Intraperitoneal Onlay Mesh Repair

Clinical Implications

Vincent M.A. Stirler

Intraperitoneal onlay mesh repair: clinical implications
Vincent M.A. Stirler

Thesis, Utrecht University, with a summary in Dutch
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Clinical Implications

Intraperitoneale Onlay Mat Herstel

Klinische Implicaties

(*met een samenvatting in het Nederlands*)

Proefschrift

ter verkrijging van de graad van doctor aan de Universiteit Utrecht op gezag van de rector magnificus, prof. dr. H.R.B.M. Kummeling, ingevolge het besluit van het college voor promoties in het openbaar te verdedigen op donderdag 25 oktober 2018 des middags te 4.15 uur

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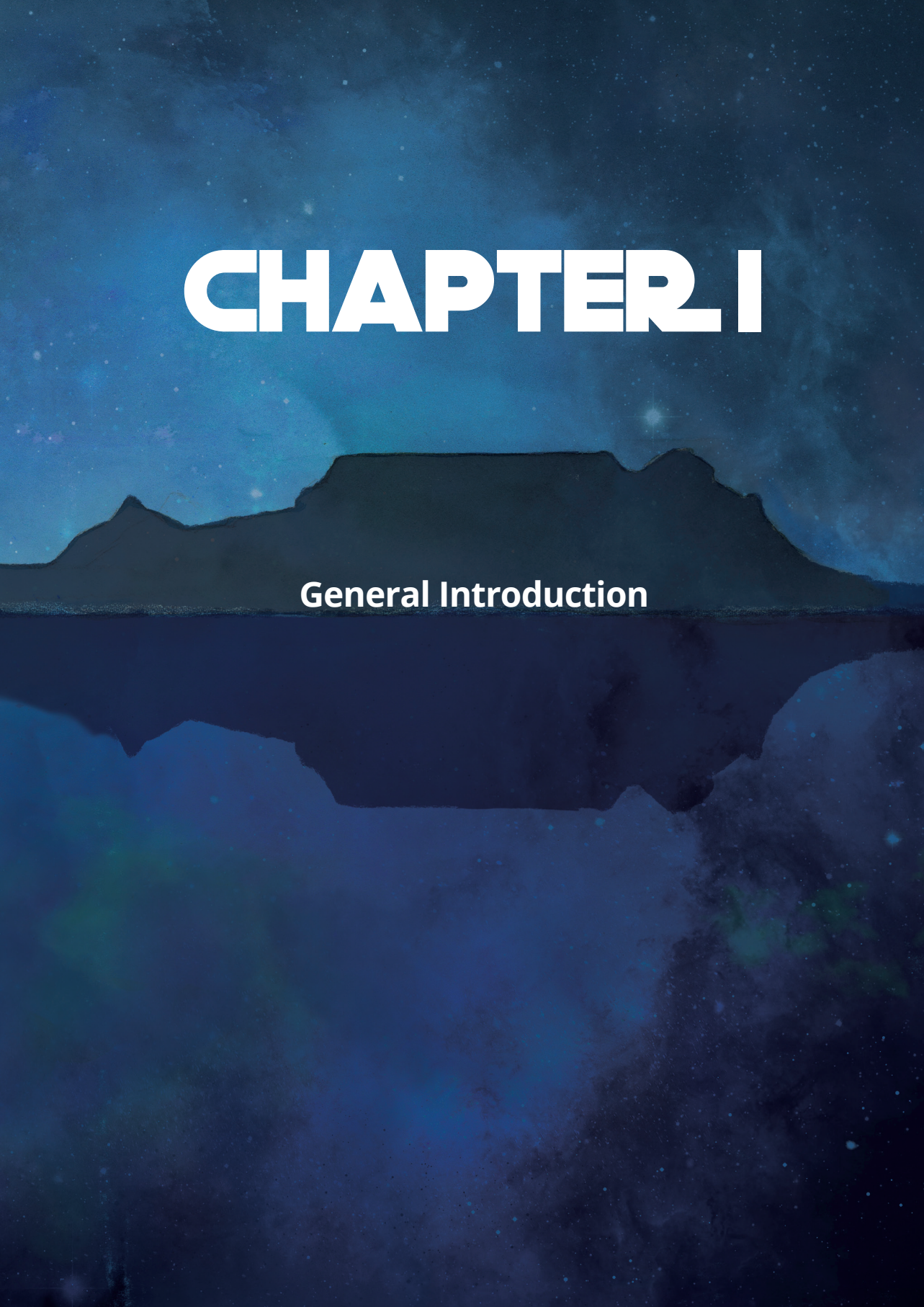

CHAPTER I

General Introduction

Historical background [1–5]

Ancient times

Over 6000 years ago, in an age when medicine was tied to magical and religious thought, descriptions of inguinal and ventral abdominal wall hernia were already documented by unknown authors in India. The first detailed description of an epigastric hernia – the term was not introduced until 1812 AD – was discovered in the Ebers Papyrus (1552 BC), which was found in the tomb of Thebes in 1862 by Professor George Ebers. The treatment of choice at that time was application of bandages to prevent protrusion of the hernia sac.

Greco-Roman era

In the Greco-Roman era, an umbilical hernia was mentioned by Hippocrates of Cos (460 – 375 BC) in the *Corpus Hippocraticum*. Several centuries later a Roman encyclopaedist and physician named Aulus Celsus (25 BC – 50 AD) described the reduction and closure of an umbilical hernia in his work *De Medicina*. He underlined the importance of a layered surgical closure of the abdominal wall to prevent (recurrent) hernia. A century later, a Greek physician called Aelius Galen (131 – 201 AD), also known as Galen of Pergamon, described the layered closing of the abdominal wall in greater detail. He suggested that the use of a paramedian incision was superior to median incision for the former was associated with less (recurrent) hernia.

The Middle Ages

No notable works were produced in the Middle Ages (500 – 1500 AD). The exception was the French surgeon Guy de Chauliac (1300 – 1368 AD) who described different types of hernia in *de Ruptura*. He introduced the concept of a truss 'for closing the gate' at the external inguinal ring.

Age of dissection

The Enlightenment brought about the Age of Dissection (1700 – 1900 AD). Systematic investigations on cadavers led to a greater understanding of the anatomy of the abdominal wall and the clinical features and surgical techniques from the Greco-Roman era were developed further. The lessons learned were extensively reported in medical journals, of which some still exist to this day.

An early classification system was introduced in 1721 by Beatus La Chausse in his *Dissertatio chirurgica de hernia ventrali*. Jean Leveille introduced the term epigastric hernia in 1812 and Jean Cruveilhier coined the term *eventration* in 1849. Pierre Gerdy performed the first documented incisional hernia repair where he inverted the hernia sac (including the skin) through the hernia opening into the abdominal cavity and sutured the edges

together. He induced adhesion formation by injecting ammonia into the hernia sac in an attempt to strengthen the repair.

In 1876 Greensville Dowell published a comprehensive review on hernia surgery. It was titled *A treatise on hernia with a new process for its radical cure*. In that review he described an invagination and ligature technique that he considered was suitable for all types of hernia of the groin and the ventral abdominal wall. He concluded that "*Giving about all is known on the subject, there will never be a better method invented than the author's*".

It was only in 1896 that Edouard Quenu documented a classification in his paper '*Traitement opértoire de l'éventration*' that distinguished incisional hernia from all other types of hernia.

Modern surgery

During the modern era of surgery – from 1900 and onwards – the concept of ventral abdominal wall hernia treatment underwent three distinct and simultaneous changes with *suturing* (simple laparoplasty), *grafting* (organic auto- and heteroplasty), and the use of *prosthetics* (alloplasty).

At the turn of the century, William Mayo [6] described his well-known overlapping suturing technique for umbilical hernia that was later modified by others for incisional hernia. Together with several variations on the same theme, recurrence rates were considerably high.

Alternatively, in 1910 Martin Kirschner reported how he harvested autologous fascia to close a hernia defect. In 1912 Edward Starr Judd described overlapping flaps of peritoneum, muscle, fascia and scar tissue. In 1913 Otto Loewe illustrated the use of cutis grafts. Many other materials were proposed from grafts of freeze-dried human fascia lata to dura mater and skin. However, just as with suturing, these techniques led to high recurrence rates. Besides, grafting caused denervation at donor sites and bulging, infection or transplant rejection (heteroplasty) at acceptor sites. One could nevertheless surmise that these attempts were precursors to the biological collagen xenografts that are in use today.

In 1900 the first attempts at repair with a prosthesis were performed with metal meshes made from braided silver wire. They were rigid and fragile and the profound fibrosis response often led to sinus formation. Later versions included stainless steel, tantalum, perlon or nylon, all of which either broke apart, disintegrated or caused intense inflammatory responses.

Modern materials

Plastics filled the void when metals were allocated for military use at the start of the Second World War. Their invention was arguably the greatest commercial development of the 20th century and contributed greatly to the treatment of ventral abdominal wall hernias. Nylon became commercially available during the war. Yet, this hydrophilic material lost its tensile strength in situ and it had to be removed in case of infection.

In 1955 Francis Usher introduced the use of polyester and at a later stage the improved hydrophobic polypropylene (Marlex). It could be extruded as a monofilament, knitted into a mesh and did not fray on the sides when cut. Additionally, the material was strong, inert, and it did not fragment even after boiling. Most importantly, the mesh incorporated well into tissue - even when infection was present. During his extensive investigations, he learned a lesson we still teach today. At the time it was common to approximate tissue under tension and plug the gap. Although relaxing incisions were made beyond the mesh, tension ultimately led to recurrences. Instead, he introduced the concept of bridging the gap with sufficient overlap thus eliminating the need to approximate tissue under tension.

In 1938, polytetrafluorethylene (PTFE) had accidentally been discovered by Roy Plunkett after a tank with its gaseous form was opened and a slippery and inert white powder was discovered. In 1943, the product was developed into Teflon by Du Pont and introduced to herniology in 1959. It was in 1963 that Teflon was expanded into a stronger structure (ePTFE) and Gore commercialised it as a mesh. It came into wider use after the introduction of laparoscopic repair (LR) of ventral abdominal wall hernia because of its rapid coverage with mesothelium (neoperitoneum) and its resistance to adhesion formation. Contrarily, the mesh did not integrate well with the abdominal wall and was not resistant to infection.

Through the years meshes were developed and manipulated into all sorts of different formats ranging from early non-absorbable synthetic meshes (e.g. Nylon, Polyester, Polypropylene) and composite meshes (expanded polytetrafluoroethylene) to recent absorbable composite meshes and tissue-based biologic implants. The search for the ideal mesh still continues to this day.

Modern technique

In open repair various different mesh positions have been developed. The *onlay* position was popularised by Jean Paul Chevrel who placed a mesh in the subcutaneous prefascial space. This position was quite susceptible to infection. The *inlay* position put a mesh in between the rectus abdominis muscles. It was abandoned because of high recurrence rates. Others advocated the *underlay* position in which a mesh was placed onto the peri-

toneal lining through a laparotomy. Yet, it is the *sublay* position of a mesh that has gained the widest acceptance to date.

The sublay position was first introduced by Jean Rives in 1973 who described a retromuscular (prefascial) mesh position [7]. Shortly after, René Stoppa described the retrofascial (preperitoneal) mesh position in 1975 [8]. The recurrence rates of the sublay position were relatively low because of three distinct advantages. First, a mesh could be placed that was much larger in surface area than the hernia defect itself. Second, its position made use of the intra-abdominal forces pressing the mesh against the abdominal wall muscles. Third, there was no direct contact between the mesh and the intra-abdominal contents. It became a widely accepted technique especially in the treatment of incisional ventral hernia (IVH).

The component separation techniques have served as an adjunct to open mesh repair in case of loss of domain with lateral retraction of the abdominal wall muscles or as a primary repair when a mesh could not be placed due to contamination at the surgical site. Two examples are the anterior component separation technique (*m.obliquus externus* release), introduced by Oscar Ramirez in 1990, and the posterior component separation technique (*m.transversus abdominis* release), introduced by Yuri Novitsky in 2006 [9, 10].

Ventral abdominal wall hernia treatment gained a distinctive new option with the introduction of laparoscopic ventral hernia repair (LVHR). The first laparoscopic repair in a patient was performed in 1982 by Ralph Ger by simply closing the peritoneal gap with the use of clips [11].

LR of primary ventral hernia (PVH) and IVH as we know it, was introduced by Karl LeBlanc and William Booth in 1993 [12]. Their intraperitoneal onlay mesh (IPOM) repair consisted of reduction of the hernia content from the hernia sac and bridging of the abdominal wall defect with an overlapping ePTFE mesh. Because IPOM placement puts a mesh in direct contact with the intra-abdominal organs, two important prerequisites were required. First, the mesh should cause as little interaction as possible on the visceral side, and second, should promote incorporation of the mesh into the abdominal wall. This has led to a multitude of mesh designs with different materials, sizes of pores, textures, weight and additives.

Definition

Ventral abdominal wall hernia can be divided into PVH, IVH and traumatic hernias. PVH are defined as a protrusion through the anterior musculo-aponeurotic coverage of the abdominal wall. They are subdivided into congenital or acquired defects and are classified according to their localisation (e.g. umbilical, epigastric) and diameter (Table 1) [13].

IVH are defined as "any abdominal wall gap with or without a bulge in the area of a post-operative scar perceptible or palpable by clinical examination or imaging" [14]. They are classified according to their localisation (midline or lateral), subdivided into several zones, whether they are recurrent or not, and according to their width and length (Table 2) [13]. Once an abdominal incision has been had, risk factors for the development of an incisional hernia are smoking, male gender, high body mass index, increasing age and surgical site infection (SSI) [15–20].

Table 1 European Hernia Society classification for primary abdominal wall hernias

Diameter		Small <2cm	Medium 2-4cm	Large >4cm
Midline	Epigastric			
	Umbilical			
Lateral	Spigelian			
	Lumbar			

Table 2 European Hernia Society classification for incisional abdominal wall hernias

Midline	Subxiphoidal	M1	
	Epigastric	M2	
	Umbilical	M3	
	Infraumbilical	M4	
	Suprapubic	M5	
Lateral	Subcostal	L1	
	Flank	L2	
	Iliac	L3	
	Lumbar	L4	
Recurrent incisional hernia?		Yes / No	
Length (cm)			
Width (cm)	W1 (<4cm)	W2 (4-10cm)	W3 (>10cm)

1

Treatment

PVH and IVH are treated with surgery in order to relieve symptoms (e.g. pain and discomfort), prevent complications (e.g. strangulation, respiratory dysfunction or skin problems) and resolve acute complications (e.g. incarceration and strangulation) [21]. An estimated one-quarter of all individuals are either born with or will develop a ventral abdominal wall hernia in their lifetime [22]. Watchful waiting in those with minimal to no physical complaints can be a reasonably safe primary treatment strategy for PVH and even IVH [23, 24].

Contrarily, the cumulative lifetime risk of acute presentation may be high. One study reports that approximately 10% of all ventral hernia repairs are performed as an emergency surgery [25]. Up to 57% of primary umbilical hernia (PUH) present with acute complications requiring emergency intervention. In such cases outcomes are poorer when compared to elective surgery [26, 27]. Patients under watchful waiting will undergo surgery at a later stage in approximately one in six patients with PVH and one in five patients with IVH. Therefore, some argue that ventral hernia should undergo early repair in order to prevent later complications.

Over time there has been a significant increase in the number of patients who undergo hernia repair. The relative distribution of hernia repairs undertaken between 2005 and 2008 were: inguinal (64%), umbilical (19%), epigastric (9%), incisional (5%), femoral (3%), other (<1%)[28].

Sutures or a mesh?

The surgical technique is divided into either open or laparoscopic repair (LR). The former can be subdivided into *suture repair* (approximation of the defect) versus *mesh repair* (bridging of the (closed) defect with a mesh). Suture repair is the simplest procedure and is accomplished in a shorter length of procedure (LOP) than mesh repair. Yet, for PVH recurrence rates after suture repair are significantly higher than for mesh repair [29–31]. Even for small PVH (<2cm) a large prospective cohort study demonstrated a higher recurrence rate after suture repair (5.6% versus 2.2%; p=0.001) at 21 months follow up [32]. Differences in recurrence rates are even more profound for IVH. After a follow of ten years, suture repair had a recurrence rate of 54-63% versus 32% with the use of a mesh [33]. However, suture repair is still considered the treatment of choice for small hernias by many due to its simplicity.

Open versus laparoscopic repair

Since the introduction of LVHR, many comparisons have been made with open repair up to a point where the first evidenced based guideline was published by the International

EndoHernia Society in 2014 [34–37]. Together with a Cochrane meta-analysis [38] and several other meta-analyses [39, 40], LVHR was deemed a safe technique that appeared to be at least as good as open repair in terms of adverse outcomes.

In these meta-analyses, two outcomes stood out in favour of LVHR. First, the rate of local infection was significantly lower when compared to open repair (3.1 versus 13.4%) [38]. Another meta-analysis reached similar conclusions in favour of LVHR (2.8% versus 16.2%) [40]. When a local infection did occur, the rate of subsequent mesh removal was significantly lower after LVHR (0.7% versus 3.5%) [39]. Second, the length of hospital stay (LOS) was consistently shorter after LVHR. Other outcome measures, such as postoperative ventral seroma, haematoma, bleeding, enterotomy, bowel obstruction, reoperation rate and postoperative pain, were not different between the two techniques.

There was a fundamental problem with the studies that have compared LR with open repair. In nearly all of them, PVH and IVH were pooled together as if they were the same clinical entity [38, 39, 41, 42]. On top of that, follow up of LR usually was much shorter, randomised controlled trials (RCT) were not blinded, different hernia sizes and locations were included in the same groups, and different materials and operative techniques were used. This heterogeneity confounds the interpretation of these studies.

Mesh fixation

Mesh fixation is necessary in LVHR. The mesh is not held between layers of the abdominal wall. Instead it is positioned onto the peritoneal lining of the abdominal cavity. Fixation is required to keep the mesh in place over the hernia defect to maintain sufficient overlap in order to prevent recurrence.

Different fixation materials are available: transabdominal sutures (TAS), penetrating fixation devices (tacks), and glue. They can be used interchangeably. An example is a combination of TAS with tacks that are both placed at the circumference of the mesh. More popular today is the double-crown technique. It entails two circles of only tacks; the outer ring placed at the circumference of the mesh and an inner ring placed around the hernia defect [43]. A third option of mesh fixation is the administration of glue (fibrin sealant) that is sprayed onto the peritoneal lining, mesh or both. Its use has not been validated as a stand-alone fixation method.

Application of TAS with tacks is more time consuming than a double-crown of tacks [44]. In animal studies the tensile strength of TAS is up to 2.5 times greater than that of nonabsorbable tacks and in turn these tacks are stronger than absorbable tacks [45, 46]. Several other in vitro studies concluded that, even fired from acute angles, nonabsorbable tacks

are significantly stronger than absorbable tacks [47–51]. There exists no long term data as to how these differences in strength between nonabsorbable and absorbable tacks translate into recurrence rates.

The choice of fixation technique is a crucial element of LVHR and influences main outcomes such as hernia recurrence, adhesion formation and postoperative pain [52, 53]. Today, nonabsorbable titanium tacks are considered the standard for mesh fixation in LVHR because of their easy use and consistent efficacy [43, 54–56]. Yet, titanium tacks remain in the body indefinitely and have been associated with (rare) complications such as dense adhesion formation, erosion of tacks into hollow viscera as well as tack hernias [57]. Arguably the most adverse clinical outcome attributed to this fixation material is postoperative pain [52, 53, 58–62].

Postoperative pain

Acute and chronic postoperative pain have a detrimental effect on a patient's quality of life. Where acute postoperative pain may temporarily delay a patient's return to work, chronic pain could be of significant concern when it leads to prolonged consumption of analgesics, restriction in daily activities and economic loss due to absenteeism. Current interests focus greatly on the genesis of postoperative pain and have led to recent technical developments such as absorbable tacks and glue.

Does infiltration with an anaesthetic agent at the points of fixation decrease pain?

Administration of local anaesthetic agents at the suture sites prior to placement of the sutures themselves resulted in lower pain scores at one hour postoperatively (2.2 versus 6.4 VAS 0-10; $p<0.05$) [58]. This pain reducing effect was limited to the duration of the anaesthetic agent itself.

Do absorbable TAS versus nonabsorbable TAS cause a different level of pain?

Investigated only once, the use of absorbable TAS did not have a pain-reduction advantage over nonabsorbable TAS at two, six and twelve weeks postoperatively [61].

Do different fixation methods cause different levels of pain?

Previous investigations into postoperative pain after LVHR have concluded that titanium tacks do not influence acute postoperative pain differently than TAS [59, 61, 63, 64]. In a meta-analysis of 24 different studies, the median percentage of *chronic* postoperative pain was not significantly different (TAS 3.75%, nonabsorbable tacks 6.35%, and combination of both 2.75%; $p<0.845$) [65]. No studies exist that investigated postoperative pain as a primary outcome measure comparing nonabsorbable with absorbable tacks.

Do fewer fixation points cause less postoperative pain?

The number of TAS or tacks and their relation to postoperative pain has not been specifically investigated before. Only mentioned once, based on a subgroup analysis, no significant correlation was observed between the number of tacks used and acute postoperative pain experienced (p=0.14) [61].

Does glue, compared to traditional fixation, cause a different level of pain?

As an alternative to penetrating mesh fixation, the use of glue is thought to cause less acute and chronic postoperative pain. At short term Erikson reported that fibrin sealant caused less postoperative pain when compared to titanium tacks. However, after one year follow up no difference in quality of life, postoperative pain, discomfort, fatigue or satisfaction was observed between the two groups. Although the study was not powered for recurrence rates, fibrin sealant mesh fixation of larger hernia defects was associated with higher recurrence rates [62, 67].

What is the impact of fascial defect closure on pain?

A recent meta-analysis concluded that closure of the fascial defect during LR results in fewer overall adverse outcome when compared to non-closure of the hernia [68]. Closure of the fascial defect did not impact postoperative pain differently.

What is the impact of mesh material on pain?

Quite a few different types of mesh are available nowadays. They can be classified as heavyweight (>80 g/m^2), medium weight (50–80 g/m^2), lightweight (35-50 g/m^2), or ultra-lightweight (<35 g/m^2) with either large, small or micro pores. It is assumed that the amount of material and the size of the pores correlate with the cellular reaction initiated after the injury of surgery and the implantation of a mesh. It is the foreign body reaction which in turn determines the biocompatibility of a mesh [69] and this may be a contributing factor for the development of chronic postoperative pain [70].

So far only two studies have compared two different types of mesh and investigated their impact on postoperative pain. One prospective randomised trial did not find any difference in acute nor chronic postoperative pain scores between heavyweight polypropylene and lightweight barrier coated polypropylene meshes [71]. Another prospective randomised trial compared the use of a lightweight titanium-coated mesh with a medium weight collagen-polyester mesh and concluded that at one month postoperatively acute postoperative pain was significantly less common with the former mesh (p=0.029). There were no differences in pain scores at six or twelve months [72].

1

Anterior cutaneous nerve entrapment syndrome

The ventral abdominal wall is innervated by the lower six intercostal nerves that originate from the spinal cord. These nerves run ventrally between the *m.transversus abdominis* and the *m.obliquus internus*. At certain intervals – posterior, lateral and anterior – nerve branches undergo a 90 degree turn and penetrate the different layers of the abdominal wall towards the skin. The anterior branch passes a fibrous ring (nerve foramen) within the lateral border of the rectus abdominis muscle [73, 74].

Normal physiology allows unimpeded motion of the neurovascular bundle at this foramen. Even when forcefully pushed from behind during excessive increases in intra-abdominal pressure (e.g. coughing, lifting) or when pulled from in front by vigorous muscle contractions (e.g. sports)[75]. Repeated compression of the neurovascular bundle against the fibrous ring causes entrapment of the neurovascular bundle and may cause pain [75, 76].

In 1926 John Carnett called this pathology intercostal neuralgia [78]. The proposed treatment at that time was the administration of analgesia and local application of heat, infrared light as well as infiltration with Novocain [79]. William Applegate introduced the term *anterior cutaneous nerve entrapment syndrome* (ACNES)[73], which still is in use today.

The actual incidence of ACNES remains unknown. It was estimated in a retrospective study that approximately 2% of all patients, who presented with acute abdominal pain at a Dutch emergency department, were diagnosed with ACNES [80]. One in eight adolescents with chronic abdominal pain were diagnosed with ACNES [81].

The diagnosis is made based on a combination of a patient's history and physical examination. Patients usually complain of unilateral circumscriptive pain corresponding to a trigger point (Fig. 1). The trigger point is tender to palpation, which increases when the abdominal wall is tensed as the patient lifts his head and shoulders (Carnett's test) [77, 78]. Additionally, sensory disturbances can be found around a trigger point. Laboratory and imaging investigations are used to rule out the differential diagnoses.

Current treatment of ACNES commences with local infiltration of a trigger point with an anaesthetic agent [82, 83]. Repeated injections, with a corticosteroid as an adjunct, can be attempted to achieve permanent pain relief in up to a third of patients [84]. In patients who fail to respond, neurectomy is the only viable treatment option so far [85]. Experimental treatment modalities include infiltration with botulinum toxin or alcohol as well as radiofrequency ablation [86].

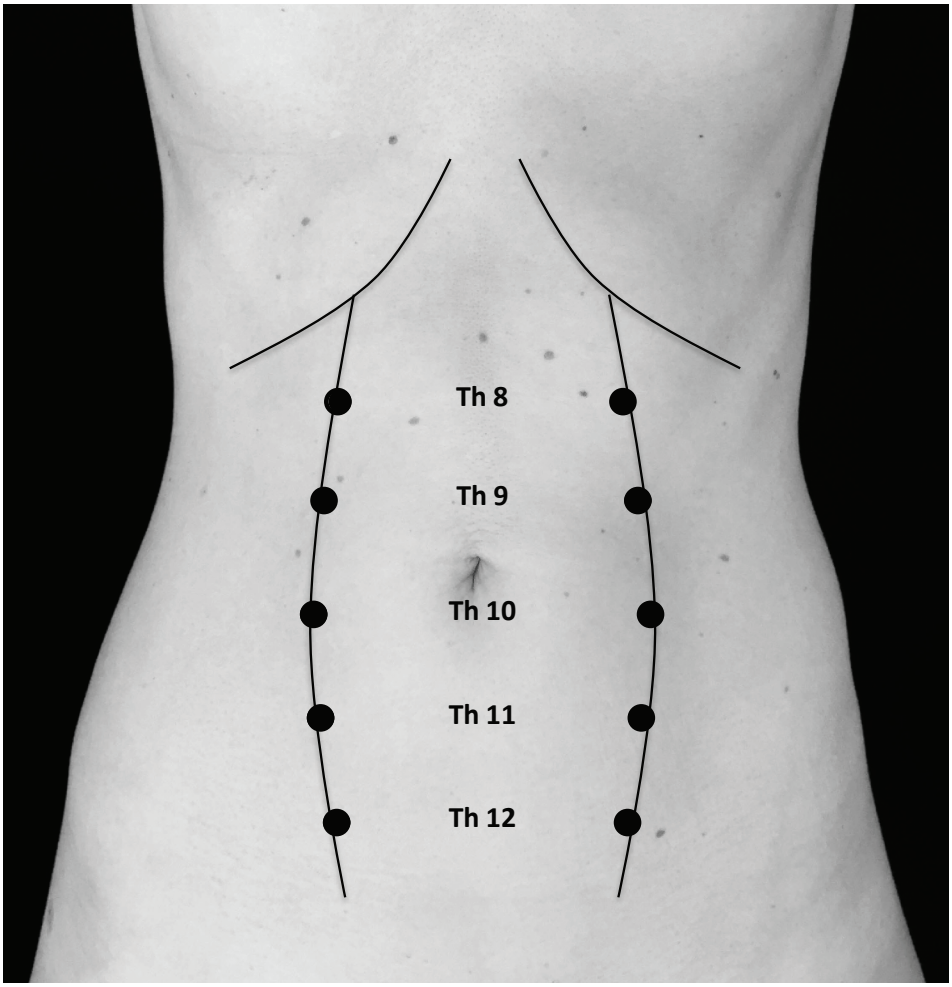

Fig. 1 Localisation of trigger points

1 Central questions and outline of this thesis

The aim of this thesis was to investigate clinical outcome after intraperitoneal onlay mesh repair (LVHR) or reinforcement (ACNES) in order to improve preoperative counselling of patients and to further advance surgical technique. To accomplish this aim, five different questions were formulated that until now have been insufficiently answered in the literature.

1. Is pooling of data justified?
   (Chapter 2)
2. What are the main complications after intraperitoneal onlay mesh placement?
   (Chapters 2 & 3 & 4)
3. How do the number and type of tacks influence postoperative pain perception?
   (Chapters 5 & 6)
4. Is a 2-port procedure for laparoscopic ventral hernia repair feasible?
   (Chapter 7)
5. Is laparoscopic intraperitoneal onlay mesh reinforcement a treatment option for intractable anterior cutaneous entrapment syndrome?
   (Chapter 8)

The following clinical studies have been conducted to answer these clinical questions.

- In **chapter 2** we investigated whether pooling of data (primary with incisional ventral hernia) was justified.
- In **chapter 3** we investigated the prevalence, clinical course and independent predictors of persistent posterior seroma after intraperitoneal onlay mesh placement.
- In **chapter 4** we evaluated the clinical consequences of intraperitoneal onlay mesh placement during pregnancy and delivery.
- In **chapter 5** we investigated the relationship between postoperative pain and the number of tacks used for fixation of a mesh.
- In **chapter 6** we investigated the relationship between postoperative pain and the type of tacks (nonabsorbable versus absorbable) used for fixation of a mesh
- In **chapter 7** we described step for step a 2-port procedure (How-I-Do-It).
- In **chapter 8** we investigated whether intraperitoneal onlay mesh reinforcement could alleviate pain caused by symptomatic anterior cutaneous nerve entrapment.

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CHAPTER 2

Laparoscopic repair of primary and incisional ventral hernias
the differences must be acknowledged

Oral presentation at the 34th International Congress of the European Hernia Society, 12–15 May 2013, Gdansk, Poland

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Abstract

Background

Interpretation of the outcome after laparoscopic repair (LR) of ventral hernias presented in the literature often is based on pooled data of primary ventral hernias (PVH) and incisional ventral hernias (IVH). This prospective cohort study was performed to investigate whether this pooling of data is justified.

Methods

The data of 1,088 consecutive patients who underwent LR of PVH or IVH were prospectively collected and reviewed for baseline characteristics, operative findings, and postoperative complications classified as Dindo-Clavien grade 3 or higher.

Results

The PVH group consisted of 662 patients, and the IVH group comprised 426 patients. The mean Association of American Anesthesiologists classification was higher in IVH group (1.92 vs 1.68; $p<0.001$), as was rate of conversion to open surgery (7 vs 0.5 %; $p<0.001$). The IVH group required more adhesiolysis (71 vs 0.9 %; $p<0.001$), a longer procedure (73 vs 42 min; $p<0.001$), and a longer hospital stay (4.53 vs 2.43 days; $p<0.001$). The recurrence rate was higher in the IVH group (5.81 vs 1.37 %; $p<0.001$), as was total complication rate (18.69 vs 4.55 %; $p<0.001$).

Conclusions

This study showed significant differences in baseline characteristics and operative findings between patients undergoing PVH repair and those undergoing IVH repair. Continued pooling of data on LR of IVH and PVH combined, commonly found in the current literature, seems incorrect.

Introduction

Primary ventral hernia (PVH) and incisional ventral hernia (IVH) of the abdominal wall are considered to be separate entities due to a different etiopathology, and the European Hernia Society has formulated separate classification systems for these two entities [1]. Interestingly, the outcome and results of laparoscopic repair (LR) of PVH and IVH have consistently been pooled together in case series and randomised clinical trials (RCTs) [2–9]. Even recent systematic reviews and meta-analysis comparing laparoscopic and open hernia repair have included RCTs that analysed a mix of PVH and IVH in the LR group [10–12].

In this prospective cohort study, we compared baseline characteristics, operative findings, and short- and long-term outcomes after LR of PVH and IVH to investigate whether this pooling of PVH and IVH data is justified.

Materials and methods

All the patients who underwent laparoscopy for a ventral hernia between January 2000 and September 2012 were included in this study. The patients with PVH were routinely scheduled for LR. The patients with IVH were scheduled for LR unless they had contraindications such as abdominal wall fistulas, loss of domain, an abdomen deemed not accessible for laparoscopy, or a preference for an open correction.

All patient characteristics, operation data, and complications were prospectively registered in an electronic database at the moment of presentation. The primary outcome measures were the postoperative complications classified as Dindo-Clavien grade 3 or higher (Table 1) [13] and the recurrence rate. The secondary outcome measures were differences in baseline characteristics, American Society of Anesthesiologists (ASA) grade [14], intraoperative findings such as incidence and duration of adhesiolysis, conversion rate, size of hernia defect, size of mesh used, length of procedure (LOP), and length of hospital stay (LOS).

Adhesiolysis was defined as any manipulation needed to prepare the abdominal working area and abdominal wall for adequate mesh placement. De-insertion of the *ligamentum teres hepatis* and removal of fat from the hernia sac in cases of epigastric and umbilical hernia were not scored as adhesiolysis. Adhesiolysis requiring more than 30 min was scored as an extensive adhesiolysis.

Operative technique

All procedures were performed by of one of two senior surgeons (JR and SR) or under their supervision. Pneumoperitoneum was routinely obtained using a Veress needle (insertion at "Palmer's point") unless the surgeon considered use of an open introduction necessary due to safety reasons. Adhesiolysis was performed when required. The *ligamentum teres hepatis* and fatty tissue were removed from the abdominal wall in preparation for placement of a mesh.

Table 1 Classification of Surgical Complications according to Dindo-Clavien

Grade	Definition
Grade 1	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions
	Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside
Grade 2	Requiring pharmacological treatment with drugs other than such allowed for grade 1 complications
	Blood transfusions and total parenteral nutrition are also included
Grade 3	Requiring surgical, endoscopic or radiological intervention
Grade 3a	Intervention not under general anesthesia
Grade 3b	Intervention under general anesthesia
Grade 4	Life-threatening complication requiring IC/ICU management
Grade 4a	Single organ dysfunction (including dialysis)
Grade 4b	Multi organ dysfunction

IC intensive care, ICU intensive care unit

All the patients underwent LR using a 1-mm-thick expanded polytetrafluoroethylene mesh (DualMesh, WL Gore and Associates, Flagstaff, AZ, USA) tailored to overlap all hernia margins at least 3 cm. No effort was made to approximate the edges of the hernia opening. The mesh was fixed either by a double-crown of tacks (ProTack; TycoUSS, Norwalk, CT, USA) or with a single circle of tacks along the periphery of the mesh combined with transabdominal sutures placed equidistant along the perimeter of the mesh. The method of fixation was determined by the surgeon for all but 199 patients who were part of randomization for another study [6].

All the patients were scheduled to return for a follow-up examination 2, 6, and 12 weeks after discharge and then thereafter when they had any type of LR-related problem. Nearly all the patients included in this study (98.4 %) were patients belonging to the adherence area of the hospital. It can be assumed that practically all these patients would return to our hospital for subsequent medical treatment, including treatment of problems related to LR of their hernias.

Data analysis

The analysis was performed on an intention-to-treat basis. For the purpose of this study, the patients were divided into two groups. Group 1 consisted of IVH, and group 2 consisted of PVH. Repair of IVH included both primary and recurrent incisional hernias as well as all recurrent PVHs. Repair of PVH included umbilical, epigastric, lumbar, and Spigelian hernias. The data were collected in an Excel database. Statistical analyses were performed using the Statistical Package for Social Sciences for Windows, version 15.0 (SPSS Inc., Chicago, IL, USA). Categorical variables were compared by the Chi square test, and continuous variables were compared using the independent-samples t test. A P value lower than 0.05 was considered statistically significant.

Results

The study enrolled 1,088 patients, 426 in the IVH group and 662 in the PVH group. The baseline characteristics of the two groups are presented in Table 2.

The operative findings are compared in Table 3, with consistent differences demonstrated between the two groups. Of the 30 conversions to open repair in the IVH group, 14 were due to bowel injury during either open introduction or subsequent adhesiolysis, and 16 were due to adhesions deemed not safe for laparoscopic lysis. Of the three converted procedures in the PVH group, one was due to bowel injury during adhesiolysis, and two were due to severe adhesions.

The postoperative complications of the two groups and pooled data are compared in Table 4. Adhesiolysis occurred almost exclusively in the IVH group, with 38 % patients requiring extensive adhesiolysis. Extensive adhesiolysis correlated with a greater number of complications (Dindo-Clavien grade ≥3) than nonextensive adhesiolysis (33% vs 12%; $p<0.001$).

Table 2 Demographic data according to hernia group

	IVH group (n=426)		PVH group (n=662)		*P* value
Mean age at operation (years)	54.99 ± 13.85		51.27 ± 13.47		< 0.001
Gender: *n (%)*					
Male	195 (45.77)		460 (69.49)		< 0.001
Female	231 (54.22)		202 (30.51)		
Mean ASA classification	1.92 ± 0.72		1.68 ± 0.70		< 0.001
Hernia localisation *n (%)*	Midline	255 (59.86)	Umbilical	456 (68.88)	
	Trocar site	68 (15.96)	Epigastric	170 (25.68)	
	Subcostal	36 (8.45)	Spigelian	35 (5.29)	
	Lumbar	18 (4.23)	Lumbar	1 (0.15)	
	Transverse	19 (4.46)			
	Pfannenstiel	7 (1.69)			
	McBurney	23 (5.56)			

IVH incisional ventral hernia, *PVH* primary ventral hernia, *ASA* American Society of Anaesthesiologists

Table 3 Operative findings of the pooled data according to hernia group

	Pooled data (*n*=1088) *n(%)*[a]	IVH group (*n*=426) *n(%)*	PVH group (*n*=662) *n(%)*	*P* value[b]
Open introduction	159 (15.07)	143 (36.11)	16 (2.43)	< 0.001
Mean no. of trocars	2.86 ± 0.78	3.16 ± 0.73	2.40 ± 0.61	< 0.001
Adhesiolysis	307 (28.22)	301 (70.66)	6 (0.91)	< 0.001
Conversion to open procedure	33 (3.03)	30 (7.04)	3 (0.45)	< 0.001
Mean hernia size (cm^2)[c]	9.86 ± 22.36	23.04 ± 33.00	2.41 ± 3.77	< 0.001
Mean mesh size (cm^2)[c]	213.16 ± 154.35	322.94 ± 199.00	148.79 ± 58.26	< 0.001
Double-crown fixation[c]	728 (69)	276 (69.70)	452 (68.59)	0.724
Median no. of tacks[c]	34.58 ± 21.28	52.15 ± 26.46	28.13 ± 14.54	< 0.001
Length of procedure (min)[c]	53.73 ± 33.70	72.56 ± 42.79	42.27 ± 19.14	< 0.001
Hospital stay (days)[c]	3.33 ± 3.99	4.53 ± 5.79	2.43 ± 1.00	< 0.001

IVH incisional ventral hernia, PVH primary ventral hernia
a Pooled data are combined data of IVH and PVH
b Comparison of the IVH and PVH groups
c Converted patients are excluded

Table 4 Early (within 30 days) and late (after 30 days) postoperative complications according to hernia group

	Pooled data (n=1055) n(%)[a]	IVH group (n=396) n(%)	PVH group (n=659) n(%)	P value[b]
Early complications				
Bleeding	4 (0.38%)	2 (0.51%)	2 (0.30%)	0.604
Prolonged Ileus	10 (0.95%)	5 (1.26%)	5 (0.76%)	0.308
Wound infection	1 (0.09%)	1 (0.25%)	0 (0.00%)	0.196
Mortality (not specific to LR)	3 (0.28%)	3 (0.76%)	0 (0.00%)	0.025
Unrecognised bowel lesion (diagnosed postoperatively)	3 (0.28%)	3 (0.76%)	0 (0.00%)	0.025
Late complications				
Pain followed by re-operation (removal of fixation)	8 (0.76%)	4 (1.01%)	4 (0.61%)	0.463
Bulging of mesh	13 (1.23%)	8 (2.02%)	5 (0.76%)	0.071
Trocar site hernia	15 (1.42%)	12 (3.03%)	3 (0.46%)	0.001
Recurrent hernia	32 (3.03%)	23 (5.81%)	9 (1.37%)	< 0.001
Clinically relevant chronic seroma	5 (0.47%)	3 (0.76%)	2 (0.30%)	0.297
Mesh infection	10 (0.95%)	10 (2.53%)	0 (0.00%)	< 0.001
Total complications (Dindo-Clavien grade ≥3)	104 (9.86%)	74 (18.69%)	30 (4.55%)	< 0.001

Converted patients are excluded
IVH incisional ventral hernia, PVH primary ventral hernia, LR laparoscopic repair
a Pooled data are combined data of IVH and PVH
b Comparison of the IVH and PVH groups

Discussion

Adult ventral hernias are defects in the abdominal wall that develop spontaneously (PVH) or as a complication of prior abdominal surgery (IVH). The latter represents a wide spectrum of either single or multiple defects that can appear at any site where an incision was made and with an extreme range in size from minimal defects to giant defects with complete loss of domain. Even if only a small segment of an incisional scar appears to be insufficient, the remainder of the scar, comprising collagenous tissue of inferior quality [15], should not be considered "entirely sufficient" and must also be corrected to prevent later development of herniation [16]. In contrast, PVHs are mostly small solitary defects originating at typical locations (e.g., epigastric or umbilical) and surrounded by healthy intact abdominal wall. As a rule, due to apparent differences in etiopathology, the literature on open repair maintains a distinct separation between PHV and IVH.

The first LR of ventral hernia of the abdominal wall was described by LeBlanc and Booth [17] in 1993. This new technique has slowly but surely gained popularity, and, probably to increase the number of patients included for analyses, the first large series pooled outcomes and results of PVH and IVH together [2, 17–19]. Although differences between LR of PVH and IVH were reported as early as 1999 [20], pooling has remained a habit to date. The results of this study demonstrate apparent differences in the baseline characteristics between the two types of ventral abdominal wall hernias. Although statistically significant, these differences do not pose as clinically significant and by themselves do not pose a strong argument against "pooling." A greater prevalence of female patients in the IVH group, for reasons not completely clear, has been noted previously [21, 22].

The operative findings of the current study, however, clearly indicate that LR of IVH is a much more complex procedure than LR of PVH in every aspect and at every stage of the operation. Access to the abdomen of IVH patients is more difficult and carries a potential risk for bowel lesion. Adhesions, exceptional in PVH patients with no previous abdominal surgery, are common in patients with IVH. All the bowel lesions and conversions in the current series were in one way or another related to adhesions. When the presented data are pooled, a conversion rate of 3 % can be misleading, masking a striking 14-fold difference between the IVH group (7 %) and the PVH group (0.5 %).

The presence of adhesions and features of their lysis seem to be critical in determining the complexity and risks of a procedure [23]. Extensive adhesiolysis was required exclusively in the IVH group and correlated with a higher percentage of complications than nonextensive adhesiolysis in the same group. The IVH group with nonextensive adhesiolysis had significantly more complications than the PVH group, in which adhesions were very rare.

Interestingly, a recent study on a similar issue [22] reported that 73 % of the PVH patients required lysis of adhesions, compared with only 0.9 % reported in the current study. The most likely explanation for this enormous difference could be that we did not encode de-insertion of the *ligamentum teres hepatis*, nearly always required for adequate application of the mesh over the hernia defect, as adhesiolysis.

After completion of adhesiolysis, the most complex part of LR, a much safer and more technical part of the procedure takes place: introduction, positioning, and fixation of the mesh. Not surprisingly, patients with IVH had larger hernia defects, requiring larger meshes and more tackers for fixation. All this together with eventual adhesiolysis contributed to a longer LOP than in the PVH group.

The mean hospital stay in this series (3.33 days) was somewhat higher than that reported in the literature (2.3–3.0 days) [2–4], possibly because at our institution LR of ventral hernias is not performed as day-care surgery, as is customary in some other institutions. A longer LOS in the IVH group is in accordance with previous studies [22, 24]. A number of factors potentially contribute to a longer LOS including differences in age and ASA grade, conversion rate, LOP, use of larger meshes and more tackers, and certainly, a higher incidence of postoperative complications.

The complication rate (Clavien grade ≥3) of 18.69 % for IVH in this study is comparable with complication rates reported in other studies (16.4–31.5 %) [25–27] and significantly higher than the rate (4.55 %) for the PVH group. A number of factors may have contributed to this dissimilarity including differences in age and ASA grade, use of more and larger trocars, adhesiolysis and overall procedural complexity, larger hernias, use of both larger meshes and more fixation, LOP, and higher recurrence rate. Similar to the conversion rate, a pooled complication rate of 9.86 % was not representative for either the IVH group, with a twofold higher complication rate, or the PVH group, with a complication rate of less than half the pooled rate. Interestingly, Kurian *et al* [22] found no significant difference in overall morbidity between the two groups (23 % for IVH vs 16 % for PVH).

A recurrence rate more than four times higher in the IVH group also can be overlooked if only pooled data are presented. Besides a larger hernia size in the IVH group, a disregard for the principle of treating the whole incision and not only a hernia defect certainly plays an important role [16].

The results of the current study demonstrate important differences in all aspects related to LR of IVH and PVH, from patient characteristics to complexity and risks of procedure to intra- and postoperative complications to late outcome. Surgeons in their "learning curve"

of acquiring skills for performance of LR must be aware of these differences and respect them. Using "pooled data" evidently leads to inexact preoperative counseling of patients and may seriously call into question the correctness of the acquired informed consent. Clearly, the practice of pooling these two entities together should come to an end.

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CHAPTER 3

Persistent posterior seroma after laparoscopic repair of ventral abdominal wall hernias

Prevalence, independent predictors and loose tacks

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Abstract

Purpose

A persistent seroma located posterior to a mesh (PPS) remains a little known complication after laparoscopic ventral hernia repair (LVHR). The aim of this large case series was to analyse the prevalence and clinical course as well as identify related factors and independent predictors of PPS.

Methods

All 1288 adult patients who underwent a LVHR with an expanded polytetrafluoroethylene mesh (ePTFE) between January 2003 and July 2014 were reviewed. Those who underwent an abdominal computed tomography (CT) scan more than three months afterwards (n=166) were included and their scans were analysed. The primary outcome measure was the prevalence of a PPS and its characteristics. The secondary outcome measures were identification of significantly related factors and independent predictors of PPS.

Results

A PPS was observed in fourteen of 166 analysed CT scans (8.4%). Eleven patients were symptomatic; conservative treatment (wait-and-see policy) was successful in eight. Three underwent relaparoscopy with removal of a thick neoperitoneum. Several instances of tack and / or mesh detachment were identified on CT scans and during relaparoscopy. Independent predictors were: >3 trocars (RR 5.0 95% CI 1.6-15.8) and use of a mesh larger than >300cm^2 (RR 9.9 95% CI 1.9-51.2).

Conclusions

A PPS is a relatively common complication after LVHR with an ePTFE mesh of usually larger hernias. A "wait-and-see" approach seems justified in most cases. Some require laparoscopic excision of the thick neoperitoneum. A PPS can cause tack and mesh detachment but the clinical consequences are unclear. Recurrences have not been observed in this series.

Introduction

A *persistent* seroma located posterior to a mesh remains a little known complication after laparoscopic ventral hernia repair (LVHR). It has been first described in 2003 by Heniford *et al* [1] who defined a *persistent* posterior seroma (PPS) as "a fluid collection [developed] under the mesh, in association with extensive peel or rind that separated the mesh and underlying fluid from the abdominal contents". Not more than one case series [2] and one case report [3] have addressed a PPS specifically, since. More reliable information on *early* posterior seroma was provided by a recent prospective cohort study limited to the first three months postoperatively [4].

Herein, we present the largest case series of PPS described so far. The aim of this study is to determine its prevalence, identify related factors and independent predictors, and discuss the clinical consequences of this complication. In addition, a novel observation of tack and mesh detachment as a result of PPS has been described.

Material and methods

The medical records of all 1288 adult patients (≥18 years) who underwent a LVHR at a teaching hospital between January 2003 and July 2014 were reviewed. Patients who underwent an abdominal computed tomography (CT) scan more than three months after LVHR - for whichever indication - were identified and included in this study.

The primary outcome measure was the prevalence and characteristics of a PPS. A PPS was defined as a fluid collection located at the visceral side of a mesh that is separated from the abdominal contents by a neoperitoneal membrane and lasting beyond three months after LVHR.

The secondary outcome measures were identification of significantly related factors as well as independent predictors of a PPS. After reviewing all abdominal CT scans, patients were divided into two groups and compared to each other - the first with PPS and the second without.

The operative technique has previously been described in detail [5]. In all cases, a 1mm thick expanded polytetrafluoroethylene (ePTFE) mesh (DualMesh™, WL Gore and Associates, Flagstaff, AZ USA) was used. Fixation was achieved with either a combination of transabdominal sutures (TAS) and tacks or a double-crown of tacks. For tacking, nonabsorbable titanium tacks (Protack™, TycoUSS, Norwalk, CT, USA) were used.

The patient characteristics, operative data and postoperative complications of the LVHR cohort were prospectively registered in an electronic database at the moment of presentation. Approval from the institutional review board was not required for this study. The procedure was recorded and representative photographs were taken for all patients with a PPS who underwent subsequent relaparoscopy.

Statistical analyses were performed using the Statistical Package for Social Sciences for Windows, version 20.0 (SPSS Inc., Chicago, IL, USA). Categorical variables were compared by the chi-square test, and continuous variables were compared using the Mann Whitney U test. A univariate analysis was performed to identify factors significantly related to a PPS. A multivariate analysis (logistic regression) was performed to obtain independent predictors of a PPS. It included all factors likely to influence development of a PPS with a univariate $P \leq 0.10$. A P value ≤ 0.05 was considered statistically significant.

Results

A total of 166 patients were identified who underwent an abdominal CT scan more than three months (median 15 months, interquartile range (IQR) 26, range 3-121 months) after LVHR. The indication for a CT scan was LVHR-related in 122 patients. They presented with swelling, pain or both. Other indications (n=44) were related to gastro-intestinal oncology, abdominal aorta reconstruction, urology, gynaecology and others.

In fourteen patients (8.4%) a PPS was detected on a CT scan after LVHR (median 6 months, IQR 7, range 4-18 months). On average, the anteroposterior thickness of a PPS as measured on an axial CT scan was 36mm (range 11-131mm). In two patients (14%) a PPS was accompanied with a ventral seroma. In six patients (43%) several tacks were detached from the abdominal wall and the mesh. No radiological recurrences were observed in conjunction with PPS. Median follow up was 11 months (IQR 13, range 9-55).

Three of the fourteen patients were asymptomatic. Eleven patients were symptomatic and had complaints of pain, swelling or both. Conservative treatment - wait-and-see policy together with analgesia - was successful in eight patients in whom physical complaints resolved spontaneously within a few months upon detection (mean 3±2, range 2-5 months). Percutaneous drainage was not considered as a treatment option. Three patients retained physical complaints and they underwent relaparoscopy.

During relaparoscopy the PPS was covered by a thick neoperitoneum that resembled a “pseudocystic wall”. After opening the thick neoperitoneum and aspirating clear fluid,

introduction of the camera allowed unhindered inspection of the mesh and the neoperitoneum from the inside.

Two types of tack detachment were observed. First, tacks were detached from the mesh but held firmly in the thick neoperitoneum (Fig. 1). The imprint of their previous position in the mesh remained visible. The tacks that were detached from the inner ring were consistent with those visibly detached on the CT scan. The tacks that were detached from the outer ring at the very edge of the mesh were not distinctly visible as detached on the CT scan. Second, the periphery of the mesh was detached from the abdominal wall with the tack still attached to the mesh itself (Fig. 2). This type of detachment can be difficult to recognize on a CT scan as well.

In general, there were always more tacks detached than was apparent beforehand on a CT scan. In rough estimation, the proportion of detached tacks was 5-10% of their total number. Regardless, there were no recurrences observed during the relaparoscopies. The thick neoperitoneum was excised and histological examination mostly showed lymphoid and collagen tissue resembling a foreign body reaction. Recovery was uneventful in all three patients and they remained pain free thereafter. No posterior seroma recurrences were detected in this small group.

Patient- and surgical-specific factors of both groups are presented in Table 1. A univariate analysis identified five significant factors related to a PPS and which were subjected to a multivariate analysis (Table 2). Two independent predictors of PPS were found: the use of >3 trocars (RR 5.0 95% CI 1.6-15.8) and the use of a mesh larger than >300cm^2 (RR 9.9 95% CI 1.9-51.2).

Table 1 Patient- and surgical-specific factors

Variable	Posterior seroma (n=14) *n (%)*	No posterior seroma (n=152) *n (%)*	P value
Gender			
Male	8 (57)	90 (59)	0.88
Female	6 (43)	62 (41)	
Mean age (years)	55.10 ± 11.86	56.48 ± 14.45	0.73
Mean ASA	1.86 ± 0.77	1.86 ± 0.69	0.98
Mean Trocars	3.71 ± 1.20	3.11 ± 0.83	0.006
Mean hernia size (cm2)	69 ± 73	24 ± 36	0.004
Mean mesh size (cm2)	504 ± 171	368 ± 257	0.016
Mean length of procedure (minutes)	86 ± 40	74 ± 50	0.10

ASA American Society of Anaestesiologists

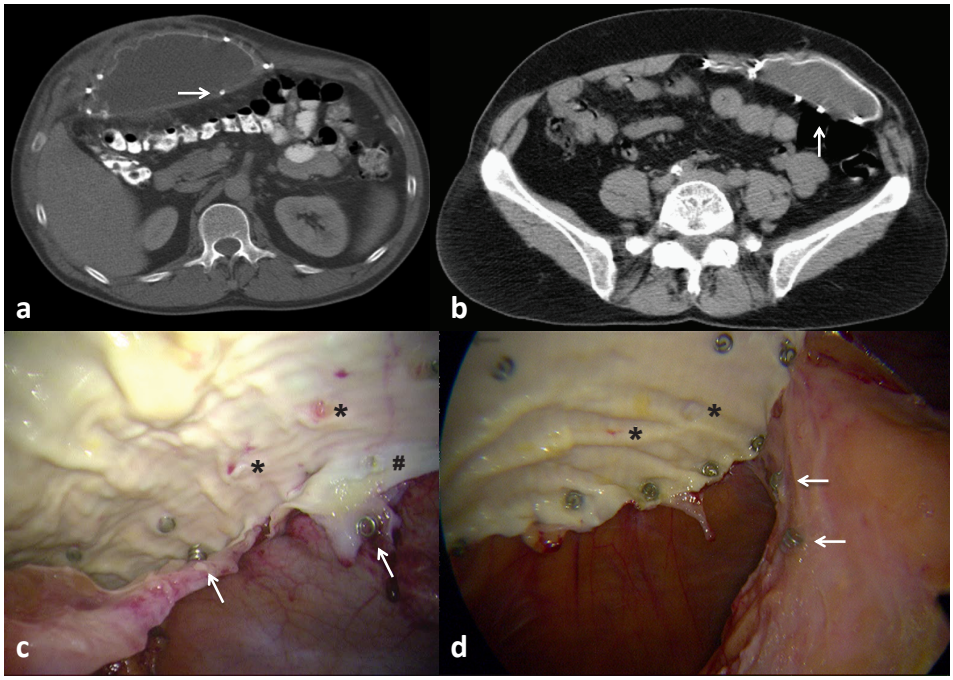

Fig. 1 **a** and **b** Loose tacks from the inner ring as seen on a CT scan (arrows). **c** and **d** Tacks still held firmly in the thick neoperitoneum (arrows). Their imprint on the mesh was still seen at the inner ring (*) as well as the outer ring (#)

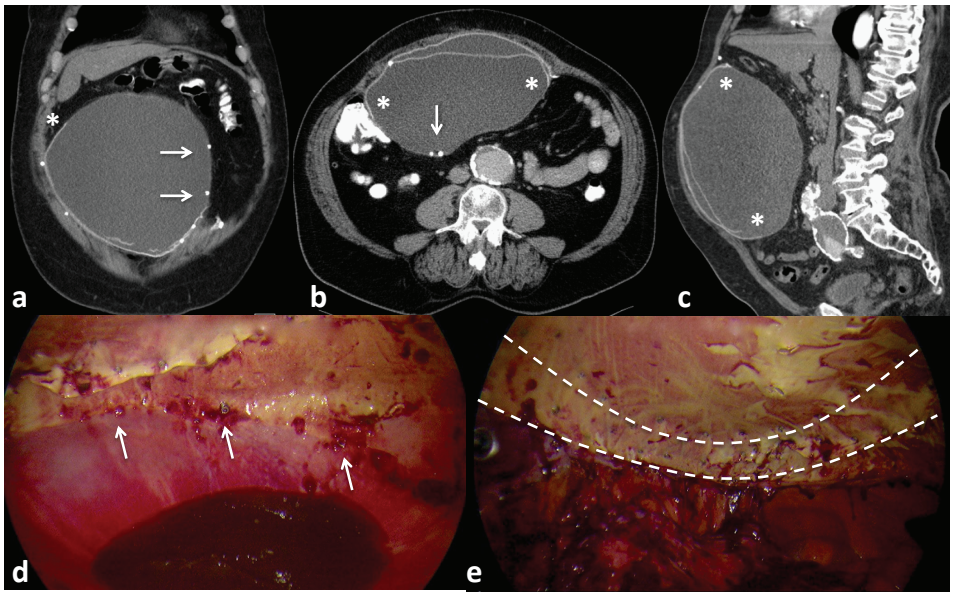

Fig. 2 Posterior seroma in one single patient presented on an abdominal CT scan and during relaparoscopy. **a**, **b** and **c** Different cross sections with loose tacks (arrows) and loose periphery of the mesh (*). **d** View from inside the posterior seroma with the thick neoperitoneum still attached to the circumference of the mesh. Several detached tacks can be seen (arrows). **e** Detachment of the periphery of the mesh from the abdominal wall (in between dotted lines)

Table 2 Univariate and multivariate analysis of predictive factors of postoperative seroma

	Seroma				
	Yes	No			
Variable	N=14	N=152	UV *P*	MV *P*	RR (95% CI)
Patient factors					
Gender					
Male	8 (57%)	90 (59%)	0.88	-	-
Female	6 (43%)	62 (41%)			
Age at operation					
≤ 50 years	5 (33%)	50 (33%)	0.84	-	-
> 50 years	9 (67%)	102 (67%)			
ASA score					
1-2	11 (79%)	125 (82%)	0.73	-	-
3	3 (21%)	27 (18%)			
Incisional hernia					
Yes	11 (79%)	96 (63%)	0.25	-	-
No	3 (21%)	56 (37%)			
Operative factors					
Number of trocars					
≤ 3	7 (50%)	128 (84%)	0.003*	0.006	5.0 (1.6-15.8)
> 3	7 (50%)	24 (16%)			
Hernia size					
≤ 15 cm^2	2 (14%)	94 (62%)	0.003*	NS	-
> 15 cm^2	12 (86%)	58 (38%)			
Mesh size					
≤ 300 cm^2	2 (14%)	90 (59%)	0.002*	0.006	9.9 (1.9-51.2)
> 300 cm^2	12 (86%)	62 (41%)			
Adhesiolysis					
Yes	11 (79%)	90 (59%)	0.15	-	-
No	3 (21%)	62 (41%)			
Operation time					
≤ 50 minutes	1 (7%)	55 (36%)	0.03*	NS	-
> 50 minutes	13 (93%)	97 (64%)			
Current operation for hernia recurrence					
Yes	4 (29%)	7 (5%)	0.001*	NS	-
No	10 (71%)	145 (95%)			

Discussion

Recently, Morales-Conde *et al* [4] investigated *early* posterior seroma in a prospective case series of 50 patients who underwent a CT scan at one week, one month and three months after LVHR. They reported an incidence of 44%, 33% and 16% respectively. The clinical evolution beyond three months of an *early* posterior seroma into a PPS was not described.

Reported prevalence of PPS in the literature ranges from 0.35% (n=3/850) [1] to 1.3% (n=6/442) [2]. In both studies only patients who returned with symptoms such as swelling and pain were investigated and it remains unknown how many cases of asymptomatic PPS went unnoticed.

The estimated prevalence of PPS observed in this series (8.4%) was much higher than previously estimated but it is not surprising since Morales-Conde *et al* [4] detected a posterior seroma in 16% of patients at three months after surgery. However, the influence of a selection bias in this series cannot be excluded: it remains unknown how many cases of PPS remained unnoticed in those who had no CT scan after LVHR.

The ePTFE mesh and titanium tacks were easily distinguished on all CT scans regardless of study protocol [6]. The unique radiopaque feature of mesh and tacks simplified the identification of a PPS and has made it unlikely that a PPS has been missed during the review of CT scans. This radiopaque feature also proved useful in detecting the detachment of tacks from the mesh as well as detachment of the mesh from the abdominal wall itself.

Whether a PPS is exclusively related to ePTFE meshes remains unclear but it seems probable. There seems to be an association between the two and we could not find a comparative group with a different type of mesh. With the anecdotal exception of two single cases, all the reported cases of PPS in the literature and in this study occurred after implantation of ePTFE meshes [1, 2, 4]. In a single case, O'Brien *et al* described a fluid collection located posterior to a biologic implant (Permacol™, Covidien, Mansfield, MA, USA) 23 months after LVHR [7].

However, it is questionable whether it was a case of a PPS because the authors used the terms "hematoma" and "bursa". In another single case, Tseretelli *et al* briefly mentioned a posterior seroma formation after implantation of a hydrophilic mesh (Parietex Composite™, Covidien, New Haven, CT, USA) without commenting on the time frame of the complication or describing the CT scan characteristics after LVHR with this radiotransparent mesh [2]. Remarkably, a recent cohort study reporting the long-term outcomes of 1326 patients after LVHR with the same hydrophilic mesh does not mention the occurrence of a PPS at all [8].

There are several possible explanations for the possibly exclusive association of PPS with ePTFE meshes. First, the ePTFE mesh seems to be predestined for the development of a PPS due to its non-porous mesh construction. All other currently used meshes (e.g. polypropylene and polyester) have a knitted mesh structure.

The secretory properties of the neoperitoneum are modulated by a local inflammatory response to the ePTFE mesh. Interestingly, the inflammatory response is more pronounced with polypropylene and polyester meshes which have not shown an association with PPS so far [9]. This might indicate that another characteristic of ePTFE mesh, such as its structure, plays an important role. Unlike the woven or knitted characteristics of other meshes, ePTFE is a single seamless structure. Despite being microporous, ePTFE has a low friction coefficient making its surface smooth and hydrophobic. Whereas the neoperitoneum paving over the ePTFE mesh is attached firmly to the tacks and the edges of the mesh, it is very loosely attached to the smooth surface of the mesh [10]. Actively secreted fluid by the neoperitoneum has a potential to separate itself from the ePTFE mesh and thus create a posterior seroma. All other meshes (e.g. polypropylene and polyester) are knitted and are embedded with strong interlinking connective tissue through the mesh pores, possibly making separation of the neoperitoneum from the mesh less likely [9].

Several factors seem to influence the occurrence of a PPS after implantation of ePTFE meshes. The results of the statistical analyses indicate that laparoscopic repair of larger ventral hernias carries a higher risk for the development of a PPS. Larger hernias require the utilisation of more resources like a larger mesh, approach from both sides of the abdomen with more trocars, and a longer procedure. Two independent predictors of PPS were identified; the use of >3 trocars (RR 5.0 95% CI 1.6-15.8) and the use of a mesh larger than >300cm^2 (RR 9.9 95% CI 1.9-51.2).

Based on these observations, a PPS could cause two types of detachment, a phenomenon described in this report for the first time. First, tacks may become detached from the mesh, which remains attached to the abdominal wall. Second, the periphery of the mesh – together with the tacks - may become detached from the abdominal wall itself. Although technically inappropriately placed tacks at the initial LVHR cannot be completely excluded, other mechanisms seem to be more probable. The accumulation of actively secreted serous fluid between the thick neoperitoneum and the mesh creates a rise of hydrostatic pressure inside that closed space. This force acts in all directions and separates the thick neoperitoneum and the mesh from each other. This process progresses gradually from a plate-like seroma into a spherical seroma (Fig. 3). It can be assumed that during this transition a tack may become detached if the strength of the attachment in the thick neoperitoneum exceeds that of the connection with the mesh and with underlying abdominal

wall. At a later stage, this process increases detachment forces of tacks at the periphery of the mesh where the thick neoperitoneum is more firmly attached than elsewhere and may pull the edge of the mesh away from the abdominal wall.

A median follow up period of eleven months was not long enough for a meaningful calculation of recurrence rate after LVHR. Nonetheless, in those cases with tack detachment no recurrences were observed. It might well be that the mesh becomes sufficiently incorporated at the abdominal wall side earlier than a PPS develops and eventual detachment takes place. Also, the increasing hydrostatic pressure induced by the PPS might on the one hand have a tendency to detach the very edges of the mesh and some of its tacks, but on the other hand it also pushes the rest of the mesh towards the abdominal wall and in that way prevents the occurrence of a recurrence.

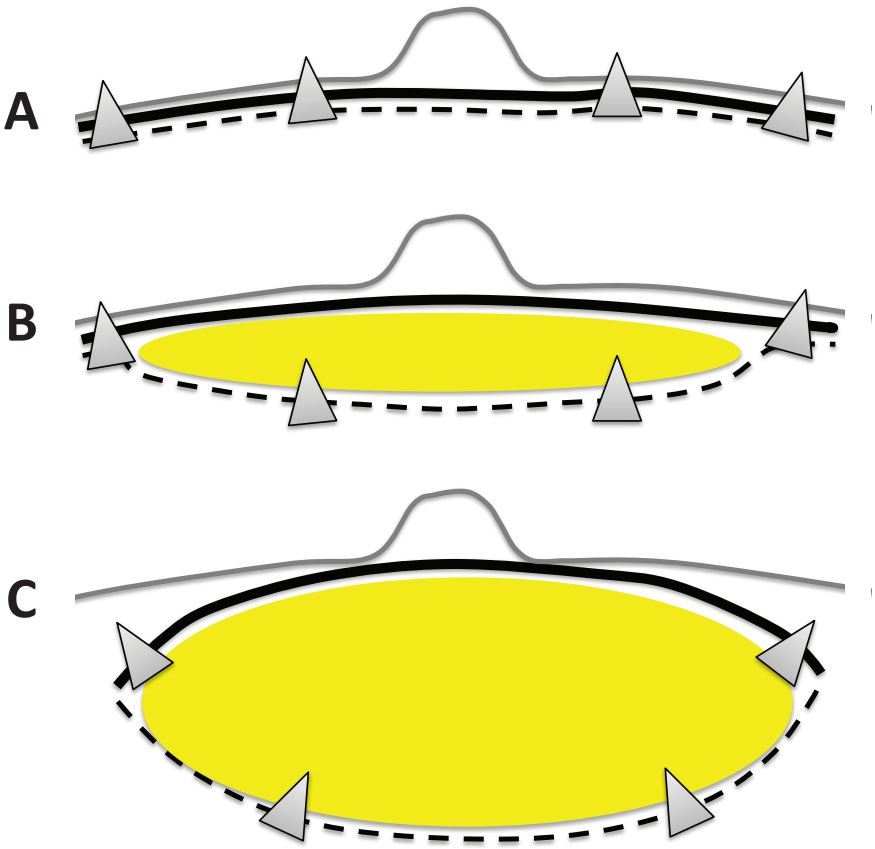

Fig. 3 A normal situation, **B** plate-like posterior seroma with inner circle tacks detached, **C** spherical posterior seroma with also the periphery of the mesh with tacks detached. Peritoneum (grey line). Mesh (black line). Thick neoperitoneum (dotted line). Tack (triangle). Posterior seroma (yellow sphere)

It remains unclear in what way mesh shrinkage influenced tack detachment after LVHR. The little available *clinical* literature on mesh shrinkage after LVHR report low contraction rates and no instances of tack detachment [11–14]. However, its role could not be ruled out.

Asymptomatic patients are likely to stay asymptomatic. In those with minimal symptoms a "wait-and-see" policy proved to be appropriate in this series. This policy is in accordance with the proposed treatment guidelines of Tseretelli *et al* [2].

Percutaneous drainage was not considered as a treatment option for two reasons. First, it carries the risk of infection of the mesh. Second, it does not offer a definitive solution for the fluid would most likely accumulate again after percutaneous drainage. Percutaneous drainage of a posterior seroma failed in all attempts according to two studies [1, 2].

Surgical treatment was indicated in approximately 21% of cases due to persisting and/or progressive symptoms. In those cases an extensive laparoscopic excision (deroofing) of the thick neoperitoneal membrane provided definitive treatment of PPS. Tsereteli *et al* reported that >50% of patients with a PPS required surgical treatment [2]. The probable explanation for this difference is that latter study included only patients who returned with significant symptoms related to PPS and did not include asymptomatic cases of PPS.

A PPS seems to be a relatively frequent complication after laparoscopic repair of usually larger ventral hernias with ePTFE meshes. An initial wait-and-see policy seems justified. A subset of symptomatic patients may require laparoscopic excision of the thick neoperitoneum that provides a good outcome. That PPS causes detachment of a significant number of tacks and the periphery of the mesh itself is a novel observation and has been described here for the first time. Clinical consequences of this phenomenon are not completely clear but recurrences have not been observed in this series.

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CHAPTER 4

Pregnancy following laparoscopic mesh repair of ventral abdominal wall hernia

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Abstract

Background

There are no data on laparoscopic repair of ventral and incisional hernias (LRVIH) in fertile women who intend to have further pregnancies. A unique series is described of 8 women who got pregnant and gave birth after LRVIH.

Methods

Medical records of 875 consecutive patients who underwent LRVIH were reviewed. Women who gave birth after LRVIH were identified. At follow-up, patients answered a questionnaire on pain, discomfort, recurrence, and problems during pregnancy and delivery and underwent a physical examination.

Results

Eight patients were identified; all agreed to inclusion. Four women received LRVIH for incisional hernia; 4 were operated on for primary ventral hernia. Median age at LRVIH was 29 years (range, 24 to 34). No postoperative complications occurred. Median time between LRVIH and delivery was 22.5 months (range, 12 to 44). Median follow-up after delivery was 23.5 months (range, 2 to 40). Five patients experienced a tearing pain in the area of hernia repair during the last months of pregnancy. This pain was not continually present and disappeared after delivery in all patients. All infants were born healthy at full term. Seven patients had a vaginal birth and one had a caesarean delivery. There were no major complications during pregnancy or delivery. At control examination, all patients were asymptomatic and, with one exception, without signs of recurrence. One patient had a swelling in the repaired area indicating either recurrence or mesh bulging. Being asymptomatic, she refused any further diagnostics.

Conclusion

LRVIH in fertile women who intend to have further pregnancies is an acceptable therapeutical option that causes no significant problems during pregnancy or delivery.

Introduction

Available data on treatment strategies for anterior abdominal wall hernias in women of childbearing age are scarce. No "best practice" guidelines exist. This is probably because the majority of women have these hernias repaired after the childbearing age [1]. However, "watchful waiting" in ventral abdominal wall hernias before pregnancy is not entirely benign. Clearly, a repair should be seriously considered at least in symptomatic patients and if the risk of incarceration of an untreated hernia seems to be present. Data regarding laparoscopic repair (LR) in this patient category are nearly completely missing. Altogether, a Medline/Embase search revealed only one case report on LR of hernia during pregnancy [2] and one case report on a patient with a successful vaginal delivery after previous LR of an omphalocele [3]. We describe a unique series of 8 women who got pregnant and gave birth following laparoscopic repair of ventral or incisional hernia (LRVIH).

Patient and methods

Medical records of all 875 patients who underwent LRVIH at the ZGT Hospital Almelo, The Netherlands, between January 2000 and April 2011 were reviewed. Female patients between 18 and 45 years of age at the time of LRVIH were identified and contacted by telephone. All women who experienced childbirth after LRVIH were asked to come to our outpatient clinic for a physical examination and to answer a questionnaire on pain, discomfort, recurrence, and problems during pregnancy and delivery.

Surgical technique

LRVIH was performed using an expanded polytetrafluoroethylene mesh (ePTFE; DualMesh, WL Gore & Associates, Flagstaff, AZ) tailored to overlap all hernia margins by at least 3cm. No attempt was made to approximate the edges of the hernia opening. The mesh was fixed either by the double-crown (DC) technique or with tacks along the periphery of the mesh and transabdominal sutures (TAS) placed equidistant along the edge of the mesh.

Data were collected in an Excel 2007 database and statistical analyses were performed using Statistical Package for Social Sciences for Windows (SPSS Inc., Chicago, IL, USA).

Results

Eight women were identified who gave birth to at least one child after LRVIH, and all agreed to return for an interview and physical examination. All patients had symptomatic ventral abdominal wall hernias before the operation (Table 1). Four patients were operated on for an incisional hernia. Two incisional hernias were caused by a Pfannenstiel incision for caesarean delivery, one incisional hernia was a trocar-site hernia after laparoscopic cholecystectomy, and one incisional hernia was in fact a recurrent epigastric hernia that was treated earlier by open primary suture correction.

Prenatal ultrasound examinations performed by gynaecologists did not mention the presence of mesh.

Median age at LRVIH was 29 (range, 24 to 34). Median operating time (skin-skin) was 44.5 minutes (range, 39 to 76). No complications occurred during surgery or postoperatively. The median time between LRVIH and first delivery after LRVIH was 22.5 months (range 12 to 44 [Table 2]). Median follow-up after surgery was 46 months (range, 19 to 72). Median follow-up after first delivery after LRVIH was 23.5 months (range, 2 to 40).

Table 1 Baseline and Operative Characteristics

Patient Number	Hernia Type	Age at Surgery	LOP (min)	Mesh Size	Fixation Method
1	Epigastric	34	42	10x15cm	DC
2	Umbilical	29	47	8x12cm	T&TAS
3	Epigastric	30	58	10x15cm	T&TAS
4	Incisional	30	34	10x15cm	DC
5	Umbilical	29	39	10x15cm	DC
6	Incisional	26	70	10x15cm	DC
7	Incisional	25	39	8x12cm	T&TAS
8	Incisional	24	76	10x15cm	T&TAS

LOP length of procedure, *DC* double-crown of tacks, *T&TAS* tacks and transabdominal sutures

One woman was admitted to the hospital twice during pregnancy for pain in the abdominal wall obviously related to her previous LRVIH. This pain was treated with oral analgesics and did not further complicate her pregnancy.

No major complications were encountered during pregnancy or during delivery. All children were born in good health and did not require hospital admission. Four women gave birth at home with a midwife (home delivery is common practice in The Netherlands), the other 4 women gave birth in the hospital. In the patient who underwent a C-section twice

after LRVIH, the first C-section was performed through the mesh that was later on closed with an nonabsorbable running suture. The second C-section was performed caudally of the mesh therefore not compromising the mesh.

Table 2 Follow-up Characteristics

Patient Number	Children Before LRVIH	Children After LRVIH	Delivery Type	Months LRVIH-Birth	Abdominal Wall Pain During Pregnancy	Recurrent Hernia
1	1	1	Vaginal	23.4	No	No
2	1	1	Vaginal	39.8	Yes	No
3	1	1	Vaginal	20.0	Yes	No
4	1	2	Caesarean Delivery	12.4	No	No
5	2	1	Vaginal	13.4	Yes	No
6	0	2	Vaginal	12.1	Yes	Yes
7	1	1	Vaginal	44.4	Yes	No
8	0	1	Vaginal (with vacuum extractor)	30.6	No	No

LRVIH laparoscopic repair of ventral or incisional hernia.

All infants were born at full term (born any time after 37 completed weeks of gestation through 42 completed weeks of gestation).

At follow-up interview, all women confirmed that preoperatively they had received extensive information about dilemmas related to the repair as well as therapeutical options. All of them had opted for LRVIH and had provided informed consent. Five women (63%) remembered a “tearing” or “pulling” pain at the area of previous repair during the last months of pregnancy, of an intensity of 50 or more on a visual analogue scale (scale 0 to 100). This pain disappeared immediately after delivery in all patients. All women (n=6) who had given birth before and after LRVIH mentioned more pain in the abdominal wall during pregnancy after LRVIH than during pregnancy before LRVIH. All women returned completely to their daily activities as before delivery, with the exception of one woman who gave birth 2 months before our follow-up examination. None of the patients experienced chronic pain in the repaired area (mean VAS 15).

At follow-up examination, one patient had a swelling in the area of previous LRVIH, probably due to a recurrence of an incisional hernia or bulging of the mesh. Being entirely asymptomatic, she did not want further diagnostics or treatment.

Discussion

Traditionally, there exists a reluctance to repair hernias in young fertile women, because of the possible disadvantageous impact on pregnancy, and possible association with a high risk of recurrence. Contrarily, no evidence exists to support "watchful waiting." There are, however, scattered reports indicating that "watchful waiting" can be harmful when symptomatic hernias progress during pregnancy due to stretching of the abdominal wall. Progressive herniation causing incarceration of the gravid uterus or strangulation of bowel can cause pressure necrosis of the hernia wall, spontaneous rupture of the hernia, premature labour, abortion, intrauterine and maternal death [4–9]. Indication for repair of a symptomatic ventral or incisional hernia in females of childbearing age should be considered to prevent the deleterious implications of herniation during pregnancy. With the aforementioned lack of evidence supporting either "watchful waiting" or repair, it is up to the surgeon to construe the best approach on a case-by-case basis.

Weighing of various risks in establishing an indication for repair should also include the risk of symptomatic hernia recurrence during pregnancy, the risk of reoperation postpartum for a hernia recurrence, and the risk of hernia repair related complications during pregnancy. In addition, potential risks of repair for a future pregnancy, such as premature labour or preterm delivery, should also be considered.

In the only larger study on ventral hernia repair before pregnancy, Abrahamson and Gorman [1] reported a series of 27 women who underwent open sutured repair. Although they did not observe recurrences either during or after subsequent pregnancies or complications during pregnancies and deliveries, reservations regarding suture repair of even small hernias are well known, because of its very high long-term recurrence rate [10]. It may be hypothesized that recurrence rates are not less after pregnancy. Reinforcement of primary suture repair with biological materials might be a very promising alternative, but studies on this issue are missing so far.

Repair of ventral abdominal wall hernias with synthetic mesh has become a "gold standard" in the general adult population. However, with the possibility of a future pregnancy in mind, there is a reluctance regarding implantation of synthetic mesh in the abdominal wall of the reproductive female. The foreign body reaction and scarring associated with mesh repair has in theory a potential to affect fertility and pregnancy. Given the expansion of the abdominal wall during pregnancy, biomaterial characteristics of shrinkage and compliance should be considered. It has been previously shown that the flexibility of the abdominal wall may be restricted by large mesh implants [11]. However, so far there are actually no

data indicating that mesh repair of symptomatic ventral hernias should be prohibited in the reproductive woman who desires future pregnancy.

Accepting that hernia repair with a larger mesh can have adverse effects on the physiology of the abdominal wall during pregnancy, we limited LR only to small hernias and used, consequently, small meshes for correction. Our experience indicates that this type of repair provides good long-term results causing no significant problems during pregnancy or at delivery. Two recent case reports describing laparoscopic mesh repair of ventral abdominal wall hernia either before [2] or during pregnancy [12], to the best of our knowledge the only reports on this issue so far, reported similar observations.

However, all available literature regarding pregnancy after mesh repair, limited to a few case reports [3, 12, 13], and our own experience, indicate that pain is a significant problem associated with the mesh repair. This pain might occasionally require prolonged narcotic medications [12] or even intravenous "Patient-Controlled Analgesia"[13]. Observation that more pain is present at pregnancy after LRVIH than at pregnancy before LRVIH clearly confirms the role of hernia repair in the genesis of this type of pain.

The development of pain after LRVIH might be caused by the fixation of the mesh [14] and the subsequent tension on this fixation during pregnancy. In this small series, the technique of mesh fixation (either double-crown tack fixation or tacks and suture fixation) at LRVIH did not influence pain during pregnancy.

Results of this study indicate that LRVIH in fertile women who intend to have further pregnancies is an acceptable therapeutical option that causes no significant problems during pregnancy or delivery. It is clear that more investigation in this area of herniorrhaphy is needed.

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CHAPTER 5

Impact of the number of tacks on postoperative pain in laparoscopic repair of ventral hernias

do more tacks cause more pain?

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Abstract

Background

The main source of postoperative pain after laparoscopic repair of ventral hernia is thought to be fixation of implanted mesh. This study aimed to analyse whether a relation exists between the number of tacks used for fixation and postoperative pain.

Methods

To reduce the number of prognostic variables, only patients with primary umbilical hernia who underwent laparoscopic repair with double-crown mesh fixation were enrolled in this study. Two groups differing only in the manner of tacking were compared. Group 1 (n = 40), collected from previous studies, showed no specific efforts to minimize the number of tacks. Group 2 was a cohort of 40 new patients who underwent double-crown fixation using the minimal number of tacks considered to provide adequate mesh fixation. To eliminate systematic and random errors, the study analysed only for postoperative pain. The severity of the patients' pain was assessed preoperatively and then 2, 6, and 12 weeks postoperatively using a visual analogue scale (VAS) ranging from 0 to 100.

Results

The mean number of tacks used differed significantly between the two groups: group 1 (45.4 ± 9.6) vs group 2 (20.4 ± 1.4) ($p = 0.001$). Postoperative pain differed significantly only at the 3-month postoperative assessment: group 1 VAS (5.78) vs group 2 VAS (1.80) ($p = 0.002$).

Conclusions

Although postoperative pain differed significantly at the 3-month follow-up assessment, both VAS scores were so low that from a clinical point of view, this difference seems irrelevant. Fewer tacks do not create less pain, nor do more tacks create more pain. This absence of a correlation between the number of tacks used and postoperative pain may indicate that pain after laparoscopic repair of at least small ventral hernias possibly is generated according to some "threshold" principle rather than according to a cumulative effect created by more points of fixation.

Introduction

Patients who undergo laparoscopic repair of ventral or incisional hernia (LRVIH) tend to have more pain postoperatively than those treated with any other minimally invasive procedure [1–3]. The main source of this pain is thought to be fixation of the implanted mesh. Mesh fixation in LRVIH involves the use of tacks, transabdominal sutures (TAS), or both. Although postoperative pain after LRVIH was traditionally linked to TAS [4, 5], a few recent studies have indicated that TAS is not the only cause of pain, pointing out the important role of tacks [6–8].

Currently, the most popular method of mesh fixation entails inserting two circles of tacks only and no TAS at all (the double-crown [DC] technique) [9]. The relation between the number of tacks used in LRVIH and postoperative pain has never been specifically analysed, and this study aimed to address that issue.

Materials and methods

Only healthy patients with primary umbilical hernias (PUHs) no larger than 2 cm who underwent a straightforward laparoscopic repair were enrolled in this study and subsequently divided into two groups. All repairs were performed by one of two surgeons well experienced with this technique using a completely standardized technique with the same materials.

The two groups differed only in the manner of tacking. The first group was historical and extracted from our previous studies [6, 10, 11]. This group consisted of 40 healthy PUH patients who underwent a "free-tacking" DC fixation without specific efforts to minimize the number of tacks used or to define a set minimum of tacks beforehand. For this group, a mesh size of 15x10 cm was routinely used.

The second group was a prospective cohort of 40 consecutive new patients who underwent DC fixation using the minimal number of tacks considered to provide an adequate fixation of the mesh. In this group, a mesh of 12x10 cm was routinely used. Assuming that intervals of 15 to 20 mm between tacks were sufficient, we considered 16 tacks adequate for the outer ring and 4 tacks sufficient for the inner ring. Hence, the desired number of tacks to be used was 20, with an option to add a few more tacks when considered needed. To ensure correct execution of the procedure, desired places for insertion of tacks were marked on the mesh before its insertion into the abdomen.

Operative technique

Pneumoperitoneum was established by use of the Veress needle. Three trocars (one 10 mm and two 5 mm trocars) were inserted left laterally. When present, hernial content, usually the omentum, was reduced and the surrounding area prepared for mesh placement. This frequently required release of the round ligament. A 1-mm-thick expanded polytetrafluoroethylene mesh (DualMesh™; WL Gore & Associates, Flagstaff, AZ, USA) was used to overlap the hernia opening by at least 3 cm. No attempt was made to reapproximate the edges of the hernia opening.

The mesh was fixed using a DC of tacks (ProTack™; TycoUSS, Norwalk, CT, USA) only. With this technique, the outer ring of tacks is placed along the periphery of the mesh, and the inner ring of tacks is placed around the hernia opening. All patients received identical postoperative analgesia and care.

Clinical follow-up evaluation

All patients were scheduled to return for an outpatient visit 2 weeks, 6 weeks, and 3 months after surgery. The severity of postoperative pain was determined by scores on a visual analogue scale (VAS; range, 0–100) obtained preoperatively (baseline) and during the outpatient visits.

Statistical analysis

Data were collected in an Excel database, and statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) for Windows version 15.0 (SPSS Inc., Chicago, IL, USA). Categorical variables were compared using the chi-square test, and continuous variables were compared using the independent-samples t test. A p value less than 0.05 was considered statistically significant.

Results

All requested data were available for all the patients. Both groups had similar patient demographic and hernia characteristics (Table 1). Of the postoperative characteristics, only the number of tacks used differed significantly between the two groups ($p = 0.001$). The mean number of tacks was 45.4 ± 9.6 in the group 1 and 20.4 ± 1.4 in group 2.

The primary outcome measure of this study, postoperative pain, did not differ significantly at 2 or 6 weeks postoperatively (Table 2). A significant difference ($p = 0.002$) between the two groups was observed only at the 3-month follow-up assessment. No recurrences or complications requiring surgical or invasive radiologic treatment occurred during the study period.

Table 1 Baseline characteristics

	Free-tacking group (n=40) *n (%)*	Controlled-tacking group (n=40) *n (%)*	*P* value
Mean age (years)	51.1 ± 13.9	53.1 ± 13.8	0.716
Male sex	28 (70)	29 (72.5)	0.975
ASA classification score			
1	25 (62.5)	17 (42.5)	0.191
2	13 (32.5)	19 (47.5)	
3	2 (5)	4 (10)	
Mean BMI	28.2 ± 5.1	28.7 ± 4.3	0.422

ASA American Society of Anaesthesiologists, *BMI* body mass index (kg/m^2)

Table 2 Visual analogue scale (VAS) scores for pain at various assessment times

	Free-tacking group (n=40)	Minimal-tacking group (n=40)	*P* value
Preoperatively	16.55 ± 21.2	20.95 ± 25.7	0.097
2 Weeks postoperatively	15.55 ± 16.2	11.70 ± 14.2	0.208
6 Weeks postoperatively	8.33 ± 14.1	5.43 ± 8.7	0.723
3 Months postoperatively	5.78 ± 12.2	1.80 ± 3.8	0.002

Discussion

Postoperative pain after LRVIH seems to be a relevant complaint during the early post-operative period, leading to increased consumption of pain medication, delayed bowel function, and extended hospital stay [12]. As is the case with mesh repair of inguinal hernias, an increasing number of clinicians now consider postoperative pain rather than recurrence the most important adverse effect of LRVIH. Consequently, current interest focuses increasingly on the genesis of pain after LRVIH and methods to reduce such pain.

The relation between postoperative pain after LRVIH and the number of tacks used has not been explicitly analysed previously. Our previous prospective randomised trial, a study with a significant number of prognostic variables that did not specifically address the same problem considered in this study, could not demonstrate any correlation [6].

Some results of the previous study indicate that *free tacking* may frequently result in *overtacking*. When a 15x10-cm mesh with tacks placed 5 mm inside the outer rim of the mesh is used, the total perimeter of tacking is approximately 38 cm. If spacing of 15 to 20 mm between tacks is desired, 20 to 25 tacks should be sufficient for the outer circle, and about 4 to 6 tacks should suffice for the inner circle. Consequently, the total number of tacks used for a DC fixation of mesh should not exceed 30 tacks. However, we used more

than 50% more tacks in our historic "free-tacking" group. For each of these operations, we unequivocally opened two tacking devices.

These results confirmed our impression that we had been prone to continue firing the tacking device until it was empty and, in general, to insert more tacks than necessary. We assume that this behaviour is not an exception among surgeons performing LRVIH.

Applying a similar calculation to a 12x10-cm mesh, which is equally sufficient for repair of a PUH as a 15x10-cm mesh, a total of 20 tacks should be sufficient. This "controlled" tacking in group 2 resulted in insertion of 55% fewer tacks and unequivocally required not more than a single tacking device per operation.

Whereas the financial effects of "controlled" tacking are obvious, its effect on postoperative pain is less clear. The data obtained in this study did not demonstrate any significant difference in pain 2 and 6 weeks postoperatively. At 3 months, postoperative pain was significantly higher in group 1 (VAS score, 5.78 vs. 1.80). However, a VAS score of 5.78 is so low that from a clinical point of view, this difference seems irrelevant. The consensus of Dutch anesthesiologists suggests moderate pain (VAS[40) as an indication for analgesics [13]. This cut-off point is obviously much higher than the highest postoperative VAS score measured in our study. However, consistently higher VAS scores in the "free-tacking" group may carry a potential to influence quality of life, resumption of activities, and the like. With our data, unfortunately we could not address this issue.

Theoretically, the potential negative consequence of decreasing the number of tacks could be internal herniation in the gaps between the tacks in the outer ring of the double-crown. In our experience with more than 800 LRVIH procedures, this problem did not occur when tacks were placed at 15- to 20-mm intervals.

In their recently published study, Sharma *et al*. [14] describe application of tacks at 3-cm intervals, with no recurrences caused by internal herniation between tacks. Consequently, it seems safe to apply tacks at intervals of 15 to 20 mm.

Another possible consequence of fewer tacks could be an increased recurrence rate. Follow-up evaluation will continue, but we have no indication of that consequence to date.

The potential deficiency of this study is that it was not randomised, and the data for the first group were extracted from a previous study [6]. The data in that study were however collected prospectively, as in group 2 of the current study, with pain as one of the main

outcome measures. The traditional disadvantages of retrospective data collection therefore do not seem applicable for this study.

The main reason for not proceeding with a prospective randomised study was ethical. Unnecessary "overtacking" carried a potential to induce more unnecessary postoperative pain, and we were already in possession of a historical group. In addition, it would needlessly increase operation costs.

The organization of this study also provided some advantages. To minimize the number of prognostic variables and to provide more accurate data on the relation between postoperative pain and the number of tacks used, we used a maximally homogeneous model of the procedure including the same site, a similar size of hernia, one type of prosthetic mesh and fixation device, a standardized technique, and identical postoperative care. This protocol made performance bias unlikely. However, the main disadvantage of such a protocol is that the results of this study are applicable only for a small PUH. For larger hernias, whose repair requires the use of more tacks, there remains the possibility of a threshold above which the number of tacks does make a difference in postoperative pain.

To minimize systematic and random errors, we analysed only one outcome: postoperative pain. Postoperative pain is however a complex issue influenced by multiple factors. If different subgroup analyses had been made, the results may have been different.

A bit disappointing, the results of this study indicate that fewer tacks do not necessarily create less pain for the patient; nor do more tacks create more pain. This absence of a correlation between the number of tacks used and postoperative pain did not lend support to hypothesis that pain after LRVIH is generated by a cumulative effect resulting from more points of fixation [6]. This may indicate the possibility that pain is generated according to some "threshold" principle. The search for less painful methods of mesh fixation in LRVIH continues.

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CHAPTER 6

Postoperative pain after laparoscopic repair of primary umbilical hernia
titanium tacks versus absorbable tacks

A prospective comparative cohort analysis of 80 patients with a long-term follow-up

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Abstract

We investigated if a novel fixation device with absorbable tacks (Securestrap™) causes less early and chronic postoperative pain after laparoscopic repair with a double-crown mesh fixation of ventral abdominal wall hernia when compared to the standard fixation device with nonabsorbable titanium tacks (Protack™). Primary outcome measure was early postoperative pain at 2, 6 and 12 weeks postoperatively. Secondary outcome measure was chronic postoperative pain measured ≥18 months after surgery. Pain levels were assessed using a visual analogue scale (VAS) ranging from 0 mm (no pain) to 100 mm (excruciating pain). Early postoperative pain was significantly lower in group two (absorbable tacks) at 6 (2 versus 5; p=0.008) and 12 weeks (1 versus 2; p=0.008) but not at follow up (6 versus 11; p=0.21). Given the very low VAS scores in both groups, the clinical significance of these finding remains open to discussion.

Introduction

Postoperative pain after laparoscopic repair of ventral or incisional hernia (LRVIH) seems to be primarily caused by the fixation of the implanted mesh. Nearly all commonly used mesh fixation techniques involve the use of tacks and their role in genesis of this pain is undoubtedly important [1–4]. Due to their easy use and consistent efficacy, nonabsorbable titanium tacks have gained wide popularity and are considered the current standard [5–8].

Increasing interest in the genesis of postoperative pain has led to recent developments such as absorbable tacks. In this prospective comparative cohort study, we investigated if a novel device with absorbable tacks – differing in material, shape, and mechanism of insertion – causes less early and chronic postoperative pain when compared to nonabsorbable titanium tacks.

Materials and methods

All adults with a symptomatic primary umbilical hernia no larger than 2 cm in diameter were included in this study. They underwent laparoscopic repair (LR) with a mesh and were divided into two groups. The surgical technique differed only in the choice of tacking device. The first group was extracted from a previous prospective comparative cohort study and included 40 consecutive patients who underwent LR with nonabsorbable titanium tacks (Protack™, TycoUSS, Norwalk, CT, USA)[1]. The second group was a prospective cohort of 40 consecutive new patients who were enrolled between August 2013 and July 2015 and underwent LR with absorbable tacks (Securestrap™, Ethicon, Somerville, NJ, USA). All patients gave their informed consent prior to surgery. Patients with any form of chronic pain syndrome were excluded from this study.

The primary endpoint of this study was early postoperative pain measured with a visual analogue scale (VAS; 0 mm (pain absent) to 100 mm (excruciating pain)) obtained preoperatively (baseline) and at outpatient visits at 2, 6 and 12 weeks after LR.

The secondary endpoint was chronic postoperative pain. We attempted a follow up of all patients in January 2017 and measured their VAS scores. All patients were at least 18 months after surgery: group one (nonabsorbable tacks) mean 93.6±5.1 months (range 72-100) and group 2 (absorbable tacks) mean 27.3±6.2 months (range 18-40).

All procedures were performed under general anaesthesia and by either of two senior surgeons (SR and JR) who already had extensive experience with LRVIH before the enrolment of the first group. A completely standardized and identical technique was used in both groups. Pneumoperitoneum was acquired with the use of a Veress needle inserted at the left subcostal margin (Palmer's point). The intra-abdominal pressure was set to a standard 12 mmHg throughout the whole procedure. In all procedures we used a two-trocar technique. The first trocar (11mm) was inserted at the left subcostal margin through which a 30° laparoscope was employed. The second trocar (5mm) was inserted on the left side at the level of the umbilicus and as lateral as possible. Preparation of the landing zone routinely included desinsertion of the round ligament. No attempt was made to approximate the edges of the hernia opening. A 1 mm thick microporous expanded polytetrafluoroethylene (ePTFE) mesh (DualMesh™, WL Gore & Associates, Flagstaff, AZ, USA) of either 12x10cm or 15x10cm was tailored to overlap the hernia by at least 4 cm in all directions. The cranial and caudal apexes of the mesh were affixed with an absorbable positioning suture with one end cut off. They were retrieved with a suture passer after the mesh had been introduced intra-abdominally through the 11mm trocar. The mesh could then be positioned by tightening of the sutures. The positioning sutures were clamped outside the abdomen once the mesh was positioned as desired. The mesh was then fixated with a double crown of tacks. The method of fixation was identical in both groups. Typically 16 tacks were placed at 15-20 mm intervals in the outer ring and 4 tacks in the middle ring with an option to place more as deemed necessary. No transabdominal sutures were used. The temporary absorbable positioning sutures were cut under tension so that they retract into the subcutaneous tissue. Patients from both groups were prescribed with the same non-opioid analgesics at discharge. No local infiltration was applied.

Data were collected in an Excel database, and statistical analyses were performed on an intention to treat analysis using the Statistical Package for Social Sciences (SPSS) for Windows version 20.0 (SPSS Inc., Chicago, IL, USA). Categorical variables were compared using the chi-square test, and continuous variables were compared using the independent-samples t-test. A *P* value less than 0.05 was considered statistically significant.

Results

Demographic data and perioperative characteristics are presented in Table 1. VAS scores at 2, 6, and 12 weeks were obtained for all patients. At follow up in January 2017 there were 13 (16%) patients lost to follow up. In group one (nonabsorbable tacks) five patients had deceased. In both groups four patients had moved and could not be contacted even after consultation with their former general practitioner.
Early and chronic postoperative pain scores are presented in Table 2.

Table 1 Demographic data and peroperative characteristics

	Nonabsorbable tacks* (n=40) n (%)	Absorbable tacks† (n=40) n (%)	*P value*
Mean age	53.13 ± 13.82	50.25 ± 13.99	0.91
Gender			
Male	28 (70)	29 (72)	0.81
Female	12 (30)	11 (28)	
ASA classification			0.66
1	17 (43)	21 (52)	
2	19 (47)	16 (40)	
3	4 (10)	3 (8)	
4	0 (0)	0 (0.)	
Mean	1.68 ± 0.66	1.55 ± 0.64	0.95
Mean BMI	28.75 ± 4.33	28.54 ± 4.25	0.76
Mean number of tacks	20.43 ± 1.43	21.80 ± 1.74	0.03
Mean hernia size (cm^2)	1.29 ± 0.82	1.58 ± 0.95	0.40
Mean mesh size (cm^2)	136.90 ± 15.48	131.95 ± 19.09	0.03

* Group one Protack™
† Group two Securestrap™
ASA American Society of Anaesthesiologists, *BMI* body mass index (kg/m^2)

Table 2 Mean preoperative and postoperative VAS scores

	Nonabsorbable tacks* (n=40) n (%)	Absorbable tacks† (n=40) n (%)	*P value*
Preoperatively	21 ± 26	14 ± 23	0.23
2 weeks postoperatively	12 ± 14	13 ± 19	0.23
6 weeks postoperatively	5 ± 9	2 ± 5	0.008
12 weeks postoperatively	2 ± 4	1 ± 3	0.008
Follow-up#	6 ± 18	11 ± 21	0.21

* Group one Protack™
† Group two Securestrap™
# Follow-up group 1 94±5 months (range 72-100) and group 2 27±7 months (range 18-40) ($p = 0.08$)
VAS visual analogue scale on a scale of 0-100 points

Three complications occurred in the early postoperative phase but none required surgery or invasive radiological intervention. One patient from group one was readmitted within one week because of a paralytic ileus and was successfully treated using conservative measures. One patient from group two developed a hospital-acquired pneumonia that was successfully treated with antibiotic medication. Another patient from group two developed a symptomatic seroma at the umbilicus. Complaints resolved spontaneously within several weeks.

At follow-up we reported mean VAS scores with relatively high standard deviations as compared to the other time points in this study. In group one (nonabsorbable tacks), two patients reported VAS scores of 80 and 70. The first patient had developed a primary epigastric hernia and underwent another LR with a mesh and became pain free thereafter. During this second laparoscopy no complications of the previous repair were observed. The second patient experienced abdominal pain not located at a particular tack fixation point. She underwent an abdominal computed tomography scan and subsequent diagnostic laparoscopy that excluded a recurrence or a complication related to the LR with a mesh. No explanation was found for her complaints. In the second group (absorbable tacks), three patients reported VAS scores of 90, 70 and 50. The first patient had developed an anterior cutaneous nerve entrapment syndrome not located at any of the tack fixation points. She underwent an anterior neurectomy and became pain free thereafter. The other two patients initially reported high VAS scores at follow up that spontaneously declined to below 10/100. An explanation for their pain was not detected.
There were no recurrences detected during the study period.

Discussion

In our vision, ideal tacks should be easy to correctly apply, provide reliable fixation of the mesh, disappear after incorporation of the mesh has been completed whilst causing as little postoperative pain as possible and be reasonably priced. User-friendly and reliable titanium tacks definitely possess some of these qualities and are considered the standard in LRVIH [7–10]. But, titanium tacks remain in the body indefinitely and involved in the most frequent adverse outcome of LRVIH – postoperative pain. In rare instances they have been associated with complications such as dense adhesion formation, erosion of tacks into hollow viscera and tack hernias [2,4,6, 11–17]. Efforts at further improvements have recently resulted in the development of absorbable tacks, which differ from titanium tacks in several important ways such as material, shape, and mode of penetration.

In this study we investigated whether absorbable tacks cause a different level of early and chronic postoperative pain when compared to nonabsorbable titanium tacks. We aimed to

create a maximally homogeneous model with identical groups of patients with the same hernia type and size, one type of prosthetic mesh, a standardized technique performed by either of two experienced surgeons, and identical postoperative care. The groups differed only in the choice of tacking device. To minimize systematic and random errors, we analysed only one outcome: postoperative pain. This protocol made performance bias unlikely and we assumed that this might compensate for the fact that the two groups were not contemporaneous.

The absorbable feature of the tacks cannot explain our findings that they cause significantly less pain at 6 and 12 weeks postoperatively since absorption of the polymer (polydioxanone) by hydrolysis is complete between 12-18 months after implantation. We hypothesize that less early pain is explained by its different shape (forked instead of spiral) and different mechanism of insertion (arrow-like instead of rotation) causing less impingement of tissue. Regarding chronic pain, the absorbable feature did not seem to be of any relevance for pain scores were low and similar in both groups.

Two factors arguably confound postoperative pain scores in this study. First, one strap more was used in group two, which was in concordance with study protocol. Based on our previous study [1], it seems unlikely that this affected the postoperative VAS scores. Second, we observed a slightly different mesh size between both groups because we trim a standard mesh to accommodate different hernia sizes. So far, there exists no data indicating that mesh size by itself can influence postoperative pain and we considered the observed difference of 4 cm^2 unlikely to influence postoperative pain.

Compared with the available literature, VAS scores (0-100) in this study seemed lower. In group one (nonabsorbable tacks) scores were lower at 2 weeks (12 versus 16[2]), 6 weeks (5 versus 9[2] and 25[3]) and 12 weeks (2 versus 6[2] and 6[9]). In group two scores were lower at 12 weeks (1 versus 11[10]). However, comparison is limited by the heterogeneous design of the reported studies that used pooled data of mostly incisional hernia of larger sizes.

From a clinical point of view, the pain scores in both groups were very low in absolute terms. We did not have to prescribe any of the study subjects with oral analgesics at follow up. The guidelines of the Dutch Society of Anesthesiologists indicate administration of analgesics for moderate pain (VAS >40) and upwards [11]. This cut-off point is far greater than any of the mean postoperative VAS score measured in this study. This put the clinical significance of our findings into question.

From a technical point of view, absorbable tacks require two sharp prongs to guide a

forked tack through the mesh and into the tissue. At 90 degree angles, fixation is readily achieved but the tack regularly fails to penetrate at more acute angles. This finding is in concordance with several in vitro studies that conclude that titanium tacks fired from perpendicular as well as acute angles provide significantly stronger fixation (tensile strength) than absorbable tacks [12–16].

Strength of this study was that we did not pool data with incisional hernia - these are separate entities that should be investigated separately [17, 18]. We chose primary umbilical hernia because this type of hernia can easily be compared between groups. It allowed us to create a model in which a uniform technique could be used differing only in the choice of tacking device therewith reducing the possibility of bias to a minimum. We focused only on this difference and its relation to postoperative pain.

We did not use 'a larger hole' to treat 'a smaller one'. Only two trocars were used during LR (11mm and 5mm) with a sum of 16mm in diameter. The average diameter of the hernias was 17mm in group 1 and 20mm in group 2 (non-significant).

The limitations of this study need mentioning. A selection bias could not be fully excluded given that it was not randomised and that the data of the first group were extracted from a previous study [1]. Even though the two groups were not contemporaneous, a performance bias is unlikely because the technique used in both groups was identical. Besides, we already had extensive experience with LRVIH of more than six years before the collection of group one. The traditional disadvantages of retrospective data collection do not seem applicable because data from group one and two were collected prospectively. Due to the study design, other complications than postoperative pain remained beyond the scope of this study. An on-going randomised controlled trial comparing absorbable tacks with titanium tacks (TACS trial) may provide additional information on this issue [19].

To the best of our knowledge, we are reporting the first prospective study comparing a relatively novel fixation device with absorbable tacks (Securestrap™) with the standard fixation device with nonabsorbable titanium tacks (Protack™). According to these results, the absorbable tacks seem to cause less early postoperative pain at 6 and 12 weeks when compared to nonabsorbable titanium tacks. At follow up chronic pain was not different between both groups. Given the very low VAS scores in both groups, the clinical significance of these finding remains questionable.

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CHAPTER 7

The two-port procedure for laparoscopic ventral hernia repair

How not to make three holes in order to close one

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Submitted to Hernia ('How-I-Do-It' section)

Abstract

Purpose

The approach for laparoscopic repair (LR) of ventral abdominal wall hernias – employing three ports even for the simplest of hernias - has not changed much over the years. Several reports have proposed a two-port procedure (2PP), but it has yet to attract wider attention. The aim of this study was to describe in great detail a useable modification of 2PP and to investigate how this 2PP compared to the standard three-port procedure (3PP) in terms of technique and safety.

Methods

All patients who underwent an elective 2PP LR of primary ventral hernia (PVH) and incisional ventral hernia (IVH) between January 2010 and July 2014 were included in this study. Exclusion criteria were LR with a simultaneous other procedure, or when transabdominal sutures were used for the fixation of the mesh. To assess the technique and safety of the 2PP described in this study, two homogenous groups of patients with primary umbilical hernia (PUH) were compared that differed only in the number of trocars (2PP versus 3PP). Primary outcome measures were differences in perioperative findings and complications Dindo-Clavien grade ≥3.

Results

A total of 371 patients underwent a 2PP for PVH (n=295) and IVH (n=76) without any conversions to 3PP or open surgery. The occurrence of postoperative complications in the sub-analysis was much lower in the 2PP group (1 versus 4.5%; p=0.02).

Conclusions

The two-port procedure seems to be at least as safe for laparoscopic repair of PVH and selected IVH compared to the three-port procedure. It is common sense not to make three holes in order to close one.

Introduction

Since Karl LeBlanc and William Booth described the technique for laparoscopic repair (LR) of ventral and incisional hernia in 1993 [1], three (or more) ports have been used even for simple primary ventral hernias (PVH) to this day. A two-port procedure (2PP) for LR has been previously described in a few reports [2–5] but it has failed to attract wider attention. Comparison of 2PP's safety and effectiveness with the conventional three-port procedure (3PP), and whether it offers any advantages over the latter, has not been conducted so far.

Here we describe a step-by-step modification of a 2PP that was applied in 371 LRs of PVH and incisional ventral hernia (IVH). In addition, 2PP was compared to the conventional 3PP in terms of technique and safety using a large homogenous cohort of patients with primary umbilical hernia (PUH). The 3PP technique has been described in detail before [6].

Surgical technique

The operative technique of 2PP is described for PUH, yet it can be employed for all PVH and simple IVH. In all cases we used a 1mm thick expanded polytetrafluoroethylene mesh (DualMesh™, WL Gore and Associates, Flagstaff, AZ USA). Fixation was achieved with a double-crown of nonabsorbable titanium tacks (Protack™, TycoUSS, Norwalk, CT, USA), and at a later stage occasionally with absorbable tacks (Securestrap™, Ethicon, Somerville, NJ, USA) for the purpose of another study.

Patient preparation included thromboembolic and antibiotic prophylaxis. All operations were performed under general anaesthesia. A patient was placed in supine position with the left arm tucked in close to the body. A nasogastric tube was routinely inserted and the stomach was decompressed. The tube was removed at the end of the procedure. A urinary catheter was not used because of the short length of the procedure. The skin was prepared with Chlorhexidine (0.5%) in alcohol (70%) and protective transparent adhesive drapes were not used.

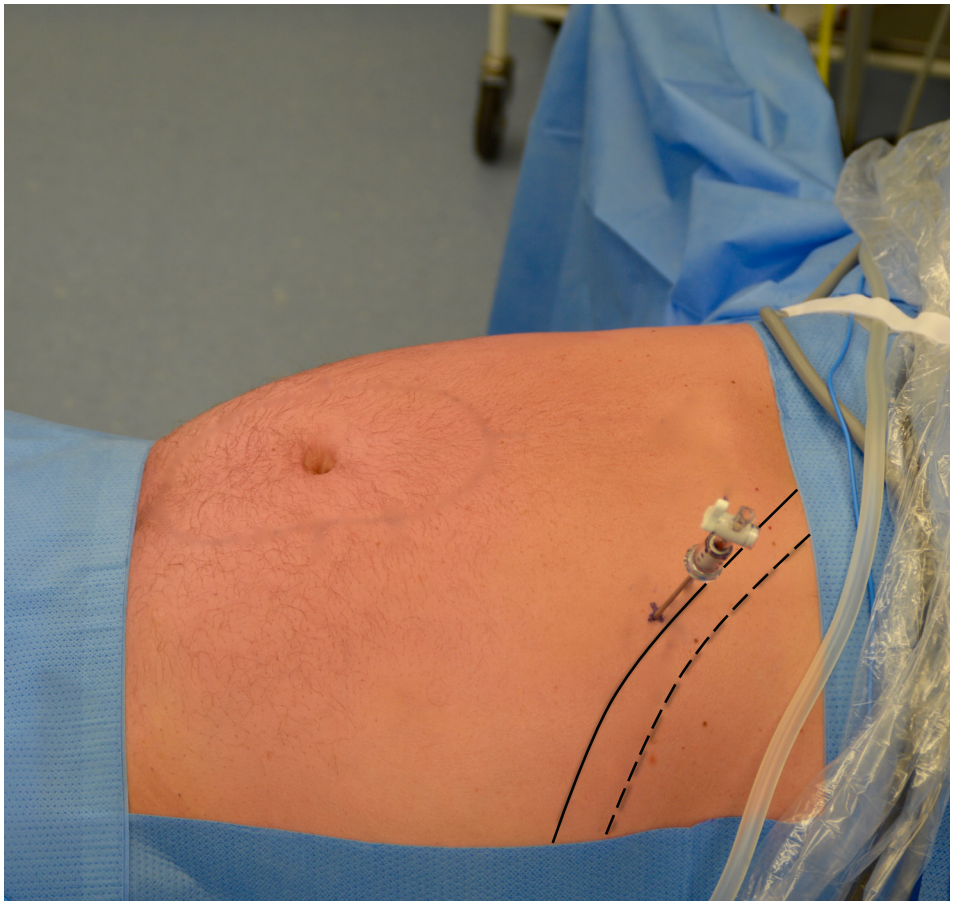

Fig. 1 Veress needle inserted 5 mm below the left costal margin on the mid-clavicular line

Pneumoperitoneum was routinely established with a Veress needle inserted 5 mm below the left costal margin on the mid-clavicular line (marginally higher than the classic Palmer's point) (Fig. 1). A properly placed needle allows free flow of gas and measures an intra-abdominal pressure that should be less than 10 mmHg.

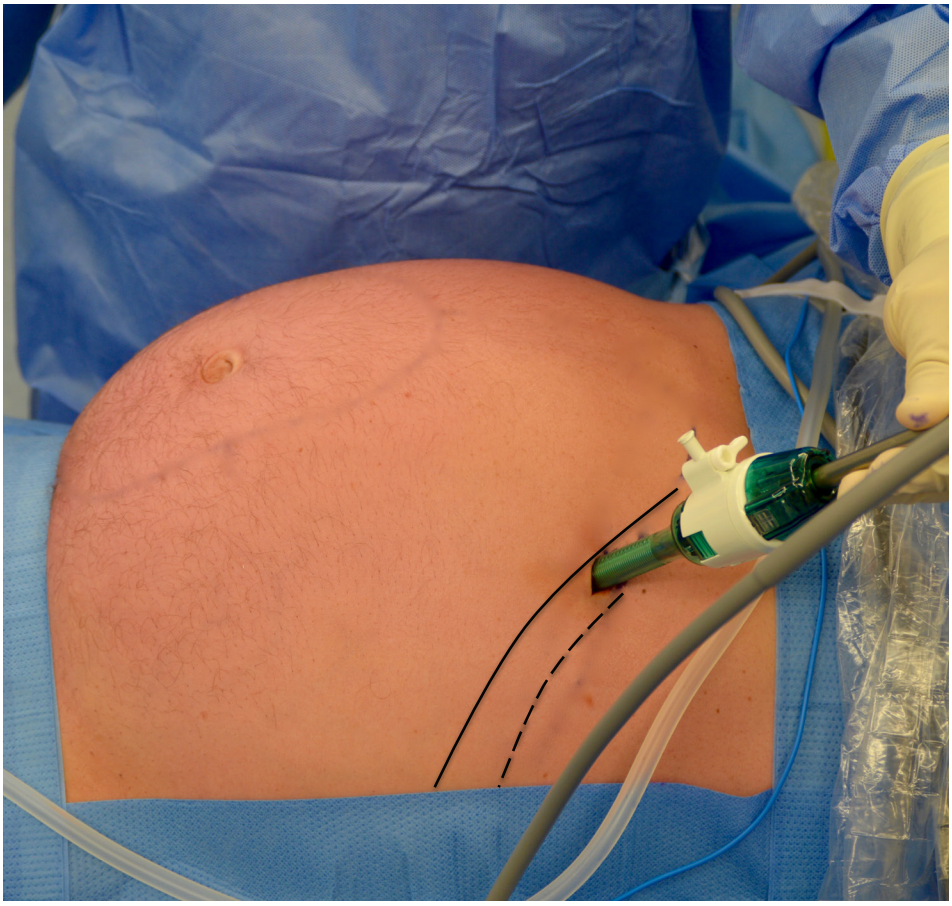

Fig. 2 Displacement of costal margin during pneumoperitoneum and subsequent positioning of trocars in group 2PP. Uninterrupted line = costal margin prior to pneumoperitoneum. Dashed line = costal margin after pneumoperitoneum

Introduction of the first trocar is one of the crucial steps in this technique. The abdominal wall stretches during insufflation and the costal margin moves cranially with a few centimeters (Fig. 2). The initial intra-abdominal pressure is set to 15 mmHg. The incision for insertion of the first trocar (11 mm) is made over the lowest rib. The tip of the trocar passes the skin perpendicularly. Before it touches the rib below, the trocar is moved distally by 1-2 cm while simultaneously the angle of introduction is changed from 90 to 45 degrees in line with the umbilicus.

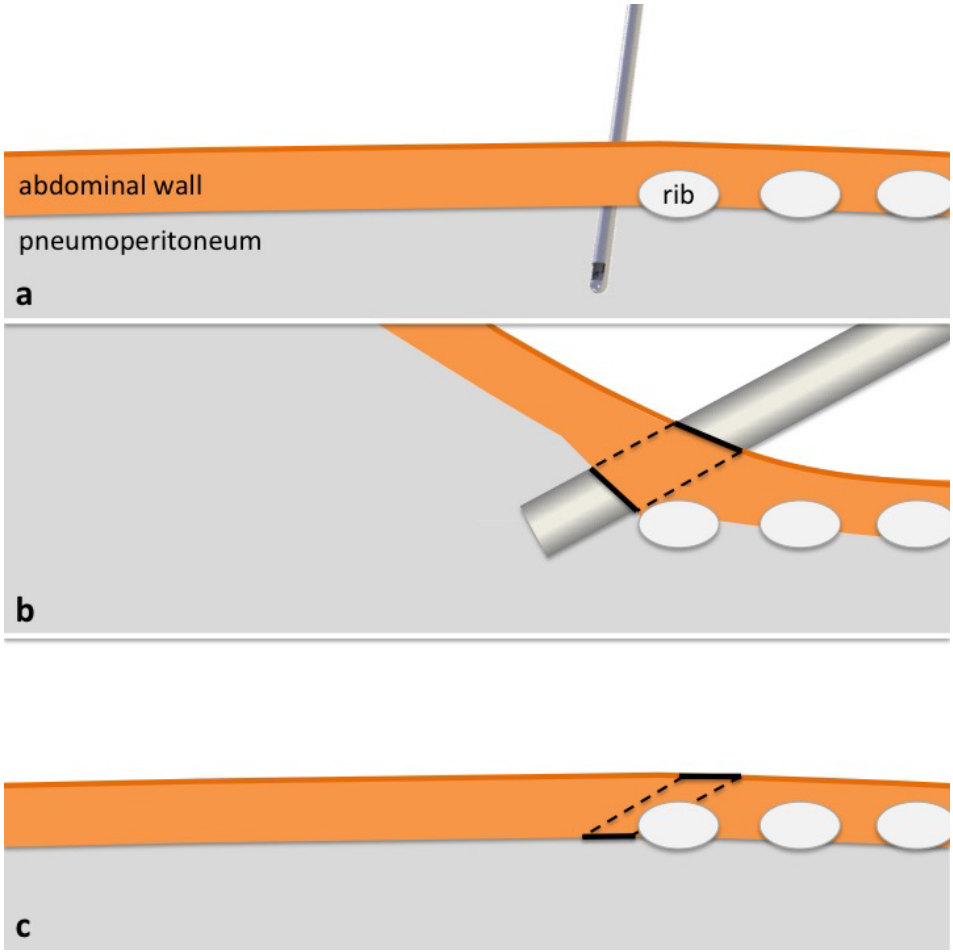

Fig. 3 Cross section at the mid-clavicular line with the lower ribs (oval shapes), the abdominal wall (orange) and the pneumoperitoneum (grey). **a** Placement of Veress needle. **b** insertion of 11mm trocar of the costal arch. **c** Coverage of the musculofascial defect by the costal arch

The trocar will pass over the lowest rib into the abdomen (Fig. 3). This method of introduction will not require closure of the musculofascial defect for it will be covered by the costal margin after desufflation.

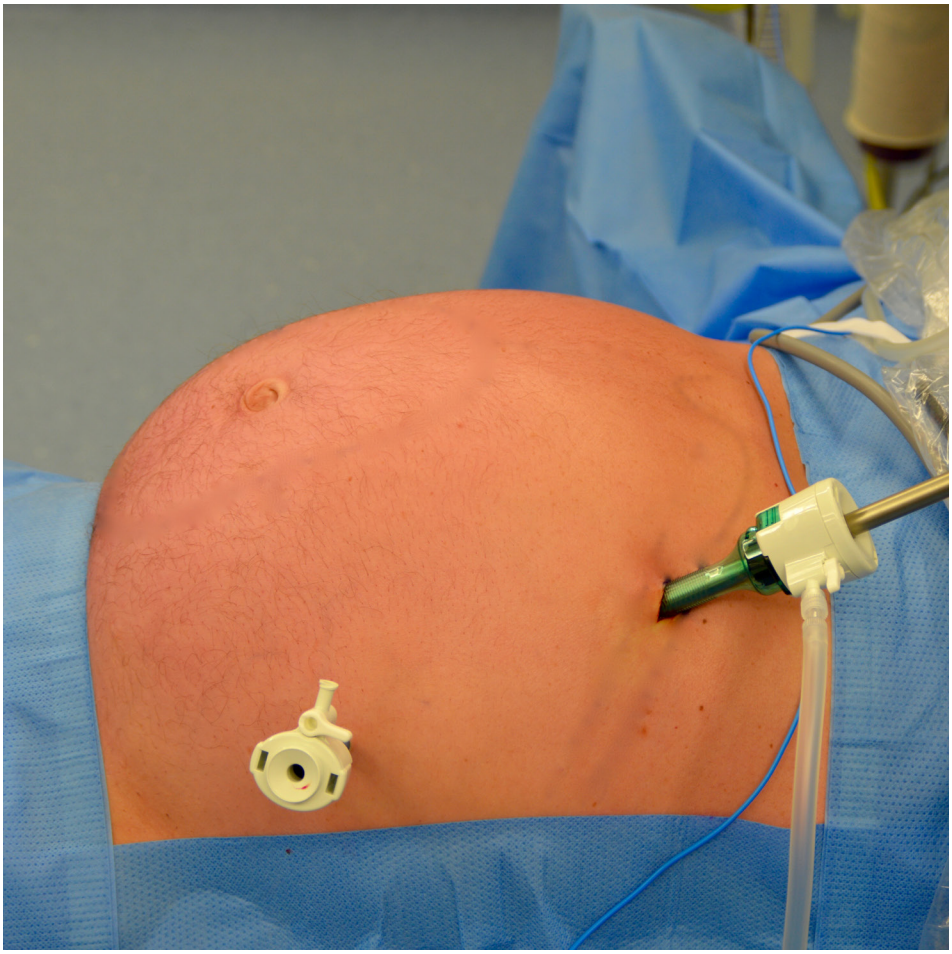

Fig. 4 Placement of the second trocar at the level of the umbilicus and as lateral as possible

The intra-abdominal pressure was set to 12 mmHg after uncomplicated introduction. A 30-degree laparoscope was routinely used. The second trocar (5 mm) is placed ipsilaterally under vision at the level of the umbilicus and as laterally as possible (Fig. 4). The farther from the umbilicus the trocar is inserted, the easier it becomes to perform ipsilateral tacking of the mesh.

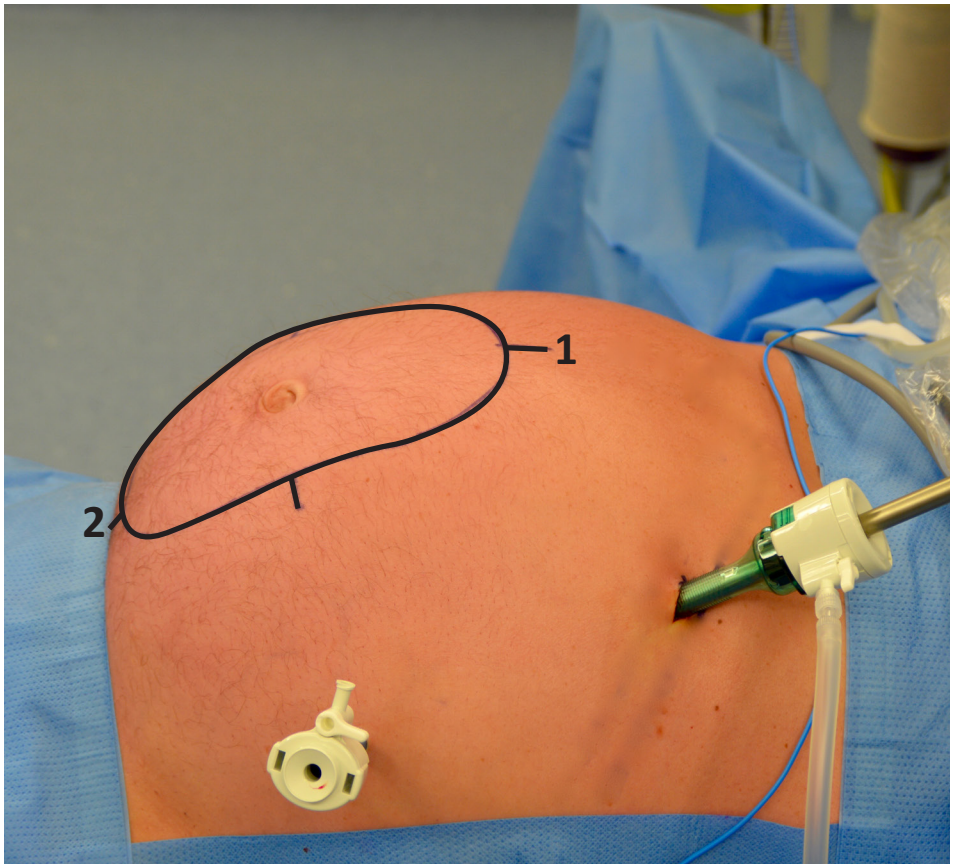

Fig. 5 Drawing of the ideal position of the mesh onto the skin with at least 3-4cm overlap. Numbers mark the entry points of the suture-passer 2-4 cm farther from the cranial and caudal edge of the mesh and with a 5 mm off set ipsilaterally to compensate for outward pushing with the tack device

A dissecting forceps is usually used to prepare the landing zone. Preparation typically includes clearing the hernia sac content and desinsertion of the round ligament (*ligamentum teres hepatis*). When excessive fat is removed from the hernia sac and cannot be taken out through the only working port of 5 mm, it is left inside the abdominal cavity.

Once the landing zone is prepared, no effort is made to approximate the edges of the hernia opening. All intra-abdominal manipulations are performed by interaction between the instrument inside the abdomen and the surgeon's other hand compressing the abdominal wall from the outside. At the end of this phase the abdominal pressure is temporarily reduced to 8-9 mmHg and the circumference of the hernia defect precisely marked with an ink-marker on abdominal skin. Then the shape of the mesh, in its real dimensions, is drawn on the patient's skin in its ideal position with at least 3-4 cm overlap in all directions (Fig. 5).

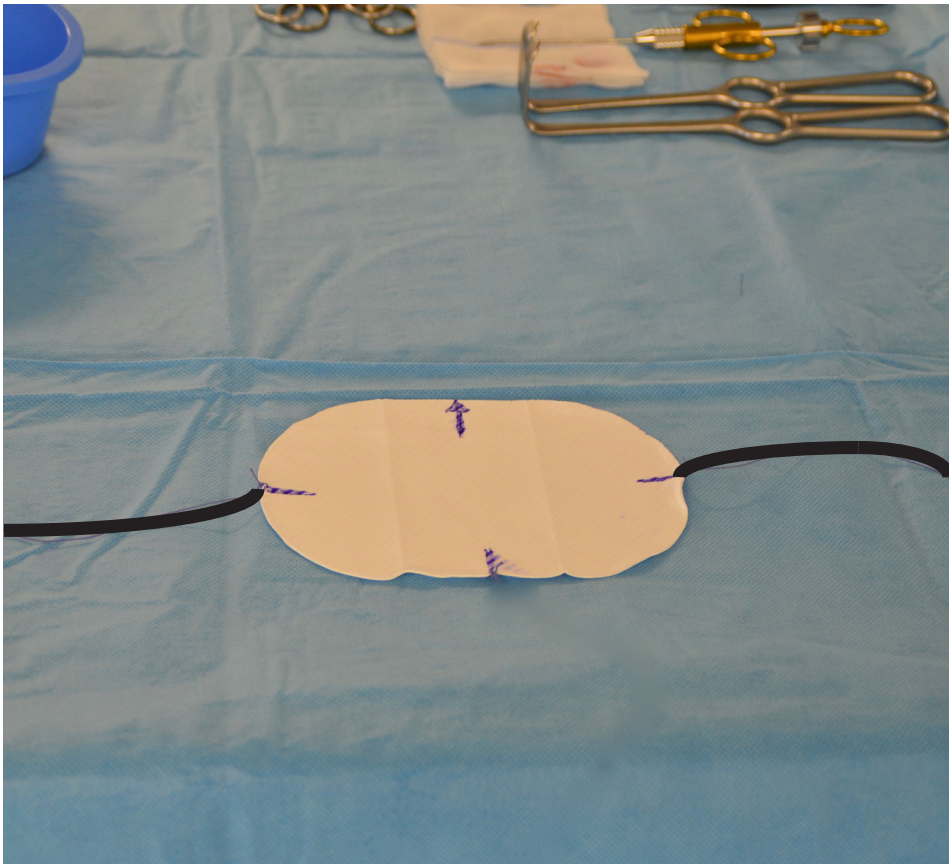

Fig. 6 Preparation of the mesh prior to insertion

Specific preparation is important prior to insertion of the mesh. A single instrument makes it difficult to unroll mesh flatly inside the peritoneal cavity, as well as lifting it and placing it properly over the hernia defect and onto the peritoneum.

In order to overcome these challenges, a few important steps are needed. First, the cranio-caudal axis on both sides of the mesh is marked with an ink-marker to aid visual orientation intra-abdominally. Second, the cranial and caudal apexes of the mesh are affixed with an absorbable suture that should be knotted with one tail cut off and the other left 5-6 cm long (Fig. 6).

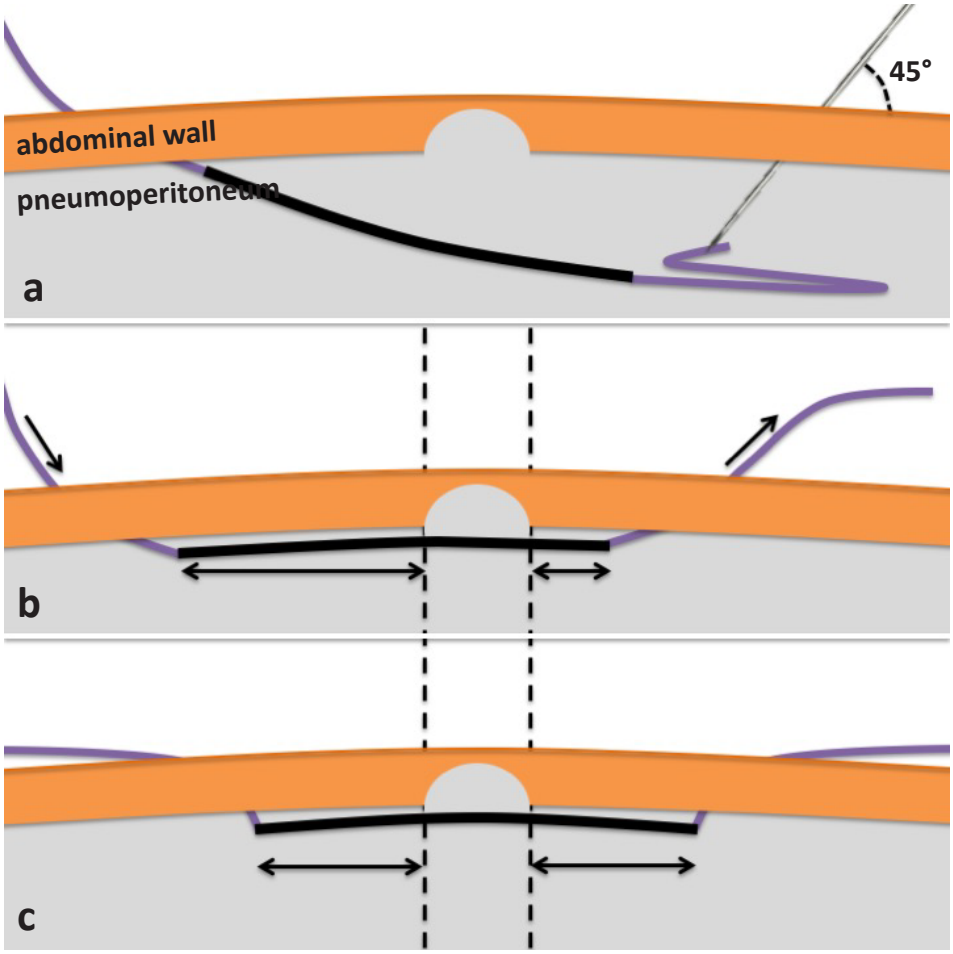

Fig. 7 Cross section at the umbilicus with the abdominal wall (orange), the pneumoperitoneum (grey) and the mesh (black). **a** Retrieval of a positioning suture. **b** Selective loosening or tightening of the positioning sutures to correct the placement of the mesh. **c** Once correct placement is achieved, the positioning sutures are temporarily clamped

The function of these sutures is to achieve and maintain adequate positioning of the mesh and to facilitate consecutive tacking. The next step is marking the points for insertion of the suture passer on the patient's skin (Fig. 5). The point of insertion is subject to the following factors. First, both apical sutures should be retrieved 2-4 cm farther than the cranial and caudal edges of the mesh in order to be able to put the mesh under adequate tension. Upon their retrieval, selective loosening or tightening of the sutures will enable desired craniocaudal positioning of the mesh (Fig. 7). Second, the sutures should be retrieved with a 5 mm offset ipsilaterally to compensate for outward pushing of the mesh when tacking the contralateral side. The mesh is rolled longitudinally with both suture tails left outside. The intra-abdominal pressure is restored to 12 mmHg for insertion of the mesh. The laparoscope is then removed and the mesh is blindly inserted through this 11 mm trocar.

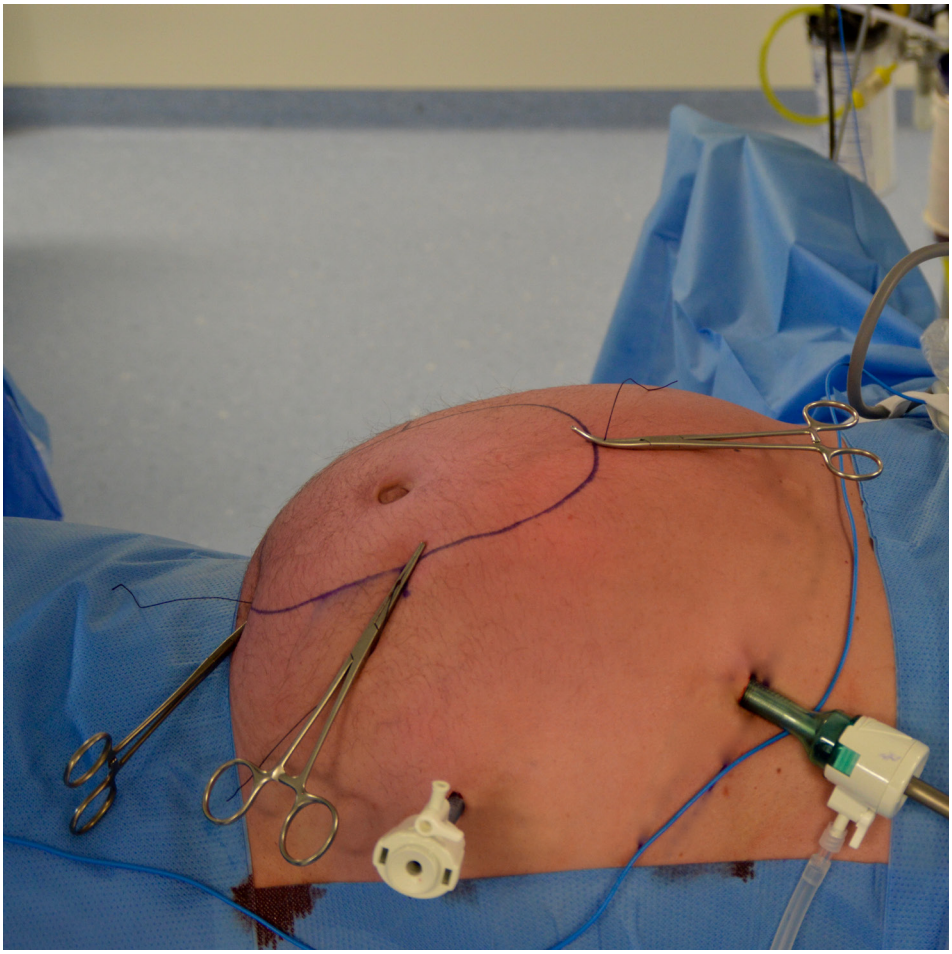

Fig. 8 Temporary clamping of the positioning sutures once the mesh has been correctly placed over the hernia

The first step in unrolling the mesh is to grasp the end of any of the previously affixed sutures and to deliver it into the jaws of a suture-passer. The latter should be introduced through one of two previously marked points (irrelevant which of the two). The suture-passer is inserted at a 45° angle in relation to the abdominal wall and the suture is pulled out until the mesh reaches the abdominal wall. The suture is then clamped at the skin level. With one apex of the mesh now fixed, it is easy to unroll the mesh, to retrieve another suture and to clamp it in the same manner as the first (Fig. 8). If all previous steps correctly performed, the mesh should be stretched well in a desired position. If correction of the position in craniocaudal direction is required, or if laxity of mesh indicates insufficient stretching, then selective loosening or tightening of the positioning sutures will enable desired corrections. The intra-abdominal pressure should be reduced to 8-9 mmHg again before tacking.

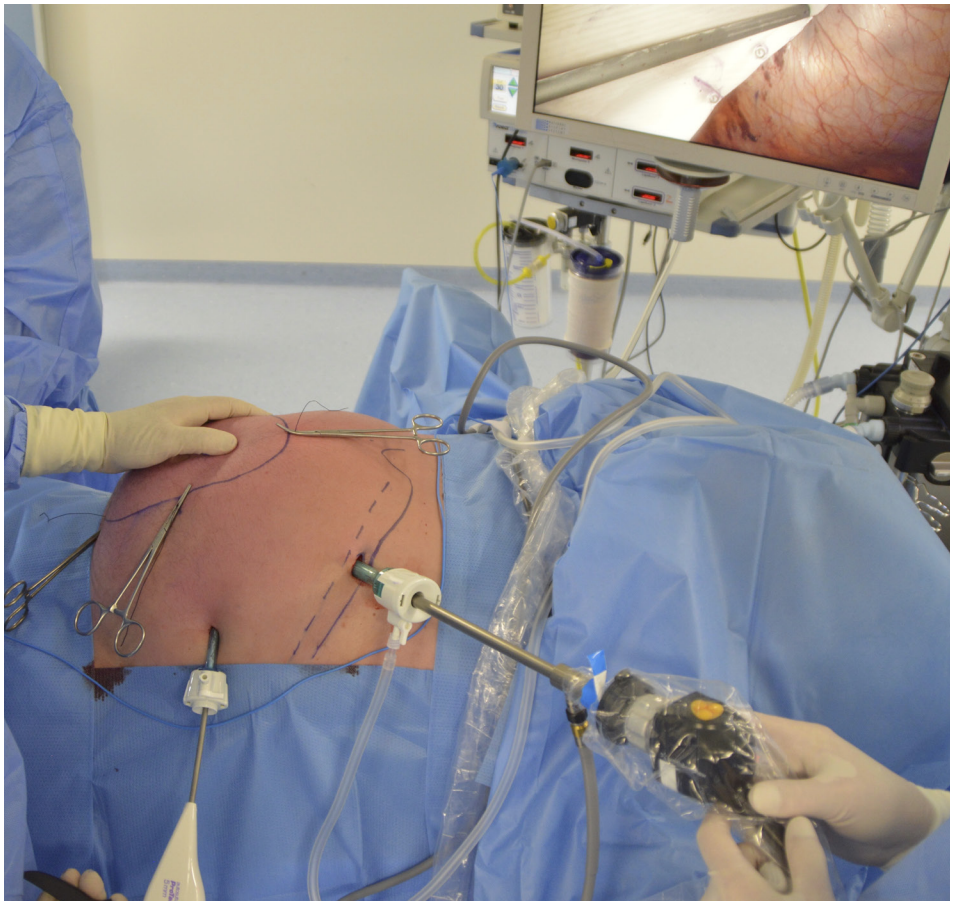

Fig. 9 The hand on the outside of the abdominal wall pushes inwards and captures the mesh between the tack device and the abdominal wall

The placement of the first few tacks is important because it will determine the quality of the repair. The quality of the fixation depends entirely on the interaction between the tack device and the other hand on the outside of the abdominal wall. The mesh should be stretched maximally before tacking by eccentrically pushing and sliding the tip of the tack device into the edge of the mesh. The hand on the outside of the abdominal wall pushes inwards and captures the mesh between the tack device and the abdominal wall (Fig. 9). A tack is fired only when a stable situation is created at an angle of around 90 degrees to the abdominal wall. In general, tacking of the ipsilateral side is technically more challenging than that of the contralateral side. The role of the outside hand is important in this phase. The middle of the ipsilateral side is always tacked first. To make this step easier, a third suture can be placed in the middle of the ipsilateral side of the mesh during the preparatory phase of the mesh.

After that, the cranial and caudal apexes are fixated the midline. Upon completing the ipsilateral outer ring of tacks, the fixation of the contralateral side also begins in the middle, with the mesh stretched maximally over the hernia defect before tacking. After completing the outer ring on contralateral side, an inner ring of tacks is placed around the hernia opening with the ipsilateral side fixated first. Then the contralateral side is fixated to correct eventual rest laxity of the mesh. If tacking is carefully performed as described, two main pitfalls in this phase will be avoided: shifting of the mesh to the contralateral side and bulging of the mesh into the hernia opening after desufflation.

Upon completion, the 5 mm trocar is removed under vision, the pneumoperitoneum is maximally deflated, and the 11 mm trocar is removed. The musculofascial defect caused by the 11 mm trocar moves back to its original position being covered by the costal margin (Fig. 3). Only the skin is closed over the two incisions. The whole procedure is accomplished with the surgeon's two hands - the "third hand" of the assistant is not required at any time.

Patients and methods

The medical records of all adult patients with a PVH or an IVH who underwent an elective 2PP LR with a mesh between January 2010 and July 2014 were identified and analysed. A comparative retrospective sub-analysis was performed to investigate the technique and safety of 2PP. In order to reduce systemic and random errors, we selected only PUH, thereby creating two homogenous groups that differed only in the number of trocars employed. We did not compare IVH for these groups would be less homogenous in comparison – due to their etiopathology and realistic chance of cross over to ≥3PP. Pooling of PVH and IVH is not justified for they are separate entities [7, 8].

All 2PP LR performed for PUH were compared with all patients who underwent 3PP LR of PUH between January 2000 and December 2009. Exclusion criteria were LR with a simultaneous other procedure, or when transabdominal sutures were used for the fixation of the mesh. Primary outcome measures were differences in perioperative findings and complications Dindo-Clavien grade ≥3 [9].

All patients were routinely scheduled to return for a follow-up examination at two, six, and twelve weeks and thereafter when they had any kind of LR-related problem.
Outcome measures were prospectively registered in an electronic database at the moment of occurrence. Statistical analyses were performed using the Statistical Package for Social Sciences for Windows, version 20.0 (SPSS Inc., Chicago, IL, USA). Categorical variables are compared with the Chi square test, and continuous variables are compared using the independent-samples t test. A 'p value' lower than 0.05 was considered statistically significant.

Results

Altogether 371 patients underwent a 2PP for PVH (n=295) and IVH (n=76) in the study period (Table 1). Dindo-Clavien grade ≥3 complications for all 2PP are presented in Table 2. Of the 76 IVH, 45 were considered simple (recurrent umbilical or epigastric hernia, TSH, post appendectomy). There were no conversions to 3PP or open surgery nor was there mortality related to LR. Data were less reliable for another 91 IVH (all complex hernias) who underwent LR with at least three trocars because it was not recorded which procedures were started as a 2PP.

A total of 412 consecutive patients with a PUH were included in the comparative sub-analysis: 202 patients in the 3PP group and 210 in the 2PP group. Patient characteristics and surgical findings are presented in Table 3. There were neither failed entries, conversions to laparotomy nor was there need for adhesiolysis. Trocar related and Dindo-Clavien grade ≥3 complications are presented in Table 4.

Table 1 Laparoscopic repair of ventral abdominal wall hernia between January 2010 and July 2014

Type of hernia		2PP	≥3PP	Total
Primary	Umbilical	210	0	210
	Epigastric	72	0	72
	Spigelian	13	0	13
Incisional	Simple*	76	0	76
	Other	0	91	91
		371 (80%)	91 (20%)	462

*Recurrent umbilical and epigastric hernia, trocar site hernia, post appendectomy

Table 2 2PP and postoperative complications (Dindo-Clavien grade ≥3)

Primary	Umbilical	210	2	Myocardial infarction Pain followed by re-operation
	Epigastric	72	1	Bleeding
	Spigelian	13	0	
	Total	*295*	*3 (1%)*	
Incisional	Simple*	76	4	Recurrence (3x) Pain followed by re-operation
	Total	*76*	*4 (5%)*	

*Recurrent umbilical and epigastric hernia, trocar site hernia, post appendectomy

Table 3 Patient characteristics and surgical findings

	3PP (n=202), *n(%)*	2PP (n=210), *n(%)*	*P* value
Mean age (years)	53.16 ± 12.96	51.86 ± 12.94	0.60
Gender			0.99
Male	151 (74.75)	157 (74.76)	
Female	51 (25.25)	53 (25.24)	
Mean ASA classification	1.73 ± 0.72	1.68 ± 0.64	0.16
BMI	27.65 ± 4.41	28.14 ± 4.11	0.24
Median number of tacks [IQR]	28 [4]	24 [4]	
Median hernia size, cm2 [IQR]	1.6 [0.5]	1.7 [0.5]	
Median mesh size, cm2 [IQR]	150 [30]	140 [30]	
Median LOP, minutes [IQR]	35 [16]	24 [10]	

3PP 3 port procedure, *2PP* 2 port procedure, *ASA* American Society of Anaesthesiologists, *LOP* length of procedure, *IQR* interquartile range

Table 4 Postoperative complications (Dindo-Clavien grade ≥3)

	3PP (n=202), *n(%)*	2PP (n=210), *n(%)*	*P* value
Trocar specific			
Abdominal wall vessel injury	0 (0)	0 (0)	-
Enterotomy	0 (0)	0 (0)	-
Trocar site hernia	2 (0.99)	0 (0)	0.15
General			
Bleeding	2 (0.99)	0 (0)	0.15
Mesh infection	0 (0)	0 (0)	-
Myocardial infarction	0 (0)	1 (0.48)	0.33
Pain followed by re-operation	1 (0.5)	1 (0.48)	0.98
Recurrent hernia	4 (1.98)	0 (0)	0.04
Seroma	0 (0)	0 (0)	-
Total complications	9 (4.46)	2 (0.95)	0.02

3PP 3 port procedure, *2PP* 2 port procedure

Discussion

In 2009 at a national meeting devoted to LR of ventral hernias, a distinguished elder Dutch professor could not spare us from his scepticism regarding procedures that "require three holes to close one [of the same size]". The undeniable element of *common sense* in his message was a wake-up call from the inertia of a 3PP to analysing what the third port really is needed for in LR of simple PVH and IVH. Upon reviewing all phases of a 3PP with a double-crown fixation, it was obvious that the third port – *the second instrument* – was used surprisingly little: to unroll the mesh *easier* and to hold the edge of mesh in position for tacking. Having previous extensive experience with application of transabdominal sutures for mesh fixation [6], the solution how to surpass the absence of the second instrument was easy to find and immediately put into practice.

The differences between this and the few published studies on the same issue are numerous [2–5]. This is the first study to compare the 2PP with the conventional 3PP and in doing so it included a much bigger cohort than in all the previous studies together. Introduction of the first trocar was different. One study used open introduction [2] and the other three [3–5] a much lower position of the first trocar. The diameter of both trocars was larger (12 and 10mm) in one study [2]. Positioning of the mesh prior to tacking was different in all studies: a central suture in the mesh pulled through the hernia defect [4], four corner sutures [2, 5] or even more circumferential sutures [3]. We experienced these methods either as imprecise or as overdone.

We compared two retrospective cohorts that differed only in the number of trocars employed (two versus three). Perioperative findings and complications were used to ascertain technical ease and safety of 2PP. In that light, the 2PP seems to be at least as good when compared to 3PP (1% versus 4.5%; p=0.02). It was also lower when compared to previously reported complication rates for PVH (4.6%) [7].

It seems that 2PP is at least as safe when compared to 3PP. Notwithstanding, caution with the interpretation of the data is warranted because of a performance bias (learning curve), recall bias (retrospective study) and a restricted length of follow up. A prospective trial with large numbers is required to establish the non-inferiority of 2PP over 3PP.

The 2PP as described here incorporates useful elements of the previously reported 2PP techniques but it is devoid of unnecessary or complicated steps. It requires less operative time and the technique can easily be reproduced and taught to surgical residents. The 2PP is suitable for LR of PVHs and not complicated IVHs. It is common sense not to make three holes in order to close one.

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CHAPTER 8

Intraperitoneal onlay mesh reinforcement of the abdominal wall
a new surgical option for treatment of anterior cutaneous nerve entrapment syndrome

Poster presentation at the 5th International Hernia Congress of the American Hernia Society, 29 - 31 March 2012, New York, USA

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Surg Endosc 2016 Jul;30(7):2711-5

Abstract

Background

Introducing a new surgical treatment for anterior cutaneous nerve entrapment syndrome. A frequently unrecognized disorder in the general population responsible for chronic abdominal wall pain with limited treatment options to date. We hypothesized that intraperitoneal onlay mesh reinforcement could dissipate excessive increases in intra-abdominal pressure and prevent entrapment of the neurovascular bundle.

Methods

Retrospective cohort analysis performed between September 2002 and March 2014. All consecutive patients diagnosed with anterior cutaneous nerve entrapment syndrome refractory to conservative treatment (n=30) underwent laparoscopic intraperitoneal onlay mesh reinforcement of the painful area in the abdominal wall. Planned follow up took place at 2, 6 and 12 weeks after surgery and at time of analysis (March 2015). Primary outcome was patients' satisfaction after treatment at short and long term (last follow up) using a verbal rating score as measurement (1= I am very satisfied; I never experience pain, 2= I am satisfied; I occasionally experience some pain, 3= I have improved but experience pain on a regular basis, 4= I have had no result on this treatment, 5= my pain is worse after treatment). Scores 1 and 2 were classified as success and scores 4 and 5 as failure of the treatment.

Results

Thirty patients underwent laparoscopic intraperitoneal onlay mesh reinforcement. None were lost to follow up (mean 54±44 months, range 12 – 122, median 38). Short- and long-term success rates were 90% and 71%, respectively.

Conclusions

Intraperitoneal onlay mesh reinforcement of the abdominal wall seems to be a promising option for the treatment of intractable anterior cutaneous nerve entrapment syndrome.

Introduction

Anterior cutaneous nerve entrapment syndrome (ACNES) is a frequently unrecognized disorder both in general practice and clinical medicine and reportedly the most frequent cause of chronic abdominal wall pain [1]. Once considered, the diagnosis is readily established by taking a history and by performing a physical examination. Initial treatment of ACNES is conservative and based on local injections with an anaesthetic agent [2]. For patients who fail to respond, surgical neurectomy has been the only viable secondary therapeutic option so far [3, 4]. Hereby we describe a completely new surgical concept as a treatment of *intractable* ACNES that is based on structural reinforcement of the abdominal wall at the painful area with intraperitoneal onlay mesh (IPOM).

Material and methods

This retrospective cohort study was performed between September 2002 and March 2014 and it included all patients with ACNES treated with IPOM in that period. The diagnosis of ACNES was established as previously described [3, 4]. In brief, it was based on a sharply localized pain with a fingertip (trigger point) at the lateral margin of rectus abdominis muscle (can usually be pointed out by the patients themselves), a positive Carnett's sign (increased tenderness during muscle tensing)[5], and exclusion of visceral and hernia pathology (by clinical, chemical and radiological examinations). Patients with a previous surgical incision in the area of pain were excluded. Upon establishing the diagnosis, conservative treatment consisted out of two or more ultrasound assisted subfascial trigger-point infiltrations with an anaesthetic (bupivacaine 5 mg/ml or lidocaine 10 mg/ml) combined with a corticosteroid (kenacort 10 mg/ml) at the pain clinic. Patients who failed to respond to conservative therapy underwent laparoscopy and IPOM reinforcement of the painful area.

All patients gave their consent prior to surgery upon being completely informed including the uncertain result of the treatment. The trigger point was carefully marked preoperatively with ink while the patient was fully awake. All operations were performed under general anaesthesia. Trocars were typically placed on the contralateral side of the trigger point. During laparoscopy the intraperitoneal localisation of the trigger point was identified either by pressing on the preoperatively placed mark with a finger or by inserting a needle in obese patients. We routinely added 15 to 20 mm all around the projected trigger point to compensate for eventual imprecisions with its intraperitoneal localisation. After identification of the painful area, the rest of the procedure was identical to laparoscopic repair of ventral and incisional hernias (LRVIH) [6]. A 1-mm thick expanded polytetrafluoroethylene

(ePTFE) mesh (DualMesh, WL Gore & Associates, Flagstaff, AZ, USA) was tailored to overlap the painful area with at least 4 cm in all directions. A mesh was tightly stretched over the painful area and was fixed with either a double ring of tacks (Protack, TycoUSS, Norwalk, CT, USA) or a combination of tacks with transabdominal sutures (TAS). Special care was taken to avoid any rest laxity of the mesh upon desufflation of the abdomen.

Patients were scheduled to return for a follow-up examination explicitly by one of the authors at 2, 6, and 12 weeks after surgery and thereafter when they had any kind of laparoscopy related problem. In March 2015 the first author interviewed all patients through the telephone.

All patient characteristics, operation data, and complications were registered at the moment of presentation in an Excel database that we were already maintaining for LRVIH. The latter did not include routine usage of quality of life measurements before and after surgery. Primary endpoint of the study was patients' satisfaction measured with a verbal rating scale (VRS) (Table 1). Scores 1 and 2 were classified as success of treatment and scores 4 and 5 as failure of treatment.

Results

Forty consecutive patients with ACNES were identified. Conservative treatment achieved a definitive satisfactory result in 10 patients (25%). Thirty patients (20 female, 10 male) retained debilitating symptoms with VRS scores of 4 or 5 thus conservative treatment was considered a failure. These patients with *intractable* ACNES underwent IPOM reinforcement of the painful area. The mean age at operation was 45 years (range 18-72 years) and the mean ASA grade was 1.53±0.63. The localization of the trigger points is presented in Figure 1.

All operations were straightforward and without intraoperative complications. We typically used a Veress needle for introduction (90%; n=27), two trocars (2.5±0.6), and a mesh with a mean size of 154±86 cm^2 fixated with a double-crown (80%; n=24). All patients stayed overnight and left the hospital with a standard regimen of non-opiate oral analgesics. There were no early postoperative complications or readmissions within one month.

There was no loss to follow-up (mean 54±44 months, range 12-122 months; median 38 months). The VRS scores at 2, 6 and 12 weeks and at follow up are presented in Figure 2.

Late complications occurred in one patient (3%). One month after laparoscopy she developed debilitating pain at the tack fixation points, not the trigger point itself, that was insufficiently responsive to opiate analgesics. At relaparoscopy all tacks and the mesh were removed and a new mesh was applied over the trigger point and fixated solely with absorbable tacks and TAS. Thereafter she remained pain free (VRS 1; follow up 20 months).

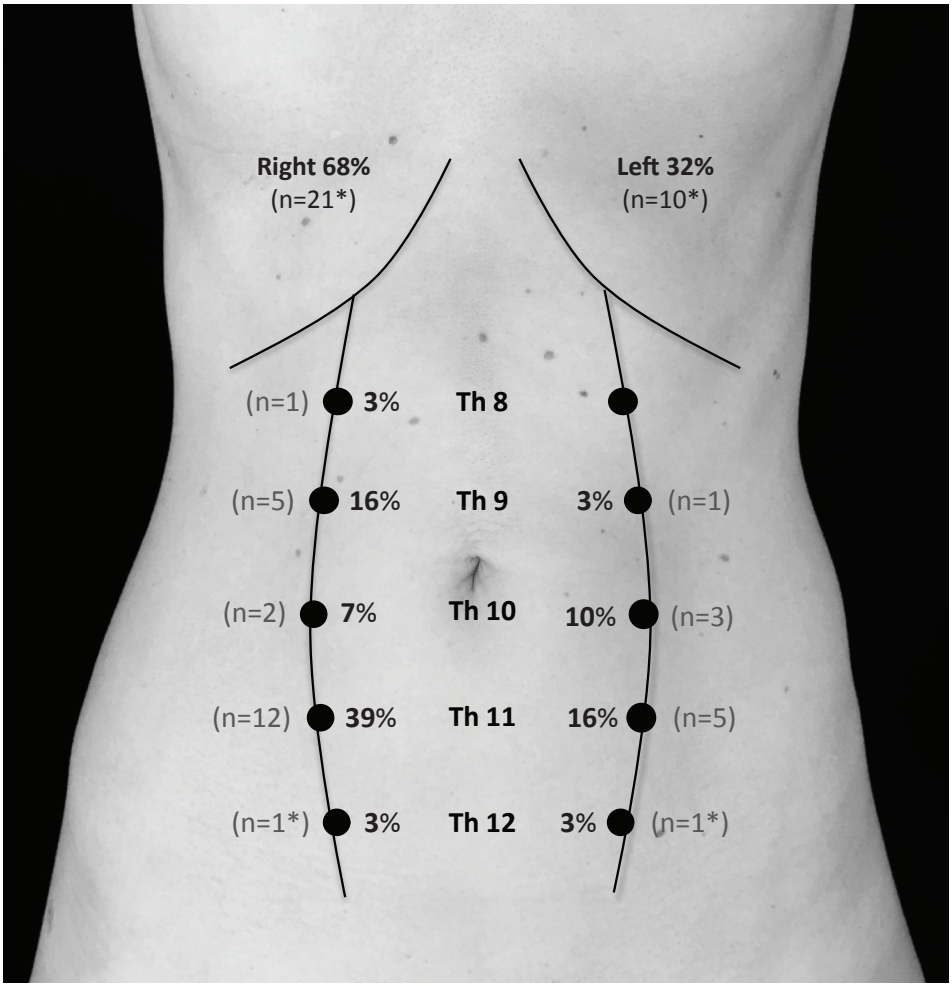

Fig. 1 Localisation of Trigger points

* One patient with bilateral trigger points

Failure of treatment occurred in five patients at follow up (mean 28±11 months, range 12-43 months, median 28 months). Four patients, who initially scored a VRS of 1 or 2, reported recurrent pain at the trigger point at follow up (VRS 4). They were managed con-

servatively without change of VRS to date. One patient reported recurrence and worsening of pain at the trigger point after four months (VRS 5). Subsequent trigger point infiltration at the pain clinic and surgical neurectomy at a referral centre did not result in improvement to date. The patient rejected further treatment.

There were no statistical significant differences in age, gender and BMI between successes and failures of the procedure. With a careful retrograde analysis at follow-up, we discovered that three patients could have been initially classified as a "chronic pain profile". All of them failed to respond well to operative treatment.

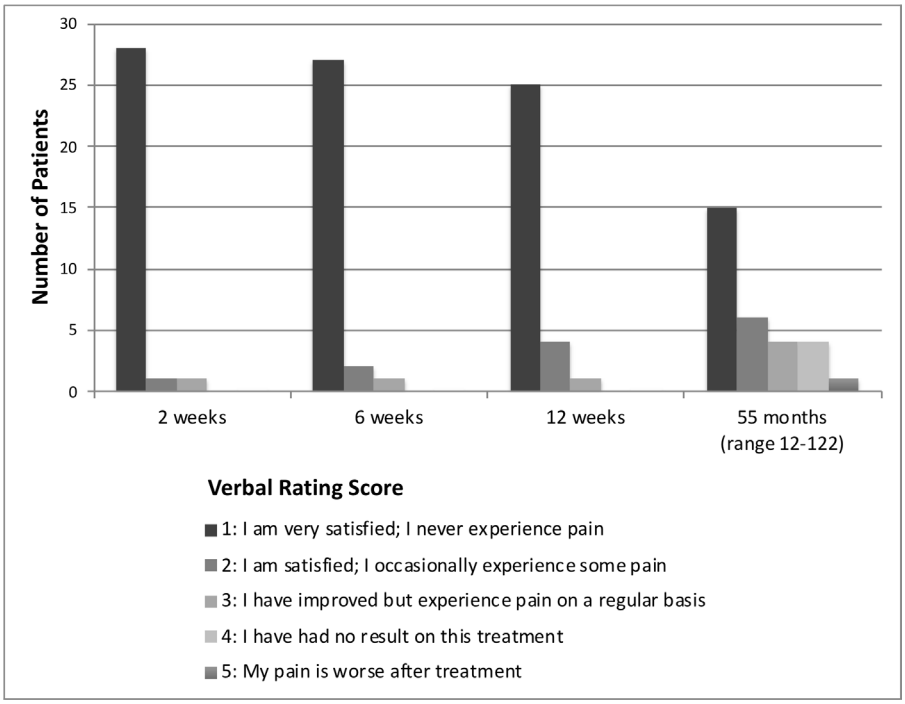

Fig. 2 Verbal rating score at 2, 6 and 12 weeks and at follow up

Discussion

In the beginning of the study period our knowledge on ACNES was moderate. We had no clear plan how to treat patients who were seeking our help for their frustrating symptoms, let alone how to approach those with *intractable* ACNES. Available literature at the time was scarce and proposed treatment limited to (repeated) trigger point infiltration. The concept of a structural reinforcement of the abdominal wall at the painful area with IPOM was actually generated by the first few patients. At that time, ACNES was an exclusion diagnosis and a proposal for a diagnostic laparoscopy seemed to be the last resort to exclude other pathology near the trigger point such as a small symptomatic Spigelian hernia, despite negative radiology, or intra-abdominal adhesions. When obtaining informed consent for the procedure, the option of *negative findings followed by no action* seemed unacceptable for those patients. Being certain of the localisation of pain, those patients insisted on some kind of therapeutical intervention such as IPOM.

At that time we found some support for this concept in a striking similarity between ACNES and sportsman's hernia, nowadays called inguinal disruption [7]. The basic feature of both conditions is localized pain exacerbated by sudden increases in intra-abdominal pressure in absence of demonstrable hernia. The mainstay of treatment of inguinal disruption is mesh reinforcement with good results already reported at that time [8–10].

Additionally, we were already very skilled with the technique of LRVIH [11] and performing an IPOM in an usually untouched abdomen in ACNES patients was of no great technical challenge. Thus anticipating low risks of an IPOM procedure, even if no improvement was registered, we decided to start with a surgical procedure that had a potential to treat ACNES.

The first results were so impressive that what initially had started as a sort of experimental procedure, quickly got enough clinical support to become our standard treatment for the occasionally appearing patient with *intractable* ACNES.

With increasing knowledge of the pathophysiology of ACNES itself, we developed a better understanding of the probable favourable mechanism of IPOM on ACNES. Neurovascular bundles of the anterior cutaneous branches of the six lower intercostal sensory nerves pass through a fibrous ring (nerve foramen) within the lateral border of the rectus abdominis muscle [12]. Normally the neurovascular bundle can move freely through the fibrous ring even when forcefully pushed from behind during excessive increases in intra-abdominal pressure (e.g. coughing, lifting) or when pulled from in front due to vigorous muscle contractions (e.g. sports) [13]. In ACNES, instead to slide unimpeded, the neurovascular bundle is repeatedly compressed against the fibrous ring and becomes entrapped thereby creating pain and sen-

sory disturbances [14, 15]. We hypothesized that IPOM could dissipate excessive increases in intra-abdominal pressure and prevent entrapment of the neurovascular bundle.

The recent British Hernia Society conference on inguinal disruption concluded that the most frequent causes of that syndrome are disruption or tears of the external oblique aponeurosis and/or the transversal fascia, resulting in weakness of the posterior wall of the inguinal canal [7]. If similar changes at the level of the posterior rectus sheath and the transversal fascia may be involved in the pathogenesis of ACNES, then reinforcement of the weakened abdominal wall at the painful area seems to make sense.

Besides the hypothesized protective effect of IPOM, the acupuncture effect of tacks placed circumferentially around the trigger point might contribute to the overall success of the procedure. In addition, by inertia we applied a microporous mesh that had already been in our routine usage for LRVIH. It could be hypothesized that IPOM with application of a macroporous, or even a small-pore mesh, might achieve even better result. Either due to its better incorporation into the abdominal wall and/or its potential to contract, both reducing possibly even more the central tensile forces. The main disadvantage of the procedure is same as in LRVIH and is related to pain caused by the fixation of mesh [6].

Meanwhile, another Dutch group pioneered extensive research on ACNES [3, 16] and promoted surgical anterior neurectomy as an effective treatment for patients with intractable ACNES [4, 17, 18]. The reported short- and long-term success rates were 71% and 61%, respectively [18]. In indeed a retrospective study with a smaller study population, using similar evaluation criteria but a completely different approach, we reached short- and long-term success rates of 90% and 71%, respectively.

Limitations of this study are inherent to its retrospective character and small sample size. For example, there possibly exists a selection bias overlapping with chronic pain syndromes. Some reserves regarding implementation of this treatment in this patient category seems reasonable. Strength of this study is no loss to follow up as well as complete patient records with no information bias as a consequence.

To validate this new treatment concept a prospectively registered cohort should be subjected to a standardised treatment protocol including pre- en postoperative quality of life measurements. Upon establishing its merit, this treatment should be subjected to a randomised comparison with neurectomy powered for mainly patients' their satisfaction postoperatively.
IPOM reinforcement of the abdominal wall seems to be a promising option for the treatment of patients suffering from *intractable* ACNES and deserves further evaluation.

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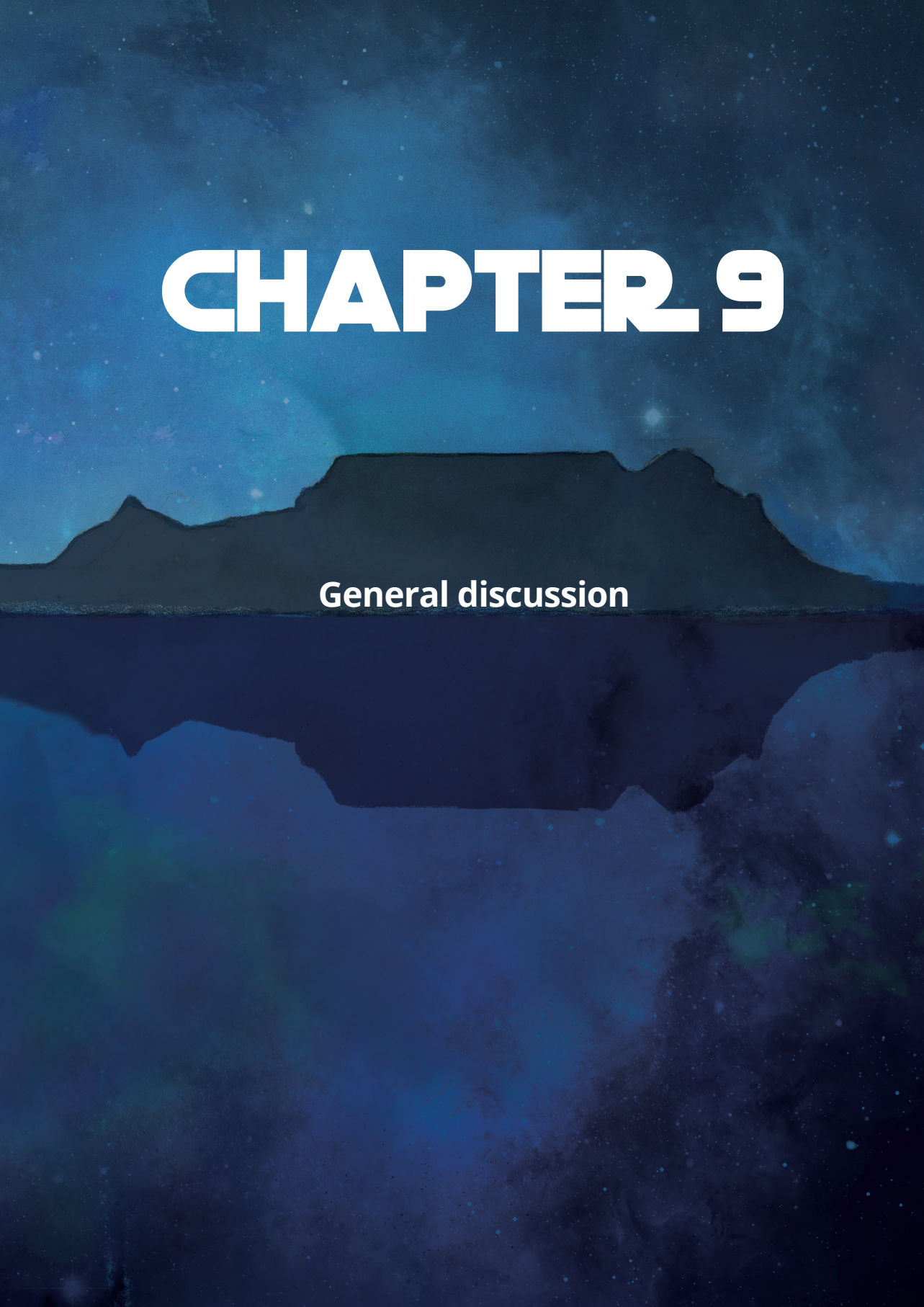

CHAPTER 9

General discussion

General discussion

The aim of this thesis was to investigate clinical outcome after laparoscopic intraperitoneal onlay mesh repair (LVHR) or reinforcement (ACNES) in order to improve preoperative counselling of patients and to further advance surgical technique. Five different questions were formulated that until now have been insufficiently answered in the literature:

1. Is pooling of data justified?
2. What are the main complications after intraperitoneal onlay mesh placement?
3. How do the number and type of tacks influence postoperative pain perception?
4. Is a 2-port procedure for laparoscopic ventral hernia repair feasible?
5. Is laparoscopic intraperitoneal onlay mesh reinforcement a treatment option for intractable anterior cutaneous entrapment syndrome?

Is pooling of data justified?

Multiple comparisons have been made to determine whether LVHR is as safe and efficacious as open repair of ventral abdominal wall hernia. Every systematic review and meta-analysis published until 2015 comprised of pooled data [1–6]. No distinction was made between PVH and IVH. This calls into question whether the conclusions reached in these reports are correct.

In **chapter 2** we investigated whether pooling of data of PVH and IVH was justified. We analysed the records of 1088 patients who underwent LR of a PVH or IVH between January 2000 and September 2012. The results showed distinct differences in all facets from patient characteristics, surgical findings and short- and long-term complications.

LR of IVH was a far more complex procedure in every aspect and at every stage of the operation. Adhesiolysis was almost exclusively related to IVH (76 vs 0.9%; p<0.001). The hernias were much larger in diameter (23 vs 2.4cm^2; p<0.001). As a consequence, LR required the use of more trocars (3.2 vs 2.4; p<0.001), larger meshes (323 vs 149cm^2; p<0.001), and more tacks (52 vs 28; p<0.001). Besides, conversions to laparotomy occurred more often (7 vs 0.5%: p<0.001).

In terms of outcome, two important distinctions would have gone unnoticed if IVH and PVH were pooled together. LR of IVH was associated with a four-fold higher grade ≥3 (Dindo-Clavien [7]) complication rate (18.69% vs 4.55%; p<0.001). Similarly, the recurrence rate was higher after LR of IVH (5.8 vs 1.4%; p<0.001). Differences in patient characteristics (such as age and ASA grade) and the greater procedural complexity undoubtedly contributed to these differences in outcome.

The results presented in **chapter 2** were asserted a year later by Köckerling *et al* who also illustrated the apparent differences between PVH and IVH [8]. They reported a lower overall postoperative complication rate for PVH (umbilical and epigastric) compared to IVH (3.2 and 3.5 vs 9.2%; p<0.0001). Likewise, at one year follow-up, a lower reoperation rate (1 and 1.2% vs 4.2%; p<0.0001) and recurrence rate (2% and 4.1% vs 6.3%; p<0.0001) were observed. Interestingly, while they had not pooled PVH and IVH, they did pool several different open techniques (suture repair, onlay, sublay, inlay and component separation) and LVHR in their analysis.

From 2015 and onwards, several meta-analyses were published that focused only on IVH [9, 10].

Conclusions

- Pooling of data of PVH and IVH cannot be justified; they are two different entities.
- A complication rate and recurrence rate of more than four times higher in the IVH group would have been overlooked if only pooled data were presented.

Clinical implications

- The differences between PVH and IVH should be taken into account during
  - Preoperative counselling of patients
  - The learning curve of residents
  - Preoperative planning, the procedure itself and the postoperative clinical course.

Future perspectives

- Avoid pooling PVH and IVH in clinical studies.

What are the main complications after intraperitoneal onlay mesh placement?

The three chapters discussed in this section contribute different perspectives on potential complications associated with IPOM placement. **Chapter 2** provides an overview of Dindo-Clavien grade ≥3 complications after LR of IVH. **Chapter 3** focuses on persistent posterior seroma. **Chapter 4** comments on the influence of IPOM placement on later pregnancy.

An overview of complications

LR of IVH is not devoid of negative outcomes and can potentially cause significant morbidity and even mortality. An overview from a large series of only IVH over a long time period did not exist in the literature. In **chapter 2** we have provided an overview of all complications Dindo-Clavien grade ≥3 [7] in a series of 396 patients who underwent LR of IVH between January 2000 and September 2012.

In total 74 (18.7%) grade ≥3 complications occurred. This number was comparable with complication rates reported in other smaller (<100) series (16-32%) [11, 12]. Extensive adhesiolysis (>30 minutes) was required in 38% and correlated with a higher rate of Dindo-Clavien grade ≥3 complications when compared to non-extensive adhesiolysis (33% vs 12%; p<0.001).

Early complications (≤30 days):

- Intra-abdominal bleeding 2 (0.5%)
- Prolonged ileus 5 (1.3%)
- Wound infection 1 (0.3%)
- Mortality not related to LR 3 (0.8%)
  - Cardiac arrest twice
  - Mesenteric ischemia once
- Unrecognised bowel lesion 3 (0.8%)

Late complications (>30 days):

- Chronic pain 4 (1%)
- Symptomatic bulging 8 (2%)
- Trocar site hernia 12 (3%)
- Recurrence 23 (5.8%)
- Symptomatic persistent ventral seroma 3 (0.8%)
- Mesh infection 10 (2.5%)

Conclusions

- Grade ≥3 complications after LR of IVH occur in almost one of five patients.
- Grade ≥3 complications after extensive adhesiolysis occur in one of three patients.

Clinical implications

- Complication rates after LR of IVH and eventual extensive adhesiolysis should be taken into account during
  - Preoperative counselling of patients
  - The learning curve of residents
  - Preoperative planning, the procedure itself and the postoperative clinical course.

Future perspectives

- Collection of similar data in a nationwide registry (e.g. a Dutch hernia registry).
  - What are the early- and late complications of LVHR on a nationwide level?
  - How do different materials and techniques influence these complications?

Persistent posterior seroma

A less known complication after LVHR is the occurrence of a seroma located posterior to a mesh (visceral side). It is a far less apparent entity than the usually visible ventral seroma. Its diagnosis is prompted with physical complaints like pain and swelling. An ultrasonography could confirm the diagnosis, but will be less informative about the quality of the repair nor will it exclude the differential diagnoses. An abdominal CT-scan is more revealing in that respect.

Posterior seroma after LVHR has been reported only twice in the literature. One short term (≤3 months) prospective cohort was published in 2015 by Morales-Conde *et al* [13]. It included fifty consecutive patients who underwent repeated abdominal CT-scans after LVHR with an ePTFE mesh. The incidence at one week, one month and three months was 44, 33 and 16%, respectively. No correlation was established with ventral seroma nor with BMI. Only the size of the prosthesis was significantly larger (p=0.048) in those with a posterior seroma. They suggested that a larger size of prosthesis led to a delayed reabsorption of the posterior seroma. Only one (2%) patient complained of discomfort and swelling that spontaneously disappeared within three months postoperatively.

One intermediate term (follow-up 6-36 months) retrospective cohort study was published in 2008 by Tsereteli *et al* [14]. They reported seven (1.6%) persistent posterior seroma (PPS) in a total of 442 patients who underwent LVHR with an ePTFE mesh. Four patients had a symptomatic PPS and underwent up to three attempts at percutaneous drainage. In

all cases the fluid collection re-accumulated quickly thereafter and the physical complaints returned. Only after relaparoscopy with removal of a thick neoperitoneum, with removal of the mesh in one patient, did PPS not reappear again.

In **chapter 3** we investigated the clinical course of PPS (persistent defined as >3 months) and identified independent predictors related to it.

Between January 2003 and July 2014 a total 1288 patients underwent LVHR with an ePTFE mesh of whom 166 (12.8%) underwent an abdominal CT-scan afterwards. A PPS was observed in fourteen (8.4%) of 166 CT scans at a median six months (IQR 7, range 4-18 months) postoperatively. Eleven patients were symptomatic. A wait-and-see policy with analgesia was successful in eight patients. Three patients underwent relaparoscopy with drainage of the PPS and excision of the thick neoperitoneum that covered the mesh. Complaints resolved in all three patients and no recurrence of a PPS was observed afterwards.

What is the aetiology of a posterior seroma? The histological examination of the excised thick neoperitoneum was consistent with a foreign body reaction in both our series as well as Tsereteli's. However, the ePTFE's foreign body reaction is not as strong as it can be with other types of meshes (polyester and polypropylene)[15]. With the exception of two anecdotal cases in the literature, the occurrence of a PPS was only seen with ePTFE meshes [13, 14, 16].

Does the structure of the ePTFE mesh itself play a role? First, the microporous (3 mm) structure does not permit interlinking bridges of connective tissue to pass through the mesh. Second, the microporous hydrophobic surface on the visceral side hampers reabsorption of the fluid when it accumulates between the neoperitoneum and the mesh. As a consequence, an interposed fluid collection can detach the neoperitoneum from the mesh. This mechanism is more profound in larger meshes and, not surprisingly, a mesh greater than 300cm^2 was an independent predictors of a PPS. This observation was similar to the single correlation established by the Morales-Conde *et al*.

Two types of tack detachment were observed in relation to PPS. First, tacks from the inner circle were detached from the mesh but held firmly in the thick neoperitoneum. This could easily be seen on a CT-scan. Second, the periphery of the mesh was detached from the abdominal wall with the tack still attached to the mesh itself. This was visible during the relaparoscopy. Nevertheless, the clinical relevance of these types of detachment was unclear since no recurrences were observed.

The clinical course of PPS is mostly mild and can initially be managed with a wait-and-see-policy with analgesia. Patients with persisting symptoms may require laparoscopic excision

of the thick neoperitoneum that provides a good outcome. Tack and mesh detachment due to PPS is a novel observation and has been described here for the first time. Clinical consequences of this phenomenon are not completely clear for recurrences have not been observed in this series.

Conclusion
- A PPS is a relatively common complication after LVHR with an ePTFE mesh of usually larger hernias.

Clinical implications
- PPS can be managed conservatively in three of four cases (wait-and-see policy).
- Laparoscopic drainage with excision of the thick neoperitoneum is effective when conservative management fails.

Future perspectives
- Does a posterior seroma develop in conjunction with other types of meshes?

Pregnancy

A clear treatment strategy does not exist for women of childbearing age with a ventral abdominal wall hernia who intend to have further pregnancies. Literature on pregnancy before or after ventral abdominal wall hernia repair remains scarce. No randomised controlled trials exist to date. The available literature consists of retrospective studies with small numbers (except for one).

Watchful waiting seems safe according to one recent large retrospective cohort study [17]. Seventeen (0.08%) umbilical hernias were observed in 20,714 pregnant women all of whom had uncomplicated full term pregnancies. Contrarily, anecdotal evidence cautions against watchful waiting, for hernias may become incarcerated during pregnancy (e.g. with a gravid uterus) [18-23].

Does expansion of the abdominal wall and increased intra-abdominal pressure during pregnancy complicate prior ventral abdominal wall repair? In a case-series of 27 women, who underwent open suture repair for PVH and IVH, no recurrences were observed after 41 full term pregnancies [24]. A recent review underlies the safety of preceding suture or mesh repair [25].

What is the clinical course of pregnancy after LVHR? In **chapter 4** we investigated the clinical course of pregnancy and delivery in eight women following LVHR with a mesh. No complications were observed during full term pregnancies and thereafter. The only

detrimental effect of an IPOM repair was pain experienced during the third trimester at the fixation points of the mesh. It was limited to the pregnancy itself and it abated after childbirth. There were no cases of chronic pain.

Conclusion

- LVHR causes no significant complications during pregnancy or delivery.

Clinical implications

- LVHR is an acceptable treatment option for women of childbearing age with a symptomatic abdominal wall hernia.

Future perspectives

- A clear treatment stratagem does not exist for symptomatic PVH or IVH in fertile women who intend to become pregnant. The necessary information may be provided by
    - A nationwide registry (e.g. Dutch hernia registry), or
    - A randomised controlled trial comparing watchful waiting with LVHR and powered for perioperative pain and patient satisfaction

How do the number and type of tacks influence postoperative pain perception?

In **chapter 5** we hypothesised that less tacks would result in less postoperative pain. To investigate the validity of this hypothesis, we compared two prospective cohorts of forty patients that differed only in the number of tacks.

All patients had a symptomatic umbilical hernia no larger than 2cm in diameter and underwent an identical elective LR with an ePTFE mesh. A double-crown fixation was implemented with the same type of nonabsorbable tack. In the first group (free tacking) no specific effort was made to minimise the number of tacks (n= 45.4 ±9.6). In the second group (controlled tacking) a predefined number of tacks was placed (n= 20.4 ±1.4). The desired places for insertion of tacks were marked on the mesh before insertion into the abdomen.

The severity of postoperative pain (VAS 0-100) was only different in favour of controlled tacking at twelve weeks postoperatively (1.80 vs 5.78; p=0.002). This statistical difference had little clinical relevance since both values were low and in practise no administration of analgesia was required.

Fewer tacks do not create less pain, nor do more tacks create more pain. It seems that a simple relation between the amount of tacks and the intensity of pain experienced by a patient does not exist. Is nociceptive pain generated according to a threshold principle?

Do absorbable tacks cause a different level of pain when compared to nonabsorbable tacks? Several different types of absorbable tacks are available, which are marketed to cause less postoperative pain without compromising the strength of the fixation. Yet, there exist few prospective clinical studies that investigate outcome of absorbable tacks in LVHR. Pooled data of PVH and IVH were used in these studies with small study populations and many prognostic variables [26, 27]. So far, evidence of their superiority over nonabsorbable tacks in terms of postoperative pain is lacking.

In **chapter 6** we hypothesised that absorbable tacks would cause less postoperative pain. To investigate the validity of this hypothesis, we compared two prospective cohorts of forty patients that differed only in the type of tack. Nonabsorbable titanium tacks (Protack™) were used in one group and absorbable tacks (Securestrap™) were used in the other. The groups consisted of similar homogenous set-up as in the previous chapter.

The severity of postoperative pain (VAS 0-100) was significantly lower in favour of absorbable tacks at six (2 vs 5; p=0.008) and twelve weeks (1 vs 2; p=0.008). As was the case in the previous chapter, the statistical difference had little clinical relevance for the VAS scores were very low in both groups and patients did not require analgesics.

Much too early for the tacks to be absorbed, we postulated that the different shape and method of insertion were responsible for the difference in acute pain. The forked shape and its arrow-like insertion of Securestrap™ possibly cause less tissue damage than a helical shaped nonabsorbable tack that was screwed into the abdominal wall (like a cork screw). Other types of absorbable tacks feature helical shapes with a cork screw like insertion similar to nonabsorbable titanium tacks. Therefore the results of Securestrap™ should not be extrapolated to other absorbable tacks.

The Securestrap™ tacks are absorbed between twelve and eighteen months according to the manufacturer. Interestingly, at follow up at least 18 months after LR, there was no significant difference in postoperative pain between the two groups. The supposed beneficent effect of the absorbable feature on postoperative pain was not observed, which puts into question whether the greater costs of absorbable tacks are worthwhile.

Recurrence after LVHR with absorbable tacks was not discussed in **chapter 6**. Yet, this aspect is relevant when considering the use of absorbable tacks instead of non-absorbable tacks. One study (based on the Danish Ventral Hernia Database) investigated recurrence rate (secondary outcome measure) after LR of IVH with either non-absorbable or absorbable tacks [28]. With a median follow up of 40 months (range 0-72), they concluded that the use of absorbable tacks was an independent risk factor for recurrence (hazard ratio 1.53, 95% CI 1.11 – 2.09; p=0.008). However, they could not discern from the registry data what specific types of synthetic mesh and absorbable tacks were used.

Conclusions

- Fewer tacks do not create less pain, nor do more tacks create greater pain.
- Absorbable tacks did not have a clinically relevant reduction on pain.

Clinical implications

- The quality of the fixation should not be compromised by placing as little tacks as possible.
- Can the use of absorbable tacks be justified when they are more costly, may be a risk factor for recurrence and, most importantly, do not seem to deliver a clinically relevant reduction on postoperative pain?

Future perspectives

- There are no randomised controlled trials that investigate the non-inferiority of absorbable tacks. One on-going randomised controlled trial comparing absorbable tacks with nonabsorbable tacks (TACS trial) may provide additional insights into acute and chronic pain after LVHR.

Is a 2-port-procedure for laparoscopic ventral hernia repair feasible?

Well over twenty years after the introduction of LVHR, three or more trocars are still used to repair PVH and IVH. The International Endo Hernia Society (IEHS) guidelines state that 'the fundamental principle of laparoscopic surgery still holds true, which is the triangulation around the area of interest with an optimal distance from the target (16-18cm)' [29].

The use of trocars is not devoid of morbidity. Vascular and visceral injury (estimated prevalence of <0.5%) are rare but potentially life threatening [30]. Trocar site infection, bleeding and pain are more common but less severe [31]. Trocar site hernia (TSH; prevalence of 1.3% [32]) vary in severity and may require emergent re-operation in case of bowel obstruction or strangulation [33]. Trocar design as a possible cause for these complications has been investigated but no clear correlations have so far emerged [34].

Is the third trocar necessary? The number and positioning of trocars have not been thoroughly looked into. So far only four small case series have mentioned a 2-port procedure (2PP) and concluded that it was effective and safe for LVHR [35–38]. The differing level of detail of these studies and no comparison with a 3-port procedure (3PP) limit their applicability in daily practise.

In **chapter 7** we described a step-by-step modification of 2PP (How-I-Do-It). All 2PP were accomplished with the surgeon's two hands – one instrument inside the abdomen and one hand on the abdominal wall. A total of 371 patients underwent a 2PP for PVH (n=295) and IVH (n=76) without any conversions to 3PP or open surgery. The IVH were of low complexity (recurrent umbilical or epigastric hernia, TSH, post appendectomy).

An important feature of the 2PP is the entry technique of the first trocar over the costal arch. Even though a 11mm trocar was inserted, the musculofascial defect was not closed after its removal for it was covered by the costal arch itself. Its position was not associated with morbidity or TSH and was easily taught to residents.

We compared two retrospective cohorts that differed only in the number of trocars employed (two versus three). Perioperative findings and complications were used as a representation of technical ease and safety. 2PP seemed to be at least as safe when compared to 3PP. Notwithstanding, caution with the interpretation of the data is warranted because of a performance bias (learning curve), recall bias (retrospective study) and a restricted length of follow up.

The effect of a learning curve on the length of procedure (LOP) was observed when switching to 2PP. The LOP in the last 50 operations with 3PP was 37±16 min. The first 50 operations with 2PP took 30±10 min while the last 50 operations with 2PP took 20±9 min. The LOP in both groups of this series was strikingly shorter when compared to other series [4, 39–45].

A large prospective comparative cohort study with a sufficiently long follow up would address the imitations of the present study. It should compare 2PP with 3PP and investigate trocar site complications as the primary outcome. The low incidence of most trocar site complications make a randomised controlled trial less suited.

A 2PP requires at least one less trocar and no assistant. It appears to be as efficient and safe for PVH and low complexity IVH. It seems common sense not to make three holes in order to close one.

Conclusion

- A 2PP seems to be at least as efficient and safe for PVH and low complexity IVH.

Clinical implications

- Less resources employed (one less trocar, no assistant, shorter length of procedure).
- Improved cosmetics with one less scar.

Future perspectives

- Proof of concept with a prospective study large enough to observe trocar related complications (e.g. Dutch hernia registry).

Is laparoscopic intraperitoneal onlay mesh reinforcement a treatment option for intractable anterior cutaneous entrapment syndrome?

In **chapter 8** we investigated whether patients suffering from *intractable* ACNES benefit from IPOM reinforcement at the trigger point. We hypothesised that IPOM reinforcement could dissipate excessive tension at the trigger point and ameliorate symptomatic entrapment of the neurovascular bundle.

Support for this hypothesis was found in another condition of the abdominal wall called inguinal disruption (ID) – formerly known as sportsman's groin [46]. The similarities are in the presentation of the syndrome, the pathophysiology as well as its treatment.

ID is characterised by circumscriptive pain felt predominantly near the pubic tubercle (trigger point). Abnormal tension in the inguinal canal causes compression of the ilioinguinal and genitofemoral nerve (entrapment) [47, 48]. ID features posterior wall weakness in 85% of cases. Reinforcement with a mesh, either through an open or laparoscopic approach, provides good to excellent results in 90% of cases [49, 50].

Current treatment for *intractable* ACNES is primary neurectomy [51]. It was significantly superior to a sham operation in a randomised controlled trial [52] and provided short- and long-term success rates of 70% and 61%, respectively [53]. Using similar evaluation criteria, but a completely different approach to *intractable* ACNES, we reached short- and long-term success rates of 90% and 71%, respectively.

It is important to note that the results in **chapter 8** were derived from a retrospective study with a relatively small sample size. This concept requires validation through a larger prospective cohort analysis that measures pre- and postoperative patient pain levels and patient satisfaction. The choice of different mesh materials, in terms of in-growth and contraction, and only absorbable material should be considered. Whence beneficent, this treatment should be subjected to a randomised controlled trial where it is compared with neurectomy.

The concept of IPOM reinforcement at the trigger point seems to be a promising treatment option for patients suffering from *intractable* ACNES and deserves further evaluation.

Conclusions

- IPOM reinforcement for *intractable* ACNES could alleviate pain felt at the trigger point with short- and long-term success rates of 90% and 71%, respectively.

Clinical implications

- IPOM reinforcement may prove to be an alternative to neurectomy. It leaves the neuro-anatomy intact and addresses the pathophysiology itself.

Future perspectives

- The potential merits of IPOM reinforcement for *intractable* ACNES warrant further evaluation.

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CHAPTER 10

Samenvatting
in het Nederlands

Samenvatting in het Nederlands

In deze thesis zijn klinische uitkomsten onderzocht van laparoscopische intra-peritoneale onlay mat correctie bij LVHR en augmentatie bij ACNES. Het doel is het verbeteren van de voorlichting aan patiënten alsook het verder ontwikkelen van chirurgische techniek. Vijf verschillende vragen staan centraal die tot op heden onvoldoende beantwoord zijn in de literatuur:

1. Is het verenigen van onderzoeksdata te verantwoorden?
2. Wat zijn de voornaamste complicaties na intra-peritoneale onlay mat plaatsing?
3. Hoe beïnvloedt het aantal en soort tacks postoperatieve pijn?
4. Is laparoscopische correctie met een mat uitvoerbaar met twee trocars?
5. Is laparoscopische augmentatie met een mat een behandelingsoptie voor refractaire ACNES?

Is het verenigen van onderzoeksdata te verantwoorden?

Laparoscopische en open correcties van ventrale buikwandbreuken zijn in het verleden veelvuldig met elkaar vergeleken in overzichtsartikelen en meta-analyses. In deze vergelijkingen zijn primaire- (PVH) en littekenbreuken (IVH) samengenomen als één entiteit. Is het verantwoord deze onderzoeksdata te combineren?

In **hoofdstuk 2** wordt de laparoscopische correctie van PVH en IVH met elkaar vergeleken. Daaruit blijkt dat er duidelijke verschillen bestaan in alle facetten van patiëntkenmerken, technische aspecten alsook korte- en langetermijncomplicaties nadien. Deze verschillen zouden onopgemerkt blijven als onderzoeksdata worden samengenomen.

Het technische aspect van de behandeling van IVH is veel complexer dan voor PVH. Adhesiolyse komt vrijwel alleen bij IVH voor (76 vs 0.9%; p<0.001). De hernia's zijn veel groter in diameter (23 vs 2.4cm^2; p<0.001). Daardoor worden er meer trocars gebruikt (3.2 vs 2.4; p<0.001), zijn de matten groter (323 vs 149cm^2; p<0.001) en worden meer tacks geplaatst (52 vs 28; p<0.001). Ten slotte komen conversies naar een open techniek vrijwel alleen bij IVH voor (7 vs 0.5%: p<0.001).

Postoperatieve complicaties van graad ≥3 (volgens Dindo-Clavien) komen significant vaker voor bij IVH (18.69% vs 4.55%; p<0.001). Hetzelfde geldt voor een hoger recidief percentage (5.8 vs 1.4%; p<0.001). Verschillen in patiëntkenmerken en de grotere technische complexiteit van de operatie dragen daaraan bij.

PVH en IVH zijn verschillende entiteiten. Belangrijke verschillen blijven onopgemerkt wanneer deze worden samengenomen in wetenschappelijk onderzoek. Om patiënten van juiste informatie te voorzien moeten deze entiteiten apart worden onderzocht. Tijdens aanleren van deze techniek is het aan te raden om eerst eenvoudig te beginnen met PVH. In het algemeen geldt ook dat de voorbereiding van een operatie anders is voor IVH dan voor PVH.

Wat zijn de voornaamste complicaties na intraperitoneale onlay mat plaatsing?

Overzicht postoperatieve complicaties

In **hoofdstuk 2** wordt een overzicht gegeven van complicaties van graad ≥3 (volgens Dindo-Clavien) na laparoscopische correctie van IVH. Er werden 74 (19%) complicaties geconstateerd. Dit percentage is vergelijkbaar met andere onderzoeken in de literatuur (16 – 32%). Uitgebreide adhesiolysis (>30 minuten) komt in 38% van de gevallen voor en correleert met een hogere kans op complicaties dan wanneer die kort van duur is (33% vs 12%; p<0.001).

Vroege complicaties (≤30 dagen):

- Intra-abdominale bloeding 2 (0.5%)
- Persisterende ileus 5 (1.3%)
- Wondinfectie 1 (0.3%)
- Mortaliteit (niet LR-gerelateerd) 3 (0.8%)
  - Myocard infarct (2x)
  - Mesenteriale ischemie (1x)
- Onopgemerkt darmletsel 3 (0.8%)

Late complicaties (>30 dagen):

- Chronische pijn 4 (1%)
- Symptomatische bulging 8 (2%)
- Trocar hernia 12 (3%)
- Recidief 23 (5.8%)
- Persisterend ventraal seroom 3 (0.8%)
- Matinfectie 10 (2.5%)

Persisterend posterieur seroom

Seroomvorming aan de intra-peritoneale zijde van de mat (posterieur seroom) is een weinig beschreven fenomeen na LVHR. De literatuur beperkt zich tot twee observationele onderzoeken.

In een kortetermijn (≤3 maanden) prospectief cohortonderzoek werd een incidentie na één week, één maand en drie maanden beschreven van respectievelijk 44, 33 en 16%. Bij eén patiënt (2%; n=50) was het posterieur seroom symptomatisch; de klachten verdwenen spontaan binnen enkele weken.

In een middellangetermijn (follow-up 6-36 maanden) retrospectief cohortonderzoek

werd een prevalentie van 1.6% vastgesteld van *persisterend* (>3 maanden) posterieur seroom (PPS). Bij vier van de zeven patiënten was het posterior seroom symptomatisch en ondergingen ieder, tot driemaal toe, aspiratie van de vochtcollectie. In alle gevallen ontwikkelde het PPS zich opnieuw en kwamen de klachten terug. Na relaparoscopie met excisie van het dikke neoperitoneum waren de patiënten klachtenvrij.

In **hoofdstuk 3** onderzochten we het klinische beloop van PPS en welke factoren een invloed hebben op het ontstaan daarvan. Tussen januari 2003 en juli 2014 ondergingen 1288 patiënten een LVHR. Bij 166 (12.8%) patiënten werd er postoperatief een CT-scan (abdomen) gemaakt. Een PPS werd vastgesteld in veertien (8.4%) van deze CT-scans met een mediane tijd van zes maanden (IQR 7, spreiding 4-18 maanden) na de operatie. Bij elf patiënten was PPS symptomatisch. Een afwachtend beleid met analgesie was succesvol in acht patiënten. Drie patiënten bleven klachten hebben en ondergingen een relaparoscopie met drainage van het PPS en excisie van het dikke neoperitoneum dat de mat bedekte. Nadien waren alle drie patiënten klachtenvrij. Er werd geen recidief PPS waargenomen.

Wat is de etiologie van een posterieur seroom? Histologisch onderzoek van het geëxcideerde dikke neoperitoneum was consistent met een vreemdlichaamreactie. Echter, deze reactie op een ePTFE mat is niet zo sterk als die kan zijn op andere materialen (polyester en polypropyleen). Met de uitzondering van twee casussen in de literatuur, komt een PPS alleen voor wanneer een ePTFE mat wordt gebruikt.

Speelt de structuur van een ePTFE mat een rol? Ten eerste, de microporeuze (3 mm) structuur van de ePTFE mat staat niet toe dat bindweefsel door de mat heen groeit. Deze eigenschap voorkomt ingroei van de mat in de buikwand. Ten tweede, de viscerale oppervlakte van de mat is hydrofoob. Het vocht dat accumuleert tussen de mat en het dikke neoperitoneum wordt niet geabsorbeerd. Deze twee eigenschappen faciliteren dat het dikke neoperitoneum van de ePTFE mat af kan worden gedrukt. Dit mechanisme is meer uitgesproken naarmate een grotere mat wordt gebruikt. Een mat groter dan 300cm² was een onafhankelijke voorspeller voor het ontstaan van een PPS. Deze observatie werd ook door Morales-Conde *et al* vastgesteld.

Een PPS ging gepaard met het loslaten van tacks in een aantal gevallen. Dit gebeurde op twee manieren. Ten eerste, tacks van de binnenste cirkel raakten los van de mat en bleven wel vast zitten in het dikke neoperitoneum. Dit werd duidelijk gezien op de CT-scan. Ten tweede raakte de periferie van de mat met de tacks daarin los van de buikwand. Omdat dit niet gepaard ging met recidieven is de klinische relevantie van het loslaten van tacks onduidelijk.

Een PPS komt regelmatig voor na LVHR met een ePTFE mat van doorgaans grotere hernia's. Het klinische beloop is meestal mild en wordt initieel behandeld met een afwachtend beleid en pijnstilling. Wanneer klachten bleven bestaan was relaparoscopie met excisie van het dikke neoperitoneum effectief gebleken. Dat tacks en de periferie van de mat zelf los kunnen raken als gevolg van een PPS werd niet eerder in de literatuur beschreven. Klinische consequenties van het loslaten zijn onduidelijk. Er werden geen recidieven geconstateerd.

Zwangerschap na LVHR

Wat zijn de gevolgen van zwangerschap na eerdere LVHR met een mat? In **hoofdstuk 4** onderzochten we het klinische beloop van de zwangerschap en de bevalling in acht patiënten na eerdere LVHR met een mat. Er werden geen complicaties geobserveerd. Het enige negatieve aspect was pijn van de buikwand tijdens het derde trimester van de zwangerschap. Dit was beperkt tot de zwangerschap zelf en verdween na de bevalling. Er waren geen gevallen van chronische pijn.

Het lijkt dat uitzetting van de buikwand en toename van de intra-abdominale druk tijdens zwangerschap geen complicerende factoren zijn na LVHR. LVHR kan als een alternatief voor conservatieve therapie besproken worden met vrouwen van fertiele leeftijd die zich presenteren met een symptomatische hernia ventralis.

Hoe beïnvloeden het aantal en soort tacks de postoperatieve pijn?

Het wordt aangenomen in de literatuur dat matfixatietechniek een belangrijke invloed heeft op de postoperatieve pijnsensatie van de patiënt. De relatie daartussen is nog altijd niet opgehelderd en blijft een punt van discussie. Twee aspecten zijn niet of onvoldoende onderzocht.

In **hoofdstuk 5** onderzochten we de hypothese dat het plaatsen van minder tacks zou leiden tot minder postoperatieve pijn. We vergeleken twee prospectieve cohorten van veertig patiënten die alleen verschilden in de hoeveelheid tacks die werden gebruikt bij het fixeren van een mat. In de eerste groep werden tacks zonder beperkingen geplaatst (n= 45.4 ±9.6). In de tweede groep werden tacks geplaatst volgens een vooraf vastgelegde methode waarbij de posities van de tacks op de mat werden getekend (n= 20.4 ±1.4).

De ernst van de postoperatieve pijn (VAS 0 – 100) was alleen verschillend bij twaalf weken postoperatief in het voordeel van beperkt gebruik van tacks (1.80 vs 5.78; p=0.002). Dit statistische verschil had geen klinische gevolgen omdat de VAS-scores in beide groepen zodanig laag waren dat in de praktijk geen analgesie werd voorgeschreven.

Hiermee lijkt dat minder tacks niet minder postoperatieve pijn veroorzaken, noch dat meer tacks meer postoperatieve pijn veroorzaken. Er is geen evenredige relatie aangetoond tussen de organische schade veroorzaakt door tacks en de mate van postoperatieve pijn ervaren door de patiënt.

In **hoofdstuk 6** onderzochten we de hypothese dat het gebruik van absorbeerbare tacks zou leiden tot minder postoperatieve pijn. We vergeleken ook hier twee prospectieve cohorten van veertig patiënten die alleen verschilden van tackmateriaal dat werd gebruikt voor de fixatie van een mat. In de eerste groep werden niet absorbeerbare titanium tacks (Protack™) gebruikt en in de tweede groep absorbeerbare tacks (Securestrap™).

De ernst van postoperatieve pijn (VAS 0 – 100) was significant lager bij zes weken (2±5 vs 5±9; p=0.008) en twaalf weken (1±3 vs 2±4; p=0.008) in het voordeel van absorbeerbare tacks. Ook hier had het statistische verschil zeer beperkte klinische relevantie omdat de gemiddelde VAS-scores zodanig laag waren in beide groepen dat analgesie niet standaard werd voorgeschreven.

Op deze korte termijn waren de tacks nog niet geabsorbeerd. We veronderstellen dat

het verschil in vorm en methode van insertie in de buikwand dit waargenomen verschil van acute pijn verklaren. De gevorkte vorm en pijlachtige manier van insertie van de absorbeerbare tack veroorzaakt mogelijk minder weefselschade dan de helixvormige tack die als een kurkentrekker in de buikwand wordt gedraaid.

De absorbeerbare tacks zijn geabsorbeerd na twaalf tot achttien weken. Er werd geen significant verschil waargenomen tussen beide groepen bij follow-up van tenminste achttien maanden na LR. Dat het veronderstelde voordelige effect van absorbeerbare tacks niet werd waargenomen na absorptie stelt ter discussie of de hogere kosten van absorbeerbare tacks te verdedigen zijn.

Het gebruik van absorbeerbare tacks (Securestrap™) leidde niet tot minder klinisch relevante acute of chronische postoperatieve pijn. Andere types van absorbeerbare tacks zijn helixvormig en worden in de buikwand gedraaid. Daardoor kunnen de resultaten van de absorbeerbare tack in dit onderzoek niet geëxtrapoleerd worden naar andere absorbeerbare tacks.

Is laparoscopische correctie met een mat uitvoerbaar met twee trocars?

Laparoscopische correctie van PVH en IVH wordt veelal met behulp van drie of meer trocars verricht. Het gebruik van trocars is niet zonder morbiditeit en kan in sommige gevallen levensbedreigende complicaties veroorzaken. Directe vaat- en darmletsels zijn beschreven. Ook infectie en pijn van de wond en trocar hernia (TSH) komen postoperatief voor.

Is de derde trocar noodzakelijk voor LVHR? Het aantal trocars en de posities daarvan zijn onvoldoende onderzocht in de literatuur. Slechts enkele kleine case-series beschrijven een twee-trocar-procedure (2PP) zonder deze met de gangbare drie-trocar-procedure (3PP) te vergelijken.

In **hoofdstuk 7** werd 2PP voor LVHR stap voor stap beschreven (How-I-Do-It). Alle procedures werden verricht met één instrument in het lichaam en de andere hand van de chirurg van buiten af op de buikwand. In totaal ondergingen 371 patiënten een 2PP voor PVH (n=295) en IVH (n=76) zonder conversie naar 3PP of open correctie. Alle IVH waren laag complex (recidief PVH, TSH, post appendectomie).

In een retrospectieve vergelijking leek 2PP tenminste zo efficiënt en veilig als 3PP. De operatie was korter van duur en het aantal complicaties lag lager. Om de bevindingen van dit onderzoek te valideren is prospectief onderzoek nodig.

Is laparoscopische augmentatie met een mat een behandelingsoptie voor refractaire ACNES?

De huidige behandeling voor refractaire ACNES is neurectomie waarbij de betrokken zenuw chirurgisch wordt verwijderd. Op basis van een gerandomiseerd gecontroleerd onderzoek worden succespercentages op korte en middellange termijn beschreven van respectievelijk 70 en 61%.

In **hoofdstuk 8** onderzochten we de hypothese dat een augmentatie met een mat excessieve druk ter plekke van een trigger point kon verminderen waardoor symptomatische beklemming van de neurovasculaire bundel wordt verholpen. Op basis daarvan werden succes resultaten op korte en middellange termijn beschreven van 90 en 71%, respectievelijk. Het concept van laparoscopische augmentatie met een mat bij de trigger point lijkt daarmee een belovende behandelingsoptie te zijn voor patiënten met refractaire ACNES en verdient verder prospectief onderzoek.

CHAPTER II

Abbreviations
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List of Abbreviations

ACNES	Anterior cutaneous nerve entrapment syndrome
BMI	Body mass index
ePTFE	expanded polytetrafluoroethylene
ID	Inguinal disruption
IPOM	Intraperitoneal onlay mesh
IVH	Incisional ventral hernia
LOP	Length of procedure
LOS	Length of stay
LR	Laparoscopic repair
LVHR	Laparoscopic ventral hernia repair
PPS	Persistent posterior seroma
PVH	Primary ventral hernia
SSI	Surgical site infection
TAS	Transabdominal sutures
VAS	Visual analogue scale
VRS	Verbal rating score

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Curriculum Vitae

Our protagonist was born on the 11th of July, 1983 in Barcelona, Spain. His parents decided he would be successful, have African adventures and serve mankind, so he was dubbed Vincent Mauro Alexander Stirler.

When Vincent had mastered his basic bodily functions, his family moved to Eindhoven, where he enjoyed his primary education at the International School. Unbeknownst to him, he had started on the path of learning about trauma through field hockey, Judo and Duck Hunt.

At age thirteen, his parents divorced. Now living with his mom in Belgium, he attended the European School in Mol, where his fascinations for literature and science began. As part of the curriculum, he was allegedly complicit in the manufacture of fireworks, the implosion of a CRT monitor and the production and successful deployment of 1.4kg of improvised smoke grenades. To his credit, the calculations were his own.

Upon entering the new millennium, he enrolled in Medicine at the University of Maastricht, attending internships for International Health Science in Birmingham (England), Neurology in Dublin (Ireland) and Internal Medicine in Pretoria (South Africa).

After graduating in 2007, he took a gap year and spent it devouring books, learning archery and spending time in nature. To fulfil his desire to help others, he worked at a petrol station and completed a lot of quests in virtual worlds, healing and saving countless pixels. Finally, on a journey in China, he found his Path.

Upon returning in 2009 he applied for a post in Almelo as a resident in surgery, training for Tropical Medicine. A year and a half later he spent four months in Hawassa, Ethiopia. In 2012 he was admitted to formal surgical training.

He stayed in Almelo for another three years, subsequently working at the University Medical Centre Groningen, 't Isala in Zwolle and the Martini Hospital in Groningen. Having been bitten by trauma surgery, he concluded his training with a proper penetrating trauma experience of five months at the Tygerberg Hospital in Cape Town, South Africa.

It was in 2013 that he and Hanneke, the love of his life, became inseparable. Together they have two beautiful but naughty daughters Olivia and Valerie.

2018
Pieter "Jos" Bryon

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Now I can afford to look back. I cannot fail to notice that the completion of this book was not possible without the help and support of others. Just as important, the many distractions from this work were welcome and much appreciated. I am well aware that good work requires effective breaks. Did I take enough breaks?

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