

Prolene Hernia System Herniorrhaphy Versus Open Inguinal Hernia Repair by Lichtenstein Tension Free Mesh Hernioplasty -A Randomized Study

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Abstract

➤ Introduction:

Prolene Hernia System is a tension free anterior inguinal hernia repair using a bilayered modification of inguinal hernia mesh. 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 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 PHS 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 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 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 Prolene Hernia System group (8 vs 0). There were two cases of recurrence in the Lichtenstein tension free mesh hernioplasty group, while no short-term recurrence was seen in 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 Prolene Hernia System group.

➤ Conclusion:

This study concludes that even though the difference between the two methods in this randomized study were small, the 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. Further prospective studies are needed to rigorously evaluate the comparative advantages of Prolene Hernia System repair in relation to other repair methods.

Keywords:- Prolene Hernia System, Myopectineal Orifice, Hernioplasty.

I. 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 operation [2] and a lower recurrence rate. Lichtenstein repair has now become the method of choice for hernia repair. However, hernia recurrence, wound complications like seroma, hematoma, chronic pain [3], 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 1999[4]. This method utilizing the Prolene Hernia System mesh is a “3-in-1 device” made of polypropylene, incorporating an underlay patch” 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[fig.1]. This device purportedly combines the benefits of the posterior and anterior repair from an open approach[5-12] 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. Inguinal hernia repair by 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 Prolene Hernia System in a tertiary care I.G. Medical College & Hospital, Shimla.

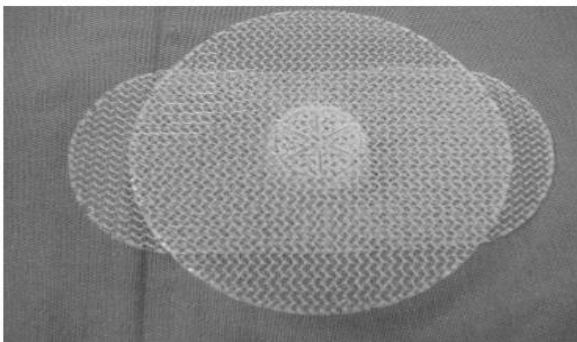


Fig 1:- Prolene Hernia System.

II. MATERIALS AND METHODS

This comparative study was conducted in the Department of Surgery, I.G.M.C. Shimla from 1st of July 2015 to 30th November 2018 and included 150 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 Prolene Hernia System was made. Patients were randomized into equal groups of 75 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 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

[Figure 3]. 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 al [2]. 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.

Prolene Hernia System repair was done by dissecting out the Pre-Peritoneal space of Bogros [Fig. 2]. The Prolene Hernia System mesh consisting of an onlay patch, an underlay patch attached with a connector was then inserted. The underlay circular mesh was deployed in the preperitoneal space behind the transversalis fascia [Fig. 3]. The connecting cylinder was fixed to the internal ring by prolene sutures. 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.

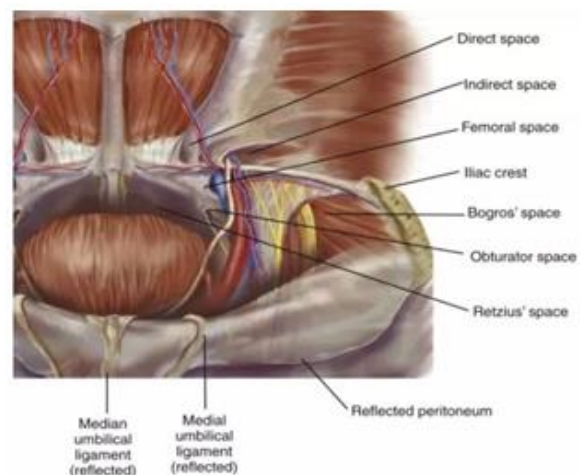


Fig 2:- Showing Pre-Peritoneal space of Bogros.



Fig 3:- Placement of Underlay Component of PHS.

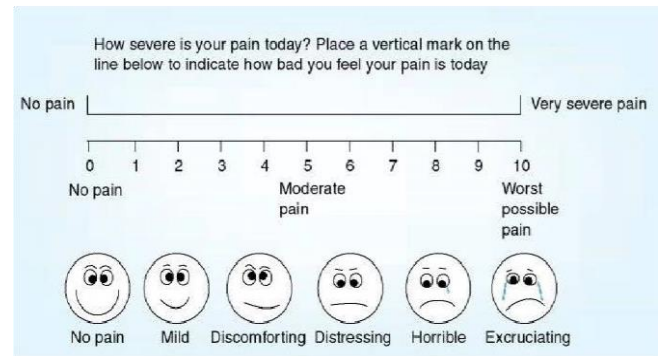


Fig 4:- Visual Analogue scale

III. RESULTS

➤ *Total Operative Time*

Duration of surgery that is the total time from skin incision to skin closure ranged from 28 minutes to 44 minutes in Lichtenstein tension free mesh hernioplasty group whereas in Prolene Hernia System group it varied between 25 minutes to 45 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 Prolene Hernia System group was 32.2 minutes with a S.D. of ± 4.04. Duration of surgery was shorter in Prolene Hernia System group (p=0.039) than the Lichtenstein tension free mesh hernioplasty group which was statistically significant [Table 1].

Lichtenstein Tension free Hernioplasty			Prolene Hernia system Hernioplasty	
Duration of Surgery (Minutes)	No. of patients	%	No. of patients	%
21-30	16	21.3%	32	43.3%
31-40	50	66.7%	40	53.3%
41-50	9	12%	33	4.4%
Total	75	100%	75	100%

Table 1:- the duration of surgery in both groups.

➤ *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 two groups was 0.326 which was not statistically significant [Table 2].

Time Interval (hours)	Lichtenstein tension free mesh hernioplasty	Prolene Hernia System
0-4	3	2
5-8	12	8
9-16	33	39
17-24	27	26
Total	75	75

Table 2:- Time Interval of Rescue Analgesia.

➤ *Intra-Operative Complications*

No intra-operative complications 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 8 cases of Lichtenstein tension free mesh hernioplasty group. However, none of the patients in Prolene Hernia System group developed any seroma. The patients were followed for 3 months to look for any recurrence, and 2 patients in Lichtenstein tension free mesh hernioplasty group showed recurrence while none of the patients in Prolene Hernia System group showed recurrence [Table 3].

Post-operative Complications	Lichtenstein Tension Free Mesh Hernioplasty		Prolene Hernia System Hernioplasty	
	No. of Patients	%	No. of Patients	%
Seroma	8	10.6%	0	0%
Recurrence	2	2.6%	0	0%

Table 3:- Post-operative complications.

➤ *Post-Operative Hospital Stay*

In the Lichtenstein tension free mesh hernioplasty group, thirty-four patients (45.33%) were discharged on 1st postoperative day. Eighteen patients (24%) were discharged on 2nd post-operative day while eight patients (10.6%) were discharged on 3rd post-operative day. In the Prolene Hernia System group, thirty-nine patients (52%) were discharged on first post-operative day while twenty patients (26.6%) were discharged on second post-operative day, and 2 patients (2.6%) 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 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 4,7].

Hospital Stay (in days)	Lichtenstein Tension Free Mesh Hernioplasty	Prolene Hernia System Hernioplasty
1	42(56.7%)	49(65%)
2	23(30%)	25(33.3%)
3	10(13.3%)	1(1.7%)
Total	75	75

Table 4:- Post-operative Hospital Stay

IV. 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.

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 Prolene Hernia System. The operative time of Prolene Hernia System was significantly shorter than Lichtenstein tension free mesh hernioplasty, which was because, in 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 to the insertion of rectus sheath 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 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 Prolene Hernia System group, respectively. There was no statistically significant difference between the two groups.

No intra-operative complications 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 eight patients (13.33%) in Lichtenstein tension free mesh hernioplasty group while none of the patients in Prolene Hernia System group showed such complication. There were two cases (2.66%) 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 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 Prolene Hernia System group. As the p value was more than 0.05 (0.053), the difference between the two groups was statistically insignificant.

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 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 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 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 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 Prolene Hernia System repair and Lichtenstein tension free mesh hernioplasty for inguinal hernia repair, although there is a trend towards lower recurrence rates with Prolene Hernia System repair which may stem from the complete coverage of the myopectineal orifice by the Prolene Hernia System mesh.

V. CONCLUSION

This study concludes that even though the difference between the two methods in this randomized study were small, the 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. Further prospective studies are needed to rigorously evaluate the comparative advantages of Prolene Hernia System repair in relation to other repair methods.

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