

National results after ventral hernia repair

Frederik Helgstrand

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Official opponents:

Peter Vilmann, Harry Van Goor, Søren Laurberg

Correspondence: Department of Surgery, Zealand University Hospital, Køge

E-mail: Freh@regionsjaelland.dk

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This thesis was based on the following papers

1. Helgstrand F, Rosenberg J, Bay-Nielsen M, Friis-Andersen H, Wara P, Jørgensen LN, Kehlet H, Bisgaard T. Establishment of a national ventral hernia database. *Hernia* 2010;14:131-5 [1]
2. Helgstrand F, Rosenberg J, Kehlet H, Bisgaard T. Nationwide analysis of prolonged hospital stay and readmission after elective ventral hernia repair. *Dan Med Bull* 2011;58:A4322 [2]
3. Helgstrand F, Rosenberg J, Kehlet H, Bisgaard T. Reoperation versus clinical recurrence rate after ventral hernia repair. *Ann Surg* 2012;256:955-958 [3]
4. Helgstrand F, Jørgensen LN, Rosenberg J, Kehlet H, Bisgaard T. Nationwide prospective study on readmission after umbilical or epigastric hernia repair. *Hernia* 2013;17:487-492 [4]
5. Helgstrand F, Rosenberg J, Kehlet H, Jørgensen LN, Bisgaard T. Nationwide prospective study of outcomes after elective incisional hernia repair. *J Am Coll Surg* 2013;216:217-228 [5]
6. Helgstrand F, Rosenberg J, Kehlet H, Bisgaard T. Outcomes after emergency versus elective ventral hernia repair: a prospective nationwide study. *World J Surg* 2013;37:2273-2279 [6]
7. Helgstrand F, Rosenberg J, Kehlet H, Bisgaard T. Low risk of trocar site hernia repair 12 years after primary laparoscopic surgery. *Surg Endosc* 2011;25:3678-3682 [7]
8. Helgstrand F, Rosenberg J, Kehlet H, Jørgensen LN, Wara P, Bisgaard T. Risk of morbidity, mortality, and recurrence after parastomal hernia repair: A nationwide study. *Dis Colon Rectum* 2013;56:1265-1272 [8]

Introduction

Ventral hernias are defined by a defect of the fascia in the abdominal wall with or without a bulge [9]. The clinical manifestations range from small incidentally found defects, over parastomal hernias, to giant and complicated hernias with fistulas and viscera located outside the abdominal cavity covered only by peritoneum and skin (loss of abdominal domain) [1, 3, 8, 10]. Symptoms range from none or few to severe pain and lifethreatening conditions [1]. Ventral hernia repairs are frequent and mostly elective (90%) procedures, but the repair methods are highly variable without sufficient evidence, and often disappointing results [1, 2, 6, 11-26].

Short- and long-term outcomes after ventral hernia repairs are mostly derived from small heterogeneous retrospective [16, 17, 27-29] or prospective [22, 25, 30, 31] studies, and underpowered randomised controlled trials [15, 24, 26, 32-37]. All with a generally short and poorly defined follow-up. The few high volume studies so far published, present retrospective data with limited hernia-specific and perioperative information [11, 38-40]. Therefore, interpretation and conversion of published results to a general population has been problematic.

Inspired by the setup and results from the Danish Inguinal Hernia Database [41, 42], we launched the Danish Ventral Hernia Database (DVHD) in 2007 [1]. By combining perioperative surgical data from DVHD and administrative data from The Danish National Patient Register, we were able to monitor national quality of ventral hernia repair on a long-term basis [43]. Until now, analyses based on DVHD data are the only national outcome studies including surgical techniques on ventral hernia repairs that have been published.

Objective

The aim of the present thesis was to describe national early and late outcome after ventral hernia repair to direct the strategy for improvement on a large-scale basis.

Methodological considerations and study limitations

Incidences and classification

In the United States of America and Denmark, approximately 350,000 and 4,500 ventral hernia repairs are performed annually, respectively [1, 44]. Ventral hernias are classified as primary or secondary [45]. Primary hernias represent approximately 2/3 of all ventral hernias and are either congenital or acquired (approximately 2/3) [1]. The primary hernias are nominated after their anatomic localisation [45]; umbilical (71% of repairs), epigastric/linea alba (25% of repairs), and other rare locations e.g.

lumbar and linea semilunaris/Spigelian hernias (4% of repairs) [1, 45-50]. Secondary hernias are complications to previous surgery and develop in relation to incisions after laparotomy (89% of repairs), laparoscopy (5% of repairs), or in relation to a stoma (6% of repairs) [1, 9, 45].

In DVHD the incisional hernias are described according to the direction of the previous incision (i.e. horizontal, vertical and other), while the European classification maps incisional hernias according to specific anatomical areas of the abdominal wall [1, 45, 51]. The different classification systems make study comparisons difficult [45, 51-53]. This thesis will refer to the Danish recommendations for classification used in the Danish Ventral Hernia Database. [51].

National Databases

The Danish Ventral Hernia Database

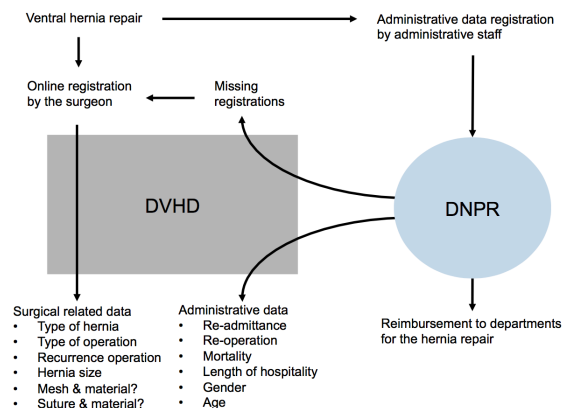
The Danish Ventral Hernia Database is the first nationwide surgical database with a systematic prospective registration of all ventral hernia repairs performed in a country [1, 54]. The DVHD is based on web-registration and is mandatory for all operating surgeons [1, 55]. The large number of surgeons contributing to the DVHD may potentially lead to misclassification of registrations. The impact of inaccurate registrations is considered negligible since the registration platform is simple and each variable is thoroughly explained on the website. Any other misconceptions are clarified at annual meetings for the surgical society or by direct contact to members of the steering group [1]. In total, 66% of the hernia repairs are registered immediately after the operation (Figure 1) [1, 55]. Individual operations are linked to patients' unique social security number, making follow-up in other health-care registers possible [55]. The overall DVHD registration rate is approximately 80% [1]. However, the registration rate varies from 60% to 100% between departments [56]. Missing registrations are identified for post-hoc registration by a complex electronic data matching of DVHD and the Danish National Patient Register (see below) (Figure 2) [1, 55, 57]. Missing registrations in DVHD are considered due to elapsed or inconsistent registration practice rather than deliberate or systematic registration errors [4, 8]. However, as long as the registration rate is below 100%, the risk of selection bias cannot be fully ignored. Surgeons from other surgical specialties (plastic-, urological-, gynaecologic surgery etc.) do not register ventral hernia repairs in DVHD, but they only rarely (<10 procedure per year) perform ventral hernia repairs [58]. The lack of these few procedures is not believed to influence overall national outcome results.

Figure 1

Online registration form for the Danish Ventral Hernia Database. Translated from Danish to English.

DVHD data have a high data agreement regarding hernia type, defect size, type of repair, concomitant surgery, primary or recurrent repair, elective or emergency repair, suture and mesh material, and mesh fixation compared with data from patient files [1, 55]. Additionally, post-hoc analysis of published validation data found no difference in 30-day readmission, -reoperation, -mortality or -recurrence repair between immediate and later registration in DVHD and hospital files [55]. This was also true for hernia type and patient demography (age, gender, hernia size). Although we demonstrated high agreement between patient files and DVHD, approximately 30% of registrations were performed later than 1 day after surgery [55]. Therefore, it would have been more appropriate to validate DVHD registrations against video recordings rather than using patient files as the gold standard.

Figure2



Data flow and follow-up in the Danish Ventral Hernia Database. The combination of data with administrative data from the Danish national patient register makes long-term follow-up and post-hoc registration of missing hernia repairs possible. DVHD = Danish Ventral Hernia Database; DNPR = Danish National Patient Register

Inspired by the DVHD, similar databases have been established in Sweden, Germany, Poland, Spain, USA, and in a Central European collaboration [28, 59-62]. These databases are based on voluntary registration, mainly from specific hernia centres without nationwide coverage, and suffer from insufficient follow-up.

The Danish National Patient Register

The Danish National Patient Register (DNPR) is a national administrative database registering all contacts between Danish citizens and the Danish healthcare system (public and private) [43]. Registrations are linked to patient's unique social security number and are based on the diagnosis-related group classification system [43]. The Danish National Patient Register data is considered comprehensive and complete >99% regarding surgical interventions [43, 63-66]. Validation between DNPR, clinical databases, and randomly selected hospital files, containing a variety of medical diagnoses and surgical procedures, is almost 100% [63-65, 67-74]. A specific validation of hernia diagnoses in DNPR is not yet available. However, due to the relatively few diagnoses covering the specific hernia disease area, it is presumed that ventral hernia data registered in the Danish National Patient Register are reliable [63]. A hernia repair that has not been registered in either the DVHD or in the DNPR cannot be identified. Because of the close relation to reimbursement, it is assumed that hernia repairs performed in relation to other more dominant procedures are more likely to be missed in DNPR registration than hernia repairs performed without concomitant surgery [66].

We used DNPR to identify administrative data on 30-day outcome (readmission, reoperation and mortality), length of postoperative hospital stay, and re-operations for recurrences, not registered in the DVHD. Data within DVHD and DNPR were combined by using patients' unique social security numbers [1]. Hereby, we secured a 100% follow-up of patients registered in the DVHD (Figure 2) [1].

Clinical databases versus randomised controlled trials

High volume data obtained from well-validated registers are appropriate for studying multiple variables and their interdependence, even if the differences in outcome are small and the diseases are rare [75]. Randomised controlled trials (RCT) and meta-analyses on RCTs are the gold standard of research and considered the highest level of evidence [76]. However, the interpretation and transferring of results from RCTs or large single centre studies to a more general patient population treated by multiple surgical approaches may be problematic [77-83]. Even in well-organised large-scale RCTs, aiming to include all patients, a considerable difference in population between included patients and eligible patients has been shown [84]. By combining data from national clinical (e.g. DVHD) and administrative (e.g. DNPR) databases, it is possible to accomplish studies with high external validity and an almost complete follow-up of all patients [1]. Thus, the results from the studies included in the present thesis reflects the outcome for the general population, regardless of whether the procedures were performed in high volume specialised clinics or in more general surgical departments.

Variables and outcome measures

In order to facilitate a high registration rate, the data entry in DVHD was kept simple, using pop-up menus, and contained a maximum of 37 variables while performing the present study series [1]. Due to the simplicity, more detailed variables such as

patients BMI, smoking habits, ASA-score, diabetes, cirrhosis, number of previous laparotomies, and information on anatomic hernia location are lacking [5, 23, 25, 45, 85-99].

Procedure volume and 30-day outcome per department are available in DVHD. However, due to registration policy, it is not mandatory for surgeons to disclose their identity. Results purely based on DVHD may therefore be criticised for being influenced from bias by the individual surgeon's expertise and decision-making [100-103].

30-days outcome

Based on data from DNPR and patient files, we presented the risk of 30-day readmission, reoperation, and death as a proxy for outcome, which are an often used and validated measure for surgical quality [104-108]. To avoid overestimation, only readmissions and reoperation directly or likely related to the hernia repair were included. A considerable amount of minor complications are treated by general practitioners and occur beyond 30-days [108, 109]. Thus, for practical reasons, the reported DNPR data on 30-day readmission, -reoperation in our studies replicate the most severe complications after ventral hernia surgery.

Hernia defect size

Hernia defect size can be measured by calculating the defect area in cm² [88, 94, 110] or using the mesh size as an indirect measure of the hernia defect [111]. For incisional hernias experts have stated that the defect width is most important to determine outcome compared with the length [45, 112]. We defined hernia size by the largest diameter (length or width) of the fascia defect [51]. The definition is supported by an overall significant correlation between hernia defect length and width, both for transverse and midline incisional hernias [5]. This correlation is also demonstrated for umbilical and epigastric hernias (n=15,612, $r=0.82$, $P<0.001$; DVHD data not previously published). The approach for measuring hernia size as longest diameter is also justified by an equally high correlation to outcome, as found for defect areas measured in cm² [94, 97]. However, later post hoc sub-analysis of data used in our study on elective incisional hernia repairs, showed that the high correlation between the hernia defect length and width mainly applied to small defects [5].

Mesh

Choice of mesh may have influence on outcome, but so far without sufficient evidence. In present study series the volume of mesh repairs was considered inadequate to assess differentiated outcome for the hundreds of different meshes on the market [113]. Results in study 2-6, and 8 [2-6, 8] could therefore be biased by the choice of mesh. However, 80-90% of the used meshes consisted of polypropylene, indicating that mainly the companies' specific designs and coatings may have contributed to the bias [1].

Recurrence

Recurrence is a frequently used primary endpoint after hernia repair, but there is no consensus on how to define recurrence. Routine follow-up laparoscopy is considered unethical, but may be the most exact way of identifying recurrence followed by imaging (CT, US), clinical examination, and reoperation for recurrence [3, 114]. Studies with short follow-up often present recurrences by clinical examination [12, 15, 24, 30, 32], whereas studies with longer follow-up predominately define recurrence as reoperation for recurrence [21, 38, 40]. Recurrence defined by a

surgical repair for recurrence makes long-term continuous follow-up possible, without the risk of patient dropouts, opposed to recurrences found by repeated clinical examinations [1, 24].

We found a four- to fivefold difference between recurrences identified by clinical examination and recurrences defined by an operation for recurrence [3]. Nevertheless, due to the potential for long-term follow-up, regardless of where patients are repaired for recurrence and the minimal risk of patient dropout, we used reoperation for recurrence as a proxy for recurrence. Also, because clinical follow-up on a nationwide basis is impractical. Reoperation for recurrence as an indirect outcome measure for recurrence precludes that the indication for reoperation for recurrence is independent of the preceding hernia repair and patient characteristics. In the present study series, gender, age, hernia size, surgical technique, use of mesh, and whether the repair was elective or emergent did not have an influence on whether patients with hernia recurrence underwent reoperation for recurrence or not [3]. Thus, even though reoperation for recurrence significantly underestimates clinical recurrence [3], the reoperation rates for recurrence registered in DVHD are considered a reliable surgical outcome measure.

Specific study limitations

In addition to the general methodological considerations and limitations discussed above, the separate studies included in this thesis have specific limitations.

Studies 1, 4 and 5 were uniquely based on data from DVHD and DNPR (see above). Results from these studies are therefore biased by surgical selection bias, limited details of hernias anatomic location, a lack of information on patient co-morbidity, and insufficient registrations. To what extent patient conditions have affected results is difficult to estimate. However, it is assumed that the surgical choice for repair was according to surgical experience and knowledge for best outcome. To account for the influence on outcome from different surgical approaches, multivariate analyses were performed, but as mentioned, the analyses only included limited patient-specific data. In order to limit the risk of the over-interpretation of results, hernia repairs secondary to other major concomitant repairs were not included in study 4 and 5.

Study 2 comprised detailed data on reasons for 30-day readmission and hospital stay longer than 5 days. The study group included data from the retrospective analyses of patient hospital files compared with register data from a nationwide cohort with less than 5 days of postoperative hospital stay. Patients were recruited from the DVHD; therefore, it can be hypothesised that results suffered from registration bias (see above). Besides being limited by the retrospective design, there was no information on co-morbidity in the control group. Thus, although 66% of patients with long hospital stay or readmissions suffered from co-morbidity, it was not possible to determine the level of impact co-morbidity had on outcome.

Study 3 compared reoperation for recurrence and recurrence found by clinical examination. One hernia specialist performed all clinical examinations and consulted with another specialist when in doubt. Any unclear case was CT-scanned, but small recurrences not recognised by clinical examination could have been ignored. Furthermore, the validation of the questionnaire used to identify possible recurrences showed that 5% of patients without recurrence suspicion had a recurrence found by clinical examination.

Therefore, the difference between clinical recurrence and reoperation for recurrence could be even higher than presented in the study.

Study 6 reported a significantly worse outcome for emergency hernia repairs compared with elective procedures. Patients were recruited from the DVHD and DNPR with the consequent pros and cons explained above. To limit the risk of interdependence between risk factors for emergency repairs, we performed multivariate analyses. Nevertheless, results on the risk factors for undergoing an emergency repair would have been more conclusive if compared with a cohort of all patients with a ventral hernia (both patients with treated and untreated hernias).

Study 7 presented the risk of a trocar site hernia repair after laparoscopy with a 12-year follow-up. Data derived from DNPR; therefore the results may be biased from non-registered repairs performed secondarily to other major concomitant surgery. As discussed, the volume of procedures not registered in DNPR does probably not affect results. Surgical-related risk factors was limited by the lack of information on the number, size, and type of trocars [115].

Study 8 addresses outcome after elective and emergency parastomal hernia repair. The national data were identified in DVHD (see above) and limited by a retrospective review of patients' co-morbidity. We used multivariate analyses based on a composite score including mortality and reoperation. It may be argued that the combination of mortality and reoperation diverge too much, but our aim was to evaluate risk for "severe outcome". The reported high risk for severe outcome would probably be even worse if we also included serious medical conditions.

Statistics

To minimise the risk for selection bias, outcomes from open and laparoscopic repairs were generally analysed separately. In the few direct comparisons between open and laparoscopic repairs, outcomes were based on intention-to-treat principles (laparoscopic repairs converted to open were classified as laparoscopic repairs) [116]. Readmission or reoperation may lead to additional readmissions or reoperations (statistical wrong sampling unit) [117]. Therefore, analyses were restricted to one readmission and one re-operation per patient, even though some patients had multiple readmissions and reoperations.

The Kaplan-Meier and log Rank method was used to calculate and compare the cumulated risk for recurrence, respectively. Kaplan-Meier analyses are frequently used to estimate the risk for recurrence after hernia surgery [21, 38, 42, 88], but tend to overestimate when applied to non-fatal events [118, 119]. The method was regarded reliable for the estimation of recurrence in our studies, since relatively few patients died during follow-up [4, 5, 118, 119].

In study 4, 5, 6, and 8 we performed multivariate analyses [4-6, 8]. The studies were exploratory and possible risk factors, defined by univariate analyses with $P < 0.20$, were included in the multivariate analyses in order to avoid influence from unlikely-associated explanatory variables [120].

Results

As mentioned above, the present thesis comprised data from DVHD and DNPR. When appropriate, information from patient files, clinical examinations, or questionnaires were added to data from DVHD and DNPR [1-8]. All studies had different objectives. The DVHD data in study 1-6 and 8 had overlapping inclusion periods. Therefore some patients were included in more than one study (Table 1). In total, the 8 separate studies included 38,267 patients and the total number of different patients was 18,928 (Table 1).

Table 1

Overview of included ventral hernia repairs and study periods

Study	Objective	Type of ventral hernia repair	Study period	Number of patients	Data source
1	Establishment of DVHD	All ventral hernias	Jan. 1, 2007 - Dec. 31, 2008	6,290	DVHD* and DNPR**
2	Reason for reoperation, death, and prolonged LOS	Elective ventral hernias	Jan. 1, 2008 - Dec. 31, 2008	2,258	DVHD, DNPR, and patient files
3	Reoperation vs. clinical recurrence	Elective umbilical, epigastric, and incisional hernias	Jan. 1, 2007 - Dec. 31, 2007	902	DVHD, DNPR, clinical examinations, patient files, and questionnaires
4	30-day outcome	Elective umbilical and epigastric hernias	Jan. 1, 2007 - Dec. 31, 2010	6,783	DVHD and DNPR
5	30-day outcome and recurrence	Elective incisional hernias	Jan. 1, 2007 - Dec. 31, 2010	3,258	DVHD and DNPR
6	Emergency vs. elective outcome	All umbilical, epigastric, and incisional hernias	Jan. 1, 2007 - Dec. 31, 2010	10,976	DVHD, DNPR, and patient files
7	Risk for trocar site hernia repair	Laparoscopies performed in 1997	Jan. 1, 1997 - Dec. 31, 2011	7,626	DNPR and patient files
8	30-day outcome	All parastomal hernias	Jan. 1, 2007 - Dec. 31, 2010	174	DVHD, DNPR, and patient files
Total number of different patients included in the study series				18,928	

*DVHD = Danish Ventral Hernia Database. **DNPR = Danish National Patient Register

Primary Ventral Hernias

Umbilical and epigastric hernias

Depending on definition, the prevalence of umbilical and epigastric hernias is 20-50% and 2-4% of the adult population, respectively [14, 47, 121] and it is estimated that only 0.1-0.5% of the umbilical hernias and 0.5-5% of epigastric hernias are repaired [14, 47]. The umbilical hernia repairs are predominantly performed in males aged 0-5 and 61-70 years, whereas epigastric hernia repairs are almost equally distributed by gender and mainly performed in patients aged 40-60 years [122]. In total, 90% of umbilical and epigastric hernia repairs are due to minor fascia defects (< 2 cm) [4, 11]. Symptoms range from none or cosmetic complaints to severe pain and life-threatening conditions [123].

Complications and risk factors

The 30-day postoperative complications after elective umbilical and/or epigastric hernia repair presented in non-nationwide and very heterogenic studies are 3-23% [23, 40, 124-126]. The national risk of 30-day readmission, reoperation, and mortality following umbilical and epigastric hernia repair shown in our study is 5.0%, 0.3%, and 0.2%, respectively [4]. Furthermore, 3% of the Danish patients are hospitalised for more than 5 days after their repair [2]. The national findings correspond to the literature, but the 30-day readmission rate is 2-3 times lower than complication rates presented in studies with clinical follow-up [11, 126, 127]. The main reasons for readmission after umbilical and epigastric repair is wound infection, haematoma, seroma, and pain [4, 11, 128].

Patient-related independent risk factors for readmission after umbilical or epigastric hernia repairs are large hernia defects, umbilical hernia, and female gender [4]. The increased complica-

tions after larger repairs parallels results from incisional hernias [5]. Female gender as a risk factor is difficult to explain and has previously only been demonstrated for inguinal hernias [129, 130]. Open and laparoscopic procedures are comparable in terms of risk of readmission after adjustment for age, gender, hernia size, and whether the repair is for a primary or recurrent hernia [4]. Our national comparison of open and laparoscopic repair in terms of early outcome summarises the inconsistent literature [4, 11, 23, 128, 131-133].

In open repairs, the use of mesh reinforcement slightly increases the risk of 30-day readmission both in our nationwide data, in small retrospective single centre studies, and in meta-analyses [4, 134, 135]. This is in contrast to a recent meta-analysis [136] and a randomised controlled trial showing no correlation between mesh and postoperative complications [127]. Thus, the overall results for early outcome states that sutures in elective primary hernia repairs cannot be recommended due to the higher risk for later recurrence [137].

Mesh fixation with tacks in open surgery increases readmission in our nationwide data compared with sutured fixation [4]. This finding is not demonstrated for laparoscopic repair [4, 128]. Tacked mesh fixation can be painful during the first postoperative days, which may explain the higher level of readmissions [124]. Laparoscopic mesh fixation with fibrin sealant causes less pain the first postoperative days and shorter hospital stays, but more recurrences compared with tacked mesh fixation [15, 124]. Mesh material and position are proposed to influence early outcome after umbilical and epigastric hernia repair [14, 138, 139]. However, this assumption has not been verified in present national high volume data, or in a RCT [4, 139].

Between 1-20% of patients with an umbilical and/or epigastric hernia repair complain of pain and discomfort after more than 1 year [12, 16, 140-142]. The risk for chronic pain and discomfort 3-years after an open umbilical and/or epigastric hernia repair is as high as 12%, and even higher in patients with a recurrence [12]. Chronic pain after small open umbilical or epigastric hernia repair is not related to mesh repairs, but may be correlated to recurrence [142, 143]. In conclusion, there is currently no evidence for best surgical practice to avoid chronic postoperative pain, except by preventing recurrence.

Reoperation for recurrence

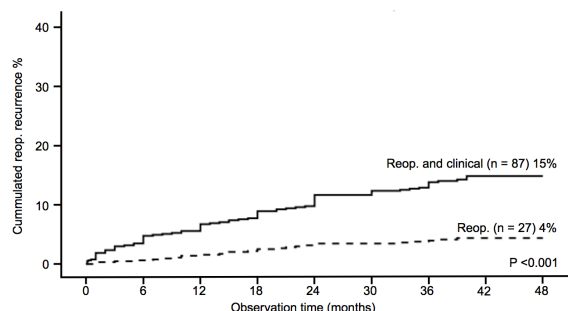
Several factors influence the risk of recurrence after umbilical and epigastric hernia repairs; the risk varies between 0% and 15% [3, 91, 127, 135, 137, 144]. The recurrence rate after a umbilical or epigastric hernia repair found by our clinical examination is increased by almost a factor of 4 compared with the cumulated reoperation rate for recurrence (Figure 3) [3]. The association between reoperation for recurrence and clinical recurrence is confirmed in a study of small (0-2 cm) umbilical hernias [143].

Studies comparing open and laparoscopic hernia repair for umbilical or epigastric hernias are in general heterogeneous [17, 131, 133, 145, 146]. Nevertheless, all studies, including ours, report comparable risks of recurrence between open mesh and laparoscopic repairs [3, 131, 133, 145, 146]. Open mesh procedures significantly reduce the risk of recurrence by up to 50% compared with open sutured repair [127, 134-137, 144]. This also applies to hernia repair of defects ≤2 cm [143]. Theoretically, repairs with absorbable sutures should correlate to higher recurrence rates

than non-absorbable sutures [14]. This is only insignificantly demonstrated for umbilical or epigastric repairs with defects ≤ 2 cm, but all suture materials are inferior to mesh in terms of recurrence rates [4, 137]. It is implied that specially designed meshes for open intraperitoneal placement may increase recurrence; however, so far, no open mesh positions have been found to be superior with regard to reducing recurrence [19, 137, 139, 140, 147]. Based on knowledge from incisional hernia repairs, it is suggested that the sublay mesh position is to prefer in open repair of larger umbilical or epigastric hernias [5] (see separate section below).

Figure 3

Risk for recurrence after 646 umbilical and epigastric hernia repairs



Correlation between reoperation for recurrence and recurrence found by examination after umbilical or epigastric hernia repair. The cumulated risk for recurrence is shown as a Hazard function.

Reop.=reoperation; Clinical=recurrence found by a clinical examination, CT or UL; n=number repairs; P-value was calculated by Log Rank.

Emergency repair

Approximately 200 emergency umbilical repairs are performed annually in Denmark [6]. If 20% of the adult Danish population (population: 4,483,840) has an umbilical hernia, the annual risk of an emergency repair is estimated to 0.02% [6, 14, 148].

In our national analysis, the 30-day readmission, reoperation, and mortality rate after emergency umbilical or epigastric hernia repair was 18%, 4%, and 3%, respectively [6]; these results are similar to those of small heterogenic studies [149-151]. The 30-day complications following emergency repair is increased up to 15-fold compared with elective repairs [6]. Female gender, old age, primary hernia (vs. recurrent hernia), umbilical hernia (vs. epigastric hernia) and defects $>2-7$ cm are all significant independent risk factors for emergency repair compared with elective repairs [6]. However, present risk factors are only indicative and must be confirmed by a comparison including a cohort of non-operated hernia patients. Emergency repair does not increase the risk of later recurrence repair [3, 14, 149].

In summary

The present thesis demonstrated disproportional high national readmission rates after elective and emergency umbilical or epigastric hernia repair. Independent risk factors for 30-day readmission are large hernia defects, umbilical hernias (vs. epigastric hernia repair), female gender, and mesh repairs. Open mesh repair slightly increases the 30-day readmission rate but reduces recurrence repair by 50% compared with sutured repairs. Sutured mesh fixation in open repairs reduces the risk of readmission. Reoperation for recurrence is significantly lower than recurrences found by clinical examination. Emergency umbilical or epigastric repairs do not increase the risk for a later operation for recurrence.

Secondary ventral hernias

Incisional hernias

An incisional hernia occurs in 10-30% of all laparotomies and is among the most common complications following open surgery [152-159]. The risk for developing incisional hernia can be reduced significantly by using sufficient slowly absorbable suture material or prophylactic mesh reinforcement during wound closure [154, 160]. The hernia defects range from a few centimetres to very large defects with loss of abdominal wall domain [5]. Consequently, repair techniques and postoperative outcome show a considerable variation. Symptoms range from very little to cosmetic complaints, pain, discomfort, skin problems, functional disability, pulmonary dysfunction, incarceration, and strangulation [161, 162].

Complications and risk factors

The risk for 30-day postoperative complications after incisional hernia repair from expert centres ranges from 10-48% [24-26, 32]. The national risk for 30-day readmission, reoperation, and mortality after elective incisional hernia repair presented in our data is 13.3%, 2.2%, and 0.5%, respectively [5]. Furthermore, 11% of patients stay in hospital for at least 5 days postoperatively, mainly because of pain, seroma, and paralytic ileus [2, 39]. The main reasons for readmission is seroma, wound infection, bleeding/haematoma, and pain [5]. As for umbilical and epigastric hernias, the complication rates in terms of readmission and reoperation after incisional hernias are 2-3 times lower than complication rates based on clinical follow-up [5, 22, 24-26, 32, 33, 39, 40].

Older patients have higher risk for 30-day mortality, regardless type of hernia repair and hernia size, but age does not affect the risk for 30-day readmission, reoperation or length of hospital stay [2, 5]. Our national result has so far only been questioned by a minor heterogenic and retrospective single centre study [163]. In agreement with the literature, the national data show a higher risk for readmission, reoperation, and longer hospital stay for patients with large hernias [2, 5, 94].

Elective midline incisional hernia repairs increase the risk of 30-day readmission by 50% compared with hernias in transverse incisions in our national data [5]. This finding complements the use of transverse incisions whenever possible, since it also prevents the risk of developing an incisional hernia [164-166]. Experts claim that ventral hernias located near the costal margin (sub-costal), the xiphoid process (subxiphoid), and the symphysis pubica (supra pubic) can be challenging due to difficulties in obtaining sufficient mesh overlap and fixation, but there is only limited outcome evidence in these atypical hernias [167]. The lack of detailed anatomic hernia localisation in our studies makes it impossible to conclude if these atypical hernia locations also affect outcome.

Early complications (30-day) and length of hospital stay after open incisional hernia repair are significantly increased compared with laparoscopic repairs, both in our nationwide data and in meta-analyses [2, 5, 39, 145, 168]. Several studies have suggested that the laparoscopic repair of incisional hernias leads to fewer but more severe complications [24, 26, 34, 145, 146, 168, 169], but this has not been confirmed in national data [5].

Open mesh repair compared with open sutured repairs is not found to increase the risk of 30-day readmission, reoperation or mortality in Denmark [5]. Randomised controlled trials and meta-analyses on whether open mesh repairs affect early complications are conflicting [32, 170, 171]. However, regardless of whether others claim that 30-day complications are higher in mesh repairs, it does not offset the higher recurrence rates for sutured repairs. The mesh position in open repairs do not affect early outcome [5, 38, 170, 172].

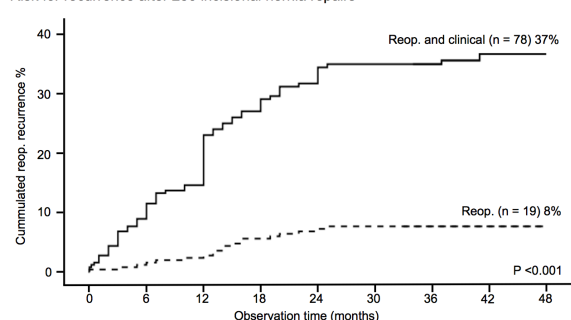
The risk of long-term complications (>1 year) after incisional hernia repair is up to 39% and the major reasons for chronic complaints are cosmetic (up to 50%), pain (11-39%), discomfort (up to 27%), and fistulas (2-6%) [20, 173-177]. In open repairs, the use of mesh tends to reduce the risk of chronic pain compared with sutured repair [20]. Thus, it could be speculated that chronic pain is correlated to recurrence as shown for umbilical and epigastric hernias [142]. Furthermore, a single study showed that polypropylene and polytetrafluoroethylene (PTFE) mesh material, bulging, and recurrence are associated with chronic pain [177]. This conclusion is based on low volume retrospective data with a high risk of statistical errors caused by multiple confounders [177, 178]. Thus, the high numbers of chronic pain and complaints and limited evidence stress the need for more research to improve late outcome [146].

Reoperation for recurrence

The overall risk of recurrence found by physical examination after incisional hernia repair varies between 0% and 63% depending on the surgical approach, the length of follow-up, and how recurrence is defined [3, 20, 24, 25, 33, 38, 171]. In our national study of unselected patients, the overall risk for a recurrence repair (open and laparoscopic) 4 years after the first hernia repair was 18.3% [5]. Most hernia recurrence repairs are performed within two years after the first hernia repair, but the risk for a recurrence repair continue beyond 4-5 years [5, 21]. As in primary hernia repairs we demonstrated that reoperation for recurrence significantly underestimates recurrence found by clinical examination (Figure 4) [3]. The findings indicate that much longer follow-ups are required to determine the true reoperation rate for recurrence as well as the true risk of recurrence found by clinical examination.

Figure 4

Risk for recurrence after 256 incisional hernia repairs



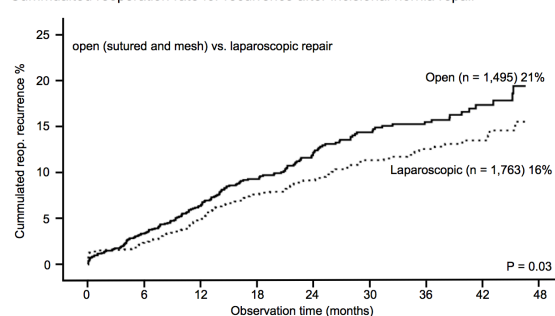
Correlation between reoperation for recurrence and recurrence found by examination after incisional hernia repair. The cumulated risk for recurrence is shown as a Hazard function. Reop=reoperation; Clinical=recurrence found by a clinical examination, CT or UL; n=number repairs; P-value was calculated by Log Rank.

Increasing incisional hernia size correlates to higher risk of a recurrence repair [5, 25, 94, 141, 179]. There are no differences in reoperation rates for recurrence between repairs for hernias in

transverse and vertical incisions [5]. Nevertheless, and without evidence, experts have stated otherwise [164, 165, 167]. The overall cumulated risk of a recurrence reoperation after incisional hernia is significantly higher in nationwide data after open repairs compared with laparoscopic repairs (Figure 5) [5]. However, patients with larger defects (>15 cm) seem to benefit from an open procedure (Giant hernia repairs; see below) [5, 180]. In open repairs, the use of mesh reinforcement significantly reduces the risk for a later recurrence repair compared with sutured repairs (nationwide data, RCTs and meta-analyses) [5, 20, 32, 146, 170]. In agreement with low volume single centre studies and meta-analysis, national data demonstrated that the best mesh position to avoid later recurrence in open repair is a sublay/retro-rectus position [5, 28, 37, 51, 172, 181].

Figure 5

Cumulated reoperation rate for recurrence after incisional hernia repair



The cumulated risk for reoperation for recurrence after open (sutured and mesh) and laparoscopic incisional hernia repair. n=number of repairs; P-value was calculated by Log Rank.

Giant incisional hernias

Repair for giant hernias represents 5-15% of incisional hernia repairs in Denmark, depending on whether the giant hernias are defined as the longest defect diameter >15 cm or >20 cm [5]. The risk of 30-day morbidity, wound infections, and recurrence (2-years follow-up) varies from 4-83%, 0-33%, and 0-53%, respectively [180, 182]. National 30-day risks of readmission, reoperation, mortality, and overall cumulated reoperation for recurrence (4-years follow-up) in giant hernia repairs (defects >15 cm) are 18%, 5%, 1%, and 23%, respectively [5]. The complexity of the repairs, and heterogeneity of the studies [180, 182, 183].

Risk of recurrence repair is significantly increased by hernia size for laparoscopic repairs, but not for open repairs [5]. However, the cumulated risk for a recurrence repair in large hernia repairs is only numerically and not significantly higher after laparoscopic repair compared with open procedures [5]. Nevertheless, data and the complexity of large midline incisional hernia repairs seem to favour open sublay mesh procedures with or without component separation [10]. In more complex repairs, general recommendations are difficult and the procedure should be tailored according to individual patients [51, 181, 182, 184].

Emergency repair

With complication rates of 21-46% after clinical follow-up, the reported results after emergency incisional hernia repairs are discouraging [150, 185-188]. In the national data, the overall 30-day readmission, reoperation, and mortality rates are 22%, 6%, and 6%, respectively [6]. Compared with elective repairs, the risk of 30-day complications is increased up to 13-fold [6].

Independent risk factors for emergency incisional hernia repairs found by comparison with elective repairs are increased age, female gender, and smaller hernia defects (0-7 cm) [6, 93, 150, 186]. The fact that patients with smaller defects are at risk for emergency repairs can theoretically be explained by a higher risk for incarceration and strangulation. However, the smallest (0-2 cm) umbilical or epigastric hernias are not associated with more emergency repairs (see above) [6]. Thus, the overrepresentation of patients with small hernias undergoing emergency repair might just be an expression of the general hernia defect size among patients with untreated hernias [3, 189]. In agreement with the sparse literature, we found a comparable risk for recurrence between emergency and elective incisional hernia repair [3, 150, 186, 188].

In summary

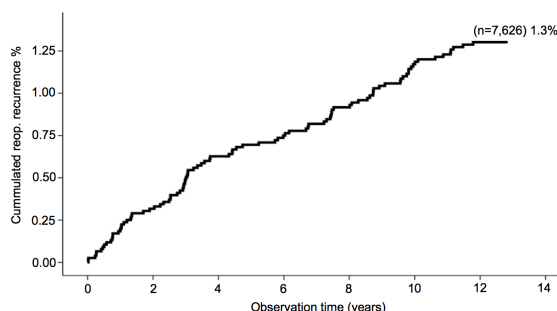
The studies on incisional hernias included in this thesis show an overall high risk of postoperative complications and recurrences after elective and emergency incisional hernia repair. Older age, larger defects, and open surgery increase the risk of early complications. Open repairs with sublay mesh position are found to be superior to other open procedures to avoid later recurrence repair. Laparoscopic repairs are the most appropriate procedure for patients with smaller incisional hernias. Emergency repair does not increase the risk for a later recurrence operation.

Trocar site hernias

The risk for wound complications at the trocar site is below 1% [190]. The risk of incisional hernias after laparoscopy (trocar site hernia) ranges from 0-5.2%, but in a single study, the risk was 26% and even higher risks have been found in morbidly obese patients [115, 191-199]. Most trocar site hernias are located in relation to the umbilicus, in non-sutured defects, and after the use of large trocars (>10 mm) [7, 115, 191, 200]. In our recent randomised controlled trial, the occurrence of trocar site hernia was not increased after single incision laparoscopic cholecystectomy with incisions of 2-3 cm compared with conventional laparoscopic cholecystectomy using 10mm trocars (the fascia was sutured in both groups) [201]. However, a meta-analysis including randomized controlled trials stated otherwise [202]. The overall national cumulated risk for a trocar hernia repair was 1.3%, 12 years after a laparoscopic procedure (Figure 6) [7].

Figure 6

Cumulated risk for a trocar site hernia repair after laparoscopy



The cumulated risk for a trocar site hernia repair after laparoscopy.
n=number of laparoscopies.

There are several studies and reviews concerning the incidence and risk factors for trocar hernia, but no data is available on out-

come after trocar site hernia repair. Since most trocar site hernias are small and located in the umbilical area, outcome is suspected to resemble umbilical hernia repairs [115]. Trocar site hernias are not found to correlate to fascia expansion for specimen removal in our national data or in the 56 literature [7, 115].

Emergency repair

As for elective repairs, there is little information on outcome after emergency trocar site hernia repair in the literature [197]. However, 16% of the trocar site hernia repairs in Denmark are performed as an emergency procedure [7], which is 2-3 times higher than shown for umbilical, epigastric, and incisional hernias [6]. Although there is no data on the prevalence of trocar site hernias, the relatively high number of emergency repairs indicates that patients with palpable or symptomatic trocar site hernias should be offered an elective repair to prevent later emergency repair [7].

In summary

We demonstrated that trocar site hernias are mainly located in the umbilical area and that the risk of a trocar site hernia repair (1.3%) is much lower than the risk of incisional hernia repair after laparotomy (10-30%). Additionally, 1/6 of all repairs for a trocar hernia are performed as emergency procedures.

Parastomal hernias

The general parastomal hernia incidence is 30-50% for colostomies [203-206] and 15-30% for ileostomies [204-206], depending on definition and length of follow-up. Approximately 25-50% of patients with parastomal hernias undergo a surgical repair [203, 205]. In Denmark, 60-70 parastomal hernia repairs are performed annually [8]. Patients with a parastomal hernia are often burdened with impaired quality of life, stoma care problems, pain, discomfort, immobilisation, bowel obstruction, and cosmetic complaints [8, 31, 204, 207]. The indication for repair is debated and surgery is usually reserved for patients with skin or stoma bag appliance problems, and in emergency situations with incarcerated or strangulated bowel [208]. The relatively low numbers of procedures performed mirrors the literature, where long-term prospective studies from specialised centres include no more than 9-72 repairs [31, 209-212].

Complications and risk factors

In open elective mesh repairs, the overall 30-day morbidity and mortality rates are reported to be 8-36% and 0-5%, respectively [8, 205, 207, 213-216]. The 30-day risk for readmission, reoperation and mortality in our nationwide study (n=174) is 21.8%, 8.5%, and 2.1% for elective repairs, respectively [8]. Severe morbidity in terms of major reoperations and death after an elective repair is 9% and 2%, respectively [8]. Patients who undergo a parastomal hernia repair generally suffer from substantial co-morbidity [8, 31, 207]. However, co-morbidity was not found to be associated with postoperative complications [8, 217]. Hernia repairs are more frequent after colostomies and have a higher risk for severe complications than hernias related to ileostomies [8].

In open sutured repairs, 30-day morbidity and mortality rates are 5-31% and 0-18%, respectively [8, 31, 207, 213]. In laparoscopic repairs, the overall 30-day morbidity and mortality rates are 9-22% and 0-3%, respectively [8, 31, 218, 219]. In a post-hoc analysis of the Danish data, the risk for reoperation and/or mortality

after elective open and laparoscopic repair are 10% and 8% ($P=0.857$), respectively [8]. Several experts claim better early results after laparoscopic procedures [31, 207, 213]. However, in our data, adjusted for type of stoma repair and emergency repair, there is no difference in risk for reoperation and/or death between open and laparoscopic repair [8]. Open elective mesh repair is not found to increase the risk for complications and there is no difference in early outcome between the laparoscopic Keyhole and Sugarbaker technique [8, 213]. The comparison of different laparoscopic approaches has been heavily debated, but final evidence is not yet available [213, 220].

Reoperation for recurrence

Depending on the technique, recurrence definition, and follow-up, the overall risk for a recurrence after parastomal hernia repair found in low volume studies ($n=10-72$) was between 3-36% [31, 210, 221-225], but can be as high as 75% [226]. The overall cumulative rate of reoperation for recurrence in our data was 10.8% [8].

Reoperation for recurrence is not correlated to gender, age, or stoma type [8].

Open parastomal hernia repairs significantly increase the risk for of recurrence (17.2%) compared with laparoscopic repairs (3.8%) in our data [8]. This finding confirms the tendencies shown by others [31, 207, 210, 211, 214]. As for other ventral hernias, open sutured repairs increase the risk of recurrences even more than open mesh repairs [8, 206, 214].

No significant difference in risk of a reoperation for recurrence has been found between the laparoscopic Keyhole and laparoscopic Sugarbaker technique in our nationwide data [8]. This result is in contrast to a review of pooled data, concluding that the Sugarbaker technique reduce recurrence by more than 50% compared with the Keyhole procedure [213]. However, the largest single centre study of the Keyhole technique reports equally low recurrence rates (2.7%, median follow-up: 36 months) [31], as shown for in the largest study of the Sugarbaker technique (6.6%, mean follow up: 26 months) [210].

Emergency repair

Mortality rates 30 days after emergency parastomal repair are between 11-25% [8, 214]. In Denmark, the risk of 30-day reoperation and death after emergency parastomal hernia repair are 34% and 25%, respectively [8]. Thus, the risk of a 30-day reoperation and death are increased 8-12 fold compared with elective repairs. The cumulated risk for a reoperation for recurrence after an emergency repair is 10.4% and comparable with elective repairs (7.3%) [8].

Poor outcomes after parastomal hernia repairs have motivated surgeons to insert a prophylactic mesh [227, 228]. All studies have shown significantly reduced recurrences by applying a mesh at the primary stoma formation [226, 227]. Also, the higher risk of hernia at the old stoma site, after stoma reversal, can probably be avoided by applying a preventive mesh at the time of stoma reversal, although this was not shown in randomised trials [229, 230].

In summary

The nationwide study on parastomal hernia repair showed high risk for severe complications and mortality, especially in emergency repairs. We demonstrated that early results are similar between laparoscopic repairs and open procedures and that

reoperations for recurrence are reduced by a laparoscopic technique (either Sugarbaker or Keyhole). Until more evidence for better results is provided, the most important step is prevention by mesh reinforcement during the stoma formation and to centralize parastomal hernia repair procedures to a few dedicated high volume centres.

Future Challenges

Pain, seroma and wound infections are major issues for better outcome after ventral hernia repairs [4, 5, 25]. Intraperitoneal mesh fixation with sutures, glue or absorbable tacks instead of titanium tacks have not met the expectations of improved long-term results [15, 231-235]. Mesh fixation with glue or absorbable tacks to reduce short and long-term pain may be the future, but this requires improved products or adjusted surgical techniques if used for intraperitoneal mesh fixation [236].

Seroma formation is a common complication after open repair and is found after almost all laparoscopic hernia repairs [4, 25, 94, 114, 139, 237-239]. Seromas may be reduced by closing the fascia in laparoscopic repair before mesh application and by using binders, but the results need to be evaluated further [13, 240-243]. The effect of applying talc or fibrin sealant on the wound surface to avoid seroma is controversial [241, 244-248]. More results are also warranted to conclude whether wound drains reduce seroma and/or increase the risk of infections [249].

The impact of mesh material on outcome has not been well investigated. Currently, more than 200 different meshes are available, all with different designs, structures and indications [113, 250-252]. The companies pace of replacing or updating old mesh products makes it difficult to provide updated research. Thus, more evidence from the manufacturers should be demanded in the future before introducing new meshes. EPTFE (microporous) meshes have been shown to increase wound infections and seroma [251, 253-255], synthetic heavy weight (≥ 140 g/m²) meshes seem to induce more shrinkage, scar tissue and inflammation [33, 251, 255-257], and biologic meshes may decrease the risk of infection [258-260]. Furthermore, the few studies on mesh materials' biocompatibility are from animals and explanted meshes [250-252]. Hopefully, similar studies will be available from prospective human trials in the near future. Therefore, the outcome from different meshes needs to be compared in large-scale register studies such as DVHD, in high volume multicentre RCT studies, or preferably in nationwide randomised studies, which could be integrated in national databases such as the DVHD.

The indications for offering a hernia repair varies between surgeons and, due to the risk of complications, patients with asymptomatic hernias are often recommended to not undergo surgery [189, 261]. As a consequence, patients may end up having an emergency repair, symptoms may become worse, or the hernia may become larger, thereby making later surgery more complicated. A single centre retrospective of 104 referred patients have demonstrated that 33% of the patients underwent an incisional hernia repair during follow-up and 24% of the repairs were conducted as emergency procedures [262]. Unfortunately, no detailed inclusion criteria's was described and elective and emergency repairs were pooled in the study [262]. Thus, the identification of patients at risk of complications and emergency repairs and performing a prospective "watchful waiting" study of non-symptomatic hernia patients are highly warranted. Additionally, it

is interesting to analyse the variation in surgeons' indications and choice of procedure for identical patients.

Long-term complications in terms of fistulas, chronic infections, adhesions, pain and quality of life after ventral hernia repairs are vital considerations when choosing the surgical approach [261, 263]. This research area needs much more attention in order to pinpoint evidence for indication and for best surgical practice, including the choice of mesh material and fixation [12, 15, 142, 264-267]. Such studies could also advantageously be integrated in, or based upon, large registers. The discrepancy between clinical recurrence and reoperation for recurrence presented, states that long follow-up with clinical examinations are necessary to determine the true recurrence rate in the future.

The ventral hernia operation and perioperative treatment ranges from easy to very difficult cases. The treatment of giant and parastomal hernias needs special attention in order to find the best surgical approach including technique for component separation [8, 180, 182, 227]. The large and complicated ventral hernias are relatively few in number and to achieve better results and obtain more experience in the treatment it is obvious to centralise these repairs to few dedicated centres [50, 51, 103, 268-270].

The present thesis has focussed on national outcome results and finding standardised techniques for best practice, which are fundamental for further improvement. However, patients are different, not only in type and size, but also in physical and mental appearance. Therefore, each patient has a different expectation to a hernia repair. Thus, future studies should also search for a more tailored approach for different patient categories regarding on type of surgery (open or laparoscopic), but also in the choice of mesh material, mesh fixation and shape of the mesh.

Summary

Ventral hernia repairs are among the most frequently performed surgical procedures. The variations of repair techniques are multiple and outcome has been unacceptable. Despite the high volume, it has been difficult to obtain sufficient data to provide evidence for best practice. In order to monitor national surgical quality and provide the warranted high volume data, the first national ventral hernia register (The Danish Ventral Hernia Database) was established in 2007 in Denmark.

The present study series show that data from a well-established database supported by clinical examinations, patient files, questionnaires, and administrative data makes it possible to obtain nationwide high volume data and to achieve evidence for better outcome in a complex surgical condition as ventral hernia. Due to the high volume and included variables on surgical technique, it is now possible to make analyses adjusting for a variety of surgical techniques and different hernia specifications.

We documented high 30-day complications and recurrence rates for both primary and secondary ventral hernias in a nationwide cohort. Furthermore, recurrence found by clinical examination was shown to exceed the number of patients undergoing reoperation for recurrence by a factor 4-5.

The nationwide adjusted analyses proved that open mesh and laparoscopic repair for umbilical and epigastric hernias does not differ in 30-day outcome or in risk of recurrence. There is a minor

risk reduction in early complications after open sutured repairs. However, the risk for a later recurrence repair is significantly higher after sutured repairs compared with mesh repairs.

The study series showed that large hernia defects and open repairs were independent predictors for 30-day complications after an incisional hernia repair. Open procedures and large hernia defects were independent risk factors for a later recurrence repair. However, patients with large defects (>15cm) seemed to benefit from an open mesh repair compared with laparoscopic repairs. Additionally, the open sublay mesh position independently decreased the risk of recurrence repair compared with other open mesh positions.

Emergency repair for a ventral hernia is dangerous and our studies revealed up to 15 times higher risk for postoperative complications than after elective repairs. Especially females, older patients, and patients with small to medium sized hernias were at risk for an emergency repair compared with elective repairs. However, the many patients with untreated ventral hernias not included in the analysis, makes conclusions on risk factors for emergency repairs problematic.

Because of the general lower morbidity and more advanced technology the proportion of laparoscopic procedures continues to increase at the expense of open surgery. The low incisional hernia rate is one of the major benefits of laparoscopic surgery. After 12 years follow-up, we demonstrated a low risk for a trocar site hernia repair, but the percentage of emergency repairs was relatively high.

Parastomal hernias are relatively common. Nevertheless, few parastomal hernia repairs are performed annually. We documented that outcome in terms of early morbidity and recurrence is unacceptable. No difference in outcome is shown between open or laparoscopic repairs, or between the laparoscopic Keyhole and Sugarbaker technique. However, the 25% risk for 30-day mortality after an emergency parastomal hernia underlines the importance of special attention on these patients by centralisation to relative few dedicated centres and by more research to provide better surgical solutions.

Based predominantly on nationwide data, the present thesis has accomplished pioneering results on outcome from ventral hernia repairs. The results have inspired to increased research, and the development of other ventral hernia databases as well as pointed out a number of risk factors for poor outcome and future challenges in ventral hernia surgery. DVHD and similar registers have a huge potential and can serve as an essential and important platform for further improvement of ventral hernia surgery in the future.

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