On the repair of inguinal hernia

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On the repair of inguinal hernia

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On the repair of inguinal hernia

PROEFSCHRIFT

ter verkrijging van de graad van doctor
aan de Universiteit Maastricht,
op gezag van de Rector Magnificus
Prof. mr. M.J. Cohen,
volgens het besluit van het College van Decanen,
in het openbaar te verdedigen
op vrijdag 27 juni 1997 om 14.00 uur

door

Geerard Lucien Beets

geboren te Mol op 19 augustus 1962

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Prof. dr. J.W. van Ree
Prof. dr. Th.J.M.V. van Vroonhoven (Universiteit Utrecht)

to my patients

"Surgeons carried out surgical methods, orthodox and heterodox; they hacked, hewed and slashed; they incised, cauterized, and scarified; they castrated young and old; they destroyed or saved the spermatic vessels; they dilated or cut the inguinal rings; they stood their victims on their heads; they bled and re-bled them unmercifully; they applied hot and cold poultices; they tortured with tobacco enemas and drastic purges; they dugged well nigh into death; they resorted to tricks of surgical legerdemain; they tried manual manipulations; they placed iron fillings on hernial tumors, hoping by magnetic action to replace them and passed patients through cleft trees with the same object in view. They used screws, pins, needles, wires - of gold, tin, lead, bronze, copper, iron - wooden spikes, ivory, testicles, animal skins, dilators, acupuncture, organic and inorganic substances (usually sutures), scalpels, scissors, salt, iodine, air, water, alcohol and acids - caustic and otherwise. Prehistoric methods solely? Roman, Greek or Byzantine? Dark or Middle Ages? Renaissance? No. Methods in vogue down to the mid nineteenth century!"

Iason AH, 1941

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Chapter 1

INTRODUCTION AND AIM OF THE THESIS

"Operations for the cure of hernia would seem to be established and beyond the possible need for further discussion and demonstration."

Ravitch MM, 1969

"The main reason for the repair of inguinal hernia remaining a problem is the wide discrepancy between the monotonous excellence achieved in personal series and the uniformly depressing results obtained by impersonal statistical reviews."

Brandon WJM, 1946

Modern inguinal hernia surgery started a century ago, in 1890, when Eduardo Bassini described his technique that was going to change hernia surgery forever.¹ He said: "Considering all that is written about the radical treatment of the inguinal hernia up until now, it can be somewhat risky to try to publish more about this subject." He could not have been more mistaken, as the surgical literature continues to abound with articles describing new techniques and modifications of old techniques. This variety of surgical techniques proves that, as yet, there is no single best method of repair. It is estimated that, despite single centre reports of recurrence rates of 1%, the overall failure rate for primary inguinal hernia repair still is 10-15%, and for recurrent inguinal hernia even 25%.²⁻⁴ In addition to the obvious suffering of the individual patient with a recurrence, a failure rate of 10-15% has enormous socioeconomic implications, as inguinal hernia repair is one of the most common surgical procedures in adult men.

The aim of this thesis is to determine how the results of inguinal hernia repair can be improved. Therefore we evaluate and compare surgical techniques of inguinal hernia repair based on Bassini's concept of suturing the musculo-aponeurotic edges of the posterior inguinal wall defect, techniques based on the more recent concept of a preperitoneal prosthetic mesh, and techniques using minimally invasive surgical technology.

The principles of Bassini's repair are well known: high ligation and excision of the indirect sac, and reconstruction of the complete posterior wall and internal ring by approximating the conjoined tendon area to the inguinal ligament. The Shouldice repair can be regarded as the ultimate perfection of the Bassini repair.⁵ From 1945 on, in a Canadian centre exclusively devoted to hernia repair, E.E. Shouldice and subsequently others have gradually developed their repair to what is now called: the Shouldice repair. By analysing their recurrences and improving the technique accordingly, the reported recurrence rate eventually became less than 1%.⁶ In a randomized trial at the University Hospital of Maastricht, in a non-hernia-specialist setting, the Shouldice repair was compared with the Bassini-Stetten repair, with regard to recurrence rates.

An additional question in this study was whether the repair should be tailored to the type of hernia, the so-called 'individualisation of inguinal hernia repair'.^{7,8} The indirect hernia with a normal firm posterior wall is often assumed to be adequately treated by high ligation of the peritoneal sac and narrowing of the internal ring, without interfering with the intact posterior inguinal wall.⁸⁻¹¹ To address these issues, the randomized trial consisted of two treatment groups: the indirect hernia with a normal firm posterior wall, and the inguinal hernia, direct or indirect, with a weak posterior wall. The first group was randomized for a Bassini-Stetten repair or high ligation and ring narrowing, and the second group for a Bassini-Stetten or Shouldice repair. The long-term results of this trial are presented in **chapter 2**.

The concept of reinforcing the posterior wall with synthetic material dates from the late 19th century, when Billroth stated that "if we could artificially produce tissues of the density and toughness of fascia, the secret of the radical cure of hernia would be discovered".¹² Surgeons have tried pedicled grafts and free grafts, autografts, homografts and xenografts of rectus muscle and rectus fascia, fascia lata, skin, peritoneum, periosteum and pericardium, aorta, dura mater, and even kangaroo tendon. The use of these materials in inguinal hernia repair was associated with problems of rejection, infection, and durability. Surgeons have used metals like silver, tantalum and stainless steel, with only modest success. In the 40's and 50's the organic polymers (plastics) were introduced in medicine and surgery. Whereas some of the initial mesh materials were unsuccessful, biocompatible synthetics like Dacron and especially polypropylene proved to be very effective for hernia repair.¹³ Although the use of synthetic meshes is gaining more acceptance in the surgical community, there still is some concern about biocompatibility.¹⁴ In **chapter 3** two commonly used polypropylene meshes are compared with regard to foreign body reaction after preperitoneal implantation in a pig model for laparoscopic inguinal hernia repair. **Chapter 4** describes the temporal evolution of the foreign body reaction after implantation in the same pig model.

The preperitoneal approach to the groin has been known for a long time, but has first been described in detail by Cheatle in 1920.^{15,16} He used a lower midline rectus-splitting linea alba incision to enter the preperitoneal space. Although very useful in incarcerated hernias and recurrent hernias, avoiding the anterior scarred tissues, it never became a popular approach. In 1959, Nyhus described the unilateral preperitoneal approach through a transverse incision.^{17,18} The combination of the preperitoneal approach with the use of a prosthetic mesh was first described by Estrin et al. in 1963¹⁹, but the procedure was to become associated with the names of French surgeons like Rives and especially Stoppa.^{20,21} The preperitoneal groin area is approached through an inguinal incision or through a lower midline incision, giving wide access to both inguinofemoral areas. Fundamental in Stoppa's procedure, also known as the Giant Prosthetic Reinforcement of the Visceral Sac (GPRVS), is the use of a very large "inlay"-prosthesis that widely overlaps any real and potential hernia orifices. The abdominal pressure, that has caused the hernia, is now used to keep the prosthesis secured in the right place, obviating the need for fixating sutures. Stoppa's GPRVS-procedure has been reported to yield low recurrence rates both for primary and recurrent inguinal hernia repair.²²⁻²⁴ The technique was introduced in our surgical department in 1985, and was, because of the initial fear of infectious complications, reserved for patients with complex recurrent inguinal hernias, including bilateral recurrences and repeated recurrences. The long-term results of a prospective study in a cohort of patients with these complex recurrent inguinal hernias is reported in **chapter 5**.

In the early nineties, after the success of the minimally invasive laparoscopic cholecystectomy, laparoscopic approaches to inguinal hernia repair have been developed.^{25,26} The initial techniques of simple suture closure of the defect, plugging of the defect with mesh, with or without an additional small mesh patch, have now largely been abandoned because of high failure rates.²⁷ The intraperitoneal onlay mesh repair (IPOM) uses a large mesh that is stapled over the defect. Although the low recurrence rates are encouraging, the technique is not widely accepted because of the adhesion formation associated with the intraperitoneal presence of a mesh. The two most common types of repair are the transabdominal preperitoneal repair (TAPP), and the total extraperitoneal repair (TEP). In these repairs, a large mesh is placed in the preperitoneal area, covering the whole inguinofemoral area, based on the 'Stoppa-principle' of a large inlay mesh. Single centre and single author reports have shown encouraging short-term recurrence rates of 0-2%.²⁸⁻³² In a large non-randomized multicentre trial a slightly higher recurrence rate of 4.5% is reported.³³ After introduction of laparoscopic techniques of inguinal hernia repair, nerve injuries were repeatedly reported, and were often related to the use of hernia staples to fix the mesh.³⁴⁻³⁸ To increase our knowledge of the preperitoneal groin anatomy, and to prevent nerve injuries during laparoscopic hernia repair, we performed cadaver studies in close cooperation with the department of anatomy and embryology of the University of Maastricht. The results of these studies are reported in **chapter 6**.

In the early nineties, the standard inguinal hernia repair in our department was the Bassini repair for primary inguinal hernia, and giant prosthetic reinforcement of the visceral sac for recurrent inguinal hernia. **Chapter 7** reports the short-term results of a randomized trial comparing the transabdominal preperitoneal laparoscopic approach with the Bassini technique for primary inguinal hernia repair. In **Chapter 8** the short-term results are presented of a randomized trial comparing giant prosthetic reinforcement of the visceral sac with the transabdominal preperitoneal laparoscopic repair for recurrent inguinal hernia.

Recurrence rate has traditionally been considered as the only relevant outcome variable in hernia surgery.³⁹ Although it is still the most important outcome variable, other issues like morbidity, reconvalescence, disability period and cost are relevant. Therefore these issues are also addressed in the randomized trials in chapter 7 and 8.

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Chapter 2

LONG-TERM FOLLOW-UP (12-15 YEARS) OF A RANDOMIZED CONTROLLED TRIAL COMPARING BASSINI-STETTEN, SHOULDICE AND HIGH LIGATION WITH NARROWING OF THE INTERNAL RING FOR PRIMARY INGUINAL HERNIA REPAIR

Beets GL, Oosterhuis KJ, Go PMNYH, Baeten CGMI, Kootstra G
Journal of the American College of Surgeons, in press.

"Whatever technique the surgeon elects, he or she will never know how good or how bad the results are unless he or she is willing to undertake a 10-year follow-up study conducted by personal examination. This is a monumental task that requires the services of an office assistant with the instincts of a Sherlock Holmes, the charm of a head waiter and the perseverance of an insurance salesman."

Berliner SD, 1983

Abstract

Shouldice repair for primary inguinal hernia is reported to have better results than classical Bassini-type of repairs. The indirect inguinal hernia with a normal, firm posterior wall is often assumed to be adequately treated by high ligation and ring narrowing. These two issues are addressed in a double randomized controlled trial.

The indirect hernia with a firm posterior wall is randomized between high ligation with ring narrowing or a Bassini-Stetten repair, and the inguinal hernia with a weak posterior wall, direct or indirect, is randomized between a Shouldice or Bassini-Stetten repair. The report focuses on long-term (12 - 15 years) recurrence rates.

From July 1980 to May 1983, 102 indirect primary inguinal hernias with a firm posterior wall (group I), and 263 primary inguinal hernias with a weak posterior wall (group II) were included. By 1995 89 patients with 100 hernia repairs had died, and in 30 repairs patients could not be located. In 41 hernia repairs a recurrence had been established previously. Of the remaining 194 hernia repairs, follow-up was updated by physical examination in 179 (92%) and by telephone interview in 15 (8%). A total of 83 recurrences were recorded, 42 % of which were asymptomatic at the time of diagnosis. Seventy-three per cent of the recurrences have occurred more than two years after the operation. With the life table method the long-term (12-15 years) recurrence rates are: I. Bassini-Stetten: 33% vs ring narrowing: 34%; II. Bassini-Stetten 32% vs Shouldice: 15% ($P=0.033$).

Shouldice is the best type of repair, although 15% recurrence rate is high. Bassini-Stetten and high ligation with ring narrowing are inadequate repairs, regardless of the type of hernia.

Introduction

Inguinal hernia is one of the most common surgical diseases. Most methods of repair are based on Bassini's principle of closing the defect in the posterior wall of the inguinal canal by approximating the musculo-aponeurotic edges. To date, there has been no consensus on the best method of repair with regard to recurrence. Reported recurrence rates vary from below 5% to even 25%.^{1,2} National statistics indicate that 10-15% of all repairs are performed for recurrent hernias.³ The Shouldice repair is repeatedly reported to have a very low recurrence rate of about 1%.^{1,4} At the time this study was started, in 1980, there were no data from randomized trials to substantiate this claim. Since that time, several randomized trials have been reported, usually with follow-up periods of less than 5 years. In a recent meta-analysis of these trials, including the short-term (2 year) results of the present trial, it is concluded that the Shouldice repair is the best conventional repair.⁵

Proponents of the 'individualisation of hernia repair' often state that the indirect hernia with a normal, firm posterior wall is adequately treated by high ligation of the peritoneal sac and narrowing of the internal ring.⁷⁻¹⁰ Although it seems logical not to 'repair' or reinforce an intact posterior wall, there are no data from randomized trials supporting this.

The standard repair in our university hospital in the late seventies was a modification of the Bassini repair, the Bassini-Stetten repair, in which the spermatic cord is transposed subcutaneously. Dissatisfaction with high recurrence rates led to the start of the presently reported randomized trial.

The aim of the study is to establish whether an intact posterior inguinal wall of an indirect hernia requires repair, and whether a three-layered Shouldice repair is better than a Bassini-Stetten repair for an inguinal hernia with a weak posterior wall. The study was set up as a double randomized controlled trial. The short-term results have been reported previously.⁶ This article focuses on the long-term recurrence rates.

Materials and Methods

From July 1980 to May 1983 patients were accrued according to the following criteria:

- Inclusion criteria: primary inguinal hernia, age ≥ 18 , male patient, elective repair and informed consent
- Exclusion criteria: life expectancy < 2 yr and major concomitant surgery.

After consent patients were randomized per hernia using the sealed envelope technique. Every inguinal hernia was doubly randomized:

- I: Bassini-Stetten versus high ligation and ring narrowing for the indirect hernia with a firm posterior wall.
- II: Bassini-Stetten versus Shouldice repair for all other inguinal hernias.

Risk factors for recurrence were recorded: previous history of contralateral inguinal hernia repair, pulmonary disease, prostatism, constipation, heavy labour.

The operations were performed by surgeons of the department of general surgery, or by surgical residents assisted by a surgeon. There were no surgeons who were specialised in hernia repair.

Operative techniques

In all repairs, the first steps are identical. After opening the external oblique fascia, the spermatic cord is isolated and inspected after removal of the cremasteric muscle. When there is an indirect hernia, the hernial sac is opened and a finger is inserted into the peritoneal cavity to palpate the posterior wall of the inguinal canal. According to each surgeon's individual judgement, the posterior wall is classified as a normal firm posterior wall, or as a weak posterior wall. The indirect hernia with a firm posterior wall is categorised in group I, and is repaired according to the randomization for group I. The indirect hernia with a weak posterior wall and the direct hernia are categorised in group II, and repaired according to the randomization for group II.

Bassini-Stetten

After high ligation and excision of the indirect hernial sac the conjoined tendon area is sutured to the inguinal ligament by means of interrupted 2/0 nylon. The upper part of the external oblique aponeurosis is brought down under the cord and sutured to the inguinal ligament using 2/0 nylon interrupted sutures. In the lateral part of the lower leaflet of the external oblique a small perpendicular cut is made for passage of the cord. The external oblique is then reflected upward underneath the cord and fixed to the underlying upper part with interrupted 2/0 nylon sutures. The cord is thus transposed subcutaneously.

High ligation and ring narrowing

After high ligation and excision of the sac the internal ring is narrowed by three medially placed interrupted 2/0 nylon sutures. The external oblique is closed over the cord.

Shouldice

A three-layer modification of the original Shouldice technique is performed. After high ligation and excision of the indirect hernial sac the transversalis fascia is opened from the internal ring to the pubic tubercle. Any excess of thinned fascia is excised. The posterior wall is reconstructed with a running 2/0 nylon suture in three layers. The first layer begins at the pubic tubercle and fixes the upper edge of the lower leaf of the fascia transversalis to the posterior aspect of the rectus muscle medially, and of the transverse abdominus muscle/aponeurosis laterally. The suture reverses at the narrowed internal ring and attaches the lower edge of the upper leaf of the fascia

transversalis to the inguinal ligament. The third layer attaches the conjoined tendon area to the inguinal ligament. The external oblique is closed over the cord.

All postoperative complications were noted. The main endpoint is the recurrence of the inguinal hernia, defined as a symptomatic or asymptomatic defect in the abdominal wall with herniation of abdominal contents, exacerbated by a Valsalva manoeuvre.

Follow-up was done by physical examination at the out-patient clinic after 1 month, 3 months, 6 months, 1 year and 2 years. The short-term results have been reported previously.⁶

In 1995, the follow-up was updated. All medical records were reviewed for evidence of recurrence after the 2 year control visit. All patients who had no recorded evidence of recurrence and who were alive were contacted for a physical examination. If patients had not replied after a second mailing, they were contacted by telephone and visited at home, if they agreed so. The physical examination was done by one of the authors, being unaware of the type of repair that had been performed.

Statistics

Statistical analysis was performed using the computer program Statistical Package for the Social Sciences (SPSS® for Windows™, Chicago, Illinois). Categorical variables in each arm of the two groups were compared with the Chi square test. Continuous variables were compared with the Students t-test when appropriate. Because of the discontinuous nature of the follow-up examination, the recurrence rates were analysed using a life table method with unequal intervals.¹¹ The outcome for the different treatment options was compared with the Wilcoxon (Gehan) test. To evaluate the pattern of recurrence in time, a life table with yearly intervals was constructed using symptomatic recurrences only, because for these recurrences an exact date of occurrence could be given. The impact of various preoperative and operative variables on the recurrence rates was analysed with a logistic regression analysis.

Results

Randomization

From July 1980 until May 1983 a total of 418 adult men with a primary inguinal hernia were treated electively in our department. In this time period 425 inguinal hernias in 375 patients were randomized. The reasons for non-randomization in 43 patients were the following: concomitant major abdominal surgery (9), consent refusal (18), and unknown reasons (16). After randomization, six hernia repairs were cancelled, for various reasons. In 54 hernia repairs there was a protocol violation: the hernias were repaired not using the technique assigned by the randomization. This occurred because in 40 hernia repairs the surgeon was not aware that the patient was a

trial patient. In another 14 hernia repairs the surgeon assigned to the repair was not familiar with the Shouldice technique and performed the standard Bassini-Stetten repair. These 54 repairs were excluded from the analysis. 49 of these repairs should have been a Shouldice repair, and 6 should have been a ring narrowing. This accounts for the skewed number of hernias in each of the trial arms. Remaining for analysis are 365 hernia repairs in 324 patients.

Patients - characteristics

Group I consists of 57 Bassini-Stetten repairs and 45 ring narrowing repairs. Patient characteristics and preoperative risk factors for recurrence are not significantly different: (Bassini-Stetten vs ring narrowing): mean age(SD): 49 years(16) vs 49 years(16); bilateral hernia: 11% vs 4% ($P=0.5$); previous contralateral hernia repair: 30% vs 16% ($P=0.1$); heavy labour: 47% vs 53% ($P=0.5$); pulmonary disease: 17% vs 9% ($P=0.2$); prostatism: 10% vs 2% ($P=0.1$); constipation 2% vs 4% ($P=0.6$).

Group II consists of 160 Bassini-Stetten repairs and 103 Shouldice repairs. Most patient characteristics and preoperative risk factors are not significantly different (Bassini-Stetten versus Shouldice): mean age(SD): 57(14) vs 57(13); bilateral hernia: 26% vs 32% ($P=0.3$); heavy labour: 32% vs 34% ($P=0.7$); pulmonary disease: 22% vs 18% ($P=0.5$); prostatism: 16% vs 15% ($P=0.9$); constipation: 11% vs 13% ($P=0.5$). The history of a previous repair on the contralateral site is significantly more prevalent in the Bassini-Stetten arm: 22% vs 11% ($P=0.03$).

Surgeons

There were 16 surgeons and 19 surgical residents involved in the operations. 34% of the operations were performed by surgeons, and 66% by residents, assisted by a surgeon. There were no differences in these proportions across the four subgroups.

Complications

The postoperative complications are listed in table 1. There were no significant differences. The overall risk of testicular atrophy and chronic groin pain is 3% and 2.7% respectively. Six patients had seven operative groin explorations for pain, and one of these patients eventually had an orchidectomy for a painful atrophic testicle.

Long-term follow-up and recurrences

By 1995 89 patients with 100 hernia repairs had died. 30 repairs were unavailable for examination because patients could not be located. These 130 repairs had been examined at the one or two year follow-up visit. In 41 hernia repairs a recurrence had been established by a previous physical examination. Of the remaining 194 hernia repairs, follow-up was updated after a mean period of 13.7 years (range: 12.2 - 15.1). This was done by physical examination in 179/194 (92%) and by telephone interview in 15/194 (8%) of hernia repairs. Physical examination was performed at the outpatient

Table 1. Postoperative complications and long-term morbidity.

	I Bassini-Stetten (n=57)	I ring narrowing (n=45)	II Bassini-Stetten (n=160)	II Shouldice (n=103)
mortality	0%	0%	0%	0%
haematoma	10% (6)	4% (2)	8% (15)	11% (11)
wound infection	2% (1)	2% (1)	1% (1)	1% (1)
re-operation for local complication	0% (0)	2% (1)	1% (1)	3% (3)
urinary complic.	2% (1)	2% (1)	1% (2)	2% (2)
pulmonary complic.	0% (0)	0% (0)	3% (5)	4% (4)
testicular atrophy	2% (1)	2% (1)	4% (7)	2% (2)
chronic pain	5% (3)	5% (2)	3% (5)	0% (0)

Values in parentheses are absolute numbers.

clinic (153), at the patients home (19), or in a nursing home (7).

A total of 83 recurrences were recorded, 42 of which were discovered at the long-term follow-up. 42% (35/83) of the recurrences were asymptomatic at the time of diagnosis. 73% (61/83) of the recurrences have occurred more than two years after the operation.

A life table with discontinuous intervals was constructed (intervals: 0-1 year, 1-2 years, 2-13.7 years). When patients had died, or were lost for follow-up, the repairs were considered as censored cases. Half of the censored cases are considered at risk for recurrence during the interval in which the censoring occurred. The cumulative recurrence rates are shown in table 2. At 13.7 years there is no difference between the two treatment arms in group I. The difference in group II in favour of the Shouldice repair is statistically significant ($P=0.033$).

Table 2. Recurrence rates for all recurrences (symptomatic and asymptomatic), calculated with the life table method.

	I Bassini-Stetten	I ring narrowing	II Bassini-Stetten	II Shouldice
1 yr	9%	2%	6%	4%
2 yr	9%	2%	7%	5%
13.7 yr	33%	34%	32%*	15%*

* Significant difference between Bassini-Stetten and Shouldice in group II ($P=0.033$).

The symptomatic recurrence life table analysis with yearly intervals, constructed to have an indication of the occurrence in time, suggests a continuing risk of recurrence (figure 1).

Figure 1. Yearly recurrence rates for symptomatic recurrences only. The onset of symptoms was taken as time of recurrence.

Bilateral disease

22% of patients had a history of previous contralateral inguinal hernia surgery and 13% of patients initially presented with a bilateral hernia. 17% of patients have developed a contralateral primary hernia during the 13.7 year follow-up period. Inguinal hernia eventually became a bilateral disease in half of our patients (52%).

Risk factors for recurrence

The following factors were analysed with a logistic regression for correlation with recurrence: age, bilateral disease, previous history of contralateral hernia repair, history of pulmonary disease, prostatic disease, constipation, heavy labour, level of the surgeon (resident vs surgeon), and technique of repair.

In group I there was a significant increased risk for recurrence associated with bilateral disease (risk: 6.6; $P < 0.04$), and with heavy labour (risk: 4.9; $P < 0.01$). In group II the only significant risk factor was the technique of repair: the risk of a recurrence after a Shouldice repair is 0.4 times the risk after a Bassini repair ($P < 0.01$). None of the other factors were significantly correlated with recurrence.

Discussion

The patients in this study are representative of the male inguinal hernia population. Most of the non-randomized patients fell within the exclusion criteria, and few patients refused trial participation. The randomization procedure in the study was not perfect. The double randomization was known to the surgeon preoperatively, and might have influenced the intraoperative classification of the hernia in group I or II. Furthermore, some patients did not have the operation assigned by randomization, because of organizational flaws. These repairs were not analysed according to the 'intention to treat-principle' because the protocol violations occurred not because of patient-related or operation-related reasons, but purely because of organizational set-up flaws, that would not occur in everyday practice. Despite these shortcomings, we believe that the study provides valuable data.

The recurrence rate after repair of an inguinal hernia with a weak posterior wall is significantly lower with the Shouldice repair (15%) than with the modified Bassini repair (32%). In a recent review and meta-analysis of six randomized controlled trials evaluating the Shouldice repair, including the short-term results of our study, Simons et al. conclude that the Shouldice repair is the best current conventional technique for inguinal hernia repair.⁵ Our study is in accordance with these findings. However, the 15% long-term recurrence rate for the Shouldice repair is higher than the <5% that is usually reported.^{1,4,5} It is well known that reported recurrence rates are not only influenced by surgical expertise and method of repair, but also by the length and

method of follow-up.^{12,13} In this study, 42% of recurrences were asymptomatic. These recurrences can be missed with follow-up by questionnaire or telephone interview.¹³⁻¹⁵ The importance of an adequate length of follow-up is shown by the fact that 73% of the recurrences in the present study have occurred after the two year follow-up period. Furthermore, the life table figure that was constructed using symptomatic recurrences suggests a lifelong continuing risk of recurrence for all repairs.(fig 1) With a physical examination in 80% of remaining patients after a follow-up period of 12 - 15 years, the results of this study are probably close to reality.

Some surgeons advocate the 'individualisation of hernia repair', and propose different types of repair for different types of hernia.⁷ In this approach, the indirect hernia with a normal, firm posterior wall is often assumed to be adequately treated by high ligation of the peritoneal sac and narrowing of the internal ring.⁷⁻¹⁰ In the present study, there is no difference between long-term recurrence rates of a Bassini-Stetten repair (33%) and a high ligation and ring narrowing (34%): both are unacceptably high. Furthermore, the recurrence rate for the Bassini-Stetten repair is similar in both hernias with a weak posterior wall (32%) and in indirect hernias with a firm posterior wall (33%). These findings argue against the concept that the indirect hernia with a firm posterior wall is essentially different from the hernia with a weak posterior wall. Our findings support the view that the adult inguinal hernia, direct or indirect, is the result of a weakening of the supporting structures in the groin, the transversus abdominus aponeurosis/transversalis fascia layer.^{13,16} In this respect the adult indirect hernia clearly differs from the pediatric inguinal hernia, in which the persistent processus vaginalis is believed to be the cause, and for which a high ligation of the peritoneal sac is the standard treatment. The repair of all adult groin hernias, direct or indirect, should include reinforcement of the complete posterior wall.

How to improve on a 15% recurrence rate after primary inguinal hernia repair? The present study involved 16 general surgeons and 19 general surgical residents, for some of whom the Shouldice repair was relatively new. Specialisation in hernia repair, as done in hernia centres, will undoubtedly result in a lower recurrence rate.¹⁷ Specialisation is a complex matter, with many organizational, financial, educational and emotional consequences, and, at present, most general surgeons do not embrace the idea.

The concept of reinforcing the posterior wall with synthetic material dates from the 19th century, when Billroth stated that "if we could artificially produce tissues of the density and toughness of fascia, the secret of the radical cure of hernia would be discovered".¹⁸ It was only recently that biocompatible synthetics like polypropylene and Dacron allowed surgeons to gain considerable experience with mesh based groin hernia repair. If the adult groin hernia is caused by a structural weakening of the supporting structures in the groin, the results of mesh-based techniques could be better than those that rely on the concept of suturing these weak tissues. The preperitoneal inlay mesh repair has been shown to give excellent results, even in difficult cases.^{2,19,20} Laparoscopic hernia repair, based on the same principle of an inlay mesh repair, is

reported to have low recurrence rates, and is now being evaluated on a wider scale. The onlay mesh repair, through an anterior approach, as advocated by Lichtenstein, has gained widespread acceptance in the USA, because of the simplicity of the procedure and its low recurrence rates.^{1,13} Only long-term follow-up of randomized trials comparing the different mesh based techniques with anterior tension repairs (i.e. Shouldice repair) will learn how to improve the results of inguinal hernia repair.

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Chapter 3

FOREIGN BODY REACTIONS TO MONOFILAMENT AND BRAIDED POLYPROPYLENE MESH USED AS PREPERITONEAL IMPLANTS IN PIGS

Beets GL, Go PMNYH, van Mameren H
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"If we could artificially produce tissues of the density and toughness of fascia and tendon, the secret of the radical cure of hernia would be discovered."

Billroth Th, 1878

Abstract

Monofilament polypropylene Prolene® mesh and multifilament Surgipro® mesh are widely used in laparoscopic inguinal hernia repair. Both types of polypropylene mesh provoke a foreign body reaction. The aim of this experimental study is to compare the multinucleate giant cell foreign body reaction to both types of polypropylene mesh.

Six Surgipro® meshes and six Prolene® meshes were implanted in 12 inguinal sites of six female Yorkshire & Dutch landway pigs using a laparoscopic transperitoneal technique. The meshes were harvested at 3, 6 and 12 weeks. For every mesh, the number of giant cells within a window of 0.362 mm² was counted at 40 different mesh-tissue interface areas.

For the Prolene® mesh the mean (SD) number of giant cells/0.362 mm² at 3, 6, and 12 weeks were 2.1 (1.8), 2.5 (2.0) and 2.6 (2.1). For the Surgipro® mesh the corresponding figures were 11.3 (5.5), 8.7 (4.8) and 11.4 (4.6), respectively. At all times the numbers of multinucleate giant cells at the mesh tissue interface were significantly larger with Surgipro® than with Prolene® ($p < 0.001$).

There is significantly more foreign body reaction after implantation of Surgipro® than Prolene® mesh.

Introduction

The most commonly used technique for laparoscopic hernia repair consists of reinforcement of the abdominal wall with a prosthetic mesh in the preperitoneal area, either transperitoneally or by a total preperitoneal procedure. Two types of polypropylene mesh are most commonly used in laparoscopic hernia repair: a monofilament Prolene® mesh (Ethicon, Somerville, NJ, USA) and a braided Surgipro® mesh (Autosuture, USSC, Norwalk, CT, USA). Since its introduction in 1961 by F. Usher et al., polypropylene mesh has been shown to incorporate well into tissue and be resistant to infection.^{1,6,9} There is, however, a mild persisting foreign body reaction with multinucleate giant cells.^{7,8} The aim of this study was to compare foreign body reaction after laparoscopic implantation of Prolene® and Surgipro® mesh in the preperitoneal inguinal area in pigs.

Materials and methods

The care of laboratory animals and all animal procedures were conducted in accordance with the Dutch law "Wet op de proefdiervoorziening". Six female Yorkshire & Dutch landway pigs were anaesthetized with azaperone 2mg/kg intramuscularly for premedication, halothane 2% for induction, and halothane 1% for maintenance after endotracheal intubation.

Six Prolene® and six Surgipro® meshes were implanted in the 12 preperitoneal inguinal areas using a laparoscopic transperitoneal technique. Prolene® mesh is knitted from monofilament, and Surgipro® from multifilament polypropylene yarn. At each of 3, 6, and 12 weeks 2 animals were killed with doses of Euthanasate®. The abdominal cavity was opened and tissue specimens containing the mesh and surrounding tissue were harvested for histological examination. No other studies or experiments were done on these animals.

Tissue specimens were fixed in 10% buffered formalin (pH7), dehydrated, embedded in Technovit 7100 and cut in 4 µm tissue sections. These sections were stained with 0.2% toluidine blue in 0.2% borax. For every mesh, four tissue sections were analysed. Ten sites of mesh-tissue interface per tissue section were randomly selected and the foreign body giant cells within a fixed window were counted, so each mesh analysis contains 40 observations. The mesh-tissue interface sites were selected with the microscope in defocus, to avoid observer bias. With a magnification of x125, the window within which the giant cells were counted corresponds to a tissue section area of 0.362 mm².

To test the reproducibility of the method the analysis was repeated five times in one of the meshes. The mean (SEM) number of giant cells in these five different analyses

Figure 1. Surgipro® braided mesh (Me) 12 weeks after implantation. Many multinucleated giant cells (GC) can be seen at the mesh-tissue interface.

Figure 2. Prolene® monofilament mesh (Me) 12 weeks after implantation. Only an occasional giant cell (GC) can be seen at the mesh-tissue interface.

was 2.15 (0.28), 2.28 (0.31), 2.63 (0.34), 2.03 (0.26) and 2.08 (0.29). These figures show that the method of counting giant cells is reproducible.

The number of giant cells in the two different mesh types was compared using the Wilcoxon Rank Sum test, and a probability of less than 0.05 was considered significant. The statistical analysis was performed with the software package Statistical Package for the Social Sciences (SPSS®).

Results

For the Prolene® mesh the mean (SD) number of giant cells/0.362 mm² at 3, 6, and 12 weeks were 2.1 (1.8), 2.5 (2.0) and 2.6 (2.1). For the Surgipro® mesh the corresponding figures were 11.3 (5.5), 8.7 (4.8) and 11.4 (4.6), respectively. There was a pronounced difference in the number of giant cells in the two types of mesh. At all times foreign body reaction was more pronounced when Surgipro® was used than when Prolene® was used ($p < 0.001$).

Discussion

After implantation, polypropylene elicits an early modest cellular infiltration which is followed by infiltration of fibroblasts and formation of collagen.^{2,5} Macrophages appear at the mesh-tissue interface. Multinucleate giant cells are derived from macrophages by fusion and are found in areas of chronic inflammation and around foreign bodies.³ The foreign body reaction from polypropylene is less pronounced than from many other suture materials, but has been shown to persist even after two years.^{7,8} Although there have been no clinical problems with this mild chronic reaction to polypropylene mesh, the long-term histological reactions are not well documented.

It is not clear why the Surgipro® mesh elicits a more pronounced foreign body reaction than the Prolene® mesh. Surgipro® is chemically identical to Marlex® and Prolene®. There are only minimal mechanical differences as a result of the slightly different structure of the fibers.⁴ The different fabric of the mesh could explain the difference in foreign body reaction. Prolene® mesh is knitted from a monofilament polypropylene fiber whereas Surgipro® mesh is knitted from a braided one. The braided fibers have a larger mesh-tissue interface than monofilaments, and this may induce a more pronounced foreign body reaction. The clinical implications of this finding remain speculative. To achieve tissue ingrowth and good fixation of the mesh, some degree of tissue reaction is needed initially. In the long-term, the mesh with the least foreign body reaction may be preferable. Follow-up studies over a longer period of time than ours are needed to evaluate the long-term differences in foreign body reaction and the consequences of a persisting foreign body reaction.

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Chapter 4

FOREIGN BODY REACTION TO POLYPROPYLENE MESH USED AS A PREPERITONEAL IMPLANT IN THE PIG - TEMPORAL EVOLUTION

Beets GL, van Mameren H, Go PMNYH

Submitted

"Although decreasing, there exists an unjustified fear regarding the routine use of mesh in the repair of inguinal and incisional hernias."

Amid PK, 1994

Abstract

Prosthetic meshes are increasingly being used in inguinal hernia repair. In the surgical community, there is some concern about the long-term biological compatibility. The aim of this study is to quantify the temporal evolution of the foreign body reaction to polypropylene mesh, after laparoscopic implantation in the preperitoneal inguinal area.

Twenty-two Surgipro® meshes were implanted in 22 preperitoneal inguinal areas in 11 female Yorkshire & Dutch landway swines using a laparoscopic transperitoneal technique. The meshes were harvested at 1, 2, 3, 4, 6, 12, and 26 weeks. For every mesh, the number of giant cells within a window of 0.56 mm² was counted at 40 different mesh-tissue interface areas.

The mean number of giant cells(SD) after 1, 2, 3, 4, 6, 12, and 26 weeks are: 0.9(2.4), 7.3(5.4), 19(8.2), 15.2(7.9), 15.9(6.9), 14.1(5.6), and 8.2(4.7). The mean number of giant cells at 12 weeks was significantly lower than at 3 weeks. The mean number of giant cells at 26 weeks was significantly lower than at 3, 4, 6, and 12 weeks.

The foreign body giant cell reaction to polypropylene mesh increases until the third week after implantation. Thereafter, it gradually decreases, and at six months, it persists at half the maximal level at 3 weeks.

Introduction

Inguinal hernia repair is one of the most common surgical procedures. In most laparoscopic and some of the open techniques, a prosthetic mesh is used to reinforce the weak abdominal wall. Since its introduction in 1963 by F. Usher, polypropylene mesh has been shown to have a good tissue incorporation, no rejection and a remarkable resistance to infection.¹⁻³ However, in the surgical community there is still concern about the long-term biological compatibility of prosthetic meshes.⁴ With polypropylene mesh, as with polypropylene suture material, there is a mild foreign body reaction with multinucleate giant cells.⁵⁻⁷ In a previous animal experiment this foreign body reaction to two types of laparoscopically implanted preperitoneal polypropylene meshes was quantified at 3, 6 and 12 weeks after implantation, by counting the number of giant cells at the mesh-tissue interface.⁸ With only 3 points in time, and with a relatively short follow-up, it was unclear whether this foreign body reaction would increase, decrease, or remain stable after this period.

The aim of this study is to quantify the temporal evolution of the foreign body giant cell reaction to polypropylene mesh after laparoscopic implantation in the preperitoneal inguinal area in a pig model.

Material en methods

Care for laboratory animals and all animal procedures were in accordance with the Dutch law "Wet op de proefdiervoorziening". Eight female Yorkshire & Dutch landway swines were anaesthetized with azaperone i.m. 2mg/kg premedication, halothane 2% induction, and halothane 1% maintenance after endotracheal intubation. 16 polypropylene meshes (Surgipro[®] mesh, U.S.S.C., Norwalk, CT, U.S.A.) were implanted in the 16 preperitoneal inguinal areas using a laparoscopic transperitoneal technique. At 1, 2, 4, and 26 weeks 2 animals were sacrificed using Euthanasate[®]. The abdominal cavity was opened and tissue specimens containing the mesh and surrounding tissue were harvested for histological examination. Tissue specimens were fixed in 10% buffered formalin (pH 7), dehydrated, embedded in Technovit 7100 and cut in 4 μ m tissue sections. These sections were stained with 0,2% Toluidine blue in 0,2% borax.

As part of a previous experiment⁸, 6 Surgipro[®] meshes had been implanted in 3 female Yorkshire & Dutch landway swines and harvested at 3, 6, and 12 weeks. The tissue sections had been processed in the same way and were now analysed again, together with the new tissue sections. For every mesh, tissue sections from four different sites were analysed. Per tissue section ten locations of mesh-tissue interface were randomly selected. The mesh-tissue interface locations were selected with the microscope in defocus, to avoid observer bias. The foreign body giant cells within a fixed window were counted at a magnification of x125. The window in which the

mesh, we obtained thus a sample of 40 observations of the number of giant cells within this area.

Statistical analysis was performed with the software package Statistical Package for the Social Sciences (SPSS®). Mean values were compared with Students t-test.

Results

The mean number of giant cells(SD) per 0.56 mm² after 1, 2, 3, 4, 6, 12, and 26 weeks are: 0.9(2.4), 7.3(5.4), 19(8.2), 15.2(7.9), 15.9(6.9), 14.1(5.6), and 8.2(4.7)(figure 1). The mean number of giant cells at 12 weeks was significantly lower than at 3 weeks ($P<0.001$). The mean number of giant cells at 26 weeks was significantly lower than at 3, 4, 6, and 12 weeks ($P<0.001$ for all 4 comparisons).

Figure 1. Mean number of foreign body giant cells/0.56 mm² at different time intervals. Error bars indicate standard deviation. *significantly lower than at 3 weeks ($P<0.001$). **significantly lower than at 3, 4, 6, and 12 weeks ($P<0.001$ for all 4 comparisons).

Figure 2. 12 weeks after implantation of the polypropylene mesh (Me). Many multinucleate giant cells (GC) can be seen. Bar = 100 μ m.

Discussion

The clinical relevance of a continuing low level of foreign body reaction remains to be established. There are no reports suggesting any adverse long-term effects of polypropylene sutures or meshes, despite its extensive worldwide use in clinical practice since 1962. Therefore, the chances of any serious adverse long-term effects must be very low.

After implantation, polypropylene elicits an early modest cellular infiltration which is followed by fibroblast infiltration and collagen formation.⁵ Mononuclear phagocytes (macrophages) appear at the mesh-tissue interface. Multinucleate giant cells are derived from macrophages by the process of fusion and are found in areas of chronic inflammation and around foreign bodies.⁹ The magnitude of this reaction varies with dependent on the type of suture or mesh material, and on the fabric of the mesh (monofilament versus multifilament).^{6-8,10} In a rabbit model, foreign body reaction to polypropylene suture has been shown to be present two years after implantation.⁶ Our experiment shows that the foreign body reaction to polypropylene mesh increases until the third week after implantation, after which it gradually decreases. At 6 months, the number of foreign body giant cells is half the number at 3 weeks.

In our previous experiment we didn't observe a decrease in foreign body reaction between 3 and 12 weeks. In the present experiment larger samples were studied, and there was therefore less chance of a statistical type II error. A small decrease in foreign body reaction was noted between 3 and 12 weeks, and the additional measurement at 26 weeks showed a further decrease. Beyond 6 months, it is expected that there will be a continuing low level of foreign body reaction.

In conclusion, the foreign body reaction to a preperitoneally implanted polypropylene mesh, most pronounced at 3 weeks, gradually decreases and persists at a low level. This does not seem to pose any clinical problem.

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Chapter 5

LONG-TERM RESULTS OF GIANT PROSTHETIC REINFORCEMENT OF THE VISCERAL SAC FOR COMPLEX RECURRENT INGUINAL HERNIA

Beets GL, van Geldere D, Baeten CGMI, Go PMNYH
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"The time has come when one may operate upon almost every case of hernia not only without danger to the patient, but also with an almost certain prospect of success."

Halsted WS, 1924

Abstract

The results of recurrent inguinal hernia repair in a prospective cohort study were evaluated. From May 1986 to December 1990 75 patients with 150 hernias (24 primary, 126 recurrent) were operated using a technique based on Stoppa's preperitoneal mesh repair (giant prosthetic reinforcement of the visceral sac; GPRVS). All patients were at high risk for recurrence: they all had bilateral hernias, mostly bilateral recurrent and often repeatedly recurrent.

All patients had a physical examination 1 week, 6 weeks and 1 year after operation. Sixty patients (94 per cent of surviving patients) had a physical examination after a mean follow-up of 5.7 (range 4-9) years. There were no major complications. There was one deep infection that healed without removing the mesh. One of the 75 patients (1 per cent) had a recurrence 2 months after the operation, due to a technical failure.

Because of the excellent results, the ease of the procedure and the low complication rate, GPRVS is the authors' operation of choice for any recurrent inguinal hernia.

Introduction

The traditional anterior approach to the repair of a recurrent hernia carries a high failure rate, from about 5 per cent for the Shouldice technique to more than 30 per cent for other procedures.^{1,2} Stoppa and colleagues³ were the first to combine the preperitoneal approach with the use of a large prosthetic mesh, covering both inguinal areas. Later the procedure became known as giant prosthetic reinforcement of the visceral sac (GPRVS).⁴ The preperitoneal approach avoids scar tissue from previous anterior repairs, and abdominal wall reinforcement is obtained by a large preperitoneal inlay prosthetic mesh rather than by approximation of aponeuroses and muscles. The procedure is therefore ideally suited for the management of recurrent hernias resulting from a weakness of the abdominal wall, especially multiple recurrent hernias and bilateral hernias. These hernias are known to be at high risk for failure after conventional repair.^{5,6} Using GPRVS for recurrent inguinal hernias, recurrence rates of 0-5.9 per cent have been reported.^{4,7-9} The method of follow-up in these reports varied from questionnaire⁹ to physical examination⁸, or was not clearly stated^{4,7}. It has been shown that follow-up with other than physical examination can fail to detect half of the recurrences.¹⁰ The reported length of follow-up is variable: 1-12 years⁷⁻⁹ or not clearly defined⁴.

The aim of this prospective cohort study was to determine the outcome of GPRVS in a group of consecutive patients with complex recurrent inguinal hernias: bilateral recurrent hernias and recurrent hernias with a primary hernia on the opposite side, with the recurrent hernia often being a multiple recurrent hernia. Postoperative complications and long-term recurrence rates evaluated by physical examination are reported.

Patients and methods

In the period between May 1986 and December 1990 75 patients (74 men) with 150 inguinal hernias were selected for GPRVS because of the presence of a complex recurrent inguinal hernia (bilateral recurrent inguinal hernia, multiple recurrent inguinal hernia with a contralateral primary hernia). Mean(s.d.) age was 65(12) years. A bilateral recurrent hernia was present in 51 patients, and 24 patients had a unilateral recurrent hernia with a primary hernia on the other side. Of the 126 recurrent hernias there were 67 repeated recurrences (figure 1). Eleven patients had severe chronic obstructive pulmonary disease, six of whom were receiving steroid medication. In all patients previous hernia repairs had been performed through an anterior inguinal approach without the use of a mesh. The exact type of previous repair could not always be established because some repairs had been performed more than 20 years earlier and because some patients were referred without operative notes.

Figure 1. Number of primary hernias, first recurrences and multiple recurrences.

All patients were operated on under general anaesthesia. Flucloxacilline was given as antibiotic prophylaxis for 24 h. A urinary catheter was introduced to maintain an empty bladder during the operation, and was removed at the end of the procedure.

With a lower abdominal midline incision through the linea alba and the fascia transversalis, access is gained to the preperitoneal and prevesical space. The peritoneal sac is dissected away from the abdominal and pelvic wall, mainly by blunt dissection. The anterior bladder wall is dissected off the pubic bone to the level of the prostate. Laterally the visceral sac is dissected off the iliac vessels, psoas and transverse abdominal muscle (figure 2a). With this manoeuvre a direct hernial sac is easily reduced. The spermatic cord is isolated by blunt dissection and a sling is put around it. Any indirect hernial sac is reduced into the abdominal cavity and dissected off the cord. When the distal sac is too large or adherent it is simply divided at the level of the internal ring. The proximal part is closed after repositioning the peritoneal contents and the distal part is left open in the inguinal canal.

When the dissection is complete on both sides, a large rectangular polypropylene mesh (26x18cm)(Marlex; C.R. Bard, Billerica, Massachusetts, USA) with two vertical slits of approximately 10 cm in the upper border (figure 2b) is positioned around the spermatic cords. The slits are closed with a running polypropylene no. 1 suture (figure 2c). By overlapping the edges of the slits, the mesh is curved according to the caudal

Figure 2a. View of the lower abdominal wall and inguinal region from the inside. Dissection is carried out in the preperitoneal plane. 1, Vas deferens; 2, iliac vessels; 3, testicular vessels; 4, epigastric vessels; 5, deep inguinal ring. 2b. Mesh with two vertical slits in the upper border. Dimensions are given in millimetres. 2c. The mesh is positioned around the spermatic cord and the slits in the mesh are closed. The mesh covers all inguinal and femoral hernial orifices and prevents an incisional hernia through the linea alba.

abdominal wall contour and is easy to apply. In an alternative technique, applied in 24 patients, the vas deferens and the spermatic vessels are dissected off the peritoneal sac. The mesh can then be applied between the visceral sac and the parietalised cord elements. In both techniques no attempt is made to close the hernia defect. The mesh is not fixed to any part of the abdominal wall. The midline incision is closed with a running polyglactin no. 1 suture. The mesh covers the caudal part of the parietal peritoneum and bladder. The intra-abdominal pressure pushes and fixes the mesh against the abdominal and pelvic wall. The mesh covers all inguinal and femoral hernial orifices and prevents an incisional hernia through the linea alba. Suction drains are not routinely used.

Operative time, postoperative hospital stay and postoperative complications were noted. Patients were routinely followed by physical examination in the outpatient clinic after 1 and 6 weeks and 1 year after operation. In December 1994 follow-up information on all patients was updated. Medical records of patients who had died were reviewed and the general practitioner was contacted for additional information after the 1-year visit. All other patients were contacted and asked to visit the outpatient clinic for a physical examination by one of the authors.

Results

Mean operative time for the bilateral hernia repair was 39 (range 28-65) min. Median postoperative hospital stay was 5 (range 1-31) days. There were no serious operative difficulties. In some patients, mainly after previous abdominal operations, the peritoneal sac was inadvertently entered. These accidental peritoneal openings were always closed meticulously.

Postoperative complications and operative reintervention are listed in table 1. Most complications were minor. One of the six patients with a postoperative haematoma or bleeding required reoperation. All superficial wound infections were treated conservatively by opening the wound. The only deep wound infection, involving the mesh, was treated by incision and drainage under general anaesthesia. Secondary healing was achieved. All wound infections healed without mesh removal. Two patients developed hydroceles in the first year after surgery, and were treated operatively.

There was one recurrence: a patient who underwent repair of a fourth recurrence on the right and a first recurrence on the left side developed a fifth recurrence on the right side 2 months after operation. Some 2 years later, the recurrent hernia became symptomatic and was repaired using an anterior approach. The mesh was found to be folded to the midline, with the abdominal contents herniating lateral to the mesh. After resection of the hernial sac, the defect was closed by suturing the edge of the mesh to the inguinal ligament. The patient was examined 4.5 years after this repair, and there

Table 1. Postoperative complications and operative reinterventions.

	n	reintervention
Postoperative death (0-30 days)	0	0
Pulmonary complications	2	0
Postoperative urinary retention	2	0
Haematoma or bleeding	6	1
Groin seroma	3	0
Superficial wound infection	5	0
Deep infection involving mesh	1	1
Testicular atrophy	0	0
Neuralgia	0	0
Hydrocele (late)	2	2
Total	21	4

was no evidence of recurrence. The other 74 patients were examined by the authors 1 and 6 weeks and 1 year after operation and had no recurrent hernia.

There was one recurrence: a patient who underwent repair of a fourth recurrence on the right and a first recurrence on the left side developed a fifth recurrence on the right side 2 months after operation. Some 2 years later, the recurrent hernia became symptomatic and was repaired using an anterior approach. The mesh was found to be folded to the midline, with the abdominal contents herniating lateral to the mesh. After resection of the hernial sac, the defect was closed by suturing the edge of the mesh to the inguinal ligament. The patient was examined 4.5 years after this repair, and there was no evidence of recurrence. The other 74 patients were examined by the authors 1 and 6 weeks and 1 year after operation and had no recurrent hernia.

In December 1994 60 patients were examined by the authors after a mean follow-up period of 5.7 (range 3.9-8.9) years. Of these, 53 patients had a physical examination at the outpatient clinic and seven were examined at home or in a nursing institution. No recurrences were detected. Of the remaining 15 patients, 11 had died from unrelated causes. There was no evidence of a recurrence after their latest visit to the outpatient clinic according to medical records and the general practitioner. Of the remaining four patients, three could not be traced and one elderly demented patient was terminally ill at home, with no signs or complaints suggestive of a recurrent hernia. Overall, 60 of 64 surviving patients (94 per cent) had a physical examination by the authors.

Although 15 of 60 (25 per cent) of the patients examined described a feeling of tightness, there were three (5 per cent) who complained of occasional minor discomfort in the groin region. One patient has had a subsequent Hartmann's

procedure for complicated diverticulitis. The lower midline incision through the mesh had been closed with polypropylene and had healed uneventfully. Another patient had a subsequent vascular procedure. Because of fibrosis around the mesh, dissection of the iliac vessels was slightly more difficult.

Patients were uniformly satisfied, and many of those with repeatedly recurrent hernia regretted not having had this operation earlier.

Discussion

In this prospective cohort study on the repair of complex recurrent hernias, at high risk for further recurrence, a recurrence rate of one of 75 patients (1 per cent) or one of 150 hernias (0.7 per cent) was achieved. The only recurrence in this series resulted from a technical failure, and was apparent 2 months after operation. This finding supports the view that failures after GPRVS occur early in the postoperative course, and are mainly due to surgical technique.^{4,11} When the mesh is properly positioned and becomes solidly fixed to the surrounding tissues, recurrences are unlikely.

This study supports the conclusion of other surgeons that GPRVS provides a definitive cure of inguinal hernias.^{4,7-9} Because of the excellent results, ease of the procedure and low complication rate, GPRVS has now become the authors' operation of choice for any recurrent inguinal hernia.

Because of an initial fear of infectious complications with the use of foreign material, the GPRVS procedure was reserved for patients with complex recurrent inguinal hernias. Although the 8 per cent incidence of infectious wound complications in this series is higher than that of 1 per cent for anterior mesh repair^{12,13}, it has never been a serious problem. The five superficial wound infections were managed on an outpatient basis and the single deep infection involving the mesh was treated adequately with incision and drainage without mesh removal. Polypropylene is known to be very resistant to infection, and infected wounds with exposed mesh most often heal without removal of the mesh.^{12,14,15} For this reason polypropylene is the mesh material of choice, although other surgeons prefer polyester meshes.^{4,7}

A laparotomy can easily be performed through the mesh. To prevent an incisional hernia through the incised mesh, the abdominal wall is closed with non-absorbable suture material (polypropylene). Access to preperitoneal and retroperitoneal structures like the ureter, bladder, prostate and iliac vessels can be slightly impeded because of fibrosis around the mesh but, in the authors' experience, this presents no real difficulty.

Patient satisfaction was remarkably high in this series. After multiple unsuccessful bilateral procedures patients sometimes had lost all hope of cure of their inguinal hernia. Some patients reported that they had been crippled for years, and were now able to do heavy labour again.

Most methods of laparoscopic hernia repair are based on the principle of the GPRVS. With application of a preperitoneal mesh widely overlapping the edges of the

defect laparoscopic hernia repair combines the best of both worlds: a sound repair with a low recurrence rate and low postoperative morbidity achieved with a less invasive technique. Because of the small access wounds and the inherent no-touch technique a lower infectious complication rate can be expected. This is supported by preliminary reports.^{16,18} The present study validates the principle of a large inlay mesh repair, on which laparoscopic hernia repair is based. Results of randomized trials are awaited for proper evaluation of laparoscopic hernia repair.^{16,19} In the meantime, GPVRS remains the author's gold standard for the repair of recurrent inguinal hernia.

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Chapter 6

ANATOMY OF THE INTERNAL INGUINAL REGION

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"No disease of the human body, belonging to the province of the surgeon, requires in its treatment a greater combination of accurate anatomical knowledge with surgical skill, than hernia in all its varieties."

Sir Astley Cooper, 1804

Abstract

Laparoscopic inguinal hernia repair can be performed by a transabdominal preperitoneal (TAPP) approach, or by a total preperitoneal (TPP) approach. Laparoscopic repair is fundamentally different from conventional anterior repair. Detailed knowledge of the preperitoneal groin anatomy is necessary to perform a TAPP or TPP repair. Standard (surgical) anatomy books are often insufficient in topographical details and variability. This article describes the anatomical details and variations of the internal inguinal region, as if approached for a TAPP repair. This knowledge can prevent complications during dissection or as a result of the use of hernia-staples in laparoscopic inguinal hernia repair. A close cooperation between surgeons and anatomists has proved very valuable in the development of this new surgical technique.

Abdominal wall hernias in the groin region are increasingly being repaired with laparoscopic techniques. Two approaches can be used: transabdominal preperitoneal (TAPP), and total preperitoneal (TPP). In both repairs a prosthetic mesh is placed in the preperitoneal area on the interior aspect of the abdominal wall to cover the defect. In TAPP repair the peritoneum is closed over the mesh. Hernia-staples can be used to fix the mesh to the abdominal wall to prevent dislodgement.

Incision and release of the peritoneum, dissection of the hernial sac and stapling the mesh can cause blood vessel and nerve injuries resulting in haematoma, pain, and numbness. Fitzgibbons et al. have reported an incidence of haematoma of 7.5%, of pain or numbness in the ventrolateral region of the thigh of 3.9%, and of pain in the groin area of 12.9%.¹ MacFadyen et al. have reported haematomas of the scrotum and the anterior abdominal wall.^{2,3} Cutaneous nerve injury by dissection or stapling can lead to impaired sensibility and pain.³

In standard textbooks on topographical and surgical anatomy the location and relation of the major groin structures is usually described starting from the outside. The introduction of laparoscopic techniques of inguinal hernia repair has stimulated the interest in the interior groin anatomy. A recent report describes the variability of the relation between the femoral lateral cutaneous nerve and the deep inguinal ring.⁴ However, this knowledge is not new. In 1908 Ruge mentioned, in a dissection manual for medical students, the variability of the sensory nerves in the region of the inguinal ligament.⁵ These variations and their relation to the iliopsoas muscle, the anterior abdominal wall and the inguinal ligament have been depicted schematically in the anatomy textbook of Rauber/Kopsch (1920)(figure 1).⁶

The lateral femoral cutaneous nerve occasionally perforates the abdominal wall cranial to the inguinal ligament. The variations in groin nerve anatomy described by Ruge are not linked to hernia repair in more recent German anatomy books. The volume 'Bein und Statik' (1972), from the anatomy series of Lanz and Wachsmuth, contains copies of Ruges findings when discussing sensory innervation of the thigh.⁷ The last volume of this series, 'Bauch' (1993), describes the variations in the course of the iliohypogastric and ilioinguinal nerves and its importance in (anterior) hernia repair.⁸ However, the variations of the genitofemoral and the lateral femoral cutaneous nerve, important for hernia repair 'from within', are not accurately described. These anatomical details are also insufficiently described in 'Surgical Anatomy' of Anson and McVay.⁹ In recent anatomy textbooks, the variability of the smaller anatomical groin structures 'from within' receives markedly less attention than the groin anatomy from 'outside' because the smaller preperitoneal structures are rarely encountered in conventional anterior hernia repair.

The authors have studied the topographical details of nerves and blood vessels in the preperitoneal area in the region of the lower anterior abdominal wall and the iliopsoas muscle, 'from within'. Dissection was performed as if the groin area was approached by laparoscopy for a TAPP hernia repair.

Figure 1. Variability of sensory pathways through the anterior abdominal wall (A and B) and in the preperitoneal fatty tissue overlying the iliopsoas muscle (C and D), and its relation to the inguinal ligament. After Ruge, 1908⁵.

The anatomical knowledge that has been obtained has been of value in discussions on management of groin hernia, on recurrence of groin hernia, and on the complications of hernia repair.¹⁰⁻¹² A detailed knowledge of the normal anatomy and the variability is considered essential for safe performance of laparoscopic inguinal hernia repair, and it is assumed that less complications will occur.¹³

Dissections

Fifteen inguinal regions of 8 preserved human male cadavers were studied. The deep frozen (-25°C) cadavers were transversely sawn, with a bandsaw, at the level of the umbilicus. After thawing, the remaining small and large bowel was removed up to the rectum. The peritoneum in the lower abdomen and pelvis was left intact. The view on the parietal peritoneum on the abdominal wall, the bladder, the iliopsoas muscle, the

internal obturator muscle and the pelvic diaphragm was comparable to the view during a laparoscopic TAPP repair.

One cm cranial to the iliopubic tract, the parietal peritoneum was transversely incised from the lateral umbilical ligament in the direction of the anterior superior iliac spine over a length of 10 cm. The peritoneum is then separated, with blunt dissection, from the preperitoneal tissues of the abdominal wall (in cranial direction), and the iliopsoas muscle and external iliac vessels (first in dorso-caudal, then in cranial direction). Blood vessels, nerves, vas deferens, and the obliterated umbilical artery are dissected in the fatty preperitoneal tissue to the point where they disappear under the iliopubic tract and the inguinal ligament.

Description of the anatomy

The topographic relations of the dissected structures are shown in figure 2. Some structures can be localised under the intact peritoneum through peritoneal folds. The obliterated umbilical artery (*plica umbilicalis medialis*), and the inferior epigastric vessels (*plica umbilicalis lateralis*) can always be identified. Often, the testicular vessels and the vas deferens can be seen. The peritoneum is somewhat more difficult to separate from the fatty tissue in the region of the internal inguinal ring, because of the presence of fibrous adhesions. The genitofemoral nerve and the testicular vessels lie immediately subjacent to the peritoneum. The testicular vessels are in close proximity to the external iliac vessels. At the level of the internal inguinal ring, immediately lateral to the inferior epigastric vessels, the vas deferens, the testicular vessels and the genital branch of the genitofemoral nerve come together and continue in the spermatic cord outside the abdominal cavity.

A variably sized branch of the epigastric artery, the pubic/obturator branch, is found deep in the fatty tissue medial of the external iliac artery and lateral of the medial umbilical fold. It runs over the inner side of the superior pubic ramus in the direction of the obturator foramen. In some cases branches of the epigastric vessels are found cranial of the superior pubic ramus. Many sensory nerves and blood vessels are found in the fatty tissue overlying the iliopsoas muscle in the area bordered by the iliopubic tract and the external iliac vessels. These blood vessels are mainly branches of the deep circumflex iliac vessels, vessels that follow a lateral course parallel to the iliopubic tract. The lateral femoral cutaneous nerve, which may consist of several branches, and the femoral branch of the genitofemoral nerve, can have a variable position in the fatty tissue on the iliopsoas muscle. In one cadaver the lateral femoral cutaneous nerve was found to perforate the anterior abdominal wall cranial to the inguinal ligament. The femoral nerve is situated at variable depths under the (sometimes thin) iliopsoas fascia, between the psoas and the iliacus muscle. This nerve thus lies centrally in the operating field, at a depth of approximately 1 cm.

Figure 2. Nerves, blood vessels and vas deferens in the preperitoneal tissue of the groin region. The parietal peritoneum has been released in cranial direction. From: *Inguinal Hernia Repair*, Schumpelick and Wantz (eds), with permission from: S. Karger AG, Basel.

The ilioinguinal nerve perforates the abdominal wall muscles at the level of the anterior superior iliac spine. Its position in the fatty tissue under the peritoneum is lateral to the laparoscopic operating field. The ureter is also situated outside the operating field, and is only encountered when the peritoneum is dissected extensively off the iliopsoas muscle in dorso-cranial direction.

Discussion

The genitofemoral and the lateral femoral cutaneous nerve can easily be damaged during a TAPP or TPP laparoscopic hernia repair. The genitofemoral nerve can be injured during the peritoneal dissection, and both nerves can be damaged by hernia-staples, used to fix the mesh. The ilioinguinal nerve is less at risk, but can be damaged by applying staples on the anterior abdominal wall cranial of the inguinal canal. Genitofemoral and ilioinguinal nerve injury can result in impaired sensibility or pain in the scrotal area, the groin area and the ventral thigh area. Lateral femoral cutaneous nerve injury leads to sensibility problems in the lateroventral thigh area.

Blood vessel injuries can lead to a scrotal haematoma (branches of the inferior epigastric vessels) or to a haematoma in the anterior abdominal wall (deep circumflex iliac vessels).

Ureteric injuries are rare in laparoscopic inguinal hernia repair, because the dissection of the peritoneum in dorso-cranial direction off the iliopsoas muscle very rarely reaches the level of the ureter.

The most easily injured sensory nerves and blood vessels are situated below the iliopubic tract, both medial and lateral of the external iliac vessels. Our study confirms the location and course of the lateral femoral cutaneous nerve and the branches of the genitofemoral nerve as described by Ruge.^{5,6} In all cases an arterial pubic/obturator branch and a large deep circumflex artery with side branches were seen.

Careful dissection of the peritoneum and the preperitoneal tissues in TAPP and TPP laparoscopic inguinal hernia repair is mandatory. The use of hernia-staples, and especially the 'blind' application of staples should be minimized. Laparoscopic inguinal hernia repair can be performed without hernia-staples. Van Steensel et al. report a recurrence rate of 1.9% in a series of 254 repairs. No nerve injuries and only 6 haematomas were observed.¹⁴

In the University Hospital of Maastricht the authors try to achieve an overlap of the mesh over the edges of the defect of at least 2 cm, in order to keep the mesh secured without hernia-staples. Prosthetic mesh quickly becomes adherent to surrounding tissues, first by fibrin, and later by connective tissue ingrowth. This has been shown in anterior mesh repair.¹⁵ In one of our patients, a recurrence was noted a few hours after a laparoscopic TAPP repair of a giant scrotal hernia. Through a lower abdominal midline incision the herniated mesh was removed and replaced by a larger one. The

mesh had already become firmly adherent to the surrounding tissues as early as 24 hrs after the first operation.

The minimal use of hernia-staples in laparoscopic inguinal hernia repair in the University Hospital of Maastricht resulted in a low incidence of postoperative sensibility impairment. In a series of 152 TAPP laparoscopic inguinal hernia repairs, starting in 1993, hernia-staples have been used in only six repairs. These were very medially located defects in which a large overlap of the mesh over the medial edge of the defect could not be obtained. There have been no sensibility problems in the area of the lateral femoral cutaneous nerve. Only 4 patients had a minor hypo-aesthesia in the ilioinguinal area, that had completely disappeared after 6 weeks. In none of these 4 patients hernia-staples had been used. The incidence of postoperative ecchymoses was 27%, the large majority of which were asymptomatic.

The authors conclude that nerve injuries can be prevented by avoiding the use of hernia-staples. With proper positioning of an adequately sized mesh the use of hernia-staples is unnecessary. The incidence of haematomas and ecchymoses is still (too) high. This is probably related to accumulation of blood and fluid through the hernia defect in the hernial cavity. In contrast to conventional repairs, this hernia defect is not closed in laparoscopic repair.

Knowledge of the topography and variability of the anatomical structures in the operative field is a prerequisite for laparoscopic inguinal hernia repair. In recent (surgical) textbooks of anatomy, descriptions of the groin region are usually related to the conventional anterior repairs. Apart from the study of the older anatomy books, it can be advised to perform cadaver dissections 'from the inside', simulating a laparoscopic view. The use of facilities offered by anatomical departments of medical faculties is to be encouraged. As been proven in the past, the cooperation between surgeon and anatomist can improve surgical treatment.

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Chapter 7

BASSINI REPAIR VERSUS LAPAROSCOPIC REPAIR FOR PRIMARY INGUINAL HERNIA:

A RANDOMIZED CONTROLLED TRIAL

Dirksen CD, Beets GL, Go PMNYH, Geisler FEA, Baeten CGMI, Kootstra G
European Journal of Surgery, in press

"If hernias occur because of the failure of the transversalis fascia to withstand the pressure to which it is subjected, the natural method of operative correction would seem to be the repair and strengthening of that fascia."

Harrison PW, 1922

Abstract

Laparoscopic inguinal hernia repair is a new treatment modality for inguinal hernia. The aim of this study is to compare the effectiveness of laparoscopic and conventional repair for primary inguinal hernia, by means of a randomized controlled trial.

Between November 1993 and July 1995, 175 patients with 217 inguinal hernias were randomized. 87 patients with 103 hernias underwent a Bassini repair and 88 patients with 114 hernias a laparoscopic repair. Laparoscopic repair was performed using the transabdominal preperitoneal (TAPP) technique. Operating time, complications, pain, convalescence, and recurrences were assessed.

Operating time was longer for laparoscopy: 82 vs 45 minutes ($P<0.001$). Patients from the Bassini group had higher postoperative pain scores (mean VAS: 2.9 vs 2.0; $P=0.002$), used more analgesics (median intake: 2 vs 0 tablets; $P=0.008$), and needed a longer convalescence time (return to work: 22 vs 14 days [$P<0.001$]; return to physical activities: 27 vs 17 days [$P<0.001$]). Mean follow-up is 24 months. Recurrence rates are 21.4% after Bassini and 6.1% after laparoscopic repair ($P=0.001$).

Laparoscopic hernia repair is a safe operation, with obvious advantages over the Bassini repair regarding pain, analgesia use, resumption of activities and recurrence. A disadvantage of the laparoscopic repair is the longer operating time.

Introduction

Inguinal hernia repair is the most common operation in The Netherlands, with approximately 24.000 operations annually.¹ Modern hernia surgery started a century ago with Bassini's description to close the defect in the posterior wall of the inguinal canal by approximating its musculo-aponeurotic edges through an inguinal incision.² In several European countries, the majority of the inguinal hernia repairs performed today, follow Bassini's principles.³⁻⁵ In the University Hospital Maastricht the Bassini repair was the standard operation for primary inguinal hernia.

Another approach is to cover the abdominal wall defect with a prosthetic mesh. The mesh can be placed anterior on the musculo-aponeurotic layer of the abdominal wall⁶, or posterior in the preperitoneal space⁷. The recurrence rates of both repairs are claimed to be low.⁸⁻⁹

Surgeons have started performing inguinal hernia repairs using various laparoscopic techniques. The transabdominal preperitoneal (TAPP) repair has become the mostly applied laparoscopic approach, because it is relatively simple and offers a good view of the anatomic structures.¹⁰⁻¹³ Laparoscopic inguinal hernia repair is essentially based on the principle of the open preperitoneal mesh repair. Recurrence rates ranging from 0-2 per cent have been reported.^{12,14-18} The laparoscopic repair has the potential to combine a low recurrence rate with a reduction of the operative trauma.

Laparoscopic hernia repair was introduced in the University Hospital of Maastricht early 1993. After an initial learning period, a randomized controlled trial was started in November 1993. The aim of the study was to compare the effectiveness of the laparoscopic TAPP repair with the standard Bassini repair for primary inguinal hernias.

Patients and methods

Study design and patient enrolment

An independent non-clinical investigator was assigned to the project by the Board of Directors of the University Hospital Maastricht. The study was approved by the institutional ethical committee and by the scientific committee. All patients eligible for general anaesthesia (ASA 1-2-3), between 20 and 80 years of age, with a primary inguinal hernia were randomly assigned to either Bassini or laparoscopic inguinal hernia repair. Pregnant women, patients with coagulation disorders, advanced carcinoma, history of lower abdominal or other pelvic surgery (except appendicectomy) and patients requiring concomitant surgery were excluded from randomization. After obtaining an informed consent, patients were randomized at the outpatient-clinic using sealed envelopes.

Outcomes and instruments

Postoperative morbidity, convalescence, pain and recurrence were assessed. Hospital stay was standardized: patients were admitted the day before surgery and were routinely discharged the morning after the operation, whenever possible. Operating time, operative findings, postoperative complications and postoperative hospital stay were recorded. The Visual Analogue Scale (VAS) from 0 (no pain) to 10 (intolerable pain) and a Verbal Rating Scale (VRS) with 4 response possibilities (no pain, mild pain, moderate pain, severe pain) were used simultaneously to record pain. At discharge patients received a questionnaire to report their pain experience, amount and type of analgesia during the first seven postoperative days. The date of resumption of paid work and physical activities (sports, walking, bicycling, etc.) was recorded. At discharge, patients were explicitly instructed there were no restrictions regarding return to routine activities, except if this would cause discomfort and pain. Physical examinations were performed at the outpatient clinic 10 days (first control-visit) and 6 weeks (second control-visit) postoperatively. Two abdominal muscle exercises were performed preoperatively and 1 day, 10 days and 6 weeks postoperatively. These exercises, a modification of a test described by Payne et al.¹⁹, were used as an objective measure of physical performance. In the first test the patient crosses the arms on the chest and performs curled sit-ups. In the second test the patient pulls up his flexed legs. These exercises were performed during 30 seconds or until the patient felt uncomfortable. Postoperative performance was expressed as a percentage of preoperative performance. To determine recurrence rate, all patients will have a physical examination once a year, up to a total follow-up of 5 years. Recurrence is defined as a symptomatic or asymptomatic defect in the abdominal wall with herniation of abdominal contents, exacerbated by a Valsava manoeuvre.

Statistical analysis

Recurrence rate was the primary outcome of the study. A power analysis, based on recurrence rates of 1 per cent for the laparoscopic repair and 12 per cent for a Bassini repair, with $\alpha = 0.05$ and $\beta = 0.1$, set the number of required hernias on 100 per treatment group. To achieve at least the number of required hernias, the number of patients was set on 200. To correct for possible preoperative withdrawals, 220 (10 per cent extra) envelopes were prepared. Results were analysed according to 'intention to treat'. Work was subdivided in non-strenuous, moderate or strenuous, according to the patient's perception. The Kolmogorov-Smirnov test was used to test for normality. The unpaired Student-T test was performed to determine differences between normally distributed variables. The unpaired Mann Whitney test was used for differences between non-normally distributed data or ordinal variables. Chi-square was used to analyse categorical variables. Two-sided P values below 0.05 were considered to indicate statistical significance.

Anaesthesia

Premedication, anaesthesia and postoperative pain medication were standardized in order to compare postoperative pain. Premedication consisted of 1000 mg paracetamol, oral or rectal. Antibiotics were not used. All patients underwent general anaesthesia of thiopentone sodium 4-5 mg/kg, vecuronium 0.1 mg/kg and fentanyl 1 µg/kg. Maintenance of anaesthesia included N₂O/O₂ mixture. Isoflurane up to 1.2 vol % and iv boli of fentanyl 1 µg/kg were used when needed. No opiate antagonists were used at the end of anaesthesia. Postoperative pain management consisted of 1000 mg paracetamol up to three times daily when needed.

Surgical procedures

In the Bassini repair, the inguinal canal is opened and inspected. An indirect sac is dissected off the spermatic cord, ligated and transected at the level of the internal ring. A direct sac is inverted. The conjoint tendon (internal oblique muscle, transversus abdominis aponeurosis and transversalis fascia) is sutured to the inguinal ligament using interrupted absorbable sutures (polyglactin). The external oblique fascia is closed over the cord.

In the laparoscopic repair (TAPP), a CO₂ pneumoperitoneum is established with the use of a Veress needle. Three cannulas are used for access to the abdominal cavity. The peritoneum is opened at the upper border of the inguinal hernia defect from the medial umbilical ligament to the level of the iliac spine. A direct sac is reduced, an indirect sac is reduced and dissected off the vas deferens and the testicular vessels. When the indirect sac is very large, it is transected. A polypropylene mesh of 10x15 cm with rounded edges is positioned over the inguino-femoral area and the defect, widely overlapping the edges. The mesh is not anchored by staples or sutures. The peritoneum is closed with a running absorbable suture. An incidentally discovered contralateral hernia is repaired at the same time.

Bassini repairs were performed by all surgeons or by surgical residents, assisted by a co-operating surgeon. Laparoscopic repairs were performed by three laparoscopic surgeons or by residents, assisted by a co-operating laparoscopic surgeon. All laparoscopic surgeons had performed at least 20 laparoscopic repairs before they entered the study.

Results

Between 15 November 1993 and 31 July 1995, 369 patients with an inguinal hernia were treated in our department. Of these patients, 159 did not participate in the study for reasons listed in table 1. Two hundred and ten patients were randomized for Bassini or laparoscopic repair. There were 35 withdrawals before surgery, mostly because of the long waiting-list period, or a preference for regional anaesthesia. This

leaves 175 randomized and operated patients for analysis. Characteristics of the two groups are comparable and listed in table 2. There were no significant differences. In the laparoscopic group more patients had a bilateral hernia repair, because with the laparoscope an unsuspected small contralateral asymptomatic hernia is easily detected, and repaired. The difference in bilateral repairs was not significantly different.

Table 1. Reasons for not participating in the trial during the period of the study.

exclusion criteria	47
ambulatory treatment/ regional anaesthesia	58
patient refusal	32
reason not registered	22
Total non-participating patients	159

Table 2. Patient characteristics.

	Bassini	Laparoscopic repair
no. of patients	87	88
no. of male patients	85 (98%)	88 (100%)
age - mean (SD)	53.7 (13.0)	53.3 (14.6)
Body Mass Index or BMI (SD)	25.1 (3.3)	24.9 (3.0)
no of hernias	103	114
no of patients with a unilateral hernia	71 (82%)	62 (70%)
no of patients with a bilateral hernia	16 (18%)	26 (30%)
no of working patients	46 (53%)	57 (65%)
intensity: non-strenuous	13 (28%)	19 (33%)
moderate	20 (43%)	25 (44%)
strenuous	13 (28%)	13 (23%)
no of physically active patients	70 (80%)	73 (83%)

Operative results

The operative results are listed in table 3. Eighty-five Bassini repairs (83%), and 32 laparoscopic repairs (28%) were performed by surgical residents, assisted by surgeons. The other operations were performed by surgeons. Operating time was significantly longer for laparoscopic repairs as compared to Bassini. The mean operating times of

Table 3. Operative results and hospital stay.

	Bassini	Laparoscopic repair
mean operative time in minutes (SD)		
unilateral hernia	45 (14.6)*	82 (28.2)*
surgeons [#]	38 (15.2)	78 (30.1)
residents [#]	46 (14.4)	87 (18.9)
bilateral hernia [§]	48 (18.5)	109 (35.9)
postoperative hospital stay / no. of patients		
< 24 hours	84 (97%)	80 (91%)
24 - 48 hours	3 (5%)	6 (7%)
> 48 hours	0	2 (2%)
operative complications		
conversion to open	NA	1
other complications	1	2

* $P < 0.005$, Student T; [#] difference between surgeons and residents for Bassini: $P = 0.6$, for laparoscopic repair: $P = 0.2$, Student T; [§] bilateral Bassini repairs were performed simultaneously.

unilateral repairs performed by residents were slightly higher as compared to surgeons, but not significantly different.

There was one vas deferens injury during a Bassini repair. One laparoscopic repair was converted to an open anterior repair due to an equipment failure. In the laparoscopic group there was one Veress needle puncture of the stomach without further consequences and one testicular vessel injury without subsequent testicular atrophy.

Postoperative morbidity

In table 4 the results for postoperative morbidity and complications are described. After a Bassini repair half of the patients have inguinal hypaesthesia. In the laparoscopic group there were more inguino-femoral ecchymoses and two patients were re-operated for a painful haematoma. After a laparoscopic repair, two patients developed a urinary tract infection and one patient a urinary retention.

Pain and use of analgesics

Figure 1 presents the results for the VAS. The preoperative VAS scores and the VAS scores at 6 weeks were not significantly different between Bassini and laparoscopy.

Table 4. Postoperative morbidity and complications

	Bassini	Laparoscopic repair
no. of patients	87	88
no. of hernias	103	114
inguinal hypaesthesia	54 (52%)*	5 (4%)*
groin swelling	25 (24%)	30 (26%)
ecchymosis	16 (16%)**	33 (29%)**
wound infection [#]	1 (1%)	2 (2%)
urinary complications [#]	0	3 (3%)
pulmonary complications [#]	1 (1%)	0
re-operation for [#] :		
recurrence	0	2 (2%)
haematoma	0	2 (2%)

Results are presented per hernia. [#] Presented per patient. * $P < 0.005$, and ** $P < 0.05$; Chi-square.

The mean VAS scores were 2.9 versus 2.0 ($P = 0.002$) during the first postoperative week (day 1 - day 7). Ten days postoperatively VAS scores were 0.9 versus 0.4 ($P = 0.045$) for respectively Bassini and laparoscopy. VAS is positively correlated with VRS ($P < 0.001$). The median total analgetic intake after seven days of 2 (mean 6.4) tablets in the Bassini group was significantly different from the median of 0 (mean 3.0) tablets in the laparoscopic group ($P = 0.008$).

Figure 1. Postoperative pain by Visual Analogue Scale.

Resumption of activities

The average disability period for work of 22 ± 11.2 (range 1-44) days in the Bassini group and 14 ± 10.1 (range 1-42) days in the laparoscopic group was significantly different ($P < 0.001$). Figure 2 presents the results for people with non-strenuous, moderate or strenuous work. Return to physical activities was 27 ± 12.6 (range 1-57) days after a Bassini repair and 17 ± 12.2 (range 1-43) days after a laparoscopic repair ($P < 0.001$). The cumulative percentages of patients that had returned to unrestricted duties and physical activities at the time of their second control-visit are presented in figures 3 and 4.

Abdominal muscle tests

Preoperative scores for patients from the Bassini and laparoscopic group were comparable for both exercises. Only the 'legs pull up' test showed a significant difference 1 day postoperatively in favour of the laparoscopic repair. Ten days and 6 weeks postoperatively Bassini and laparoscopy had comparable results for both exercises.

Figure 2. Sick leave stratified by intensity of work. * $P < 0.05$; ** $P < 0.005$; Chi-square.

Figure 3. Cumulative percentage of patients returning to

work. * P=0.005; Chi-square

Figure 4. Cumulative percentage of patients resuming physical activities. * P<0.005; ** P<0.01; Chi-square.

Follow-up

Mean follow-up until October 1996 is 24 months (range 15-36). Of the Bassini group, 85 (98%) patients have been evaluated by physical examination and 2 patients by telephone interview one year postoperatively. The 2- years follow-up has been completed in 38 (44%) patients. Of the laparoscopic group, 82 patients (93%) have been evaluated by physical examination and 4 patients by telephone interview one year postoperatively. The 2- years follow-up has been completed in 34 (39%) patients.

In the Bassini group, a total of 22 recurrences in 22 patients have been recorded. Nineteen of the 85 repairs (22%) performed by surgical residents, and 3 of the 18 repairs (17%) performed by surgeons, resulted in a recurrent hernia. Recurrence rates between surgical residents and surgeons were not significantly different ($P=0.6$). At the time of diagnosis, 8 recurrences were asymptomatic, 2 of which later became symptomatic. So far, 9 recurrences have been repaired.

In the laparoscopic group, 7 recurrences were noted in 7 patients. Three of 32 repairs (9%) done by surgical residents, and 4 of 82 repairs (5%) performed by surgeons, resulted in a recurrent hernia. This difference is not significant ($P=0.08$). Two recurrences were immediate and repaired within 24 hours of the primary operation. Four recurrences were asymptomatic. So far, 4 recurrences have been repaired. Recurrence rates are 21.4% after a Bassini repair and 6.1% after a laparoscopic repair ($P=0.001$).

One year after a Bassini repair, there were 8 cases (8%) of inguinal hypaesthesia and 12 (12%) of chronic wound pain. In nine patients this was described as minor discomfort, in two as moderate pain, and in one as severe pain. This last patient suffered from a severe neuralgia, not relieved by nerve infiltration and operative groin exploration. One year after a laparoscopic repair, the only patient with persistent hypaesthesia was the one who required conversion to an open anterior approach. In the laparoscopic group there were 17 cases of chronic groin pain (15 per cent). In all but one this was described as minor discomfort. One patient with moderate chronic pain had a small painful lump near the pubic tubercle. He had a groin exploration and a small piece of folded mesh was removed.

Discussion

To determine the procedure of choice for inguinal hernia repair, several issues need to be evaluated: safety, technical difficulty, postoperative discomfort, convalescence, recurrence rate and cost.^{20,21} Although the cost of laparoscopic hernia repair compared to Bassini repair is important in determining the most "cost-effective" treatment, this question was not the issue in this study and therefore will not be discussed extensively.

The rate and severity of complications was similar in both groups. Severe laparoscopy-related complications, like small bowel obstruction, bowel or bladder

perforation or major vascular injury did not occur.²²⁻²⁵ After a Bassini repair, half of the patients experience some form of inguinal hypaesthesia. In eight per cent this was still present after 1 year and in one patient this was accompanied by a disabling neuralgic groin pain. After a laparoscopic repair, patients did not suffer from persistent neuralgic pain. The reported incidence of neuralgia after a laparoscopic hernia repair is 2-3 per cent.^{24,26} This is usually caused by nerve entrapment and can be prevented by avoiding the use of staplers as in this study.

A disadvantage of the laparoscopic hernia repair is the longer operating time as compared to the Bassini repair. This is confirmed by other reports comparing laparoscopy with open repairs.^{19,27,28} Besides a different anatomy, the laparoscopic repair requires considerable laparoscopic skills. Operating time will decrease with growing experience as has been observed by others.²⁹⁻³¹

Resumption of activities is significantly quicker after a laparoscopic repair. The largest difference in return to work is found in patients with a strenuous job, a result supported by Payne et al.¹⁹. A shorter recuperation period after a laparoscopic repair has been reported in several comparative studies.^{19,27-29,33,34} This result was also widely found in studies on laparoscopic cholecystectomy. It supports the assumption that laparoscopic surgery is able to decrease the cost to society by reducing "productivity losses".

After a laparoscopic repair patients experience less pain and use half of the amount of analgesics compared to the Bassini group. Our results resemble those of other reports.^{19,28, 30,32,41} Although the overall difference in postoperative pain is modest, it is apparently associated with a difference in recuperation period.

A disadvantage of the laparoscopic repair is that general anaesthesia is preferred for patient comfort and safety. Patients who prefer or need local or regional anaesthesia cannot be managed laparoscopically. Most conventional repairs can be performed under local or regional anaesthesia.

Our choice of the conventional procedure can be argued. We have chosen a Bassini repair with absorbable sutures for two reasons: firstly, it was our standard repair for inguinal hernia and secondly, a Dutch survey in 1995 and a German survey in 1983 have shown that a Bassini type of procedure was the most popular repair in these countries, and absorbable suture material was most frequently used.^{4,5} Recently several randomized trials have shown that the Shouldice repair is the best conventional repair.³⁶ In Germany, the Shouldice repair has now replaced the Bassini repair, according to a survey in 1992.³⁷ With a Shouldice repair as conventional procedure, the recurrence rates in the present study probably would have been different. The results of the study with regard to pain and resumption of activities most likely apply to all conventional 'anterior tension repairs', as the postoperative pain and disability is believed to be caused by suturing the conjoint tendon/transversalis fascia to the inguinal ligament/iliopubic tract.

The results with respect to short-term recurrence rates favour the laparoscopic repair. However, the 6.1% recurrence rate is higher than the a priori expected 1%. The

6.1% short-term recurrence rate for laparoscopy is slightly higher than the 4.5% in a large non-randomized multicentre trial.²⁶ Other series report recurrence rates of 0-2%^{30,31,38-40} but these include results of personal experiences in non-randomized patients. Because a laparoscopic repair aims to reinforce the whole inguino-femoral area with a prosthetic mesh, all recurrences must be considered as technical errors and thus preventable. Four of the seven recurrences occurred within six weeks and two even within 24 hours. The recurrences that have been repaired had all occurred medial to the mesh and are probably due to incorrect positioning of the mesh and/or not stapling of the mesh. We now place the mesh more medial, on the pubic bone anterior to the bladder, at least until the midline. Occasionally we use staples to secure the medial position of the mesh.

The 21.4% recurrence rate after the Bassini repair is excessively high. This could have many reasons. We already mentioned the use of absorbable suture material. Although results of randomized trials comparing absorbable with nonabsorbable suture materials are conflicting⁴¹⁻⁴⁶ most experts in hernia surgery recommend the use of nonabsorbable sutures.^{47,48} Our data may indicate the insufficiency of absorbable sutures, as our own 1-year recurrence rate of conventional repair with nylon was 5-10% in the early eighties.⁴⁹

It has often been said that success of inguinal hernia repair is highly dependent on meticulous surgical technique. Although difficult to prove, it is reasonable to assume that specialisation in inguinal hernia repair will lower the recurrence rates.⁵⁰ In our study, Bassini repairs were performed either by surgeons, or by residents assisted by a surgeon, none of whom is specialised in hernia repair.

Another possible reason for the high short-term recurrence rate is our meticulous follow-up and our definition of recurrence, which includes asymptomatic hernias. Almost half of the recurrences were asymptomatic and detected at the additional control-visits. In a 'normal' situation (no trial) these recurrences might have remained unnoticed for a long time.

The recurrence rate of conventional repairs like the Bassini or the Shouldice repair has been noted to rise with continuing follow-up.^{48,49} This is probably due to further deterioration of the supporting structures of the groin. In laparoscopic hernia repair, the whole inguino-femoral area is reinforced by a nonabsorbable prosthesis. Late recurrences are unlikely, in contrast to the early recurrences caused by technical errors. Whether or not this advantage of laparoscopic repair is true will be noted with continuing follow-up of randomized trials.

The authors conclude that laparoscopic transabdominal preperitoneal hernia repair is a safe operation with few and minor complications. Laparoscopic hernia repair has obvious advantages over the Bassini operation regarding postoperative pain, analgesia use and resumption of activities. Our present recurrence rates show that the laparoscopic hernia repair is superior to the Bassini repair. Because of the unacceptably high recurrence rate, we no longer perform the Bassini repair. The laparoscopic repair is a technically difficult operation and requires a longer operating time. In addition, our

recurrence rate for laparoscopic repair was higher than expected. Therefore, we hesitate to accept the laparoscopic technique as the new standard repair for primary inguinal hernia. It is, however, a good option for a laparoscopically skilled surgeon.

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Chapter 8

OPEN OR LAPAROSCOPIC PREPERITONEAL MESH REPAIR FOR RECURRENT INGUINAL HERNIA:

A RANDOMIZED CONTROLLED TRIAL.

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Submitted

"..the single most important factor in both recurrences and complications of herniorrhaphy is ill-conceived attempts at approximating normally unopposed and structurally compromised tissues under tension"

Robbins AW and Rutkow IM, 1993

Abstract

Giant Prosthetic Reinforcement of the Visceral Sac (GPRVS), an open preperitoneal mesh repair, is one of the most solid groin hernia repairs. Laparoscopic transabdominal preperitoneal repair (TAPP) is based on the same principle, and is expected to combine low recurrence rates with minimal postoperative pain and early resumption of activities. The aim of this study is to compare laparoscopic with open preperitoneal mesh repair for recurrent inguinal hernia.

From November 93 to March 96, 79 patients with 93 recurrent hernias and 15 concomitant primary hernias were randomized to GPRVS or TAPP. Operating time, complications, pain, analgesia use and disability period, and recurrences were recorded. Patients were seen 10 days, 6 weeks, 1 year and 2 years after operation.

Thirty-seven patients were randomized for GPRVS, and 42 patients for TAPP. Mean operating time (min): 56 GPRVS vs 79 TAPP ($P < 0.001$). Most complications were minor, except for a pulmonary embolus and an ileus, both after GPRVS. Wound problems: 4/37 (11%) GPRVS vs 0/42 TAPP ($P = 0.04$). Mean pain score (VAS): 2.9 GPRVS vs 2.2 TAPP ($P = 0.005$). Median analgesia use (tablets): 3.5 GPRVS vs 1 TAPP ($P = 0.06$). Average disability period in days (GPRVS vs TAPP): 23 vs 13 ($P = 0.03$) for work, and 29 vs 21 ($P = 0.07$) for other physical activities. Mean follow-up is 21 months. Recurrence rates: 1/52 (1.9%) for GPRVS vs 7/56 (12.5%) for TAPP ($P = 0.04$). Hospital costs (Dutch Fl.) were comparable: 2045 (GPRVS) and 2004 (TAPP).

Laparoscopic repair of recurrent inguinal hernia has a lower morbidity than GPRVS. However, it is a difficult operation with a potentially higher technical failure rate than GPRVS. With regard to recurrence rates, the open preperitoneal prosthetic mesh repair remains the best repair for most patients and surgeons.

Introduction

The traditional anterior approach in the repair of a recurrent hernia carries a high failure rate: from approximately 5% for the Shouldice technique to more than 30% for other techniques.¹ The use of a large preperitoneal mesh for the repair of recurrent inguinal hernia, as propagated by Stoppa et al., has been shown to be very effective.^{2,3} In a series of complex recurrent inguinal hernias, our recurrence rate with this "giant prosthetic reinforcement of the visceral sac" technique (GPRVS) was 1%, and the procedure has become our standard repair for recurrent inguinal hernias.⁴

Laparoscopic repair is based on the same principles of a preperitoneal mesh repair. It could combine the low recurrence rate of the open technique with a quick postoperative recovery. Several randomized trials have addressed this issue in comparing laparoscopic with conventional anterior repair - and the Lichtenstein repair in one trial, and including mainly or exclusively primary inguinal hernia patients.⁵⁻¹¹ There have been no reports of trials comparing laparoscopic with open preperitoneal mesh repair, or trials for recurrent inguinal hernia.

The aim of this randomized controlled study is to compare morbidity, cost, and recurrence rates of laparoscopic transabdominal preperitoneal mesh repair (TAPP) and open preperitoneal mesh repair (GPRVS) for recurrent inguinal hernia.

Patients and Methods

Study design

An independent non-clinical investigator was assigned to the project by the Board of Directors of the University Hospital Maastricht. The randomized controlled trial was approved by the institutional ethical committee and by the scientific committee. All patients eligible for general anaesthesia (ASA 1-2-3), between 20 and 80 years of age, with a unilateral or bilateral recurrent inguinal hernia, were randomly assigned to either GPRVS or TAPP repair. Patients with a concomitant primary hernia were not excluded. Pregnant women, patients with coagulation disorders, advanced carcinoma, history of lower abdominal or other pelvic surgery (except appendectomy), patients requiring concomitant surgery, and patients with a recurrence after a preperitoneal repair were excluded from randomization. Patients with giant scrotal recurrent hernias were also excluded, because these hernias can be difficult to manage laparoscopically. After obtaining a written informed consent, patients were randomized using the sealed envelope technique.

Outcomes and instruments

Postoperative morbidity, convalescence, pain, cost, and recurrence were assessed. Hospital stay was standardized: patients were admitted the day before surgery and

were discharged the morning after the operation, whenever possible. Operating time, operative findings, postoperative complications and postoperative hospital stay were recorded. Postoperative pain was measured with the Visual Analogue Scale (VAS) from 1 to 10 (no pain - intolerable pain) and a Verbal Rating Scale (VRS) with 4 response possibilities (no pain, mild pain, moderate pain, severe pain). At discharge, patients received a questionnaire to report pain levels, amount and type of analgesia use during the first 7 postoperative days. The date of resumption of work and physical activities was recorded. Patients were instructed that there were no restrictions regarding return to routine activities, except if this would cause discomfort or pain.

Two abdominal muscle tests were used as an objective measure of physical performance. These exercises were a modification of a test described by Payne et al.(5). In the first test the patient crosses the arms on the chest, and performs curled sit-ups. In the second test the patient pulls up his flexed legs. These exercises were performed during 30 seconds, or until the patient felt uncomfortable. Muscle tests were performed before the operation, and 1 day, 10 days, and 6 weeks after the operation. Postoperative performance of these muscle tests was expressed as a percentage of preoperative performance.

Follow-up is performed by physical examination by the authors 10 days, 6 weeks, 1 year, 2 years and eventually 5 years after operation. A recurrent hernia is defined as any symptomatic or asymptomatic defect in the abdominal wall with herniation of abdominal contents, exacerbated by a Valsalva manoeuvre.

Anaesthesia

Premedication, anaesthesia and postoperative pain medication were standardized. Premedication consisted of paracetamol 1000 mg. All patients underwent general anaesthesia with thiopentone sodium 4-5 mg/kg, vecuronium 0.1 mg/kg and fentanyl 1µg/kg. Maintenance of anaesthesia included N₂O-O₂ mixture. Isoflurane up to 1.2 vol% and iv boli of fentanyl 1µg/kg were used when required. No opiate antagonists were used at the end of anaesthesia. Postoperative analgesia consisted of 1000 mg paracetamol 3 times daily, when required.

Operative techniques

The open repairs were performed by 5 surgeons, or by surgical residents assisted by one of the 5 surgeons. Laparoscopic repairs were performed by 4 laparoscopic surgeons with varying experience in laparoscopic hernia repair, or by surgical residents assisted by one of the four laparoscopic surgeons.

The GPRVS is by definition a bilateral reinforcement. A concomitant primary hernia, either known preoperatively or discovered intra-operatively is therefore automatically repaired. With the laparoscopic repair, all preoperatively and intraoperatively discovered hernias are repaired, and normal inguinal areas are not reinforced.

A urinary catheter was introduced to maintain an empty bladder during the operation, and was removed at the end of the procedure. Prophylactic antibiotics were used only for the GPRVS procedure. The details of the GPRVS have been described previously.⁴ Through a lower abdominal midline incision access is gained to the preperitoneal and prevesical space. The peritoneal sac is dissected away from the abdominal and pelvic wall, and the hernial sac is reduced. A large polypropylene mesh (26x18cm) (Marlex®, C.R. Bard, Billerica, MA, USA), with two vertical slits of approximately 10 cm in the upper border is positioned around the spermatic cords. The vertical slits are closed with a running nonabsorbable suture. The large mesh covers both inguino-femoral areas.

In the laparoscopic transabdominal preperitoneal repair (TAPP), a CO₂ pneumoperitoneum is created with a Veress needle. Three cannulas are used for access to the abdominal cavity. The peritoneum is opened at the upper border of the inguinal hernia defect from the medial umbilical ligament to the level of the iliac spine. A direct sac is reduced, an indirect sac is reduced and dissected off the vas deferens and the testicular vessels. When the indirect sac is very large, it is transected. A polypropylene mesh of 10 x 15 cm (Prolene®, Ethicon, Somerville, N.J., USA) with rounded edges is positioned over the inguino-femoral area, widely overlapping the edges of the hernial defect. The mesh is not anchored by staples or sutures. The peritoneum is closed with a running absorbable suture.

Costs

The cost analysis was carried out from the hospital perspective. The treatment of an inguinal hernia consisted of 5 activities: outpatient clinic preoperatively, a hospital day, operation, recovery-room stay, and outpatient clinic postoperatively. The costs per activity consisted of direct and indirect cost. Direct costs included personnel costs and both medical and non-medical material costs. Indirect costs consisted of the general overhead. Costs of laboratory tests, X-rays, medications, etc. were allocated to the activity in which they were requested or given. Costs of complications (additional outpatient visits, readmissions etc..) were calculated separately. Costs are presented in Dutch Fl.

Statistical analysis

Results were analysed according to 'intention to treat'. The Kolmogorov-Smirnov test was used to test for normality. The unpaired Student-T test was performed to determine differences between normally distributed variables. The unpaired Mann Whitney test was used for differences between non-normally distributed data or ordinal variables. Chi square test was used to analyse categorical variables, and Fischer's exact test was used when any expected cell value in a 2x2 table was less than 5. P values less than 0.05 were considered to indicate statistical significance.

Results

From November 93 until March 96, a total of 129 patients aged between 20 and 80 with a unilateral or bilateral recurrent inguinal hernia were treated in our department. Seventy-nine of these patients were randomized. Reasons for non inclusion are: ambulatory treatment: 3, regional anaesthesia: 10, previous lower abdominal surgery: 4, concomitant surgery: 5, giant scrotal recurrence: 5, previous preperitoneal repair: 3, patient refusal: 6, and unknown: 6. Eight patients experienced a recurrence while participating in a trial for primary inguinal hernia repair, and were not included in a second trial for ethical reasons.

Patient characteristics are given in table 1. The two groups are comparable.

Table 1. Patient characteristics.

	GPRVS	Laparoscopic repair
patients	37	42
female patients	1	1
working patients	16 (43%)	16 (38%)
patients performing physical activities	29 (78%)	33 (79%)
age (SD)	57 (13)	58 (12)
Body Mass Index (SD)	25.1 (2.8)	24.2 (2.9)
risk factors for recurrence*	11 (30%)	10 (24%)
recurrent hernias	41	52
concomitant primary hernias	11	4

* prostatism, COPD, obstipation, or strenuous physical labour

Operative results and hospital stay

Sixty-five per cent of the GPRVS procedures and 29% of the laparoscopic repairs were performed by surgical trainees ($P<0.001$). One patient assigned to a laparoscopic repair underwent a GPRVS procedure because of laparoscopic equipment supply problems. According to the intention to treat principle, he is retained for analysis in the laparoscopic group. Operating time (SD) was significantly different: 56(16) min for GPRVS versus 79(32) min for laparoscopic repair ($P<0.001$). After a GPRVS, 77% of patients were discharged within 24 hrs, as compared to 92.5% of patients after a laparoscopic repair ($P=0.02$).

Complications

Complications are listed in table 2. One patient was readmitted 8 days after a GPRVS with an ileus. At laparotomy small bowel loops were found to be adherent to the mesh through a peritoneal tear. This was easily corrected and the patient had an uneventful recovery. One patient was readmitted with a pulmonary embolus, and was treated with standard anticoagulation therapy. All wound infections were superficial. They were treated on an outpatient basis, and healed without further problems. Two patients eventually had a scar excision under local anaesthesia for cosmetic reasons.

Table 2. Complications. *P=0.04

	GPRVS	Laparoscopic repair
vas deferens injury	0	1
urinary	1 (retention)	2 (infection)
chest infection	0	1
pulmonary embolus	1	0
ileus / laparotomy	1	0
wound infection	4*	0*
haematoma	5	10
seroma	7	10
inguinal hypaesthesia	0	0
painful testicle (transient)	1	2
testicular swelling (transient)	2	2
testicular atrophy	1	0
chronic neuralgia	0	0

*P=0.04

Pain and analgesia use

The mean VAS scores (SD, range) during the first postoperative week were 2.9 (1.5, 0-7) for GPRVS and 2.2 (1.6, 0-7) for the laparoscopic repair (P=0.005). Median (1st-3rd quartile) VRS scores were 1 (1-1) for GPRVS and 1 (1-1) for laparoscopic repair (P=0.05). Ten days and 6 weeks after operation VAS and VRS scores were comparable. The median total analgesia use (range) in the first postoperative week was 3.5 (0-11) tablets in the GPRVS group, and 1 (0-6) tablets in the laparoscopic group (P=0.06).

Resumption of activities

The average disability period for work (SD, range) was significantly different: 23 (12.4, 1-41) days for GPRVS and 13 (8.2, 1-30) days for TAPP ($P=0.03$). Return to physical activities was after 29 (13.4, 1-57) days for GPRVS and 21 (15.5, 1-74) days for TAPP ($P=0.07$).

Abdominal muscle tests

Preoperative absolute performance was comparable in both groups for both muscle tests. The results are presented in figure 1. Postoperative performance was significantly better in the laparoscopic group at the first and the tenth postoperative days. At six weeks, results were comparable for both groups.

Costs

The costs are presented in table 3. Additional costs resulting from complications are 4630 FI for all GPRVS procedures (mean additional cost of 213 FI), and 336 FI for all TAPP procedures (mean additional cost of 8 FI). When these additional costs are included, GPRVS becomes slightly more expensive than the laparoscopic repair. Cost of recurrences is not included in the analysis, because it is unclear how many eventually will require a repair.

Table 3. Costs (in Dutch FI).

	GPRVS	Laparoscopic repair
theatre costs	963	1218
other costs*	869	778
costs of complications	213	8
total costs	2045	2004

*outpatient clinic, hospital stay, recovery room

Follow-up and recurrences

The mean follow-up time in November 1996 is 21 months (range: 8-36).

In the GPRVS group one patient died of pulmonary disease within the first year after his hernia repair. One patient moved abroad after the 1 year follow-up. Thirty-two patients have completed the 1 year follow-up, and 15 patients the 2 year follow-up.

Sit-up test

Knees-up test

Figure 1. Abdominal muscle tests. Postoperative performance is expressed as percentage of preoperative performance. * $P < 0.001$; ** $P = 0.01$; *** $P = 0.001$; Student T-test.

In the laparoscopic group one patient died of a previously unknown malignancy 6 months after his hernia repair. In the course of his disease, he underwent a laparotomy, on which occasion the hernia repair was found to be intact. Thirty-four patients have been examined after 1 year, and 13 patients after 2 years.

The actual recurrence rate after GPRVS is 1/52 hernias (1.9%), or 1/37 patients (2.7%). One small asymptomatic recurrence was found at physical examination 1 year after operation. The patient had a postoperative wound infection, for which additional outpatient clinic visits were required. The small recurrence may have gone unnoticed because attention was directed at the wound problem. The asymptomatic recurrence has not been repaired. There were no cases of severe chronic pain. One patient had a persistent minor groin pain.

The actual recurrence rate after laparoscopic repair is 7/56 hernias (12.5%), or 6/42 patients (14.3%). Four of the recurrences had been described as 'seroma' or 'bulging' 6 weeks after operation, and were found to be recurrences at the 1 year follow-up. One patient with a recurrence diagnosed after one year had not attended the 6 week follow-up visit. Two recurrences had been noted by the patients, one after 3 months, and one after 5 months. Four of the seven recurrences were asymptomatic at the time of discovery, two of which later became symptomatic. So far, two recurrences have been repaired. They were both medial recurrences, and obviously the prosthetic mesh had not been placed medially enough. The difference in recurrence rates, 1.9% for GPRVS, and 12.5% for TAPP, is statistically significant ($P=0.04$). There were no patients with severe chronic pain. Two patients had a persistent minor groin pain. Two patients have developed an asymptomatic recurrence from a previously conventionally repaired contralateral hernia.

Discussion

The difference in recurrence rates, 1.9% for GPRVS and 12.5% for TAPP, is clearly in favour of the open preperitoneal mesh repair. The 12.5% recurrence rate after laparoscopic recurrent inguinal hernia repair in our series is higher than expected. Felix et al. report a series of laparoscopic repair of 90 recurrent hernias, in which only one failure was observed.¹² In series and randomized trials of laparoscopic inguinal hernia repair, summarized in a recent review article, the short-term recurrence rate is usually less than 5%.¹³

Our strict adherence to physical examination as a follow-up method and our definition of recurrence could explain part of our higher recurrence rate. This includes also the small asymptomatic hernias discovered during follow-up, some of which might never require a repair. In the present study, only 2 of the 8 recurrences have been repaired so far.

The higher recurrence rate after the laparoscopic mesh repair could indicate that the laparoscopic repair is not as good as the open repair. However, in both techniques the aim is to cover the whole inguinofemoral area by a preperitoneal prosthetic mesh,

and recurrences should not occur. When they do occur, recurrences must be considered as technical failures. The difference in recurrence rate, 1.9% for GPRVS and 12.5% for the laparoscopic repair, indicates that laparoscopic repair is substantially more difficult, and that the potential for technical failure is higher.

It has been shown that most recurrences after laparoscopic repair are due to too small a mesh, or not using staples to fix the mesh.¹⁴ We have used a large mesh of 10cmx15cm which was not stapled. Most of our recurrences after laparoscopic hernia repair have occurred medially, and accordingly, we now place the mesh at least until the midline, and occasionally use hernia-staples when an adequate (2cm) overlap cannot be achieved medially. The learning curve effect has been observed by several authors.^{15,16} In the present study, the laparoscopic repair was performed or assisted by 4 laparoscopic surgeons, with varying experience in laparoscopic hernia repair. The learning curve may have been underestimated. It is reasonable to assume that the recurrence rate of an experienced laparoscopic hernia surgeon will be lower than the 12.5% presently reported.

The mean follow-up is 21 months. For conventional repair, it has been estimated that only 25% of recurrences occur within the first postoperative year, whereas 50% will appear after 5 years.¹⁷ For the open preperitoneal mesh repair, the long-term recurrence rate is not substantially different from the short-term recurrence rate.^{2,4} This is also expected for the laparoscopic repair, as it is based on the same method of inlay mesh repair. Therefore, we believe that the long-term results of this study will be essentially the same.

Two of the complications after GPRVS, a pulmonary embolus and a mechanic ileus requiring a laparotomy are potentially dangerous, and are indicative of the invasiveness of the procedure. As expected there were less wound problems after a laparoscopic repair than after a GPRVS.

Randomized trials have shown that laparoscopic repair causes less postoperative pain and less postoperative disability than a (conventional) anterior inguinal hernia repair.^{5,11} In both open and laparoscopic preperitoneal mesh repair, there is no tension on the musculo-aponeurotic groin structures. Goodwin et al. have compared, in a prospective nonrandomized study, laparoscopic repair with a unilateral preperitoneal mesh repair through a groin incision.¹⁸ They found no difference in postoperative pain and disability period. The differences observed in our study, can only be explained by the lower abdominal midline incision in the open repair. It is clear that less pain and disability benefit both individual patients and society. However, when asked for, most patients consider the traditional outcome measure of recurrence more important than the speed of recovery.¹¹

In this study, the hospital cost of both procedures was comparable. The two major complications after GPRVS contributed considerably to the cost of the open procedure. Laparoscopic hernia repair can easily be performed in a day-surgery setting, as shown by Evans et al.¹⁹ These authors report, after having performed 300 laparoscopic repairs, operating times of 24 min for unilateral and 38 min for bilateral

repair. In this setting, laparoscopic repair is substantially less expensive than reported in our study.

Laparoscopic recurrent inguinal hernia repair causes less postoperative pain and disability than GPRVS. Laparoscopic repair is technically more difficult, and the potential for technical failure is higher. When discussing treatment options with a patient, all of the above mentioned items should be addressed. In our opinion, laparoscopic inguinal hernia repair should only be performed by experienced laparoscopic surgeons who assess their personal recurrence rates. With regard to recurrence rates, the open preperitoneal mesh repair remains the best repair for most patients and surgeons alike.

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Chapter 9

SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

"We should remember, however, that the surgeons who report most of the results do not perform most of the hernia repairs."

Kirk RM, 1983

The studies in this thesis reflect the practice of inguinal hernia repair in an academic surgical department over a period of 15 years. This practice has been subject to change, and this is reflected in differences in set-up of the trials. Whereas in the early eighties the distinction between direct and indirect hernias strongly influenced the design of the trial, it was of no importance in the more recent trials. The short-term results of the early trial had shown no advantage of the Shouldice repair, and therefore the Bassini remained the standard repair. Only recently it has become clear that the Shouldice repair has better long-term results, and should have become the standard repair. The subcutaneous transposition of the spermatic cord that was performed in the Bassini-Stetten repair in the early eighties was no longer considered essential in the Bassini repair in the nineties. Conventional repairs in the eighties were performed with non-absorbable sutures (nylon). Because of the occasional chronic wound problems associated with the use of nylon sutures, it became practice to perform the repair with absorbable sutures (polyglactin). Of considerable interest, and somewhat contradictory to the previous, is the gradual increase in the use of non-absorbable prosthetic mesh. When introduced in our department in the mid-eighties, it was strictly reserved for patients with bilateral, multiple recurrent inguinal hernia. Because of its success in this group of patients, the indications for the use of mesh were expanded to include all recurrent inguinal hernias. The most recent trend is to use prosthetic mesh for primary inguinal hernia repair.

The definition of a recurrent hernia that is used throughout the previous chapters is that of any symptomatic or asymptomatic defect in the abdominal wall with herniation of abdominal contents, exacerbated by a Valsalva manoeuvre. This includes the small asymptomatic hernias discovered during follow-up by physical examination, some of which may never require a repair. The recurrence rates obtained with this definition may be slightly higher than clinically relevant. However, every other definition would involve a subjective decision on which hernia requires a repair and which hernia can be left alone, and could be a source of bias from the part of the examining surgeon.

Summary

The aim of this thesis is to determine how the results of inguinal hernia repair can be improved. Therefore we evaluate and compare surgical techniques of inguinal hernia repair based on Bassini's concept of suturing the musculo-aponeurotic edges of the posterior inguinal wall defect, techniques based on the more recent concept of a preperitoneal prosthetic mesh, and techniques using minimally invasive surgical technology.

The randomized trial in **chapter 2** shows that the long-term (12-15 yr) recurrence rate after repair of an inguinal hernia with a deficient posterior wall is significantly lower with the Shouldice repair (15%) than with the Bassini-Stetten repair (32%). However, a 15% recurrence rate for the Shouldice repair is higher than what is usually reported. It is well known that reported recurrence rates are not only influenced by surgical expertise and method of repair, but also by the length and method of follow-up. With a physical examination in 80% of remaining patients after a follow-up period of 12 - 15 years, the results of our study are probably close to reality.

There is no difference in recurrence rates of a Bassini-Stetten repair and a high ligation and ring narrowing for the indirect hernia with a firm posterior wall. The recurrence rates in both treatment arms are unacceptably high (33%). They are not different from the results for the Bassini-Stetten repair of a hernia with a weak posterior wall (32%). These findings support the view that the adult inguinal hernia, direct or indirect, is the result of a weakening of the supporting structures in the groin, the transversus abdominus aponeurosis/transversalis fascia layer.

In all treatment arms, there is a continuing risk for recurrence. Seventy-three per cent of the recurrences have occurred more than 2 years after the operation. All this again suggests a deterioration of the groin structures as an etiological factor for hernia.

Although the Shouldice repair has the best results, all three conventional repairs have high long-term recurrence rates.

In **chapter 3**, it is shown that, in a pig model for laparoscopic preperitoneal hernia repair, a multifilament polypropylene mesh induces more foreign body giant cell reaction than a monofilament polypropylene mesh. In **chapter 4**, this foreign body giant cell reaction is shown to increase until the third week after implantation. Thereafter, it gradually decreases, and at six months, it persists at half the maximal level at 3 weeks.

The clinical relevance of a continuing low level of foreign body reaction remains to be established. There are no reports suggesting any adverse long term effects of polypropylene sutures or meshes, despite its extensive worldwide use in clinical practice since 1962. Therefore, the chances of any serious adverse long term effects must be very low.

laparoscopic repair after a mean follow-up period of 21 months. With regard to recurrence rates, the open preperitoneal mesh repair remains the best repair.

Conclusions - recommendations

Conventional hernia repair, based on the concept of suturing together the musculo-aponeurotic edges of the defect, is troubled by high recurrence rates. The best conventional repair, the Shouldice repair, still has a considerable long-term recurrence rate. In our department, this was more than 10% after 12-15 years. The most traditional repair, the Bassini-repair, should no longer be performed because of the unacceptably high recurrence rate.

The traditional classification of direct (medial) and indirect (lateral) inguinal hernia does not have any clinical relevance. The long-term recurrence rates are similar. Whereas the pediatric inguinal hernia is adequately treated by high ligation, the adult indirect inguinal hernia is not. The pediatric and the adult inguinal hernia are two different diseases, with different etiologies: a persisting processus vaginalis in the child, and a weakening of the supporting groin structures (transversus abdominus aponeurosis/transversalis fascia layer) in the adult. In the adult inguinal hernia, repair or reinforcement of the complete posterior wall is essential, regardless of the type of hernia. After a conventional repair, patients are at lifelong risk for recurrence, due to further deterioration of the supporting groin structures.

With Stoppa's open preperitoneal mesh repair (giant prosthetic reinforcement of the visceral sac), recurrences are rare, even in the most difficult of cases. The abdominal pressure, a factor that promotes herniation, is used to keep the large "inlay"-prosthetic mesh secured in the preperitoneal groin area. This concept has proved to be valid, and a lasting repair can be achieved. Recent mesh materials like polypropylene, polyester, and e-PTFE have been shown to be safe and reliable. Polypropylene is our mesh material of choice, because of its resistance to infection and its extensive clinical use in hernia repair since 1962.

Laparoscopic groin hernia repair is based on the valid principle of a preperitoneal mesh repair. It is less invasive than the open repairs, causing less wound problems, less pain and a quicker recovery. Laparoscopic inguinal hernia repair is not an easy operation. It requires considerable laparoscopic skills, and initially, long operating times and technical failures can be expected. With increasing experience, operating times equivalent to those in open surgery, and long-term recurrence rates of well below 5% can be achieved. For surgeons who want to start performing laparoscopic hernia repair, we recommend proper training, strict follow-up by physical examination in the first 25-50 patients, and reoperation for all recurrences, to identify the reason for failure.

Any discussion on inguinal hernia repair is incomplete without mentioning the anterior tension-free repairs, of which the Lichtenstein repair is the most widely known. In this

repair the defect in the posterior wall is bridged by a prosthetic mesh through an anterior groin approach, and no attempt is made to close the defect. It is an easy repair, that can be carried out even under local anaesthesia. Short-term results are excellent. The long-term results have not yet been evaluated properly, but when they prove to be comparable to those of preperitoneal mesh repairs, anterior tension-free repairs will become attractive alternatives.

The surgeon who is consulted by a patient with an inguinal hernia has to consider four treatment options: a Shouldice repair, an anterior tension-free mesh repair, a laparoscopic mesh repair, and an open preperitoneal mesh repair of the Stoppa type. The Stoppa repair is undoubtedly the best option for any complex groin hernia (giant scrotal hernia, large bilateral hernia, concomitant incisional hernia). Recurrent hernias are best treated with a prosthetic mesh. For all other hernias, the advantages and disadvantages of each of the repairs should be discussed with the patient. A repair should be chosen, taking into account the patient's preference and expectations, and the surgeon's preference, skills, and experience.

The aim of this thesis was to determine how the results of inguinal hernia repair can be improved. We have shown that preperitoneal prosthetic mesh repairs have substantially lower recurrence rates than the conventional non-mesh anterior repairs. The laparoscopic preperitoneal mesh repair, while having the advantages of minimal invasiveness, is a technically difficult operation, and should only be performed by experienced laparoscopic surgeons to obtain optimal results.

Chapter 10

SAMENVATTING, CONCLUSIES EN AANBEVELINGEN

In **chapter 5**, the principle of a large preperitoneal mesh repair is shown to be very effective. In a group of patients with complex recurrent inguinal hernias, mostly bilateral recurrent and often repeated recurrent hernias, treated with Stoppa's giant prosthetic reinforcement of the visceral sac procedure, the recurrence rate after 4-9 years is only 1%. Failures after this procedure generally occur early in the postoperative course, and are due to surgical technique. Because of the excellent results, the ease of the procedure, and the low complication rate, GPRVS had become our operation of choice for any recurrent inguinal hernia.

The anatomical study in **chapter 6** has demonstrated important features of the groin anatomy 'from within'. Surgeons have not been familiar with the laparoscopic preperitoneal view. For safe performance of laparoscopic inguinal hernia repair, knowledge of the exact location of arteries, veins and nerves is a prerequisite. The study demonstrates the superficial location and considerable variation in the course of the smaller sensory nerves (genitofemoral, lateral femoral cutaneous, ilioinguinal) and the small blood vessels. The nerve injuries that have been associated with laparoscopic hernia repair are often caused by hernia-staples. The study identifies areas where staples can be used with relatively safety. Nerve injuries can be prevented by avoiding the use of staples.

The randomized trial in **chapter 7** compares the Bassini-repair with the transabdominal preperitoneal laparoscopic repair for primary inguinal hernia. At the time the study was started, the Bassini repair was still our standard repair for primary inguinal hernia, as it was in the majority of Dutch surgical departments. Subsequently, reports of randomized trials, including our own (chapter 2), have established the superiority of the Shouldice repair, which should now be considered as the gold standard of conventional repair against which any new method should be compared.

Laparoscopic hernia repair is a safe operation, which has obvious advantages over the Bassini repair regarding pain, analgesia use, resumption of activities, and recurrence rate. The recurrence rate is 6.1% for the laparoscopic repair and 21.4% for the Bassini repair after a mean follow-up period of 2 year. The exceptionally high recurrence rate after a Bassini repair is difficult to explain. The use of absorbable suture material may be one of the reasons. Disadvantages of the laparoscopic repair are the technical difficulty of the procedure and the longer operating time.

The randomized trial in **chapter 8** has compared the open preperitoneal mesh repair (Stoppa's giant prosthetic reinforcement of the visceral sac) with the laparoscopic transabdominal preperitoneal mesh repair for recurrent inguinal hernia. Although the laparoscopic repair has the benefits of a less invasive repair with regard to postoperative pain and activity resumption, the potential for technical failure is higher. This is reflected in the recurrence rates of 1.9% for the open repair, and 12.5% for the

De onderzoeken die de basis vormen voor dit proefschrift bestrijken een periode van ruim 15 jaar. De chirurgische praktijkvoering in een academische afdeling is in een dergelijke periode uiteraard aan verandering onderhevig, en dit is terug te vinden in de opzet van de verschillende trials. In het begin van de jaren tachtig had het onderscheid tussen een laterale en een mediale breuk nog een belangrijke invloed op het design van de trial, terwijl dit in de latere trials geen enkele rol speelde. De korte termijnresultaten van de eerste trial toonden geen belangrijke verschillen en daarom bleef het herstel volgens Bassini de standaard. Later is duidelijk geworden dat het Shouldice herstel betere lange termijnresultaten heeft, en dat dit het nieuwe standaardherstel had moeten worden. Het subcutaan plaatsen van de funiculus in de Bassini-Stetten operatie van begin jaren tachtig werd later, met de Bassiniplastiek, niet meer uitgevoerd. Het conventioneel herstel werd in het begin van de jaren tachtig uitgevoerd met niet-resorbeerbaar hechtmateriaal (nylon). Het gebruik van nylon was geassocieerd met een klein percentage chronische wondproblemen, en later werd het conventioneel herstel standaard uitgevoerd met resorbeerbaar hechtmateriaal (polyglactine). Van belang is verder het toenemend gebruik van niet-resorbeerbare kunststofprothesen in deze periode. Vanaf het midden van de jaren tachtig worden deze gebruikt voor het herstel van liesbreuken. Initieel werd het gebruik van kunststofprothesen voorbehouden voor patiënten met beiderzijdse herhaalde recidiefbreuken. Dit bleek erg succesvol en de indicatie werd uitgebreid naar alle recidiefbreuken. Recent is er een trend om ook primaire breuken met kunststofprothesen te herstellen.

De in dit proefschrift gehanteerde definitie van een recidiefhernia is deze van elk symptomatisch of asymptomatisch defect in de buikwand met hernatie van abdominale inhoud, toenemend met een Valsalva-manoeuvre. Met deze definitie worden ook de kleine asymptomatische recidieven meegerekend, die tijdens een follow-up onderzoek gevonden worden. Sommige van de op deze manier ontdekte breuken hoeven wellicht nooit hersteld te worden, en de recidiefpercentages gebaseerd op de bovenstaande definitie zijn dan ook iets hoger dan de klinisch relevante recidiefpercentages. Om dit te vermijden zou de onderzoekende arts telkens een uitspraak moeten doen over de wenselijkheid en/of noodzakelijkheid van een operatief ingrijpen bij een vastgestelde recidiefhernia. Dit is uiteraard een erg subjectieve beslissing, en om deze reden is in dit proefschrift de eerdergenoemde ruime definitie gehanteerd.

Samenvatting

Het doel van dit proefschrift is te onderzoeken hoe de resultaten van liesbreukherstel kunnen worden verbeterd. Hiervoor worden verschillende heelkundige technieken van liesbreukherstel geëvalueerd en vergeleken. Behandeld worden: technieken gebaseerd op het concept van Bassini waarbij het defect in de achterwand van het lieskanaal gesloten wordt door het aan elkaar hechten van musculo-aponeurotische structuren, technieken gebaseerd op het meer recente concept van de preperitoneale kunststof-prothese, en minimaal-invasieve technieken.

Uit het gerandomiseerde onderzoek in **hoofdstuk 2** blijkt dat het lange-termijn recidiefpercentage (12-15 jaar) na het herstel van een liesbreuk met een insufficiënte achterwand significant lager is na een Shouldice-plastiek (15%) dan na een Bassini-Stetten plastiek (32%). Het recidiefpercentage van 15% na een Shouldice herstel is hoger dan wat doorgaans gerapporteerd wordt. Recidiefpercentages worden niet alleen beïnvloed door chirurgische techniek en expertise, maar ook door de lengte en de kwaliteit van de follow-up. Met een lichamelijk onderzoek in 80% van de beschikbare patiënten na een follow-up duur van 12 tot 15 jaar, zullen de resultaten van ons onderzoek de reële situatie goed benaderen.

Er is geen verschil in recidiefpercentages tussen een Bassini-Stetten herstel en een hoge breukzakresectie met anulusvernauwing voor de laterale breuk met een stevige achterwand. Dit recidiefpercentage van 33% is onacceptabel hoog, en verschilt nauwelijks van de 32% recidieven na Bassini-Stetten voor de breuk met een verzwakte achterwand. Deze bevindingen ondersteunen het idee dat zowel de mediale als de laterale liesbreuk bij de volwassene veroorzaakt wordt door een verzwakking van de steungevende weefsels in het liesgebied, de aponeurose van de musculus transversus abdominus en de fascia transversalis.

In elk van de vier armen van de trial is er een blijvend risico op recidief. Het blijkt dat 73% van alle recidieven ontstaan zijn meer dan 2 jaar na de operatie. Ook deze bevinding ondersteunt de hypothese van weefselverzwakking als een belangrijke etiologische factor voor het ontstaan van liesbreuken.

De meest opvallende bevinding van het onderzoek is dat de resultaten van alle drie onderzochte conventionele behandelmethoden teleurstellend zijn, ook al heeft het Shouldice-herstel de laagste recidief percentages.

In **hoofdstuk 3** wordt in een diermodel voor laparoscopisch preperitoneaal liesbreukherstel aangetoond dat een multifilament polypropyleen prothese meer vreemd-lichaam reuscelreactie opwekt dan een monofilament polypropyleen prothese. In **hoofdstuk 4** wordt aangetoond dat deze vreemd-lichaam reuscelreactie in de eerste drie weken na implantatie toeneemt, en daarna geleidelijk daalt. Na 6 maanden is deze reactie gedaald tot de helft van het maximale niveau op 3 weken.

De klinische relevantie van een persisterende vreemd-lichaam reactie is nog niet duidelijk. Ondanks het wereldwijd gebruik op grote schaal sinds 1962 zijn er tot dusverre geen aanwijzingen voor nadelige lange-termijn effecten van polypropyleen hechtmateriaal en prothesen. Hieruit kunnen we concluderen dat het risico op ernstige nadelige effecten bijzonder klein is.

In **hoofdstuk 5** wordt de degelijkheid aangetoond van het principe van liesbreukherstel met een grote preperitoneale kunststofprothese. In een groep patiënten met complexe recidiefbreuken - beiderzijdse recidieven en herhaalde recidiefbreuken - bedraagt het recidiefpercentage 4 tot 9 jaar na de ingreep slechts 1%. De zeldzame recidieven na deze operatie volgens Stoppa (of giant prosthetic reinforcement of the visceral sac) treden meestal op kort na de operatie, en berusten op chirurgisch-technische fouten. Omwille van de uitstekende resultaten, de relatieve eenvoud van de procedure en de lage kans op complicaties is de operatie volgens Stoppa onze voorkeursoperatie voor de recidiefbreuk.

De anatomische studie in **hoofdstuk 6** benadrukt belangrijke aspecten van de anatomie van de liesregio van 'binnen uit'. Het laparoscopische zicht op de preperitoneale regio is de meeste chirurgen minder goed bekend. Kennis van de exacte ligging van arteriën, venen en zenuwen is absoluut noodzakelijk voor het veilig uitvoeren van een laparoscopische liesbreukoperatie. In de studie wordt aangetoond dat de kleinere bloedvaten en vooral de sensibele zenuwen (n. genitofemoralis, n. cutaneus femoris lateralis, n. ilioinguinalis) vrij oppervlakkig liggen en een variabel verloop kunnen hebben. De zenuwletsels die beschreven zijn bij laparoscopisch liesbreukherstel worden vaak veroorzaakt door het gebruik van de zgn. hernia-staples om de prothese te fixeren. In de anatomische studie worden zones beschreven waar deze hernia-staples relatief veilig gebruikt kunnen worden. Het aantal zenuwletsels kan beperkt worden door de hernia-staples helemaal niet te gebruiken.

Het gerandomiseerde onderzoek in **hoofdstuk 7** vergelijkt het Bassini-herstel met het transabdominaal preperitoneaal laparoscopisch herstel voor de behandeling van de primaire liesbreuk. Zoals in de meeste chirurgische afdelingen in Nederland was de standaard-techniek voor primair liesbreukherstel ook bij ons nog steeds de Bassini-operatie. Later is aangetoond door verschillende gerandomiseerde onderzoeken, waaronder ons eigen onderzoek beschreven in hoofdstuk 2, dat het herstel volgens Shouldice het beste conventionele herstel is, de gouden standaard waarmee elke nieuwe methode moet vergeleken worden.

Laparoscopisch herstel is veilig, en heeft voordelen ten opzicht van het Bassini-herstel met betrekking tot postoperatieve pijn, analgetica-gebruik, hervatting van de normale activiteiten, en recidieven. Het recidiefpercentage na een follow-up duur van gemiddeld 2 jaar bedraagt 6,1% voor het laparoscopisch herstel en 21,4% voor het Bassini-herstel. Het uitzonderlijk hoge recidiefpercentage na de Bassiniplastiek is

moeilijk te verklaren. Het gebruik van resorbeerbaar hechtmateriaal zou één van de redenen kunnen zijn. De nadelen van het laparoscopisch herstel liggen in de technische moeilijkheidsgraad van de operatieve procedure, en de langere operatietijd die hiervoor nodig is.

Het gerandomiseerde onderzoek in **hoofdstuk 8** vergelijkt het open preperitoneaal prosthethische herstel volgens Stoppa met het laparoscopische transabdominaal preperitoneaal prosthethisch herstel voor de behandeling van de recidiefliësbreuk. Het laparoscopisch herstel heeft ook hier de voordelen van de minimaal invasieve technieken met betrekking tot postoperatieve pijn en activiteitenherleving. De kans op recidieven door operatief-technische fouten is echter hoger bij de laparoscopische operatie. Na een gemiddelde follow-up duur van 21 maanden bedragen de recidiefpercentages 1,9% voor het open herstel en 12,5% voor het laparoscopische herstel. Wat recidiefpercentages betreft blijft het open preperitoneale herstel met een kunststofprothese de beste operatietechniek.

Conclusies en aanbevelingen

Conventioneel liesbreukherstel is gebaseerd op het concept van Bassini waarbij het defect in de achterwand van het lieskanaal gesloten wordt door het aan elkaar hechten van de musculo-aponeurotische structuren. De recidiepercentages van deze conventionele liesbreukoperaties zijn teleurstellend hoog. De plastiek volgens Shouldice is het beste conventionele herstel, maar ook hierbij zijn de recidiepercentages op lange termijn aanzienlijk. Binnen onze eigen chirurgische afdeling bedroeg het recidiepercentage 12-15 jaar na de operatie meer dan 10%. Het Bassini herstel, de traditionele operatie, zou niet meer uitgevoerd mogen worden omwille van het inacceptabel hoge recidiepercentage.

De traditionele indeling in mediale en laterale liesbreuken heeft geen klinisch belang. In tegenstelling tot de liesbreuk bij een kind, is een laterale liesbreuk bij een volwassene niet adequaat behandeld met een hoge breukzakresectie. Liesbreuken bij kinderen en volwassenen moeten beschouwd worden als verschillende aandoeningen, met een verschillende etiologie. Bij het kind wordt een liesbreuk veroorzaakt door een persisterende processus vaginalis. Bij de volwassene daarentegen ligt de oorzaak in een verzwakking van de steungevende weefsels in het liesgebied, de aponeurose van de musculus transversus abdominus en de fascia transversalis. Bij een volwassene moet dan ook steeds de gehele achterwand hersteld of verstevigd worden, ongeacht het type van de breuk. Na een conventioneel herstel is er, omwille van de verdere verzwakking van de steungevende weefsels, een blijvend risico op een recidiefbreuk.

Met de operatie volgens Stoppa, waarbij een grote preperitoneale kunststofprothese over de binnenkant van het buikwanddefect aangebracht wordt, zijn recidieven zeldzaam, en dit zelfs bij de moeilijkste liesbreuken. De intra-abdominale druk, die hernatie bevordert, wordt bij deze techniek gebruikt om de grote kunststofprothese op zijn plaats te houden. Op deze manier is de buikwand blijvend hersteld. Recente kunststofprothesematerialen zoals polypropyleen, polyester en e-PTFE zijn veilig en betrouwbaar. Polypropyleen is bijzonder resistent tegen infectie, en de prothesen worden reeds sedert 1962 uitgebreid gebruikt voor liesbreukherstel. Omwille van deze redenen gaat onze voorkeur uit naar dit materiaal.

Laparoscopisch liesbreukherstel is gebaseerd op het principe van de preperitoneale kunststofprothese. Het laparoscopisch herstel is minder invasief dan het open herstel, en veroorzaakt minder wondproblemen. Patiënten hebben minder postoperatieve pijn, en het postoperatieve herstel is sneller. Het laparoscopisch liesbreukherstel is geen eenvoudige operatie, en vereist een uitgesproken laparoscopische vaardigheid. Hierdoor is in de beginperiode dat een chirurg deze operaties uitvoert de kans op recidieven door technische fouten hoger, en is ook de operatieduur langer. Na deze zogenaamde 'learning curve' kunnen recidiepercentages behaald worden van 5% of minder, en is de operatieduur vergelijkbaar met die van een conventioneel herstel.

Voor chirurgen die laparoscopisch liesbreukherstel willen uitvoeren gelden de volgende aanbevelingen: een goede training in laparoscopisch liesbreukherstel, goede na-controles door lichamelijk onderzoek bij de eerste 25-50 patiënten, en heroperatie van de recidieven om de oorzaak van het technisch falen te achterhalen.

Elke discussie over liesbreukherstel is onvolledig zonder een bespreking van de zogenaamde 'tension-free repairs', waarvan de Lichtensteinplastiek de belangrijkste is. Bij deze plastiek wordt, via een liesincisie, het defect in de achterwand bedekt door een kunststofprothese. Het is een eenvoudige operatie, die goed onder lokale anesthesie uitgevoerd kan worden. De korte termijnresultaten zijn bijzonder goed, maar de lange termijnresultaten zijn nog niet voldoende geëvalueerd. Wanneer deze vergelijkbaar zouden zijn met de resultaten van de preperitoneaal geplaatste kunststofprothesen, dan wordt deze operatie volgens Lichtenstein een bijzonder aantrekkelijke alternatief.

De chirurg die een patiënt met een liesbreuk wil behandelen, heeft de keuze uit vier soorten ingrepen: een conventionele ingreep van het Shouldice-type, een anterieur 'tension-free' operatie, een laparoscopische operatie, en een open preperitoneaal operatie van het Stoppa-type. De Stoppa ingreep is zonder twijfel te verkiezen voor de ingewikkelde, moeilijke breuken zoals grote scrotaalbreuken, beiderzijdse grote breuken, en liesbreuken in combinatie met littekenbreuken. Recidiefbreuken worden het best hersteld met een kunststofprothese. Voor alle andere liesbreuken moeten de voor- en nadelen van de verschillende methodes met de patiënt besproken worden. Uiteindelijk moet een herstel gekozen worden, rekening houdend met de voorkeur en verwachtingen van de patiënt, en de voorkeur, ervaring en handigheid van de chirurg.

Het doel van dit proefschrift was te onderzoeken hoe de resultaten van liesbreukherstel kunnen worden verbeterd. Aangetoond is dat operatietechnieken waarbij preperitoneale kunststofprothesen gebruikt worden beduidend lagere recidief-percentages hebben dan de conventionele operaties via anterieure weg waarbij geen prothesen gebruikt worden. Het laparoscopisch liesbreukherstel is een technisch moeilijke operatie, maar biedt de patiënt de voordelen eigen aan minimaal invasieve chirurgie. Om optimale resultaten te bekomen moet de operatie uitgevoerd worden door chirurgen met ervaring in laparoscopische technieken.

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Curriculum Vitae

Geerard Beets was born on August 19th 1962 in Mol, Belgium. In 1980 he graduated from the Sint-Jan-Bergmans college in Mol. He studied medicine at the Catholic University of Leuven, and graduated with distinction in June 1987. In August 1987 he started his surgical training at the University Hospital Leuven (Chairman Prof dr JA Gruwez, and later Prof dr PLO Broos). As a part of his surgical training he worked one year with Mr WB Campbell at the Royal Devon and Exeter Hospital in Exeter, UK, and one year with dr J Hendrickx at the Salvator hospital in Hasselt, Belgium. He finished his surgical training in July 1993 and started as a fellow at the surgical department of the University Hospital of Maastricht (Chairman Prof dr G Kootstra). Since February 1996, he is a staff member of the surgical department at the University Hospital of Maastricht.

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