



Variables in the Danish Hernia Databases: inguinal and ventral

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Background: Some clinical questions are best answered by a database study design, and the two Danish Hernia Databases have been a driver of both national and international hernia research for many years. We wanted to give a detailed overview of the currently registered data in the Danish Inguinal Hernia Database and the Danish Ventral Hernia Database.

Methods: The Danish Inguinal Database was launched in 1997, and the Danish Ventral Hernia Database in 2007. It is mandatory for Danish surgeons to enter operative data after each hernia repair, both in public and private hospitals. The variables in the two databases have been updated regularly.

Results: The two databases started with quite simple registration forms and have over the years developed into more complex registries. In the article we give a detailed overview of the currently registered data in the two databases. During the period January 1, 1998 to December 31, 2019 a total of 181,715 patients were registered in the databases. For inguinal hernia repair through the lifespan of the database, 22% were done by laparoscopy and 62% by Lichtenstein repair. There was about twice as high reoperation rate for recurrence for bilateral compared with unilateral hernias. Ventral hernias in the database comprised 54% umbilical hernias, 23% incisional hernias, and 15% linea alba hernias. For ventral hernias we observed decreased use of intraperitoneal mesh placement and increased use of onlay procedure. In recent years the use of laparoscopic technique for ventral hernia repair has slightly decreased and open procedures slightly increased.

Conclusions: The two Danish hernia databases register all hernia repairs in Denmark where it is mandatory for surgeons to enter operative data after each operation. Variables have been updated several times over the years when new scientific questions needed answers. National databases give the opportunity to follow development in daily clinical practice and to answer important scientific questions.

Keywords: Inguinal hernia; ventral hernia; databases; registries; quality; outcome

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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) (1) and there are ongoing efforts in some countries to launch additional national registries.

Traditionally, medical and surgical research have focused

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on randomized controlled trials (RCTs) as the golden standard. RCTs are excellent tools for studying a specific intervention while all other influencing factors are either eliminated or assumed to be equally distributed between study groups. This results in excellent internal validity, but the patients as well as operating surgeons have typically been selected carefully for inclusion in such trials. Thus, external validity is not sufficiently high for broader clinical implementation. In this context, national clinical databases are excellent tools when studying daily clinical routines with the highest possible external validity. In surgery, many important clinical questions cannot be answered in the context of an RCT. Although being heavily criticized by non-surgeons (2), this is the reason why surgical research often uses an observational design.

The aim of the current paper was to give an update on the registered parameters in the two Danish Hernia Databases, the Danish Inguinal Hernia Database and the Danish Ventral Hernia Database, as well as give an overview of the available data. We present the following article in accordance with the MDAR reporting checklist (available at <http://dx.doi.org/10.21037/ls-20-125>).

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 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.

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 Herniated 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.

Results

Inguinal hernia

Data presented here cover the period January 1, 1998 to December 31, 2019. During this period a total of 181,715 patients were registered in the database comprising 18,710 females (10.3 %) with a national registration rate of 90.2% for 2018. We restructured database entries into individual patients, thus two entries for a bilateral operation are presented as one patient having a bilateral operation. In total, 85.8% of patients were only operated once in the course of the database (either left, right, or bilateral). For the first procedure, the sides of surgery were right n=98,648 (54.3%), left n=70,919 (39.0%), and bilateral n=12,148 (6.7%). See *Table 3* for details of type of surgery for these

Registration form - Danish Hernia Database

Social security number			Name of patient		
<input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			<input style="width: 100%;" type="text"/>		
Date of operation		Hospital/dep./clinic		Operators init./code	
<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
Type of patient			Date of admittance		
<input type="checkbox"/> Day case (ambulatory) <input type="checkbox"/> Elective, admitted <input type="checkbox"/> Acute			<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>		

Side		Operation for recurrence	
If operation bilateral - please fill out two separate forms <input type="checkbox"/> Left <input type="checkbox"/> Right		<input type="checkbox"/> Yes <input type="text"/> Number of recurrences <input type="checkbox"/> No	
Anaesthesia		Operative findings	
<input type="checkbox"/> Spinal/Epidural <input type="checkbox"/> General anaesthesia <input type="checkbox"/> Local anaesthesia		<input type="checkbox"/> Inguinal hernia <input type="checkbox"/> Direct <input type="checkbox"/> Sliding hernia <input type="checkbox"/> Indirect <input type="checkbox"/> Femoral hernia <input type="checkbox"/> No hernia found Other pathology _____	

Open procedure		Laparoscopic procedure	
<input type="checkbox"/> Bassini	<input type="checkbox"/> Plug, fixated	<input type="checkbox"/> Intraperitoneal	
<input type="checkbox"/> McVay	<input type="checkbox"/> Plug, ufixated	<input type="checkbox"/> Extraperitoneal	
<input type="checkbox"/> Shouldice	<input type="checkbox"/> Lichtenstein	<input type="checkbox"/> Other laparoscopic procedure (specify) _____	
<input type="checkbox"/> Annuloraphy	<input type="checkbox"/> Mesh, ufixated		
<input type="checkbox"/> Extirpation of sack	<input type="checkbox"/> Other open operation (specify) _____		
Type of mesh used		If laparoscopic procedure converted to open - please note under "Remarks"	

Remarks

Figure 1 The original paper-based registration form for the Danish Inguinal Hernia Database. This was replaced by an online version in 2007.

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

The image shows a screenshot of a web-based registration form for ventral hernia. The form is titled "Ventral hernia: Registration" and is part of a system called "KMS 1.4". The form is divided into several sections:

- Header:** Includes fields for "Patient: i", "GPR-Number", "Ventralhernie: Registrering", "Print", "Gem", "Gem & forlad", "Indlever", "Indlever & forlad", and "Indlever & forlad".
- Date of operation:** A "Calendar" field.
- Surgeon:** A field for "(initialer/kode)".
- Elective/acute:** Radio buttons for "Elective" and "Acute".
- Primary/secondary operation:** Radio buttons for "Primary intervention", "Secondary intervention", "1st. Hernia operation", and "Recurrence operation".
- Type of hernia:** A "Choice" dropdown menu with options: "Incisional hernia", "Umbilical hernia", "Linea alba hernia", "Stomal hernia", "Port hernia", and "Other".
- Defects:** Fields for "Number of defects (?)", "Total vertical length (?) (cm)", and "Total horiz. length (?) (cm)".
- Operation:** Radio buttons for "Open", "Laparoscopic", and "Laparoscopic converted to open".
- Mesh type:** A "Choice" dropdown menu.
- Mesh size (cm):** Fields for "Length", "X Width", and "Min. overlap (cm)".
- Mesh location:** A "Choice" dropdown menu.
- Mesh fixation:** A "Choice" dropdown menu.
- Closure:** Radio buttons for "Mesh closure" (Yes/No), "Suture closure" (Yes/No), and "Stomal relocation" (Yes/No).
- Type of suture (filament):** Radio buttons for "Multifilament" and "Monofilament".
- Suture (absorp.):** Radio buttons for "Absorbable" and "Non-absorbable".
- Additional procedures:** Radio buttons for "No mesh", "Decompressive incisions", "Fascia plastic", and "Mesh reinforcement".

Red callouts highlight specific features:

- Pop-up:** A red box highlights the "Mesh type" and "Mesh size (cm)" fields.
- Pop-down:** A red box highlights the "Type of suture (filament)" and "Suture (absorp.)" fields.
- Pop-down:** A red box highlights the "Defects" section, specifically the "Number of defects" field.
- Pop-down:** A red box highlights the "Type of hernia" dropdown menu.
- Describe:** A red box highlights the "Describe" button.

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.

Table 1 Variables in the Danish Inguinal Hernia Database

Parameter	Level 1	Level 2
Date of surgery		
Hospital or private clinic, name		
Surgeon's national identification code		
Patient characteristics	Age (generated from social security number); sex (generated from social security number); site of hernia (left; right; bilateral*); recurrent hernia (y/n)	If yes: recurrence number
Operative conditions	Elective/acute (y/n); supervised surgery (y/n); type of anaesthesia (general; regional; local)	
Operative findings	Type of hernia (inguinal; femoral; combined); sliding hernia (y/n); size of hernia defect (<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)	If inguinal or combined: direct, indirect, saddle (pantaloon), unspecified
Operative technique	Type of operation** (Lichtenstein, Onstep, other open mesh repair, open non-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)	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 tacks, specify: Absorbatack, Optifix, Protack, Capsure, Reliatack, Securestrap, other (text). If suture, specify: not self-locking, V-Loc, Stratafix, other self-locking

*: 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.

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 2 Variables in the Danish Ventral Hernia Database

Parameter	Level 1	Level 2
Date of surgery		
Hospital or private clinic, name		
Surgeon's national identification code		
Patient characteristics	Age (generated from social security number); sex (generated from social security number); weight; height (calculating BMI); smoking within last 6 weeks; medically treated comorbidity excluding hypertension, specify diabetes, cardiac, pulmonary, other (hepatic, renal, brain, thyroid); hernia repair, is it the primary (main) or a secondary procedure? recurrent hernia (y/n); botox, preoperative administration	If yes: recurrence number
Operative conditions	Elective/acute (y/n); supervised surgery (y/n); antibiotics, perioperative administration	
Operative findings	Type of hernia (incisional, umbilical, epigastric, spiegel, port site, parastomal, other); direction of scar (longitudinal, transverse); European Hernia Society Classification [M1-M5, L1-L4 (right), L1-L5 (left)]; fascial defects, total number; fascial defects, total length (cm); fascial defects, total width (cm); rectus diastasis (>2 cm between rectus muscles); contamination level (clean, potentially contaminated, contaminated, dirty)	If parastomal, specify colostomy, ileostomy or urostomy. If other, specify (text)
Operative technique	Type of operation (open, laparoscopic, combined open and laparoscopic, laparoscopic converted to open, r-assisted laparoscopic, r-assisted laparoscopic converted to laparoscopic or open, other minimally invasive); component separation (y/n); defect closure with suture (y/n); use of mesh (y/n); type of mesh, selection from drop-down menu including other type of mesh; mesh placement (onlay, inlay, sublay/retromuscular, retromuscular + preperitoneal (TAR), intraperitoneal; other); mesh: width, length (cm); mesh overlap, minimal value (cm); if incisional hernia, whole scar covered with mesh? if parastomal hernia, specify keyhole, Sugarbaker, keyhole and Sugarbaker; 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 skin, specify: not intracutaneous suture, intracutaneous, staples, other technique	If other minimally invasive, specify: MILOS, eMILOS, eTEP, other procedure [specify (text)]. If component separation, specify: (I) open, endoscopic, open and endoscopic. (II) unilateral, bilateral. (III) external oblique, transversus abdominis, external oblique and transversus abdominis. If suture closure, specify: (I) mono- or multifilamentous suture. (II) quickly resorbable (specify Vicryl, Dexon, Monocryl), slowly resorbable (specify PDS, Maxon, Monomax), non-resorbable [specify Prolene, nylon, Ethibond, Mersilene, other (text)]. (III) non-locking or locking suture (specify V-loc, Stratafix, other). If other type of mesh, specify mesh (text). If suture, specify a. monofilamentous or multifilamentous, b. quickly restorable (specify Vicryl, Dexon, Monocryl), slowly resorbable (specify PDS, Maxon, Monomax), non-resorbable (specify Prolene, nylon, Ethibond, Mersilene, other (text)), c. non-locking or locking suture (specify V-loc, Stratafix, other). If tacks, specify: absorbable, non-absorbable. If tacks, specify: Absorbatack, Capsure, Optifix, Protack, Reliatack, Securestrap, other (text)

r-assisted, robot-assisted; MILOS, Mini- or less-open sublay; eMILOS, endoscopic MILOS.

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

Table 3 The type of surgery for first inguinal hernia repair in the Danish national Hernia Database

Type of surgery	All years, n (%)	2019, n (%)
Laparoscopic	39,348 (21.7)	3,373 (61.0)
Lichtenstein	112,158 (61.7)	1,795 (32.4)
Laparoscopic converted to open	8 (0.0)	8 (0.1)
Mixed (bilateral procedures)	198 (0.1)	3 (0.1)
Onstep	976 (0.5)	63 (1.1)
Robot	353 (0.2)	173 (3.1)
Robot converted	5 (0.0)	1 (0.0)
Other open mesh	12,212 (6.7)	36 (0.7)
Other procedure	5,538 (3.0)	13 (0.2)
Infra ligament	1,749 (1.0)	21 (0.4)
Combined infra and supra ligament	1,385 (0.8)	16 (0.3)
Open non-mesh	7,785 (4.3)	32 (0.6)
Total	181,715 (100.0)	5,534 (100.0)

Numbers are given for all years and for 2019.

Table 4 Findings at laparoscopic inguinal hernia repair in 39,348 operations performed as the first procedures. A total of 7,050 (17.9%) operations were performed in female patients

Finding	n	%
Femoral	2,028	5.2
Inguinal	36,119	91.8
No hernia found	88	0.2
Different hernias on both sides	1,113	2.8
Total	39,348	100.0

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).

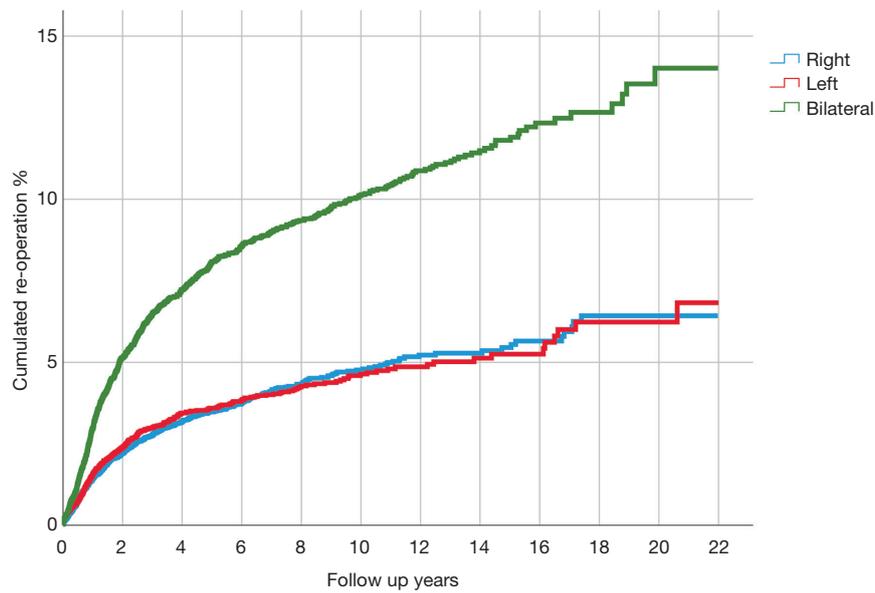


Figure 3 Cumulated reoperation rate for laparoscopic inguinal hernia repair by TAPP technique. Reoperation rate are given as % and follow-up in years.

Table 5 Type of hernia in the Danish Ventral Hernia Database

Type of hernia	n	%
Umbilical hernia	29,188	54.1
Incisional hernia	12,254	22.7
Linea alba hernia	8,080	15.0
Port site hernia	1,861	3.4
Parastomal hernia	1,267	2.3
Other type of hernia	1,205	2.2
Stoma reversal hernia	97	0.2

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 an important place in hernia research, and they will potentially be able to change clinical practice around the world. Locally, in our country, the

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

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

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.

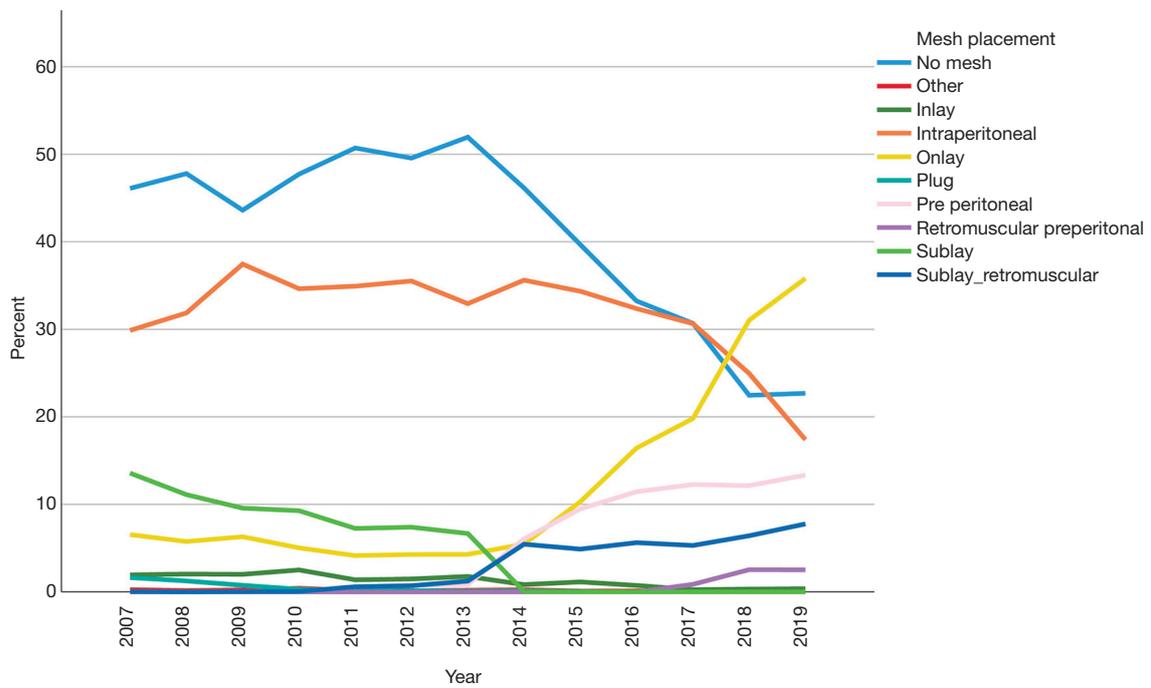


Figure 4 Development in use of mesh for all patients with primary registered procedure in the Danish Ventral Hernia Database.

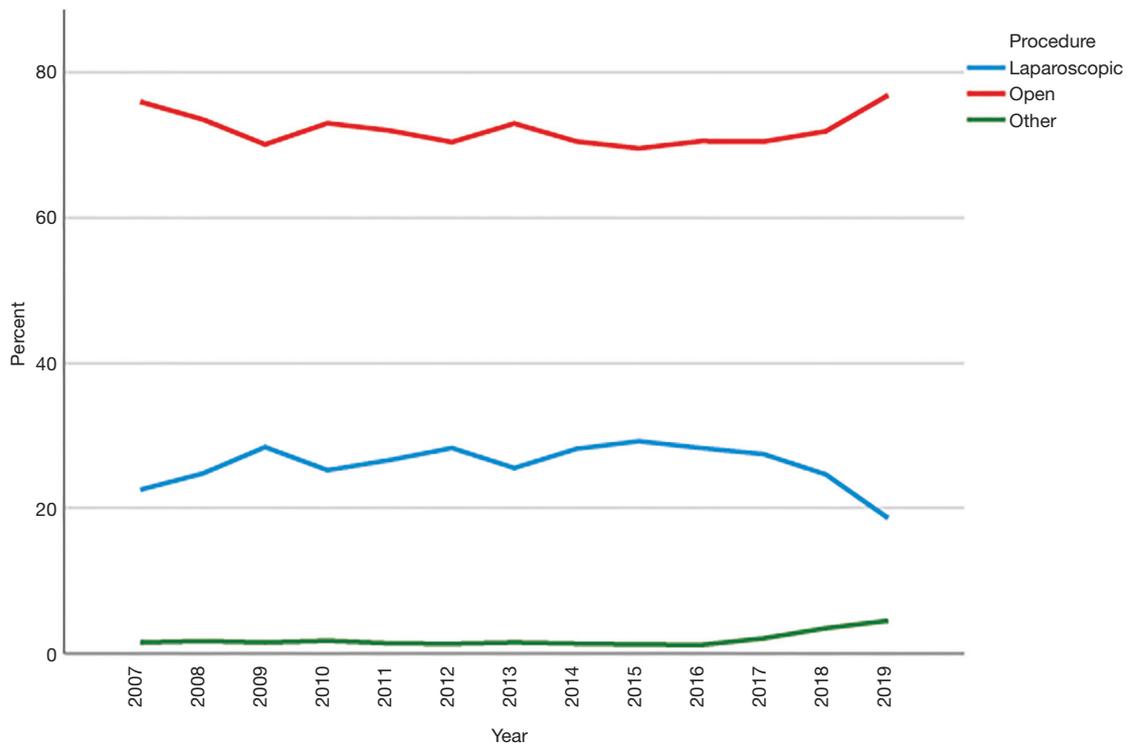


Figure 5 Development in use of surgical approach for all patients in the Ventral Hernia Database. Categories <5% have been combined into "other".

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.

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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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