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ORIGINAL ARTICLE

Adding sutures to tack fixation of mesh does not lower the re-operation rate after laparoscopic ventral hernia repair: a nationwide cohort study

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Abstract

Background There are various ways of fixating an intraperitoneal onlay mesh during a laparoscopic ventral hernia repair. The risk of complications is high, and around 22% of the hernias will recur within 3.5 years. The aim of this study was to assess if sutures in addition to tack fixation would reduce the re-operation rate for recurrence compared with permanent tacks without sutures.

Methods This study was based on the data from the nationwide Danish Ventral Hernia Database, which contains information of ventral hernia repairs from all hospitals in Denmark. Two different cohorts of patients were created and analyzed separately. The primary outcome was the re-operation rate for recurrence, analyzed with the Cox regression model and illustrated with a Kaplan-Meier plot adjusted for confounders. The follow-up period was defined as months from the first hernia repair to re-operation for recurrence, death, or the 1st of June 2017.

Results The first cohort included 598 patients with absorbable sutures and tacks compared with 1793 patients with permanent tacks. The second cohort included 72 patients with permanent sutures and tacks compared with 216 patients with permanent tacks. In the suture groups, the tack material was either permanent or absorbable. When adjusting for possible confounders in the Cox regression model, there were no significant differences in the re-operation rate for recurrence between the groups in the two cohorts.

Conclusion Adding sutures, either absorbable or permanent, to tack fixation of mesh during laparoscopic ventral hernia repair did not influence the re-operation rates for recurrence.

Keywords Ventral hernia · Laparoscopic · Mesh · Fixation · Tacks · Sutures

Introduction

Laparoscopic ventral hernia repair is a frequent operation, and the recurrence rates are reported to be as high as 22% after 3.5 years of follow-up [1]. There are various ways of fixating an intraperitoneally placed mesh [2], but the most frequently used technique in Denmark is by absorbable or permanent tacks without sutures [3]. A recent nationwide Danish study found that mesh fixation with permanent tacks had a significantly lower recurrence rate compared with absorbable tacks [1]. A guideline suggested that mesh fixation with permanent sutures alone may result in an even lower recurrence rate compared with permanent tacks [2]. Thus, we hypothesized that adding sutures to tack fixation of mesh would result in a lower recurrence rate compared with permanent tacks without sutures.

The purpose of this study was to investigate if patients receiving mesh fixation with sutures and tacks had a lower re-operation rate for recurrence compared with patients receiving permanent tacks without sutures. The re-operation rate was used as a proxy for the recurrence rate.

Methods

This nationwide cohort study was based on prospectively collected data from the Danish Ventral Hernia Database and reported according to the RECORD statement [4]. The Danish Ventral Hernia Database is a validated nationwide database

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with information on ventral hernia repairs. The registration rate is currently 77% [5] with an estimated accuracy of 94% (if patient files are considered as the gold standard) [6]. The information in the database originates from all hospitals in Denmark (private and public) and contains perioperative information, such as type and size of hernia, surgical approach, type and size of mesh, fixation technique, and if the repair was a primary repair or a re-operation (repair for a recurrent hernia). The database does not contain information on the number of tacks or if they were used in a single or a double crown manner. The database neither contains information on the number of sutures used and if the sutures were pre-attached by the manufacturer or added by the surgeon. However, in Denmark, it is uniformly recommended that tacks are used in a double crown manner. We assumed that all sutures, if used, were transfascial sutures used to secure at least the corners of the mesh. Patients' unique civil registration number is used for all contacts to the Danish healthcare system. Because of the automatic linkage between the perioperative data entered by surgeons into the Danish Ventral Hernia Database and the administrative data from the Danish National Patient Register [7], it is possible to follow all patients registered in the Danish Ventral Hernia Database until death or emigration regardless of where patients are treated later. All data were extracted from the 1st of January 2007 (the beginning of the database) until 1st of June 2017.

Adult patients (≥ 18 years) with an elective primary laparoscopic ventral hernia repair with the insertion of an intraperitoneal onlay mesh were included. All following ventral hernia repairs were considered as re-operations for a ventral hernia recurrence. Patients were excluded if the first registered operation in the database was an operation for a recurrence or if the mesh was fixated without tacks. The types of hernias included were either primary (umbilical/epigastric) or incisional hernias. Patients with parastomal-, spigelian-, or lumbal hernias were excluded. The Physiomesh® has recently been withdrawn because of high recurrence rates [8]. Therefore, all patients receiving this mesh were excluded. Patients were also excluded if the hernia repair was performed as a secondary procedure to another operation, if the repair was performed with component separation, or if there were missing data of fixation technique, fixation material, mesh material, or type of hernia. Follow-up was defined as months from the first operation to a re-operation for recurrence, death, emigration, or end of the inclusion period (the 1st of June 2017).

Patients who had received both sutures and tacks for mesh fixation were identified and divided into two groups: one group with permanent sutures and tacks and one group with absorbable sutures and tacks. In both groups, the tack material was either absorbable or permanent.

To limit the risk of selection bias [9], each patient in the suture groups was matched with three patients who had received permanent tacks without sutures. The exact matching procedure was chosen, including variables that we believed might influence the choice of mesh fixation technique. Thereby, two cohorts were created: [permanent sutures and tacks] versus [permanent tacks] and [absorbable sutures and tacks] versus [permanent tacks]. A patient who had received permanent tacks without sutures could be matched with patients in both suture groups. The matching criteria were defined before analyses as age ± 10 years, sex, and hernia size ± 10 cm^2. The main outcome was re-operation, which was used as a measurement for recurrence. A re-operation was defined as a subsequent ventral hernia repair.

In 2014, the technique of closing the fascial defect was introduced in Denmark and implemented as a variable in the Danish Ventral Hernia Database. Therefore, operations before 2014 were considered as repairs without defect closure. The size of the defect is registered as length (cm) and width (cm) and was calculated to an area (cm^2) with the formula of an ellipse ($\text{length} \cdot \text{width} \cdot \frac{1}{4} \cdot \pi = \text{area}$).

Statistical analyses were conducted with the statistical program SPSS version 22.0 (IBM, Armonk, NY, USA). p values ≤ 0.05 were defined as statistically significant. Categorical variables were presented as crude rates and compared with the chi-squared test. Continuous variables were assessed for normal distribution by evaluating histograms. Continuous variables were presented as mean and standard deviation (SD) or median and interquartile range (IQR) depending on the distribution and compared with the t test or the Mood's median test. The adjusted cumulated re-operation rates for recurrence for the fixation techniques are illustrated with Kaplan-Meier plots. Possible confounders that may have influenced the re-operation rate were fitted in a Cox regression and presented with hazard ratios (HR). For the Cox regression, the backward stepwise elimination model was used. The cutoff was set at $p < 0.2$. Initially, the included variables were fixation technique, age, sex, hernia size, mesh material, hernia type, and defect closure. A sub-analysis was performed by the Cox regression in which the effect of the tack material used in combination with the sutures was assessed. A post hoc sample size calculation was performed to assess the sample size required to achieve a significant difference based on the crude re-operation rates for recurrence, using GPower 3.1 (Faul, Buchner, Erdfelder and Lang; University of Kiel, Germany) with a power of 0.80 and an alfa of 0.05.

This study was approved by the Danish Data Protection Agency (j. no. 2008-58-0020, REG-032-2017). According to Danish law, ethical approval was not required.

Results

Initially, 11,018 patients were assessed for eligibility. Two different cohorts were created and analyzed separately

(Fig. 1). One cohort consisted of 598 patients who had received absorbable sutures and tacks compared with 1793 patients who had received permanent tacks (AST cohort), matched in a ratio of 1:3. The other cohort consisted of 72 patients who had received permanent sutures and tacks compared with 216 patients who had received permanent tacks (PST cohort), also matched in a ratio of 1:3. In both suture groups, the tack material could be either permanent or absorbable, regardless of the suture material.

Patient characteristics of the two cohorts are presented in Table 1. In both cohorts, there were significant differences in the type of mesh material used. The group with absorbable sutures and tacks was significantly different compared with the group with permanent tacks without sutures regarding the number of patients with defect closure, mesh length, number of defects, months of follow-up, postoperative days of admission, and in the total number of re-operations. Age, sex, hernia size, mesh overlap, and mesh width were balanced between the groups (Table 1).

After a median of 16 months of follow-up, the crude re-operation rate for recurrence absorbable sutures and tacks was 2.8% (17/598), which was significantly lower than for permanent tacks without sutures, 6.8% (122/1793) ($p < 0.005$). However, the latter had a considerably longer median follow-up of 56 months. Permanent sutures and tacks had a crude re-operation rate for recurrence of 11.1% (8/72) versus 6.9% (15/216) for permanent tacks without sutures, $p = 0.26$, and both groups had a median follow-up of 58 months.

In the Cox regression, the type of mesh fixation technique did not influence the re-operation rate for recurrence and was therefore not included in the final model. For the AST cohort, only hernia type influenced the risk of re-operation for recurrence. It was a significant protective factor to have a primary hernia repair (umbilical/epigastric/linea alba) compared with an incisional hernia repair, HR = 0.52 (95% CI 0.31–0.86), $p = 0.01$. In the analysis of the PST cohort, hernia type and mesh material were the only variables that contributed to the final model. For the PST cohort having a primary hernia (vs. incisional), HR was 0.34 (95% CI 0.12–1.01), $p = 0.05$. The

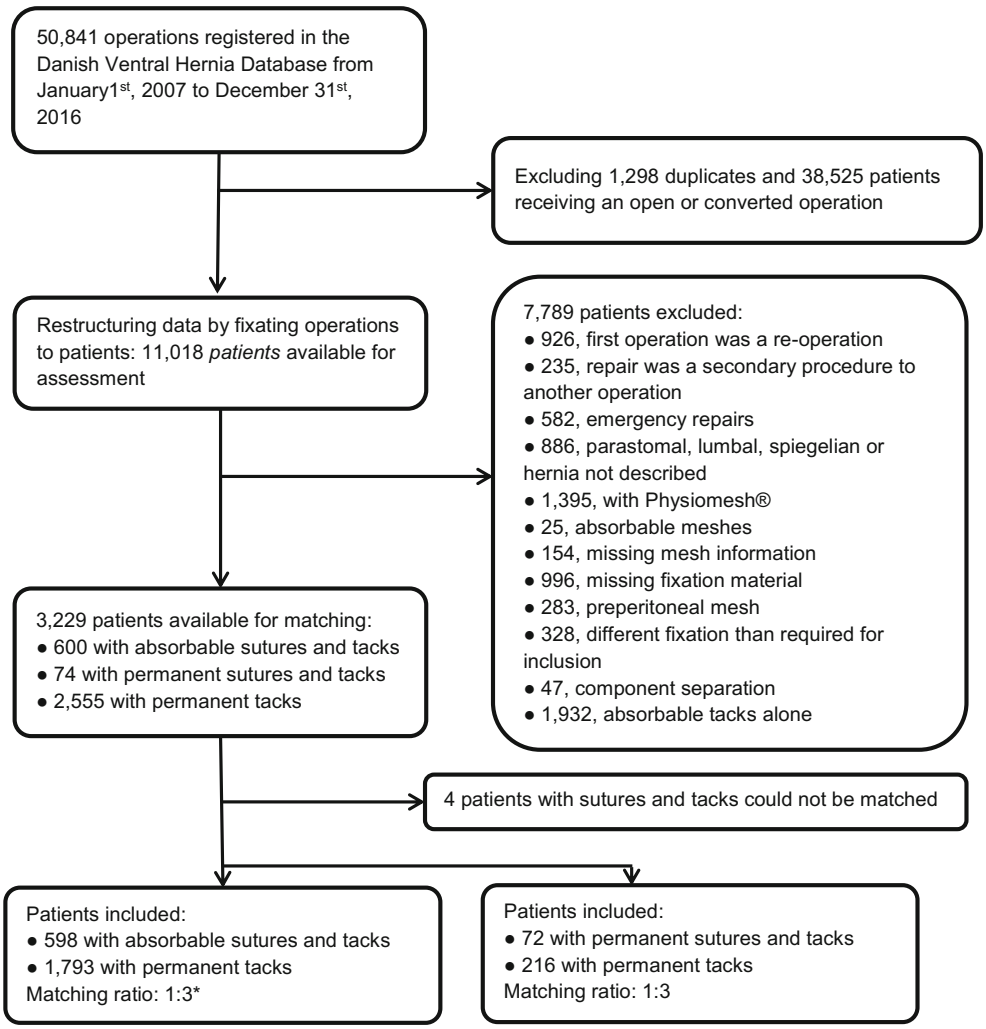

Fig. 1 Flowchart showing how the study population was selected. *One patient could only be matched with two patients receiving permanent tacks as mesh fixation

Table 1 Patient characteristics. *n* number, *IQR* interquartile range, *PVDF* polyvinylidene fluoride, *PP* polypropylene, *PE* polyester, *PTFE* polytetrafluoroethylen

	Absorbable sutures and tacks	Permanent tacks	*p* value	Permanent sutures and tacks	Permanent tacks	*p* value
Number of patients	598	1793		72	216	
Females, *n* (%)	262 (44)	785 (44)	1.00	35 (49)	107 (50)	0.89
Age, median (IQR)	57 (48–67)	57 (48–66)	0.71	58 (49–66)	59 (50–66)	0.89
Hernia size, cm^2, median (IQR)	7.1 (3.1–19.6)	7.1 (3.1–19.6)	0.35	19.6 (8.6–49.5)	15.7 (7.1–47.1)	0.63
Primary/incisional, *n* (%)	288 (48)/310 (52)	944 (53)/849 (47)	0.06	24 (33)/48 (67)	78 (36)/138 (64)	0.67
Closure of defect, *n* (%)	328 (55)	342 (19)	< 0.01	10 (14)	20 (9)	0.27
Mesh material, *n* (%)						
- PP	38 (6)	941(52)	< 0.01	10 (14)	128 (59)	< 0.01
- PE	525 (88)	526 (29)		51 (71)	53 (25)	
- PVDF+PP	35 (6)	293(16)		11 (15)	30 (14)	
- PTFE	0 (0)	33 (2)		0 (0)	5 (7)	
Mesh overlap, cm, median (IQR)	5 (5–5)	5 (4–5)	0.33	5 (5–5)	5 (5–5)	0.50
Mesh size, cm, median (IQR)						
- Width	15 (12–15)	15 (12–15)	0.28	15 (15–20)	15 (13–20)	0.94
- Length	15 (12–20)	15 (12–15)	0.01	15 (15–22)	15 (13–20)	0.58
Number of hernia defects, median (IQR)	1 (1–2)	1 (1–1)	< 0.01	1 (1–2)	1 (1–2)	1.00
Months of follow-up, median (IQR)	16 (8–29)	56 (23–80)	< 0.01	58 (45–66)	58 (24.5–81)	1.00
Days of postoperative admission, median (IQR)	0 (0–1)	1 (0–1)	< 0.01	1 (0–2)	1 (0–2)	0.19
Re-operations, *n* (%)	17 (2.8)	122 (6.8)	< 0.01	8 (11.1)	15 (6.9)	0.26

mesh material had the following results: polyvinylidene fluoride + polypropylene, HR 1.00 (ref); polyester, HR = 2.88 (95% CI 0.80–10.42), $p = 0.11$; polypropylene, HR = 0.43 (95% CI 0.10–1.81), $p = 0.25$; polytetrafluoroethylene, HR = 0.00 (95% CI 0.00–$9.49 \cdot 10^{290}$), $p = 0.99$.

The adjusted cumulated re-operation rates for recurrence for the two cohorts are illustrated in Fig. 2 and Fig. 3. Figure 2 is adjusted for hernia type and Fig. 3 is adjusted for hernia type and mesh material. There was no difference in the adjusted cumulated re-operation rates for recurrence between absorbable sutures and tacks versus permanent tacks without sutures (Fig. 2). There was neither any difference between the re-operation rate for recurrence between permanent sutures and tacks versus permanent tacks without sutures (Fig. 3). The sub-analyses did not find any significant impact on the risk of re-operation for recurrence, regardless if the tack material was absorbable or permanent when used in combination with sutures, and is therefore not shown.

A post hoc sample size calculation was performed based on the crude re-operation rate for recurrence. In the AST cohort, the minimum sample size required in order to achieve a significant difference was found to be 251 and 750 patients, respectively, which was lower than the actual sample size (598 and 1793 patients). To achieve a significant difference in the PST cohort, the required sample size was 377 and 1132 patients, which was larger than the actual sample size (72 and 216 patients).

Discussion

In this nationwide cohort study based on the Danish Ventral Hernia Database, we found no effect on the re-operation rate

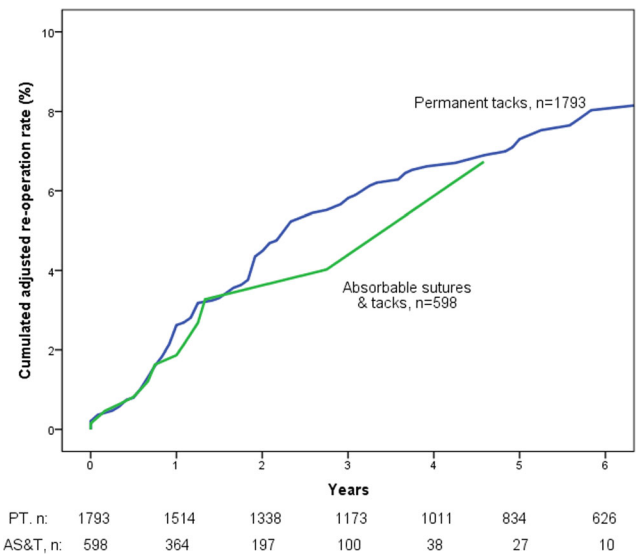

Fig. 2 Cumulated re-operation rate for recurrence, adjusted for confounders. Comparison of patients with a mesh fixated with absorbable sutures and tacks versus permanent tacks without sutures, $p \geq 0.2$. The table below the graph demonstrates patients remaining at risk for each year. PT, patients with permanent tacks; AS&T, patients with absorbable sutures and tacks; n, number of patients

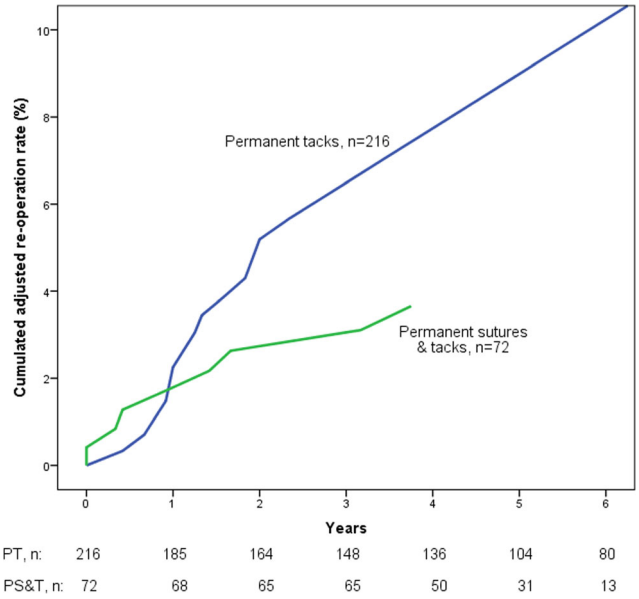

Fig. 3 Cumulated re-operation rate for recurrence, adjusted for confounders. Comparison of patients with a mesh fixated with permanent sutures and tacks versus permanent tacks without sutures, $p \geq 0.2$. The table below the graph demonstrates patients remaining at risk for each year. PT, patients with permanent tacks; PS&T, patients with permanent sutures and tacks; n, number of patients

for recurrence when using both sutures and tacks compared with permanent tacks without sutures for laparoscopic intraperitoneal mesh fixation.

A randomized controlled trial that compared three mesh fixation techniques found no difference in the recurrence rate for mesh fixation with absorbable sutures and absorbable tacks, fixation with permanent tacks without sutures, and fixation with permanent sutures with permanent tacks [10]. However, the postoperative follow-up was only 3 months, and since the recurrence rate increases over time [11], the follow-up might have been insufficient in order to find any potential differences in the recurrence rate. Another randomized controlled trial that compared mesh fixation of permanent sutures and tacks versus permanent tacks without sutures, with a follow-up of 24 months, neither found a difference in recurrence rates [12]. In contrast to our study, both of those studies only used a single row of tacks in addition to sutures, whereas the standard in Denmark is a double crown (two rows) fixation. A recently published systematic review with a network meta-analysis also investigated the mesh fixation techniques [13]. Among other fixation techniques, the study also compared tacks versus tacks and sutures and found no difference in the recurrence rates. In accordance with the two randomized controlled trials and the network meta-analysis [10, 12, 13], we did not find any benefits of using transfascial sutures in addition to tack fixation of mesh.

The strengths of this prospective nationwide cohort study were the high follow-up rate and the low risk of recall bias since operations are typically coded in the database immediately after the procedure. This study included a large number of patients from both public and private hospitals, and because of the registry-based follow-up, it even included patients with a re-operation for recurrence at a different hospital than the first repair. There might have been some selection bias from the surgeons' choice of fixation technique based on the type and size of the hernia, comorbidities, and surgical preferences. We sought to limit these effects through the matching process and by the adjusted Cox regression model. The Cox regression was fitted with defect closure, mesh material, hernia type, age, sex, and size of the defect, which have been shown to affect the risk of recurrence [14, 15]. Other known risk factors for recurrence, such as smoking, body mass index (BMI), and diabetes mellitus [16], were not listed in the database. It was therefore not possible to adjust for these factors, but we assume that they were evenly distributed between the groups. However, our analysis found that only having an incisional hernia increased the risk of re-operation for a recurrence. The heterogeneity between the groups in AST cohort is a limitation. The higher percentage of patients with defect closure for patients with absorbable sutures and tacks compared with permanent tacks could have influenced the results. Even though defect closure did not affect the risk of having a re-operation for recurrence in this study, a recent systematic review did find that defect closure reduced the risk of recurrence [14]. Since the Danish Ventral Hernia Database only had information of defect closure from 2014 and onwards, it is possible that a higher number of patients have received defect closure, which could have influenced the results. The type and manufacture of mesh varied. This resulted in a significantly different distribution of mesh material between the compared groups in both cohorts. Any potential benefit or disadvantage of mesh material was attempted to be limited through the Cox regression. However, due to these differences between the groups, it cannot be excluded that the mesh materials may have influenced the results. A limitation was also that the pore size and weight of the mesh were not considered, which in animal studies has been shown to affect tissue ingrowth and integration of the mesh [17]. The combination of specific meshes and fixation techniques, which in an animal study has shown to result in different recurrence rates [18], was neither considered. There were neither any information if surgeons had used the tacks in a single- or a double crown manner, and even though the double crown technique is recommended in Denmark, there is no validation of this in the Danish Ventral Hernia Database.

Patients with absorbable sutures and tacks had a significantly higher number of defects and larger meshes compared with patients with permanent tacks without sutures. This could be the reason the surgeons have used sutures in addition to tacks and might be the reason why there was no effect of these additional sutures.

Because of the registry study design, this study was limited by several factors because of unknown/unregistered factors, which in this study included comorbidities, number of tacks, if tacks were used in a double or single crown manner, number of sutures, etc. Because of the study design, the compared groups in the AST cohort ended up with varying follow-up periods. Therefore, randomized controlled trials (RCT) are needed, which compare double crown tacks versus double crown tacks with sutures in two homogeneous groups. In performing this type of study, we would recommend that the number of tacks and sutures are standardized and registered.

Patients with absorbable sutures with tacks had a significantly lower crude re-operation rate for recurrence, which might be explained by a shorter follow-up period compared with permanent tacks without sutures. When adjusting for the confounder (hernia type) and the difference in follow-up, the analysis did not find any differences in the re-operation for recurrence rates. The sample size was found to be sufficient for the AST cohort in the post hoc sample size calculation. However, the group with absorbable sutures and tacks had 40 months shorter follow-up than the group with permanent tacks without sutures, and even though the cox regression adjusts for the time difference, it does create some uncertainty when comparing these two groups. The post hoc sample size calculation revealed that if there truly exists a difference in the PST cohort similar to the crude re-operation rates found in this study, then the number of patients in the PST cohort was too small, which is a potential limitation. Since there was a tendency towards a lower cumulated re-operation rate for recurrence for the group receiving permanent sutures and tacks, there might be a type-2 error, and a larger sample size may have provided a statistically significant difference.

Throughout the literature, it is discussed if sutures may cause more postoperative pain than tacks. One randomized controlled trial found that sutures with tacks resulted in significantly higher levels of postoperative pain at 3 months without a difference in the recurrence rate, compared with permanent tacks without sutures [12]. Another study found that postoperative pain levels were equal between patients receiving mesh fixation with absorbable sutures and tacks, permanent sutures and tacks, and tacks without sutures [10]. Thus, if additional sutures do not reduce the recurrence rate and possibly cause more chronic postoperative pain, there is probably no place for additional suture fixation of the mesh in ventral hernia repairs. Our results suggest that adding sutures to tack fixation of mesh is an unnecessary procedure compared with permanent tacks without sutures. However, studies assessing chronic pain as the primary outcome with longer follow-up and proper sample size calculations are needed.

In conclusion, adding sutures to tack fixation of mesh in laparoscopic ventral hernia repairs did not reduce the re-operation rate for recurrence. Although the study used nationwide data, the sample sizes may have been too small for an effect to reach statistical significance. Thus, randomized controlled trials with a large population, longer follow-up, and with an assessment of postoperative chronic pain are needed in order to make a final statement of the place for suture fixation in laparoscopic ventral hernia repair.

Authors' contributions Baker contributed substantially to the study conception and design and analysis and interpretation of data and drafted the work. Öberg, Andresen, and Rosenberg contributed substantially to the study conception and design and the interpretation of data and revised the work critically for important intellectual content. Helgstrand contributed to the conception and design of the work and revised it critically for important intellectual content. All authors gave final approval of the version to be published and have agreed to be 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.

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Compliance with ethical standards

Conflicts of interest Baker and Öberg declare that they have no conflict of interest. Andresen has received personal fees from Bard outside the submitted work. Helgstrand has received personal fees outside the submitted work from Medtronic and Bard. Rosenberg has received personal fees from Bard and Merck, outside the submitted work.

Research involving human participants For this type of study formal consent is not required.

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