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Research Article

Comparison of two layered prolene mesh hernia repair versus conventional lichtenstein mesh repair for postoperative pain in inguinal hernias: a randomized control trial

Manoranjan UD[1], Mallikarjuna Manangi[1], Arun BJ[2], Niranjan Nagaraj[3]*

[1]Department of Surgery, Victoria Hospital, Bangalore Medical College and Research Institute, Bangalore-560002, India
[2]Department of Respiratory medicine Kempegowda institute of medical sciences Bangalore-560002, India
[3]Department of Paediatrics, SP Medical College, Bikaner, Rajasthan, India

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***Correspondence:**
Dr. Niranjan Nagaraj,
E-mail: getniranjan806@yahoo.com

ABSTRACT

Background: Inguinal hernia surgery is the most frequently performed operation in general surgery and so even modest improvements in clinical outcomes are important. This study has been taken as an initiative to compare the post-operative pain after conventional Lichtenstein's meshplasty against two layered prolene mesh Hernia repair.
Methods: This is a randomized control study done in our hospital over period of one year between December 2014 to December 2015. In this study out of 60 patients who underwent mesh repair 30 underwent two layered prolene mesh Hernia repair and 30 underwent conventional Lichtenstein mesh repair. All collected was tabulated and statically analyzed by using SPSS software.
Results: All patients in both groups were male patients. Majority of the hernias were of the right side. Maximum pain score was seen at 2 weeks and minimum pain at 12 weeks. Pain at 2 weeks was 5.7±0.56 in MPHS group and 5.9±0.69 in CLMR group. At 12 weeks it was 1.0±0.30 and 1.1±0.35 respectively in both groups. The mean reduction of pain from 2nd to 12th week was 4.8±0.47 in TLPMR group and 4.7±0.70 in CLMR group. No statistical significant difference was noted as demonstrated by Mann Whitney U test. Wilcoxon signed ranks test also demonstrated that there was no statistically significant difference between the 2 groups.
Conclusions: There is apparent advantage in the use of two layered prolene mesh repair over other conventional mesh repairs.

Keywords: Hernia, Two layered, Repair, Lichtenstein, Prolene mesh

INTRODUCTION

Postoperative pain is a major concern because it affects multiple systems and induces physiological, immunological, and psychological changes.[1,2] Despite many advances in the provision of pain services, acute pain after surgery remains a serious causes of sever suffering that is often undermanaged despite our best efforts.[3] Acute pain can be persisted, the tissue damage of surgery setting up pathophysiological processes in the peripheral and central nervous system that may produce chronicity.[4] The association between surgery, acute pain and on-going severe chronic pain is well defined.[5,6] There is therefore a pressing need of advances in the techniques

we can use to improve analgesia efficacy, and perhaps reduce the incidence of chronic suffering after surgery. Inguinal hernioplasty is an evolving surgical solution to an age old problem. It is one of the most frequently performed operations in general surgery and so even modest improvements in clinical outcomes are important. The most important criteria for the choice of method are safety (morbidity and mortality), recurrence rates and convenience for the patient and post-operative pain.

The use of prosthetic meshes for open surgical repair of inguinal hernia has become increasingly popular in western countries as well as in India. Prosthetic meshes were first introduced in 1958 and have since evolved over the years. The Lichtenstein "tension-free" mesh repair is currently the gold standard to which all other repairs are compared.[7] The prolene hernia system introduced in 1998 further revolutionized the field by providing a combined anterior and posterior repair with results similar to Lichtenstein's repair. The only drawback of the prolene hernia system was the high cost involved especially in the setting of developing countries. This can be overcome by a few modifications in the technique such as the one proposed in this study.

Lichtenstein tension- free hernioplasty[7-9]

A 5 cm skin incision which starts from the pubic tubercle and extends laterally within Langer's line is made. External oblique aponeurosis is opened and its lower leaf freed from spermatic cord and upper leaf from underlying internal oblique muscle. The cord with its cremasteric covering is separated from the floor of inguinal canal and pubic bone. Cremasteric sheath is incised longitudinally and indirect hernial sac is freed from the cord to a point beyond the neck of sac and inverted into the abdomen.

Tension-free hernioplasty using a bilayer prosthesis[10-12]

The bi-layer polypropylene device is known as prolene hernia system (PHS), introduced in 1998 and is constructed in a three in one model. The inguinal canal is approached from an anterior approach after dividing the skin, Scarpa's fascia and the external oblique aponeurosis. The cord is examined for any indirect sac. In indirect hernias, sac is inverted and pocket created in the pre-peritoneal space.

For decades, long-term analysis of results of hernia repair concentrated on post-operative pain and recurrence rates. More recently however, several studies have focused on aspects of chronic pain and quality of life after hernia repair. This technique differs from the Lichtenstein's repair in only a few steps. Hence the study has been taken as an initiative to compare the post-operative pain after conventional Lichtenstein's meshplasty against two layered prolene mesh hernia repair.

METHODS

This is a randomized control study done in our hospital over period of one year between December 2014 to December 2015. Informed consent was taken from the patient after explaining the pros and cons of both the procedures, but the patient was blinded to the operative procedure followed. The study a criterion includes: All patients requiring mesh repair for inguinal hernias; Unilateral or bilateral inguinal hernias and exclude: Immuno compromised individuals; Patients with tuberculosis and cough; patients with post-surgery wound infection (redness and purulent discharge); Patients with recurrent hernia. The pain grading charts obtained from the patient were received and analyzed by another post graduate student in the department of general surgery who was unaware of the operative technique followed in each patient

All the patients (60 patients) scheduled for inguinal hernia repair using the modified prolene hernia system repair and conventional Lichtenstein mesh repair technique and who met the inclusion criteria were considered for the study. Randomization was done by computerized randomization table into 2 groups, group A (two layered prolene mesh repair) and group B (conventional mesh repair). Group A patients underwent two layered prolene mesh repair using standard polypropylene mesh and group B patients underwent conventional mesh repair. All patients will undergo routine pre-operative investigations including Complete blood counts, Blood urea and serum creatinine, BT and CT, Urine routine and microscopy, Ultrasonography of the abdomen. All patients received the same analgesics i.e. diclofenac sodium 50 mg intra-muscularly post-operatively. Groin pain-This was measured on a Visual Analogue Scale ranging from 0 (no pain) to 10 (unbearable pain) from 2 weeks to 12 weeks post operatively every 15 days. Patients were explained that a scoring of 1-3 constituted minimal pain, 4-7 was moderate pain and 8-10 was severe unbearable pain. All collected was tabulated and statistically analyzed by using SPSS software.

RESULTS

The present study was conducted in victoria hospital and medical research centre, Bangalore and the findings are tabulated as below. During the study year from December 2014 to December 2015, 60 patients with inguinal hernias were randomized into study (two layered prolene mesh repair) and control (conventional lichtenstein mesh repair) group. These groups were studied for groin pain post-operatively. The pain was assessed by visual analogue score of 0-10. Patients were explained that 1-3 constituted mild pain, 4-7 moderate pain and 8-10 was severe pain. In this study all patients in both groups were male patients in this study it was noted that most of the patients were in the middle aged group of 41-60 years in both the groups. There was no significant statistical

difference between the two groups. In this study, majority of the hernias were of the right side. Again no significant statistical difference was seen between the two groups. Maximum pain score was seen at 2 weeks and minimum pain at 12 weeks. It was also observed that the pain score in both groups were comparable at all weeks with no statistically significant difference noted as per Mann Whitney U test. Pain at 2 weeks was 5.7±0.56 in MPHS group and 5.9±0.69 in CLMR group. At 12 weeks it was 1.0±0.30 and 1.1±0.35 respectively in both groups. The mean reduction of pain from 2nd to 12th week was 4.8±0.47 in TLPMR group and 4.7±0.70 in CLMR group. No statistical significant difference was noted as demonstrated by Mann Whitney U test. Wilcoxon signed ranks test also demonstrated that there was no statistically significant difference between the 2 groups.

Table 1: Comparison of groin pain.

Group	2 weeks	4 weeks	6 weeks	8 weeks	10 weeks	12 weeks
A	5.7±0.56	4.9±0.63	3.7±0.53	3.0±0.61	1.7±0.53	1.0±0.30
B	5.9±0.69	4.9±0.71	3.8±0.74	3.0±0.74	1.6±0.62	1.1±0.35
Mann whitney U test	Z = 0.939 P = 0.347	Z = 0.172 P = 0.863	Z = 0.585 P = 0.558	Z = 0.354 P = 0.723	Z = 0.809 P = 0.419	Z = 0.471 P = 0.683

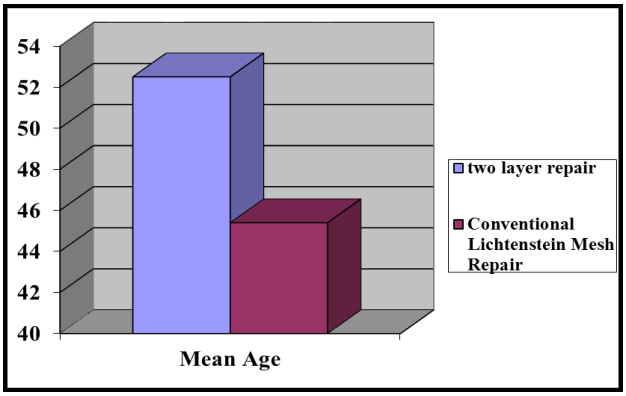

Figure 1: Mean age of the patients.

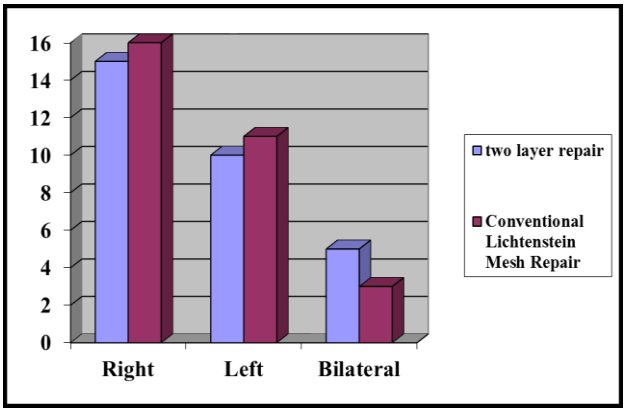

Figure 2: Comparison of side of hernia.

Table 2: Mean reduction of pain from 2nd week to 12th week.

Group	Pain score
Two layer prolene mesh repair	4.8±0.47
Conventional lichtenstein mesh repair	4.7±0.70
Mann Whitney U test	Z = 0.944 P = 0.345

Table 3: Wilcoxon signed ranks test.

Two layer prolene mesh repair	Z = 4.412
Conventional lichtenstein mesh repair	Z = 4.093

DISCUSSION

Inguinal hernia surgery is the most frequently performed operation in general surgery and so even modest improvements in clinical outcomes are important. The most important criteria for the choice of method are safety (morbidity and mortality), recurrence rates and risk of chronic groin pain. Chronic groin pain has been reported to be 25-30% in literature. It is not only described as pain but also as stinging, nipping or itching etc. Considering the large number of inguinal hernia surgeries performed every year, this chronic groin pain is a serious problem.

The causes for chronic groin pain put forward are: Tissue handling, foreign body reaction, Sutures for fixing the mesh, Nerve entrapment. The use of mesh has become well established in inguinal hernia surgery. The stability of the mesh must match the physiological forces exerted on the abdominal wall. The ideal mesh is selected on important characteristics like: Minimal foreign body response, Tensile strength, Pore size, Biocompatibility, No degradation, Tissue integration, No adhesion/ fistula formation.

The aim of the present study was to compare the post-operative pain using two layered prolene mesh repair against the conventional lichtenstein's mesh repair. The groin pain was assessed by visual analogue Scale on a scale of 1 to 10 with 1-3 being mild pain, 4-7 being moderate pain and 8-10 being severe pain. All the patients presented with groin swelling in both groups. All patients in both groups were male. The mean age and standard deviation in group A and group B is 52.5±15.26 and 45.4±16.21 respectively. In group A mean pain score at 2 weeks was 5.7±0.56 and at 12 weeks it was 1.0±0.30.

In group B mean pain score at 2 weeks was 5.9±0.69 and at 12 weeks it was 1.1±0.35. P value was insignificant for every assessment of both groups.

In this study, no patient's experienced severe pain in either group at 2 weeks, only mild to moderate pain was reported. Though not included in the aims of this study it is worthwhile to mention that most patients resumed their full activities by 4 weeks. The prolene hernia system is known to confer the benefits of both an anterior repair (Lichtenstein's mesh repair) and a posterior repair (Laparoscopic repair).[7] The prolene hernia system covers the entire myopectineal orifice of fruchad thus providing a complete repair whereas the Lichtenstein's repair does not cover for femoral hernia and there is always a possibility of hernia recurrence between the posterior wall and the mesh.[8] The downside of the prolene hernia system (PHS) is the high cost involved (approximately rupees 11000) compared to conventional mesh repair (approximately rupees 3000). This is especially a big problem in developing countries with already over-burdened medical and healthcare systems. But in this novel technique in this study, we can give the benefits of a PHS bi-layer repair at the same cost of the conventional mesh repair. This is so because we use a single mesh (divided in 2 pieces) and the same suture material provided in the hernia kit without any need for extra material.[9-12] This present study is only limited to post-operative pain following hernia surgery by both methods. Further studies need to be done to assess other factors such as quality of life and recurrences.

CONCLUSION

This study showed that with the use of two layered prolene mesh repair, pain is comparable to the conventional Lichtenstein mesh repair while providing a more complete repair to the patient at the same cost. In a conclusion, there is apparent advantage in the use of two layered prolene mesh repair over other conventional mesh repairs. The short term follow up of the study did not allow any conclusion regarding recurrence of hernia, thus larger cohorts with longer follow up are needed.

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