Inguinal Hernia Management

Focus on Pain

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Inguinal Hernia Management: Focus on Pain

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Contents

Chapter 1

General introduction

In the Netherlands approximately 31,000 inguinal hernias are corrected yearly, making it one of the most frequently performed operations in surgery. The majority of inguinal hernia repairs is conducted in male patients older than 50 years[1]. Since recurrence rates have been reduced to a few per cent after mesh repair, nowadays morbidity associated with open inguinal hernia repair is mainly related to chronic pain[2-4]. The incidence of chronic pain has been reported to be up to 53%[3], however reported incidences are variable due to different definitions of chronic pain. A working group that recently developed the European Hernia Society (EHS) guidelines for treatment of inguinal hernia estimated the overall incidence of moderate to severe chronic pain after hernia surgery to be around 10-12%[5].

The primary endpoint in studies regarding inguinal hernia repair has been recurrence up to now. Currently, such studies have also focused on chronic pain. The choice for surgical treatment of an inguinal hernia is based on dissolving pain and discomfort associated with the hernia. Additionally, this prevents an emergency operation necessary in case of incarceration and/or strangulation of the previous harmless hernia that is associated with higher morbidity and mortality compared to elective surgery[6, 7]. However, the indication for elective surgery should not only depend on consideration of mortality rates that are associated with emergency and elective repair. The rate of incarceration and/or strangulation of a conservatively treated hernia, the rate of recurrence of a hernia postoperatively, contra-indications, preoperative pain and discomfort associated with the hernia, the natural course of pain and the incidence of chronic postoperative pain should also be taken into account.

Symptomatic inguinal hernias should be operated on electively according to the EHS guidelines for treatment of inguinal hernia[5]. Furthermore, according to these guidelines watchful waiting is an acceptable option for men with minimally symptomatic or asymptomatic inguinal hernias. According to the inguinal hernia guideline of the Association of Surgeons of the Netherlands (ASN) in small, easily reducible, asymptomatic and mild-symptomatic inguinal hernia in the adult with or without contra-indications, watchful waiting might be considered[8]. However, general health of patients might decline during watchful waiting, resulting in a riskier elective hernia correction in case of increasing pain or discomfort that is associated with the initial asymtomatic hernia. A reduction in recurrence rate associated with the use of open mesh repair compared to open repair without a mesh[4], incited the ASN and the EHS to recommend a mesh technique in case of the primary unilateral inguinal hernia repair[9, 10].

The commonest types of chronic postoperative pain are somatic and neuropathic[3, 11, 12]. Peroperative recognition of the course of the nerves and subsequent division, resection or preservation during open hernia repair may influence the incidence of chronic postoperative pain. However, there seems to be no consensus on whether or not to identify and subsequently divide, resect or preserve these nerves together, or separately, during surgery[13].

One of the features of the Shouldice repair is routine sacrifice of the lateral cremasteric bundle, a structure that contains the external spermatic vessels and the genital branch of the genitofemoral nerve. Furthermore, Bendavid reported on behalf of the Shouldice Hospital that in 90% of patients with chronic postoperative inguinal pain at the Shouldice Hospital the ilioinguinal and iliohypogastric nerves were reported to be carefully preserved in the operative report. Therefore Bendavid recommends intentional severance based on the concept of 'no nerve no pain'[13]. This coincides with the views of George Wantz[14]. Recently Amid formulated the key principles of the Lichtenstein hernia repair[15, 16]. This includes identification and protection of the inguinal nerves not interfering with the position of the mesh.

There is a discrepancy between the complication rate associated with the Lichtenstein repair, the most frequently performed hernia repair in the Netherlands, reported by the Lichtenstein Hernia Institute and that reported by others[3, 15-19]. Causalgia syndromes affecting all three inguinal nerves have been described: ilioinguinal and iliohypogastric nerves, and genital branch of genitofemoral nerve. The EHS and ASN guidelines mention damage to one or all three inguinal nerves as a cause of chronic postoperative pain[10, 20]. Until now no consensus consists on the management of this syndrome, varying from the chronic administration of analgesics up to neurectomy or excision of the mesh in case of 'meshoma' (fibrotic hyperreaction around mesh).

Aim of the thesis

The clinical impact of chronic pain as a complication of hernia surgery is illustrated by reporting two patients suffering from chronic postoperative pain. It is investigated which treatment, operation or observation, would be better in case of asymptomatic or mild symptomatic elderly male inguinal hernia patients taking all concerning factors into account by means of a Markov and sensitivity analysis. To determine the influence of the introduction of mesh material on the incidence of chronic pain, a 10 year follow-up is conducted of patients originally randomized to undergo open non-mesh or open mesh hernia repair. A questionnaire is sent to identify possible disparities between the state-of-art Lichtenstein repair and its application in the Dutch general practice with respect to technical aspects of the Lichtenstein repair which are suggested to be involved in the development of chronic pain. Additionally, the influence of different types of peroperative inguinal nerve management on the incidence of chronic postoperative pain is investigated and anatomical zones are defined that facilitate efficient identification of the nerves on the basis of an anatomical study. Finally, the feasibility of a three-nerve-recognizing Lichtenstein hernia repair as advocated by Amid is evaluated.

Chapter 2

Operation compared to watchful waiting in elderly male inguinal hernia patients

INguinal hernia: Conservative or operative Approach (INCA) Trialists' Collaboration

Journal of the American College of Surgeons, In press

Abstract

Objective

To investigate whether operation or watchful waiting would be better in case of mildly symptomatic and asymptomatic elderly male inguinal hernia patients.

Methods

Studies were identified investigating risk of incarceration and/or strangulation, mortality associated with elective and emergency repair, risk of recurrence and crossover rate from watchful waiting to operation. A Markov model was developed to estimate life expectancy for patients who are treated by operation or watchful waiting taking these parameters into account. Life expectancies were calculated by means of second order Monte Carlo simulation. Extensive sensitivity analyses were conducted to identify parameters that influence the optimal decision. Additionally, studies investigating pain before and after assignment of watchful waiting or operation, in this subset of patients were identified.

Results

The mean mortality rate associated with elective and emergency repair were 0.2% (range: 0-1.8%) and 4.0% (range: 0-22.2%), respectively. The annual probability of incarceration and/or strangulation associated with watchful waiting was 0.4% (range: 0.2-2.7%). On the basis of several randomized trials investigating recurrence, we estimated the annual probability of a recurrence to be 0.9%. Among patients with no or mild symptoms the annual crossover rate from watchful waiting to operation was 13% (range: 8.0-19.5%). The mean life expectancy for patients undergoing watchful waiting was 26.88 (CI: 26.873-26.884) years compared to 26.89 years (CI: 26.880-26.891) for those undergoing hernia repair. The optimal decision was sensitive to the procedural mortality rates and the annual risk of incarceration and/or strangulation.

Conclusion

The available data suggest that life expectancy for mildly symptomatic or asymptomatic elderly male inguinal hernia patients associated with watchful waiting or operation differs very little supporting equipoise in this situation.

Introduction

Inguinal hernia repairs are mainly performed in male patients older than 50 years[1]. Although watchful waiting may be considered in mildly symptomatic and asymptomatic patients, according to the inguinal hernia guideline of the European Hernia Society[10], inguinal hernia patients without contra-indications are usually treated operatively.

The rationale for surgical treatment is to cure inguinal pain and discomfort associated with the hernia and to prevent emergency surgery in case of incarceration and/or strangulation, which is clearly associated with higher morbidity and mortality [6, 7]. The indication for elective surgery, however, should not only depend on consideration of the mortality rate that is associated with emergency and elective repair. The risk of incarceration or strangulation itself requiring emergency repair should be considered as well. Additionally, the risk of recurrence and crossover rates from conservative to operative management in this group of patients should be taken into account.

Recently, two randomized trials have reported that pain is not significantly different at one or two years after assigning open tension-free hernia repair or watchful waiting in case of asymptomatic or mildly symptomatic inguinal hernia compared to preoperative pain levels[21, 22]. Furthermore, one third of patients presenting with an inguinal hernia with a mean age of 60 years (range: 45-71) have been reported to be asymptomatic[23]. Another study reported that 81% of patients (of which 62% older than 50 years of age) did not suffer from any inguinal pain at rest which included 27% that had no pain at all[24].

All the factors mentioned above are of significance considering repair of inguinal hernia in elderly male patients. Neuhauser conducted a life-expectancy analysis including most of these factors in 1977 concluding that elective hernia repair does not prolong life in the elderly, while it may or may not improve the quality of life and that life expectancy would be determined mainly by the yearly rate of strangulation[25].

The aim of this study was to investigate which treatment, operation or watchful waiting, would be better in case of asymptomatic or mildly symptomatic elderly male inguinal hernia patients by means of a literature review and a Markov model integrated relevant parameters.

Methods

Studies in which the following outcome measures were studied were included: risk of incarceration and/or strangulation, mortality associated with elective and emergency hernia

repair (in case of incarceration and/or strangulation), risk of recurrence and crossover rates from watchful waiting to operation. Studies were identified by searching PubMed, the Cochrane Library (Issue 1,2007), scholar.google.com and Current Controlled Trials (search across multiple registers including the National Health Service in England and US ClinicalTrials.gov). Search terms used and cross-checked were 'hernia, inguinal', 'strangulation', 'incarceration', 'mortality', 'elective', 'emergency' and 'hernia repair'. Studies containing data regarding femoral and inguinofemoral hernia were excluded from analysis. Randomized trials published after 1990 comparing open and laparoscopic hernia repair were also included with respect to elective mortality rates since there is no evidence of a significant difference in mortality between both types of repair. Randomized controlled trials and prospective and retrospective cohort studies were included. Reviews and references of the articles retrieved were checked for additional studies. Letters to the editor, abstracts and comments were excluded. Only articles written in English were reviewed.

Additionally, studies investigating pain before and after assigning operative or conservative management in case of mildly symptomatic and asymptomatic elderly hernia patients, were included. The same databases were searched and terms cross-checked were 'hernia, inguinal', 'hernia repair', 'pain, postoperative' and 'pain, chronic'.

Additionally, data regarding hospital admissions in the Netherlands in 1998, 2001 and 2003 were requested from the National Medical Registration (LMR, Prismant). From 1986 all general hospitals, academic hospitals and a few categorical hospitals are associated with the LMR. The number of patients with main diagnosis 'inguinal hernia with/without obstruction and/or gangrene' (registrationcode 5500, 5501 and 5509) that were operated were recorded and the number of patients that died during this admission were noted.

Data were extracted by two of the authors (ARW and GvR) independently. Levels of evidence were assessed according to the Oxford Centre for Evidence Based Medicine levels of evidence[26]. Discrepancies were resolved by consensus. The following data were abstracted: type of study, number of patients, baseline characteristics, type of treatment and if applicable risk with regard to one of the parameters mentioned above.

Probabilities of incarceration and/or strangulation differed with respect to follow-up between studies. We therefore converted the observed probabilities of incarceration and/or strangulation and risks of recurrence into annual rates assuming a constant rate of irreducibility and risk of recurrence, respectively. We calculated the average annual rate, weighted by the size of patient groups.

A Markov decision model was developed (TreeAge Pro 2008) with a cycle length of one year, to calculate the life expectancy of a 50-year old patient with an inguinal hernia treated electively or by watchful waiting (Figure 1). Figure 1 shows a schematic overview of the decision tree. The management strategies compared are elective surgery and watchful waiting.

During elective surgery, patients die or survive. If the patients survive, they entered the Markov model. During the annual cycle, patients may die from other causes, they may have a recurrence of the hernia, which may or may not be treated electively or urgently. In case of watchful waiting patients face risk of incarceration and/or strangulation after which emergency surgery will take place. In this group patients entered the Markov cycle in which the same events could occur.

We assumed that the number of operations was limited to two. Assumptions were made that on average 30% of patients experiencing recurrence will undergo a secondary hernia repair (with a minimum of 0% and maximum of 60%). Most patients are not even aware that they are experiencing a recurrence [27, 28]. Furthermore, it was assumed that the risk of incarceration and/or strangulation after previous hernia repair is the same as this risk in case of watchful waiting.

Furthermore, second order one way and multi-way sensitivity analyses were conducted to determine what input parameters mostly influenced life expectancy. Worst and best case scenarios were conducted.

Results

Review

Most studies included in this review reported one or more of our outcome measures. In total, 26 articles[7, 19, 21-25, 29-47] were selected of which 15 [7, 19, 21, 22, 25, 33-42] and 16 [7, 23, 25, 30-35, 37-42, 48] articles investigated the mortality rates associated with elective and emergency repair, respectively (Table 1). Six studies [21-23, 25, 31, 38] investigated the risk of incarceration and/or strangulation of non-surgically treated inguinal hernia (Table 1). However, periods in which hernia got obstructed and/or strangulated differed between studies. Study specifics are included through footnotes that are in the appendix.

Two randomized trials that both primarily investigated pain pre- and post-treatment assignment in case of watchful waiting and operative management of asymptomatic and mild symptomatic inguinal hernia, also investigated mortality associated with elective hernia

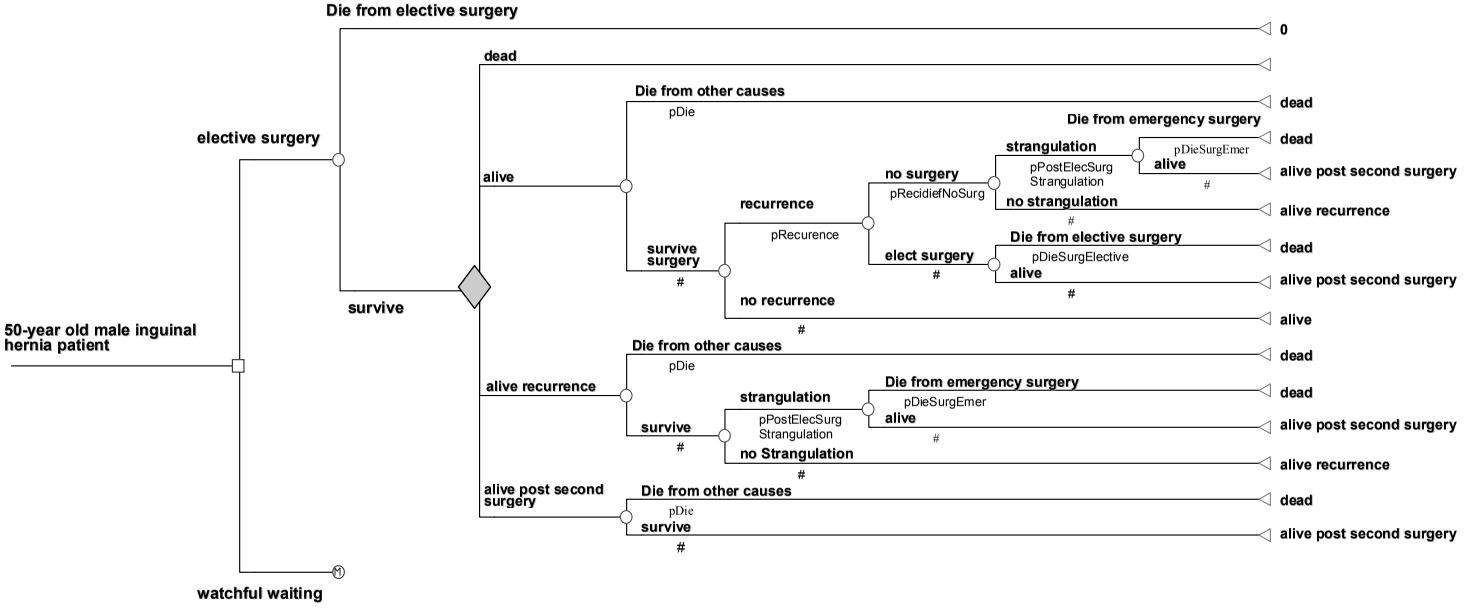

Figure 1. Decision model for treatment of a 50-year old male inguinal hernia patient with Markov subtree for elective surgery in case of elderly male inguinal hernia patient. Chances involved with each subtree are noted below each separate tree. After the third bifurcation all patients are 'alive'. The two lower subtree's after the third bifurcation represent what happens with patients that are alive after surgery with or without a recurrence.

Table 1. Characteristics of studies

Study	Year	Type	Study location	Hospitals	Study period	Level of evidence
Mortality associated with elective hernia repair						
Williams et al.[42]	1966	Cohort retrospective	USA	1	1951-1960	2b
Neuhauser et al.[25]	1977	Cohort retrospective	USA	Social security data	1971	2b
Tingwald et al.[41]	1982	Cohort	USA	1	1975-1980	2b
Nehme et al.[40]	1983	Cohort retrospective	USA	Multihospital study	1971-1980	2b
Allen et al.[39]	1987	Cohort retrospective	UK	1	1984	2b
Gallegos et al.[38]	1991	Cohort retrospective	UK	1	1987-1989	2b
Oishi et al.[37]	1991	Cohort retrospective	USA	2	1982-1990	2b
Primatesta et al.[7]	1996	Cohort retrospective	UK	Register	1976-1986	2b
MRC Group[36]	1999	RCT	UK	26	1994-1997	2b
Bay-Nielsen et al.3[35]	2001	Cohort prospective	Denmark	83, Danish hernia database	1998-2000	2b
Ohana et al.[34]	2004	Cohort retrospective	Israel	1	1992-2002	2b
Neumayer et al.[19]	2004	RCT double-blind	USA	14	1999-2003	1b
Fitzgibbons et al.[22]†	2006	RCT double-blind	USA	5	1999-2004	1b
O'Dwyer et al.[21]‡	2006	RCT double-blind	UK	1	NR	1b
Nilsson et al.[33]	2007	Cohort prospective	Sweden	90, Swedish hernia register	1992-2004	2b
Mortality associated with emergency hernia repair						
Williams et al.[42]	1966	Cohort retrospective	USA	1	1951-1960	2b
Neuhauser et al.[25]	1977	Cohort retrospective	USA	Social security data	1971	2b
Neutra et al.[31]	1981	Cohort retrospective	Colombia	National survey	1964-1973	2b
Tingwald et al.[41]	1982	Cohort	USA	1	1975-1980	2b
Nehme et al.[40]	1983	Cohort retrospective	USA	Multihospital study	1971-1980	2b
Allen et al.[39]	1987	Cohort retrospective	UK	1	1984	2b
Gallegos et al.[38]	1991	Cohort retrospective	UK	1	1987-1989	2b
Oishi et al.[37]	1991	Cohort retrospective	USA	2	1982-1990	2b
Rai et al.[30]	1998	Cohort retro/prospective	India	1	1985-1995	2b
Bay-Nielsen et al.[35]	2001	Cohort prospective	Denmark	83, Danish hernia database	1998-2000	2b
Kulah et al.[48]	2001	Cohort retrospective	Turkey	1	1996-2001	2b
Hair et al.[23]	2001	Cohort retrospective/ prospective	UK	2	1994-1997	2b
Primatesta et al.[7]	1996	Cohort retrospective	UK	Register	1976-1986	2b
Ohana et al.[34]	2004	Cohort retrospective	Israel	1	1992-2002	2b
Alvarez et al.[32]	2004	Cohort retrospective	Spain	1	1992-2001	2b
Nilsson et al.[33]	2007	Cohort prospective	Sweden	90, Swedish hernia register	1992-2004	2b
Risk at strangulation/incarceration inguinal hernia without repair						
Neuhauser et al.[25]	1977	Cohort retrospective	USA	Social security data	1880-1884	2b
Neutra et al.[31]	1981	Cohort retrospective	Colombia	National survey	1964-1973	2b
Gallegos et al.[38]	1991	Cohort retrospective	UK	1	1987-1989	2b
Hair et al.[23]	2001	Cohort retrospective/ prospective	UK	2	1994-1997	2b
Fitzgibbons et al.[22]†	2006	RCT double-blind	USA	5	1999-2004	1b
O'Dwyer et al.[21]‡	2006	RCT double-blind	UK	1	NR	1b
Pre- and postoperative pain after a- and mild- symptomatic inguinal hernia repair						
Page et al.[24]*	2002	Cohort prospective	UK	1	1998-2000	
Fitzgibbons et al.[22]†	2006	RCT double-blind	USA	5	1999-2004	1b
O'Dwyer et al.[21]‡	2006	RCT double-blind	UK	1	NR	1b
Natural pain history of untreated symptomatic hernia						
Hair et al.[23]	2001	Cohort retrospective/ prospective	UK	2	1994-1997	
Fitzgibbons et al.[22]†	2006	RCT double-blind	USA	5	1999-2004	1b
O'Dwyer et al.[21]‡	2006	RCT double-blind	UK	1	NR	1b

NR = not reported
NA = not applicable
* Open tension-free mesh repair
† Lichtenstein repair or observation
‡ Open tension-free mesh repair or observation

repair, risk of incarceration and/or strangulation and crossover rates from the watchful waiting to the operation group and mortality associated with elective repair [21, 22].

Mortality associated with elective hernia repair

Mortality associated with elective hernia repair was investigated as a primary outcome measure in 11 studies [7, 22, 25, 33-35, 37, 40-42, 49] and as secondary outcome in six [19, 21, 36, 38, 39, 45, 47]. The mortality rates associated with emergency and elective repair by Haapaniemi et al.[49] were excluded from analysis since their patients, recorded from 1992 until 1997 by the Swedish Hernia Register, originated from the same database from which Nilsson et al.[33] reported, representing the Swedish Hernia Register from 1992 until 2004. The mortality reported by Palumbo et al[25, 45, 47] was also excluded from analysis since it was not clear how many patients were operated at the time of incarceration or strangulation. The mean mortality associated with elective hernia repair was 0.2% (range: 0-1.8%) (Table 2).

Mortality associated with emergency repair

Mortality associated with emergency hernia repair was investigated as a primary outcome measure in 13 studies [7, 25, 32-35, 37, 40-42, 46, 48, 49] and as a secondary outcome in seven[23, 30, 31, 38, 39, 43, 44]. The study by Kurt et al.[44] was excluded from analysis since the mortality was reported for all types of incarcerated abdominal wall hernias and not specifically for inguinal hernia. The study by Kauffman et al. [46] was excluded from analysis since mortality was assessed only after extended surgical treatment of incarcerated inguinal hernia including initial reduction of the incarcerated hernia if no strangulated or gangrenous bowel was expected. The study by Askew et al.[43] was excluded since mortality associated with emergency surgery after strangulation of specifically inguinal hernia was not reported. The mortality rates associated with emergency and elective repair by Haapaniemi et al.[49] were excluded from analysis since their patients, originated from the same database from which Nilsson et al.[33]. The mean mortality associated with emergency hernia repair was 4.0% (range: 0-22.2%) (Table 2).

Rate of incarceration and/or strangulation

The rate of incarceration and/or strangulation has been investigated by four retrospective cohort studies [23, 25, 31, 38] as a primary outcome and two randomized trials as a secondary outcome[21, 22]. We converted the observed probabilities of incarceration and/or strangulation into annual rate assuming a constant rate of incarceration and/or strangulation. The yearly rate of irreducibility associated with a non-operative approach was 0.4% (range: 0.2-2.7%) (Table 2). The type of event differed between studies (Table 2).

Table 2. Mortalities associated with elective and emergency inguinal hernia repair and the risk at incarceration and/or strangulation in case of non-surgical inguinal hernia treatment

Study	Mortality elective repair			Mortality emergency repair			Risk at incarceration and/or strangulation of a non-surgically treated hernia		
	N	Death	Mortality rate (%)	N	Death	Mortality rate (%)	N	Annual risk of incarceration/ strangulation (%)	Type of event: incarceration and/or strangulation
Williams et al.*	222	4	1.8	48	6	12.5	NA	NA	NA
Neuhauser et al.†	71651	NR	0.5	7495	NR	4.7	8633	0.4	Strangulation or incarceration
Tingwald et al.‡	44	0	0	15	1	22.2	NA	NA	NA
Nehme et al.§	1044	14	1.3	235	18	7.7	NA	NA	NA
Allen et al. ‖	49	0	0	46	1	2.2	NA	NA	NA
Gallegos et al. #	417	0	0	22	0	0	439	1.8	Strangulation
Oishi et al. ¶	1758	0	0	67	2	3.0	NA	NA	NA
Primatesta et al. **	27937	28	0.1	2738	47	1.7	NA	NA	NA
MRC Group††	915	0	0	NA	NA	NA	NA	NA	NA
Bay-Nielsen et al. ‡‡	23695	55	0.2	1156	81	7.0	NA	NA	NA
Ohana et al. §§	200	0	0	67	4	6.0	NA	NA	NA
Neumayer et al. ‖‖	1983	4	0.2	NA	NA	NA	NA	NA	NA
Fitzgibbons et al. ##	294	0	0	NA	NA	NA	256	0.2	Acute hernia incarceration without strangulation
O'Dwyer et al. ***	75	1	1.3	NA	NA	NA	75	0.9	Acute hernia
Nilsson et al. †††	66897	95	0.1	4167	134	3.2	NA	NA	NA
Alvarez et al. ‡‡‡	NA	NA	NA	70	2	2.9	NA	NA	NA
Neutra et al. §§§	NA	NA	NA	31	NR	12.0	46608	0.4	Incarceration and strangulation
Rai et al. ‖‖‖	NA	NA	NA	181	11	6.1	NA	NA	NA
Kulah et al. ###	NA	NA	NA	113	4	3.5	NA	NA	NA
Hair et al. ****	NA	NA	NA	10	0	0	61	2.7	Irreducibility requiring operation
NMR, Prismant	45026	34	0.1	1631	49	3.0	NA	NA	NA
Total average	242207	596	**0.2**	18092	715	**4.0**	56072	**0.4**	

NR = not reported
NA = not applicable

Crossover rate

The crossover from watchful waiting to operation has been reported by two randomized trials[21, 22]. Fitzgibbons et al.[22] reported 85 patients of in total 364 (23.4%) patients of the watchful waiting group to cross over during first two years of follow-up to have their hernia repaired. Seventy-three of these patients (86%) reported progression of pain or discomfort to be the reason for crossing over. Forty patients of the total 85 patients (47%) developed pain and discomfort interfering with daily activity. This two-year crossover rate amounts to a yearly rate of approximately 11.7%. Additionally, O'Dwyer et al.[21] reported that 15 of 77 patients crossed over within one year. Therefore, their reported risk of crossover was 19.5%.

Combining these figures 13% (range: 8.0-19.5%) of mild symptomatic and asymptomatic inguinal hernia patients assigned to watchful waiting management will crossover for inguinal hernia repair.

Recurrence rate

A meta-analysis of long-term follow-up studies concerning recurrence is reported by inguinal hernia guideline of the European Hernia Society. Data of all trials with a follow-up of over 48 months were reported comparing recurrences after Lichtenstein and endoscopic repair [27, 50-54]. We converted the observed probabilities of recurrence into annual rates assuming a constant rate of recurrence. Since no significant difference in recurrence rate between the Lichtenstein technique and endoscopic repair is reported, we calculated a mean yearly recurrence rate of 0.9% (range: 0.2-4.0%).

Baseline and sensitivity analyses

All probability estimates were modelled using beta distributions, except for the crossover rate with a triangular distribution. Life expectancy for a 50-year old male without a hernia calculated on the basis of age- and sex-specific mortality rates from the U.S. life tables of the general population was 26.95 years. Second order Monte Carlo simulation showed that the mean life expectancy for a patient with inguinal hernia who underwent watchful waiting was 26.88 (CI:26.873-26.884) compared to 26.89 years (CI:26.880-26.891) for a patient who was operated.

Sensitivity analyses showed the optimal decision to be sensitive to the procedural mortality rates and the annual rate of incarceration and/or strangulation. More extensive threshold analysis for these four variables separately indicated that in case of mortality associated with emergency repair being lower than its threshold value of 4.2%, the optimal choice is observation. Additionally, in case of mortality associated with elective repair being higher than 0.2% or a risk of incarceration and/or strangulation being lower than its threshold value of 0.5%, the optimal choice is observation. The other variables did not influence the choice of policy individually.

A two-way sensitivity analysis was performed adjusting the distributions of mortality associated with emergency repair and the annual rate of incarceration and/or strangulation into the highest reported values (22.2% and 4.5%, respectively), representing the worst case scenario. In this case, mean life expectancy for a patient undergoing observational management was 26.06 and 26.85 for a patient undergoing operation using second order Monte Carlo simulation.

In a more realistic simulation we took the highest value of mortality associated with elective repair (1.8%) and the lowest value regarding the yearly risk of incarceration and/or strangulation (0.2%). This resulted in a life expectancy of 26.46 and 26.57 for elective surgery and watchful waiting, respectively.

Pain

Three studies reported pre- and postoperative pain with regard to inguinal hernia repair (Table 1)[21, 22, 24]. Fitzgibbons et al. [22] and O'Dwyer et al.[21] both investigated pre- and postoperative pain in asymptomatic and mild symptomatic patients in a randomized setting. Both studies compare watchful waiting with standard open tension-free mesh repair. Fitzgibbons et al.[55] randomized inguinal hernia patients that were either completey asymptomatic or minimally symptomatic without interference with normal activity. Pain limiting activities were similar for watchful waiting vs surgical repair (5.1% vs 2.2%, respectively; P=0.52) after two years although a trend is visible in favour of surgical repair that might be significant in an adequately powered group. O'Dwyer randomized patients without inguinal pain at rest or movement. Visual analogue pain scores at rest or movement after one year did not differ between observative or operative management (3.7 and 5.2 mm (P=0.34) at rest; 7.6 and 5.7 mm (P=0.39) on movement, respectively).

Page et al.[24] followed up 63% of in total 323 patients at one year of whom preoperative pain scores at rest and on movement were reported. Severity of preoperative pain was no inclusion criterium. While overall the group showed a significant reduction in pain scores at rest and moving, this was due mainly to the large effect observed in patients with high preoperative values. Patients not reporting any pain preoperatively at rest had significant pain scores at one year (P=0.001).

Discussion

Studies investigating mortality rates associated with elective and emergency hernia repair differ with respect to coexisting comorbidity, mean age of patients, type of anaesthesia, duration of symptoms before emergency admission and the length of postoperative period. This makes any conclusions hazardous as all these factors could have a significant influence on mortality.

Most studies report that local anaesthesia carries advantages compared with general and/or regional anaesthesia[33, 56, 57]. These include shorter duration of admission, less postoperative urinary retention and less postoperative pain [10, 56-59]. However, a random-

ized clinical trial by O'dwyer et al did not reveal any difference between local and general anaesthesia[60].

Differences between different types of anaesthesia with respect to mortality can not be assessed since mortality after elective inguinal hernia repair is too low.

In comparing complications related to the type of anaesthesia Williams et al. [42]reported that general and spinal anaesthesia were associated with the highest complication rate, usually from respiratory or circulatory origin, whereas local anaesthesia was associated with the lowest number of complications even though it was employed in most of the poor risk patients. Nehme et al.[40] reported general and, to a lesser extent, spinal anaesthesia to be associated with a higher rate of serious postoperative complications, including postoperative death compared to local anaesthesia even though it was employed in the sickest and oldest patients.

The mortality rate is low following both open and laparoscopic elective operations but significantly increases after emergency surgery[33]. Neumayer et al. in comparing 1983 laparoscopic and Lichtenstein repairs, reported four death to be related to the operation of which three after laparascopic repair and one after open repair[19].

Not all studies noted the length of postoperative period patients were studied for postoperative mortality[7, 23, 30, 31, 40-42, 48]. Bay-Nielssen et al.[35] recorded mortality related to the operation until 30 days postoperative. In the study by Nilsson et al. [33] morbidity and mortality beyond 30 days postoperatively were not reported. However, this might underestimate mortality by exclusion of deaths that would still have been related to the operation. In the study by Neumayer et al. [19] a special committee decided what deaths, beyond 30 days as well, could be attributed to the elective surgical intervention. A special end-points committee determined two deaths beyond 30 days postoperatively also to be related to the operation: one after a perioperative myocardial infarction and another resulting from complications from bowel obstruction in a femoral hernia which presumably was missed at the time of the study operation (Table 2).

Furthermore, one study did not mention whether the group under investigation also consisted of patients with femoral hernia[30]. Rai et al. [30] did differentiate type of hernia with respect to complications, but not with respect to their reported mortality rate associated with emergency repair. According to Nillson et al. [33] the 30 day standardized mortality ratio after a femoral hernia is raised seven folds for both genders (15 years of age or older), whereas this rate after inguinal hernia operation is only modestly increased compared with the death risk of the background population. Additionally, Nilsson et al.[33] reported bowel resection which is associated

with a 20-fold mortality rate increase. This is undertaken in 21.3% of emergency femoral hernia operations compared to 5.4% of emergency inguinal hernia operations (P<0.001). Therefore, mortality rate associated emergency repair reported by Rai et al.[30] might be overestimated.

Late hospitalization in case of incarceration and/or strangulation is linked to a higher surgical morbidity and mortality[61]. All deaths after emergency repair reported by Williams et al. [42] had suffered from intestinal obstruction for longer than three days before admission. Nehme et al. [40] reported 16 of 18 deaths after emergency repair to have intestinal obstruction or strangulation for more than 48 hours. Rai et al. [30] concluded viability of contents in complicated hernias to be correlated directly with delay in presentation (or duration of irreducibilty); the longer the delay, the likelier the occurrence of gangrene (P<0.05). Kulah et al.[48] reported patients who presented more than 48 hours after the onset of symptoms to have a higher rate of postoperative morbidity and mortality and a significant higher rate of strangulation, bowel resection and hospital stay. In other studies duration of acute symptoms before admission and emergency repair was not reported[7, 23, 31, 33, 35, 38, 41].

In our decision model we assume an incarcerated hernia is treated by an emergency operation. However, selective reduction of incarcerated inguinal hernia in the adult is also a possibility when viable bowel is suspected. This enables the surgeon to perform elective surgery when associated diseases are corrected or improved. Kauffman et al, investigating 162 incarcerated hernia, reported mortality associated with emergency surgery for incarcerated inguinal hernia, even when bowel is viable, to be far in excess of mortality from reduction of incarcerated hernia. This mortality would be caused by reduction of nonviable bowel[46].

According to Williams et al.[42] failure of controlling associated diseases preoperatively contributed to high emergency mortality rate. Five of the six deaths resulted directly as a result of failure to control associated diseases. Tingwald et al. [41] reported myocardial infarctions to occur postoperatively in three patients with a known history of cardiovascular disease including one peroperative myocardial infarction, resulting in death within 30 days postoperatively. Nilsson et al. [33] reported that patients with ASA score I and II have a very low risk for postoperative mortality whereas the mortality risk is raised significantly for both men and women with ASA score III to IV.

According to a review study by Schumpelick et al.[6] mortality associated with elective repair would be less than 0.01%. This mortality rate is much lower compared to the mean value reported in this study of 0.2%. Additionally, Schumpelick et al.[6] reported that the mortality rate in case of emergency repair and very elderly patients could be as high as five per cent which approximately coincides with our mean mortality rate of 4.0%.

There is a discrepancy between the mean risk of recurrence of 4.7% and the reoperation rates that are reported by large databases. The Danish hernia database reported a percentage of operations for recurrent hernia of 13.5% at the end of 2005. Aufenacker et al. reported an operation rate for recurrent hernia of 14.1% in 2001[62].

One prospective cohort study investigating pre- and postoperative pain levels reported results in favour of observative management in case of asymptomatic hernia[24]. Both randomized trials investigating pre- and postoperative pain in case of asymptomatic and mild symptomatic hernia reported no significant difference with respect to chronic pain after observative or operative management[21, 22]. However, both studies showed a trend in favour of operative management. This is remarkable since these studies compare watchful waiting with standard open tension-free repair. Laparoscopic repair should also be compared. Additionally, the level that was assumed clinical relevant used in the power analysis, might have been too little to detect a significant difference and could be challenged. O'Dwyer et al.[21] assumed a difference in pain at one year of 20% between groups as a clinically significant difference with a 80% power. Therefore, studies invesigating pre- and postoperative pain in case of asymptomatic and mild symptomatic inguinal hernia could be strengthened by additional randomized trials into pre- and postoperative pain.

In our model life expectancy between the two treatment groups is merely sensitive to the procedural mortality rates and the annual risk of incarceration and/or strangulation. Therefore, this might influence optimal treatment strategy. However, since a Markov model permits no statistical testing, the significance of the difference we report in life expectancy is not clear. Mortality associated with elective inguinal hernia surgery is lower than mortality rates from the U.S. life tables of the general population. Chances are higher to die from other causes than an inguinal hernia and its subsequent elective treatment. Therefore, differences between two treatment strategies only become apparent when mortality rate increases in case of an emergency repair which is influenced by the incidence of incarceration and/or strangulation.

In conclusion, the available data suggest that life expectancy for male elderly inguinal hernia patients associated with watchful waiting or operation differs very little. Therefore, the general doubt regarding operating on mild symptomatic and asymptomatic elderly hernia patients, illustrated by two recent randomized trials investigating pre- and postoperative pain for these type of managements, is justified. Sensitivity analyses showed mortalities associated with elective and emergency repair and the rate of incarceration and/or strangulation in their reported ranges, to be of influence on type of policy. In case of asymptomatic and mild symptomatic patients there seems to be no difference in pain relieve between watchful waiting and operation. Currently we investigate pre- and postoperative pain levels in

mildly symptomatic and asymptomatic patients in a randomized clinical setting which could supplement the existing data by Fitzgibbons et al.[22] and O'Dwyer et al.[21]. Furthermore subgroup analysis is conducted regarding differences between open and laparoscopic repair.

Acknowledgements

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INCA (INguinal hernia: Conservative or operative Approach) Trialists' Collaboration

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Appendix footnotes Table 2

* Two-hundred-seventy patients older than 60 years of age of which 48 and 222 inguinal hernia patients (direct, indirect, sliding or pantaloon) were operated through an emergency or an elective repair, respectively. Males predominated 13 to 1. In 75% a Bassini repair was employed. Other repairs included McVay and Halsted. It was not mentioned among what period mortality was assessed. Age and physical condition were comparable for both groups. Mortality associated with elective repair included 2 deaths from pulmonary emboli, 1 from staphylococcal enterocolitis and 1 from pneumonia and pulmonary insufficiency. Ten per cent of the emergency operations were undertaken to rectify incarceration in a direct hernia. All deaths associated with emergency surgery had had intestinal obstruction for longer than 3 days before admission; 2 died of acute myocardial infarction, 2 of progressive infection, 1 of pulmonary embolus and 1 of progressive pneumonia and uremia. The exact moment of death in relation to surgery was not reported. General anesthesia was associated with the highest respiratory complication rate, spinal anesthesia with the highest incidence of genitourinary complications and local anesthesia was associated with the lowest number of complications in spite of the fact that it was anesthetic of choice in most of the poor risk patients. It is not reported whether type of anesthesia influenced mortality.

† Mortality rates were calculated by means of medicare diagnosis and discharge characteristics regarding inguinal hernia patients with obstruction (which means permanently incarcerated with obstruction with or without strangulation) or without obstruction, from January to December 1971 (source: Social Security Administration, Dept. Of Health, Education and Welfare). These Social Security data were based on discharge status and not 30-day postoperative status. The number of patients that were discharged dead after surgical or other treatment were reported, however not specifically the number of patients that died after an emergency or elective repair. However, the operative mortality overall for both groups was reported. Nothing was reported with respect to the male-female ratio and type of repair technique. To estimate the risk at incarceration and/or strangulation Neuhauser used data from a patient serie from Paul Berger's truss clinic in Paris where 8633 patients (males and females) were treated by means of a truss in an era when elective hernia repairs were not done. These patients over age 10 had a mean age of onset of 43.1 years and a mean age of presentation at his clinic of 51.3 years. We have to take into account that a part of these patients if not all were treated with a truss. The probability of an accident per hernia year is probably a slight overestimation of the true risk since 90% of these patients had an inguinal hernia. Other hernia that were also included such as a femoral hernia are associated with a higher risk at incarceration and/or strangulation. Probability of accident per hernia year was 0.0037.

‡ In total 62 patients underwent inguinal hernia repair of which 44 elective and 18 emergency. Mean age of the total group was 76.9 years (range: 70-91). Thirty-four, 14, 10 and 4 patients had a indirect hernia, direct hernia, a combination of hernia or a femoral hernia, respectively.

The type of repair performed included Bassini and McVay in equal frequency for treatment of indirect hernia. The majority of the other type of hernia were treated by McVay. General, spinal and local anesthesia were used in 36, 13 and 13 patients, respectively. In the 18 patients that were operated on by an emergency repair, the hernia was incarcerated at time of operation. The 18 incarcerations occured in 14 indirect, 3 femoral and 1 direct hernia. Of these emergency repairs 4 patients died. However, 3 deaths occured in patients with an incarcerated and obstructed femoral hernia which are not included in our analysis: 4 myocardial infarctions occured postopertively in 3 patients with cardiovascular disease preoperatively that all died within 30 days postoperatively. Additionally, pulmonary emboli occured in 2 patients of which one died. All of the deaths occured in patients receiving either general or spinal anesthesia. The authors were not able to attribute the high mortality to either age or the amount of comorbidity, neither of which differed significantly in those undergeoing elective or emergency repair.

§ Of a total of 1755 groin hernias 1279 were surgically repaired of which 1044 electively and 235 as an emergency. The mean age of the total group of 1496 with 1755 hernias was 78.2 years (range: 65-96). The 235 emergency operations included 57 laparotomies and 214 groin explorations with bowel resection in 26 patients and sigmoid resection with Hartmann's procedure in 7 patients. Local, spinal and general anesthesia were used in the repair of respectively 421, 312 and 546 cases. McVay's technique was most frequently used (632 repairs) after Bassini (342), Shouldice (234), Halsted (59), preperitoneal (9) and mesh prosthesis (5). Type of hernia distribution was as follows: 785 indirect, 618 direct, 227 femoral and 125 pantaloon hernias. The most common direct cause of death was cardiovascular deficit which killed 26 patients. The following causes of death were reported for all 32 deaths after emergency and elective surgery: myocardial infarction, cardiac arrythmias and cerebrovascular accidents resulting in death was reported in 15 patients. Congestive heart failure, pulmonary embolism, a lobar pneumonia and a multiple organ failure with septic shock were the causes of death in respectively 11, 3, 1 and 2 patients. Of the patients who died 16 had intestinal obstruction or strangulation for more than 48 hours. Seven patients died preoperatively while being resuscitated from the severe physiologic and metabolic complications that resulted from strangulation and bowel obstruction.

‖In total 95 patients over the age of 65 years of which 46 (48%) was repaired as an emergency and 49 electively. The median age of the emergency and elective group differed significantly, 76 (range 65-88) and 70 (range 65-88) years, respectively. The only death occurred in the emergency group. The type of event in case of an emergency repair was not specified. Gender distribution, type of anesthia, type of repair, physical condition and number of surgerons participating or experience of surgeons were not reported. A description of the patient that died was not reported.

Fourteen of 22 patients that required an emergency repair had evidence of comprised tissue at operation, in one case it was necessary to resect a strangulated loop of bowel. Four of the strangulations occurred in recurrent hernia, of which there were a total of 60. Median age of 22 patients presenting with a clinically strangulated hernia was 65.5 years (range: 17-87) and for those with non-strangulated hernias 59 years (range: 19-89). Cumulative probability of strangulation at 1 year (2.8% after 3 months, 4.5% after 24 months and 8.6% after 60 months). We converted the 60 months probability of incarceration and/or strangulation of 0.086 into a 1 year probability of 0.018 assuming a constant rate. Approximately one third of the cumulative risk of strangulation at 60 months was reached in the first 3 months of a hernia's presence. Strangulation was assessed in two different ways: as a working diagnosis that led to immediate operation and as the finding at operation of tissue whose viability was already compromised.

¶ In two subgroups 1758 elective and 67 emergency inguinal hernia patients (of which 50 with incarceration and 17 with bowel obstruction at presentation) were analysed. The mean age was calculated for the total group of 1777 elective (of which 1758 and 19 inguinal and femoral hernia, respectively) and 82 emergency groin hernia patients (of which 67 and 15 inguinal and femoral hernia, respectively): 51.7±17.5 for 1777 elective repairs, 50.3±20.8 for 57 patients presenting with incarceration and 65.6±14.5 for 25 patients presenting with bowel obstruction. Age differed significantly between the elective & incarcerated group and incarcerated & bowel obstructed group. In the total group 5 patients of advanced age (68, 79, 81, 81 and 83) died: one woman and 2 men with femoral hernia and 1 woman and 1 men with inguinal hernias. Four of 5 patients had undergone resection of necrotic bowel and died of septic multiorgan failure. The remaining death was caused by a postoperative pulmonary embolus. The total group of 1859 included 1782 man and 77 women. Type of anesthesia, type of repair, the physical condition, the number of surgeons and experience of the surgeons were not reported.

** Of in total 28399 diagnosed hernias 27937 and 2738 were elective and emergency admissions, respectively. Of the operations in elective and emergency admissions 1088 (4%) and 573 (21%) were performed on patients aged younger than 1 year and 6690 (24%) and 1133 (41%) on patients aged older or equal to 65 years, respectively. The median age for patiens in elective and emergency repair was 53 and 58 years, respectively. Postoperative mortality was calculated as the number of deaths after operation, wherever they occured. However, values included in this analysis are the number of death within 30 days after the operation derived from figure 3 since it is not clear that deaths occuring after this period are directly related to the intervention. The most common certified underlying causes of death were cardiovascular causes and respiratory causes. No details are reported regarding type of anesthesia.

†† 928 patients with inguinal and femoral hernia were randomly assigned to laparoscopic (468) or open hernia repair (460). Mean age of both groups was 55.3 and 55.7, respectively. Percentage male patients 94.2 and 96.7, respectively. There were no operation related deaths.

‡‡ Bay-Nielsen et al. primarily investigated the reoperation rates after different types of hernia surgery in Denmark. Mortality rates are based on 30-days postoperative status. Median age of acute cases was 73 years (range: 58-81). Of all electively operated 19752 primary hernias (of in total 23695 hernia of which 3943 were operated for recurrent hernia), 4373 (22%) were operated by a conventional anterior nonprosthetic repair, 14832 (75%) by an anterior prosthetic repair and 547 (3%) by a laparoscopic repair.

§§ Two hundred and 67 patients were analysed after elective and emergency hernia repair (for incarceration or strangulation), respectively. Mortality and its cause occurring within 30 days of surgery were assessed. Among the elective and emergency group 85% and 88% were males, respectively. Mean ages were 57.9 and 69.1 years, respectively. The most common types of anaesthesia in both groups were general and regional. Bassini type of repair predominated in both groups and was followed by Lichtenstein and TEP repair. Four patients in the emergency group died mostly of congestive heart failure and respiratory insufficiency following pneumonia. All death occurred in patients classified as ASA score III or IV. Mortality was clearly linked with high ASA score rather than directly related to surgical complications.

‖‖ Neumayer et al. randomised 2164 patients to either open or laparoscopic hernia repair. After randomisation 1983 patients were treated as assigned: 994 and 989 were treated by open and laparoscopic repair, respectively. Within 30 days there were 2 deaths in the laparoscopic group (both considered to be related to the surgery) and none in the open group. Two deaths beyond 30 days postoperatively were also determined to be related to the operation by the end-points committee. The causes of these 4 deaths were a pulmonary embolus, an intestinal injury, a perioperative myocardial infarction requiring coronary-artery bypass surgery and a complication from a bowel obstruction in a femoral hernia, presumably missed at time of study operation.

One life-threatening complication occurred in each of 3 patients: postoperative bradycardia, deep venous thrombosis, and postoperative hypertension requiring hospitalization. One patient from the observative group experienced an incarceration (without strangulation) within 2 years, another patient experienced an incarceration with bowel obstruction after 4 years (a total follow-up of 4.5 years) which was reduced with sedation and repaired electively. The hernia accident rate was 0.0018 events per patient-year. None of the 22 deaths among all enrolled patients was attributed to the study.

*** Acute hernia after a mean follow-up of 574 days. Seventy-five patients were seen after 1 year follow-up. The amount of patients followed up after 574 days has not been stated explicitely. One patient had an acute hernia during a follow-up of 574 days. We converted this 574 days probability of into a one-year probability of incarceration and/or strangulation of 0.009 assuming a constant rate of incarceration and/or strangulation. This hernia was reduced. It is not clear whether this was conducted operatively or not.

††† Mortality rates within 30 days of surgery apply to male inguinal hernia patients older or equal to 50 years of age.

‡‡‡ In total 147 patients who underwent emergency surgery for incarcerated groin hernias were analysed. Median age was 70 years (range: 24 to 96). There were 77 men (52.4%) and 70 women (47.6%). Femoral hernia and inguinal hernia were seen in respectively 77 and 70 patients. Surgical repair was performed under general anesthesia in 72 cases (49%), spinal anesthesia in 74 cases (50%) and local anesthesia in one (1%). Spinal anesthesia was most performed in inguinal hernias (56%). Tension-free, McVay, Bassini and preperitoneal repair were performes in respectively 31, 25, 22 and 22%. Postoperative mortality was recorded in 5 patients (3.4%) in the total group of 147 patients and in 2 patients of the inguinal hernia subgroup of 70 patients (2.9%). The causes of death: respiratory failure in 2 patients who had chronic obstructive pulmonary disease (ASA class III and IV), sepsis in 2 patients who had undergone resection of necrotic bowel in reoperations (both ASA class III) and multiorgan failure in 1 case (ASA class IV). The duration of symptoms, late hospitalization, concomitant disease and ASA class III/IV was significantly related with a higher mortality. Type of anesthesia (spinal or general) was not found to be significant factor linked with mortality.

§§§ Neutra et al applied hernia prevalence figures from a total national survey in the mid-1960s to the population of one city in the early 1970s of which the incarcerated cases were determined. They report only the number of herniated persons aged 50 and older and events occurring in this age group. They do not report at which moment in relation to moment of surgery the deaths occurred. Assuming that 4% of cases will be occurring outside the hospital with 100% case fatality and that these case fatalities are equal to that in the hospital, their rate was increased by a factor of 1.25, accounting to a yearly risk of incarceration in adults of 3.8 per 1000.

‖‖‖ A total of 218 complicated groin hernias (obstructed and/or strangulated) were identified (181 adults and 37 children of whom 42 adults were prospective). A total of 11 adults with complicated hernia died in which coexisting illnesses (mainly cardiovascular) were the main cause of mortality making them poor risk candidates for surgery and anesthesia. Four patients died of septicemia with gangrenous hernia contents, 5 due to cardiovascular complications (e.g.cardiogenic shock, myocardial infarction, ventricular tachycardia and cardiac failure) and 2 due to chronic renal failure and diabetes with keto-acidosis. Time of death in relation to surgery was not recorded.

In total 189 patients with a median age of 70 years (range 65-100) were investigated of which 113, 42, 13 and 21 had an inguinal, femoral, incisional or umbilical hernia that required emergency hernia repair, respectively. Method of repair was largerly determined by surgeon's preference. In the total group of 189 patients tension-free hernia repair was most frequently performed and applied in 40% of patients. Other repairs included Bassini (19%), anatomic repair (16%), McVay (15%), preperitoneal (9%) and mayo repair (2%). Fifty-six per cent of in total 103 indirect hernias was incarcerated and 44% strangulated. Additionally, 70% of in total 10 direct hernias was incarcerated and 30% strangulated. Twenty percent of direct hernias and 11 per cent of indirect hernias required bowel resection. Other mean measurements such as ASA class and type of repair apply to the whole group including other type of hernias and are therefore not mentioned. Ten patients died in the whole group of 189 patients. However, 4 patients died from emergency surgery associated with an (indirect) inguinal hernia. Causes of all ten patients included 4 patients with congestive heart failure, 4 with adult respiratory distress syndrome, 1 pulmonary embolism and 1 patient that died of urinary bladder cancer. Patients who presented more than 48 hours after the onset of symptoms had a higher rate of postoperative morbidity and mortality and a significant higher rate of strangulation, bowel resection and hospital stay.

**** Length of follow-up regarding patient that had their hernias between 1 and 5 years was not mentioned. Therefore only 61 patients are reported in our table that had their hernias for 5 years or longer. We converted the 108 months probability of incarceration and/or strangulation of 0.213 into a 1 year probability of 0.027 assuming a constant rate.

Chapter 3

Chronic pain, a significant complication after Lichtenstein hernia repair

Translated and adapted from:
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Abstract

Two male patients, aged 37 and 56, suffered from chronic pain after a Lichtenstein hernia repair. Since mesh-based repair techniques have decreased the recurrence rate, postoperative inguinal pain has become the most important complication of these operations. Three months after surgery, 20% of the patients experience some pain. In 12% of the patients this pain limits daily activities and 1-3% of the patients are invalidated by neuralgic pain. Preventing damage to sensory nerves during the operation is one way of preventing neuralgic pain. Damaged sensory nerves should be excised. Neuralgic pain after the operation may be alleviated by tricyclic depressants, opioids or antiepileptic drugs. In selected patients with chronic pain of neuropathic origin neurectomy is indicated. In one of the patients presented, pain disappeared after neurectomy of the ilioinguinal nerve. Triple neurectomy in the other patient, however, was unsuccessful.

Introduction

The evidence-based inguinal hernia guideline of the Association of Surgeons of the Netherlands (ASN) recommends a Lichtenstein hernia repair in case of a primary unilateral inguinal hernia; in this repair the inguinal floor is reinforced by means of a polypropylene mesh (figure 1)[63, 64]. After the introduction of hernia repair with mesh the incidence of a recurrent inguinal hernia decreased from 15-20% to less than 5%[65-68]. As a result of this decline, currently chronic postoperative pain is the main subject of investigation. Although the incidence of chronic postoperative pain might have been the same over the years, not much attention was being paid to this since prevention of recurrence was main priority. Currently, pain is considered the most important complication. Three months postoperatively 20% of patients still have pain and 12% experience pain that limits daily activity. One year postoperatively 1-3% still experiences invalidating pain[11, 68-70].

Pain is considered chronic when lasting longer than 3 months after operation[71]. Chronic pain is suggested to be of neuropathic, somatic or visceral origin. The commonest types of pain are somatic and neuropathic[11, 12, 72]. The cause of pain is sometimes difficult to determine and therefore difficult to treat[73-77]. Additionally, the incidence and severity of pain seems to be underestimated[12].

By means of two patient histories we describe the occurrence of chronic pain after Lichtenstein hernia repair. Furthermore, we discuss causes, diagnostic measures and treatment possibilities.

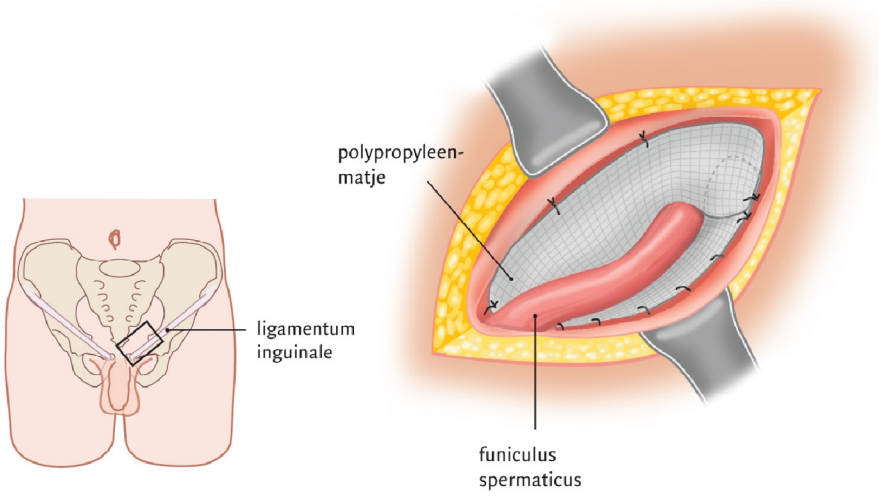

Figure 1. Lichtenstein hernia repair, an open inguinal hernia repair. The inguinal floor is reinforced by means of a polypropylene mesh after reduction of the hernia sac. The sutures on the cranial side of the mesh are not obliged.

Patient A

A healthy male of 37 years old was operated on for a bilateral inguinal hernia by means of a bilateral Lichtenstein hernia repair. In the operation report it was noted that bilaterally the ilioinguinal nerve (IIN) was identified. It was transected at the right side and preserved at the left side. Postoperatively the patient experienced pain in the left groin limiting him with respect to his daily activity. He experienced electric shocks and a pain increase on movement and especially during Valsalva. He used pain medication on a daily basis.

At physical examination he indicated pain in the left groin at the scar and caudally from the scar. Except from allodynia, sensibility in the groin was undisturbed. There was no hernia recurrence. The diagnosis stated 'neuralgia along the course of the IIN'.

The patient was treated with a test blockade with 10 ml bupivacaine 0.25%. The injection was placed in the anatomical plane between the aponeurosis of the external oblique muscle and the internal oblique muscle just medially from the anterior superior iliac spine. By means of this injection pain of neuropathic origin, which should be alleviated, can be differentiated from other types of pain. The patient indicated that he was pain free after the injection for several hours after which the pain slowly returned.

At operative exploration a thickened IIN was seen with adhesions to the polypropylene mesh. The nerve was resected over a length of 2 cm and the proximal nerve end was buried within the fibers of the internal oblique muscle. After the healing of the wound this patient was totally pain free. He experienced an analgesic area medial from the scar in the sensory area of the IIN. After 9 months patient was still pain free.

Patient B

A 56 year old male inguinal hernia patient was operated on for a unilateral left inguinal hernia by means of a Lichtenstein hernia repair. His history included two treatments for back and hip pain by pain specialists. At both occasions no specific pathology was objectified. Subsequently, the patient was seen by painspecialists and treated for a painsyndrome.

Initially after the inguinal hernia correction the patient had no complaints. However, after several weeks he visited the outpatient clinic with severe invalidating pain in the operation area of the left groin. The pain was position dependent; only with stretched legs the pain was endurable. He used several different pain medications. Tinel's sign was negative. Since the patient had no sensory deficits in the groin and considering the patient's history, the surgeon did not expected his complaints to be of neuropathic origin.

De anesthesiologist performed testblockades of the IIN and the iliohypogastric nerve (IHN), without any success. He considered the pain therapy resistant. Subsequently, the surgeon performed another testblockade. Since this was shortly successful the possibility of a triple neurectomy was explained to the patient. This entails resection of the 3 nerves in the groin: IIN, IHN and genital branch of genitofemoral nerve (GB)[76]. Despite the surgeon's doubts regarding the effect, the patient chose the operation. A triple neurectomy was performed. The resection of the 3 nerves was confirmed histologically. The result was unsatisfactory. Several months after the operation the patient still experienced invalidating pain in the groin.

Pain after an inguinal hernia is a complex problem that is a diagnostic and therapeutic challenge to the surgeon, general practitioner and anesthesiologist. In view of the high number of inguinal hernia patients being operated by a Lichtenstein hernia repair, more than 12,000, it is important to inform Dutch surgeons as comprehensive as possible[78]. Although the Lichtenstein hernia repair is considered a simple, safe and reproducible technique, one may not underestimate the learning curve[79]. General practitioners and pain specialists ought to be informed about the symptoms, diagnostic tools and treatment of patients experiencing postoperative pain.

Causes

There are several causes of chronic pain after placement of a polypropylene mesh (table 1). It is thinkable on theoretic grounds that this method is associated with a higher risk at nerve damage and therefore incidence of neuropathic pain. The pain could be explained by an early or late fibrotic reaction of the mesh with adhesion formation of a nerve or entrapment of a nerve by sutures. The three sensory nerves in the groin, the IIN, IHN and GB have multiple aberrations that are sometimes difficult to identify (figure 2)[80, 81]. One or more nerves can surely come into contact with the surface of the mesh.

Pain of somatic origin can develop by tension on the mesh after shrinkage, a suture through the periost of the tuberculum of the pubic bone, a recurrent hernia and sometimes by

Table 1. Causes of chronic pain after open hernia repair

Type of pain	Cause
Neuropathic	Adhesion nerve to mesh
	Suture entrapment
	Peroperative iatrogenic nerve injury
Somatic	Recurrent inguinal hernia
	Tension on mesh
	Suture through periosteum of pubic tubercle
Visceral	Ligation or resection hernia sac

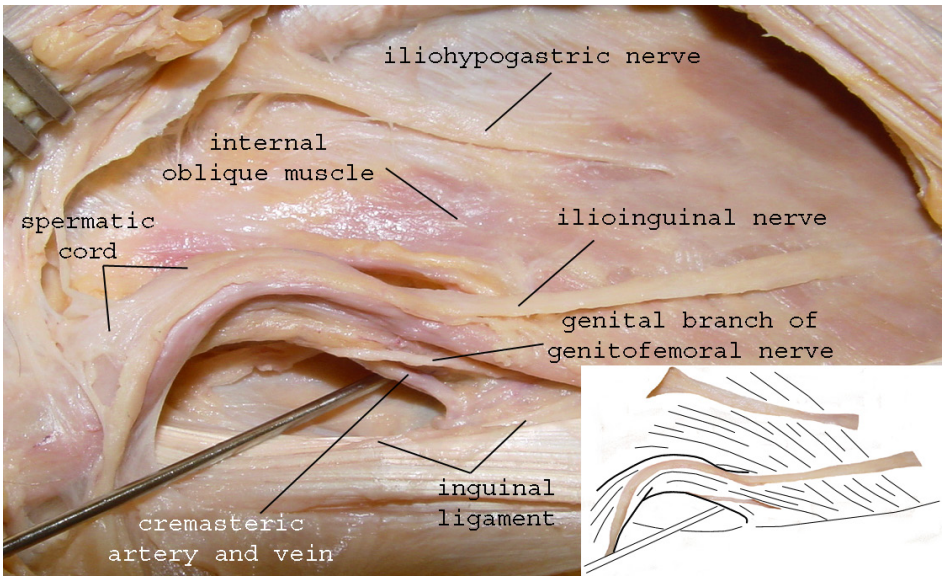

Figure 2. Course of the three inguinal nerves encountered during open hernia repair. The anatomic variability of the course of these nerves is high.

postoperative seroma formation[82]. Additonally, one must keep in mind the possibility of ischemic pain caused by devascularization of the testis.

Prevention

A careful operation technique and good anatomic knowledge could prevent pain of neuropathic origin[83, 84]. Injury to a nerve can initiate an inflammatory reaction that can lead for example to adhesions between the nerve and the mesh. If nerve tissue has been injured or if contact with the mesh is inevitable as a result of the anatomical course of the nerve, it is advised to resect the nerve as proximally and distally as possible and to bury the proximal nerve end in the fibers of the internal oblique muscle or even in the preperitoneal space[76, 85]. However convincing evidence of the effect of this method is lacking.

The alternative is routine nerve transection[86-89]. In 2 randomized studies routine transection of the IIN did not cause sustainable complaints. However it did not decrease the incidence of chronic postoperative pain[86, 87]. In one study a decrease in postoperative pain was noted[88]. Transection of the sensory nerves results in hypoalgesia or analgesia in a small area in the groin or the scrotum; a male patient usually is not affected by this deficit. However, in female patients this could result in analgesia of the major labia; females do experience this as a problem. Therefore in female patient transection of the GB (innervates skin of major labia) should be prevented.

The surgeon should report how the nerves were managed (recognition of IIN and IHN directly, recognition of GB or cremasteric vessels that run parallel to the GB, iatrogenic injury, resection or preservation, proximal and distal level of division in case of resection, handling of the nerve ends, position with respect to the mesh if preserved). After closure of the aponeurosis of the external oblique muscle, the inguinal canal and the subcuticular space can be infiltrated with 5-8 ml bupivacaine 0.25% to decrease the incidence of postoperative pain[90]. There is no proof of a positive effect of local anesthesia on chronic neuropathic pain.

Diagnostic Tools

In case of severe pain of neuropathic origin shortly postoperatively one can suffice with history and physical examination. If there is doubt with regard to the origin of the pain after physical examination, an MRI during Valsalva should be considered to exclude a recurrent hernia or wrinkling of the mesh. Additionally, other pathologies can be ruled out by MRI such as infection or a tumor. A recurrent hernia can also be demonstrated by a herniography. However, with this technique a parafunicular lipoma remains invisible since this can exist without a hernia sac. Ultrasonography gives a dynamic imaging, but is dependent on the experience and skills of the radiologist. A negative outcome does not rule out pathology. Considering the invasive character an endoscopy or groin exploration is a last resort. This should only be applied when all other modalities were inconclusive[64].

Nerve Blockade

After ruling out a recurrent hernia it is advised to block the nerve with a bupivacaine injection. If the pain subsides after a few hours, this is highly suggestive of an entrapped or injured nerve and neurectomy should be considered[91]. Attention should be paid to the possibility of a placebo-effect of the injection. The nerves should be identified and treated individually. Possibly neurophysiological studies can be helpful identifying the nerves.

Conservative Treatment

If the painkillers like paracetamol, NSAID's or opioids are not effective, it is possible to employ neuropathic specific medications. Pain-teams already are using tricyclic antidepressants and anti-epileptics for years.

Operative Treatment

In case of a recurrent hernia or a meshoma operative exploration should be considered. In case of nerve entrapment or nerve injury neurolysis, transection or resection of the associ-

ated nerve have been described. However In case of neurolysis there remains a risk at recurrent hernia. Best results are achieved by extended triple-neurectomy. During this operation all three inguinal nerves are resected for a length as wide as possible and be transected as proximally and distally as possible. Additionally, nerve fibers in the lamina propria of the vas deferens originating from the hypogastric plexus are resected[76, 92].

Pain-team

In doubt the pain is of a neuropathic origin a pain specialist should be consulted. Subsequently, certain pain medications will be applied such as amitriptyline, opioids, gabapentin and nerve blockades on the level of the nerve roots. With a great deal of patients the pain subsides without operative intervention. This can take months or years in some rare cases. Good information can be reassuring. Table 2 gives an overview with respect to possible treatment modalities in case of severe chronic pain of a Lichtenstein hernia repair.

Table 2. Recommendations with regard to prevention and treatment of chronic pain, in specific for pain of neuropathic origin

Preoperative
Painscore (visual analogue scale)
Pain history (use of analgesics)
Peroperative
Desciption in operative report of:
Recognition inguinal nerves direct/indirectly
Iatrogenic injury
Resection/ preservation
Proximal/ distal level of division
Handling nerve ends
Position nerves in relation to mesh in case of preservation
Wound infiltration with bupivacaine
Postoperative
Painscore (visual analogue scale)
- in case of severe neuropathic pain directly postoperative:
Re-exploration
Pain medication (paracetamol, NSAID's)
MRI to diagnose recurrence or meshoma
- in case of chronic pain:
Diagnostic bupivacaine injection
Neurofysiological testing area of operation area
Consulting of pain specialist
Specific medication (tricyclic antidepressants, opioids, anti-epileptics)
Nerve blockade at root level
Neurectomy in selected patients
Prevention
Adequate anatomical knowledge (adequate training, refreshing courses for surgeons)

In conclusion, severe and chronic postoperative pain seems to be an underestimated complication after inguinal hernia repair. The presumptions with regard to the origin and possibilities with respect to diagnostic tools and treatment are not supported by literature[77]. Patient A experienced a typical pain of neuropathic origin that could be treated successfully by neurectomy. Patient B experienced pain that was difficult to treat. He did not experience a typical neuralgia and he had a history of pain syndromes. The effect of treatment was unsatisfactory.

Probably prevention of neuralgia is the best strategy. To prevent injury or entrapment of nerves a good knowledge of anatomy and careful operation technique are essential. Neuropathic pain after inguinal hernia repair should be recognized timely by all care takers, from surgeon to nurses to general practitioner to pain specialist. A multidisciplinary workup by devoted specialists, like a surgeon and anesthesiologist is advised. Furthermore, it is essential to conduct pathophysiological and clinical studies into better preventive, diagnostic and therapeutic modalities.

Chapter 4

Randomized clinical trial of mesh versus non-mesh primary inguinal hernia repair: long-term chronic pain at 10 years

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Surgery, November 2007 142:695-698

Abstract

Background

Open mesh or non-mesh inguinal hernia repair may influence the incidence of chronic postoperative pain differently.

Methods

A total of 300 patients scheduled for repair of a primary unilateral inguinal hernia were randomized to non-mesh or mesh repair. The primary outcome measure was clinical outcome including persistent pain and discomfort interfering with daily activity. Long-term results at 3 years of follow-up have been published. Included here are 10-year follow-up results with respect to pain.

Results

Of the 300 patients, 87 patients (30%) died and 49 patients (17%) were lost to follow-up. A total of 153 were physically examined in the outpatient clinic after a median long-term follow-up of 129 months (range, 109 to 148 months). None of the patients in the non-mesh or mesh group suffered from persistent pain and discomfort interfering with daily activity.

Conclusion

Our 10-year follow-up study provides evidence that mesh repair of inguinal hernia is equal to non-mesh repair with respect to long-term persistent pain and discomfort interfering with daily activity. An important new finding from the patient's perspective is that chronic postoperative pain seems to dissipate over time.

Introduction

The use of prosthetic mesh allows tension-free inguinal hernia repair and has proven to result in less recurrences. Concomitant with popularization of this repair, it has become clear that morbidity associated with this operation mainly consists of chronic groin pain. Long-term randomized studies with 5-year follow-up to investigate chronic groin pain after open mesh versus non-mesh hernia repair have not been published. To determine the influence of the introduction of mesh material on the incidence of chronic pain, we conducted a randomized double-blind study of open non-mesh versus mesh hernia repair. In 2002, we published the 3-year follow-up results, which indicated that mesh repair was comparable to non-mesh repair with respect to chronic postoperative pain at 1, 6, 12, 18, 24, and 36 months [63, 93]. The purpose of this paper is to report the results at 10 years of follow-up.

Methods

Between September 1993 and January 1996, 300 patients older than 18 years of age scheduled for repair of a primary unilateral inguinal hernia were randomized to open mesh or non-mesh repair. Patients could only be enrolled once and were not included if they suffered from bilateral inguinal hernia. Six hospitals participated in the study. The study was designed to mimic clinical reality in general surgery. The conventional method, therefore, was not standardized, and no specialized hernia centers participated in the study. The protocol was approved by the ethics committees of all the participating hospitals.

Non-mesh repair was performed according to each surgeon's method of choice, provided that 2-0 polypropylene sutures (Prolene; Ethicon, Johnson & Johnson, Sommerville, NJ, US) were used. Mesh repair was performed according to a strict protocol, as described by Lichtenstein and Shulman using a Prolene or Marlex (CR Bard Inc, Billerica, Mass, US) polypropylene prosthetic mesh of 7.5×15 cm. The primary outcome was clinical outcome including persistent pain and discomfort interfering with daily activity 10 years after the procedure.

Follow-up was done by physical examination at the outpatient clinic after 1 week, 1 month, 6 months, 1 year, 2 years, and 3 years. A more meticulous description of the methods has been published previously by Vrijland et al[93].

Long-term follow-up occurred from June 2005 until January 2006. All patients were asked to complete a questionnaire. If the patients had not replied after a second mailing, they were contacted by telephone, and visited at home if they agreed. Patients were asked whether they suffered from persistent pain and discomfort interfering with daily activity, paroxysmal

pain during intensive activity not interfering with daily activity (such as sports or gardening), chronic obstructive pulmonary disease, obstipation, or prostatism. Physical examination was conducted by R.N.v.V. or A.R.W., who were blinded to the type of repair that had been performed.

The number of patients suffering from chronic pain was compared between the mesh and non-mesh groups by intention to treat with the Fisher exact test. All statistical tests were 2-sided; $P \leq .05$ was considered significant. All statistical analyses were performed using the Statistical Package for Social Sciences for Windows (SPSS Inc, Chicago, Ill. US).

Results

A total of 300 patients were randomized; 11 patients were excluded. Of these, 4 patients appeared to have another type of hernia at operation; 1 patient needed bilateral repair; the operation was cancelled for 3 patients. In spite of inclusion in the trial, 2 patients underwent laparoscopic inguinal hernia repair, and 1 patient withdrew informed consent before operation.

Of the remaining 289 patients, 143 were randomized to the non-mesh repair group and 146 to mesh repair (Fig 1). The type of hernia repair in the non-mesh repair group was Bassini-McVay in 75 patients (52%), Shouldice in 36 (25%), Bassini in 26 (18%), and McVay in 3 (2%). A total of 3 patients received a mesh because the surgeon decided intraoperatively that a mesh would be preferable. In the mesh repair group, 1 patient received a resorbable polyglactin 910 mesh (Vicryl; Ethicon, Johnson & Johnson), which was used in error. In addition, 7 patients did not receive a mesh repair; these operations were marked as conversions.

A total of 87 patients (30%) died within the long-term follow-up period (Fig 1); the causes of death were unrelated to the performed inguinal hernia repair. A total of 49 patients (17%) were lost to follow-up. In the outpatient clinic, 153 patients were physically examined—80 in the non-mesh group and 73 in the mesh group. Median long-term follow-up of these patients was 128 months (range, 109 to 148 months) and 129 months (range, 112 to 147 months) for non-mesh repair and mesh repair, respectively (Table I). The type of hernia repair in the non-mesh repair group consisted of Bassini-McVay in 41 patients (51%), Shouldice in 16 (20%), Bassini in 20 (25%), and McVay in 3 (4%). Of the 3 patients in the non-mesh group that were converted at baseline to receive a mesh, 1 patient died and 2 did not report any form of pain. In the mesh group, 7 patients were converted at baseline to receive a non-mesh repair; 3 of these patients died and 4 were lost to follow-up.

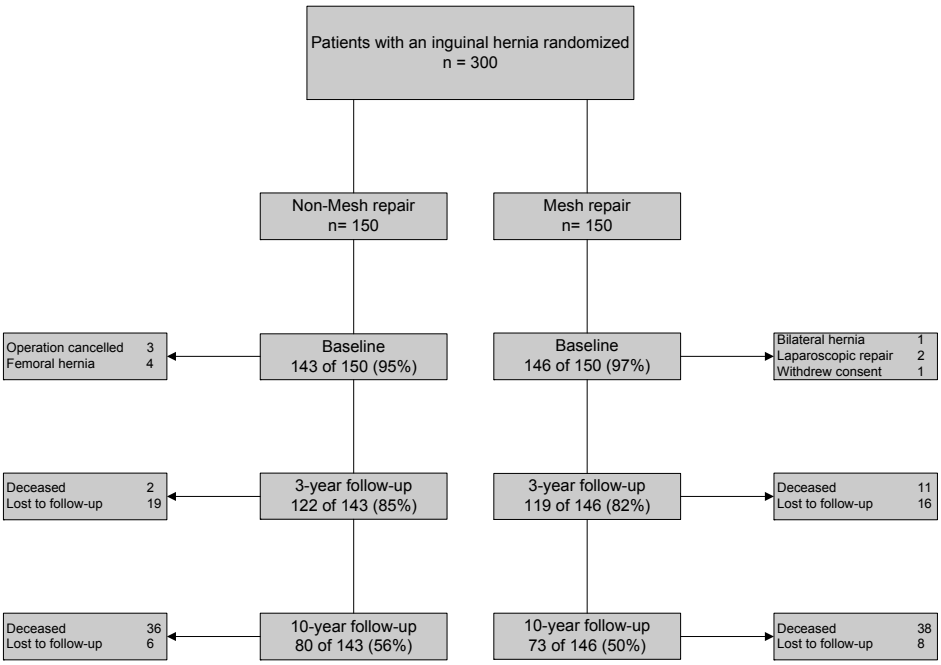

Figure 1. Flowchart of baseline, 3- and 10-year follow-up periods.

After a median follow-up of 129 months, none of the patients in either the non-mesh or the mesh group suffered from persistent pain and discomfort interfering with daily activity (Fig 2). Some patients reported paroxysmal pain during intensive activity not interfering with daily activity (such as sports or gardening), which did not last longer than 1 day. This type of paroxysmal pain occurred in 10% of the patients in the non-mesh group and 14% of patients

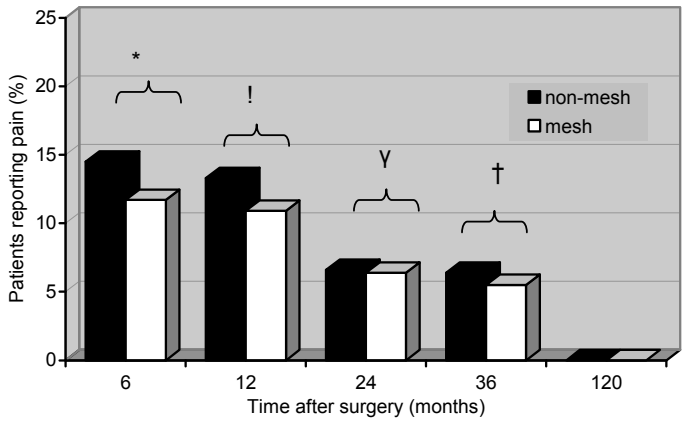

Figure 2. Proportion of patients reporting pain following non-mesh and mesh inguinal hernia repair. *P=.037. [!]P=.339. [γ]P=.571. [†]P=.464 (chi-square test).

Table 1. Characteristics of patients with inguinal hernia in the 10-year follow-up period

	Total			Non-mesh repair			Mesh repair		
	(N=153)			(N=80)			(N=73)		
Men	149 (97%)			78 (97%)			71 (97%)		
Age (years):median (range)	66 (30-96)			62 (30-96)			66 (35-87)		
Follow-up (months): median (range)	129 (109-148)			128 (109-148)			129 (112-147)		
Body mass index (range)*	24.6 (18.6-34.5)			24.4 (19.0-33.9)			24.4 (18.6-34.5)		
Contralateral hernia (%)	35 (23)			20 (35)			15 (21)		
COPD (%)	17 (11)			7 (9)			10 (14)		
Constipation (%)	7 (5)			4 (5)			3 (4)		
Prostatic Disease (%)	32 (21)			13 (16)			19 (26)		
Level of experience:									
Resident, senior, surgeons	54	11	88	29	5	46	25	6	42
(%)	(35%)	(7%)	(58%)	(36%)	(6%)	(58%)	(34%)	(8%)	(58%)

COPD, chronic obstructive pulmonary disease

* The body mass index was calculated as the weight in kilograms divided by the square of height in meters

in the mesh group. The type of hernia repair was not significantly correlated with paroxysmal pain during intensive activity not interfering with daily activity (P = .31). In the non-mesh repair group, 7 patients (9%) suffered from numbness in the groin region compared with 14 patients (19%) in the mesh repair group (P = .047). Chronic groin pain was not correlated with the level of experience of the surgeon (P = .449) (Table 1). Surgeons with a higher level of expertise in hernia surgery performed more non-mesh operations, including 81% of the Shouldice operations and 81% of the Bassini operations. No significant correlation between age, obesity, history of pulmonary disease, constipation, or prostatic disease with groin pain was found (Table 1).

Discussion

According to a review study by the EU Hernia Trialist Collaboration[67] reviewing all randomized or quasi-randomized trials comparing open-mesh with non-mesh methods published until 1999, a minority of studies reported a measure of postoperative chronic pain. Of the 15 trials included in the review study, 12 compared a flat mesh to non-mesh repairs. The mean or median duration of follow-up of all 15 of the studies ranged from 6 days to 5 years. There were few reported cases of chronic pain, with reported rates similar for mesh and non-mesh groups[67].

Individual patient data were collected and a meta-analysis was conducted and published by the Cochrane Library[4]. This review reported 17 studies in which a flat mesh was compared to non-mesh hernia repair, including three previously unpublished studies identified by the EU Trialist Collaboration. The results suggested that persisting pain was less frequent after mesh repair than after non-mesh repair, but this result was dependent on one trial by Koninger et al, and data were not available for 11 of the total of 20 trials included in the study[4, 94].

Poobalan et al[11] reviewed studies investigating postoperative pain after inguinal hernia repair that were published between 1987 and 2000, almost simultaneously to the review mentioned above. Two studies were reported in which open flat mesh and non-mesh repairs were compared, the same study reported by the EU Trialist Collaboration[95]. This included a nonrandomized study by Amid et al[96] reporting less chronic pain with mesh repair.

Of the studies published after 1999, Nordin et al[66] reported no significant difference in chronic pain after 3 years between the Shouldice and Lichtenstein repair (4.2% and 5.6%, respectively), as our our long-term data at 3 years of follow-up suggest. Miedema et al[97] reported a higher incidence of chronic pain after the Lichtenstein repair compared with a Shouldice repair (38% and 7%, respectively; $P < .05$). However follow-up included only 60% of patients.

Long-term follow-up is difficult to obtain because many patients undergoing hernia repair are lost to follow-up, do not show up, or have died. The mean age at long-term follow-up was 66 years. Although time-consuming and incomplete because of patients who had died or lost to follow-up, our data indicate that long-term follow-up is of great importance for research regarding inguinal hernia repair.

In our study, none of patients from either group experienced persistent pain interfering with daily activity, suggesting that neuropathic pain that is caused by neuroplastic changes in the central nervous system following nerve injury in the inguinal region, disappears over time[72]. According to some, this type of neuropathic pain is the main cause of postoperative chronic pain. Our data, therefore, provide insight into the course of chronic pain that is supposed to be predominantly caused by neuroplastic changes in the central nervous system.

In conclusion, our 10-year follow-up study provides evidence that mesh repair of inguinal hernia is equal to non-mesh repair with respect to long-term chronic pain. It is also the only study to provide follow-up of more than 5 years. An important new finding is that chronic postoperative pain of neuropathic or somatic origin seems to dissipate over time[11, 12, 72]. Because chronic pain can be debilitating, this knowledge is very interesting from the patient's perspective and, therefore, from the doctor's perspective as well.

Chapter 5

Surgical techniques preventing chronic pain after Lichtenstein hernia repair: state-of-the-art vs daily practice in the Netherlands

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Abstract

Background

Morbidity associated with open inguinal hernia repair mainly consists of chronic pain. The aim of this study was to identify possible disparities between state-of-the-art Lichtenstein repair, and its application in general practice.

Methods

A questionnaire was mailed to all surgeons and surgical residents (n = 1,374) in the Netherlands in February 2005. The objective was to determine the state of general practice with respect to technical steps during the Lichtenstein repair that are suggested to be involved in the development of chronic pain, as recently updated by Lichtenstein's successor, Amid.

Results

More than half of the respondents do not act according to the Lichtenstein guidelines with respect to surgical steps that are suggested to be involved with the origin of chronic pain of somatic origin. Compliance with Amid's guidelines with respect to the handling of the nerves is variable. Surgeons conducting high numbers of inguinal hernia repair are more likely to operate according to the key principles of the state-of-the-art Lichtenstein repair.

Conclusion

There is a substantial disparity between the state-of-the-art Lichtenstein repair and its application in general practice with respect to steps that are suggested to play a role in the origin of chronic groin pain.

Introduction

In recent years it has become clear that morbidity associated with open inguinal hernia repair mainly consists of chronic inguinal and scrotal pain of neuropathic and somatic origin[3, 11, 12]. There is a discrepancy between the complication rate associated with the Lichtenstein repair, the most frequently performed hernia repair in the Netherlands, reported by the Lichtenstein Hernia Institute and that reported by others[3, 15-19].

Amid described the principles of the operation in 1993 and recently formulated the key principles that may play a role in the origin of chronic pain[15, 98]:

- Fixation of a slightly relaxed mesh, which will be under tension in the upright body position and will be subject to shrinkage
- No fixation of the mesh to periosteum of the pubic bone, which could result in pubic osteitis
- Inversion of (in)direct hernia sacs without ligation or resection
- Identification and protection of the three inguinal nerves
- Avoidance of entrapment of the iliohypogastric nerve (IHN) during mesh fixation cranially
- Avoidance of unnecessary stripping and excision of cremasteric fibers, which can result in injury of the nerves, small blood vessels, and vas deferens

The aim of this study was to identify possible disparities between the state-of-the-art Lichtenstein repair and its application in Dutch general practice with respect to the surgical key principles described by Amid.

Materials and methods

An anonymous questionnaire (available from the authors on request) was mailed to all members of the Association of Surgeons of the Netherlands (ASN), 916 surgeons and 458 surgical residents covering 90–95% of all surgery in the country. The recipients were asked to return the completed questionnaire by means of the enclosed reply postcard. Two reminders were sent. In December 2005 the database was closed.

The primary objective was to determine general practice with respect to technical aspects of the Lichtenstein repair that are suggested to be involved in the development of chronic pain, as recently updated by Lichtenstein's successor Amid[15]: the nerve aspect of inguinal hernia repair, treatment of the hernia sac and cremasteric fibers, and fixation and shape of the mesh. Secondarily, outcomes were compared between surgeons and residents. Additionally, out-

comes were compared between respondents conducting high numbers of inguinal hernia repairs and respondents conducting fewer inguinal hernia repairs. Graded outcomes were compared by means of the Mann–Whitney test. Outcomes in percentages were compared by means of Fisher's exact test. All statistical analyses were performed using Statistical Package for Social Sciences for Windows (SPSS, Chicago, IL, USA).

Results

We received a total of 648 questionnaires: 466 completed by surgeons (response rate 51%) and 182 completed by surgical residents (response rate 40%). After excluding respondents who do not operate on inguinal hernia, we further narrowed the sample to include only physicians who operated according to the Lichtenstein technique in 75% or more of cases: 524 questionnaires (81% of all the respondents completed by 357 and 167 surgeons and residents, respectively). All subsequent results are based on this group.

The majority of respondents (57%) performed more than 30 hernia repairs on a yearly basis. The remaining 43% performed 1–29 hernia repairs. Forty-two and 11% of surgeons and residents together estimated the incidence of chronic pain to be 0–9 and 10–24%, respectively. The rest of the respondents (47%) indicated that they did not know the exact incidence.

Somatic and visceral aspects

Three steps during the Lichtenstein repair are suggested to play a role in the origin of chronic pain that is somatic or visceral in character (Table 1). Fifty-two per cent claimed to employ a laxity during fixation of the mesh. Thirty per cent ligated and excised the hernia sac rarely or never. Finally, 45% of the respondents did not fixate the mesh by means of one or more sutures through the periosteum of the pubic bone.

Table 1 General practice with respect to technical steps during the Lichtenstein repair that are suggested to be involved in the development of chronic pain. Respondents performed at least 75% of IH repairs according to the Lichtenstein technique

Neurological aspects

Certain surgical steps are suggested to play a role in the origin of chronic pain of neuropathic character (Table 1). The percentage of respondents that intended to identify the ilioinguinal nerve (IIN) was 84%. The percentage that intended to identify the IHN and genital branch of genitofemoral nerve (GB) was 32 and 36%, respectively, with no significant difference

Table 1. General practice with respect to technical steps during the Lichtenstein repair that are suggested to be involved in the development of chronic pain. Respondents performed at least 75% of inguinal hernia repairs according to the Lichtenstein technique.

Group **Group and characteristics**	**Surgeons, n (%)**	**Residents, n (%)**	**Total, n (%)**	**P Value**
Fixation of a mesh with a ripple (dome-shaped)				
Yes	185 (52)	90 (54)	275 (52)	P=0.707*
No	172 (48)	77 (46)	249 (48)	
Missing data	0	0	0	
Mesh fixation to periost pubic bone				
Yes	188 (53)	100 (60)	288 (55)	P=0.132*
No	169 (47)	67 (40)	236 (45)	
Missing data	0	0	0	
Ligation and resection hernia sac				
Always	103 (30)	39 (4)	142 (28)	P=0.612†
Usually	138 (40)	80 (25)	218 (43)	
Rarely	80 (23)	41 (48)	121 (24)	
Never	23 (7)	6 (24)	29 (6)	
Missing data	13	1	14	
Intention to identify the ilioinguinal nerve				
Yes	293 (83)	144 (86)	437 (84)	P=0.35*
No	62 (17)	23 (14)	85 (16)	
Missing data	2	0	2	
Intention to identify the iliohypogastric nerve				
Yes	110 (31)	58 (35)	168 (32)	P=0.45*
No	245 (69)	109 (65)	354 (68)	
Missing data	2	0	2	
Intention to identify the genital branch				
Yes	130 (37)	58 (35)	188 (36)	P=0.75*
No	225 (63)	109 (65)	334 (64)	
Missing data	2	0	2	
Nerve resection in principle				
No	297 (86)	146 (88)	443 (87)	P=0.244*
Ilioinguinal	19 (6)	17 (10)	36 (7)	P=0.672*
Iliohypogastric	5 (1)	0	5 (1)	
Genital	10 (3)	0	10 (2)	
Two or more nerves	13 (4)	2 (1)	15 (3)	
Missing data	13	2	15	
Attention to iliohypogastric nerve during mesh fixation				
Yes	226 (63)	90 (54)	316 (60)	P=0.044*
No	131 (37)	77 (46)	208 (40)	
Missing data	0	0	0	
Excision cremaster muscle fibers				
Always	32 (9)	11 (7)	43 (8)	P=0.105†
Usually	119 (33)	41 (25)	160 (31)	
Rarely	146 (41)	90 (54)	236 (45)	
Never	60 (17)	25 (15)	85 (16)	
Missing data	0	0	0	
Total	357	167	524	

* Outcome in percentages were compared between surgeons and residents by means of Fisher's exact test

† Graded outcomes were compared between surgeons and residents by means of Mann-Whitney test

between surgeons and residents (Table 1). Eighty-seven per cent of surgeons and residents indicated that they did not divide any nerve as recommended by Amid.

Sixty per cent indicated that they paid attention to the course of the IHN while suturing the upper leaf of the mesh to the rectus sheath and internal oblique aponeurosis. Additionally, 61% excised cremasteric fibers rarely or never. Seventy-three per cent agreed on the importance of further research of nerve handling in inguinal hernia surgery in view of the frequent chronic pain.

We compared outcomes between surgeons who conducted high numbers of inguinal hernia repairs (≥30 corrections yearly) and surgeons conducting fewer (1–29) hernia repairs. Surgeons who conducted high numbers of inguinal hernia repairs were more likely to employ a laxity during fixation of the mesh (59 vs. 44%, respectively; $P = 0.001$), more likely to intend to identify the GB (44 vs. 25%, respectively; $P < 0.000$) and more likely to pay attention to the course of the IHN during mesh fixation (70 vs. 48%, respectively; $P < 0.0001$). No significant difference was found for those intending to identify the IIN or IHN, intending to divide any nerve, and fixing the mesh to the periosteum of the pubic bone.

Discussion

Although chronic pain after inguinal hernia repair is a frequent and serious complication, little is known about diagnosis and treatment. The results of this questionnaire show that performance of general surgeons and residents needs improvement. Some issues need discussion:

Probably the response rate is underestimated since only 7% of the responding surgeons claimed not to operate inguinal hernia at all and the questionnaire was sent to all surgeons including pediatric, thoracic, vascular and trauma surgeons. Furthermore respondents could have completed the anonymous questionnaire on behalf on the entire surgical staff. Since a substantial percentage of the surgeons and residents (42%) estimated the incidence of chronic pain to be 0–9%, this problem seems to be highly underestimated in the Netherlands[3]. However, 47% indicated that they did not know the exact incidence of chronic pain. It is likely that estimation and not a formal investigation gives an underestimation of the true complication rate. No randomized controlled trials have been conducted investigating the influence of a slightly relaxed mesh, mesh fixation through the periosteum of the pubic bone and hernia sac resection on postoperative chronic pain.

According to Poobalan et al.[11] and Kehlet et al.[72], chronic pain is predominantly neuropathic in character. Recently, Alfieri et al.[84] reported that failure to identify the inguinal nerves is significantly correlated with chronic pain, with the incidence of chronic pain increasing with the number of undetected nerves. Additionally, nerve division (intentionally or after accidental nerve injury) would be correlated with a higher incidence of chronic pain. However, Lik-Man Mui et al.[88] reported significantly less chronic pain after division of the IIN compared to preservation. So the best evidence available is "expert opinion," level 5.

More than half of the respondents did not act according to the Lichtenstein guidelines with respect to surgical steps that are suggested to be involved with the origin of chronic pain of somatic origin. Additionally, compliance with Amid's guidelines for neurological aspects was variable. A previous Dutch national survey in 1995 already showed many modifications to the Bassini repair and Shouldice technique[99].

It is remarkable that respondents indicated that they intended to identify the GB more often than the IHN since identification of the GB is more comprehensive than identification of the IHN. This suggests an inadequate knowledge of neurological inguinal anatomy. A previous United Kingdom survey by Ravindran et al.[100], investigating intra-operative handling of structures in the inguinal canal, suggested confusion over anatomy as well. Therefore, identification of the three inguinal nerves should be included in the operative notes. Our data suggest the same trend as Ravindran et al. with respect to intention to identify nerves. In their study the IIN, IHN and GB were not routinely visualized in 7, 42 and 56% corresponding to the trend in our findings of 16, 68 and 64%, respectively. Surgeons who conducted high numbers of inguinal hernia repair were more likely to operate according to the key principles of the state-of-the-art Lichtenstein repair.

Obviously, there is a discrepancy between the state-of-the-art Lichtenstein repair and its application in surgical practice in the Netherlands. A wide variety of personal interpretations are employed and are being taught. However, it is not clear to what extent widely different interpretations of a standardized technique negatively influence outcome. At the same time, because of lack of uniformity of interpretation and training, any results of the Lichtenstein technique in the Netherlands can never be scientifically evaluated. Furthermore, the theoretical merits of the surgical steps with regard to the Lichtenstein technique as reported by Amid should be investigated in a standardized randomized setting. This national survey will provide us with information for preparation of new studies regarding chronic pain and discomfort after inguinal hernia repair.

Chapter 6

Nerve management during open hernia repair

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Abstract

Background

Peroperative identification and subsequent division or preservation of the inguinal nerves during open hernia repair may influence the incidence of chronic postoperative pain.

Methods

A systematic literature review was performed to identify studies investigating the influence of different types of nerve management.

Results

Based on three randomized studies the pooled mean percentage of patients with chronic pain after identification and division of the ilioinguinal nerve was similar to that after identification and preservation of the ilioinguinal nerve. Two cohort studies suggested that the incidence of chronic pain was significantly lower after identification of all inguinal nerves compared with no identification of any nerve. Another cohort study reported a significant difference in the incidence of chronic pain in favour of identification and facultative pragmatic division of the genital branch compared with no identification at all.

Conclusion

The nerves should probably be identified during open hernia repair. Division of and preservation of the ilioinguinal nerve show similar results.

Introduction

A review by Poobalan et al.[3] of studies of inguinal hernia repair between 1987 and 2000 showed the incidence of chronic postoperative pain to be up to 53% (range 0-53%), making it the most frequent complication after surgery. The commonest types of chronic postoperative pain are somatic and neuropathic[11, 12, 72]. Causalgia syndromes affecting all three inguinal nerves (ilioinguinal nerve (IIN), iliohypogastric nevre (IHN) and genital branch of the genitofemoral nerve (GB)) have been described. There is no consensus on whether or not to identify and subsequently divide or preserve these three nerves together, or separately, during surgery[13]. Lichtenstein and his successor Amid[15, 16] recommend preservation of all three nerves, whereas Wantz[14] recommends intentional severance based on the concept of no nerve, no pain. This review evaluates the influence of peroperative inguinal nerve identification and subsequent division or preservation on the incidence of chronic postoperative pain.

Methods

Studies on the effect of peroperative inguinal nerve identification and subsequent division or preservation were included if they contained data on pain lasting longer than 3 months after operation[71]. Randomized, prospective and retrospective cohort studies were included. Reviews and references of the articles retrieved were checked for additional studies. Letters to the editor, abstracts and comments were excluded. English, German and French articles were reviewed.

Studies were identified by searching PubMed, The Cochrane Library (Issue 1, 2006), scholar.google.com and Current Controlled Trials (search across multiple registers including the National Health Service in England and US ClinicalTrials.gov). Search terms used and cross-checked were pain, postoperative, pain, chronic, hernia, inguinal, denervation and neurectomy.

Data were extracted by two authors (A.R.W, R.N.v.V.) independently. Study quality was assessed according to a number of variables, such as the quality of methodological reporting, whether studies were randomized, non-randomized, prospective or retrospective, method of randomization and allocation concealment, blinding of outcome assessors, attempts made to minimize bias, sample sizes and ability to measure true effect. Levels of evidence were assessed according to the Oxford Centre for Evidence Based Medicine levels of evidence[26, 101]. Discrepancies were resolved by consensus. The following data were abstracted: type of study, number of patients, baseline characteristics, type of repair, peroperative nerve treatment, follow-up period, incidence of chronic pain and type of assessment.

From the data provided in the individual studies, the pooled means for chronic pain after hernia repair and their 95 per cent confidence intervals (c.i.) were calculated using the random-effects model described by Laird and Mosteller[102]. A pooled mean percentage of patients with chronic pain at 6 months after operation was calculated from three randomized clinical trials investigating the influence of IIN preservation or division[86-88].

Results

Thirteen articles on the influence of inguinal nerve management were identified, of which one letter to the editor, one editorial and one comment were excluded[103-105]. Two studies that investigated the influence of IHN and IIN division in one group were excluded as there were no comparable groups in which these nerves were preserved[106, 107]. Another study investigating the influence of IIN division compared with preservation was excluded as not all the required data were reported[108]. This left seven studies for analysis, including three randomized trials and four cohort studies (of retrospective and prospective character) (Table 1)[83, 84, 86-88, 109, 110]. Of these seven studies, four investigated the influence of IIN division compared with IIN preservation[86-88, 110], including the three randomized trials. In addition, two other studies compared the influence of no inguinal nerve identification with

Table 1. Characteristics of studies

Reference	Type	Study location	No. of institutions/ surgeons	Study period	Surgical technique	Level of evidence*
Ilioinguinal nerve division *versus* preservation						
Ravichandran et al.[86]	RCT double-blind pilot	UK	1/ 1	NR	Tension-free mesh repair	2b
Picchio et al.[87]	RCT double-blind	Italy	4/ NR	1997-2002	Trabucco	1b
Mui et al.[88]	RCT double-blind	China	1/ 4	2003-2004	Lichtenstein repair	1b
Dittrick et al.[110]	Cohort retrospective	USA	NR/ 2†	1997-2003	Lichtenstein repair	2b
No identification of any nerve *versus* identification and preservation of all nerves						
Izard et al.[83]	Cohort prospective	France	1/ 1	1979-1992	McVay	2b
Alfieri et al.[84]‡	Cohort prospective	Italy	11/ NR	2002-2003	Lichtenstein or Trabucco	2b
No identification of genital branch *versus* identification and facultative pragmatic division of genital branch§						
Tons and Schumpelick[109]	Cohort prospective	Germany	1/ NR	1985-1988	Shouldice	2b

* Oxford-Centre for Evidence Based Medicine (http://www.cebm.net/levels_of_evidence.asp)[26,101]. †Two surgeons of whom one routinely divided and one routinely preserved the ilioinguinal nerve. ‡Groups included in this analysis are part of a broader prospective cohort study by Alfieri et al. In group I (n=380) all nerves were identified with the following subgroups: subgroup A, all nerves preserved (n=310); subgroup B, all nerves divided (n=10); and subgroup C, one or two nerves injured/divided (n=60). In group II no nerves were identified (n=189). Group III (n=404) consisted of two subgroups: subgroup D, one nerve was not identified (n=260); and subgroup E, two nerves were not identified (n=144). §Genital branch of the genitofemoral nerve was divided in 24 per cent. RCT, randomized clinical trial; NR, not reported.

identification and preservation of all inguinal nerves[83, 84]. Finally, one study compared the influence of no identification with identification and subsequent pragmatic facultative division of the GB[109].

Table 2 shows the baseline characteristics of patients included in this review by study and by treatment group. Most of the characteristics were not significantly different between treatment groups. A significant difference was, however, present in the proportion of patients with a combined or direct inguinal hernia in the study by Tons and Schumpelick[109] (Table 2).

Table 2. Characteristics of patients

Reference	No. of patients	Men (%)	Mean age (y)	Hernia type (%)				Preoperative pain (%)	No ilioinguinal nerve identified (%)
				Indirect	Direct	Combined	Other		
Ilioinguinal nerve identification and division									
Ravichandran et al.[86]	20*	100	65*	NR	NR	NR	NR	NR	0
Picchio et al.[87]	405	92	57	68	30	3	0	55†	10
Mui et al.[88]	50	100	65	NR	NR	NR	NR	10‡	0
Dittrick et al.[110]	66	77	68	NR	NR	NR	NR	NR	0
Ilioinguinal nerve identification and preservation									
Ravichandran et al.[86]	20*	100	65*	NR	NR	NR	NR	NR	20
Picchio et al.[87]	408	89	59	66	30	4	0	49†	13
Mui et al.[88]	50	100	63	NR	NR	NR	NR	14‡	0
Dittrick et al.[110]	24	79	58	NR	NR	NR	NR	NR	0
No identification of any nerve									
Izard et al.[83]	441	NR	NR§	64#	21#	5#	9#	NR	NA
Alfieri et al.[84]§	189	97¶	55¶	NR**	NR**	NR**	NR**	NR**	NA
Identification and preservation of all inguinal nerves									
Izard et al.[83]	891	NR	NR§	67#	17#	6#	10#	NR	NA
Alfieri et al.[84]§	310	97¶	55¶	NR**	NR**	NR**	NR**	NR**	NA
No identification genital branch									
Tons and Schumpelick[109]	237	100	NR	52	18	30	0	NR	NA
Identification and facultative pragmatic division genital branch									
Tons and Schumpelick[109]	223	100	NR	51	28	21	0	NR	NA

* The procedures were performed in one group of 20 patients with bilateral hernia and a mean age of 65.2 years. The ilioinguinal nerve was divided on one side and preserved on the other side, determined by randomization. †Pre-operative pain (no significant difference). ‡ At least mild pain pre-operatively at rest on a four-point verbal scale: 0, none; 1, mild; 2, moderate; and 3, severe (no significant difference, P=0.54). §An age distribution was given for the whole group. #Hernia type distribution among patients with follow-up greater than 5 years (911 patients in total). ¶Mean percentage of men and the mean age of the total study group. **Type of hernia and type of repair were recorded for the total group. No correlation was found between moderate to severe pain and type of hernia or repair technique used (P=0.67 and P=0.2, respectively). NR, not reported; NA, not applicable.

Table 3. Pain after ilioinguinal nerve division or preservation

Study	No. of Patients	Pain at 6 months (%)
Ilioinguinal nerve identification and division		
RCT		
Ravichandran et al.[86]	20	5†
Picchio et al.[87]	358	34‡
Mui et al.[88]	50	8§
Mean*		21 (0.43) #
Cohort		
Dittrick et al.[110]	65	3¶
Ilioinguinal nerve identification and preservation		
RCT		
Ravichandran et al.[86]	20	5†
Picchio et al.[87]	354	37‡
Mui et al.[88]	50	29§
Mean*		23 (0.47)#
Cohort		
Dittrick et al.[110]	23	26¶

* Mean based on random-effects model. Values in parentheses are 95 per cent confidence intervals. †Minor wound discomfort (no statistically significant difference). ‡At least mild pain on a four-point verbal scale: 0, none; 1, mild; 2, moderate; and 3, severe (no statistically significant difference). §Incidence of at least mild pain on exertion (statistically significant difference, P=0.008). #No statistically significant difference between pooled means of the group in which the ilioinguinal nerve was identified and divided and the group in which the ilioinguinal nerve was identified and preserved. ¶Endpoint was presence of neuralgia (statistically significant difference, P<0.001). RCT, randomized clinical trial.

All four studies investigating the influence of IIN division or preservation reported the incidence of chronic pain at 6 months after surgery. The three randomized studies, on which the calculated pooled mean percentage of patients with chronic pain was based, reported results of 851 procedures (428 with IIN division and 423 after IIN preservation) (Table 3). No significant difference was found in the pooled mean percentage of patients with chronic pain after identification and subsequent division of the IIN (21 (95 per cent c.i. 0 to 43)%) or identification and subsequent preservation of the IIN (23 (95 per cent c.i. 0 to 47)%) (Table 3). Both studies in which the influence of identification and preservation of all nerves was compared with no identification at all reported a significant difference in chronic postoperative pain in favour of identification (Table 4)[83, 84].

Tons and Schumpelick[109] recorded persistent pain after a mean (range) of 16·4 (12-25) months in a group of 237 patients in whom the GB was not identified and in a group of 223 in whom the GB was identified and divided facultatively on a pragmatic basis. This cohort study showed a significant difference in the percentage of patients with chronic pain, determined by two independent researchers and including three neurological tests and a nerve block to determine the neuropathic character of the problem, in favour of the group in which the genital branch was identified and pragmatically divided (4.2 versus 1.4%; P < 0·05).

Table 4. Pain after no identification of any nerve or identification and preservation of all nerves

Study	No. of Patients	Pain(%)*
No identification of any nerve		
Izard et al.[83]	297	3.7†
Alfieri et al.[84]	189	4.7‡
Identification all nerves and preservation		
Izard et al.[83]	614	1.6†
Alfieri et al.[84]	310	0.0‡

* The study by Alfieri et al. examined pain at 6 months after surgery, whereas the follow-up by Izard et al was greater than 5 years. †At least major symptoms (discomfort on effort) and persistent and disabling symptoms measured on a four-point scale: 1, no pain; 2, minor symptoms (often minimal and transient); 3, major symptoms (discomfort on effort); and 4, persistent or disabling symptoms. The difference was statistically significant ($p<0.001$). ‡Moderate to severe pain based on a four-point verbal rank scale: none, mild, moderate or severe. The difference was statistically significant.

Discussion

Chronic pain may be somatic, neuropathic or visceral in origin. Cunningham et al.[12] reported that the most common type of chronic pain after surgery was of somatic origin, whereas Poobalan and colleagues[11]and Kehlet and co-workers[72] believe it to be predominantly neuropathic in character. Neurectomy and mesh or staple removal as a treatment for chronic pain after hernia repair has yielded variable results[77].

The present study has shown that the incidence of chronic pain is significantly less after identification of all three inguinal nerves than after no identification at all in both of two cohort studies (Table 4)[83, 84]. No pooled mean was calculated from these studies as the type of operation differed between them (McVay, Lichtenstein hernia repair and Trabucco's technique). Studies investigating the influence of division and preservation of the IIN are conflicting. Two randomized studies found no significant difference with respect to the incidence of chronic pain[86, 87], but a further randomized trial and one retrospective cohort study suggested a significant difference in favour of division[88, 107].

A pooled mean percentage of patients with chronic pain was calculated on the basis of the three randomized trials as reported pain was similar for severity and time, although the pain scales used were different: at least minor wound discomfort[86], at least mild pain on a four-point verbal scale (none, mild, moderate or severe)[87] or incidence of at least mild pain on exertion (mild or severe pain)[88]. As all studies determined pain at 6 months after operation, this point in time was used for comparison. The pooled mean did not show any significant difference between the two treatment groups (Table 3). Because of the heterogeneity, the pooled results should be interpreted with caution, but a random-effects model was used to take this variation between studies into account.

Pain assessment in the three studies was limited with respect to the following factors that were not recorded: current pain medication, nerve block to determine the neuropathic character and quantitative sensory testing thresholds. However, light touch and pain sensitivity were assessed by an observer in the studies by Picchio et al.[87] and Ravichandran et al.[86]. Mui et al.[88] assessed skin sensitivity by Semmes-Weinstein monofilament testing. In two studies the level of preoperative pain was included as a baseline patient characteristic and they did not show a significant difference between the groups (Table 2)[87, 88]. No pain scores or questionnaires were included from which postoperative pain might be differentiated as of somatic, neuropathic or visceral origin. Kehlet et al.[111] have proposed a scheme for uniform assessment of chronic postoperative pain (including the factors mentioned above) that should provide a more exact description of the incidence, the type and the socioeconomic consequences of the chronic pain state.

As appropriate data have not been reported, this review could not assess the incidence of numbness after nerve division or problems deriving from the division of the motor part of the GB. Tons and Schumpelick[25] reported the cremaster reflex to be absent in all patients after division of the genital branch, and to be absent after no identification and identification of the genital branch in 51 and 46% of patients respectively. The clinical implications of an absent cremaster reflex are unclear.

With respect to handling of injured nerves, only expert opinion has been published. According to Schumpelick[112], injured nerves should be divided as proximally as possible. In studies investigating neurectomy as a treatment for postoperative chronic pain, the inguinal nerves under investigation were resected as far proximally as possible[76, 113, 114]. Amid[76] resected the three nerves as far proximally and distally as possible, to include the involved segment and account for the numerous neural communications that exist between the three inguinal nerves. Types of proximal nerve-end treatment after division include crushing, ligation by non-absorbable suture to close the neurilemmal sheath, coagulation, and application of either absolute or 12 per cent phenol solution to the nerve end to prevent neuroma formation[114]. One way to prevent nerve scarring in the operative field is to resect the nerve under tension so that it retracts behind the peritoneum; another is to implant the ligated proximal end of the IIN and IHN within the fibres of the internal oblique muscle to prevent the ends from adhering to the inguinal ligament and/or external oblique aponeurosis[76, 113]. These different types of treatment have been investigated in situations of therapeutic neurectomy after inguinal nerve entrapment but not during primary hernia repair[76, 113, 114].

In conclusion, the available data suggest that the inguinal nerves should be identified during open repair of hernia (grade of recommendation B) [26, 80, 101]. In terms of outcome,

there is little difference between dividing or preserving the IIN (grade of recommendation A). Pragmatic division of the GB seems beneficial (grade of recommendation C).

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Sir

We read with great interest the review written by Wijsmuller et al.; however, there seem to be discrepancies between the data and the conclusions. In fact, both Picchio and Dittrik[87, 110] investigated the influence of removal (not division) versus preservation of the IIN, and so Wijsmuller et al. have confused the terms division and resection, which will strongly influence their conclusions. The studies by Ravichandran and Mui[86, 88] are limited by the very small sample size, with only 20 patients and 50 patients in each arm, meaning that the studies cannot reach any statistical power[115]. Ton and Shumpelick[109] considered the genital branch nerve alone and do not provide any data relating to the other two nerves, thus their results may be distorted because these nerves could be unintentionally divided or injured.

Finally, in accepting the assumptions of Wijsmuller et al. that prophylactic neurectomy should be considered routinely, we should also therefore extend neurectomy to the other two sensory inguinal nerves, possibly causing more serious complications (including bleeding from external spermatic vessels) and longer operating time for a previously simple and fast surgical procedure. In accordance with Izard's study[83], our study[84] clearly demonstrates that pain is not reported when all three nerves are preserved, and the risk of developing groin pain increases with the number of nerves not detected.

Author's reply

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Sir

We thank Dr Alfieri and colleagues for their reaction. The difference between neurectomy and nerve transection might indeed be a factor of influence on the incidence of pain. However, there are no evidence-based arguments supporting this hypothesis. Furthermore, a distinct discrimination between neurectomy and nerve transection is hazardous, since the extent of neurectomy was not defined in three and wrongly described in one study of in total four studies in which IIN division was compared to preservation. Therefore in the discussion of our results we have emphasized the importance of uniform pain assessment in future studies including perioperative data like nerve handling. Ravichandran et al.[86] reported to merely divide the nerve lateral to the internal ring. Picchio et al.[87] reported that they divided the nerve lateral to the internal ring but did not report where the nerve was divided caudally. The same applies to the paper by Dittrick et al.[110]. The interruption of interconnecting neural branches has been hypothesized to represent the advantage of neurectomy instead of transection. The mere mentioning of neurectomy without anatomical precision must not be regarded as a definite variety, compared to neural transection.

Finally, Mui et al.[88] indeed reported the excision of the IIN as far laterally as to the internal ring and medially to where it entered the rectus muscle. However, this nerve does not enter the rectus muscle but runs ventrally to the spermatic cord through the external ring to innervate the medial part of the thigh and/or the lateral part of the scrotum.

Although the study by Ravichandran et al. was underpowered, this does not exclude calculating a pooled mean percentage by means of a random-effects model taking variation between studies into account.

Tons et al.[109] did provide data about the handling of the IIN and IHN since they reported that they have performed 460 Shouldice repairs. According to state-of-the-art Shouldice repair these nerves should be identified, isolated and preserved if feasible[116]. This was confirmed by personal communication to the authors in March 2006 in preparation of this review analysis.

Alfieri et al.[84] reported the incidence of chronic pain after 6 months to be zero in 310 patients when all three nerves were identified and preserved, 40% in 10 patients after identification and division of all nerves and 1.7% in 60 patients after identification of all nerves and

subsequent division or injury to one or two nerves. The authors are right to conclude that no patients experienced pain after identification and preservation of all nerves. However, they were not able to correlate chronic pain and division of any single nerve statistically because of the small number of patients presenting with chronic pain[84].

By suggesting that prophylactic triple-neurectomy is propagated in our study, Alfieri et al. unfortunately misinterpreted our conclusions. We stated that the inguinal nerves should be identified, and that division and preservation of the IIN shows similar results. Also identification and facultative (pragmatic) division of the GB seems favourable compared to no identification at all, as in just 24% of patients of the group in which the GB was identified, the GB was divided.

Chapter 7

Nerve-identifying inguinal hernia repair: a surgical anatomical study

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Abstract

Background

Pain syndromes of somatic and neuropathic origin are considered to be the main causes of chronic pain after open inguinal hernia repair. Nerve-identification during open hernia repair is suggested to be associated with less postoperative chronic pain. The aim of this study was to define clinically relevant surgical anatomical zones facilitating efficient identification of the three inguinal nerves during open herniorrhaphy.

Methods

Through dissection of 18 inguinal areas of embalmed and unembalmed human cadavers, identification zones were developed for the inguinal nerves (in particular for the genital branch).

Results

The iliohypogastric nerve was identifiable running approximately horizontally and ventrally to the internal oblique muscle perforating the external oblique aponeurosis at a mean of 3.8 cm (range 2.5–5.5 cm) cranially from the external ring. When present, the ilioinguinal nerve was identifiable running ventrally and parallel to the spermatic cord, dorsally from the aponeurosis of the external oblique muscle. Identification of the genital branch of the genitofemoral nerve was more comprehensive. The course of the genital branch is laterocaudal at the level of the internal inguinal ring.

Conclusion

Based on the newly defined identification zones, peroperative identification of all inguinal nerves is possible. Further research is warranted to assess clinical feasibility of these zones and to evaluate the influence of (facultative) division, preservation or omittance of the identification of inguinal nerves on the incidence of chronic pain.

Introduction

In the Netherlands approximately 32,000 inguinal hernias were corrected in 2004, representing the most frequently performed operation in general surgery[1]. In recent years it has become clear that morbidity associated with this operation mainly consists of chronic inguinal and scrotal pain, which can be very debilitating and can lead to costly multidisciplinary medical consultations[3]. Reported causes of chronic pain include pain syndromes of somatic, neuropathic and visceral origin. Cunningham et al.[12] reported the most common type of chronic postoperative pain to be of somatic origin, whereas according to Poobalan et al.[11] chronic postoperative pain is predominantly neuropathic in character. Alfieri et al.[84] reported that failure to identify the inguinal nerves is significantly correlated with the presence of chronic pain, the incidence of chronic pain increasing with the number of nerves undetected. Causalgia syndromes of all three inguinal nerves (ilioinguinal nerve (IIN), iliohypogastric nerve (IHN) and genital branch (GB) of genitofemoral nerve (GFN)) have been described[73, 75, 76, 109, 113, 114, 117-133].

Views on whether or not to divide, preserve or ignore the nerves are diverse. Lichtenstein et al. recommend preservation of the inguinal nerves whereas Wantz et al. recommend intentional severance based on the concept of "no nerve, no pain"[14-16]. Studies on the influence of division or preservation of one or more inguinal nerves on postoperative chronic pain have reported variable outcomes[83, 84, 86, 87, 109, 110]. The inguinal hernia guideline of the Association of Surgeons of the Netherlands propagates division of the cutaneous nerves during open hernia repair only in the case of already existing nerve injuries or interference with the position of the mesh[64].

Several anatomical studies on inguinal nerves have been performed with emphasis on the anatomic variability of the course of the nerves instead of clinically relevant surgical anatomical zones facilitating efficient identification of these nerves[81, 134-144]. In particular the GB has been poorly described in this manner. Therefore, the objective of this study was the definition of anatomical zones that facilitate efficient identification of the nerves, in particular the GB enabling the surgeon to identify and subsequently divide or preserve the nerves and to facilitate future randomized studies into the influence of division, preservation or omittance of the identification of inguinal nerves on postoperative pain. Zones were defined with regard to the Lichtenstein tension-free hernioplasty, which is the gold standard for unilateral inguinal hernia repair in the Netherlands[15, 64]. Likewise, open tension-free hernia repair is thought to be the principal surgical method of hernia repair in the UK[145].

Materials and methods

The anatomy of the three inguinal nerves encountered during open hernia surgery was determined through dissection of 8 unembalmed and 10 embalmed human cadaveric inguinal areas. Since the gender of approximately 90% of all inguinal hernia patients is male, no female anatomic specimens were included[1]. Among others, the following data were recorded:

1 Presence or absence of each inguinal nerve
2 Course of the IHN and IIN with regard to the spermatic cord and the incision made in accordance with the Lichtenstein tension-free hernioplasty (5 cm in a lateral direction from the pubic tubercle within the skin lines)
3 Location at which the IHN perforates the aponeurosis of the external oblique muscle with regard to the (superficial) external (inguinal) ring and its distance cranially to the upper edge of the internal ring
4 Number of branches into which the IHN nerve splits up before perforating the aponeurosis
5 Location at which the GB enters the inguinal canal near the (deep) internal (inguinal) ring and leaves the canal through the external ring
6 Course of the GB with regard to the spermatic cord and the cremasteric (external spermatic) artery and vein ("blue line").

To confirm that the tissue identified as nerve tissue macroscopically was in fact nervous tissue, we continued dissection preperitoneally to the level of the psoas muscle and laterally to the neurovascular plane. Additionally, microscopic sections were produced of the presumed nerve structures. Finally, on the basis of the anatomical findings we designed efficient anatomical identification zones, in particular for the GB.

Results

The IHN and GB were present in all dissected inguinal areas (Table 1). In 4 of the 18 dissected inguinal areas no IIN could be detected (bilaterally in two bodies).

Table 1. Characteristics of each individual nerve with regard to its presence and its course through the exposed area

	Ilioinguinal nerve	Iliohypogastric nerve	Genital branch
Presence, mean (%)	14 (78)	18 (100)	18 (100)
Perforation of internal oblique muscle lateral from Lichtenstein incision, mean (%)	8 (57)	16 (89)	NA

NA: not applicable

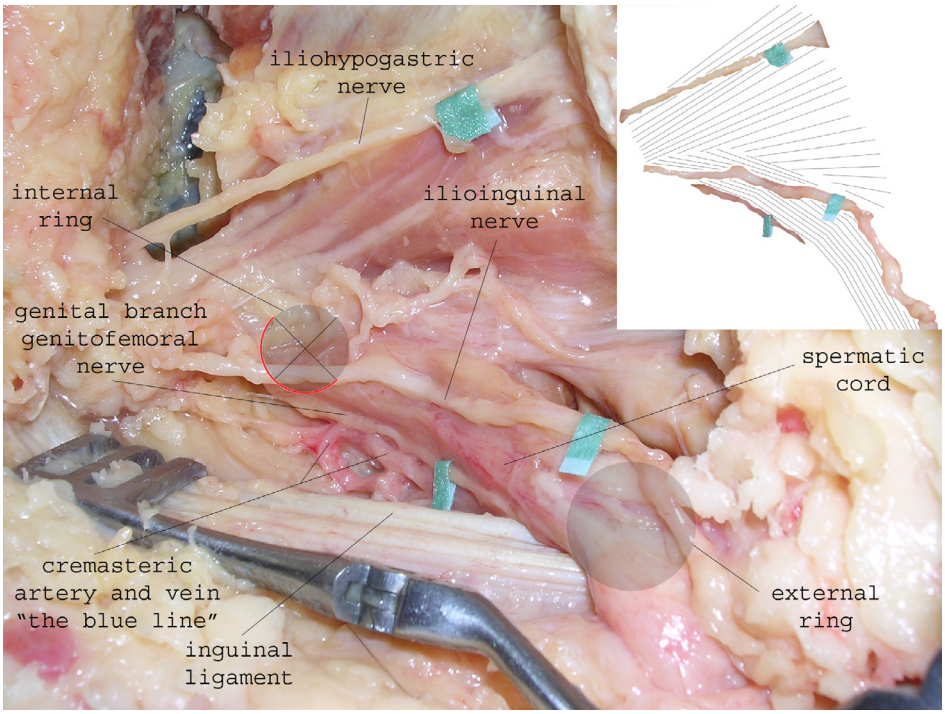

Figure 1. Ventral view of the right inguinal area. The aponeurosis of the external oblique muscle is opened, showing the inguinal canal including the three inguinal nerves: ilioinguinal and iliohypogastric nerve and the genital branch of the genitofemoral nerve parallel to the "blue line", the cremasteric artery and vein. To clarify the muscle and nerve structures, a small exemplification in the upper-right corner is represented including the three nerves and the direction of the muscle fibers of the internal oblique and cremaster muscles. The laterocaudal part of the internal ring in the frontal plane is denoted by the color red.

The Iliohypogastric Nerve

In 89% the IHN pierced the internal oblique muscle laterally from the Lichtenstein incision such that it could be detected through the entire exposed area after opening the aponeurosis of the external oblique muscle running at a mean of 2.4 cm (range 1.5-4.4 cm) cranially to the internal ring (Fig. 1). However, in 11% (2 different cadavers) the IHN perforated the internal oblique muscle approximately halfway along and cranially to the spermatic cord. Subsequently, the IHN coursed approximately horizontally and ventrally to the internal oblique muscle perforating the external oblique aponeurosis at a mean of 3.8 cm (range 2.5-5.5 cm) cranially from the external ring (Fig. 2). In 89% the IHN perforated the external oblique aponeurosis as one single branch; in 17% it split into 2 or 3 branches just before perforating the external oblique aponeurosis.

The Ilioinguinal Nerve

In 57% the IIN pierced the internal oblique muscle laterally from the incision (Table 1). In the other 43% the IIN pierced the internal oblique muscle just laterally from the internal ring.

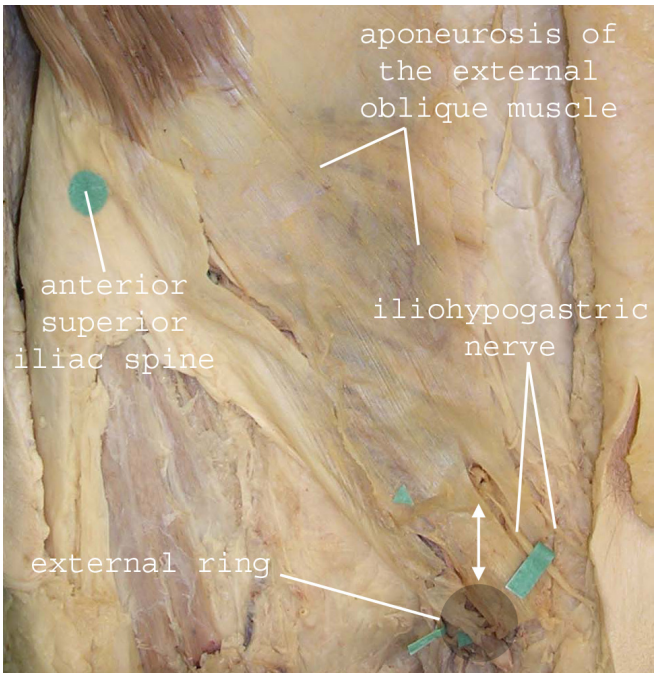

Figure 2. Ventral view of the right inguinal area. The aponeurosis of the external oblique muscle is perforated by two branches of the iliohypogastric nerve cranially to the external ring.

When present, the IIN was easy to identify running ventrally and parallel to the spermatic cord, dorsally from the aponeurosis of the external oblique muscle, after which it left the inguinal canal by passing through the external ring ventrally from the spermatic cord (Fig. 1).

The Genital Branch

The vast majority of GB's (94%) entered the inguinal canal laterocaudally through the internal ring in the frontal plane (Fig. 1); only one entered a few millimeters caudally from the internal ring together with the cremasteric artery and vein through the transversalis fascia.

All but one observed GB joined the cremasteric artery and vein to run within the cremasteric fascia. Although coursing parallel to the cremasteric artery and vein only 22% of the GB's were running exactly adjacent to the cremasteric vessels forming a neurovascular bundle. Seventeen GB's (94%) were still clearly present at the external ring. After running through the inguinal canal at the dorsocaudal side of the spermatic cord, 44% passed dorsally, 28% medially, and 22% laterally to the spermatic cord through the external ring. Therefore, the course variability of the GB is least, proximally and laterocaudally to the internal ring (Fig. 3).

Tissue identified as nerve tissue macroscopically was confirmed to be nervous tissue microscopically in 100% of the cases in which microscopic sections were produced (Fig. 4).

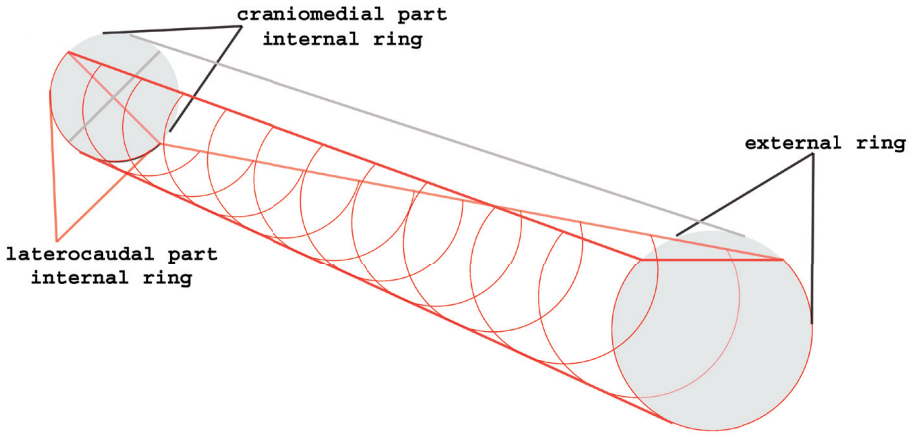

Figure 3. Schematic representation of a right inguinal canal and the course of the genital branch designated by the red shading. The genital branch of the genitofemoral nerve should be identified proximally and laterocaudally at the level of the internal ring in the frontal plane where its course variability is least.

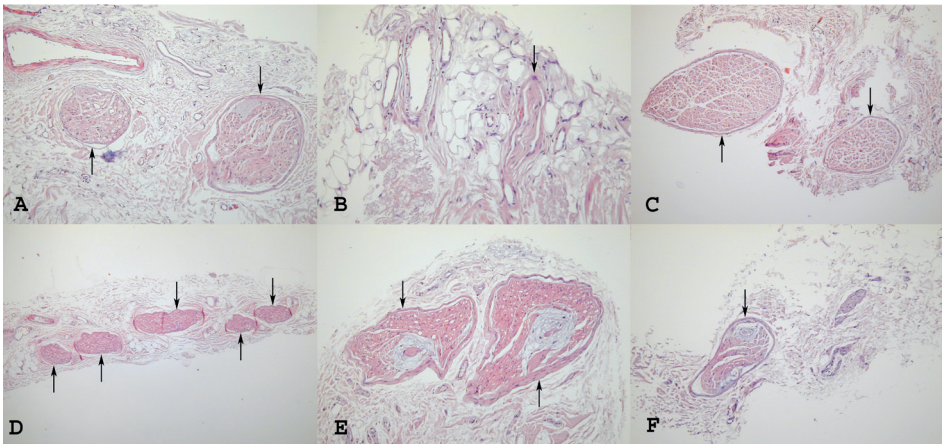

Figure 4. Microscopic transversal sections of the nerve branches of the iliohypogastric, ilioinguinal nerve, and the genital branch of the genitofemoral nerve of the right inguinal area (respectively A, B, and C) and the left inguinal area (respectively D, E and F) of an embalmed cadaver (original magnification).

Discussion

Recent anatomical studies reported several variations on the "classical" course of the inguinal nerves, as represented in standard anatomical textbooks and atlases.

The Iliohypogastric Nerve

An aberrant course of the IHN is described by Al-dabbagh[137]. In 21.8% the author observed a single stem from which the IIN and IHN originated, and in 83.3% only midway between the

internal and external ring, ventrally to the internal oblique muscle. We did not encounter such a variation.

The ilioinguinal nerve

Oelrich and Moosman cited variations with regard to the course of the IIN based on an anatomical study[144]. They observed an aberrant course in 35%. In these variations, the IIN was running dorsally and within the spermatic cord and emerged through the external ring posteriorly to the spermatic cord. In this case the ilioinguinal sensory component was incorporated within the GFN at the level of the first and second lumbar nerves, from which level both nerves arise. Caudally to this convergence it entered the inguinal canal together with the GB. Oelrich and Moosman's data correspond with our finding that the IIN could not be identified in 22% of our dissections. The ilioinguinal sensory component could already have been incorporated within the GFN at the level of the lumbar nerves. However, the findings of Al-dabbagh are in disagreement, reporting only two instances with this aberrant course.

Rab et al.[136] classified the variations and branching patterns of the IIN and GFN into four different categories. Only one type (20.3%) corresponded with the classic pattern of distribution in which the IIN and GB innervate the skin of the medial part of the thigh and the skin of the scrotum respectively. In two other patterns (71.8%), either the GB or the IIN would not reach further than the external ring and one of them would innervate the skin that is otherwise innervated by both nerves.

With regard to the inguinal canal Rab et al. reported a 56.3% correspondence with the "classical" course and relationship between the different nerves. In the other 43.7% the IIN was incorporated in the GFN entering the inguinal canal at the internal ring, corresponding to the findings of Oelrich and Moosman[144].

The Genital Branch

In addition to the variations on the course of the GB as stated above, Rab et al.[136] reported that in 28.1% no GB was present in the inguinal canal. Liu et al.[138] reported that in 97% of cases the GB ran within the spermatic cord corresponding to our study in which all GB were detected within the cremasteric fascia.

All anatomical studies of the GB report that it enters the inguinal canal through the internal ring. A specific description of the location where the GB enters the inguinal canal through the internal ring is found only in an editorial by Amid[76]; the GB enters the inguinal canal through the internal ring just deep to the lateral crus of the internal ring. Our findings confirm the comment made by Lytle[146] in response to a case report by O'Brien[129] discussing a case of genitofemoral neuralgia and anatomy of the GB. According to O'Brien the GB en-

ters the inguinal ring through the internal ring. However, Lytle comments that in inguinal hernia repair the GB is observed to enter the inguinal canal not through the internal ring but through the posterior inguinal floor about 1 cm medially to the ring. In one dissection during our study the GB did indeed not enter the inguinal canal through the internal ring, but caudally to the internal ring after perforating the transversalis fascia.

According to Amid et al.[15], after passage through the inguinal ring the GB is accompanied by the cremasteric artery and vein to form a neurovascular bundle. The cremasteric vein is called the "blue line" by Amid because it is clearly visible as such. This corresponds with our findings with regard to its parallel course to this blue line, although we only observed 22% of the GB situated in exactly the same anatomical plane running just adjacent to the cremasteric vessels and representing a real neurovascular bundle.

The demonstrated anatomic variability of these three inguinal nerves is the probable reason for the variable nerve block success rate as a diagnostic or therapeutical means. In the case of difficulty identifying the IHN, the upper leaf of the external oblique aponeurosis should be separated medially and cranially and lifted cautiously until the IHN is identified perforating the aponeurose at a zone 2.5–5.5 cm (3.8 cm) cranial from the external ring (Fig. 2). The mean distance cranially from the IHN to the internal ring (2.4 cm) was smaller than its distance to the external ring (3.8 cm). In two inguinal areas the nerve ran within fibers of the internal oblique muscle. In this configuration the nerve would be liable to injury during fixation of the upper edge of the mesh to the internal oblique muscle[147].

Our study indicates the GB to be identified during meticulous proximal dissection of the spermatic cord from the inguinal floor, at a zone laterocaudally at the level of the internal ring where the variability of its course is least prominent after which it runs parallel to the cremasteric artery and vein, denoted by the "blue line" by Amid (Fig. 3).

In conclusion, despite a limited sample size this study shows efficient identification zones with regard to all three inguinal nerves during open inguinal hernia surgery, including the GB, as yet not routinely dissected by the vast majority of surgeons. It might be expected that as in all other non-inguinal hernia-related operation techniques, recognition of the course of nerves and the interference with the operative field will improve the outcome of operations. To tackle the ongoing problem of chronic pain after inguinal hernia surgery further research is warranted to assess the clinical feasibility of the identification zones and to study the influence of division, preservation or omittance of identification of inguinal nerves on postoperative pain.

Chapter 8

Feasibility study of three-nerve-recognizing Lichtenstein procedure for inguinal hernia

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Abstract

Background

Inguinal nerve identification during open inguinal hernia repair is associated with less chronic postoperative pain. However, most Dutch surgeons do not identify all three inguinal nerves when carrying out this procedure. The aim of this study was to evaluate the feasibility of a nerve-recognizing Lichtenstein hernia repair and to measure the extra time required for surgery

Methods

Forty patients with primary inguinal hernia were operated on following the nerve-recognizing Lichtenstein hernia repair by four experienced hernia surgeons from four different Dutch teaching hospitals. The additional time needed to identify each individual nerve was recorded, and iatrogenic nerve injuries and anatomical characteristics were registered.

Results

Identification of the iliohypogastric and ilioinguinal nerve was each performed within 1 min. Identification of the genital branch was notably more difficult but could usually be performed within 2 min. Identification of the cremasteric vein, running parallel to genital branch, was less comprehensive. The incidence of major anatomical variations was low. Twenty-five per cent of ilioinguinal nerves, however, could not be identified. In five patients inguinal nerves were damaged iatrogenically during standard manoeuvres of the Lichtenstein hernia repair.

Conclusion

Three-nerve-recognizing Lichtenstein hernia repair is feasible and non-time-consuming if the surgeon has appropriate anatomical knowledge. In view of the low incidence of major anatomical variations, knowledge of standard inguinal nervous anatomy should be adequate. This procedure could enable the surgeon to prevent of recognize iatrogenic nerve damage and offer an opportunity to perform deliberate neurectomy as an alternative to accidental nerve injury.

Introduction

In inguinal hernia surgery the use of open mesh repair is associated with a reduction in recurrence rate of between 50 and 75% compared with open repair without mesh[4]. In this respect the inguinal hernia guideline of the Association of Surgeons of the Netherlands (ASN) recommends the Lichtenstein procedure for primary unilateral inguinal hernia repair (grade of recommendation B)[9].

As the recurrence rate is reduced to less than 5% after mesh repair, nowadays long-term morbidity associated with open inguinal hernia repair is mainly related to chronic pain[2, 3]. It is difficult to estimate the true incidence of chronic pain as the type of pain assessment differs among studies. A review by Poobalan et al.[3] of studies of inguinal hernia repair between 1987 and 2000 showed the incidence of chronic pain to be up to 53 (range 0-53)%. However, probably only 2-4% of patients are adversely affected by chronic pain in daily life[72]. The most common types of chronic postoperative pain are of somatic or neuropathic origin[11, 12, 72]. Two prospective cohort studies reported the incidence of chronic pain to be significantly less after identification of all three inguinal nerves compared with no identification at all[83, 84]. This suggests that all three inguinal nerves should be identified during open inguinal hernia repair, as recommended by Amid[15, 89].

Although the genital branch (GB) is not specifically referred to, the inguinal hernia guideline of the ASN mentions damage to one or all three inguinal nerves as an important cause of chronic postoperative pain. However, a questionnaire among Dutch surgeons and residents reported that only 84, 32 and 36% of respondents plan to identify the ilioinguinal (IIN), iliohypogastric (IHN) and GB respectively, when carrying out Lichtenstein hernia repair[148]. Thus, the majority of respondents do not plan to identify the inguinal nerves, as advocated by Amid, resulting in a discrepancy between the state-of-the-art three-nerve-recognizing Lichtenstein procedure and its application in Dutch surgical practice. Furthermore, unpublished data from this questionnaire indicate that the majority of respondents assume a low feasibility of identification of all three inguinal nerves, assuming identification of all nerves to be too time consuming.

The objective of this study was to evaluate the feasibility of a nerve-recognizing Lichtenstein hernia repair and to measure the extra time required for surgery.

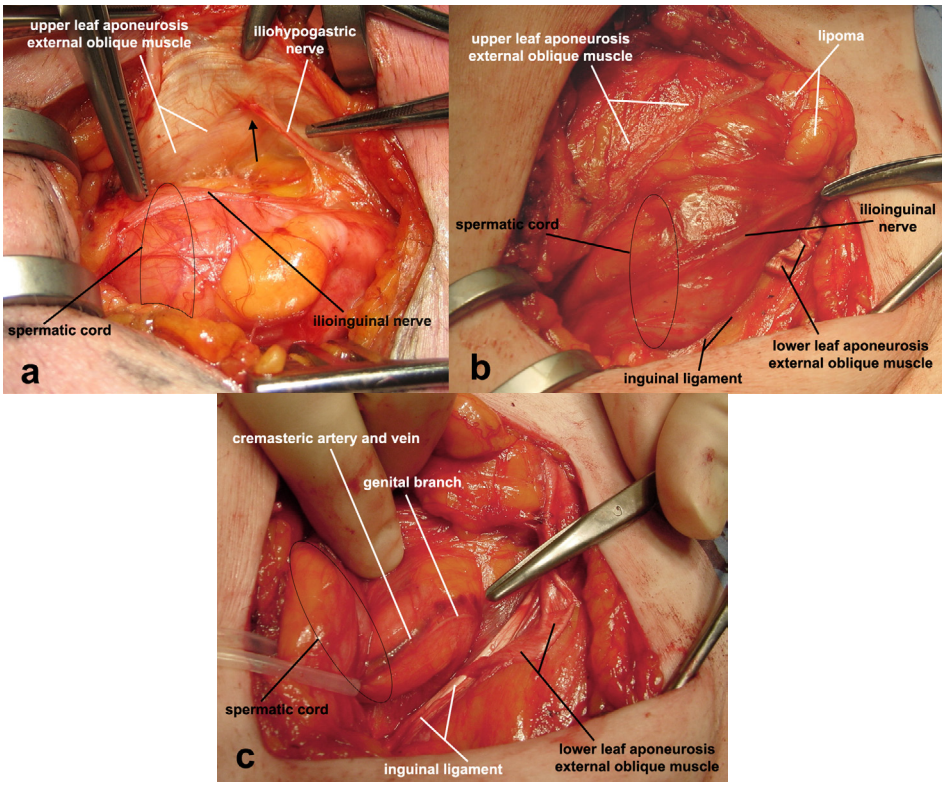

Figure 1. Photographs of the inguinal nerves taken during the course of hernia surgery showing a the iliohypogastric nerve, b the ilioinguinal nerve and c the genital branch of the genitofemoral nerve.

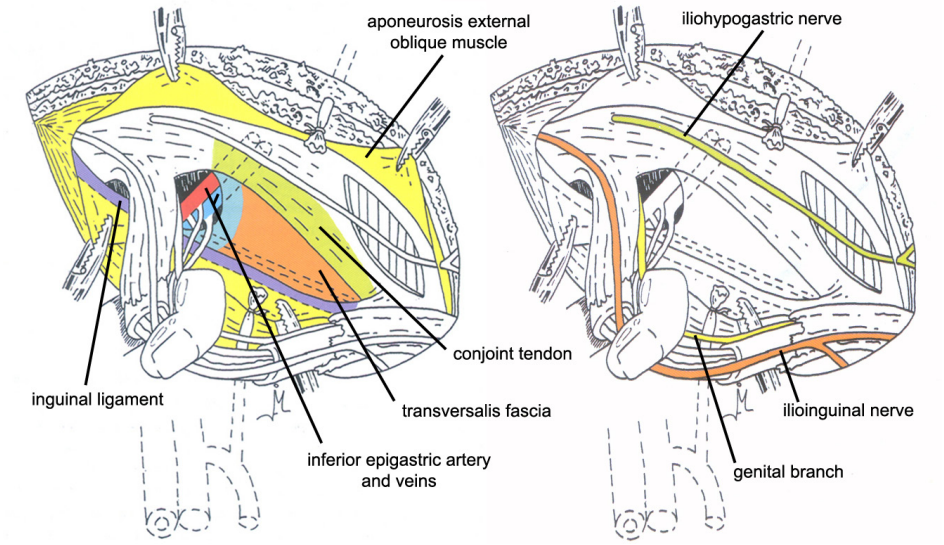

Figure 2. Schematic diagram of the 'standard anatomy' of the three inguinal nerves.

Materials and methods

Forty consecutive adult men with a primary inguinal hernia were included in this study. Four experienced hernia surgeons (from two high-volume teaching hospitals, one university hospital and one specialized hernia clinic) participated in the study. Each of them conducted ten nerve-recognizing Lichtenstein hernia repairs. Four series (four surgeons) of ten consecutive patients with a total of 40 Lichtenstein repairs were included in this study.

With over 60 accumulated years of inguinal hernia surgery all four surgeons were classified as experienced. They had all conducted more than 250 Lichtenstein hernia repairs in accordance with other studies regarding the proficiency of surgeons[149]. All types of anaesthesia were used (local, epidural and general anaesthesia). All patients gave informed consent.

The aim was to identify the IHN, IIN and GB after incising the aponeurosis of the external oblique muscle. Each identified nerve was photographed by the operating theatre nurse as proof (Fig. 1). The photographs were used as a control by the surgeon and the assisting resident, and were also used for drawing the anatomical course of the nerve in a schematic diagram after surgery. The photographs and drawings were also reviewed by an anatomist. The time measurements was conducted as follows: after incising the aponeurosis of the external oblique muscle the surgeon gave the theatre nurse a sign to start measuring the time needed to identify each nerve, and the extra time needed to identify each individual nerve was recorded. Each nerve was also scored after surgery as 'for sure', 'probably', 'maybe', or 'probably not' representing the appropriate nerve. In case of 'probably', 'maybe' or 'probably not' the operator made a note of the discussion. Although the participating surgeons were experienced hernia surgeons, the study committee concluded that a preceding meeting discussing variations on the classical course of the three inguinal nerves, led by an anatomist, would be preferable[80]. Additionally, several dissections were performed on embalmed human cadavers.

The focus of the study was on the standard anatomy of all three inguinal nerves (Fig. 2). The IHN normally runs approximately horizontally and ventrally to the internal oblique muscle at a mean of 2.4 (range 1.5-4.4) cm cranially to the internal ring, after which it perforates the aponeurosis of the external oblique muscle at a mean of 3.8 (range 2.5-5.5) cm cranially to the external ring. In 11% of patients the nerve runs within the fibres of the internal oblique muscle at the level of the internal ring and therefore is invisible. The IIN, when present, is commonly identifiable running ventrally and parallel to the spermatic cord, dorsally to the aponeurosis of the external oblique muscle. The GB in general runs in a zone laterocaudally to the internal ring at which level the variability of its course is least prominent; more distally it runs parallel to the cremasteric artery and vein, also known as the blue line[15].

Results

The course of the IHN was recognized in 38 of the 40 patients within a mean of less than 1 (range 0-5) min (Table 1). After operation all 38 IHNs were described as piercing the internal oblique muscle laterally to the inguinal incision and following its track as described in anatomy textbooks. All were reported to be for sure the IHN.

Table 1. Characteristics of the three inguinal nerves noted during hernia surgery in 40 patients

	Nerve detected	Extra time needed to identify nerve (min)	Iatrogenic injury to nerve	Nerve interfering with mesh
Iliohypogastric nerve	38	<1 (0-5)	1	3
Ilioinguinal nerve	30	<1 (0-4)	2	0
Genital branch	35	1.5 (1-6)	2	0

Values in parentheses are ranges

The IIN was visualized in 30 patients (Table 1), the mean time needed to recognize it being less than 1 (range 0-4) min. After operation in 24 patients its course was drawn and recognized as described in anatomy textbooks. In six patients the nerve branched over the spermatic cord, dividing into one or more branches. The surgeons were never in doubt that the identified structure indeed represented the IIN. In the ten patients in whom the IIN could not be identified the search was stopped after 6 min.

The GB was identified in 35 patients (Table 1). In ten the identified structure could not be classified as for sure the GB (probably, n=3; maybe, n=5; probably not, n=2). The different reasons for doubt were based on the course of the nerve (laterocaudal entrance through internal ring but not following blue line, n=3) or the macroscopic features of the structure (structure might be vessel or muscle fibre, n=4). In three patients no reason for doubt was given. In the five patients in whom the GB could not be identified, the blue line was also not identified. The mean identification time was 1.5 (range 1-6) min.

One IHN was damaged during surgery after being retracted behind the wound retractor (Table 1). In three patients the IHN was prophylactically neurectomized as proximally and distally as possible, as recommended by the Dutch guidelines, because the course of the nerve was found to be interfering with the upper edge of the mesh. In two patients the IIN was damaged iatrogenically during incision of the external oblique aponeurosis. Prophylactic neurectomy was then performed as proximally and distally as possible. Two GB's were damaged during luxation of the spermatic cord.

Discussion

Long-term morbidity associated with open inguinal hernia repair mainly consists of chronic pain. Amid[15] advocates recognition of all three inguinal nerves to prevent injury causing chronic postoperative pain. However, only a minority of surgeons in the Netherlands follow a policy of nerve-recognizing inguinal hernia surgery. The fact that Dutch surgeons traditionally have not specifically been trained in nervous inguinal anatomy may well be responsible for this. As several studies point out, a nerve-recognizing Lichtenstein procedure is a logical step for minimizing postoperative groin pain[83, 84]. Such an approach can be advocated for two reasons: identification of the nerves for preservation or for performing standard neurectomy in case of interference with the position of the mesh. Either way, all inguinal nerves should always be identified. However, most Dutch surgeons believe that identification of all three inguinal nerves is too difficult and time consuming[148].

This study shows that nerve damage during the Lichtenstein hernia repair is not uncommon. Although all 40 hernia repairs were of a nerve-recognizing character, there were five iatrogenic nerve lesions. It might be argued that these lesions were inflicted as a result of trying to identify the nerves, but in fact they were not caused during the identifying stages of the operations, but during standard manoeuvres of the Lichtenstein hernia repair (spreading of wound with retractor, opening of aponeurosis of external oblique muscle, or luxation of the spermatic cord). It could even be suggested that these lesions were identified because the mind of the participating surgeon was focused on the nerves, and subsequently neurectomy could be performed. In this respect it is thought that neurectomy is a better alternative than nerve injury, because neurectomy causes only numbness instead of pain[112, 150]. This is also why neurectomy of the IHN was performed deliberately when the nerve was interfering with the mesh, because mesh involvement of the IHN is considered a common reason for postoperative pain.

In a non-nerve-identifying approach more trauma could be inflicted to the nerves, for example by nerve entrapping sutures of the IHN cranially to the internal ring, at which level the nerve runs within the fibres of the internal oblique muscle in 11% of the male population. Furthermore, the GB could be injured when bluntly luxating the spermatic cord when not having identified the blue line as a landmark for the cremasteric vein, to which the GB is almost always adjacent[15, 80].

Twenty patients showed a standard anatomical pattern with regard to all three inguinal nerves. The anatomical variations in the other half were based on subtle details (such as branched IIN or GB not adherent to blue line), and mostly involved absence of the IIN (ten of 40 patients). This is in accordance with human cadaver studies, which also show that

one-quarter of people do not have an IIN[80]. This suggests that a thorough knowledge of standard inguinal anatomical features is necessary to carry out this procedure.

The extra time needed to recognize the course of the nerves appeared to be minimal, with only seconds for the IHN and IIN. The GB was unanimously considered to be the hardest nerve to identify, but the mean identification time was only 1.5 min. The specific problem with identification of the GB was doubt regarding the exact character of the structure found, resulting from its small diameter. Nevertheless, the blue line (cremasteric vein) as a landmark for the GB could easily be identified in the vast majority of patients (35 of 40). This study shows that identifying all three inguinal nerves will only add 3-4 min to the operating time.

The additional time spent during the surgical procedure should not be a reason to avoid a nerve-recognizing Lichtenstein hernia repair. It is technically feasible provided that surgeons are experienced in inguinal hernia repair and anatomically trained. It might not be possible to avoid all iatrogenic nerve lesions caused by standard manoeuvres during Lichtenstein hernia repair by means of nerve-recognizing inguinal hernia surgery; however, the technique offers an opportunity to detect perioperative nerve lesions, facilitating nerve resection as a better alternative to nerve injury.

Chapter 9

General discussion and future perspectives

Best practice management of elderly male patients with asymptomatic or mild symptomatic inguinal hernia is mainly determined by the expected improvement in quality of life since life expectancy differs very little after operation or non-operative treatment (Chapter 2). With the general surgeon becoming scarce, an improvement in surgical technique and postoperative quality of life is to be expected by the dedicated hernia surgeon.

Neuhauser conducted a life-expectancy analysis concluding that elective hernia repair does not prolong life in the elderly, while it may or may not improve the quality of life and that life expectancy would be most influenced by the yearly rate of strangulation[25]. Our conclusions support that of Neuhauser stating that life expectancy for elderly male inguinal hernia patients associated with operation and watchful waiting differs very little. Therefore, general doubt regarding operating on mild and asymptomatic inguinal hernia in these elderly patients, seems justified since these patients run a risk of developing chronic pain and even recurrence. However, there is also a risk of developing comorbidities during watchful waiting that increase subsequent mortality and morbidity that is associated with a delayed elective inguinal hernia repair. However, the extent of this problem is unclear but should be taken into consideration.

As illustrated in Chapter 3 not all patients suffering from chronic pain will improve by performing a neurectomy. Differentiating chronic pain of neuropathic origin from nociceptive origin remains difficult, if not impossible. Symptoms and mechanics involved in a particular pain condition cannot always be predicted. Because of the plasticity of the nervous system, changes that occur in response to abnormal experiences are unpredictable[151]. Therefore, symptoms associated with nerve damage are very unspecific. Kehlet et al have conducted extensive research into the characterization of post-herniorraphy pain. They designed a quantitative sensory testing protocol to examine the presence of sensory loss and neuroplasticity in patients with moderate/severe chronic pain and patients without chronic pain after open mesh repair[152]. All patients had sensory changes on the operated side compared to the contra-lateral side, which is more pronounced in patients with pain than those without[153]. However, in only a proportion of patients these sensory changes coincide with chronic pain[2]. Therefore, subgroups which may benefit surgical treatment can not yet be identified.

Studies investigating treatment of chronic pain propagate nerve blocks proximal or at the pain sites in patients experiencing symptoms that are suggested to be involved with pain from neuropathic origin like sharp, stabbing and burning pain with a trigger point[154, 155]. In case of relief and an effective second nerve block without long term effect, a directed tailored removal of the affected nerve only should follow. Amid however propagates an extended triple-neurectomy approach[76, 92].

Identifying the main cause of pain peroperatively is difficult if not impossible. Abnormalities are encountered such as neuromas or perineural fibrosis. More than half of all neuromas are suggested to be painless[156]. Additionally, it is not clear in what way neurectomy could affect the existence of chronic pain of nociceptice origin. This supports the better results that are achieved by (extended) triple-neurectomy compared to directed neurectomy. Determining specificity of diagnostic differentiating measures remains difficult since objectifying the causes of chronic pain might be difficult. Therefore, since there are no reliable differentiating measures in case of chronic pain, prevention still remains the panacea to chronic groin pain.

This thesis focuses on the influence of chronic postoperative pain on hernia management and peroperative prevention of chronic pain.

Chapter 4 reports no difference in long-term chronic pain after non-mesh or mesh repair of inguinal hernia. Furthermore, chronic pain seems to dissipate over time. Studies investigating the influence of light-weight versus heavy-weight meshes on pain show a slight advantage towards light-weight meshes. [157-161]. During a recent consensus conference on guidelines for postherniorraphy chronic pain syndrome it was concluded that the ilioinguinal nerve and iliohypogastric nerve are protected by an investing fascia of the internal oblique muscle and a layer of areolar connective tissue that is localized between the external and internal oblique muscles[162]. This investing fascia should be left intact to prevent direct contact between the mesh and the nerves. The genital branch of the gentiofemoral nerve is covered by the deep cremasteric fascia that should also be left intact.

The debilitating complication of chronic pain should be minimized. This thesis demonstrates that there is room for such an improvement by prevention. Compliance among Dutch surgeons and residents with Amid's guidelines regarding steps that are suggested to be involved in the origin of chronic pain, is variable (Chapter 5). A wide variety of personal interpretations are employed and are being taught. History already showed this lack of compliance with other types of hernia repair. A Dutch national survey in 1995 showed many modifications to the Bassini repair and Shouldice technique[99].

This lack of compliance could be a result of skepticism regarding steps that are suggested to be involved in the origin of pain, unawareness of these steps, inadequate anatomical knowledge or a combination of these factors. However, the inguinal hernia guideline of the Association of Surgeons of the Netherlands (ASN), published in 2003, does stress identification of the three inguinal nerves to recognize and prevent iatrogenic injury. Therefore, surgeons and residents should be made aware of the course of the nerves. Inadequate knowledge of anatomy is supported by our own questionnaire as well as a United Kingdom survey by Ravindran et al.[100], investigating peroperative handling of structures in the inguinal canal.

This thesis reviews studies from which we can conclude that inguinal nerves should probably be recognized peroperatively since this is associated with less pain (grade of recommendation B)[83, 84] (Chapter 6). This coincides with the expectation that as in all other non-inguinal hernia-related operation techniques, recognition of the course of the nerves and the interference with the operative field will improve the outcome of operations. A higher level of evidence is not feasible since merely awareness of surgeons that they are participating in a trial comparing nerve identification to no identification at all, would generate worthless results. We have to take into account that indistinct terminology regarding nerve management has influenced and distorted some study results. This is illustrated by Alfieri's comment on our review study[163]. Therefore uniform terminology is required.

In chapter 7 identification zones are defined that should facilitate efficient peroperative recognition of the three inguinal nerves, if present. The iliohypogastric nerve and genital branch of the genitofemoral nerve were identifiable in all dissections. The ilioinguinal was identifiable in 78%. However, this nerve could have been incorporated in the iliohypogastric nerve at lumbar level. Additionally, cases have been reported of an ilioinguinal nerve perforating the aponeurosis of the external oblique muscle before the external ring, running subctutaneously and therefore at risk while approximating Scarpa's fascia. By means of these zones a better recognition-rate should be possible than reported by our questionnaire (Chapter 5).

Chapter 8 reports a group of forty patients with primary inguinal hernia that were operated on following the nerve-recognizing Lichtenstein hernia repair by four experienced hernia surgeons from four different Dutch teaching hospitals. It reports that nerves should be recognized, reporting five iatrogenic nerve lesions by experienced hernia surgeons during standard maneuvers during the Lichtenstein hernia repair despite the nerve-focused mind. In these cases a subsequent nerve resection could be performed as a better alternative to nerve injury. This study shows that identifying all three inguinal nerves or the ilioinguinal and iliohypogastric nerve and the cremasteric vein will cost no more than three to four minutes additional operation time. The genital branch of the genitofemoral nerve runs parallel to the cremasteric vessels in the vast majority of patients. Therefore, the geniital branch can be identified indirectly by identifying the cremasteric vein. This offers an opportunity to detect peroperative nerve lesions facilitating nerve resection as a better alternative to nerve injury.

Besides iatrogenic nerve injuries or nerve entrapment by sutures, animal studies have reported ultrastructural nerve changes resulting from mesh inflammation[164]. It is not clear whether there is a correlation between these ultrastructural nerve changes and chronic pain since this has not been investigated. However, these microscopic changes coincide with the current attitude that nerves should be resected when interfering with the position of the mesh[165].

To stimulate surgeons and residents to get familiar with inguinal anatomy, we suggest that recognition of the ilioinguinal and iliohypogastric nerve and the cremasteric vein should be recorded in the operative notes. Additionally, surgeons and residents should be able to identify 'standard' inguinal anatomy. Recently at an international consensus conference on guidelines for postherniorraphy chronic pain syndrome, it was concluded that in 70-90% of operations the surgeon should be able to recognize all three inguinal nerves as separate nerves[162].

Given the high incidence of chronic postoperative pain after open hernia surgery and the influence of nerve-recognition, uniform terminology regarding nerve management should be applied. Additionally, steps that have suggested to be involved with the origin of somatic and visceral pain should be reported. Results of studies investigating neurectomy versus preservation of one or more nerves should mention whether the other nerves were or were not recognized and which type of treatment to the cut ends was applied[162]. Proximal and distal level of section should also be noted. These details should also be included in a standardized operative report offering a better starting point in case of postherniorraphy chronic pain facilitating operative treatment like triple neurectomy. Further studies are warranted to identify diagnostic measures that can differentiate chronic pain of neuropathic origin from nociceptive origin assuming surgery as a better option in case of chronic pain of neuropathic origin. However, conductance of such a descriptive study seems difficult since even at operation the cause of pain might be hard to objectify. Furthermore, operative results might be better if hernia surgery was to be conducted solely by dedicated surgeons. Dedicated surgeons are expected to be more knowledgeable with respect to anatomy and materials. It might be expected that as in all other non-inguinal hernia-related operation techniques, recognition of anatomy will improve the outcome of operations.

An instrument that could positively influence outcome would be an objective 'result-of-care' registration for the treatment of hernia by analogy of the Dutch Surgical Colorectal Audit and the National Bowel Cancer Audit Project in the United Kingdom. This could generate information to surgeons, residents and patients, considering the incidence of chronic pain and hernia recurrence. Additionally, this could lead to a re-appraisal of current policies regarding nerve management since a majority of Dutch surgeons does not recognize the inguinal nerves despite being described as one of the key principles of the Lichtenstein hernia repair. A one year follow-up after inguinal hernia repair should be conducted to validate outcomes. Obviously these results should be weighted according to a preoperative score including factors that have proven to be prognostic for pain or a hernia recurrence.

Residents from two Dutch academic centers are allowed to operate laparoscopically only after passing a basic laparoscopic skills course including inguinal anatomy. The same should

apply to open inguinal hernia repair. Residents should only be allowed to operate on inguinal hernia after passing a structured course on inguinal anatomy and different types of hernia repairs.

There is still no clear algorithm in case of chronic postoperative pain after open hernia repair. In case of chronic pain, a recurrence should be excluded as cause of pain. A recurrence with typical pain at the hernia site should be treated by total extraperitoneal approach. However, treating a recurrent hernia with atypical chronic pain, possibly of neuropathic origin, by total extraperitoneal repair, could complicate the case[166]. In case of persisting pain, it could be related to nerves running anteriorly and preperitoneally. Currently, an evidence-based algorithm is being developed assessing these matters.

In conclusion, life expectancy for mild symptomatic or asymptomatic elderly male inguinal hernia patients associated with watchful waiting or operation differs very little. Therefore, the most important factor influencing type of management is improvement of quality of life by dedicated hernia surgeons. This thesis indicates that nerve recognition, that is associated with less chronic pain, should be much more emphasised in daily practice. This could be stimulated by obligated systematic registration of nerve management in operative reports, structured anatomy courses and a 'results-of-care' registration.

Summary

Chapter 1

Inguinal hernia repair is one of the most frequently performed operations in surgery of which the majority is conducted in elderly male patients. As the recurrence rate is reduced to less than 5% after mesh repair, nowadays long-term morbidity associated with open inguinal hernia repair is mainly related to chronic pain. Reported incidences, up to 53%, are variable due to different definitions of chronic pain. Recently, a working group that developed the European Hernia Society guideline for treatment of inguinal hernia estimated the overall incidence of moderate to severe chronic pain to be about 10-12%. There is a discrepancy between the complication rate associated with the Lichtenstein repair, the most frequently performed hernia repair in the Netherlands, reported by the Lichtenstein Hernia Institute and that reported by others.

One third of patients presenting with inguinal hernia have been reported to be asymptomatic. Recently, two randomized trials have reported that chronic pain is not significantly different after assigning open tension-free hernia repair or watchful waiting in case of asymptomatic or mild symptomatic inguinal hernia compared to preoperative pain levels. Neuhauser conducted a life-expectancy analysis in 1977 concluding that elective hernia repair does not prolong life in the elderly, while it may or may not improve the quality of life.

The commonest types of chronic postoperative pain are somatic and neuropathic. Peroperative recognition of the course of the nerves and subsequent division, resection or preservation during open hernia repair may influence the incidence of chronic postoperative pain. However, there seems to be no consensus on whether or not to identify and subsequently divide, resect or preserve these nerves together, or separately, during surgery.

Chapter 2

To the analogy of Neuhauser, we calculated life expectancy for inguinal hernia patients who are treated by operation or watchful waiting. In order to update the required parameters for this analysis, studies were identified investigating risk of incarceration and/or strangulation, mortality associated with elective and emergency repair, risk of recurrence and crossover from watchful waiting to operation. The mean mortality rate associated with elective and emergency repair were 0.2% (range: 0-1.8%) and 4.0% (range: 0-22.2%), respectively. The annual probability of incarceration and/or strangulation associated with watchful waiting was 0.4% (range: 0.2-2.7%). On the basis of several randomized trials investigating recurrence, we estimated the annual probability of a recurrence to be 0.9%. Among patients with no or mild symptoms the annual crossover rate from watchful waiting to operation was 13% (range: 8.0-19.5%). The mean life expectancy for patients undergoing watchful waiting was 26.88

(CI: 26.873-26.884) years compared to 26.89 years (CI: 26.880-26.891) for those undergoing hernia repair. The optimal decision was sensitive to the procedural mortality rates and the annual risk of incarceration and/or strangulation. The available data support Neuhauser's conclusion, that life expectancy for mild symptomatic or asymptomatic elderly male inguinal hernia patients associated with watchful waiting or operation differs very little supporting equipoise in this situation. Therefore, best practice management of elderly male patients with asymptomatic or mild symptomatic inguinal hernia is mainly determined by the expected improvement in quality of life.

Chapter 3

This chapter illustrates the clinical impact of chronic pain as a complication of hernia surgery by reporting two patients suffering from chronic postoperative pain after Lichtenstein hernia repair. In one of the patients presented, the neuralgic pain disappeared after neurectomy of the ilioinguinal nerve. Triple neurectomy in the other patient, however, was unsuccessful. Differentiating chronic pain of neuropathic from nociceptive origin remains difficult, if not impossible. Symptoms and mechanics involved in a particular pain condition cannot always be predicted because the plasticity generated in the nervous system implies an unpredictable chain of events. Therefore, prevention of neuralgia remains the best strategy.

Chapter 4

In order to gain insight in the influence of mesh or non-mesh inguinal hernia repair on chronic pain, 300 patients scheduled for repair of a primary unilateral inguinal hernia were randomized to non-mesh or mesh repair. Long-term results at three years of follow-up have been published. Included here are 10-year follow-up results with respect to pain. None of the patients in the non-mesh or mesh group suffered from persistent pain and discomfort interfering with daily activity. Therefore, this chapter concludes there is no difference in long-term chronic pain after both types of repair.

Chapter 5

There is a discrepancy between the complication rate associated with the Lichtenstein repair reported by the Lichtenstein Hernia Institute and that reported by others. Therefore, we mailed a questionnaire to all surgeons and surgical residents in the Netherlands to determine the state of general practice with respect to technical steps during the Lichtenstein repair that are suggested to be involved in the development of chronic pain, as recently updated by Lichtenstein's successor, Amid. This revealed a substantial disparity between the state-of-the-art Lichtenstein repair and its application in general practice.

Chapter 6

There seems to be no consensus on whether or not to identify and subsequently divide, resect or preserve these nerves together, or separately, during surgery. Therefore we conducted a systematic literature review identifying studies investigating the influence of different types of nerve management. Based on three randomized studies the pooled mean percentage of patients with chronic pain after identification and division of the ilioinguinal nerve was similar to that after identification and preservation of the ilioinguinal nerve. Two cohort studies suggested that the incidence of chronic pain was significantly lower after identification of all inguinal nerves compared with no identification of any nerve. Another cohort study reported a significant difference in the incidence of chronic pain in favour of identification and facultative pragmatic division of the genital branch compared with no identification at all. This chapter concludes that nerves should probably be identified during open hernia repair.

Chapter 7

In chapter 6 it was concluded that nerves should be identified during open hernia repair. Therefore, we conducted a anatomical study to define clinically relevant surgical anatomical zones for identification of the inguinal nerves encountered during open hernia repair. The iliohypogastric nerve was identifiable running approximately horizontally and ventrally to the internal oblique muscle perforating the external oblique aponeurosis at a mean of 3.8 cm (range 2.5–5.5 cm) cranially to the external ring. When present, the IIN was identifiable running ventrally and parallel to the spermatic cord, dorsally to the aponeurosis of the external oblique muscle. Identification of the genital branch was more comprehensive. The course of the genital branch is laterocaudal at the level of the internal inguinal ring. This should facilitate peroperative identification of the inguinal nerves.

Chapter 8

In chapter 6 it was concluded that inguinal nerve identification during open inguinal hernia repair is associated with less chronic postoperative pain. Therefore, we evaluated the feasibility of nerve-recognizing Lichtenstein hernia repair on the basis of the surgical anatomical identification zones, described in chapter 7. Forty patients with primary inguinal hernia were operated on following the nerve-recognizing Lichtenstein hernia repair by four experienced hernia surgeons from four different Dutch teaching hospitals.

Identification of the iliohypogastric nerve and ilioinguinal nerve was each performed within one minute. Identification of the genital branch was notably more difficult but could usually be performed within two minutes. Identification of the cremasteric vein, running parallel to

genital branch, was less comprehensive. The incidence of major anatomical variations was low. Twenty-five per cent of ilioinguinals nerves, however, could not be identified. In five patients inguinal nerves were damaged iatrogenically during standard manoeuvres of the Lichtenstein hernia repair.

From these results it can be concluded that a three-nerve-recognizing Lichtenstein hernia repair is feasible and is not time consuming if the surgeon has appropriate anatomical knowledge. In view of the low incidence of major anatomical variations, knowledge of standard inguinal nervous anatomy should be adequate. Nerve recognition could enable the surgeon to prevent or recognize iatrogenic nerve damage and offer an opportunity to perform deliberate neurectomy as an alternative to accidental nerve injury.

Samenvatting

Hoofdstuk1

Correctie van een liesbreuk is één van de meest voorkomende operaties waarvan het merendeel bij oudere mannen uitgevoerd wordt. Het risico op een recidief breuk is na de introductie van de spanningsvrije (tension free) liesbreukoperatie met behulp van een polypropyleen mat (mesh) naar minder dan 5% gedaald. Sindsdien wordt de morbiditeit op de lange termijn met name door de incidentie van chronische postoperatieve liespijn bepaald. De incidenties die worden gerapporteerd zijn wisselend ten gevolge van de verschillende definities van chronische pijn zoals die in de literatuur worden gehanteerd. Onlangs schatte een werkgroep die verantwoordelijk is voor de Europese liesbreukrichtlijn (European Hernia Society) de incidentie van matige tot ernstige postoperatieve chronische liespijn op 10-12%. De Lichtensteinplastiek is de meest uitgevoerde open liesbreukoperatie in Nederland. Tussen het aantal complicaties zoals gerapporteerd door de Lichtenstein kliniek en door andere onderzoekers bestaat wel een verschil.

Eén derde van alle liesbreukpatiënten zou preoperatief klachtenvrij zijn. Onlangs bleek uit twee gerandomizeerde trials dat chronische pijn niet significant verschilt in geval van expectatief beleid in vergelijking met operatie. Dit onderzochtten de auteurs bij patiënten die asymptomatisch of mild-symptomatisch waren. In 1977 berekende Neuhauser de levensverwachting voor patiënten die expectatief of operatief zouden worden behandeld. Hij concludeerde dat een electieve liesbreukoperatie de levensverwachting niet verlengt, maar dat deze wel van invloed op de kwaliteit van leven kan zijn.

De meest voorkomende typen van chronische postoperatieve liespijn zijn van somatische en neuropathische aard. Peropatieve identificatie van de inguinale zenuwen en het daaropvolgend klieven, reserceren of sparen ervan zouden van invloed kunnen zijn op de incidentie van chronische postoperatieve liespijn. Er lijkt echter geen consensus te bestaan ten aanzien van het peroperatieve beleid omtrent de inguinale zenuwen.

Hoofdstuk 2

Naar analogie van Neuhauser werd de levensverwachting berekend voor liesbreukpatiënten die expectatief of operatief worden behandeld. Verschillende studies werden gevonden waarin parameters werden onderzocht voor de analyse met betrekking tot het: risico op incarceratie en/of strangulatie, voor de bepaling van de mortaliteit geassocieerd met electieve en spoedoperatie, het risico op recidief breuk en 'crossover' van expectatief beleid naar operatie. De gemiddelde mortaliteit die gepaard gaat met electieve en spoed operatie was respectievelijk 0.2% (range: 0-1.8%) en 4.0% (range: 0-22.2%). De jaarlijkse kans op incarce-

ratie en/of strangulatie die gepaard gaat met expectatief beleid was 0.4% (range: 0.2-2.7%). Op basis van verscheidene gerandomizeerde trials ten aanzien van het risico op een recidief liesbreuk, berekenden wij een jaarlijkse kans op een recidief breuk van 0.9%. Onder patiënten zonder of met milde symptomen was de jaarlijkse kans op 'crossover' van expectatief naar operatief beleid 13% (range: 8.0-19.5%). De gemiddelde levensverwachting voor patiënten met expectatief beleid was 26.88 (CI: 26.873-26.884) jaren in vergelijking tot 26.89 jaren (CI: 26.880-26.891) voor degenen die operatief werden behandeld. De beslissing van operatie of expectatief beleid was afhankelijk van de procedurele mortaliteit en de jaarlijkse kans op incarceratie en/of strangulatie. De gegevens uit de literatuur ondersteunen de conclusie van Neuhauser dat de levensverwachting voor oudere liesbreukpatiënten weinig verschilt in geval van expectatief in vergelijking met operatief beleid. Zodoende wordt de beleidskeuze in geval van oudere liesbreukpatiënten met weinig tot geen klachten met name door de te verwachten verbetering van de kwaliteit van leven bepaald.

Hoofdstuk 3

Dit hoofdstuk illustreert het klinische belang van chronische postoperatieve liespijn als complicatie van liesbreukchirurgie door de presentatie van twee patiënten die lijden aan chronische pijn na een Lichtensteinplastiek. Bij één van de patiënten verdween de pijn na neurectomie van de nervus ilioinguinalis. Neurectomie van alle drie lieszenuwen (triple-neurectomie) was bij de andere patiënt echter niet succesvol. Differentiatie van chronische pijn van neuropathische of nociceptieve oorsprong blijft moeilijk, zo niet onmogelijk. Symptomen en mechanismen zijn soms ten gevolge van de plasticiteit van het zenuwstelsel onvoorspelbaar. Zodoende blijft preventie van zenuwletsel de beste strategie.

Hoofdstuk 4

Teneinde de invloed te kunnen beoordelen van een polypropyleen mat op chronische postoperatieve liespijn, werden 300 patiënten die initieel waren gerandomizeerd naar mat of geen-mat liesbreukcorrectie na gemiddeld 10 jaar teruggezien. De lange termijns-resultaten na 3 jaar waren reeds gepubliceerd. In dit hoofdstuk worden de 10-jaars follow-up resultaten ten aanzien van chronische postoperatieve liespijn gepresenteerd. In geen van de patiënten uit beiden groepen was er sprake van persisterende pijn en ongemak. Zodoende wordt geconcludeerd dat er op de lange termijn geen verschil is met betrekking tot chronische postoperatieve liespijn tussen beide groepen.

Hoofdstuk 5

Er is een discrepantie tussen het aantal complicaties na de Lichtensteinplastiek zoals door de Lichtenstein kliniek zelf gerapporteerd en die zoals door anderen gepubliceerd. Een vragenlijst werd naar alle chirurgen en chirurgische opleidings assistenten in Nederland verstuurd. Hierin werd naar hun mening geïnformeerd ten aanzien van de technische stappen tijdens de Lichtensteinplastiek waarvan wordt gesuggereerd dat die met het ontstaan van chronische pijn zijn geassocieerd. Recent zijn deze stappen door Lichtenstein's opvolger Amid geüpdate. Er bleek een substantieel verschil tussen de state-of-the-art Lichtensteinplastiek en zijn toepassing in de dagelijkse chirurgsiche praktijk te bestaan.

Hoofdstuk 6

Er bestaat geen consensus met betrekking tot het wel of niet identificeren van de inguinale zenuwen en het vervolgens wel of niet klieven, reserceren of sparen ervan. Een systematic review werd uitgevoerd waarin publicaties werden opgenomen waarin de invloed van verschillend beleid omtrent de zenuwen werd onderzocht. Het gemiddelde 'gepoolde' percentage patiënten met chronische postoperatieve liespijn na identificatie en doornemen van de nervus ilioinguinalis was gelijk aan het percentage patiënten met chronische postoperatieve liespijn na identificatie en sparen van deze zenuw. Deze conclusie is gebaseerd op drie gerandomizeerde studies. Vanuit twee cohortstudies wordt gesuggereerd dat de incidentie van chronische pijn na identificatie van alle lieszenuwen in vergelijking met het niet identificeren ervan significant lager is. In een andere cohortstudie wordt een significant verschil met betrekking tot de incidentie van chronische pijn gerapporteerd ten gunste van de identificatie en het facultatief doornemen van de genitale tak van de nervus genitofemoralis in vergelijking met het niet identificeren ervan. Concluderend lijkt het het beste om de inguinale zenuwen tijdens open liesbreukchirurgie te identificeren.

Hoofdstuk 7

In hoofdstuk 6 wordt geconcludeerd dat de inguinale zenuwen tijdens open liesbreukchirurgie geïdentificeerd behoren te worden. In dat verband werd een anatomische studie uitgevoerd ter identificatie van klinisch relevante chirurgisch anatomische zones ter identificatie van de lieszenuwen bij open liesbreukchirurgie. De nervus iliohypogastricus was te herkennen aan zijn horizontale verloop ventraal ten opzichte van de musculus obliquus internus waar deze op gemiddeld 3.8 cm (range 2.5-5.5 cm) craniaal ten opzichte van de annulus externus de aponeurose van de musculus obliquus externus perforeert. De nervus

ilioinguinalis is te identificeren aan het verloop ventraal en parallel aan de funiculus, dorsaal ten opzichte van de aponeurose van de musculus obliquus externus. De identificatie van de genitale tak van de nervus genitofemoralis bleek lastiger te zijn. Het verloop van de genitale tak is laterocaudaal op niveau van de annulus internus. Deze informatie zou peropatieve identificatie van de lies zenuwen moeten faciliteren.

Hoofdstuk 8

In hoofdstuk 6 wordt geconcludeerd dat identificatie van de lieszenuwen met minder post-operatieve chronische pijn gepaard gaat. In die zin werd de uitvoerbaarheid onderzocht van een zenuw-bewuste Lichtensteinplastiek op basis van de chirurgisch anatomische zones die in hoofdstuk 7 beschreven zijn. Veertig patiënten met een primaire liesbreuk werden door vier ervaren liesbreuk chirurgen werkzaam in vier verschillende Nederlandse ziekenhuizen volgens de zenuw-bewuste Lichtensteintechniek geopereerd.

De identificatie van zowel de nervus iliohypogastricus als de nervus ilioinguinalis was binnen één minuut uitgevoerd. De identificatie van de genitale tak was lastiger maar kon meestal binnen twee minuten plaatsvinden. De identificatie van de vena cremasterica, die parallel verloopt aan de genitale tak, was gemakkelijker. De incidentie van significante anatomische variaties was laag. In vijfentwintig procent kon de nervus ilioinguinalis niet worden geïdentificeerd. Bij vijf patiënten werd een lieszenuw tijdens een standaardmanoeuvre van de Lichtenstein operatie iatrogeen beschadigd.

Op basis van deze resultaten kan men concluderen dat een 3-zenuw-bewuste Lichtensteinplastiek onder voorwaarde van gedegen anatomische kennis uitvoerbaar is en niet veel tijd vergt. In het kader van de lage incidentie van belangrijke anatomische variaties zou kennis van de standaard anatomie van de inguinale zenuwen afdoende moeten zijn. Met deze procedure zou de chirurg iatrogene zenuwschade moeten kunnen voorkomen en herkennen. Tevens biedt dit de mogelijkheid om neurectomie uit te voeren in geval van accidentele zenuwschade.

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Curriculum Vitae Auctoris

Arthur Randolph Wijsmuller was born in Haarlem on September 1st, 1980. In 1999 he finished secondary school (Stedelijk Gymnasium, Haarlem) and started his medical training in 2000 at the Erasmus University Medical Center Rotterdam. As a student he conducted research at the Department of Surgery of the Erasmus University Medical Center (prof.dr. J.F.Lange and prof.dr. J.Jeekel). After graduating the doctoral's degree and before starting rotations, he was allowed to continue this project for 2 years as a research fellow after which he continued rotations. The results of this research are presented in this thesis. After his rotations he started his surgical training at the IJsseland Hospital in Capelle aan den IJssel (dr. I.Dawson) after which he was accepted as a resident in general surgery at the Erasmus University Medical Center (prof.dr. J.N.M IJzermans). Currently, he is continuing his surgical training in the Sint Franciscus Gasthuis (dr.A.J.H. Kerver) in Rotterdam.