Laparoscopic Ventral and Incisional Hernia Repair

Eelco B. Wassenaar

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GORE DUALMESH(R) PLUS Biomaterial
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Laparoscopic Ventral and Incisional Hernia Repair

Laparoscopisch herstel van voorste buikwandbreuken
(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 J.C. Stoof, ingevolge het besluit van het college voor promoties in het openbaar te verdedigen op vrijdag 16 oktober 2009 des middags te 2.30 uur

door

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geboren op 14 december 1973
te Groningen

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Contents

1

Introduction

Ventral and incisional hernia repair is one of the most frequently performed operations in daily surgical practice. It is estimated that in the United States each year more than 100,000 ventral and incisional hernia repairs are performed [1]. Ventral hernias can be defined as primary, congenital or non-operatively acquired defects in the musculo-aponeurotic coverage of the abdomen, situated between the costal arch, pubic bone and the semilunar lines. Examples of ventral hernias are umbilical, epigastric and spigelian hernias. Incisional hernias are defined as any abdominal wall defect with or without bulge in the area of a postoperative scar, perceptible or palpable by clinical examination or imaging [2].

For a very long time these disorders were treated non-operatively using trusses or some other type of support. If surgical therapy was undertaken the margins of the defects were simply (re-) approximated by primary suturing [3, 4]. Results of this suture repair of abdominal wall hernias were disappointing, with recurrence rates of 54% to 63% [5, 6].
In order to improve these results additional relaxing incisions in the rectus sheaths were used to decrease tension on the suture line [7]. However, this often resulted in new hernias at the site of these incisions and was still accompanied by similarly high recurrence rates [8].
Introduction of synthetic meshes dramatically changed the surgical practice because of significantly lower recurrence rates. Long-term follow-up data of a randomized controlled trial comparing the two techniques show a recurrence rate of 63% for suture repair compared to 32% for mesh repair [6].

Generally there are two ways to use a mesh in hernia repair, either as a bridging measure or as an augmenting support. When using the mesh as an augmentation, the abdominal wall is first reconstructed by complete closure of the musculo-aponeurotic structures. The mesh is then placed either on top of the reconstructed abdominal wall (onlay, position A) or below (sublay, position B).

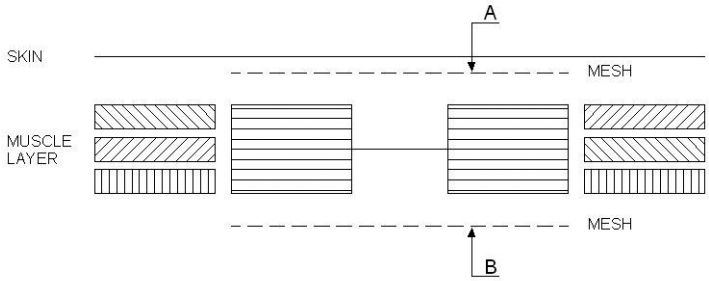

Figure 1

With the bridging technique, muscles are not brought together and the abdominal wall therefore is not reconstructed. The mesh is simply used to bridge the defect with adequate overlap on all sides.

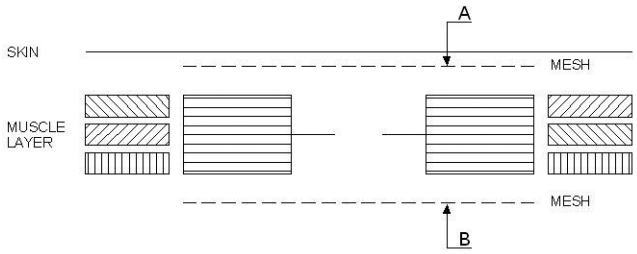

Figure 2

Laparoscopic ventral and incisional hernia repair (LVIHR) was first described in 1993. LeBlanc and Booth published their experience with a series of five patients. Expanded polytetrafluoroethylene patches were stapled to the anterior abdominal wall using tacks [9]. The authors hypothesized that normal positive abdominal pressure supports anchoring of the mesh against the abdominal wall.

An important difference between open and laparoscopic repair is the position of the mesh. In open repair the mesh is preferably placed in a sublay position with respect to the abdominal muscles and extra-peritoneally, preventing direct contact between the mesh and intra-abdominal organs. In laparoscopic repair the mesh is also in a sublay position but placed intra-peritoneally, inevitably allowing direct contact of the mesh with intra-

abdominal organs. As a consequence, intensive research has been done to develop special meshes suitable for intra-peritoneal placement that would cause minimal intra-abdominal adhesions. Information on adhesion formation or incorporation into the abdominal wall of these meshes however is primarily based on animal studies [10-16]. Only one publication has specifically addressed findings at re-operation after these meshes were used for LVIHR [17] and in one series this issue was addressed briefly [18].
In 2000 LeBlanc and Booth published a series of 100 patients with LVIHR emphasizing the need for adequate overlap of the hernia defect and proper fixation of the mesh [21]. Development in fixation technique since the first publication of LVIHR has been prominent to attain a properly secured mesh. Due to high early recurrence rates when only tacks were used to fix the mesh, transabdominal sutures were added [21]. As an alternative to this, other authors advised adding a circle of tacks to the standard number of tacks [22]. A review comparing these fixation techniques was not able to conclude which method should be used [23]. Because of multiple variations in the techniques used in the publications that were reviewed and the low quality of the studies, no significant differences could be found in complication and recurrence rates. In present practice for LVIHR the abdominal wall gap is usually bridged, without abdominal wall reconstruction. Although two authors do suture the hernia defect before fixation of the mesh [18, 24], most think abdominal wall reconstruction is not necessary to create a repair with minimal recurrence rates as long as sufficient overlap is ensured [25].

In several studies minimally invasive surgical techniques are shown to be advantageous to open surgery, as for example in Cochrane reviews of cholecystectomy and inguinal hernia repair [19, 20]. Alleged advantages of laparoscopic surgery such as shorter hospital stay, less pain and less infection, might also apply to ventral and incisional hernia repair. So far though no study has been able to prove this.

The improvements in mesh fixation technique and the use of larger meshes to create greater overlap of the defect [26, 27] might have led to the decreased recurrence rates in published series of LVIHR [28, 29]. Therefore, other complications are becoming important. As in inguinal hernia repair, post-operative pain currently is an important issue [30]. Post-operative pain persisting more than three months after LVIHR is commonly reported in large series and case reports [28, 31, 32]. After inguinal hernia repair, chronic pain has been attributed to mesh fixation [33]. Fixation of the mesh during LVIHR therefore also is considered to be an important causative factor for post-operative pain, although multiple theories exist. Some authors believe pain is caused by the transabdominal sutures [26, 32], others hold the tacks responsible [31]. No randomized trials comparing fixation methods with regard to post-operative pain have been published so far.

Central questions and outline

The aim of this thesis is to study complications and techniques of LVIHR, thereby offering improvements in technique. To accomplish this aim we will try to address questions on LVIHR that until now have not been adequately answered in the literature:

- What causes recurrence after LVIHR?
- How can we treat chronic post-operative pain?
- How should the mesh be fixated?
- What are the clinical consequences of intra-abdominal mesh placement?

We have conducted the following clinical studies to find answers to these questions.
Chapter 2 is a retrospective study on recurrences after LVIHR. We reviewed these recurrences in search of causes and preventive measures.
A fatal complication after LVIHR prompted us to search for the cause of this death. *Chapter 3* tries to draw conclusions on what went wrong and if this death could have been prevented.
We performed a study on solutions for chronic post-operative pain. In dealing with patients with pain, various treatments were used. *Chapter 4* tries to find an answer to the causes of chronic post-operative pain and how it can be treated.
Mesh fixation is an important part of LVIHR. In *chapter 5*, three different mesh fixation techniques are compared in a randomized trial with special emphasis on post-operative pain and quality of life.
Chapter 6 is a study comparing operation time for two different mesh fixation techniques. Little information is available on the consequences of intra-abdominal mesh placement and its impact on subsequent abdominal operations. *Chapter 7* shows the results of a series of patients after LVIHR that have been re-operated. We studied the adhesions to the mesh and their possible clinical consequences.

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2

Recurrences after laparoscopic repair of ventral and incisional hernia: lessons learned from 505 repairs

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Abstract

Background: All hernia recurrences in a series of 505 patients who underwent laparoscopic repair of a ventral hernia (n = 291) or incisional hernia (n = 214) were analyzed to identify factors responsible for the recurrence.

Methods: In all laparoscopic repairs, an expanded polytetrafluoroethylene prosthesis overlapping the hernia margins by ≥ 3 cm was fixed with a double ring of tacks alone (n = 206) or with tacks as well as sutures (n = 299). During the mean follow-up time of 31.3 ± 18.4 months, 9 patients (1.8%) had a recurrence; eight recurrences were repaired laparoscopically. Operative reports and videotapes of all initial repairs and repairs of recurrences were analyzed.

Results: All recurrences followed an incisional hernia repair ($p < 0.001$). Five recurrences developed after mesh fixation with both tacks and sutures and 4 after mesh fixation with tacks alone ($p = 1.0$). All recurrences were at the site of the apparently sufficient original incision scar: in 8 patients, the recurrent hernia was attached to the mesh; in 1, it developed in another part of the scar. All initial repairs had been performed without technical errors. Upon repair of the recurrences, a new, larger mesh was placed over the entire incision, not just the hernia. There were no re-recurrences during follow-up (mean 19.8 ± 10.3 months).

Conclusions: Recurrence after incisional hernia repair appears to be due primarily to disregard for the principle that the whole incision—not just the hernia—must be repaired. Our experience supports the idea that the entire incision has a potential for hernia development. Insufficient coverage of the incision scar is a risk factor for recurrence after laparoscopic repair of ventral and incisional hernia.

Introduction

Laparoscopic repair of ventral and incisional hernia (LRVIH) offers the benefits of a short hospital stay, less morbidity, and low recurrence rate. Recent reviews have indicated that the recurrence rate after LRVIH is now about 3% or 4% [1-3], which is markedly lower than the rate after open repair. However, little information exists on the factors that contribute to the recurrences that do develop after LRVIH. We therefore analyzed all hernia recurrences in a series of 505 patients who underwent LRVIH with the goals of identifying aspects of the operative procedure, patient and hernia characteristics, and operative outcomes associated with recurrence and of ascertaining ways to promote additional decrease in recurrence rates.

Patients and methods

Between January 2001 and December 2007, 2 senior surgeons (J.T.F.J.R and S.R.) individually attempted to perform LRVIH in 521 patients. Conversion was necessary in 16 cases (3.1%) because adhesiolysis could not be completed laparoscopically or a bowel lesion was detected. Thus, 505 patients underwent LRVIH. Early in the series, the operations consisted predominantly of ventral hernia (VH) repairs, which are technically easier to perform than incisional hernia (IH) repairs, and a few relatively simple IH procedures. The proportion of more complex incisional hernia repairs increased gradually with the number of LRVIH operations done, from 32% in the initial one hundred operations, to 42% and 46% in the second and third hundred, reaching 50% in the fourth hundred.

Operative technique

All patients in the series underwent LRVIH using an expanded polytetrafluoroethylene mesh (ePTFE; DualMesh, WL Gore & Associates, Flagstaff, AZ) tailored to overlap all hernia margins by at least 3 cm. No attempt was made to reapproximate the edges of the hernia opening.

In 299 patients, the mesh was fixed with tacks (ProTack, TycoUSS, Norwalk, CT) placed circumferentially at 1-cm intervals as well as with transabdominal sutures (TAS). The TAS used were nonabsorbable (Mersilene; Ethicon, Norderstedt, Germany) in 238 patients and absorbable (Vicryl; Ethicon) in 61. The TAS were placed circumferentially at 4- to 5-cm intervals by using a suture passer instrument (Gore Suture Passer, WL Gore & Associates), and each suture encompassed 1 cm of tissue. The TAS were tied down with care to avoid knotting the thread too tightly. Knots were buried in the subcutaneous tissue. In the remaining 206 patients, the mesh was fixed only with a double crown (2 rings) of tacks.

The outer ring of tacks was placed in the same position as the TAS used in the TAS-and-tack method. Tacks in the inner ring were placed around the hernia opening at 1-cm intervals. The size of the hernia did not play a role in selection of the method used to attach the mesh. In the first 204 patients, the selection was the surgeon's preference. Subsequently, the mesh-fixation technique was randomly determined as part of an ongoing study of the possible effect of the fixation method on postoperative pain.
All patients were scheduled to return for a follow-up examination 2, 6, and 12 weeks and 1 year after the operation and annually thereafter. All patients for whom a recurrence was suspected but not clinically obvious underwent an ultrasonographic or computerized tomographic (CT) assessment or both. A few patients with symptoms underwent diagnostic laparoscopy. Eight of 9 observed recurrences were repaired laparoscopically.

Data collection and analysis
Operative reports and, when available, videotapes of the initial repairs (n = 2) and repairs of the recurrences (n = 8) were examined. The following data were collected for each patient: age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) classification, history of previous abdominal operations and hernia repairs, type of hernia, location of hernia, size of prosthetic mesh implanted, type of mesh fixation, operating time, complications, length of hospital stay, and hernia recurrences.
Data were analyzed with use of the Fisher exact test, Chi-Square test and Wilcoxon test. A *p*-value of less than 0.05 was considered to represent a significant difference.

Results

Table 1 shows characteristics of the 505 patients in the series, including the location of their hernias. Among the patients who underwent IH repair, 59 (28%) had already had a recurrence of one or more hernias previously repaired with use of an open approach.

Table 1. Patients' characteristics (total *n* = 505)

Characteristic	Value*
Gender: M/F	306/199
Mean (± SD) age, years	53.5 ± 13.8
Mean (± SD) BMI (based on kg/m^2)	29.8 ± 5.2
Mean (± SD) ASA score	1.6 ± 0.7
Hernia type	
Ventral hernia	291
Umbilical	206
Epigastric	65
Spigelian	20
Incisional	214
Midline	94
Subcostal right	27
Transverse right or left	16
McBurney	11
Lumbar	1
Parastomal	2
Pfannenstiel	6
Other†	57

* Values are numbers of patients or hernias unless otherwise specified
† Recurrent umbilical, recurrent epigastric, trocar site
BMI, body mass index; ASA, American Society of Anesthesiologists

Table 2 shows a comparison of characteristics in patients with IHs and patients with VHs. Conversions to open repair were significantly more common, and mesh sizes were significantly larger, in the IH group. Data regarding size of hernia were either not complete or not precise, particularly in the VH group.

In 3 patients (0.7%), all of who underwent IH repair, a missed bowel lesion necessitated a reoperation 1 to 4 days after the repair. During reoperation, the mesh was removed and the hernia was closed primarily. Subsequently, the hernia recurred in all 3 patients. These patients were not included in our analysis of factors associated with recurrence after LRVIH.

Table 2. Characteristics of ventral and incisional hernias in the series

Characteristic	Ventral hernias	Incisional hernias	*p* value
Mean (± SD) mesh size (cm^2)	155.8 ± 59.9	334.0 ± 202.1	0.001
Conversions to open repair (*n*)	2	14	<0.001
Hernia recurrences during follow-up (*n*)	0	9	<0.001

Table 3 shows the (post-) operative complications.

Table 3. (Post-) operative complications in the series (excluding bulging and recurrence)

Complication	*n*	*%*
Intraoperative		
enterotomy	4	0.8
trocar site bleeding / hematoma	14	2.8
Early postoperative		
prolonged ileus	6	1.2
seroma / hematoma	43	8.6
urinary retention	12	2.4
trocar site infection (mesh removal)	3	0.6
missed bowel lesion (mesh removal)	3	0.6
ileus/small bowel herniation through trocar site	1	0.2
mesenterial ischemia (mortality)	1	0.2
myocardial infarction (mortality)	1	0.2
Late postoperative		
pain lasting > 3 months	11	2.2
trocar site hernia	5	1.0
mesh infection (removal)	1	0.2
ileus / smal bowel obstruction	1	0.2

The mean follow-up time in the series was 31.3 ± 18.4 months (range, 1-79 months). Attendance at follow-up visits within one year of surgery was excellent and 99% of patients were seen at 3-month controls (472/476) and 95% at one-year controls (381/401). Attendance at annual follow-up controls thereafter was lower and declined progressively to 72% (241/316), 51% (103/201) and 43% (42/98) at 2-, 3-, and 4-years consecutively. During follow-up, 13 patients had onset of pain (n = 11), swelling (n = 10), or both (n = 8) in the hernia repair area. A hernia recurrence was clinically obvious in 7 of these patients. In the remaining 6, a clinical diagnosis of recurrence could not be made with certainty, and the differential diagnosis included bulging of the mesh or chronic pain at TAS sites not resolved by local infiltration with anesthetic agents. CT scanning was performed in 4 patients and did not show a recurrence in any. One of these patients, who was one of the patients with nonpainful swelling, required laparotomy because of malignant disease. The other 2 patients, who did not have a CT-scan, underwent diagnostic laparoscopy, which detected a recurrent hernia.

Thus, a recurrence was confirmed in 9 patients (1.8%), all of whom had undergone repair of an IH ($p < 0.001$). Table 4 shows the locations and characteristics of the 9 recurrences. The recurrences were observed a mean of 14.2 ± 9.9 months postoperatively. Eight of the patients with recurrence had undergone repair of a first IH; the ninth was treated for an IH recurrence. Compared with the other patients in the series who underwent IH

repair, patients with an IH recurrence had a similar age (54.4±13.2 years; p = 0.81), gender distribution (6M/3F; p = 0.31), BMI (31.0±5.2kg/m^2; p = 0.36), ASA score (1.7±0.5, p = 0.17), operating time (89.6±21.3 min.; p = 0.20) and size of prosthetic mesh implanted (428.0±200.9 cm^2; p = 0.15) as well as postoperative hospital stay (3.2±3.1 days; p = 0.74).

Table 4. Characteristics of the 9 incisional hernia recurrences

						Area of recurrence	
Case*	Location	Defect size (cm^2)	Mesh size (cm^2)	Fixation method	Time (months) to recurrence	Line of scar	Attached to mesh
19	Rt SC	2	96	TAS	34	Yes	Yes
100	Rt ext SC	40	435	TAS	34	Yes	Yes
161	Rt trans	45	600	DC	3	Yes	No
164	Rt SC	100	696	TAS	10	Yes	Yes
167	Rt SC	75	570	TAS	12	Yes	Yes
182	ML	110	600	DC	12	Yes	Yes
296	ML	15	285	TAS	11	Yes	Yes
364	ML	60	285	DC	13	Yes	Yes
365	ML	49	285	DC	14	Yes	Yes

* Consecutive within series of 505 cases
Rt, right side; SC, subcostal; TAS, transabdominal sutures; ext, extended; DC, double crown (2 rings) of tacks; ML, midline; trans, transverse

Seven patients with recurrence had no intraoperative or postoperative complications, including infection. One patient had a large postoperative seroma that resolved without intervention. Another patient developed a post-operative ileus that was conservatively treated.

Five recurrences developed in patients in whom the mesh was fixed with both tacks and TAS (nonabsorbable TAS in 4 cases; absorbable TAS in 1). There were 4 recurrences in patients in whom the mesh was fixed only with a double ring of tacks ($p = 1.0$).

Interestingly, all recurrences were at the site of what had initially appeared to be a sufficient incision scar. In 8 patients, the recurrent hernia was attached to the mesh (Fig. 1); in 1, it developed in another part of the incision scar, with a bridge of sufficient scar between the repair site and the recurrence (Fig. 2). The evaluation of operative reports and videotapes of the initial repairs in the patients with recurrence confirmed that 8 of the repairs were performed in a technically correct manner and after an assessment of the whole incision region, thereby excluding the possibility of a missed hernia. In the other patient, who had an IH in the central part of a long midline incision, most of the incision was dissected free of adhesions during the initial repair and the hernia defect was covered with a large prosthetic mesh (30 by 20 cm). The epigastric end of the incision, however, was neither dissected free nor covered with mesh. This became the site of the recurrence; thus, an asymptomatic hernia may have been missed during the initial repair.

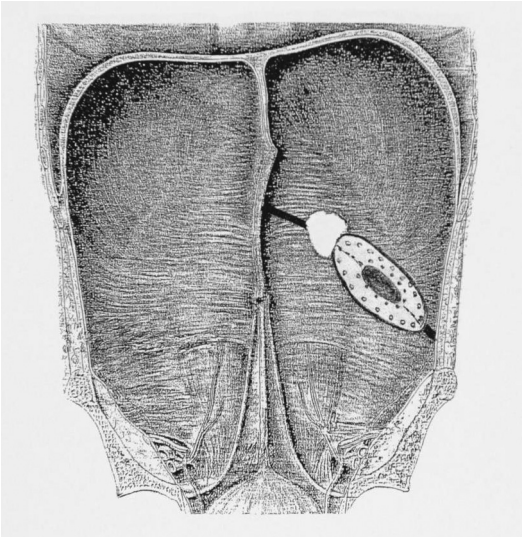

Figure 1 Schematic showing recurrent hernia attached to the mesh

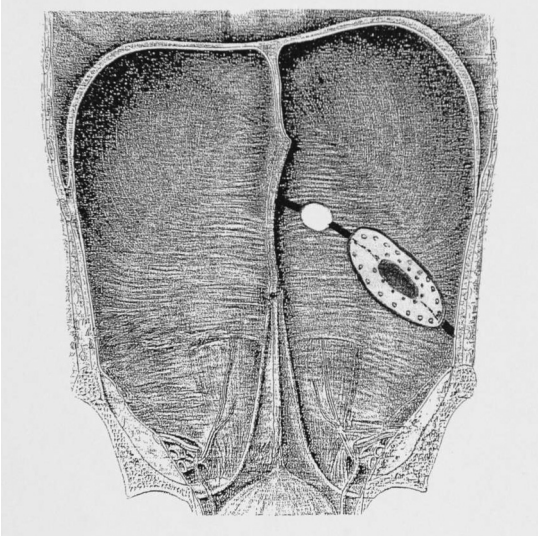

Figure 2 Schematic showing recurrent hernia in another part of the incision scar, with a bridge of sufficient scar between the repair site and the recurrence

One symptom-free patient with a recurrent hernia did not want his recurrence to be treated. In all 8 patients who opted for reoperation, recurrences were repaired laparoscopically, with placement of a new, larger mesh over the entire incision, not just the hernia. No re-recurrences were observed during the follow-up period (mean 19.8 ± 10.3 months) after these repairs.

The 4 patients who had symptoms suggestive of a recurrent hernia but in whom laparotomy or laparoscopy definitively excluded a recurrence were all found to have bulging of the mesh. The patient who underwent laparotomy for malignant disease, a procedure that included removal of the mesh implanted during hernia repair, had a sufficient repair but with a central bulging of the mesh into the original umbilical hernia (Fig. 3). In the other 3 patients, laparoscopy showed a protrusion or bulging of mesh that may have been too loosely stretched across the hernia defect during LRVIH. These findings were in accordance with preoperative CT scanning results: recurrence was not detected, but mesh bulging appeared possible in 2 of the 3 patients studied (Fig. 4). Mesh bulging was corrected by stretching a new, larger mesh tightly over the entire previous repair. Subsequently, the patients remained symptom-free during a median follow-up period of 17 months.

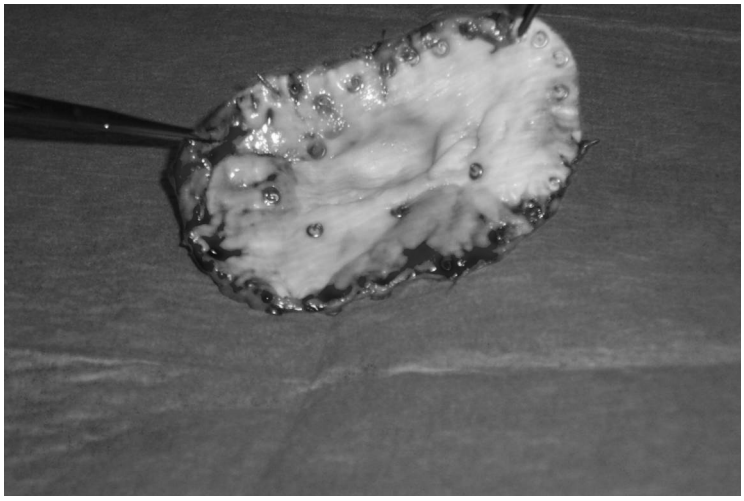

Figure 3 Photograph of the removed mesh obtained at laparotomy shows central bulging of the mesh

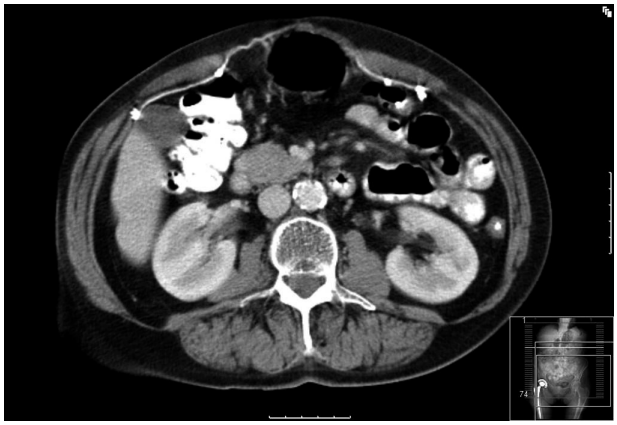

Figure 4 CT scan demonstrating sufficient repair but showing protrusion of the loosely stretched mesh into the hernia

Discussion

The most important endpoint in hernia surgery is recurrence rate. LRVIH has been steadily increasing in popularity because of its several advantages over other techniques, especially its low recurrence rate. Since the introduction of LRVIH in 1991, the importance of widely overlapping the hernia defect and adequately fixing the mesh [4, 5] in preventing recurrence has been recognized, and these procedures have been incorporated into the LRVIH operations performed today. However, despite the drop in hernia recurrence rate with LRVIH [1-3], the causes of recurrence, especially after technically correct repairs, are poorly understood. Factors that have been suggested to be responsible for the failure of LRVIH, aside from technical errors such as inadequate overlap and inadequate fixation, are shown in Table 5.

Our series of 505 patients, which began in 2001, when the technical procedures required to insure the success of LRVIH were already well known, represents a relatively homogenous pool of repairs that is largely devoid of early technical pitfalls. Thus, it appeared to be an especially suitable study group for an analysis of factors other than technical errors that contribute to recurrences after LRVIH. Our analysis in this group found that none of the factors listed in Table 5 were associated with recurrence.

Infection in the absence of enteral contamination is an extremely rare complication of LRVIH; we had 4 (0.8%) infections in our series, all of which required mesh removal. Our series also included 3 missed bowel lesions that required removal of the mesh a few days after LRVIH. After mesh removal, the patients underwent primary herniorrhaphy that resulted in a recurrence. We consider such events complications of LRVIH, rather than

recurrences, so we excluded them from our analysis of recurrent hernias.
Hernias that have recurred after at least one repair have been reported to have a higher recurrence rate than nonrecurrent hernias, after either open repair [17] or LRVIH [11-13]. Our experience does not support these observations. Perhaps LRVIH is especially effective for treating challenging recurrent hernias, as has previously been suggested [18].
The risk of recurrence may be increased during the early phase of learning LRVIH and as a result of premature attempts to perform complex repairs before the necessary basic skills have been acquired [11, 14, 15]. The learning curve in our series was gradual and does not appear to have played an important part in hernia recurrence, which developed in patients operated on in a range of time points within the series. These data suggest that a gradual increase in the complexity of repairs performed can minimize the effect of the learning curve on recurrence rate.
Obese patients did not appear to be at a higher risk for recurrence in our series. This observation supports previous findings indicating that LRVIH can have the same outcome in obese patients as it does in nonobese patients [19-21]. In addition, defect size, correlating with mesh size, operating time, and complications, although they correlate with each other and together indicate the complexity of a repair, do not appear to have increased the risk of recurrence in our series or some others [22, 23], although contradictory results have been reported [12, 16].
Recurrence rate was significantly higher after IH repair compared with VH repair in our series, which had no recurrences after VH repair. The reasons why IH repairs apparently have a higher risk of failure may be hernia-related, repair-related, or both. Laparoscopic repair of IH is more complex, primarily because adhesiolysis is more challenging. In most VH cases, this preparation phase is either unnecessary or is much easier than in IH cases. The greater complexity of the preparation phase in IH repairs increases the number of conversions and incidence of missed bowel lesions, almost all of which occur in patients undergoing treatment for an IH. However, once the preparation phase is completed and good exposure of the hernia opening and surrounding abdominal wall obtained, IH repair is technically identical to VH repair. The larger size of the hernia opening in IH cases and the consequent need to use larger meshes increase the technical challenge and operating time, but these factors have not been definitively identified as risk factors for recurrence after technically sound repairs.
We are not able to present information on hernia size, although it might be very relevant. The significant difference in mesh size used for repair of IH however strongly indicates that hernia size in that group is also significantly larger. Consequently, increasing hernia size as a risk factor for recurrence cannot be dismissed.
All the recurrent hernias in our series were at the site of an apparently sufficient incision scar and were either attached to the mesh (8 patients) or located in another part of the

scar (1 patient). These observations suggest that the main reason for recurrence after laparoscopic repair of IH is disregard for a principle that is well accepted in open hernia repair: the whole incision—not just the hernia—must be addressed [24].

Flum et al [25] analyzed an epidemiologic database on IHs and concluded that even after mesh repair, there is a continuing, linear rise in hernia recurrence rate during the years after surgery. This suggests the existence of a biologic problem related to the scarring process. Reinforcement of the closed hernia gap by mesh is based on the assumption that ingrowth of fibrous tissue into the prosthetic material will form a scar-mesh compound. Although the intensity of scar formation is influenced by the amount of material, its quality is not improved by larger amounts of mesh [24, 26]. Therefore, mesh fixation from fibrosis cannot prevent recurrence unless there is a wide overlap of mesh over the scar that ensures that healthy tissue is present underneath the prosthesis.

Recognizing that IH formation is a problem of the scar and that scar near the hernia opening that macroscopically appears to be sufficient intraoperatively cannot be considered healthy tissue, Conze et al [27] postulated that IH repair must address the complete fascia scar instead of just the fascia defect. If this principle is valid in open retromuscular IH repair, it is even more important in laparoscopic procedures because, compared with the meshes used in open surgery, ePTFE and most of the other materials employed in LRVIH have a relatively low fibrosis-inducing potential. Thus, along with a wide overlap and adequate mesh fixation, a crucial component for the success of LRVIH appears to be the presence of good-quality tissue underneath the mesh. Assuming that all the initial IH repairs in our series were performed correctly, our results indicate that the entire incision has a potential for hernia development. Whether mesh detachment from the lower-quality scar tissue to which it was fixed or development of a new hernia in another part of the same incision scar is predominantly responsible for recurrences after IH repair is unknown. For VHs, the same potential for hernia development does not appear to be present because the tissue surrounding the opening in a VH is intact and healthy. Therefore, currently employed laparoscopic procedures appear to be adequate for repair of VHs, none of which recurred in our series.

Several previous studies observed a recurrence pattern similar to that in our series. LeBlanc et al [4] reported 1 case with a recurrence at an incision just beneath the implanted mesh. Chelala et al. [28] described 2 identical cases, and Bageacu et al [29] had four similar recurrences. Since we began to address the entire scar, rather than just the hernia, in laparoscopic IH repair, we have not had a recurrence in a patient who underwent this procedure.

In our series, recurrences were not significantly (p = 0.14) more likely to develop at transverse incisions (ie, right subcostal plus transverse incisions; 5 recurrences in 43 sites [11.6%]) than in midline incisions (4 recurrences in 94 sites [4.3%]). Most transverse

incisions were right subcostal incisions, which had the highest recurrence rate in the series (14.8%). Hernias in such incisions are challenging to repair because the cranial edge of the mesh must be fixed behind the rib cage. However, none of the recurrent hernias in right subcostal incisions in our series were due to a mesh disruption at the cranial edge. Instead, the recurrent hernia was attached to the left or right side of the mesh at what was an apparently sufficient incision scar.

In contrast, the incidence of recurrence after repair of midline IHs was relatively low. Therefore, in such cases, a plan to repair the entire incision should be considered in relation to the risks of additional adhesiolysis and the increased technical demands of such a repair.

At sites of recurrence, the disrupted mesh usually protrudes into the hernia defect. However, even in sufficient repairs, a loosely stretched mesh can protrude into the defect when the pneumoperitoneum is released. This may result in bulging that is occasionally symptomatic and almost impossible to differentiate from a recurrence clinically. Therefore, to ensure a good tension-free repair without mesh protrusion, the prosthesis should be stretched tightly [30]. Another possible cause of bulging is a spontaneous approximation of the fascial edges, which occurs in most patients after LRVIH [31]. This process is not well understood, but it may induce some late laxity in appropriately stretched mesh. In small defects, even minimal laxity may allow the mesh to protrude into the hernia. In addition, bulging may be particularly noticeable if the defect is small (Fig. 3). In larger hernias, more laxity would be necessary for the mesh to protrude into the defect, and the protrusion would probably not be as noticeable because the curvature of the bulge would be more gradual (Fig. 4).

DualMesh, the prosthesis used in our series, can be visualized on CT scans, so imaging usually allows the clinician to determine whether the patient has a recurrence or bulging from a mesh protrusion. However, in symptomatic patients, differentiating between the two is somewhat irrelevant therapeutically because both necessitate a new repair. Symptomatic bulging, though not a recurrence, must be considered an important postoperative complication of LRVIH.

Conclusion

LRVIH that addresses only the hernia opening appears to be adequate for VHs but not IHs. Our experience indicates that the entire incision has a potential for hernia development. The most common cause of hernia recurrence after laparoscopic repair of IHs is disregard for a principle that is established in open hernia repair: the whole incision—not just the hernia—must be addressed.

Insufficient coverage of the incision scar is a risk factor for recurrence after LRVIH.

Acknowledgments

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3

Fatal intestinal ischemia after laparoscopic correction of incisional hernia

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Abstract

Background and objectives: Intestinal ischemia is a very rare complication of laparoscopic procedures. In this report, we describe the first case of fatal large bowel ischemia in the aftermath of laparoscopic incisional hernia repair.

Methods: A literature search using PubMed was performed to identify all published cases of intestinal ischemia following laparoscopic procedures.

Results: Our search revealed 13 cases of intestinal ischemia following various laparoscopic procedures. Including this one, 10 of 14 cases reported on so far had impaired cardiovascular, hepatic or renal function or atherosclerosis. None of these patients-at-risk survived. In this series, no indications of faulty operative technique could have been identified.

Conclusions: Patient related risk factors seem to play the most important role in the development of this rare but devastating complication. Preventive measures and methods to identify patients at risk for developing intestinal ischemia during and after laparoscopy are not completely clear. Patient selection, an optimal hydration status, an optimized technique with lowest insufflation pressure possible and intermittent decompressions of the abdomen when the procedure is lengthy, are the measures that have a potential to prevent this complication. Whatever laparoscopic procedure has been performed, intestinal ischemia should be considered in any patient with nonspecific abdominal symptoms.

Introduction

Intestinal ischemia is a rare complication following laparoscopic procedures. It has been described after laparoscopic cholecystectomy [1-9], inguinal hernia repair [10], gynecologic myolysis [11], and fundoplication [12, 13]. Laparoscopic repair of ventral and incisional hernia (LRVIH) is gaining popularity due to its low recurrence rate, short hospital stay, and low complication rate. In this report, we describe a case of fatal intestinal ischemia following LRVIH.

Case report

A 47-year-old obese woman (BMI of 42) with a large incisional hernia at midline laparotomy was referred for laparoscopic correction. Her medical history was significant for hypertension, trans-abdominal gynecologic surgery, peripheral vascular disease, and included multiple angioplasties of the iliac arteries.

Carbon dioxide was used to create pneumoperitoneum. Intra-abdominal pressure was maintained at 12 mm Hg throughout laparoscopy. Laparoscopic correction was uneventful but lengthy (240 min) due to extensive adhesiolysis. A 15-minute break that included decompression of the abdomen was made halfway through the operation. This is locally a common practice during long operations and was not triggered by any specific adverse event. The total duration of the pneumoperitoneum was 215 min. Blood pressure remained stable throughout the procedure. The hernia defect measured 20 by 16 cm and correction required application of two 30x20 cm expanded polytetrafluoroethylene meshes (DualMesh®, WL Gore, Flagstaff, AZ, USA). The meshes were fixed both with tackers (ProTack®, TycoUSS, Norwalk, CT, USA) and trans-abdominal sutures.

Initially, recovery was uneventful. On postoperative day 3 the patient developed a paralytic ileus without localized tenderness. A plain abdominal X-ray and ultrasound showed distended bowel. C-reactive protein was significantly raised. In order to evaluate the possibility of a missed bowel lesion we decided on a relaparoscopy. Intra-abdominal pressure was maintained at 12 mm Hg throughout this short procedure that took not more than 12 minutes. Upon exploration, only bowel distension was found with no signs of contamination, perforation, or ischemia. Given these findings, no action was undertaken. Postoperatively, the patient developed systemic inflammatory response syndrome, respiratory insufficiency, and required transfer to the ICU. Within the next few days, the patient slowly stabilized, required less and less support, and presented no apparent infection. On postoperative day 9 she produced bloody diarrhea that prompted us to perform a colonoscopy. Examination revealed severe ischemic colitis in the transverse colon.

Mesenteric angiography was performed showing an occluded superior mesenteric artery and a compensatory distended inferior mesenteric artery with a pinpoint stenosis at its origin. Balloon angioplasty (figure 1) successfully dilated this stenosis, the patient was placed on anticoagulants and, afterward, the patient steadily improved. However, 5 days later her situation suddenly deteriorated. Another colonoscopy was performed that showed multiple perforations of the ischemic transverse colon. At subsequent laparotomy, a fecal peritonitis due to multiple perforations of the ischemic ascending and transverse colon was found. Resection of the ischemic colon was performed and both contaminated meshes were removed. Postoperatively, the patient deteriorated further and died the next day, 16 days after the first operation. Histological examination of resected bowel showed extensive ischemia with multiple transmural ulcerations and perforations. The family of the patient did not agree to an autopsy.

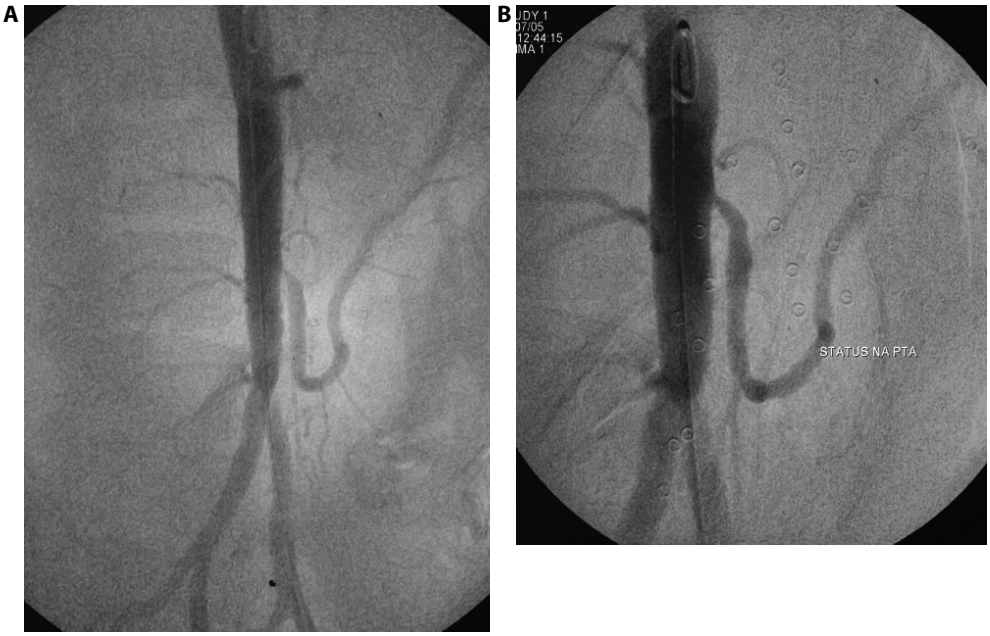

Figure 1 Before (A) and after (B) angioplasty

Discussion

Acute mesenteric ischemia is the result of a sudden reduction in intestinal blood flow that is insufficient to meet the metabolic demands of the bowel. Specific risk factors include advanced age, atherosclerosis, low cardiac output states, cardiac arrhythmias, severe cardiac valvular disease, administration of medications known to reduce intestinal perfusion (such as diuretics, digoxin, alpha-adrenergic agonists), various forms of shock, septicemia, dehydration, hypotension, and others. [14].

Surgical intervention by itself also carries a potential to compromise bowel perfusion. Although there are a few cases of fatal bowel ischemia described after open cholecystectomy [15], various cardiac [16] and peripheral vascular procedures [17], cystectomy [18], esophagectomy [19], etc., the incidence of postoperative bowel ischemia is extremely low. This indicates that the effects of surgery on bowel perfusion are usually well tolerated and have no clinical consequences.

A number of physiologic changes during laparoscopy create an additional risk of compromised mesenteric circulation. The intra-abdominal hypertension created by the pneumoperitoneum reduces mesenteric perfusion, cardiac output, and mesenteric outflow [20, 21]. The reverse Trendelenburg position, frequently used in laparoscopy, exaggerates the above effects [22]. Direct absorption of insufflated carbon dioxide into the circulation may also lead to mesenteric vasoconstriction [23]. However, all these adverse physiological effects of pneumoperitoneum are obviously well tolerated in the vast majority of patients, since a clinically manifested bowel ischemia after laparoscopic procedures is an extremely rare complication. A literature search using PubMed revealed only 13 case reports before the present one [1-13] (Table 1). Once it occurs though, intestinal ischemia following laparoscopic procedure is a devastating complication. Eleven of 14 patients including this one died as a consequence, creating an overall mortality of 79%.

Rapid diagnosis is essential to prevent the catastrophic events associated with mesenteric ischemia. Since early signs and symptoms are nonspecific, the diagnosis depends mostly upon a high clinical suspicion. However, given the negligible incidence of intestinal ischemia amid the large number of laparoscopic procedures performed, the diagnosis is as a rule missed or delayed. In only one reported case the diagnosis was established clinically and relatively early [9]. This patient was treated with high dose anticoagulants and recovered. In all other reported cases, the diagnosis was established either at laparotomy for acute abdomen or at autopsy.

The risk seems to be particularly high in patients with impaired hepatic or renal function or atherosclerosis. Including this one, 10 of 14 cases (71%) reported on so far had at least

one of previously mentioned risk factors present [1, 2, 4, 5, 7, 8, 10, 12, 13]. None of these patients-at-risk survived. Two of 3 patients who survived were very young.

It has been previously stated that the risk is higher when the laparoscopic procedure is lengthy [10]. Although in this case intestinal ischemia developed after an indeed very lengthy procedure, data from literature are not providing a strong support to that view. Of 13 previously published reports, duration of surgery was specified in 10 of them [1-6, 10-13] in average equaling 67.5 minutes (median 62.5 minutes, range 22-120 minutes) what is quite usual for procedures that were performed.

Intermittent decompression of gas during pneumoperitoneum has been suggested as a wise preventive measure [1]. We used decompression once halfway this long procedure but it did not prevent development of fatal intestinal ischemia.

It is probably a futile endeavor to precisely determine the specific role of laparoscopy in the cascade of events that led to mortality in the patient we describe. Long laparoscopy in the patient at risk with unknown preexisting compromised mesenteric circulation definitely carried a potential to further compromise bowel perfusion. It is also possible that development of postoperative ileus in combination with systemic inflammatory response syndrome played a triggering role in development of this complication. No signs of intestinal ischemia at relaparoscopy and a relatively long clinical course in our patient might offer certain support to this second possibility.

To the best of our knowledge, this is the first reported case of intestinal ischemia following LVIHR and the only one we have experienced in a series of 401 LRVIH performed so far (incidence of 0.25%). Carbajo et al., reporting earlier on their experience with LVIHR, mentioned in brief among postoperative complications "a case of a small bowel leakage due to ischemia" but did not provide any further details on this issue [24].

Patient selection, an optimal hydration status, an optimized technique using the lowest insufflation pressure possible and intermittent decompressions of abdomen when the procedure is lengthy, are the measures that have a potential to prevent this rare complication. Whatever laparoscopic procedure has been performed, intestinal ischemia should be considered in any patient with nonspecific abdominal symptoms.

Reported cases of intestinal ischemia after laparoscopic procedures									
Author	Reference	Age (years)	Risk factors	Operation	OR-time(min)	IAP(mmHg)	Symptoms (days)	Diagnosis	Outcome
Paul	1	68	+	Cholecystectomy	85	15	4	at laparotomy	death
Jaffe	2	76	+	Cholecystectomy	70	NS	3	at laparotomy	death
Dwerryhouse	3	36	-	Cholecystectomy	50	15	2	at laparotomy	recovery
Schorr	4	62	+	Cholecystectomy	40	NS	3	at autopsy	death
Andrei	5	72	+	Cholecystectomy	50	15	8	at laparotomy	death
Leduc	6	57	-	Cholecystectomy	120	15	3	at autopsy	death
Sternberg	7	60	+	Cholecystectomy	NS	14	8	at laparotomy death	
Thiele	8	87	+	Cholecystectomy	NS	NS	4	NS	death
Klugewitz	9	41	-	Cholecystectomy	NS	NS	1	endoscopy	recovery
Bandyopadhyay	10	78	+	Inguinal hernia	22	10	1	at autopsy	death
Hasson	11	34	-	Gynecological	75	15	4	at laparotomy	recovery
Mitchell	12	55	-	Nissen	55	NS	1-4	at laparotomy	death
Garcia Diaz	13	20	+	Nissen	105	14	7	at laparotomy	death
Wassenaar	Present case	47	+	Incisional hernia	215	12	3	endoscopy	death

NS=not specified
IAP=intra abdominal pressure
Symptoms=post-operative day of onset of symptoms

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4

Removal of transabdominal sutures for chronic pain after laparoscopic ventral and incisional hernia repair

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Abstract

Some patients who have undergone laparoscopic repair of ventral and incisional hernia have persistent postoperative pain, assumed to be caused by the presence of transabdominal sutures. We investigated whether removal of these sutures relieves discomfort.

Of 375 patients who underwent laparoscopic repair of ventral and incisional hernia, six patients (1.6%) had persistent pain resistant to conservative therapy. These patients underwent relaparoscopy and removal of transabdominal sutures at all apparent pain sites.

Postoperatively, three patients had complete pain relief. Two patients had some improvement but moderate, less localized, pain remained. The sixth patient experienced no change at all. Removal of transabdominal sutures deemed responsible for pain may occasionally provide relief, but the results of removal seem unpredictable and less effective than previously assumed.

Introduction

Laparoscopic repair of ventral and incisional hernias (LRVIH) has been shown to be safe and efficacious and has revolutionized the care of patients with these problems. However, a small subset of patients who have undergone LRVIH suffer prolonged or persistent postoperative pain that may reduce the overall benefit of the procedure. Since that pain is frequently associated with movement and a pulling sensation at the site of transabdominal sutures (TAS), most authors believe that TAS are the cause of this infrequent but serious problem [1, 2]. In some cases, when the pain is resistant to medical treatment, removal of all TAS at the site of the pain remains a logical therapeutical option that is claimed to be very effective [3, 4]. We reviewed our experience with six patients who have undergone relaparoscopy for persistent pain after LIVHR and investigated whether TAS removal actually relieves this chronic postoperative pain.

Methods

Between January 2001 and July 2006, a total of 375 patients underwent LRVIH with an expanded polytetrafluoroethylene mesh (DualMesh®, WL Gore, Flagstaff, AZ, USA) tailored to overlap all hernia margins by at least 3 cm. No attempt was made to reapproximate the edges of the hernia opening. In 250 patients, the mesh was fixed both with tackers (ProTack®, TycoUSS, Norwalk, CT, USA) circumferentially at intervals of 1 cm and with TAS. TAS were placed circumferentially at 4-5 cm intervals using a suture passer (Gore Suture Passer Instrument®, WLGore, Flagstaff, AZ, USA) and were encompassing 1 cm of tissue. The sutures were tied down with care to avoid knotting the thread too tightly and the knots were buried in the subcutaneous tissue. In the remaining 125 patients, the mesh was fixed with a double crown of tackers without the use of TAS. With this technique, the outer ring of tackers is the same as in TAS technique. The inner ring of tackers is placed around the hernia opening about 1 cm apart.

The size of the hernia did not play any role in the selection of the mesh fixation method. In the first 204 patients, the method of mesh fixation was based purely on the surgeon's preference. For the last 171 patients, the mesh fixation technique was randomly chosen in conjunction with a study at our hospital that compares postoperative pain following these two methods of mesh fixation. This study began in February of 2005 and is ongoing. All patients were controlled at two, six, and twelve weeks postoperatively. All patients received a prescription for oral analgesics postoperatively.

Prolonged pain was described as pain that lasted at least two weeks postoperatively. Patients with prolonged pain that seemed to be related to specific TAS, not responding to

oral analgesics, were treated with site-specific injections of local anesthetics as previously described by Carbonell [1]. Patients were controlled two weeks after injections. If pain persisted, injections were repeated one more time. No more than two injections were performed at a painful TAS site. Oral analgesics were continued until pain subsided. Patients were classified as having chronic pain if postoperative pain lasted for more than three months [5].

Statistical analysis was done using Fisher's exact test. P value less than 0.05 was considered to be statistically significant.

Results

One hundred and five patients (28%) had prolonged postoperative pain that was treated with anti-inflammatory medications and reassurance. There was no statistical difference in the frequency of prolonged postoperative pain between the TAS technique (82/250) and the technique with tacks only (23/125). A subset of patients with TAS fixation (n=14) had pain located directly at specific TAS sites. These patients were treated with site-specific injections of local anesthetics. In the vast majority of patients with prolonged postoperative pain, the latter resolved either with time or after injections. However, six patients (2 men and 4 women, median age 38 years), all with mesh fixation that involved TAS, experienced a persisting pain longer than three months resistant to all treatment efforts including injections of local anesthetics at the painful TAS sites (overall incidence of 1.6 per cent). Although the chronic postoperative pain was only seen in patients with mesh fixation that involved TAS (group incidence of 2.4 per cent), that difference was not statistically significant (p=0.09).

Three patients had a recurrent umbilical hernia, one patient had a primary umbilical hernia, one patient had a trocar hernia, and one patient had a recurrent incisional hernia after Rives-Stoppa repair. In five of these patients a 15 by 10 cm mesh had been fixed with eight TAS. In one patient, the mesh of 19 by 15 cm had been fixed with 12 TAS.

No significant relation was found between body mass index or size of hernia defect and postoperative pain. Of note is, however, that five of six patients with chronic pain had a very small size hernia.

All patients could identify the specific location and the number of painful TAS sites among their total sites (4/8, 2/8, 4/8, 5/8, 1/8, and 2/12 sites; 18 sites overall). The first patient in this series underwent relaparoscopy and removal of TAS only at painful TAS sites. The other patients underwent relaparoscopy and removal of all TAS.

At relaparoscopy, none of the patients was found to have a recurrent hernia. One patient had no adhesions at all and five patients had mild adhesions easy to separate involving

the omentum only. Only seven of the 18 apparently pain-causing TAS were found to be possibly knotted too tightly. A laparoscopic dissecting forceps could be inserted without difficulty under the other 11 knots, thus demonstrating that the thread was not knotted too tightly.
Postoperatively, two patients experienced direct and complete pain relief. One patient became pain-free after a period of several weeks. Two patients had some improvement but moderate or marked pain remained, although it was less precisely localized. One of these two patients was the very first one in this series in whom we removed only TAS at painful sites (n=4). Later on, this patient underwent re-relaparoscopy and removal of remaining TAS (n=4), afterwards experiencing subsequent relief. The sixth patient had no change at all. There was no relationship found between temporary positive response to local injection of anesthetics and symptom resolution after suture removal.
During a median follow-up of 30 months none of these patients developed a recurrence. In the entire series of 375 corrections, there were six recurrences (1.6%). Five recurrences occurred after mesh fixation with tacks and sutures and one after mesh fixation with a double ring of tacks alone (p=0.35).

Discussion

Although postoperative pain seems to be less severe after a LRVIH compared to an open procedure [6, 7], a LRVIH tends to be exceedingly painful compared with other minimally invasive procedures in the early postoperative period [8, 9].
Early postoperative pain after LRVIH is usually self-limiting and resolves within a week or two in the majority of patients [2]. However, postoperative pain exceeding two weeks is not uncommon and occurs in around one fourth of patients [1, 10]. This longer-term discomfort requires treatment with oral narcotics or non-steroid anti-inflammatory drugs and usually resolves within 6 to 8 weeks. Costanza and colleagues defined chronic pain as pain lasting for more than eight weeks [8]. They reported on eight such cases, in all of whom the pain was resolved either with time or injections of local anesthetics.
However, the really problematic cases are those in which the pain keeps persisting, and is not resolved with time and with treatment as described above. We have found that 1.6 per cent of patients who had undergone LRVIH have a persistent pain that can be classified as "chronic". In the largest series on LRVIH that has been published so far, Heniford and colleagues found the same incidence of chronic pain [11]. Surprisingly, the problem of chronic postoperative pain following LRVIH has received little attention so far and has been addressed in only one report [12].

The main reason for significant postoperative pain after LRVIH seems to be fixation of the mesh to the abdominal wall. Since this pain is frequently associated with movement and a pulling sensation at the site of TAS, most authors believe that TAS are the cause of this problem [1, 2]. Observation that injections of local anesthetics at the TAS sites frequently result in resolution of the symptoms [1, 2] adds further support to this belief.

Severe abdominal wall pain is also a well-known and frequent problem after Rives-Stoppa conventional repair of incisional hernia, a technique that also includes insertion of TAS to fix the prostheses. Although the incidence of long-term postoperative pain seems to be higher in the latter technique, between 14-27 per cent [13, 14], to the best of our knowledge there is no specific information on either the incidence of permanent pain in these patients or on solutions for treatment.

Our observation that only patients who had TAS experienced a chronic pain adds further support to the theory that TAS cause this pain. Consequently, removal of all TAS at the site of the apparent pain remains a logical "last resort" effort to alleviate the discomfort. Although this therapeutical solution has been claimed to be "very effective in nearly every patient" [3], our analysis of existing literature has revealed not more than two case-reports so far [4, 15]. In these cases, laparoscopic removal of TAS at painful sites resolved the symptoms immediately.

Our experience casts doubt on the efficacy of TAS removal to alleviate the chronic pain after LRVIH. Removal of TAS deemed responsible for pain may occasionally provide relief, but we found that the results of removal were unpredictable and less effective than previously assumed.

This indicates that TAS might not be the only cause of chronic pain after LRVIH. Bageacu et al. have already reported on the occurrence of severe pain in relation to the use of tackers [10]. By using fixation consisting of double crown of tackers only, Carbajo et al. have reported on 7.4 per cent incidence of persistent postoperative abdominal pain [16]. Obviously, the role of posterior fascial tackers as a source of or a contributor to the chronic postoperative pain should not be underestimated.

Whether closing the hernia defect prior to application of the mesh helps prevent chronic pain is not clear. As the vast majority of authors, we did not do it. In two large series that did use this technique, the reported incidence of chronic pain was 2.5 [17] and 3.1 per cent [18]. This may indicate that closure of the defect with subsequent traction may even contribute to chronic postoperative pain.

Since early years of LRVIH, there has been a strong belief among pioneers of this technique that reliable fixation of the mesh can only be achieved with TAS technique [3, 19, 20].

Another technique of fixation introduced later and consisting of double crown of tackers only has been gaining increasing popularity due to a few specified advantages: technical simplicity, less incisions in the skin and shorter operative time [16, 21]. One of the most

interesting issues on LRVIH currently being debated is which of these two techniques is better. Randomized studies comparing the two techniques have yet to be finalized or performed. Review of the published literature indicates that the two laparoscopic mesh fixation techniques are similar in main outcome parameters such as recurrence and complication rate [22]. The search for the most reliable and least painful method of mesh fixation in LRVIH must continue through controlled studies.

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Mesh-fixation method and pain and quality of life after laparoscopic ventral or incisional hernia repair: a randomized trial of three fixation techniques

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Abstract

Background Persistent, activity-limiting pain after laparoscopic ventral or incisional hernia repair (LVIHR) appears to be related to fixation of the implanted mesh. Specific mesh-fixation methods have been implicated as causing pain, but a randomized study comparing commonly used fixation techniques with respect to postoperative pain and quality of life has not previously been reported.

Methods A total of 199 patients undergoing non-urgent LVIHR in our unit between August 2005 and July 2008 were randomly assigned to one of three mesh-fixation groups: absorbable sutures (AS) with tacks; double crown (DC), which involved two circles of tacks and no sutures; and nonabsorbable sutures (NS) with tacks. All operations were performed by one of two experienced surgeons, who used a standardized technique and the same type of mesh and mesh-fixation materials. The severity of the patients' hernia-site pain was assessed preoperatively and 2 weeks, 6 weeks, and 3 months postoperatively by using a visual analog scale (VAS). Quality of life (QoL) was evaluated by administering a standard health survey before and 3 months after surgery. Results in the three groups were compared.

Results The AS, DC, and NS mesh-fixation groups had similar patient demographic, hernia, and operative characteristics. There were no significant differences among the groups in VAS scores at any assessment time or in the change in VAS scores from preoperative to postoperative evaluations. The QoL survey data showed a significant difference among groups for only two of the eight health areas analyzed.

Conclusion In this trial, the three mesh-fixation methods were associated with similar postoperative pain and QoL findings. These results suggest that none of the techniques can be considered to have a pain-reduction advantage over the others. Development of new methods for securing the mesh may be required to decrease the rate or severity of pain after LVIHR.

Introduction

Laparoscopic ventral and incisional hernia repair (LVIHR) continues to increase in popularity because of its low rates of complications and hernia recurrence and short hospitalization and recovery times [1-3]. Because reported rates of recurrence after LVIHR have been as low as 2% or 3% [4, 5], research attention has shifted to other aspects of this procedure. For example, patients who undergo LVIHR tend to have more pain in the early postoperative period than those who have a different minimally invasive operation [6-8], and, as a result, LVIHR usually cannot be performed as a day-case procedure. Pain at the hernia site after LVIHR is usually self-limiting, but it persists for more than 2 weeks in up to one fourth of patients [9, 10]. Moreover, some patients experience chronic pain, which is usually defined as pain lasting longer than 8 weeks [6, 11, 12].

The occurrence of postoperative pain in patients who have undergone LVIHR has been ascribed to mesh fixation and the use of transabdominal sutures (TAS) [13], metal fixation devices (eg, tacks), or both [14]. Currently, two methods of mesh fixation are commonly employed. One involves placement of both nonabsorbable TAS and tacks; the other entails insertion of two circles of tacks without TAS (the double crown [DC] technique) [15]. Another alternative is to use absorbable TAS and tacks. To our knowledge, no randomized trial has previously compared the nonabsorbable TAS (NS), DC, and absorbable TAS (AS) mesh-fixation techniques with respect to specific outcomes of LVIHR. We therefore conducted a randomized investigation with the aim of determining whether pain and quality of life (QoL) after LVIHR varied according to the type of mesh fixation (NS, DC, or AS) performed during surgery.

Methods

Patients

The protocol for this study was approved by the ethics committee of Medisch Spectrum Twente (Enschede, the Netherlands) and the local ethics committee. Patients between 18 and 80 years old who required non-urgent surgery for an incisional or ventral hernia between August 2005 and July 2008 were considered for enrollment. Patients with a chronic cough, ascites, an active abdominal infection, or complete loss of abdominal domain due to hernia were excluded from the study, as were those receiving peritoneal dialysis or more than 15 mg of prednisone per day and those who had previously undergone LVIHR. All patients enrolled in the trial provided informed consent to participate.

Operative techniques

All patients were given low-molecular-weight heparin subcutaneously to provide prophylaxis for thrombosis, and all were placed under general anesthesia for their operation. In all cases, LVIHR was done by one of two surgeons who had performed more than 100 such procedures before the study began.

Pneumoperitoneum was obtained by using either a Veress needle or an open technique [16]. A 30-degree camera was inserted through a 10-mm trocar. Other trocars were inserted under direct visual. The hernia was exposed and the surrounding area prepared for mesh placement. All patients were given a 1-mm-thick expanded polytetrafluoroethylene mesh (DualMesh; WL Gore & Associates, Flagstaff, AZ, USA) tailored to overlap all hernia margins by at least 3 cm. No attempt was made to reapproximate the edges of the hernia opening. The method of mesh fixation for each patient was determined by means of computerized random generation of a number just before the operation. The number was given to the surgeon, who then used the mesh-fixation technique previously assigned to that number. Patients were not routinely told which method had been used in their procedure, but this information was not withheld when a patient specifically requested it.

In patients randomly assigned to the AS mesh-fixation group, titanium helical tacks (ProTack; TycoUSS, Norwalk, CT, USA) were placed approximately 5 mm inside the edge of the mesh along its entire perimeter, about 1.5 to 2.0 cm apart. Absorbable TAS (Vicryl; Ethicon, Norderstedt, Germany) were then inserted every 4 to 5 cm by using a Gore Suture Passer (WL Gore & Associates). Each of the TAS encompassed 0.5 to 1 cm of tissue. The TAS were tied down with care taken to avoid knotting the thread too tightly, and all knots were buried in the subcutaneous tissue. In patients in the DC group, one circle of titanium helical tacks was placed in the same position as in the patients in the AS mesh-fixation group and another circle was placed inside that circle, around the hernia opening. The tacks in the inner circle were spaced about 1.0 to 1.5 cm apart. No TAS were inserted. In the NS group, the mesh-fixation technique was the same as that used in the AS group, except that the TAS were made of a nonabsorbable material (Mersilene; Ethicon, Norderstedt, Germany).

After fixation of the mesh, the trocars were removed and the pneumoperitoneum was released. Fascial closure was done at all trocar sites that were 10 mm in diameter or larger. No special bandages were applied. Immediately after the operation, the surgeon completed a detailed report on patient, hernia, and operative characteristics.

All patients received standard postoperative care, including mobilization and return to a normal diet as quickly as possible. Patient-controlled analgesia (morphine) was provided for the first 24 hours after surgery. Even patients with minimal pain or discomfort were given acetaminophen (1 g 4 times daily) and a nonsteroidal anti-inflammatory agent (ibuprofen; 600 mg 3 times daily) for at least 3 days. The study protocol allowed administration of additional opioid and nonopioid analgesic agents if necessary.

Clinical follow-up

All patients were scheduled to return for an outpatient visit 2 weeks, 6 weeks, and 3 months after surgery. The primary outcome measure in the study was the presence and severity of postoperative pain as determined by scores on a visual analog scale (VAS; range, 0 to 100) obtained preoperatively (baseline) and during the outpatient visits. The study also assessed QoL by means of administration of the RAND 36-Item Short Form Health Survey 1.0 (SF-36) preoperatively and at the 3-month follow-up visit.

The abdominal wall was examined at all outpatient visits. Patients in whom pain impairing daily activities persisted for more than 6 weeks or a hernia recurrence was suspected underwent ultrasonography or computed tomography. Prolonged postoperative pain was treated with oral analgesic agents and, in cases in which painful sites were well-defined, local infiltration of an analgesic. Postoperative complications were scored according to the classification system described by Dindo et al [17]. Seromas and hematomas were considered complications when they limited daily activities or required drainage. Hernia recurrences were recorded but were not analyzed in this short-term study.

Statistical analysis

Data analysis was performed by using SPSS for Windows, version 15 (SPSS Inc, Chicago, IL). Results in the three mesh-fixation groups were compared by performing analysis of variance or Kruskal-Wallis tests (continuous variables) and chi-square or Fisher exact tests (categorical variables). When a significant difference in continuous, normally distributed variables was found, post hoc testing was done with Tukey's HSD test. A p value of < 0.05 was considered to represent statistical significance.

An a priori power analysis was performed with the following assumptions: alpha = 0.05, power = 80%, with a difference between groups of 8 in the change in VAS scores from baseline to the postoperative period considered clinically relevant. The estimated SD for the change from baseline values was 15. Under these assumptions, we calculated that 56 patients per group were required.

Results

A total of 215 patients were considered for enrollment in the study, and 199 met the inclusion criteria and were initially randomly assigned to one of the three mesh-fixation groups (Figure 1). Twenty-seven of the 199 patients were subsequently excluded from the study or lost to follow-up. Randomization was not possible in five of these patients because of location of the hernia near the ribs: it was not possible to fix the mesh according to protocol with sutures in this location. Thus, 172 entered the analysis phase of the trial.

Complete VAS scores were available for 143 patients (83%), and complete preoperative and 3-month-postoperative SF-36 forms were obtained from 110 patients (64%).

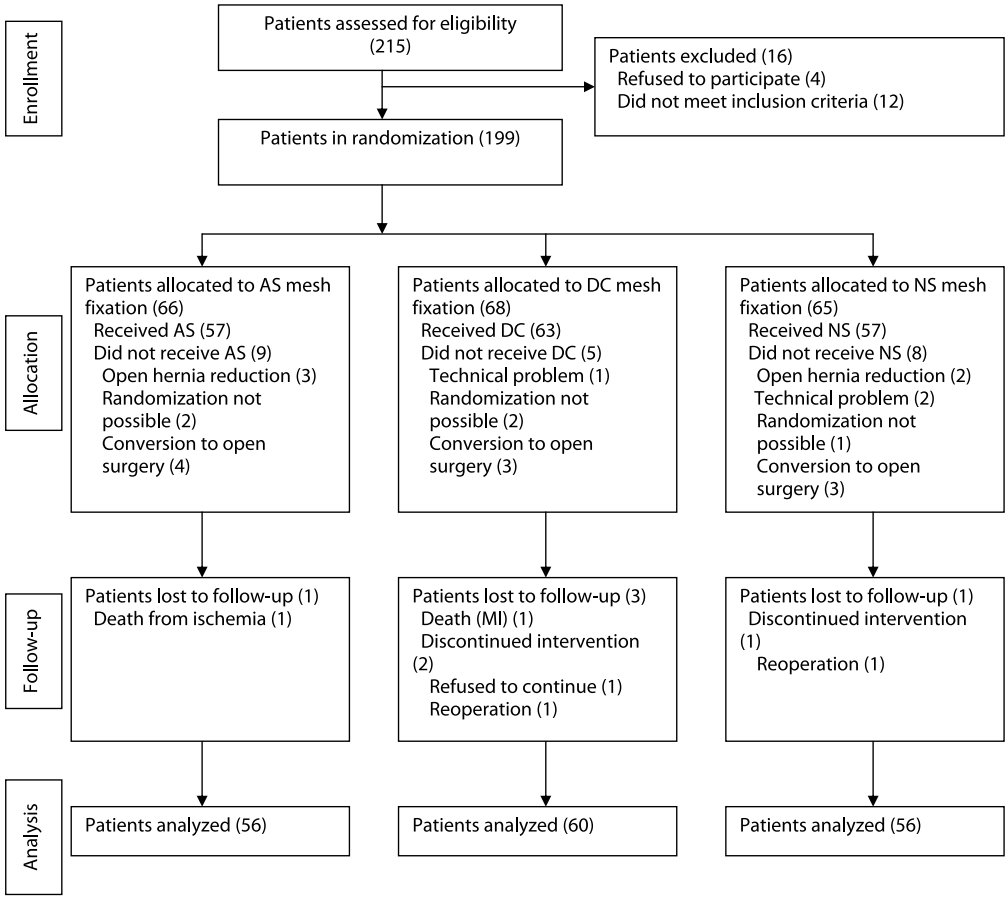

Figure 1 Flow diagram of participants' progress through a randomized study comparing three methods of mesh fixation during laparoscopic ventral or incisional hernia repair. Values in parentheses are numbers of patients.

AS, absorbable sutures; DC, double crown method; NS, nonabsorbable sutures; and MI, myocardial infarction.

The AS, DC, and NS mesh-fixation groups had similar patient demographic and hernia characteristics (Table 1). Moreover, there were no significant differences among the three groups in conversions to open surgery, mesh or hernia size, numbers of trocars used, or length of postoperative hospital stay (Table 2).

Table 1 Patient demographic and hernia characteristics, according to mesh-fixation group

	Mesh-fixation group			
Characteristic	AS (n = 56)	DC (n = 60)	NS (n = 56)	Overall (n = 172)
Mean (± SD) age in years	54.7 (12.9)	51.6 (13.8)	52.4 (12.7)	52.9 (13.2)
Sex: M/F	39/17	33/27	36/20	108/64
Mean (± SD) BMI (kg:m^2)	29.1 (4.9)	28.7 (5.4)	29.9 (5.7)	29.2 (5.3)
ASA class (no. of patients)[a]				
1	25	37	23	85
2	23	16	27	66
3	7	5	4	16
IH (% of patients)	35.7	35	30.4	33.7
Recurrent IH (% of patients)[b]	10	10	11.1	10.7

AS, absorbable sutures; DC, double crown; NS, nonabsorbable sutures; BMI, body-mass index, ASA, American Society of Anesthesiologists; IH, incisional hernia
[a] ASA class was not reported for all patients
[b] All in patients in whom the initial hernia was treated with an open surgical procedure

Table 2 Operative and postoperative characteristics, according to mesh-fixation group[a]

	Mesh-fixation group				
Characteristic	AS	DC	NS	Overall	Value[b]
No. (%) conversions to open surgery	4 (7)	3 (5)	3 (5)	10 (6)	—
Mesh size (cm^2)	233.9 (154.2)	223.5 (149.7)	201.4 (126.6)	219.7 (144)	0.75
Hernia size (cm^2)	23.4 (61.5)	22.5 (56.1)	11.3 (29.6)	19.2 (51.2)	0.88
No. of tacks	41.3 (14.4)	55.6 (22.4)	35.9 (11.5)	44.5 (18.8)	< 0.001
No. of sutures	8.8 (3.2)	NA	8.8 (2.6)	8.8 (2.9)	0.97
No. of trocars	3.1 (0.4)	3.1 (0.5)	3 (0.1)	3.1 (0.4)	0.32
Operating time (min)	60.3 (23.4)	46.8 (22.9)	53.4 (18.9)	53.3 (22.4)	0.005
Postoperative stay (days)	2.1 (2.2)	1.7 (1.3)	1.9 (1.3)	1.9 (1.6)	0.57

AS, absorbable sutures; DC, double crown; NS, nonabsorbable sutures; NA, not applicable
[a] Values are means (± SD) unless otherwise indicated
[b] For differences among the three groups

On post hoc analysis, operating time was significantly shorter in the DC group compared with the AS group ($p = 0.03$) and somewhat shorter in the DC group than in the NS group ($p = 0.24$). Because the DC mesh-fixation method uses an extra circle of tacks, repairs in which this technique was employed required significantly more tacks than were necessary in either the AS or NS procedures. AS and NS mesh fixation required about the same number of TAS.

Mean VAS pain scores in each of the three mesh-fixation groups at the preoperative and three postoperative assessment times, as well as the change in scores from the preoperative to the postoperative period at 3 months, are shown in Table 3. The scores in the three groups were similar at all times, as was the extent of change in scores. A separate analysis of the VAS scores in the DC group found no significant correlation between the number of tacks used and postoperative pain (correlation coefficient 0.20; $p = 0.14$). Because the number of TAS used was predominantly 8, no statistical analysis could be performed on the relation between TAS and post-operative pain.

Table 3 VAS scores for pain at various assessment times, according to mesh-fixation group[a]

	Mesh-fixation group			
Assessment time	AS	DC	NS	Value[b]
Preoperative	21.1 (20.7)	20.5 (23.6)	26.4 (27.8)	0.43
2 weeks postoperative	15.8 (15.6)	16.3 (20.8)	20.7 (21.8)	0.38
6 weeks postoperative	6.2 (10.2)	8.6 (19.6)	8.8 (16.4)	0.76
3 months postoperative	4.5 (10.5)	5.8 (12.5)	11.2 (21.2)	0.41
Postoperative score minus preoperative score[c]	-17.3 (-23.6 to -11)	-14.7 (-22.2 to -7.3)	-15.9 (-25 to -6.7)	0.9

VAS, visual analog scale; AS, absorbable sutures; DC, double crown; NS, nonabsorbable sutures
[a] Values are means (± SD), except for postoperative minus preoperative score, for which means (95% confidence interval) are shown
[b] For differences among the three groups
[c] Postoperative score at 3 months minus preoperative score was used

QoL scores derived from the SF-36 survey are shown in Table 4. Post hoc analysis revealed a significant difference between the AS and DC groups in physical functioning measures ($p = 0.017$) and between the AS and NS groups in measures of role limitations due to emotional problems ($p = 0.021$). For both these QoL indicators, patients in the AS group had better outcomes after LVIHR.

Table 4 Postoperative scores (3 months after surgery) minus preoperative scores for the eight health concepts on the SF 36-Item Short Form Health Survey, according to mesh-fixation group[a]

	Mesh-fixation group			
Health concept	AS	DC	NS	*p* Value
Physical functioning	13.5 (6.5 to 20.5)	2.4 (-3.2 to 7.9)	9.2 (4.5 to 13.9)	0.021
Role limitations due to physical problems	8.6 (-5.2 to 22.4)	10.8 (-2.1 to 23.8)	9.2 (-1.5 to 19.9)	0.97
Role limitations due to emotional problems	13.2 (-1.6 to 28)	-8.3 (-19.3 to 2.6)	-11.7 (-25.1 to 1.7)	0.017
Energy/fatigue	3.2 (-6 to 12.4)	-2 (-7.9 to 3.9)	-3.4 (-7 to 0.2)	0.32
Emotional well being	3.4 (-3.2 to 9.9)	0.6 (-4 to 5.2)	1 (-3.2 to 5.2)	0.71
Social functioning	8.9 (-0.6 to 18.3)	1.4 (-5.3 to 8.1)	-2.4 (-8.9 to 4.1)	0.1
Pain	20.7 (11.2 to 30.2)	14.9 (7.8 to 22)	9.6 (2.5 to 16.7)	0.14
General health	-15.7 (-23.2 to -8.2)	-13.5 (-18.5 to -8.5)	-13.4 (-18.7 to -8.2)	0.83

AS, absorbable sutures; DC, double crown; NS, nonabsorbable sutures
[a] Values are means (95% confidence intervals)

Table 5 shows the postoperative complications in the study. The patient who was readmitted to the hospital after surgery required help in performing activities of daily living. Five patients in the study (one each in the AS and DC groups and three in the NS group) required reoperation for chronic pain that did not resolve with conservative treatment. There was no significant difference in reoperation rate for chronic pain between the three groups ($p = 0.41$). These patients underwent either removal of the TAS used to affix the mesh (n = 2) or removal of the entire mesh and insertion of a new mesh (n = 3). Two of the patients with mesh removal and one with TAS removal became symptom free. The two other patients, one with non-absorbable sutures and one with double crown fixation, remain with pain symptoms.

During the 3-month follow-up period in the study, no patient had a hernia recurrence. Subsequently, there were two recurrences, one in the AS group and one in the DC group ($p = 1.0$).

Table 5 Complications of surgery and Dindo complication grade, according to mesh-fixation group[a]

	Mesh-fixation group			
Complication	AS	DC	NS	No. (%) of all patients[b]
Urinary retention	3	2	1	6 (3.5)
Prolonged ileus	1	—	1	2 (1.2)
Readmission to hospital	1	—	—	1 (0.6)
Seroma	1	—	—	1 (0.6)
Hematoma	3	3	1	7 (4.1)
Bulging	1	—	1	2 (1.2)
Pain requiring reoperation	1	1	3	5 (2.9)
Trocar hernia	1	1	1	3 (1.7)
Hernia recurrence	1	1	—	2 (1.2)
Dindo grade[c]				
1	9	5	4	18 (10.5)
3b	4	3	4	11 (6.4)

AS, absorbable sutures; DC, double crown; NS, nonabsorbable sutures
[a] Values are numbers of patients unless otherwise indicated
[b] Twenty-nine complications were observed in the study (complication rate, 16.9%), with 13, 8, and 8 complications, respectively, in the AS, DC, and NS groups
[c] Grade 1: Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions; Grade 3b: Intervention under general anesthesia

Discussion

Secure fixation of the mesh and an adequate overlap of all hernia margins with the prosthetic material are crucial to the success of LVIHR. The two most widely used mesh-fixation methods (the AS and DC techniques) in LVIHR provide reliable results with similarly low recurrence rates [1, 18]. However, fixation of the mesh to the abdominal wall also appears to be the most important source of postoperative pain. The importance of this problem was indicated by the recent study of Eriksen et al., who found that LVIHR was associated with considerable postoperative pain and fatigue in the first month after surgery and had significant effects on patients' QoL for up to 6 months postoperatively [8]. As is the case with mesh repair of inguinal hernias, an increasing number of clinicians and researchers now consider postoperative pain, rather than recurrence, the most important adverse effect of LVIHR.

Because pain after LVIHR is frequently associated with movement and a pulling sensation at the site of TAS placement, most authors think that the pain is caused by the TAS [9, 13]. The finding that injections of local anesthetics at TAS sites frequently result in pain resolution [9] supports this assumption. However, Carbajo et al. [12] reported a high rate of persistent pain (7.4%) after LVIHR procedures in which two circles of tacks alone (no

TAS) were used to secure the mesh. Bageacu et al. [10] observed severe pain in patients in whom tacks were used in laparoscopic repair of incisional hernias. We previously found that removal of TAS implicated in the development of chronic pain after LVIHR does not always relieve the pain [14]. These and other findings indicate that TAS are not the only cause of pain after LVIHR but that tacks may play an important role. Both a review by LeBlanc [18] and a case-controlled study by Nguyen et al. [19] suggested that TAS fixation and tack fixation are equally likely to be associated with postoperative pain, but this hypothesis has not previously been investigated in a randomized trial.

The aim of the current randomized trial was to provide more reliable data on the relation between pain after LVIHR and the method used to fix the mesh. The study found no significant differences among three mesh-fixation techniques with respect to VAS pain scores at either 2 weeks, 4 weeks, or 3 months after surgery. The only significant difference among the groups was that operating time was shorter in the DC group compared with the AS group, probably because it takes longer to place TAS around the perimeter of the mesh than to insert a second circle of tacks [20]. Our results indicate that the most commonly used methods to secure the mesh during LVIHR have a similar association with postoperative pain and that none of these techniques can be considered to have a pain-reduction advantage over the others.

The QoL assessments in the study found that, compared with their preoperative status, patients in all three mesh-fixation groups had improvements in QoL by 3 months after LVIHR. In addition, only minimal intergroup differences in postoperative QoL measures were observed.

It is possible that the use of DC and NS mesh-fixation in LVIHR provides mesh fixation that is more secure than is necessary to prevent recurrence, while increasing the risk of postoperative pain. Therefore, in this study, we included a group of patients in whom absorbable, rather than nonabsorbable, TAS were employed to affix the mesh, speculating that if postoperative pain is due to the presence of a permanent mesh-fixation device, the potential for such pain might decrease over time in patients in whom an absorbable material is used instead. We found, however, that for the first 3 months after LVIHR (long after the point at which absorbable TAS would have been retained), pain scores in the AS mesh-fixation group were not significantly different from those in either the NS or DC group. These results are similar to those in a previous study that failed to detect any significant difference between mesh fixation using absorbable TAS and fixation using nonabsorbable TAS with regard to postoperative pain after Lichtenstein inguinal hernia repair [21]. Interestingly, the absence of a correlation between the number of tacks and postoperative pain in the current trial may indicate that pain after LVIHR is generated according to some "threshold" principle rather than being due to a cumulative effect from many fixation points.

One possible limitation of our study was sample size. However, if large differences in outcomes among the AS, DC, and NS mesh-fixation techniques had existed, our power calculation indicated that enough patients completed that study to allow such differences to be detected. During the allocation phase of the trial, 22 patients (11%) were excluded for various reasons. The excluded patients were about evenly distributed among the three mesh-fixation groups however, so their removal was unlikely to have biased the results. An absence of blinding may introduce observation bias, but this seems unlikely to have occurred in our investigation because the fixation groups were well-matched with respect to patient, hernia, and operative characteristics, including the proportion of ventral, incisional, and recurrent lesions in each group, the number of trocar sites, hernia and mesh size, and the number of tacks and TAS (when used). Furthermore, the only way in which the patients could have been completely blinded to their mesh-fixation technique would have been to perform sham abdominal incisions (as for TAS placement) in those in the DC group, and this would have been impractical and unethical.

To minimize systematic and random errors, we analyzed only two outcomes: postoperative pain and QoL. To reduce the number of prognostic variables, the same type of mesh, tacks, and nonabsorbable or absorbable TAS were used in all operative procedures, which were performed by one of two experienced surgeons, who used a standardized technique. This protocol made introduction of performance bias unlikely.

Mesh fixation is essential in LVIHR and cannot be abandoned because it may cause or increase the intensity of postoperative pain. On the other hand, it has been suggested that certain modifications in the LVIHR procedure may reduce the risk or severity of pain. For example, closing the hernia defect before placement of the mesh has been proposed. However, most surgeons (including us) do not close the defect. Probably they assume, as we do, that the resulting traction may contribute to the onset or severity of postoperative pain. Moreover, in two large case-series in which defect closure was performed, the rates of chronic pain (2.5% [22] and 3.1% [4], respectively) were similar to those in major studies in which closure was not done.

Some recent research has focused on new, possibly less pain-inducing, mesh-fixation techniques. Olmi et al. [23] observed a low rate of postoperative pain (assessed with VAS scoring) in a series of 40 patients in whom fibrin glue was used to fix the mesh during laparoscopic repair of small and medium-sized abdominal wall defects. In a randomized controlled trial in pigs, Eriksen et al. [24] showed that laparoscopic intraperitoneal fixation of mesh with fibrin sealant was technically feasible and safe. Substantial additional research is required to ascertain whether the use of such techniques will decrease the rate or severity of pain after LVIHR while resulting in the same low recurrence rate.

Conclusions

In a randomized study that compared methods for securing the mesh during LVIHR, the AS, DC, and NS techniques were associated with similar postoperative pain and QoL findings. These results suggest that none of the techniques can be considered to have a pain-reduction advantage over the others. Development of new mesh-fixation methods may be required to address the issue of pain after LVIHR.

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6

Impact of mesh fixation technique on operation time in laparoscopic repair of ventral hernias

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Abstract

Background: Fixation of the prosthesis is one of the critical components of laparoscopic repair of ventral and incisional hernia (LRVIH). The impact of fixation technique used on operative time has never been analyzed. We compared duration of the operation according to the fixation technique used in a series of 138 patients with primary umbilical hernia (PUH).

Methods: All patients underwent a straightforward repair by using completely standardized techniques. One hundred and seven patients had mesh fixation with a single crown of tacks (ProTack®, TycoUSS, Norwalk, CT, USA) and eight transabdominal sutures (TAS). Thirty-one patients had mesh fixation with a double crown of tacks (DC) without TAS.

Results: There were no significant differences in age, sex, hospital stay, and morbidity between the two groups. Mean operating time for the technique with TAS was 50.6 minutes compared to 41.4 minutes for the DC technique. Mean difference in operating time was 9.2 minutes. This difference was significant (p=0.002). During a mean follow-up of 26.4 months, there were no recurrences in the entire series.

Conclusions: The difference in operative times between the two operative techniques can be entirely accounted to the difference in time needed for insertion of eight TAS as compared to time needed for application of an inner crown of tacks. This strongly indicates that insertion of every single TAS prolongs LRVIH for approximately one minute. As long as no significant differences between the two fixation techniques are demonstrated on issues of recurrence, complications, and postoperative pain, the time difference we have measured might be an argument in favor of DC technique, especially when mesh fixation would require a large number of TAS.

Introduction

Laparoscopic repair of ventral and incisional hernia (LVIHR) is gaining increasing popularity due to its low recurrence rate, short hospital stay, and low complication rate. Fixation of the prosthesis is one of the critical components of LVIHR. Currently, the two most popular methods of mesh fixation are the use of helical tacks either with or without transabdominal sutures (TAS). Overall it appears that the two laparoscopic mesh fixation techniques are similar in outcomes [1]. However, the impact of the applied fixation technique on operative time has never been analyzed. We compared duration of the operation according to the fixation technique used in a series of patients with primary umbilical hernia (PUH) who underwent a straightforward repair by using completely standardized techniques.

Patients and Methods

Data were collected from operative reports of all 167 patients who underwent laparoscopic repair of PUH up to January 2007. To make the data more homogenous, we excluded patients who required adhesiolysis (n=13) or simultaneously underwent another procedure (n=12), or with whom a minor complication occurred intraoperatively, i.e. bleeding or equipment problem (n=4). The remaining 138 patients underwent straightforward repair of PUH by using a completely standardized technique and they represented the study group used to compare operative times between the two mesh fixation techniques.

Pneumoperitoneum was established by using a Veress needle. Three trocars (10-, 5-, and 5- mm) were inserted left laterally. A 1-mm-thick expanded polytetrafluoroethylene mesh (DualMesh®, WL Gore, Flagstaff, AZ, USA) of 15 by 10 cm was used to overlap the hernia opening by at least 3-4 cm. The mesh was fixed using one of the following two techniques: either 1) with tacks (ProTack®, TycoUSS, Norwalk, CT, USA) along the periphery of the mesh at intervals of 1-1.5 cm and eight TAS placed equidistant also along the periphery (n=107, further called TAS technique) or 2) with a double ring of tacks alone without the use of TAS (n=31, further called DC technique). With this technique, also known as a "double crown technique" [2], the outer ring of tacks is the same as in TAS technique. The inner ring of tacks is placed around the hernia opening about 1 cm apart. TAS were pulled through the abdominal wall with a suture passer (Gore Suture Passer Instrument®, WLGore, Flagstaff, AZ, USA). In the first 84 patients, the method of mesh fixation was based on the surgeon's preference. For the last 54 patients, the mesh fixation technique performed was randomly chosen in conjunction with another study being done at our hospital that compares postoperative pain following these two methods of mesh fixation. Once the fixation was

completed, the abdomen was desufflated and the trocar site of 10-mm and skin were closed.
The time taken from the stab wound for insertion of a Veress needle to completion of skin closure was recorded to the nearest minute.
Statistical analysis was done using the t-test. Significance was set at a $p<0.05$.

Results

Of the 138 patients in our study group, 106 were male and 36 female. Mean age was 55.0±12.3 years. The TAS and DC group were found to be well matched for sex and age.
Mean operating time for the TAS technique was 50.6 minutes compared to 41.4 minutes for the DC technique. Mean difference in operating time was 9.2 minutes. This difference was significant ($p=0.002$).
Mean postoperative hospital stay was identical for both groups and equaled one day. Postoperative complications included seroma lasting longer than six weeks in seven patients and chronic pain at TAS sites in one patient. All seromas resolved without intervention. The patient with persisting pain underwent relaparoscopy and removal of all eight TAS that provided complete pain relief. There were no significant differences in morbidity between the two groups. No recurrences were detected during a mean follow-up of 26.4±25.6 months.

Discussion

Besides prosthetic material that must sufficiently overlap the hernia defect, a reliable fixation of the prosthesis against the abdominal wall is a crucial component for success of LVIHR. Since early years of LVIHR, there has been a strong belief among pioneers of this technique that reliable fixation of the mesh can only be achieved with TAS technique [3, 4] and, in addition, that sutured mesh fixation is an imperative in LVIHR [5]. Another technique of fixation introduced later and consisting of double crown of tacks only has been gaining increasing popularity due to a few specified advantages: technical simplicity, less incisions in the skin and possibly shorter operative time [2, 6]. One of the most interesting issues on LVIHR currently being debated is which of these two techniques is better. Prospective randomized studies comparing the two techniques are missing. Meta-analysis of published literature indicates that the two laparoscopic mesh fixation techniques are similar in main outcome parameters such as recurrence and complication rate [1]. In the same analysis, the use of tacks alone resulted in a slightly shorter operative

time than when TAS technique was used. However, in most of the studies that were included in this meta-analysis, fixation with tacks was performed by applying only a single row of tacks or technical details of the tack fixation technique were not explained. Reliable data comparing TAS technique and DC technique are definitely missing.

We decided to compare the two techniques in a maximally homogenous model of the procedure: same site of hernia, same logistics of the operation, same prosthetic material, same fixation device, and same operation technique until the moment that the outer ring of tacks is completed. The only difference between the two techniques was the completion of the mesh fixation. In one technique eight TAS had to be inserted and in the other technique usually 6 to 8 tacks of inner crown. Once the fixation had been completed, whatever the method was, the rest of the procedure was again identical. Obviously, the difference in operative times between the two operative techniques can be entirely accounted to the difference in time needed for insertion of eight TAS compared to time needed for application of an inner crown of tacks. Since tacking of the inner crown takes definitely not more than one minute in laparoscopic repair of PUH, insertion of eight TAS required at least eight minutes. This strongly indicates that insertion of every single TAS prolongs LVIHR by approximately one minute.

A laparoscopic repair of PUH is definitely the least complex procedure among all LVIHRs. Insertion of TAS is probably easier than in other LVIHRs due to a central location of the hernia, a general absence of adhesions, maximal space between the distended abdominal wall and the bowel underneath, and an excellent view. It may be anticipated that insertion of TAS during more complex laparoscopic repairs of incisional hernias at less suitable sites, in the presence of adhesions and proximity of the bowel can be much more challenging and as a consequence will require more time than during repair of a PUH.

Our results indicate that LVIHR by using DC technique indeed requires less operative time than when TAS technique is used. As long as no significant differences between the two fixation techniques are demonstrated on issues of recurrence, complications, and postoperative pain, the time difference we have measured might be an argument in favor of DC technique, especially when mesh fixation would require a large number of TAS.

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Subsequent abdominal surgery after laparoscopic ventral and incisional hernia repair with an expanded polytetrafluoroethylene mesh - a single institution experience with 72 reoperations

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Abstract

Purpose Laparoscopic ventral and incisional hernia repair (LVIHR) carries a risk of adhesion formation and can influence subsequent abdominal operations (SAOs). We performed a retrospective study of findings during reoperations of patients who had previously had a LVIHR by using an expanded polytetrafluoroethylene mesh (DualMesh®, WL Gore, Flagstaff, AZ, USA).

Methods Medical records of all 695 patients who had LVIHR at our hospital were reviewed. Patients who underwent SAO for various indications were identified (n=72) and analyzed.

Results Seven LVIHR patients (1%) had early SAO (within a few days). In 6 of them a complication required mesh removal. In all these patients with peritonitis there were no adhesions against the implant. Late SAOs (after more than one month) were performed in 65 patients (9.4%). Only one patient required acute surgical intervention due to an LVIHR-related adhesion (0.15%). Laparoscopy was performed in 83% and laparotomy in 17% of patients. Adhesions against the implant were present in 83% of patients; in 65% the adhesions involved omentum only and in 18% they involved the bowel. Adhesiolysis was always easy and caused no bowel lesions. SAOs were devoid of postoperative complications.

Conclusions In this largest series of reoperations after LVIHR, the majority of patients had mild or moderate adhesions against the implant. The specific observations that: (1) no relaparoscopies had to be converted, (2) no lesions were performed during adhesiolysis, and (3) SAOs have practically been devoid of peri- and postoperative complications indicate that SAOs can safely be performed after previous LVIHR with DualMesh.

Introduction

Classic prosthetic materials used in conventional incisional hernia repair carry a potential to induce severe complications when placed in the abdominal cavity. Complications such as development of dense adhesions, bowel erosions and enterocutaneous fistulas have been reported [1-3]. They may also significantly complicate subsequent abdominal surgery [3]. Therefore application of these materials in laparoscopic ventral and incisional hernia repair (LVIHR) is nowadays generally avoided. New prosthetic materials that present higher biocompatibility, trigger less foreign-body reaction, and are more suitable for placement within the peritoneal cavity provided the base for development of LVIHR and triggered expansion and popularity of this new technique. Major complications due to these materials seem minimal, but experience is still limited. Despite increasing popularity of LVIHR, long-term consequences of intraperitoneal implantation of a synthetic mesh remain a concern. LVIHR carries a risk of adhesion formation and also has the potential to influence subsequent abdominal operations (SAOs). Reoperative findings in patients with prior LVIHR may provide the most valuable information on these issues. We therefore conducted a retrospective study of findings during reoperation in patients who had previously undergone a LVIHR using an expanded polytetrafluoroethylene mesh (DualMesh®, WL Gore, Flagstaff, AZ, USA).

Patients and Methods

Medical records of all 695 patients who had a LVIHR between January 2001 and May 2009 at our hospital were reviewed. In all these patients a DualMesh prosthesis overlapping the hernia margins by ≥ 3 cm was fixed with a double ring of tacks (ProTack, TycoUSS, Norwalk, CT, USA) alone (n = 385) or both tacks and transabdominal sutures (n = 310). The mean follow-up period was 35.6±20.3 months. All patients who had SAO, for various indications, were identified for this retrospective review. The study population was divided into two groups: "early" SAOs consisting of patients who had SAO within a few days of LVIHR either due to an early postoperative complication or suspicion of such complications, and "late" SAOs consisting of patients who were devoid of early postoperative complications after their LVIHR and had SAO at least one month after LVIHR. A period of one month was selected assuming that adhesion formation would require some time.

The following data were collected and reviewed: indication for LVIHR, mesh fixation technique, time laps between LVIHR and SAO, indication for SAO, emergency status and surgical approach at SAO (laparotomy or laparoscopy). Peri-operative findings reviewed included contamination level, presence and characteristics of adhesions to implants, type

of procedure performed and all problems or complications. Data acquisition included analysis of operative reports and of existing film material since nearly all relaparoscopies were recorded. At most relaparotomies representative photographs were taken, that were also studied. Postoperative complications of all kinds were reviewed.
The adhesions encountered were classified according to two severity scales: the first is described by Diamond [4] and the second by Zuhlke [5]. The first classification is not in common usage among surgeons in Europe but it was used in the only article ever published on the issue of postoperative adhesions after LVIHR with DualMesh [6]. In the severity scale of Diamond, a score of 0 was assigned if no adhesions were present; a score of 1 if filmy, avascular adhesions were present; a score of 2 for vascular or dense adhesions, or both; and a score of 3 for cohesive adhesions. The classification of Zuhlke is one of the most widely used among surgeons worldwide and reflects the characteristics of adhesiolysis. In brief, grade 0 means no adhesions; grade 1 filmy adhesions easy to take down; grade 2 when blunt dissection is sufficient; grade 3 when sharp dissection is necessary; and grade 4 when organ damage is likely during adhesiolysis.
Data were collected in an Excel database, and statistical analyses were performed using Statistical Package for Social Sciences for Windows (SPSS Inc., Chicago, IL, USA). Statistical significance ($p<0.05$) was determined using t-test and Fisher's exact test.

Results

There were 72 LVIHR patients who had SAO for various indications (10.4%).
Seven LVIHR patients (1%) had early reoperation within a few days of LVIHR. In six of them a missed bowel lesion or an infection required a mesh removal. In all these patients with peritonitis there were no adhesions against the implant. In one patient we decided on a "second look" on postoperative day 3 in order to evaluate the possibility of a missed bowel lesion – which was not found. The first adhesions against the mesh and tacks were present.
"Late" SAOs were performed on 65 patients (9.4%). There were 34 men and 31 women. Initial LVIHR was performed for an incisional hernia in 47 patients and for a primary ventral hernia in 18 patients. In 34 of these patients the mesh was fixed both with tacks and with transabdominal sutures and in 31 patients the mesh was fixed only with a double ring of tacks.
The median time laps between LVIHR and SAO was 14 months (range 2-67). Indications for SAOs are shown in Table 1. The two surgeons (S.R. and J.T.F.J.), who had also performed all LVIHR, performed nearly all SAOs (n=61/65; 94%). Surgeons without previous experience of LVIHR performed three urgent and one elective SAOs.

Table 1. Indications for late SAO after LVIHR (n=65)

Indication	No	%
LVIHR related	**42**	**65**
Hernia recurrence	14	22
Trocar-site hernia	7	11
Symptomatic bulging	5	8
Chronic pain	12	18
Late mesh infection	3	5
Bowel obstruction	1	1
LVIHR not-related	**23**	**35**
Gastrointestinal malignancy	4	6
Cholecystectomy	3	5
Appendicitis	1	1
New abdominal wall hernia	8	13
Paraesophageal hernia	1	1
Insertion of catheter for peritoneal dialysis	2	3
Gynaecological disorder	3	5
Bowel obstruction	1	1

The vast majority of SAOs were elective (n=62/65; 95%). Three SAOs (5%) were urgent: one due to LVIHR-unrelated bowel obstruction and two due to LVIHR-related bowel obstruction caused by an adhesion to a tack and due to a herniation through a trocar-site. In the two last patients, at SAO the mesh was removed and the hernia was closed primarily.

Initial approach at SAOs was predominantly through laparoscopy (n=54/65; 83%). Laparotomy was performed in 11 patients (17%). None of the laparoscopies had to be converted to open surgery. During open introduction of the first trocar for an elective laparoscopic cholecystectomy by a surgeon not familiar with LVIHR the urinary bladder was opened in one patient. This happened because a site well below the umbilicus was chosen in an attempt to avoid the LVIHR mesh placed in the umbilical area. After suturing the lesion and placement of a urinary catheter, the procedure was further performed uneventfully.

At SAO-laparoscopies, introduction of trocars through the mesh of previous LVIHR was always avoided. At SAO-laparotomies, an incision through the mesh was avoided whenever possible. In four patients that was not possible. In three of them we decided for a prophylactic mesh removal. After completing the procedure, closure of laparotomy included a primary closure of the hernia. Two of these three patients developed a recurrent hernia that was again repaired laparoscopically. In one patient the mesh was closed with nonabsorbable sutures and left in place. Sixteen months later we had to remove the mesh due to a delayed mesh infection.

Adhesions against the implanted LVIHR material were present in 83% (n=54/65) of patients. In 42 patients (65%) the adhesions involved omentum only and in 12 patients (18%) they also involved the bowel. The adhesion scores are shown in Table 2. There were no significant differences in incidence of adhesions and their grade between the two used mesh fixation techniques. There were no differences in severity of adhesions between patients who had SAO within 13 months of LVIHR (n=32; average Diamond score=1.06; average Zuhlke score= 1.11) and patients who had SAO 14 or more months after LVIHR (n=33; average Diamond score=1.13; average Zuhlke score= 1.07). Adhesions were predominantly against exposed elements of LVIHR: either titanium tacks, especially those not completely inserted, or the edge of the mesh which was dangling into the abdominal cavity with a parietal "rough" side of DualMesh exposed. Even in the patient who had the "second look" operation on the 3rd postoperative day, the first adhesions were present at these exposed sites. No adhesions were found at the site of transabdominal sutures.

Table 2. Adhesion scores for late SAO after LVIHR (n=65)

	Diamond n (%)	**Zuhlke** n (%)	
0	11 (17)	**0**	11 (17)
1	42 (65)	**1**	29 (44)
2	10 (15)	**2**	22 (34)
3	2 (3)	**3**	3 (5)
4	0 (0)		

All "late" SAOs showed a mesh completely covered with a layer of tissue resembling the patient's peritoneum. Adhesions were always against this neoperitoneum and never directly against the mesh, with the exception of those against the dangling edge of the mesh (Figure 1). The neoperitoneum was unequivocally attached very loosely to the mesh and only more firmly against the tacks. As a consequence, adhesiolysis was as a rule easy and required little effort: once penetrating the neoperitoneal membrane and entering the dissection plane between the mesh and the neoperitoneum, the latter could be bluntly removed from the underlying mesh surface *en bloc* with all present adhesions (Figure 2). This very efficient technique was avoided only at contaminated SAOs by using the protection of the neoperitoneum to prevent exposure of the mesh to infection. In such cases, a sharp dissection was usually needed to take adhesions down from the neoperitoneum. In a small subset of patients a challenging adhesiolysis was necessary. This was primarily due to dense adhesions caused by extensive tacking and subsequent multiple adhesions against these tacks. We are under the impression that adhesions against tacks are as a rule firmer than adhesions against the neoperitoneum. No bowel or other organ lesions occurred during adhesiolysis.

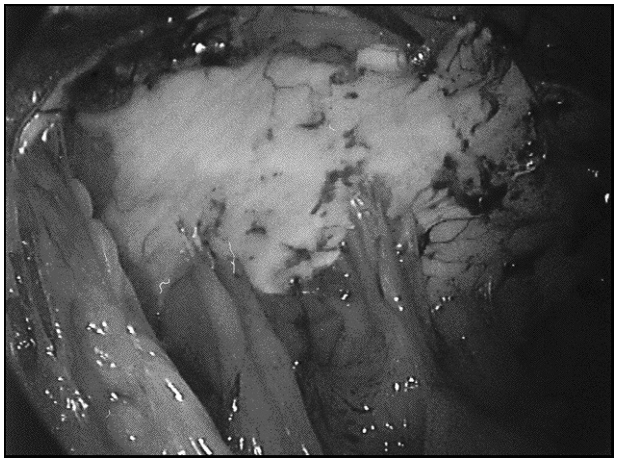

Figure 1. Adhesions against the neoperitoneum as seen during relaparoscopy.

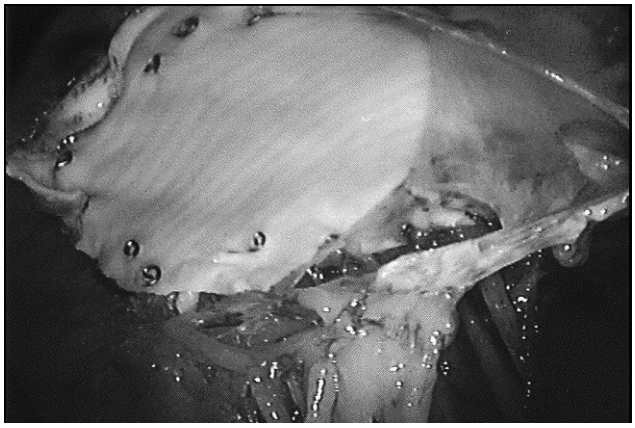

Figure 2. Adhesiolysis during relaparoscopy by removing the neoperitoneum from the mesh.

The vast majority of SAOs were "clean" procedures (n=57/65; 88%). Eight SAOs (12%) were contaminated: three late mesh infections required removal of the mesh after which the hernia was closed primarily; five contaminated SAOs were not related to previous LVIHR: three colorectal resections, one perforated appendicitis, and one gallbladder empyema with peri-operative perforation of the gallbladder. In all five patients adhesiolysis was performed with care to leave the neoperitoneum intact in order not to expose the mesh that was left in place to infection. None of these five procedures resulted in mesh infection. With the exception of previously mentioned urinary bladder lesion during open introduction of a trocar, there were no other peri-operative complications. SAOs were devoid of early postoperative complications. Of six SAO patients who underwent removal of the mesh with primary closure of the hernia defect, five patients developed a hernia recurrence as a late complication.

Discussion

Adhesion formation after LVIHR remains a concern. A large number of experimental studies addressed this important issue but diversity of experimental models, animals used, study times, methods used for measuring, and, above all, the extremely wide range of reported results even for identical meshes have made it difficult to make reliable clinical conclusions [7-12]. Very few clinical studies on adhesions after LVIHR, complications caused by them, and their impact on subsequent abdominal surgery have been published. A recent study indicated that a functional cine MRI might be valuable in the detection of adhesions against the mesh after LVIHR [13]. However, reoperative findings in patients with prior LVIHR still provide the most valuable information on the issue of adhesions after intraperitoneal implantation of synthetic mesh. These findings therefore presently remain the "gold standard" for evaluation of consequences of LVIHR.

Summarizing available data including information obtained from the industry, we estimate that so far nearly 500.000 patients have had a LVIHR and that each year 100.000 or more new repairs will be performed. A certain, but still unknown, percentage of LVIHR patients will definitely undergo such surgery sometime later in their life. Nearly all patients who had LVIHR at our hospital (n=684/695; 98.4%) are patients who belong to the adherence area of our hospital. It can be assumed that practically all these patients would return to our hospital for subsequent medical treatment including SAO. Consequently, the incidence of "late" SAOs of 9.4% that we found in this series probably realistically reflects the percentage of patients that undergo SAO within a few years of LVIHR. A similar incidence of 8.75% has been reported in the only large series on LVIHR that provided information on this issue [14].

Indication for SAO in this series was related to some complication of prior LVIHR in 65% of the patients. It is striking that in only 14 of these 42 patients this was a hernia recurrence while in the remaining 28 patients some other complication of LVIHR was the indication for SAO. This also suggests that the recurrence rate of 2% (n=14/695) in this series is an insufficient parameter of important adverse outcomes of LVIHR. The rate of SAOs that was related to LVIHR in this series was 6% (n=42/695). This may provide a much more realistic rate of adverse outcome.

To the best of our knowledge, only two studies have reported on reoperative findings and adhesions in larger number of LVIHR patients [6,14]. One of these specifically addressed the issue of adhesions against DualMesh [6]. We found a higher incidence and more severe adhesions than reported in that study. Since the same material and the same technique were used in both series, the possible explanation for this difference is that we analyzed only "late" SAOs while the other study included a significant percentage of early reoperations. The latter are frequently performed in the presence of peritonitis that,

according to our experience, seems to prevent adhesion formation. When findings of our "early" and "late" SAOs are combined, obtained results are very similar to results of the other study [6]. The second relevant study reported on reoperative findings after LVIHR with a Parietex mesh (Sofradim, Trevoux, France) that was fixed with transabdominal sutures only and without tacks [14]. The incidence and severity of adhesions reported in that study was lower than in this study. There are two possible explanations for that difference. The first is that DualMesh simply induces more adhesions than Parietex mesh. The second might be related to mesh fixation method. According to our observations, a transabdominal suture was never the site of adhesions. During all SAOs that we performed, we had the impression that *the shape* is more responsible for adhesion formation than *the material*. Any protruding component of LVIHR repair -either a dangling edge of the mesh or an exposed tack- is prone to become the site of an adhesion. Transabdominal sutures do not protrude into the abdominal cavity, which is most likely the reason why adhesions do not develop at their sites. This observation has been mentioned in publications of animal studies [15, 16].

However, as the primary endpoint, adhesion frequency and severity might be misleading. Many patients are asymptomatic despite dense adhesions, whereas others with a single adhesion may develop small bowel obstruction [17]. This is the reason why adhesion-scoring systems remain invalidated; there is simply no useful correlation between the extent of adhesion formation and clinical outcome. In our experience, an LVIHR-related complication very rarely causes a surgical emergency. Assuming that herniation through a trocar site opening can occur after any laparoscopy, we only experienced a single case that required acute surgical intervention due to an LVIHR-related-adhesion. With a cumulative follow-up period exceeding 2000 years for all 695 patients, this suggests the incidence of only 0.15 percent. This may indicate that a fear of adhesions as a possible cause of long-term complications after LVIHR with a DualMesh is not justified.

When a SAO has to be performed in LVIHR patients, a surgeon with either expertise in LVIHR or at least familiarity with the technique is highly preferable. Performance of SAO after LVIHR requires detailed preoperative information on position, size, and fixation of the previously implanted mesh. Good planning of the approach, awareness of impact of contamination on type of adhesiolysis, good judgment when to remove a mesh and when to leave it in place are all very important factors. A few problems identified in this study were related to suboptimal decisions made by surgeons without experience in LVIHR. We assume that with an increasing number of LVIHR performed each year, the chance for such events will rise. This suggests the need for educating a wide spectrum of surgeons without experience in LVIHR on the basic principles of SAOs in LVIHR patients.

Conclusion

This study is one of the first to focus on the potential problems of performing SAO after previous LVIHR. The specific observations that: (1) not a single relaparoscopy had to be converted, (2) no lesions were performed during adhesiolysis and (3) SAOs were practically devoid of peri- and postoperative complications, indicate that SAOs can safely be performed after LVIHR. Clinical reoperative findings on all currently used meshes for LVIHR are needed to determine the comparative effectiveness of these materials in preventing adhesions and all other complications related to LVIHR.

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8

Summary

The aim of this thesis was to address possible improvements in technique of laparoscopic ventral and incisional hernia repair (LVIHR) by studying complications and technical aspects. Six studies were performed trying to answer questions on issues that until now have not been adequately answered in the literature.

In *Chapter 2* all recurrences in a series of LVIHRs were studied. Nine patients with a recurrence were found in a series of 505 patients (1.8%). We tried to identify factors responsible for recurrences. All original surgical reports were studied as well as videos of the laparoscopic repairs of recurrences (n = 8). All recurrences developed after incisional hernia repair. There were no recurrences after primary ventral hernia repair. There was no difference in recurrence rate comparing the two mesh fixation techniques used. All recurrences in our series developed at the site of the incision-scar that was not covered with mesh. During the original repair this part of the incision-scar was deemed not to be insufficient and according to the surgical report adequate overlap was used.
We therefore conclude that a risk factor for the development of recurrence in repair of an incisional hernia appears to be an incomplete coverage of the whole original incision by mesh.

Chapter 3 describes a fatal case of intestinal ischemia after LVIHR. All published cases in the literature on intestinal ischemia following laparoscopic procedures were studied. The use of pneumoperitoneum seemed to be a risk factor for development of intestinal ischemia, especially in patients who had impaired cardiovascular, hepatic or renal function or a history of atherosclerosis. Patient selection and optimized technique are the measures that might be able to prevent this complication.
Intestinal ischemia therefore seems to be more related to laparoscopy in general than to LVIHR specifically.

In *Chapter 4* we analyzed the effect of suture removal on persistent post-operative pain following LVIHR. We identified six patients who experienced persistent post-operative pain after LVIHR, despite optimal conservative treatment. These patients underwent a relaparoscopy, during which all transabdominal sutures at apparent pain sites were removed. Post-operatively three patients had complete pain relief, leading to the assumption that chronic post-operative pain might be due to these transabdominal sutures. Nonetheless, two other patients only experienced some improvement in pain and one patient had no change in pain at all.
We conclude that up to now there is no one single treatment option for chronic post-operative pain after LVIHR. In selected cases removal of transabdominal sutures can be beneficial.

In *Chapter 5* the results of a randomized study on mesh-fixation technique and pain and quality of life after LVIHR are presented. A total of 199 patients were randomly assigned to one of three mesh-fixation groups. Fixation was either with non-absorbable sutures and one circle of tacks, absorbable sutures and tacks or two circles of tacks without sutures. A total of 172 patients were available for follow-up. Pain at two, six and 12 weeks after surgery and quality of life three months after surgery were studied. The three groups were comparable concerning patient demographics, type of hernia and operative characteristics. No significant differences were found among the groups in pain scores at any time point studied. There were only small differences between the three groups in quality of life analysis.
We therefore conclude that there appear to be no significant differences in post-operative pain and quality of life between these three mesh-fixation techniques.

In *Chapter 6* a study investigating the impact of mesh-fixation technique on operative time in laparoscopic ventral hernia repair is presented. A series of 138 patients with primary umbilical hernia was studied. Patients were retrospectively divided into two groups according to mesh fixation: transabdominal sutures and a single circle of tacks (TAS; n=137) or a double circle of tacks without the use of sutures (DC; n=31). Operative times of the groups were compared. There were no differences in patient characteristics between the groups. There was a significant time advantage for the DC group compared to the TAS group (mean difference 9.2 minutes). This difference can be explained by the time it takes to insert eight transabdominal sutures, compared to adding an extra circle of tacks.
Although there is an absolute operative time advantage when using the DC technique compared with the TAS technique in primary umbilical hernia repair, this might be relatively immaterial when applied to an incisional hernia repair with lengthy adhesiolysis. Therefore, on the basis of these studies we cannot advise the use of one of these mesh-fixation methods over the other.

In *Chapter 7* the largest single center series of reoperations after LVIHR is described. Seventy-two patients with subsequent abdominal operation (SAO) were studied on adhesion formation to the mesh. In all original LVIHRs an expanded polytetrafluoroethylene mesh (ePTFE) was fixed using a single circle of tacks and sutures or a double circle of tacks without sutures. Seven patients had SAO within a few days of their LVIHR, most due to signs of peritonitis because of a missed bowel lesion. No adhesions to the mesh were found when peritonitis was present. Sixty-five patients (9.4% of LVIHR) had SAO between two and sixty-seven months after LVIHR. Forty-two patients had SAO related to previous LVIHR (65%) for various reasons. Only one of these required an acute surgical intervention

due to bowel obstruction related to the previous LVIHR (0.15%). Laparoscopic SAO was possible in 83% of patients and laparotomy was performed in 17%. Adhesions against the mesh were present in 83% of patients, but adhesiolysis was always easy. No postoperative complications were found after SAO.

Three specific observations can be made:

(1) no relaparoscopies had to be converted,

(2) no inadvertent bowel lesions were encountered during adhesiolysis, and

(3) SAOs were practically devoid of peri- and postoperative complications.

This indicates that SAOs can safely be performed after previous LVIHR with an ePTFE mesh. We therefore conclude that the clinical consequences of intra-abdominal mesh placement during LVIHR seem insignificant.

9

Conclusions and Future Perspectives

In *chapter 2* we tried to answer the question of what causes recurrence. Many risk factors for recurrence are mentioned in literature: patient factors such as race (African American), high body mass index, smoking and post-operative wound infection and hernia factors such as size of hernia and previous corrections [1-6]. These publications though have contradictory conclusions, offering different significant risk factors.
In our study we found that recurrences occurred due to the technique we used in our initial repair. Technique factors that have been mentioned in literature are lack of overlap and fixation method used [7-10]. The cause for recurrences in our study on recurrences after LVIHR seemed to be a lack of covering the entire original scar, including the parts that did not show signs of insufficiencies, with a mesh. This can be seen as a form of lack of overlap. Whether covering the entire incision could have prevented all recurrences in our series is unclear. In patients who had primary ventral hernia repair we did not find recurrences. In these cases overlap of the whole defect was always ensured. This adds support to the conclusion that adequate overlap is an extremely important issue in preventing recurrences.

The question how to treat chronic post-operative pain was addressed in *chapter 4*. In literature various treatments have been mentioned for chronic post-operative pain once recurrence has been ruled out: oral analgesics, injection with analgesics of painful sites and relaparoscopy with suture removal or complete mesh removal [11-13]. We found that there is no single treatment for chronic post-operative pain after LVIHR. Unfortunately there are patients that remain with chronic pain even after relaparoscopy with suture removal has been performed.

In *chapter 5* we tried to answer the question on how the mesh should be fixated. Post-operative pain was chosen as the outcome measure to compare three different fixation methods. We conclude that there is no difference in post-operative pain comparing these methods. Therefore we cannot answer this question at present. A study with longer follow-up looking at recurrence might be able to answer this question.
Post-operative pain though is becoming a very important issue in LVIHR, as it is inguinal hernia repair [14]. Fixation of the mesh seems to be the primary cause for this pain, as supported in our studies of different fixation methods; all fixation techniques appeared to be equally painful.
As in inguinal hernia repair, fixation of the mesh by absorbable tacks [15], a fibrin sealant [16] or glue [17] is a point of interest and research. If these types of fixation offer durable results with less post-operative pain, then traditional fixation methods might be rejected.
Another possible cause for post-operative pain after LVIHR however might be the inflammatory reaction the mesh creates in the peritoneum. This reaction is thought to

be necessary to initiate ingrowth of fibrous tissue from the abdominal wall into the mesh [18-20] but also might create part of the experienced post-operative pain.
At present, biological meshes are mainly used when risk or presence of infection exists [21, 22]. These meshes have a different effect on the peritoneum and have been shown to create less inflammatory reaction than traditional meshes [23]. Whether this leads to less post-operative pain with comparable ingrowth and strength remains to be seen.

Closing the hernia defect before applying the mesh is currently not common practice in LVIHR. Two authors have published on this issue [24, 25] with one series reporting a low post-operative pain rate [25]. To assess if post-operative pain is less when the hernia defect is closed, a well-designed study has to be performed. One has to take into account though that closing the defect laparoscopically might not be possible when the defect is large.

In *chapter 6* the results of another study on fixation methods in LVIHR are shown. We compare operation length in a standardized LVIHR: primary umbilical hernia repair. We conclude that there is a significant time advantage in using the double crown technique compared with the technique using a single circle of tacks with transabdominal sutures in laparoscopic umbilical hernia repair. Whether this time advantage remains when large incisional hernias are repaired requiring extensive adhesiolysis is not clear. In chapter 5 we did find a significant difference in operating time between the double crown group and the absorbable sutures group, but not with the non-absorbable group. These groups though consist of approximately one third incisional hernias and two-thirds primary ventral hernias. We did not find any other publication specifically addressing this issue in literature.

In *chapter 7* we tried to find the answer to what the clinical consequences are of intra-peritoneal mesh placement. Many studies have been done on adhesion formation due to intra-abdominal mesh placement. Very few studies have actually looked at clinical consequences of these meshes. Cobb et al. published about a longer hospital stay due to non-infectious fever that was related to a certain property of a mesh being used for LVIHR [26]. Koehler et al. looked at re-operative findings as we did in our study [27]. Unfortunately they do not mention the reason for re-operation in their cases, which makes it difficult to deduct the clinical consequences of the adhesions to the mesh they found. Recently Moreno-Egea et al. published a series of 200 LIVHRs with a median follow-up of 6 years using a composite mesh [6]. They report only one urgent re-operation due to bowel obstruction (0.5%) related to intra-abdominal mesh placement. In our series we report also only one urgent re-operation related to the mesh (0.15%). Therefore we can conclude that the clinical consequences of intra-abdominal mesh placement seem small.

Currently more than ten different meshes are available, all specifically designed for intra-abdominal use. New meshes are being developed for LVIHR every year. Are these meshes better than what is available right now? Many studies have tried to compare these meshes in search of the ideal mesh, but almost no data is available on these meshes in human beings [28]. With the development of biological meshes even more options are available to the individual surgeon. Therefore it is not possible at this time to give recommendations based on scientific evidence concerning the best mesh to be used.

Surgeons have to rely on good judgment and vast experience in LVIHR to choose the right mesh with the right fixation method. Good judgment and vast experience are also part of the surgical skills necessary to safely perform the often-difficult adhesiolysis in this operation. A missed bowel lesion remains the most devastating complication after LVIHR. Therefore, it is not only necessary to perform research to improve materials and technique in LVIHR, but also imperative to adequately train surgeons to safely perform this complex minimally invasive procedure.

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10

Nederlandse samenvatting

Herstel van buikwandbreuken is één van de meest uitgevoerde operaties in de huidige chirurgische praktijk. Voorste buikwandbreuken worden onderverdeeld in primaire breuken, zoals navelbreuken, en in breuken die ontstaan zijn na een operatie, zogenaamde littekenbreuken. Ze worden gedefinieerd als defecten in de spier-fascie bedekking van de buikholte tussen de ribben, bekkenrand en buitenste randen van de buikspieren.
Voorheen werden deze afwijkingen behandeld zonder operatie met bijvoorbeeld breukbanden. Als een operatie toch werd uitgevoerd dan werden de randen van het defect aan elkaar gehecht zonder extra versteviging. De resultaten hiervan waren vaak teleurstellend. Met de introductie van kunststof matten werden de resultaten beter.
Herstel van deze breuken door middel van een kijkoperatie (laparoscopie) werd voor het eerst vermeld in 1993. Een kunststof mat werd van binnenuit vastgemaakt tegen de voorste buikwand. Op deze manier werd gebruik gemaakt van de positieve druk in de buik, die ervoor zorgt dat de mat nog steviger tegen de buikwand wordt aangedrukt.
In de loop der jaren werd de techniek van de laparoscopische correctie verbeterd door nieuwe manieren om de mat vast te maken. Tevens werden nieuwe matten ontwikkeld, die mogelijk minder verklevingen geven in de buik.
Ondanks deze verbeteringen en het gebruik van laparoscopie gaat herstel van buikwandbreuken gepaard met complicaties zoals recidieven en pijn na de operatie.
In dit proefschrift proberen wij antwoord te geven op een aantal vragen:

- Wat veroorzaakt recidieven?
- Hoe moet pijn na de operatie worden behandeld?
- Hoe kan de mat het beste worden vastgemaakt?
- Wat zijn de consequenties van het plaatsen van een mat in de vrije buikholte?

Om deze vragen te kunnen beantwoorden hebben wij zes studies uitgevoerd.

In *hoofdstuk 2* is een serie van laparoscopische buikwandbreuk correcties bestudeerd op zoek naar recidieven. Door deze recidieven te bestuderen hoopten wij verbetering in techniek te bewerkstelligen. Er werden negen recidieven gevonden waarvan de originele ingrepen en de hersteloperatie werden bestudeerd. Recidieven bleken in alle gevallen te zijn ontstaan in een deel van het litteken waar in eerste instantie geen hernia gezien werd, maar dat niet bedekt was geweest door de mat. Wij concluderen dat in onze serie de recidieven waarschijnlijk veroorzaakt werden door het niet bedekken van het volledige litteken.

Hoofdstuk 3 beschrijft een complicatie van een littekenbreukcorrectie met fatale afloop. Een patiënte overlijdt na de operatie door afsterven van de darm. In de literatuur werd gezocht naar vergelijkbare complicaties en mogelijke oorzaken. Laparoscopie op zich lijkt een risicofactor te kunnen zijn voor het ontwikkelen van deze complicatie in patiënten

met hart- en vaatziekten. De druk die in de buik wordt ontwikkeld met kooldioxide gas om ruimte te krijgen, kan de doorbloeding van de darm in dergelijke patiënten verminderen.

In *hoofdstuk 4* wordt de behandeling van chronische post-operatieve pijn onderzocht. Als conservatieve maatregelen niet voldoende soelaas boden, werd een laparoscopie verricht waarbij de hechtingen die door de mat zaten werden verwijderd. Drie van de zes patienten die op deze wijze werden behandeld, hadden onmiddellijk baat bij deze ingreep. Bij twee patiënten gaf dit enige verlichting en bij één patiënt gaf het geen verlichting. Wij concluderen dat er niet één standaard behandeling van chronische pijn na laparoscopische correctie van buikwandbreuken is. In geselecteerde gevallen kan het verwijderen van hechtingen uitkomst bieden.

In *hoofdstuk 5* wordt een studie beschreven naar fixatie-methoden van de mat tijdens laparoscopische correctie van buikwandbreuken. Er werden 199 patienten gerandomiseerd in drie groepen die verschillende fixatiemethoden ondergingen. Er werd gekeken naar post-operatieve pijn en kwaliteit van leven. Twee, zes en twaalf weken na de operatie was er geen verschil in post-operatieve pijn tussen de drie groepen. Er waren minimale verschillen in kwaliteit van leven tussen de drie groepen twaalf weken na de operatie.

In *hoofdstuk 6* worden twee fixatie-methoden met elkaar vergeleken wat operatietijd betreft. Er werd een tijdsvoordeel gevonden voor de techniek waarbij geen hechtingen werden gebruikt, maar extra tacks (soort nietjes) om de mat vast te maken. Of dit verschil relevant is bij lastigere ingrepen zoals littekenbreuk correcties is onduidelijk.
Op basis van de resultaten van de studies in *hoofdstuk 5 & 6* kunnen wij geen advies geven welke fixatie-methode gebruikt zou moeten worden.

Hoofdstuk 7 beschrijft een serie re-operaties nadat eerder een laparoscopisch herstel van een voorste buikwandbreuk is uitgevoerd. Er werd gekeken naar verklevingen tegen de mat. Vijfenzestig patienten werden om verschillende redenen gere-opereerd. In 65% van de gevallen had deze re-operatie iets te maken met de eerdere buikwandbreuk correctie. Slechts in één geval was er een reden om met spoed te opereren. Wij concluderen dat de nadelige consequenties van het gebruik van een mat bij buikwandbreuk-correcties nihil zijn.

De vragen die wij stelden aan het begin van dit proefschrift kunnen als volgt beantwoord worden:
Wat veroorzaakt recidieven? In onze serie lijken de recidieven te zijn ontstaan omdat de mat slechts het defect (met enige overlap) had bedekt en niet het gehele litteken van de eerdere ingreep. Of het volledig bedekken alle recidieven had kunnen voorkomen kunnen we niet met zekerheid zeggen.
Hoe moet pijn na de operatie behandeld worden? Er is niet één gouden behandeling voor post-operatieve pijn. Afhankelijk van de specifieke klachten en de patient zelf dient besloten te worden wat de beste behandeling is.
Hoe kan de mat het beste vastgemaakt worden? Op basis van onze studies kunnen wij op dit moment geen antwoord geven op deze vraag. Als de lange termijn gegevens bekend zijn van onze gerandomiseerde studie naar fixatie-methoden hopen wij deze vraag beter te kunnen beantwoorden.
Wat zijn de consequenties van het plaatsen van een mat in de vrije buikholte? De consequenties van het plaatsen van een mat lijken op basis van onze studie klein.

In *hoofdstuk 9* wordt nog ingegaan op mogelijke toekomstige veranderingen op het gebied van de laparoscopische behandeling van voorste buikwandbreuken.

11

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Curriculum vitae

Eelco Barthout Wassenaar werd op 14 december 1973 geboren in Groningen uit een Nederlandse vader en een Amerikaanse moeder. Na een zeer gelukkige jeugd gevuld met veel sport en muziek, studeerde hij 1 jaar lang aan DePauw University in de Verenigde Staten. In 1993 ging hij in Utrecht studeren. Na een jaar uitgeloot te zijn begon hij in 1994 met Geneeskunde. In Utrecht werd genoten van alle facetten van het studentenleven inclusief studentenhuis en –vereniging, hockey en uiteraard studie.
Om in 1996 aan de Olympische Spelen van Atlanta deel te kunnen nemen, werd de studie een jaar stilgelegd. Na in 2002 de studie te hebben afgerond, werkte Eelco als basisarts bij de afdeling chirurgie van het Meander Medisch Centrum. In 2003 werd begonnen met de opleiding Algemene Heelkunde in Almelo (opleider dr van Baal). In Almelo werd al spoedig begonnen met het onderzoek dat heeft geleid tot dit proefschrift, onder leiding van dr Rakic. De opleiding werd in juli 2009 in Utrecht (opleider prof. dr Borel Rinkes) afgerond, waarna hij met zijn vrouw Chantal en hun drie kinderen naar Seattle verhuisde. Hier is Eelco twee jaar als fellow minimaal invasieve chirurgie verbonden aan de Universiteit van Washington (opleiders dr Oelschlager en prof Pellegrini).

Eelco Barthout Wassenaar was born on December 14th 1973 to a Dutch father and an American mother. After a very happy youth, filled with sports and music, he was given the opportunity to go to colleger for a year at DePauw University, USA. In 1993 he went to Utrecht where he started medical school in 1994. There he enjoyed student life to the fullest, including fraternity, field-hockey and ofcourse studying.
To be able to compete in the 1996 Olympics in Atlanta he postponed his study for a year. He finished medical school in 2002 and started working in Amersfoort. In 2003 he started his training towards becoming a general surgeon, first in Almelo (director dr van Baal) and from 2007 onwards in Utrecht (director prof. dr Borel Rinkes). In Almelo he started the research that led to this thesis under the guidance of dr Rakic. After completing his general surgery residency in 2009 Eelco moved to Seattle with his wife Chantal and their three children. There he is fulfilling a two-year fellowship in minimally invasive surgery at the University of Washington (director dr Oelschlager, chair dr Pellegrini).

Foto achterzijde:
Hondje op OK-tafel, Tibbe en Amélie superviseren. “Papa moet nog een beetje oefenen”.