The Lichtenstein inguinal hernia repair : applicability, antibiotic prophylaxis and complications

Aufenacker, T.J.

The Lichtenstein
inguinal hernia repair

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Applicability, Antibiotic prophylaxis and Complications

ACADEMISCH PROEFSCHRIFT

ter verkrijging van de graad van doctor aan de Universiteit van Amsterdam op gezag van de Rector Magnificus prof.mr. P.F. van der Heijden ten overstaan van een door het college voor promoties ingestelde commissie, in het openbaar te verdedigen in de Aula der Universiteit op vrijdag 27 januari 2006, te 12.00 uur door Theodorus Johannes Aufenacker

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Promotiecommissie

Promotor

Prof. dr. D.J. Gouma

Co-Promotor

Dr. M.P. Simons

Overige leden

Prof. dr. P.M.M. Bossuyt
Prof. dr. T.M. van Gulik
Prof. dr. ir. H.A. Heij
Prof. dr. J. Jeekel
Prof. dr. A.N. Kingsnorth
Prof. dr. H.Obertop

Faculteit der Geneeskunde
Universiteit van Amsterdam

And so it begins .....

Voor pap & mam.

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.

Bassini 1890

CONTENTS

Het begin is het belangrijkste deel van het werk.

Plato

General Introduction and outline of the thesis

History of hernia surgery

The only cure of an inguinal hernia is by means of surgical repair. Most likely inguinal hernias are as old as mankind itself. Several historical facts support this statement; for instance the mummy of Ramses V (twentieth dynasty, 1156–1151 BC) had a clear hernial sac in the groin.[1] Whether hernia operations were performed at that time is debatable[2] but inguinal hernias have been a subject of interest since the dawn of surgery.

In the past (AD 50) surgery was only used in large protrusions or strangulation. The incision was made in the scrotum just below the pubis, and the sac was dissected from the cord and excised, the wound left open to granulate. If large, it was cauterized to enhance scar formation.[3] Repair techniques were attempted usually with poor results together with sacrificing the testis, as early as the middle ages. It was not until William of Salicet (circa 1210–1277), that excision of the testicle as an essential part of the operation for the care of hernia was rejected.[3]

New surgical knowledge flourished during the Renaissance. During this period Ambroise Paréé, in his book *The Apologie and Treatise*[4], devoted a chapter to hernias and started the debate about surgery for inguinal hernia. Since then knowledge about the anatomy of the groin quickly accumulated. In 1804 Astley Cooper defined the transversalis fascia as the main barrier for herniation. But in those days there was almost no surgical progress because of lack of proper anaesthetics and absent knowledge of antiseptic procedures. Most surgeons who used an inguinal approach excised the sac and left the wound open to heal by secondary intention (i.e., McBurney procedure).[5]
It was Lister who introduced antiseptic surgery (1870). This was followed by Halsted's introduction of gloves in 1896.[6] When von Mickulicz translated antiseptic surgery to aseptic surgery in 1904, the scene was set for the techniques of modern hernia surgery to develop.[7]
During the same period (1887) Edoardo Bassini developed a new approach for inguinal hernia repair consisting not only of ligation of the sac but he also performed a reconstruction of the inguinal floor. After complete incision of the transversalis fascia reconstruction consisted of suturing a "triple layer" of the transversalis fascia, the transverses abdominis and the obliquus internus muscles together with their conjoint tendon to Pouparts ligament. He was also the first to perform an adequate follow-up of a large series of patients and hereby initiated hernia research. Since then many modifications or improvements of inguinal hernia repair came and went. In 2001 at least 7.7%[8] of primary inguinal hernias in the Netherlands were still corrected by a (modified) Bassini technique.

All modifications finally resulted in the optimal conventional hernia repair technique popularized by Earle Shouldice (1969). The Shouldice repair technique resembles the original Bassini technique. The transversalis fascia is completely incised and a four layer overlapping reconstruction is performed originally using running steel wire. The superiority of Shouldice over Bassini has been proven in trials.[9,10]
One of the problems of the conventional repair was the tension placed on the tissues resulting in more short term post operative pain and possibly leading to recurrences. An alternative for solving the problem of repair under tension is to use (non)resorbable material foreign to the repair site. A wide variety of homologous and heterologous graft materials were used to strengthen the repair, for instance kangaroo tendon by Marcy[11] as early as in 1887.

The earliest use of prosthetic reinforcements for hernia repair was the use of silver wire coils by Phelps in 1894. He approximated the layers of the abdominal wall over the coils, and used the foreign body reaction and fibrosis to reinforce the repair.[12] In 1959, Koontz and Kimberly[13], started research on non-metallic synthetic prosthesis like Dacron, Teflon, Nylon mesh and Orlon cloth. Their main problem was infection and as a rule an abscess cavity was found when an infection occurred. In the same year Usher[14] introduced a new polypropylene plastic mesh called Marlex 50. This mesh was pliable and could be used in the groin without discomfort. Furthermore it seemed less affected by infection and even in the presence of infection granulation tissue would grow through the mesh. In 1962 Usher[15] reported on 541 cases of large and more difficult hernia repairs of which 183 inguinal hernia repairs, in the latter group none of the mesh had to be removed for infection. The last step towards complete tension free anterior hernia repair was made by Irvin Lichtenstein[16] who since 1984 performed primary inguinal hernia repair employing Marlex mesh prosthesis to bridge the direct floor of the groin without approximation of the tissue defect. Since then mesh based repairs have become the golden standard[17,18,19] in inguinal hernia repair and in the united states over 295.000[20] Lichtenstein repairs are performed each year. The posterior or preperitoneal approach has been used since 1876[21] but it lasted until 1990[22] before the polypropylene mesh was endoscopically placed in the preperitoneal space and a truly tension free repair was developed. But even in recent studies the Lichtenstein inguinal hernia repair is superior on almost every topic compared with the endoscopic repair and therefore the golden standard.[23]

The products described as polypropylene mesh such as Bard mesh (BARD), Premilene Mesh (BBraun), Prolene mesh (Ethicon, Johnson & Johnson), Prolite mesh (Atrium Medical Corporation) and Surgipro (US Surgical Corporation, Tyco Healthcare) are products with great similarity regarding the basic monofilament material but differ in knit construction, weight and other characteristics.

The Problem

Until the introduction of the mesh based repairs the surgeons' main concern was the prevention of a recurrent hernia. Since Lichtenstein published one of his first articles on his repair[16] technique the use of mesh in primary inguinal hernia repair has become more popular in western countries.[17,18,24-27] This resulted in an evidence based reduction of hernia recurrence[17,18] and in dedicated centres like the Lichtenstein Hernia Institute recurrence rates dropped even below 1%. As the recurrence rates are decreasing the surgeons' attention is shifting from preventing recurrences to preventing other complications like chronic neuropathic pain and wound infection. For the problem of wound infection there was no evidence in 1998 whether or not antibiotic prophylaxis was indicated for the prevention of wound infection in a mesh based repair. The topic of neuropathic pain is recently getting more and more attention but there is still much unclear, especially concerning treatment[28] of this difficult and frequent complication.

Aim of the thesis

In the present thesis a number of questions regarding the acceptance of the Lichtenstein technique, the usefulness of antibiotic prophylaxis and the prevalence of complications are evaluated. The aim of the thesis was to examine:

- The evolution of the Lichtenstein hernia repair in a well defined region in The Netherlands (Amsterdam) and how its implementation influences the recurrence rates?
- The percentage of Lichtenstein hernia repairs in The Netherlands before introduction of the Dutch Guidelines on inguinal hernia repair?
- Whether use of the Lichtenstein inguinal hernia repair, according to the Dutch Guidelines, does influence the recurrence rates?
- Is antibiotic prophylaxis necessary for the prevention of wound infections in patients undergoing Lichtenstein inguinal hernia repair? Can a prospective multi-centre randomized controlled trial and a meta-analysis answer this question?
- What are the results of Lichtenstein inguinal hernia repair in "general practice"? Which complications can be expected and what is the recurrence rate? What is the incidence of chronic neuropathic pain?
- Are there differences between hernia surgery in a teaching and a non-teaching hospital? Are the results comparable to those reported from dedicated centres?
- Can an adequate, high quality randomized clinical trial be performed in general practice if funding is not provided?

Outline of the thesis

The studies in this thesis discuss several aspects of inguinal hernia repair and the Lichtenstein repair in particular as mentioned above. The main attention is aimed at two aspects of the Lichtenstein repair (applicability and prevention of complications) with three chapters each before the thesis is concluded by a critical evaluation of the quality of the main trial.

In **Chapter 1** the Lichtenstein inguinal hernia repair is described together with possible complications and how they can be treated because no study is complete without a proper description of its main parameter.

The implementation of the Lichtenstein inguinal hernia repair in the Amsterdam region (1994-2001) together with other changes in hernia surgery is evaluated in **Chapter 2.** The influence of the use of mesh based repairs on recurrence rates in one region of the Netherlands is documented. The aim of this study was to analyse whether changes in technique influenced the operation rate for recurrence.

In **Chapter 3** an inventory in the Netherlands (2001) on the use of the advised mesh based repair (Lichtenstein) according to the Dutch Guidelines on inguinal hernia repair is made. This study was performed before the introduction of the Guidelines. The goal of this study was to set a baseline analysis and at the same time to perform an inventory of inguinal hernia surgery in the Netherlands. It was of primary interest to assess the operating techniques and the percentage of operations performed for recurrences.

The Lichtenstein hernia repair is the first choice for primary inguinal hernia according to the Dutch Guidelines. The use of this technique is expected to reduce the number of recurrences. To analyze if guidelines influence the quality of inguinal hernia repair 2535 patients operated in the OLVG hospital from 1994-2004 are described in **Chapter 4**. The hospital worked according to the preliminary guidelines since 1998. Therefore a particular interest in a possible reduction of recurrences after a previous repair at this hospital is present.

One of the most feared complications in mesh based inguinal hernia repair is an infection of the mesh. The question whether or not antibiotic prophylaxis is indicated in the Lichtenstein repair is answered in **Chapter 5.** In this chapter the results of the double blind randomized placebo controlled multi-center trial including 1040 patients and evaluating wound infections is presented.

In an attempt to end the discussion on the subject of the use of antibiotic prophylaxis in inguinal hernia repair a meta-analysis was performed. The results of this study with level 1A evidence on the topic are documented in **Chapter 6.**

In the hands of experts from dedicated hernia centers optimal results of the Lichtenstein repair can be achieved. The question if these results can also be obtained in a general practice is answered in **Chapter 7.** The incidence of another serious complication in inguinal hernia repair (Chronic neuropathic pain) is another main subject of this study. Also the prevalence of other complications is documented together with an analysis if the level of surgical expertise influences the occurring complications.

All randomized controlled trials use source data to perform the analysis needed for a firm conclusion about the analyzed topic. Most randomized controlled trials in particular the more difficult multi-center RCT's need funding for adequate data accumulation and processing. The quality of the source data has never been the subject of a study. In **Chapter 8** the factors and complications in gathering the source data of the study presented in chapter 5 are displayed. And by doing so a critical evaluation of the quality of the study is performed.

In **Chapter 9** the findings from the different studies are summarized and the general conclusions from this thesis are presented.

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The technique

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....yet impersonal reviews indicate that the recurrence rate remains excessively high and fairly constant, whatever method and material is employed

PWJM Brandon 1946

The Lichtenstein inguinal hernia repair

Chapter 1

Th.J. Aufenacker | M.P. Simons | D. van Geldere

Nederlands tijdschrift voor HeelkundeSubmitted

Abstract

The first choice for symptomatic primary one sided inguinal hernia is currently the Lichtenstein repair according to the advice from the Dutch Evidence Based Guideline on inguinal hernia repair. This article uses the recent literature to describe a safe method to perform the Lichtenstein repair. Also the most frequently occurring complications and their treatment are presented.

Introduction

The evidence based Guidelines on inguinal hernia repair, published in 2003, recommend a Lichtenstein repair for symptomatic primary unilateral inguinal hernia.[1,2] This technique was first described in 1989 by Irvin L. Lichtenstein (a surgeon from Los Angeles 1920-2000) who reported the results from 1000 primary inguinal hernia patients operated in his clinic with this tension free repair.[3] Since this first controversial publication his partner Parviz K. Amid popularized the technique throughout the world through many publications and workshops. Currently the repair is, in many western countries, the first choice in the treatment of inguinal hernia in adults.[4,5,6,7] In the united states 295.000 Lichtenstein repairs were performed in the year 2003.[4] Amid reports the technique to be cheap, relatively easy to learn and teach, with low complication rates (recurrence, pain, infection) and easy to perform under local anaesthetics. From the literature it is known that the results are promising with a low percentage recurrences (< 5%)[8,9,10] and a very low risk of wound infection (<2%).[7,11] The publications on postoperative pain are however, although presumably not related to the technique, alarming.[8,12-16] In the long term around 10-30% of patients has pain complaints in the operated groin and the optimal therapy is still subjective to debate and evidence on this subject is scarce.[16] In the Netherlands (2001) at least 39%[7] of inguinal hernia were corrected with this technique and it is certain that this percentage will rise in the future.

The aim of this article is to describe the Lichtenstein inguinal hernia repair and to point out the pitfalls. Also ways of preventing complications and possible treatment when they do occur are described. Much of the data presented here is based on publications of Amid.[17-21]

Lichtenstein inguinal hernia repair

For the correct technique of operating under local anaesthetics we refer to the article of Amid et al. in the Annals of Surgery.[17] In low risk patients antibiotic prophylaxis is not indicated[11], for immunocompromised patients (HIV, malignancy, diabetes) there is no evidence based recommendation. It has to be taken into account that clear sight on the medial side of the inguinal canal is important to place the prosthetic mesh with an overlap of at least 2 cm medial to the pubic tubercle. For proper exposition an incision is made with 6-7 cm length starting just medial and above the pubic tubercle following the skin lines towards a point halfway of Poupart's ligament where the internal annulus is located. It is usually necessary to ligate the superficial epigastric vessels (do not coagulate). The subcutaneous tissue and its fascia are opened until the external aponeurosis is exposed. With attention for the ilioinguinal nerve the aponeurosis externa is opened from the external annulus until 2 cm lateral of the internal annulus. The lower half of the external aponeurosis is freed from the spermatic cord until Poupart's ligament is reached; the upper half is dissected until 3-4 cm above the inguinal canal. During this part of the operation the external aponeurosis is freed from the internal oblique muscle and attention must be given to the iliohypogastric nerve which preferably is spared. More laterally (5-6 cm from the internal annulus) the external aponeurosis is dissected from the internal oblique muscle for later placement of the lateral parts of the prosthesis. The spermatic cord is freed from the floor of the inguinal canal and here it is important to include the cremasteric vessels, the ilioinguinal nerve and the genital branch of the genitofemoral nerve in the spermatic cord. The genital branch of the genitofemoral nerve is just beside the cremasteric vessels and can be kept protected next to these vessels. Inadequate attention to this nerve may carry the risk of catching the nerve in a stitch with subsequent neuralgia. The spermatic cord must be freed at least 2 cm past the pubic tubercle for proper medial overlap of the prosthesis. By freeing and lifting the spermatic cord it is preferred to leave the ilioinguinal nerve unharmed in the cremasteric sheet. (Figure 1.)

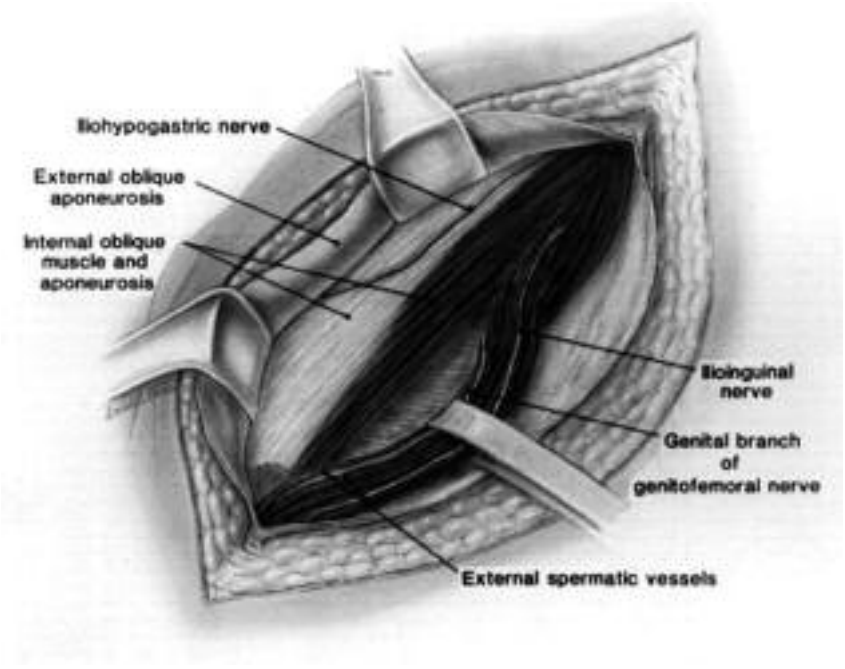

Figure 1

Anatomical plane for the mesh in Lichtenstein repair with lifted spermatic cord and the involved nerves. (P.K. Amid, Lichtenstein hernia institute, LA, USA)

After lifting the spermatic cord from its avascular plane the cremasteric muscle is longitudinally split on the ventral side to identify an indirect hernia sac. If such a sac is present it is freed from the cord until within the internal annulus and repositioned in the preperitoneal space or resected after ligation. Lipoma of the cord can be resected. In large scrotal hernia it is wise to transect the hernia sac and leave the distal section in place after opening it at the ventral side. Dissection of this part of the sac is likely to increase the chance of damage to the spermatic vessels. In the case of a large direct hernia the transversalis fascia can be inverted and with a purse string (Vicryl) kept in place for easier placement of the prosthesis. During this phase of the operation the presence of a second hernia must be excluded (femoral or combined direct and indirect). A poly-propylene mesh of 7 by 14 cm is large enough and can be shaped according to the anatomical measurements and hernia type. The mesh is fixed on the lateral rectus sheath with a Prolene 3.0 wire starting 2 cm cranio-medially of the pubic tubercle. The periostal layer of the pubic tubercle itself must be avoided while stitching the mesh on Poupart's ligament with the running suture in a few (3-4) tension free steps until just lateral of the internal annulus. (Figure 2.)

Figure 2

The mesh is stitched on Poupart's ligament starting 2 cm cranio-medially of the pubic tubercle. (P.K. Amid, Lichtenstein hernia institute, LA, USA)

The mesh is now slit coming from the lateral edge until just medial of the internal annulus to create two tails with the smaller tail (one third of the width) below. The upper wide tail (2/3) of the mesh is passed underneath the spermatic cord. The wide uppertail is crossed and placed over the narrower one. Both tails are stitched on Poupart's ligament and by doing so a dome shape of the mesh is created and the laxity of the tension free repair is created (figure 3).

The prosthesis is then trimmed to cover 5-6 cm of the transversalis fascia lateral to the internal ring. The mesh is then placed under the external aponeurosis cranially and damage to the iliohypogastric nerve is prevented. In case of interference of the nerve the mesh is adjusted or the nerve is cut and placed (buried) in the underlying muscle. The large variation of the position of the iliohypogastric and ilioinguinal nerve must be kept in mind. One or two Vicryl stitches can be used to keep the mesh in place on the cranial edge of the mesh. Attention must be given to the position of the iliohypogastric nerve which can be intramuscular and therefore caught in these stitches.
The external aponeurosis is closed over the mesh and spermatic cord and entanglement of the ilioinguinal nerve must be prevented. The subcutaneous fascia is approximated and the skin is closed preferably with resorbable stitches. In case of general anaesthetics the wound can be infiltrated with 10 cc

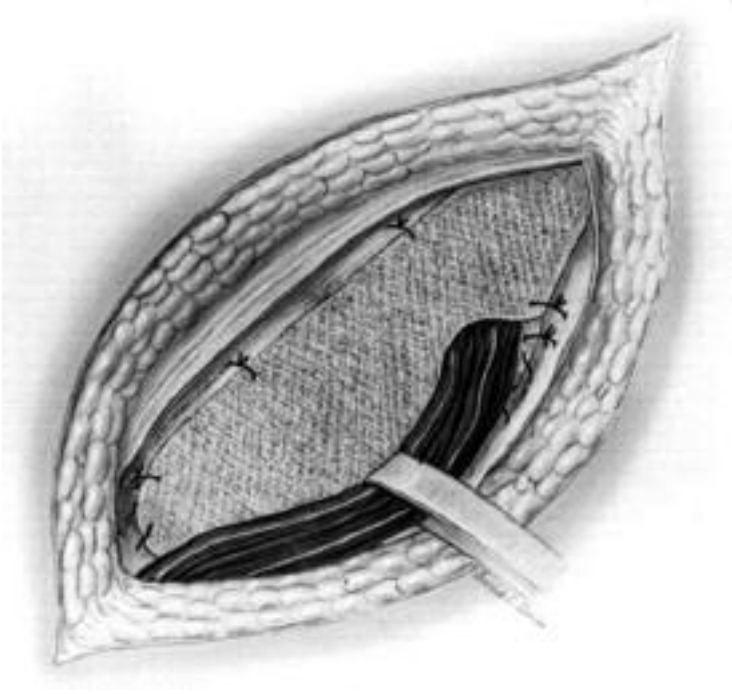

Figure 3

The mesh is fixed in its position. The stitches on the upper edge of the mesh are not obligatory and are meant to safeguard a good position of the mesh. (P.K. Amid, Lichtenstein hernia institute, LA, USA)

Bupivacaine by using 5 cc under the external aponeurosis and 5cc subcutaneously to reduce postoperative pain. In spinal anaesthetics this seems less useful. Several hours after the operation and after urinating spontaneously the patient can be discharged. Postoperatively no restrains on the part of exercise, what can be done may be done. Especially lifting items is not prohibited.[22]

Important technical details

1. The mesh must have sufficient medial overlap to prevent a direct recurrence. It is demonstrated that meshes shrink up to 30%. Therefore especially a direct hernia is at risk for a direct recurrence.
2. The mesh placement must be tension free and slight dome formation in a supine patient is essential. Tension is a potential cause of pain and traction on Poupart's ligament may cause femoral hernia.
3. The mesh must be fixed in a flat position and buried under the external aponeurosis.
4. The three inguinal nerves should be spared where possible. But cutting them and then burying in a muscle is a reasonable alternative if needed. When a nerve is damaged or in contact with the mesh it is wise to cut the nerve and bury in the muscles.

Complications

When a postoperative bleeding with tension on the skin occurs it is wise to evacuate the haematoma and attempt to stop the cause of the bleeding. Seroma will resorb spontaneously in most cases. Fine needle aspiration of this seroma will only increase the risk of infection and is not advised.[23] Superficial wound infections (1.4%)[11] are treated, after a culture swab, with antibiotics aimed at the most common bacteria (Staphylococcus Aureus)[11] therefore Flucloxacilline is the first choice of treatment. In the presence of a deep infection (0.3%)[11] not only antibiotics are given but an adequate drainage of the wound is essential. Usually opening of the external aponeurosis is needed and it should be left open. The mesh can remain in place and the wound can be treated according to the local customs and vacuum assisted closure (VAC) can be a good solution. Most of the deep infections can be managed this way. In only a few cases removal of the mesh is necessary for instance in chronic sinus formation or fisteling (0,09%[24]) remarkably enough even after removing the mesh the recurrence is frequently absent because of scar tissue formation. Postoperative pain can be divided into acute and chronic neuropathic pain or somatic pain. The acute neuralgic pain is usually caused by a nerve caught in a stitch and the patient starts complaining of severe pain with electrical impulses directly after the operation. The treatment of choice is an instant reoperation with identification of the nerve involved and freeing or cutting it. In case of chronic neuropathic pain probably it is best to perform a triple neurectomy.[19] Unfortunately there is little scientific evidence on this subject and a diagnostic episode with temporarily nerve blocks should be performed before this intervention.[16] The somatic pain covers a wide area of complaints and pain medication together with watchful waiting is probably the best treatment. If an osteitis pubicum is present a percutaneous corticosteroid injection could be of therapeutic value.

Conclusion

The Lichtenstein inguinal hernia repair is currently the first choice for primary unilateral hernia. Like every surgical technique a learning curve is present. In this article frequently appearing perioperative difficulties and several postoperative complications together with the therapy are described.

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Je moet in feite gewoon niet te diep

nadenken en dan klopt alles.

Herman Finkers

Hernia surgery changes in the Amsterdam region 1994-2001

Decrease in operations for recurrent hernia

Chapter 2

Th.J. Aufenacker | D.H. de Lange | M.D. Burg | B.W. Kuiken | E.F. Hensen | I.G. Schoots | D.J. Gouma | M.P. Simons

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Abstract

Background: Inguinal hernia (IH) surgery has changed substantially in the past decade. Conventional (non-mesh) techniques have largely given way to prosthesis.

Objective: This study's aim was to analyse whether changes in technique used for IH repair influenced the operation rate for recurrence.

Methods: A retrospective study was performed of all adult males who had undergone IH surgery in the Amsterdam region during calendar years 1994, 1996, 1999 and 2001. Data were obtained for 3649 patients and included patient demographics, hernia type and surgical technique.

Results: We observed a decrease in the use of conventional techniques and a significant increase ($p<0.05$) in the use of prosthetic materials. The number of operations performed for recurrent hernia decreased from 19.5% (216/1108) in 1994, to 16.8% 197/1170) in 1996, to 14.0% (152/1088) in 1999 and to 14.1% (40/283) in 2001. When comparing 1999 and 2001 with 1994 there was a significant decrease in operations performed for recurrent hernia ($p=0.005$). There was also a significant increase in supervision of the surgical resident by a surgeon.

Conclusion: In the period from 1994 to 2001 we have seen a significant increase in the use of prosthesis for IH repair in adult males in the Amsterdam region. Surgical residents are receiving more attending surgeon supervision in the operating theatre. These two factors may explain the decrease in operations performed for recurrent IH from 19.5% to 14.1%.

Introduction

In the past decade extensive changes in inguinal hernia (IH) treatment have occurred. There has been a decrease in the use of conventional techniques (Bassini, Shouldice) and an increase in prosthetic use (Lichtenstein, Laparoscopic repair) as previously described by several authors.[1,2,3]

This change has come about as surgeons seek to reduce IH recurrence rates. Several studies have reported high percentages of operations for recurrence in nationwide databases i.e. Sweden ('92-'96) 16-17%[4], Sweden ('96-'98) 15%[3], and Denmark ('98-'00) 17%.[1] In one study from Scotland ('98-'99)[5] a low percentage of recurrent hernia (8%) was reported. Unfortunately, a reliable determination of recurrence after hernia surgery is difficult. This is due to the fact that a large group of long-term follow-up patients is needed and all these patients should be examined rather than simply questioned.[6]

Alternatively, an analysis of the number of operations for recurrent IH in a defined region over several years could be undertaken. This method was used for this study to describe IH surgery in a large region of The Netherlands. The reoperation rate for recurrent IH during a 2 to 5 year follow-up period captures approximately 50% of the actual recurrences since many remain asymptomatic. The true recurrence rate may then be obtained by doubling the reoperation rate.[6,7]

We performed 4 reviews of IH repairs done in the Amsterdam region. The first was of 1994[8] IH repairs when most were done with non-mesh techniques.

A second review of 1996[9] data was carried out. During this time period there was a significant increase in prosthesis use and a significant decrease in the number of operations performed for early (< 2 years) recurrence. The same inventory was made for the years 1999 and 2001. We studied whether there was an increase in the use of prosthesis and whether there were changes in the percentage of operations for recurrence. The aim of this study has been to analyse whether changes in technique influenced the operation rate for recurrence.

Patients and methods

A retrospective study was performed which included all male adults (>18 years) undergoing IH surgery in the Amsterdam region which is inhabited by more than a million people. Data from all hospitals (university, large training hospitals and district hospitals) were included. All hernia operations in 1994, 1996, 1999 and the first quarter of 2001 were analyzed. In 2001 only data from the first three months was collected because this was part of an inventory study, which was performed in the Netherlands as part of the introduction of guidelines for groin hernia surgery. The parameters analyzed included patient demographics, hernia characteristics and surgical technique used. Patients were contacted to supply missing data as necessary. A recurrent hernia was defined as any inguinal or femoral hernia, in a patient previously operated on for any type of IH. A patient with a bilateral hernia with a recurrence on one side and a primary hernia on the other side was classified as one patient with a recurrent hernia. Primary bilateral hernias were counted as one hernia. The data were analyzed using the chi-square test. A p-value of 0.05 was considered to be significant.

Results

In the Amsterdam region 3649 adult males were operated on for IH in 1994, 1996, 1999 and 2001. The average age was 56.5 years (age range 18 to 98 years). The following IH types were seen: indirect 1970/3649 (54.0%), direct 1343/3649 (36.8%), and combined 336/3649 (9.2%). A bilateral operation was performed in 406/3649 (11.1%). There were 61 emergent operations for painful, irreducible hernias (1.7%); the remainder was performed (semi-)electively. No statistically significant differences in patient and hernia characteristics were observed over the 4 years analyzed. (Table 1)

Table 1

Patient, hernia and surgical characteristics.

	1994 n = 1108	1996 n = 1170	1999 n = 1088	2001 n = 283
Age (Yrs)	57 (18-96)	56 (18-94)	56 (18-98)	58 (19-89)
Type of hernia				
Indirect	53.8%	54.4%	54.2%	52.2%
Direct	40.0%	34.8%	35.7%	36.9%
Combined	6.2%	10.8%	10.1%	10.9%
Bilateral	11.0%	10.6%	11.7%	11.7%
Acute operation	1.7%	1.0%	2.4%	1.4%
Recurrence	19.5%	16.8%	14.0%	14.1%
Local anaesthetic	0.8%	1.9%	0.8%	1.4%
Ambulatory care	20%	24%	40%	51%

The number of operations for recurrent hernia decreased from 19.5% (216/1108) in 1994 to 16.8% (197/1170) in 1996 and 14.0% (152/1088) in 1999. In 2001 40 out of 283 (14.1%) patients had an operation for recurrence. When comparing 1999 and 2001 with 1994 there is a significant decrease (p=0.005; OR: 0.67 (95%CI:0.53-0.85)). For 80% of patients this recurrence was their first, for 14% their second and for 6% their third or higher. This distribution was almost identical for each year analyzed. The use of local anaesthetic remained limited to 1.4% of patients in 2001; this was 1.9% in 1996. There was an increase in operations done in ambulatory care from 20% in 1994, to 24% in 1996, to 40% in 1999, to 51% in 2001. There was a statistically significant decrease in the use of non-mesh techniques and increase in the use of prosthetic materials. In 2001 no non-mesh technique was used to repair a recurrent hernia. The hernia repair techniques used in the study years are shown in table 2 for primary hernia and table 3 for recurrent hernia. In the last column, data from the first quarter of 2001 are extrapolated to the entire year.

Table 2

Techniques used for primary hernia repair in the Amsterdam region from 1994 to 2001.

Technique	1994 n (%)	1996 n (%)	1999 n (%)	2001 n (%)	2001 data Extrapolated
Non-mesh	797(89.3)	655(67.3)*	279(29.8)*	25(10.3)*	100
Bassini	558(66.2)	295(30.3)*	80(8.5)*	1(0.4)*	4
Shouldice	177(19.8)	310(31.9)*	151(16.1)*	21(8.6)*	84
Other [a]	62(7.0)	50(5.1)	41(4.4)	3(1.2)*	12
Prosthesis	95(10.7)	318(32.7)*	657(70.2)*	218 (89.7)*	872
Lichtenstein	34(3.8)	223(22.9)*	425(45.4)*	151(62.1)*	604
Laparoscopic	51(5.7)	62(6.3)	82(8.8)*	23(9.5)	92
Other [b]	10(1.1)	33(3.4)	150(16.0)*	44(18.1)	176
Total	892	973	936	243	972

*Significantly decreased or increased compared to the previous data ($p \leq 0.05$).
[a] Hernial sac resection, Mc Vay; [b] Plug and Patch, Wantz, Stoppa

Table 3

Techniques used for recurrent hernia repair in the Amsterdam region from 1994 to 2001.

Technique	1994 n (%)	1996 n (%)	1999 n (%)	2001 n (%)	2001 data Extrapolated
Non-mesh	118(54.6)	60(30.4)*	21(13.8)*	0(0)*	0
Bassini	96(44.4)	39(19.8)*	8(5.3)*	0(0)	0
Shouldice	6(2.8)	9(4.5)	7(4.6)	0(0)	0
Other [a]	16(7.4)	14(7.1)	6(3.9)	0(0)	0
Prosthesis	98(45.4)	137(69.6)*	131(86.2)*	40(100)*	160
Lichtenstein	21(9.7)	70(35.5)*	49(32.2)*	15(37.5)	60
Laparoscopic	47(21.8)	26(13.1)	31(20.4)*	12(30)*	48
Other [b]	30(13.8)	41(20.7)	51(33.6)*	13(32.5)	52
Total	216	197	152	40	160

*Significantly decreased or increased compared to the previous data ($p \leq 0.05$).
[A] Hernial sac resection, Mc Vay; [B] Plug and Patch, Wantz, Stoppa

When analyzing the previous technique used in recurrent hernia (table 4.) there is a decrease in recurrence after non-mesh techniques mainly due to a decrease in the use of Bassini, but a transitory doubling of the Shouldice percentage. The rising number of recurrence after prosthesis is also significant for Lichtenstein. All nine recurrent hernias after Lichtenstein hernioplasty (1999) were of the direct type.

Table 4

Previous techniques used in recurrent hernia.

Technique	1996 n (%)	1999 n (%)	2001 n (%)	2001 data Extrapolated
Non-mesh	178 (90.4)	121 (79.6)*	31 (77.5)	124
Bassini	157 (79,7)	96 (63.2)*	24 (60.0)	96
Shouldice	12 (6,1)	20 (13.2)*	3 (7.5)	12
Other	9 (4,6)	5 (3.3)	4 (10.0)	16
Prosthesis	11 (5,6)	23 (15.1)*	6 (15.0)	24
Lichtenstein	2 (1,0)	9 (5.9)*	4 (10.0)	16
Laparoscopic	4 (2,0)	6 (3.9)	0 (0)	0
Stoppa	4 (2,0)	5 (3.3)	0 (0)	0
Other	1 (0,5)	3 (2.0)	2 (5.0)	8
Unknown	8 (4,1)	8 (5.3)	3 (7.5)	12
Total	197	152	40	160

* Significantly decreased or increased compared to the previous data ($p \leq 0.05$).

The number of early recurrences (<2 years) did not differ in time. Table 5 demonstrates an increasing interval between previous operation and recurrence. In 1994, 47% of patients with a recurrent hernia had their previous operation more than 5 years ago compared with 50% in 1999. In 2001 this percentage increased to 73%.

Table 5

Recurrent hernia, time after previous operation.

	1994 n (%)	1996 n (%)	1999 n (%)	2001 n (%)
<2 years	57 (26.3)	40 (20.3)	38 (25.0)	10 (25.0)
2-5 years	51 (23.6)	50 (25.3)	28 (18.4)	1 (2.5)
5-10 years	36 (16.6)	32 (16.2)	23 (15.1)	5 (12.5)
>10 years	67 (31.0)	68 (34.5)	53 (34.9)	24 (60.0)
Unknown	5 (2.3)	7 (3.6)	10 (6.6)	0 (0.0)
Total	216	197	152	40

In 1999, 740 IH operations were performed in a training hospital, 166 (22.4%) were performed by residents alone. When comparing to 1996 this was a significant decrease 159/521 (30.5%). Accordingly there was a significant increase in operations performed by a resident with attending surgeon supervision as shown in table 6. When comparing 2001 to 1999 a same significant pattern was seen.

Table 6

Skill of operating surgeon in teaching hospital.

	1996 n (%)	1999 n (%)	2001 n (%)
Surgeon	71 (13.6)	95 (12.8)	15 (8.6)
Surgeon + Resident	98 (18.8)	135 (18.2)	39 (22.5)
Resident + Surgeon	193 (37.0)	342 (46.2)*	101 (58.4)*
Resident	159 (30.5)	166 (22.4)*	18 (10.4)*
Unknown	0 (0.0)	2 (0.2)	0 (0.0)
Total	521	740	173

* Significantly decreased or increased compared to the previous data ($p \leq 0.05$).

Discussion

In this study in the Amsterdam region the total number of inguinal hernia repair and the patient characteristics remained nearly constant.

A significant decrease in operations performed for recurrent hernia, from 19.5% in 1994 to 14% in 1999 and 2001 was found. It has to be taken into account that these percentages only reflect operated recurrent hernias, and many patients with asymptomatic recurrences may not have undergone surgery. It has been suggested by other researchers that the actual recurrence rate may be estimated by doubling the number of operations performed for recurrent hernia.[7] Nevertheless, this decrease could be an indication of the improved quality of hernia repair within the last 5 years because the total number of recurrent hernias is decreasing and the interval between previous operation and recurrence is increasing. This increase in "old" recurrence suggests an even further decrease in the total number of recurrent hernias. The improved recurrence rates in the group 2 to 5 years after previous operation can be explained by the rise in number of Shouldice and Lichtenstein repairs in earlier years, but then it is hard to explain the stable percentage of recurrences within 2 years. One explanation might be the "technical failures" after a Lichtenstein repair, resulting in an early direct recurrence. The number of operations performed in ambulatory surgery is increasing (51%) and is almost as high as reported in other countries in the previous years (54-59%).[1,3]

Also the use of local anesthetics is surprisingly low (<2%) compared to Scotland 6%[5], Sweden 7%[3] and Denmark 18%.[1] The reluctance of surgeons to operate under local anesthesia is hard to explain since small modifications make it possible to perform an operation without discomfort to patients.[10]

We witnessed an increase in the Amsterdam region in the use of the Lichtenstein hernia repair technique over the study years although during that time period there was no evidence that this technique was superior to others. Since then many studies have proven the superiority of this tension free repair[11] or other mesh repairs over non-mesh repairs.[12,13,14,15] This study confirms the increasing popularity of the Lichtenstein hernia repair technique. Other techniques, using prosthesis, are increasing in frequency as well. The Bassini technique is waning, as in the Shouldice repair. These changes have also been seen in other countries.[1,4]

Prosthetic use for recurrent hernia has increased even more from 86% in 1999 towards 100% in 2001. This mirrors the findings of a Swedish study by Haapaniemi, et al where 82% of recurrent hernias were repaired with mesh technique.[3] This study also found that use of mesh in recurrent hernia provides a relative risk reduction for recurrence. The NHS is Scotland corrects recurrent hernia in 91% of patients with some type of mesh repair.[5]

The past 5 years there has also been an increase in attention for hernia surgery as demonstrated in the significant rise in supervision of surgical residents by surgeons during operations. This will without a doubt improve the outcome of

hernia surgery. This may be supported by research done in Scotland where 95% of operations was done in the presence of a surgeon with a lower percentage of operations performed for recurrence (8%).[5] It is however difficult to analyse the factor that most influences results whether it is the technique or the expertise and level of experience of the surgeon. One could hypothesize that a Shouldice by an expert is just as good as a Lichtenstein by a non expert. "Choose the surgeon and not the technique" is a well known proverb.
In 2003, new guidelines for groin hernia surgery were introduced in The Netherlands. One of the hospitals involved in this study had adopted and used these guidelines in 1998. It is very promising to see that at this hospital all 7 operated recurrences (2001) had their previous operation elsewhere.
In contradistinction, 1 out of 3 recurrences in the other hospitals was one of their own. This study of 3649 patients has some limitations of course. It is retrospective and the number of recurrences is measured indirectly tending to underestimate actual IH recurrence rates. Furthermore the previous technique used in recurrent hernia has to be correlated with the total number of this technique performed in previous years. This means that the demonstrated reduction in recurrences after Bassini and the increase of recurrence after prosthetic repair cannot easily be interpreted.

The results also show that no technique is perfect, as demonstrated by an increase in recurrence after the use of prosthesis as a preceding technique (15%). In most of these cases the Lichtenstein hernia repair was used. Since all recurrences after this method were of the direct type this may be explained as technical failures or due to the learning curve of the surgeons [16,17]. This is supported by Bay-Nielsen who stated "the most plausible explanation of the direct recurrences is an insufficient medial mesh fixation and overlap over the pubic tubercle. By increased attention to this aspect more than half of the recurrences after Lichtenstein repair could possibly be avoided." [18]

Conclusion

In the period from 1994 to 2001 we have seen a significant increase in the use of prosthesis for IH repair in adult males in the Amsterdam region. Surgical residents are receiving more attending surgeon supervision in the operating theatre. These two factors may explain the decrease in operations performed for recurrent IH from 19.5% to 14.1%.

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Observo, ergo est

Inguinal hernia surgery in The Netherlands

A baseline study before the introduction of the Dutch Guidelines.

Chapter 3

D.H. de Lange | Th.J. Aufenacker | M. Roest |

R.K.J. Simmermacher | D.J. Gouma | M.P. Simons.

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Abstract

Background: In 2003 the Dutch Guidelines for treatment of inguinal hernia (IH) were published. For treatment of IH in adults, the evidence based guidelines recommend the use of a mesh repair technique. In order to be able to evaluate the effects of these guidelines, a base-line analysis of inguinal hernia surgery before introduction of these guidelines, has been performed. The second analysis will be performed three years (January-March 2006) after the publication of the Guidelines.

Objective: To make an inventory of IH surgery in the Netherlands, before the introduction of guidelines for IH treatment, to serve as a base-line for future evaluation of the impact of the implementation of these guidelines.

Methods: A retrospective descriptive study was performed in 2003 using patient and operation charts including IH repairs performed in the Netherlands in a three months period (January-March 2001).

Results: 97/133 (73%) hospitals cooperated with the study generating data from a total of 4386 IH in 3979 patients (3284 adults, 695 children). In 2839 (78%) adult inguinal hernias, mesh techniques were used versus 800 (22%) hernias treated with non-mesh techniques. In the study period 484 (14.7%) adult patients were operated for a recurrent hernia from previous years. Early recurrence (< 1 year) occurred in 2.2% of all patients. Wound infection was documented in 0.8% of all IH. The mortality rate was 0.1%. 1257 of 3284 (38.3%) adults, and 566 of 695 children (81.4%), were operated in ambulatory care.

Conclusion: In the episode prior to implementation of the Dutch evidence based Guidelines for treatment of inguinal hernia, 2839(78%) adult hernias were treated with mesh repair and 484 (14.7%) patients were treated for a recurrent hernia.

Introduction

In 2003 a Dutch committee developed evidence based guidelines for the treatment of inguinal hernia (IH) in children and adults. Main recommendations of the guidelines were to use a mesh based repair technique in adult patients, preferably in day surgery, and to consider local anaesthesia when performing open anterior repair. For primary one-sided IH the Guidelines recommend a Lichtenstein repair technique. For recurrences after an anterior repair and bilateral hernia, an endoscopic repair technique is recommended, provided a trained team is available. The Guidelines furthermore consist of 20 chapters with recommendations concerning all aspects of IH surgery from diagnosis to postoperative treatment.

It is expected that the guidelines will improve the quality, efficiency and transparency in IH surgery. To be able to evaluate the implementation of these guidelines, a base-line analysis of IH surgery was performed. The results of this base line analysis are to be compared with a second analysis that will take place in 2006, in order to establish a possible effect of the implementation of the guidelines on IH surgery in the Netherlands. More use of mesh technique will hopefully show a decrease in operations for recurrence.

The goal of this study was to set a baseline analysis and at the same time to perform an inventory of IH surgery in the Netherlands. It was of primary interest to assess the operating techniques and the percentage of operations performed for recurrences. The secondary goal was to make an inventory of other aspects like frequency of ambulatory care surgery, type of anaesthesia, level of surgical expertise and complications.

Patients and methods

A retrospective descriptive study of IH repairs performed in the Netherlands in the period January-March 2001 was performed. All patients had been operated at least a year prior to the data collection. All Dutch hospitals (133) were asked to participate and if they agreed (97), to provide the data of all operated patients in the study period. The various hospital registration systems were used to identify all patients (derived from all performed operative procedures). All data was retrieved from on site visits in 2003 and with original patient and operation charts by one of the authors (DL, TA, MR).

The following data were obtained; age, type of hospital (academic centres, teaching hospitals and non-teaching hospitals), admission or day surgery, operation for primary or recurrent hernia with previous operation technique, unilateral / bilateral hernia, the number of years after previous repair (in recurrent hernia), acute versus elective surgery and the number and type of complications. From the operation reports the type of hernia, the operation technique, expertise of the surgeon, and type of anaesthesia were obtained. Patients with a bilateral hernia were evaluated as two separate hernias in two different patients.

analyzed. Femoral hernias were excluded from this inventory.
The numbers involving surgeons or residents performing the operation are solely based on the data from (academic and district) teaching hospitals (43/97 participating hospitals).

Statistical analysis

Data were expressed as mean ± standard deviation (SD). Comparison of data was performed using the Student t-test for paired and unpaired data when appropriate. Proportions were compared using Chi-square analysis with Yates' correction. For all tests, a p-value <0.05 was considered significant.

Results

The study included 97 of the 133 (73%) hospitals in The Netherlands in 2001 (6/8 academic centres, 37/46 teaching hospitals and 54/79 non-teaching hospitals). This resulted in a total of 4386 IH in 3979 patients (3284 adults, 695 children). The mean age of adults was 57.6 years (range 18.5-96.5), and in children 4.2 years (range 0.1-17.9).

Children (<18 years)

General findings

Six hundred and ninety-five children were operated with a total of 747 hernias. Five hundred and sixty six children (81.4%) underwent their operation in day surgery, 136 (18.2%) of the operations were performed in a paediatric hospital. In Table 1 the patient, hernia and surgical characteristics are outlined.

Operation techniques

Hernia sac resection was performed in 719 IH (96.3%) of cases. The Bassini and Shouldice techniques were used in respectively 10 and 6 cases (total 2.1%). In 5 (0.7%) patients a mesh technique was used (Lichtenstein (3), Grid Iron (1) and a plug (1)). The mean age in these patients was 15.6 years (12.9-17.7). It concerned 3 direct and 2 indirect hernias. In 7 cases (0.9%) the technique was unknown or data were missing.

Thirty-five (4.7%) patients underwent acute or semi acute surgery for strangulated or incarcerated hernia. In 45/410 (10.9%) children (4 years), a contra lateral exploration was performed. In the clinics with paediatric surgeons this percentage was 38.5% (37/96). The mean age of these children was 0.7 years (0.1-3.9).

Table 1

Patient hernia and surgical characteristics in 695 children with 747 inguinal hernias.

	N	%
Sex (male)	541	77.8
Location		
Right	416	55.7
Left	227	30.4
Bilateral	52	13.9
Type of hernia		
Indirect	560	96.9
Direct	13	2.2
Combined	5	0.9
Not specified in chart	169	
Recurrent hernia	21	2.8
Day surgery	566	81.4
Anaesthesia		
General anaesthesia	545	87.8
General anaesthesia and caudal block	65	10.5
Spinal	11	1.7
Not specified in chart	126	
Surgeon (only teaching hospitals n=405)		
Surgeon	123	30.4
Surgeon + resident	109	26.9
Resident + surgeon	163	40.2
Resident alone	10	2.5

Complications

Forty-four (5.9%) complications were registered. Fourteen (1.9%) patients were found to have a recurrence within 12 months, all after hernia sac resection. They all underwent a second operation within twelve months. In 12 cases (1.6%) haematoma/seroma occurred. There were 13 (1.7%) reports of pain, of which in two patients (0.3%) the pain lasted longer than three months. Two patients (0.3%) had a wound infection, and in one case (0.1%) there was a postoperative bleeding which did not need another operation.

Adults (>18 years)

General findings

A total of 3639 hernia repairs in 3284 patients were performed. 2017 of 3639 (55.4%) repairs were performed in non-teaching hospitals and 1622 of 3639 (44.6%) in teaching hospitals (including academic centres). In table 2 the patient, hernia and surgical characteristics are outlined.

Table 2

Patient, hernia and surgical characteristics in 3284 patients with 3639 inguinal hernias.

	N	%
Sex (male)	3137	95.5
Location		
Left	1395	42.6
right	1521	46.5
bilateral	355	10.9
Type of hernia		
indirect	1553	48.1
direct	1395	43.1
combined	285	8.8
Not specified in chart	406	
Recurrent hernia	484	13.3
first recurrence	395	81.6
> 1 recurrence	89	18.4
Day surgery	1257	38.3
Anaesthesia		
General anaesthesia	1484	54.3
Spinal	1062	38.8
Local	188	6.9
Not specified in chart	905	
Surgeon (only teaching hospitals n=1680 patients)		
Surgeon	349	20.8
Surgeon + resident	348	20.7
Resident + surgeon	648	38.6
Resident alone	335	19.9

Operating techniques

The IH repair techniques used are displayed in table 3. In 2839 (78.0%) of all IH operations a mesh repair technique was used and in 800 (22.0%) a conventional (non-mesh) technique; 86.2% of patients with a recurrent IH were this time operated using a mesh repair technique.

In teaching hospitals (including academic centres), more hernias (1350/1622, 83.2%) were treated with mesh than in non-teaching hospitals (1481/2017, 73.4%, p<0.01). Also an endoscopic repair technique was performed more frequently in teaching hospitals (303/1622, 18.7%) than in non-teaching hospitals (182/2017, 9.0%, p<0.01).

Of the 710 hernias (355 patients) with a bilateral hernia 621(87.5%) were treated with a mesh technique and 89 (12.5%) without the use of mesh techniques. Seventy nine patients with bilateral hernias (158 hernias, 22.3%) underwent an endoscopic repair. In Bilateral hernias an endoscopic repair technique 158/710 (22.3%) was used more often than in unilateral hernias 328/2929 (11.2%), p<0.01.

Seventy-one (2.0%) patients underwent acute surgery for strangulated or incarcerated hernia. The previous technique used in recurrent IH is outlined in table 4. The interval between the last IH operation and the operated recurrence is reported in table 5. In patients operated for recurrence 42 % had undergone the prior operation more than ten years ago.

Admitted adult patients were older than patients treated in day surgery; 60.7 ±16 years versus 52.2 ±15 years (p< 0.01).

The average duration of hospitalisation was 1.7 days ±1.7 (1-40).

Table 3

Repair techniques used in 3284 adult patients with 3639 inguinal hernias divided in 3155 primary and 484 recurrent inguinal hernias.

	n	%	n	%
No Hernia's	**3155**		**484**	
Mesh repair	**Primary**		**Recurrent**	
Lichtenstein	1244	39.4	201	41.5
Endoscopic	395	12.5	91	18.8
TEP	356	11.3	74	15.3
TAPP	39	1.2	17	3.5
Plug and Patch	250	7.9	37	7.6
Lichtenstein and plug	160	5.1	23	4.8
Ugahary (grid iron)	153	4.8	15	3.1
Stoppa	78	2.5	34	7.0
Other	142	4.5	16	3.3
Non-mesh repair				
Shouldice	302	9.6	12	2.5
Bassini & variations	243	7.7	20	4.1
Herniotomy	120	3.8	23	4.8
Other	68	2.2	12	2.5

Table 4

Preceding techniques in 484 adults with recurrent hernia.

Technique	n 484	n (%) 139 patients with recurrence within 5 years after prior operation
Mesh		
Lichtenstein	33	31 (94)
TEP	13	9 (69)
TAPP	3	2 (67)
Ugahary (grid iron)	13	9 (69)
Pre-peritoneal	13	10 (77)
Plug and Patch	3	3 (100)
Non-mesh		
Bassini and variations	118	39 (33)
Other conventional*	65	26 (40)
Shouldice	28	10 (36)
Not specified in chart (mesh and non-mesh)	195	

Table 5

Time between inguinal hernia repair and recurrence in 484 patients with recurrent hernia

Time to recurrence	N	% of total recurrences
< 2 years	100	20.7
2-5 years	73	15.1
5-10 years	100	20.7
> 10 years	202	41.7
Not specified in chart	9	1.8

Complications

In 813 (22.3%) cases one or more (total 916) complications occurred during or after operation as is shown in table 6. Four patients died during hospital admission (bowel perforation after Lichtenstein, bladder perforation after Lichtenstein, bronchospasm after Stoppa and a cardiac arrest one day post-surgery after Lichtenstein). Hundred eleven (3.4%) patients underwent a re-operation. 74 (2.2%) because of a recurrence (within one year), 22 (0.7%) because of hematoma, seven (0.2%) because of neuralgia, three (0.1%) because of a wound infection, and five (0.2%) for other reasons. In one patient with a deep infection, the mesh was removed. The three bowel perforations originated after respectively a TEP, Lichtenstein and PHS repair technique.

Table 6

Complications in 3284 patients after 3639 inguinal hernia repairs

Complication		N = 916
Major		
	Early recurrence	74 (2.0)
	Pain > 3 months	62 (1.7)
	Wound infection	32 (0.9)
	Testicular atrophia	4 (0.1)
	Bowel perforation	3 (0.08)
	Mesh removal	1 (0.03)
	Bladder perforation	1 (0.03)
	Mortality	4 (0.1)
Minor		
	Haematoma / seroma	421 (11.6)
	Pain < 3 months	308 (8.5)
	Urine retention	17 (0.5)
	Wound dehiscence	3 (0.8)
	Other	52 (1.4)

Discussion

The present study of 4386 inguinal hernia repairs in 3979 patients performed between January and March 2001 in The Netherlands will be used as base-line analysis to be able to evaluate the implementation of the Dutch Guidelines for inguinal hernia repair. This is the first study evaluating the different techniques used for treatment of inguinal hernias in 73% of Dutch hospitals.

In the series of paediatric inguinal hernia the most remarkable and worrying fact was the high incidence of early recurrences. In univariate analysis, surgeon's experience, patients' age and type of hospital were no significant risk factors for early recurrence. However these recurrences should be considered as technical failures. There was no significant difference between the paediatric hospitals (1.5%) and the other hospitals (2.0%). The subject of contralateral exploration remains controversial. In this study 10.9% of all children ≤ 4 years underwent a contralateral exploration. In the paediatric clinics this percentage was much higher (38.5%). This is probably related to the higher prevalence of prematurely born or high risk patients, and the low mean age (0.7 years, range 0.1-3.9).

The Dutch Guidelines recommend that contralateral exploration should not be performed routinely but can be considered in patients with a high risk of double sided hernia (prematures, children with VP drainage), high risk of strangulation or high risk of general anaesthesia (prematures).[1]

In 3284 adult patients a wide variety of operating techniques was used. In 78% of the operations a mesh based technique was used. This percentage is in concordance with the data reported from other countries.[4,5,6] Because the guidelines recommend a mesh technique (preferably Lichtenstein) in all adults it is assumed there will be a decrease in the variety of techniques used and an increase in the number of operations performed with the use of a mesh technique.

In recent years many articles have discussed the treatment of inguinal hernia repair.[7,8,9,10] One can not expect that all surgeons are up to date with details from all studies but it is remarkable to see that 7.2% of operations are still performed using the Bassini technique which has been demonstrated to be inferior to the Shouldice technique ever since 1996.[11]

Furthermore, there is a significant difference in frequency of the use of mesh techniques by teaching hospitals and non-teaching hospitals (83.5% versus 73.8%, $p<0.01$). Moreover the endoscopic techniques are also performed more often in teaching hospitals (303/1602, 18.9%) than in non-teaching hospitals (182/1990, 9.1%), $p<0.01$. This suggests, as one may expect, that in teaching hospitals more attention is paid to new developments in inguinal hernia treatment.

The guidelines recommend ambulatory care surgery for every patient as it is as safe and effective as admission, but at lower costs. [12,13] The vast majority of patients in this study were still admitted in the hospital (63.6%). This is an opportunity for improvement. It is shown in the literature that even a selected

group of older patients and patients with ASA III can be operated in ambulatory care surgery.[14,15,16] In some countries 80% of patients are treated on an ambulatory basis, which is probably related to reimbursement policies. In The Netherlands in 2001 there was no real incentive to perform an inguinal hernia repair in day-care because of reimbursement.[17]

An important objective of the guidelines is to reduce the number of recurrences. The percentage of patients treated for recurrent hernia in this study is 14.7%. This is in line with data from Denmark but higher than Scotland, countries in which comparable studies have been performed.[4,5] It has to be taken into account that these percentages only reflect operated recurrent hernias, whereas many patients with asymptomatic recurrences may not have undergone surgery. No technique is perfect as demonstrated by the 78 patients with a recurrence after mesh repair. As it is unknown how many patients per technique were at risk for recurrence it is difficult to draw conclusions; it is a fact however that recurrences occur with all techniques.[18]

The guidelines recommend to consider the use of local anaesthesia in patients with a primary unilateral hernia.[1] In this study only 6.9% of the patients underwent surgery under local anaesthesia. In most cases it concerned patients with high co-morbidity. The preference and the experience of the surgeon with local anaesthesia is an important factor in the decision to use local anaesthesia. Studies have shown no difference in economics and patient recovery after local or general anaesthesia.[19]

Despite the fact that this was a retrospective study, with the risk of under-estimation, the total percentage of complications was high (22.3%). The percentage of pain reports was 8.6% in the follow-up. 1.7% of patients suffered from pain after 3 months or more. These percentages are low compared to studies in which prospective questionnaires where used [20,21] probably demonstrating the drawback of retrospective studies. It is worrying that 2.2% of patients developed a recurrence within one year. No significant differences can be found in operation technique, level of surgical expertise, or the type of hospital between this group and non-recurrent patients.

Surprisingly two of the three reported bowel perforations were caused by an anterior technique. In only one case it occurred in an endoscopic procedure. Bladder perforation occurred only once after a Lichtenstein procedure; and never occurred after an endoscopic correction, although this complication has been feared in this technique. Despite the fact that the results may be subject to bias as it is a retrospective analysis of patient charts, it generates a large amount of reliable information and good insight into the practice of inguinal hernia surgery in a recent period.

Conclusion

Before implementation of the Dutch evidence based Guidelines for treatment of inguinal hernia, 2839(78%) adult patients were treated with mesh repair and 484 (14.7%) patients were treated for a recurrent hernia. Implementation of the evidence based Guidelines for inguinal hernia will hopefully demonstrate an improvement in patient care with more use of mesh techniques (resulting in a lower recurrence rate) and more use of day surgery and local anaesthesia (resulting in more cost effectiveness and safety).

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Ontmoeten wij iemand die ons dank schuldig is, terstond valt het ons in. Hoe vaak ontmoeten wij echter iemand, wie wij dank schuldig zijn zonder daaraan te denken?

Albert Einstein

Do guidelines influence results in inguinal hernia treatment?

A descriptive study of 2535 hernia repairs in one teaching hospital from 1994-2004.

Chapter 4

Th.J. Aufenacker | S.P. Schmits | D.J. Gouma | M.P. Simons

HERNIA SUBMITTED

Abstract

Background: The OLVG hospital is a large district teaching hospital with a residency program for general surgery. Since 1998 inguinal hernia (IH) repairs in this hospital were performed according to the preliminary 'Evidence Based Guidelines' concerning IH repair. The aim of this study was to analyse whether the use of the Guidelines improves the quality of IH repair measured in terms of a reduction of the operated recurrences especially from the patients who underwent the previous repair in this hospital.

Methods: A retrospective study was performed which included all male adults (>18 years) undergoing IH surgery in the OLVG hospital for a primary or recurrent IH from 1994 until 2004.

Results: The use of mesh for primary hernia increased significantly from 0.6% in 1994 to 100% in 2004 ($p<0.001$). The number of operations performed for recurrent IH fluctuated between seven and almost eighteen percent. However the tendency towards a decrease in recurrence is clearly demonstrated by comparing the average recurrence rates of three time periods namely '94-'98 (15.8%) and '02-'04 (10.6%), proving a significant decrease ($p<0.002$). The decreasing share of recurrences previously operated in the study hospital from 64.3% (1994) to 14.3% (2004), was striking ($p<0.001$). The prior operation performed before the recurrence was mesh based in an average of 42/273 (15.4%) and increased per year.

Conclusion: Between 1994 and 2004 a significant increase in use of mesh based techniques for treatment of IH, influenced by the Dutch evidence based Guidelines, probably resulted in a significant decrease in operations performed for recurrent IH.

Introduction

The OLVG is a large district teaching hospital with a residency program for general surgery. Each year between 275 and 350 inguinal hernia (IH) repairs are performed. From 1996 onwards the treatment strategy for IH repairs shifted from mainly non-mesh repairs to mesh repair. Since 1998 IH repairs in this hospital were performed according to the preliminary 'Evidence Based Guidelines' concerning inguinal hernia repair. In 2003 the Dutch Evidence Based Guidelines[1] on IH repair were published. As the chairman of the committee (MS) is a general surgeon in the OLVG, the preliminary Guidelines could be implemented well before the official publication. In summary the recommendations are the use of mesh based techniques in adults, limited indications for endoscopic repair (primary bilateral hernia and recurrence after anterior repair, performed by well trained teams), operation preferably performed in day surgery and to consider the use of local anaesthesia when performing open anterior repair.
The Guidelines furthermore consist of 20 chapters with recommendations concerning all aspects of IH surgery from diagnosis to postoperative treatment.[1]
It is well known that implementation of guidelines is a very difficult problem. Therefore it is most interesting what the impact of these guidelines will be.
To perform a proper analysis of this impact a baseline nationwide analysis[2] (January-March 2001) of IH surgery in the Netherlands preceding the implementation of the guidelines was performed. These results will be compared to a second analysis that will take place in 2006. In the OLVG implementation could be studied earlier because of the above mentioned factors. In this study the results of eleven years of hernia surgery in a teaching hospital already working according the Guidelines from 1998 onwards are evaluated and compared.
The aim of this study was to analyse whether the use of the Guidelines improves the quality of IH repair in terms of a reduction of the operated recurrences especially from the patients who underwent the previous repair in this hospital. .

Patients and methods

A retrospective study was performed which included all male adults (>18 years) undergoing IH surgery in the OLVG hospital for a primary or recurrent inguinal hernia in 1994, 1996 and from 1998 until 2004. The analysis is performed in three time episodes to reduce the amount of data presented in the tables. The first (1994-1998) period was before the Guideline development. Second (1999-2001) period was during the development and the third after completion of the Guidelines (2002-2004). The parameters analyzed included patient demographics, hernia characteristics and surgical techniques used. Data were retrieved from original patient and operation charts. Patients were contacted to supply missing data as necessary and where possible. A recurrent hernia was defined as any inguinal or femoral hernia, in a patient previously operated on for any type of IH. The location of the previous operation was recorded to separate referrals from patients who underwent the previous repair in the study hospital. In patients with a bilateral hernia both hernias were evaluated separately.
The data were analyzed using the chi-square test. A p-value of ≤ 0.05 was considered to be significant.

Results

General findings

In nine years 2535 inguinal hernias were repaired in 2243 patients. Patient and hernia characteristics like mean age, hernia type, percentage incarcerated (2.7%) and bilateral hernia (12.9%) were almost the same over the analyzed years. No relevant differences in patient and hernia characteristics were observed over the 11 years period analyzed. (Table 1)
The percentage operations performed for recurrent IH fluctuated between seven and almost eighteen. The percentage decreased between 2000 and 2001 ($p=0.053$) but then again almost significantly ($p=0.059$) increased between 2002 and 2003. However the tendency towards a decrease in recurrence is clearly demonstrated by comparing the average recurrence rates of the three time intervals namely 1994-1998 (15.8%) with 1999-2001 (10.4%) and 2002-2004 (10.6%) proving a significant decrease ($p<0.002$). For 79% of patients the recurrent IH was their first, for 17% their second and for 4% their third or higher. Each year secondary operations had to be performed because of severe neuralgia (0.3-0.9%). The use of local anaesthetics was limited to a maximum of 7.4% and showed no increasing tendency. During the last three years over 65% of IH repairs were performed in day surgery. This was a significant increase when compared to the first period (1994-1998). ($P< 0.001$) Accordingly the length of stay was halved in those years from 4.3 towards 1.9 days.

Table 1

Patient, hernia and surgical characteristics in 2243 patients with 2535 hernias.

No patients	1994 – 1998 n=578	1999 – 2001 n= 808	2002 - 2004 n=857
No Hernias	650	906	979
Age (Yrs)	56.0	54.1	55.1
Type of hernia			
Indirect (%)	42.3	50.0*	50.4
Direct (%)	43.4	38.4*	38.6
Combined (%)	11.8	8.8	7.6
Femoral (%)	0.5	1.2	0.6
Unknown (%)	2.0	2.5	2.7
Bilateral (%)	12.5	12.1	14.2
Right sided (%)	51.8	55.5	54.5
Length of surgery (minutes ± SD)	56.7 ± 27.9	56.2 ± 24.1	58.2 ± 21.1
Acute operation (%)	3.3	1.9	3.0
Recurrence total (%)	15.8	10.4*	10.6
Recurrence previous repair OLVG (%)	6.6	3.2*	2.5
Reoperation Neuralgia (%)	0.4	0.5	0.5
Local anaesthetic (%)	3.5	4.8	4.1
Ambulatory care (%)	14.7	57.4*	65.2*
Length of stay (days ± SD)	4.3 ± 2.4	2.1 ± 1.7*	1.9 ± 1.6

*Significantly decreased or increased compared to the previous data period ($p \leq 0.05$).

Operation techniques

The use of mesh for primary hernia increased significantly from 0.6% in 1994 to 100% in 2004 ($p<0.001$). In the year 2004 in 82% of cases a Lichtenstein repair was performed. (Table 2) In 1998 bilateral primary hernia were endoscopically operated in 7% of patients. In the last three years of the study this percentage increased to 69%. ($P<0.001$)

Table 2

Techniques used for primary hernia repair from 1994 to 2004.

Technique	1994 – 1998 n (%)	1999 – 2001 n (%)	2002 – 2004 n (%)
Non-mesh	**307 (56.1)**	**73 (9.0)***	**21 (2.4)***
Bassini	100 (18.3)	0*	0
Shouldice	203 (37.1)	63 (7.8)*	17 (1.9)
Other [a]	4 (0.7)	10 (1.2)	4 (0.5)
Prosthesis	**240 (43.9)**	**739 (91.0)***	**854 (97.6)***
Lichtenstein	220 (40.2)	634 (78.1)*	713 (81.5)
Endoscopic	19 (3.5)	101 (12.4)*	141 (16.1)*
Other [b]	1 (0.2)	4 (0.5)	0
Total	547	812	875

*Significantly decreased or increased compared to the previous data period ($p \leq 0.05$).
[a] Hernial sac resection, Mc Vay;
[b] Plug and Patch, Wantz, Stoppa

In recurrent hernia the use of mesh increased from 46.4% in 1994 → 95.2% in 2004, $p<0.001$. (Table 3) The non-mesh repairs for recurrent hernia in recent years were only performed in cases in which there was an increased risk of infection of mesh. In the last 5 years 48% of recurrent hernias were operated using an endoscopic (TEP) repair.

Table 3

Techniques used for recurrent hernia repair from 1994 to 2004.

Technique	1994 – 1998 n(%)	1999 – 2001 n(%)	2002 – 2004 n(%)
Non-mesh	**23 (22.4)**	**3 (3.2)***	**3 (2.9)**
Bassini	13 (12.6)	0*	0
Shouldice	5 (4.9)	0*	2 (1.9)
Other [a]	5 (4.9)	3 (3.2)	1 (1.0)
Prosthesis	**80 (77.6)**	**91 (96.8)***	**101 (97.1)**
Lichtenstein	39 (37.9)	28 (29.8)	41 (39.4)
Endoscopic	19 (18.4)	47 (50.0)*	48 (46.2)
Other [b]	22 (21.3)	16 (17.0)	12 (11.5)
Total	103	94	104

*Significantly decreased or increased compared to the previous dataperiod ($p \leq 0.05$).
[a] Hernial sac resection, Mc Vay;
[b] Plug and Patch, Wantz, Stoppa

The level of expertise of the operating surgeon is shown in table 4. The variation between the years is considerable but seemingly not influenced by the Guidelines. However for the 3 time periods a significant rise in supervision is demonstrated. The same variation is seen when only the recurrent IH are considered, only then the number of surgeons performing the operation is significantly higher.

Table 4

Skill of operating surgeon in teaching hospital performing inguinal hernia repair.

No hernias:	1994 – 1998 n = 650	1999 – 2001 n = 906	2002 – 2004 n = 979
Surgeon (%)	57 (8.8)	64 (7.1)	70 (7.1)
Surgeon + Resident (%)	127 (19.5)	234 (25.8)*	283 (28.9)
Resident + Surgeon (%)	301 (46.3)	382 (42.2)	461 (47.1)*
Resident (%)	140 (21.5)	226 (24.9)	165 (16.9)*
Unknown (%)	25 (3.9)	0	0

* Significantly decreased or increased compared to the previous period ($p \leq 0.05$).

Characteristics of the recurrent hernia

The number of operated recurrent hernia decreased from 15.1% in 1994 to 7.4% in 2002, $p<0.007$ but increased in 2003 and 2004 (11.8% respectively 12.2%). The decreasing share of recurrences previously operated in the study hospital from 64.3% (1994) and 27.3% (2002) to 14.3% (2004), $p<0.001$ was striking. In 2004 only six "own" recurrences were operated in the OLVG.

The prior operation performed before the recurrence was mesh based in 42/273 (15.4%) gradually increasing over the separate years. (Table 5) Over 60% of recurrences after Lichtenstein hernia repair were of the direct type. And 64% of recurrences after the Lichtenstein technique were previously operated in this hospital. In six of the eight recurrences after endoscopic repair (75%) the last operation was performed in the OLVG hospital.

Table 5

Preceding techniques in recurrent hernia. Data from 1994 not available.

Technique No hernias:	1996 – 1998 n = 75	1999 – 2001 n = 94	2002 – 2004 n = 104
Non-mesh (%)	**71 (94.7)**	**76 (80.9)***	**63 (60.6)***
Bassini (%)	46 (61.4)	40 (42.6)*	25 (24.1)*
Shouldice (%)	7 (9.3)	8 (8.5)	10 (9.6)
Other(%) [a]	18 (24.0)	28 (29.8)	28 (26.9)
Prosthesis (%)	**1 (1.3)**	**16 (17.0)***	**25 (24.0)**
Lichtenstein (%)	0	11 (11.7)*	17 (16.3)
Laparoscopic (%)	0	2 (2.1)	6 (5.8)
Other (%)[b]	1 (1.3)	3 (3.2)	2 (1.9)
Unknown (%)	3 (4.0)	2 (2.1)	16 (15.4)

* Significantly decreased or increased compared to the previous data ($p \leq 0.05$).
[a] Hernial sac resection, Mc Vay;
[b] Plug and Patch, Wantz, Stoppa

The interval between IH repair and operation for recurrence seemed to prolong at the start of the new millennium but in recent years this pattern has turned back to its original variance. (Table 6) Although the group of patients operated more than 10 years ago has definitely increased. This is clearly demonstrated by comparing the average recurrence rates of two 5 year intervals namely 1994-1998 (35.0%) and 2002-2004 (59.6%) proving a significant increase of patients with a more than 10 years interval. ($p<0.001$) The decrease of patients with a recurrence within 2 years from 17.0% (1999-2001) towards 8.7% (2002-2004) seems promising though not significant ($p<0.08$)

Table 6

Time between inguinal hernia repair and recurrence.

No hernias:	1994 – 1998 n = 103	1999 – 2001 n = 94	2002 – 2004 n = 104
<2 years (%)	15 (14.6)	16 (17.0)	9 (8.7)
2-5 years (%)	22 (21.3)	11 (11.7)	13 (12.5)
5-10 years (%)	27 (26.2)	24 (25.5)	15 (14.4)*
>10 years (%)	36 (35.0)	42 (44.7)	62 (59.6)*
Unknown (%)	3 (2.9)	1 (1.1)	5 (4.8)

* Significantly decreased or increased compared to the previous data ($p \leq 0.05$).

Discussion

In the OLVG hospital there was a significant decrease during an eleven years period (1994-2004) in the number of operations performed for recurrences compared with the total number of primary inguinal hernia. ($p<0.001$) A possible explanation is the increase of mesh based techniques according to the 'Evidence Based Guidelines' on inguinal hernia repair. It has to be taken into account that these percentages only reflect operated recurrent hernias, as many patients with asymptomatic recurrences may not have undergone surgery. Another positive influence can be expected from the increased attention for IH repair. In several studies a correlation between improved results and supervision combined with training is suggested.[3,4,5] This is also demonstrated for the supervision in this one hospital study and difficult to measure for the training aspects. In this hospital much attention is given to theoretical and skills education in inguinal hernia repair.

The aim of this study was to record the changes caused by the Guidelines and to analyse the impact of these changes on the expected reduction of recurrent IH. Four main technical recommendations of the Guidelines were: the use of mesh, endoscopic repair in bilateral or recurrent hernia, consider using local anaesthetic when performing open anterior repair and more day surgery.

The implementation of many recommendations of the Guidelines has been fulfilled.

The use of mesh increased up to 100% in primary hernia and in recurrent hernia the use of mesh rose even 2 years sooner to a maximum. The endoscopic repair for bilateral hernia was performed according to the Guidelines in 69% of cases. In recurrent hernia repair the use of endoscopic surgery started earlier but over the last five years only 48% were corrected this way. The benefits of the endoscopic IH repair consist of a quicker postoperative recovery and reduction in costs in bilateral hernia.[6,7,8,9] The benefit of an endoscopic repair after an

anterior repair in recurrent hernia is even greater because of a reduction of complications like spermatic cord or inguinal nerve injury. The reason for this suboptimal percentage is that the endoscopic repair is not practised by all the surgeons and in the high risk patients (elderly, patients with prior laparotomies) the use of endoscopic repair with the obligatory general anaesthetic was avoided by performing an anterior repair under local anaesthetic. The gain of local anaesthetic (LA) in open anterior repair is based on a reduction of operative personnel and quicker return to activity.[10,11] Yet its use is limited to a maximum of 7.4% probably caused by the fact that there is a resident training program. Indications today for LA are patients not suited for general or spinal anaesthetics or patients requesting LA, this pattern is the same for The Netherlands[2] in 2001. Since day surgery is safe and effective[12,13] for IH treatment and because it reduces costs the increase to 65% of the operations performed this way is expected. In The Netherlands in 2001 the percentage day surgery was only 38%.[2] The impact of the Guideline is best demonstrated by the decrease in recurrence demonstrated by comparing the average recurrence rates of three time intervals namely 1994-1998 (15.8%) with 1999-2001 (10.4%) and 2002-2004 (10.6%) proving a significant decrease ($p<0.002$). The surgical practice furthermore is a referral centre for recurrences explaining the fact that total number of recurrences is not decreasing anymore. In 2004 only 6 recurrences were from the own practice this was 1.7% of the total number of hernia. In 1994 this percentage was 9.7%. As there are only a few laparoscopic surgeons in the Amsterdam area performing hernia surgery many recurrences from other hospitals are referred for endoscopic treatment. The last positive study observation is the increasing number of patients with a 10 year interval between primary and recurrent hernia since this group has a longer "disease free" interval. This increase is probably indicating that there is a backlog of non mesh treated patients still acquiring recurrences. The fact that a steep rise in recurrences after mesh repair stays out is a promising sign.

This study including 2243 patients has still some limitations. It is retrospective and the number of recurrences is measured indirectly tending to underestimate actual IH recurrence rates. Furthermore the previous technique used in recurrent hernia has to be correlated with the total number of this technique performed in previous years. This means that the demonstrated reduction in recurrences after Bassini and the increase of recurrence after prosthetic repair cannot easily be interpreted.

The results also show that no technique is perfect, as demonstrated by an increase in recurrence after the use of prosthesis as a preceding technique (15.4%). In many (66%) of these cases the Lichtenstein hernia repair was used which is not surprising since this is the preferential treatment. However since many recurrences (60%) after this method were of the direct type these may be explained as technical failures or due to the learning curve of the surgeons and residents.[14,15] The most plausible explanation of the direct recurrences is an

insufficient medial mesh fixation and overlap over the pubic tubercle. By increased attention to this aspect more than half of the recurrences after Lichtenstein repair could possibly be avoided.[16] The last critical remark can be made about the 9/1619 (0.5%) patients who underwent neurectomy because of post operative neuralgia. This complication, together with the in this study not measured chronic pain after IH repair, should be the main focus of future research since evidence on this subject is scarce but the complication serious.[17,18]

Conclusion

Between 1994 and 2004 a significant increase in mesh corrected IH influenced by the Dutch evidence based Guidelines resulted in a significant decrease in operations performed for recurrent IH, an increase in operations performed in daycare and more attention to training and supervision of operations. The other recommendations of the Guidelines (use of LA and endoscopic repair) were partly implemented mainly caused by patient factors and because not every surgeon has mastered these techniques. Because of the Guidelines more improvement of the patient care and surgical results is likely to be expected.

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Er zou weinig van mij overblijven als ik alles terug moet geven

wat ik aan anderen te danken heb.

Johann Wolfgang von Goethe

The role of antibiotic prophylaxis in prevention of wound infection after Lichtenstein open mesh repair of primary inguinal hernia.

A multicenter double-blind randomized controlled trial.

Chapter 5

Th.J. Aufenacker | D. van Geldere | T. van Mesdag | A.N. Bossers | B. Dekker | E. Scheijde | R. van Nieuwenhuizen | E. Hiemstra | J.H. Maduro | J.W. Juttmann | D. Hofstede | C.Th. M. van der Linden | D.J. Gouma | M.P. Simons

Annals of Surgery 2004 Dec;240(6):955-60; discussion 960-1.

Abstract

Objective: To determine whether the use of prophylactic antibiotics is effective in the prevention of post-operative wound infection after Lichtenstein open mesh inguinal hernia repair.

Summary Background Data: A recent Cochrane meta-analysis (2003) concluded that 'antibiotic prophylaxis for elective inguinal hernia repair cannot be firmly recommended or discarded'.

Methods: Patients with a primary inguinal hernia scheduled for Lichtenstein repair were randomized to a preoperative single dose of 1.5 g intravenous cephalosporin or a placebo. Patients with recurrent hernias, immunosuppressive diseases or allergies for the given antibiotic were excluded. Infection was defined using the Centers for Disease Control and Prevention criteria.

Results: We included 1040 patients in the study between November 1998 and May 2003. According to the intention to treat principle 1008 patients were analyzed. There were 8 infections (1.6%) in the antibiotic prophylaxis group and 9 (1.8%) in the placebo group (p=0.82). There was 1 deep infection in the antibiotic prophylaxis group and 2 in the placebo group (p=0.57). Statistical analysis showed an absolute risk reduction (ARR) of 0.19% (95%CI: -1.78%-1.40%) and a number needed to treat (NNT) of 520 for the total number of infections. For deep infection the ARR is 0.20% (95%CI: -0.87%-0.48%) with a NNT of 508.

Conclusion: A low percentage (1.7%) of wound infection after Lichtenstein open mesh inguinal (primary) hernia repair was found and there was no difference between the antibiotic prophylaxis or placebo group. The results show that in Lichtenstein inguinal primary hernia repair antibiotic prophylaxis is not indicated in low risk patients.

Mesh repair is, in many western countries, rapidly becoming the most popular technique for repair of inguinal hernia.[1-6] Of the open mesh repair techniques the Lichtenstein hernia repair is most frequently used. The Lichtenstein technique is a tension free repair of the weakened inguinal floor using a polypropylene mesh.[7] It is uncertain whether antibiotic prophylaxis is necessary as prevention against postoperative wound infections which occur in 0-9% of inguinal hernia repairs.[8] Especially when a foreign body, like polypropylene mesh is involved, a deep infection should be prevented. Surgeons at the Lichtenstein Hernia Institute sprinkled bacitracin and polymyxin powder into the wound to prevent infection, but some time ago this strategy was abandoned.[9] Few clinical trials have addressed this issue. One trial showed a significant (10-fold) decrease in wound infections with intravenous antibiotic prophylaxis in mesh repair[10]; two others did not.[11,12] A Cochrane meta-analysis[13] in 2003 concluded that 'antibiotic prophylaxis for elective inguinal hernia repair cannot be firmly recommended or discarded' and 'further studies are needed, particularly on the use of mesh repair'.

Since many randomized trials and meta-analyses have shown that mesh repair reduces the risk of hernia recurrence, the prosthetic repair is worldwide accepted as the gold standard in inguinal hernia repair.[5,6,14-16] Both in the United States and Europe over 1.000.000 inguinal hernia repairs are yearly performed[16] and therefore any improvement in their treatment could have a large medical and economical impact. Especially a reduction in the number of wound infections would have a great impact. Conversely, discarding the use of antibiotic prophylaxis in inguinal hernia repair could reduce the risks of toxic and allergic side effects, the possible development of bacterial resistance[17] or superinfections and reduce costs.

To assess if systemic antibiotic prophylaxis prevents wound infection in Lichtenstein inguinal hernia repair a multi-center double-blind placebo controlled randomized trial was performed in the Netherlands.

Patients and methods

Three nonteaching and one teaching general hospital participated in this study. Surgical residents and surgeons in participating hospitals enrolled patients and performed the operations. The ethics committees of all hospitals approved the study and all patients gave informed consent.

Characteristics of the patients

Patients with a primary uni- or bilateral inguinal hernia and an indication for Lichtenstein hernia repair were eligible for the study. Exclusion criteria were: age under 35, the need for antibiotics for a different reason, immunosuppressive disease (diabetes mellitus, malignancy, HIV) or medication (glucocorticoid therapy), allergy to the given antibiotic, recurrent hernia or the inability to get an informed consent. In order to get insight in a potential selection bias all eligible patients in one of the four hospitals were registered.

Random assignment to treatment groups

The patients were double-blinded randomly assigned to either intravenous placebo or antibiotic prophylaxis. A pharmacist carried out randomization according to a computer-generated list in blocks of 10 patients with stratification for each hospital.

Surgical technique and antibiotic prophylaxis

The operations were performed either by a board certified surgeon or a (supervised) resident. In short: the groin of the patient was shaved just before or in the operating theatre. A standard Lichtenstein hernia repair was performed as described by surgeons from the Lichtenstein Hernia Institute.[7,9] Two surgeons with a special interest in hernia surgery educated the participating hospitals in the standard technique. A monofilament polypropylene flat mesh (Bard ® or Autosuture ®) was sutured in place with monofilament polypropylene suture (Prolene). Anesthesia and skin closure were not standardized.
The trial medication consisted of either 50 ml sterile saline (placebo) or 50 ml sterile saline with 1500 mg Cefuroxim (2nd generation cephalosporin). Cefuroxim was chosen because of its known activity against the causative pathogens in inguinal wound infection. The half-life time of this antibiotic is 1-2 hours and therefore a single dose supplies therapeutic levels until a few (3-7) hours after wound closure. A pharmacist prepared the trial medication under laminar airflow condition and it was packed in non-transparent material to exclude optical differences. The anesthesiologist administered the trial medication at the induction of anesthesia. The exact timing of administering was not standardized, thereby copying daily practice.

Data collection and follow-up

Data collection was standardized and performed by residents and surgeons in the participating hospitals. The patients were requested to return to the outpatient clinic at one, two and twelve weeks for a standardized history taking and physical examination. In most cases the surgeon who performed the operation did not perform the follow-up. In case of missing observations the patients were contacted and a standardized telephone interview was performed.

End points

The primary end point of the study was wound infection as defined by the Centers for Disease Control and Prevention criteria (C.D.C.).[18,19] In this definition superficial infection occurs within 30 days after operation and involves only skin or subcutaneous tissue; deep infection involves fascial and muscle layers and, when related to an operation where an implant is used, may occur up to one year.

Statistical analysis

The power of the trial (α 0.05, β 80%, two-sided) was based on the assumption that antibiotic prophylaxis reduces the wound infection rate from 4% (average in literature) to 1%. The sample size calculated was 978 patients. Since we expected a dropout of 5% we randomly allocated 1040 patients. Data for all patients who were randomly assigned to a treatment group and underwent surgery were primarily analyzed on an intention to treat basis. A per-protocol analysis, which excluded patients with major protocol violations, was also performed. The third analysis performed was an as-treated analysis; that is, patients were assigned to a group based on whether they did actually get antibiotics or not. No interim analyses were performed. Continuous normally distributed data are expressed as median with 25%-75% quartiles. Chi-square or Fisher's exact tests were used to compare proportions. Multivariate analysis of various risk factors (when $p<0.10$ in univariate analysis) for infection was performed with binary logistic regression analysis. For all analysis the SPSS package was used. All analysis were made under the guidance of an epidemiologist.

Results

One thousand and forty patients were included in the study between November 1998 and May 2003. Twenty-five patients were not enrolled in the primary analysis: twelve patients withdrew informed consent, thirteen were eventually not operated. Another group of nineteen patients with an in our view acceptable protocol violation (mainly age below 35 or presumed allergy) was included in the analysis. According to the intention to treat principle 1008 patients were analyzed. (Figure 1) Randomization was successful: there were no significant differences in patient or operation characteristics. (Table1.)

Figure 1

Trial profile of randomized controlled trial for antibiotic prophylaxis in Lichtenstein inguinal hernia repair. * One death because of operation related complications.

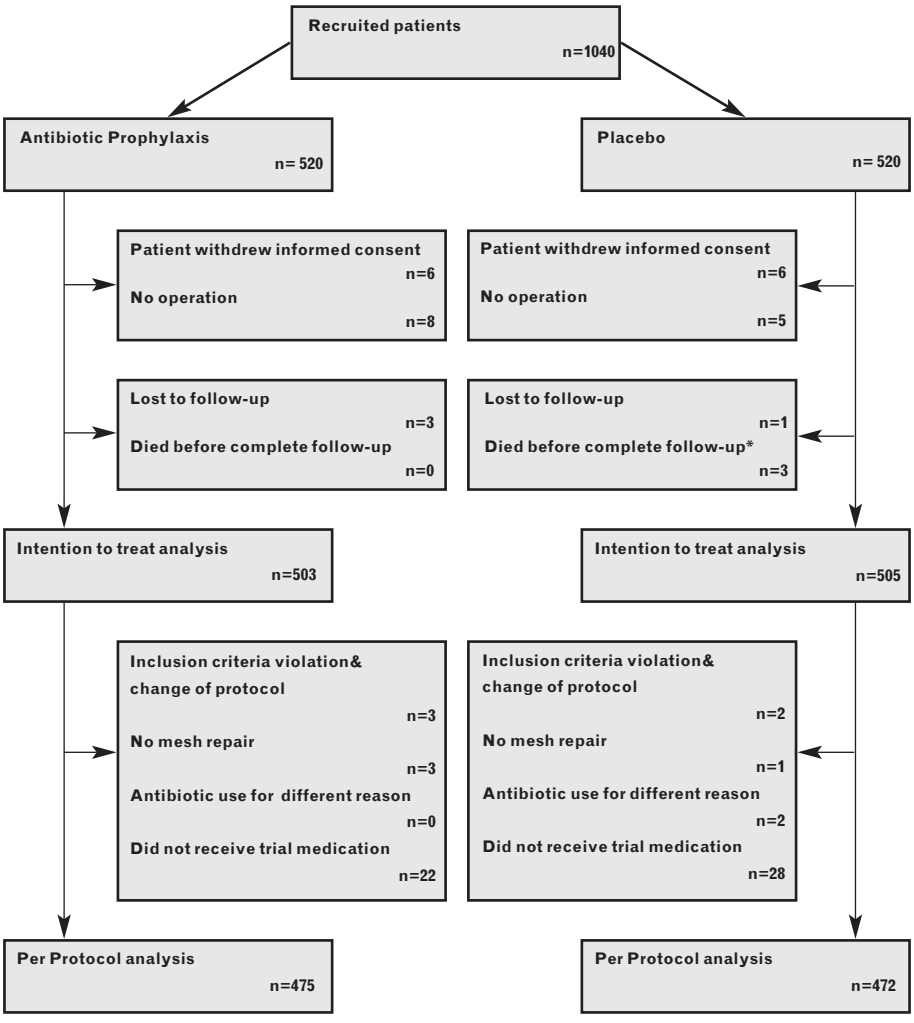

Table 1

BASE LINE AND OPERATIVE CHARACTERISTICS OF 1008 PATIENTS WITH PRIMARY INGUINAL HERNIA RANDOMIZED BETWEEN ANTIBIOTIC PROPHYLAXIS AND PLACEBO.

Characteristic	Antibiotic Prophylaxis (n=503)	Placebo (n=505)
Age – Yr (mean ± SD)	58.28 ± 12.9	58.22 ± 13.2
Sex – No. (%)		
Male	481 (95.6)	490 (97.0)
Female	22 (4.4)	15 (3.0)
Characteristics of hernia- No. (%)		
Direct	198 (39.4)	208 (41.2)
Indirect	221 (43.9)	233 (46.1)
Combined	76 (15.1)	60 (11.9)
Unknown	8 (1.6)	4 (0.8)
Surgeon – No. (%)		
Resident	212 (42.1)	225 (44.6)
Certified surgeon	291 (57.9)	280 (55.4)
Anesthesia – No. (%)		
Local	10 (2.0)	7 (1.4)
Spinal	180 (35.8)	191 (37.8)
General	311 (61.8)	303 (60.0)
Unknown	2 (0.4)	4 (0.8)
Bilateral hernia – No. (%)	27 (5.4)	29 (5.7)
Disinfectant – Iodine – No. (%)	493 (98.0)	496 (98.4)
Operation in day surgery– No. (%)	231 (46.1)	232 (45.9)
Use of drains – No. (%)	11 (2.2)	4 (0.8)
Duration of surgery – Min.		
Median (25%-75% quartiles)	40 (30-50)	40 (28-51)
Incision length – Cm.		
Median (25%-75% quartiles)	8.0 (7.0-8.3)	8.0 (7.0-8.0)

In one of the four participating hospitals (OLVG) all eligible patients were registered. During three years of the study period 625 patients were scheduled for Lichtenstein hernia repair, 483 were eligible and 363 (75%) were eventually recruited in the study. Not included were 120 patients for the following reasons: 96 (20%) refused to participate and 24 (5%) were not asked to participate. These numbers could be slightly different for other hospitals.

Follow up was not complete: 199 patients missed their third follow-up (12weeks). Of this group 195 (98%) could be contacted by telephone. The four patients (0.4%) lost to follow-up and three (0.3%) deceased patients had no indication of an occurring wound problem at their last visit to the outpatient clinic but did not contribute to the intention to treat analysis.

The number of wound infections was eight (1.6%) in the antibiotic prophylaxis group and nine (1.8%) in the placebo group (p=0.82). There were three (0.3%) deep infections: one in the antibiotic prophylaxis group and two in the placebo group (p=0.57). Statistical analysis showed an absolute risk reduction (ARR) of 0.19% (95% CI: -1.78%-1.40%) and a number needed to treat (NNT) of 520 to prevent one infection. For the deep infection the ARR is 0.20% (95% CI: -0.87%-0.48%) with a NNT of 508 to prevent one infection.
Other postoperative infectious complications showed no significant differences between groups (table 2). One patient died of pulmonary complications and a bleeding gastric ulcer.

For the per protocol (Antibiotic prophylaxis: 8/475=1.7% and placebo: 8/472=1.7%) and as treated analysis (Antibiotic prophylaxis: 9/540=1.7% and placebo: 8/480=1.7%) no significant differences were observed.
In the univariate analysis sex (female, p<0.01), bilateral hernia (p=0.03) and age above 60 years (p=0.02) were identified as risk factors for infection. Multivariate analysis of these factors together with operation not performed in day surgery (p=0.06) and operation performed by a resident (p=0.07) was performed. This analysis reached significance for sex (female, p<0.01) as an independent risk factor for infection.

Table 2

POSTOPERATIVE COMPLICATIONS OF 1008 PATIENTS AFTER PRIMARY INGUINAL HERNIA REPAIR RANDOMIZED BETWEEN ANTIBIOTIC PROPHYLAXIS AND PLACEBO.

Variable	Antibiotic group (n=503)	Placebo group (n=505)
Wound infection	8(1.6%)	9(1.8%)
Deep	1(0.2%)	2(0.4%)
Superficial	7(1.4%)	7(1.4%)
Reoperation within 12 weeks because of neuralgia	2(0.4%)	2(0.4%)
Removal of infected mesh	1(0.2%)	1(0.2%)
Urinary tract infections	3(0.6%)	2(0.4%)
Pulmonary infections	2(0.4%)	1(0.2%)
Orchidectomy	1(0.2%)	0(0.0%)
Other postoperative antibiotic prophylaxis	1(0.2%)	2(0.4%)
Total	18(3.6%)	17(3.4%)

The details of the patients with a postoperative wound infection are displayed in table 3. All three patients with deep wound infections had a culture with Staphylococcus aureus. One patient was treated with intravenous antibiotics and surgical drainage and recovered completely. Two other patients were treated with repeated courses of oral antibiotics and drainage of the wound. A persistent sinus necessitated removal of the mesh in both patients. Although recurrence was no end point of this study we documented six (0.6%) recurrences.

Table 3

DETAILS OF PATIENTS WITH A WOUND INFECTION FROM A GROUP OF 1008 PATIENTS AFTER PRIMARY INGUINAL HERNIA REPAIR RANDOMIZED BETWEEN ANTIBIOTIC PROPHYLAXIS AND PLACEBO.

	Days Postop	Cultured Microorganism	Superficial Or Deep	Treatment	Readmittance
Antibiotic Group	14	Staphylococcus aureus Anaerobic coccus	Superficial	Drainage Antibiotics	No
	10	Enterococcus faecalis Corynebacterium	Superficial	Antibiotics	No
	14	Corynebacterium	Superficial	Drainage	No
	80	Staphylococcus aureus Hemolyt.Streptococcus.	Deep	Antibiotics Mesh removal	Yes
	8	No culture performed	Superficial	Drainage	No
	15	No culture performed	Superficial	Antibiotics	No
	28	No culture performed	Superficial	Antibiotics	No
	14	Group G Streptococcus Aspergillus fumigatus	Superficial	Drainage Antibiotics	No
Placebo Group					
	7	Skin bacteria	Superficial	Drainage	No
	8	Staphylococcus aureus	Deep	Drainage Antibiotics	Yes
	15	Staphylococcus aureus	Superficial	Drainage	No
	10	No culture performed	Superficial	Drainage	No
	7	Staphylococcus aureus Group G Streptococcus	Deep	Drainage Antibiotics Mesh Removal	Yes
	8	Staphylococcus aureus	Superficial	Drainage Antibiotics	Yes
	20	Mixed culture	Superficial	Drainage	No
	10	Mixed culture	Superficial	Drainage	No
	11	No culture performed	Superficial	Drainage	No

Discussion

Both in the USA and Europe over one million inguinal hernia repairs are yearly performed.[16] The majority of these repairs are nowadays performed using a variety of mesh techniques of which the Lichtenstein "open flat mesh repair" is the most popular.[1,3,4,16] Inguinal hernia repair is an elective clean operation and the postoperative wound infection rate should be very low. Prophylaxis in clean operations has been shown of value in other areas of surgery such as trauma[20] and vascular surgery[21,22] but in inguinal hernia repair its benefit remains uncertain.

In this large, randomized, placebo-controlled double-blind trial analyzing wound infections after Lichtenstein hernia repair, there was no significant difference in the rate of wound infections between groups of patients receiving antibiotic prophylaxis (1.6%) or placebo (1.8%). This study was performed in general practice with a representative mix of general and teaching hospitals and surgical experience. In the Netherlands there are no specialized hernia centers.

Overall infection rate was low (1.7%) compared to a similar trial of Yerdel et al[10] (4.8%). The relatively low incidence of wound infection (1.8%) in our placebo group compared to the 9 % in the study of Yerdel et al[10] may be explained by patient- and operation characteristics. Previous studies suggest that these factors influence the risk of wound infection[19] (Table 4). Differences were the duration of operation (1.5 times longer in the Turkish study), more use of drains[23] and repeated aspiration of seromas that could cause secondary infections. In both studies immunosuppressive disease was an exclusion criterion. In Yerdel's study (2001)[10] of 280 patients a significant (10-fold) reduction of wound infections (from 9% to 0.7%) was found. The number of deep infections, however, was also low and not significantly different from our study. Unfortunately, the study was prematurely stopped because of the high rate of wound infection. It is likely that the study was underpowered.

A potential drawback of our study is the timing of administration of the antibiotic prophylaxis: 30 minutes before incision is difficult to organize in most hospitals. In theory the optimal timing of the administration should be so that the bactericidal concentration is maximal in serum and tissues by the time the skin is incised.[19,24] We chose a pragmatic approach, adhering to daily practice.

Another drawback is the shortcoming of the follow-up at three months, since 20% was done by telephone. There might be an observational error but these patients were told to come back if there was any complaint and they had no sign of infection at previous visits. It is unlikely that patients do not remember an infection and there is evidence that patients are accurate in determining when a wound is not infected.[25,26] It can be assumed that especially a deep infection would be remembered and, therefore, it is unlikely that this potential bias influences the final results. An explanation for the incomplete follow-up at twelve weeks might be that the study was not officially funded and that follow-up was performed during routine practice.

Table 4

PATIENT AND OPERATION CHARACTERISTICS THAT MAY INFLUENCE THE RISK OF WOUND INFECTION DEVELOPMENT.[19]

Patient	Operation
Age	Duration of surgical scrub
Nutritional status	Skin antisepsis
Diabetes	Preoperative shaving
Smoking	Preoperative skin prep
Obesity	Duration of operation
Coexistent infection at a remote body site	Antimicrobial prophylaxis
Colonization with microorganisms	Operating room ventilation
Altered immune response	Inadequate sterilization of instruments
Length of preoperative stay	Foreign material in the surgical site
	Surgical drains
	Surgical technique

Since there is no benefit in the use of antibiotic prophylaxis for inguinal hernia repair in low risk patients its use is not cost effective. Because of an unknown impact on bacterial resistance[17] the use of routine antibiotic prophylaxis in primary inguinal hernia repair should be discouraged. The cost benefit for one patient is relatively limited (13.54 Euro[27]). However, because of the large number of inguinal hernia repairs performed in low-risk patients (estimated 70% of all hernias) discarding the use of antibiotic prophylaxis will save around 10 million Euro in the U.S. and Europe. In contrast, if a wound infection occurs, it has been postulated that there is an increase in the recurrence rate[28, 29] but this was in particular when non-mesh techniques were performed. A major problem occurs when the mesh is infected. Several studies reported late-onset of mesh infection or chronic groin sepsis[30,31] eventually leading to complete mesh removal. In this study three deep infections are reported. In all Staphylococcus aureus was cultured resulting in mesh removal in two patients (0.2%).

Conclusion

In this trial, performed in general practice, a low wound infection rate (1.7%) after Lichtenstein inguinal (primary) hernia repair was found. The results show that in Lichtenstein inguinal primary hernia repair antibiotic prophylaxis is not indicated in low risk patients.

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Lao Tse

Systematic review and meta-analysis of the effectiveness of antibiotic prophylaxis in prevention of wound infection after mesh repair of abdominal wall hernia

Chapter 6

Th.J. Aufenacker | M.J.W. Koelemay | D.J. Gouma | M.P. Simons

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Abstract

Objective: Does systemic antibiotic prophylaxis prevent wound infection in abdominal wall hernia repair with mesh?

Methods: A systematic review of the available literature identified from multiple databases using the terms "hernia" and "antibiotic prophylaxis" was performed. Randomized placebo controlled trials with use of antibiotic prophylaxis (AP) in mesh abdominal wall hernia repair with explicitly defined wound infection criteria and a minimal follow up period of one month were included. After independent quality assessment and data extraction, data were pooled for meta-analysis using a random effects model.

Results: The search process identified eight relevant papers reporting data on AP in abdominal wall surgery with mesh reinforcement. Two papers reported on the use of AP in umbilical, incisional or laparoscopic hernia surgery. Six articles concerning AP in inguinal and femoral (groin) hernia were suited for meta-analysis. The total number of infections for groin hernia in the placebo group was 38/1277 patients (3.0%) and 18/1230 patients (1.5%) in the antibiotic group. Antibiotic prophylaxis did not significantly reduce the incidence of infections OR 0.54 (95%CI:0.24-1.21), number needed to treat (NNT) of 74. The number of deep infections was 6 in the placebo group (0.6%) and 3 in the antibiotic prophylaxis group (0.3%) with an OR of 0.50(95% CI:0.12-2.09).

Conclusion: Antibiotic prophylaxis does not prevent the occurrence of wound infection in groin hernia surgery and therefore is not indicated in low-risk patients. More trials are needed for complete evidence in the other areas of abdominal wall hernia.

Introduction

Mesh repair is, in many western countries, rapidly becoming the most popular technique for repair of abdominal wall hernia.[1-7] More than 70% of abdominal wall hernias comprise inguinal hernia and in the western world the majority are being repaired with use of a prosthetic mesh. The most popular technique is the Lichtenstein hernia repair with a flat mesh to reinforce the inguinal wall. In incisional hernia repair (second most frequent abdominal wall hernia) mesh repair results in a lower recurrence rate compared with suture repair.[3] Other abdominal wall hernias like umbilical and epigastric hernias are also more frequently being repaired with mesh based techniques.

Although frequently used, it is uncertain whether antibiotic prophylaxis is indicated as prevention against postoperative superficial and deep wound infections after mesh repair of abdominal wall hernia. The incidence of infections after inguinal hernia repair has been reported to vary from 0 to 9%.[8] Especially, when a foreign body, such as a polypropylene mesh, is used prevention of a deep infection is of paramount importance. A Cochrane review meta-analysis for inguinal hernia[9] in 2004 concluded that 'antibiotic prophylaxis for elective inguinal hernia repair cannot be firmly recommended or discarded' because the number of included patients was limited and 'further studies are needed, particularly on the use of mesh repair'. Recently new information became available. Since many randomized trials and meta-analyses have shown that mesh repair reduces the risk of hernia recurrence, the mesh repair is accepted as the first choice in abdominal wall hernia repair.[2,3,6,7,10-13] Both in the United States and Europe over 1.5 million abdominal wall hernia repairs (of which 70% groin hernia repairs) are performed annualy[13] and therefore any improvement in their treatment could have a large medical and economical impact. Especially a reduction in the number of wound infections would have a great impact on patient satisfaction, sick-leave and wound care. Conversely, discarding the use of antibiotic prophylaxis in hernia repair could reduce the risks of toxic and allergic side effects, the possible development of bacterial resistance[14] or superinfections and reduce costs. To assess if systemic antibiotic prophylaxis prevents wound infection in mesh abdominal wall hernia repair a systematic review and where possible a meta-analysis of randomized controlled trials was carried out.

Methods

A Medline, EMBASE, CINAHL, DARE, ACP, LILACS and Cochrane register search using the terms "hernia" and "antibiotic prophylaxis" was carried out to identify randomized controlled trials on the subject published between 1966 and March 2005. All languages were considered. The search was performed independently by two reviewers (TA, MK) who selected potentially relevant papers based on title and abstract. References from the selected papers were used for search completion. Field experts were contacted for potential data and abstract books of leading hernia meetings during the last five years were manually checked for unpublished data. All randomized placebo controlled trials with use of antibiotic prophylaxis in mesh abdominal wall hernia repair with explicit defined wound infection criteria and a minimal follow up period of one month were included. Each paper was reviewed independently by three reviewers (TA, MK, MS) and a quality assessment was performed according to Jadad's scoring system.[15] Discrepancies between the reviewers were resolved by consensus. Only papers with a Jadad score of ≥3 were considered appropriate for further analysis. Data was extracted from the studies and pooled using review manager[16] from the Cochrane collaboration. A χ^2 test for heterogeneity of study results was performed. If heterogeneity could not be detected data were pooled using a random effects model to correct for clinical diversity and methodological variations between studies. The effectiveness of antibiotic prophylaxis to prevent wound infection was expressed as odds ratios (OR) for dichotomous data and their 95% confidence interval (CI). Numbers needed to treat (NNT) and 95% CI were calculated from the OR and the back ground risk of wound infection in the patients in the placebo groups. No subgroup analysis was performed. If it remained unclear from a study whether data were presented for patients or hernias a sensitivity analysis (worst case scenario) was performed by varying the distribution of bilateral hernia between treated and placebo groups.

Results

The search resulted in 26 potentially relevant studies and identified eight papers reporting prospective randomized data on the use of antibiotic prophylaxis in abdominal wall surgery with prosthetic reinforcement. Eighteen papers were excluded because six used non mesh techniques, one made a comparison between different prophylactic regimes and eleven were not randomized controlled trials.

Table 1 shows a summary of the eight included randomized trials and the outcome of the assessment. The results of the three assessments did not differ between the three reviewers. The study of Abramov[17] described a small group of 35 hernias of which only 23% were repaired with mesh. Despite several flaws in design, including lack of proper randomisation, this study is the only one addressing the randomisation of antibiotic prophylaxis in umbilical and

incisional repair and therefore it was accepted for the systematic review. The only laparoscopic study of Schwetling[18] was considered weak (incorrect randomisation and lack of definition of wound infection) but in the absence of more studies considered best evidence. Both previously mentioned studies were the only documented trials on the subject and therefore were not suited for any form of meta-analysis.

Table 1

Results and quality of presumed prospective randomized studies on the use of antibiotic prophylaxis in prevention of wound infection after mesh abdominal wall hernia repair.

Reference	Jadad score	No. of patients	Infection %	Correct Randomisation?	Double blind?	Wound infection definition?	Follow up period?	Accepted in meta-analysis?
Incisional and umbilical hernia mesh repair								
Abramov[17] 1996	0	35	25.7%	No, alternately	no	yes	1 month	No, only 23% mesh repair. Best evidence
Laparoscopic inguinal hernia mesh repair (TAPP)								
Schwetling[18] 1998	0	80	0.0%	No, alternately	no	No definition	Unknown	No. Best evidence
Open inguinal and femoral hernia mesh repair								
Morales[19] 2000	4	524	1.9%	yes	yes	yes	1 year	yes
Yerdel[20] 2001	5	269	4.8%	yes	yes	CDC criteria25	1 year	yes
Celdran[21] 2004	4	91	4.4 %	yes	yes	CDC criteria25	2 years	yes
Oteiza[22] 2004	3	247	0.4%	yes	no	CDC criteria25	1 month	yes
Aufenacker[23] 2004	5	1008	1.7 %	yes	yes	CDC criteria25	3 months	yes
Perez[24] 2005	5	360	3.1%	yes	yes	CDC criteria25	1 month	Yes

. The patient characteristics of the 6 RCT's on open inguinal and femoral hernia mesh repair are documented in table 2

Table 2

Patient and study characteristics of six randomized controlled trials on antibiotic prophylaxis in inguinal and femoral hernia mesh repair.

Complication	Morales[19] N= 524[a]	Yerdel[20] N= 269[a]	Celdran[21] N=99[b]	Oteiza[22] N= 247[a]	Aufenacker[23] N=1008[a]	Perez[24] N=360[a]
Total infections (%)	1.9%	4.8%	4.4%	0.4%	1.7%	3.1%
Deep infection (%)	0.8%	1.5%	0%	0%	0.3%	0.6%
Mesh removal (%)	0.8%	1.1%	0%	0%	0.2%	0.6%
Body mass index (mean)	Not documented	25.0	26.2	Not documented	Not documented	Not documented
Diabetes	Not documented	Study exclusion criterion	18 (18.1%)	Not documented	Study exclusion criterion	Not documented
Recurrent hernia	39 (7.4%)	Study exclusion criterion	13 (13.1%)	Study exclusion criterion	Study exclusion criterion	Study exclusion criterion
Duration of surgery	34 minutes	63 minutes	65 minutes	40 minutes	40 minutes	53 minutes
Surgeon (%)	524 (100%)	0 (0%)	75 (75.8%)	247 (100%)	571 (56.6%)	Not documented
Residents (%)	0 (0%)	269 (100%)	24 (24.2%)	0 (0%)	437 (43.4 %)	
Bilateral Hernia	0 (0%)	0 (0%)	8 (8.8%)	Study exclusion criterion	56 (5.6%)	Study exclusion criterion
Femoral Hernia	23 (4.4%)	Study exclusion criterion	Study exclusion criterion	20 (8.1%)	Study exclusion criterion	Study exclusion criterion
Use of drains	Study exclusion criterion	60 (22.3%)	Not documented	Not documented	15 (1.5%)	0 (0%)
Local anaesthetics	Not documented	111 (41.3%)	99 (100%)	226 (91.5%)	17 (1.7%)	0 (0%)
Day surgery	51 (9.7%)	Not documented	99 (100%)	247 (100%)	463 (45.9%)	Not documented
Mesh Type	Polypropylene	Polypropylene	Polypropylene	Polypropylene	Polypropylene	Polypropylene
Exclusion Bias[26]	30/554 (5.4)	11/280 (3.9%)	0/91 (0%)	3/250 (1.2%)	7/1015 (0.7%)	0/360 (0%)

[a] N= number of patients; [b] N= number of hernias (91 patients)

Based on the quality assessment these six studies were found suited for meta-analysis regarding the use of antibiotic prophylaxis including 2464 open inguinal and 43 femoral hernia repairs. The included studies are presented with the main interventions and results in table 3.

Table 3

Results of individual studies accepted in the systematic review on the use of antibiotic prophylaxis in prevention of wound infection after mesh abdominal wall hernia repair.

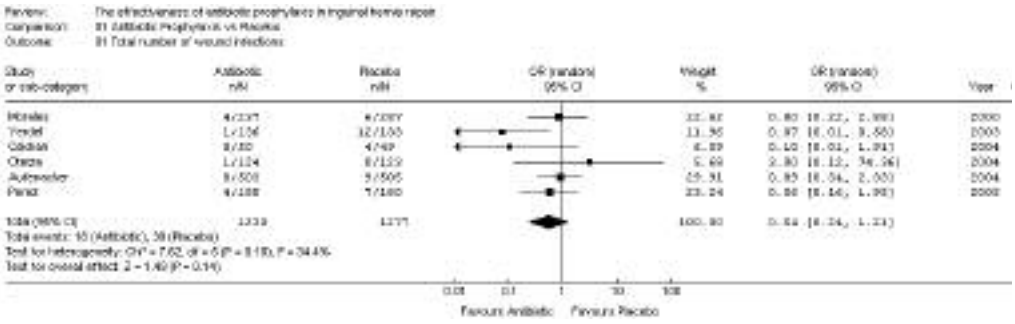
Reference	n	Mean age (years)	Sex male (%)	Type of antibiotic	Infection placebo group (patients, %)	Infection intervention group (patients, %)	p-value	NNT
Incisional (inc.) and umbilical (umb.) hernia mesh repair								
Abramov[17]	16 inc.	55	?	Cefonicid 1 g	4/8 50%	0/8 0%	0.076	2
	19 umb.	52	?		4/10 40%	1/9 11%	0.303	3
Laparoscopic inguinal hernia mesh repair (TAPP)								
Schwetling[18]	80	55	86	Cefuroxim 1.5 g	0/40 0%	0/40 0%	1.0	∞
Open inguinal and femoral hernia mesh repair								
Morales[19]	524	54	90	Cefalozin 2g	6/287 2.1%	4/237 1.7%	0.737	248
Yerdel[20]	269	56	93	Ampicillin + Sulbactam 1.5 g	12/133 9.0%	1/136 0.7%	0.002	13
Celdran[21]	91	58	90	Cefazolin 1g	4/49* 8.2%	0/50* 0.0%	0.059	13
Oteiza[22]	247	57	85	2 g Amoxicillin Clavulanic acid	0/123 0.0%	1/124 0.8%	0.318	NNH 124
Aufenacker[23]	1008	58	96	Cefuroxim 1.5 g	9/505 1.8%	8/503 1.6%	0.813	520
Perez[24]	360	61	98	Cefazolin 1 g	7/180 3.9%	4/180 2.2%	0.540	59

*number of hernias (91 patients)

The total number of infections for groin hernia was 38/1277 patients (3.0%) in the placebo group and 18/1230 patients (1.5%) in the antibiotic group. The pooled data for the 6 studies is presented in figure 1. There was no statistical heterogeneity (chi-square p=0.18). The OR for wound infection after antibiotic prophylaxis was 0.54 (95% CI: 0.24-1.21) resulting in a number needed to treat (NNT) of 74. The Celdran study did not specify in which group the 8 bilateral hernias were included therefore a sensitivity analysis was performed (worst-case scenario: infection rate in Celdran's placebo group 4/41=9,8%) resulting in an OR of 0.53(95% CI: 0.23-1.21).

Figure 1

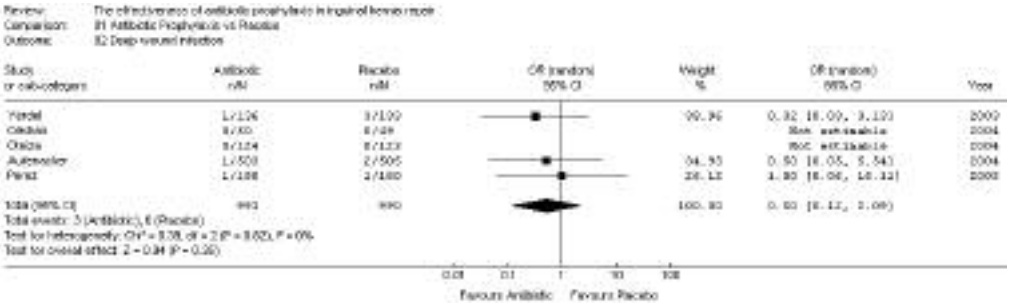
Pooled data of 6 studies on the use of antibiotic prophylaxis in prevention of wound infection after mesh inguinal hernia repair.



The number of deep infections in inguinal and femoral hernia repair was six in the placebo group (0.6%) and three in the antibiotic prophylaxis group (0.3%) with an OR of 0.50 (95% CI: 0.12-2.09) and NNT of 401. The pooled data of five studies (Morales data was not available) is presented in figure 2.

Figure 2

Pooled data of 5 studies (Morales data not available) on the use of antibiotic prophylaxis in prevention of deep wound infection after mesh inguinal hernia repair.



Discussion

In this systematic review on the effectiveness of antibiotic prophylaxis in abdominal wall hernia mesh repair the six RCT's concerning groin hernia lead to valuable conclusions whereas the yield for other abdominal wall hernia's was disappointing.

For groin hernia the reported rate of wound infection (2.2%) after mesh repair in RCT is not higher than the percentage after conventional sutured repair[9] (4.3%). Since the use of antibiotics is not likely to increase the percentage of wound infection the net effect of studies designed as those that were included will almost always be zero or in favor of the patients receiving prophylaxis and therefore on the left (favours antibiotic) side of the forest plot. The meta-analysis of 6 studies on the use of antibiotic prophylaxis in prevention of wound infection after mesh groin hernia repair does not favor the use of antibiotic prophylaxis OR of 0.54 (95% CI: 0.24-1.21) and NNT 74.

An infection percentage in low-risk patients, undergoing clean inguinal or femoral hernia surgery lasting less than one hour, should be below 2%[27]. And therefore the question should be: 'should we administer antibiotics to all patients undergoing clean surgery to spare a few (sometimes a very few) superficial wound infections?[28] Because superficial infections require a relatively simple treatment of wound drainage frequently combined with antibiotics and since the rare deep infections result in a low number of mesh removal (0.09%[29] -1.1%[20]) with remarkable seldom recurrence of the hernia there remains no routine indication for antibiotic prophylaxis in low-risk patients. Discarding the use of antibiotic prophylaxis in hernia repair could reduce the risks of toxic and allergic side effects, the possible development of bacterial resistance[14] or superinfections and will reduce costs.

If patient or surgical characteristics[27] however prove the existence of a much higher percentage of wound infection as demonstrated by two of the inguinal hernia studies the use of antibiotic prophylaxis could be reevaluated. In the trials with high wound infection percentages two striking differences can be seen: the duration of surgery is 1.5 times longer (64 minutes) and drains were used more often (22%), both known risk factors for infection.[27,30]

This review shows the lack of randomized studies in laparoscopic, incisional and other abdominal wall hernia repairs on the subject of wound infection. The only laparoscopic inguinal hernia (TAPP) repair study discussed 80 patients without proper randomization (alternately) but demonstrated no infections. This study virtually excludes the presence of a high percentage of wound infection in laparoscopic repair. There is some logic in this low infection rate since the minimal invasive approach consists of small and occluded incisions although there is an average of 18 minutes longer operation time compared with an open repair.[31] Considering these aspects and as long as hard evidence is lacking it is probably acceptable to conclude that in laparoscopic inguinal hernia repair no antibiotic prophylaxis is needed.

The infection rate is significantly higher in incisional hernia repairs than in inguinal. The larger wounds require more dissection and frequently demand entry in to the peritoneal cavity and thereby leading to a higher risk of bacterial contamination. Also the higher risk of seroma and haematoma formation dictates the use of drains augmenting the chance of contamination of the prostethic material.[30] The few clinical controlled trials addressing this subject are all biased because of inadequate or no randomization. The study of Abramov[17] demonstrated a reduction of wound infection after umbilical and incisional repair with antibiotic prophylaxis even when only 23% was corrected with mesh. A non randomized study of Rios[32] reported a reduction of wound infection in 216 patients with incisional hernia from 18.1% towards 13.6% with the use of antibiotic prophylaxis. Formally it has to be concluded that there is no evidence on the use of antibiotic prophylaxis in incisional hernia repair. Therefore placebo controlled trials should be performed in this area but it can be postulated that the therapeutic effect should rather be investigated in trials with randomization between a single dose and several days of antibiotics.

We do not think that we missed important publications in our thorough search of the literature and by our contacts with authorities in the field. It is difficult to assess the possibility of publication bias, resulting in leaving out the studies that showed no effect of antibiotic prophylaxis for the procedures included in our analysis. However, if publication bias exists, the effect of antibiotic prophylaxis would be even more modest than we found in our meta-analysis, as failure to include the grey literature has been reported to overestimate a treatment effect with 15%[33].

From this systematic review it can be concluded that there is no indication for routine antibiotic prophylaxis (especially in low risk patients) in groin mesh hernia repair. For mesh repair of small other abdominal wall hernia's like umbilical and epigastric hernia possibly the same conclusion can be drawn from the results concerning groin hernia mesh repair. For incisional hernia mesh repair there is insufficient evidence from RCT's to draw conclusions but infection rates in non-randomized studies are relatively high and therefore it is recommended to give an antibiotic prophylaxis in awaitance of further studies.

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Als het niet gaat zoals het moet, dan moet

het maar zoals het gaat.

Dr H. Kroes

Complications after Lichtenstein inguinal hernia repair

A comparison of teaching and non teaching hospitals

Chapter 7

Th.J. Aufenacker | D. van Geldere | E. Scheijde | J.W. Juttmann | D.J. Gouma | M.P. Simons

British Journal of Surgery Submitted

Abstract

Background: Considering the relative low incidence of recurrence in inguinal hernia surgery the focus has in recent years shifted from the prevention of recurrence towards the prevention of other complications like postoperative persisting or chronic pain.

Objective: The aim of this prospective cohort study was to identify the prevalence of recurrence but in particular other (long term) complications after Lichtenstein repair and to compare the results of teaching and non teaching hospitals. The main questions were: Is it possible to safely perform the Lichtenstein inguinal hernia repair in a teaching hospital where most operations are performed by (supervised) residents?

Methods: Three non teaching and one teaching general hospital participated in this prospective cohort study. 282 patients were asked to visit the outpatient clinic 4 years after surgery for a standardized medical history, standardized questionnaires and physical examination. To measure the quality of life the short-form 36 was used. To properly quantify the level of pain, patients were asked to fill in chronic pain grade questionnaires (SF-MPQ and von Korff).

Results: The follow-up was 90.1% (254 patients).The operations in the teaching hospital took significantly more time(1.5x, p<0.001). There were 4 recurrences (1.6%) without difference between the hospital types. There was a significant difference regarding certain aspects of pain 4 years postoperatively in favour of non teaching hospitals. At physical examination the pain was significantly more severe while pressing the pubic tubercle 45/111(41%) vs. 36/143 (25%), P< 0.01 in patients operated in the teaching hospital. Although these patients had more pain 4 years after surgery their activities measured by SF-36 and chronic pain grade questionnaire were not significantly influenced.

Conclusion: The patients from the teaching hospital report significantly more often pain while pressing the pubic tubercle probably due to the medial fixation of the mesh and damage to the periosteum. More attention should be given to the training aspect regarding the medial overlap and fixation of the mesh in Lichtenstein inguinal hernia repair. The overall study results are comparable to the literature from general surgical clinics.

Introduction

Since mesh repair techniques demonstrate low recurrence rates (<3%) the focus in inguinal hernia research has in recent years shifted from the prevention of recurrence towards the prevention of other complications like postoperative persisting or chronic pain. Chronic pain after herniotomy has primarily been assumed to be of neuropathic origin and may be as high as 5- 30%.[1-5] Several studies have tried to standardize the documentation[6] or present an evidence based treatment[7] of chronic neuropathic pain. Still there is much debate about the incidence and little is known about the causes. The use of mesh was suggested to be a factor in postoperative pain but several studies contradict this statement[8,9] and some studies even suggest the opposite.[10] Also the impact of elective transection of the ilioinguinal nerve was assessed but this made no difference.[11,12] Another possible factor is the level of expertise of the surgeon. One study has demonstrated a correlation between experience (resident post graduate year) and recurrence.[13] On the topic of pain however this has not been analyzed before. The aim of this prospective cohort study was to identify the prevalence of (long term) complications and to compare these between teaching and non teaching hospitals. The main focus was on reoperations, recurrence and the influence of chronic pain on the quality of life. The main question was: How are the results of the Lichtenstein inguinal hernia repair in a teaching hospital, where most operations are performed by (supervised) residents, compared to the results from non teaching hospitals where most operations are performed by board certified surgeons?

Patients and methods

Between 1998 and 2003 one thousand and forty patients were randomized in the Lichtenstein Antibiotics Trial (LAT).[14] This multi-centre double-blind randomized controlled trial was performed to determine the role of antibiotic prophylaxis in the prevention of wound infections after Lichtenstein hernia repair. It was concluded that the use of antibiotic prophylaxis was not indicated in low risk patients.[14]

One teaching and three non teaching general district hospitals participated in this prospective cohort study. For the present study all patients operated in 2000 and selected from the previous mentioned trial (LAT) [14] were invited to participate. A total of 282 patients were requested to visit to the outpatient clinic in October and November 2004 to fill in questionnaires and to undergo a physical examination. The year 2000 was chosen as this was the first year that all participating hospitals were including patients at "maximum" speed and to obtain a long follow-up.

Characteristics of the patients

Patients were recruited from the LAT[14] and were randomized between an antibiotic and placebo group. In short: All patients had a primary uni- or bilateral inguinal hernia and a Lichtenstein hernia repair was performed in the year 2000. In the LAT patients, the following exclusion criteria were used: age under 35, the need for antibiotics for a different reason, immunosuppressive disease (diabetes mellitus, malignancy, HIV) or medication (glucocorticoid therapy), allergy to the given antibiotic, recurrent hernia or the inability to get an informed consent.

Surgical technique and antibiotic prophylaxis

The operations were performed either by a board certified surgeon or a (supervised) resident. In short: the groin of the patient was shaved just before or in the operating theatre. A standard Lichtenstein hernia repair was performed as described by surgeons from the Lichtenstein Hernia Institute.[15,16] Two surgeons with a special interest in hernia surgery educated the participating hospitals in the standard technique. A monofilament polypropylene flat mesh (Bard ® or Autosuture ®) was sutured in place with monofilament polypropylene suture (Prolene). Anaesthesia and skin closure were not standardized.

The trial medication consisted of either 50 ml sterile saline (placebo) or 50 ml sterile saline with 1500 mg Cefuroxim (2nd generation cephalosporin). The anaesthesiologist administered the trial medication at the induction of anaesthesia.

Data collection

Data collection of patients participating in the present study was performed by the main investigator (TA) during on site visits in the participating hospitals. The patients were requested to return to the outpatient clinic for a standardized history taking, standardized questionnaires and physical examination. The patients' charts were also available for analysis. In case patients refused to visit the hospital they were contacted and a postal questionnaire combined with a standardized telephone interview was performed.

Outcome measures

A hernia recurrence was defined as an inguinal or femoral swelling in the previously operated groin with or without Valsalva manoeuvre or a weakness in the groin area. Mesh abnormalities (folding, wrinkling, knots) were registered if present. Neuropathic pain (neuralgia) was considered when paresthesia, dysesthesia or hyperalgesia were present with partial or complete loss of sensation in skin areas innervated by the iliohypogastric nerve, the ilioinguinal nerve, or the genital and femoral branches of the genitofemoral nerve. The nociceptive pain (somatic, related to tissue injury) was documented when present which is located in the area around the scar and commonly localized on the common ligamentous insertion to the pubic tubercle. Also testicular atrophy was documented when present. The sensory functions in the area were tested by comparing the operated with the non operated side or in case of a bilateral hernia a dermal region nearby.

For persisting pain a visual analogue scale (VAS) was used with a range of 0 (best score) to 100 (worst score). The use of analgesics was documented. The exact location of pain in rest and with compression of the operated area was documented using an anatomical chart. Several questions were asked about the intensity and the impact of the pain and if the patient suspected a recurrent hernia. To measure the quality of life the short-form 36 was used. Patients were asked to fill in the short-form Mc Gill pain questionnaire (SF-MPQ)[17] and the chronic pain grade questionnaire (von Korff)[18] to properly quantify the level of pain if they reported any pain.

Statistical analysis

If data were normally distributed the mean (± SD) is used; in non-Gaussian data the median (25%-75 or 90% quartiles) was selected. The data were analyzed using the chi-square test with Fisher's exact test where appropriate. The Mann-Whitney U test was used to compare two independent samples. A p-value of 0.05 was considered to be significant.

Results

282 patients underwent their operation in the year 2000 Extensive attempts to contact all patients were performed resulting in a response rate of 90.1% (254 patients) divided over both hospital types according to table 1. Four years after the operation 28 patients (9.9%) could not be reached for the following reasons: twelve were deceased, twelve were lost to follow-up, two suffered from dementia, one refused further cooperation and one appeared to have an incisional hernia during surgery instead of an inguinal hernia. Of the 254 patients 44 (17.3%) refused to visit the outpatient clinic and a postal questionnaire combined with a standardized telephone interview was performed. The surgical findings, patient and hernia characteristics divided between the teaching and non teaching hospitals are shown in table 1.

The significant differences on the points of perioperative marcaine block, operations performed in day surgery and nerve division are explained by local habits of the teaching hospital. The operations in the teaching hospital took significantly longer (1.5x, $p<0.001$) but were performed through significantly shorter incisions.

Postoperative short-term complications in need of an intervention occurred in 10 (3.9%) patients. In table 2 complications during the three months follow-up are shown. There were no significant differences between teaching and non teaching hospitals on this subject.

Table 1

Patient characteristics and hernia types of 254 patients divided between teaching and non teaching hospitals.

Number of actual responders		Teaching Hospital n=111	Non teaching Hospitals n= 143	Total n=254
Age – Yr (mean ± SD)		57.5 ± 12.3	58.3 ± 11.2	57.9 ± 11.7
Sex - Male (%)		104 (93.7)	138 (96.5)	242 (95.3)
Preoperative painful hernia No (%)		81 (73.0)	98 (68.5)	179 (70.5)
VAS median (25-75% quartiles)		31 (0-60)	25 (0-50)	25 (0-50)
Operations in day surgery No (%)		80 (72.1)*	29 (20.3)*	109 (42.9)
Level of surgical expertise- No (%)				
Certified Surgeon		10 (9.0)*	136 (95.2)*	146 (57.5)
Resident with surgeon		88 (79.3)*	7 (4.8)*	95 (37.4)
Unsupervised resident		13 (11.7)*	0*	13 (5.1)
Anaesthesia – No (%)	Local	2 (1.8)	0	2 (0.8)
	Spinal	50 (45.0)	77 (53.8)	127 (50.0)
	General	59 (53.2)	66 (46.2)	125 (49.2)
Hernia type - No (%)	Direct	43 (38.7)	58 (40.6)	101 (39.8)
	Indirect	50 (45.0)	64 (44.8)	114 (44.9)
	Combined	18 (16.2)	21 (14.7)	39 (15.3)
Bilateral hernia - No (%)		4 (3.6)	7 (4.9)	11 (4.3)
Documented nerve division -No(%)				
	Ilioinguinal	16 (14.4)*	2 (1.4)*	18 (7.1)
	Iliohypogastric	8 (7.2)†	1 (0.7)†	9 (3.5)
	Genitofemoral	4 (3.6)†	0†	4 (1.6)
Perioperative Marcaine block No(%)		53 (47.7)*	0*	53 (20.9)
Drains – No (%)		2 (1.8)	3 (2.1)	5 (2.0)
Duration of surgery – Min. Median (25%-75% quartiles)		45 (40-60)‡	28 (24-40)‡	36 (25-45)
Incision length – Cm. Median (25%-75% quartiles)		7.0 (6.8-8.0)‡	8.0 (8.0-9.0)‡	8.0 (7.0-9.0)
Blood loss – ml Median (25%-75% quartiles)		3.0 (0-10)•	8.0 (0-15)•	3.0 (0-11)

* Chi-square significant (p<0.0001),† Chi-square significant (p<0.01), ‡ Mann-Whitney U test (p<0.0001),
• Mann-Whitney U test (p<0.03).

Table 2

The short-term postoperative complications and follow-up of 254 patients divided between teaching and non teaching hospitals.

	Teaching hospital n= 111	Non teaching hospitals n = 143	p-value χ^2
Reoperation No (%)			
Postoperative bleeding	0	1 (0.7)	0.564*
Orchidectomie	0	1 (0.7)	0.564*
Wound infection –No (%)			
Superficial	1 (0.9)	2 (1.4)	0.594*
Deep	0	0	-
Bladder retention – No (%)	0	2 (1.4)	0.316*
Percutaneous drainage of seroma - No (%)	1 (0.9)	2 (1.4)	0.594*
Total of complications with intervention - No	2 (1.8)	8 (5.6)	0.110*
Follow-up one week – No (%)			
Pain	28 (25.2)	24 (16.8)	0.098
Swelling	56 (50.5)	83 (58.0)	0.228
Haematoma	26 (23.4)	29 (20.3)	0.546
Follow-up two weeks– No (%)			
Pain	10 (9.0)	14 (9.8)	0.833
Swelling	38 (34.2)	45 (31.5)	0.641
Haematoma	9 (8.1)	8 (5.6)	0.427
Follow-up three months – No (%)			
Pain	9 (8.1)	6 (4.2)	0.190

* Chi-square (fisher's exact)

The long-term follow up (four years postoperatively) concerning recurrence, pain, sensory disturbance and patient satisfaction is shown in table 3. There was no significant difference in recurrence rate (1,6%). Four patients thought the hernia recurred but only one of these patients had an actual recurrence at physical examination. The four patients with a recurrence were not motivated for a second operation and were asymptomatic in three cases. The recurrence was presumably direct in two cases (operated by the same resident) in the teaching hospital and indirect in the non teaching hospital. One patient in the teaching hospital was re-operated because of a suspected recurrence but during the endoscopic procedure no recurrence but a lipoma of the cord was found. There was a significant difference ($p=0.04$, Mann-Whitney U test) concerning the pain four years postoperatively disadvantageous to patients from the teaching hospital even though the median was similar. Pain perception was mainly different during coughing and standing up. At physical examination the pain was significantly more severe while pressing the pubic tubercle in patients operated in the teaching hospital. Two patients from this hospital had pain on the lateral side of the mesh where the two tails of the mesh were wrinkled and palpable.

In thirteen patients (5.1%) there was partial or total sensory disturbance involving the ilioinguinal, iliohypogastric or genitofemoral nerve. Of this group only two patients had a documented division of the involved nerve. The other 29 patients with documented nerve division had no sensory disturbances in the area of the involved nerves. Patients with a documented division of the nerve did not report more pain. Three patients reported hyperalgesia in the groin; none of them had a documented division of a nerve. Two patients (one from each hospital type) were reoperated because of chronic pain complaints, one in 2002 exploration with division of the ilioinguinal nerve and one in 2005 triple neurectomy, both reported reduced pain after the second operation.

Table 3

The long-term (4 yrs) postoperative complications of 254 patients divided between teaching and non teaching hospitals.

		Teaching hospital n= 111	Non teaching hospitals n = 143	p-value χ^2
Physical examination at outpatient clinic – No (%)		94 (84.7)	116 (81.1)	0.456
Recurrence– No (%)		2 (1.8)	2 (1.4)	0.589*
Testicular atrophy– No (%)		0	1 (0.7)	0.563*
Mesh wrinkled or palpable cranial stitch– No (%)		8 (7.2)	11 (7.7)	0.884
Pain score preoperatively				
Number with pain– No (%)		81 (73.0)	98 (68.5)	0.441
VAS median (25-90% quartiles)		31 (0-75)	25 (0-66)	0.100‡
Pain score (resting) 4 yrs postoperatively				
Number with pain– No (%)		21 (18.9)	13 (9.1)	0.023
VAS median (25-90% quartiles)		0 (0-20)	0 (0-5)	0.038‡
Frequency of Pain 4 yrs postoperatively– No (%)				
Never painful		82 (73.9)	100 (69.9)	0.489
Sometimes		22 (19.8)	41 (28.7)	0.105
Frequently		3 (2.7)	0	0.082*
Always		3 (2.7)	2 (1.4)	0.382*
Some level of pain during– No (%)				
Resting		7 (6.3)	6 (4.2)	0.449
Coughing		10 (9.0)	2 (1.4)	0.005*
Standing up		9 (8.1)	2 (1.4)	0.009*
Weight lifting		18 (16.2)	18 (12.6)	0.411
sports activities		16 (14.4)	11 (7.7)	0.085
Pain location on physical exam				
Pain pressing pubic tubercle– No (%)		45 (40.5)	36 (25.2)	0.009
VAS median (25-90% quartiles)		0 (0-36)	0 (0-15)	0.001‡
Pain pressing Poupart's Ligament– No (%)		17 (15.3)	22 (15.4)	0.988
VAS median (25-90% quartiles)		0 (0-10)	0 (0-10)	0.661‡
Physical exam (sensory) – No (%)				
Reduced sensory function	On the scar	17 (15.3)	28 (19.6)	0.377
	Below the scar	26 (23.4)	10 (7.0)	0.001
Absent sensory function	On the scar	1 (0.9)	2 (1.4)	0.594*
	Below the scar	1 (0.9)	1 (0.7)	0.684*
Sensory disturbance associated with nerves– No(%)				
Ilioinguinal		2 (1.8)	1 (0.7)	0.406*
Iliohypogastric		5 (4.5)	2 (1.4)	0.133*
Genitofemoral		2 (1.8)	1 (0.7)	0.406*
Satisfied with the operation result– No (%)		100 (90.1)	135 (94.4)	0.195
Wants the operation performed in the same way		104 (93.7)	134 (93.7)	0.997

* Chi-square (fisher's exact), ‡ Mann-Whitney U test.

Further parameters for the assessment of the chronic post-herniorrhaphy pain including the pain scores and SF-36 are documented in table 4. The sixty patients (23.6%) without pain before the operation did not develop any long term pain in rest but six (10%) reported having sometimes pain. Almost 80 percent of patients with pain before the operation did not have any pain in rest after the operation; the mean reduction in VAS score was 37.8 points.
Although the patients operated in the teaching hospital had more pain four years after surgery, their activities were not significantly influenced. This is supported by the von Korff pain score. All patients with pain after surgery scored grade 1(Low disability low intensity). When looking at the sub scores for pain intensity and disability score the first showed a significant difference, the latter did not. The short form Mc Gill pain questionnaire (SF-MPQ) demonstrated significant differences in pain experience on the present pain, overall pain intensity and total score disadvantageous to patients from the teaching hospital. The overall mean pain experience (10% SF-MPQ) corresponds with the pain intensity documented by patients with rheumatoid arthritis. The SF-36 with its eight domains and two component scores showed no significant differences between the two groups of patients. The three most important scores in this setting are demonstrated in table 4. When comparing the scores with normative data of Dutch patients (age range 46-55) more points in the post surgery group were scored on the subjects: role physical, bodily pain and role emotional. (Respectively 8, 11, 5 points) The other scores were similar.

Table 4

Parameters for the assessment of the chronic post-herniorrhaphy pain of 254 patients divided between teaching and non teaching hospitals.

		Teaching hospital n= 111	Non teaching hospitals n = 143	p-value χ^2
Pain score (resting) 4 yrs postoperatively				
	Number with pain– No (%)	21 (18.9)	13 (9.1)	0.023
	VAS median (25-90% quartiles)	0 (0-20)	0 (0-5)	0.038‡
In need of pain medication? – No (%)		3 (2.7)	0	0.082*
Pain elsewhere in your body? – No (%)		38 (34.2)	41 (28.7)	0.342
When did the groin pain start? – months				
	median (25-75% quartiles)	2 (0-12)	3 (0-17)	0.953‡
The pain is similar or worse after surgery – No (%)		5 (4.5)	1 (0.7)	0.059*
Pain originating from– No (%)	Scar	11 (9.9)	15 (10.5)	0.880
	Testis	6 (5.4)	7 (4.9)	0.855
	Pubic Tubercle	9 (8.1)	6 (4.2)	0.190
	Radiating	6 (5.4)	5 (3.5)	0.458
	During orgasm	6 (5.4)	2 (1.4)	0.074*
Does the pain stand in the way of activities?No(%)				
	Yes, working	1 (0.9)	1 (0.7)	0.684*
	Yes, hobbies	0	1 (0.7)	0.563*
	Yes, rising from low chair	2 (1.8)	1 (0.7)	0.406*
	Yes, sitting down > 30 min	1 (0.9)	2 (1.4)	0.594*
	Yes, standing up >30 min	1 (0.9)	2 (1.4)	0.594*
	Yes, walking on stairs	0	1 (0.7)	0.563*
	Yes, shopping	0	1 (0.7)	0.563*
	Yes, driving a car	1 (0.9)	2 (1.4)	0.594*
	Yes, travelling by bus or train	0	1 (0.7)	0.563*
	Yes, daily activities	5 (4.5)	3 (2.1)	0.232*
	Yes, sport activities	8 (7.2)	5 (3.5)	0.183
Mc Gill pain questionnaire	Sensory pain	3 (2-6)	2 (1-3)	0.058‡
median (25-75% quartiles)	Affective pain	0 (0-2)	0 (0-1)	0.654‡
	Present Pain	0 (0-16)	0(0-0)	0.005‡
	Overall pain intensity	1 (1-2)	1 (0-1)	0.031‡
	Total score Percentage	10.0 (7-20)	7.5 (3-11)	0.016‡
Chronic pain grade questionnaire (von Korff)				
Grade 1 Low disability low intensity– No (%)		25 (22.5)	38 (26.6)	0.458
	Sub scores pain intensity			
	median (25-75% quartiles)	16.7 (9-29)	7.0 (3-18)	0.004‡
	Sub scores disability score			
	median (25-75% quartiles)	0 (0-10)	0 (0-0)	0.098‡
Quality of life (SF-36)	Bodily pain	81.8 ± 22.1	84.3 ± 19.4	0.534‡
Mean ± SD	Physical component score	50.6 ± 9.5	51.5 ± 8.5	0.337‡
	Mental component score	49.7 ± 9.4	50.4 ± 9.3	0.249‡

* Chi-square (fisher's exact), ‡ Mann-Whitney U test.

Discussion

In this study of 254 inguinal hernia patients repaired with the Lichtenstein technique performed in one teaching and three non teaching hospitals good results with low recurrence rates and relatively low pain scores are presented. Operative time in the teaching hospital was significantly longer (1.5x) which is not surprising and a known factor in the cost of surgical education.[19] The short-term postoperative complications are not significantly different between the two hospital types and reflect the data in the literature. Remarkably when compared with the long-term follow-up the pain after three months is also not different for the two groups. The most important aim of this study was the long-term follow up. The recurrence rate presented (1.6%) is according to the international literature. In specialized centres the recurrence rates with open mesh repairs are 0.5%[20] or less and in the hands of general surgeons the percentage in open mesh repair is 1.1%.[10] But these data are reported with various and relative short follow-up and almost all below the four years interval of the present study. When comparing these results with scarce available data partly involving mesh repairs with comparable long term follow-up and physical examination for identification of recurrence the results are good.[21] The recurrence rate after inguinal hernia surgery in the teaching hospital (1.8%) has dramatically improved when compared to data from a randomized study[22] published in 1996 from the same hospital reporting higher recurrences rates both after Shouldice repair (5.7%) and after Bassini (10.6%) after only two years follow-up. This improvement can be explained by the increased attention for training and the use of mesh. There is no significant difference between the two hospital types regarding recurrence rates. Twice as many patients (18.9%) reported pain in the teaching hospital when comparing this with the non teaching hospitals (9.1%) this is highly significant higher ($p = 0.023$). The percentage of the complete study group is 13.4% and is within the wide range reported in literature.[1-5] Fortunately most of these patients report having their pain only sometimes and in specific situations and it can probably be classified as mild chronic discomfort. Unfortunately 3.1% of patients have frequent or permanent pain which influences their daily or sports activities. This percentage is not different between hospital types and in concordance with the literature.[3,23] The question is why do patients report more pain in the teaching hospitals and does this influence their daily life? During physical examination the sensory function is not different between the two groups. Remarkably the sensory function is frequently normal or slightly reduced even if one or more of the involved nerves are transected. Patients from the teaching hospital report significantly more pain while pressing the pubic tubercle (41% vs 25%, $P < 0.01$) and the VAS score while pressing is significantly higher. Almost always this correlates with their reported pain location. This probably is due to the medial fixation of the mesh by a deep stitch through the periosteum which is a long known factor of pain[16]. This part of the operation is difficult to supervise since the supervising surgeon usually stands on the other

side of the patient and strongly dependents of the operating residents experience. The same problem has been reported on the subject of recurrence where also the medial overlap is difficult to supervise.[13] The pain is no reason for patients in teaching hospitals to use more analgetics nor does it reduce their activities. This is supported by von Korff's chronic pain grade questionnaire where patients indeed report more pain in teaching hospitals but the disability score is not different. The Mc Gill pain questionnaire also supports the higher pain levels in teaching hospitals. The quality of life measured by means of SF-36 is not different between the two hospital types.

In this prospective study the surgeon's expertise (resident versus surgeon) was not randomized and therefore the best level of evidence was not reached. One can however predict that such a study is difficult to perform with complete informed consent. The same statement can be made about the randomisation between expert surgeons and general surgeons. So probably this is the best evidence possible on this subject. Also a potential bias is formed by comparing a population of patients from a large city (Amsterdam) with people from the country side but although patients from the city reported more preoperative pain this was not significant and is not likely to explain the differences postoperatively. It can be concluded that the results in the four hospitals are in the range of the results in dedicated centres and also comparable with the literature from general practice. Therefore it might be concluded that good results in hernia surgery can also be obtained in a teaching hospital. In the teaching hospital much attention is given to theory and skills training and almost 80% of operations are performed by residents under supervision. In this study the training of residents does influence the hernia repair on the subject of pain on the pubic tubercle but this does not influence the recurrence rates, patient's performance or his satisfaction with the operative results. The pain topic remains a challenge with little evidence on the diagnostic process and treatment but it is safe to conclude that a good operation technique is essential. We suggest even more attention to the training aspect regarding the medial overlap and fixation of the mesh in Lichtenstein inguinal hernia repair.

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Als we wisten wat we deden, heette het

geen onderzoek.

Albert Einstein

What is the quality of an unfunded multicenter randomized trial in general hospitals? An audit.

Chapter 8

Th.J. Aufenacker | J. Bannenberg | D. van Geldere | E. Scheijde | J.W. Juttmann | D.J. Gouma en M.P. Simons

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Abstract

Objective: To determine whether a randomized clinical trial in general hospitals can be performed in a reliable way without financial support.

Methods: The Lichtenstein Antibiotic Trial performed in 4 hospitals between 1998-2003 was analyzed. The results state that antibiotic prophylaxis is not indicated in low-risk patients during inguinal hernia surgery. This audit analyzed the patient charts and study forms of 98 random patients on several quality criteria and was performed by independent researchers.

Results: In all participating clinics approval of the MEC was obtained. From 63/98 (64%) of patients a proper informed consent was acquired. The last (third) follow-up was missed in 23/98 (23%) audit patients. These patients were contacted by telephone which was successful in 98% of cases. The documentation of data in patient charts and at the same time in the study forms was successful in 90% of the, during the operation used, randomisation forms and in 75% of the follow-up registration forms. The trial protocol was pursued on almost every point.

Conclusion: This audit demonstrates a number of flaws which appeared more frequently than expected. Due to a relative simple study objective, the simplicity of the study endpoint and many accessory efforts adjacent to the protocol the study's crucial data could be gathered and an adequate conclusion drawn. In a study with a more complex objective this could not have been the case. Therefore it is almost impossible to perform a reliable unfunded multicenter randomized trial with a complex objective.

'Evidence based medicine' is nowadays a solid base for good clinical practise and several aspects have been highlighted in the past.[1,2] The randomized controlled trial (RCT) is one of the best methods for answering clinical questions about diagnostics, therapy and prognosis. Usually a good RCT must include several hundreds of patients to reach adequate power. Performing a large RCT is not easy and often mustfrequently has to be performed in a multicenter setting to include the patient within a reasonable time. The protocol must be reviewed and approved by a medical ethical committee (MEC). Furthermore firm regulations must be followed when performing RCT for example 'good clinical practice' (GCP) for clinical research on medication and ISO14155 for research on clinical instruments.

Correct documentation of study methods, data processing and results in an article is performed according to the CONSORT statement[3] and is based on the original data of the RCT. The correctness and completeness of these original data is essential. Safe guarding the correct *execution* of a trial and implementing the various regulations takes more and more time and attention.

It is because of these points that a good RCT almost always needs support of a study coordinator who constantly protects the quality of the trial and adequately processes the data.

Many studies nowadays are supported by fulltime researchers and/or research agencies with special scientific skills and they ensure the quality and completeness of the data source. In this article the quality of an unfounded prospective randomized multicenter trial is analyzed by a research agency (Factory, CRO for medical devices) specialized in managing clinical studies.

The study under evaluation was performed in four general hospitals by doctors performing science as a supplement to their daily patient related work. In none of the hospitals researchers were available with structural time to check the data and preserve the quality. All follow-up of the patients was performed during regular consulting hours by a group of surgeons and residents. The question for this audit was: can an unfunded randomized clinical trial be performed in a general hospital with the essential quality?

Patients and methods

Study characteristics and results

The original study (Lichtenstein Antibiotics Trial) was performed in four general Dutch hospitals (one teaching hospital, three at that time nonteaching hospitals) between 1998-2003.[4] The study was double blind, randomized and involved 1040 patients undergoing Lichtenstein inguinal hernia repair[5] (correction with a polypropylene mesh, first choice according to the Dutch Gguidelines on inguinal hernia repair).[6] Patients were randomized between a single dose of antibiotics (1500 mg Cefuroxim) and placebo to analyse the effect on the prevention of wound infections. Primary endpoint was the percentage wound infections within three months after surgery. There were eight infections (1.6%) in the antibiotics group and nine (1.8%) in the placebo group (p=0.82). Statistical analysis revealed an absolute risk reduction (ARR) of 0.19% (95% CI: -1.78%-1.40%) and a 'number needed to treat' (NNT) of 520 for the total number of infections. The results show that antibiotic prophylaxis is not indicated in Lichtenstein inguinal hernia repair involving low-risk patients.

Audit description

The data for this audit was collected by three researchers from the independent research agency in the years 2001, 2002 en 2003 during on site visits of the four hospitals involved. The patients, around 26 per hospital, were selected from the total population of patients in each hospital by the researchers. During the audit the official patient records and study forms of included patients were compared. The quality criteria analyzed are displayed in table 1.

Table 1

Analyzed quality criteria on behalf of the audit of the Lichtenstein Antibiotics Trial.

1. Is the study approved by the medical ethical committee (MEC)?
2. Does the 'case report form' (CRF) correspond with the protocol?
3. Is the informed consent form signed by the included patients?
4. How accurate was the follow-up of patients one week, two weeks and three months postoperatively?
5. How precise and complete is the registration on the CRF's?
6. Does the researcher in the participating hospital adhere to the protocol?

Each case report form (CRF), the registration form for the trial data, was checked on the various pages for missing data. The data needed for final results like the randomisation form with perioperative data including the randomisation code and the postoperative follow-up registration after 1, 2 weeks and three months was controlled. The exact date of each postoperative follow-up was documented and compared with the planned date according to the protocol. In the protocol no time interval was defined for the follow-up only a single date was given. The most important goal of the CRF is to record the endpoint described in the protocol. In this study the occurrence of an infection within three months postoperatively was the endpoint. The infection criteria were defined by the centres for disease control (CDC).[7] An occurring wound infection was classified as superficial or deep according to criteria implemented in the CRF. The data in the original patient charts were also compared to the CRF. Everything registered on the CRF should also be documented in the patient charts. This is called source data verification.

Results

1. Is the study approved by the medical ethical committee (MEC)?
   In al participating clinics approval was given before the start of the study. The report on this was not always available during the visit of the auditors.
2. Does the 'case report form' (CRF) correspond with the protocol?
   In all 4 hospitals the same CRF's are used as described in the protocol. On this CRF the infection criteria are registered according to a list of questions. The interpretation of the answers is not registered on the CRF.
3. Is the informed consent form signed by the included patients?
   Table 2 reports the number of analyzed patients and the quality of the informed consent forms. The total sample size was 105 (11%) of the 940 at that time included patients. The patients were selected by the auditors. Because of study exclusion (7) 98 patients were found suited for the audit. The study exclusion varied between the different clinics but was in line with the data from the complete study. From 63/98 (64%) of the patients a proper informed consent could be found. The other forms were incomplete or empty.

Table 2

Data from the audit of the Lichtenstein Antibiotics Trial regarding the number of patients analyzed and the quality of the informed consent.

	Hospital 1	Hospital 2	Hospital 3	Hospital 4	Complete Audit	Complete Study
Number of patients included when the audit was performed.	300	140	123	377	940	940/1040
Size of the audit sample.	28/300 (9%)	28/140 (20%)	24/123 (20%)	25/377 (7%)	105	105/940 (11%)
Patients excluded from the study						
Did not receive trial medication	1/28 (4%)	2/28 (7%)	0 (0%)	1/25 (4%)	4/105 (4%)	50/1040 (5%)
No mesh repair	0 (0%)	1/28 (4%)	0 (0%)	0 (0%)	1/105 (1%)	4/1040 (0,4%)
No operation	0 (0%)	1/28 (4%)	0 (0%)	0 (0%)	1/105 (1%)	13/1040 (1%)
Patient withdrew informed consent	0 (0%)	1/28 (4%)	0 (0%)	0 (0%)	1/105 (1%)	12/1040 (1%)
Available and suited for analysis	27	23	24	24	98	-
Informed consent form						
Signed by patient	22/27 (81%)	21/23 (91%)	0/24 (0%)*	20/24 (83%)	63/98 (64%)	-
Signed date missing	4/27 (15%)	1/23 (4%)	0 (0%)	0 (0%)	5/98 (5%)	-
Form missing	1/27 (4%)	1/23 (4%)	24/24 (100%)*	0 (0%)	26/98 (27%)	-
Form not signed	0 (0%)	0 (0%)	0 (0%)	4/24 (17%)	4/98 (4%)	-
Total number of incomplete IC	5 /27 (19%)	2 (9%)	24 (100%)	4 (17%)	35 (36%)	-

* all patients were informed about the study, informed consent was only obtained by verbal agreement and was frequently (67%) noted in the patient charts.

4. How accurate was the follow-up of patients one week, two weeks and three months postoperatively?
   The accuracy on the follow-up time intervals is displayed in table 3. The defective follow-up in hospital three is striking. 10/24 (42%) of patients missed their 2nd and 3rd follow-up. They were instructed to come back in case of wound or groin alterations. The 3rd follow-up (after three months) was missed by 23/98 (23%) of the audit patients. In the complete study this was the case in 199/1040 (19%) of the patients. These 199 patients were then contacted by telephone which was successful in 195 (98%). The timing of the follow-up is good on average(8, 16 and 93 days). It is surprising to see the broad time interval of the third follow-up moment (90 days) since this control varies between 30 tot 240 days postoperatively. Most 1st and 2nd check-ups were correctly timed demonstrated by the reported mean and standard deviation (SD).

Table 3

Data from the audit of the Lichtenstein Antibiotics Trial concerning the accuracy of the follow-up time interval.

Size of the audit sample	Hospital 1	Hospital 2	Hospital 3	Hospital 4	Complete Audit
(number of patients)	28/300	28/140	24/123	25/377	105/940
Available and suited for analysis	27	23	24	24	98
Follow-up 7 days					
Number of days Average (± SD)	7,2 (± 1,1)	8,9 (± 1,7)	8,7 (± 3,1)	8,0 (± 1,1)	8,1 (± 2,0)
1st Follow-up missing	0/27 (0%)	1/23 (4%)	2/24 (8%)	0/24 (0%)	3/98 (3%)
Follow-up 14 days					
Number of days Average (± SD)	15,1 (± 2,8)	19,3 (± 5,6)	14,8 (± 1,3)	15,4 (± 2,1)	16,4 (± 4,1)
2nd Follow-up missing	3/27 (11%)	2/23 (9%)	20/24 (83%)	1/24 (4%)	26/98 (27%)
Follow-up 3 months (90 days)					
Number of days Average (± SD)	88,6 (± 4,1)	79,4 (± 47,4)	103,9 (± 19,6)	95,4 (± 18,8)	91,1 (± 26,7)
3rd Follow-up missing	2/27 (7%)	6/23 (26%)	10/24 (42%)	5/24 (21%)	23/98 (23%)

5. How accurate and complete is the registration on the CRF's?
   The precision accuracy of the registration on the CRF's is reported in table 4. The relevant data needed to judge whether or not an infection was present was almost always correctly noted on the CRF. For source data verification this data should be documented on the CRF and in the patient chart. On this point 90% of randomisation forms and 75% of follow-up forms were correctly filled in. In the other cases the relevant data was only registered on the CRF or sometimes only in the charts. In rare occasion there was a mismatch between the CRF and the chart. This was for instance the presence of swelling but this never compromised the conclusion about a possible infection.
6. Does the researcher in the participating hospital adhere to the protocol?
   The trial protocol was followed on nearly all points. Only in the third hospital the informed consent was not registered with a signature of the patient but a verbal consent was acquired and documented in the patients chart in 67% of cases. In all locations the correct version of the protocol with the corresponding CRF and informed consent were used.

Table 4

Data from the audit of the Lichtenstein Antibiotics Trial regarding the accuracy of the filled in case report forms (CRF's).

	Hospital 1	Hospital 2	Hospital 3	Hospital 4	Complete Audit
Size of the audit sample (number of patients)	28/300	28/140	24/123	25/377	105/940
Available and suited for analysis	27	23	24	24	98
Inclusion form					
Relevant data noted in chart and on CRF.	24/27 (89%)	22/23 (96)	23/24 (96%)	19/24 (79%)	88/98 (90%)
Relevant data only noted in chart.	3/27(11%)	1/23 (4%)	1/24 (4%)	5/24 (21%)	10/98 (10%)
Randomisation form*					
Relevant data noted in chart and on CRF.	27/27 (100%)	17/23 (74)	23/24 (96%)	21/24 (88%)	88/98 (90%)
Relevant data only noted on CRF or only in chart ‡	0/27 (0%)	2/23 (9%)	1/24 (4%)	3/24 (12%)	6/98 (6%)
Incision length and blood loss not documented	0/27 (0%)	4/23 (17%)	0/24 (0%)	0/24 (0%)	4/98 (4%)
Follow-up 7 days					
Relevant data noted in chart and on CRF.	21/27 (78%)	11/23 (48%)	22/24 (92)	15/24 (63%)	69/98 (70%)
Relevant data only noted on CRF or only in chart ‡	6/27 (22%)	11/23 (48%)	0/24 (0%)	9/24 (37%)	26/98 (27%)
1st Follow-up missing	0/27 (0%)	1/23 (4%)	2/24 (8%)	0/24 (0%)	3/98 (3%)
Follow-up 14 days					
Relevant data noted in chart and on CRF.	20/27 (74%)	9/23 (39%)	4/24 (17%)	21/24 (88%)	54/98 (55%)
CRF not used data only noted in chart‡	4/27 (15%)	12/23 (52%)	0/24 (0%)	2/24 (8%)	18/98 (18%)
2nd Follow-up missing	3/27 (11%)	2/23 (9%)	20/24 (83%)	1/24 (4%)	26/98 (27%)
Follow-up 3 months					
Relevant data noted in chart and on CRF.	19/27 (71%)	9/23 (39%)	14/24 (58%)	16/24 (67%)	58/98 (59%)
Relevant data only noted on CRF or only in chart ‡	6/27 (22%)	8/23 (35%)	0/24 (0%)	3/24 (12%)	17/98 (17%)
3rd Follow-up missing	2/27 (7%)	6/23 (26%)	10/24 (42%)	5/24 (21%)	23/98 (24%)

‡ Source data verification impossible.
* Incision length and length of surgery are frequently missing in the operation reports therefore source data verification is impossible on this point.

Discission

This audit analyzed 6 quality criteria of an unfunded multicenter randomized trial. For this purpose 105 patients were selected from the 940 patients participating at that time (11%). The audit is a snapshot to judge the quality of the source data essential for a scientific study.

In all reported cases the protocol corresponds with the CRF's and the MEC approved the study in all participating clinics. In one out of four hospitals the informed consent was verbally acquired after informing the patient according to protocol. The Dutch legislation (WMO)[8] demands however that patients participating in trials sign an informed consent form. In this case this rule was not followed and at least the verbal consent should have been noted in all charts. In this hospital this was only provided in 67% of cases. Also relatively many 2nd follow-up controls were missed in this clinic. Unfortunately the 3rd control (after 3 months) was not performed in 23 out of the 98 (23%) audit patients. In the complete study this was happened in 199/1040 (19%) patients.

This can lead to an observational error with an under registration of the infections. Fortunately other studies have shown that patients can reliable judge that a wound is not infected.[9,10] In this study the missing data was completed by a telephonic inquiry which was successful in 195/199 (98%) patients. The timing of follow-up demonstrated a wide interval especially for the third control. In the study protocol no time period for the follow-up was defined so by strictly adhering to the protocol all patients not follow-up on the exact day should be excluded from the analysis. But also on this point no data loss is registered because of the late follow-up. During patient selection, operation and follow-up the administration on patient chart and CRF should both be correct for proper source data verification according to good scientific research. In this audit this administration was complete in 90% of peroperative randomisation form and in 75% of the follow-up registration. This did not result in a reduced quality or different study results. The reason for the missing data can be found in the fact that all scientific work had to be done during routine work like visits to the outdoor patient clinic. Because the study was unfunded there was almost no time for on site visits, training and interim quality control of data. Of course the evidence based principles[11] were followed in this study. For instance "are the study groups double blind, randomized and correctly analyzed?", "are the study results relevant for clinical use and applicable for the own patient population?" These factors have not all been analyzed in the audit because the goal of this audit was to determine if the study was performed according to protocol and to verify the quality of the source data used for analysis. This audit display several shortcomings which occur more frequently than expected. Incomplete gathering of data is difficult to prevent without a study coordinator who can frequently verify the quality of follow-up and adherence to the protocol. In this study due to the relative simple endpoint and many extra efforts the crucial data could be gathered and an adequate conclusion reached. In studies with a more complex

objective this would not have been possible. In such a situation the study would probably not result in evidence based results or the study endpoints would not have been reached. We therefore conclude that for studies (especially RCT) the quality of the source data should be reported. Performing a data-audit by an independent organisation is only one of the ways this can be done. Only after this conditions is fulfilled a level 1B (RCT of good quality) score can be reached. When data gathering has to be flawless more time and therefore money is needed for careful monitoring of the study and strict discipline in every aspect of the protocol must be demonstrated. For studies like the one describe above the individual motivation of the researchers has strong influence on the quality of the gathered data and on the reliability of the results.
Our conclusion must be: It is almost impossible to perform reliable unfunded multicentric randomized controlled trails without proper support during data management in studies with complex objectives.

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Alles moet zo simpel mogelijk

gemaakt worden, maar niet simpeler.

Albert Einstein

Summary and conclusions

Samenvatting en conclusies

Chapter 9

Summary and conclusions

The aim of this thesis was to study several aspects of the Lichtenstein inguinal hernia repair, the most popular hernioplasty currently available. In 1894 the first prosthetic reinforcements were used to repair inguinal hernia eventually evolving towards a complete tension free hernia repair for primary inguinal hernia described by Irvin Lichtenstein. He performed since 1984 primary inguinal hernia repair using Marlex mesh prosthesis to bridge the entire floor of the groin without approximation of the tissue defect.
Since then mesh based repairs became the golden standard in inguinal hernia repair and in the United States over 295.000 Lichtenstein repairs are performed each year. In the Netherlands the use of mesh increased from 2001 towards 2003 with 42%.

The studies in this thesis discussed several aspects of inguinal hernia repair and the Lichtenstein repair in particular. The main attention was aimed at the applicability and the prevention of complications of the Lichtenstein repair.

In **Chapter 1** the technique of the Lichtenstein hernia repair was described together with possible complications and how they should be treated. The Lichtenstein hernia repair is the first choice for inguinal hernia repair according to the 2003 Dutch evidence based Guidelines.

The implementation of the Lichtenstein hernia repair in the Amsterdam region (1994-2001) together with other changes regarding techniques in inguinal hernia surgery were described in **Chapter 2.** Conventional (non-mesh) techniques are largely replaced by prosthesis (91% in 2001) of which 64% are Lichtenstein repairs. Data were obtained on 3649 patients demonstrating a significant decreasing number of operations performed for recurrent hernia from 19.5% in 1994 to 14.1% in 2001 (p=0.005). Also surgical residents are receiving significantly more attending surgeon supervision in the operating theatre. These two factors may explain the decrease in operations performed for recurrent inguinal hernia and probably even better results can be expected in the near future.

In **Chapter 3** an inventory in the Netherlands (January-March 2001) on the use of mesh based repairs was made. 97/133 (73%) Dutch hospitals cooperated with the survey generating data from a total of 4386 inguinal hernias in 3979 patients.
In the episode prior to implementation of the 2003 'Dutch Evidence Based Guidelines' for treatment of inguinal hernia, 2839 (78%) adult patients were treated with mesh repair and 484 (14.7%) patients were treated for a recurrent hernia. The Lichtenstein hernia repair was used in 57% of mesh repairs demonstrating that in The Netherlands it is the most popular method for treatment of inguinal hernia.

In **Chapter 4** 2535 patients with an inguinal hernia operated in the OLVG hospital from 1994-2004 were described. Since 1998 inguinal hernia repairs in this hospital were performed according to the preliminary 'Evidence Based Guidelines' concerning inguinal hernia repair. The use of mesh for primary hernia increased significantly from 0.6% in 1994 to 100% in 2004 ($p<0.001$). In 2004 82% of primary hernias were operated with a Lichtenstein repair. The tendency towards a decrease in recurrence is clearly demonstrated by comparing the average recurrence rates of three time periods namely '94-'98 (15.8%) and '02-'04 (10.6%), proving a significant decrease ($p<0.002$). The decrease of recurrences, with a previous repair in the OLVG hospital, from 64.3% (1994) to 14.3% (2004), was striking ($p<0.001$). This supports the expected beneficial effects of the Guidelines.

The question whether or not antibiotic prophylaxis is indicated in the Lichtenstein repair was answered in **Chapter 5.** In this double blind randomized placebo controlled multi-center trial of 1040 patients a low percentage (1.7%) of wound infection after Lichtenstein hernia repair was found. There were eight infections (1.6%) in the antibiotic prophylaxis group and 9 (1.8%) in the placebo group ($p=0.82$). There was 1 deep infection in the antibiotic prophylaxis group and 2 in the placebo group ($p=0.57$). Statistical analysis showed an absolute risk reduction (ARR) of 0.19% (95%CI: -1.78%-1.40%) and a number needed to treat (NNT) of 520 for the total number of infections. These results show that in Lichtenstein inguinal primary hernia repair antibiotic prophylaxis is not indicated in low risk patients.

In **chapter 6** the results of a Level 1A meta-analysis on the use of antibiotic prophylaxis in inguinal hernia repair were reported. Six randomized controlled trials were suited for analysis. The total number of infections for groin hernia in the placebo group was 38/1277 patients (3.0%) and 18/1230 patients (1.5%) in the antibiotic group. Antibiotic prophylaxis did not significantly reduce the incidence of infections OR 0.54(95%CI: 0.24-1.21), number needed to treat (NNT) of 74. It is concluded that antibiotic prophylaxis does not prevent the occurrence of wound infection in groin hernia surgery and therefore is not indicated in low-risk patients.

In **chapter 7** the 4 year follow-up of 254 patients with a Lichtenstein inguinal hernia repair from teaching and nonteaching hospitals demonstrated results comparable to the literature from general surgical clinics concerning recurrence (1.6%) and chronic pain (13.4%). The patients from the teaching hospital reported significantly more pain during physical examination while pressing the tuberculum pubicum, 45/111(41%) vs. 36/143 (25%), $P< 0.01$, probably due to the medial fixation of the mesh and damage to the periosteum. Although these patients had more pain four years after surgery their activities measured by SF-

36 and chronic pain grade questionnaire were not significantly influenced. More attention to the training of surgical residents regarding the medial overlap and fixation of the mesh in Lichtenstein inguinal hernia repair was suggested.

In **chapter 8** the audit of the Lichtenstein Antibiotics Trial demonstrated a number of flaws which appeared more frequently than expected. For instance the last (third) follow-up after three months was not performed as scheduled in 23/98 (23%) of audit patients. These patients were contacted by telephone which was successful in 98% of cases. Due to a relative simple endpoint of the study and many accessory efforts adjacent to the protocol the study's crucial data could be obtained and an adequate conclusion drawn. In a study with a more complex data accumulation this would probably not have been the case. Therefore it seems almost impossible to perform a reliable unfunded multicenter randomized trial with a complex objective.

The **General conclusions** of this thesis: the Lichtenstein inguinal hernia repair has become a popular technique in the Netherlands as well as around the world. By advising the use of mesh and particularly the use of the Lichtenstein technique according to the 'Dutch Evidence Based Guidelines' the implementation of this technique is likely to increase. It is very likely that mesh based repairs are a reason for the reduction of recurrences now and in times to come.
Routine use of antibiotics in Lichtenstein inguinal hernia repair is not indicated to prevent wound infections in low-risk patients and should be abandoned to prevent bacterial resistance and reduce costs. In patients with a suppressed immune response the use of antibiotics is still open for discussion.
Proper training of surgical residents (more skills labs) will not only reduce the number of recurrences (especially the direct) but should also reduce postoperative (chronic) long-term pain especially related to the pubic tubercle in Lichtenstein repairs.
For randomized controlled trials the quality of the source data is essential.
In unfunded trials ensuring a high quality of data collection and complying with the rules of good research is maybe an impossible challenge.

The Crystal Ball

The results of the studies in this thesis show that the Lichtenstein repair technique is the most popular treatment for inguinal hernia and recurrence rates are decreasing in hospitals that follow The Dutch Guidelines for treatment of inguinal hernia. Unfortunately they also confirm the high percentage of post operative chronic pain. It seems logical that much attention must be given to training in inguinal hernia repair as many complications could and should be preventable. Little is known about the true cause of chronic pain and treatment strategies are difficult and certainly not uniform. In future years studies should focus on this important issue. Low recurrences should not be accompanied by relatively high percentages of chronic pain, on the other hand low post operative pain percentages, if possible, should not be accompanied by a higher recurrence rate. Finding the perfect technique is the big challenge surgeons face. Other remaining important questions: should hernia surgery be performed in dedicated centres by specialist hernia surgeons and what is the true learning curve of different techniques?

Further improvements in the area of inguinal hernia repair will be made on other topics than recurrences like chronic pain reduction, possibly by using light weighted mesh and human fibrin glue for a sutureless Lichtenstein procedure. The results of studies with sufficient follow-up can be expected in a couple of years. It is likely that the modifications reduce pain because a mesh with more extensive scar tissue formation and fixation with a stitch to the pubic tubercle are known causes for pain. The remaining question will be: what is the price for this pain reduction, will there be more recurrences?

As long as the use of laparoscopic materials remains more expensive and the technique difficult to learn it is very likely that for unilateral primary inguinal hernia the anterior mesh approach preferably Lichtenstein repair will remain the optimal surgical technique.

The only possible downside of mesh based repairs is the possibility of mesh induced infertility. This area deserves more attention in upcoming studies.

Until we find a genetic answer for collagen abnormalities which can result in (recurrent) inguinal hernia or nanotechnologies for persistent open processus vaginalis, a surgeon will be needed to correct an inguinal hernia. Probably in time operations for inguinal hernia will not be performed in all groups of patients with asymptomatic hernia.

In the near future it will be standard to report the quality of source data in randomized controlled trials and the use of antibiotic prophylaxis in Lichtenstein primary inguinal hernia repair will be obsolete in low-risk patients.

Samenvatting en conclusies

Het doel van dit proefschrift was het bestuderen van diverse aspecten van de Lichtenstein plastiek, dit is momenteel de meest gebruikte operatie techniek voor liesbreuken. In 1894 werden de eerste kunstmatige verstevigingen gebruikt tijdens liesbreukoperaties waarna dit geleidelijk evolueerde naar de spanningsloze liesbreuk techniek voor primaire breuken beschreven door Irvin Lichtenstein. Hij corrigeerde sinds 1984 primaire liesbreuken met behulp van een Marlex mat, om de zwakke plek in de buikwand te overbruggen in plaats van het onder spanning aan elkaar hechten van de randen van de zwakke plek. Sindsdien zijn de technieken waarbij een kunststof matje (mesh) gebruikt wordt tot gouden standaard verheven en in de Verenigde Staten worden elk jaar 295.000 Lichtenstein plastieken verricht. In Nederland is het gebruik van kunststof matjes tussen 2001 en 2003 met 42% gestegen.

De studies in dit proefschrift beschrijven diverse aspecten van de liesbreukchirurgie en de Lichtenstein plastiek in het bijzonder. De meeste aandacht was gericht op de toepasbaarheid van de techniek en de preventie van complicaties van de Lichtenstein plastiek.

In **Hoofdstuk 1** werd de techniek van de Lichtenstein plastiek beschreven tezamen met potentiële complicaties en hoe die behandeld kunnen worden. De Lichtenstein plastiek is de eerste keuze voor liesbreuk chirurgie volgens de Nederlandse Richtlijn voor liesbreuk chirurgie.

De implementatie van de Lichtenstein plastiek in de Amsterdamse regio (1994-2001), tezamen met andere veranderingen in de liesbreukchirurgie technieken, werd beschreven in **Hoofdstuk 2**. Conventionele (zonder kunstof matje/mesh) technieken zijn grotendeels vervangen door technieken waarbij kunststof materiaal wordt gebruikt (91% in 2001). Hiervan is 64% een Lichtenstein plastiek. Data betreffende 3649 patiënten was beschikbaar voor analyse waarmee een significante daling van het aantal operaties voor recidief liesbreuken van 19,5% in 1994 naar 14,1% in 2001 (p=0,005) kon worden aangetoond. Tevens bleek dat chirurgen in opleiding meer begeleiding kregen tijdens hun operaties in de loop der jaren. Deze twee factoren kunnen de daling van het aantal operaties voor recidief liesbreuken verklaren en hiermee is er een reële hoop op betere resultaten in de nabije toekomst.

In **Hoofdstuk 3** werd een inventarisatie naar het gebruik van mesh gerelateerde liesbreuktechnieken in Nederlands (januari -maart 2001) gemaakt. 97/133 (73%) van de Nederlandse ziekenhuizen werkten mee aan het onderzoek waarbij data over 4386 liesbreuken bij 3979 patiënten beschikbaar kwam. In de periode voor de implementatie van de Nederlandse Richtlijn voor liesbreuk chirurgie (verschenen in 2003), werd 78% (2839 patiënten) van de liesbreuken bij

volwassenen met een matje gecorrigeerd en 484 (14,7%) van de patiënten werd behandeld voor een recidief liesbreuk. De Lichtenstein plastiek werd in 57% van de mesh gerelateerde operaties verricht, waarmee werd aangegeven dat dit de meest populaire methode van dat ogenblik in Nederland was.

In **Hoofdstuk 4** werden de resultaten van 2535 liesbreukpatiënten geopereerd in het OLVG ziekenhuis in de periode 1994-2004 beschreven. Sinds 1998 werden liesbreuk operaties in dit ziekenhuis verricht volgens de voorlopige 'Evidence Based Richtlijn' voor de behandeling van een liesbreuk. Het gebruik van mesh technieken voor primaire liesbreuken nam significant toe van 0,6% in 1994 naar 100% in 2004 ($p<0,001$). In 2004 werd 82% van de primaire liesbreuken met behulp van een Lichtenstein plastiek verzorgd. De afname van het aantal operaties voor recidief liesbreuken wordt duidelijk geïllustreerd wanneer het gemiddelde aantal recidief operaties over perioden wordt vergeleken. Bijvoorbeeld tussen '94-'98 (15,8%) en '02-'04 (10,6%), waar een significante daling optrad ($p<0,002$).
De daling van het aantal recidief breuken waarbij de vorige operatie in het OLVG plaatsvond was nog indrukwekkender namelijk van 64,3% (1994) naar 14,3% (2004), $p<0,001$. Deze bevindingen ondersteunen het te verwachten gunstige effect van de richtlijn.

De vraag of er een indicatie bestaat voor antibiotica profylaxe tijdens een Lichtenstein plastiek werd beantwoord in **Hoofdstuk 5**. In deze dubbelblinde, gerandomiseerde, placebo gecontroleerde, multi-center studie van 1040 patiënten werd een laag percentage (1,7%) wondinfecties na een Lichtenstein plastiek gevonden. Er waren 8 infecties (1,6%) in de antibiotica profylaxe groep en 9 (1,8%) in de placebo groep ($p=0,82$). Er was 1 diepe infectie in de antibiotica profylaxe groep en twee in de placebo groep ($p=0,57$). Statistische analyse toonde een absolute risico reductie (ARR) van 0,19% (95%CI: -1,78%-1,40%) en een 'number needed to treat' (NNT) van 520 voor het totale aantal infecties. Deze resultaten tonen aan dat bij een Lichtenstein plastiek voor primaire liesbreuken er geen indicatie bestaat voor antibiotica profylaxe bij laag risico patiënten.

In **Hoofdstuk 6** werden de resultaten van een niveau 1A meta-analyse naar het gebruik van antibiotica profylaxe bij liesbreukoperaties vermeld.
Zes gerandomiseerde studies bleken geschikt voor analyse. Het totale aantal infecties voor lies en femoraal breuken was in de placebo groep 38/1277 patiënten (3.0%) en in de antibiotica profylaxe groep 18/1230 patiënten (1.5%). Antibiotica profylaxe bleek de incidentie van infecties niet significant te reduceren OR 0.54 (95%CI: 0.24-1.21, 'number needed to treat' (NNT) was 74.
Er werd geconcludeerd dat antibiotica profylaxe het optreden van wondinfecties na lies en femoraal breuken bij laag risico patiënten niet voorkomt.

In **Hoofdstuk 7** werden de resultaten na 4 jaar follow-up van 254 patiënten met een Lichtenstein plastiek verricht in opleiding en niet-opleiding ziekenhuizen besproken. De resultaten bleken vergelijkbaar met de literatuur uit algemene ziekenhuizen met betrekking tot recidief kans (1,6%) en chronische pijn (13,4%). De patiënten uit het opleidingsziekenhuis melden significant vaker pijn tijdens het lichamelijk onderzoek waarbij druk op het tuberculum pubicum werd uitgeoefend, 45/111(41%) vs. 36/143 (25%), P< 0.01, waarschijnlijk door de mediale fixatie van de mat en schade aan het periost.
Hoewel deze patiënten dus meer pijn hadden 4 jaar na hun operatie waren hun activiteiten gemeten via de SF-36 en de chronische pijn vragenlijsten niet significant beïnvloed. Meer aandacht voor de trainingsaspecten ten aanzien van de mediale overlap en fixatie van de mat tijdens de Lichtenstein plastiek werd aanbevolen.

In **Hoofdstuk 8** toonde de audit van de Lichtenstein Antibiotica Trial een aantal tekortkomingen die vaker voorkwamen dan verwacht. Bijvoorbeeld de ontbrekende laatste (3e) follow-up na drie maanden bij 23/98 (23%) van de audit patiënten. Deze patiënten zijn toen telefonisch gecontacteerd hetgeen bij 98% succesvol was. Dankzij de relatief eenvoudige vraagstelling, het eenvoudig te bepalen eindpunt en door veel extraprotocollaire inspanningen kon de cruciale data toch verzameld worden en is de studie adequaat verlopen. Bij studies met een wat complexere vraagstelling zou dit waarschijnlijk niet het geval geweest zijn. Er werd geconcludeerd dat ongefinancierd multicentrisch gerandomiseerd klinisch onderzoek met complexe vraagstellingen zonder ondersteuning bij het volledige datamanagement vrijwel niet betrouwbaar naast de dagelijkse werkzaamheden kan worden uitgevoerd.

De **Conclusies** van dit proefschrift zijn: de Lichtenstein plastiek is de meest populaire techniek voor liesbreuk operaties in Nederland en in de wereld. Het advies van de Nederlandse Richtlijn voor liesbreuk chirurgie om mesh te gebruiken en in het bijzonder de Lichtenstein plastiek zal de toepasbaarheid van de techniek alleen maar laten toenemen. Het is zeer waarschijnlijk dat het gebruik van mesh een reden is voor de afname van het aantal recidieven, zowel op dit moment als in de toekomst.
Routinematig gebruik van antibiotica tijdens een Lichtenstein plastiek is niet geïndiceerd om een wondinfectie te voorkomen bij laagrisico patiënten.
Om allergische reacties, bacteriële resistentie te voorkomen en de kosten te reduceren dient het gebruik dan ook achterwege te blijven. Bij patiënten met een onderdrukt afweersysteem blijft er ruimte voor discussie omtrent het nut van antibiotica profylaxe. Een optimale training van chirurgen in opleiding (meer skills labs) zal niet alleen het aantal recidieven (in het bijzonder de mediale) verminderen, maar ook de frequentie van postoperatieve chronische pijn, vooral ten aanzien van pijn ter plaatse van het tuberculum pubicum.

Voor gerandomiseerde studies is de kwaliteit van de brondata essentieel. In ongefinancierde studies is het waarborgen van een hoge kwaliteit van de brondata en het volgen van de regels voor goed wetenschappelijk onderzoek bijna een onmogelijke opdracht.

De Kristallen Bol

De resultaten van de studies in dit proefschrift tonen aan dat de Lichtenstein plastiek de meest populaire behandeling voor liesbreuken is en dat het aantal operaties voor recidief liesbreuken afneemt in ziekenhuizen die de Nederlandse Richtlijn voor liesbreuk chirurgie volgen.
Helaas bevestigen zij ook het hoge percentage chronische pijn. Het lijkt logisch dat er veel aandacht dient te zijn voor de opleiding met betrekking tot liesbreuk operaties, omdat de meeste complicaties kunnen en moeten worden voorkómen. Er is echter relatief weinig bekend over de ware oorzaak van chronische pijn en de behandeling hiervan is moeizaam en zeker niet uniform. In de nabije toekomst dienen onderzoeken zich dan ook op dit belangrijke onderwerp te richten. Lage recidiefkansen dienen niet samen te gaan met een relatief hoog percentage chronische pijn, echter een laag percentage chronische pijn moet, indien mogelijk, niet samengaan met een hogere recidiefkans. Het vinden van de perfecte operatietechniek zal dan ook de grote uitdaging voor chirurgen zijn.
Andere overblijvende belangrijke vragen zijn: zou liesbreukchirurgie in toegewijde centra door gespecialiseerde chirurgen moeten geschieden en wat is de ware leercurve van de diverse liesbreuktechnieken?
Verdere verbetering op het gebied van de liesbreuk chirurgie zal niet zozeer te verwachten zijn ten aanzien van verkleining van de recidief kans, maar meer met betrekking tot reductie van de chronische pijn, bijvoorbeeld door het gebruik van lichtgewicht matten en het lijmen (fibrinelijm) van de mat voor een hechtingloze Lichtenstein plastiek. De resultaten van studies met voldoende follow-up zullen over enkele jaren beschikbaar zijn. Het is reëel om verbetering te verwachten van deze modificaties op het gebied van chronische pijn reductie, aangezien uitgebreidere littekenvorming en de hechtingen in de buurt van het tuberculum pubicum bekende oorzaken zijn voor pijnklachten. De vraag is echter wat is de prijs voor deze verbetering, aangezien ze niet meer kans op recidief mogen betekenen.
Zolang het gebruik van laparoscopie duurder blijft en aangezien deze operatietechniek lastig te leren is, is het zeer waarschijnlijk dat voor enkelzijdige primaire liesbreuken een anterieure plastiek met een matje bijvoorkeur de Lichtenstein plastiek de optimale chirurgische therapie blijft.
Het enige potentiële nadeel van de matjes is de theoretische mogelijkheid van onvruchtbaarheid door gebruik van mesh. Dit onderdeel verdient meer aandacht in toekomstige studies.

Totdat we een genetische oplossing vinden voor afwijkingen in de collageen aanmaak hetgeen kan resulteren in een (recidief) liesbreuk en zolang we geen nanotechnologiën hebben voor een persisterende open processus vaginalis, zal een chirurg nodig zijn om een liesbreuk te corrigeren.
Waarschijnlijk zal op korte termijn een asymptomatische liesbreuk bij alle volwassen patiënten niet meer worden geopereerd. In de nabije toekomst zal de kwaliteit van de brondata van gerandomiseerde studie standaard gerapporteerd worden en het gebruik van antibiotica profylaxe tijdens operaties voor primaire liesbreuken van laag risico patiënten zal obsoleet zijn.

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Curriculum vitae

Theo Aufenacker werd geboren op 25 augustus 1973 in Alkmaar. In 1991 behaalde hij zijn atheneum diploma op het Jan Arentsz College in Alkmaar. Daarna studeerde hij geneeskunde aan de Vrije Universiteit te Amsterdam, gaf met veel plezier anatomielessen, en behaalde zijn artsexamen (cum laude) in 1998. Hierna begon hij te werken in het Onze Lieve Vrouwe Gasthuis (OLVG) te Amsterdam als AGNIO chirurgie o.l.v. Dr. H.F.W. Hoitsma. In deze tijd werden de eerste schreden op het onderzoeksgebied reeds gezet o.l.v. Dr. M.P. Simons uiteindelijke leidend tot dit proefschrift en de Schoemaker prijs (2004).
Daarna kon hij in 2000 de opleiding tot chirurg aanvangen in het OLVG (opleider Dr. N.J.M. Out). In 2002 en 2003 werd de opleiding vervolgd in het Academisch Medisch Centrum (opleiders Prof.dr. H. Obertop & Prof.dr. D.J. Gouma). Waarna de opleiding eind 2005 in het OLVG werd voltooid. Sinds januari 2006 is hij werkzaam als chef de clinique in hetzelfde ziekenhuis.

Theo J. Aufenacker was born on the 25th of august 1973 in Alkmaar, the Netherlands. In 1991 he graduated from highschool (Atheneum) at the Jan Arentsz College in Alkmaar. After this he entered medical school at the Free University of Amsterdam. He took pleasure in teaching anatomy and graduated (cum laude) in 1998. He started working as a surgical resident (AGNIO) at the department of surgery at the Onze Lieve Vrouwe Gasthuis (OLVG) in Amsterdam. (Head Dr. H.F.W. Hoitsma). During this period the first steps in the research of inguinal hernia were made (supervision Dr. M.P. Simons) leading to this thesis and the Schoemaker award (2004). In 2000 he started the surgical training in the OLVG (Head Dr. N.J.M. Out). In 2002 and 2003 the training continued in the Academic Medical Centre (Head Prof.dr. H. Obertop & Prof.dr. D.J. Gouma). After which he finished his training in the OLVG at the end of 2005. Since January 2006 he is working as a surgeon in the OLVG.

And so it ends .....

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