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

Aufenacker, T.J.

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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