Surg Endosc (2017) 31:4077–4084
DOI 10.1007/s00464-017-5454-8

Mesh fixation methods and chronic pain after transabdominal preperitoneal (TAPP) inguinal hernia surgery: a comparison between fibrin sealant and tacks

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Received: 31 August 2016 / Accepted: 3 February 2017 / Published online: 23 February 2017

Abstract
Introduction Mesh fixation techniques have been associated with pain after groin hernia surgery. The aim of this study was to compare fibrin sealant and tacks for mesh fixation in laparoscopic inguinal hernia repair regarding long-term persistent pain.
Methods Through the Danish Hernia Database, we identified patients operated for groin hernia using the transabdominal preperitoneal laparoscopic technique (TAPP) from 2009 to 2012 with fibrin sealant for mesh fixation. These were matched in a ratio of 1:2 with patients operated with TAPP using tacks. All patients were sent a validated questionnaire (the inguinal pain questionnaire) between March 2013 and June 2014. The primary outcome was pain at follow-up.
Results A total of 1421 patients (84% males) answered the questionnaire (34% fibrin sealant, 66% tacks). The median follow-up was 35 months (range 12–62). Preoperative pain was associated with postoperative pain ($p < 0.005$), which was confirmed by multivariate analysis (OR 1.57 (CI 95% 1.40–1.77)). Furthermore, male gender was protective against postoperative pain (OR 0.47 (CI 95% 0.29–0.74)). A total of 18% in the fibrin sealant group and 20% in the tacks group reported pain during the past week at follow-up, and 6 and 7% reported pain not possible to ignore ($p = 0.44$). No difference was found between the fixation methods regarding getting up from a chair, sitting, or standing for more than 30 min, walking up stairs, driving a car, doing exercise, or the need for postoperative analgesics or postoperative sick leave (all $p > 0.20$).
Conclusion Mesh fixation technique did not affect long-term persistent pain. A large number of patients reported persistent pain regardless of mesh fixation technique, which emphasizes the need for preoperative information. Preoperative pain was a risk factor for persistent pain, whereas male gender was protective.

Keywords Inguinal hernia · Laparoscopy · Mesh fixation · Tacks · Glue · Fibrin sealant

Repair of groin hernia is among the most common surgical procedures worldwide [1]. The nature of a hernia often affects patients in their ability to be physically active due to pain, or has negative cosmetic effects. Furthermore, there is a risk of the hernia to incarcerate or strangulate, which may result in serious morbidity. The repair of inguinal hernias is often considered a small procedure with minimal risk of complications. There is, however, risk of long-term recurrence [2, 3] and risk of developing pain during sexual activity [4, 5]. In fact, the largest problem with inguinal hernia surgery today remains the risk of chronic pain [1]. Chronic pain may vary widely, ranging from occasional discomfort without effect on daily living to disabling symptoms leading to socioeconomic consequences. Among risk factors for developing chronic pain are open surgery [6], mesh materials [7], and fixation methods of the mesh [8]. The risk of debilitating chronic pain has been estimated to be in the range of 0.5–6% [9].

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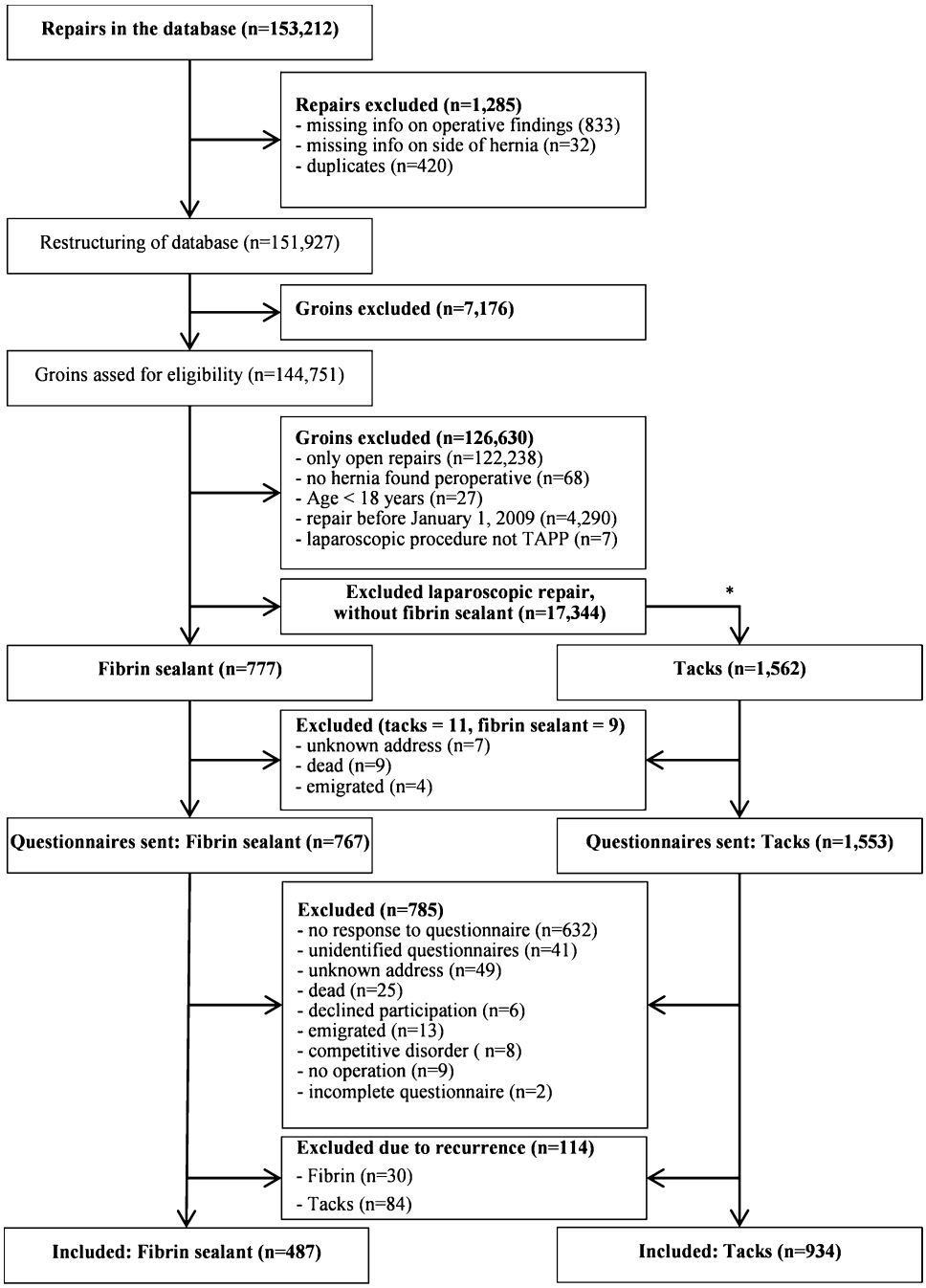

Fig. 1 Flow of repairs through the study. *Asterisk* demonstrates that repairs that were excluded from the fibrin sealant group were used as the base population to find matches. The 1562 repairs with tack fixation were matched in a ratio of 2:1 with the fibrin sealant repairs

During laparoscopic transabdominal preperitoneal (TAPP) repair of inguinal hernias, the mesh is usually fixated to the surrounding tissue. Fixation can be with self-fixating mesh, tacks (absorbable or not absorbable), or glue. The purpose of this study was to examine long-term persistent pain after TAPP hernia repair using fibrin sealants versus tacks for fixation of the mesh.

Materials and methods

This study was a matched cohort study by means of patient-reported outcomes regarding chronic pain. This study is reported according to the STROBE statement [10]. The cohort for this study was identified in the Danish Hernia Database. The database started prospectively to register all groin hernia surgeries from January 1,

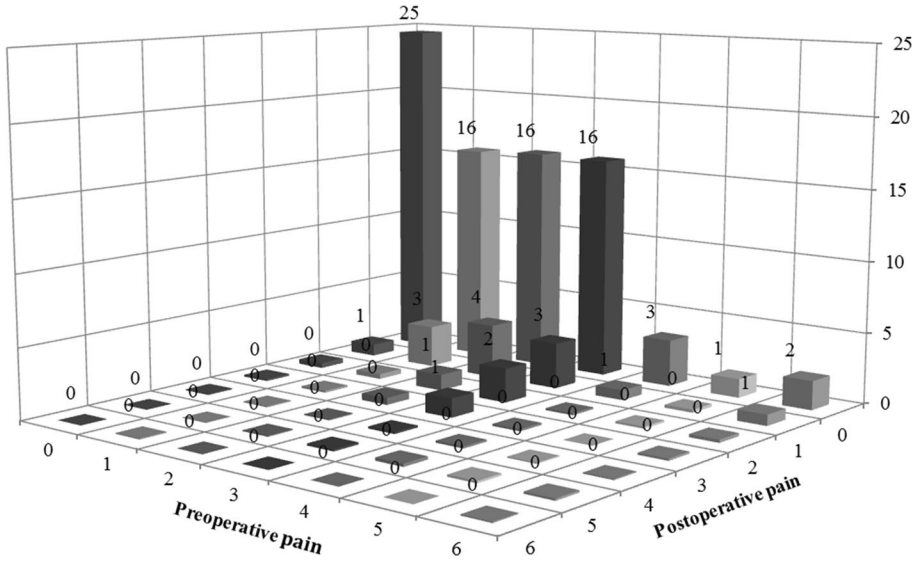

Fig. 2 Pain matrix demonstrating the relation between preoperative pain and postoperative pain. The vertical axis represents percent of the patients responding to both preoperative and postoperative questions ($n=1413$). The *numbers* along the scales refer to level of worst pain in the last week as seen in Tables 2 and 3, with *0* "no pain", *1* "pain present, but can easily be ignored"; *2* "pain present, cannot be ignored, but does not interfere with everyday activities"; *3* "pain present, cannot be ignored, interferes with concentration on chores and daily activities"; *4* "pain present, cannot be ignored, interferes with most activities"; *5* "pain present, cannot be ignored, necessitates bed rest"; and *6* "pain present, cannot be ignored prompt medical advice sought"

Table 1 Demographics of included patients

	Fibrin sealant ($n=487$)	Tacks ($n=934$)
Women *n* (%)	75 (15.4)	148 (15.8)
Age median (range) years	61 (23–89)	60 (20–91)
Follow-up median (range) months	27 (6–62)	35 (12–62)
Primary hernia *n* (%)	382 (78.4)	735 (78.7)
Elective procedures *n* (%)	485 (99.6)	914 (97.9)
Inguinal hernia *n* (%)	462 (94.8)	872 (93.4)
Femoral hernia *n* (%)	20 (4.1)	42 (4.5)
Combined (inguinal + femoral) *n* (%)	5 (1.0)	20 (2.1)

1998 and is still ongoing. The operating surgeon registers patient-related and perioperative data in the database following every repair of a groin hernia. There is no organized follow-up of patients in the registry; however, patients can be identified by their unique personal identification number (PIN), and therefore it is possible to contact the patient at a later stage or to link the hernia database with other registries. A more detailed description of the content and organization of the database can be found elsewhere [11].

The cohort study was planned to cover several outcomes: one being the long-term recurrence [12], the second being pain during sexual activity [13], and lastly the present study that reports on chronic pain. Patients included in this study had to be registered in the Danish Hernia Database. They had to be at least 18 years old, had a groin hernia (inguinal, femoral, or combined), and had been operated with TAPP with the mesh fixated with either fibrin sealant or tacks. The operation should have been conducted between 2009 and September 2012 in order to allow proper length of follow-up for all patients.

Patients were excluded if they had been operated with fibrin sealant previously, if they had been operated with other surgical technique than TAPP for a groin hernia, if there were missing information on the date of surgery, or if the patients were later operated for a recurrent hernia.

The patients with mesh fixated with fibrin sealant were matched in a ratio of 1:2 on sex and age with a group of

Table 2 Preoperative pain, from *Inguinal Pain Questionnaire*

Overall, both sexes	Fibrin sealant *n* (%)	Tacks *n* (%)
No pain	132 (27.3)	235 (25.3)
Pain present		
But can easily be ignored	99 (20.5)	174 (18.7)
Pain present, cannot be ignored		
But does not interfere with everyday activities	107 (22.1)	197 (21.2)
Interferes with concentration on chores and daily activities	104 (21.5)	223 (24.0)
Interferes with most activities	21 (4.3)	45 (4.8)
Necessitates bed rest	6 (1.2)	21 (2.3)
Prompt medical advice sought	15 (3.1)	34 (3.7)

Table 3 Pain at time of follow-up

Overall, both sexes	Fibrin sealant *n* (%)	Tacks *n* (%)
No pain	396 (81.6)	743 (79.7)
	388 (79.8)	*728 (78.0)*
Pain present		
But can easily be ignored	59 (12.2)	121 (13,0)
	59 (12.1)	*121 (13.0)*
Pain present, cannot be ignored		
But does not interfere with everyday activities	18 (3.7)	48 (5.2)
	22 (4.5)	*46 (4.9)*
Interferes with concentration on chores and daily activities	9 (1.9)	17 (1.8)
	10 (2.1)	*24 (2.6)*
Interferes with most activities	1 (0.2)	1 (0.1)
	4 (0.8)	*5 (0.5)*
Necessitates bed rest bed rest	2 (0.4)	1 (0.1)
	2 (0.4)	*8 (0.9)*
Prompt medical advice sought	0 (0)	1 (0.1)
	1 (0.2)	*1 (0.1)*

"Estimate the pain you feel right now in the operated groin". No difference was found between fibrin sealant and tacks, $p = 0.693$. In italic is the response to "Estimate the worst pain you felt in the operated groin during this past week", $p = 0.89$

patients that had their mesh fixated with tacks. Age was categorized into 5-year intervals. The primary outcome for this study was postoperative pain measured by the inguinal pain questionnaire (IPQ) [14]. Follow-up was defined as the time from surgery to filling out the questionnaire.

The postal addresses of all patients were retrieved from the Danish Social Security registry based on the PIN number of each patient. The envelope contained an information letter, the questionnaire, and a return envelope. The validated IPQ [14] asks about pain right now, worst pain in the last week, as well as the degree of pain, and whether groin pain has affected a range of daily activities. When patients did not return the questionnaire, they were contacted again in order to increase the response rate. If the returned questionnaire gave rise to further questions i.e. because of unclear answers or if the patient had missed some questions, an investigator would contact the patients by phone in order to clarify. If patients did not respond in spite of several attempts, they were excluded from the study.

For the present study regarding chronic pain, a total sample size of 672 patients was needed with allocation ratio of 1:2, significance level set at 0.05, and the statistical power at 0.80. This was based on the assumption that one in 100 patients would have chronic pain if the mesh was fixated with glue and five in hundred patients if the mesh was fixated with tacks [15].

Data were handled and analyzed using IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp. SAS Power and Sample Size 13.2 were used for sample size calculations. Categorical data were described using

Table 4 Worst pain "right now" at the time of follow-up for female patients

Women	Fibrin sealant *n* (%)	Tacks *n* (%)
No pain	56 (74.7)	107 (72.3)
	55 (73.3)	*107 (72.3)*
Pain present		
But can easily be ignored	9 (12.0)	22 (14.9)
	8 (10.7)	*22 (14.9)*
Pain present, cannot be ignored		
But does not interfere with everyday activities	5 (6.7)	14 (9.5)
	7 (9.3)	*7 (4.7)*
Interferes with concentration on chores and daily activities	3 (4.0)	4 (2.7)
	2 (2.7)	*10 (6.8)*
Interferes with most activities	1 (1.3)	0
	2 (2.7)	*1 (0.7)*
Necessitates bed rest	1 (1.3)	0
	1 (1.3)	*0 (0.0)*
Prompt medical advice sought	0	1 (0.7)
	0 (0.0)	*1 (0.7)*

Pain during the last week is seen in italic

crude numbers and percentages and compared using χ^2 test or Fisher's exact test. Continuous data were described using mean and standard deviation, and in case of data not being normally distributed, median and range were used. A multivariate logistic regression analysis was conducted in order to determine risk factors for chronic pain. The following covariates were entered into the model: primary/recurrent hernia, male/female, planned/emergent surgery, fibrin sealant/tacks for fixation, type of groin hernia (direct, indirect, or femoral), and preoperative pain. A $p \leq 0.05$ was considered significant.

Approval from ethics committee was not required for this study according to Danish law. The study received approval from the Danish Data Protection Agency (journal number: 2011-41-6856). Furthermore, the study was registered on http://www.clinicaltrials.gov (NCT 01597011).

Results

Initially, 153,212 repairs were identified in the database. Following exclusion of repairs and restructuring of the database, a total of 777 repairs with fibrin sealant were identified. They were matched with 1562 repairs with tacks, and the questionnaires were sent. Finally, 487 repairs with fibrin sealant and 934 repairs with tacks were included for analysis (Fig. 1). Only patients that did not have a recurrent hernia were included for analysis, and the overall response rate was 66%.

The sex and age distribution were similar in the two groups, given that they were matched on age and sex. Eighty percent in each group had a primary hernia, and the vast majority of patients received elective repair of their groin hernia (Table 1).

Preoperatively, 73% of patients in the fibrin sealant group and 75% in the tacks group reported varying degrees of inguinal pain (Table 2). For the postoperative questionnaire questions, 18% in the fibrin sealant and 20% in the tacks group had varying degrees of groin pain (Table 3). No statistical difference was found between the two groups regarding the pain. Both "pain right now" and "pain during the last week" were investigated, and no difference was found. Using the preoperative and postoperative pain data, it was possible to create a pain matrix of pre- and postoperative pain. A total of 1430 patients answered the pre- and postoperative questions. There were 25% reporting no pain both before and after surgery. There were another 54% reporting no pain after surgery, but pain before surgery. The remaining 21% of patients experienced pain to some degree both before and after surgery (Fig. 2).

Fifteen percent of the participants in this study were female (Table 1). For the female subgroup, no difference was found between the fibrin sealant and the tacks group, but females seemed to have a higher level of pain. Thus, 25.3% of the female patients with fibrin sealant and 27.7% of the patients with tacks had some degree of pain, with 13.3 and 15.6% having not ignorable pain (Table 4).

Among the patients with pain at follow-up, 89 patients with fibrin sealant and 189 patients with tacks, and the IPQ revealed that 22 (25%) from the fibrin sealant group and 59 (31%) from the tack group reported constant pain every

day. This corresponded to overall 4.5% from the fibrin sealant group and 6.3% from the tacks group.

The IPQ also asks about getting up from a chair, sitting for more than 30 min, standing for more than 30 min, walking up stairs, driving a car, or doing exercise. No differences were found between the fibrin sealant fixation and the tack fixation for these questions with all p-values larger than 0.2. Moreover, no differences were found between the groups regarding the need for postoperative use of analgesics or sick leave within the past few months ($p=0.44$ and $p=0.19$, respectively).

In a multivariate analysis, it was investigated which factors affected the risk of chronic pain. The outcome was dichotomized with cutoff set at "Pain that could not be ignored in the past week" or worse allowing a logistic regression analysis to be performed. The covariates regarding *fixation, planned/emergent procedure, type of groin hernia*, and *primary/recurrent hernia* showed no effect on the risk of having pain that could not be ignored in the past week or worse ($p>0.5$ for all). Male sex was a protective factor against postoperative pain with an odds ratio of 0.47 (95% CI 0.29–0.74, $p=0.001$). The level of preoperative pain was also a significant contributor to the risk of developing postoperative chronic pain with an odds ratio of 1.58 (95% CI 1.47–1.8, $p<0.0005$). This means that for each increase in the level of preoperative pain measured with the IPQ, the risk of developing postoperative pain increased by a factor 1.5.

Discussion

This cohort study with patient-reported outcomes comparing fibrin sealant with tacks for mesh fixation during laparoscopic TAPP repair for groin hernia found that fixation method had no effect on the risk of chronic pain. In a multivariate analysis, male sex was protective against chronic pain, and preoperative pain was a significant risk factor for having chronic pain postoperatively.

Our findings are in accordance with earlier findings and provide data for the current international guidelines [16, 17]. Previously, it has been recommended to use non-penetrating fixation of the mesh for the prevention of acute and chronic pain [18]. However, recent updates of the guideline from the International Endohernia Society changed the recommendations, so it now recommends the use of fibrin sealant for the fixation of mesh to prevent acute pain, but without mentioning chronic pain [16]. Thus, our data could not support a recommendation of fibrin sealant when looking at chronic pain because we could not show a difference compared with tack fixation. The high percentage of patients with chronic pain in both groups could be explained by the use of a standardized, validated, and sensitive questionnaire.

The question regarding optimal mesh fixation methods in laparoscopic repair of groin hernias is still being discussed, and a Cochrane review protocol has been published trying to answer the question of optimal technique [19]. Unfortunately, this protocol has not been followed up by a systematic review yet. The mesh fixation with fibrin sealant does not seem to reduce chronic pain in the long term. However, there might be advantages in shorter terms. Tacks can cause complications because of the penetrating nature of the methods. Because the tackers are deployed into the tissue of the abdominal wall, the surgeon cannot know with certainty if smaller vessels or nerves might be damaged. The longer the tacker, the deeper it might go in the tissue, and thus, there is a risk of damaging vessels and nerves [20]. However, such complications are rare and do not give enough "signal" to be demonstrated in a material like this cohort study. Prospective clinical trials or registry studies with identification of the few severe cases are therefore needed. Our results are in accordance with a randomized clinical trial showing no difference in pain at 12 months' follow-up with the use of tacks versus fibrin sealant [21]. When choosing fixation methods of the mesh in laparoscopic inguinal hernia surgery, several factors have to be taken into account: the risk of acute pain, risk of damage to nerves and vessels, and the risk of chronic pain. The theoretical benefit of nonpermanent fixation such as glue or absorbable tacks is that the irritation or inflammation from the fixation might disappear over time. Furthermore, the risk of damaging vessels or nerves can be minimized if a nonpenetrating fixation device is used, such as glue.

To our knowledge, this is the largest subgroup of female patients reported regarding chronic pain following TAPP repair of groin hernias. Female patients were at greater risk of developing chronic pain, even when adjusting for fixation method, preoperative pain, and primary/recurrent hernia. In addition, female patients seem to be at greater risk of early postoperative pain [22]. Therefore, future studies need to address gender differences in the results or focus on female patients, and there might be a need for a more individualized treatment depending on gender.

This study found that preoperative pain affected the risk of postoperative pain. This is in line with results from a cohort study of ventral hernias, where preoperative pain was the strongest predicting factor for postoperative pain [23]. The same has been demonstrated in a cohort of open repair of inguinal hernias where preoperative pain also greatly affected the risk of postoperative pain [24].

This is a large prospective cohort study which made use of a validated questionnaire giving strength to the results. However, limitations do exist. It was not possible with the current database to distinguish between

absorbable and non-absorbable tacks and detailed information regarding number and placement of tacks, and characteristics of mesh was not available. The choice of either tacks or glue was up to the discretion of the surgeons, which could result in different case mixes in the two groups. This possible imbalance has been minimized by matching the groups. Patients were asked about their preoperative pain at the follow-up, which was a long time after surgery. This could result in recall bias because patients might not remember to which degree they had problems with their hernia, and it has to be taken into account when interpreting the results. However, our findings are in line with the results from ventral hernias as well as open repair of inguinal hernias. The size of the defect in the abdominal wall was not a registered parameter for the repairs included in this analysis. Therefore, size could not be taken into account when analyzing risk of chronic pain in relation to fixation methods. However, if tacks have been used for larger hernias and glue for smaller hernias, the risk of chronic pain should have been higher for the tack group, but no difference was found. This indicates that even if the information regarding size of the hernias had been available, the results and conclusion would be the same. The response rates in both groups were around 66% which could be a limitation. However, there were no differences in demographics between the groups, and the comparisons of tacks versus glue are therefore valid. The reason for the high proportion of patients with chronic pain may be that patients without pain were less likely to return the questionnaire, and therefore, among the responders, there are a higher proportion of patients with pain. However, the response rate was the same in both groups, and therefore, the comparison of glue versus tacks is still valid, demonstrating no differences.

The perspectives of this study could be a recommendation of either fibrin sealant or tacks for fixation of mesh. However, no difference in pain could be demonstrated for fibrin sealant versus tacks. Furthermore, this report forms the third and final report of this large cohort study, and the previous studies found the same recurrence rate and the same level of pain during sexual activity at follow-up between the two groups of patients [12, 13]. Therefore, the firm recommendation of fibrin sealant is not justified based on these long-term complications, and the choice of fixation technique is therefore left to the surgeon in each case. However, there may be a gain in short-term outcome with reduced early postoperative pain when using fibrin sealant compared with tacks for mesh fixation in TAPP repair [17, 25].

In conclusion, no difference in postoperative chronic pain could be demonstrated between patients operated with fibrin sealant versus tacks for fixation of the mesh during laparoscopic TAPP inguinal hernia repair.

Compliance with ethical standards

Disclosures Dr. Andresen reports having received personal fees from Bard, outside the submitted work. Dr. Rosenberg reports having received grants and personal fees from Bard, personal fees from Merck, outside the submitted work. Drs. Fenger, Burcharth, and Pommergaard have no conflicts of interest or financial ties to disclose.

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