Introduction

There are currently seven national or international hernia registries around the world (Danish Hernia Database, Swedish Hernia Registry, Herniamed, EuraHS, Club Hernie, EVEREG and AHSQC) and there are ongoing efforts in some countries to launch additional national registries.

Traditionally, medical and surgical research have focused...
The intention of both bases has, from the beginning, been that the generated data should result in a reduction in morbidity and operations for recurrence after hernia surgery. Furthermore, registration should allow evaluation of new treatments and implants (mesh, tacks, etc.). The design of the databases allows life-long control of registered patients which makes it an ideal platform for pre-marketing evaluation and post-marketing surveillance of new hernia specific products as demanded by new regulations in the European Union (9). Recently, data from the Ventral Hernia Database as well as from the German Herniamed database resulted in the withdrawal of a specific mesh from the international market (10,11).

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). However, this study did not require ethical committee approval or patient consent according to Danish law. To obtain the data for the current analyses we received permission from the Danish Data Protection Agency and the Clinical Quality Development Program in the Regions of Denmark (RKKP).

Data for this study were extracted from the Danish Hernia Database, both the inguinal as well as the ventral part of the database. Data were extracted for the period January 1, 1998 to December 31, 2019. Data were analyzed with descriptive statistics with means and standard deviations for normally distributed continuous data. For categorical data, counts (n) and percentages were used. Cumulated re-operation rates were illustrated with the use of the Kaplan Meier method. No statistical comparisons were made. All data were analyzed, and graphs produced with IBM SPSS version 25.

Methods

The Danish Inguinal Hernia Database was established in 1997 aiming to monitor outcomes after inguinal hernia repair thus creating a scientific basis for improvement of quality over time based on national data (3,4). Registration of hernia operations is mandatory, and the databases are publicly funded. Registration started January 1, 1998 using a single page (paper) registration form (Figure 1) focusing on basic information in inguinal hernia repair. The data are merged with data from the Danish Patient Registry resulting in a wealth of data answering some questions and raising others. The process resulted in several publications within a few years (5) and started a new interest in hernia research worldwide. January 1, 2007 the inguinal base went on-line via a safe server-based system. Simultaneously, the Danish Ventral Hernia Database (6,7) was launched, again with a simple registration form (Figure 2) and also online.

The design of the databases allows life-long control of new treatments and implants (mesh, tacks, etc.). The variables in both databases have been updated regularly, latest July 1, 2020 (Tables 1,2), due to a demand for up to date, clearly defined and standardized datasets (8). Outcome data for the many scientific publications from the database depend on the hypothesis and scientific question, and as these may change over time, the steering committee decides for updates of variables when needed.
first-time operations.

Laparoscopic inguinal hernia repair was performed in 39,348 operations as the first procedures, with 7,050 (17.9%) operations in female patients. The findings during the laparoscopic operations for inguinal hernia are given in Table 4. The cumulated reoperation rate for laparoscopic inguinal hernia repair can be seen in Figure 3. The crude reoperations rates for recurrence for right sided hernias

Figure 1 The original paper-based registration form for the Danish Inguinal Hernia Database. This was replaced by an online version in 2007.
Figure 2 The initial simple online registration form for the Danish Ventral Hernia Database [reproduced with permission from Hernia (6)]. The registration form has since become more complicated with more variables.
were 588/17,659 (3.3%), for left sided hernias 404/11,415 (3.5%), and for bilateral hernias 870/10,274 (8.5%).

Ventral hernia

Data presented here cover the period January 1, 2007 to December 31, 2019. During this period a total of 60,232 operations in 53,952 patients were registered in the database with 5,210 patients being registered with more than one procedure. The national registration rate for the Ventral Hernia Database was 78.7% for 2018. Most operations were for one hernia, but 2,785 procedures were for more than one type of hernia (e.g., umbilical and incisional). During the patients’ first registered repairs their mean age were 54 years (SD 15.1), 31,642 (58.6%) were male, and 47,819 (88.6%) repairs were elective. The different types of hernias can be seen in Table 5. As seen in Table 6, the majority of reoperations for recurrence were performed in patients having a laparoscopic repair as their primary operation.

As robot-assisted technique is still new in Denmark, only 195 patients were operated with this technique. This comprised 88 umbilical hernias, 49 incisional hernias, 26 linea alba hernias, 16 other type of hernias, 14 port site hernias, and 2 parastomal hernias. For these operations mesh placement was sublay retromuscular in 85 patients, retromuscular preperitoneal in 46 patients, preperitoneal in 44 patients, intraperitoneal in 18 patients, and onlay in 2 patients. Of the 195 patients undergoing robot-assisted hernia repair, 185 patients had one hernia, and 10 had more than one hernia.

Table 1 Variables in the Danish Inguinal Hernia Database

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Level 1</th>
<th>Level 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital or private clinic, name</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgeon’s national identification code</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient characteristics</td>
<td>Age (generated from social security number); sex (generated from social security number); site of hernia (left; right; bilateral*); recurrent hernia (y/n)</td>
<td>If yes: recurrence number</td>
</tr>
<tr>
<td>Operative conditions</td>
<td>Elective/acute (y/n); supervised surgery (y/n); type of anaesthesia (general; regional; local)</td>
<td></td>
</tr>
<tr>
<td>Operative findings</td>
<td>Type of hernia (inguinal; femoral; combined); sliding hernia (y/n); size of hernia defect (&lt;1; 1; 2; ≥3 fingers; unknown); iliohypogastric nerve (seen and preserved; seen and divided; not seen); ilioinguinal nerve (seen and preserved; seen and divided; not seen); additional operative findings (text)</td>
<td>If inguinal or combined: direct, indirect, saddle (pantaloon), unspecified</td>
</tr>
<tr>
<td>Operative technique</td>
<td>Type of operation** (Lichtenstein, Onstep, other open mesh repair, laparoscopic, laparoscopic converted to open, r-laparoscopic, r-laparoscopic converted to laparoscopic or open, other procedure); type of mesh, selection from drop-down menu including other type of mesh; mesh: width, length (cm); mesh fixation technique (suture, tacks, suture and tacks, clips, glue, glue and suture, glue and tacks, self-fixing mesh, other fixation, no fixation); closure of peritoneal defect, only for laparoscopic TAPP (suture, tacks, clips, glue, other, not relevant)</td>
<td>If other open mesh repair, specify: plug, plug and patch, other, specify (text). If open non-mesh repair, specify: anuloraphy, McVay, Bassini, Shouldice, other, specify (text). If laparoscopic, specify: transperitoneal, preperitoneal. If other procedure, specify procedure (text). If other type of mesh, specify mesh (text). If glue, specify: Histoacryl, Tisseel, other (text). If tacks, specify: absorbable, non-absorbable. If suture, specify: not self-locking, V-Loc, Stratafix, other self-locking</td>
</tr>
</tbody>
</table>

*: opens two separate entry forms – one for each side. **: includes these two additional options for femoral hernias: 1. Open infra-ligamentous repair [plug or other method - specify (text)] and 2. Open combined infra- and supra-ligamentous repair, specify: mesh, modified McVay, Onstep, McVay, other [specify (text)]. r-laparoscopic, robot-assisted laparoscopic.
The development in use of mesh during the existence of the Ventral Hernia Database appears in Figure 4. The most remarkable development is the increased use of mesh (decreased use of no mesh), the increased use of onlay mesh placement, and the decreased use of intraperitoneal (IPOM) mesh placement. Development in use of surgical approach
for all patients can be seen in Figure 5. It shows a new trend of decreasing use of laparoscopic technique with increased use of open methods.

**Discussion**

The two Danish hernia databases have run successfully for many years. Numerous scientific publications have emerged from the data (5) and quality of care for patients with hernia has increased along an increased international awareness on this common condition. Databases have emerged in many other countries and it will be advantageous in the future to be able to combine data from different databases (1). Variables in the Danish Databases have developed over the years when new scientific questions needed answer. The databases are run by a steering committee, and all surgeons in Denmark are obliged to enter data after each operation. Currently, the steering committee is discussing further collaboration with members of the industry as well as exporting the database concept to several European countries. Denmark is a small country (<6 mill inhabitants; ~17,000 hernia operations per year) and as a result it takes time to get sufficient data for relevant evaluation. Imagine what effect pooled data from identical databases in countries with a total of maybe 50–100 million inhabitants would have on our insight in treatment strategies and use of implants.

The databases aim at implementing pre- and postoperative Patient-Reported Outcome Measures (PROMs). It is, however, not without problems. Almost all relevant data concerning this topic are based on measures defined by doctors and not patients (12) and the currently available PROMs are most often not sufficiently validated (13,14). Work on identifying patient defined measures and with relevant validation are ongoing and will hopefully soon be integrated in the databases if possible, considering the European General Data Protection Regulation (GDPR) (15). Thus, there are still some obstacles, but we hope to include PROMs in a few years from now.

Register-based research has its advantages, especially when studying delayed health effects of treatment (16).
Randomized clinical trials will typically include a selected population with many exclusion criteria, resulting in high internal validity but low external validity. Observational studies, however, describe usual clinical practice without any predefined study-specific intervention, and for the study of late outcomes especially in terms of reoperation for recurrence after hernia repair, the observational registry-based study design is optimal. Thus, studies based on national hernia registries have in important place in hernia research, and they will potentially be able to change clinical practice around the world. Locally, in our country, the

![Cumulated reoperation rate for laparoscopic inguinal hernia repair by TAPP technique. Reoperation rate are given as % and follow-up in years.](image)

**Figure 3** Cumulated reoperation rate for laparoscopic inguinal hernia repair by TAPP technique. Reoperation rate are given as % and follow-up in years.

<table>
<thead>
<tr>
<th>Type of hernia</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Umbilical hernia</td>
<td>29,188</td>
<td>54.1</td>
</tr>
<tr>
<td>Incisional hernia</td>
<td>12,254</td>
<td>22.7</td>
</tr>
<tr>
<td>Linea alba hernia</td>
<td>8,080</td>
<td>15.0</td>
</tr>
<tr>
<td>Port site hernia</td>
<td>1,861</td>
<td>3.4</td>
</tr>
<tr>
<td>Parastomal hernia</td>
<td>1,267</td>
<td>2.3</td>
</tr>
<tr>
<td>Other type of hernia</td>
<td>1,205</td>
<td>2.2</td>
</tr>
<tr>
<td>Stoma reversal hernia</td>
<td>97</td>
<td>0.2</td>
</tr>
</tbody>
</table>

**Table 5** Type of hernia in the Danish Ventral Hernia Database

<table>
<thead>
<tr>
<th>Variable</th>
<th>n/y</th>
<th>%</th>
<th>2019*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laparoscopic converted to open</td>
<td>103/761</td>
<td>13.5</td>
<td>38</td>
</tr>
<tr>
<td>Laparoscopic</td>
<td>1,183/14,127</td>
<td>8.4</td>
<td>699</td>
</tr>
<tr>
<td>Open</td>
<td>2,868/38,810</td>
<td>7.4</td>
<td>2,878</td>
</tr>
<tr>
<td>Robot assisted</td>
<td>5/195</td>
<td>2.6</td>
<td>93</td>
</tr>
<tr>
<td>Other minimal invasive</td>
<td>0/35</td>
<td>0.0</td>
<td>30</td>
</tr>
<tr>
<td>Open converted to laparoscopic</td>
<td>0/24</td>
<td>0.0</td>
<td>9</td>
</tr>
<tr>
<td>Total</td>
<td>4,159/53,952</td>
<td>7.7</td>
<td>3,747</td>
</tr>
</tbody>
</table>

The column 2019 gives the number of primary procedures in 2019. *For 2019, the re-operation for recurrence has not been added, since the follow up is very short.

**Table 6** Reoperations for recurrence (n) relative to the number of primary procedures (y) in 53,952 patients having a reoperation for recurrence after ventral hernia repair

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Figure 4 Development in use of mesh for all patients with primary registered procedure in the Danish Ventral Hernia Database.

Figure 5 Development in use of surgical approach for all patients in the Ventral Hernia Database. Categories <5% have been combined into “other”.
Danish Hernia Databases have changed clinical practice as a product of numerous scientific studies (5) as well as yearly meetings where results are discussed with clinicians from all hospitals performing hernia operations. As examples we have through the years streamlined surgical techniques for the Lichtenstein and laparoscopic inguinal hernia repairs, we have almost fully removed other surgical methods than these two modalities (Table 3), we have removed the use of regional anaesthesia (spinal and epidural) for inguinal hernia surgery, and we have moved the majority of inguinal hernia repairs from open to laparoscopic technique (Table 3).

In conclusion, this paper provides an update on the registered parameters in the two Danish Hernia Databases. The databases are continuously used for answering clinically relevant questions and evaluation of surgical methods and implants in order to improve clinical outcome for the patients.

Acknowledgments

Funding: None.

Footnote

Provenance and Peer Review: This article was commissioned by the editorial office, Laparoscopic Surgery for the series “Hernia Surgery”. The article has undergone external peer review.

Reporting Checklist: The authors have completed the MDAR reporting checklist. Available at http://dx.doi.org/10.21037/ls-20-125

Data Sharing Statement: Available at http://dx.doi.org/10.21037/ls-20-125

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/ls-20-125). The series “Hernia Surgery” was commissioned by the editorial office without any funding or sponsorship. JR served as the unpaid Guest Editor of the series and serves as an unpaid editorial board member of Laparoscopic Surgery from Feb 2020 to Jan 2022. HFA reports grants from Medtronic, Sofradim, and Trevoux (France) outside the submitted work. The authors have no other conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). However, this study did not require ethical committee approval or patient consent according to Danish law. According to Danish law, no informed consent is required from patients anonymously reported as in the current study.

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Cite this article as: Rosenberg J, Friis-Andersen H, Jørgensen LN, Andresen K. Variables in the Danish Hernia Databases: inguinal and ventral. Laparosc Surg 2021.