



Laparoscopic approach to ventral incisional hernia: absorbable or non-absorbable tacks? – a meta-analysis

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Background: To compare feasibility and effectiveness of absorbable and non-absorbable mesh fixation techniques in laparoscopic ventral incisional hernia repair.

Methods: A PubMed Embase, Google Scholar systematic review was carried out. Primary and secondary endpoints were considered. Odds ratio (OR) for each item was pooled and no bias according to QUADAS-2 tool and funnel plot asymmetry test were found.

Results: Five randomized controlled trials, including 1,091 patients, were enrolled. There was no difference between the two techniques in terms of postoperative morbidity (OR: 1.03, P=0.910), seromas (OR: 0.77, P=0.520), adhesion formations (OR: 0.49, P=0.560) and chronic pain (OR: 0.81, P=0.260). Risk of recurrence was significantly higher in the absorbable group (OR: 1.67, P<0.001).

Conclusions: The adoption of absorbable or non-absorbable tack techniques does not influence patients’ outcome. However, non-absorbable devices should be selected in high risk of recurrence cases.

Keywords: Incisional hernia; laparoscopy; mesh fixation; outcomes

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Introduction

An incisional abdominal hernia is a relative common surgical problem after laparotomies with a not negligible historical incidence and symptomatic cases (1).

Laparoscopic approach for ventral incisional hernia is both a safe and effective strategy to repair abdominal parietal defects, gaining wide acceptance as a valid alternative to classical open approaches (2). Favors for a minimally invasive strategy lie first of all upon patients’ outcomes, such as less surgical site infections, shorter hospital stay and an early return to daily activities (3).

However, notwithstanding these evidences and the advent of new strategies from a daily flooded device market, chronic postoperative pain and minor morbidities still argue relevant complaints especially on tack fixation methods (4,5), although these latter are often preferred due to their feasibility and effectiveness (6). Basing on this controversially discussed topic and the effects on both short- and long-term outcome after laparoscopic ventral incisional hernia repair (LVIHR), the safety of absorbable tack (AT) and non-AT (NAT) fixation technique has been investigated through a systematic review and meta-analysis by evaluating

Table 1 Studies' design and surgical techniques

Author	Year	Country	Type of study	Period	Enrolled patients	Inclusion criteria	Technique
Christoffers	2015	Denmark	National PSRT	2008–2012	816	NA	NA
Colak	2015	Turkey	Single center RCT	2010–2014	51	Elective surgery	AT Group: AbsorbaTack [®] , Covidien; NAT Group: Protack [®] , Tyco Healthcare
Bansal	2016	India	Single center RCT	2012–2014	90	Incisional or primary ventral hernia up to 15 cm in size	AT Group: Securestrap [®] , Ethicon; NAT Group: Protack [®] , Tyco Healthcare
Stirler	2017	Netherlands	Single center RCT	2013–2015	80	Hernia up to 2 cm	AT Group: Securestrap [®] , Ethicon; NAT Group: Protack [®] , Tyco Healthcare
Vallabhkhair	2018	India	Single center RCT	2015–2017	54	None reported	NA

PSRT, perspective randomized trial; RCT, randomized controlled trial; NA, not applicable.

their pooled influence on postoperative morbidities.

Methods

Study design

A PubMed-MEDLINE Embase, Google Scholar literature research was carried out by four investigators from the authors' panel in order to identify relevant articles published from Jan 01, 2013 to Sep 30, 2018. The choice of a defined time interval should be traced back to the attempt of a homogeneous comparison among studies on the basis of a consolidated skill expertise on techniques and the availability of latest generation devices and material resources. The medical subject heading (MeSH) terms at the Boolean function were as follows: (((((((((((laparoscopic) AND incisional hernia) OR ventral hernia) AND repair) AND absorbable) AND non-absorbable) OR titanium) AND tacks) OR tackers) AND ("2013/01/01"[PDAT]: "2018/09/30"[PDAT])). In addition to this process, a manual selection from unidentified references was included, with the last search run on October 10, 2018. All potentially relevant articles were reviewed and checked through a three-phase process (title, abstract and full-text evaluation) basing on the following inclusion criteria: (I) LVIHR; (II) cohort analysis between absorbable and NAT fixation techniques; (III) exhaustive description of surgical techniques; (IV) clearly definition of patients' outcome according to short-term and long-term morbidities; (V) articles written only in English. Only prospective randomized-controlled trials (RCT) were included, as the poor statistical relevance of the other types of articles (i.e., review, single-center original articles, retrospective articles, states of art and case reports).

Trials comparing laparoscopic versus open approaches as far as experimental reports were excluded. All selected articles were individually analyzed with subsequent data extraction by three independent reviewers to collect the following information: authors, year of publication, country of publication, the period of enrollment and number of patients, study inclusion criteria (if applicable) and surgical technique (*Table 1*).

Endpoints

The primary endpoint for this analysis was postoperative morbidity in relation to mesh fixation technique (AT *vs.* NAT).

Secondary endpoints included the evaluation of:

- (I) Postoperative seroma or parietal fluid collections;
- (II) Small bowel obstructions due to adhesions formation;
- (III) Ventral incisional hernia recurrence;
- (IV) Chronic pain.

Statistical analysis

The meta-analysis was conducted with Microsoft Excel 2016 (Microsoft[®], Redmond, USA) and with IBM SPSS version 20.0 (IBM[®], Segrate MI, Italy). All data have been recorded as absolute numbers (N), percentages (%), mean, standard deviation (SD) with their relative 95% confidence interval (95% CI). Statistical differences or correlations between cohorts were evaluated with paired t-test both for categorical and continuous variables.

For each endpoint, a summarized plot according to

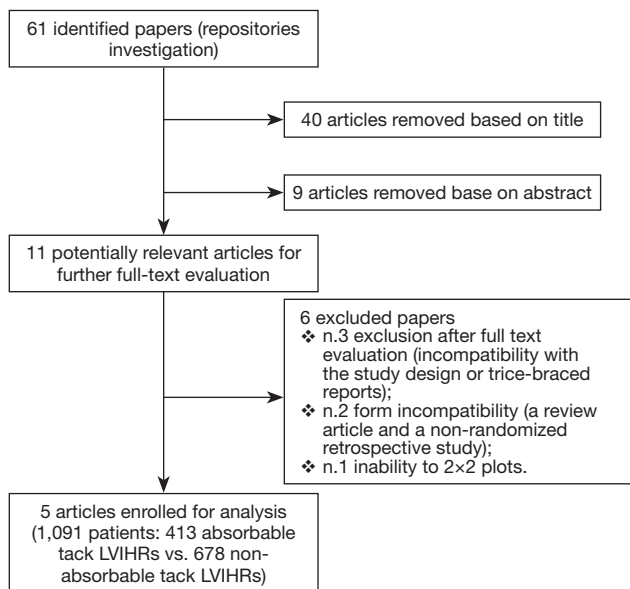


Figure 1 Articles' eligibility process: a flow chart. LVIHR, laparoscopic ventral incisional hernia repair.

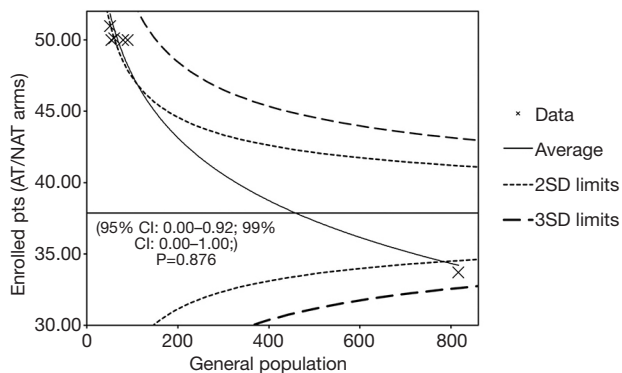


Figure 2 Asymmetry funnel plot test for selection bias. AT, absorbable tack; NAT, non-absorbable tack.

positive and negative occurrences was constructed. Odds ratio (OR) was calculated on the basis of the formula: N exposed group with a bad outcome/ N exposed group with a good outcome upon N control group with bad outcome/ N control group with good outcome. In order to assess the overall test effect for each analyzed endpoint, Z-level function was derived. A value <0.05 was considered statistically significant for both Z and P values.

Moreover, OR forest plots were derived for each article's item and for cumulative occurrences, according to their weight percentage. In addition, publication bias was

evaluated by a funnel plotting asymmetry test with relative standard error (SE), 95% limit ($\sigma 2$ SD), 99.9% ($\sigma 3$ SD) limit and a trend line with its relative p-coefficient. A P value less than 0.05 indicated the presence of asymmetry and therefore of selection bias.

Results

Data extraction process

After a primary evaluation according to the Boolean function, 61 relevant articles were identified by four independent investigators for further analysis. Thereafter, 40 were removed on title evaluation and subsequently ulterior nine in accordance with their abstract. Concerning the remaining 11 potentially relevant articles, a second-step analysis was brought throughout a full-text evaluation. Only five articles were enrolled for meta-analysis (7-11) (Table 1). In particular, six papers were excluded due to: (I) incompatibility of the study design or trice-braced cohort studies (three articles); (II) form incompatibility (a review article and a non-randomized retrospective study) and finally, (III) inability to extract patients' cohorts due to lack of relevant data. At the end of the process, 1,091 patients (413 AT LVIHR and 678 NAT LVIHR) were enrolled (Figure 1).

Quality assessment

Firstly, a primary search for potential articles' selection bias was evaluated through an asymmetry funnel plotting test which confirmed statistical heterogeneity among the enrolled population (95% CI: 0.00-0.92; 99% CI: 0.00-1.00; $P=0.876$) (Figure 2).

Further quality analysis of the eligible articles was carried out according to QUADAS-2 criteria (<http://www.gimbe.org/pagine/1101/it/quadas2>), as reported in Table 2. Sources of bias were found in standards and protocols in one study and in the same one, some issues regarding patients' selection and study timing resulted unclear. Concerning with applicability, patients' selection was unclear in one study with high risk of bias for standards and protocols (Figure 3).

Patients' cohorts evaluation

Accounting 1,091 enrolled patients into two cohorts (413 AT vs. 678 NAT), no significant differences for gender, mean age and defect size were reported (male/female:

Table 2 QUADAS-2 articles' quality assessment

Author	Risk of bias				Applicability		
	Patients' selection	Study test	Standards	Timing	Patients' selection	Study test	Standards
Christoffers <i>et al.</i>	L	L	L	L	L	L	L
Colak <i>et al.</i>	L	L	L	L	L	L	L
Bansal <i>et al.</i>	L	L	L	L	L	L	L
Stirler <i>et al.</i>	L	L	L	L	L	L	L
Vallabhbai <i>et al.</i>	U	L	H	U	U	L	H

L, low; U, unclear; H, high.

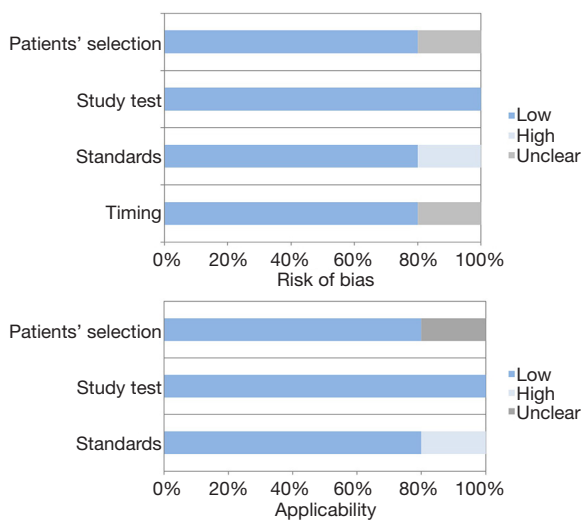


Figure 3 QUADAS-2 articles' quality assessment plot.

174/239 *vs.* 309/369, 95% CI: -2.64 to 9.44, $P=0.267$, mean age: 51.67 ± 6.35 *vs.* 52.11 ± 6.64 years, 95% CI: -0.36 to 1.24, $P=0.289$ and defect size: 27.29 ± 29.94 *vs.* 28.95 ± 28.88 , 95% CI: -1.93 to 5.25, $P=0.364$, respectively). However, concerning body mass index (BMI), mean NAT group BMI was significant superior than its counterpart (BMI AT *vs.* NAT: 28.91 ± 2.84 *vs.* 29.64 ± 3.96 kg/m², 95% CI: 0.29–1.17, $P=0.001$) (Table 3).

Surgical data

Notwithstanding comparable surgical approaches, more tacks were fixed in NAT group (AT *vs.* NAT: 11.90 ± 14.00 *vs.* 15.47 ± 18.77 , 95% CI: 1.47–5.67, $P=0.001$), though related mean operative time was inferior to AT cohort (AT *vs.* NAT: 100.55 ± 33.16 *vs.* 94.90 ± 38.32 min, 95% CI: -10.11 to 1.18, $P=0.013$) (Table 3).

Short and long-term outcomes

Postoperative morbidity

Postoperative complications were reported in three studies, enrolling 211 patients (AT *vs.* NAT: 111 *vs.* 110). At the weighted-pooled analysis, no significant cumulative effect was found (40.72% *vs.* 23.08% *vs.* 36.20%, $P=0.584$). With a rough morbidity incidence of 25.22% and 24.54%, there was no difference between cohorts (OR: 1.03, 95% CI: 0.56–1.91, $P=0.910$) with a cumulative Z-test effect of 0.11 (Table 4) (Figure 4A).

Postoperative hospital stay

Hospital stay was significantly longer in AT group when compared to non-absorbable one (2.07 ± 0.04 *vs.* 1.89 ± 0.85 days, 95% CI: -0.26 to 0.09, $P<0.001$) (Table 4).

Postoperative seromas

Postoperative fluid collections were reported in three studies, enrolling 211 patients (AT *vs.* NAT: 111 *vs.* 110). At the weighted-pooled analysis, no significant cumulative effect was found (40.72% *vs.* 23.08% *vs.* 36.20%, $P=0.584$). With a rough incidence of 10.81% and 13.63%, there was no difference between cohorts (OR: 0.77, 95% CI: 0.34–1.72, $P=0.520$) with a cumulative Z-test effect of 0.64 (Table 4) (Figure 4B).

Small bowel obstruction

Postoperative peritoneal adhesions were reported in two studies, enrolling 141 patients (AT *vs.* NAT: 71 *vs.* 70). At the weighted-pooled analysis, a significant cumulative effect from one study was reported (63.83% *vs.* 36.17%, $P<0.001$). With a rough adhesion incidence of 1.41% and 2.85%, there was no difference between cohorts (OR: 0.49, 95% CI: 0.04–5.48, $P=0.560$) with a cumulative Z-test effect of

Table 3 Demographics and surgical data

Demographics	Enrolled pts (N=1,091)		95% CI	P value
	Absorbable tacks (N=413)	Non-absorbable tacks (N= 678)		
Gender (%)			-2.64 to 9.44	0.267
Male	174 (42.13)	309 (45.57)		
Female	239 (57.87)	369 (54.43)		
Age (SD) (years)	51.67 (6.35)	52.11 (6.64)	-0.36 to 1.24	0.289
BMI (SD) (kg/m ²)	28.91 (2.84)	29.64 (3.96)	0.29–1.17	0.001
Defect size (SD) (cm ²)	27.29 (29.94)	28.95 (28.88)	-1.93 to 5.25	0.364
N. tacks (SD)	11.9 (14.00)	15.47 (18.77)	1.47–5.67	0.001
Operative time (SD) (min)	100.55 (33.16)	94.90 (38.32)	-10.11 to 1.18	0.013

SD, standard deviation; 95% CI, 95% confidence interval.

Table 4 Absorbable vs. non-absorbable mesh fixation: short- and long-term outcomes

Outcomes	No. patients	AT		NAT		OR	95% CI	P value
		N	% (mean)	N	% (mean)			
Morbidity	211	111	25.22	110	24.54	1.03	0.56–1.91	0.910
Hospital stay (days)	1,091	431	(2.07±0.04)	678	(1.89±0.85)	–	-0.26 to 0.09	<0.001
Seromas	211	111	10.81	110	13.63	0.77	0.34–1.72	0.520
Small bowel obstruction	141	71	1.41	70	2.85	0.49	0.04–5.48	0.560
Recurrence	1,091	431	19.61	678	14.60	1.67	1.21–2.31	<0.001
Chronic pain	1,041	387	12.66	653	15.16	0.81	0.56–1.17	0.260

AT, absorbable tacks; NAT, non-absorbable tacks.

0.58 (Table 4) (Figure 4C).

Recurrence

Recurrences were reported in five studies, enrolling 1,091 patients (AT vs. NAT: 413 vs. 678). At the weighted-pooled analysis, a significant cumulative effect from one study was reported (8.25% vs. 4.67% vs. 7.33% vs. 74.79% vs. 4.94%, $P=0.018$). With a rough incidence of 19.61% and 14.60%, there was difference between cohorts with a cumulative Z -test effect of 3.13 and favouring NAT fixation technique (Table 4) (Figure 4D).

Chronic pain

Chronic pain was reported in four studies, enrolling 1,040 patients (AT vs. NAT: 387 vs. 653). At the weighted-pooled analysis, a significant cumulative effect from one study was reported (8.65% vs. 7.69% vs. 78.46% vs. 5.19%,

$P=0.037$). With a rough chronic pain (more than the third postoperative month) incidence of 12.66% and 15.16%, there was no difference between cohorts (OR: 0.81, 95% CI: 0.56–1.17, $P=0.260$) with a cumulative Z -test effect of 1.11 (Table 4) (Figure 4E).

Discussion

An incisional hernia, an abdominal parietal defect, results from a failure of fascial layers healing and its incidence is historically estimated up to 20% of laparotomies with a not negligible percentage of symptomatic cases (12). Among these, almost 90% early develop within three years after initial surgery (13). However, notwithstanding its pathological and socioeconomic impact on patients' quality of life and loss of productivity, current management still claims debate especially in face of serious complications

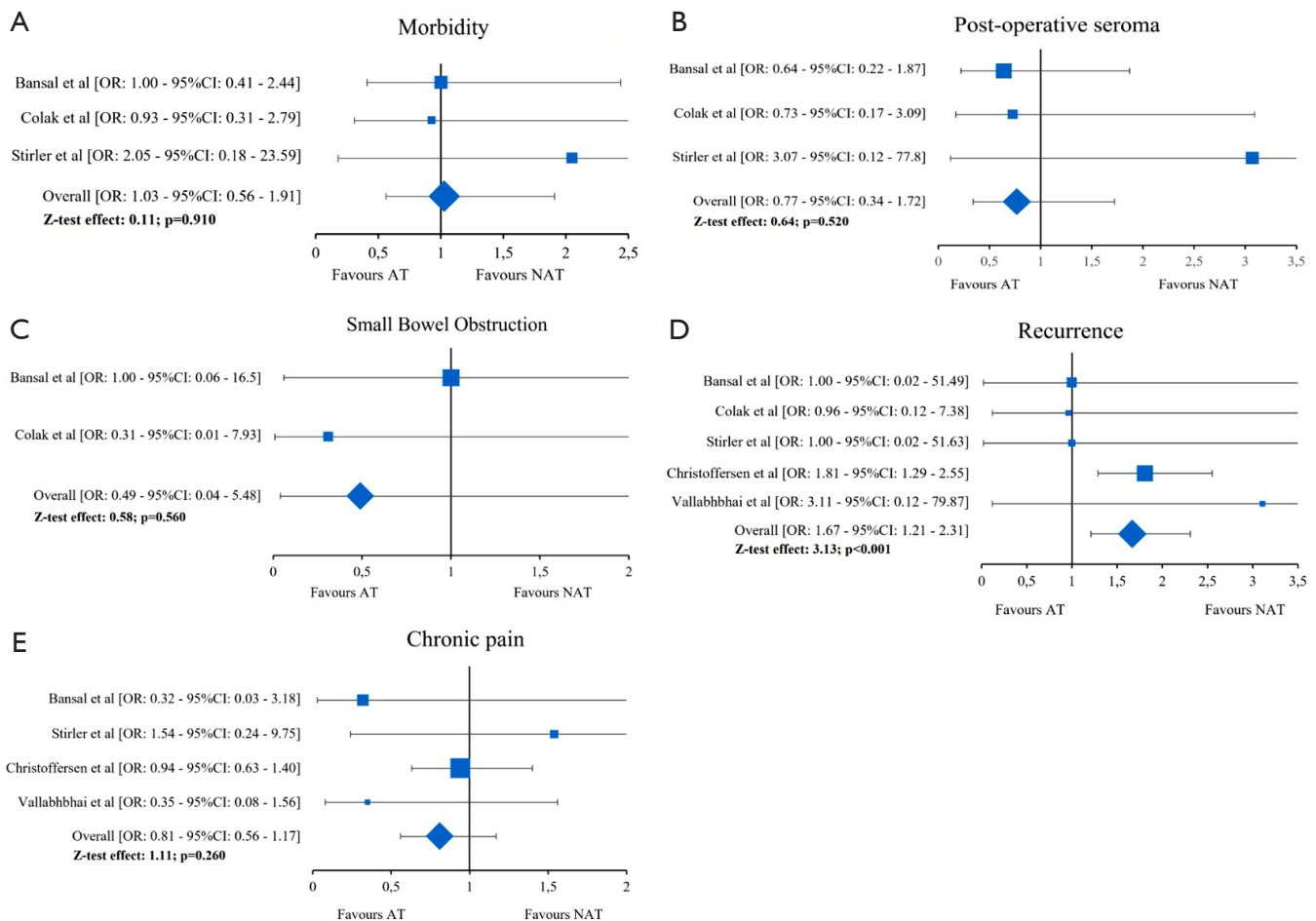


Figure 4 Patients' outcome: forest plots. (A) Postoperative morbidity; (B) postoperative seroma or fluid collections; (C) small bowel obstruction; (D) ventral hernia recurrence; (E) postoperative chronic pain. OR, odds ratio; CI, confidence interval; AT, absorbable tack; NAT, non-absorbable tack.

such as the onset of chronic pain, bowel obstruction or strangulation (14). If minimally invasive surgical strategies should be advised, as stated by the International Endohernia Society guidelines (2), laparoscopic repair is not always suitable, especially for large size groins or for parietal defects close to costal margins or pelvis (15). These techniques include both intraperitoneal and extraperitoneal onlay mesh positioning with or without primary fascial closure and secured with either tacks or sutures and carry many advantages such as low recurrence rates, shorter hospital stay, good cosmetic outcome and low complication rates as compared with open approaches (16).

Recurrence is one of the most important issues of incisional and ventral hernia repair and remains an unsolved clinical issue with increased morbidity, redo surgery rates,

longer hospital stay and mortality (17). According to previous reports, recurrence rates range from 2.5% to 9.8% (18-20), while in our analysis incidence reached 16.49% of cases. Several putative contributing factors, such as pathological and technical ones, have been advocated. With regards with the previous ones, mild to severe obesity (BMI >35 kg/m²), smoking status and secondary diastasis recti significantly predispose to relapse (17). On the other hand, an incomplete anterior rectal fascia closure, post-operative infection, mesh spillage or shrinkage and inadequate fixation are predisposing factors (18). Although several methods of suturing have been reported, there is no consensus about the optimal strategy (21), though both non-absorbable and AT mesh fixation techniques have been widely accepted.

Concerning with biodegradable devices, they could

present the theoretical possibility of loss of tensile strength over time leading to mesh migration, shrinkage or fixation failure due to their biomechanical properties. In this regard, results seem to support these evidence as being AT technique at risk of postoperative relapse (OR: 1.67, 95% CI: 1.21–2.31, $P < 0.001$). In contrast, Lepere *et al.* (22), in a multicenter study enrolling 105 patients with abdominal parietal defects and surgically treated with resorbable fixation devices, reported no recurrences, but follow-up was limited by embracing only one year. Cavallaro *et al.* (23), in a non-randomized retrospective study involving 38 incisional hernia patients, reported no difference in recurrence between titanium and AT groups (7.14% *vs.* 3.85%). However, results seem to be influenced by an asymmetrical distribution of cases, as being M2-M4 (i.e., epigastric and infraumbilical) hernias more common in the absorbable than in the titanium brace ($n: 12$ *vs.* 2).

Laparoscopic mesh fixation is regarded particularly painful (24,25). Physiopathologically, helical tacks may cause peritoneal irritation, muscle or vessel injury as far as nerve entrapment (26). For these reasons, non-invasive fixation strategies have been recently proposed on the attempt to optimize post-LIVHR pain, yielding a number of reports over the recent years (27,28). However, publications lack uniformity in outcome description due to several scores used to evaluate preoperative and postoperative pain and thus leading to insufficient recommendations on which approach should be adopted. According to our results, there was no difference in chronic pain between cohorts (AT *vs.* NAT: 12.66% *vs.* 15.16%; OR: 0.81, 95% CI: 0.56–1.17, $P = 0.260$), which is consistent with those reported by Reynvoet *et al.* (6) who, in a systematic review, found no difference in postoperative pain according to technique. In this regard, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) (29) recommend a case-based approach on fixation technique by considering size, shape and location of the hernia defect. Moreover, neither the defect extension nor the number of tacks influence postoperative pain, as being no cumulative effects between number of fixation points and chronic neuralgia (30).

Schoenmaeckers *et al.* (31), investigating the effects of tack fixation in a double cohort study enrolling eighty patients, concluded Visual Analogue Scale (VAS) score was so low from a clinical point of view that fewer tacks did not create less pain, nor do more tacks create more pain. Otherwise speculating about some differences about absorbable fixation, Lepere *et al.* (22) showed at first postoperative month only 10% of patients suffered from

low pain (VAS scores: 0.3–3.1) and 98% of them were totally pain-free at 1 year.

Concerning with seromas or postoperative fluid collections, they appear to be a common event after laparoscopic incisional hernia repair which unless a proper diagnosis could lead to detrimental strategies such as reinterventions. We found an incidence of 12.22% in our series, which is consistent with those reported by Sodergren and Switft (32). However, tack adoption does not influence them (OR: 0.77, 95% CI: 0.34–1.72, $P = 0.52$) rather than size of peritoneal sac or a high BMI.

Finally, according to our results, the mean operative time was significantly longer in the AT cohort (100.55±33.16 *vs.* 94.90±38.32 min, $P = 0.013$), reasons remain unclear. In fact, both types of fixation should be taken relatively the same time intraoperatively. One could argue some differences in penetration power or material properties to achieve fixation which could influence the timing and device feasibility, but data on this aspect still lack and experimental model studies urge. On the other hand, another reason could be found in surgical bias in the adoption of absorbable devices wrongly weaker perceived and leading to the application of more tack or trans-fascial sutures rather than in non-absorbable cases.

Limits of the study

Although a systematic approach, our conclusions should be interpreted in the context of some limitations: first, most of eligible articles had a low sample size with an undeniable possibility of type 2 error; and second, at the weighted-pooled analysis, one study (7) strongly influenced evidence, as reported for recurrences, chronic pain and the risk of small bowel obstructions. On the other hand, notwithstanding these limitations and an explicit approach, overall Z-test effect significance was reached only at relapse analysis with an undeniable level of absolute recommendation ($Z = 3.13$).

Conclusions

The adoption of ATs or NATs for mesh fixation in laparoscopic incisional hernia repair does not influence patients' clinical outcome and quality of life, except for an increased risk of recurrence when a biodegradable device is used. Therefore, their preference should be dictated by the coexistence of predisposing risk factors for recurrence, such as patients' comorbidities, and not by presumed technical device properties.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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