A Prospective Comparative Study in Laparoscopic Inguinal Hernia Repair with Regard to Fixation and Non-Fixation of Mesh in a Tertiary Care Centre in Northern India

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ABSTRACT

BACKGROUND

The debate between fixation and non-fixation of mesh in laparoscopic hernia surgery has been going since the advent of this technique. While earlier studies insisted on mesh fixation, emerging studies are now supporting elimination of mesh fixation. Therefore, a prospective comparative study was performed in tertiary health care centre in northern India to compare the incidence of recurrence, post-operative pain and chronic groin pain between mesh fixation and non-fixation. In this study, we wanted to compare the intra-operative complications, post-operative pain and recovery, duration of hospital stay, incidence of chronic groin pain and pain during follow up visits and incidence of recurrence in laparoscopic inguinal hernia repair between fixation and non-fixation of mesh.

METHODS

A prospective comparative study was conducted among 50 patients admitted in surgery unit in a tertiary health care centre in northern India from January 2019 to October 2020 and were divided into two groups (group A - fixation, group B - non-fixation). Different factors such as post-operative pain, analgesia required post-operatively, duration of hospital stay, chronic groin pain and recurrence were compared between the two groups. Patients were followed up at 1, 3, 6 and 12 months.

RESULTS

The mean pain score at the end of 1 month and 3 months was higher in patients in the mesh fixation group. The days required by patients to resume their routine activities was lesser in patients in the non-fixation group. The recurrence rate was found to be similar in both the groups.

CONCLUSIONS

Mesh fixation offers no clear advantage over non-fixation and non-fixation can be considered as the preferred alternative as this procedure has less chance of post-operative pain, early ambulation and no increased risk of recurrence.

KEYWORDS

Laparoscopic Inguinal Hernia Repair, Mesh Fixation, Mesh Non-Fixation

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BACKGROUND

Inguinal hernia is the bread and butter of every budding general surgeon. With the gaining popularity of laparoscopic procedures even in rural parts of India, laparoscopic hernia surgery has now become the preferred alternative for open mesh hernioplasty.

Laparoscopic hernia surgery offers significant advantage over open procedure as it results in a smaller surgical scar, reduced duration of hospital stay and early ambulation. Another matter of debate in laparoscopic hernia surgery is between fixation and non-fixation of mesh. Earlier studies pointed out that non-fixation of mesh lead to increased rate of recurrence.

Now, there are several studies supporting the fact that non-fixation of mesh is better alternative as it has comparatively less post-operative pain and no increased risk of recurrence. In our study we have tried to find out the different advantages and disadvantages of mesh fixation and non-fixation.

Objectives

- To compare the intraoperative complications in laparoscopic inguinal hernia repair between mesh fixation and non-fixation.
- To compare the post-operative pain and recovery in laparoscopic inguinal hernia repair between mesh fixation and non-fixation.
- To evaluate the duration of hospital stay in laparoscopic inguinal hernia repair between mesh fixation and non-fixation.
- To evaluate the difference in incidence of chronic groin pain and pain during follow up visits in laparoscopic inguinal hernia repair between mesh fixation and non-fixation.
- To identify incidence of recurrence in laparoscopic inguinal hernia repair between mesh fixation and non-fixation.
- To evaluate the cost-effectiveness of mesh fixation versus mesh non-fixation in laparoscopic inguinal hernia repair.

METHODS

This prospective comparative study was carried out on a total of 50 patients admitted in surgery unit in a tertiary health care centre in northern India from January 2019 to October 2020. The patients were randomized into two groups.

- Group A: Mesh fixation group (n = 25)
- Group B: Non-fixation group (n = 25)

Inclusion Criteria

- Adults > 18 years of age with informed consent
- Patients with both unilateral and bilateral inguinal hernia
- No previous major surgeries.
- ASA I & II patients (American Society of Anesthesiologists).

Exclusion Criteria

- Adults < 18 years of age
- Femoral hernia
- Strangulated and incarcerated hernia
- Recurrent hernia
- Patients with a high anesthetic risk (ASA IV)

Surgical Technique

Totally Extrapreitoneal (TEP) or transabdominal preperitoneal approach (TAPP) endoscopic inguinal hernia repair was performed with the patient under general anaesthesia by using a midline, 3-trocar technique. Polypropylene mesh sized 15 x 15 cm used to cover the entire myopectineal orifice including the hernia defect. The mesh would be fixed to Cooper's ligament and the anterior abdominal wall using 3 to 6 spiral tacks in patients enrolled in the tacking arm of the study (Group A). A pre-formed 15 x 15 cm mesh would be used without tack fixation in patients enrolled in the non-tacking arm of the study (Group B).

Tools

Visual Analogue Scale (VAS) was used for assessment of pain in patients undergoing surgery (Figure 1).

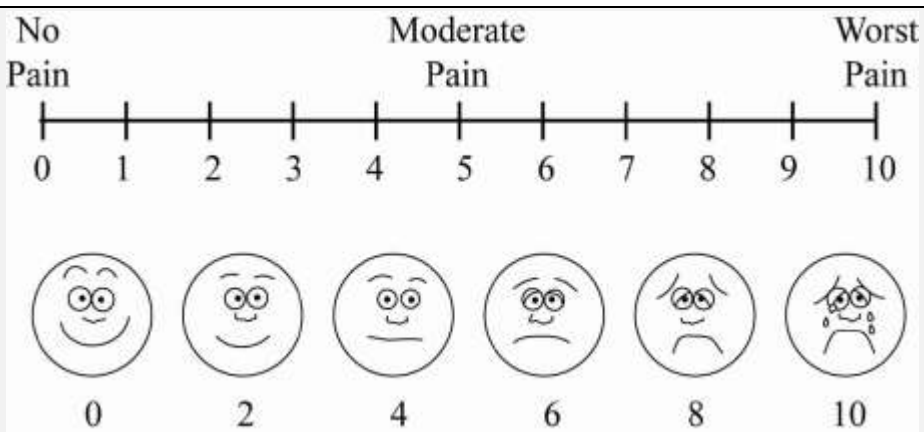

Figure 1. Visual Analogue Scale

Statistical Analysis

The statistical analysis was done using SPSS (Statistical Package for Social Sciences) version 22.0 statistical analysis software. The following were used to interpret the data obtained,

1. Mean
2. Standard Deviation
3. Chi-square test
4. P - value (< 0.05 was considered statistically significant)

Follow Up

Patients were included in a follow-up protocol and reviewed in the out-patient department (OPD) consulting room at 1, 3, 6 and 12 months. Recurrence was defined as a palpable hernia or a clear defect of the abdominal wall, which in the event of doubt was confirmed by ultrasound. Follow-up was considered complete when it included a physical examination at 12 months.

RESULTS

	Fixation	Non-Fixation
Age (mean ± sd)	52.3 ± 10.5	50.5 ± 9.2
Duration of symptoms	12.28 ± 4.03	11.64 ± 3.28
Unilateral	19	21
Right	15	15
Left	4	6
Bilateral	6	4
Direct	4	3
Indirect	21	22

Table 1. Patient Demographic Details

A total of 50 patients underwent repair of 55 inguinal hernias in our study. The mean age in group A was 52.3 ± 10.5 and the mean age in Group B was 50.5 ± 9.2. There was no significant difference in age between the two groups (P = 0.522). The mean pain score 24 hours after surgery in group A was 3.6 ± 0.9 and in group B it was 2.9 ± 0.6. Using the chi square test, we found that there was no statistically significant difference with regard to pain after the first 24 hours of surgery between the two groups.

	Fixation	Non-Fixation	Total
Less pain (vas 1,2)	2 (80 %)	6 (24 %)	8 (16 %)
More pain (vas 3,4)	23 (20 %)	19 (76 %)	42 (84 %)
Total	**25**	**25**	**50**

Table 2. Pain Score at 24 Hours Post Operatively

We observed that the mean pain scores at 1 month and 3 months in the mesh fixation group were 3.4 ± 0.6 and 2.2 ± 1.0 which were significantly higher than patients in non-fixation group which was 3.0 ± 0.7 and 1.6 ± 0.6. There was a statistically significant difference in pain score at the end of 1 month and 3 months. However, there was reduction in pain in both groups over the period of time. At the end of 6 months and 12 months, there was significant reduction in mean pain score in both the groups and no patients had significant pain. The mean duration required to resume routine activities after surgery by patients in the fixation group was 8.2 ± 0.7 and the mean duration required by patients in the non-fixation group was 7.7 ± 0.8. There was statistically significant difference between the two groups.

	Fixation	Non-Fixation	Total
Less pain (vas 1,2)	1 (4 %)	5 (20 %)	6 (12 %)
More pain (vas 3,4)	24 (96 %)	20 (80 %)	44 (88 %)
Total	**25**	**25**	**50**

Table 3. Pain Score at 1 Month

	Fixation	Non-Fixation	Total
Less pain (vas 1,2)	19 (76%)	24 (96 %)	43 (86%)
More pain (vas 3,4)	6 (24 %)	1 (4 %)	7 (14 %)
Total	**25**	**25**	**50**

Table 4. Pain Score at 3 Months

	Fixation	Non-Fixation	Total
< 1 week	4 (16 %)	11 (44 %)	15 (30 %)
> 1 week	21 (84 %)	14 (56 %)	35 (70%)
Total	**25**	**25**	**50**

Table 5. Days Required to Return to Routine Activities

The mean hospital stay for fixation group was observed to be 3.9 ± 0.8 and in non-fixation group as 4.0 ± 0.7 and this was found to be statistically insignificant. We also encountered one case of vascular injury to the inferior epigastric artery in the mesh fixation group which was managed by suturing the vessel. The incidence of intra operative complication was found to be similar with no significant difference between the two groups.

In our study, two patients (8 %) in group A and 3 patients (12 %) in group B developed seroma which was found to be statistically non-significant. The seroma in these patients was managed conservatively and resolved spontaneously. 12 % of patients in group A and 16 % of patients in group B had urinary retention post-operatively and were managed by catheterisation. This incidence was found to be statistically non-significant. In our study, 4 % patients in group A and 12 % patients in group B had wound infection. Though the incidence was slightly higher in non-fixation group it was found to be statistically non-significant. The infection was not deep enough and was managed by regular dressing and antibiotics according to pus culture and sensitivity.

Recurrence was observed in only one patient in non-fixation group and none of the patients in the fixation group had recurrence and this was found to be statistically non-significant. Also, 1 patient in each group had mesh infection and the incidence was found to be statistically non-significant. Both the patients required mesh removal.

We also observed that mesh non-fixation was found to be cost effective as patients undergoing mesh fixation had to bear the additional cost of tacker.

Variable	Fixation Group	Non-Fixation Group	P Value	Significance
Pain score at 24 hours post op	3.6 ± 0.9	2.9 ± 0.6	0.122	Not significant
Analgesia required post op	2.8 ± 0.7	2.6 ± 0.8	0.352	Not significant
Post op wound infection	1 (4 %)	3(12 %)	0.302	Not significant
Post op seroma	2 (8 %)	3(12 %)	0.641	Not significant
Post op urinary retention	3 (12 %)	4(16 %)	0.687	Not significant
Duration of hospital stay	3.9 ± 0.8	4.0 ± 0.7	0.640	Not significant
Days required to return to routine activity	8.2 ± 0.7	7.7 ± 0.8	0.022	Significant
Pain score at 1 month	3.4 ± 0.6	3.0 ± 0.7	0.035	Significant
Pain score at 3 months	2.2 ± 1.0	1.6 ± 0.6	0.013	Significant
Pain score at 6 months	1.3 ± 0.7	1.1 ± 0.4	0.221	Not significant
Recurrence	0	1(4 %)	0.327	Not significant
Mesh infection	1(4 %)	1(4 %)	1	Not significant
Intra op vascular injury	1(4 %)	0	0.317	Not significant

Table 6. Consolidated Table Comparing Various Factors between Mesh Fixation and Non-Fixation Group

DISCUSSION

A lot of studies have been conducted in laparoscopic hernia surgery with regard to mesh fixation versus non-fixation. The major concern in laparoscopic inguinal surgery is chronic groin pain and recurrence. The ideology behind fixation of mesh in LIHS is to prevent mesh migration thus reducing the incidence of recurrence. But various studies have now reported that there is no significant difference in recurrence between mesh fixation and non-fixation. Our observations based on the study conducted in our tertiary care health centre are presented below.

Pain Score (Post-Op & Follow Up)

In our study, the mean pain score after 24 hours of surgery between the two groups were similar and there was no statistically significant difference (P = 0.122). However, the mean pain score at the end of 1 month (P = 0.035) and 3 months (P = 0.013) was significantly higher in patients in the mesh fixation group. Mohammed et al.[1] also reported similar findings in his study that the mean pain score 24 hours after surgery in Group A was 1.25 ± 2.38 and in group B was 0.90 ± 1.97, with no significant difference in post-operative pain in both groups. Kalidarei B et al.[2] in his study reported that the pain score of patients 1 day after the surgery was not statistically significantly different between the two groups (P = 0.241). However, the pain score at the time of release in Group A with a mean of 3.34 ± 2.26 was statistically significantly higher than that of Group B, with a mean of 2.03 ± 2.18 (P = 0.010). In addition, the mean of pain score in Group A was 2.76 ± 1.62 and 2.34 ± 1.37, at 1 and 2 weeks after the surgery, respectively, which was higher than that of Group B, with a mean score of 1.74 ± 1.50 and 1.41 ± 1.29, at 1 and 2 weeks after the surgery, respectively (P < 0.05). The pain score of the two groups showed no statistically significant difference at 1- and 6-month follow-up (P > 0.05). Rekhi HS et al.[3] inferred that patients included in the fixation group experienced more pain at the end of 1st week. P - value was analysed to be 0.001 by t-test, which signified highly significant results. They also observed that mesh fixation increases the incidence of post-operative pain significantly at the end of 2nd week with P - value as 0.002. When pain was compared at the end of 1 month, mean was calculated as 0.40 in the fixation group and 0.00 in non-fixation group. P - value for this analysis was found to be 0.072, which showed non-significant results. None of the 30 patients experienced any pain at 6 months. Contrary to our study Darwish AA et al.[4] reported that there was statistically significant difference in pain in mesh non-fixation group at 24 hours post-operatively. In group A, the first 24-h post-operative pain had a mean of 4.067 ± 1.112, whereas in group B the value was 1.967 ± 0.765. With respect to the follow-up, the pain in group A after 1 week was 3.567 ± 1.331, after 1 month 2.633 ± 1.520, after 6 months 1.867 ± 1.613, and after 12 months 1.233 ± 1.501. The pain in group B after 1 week was 0.967 ± 0.765, after 1 month 0.4 ± 0.563, after 6 months 0.167 ± 0.379, and after 12 months 0.033 ± 0.183. There was a statistically significant decrease in post-operative pain and chronic pain in group B than in group A.

Duration of Hospital Stay

Laparoscopic surgery is a boon to surgical fraternity with its advantage of shorter hospital stay, faster recovery and earlier return to normal activities. In our study, mean hospital stay for fixation group was observed to be 3.9 ± 0.8 and in non-fixation group as 4.0 ± 0.7 and this was found to be statistically insignificant (P = 0.640). Similar findings were observed in studies conducted by

- Mohamed H ED et al.[1] who reported that the mean hospital stay in group A was 1.35 ± 0.67 in comparison with 1.30 ± 0.66 in group B (P = 0.74), which is statistically insignificant.
- Kochar S, et al.[5] also reported similar findings in which the mean post-operative hospital stay in patients in group A was 2.00 ± 0.78 days whereas in patients of group B it was 1.66 ± 0.84 days. This was found to be statistically non-significant (P > 0.05)
- Rekhi HS et al.[3] observed in her study observed that the mean hospital stay for fixation group was observed to be 2.80 days and in non-fixation group as 2.53 days, which was statistically non-significant.

Days Required to Resume Routine Activities

The mean duration required to resume routine activities after surgery by patients in the fixation group was 8.2 ± 0.7 and the mean duration required by patients in the non-fixation group was 7.7 ± 0.8. There was statistically significant difference between the two groups (P = 0.022). In a study by, Darwish AA et al.[4] the patients in group A returned to work after 7.867 ± 2.662 days and in group B after 5.033 ± 1.189 days. These findings were similar to findings in our study.

Intra Operative Complications

In our study we encountered one case of vascular injury to the inferior epigastric artery in the mesh fixation group which was managed by suturing the vessel. The incidence of intra operative complications was found to be similar with no significant difference between the two groups (P = 0.317).

Post-Operative Complications

In our study, two patients (8 %) in group A and 3 patients (12 %) in group B developed seroma which was found to be statistically non-significant (P = 0.641). The seroma in these patients was managed conservatively and resolved spontaneously. 12 % of patients in group A and 16 % of patients in group B had urinary retention post-operatively and were managed by catheterisation. This incidence was found to be statistically non-significant (P = 0.687). In our study, 4 % patients in group A and 12 % patients in group B had wound infection. Though the incidence was slightly higher in non-fixation group it was found to be statistically

non-significant (P = 0.302). The infection was not deep enough and was managed by regular dressing and antibiotics according to pus culture and sensitivity. The incidence of these complications was found to statistically non-significant in studies conducted by Mohamed H ED et al.[1] Kochar S et al.[5] Messaris E et al.[6] and Darwish AA et al.[4] In contrast to our study, Kaliderai et al.[2] reported that the incidence rate of urinary retention in the 1st week after the surgery was statistically significantly higher in Group A as compared with Group B (P < .05)

Recurrence

In our study, recurrence was observed in only one patient in non-fixation group and none of the patients in the fixation group had recurrence and this was found to be statistically non-significant (P = 0.327). Mohamed H ED et al.[1] reported recurrence in one (5 %) patient only in group B in the post-operative visit (after 1 week) who presented with right-side oblique inguinal hernia (funicular type), with completion of dissection of the sac with high ligation and separation and leaving the distal end as the sac was too long. Incomplete sac dissection and the presence of lipoma of the cord with rolled up mesh may be the cause of the recurrence after 1 week. Ayyaz et al.[7] found in their study on 63 patients that only one recurrence was encountered in 5-year follow-up in the group of non-fixation. However, in the study by Sajid et al.[8] four patients developed recurrent inguinal hernia in 691 patients having mesh fixation and three patients developed recurrent inguinal hernia in 691 patients having non mesh fixation. Kalidarei B et al.[2] reported no recurrence in the fixation group, whereas there was 5.1% recurrence in the non-fixation group (P > 0.05), however, there was no significant difference between the two groups in terms of recurrence rate. Kochar S et al.[5] reported that none of the study groups had recurrence which showed that non-fixation of mesh in TEP repair was not associated with an increased risk of hernia recurrence. Rekhi HS et al.[3] found that 2 patients had recurrence in the fixation group and none in the non-fixation group. By chi square test, P - value was found to be 0.143, which is insignificant. Darwish AA et al.[4] the rate of recurrence in group A was 0 % (no patients) and in group B 3.3 % (one patient). This was considered statistically nonsignificant. Prasad D et al.[9] Recurrence was higher among patient having mesh fixation and it was not statistically significant. All the studies had similar findings stating that the incidence of recurrence is equal in fixation and non-fixation group and the fixation of mesh does not necessarily prevent recurrence.

Mesh Infection

In our study, 1 patient in each group had mesh infection and the incidence was found to be statistically non-significant (P = 1.00). Both the patients required mesh removal. Kochar S, et al.[5] reported 3 male patients who developed post-operative mesh infection after LIHR. In all the three cases, infection could not be stopped after diagnosis despite drainage and antibiotic coverage, and then it was decided to remove the mesh. These findings were similar to the findings in our study.

CONCLUSIONS

Mesh non-fixation in laparoscopic inguinal hernia repair should be the preferred alternative to mesh fixation as there is less chance of post-operative pain, it is cost-effective, patient's recovery is much faster in comparison with mesh fixation. Also, recurrence is similar to patients with mesh fixation proving that mesh fixation offers no clear advantage over non-fixation.

Limitations

1. The patients taken up for the study were predominantly from northern India, in and around Kanpur district. Therefore, the results of the present study may not be representative of the whole of the country or the world at large.
2. The number of patients included in the present study were less in comparison to other studies.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.
Financial or other competing interests: None.
Disclosure forms provided by the authors are available with the full text of this article at jebmh.com.

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