Comparison of the Clinical Outcome and Complications in Laparoscopic Hernia Repair of Inguinal Hernia With Mesh Fixation Using Fibrin Glue vs Tacker

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Abstract Although laparoscopic repair offers a quick and less morbid way of treating hernias, complications like hematoma, seroma, neuralgia, recurrence, mesh infection, hydrocele, etc. are known. The present study was undertaken to compare various clinical outcomes between mesh fixation using fibrin glue and mesh fixation with tacker in a 3-months follow-up. One hundred patients aged 18 to 60 years having inguinal hernia admitted in Poona Hospital and Research Centre, Pune, between October 2012 and November 2014 for laparoscopic hernia surgery and ready to participate in this study were included. All of them underwent laparoscopic repair of hernia by total extra peritoneal (TEP) method following sample surgical protocol in all of them except for method of mesh fixation. Mean time calculated from insertion of the first trocar to beginning of skin suturing was 54.9 min in tacker group and 50.3 min in fibrin glue group with no statistically significant difference between the two. The incidence of urinary retention was significantly higher in tacker (34 %) as compared to fibrin glue (12 %) group. Incidence of hematoma was significantly higher in tacker group in 15-day follow-up, but there was no significant difference in hematoma formation at hernial sites in both groups after 15 days of follow-up. The incidence of neuralgia was significantly higher in the tacker group (24 %) compared with the fibrin glue group (2 %). Significantly, more number of people in the fibrin glue group 68 and 90 %, respectively, returned to work during 15 and 30 days follow-up as compared to the tacker group 46 and 64 %. Fibrin glue can be considered as an alternative to tacker for mesh fixation.

Keywords Laparoscopic hernia repair · Fibrin glue · Tack for mesh repair · Visual cosmesis scale

Introduction

Although laparoscopic repair offers a quick and less morbid way of treating hernias, complications like hematoma, seroma, neuralgia, recurrence, mesh infection, hydrocele, etc. are known [1]. These complications arise either due to patient factor (obesity, large hernia, and variant anatomy), surgeon factor (lack of skill or anatomical knowledge), or technique [2, 3]. Tacker piercing the tissue can cause injury to the nerve thus, to avoid it, a novel method has evolved where mesh is just stuck with tissues using fibrin glue. Study showed that it resulted in decrease in post operative neuralgia as it causes minimal trauma to the tissue [4]. Fibrin glue is also said to be hemostatic and thus incidences of hematoma are also decreased [5]. Various techniques of hernia repair including laparoscopic hernia repair and the complications of the procedure have been reported in many studies [6–13].

There is paucity of literature on the use of glue in laparoscopic hernia repair. The present study was undertaken to compare various clinical outcomes between mesh fixation using fibrin glue and tacker in a 3-month follow-up.

Methodology

All patients aged 18 to 60 years having unilateral inguinal hernia and having hernial defect size between 2 and 5 cm as its largest dimension (henceforth referred as sac size), admitted in Poona Hospital and Research Centre between October 2012 and November 2014 for Laparoscopic Hernia surgery, and ready to participate in this study were included after

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explaining potential advantages, risk, and cost of fibrin glue and tack for mesh fixation. Permission was obtained from Institutional Ethics Committee (IEC) and scientific advisory committee of the institution.

Inclusion Criteria

The inclusion criteria are as follows:

1. Patient aged 18 to 60 years
2. Inguinal hernia (direct or indirect; unilateral)
3. Patient fit for general anesthesia and pneumoperitoneum
4. Inguinal hernia having hernial defect size between 2 and 5 cm as its largest dimension

Exclusion Criteria

The exclusion criteria are as follows:

1. Complicated (strangulated, incarcerated, obstructed, etc.) inguinal hernia
2. Patient not fit for GA or pneumoperitoneum (COPD, coronary insufficiency, etc.)
3. Not willing to participate in the study
4. Bilateral hernia
5. Femoral hernia
6. Pregnancy
7. Psychologically unstable
8. Huge inguinoscrotal hernia (sac size >5 cm)

Sample size of 50 was calculated for each group [14, 15]. All 100 patients were divided into 50 blocks (block randomisation). Within a block, one patient was case while other was control. For randomisation, randomiser software from www.randomizer.com was used. If the randomiser gave result of (0,1) for a particular block, then the first patient of the block underwent mesh fixation by tackers while the second patient of block underwent mesh fixation by fibrin glue and vice versa if (1,0) was the result for a block. Thus, within a block, one patient was case while other acted as control. If any of the patients left the study before completion, his/her place in the block was given to the next patient. All patients confirmed clinically to have inguinal hernia. Size of sac was confirmed by USG.

All laparoscopic repairs were done by total extra peritoneal (TEP) method following the sample surgical protocol in all of them except for method of mesh fixation, i.e., fibrin glue in one group and tacks in the other (Fig. 1). For the tackers group, on an average 5 to 8 tacks were used first one being on the pubic tubercle, along the iliopectic tract and then over the aponeurotic arch, while in the fibrin glue group, glue drops

Fig. 1 Mesh fixation with fibrin glue and tackers

were spread at borders and center making mesh stick with transversalis fascia (henceforth referred as pseudosac).

Statistical analysis was done by using standard error of difference between two proportions for qualitative data and standard error of difference between two means for quantitative data.

Patients were followed post operatively up to 3 months. In the first month, patients were followed every fortnightly then once a month for 3 months. Patients were thoroughly examined. Those who developed any complication were appropriately treated.

Patients were given a cosmesis grading scale (where cosmesis was graded as worse than before (1), same as before (2), slightly better than before (3) and much better than before (4)) and pain visual analog scale (VAS) which included no pain (0), mild annoying pain (2), nagging uncomfortable troublesome pain (4), distressing miserable pain (6), intense dreadful horrible pain (8), and worst unbearable excruciating pain (10) at each follow-up to determine if patients were satisfied with hernia surgery and how much post operative pain was bothering them.

Results

Between October 2012 and November 2014, 113 patients with inguinal hernia were registered in this study. Twelve patients were excluded from the study owing to bilateral inguinal hernia (6), huge inguinoscrotal sac (sac size >5 cm) (4), and 2 refused to participate. A total of 101 patients were enrolled in study thus constituting a total of 101 hernias. There were total 69 direct hernias (33 in fibrin glue and 36 in tackers), 24 indirect hernias (13 in fibrin glue and 11 in tackers), and 8 pantaloon hernia (4 in each group). All patients completed the 3-month follow-up except for one in tackers group, probably because the

Table 1 Characteristics of patients at baseline

Characteristics	Tacker (N=50)	Fibrin glue (N=50)	P value
Age, no. (%)			
20<30 years	7 (14 %)	9 (18 %)	0.585
30<40 years	14 (28 %)	16 (32 %)	0.662
40<50 years	25 (50 %)	20 (40 %)	0.315
50<60 years	4 (8 %)	5 (10 %)	0.727
Mean age (SD)	41.7 (±8.51)	40.64 (±8.39)	0.929
Gender, no. (%)			
Male	35 (70 %)	38 (76 %)	0.499
Female	15 (30 %)	12 (24 %)	
Medical history, no. (%)			
Diabetes	19 (38 %)	15 (30 %)	0.398
Hypertension	25 (50 %)	20 (40 %)	0.315
Obesity	20 (40 %)	16 (32 %)	0.405
Smoking	16 (32 %)	16 (32 %)	1
BMI, no. (%)			
20<25	13 (26 %)	16 (32 %)	0.508
25<30	18 (36 %)	17 (34 %)	0.834
30<35	15 (30 %)	12 (24 %)	0.499
≥35	4 (8 %)	5 (10 %)	0.727
Mean BMI (SD)	28.72 (±4.52)	28.92 (±4.66)	0.975
Size of hernial sac (%)			
2–3 cm	28 (56 %)	34 (68 %)	0.095
3–4 cm	18 (36 %)	13 (26 %)	0.095
>4 cm	4 (8 %)	3 (6 %)	0.095
Mean sac size (SD)	3.23 (±0.74)	2.98 (±0.73)	0.809
Type of hernia (%)			
Direct	33 (66 %)	35 (70 %)	0.668
Indirect	13 (26 %)	11 (22 %)	0.640
Pantaloon	4 (8 %)	4 (8 %)	1

patient was staying far away from the hospital, who was excluded from study.

As shown in Table 1, both groups were matched for age, sex, body mass index (BMI), type of hernia, size of hernial sac, and comorbidities like hypertension, diabetes, and obesity.

It can be seen from Table 2 that there was no statistically significant difference in mean operating time, mean hospital stay, and mean visual cosmesis scale (VCS) grading in two groups.

As depicted in Table 2, mean visual analog pain scale was significantly higher in the tackler group as compared to the fibrin glue group, 5.76 and 2.32 at 15 days and 5.44 and 2.12 at 3 months, respectively. The tackler group showed significantly higher incidence of urinary retention and neuralgia.

Incidence of hematoma was significantly higher in the tackler group in the 15-day follow-up, but there was no significant difference in hematoma formation at hernial sites in both

groups after 15 days of follow-up. There was no significant difference in seroma collection at hernial site in two groups up to 1 month follow-up, while there was significantly higher incidence of seroma in the tackler group thereafter. Significantly more number of people in fibrin glue group 68 and 90 %, respectively, returned to work during 15 and 30 days follow-up as compared to the tackler group 46 and 64 %.

One patient in each group developed orchitis at 15 days follow-up whereas recurrence of hernia was found in four patients in the tackler group.

There were no reports of any allergic reaction, anaphylaxis, and infection in both groups.

Discussion

New technologies and techniques are evolving in hernia surgeries to keep complications at minimum. Laparoscopic repair although a costlier option is better in terms of patient comfort and timesaving [16]. Suturing of mesh is technically difficult and time-consuming thus to fix it to the tissue to prevent its displacement, tackler was developed and used [10]. Looking at cost difference, pros, and cons, it is evident that laparoscopic mesh repair is a surgery preferred by higher socioeconomic class. But laparoscopic hernia repair is not free of complications. Different techniques and materials are being tried. Many trials and meta-analysis are being conducted to establish the best method for laparoscopic inguinal hernia repair. The present study has compared various clinical outcomes in laparoscopic repair of hernia when mesh was fixed with fibrin glue vs when fixed with tacks.

Operating Time

Fitzgibbon et al. [17] who conducted multi institutional prospective study of transabdominal preperitoneal (TAPP), totally extraperitoneal (TEP), and intraperitoneal onlay mesh (IPOM) in 686 patients, and 869 hernias stated that the average operating time was 70 min for unilateral and 90 min for bilateral repair. In a meta-analysis study by Shinde [5] on 832 patients, operating time in the fibrin glue group was 35 min whereas 25 min for the tackler group. The time difference was attributed to need for sutures for peritoneal flap closure in the fibrin glue group. Bansal et al. [11] have compared the operating time in mesh fixation with tackler (52.6 min) and suturing (77.5 min). Tolver et al. [15] conducted a study in which TAPP was done for 100 patient using fibrin glue for 50 and tack for rest of the 50 patients. Mean operating time was 27 min for the tackler group and 30 min for the fibrin glue group. In a study conducted by Ceccarelli et al. [4], average operating time for the fibrin glue group was 35 min whereas it was 25 min for the tackler group.

Table 2 Clinical outcomes

Characteristics	Tacker (N=50)	Fibrin glue (N=50)	p value
Mean operating time (SD)	54.9 ($\pm$ 5.79)	50.3 ($\pm$ 4.05)	0.515
Average hospital stay (SD)	2.38 ($\pm$ 0.60)	2.14 ($\pm$ 0.35)	0.728
Incidence of post operative urinary retention (%)	17 (34 %)	6 (12 %)	0.009
Incidence of hematoma formation (%)			
15 days	4 (8 %)	0 (0 %)	0.041
30 days	1 (2 %)	0	0.315
2 months	0	0	–
3 months	0	0	–
Incidence of seroma (%)			
15 days	6 (12 %)	3 (6 %)	0.294
30 days	8 (16 %)	4 (8 %)	0.218
2 month	10 (20 %)	2 (4 %)	0.014
3 months	7 (14 %)	1 (2 %)	0.027
Mean visual cosmesis scale (VCS) grading (SD)			
15 days	2.9 ($\pm$ 0.94)	3.62 ($\pm$ 0.63)	0.608
30 days	3.04 ($\pm$ 0.92)	3.72 ($\pm$ 0.49)	0.513
2 months	2.82 ($\pm$ 1.01)	3.76 ($\pm$ 0.47)	0.400
3 months	2.8 ($\pm$ 0.77)	3.76 ($\pm$ 0.42)	0.278
Incidence of neuralgia (%)			
15 days	12 (24 %)	3 (6 %)	0.012
30 days	10 (20 %)	2 (4 %)	0.012
2 month	12 (24 %)	1 (2 %)	0.001
3 months	11 (22 %)	0	0.0004
Average visual analog pain scale (SD)			
15 days	5.76 ($\pm$ 1.36)	2.32 ($\pm$ 1.00)	0.043
30 days	5.56 ($\pm$ 1.40)	2.2 ($\pm$ 0.72)	0.033
2 months	5.6 ($\pm$ 1.44)	2.14 ($\pm$ 0.67)	0.030
3 months	5.44 ($\pm$ 1.55)	2.12 ($\pm$ 0.62)	0.047
Return to work (%)			
15 days	23 (46 %)	34 (68 %)	0.026
30 days	32 (64 %)	45 (90 %)	0.002
2 month	41 (82 %)	45 (90 %)	0.249
3 months	47 (94 %)	49 (98 %)	0.307

In the present study, mean time calculated from insertion of first trocar to beginning of skin suturing was 54.9 ($\pm$ 10.56) min in the tackler group and 50.3 ($\pm$ 8.1) min in the fibrin glue group with no statistically significant difference between the two. In TEP repair, no peritoneal flap closure is involved. Thus, surgical time for both groups was similar while in TAPP repair after mesh is fixed with glue, peritoneal flap has to be sutured thus more time is consumed compared to tack fixation where the flap is also tacked.

Average Hospital Stay

In the studies conducted by Shinde [5] and Ceccarelli et al. [4], mean hospital stay was 24 h for both groups. In the present

study, mean hospital stay of patients in the tackler group was 2.38 ($\pm$ 1.19) days whereas 2.14 ($\pm$ 0.69) days for the fibrin glue group. There was no significant difference between the two groups.

Urinary Retention

Fitzgibbon et al. [17] observed an overall rate of urinary retention was 5.8 %. In the present study, overall 23 % patients had urinary retention, 17 patients in the tackler group and 6 in the fibrin glue group. All these patients were relieved of retention by Foley's catheter which was kept overnight and removed in the morning so as to encourage mobilisation. There were no cases of re retention. Many factors affecting urinary

retention such as age, prostatomegaly, type of anesthesia, pain, and opioid analgesic [18, 19] need to be considered while studying incidence of urinary retention but data regarding age group and type of anesthesia in reference study was not available.

Seroma and Hematoma

Fitzgibbon et al. [17] reported a total of 1.2 % of hematoma and 3.4 % of seroma in their study. Out of 3.4 %, 1 % required aspiration of seroma. Shinde [5] stated that no hematoma was observed in the fibrin glue group whereas 1.14 % in the tackler group. He further stated that 2.4 % patients developed seroma in the fibrin glue group as compared to 2.29 % in the tackler group. Fine [20] conducted a case series of 38 patients where in all patients Surgisis mesh was fixed with fibrin glue. He reported seroma in 2.63 % patient and hematoma in 5.26 % patients. Tolver et al. [15] found slightly higher incidence of seroma in tackler group 10 % as compared to the fibrin glue group 6 %, but there was no incidence of hematoma in his study.

In the present study, 4 (8 %) patients in the tackler group developed hematoma at the hernial site while none in the fibrin glue group. Our findings regarding hematomas were quite consistent with other studies.

In the first 15 days, six patients from tackler and three from fibrin glue developed seroma. Most of these seromas were diagnosed by an investigator, and patients were asymptomatic. By the end of 3 months, seroma has subsided in three of four patients in the fibrin glue group, while in the tacklers group, it persisted in seven patients developing seroma. In three patients, it required percutaneous aspiration; in others, it resolved with conservative management. Seromas were significantly higher in the tackler group than in the fibrin glue. This can be attributed to obliteration of dead space quickly achieved by fibrin glue. Fibrin glue has been used by plastic surgeons to prevent seromas in grafts [21]. Incidence of seroma in the present study was higher than other studies possibly because sensitive criteria (clinically as well as radiologically, i.e., by USG) were used. Hence, the presence of the slightest collection was reported. Another possibility is meticulous dissection of sac done to prevent early recurrences could have caused more seromas [22]. But patient cosmesis perception was the same in both groups, probably because development of small seroma does not affect cosmesis.

Groin Pain and Orchitis

A study conducted by Fortelny et al. [11] with 89 patients having 110 hernia with 1-year follow-up, average VAS score was 0.4 for those whose mesh was fixed with fibrin glue and 0.9 for those in whom it was done with tackler. The study did not show any significant increase in pain caused by tackler.

Ceccarelli et al. [4] reported no groin pain in both groups although he found increased pain at the trocar site in the tackler group. A meta-analysis conducted by Kaul et al. [10] of 662 hernia repairs where in 394 mesh were fixed with tacks while in 268 mesh were fixed with fibrin glue found that incidence of pain was significantly higher in the tackler group. Stark et al. [23] reported incidence of pain in 4.2 % of patients. Tolver et al. [15] reported that day 1 scores and all cumulated scores of pain during rest, discomfort, and fatigue were significantly lower in the fibrin group compared with the tackler group (all p values ≤ 0.02).

In present study, mean VAS score was 5.44 in the tackler group and 2.12 in the fibrin glue group. At third month, incidence of neuralgia was 22 % in the tackler group whereas none in the fibrin glue group. The cause of so much difference in pain scores of different studies may be the use of different pain scales in each study. But all of them have shown statistically significant difference in pain scores between fibrin glue and tackler group.

Recurrence

Fitzgibbon et al. [17] reported overall recurrence rate after mean 23 months (15–34 months) follow-up was 4.5 % (39 recurrences in 867 hernias) of which 5 % were in TAPP ($n=562$), 5.1 % in IPOM ($n=217$), and 0 % in TEP ($n=87$). Ceccarelli et al. [4] did not observe any recurrence in both the groups. Fine [20] reported a recurrence in 1 out of 38 patients (2.63 %) at 13 months (± 6 months) follow-up in the fibrin glue group. Tolver et al. [15] reported two recurrences in the fibrin glue group at 6 months while nil in tackler group.

In the present study, recurrence was seen 1 % at 1 month and 3 % at 3 months follow-up. The cause of recurrence could be improperly placed mesh or displaced mesh [7]. The recurrence needed further investigation but could not be undertaken due to time constraint. There was higher incidence of recurrence in the present study compared to other studies. This could be due to differences in comorbidities and genetic make up of the two population groups. Since the study population for the current research is Indian ethnic group which differ from European population in terms of muscle strength, tendency for obesity, tendency for constipation, etc. Also, the comorbidities like obesity, prostatomegaly, chronic bronchitis, etc. that contribute to recurrence have not been matched in the current study population and the abovementioned study population.

As far as the comparison of glue and tackler is concerned, there was no significant difference as in other studies. An animal (pig) experimental study by Katkhouda et al. [13] stated no significant graft motion after fixation with tack or fibrin glue compared with no fixation. Also, fibrin glue has caused more inflammatory and fibrous reaction leading to better

fixation. Thus, there is no reason for increased recurrence due to improper mesh fixation in the fibrin glue group.

Return to Work

Fine [20] reported that 21 patients out of 38 (55.3 %) of fibrin glue for fixation of surgis mesh group had returned to work in less than 5 days.

In the present study at 15 days follow-up, it was found that 34 out of 50 patients (68 %) in the fibrin glue group had returned to work as compared to 23/50 (46 %) in the tacker group. There was a statistically significant difference between the two groups. Among the fibrin glue group, early return to work was more, possibly because there was less pain thus allowing lesser limitations to normal work ability. The return to work at 30 days in the tacker group was only 64 %. In the current study, a quite stringent criteria were used to define return to work where return to work not only included return to occupation but also complete return to normal daily routine work. In the tacker group, it was low due to more pain and altered sensation in the groin; thus, it looks lower than other studies where return to work merely means returning to occupation.

Conclusions

1. Fibrin glue when used for mesh fixation had advantages of lowering neuralgias and post operative pain compared with tacker.
2. Incidences of hematoma and seroma formation were less in fibrin glue compared with tacker fixation.
3. Patients developing urinary retention were less when fibrin glue was used for mesh fixation.
4. Patients who were treated with fibrin glue for mesh fixation returned to work earlier as compared to tacker.
5. Use of fibrin glue for fixation of mesh did not increase chances of mesh displacement and recurrence.
6. Use of fibrin glue for mesh fixation compared to tacker did not alter operating time, hospital stay, and patient's cosmetic satisfaction.

Thus, fibrin glue may be considered as an alternative to tacker for mesh fixation.

Limitations of the Study

Although all procedures and methods involved in the study were as per standard scientific recommendations, certain inevitable limitations still remained:

1. Study was performed in a limited time span, hence follow-up was of short duration of 3 months.

2. Blinding was not done and chances of bias in selection, clinician observation, and patient's view regarding pain and cosmesis exist.
3. All surgeries were not conducted by the same surgeon, thus difference in surgical skills and anatomical knowledge could have affected the outcome; but all surgeries were performed by following the same pre-decided protocol, and it was ensured that all surgeons were of same experience and capability.

Recommendations

1. Further studies must be conducted to compare tack fixation with fibrin glue mesh fixation for laparoscopic repair of inguinal hernia with larger sample size and follow-up for longer period.
2. Use of fibrin glue should be encouraged especially in young and active patients to provide more pain free life years.
3. For patients at increased risk of hemorrhage or hematoma formation, glue should be preferred over tack fixation.

Compliance with Ethical Standards

Conflict of Interest Dr. Prasant Chandra, Dr. Deepak Phalgune, and Dr. Shashank Shah declare that they have no conflict of interest.

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