

Original Research Article

Comparison between the composite heavy weight prolene mesh versus the prolene soft mesh for the reduction in post-operative pain in patients undergoing lichensteins mesh repair for inguinal hernias

Abhijit Medikeri¹, Praveen Kamatagi^{2*}

¹Department of General Surgery, KIMS, Koppal, Karnataka, India.

²Department of General Surgery, KLE Prabhakar Kore JNMC, Belgaum, Karnataka, India

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*Correspondence:

Dr. Praveen Kamatagi,

E-mail: kamatgipraveenms@gmail.com

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ABSTRACT

Background: Globally, inguinal hernia is the most common type of hernia, comprising of approximately 75% of all abdominal wall hernias. Aim of the study was to compare the heavyweight composite polypropylene mesh versus the prolene soft mesh for the reduction of post-operative pain in patients undergoing lichensteins mesh repair for inguinal hernia.

Methods: This study was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum attached to KLE University's J.N.M.C Belgaum.

Results: Male preponderance was seen with 96.67% of patients in group SP and all (100%) patients in group RP were males. The mean age in group SP was 51.93±18.73 years compared to 49.50±14.03 years in group RP (p=0.571). The mean duration of the disease was 12.67±9.85 months in group SP whereas in group RP it was 15.10±8.98 months (p=0.321). The mean pulse rate in group SP and RP (79.60±5.64 vs 82.37±5.46 /min; p=0.059), systolic blood pressure (120.33±9.99 vs 124.33±11.94 mmHg; p=0.165) and diastolic blood pressure (73.73±6.76 vs 75.80±8.59 mmHg; p=0.305) were comparable. Right position was noted in 56.67% of patients in group SP compared to 50% of patients in group RP (p=0.673).

Conclusions: Prolene soft mesh (lightweight macro-porous polypropylene mesh) significantly reduced the post-operative pain in patients undergoing lichensteins mesh repair for inguinal hernia as compared to heavyweight composite polypropylene mesh.

Keywords: Inguinal, Lichensteins mesh repair, Prolene soft mesh, Polypropylene mesh

INTRODUCTION

Inguinal hernia repair is one of the most common general surgical operations worldwide accounting for 10 to 15% of all surgical procedures and is the second most common surgical procedure after appendectomy.^{1,2}

The management of inguinal hernia poses therapeutic challenges to general surgeons practicing in resource-

limited countries.³ Late presentation of the disease coupled with lack of modern therapeutic facilities such as laparoscopy and mesh are among the hallmarks of the disease in developing countries.^{3,4}

Since Bassini published his original description of inguinal hernia repair in 1887, many techniques for hernia repair such as Shouldice, Darning, Desarda, Modified Bassini, Lichtenstein mesh repair and the more

recent laparoscopic repair have been published.^{2,5} Laparoscopic and Lichtenstein mesh repair are becoming popular in recent days as they are associated with rapid return to normal activities with low recurrence rates.^{6,7}

The concept of hernia repair underwent a sea change with the introduction of monofilament knitted polyethylene plastic mesh in 1958 and later in 1962 of knitted, malleable PPM Prolene mesh.^{8,9} American surgeon Francis Usher fabricated and developed both the materials. His innovations paved the way for advances that are accepted without question today. PPM remains most popular both in open and laparoscopic surgery. However, the first popular nonmetallic mesh was a machine knitted polyester polymer called Dacron.

Emphasizing the Halstead principle of no tension, the Lichtenstein repair advocated the routine use of mesh in 1984. The prosthesis used to reinforce the weakened posterior inguinal wall is placed between the transversalis fascia and the external oblique aponeurosis and extends well beyond the Hesselbach triangle. Mesh implants do not actively shrink, but they are passively compressed by the natural process of wound healing. Shrinkage of mesh occurs only to the extent to which the tissue contracts.¹⁰

Although the use of traditional microporous or heavyweight polypropylene meshes in the last 2 decades have reduced the incidence of recurrence after hernia surgery to less than 1%, a major concern has been the formation of a rigid scar plate causing patient discomfort and chronic pain, impairing quality of life. More than 50% of patients with a large mesh prosthesis in the abdominal wall complain of paresthesia, palpable stiff edges of the mesh, and physical restriction of abdominal wall mobility.¹¹

Light-weight, composite mesh thus was developed with the conviction that the ideal mesh should be just strong enough to handle the pressure of the abdominal wall and still be low in mass and as thin as possible. The advantage of large pore size mesh is that tissue is able to grow through the large pores of the mesh and create a thinner, more integrated scar. The new light-weight, composite meshes offer a combination of thinner filament size, larger pore size, reduced mass and a percentage of absorbable material. Thus, there is less foreign body implanted, the scar tissue has greater flexibility (with almost physiologic abdominal wall mobility), there are fewer patient complaints, and the patient's quality of life is better.¹⁰

The use of light-weight mesh for Lichtenstein hernia repair did not affect recurrence rates, but it did improve some aspects of pain and discomfort 3 years after surgery.¹² According to data from current randomized, controlled trials and retrospective studies, light meshes seem to have some advantages with respect to postoperative pain and foreign body sensation.^{13,14}

Hence the present study was undertaken to compare the heavyweight composite polypropylene mesh versus the prolene soft mesh (lightweight macro-porous polypropylene mesh) for the reduction of post-operative pain in patients undergoing lichtensteins mesh repair for inguinal hernia.

METHODS

This one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum attached to KLE University's Jawaharlal Nehru Medical College, Belgaum over a period one year from January 2012 to December 2012. The study was approved from the Ethical and Research Committee, Jawaharlal Nehru Medical College, Belgaum prior to the commencement.

60 Patients admitted with inguinal hernia requiring mesh repair were studied. The effect size is not available, hence the sample size was taken as 60, with 30 in study group (lightweight macro-porous – prolene soft) and 30 in control group (heavy weight composite prolene mesh).

All patients with inguinal hernia undergoing mesh repair were included in the study and the patients with pregnancy, subjects with pulmonary tuberculosis, subjects with uncontrolled diabetes mellitus, Subjects with chronic cough, subjects with strangulated/obstructed hernia were excluded from the study.

The patients fulfilling selection criteria were informed in detail about the nature of the study, especially the benefits of using the heavy weight and the light weight mesh in lichtensteins mesh repair and a written informed consent was obtained.

Randomization

The patients were randomized by asking them to pick an opaque brown concealed envelop which furnished the information regarding the choice of mesh for their hernia repair. Based on the option picked up, the patients were divided into two groups of 30 each as below;

- Patients who selected prolene soft mesh (light-weight mesh) in lichtensteins repair of inguinal hernia formed group SP (study group).
- Those who selected composite polypropylene mesh (Heavy-weight mesh) were assigned to group RP (control group).

Demographic data such as age, sex and history was obtained through an interview. Details such as duration, lump size were noted. Further these patients were subjected to clinical examination and the findings such as size, visible peristalsis, cough impulse, position were noted on a predesigned and pretested proforma.

Investigations

The following tests were subjected to the following investigations routine blood counts - hemoglobin, total leucocyte counts, differential counts, red blood cell counts and esr, blood urea nitrogen, serum creatinine, bleeding and clotting time, urine routine and microscopy, chest x-ray and ECG.

Pain management

Post operatively patients of both the groups were given the same analgesics that is, Injection Diclofenac 50mg IM 1-0-1.

Outcome variables

Pain was assessed based on Visual Analogue Score ranging from 0 to 10 considering 0 as no pain and 10 as maximum pain. Further the pain was divided into categories viz. Mild - VAS score ≤ 3; Moderate – VAS score between 4 to 6; Severe – VAS score ≥ 7

Follow up

Patients were followed up at following intervals; from post operative 1week (before discharge); 2 weeks follow up; 4 weeks follow up.

Statistical analysis

The data obtained was coded and entered in Microsoft Excel Spreadsheet. The categorical data was expressed as rates, ratios and percentages and comparison was done using Fishers exact test and chi-square test. Continuous data was expressed as mean±standard deviation. A ‘p’ value of less than or equal to 0.05 was considered as statistically significant.

RESULTS

In the present study 96.67% of patients in group SP and all (100%) in group RP were males.

Table 1: Sex distribution.

Sex	Group SP (n=30)		Group RP (n=30)	
	N	Percentage	N	Percentage
Male	29	96.67	30	100.00
Female	1	3.33	0	0.00
Total	30	100.00	30	100.00

In the present study, group SP the mean age was 51.93±18.73 years compared to 49.50±14.03 years in group RP. However, the difference was statistically not significant (p=0.571) Table 2.

In the present study the mean duration of the disease was 12.67±9.85 months in group SP whereas in group RP it

was 15.10±8.98 months. However, this difference was statistically not significant (p=0.321).

Table 2: Mean age.

Variables	Group SP (n=30)		Group RP (n=30)		P-value
	Mean	SD	Mean	SD	
Age (years)	51.93	18.73	49.50	14.03	0.571

Table 3: Mean duration.

Variables	Group (n=30)	SP	Group (n=30)	RP	P value
	Mean	SD	Mean	SD	
Duration (months)	12.67	9.85	15.10	8.98	0.321

In this study, the mean pulse rate in group SP and RP (79.60±5.64 vs 82.37±5.46 /min; p=0.059), systolic blood pressure (120.33±9.99 vs 124.33±11.94 mm Hg; p=0.165) and diastolic blood pressure (73.73±6.76 vs 75.80±8.59 mm Hg; p=0.305) were comparable.

In the present study right position was noted in 56.67% of patients in group SP compared to 50% of patients in group RP. However, this difference was statistically not significant (p=0.673).

In this study during first follow up, all the patients in group SP reported pain scores between 4 to 6 (moderate pain) compared to 60% patients in group RP and 40% of patients reported pain scores of >7 (sever pain) in group RP. This difference was statistically significant (p<0.001).

In this study during second follow up, majority of the patients (90%) in group SP reported pain scores ≤3 (mild pain) compared to 26.67% patients in group RP. Pain score between 4 to 6 (moderate pain) were seen in 10% of patients in group SP compared to 66.67% of patients in group RP and 6.67% of patients reported pain scores of >7 (severe pain) in group RP. This difference was statistically significant (p<0.001).

In the present study during third follow up, all the patients (100%) in group SP reported pain scores ≤3 (mild pain) compared to 53.33% patients in group RP. In group SP, 46.67% of patients had pain scores between 4 to 6 (moderate pain). This difference was statistically significant (p<0.001).

In the present study the mean pain scores in group SP during first (4.50±0.57 vs 5.97±1.07), second (2.30±0.88 vs 4.27±1.48) and third (0.63±0.72 vs 2.57±1.79) were significantly less compared to group RP (p<0.001).

Table 4: Mean VAS scores

Follow up	Group (n=30)		Group RP (n=30)		P-value
	Mean	SD	Mean	SD	
First	4.50	0.57	5.97	1.07	<0.001
Second	2.30	0.88	4.27	1.48	<0.001
Third	0.63	0.72	2.57	1.79	<0.001

In this study, the mean reduction in pain score from first follow up to third follow up was comparable in group SP (3.90 ± 0.97) and RP (3.40 ± 1.33) ($p=0.092$).

DISCUSSION

The evidence-based inguinal hernia guidelines recommends a Lichtenstein hernia repair in case of a primary unilateral inguinal hernia; in this repair the inguinal floor is reinforced by means of a polypropylene mesh.¹⁵ After the introduction of hernia repair with mesh the incidence of a recurrent inguinal hernia decreased from 15-20% to less than 5%.¹⁶ As a result of this decline, currently chronic postoperative pain is the main subject of investigation. Although the incidence of chronic postoperative pain might have been the same over the years, not much attention was being paid to this since prevention of recurrence was main priority.

Currently, pain is considered the most important complication. Three months postoperatively 20% of patients still have pain and 12% experience pain that limits daily activity. One year postoperatively 1-3% still experiences invalidating pain.¹⁶ Studies investigating the influence of light-weight versus heavy-weight meshes on pain show a slight advantage towards light-weight meshes.¹⁷ The Lichtenstein open tension-free mesh hernioplasty, performed under local anesthesia, is a simple technique and trained surgical residents are able to perform it without compromising the patient's care and long-term outcome. The procedure is time tested, safe, and economical, as well as being quick and easy to perform. In addition, it carries fewer complications and has become the gold standard in open tension-free hernioplasties.¹⁰

Indeed, postoperative pain after a Lichtenstein hernioplasty is minimal; according to a meta-analysis of all reported randomized studies, the pain is comparable to that occurring after laparoscopic repair.¹⁰ In this study during first follow up, findings suggest that, significantly higher number of patients who underwent lichtensteins repair of inguinal hernia under prolene soft mesh (light-weight mesh) had mild and/or moderate pain but in those who had lichtensteins repair of inguinal hernia under polypropylene mesh (Heavy-weight mesh) had moderate and/or severe pain ($p<0.001$). Similarly, during second follow up, findings showed significantly higher number of patients with mild pain in those who underwent Lichtensteins repair of inguinal hernia under prolene soft mesh (light-weight mesh).

At the third follow up, findings suggest that, the patient who underwent Lichtensteins repair of inguinal hernia under prolene soft mesh (light-weight mesh) had very mild pain compared to those who had Lichtensteins repair of inguinal hernia under polypropylene mesh (heavy-weight mesh).

Meshes are associated with a reduced risk of chronic pain compared to suture repair. This is thought to be related to the ability to use tension-free technique rather than the mesh itself. However, pain remains a serious complication of mesh repair and can occur for a variety of reasons. This is supported by most studies, although disputed by some. Some authors have also suggested that absorbable meshes may have a role in reducing chronic pain.¹⁸

The use of light-weight mesh for Lichtenstein hernia repair did not affect recurrence rates, but it did improve some aspects of pain and discomfort 3 years after surgery.¹⁰ According to data from current randomized, controlled trials and retrospective studies, light meshes seem to have some advantages with respect to postoperative pain and foreign body sensation.¹⁹

A randomized trial examined whether lightweight (LW) polypropylene mesh (large pore size, partially absorbable) could have long-term benefits in reducing chronic pain and inflammation after inguinal hernia repair. Other study concluded that, use of LW mesh for Lichtenstein hernia repair improved some aspects of pain and discomfort 3 years after surgery.¹⁴ Use of lightweight mesh was associated with significantly less pain on exercise after 6 months ($p=0.042$). Study concluded that, lightweight polypropylene mesh may be preferable for Lichtenstein repair of inguinal hernia.²⁰

A systematic review and a meta-analysis of RCTs were carried out to determine whether the use of lightweight meshes influenced the pain. No significant difference was observed concerning severe pain (OR, 0.99; 95 % CI, 0.48-2.02; $p=0.97$). Description of any pain resulted in a significant improvement in the lightweight group (OR, 0.65; 95% CI, 0.50-0.84; $p=0.001$). Study concluded that, use of lightweight mesh did not neither increase the recurrence rate nor reduce the incidence of severe pain. However study recommended that, lightweight meshes could be considered as a material of choice in primary inguinal hernioplasty.²¹

Another study found that lightweight mesh repair was associated with a significant less incidence of chronic postoperative pain (OR = 0.72, 95 % CI (0.57, 0.91)). The study concluded that, lightweight mesh repair do have advantages in terms of chronic postoperative pain and recommended further well-structured trials with improved standardization of hernia types, operative techniques are necessary.²²

Limitation

Limitation of study was needs long follow up of patients up to 5 -10 years.

CONCLUSION

The results of the present study were in agreement with the other studies which showed the role of lightweight mesh in reducing immediate and long term post-operative pain. However, interestingly the mean reduction in pain score from first follow up to third follow up was comparable in group SP (3.90±0.97) and RP (3.40±1.33) (p=0.092) which again prompts the validation of lightweight mesh in the assessment of immediate pain following the Lichtenstein inguinal hernia repair. However, this disparity between the significantly lower pain scores and lack of significance in mean reduction in pain scores could be attributed to the smaller sample size.

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