

High agreement between the Danish Ventral Hernia Database and hospital files

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ABSTRACT

INTRODUCTION: Ventral hernia repairs are common surgical procedures and quality monitoring with a high validity is mandatory. The aim of the present study was to validate the data quality of the Danish Ventral Hernia Database (DVHD).

MATERIAL AND METHODS: All ventral hernia repairs performed in the Region of Zealand and registered in the DVHD between 1 October 2010 and 1 October 2011 were included. Eleven clinically relevant surgical variables in the DVHD were compared for agreement with data in hospital files.

RESULTS: The Region of Zealand cohort included 410 ventral hernia repairs corresponding to 13.8% of the repairs registered in the DVHD in Denmark during the inclusion period. There was 89-99% agreement between data in the DVHD and hospital files ($\kappa = 0.75-0.99$).

CONCLUSION: The present study based on a regional cohort suggests that the DVHD can be used as a reliable tool to monitor clinical quality following ventral hernia repair.

FUNDING: not relevant.

TRIAL REGISTRATION: The study was approved by the Danish Data Protection Agency, ref. no. 2008-58-0020 and registered at clinicaltrials.gov (NCT01827410).

Ventral hernia repair is a common surgical procedure with more than 3,000 repairs performed in Denmark and 400,000 in the United States annually [1-3]. However, surgical outcome following ventral hernia repair is not always optimal [2-7] and the Danish Ventral Hernia Database (DVHD) was established in 2007 to monitor and improve surgical quality following ventral hernia repair [8]. However, the quality of DVHD registrations has not previously been validated [8].

The present study was undertaken to compare data in the DVHD with data from hospital files on ventral hernia repairs.

MATERIAL AND METHODS

All patients with a ventral hernia repair performed in the Region of Zealand (820,000 inhabitants) and registered in the DVHD were included. The study period ran from 1 October 2010 to 1 October 2011.

DVHD data entry is based surgeon-driven prospective online web-registration immediately after the operation. If not performed directly after the operation, post

hoc registration from hospital files is secured through a standardised reminder system [8]. Reminders are obtained by computerized merging of DVHD and Danish National Patient Register (DNPR) data, as described in detail elsewhere [8, 9].

In the present study, data from the DVHD were compared with information recorded in patients' hospital files by blinded observer assessment. Thus, two "blinded" investigators analysed data from the DVHD and from hospital files. For this purpose, eleven clinical relevant variables registered in DVHD were chosen. The variables were type of hernia, surgical technique, if hernia repair was the primary reason for operation, primary or recurrent hernia repair, elective or emergency repair, hernia size, mesh or sutured repair, suture material, mesh position, mesh product, and mesh fixation methods. Agreement between the DVHD and the hospital files was defined as identical registration and was assessed at three levels: overall agreement regardless the day of registration, agreement for data registered in the DVHD the same day as the repair (perioperative registrations), and agreement for data registered one day or more after repair (post hoc registrations). Hernia size was defined as largest stated diameter in cm. Before study start, we decided that ≤ 1 cm discrepancy between measures in the DVHD and the hospital files was allowed to avoid minor decimal inaccuracies. We defined that in the patient files, an elective repair was a planned repair and emergency repair was a hernia repair performed during a non-planned hospitalization. Suture material was categorized as fast-absorbable, slow-ab-

ORIGINAL ARTICLE

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Dan Med J
2013;60(10):A4708



High agreement between the Danish Ventral Hernia Database and hospital files in the Region of Zealand.

TABLE 1

Hernia characteristics for procedures included in validation of The Danish Ventral Hernia Database.

	Total (N = 410)	Laparoscopic (N = 128)	Open (N = 277)	Converted (N = 5)
<i>Gender, n (%)</i>				
Female	163 (39.8)	44 (34.4)	116 (41.9)	3 (60.0)
Male	247 (60.2)	84 (65.6)	161 (58.1)	2 (40.0)
Age, years, median (range)	54 (20-93)	56 (25-86)	52 (20-93)	59 (42-73)
Hernia defect size, cm, median (range)	2.0 (0.2-34.0)	4 (1.0-25.0)	1.2 (0.2-34.0)	5.0 (2.0-16.0)
Mesh repair, n (%)	241 (58.9)	128 (100)	109 (39.4)	4 (80.0)
Sutured repair, n (%)	169 (41.2)	0 (0)	168 (60.6)	1 (20.0)
<i>Type of hernia, n (%)</i>				
Umbilical	220 (53.7)	50 (39.1)	169 (61.0)	1 (20.0)
Incisional	100 (24.4)	50 (39.1)	47 (17.0)	3 (60.0)
Epigastric	68 (16.6)	15 (11.7)	52 (18.8)	1 (20)
Parastomal	5 (1.2)	3 (2.3)	2 (0.7)	0 (0)
Port	11 (2.6)	5 (3.9)	6 (2.2)	0 (0)
Other	6 (1.4)	5 (3.9)	1 (0.4)	0 (0)

TABLE 2

Agreement between patient files and The Danish Ventral Hernia Database (N = 410).

Compared parameter	Overall agreement		Missing data n (%)
	% (CI 95%)	κ (CI 95%)	
Type of hernia	95.6 (94.9-98.4)	0.93 (0.90-0.96)	0
Open, laparoscopic or converted	99.0 (98.1-100)	0.98 (0.96-1.00)	0
Concomitant surgery	98.5 (97.4-99.7)	0.92 (0.86-0.98)	0
Primary or recurrent repair	95.4 (93.3-97.4)	0.78 (0.68-0.87)	0
Elective versus emergency	98.0 (96.7-99.4)	0.92 (0.86-0.99)	0
Hernia size: widest diameter	94.1 (91.7-96.4)	0.93 (0.90-0.96)	22 (5.3)
Mesh or no mesh	99.5 (98.8-100)	0.99 (0.97-1.00)	0
Sutured repair: suture material	89.2 (84.4-93.9)	0.75 (0.64-0.85)	3 (1.2)
<i>Mesh repair</i>			
Position	94.1 (91.1-97.1)	0.87 (0.81-0.94)	6 (2.5)
Mesh product	94.3 (91.3-97.3)	0.93 (0.89-0.96)	14 (5.8)
Mesh fixation	99.2 (98.0-100)	0.99 (0.97-100)	4 (1.7)

CI = confidence interval.

sorbable, and non-absorbable material. The mesh product was categorized according to its commercial product name.

Statistics

Agreement of data in the DVHD and hospital files was assessed as percentage of complete agreement supported by chance corrected kappa values (κ) (< 0.00 = poor agreement; 0.00-0.20 = slight agreement; 0.21-0.40 = fair agreement; 0.41-0.60 = moderate agreement; 0.61-0.80 = substantial agreement; 0.81-1.00 = high agreement). The DVHD has no missing data since registrations cannot be completed if some information is lacking. In case of missing information in the hospital files, the comparison with DVHD data was excluded from the analyses.

Data are presented as median (range) if not stated otherwise. Confidence intervals were 95% (95% CI).

Trial registration: The study was approved by the Danish Data Protection Agency, ref. no. 2008-58-0020 and registered at clinicaltrials.gov (NCT01827410).

RESULTS

During the one-year study period, 410 operations in 408 patients were included in the analysis. Thus, our regional cohort accounted for 13.8% of all ventral hernia repairs registered in the DVHD during the inclusion period. The characteristics of hernia repairs are shown in **Table 1**. There were 272 (66.3%) perioperative registrations (same day as the hernia repair), whereas 138 (33.7%) registrations were post hoc (more than one day after the hernia repair). The median post hoc DVHD registration delay was 154 days after surgery (range 1-450 days). Missing data on at least one variable were found in 41 (10.0%) hospital files (predominantly on hernia defect size (22 files)).

The overall agreement (regardless of time of registration) between each variable in the DVHD and hospital files was substantial to high and varied between 89% and 99% ($\kappa = 0.75-0.99$) (**Table 2**). Perioperative and post hoc agreements varied between 90.0% and 99.2% ($\kappa = 0.78-1.00$) and 87.9-100% ($\kappa = 0.63-1.00$), respectively (**Table 3**). Thus, the agreement of both perioperative and post hoc registration with the DVHD was substantial to high.

The lowest κ values were those concerning suture material 89.2% ($\kappa = 0.75$; CI 95%: 0.64-0.85). In five of the 18 ventral hernia repairs with disagreement on the suture material variable, the difference was between slow- and fast-absorbable suture; and in the remaining 13 repairs, the difference was between non-absorbable and absorbable suture.

DISCUSSION

This study basically found a satisfactory, high agreement between data in the DVHD and hospital file data.

Results from the DHDB have shown that the continuous data registration and information on outcome has led to a more uniform choice of surgical technique and also an improved outcome for ventral and inguinal hernia repairs [10-12]. However, improved outcome by quality monitoring per se may be difficult to prove [13]. Nevertheless, a drive towards official monitoring to secure surgical quality has been increasingly argued for within Danish healthcare. The present study provides data indicating a satisfactory, high agreement between a clinical database and patients' hospital files for both perioperative and post hoc database registrations.

The only area for which data agreement was not at

the highest level was suture material. In hospital files, the commercial name of the suture was typically stated rather than the type of suture material, whereas in the DHDB the properties of the suture were registered (monofilament, multifilament, absorbable, non-absorbable, etc.).

Therefore, lack of agreement in suture material may in part be explained by surgeon's lack of knowledge about the properties of the different sutures. This is inopportune as suture material seems to affect outcome after ventral hernia repair [14] and correct registration is therefore extremely relevant. But, as discussed below, it can only be speculated whether data from the DVHD or journal files are more reliable.

The DNPR is a validated administrative national register covering all contacts to Danish healthcare providers (public and private) [15-18]. All registrations in the DNPR as well as the DVHD are based on patients' unique social security number. By merging data from the DVHD and the DNPR, surgical and administrative data such as length of hospital stay, concomitant procedures, readmissions, reoperations, recurrence operations and death are combined.

Moreover, missing registrations in the DVHD are also identified [8]. In order to increase registration rates, surgical departments are encouraged to perform even post hoc registration of missing operations. A high registration rate reduces the risk of bias and provides a nationwide perspective on results [19]. We found that post hoc registrations did not seriously compromise data quality [19]. However, late post hoc registration may be based on patient files and therefore correct information in patient files is crucial. Data entry into the DHDB is mandatory.

Nevertheless, we had a high level of post hoc data entry and the median period for post hoc data entry was surprisingly long (154 days). Thus, the continuous reminder system based on electronic matching between the DHDB and the DNPR 4-6 times a year is important to obtain high registration rates [8].

There are study limitations in the present analysis. The DVHD is a national database and the present study was based on a sample (cohort) from the Region of Zealand and may therefore not be representative of national results. However, our sample included approximately 14% of all repairs registered in the period with the same distribution of different hernia types as was found in the national data [8].

Another limitation is the comparison of data in the DVHD with hospital files. In this context, hospital files were the gold standard [20]. However, in the present study, 10% of the hospital files missed information regarding the surgical procedure. Thus, it can be speculated that some registrations in the DVHD were actually



TABLE 3

Validation of perioperative or post hoc registered data in The Danish Ventral Hernia Database.

Compared parameter	Perioperative registration ^a (N = 272)			Post hoc registration ^b (N = 138)		
	n	κ	(CI 95%)	n	κ	(CI 95%)
Type of hernia	272	0.95	(0.92-0.99)	138	0.89	(0.82-0.96)
Open, laparoscopic or converted	272	0.98	(0.96-1.00)	138	0.98	(0.06-1.00)
Concomitant surgery	272	0.94	(0.86-1.00)	138	0.90	(0.78-1.00)
Primary or recurrent repair	272	0.84	(0.74-93.4)	138	0.63	(0.41-0.85)
Elective versus emergency	272	0.94	(0.86-1.00)	138	0.89	(0.81-0.98)
Hernia size: widest diameter	260	0.95	(0.92-0.98)	128	0.89	(0.83-0.95)
Mesh or no mesh	272	1.00	(1.00-1.00)	138	0.96	(0.91-1.00)
Sutured repair: suture material	100	0.78	(0.65-.90)	66	0.70	(0.50-0.89)
<i>Mesh repair</i>						
Position	169	0.89	(0.82-0.96)	67	0.84	(0.72-0.96)
Mesh product	161	0.95	(0.92-0.99)	66	0.86	(0.77-0.96)
Mesh fixation	168	0.98	(0.95-1.00)	69	1.00	(1.00-1.00)

CI = confidence interval.

a) Registration same day as the ventral hernia repair.

b) Registration a minimum of one day after the ventral hernia repair.

more accurate than the corresponding information from the hospital files. Furthermore, the present validation may be limited by inadequate information from hospital files. Even though it is considered impossible in the daily surgical setting, the optimal validation of the DHDB would imply a random comparison of online DHDB registrations with video recording of the surgical procedures.

CONCLUSION

We found an acceptable, high agreement between data in the DVHD and hospital files suggesting that data in the DVHD are reliable and may be used for national monitoring of clinical quality following ventral hernia repair.

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ACCEPTED: 18 July 2013

CONFLICTS OF INTEREST: Disclosure forms provided by the authors are available with the full text of this article at www.danmedj.dk.

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