

## LOW RECURRENCE RATE IN HERNIA REPAIR – RESULTS IN 300 PATIENTS WITH OPEN MESH REPAIR OF PRIMARY INGUINAL HERNIA

R. G. Holzheimer

Chirurgische Praxisklinik Sauerlach, Germany

### Abstract

**Introduction:** There are about 700.000 open mesh repairs done as day surgery procedure in the United States each year; in Germany in 2003 only about 6% of inguinal repairs were done as day surgery procedure.

**Study goal:** Prospective evaluation of complications, recurrence, and chronic postoperative pain after primary inguinal hernia repair with Ultrapro® mesh in 300 consecutively operated patients in our clinic.

**Material and methods:** 300 consecutive patients with primary inguinal hernia repair with Ultrapro® mesh were prospectively followed-up. All patients had a defect of the posterior floor (Nyhus III). All patients received antibiotic/anti-thrombotic prophylaxis, pre-emptive pain treatment and were operated by the same surgeon according to a modified Lichtenstein technique. Patients were seen at day 1, day 10, 3 and 12 months after the operation and contacted in case they did not show up.

**Results:** Mean age was 51 years (19-86 years), 218 men (mean age 50) and 82 women (mean age 52). There were 170 direct, 28 indirect and 157 direct and indirect hernias (n = 355). All patients had a defect of the posterior floor (Nyhus IIIa and b). In 55 patients we treated a bilateral hernia. There was no intra-operative complication. One patient (0.3%) complained from minor postoperative nausea and vomiting (PONV). One male patient (smoker) (0.3%) developed an inflammatory reaction in the groin incision; in five patients subcutaneous inflammatory tissue granuloma or seroma were treated surgically. There was neither a case of deep venous thrombosis (DVT), nor pulmonary embolus (PE), nor significant surgical site infection. The mean follow-up of the patients was 13 months (range 1-30 months); 98% of the patients were included in the follow-up. There were four recurrences (1.1%) in 355 hernia repairs. There was no case of chronic pain related to the hernia repair nor a mesh-related complication. 14 patients (4.66%), who had complaints several months after the operation, were thoroughly evaluated and diagnosed to have other causes (interventrebral disc prolapse, neuropathy, adverse event of a hip joint replacement)

**Conclusion:** Open mesh inguinal primary hernia repair can be safely performed with excellent success and good cosmetic results in patients in a specialised ambulatory clinic and is therefore an economic alternative for in-hospital treatment. In comparison to the increased risk for serious complications in laparoscopic

inguinal hernia repair there was none in this series. Chronic pain can be successfully prevented by surgical technique and pre-emptive analgesic therapy. The recurrence rate, which has been associated with surgical experience, is low. The results of postoperative pain are only comparable when the patients are seen by the surgeon; evaluation by questionnaire is not sufficient.

### INTRODUCTION

In contrast to the United States where 80-90% of inguinal hernia repairs are done as day surgery procedure, in Germany more than 90% of the inguinal hernia repairs are performed in the hospital and only 6% as day surgery procedure. (Toftgaard 2003).

The most commonly performed inguinal hernia repair in the United States is the Lichtenstein procedure (295.000 or 37%) followed by plug repair (270.000 or 34%) (Rutkow 2003). The initial enthusiasm for the laparoscopic inguinal hernia repair has not been sustained as the operation is performed only in 10-15% of cases (Rutkow 2003; Fitzgibbons and Puri 2006). The Netherlands Surgical Association recommends the Lichtenstein procedure for primary inguinal hernia repair. Laparoscopic procedures should be used only for specific indications (Simons et al. 2003). Nowadays primary inguinal hernia repair can be performed safely in an ambulatory or day surgery clinic for most patients (ASA I, II, and with exceptions III). Advantages of ambulatory treatment are a decreased risk of nosocomial infection and thrombosis. Older patients are less likely to suffer from transitional syndrome than in the hospital. The quality of hernia repair can be assessed by the complication and recurrence rate and the frequency of chronic postoperative pain (Hawn et al. 2006).

The aim of this study was to evaluate the outcome of primary inguinal hernia repair with a modified Lichtenstein technique using Ultrapro® (Ethicon, NJ, USA) in an ambulatory clinic in 300 consecutive patients. The evaluation of our experience with hernia repair with suture technique or other mesh implants is not subject of this study.

### MATERIAL AND METHODS

300 consecutive patients with primary inguinal hernia (ASA I,II, with few exceptions III; risk evaluation for each patient was done by surgeon, anaesthesiologist

and family practitioner) were prospectively recorded and followed up after open mesh hernia repair (Ultra-pro<sup>®</sup>, Ethicon Norderstedt, Germany) in case of a defect of the posterior floor and/or enlarged internal inguinal ring. Inguinal hernia repair followed a modification of the Lichtenstein technique with plastic reconstruction of the posterior floor and the inguinal ring (Holzheimer 2004). Patients received one-shot antibiotic prophylaxis and pre-emptive pain treatment. In most instances patients were operated under general anaesthesia (no intubation, no relaxation) and laryngeal mask. Patients were allowed to drink and eat as well as to walk within the institution starting 1 hour after the end of the operation and left for home four hours after the operation. Patients are seen at day 1 and 10 after the operation, and three months and 1 one year after the operation, routinely. In case the patients did not show up they were contacted. Complications, recurrence and chronic postoperative pain were the main outcome parameters. A smaller group of patients (n = 50; including patients with recurrent hernia) have been questioned according to the SF-36; the results have been published before (Holzheimer 2004).

## RESULTS

There were 300 consecutive patients (mean age 51 years; 19-86 years) with a primary inguinal hernia treated in our clinic. 112 patients (37.3%) were 60 years and older; 10 patients (3.3%) were 80 years and older. 218 men (mean age 50) and 82 women (mean age 52) had 355 herniotomies, in 55 patients bilateral hernias were present and operated. There were 170 direct, 28 indirect and 157 direct and indirect hernias. 8 patients had a scrotal hernia, in one patient the inguinal ligament has been torn away from its insertion in the pubic bone. In 57 hernias the posterior wall defect was accompanied by a distended internal ring and in 68 cases by a defect of the anterior wall. All patients had a defect of the posterior floor (Nyhus III). None of the patients suffered from an intra-operative complication. In 7 patients who had a complicated form of a hernia (scrotal hernia, traumatic hernia, reduced thrombocytes, and long-term anticoagulation therapy) a drain was placed and removed without any complication after the operation.

A minor form of postoperative nausea and vomiting (PONV) has been observed in one patient (0.3%). One female patient (0.3 %) who was on psychiatric medication had a transient uncomplicated urinary retention.

One younger heavy smoking male patient (0.3%) developed an inflammation of the incision area 10 days after the operation. A mild inflammation of hair follicles postoperatively was seen in 5 patients and required no further surgical treatment (1.6 %).

There were neither significant surgical site infection, nor deep venous thrombosis (DVT) or pulmonary embolus (PE) observed.

10 patients (3.3 %) had a minor haematoma which disappeared shortly after operation without any intervention.

Five patients (1.6%) had to be surgically treated for a subcutaneous inflammatory reaction. In three female

patients subcutaneous tissue (chronic fibrosing inflammation due to foreign tissue granuloma; chronic folliculitis) has been removed several months postoperatively; in one patient (male) who has taken aspirin an organized haematoma was removed 2 months later, and in one patient a seroma developed which had to be drained.

The mean follow-up of the patients was 13 months (range 1-30 months); 98% of the patients were included in the follow-up; one patient has died for other reasons (cancer) one year after hernia repair, one patient has moved, four patients could not be followed up after the operation.

There was no case of chronic pain related to the hernia repair. 14 patients (4.66) had complaints in the groin, leg, hip or lower abdomen several months after the operation and were sent for neurological evaluation after a recurrent hernia was excluded by physical and ultrasonographical examination and local infiltration of the ilioinguinal and iliohypogastric nerves did not respond. The patients had either an intervertebral disc alteration with nerve entrapment, or neuropathy. One male patient suffered from a laceration of muscles/tendons which was caused during an artificial hip joint replacement several months before the inguinal hernia repair.

In four patients (4/355 1.1%; three males and one woman) a recurrent hernia has been recognized, which has been repaired without any adverse event.

There was no case of mesh-related complication.

## DISCUSSION

In Germany, inguinal hernia repair is still rarely done as ambulatory or day surgery procedure (6%) (Toftgard 2003). In other countries like the United States groin hernia repair is commonly performed as out-patient procedure in 80-90% of all cases (Rutkow 2003).

In the United Kingdom mesh is used in 90% of inguinal hernia repair, 6% are non-mesh procedures and 4% of inguinal hernia repairs are performed as laparoscopic procedure (Ravindram et al. 2006). Rodriguez-Cuellar et al. (2005) reported similar counts: 50% Lichtenstein procedure, 17.1% Rutkow-Robbins mesh plug, 8.5% Shouldice and 5.2% laparoscopic surgery. In Germany 72.6% are performed as conventional anterior inguinal hernia repair and 26.7% laparoscopic inguinal hernia repair (Wojtyczka et al. 2003).

The patient's risk to suffer from a complication may be associated with the experience and expertise of the surgeon. Main postoperative complications of inguinal hernia repair are haematoma/seroma, orchitis, neuralgia and others (infection). Hawn et al. (2006) observed complications in 342/1603 (21.3%) of patients within 2 years. The overall complication rate has been reported to range from 8% - 21.3% after inguinal hernia repair (Kald et al. 1998; Hawn et al. 2006).

### HAEMATOMA/SEROMA

Haematoma/seroma rates may range from 2% to 39.2% (Hair et al. 2000; Rodriguez-Cuellar et al. 2005). Fitzgibbons et al. (1995) reported 17.1% haematoma/seroma complications related to laparoscopic hernior-

rhaphy. We have seen minor haematoma in 10 patients (3.3%).

#### ANTITHROMBOTIC PROPHYLAXIS

Although many surgeons do not provide thrombotic prophylaxis to their patients (Beckman et al. 2006) it is in the interest of the patient to offer antithrombotic prophylaxis (stockings and low molecular weight heparin) also in case of open-mesh inguinal hernia repair. We have seen no case of DVT or PE. According to information provided by the German Phlebological Society (Gerlach 2006) one case of deep venous thrombosis will cost approximately 80.000 Euro.

#### DRAINS

In general, there is no need to insert drainage in open-mesh herniorrhaphy (Willy et al. 2003). Peiper et al. reported that 14% of patients with drains inserted during inguinal hernia repair and 16% of patients without drains underwent percutaneous seroma puncture (1997). In complicated hernia repair suction drainage for 24 hours significantly reduced the incidence of wound haematoma, seroma or infection from 48.7% to 17.6% ( $p > 0.01$ ) (Beacon et al. 1980). In this series drains were inserted only in 7 patients (2.3%) who presented intra-operatively a complicated form of an inguinal hernia, e.g., reduced thrombocytes, long-term anticoagulation, scrotal or traumatic hernia. Drains were removed without any complication.

#### WOUND INFECTION

The wound infection rate may vary from 1% - 10% (Taylor et al. 1997; Hair et al. 2000; Aufenacker et al. 2004; Taylor et al. 2004; Terzi et al. 2005). One young male patient, who is heavy smoking, had a superficial inflammation of the groin incision which needed conservative wound care. It is known that smoking increases the risk for infection. Preoperative smoking cessation may improve surgical outcomes (Finan et al. 2005).

#### ORCHITIS AND TESTICULAR ATROPHY

Orchitis and testicular atrophy occur rarely (0.03-2%) after inguinal hernia repair (Fong and Wantz 1992; Reid and Devlin 1994; Dieudonné 2002; Verstraete and Swannet 2003), but should be mentioned for informed consent. There was no orchitis or testicular atrophy in our study.

#### HAEMATOMA/SEROMA REQUIRING SURGICAL INTERVENTION

Haematoma, seroma or infection may seldom require surgical intervention. In this series there were 5 patients (1.6%) who required surgical removal of scar tissue, seroma/haematoma, foreign tissue granuloma or chronic folliculitis. In a large series of one thousand hernia repairs (Lichtenstein repair in 741 patients) under unmonitored local anaesthesia Callesen et al. (2001) reported that 29 patients (3.91%) had compli-

cations ( $n = 15$  postoperative bleeding or haematoma;  $n = 14$  infection) requiring surgical intervention.

#### SERIOUS COMPLICATIONS

Serious complications rarely occur during or after open-mesh inguinal hernia repair. We have seen no incidence of serious complication in this series. Callesen et al. 2001 observed 6 cases (0.6%) of cardiovascular and respiratory events in 1000 patients operated for inguinal hernia (Callesen et al. 2001).

#### ANAESTHESIA

Residual effects of anaesthesia may be urinary retention, nausea, vomiting, sedation (Callesen et al. 2001). We observed one case (0.3%) of nausea and vomiting.

#### URINARY RETENTION

The rates of urinary retention after hernia repair with general anaesthesia vary from 0%-2.3% (Kark et al. 1998; Hair et al. 2000; Rutkow and Robbins 1998) or may be even higher after spinal and general anaesthesia with unrestricted fluid load (Petros et al. 1991). In this series we had one woman (0.3%) who suffered from urinary retention. This patient was on medication for a psychiatric disease, which is known to lower the threshold for urinary retention.

#### MORTALITY

We observed no case of mortality in this series. This is certainly also an effect of the combined efforts of surgeon, family practitioner and anaesthesiologist to perform a risk evaluation before the decision to operate. Mortality rates in inguinal hernia repair in Scotland range from 0.2%-0.3% mainly due to cardiovascular events (Myocardial infarction, deep venous thrombosis) (Hair et al. 2000).

#### RECURRENCE

The effectiveness of inguinal hernia repair may be measured by the rate of recurrence and neuralgia (Hawn et al. 2006). We observed 4 recurrences in 355 operations (1.1%) during a mean follow-up of 13 months (range 1-30 months). In recent studies with larger population the recurrence rate was given to be 4.9% to 15% (Kald et al. 1998; Hair et al. 2000; Haapaniemi and Nilsson 2002; Neumayer et al. 2004; Hawn et al. 2006).

#### POSTOPERATIVE CHRONIC PAIN

Patients are classified as having chronic pain if postoperative pain lasts for more than three months (International Association for the study of pain 1986). Bay-Nielsen et al. reported in 2001 on the results of a nationwide questionnaire study. 28.7% of patients complained to have chronic pain. However, there may be a wide range of the incidence of chronic pain 1 year after hernia: 0.7% to 54% (Hair et al. 2000; Bay-Nielsen et al. 2001; Haapaniemi and Nilsson 2002; Kingsnorth

et al. 2003; Poobalan et al. 2003; Verstraete and Swanet. 2003). Several factors may have an influence on the rate of chronic pain. Pain measurement and grading may not be adequately done by a one-dimensional scale such as the Visual Analogue Score (VAS) pain score or by recording the number and types of analgesics. The patients' perception of pain may be different (Nienhuijs et al. 2005). 14 patients (4.66%) in our series were demonstrated to have chronic pain not related to hernia repair but to other causes, e.g., neuropathy, damage during an artificial hip joint implantation or vertebral disc disease. This has been discovered by clinical exclusion of groin pathology and a thorough neurological examination of the patient.

### CONCLUSION

Open mesh inguinal primary hernia repair can be safely performed with excellent success and good cosmetic results in patients of all ages in a specialised ambulatory clinic. In comparison to laparoscopic inguinal hernia repair there is a decreased risk for serious complications. Ultrapro<sup>®</sup> mesh is well tolerated and is not associated with special complications. Chronic postoperative pain can be prevented by surgical technique and pre-emptive analgesic therapy. The development of recurrence and chronic pain depends on the expertise and experience of the treating surgeon. Open mesh inguinal primary hernia repair in a specialised ambulatory clinic is the future treatment with regard to outcome, quality of life and finally also the financial budget.

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*Address for correspondence:*

Prof. Dr. René G. Holzheimer  
Tegernseer Landstr. 8  
82054 Sauerlach (near. Munich)  
Germany  
Tel. +49-8104-887822  
Fax +49-8104-887824  
Gresser.holzheimer@web.de