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ORIGINAL ARTICLE

Decreased re-operation rate for recurrence after defect closure in laparoscopic ventral hernia repair with a permanent tack fixated mesh: a nationwide cohort study

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Abstract

Purpose To investigate whether defect closure in laparoscopic ventral hernia repair reduces the re-operation rate for recurrence compared with no defect closure.

Methods Data were extracted from the Danish Ventral Hernia Database. Adults with an elective laparoscopic ventral hernia repair with tacks used as mesh fixation were included, if their first repair was between the 1st of January 2007 and the 1st of January 2017. Patients with defect closure were compared with no defect closure. Re-operation rates are presented as crude rates and cumulated adjusted re-operation rates. Sub-analyses assessed the effect of the suture material used during defect closure and also whether defect closure affected both primary and incisional hernias equally.

Results Among patients with absorbable tacks as mesh fixation, 443 received defect closure and 532 did not. For patients with permanent tacks, 393 had defect closure and 442 did not. For patients with permanent tacks as mesh fixation, the crude re-operation rates were 3.6% with defect closure and 7.2% without defect closure ($p = 0.02$). The adjusted cumulated re-operation rate was significantly reduced with defect closure and permanent tacks (hazard ratio = 0.53, 95% confidence interval = 0.28–0.999, $p = 0.05$). The sub-analysis suggested that defect closure was only beneficial for incisional hernias, and not primary hernias. We did not find any benefits of defect closure for patients with absorbable tacks as mesh fixation.

Conclusion This nationwide cohort study showed a reduced risk of re-operation for recurrence if defect closure was performed in addition to permanent tacks as mesh fixation during laparoscopic incisional hernia repair.

Keywords Ventral hernia · Defect closure · Laparoscopy · Mesh · Tacks

Introduction

Ventral hernia repair is a common procedure and more than 4500 repairs are performed each year in Denmark [1] with either the open or laparoscopic approach. In Denmark, the most common laparoscopic procedure is with an intraperitoneally placed mesh fixated with permanent or absorbable tacks without transfascial sutures [2]. A previous Danish study found that mesh fixation with permanent tacks resulted in fewer recurrences than mesh fixation with absorbable tacks, with recurrence rates of 18 and 29%, respectively [3]. However, it is important to improve the surgical technique to lower the recurrence rates further, and one way to do so might be to perform defect closure before securing the mesh during a laparoscopic ventral hernia repair. One guideline does recommend defect closure [4], even though high-level evidence is absent on the subject. Since the recurrence rates are high, it is important to investigate if defect closure truly reduces the recurrence rate in a nationwide study.

The purpose of this study was to investigate whether defect closure in laparoscopic ventral hernia repair reduces the re-operation rate for recurrence compared with no defect closure.

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Methods

This nationwide cohort study is based on prospectively collected data from the Danish Ventral Hernia Database (DVHB) and is reported according to the RECORD statement [5]. The DVHB is a nationwide database with a registration rate of 77% [6] and is validated with an estimated data accuracy of 94% [7]. In Denmark, every person has a unique personal identification number which is used for all hospital visits. All hospital encounters are registered in the Danish National Patient Register [8], which is linked to the DVHB through the personal identification number. The linkage ensures a transfer of administrative information of ventral hernia operations to the DVHB even if an operation is not registered in the database by the operating surgeon, or if the repair is performed at a different hospital (both private and public) than the first repair. The linkage also provides information if a patient dies or emigrates, which ensures a 100% follow-up rate. The database contains perioperative information such as date of admission, hernia type, and hernia size, if the operation was the patient's first hernia operation or a re-operation, surgical approach, and if defect closure was performed. However, perioperative information such as anesthesia and trocar technique is not included. The DVHB also contains information of which mesh fixation was used and if the material was absorbable or permanent. The database does not contain information of the length of the tacks, nor if the tacks were used in a double- or single-crown manner. However, in Denmark, it is recommended that the tacks are used in a double crown manner. For this study, the first registered operation was considered as a patient's first repair, unless it was stated that the operation was a re-operation. Any following operation for a ventral hernia was considered as an operation for a recurrent ventral hernia, i.e., a re-operation. Data were extracted the 1st of June 2017.

We included adults (≥ 18 years) that had received a laparoscopic ventral hernia repair with a permanent mesh, fixated only by tacks without transfascial sutures. All operations were elective for either a primary (umbilical or epigastric) or incisional hernia. Patients were only included if they had the first ventral hernia repair between the 1st of January 2007 and 1st of January 2017 allowing at least 5 months of follow-up. Patients were excluded if the first registered operation was registered as a re-operation, if the operation included component separation, or if it was a spigelian, parastomal, or a lumbar hernia. We also excluded patients who had received the Physiomesh® because of its association with an increased recurrence rate [9]. Patients were also excluded if the hernia repair was a secondary procedure to another operation or if there were missing data on mesh fixation, defect closure, fixation material, or type of hernia.

Because the fixation technique of the mesh can influence the recurrence rate [3], it was decided to analyze patients separately in two groups based on the fixation technique. Thus, we created one cohort of patients with absorbable tacks as mesh fixation, and another cohort with permanent tacks as mesh fixation. In these two cohorts, the effect of defect closure was compared with no defect closure. We attempted to limit the risk of selection bias by matching the area of the hernia defect within ± 5 cm^2. All patients with defect closure that fulfilled the eligibility criteria were included and matched with patients without defect closure.

The primary outcome was to compare the re-operation rate for recurrence between defect closure and no defect closure separately for each cohort. The secondary outcome was to assess the effect of defect closure with either absorbable or permanent sutures compared with no defect closure. Because primary and incisional hernias might have different etiologies, a preplanned sub-analysis was also performed to assess if there were different effects of defect closure depending on the hernia subtype. In the DVHB, hernia size is registered as length and width, which we re-calculated to an area (cm^2) with the formula of an ellipse: width * ½ * length * ½ * π = area.

Data and statistical analyses were handled by the statistical program SPSS version 22.0 (IBM, Armonk, NY, USA). p values ≤ 0.05 were considered statistically significant. Categorical data were presented as crude rates, i.e., number of cases divided by the total number of patients. These data were then compared with either the Chi-squared test or the Fisher's exact test. Continuous data were assessed for normal distribution with the Shapiro–Wilk test, and a $p > 0.05$ was considered as normally distributed data, which were then presented as mean and standard deviation (SD) and compared with the student's t test. Data that were not normally distributed were presented as median and interquartile range and compared with the Mann–Whitney U test. The cumulated re-operation rates were analyzed with a Cox regression model fitted with the variables age, hernia size, and hernia type, and if defect closure was performed. Calculations from the Cox regression are presented as hazards ratios (HR), 95% confidence interval, and p values. The cumulated re-operation rates are illustrated in a Kaplan–Meier plot adjusted for the same confounders used in the Cox regression. Two sub-analyses were also conducted. The first sub-analysis analyzed if the suture material used for defect closure had an effect on the re-operation rate using a Cox regression fitted with the variables age, hernia size, hernia type, and if defect closure was performed with absorbable sutures, permanent sutures, or not performed. The second sub-analysis assessed if defect closure affected the re-operation rate equally for primary and incisional hernias. To do this, primary and incisional hernias were subdivided and analyzed separately with

a Cox regression model using the same variables as in the main analysis.

The study was approved by the Danish data protection agency (j. no. 2008-58-0020, REG-032-2017) and no ethical approval was required according to Danish law.

Results

The flowchart (Fig. 1) illustrates how the study population was achieved from the 11,018 patients initially assessed for eligibility. Two cohorts were created based on the tack material used for mesh fixation. In the cohort of patients with absorbable tacks as mesh fixation, there were 443 patients with defect closure and 532 patients without defect closure, with a matching ratio of 1:1.2. In the cohort of patients with permanent tacks as mesh fixation, there were 393 patients with defect closure and 442 patients without defect closure, with a matching ratio of 1:1.1. Patient characteristics are presented in Table 1. In both cohorts, patients with defect closure were significantly different compared with patients without defect closure regarding distribution of sex, hernia type, mesh material, centimeters of mesh overlap, and months of follow-up. The patients with absorbable tacks as mesh fixation were also significantly different regarding hernia size and number of postoperative days of admission. Age and number of defects were balanced between the groups in both cohorts.

For patients with absorbable tacks as mesh fixation, the crude re-operation rates were 6.3% for those with defect closure and 6.8% for those without defect closure, $p = 0.779$ (Table 1). For patients with a mesh fixated with permanent tacks, the crude re-operation rates were 3.6% for those with defect closure and 7.2% for those without defect closure, $p = 0.020$ (Table 1).

In the main analysis (Table 2), we found that for patients with absorbable tacks as mesh fixation, defect closure did not affect the re-operation rate, $p = 0.975$. However, defect

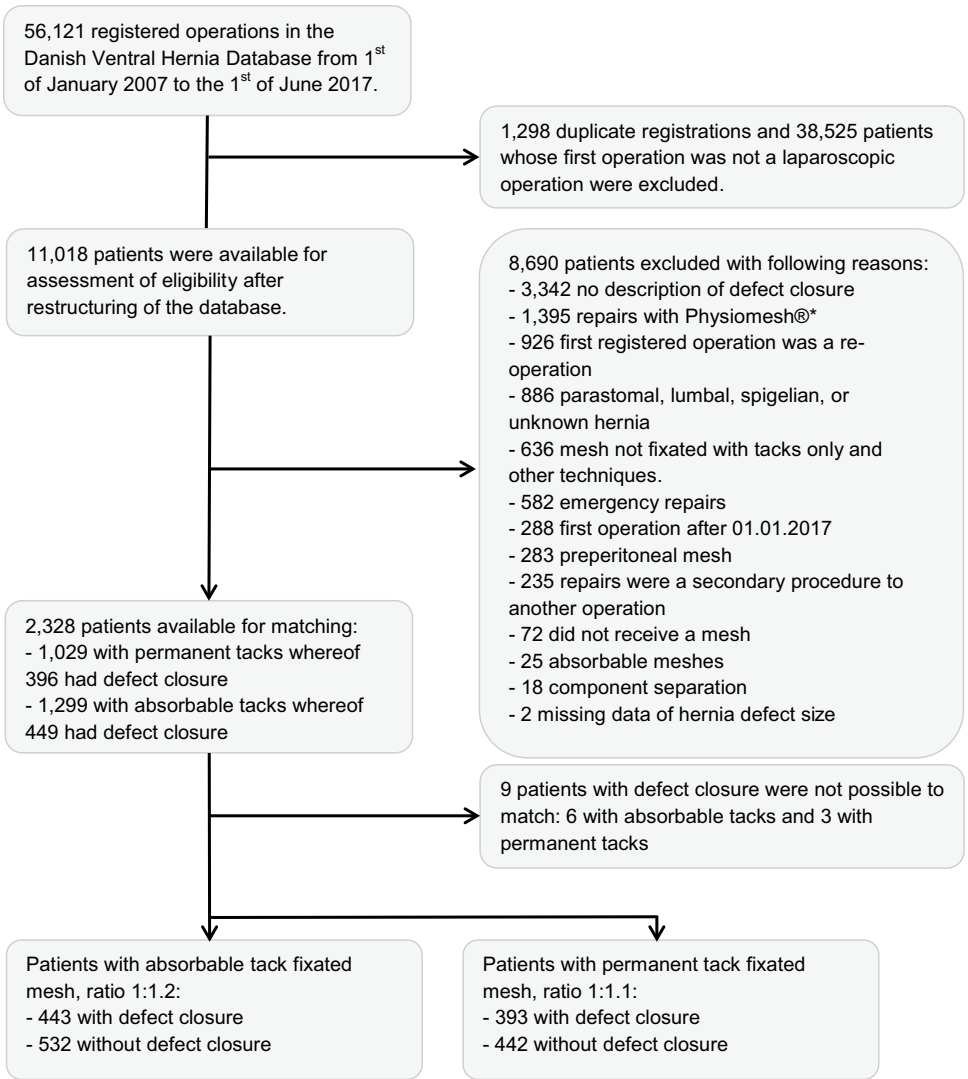

Fig. 1 Flowchart illustrating the selection process of the included patients from the Danish Ventral Hernia Database. Asterisk: excluded due to higher risk of recurrence [9]

Table 1 Patient characteristics

	Absorbable tack fixation of mesh			Permanent tack fixation of mesh		
	Closure	No closure	*p*	Closure	No closure	*p*
Number of patients	443	532		393	442	
Female sex[a], *n* (%)	216 (48.8)	219 (41.2)	0.018	170 (43.3)	176 (39.8)	0.000
Age, median (IQR)	59 (49–68)	57 (48–67)	0.151	56 (46–65)	56 (48–65)	0.656
Hernia size ($cm^{2)}$, median (IQR)	9.4 (4.7–23.6)	7.1 (3.1–19.6)	0.002	7.1 (3.1–12.6)	7.1 (3.1–14.1)	0.239
Primary/incisional, *n* (%)	183 (41)/260 (59)	285 (54)/247 (46)	< 0.001	236 (60)/157 (40)	227 (51)/215 (49)	0.012
Mesh material, *n* (%)			< 0.001			< 0.001
Polyester	393 (89)	402 (76)		248 (63)	147 (33)	
Polypropylene	31 (7)	50 (9)		142 (36)	232 (52)	
PVDF + PP	18 (4)	75 (14)		2 (1)	56 (13)	
Unknown	1 (0)	5 (1)		1 (0)	7 (2)	
Mesh overlap (cm), median (IQR)	5 (5–5)	5 (5–5)	0.035	5 (5–5)	5 (4–5)	< 0.001
Number of defects, median (IQR)	1 (1–1)	1 (1–2)	0.127	1 (1–1)	1 (1–1)	0.800
Postoperative days of admission, median (IQR)	1 (0–2)	0 (0–1)	< 0.001	0 (0–1)	0 (0–1)	0.190
Months of follow-up, median (IQR)	27 (16–39)	35 (20–49)	< 0.001	28 (13–42)	33 (15–49)	0.001
Re-operations, *n* (%)	28 (6.3)	36 (6.8)	0.779	14 (3.6)	32 (7.2)	0.020
Suture material, *n* (%)						
Permanent suture	260 (59)	–		336 (85)	–	
Absorbable suture	183 (41)	–		56 (15)	–	

n number of patients, *IQR* interquartile range, *PVDF + PP* polyvinylidene fluoride and polypropylene

[a]Compared with males

Table 2 Cox regression model assessing risk of re-operation, adjusted for possible confounders, including a sub-analysis where the variable of defect closure or not was replaced with a variable of which suture material that was used for defect closure

	Absorbable tack fixation of mesh Analysis of defect closure; risk of re-operation		Permanent tack fixation of mesh Analysis of defect closure; risk of re-operation	
	HR (95% CI)	*p*	HR (95% CI)	*p*
Age, years	0.98 (0.97–1.00)	0.097	1.01 (0.99–1.04)	0.379
Hernia size ($cm^{2)}$	1.00 (0.99–1.01)	0.543	0.99 (0.97–1.01)	0.310
Primary hernia versus incisional (ref)	0.55 (0.31–0.97)	0.038	0.45 (0.24–0.86)	0.015
Defect closure versus no closure (ref)	0.98 (0.59–1.61)	0.975	0.53 (0.28–0.999)	0.050
Sub-analysis—effect of suture material[a]				
No defect closure	1.00 (ref)	–	1.00 (ref)	–
Absorbable suture	0.86 (0.422–1.74)	0.670	0.77 (0.24–2.52)	0.670
Permanent suture	1.14 (0.64–2.02)	0.648	0.50 (0.25–0.99)	0.046

HR hazard ratio, *CI* 95% confidence interval

[a]In the sub-analysis, the hazard ratios of the other variables did not differ from the main analysis and are, therefore, not shown

closure was a significant protective factor and reduced the re-operation rate for patients with permanent tacks as mesh fixation with HR = 0.53 and $p = 0.050$. Age and hernia size did not significantly affect the re-operation rate in neither cohort. It was a protective factor against re-operation for recurrence in both cohorts to have a primary hernia compared with an incisional hernia. The adjusted cumulated re-operation rates are illustrated in Fig. 2.

The first sub-analysis assessed the effect of which suture material that was used during defect closures, and the results are presented in the bottom of Table 2. In these analyses, age, hernia size, and hernia type did not differ from the main analysis and are, therefore, not shown. For patients with absorbable tacks as mesh fixation, defect closure did not affect the re-operation rate ($p = 0.648$) regardless of whether it was performed with permanent or absorbable sutures. For

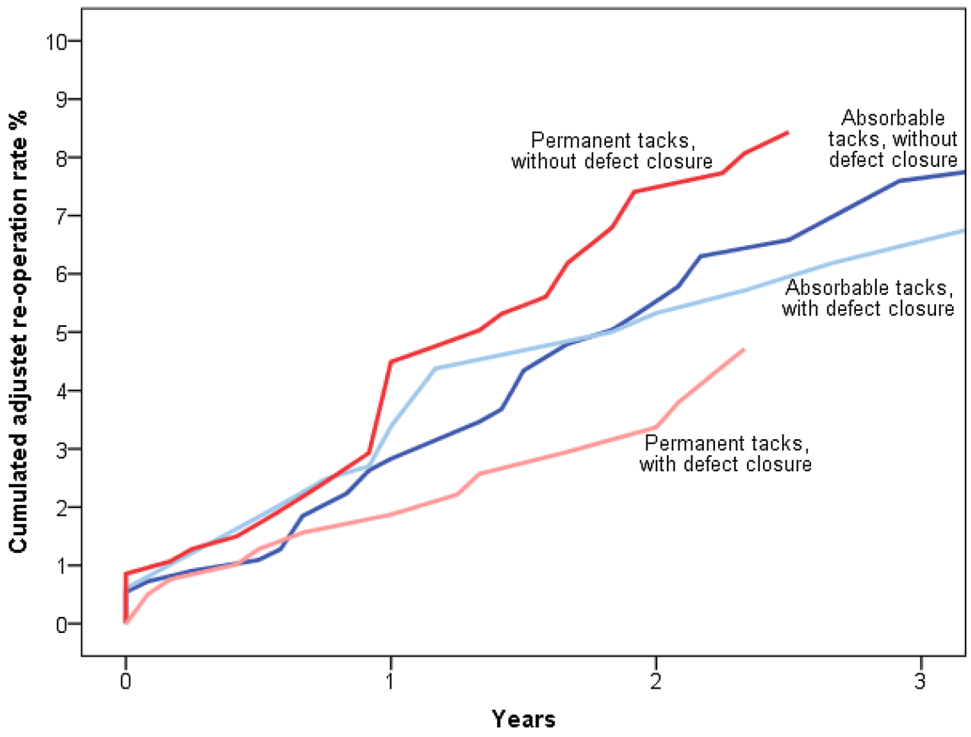

Fig. 2 Cumulated adjusted re-operation rate for recurrence for patients who had a laparoscopic ventral hernia repair with the insertion of a mesh fixated with either absorbable or permanent tacks. The curves illustrate the re-operation rate for patients who had defect closure versus those who did not, adjusted for age, hernia size, and hernia type (primary or incisional hernia). For patients with permanents tacks as mesh fixation, defect closure significantly reduced the risk of re-operation compared with no defect closure, $p = 0.050$

Table 3 Sub-analysis of the effect of defect closure on re-operation rate with a cox regression model

	Absorbable tack fixation of mesh Sub-analysis—primary and incisional hernias			
	Primary hernias		Incisional hernias	
	HR (CI)	*p* value	HR (CI)	*p* value
Age	0.99 (1.00–1.02)	0.471	0.98 (0.96–1.00)	0.096
Hernia size ($cm^{2)}$	1.05 (1.02–1.08)	0.000	1.00 (0.99–1.01)	0.994
Defect closure versus no closure (ref)	1.27 (0.52–3.13)	0.601	1.00 (0.54–1.84)	0.999

Two sub-cohorts with a mesh fixated with absorbable tacks and had either an incisional hernia or a primary hernia

HR hazard ratio, *CI* 95% confidence interval

Table 4 Sub-analysis of the effect of defect closure on re-operation rate with a cox regression model

	Permanent tack fixation of mesh Sub-analysis—primary and incisional hernias			
	Primary hernias		Incisional hernias	
	HR (CI)	*p* value	HR (CI)	*p* value
Age	1.03 (0.99–1.07)	0.157	1.00 (0.97–1.03)	0.932
Hernia size ($cm^{2)}$	1.03 (0.98–1.09)	0.190	0.97 (0.96–1.01)	0.211
Defect closure versus no closure (ref)	0.83 (0.32–2.20)	0.715	0.35 (0.14–0.86)	0.022

Two sub-cohorts with a mesh fixated with permanent tacks and had either an incisional hernia or a primary hernia

HR hazard ratio, *CI* 95% confidence interval

patients with permanent tacks as mesh fixation, it was a significant protective factor if defect closure was performed with permanent sutures compared with no defect closure. Defect closure with absorbable suture ($n = 56$) did not affect the re-operation rate.

In the second sub-analyses (Tables 3, 4), defect closure was assessed for primary and incisional hernias separately. For patients with absorbable tacks as mesh fixation (Table 3), defect closure did not affect the re-operation rate for primary or incisional hernias ($p = 0.601$ and $p = 0.999$). Patients with a primary hernia had an increased risk of re-operation with increasing hernia size, which was not observed for incisional hernias. For patients with permanent tacks as mesh fixation and either a primary or incisional hernia (Table 4), the analyses found that age and hernia size did not affect the re-operation rate. The re-operation rate was neither affected for primary hernias, regardless if they had defect closure or not. However, for incisional hernias with permanent tacks as mesh fixation, it was a significant protective factor with a reduced risk of re-operation if defect closure was performed.

Discussion

This nationwide cohort study based on the Danish Ventral Hernia Database found that patients with permanent tacks as mesh fixation had a significantly lower risk of re-operation for recurrence if defect closure was performed compared with no defect closure. Furthermore, the sub-analysis found that defect closure should be with permanent sutures, since it reduced the re-operation rate.

Current guidelines discuss if defect closure should be performed [4, 10]. One of them recommended defect closure based on low evidence studies [4], whereas the most recent guideline from 2016 did not recommend defect closure, because it was the authors' opinion that more evidence on the subject was needed [10]. Therefore, the result from this nationwide database study provides new knowledge, namely that it seems beneficial to perform defect closure with permanent sutures prior to mesh placement in laparoscopic ventral hernia repair in regards to the risk of re-operation, and that mesh fixation should preferably be performed with permanent rather than absorbable tacks. Recently, a meta-analysis found that defect closure reduced adverse hernia site events such as recurrences [11]. However, the heterogeneity between the included retrospective observational studies was high with an I^2 (heterogeneity estimate) of 97%, and the results should, therefore, be interpreted cautiously, since, normally, the pooled estimate should not be reported if $I^2 > 75\%$ [12]. Furthermore, the included studies used different defect closing techniques, such as extracorporeal or intracorporeal defect closure with either interrupted or continued sutures, which could be of either absorbable or permanent material [11]. These variations of the defect closing technique are also indications of why more studies on the area are needed.

Regarding the choice of material, there was a tendency towards using permanent suture for the defect closure. For the cohort with permanent tacks as mesh fixation, 85% had also received permanent sutures for defect closure, whereas only 59% had received permanent sutures in the cohort of patients with absorbable tacks as mesh fixation. A randomized-controlled trial investigated defect closure with absorbable sutures and found that this type of defect closure did not influence the recurrence rate [13], which was confirmed in the sub-analysis in this study. An observational study investigated defect closure with permanent sutures in 112 patients with absorbable tacks as mesh fixation and found that defect closure reduced the recurrence rate [14]. In our study, we also found a significant effect of permanent sutures used for defect closure, but only for the cohort of patients with permanent tacks as mesh fixation. This could indicate that, for the patients with absorbable tacks as mesh fixation, there might have been some influencing factors that were not considered in either their or our study.

In the second sub-analysis, we found that defect closure only reduced the re-operation rate for incisional hernias with permanent tacks as mesh fixation. Even though the sub-cohort was not matched on hernia size, it was accounted for in the Cox regression model. Other authors have previously suggested that it is important to distinguish between primary and incisional hernias when considering the risk of recurrence [13, 15, 16], which was confirmed by our results.

The strengths with this study were the 94% accuracy of the database [7], the 7+ years of nationwide data from both private and public hospitals, the minimal risk of surgeon's recall bias, and the high follow-up rate. It cannot be excluded that there might have been some selection bias regarding who received defect closure, but this was minimized by the matching process. A limitation of this study was the heterogeneity between the compared groups in each cohort, such as the distributions of mesh material and follow-up period. However, all patients who had received Physiomesh® [9] were excluded, and to our knowledge, there are no other meshes that have been proven to affect the recurrence rate. Unfortunately, when entering the perioperative information in DVHB, some surgeons only stated the mesh material and not the trade name of the mesh, which means that there is a possibility that some of the included operations included the use of the Physiomesh®. Because of the different follow-up times, comparison of the crude re-operation rates should be interpreted with caution. However, the effect of the different follow-up times is minimized by the Cox regression, which adjusts for differences in the follow-up time.

Increased mesh overlap does decrease the risk of re-operation [17], and in both cohorts, there was a significantly different mesh overlap between the compared groups. However, these differences were minimal. Hernia type, which was also significantly different, was included and adjusted for in the analyses, and we do not expect it to have affected the results. Nevertheless, incisional hernias are associated with more comorbidity and complications [15, 16], and the group of patients with absorbable tacks as mesh fixation and defect closure did have a larger percent of incisional hernias compared with no defect closure. Combined with more postoperative days of admission for these patients, it could indicate that there was an unequal distribution of comorbidities and complications in the cohort with absorbable tacks as mesh fixation. Patients with absorbable tacks and defect closure also had a significantly larger area of defect size than patients without defect closure. This could also have diminished a potential effect of defect closure in this cohort. To our knowledge, there is no evidence which suggests that any specific closing techniques should be preferred or if the sutures should be continuous or interrupted. Unfortunately,

we could not elaborate on this, since the database does not contain this information. Further possible limitations may be that the DVHB does not contain information of which type of absorbable suture that was used, the length of the tacks, and number of trocars used, or any argumentation for the surgeons' operational choices. It would also have been interesting to analyze other variables that may influence the recurrence rate such as body mass index (BMI), diabetes and smoking status [18], but this information was neither available. Even though the re-operation rate is an underestimation of the true recurrence rate [19], the re-operation is a valid measurement and we assumed that this underestimation was equally distributed between the groups.

Other authors have raised concern if defect closure would increase the abdominal wall tension and thereby cause more postoperative chronic pain [11, 20]. However, the evidence on the subject is sparse; and to this point, no association has been found between defect closure and chronic pain [21]. One study that used extracorporeal defect closure, which involved the rectus muscle, found that defect closure improved the level of postoperative activity compared with patients without defect closure [21]. Our results indicate that surgeons should perform defect closure with permanent sutures when also performing a laparoscopic incisional hernia repair with permanent tacks as mesh fixation. Defect closure with absorbable sutures did not reduce the re-operation rate in this study. These results should be interpreted with caution, since there were only few patients who had received absorbable sutures and it is possible that a type 2 error has occurred. However, according to our results, defect closure should be performed if surgically feasible. Future studies investigating chronic pain, quality of life, postural stability, and other outcomes are needed, as well as studies investigating the different closing techniques are also warranted.

In conclusion, this nationwide cohort study found a reduced risk of re-operation for recurrence if defect closure was performed with permanent sutures in addition to laparoscopic ventral hernia repair with permanent tacks as mesh fixation. The preplanned sub-analysis found that defect closure was only beneficial for incisional hernias and not for primary hernias.

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Compliance with ethical standards

Conflict of interest JJB and SÖ declare that they have no conflict of interest. KA has received personal fees from Bard outside the submitted work. JR has received personal fees from Bard and Merck, outside the submitted work.

Ethical approval This article did not require ethical approval of any kind.

Human and animal rights This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent For this type of study formal consent is not required.

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