Cyanoacrylate Glue Versus Absorbable Tacks in Mesh Fixation for Laparoscopic Extraperitoneal Inguinal Hernia Repair: A Randomized Controlled Trial

Michael Issa, MD, Mark Tacey, MBiostat,†‡ Joshua Geraghty, MD,* Atandrila Das, FRACS,* Arun Dhir, FRACS,* Krinal Mori, FRACS,*‡ and Henry To, FRACS**

Background: Cyanoacrylate glue (Glubran 2) is a synthetic adhesive mesh fixation material. Its utility is being evaluated in laparoscopic total extraperitoneal (TEP) inguinal hernia repair (IHR). A multicentre randomized controlled trial was performed comparing Glubran 2 to standard of care absorbable tacks, particularly assessing chronic postoperative inguinal pain and its effects.

Materials and Methods: Patients undergoing elective TEP IHR at 2 centers from 2017 to 2019 were randomly assigned to Glubran 2 or absorbable tack mesh fixation, and followed for 6 months. All other aspects of surgery and aftercare remained the same. Surgeons documented operative and fixation time, and the placement of fixation on standardized diagrams. Via a questionnaire, aspects of inguinal pain were evaluated before surgery, and at various timepoints postoperatively over 6 months. Postoperative clinical factors were also collected.

Results: A total of 106 operative sides were randomized to either glue (51) or tack (55) mesh fixation over a 14-month period. Similar median operative times between tack (83.0 min) and glue fixation (75.0 min) were observed. There were no significant surgical complications or observed hernia recurrences in either group. There was no significant difference in pain scores between the 2 groups at all time-points after analysis through mixed effects modeling. Temporal pain profiles over time were also similar. Totally, 55% of patients in the glue group had returned to work within 2 weeks of surgery. There was no increase in complications or pain scores despite regular lateral fixation of glue in these patients.

Conclusion: Adding to known data, we observed no significant difference in postoperative pain, demonstrating that cyanoacrylate glue is a viable and safe alternative fixation method to absorbable tacks in laparoscopic TEP IHR. As secondary outcomes, cyanoacrylate glue permits some patients to return to work early, and we observed regular lateral mesh glue fixation without increased pain or complications.

Key Words: hernia, laparoscopic, inguinal, cyanoacrylate, tacks, pain

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Inguinal hernia repairs (IHR) are among the most common surgical procedures performed worldwide, with an estimated twenty million of these operations occurring every year.[1,2] A variety of surgical approaches and mesh fixation methods for IHR have been developed over the past few decades. There has been an increase in the use of laparoscopic techniques in IHR, with the 2 most common being transabdominal preperitoneal and totally extraperitoneal (TEP) approaches. These minimally invasive procedures have demonstrated comparable rates of recurrence and complications, with many clinical advantages, such as less postoperative pain than open techniques.[3–5] A component of these procedures is fixation of the mesh, with a number of methods used in laparoscopic IHR as assessed by postoperative outcomes. Sutures, tacks, or glues are all equally effective as mesh fixation materials, with some advocating no fixation at all.[6,7]

A reported outcome measure in IHR is chronic postoperative inguinal pain (CPIP). CPIP, also known as postherniorrhaphy neuralgia, is a well-described complication of IHR, with reported rates ranging from 0.5% to 16%.[8–12] CPIP is often categorized as pain lasting >3 months since surgery, although definitions do vary.[9,13] It is postulated that glue-based alternatives for mesh fixation have reduced CPIP compared with tacks because of a lack of penetrating fixation.[14–16] Studies evaluating glue fixation concentrate on CPIP and lack functional assessment.[16]

A glue sub-type is cyanoacrylate glue, which may offer further advantages over tissue glue and tack fixation because of stronger adhesion.[17] It is a synthetic fixation material that provides secure and quick adhesion through high polymerization rates, and has proven histocompatibility, good epithelization and negligible local inflammatory reaction.[18] Cyanoacrylate glue has been studied in laparoscopic transabdominal approaches and open hernia repair, demonstrating equivalent recurrence rates and lower postoperative pain.[18,19] There are some studies comparing cyanoacrylate glue fixation to standard of care tack fixation in laparoscopic TEP repair,[20–22] but none performed in the Australian setting. Our study aimed to add to the established literature with the primary outcome of comparing the incidence of CPIP between cyanoacrylate glue and absorbable tack fixation of mesh (the standard of care) in laparoscopic

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From the *Department of Surgery; †Office of Research, Northern Health, Epping; and ‡Northern Clinical School, The University of Melbourne, Melbourne, Vic., Australia.
M.I. and H.T. are co-authors.
The study was approved by the Austin Health Human Research Ethics Committee (Austin Hospital, 145 Studley Road, Heidelberg VIC 3084), approval number HREC/17/Austin/337. The study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.
Informed consent was obtained from all individual participants included in the study. Participants signed informed consent regarding publishing their data.
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Reprints: Michael Issa, MD, Northern Health, Melbourne, Vic. 3076, Australia (e-mail: michael.issa@nh.org.au).
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TEP IHR, particularly examining temporal changes in pain. As secondary outcomes, we wanted to identify contributing intraoperative factors and functional outcomes.

MATERIALS and METHODS

Following the CONSORT protocol for randomized controlled trials,[23] this was a multicentre, unblinded, parallel-group, controlled superiority trial, with a balanced randomization of 1:1. We used tacks as the control group as this was the current standard of care at our institute and country. It was conducted at 2 tertiary level hospitals in Melbourne, Australia, and was approved by the Austin Ethics Committee (number HREC/17/Austin/337) and registered with the Australia and New Zealand Clinical Trials Registry (Trial Registration number: ACTRN12620000742976). Eligible participants were adults aged 18 years or over who were booked for elective laparoscopic TEP IHR. Exclusion criteria were a body mass index >40, an inability to tolerate general anesthesia, the presence of an inguinoscrotal or irreducible hernia, emergency repair, recurrent hernia, or patients with a history of preoperative chronic pain on regular opioids or neuropathic agents.

Randomization and Allocation Concealment

For allocation of patients into each group, random sequence generation was performed through the use of a study envelope which contained questionnaires for either glue or tack fixation in a 1:1 ratio. Simple randomization was performed by selecting a questionnaire from this envelope on the day of the patient's surgery, once they were enrolled into the trial. This provided random allocation of the patient to 1 group of the trial. In the case of bilateral hernias, randomization was completed separately for each hernia side with subsequent adjustment during data analysis. The envelope was opaque, thus ensuring appropriate allocation concealment until after the questionnaire had been pulled from the envelope. The study envelope was stored within a secured office. The sequence generation and allocation concealment processes were undertaken by the chief investigator of the trial.

Interventions

Eligible care providers were all Fellows of the Royal Australasian College of Surgeons (RACS) who had performed >50 TEP IHRs. There was no allocation of surgeons to either group. Operative set-up and dissection involved preoperative antibiotics and intraoperative anticoagulation. Urinary cauterization was not used. A standard, 3-port technique utilized a 12 mm balloon dissector at the umbilicus, and 2 5 mm working ports. The preperitoneal space was created using the balloon dissector. Carbon dioxide gas insufflation at pressures of 12 to 15 mm Hg maintained the space. The hernia sac was separated from the vas deferens/round ligament and the inferior epigastric vessels. Either a Bard 3D (Bard, New Jersey) or Parietex Anatomical (Medtronic, Minnesota) mesh was fixed over the hernia defect according to surgeon preference, as previous studies did not show difference in CPIP because of mesh type.[24,25] The same sized Bard or Parietex mesh was used for all patients.

Glubran 2 (Matrix Surgical, Vic., Australia) is a cyanoacrylate glue that is modified by the addition of a monomer synthesized by the manufacturer. Intraoperatively, it is applied using a laparoscopic glue application tool. All participating surgeons were instructed to apply the glue using a standardized method supplied by the manufacturer. This involved applying ~1 drop of glue per square centimeter of mesh, 1 drop at a time. Surgeon adherence to this method was enhanced by the presence of the manufacturer's representative during the operation. AbsorbaTacks (Medtronic) are absorbable synthetic polyester copolymer tacks applied using a laparoscopic fixation device. No standardized locations for mesh fixation were used, to replicate real-world fixation performed by a variety of surgeons. Also, standardized locations for mesh fixation in TEP repair have yet to demonstrate differences in outcomes. We acknowledge that operator bias may be introduced by not standardizing mesh choice or fixation placement.

Outcome Assessment

The primary outcome measure was change in mean groin pain scores as assessed using validated tools for pain assessment, including a visual analog scale (VAS) and numeric rating scale for pain.[26] Several functional questions were included relating to the impact of pain on activities of daily living (see Document, Supplemental Digital Content 1, demonstrating the patient questionnaire, http://links.lww.com/SLE/A262). Time-points for data collection were preoperatively on the day of surgery (D0), on postoperative days 1 (D1), 14 (D14), 90 (D90), and 180 (D180). Pain scores >3 at D90 suggested CPIP. All outcomes were assessed by a single investigator, and reviewed by the investigating team, during the entirety of the study.

For secondary outcome measures, medical records were reviewed for postoperative complications and hernia recurrence. Intraoperative measures were collected by postoperative completion of a template by the operating surgeons (see Document, Supplemental Digital Content 2, demonstrating the postoperative template, http://links.lww.com/SLE/A263). These included operative time, fixation time, and spatial location of mesh fixation, which was illustrated on a schematic image of the intra-abdominal inguinal region.[27] Fixation location was divided into medial and lateral according to the lie of the inferior epigastric vessels.

Sample Size Calculation and Statistical Methods

The sample size estimation aimed to see a reduction of 2 points or greater of the mean VAS pain score, leading to an effect size of 1.0, with SD of 2.0. Assuming a 1:1 randomized allocation to each arm, a type I error rate of 0.05 and type II error rate of 0.2, a sample size of $n=63$ was required to be recruited in each group. There was no allowance made in the sample size calculation for attrition.

Statistical significance was set at $P<0.05$, with statistical analysis performed using Stata/SE version 15.1 (StataCorp LP, College Station, TX). Adjustments to the protocol were 2 interim analyses performed during recruitment, and the exclusion of patients with heterogeneous fixation during final data analysis, because of the difficulty of having the same patient randomized to both study groups. Heterogeneous fixation occurred if a patient undergoing bilateral repair received glue fixation on one side, and tack fixation on the other. Analyses were conducted on an intention-to-treat basis, with patients only considered in the analysis who had a baseline pain score recorded. Repeated measure models were used to assess change in VAS score over time and differences within each group, assuming unstructured covariance for each outcome. Bilateral hernias being operated on synchronously were considered as being clustered within the patient, with results presented at the hernia level. Linear mixed effects models were considered to assess VAS as a continuous score, with results presented as

means and SDs, with corresponding 95% confidence intervals. Variables found to be significantly different at baseline across the 2 arms [ie, age and American Society of Anaesthesiologists physical status classification (ASA)] were included as covariates. Sensitivity analyses were conducted to assess the effect of imputing missing observations over follow-up time-points, with missing observations imputed with chained equations, using sex, age, ASA, laterality, hernia type, and mesh type as variables to predict missing values.[28,29]

RESULTS

A total of 87 patients with 122 sides were recruited for the study, with 60 allocated to cyanoacrylate glue fixation (intervention group) and 62 to absorbable tack fixation (control group). To replicate real-world interoperator variation, a total of 17 experienced general surgeons familiar with TEP hernia repair and with the study protocol performed the operations, reflecting the diversity of contributors to the study. In the glue group, 2 patients were excluded because of intraoperative factors and were converted to alternative repair techniques—1 underwent an open repair, while another patient underwent a transabdominal preperitoneal repair. Seven patients (14 hernias) were excluded from the analysis because of heterogenous fixation (different fixation method on each side), while 2 patients in the glue group had insufficient data collection. Two further patients in the glue group and 5 in the tack group had incomplete follow-up, with the mixed effects model able to account for this incomplete data at respective time-points (Fig. 1).

For patient demographics and hernia characteristics, there was a statistically significant difference in glue patients demonstrating lower age and lower ASA scores than tack patients (Table 1). As mean ASA score was close to 2 in both groups, we did not feel that this would affect the final results. This was confirmed when adjusting for age and ASA in the mixed effects model, with no material changes to the effect sizes. No statistically significant differences were seen in types of hernias identified and mesh types used (Bard 3D or Parietex).

There were no differences in postoperative length of stay, with the majority of patients either being discharged on the same day (n = 30, 37.5%) or the following day (n = 47, 58.6%).

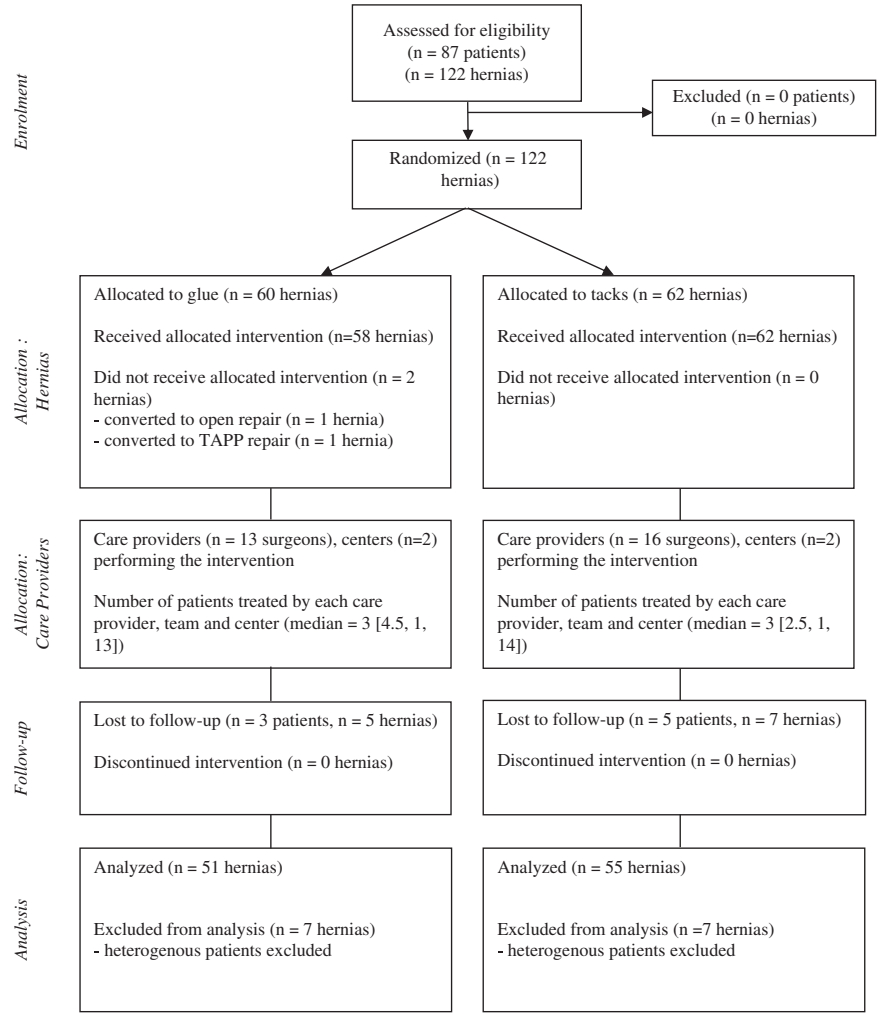

FIGURE 1. Modified CONSORT flow diagram for individual randomized controlled trials of nonpharmacologic treatments. TAPP indicates transabdominal preperitoneal.

TABLE 1. Patient Demographics and Hernia Characteristics

Factor	Tacks, n (%)	Glue, n (%)	*P*
N	55	51	
Age, mean (SD)	57.9 (15.2)	48.5 (14.0)	0.001
Sex			1.00
Male	53 (96)	49 (96)	
Female	2 (4)	2 (4)	
ASA			0.007
1	20 (36)	18 (35)	
2	24 (44)	32 (63)	
3	11 (20)	1 (2)	
Laterality			0.32
Left	28 (5)	21 (41)	
Right	27 (49)	30 (59)	
Hernia type			0.33
Direct	23 (42)	23 (45)	
Indirect	24 (44)	17 (33)	
Pantaloon	4 (7)	9 (18)	
No defect	4 (7)	2 (4)	
Mesh type			0.31
Bard 3D	28 (51)	31 (61)	
Parietex	27 (49)	20 (39)	

ASA indicates American Society of Anaesthesiologists physical status classification.

Median mesh fixation time was 5 minutes in both glue and tack groups ($P=0.22$). Median operative times were 83.0 minutes in the tack group, and 75.0 minutes in the glue group ($P=0.68$). There was no statistically significant difference in lateral fixation (40% tacks vs. 59% glue, $P=0.11$) between the groups (Table 2). Mesh fixation below the iliopubic tract was not observed during this study.

We observed no statistically significant differences in mean pain scores between the glue and tack groups at each of the follow-up time-points, using pain scores as a continuous variable, with the mixed effects model adjusting for age and ASA differences between groups (Table 3, Fig. 2). Over time, the same adjusted analysis showed the pain scores in the tack group would significantly increase from D0 to D1 by 0.966 ($P=0.019$), then reduce significantly when compared with D0 at the D14, D90 and D180 time-points (all $P<0.001$) (Table 4). For the glue group, the pain score changes (effect size) at each postoperative time point demonstrated no statistically significant difference when compared with the tack group (Table 4). High VAS pain scores (10, 8, and 7) representing outlier data were reported by 3 patients at the D180 time-point, but did not materially impact the mean values between both groups at final analysis. Only minor differences were observed during sensitivity analyses to consider the effect of imputing missing observations over the follow-up time-points between the two study groups.

TABLE 2. Fixation Location

	N (%)		
Fixation Location	**Tacks**	**Glue**	***P***
Lateral fixation			0.11
No	13 (24)	6 (12)	
Yes	22 (40)	30 (59)	
Unknown	20 (36)	15 (29)	
Medial fixation			0.54
No	0	0	
Yes	35 (64)	36 (71)	
Unknown	20 (36)	15 (29)	

TABLE 3. Mean Pain Scores at Each Time-point

	Pain Scores, Mean (SD)		
Time-Points	**Tacks**	**Glue**	***P***
Preoperative	3.1 (2.8) (n = 55)	3.1 (3.0) (n = 48)	0.94
D1	4.1 (3.0) (n = 54)	3.6 (3.2) (n = 46)	0.40
D14	1.6 (2.0) (n = 53)	1.9 (2.5) (n = 46)	0.44
D90	0.7 (1.7) (n = 52)	0.7 (1.6) (n = 46)	0.94
D180	0.6 (1.7) (n = 48)	0.8 (1.9) (n = 46)	0.56

55% (n = 21) of patients in the glue group had returned to work by the D14 time point, compared with 38% (n = 15) of tack patients, although this was not statistically significant ($P=0.080$). There were no significant differences noted in other functional assessments. Chronic pain (VAS > 3 at D90) was demonstrated in 9 patients, representing 11.5% of the study participants. This rate was in keeping with reported rates.[8–12] When evaluating postoperative complications, 4 patients had groin hematomas within 1 week postoperative, all from the glue group and all managed conservatively ($P=0.052$). One patient in the glue arm underwent a diagnostic laparoscopy 16 months after their initial hernia repair for investigation of chronic pain, for which no cause was found. No seromas or hernia recurrences were reported during the study period.

DISCUSSION

Our key finding was that there was no significant difference in postoperative mean groin pain scores between patients receiving cyanoacrylate glue or absorbable tack fixation in TEP IHR. We acknowledge that our primary outcome is not a new finding and our results are consistent with reported data. In addition to this, we have also confirmed a similar temporal trend of pain over time, and noted the absence of complications with glue lateral fixation, which are new secondary observations amongst others as discussed.

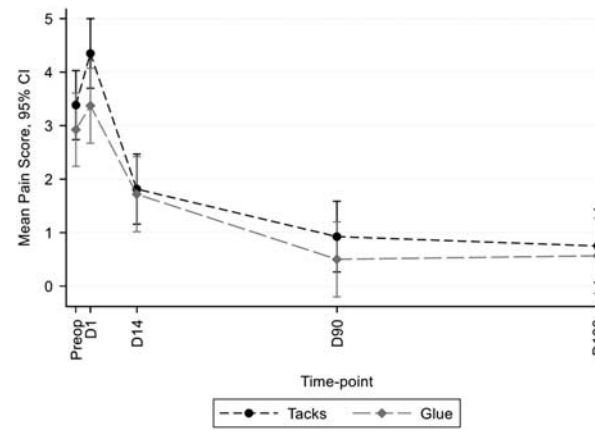

FIGURE 2. Mean pain scores at each time point for tack (circle) and glue (diamond) patients, with the 95% confidence interval illustrated by error bars. CI indicates confidence interval.

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TABLE 4. Mixed Effects Model Comparing Difference in Mean Pain Score Between Glue and Tacks and Each Time-point

Comparison/Variable	Coefficient	95% CI	*P*
Glue vs. tacks at baseline	−0.459	−1.422 to 0.504	0.350
Age	−0.039	−0.064 to −0.015	0.002
ASA			
1	Reference	—	—
2	−0.178	−0.898 to 0.542	0.629
3	0.017	−1.078 to 1.112	0.975
Change over time (for tacks group)			
Preoperative	Reference	—	—
D1	0.966	0.160 to 1.771	0.019
D14	−1.570	−2.380 to −0.760	<0.001
D90	−2.459	−3.273 to −1.644	<0.001
D180	−2.633	−3.467 to −1.799	<0.001
Effect size (glue vs. tacks) at each time-point			
Preoperative	Reference	—	—
D1	−0.519	−1.705 to 0.666	0.390
D14	0.364	−0.824 to 1.552	0.548
D90	0.036	−0.155 to 1.227	0.953
D180	0.275	−0.929 to 1.480	0.654

ASA indicates American Society of Anaesthesiologists physical status classification; CI, confidence interval.

There have been 2 meta-analyses of randomized controlled studies summarizing use of biosynthetic glue fixation in laparoscopic IHR, using mechanical fixation as the control, focusing on postoperative pain and surgical complications. Tavares et al performed a network meta-analysis comparing glue subtypes versus mechanical fixation and analyzed surgical outcomes in laparoscopic IHR.[30] From 13 trials, they identified 5 trials which specifically used cyanoacrylate-based fixation agents (4 using TEP approach). They did not find any differences in recurrence or surgical complications between bioglue and synthetic glue, but did not analyze pain scores or functional outcomes. They did find that there was less urinary retention in glue fixation, implying less immediate postoperative pain and opioid use. This review noted the limited number of studies which used cyanoacrylate glue, and the wide range of measured outcomes which limited their conclusions. Antoniou et al reviewed 9 randomized controlled trials (2 using TEP approach but only 1 with both TEP and biosynthetic glue) to determine the advantages of nonpenetrating (adhering meshes and adhesive materials such as glues) versus penetrating (tacks) fixation types.[31] They found that there was a nonsignificant trend toward less postoperative pain beyond 3 months with nonpenetrating mesh fixation techniques, and similar duration of surgery, morbidity, and risk for recurrence, therefore advocating the use of biosynthetic glues as an alternative approach.

With these results in mind, we chose to focus our study on patient recovery and pain perception. We also did not identify any significant difference in surgical complications such as postoperative seromas or early hernia recurrence. While 4 patients in our study in the glue group did experience postoperative hematomas, these did not confer significant surgical morbidity as they were all nonoperatively managed.

Our study adds to the literature to confirm the safety and efficacy profile of cyanoacrylate glue, and it presents glue as a viable and safe alternative for mesh fixation. New information in our study shows a similar temporal change in pain over time between glue and tack groups, as seen by a similar gradual reduction in mean pain scores at each measured time-point. This highlights a similar recovery phase between the 2 methods suggesting similar internal healing processes. This information can be used to advise patients of their expected recovery timeline. Of note, other studies have used alternative temporal methods such as serial inflammatory response marker measurements over time and have shown similar results.[32]

Return to work is often seen as a key milestone in recovery and a good marker of normal function,[33] and our study shows that a proportion of patients do return to work early in the glue group. While our study was not powered to detect differences in secondary outcomes, an analysis performed before the exclusion of patients who had undergone heterogenous fixation shows a statistically significant difference in return to work between the two groups, with 52% of glue patients returning by D14, compared with 35% of tack patients ($P = 0.046$). Of note, postoperative recovery instructions were not standardized among patients in our study, although the standard of practice at our health service was to instruct patients to take a minimum of 2 weeks off work after laparoscopic IHR surgery, while permitting work earlier if comfortable. This observation may be partially accounted for by the younger overall age of the patients that received glue fixation as they are likely to return to work earlier, however, it occurred despite similar reported pain scores at the same time point, thus suggesting that patients with glue fixation may have had a different perception of pain to allow for an earlier return to higher levels of activity such as work. Perhaps glue could lead to a lower dynamic component of pain as it does not have a tangible, fixed component (tack) to contribute to this sensation. A detailed quality of life questionnaire at the same time-points, such as one that details the nature of each patient's work, may explore factors that could lead to this finding.

Of interest, we identified a proportion of patients where cyanoacrylate glue was used in lateral mesh fixation without effect to pain scores or any further surgical complications. To our knowledge, this is the first study where intraoperative reporting of the location of tack or glue placement has been performed. Lateral fixation is often utilized to prevent curling or movement of the edge of the mesh, as inadequate lateral fixation has been described as a precursor to hernia recurrence.[34] Acknowledging the limited sample size (30% of patients had missing datapoints), lateral fixation with cyanoacrylate glue does not appear to compromise medium-term complications or pain outcomes when it was performed. This secondary outcome highlights another advantage of glues to permit fixation at any point in the dissected area, removing the potential for serious consequences should penetrating fixation be required or misplaced.

Some new data and recommendations have been published since the completion of our study. We acknowledge recent recommendations for nonfixation of mesh in laparoscopic IHR,[6] and a comparison could be further explored in future trials. An international consensus study recommended nonfixation for mesh, with the exception of large direct hernias, but acknowledged the lack of evidence demonstrating superiority of different fixation materials.[35] These guidelines and other studies also postulate that the majority of postoperative pain is not related to mesh and fixation types, but rather to other factors such as the degree of inflammatory reaction from operative dissection, preoperative inguinal pain, and poor control of early postoperative

pain.[11,36,37] We also acknowledge these factors as potential confounders to our results but also note our attempts to mitigate against them by preoperative pain screening, standardization of technique and routine postoperative care.

Our study had several limitations. First, we acknowledge the low sample size in each arm that can contribute to the lack of statistically significant findings. However, we used an a priori sample size calculation performed before study commencement, with the study being further strengthened by its prospective nature and in-depth analyses of postoperative pain. Second, we used a standardized but limited measurement of postoperative pain, and provided the surgical teams liberty to their preferred analgesia regimen in the intraoperative or postoperative period. Causes of chronic postoperative pain are multifactorial, including patient factors (pain threshold and psychological factors), mesh characteristics (composition, pore size), and intraoperative factors (operative dissection and nerve injury).[37] We felt that a regimented pain analysis would be complex and more difficult to administer, but may delve deeper into causes, pain characteristics, and its specific lifestyle effects Third, we identified a significant difference in age and ASA between our randomized groups, but this was corrected in our multivariable mixed effects model, with these methods also accounting for a few missing observations in follow-up. Our assessments of the adjustment for age and ASA and the imputation of missing values did not indicate any material differences in our findings. However, young age has been demonstrated as a known predictor for chronic pain.[38] Fourth, a proportion of intraoperative data was missing which could not be adjusted for, leading to a small sample size to assess hernia fixation location. However, our study was initially powered to assess the main outcome of postoperative pain, and was not powered to assess secondary outcomes. Finally, we focused on medium-term data, and a longer study period may identify long-term hernia recurrence and follow patients with chronic pain >6 months.

CONCLUSION

In conclusion, consistent with the literature, our study has demonstrated no material difference in postoperative pain between cyanoacrylate glue and absorbable tacks for mesh fixation in laparoscopic TEP IHR. Both methods demonstrate minimal complications over a 6-month period, and a similar pain profile over time. Furthermore, lateral fixation of glue is safe and does not affect postoperative pain. Using robust methodology, our findings support the use of cyanoacrylate glue as a viable alternative to absorbable tacks in mesh fixation.

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