STUDY OF PROLENE HERNIA MESH SYSTEM IN MANAGEMENT OF PRIMARY INGUINAL HERNIA REPAIR

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ABSTRACT: BACKGROUND: Inguinal hernia is common disease known to surgeons since ages. Since Bassini first described repairing an inguinal hernia by suturing the conjoint tendon to the inguinal ligament in 1889, the primary surgical objective has been to adequately cover the myopectineal orifice to prevent recurrence. Lichtenstein et al coined the term "tension- free" repair and advocated this approach in 1986. There are different tension free repairs like open anterior (anterior mesh, plug and patch) open posterior approach, laparoscopic posterior patch and Kugel's plug technique. In 1998, the PHS mesh, consisting of an onlay and an underlay patch attached with a connector, was introduced as an option for tension-free open repair of inguinal hernias. **DESIGN:** The present study of prolene hernia mesh system in primary inguinal hernia repair has been carried out at Indira Gandhi Government Medical College and Hospital, Nagpur between the time period, June 2005 – 2007 with a follow up of 5 years. Total 75 cases were studied, operated and followed up for a period of 5 years. Data related to the demographic details, complaints, physical examination findings, intraoperative findings, post-operative stay, complications were collected and analysed. **OBSERVATION:** After primary inguinal hernia repair with prolene hernia mesh system, 46.66% patients were hospitalized for 3-5 days. Total operative duration required for prolene hernia mesh system repair was 40-60 min in 42.66% cases.42.6% of patients had returned to normal routine work within 1-2weeks of surgery. The complication rate was 16%, which included fever in 3% cases, Seroma in 2.66% cases, haematoma in 1.33% cases and cord oedema in 4% cases, wound infection found in 1.33% patients, chronic groin pain in 2.66% and persistent cord oedema in 1.33% patients. No recurrence was observed in 65 follow up patients. **CONCLUSION:** The prolene hernia system provides all the advantages of a tension-free repair, including less discomfort, rapid return to normal activity low recurrence rates and minimum postoperative complications. **KEYWORDS:** Inguinal hernia, Prolene mesh system

INTRODUCTION: Inguinal hernia is common disease known to surgeons since ages. Many attempts for successful treatment have been made. It is established that surgery is the only mode of treatment. Inguinal herniorrhaphy is an evolving surgical solution to an age-old problem. Since Bassini first described repairing an inguinal hernia by suturing the conjoint tendon to the inguinal ligament in 1889, the primary surgical objective has been to adequately cover the myopectineal orifice to prevent recurrence. The initial Bassini repairs that were later modified by Halstead and McVay were performed under tension because of the direct approximation of tissue with resultant high recurrence rates reported to be between 5% & 21%.⁽¹⁻³⁾ In 1958, Usher et al was the first to perform inguinal herniorrhaphy by using prosthetic mesh, thereby eliminating the tension associated with tissue approximation.⁽⁴⁾ However, mesh repair did not gain widespread acceptance until Lichtenstein et al coined the term "tension- free" repair and advocated this approach in 1986.⁽⁵⁾ The introduction

of mesh for the repair of inguinal hernias significantly decreased the recurrence rates observed with the tissue repairs.

Understanding the inguinal canal anatomy, specifically the myopectineal orifice, which is composed of a lateral, medial, and femoral triangle, is of paramount importance to the successful repair and prevention of hernia recurrence. Currently, there are multiple tension– free techniques, which include the open anterior repair (onlay patch, plug and patch), Open posterior repair (Stoppa – Rives technique; Kugel; CR Bard Inc, Murray Hill, NJ), combined posterior and anterior repair through an anterior approach

(Prolene Hernia System; Ethicon, Inc, Somerville, NJ) and the closed posterior approach (laparoscopic). Of these repairs, only the laparoscopic repair and the PHS mesh provide complete coverage of myopectineal orifice.

During the 1990s, with advances in laparoscopic technology, the laparoscopic inguinal hernia repair was introduced with preliminary reports documenting recurrence rates, ranging from 3% to 10%. ⁽⁶⁻⁸⁾

In 1998, the PHS mesh, consisting of an onlay and an underlay patch attached with a connector, was introduced as an option for tension-free open repair of inguinal hernias. In theory, this repair combines the benefits of a posterior and anterior repair from an open approach.^(9,10) PHS mesh has been touted for the repair of direct, indirect, and femoral hernias with extremely low recurrence rates secondary to complete coverage of the myopectineal orifice.

The present work of prolene hernia mesh system in primary inguinal hernia repair takes into consideration, all the above principles. The objective is to study feasibility of using the prolene hernia system, postoperative results in terms of patients comfort, hospital stay, and duration to return to normal activity, postoperative complications and recurrence rates.

DESIGN: The prolene hernia mesh system is a novel concept developed for tension free repair of inguinal hernia. The present study of prolene hernia mesh system in primary inguinal hernia repair has been carried out at Indira Gandhi Government Medical College and Hospital, Nagpur between the time period, June 2005 – 2007.

Total 75 cases were studied, operated and followed up for a period of 2 years.

The inguinal hernia repair was done with the technique as described by company Johnson and Johnson.

All patients of inguinal hernia admitted in the hospital were essentially evaluated in outpatient department.

Patients were studied and data was collected related to demographic details, clinical history and examination findings, post op recovery and complications.

Selection of subject: All patients between 30-80 years of age are included,

- All type of inguinal hernia are included whether direct, indirect or combined.
- Only unilateral inguinal hernias are included in this study.
- Irreducible inguinal hernias are excluded from study.
- Obstructed and strangulated inguinal hernias are excluded.
- Recurrent inguinal hernia cases are excluded.

1) Preoperative preparation: Local skin infection, if any was treated by appropriate treatment on consultation with dermatologist.

Chronic Precipitating factors such as cough, constipation urinary complications were investigated and treated prior to operation. Evaluation of fitness was done after consultation with the physician.

Smokers were asked to stop smoking for at least 1 month prior to surgery. The part including scrotum to perineum was shaved on the day before operation and betadine was applied to the part. Patients were allowed to take soft diet on the previous night. Patient were kept nil by mouth after 10 pm on previous night.

Soap water enema was given on the morning of operation.

Patients were asked to take bath on the day of operation and betadine was applied on the part.

On the operation table preliminary cleansing was done with betadine solution and followed by methylated sprit.

- 2) Anaesthesia: Spinal, GA
- **3) Operative procedure:** An oblique 4-5 cm skin incision was made in the inguinal region and the inguinal canal was opened in layers. The cord structures were hooked up in the region of the pubic tubercle and held. The cremaster was incised and the cord structures and hernial sac were dissected from it by blunt and sharp dissection.

The hernial sac was then delineated and dissected free from the cord structures. Indirect sac was inverted and reduced into the peritoneal cavity or alternately twisted transfixed and excised.

The preperitoneal plane was created by passing a finger or a piece of gauze through the internal ring itself. The underlay patch was spread out in the preperitoneal space created. The onlay mesh was then spread out over the posterior wall of the inguinal canal. This was fixed using 3-4 interrupted sutures of 2-0 polypropylene. Haemostasis was achieved and inguinal canal closed in layers.

We use prophylactic antibiotics for our patient. Patients were given 3 doses of IV cefotaxim 1gm postoperatively followed by oral Ampirock 375 mg BD.

Post-operative care: All patients were mobilized after 4-6 hours of surgery.

- Patients were kept nil orally for 2 hours.
- Oral antibiotics for 7 days.
- All patients were discharged within 24-48 hour if no complications developed and called after 7days for removal of stitches.
- Postoperatively on discharge, patients were advised not to lift heavy weight and avoid cycling for 6 week.
- Patients were followed up for a period of 2 years.

The study of prolene hernia mesh system in primary inguinal hernia repair was carried out at Indira Gandhi Government Medical College and General Hospital, Nagpur from June 2005 to December 2007.

Sl. No.	Age group	No. of cases	Percentage	
1	30 – 40 years	16	21.33%	
2	41 – 50 years	20	26.66%	
3	51 – 60 years	19	25.33%	
4	61 – 70 years	15	20%	
5	71 – 80 years	5	6.66%	
		75	100%	
Table 1: Age incidence				

Total of 75 cases were studied and the observations were as follows:

Although age is no bar for development of hernia, in our study patients below 30 years of age were not included because PHS is not indicated below this age group. Out of 75 patients, the maximum no. of cases i.e. 39 patients (52%) were found in 5th and 6th decade followed by 16 patients (21.33%) in the 4th decade, 15 patients (20%) in 7th decade of life. The incidence was less in 8th decade.

Gender	No. of case	Percentage		
Male	72	96%		
Female	3	4%		
	75	100%		
Table 2: Sex incidence				

In the present study there were 72 male patients and 3 female patients. The male to female ratio is 24:1.

Sl. No.	Side	No. of cases	Percentage	
1	Right	40	53.33%	
2	Left	35	46.66%	
		75	100%	
Table 3: Side of hernia				

Out of 75 cases, 40 cases (53.33%) of hernias were right sided, while 35 patients (46.66%) were left sided. Bilateral hernia cases were not included in this study.

Sl. No.	Factors	No. of cases	Percentage
1	Chronic cough	12	16%
2	Chronic constipation	7	9.33%
3	Difficulty in micturition	5	6.66%
	Operated case of vesical		
4	calculus, urethral	3	4%
	stricture, B.H.P.)		
5	Heavy weight lifting	27	36%
6	No predisposing factors	21	28%
Table 4: Predisposing factors			

In the present study, out of 75 patients, 27 patients (36%) had history of heavy weight lifting, 12 patients (16%) presented with chronic cough, 7 patients (9.33%) had prolonged history of chronic constipation, 5 patients (6.66%) gave history of difficulty in micturation and 3 patients (4%) were operated for vesical calculus, urethral stricture or benign hypertrophy of prostate. In 21 patients (28%) no predisposing factor was found.

Sl. No.	Diseases	No. of cases	Percentage
1	Diabetes mellitus	3	4%
2	Ischaemic heart disease	1	1.33%
3	Pulmonary Koch's, bronchial asthma, COAD	5	6.66%
4	Hypertension	5	6.66%
5	No associated disease	61	81.33%
		75	100%
Table 5: Associated diseases			

Out of 75 patients, maximum number of patients i.e. 61(81.33%) were presented with no associated disease, 5 patients (6.66%) had history of pulmonary Koch's, COAD or bronchial asthma, 5 patients (6.66%) were newly detected cases of hypertension, 3 patients (4%) were having diabetes mellitus and 1 patient (1.33%) presented with history of ischaemic heart disease.

Sl. No.	Nature of work	No. of cases	Percentage	
1	Heavy	27	36%	
2	Moderate	38	50.66%	
3	Sedentary	10	13.33%	
		75	100%	
Table 6: Nature of work				

Out of 75 patients, majority of patients i.e. 65 (86.66%) were moderate to heavy workers. While only 10 cases (13.33%) were sedentary workers.

- Heavy workers \rightarrow Farmers and labourers.
- Moderate workers \rightarrow waiter, barbers, chowkidars.
- Light workers \rightarrow Teachers, Shopkeepers.

Sl. No.	Symptoms	Right	Left	Total
1	Swelling	40(53.33%)	35(46.66%)	75(100%)
2	Discomfort	25(33.33%)	23(30.66%)	48(64%)
3	Pain	9(12%)	11(14.66%)	20(26.66%)
Table 7: Presenting Symptoms				

In the present study, swelling was the single most persistent symptom observed in all 75 cases (100%) associated with discomfort in 48 cases (64%). In 20 cases (26.66%) pain was associated with swelling.

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Sl. No.	Type of Hernia	Right	Left	Total
1	Indirect	11(14.66%)	9(12%)	20(26.66%)
2	Direct	22(29.33%)	21(28%)	43(57.33%)
3	Combined(Direct + Indirect)	7(9.33%)	5(6.66%)	12(16%)
Table 8: Type of hernia				

In the present study, out of 75 patients, 20 cases (26.66%) were of indirect inguinal hernia, out of which 11 cases (14.66%) were on right side and 9 cases (12%) on left side. Direct inguinal hernia was seen in 43 cases (57.33%), out of which 22 cases (29.33%) were on right side and 21 cases (28%) on left side. Combined variety (Direct + Indirect) was seen in 12 cases (16%), out of which 7 cases (9.33%) were on right side and 5 cases (6.66%) on left side.

Sl. No.	Туре	Right	Left	Total
1	Bubonocele	3(15%)	5(25%)	8(40%)
2	Funicular	7(35%)	4(20%)	11(55%)
3	Complete	1(5%)	-	1(5%)
		11(55%)	9(45%)	100%
Table 9: Type of hernia extent(i.e. individual indirect inguinal hernia)				

Out of 20 cases of indirect inguinal hernia bubonocele was seen in 8 cases (40%), out of which 3 cases (15%) were on right side and 5 cases (25%) on left side. Funicular variety was seen in 11 cases (55%), out of which 7 cases (35%) were on right side and 4 cases (20%) on left side. Complete inguinal hernia variety was seen in only 1 case (5%) on right side.

Sl. No.	Duration in days	No. of cases	Percentage	
1	1 -2 days	14	18.66%	
2	3 – 5 days	35	46.66%	
3	5 – 7 days	16	21.33%	
4	After 7 days	10	13.33%	
		75	100%	
Table 10: Showing duration of hospital stay after surgery				

In our study out of 75 patients, maximum number of cases 35 (46.66%) were discharged within 3-5 days, 14 cases (18.66%) were discharged within 1–2 days, 16 cases (21.33%) were discharged in 5 – 7 days and 10 cases (13.33%) were discharged after a period of 7 days, in which 2 patients had seroma, 3 patients had cord oedema, 1 patient developed haematoma, wound infection in 1 case and chronic groin pain in 2 cases.

Sl. No.	Operative duration (min)	No. of cases	Percentage	
1	20 – 40 min	25	33.33%	
2	40 - 60 min	32	42.66%	
3	>60 min	18	24%	
		75%	100%	
Table 11: Showing operative duration				

Out of 75 patients, maximum number of cases i.e. 32 patients (42.66%) operated in the duration of 40 - 60 min followed by 25 cases (33.33%) in 20-40 min and 18 patients (24%) required operative duration more than 60 min.

Sl. No.	Post-operative period (weeks)	No. of cases	Percentage	
1	Within 1 to 2 weeks	32	42.66%	
2	Within 2 – 3 weeks	28	37.33%	
3	After 3 weeks	15	20%	
		75%	100%	
Table 12: Showing no. of patients doing normal routine work in post-operative period				

Out of 75 patients, 32 patients joined their routine work within 1 -2 weeks, 28 patients (37.33%) within 2 – 3 week, 15 patients (20%) joined after three weeks period.

Sl. No.	Complications	No. of cases	No. of days to resolve	Percentage
1	Fever	2	3	2.66%
2	Haematoma	1	9	1.33%
3	Cord oedema	3	10 – 15	4%
4	Seroma formation	2	8	2.66%
5	Epididymo orchitis	-	-	-
6	Post spinal headache	-	-	-
7	Induration	-	-	-
Table 13: Showing immediate postoperative complications				

Out of 75 cases, cord oedema developed in 3 cases (4%) which subsided within 10-15 days with conservative management. Seroma developed in 2 cases (2.66%), while haematoma in 1 patient (1.33%) which subsided within 7 to 10 days.2 patients (2.66%) had fever secondary to urinary tract infection managed conservatively with antibiotics.

Sl. No.	Complications	No. of cases	No. of days to resolve	Percentage
1	Wound infection	1	1 month	1.33%
2	Numbness/ Paresthesia/ Groin pain	2	2 months	2.66%
3	Persistent cord oedema	1	3 weeks	1.33%
4	Testicular atrophy	-	-	-
5	Graft rejection	-	-	-
6	Recurrence	-	-	-
Table 14: Delayed complications				

Out of 75 patients, one patient (1.33%) developed wound infection which took 1 month to resolve following treatment with broad spectrum antibiotics, 2 patients (2.66%) had chronic groin pain which took 2 months to subside, persistent cord oedema in 1 patient (1.33%) which took 3 weeks to resolve, following anti-inflammatory treatment. There was no cases of recurrence during follow-up period.

Sl. No.	Results	No. of cases	Percentage	
1	Completely cured	70	93.33%	
2	Recurrence	-	-	
3	Not reported for follow-up	5	6.66%	
4	Mortality	-	-	
Table 15: Results				

Out of 75 cases, 70 cases were cured completely after prolene hernia mesh system repair, 5 cases did not report for follow up. There was no recurrence and mortality in the present study.

From this study, the following conclusion could be drawn: The prolene hernia system provides all the advantages of a tension-free repair, including less discomfort, rapid return to normal activity low recurrence rates and minimum postoperative complications.

The prolene hernia system is a novel approach for the management of inguinal hernias with encouraging initial results. The cost factor may be a major drawback, especially in developing countries. The long term efficacy needs to be studied with larger prospective double- blind randomized trails, with longer follow – up.

We believe that hernia repair with prolene hernia system is a valid choice, comparable to other common technique but we suggest that it should be used particularly in primary inguinal hernias, with major relaxation of the posterior inguinal wall or the entire myopectineal orifice, and should be considered as an alternative choice for repair of primary inguinal hernia.

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