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Prospective comparative study of mesh fixation in laparoscopic TEP hernia repair using tacker versus cyanoacrylate versus fibrin glue tep mesh fixation with cyanoacrylate

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ABSTRACT

Background: Laparoscopic inguinal hernia repairs done by totally extra peritoneal (TEP) or trans abdominal preperitoneal techniques require mesh fixation which is commonly done by either tackers or fibrin glue. In this study, we discuss about using cyanoacrylate glue for mesh fixation as a more cost effective but equally suitable alternate. **Aims and Objectives:** The aim of the study was to evaluation of suitability of using highly economical cyanoacrylate ($ 0.13) with tackers ($ 318.52) and fibrin glue ($ 11.94) for mesh fixation during TEP hernia repair. **Materials and Methods:** A comparative study was done in the Department of Surgery over a period of 3 years (2018–2021). This study included 210 patients who underwent laparoscopic TEP hernia repair. Cases were randomized into three groups of 70 subjects each: Group A - mesh was fixed with tacker, Group B - mesh was fixed using cyanoacrylate, and Group C - mesh was fixed with fibrin glue. Subjects were followed up for 3 months. Type of presentation, diagnosis, and type of mesh fixation were compared to post-operative complications that included pain, seroma, hematoma, and urinary retention findings were recorded and data were statistically analyzed using "SPSS" software. **Results:** Decreased incidence of post-operative pain (P = 0.01) and hematoma was observed in Group B as compared to Groups A and C. Average hospital stay was significantly less in fibrin glue group (P = 0.02) and cyanoacrylate group (P = 0.02) as compared to tacker group. There was same incidence of postoperative urinary retention (P = 0.520) and seroma (P = 0.354) formation between all groups. Patients of Group B started daily activities earlier at 15 days follow-up (P = 0.032) as compared to Groups A and C. **Conclusion:** Cyanoacrylate and fibrin glue fixation of mesh in laparoscopic TEP have better outcomes when compared to tackers. Furthermore, as cyanoacrylate is 300 times cheaper than tacker and 10 times cheaper than fibrin glue, this imparts a huge cost advantage to this technique in developing countries. Therefore, use of cyanoacrylate for mesh fixation in laparoscopic TEP can be safely advocated over tackers and fibrin glue.

Key words: Cost effective; Cyanoacrylate; Laparoscopic hernia repair; Tackers; Totally extra peritoneal

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INTRODUCTION

Hernia is defined as protrusion of whole or part of viscus through the wall that contains it. In daily practice, it is observed, that inguinal hernias are the most common hernias. They can be indirect (contents herniating through the deep ring) or direct (contents herniating medial to the deep ring due to muscle weakness) or Pantaloon hernias (containing indirect and direct components simultaneously).[1]

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The medical world has seen tremendous developments in the field of inguinal hernia repair.[2] Herniorrhaphy was associated with a higher rate of recurrence.[3] Recurrence has significantly decreased with the advent of hernioplasty which advocated use of a mesh for posterior wall strengthening. Meta-analyses have shown the superiority of mesh repair over suture repair.[4] Laparoscopic inguinal hernia repairs are done by totally extra peritoneal (TEP) or trans abdominal preperitoneal techniques. There are of two types of methods for mesh fixation- mechanical and non-mechanical. Mechanical methods include sutures and tackers whereas non-mechanical techniques include tissue adhesives (glues) and self-gripping meshes and 3D meshes. Mechanical methods cause more post-operative pain and increased risk of seroma formation, hematoma and osteitis. Mesh fixation was done initially with staples (tackers) that can lead to nerve injury and chronic postoperative pain. The material used for tacking evolved from permanent to absorbable in view of chronic pain being hypothesized due to the presence of the titanium inside abdomen.

Nowadays, mesh fixation by fibrin glue has gained popularity due to its advantages of decreased post-operative pain and hematoma as compared to tackers, in addition to its hemostatic action.[5,6] Fibrin glue is a biodegradable substance that contains human derived fibrinogen and thrombin activated by calcium chloride. It has proved to be effective in multiple clinical applications.

However, both fibrin glue ($ 11.94) and tacker ($ 318.52) are expensive and add to the cost of surgery, that many in the developing world cannot afford. Therefore, in an attempt to develop a more cost effective and equally suitable alternate, we decided to study the use of cyanoacrylate [$ 0.13] as a mesh fixing agent during laparoscopic TEP hernia repair. To assess the suitability of cyanoacrylate, we compared it to mesh fixed with tacker and fibrin glue and studied short-term outcomes included pain, local numbness, hematoma, seroma, wound infection, and urinary retention. Long-term outcomes that were studied included chronic pain, sensation of extraneous body, recurrence, operation time, and the time to return to work.

Aims and objectives

The aim of the study was to evaluation of suitability of using highly economical cyanoacrylate ($ 0.13) with tackers ($ 318.52) and fibrin glue ($ 11.94) for mesh fixation during TEP hernia repair.

MATERIALS AND METHODS

A comparative study was done in the department of surgery for a period of 3 years (2018–2021) in 210 subjects who underwent laparoscopic TEP hernia repair. The study was pre-approved by the Institutional Ethics Committee (IEC) for the final permission. After obtaining the permission of IEC the study was conducted. Cases were randomized and distributed in three groups of 70 each. Group A included patients who underwent laparoscopic TEP hernia repair with mesh fixed with tacker, Group B underwent laparoscopic TEP hernia repair with mesh fixed using cyanoacrylate, and Group C underwent laparoscopic TEP hernia repair with mesh fixed with fibrin glue. The subjects were followed up for 3 months and type of presentation, diagnosis, type of mesh fixation was compared to post-operative complications that included pain, seroma, hematoma, and urinary retention. Findings were recorded and data were statistically analyzed using "SPSS" software.

Adult patients age above 18 years diagnosed with uncomplicated direct, indirect and combined inguinal hernia with a sac size less than 5 cm and who were fit for general anesthesia were included in the study. Patients with any other groin hernia, recurrent hernia or complications such as irreducibility, obstruction, and incarceration were excluded as were patients in whom surgery was converted to open mesh repair because of intra-operative difficulty.

All patients were explained about the surgical procedure and risk and written informed consent was taken. Size of hernial sac was confirmed by ultrasound preoperatively and selected patients underwent hematological and radiological investigations. Overnight fasting patients were taken up for surgery and antibiotic prophylaxis (ceftriaxone 1000 mg) was administered. A 10 mm infra umbilical incision was made, rectus sheath incised and preperitoneal space dissected using finger dissection. 10 mm port was then inserted and telescope was used to visualize the pubic tubercle. The remaining two 5 mm ports were inserted under vision in the midline for working instruments. Preperitoneal space was dissected and hernial sac identified. Cord structures identified and skeletonized. Hemostasis was secured and 15×15 cm polypropelene mesh (prolene) was inserted into the preperitoneal space. An opaque sealed envelope that decided posting of the patient into one of the three groups was opened and patients were randomized into respective groups.

In the Group A, 4 tackers were used to fix the mesh to the pubic tubercle, Cooper's ligament and abdominal wall. In Groups B and C, after complete spread of mesh in preperitoneal space, cyanoacrylate was applied (Group B), while in Group C, fibrin glue was used all over the mesh to fix the mesh to the transversalis fascia. Fibrin glue (Group C) and cyanoacrylate in (Group B) were applied using wide bore needle 16/18 gauze or spinal needle. Patients were asked to mobilize and take oral feeds 8 h

postoperatively and were discharged after passing of flatus and motion. Follow-up visits were scheduled after 15 days, 1 month, 2 months, and 3 months.

Complications and pain were assessed using visual analog scale (VAS) on post-operative day 1 and every follow-up visit. The following outcomes were recorded: Hospital stay, operating time, incidence of postoperative urinary retention, hematoma and seroma formation, post-operative groin pain, and return to daily activities. Data were collected, coded and recorded in MS Excel spread sheet and analyzed using Statistical Package for Social Sciences (SPSS) software**.** P<0.05 is taken as significant. The sample size of 210 patients was calculated considering a margin of error of 5%.

RESULTS

Distribution of patients with respect to age and body mass index among the groups (Table 1) shows no statistical difference. Males were more than females in all groups and their distribution between groups was not statistically significant (Table 1). Hernial sac size was also not statistically different between groups (Table 1).

Average hospital stay was significantly less in fibrin glue group (P=0.02) and cyanoacrylate group (P=0.02) when compared to tacker group. There was no significant difference between fibrin glue and cyanoacrylate group with respect to hospital stay. 12 out of 210 patients had post-operative urinary retention and the results were not statistically different between the three groups (P=0.520).

Table 1: Patient demographics and hernia characteristics

Group (n=210 number of patients)	A (Tacker) 33% of n	B (Fibrin glue) 33% of n	C (Cyanoacrylate) 33% of n
Age (years)			
18–30	9	11	10
30–40	10	11	12
40–50	39	37	36
50–60	10	10	11
60–65	2	2	1
Gender			
Male	58	60	62
Female	12	10	8
Comorbidities			
Absent	45	39	46
Present	25	31	24
BMI			
18.5–24.9	34	34	36
25–29.9	30	32	31
≥30	6	4	3
Type of hernia			
Direct	22	22	21
Indirect	40	44	43
Both	8	4	6
Size of hernia sac			
<3 cm	34	36	35
3–5 cm	36	34	35

Four patients in tacker group, one patient in the cyanoacrylate, and two patients in fibrin glue group had post-operative hematoma formation at 15 days of follow-up. The difference was significant between tacker versus cyanoacrylate group (P=0.016), with no significant difference in other group comparison (tacker vs. fibrin, and fibrin vs. cyanoacrylate).

The incidence of seroma formation was not significant (P=0.354) among three groups at 15 days of follow-up. Hematoma and seroma were managed conservatively with medications and compression bandages. There were no secondary complications seen due to hematoma and seroma.

Pain as measured by VAS was significantly less in cyanoacrylate (P=0.01) and fibrin glue (P=0.01) group when compared to the tacker group during all follow-ups beginning from post-operative day 1 (Table 2).

About 82% and 80% of patients in cyanoacrylate and fibrin glue group, respectively, (statistically significant; P=0.032) could return to daily work activities at 15 days follow-up when compared to only 50% of patients of tacker group. There was no difference among three groups with respect to return to daily activities at 30 days, 2 months, and 3 months follow-up. No hernia recurrence was noted in all the groups at the end of 3 months follow-up.

DISCUSSION

In two meta-analyses by Kaul et al., and Shi et al., comparing staple and fibrin glue fixation of mesh in TEP no statistical difference in the operating time was found.[7,8] In this study also there was no statistically significant difference in the operating time among the three groups. This shows that all three fixation techniques could be done with ease.

Hospital stay was significantly less for cyanoacrylate and fibrin glue fixation groups as compared to tacker group which can be explained to be due to early mobilization of patients and lesser pain in the former two groups. In several studies it has been shown that use of postoperative analgesics (pain) was significantly less in the fibrin glue group as compared to tackers groups.[9]

There were four cases of hematoma in tacker, 1 in cyanoacrylate and 2 in fibrin glue groups. This might be because of increased trauma caused by the tackers. The result was statistically significant for hematoma when

Table 2: Post-operative outcomes

Group (n=210 number of patients)	A (Tacker) 33% of n	B (Fibrin glue) 33% of n	C (Cyanoacrylate) 33% of n	P -value
Mean operating time (hours)	80.1±8.4	78.42±6.1	76.6±4.2	
Avg. hospital stay (hours)	62.1±4.8	48.2±4.2	48.6±6.4	0.02
Post-operative urinary retention	6	3	3	0.520
Incidence of hematoma (15 days)	4	2	1	0.016
Incidence of seroma (15 days)	6	4	3	0.354
Avg. VAS				
POD 1	5.2±1.6	3.2±1.1	3.2±0.8	0.01
POD 15	3.1±0.8	1.8±0.8	1.9±0.7	
Post-op 1 month	2.6±0.4	1.6±0.8	1.6±0.4	
Post-op 2 months	2.4±0.5	1.3±0.4	1.2±0.5	
Post-op 3 months	2.1±0.6	1.0±0.3	1.0±0.4	

comparison was done between cyanoacrylate and tacker groups. There was no statistical difference in seroma formation among three groups. The same was proven in the meta-analysis by Kaul et al., and Mario Testini et al.[7,10]

A study done by Choi et al., showed that there was no significant difference in the postoperative complications such as seroma, hematoma, and urinary retention between the tacker and fibrin glue groups.[9] In few studies, post-operative urinary retention incidence was significant in the tacker group when compared to the fibrin glue group and it correlated with the number of tackers applied.[11,12]

Even though mesh hernioplasty has significantly reduced recurrence rates of hernia, post-operative chronic postoperative pain may severely impair standard of life.[13] A range of etiologies are proposed for chronic pain after hernia repair, these include nerve compression during mesh fixation, chronic persisting inflammation due to foreign mesh, and mesh contraction causing irritation to the nerve endings.[13,14] Fibrin glue has been compared with sutures in open hernia surgery and was found to be related to significantly lesser postoperative pain.[15-17] This is also proved in our study.

However, few studies did not show any statistically significant difference in chronic pain.[18,19] In a review of 1000 procedures of mesh fixation with fibrin glue in TEP by Berney, the incidence of chronic pain was as low as 1%.[20] In the present study, in fibrin glue fixation group a greater proportion of patients had resumed daily activities significantly earlier when compared to the tacker group. Mario Testini et al., compared 156 patients with mesh fixation by suture versus fibrin glue versus cyanoacrylate and found that long-term morbidity was significantly higher in the suture group (11.86%) than in the fibrin glue (0%, P=0.001) and cyanoacrylate (1.78%, P=0.03) groups.[10] *In vitro* studies revealed that the fibrin glue provides stronger fixation of mesh when compared to tackers.[21] The adhesive strength of cyanoacrylate glue is greater than that of fibrin glue but fibrin glue is physiological.[22] Main disadvantage of using fibrin glue and cyanoacrylate is their adherence to instruments mandating repeated cleaning; this is more with cyanoacrylate than fibrin glue.[23]

The major limitations of this study are its short follow period of 3 months. This period is insufficient to comment and compare on hernia recurrence among groups. The strengths include randomization and uniformity in technique of surgery as all surgeries were performed by the same team.

Limitations of the study

1. IT is not a multicentric study.
2. Cyanoacrylate infiltration has to be done quickly, otherwise it dries up.

CONCLUSION

Cyanoacrylate and fibrin glue fixation of the mesh in TEP have better outcomes with respect to post-operative pain, chronic pain, and early return to daily activities when compared to tackers. Cyanoacrylate is 300 times cheaper than tacker and 10 times cheaper than fibrin glue making it a cost-effective technique in developing countries. Therefore, cyanoacrylate can be safely advocated over tackers and fibrin glue for mesh fixation in TEP.

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Author's Contribution:
AS- Concept and design of the study, Interpreted the results, reviewed the literature and manuscript preparation; - Concept, coordination; **MK-** Prepared first draft of manuscript, Statistical analysis and interpretation, Reviewed the literature, Manuscript Revision; **SS-** Reviewed the literature, Manuscript preparation, Manuscript Revision; **YHS-** Prepared first draft of manuscript, Statistical analysis and interpretation; **TA-** Reviewed the literature, Manuscript preparation; **AS-** Manuscript preparation, Reviewed the literature.

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