

Review

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Data and outcome of inguinal hernia repair in hernia registers – a review of the literature

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Abstract: Register-based observational studies in inguinal hernia repair deliver real-world data from very large patient populations and give answers to important clinical questions never evaluated in randomized controlled trials. Data from hernia registers can provide evidence of effectiveness of therapies in the general population. Hernia registers with high case load have existed in Sweden since 1992, in Denmark since 1998, and in Germany/Austria/Switzerland since 2009. In this review, the most important findings of register-based observational studies in inguinal hernia repair are presented. After an intensive literature search, 85 articles are relevant for this review. Numerous findings from these register-based studies have been incorporated into the various guidelines on inguinal hernia repair. These highlight the particular importance of hernia registers in answering key scientific and clinical questions in hernia surgery. The myriad of surgical techniques described – spanning more than 100 and with ongoing new additions – as well as the large number of associated medical devices call for, more than in other surgical disciplines, meticulous documentation of the methods used for the treatment of inguinal hernias.

Keywords: Danish Hernia Database; Herniamed Hernia Register; inguinal hernia repair; Swedish Hernia Register.

Introduction

Randomized controlled trials (RCTs) and register-based observational research can be partners in the evolution of medical evidence [1]. The strength of RCTs rest on their excellent internal validity, which is based largely on the power of randomization [1]. Although randomization minimizes the risk of bias by confounding, there are other biases inherent

into RCTs that limit their applicability to the care of patients in routine practice [1]. Although register-based observational research does not enjoy the same level of internal validity as RCTs, well-designed observational studies can offer superior external validity and provide a unique opportunity to evaluate new treatments and their outcomes in routine practice [1]. Register-based observational studies provide insight into delivery of care in routine practice to all patients, including the elderly and those with comorbidity [1]. They can also address questions that have not, and will not, be evaluated in an RCT [1]. Register-based observational studies can provide evidence of effectiveness of therapies in the general population [1]. In addition to the gold standard of evidence-based medicine (i.e. RCT), especially surgical innovations should in parallel involve a prospective recording of data on patients in a database (i.e. a register) [2]. In the new World Guidelines of Groin Hernia Management, the development and implementation of hernia registers in countries or regions with long-term follow-up is recommended. Hernia registers with high case load are existing in Sweden since 1992 [3], in Denmark since 1998 [4], and in Germany/Austria/Switzerland since 2009 [5]. In this review, the most important findings of register-based observational studies in inguinal hernia repair are presented.

Materials and methods

Searches were performed in PubMed and Medline as well as in the reference lists of all included publications for relevant studies. The search terms were “hernia register”, “Swedish Hernia Register”, “Danish Hernia Database”, and “Herniamed”. A total of 354 publications were identified and screened. Finally, 85 articles were relevant for this review.

Results

Impact of occupational mechanical exposures

First-time inguinal hernia repairs in the period 1998–2008 were identified in the Danish Hernia Database.

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The risk of lateral hernia repair increased with ton-years, frequent-heavy-lift-years, and standing-years, with odds ratios (ORs) of up to about 1.4. In general, the risk of medial hernia repair was unrelated to the exposures. The findings suggest an increased risk of lateral inguinal hernia repair in relation to occupational mechanical exposures [6].

The Danish Hernia Database provided information about 34,822 patients, who had their first inguinal hernia repair 1998–2008, on repairs and reoperations for recurrence [7]. The registered occupational codes and a job exposure matrix based on expert's rating was used to estimate total load lifted per day, frequency of heavy lifting, and number of hours per day spent standing/walking. The data did not reveal exposure-response relationships between occupational mechanical exposure and the hazard ratio (HR) of reoperation for recurrence [7].

Effect of body mass index (BMI)

In a study from the Swedish hospital discharge register, an inverse relationship was found between BMI and risk for groin hernia [8]. With each BMI unit (3–4 kg), the relative risk (RR) for groin hernia decreased by 4% ($p < 0.0001$). Compared to men of normal weight, obese men had a 43% lower risk [$p = 0.0008$, 95% confidence interval (CI) 21–59%]. The authors concluded that obviously hernia may be more easily detected in lean men, but a true protective effect cannot be excluded [8].

Of the 49,094 patients in the Swedish Hernia Register (2003–2007), 5.2% were obese. After stratification for gender, the risk for postoperative complications significantly increased for overweight men (HR 1.23, 95% CI 1.03–1.47; $p = 0.024$) and obese men (HR 1.54, 95% CI 1.09–2.18; $p = 0.013$) but not for women. Reoperation for recurrence of groin hernia has an increased ratio of 1.20 (95% CI 1.00–1.40) in overweight patients [9].

Risk factors for complications

Data from the Swedish Hernia Register (1998–2009) with 150,514 herniorrhaphies were analyzed with respect to postoperative complications occurring within 30 days of surgery. Risk factors significantly affecting the rate of postoperative complications were laparoscopic repair (OR 1.35, 95% CI 1.24–1.47) and open preperitoneal techniques (OR 1.31, 95% CI 1.15–1.49), with open anterior mesh as the reference category [10]. Other significant risk factors were general anesthesia (OR 1.30, 95% CI 1.23–1.37) and regional anesthesia (OR 1.53, 95% CI 1.43–1.63), with local

anesthesia as the reference category, emergency procedures (OR 1.53, 95% CI 1.43–1.63), recurrent hernia repair (OR 1.39, 95% CI 1.27–1.52), femoral hernia (OR 1.30, 95% CI 1.14–1.48), age older than 65 years (OR 1.26, 95% CI 1.21–1.31), and duration of surgery exceeding 50 min (OR 1.27, 95% CI 1.22–1.33) [10].

During the study period from 2002 to 2011, 133,074 open inguinal hernia repairs were registered in the Swedish Hernia Register. In the multivariate logistic regression analysis, a significantly increased risk for hemorrhage or hematoma within 30 days after surgery was seen for older patients, males, liver cirrhosis, peripheral vascular disease, and connective tissue disease ($p < 0.05$) [11]. High age (> 80 years), previous history of peripheral vascular disease, connective tissue disease, and male gender were risk factors for wound dehiscence ($p < 0.05$). Liver cirrhosis, chronic kidney disease, BMI > 25 , and male gender were associated with an increased risk for postoperative wound infection ($p < 0.05$) [11]. A significant increased risk for reoperation for superficial infection or bleeding was seen in patients with peripheral vascular disease and elderly patients ($p < 0.05$) [11].

In the Herniamed Hernia Register with 24,571 laparoscopic primary inguinal hernia repairs, a higher perioperative complication rate is observed in particular from age 80 years [12].

Influence of volume

In the Danish Hernia Database with 26,304 recorded groin hernia repairs (1998–2000), no difference in reoperation rates for recurrence was seen after comparison of participating centers ($n = 11$) at which more than 250 herniorrhaphies were done yearly (2.1%; 1.9–2.4) and of those ($n = 42$) at which fewer than 100 herniorrhaphies were done yearly (2.1%; 1.7–2.5) [13].

The analysis of the Danish Hernia Database with 87,840 patients (1998–2005) revealed that the nationwide Danish hernia collaboration with two annual meetings discussing own results and those of the other has led to more than 50% reduction in reoperation rates for recurrence [14].

Based on 86,409 patients in the Swedish Hernia Register (1996–2004), a significantly higher rate of reoperations for recurrence in surgeons who carried out one to five repairs a year than in surgeons who carried out more repairs could be proven [15].

The data of the Herniamed Hernia Register with 16,290 laparoscopic inguinal hernia repairs revealed that low-volume (< 25 repairs/year) surgeons had a

significantly higher recurrence rate compared to high-volume (≥ 25 repairs/year) surgeons (OR 1.494, CI 1.065–2.115; $p = 0.023$) [16].

A total of 14,532 laparoscopic repairs from the Danish Hernia Database for elective primary inguinal hernias were included for analysis. Centers reporting less than 50 laparoscopic procedures a year had a significantly higher cumulative reoperation rate for recurrence compared to centers reporting more than 50 procedures a year (9.97% vs. 6.06%; $p < 0.001$) [17].

Influence of operating time

The analysis of the Swedish Hernia Register with 123,917 primary groin hernia repairs (1998–2007) showed an RR of reoperations for recurrence of all patients operated on in less than 36 min, 26% higher than that of all patients with an operating time of more than 66 min (1.26, 95% CI 1.11–1.43). The authors concluded that the surgeon should avoid speed in hernia surgery and maintain thoroughness throughout the procedure [18].

Choice of anesthesia

From 1992 to 2001, 59,823 inguinal hernia repairs were recorded in the Swedish Hernia Register. The multivariate analysis showed that local anesthesia was associated with a significantly increased risk for reoperation for recurrence in primary inguinal hernia repair [19].

In the Danish Hernia Database with 43,123 patients (1998–2005) with Lichtenstein mesh repair, the analysis showed no overall difference in reoperation rate for recurrence (about 3.5% after 5 years), whether performed in local or general regional anesthesia, but reoperation rates for recurrence were about 50% higher when performed for a direct hernia than for an indirect hernia with the use of local anesthesia [20].

In the Danish Hernia Database from a total of 57,505 recorded elective open operations, 63.6% were performed in general anesthesia, 18.3% in regional anesthesia, and 18.1% in local anesthesia [21].

Complications after groin hernia repair were more frequent in patients 65 years and older (4.5%) compared to younger patients (2.7%; $p < 0.001$). In patients 65 years and older, medical complications were more frequent after regional anesthesia (1.17%) compared to general anesthesia (0.59%; $p = 0.003$) and urological complications were more frequent after regional anesthesia (0.87%) compared to local infiltration anesthesia (0.09%; $p = 0.006$). The

authors concluded that the use of regional anesthesia in elderly patients is not supported by existing evidence [22].

Mortality after emergency and elective inguinal and femoral hernia repair

Of 104,911 inguinal hernias in the Swedish Hernia Register, 5280 (5.1%) were treated emergently compared to 1068 (36.5%) of 2927 femoral hernias [23]. Femoral hernia operations comprised 1.1% of groin hernia operations on men and 22.4% of operations on women. After femoral hernia operations, the mortality risk was increased 7-fold for both men and women. Mortality risk was not raised above that of the background population for elective groin hernia repair, but it was increased 7-fold after emergency operations and 20-fold if bowel resection was undertaken [23].

Of 51,233 patients in the Danish Hernia Database, 1829 had an emergency operation (3.6%). The overall mortality rate after emergency groin hernia surgery was 147 of 1829 (8%) [24]. Deaths after emergency hernia surgery occurred in an elderly population (median age 83 years, range 54–97) with concomitant disease, where half of the cases were women and half of the cases suffered from femoral hernias [24].

Of 103,710 groin hernia operations (1992–2004) in the Swedish Hernia Register, 292 patients died within 30 days of surgery (0.28%) [25].

In the Swedish Hernia Register, 3980 femoral hernia repairs were registered, 1490 on men and 2490 on women. Also, 1430 (35.9%) patients underwent emergency surgery compared to 4.9% of the 138,309 patients with inguinal hernias [26]. Bowel resection was performed in 22.7% (325) of emergent femoral repairs and 5.4% (363) of emergent inguinal repairs. Women had a substantial overrisk for undergoing emergency femoral surgery compared to men (40.6% vs. 28.1%). An emergency femoral hernia operation was associated with a 10-fold increased mortality risk, whereas the risk for an elective repair did not exceed that of the general population. In elective femoral hernias, laparoscopic (HR 0.31, 95% CI 0.15–0.67) and open (HR 0.28, 95% CI 0.12–0.65) preperitoneal mesh techniques resulted in fewer reoperations for recurrence than suture repairs [26]. Therefore, femoral hernias should be operated with higher priority to avoid incarceration and be repaired with mesh [26].

Femoral hernias

A study of 34,849 groin hernia repairs from the Danish Hernia Database demonstrated a 15-fold greater incidence

of femoral hernia after inguinal herniorrhaphy compared to the spontaneous incidence [27]. These femoral recurrences occurred earlier than inguinal recurrences, suggesting that they were possibly femoral hernias overlooked at the primary operation [27].

Between 1992 and 2003, the Swedish Hernia Register included 6895 groin hernia repairs in women and 83,753 in men. A higher proportion of emergency operations were carried out in women (16.9%) than men (5.0%), leading to bowel resection in 16.6% and 5.6%, respectively [28]. During reoperation for recurrence, femoral hernias were found in 41.6% of the women who were diagnosed with a direct or indirect inguinal hernia of the primary operation. The corresponding proportion for men was 4.6% [28].

In the Danish Hernia Database from 1998 to 2003, 3696 femoral inguinal hernia repairs were recorded. The overall reoperation rate for recurrence was 4.3%, which was slightly higher compared to male inguinal herniorrhaphies with 3.1% ($p=0.001$) [29]. The reoperation rate for recurrence was independent of the type of surgical repair. In 41.5% of the reoperations for recurrence, a femoral hernia was found compared to 5.4% in males. The frequent finding of a femoral hernia at reoperation for recurrence suggests the need for the exploration of the femoral canal at the primary operation [29].

A total of 1967 individuals recorded in the Swedish Hernia Register operated on for a femoral hernia (1997–2006) were sent a questionnaire on symptoms, experience, and contact with the healthcare system before surgery for their femoral hernia [30]. Patients who had elective femoral hernia surgery and patients who had emergency femoral hernia surgery differ in previous symptoms and healthcare contacts. Patients who need emergency surgery are often unaware of their hernia and frequently completely asymptomatic before incarceration. Early diagnosis and expedient surgery are warranted, but the lack of symptoms hinders earlier detection and intervention in most cases [30].

A total of 3970 primary femoral hernia repairs recorded in the Danish Hernia Database (1998–2012) were analyzed. Also, 27.3% of the femoral hernias occurred in men [31]. There were 2413 elective repairs (60.8%) and 1557 emergency procedures (39.2%). In a multivariate analysis, laparoscopic repair was found to result in a reduced risk of reoperation for recurrence (HR 0.33, 95% CI 0.09–0.95) compared to open repair. The risk of reoperation for recurrence was higher in women (HR 1.95, 95% CI 1.10–3.45). Thus, laparoscopic repair of a femoral hernia reduces the risk of reoperation for a recurrence compared to open repair [31].

From a total of 5893 females in the Danish Hernia Database with primary elective inguinal hernia repair, 305 developed a recurrence (5.2%), 61% inguinal recurrence, 38% femoral recurrence, and 1% no recurrence. All femoral recurrences occurred after previous open anterior operation [32].

An inguinal pain questionnaire was sent to 1967 patients recorded in the Swedish Hernia Register (1994–2006), who had a repair for primary unilateral femoral hernia [33]. Some degree of pain during the previous week was reported by 24.2% of the patients. Pain interfered with daily activities in 5.5% of the patients [33]. Emergency surgery (OR 0.54, 95% CI 0.40–0.74) and longer time since surgery (OR 0.93, 95% CI 0.89–0.98 for each year added) were associated with a lower risk for chronic postoperative pain, whereas a higher level of preoperative pain was associated with a higher risk for chronic pain (OR 1.17, 95% CI 1.10–1.25). Surgical technique was not found to influence the risk for chronic pain in multivariate logistic regression analysis [33]. In contrast to inguinal hernia surgery, no risk factor related to surgical technique was found.

Perioperative outcome of inguinal hernia repair

In the Swedish Hernia Register, 143,042 patients, 8% women and 92% men, were registered between 2002 and 2011. Intraoperative complications that occurred in 801 repairs (0.56%), 592 patients (0.41%) suffered from cardiovascular events and 284 (0.20%) suffered from a severe surgical event within 30 days of groin hernia surgery [34]. Emergency operation was a risk factor for both cardiovascular and severe surgical adverse events [34]. In men, bilateral hernia and sliding hernia approximately doubled the risk for severe surgical events [34]. Methods other than open anterior mesh repair increased the risk for surgical complications [34].

In the Herniated Hernia Register, a significant difference was noted in the rate of postoperative complications occurring within 30 days, which was 4.9% for bilateral inguinal hernia repair in transabdominal preperitoneal (TAPP) technique compared to 3.9% for unilateral inguinal hernia ($p=0.009$) [35]. The postoperative complications necessitated reoperation in 0.9% of the patients after unilateral inguinal hernia repair and in 1.9% of the patients after bilateral inguinal hernia repair, thus attesting to the significantly higher risk presented by bilateral inguinal hernia repair ($p<0.001$) [35].

For total extraperitoneal (TEP) inguinal hernia repair, a greater probability of reoperation for complications

(0.82% for unilateral TEP vs. 1.78% for bilateral TEP; $p < 0.001$) in the unadjusted analysis was also confirmed in the multivariable model (OR 2.35, 95% CI 1.504–3.322; $p = 0.001$) [36].

The analysis of 17,594 patients from the Hernia-med Hernia Register revealed that open recurrent repair compared to open primary operation in inguinal hernia repair is a significant risk factor for higher intraoperative ($p = 0.01$) and postoperative ($p = 0.05$) complication rates, recurrence rates ($p < 0.001$), and pain rates ($p < 0.001$) [37].

In 20,624 patients from the Hernia-med Hernia Register, there were significant differences comparing endoscopic repair of primary versus recurrent male unilateral inguinal hernias in the postoperative complication rates (3.20 vs. 4.03%; $p = 0.036$), reoperation rate due to complications (0.84 vs. 1.33%; $p = 0.023$), pain at rest (4.08 vs. 6.16%; $p < 0.001$), pain on exertion (8.03 vs. 11.44%; $p < 0.001$), chronic pain requiring treatment (2.31 vs. 3.83%; $p < 0.001$), and recurrence rates (0.94 vs. 1.45%; $p = 0.0023$) [38].

In the comparison of TAPP vs. TEP in 17,587 patients from the Hernia-med Hernia Register, the intraoperative and general postoperative complication rates as well as the reoperation rates for complications show no significant differences. A higher postoperative complication rate for TAPP, which could be managed conservatively, is partly explained by larger defect sizes, more scrotal hernias, and older age [39].

The comparison of 10,555 Lichtenstein operation with 6833 TEP procedures from the Hernia-med Hernia Register show in the multivariable analysis benefits for the TEP as regards the postoperative complication rate ($p < 0.001$), pain at rest rate ($p = 0.011$), and pain on exertion rate ($p < 0.001$) [40].

Of the 82,911 patients enrolled in the Hernia-med Hernia Register who had undergone inguinal hernia repair, 9115 (11%) were operated on while receiving antithrombotic therapy or with existing coagulopathy. The rate of postoperative secondary bleeding, at 3.91%, was significantly higher in the risk group with coagulopathy or receiving antithrombotic therapy than in the group without that risk profile at 1.12% ($p < 0.001$). Multivariable analysis revealed other influence variables that, in addition to coagulopathy or antithrombotic therapy, had a relevant influence on the occurrence of postoperative bleeding. These were open operation, higher age, higher ASA score, recurrence, male gender, and large hernia defect [41].

The analysis of 48,201 endoscopic and 36,832 open inguinal hernia repairs from the Hernia-med Hernia Register did not identify any significant influence of antibiotic

prophylaxis on postoperative surgical site occurrences for the endoscopic approach but not for the open approach [42]. Antibiotic prophylaxis should be administered for open inguinal hernia repair [42].

Mesh fixation in inguinal hernia repair

An analysis of 8314 laparoscopic groin hernia repairs from the Danish Hernia Database with mesh fixation using tackers ($n = 7530$) or fibrin sealant ($n = 784$) showed a significantly lower reoperation rate for the fibrin sealant than for the tacks (0.89 vs. 2.94%; $p = 0.031$) [43].

In a median follow-up time of 31 months, 1535 patients enrolled in the Danish Hernia Database after a TAPP inguinal hernia repair returned a questionnaire, showing no significant difference in the reoperation for recurrence rate with meshes fixed with fibrin sealant compared to tacks [44].

The data of 11,228 TAPP procedures from the Hernia-med Hernia Register did not show any significant difference in the recurrence rate with fixation in 7422 patients (0.88%) versus no fixation in 3806 patients (1.1%; $p = 0.259$). Multivariable analysis of all potential influence factors (age, ASA, BMI, risk factors, defect size, mesh fixation, localization of defect, and mesh size) did not identify any factor that impacted recurrence on 1-year follow-up. Only for medial and combined defect localization versus lateral localization was a highly significant effect identified ($p < 0.001$) [45]. With mesh fixation in the medial inguinal hernia group, it is possible to significantly reduce the recurrence rate with mesh fixation. Between the various fixation techniques (tacker, glue, suture, and combination), there was no significant difference in the recurrence rate [45].

Patients ($n = 1110$) enrolled in the Swedish Hernia Register were included in a questionnaire concerning recurrence after TEP inguinal hernia repair. Recurrent operation was carried out in 1.4% during 7.5 years of follow-up, with no difference between permanent fixation and no fixation or nonpermanent fixation [46].

In addition, 82,015 Lichtenstein inguinal hernioplasties with sutured mesh fixation were enrolled from 2002 to 2009 in the Swedish Hernia Register. There was no significant difference in risk for reoperation for recurrence after mesh fixation with standard nonabsorbable sutures (RR 1) or long-term absorbable sutures (RR 1.12, 95% CI 0.81–1.55; $p = 0.49$). Short-term absorbable sutures, however, more than doubled that risk (RR 2.23, 95% CI 1.67–2.99; $p < 0.001$). Short-term absorbable sutures should therefore be avoided in Lichtenstein inguinal hernia repair [47].

In a study of 2095 patients from the Herniated Hernia Register with Lichtenstein inguinal hernia repair using self-gripping meshes, 816 (38.95%) received an additional suture fixation and 1279 (61.05%) received no additional fixation. No difference could be observed in terms of post-operative complications, chronic pain requiring treatment, and recurrence rates [48].

Methods of follow-up

Prospective data were retrieved from the Swedish Hernia Register of patients with groin hernia repair in 1994. The objective of this study was to evaluate recurrence rate and chronic groin pain 3 years after hernia repair and to validate a postal questionnaire with selective physical examination as a method of follow-up. Three years after operation, patients were mailed a three-item questionnaire and invited to have a physical examination. Those examined answered a detailed questionnaire about pain and functional impairment. Depending on the definition of recurrence, the rate varied between 10% and 15%. Eighteen percent of the patients reported groin pain at follow-up [49]. Thus, participation in a register and follow-up by a three-item questionnaire and selective physical examination provide a solid basis for quality control [49].

Recurrence

In the Herniated Hernia Register, 18,774 inguinal hernia recurrent operations (2009–2015) were recorded. Only 57% of all recurrences occurred within 10 years of the previous inguinal hernia operation. Some of the remaining 43% of all recurrences occurred only much later, even after more than 50 years [50].

The overall recurrence rate in a 5-year period of 142,578 inguinal hernia repairs recorded in the Swedish Hernia Register was 4.3%. Multivariate analysis showed that recurrence after surgery for recurrent hernia occurred relatively early ($p < 0.05$). Recurrence also appeared early if postoperative complications were registered ($p < 0.05$; 51). Recurrence after suture repair or laparoscopic repair appeared relatively early compared to recurrence after open mesh repair ($p < 0.05$). In a separate analysis, a relatively higher risk for early recurrence was seen for all sutured repairs compared to all mesh repairs ($p < 0.05$) [51].

Between 1992 and 2000, 46,745 hernia repairs were recorded in the Swedish Hernia Register. Of these, 18,057 repairs were performed with open nonmesh methods and included in the analysis. Using nonabsorbable suture as

reference, the RR of reoperation for recurrence after repair with early absorbable suture and later absorbable suture was 1.50 (95% CI 1.22–1.83) and 1.03 (95% CI 0.83–1.28), respectively. Using the Shouldice repair as reference, other sutured repairs were associated with a significantly higher RR of reoperation for recurrence (1.22, 95% CI 1.03–1.44) [52].

In 13,674 primary inguinal hernia repairs collected in the Danish Hernia Database with an observation interval of 5 years or more, the risk of reoperation for recurrence after Lichtenstein repair was a quarter of that after sutured repair (HR 0.25, 95% CI 0.16–0.40) for 60–96 months after surgery [53]. After 5 years, the reoperation rate for recurrence increased continuously after sutured repair but not after mesh repair [53].

In the Danish Hernia Database from 1998 to 2005, 3181 men between ages 18 and 30 years with a primary repair of a primary indirect inguinal hernia were included [54]. A primary sutured repair was performed in 1120 men (median age 23 years, range 18–30) and a Lichtenstein mesh repair in 2061 young men (24 years, range 18–30). The observation time after sutured repair was median 62 months (range 0–96) and 41 months (range 0–96) after a Lichtenstein repair. Reoperation rate for recurrence after sutured repair was almost three-fold as high (3.5%) compared to a Lichtenstein repair (1.2%; $p = 0.0003$) [54].

In the Swedish Hernia Register, surgeons documented whether the indirect sac was managed by division leaving the distal part in place, excision on invagination [55]. An indirect hernia was found in 48,433 operations. The sac was excised in 49.5%, invaginated in 37.6%, and divided in 12.9% of the operations. For indirect hernia repair, the RR for reoperation for recurrence was 0.63 (95% CI 0.51–0.79) for excision of the sac and 0.72 (95% CI 0.53–0.99) for division compared to invagination. Therefore, the excision of the indirect hernia sac in inguinal hernia repair is associated with a lower risk of hernia recurrence than division or invagination [55].

In the Swedish Hernia Register in the years 1992–1999, 33,416 unilateral and 1487 bilateral operations on 2974 groin hernias were recorded. A laparoscopic method was used for 1774 (60%) of bilateral repairs and 3285 (10%) unilateral repairs ($p < 0.0001$) [56]. The cumulative incidence of reoperation for recurrence at 3 years for groin hernias after bilateral and unilateral repair was 4.1% (95% CI 3.1–5.1) and 3.4% (95% CI 3.1–3.7), respectively. After adjustment for other risk factors, the OR for reoperation for recurrence after bilateral repair was 1.2 (95% CI 0.9–1.5) with unilateral repair as reference. The OR for reoperation after laparoscopic bilateral repair compared to open bilateral repair was 0.9 (95% CI 0.6–1.4). Thus, the simultaneous repair of

bilateral hernias does not increase the risk of reoperation for recurrence and there is no significant difference in the risk of reoperation for recurrence after bilateral repair using open or laparoscopic techniques [56].

Among the 85,314 male patients in the Danish Hernia Database with an elective primary inguinal hernia repair (56% indirect, 44% direct), the overall reoperation rate for recurrence was 3.8% [57]. Direct inguinal hernias resulted more often in reoperation for recurrence than indirect inguinal hernias (5.2% vs. 2.7%; $p < 0.001$). Direct inguinal hernia repair resulted in a greater risk of reoperation for recurrence than indirect inguinal hernia repair [57].

From 1996 to 1998, 17,985 groin hernia operations were recorded in the Swedish Hernia Register, 15% for recurrent hernia and 85% for primary hernia. At 24 months, the risk for having had a reoperation for recurrence was 4.6% after recurrent hernia repair and 1.7% after primary hernia repair [58].

In a cohort study based on the Danish Hernia Database, 4344 recurrent inguinal hernia repairs showed that a Lichtenstein recurrent operation after a previous Lichtenstein primary operation had a significant higher re-operation rate than a laparoscopic recurrent operation after a previous Lichtenstein primary operation (crude rate 8.7 vs. 3.1%; $p < 0.0005$; HR 2.46, 95% CI 1.76–3.43) [59].

Altogether, 174,527 hernia operations were recorded in the Swedish Hernia Register between 1992 and 2008, including 19,582 reoperations for recurrence (11.2%). The preceding repair was included in the register for 5565 of these recurrent repairs [60]. With laparoscopic repair as reference, the HR for re-recurrence after recurrent repair was 2.55 (95% CI 1.66–3.93) after sutured repair, 1.53 (95% CI 1.20–1.95) after Lichtenstein repair, 2.31 (95% CI 1.76–3.03) after plug repair, and 1.36 (95% CI 0.95–1.94) after open preperitoneal mesh repair. The laparoscopic and open preperitoneal mesh methods of repair for recurrent groin hernias were associated with the lowest risk of reoperation for re-recurrence [60].

In the Swedish Hernia Register between 1992 and 2006, there were 12,104 recurrent cases of inguinal hernia repaired once, two repairs in 4199 cases, three repairs in 310 cases, four repairs in 32 cases, and five repairs in 3 cases [61]. The risk for further reoperation increased with the number of previous repairs ($p < 0.001$). The difference in the HR for reoperation between Lichtenstein repair and laparoscopic repair was significant for the first two repairs ($p < 0.05$). Laparoscopic preperitoneal repair provides the best surgical outcome in repeated groin hernia recurrence [61].

In the Danish Hernia Database, the cumulated re-operation rate after primary Lichtenstein repair ($n = 1124$) was significantly reduced after laparoscopic

operation for recurrence (1.3%, 95% CI 0.4–3.0) compared to open repairs for recurrence (Lichtenstein 11.3%, 95% CI 8.2–15.2; nonmesh 19.2%, 95% CI 14.0–25.4). The authors concluded that laparoscopic repair is recommended for reoperation for recurrence after primary open Lichtenstein repair [62].

From 7371 reoperations for recurrence in the Danish Hernia Database, 1883 (26%) were performed at a different healthcare facility [63]. One in four patients underwent repair for recurrent inguinal hernia at a different facility than the prior repair [63].

TEP was the chosen operation in 737 of 2236 recurrent inguinal hernias after Lichtenstein operation in the Swedish Hernia Register. The most likely location for a recurrence was the same as the primary operation [64].

Chronic groin pain

In a postal questionnaire study of 2456 patients from the Swedish Hernia Register, 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 [65].

A questionnaire concerning postherniorrhaphy pain in 2583 patients from the Swedish Hernia Register revealed that factors associated with an increased risk of residual pain were age below median, operation for recurrence, open repair technique, history of preoperative pain, and less than 3 years from surgery [66].

A questionnaire study of 952 patient from the Swedish Hernia Register showed that both preoperative pain and pain in the immediate postoperative period are strong risk factors for chronic groin pain [67].

All 195,707 repairs registered in the Swedish Hernia Register between 1999 and 2011 were included in a study. Of these, 28,947 repairs were excluded as they registered as procedure on the same patient after a previous repair [68]. Age, gender, hernia anatomy, method of repair, and postoperative complications were included in the analysis [68]. Risk factors for being reoperated for pain were age median, female gender, direct hernia, Lichtenstein repair, plug repair, bilateral repair, and postoperative complication [68].

In the 2-month period between February 1, 1998 and March 31, 1998, 1652 patients were registered in the Danish Hernia Database as having undergone surgery for an inguinal or femoral hernia and 1443 questionnaires were mailed. Pain in the groin area was reported by 28.7%, and 11.0% reported that pain was interfering with work or leisure activity. Older patients had a lower incidence of

pain. There were no differences in the incidence of pain with regard to the different types of hernia, different types of surgical repair, or different types of anesthesia [69].

In a postal questionnaire study carried out within the Danish and Swedish Hernia Database Collaboration, some 2612 patients responded (response rate 80.9%), of whom 1250 had undergone a Lichtenstein, 630 a Shouldice, and 732 a Marcy repair [70]. Chronic pain had been experienced within the previous month by 22.9% of the patients who responded. There was an overall decrease in pain with time, from 29.7% at 6–12 months to 18.1% at 37–48 months after surgery, with no overall differences between the three types of repair. Pain was more common in patients younger than 40 years [70].

Consecutive unilateral, first and second recurrent inguinal hernia repairs, registered between 1998 and 2007 in the Swedish Hernia Register, were included. Follow-up was performed in 2009 based on the inguinal pain questionnaire and selective clinical examination [71]. Altogether, 671 first recurrent repairs were analyzed: 329 anterior mesh repairs, 161 endoscopic and 181 open posterior mesh repairs. If the index repair was anterior, the endoscopic posterior mesh repair was associated with a lower risk of chronic pain and disability compared to anterior mesh repair (OR 0.54, 95% CI 0.30–0.97; $p=0.039$). The risk of chronic pain increased after a second recurrent repair. Thus, endoscopic repair, for the first recurrent groin hernia surgery, after an index anterior repair, was associated with less chronic pain. Chronic pain increased after a second recurrent repair [71].

All patients who had undergone surgery for persistent pain after previous groin hernia surgery from 1999 to 2006 were identified in the Swedish Hernia Register ($n=237$). There was no significant difference in outcome between mesh removal and the removal of sutures at the tubercle or interventions aimed at the ilioinguinal nerve in 95 males and 16 females [72]. Decrease in pain was reported by 69 patients (62%), no change in pain by 21 patients (19%), and increase in pain in 21 patients (19%) [72].

Sexual dysfunction

A nationwide detailed questionnaire study of pain-related sexual dysfunction in all men ages 18–40 years undergoing inguinal herniorrhaphy between 2002 and 2003 ($n=1015$) based on the nationwide Danish Hernia Database was performed. Combined frequent and moderate to severe pain from the previous hernia site during activity was reported by 18.4%. Pain during sexual activity was reported by 22.1% of the patients, of which 6.7%

had moderate or severe pain occurring every third time or more. Genital or ejaculatory pain was found in 12.3%, and 2.8% patients reported that the pain impaired their sexual activity to a moderate or severe degree [73].

In a prospective study, a questionnaire was sent by mail to a group of 376 men ages 18–55 years, who had undergone bilateral mesh repair, as identified in the Swedish Hernia Register. The results of this prospective study in men do not support the hypothesis that bilateral inguinal hernia repair with alloplastic mesh prosthesis causes male infertility at a significant greater rate than those operated without mesh [74].

Men born between 1950 and 1989, with a hernia repair registered in the Swedish Hernia Register between 1992 and 2007, were cross-linked with all men in the same age group with the diagnosis of male infertility according to the Swedish National Patient Register [75]. Overall, 34,267 men were identified with a history of at least one inguinal hernia repair. A total of 233 (0.7%) of these had been given the diagnosis of male infertility after their first operation. Any difference was not found between expected and observed cumulative incidences of infertility in men operated with hernia repair. Men with bilateral hernia repair had a slightly increased risk for infertility when mesh was used on either side. However, the cumulative incidence was less than 1%. Thus, inguinal hernia repair with mesh is not associated with an increased incidence of, or clinically important risk for, male infertility [75].

A study population of the Danish Hernia Database comprised all men ages 18–50 years ($n=1671$), who underwent primary laparoscopic herniorrhaphy between 1998 and 2009. Questionnaires regarding dysejaculation and pain during sexual activity were mailed 3 months to 12 years after surgery, and 1172 patients were included for analysis. The response rate was 68.7% ($n=805$). Dysejaculation occurring after laparoscopic repair was present in 3.1%. Pain from the groin or genitals during sexual activity was reported by 10.9% of the patients, and 2.4% reported that the pain had impaired their sexual activity to a moderate or severe degree. Older patients and patients with longer follow-up had lower prevalence of pain during sexual activity [76].

Using the Danish Hernia Database, patients operated laparoscopically for groin hernia with a TAPP procedure with fibrin sealant or tacks for mesh fixation were sent a questionnaire regarding sexual dysfunction. Pain during sexual activity was present in 115 of 1019 (11.3%) males and 17 of 147 (11.6%) females. There was no difference between fibrin sealant and tacks for mesh fixation and no difference between genders. Pain intensity, characteristics, and origin were comparable between fibrin sealant

and tacks for both genders. A relationship was found between a higher rate of sexual dysfunction and lower age for both genders [77].

Intestinal obstruction

The Swedish Hernia Register with 33,275 patients operated on for single primary unilateral groin hernia for the period 1992–2000 was linked to the Swedish Inpatient Register and the Swedish Death Register for the period 1987–2000 [78]. The risk of postoperative intestinal obstruction was low, which was 1.02 per 1000 person-years. The highest adjusted RRs were found in patients with previous admissions for abdominal inflammation or operations. The RR was 2.79 (95% CI 1.01–7.42) after TAPP and 0.57 (95% CI 0.07–4.33) after TEP compared to patients operated on by the Lichtenstein method. None of the patients undergoing open hernia operations had a significantly increased risk. TAPP increased the risk of postoperative intestinal obstruction, but other risk factors, especially previous abdominal surgery or inflammation, have greater influence [78].

Conclusion

RCTs and meta-analyses are the gold standard in evidence-based medicine. Several key questions in hernia surgery have not been answered so far by RCTs and will probably not be in the future either. Besides, data are needed to confirm that the findings from RCTs and meta-analyses can also be implemented in routine practice. This applies, in particular, to the growing proportion of elderly and multimorbid patients undergoing hernia surgery. The present review based on three European hernia registers demonstrates the range of insightful findings that can be gleaned from multi-institutional prospective observational studies. Many of these findings have also been integrated into the various guidelines on inguinal hernia repair [79–84]. It can therefore be stated with certainty that, for scientific evaluation of inguinal hernia surgery, RCTs and register-based observational studies are partners in the evolution of medical evidence [1].

Author Statement

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Ethical approval: The conducted research is not related to either human or animals use.

Author Contributions

Ferdinand Köckerling: Data analysis; Writing of the manuscript; Approval of the manuscript.

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Supplemental Material: The article (DOI: 10.1515/iss-2016-0206) offers reviewer assessments as supplementary material.

Reviewer Assessment

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Ferdinand Köckerling*

Data and outcome of inguinal hernia repair in hernia registers – a review of the literature

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Reviewers' Comments to Original Submission

Reviewer 1: anonymous

Dec 14, 2016

Reviewer Recommendation Term:	Accept
Overall Reviewer Manuscript Rating:	90
Custom Review Questions	Response
Is the subject area appropriate for you?	5 - High/Yes
Does the title clearly reflect the paper's content?	5 - High/Yes
Does the abstract clearly reflect the paper's content?	5 - High/Yes
Do the keywords clearly reflect the paper's content?	5 - High/Yes
Does the introduction present the problem clearly?	4
Are the results/conclusions justified?	5 - High/Yes
How comprehensive and up-to-date is the subject matter presented?	5 - High/Yes
How adequate is the data presentation?	5 - High/Yes
Are units and terminology used correctly?	5 - High/Yes
Is the number of cases adequate?	5 - High/Yes
Are the experimental methods/clinical studies adequate?	4
Is the length appropriate in relation to the content?	5 - High/Yes
Does the reader get new insights from the article?	5 - High/Yes
Please rate the practical significance.	5 - High/Yes
Please rate the accuracy of methods.	5 - High/Yes
Please rate the statistical evaluation and quality control.	5 - High/Yes
Please rate the appropriateness of the figures and tables.	N/A
Please rate the appropriateness of the references.	5 - High/Yes
Please evaluate the writing style and use of language.	5 - High/Yes
Please judge the overall scientific quality of the manuscript.	5 - High/Yes
Are you willing to review the revision of this manuscript?	Yes

Comments to Authors:

This is an excellent review based on hernia registries. It can be assumed that the presented data are even more important than results from RCTs because registry data reflect the clinical routine outside of clinical trials. Surgeons involved in hernia treatment should be aware of the results of the presented registries.

Reviewer 2: anonymous

Dec 28, 2016

Reviewer Recommendation Term:	Accept
Overall Reviewer Manuscript Rating:	92
Custom Review Questions	Response
Is the subject area appropriate for you?	5 - High/Yes
Does the title clearly reflect the paper's content?	5 - High/Yes
Does the abstract clearly reflect the paper's content?	5 - High/Yes
Do the keywords clearly reflect the paper's content?	5 - High/Yes
Does the introduction present the problem clearly?	5 - High/Yes
Are the results/conclusions justified?	4
How comprehensive and up-to-date is the subject matter presented?	5 - High/Yes
How adequate is the data presentation?	4
Are units and terminology used correctly?	5 - High/Yes
Is the number of cases adequate?	5 - High/Yes
Are the experimental methods/clinical studies adequate?	5 - High/Yes
Is the length appropriate in relation to the content?	5 - High/Yes
Does the reader get new insights from the article?	5 - High/Yes
Please rate the practical significance.	5 - High/Yes
Please rate the accuracy of methods.	4
Please rate the statistical evaluation and quality control.	5 - High/Yes
Please rate the appropriateness of the figures and tables.	N/A
Please rate the appropriateness of the references.	5 - High/Yes
Please evaluate the writing style and use of language.	5 - High/Yes
Please judge the overall scientific quality of the manuscript.	5 - High/Yes
Are you willing to review the revision of this manuscript?	Yes

Comments to Authors:

The author presents in this excellent review important data referring to hernia registers. Even though RCTs are indispensable for medical evidence these results from registers clearly contain a high practical relevance for surgeons dealing with hernia repair techniques.
