# Laparoscopic hernia surgery in Sweden 2010 to 2020 – scientifically highlights from the national Swedish Hernia Register

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Abstract: The Swedish Hernia Register (SHR) is a national quality register with more than 350,000 prospectively registered groin hernia repairs. Studies from the SHR have addressed important and clinically relevant issues within the field of laparoscopic groin hernia surgery and the aim of this paper is to present five of the most innovative patient-oriented publications including analysis of laparoscopic hernia repairs based on data retrieved from the SHR published between 2010 and 2020. After a Medline search was conducted, papers were graded and five papers were selected because of their specific nature, quality of methodology or international interest. The papers in our review studied a wide range of topics such as the risk of male infertility after mesh repair, risk of groin hernia surgery after open and minimally invasive prostatectomy, chronic pain after groin hernia surgery vs. method of repair, gender differences in risk of reoperation vs. method of repair and risk of reoperation vs. low and high molecular weight of the mesh. When gathering large amount of high-quality data, including almost total national coverage of all inguinal surgeries performed, it is possible to make valid conclusions and recommendation even on rare conditions and to sort out techniques that does not perform as intended, or does not apply to specific clinical situations. The studies above show that a laparoscopic repair is associated with a decreased risk of chronic pain for both gender to the price of a significantly higher risk of reoperation in men. The contrary is shown in women with a decreased risk of reoperation using laparoscopic repair compared to open repair.

Keywords: National registers; laparoscopic surgery; totally extra-peritoneal (TEP); inguinal hernia; femoral hernia

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# Introduction

The practice of laparoscopic hernia surgery has rapidly increased during the last three decades and has been fueled by an increasing body of evidence supporting the benefit of laparoscopic hernia surgery in selected situations as well as uncritical rapture over a novel technique. To some extent, the evidence regarding laparoscopic hernia surgery derives from well-designed randomised controlled trials undertaken at tertiary centers (1,2). The internal validity

of these trials is often high, reflecting the fact that a wellplanned randomisation makes all other things but the intervention equal. However, RCTs study the efficacy of an intervention performed by experts under optimal circumstances in selected patients in contrast to national register studies the effectiveness of routine care offering a high external validity. Furthermore, few RCT have sufficient statistical power and follow-up to detect rare and late occurring events, e.g., severe persisting postoperative pain, infertility and neglected femoral hernias in women. Notwithstanding the impact of the randomised controlled trials, several of the most important studies on laparoscopic hernia surgery have evolved from large population-based register studies (3,4). Since many important outcomes after hernia surgery, in particular persisting pain and recurrent hernias, require long-term-follow-up and large cohorts of patients, observational population-based studies based on patient registries have the potential to provide evidence that cannot be achieved in small randomised controlled trials performed at highly specialized units. Some of the registerbased studies on laparoscopic hernia surgery are based on data from the Danish Hernia Database and Swedish Hernia Register (SHR).

The SHR was founded in 1992 and has grown to cover more than 98% of all groin hernia repair performed in Sweden (5). The main outcome measures reported from the register are risk of reoperation (6-8), 30 days complication rate (9), and since 2012, chronic pain (9-11). Up until today some 70 publications are based upon data from the SHR addressing patient related issues concerning the field of open and laparoscopic groin hernia surgery.

The aim of this paper is to present five of the most innovative publications to reflect the quality of laparoscopic hernia surgery in relation to open techniques from a national perspective based on data from the SHR published between 2010 and 2020. A secondary aim is to address the specific nature of register studies and stress their strengths as well as weaknesses further when having a longer time perspective on the respective study as time has passed since their respective publication.

The SHR is a non-mandatory national quality register with

the aim to "describe and analyse hernia surgery and stimulate

improvements at the participating units" (12). A database

# Methods

# The SHR

of more than 350,000 repairs have been prospectively assembled. Using the personal identification number (13), unique for each Swedish citizen the operation is followed until reoperation for recurrence or death/emigration of the patient, regardless of where in Sweden the reoperation is carried out.

Other outcome measures are 30-day complication rate registered according to the Clavien Dindo classification (14), and since 2012 patient reported outcome measure (PROM) is assessed using a patient questionnaire sent to the patient one year after the operation with an answering rate as high as 75% (15). Variables in the register include information on the patient such as age, gender, ASAscore, BMI, concomitant diseases as well as details about the procedure such as hernia anatomy, mode of operation, type of operation and anesthesia. Each year data from 10% of aligned units are validated using hospital records. The register has been found to include some 98% of all eligible operations (16).

It was decided by the authors of this review to present the five most important papers either seen from a research quality perspective or papers that has been highly cited and recognized internationally. All papers based upon data from the SHR are approved by the Ethics committee as stated in the articles.

# Selection of highlight papers

The main author conducted a search in Medline, for English language articles only. A combination of MeSH terms related to groin hernia surgery and the SHR were used. Papers including patients having had a laparoscopic groin hernia repair published between January 2010 and march 2020 were considered for inclusion. Papers of interest, found through references in the published papers, were also assessed for eligibility. The abstracts were sent to the members of the steering committee of the SHR and graded (0 to 3) including a summary if the three dimensions; Originality, Methodology and "International recognition". Grading scale: 0 = non-acceptable; 1 = acceptable; 2 = good; 3 =eminent. In a consensus meeting in March 2020 the steering committee discussed the papers having a Grade 1 to 3. Members are elected to the steering committee because of their academic as well as their clinically interest and achievements within the field of hernia surgery in Sweden. Members are elected for 2 respective 4 years depending on their position in the committee. In a consensus meeting in March 2020 the steering committee discussed the

#### Laparoscopic Surgery, 2021

papers having a Grade 1 to 3. Members were advised to refrain from the poll when biased because of any personal involvement in any of the articles. In addition to select the "Five highlights" from the register the selection was also made with the aim to depict different methodologies unique for register studies. The top five publications according to originality, method, and international potential were chosen in consensus.

# Results

Thirty-nine articles based upon data from the SHR between 2010 and 2020 were identified having a Grade 1 to 3. Seven papers, studying only open hernia surgery, were excluded. After grading and discussion in the consensus-meeting five papers were selected because of their specific nature, quality of methodology or of international interest. The five papers are presented below in order of date of publication.

# Hallen M, Westerdahl J, Nordin P, et al. Mesh hernia repair and male infertility: a retrospective register study. Surgery 2012;151:94-8. Reference (17)

# Introduction

Since the introduction of mesh repair the risk of recurrence has decreased substantially and today, mesh is recommended as the method of choice for hernia repair (3). However, long-term adverse events such as chronic pain and male infertility were widely discussed (18). To assess whether or not groin hernia repair interfered with male fertility data were cross-linked between two national registers; SHR and the Swedish national patient register.

# Methods

All men born between 1950 and 1989 with both a hernia repair registered in SHR and a diagnosis of infertility (ICD code N46.9) in the Swedish National Patient Register were identified. The observed cumulative incidence of infertility was compared with the expected cumulative incidence.

# Results

Two hundred and thirty-three (0,7%) out of 34,267 men with a history of at least 1 inguinal hernia repair, had been given the diagnosis of male infertility after their first operation. No differences between expected and observed cumulative incidences of infertility in men operated with hernia repair was found. After bilateral mesh hernia repair a small but increased risk was noted, however, still below 1%.

# Conclusions

"Inguinal hernia repair with mesh is not associated with an increased incidence of, or clinically important risk for, male infertility." Because of this study, fear of infertility after groin hernia surgery does not have to be taken into account when deciding on method of repair in young men.

# Nilsson H, Stranne J, Stattin P, et al. Incidence of groin bernia repair after radical prostatectomy: a population-based nationwide study. Ann Surg 2014;259:1223-7. Reference (19)

# Introduction

During the late 1990s and the beginning of the early 2000s reports showed an increased incidence of groin hernias after open radical prostatectomy procedures (20-22). The aim of was to assess whether there was an increased risk of groin hernia surgery after treatment of prostate cancer and if the risk differed after open respective robot-assisted laparoscopic surgery.

# Methods

The study was conducted as an observational, retrospective, cohort study based on data from the PCBaSe 2.0, a database composed of not less than 17 national registers, including the SHR. The incidence of groin hernia repair was analysed in men with prostate cancer treated with either radiation therapy or prostatectomy (open as well as robot-assisted). These men were compared with a control group including more than 100,000 men free of prostate cancer and matched for area of residence and age. Hazards ratios (HR) were calculated using the Cox proportional hazard mode.

# Results

Men operated for prostate cancer had three times increased risk of having a groin hernia repair after prostate cancer. The risk was somewhat higher after open *vs.* robot assisted laparoscopic surgery.

#### Conclusions

In this study several nationwide registers were crosslinked, thereby providing a control-cohort of more than 100,000 men free of prostate cancer. Risk of reoperation rate was used as a surrogate endpoint instead of an incidence of groin hernia. The risk of having a groin hernia repair is increased after prostatectomy. Further studies are needed to differentiate between open and minimally invasive prostatectomy.

#### Page 4 of 8

# Lundstrom KJ, Holmberg H, Montgomery A, et al. Patient-reported rates of chronic pain and recurrence after groin hernia repair. Br J Surg 2018;105:106-12. Reference (15)

# Introduction

One major concern after groin hernia surgery is the risk of chronic pain. In previous studies, the prevalence of persistent pain has varied greatly (23,24).

Most studies are small and performed on selected patients. This study is a unique combination using Patient Reported Outcome Measures (PROM) and national registry data to assess chronic pain and reoperation rate comparing different methods of operation.

# Methods

All patients having an elective unilateral groin hernia repair in Sweden between September 2012 and April 2015 were sent a questionnaire by mail one year after surgery. Persistent pain; defined as at least "pain present, cannot be ignored, and interferes with concentration on everyday activities" in the past week was the primary outcome. Reoperation for a recurrence recorded in the register was the secondary outcome.

# Results

The response rate was 75.5% and in total, 22,917 patients were analysed. Persistent pain present one year after hernia repair was reported by 15.2% of patients. Total extraperitoneal repair was associated with the lowest risk compared with open anterior mesh repair. Totally extraperitoneal (TEP) repair had an increased risk of reoperation for recurrence (adjusted OR 2.14, 1.52 to 2.98), as did open preperitoneal mesh repair (adjusted OR 2.34, 1.42 to 3.71) after two and a half year follow-up.

# Conclusions

The risk of having persistent pain 1 year after groin hernia repair in routine surgical practice was 15.2%. This figure was lower in patients who had surgery using laparoscopic techniques, but to the price of a significantly higher risk of reoperation for a recurrence.

# Nilsson H, Holmberg H, Nordin P. Groin bernia repair in women - A nationwide register study. Am J Surg 2018;216:274-9. Reference (5)

# Introduction

Compared to men with an estimated lifetime risk of a groin

hernia repair of 27% groin hernias in women are rare (25). Previous studies from the SHR and the Danish Hernia Database had shown that women have a higher reoperation rate, that the reoperations were undertaken earlier and that 40% of the reoperated hernias were femoral compared to 5% in men (26,27). The aim of this study was to investigate the reoperation for recurrence in men and women with respect to method of repair, hernia anatomy and year of operation.

# Methods

Cumulative risk of reoperation after groin hernia surgery was calculated with respect to method of repair divided into open anterior, open suture, Lichtenstein, laparoscopic repair, and open retroperitoneal repair.

# Results

Between 1992 and 2013, 17,545 (8%) out of 221,108 eligible operations were performed on women. The risk of being operated for recurrence after laparoscopic surgery was lower in women, RR 0.4 (95% CI: 0.3–0.7) but increased in men, RR 2.3 (95% CI: 2.0–2.7), compared to the Lichtenstein technique.

# Conclusions

The reoperation rate for recurrence differed significantly between men and women when comparing for operative technique used. Women had a decreased risk of reoperation after a primary laparoscopic approach which visualises all hernia orifices in the groin, compared to the contrary for men.

Melkemichel M, Bringman S, Widhe B. Lower recurrence rate with heavyweight mesh compared to lightweight mesh in laparoscopic totally extra-peritoneal (TEP) repair of groin hernia: a nationwide population-based register study. Hernia 2018;22:989-97. Reference (28)

# Introduction

Lightweight meshes (LWM) have shown benefits compared to heavyweight meshes (HWM) in terms of less postoperative pain and/or stiffness after open inguinal hernia repair. The aim of the study was to compare reoperation rate for recurrence of LWM to HWM in TEP repair.

# Methods

All groin hernias operated using the TEP technique

#### Laparoscopic Surgery, 2021

between January 1th 2005 and December 31th 2013 in SHR were included. Primary endpoint was reoperation for recurrence identified as a re-entry into SHR.

# Results

In total, 13,839 TEP repairs were identified and 491 (3.5%) were re-operated for recurrence. The risk of reoperation for recurrence was higher if an LWM was used 4.0% (HR 1.56, P<0.001) compared to an HWM 3.2%. In a multivariate analyses risk factors identified were direct hernias and large hernias with a defect exceeding 3 cm.

#### Conclusions

In TEP, the use of LWM was associated with an increased risk of reoperation for a recurrence compared to HWM. Direct hernias and large hernia defects may benefit from a repair using an HWM to minimize the risk of a recurrence.

# Discussion

These five original papers published between 2010 and 2020 are based upon prospectively registered data from the SHR. They were selected to reflect the quality of laparoscopic hernia surgery in relation to open techniques from a national perspective. The external validity is high due to the national coverage of the register and based on the above papers, surgeons all over the world have the possibility to inform patients of both gender on the risk for infertility, chronic pain and reoperation using different techniques. A laparoscopic repair is associated with a decreased risk of chronic pain for both gender to the price of a significantly higher risk of reoperation in men. The contrary is shown in women with a decreased risk of reoperation using laparoscopic repair compared to open repair.

There are certain points in the methodology used in the articles above that we would like to address further.

Register studies are observational studies, studying the effectiveness in routine care, in contrast to experimental trials, that are investigational, studying the efficacy or the results obtained by experts under optimal conditions (29). Widely recognised as the golden standard to evaluate pharmacological interventions, randomised controlled trials (RCT) pose specific problems in surgical research with a limited external validity based upon the expert setting. Register studies are based on unselected data, usually with few inclusion or exclusion criteria's resulting in a high external validity. Hence, it is possible to extrapolate the results from such studies. However, there is no randomisation between different interventions. Associations may be seen but it is not possible to draw conclude cause and effect. Therefore, register studies could be seen as a good complement to RCTs by assessing the impact of different treatments used in clinical practice when applied by majority of surgeons in a specific community or country. Köckerling et al. used the advantage of large number of operations presented from the German HerniaMed register when assessing the risk of reoperation for a recurrence comparing two type of meshes (30). It was demonstrated that heavy-weight meshes were associated with a decreased risk of reoperation compared to low-weight meshes. When breaking down data it was shown that this risk was higher only for patients with direct hernias. This is the same conclusions that we came to in our register-based study by Melkemichel et al. (11). It was concluded to suggest the use of a heavy-weight mesh in direct hernias when using the TEP technique.

Meshes used for surgical purposes has until recently been classified as group II devices. These devices would need premarket clinical studies to be accepted for clinical use. Given the large cohorts of repairs registered in hernia databases makes it possible to detect rare adverse events or deviations arising after the use of a specific mesh/devises. One important example of this happening is the withdrawal of Physiomesh for laparoscopic use after the German/ Austrian HerniaMed register noted a markedly increased recurrence rate compared with other contemporary meshes; 12% vs. 5% (30). When assessing the risk of having groin hernia surgery performed after prostatectomy the authors stratified the control-group of men for age, the area of living and not having the diagnosis of prostatic cancer (19). This type of stratification is possible by crosslinking the hernia register with other national registers.

When reading or performing register studies one must be aware of the limitations. Register studies are in most cases observational and hence one has to consider potential bias of confounding variables. The coverage of SBR is 98% which is very high as opposed to many other registers. In registers with a low coverage of patients there is a risk that only the most skilled and interested surgeons participate and hence the results will be biased in terms of generalizability for a general surgeon in other settings. Register also have a limit for the extent of follow up. For example, examining all patients for a hernia recurrence within a register study is not possible. The large amount of patients prohibit personal interaction with all patients as well as a limit of how many variables that can be registered. Reoperation

#### Page 6 of 8

for a recurrence has thus gained acceptance as a clinically important outcome (31). The coverage and correctness of the variables registered is also of vital importance for the conclusion you can draw. For the SHR 10% of units are validated annually with respect to coverage and correctness of the variables registered.

# Future challenges and perspectives

Given that RCT and register studies complement each other, a new methodological study design has emerged, called "register based randomized controlled trials". These studies have the advantage to enable rapid consecutive enrollment, longer follow up, being less costly, and be in line with Register Studies (32). The results seem to be more generalized to the general population. However, national quality registers enable us to find answer to many questions that are difficult to address in other scientific settings. The greatest challenge for the future will be to ask the clinically relevant questions that are of importance for the hernia patients per see.

# Conclusions

The five studies presented are all based on the SHR data. It is a selection of papers that have made a major impact on treatment strategies for different inguinal hernia conditions. When gathering large amount of high-quality data, including almost total national coverage of all inguinal surgeries performed, it is possible to make valid conclusions and recommendations to share with hernia surgeons, not only on a national, but also on an international basis. There is also a possibility to give recommendations on very rare conditions and to sort out techniques that does not perform as intended, or does not apply to specific clinical situations. Individual surgeons and surgical units can compare their performance status in relation to others, to be used for improvements, for education or for correction of strategies applied.

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