Mortality and Morbidity after groin hernia surgery

- the role of nationwide registers in finding and analysing rare outcomes

Hanna Nilsson
“Nothing so prevents the occurrence of complications as one’s awareness and fear of them”

Robert Bendavid, 1998
ABSTRACT

Introduction: Groin hernia surgery is one of the most common surgical procedures world-wide. Although mainly uncomplicated, the large volume of these operations makes it important to consider severe postoperative complications. The Swedish Hernia Register (SHR) started in 1992 and has grown to include more than 95% of all groin hernia operations performed in Sweden empowering it to be merged with other registers in population-based studies. The aim of this thesis is to merge SHR with other nation-wide registers to analyse postoperative mortality, cardiovascular morbidity, surgical hazards, as well as to study the influence of prostatectomy upon the risk for subsequent groin hernia surgery.

Methods: SHR was interlinked with the Cause of Death Register to find standardised mortality ratio, the National Prostate Cancer Register to find incidence of groin hernia surgery after prostatectomy compared to a control group and with the National Patient Register to find morbidity within 30 days of groin hernia surgery. In paper II, medical records of deceased patients were retrieved and scrutinised.

Results: Elective groin hernia surgery was found to be a low risk procedure even for elderly patients. The mortality risk within 30 days of emergency surgery was raised sevenfold compared to that of the background population. Women had a threefold increased risk of postoperative mortality compared to men. Patients with bowel obstruction, not examined for groin hernia in the emergency room, were subject to more radiological examinations and were operated significantly later than patients with a clinical diagnosis of groin hernia. Compared to men, significantly fewer women were examined for groin hernia in the emergency ward, 61% vs. 78%, (P=0.04). High age, co-morbidity, emergency operation, and regional anaesthesia were risk factors for cardiovascular events. Compared to open anterior mesh repair, all other methods were associated with increased risk of surgical complication, intraoperatively or postoperatively. A threefold increase in groin hernia surgery was seen after radical prostatectomy, conventional as well as minimally invasive.

Discussion: Women are significantly overrepresented concerning mortality after groin hernia surgery. This thesis shows the importance of nation-based registers in the analysis of infrequent phenomena in surgical care.

Keywords: Groin hernia, Inguinal Hernia, Femoral Hernia, Mortality, Morbidity, Prostatectomy

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List of papers included

This thesis is based upon the following papers that will be referred to by their roman numerals in the text:

I  Nilsson H, Stylianidis G, Haapamaki M, Nilsson E, Nordin P.
    Mortality after groin hernia surgery.

II Nilsson H, Nilsson E, Angeras U, Nordin P.
    Mortality after groin hernia surgery: delay of treatment and cause of death.

III Nilsson H, Stranne J, Stattin P, Nordin P.
    Incidence of Groin Hernia Repair After Radical Prostatectomy
    A Population-Based Nationwide Study.

IV Nilsson H, Sandblom G, Angerås U, Nordin P.
    Serious adverse events within 30 days of groin hernia surgery
    Manuscript
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<td>EHS</td>
<td>European Hernia Society</td>
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<tr>
<td>HR</td>
<td>Hazards Ratio</td>
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<td>HRT</td>
<td>Hormone Replacement Theory</td>
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<td>ICD</td>
<td>International Classifications of Diseases</td>
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<td>IH</td>
<td>Inguinal Hernia</td>
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<td>MIRP</td>
<td>Minimally Invasive Radical Prostatectomy</td>
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<td>NPCR</td>
<td>National Prostate Cancer Register</td>
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<td>NPR</td>
<td>Swedish National Patient Register</td>
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<td>OR</td>
<td>Odds Ratio</td>
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<td>PCa</td>
<td>Prostate Cancer</td>
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<td>PCBaSe</td>
<td>Prostate Cancer Base Sweden</td>
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<td>PPV</td>
<td>Patent Processus Vaginalis</td>
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<td>RCT</td>
<td>Randomised Controlled Trials</td>
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<td>RRP</td>
<td>Radical Retropubic Prostatectomy</td>
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<td>RT</td>
<td>Radiation Therapy</td>
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<td>SHR</td>
<td>Swedish Hernia Register</td>
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<td>SMR</td>
<td>Standardised Mortality Ratio</td>
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<td>ASIS</td>
<td>Anterior Superior Iliac Spine</td>
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<td>TAPP</td>
<td>Trans-Abdominal PrePeritoneal laparoscopic repair</td>
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<tr>
<td>TEP</td>
<td>Totally ExtraPeritoneal laparoscopic repair</td>
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<tr>
<td>TIPP</td>
<td>Trans-Inguinal PrePeritoneal repair</td>
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Definitions in short

**Reducible hernia**  
A hernia that reduces into the abdominal cavity when lying down or when massaged if standing.¹

**Incarcerated hernia**  
A hernia that cannot be reduced into the abdominal cavity with manual pressure.

**Strangulated hernia**  
A hernia with impairment or absence of blood supply to the content of the hernia sac.

**Sliding hernia**  
A hernia containing a retroperitoneal organ, with or without its mesentery,² and where the abdominal viscus forms part of the hernial sac.³
**Introduction**

Groin hernia is a common disorder and its repair one of the most frequently performed surgical procedures in the western world. The lifetime prevalence of groin hernia *repair* has been estimated to be 27% in men and 3% in women.⁴ More than 20 million hernia operations are performed each year around the globe.⁵ Some 16 000 operations on patients above the age of 15 years are registered annually in the Swedish Hernia Register (SHR).⁶ Changes in groin hernia surgery over the last century have led to improved results with low recurrence rates, and an increased concern for patient satisfaction.⁷,⁸ The magnitude of repair makes groin hernia surgery an important area of research, not only for the patient and his clinician, but also for all authorities responsible for health economy and allocation of ever-dwindling resources. Although often considered a minor procedure performed as day-case surgery, serious events do occur after groin hernia surgery, and registers play an important role in finding and analysing events that are too rare to be identified by randomised controlled trials (RCT). The aim of this thesis is to analyse serious events after groin hernia surgery, and the risk for groin hernia operation after radical prostatectomy, using data from large nationwide registers.

**History, definition and prevalence of groin hernia**

The word “hernia” descends from the Greek meaning “bud or shoot”.⁹ In medical anatomy it is used to describe an abnormal protrusion of an organ through a weakness in the wall of the cavity that normally withholds it.¹⁰ Groin hernia specifically occurs when an intra-abdominal organ or peritoneum protrudes through a weakness in the abdominal wall in the area above or below the inguinal ligament, giving rise to an inguinal or a femoral hernia. Manuscripts from the ancient cultures of Mesopotamia and Egypt¹¹ bear witness of groin hernia, ensuring us that the disorder is as old as mankind itself, but exactly how common groin hernia is in men and women is an area that remains unknown. Even today, the most cited hernia prevalence study was performed in Jerusalem in the 1970s, where Abramson
et al. found a lifetime prevalence rate of 48% in men aged 75 years and older.12

**Symptoms and indication for surgery**

The symptoms of groin hernia vary from symptom-free to discomfort or pain. If not operated, groin hernias can enlarge in size and cause mechanical and hygienic hindrance, and in a worst case scenario, acute incarceration. In countries with unmet demands for surgery, untreated groin hernias are often associated with significant psychosocial stigmas,13 morbidity and even mortality,14 and they also affect young individuals who are often the most productive members of society.15,16

Surgery is the only cure for groin hernia and the aim of an operation is to reduce symptoms and to prevent an acute complication such as incarceration, strangulation or intestinal obstruction. A truss is less of an option in today’s management of groin hernia.17 Watchful waiting is an acceptable short-term alternative,18,19 but in the long run patients tend to be operated upon because of the development of symptoms.20,21 Elderly patients should be considered for operation since elective groin hernia surgery has been shown to be a low-risk procedure even in elderly patients with known co-morbidity.22-24 Quality of life, in terms of physical functioning and pain, improved significantly after repair also in elderly.25 Groin hernia surgery is associated with complications such as chronic pain, infection, seroma, but also with intraoperative surgical or cardiovascular complications, and patients should be adequately informed before entering the surgical theatre.

A patient with acute symptoms of incarcerated or strangulated hernia should be operated on immediately since it is hard to differentiate between strangulated and incarcerated groin hernia.26,27 Incarcerated and even strangulated hernias are overlooked on the emergency ward because of inadequate or lack of physical examination even though the patient has symptoms consistent with bowel obstruction.28 For example, Hjaltson29 discovered that 13% (6/46) of emergency femoral hernias were found during laparotomy initiated because of bowel obstruction. He also noticed that half of patients treated for acute hernia were without inguinal pain but complained of diffuse symptoms related to bowel obstruction. Whereas adhesions are the most common cause of small bowel obstruction, groin hernia is the most
common cause of strangulation in patients with small bowel obstruction.\textsuperscript{30}

Bowel obstruction due to adhesions may resolve spontaneously, but strangulation will not. Intestinal obstruction\textsuperscript{31} and necrosis followed by resection are associated with high morbidity and mortality,\textsuperscript{32,33} and hence all signs of bowel obstruction must lead to a physical examination for inguinal/femoral hernia.

\textbf{Figure 1.} The importance of examining the patient and to fold aside the blanket while doing so has to be emphasised. Femoral hernias are found below the inguinal ligament and can be hard to find if not looked for systematically and thoroughly. Illustration by Anna Erlandsson.
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In Sweden and in England approximately 5% of all groin hernias are operated on as an emergency cases associated with significantly increased morbidity. However, only a fraction of these patients undergo concomitant bowel resection because of strangulation. The risk for strangulation is low in inguinal hernia. Gallegos et al. estimated the cumulative probability of strangulation to be 2.8% for inguinal hernia in the first 3 months after onset of symptoms. Femoral hernias, however, are over-represented in emergency surgery with and without bowel resection, and have been shown to have a high tendency to incarcerate and strangulate with subsequently increased morbidity. For that reason femoral hernias are usually considered for surgery even though symptoms are mild or absent. However, as with inguinal hernia it is not clear whether prophylactic elective surgery prevents emergency surgery, since it has been shown that 53% of all patients operated acutely for femoral hernia were unaware of their hernia prior to operation.

Gender differences

The prevalence of groin hernia, and hernia anatomy differ between genders. The inguinal canal is created prenatally when the testicles in men and the round ligaments in women descend from their intra-abdominal origins to the scrotum/labia majora. Prevalence of inguinal hernia surgery has two peaks, one in early childhood and one in old age, and this applies to both genders. Congenital hernias in small children are indirect; caused by a failure of the peritoneal sac, the processus vaginalis, to obliterate resulting in a patent processus vaginalis (PPV). Child hernias are successfully repaired by simple high ligation of the hernia sac, an operation associated with a high recurrence rate in male adults. Hence, even though anatomically identical, they are considered separately from the adult groin hernia and are not further discussed in this thesis. More than 92% of all groin hernias reported in the SHR are performed on men, and inguinal hernia is 13 times as common in men than in women. However, the incidence of femoral hernia has a female predominance of 1.8:1. This means that femoral hernia comprises more than 20% of groin hernias in women compared to less than 2% in men. In contrast to inguinal hernia, femoral hernia is rare in children, and the prevalence increases with age.
**Groin anatomy**

The abdominal wall, consisting of muscles, their aponeuroses and fascias, maintain the integrity of the abdominal cavity. At the point where the spermatic cord and femoral vessels leave the abdominal cavity in the groin, a weakened area is created often referred to as the myopectineal orifice of Fruchaud. It is quadrangular in shape and can be divided into three triangles; lateral, medial and femoral. Direct hernias protrude through the medial triangle, (Hesselbacks Triangle) bordered laterally by the inferior epigastric vessels, medially by the rectus muscle, and inferiorly by the inguinal ligament. Indirect hernias are located above the inguinal ligament and lateral to the inferior epigastric vessels. Femoral hernias protrude in the femoral canal that is 1-2 cm long and located below the inguinal ligament. Studies have shown that even for experienced examiners/surgeons, it is not possible to differentiate between an indirect and a direct inguinal hernia by physical examination alone and it may even be difficult to distinguish between a femoral and an inguinal hernia.

The following three muscles are components of the abdominal wall and important for the hernia surgeon. The **external oblique muscle** arises from the lowest ribs. Caudally, its aponeurosis is condensed to the inguinal ligament, passing from the anterior superior iliac spine (ASIS) to the pubic tubercle. An opening in the aponeurosis just above the pubic tubercle creates the triangular external inguinal ring through which the spermatic cord and the round ligament run.

The **internal oblique muscle** arises from the lateral half of the inguinal ligament and extends upwards medially. In the inguinal canal, the spermatic cord passes adjacent or medial to this muscle, and the cord is coated with muscle strips, the cremaster muscle, when passing alongside.
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Figure 2. Groin anatomy frontal view. The three potential groin hernia sites are illustrated in relation to the inguinal ligament and inferior epigastric vessels. Illustration by Anna Erlandsson.

The transverse abdominal muscle consists of more aponeurosis and much less muscle than the two muscles mentioned above. The lower border of the transverse abdominal aponeurosis is called “the arch.” Immediately deep to the transverse abdominal muscle lies the transversalis fascia. Some authors mean that the posterior wall below the arch consists of the transversalis fascia alone creating, a weak area where direct herniation can occur. Others mean that the posterior wall in all humans is made up of the aponeuroses of the internal oblique muscle, the transverse abdominal muscle, and transversalis fascia, although it varies in strength between individuals.

The internal ring of the inguinal canal has a shuttle mechanism first described by Lytle in 1945. The U-shaped medial margin of the ring has two limbs extending superiorly and laterally, attached to the transverse muscle. Any increase in intra-abdominal pressure pushes the covering
peritoneum forward to press the valvular ring more securely around the cord. Also when coughing the columns of the ring are pulled together and the U is drawn upward, and laterally, hence “closing” the exit.56

Several attempts to classify groin hernia more precisely have been made including a unified effort of the European Hernia Society (EHS)61-63 without reaching a widely used consensus. In this thesis the classification is simple: femoral, direct and indirect inguinal hernia.

**Anatomy and prostatectomy**

In 1996 Reagan et al64 published the first report indicating that the incidence of groin hernia increased after Radical Retropubic Prostatectomy (RRP). Since then a number of studies have confirmed an increased incidence of groin hernia after prostatectomy compared to various control groups.65,66 Reported incidence rates vary from 6.7%-38.7%67 and variations might be attributed to differences in observation time and methods used for identifying groin hernia. Two large studies in Canada68,69 analysed incidence of groin hernia repair after prostatectomy compared to patients receiving Radiation Therapy (RT) or operated for other urologic diseases. They found that also groin hernia repair increased significantly after prostatectomy, however they could not differentiate between influence of open prostatectomy and minimally invasive prostatectomy (MIRP). As mentioned earlier information of incidence of groin hernia in the population, for men and women, is scarce making it hard to interpret the reported incidence after prostatectomy.

The reasons for increased risk of hernia formation indicated in the above studies are unknown. Stranne et al70 have argued for that it is the midline incision that disrupts and destroy the transversalis fascia, important for the integrity of the myopectinal orifice of Fruchaud. Others have noted an association between postoperative anastomotic stenosis71 and theorised that an increase in intra-abdominal pressure, may cause hernia formation, in a patent processus vaginalis. Fischer and Wants points out that the retractor in RRP is placed near the area of the internal ring where it “deleteriously stretches, strains, and deforms the groin”.72 The first and last arguments would be in favor of MIRP where incisions and retractors are placed differently. Some studies73 indicate that this is the case but further studies are warranted.
Methods of repair

Modern methods of groin hernia repair focus on reconstructing or strengthening the posterior wall of the inguinal canal. Until the mid 20th century this was mainly achieved by sutured repairs such as the Bassini or later on, the Shouldice repair.

Open anterior repair

Eduardo Bassini, one of the most astonishing men in groin hernia history, was born in 1844. After graduation in medicine at the age of 22, his postgraduate training was with Billroth in Vienna, Langenbeck in Berlin, Nussbaum in Munich and Lister in London. His interest in the inguinal region is said to have come from a bayonet injury where he consequently developed a faecal fistula in the right groin. This interest resulted in a new surgical technique for groin hernias, and the method of Bassini first reported in the 1890s was depicted step by step by Bassini’s pupil, Professor Catterina, in an atlas named “The operation of Bassini.” It is not merely his operative technique that made him into a master, but also the antiseptic methods applied that included depilation, followed by cleansing of the patient’s body with antiseptic solution. Intra-operatively he tested the repair by lightening the anaesthetic of the patient who subsequently woke up and vomited. Furthermore, a low infection rate of 4%, early ambulation, no truss, and an extensive follow-up of 262 patients with a 2.7% recurrence rate gives witness to the most thorough and knowledgeable of surgeons, even by today’s standards. An essential part of his operation is the division of the cremaster muscle and transversalis fascia, providing the surgeon with complete insight of the internal opening and inspection of all potential hernia sites. Reconstruction of the posterior wall is then accomplished by suturing the threefold layer (internal oblique muscle, transverse abdominal muscle and transversalis fascia) with single non-absorbable sutures to the inguinal ligament.
Figure 3. Eduardo Bassini, 1844-1924, was an exceptional surgeon with recurrence rate comparable of today. Preparations started the day before surgery where an assistant overlooked by Bassini himself, shaved the patients’ whole body, apart from facial hair. Then the bodies were cleansed with antiseptic solution and finally covered by linen drenched in the same. When Bassini left the room a nurse stayed to make sure that the patients did not move. Illustration by Anna Erlandsson

The reinforcement of the posterior wall of the inguinal canal made it possible to cure inguinal hernias, but it was inadequate for femoral hernias. In a modification known as the Mc Vay repair, the internal oblique and transverse abdominal muscles are attached to Cooper's ligament, thereby narrowing or closing the femoral canal. This is made possible through a relaxing incision in the anterior rectus sheath whereby the various components of the abdominal wall are displaced laterally and inferiorly.
Earl Shouldice, in Toronto, also stressed that all potential hernia sites must be assessed and repaired if necessary. A missed hernia was frowned upon as a cardinal mistake. Like Bassini he emphasised the importance of the transversalis fascia in reconstructing the posterior wall of the inguinal canal. Shouldice repaired the posterior wall with four layers and a running steel-wire suture. Later Kux et al. showed equally good results using a modification with a two-layer technique. Apart from using steel-wire and suturing four separate layers, the similarities between the Bassini and the Shouldice repair are evident.

Unique for the reports describing the two techniques is the thorough follow-up of patients. More than a century before the SHR, Bassini reported a 2.7% (7/262) recurrence rate in a four-year follow-up. In 1953 Shouldice presented a 0.8% recurrence rate after ten years that has stayed below 1% in the hands of the surgeons at the Shouldice Clinic. This technique, reproducible by other surgeons, suggests the Shouldice repair to be the “gold standard” of sutured repair.

**The tension-free hernioplasty**

The use of synthetic mesh in groin hernia markedly reduces the risk for hernia recurrence regardless of placement method, compared to sutured repair. Already in the late 50’s after careful in vitro studies, Usher showed how to use polypropylene monofilament mesh in groin hernia surgery to avoid tension in the tissue. However, it was not until 1986 when Irving Lichtenstein published a report of a tension-free hernioplasty, that the mesh technique was used in a larger scale. Under local anaesthesia, a floppy net was inserted, covering the defect in the transversalis fascia thereby reconstructing the posterior wall of the inguinal canal without tension. Lichtenstein questioned why one should strive to “reconstruct normal anatomy when the mere presence of a hernia has already attested to the deficiency” of the inguinal floor. The repair known as Lichtenstein repair was a giant leap forward towards a lower recurrence rate. In 2005, it was the preferred method in high income countries where 96% of British, 99% of Japanese and 86% of American surgeons practiced it. In Sweden hernia surgery changed dramatically - from a majority of repair performed as sutured repair in 1992 to a majority of repair performed as Lichtenstein repair four years later (Figure 4). A similar trend was reported in other countries.
such as Denmark\textsuperscript{5} and the Netherlands.\textsuperscript{93} Today the Lichtenstein repair represents more than 70\% of groin hernia repair in Sweden\textsuperscript{6} and has the best results in the hands of Swedish surgeons regarding reoperation rate.\textsuperscript{94} Modifications concerning the anchoring of the mesh with glue or self-fixating mesh have yielded similar results in terms of postoperative pain\textsuperscript{95} and recurrence rate.\textsuperscript{96} Lightweight mesh has better results than heavyweight in terms of postoperative pain, with similar recurrence rates,\textsuperscript{97} and in fact, even sterilised mosquito-net can be used with excellent results\textsuperscript{98,99} in safe\textsuperscript{100} hernia surgery. Plug repairs, with equally low recurrence rates, have been associated with complications (especially pain) maybe because of its three-dimensional shape.\textsuperscript{101}

**Methods of repair in men, 1992-2012**

![Graph showing methods of repair in men, 1992-2012. Dramatic changes occurred during the 1990’s when Lichtenstein repair was introduced.](image-url)

*Figure 4. Choice of operative technique in 219 047 repair registered in men, 1992-2012. Dramatic changes occurred during the 1990’s when Lichtenstein repair was introduced.*
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**Preperitoneal repair**

In the groin region, behind the transversalis fascia and anterior to the peritoneum and the abdominal cavity, lies the preperitoneal space often referred to as the space of Bogros. Many surgeons have been involved in the continuous refinement of the preperitoneal technique. In the 1920s Cheatle entered the space of Bogros via a midline incision. Stoppa described his giant (bilateral) prosthetic reinforcement of the visceral sac (GPRVS) covering all hernia sites. Read, placed the mesh preperitoneally via an inguinal incision, nowadays referred to as the Trans-Inguinal Pre-Peritoneal technique, (TIPP). Nyhus popularised this technique by using a unilateral paramedian incision, initially by suturing the transverse muscle to the iliopubic tract and later by using mesh for reconstruction of the posterior wall of the inguinal canal. Today, the posterior approach (endoscopic or open) has been recommended for women and in recurrent hernia surgery where the primary operation has been performed with an anterior approach.

There are three important advantages with the preperitoneal approach: it avoids the distortion of the inguinal canal leaving intact nerves and testicular blood supply; it permits inspection and potential cure for all hernia sites in the groin; and if performed as open surgery it allows for easy access to the abdominal cavity if necessary.

**Laparoscopic repair**

The first laparoscopic hernia repair was reported in 1982 and the technique introduced a “novel” view of the well-known preperitoneal space where the myopectineal orifice is easily visualised and covered with a mesh, a potential solution for all hernia sites. In the Trans-Abdominal Pre-Peritoneal approach (TAPP) the pre-peritoneal space is reached via the abdomen where the peritoneum is incised and folded aside during the operation. In the Totally Extra-Peritoneal approach (TEP) the preperitoneal space is reached directly without entering the abdominal cavity, thereby minimising the risk for abdominal visceral complications. According to some studies laparoscopic and open repairs result in similar recurrence rates whereas others show a higher recurrence rate after laparoscopic surgery compared to Lichtenstein. A meta-analysis performed by O’Reilly et al.
found a significant increase in the risk for recurrence with the TEP compared to the open technique, whereas the TAPP was equivalent to open mesh repair regarding recurrence, but had a higher perioperative morbidity rate. The laparoscopic technique requires general anesthesia for most patients, which is a disadvantage, but it is easily performed as day-case surgery. Compared to Lichtenstein, the laparoscopic technique has higher long-term costs\textsuperscript{114,115} and a longer learning curve\textsuperscript{116,117} whereas, chronic pain after five years is higher for the open technique, albeit low for both.\textsuperscript{118} If the technique is available, EHS guidelines\textsuperscript{17} recommend it for bilateral hernia, for recurrent surgery when the primary operation has been performed with an anterior approach, and for women.

**Method of operation in women, 1992-2012**

![Graph showing trend of operative technique in women, 1992-2012](image)

*Figure 5. Trend of operative technique in 19,239 repair registered in women in SHR, 1992-2012. As in men Lichtenstein technique increased in mid 1990s but has since dropped in number in favor of preperitoneal technique.*
**Methods of anaesthesia**

Groin hernia surgery can be performed using the three principal forms of anaesthesia.

1. General anaesthesia
2. Regional anaesthesia
3. Local anaesthesia

**Method of anaesthesia registered in SHR, 1992-2012**

![Graph showing the percentage of different types of anaesthesia used from 1992 to 2012.](image)

*Figure 6. Method of anesthesia in men registered in SHR, 1992-2012. The use of spinal or regional anaesthesia has decreased markedly below 10% while use of local anaesthesia increased during the 1990’s. However, local anaesthesia is not used for more than 20% of operations registered.*

Local anaesthesia has been used at the Shouldice clinic in 95% of patients for more than 50 years.\textsuperscript{83,119} Lichtenstein also used local anaesthesia for tension-free repair, and tried to explode the myth that “the use of local anaesthesia for inguinal herniorrhaphy requires special expertise and increases the length and difficulty of the operation.”\textsuperscript{52} The technique\textsuperscript{120} is simple but requires practice.\textsuperscript{121} Three large randomised controlled trials comparing local, regional and general anaesthesia provided robust evidence showing that local anaesthesia is time-saving, cost-effective, and that surgeons are able to operate as day-case surgery with greater patient satisfaction.\textsuperscript{122-126} Regional anaesthesia has been associated with an increased morbidity rate\textsuperscript{127} compared to local and general anaesthesia, especially
cardiovascular complications probably due to induced bradycardia and cardiac arrest.

Local anaesthesia also has the advantage of a conscious patient able to cough to demonstrate the hernia intraoperatively, if necessary. Despite the advantages of local anaesthesia, surgeons only use the technique in 17% of operations performed in Sweden. However, the variation among hospitals is great and one unit uses local anaesthesia for 80% of its patients with excellent results. As for surgery, the panorama of anaesthesia has changed dramatically over the past 20 years (Figure 6). In 1992, 75% of operations were performed under regional anaesthesia; in 2012 this was less than 10%. EHS guidelines recommend local anaesthesia for open repair and do not recommend regional anaesthesia at all.

**Complications of groin hernia repair**

Complications commonly associated with groin hernia repair are haematoma, seroma, pain and infection. A meticulous, nerve-saving dissection technique and careful haemostasis is therefore important. Testicular atrophy is a feared, but rare, complication caused either by impairment of the venous flow or hypoxic reaction secondary to obliteration of the blood supply to the testicle. In the SHR 8% (11,995/150,514) of patients had one or more complications registered within 30 days of surgery. Preperitoneal techniques, open as well as laparoscopic, were associated with an increased complication risk with odds ratios of 1.35 (1.24-1.47) and 1.31 (1.15-1.49), respectively. Bleeding, arterial or venous, may occur in all groin hernia repairs, and from all vessels in the surgical field. However, three vessels should be especially feared during operation; the pubic branch of the obturator artery, sometimes referred to as the corona mortis; the deep inferior epigastric vessels; and the external iliac artery and vein. Laparoscopic repair has been associated with more serious complications than the other methods.

Complications are largely associated with emergency operations. Other risk factors known are recurrent hernias, sliding hernias, and bilateral hernias.
Swedish Hernia Register

In 1992 the Swedish Hernia Register started with 8 aligned hospitals. It is a national quality register aimed to “describe and analyse hernia surgery and stimulate improvements at the participating units.” Today, more than 20 years later, almost all groin hernia operations performed in Sweden are registered in the SHR, providing a database of more than 250,000 prospectively registered operations. More than 40 publications and 9 theses have been based upon SHR data.

With permission to use personal identification numbers, a number unique for each Swedish citizen, patients are followed prospectively from operation until reoperation for recurrence or death, regardless of where in the country the reoperation is performed. Information is registered on-line at the time of the operation. Follow up is not required but the participating units have an obligation to report all complications within 30 days of surgery that comes to their knowledge. Data are processed annually, and feed-back is available for each participating unit, where outcomes obtained at a specific unit are compared with results obtained at all participating units combined. Overall information is obtainable on the web for all interested to read. Five independent evaluators randomly visit 10% of the aligned units each year and check the validity of the data registered in the SHR, as well as check for operations not registered. The register has been found to include some 98% of all operations eligible.

Already in 1998 one could see that the participation in SHR resulted in better care for the patients at the aligned hospitals. A comparison between two hospital cohorts one participating in the SHR from the start (1992) and the other joining in 1995 indicated that both quality and cost-effectiveness improved with register participation.

Today, it is evident that the quality of groin hernia surgery offered to patients in Sweden has improved. The proportion of recurrent hernias (of all hernias operated) decreased from 17% in 1995 to 9% in 2012. Day-case surgery has increased from below 35% to 80%, and the risk for re-operation for recurrence has decreased markedly. (Figure 7)
Figure 7. Cumulative incidence of reoperation for hernia repairs registered in SHR for three time-periods. Between 1992 and 1998 the cumulative reoperation rate for recurrence was nearly 3% in two years follow up. Little more than a decade later the cumulative incidence of reoperation has decreased to approximately 1.5%.
Register studies

Register studies are observational, studying the *effectiveness* in routine care, in contrast to experimental trials that are investigational, studying the *efficacy* or the results obtained in expert hands when correctly applied to appropriate patients.\(^\text{143}\) Widely recognised as the gold standard to evaluate pharmacological interventions,\(^\text{144}\) randomised controlled trials (RCT) pose specific problems in surgical research.\(^\text{145,146}\) In this respect register studies can complement RCT’s by revealing the impact different treatments have in wider practice.\(^\text{147}\)

In Sweden there are **mandatory registers** and **national quality registers**. Examples of mandatory registers, initiated and controlled by the *National Board of Health and Welfare*, are the *Swedish Cancer Register*, the *Cause of Death Register* and the *Swedish National Patient Register* (NPR).\(^\text{148}\) National quality registers are non-mandatory for hospital/units and aim at improving the quality of care for patients with specific diseases/interventions included in the registers. Some features are important for all registers.

**Inclusion** is regulated by law for mandatory registers. Quality registers, on the other hand, must appeal to participating units. The SHR, for example, offers its participants an opportunity to improve their outcome by giving feedback in an annual report.

**Validity** is crucial for register studies, and validation is a complicated task requiring cross-checking. A register with incorrect or missed data is of limited use.

**The ability to trace patients.** All Sweden citizens have a unique personal identification number\(^\text{138}\) making the patient traceable in the healthcare system, and enables registers to merge with one another to broaden fields of research. The fruit of one such merger of 11 nationwide registers is called PCBaSe. This database has made it possible to investigate clinically relevant issues such as adverse outcome after prostatic cancer treatment; implication of co-morbidity,\(^\text{149,150}\) psychiatric health and suicide risk,\(^\text{151,152}\) risk for cardiovascular complications,\(^\text{153,154}\) healthcare provided contra social group,\(^\text{155}\) and watchful waiting or not.\(^\text{156,157}\)
Extrapolation to the population. As stated above the external validity for nationwide register data is high. Register studies are epidemiological and in contrast to RCTs without inclusion- or exclusion criteria i. e. unselective data.

Changes over time. In RCTs, it is not possible to have a follow-up that stretches for more than a few years because of the high cost. A register study, however, is an excellent tool for observing changes over long periods of time. Late re-operation for recurrence is one endpoint that cannot easily be examined by RCTs, whereas it is readily investigated by register studies.

Short-term recurrence rates can accurately be determined in RCTs using both physical and radiologic examinations because of the limited number of patients. Without the use of questionnaires, recurrence rates cannot be examined in the SHR, which is why register studies are forced to use the endpoint re-operation for recurrence.

The importance of a control group. In the beginning of the 2000s, the reputation of observational studies became tainted when they suggested negative associations between the use of hormone replacement therapy (HRT) and a risk for cardiovascular events. The authors of one of these observational studies did indeed reflect on this when writing: “the associations described may reflect differences between hormone users and non-users rather than the effect of hormones themselves.” According to a RCT, no such effect could be ascribed to HRT, while other harmful effects were noted instead. When investigating for example a risk of a cardiovascular event the risk should be put in the context of corresponding risks in the background population. As depicted in the example above, choice of comparison group is more critical in observational studies than in interventional studies where patients often are randomly allocated to equalise the groups being compared.

Registers are powerful tools when studying rare adverse events. Thomas Kuhn, an American professor and author of “The structure of scientific revolution” described the scientific community living in different paradigms each and every one by its own “truths” and “normal knowledge”. Anomalies within this “normal science” are too small (or rare) for the individual scientist to consider them worth exploring. However, eventually
and collectively, anomalies cannot be ignored causing a model drift, model crisis and eventually a model revolution ending in a paradigm shift where new “normal knowledge is formed”. An example from the SHR’s history is used to illustrate this issue:

![Cumulative risk of reoperation in men](image)

**Figure 8. Cumulative risk of reoperation vs. method of repair in men, 1992-2012.** Compared to the Lichtenstein technique all other methods of repair are associated with increased risk of reoperation.
The Lichtenstein technique was associated with a low recurrence rate (Figure 8) and reproducible results, initially assumed (normal knowledge) to give equally good results regardless of gender. Hence, women were treated with a method acknowledged to be excellent in men. After a decade more than 6 895 groin hernia repairs in women had been registered in the SHR. When men and women were analysed separately, it became clear that the technique proven best for men had inferior results in women. (Figure 9)

![Cumulative risk of reoperation in women, 1992-2012](image)

*Figure 9. Cumulative risk of reoperation in women 1992-2012. The Lichtenstein technique is set as reference. A 2% reoperation for recurrence rate is reached within a year for the Lichtenstein repair whereas the preperitoneal laparoscopic technique has significantly lower reoperation for recurrence rate.*
In hindsight this should have been suspected from the information known at that time. The Shouldice hospital had noted that more than half of all patients operated for femoral hernia were reoperations. 79 Mikkelsen et al. 162 noted a fifteen-fold increase in incidence of femoral hernias in reoperations for recurrence compared with the spontaneous incidence. In the SHR, 42% of women re-operated for recurrence, had a femoral hernia whereas the corresponding figure for men was 5%.161 Oddly enough, the exact same figures were reported by the Danish Hernia Register; 42% and 5%.163 One conclusion from both studies was that femoral hernias are overlooked at operations for inguinal hernias. Hence, the internal orifices of both inguinal and femoral hernias should be explored in groin hernia surgery, in women. As femoral hernias are relatively more common in women, they should be repaired with a technique that allows easy visualisation of the sites for both inguinal and femoral hernias i.e. with a preperitoneal technique - open or laparoscopic. These techniques were also found superior in women when re-operation was set as a quality endpoint.161 The figures above show cumulative re-operation rates with respect to method of repair for men and women.
Aims of the thesis

I. To investigate the mortality after groin hernia surgery, adjusted for mortality in the background population.

II. To investigate symptoms, cause of death, and treatment of patients who died within 30 days after groin hernia operation.

III. To investigate the incidence of groin hernia surgery after prostatectomy and radiation therapy for prostate cancer compared to a control population.

IV. To investigate severe postoperative adverse events within 30 days after groin hernia repair.
Methodological considerations

The register studies below are hypothesis-creating rather than hypothesis-driven. The aims of the studies are to depict and analyse reality. Below follows a description of registers, other than the SHR, used in the studies:

**The Cause of Death Register:** started in 1961. For all Swedish citizens dying in or outside Sweden, date and cause of death is registered according to ICD-9, or ICD-10 reference codes. The under-reporting is low (less than 0.4% in 1986).\(^{164}\)

**The Swedish Cancer Register** includes all patients in Sweden with a diagnosis of cancer. It is regulated by law that cancer diagnoses must be reported both by the clinician and the pathologist.\(^{165}\) Approximately 60 000 cases of cancer are reported each year in Sweden.

The **Swedish National Patient Register** (NPR) also called Hospital Discharge Register collects information on in-patient care, including surgical procedures and discharge diagnoses according to ICD-9 or ICD-10 reference codes.\(^{148}\) It started in 1964 and received complete coverage in 1989. From 2001, outpatient visits such as day-case surgery are included. The completeness of this register has been shown to be high, and in 2007 drop-outs not registered in the register were estimated to be less than 1%.\(^{166}\)

**The National Prostate Cancer Register** (NPCR) was established in 1996 and includes all patients with the diagnosis prostate cancer (PCa) covering more than 96% of all PC cases registered in the Swedish Cancer Register.\(^{167}\) The validity of primary treatment registered in the NPCR is above 90% correct for curative treatment and surveillance, and more than 95% correct for endocrine treatment.\(^{168}\)

**PCBaSe 2.0** is a database with information from a merger of the NPCR and eleven other Swedish nationwide registers.\(^{168,169}\) Information in the PCBaSe 2.0 runs from 1998-2008 and it is based upon 119,777 patients registered in the NPCR. Unique for this database is their control-group. For every man
with PCa included, two or five (depending on year of inclusion) men without a diagnosis of PCa were randomly selected, matched for age and place of residence. The control-group consists of more than 600,000 men.

**Paper I**

Paper I is an observational cohort study with a comparison group. The SHR was merged with the Cause of Death Register to find patient mortality within 30 days of groin hernia surgery. The mortality rate was compared with that of the Swedish background population using a standardised mortality ratio (SMR) (see statistical considerations). The SMR was analysed for gender, method of repair, anaesthesia, groin anatomy, age, ASA-score and mode of admission, among patients operated for groin hernia.

**Paper II**

Paper II is a descriptive study, analysing the care given to patients who died within 30 days after hernia surgery. In order to find out why patients in Paper I had died within 30 days of surgery medical records of deceased patients were examined. A request was sent to all participating units for the medical records of each and every one of the deceased patients. Data in the SHR are collected prospectively for each operation. However, patient files were retrieved retrospectively. Parameters looked for in the medical records were: symptoms at admission; examination in the emergency department; radiologic examination; and time from hospital admission to surgery.

**Paper III**

Paper III is an observational, retrospective, cohort study based on data from the PCBaSe 2.0. The incidence of groin hernia repair was analysed for men with prostate cancer treated with radiation therapy and prostatectomy (open as well as minimally invasive), and compared with a control group of more than 100,000 men free of prostate cancer matched for area of residence and age. The Cox proportional hazard model was used to calculate hazards ratios (HR).
Paper IV

Paper IV is an observational cohort study where SHR was merged with the NPR to find severe complications, both medical and surgical, within 30 days after groin hernia surgery. Intraoperative complications were found in SHR, and ICD and reoperation codes were found in NPR. Odds ratios were calculated using multivariate logistic regression analyses to compare the risk for cardiovascular or adverse surgical events. Variables of interest were method of operation and anaesthesia, hernia anatomy, age, ASA-score, and mode of admission. A 95% confidence interval was used to estimate the precision of OR.
Statistical considerations

Standardised Mortality Ratio (SMR) was used in paper I to relate the mortality rate of patients to that of the background population. The SMR equals the observed number of deaths in the study group divided by the expected number of deaths in a Swedish population with same composition as the study group. An SMR above 1 is equivalent to an increased risk compared to that of the background population and an SMR below 1 with a decreased risk.

Odds Ratio (OR): a comparison of two odds: the odds of the event occurring in one group divided by the odds of the event occurring in the other group. It does not equal relative risk (RR) when the proportion with the outcome is greater than 5-10%, meaning that the term has little clinical relevance or meaning with higher incidence rates.\textsuperscript{171} If the OR is 1 the RR is 1. In all other circumstances they will differ.

Hazards Ratio (HR): The hazard rate is the probability that if the event has not already occurred that it will occur in the next time interval divided by the length of that interval.\textsuperscript{172} The assumption in proportional hazard model for survival analysis is that the hazard in one group is a constant proportion of the hazard in the other group. This proportion is Hazards Ratio.

Translated to fit paper III it means: the odds that the time to hernia operation is less for a patient in the treatment group than for a patient in the control group.

Relative Risk (RR): or risk ratio is the risk of outcome in the exposed group divided by the risk of outcome in the unexposed. If the risk of the outcome is the same in both groups then the RR is 1.0 indicating no association between exposure and outcome.\textsuperscript{171}
Results

Paper I

Between the years 1992 and 2004, 292 out of 103,710 patients died within 30 days after surgery. Table 1 shows the SMRs versus groin anatomy, gender, mode of admission, and bowel resection. Red numbers indicate a significantly increased risk compared to the background population, and green numbers a significantly decreased risk. An emergency operation was associated with an increased risk especially in women, as was femoral hernia with a SMR of 6.8 (4.3-10.3) in men and 7.2(4.8-10.3) in women.

Table 1. SMR in relation to anatomy, gender and mode of admission

<table>
<thead>
<tr>
<th></th>
<th>No op.</th>
<th>Observed deaths</th>
<th>Expected deaths</th>
<th>SMR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anatomy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inguinal</td>
<td>100,816</td>
<td>241</td>
<td>175</td>
<td>1.38</td>
<td>1.2 – 1.6</td>
</tr>
<tr>
<td>Femoral</td>
<td>2,894</td>
<td>51</td>
<td>7</td>
<td>7.01</td>
<td>5.2 – 9.2</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>95,692</td>
<td>235</td>
<td>167.69</td>
<td>1.40</td>
<td>1.2-1.6</td>
</tr>
<tr>
<td>Women</td>
<td>8,018</td>
<td>57</td>
<td>13.67</td>
<td>4.17</td>
<td>3.2-5.4</td>
</tr>
<tr>
<td><strong>Elective surgery</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No bowel resection</td>
<td>97,231</td>
<td>104</td>
<td>157</td>
<td>0.66</td>
<td>0.5 - 0.8</td>
</tr>
<tr>
<td>Bowel resection</td>
<td>202</td>
<td>3</td>
<td>0</td>
<td>6.98</td>
<td>1.4 - 20.4</td>
</tr>
<tr>
<td>Total</td>
<td>97,433</td>
<td>107</td>
<td>157</td>
<td>0.68</td>
<td>0.6 - 0.8</td>
</tr>
<tr>
<td><strong>Emergency surgery</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No bowel resection</td>
<td>5,783</td>
<td>123</td>
<td>24</td>
<td>4.95</td>
<td>4.1 - 5.9</td>
</tr>
<tr>
<td>Bowel resection</td>
<td>494</td>
<td>62</td>
<td>3</td>
<td>21.53</td>
<td>16.5 – 27.6</td>
</tr>
<tr>
<td>Total</td>
<td>6,277</td>
<td>185</td>
<td>27</td>
<td>6.70</td>
<td>5.8 – 7.7</td>
</tr>
</tbody>
</table>
**Paper II**

242 medical records (of 292 deceased patients) were retrieved and scrutinised. One quarter (38/152) of 152 patients operated acutely had a femoral hernia. In 70% (107/152) of emergency operations, patients were admitted because of symptoms of bowel obstruction with or without a palpable hernia.

Women were less likely to be examined for groin hernia in the emergency ward, 61% vs. 78% (P=0.04), even though they had symptoms indicating bowel obstruction. If admitted for bowel obstruction without a correct diagnosis, 30% were operated within 24 hours compared to 82% if the diagnosis of groin hernia was determined in the emergency ward.

*Table 2. Diagnosis on the emergency department vs. time to surgery*

<table>
<thead>
<tr>
<th></th>
<th>Bowel obstruction without known hernia</th>
<th>Bowel obstruction with known hernia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Op within 24 h</td>
<td>30%</td>
<td>82%</td>
</tr>
<tr>
<td>Op after 24 h</td>
<td>70%</td>
<td>18%</td>
</tr>
</tbody>
</table>
Mortality and Morbidity after Groin Hernia Surgery

Paper III

26,608 men with PCa treated with open prostatectomy (RRP), minimally invasive prostatectomy (MIRP) or radiation therapy (RT) were included in the study together with a control group of 105,422 men without PCa. After six years approximately 4% of the control population had been subjected to groin hernia repair in contrast to 14% of patients operated with open prostatectomy. A small but significant difference was seen between open and minimally invasive surgery, where 11% were operated after 6 years. 8% of patients with prostate cancer who received radiation therapy had been operated for hernia by 6 year. With the control group as reference Hazards ratios were 3.95(3.70-4.21) for open prostatectomy 3.37(2.95-4.21) for minimally invasive prostatectomy and 1.84(1.66-2.04) for patients treated with radiation therapy.

As seen in table 3, it was the proportion indirect hernias that increased after open prostatectomy.

*Table 3. Hernia anatomy as registered in SHR in patients treated for PCa and controls*

<table>
<thead>
<tr>
<th></th>
<th>Femoral(%)</th>
<th>Combined(%)</th>
<th>Indirect(%)</th>
<th>Direct(%)</th>
<th>Other(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>1</td>
<td>10</td>
<td>53</td>
<td>36</td>
<td>0.4</td>
</tr>
<tr>
<td>RT</td>
<td>1</td>
<td>8</td>
<td>65</td>
<td>26</td>
<td>1</td>
</tr>
<tr>
<td>RRP</td>
<td>0.4</td>
<td>6</td>
<td>77</td>
<td>16</td>
<td>1</td>
</tr>
<tr>
<td>MIRP</td>
<td>0.4</td>
<td>10</td>
<td>66</td>
<td>23</td>
<td>0</td>
</tr>
</tbody>
</table>
Paper IV

According to NPR, 612 out of 143,042 patients, 12,001 (8%) women and 131,041 men (92%), suffered from at least one cardiovascular event within 30 days after surgery, and 295 groin hernia repairs were followed by a serious surgical event detected either by discharge diagnosis or by re-operation code. According to SHR, in 815 repair one or more intraoperative complications occurred. Male gender was associated with a significantly increased risk for cardiovascular events compared to women. Age above 60 years, ASA-score above 2, emergency operation, and regional anaesthesia was associated with increased risk for cardiovascular complications. All method of operation apart from open anterior mesh repair were associated with an increased risk either for intraoperative complication noted in SHR or severe surgical complication detected by registered codes in NPR. In addition bilateral hernia, sliding hernia, and recurrent hernias were associated with increased risk for both intra-operative complication and severe surgical complication.

Table 4. Odds ratio for severe surgical complications recorded in NPR vs. method of operation

<table>
<thead>
<tr>
<th>Method of op</th>
<th>Odds ratio</th>
<th>p-value</th>
<th>95%CI</th>
<th>Odds ratio</th>
<th>p-value</th>
<th>95%CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open anterior</td>
<td>1(Reference)</td>
<td></td>
<td></td>
<td>1(Reference)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laparoscopy</td>
<td>0.9</td>
<td>0.626</td>
<td>0.5-1.6</td>
<td>1.0</td>
<td>0.980</td>
<td>0.3-3.7</td>
</tr>
<tr>
<td>Open posterior</td>
<td>2.4</td>
<td>0.007</td>
<td>1.3-4.4</td>
<td>2.3</td>
<td>0.089</td>
<td>0.9-5.8</td>
</tr>
<tr>
<td>Suture repair</td>
<td>2.2</td>
<td>&lt;0.001</td>
<td>1.4-3.5</td>
<td>0.5</td>
<td>0.318</td>
<td>0.1-2.1</td>
</tr>
<tr>
<td>&quot;Other” repair</td>
<td>2.2</td>
<td>0.041</td>
<td>1.0-4.7</td>
<td>2.3</td>
<td>0.067</td>
<td>1.0-5.5</td>
</tr>
</tbody>
</table>
Conclusion

- Elective groin hernia repair is a low risk procedure even in elderly

- Emergency hernia operation is associated with considerable mortality and morbidity

- In groin hernia repair, women have a higher mortality risk than men due to a greater risk for emergency procedure irrespective of hernia anatomy and a greater proportion of femoral hernia.

- A physical examination for groin hernia in patients with bowel obstruction shortens time to operation

- Regional anaesthesia is associated with an increase in cardiovascular morbidity compared with local anaesthesia

- Emergency hernia, sliding hernia, bilateral hernia and recurrent hernias were associated with an increased risk of surgical complications.

- Groin hernia repair is significantly increased in patients treated with open prostatectomy, minimally invasive prostatectomy as well as after radiation therapy for PCa, compared to a control cohort.
General Discussion

Great improvement in hernia repair in Sweden has occurred since the onset of the Swedish Hernia Register in 1992, to the benefit of groin hernia patients. The nationwide recurrence rate has dropped below 2% in two years, day-case surgery is well-established, and the proportion of operations performed under local anaesthesia has increased, albeit still low. This thesis also demonstrates that convergence of registers is feasible, informative and useful when performing studies on rare events.

Strengths and weaknesses

The registers used in the thesis have all been shown to have a high validity, crucial for register studies, and they are also nationwide meaning that no class, group, or patient category is excluded. Hence, the results obtained are applicable to patients in the waiting room or on the emergency ward in any hospital or unit. Observational register studies, such as those presented in this thesis, are important complements to randomised controlled trials, where experts exert their skill under optimal conditions.\textsuperscript{173}

One important strength of register studies is the great number of patients and operations registered, making it possible to find and analyse rare events such as mortality and severe adverse events. The number of patients needed to address these rare outcomes in a RCT is too large to be feasible.

The exceptional PCBaSe database is a golden example of convergence of registers. The strength of Paper III, besides the vast number of operations, is the unique control group created in PCBaSe, making it possible to relate the incidence of groin hernia repair to the background population. In the control group a mere 4% had been operated within 5 years, a figure which concurs with findings from the Danish register where 4.14% CI 4.0–4.29% of all males aged 75–80 years in Denmark were operated for an inguinal hernia at least once during a 4-year period.\textsuperscript{47}
Operation for groin hernia or reoperation for recurrence are blunt endpoints since we know that the incidence of groin hernia exceeds that of groin hernia surgery. In Paper I, selection bias may be suspected since electively operated patients have a lower mortality rate than the background population, suggesting that surgeons tend to select healthy patients for hernia surgery. In Paper III, a potential detection bias is that all patients with prostate cancer visit a doctor on a regular basis in contrast to controls.

An obvious weakness in register studies is the lack of personal information of each patient. However, it is possible to combine register studies with complementary questionnaires or with analyses of patient files as in Paper II.

**Main findings**

In Paper I it was found that mortality after elective groin hernia repair is low, even lower than for the background population. Together with other studies this supports the decision to operate an elderly man or women suffering from groin hernia electively, and even suggests that indications for patients with co-morbidity should be widened. Emergency hernia surgery, on the other hand, is known to be associated with increased mortality and morbidity, a truth confirmed in Papers I and IV.

For the first time in a larger study it was concluded that patients operated on because of bilateral hernias have a significantly higher risk of having a severe adverse event and intraoperative complications. This must considered when planning for operation in individuals with bilateral hernias. Risk for intraoperative or severe complications were also influences by the method of repair chosen and this must also be taken into account when planning the operation for the individual patient at your clinic.

Women have a higher mortality risk than men because of a higher proportion of femoral hernias and a higher fraction of emergency operations regardless of hernia anatomy. According to the medical files, women with incarcerated groin hernias were at a higher risk than men for not having a correct diagnosis on the emergency department. Kjaergaard et al. analysed patient deaths in the Danish Hernia Register, and also observed that 41% of patients lacked an examination for groin hernia with subsequent delayed diagnosis
and treatment. Also, McGugan et al found that 59% of femoral hernia operation that led to death was performed outside office-hours and often by junior staff.\footnote{176} Overall mortality after femoral hernia surgery in women in their study was 3.1 \% (37/1184). The awareness of the increased morbidity/mortality in this group of patients hopefully results in less time to surgery, better preoperative care, and consultation of more experienced surgeon and/or anaesthesiologist when needed.

The three-fold elevated risk for having a groin hernia operation after open as well as minimally invasive surgery for prostate cancer has implications both for the urologist, the surgeon and the health economist. In contrast to our findings, minimally invasive surgery has previously been associated with a lower risk for groin hernia than open radical prostatectomy.\footnote{73} However, a recent study by Carlsson et al. showed that minimally invasive surgery was associated with a greater risk for any hernia repair, and specifically for incisional hernia repair, compared to open prostatectomy.\footnote{177} Since prostatectomies are increasing in number, the number of hernias will increase, and cooperation between urologists and surgeons is required, to meet the increased risk for both incisional and groin hernia repair.
Future perspectives

Prevalence studies on groin hernia in the normal population, especially in women, are needed in order to improve interpretation of results from register studies and to improve our advice to patients on whether to operate their hernia or not. With the convergence of registers we can stretch the use of register studies further to investigate parameters such as the socio-economic impact on groin hernia mortality and morbidity. A famous hernia surgeon wrote “Nothing so prevents the occurrence of complications as one’s awareness and fear of them.”[31] In order to decrease the mortality and morbidity seen after emergency hernia operations and operations for femoral hernia repair, recurrent hernia repair, bilateral hernia repair and female groin hernia repair in general, it may be appropriate for two surgeons to attend such operations. My sincere hope is that the present excess mortality in women after (emergency) groin hernia repair will decrease because of our better awareness of associated risks. I also believe that this should be controlled with follow-up studies as outlined in Paper I.
Sammanfattning på svenska


Syftet med avhandlingen är att utvidga registrets användningsområde genom att samköra SBR med andra nationella register för att studera ovanliga händelser och allvarliga komplikationer efter ljumskbräckskirurgi.

Delarbete I


Delarbete II

För att ta reda på varför patienterna avled granskades 242 av 292 journaler över patienter som avlidit inom 30 dagar efter ljumskbräckoperation. Ett inklämt ljumskbräck ger symtom som vid tarmvred med magsmärta, kräkning och utebliven avföring. Trots detta ljumskbräcksundersöktes bara 61 % av kvinnor, med tarmvredssymtom jämfört med 78 % av männen. De patienter där läkaren inte ställde diagnosen inklämt ljumskbräck på akutmottagningen utsattes i högre utsträckning för (onödig) radiologisk
undersökning och opererades betydligt senare jämfört med patienter som erhöll diagnosen ljumskbräck på akutmottagningen. Ett viktigt budskap från studien är riktat till läkaren på akutmottagningen. Undersök ljumskarna hos alla som kommer med symtom på tarmvred!

**Delarbete III**


**Delarbete IV**

Diskussion

Registerstudier kan identifiera ovanliga och allvarliga händelser under en lång tidsperiod, något som inte låter sig göras med randomiserade studier. Med hjälp av nationella register fann vi att ljumskbräckskirurgi är betydligt vanligare efter radikal operation för prostatacancer än i normalbefolkningen, något som bör föranleda diskussion mellan kirurger och urologer. Genom att samköra svenskt bräckregister med flera andra register har vi belyst en rad omständigheter och riskfaktorer för ökad dödlighet och svåra komplikationer efter bräckkirurgi. Min förhoppning är att vetskapen härom kommer att förbättra vården för patienter med ljumskbräck, särskilt kvinnor som söker vård med tecken på tarmvred, där en noggrann undersökning kan vara livsavgörande.
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References


Appendices (Papers I-IV)