without those risk factors. This finding is in line with studies reporting that prehabilitation might facilitate amelioration of the preoperative condition of patients undergoing complex abdominal wall repair (15, 17, 23, 27). A recent systematic review performed by Jensen also concluded that smoking cessation and weight loss for obese patients led to reduced complication risks, as was seen in this study (28).

The conclusion of this study is based on patients operated before the COVID-19 pandemic, because during the pandemic patients were not able to prehabilitate accurately under supervision, nor could bariatric surgery be performed to correct morbid obesity, before definitive hernia repair. The conclusion is limited by the retrospective nature of this study and the fact that outcome of prehabilitated patients with risk factors could not be compared to non-prehabilitated patients with risk factors. In our cohort, all patients with modifiable risk factors were treated with prehabilitation.

The multidisciplinary team meeting provides comprehensive, patient-centered care and acts as a platform to discuss the optimal treatment strategy for a patient. Implementing this multidisciplinary team meeting to a complex hernia care pathway was promoted by several authors and even demonstrated improved outcomes after complex abdominal wall reconstruction (32-34). Improved outcome may be a consequence of optimized patient selection by the MDT.

Table 2. Preoperative characteristics of patients that underwent complex abdominal wall surgery

	Total	I (no risk factors)	II (prehabilitated patients)	<i>p</i>
<i>n</i>	259	133	126	
Hernia factors				
Width < 10 cm (<i>n</i> , %)	137 (53)	77 (58)	60 (48)	
Width 10-20 cm (<i>n</i> , %)	109 (42)	50 (38)	59 (47)	0.254
Width > 20 cm (<i>n</i> , %)	13 (5)	6 (5)	7 (6)	
Recurrent hernia (<i>n</i> , %)	79 (31)	38 (29)	41 (33)	0.488
Patient factors				
Age (median, IQR)	128 (54-68)	63 (54-68)	65 (57-72)	0.052
Smoking (<i>n</i> , %)	37 (14)	5 (4)	32 (25)	< 0.001
BMI (median, IQR)	58 (25-29.5)	28 (25-29.5)	30 (27-33)	< 0.001
BMI > 30 (<i>n</i> , %)	87 (34)	22 (17)	65 (52)	< 0.001
BMI > 35 (<i>n</i> , %)	17 (7)	3 (3)	14 (11)	0.004
Diabetes (<i>n</i> , %)	29 (11)	10 (8)	19 (15)	0.054
HbA1c (median, IQR)	89 (34-54)	41 (34-54)	48 (42-57)	0.014
HbA1c > 65 (<i>n</i> , %)	3 (3)	0 (0)	3 (3)	0.094
Immunosuppressives (<i>n</i> , %)	14 (5)	4 (3)	10 (8)	0.079
COPD (II-IV) (<i>n</i> , %)	42 (16)	17 (13)	25 (20)	0.123
Pulmonary preparation (<i>n</i> , %)	62 (24)	24 (18)	38 (30)	0.022
MET score (median, IQR)	13 (6-8)	7 (6-8)	6 (5-7)	0.004
MET score < 4 (<i>n</i> , %)	20 (8)	8 (6)	12 (10)	0.290
cP 0 (<i>n</i> , %)	179 (69)	114 (86)	65 (52)	< 0.001
cP 1 (<i>n</i> , %)	80 (31)	19 (14)	61 (48)	
Wound factors				
cW 0 (<i>n</i> , %)	212 (82)	111 (83)	101 (80)	0.491
cW 1 (<i>n</i> , %)	47 (18)	22 (17)	25 (20)	
Previous wound infection (<i>n</i> , %)	94 (36)	44 (33)	50 (40)	0.270
HPW Classification				
HPW 1 (<i>n</i> , %)	80 (31)	54 (41)	26 (21)	
HPW 2 (<i>n</i> , %)	129 (50)	54 (41)	75 (60)	
HPW 3 (<i>n</i> , %)	42 (16)	22 (17)	20 (16)	0.003
HPW 4 (<i>n</i> , %)	8 (3)	3 (3)	5 (4)	

BMI body mass index (kg/m²), *COPD* chronic obstructive pulmonary disease, *MET* metabolic equivalents, *cW 1* contaminated field, *HPW* hernia, patient, wound. cP1: at least one patient risk factor present (BMI > 35, active smoker, use of immunosuppressives, diabetes), cW1: CDC2-4 wound classifications (clean-contaminated, dirty-contaminated or dirty surgical field). Statistically significant values are shown in bold.

Table 3. Effect of prehabilitation in patients with modifiable risk factors in 126 patients

<i>n</i> = 126	I Before	II After	<i>p</i>
Patient factors			
Smoking (<i>n</i> , %)	32 (25)	16 (13)	0.0103
BMI (median, IQR)	30 (27-33)	29 (27-31)	< 0.001
BMI > 30 (<i>n</i> , %)	65 (52)	48 (38)	0.0312
BMI > 35 (<i>n</i> , %)	14 (11)	7 (6)	0.1106
Diabetes (<i>n</i> , %)	19 (15)	19 (15)	1.000
HbA1c (median, IQR)	48 (34-54)	47.5 (42-55)	0.065
HbA1c > 65 (<i>n</i> , %)	3 (1)	1 (1)	0.3134
Immunosuppressives (<i>n</i> , %)*	10 (8)	5 (4)	0.1831
MET score < 4 (<i>n</i> , %)	12 (10)	5 (4)	0.0787

*Patients who did not alter their regular immunosuppressives schedule were considered still using immunosuppressives
 Statistically significant values are shown in bold

Table 4. Perioperative characteristics of patients that underwent complex abdominal wall surgery

	Total	I (no risk factors)	II (prehabilitated patients)	<i>p</i>
<i>n</i>	259	133	126	
Surgery time (mean, minutes)	135.5 (90-168)	132.9 (87-164)	138.2 (92.5-173)	0.244
Type of myofascial release				
Retrorectus (<i>n</i> , %)	132 (51)	71 (53)	61 (48)	
Unilateral TAR (<i>n</i> , %)	18 (7)	6 (5)	12 (10)	
Bilateral TAR (<i>n</i> , %)	48 (19)	21 (16)	27 (21)	
eCST (<i>n</i> , %)	56 (22)	33 (25)	23 (18)	
Ramirez (<i>n</i> , %)	5 (34)	2 (34)	3 (34)	0.257
Contamination of the surgical field (<i>n</i> , %)	39 (15)	22 (17)	17 (13)	0.493
Infected mesh (<i>n</i> , %)	21 (8)	11 (8)	10 (8)	0.921

TAR transversus abdominis release, eCST endoscopic component separation technique



Table 5. Postoperative Outcome Measures

	Total	I (no risk factors)	II (prehabilitated patients)	<i>p</i>
<i>n</i>	259	133	126	
SSO (<i>n</i> , %)	87 (34)	43 (32)	44 (35)	0.659
Seroma I-II (<i>n</i> , %)	22 (8)	9 (7)	13 (10)	0.306
Seroma III-IV (<i>n</i> , %)	19 (7)	10 (8)	9 (7)	0.908
Hematoma I-II (<i>n</i> , %)	28 (11)	12 (9)	16 (13)	0.341
Hematoma III-IV (<i>n</i> , %)	8 (3)	3 (2)	5 (4)	0.426
SSE	18 (7)	6 (5)	12 (10)	0.113
SSI	31 (12)	14 (11)	17 (13)	0.462
SSOPI	13 (5)	6 (5)	7 (6)	0.700
Systemic complications				
0 (<i>n</i> , %)	165 (64)	81 (61)	84 (67)	0.190
1 (<i>n</i> , %)	60 (23)	31 (23)	29 (23)	
2 (<i>n</i> , %)	17 (7)	13 (10)	4 (3)	
> 2 (<i>n</i> , %)	17 (7)	8 (6)	9 (7)	
Airway infection (<i>n</i> , %)	54 (21)	28 (21)	26 (21)	0.934
Pulmonary embolism (<i>n</i> , %)	6 (34)	5 (4)	1 (34)	0.113
Gastrointestinal (<i>n</i> , %)	24 (9)	10 (8)	14 (11)	0.319
Cardial (<i>n</i> , %)	10 (4)	7 (5)	3 (34)	0.229
Other complications (<i>n</i> , %)	45 (17)	24 (18)	21 (17)	0.769
Mortality (<i>n</i> , %)	4 (2)	3 (2)	1 (1)	0.340
Length of stay (median, IQR)	6 (5-8)	6 (5-8)	6 (5-8)	0.401
Admission > 7 days (<i>n</i> , %)	57 (22)	27 (20)	30 (24)	0.496
Reoperation (<i>n</i> , %)	14 (5)	4 (3)	10 (8)	0.079
Readmission (<i>n</i> , %)	12 (5)	4 (3)	8 (6)	0.201

SSO surgical site occurrence, seroma/hematoma I-II: no clinical significance, seroma/hematoma III-IV: clinical significance-needing intervention, SSE surgical site event, SSI surgical site infection, SSOPI surgical site occurrence requiring procedural interventions

In our experience, the process of optimizing patient selection in the MDT passes a learning curve (8, 35). Firstly, it was noticed that outcome could be improved by sticking tighter to the predetermined prehabilitation goals. In particular, the requirement to have a BMI < 30, and completely refrain from smoking, became, over

time, an absolute prerequisite to be eligible for hernia repair. Improved adherence to the prehabilitation protocol, may have contributed to the good outcome in the high risk patients. Secondly, the decision not to operate a complex hernia patient with (unmodifiable) risk factors is difficult. Formerly, these decisions were made by a surgeon in 'splendid isolation' (33). By sharing in a team approach to care, these decisions became better substantiated. Subsequential analysis of these decisions improved the decision-making process in the MDT over time. Thirdly, increased attention for other risk factors developed (36). Involving a geriatric physician in the multidisciplinary team meetings aids in addressing age-related risk factors (37). Likewise, involving a psychiatrist, psychologist, or mental caretaker may decrease anxiety, medication usage, withdrawal symptoms or delirium in patient with mental diseases (38). Finally, positive patient feedback, in combination with the results of this study, led to the continuation of the prehabilitation process. Noticeably, in some patients, increased exercises, a lower weight or stopped nicotine abuse (no more coughing) led to disappearance of hernia related symptoms, which even dissolved their quest for repair (39).

To analyze the effects of prehabilitation, comparing centers that use a strict prehabilitation protocol, versus centers that do not use such a protocol, may shine light on this topic. However, as suggested in this study, the positive relation between prehabilitation and outcome may also be strongly influenced by the presence of an MDT with optimal patient selection. A lot of uncovered ground in this area of surgery is present, and further extensive research should be conducted to establish the best care pathway for this patient population.

While balancing patients demands and expectations, against the risk of surgery, the most difficult part of prehabilitation proves to be motivating and persuading the patient and preventing the surgeon from instant surgery. Prehabilitation is a promising tool to improve outcome in complex hernia patients. "First treat the patient, then treat the hernia".

Conclusion

Prehabilitation of patients with modifiable risk factors may downstage complex hernia patients from high risk to low risk patients. Prehabilitation may have a favorable effect on outcome and the indication of a such preconditioning program might be at the discretion of a multidisciplinary team meeting. Future research could focus on the extent of such program to assess its value.

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Chapter 7

Prehabilitation of complex ventral hernia patients with Botulinum: a systematic review of the quantifiable effects of Botulinum

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Abstract

Purpose Complex ventral hernia repair (CVHR) encompasses patient optimization, primary fascial closure (PFC), mesh reinforcement and component separation technique (CST), if needed. High rates of complications after CST are still reported. Prehabilitation by managing preoperative modifiable risk factors, like abdominal wall compliance, possibly reduces these rates. Compliance can be modified by intramuscular injection of Botulinum in the lateral abdominal wall muscles (LAWM). Paralysis leads to elongation of these muscles, which may facilitate PFC and/or prevent CST. Evidence to use Botulinum in hernia patients is scarce and fragmented. An update of evidence for the effect of Botulinum is presented.

Methods A multi-database search was conducted for Botulinum studies in ventral hernia patients. A systematic review was performed to describe its primary effect on compliance (LAWM elongation) and secondary effects like PFC \pm CST rate, complications and recurrence.

Results 14 studies were included (377 patients) with a HDW of median 12 (10-15) cm. A typical intervention consisted of 200-300 U Botulinum in 3 points per hemi-abdomen under US guidance, > 2 weeks preoperatively and evaluated by CT just before operation. The primary effect was a median LAWM elongation of 4.0 cm per side without complications of the injection (four studies, 107 patients). The median PFC rate was 100%, CST rate 38%, wound-related complications 19%, medical complications 18% and recurrence 0% (14 studies).

Conclusion Botulinum safely elongates the abdominal wall muscles, but the level of evidence available remains low. Any patient in whom PFC is expected to be difficult, could be a candidate for prehabilitation with Botulinum.

Introduction

The main principles in complex ventral hernia repair are to optimize the patient, to achieve primary fascial closure and to use mesh reinforcement following, if needed, a component separation technique (CST) (1). Despite innovations in surgical techniques and meshes, expert centers still report high rates of wound complications (up to 35%) and medical complications (up to 27%) after complex ventral hernia repair (CVHR) with CST (2-6).

The path to achieve more desirable outcomes is traditionally paved by publications of new surgical techniques. However, careful exploration of the methodology in recent studies on CVHR shows the increasing emphasis on the importance of preoperative patient optimization (4, 6, 7). Prehabilitation has the potential to reduce the rate of postoperative complications in general (8). Examples in hernia care of managing preoperative modifiable risk factors, like nutritional state, physical condition, use of alcohol, nicotine abuse or anxiety have been published before (9-13). It has even been suggested that optimal prehabilitation has more influence on outcome than the surgical technique itself (13).

Compliance of the abdominal wall or 'ease of the abdominal wall to distend' is one of those preoperative modifiable risk factors (14-16). Compliance is defined by the elasticity of the different muscle layers of the abdominal wall (anterior and lateral parts) and to a lesser extent the diaphragm muscle. A patient with a 'tight' abdominal wall is more likely to develop complications due to an increased tension in the repair line and intra-abdominal hypertension, after CVHR, than a patient with a 'flaccid' abdominal wall (14, 17). Abdominal wall compliance is unique for each patient, difficult to predict and largely determined by non-modifiable factors like gender, anthropomorphic features, comorbidities, previous meshes and fibrotic or denervated areas (14, 15, 18). Still, surgical modification of compliance is possible: preoperatively by application of a progressive pneumoperitoneum (PPP) or by subcutaneous placement of tissue expanders, and per-operatively by a component separation technique (19, 20).

Compliance can also be modified chemically by intramuscular injection of paralyzing neuromuscular blocking agents, like Botulinum Toxin A. This so called 'chemical

component relaxation' is less invasive than any of the surgical techniques (20, 21). Changes in abdominal wall compliance after Botulinum can be measured by step-wise increment of the intra-abdominal volume by insufflation of air (PPP) or fluid until signs or symptoms of intra-abdominal hypertension develop (14, 15, 22, 23). A significant difference in abdominal volume was noted in two animal studies that both compared intramuscular injection of saline versus Botulinum (23, 24). The direct effect on compliance was also demonstrated in human studies using Botulinum in combination with PPP (25-28). A less invasive and easier method to determine the effect on compliance is measuring the elongation of the lateral abdominal wall muscles (LAWM) on CT (29). No animal studies have ever been performed to validate this phenomenon, although one study in 10 pigs demonstrated improved medialization of the rectus muscle if Botulinum in the left hemi-abdomen was compared to saline in the right hemi-abdomen (30). Reduction of the hernia defect width (HDW) is a less good outcome parameter, especially in patients with a large loss of domain (LOD) or with stomas or extensive scarred tissues, because the eviscerated abdominal contents or (unilateral) fibrotic areas may prevent actual HDW reduction (31, 32). Thereby, the effect on HDW was reported differently in two mice models: Lien (33) demonstrated a significant HDW reduction after Botulinum injection, but Rodriguez (24) found no difference.

The first systematic review in humans (compromising two studies) dates from 2016 (20) and was followed by a meta-analysis (compromising three studies) in 2017 (34). The latter concluded that Botulinum lead to a significant LAWM elongation of mean 3.3 cm per side (and a 5.8 cm HDW reduction).

Subsequently it was hypothesized that reduced lateral tension may facilitate primary fascial closure (PFC) and might even prevent CST in CVHR patients. A third systematic review from 2017 (compromising 6 studies) used these variables only as endpoints and calculated a 84% PFC and 24% CST rate (35). However, achieving PFC with or without CST is dependent of many other factors than the presence of a flaccid abdominal wall alone (Table 1). Therefore, these outcome measures are less suitable to objectify the primary effect of Botulinum, especially in patients where other compliance modulating techniques, like PPP, were also applied (27, 31).

Table 1. Factors, other than hernia size, that play a role in the preoperative consideration and per-operative final decision to apply a component separation technique to achieve primary fascial closure

Preoperatively	
Hernia history	Previous hernia repairs (with Rives-Stoppa repair or anterior /posterior CST and/or meshes) may preclude a CST due to inaccessible preperitoneal or intermuscular planes which may lead to bridging
Hernia location	An initial hernia transverse width > 10 cm is usually reported in large CST series, but non-midline hernias or hernias near a bony structure may require a CST due to their complex location, independent of a large hernia width
Abdominal wall quality	Infected areas (skin ulcers, enterocutaneous fistulae, stomata), atrophic abdominal muscles or loss of substance may exclude CST and lead to bridging
Experience of the surgeon	Unfamiliarity with any (anterior, posterior or endoscopic) CST may lead to bridging instead of primary fascial closure with CST.
Availability of robotic assist	The threshold to perform a (posterior) CST may be lowered in robot-assisted laparoscopic repairs
Peroperatively	
Prehabilitation effects of other interventions	E.g., a progressive pneumoperitoneum or radical weight reduction increases abdominal wall compliance which may reduce the need for CST
General anesthesia	Deep muscle relaxation by systemic (non-)depolarizing neuromuscular blockage may make a planned CST unnecessary
Adverse per-operative events	E.g., massive spillage by unintended enterotomy may postpone a planned CST
Experience of the surgeon	Assessing, whether the tension between the medial fascial borders is physiological and primary fascial closure without CST is possible, is subjective

Since 2016, nine descriptive reviews on Botulinum were published and all concluded that Botulinum is a safe, promising technique to modify abdominal wall compliance and probably diminish necessary surgical trauma (10, 16, 21, 32, 36-40). However, small sample sizes, heterogeneity between patients, hernia types and surgical techniques, use of different Botulin regimes and end points, as well as overlapping publications, resulted that no recommendations regarding the use of Botulinum as adjunct intervention could be made in a recent guideline on the treatment of abdominal wall hernias (36).

In determining the place of Botulinum in ventral hernia surgery, analyzing its primary effect substantiates more than describing a desired outcome parameter which is subject to many confounding variables (27, 31). Since the last systematic review on LAWM elongation was published three years ago and new studies have emerged, a new systematic review was conducted to update on the quantifiable effect of Botulinum in complex ventral hernia patients.

Methods

Search strategy

A multi-database (PubMed-Medline, Embase and CINAHL) search was performed from 2006 (date of the first publication of Botulinum in the abdominal wall of rats) until August 13th, 2020. Search terms for Pubmed/Medline were (((("botulinum toxins"[MeSH Terms] OR Botulin[tiab]) OR Dysport[tiab]) OR Botulinum toxin[tiab]) OR Botulinum toxins[tiab]) AND (((((((((((((((("hernia, ventral"[MeSH Terms] OR Ventral Hernias[tiab]) OR Ventral Hernia[tiab]) OR Abdominal wall hernia[tiab]) OR Abdominal wall hernias[tiab]) OR abdominal wall reconstruction[tiab]) OR abdominal wall reconstructions[tiab]) OR "hernia, ventral/surgery"[Mesh Terms]) OR "hernia, ventral/drug therapy"[Mesh Terms]) OR ("Herniorrhaphy"[Mesh] AND "ventral"[tiab])) OR ("Herniorrhaphy"[tiab] AND "ventral"[tiab])) OR ("Hernia repair"[tiab] AND "ventral"[tiab])) OR ("Hernia repairs"[tiab] AND "ventral"[tiab])) OR ("Incisional Hernia"[Mesh] AND "ventral"[tiab])) OR ("Incisional Hernia"[tiab] AND "ventral"[tiab])) OR ("Incisional Hernias"[tiab] AND "ventral"[tiab])). Search terms for Embase were "Botulinum" and "ventral hernia". Search terms for CINAHL were "Botulinum Toxins" AND "Hernia, Abdominal+". All eligible citations were reviewed independently (JAW and TdVR) and in case of disagreement a third party (SN) was consulted. Sequential review of title, abstract and finally full text was performed to establish selection as per Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidance (PRISMA) (41).

Outcome measures

Primary outcome is the preoperative modifying effect of Botulinum on abdominal wall compliance in complex ventral hernia patients quantified by the elongation of the lateral abdominal wall muscles (LAWM). Complications and side effects due to Botulinum were also recorded.

Secondary outcomes are hernia defect width (HDW) reduction, the rate of primary fascial closure (PFC), the rate of component separation technique (CST), wound-related complications (surgical site occurrences, i.e. SSO) (42), medical complications, recurrence and follow-up.

Exclusion and inclusion criteria

Duplicates and citations that did not report on the use of Botulinum in ventral hernia patients, but in other diseases like achalasia or musculoskeletal disorders are excluded. Studies that used a combination of Botulinum with a progressive pneumoperitoneum were also not included, because it is not possible to distinguish each individual effect on abdominal wall compliance (25). Case reports, animal studies and abstracts from congresses or conferences were also excluded.

Full text analysis was performed to include studies in humans with abdominal wall (ventral) hernias, pre-treated with Botulinum, reporting on at least one primary and/or secondary outcome measure, in any language. Reviews, invited commentaries and studies designed to evaluate a diagnostic or surgical instrument in hernia patients pre-treated with Botulinum, were considered not eligible. Studies from the same institution were carefully scrutinized on accrual dates, to exclude overlapping case series in previous publications. Only studies that did not overlap other included publications were included. Bibliographic references from included studies were searched to identify additional relevant studies.

Study characteristics

Main study objective, dates and duration of patient accrual, patients characteristics (if reported: gender, age, BMI, history of hernia repairs, co-morbidities), hernia characteristics (location, transverse width, size, contamination), Botulinum type, dose, total number of injection points, number of injected oblique muscles and duration between Botulinum administration and operation, type of radiological guidance tools to administer Botulinum (ultrasound (US) or electromyography (EMG)), assessment of the efficacy of Botulinum by preoperative Computed Tomography (CT), type of surgical repair (open or laparoscopic), use of a mesh and final conclusion per study were recorded.

Results

Search strategy

After removing duplicate citations, 287 unique records were identified. (Figure 1) Excluded citations were studies discussing other diseases than an abdominal wall hernias ($n = 186$), studies that combined Botulinum with a progressive pneumoperitoneum ($n = 28$), conference or congress citations ($n = 21$), case reports ($n = 14$), experimental studies in animals ($n = 3$) and an unpublished citation (1). The 20 eligible studies that were also excluded were reviews ($n = 14$), studies with overlapping case series ($n = 3$) or studies that investigated a diagnostic modality (3D-CT imaging, EMG) ($n = 2$) or a novel endoscopic instrument ($n = 1$). Finally, 14 studies that evaluated primary and/or secondary outcomes, remained for data extraction, comprising 377 patients. (Search strategy and results available in supplementary material).

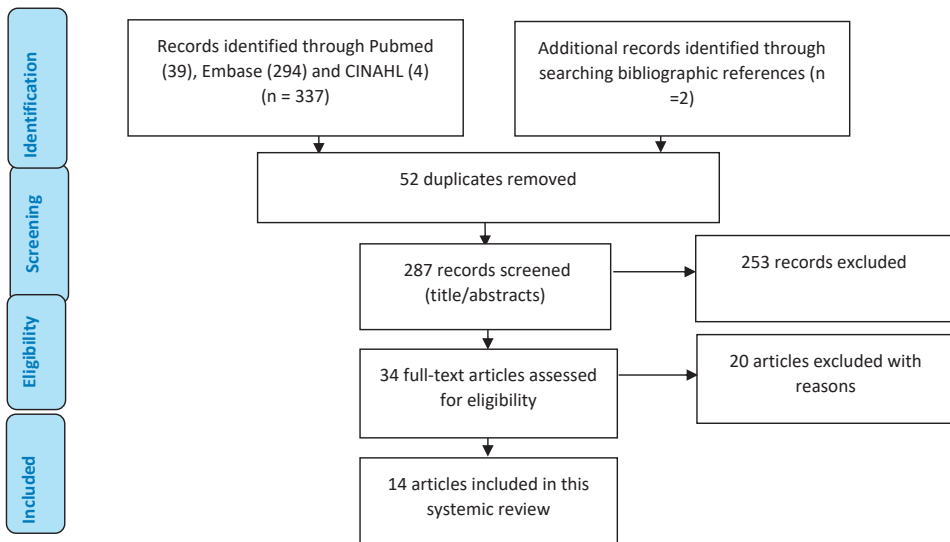


Figure 1. PRISMA FLOW diagram

Methodological quality

The Minors score for the 10 non-comparative studies was median 6 points (range 3-10) out of maximum of 16 points and for the four comparative studies median 17 points (range 15-21) out of maximum of 24 (Table 2).

General study characteristics

Heterogeneity between all studies is present in terms of patient characteristics (comorbidities, history, age, BMI, smokers), hernia type (size, hernia location, LOD, contaminated field, acute open abdomen or long standing ventral hernia), type, dose and timing of Botulinum, type of surgery (open/laparoscopic) and primary endpoints (abdominal wall compliance, PFC, use of analgesics, feasibility of laparoscopic surgery). A high rate (> 80%) of complex hernias, in terms of a history of at least one previous hernia repair, was present in the three Australian studies (90 patients) (17, 43, 44). In other studies the rate of previous hernia repairs was lower or not reported.

Technical aspects of Botulinum injections

The USA and Denmark studies described a setting in which Botulinum injection was performed under local anesthesia or where conscious sedation could be administered (45-47) Other studies described that the Botulinum injection was administered in a radiological department or clinical outpatient setting. Most (71%) studies injected Botulinum more than 2 weeks before the operation. In one study, Botulinum was injected 0-6 days preoperatively because the primary indication was post-operative pain reduction (46) or administered on the day of the damage control laparotomy, to support PFC in a later operation (48). In 75% of the studies, patients received Botox®. Significant results in elongation were noted with 200-300 Units, distributed over 3-5 injection points per hemi-abdomen, under US or EMG guidance, equally distributed into each of the three LAWM. No CT-guidance techniques were reported (21).

Table 2. MINORS score per study that evaluated the effect of Botulinum Toxin A injection on abdominal wall compliance in complex ventral hernias

	2009	2013	2013	2014	2014	2014	2015	2016	2017	2018	2019	2019	2020	2020
	Ibarra	Zendejas	Zielinski	Ibarra	Chaves	Lopez	Zielinski	Elstner	Chan	Kohler	Nielsen	Elstner	Bueno	Catalan
Non-randomized studies														
1	1	2	1	2	2	1	2	2	1	1	2	2	2	2
2	0	0	2	0	0	0	2	0	0	0	0	2	2	0
3	2	0	0	1	0	0	2	2	0	0	0	2	2	0
4	2	2	2	2	1	1	1	2	1	1	1	2	1	1
5	0	1	0	0	0	0	2	1	0	0	0	1	1	1
6	1	1	0	2	1	1	0	1	1	1	0	2	1	2
7	2	2	0	2	2	2	2	C	2	2	0	2	1	0
8	0	2	0	0	0	0	0	0	0	0	0	0	0	0
Comparative studies														
9									2			2	1	
10									2			2	1	
11									2			2	2	
12									1			2	1	
Total score	8	16	5	9	6	5	18	10	5	5	3	21	15	6

MINORS methodological index for non-randomized studies

Exceptions to the standard three-layer technique are the studies from Ibarra-Hurtado, who injected Botulinum first only in the external oblique muscle (in 2009) (29) and later (in 2014) (49) between the external and internal oblique muscles. In the studies from Chan (2018) (43) and Elstner (2020) (44) only two-layer injection, excluding the transversus muscle, was performed. Elstner compared the standard three-layer with the two-layer injection and concluded a significant effect on elongation with both techniques, albeit without a difference between the two. Assessment of the efficacy of Botulinum, controlled by a CT just before the operation, was performed in half (57%) of the studies after median 4 weeks.

Primary effect of Botulinum

Four studies (107 patients) described a significant elongation in the LAWM of median 4.0 cm (17, 43, 44, 49) (Table 3). The studies differed among themselves in base line characteristics and injection techniques. (Table 3, 4) The 90 patients in the three Australian studies had a lower BMI (median 32) and smaller hernias (median width 11.4 cm) than the 17 patients in the Mexican study (BMI 35, HDW 14.7 cm). The single randomized study demonstrated that 200 U Botox® in the LAWM reduced the muscle length significantly by median 3.8 cm, independent whether two or three LAWM were injected (excluding the transverse abdominis muscle) (44).

No Botulinum related complications, requiring any form of treatment, were described. Side-effects like back pain ('some' patients), pain at the injection site (1 patient) and dyspnea (1 patient) were the most serious complaints (44, 45). Other reported side effects included superficial bruising, weak cough or sneeze, and a sense of distension or bloating. In general, side effects were noticeable, not disabling. In most cases an abdominal binder had good effect and the symptoms resolved after surgery.

Table 3. Characteristics of studies that evaluated lateral abdominal wall muscle elongation and hernia defect width reduction after Botulinum in ventral hernia patients

	Ibarra	Ibarra	Chaves	Elstner	Chan	Elstner	subtotal or median
<i>n</i>	Mexico 2009	Mexico 2014	Mexico 2014	Australia 2017	Australia 2018	Australia 2019	133
MINORS score	12	17	14	32	12	23	23
Main study objective	8	9	6	10	5	21	9 (3-21)
Prospective study	propose BTA	increase LAW/M	evaluate BTA	facilitate PFC	lap. repair	spare TAM	
Patient accrual	+	+	-	+	-	+/Comp.	58% prospective
Age	'07-'09	'09-'11	'12-'14	'13-'15	'16-'17	'15-'18	2007-2018
Midline hernias	34	35	58	58	72	62	(34-72)
HDW, median (cm)	100%	100%	71%	72%	58%	?	(58-100)
HDS, mean (cm ²)	13.8	14.7	14.6	12.3	10.0	11.3	(10.0-14.7)
Botulinum type	Dysport®	Dysport®	Botox®	Btx/Dysp	Botox®	Botox®	(176-282)
Total dose of Botulinum	500	500	100	300/500	200-300	200	Botox®
Number of injections	10	10	10	6	6	6	100-300/500
Number LAW/M injected	1 (MOE)	2	3	3	2	3	6 injections
Guidance technique	EMG	EMG	EMG	US	US	US	3 LAW/M
Injection > 2 weeks A.O	+	+	+	+	+	+	US
CT after 2-4 weeks, A.O	+	+	+	+	+	+	> 2 weeks
Ventral hernia repair	open	open	open	lap.	lap.	lap.	CT A.O.
							open VHR

Table 3. (continued)

	Ibarra	Ibarra	Chaves	Elstner	Chan	Elstner	Subtotal or median
	Mexico	Mexico	Mexico	Australia	Australia	Australia	
	2009	2014	2014	2017	2018	2019	
Use of a mesh in all	?	+/-	+/-	+	+	+	67% use of mesh
Primary outcome measure							
Gain in LAWM length (cm)		2.5		4.0	4.0	3.6	4.0 (2.5-4.0)
Decrease HDW (cm)	5.3	4.8	0.3				4.8 (0.3-5.3)
Sign. effect LAWM	+	+	-	+	+	+	83%
Secondary outcome measures							
Prim. fascial closure	100%	100%	79%	100%	100%	100%	100% (79-100)
PFC without CST	50%	47%	64%	81%	100%	100%	81% (47-100)
PFC with CST	50%	53%	36%	19%	0%	0%	19% (0-53)
Wound related compl.	17%	41%	14%		8%		15% (8-41)
Medical complications ^a			14%		8%		11% (8-14)
Recurrence	0%	0%	0%	0%	0%	0%	0%
Follow-up (months)	9	49	15	19	18	24	19 (9-49)
Conclusion of the study	decreases HDW	increases LAWM	benefit unclear	enables PFC	lap. is feasible	TAM can be spared	83% positive effect

LAWM lateral abdominal wall muscles; BTA Botulinum Toxin A, PFC primary fascial closure, LAP laparoscopically, TAM transversus abdominis muscle, COMP comparative study, HDW/hernia defect width, CST component separation technique (excluding RSRR), RSRR Rives-Stoppa retromuscular repair, EMG electromyography, US ultrasound, CT Computed tomography, AO ante operationem, VHR ventral hernia repair.

^aMedical complications related to intra-abdominal hypertension like pulmonary infection, pulmonary embolism, deep venous thrombosis, acute renal failure, cardiac failure

Table 4. Patient characteristics of studies that evaluated LAWM lengthening after Botulinum

	Ibarra	Elstner	Chan	Elstner
	Mexico	Australia	Australia	Australia
	2014	2017	2018	2019
<i>n</i>	17	32	12	46
Previous hernia repairs				1.3 (0-5)
0	100%	22%	17%	
1		31%	17%	
≥ 2		47%	67%	
Patient				
Male	100%	53%	17%	
BMI	35 (± 12)	32 (22-54)	27 (23-62)	33 (23-51)
Diabetic		28%		
Smokers		9%	8%	
ASA (median)			3 (1-4)	
Cardiopulm. diseases		22%		
CCI			3 (1-5)	
Wound contamination	41%	0%	0%	
Mesh location		IPOM	IPOM	IPOM

CCI Charlson Comorbidity Index, IPOM Intraoperative Onlay Mesh

Secondary effects

Median HDW reduction was 4.8 cm in three studies (29, 49, 50). In two studies (29 patients) a significant HDW reduction of mean 5.1 cm was demonstrated (40, 41). One study (14 patients) did not demonstrate a significant effect on HDW, although a reduction in HDW in 50% of the patients was reported in that study (46). This study used the lowest dosage of Botox® (100 U) compared to the other studies. No study reported about HDW reduction since 2014. Two studies (39 patients) also demonstrated a thinning of the LAWM of mean 0.9 cm (41, 43).

All 14 studies described the PFC rate (median 100%) and a supplemental CST was necessary in median 38% of the patients. In 8 studies the PFC ± CST rates were the only outcome measures (10, 31, 32, 45-48, 51) (Table 5). No linear relation between the primary HDW and the rate of PFC and CST could be assessed (Figure 2).

Table 5. Studies that evaluated the secondary effects of Botulinum in ventral hernia patients

	Zendejas	Zielinski	Lopez	Zielinski	Kohler	Nielsen	Bueno	Catalan	
	USA	USA	Mexico	USA	Austria	Danmark	Spain	Spain	total or median range
	2013	2013	2015	2016	2019	2019	2020	2020	
n	22	18	36	24	31	37	40	36	377
MINORS score	16	5	5	18	5	3	15	6	7 (3-21)
Main study objective	reduce pain	evaluate BTA	experience	PFC after OA	experience	assess safety	CST vs. BTA+RS	long term recurrence	
Prospective study	-/Comp.	-	-	+/Comp.	-	-	+/Comp.	-	36% prospective
Patient accrual	'10	'09-'10	'11-'13	'11-'14	'13-'18	-	'16-'19	-	2007-2019
Age	62	66	52	58	63	59	52	61	59 (34-72)
Midline hernias	95%	100%	95%	100%	85%	92%	100%	?	95% (58-100)
HDW, median (cm)	?	?	12.5	?	12.2	12.1	15.5	13.9	124 (10-15)
HDS, mean (cm ²)	60				132	238			176 (60-282)
Botulinum type	Botox®	Botox®	Botox®	Botox®	Botox®	Botox®	Dysport®	Botox®	Botox®
Total dose of Botulinum	300	300	?	150	300	300	500	300	100-500
Number of injections	6	6	10	6	6	6-10	10	6	75% 6 injections
Number of muscles	3	3	3	3	3	3	3	3	82% 3 LAWM
Guidance technique	US	US	US	US	US	US	US	US	79% US
Injection > 2 wks A.O.	-	-	+	-	+	+	+	+	71% > 2 wks
CT after 2-4 wks, A.O.	-	-	+	-	+	?	?	-	57% pre-op CT
Ventral hernia repair	open/lap.	open	open	open	open	open	open	open	75% open VHR
Use of a mesh in all	+	?	+	?	+	+	+	+	71% use of mesh

Table 5. (continued)

Secondary outcome measures										
Primary fascial closure	41%	83%	86%	96%	94%	100%	100%	78%	100%	(79-100)
PFC without CST	56%	47%	87%		55%	59%	100%	24%	61%	(19-100)
PFC with CST	44%	53%	13%		45%	41%	0%	76%	38%	(0-53)
Wound related compl.	9%	50%	25%	8%	18%	24%	15%	28%	17%	(8-50)
Medical complicationsa	23%	17%		25%	6%	24%	10%		16%	(0-24)
Recurrence	9%		0%		6%		0%	1.1%	0%	(0-11)
Follow up (months)	16		12		12		20	2.4	18	(9-49)
Conclusion of the study	reduces pain	prevents CST	prevents CST	no benefit	prevent CST	a safe adjunct	downstage repair	unclear	79%	positive effect

LAWM lateral abdominal wall muscles, BTA Botulinum Toxin A, PFC primary fascial closure, LAP laparoscopic/ly, TAM transversus abdominis muscle, COMP Comparative study, HDW Hernia defect width, HDS hernia defect size, MOE Musculus Obliquus Externus, CST component separation technique (excluding RSRR), RSRR Rives-Stoppa retromuscular repair, EMG electromyography, US ultrasound, CT Computed tomography, AO ante operationem

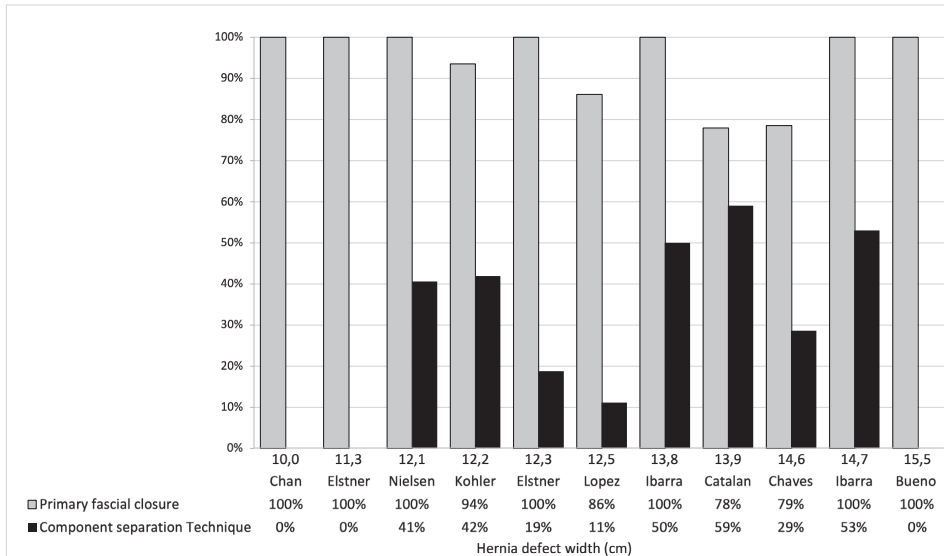


Figure 2. Relation between hernia defect width and rate of midline closure or component separation after Botulinum injection

In the three comparative studies, that did not analyze LWAM elongation, it was concluded that: (a) the PFC rate (96%) was not different between patients that randomly received 150 U Botox® versus a placebo, one day after an open abdomen for damage-control laparotomy (48); (b) the PFC rate (100%) was not different between patients that were randomly assigned between 500 U Dysport® followed 4 weeks later with a Rives-Stoppa retromuscular repair (RSRR) and sublay mesh versus no Dysport® pre-treatment and primary repair by Ramirez (without RSRR) and an onlay mesh (31), and (c) the PFC rate (41%) was not different between patients that received 300 U Botox® 1 week before hernia repair versus a historical matched control group that was not treated with Botox® (46).

Reported mortality was 4/377 (1%). Wound related complications (SSO) were reported in 56 of 299 patients (median 17%) in 12 studies: Surgical Site Infections (SSI) 7%; seroma 6%; wound dehiscence 4%, hematoma 2%; skin necrosis 2% and enterocutaneous fistula in 1% (Table 4). Medical complications occurred in median 16% of the patients (8 studies in 198 patients). The complications were mainly pulmonary (6%), renal (7%), cardiac (4%) or gastro-intestinal (2%). Overall rate of re-interventions due to SSO was 3% (8 studies, 191 patients) and were mainly

performed for SSI or hematoma (10, 29, 43, 45, 47, 49, 50). Thirty-day re-admission rate was 12% (2 studies, 68 patients) (10, 45). Median recurrence was 0% within a median of 18 months follow-up (11 studies, 298 patients), an adequate duration of follow-up (> 2 years) was reported in three studies with a median recurrence of also 0% (0-11) (32, 44, 49).

One study demonstrated that the postoperative use of opioid analgesia after CVHR was significantly lower in 22 patients that were pre-treated with Botulinum compared to a historical control group of 66 matched patients that did not receive Botulinum (46).

Discussion

Primary effect of Botulinum

This systematic review demonstrated that Botulinum, injected into the lateral abdominal wall muscles of 107 patients with large ventral hernias (median 11.8 cm) led to median 4.0 cm elongation per side, against a minimum of side effects. This result is based on new data and is not biased by overlapping cohorts or other compliance modulating techniques (Table 6). This result confirms Weissler's meta-analysis from 2017, that found 3.3 cm elongation in 44 patients. Interpretation of this result should be cautious due to the overall small number of patients it is based upon, the heterogeneity between and moderate methodological quality of most included studies, as well as the fact that this effect was confirmed in three different hernia centers only, mainly originating in Australia. Despite these limitations, this result strengthens the theorem that Botulinum modulates the abdominal wall compliance.

Secondary effects of Botulinum

The effect of Botulinum on the reduction of the hernia defect width is varying, like in the animal studies, and remains unclear, while being underreported.

The supposed effect on the primary fascial closure rate was meanwhile high in the 377 patients with (very) large ventral hernias, suggesting increased abdominal wall compliance after Botulinum. Also, two-third of the patients with these large hernias

did not require an additional component separation technique. Some authors therefore suggested that Botulinum aids in decreasing the rate of bridging and preventing CST, described as “down staging hernia repair” by Bueno-Lleda (10, 17, 31, 47, 51). The latter author found in their prospective and (more or less randomized) study in large hernias patients (mean HDW 15 cm) that a Rives-Stoppa repair after adjunct Botulinum leads to the same PFC rate, as patients treated by the more traumatic Ramirez procedure (without Botulinum) (31). Although this secondary effect of Botulinum is tempting to assume, other supporting evidence is lacking. Moreover, two other comparative studies demonstrated no added effect of Botulinum on the PFC rate (although the dosage was low in one study (48) and the timing of administration before final midline closure short in both (46)).

It is difficult to test the hypothesis whether Botulinum has effect on PFC. There is no objective measuring rod to distinguish preoperatively whether a specific patient will achieve PFC (with or without a supplementary CST) in absence of Botulinum (27). Even hernia defect width cannot predict PFC, as was demonstrated in this review (Figure 2). Analyzing studies with large series of patients that underwent any form of CST show that different combinations of HDW (9-17 cm), HD size ($280 \pm 221 \text{ cm}^2$) and LOD (> 20%) are present in these patients (4, 6, 7, 25, 52). A high number of variables makes it very hard to develop an evidence-based treatment algorithm (27). Thus, only from a very optimistic point of view it may be suggested that Botulinum helps to achieve primary fascial closure or prevent CST.

The desired effect of Botulinum on the reduction of complications and recurrence cannot be evidenced by this review, although wound-related complications (17%), medical complications (16%) and recurrence (0%) appear somewhat lower than those reported in other large series of CST patients (2, 4, 18).

Table 6. (continued)

Bueno-Lledo	2017	Hernia	0	45 ^c				*	*	*	*
Bueno-Lledo	2018	Surg Endosc	0	70 ^c							*
Bueno-Lledo	2019	Ann Surg	0	80 ^c			*	*			*
Nielsen	2019	Hernia	37								*
Kohler	2019	Chirurg	31								*
Chan	2019	ANZ J Surg	12								*
Catalan-Garza	2020	Updates Surg	36								*
Elstner ^b	2020	Hernia	46								*
Bueno-Lledo	2020	Surgery	40	80							*
Deerenberg ^d	2020	J Surg Res	108								*

DR descriptive review, SR systematic review, MA meta-analysis

^a Results also published in follow-up studies (I) and (II)

^b Accrual overlap of patient with study (II)

^c Botulinum combined with progressive pneumoperitoneum

^d unpublished study yet

Indications for prehabilitation with Botulinum

The most advancement is achieved in patients with large centrally located hernias (EHS grading system M2-4) because the LAWMM can stretch to a maximum without being limited by bone structures (rib cage, iliac or pubic bone) (53). The effect of Botulinum on hernia width reduction in non-midline hernias is reported to be less (17).

Hernias with an extensive loss of domain (i.e. volume of incisional hernia/volume of abdominal cavity > 20%) would suit the eligibility. These patients are at risk for abdominal compartment syndrome or pulmonary complications after reduction and attempt to achieve PFC (25). Relaxation of the LAWMM allows a partial or complete preoperative reduction of herniated intestine and solid viscera into the abdominal cavity (17). Adding a series of progressive pneumoperitoneum after Botulinum is suggested to adapt these patients even better to the postoperatively changed abdominal pressure conditions. Promising results, as well as serious complications, of this combined techniques have been described (6, 22, 25-27, 54, 55). A decreased postoperative tension at the linea alba was suggested to prevent recurrent hernia formation (33). Thus, an additional indication could be patients with multiple risk factors (morbid obesity, diabetes, smoking, pulmonary disease, multiple failed previous repairs, open abdomen treatment, use of a biological/biosynthetic mesh and others) which predispose to a more than average risk for a recurrence after CVHR. In those patients a prolonged period of postoperative paralysis may provide additional protection. Some even considered a postoperative “top-up” dose, common practice in neurological and cosmetic disorders, as the effect of the first Botulinum dose begins to subside (18).

Botulinum is known to reduce pain in patients with chronic migraine or cervical dystonia (56, 57). Decreasing myofascial pain by Botulinum in hernia patients has also been described, however this is still largely an unexplored area of indication (46, 58).

Timing, dose and technique of Botulinum injection

Botulinum administered between 2-4 weeks preoperatively is supposed to give the maximum effect at the time of surgery, as was demonstrated in the four studies

that evaluated elongation. The three studies that used Botulinum less than two weeks before surgery had a varying outcome on PFC rate (41%-96%) (46-48).

This review demonstrated that a 200-300 U Botox® (in three studies) or 500 U of Dysport® (in two studies) lead to a significant LAWM elongation. Less than 200 U Botox® seems ineffective because two studies demonstrated that 100 U or 150 U Botox® had no benefit in terms of HDW reduction (50) or PFC (48). However the actual elongation per side was not described in those studies. It is unknown whether more than 300 U Botox® results in more LAWM elongation. Because the maximum cumulative dose is 400 U Botox® (FDA) and since no cases of botulism due to a Botulinum overdose have been described in hernia literature, this is an area for further research (59).

The effects of Botox® and Dysport® are not completely comparable in terms of doses (60). Most experience is described with Botox®.

Ultrasound is required to identify the muscles and prevent injection into the peritoneum, other fascial planes or scarred tissues (25). EMG can also be used to identify a fibrotic or denervated muscle, although limitations of this technique were reported (18). Deerenberg published a detailed image-guided protocol using low-dose CT fluoroscopy (21).

Most (82%) studies used the three lateral muscle bellies for injection of Botulinum. Two studies described a similar significant result on elongation while sparing the transversus muscle, being the 'truncal stabilizer' (43, 44). It was suggested that maintaining truncal and spinal stability avoids back pain from spinal overload (44). However, a detailed analysis of symptoms was not undertaken to quantitatively compare the two groups in this study, thus the effect of sparing the transversus muscle on back pain is unknown.

Summarizing the methodologies of Botulinum administration from the included studies lead to the following protocol: administer 300 U of Botox®, at least 2 weeks preoperatively under US guidance in the transversus abdominis, internal and external oblique muscle bellies, at three different injection points per lateral hemi-abdomen to achieve maximal elongation of the lateral abdominal wall muscles at the time of operation.

Premedication, a maximum volume of 5 cc per single muscle-belly and collaboration with anesthesiologists in some patients may additionally benefit patient's comfort (18).

Objections to use Botulinum as a prehabilitating intervention

First, there are additional costs (0.5-1 euro per unit of Botulinum). Secondly, local pain at the injections site or back pain has been reported in some of the included studies. Thirdly, a clear impact of Botulinum on the rate of postoperative complications could not be assessed.

Rationale for clinical use of Botulinum

Botulinum for ventral hernias is "off-label use", which requires special consideration before implementation into a clinical care pathway. Thus, not only from the perspective of national medication regulations, but also from health insurers and scientific review committees, a solid rationale is necessary before Botulinum can be translated towards clinical practice (4, 7, 10, 21).

Although the aforementioned conclusions on the modulating effect on the abdominal wall by Botulinum are based on a thin body of evidence, the use of Botulinum in daily practice can still be rationalized if a comparison with the 'bundle of care' is being made. Handling this protocol during surgery reduces postoperative infections by administering preoperative antibiotics at the right moment, keeping door movements at a minimum, keeping the patient warm, wearing a face mask and so on. Likewise, implementing an extensive set of prehabilitation measurements is also likely to have a positive effect on outcome. These protocols share the characteristic that, although the contribution of each component on outcome is almost impossible to measure, as a 'complete bundle of care', they have added value. That is where Botulinum may have its place, part of an comprehensive prehabilitation program (Table 7).

Table 7. Rationale for the use of Botulinum as prehabilitation intervention

Rationale	Intended effect	Measurable result
Improve abdominal wall compliance (stretching)	Muscle paralysis	Elongation of the LAWMM (CT)
	Reduce lateral traction	Hernia defect width reduction (CT) Reduction of eviscerated hernia contents
Reduce surgical trauma	Primary fascial closure	Bridging rate
	Prevent CST	CST rate
	Diminish morbidity	SSO rate Medical complications rate Length of stay
	Reduce midline tension	Two-year recurrence rate
Potential effects of Botulinum		
Postoperative adaptation	Gradual transition to a new abdominal wall compliance	Quality of life
Pain modulator	Postoperative pain reduction	Use of opioids, Visual Analog Scale on pain
Prevention	Prolonged paralysis prevent hernia formation in high risk patients	Incisional hernia rate/recurrence rate

LAWMM lateral abdominal wall muscles, CT computed tomography, CST component separation techniques, SSO surgical site occurrences

Future research

The impact from Botulinum on outcome is difficult to assess within the spectrum of comorbidities, contaminated fields, operative techniques, different prostheses, centralization, dedicated surgeons or prehabilitation programs (61, 62). To evaluate the potency of Botulinum in future studies, at least LAWMM elongation should be assessed preoperatively by CT. The desired effect of Botulinum on the PFC±CST rate can only be determined adequately if, during a preoperative multidisciplinary meeting, a decision is made and documented, whether a PFC with or without CST will be necessary, to achieve PFC in that specific patient, assuming no Botulinum is used.

Conclusion

Eleven years have passed since Botulinum was used for the first time in the abdominal wall of humans to facilitate closure of an open abdomen. This systemic review quantified the effect of Botulinum by evaluating the reported elongation of the lateral abdominal wall muscles after injection. Administration did not lead to

local complications. An elongation of median 4 cm per side was found. Reported primary fascial closure rate was high, avoiding component separation techniques in two-third of the patients, although without remarkable effects on the postoperative complication rate. Recurrence rate was very low.

Botulinum pre-stretches the abdominal wall which makes approximation of the midline and mesh placement probably easier. But the level of evidence available to substantiate this remains low. The same applies for the following recommendation: any patient with a ventral midline hernia, in whom primary midline closure is expected difficult to achieve, can be considered a candidate for prehabilitation with Botulinum. There is hardly any harm in trying.

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PART II

Optimizing the *operative* care pathway:
tailored surgical approach

Chapter 8

eCST: The endoscopic-assisted component separation technique for (complex) abdominal wall reconstruction

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Abstract

Introduction In 1990, Ramirez introduced his component separation technique (CST) based on enlargement of the abdominal wall for reconstruction of large abdominal wall defects. CST is prone to postoperative wound complications which lead to modification of the technique to an endoscopic assisted CST. The details of the technique are described in detail with illustrations and report the results of a 36 patient cohort.

Materials and methods Between 2014 and 2018, patients with midline hernias without previous subcutaneous dissection underwent endoscopic-assisted anterior components separation technique (eCST) with retro-rectus mesh enforcement in an expert center for abdominal wall reconstructions. Prospective data were gathered during inpatient care and at least 2 years of follow-up.

Results A total of 36 eCST procedures were performed. Eight patients (22%) had postoperative seroma in the dissection plan between external and internal rectus muscle, 3 (8%) had a hematoma, 1 (3%) had wound dehiscence. Clinical relevant SSEs were present in 4 patients (11%) and consisted of 3 (8%) puncture in seroma, 1 (3%) patient needed a blood transfusion due to large hematoma. One patient was re-operated within 90 days; however, this was the placement of a surgical tracheostomy. Three patients had a recurrence in a mean follow-up length of 24 months.

Conclusion eCST can be useful in selected patients.

Introduction

Over 20% of midline laparotomies causes an incisional hernia within 10 years (1, 2). Especially the larger ones can be challenging in preconditioning the patient, choosing and performing an appropriate reconstruction. One of those options is the (anterior) Components Separation Technique (CST) as described by Ramirez et al. in 1990 (3). This technique is based on an open enlargement of the abdominal wall surface by transection of the external oblique muscle to create a compound flap of the internal oblique and transverse muscle that can be advanced towards the midline. CST can be used to close hernias up to 20 cm width in the waistline, however, due to the large wound surface patients are prone for postoperative wound complications (52%) (4). Furthermore, reconstruction using the original technique (of Ramirez) without a mesh, resulted in a high recurrence rate in the long term (4, 5). The high incidence of wound complications are probably caused by transection of peri-umbilicular perforators, the large skinflaps and wound surface (4, 5). In an attempt to reduce postoperative wound complications, an endoscopic assisted version of the anterior Component Separation Technique (eCST) was developed. Wound surface is hereby reduced and the peri-umbilicular perforators of the abdominal skin are spared. Ultimately, it was demonstrated that eCST was associated with a trend towards less wound complications compared to open anterior CST (6-15). More recently, twenty years after the development of the eCST, the Posterior Component Separation technique with Transversus Abdominis Release (PCS-TAR) was developed. The PCS-TAR technique has gained a huge popularity, which is demonstrated by the high number of PCS-TAR citations, derived from Pubmed between 2014 and September 2019, compared to CST and ECST, respectively, 116, 13 and 11.

This study aims to define indications for the use of eCST within the palet of current component separation techniques.

Historical overview

Lowe et al. were the first who described an Endoscopic assisted CST (16). Using this technique of Lowe a dissection balloon was placed in the subcutaneous space ventral to the anterior rectus fascia and fascia of the external oblique muscle. After removal of the balloon the transection of the external oblique muscle was performed by endoscopic scissors and under direct endoscopic vision (top-down). Although the peri-umbilicular perforator were not damaged, there was still a large wound surface in the subcutaneous plane resulting in seromas (17). Maas et al. first described the technique where the dissection balloon was placed in the avascular plan between external and internal oblique muscle. After removal of the dissection balloon an extra trocar was placed to dissect the insertion of the external oblique muscle by endoscopic scissors and under direct endoscopic vision (bottom-up) (17). Both Lowe et al. and Maas et al. described a hybrid technique which means that the myofascial release was performed using the endoscopic technique after a laparotomy was performed for adhesiolysis and remove former scar (16, 17).

Ethics committee approval

The study was approved by the Local Institutional Review Board (No.: 0492-595681).

Performing eCST

Step 1) 'Indication'

Most important is proper patient selection. Only patients should be selected for an anterior (endoscopic assisted) Components Separation Technique with a longitudinal midline abdominal wall defect within the lateral borders of the rectus abdominus muscle.

Ideally, a multi-disciplinary approach should define the general physical and mental condition of the patient, including pulmonary screening, radiological examination using abdominal CT-scans is a prerequisite (Table1), preoperative screening by anaesthesiologist and discussed in a multi-disciplinary team meeting.

Table 1. Preoperative CT-scan

Size and location of the defect using EHS classification
Presence of a diastase recti
Condition of the muscle needed for reconstruction
Amount of retraction (rectus to defect ratio)
Percentage of evisceration
Presence of old implants (mesh or tackers)
Infection or abscess

A preoperative prehabilitation protocol, including preoperative physical therapy, is used to optimize the patient by reducing preoperative risk factors. Patients with chronic obstructive pulmonary disease (COPD; Tiffenau index < 70%) should receive pre- or perioperative pulmonary preparation to prevent exacerbation. There might be some suggestions that preoperative Inspiratory Muscle Training (IMT) reduces pulmonary complications (18). Patients with severe obesity should be stimulated to lose weight under supervision of a physical therapist, ideally the Body Mass Index (BMI) should be below 30 kg/m² before surgery. Smoking should be stopped preoperatively at least for 4 weeks (Table 2).

Table 2. Patient related riskfactors

BMI > 30
Smoking
Diabetes
COPD/astma/OSAS
Heart disease
anticoagulation
Immunosuppressive medication

Step 2) 'Per-operative preparation'

- The patient is placed in a supine position, both arms are tucked in alongside the trunk using a cotton sheet sheet to be able to approach the lateral side of the abdomen easily.

- It can be very useful to position the patient with pelvis just above the angulation of the operation table.
- The operation field is created using sterile drapings and extends from the thorax to the pubic area and as far lateral as possible.

Step 3) 'Access the abdomen & perform adhesiolysis'

- The midline scar is excised and the hernia is reduced.
- The hernia sac is removed.
- Adhesiolysis performed as far as the lateral peritoneal fold on both sides of the abdomen in order to investigate non midline defect (missed on preoperative CT-scan), which could change the operative plane. To facilitate palpation of the abdominal wall from inside out (useful for trocar positioning) and for optimal sifting to the midline.

Step 4) 'Create the lateral endoscopic pockets'

See Figures 1 and 2 for optimal trocar placement of two trocars and position of the 'endoscopic pocket'.

Lower the legs by smooth "hyper" extension in the pelvis and angulate the patient a little bit to the opposite side.

A small 1.5 cm incision is made 2 cm subcostal, in line with the superior anterior iliac spine approximately 5 cm laterally from the rectus muscle. This can easily be checked by palpation "around" the rectus muscle. The fascia of the external oblique muscle is identified and incised, the muscle fibres are spread and a blunt tip balloon trocar (10 mm AutoSuture BTT, Medtronic®) is placed in the plane between the external and internal oblique muscle. Insufflation commences, a 5 or 10 mm 30° endoscope is introduced and used to separate the loose connective tissue between the external and internal oblique muscle, thus creating the 'endoscopic pocket'. One 5 mm trocar with balloon is placed under direct vision 3 cm distal to the blunt-tip trocar. Using (electro coagulation) scissor the pocket is extended cranially 5 cm above the costal margin, distally towards the inguinal ligament and laterally to the aponeurosis of the external oblique muscle (Figure 1). Being careful on top of the costal margin for small vessels on the lateral side. The external oblique muscle is

now released, using dissection hoke in combination with coagulation, approximately 1 cm lateral to the rectus abdominal muscle 5 cm cranial of the costal margin until the inguinal region in order to create a compound flap consisting of the internal oblique and transverse muscle. See Figure 3 for an endoscopic view inside the endoscopic pocket after the external oblique muscle has been transacted. The same procedure is performed on the contralateral side. The trocars are removed and the external oblique fascia is closed with a single resorbable suture.

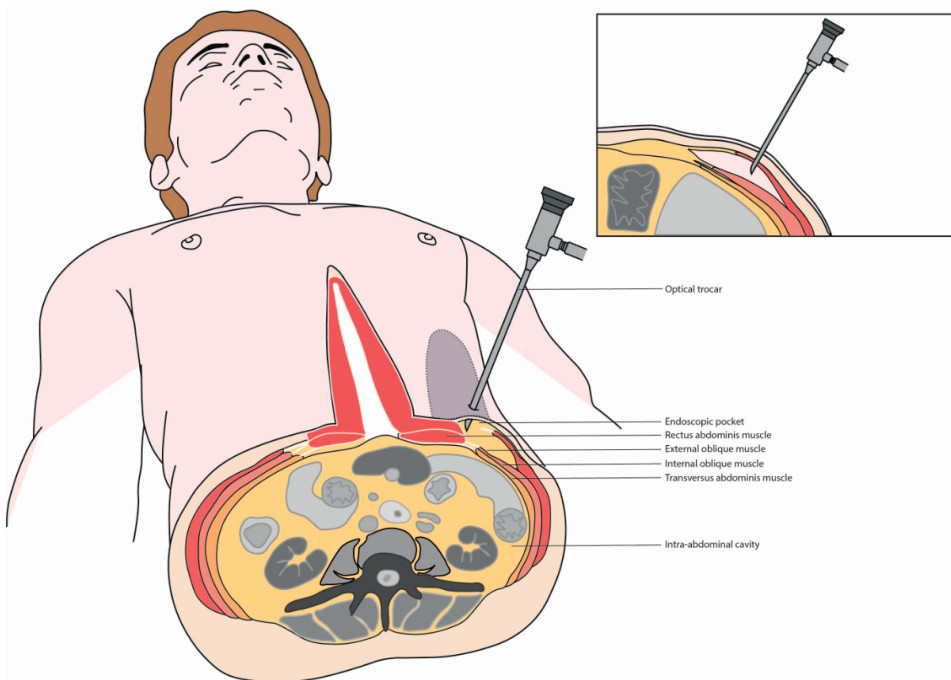


Figure 1. Trocar position eCST

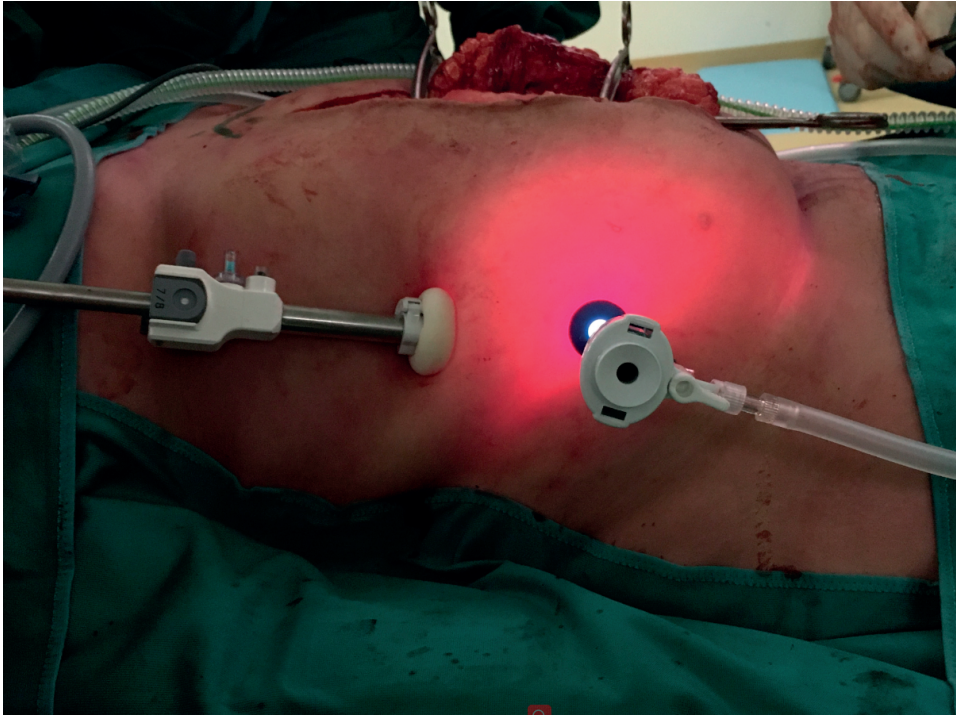


Figure 2. Trocar position eCST

Step 4) 'Create the lateral endoscopic pockets using a dissection balloon' following Jorgensen

Alternative is the technique as described by Jorgenson (19). The first step is a small incision at the costal margin and splitting the external oblique muscle (Figure 3). A dissection balloon is placed in distal direction and in the avascular plane between external and internal oblique muscle. Under video endoscopic vision the balloon is insufflated with care and kept in place for several minutes. After desufflation of the dissection balloon it can be changed for a blunt tip trocar and regular insufflation started. A second 5 mm trocar places just below and entrance to the pocket. The external oblique muscle is now released approximately 1 cm lateral to the rectus abdominal muscle. Last step in this approach is dissection of the external oblique muscle in the region using a clamp and electro-coagulation after removing the trocar. The trocars are removed and the external oblique fascia cannot be closed.

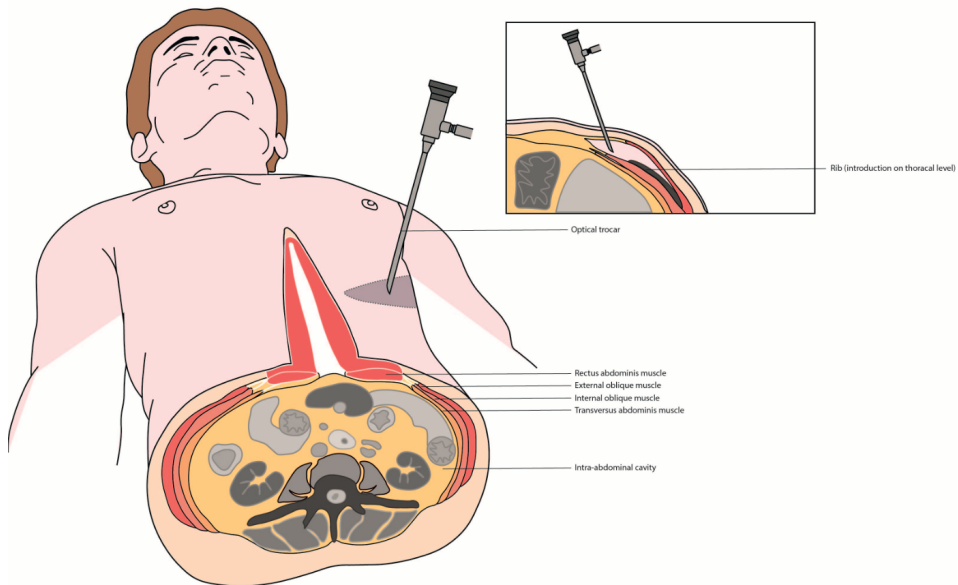


Figure 3. Trocar position eCST following Jorgensen

Step 6) 'Primary fascia closure'

The newly created compound flap consisting of the rectus muscle, internal oblique muscle and transverse abdominal muscle (see enlargement in Figure 4) can now be advanced approximately 6-8 cm towards the midline on either side. Closing gaps between 10 and 15 cm in width. The posterior rectus fascia is opened and dissected following Rives-Stoppa for xyfoid until the pubic bone (20). The fatty triangle must be fully opened. Care not to damage the neurovascular bundles on the lateral site of posterior rectus sheath.

The posterior rectus abdominis fascia is in most patients of good quality and can be closed in the midline using a continues slowly resorbable running 2/0 suture with small steps, small bites principle. A sublay position of the prosthetic lightweight mesh (underneath the rectus abdominis muscle, on top of the posterior rectus fascia) is preferred due to the reduced risk of bowel adhesions. In our opinion it is not necessary to fixate the mesh. It diminishes the changes of bowel leasions or post-operative pain. The anterior rectus abdominis fascia is closed using a continues slowly resorbable running 2/0 suture with small steps, small bites principle,

according to the Stich trial. The subcutaneous plane is always closed using resorbable 2/0 sutures. No drains are used. The skin is closed and the wounds are dressed.

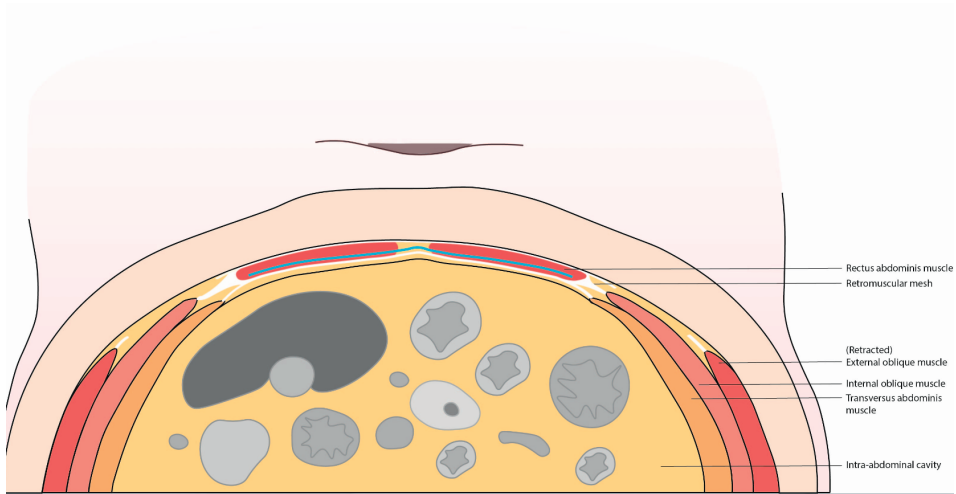


Figure 4. Retromuscular mesh placing after eCST

Tips and Tricks

Tip 1) ‘Presence of a uro- or enterostomy’

The presence of a uro- or enterostomy limits the surgical techniques that can be used for ventral hernia repair. However, eCST can be used in these patients if a “sublay” position of the mesh is feasible. Most important is the location of uro- or enterostomy in relation to the lateral border of the rectus (located in the centre of the rectus muscle) in order to have sufficient mesh overlap. An ECST should not be used if the uro- or enterostomy must be replaced or if a parastomal hernia is present. In these situations a myofascial release using transversus abdominal release (TAR) should be recommended (21).

Tip 3 ‘Monitor position’

During eCST orientation inside the endoscopic pocket may be difficult for the performing surgeon. In order to assist the surgeon with orientation during the

endoscopic release two endoscopic video monitors are used, one at the head of the operating table and one at the bottom end of the operating table. If the surgeon points the endoscope towards the head of the patient, the monitor located at that side of the table is used and vice versa if the endoscope is pointed towards the feet of the patient.

Tip 4 ‘Creating the endoscopic pocket’

The ‘space’ between the external and internal oblique muscle may be difficult to identify due to its resemblance to the ‘space’ between the transverse and the internal oblique muscle. However, after placement of the balloon trocar and insufflation of the ‘endoscopic pocket’ the surgeon can quickly check if he is creating the endoscopic pocket between the external and internal oblique muscle or (by mistake) in between the internal oblique and the transverse abdominal muscle since the first is an avascular plane and shouldn’t be accompanied by any bleeding during dissection of the connective tissue and the later is not.

Tip 5 ‘Postoperative care’

Patient is advised to wear an abdominal binder for at least 4 weeks and avoid heavy lifting for 6 weeks, although there is a lack of evidence to support this (22).

Experience

Our current practice is a single-center (regional referral center for abdominal wall surgery), retrospective series of patients who underwent elective incisional hernia repair through an eCST ($n = 36$) with retro-rectus mesh position between September 2014 to December 2018 with a follow-up of at least 2 years. Data are collected prospectively in a hospital-based database. All patients received standard preoperative work-up and are discussed preoperatively in a multidisciplinary setting with several hernia-specialized surgeons, pulmonologist, anesthetist, intensive care physician and a specialized abdominal wall case manager. Together, they set up a patient tailored treatment plan and discuss the most suitable surgery.

Patients are included if they met the following criteria: age > 18 years, hernia size confirmed by abdominal computed tomography (CT) scan; hernia repair with a sublay mesh; use of a lightweight polypropylene mesh or poly-4-hydroxybutyrate mesh in contaminated situation (since 2016).

Table 3 summarizes their demographics, which are assessed preoperatively.

Table 4 describes the operative and postoperative characteristics. A postoperative SSO rate of 25%, some patients had multiple SSOs. However, a small amount were clinically relevant surgical site events. Eight patients (22%) had postoperative seroma in the dissection plane between external and internal rectus muscle, 3 (8%) had a hematoma, 1 (3%) had wound dehiscence. Clinically relevant SSEs were present in 4 patients (11%) and consisted of 3 (8%) puncture in seroma, 1 (3%) patient needed blood transfusion due to large hematoma. One patient was re-operated within 90 days, however this was the placement of a surgical tracheostomy.

Table 3. Per- and postoperative data

	eCST (n = 36)
Mesh type	
Synthetic	30 (83%)
Biosynthetic	7 (19%)
Operative time	167 (120-290)
SSO	9 (25%)
SSE	4 (11%)
Pulmonary complications	8 (22%)
Length of stay > 14 days	4 (11%)
Re-operation	1 (3%)
Recurrence	3 (8%)

Three patients had a recurrence in a mean follow-up length of 24 months. One patient was diabetic, smoked and had a previous hernia repair and was classified as HPW stage 2; one patient smoked and had a previous hernia repair; one was obese and had a stoma.

Table 4. Patient demographics and hernia characteristics

eCST (n = 36)	
Sex	
Male	19 (53%)
Female	17 (47%)
Age (year)	61 (31-84)
BMI (kg/m ²)	28 (21-37)
Obesity BMI > 30	13 (36%)
Hernia size (cm ²)	173 (31-436)
Comorbidities	
DM	4 (11%)
COPD > Gold II	3 (8%)
Immunosuppression	1 (3%)
ASA score	
1	3 (8%)
2	23 (64%)
3	10 (28%)
HPW	
2	30 (83%)
3	6 (17%)
4	0
VHWG 2012	
1	6 (17%)
2	23 (64%)
3	7 (19%)
Midline	36 (100%)
CDC	
1	12 (33%)
2	20 (56%)
3	2 (6%)
Stoma in situ	1 (3%)

Discussion

Endoscopic assisted anterior Components Separation Technique can be used to reconstruct midline abdominal wall hernias with defect of 7-15 cm at the waistline even in patients with a uro- or enterostomy. If an anterior myofascial release is used to reconstruct large abdominal wall defect the endoscopic assisted CST seems superior to the classical open anterior CST with respect to SSO (19).

Our technique to perform the endoscopic release differs from previously published methods such as performed by Lowe et al. (16). In our opinion using a distension balloon to create a subcutaneous space has little advantage over the original technique described by Ramirez et al. because of trauma to the skin vascularization (3). Rosen et al. and Fox et al. described an endoscopic method using the plane between the internal and external oblique muscles, though they lack full endoscopic control since a dissection balloon is used and the external oblique fascia is incised in three places because an extra trocar is needed to complete transection of the external oblique muscle (9, 23-25). The use of full video-endoscopic guidance to create a space in the avascular plane between the internal and external oblique muscle and transect the external oblique aponeurosis is a safe operative technique and causes less trauma to the skin vascularization. Although the dissection in the technique described by Jorgenson is quite elegant, especially for the ergonomics of the surgeon, it is not that controlled because the balloon can easily damage small vessels. These small bleedings can be difficult to control by coagulation.

As the complexity of the abdominal hernias increases, the discussion about surgical techniques evolves.

A systematic review by Cornette et al. compared the SSO rates in eCST and PCSTAR surgery (26). They found a SSO rate of 23.7% ($n = 761$) for PCSTAR and 20.3% ($n = 193$) for eCST which did not differ significantly. It is hard to compare our study outcomes with these outcomes, because of the large heterogeneity in baseline patient characteristics in the studies used in the systematic review. Several of the included studies showed patient age, contaminated wound status and hernia width to be possible predictors of a surgical site infection and thus SSO (26).

Recent systematic review of Balla et al. about eCST + laparotomy (hybrid) vs. complete eCST (endoscopy in combination with laparoscopy) vs. Robot PCS-TAR shows some superiority of the PCS-TAR considering SSO, the main difference between the techniques is the midline laparotomy which is necessary in the eCST. This midline laparotomy is sometimes unavoidable, which makes the groups not completely comparable (27).

In hernia surgery, one size does not seem to fit all. The eCST is well suitable in defects smaller than 15 cm because of the limited dissection. Therefore, the endoscopic approach is primarily for midline hernia defects that reach up to a maximum of 2 cm medial from the semilunar line (14). For hernias located < 2 cm of the semilunar line or passing it, the PCS-TAR has been shown to be an excellent option for abdominal wall repair. Large lateral and flank hernias should have a mesh overlap of at least 5-7 cm, which only can be achieved by a PCS-TAR procedure (21). Besides, hernias near bony structures, like subxyphoid or suprapubic, do not benefit from anterior component release but are suited for PCS-TAR (Table 5) (21).

Table 5. Indications for eCST and PCS-TAR

	Indications for eCST	Indications for PCS-TAR
Location	Midline hernia (M2, 3, 4)	Hernia near bony structure (M1, M5) Lateral hernia (L1-L4)
	Parastomal hernia with border > 2 cm medial from semilunar line	Parastomal hernia with border < 2 cm medial from semilunar line or passing semilunar line
Size	Hernia width 10-20 cm	Hernia width 10-25 cm
History	Previous repair with intraperitoneal mesh	Previous repair with anterior component separation

The trocar position and number of trocars depend on the surgeons' preference. In our opinion, two lateral trocars give the best exposure to perform the dissection. Trocar position at the costal margin probably has better ergonomics.

In conclusion, reconstruction in complex abdominal wall defects is tailored surgery and demands skills of several techniques to reconstruct the abdominal wall. The choice which techniques should be performed depends on hernia and patients characteristics. eCST can be useful in selected patients. The surgeons in any center of excellence for hernia surgery should be familiar with the endoscopic assisted CST.

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Chapter 9

Systematic review of transversus abdominis release in complex abdominal wall reconstruction

Hernia. 2019 Feb;23(1):5-15

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Abstract

Background Transversus abdominis release (TAR), as a type of posterior component separation, is a new myofascial release technique in complex ventral hernia repair. TAR preserves rectus muscle innervation, creates an immense retromuscular plane and allows bilaminar ingrowth of the mesh. The place of the TAR within the range of established anterior component separation techniques (CST) is unclear. Aim of this systematic literature review is to estimate the position of the TAR in the scope of ventral hernia repair techniques.

Methods MEDLINE, Embase, Pubmed and the Cochrane controlled trials register and Science citation index were searched using the following terms: 'posterior component separation', 'transversus abdominis release', 'ventral hernia repair', 'complex abdominal wall reconstruction'. To prevent duplication bias, only studies with a unique cohort of patients who underwent transversus abdominis release for complex abdominal wall reconstruction were eligible. Postoperative complications and recurrences had to be registered adequately. The rate of surgical site occurrences and recurrences of the TAR were compared with those after anterior CST, published earlier in two meta-analyses.

Results Five articles met our strict inclusion criteria, describing 646 TAR patients. Methodological quality per study was good. Mean hernia surface was 509 cm² and 88% of the hernias were located in the midline. Preoperative risk stratification was distributed in low risk (10%), co-morbid (55%), potentially contaminated (32%) and infected (3%). Pooled calculations demonstrated a mean SSO rate of 15% after TAR (20-35% after anterior CST) and a mean 2-year hernia recurrence rate of 4% (13% after anterior CST). Mean hernia surface was 300 cm² in anterior component separation studies.

Conclusion This review demonstrates that the transversus abdominis release is a good alternative for anterior CST in terms of SSO and recurrence, especially in very large midline ventral hernias.

Introduction

Techniques in complex abdominal wall reconstruction have developed rapidly over the past decades. Optimal repair as recommended by the American based Ventral Hernia Working Group (VHWG) comprises a rectus to rectus re-approximation under physiological conditions, use of a sublay mesh and a myofascial release, if necessary (1-4).

Since 1990 the Ramirez technique, or Component Separation Technique (CST), became popular (5). CST is a release of the external oblique muscle fascia via a direct open approach. To reduce the rather high rate of wound morbidity, due to the large area of subcutaneous undermining, an endoscopic technique was developed in 2000 (6, 7). Two recently performed systematic reviews comparing both approaches showed benefits for the endoscopic-assisted technique in terms of a lower rate of surgical site occurrences (SSO), 20% versus 35%, not compromising the average recurrence rate of 13% (8, 9).

In order to improve these results and treat larger defects at challenging locations, other ways to achieve further dissection of the abdominal wall, lateral beyond the linea semilunaris, have been explored. In 2008 intramuscular dissection between the internal oblique and transverse muscle was reported (10, 11). To differentiate this technique from the anterior approach in CST, it was described as Fascial or Posterior Component Separation (PCS). However this route inevitably leads to dissection of the neurovascular bundles to the rectus muscles. In 2012 another form of PCS was introduced that actually preserves the rectus muscle innervation: the Transversus Abdominis muscle Release (TAR) (12, 13). More recently, robot-assisted laparoscopic TAR has been described, in a desire to reduce wound morbidity to a further extent (14-16).

The anterior CST has the advantage of a formidable medialization of the rectus fascia up to 5 cm per side, especially at the umbilical level (5, 17). This medialization can be increased up to 10 cm per side if the rectus muscle is separated from its encasement from the posterior rectus sheath. However, the extent of medialization near the xiphoid and pubic bone is limited by the rib cage and iliac crest with the inguinal ligament, respectively (18). Also, in non-midline hernias, such as

lumbar, parastomal or subcostal hernias, an anterior release may be difficult because the external oblique muscle fascia is part of the hernia and may already have been damaged at this level, albeit a release might not be impossible (19). Another disadvantages of anterior CST in very large hernias with significant loss of domain is that a bridging mesh is often necessary, increasing the risk of recurrence, bowel adhesions or enteric fistula formation (3, 20).

The posterior technique with TAR has the advantage of creating an immense retro-muscular plane that allows for a large area of mesh ingrowth between two extra-peritoneal layers (18, 21). Very large meshes can be used (up to 4500 cm²) (4). A mesh in this plane covers hernias near bony structures and non-midline defects (22). The mesh also protects the area of the dissected and released transverse muscle preventing development of hernias at the linea semilunaris, which is a known complication of the anterior CST with sublay mesh placement (10, 23). Large mesh reinforcement of the visceral sac leads to improved core stability (24, 25). However, three cadaveric studies demonstrated less medialization of the rectus fascia with the posterior technique compared to the anterior technique (13, 26, 27). On the other hand, this phenomenon was contradicted by others in clinical practice (12, 23, 28-30).

The aim of this review is to estimate the position of the TAR within the scope of ventral hernia repair techniques.

Methods

A systematic review of TAR studies was performed in accordance with the PRISMA statement (31). These results are compared with the results of two previously published systematic reviews of anterior techniques (8, 9). This study was registered on PROSPERO No. CRD42018085172 on 18 January 2018.

Search strategy

A structured literature search, by validated methods of the Cochrane collaboration, was performed in MEDLINE, Embase, PubMed, the Cochrane controlled trials register and Science citation index, and through cross referencing by two independent

reviewers (JT/JW) (32). The publication date was limited to the past ten years. Last search was conducted 23rd September 2018 and performed during the first revision of the manuscript.

The following terms in were used: 'Transversus abdominis release' OR 'transversus abdominis muscle release' OR 'posterior component separation' OR 'posterior component separation technique' OR 'posterior component separation with transversus abdominis release' OR 'open transversus abdominis muscle release' OR 'robot transversus abdominis muscle release' OR 'robot assisted transversus abdominis release' OR 'robot transversus abdominis release' AND 'complex abdominal wall surgery' OR 'ventral hernia repair' OR 'complex abdominal wall reconstruction' AND 'surgical site occurrence' OR 'surgical site infections' OR 'wound morbidity' OR 'complications' OR 'recurrence'. Both medical subject heading terms and free text terms were used.

Relevant studies concerning TAR were selected and reviewed by two independent authors for inclusion. In case of disagreement regarding the eligibility for inclusion of an article, the study quality or data abstraction, a third reviewer (TdVR) was consulted for arbitration.

Study selection criteria

To prevent duplication bias, studies were included if they originated from a unique cohort. In case of multiples publications from one center, the most recently published study was considered to be comprehensive for other previously published series from the same center. Studies were included if they described at least the following characteristics: adult patients with complex ventral hernias (complexity is defined by defects that need a myofascial release to achieve rectus to rectus closure), restoration of the abdominal wall using open or (robot-assisted) laparoscopic TAR and adequate description of either of the following endpoints: hernia recurrence, SSO's or other complications, and a minimal follow-up of three months.

Exclusion criteria were case series including less than five patients and studies that did not describe the surgical technique in detail. Additionally, other types of PSC, for example by preperitoneal plane dissection or intramuscular component separation were excluded. Studies that focused on non-midline hernias, for example

TAR for parastomal or lumbar hernias, were excluded as well to create an uniform patient cohort of mainly midline hernia patients.

Technique

The TAR was performed in a comparable manner in all studies (12, 13). A midline laparotomy was generated followed by complete adhesiolysis. The rectus sheath was then incised approximately 0.5-1 cm from its medial border exposing the rectus muscle and posterior rectus sheet. This retromuscular plane was extended to the retroxiphoid space superior and the space of Retzius inferior. Laterally, the plane was extended to the linea semilunaris until the neurovascular bundles were visualized medially. To preserve these perforators, 0.5-1 cm medial from the neurovascular bundles, the posterior lamel of the musculus obliquus internus (MOI) was incised exposing the transverse muscle (TM) in the upper abdomen and the inserting fascia of the TM in the lower abdomen. The transversus abdominis fascia and muscle were then subsequently transected exposing the underlying peritoneum/transversalis fascia. The next step was dissecting the TM from the peritoneum/transversalis fascia by sharp and blunt dissection, creating a large plane bordered by the lateral edges of the psoas muscle, retro xyphoidal space and Retzius' space. After complete posterior component separation, the medialized posterior rectus sheaths were then re-approximated. A mesh was placed in retromuscular position between the fasciae and selectively secured anteriorly with slowly absorbing monofilament stitches. Closed-suction drains were placed on top of the mesh. Restoration of the linea alba is then completed by re-approximating the anterior rectus sheaths with a running slowly absorbable monofilament suture. Subcutaneous tissues may be irrigated with saline and skin is closed in layers (4, 13).

In case of robot-assisted laparoscopic TAR (R-TAR) the patient is placed in supine position and a complete laparoscopic procedure is performed (16). Robotic ports are placed along the anterior axillary line at one side. Adhesiolysis is performed as needed, hernia sac contents are reduced, and a retro-rectus dissection is performed to the semi-lunar line. The subsequent steps mimic the open TAR in transversus abdominis muscle division and dissection above the costal margin to the central tendon of the diaphragm superiorly and to the retro-pubic space inferiorly.

These steps are repeated for the contralateral abdominal wall after redocking the robot. Then the hernia sac is imbricated down with a continuous barbed absorbable suture, the anterior fascia is closed, a mesh is placed retromuscular and ultimately the posterior rectus fasciae are approximated and closed intraperitoneally (14, 16, 33). In another variant first the medialized posterior sheaths are re-approximated, then the trocars are repositioned in the ventral compartment, closure of the anterior sheath is accomplished and the mesh is positioned (34).

Outcome definition

Primary outcome measurements are wound morbidity and hernia recurrence. Wound morbidity is described as surgical site occurrences (SSO) independent if their clinical significance lead to any kind of intervention. SSO's are: surgical site infections (SSI), cellulitis, necrosis, non-healing wound, seroma, hematoma, dehiscence or fistula. The reported rate of SSO's was considered relevant if at least a follow-up of 90 days was available (35, 37). The reported rate of hernia recurrence was considered relevant after a follow-up of at least 24 months (38).

Quality assessment

The quality of nonrandomized clinical studies was evaluated using the methodological index for non-randomized studies (MINORs) criteria (39).

Data extraction

Data extraction was performed in duplicate by two independent reviewers (JT/JW) including the following study variables: retrospective or prospective design, demographics of study population, number of patients included, size of the defect, previous hernia repair, previous abdominal surgeries, preoperative wound classification, types of prosthesis used, surgical technique, operative details (blood loss and duration of operation), complications in terms of surgical site events, surgical site occurrences and surgical site infections (CDC), hernia recurrence, need for re-operation and duration of follow-up. All newly developed ventral hernias after TAR were classified as a recurrence, independent of the location of the recurrence.

Calculations

As the size of each included study cohorts will differ mutually, a weighted mean will be used in all calculations to determine the relative importance of each mean on the overall average, which will synthesize the observed results.

Results

Study selection

Fifty-eight unique citations were identified in PubMed and through cross referencing (Figure 1). No additional study was extracted from the Cochrane Database of Systematic Reviews, Science citation index or MEDLINE. Ultimately, five studies describing the results of open TAR were eligible (4, 16, 40-42).

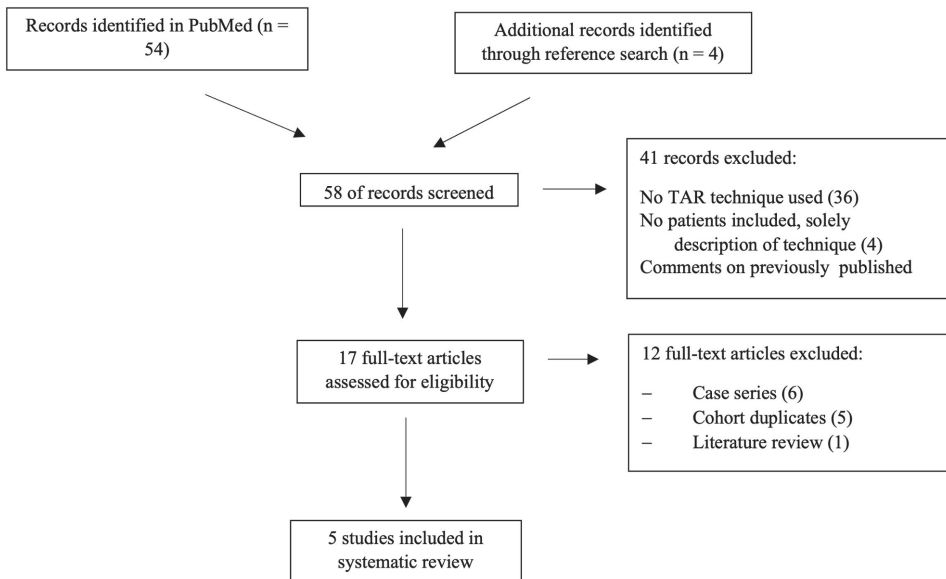


Figure 1. PRISMA Flow chart shows the method of inclusion of trials/studies in the systematic review (n number of studies): this flowchart is in accordance with the PRISMA statement 2009

Study characteristics

The five studies comprised a total of 646 patients (Table 1). Four studies originated in the United States and one in the United Kingdom (42). All were retrospective cohort studies. Two comparative studies were included: one comparing open TAR with ACS, and one comparing open TAR with R-TAR (16, 41). All studies were single centered, except Parent's study, which enrolled patients from three different academic surgical centers (41).

The MINORS score in the three non-comparative studies ranged from 10 to 11 (max. 16) and in the two comparative studies from 16 to 21 (max. 24).

Table 1. Methodological quality of studies (MINORS) describing TAR

Author	Design	<i>n</i>	MINORS (max)
Winder 2016 Hershey, USA	Cohort study	37	11 (16)
Parent 2016 Washington, USA	Comparative cohort study PCS/TAR versus ACST	67/75	21 (24)
Novitsky 2016 Cleveland, USA	Cohort study	428	10 (16)
Bittner 2017 Richmond, USA	Comparative cohort study PCS/TAR versus R-TAR	76/26	16 (24)
Appleton 2017 Prescott, UK	Cohort study	12	10 (16)

MINORS methodological index for non-randomized studies, *PCS/TAR* posterior component separation with transversus abdominis release, *ACS* anterior component separation technique, *R-TAR* robot assisted transversus abdominis release

Patient characteristics and intraoperative details

In the total group of patients the weighted mean age was 57 years (52-62) and body mass index (BMI) 33 (30-34) kg/m² (Table 2). The mean rate of patients with diabetes, nicotine abuse and Chronic Obstructive Pulmonary Disease (COPD) was 21%, 8% and 12%, respectively. Overall, patients underwent up to four previous abdominal surgeries including two previous hernia repairs.

Mean hernia surface in the complete population was 509 cm² (235-606) and 88% of the hernias were located in the midline. The preoperative wound classification, reported in one study, demonstrated that two-third of 428 patients had a clean wound (4). The preoperative VHWG risk stratification in 544 patients was: Low risk: 10%; Comorbid: 55%; Potentially contaminated: 32% and Infected in 3% (1).

The mean operative time was 280 minutes (251-383) and had mean 188 mL blood loss (Table 3). Primary fascial closure was achieved in nearly all patients (98%). In 88% of the patients a synthetic mesh was placed, a biological mesh in 7%, a hybrid (synthetic/biological) mesh in 3% and an absorbable synthetic mesh in 2%.

Table 2. Patient demographics

	Winder	Parent	Novitsky	Bittner		Appleton
				O-TAR	R-TAR	
<i>n</i>	37	67	428	76	26	12
Mean age (years)	58	56	58	55	52	62
Gender (male percentage)	14 (38)	28 (42)	186 (44)	35 (46)	9 (33)	9 (75)
Mean BMI (kg/m ²)	32	31	34	32	33	31
Diabetes (%)	9 (24)	12 (18)	90 (21)	17 (22)	0	1 (8)
Smoker (%)	1 (3)	9 (13)	37 (7)	10 (13)	0	0
COPD (%)	0	13 (19)	51 (12)	8 (11)	7 (25)	1 (8)
Previous abdominal surgeries	2	3	4			
Previous hernia repairs			2			
Hernia width (cm)			15	14	12	12
Hernia surface (cm ²)	392	340	606	260	235	
Hernias located in midline (%)	33 (89)			68 (90)	22 (83)	11 (92)
Preoperative wound classification (%)						
Clean			283 (66)			
Clean-contaminated			111(26)			
Contaminated			34 (8)			
Dirty			0			
VHWG risk stratification (%)						
Low risk	4 (11)	3 (5)	47 (11)			1 (8)
Comorbid	25 (68)	37 (55)	236 (55)			0
Potentially contaminated	6 (16)	19 (28)	145 (34)			3 (25)
Infected	2 (5)	8 (12)	0			8 (67)

O-TAR open transversus abdominis release, *R-TAR* robotic transversus abdominis release, *BMI* body mass index, *COPD* chronic obstructive pulmonary disease, *VHWG* ventral hernia working group classification (2010)

Table 3. Operative characteristics and outcome

	Winder	Parent	Novitsky	Bittner		Appleton
				O-TAR	R-TAR	
<i>n</i>	37	67	428	76	26	12
Operative time (min)	359	366	251	287	365	383
Estimated blood loss (ml)	190		188			0
Primary fascial closure (%)	37 (100)	67 (100)	416 (97)	76 (100)	26 (100)	12 (100)
Type of mesh						
synthetic (%)	30 (81)	37 (55)	428 (100)	50 (65)	24 (92)	2 (17)
hybrid (%)	5 (14)			13 (17)	1 (4)	
absorbable synthetic (%)				9 (12)	1 (4)	1 (8)
biologic (%)	2 (5)	30 (45)		4 (5)		9 (75)
Concomitant procedure (%)		18 (27)		12 (16)	0	4 (33)
Outcome						
Surgical site occurrence or event (%)	2 (5)	13 (19)	80 (19)	2 (3)	1 (4)	1 (8)
Surgical site infection (%)		2 (3)	39 (9)	2 (3)	1 (4)	2 (17)
Recurrence (%)	1 (3)	4 (6)	13 (4)	nr		2 (17)
Follow-up (months)	21 (12-42)	8 (6-13)	32 (12-84)	3		24 (18-37)

O-TAR open transversus abdominis release, *R-TAR* robotic transversus abdominis release

Complications and hernia recurrence

SSO's were mean 15% (in 4 studies) and SSI's 7% (in all studies) (Table 3). Detailed specifications of the SSI's into superficial, deep or organ space were available in one study and respectively divided into 72% superficial SSI's and 18% deep SSI's (4). Medical complications not related to the wound were reported in two studies. These included urinary tract infections (9%), pneumonia (8%), cardiovascular complications (8%), deep venous thrombosis or pulmonary embolism (6%), and ileus (4%) (4, 40).

Overall follow-up was mean 25 (3-32) months. The hernia recurrence rate after 24 months was mentioned in 2 studies and was mean 4% (4, 42).

Discussion

Six years after the first series on the transversus abdominis muscle release was published, this systematic review on 646 unique patients suggests that the TAR has a wound morbidity rate that is comparable to the anterior component separation techniques (15% versus 20%), but a much lower recurrence rate (4% versus 13%). This conclusion is based on five unique studies, each with a good methodological quality, adequate description of technique, complications and follow-up. Moreover, this study lacks duplication bias, which was present in previously published systematic reviews on TAR (18, 43, 44).

The low recurrence rate of TAR might be explained by the fact that that a mesh was used in all TAR patients (61-73% mesh used in the anterior CST meta-analysis), that the best location to prevent recurrence (sublay) was used (mostly onlay or underlay in the anterior CST meta-analysis) and that almost all patient (98%) had a final rectus-to-rectus closure without bridging (2, 3). Retromuscular mesh placement has the lowest recurrence rate in general (7%) compared with other mesh positions like underlay (15%), which is often used in CST to prevent semilunar herniation (3).

The low recurrence rate of TAR is even more compelling, considering that the TAR was used in patients with hernias of twice the size (mean 500 cm²) compared to those reported repaired with the anterior CST technique (mean 300 cm²) (8, 9, 45). The absence of bridging within this TAR population with large midline hernias indicates that the TAR seems to afford an even more medial mobilization of the recti fasciae than the anterior CST, at least in a clinical setting (4, 29). Also, the possibility to place a much larger mesh after TAR than after CST may also have aided in this low recurrence rate. The reason why the SSO rate in TAR is not substantially lower than with anterior CST remains unclear. Possible explanations are the creation of a formidable area of dissection with its inherent risk of seroma/hematoma formation and infection, as well as potential difficulties of closing the anterior rectus fascia over the mesh, resulting in an area of less well protected mesh, covered by skin and subcutaneous fat only (13, 27).

The high recurrence rate in Appleton's TAR study (17% after 2 years) and in Parent's TAR study (6% after 9 months) is explained by their use of resorbable biological

meshes in 75% and 45% of their patients respectively. These results are comparable with earlier published studies on biologic meshes in contaminated fields with recurrence rates oscillating between 30-50% (46, 47). These observations underscore the advantages of a (synthetic) mesh in prevention of recurrence (2).

Some precaution is necessary in the interpretation of the low recurrence rate after TAR, in comparison with the anterior component separation technique. First, the low recurrence rate is largely determined by one tertiary expert center that accounted for 66% of the 646 patients (4). Secondly, the number of eligible studies was a threefold lower in this TAR review than in the CST meta-analysis, thus not representing daily practice in the same manner. Thirdly, absence of randomized controlled trials, heterogeneity between the studies in patient demographics, hernia factors and intra-operative characteristics, as well as inconsistency in reporting outcomes hamper adequate comparison of the SSO and recurrence between the different techniques, a well-known feature within evidence based ventral hernia research (48).

The Case Comprehensive Hernia Center (CCHC) in Cleveland USA is pioneering in ventral hernia repair and were the first to publish the efficacy of TAR (12). The CCHC provides a steady flow of relevant publications in the field of TAR (Table 4). They have also demonstrated that TAR can be applied with good results in specific complex cases like in patients with a history of an open abdomen, with an enterocutaneous fistula, after a previously performed anterior component separation, with a contaminated field and the use of a biological mesh, with a parastomal hernia, with a incisional lumbar hernia after kidney transplantation under immunosuppression and even in giant hernias with the use of quilted meshes (12, 22, 23, 30, 49-53).

Table 4. List of publications from, or in conjunction with, the Case Comprehensive Hernia Center Cleveland, USA, that were used in three different reviews

Author	Year	Other specific indication for TAR	n	Accrual	Clean wound	SSE SSO	Recurrence	Follow-up	Review Jones 2016	Review Cornette 2017	Review Hodgkinson 2018
Novitsky	2012		42	2006-2009	100%	24%	5%	26	*		*
Krpata	2012	TAR versus ACST and e-ACST	55	2006-2011	93%	24%	4%	7	*	*	*
Krpata	2013	ECF takedown	10	2008-2012	0%	nr	21%	20	*		
Ragiani	2014	Parastomal hernia	46	2006-2013	0%	59%	11%	13	*		
Pauli ^a	2015	History of ACST	29	2011-2013	62%	45%	3%	11	*	*	*
Petro	2015	History of open abdomen; after ACST(4); with ECF(7),PH(5),LH(1)	34	2010-2013	38%	35%	15%	18	*	*	*
Petro	2015	LH after kidney transplant	11	2007-2013	100%	36%	9%	12	*	*	
Posielski	2016	Quilted meshes in giant hernias	32	nr	100%	25%	6%	9			*
Fayazade ^b	2016	Biological meshes in contaminated fields	77	2007-2014	8%	43%	13%	12	*	*	*
Novitsky	2016		426	2006-2014	66%	19%	4%	32	*	*	

TAR transversus abdominis release, ACST anterior component separation technique, e-ACST endoscopic-anterior component separation technique, OA open abdomen, ECF enterocutaneous fistulae, PH parastomal hernia, LH lumbar hernia

^aCombined patients with the Penn state Hershey Medical Center, Hershey, USA

^bCombined patients with the Anne Arundel Medical Center, Annapolis, USA

Comparison with previous reviews

The first review on TAR, published by Jones from the Penn State Hershey Medical Center (PSHMC), Hershey, USA in 2016, concluded a SSO rate of 24-59% and suggested, due to an inadequate follow-up, a recurrence of 5% in 2 years (18). This conclusion was drawn from 261 patients who underwent repair for a rather diffuse spectrum of indications. Clean wounds were present in 68% of these patients. Seven studies originated from the CCHC comprising 227 patients (87%) and one preliminary study with 34 patients (13%) from their own center, later published by Winder et al. (12, 22, 30, 40, 49, 51, 53, 54).

The second systematic review by Cornette in 2017 compared four different component separation techniques: open anterior, endoscopic anterior, perforator preserving open anterior and TAR (43). In their TAR analysis 759 patients were included with clean wounds in 61%, resulting in a recurrence of 5.3% and SSO of 23.7%, which is also comparable with Jones' review. Cornette concluded that TAR had the lowest recurrence rate, albeit the highest rate of SSO, of all four techniques. Cornette included six studies from the CCHC comprising 632 patients, one study from the PSHMC (37 patients) and one older study from Spokane, USA (4, 11, 22, 23, 30, 40, 50, 51). The latter study with 90 patients did not perform a TAR but a variation of PCS by creating an intermuscular plane between the transversus and internal oblique muscle, without dividing and releasing the transversus muscle (11). One of the six CCHC studies was the impressive cohort study published by Novitsky in August 2016, that accrued 426 patients between 2006 and 2014. However, these patients have overlap with previous studies from the CCHC that accrued patients during the same time span (4, 12, 22, 23, 30, 50, 51). In summary, the conclusions of their TAR analysis were based on 83% (632/759) CCHC patients.

This duplication-bias issue was addressed by Hodgkinson in their meta-analysis from March 2018 comparing open CST with PCS/TAR for large midline hernias (44). After contacting the corresponding author of the CCHC, Hodgkinson et al. concluded that, although there was an overlap between some CCHC studies, this was not significant and three of the overlapping CCHC studies were included in their analysis (23, 51, 52). Moreover, the authors did not include or refer to Novitsky's

large 2016 study, probably because the rate of midline hernias was not mentioned, being an inclusion criterion in their meta-analysis. However, in the Methods section of Novitsky publication is stated that 'a midline laparotomy was made', suggesting at least a significant portion of midline hernias (4). Nevertheless, Hodgkinson concluded in 281 TAR patients (with clean wounds in 60%), a comparable 5.7% recurrence and a total (superficial and deep) wound complication rate of 20.4%. This was based on six CCHC studies comprising 269 (96%) patients and on one study from the UK with 12 patients (4%) (12, 23, 30, 42, 50-52).

To overcome the duplication-bias discussion in this review, it was decided to consider the Novitsky's study with 426 patients (66% clean wounds) to be comprehensive for the nine previously published CCHC studies, with a total of 336 patients (52% clean wounds) (Table 4). Rigorous exclusion of these nine CCHC studies, that also incorporated many contaminated cases like enterocutaneous fistula or parastomal hernias, dropped the SSO to 15% in this review. Although an overall 5-11% decrease in SSO is substantial, the gain is not as much as one may expect by the 14% increase in rate of patients with clean wounds. Other patient and hernia characteristics, as well as the TAR technique itself, may be responsible for maintaining this rather high rate of SSO after TAR.

Exclusion of the nine CCHC studies did not change the 2-year recurrence rate: this remains stable at 4% and is a good result in comparison to anterior component separation.

Another effect of excluding the older CCHC studies is that the rate of CCHC patients in our review dropped to 66%, which is the lowest compared to the other reviews (87%, 83% and 96%, respectively) (18, 43, 44). This diminishes the influence of a single expert center on the final results and strengthens the conclusions of this review in 'real-life'.

The latest literature study on component separation techniques by Scheuerlein from March 2018, described six CCHC studies and the systematic review of Cornette (55). They also concluded that posterior CST is better than anterior CST with regard to the recurrence rate, rather than to SSO, which is in concordance with the findings of our review.

Robot TAR

It seems that the sequel of the TAR has skipped the pure laparoscopic phase and instantly leaped into the robot-assisted laparoscopic era. The robot-driven instruments permit more degrees of freedom intraperitoneally than the manually operated instruments. This makes the intraperitoneal closing of the posterior fascia feasible, which is a very demanding procedure in a pure laparoscopic setting, although not impossible (15).

The only robot-assisted laparoscopic TAR (R-TAR) study that could be included in this review, suggested that R-TAR is promising, because no differences in outcomes were observed between open and R-TAR (16). A reduction in systemic complications and length of stay was demonstrated at the expense of an increased operation time and higher costs. However, R-TAR was performed in patients with smaller hernia dimensions (mean 235 cm²).

That R-TAR is also applicable in large hernias (width > 30 cm) with significant loss of domain was demonstrated by Halka in 57 patients, not included in this review due to an inadequate follow-up of 1 month (33). In case of a large hernia defects that exceeds the limits of robotic suturing (> 13 cm), or voluminous hernia sacs with or without a thinned skin or skin ulcers, or in patients with large pieces of a prior mesh, a hybrid robotic approach was performed (in another 25 patients). The difference with the R-TAR procedure is that during the robotic procedure, the posterior fasciae are closed. Then the hernia sac is opened via a midline incision followed by skin and soft tissue debridement to remove any potential space for seroma formation, a mesh is placed and the anterior fascia is re-approximated. In over 90% clean wound patients, Halka demonstrated an impressive low SSO of 4-7%. This was confirmed by the study of Martin-del-Campo, affiliated to the CCHC, in 76 open TAR patients. He demonstrated 12% SSE, while it was reduced to 3% with the R-TAR (14). This study also lacked adequate follow-up.

The results of these Robotic TAR procedures for larger ventral hernias are promising, not only because it seems feasible, but also because of the low SSO rate.

Sandwich

Another popular technique to repair large incisional hernias in the UK and some Scandinavian countries is the “Peritoneal Flap” hernioplasty (29, 56, 57). This low tension repair, increases the abdominal domain by placing a bridging mesh between the medialized rectus muscles and covering at the same time the mesh completely by mobilized peritoneal flaps (as a sandwich). A recurrence rate of less than 13% after a follow-up of 1-7 years is reported. However a high rate of wound complications (up to 68%) was reported as well (57). This technique is interesting but the bridging component may ultimately result in a high recurrence rate or symptomatic bulging, because the linea alba is not restored (20, 54).

Complex abdominal wall repair is a tailored surgery. The choice of technique is based on both patient and hernia characteristics, as well as local experience and availability of equipment and meshes. In daily practice, the open CST (Ramirez) is the most performed type of myofascial release (54). It has a well-established reputation and used to be an elegant solution for large hernia repair. Although endoscopic assisted CST is better in reducing SSO, the learning curve has prevented a widespread use of this elegant technique. This review underscores the benefits of the TAR. Intra-operatively, the TAR seems to allow for more medial mobilization of the rectus muscles than the conventional anterior release, making it especially useful for very large midline ventral hernias. The TAR is also reported to be useful for non-midline defects, hernias near bony structures, parastomal hernias or in contaminated cases.

Conclusion

Within the range of myofascial techniques for complex ventral hernias, the TAR is a good alternative for any of the anterior component separation techniques in terms of recurrence (5%) and, to some lesser extent, SSO (15%). Ideally, the definitive indications for a (e)CST, TAR, Robot-TAR should be determined after a randomized multicenter controlled trial. Until then, the published benefits of the (robot) TAR will definitively make the TAR one of the procedures of choice for a large proportion of complex ventral hernia patients.

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PART III

Optimizing the *postoperative* care pathway:
evaluation



Chapter 10

Assessing textbook outcome after implementation of transversus abdominis release in a regional hospital

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Abstract

Background The posterior component separation technique with transversus abdominis release (TAR) was introduced in 2012 as an alternative to the classic anterior component separation technique (Ramirez). This study describes outcome and learning curve of TAR, five years after implementation of this new technique in a regional hospital in The Netherlands.

Methods A standardized work up protocol, based on the Plan-Do-Check-Act cycle, was used to implement the TAR. The TAR technique as described by Novitsky was performed. After each 20 procedures, outcome parameters were evaluated and new quality measurements implemented. Primary outcome measure was Textbook Outcome, the rate of patients with an uneventful clinical postoperative course after TAR. Textbook Outcome is defined by a maximum of seven days hospitalization without any complication (wound or systemic), reoperation or readmittance, within the first 90 postoperative days, and without a recurrence during follow-up. The number of patients with a Textbook Outcome compared to the total number of consecutively performed TARs is depicted as the institutional learning curve. Secondary outcome measures were the details and incidences of the surgical site and systemic complications within 90 days, as well as long-term recurrences.

Results From 2016, sixty-nine consecutive patients underwent a TAR. Textbook Outcome was 35% and the institutional learning curve did not flatten after 69 procedures. Systemic complications occurred in 48%, wound complications in 41%, and recurrences in 4%. Separate analyses of three successive cohorts of each 20 TARs demonstrated that both Textbook Outcome (10%, 30% and 55%, respectively) and the rate of surgical site events (45%, 15%, and 10%) significantly ($p < 0.05$) improved with more experience.

Conclusion Implementation of the open transversus abdominis release demonstrated that outcome was positively correlated to an increasing number of TARs performed. TAR has a long learning curve, only partially determined by the technical aspects of the operation. Implementation of the TAR requires a solid plan. Building, and maintaining, an adequate setting for patients with complex ventral hernias is the real challenge and driving force to improve outcome.

Introduction

Major surgeries in an aging population maintain the surgical epidemic of incisional hernias (1, 2). Repairing these hernias remains fraught with complications, especially if a patient need a component separation technique (CST) for primary fascial closure (3-6). Such complex abdominal wall repair procedures can be challenging, require well-organized perioperative multidisciplinary guidance and a team which should be able to adopt new techniques (7).

Latest alteration in component separation techniques is the transversus abdominis release (TAR) (8-15). This posterior CST was introduced in 2012 as an alternative to the classic anterior component separation technique (Ramirez) (8, 16). The TAR is also a myofascial release intended to decrease midline tension, but has an improved overlap of large defects and hernias near bony structures. The safe plane in which the mesh is positioned and lack of extended subcutaneous dissection are also assets (17, 18). Because TAR seemed to have less surgical site occurrences and recurrences than Ramirez, TAR became popular in many hernia centers over the world (10, 11, 19, 20).

The operation itself is described as technically difficult, requiring an intimate understanding of pertinent anatomy to avoid TAR pitfalls (12, 14, 21). Division of incorrect layers lead to neurovascular lesions, semilunar hernias, interparietal herniation, and recurrences. Multiple authors mentioned a learning curve of the TAR and advised implementation only after adequate training and proctoring of the first 5-15 cases, depending on the experience in open Rives-Stoppa repair (9-15).

In 2016, a team of surgeons from a regional hospital in The Netherlands commenced with the TAR after attending a TAR workshop with hands-on cadaveric dissections. This study aims to describe the outcome and learning curve of TAR, after implementation of this new technique in a dedicated hernia center.

Material and methods

Setting

The Elkerliek Hospital in Helmond, The Netherlands, is a non-teaching regional hospital with three experienced hernia surgeons performing 75 complex ventral hernia repairs per year. Before the TAR was implemented, endoscopic anterior CST and open Ramirez were standard techniques for complex hernia patients.

Study design

The Plan-Do-Check-Act (PDCA) cycle, or Demming cycle, was used to implement TAR and repeatedly evaluate outcome (22). PDCA is a four-step problem-solving process involving plan (establishing the processes needed to deliver results according to the desired outcome), do (implement the new process on a small scale), check (measure the new process and observe any differences between that and the desired outcome), and act (analyze the difference between observed and expected to determine the cause). The iterative nature of repeated PDCA cycles is critical prerequisite of value-based healthcare (23, 24). In this study, plan comprised a standardized work up protocol for each complex hernia patient and continuous registration of at least 200 characteristics per patient in a database. Do was implementation of the TAR. Outcome was checked after each episode of 20 procedures. Specific measurements to improve outcome were defined and subsequently implemented (act). The effect of these measurements was checked again after the next 20 procedures, new measurements were developed and the cycle repeated itself. All patients consented with the TAR and postoperative data analysis. The Institutional Review Board approved this review.

Standardized work-up protocol

All eligible patients were informed, both orally and digitally by the patient journey app. After consent, each patient with a symptomatic complex ventral hernia was presented at a monthly multidisciplinary team (MDT) meeting, involving experienced hernia surgeons, anesthetist, ICU physician, pulmonologist, physical therapist and case manager. Patients were discussed according a four-step protocol: (I)

hernia was graded according the EHS and the Hernia Patient Wound staging system (25-27). According the Dutch guideline for incisional hernias, a complex ventral hernia is any hernia HPW stage II-IV (28, 29). Hernias < 10 cm width were also included if a primary fascial closure could not be achieved without an additional component separation technique, like hernias located against a bony structure or hernias with a significant loss of domain (LOD) > 20% (25, 26, 28, 30). LOD was assessed by the Sabbagh method (30, 31). Parastomal hernias were classified by the EHS parastomal hernia classification (32); (II) surgical options were discussed. Patients with a lateral hernia or midline hernia that passed the semilunar line were initially selected; (III) potential modifiable factors for prehabilitation were identified and feasible goals that had to be achieved for the patient were assessed. Active counseling was provided to ensure a BMI < 30 kg/m², smoking cessation more than 4 weeks prior to surgery, glycemic control for diabetics and an optimal mental, physical, cardiopulmonary and nutritional status (5, 33). Preoperative Botulinum was not applied (34); (IV) the decision was made to plan an operation, postpone surgery until the prehabilitation goals were met or waive any operation.

Standardized TAR technique

Each patient was operated by two surgeons. Prophylactic antibiotics were administered. Midline laparotomy with excision of the scar was followed by resection of the hernia sac and complete reduction of bioburden, including formerly implanted meshes. A complete enterolysis between bowels and parietal peritoneum was performed. The rectus sheath was then incised approximately 0.5-1 cm from its medial border exposing the rectus muscle and posterior rectus sheet. This retromuscular plane was extended to the retroxyphoidal space superior and the space of Retzius inferior. Laterally, the plane was extended to the linea semilunaris until the neurovascular bundles were visualized medially. To preserve these perforators, 0.5-1 cm medial from the neurovascular bundles, the posterior lamel of the musculus obliquus internus (MOI) was incised exposing the transverse muscle (TM) in the upper abdomen and the inserting fascia of the TM in the lower abdomen. The transversus abdominis fascia and muscle were then subsequently transected exposing the underlying peritoneum/transversalis fascia (PTF). The next step was dissecting

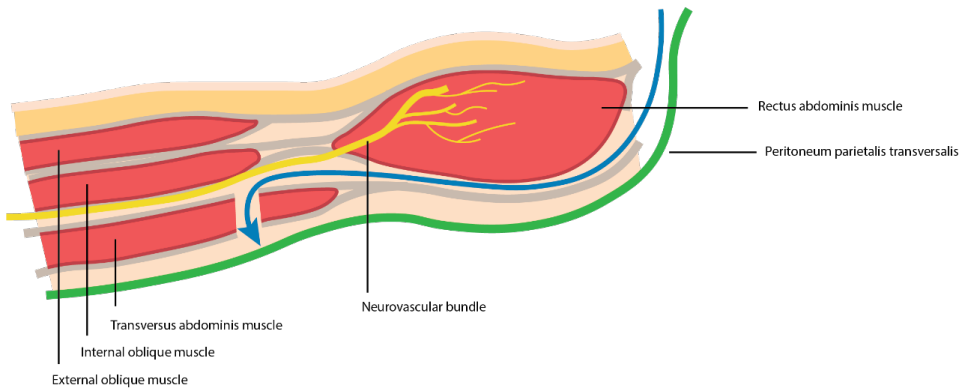
the TM from the PTF by sharp and blunt dissection, creating a large plane bordered by the lateral edges of the psoas muscle, retroxyphoidal space and Retzius' space (Figure 1A). Defects in the PTF that could not be closed, were managed with omentum or an inlay dual layer mesh (Ventralite ST™, BD). After complete posterior CST, the medialized posterior rectus sheaths were then re-approximated with a running slowly resorbable 2/0 monofilament (small bites and steps). A large mesh was placed in retromuscular position between the fasciae and selectively secured anteriorly with two slowly absorbing 2/0 monofilament stitches. The preferred mesh was a permanent large pore monofilament polypropylene mesh (30 x 30 cm Soft Mesh™, BD) in CDC wound class 1-2 or a long-term bioresorbable monofilament Poly-4-hydroxybutyrate mesh (40 x 20 cm or 30 x 25 cm Phasix™, BD) in case of contaminated surgical fields (CDC wound class 3-4), at the surgeons discretion (35). Closed-suction drains were placed laterally on the mesh (8, 21, 36). The anterior rectus sheaths were reapproximated with a running slowly resorbable 2/0 monofilament. Subcutaneous tissue was closed with an absorbable polyfilament running suture (Figure 1B). A subcutaneous drain was placed at the surgeons discretion. Skin was closed intracutaneously with rapid absorbable monofilament and a sterile adhesive plaster and abdominal binder were applied. After 6 weeks of wearing a binder day and night in combination with reduced activities, a protocolized rehabilitation program under guidance of a physical therapist was commenced.

Outcome measures

Primary outcome measure is Textbook Outcome (TO): the rate of patients with an uneventful clinical postoperative course after TAR. Textbook Outcome is defined in this study by a maximum of 7 days hospitalization without any complication (wound or systemic), reoperation or readmittance, within the first 90 postoperative days, and without a recurrence during follow-up. While comparison of complication rates between hernia studies is biased by registration and interpretation issues, Textbook Outcome enables a comprehensive summary of simple and unambiguous clinical care parameters. Textbook Outcome is used in other surgical specialties for both internal quality improvement and comparison with other studies (37, 38). The number of patients with a Textbook Outcome compared to the total

number of consecutively performed TARs is depicted as the institutional learning curve. The institutional learning curve of applying TAR for complex abdominal wall hernias is not equivalent to the surgical TAR learning curve, defined by a minimum number of operations needed for a surgeon to master TAR.

A



B

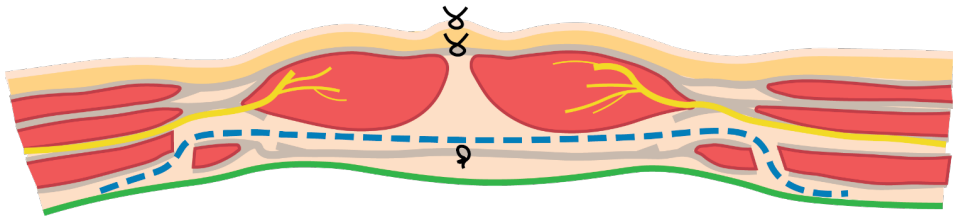


Figure 1. (A) Schematic overview of posterior component separation technique with transversus abdominis release. (B) Final situation after TAR with retromuscular, preperitoneal mesh in place.

Secondary outcome measures were the details and incidences of the surgical site and systemic complications within 90 days, as well as long-term recurrence and bulging rates. Wound complications were grouped under surgical site occurrences (SSO) and surgical site events (SSE) (39). SSE are all SSIs and clinically relevant SSO. SSOPI are SSO requiring a Procedural Intervention, like percutaneous drainage, wound opening, debridement, negative pressure wound therapy (NPWT) or mesh removal. Seromas and hematomas were subcategorized according the Morales-Conde classification into incidental seromas/hematomas (present max six months)

or complicated seromas/hematomas (> 6 months with discomfort or complications that needed intervention) (40). Complications were graded by the Clavien-Dindo classification system (I-V): severe complications are type IIIb, IVa, IVb and V (41). A recurrence was defined as any new protrusion of the contents of the abdominal cavity or preperitoneal fat through a defect in the abdominal wall at the site of a previous repair of an abdominal wall hernia (42). Postoperative bulging is a bulge in the area of previously repaired hernia. In case of a suspected recurrence, clinical evaluation and CT were always performed.

Statistics

Continuous variables are presented as mean (SD) and categorical variables by number (proportion). To evaluate the differences between the two independent groups, for continuous variables the Mann-Whitney U Test was used and for categorical variables the Fisher's exact test. A $p < 0.05$ (two-tailed) was considered statistically significant. Statistical analysis was performed using Microsoft Excel and IBM SPSS Statistics 27.

Results

During five and a half years (1 January 2016 to 1 July 2021), 491 consecutive complex hernia patients were discussed at the MDT meetings, of whom 289 patients (59%) were ultimately operated. A total of 132 (46%) patients underwent an elective CST: 69 TAR, 57 endoscopic anterior CST (ECST) and 6 Ramirez. Over the years, the rate of anterior CST decreased gradually to zero and TARs increased to 100%. The baseline characteristics and HPW stages of the 69 TAR patients were distributed per group of 20 consecutive patients and demonstrated no relevant differences between these groups (Table 1). Comorbidity according the HPW classification (P1) was present in 29% of all patients. Preoperative contamination of the surgical field (W1) was present in 33% of the patients, due to a stoma ($n = 21$), an ulcerated skin ($n = 1$) or open mesh ($n = 1$). Two-third (61%) of the patients were first referred for prehabilitation. Ten (14%) patients had stage I (HPW 'non-complex', < 10 cm) hernias, but still needed TAR because of location against the xiphoid

or iliac crest, and/or a LOD > 20%. Over the years, patients tended to be older ($p = 0.07$), but had less diabetes ($p = 0.06$) and less stoma-related procedures ($p = 0.14$).

Table 1. Demographics of patients that underwent a TAR

Episode	I	II	III	IV	Total	<i>p</i> -value
<i>n</i>	20	20	20	9	69	
Hernia factors						
Previous incisional hernia repair, <i>n</i> (%)	5(25)	6(30)	7(35)	2(22)	20(29)	0.788
Previous wound infection, <i>n</i> (%)	13(65)	6(30)	10(50)	3(33)	32(46)	0.932
Hernia location						
Midline (EHS M1-4,L0), <i>n</i> (%)	10(50)	13(65)	15(75)	5(56)	43(62)	0.823
Lateral (EHS M0,L1-4)	1(5)	2(10)	0(0)	3(33)	6(9)	
Mixed (EHS M1-4,L1-4), <i>n</i> (%)	9(45)	5(25)	5(25)	1(11)	20(29)	
Stoma present (including Bricker), <i>n</i> (%)						
Presence of a concomitant parastomal hernia	4(20)	2(10)	5(25)	3(33)	14(20)	0.391
Parastomal hernia with concomitant midline hernia (EHS type III/IV)	4(20)	1(5)	4(20)	1(11)	10(14)	0.472
Planned concurrent abd. procedure	7(35)	4(20)	2(10)	3(33)	16(23)	0.245
Hernia width on CT (cm), mean (SD)						
H1: 0-9.9 cm, <i>n</i> (%)	5(25)	6(30)	2(10)	3(33)	16(23)	0.238
H2: 10-19.9 cm, <i>n</i> (%)	13(65)	11(55)	17(85)	6(67)	47(68)	
H3: > 20.0 cm, <i>n</i> (%)	2(10)	3(15)	1(5)	0(0)	6(9)	
Area of hernia ^a (cm ²), mean (SD)	153.0(112.0)	140.3(120.8)	157(105.0)	98.0(85.8)	143.3(109.0)	0.267
Loss of domain > 20%, <i>n</i> (%)	7(35)	3(15)	4(20)	2(22)	16(23)	0.503
Loss of substance, <i>n</i> (%)	9(45)	7(35)	8(40)	3(33)	27(39)	0.122
Patient factors						
Age (years), mean (SD)	62.6(11.6)	58.5(8.5)	62.5(11.0)	69.6(6.3)	62.3(10.5)	0.073
Males, <i>n</i> (%)	11(55)	11(55)	11(55)	4(44)	37(54)	0.819
Oncological history, <i>n</i> (%)	5(25)	5(25)	12(60)	3(33)	25(36)	0.090
ASA class III, <i>n</i> (%)	6(30)	4(20)	1(5)	2(22)	13(19)	0.364
COPD GOLD I-IV, <i>n</i> (%)	4(20)	4(20)	7(35)	1(11)	16(23)	0.851
Cardiovascular disease	7(35)	5(25)	7(35)	2(22)	21(30)	0.811
Use of oral anticoagulants, <i>n</i> (%)	9(45)	7(35)	6(30)	4(44)	26(38)	0.921
BMI (kg/m²), median (SD)						
Obesity (BMI > 30 kg/m ²), <i>n</i> (%)	9(45)	3(15)	4(20)	2(22)	18(26)	0.198
P1: Morbid obesity (BMI > 35 kg/m ²)	1(5)	0(0)	0(0)	2(22)	3(4)	
P1: Current smoker past 4 weeks, <i>n</i> (%)						
Former smoker	15(75)	13(65)	14(70)	4(44)	46(67)	0.432

Table 1. (continued)

P1: Diabetes, <i>n</i> (%)	7(35)	2(10)	0(0)	4(44)	13(19)	0.060
P1: Use of Immunosuppression, <i>n</i> (%)	1(0)	0(0)	3(15)	0(0)	4(6)	
At least one P1 factor present, <i>n</i> (%)	8(40)	2(10)	5(25)	5(56)	20(29)	0.189
Wound factors						
W1: CDC wound class 2-4, <i>n</i> (%)	7(35)	5(25)	7(35)	4(44)	23(33)	0.367
Preoperative HPW stage				(0)		
I H1P0W0	3(15)	5(25)	2(10)	0(0)	10(14)	0.415a
II H1P1W0;H2P0-1W0	10(50)	9(45)	11(55)	4(44)	34(49)	
III H1-2P0-1W1;H3P0W0	5(25)	4(20)	6(30)	5(56)	20(29)	
IV H3P1W0;H3P0-1W1	2(10)	2(10)	0(0)	1(11)	5(7)	
Patients referred for prehabilitation	11(55)	9(45)	15(75)	7(78)	42(61)	0.154

TAR (Posterior component separation technique with) transversus abdominis release, *EHS* European hernia society, *ASA* American society of anesthesiologists, *COPD* chronic obstructive pulmonary disease, *BMI* body mass index, *CDC* center of disease control, *HPW* hernia patient wound classification (H1, H2 or H3; P0 or P1; W0 or W1)

^aStage I and II versus stage III and IV

Table 2 demonstrates the monthly caseload, partially influenced by the Covid pandemic in latter episodes. The rate of contaminated surgical fields increased during surgery from 33% to overall 42% of the patients, due to 6 (W0) patients that had unintended bowel lesions (4) or an unexpected infected mesh that was explanted (2). Other intra-operative characteristics demonstrated no significant differences, except for the application of topical microporous polysaccharide hemospheres (MPH) (Arista™, Absorbable Surgical Hemostat, BD) to prevent hematomas and seromas, which commenced after the 31st patient. Mean operation time reduced after 60 TARs by half an hour.

Table 2. Intra-operative characteristics of patients that underwent a TAR

Episode	I	II	III	IV	Total	<i>p</i> -value
<i>n</i>	20	20	20	9	69	
Time span (months)	31	11	13	11	66	
Caseload per month	0.6	1.8	1.5	0.8	1.0	
Contaminated surgical field, <i>n</i> (%)	8 (40)	7 (35)	10 (50)	4 (44)	29 (42)	0.805
Planned concurrent abdominal procedure (stoma reversal or replacement), <i>n</i> (%)	7 (88)	4 (57)	2 (20)	3 (75)	16 (55)	
Unintended contamination of the surgical field (complete bowel lesions), <i>n</i> (%)	3 (15)	3 (43)	1 (10)	1 (25)	8 (28)	0.728
Extirpation of an infected mesh, <i>n</i> (%)		1 (14)	3 (30)	1 (25)	5 (17)	
Blood loss (ml), mean (SD)	103 (151)	240 (483)	184 (425)	184 (335)	176 (372)	0.718
Bilateral TAR performed, <i>n</i> (%)	17 (85)	15 (75)	14 (70)	5 (56)	51 (74)	0.389
Synthetic mesh, <i>n</i> (%)	16 (80)	17 (85)	18 (90)	8 (89)	59 (86)	0.825
Complete anterior fascial closure, <i>n</i> (%)	19 (95)	19 (95)	19 (95)	9 (100)	66 (96)	0.911
Use of topical MPH (powder)	0 (0)	10 (50)	16 (80)	6 (67)	32 (46)	0.005^a
Drain placement, <i>n</i> (%)	10 (50)	8 (40)	4 (20)	2 (22)	24 (35)	0.184
Operation time (min), mean (SD)	186 (84)	174 (56)	180 (42)	160 (52)	178 (61)	0.751

TAR (posterior component separation technique with) transversus abdominis release, MPH microporous polysaccharide hemospheres

^aPeriod I and II versus period III and IV

bold + *p*-value < 0.05

The rate of patients with one, or more, systemic complication (48%) was higher than patients with any wound complication (41%). Pneumonia (28%), ileus (14%) and anemia (14%) were most frequent (Table 3). No mortality was noted. SSO and SSI demonstrated a tendency to decrease (respectively, $p = 0.07$ and 0.08) and SSE significantly decreased in the different episodes ($p < 0.05$). Two thirds of all seromas and half of all hematomas were complicated. Eight patients developed a SSOPI (12%) of whom four patients (7%) were reoperated. During the first episode, two patients needed wound debridement (one reoperation, one outpatient), one patient underwent a mesh explant (reoperation) and one patient local excision of exposed synthetic mesh (outpatient, after 82 days). During the second episode one patient needed wound debridement (outpatient) secondary to an unnoticed bowel injury (that spontaneously healed) and one patient underwent mesh explant

(reoperation) secondary to an abdominal compartment syndrome. In this patient the posterior fascia could be closed again and a biosynthetic mesh placed on top. The anterior rectus fascia was left open and negative pressure wound therapy was applied. In both the third, and in the fourth episode, one patient each needed wound debridement (one reoperation, one outpatient). Application of MPH did not reduce the rate of seromas ($p = 0.53$) or hematomas ($p = 0.14$) significantly. In none of the patients, intraparietal herniations or semilunar hernias were noted. Length of hospital stay decreased from twelve to seven days ($p = 0.16$). Readmissions occurred due to wound problems in three patients or constipated stomas in two. Recurrence rate was 4%: all three cases were related to contaminated surgical fields and use of biosynthetic meshes. No iatrogenic semilunar hernias or intraparietal herniations were encountered. Bulging occurred in five patients (7%) and all were laterally located. Three of the six lateral hernias (one with a Bricker) bulged, one mixed hernia bulged laterally after a previous ipsilateral Ramirez and in one patient mixed hernia bulged due to a pre-existent absent unilateral rectus muscle. One year mortality rate was 1% (cerebrovascular attack 11 months after TAR) and two-year mortality rate 4% (another 2 patients died after 19 and 22 months due to oncological causes).

Contamination of the surgical field was positively correlated to the development of SSOPI ($p = 0.01$). Preoperative HPW stage was not significantly correlated with any of the outcome parameters. A significant ($p = 0.01$) increase in patients with a Textbook Outcome was found over time (Table 4). After the second episode (40 TARs), Textbook Outcome increased to 55%. The institutional learning curve of TAR demonstrated a gradient of 0.5 and was still rising after 69 procedures (Figure 2).

Table 3. Short (90-day) and long term complications of patients that underwent a TAR

Episode	I	II	III	IV	Total	<i>p</i> -value
<i>n</i>	20	20	20	9	69	
Wound morbidity						
Patients with any SSO, <i>n</i> (%)	12 (60)	9 (45)	4 (20)	3 (33)	28 (41)	0.072
Seroma type I-IV, <i>n</i> (%)	5 (25)	4 (20)	2 (10)	2 (22)	13 (19)	0.659
Surgical Site Infection (SSI), <i>n</i> (%)	7 (35)	3 (15)	1 (5)	1 (11)	12 (17)	0.079
Hematoma type I-IV, <i>n</i> (%)	5 (25)	2 (10)	2 (10)	1 (11)	10 (14)	0.494
Wound dehiscence, <i>n</i> (%)	6 (30)	1 (5)		1 (11)	8 (12)	
Enterocutaneous fistula, <i>n</i> (%)	1 (5)				1 (1)	
Patients with SSE, <i>n</i> (%)	9 (45)	3 (15)	2 (0)	2 (22)	16 (23)	0.045
Patients with SSOP, <i>n</i> (%)	4 (20)	2 (10)	1 (5)	1 (11)	8 (12)	0.517
Systemic complications, <i>n</i> (%)	13 (65)	10 (50)	6 (30)	4 (44)	33 (48)	0.173
Pneumonia, <i>n</i> (%)	6 (30)	5 (25)	6 (30)	2 (22)	19 (28)	0.957
Paralytic ileus, <i>n</i> (%)	4 (20)	2 (10)	3 (15)	1 (11)	10 (14)	0.825
Anemia requiring blood transfusion, <i>n</i> (%)	5 (25)	3 (15)		2 (22)	10 (14)	0.127
Decompensatio cordis, <i>n</i> (%)	2 (10)	1 (5)			3 (4)	
Abdominal compartment syndrome, <i>n</i> (%)		1 (5)			1 (1)	
Maximal Clavin-Dindo classification						
IIIb	2 (10)	1 (5)			3 (4)	
Iva	2 (10)				2 (3)	
Ivb		1 (5)			1 (1)	
Reoperation < 90 days, <i>n</i> (%)	2 (10)	2 (10)	1 (5)		5 (7)	
Length of hospital stay (days), mean (SD)	11.2 (9.3)	8.5 (6.2)	7.5 (3.5)	7.2 (3.8)	8.9 (6.6)	0.164
Readmission, <i>n</i> (%)	1 (5)		1 (5)	2 (22)	4 (6)	0.169
Follow-up (months), median (SD)	37.0 (12.0)	28.2 (4.8)	23.3 (3.5)	12.3 (3.7)	27.2 (10.7)	
Recurrence, <i>n</i> (%)	2 (10)	1 (5)			3 (4)	0.548
Bulging, <i>n</i> (%)	1 (5)	1 (5)		3 (33)	5 (7)	0.398

SSO surgical site occurrence, SSE surgical site event, SSOP SSO requiring procedural intervention

bold + *p*-value < 0.05

Table 4. Textbook Outcome of patients that underwent a TAR

Episode	I	II	III	IV	Total	p-value
<i>n</i>	20	20	20	9	69	
1. Hospital stay ≤ 1 week, <i>n</i> (%)	7 (35)	11 (55)	13 (65)	6 (67)	37 (54)	
2. No Surgical Site Occurrences < 90 days, <i>n</i> (%)	8 (40)	11 (55)	16 (80)	6 (67)	41 (59)	
3. No systemic complications < 90 days, <i>n</i> (%)	7 (35)	10 (50)	14 (70)	5 (56)	36 (52)	
4. No reoperations < 90 days, <i>n</i> (%)	18 (90)	18 (90)	19 (95)	9 (100)	64 (93)	
5. No readmission < 90 days, <i>n</i> (%)	19 (95)	20 (100)	19 (95)	7 (78)	65 (94)	
6. No recurrence during follow-up, <i>n</i> (%)	18 (90)	19 (95)	20 (100)	9 (100)	66 (96)	
Textbook outcome (all 6 items present), <i>n</i> (%)	2 (10)	6 (30)	11 (55)	5 (56)	24 (35)	0.012

bold + p-value < 0.05

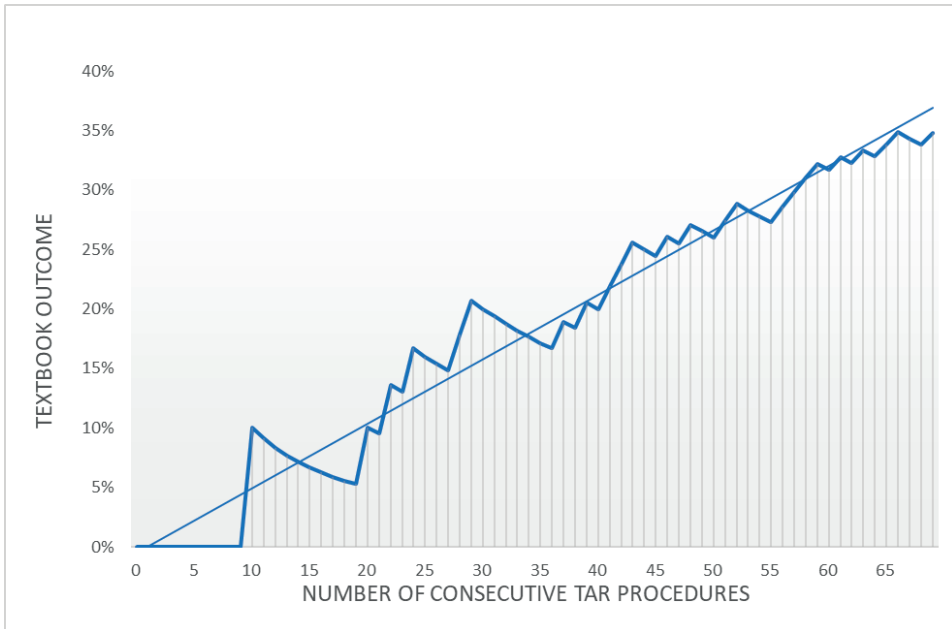


Figure 2. Institutional learning curve of applying TAR for complex abdominal wall hernias

Check and act: Evaluation of outcome (TO, SSO, SSE, SSOPI) and quality measurements implemented

Outcome evaluation after the first episode of 20 patients

Textbook Outcome was 10% and the rate of wound complications twice compared to other TAR studies. TAR implementation developed slowly and rate of contaminated fields was high (40%).

Measurements: 1) decreasing contaminated surgical fields by expanding the indication for TAR to include more midline hernias and hernias near bony structures, 2) decreasing SSO by improving prehabilitation (sticking more tight to the predetermined goals, in particular the requirement to have a BMI < 30), 3) increasing the number of monthly complex hernia repair slots and, 4) decreasing hematomas and seromas by increased attention for meticulous dissection in combination with the application of MPH in flanks, on the mesh and subcutaneously.

Outcome evaluation after the second episode of 20 patients

Textbook Outcome increased to 30%, SSE rate decreased from 45% to 15% ($p = 0.04$), SSO and SSOPI rates also decreased (n.s.). The rate of systemic complications (50%), especially pneumonias, remained high. Although more midline hernias were included, contaminated surgical fields did not decrease (35%). Median BMI decreased, monthly case load tripled, and MPH was applied. ACS developed in one patient. Measurements: 1) Reevaluation of the operative protocol: consultation with anesthesiologists led to measuring of the pulmonary plateau pressures under deep neuromuscular block (confirmed by post-tetanic-count stimulation), just before and immediately after midline closure. An arbitrary increase of ≥ 6 mm Hg may increase the risk of postoperative pulmonary failure or ACS and could alter the operative strategy from midline closure with an augmenting mesh to a bridging procedure. 2) Reduce drain placement while using MPH application.

Outcome evaluation after the third episode of 20 patients

Textbook Outcome increased to 55% and rate and severity of both wound and systemic and complications was further reduced: SSO to 20% ($p = 0.03$), SSE 10% ($p =$

0.02), SSOPI 5% ($p = 0.07$), despite contaminated fields in 50%. Referrals for prehabilitation increased to 75%. Lack of ICU-capacity due the Covid pandemic severely decreased caseload. Drain placement minimized from 50% to 20%. Rate of systemic complications decreased from 65% to 50% to 30% in the third cohort ($p = 0.08$). Severe complications (Dindo > IIIa) did not occur. Measuring the pulmonary plateau pressures did not alter any operative strategy, nor did it reduce the rate of pulmonary infections (30%). Measurement: 1) decrease the rate of patients that need a postoperative ICU bed. The respiratory risk score, developed by Fischer, predicts the risk of postoperative respiratory failure after CAWR (43). This score was implemented to enhance the MDT decision for the need of ICU beds after CAWR. 2) Expand the indication for TAR to giant isolated flank hernias.

Discussion

Five years after implementing the TAR in our hospital, Textbook Outcome occurred in 35% of 69 consecutive TAR patients. More patients (47%) developed systemic complications, than wound complications (41%). Separate analyses of three comparable cohorts of each 20 consecutive TAR patients demonstrated that both Textbook Outcome (10-30-55%) and clinical relevant wound complications (45-15-10%) significantly improved over time. After 69 TARs, the institutional learning curve of performing TARs for complex abdominal wall hernias still did not flatten.

Strength and limitations

The strength of this conclusion is based on the 'real world' design of this study: all consecutive TAR patients were included and perioperative characteristics and complications were recorded meticulously. A strict protocol to select and prehabilitate complex hernia patients was used, a dedicated multidisciplinary team was present and the hospital was equipped with three experienced hernia surgeons. Repeated evaluations (PDCA cycle) generated a deeper insight in the dynamics of different outcome parameters during the course of this study, which helped in defining and implementing new quality measurements.

This study is limited by its retrospective nature. Also, quality of life, perhaps the most important outcome parameter in complex hernia surgery, was yet not evaluated in our patients (15). Preoperative Botulinum, which might have increased the rate of primary fascial closures or reduced the overall rate of CST, was still not standardized within our protocol (34, 44). This study was not powered to demonstrate that HPW stratification would lead to significant differences in outcome per stage, or to detect variables (like MPH) that may improve outcome independently.

Evaluation of outcomes

Our results were compared to similar publications from single institutions, that also reported on their initial TARs (maximum 100 patients) (8, 11, 13, 15, 20, 45-49). Three studies described the rate of patients without any wound complications during hospitalization, which was 61-76% (45-47). After the initial 40 TARs in this study, Textbook Outcome increased to 55% in the next 20 patients. This approaches these rates, although those studies did not take a 90-day inclusion period, systemic complications, re-admissions or recurrences into account. Wound complications reported in comparable studies (SSO 3-39%, SSE 3-14%, SSOPI 3-12%) resemble the results reported here, except for SSE (23%), which was high in the first episode (8, 11, 13, 15, 18, 20, 45-49). While SSE is underreported in most studies, and no specific cause can be designated, this may be related to the TAR learning curve (8, 13, 15, 48, 49). The rate of patients without any systemic complication cannot be deduced in any other study, nor can it be adequately compared with our results. Reported rates of recurrences (0-6%) parallel our results (4%).

Larger cohort studies or data from national registries, varying from 184 to 3109 TAR cases, demonstrated slightly better outcomes than the smaller series: SSO 18-31%, SSE 19%, SSOPI 5-9% and recurrence 3-4% (6, 10, 18, 19, 50, 51), which may be due to some learning curve effect.

The finding that more systemic, than wound, complications were noted in our series is interesting, especially in the light of 42% contaminated surgical fields. Increased attention for prehabilitation may have positively affected the SSO rate. The high rate of former smokers (67%) and COPD (23%), a higher rate of forced primary midline closure after TAR that leads to intraabdominal hypertension, a low

threshold to register complications, or the fact that underreporting of systemic complications is common in TAR publications, may also have played a role in this high rate of systemic complications (11, 20, 45).

Learning curve

The previously reported learning curve to master TAR (around ten) correlates with our SSE rate being the highest in our first episode, more specifically, in the first ten patients (9, 12). However, TAR-specific complications, like damage to the perforating neurovascular bundles, non-closable peritoneal defects, extreme lateral (paracolic) enterolysis leading to unintended bowel injuries with fecal spillage, or primary closure under too much tension leading to an abdominal compartment syndrome, occurred mainly in our first 40 patients. In our experience, mastering the TAR technique may indeed require 5-10 procedures, but understanding for whom the TAR is the best solution, requires more than 10 TARs, and an extensive experience in mastering other component separation techniques as well.

Several authors have emphasized that the real challenge in complex hernia surgery is adequate patient selection (10, 12, 52, 53). Maloney demonstrated in 775 CST patients, that 168 'ideal' patients (BMI < 35, not diabetic, no history of smoking, synthetic mesh used, complete fascia closure and a noncontaminated field) had a SSO rate of 21%, compared to 39% in 607 'non-ideal' patients ($p < 0.05$) (10). This not only demonstrates that CST has a high SSO rate and that the institutional learning curve will never be 100%, but also that outcome may be improved by converting 'non-ideal' patients into 'ideal' patients, possibly by effective prehabilitation (54). Centralization of hernia surgery (52, 53, 55), prehabilitation of modifiable factors like BMI, smoking behavior or physical condition (54, 56-58), building multidisciplinary teams (7), assessing the quality of life by analyzing short- and long term patient-reported outcomes (13, 15, 49), are all quality measurements that improve patient selection and outcome. Thus, the continuous inclination of our straight-lined institutional learning curve, even after 69 TARs, does not only reflect our technical development, but also the improved capabilities in patient preparation and selection.

Future

There seems a commendable trend in hernia literature to present perioperative data more precisely (11, 13, 15). Still, interpreting outcome between hernia studies remains comparing 'apples to oranges' (42, 59). This can be improved by the unambiguous variable 'Textbook Outcome'. Textbook Outcome is easy to understand for patient and health care workers and proved to be a valuable and simple tool to monitor the learning curve. To the best of our knowledge, this study is the first in hernia literature using Textbook Outcome, a simple, powerful and positive parameter. Therefore, future studies describing (new) operative techniques might consider using Textbook Outcome as a function of the learning curve, to put a technique in a broader perspective and make results more comparable. 'Significantly improved quality of life' should also become an important element in a new definition of Textbook Outcome.

Conclusion

The five-year results after implementing the open transversus abdominis release in a regional hospital are presented. Outcome was positively correlated to an increasing number of TARs performed. TAR demonstrated to have a long learning curve, only partially determined by the technical aspects of the operation. Implementation of the TAR in a regional hospital is feasible, but requires a solid plan. Building, and maintaining, the adequate setting for patients with these complex ventral hernias is the real challenge and driving force to improve outcome.

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Chapter 11

General discussion and future perspectives

In most patients, abdominal wall surgery is quality-of-life surgery. In patients with cancer, increasing overall survival is the main indication to perform surgery. The cure should not be worse than the disease. In patients with complex hernias, improving the quality of life is main indication for surgery, the cure may not be worse than the disease. From this perspective, decision-making to perform or not perform surgery, is a delicate matter.

This thesis aims to demonstrate improvements in quality of care for patients with complex abdominal wall hernias, by optimizing the care pathway. The pathway comprises a multidisciplinary team meeting with risk stratification (the delicate decision), a prehabilitation program, tailored surgery and regular evaluations. First, the rationale for a multidisciplinary approach is discussed, and secondly, its effect on the quality of care in complex hernia patients.

A multidisciplinary team approach to improve the quality of care

The history of improving the quality of care in hernia surgery starts with single, enthusiastic surgeons, reporting excellent results from a unique technique (1). However, most of these single surgeon, single center publications did not outgrow the level of ‘expert opinion’.

Around the millennium, hernia repair gained much more attention. In conjunction with an ‘incisional hernia epidemic’, the amount of literature increased exponentially. Evidence Based Medicine (EBM) peaked (2). Cohort studies and randomized controlled trials (RCT) provoked a plethora of meta-analyses (3-10). Guidelines formulated strong recommendations such as: use a mesh, perform minimal invasive surgery, retrorectus mesh position is superior in non-complex hernias, and avoid bridging by closing the midline defect (9-12). However, despite this scientific progress, most clinical recommendations remained weak (8, 13-18). Results of RCT’s, designed to prove a one-size-fits-all hypothesis, were met with skepticism, because they were tested in heterogeneous patient populations, treated by surgeons with

different skills, in different hospitals (19). High level evidence remains scarce in hernia surgery. Also, patients and health providers in the general population are different from selected RCT patients. The gold standard of EBM has limitations in its applicability to real patient care.

While many important clinical questions remain unanswered, because they cannot be addressed in RCT's, clinicians rely on observational research. Since 1992 several (inter)national hernia registries emerged, mainly in Europe, but later also in the USA. Published results of their data-analysis provide deeper insight in outcomes of real-life hernia surgery (3). Although treatment outcomes from both observational studies and RCTs are similar in most cases, registry conclusions are limited by selection and input bias, especially in the voluntary registries (20).

Simultaneously, costs of hernia care exploded (21). Enthusiastic surgeons, applying new techniques in increasingly complex hernias and patients, led to longer operation times, high complications rates with prolonged hospital (ICU) stay and re-operations. The, industry-driven, tsunami of very expensive biological meshes and sophisticated laparoscopic instruments also did not help to limit increasing costs. Hospital management put complex hernia surgery under the magnifying glass. Costs needed to be reduced and quality improved (22, 23).

As a consequence of the unsustainable financial situation in health care, Porter introduced 'Value Based Health Care' (VBHC) in 2009. VBHC is a complex concept that aims to 'increase value for patients, by achieving good outcomes efficiently' (24). Improving value, or quality of care, requires measuring true health outcomes. However, defining true health outcomes is difficult, because patients, physicians, hospital management and insurance companies appreciate outcome very differently: quality of life, complications, or costs.

Ramshaw (2015), an American hernia surgeon, and scientist, described how VBHC could be applied to real care of complex hernia patients (25, 26). While the systems

that are involved with care are extremely complex, Ramshaw borrowed the term ‘systems and data science’ from the discipline of physics. The principles accommodate the constant change and biologic variability in our world. One basic tenet of ‘systems and data science’ is that, if something can be measured in the context of a definable process, it can be improved. Another principle is to use tools for learning and improve whatever is measured in the real world. Tools like clinical quality improvement (CQI) and nonlinear analytics can be used in health care. CQI comprises real-world, real-time data collection and outcomes measurement with the application of process improvement ideas that are applied to a definable patient care process (26).

To actually apply ‘systems and data science’, first a group of people, that provides and receives care in a specific patient care process, must be identified and congregated as a multidisciplinary team (MDT). Secondly, the context of that specific care process (the ‘definable process’) must be described by this MDT, because they know best what defines value, and how to improve it. Thirdly, CQI should be applied. Periodic analyses and feedback loops allow the clinical team to gain insight into factors correlated with outcomes. CQI initiatives should be focused on improving the value of care from a patient’s perspective.

Ramshaw et al. published many different CQI examples (26). After patients reported negative experiences with drains (pain, leakage, etc.), they quit to use drains. Noticing many side-effects of postoperative opioid use (nausea, ileus) led to the implementation of TAP blocks. High costs led to diminished use of biological meshes (they stopped applying them in ‘mild’ contaminated cases). Evaluation of each CQI still demonstrated good outcomes in their patients.

While some variables are less obvious in complex hernia repair, not all steps to improve the care pathway can be objectively measured.

Once, during an MDT meeting, a patient care manager spoke up. She had noticed, that ‘difficult’ patients (patients that were more challenging to deal with before surgery), also had more than often ‘difficult’ postoperative outcomes. She described patients who were angry, had unrealistic expectations, expected a “quick fix”, or had high anxiety levels or controlling personalities. While the MDT lacked expertise in this area, they consulted a psychologist. The MDT settled ultimately on a simple subjective measure, which they named ‘emotional complexity’ and provisionally graded this into ‘high-medium-low’. After nine months, they analyzed their data and found that emotional complexity appeared to be the strongest (modifiable) factor predicting outcome. From neuroscientific research, it is known that traumatic events have neurophysiologic impact on the brain, and a patient's neurocognitive and emotional state is related to surgical outcome. This insight led Ramshaw’s hernia team to presurgical neuro-cognitive evaluation and implementation of cognitive behavioral therapy, as part of a prehabilitation program (19, 25-27).

This example perfectly reflects a full CQI. The attentiveness of the patient care manager, and the alertness of the MDT to seek expertise, subsequently initiate, and perform a simple study, evaluate the results and implement a new quality measure, reflect both the multidisciplinary aspect, the team aspect, as well as applying feedback loops.

The multidisciplinary team approach was adopted by other surgeons. Heniford (2018) reported that interdisciplinary collaboration was the key factor for success of a complex hernia program in centers of excellence (21). Kockerling (2019) stated on behalf of the EHS, that a preoperative multidisciplinary assessment of complex cases is mandatory for accreditation as a hernia center (28). Kollais (2022) published the first systematic review about MDT pathways in complex hernia patients (29). The consensus was that an MDT, incorporated in a care pathway, can provide comprehensive, patient-centered care with improved postoperative outcomes. An MDT should not only require (hernia, gastrointestinal and plastic) surgeons, but

also radiologists, anesthetists and other specialists that deal with these patients (pulmonologists, ICU physician, physiotherapist, etc.). The MDT should aim to achieve pre-optimization and plan the definitive repair (1, 19, 21, 29-31). Furthermore, the review concluded that that improving outcomes requires a prospective data collection in a clinical registry, with regular quality conferences.

From an EBM point of view, an RCT is needed to answer whether postoperative outcomes are different in complex hernia patients, randomized between referred for surgery after a single surgeon visit, versus after an MDT discussion. However, given the aforementioned arguments and the ubiquity of MDT's in oncological care pathways, performing such a trial seems pointless. Just like the study that randomizes between using and not using a parachute to prevent death, when jumping from a flying aircraft (32).

To conclude, in conjunction with the aforementioned scientific paradigm shift, from evidence to value, quality improvement in hernia surgery shifted from 'treating the hernia', to 'treating the patient with a hernia'. The degree of medical and surgical complexity, and the significant resources required to support complex hernia patients, necessitates a multidisciplinary approach of the patient. It may be concluded that every complex hernia patient should have an integral approach by an established multidisciplinary team, which also incorporates quality assurance.

Results of optimizing essential components of the care pathway by a multidisciplinary approach on the quality of care

The multidisciplinary team

Without a blueprint, the MDT described in this thesis in our hospital, commenced in 2012. Soon the members realized that the decision made by the MDT had enormous impact for patients. A 'no go' for surgery, remained a 'no go', an advice, mostly followed by the referring consultant. This perceived responsibility required a swift upgrade of the decision-making process in the MDT, while referrals from all

over the country increased. Cases were streamlined, discussions became more structured, and well-defined protocols, concerning risk stratification, prehabilitation (and rehabilitation), and tailored surgery, were developed and applied. Gradually, discussions became more substantive, while the accent changed from repair to risk for the patient. Decisions were better substantiated with arguments. The nurse practitioner was documenting and guarding the process of decision-making, and adjusting when necessary. Along with the MDT's learning curve, the quality of care, in terms of selecting the right patient for surgery or ICU, improved (Chapter 3 and 6).

The added value of non-surgical specialists to the MDT is indispensable. Pulmonologists explain whether patients can cope with postoperative pulmonary plateau pressure changes (33) (Chapter 4). Anesthetists advise how to manage and improve comorbidities (Chapter 6). Intensive care physicians analyze patient's coping mechanism for SIRS (Chapter 3). Sporting physicians and physiotherapists clarify patient's capability to exercise, control and execute the (p)rehabilitation protocols (Chapter 5).

Although an MDT requires an investment in time, efficient collaboration and communication between the members contribute to the added value of the MDT and improved quality of care for complex hernia patients (Chapter 3, 5, 6 and 10).

Risk stratification

Ideally, risk stratification grades patients into stages, which accurately can predict outcomes (complications, recurrence) after hernia repair. This requires standardization of preoperative (patient and hernia), operative, and postoperative (complications) characteristics (34). Although some variables are still not well-defined, standardization, especially from results, has improved considerably recent years (35-38). Risk stratification makes comparison of patient cohorts possible, essential for own data analysis and meaningful discussions about the results of clinical research (39).

Risk stratification improves quality, by selecting patients fit for surgery. Almost half of the patients that were selected to prehabilitate in our series, succeeded in losing weight and/or smoking cessation. While these ‘down-staged’ patients had the same outcomes as patients without these risk factors, quality was improved (Chapter 6). Risk stratification is lean. Improved stratification diminished the rate of unnecessary postoperative ICU admissions in our patients over the years (Chapter 3). Risk stratification stimulates patients to change behavior, just like the Cedar app does (40). We learned, from explaining patients their HPW stage and what they can do to downstage this, that this acted as an incentive for patients to actually modify their risk factors. Also, patients who know their risks, are well-informed patients, which facilitates shared decision-making (41).

Almost all ventral hernia risk stratification systems are not generalizable, unvalidated, or too difficult to use in daily practice (42-50). Such systems make more “mathematical sense”, than clinical sense (43, 51, 52). Although the VHWG classification is most cited, HPW also incorporates hernia width (53). It is an easy-to-use and comprehensive staging system, that proved useful for stratification and analysis of our own data (Chapter 3, 6 and 10). HPW is limited because it lacks hernia volume (loss of domain), a risk factor related to pulmonary complications, as we demonstrated in our early series (Chapter 4). Neither does it incorporate age or COPD, also relevant risk factors (33, 54-61). Despite these shortcomings, HPW seems to be the best grading system to stage complex abdominal wall hernia patients to date.

Prehabilitation

After an era of focusing at enhanced recovery after surgery (ERAS), accent shifted several years ago to the preoperative setting (62). Preoperative identification of modifiable risk factors (prehabilitation) enables patient optimization and improves postoperative outcome, also in complex hernia patients (63-69).

While preconditioning requires a multi-modal approach, it is imperative to organize a structured setting and have strong partnerships with a (dedicated abdominal

wall) physiotherapist, sporting physician, diabetic nurse practitioner and dietitian. A weight balance and urinary cotinine tests must at least be available at the outpatient department. Financial agreements with the hospital or insurance companies are essential for the success of such a program. Sometimes, a radiologist is needed, in case of preoperative application of Botulinum in the oblique muscles (Chapter 7). Stretching the abdominal wall in large hernias may prevent a component separation techniques or prevent an incomplete midline closure (70).

Overall, 10% of our patients are red (no surgery), 55% orange (prehabilitation), and 35% green (fit for surgery). After offering all orange patients a preconditioning program, nearly half become green: ultimately resulting in 65% of all MDT-discussed patients to be operated. The value of further preoperative preparation was clearly demonstrated in the orange patients (Chapter 6). Over the years, we learned to define better the preparation goals per patient, and hold on tighter to these goals. At first, we postponed surgery until all modifiable risk factors were optimized to a point where no further improvement could be expected (63). However, due to patient expectations and waiting list issues, we set a limit of six months, in which the goals set in the prehabilitation program had to be achieved. Only patients, who undergo bariatric surgery before hernia repair, are allowed to wait longer.

On basis of these results we advocate prehabilitation, under the outlined circumstances, as a quality measure. Some physicians still believe that a patient with a large hernia should not exercise. This dogma has changed, while no adverse events occurred in our patients with very large hernias (median 16 cm), who trained during three months with an intensive exercise program (Chapter 5). This finding is in line with evidence surrounding the feasibility of physical therapy prehabilitation protocols in ventral hernia repair (71, 72).

Tailored surgery

Like rest of the world, open anterior Components Separation Technique (CST), as described by Ramirez, was the most performed technique to repair large hernias. In 2012, the endoscopic CST (eCST) was implemented. In this thesis, our eCST

results were analyzed after four years, and proved positive, in line with published data (5, 73) (Chapter 8). Then, the posterior CST with Transversus Abdominis Release (TAR) emerged as a new technique. After performing a systematic review, to define its place within the spectrum of hernia repairs, the technique was adopted in 2016, and introduced in our center as one of the first in The Netherlands (Chapter 9). We found that TAR is a game changer for many complex hernias, but still has a long institutional learning curve (Chapter 10). Not all large hernias need a TAR, pure midline hernias less than 15 cm width, not closely positioned to a bony structure, and extending to maximal 2 cm medial of the semilunar line, are still good indications for eCST (Chapter 8). Ramirez has become obsolete over the years in our center.

Complex hernia surgery aims to improve the quality of life by restoring the original anatomy of the abdominal wall. Surgical expertise in multiple techniques is of upmost importance for outcome, because there is definitively no one-size-fits-all solution for all complex hernia patients.

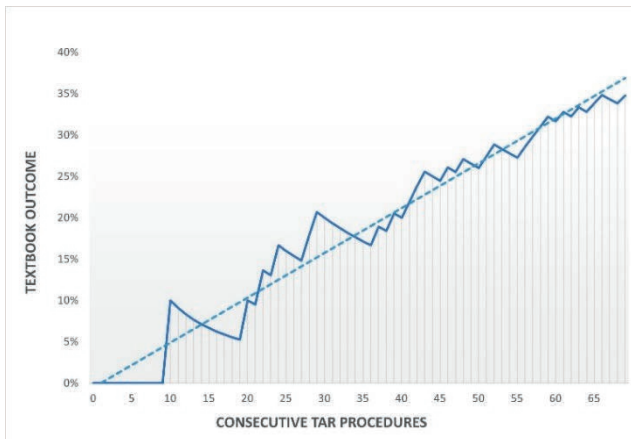
Evaluation

The Plan-Do-Check-Act (PDCA) cycle was used to continuously evaluate new quality measurements in our hospital (Chapter 10). The PDCA is a four-step problem-solving process with an iterative nature (74). PDCA creates feedback loops, just like CQI. PDCA was used to evaluate outcomes of many implemented quality measures, like starting eCST (instead of Ramirez), later TAR, using microporous polysaccharide hemospheres (Arista™) to minimize hematomas and seromas (instead of placing drains), measuring the pulmonary plateau pressures during the operation (to adjust the midline closure technique), evaluating risk stratification tools (to improve ICU planning), and so on (Chapter 3, 6, 8 and 10). Evaluation of own data is essential to improve quality of care, by ‘closing the loop’, which enables to adjust the care pathway (75).

The complex hernia care pathway

After surveying most of the surgeons in all Dutch hospitals (2018), the state of abdominal wall hernia surgery could be summarized as: hernia surgery is performed everywhere, by every surgeon, by every technique. This also applied to complex hernia surgery in most hospitals. Only 3% of the hospitals could be assigned as a dedicated hernia center, according the ACCESS accreditation requirements (76, 77) (Chapter 1).

The care pathway is the foundation under an integral, patient centered approach and should be revised annually. It takes years to tune the pathway, increase the volume of patients, collect data, figure out how to measure outcomes and apply feedback loops. This all occurs with trial and error. Our TAR learning curve visualizes the capabilities of the MDT to select and treat eligible patients (Chapter 10).



Future perspectives

Complex incisional hernia patients have often suffered from traumatic events in the health care system (19). The impact of a hernia on a patients' QoL and psychological wellbeing is still poorly researched. While QoL is the main indication for hernia surgery, this should be studied in more detail (78).

To optimize risk stratification, the HPW classification should be modified, just like TNM is currently in its 8th edition (79). In case of any type of prehabilitation, the prefix ‘y’ could be added before HPW, just like neo-adjuvant therapy in the TNM classification. ‘Hernia’ (H) should be stratified further into subgroups like “a” (no loss of domain, according Tanaka’s method), “b” (with LOD). The Patient (P) factor should also be positive in case of a high age and/or presence of COPD. After these modifications, the HPW classification should be validated, subsequently endorsed by international societies such as the European Hernia Society and the American Hernia Society, for international implementation (63).

Other risk factors should be evaluated for complex hernia patients. Involving a geriatric physician in the MDT may aid in addressing age-related risk factors (33). Likewise, involving a psychiatrist, psychologist, or mental caretaker, may decrease anxiety, medication usage, withdrawal symptoms or delirium in patient with mental diseases (35).

Deeper insight is needed how patients perceive prehabilitation and what the results are of prehabilitation. We noticed that patients sometimes do not want to be operated after prehabilitation, because increased exercises, a lower weight, or nicotine abstinence (no more coughing) led to disappearance of their hernia related symptoms. Also, it is unclear whether prehabilitation leads to more emergency surgeries, as was stated in one study (80). Prehabilitation with Botox® and a progressive pneumoperitoneum may make giant hernia repair possible (81). The natural disease course in red-coded patients is also an unexplored area of research.

Finally, factors influencing the quality and functioning of the multidisciplinary team meetings should be evaluated in PDCA cycles (82).

Conclusion

The era in which quality of complex hernia surgery is improved by a single, enthusiastic surgeon, reporting excellent results from a unique technique, has past.

Treating patients with complex abdominal wall hernias requires a solid, multidisciplinary care pathway. Building, and maintaining, the adequate setting for such a pathway is the real challenge, and driving force, to improve outcome.

This thesis described the results of implementing a complex hernia care pathway. It was demonstrated that quality of care improves, if every complex hernia patient is approached integrally, by an established multidisciplinary team, that knows how to stratify risks, apply prehabilitation, tailor surgery, and constantly evaluate the delivered quality. First treat the patient, then treat the hernia.

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Summary

Chapter one

Patients with complex abdominal wall hernias constitute both a notable and neglected group of patients, with a decreased quality of life and considerable risk of hernia-related complications. The rationale, and first steps, to improve quality of care for these patients is described in the introduction. Details of our complex hernia program, which were formalized in the multidisciplinary care pathway, are highlighted. Publication of our opinion piece ‘Complex hernia patients deserve attention’ (2015) fueled the volume of referred patients in our hospital. This thesis is a recapitulation of the results of multiple clinical quality improvements, performed to optimize the care pathway and quality of care for these patients.

Chapter two

‘Attention’ improves quality of any process. Similar subjective factors, like interdisciplinary cooperation and external endorsement, were necessary to implement objective measurements like a business case, a database, or hernia slots in the care pathway. However, the results of these measurements on delivered quality were unknown. Dutch benchmark data on quality, and information, which components of the care pathway were essential, were lacking.

In 2019, evidence-based requirements for accreditation as a hernia center were published: high volume, experienced surgeons, use of a database and quality control. Governmental data were combined with the results of a representative survey with 426 respondents (27%) of all (1.554) Dutch general surgeons, working in all 75 hospitals. The four requirements were present in 51% (volume), 97% (experience), 39% (database), and 15% (quality control) of all Dutch hospitals. Only, two hospitals (3%) met all four criteria. This study demonstrated that the presence of essential quality components across Dutch hospitals was very dispersed and that quality of (complex) hernia surgery is still largely unknown in The Netherlands.

That same year (2019) two important quality measures were implemented in the Netherlands: publication of the Incisional Hernia Guideline, distinguishing non-complex from complex hernias, and formal assignment of incisional hernia surgery to certified Gastro-Intestinal surgeons. Participation in a national (complex) hernia

registry is still not mandatory in The Netherlands. Formal accreditation of 'Hernia centers of excellence' commenced in 2023.

Optimizing the preoperative care pathway: risk stratification

Chapter three

High risk patients need to be identified during the multidisciplinary team (MDT) meeting. The MDT decides whether a postoperative ICU bed needs to be planned for such a patient. Risk-stratifying tools like the Fischer score (predicting postoperative respiratory failure) and HPW classification (predicting postoperative wound complications) support decision-making. A justified ICU admission was a patient that actually needed an ICU intervention within the first 24 hours postoperatively. Whether the decisions were correct, could only be established postoperatively.

In a cohort of 232 operated complex hernia patients, the MDT decided ICU admission in 38%. Intra-operative events changed the MDT decisions in 15%. Ultimately, 42% of all patients went to the ICU, and 27% of all patients proved justified ICU patients. Backward stepwise multivariate logistic regression analysis demonstrated that the MDT's decision for a planned ICU admission (76%) was more accurate than any of the other risk-stratifying tools (Fischer score 70%, HPW 69%). This study demonstrated the added value of an MDT in risk stratification of patients with complex abdominal wall hernias.

Chapter four

The risk of pulmonary complications, after repairing patients with large hernias and much evisceration, was not well defined. Although some studies have described a correlation between hernia volume and pulmonary changes, none provided strong evidence to identify hernia volume as a risk factor for pulmonary complications. This relation was studied in 35 patients who underwent eCST ($n = 20$) or Ramirez ($n = 15$). The median defect volume was 474 cm³, calculated by Multiple Plane Reconstruction of standard abdominal CT-scans. Ten patients developed respiratory complications. Uni- and multivariate analysis demonstrated that pulmonary complications were strongly associated with 'hernia volume' ($p = 0.045$). This study

demonstrated unambiguously that hernia volume is correlated with postoperative pulmonary complications.

Optimizing the preoperative care pathway: prehabilitation

Chapter five

Patients with complex hernias have an increased risk of postoperative complications. Improving a patient's physical capacity by preoperative exercise therapy, as part of prehabilitation, may lead to a faster recovery after repair. But, obese patients with large hernias are often reluctant to perform sports, fearing complications of the large hernia. A feasibility study was performed in 11 patients with a median BMI of 32 and hernia width of 16.0 cm. The intervention consisted of a three month lasting exercise program consisting of cardiovascular-, strength and respiratory muscle training under direct supervision of a physiotherapist. All patients completed the training program. Physical capacity ($VO_2\max$) and QoL improved, while no adverse events, like strangulation, occurred. All patients had subsequently a successful hernia repair. This study demonstrated that prehabilitation by intensive exercise therapy is feasible in patients with large complex hernias.

Chapter six

Prehabilitation of modifiable risk factors, like smoking, excessive weight, or low physical training status, may prevent complications in patients after complex hernia repair. Outcomes of 133 healthy patients were retrospectively compared to 126 comorbid patients with modifiable risk factors, who were operated after a preconditioning program. The prehabilitated group had a higher median BMI ($p < 0.001$), higher HbA1c ($p = 0.014$), more smokers ($p < 0.001$) and higher HPW classes ($p < 0.003$). All risk factors improved after prehabilitation. There were no significant differences in type of myofascial repairs between the groups. Ultimately, wound and systemic complications, as well as length of stay did not differ between the groups. This study demonstrated that prehabilitation facilitates patients with modifiable risk factors in achieving the same results as patients without those risk factors.

Chapter seven

Primary midline closure of very large hernias may induce systemic and wound complications in complex hernia patients. A more stretchable abdominal wall may prevent these complications. Evidence that Botulinum, injected in the lateral abdominal wall muscles, increases the extensibility (compliance) is scarce. A systematic review comprising 14 studies (377 patients) with a median hernia width of 12 (10-15) cm was performed. The primary prehabilitation effect was a muscle elongation of median 4.0 cm per side, without reported complications of the Botulinum injection. The median primary midline closure rate was 100%, wound-related complications 19%, medical complications 18% and recurrence 0% (14 studies). This study demonstrated that, in patients in whom midline closure is expected to be difficult, Botulinum safely elongates the abdominal wall muscles.

Optimizing the perioperative care pathway: tailored surgery

Chapter eight

The endoscopic Component Separation Technique (eCST) was introduced in 2014 in our hospital as an endoscopic alternative for the open Ramirez technique. Indications, technical details and results of the eCST are described in 36 patients. Patients with a longitudinal midline abdominal wall defect within the lateral borders of the rectus abdominus muscle should be selected. Postoperative complications were limited: seroma (22%), hematoma (8%), wound dehiscence (3%) or recurrence (8%). This study demonstrated that eCST is useful in selected patients with good results.

Chapter nine

A systematic literature review of the posterior component separation technique with transversus abdominis release (TAR) was performed to estimate its position within the scope of abdominal wall hernia repair techniques. Five studies, describing 646 TAR patients with large midline hernias (mean surface 509 cm²) demonstrated wound complications in 15% (20-35% after anterior CST) and two-year hernia recurrences in 4% (13% after anterior CST). This review demonstrates that the

transversus abdominis release is a very good alternative for anterior CST in terms of wound complications and recurrence, especially in very large midline ventral hernias.

Optimizing the postoperative care pathway: evaluation

Chapter ten

Five years results of the transversus abdominis release (TAR) were evaluated, after this technique was introduced in our hospital in 2016. After each 20 procedures, outcome parameters were evaluated and new quality measurements implemented. Primary outcome was Textbook Outcome (an uneventful clinical postoperative course after TAR) and the institutional learning curve (number of Textbook Outcome patients compared to the total number of consecutively performed TARs). Three successive cohorts of each 20 TARs demonstrated that both Textbook Outcome (10%, 30% and 55%) and the rate of surgical site events (45%, 15% and 10%) significantly improved with more experience. Overall Textbook Outcome was 35%, and the institutional learning curve did not flatten after 69 consecutive TAR patients. This study demonstrated that TAR has a long learning curve, only partially determined by the technical aspects of the operation.

Samenvatting

Hoofdstuk 1

Patiënten met complexe littekenbreuken vormen zowel een aanzienlijke, als min of meer verwaarloosde, groep patiënten met een verminderde kwaliteit van leven en een aanzienlijk risico op breuk-gerelateerde complicaties. De grondgedachte en de eerste stappen om de kwaliteit van zorg voor deze groep patiënten te verbeteren, worden beschreven in de inleiding. Details van ons complexe littekenbreukprogramma, vastgelegd in een multidisciplinair zorgpad, worden uitgelicht. De publicatie van ons opiniestuk 'Complexe littekenbreuk verdient aandacht' (2015) heeft het aantal doorverwezen patiënten doen stijgen. Dit proefschrift is een overzicht van de resultaten van meerdere klinische kwaliteitsverbeteringen, uitgevoerd om het zorgpad en de kwaliteit van zorg voor deze patiënten te verbeteren.

Hoofdstuk 2

'Aandacht' verbetert de kwaliteit van elk proces. Vergelijkbare subjectieve elementen, zoals interdisciplinaire samenwerking en externe ondersteuning, waren nodig om objectieve maatregelen, zoals een businesscase, een database of operatieslots, in het zorgtraject te implementeren. De resultaten van deze maatregelen op de kwaliteit van onze zorg waren echter niet bekend. Nederlandse benchmarkgegevens over kwaliteit ontbraken, evenals informatie over welke onderdelen van het zorgpad echt essentieel zijn.

In 2019 zijn evidence-based eisen gepubliceerd, om in aanmerking te komen voor accreditatie als herniacentrum: hoog volume, ervaren chirurgen, gebruik van een database en een systeem van kwaliteitscontrole. Gegevens van de overheid werden gecombineerd met de resultaten van een representatief onderzoek, met 426 respondenten (27%) van alle (1.554) Nederlandse algemeen chirurgen, werkzaam in de 75 ziekenhuizen. De genoemde vier eisen waren aanwezig in 51% (volume), 97% (ervaring), 39% (database) en 15% (kwaliteitscontrole) van alle Nederlandse ziekenhuizen. Slechts twee ziekenhuizen (3%) voldeden aan alle vier de eisen. Uit dit onderzoek bleek dat de aanwezigheid van de essentiële kwaliteitscomponenten zeer verspreid was over de Nederlandse ziekenhuizen en dat de kwaliteit van (complexe) herniachirurgie nog grotendeels onbekend is.

Datzelfde jaar (2019) werden in Nederland twee belangrijke kwaliteitsmaatregelen geïmplementeerd: publicatie van de Richtlijn Littekenbreuken, waarin onderscheid wordt gemaakt tussen niet-complexe en complexe littekenbreuken, en formele toewijzing van littekenbreukoperaties aan gecertificeerde gastro-intestinale chirurgen. Deelname aan een landelijke (complexe) hernieregistratie is in Nederland nog niet verplicht. In 2023 is gestart met de formele accreditatie van 'Hernia centers of excellence'.

Optimalisatie van het preoperatieve zorgpad: risico inschatting

Hoofdstuk 3

Tijdens het multidisciplinaire teamoverleg (MDT) wordt het operatierisico van elke patiënt ingeschat, om te bepalen of er postoperatief een IC-bed gereserveerd moet worden. Risico-voorspellende instrumenten, zoals de Fischer-score (voorspelt postoperatieve respiratoire insufficiëntie) en HPW-classificatie (voorspelt postoperatieve wondcomplicaties) helpen bij deze besluitvorming. Of de beslissingen juist waren, kan pas postoperatief worden vastgesteld. Een terechte IC-opname betreft die patiënt, die binnen de eerste 24 uur postoperatief daadwerkelijk IC ondersteuning nodig had, meer dan alleen observatie.

In een cohort van 232 geopereerde complexe herniapatiënten besloot het MDT bij 38% tot een IC-opname. Door peroperatieve gebeurtenissen veranderden de initiële MDT-beslissing in 15% van de patiënten. Uiteindelijk ging 42% van alle patiënten naar de IC. Van alle geopereerde patiënten bleek 27% een terechte IC-patiënt te zijn. Met achterwaartse stapsgewijze multivariate logistische regressieanalyse bleek de beslissing van het MDT voor een geplande IC-opname nauwkeuriger (76%) dan elk van de andere risico-voorspellende instrumenten (Fischer score 70% en HPW 69%). Dit onderzoek toonde de meerwaarde aan van een MDT in het zorgtraject van patiënten met complexe buikwandbreuken.

Hoofdstuk 4

Het risico op pulmonale complicaties, na een operatie van patiënten met grote hernia's en veel evisceratie, was nimmer goed gedefinieerd. Hoewel sommige studies

een correlatie hebben beschreven tussen herniavolume en veranderingen in longcapaciteit, leverde geen enkele studie sterk bewijs om herniavolume te identificeren als een risicofactor voor pulmonale complicaties. Deze relatie werd bestudeerd bij 35 patiënten die een eCST ($n = 20$) of een Ramirez ($n = 15$) ondergingen. Het mediane volume van het defect was 474 cm^3 , berekend door Multiple Plane Reconstruction toe te passen op standaard abdominale CT-scans. Tien patiënten ontwikkelden pulmonale complicaties. Uni- en multivariate analyse toonden aan dat pulmonale complicaties geassocieerd waren met herniavolume ($p = 0,045$). Deze studie toonde aan dat herniavolume sterk gecorreleerd was met postoperatieve pulmonale complicaties.

Optimalisatie van het preoperatieve zorgpad: prehabilitatie

Hoofdstuk 5

Patiënten met complexe littekenbreuken hebben een verhoogd risico op postoperatieve complicaties. Het verbeteren van de fysieke belastbaarheid van een patiënt door middel van preoperatieve fysiotherapie, als onderdeel van de prehabilitatie, kan leiden tot een sneller postoperatief herstel. Maar zwaarlijvige patiënten met grote hernia's zijn vaak terughoudend om te sporten, uit angst complicaties te ontwikkelen door de grote breuk.

Er is een haalbaarheidsstudie uitgevoerd bij 11 patiënten met een mediane BMI van 32 en een herniabreedte van 16,0 cm. De interventie betrof een drie maanden durend oefenprogramma bestaande uit cardiovasculaire, kracht- en ademhalingspijlertraining, onder directe supervisie van een fysiotherapeut. Alle patiënten konden de drie maanden oefentherapie geheel afmaken. Er deden zich geen complicaties voor, zoals beknelling van de breuk. Fysieke capaciteit (VO_2max) en kwaliteit van leven verbeterden ook. Alle patiënten hadden vervolgens een succesvolle hernia-operatie. Deze studie toonde aan dat prehabilitatie door intensieve oefentherapie goed mogelijk is bij patiënten met grote complexe littekenbreuken.

Hoofdstuk 6

Prehabilitatie van aanpasbare risicofactoren, zoals roken, overgewicht of een lage fysieke trainingsstatus, kan complicaties bij patiënten na een complexe hernia operatie voorkomen. De postoperatieve resultaten van 133 gezonde patiënten werden retrospectief vergeleken met 126 patiënten met aanpasbare risicofactoren, die werden geopereerd na een preconditioneringsprogramma. De geprehabiliteerde groep had een hogere BMI ($p < 0,001$), hogere HbA1c ($p = 0,014$), meer rokers ($p < 0,001$) en hogere HPW-klasse ($p < 0,003$). Alle risicofactoren verbeterden na prehabilitatie. Er waren geen significante verschillen in het aantal myofasciale reparaties. Uiteindelijk verschilden wond- en medische complicaties, evenals de verblijfsduur, niet tussen beide groepen. Deze studie toonde aan dat prehabilitatie ervoor zorgt dat patiënten met relevante aanpasbare risicofactoren dezelfde resultaten bereiken als patiënten zonder die risicofactoren.

Hoofdstuk 7

Het sluiten van de midline van zeer grote hernia's kan complicaties veroorzaken bij complexe herniapatiënten. Een meer uitrekbare buikwand kan deze complicaties voorkomen. Bewijs dat Botulinum, geïnjecteerd in de laterale buikwandspieren, de rekbaarheid (compliantie) verhoogt vóór de eigenlijke operatie, is schaars. Er werd een systematische review uitgevoerd van 14 onderzoeken (377 patiënten) met een mediane herniabreedte van 12 (10-15) cm. Het primaire prehabilitatie-effect was een spierverlenging van gemiddeld 4,0 cm per zijde, zonder complicaties van Botulinum. Het percentage geslaagde midline sluitingen was mediaan 100%, wondcomplicaties 19%, medische complicaties 18% en recidief hernia 0% (14 studies). Deze studie toonde aan dat bij patiënten bij wie het sluiten van de midline naar verwachting moeilijk zal zijn, Botulinum de buikwandspieren veilig verlengt.

Optimalisatie van het peroperatieve zorgpad: chirurgie op maat

Hoofdstuk 8

De endoscopische Component Separatie Techniek (eCST) werd in 2014 in ons ziekenhuis geïntroduceerd als endoscopisch alternatief voor de open Ramirez-techniek. Indicaties, technische details en resultaten van de eCST werden beschreven van 36 patiënten. Patiënten met een longitudinaal defect in de midline van de buikwand, binnen de laterale randen van de musculus rectus abdominus, komen het beste in aanmerking hiervoor. Postoperatieve complicaties waren beperkt: seroom (22%), hematoom (8%), wonddehiscentie (3%) en recidief hernia (8%). Deze studie toonde aan dat eCST goede resultaten geeft bij geselecteerde patiënten.

Hoofdstuk 9

Om de plaats van de posterieure Component Separatie Techniek (CST) met Transversus Abdominis Release (TAR) binnen het palet van operatietechnieken voor littekenbreuken te bepalen, werd een systematische literatuurstudie uitgevoerd. Vijf artikelen, tezamen 646 TAR-patiënten met grote midline littekenbreuken (gemiddeld oppervlak 509 cm²), toonden wondcomplicaties aan bij 15% (20-35% na anterieure CST) en recidief breuken bij 4% (13% na anterieure CST). Deze review toont aan dat TAR een zeer goed alternatief is voor anterieure CST in termen van wondcomplicaties en recidieven, vooral bij zeer grote midline littekenbreuken.

Optimalisatie van het postoperatieve zorgpad: evaluatie

Hoofdstuk 10

De 5-jaar resultaten van de transversus abdominis release (TAR) werden geëvalueerd, nadat deze techniek in 2016 in ons ziekenhuis werd geïntroduceerd. Na elke 20 procedures werden uitkomstparameters geëvalueerd en nieuwe kwaliteitsmaatregelen geïmplementeerd. Primaire uitkomstmaat was Textbook Outcome (een ongecompliceerd postoperatief beloop na TAR) en de institutionele leercurve

(aantal Textbook Outcome patiënten op het totale aantal achtereenvolgens uitgevoerde TARs). Drie opeenvolgende cohorten van elk 20 TARs toonden aan dat zowel het Textbook Outcome (10%, 30% en 55%), als het aantal klinisch relevante wondcomplicaties (45%, 15% en 10%) significant verbeterden met meer ervaring. Textbook Outcome was 35% over alle patiënten en de institutionele leercurve vlakke niet af na 69 opeenvolgende TARs. Deze studie toonde aan dat TAR een lange leercurve heeft, slechts gedeeltelijk bepaald door de technische aspecten van de operatie.

Samenvatting Helmonds

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De miste mense wete wa `n liesbreuk of `n boiknavelebreuk is. Ne bult zo grouwt as `n pingpongbulleke of as `n appelesien. Dan kumt dur `n zòöfte plek tusse de boikspiere `t voejr van oew pens naor boite soms mi dèrrum en al. Van zonne bult kende `n houwp geneuk kriege as da afklemt. Da duu verrekkes zir en dan bestu de kans da oew dèrrum afstèrreve.

Dorrum laote de miste zuneige operere. Dan wort die zak teruggedawt, `t gat wort dichtgenèjt en verstevigt mi `n plastieken matje. Da gèft n`n honderste tref dè `t terugkumt.

Nao `n boikoperasie, bevobbelt um `n grouwt stuk dèrrum eweg te haole, is `t litteken ok zon zòöfte plek waordur `n breuk ken ontstaon, `n littekenbreuk. Da kumt in virtiejn persent vur. Mistentijds `n klèn die hèndig ken worre opgekallefatert. Soms is zon breuk zo grouwt as `n foebol of nog grotterder. Da nuume ze dan ne komplekse littekenbreuk. Daor hedde mistentijds veul laast af. Mense skame zuneige en `t duu ping. Mar ok dur trubbel baj tralderhaand aktievieteite. Daorum wille die mense zuneige liggeluk laote operere. `t Is nie zonder riskossie um zonne foebol terug in de boik te dawwe en `t gat tusse de boikspiere dicht te make mi zonne plastieken mat. `t Is krèk assof `n korselet zo strak wort dichtgerigge dagge d`r dempig van wort. In dertig persent gu de wond zwere, kumt `r gezworrenat oit, skeurt ope en dan kumt de breuk wir terug. Da ziedde vural baj mense mi vetzucht of die soiker hebbe, gèr `n siegretje rouwke of nie zat bewege. Umdè ze nie gèr van `t bed op `t strawwe raoke, worre veul pasjente nie geopereert.

In tweiduzendentwèlluf daachte waj in `t Elkerliekziekehois wa vur dees pasjente te kenne doewn dur vur de operasie `t riskossie goewt in te skatte.

Daor gu dees dissertasie over: Hoe kenne waj dees groep pasjente better hellepe? Uurst make waj `n houwp afsprake um `t zurrigperses better te organisere. “`t Zurrigpad” wier beskrivve en waj wilde van aander ziekehoize lère (H1). Zouwe ontdekte waj detter in Nederland nie veul ziekehoize zing die hierin zing gespesjaliezeert (H2). Daorum moesse waj `t wiel zelluf oitvinge. Waj organizeerde elleke maond `n overleg mi `n hille kwak dogters en `n heil dil aander ziekehoisvolluk. Dan wier `r riskossie vur elluke pasjent besproke. Da overleg bleek nie vur Jan mi de

korte aachternaom te zing. Ons onderzoek demonstreerde da de kans op komplikasies heil goewt in te skatte waar. Nog better dan mi aander meetsysteme (H3). Weiter hebbe waj bewizze da hoe grotter de breuk hoe dikker de pasjent nao de operasie `n longontsteking krie (H4). OK bleek da pasjente mi overgewicht ginne skrik hoeve te hebbe um te gaon sporte (H5). Verders zage waj da de pasjente wezeluk minder komplikasies krigge asse stopte mi rouwke, afviele en meier ginge bewege (H6). Waj makte binnen ons zurrigpad over aal dees dinger doidelukke afsprake.

Mar waj vergate nie onze operasietechniek te onderzujke. As `t nie lukt um `n heil grouwte littekenbreuk in de midde van de boik te sloite, moet de boikwand weiter opererekt worre. Waj hebbe onderzòdcht of di chemies ken dur vur de operasie Botox bezèje de breuk in te spoite waordur de boikwand zòdfter wier (H7). Mar `t ken ok sjiergies dur ein van de drierj skoine boikspiere in te snije. Daorvur hebbe waj tweje nèj technieke geannalieseert. Baj dein wort de vurste skoine boikspier vieja `n kiekoperasie ingesneje (H8). Baj daander worre de aachterste skoine boikspiere ingesneje (H9). Bèèj de technieke zin vurdillig maor da verskilt per pasjent en per breuk (H10). Um dè goewt in te skatte is da maandeluks overleg essensjeel. Naw wittet krèk!

Valorisation addendum

This paragraph consists of a reflection, for a broad audience, on the scientific and social impact of the results of the research described in the thesis.

Scope

Inguinal, umbilical or epigastric hernias are commonly present and often visible as a hump on the belly (abdominal wall). This hump contains a sac with fat and intestines, that bulges through a hole in the abdominal wall. To prevent a potentially dangerous incarceration of the content in the sac, an operation may be required. The sac is then pushed back through the hole and the hole is surgically narrowed or closed with stitches and reinforced with a mesh.

Besides a hole through a natural weak spot in the abdominal wall, these humps may also be due to a previous surgical cut (incision) in the abdominal wall. Incisions that heal inadequately may lead to an incisional hernia. This occurs at least in one of every eight patients (13%) that underwent any type of an abdominal operation. Especially older patients with other diseases (comorbidities) are prone to develop incisional hernias. If such an incisional hernia remains small and patients have no complaints, surgical repair may not be needed. In other cases, surgery of small incisional hernias may be of help to reduce complaints and decrease the risk of strangulation.

But if the hernia develops into a very large hump over time, with a hole larger than 10 cm, repair becomes complex. International studies demonstrated that at least one of seven (15%) incisional hernia repairs were performed for complex hernias.

The presence of a complex hernia may reduce quality of life, due to shame, inability to perform daily activities, pain or other complications. Pushing a large hump into the belly and then surgically closing the hole over a mesh, leads to a



very tight abdominal wall. This again may cause pain or complications like infection, problems with breathing, or even worse. These complications occur in more than one-third of the patients, especially if they suffer from overweight, diabetes, smoking, immobility or if the patients are of advanced age. That is why surgeons are reluctant to operate on these patients, because the remedy (a complex hernia operation) can be worse than the disease (diminished quality of life due to a complex hernia).

Annually, some 100.000 abdominal operations are performed in The Netherlands, of whom an estimated 13.000 (13%) may develop an incisional hernia in the following years. From 4.200 incisional hernias that are operated annually in the Netherlands, 630 (15%) may be assigned as a complex hernia, but the actual incidence of complex abdominal wall hernias will be higher. Despite one third of all abdominal operations are performed nowadays laparoscopically, with less risk for develop a large incisional



hernia, the incidence of incisional hernias in the USA is still rising. This has been described as having 'epidemic' proportions. Failure of primary hernia repairs and performing increasingly complex abdominal operations in an ageing population with many comorbidities, will maintain this epidemic.

Incisional hernias are a chronic and cyclical disease. With each failed repair, costs exponentially increase due to morbidity, readmissions and reoperations. In an USA cohort of 500.000 patients that underwent any form of abdominal surgery, sequential treatment of incisional hernias costed at least 250 million dollar per year. If preventative risk-reductive interventions can be implemented, millions can and will be saved.

Main aim, results and conclusions of the thesis

This thesis aimed to improve the quality of care for patients with a complex abdominal wall hernia and demonstrated that the quality of care for these patients can be improved, if every complex hernia patient is approached integrally by an established multidisciplinary team, that knows how to stratify risks, apply prehabilitation, tailor surgery, and repeatedly evaluate the delivered quality of care.

Relevance

Although complex abdominal wall hernia comprises only a small portion of all hernia presentations, it accounts for more than half of total hernia repair expenses. The application of multidisciplinary care principles to the management of patients with complex abdominal wall hernias is a relatively novel concept.

The long-term impact of this thesis is providing complementary scientific evidence for: (a) the consensus, recently made by 32 international hernia experts, that centers offering complex abdominal wall repair can only deliver good and sustainable outcomes, if a multidisciplinary pathway framework is used, instead of single-handed care; (b) the conclusion of a recent systematic review on multidisciplinary complex hernia care, that a multidisciplinary care pathway has potential to facilitate pre-optimization with prehabilitation and improve postoperative outcomes, by providing a tailored approach to the complex medical, surgical and psychosocial requirements of this patient cohort.

International variation in classifications to stage patients, hernias or outcome measures makes result interpretation and comparison challenging and weakens meaningful scientific discussions about treatment effects. This research used the so-called Hernia-Patient-Wound (HPW) classification. Endorsement of this classification by our team had national impact, while this classification was formally acknowledged by the Dutch Association of Surgeons in their first guideline on incisional hernias (2019). After publication of this guideline, the Dutch Health Authority formalized complex incisional hernias as a unique hernia repair registration code with a different reimbursement.

Introduction of the multidisciplinary complex hernia care pathway also had impact on referral patterns. More than 70% of our patients originate from outside the region of adherence. Similar Dutch hospitals aiming at complex hernia centralization also used our pathway to create a regional hernia network.

The complex hernia care pathway had much local impact. The number of complex hernia operations increased from 20 to 100 per year. A higher case volume increased experience for the multidisciplinary team and individual surgeons. Postoperative complications subsequently decreased which led to shorter hospital stay. Insurance company endorsed referral of complex patients to the hospital which fueled the cycle of improvement. Interest in complex hernia patients by adjacent specialists grew, which converged pathways and aligned treatment protocols. Finally, the research had an enormous patient impact: quality of life and value of care was increased for most of our patients.

Suggestions to further improve outcome for these patients within this multidisciplinary framework is to explore patient psychological wellbeing (quality of life, patient-reported experience/outcome measures (PREMS/PROMS)) and analyze the results of prehabilitation. To optimize allocated resources and multidisciplinary care benefits, clear referral criteria should be defined to ensure appropriate patient selection (HPW classification validation). Postoperative care pathways should be researched deeper and described in detail. Decreasing the mesh-footprint by developing soluble (liquid?) meshes or, even better, discovering components that prevent hernia formation, will ultimately be the 'holy grail'.

Target audience

The research presented in this thesis is relevant for all health care professionals who want to focus on the treatment of complex hernia patients. It provides insight for medical specialists, health care policy makers, partners in industry and individual patients, to understand the 'complexity' of complex hernia care. The target audience was informed by publishing and presenting the results of this thesis in international medical journals, at (inter)national congresses, educational sessions, webinars, and during mirror meetings with patients.

Conclusion

The burden of a complex hernia can be immense for patients, for society, but also for surgeons and hospitals considering treating these patients. Although surgical techniques, instruments and meshes have advanced greatly recent decades, surgical repair is only an option, when quality of life of the patient can be improved safely. This thesis is a call to treat these patients in a multidisciplinary care pathway, a guide to implement such a pathway, and a plea for centralization and registration of outcomes. First treat the patient, then the hernia.

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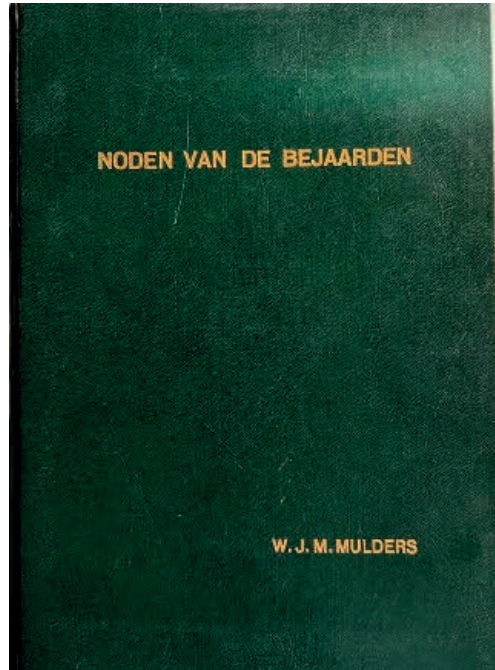
en ook voor mij. Wat een geluk om jou als broer te hebben en wat een eer, jou als paranimf aan mijn zijde te mogen hebben.

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Curriculum Vitae

Born on July 30th, 1968, in Utrecht, of two wanderlust parents, Johannes Wegdam went via Kerkrade, Hwidiem (Ghana) and Tilburg to Ede, where he completed the Gymnasium at the Marnix College in 1987. Leaving his parents, two sisters and a brother behind, he continued at the State University of Groningen and commenced his medical study in 1988.



As a student he participated four years in the Liver Transplantation Group (prof. dr. M.D. Slooff), which fueled his inherited passion for surgery. He subsequently investigated malaria for several months at the Kenia Medical Research Institute in Kisumu (dr. A. Githeko) in 1993, followed by a two-year period of internships at the St. Elisabeth Hospital (Sehos) in Curaçao, Dutch Antilles (1994-1996).

After graduation as MD, surgical residencies in Tilburg and Arnhem led him to start his surgical training in 1999 at the Rijnstate Hospital in Arnhem (dr. W.F. Eggink and prof. dr. J.H.G. Klinkenbijn) and the Radboud University Medical Center (prof. dr. R.P. Bleichrodt). During these years, several clinical immersions took place at the Holy Family Hospital in Techiman, Ghana (supervised by H.H.J. Wegdam) and the Sehos, Curaçao (supervised by dr. J.N. van Leeuwen). In 2005 he certified as a general surgeon, gastro-intestinal surgeon and surgical oncologist. Ten years after leaving Groningen as a medical student, he returned as a surgeon at the Transplant Surgery and Organ Donation Unit of the University Medical Center Groningen (UMCG). Subsequently, a two-year Fellowship (Advanced Laparoscopic) Gastro-intestinal Surgery begun at the Medical Center Leeuwarden (prof. dr. J.P.E.N. Pierie) and ended in the UMCG in 2007 (prof. dr. R.J. Ploeg).

In 2008, he continued at the Elkerliek Hospital, Helmond. While introducing laparoscopic colorectal surgery, he also redesigned the colorectal care pathway, which was honored with the Elkerliek Patient Award in 2010. After dr. T.S. de Vries Reilingh joined the Elkerliek in 2011, their focus broadened to complex abdominal wall hernias. The colorectal care pathway was copied to complex hernia patients. In a strong collaboration with dr. S.W. Nienhuijs, surgeon in the Catharina Hospital,

Eindhoven, the first multidisciplinary complex hernia care pathway was successfully implemented in the Elkerliek in 2012. The European Hernia Society conferred the honorary title 'Fellow of the European Board of Surgeons, Abdominal Wall Section', to each of these three surgeons, in 2021. The Elkerliek Hernia Center awaits formal denomination as Expert Hernia Center in the Netherlands, in 2024.

Research, under guidance of prof. dr. N.D. Bouvy, Maastricht University Medical Centre, and co-promotores, led to his first hernia publication, as primary author, in 2019, and ultimately this thesis in 2023.

In 2000 he married Marjolijn Blans and the couple was blessed with Mees (2002), Piet Hein (2003) and Floortje (2006). His extra-curricular activities comprise co-invention of the Funsticker (1994), co-founder of the 'Jonge Orde' (2002), chairman of Dutch Association of Surgical Residents 'VAGH' (2005), member/chairman of the Surgical Quality Audit Committee of the Dutch Society of Surgeons (2013-2023), sailing, listening bossa and reading fiction.

List of publications

Hernia related publications

Impact of a multidisciplinary team discussion on planned ICU admissions after complex abdominal wall reconstruction. **J.A. Wegdam**, D.L.C. de Jong, M.J.C.A.M. Gielen, S.W. Nienhuijs, A.F.M. Füsers, N.D. Bouvy, T.S. de Vries Reilingh. *Hernia*. 2023 Jun;27(3):623-633.

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eCST: The endoscopic-assisted component separation technique for (complex) abdominal wall reconstruction. T.S. de Vries Reilingh, S.W. Nienhuijs, D.L.C. de Jong, E.M.M. Mommers, **J.A. Wegdam**. *Int J of Abdom Wall Hernia Surg*. 2022;5(1):13-20.

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