



MODIFIED PROLENE HERNIA SYSTEM HERNIOPLASTY VERSUS LICHTENSTEIN TENSION FREE MESH HERNIOPLASTY -A RANDOMIZED STUDY

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ABSTRACT

INTRODUCTION: Modified prolene hernia system is a tension free anterior inguinal hernia repair using a bilayered modification of inguinal hernia mesh system. Inguinal hernia repair by Prolene is comparable with almost equal operating time, smaller incision and with a trend towards decreased complications rate and reduced rate of recurrences.

AIM: This study was conducted to study and to compare the results of Modified prolene hernia system and Lichtenstein Tension Free mesh hernioplasty with respect to its operative time, post-operative pain, intra/post-operative complications and total hospital stay.

METHODS: The effectiveness of MPHS were compared to Lichtenstein tension free mesh hernias repair in patients presenting with uncomplicated Inguinal Hernia for elective surgery in the Surgery department of IGMC, Shimla.

RESULTS: Duration of surgery was shorter in Modified prolene hernia system group (p=0.04) than the Lichtenstein tension free mesh hernioplasty [32 vs 34 minutes]. The mean pain intensity in present study was 2.9 in Lichtenstein tension free mesh hernioplasty group and 2.7 in Modified prolene hernia system, No intra-operative complications were seen with either of the two groups. Post-operative complications in the form of seroma formation were more in Lichtenstein tension free mesh hernioplasty group than Modified Prolene Hernia system group (4 vs 0). There was one case of recurrence in the Lichtenstein tension free mesh hernioplasty group, while no short-term recurrence was seen in Modified Prolene Hernia system group over 12 weeks. Mean duration of post-operative hospital stay was 1.57 days for Lichtenstein tension free mesh hernioplasty group and 1.33 days for Modified Prolene Hernia system group.

CONCLUSION: This study concludes that even though the difference between the two methods in this randomized study were small, the Modified prolene hernia system repair method for open inguinal hernia repair was associated with a shorter operative time, lower rate of recurrence, as well as fewer complications when compared with the Lichtenstein tension free mesh hernioplasty. Modified Prolene Hernia System, cost wise is more economical than conventional Prolene Hernia system. Further prospective studies are needed to rigorously evaluate the comparative advantages of Modified prolene hernia system repair in relation to other repair methods.

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INTRODUCTION

Hernias are a common problem, males being twenty times more commonly affected than females. Hernia is derived from the Latin word for rupture and is defined as an abnormal protrusion of an organ or tissue through a defect in its surrounding walls. Edoardo Bassini (1844-1924) of Italy considered as the “Father of Hernia surgery” incorporated the developing disciplines of antisepsis and anaesthesia with a new operation that included reconstruction of the inguinal floor by suturing the conjoint tendon to the inguinal ligament, along

with high ligation of the hernia sac. Since then the primary surgical objective has been to cover the anatomic hole, termed myopectineal orifice by Henri Frauchad, through which “Hernia” protrudes, to prevent hernia recurrence.

Later in 1986, Lichtenstein conceptualized that by using mesh prosthesis to bridge the hernia defect thereby avoiding the tension resulting in a less painful operation² and a lower recurrence rate. Lichtenstein repair has now become the method of choice for hernia repair. However, hernia recurrences, wound complications like seroma, hematoma,

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chronic pain³, nerve entrapment are few of the complications affecting patients 'quality of life.

The latest tension free mesh technique, Prolene Hernia system was introduced by Dr. Arthur Gilbert in 1999⁴. This method utilizing the prolene hernia system mesh is a "3-in-1 device" made of polypropylene, incorporating an underlay patch" (Fig.1) that is positioned in the pre-peritoneal space, an "onlay patch" that is placed on the inguinal floor, and a "connector" that is placed through the hernia defect and connects the two patches. This device purportedly combines the benefits of the posterior and anterior repair from an open approach⁵⁻¹² and it is the only tension free device that covers the entire hernia prone area called the "Myopectineal orifice" while the other techniques leave areas of this region of abdominal wall vulnerable for recurrence. Modified Prolene Hernia system (Fig.2) is an economical, and cost-effective modification of Prolene Hernia system. It is similar to Prolene Hernia system, and offers similar complication and recurrence rates. It is associated with lesser post-operative complication and recurrence rates as compared to Lichtenstein tension free mesh hernioplasty.

It is much cheaper and thus offers an effective alternative to Lichtenstein tension free mesh hernioplasty & conventional prolene hernia system, especially in developing countries. Inguinal hernia repair by Modified prolene hernia system is comparable with shorter operating time, smaller incision and with a trend towards decreased complications rate and reduced rate of recurrences. With this study we have compared the results of a prospective, randomized, observational clinical study comparing open inguinal hernia repair by Lichtenstein tension free mesh hernioplasty versus Modified prolene hernia system hernioplasty in I.G. Medical College & Hospital, Shimla.

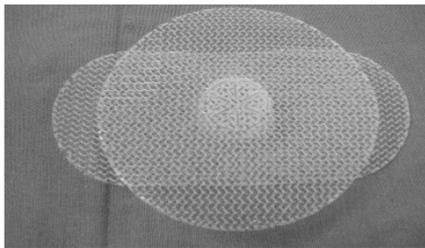


Fig 1 Conventional Prolene Hernia system.



Fig 2 Modified Prolene Hernia system

MATERIALS AND METHODS

This comparative study was conducted in the Department of Surgery, I.G.M.C. Shimla from 1st of July 2016 to 30th November 2018 and included 80 patients presenting in O.P.D./ emergency with inguinal hernia (Unilateral or Bilateral). All patients advised to undergo an elective primary inguinal hernia repair were considered for inclusion. The exclusion criteria

were complicated/ Strangulated inguinal hernia and Recurrent inguinal hernia, Femoral Hernia, Pregnancy, Previous pelvic surgery. A clear disclosure of the benefits and pertinent risks of both Lichtenstein tension free mesh hernia repair and repair using Modified prolene hernia system was made. Patients were randomized into equal groups of 40 patients each. Group A included patients in whom Lichtenstein tension free mesh repair for inguinal hernia was done and Group B included patients who underwent inguinal hernia repair by Modified prolene hernia system.

Postoperative Course

The postoperative care was identical for both groups. Intravenous analgesics [Lornoxicam 8 mg] and anti-emetics [Ondansetron 4 mg] were administered on demand.

Data Collection

Total surgery time was calculated from the start of incision up to skin closure in both the procedures. Pain intensity was measured by using visual analogue scale (Fig.5). It was calculated at 0, 4, 8, 16 and 24 hours, post operatively. Total hospital stay was calculated from the day of operation till discharge from the hospital. The results were statistically evaluated and analyzed by Chi Square test.

Operative Principles

After informed consent, all cases were operated in supine position under Spinal anaesthesia. Spinal anaesthesia was given using 3 to 3.2 ml of 0.5% Bupivacaine, exact quantity being guided by height and weight of the patient. Open hernia repair with a mesh prosthesis was performed through an oblique skin incision of 5 to 6 cm in length which was made from the internal to the external ring.

Lichtenstein tension free mesh hernioplasty was performed as described by Amid et al². Polypropylene mesh prosthesis with a minimum size of 16 x 8 cm for an adult was positioned over the inguinal floor. The mesh was then secured to the insertion of rectus sheath to the pubic bone overlapping the bone by 1 to 2 cm. This suture was continued with up to four passages, to attach the lower end of the patch to the inguinal ligament just lateral to the internal ring. The upper edge of the mesh was sutured in place, by two sutures, one to the rectus sheath, other to the internal oblique aponeurosis, just lateral to the internal ring.

Modified Prolene Hernia system was prepared for average built Indian patient by cutting 7.5cm x15cm prolene mesh in two part and the smaller part is stitched to the larger part of the mesh with two sutures of 2-0 prolene and having a gap of about 1cm (Fig.3). Modified Prolene Hernia system repair was done by dissecting out the Pre-Peritoneal space of Bogros. The Modified Prolene Hernia system mesh consisting of an onlay patch, an underlay patch attached with sutures was then inserted. The underlay circular mesh was deployed in the preperitoneal space behind the transversalis fascia (Fig.4). And the overlay flat mesh was placed above the transversalis fascia which was secured by using interrupted sutures to the rectus tendon just above its insertion into the pubic tubercle, the conjoint tendon and the shelving edge of the inguinal ligament.

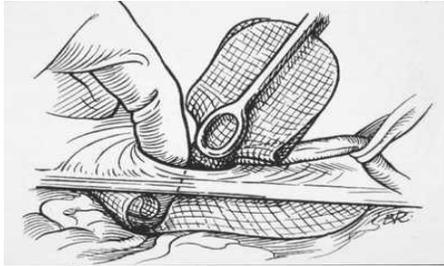


Fig 3 Showing preparation of MPHS.



Fig 4 Placement of Underlay Component of MPHS.

RESULTS

Total Operative Time

Duration of surgery that is the total time from skin incision to skin closure ranged from 26 minutes to 50 minutes in Lichtenstein tension free mesh hernioplasty group whereas in Modified Prolene Hernia system group it varied between 26 minutes to 48 minutes. The mean duration of surgery for Lichtenstein tension free mesh hernioplasty group was 34.47 minutes with a S.D. of ± 4.33 while the mean duration of surgery in Modified Prolene Hernia system group was 32.2 minutes with a S.D. of ± 4.04 . Duration of surgery was shorter in Modified prolene hernia system group ($p=0.039$) than the Lichtenstein tension free mesh hernioplasty group which was statistically significant (Table 1).

Table 1 The duration of surgery in both groups.

Lichtenstein Tension free Hernioplasty			Modified prolene hernia system Hernioplasty	
Duration of Surgery (Min.)	No. of patients	%	No. of patients	%
21-30	8	20.0%	10	25.0%
31-40	25	62.5%	21	52.5%
41-50	7	17.5%	9	22.5%
Total	40	100%	40	100%

POSTOPERATIVE PAIN

Pain was measured by Visual Analogue Scale (Fig.4) and pain score was made for 24 hours i.e. at 0, 4, 8, 16, and 24 hours. Time to first demand of rescue analgesia was noted. Mean time interval of rescue analgesic post-operatively was 14.67 hours for Lichtenstein tension free mesh hernioplasty group and 4, 8, 16 and 24 hours post operatively for the second group and was 0.326 which was not statistically significant [Table 2].

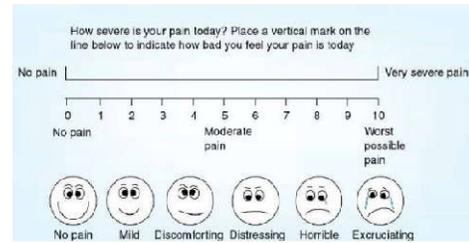


Figure 5 Visual Analogue scale

Table 2 Time Interval of Rescue Analgesia.

Time Interval (hours)	Lichtenstein tension free mes Hernioplasty	Modified Prolene Hernia System Hernioplasty
0-4	3	2
5-8	6	4
9-16	17	20
17-24	14	14
Total	40	40

Intra-Operative Complications

No intra-operative complication such as injury to nerves/injury to vas or injury to bowel was seen with either of the two groups.

Post-Operative Complications

Seroma formation was seen in 4 cases of Lichtenstein tension free mesh hernioplasty group. However, none of the patients in Modified prolene hernia system group developed seroma. The patients were followed for 3 months to look for any recurrence, and 1 patient in Lichtenstein tension free mesh hernioplasty group showed recurrence while none of the patients in Modified prolene hernia system group showed recurrence (Table 3).

Table 3 Post-operative complications.

Post-operative Complications	Lichtenstein Tension Free Mesh Hernioplasty		Modified prolene hernia system Hernioplasty	
	No. of Patients	%	No. of Patients	%
Seroma	4	10%	0	0%
Recurrence	1	2.5%	0	0%

Post-Operative Hospital Stay

In the Lichtenstein tension free mesh hernioplasty group, 23 patients (57.5%) were discharged on 1st postoperative day. Twelve patients (30%) were discharged on 2nd post-operative day while five patients (12.5%) were discharged on 3rd post-operative day. In the Modified Prolene Hernia system group, twenty-six patients (65%) were discharged on first post-operative day while thirteen patients (32.5%) were discharged on second post-operative day, and 1 patient (2.5%) was discharged on the 3rd post-operative day.

Mean duration of post-operative hospital stay was 1.57 days for Lichtenstein tension free mesh hernioplasty group and 1.33 days for Modified Prolene Hernia system group. As the p value was more than 0.05 (0.053), the difference between the two groups was statistically insignificant [Table 4].

Table 4 Post-operative Hospital Stay.

Hospital Stay (in days)	Lichtenstein Tension Free Mesh Hernioplasty	Prolene Hernia System Hernioplasty
1	23(57.5%)	26(65%)
2	12(30%)	13(32.5%)
3	5(12.5%)	1(2.5%)
Total	40	40

Cost Effectiveness



Fig Showing comparison of price of prolene mesh and

Modified Prolene Hernia system

The prolene mesh sizing 7.6 cm X 15 cm, from which the Modified prolene hernia system is prepared costs about Rs.1958/-, while the conventional prolene hernia system costs about Rs.9340/-

DISCUSSION

Edoardo Bassini in 1884 revolutionized the hernia surgery by devising a technique for the reconstruction of the inguinal canal and restoration of patients' anatomy. This was further improved upon by Irving Lichtenstein in 1964, when he introduced the concept of tension free mesh repair for inguinal hernia. Since then Lichtenstein tension free mesh hernioplasty has been the gold standard for anterior inguinal hernia repair, its advantages being less post -pain, low recurrence rates, easy to learn technique. However, wound complications like seroma/hematoma, postoperative pain, nerve entrapment, and recurrence prompted the development of new mesh materials and designs and also necessitated the development of a technique to ensure complete coverage of the myopectineal orifice of Frauchad, thereby minimizing the rates of recurrence.

Modified prolene hernia system combines the benefits of the posterior and anterior repair from an open approach and it was the only tension free device that covered the entire hernia prone area called the "Myopectineal orifice" while the other techniques were prone to leave areas of this region of abdominal wall vulnerable for recurrence. It was also found to be efficacious in the repair of umbilical, epigastric, Spigelian and small incisional hernias.

In the present study mean duration of surgery was 34 minutes 28 seconds in Lichtenstein tension free mesh hernioplasty group and 32 minutes 12 seconds in Modified Prolene Hernia system. The operative time of Modified prolene hernia system was significantly shorter than Lichtenstein tension free mesh hernioplasty, which was because, in Modified prolene hernia system repair, only 2-3 interrupted fixation sutures were used to secure the onlay patch, to the rectus tendon just above its insertion into the pubic tubercle, the conjoint tendon and the shelving edge of the inguinal ligament whereas in

Lichtenstein tension free mesh hernioplasty the mesh was secured from the insertion of rectus sheath, reflected part of inguinal ligament and up to the pubic bone. The mean pain intensity in present study was 2.9 in Lichtenstein tension free mesh hernioplasty group and 2.7 in Modified Prolene Hernia system. Mean time interval to demand of rescue analgesia was 14.67 hours and 14.53 hours for Lichtenstein tension free mesh hernioplasty group and Modified Prolene Hernia system group, respectively. There was no statistically significant difference between the two groups.

No intra-operative complication such as injury to nerves/injury to vas or injury to bowel was seen with either of the two groups. Post-operative complications in the form of Seroma formation were seen in four patients (10%) in Lichtenstein tension free mesh hernioplasty group while none of the patients in Modified Prolene Hernia system group showed such complication. There was one case (2.5%) of short-term recurrence in the Lichtenstein tension free mesh hernioplasty group in the mean follow up period of 12 weeks, while no short-term recurrence was seen in Modified prolene hernia system group over 12 weeks.

Mean duration of post-operative hospital stay was 1.57 days for Lichtenstein tension free mesh hernioplasty group and 1.33 days for Modified prolene hernia system group. As the p value was more than 0.05 (0.053), the difference between the two groups was statistically insignificant.

Modified prolene hernia system in open inguinal hernia repair had a statistically significant, lesser operative time than Lichtenstein tension free mesh hernioplasty, which was because lesser number of securing fixation sutures were required in Modified prolene hernia system repair, as compared to Lichtenstein tension free mesh hernioplasty, which saves the time, thereby decreasing the intraoperative time. No significant difference was found in post-operative pain in either Lichtenstein tension free mesh hernioplasty or Modified prolene hernia system for open inguinal hernia repair. There was no significant difference in terms of analgesic use in Lichtenstein tension free mesh hernioplasty or Modified prolene hernia system for open inguinal hernia repair. There was no difference in intra-operative complications rate in either of the two groups. Post-operative complications rate in the form of seroma formation was significantly lower with Modified Prolene Hernia system repair than Lichtenstein tension free mesh hernioplasty, due to lesser tissue handling, lesser number of sutures required with it. Use of either of the two methods for inguinal hernia repair did not have any significant impact on the duration of post-operative hospital stay in the hospital.

No significant difference was observed in the rate of recurrence between Modified prolene hernia system repair and Lichtenstein tension free mesh hernioplasty for inguinal hernia repair, although there is a trend towards lower recurrence rates with Modified prolene hernia system repair which may stem from the complete coverage of the myopectineal orifice by the Modified prolene hernia system mesh.

CONCLUSION

This study concludes that even though the difference between the two methods in this randomized study were small, the Modified Prolene Hernia system repair method for open

inguinal hernia repair was associated with a shorter operative time, lower rate of recurrence, as well as fewer complications when compared with the Lichtenstein tension free mesh hernioplasty. Main advantage of modified Prolene Hernia system is its cost effectiveness and it is more suitable for developing countries like India. Further prospective studies are needed to rigorously evaluate the comparative advantages of Modified Prolene Hernia system repair in relation to other repair methods.

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