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PATIENT-ORIENTATED ASPECTS OF THE POSTOPERATIVE COURSE AFTER HERNIA SURGERY

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To Mona-Lisa and Anna

ABSTRACT

Operations for inguinal hernia are one of the most common surgical procedures performed. With the development of mesh techniques, recurrence rates have improved radically and patient-orientated endpoints have evolved as important outcome measures.

In recent studies, 15-50% of patients may experience some form of pain years after repair. One reason for the diverging results is the lack of a uniform assessment of postoperative pain. Pain is not defined, nor is it measured in the same way in the different studies. Moreover, postoperative complications are infrequently recorded in everyday surgical practice and many hospitals lack a continuous structured follow-up, making reliable quality assurance assessments difficult. As quality assurance protocols are often retrospective studies rather than prospective, they will have to rely on questionnaires to be answered by the patient to get an estimate of postoperative pain and adverse events. In order to improve the performance in hernia surgery, the National Hernia Register (NHR) was started in Sweden in 1992 and today more than 90% of all inguinal and femoral hernia operations in patients 15 years and older are prospectively recorded. Information on age, gender, type of hernia as noted during the operation and type of repair as well as observed complications are recorded. Patients are entered in the register by their unique National Identification Number and can thus be traced in the register for subsequent operations regardless of the unit performing the operation as well as in other national registers. As of today more than 120 000 operations are gathered in the register.

In the following papers, making the basis of this thesis, we have studied the following issues:

Paper I is a study on the discordance between the patient's and the surgeon's perception of complications. Some 206 patients having surgery for inguinal hernia were invited to a follow-up 3-6 weeks after the operation. The patient was asked to fill in a questionnaire with 12 questions concerning postoperative complications prior to the visit. The examining surgeon who had not participated in the operation and was blinded to the patient's questionnaire filled in a similar protocol. The concordance between the surgeon and the patient in assessing complications was poor and reflects their different understanding of "adverse events", the surgeon assessing technical complications and the patient the symptoms.

Paper II is based on a questionnaire study of postoperative adverse events submitted to 1643 patients recorded in the hernia register during 2 consecutive months in 2002. The response rate was 88% (1448 patients). The most common complications recorded were haematoma in 203 (14%) patients, severe pain in 168 (12%) patients, testicular pain in 120 (8%) patients and infection in 105 (7%) patients. The risk-factors for complications were age below the median of 59 years and laparoscopic repair. The National Hernia Register covered 25% of the complications recorded by the patients in the questionnaire, reflecting that a passive recording of complications, i.e. the clinic only record what comes to their knowledge, is less accurate than a structured follow-up.

The study showed that a structured follow-up may improve quality control of surgery, since only a small number of the adverse events perceived by the patient came to the knowledge of the health-care provider.

Paper III introduces the novel Inguinal Pain Questionnaire (IPQ) which is the first assessment instrument specifically designed for evaluation of pain after hernia surgery. The questionnaire consists of 18-items and is divided in a pain intensity section using a 7-step behavioural rating scale and a section for interference with daily activities with a dichotomous scale. The aim of this study is to test its validity and reliability. The validity is tested in 100 patients filling in the IPQ and Brief Pain Inventory 1 and 4 weeks after the operation for a unilateral groin hernia. Reliability and internal consistency was tested in another 100 patients filling in the IPQ 3 years after the operation on 2 occasions one month apart. Non-surgery related pain was analysed in a cohort of 2853 patients derived from the NHR, and they were sent the IPQ by regular mail 2-3 years after the operation. Non-surgery related pain was assessed by comparing pain in the groin having surgery to the side that did not. In conclusion the validity, reliability and internal consistency were acceptable. The non-surgery related pain did not exceed 5.5% for any item.

Paper IV is a study on long-term pain after hernia surgery. From the NHR 2853 patients having surgery for a unilateral groin hernia were sent the IPQ 2-3 years after the operation by regular mail with 2456 patients (86%) responding. In response to the question “worst pain past week” 758 patients (31%) reported some pain and 144 patients (6%) reported pain that interfered with daily activities. Age below median, a high level of preoperative pain, techniques involving an anterior approach and the occurrence of any postoperative complication were found to predict long-term pain.

In conclusion, quality assurance in groin hernia surgery can be facilitated by the use of local or national registers together with a structured follow-up in order to identify risk-factors and encourage a high standard of care.

LIST OF PUBLICATIONS

This thesis is based on the following publications and will be referred to in the text by these numbers:

I. Fränneby, U. Gunnarsson, U. Wollert, S. Sandblom, G. Discordance between patient's and surgeon's perception of complications following hernia surgery. Hernia (2005) 9: 145-149.

II. Fränneby, U. Sandblom, G. Nyrén, O. Nordin, P. Gunnarsson, U. Self-reported adverse events after groin hernia repair; a population-based register study. Submitted.

III. Fränneby, U. Gunnarsson, U. Andersson, M. Heuman, R. Nordin, P. Nyrén, O. Sandblom, G. Validation of the Inguinal Pain Questionnaire; a novel instrument for the assessment of chronic pain after hernia surgery. Submitted.

IV. Fränneby, U. Sandblom, G Nordin, P. Nyrén, O. Gunnarsson, U. Risk-factors for long-term pain after hernia surgery. Annals of Surgery 2006; 244 (2): 212-219.

CONTENTS

LIST OF ABBREVIATIONS

BMI	Body Mass Index
BPI	Brief Pain Inventory
CI	Confidence Interval
DIBS	Duration-intensity-behaviour-scale
CDR	The Central Cause of Death Register
IASP	The International Organisation for the Study of Pain
IPQ	The Inguinal Pain Questionnaire
NRN	The National Registration Number
OR	Odds Ratio
SD	Standard Deviation
SHR	The Swedish Hernia Register
VAS	Visual Analogue Scale
VRS	Verbal Rating Scale
WOMAC	Western Ontario and McMasters Osteoarthritis Index

INTRODUCTION

Definition

A hernia is the protrusion of a viscus or a part of it through an abnormal opening in the walls of its containing cavity [1]. In the concept of a groin hernia we have included both inguinal and femoral hernias. In the following papers we have studied groin hernias with a special reference to pain following surgery for its cure.

Pain is defined by the International Association for the Study of Pain (IASP) as "An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage". A note is given that pain is always subjective [2].

Incidence

The operation for groin hernias is one of the most common surgical procedures performed and every fourth man is expected to have a hernia operation during his lifetime. The annual incidence rate of hernia operations is estimated to more than 200 operations/100 000 persons and year. Approximately 7% of groin hernias occur in women and nearly 25% of those are of the femoral type [3].

Historical notes

Hernias have been described as far back as 1552 BC in the Egyptian *Papyrus of Ebers* [4]. If operations were performed for hernia at that time is not clear. Tightly fitting bandages were used by physicians in Alexandria at 900 BC as seen on statuettes. Celsus introduced Greek and Alexandrian medicine to Rome in 50 BC with trussing for the management of pain. In strangulated cases an incision was carried out in the scrotum and the hernial sac excised. The wound was left open to granulate and was cauterised if large. The cauterisation was used to enhance scarring and thus provide extra support to the groin. In the Byzantine era in 324-1453 AD anatomical knowledge advanced when dissection of the human body was permitted. Aetius of Amida in the 6th century AD wrote a medical compendium in 16 books called the *Tetrabiblos*. These books cover many surgical fields and contain a description of the technique used for dealing with inguinal hernias. The main features of the operation are groin incision, removal of the hernial sac below the subcutaneous orifice and stitching the skin [5].

Further knowledge on anatomy was gained during the renaissance but the hernia operations were performed in the same way as in the ancient era. Anaesthesia was introduced in 1846 and in 1869 Lister performed the first antiseptic hernia operation in Glasgow [6]. The operations performed were basically to push the hernial sac back in to the external orifice and suturing it around the cord without opening the external oblique aponeurosis. Lucas-Championniére in 1881 was the first surgeon to open the external oblique aponeurosis, performing a high ligation of the sac and to tighten the internal ring. Results were however discouraging as seen from the review of the European experience by Kocher in 1890 and the American experience by Bull in 1891. Mortality ranged from 2-7% due to sepsis, peritonitis and haemorrhage.

It was not until the late 1880s that the modern surgical techniques were developed with the help of antiseptics and anaesthesia. In 1887 the Italian Surgeon Eduardo Bassini presented his series of operations with a recurrence rate of only 4% with the postoperative observation time of 4.5 years. His procedure made a significant change of old methods and leads us to the modern approach on inguinal hernia repair. His main contributions were a standardised procedure with:

a) Complete division of the external oblique aponeurosis.
b) A complete division of the transversalis fascia.
c) Dissection and isolation of the cord.
d) A high ligation of the hernial sac.
e) The reconstruction of the posterior inguinal wall, with an interrupted single layer of sutures.
f) The use of a non absorbable suture, in this case silk.
g) A structured follow up.

Ever since Dr Bassini presented his excellent results, attempts at reproducing his achievements in modern times have led to various results with recurrence rates ranging from 5-40%. The failures are probably due to the later corruption of Bassinis' procedure with simple inversion of the posterior wall instead of division of the transversalis fascia. Modification of the Bassini procedure and the introduction in the 1950s of a 4-layer repair with continuous non absorbable suture, the Shouldice repair, have in specialised centres led to recurrence rates as low as 2 %. Outside specialised centres, these fine results have not been reproduced.

Already Bassini realised that tension in the repair could lead to pain and recurrence and proposed the invention of a prosthesis. The relaxing incision in the rectus sheet was introduced in the 1900s by Wöffler and the technique was spread and widely adopted. Various prosthetic materials were tried, such as fascia lata strips, dural and skin grafts. An external prosthesis, a temporary wooden plug, pushing the scrotal skin and testicle in front of it to plug and produce scarring of the inguinal canal was used in the 1830s by C. W. Wutzer and became popular. The first mesh which was made of fine silver filigree was used by Witzel and Goepel in Germany in 1900. Tantalum mesh introduced in the 1950s had the same problem as silver mesh, rigidity, bad tissue integration resulting in fibrotic response with occasional sinus formation and sometimes breakage of the mesh with a hernia recurrence as a result.

The search for the ideal prosthesis went on and Cumberland postulated eight still valid criteria for the ideal prosthetic material in 1950s. The material should be chemically inert, not excite a foreign body or inflammatory reaction, should be non-carcinogenic, and not produce a state of allergy or hypersensitivity, capable of resisting mechanical strains, capable of being fabricated in the required shape and capable of being sterilised.

These drawbacks with inert metal prosthesis and failing dural grafts lead Usher in 1958, after animal experiments with good tissue integration, to the use of polypropylene mesh for the first time in hernia surgery. In 1989 Lichtenstein and associates reported on the "tension-free repair" with primary repair of the floor of the inguinal canal using a

polypropylene mesh. The mesh is sutured to the inguinal ligament and conjoined tendon with a slit for the cord without causing any tension to the tissues. The procedure, known as the Lichtenstein procedure, has today become the gold standard of inguinal hernia repair.

Considering the magnitude of primary operations performed world wide followed by reoperations for recurrence or complications, the cost for society and the pain and discomfort for the individual are considerable. Therefore, the search for the ideal method of inguinal hernia repair with the best possible result and a minimum of complications and postoperative discomfort is of crucial importance and is still ongoing.

Nerve supply of the groin

The nerves supplying the groin originate from the lumbar plexus which is formed in the Psoas Major muscle by the anterior rami of the upper four lumbar nerves. The exact course and distribution may vary between individuals. The sensory nerves of the groin communicate freely and variably among individuals. The main principle is outlined as follows [7, 8].

The iliohypogastric nerve is formed by the L1 and partly by the Th 12 roots and emerges from the lateral border of the upper part of the Psoas Major muscle and transverses obliquely across and in front of the Quadratus Lumborum muscle to the Iliac crest. Here the nerve penetrates the transverse muscle and then passes in the interval between Transverse and Internal Oblique muscles which it also supplies. The nerve then divides to the Lateral and Anterior Cutaneous Branches. The Anterior Cutaneous Branch then passes 1 inch above the Anterior Superior Iliac Spine and becomes subcutaneous when it perforates the External Oblique muscle 1 inch above the superficial inguinal ring. It supplies the skin over the suprapubic area.

The Ilioinguinal nerve arises from the first Lumbar nerve root and leaves the lateral border of the Psoas Major muscle below the Iliohypogastric nerve and crosses obliquely in front of the Quadratus Lumborum and Iliacus muscles. It runs tightly over the iliac crest and then perforates the Transverse Muscle just medial to the anterior superior iliac spine. It then pierces through the Internal Oblique muscle, communicates with the Iliohypogastric Nerve and joins the spermatic cord and exits through the external inguinal orifice. The nerve gives off strands to the transverse, internal and external oblique muscles and supplies the skin over the upper medial aspect of the thigh, upper part of scrotum and penile root or Labia Majora and Mons Pubis in females.

The Genitofemoral nerve from the L1 and L2 nerves emerges through the Psoas Major muscle and runs on the anterior side of it behind the Peritoneum. It consists mainly of sensory fibres but also has motor components to the Cremaster muscle. The nerve crosses behind the Ureter and then divides into the Femoral and Genital branch. *The Femoral branch* passes over the External Iliac artery, passes under the Iliopubic tract and penetrates the Femoral sheet where it supplies the skin over the upper part of the Femoral triangle. *The Genital branch* crosses the lower part of the External Iliac artery

and enters the inguinal canal through the ventral aspect of the deep inguinal ring. The nerve runs within the cord between the Cremaster muscle and spermatic fascia, most often on the inferior part. It provides motor fibres to the Cremaster muscle and supplies the skin over the Scrotum or Mons Pubis and Labium Major in women.

The Swedish Hernia Register

The Swedish Hernia Register (SHR) started in 1992 with its main aim to improve quality in hernia surgery and to reduce recurrence rates. The recurrence rate is defined in the register as the number of operations for recurrence in relation to all hernia operations performed, *i.e.* the reoperation frequency. The reoperation frequency equals the true recurrence rate by a factor of 1.6-2.0 [9]. The goal was to reduce the 2-year cumulative reoperation frequency to a level below 2%, meaning that no more than 2% of the operations should have recurred after 2 years of observation time. This goal has, indeed, been reached. A cumulative reoperation frequency of 3.7% among patients operated in 1992-1994 has dropped to 1.9% among those operated in 1999-2001 [3]. These results have been obtained with the introduction of tension free procedures and a continuous audit.

Recent reports have estimated the prevalence of pain several years after the surgical treatment of inguinal hernia to be as high as 50 % [10]. These results indicate that chronic pain after hernia surgery today is a quantitatively larger problem than the recurrence of a new hernia. The lack of a uniform assessment standard of postoperative chronic pain following inguinal hernia surgery has led to diverging results on its presence and impact on daily living.

In the Swedish Hernia Register (SHR), detailed information on more than 120,000 groin hernia repairs has been compiled since 1992. Every inguinal or femoral hernia operation in patients of ages 15 years or older at participating units is recorded according to a standardised protocol. Variables recorded include age, gender, mode of admission, time on waiting list, type of hernia as noted during operation, size of the defect, method of repair, postoperative complications and reoperations for recurrence. A structured clinical follow-up is not mandatory, but any complication observed by the operating unit within 30 days after surgery has to be recorded in the database. The register is continuously being validated [11]. Every Swedish resident has a unique National Registration Number (NRN) which is universally used in official contexts, including entries in population and health registers, as well as in medical case records. The NRN makes follow-up possible through cross-linkages within the SHR and also through record linkages to the Swedish Cause of Death Register (CDR) and the continuously up-dated and virtually complete National Inpatient Register.

GROIN HERNIA SURGERY

Hernia repair has previously focused on recurrences after repair. The results Dr Bassini achieved in 1890 have not consistently been reproduced afterwards. It may be because of the widespread corruption of the original procedure in which the transversalis fascia was not divided but merely duplicated. Recurrence rates for the Bassini procedure have in later studies proved to be 4-28% [12] [13] [14]. The introduction in the 1950s by the 4-layer Shouldice technique have been shown safer than the single layer Bassini technique in terms of having a lower recurrence rate (RR 1.15) [15]. In specialised centres the Shouldice technique has recurrence rates below 2% but is a technically demanding procedure and has a long learning curve. It has become the gold standard of open sutured methods and still has its place in patients not suited for mesh repair such as in young patients with an almost intact deep inguinal orifice and in infected cases. It has also been shown that the use of non-absorbable sutures is superior to absorbable sutures in preventing recurrence [16].

The development of mesh repair and systematic quality control has further reduced the recurrence rate and is now about 2% after 2 years observation time [3, 11]. At present the most frequently used technique is the Liechtenstein procedure in which the hernial sac is either reduced or excised and a flat mesh is inserted via a groin incision under the External Oblique aponeurosis and sutured on top to the Tuberculum Pubis, Inguinal Ligament and Internal Oblique with a slit for the cord.

The role of the laparoscopic technique introduced in the 1990s is under debate. It gives a quicker postoperative recovery, a more rapid return to work and causes less chronic pain but may convert the open anterior operation under local anaesthesia to an more extensive operation under general anaesthesia [17-19]. Further, laparoscopic approach has in some studies more severe complications, more recurrences, a longer learning curve and is more costly for the health care system [20-24]. Other studies have proven the opposite [25]. The ideal setting for laparoscopic hernia operations seems to be in specialised centres and preferably for recurrent and bilateral hernias [26]. In January 2001 the National Institute of Clinical Excellence (NICE) in Great Britain issued guidance that stated, “For repair of primary inguinal hernia, open mesh should be the preferred surgical procedure”. These guidelines does not seem to have a great impact on the surgeons behaviour as the number of laparoscopic hernia repairs on primary hernias are increasing in England [27]. According to data in the Swedish Hernia Register, laparoscopic repair in Sweden had its peak in 1996 when nearly 20% of all groin hernias were done by this technique. The proportion of laparoscopic repair has since then declined to 6% in 2005 [3].

The gold standard today for primary inguinal hernia repair is the Lichtenstein procedure which has a short learning curve, can be performed on an ambulatory basis under local anaesthesia and gives excellent results in terms of recurrences [3, 14, 28, 29]. The Shouldice and laparoscopic repair on the other hand have long learning curves and is surgeon dependent for their outcome [30].

Numerous different variations of mesh techniques have recently been introduced beside the Liechtenstein repair, such as the Prolene® Hernia System and the mesh plug repair. No significant difference can be seen between these methods in postoperative pain, quality of life and recurrences and the choice of procedure is the one preferred by the surgeon [31] (Paper IV).

With low recurrence rates, chronic pain is now quantitatively a larger problem than recurrences and varies between 20-50% [10, 32-36] (Paper IV). The difference in patients recorded with chronic pain can to some extent be explained by the lack of a uniform assessment standard. The assessment of pain is complex and can be done in a number of ways as will be discussed more in depth in the following sections.

INSTRUMENTS FOR THE EVALUATION OF PAIN AND QUALITY OF LIFE

The well-being and patient satisfaction of patients after surgical interventions is a matter of growing importance [11, 33, 37, 38]. In order to assess patients postoperatively and to get outcomes that are universally comparable, valid and reliable instruments are needed. A large number of questionnaires and instruments have thus been developed for the measurement of pain and quality of life [39]. Most of the widely spread instruments are non-disease specific and measure pain-scores and the quality of life from a broad perspective [40-50]. As pain and the perception of quality of life is a subjective experience, the majority of assessment methods used today are of the self-recording type.

According to Macrae, the 4 following criteria has to be fulfilled in order to classify pain as chronic post-surgical [51].

1. The pain developed after a surgical procedure.
2. The pain is of at least 2 months duration.
3. Other causes of pain should have been excluded.
4. The possibility that the pain is continuing from a pre-existing problem has to be excluded.

Pain measurement can be performed by using a variety of pain intensity scales. It is not clear which of them is the most efficacious. *Numerical rating scales* are made up lines or numbered boxes. The patient makes a mark on this scale that usually goes from 0 to 10 or 100 and the extreme represents the maximum amount of pain. In v*erbal rating scales* the patient can chose from a list of words describing the different levels of pain. *Behavioural rating scales*, a form of verbal scale, use a set of words describing what actions the patient take when experiencing pain. Listed below are the ones most often used for follow-up after surgical treatment (fig 1).

The Visual Analogue Scale (VAS) is the simplest and most frequently used for the measurement of postoperative pain in everyday surgical practice. It consists of a 10 cm straight line anchored by the 2 extremes “no pain” and “pain as bad as it could be”. The patient is asked to make a mark on a line representing the perceived level of pain. Scoring is made by measuring the distance from “no pain” to the mark [52, 53]. The VAS can only be presented in written form and care must be taken if photocopied so that the scale is not distorted.

The 101-Numerical Rating Scale (101-NRS) is a numerical scale from 0 to 100 with 0 representing the one extreme “no pain” and 100 the other extreme “pain as bad as it can be”. The number stated by the patient represents his or her perceived level of pain. This scale can be presented in written or verbal form.

The Box Scale 11 (BS-11) is a numerical scale and consists of 11 numbers, 0 to 10 surrounded by boxes. As in the other numerical scales, 0 means no pain and 10 mean the maximum amount of pain experienced. The patient is asked to mark with an 'X' in the appropriate box corresponding to the level of pain.

Verbal Rating Scales (VRS) consists of a list of adjectives that describe different levels of pain. The 5-point VRS is used in the McGill pain Questionnaire.

The Duration Intensity Behaviour Scale (DIBS) is an adaptation of a pain scale developed by Budzynski et al. for tension headache and later used in other pain comparison studies [40, 54, 55]. The patient is asked to rate pain on a 7-point scale, using ratings that are operationally defined in terms of overt behavioural events rather than verbal intensity descriptors. In addition the duration is rated separately. The DIBS has been validated against the VAS and was found to have a greater temporal stability [41].

Below in figure 1 are the different pain rating scales presented.

Fig.1 Pain rating scales

The Visual Analogue Scale (VAS)

Please indicate on the line below the mark that best describes your pain. A mark on the left end would mean "no pain" and a mark on the right end would mean "pain as bad as it could be".

No pain Pain as bad as it could be

The 101-pointNumerical rating scale (NRS-101)

Please indicate on the line below that number between 0 and 100 that best describes your pain. A zero (0) would mean "no pain" and one hundred (100) would mean "pain as bad as it could be".

0 **100**

The 11-point Box scale (BS-11)

If a zero (0) means "no pain" and a ten (10) means "pain as bad as it could be" on this scale of 0 to 10, what is your level of pain? Put an X through that number.

0	1	2	3	4	5	6	7	8	9	10

The 4 point Verbal Rating Scale (VRS-4)

- No pain
- Some pain
- Considerable pain
- Pain which could not be more severe

The 5-point Verbal Rating Scale

- Mild
- Discomforting
- Distressing
- Horrible
- Excruciating

The Duration Intensity Behaviour Scale

No pain

1. Pain present, can easily be ignored
2. Pain present, can easily be ignored, does not interfere with everyday activities
3. Pain present, cannot be ignored, interferes with all activities
4. Pain present, cannot be ignored, necessitates bed rest
6. Pain present, cannot be ignored, prompt medical advice sought

Pain Questionnaires

The McGill Pain Questionnaire by Melzack provides a quantitative profile of pain and is divided in 3 major classes with 20 subclasses of pain [42, 43]. In each class the patient can choose one word from a group of words describing the pain experience. The major classes are sensory-discriminative, motivational affective and cognitive-evaluative pain. This extensive questionnaire was intended for cancer related pain but has been used for all forms of chronic pain and has lately been validated for post-surgical pain [44]. The short version of the questionnaire was introduced in 1987.

The Brief Pain Inventory (BPI) was initially developed to measure pain intensity and interference with daily activities in cancer patients [45]. It has recently been validated for non-malignant pain [46]. The questionnaire is available in a short and long version. The short form of the questionnaire consist 15 questions. The BPI measures both the intensity of pain as well as the interference with daily activities.

General health questionnaires

The Short Form (SF-36) is a short form measure of generic health in the general population [47]. It consists of 36 items and measures 8 dimensions of physical health. The health concepts measured are physical functioning, role limitations due to physical health, bodily pain, general health, vitality, social functioning, role limitations due to emotional problems and emotional health. A verbal descriptor scale is used throughout the questionnaire.

EuroQol is the result of a joint project set by several European centres [48, 49]. This instrument is a standardised, non-disease-specific questionnaire for describing and valuing health-related quality of life. The EuroQol group is concerned with cross-national comparisons of health.

The BPI is presented below in figure 2..

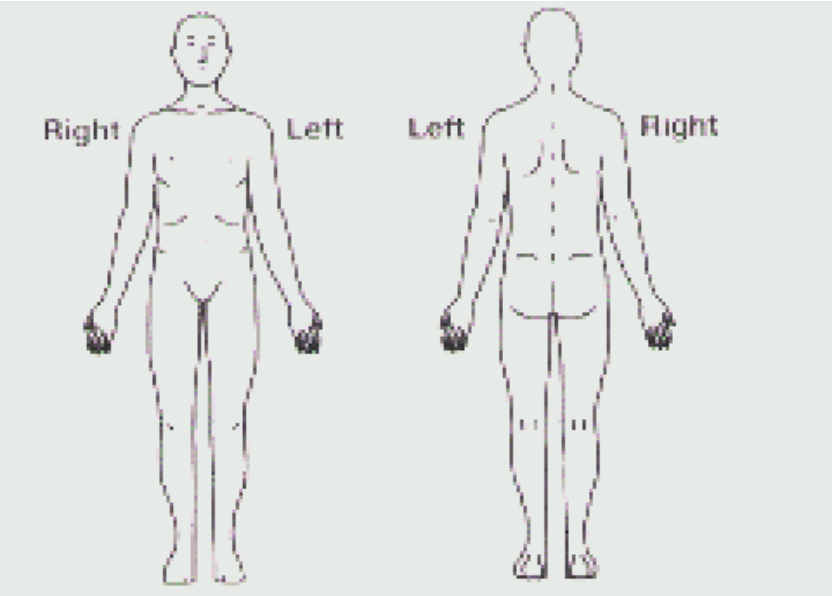
Figure 2.

The Brief Pain Inventory, BPI

1) Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

1. yes 2. no

2) On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3) Please rate your pain by circling the one number that best describes your pain at its WORST in the past week.

0 1 2 3 4 5 6 7 8 9 10

No pain — Pain as bad as you can imagine

---

4) Please rate your pain by circling the one number that best describes your pain at its LEAST in the past week.

0 1 2 3 4 5 6 7 8 9 10
No pain — Pain as bad as you can imagine

---

5) Please rate your pain by circling the one number that best describes your pain on the AVERAGE.

0 1 2 3 4 5 6 7 8 9 10
No pain — Pain as bad as you can imagine

---

6) Please rate your pain by circling the one number that tells how much pain you have RIGHT NOW.

0 1 2 3 4 5 6 7 8 9 10
No pain — Pain as bad as you can imagine

---

7) What treatments or medications are you receiving for your pain?

---

8) In the past week, how much RELIEF have pain treatments or medications provided? Please circle the one percentage that most shows how much.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
No relief — Complete relief

---

9) Circle the one number that describes how, during the past week, PAIN HAS INTERFERED with your:

A. General Activity:

0 1 2 3 4 5 6 7 8 9 10
Does not interfere — Completely interferes

B. Mood

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
interfere interferes

C. Walking ability

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
interfere interferes

D. Normal work (includes both work outside the home and housework)

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
interfere interferes

E. Relations with other people

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
interfere interferes

F. Sleep

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
interfere interferes

G. Enjoyment of life

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
interfere interferes

QUALITY ASSURANCE

Patients having surgery for inguinal hernias, are usually not assessed postoperatively for complications or persisting symptoms apart from recurrences. It is important for the continuous quality assessment to get a more complete picture of the patient related aspects of complications, persisting pain and functional impairment.

In order to reach this goal, a uniform assessment standard of measuring chronic pain and impact on daily living is needed. Risk-factors for all forms of complication including chronic pain need to be identified in order to find ways to improve the care. Moreover, the assessment method used should be valid, reliable and easy to use for both the patients and the doctor. As many postoperative complications are a subjective experience of symptoms, the use of self-recording questionnaires is one way of recording the events and a better knowledge of how the patient and doctor perceive the aspect of complications becomes important in the overall assessment.

These concerns are the background for the following papers making up this thesis.

AIMS OF THE THESIS

As chronic pain after surgical treatment of a groin hernia is a quantitatively larger problem than recurrences and postoperative complications are connected to chronic pain, the aims of this thesis are to:

1. Investigate the degree of concordance between the patients and doctors perception of complications following surgery for inguinal hernia (paper I).

2. Quantify the occurrence of complications following hernia surgery, to identify their possible risk-factors and to evaluate the importance for the overall quality of hernia repair (paper II).

3. To introduce a uniform assessment standard of chronic pain after hernia surgery (paper III).

4. Quantify the magnitude of chronic pain after groin hernia surgery and the impact on daily activities and to identify possible risk-factors for its appearance (paper IV).

MATERIALS AND METHODS

Paper I

In this study we investigated the patients and doctors perception of complications following hernia surgery for the first postoperative month. From the group of patients who underwent elective surgery for groin hernia at the Samariterhemet Hospital, Uppsala, in 2003, 206 consecutive patients were invited to an appointment 3-6 weeks after their operation. At this visit the patient was asked to answer a questionnaire about his/her general perception of the post-operative period and any additional specific adverse event. A clinical examination was performed at the same visit by a surgeon who had not participated in the operation. A similar protocol was filled in by the examining surgeon who was unaware of what the patient had responded.

Paper II

The occurrence of postoperative complications in the first 30 postoperative days is investigated by identifying 2 complete month-cohorts of patients included in the SHR. Patients with a unilateral primary repair (N=1643) were included and mailed the same questionnaire as in paper I, asking questions about the patients general perception of the early postoperative period and any specific adverse events. The results of the questionnaire are compared to the corresponding data in the SHR by cross-linking and using the person-specific NRN. The magnitude of complications as well as risk factors for its occurrence can thus be identified. It is also possible to find to what extent the healthcare departments involved in the SHR get information on complications.

Paper III

The novel self-recording instrument for chronic pain following inguinal hernia surgery, The Inguinal Pain Questionnaire (IPQ) is validated in this study. Validity and reliability testing was performed in three separate samples. The first set of 100 patients (group A) was sent the IPQ and the previously validated Brief Pain Inventory (BPI) on day 7 and 28 after the operation. By comparing the responses for the IPQ and BPI and the responses after 1 and 4 weeks we can investigate the construct and criterion validity. In group B another 100 patients were sent the IPQ 3 years after the operation on 2 occasions one week apart. In this group the test-retest repeatability, logical coherence and internal consistency was examined. Group C consisted of the 3000 patients from the study in paper IV and was used to analyse non-surgery-related pain.

Paper IV

The prevalence of chronic pain following inguinal hernia surgery and its impact on daily activities was examined by using a recently developed questionnaire, the Inguinal Pain Questionnaire (IPQ), which was also validated in paper III. This questionnaire is divided in 2 sections with questions on the severity of pain and interference with daily activities and contains 18 items that take about 10 minutes to fill in. By using the SHR we identified 3000 patients who had undergone a unilateral inguinal hernia operation 3 years earlier. After cross-linking with the Central Cause of Death Register (CDR), the IPQ-questionnaire was sent by regular mail to surviving patients. Reminding letters were sent after 5 and 10 weeks. The responses in the questionnaire were matched to corresponding data compiled in the SHR for the index operation in order to estimate the prevalence of chronic pain and to identify risk factors for its occurrence.

RESULTS

Discordance between the patient's and surgeon's perception of complications following hernia surgery (paper I)

Of the 206 patients invited to follow-up, 174 (84.5 %, 161 men and 13 women) filled in the questionnaire and underwent clinical examination. Mean age was 55 years, SD 14 years. A total of 190 complications were revealed by the questionnaire, 32 of which had forced the patient to seek medical advice. There were 131 complications registered as a result of the follow-up clinical examinations and history. Kappa levels ranged from 0.11 for urinary complications to 0.56 for constipation. The overall agreement between patient's and doctor's perception of complication was poor. Although the surgeon has a better knowledge of what to expect in the postoperative period only the patient has a complete picture of the symptoms and adverse events.

Self-reported adverse events after groin hernia repair; a population based register study (Paper II).

The response rate was 1448/1653 (88.1%, 1341 men and 107 women) with mean age 59 years (SD 16). The most common complications were haematoma in 203 patients (14.4%), severe pain in 168 patients (11.8%), testicular pain in 120 patients (8.3%) and postoperative infection in 105 patients (7.4%). In the analysis of risk factors, young age (≤59 years, OR 1.52; 95% CI 1.19-1.93) and laparoscopic hernia repair (OR 2.44; 95% CI 1.11- 5.37) was associated with a significantly increased risk for postoperative complications when viewing the questionnaires.

Validation of Inguinal Pain Questionnaire; a novel instrument for assessment of chronic pain after hernia surgery (paper III)

In group A, a significant decrease in pain rating for all items concerning the operated groin was observed 1-4 weeks after surgery. Significant correlations were seen between all IPQ items concerning postoperative pain in the operated groin and the corresponding BPI pain intensity items. The rate of logical incoherence did not exceed 5.5% for any item. The Kappa levels in the test-retest in group B were higher than 0.5 for all items except for 3 items. Cronbachs alpha was 0.83 for questions on pain intensity and 0.74 for interference with daily activities. The IPQ shows good validity and reliability and can be used for the assessment of chronic post herniorrhaphy pain.

Risk factors for long-term pain after hernia surgery (paper IV)

After two reminders, 2456 (86%) of the 2853 patients still alive had responded (2299 men and 157 women). Their mean age at operation was 58.2 years. In response to the question "worst perceived pain past week", 758 patients (31%) reported pain to some extent. In 144 cases (6%) the pain interfered with daily activities. Age below median, a high level of pain before the operation, and occurrence of any postoperative complication were found to significantly and independently predict long-term pain in a multivariate logistic analysis where "worst pain past week" was used as outcome variable. The same explanatory variables, along with a technique of repair using the anterior approach i.e. groin incision, were found to predict long-term pain with "pain right now" as outcome variable.

DISCUSSION

The patients' perception of complications

Bearing in mind that postoperative complications are strongly associated with chronic pain, as seen in paper II, it is important to investigate how the surgeon and the patient perceive the aspect of complications. This is studied in paper I. The agreement between the patient and the doctor on when a postoperative event becomes a complication is poor in this study. What the surgeon observes as a normal postoperative event can by the patient be experienced as something not belonging to the expected healing process. Many of the patient-defined complications are not of such a severe degree as to be registered as surgical complications. But this does not necessarily mean that questionnaires are of less value in attempts to register complications. Postoperative visits as well as self-administered structured forms complement each other and together cover the patients' and doctors' perceptions of complications.

Of crucial importance is preoperative information of the particular procedure, risks and complications [56]. This should be presented to the patient not only as brief information in the out-patient clinic but also in written form. Doctors are poor in disclosing potential risks with surgery and in achieving consent for surgery [57]. Insufficient information for patients may be one factor responsible for the differing perception of complications between the doctor and the patient in paper I.

Risk factors for complications

Postoperative complications following hernia surgery are associated with a higher rate of postoperative chronic pain as seen in paper II. We investigated the magnitude of complications for the first postoperative month and also looked to see how much of this information was recorded in the register. By cross-linking the questionnaire to the SHR we were able to look for risk factors for complications including chronic pain. Age below the median of 59 years and laparoscopic approach were risk factors for complications as defined by the questionnaire responses. Low age as a risk-factor for postoperative pain is well known [31, 36, 58] and other studies have reported a higher complication rate or more severe complications after laparoscopic repair [18, 22].

The complications recorded in the SHR, reflecting what is found in the patient records, covered only 25 % of the complications stated by patients in the questionnaire. This means that complications passively recorded without structured follow up will be insufficient. The SHR has, however, a high validity [11]. What is found in the patient record on complications is also found in the SHR, but not all symptoms that the patients experience are brought to the operating units' attention. Some of the complications were treated at health care units not connected to the SHR, and sometimes the patient did not seek help for their symptoms at all. Again it is important to stress that a well thought-out follow-up with both structured forms and clinical examination gives the best quality information and covers both the patients and surgeons experience.

Quality assurance for the health care services in the future will improve with more quality registers and a structured follow-up where the patient satisfaction after treatment is taken in to account.

The IPQ

There is not at present any universally accepted standard for measuring postoperative pain in hernia surgery [59]. The novel questionnaire, IPQ that we used in paper IV for assessment of postoperative chronic pain following hernia surgery is validated in paper III. The questionnaire shows a good validity and reliability and can be used for the evaluation of chronic post herniorrhaphy pain. The information obtained will be even stronger and more useful if it is used together with a local or national hernia register for cross-linking of data. Referring to paper I on the disagreement between the patient's and doctor's perception of complications, it is reasonable to raise the question as to whether the agreement would be equally low for the IPQ. The answer is that what should be registered as a complication might be a matter of opinion, but what is perceived as postoperative discomfort or pain is solely in possession of the bearer, *i.e.* the patient.

Pain and risk-factors for pain

We have found in paper IV that 31% of patients having surgery for inguinal hernia still experience some form of discomfort 2-3 years after the operation. In 6% of the cases the discomfort was severe enough to interfere with daily activities. In contrast, the cumulative 2-year reoperation rate of inguinal hernia is now below 2% [3]. With this in mind, chronic pain appears to be a quantitatively larger problem than recurrences. It is therefore reasonable to adopt long-term pain after hernia surgery as an alternative endpoint.

The different surgical techniques for repair, using the anterior approach or use of different heavyweight meshes or suture material have no effect on the development of chronic pain [12, 29, 34, 60, 61]. In our studies a laparoscopic approach is associated with less chronic pain. In paper IV, age below median, a high level of pain before the operation and complications after surgery were significant predictors of long-term pain. These findings are in agreement with previous studies [19, 36, 62]. Of these, the anterior approach and postoperative complications are the only variables that can be influenced. Postoperative complications are likely to be controlled by a more rigorous quality assurance at each operating unit.

Pain memory

Many studies on post-surgical pain rely on the patients' accurate recollection of preoperative pain levels. The IPQ used in paper III and IV have a question, item number 1, asking the patient to remember the preoperative level of pain. In the study in paper IV some patients had to recollect the pain level as long as 3 years earlier. How well can patients accurately remember previous pain and recall that level of pain? Is it worth while asking such a question and will reliable data come out? Few studies have addressed this issue but in a study by Hunter using the McGill Pain Questionnaire, neurosurgical patients were able to accurately remember the level of pain 5 days earlier

[63]. The best results were obtained for pain expressed with verbal descriptors. In another study using the SF-36 and Western Ontario and McMaster Osteoarthritis Index (WOMAC), total knee arthroplasty patients' recall of preoperative pain and functional status with a mean of 2.5 years earlier was moderate [64]. The WOMAC questionnaire measures pain scores on a VAS scale. By using behavioural rating scales patients seem, however, more able to remember pain levels accurately as compared to the VAS [41, 55]. These findings suggest a cognitive component for guiding remembered pain recordings and further that the choice of measuring scale is important. It is possible that the behavioural rating scale is more reliable in terms of remembering pain compared to other instruments since the patients do not have to transform their experienced level of pain into another dimension as is the case with the VAS. The best option, however, is to record the level of pain before surgery, and to eliminate sources of pain other than that caused by the target pathology. But in many instances in retrospective analysis where preoperative pain scores are not available, this is not possible.

POSSIBLE SOURCES OF PAIN

The influence on nerve division, tension and repair technique

The ilioinguinal and genitofemoral nerve are sometimes accidentally and sometimes deliberately severed during operation. The effect on postoperative pain and sensory loss and discomfort has been studied in randomised trials [65, 66]. The patients were randomised in a double-blind fashion for division of the ilioinguinal nerve. Both studies concluded that there was no increase in chronic postoperative pain or discomfort following nerve division. However, on sensory examination, the loss of touch and pain sensation was greater on the side where the nerve was damaged, although the patient was usually unaware of it at 1-year follow-up. These data concur with another study where numbness after repair was not a cause of morbidity [67].

Tension free repairs have been developed primarily to reduce recurrence of a hernia after surgery. Theoretically, the reduced tension in the tissues could also lead to less postoperative pain. This influence of tissue tension on postoperative pain has been studied with the Shouldice technique and no correlation was found between tissue tensions as measured during operation and recorded VAS scores in the early and late postoperative period [68, 69]. Tension can therefore not be considered to be the cause of pain after repair.

Evidence that tension in the tissues is not correlated with pain scores after repair has indirectly been confirmed in studies comparing different techniques of repair. These studies conclude that non-mesh repairs had more recurrences compared to mesh repairs but there was no difference in the number of patients complaining of long-term pain [12, 13, 29, 60, 70].

Minimal dissection has been proposed to cause less pain and quicker recovery as in the plug and patch repair [71]. These data have not been confirmed in a study by Callesen et al where ligation of the hernial sac alone or combined with annulorrhaphy was compared to the Liechtenstein technique [62]. In this study, there was no difference

between the groups in recorded pain scores for rest, cough and mobilisation. Still other studies have achieved the same pain scores when comparing the Prolene® Hernia System, Lichtenstein technique and PerFix Plug® [31, 72]. These data agree with the findings in paper IV where no differences can be seen in postoperative pain between different anterior techniques. Choosing a different anterior technique does not influence the development of chronic pain. However, in a study by Kingsnorth and colleagues the PerFix Plug® was associated with more pain than the Lichtenstein procedure at a 1 year follow-up [73].

Biomechanical aspects of meshes

If we exclude technical failures such as suture break and knot slip as the reason for a recurrence of a hernia after repair it leaves us with tissue break as the cause. Recent studies imply deficient collagen formation as one of the important causes in the development of a hernia [74]. This finding is an important argument for implanting foreign material to enhance the tissues in the repair procedures.

The majority of meshes used for hernia surgery today contain polypropylene. Polypropylene induces a chronic inflammation and enhances scar tissue formation as can be seen in experimental animal studies as well as in studies of meshes explanted for complication [75, 76]. A persistent foreign body reaction can still be detected even 15 years after insertion as seen in a study by Klosterhalfen and colleagues implying that mesh is not inert with respect to the local inflammatory processes [76]. The chronic inflammation induced is proportional to the amount of foreign body deposited. Reducing the amount of implanted material and increasing the pore size leads to a better tissue integration of the mesh but does not alter the resistance to biomechanical pressure in a clinically important way [75, 76].

Implanted meshes shrink and fold as a consequence of the induced inflammatory response and scarring. In animal experiments using standard heavyweight mesh the reduction showed to be 25% in horizontal and vertical directions resulting in shrinkage of 46% of the original mesh area. When using lightweight meshes containing less than one-third of the polypropylene as compared to the heavyweight, the shrinkage was reduced to 34% of the original size [77].

Implanted prosthesis has in experimental animal studies shown to have the potential of inducing soft tissue sarcomas. One of the polymers evaluated in an expert meeting on the carcinogenic risk of implants was polypropylene, which is the most frequently used material in hernia implants. There was sufficient evidence of sarcoma induction in animal studies [78]. In a recently performed animal study by Witherspoon with implanted mesh in mice for up to two years observation time, these results could not be reproduced [79]. In clinical practice soft tissue sarcomas in the groin are rarely seen and the connection to implanted mesh seems unlikely, but more studies should be performed.

Lightweight or heavyweight mesh

The findings that the inflammation and shrinkage is proportional to the amount of polypropylene deposited in the tissues raise the question as to whether a mesh with less polypropylene could give a more favourable result in terms of long-term pain and patient discomfort. This has been studied in several randomised trials [80-82]. Patients having received a lightweight mesh had less pain on exercise and improved quality of life on follow-up up to 4 years after surgery compared to those having a heavyweight mesh. Further, the patients with a lightweight mesh had fewer complaints of foreign body sensation and stiffness in the groin. There was no increase in recurrences except in one of the studies were there were more recurrences in the lightweight group. These recurrences came from a single centre of the five involved in that study and on closer examination it appeared to be related to inferior suture bites of the lightweight mesh [81].

POSTOPERATIVE INFECTION

It remains uncertain if antibiotic prophylaxis can reduce the incidence of postoperative infections in groin hernia repair. Data from the NHR does not support its use [3]. Infection, studied in animal experiments, impairs tissue integration of the mesh and leads to more recurrences as also has been seen in clinical studies [83, 84]. In a recent systematic review of randomised trials, antibiotic prophylaxis did not prevent postoperative infections [85]. There are no studies addressing the long-term effects after superficial infections but mesh removal for deep infection causes more recurrences but does not seem to induce chronic pain [86].

THE FUTURE

There are sufficient data to conclude that long-term post herniorrhaphy pain is quantitatively a larger problem than recurrences and affects around one-third of the patients having an operation. One of the problems of getting comparable outcomes from different studies is that there is no uniform way in which pain is defined or measured during the studies. Agreement on a uniform assessment protocol is therefore needed.

The causes of pain after inguinal hernia surgery are unknown. Tension, the method of anterior repair, the use of mesh or even nerve division does not seem to influence the development of post repair pain. Significantly less pain is seen in posterior approach procedures compared to anterior approach. As for anterior procedures, it can be the dissection to free and reduce the hernia with manipulation of the tissues that induces pain, but the different techniques of anterior repair are less important. More research is needed to find out the mechanism and causes of postoperative pain in these patients.

The development of new prosthetic materials is ongoing with lightweight and titanium coated meshes as some of the latest inventions. The data seem promising and suggest that results will improve, but these materials will probably not eradicate the problem with post repair pain since this still occurs in patients having minimal procedures such as Marcy's annulorrhaphy. Perhaps a whole new approach to hernia repair has to be adopted. The culturing and expansion of the patients own collagen looks promising and could be the answer; it remains to be seen though if it can be implanted in a non-operative procedure [87].

The potential carcinogenic property of the prosthesis used in hernia surgery has not been an evident problem in clinical practice. Further research is needed. One way to go about this would be to link the Swedish and Danish hernia registries to their corresponding national cancer registers. This would probably give the answer as to weather patients having a hernia repair with mesh are overrepresented with soft tissue sarcomas. One problem might be that the observation period is too short since the Swedish Hernia Register was started in 1992 and therefore has to short exposure time for potential tumours to develop.

Although a significant proportion of patients are found to suffer from short-term complications and on follow-up have more or less debilitating pain. The surgeon gets the impression that the patient is somewhat happy with the procedure anyway and finds the current condition better than the preoperative state. Local and national hernia registers should in the future include information on patient satisfaction: is the patient satisfied with the outcome? Would he or she do it again and would they recommend the procedure to someone else? I would like to see that outcome in future trials apart from regression analysis, chi-2 tests, quality of life short forms and numeric or verbal pain rating scales.

CONCLUSIONS

- The concordance between the patients' and doctors' perception of complications following a hernia repair in a structured follow-up is poor. Patients and doctors have different views as to what constitutes a complication. The doctor has more knowledge of what to expect in the postoperative period, but the patient is the only one who has the full experience of symptoms and events. Neither view can be regarded as more important. The doctors' and patients' views together complete the picture of postoperative complications.

- The most common short-term complications following inguinal hernia repair are haematoma, severe pain and infection. When passively recording complications without a structured follow-up 6% of the patients are recorded as having any form of complication. When using active follow-up with a questionnaire almost 24% of the patients state an adverse event. A questionnaire provides valuable information in the quality assurance of the care provided.

- The novel Inguinal Pain Questionnaire (IPQ) is developed for the use of a uniform assessment of postoperative pain after inguinal hernia surgery. The validity and reliability are sufficient for routine clinical use.

- Long-term pain affects nearly one third of the patients being subject to an inguinal hernia repair. Most of them have mild pain, but in 6% of the patients it affects the activities of daily living. The risk-factors for acquiring long-term pain are low age, a high level of pain before the operation, the occurrence of any form of complication and a repair technique with an anterior approach.

SAMMANFATTNING PÅ SVENSKA (SUMMARY IN SWEDISH)

Inledning

I Sverige finns sedan 1992 ett nationellt kvalitetsregister för operationer av ljumskbråck, Svenska Bråckregistret (SBR). Där finns patientdata som kön, ålder, BMI och tidigare operationer samt operationsdata som operationstid, storlek på bråckdefekt, sutur- och materialval och registrerade 30-dagars komplikationer inmatade för ca 120 000 operationer. Detta register täcker ca 90 % av de opererande klinikerna i Sverige. Registret som stöds av Socialstyrelsen och Sveriges Kommuner och Landsting är personnummerbaserat vilket innebär att patienterna kan följas i tiden oavsett vid vilket sjukhus operationer sker för nya bråck samt att de kan följas i olika befolkningsregister. Registret kvalitets kontrolleras fortlöpande. Vi har via bråckregistret fått tillgång till data för år 2000 och 2002. Avhandlingen bygger på följande arbeten:

Arbete 1: *U. Fränneby, U. Gunnarsson, S. Wollert, G. Sandblom: Discordance between the patient's and surgeon's perception of complications following hernia surgery. Hernia (2005) 9: 145-149.*

Bakgrund: Studien genomfördes för att bedöma samstämmigheten mellan läkare och patient om deras uppfattning av vad som är en komplikation efter operation av ljumskbråck.
Metod: På Samariterhemmet, Uppsala erhöll 206 patienter 4 veckor efter operation av ljumskbråck ett frågeformulär om komplikationer som inträffat inom de första 30 dagarna efter operationen samt fick tid för en läkarkontroll. Läkaren fyllde i samma formulär om komplikationer som patienten, men fick inte veta vad patienten hade svarat.
Resultat: 174 (84,5 %, 161 män, 13 kvinnor) patienter fullföljde enkät och återbesök. I enkäten registrerades 190 komplikationer mot 131 vid läkarundersökning. Kappavärden för samstämmighet varierade från 0,11 för urinvägssymptom till 0,55 för obstipation.
Konklusion: Samstämmigheten är dålig mellan patient och läkare om vad de uppfattar som postoperativ komplikation. Läkaren kan ha en bättre uppfattning om vad som förväntas vara normalt postoperativt förlopp och hur komplikationer ska kategoriseras medan patienten äger upplevelsen av sina symptom. Varken läkarens eller patientens uppfattning kan tas som norm för vad som ska bedömas vara en komplikation. Bådas uppfattning kompletterar bilden av postoperativa komplikationer och besvär.

Arbete 2: *U. Fränneby, G. Sandblom, O. Nyrén, P. Nordin, U. Gunnarsson. Self-reported adverse events after groin hernia repair, a population-based register study. Inskickat i till British Journal of Surgery.*

Bakgrund: Många kliniker har ingen strukturerad uppföljning efter operation av ljumskbråck och en stor del av komplikationerna kan förbli okända för den opererande kliniken. Detta leder till brister i kvalitetssäkringsarbetet. I denna studie undersöktes frekvens, typ av och riskfaktorer för komplikation inom den första postoperativa månaden med hjälp av enkät.
Metod: Under 2003 skickades samma enkät som i delarbete 1 ut till de 1643 patienter som fanns registrerade i Svenska Bråckregistret (SBR) under november-december 2002. Svar från enkäten kopplas till data i SBR.
Resultat: Svar erhölls från 1448 (88,1 %) patienter varav 1341 (92,6%) var män och 107 (7,4 %) kvinnor. Medelåldern var 59 år. Vanligaste postoperativa komplikationerna var blödning hos 203 (14,0 %) patienter, svår smärta hos 168 (11,6 %), testikelsmärta hos 120 (8,3 %) och infektion hos 105 (7,3 %) patienter. Riskfaktorer för att få en komplikation var ålder under median 59 år och laparaskopisk operation (titthålsoperation). Utan formulär hade endast 25 % av komplikationerna registrerats.
*Konklusio*n: Vanligaste komplikationerna efter ljumskbråcksoperation var hematom, svår smärta i operationsområdet, testikelsmärta samt infektion Riskfaktorer för att utveckla komplikation var ålder under median 59 år och laparaskopisk operation. Enkätuppföljning ökar klinikernas kännedom om komplikationer och förbättrar kvalitetsarbetet.

Arbete 3: *U. Fränneby, G. Sandblom, M. Andersson, R. Heuman, P. Nordin, O. Nyrén, U. Gunnarsson: Validation of the Inguinal Pain Questionnaire; a novel instrument for assessment of chronic pain after hernia surgery. Inskickat till Quality of Life Assurance.*

Bakgrund: Kronisk smärta efter operation av ljumskbråck är ett viktigt problemområde men det saknas ett bra instrument för att utvärdera detta. Vi har utvecklat ett formulär, Inguinal Pain Questionnaire (IPQ) med 18 frågor för att utvärdera dessa smärtor. I denna studie valideras (kvalitetssäkras) detta f.
Metod: I valideringsgruppen (grupp A) erhöll 100 patienter IPQ samt det validerade formuläret Brief Pain Inventory (BPI) en och fyra veckor efter operation. I reliabilitetstestet (grupp B) erhöll 100 patienter IPQ i 2 omgångar, 3 år efter operation med 1 månads intervall. I grupp C med 2853 patienter validerades den icke-kirurgiska smärtan genom att patienten jämför smärtintensitet mellan den opererade och icke opererade ljumsken.
Resultat: En signifikant ($p<0,001$) minskning av IPQ relaterad smärta sågs under de 4 första veckorna efter operation. Det var en signifikant ($p<0.05$) överensstämmelse med BPI i frågor rörande smärtintensitet vilket tas som intäkt för criterion validity. Logiska fel översteg inte 5,5% för någon fråga. Kappavärden i test-retst situationen i grupp B var högre än 0,5 för alla frågor utom 3. Cronbachs alfa var 0,83 för frågor om smärtintensitet och 0,74 för frågor om dagliga aktiviteter.
Konklusion: Validiteten och reliabiliteten är tillräckligt god för rutinmässigt kliniskt bruk.

Arbete 4: *U. Fränneby, G. Sandblom, P. Nordin, O. Nyrén, U. Gunnarsson: Risk factors for long-term pain after hernia surgery. Accepterat 2006-02-22 Annals of Surgery*:

Bakgrund: Kronisk smärta efter operation av ljumskbråck är vanligare än recidiv men få större populationsbaserade studier är utförda. Syftet med studien är att kartlägga förekomsten av kronisk smärta och eventuell funktionsinskränkning 2-3 år efter operation av ljumskbråck samt att identifiera riskfaktorer för dess uppkomst.
Metod: Frågeformuläret för kronisk smärta efter operation av ljumskbråck, The Inguinal Pain Questionnaire (IPQ), där smärtintensitet och inverkan på dagliga aktiviteter penetreras i 18 frågor och tar ca 10 minuter att fylla i användes. Formuläret sändes år 2003 till 2853 patienter av de 9280 som fanns registrerade i SBR år 2000. Svaren i formulären kopplades till operationsdata i SBR.
Resultat: Svarsfrekvensen blev 2456 (86 %, 2299 män, 157 kvinnor). 758 (31 %) av patienterna angav någon form av smärta. Hos 144 (6 %) gav smärtan funktionshinder. Riskfaktorer för att utveckla kronisk smärta var ålder under median 58,2 år, hög preoperativ smärtnivå samt postoperativa komplikationer. I multivariat logistisk analys uppvisade operationsmetoder via bakre reparation som laparaskopi mindre risk för kronisk smärta än operation via ljumsksnitt.
Konklusion: Funktionsinskränkande smärta förekommer i högre grad än recidiv av nytt bråck efter operation. Postoperativa komplikationer ökar risken för långvarig smärta. Vad gäller operationsteknik rekommenderar vi ytterligare studier.

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