



RESEARCH ARTICLE

RANDOMIZED CLINICAL TRIAL COMPARING LIGHTWEIGHT AND HEAVYWEIGHT
POLYPROPYLENE MESHES IN ENDOSCOPIC TOTALLY EXTRA PERITONEAL
GROIN HERNIA REPAIR

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ABSTRACT

Background: Totally Extra Peritoneal (TEP) Approach in strengthening of posterior wall defect by placing a prosthetic mesh by a posterior approach is commonly practiced for hernia repair. There was a paucity of literature on the long term analysis of outcomes using heavy weight and light weight meshes.

Objective: To compare the outcomes in endoscopic total extra-peritoneal groin hernia repair using lightweight and heavyweight polypropylene mesh.

Materials and Methods: It was a hospital based prospective randomized clinical trial conducted among 66 patients over a period of 5 years to compare the outcomes of patients following laparoscopic total extra-peritoneal technique of tension free groin hernia repair using standard heavyweight (Prolene®) and lightweight (Ultrapro®) mesh prosthesis. A total of 32 participants were included in heavyweight mesh group and 34 in lightweight mesh group. All patients were randomly divided into two groups by computer generated random number tables. The study participants were followed for a period of 5 years to assess occurrence of chronic groin pain, recurrence, operative time, postoperative pain on days 0, 1 and 7 (VAS scores), return to normal daily activities, testicular pain and seroma formation.

Results: The mean age + SD of study participants in lightweight meshgroup was 54.14 ± 8.33 yrs while it was 54.84 ± 6.75 yrs in heavyweight meshgroup and all study participants were males except one. The average time for return to normal daily activities was 2.35 days in lightweight meshgroup while it was 3.12 days in heavyweight meshgroup (p value =0.01). Post operative pain on day 7 and chronic groin pain was statistically significantly lower in lightweight mesh group than heavyweight meshgroup (p value<0.01).

Conclusion: The use of lightweight mesh for groin hernia repair is a safe and viable option. It offers many advantages in terms of decreased chronic groin pain and decreased post operative morbidity

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INTRODUCTION

Hernias among the oldest known afflictions of mankind and equally old are the attempts at its treatment. Since the oldest approach for its management; asepsis, high ligation of sac and narrowing of internal ring remains the three most important principles in hernia surgery. However recurrence remains a major challenge with considerably high rates in different hernia repair procedures (Lau, 2002 and Legutko, 2008). In an attempt to reduce the recurrence in hernia repair procedures, Eduardo Bassini in 1889 (Bassini, 1889), introduced principle of reconstruction of the posterior wall of the inguinal canal. This was followed by Shouldice technique of imbrication of transversalis fascia and strengthening the posterior wall in four layers of fascia and aponeurosis. These modifications resulted in reduction in recurrence rate to around 3% (Shouldice, 2003).

With the emergence of concept of tensionless repair, various autologous and non-autologous materials were introduced to bridge the posterior wall defect. Use of polypropylene mesh as a synthetic prosthesis continues to be a standard in open inguinal hernia repair (Usher, 1962 and Amid, 2004). Since the introduction of surgical meshes in 1959 (Usher, 2004), the main interest of surgeons in the past decade was focused on surgical techniques to optimize hernia repair and mesh prosthesis placement (Bay-Nielsen, 2001; Cassar, 2002 and Macintyre, 1995). The make of the prosthetic mesh itself seemed to have little impact on the clinical outcome after hernia repair and the meshes were regarded as biologically inert. With time, this trend changed in early and mid 1990's with increasing reports of mesh related complications after heavy mesh based hernia repair (Seid, 1994; Bower, 1996 and Leber, 1998). With the advent of laparoscopic surgery in

hernia repair and continued refinements afterwards, Totally Extra Peritoneal (TEP) Approach in strengthening of posterior wall defect by placing a prosthetic mesh by a posterior approach is commonly practiced (Ger, 1982). Both small and large porous heavyweight and lightweight mesh modifications represent totally different patho-physiologic views of hernia repair. Meshes in the heavyweight group are made with thick polymer fibres, have small pores (<1mm), high tensile strength and large surface area. Heavy weight meshes have been designed to provide maximum mechanical stability, based on the idea of closing the hernia gap with a stiff, non flexible device inducing maximum scar tissue (Usher, 1970 and Amid, 1994). In contrast, lightweight meshes are made of small polymer fibres, have larger pores(>1mm) and high flexibility. The tensile strength is adapted to that of local tissues which leads to a significant reduction of scar tissue resulting in a long term flexible repair (Klinge, 1996; Klinge, 2002 and Klosterhalfen, 1997). However, there was a paucity of scientific literature in Indian settings on the long term analysis of outcomes using heavy weight and light weight meshes so as to guide surgeons for laparoscopic inguinal hernia repair. Therefore, this study was conducted with an objective to compare the outcomes in endoscopic total extra-peritoneal groin hernia repair using lightweight and heavyweight polypropylene mesh.

MATERIALS AND METHODS

It was a hospital based prospective randomized clinical trial conducted over a period of 5 years in the Department of Surgery in a medical college hospital in Srinagar, India to compare the outcomes of patients following laparoscopic total extra-peritoneal technique of tension free groin hernia repair using standard heavyweight (Prolene®) and lightweight (Ultrapro®) mesh prosthesis. Sample size was calculated on the basis of a previous study¹⁹ taking 5% error and 80% power in which a difference of 9.3% in proportion of study participants who had chronic pain was reported after hernia repair with lightweight and heavyweight mesh. This came out to be 172. However due to constraints of time and resources, a total of 66 patients were included in the present study. 66 patients were divided into two groups of 34 each randomly. However, 2 patients in heavyweight mesh group could not be followed up leaving a total of 32 participants in heavyweight mesh group and 34 in lightweight mesh group. All patients who were planned for laparoscopic total extra-peritoneal repair of groin hernia constituted the study population. All patients aged 18 to 75 years with either unilateral or bilateral groin hernia were randomly divided into two groups by computer generated random number tables. Patients in group 1 underwent mesh hernioplasty using heavyweight (Prolene®) mesh (HWM) whereas group 2 patients were operated using lightweight (Ultrapro®) mesh (LWM).

Patients with recurrent hernia, having any complications of hernia (obstruction, strangulation), malignancy or immunosuppression, connective tissue disorder, very high risk cases for general anesthesia related complications like cardiopulmonary co-morbidities, bleeding diathesis, pregnant females, symptomatic bladder outflow obstruction with significant post void residual volume were excluded. All study participants were admitted one day before surgery. Following admission, detailed history was elicited and physical examination was performed. All relevant blood investigations, chest radiograph, electrocardiography and ultrasonography

were performed. All surgeons undertaking the procedure were blinded of the inclusion of the patients in the present study. Intravenous antibiotic was administered three hours preoperatively in all cases. Analgesics were initially given through parenteral route and increments were given according to the severity of pain as analyzed by a Visual Analogue Score (VAS). The procedure is performed under general anesthesia in both the groups. A 2-cm transverse infraumbilical incision was made extending from the midline to the side opposite the hernia. Blunt dissection was then performed to expose the anterior rectus sheath.

Once the anterior rectus sheath was cleaned off, a 15-mm incision was made in the anterior sheath using a scalpel. Once the rectus abdominus muscle was exposed, it was swept laterally to expose the posterior rectus sheath. A dissecting balloon trocar was then passed inferiorly through the envelope created by the anterior and posterior rectus sheaths into the pre-peritoneal space until it came into contact with the symphysis pubis. Once the pubis was reached, the laparoscope was passed through the trocar and the balloon was inflated under direct visualization. A low-pressure pneumo-peritoneum was created by placing a 10-mm Hasson trocar through the subumbilical incision. A laparoscope was then inserted into this space. Two 5-mm trocars were placed in the midline under direct visualization. The first was placed 1cm cephalad to the pubic symphysis. The second 5-mm trocar was placed as cephalad as possible in the midline. It was followed by cleaning off the Cooper's ligament to develop the lateral space. Dissection of the hernia sac began by defining the type of hernia based on the relationship of the hernia to the epigastric vessels. All repairs were performed using mesh. A polypropylene mesh, 6 × 6-inch flat sheet was used. Mesh was prepared by trimming it to a 15x12cm sheet with angles cut in to accommodate the anatomy of the Cooper ligament and a notch placed to ride over the iliac vessels. The mesh was then tightly rolled up and passed, using a grasper, through the 10-mm periumbilical trocar.

The laparoscope was replaced into the trocar and the mesh was unrolled in the pre peritoneal space and oriented correctly. Once the mesh was in place, the pneumo-peritoneum was released while pinning the mesh flat against the abdominal wall laterally with the graspers. When the anterior abdominal wall and peritoneum were re-approximated by the loss of the pneumo-peritoneum, graspers were withdrawn ensuring that the mesh did not roll or crease during release of the pneumo-peritoneum. The periumbilical trocar site was closed with a 0 Vicryl (Polyglactin 910; Ethicon) figure of eight fascial closure suture. The skin of all three trocars was closed using absorbable subcuticular 4-0 sutures. Steri-strips were then applied followed by sterile occlusive dressings or band-aids. The study participants in both the groups were followed post surgery for a period of 5 years and parameters of chronic groin pain, recurrence, operative time, postoperative pain on days 0, 1 and 7 (VAS scores), return to normal daily activities, testicular pain and seroma formation were assessed.

Definition of outcome variables

- Chronic Groin pain; defined as pain persisting more than 6 months after surgery.
- Hernia Recurrence: presence of a recurrent hernia confirmed clinically as well as radiologically.

Ethical considerations: Written informed consent was obtained from each participant before inclusion in the study. Prior ethical clearance for the study was obtained from Institutional Ethics Committee. The option to opt out of the study was open to all study participants without any clause. Standard care was given to everyone even if someone refused to participate in the study.

Statistical analysis: Data analysis was done using SPSS version 17. The results were explained in simple proportion and mean (\pm Standard deviation). Difference between groups was assessed using chi square test/fisher's exact test for qualitative data and t-test for quantitative data. P value of less than 0.05 was considered statistically significant.

RESULTS

Socio-demographic profile: As shown in Table 1, a majority of study participants belonged to the age group of 46-55 yrs in both the groups. The mean age \pm SD of study participants in lightweight meshgroup was 54.14 ± 8.33 yrs while it was 54.84 ± 6.75 yrs in heavyweight meshgroup.

This difference was not statistically significant (p value = 0.71). Almost all study participants were males (98.5%). There was only one female participant in the heavyweight meshgroup. No statistically significant difference was found between the sex distribution in the two groups (p=0.48).

Features of hernia among study participants: As given in Table2, indirect hernias were more common in both the groups. There was no case of pantaloon type of hernias in present study. There was no statistically significant difference in the distribution of type of hernia in the two groups (p value 0.57). A majority of patients presented with painless swelling in the groin in both groups. Other common complaint was feeling of heaviness in the groin region accompanied with the swelling. Intermittent groin pain was least common - 7.6% of the total number of patients. However there was no statistically significant difference between presenting symptoms in the two groups (p value = 0.69).

Operative and follow up findings: Table 3 shows operative and early post operative findings in two groups. The mean operative time in the lightweight meshgroup was 100.87 ± 6.45

Table 1. Socio-demographic distribution of study participants in two groups

Characteristic	Lightweight Mesh Group N=34(%)	Heavyweight Mesh Group N=32(%)	Total N=66(%)	p value
Age group (in years)				
35-45	3 (8.8%)	2 (6.2%)	5 (7.6%)	0.71
46-55	15 (44.1%)	16 (50.1%)	31 (46.9%)	
56-65	13 (38.3%)	12 (37.5%)	25 (37.9%)	
66-75	3 (8.8%)	2 (6.2%)	5 (7.6%)	
Mean age \pm SD	54.1 \pm 8.3	54.8 \pm 6.7	54.4 \pm 7.5	
Gender				
Male	34 (100.0%)	31 (96.9%)	65 (98.5%)	0.48
Female	0 (0.0%)	1 (3.1%)	1 (1.5%)	

Table 2. Distribution of study participants according to hernia related features

Features of hernia	Lightweight Mesh Group N =34(%)	Heavyweight Mesh Group N =32(%)	Total N =66(%)	p value
Type of hernia				
Direct	10 (29.4%)	7 (21.9%)	17 (25.8%)	0.57
Indirect	24 (70.6%)	25 (78.1%)	49 (74.2%)	
Presenting complaints				
Groin Swelling; Painless	22(63.7%)	25(78.1%)	47(71.2%)	0.69
Groin Swelling;Heaviness	9(26.5%)	5(15.6%)	14(21.2%)	
Groin Swelling; Intermittent Pain	3(8.8%)	2(6.3%)	5(7.6%)	

Table 3. Comparison of operative and post-operative findings in two groups

Findings	Lightweight Mesh Group N =34(%)	Heavyweight Mesh Group N =32(%)	Total N =66(%)	p value
Operative Time				
85-95	9 (26.5%)	16 (50.0%)	25 (37.8%)	0.002
96-105	17 (50.0%)	12 (37.5%)	29 (43.9%)	
106-115	8 (23.5%)	3 (9.3%)	11 (16.7%)	
Mean time \pm S.D	100.87 \pm 6.45	94.89 \pm 6.02	97.96 \pm 6.90	
Testicular pain				
Present	2 (5.9%)	3 (9.4%)	5 (7.6%)	0.66
Absent	32 (94.1%)	29 (90.6%)	61 (92.4%)	
Return to normal daily activities (in days)				
1-2	23(67.6%)	6 (18.8%)	29 (43.9%)	0.01
3-4	9 (26.5%)	22 (68.7%)	31 (47.0%)	
5-6	2 (5.9%)	4 (12.5%)	6 (9.1%)	
Mean	2.35 \pm 1.01	3.12 \pm 0.87	2.72 \pm 1.02	
Early Post Operative Pain				
Day 0	5.5	5.15	5.33	0.7
Day 1	5.08	5.09	5.06	0.66
Day 7	2.3	3.8	3.03	0.04

minutes which was statistically significantly higher than that of heavyweight meshgroup (94.89±6.02 minutes) with p value of 0.002. 3 (9.4%) study participants in the heavyweight meshgroup and 2 (5.9%) in lightweight meshgroup reported presence of testicular pain but this difference was not statistically significant (p value = 0.67). None of the study participants developed seroma postsurgery in any group. The average time for return to normal daily activities (up and about from bed, visiting toilet) was 2.35 days in lightweight meshgroup which was statistically significantly lower than 3.12 days in heavyweight meshgroup (p value =0.01). Post-operative pain was also measured using visual analogue scale on day 0, 1 and 7. Multiple values were taken from each study participants at three hourly intervals and the average of the reported values was taken. There was no statistically significant difference between the scores in two groups on days 0 and 1 but on day 7, lightweight meshgroup showed statistically significantly lower pain scores than heavyweight meshgroup with p value = 0.04.

Outcome of surgery in two groups: During a follow up period of 5 years, there were 3 recurrences in the lightweight meshgroup and 2 recurrences in heavyweight meshgroup. However the observed difference was statistically not significant. Study participants were also assessed for presence of groin pain at 6, 12 and 18 months post surgery. In both groups, the complaint of groin pain reduced from 6 month to 18 months post surgery. At 18 months, none of the patients in the lightweight meshgroup had groin pain whereas 4 (12.5%) patients in heavyweight meshgroup complained of groin pain. This difference of groin pain was statistically significant at 18 months of follow up (p value = 0.04).

Table 4. Outcome of surgery during follow up period in two groups

Follow up period	Outcome	Lightweight Mesh Group N =34(%)	Heavyweight Mesh Group N =32(%)	P value
6 months	Recurrence	0 (0.0%)	0 (0.0%)	-
12 months		1 (2.9%)	1 (3.1%)	0.51
18 months		2 (5.9%)	1 (3.1%)	0.87
6 months	Chronic groin pain	3 (8.8%)	6 (18.7%)	0.29
12 months		2 (5.9%)	5 (15.6%)	0.25
18 months		0 (0.0%)	4 (12.5%)	0.04

DISCUSSION

The present study was done in light of conflicting findings which were a posing hurdle for surgeons to make a decision on type of mesh to choose for hernia repair procedures. It was reported that too much of foreign material in the conventional heavyweight mesh in hernia repair is responsible for unfavorable outcomes like chronic groin pain and abdominal wall stiffness (Klinge, 1996). At the same time, there were reports that lightweight mesh was possibly a cause of increase in hernia recurrence rate due to lesser tensile strength (Akolekar, 2008 and O'Dwyer, 2005). In the present study, recurrence rates in the lightweight mesh group and heavyweight mesh group were comparable throughout the follow up period. This was consistent with the findings reported by Tamme C et al (Tamme, 2010), in their study which demonstrated that recurrence rates were not higher with use lightweight mesh. Though Chowbey PK et al (Chowbey, 2010) in their study found a higher recurrence rate with lightweight mesh for larger hernia cases due to greater

tendency to get displaced from their intended position during desufflation at the end of endoscopic repair. Chronic pain is one of the most serious long-term complications and has always been an important goal for improving outcome in hernia repair procedures (Kehlet, 2008). Demographic characteristics⁶³ and duration of existence of hernia before surgery (Thompson, 2008), do not determine post operative groin pain as significantly as surgical/technical factors. In the present study, chronic groin pain with lightweight mesh group was significantly lesser as compared with heavyweight mesh group. This was consistent with the findings reported by Chowbey PK et al with incidence of chronic groin pain being 3.7% in lightweight mesh group as compared to 7.1% in heavyweight mesh group (Chowbey, 2010). Similarly, Agarwal BB et al in their double blinded randomized controlled study stated that pain scores in patients receiving lightweight mesh were consistently lower than the heavyweight mesh group over a follow up of 1 year (Agarwal, 2009). The mean operative time for total extra peritoneal using lightweight mesh was higher than heavyweight mesh group by 6 minutes. This may be due to difficulty in laying out and positioning of the lightweight mesh because of its lesser degree of stiffness and greater pliability. Similar results were reported by Bringman S et al (Bringman, 2005). Present study found a lower proportion of study participants reported testicular pain in lightweight mesh group than heavyweight mesh group. Similar findings were reported by Aggarwal BB et al²⁷ in their study stating a higher level of discomfort or pain during sexual activity on the side in which heavyweight mesh was deployed. Earlier return to average daily activities was observed in patients in the lightweight mesh group than heavyweight mesh group. This was similar to findings reported in another study done by Bringman S et al. in which also, an earlier return to work in patients receiving the lightweight mesh was reported.

Conclusion

The use of lightweight mesh for groin hernia repair is a safe and viable option. It offers many advantages in terms of decreased chronic groin pain and decreased post operative morbidity.

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Conflict of interest: None

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