



Optimizing outcomes after hernia repair: scientific highlights from the Danish Hernia Database 2010–2020

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Abstract: The National Danish Inguinal Hernia Database (1997) and Ventral Hernia Database (2007), together the Danish Hernia Database, was launched to monitor and optimize surgical quality and outcomes after hernia repairs. The purpose of the present qualitative review was to present five “highlight” publications from the 123 published/in press (October 2020) original publications from the Danish Hernia Database. Two international hernia experts independently nominated 10 publications from the Database publication list published between 2010 and 2020. Each of the 10 members of the database steering group ranked the 10 publications according to the following three categories: (I) originality, (II) methodology, and (III) clinical impact. The publications were ranked as 1= good, 2= very good, 3= outstanding. The five publications with the highest score were depicted as highlights. The publications dealt with: (I) long-term mesh-related complications after incisional hernia repair, (II) outcomes after parastomal hernia repairs, (III) mesh or suture repair of ventral hernias in women having subsequent pregnancy, (IV) reoperation for recurrence versus clinical recurrence rates, and (V) recurrence rates after resorbable versus non-resorbable tackers for laparoscopic ventral hernia repair. Data from the Danish Hernia Database is internationally acknowledged. The nationwide Danish data supplements the higher-ranking evidence by randomized controlled trials (RCTs) by adding evidence-based answers to scientifically clinically relevant questions. The Danish Hernia Database is still active after more than 20 years.

Keywords: Hernia; surgery; laparoscopic; repair; operation; review; database; registry

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Introduction

Internationally, there has been an increasing effort from national large-scale hernia registries to improve surgical quality in the treatment of ventral and inguinal hernia disease. It is generally accepted that the Swedish Hernia Registry, Herniamed, European Registry for Abdominal Wall Hernias (EuraHS), Club Hernie (France), the Spanish

Register of Incisional Hernia (EVEREG), the Abdominal Core Health Quality Collaborative (ACHQC), and the Danish Hernia Database have substantially contributed to guide hernia surgeons in their daily surgical practice to improve patient outcome. Also, hernia registries have a proven and significant potential for a future imperative of marketing surveillance for manufacturers of meshes, fixation devices etc. (1,2).

Traditionally, registry data are regarded low-ranged in the evidence pyramid likely to reflect daily surgical practice (high external validity) and therefore difficult to replicate 100%. In contrast, the higher evidence-rated, randomized controlled trials (RCTs) are methodologically difficult and can be repeated if performed under the same conditions (high internal validity) but the studies are often designed for a limited group of patients in order to obtain sufficient statistical power (3). RCTs have strong potential for verifying new perioperative strategies based on a hypothesis raised by for example registry data. The nature of a national or regional clinical database including thousands of operations allows long-term follow-up to monitor small changes in e.g., recurrence rates and rare (but dangerous) complications using different surgical techniques.

The purpose of the present qualitative review was to present five so-called “highlight” publications from the Danish Hernia Database within the last 10 years. Characteristics of the Danish Hernia Database will briefly be explained and the highlight paper selection process will be described. The highlight publications will be presented with focus on study motivation, originality, methodology, and clinical impact. Thus, the present review is not meant to be a critical evidence-based systematic review of the entire hernia literature but purely a presentation of the academic activity in the Danish Hernia Database.

The Danish Hernia Database

The Danish Inguinal Hernia Database was launched in 1997 (4,5) and was followed by the Ventral Hernia Database in 2007 (6,7) (the Danish Hernia Database). The Swedish Hernia Registry and the Danish Hernia Database are the only national registries. In the Danish Hernia Database, the participation is governed by public decrees to register (8). For various reasons, the registration rate varies per year in the range 80–95% (7,9). Several intraoperative variables are registered and a near to 100% follow up and validation is secured by merging data with the National Patient Registry (7,9). The Database contains a total of 181,715 and 60,232 inguinal and ventral hernia repairs, respectively (31 December 2019). Laparoscopic repairs accounts for 22% and 26% of all the inguinal and ventral hernia repairs, respectively. The database only includes all Danish patients (≥ 18 years) undergoing elective or emergency hernia repair. During the 23 years of the database existence, a total of 123 peer reviewed papers (October 2020) with original data from the registry have been published [115 published/

in press (72 and 42 with inguinal and ventral hernia focus, respectively) and 11 manuscripts are currently submitted (October 2020)] (*Figure 1*).

The five highlight publications

The highlight publications contained database results after either laparoscopic alone or laparoscopic data in combination with open repair.

Studies were selected from the Danish Hernia Database publication list (www.herniedatabasen.dk) from a 10-year period (2010–2020). The selection criteria were not restricted to publications in high-impact scientific journals or publications with an optimal study design. To minimize the risk of bias the following selection strategy was used: two international hernia experts (outside the selection committee and database steering board) independently nominated 10 publications from the 10-year publication list. The selection criteria were based on subjective assessment and founded on originality, methodological strength, and clinical impact. The final selection of the 10 publications was obtained after consensus. Then the 10 individual members of the database steering group ranked the 10 publications according to following three categories: (I) originality, (II) methodology, and (III) clinical impact using the ranking 1= good, 2= very good, 3= outstanding. Thus, the five publications with the highest score were depicted as highlights. If there were equal points among the highest scoring publications, lots were drawn

Reference (10)

Motivation

Incisional hernia repair is among the most common surgical procedures performed (11,12). Nevertheless, evidence for long-term mesh-related complications was not available.

Originality

This was the first and so far, the only published study, presenting long-term national outcome results on mesh complications and/or operation for recurrence.

Method

Four years of data from the Danish Hernia Database were merged with a manual review of patient records and the National Health Registry. The median follow-up period was 5 years with a 100% follow-up with repair for recurrence and mesh-related surgical complications.

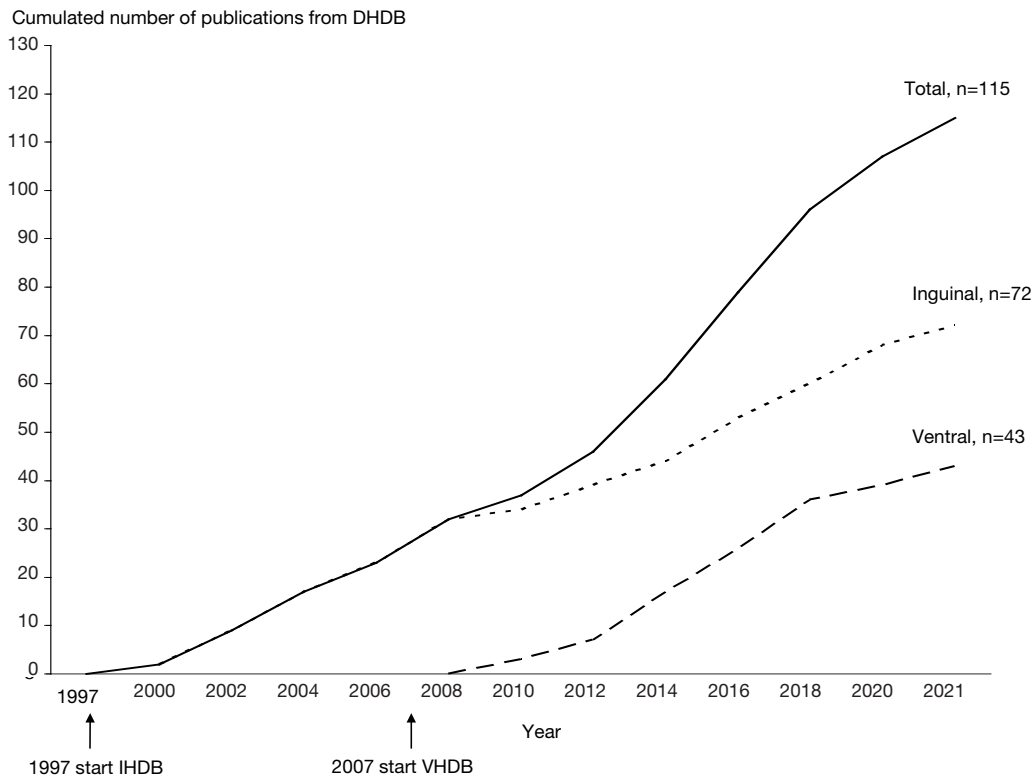


Figure 1 Peer reviewed inguinal and ventral hernia publications from the DHDB from 1997 to September 2021. Publications from 2021 are all in press. DHDB, Danish Hernia Database; IHDB, Inguinal Danish Hernia Database; VHDB, Ventral Hernia Database.

Clinical impact and discussion

This study is one of the most cited studies from the Danish Hernia Database. The study identified that 4–5% of patients with a mesh reinforced hernia repair over time undergo surgery for a mesh complication. Overall complication rates after laparoscopic repair were lower, but considered more serious than after open mesh repairs. The progressively increasing rate of serious mesh-related complications is partially offset by recurrence benefits from mesh reinforcement. The study also found that up to 20% of patients end up being operated on for recurrence and that recurrences can be reduced by approximately 50% if a mesh is used. Regardless of technique, the risk of recurrence continued to appear almost linearly throughout the 5-year follow-up period. Until recently, this was the only study published about long-term mesh-related complications. Since then another study based on data from the Danish Hernia Database has identified complications related to a specific mesh (1). The results were not based on randomized data and selection bias and imbalance between the groups in terms

of patient related risk factors such as diabetes, smoking and BMI at baseline could not be fully controlled for (1,13). The study highlighted the importance of long-term follow-up and the huge potential of the national registry design.

In conclusion long-term follow-up seems mandatory to evaluate important outcome measures after incisional hernia repair.

Reference (14)

Motivation

At the time of publication, data on parastomal hernia repair were few and highly heterogenic including a maximum of 72 patients (15,16).

Originality

Nationwide consecutive data on 174 patients with a parastomal hernia repair were identified. This resulted in the largest study to date on outcomes after parastomal hernia repair.

Method

Patients receiving an emergency or elective primary parastomal hernia repair by open or laparoscopic technique were included. The primary outcome was 30-day surgical complications and mortality.

Clinical impact and discussion

Parastomal hernia repair was associated with a high risk (17%) of early reoperation and mortality. Emergency repair was a high-risk procedure with a mortality rate of 25% within 30 days of the repair. Centers with more than four procedures per year had significantly better results compared with centers performing four or less procedures. Repair of parastomal hernia is associated with a considerable risk, especially after emergency repair. After publication of this study, it was decided in Denmark to restrict parastomal hernia repair to five specialized hernia centers performing both elective and emergency repairs in order to improve the quality of parastomal hernia repairs. The current study was the first to evaluate nationwide data on parastomal hernia repairs and reported that parastomal hernia repair is a procedure associated with a high risk of morbidity and mortality and with worst outcomes in low-volume centers. A limitation of the study was, although the largest at the time of publication, the relatively small number of included patients and that the primary outcome was based on a composite score. Studies published shortly after including a large database study from the US and a meta-analysis reported morbidity rates after parastomal hernia repairs between 12–17% (17,18). The mortality rates were similar in the laparoscopic and open groups and were significantly lower than in the Danish study. Emergency results were not reported.

In conclusion, parastomal hernia repair is a high-risk procedure and results may improve if treatment is restricted to high-volume centers.

Reference (19)

Motivation

Mesh repair as compared to suture repair reduces the incidence of recurrence after repair of umbilical or epigastric hernias (20,21). It is unclear if these findings can be extrapolated to females, who become pregnant after the hernia repair, as increasing tension is exerted on the abdominal wall during pregnancy (22). Moreover, there is limited evidence regarding mesh-related chronic pain after a subsequent pregnancy.

Originality

This study collected data from three national health registries (Danish Hernia Database, Danish Birth Registry, and Danish National Health Registry) and from patient questionnaires.

Method

Recorded data included surgical technique (mesh or suture repair) according to records in the Danish Hernia Database, subsequent pregnancies, moderate or severe chronic pain, and hernia recurrence (self-reported clinical or verified at operation). The study cohort consisted of all women who had become pregnant after the index hernia repair (n=212) in combination with a 1:2 propensity-score matched control group of women without succeeding pregnancies (n=436). Questionnaires were sent out to 212 and 420 women, respectively. The response rate was 70%.

Clinical impact and discussion

A total of 29% women developed hernia recurrence after a subsequent pregnancy. Mesh repair reduced this rate by 56%, but the results indicated that mesh reinforcement came with a price of increased risk of chronic pain (17.5%) compared with suture repair without a mesh (9.5%). The study also demonstrated a higher recurrence rate in parous women. Study limitations included potential selection bias and inadequate power for detailed evaluation of surgical technique. The study demonstrated that registry-driven data are valuable under conditions when randomized trials are unrealistic (23,24), as they guide decision making for the general surgeon. Since watchful waiting has been found safe in women diagnosed with a primary hernia and subsequently becoming pregnant, the current study suggests that these patients should not undergo mesh repair before their last pregnancy, if symptoms attributed to the hernia are only sparse.

In conclusion, a sutured non-mesh repair may be offered to reduce the risk of chronic pain but on the expense of a higher risk of recurrence, if a hernia repair cannot be postponed.

Reference (25)

Motivation

In the hernia literature, outcome after hernia repair is most often reported as recurrence rates or reoperation rates for recurrence. However, the relationship between reoperation rates for recurrence and clinical recurrence rates was not

known for ventral hernias. The aim of the study was to compare the reoperation rate with clinical recurrence (reoperation rate plus clinical demonstrable recurrences) after umbilical, epigastric and incisional hernia repair.

Originality

This study is the only systematic evaluation of the relationship between reoperation rates for recurrence and true recurrence rates after ventral hernia repair. The authors obtained a high response rate of 95%, the study covered almost half of the country, and patients were followed for 4 years indicating a satisfactory external validity of study findings.

Methods

Prospective clinical follow-up Danish Hernia Database data was conducted using a validated questionnaire on reoperation and possible recurrence. Suspicion of recurrence was the criterion for clinical examination, and telephone interview and/or hospital files confirmed reoperation.

Clinical impact and discussion

This study demonstrates that the overall recurrences after primary ventral hernia repair exceeded the reoperation for recurrence by a factor four, and by a factor five after incisional hernia repair. Thus, studies based on reoperation rates for recurrence after ventral hernia repair will most likely underestimate the true recurrence rates. There may be cultural differences around the world in pain perception (26,27) and thereby when patients will seek surgical care for hernia related symptoms. The gap between reoperation and clinical recurrence might therefore differ between cultures. However, it was interesting that most of the patients chose not to have a second repair simply because they had mild or no symptoms. Thus, recurrence rate may not always be the most relevant parameter to study and patient-reported outcome measures (PROMs) such as pain and discomfort may be more important (28-30).

In conclusion, this study showed that reoperation rates do not reflect true recurrence rates after ventral hernia repair.

Reference (31)

Motivation

Laparoscopic ventral hernia repair was introduced in 1993 (32). Due to the preliminary good results and ease of

use the technique gained widespread use worldwide. Over time it became evident that the use of permanent fixation with sutures and/or tackers from time to time resulted in both severe acute and longstanding postoperative pain (33). In an effort to counter the pain problem, numerous alternative devices/techniques (sutures, resorbable tackers, glue, etc.) for fixation of the mesh were advocated (34). However, fixation devices may affect outcome (recurrence, pain, complications) (35). In this study by Christoffersen *et al.* (31,36) the aim was to compare the risk for recurrence and chronic pain after laparoscopic ventral hernia repair using either permanent or absorbable tackers in patients with a bridged intraperitoneal onlay mesh (IPOM) repair.

Originality

The sheer number of fixation devices and combinations thereof (34) render the use of RCTs difficult to use in the present scenario. The present study was, and still is, the largest of its kind and has since it is based on national registry data a high external validity.

Methods

Several health databases including the Danish Hernia Database were merged to identify a 4-year cohort undergoing laparoscopic ventral hernia repair for an incisional hernia.

Clinical impact and discussion

The authors concluded that the use of resorbable tackers involved a significant increase in recurrence but had no effect on chronic pain. In contrast, Khan *et al.* (37) concluded that there was no difference in both recurrence and pain. Unfortunately, this review is seriously flawed by including a trial (35) that only used permanent tackers in combination with resorbable and non-resorbable sutures in the meta-analysis rendering the conclusion invalid. The optimal mesh fixation technique has yet to be demonstrated (38).

In conclusion, based on the present study it seems relevant to avoid use of resorbable tackers in laparoscopic bridged IPOM repairs.

Discussion

In this qualitative review focus was on the Danish Hernia registries and five highlight Danish publications were depicted and many important publications with significant international penetration are constantly reported from other international hernia registries. The present review

was not performed as a critical evidence-based systematic review since this was outside the scope and purpose of the analysis.

Despite the differences, diversity of variables, and the way data are collected for each of the listed hernia registries, it is believed that the collaboration between hernia registries to merge data across country borders could significantly contribute to clinical research and complements RCT findings in laparoscopic and open hernia repair. Nevertheless, until now, no RCTs have shown diametrically different results compared with registry-based studies regarding outcomes after hernia repairs. Examples of parallel findings in RCTs and register-based studies include results after open mesh or suture repair in patients undergoing umbilical hernia repair (21,39) and laparoscopic closure of the fascial defect during laparoscopic umbilical hernia repair (36,40,41). Several initiatives [among other from Belgium in the process of building up a nationwide hernia registry and American Hernia Society (Abdominal Core Health Quality Collaborative Coordinated Registry Network International Harmonization, AHQC)] have been taken to improve outcomes after hernia repairs.

Until now most studies from the Danish Hernia Database and other registries have focused on hard outcomes such as recurrence, postoperative morbidity, mortality etc. There are only few studies on patients' preoperative versus postoperative complaints (PROMs) and the indication to offer a repair (30). However, patients' preoperative hernia complaints and the indication to offer an elective hernia repair should be offset by the risk of recurrence and surgical and mesh-related complications as well as postoperative PROMs. Finally, a collaboration between the industry stakeholders and international registry collaboration is warranted to guarantee the optimal treatment of patients undergoing a hernia repair.

The selection of the Danish highlights publications was subjective more than based on scientific principles. The selection committee were all members of the Steering Board and the members were often themselves authors of the publications that could be chosen. This may have presented a bias.

In conclusion, The Danish Hernia Database has been active for more than 20 years and continuously delivered evidence to improve surgical outcomes after hernia repair. The nature of the nationwide data from the Danish Hernia Database with nearly 100% follow up has contributed with important supplement to the higher-ranking evidence from RCTs by adding evidence-based answers to scientifically

clinically relevant questions with high external validity which are outside of methodology of RCTs.

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Footnote

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