A CLINICAL STUDY OF ONLAY-INLAY MESH IN INDIRECT INGUINAL HERNIAS

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ABSTRACT

BACKGROUND

In 1998, Onlay-Inlay (Prolene Hernia System) mesh was introduced as an option for tension-free open repair of inguinal hernias. In theory, this repair combines the benefits of the posterior and anterior repair from an open approach with extremely low recurrence rates secondary to complete coverage of the myopectineal orifice. This study is an attempt to evaluate the benefits offered by Prolene Hernia System and the feasibility of technique in the context of Indian population.

Aims and Objectives- To study the outcome of inguinal hernia repair with Onlay-Inlay Mesh (PHS) in terms of Effectiveness of Prolene Hernia System, Postoperative pain, Postoperative complications, Duration of hospital stay, Duration of return to normal activities, Recurrence, Cost and Affordability of PHS.

MATERIALS AND METHODS

The data for this prospective observational study was obtained from 30 patients undergoing PHS repair in Mahatma Gandhi Memorial Hospital/ Kakatiya Medical College, Warangal between January 2015 and September 2016 inclusive of a follow-up period of 6 months.

RESULTS

The mean age of patients presenting with inguinal hernia was 54.8 years with majority of patients in the age group of 51 - 60 years. Farmers (36.67%) and labourers (20%) were commonly affected owing to their strenuous work. Right sided inguinal hernia (53.3%) was common compared to left (33.3%). BPH and HTN causing straining symptoms were the most common associated factors in 33.33% and 23.33% of cases respectively. The mean duration of surgery was 41 minutes, immediate postoperative pain was 3.6 (mean) on VAS at 24 hrs., postoperative wound infection was seen in 1 case (3.3%) and postoperative seroma formation was seen in 1 case (3.3%). The mean duration of hospital stay was 4.6 days and the patients resumed normal activities by 10 days (mean) after PHS repair.

CONCLUSION

The (Prolene Hernia System) Onlay-Inlay tension-free mesh repair is a simple, straightforward technique without the need for complex instrumentation without compromising the safety or the long-term success of the procedure.

KEYWORDS

Prolene Hernia System, Onlay, Inlay, Hernia.

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BACKGROUND

Inguinal hernia is one of the most common surgical problems worldwide.^{1,2} Several surgical techniques have been implemented for inguinal hernia repair, using both the open and laparoscopic approaches. Tension free techniques became the gold standard for hernia repair.^{3,4,5} A wide variety of prosthetic biomaterials have been utilised to abolish tension associated with pure tissue repairs and to restore the integrity of the inguinal canal floor by stimulating fibrocollagenous tissue ingrowth. Search for a near perfect modality of treatment of inguinal hernia has not yet ended. The rapid evolution of surgical techniques employing newer mesh designs and materials has expanded the surgeon's armamentarium.

The Polyethylene (Marlex) mesh, first introduced by Usher,⁶ has gained a lot of popularity and was used in different designs by many surgeons. The use of the prolene hernia system (PHS) for inguinal hernia repair began in 1998.⁴ The Onlay-Inlay Mesh (PHS) combines many of the advantages of the earlier tension-free repair techniques. This is attributed to its three components namely the underlay patch (for peritoneal placement, the onlay patch (for subfascial placement and the connector that connects the two patches and acts as a plug.⁶

Theoretically, PHS has an ideal structure to reinforce and maintain the posterior wall of the inguinal canal without any tension, which should minimise the risk of recurrence and complications; however, these theoretical advantages have not been fully evaluated. Because inguinal hernia repair is performed so frequently, relatively modest improvements in clinical outcomes will have a significant impact on a large number of people. Conversely, any morbidity associated with surgery could result in substantial human, economic and social burdens. This study is an attempt to evaluate the benefits offered by Prolene Hernia System and the feasibility of technique in the context of Indian population.

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Aims and Objectives

The aim of the study is to determine the outcome of indirect inguinal hernia repair with onlay-inlay mesh (PHS) done from January 2016 to September 2017 (including 6 months of follow-up period in MGM Hospital/ Kakatiya Medical College, Warangal. It is a prospective observational study.

To Study the Outcome of Inguinal Hernia Repair with Prolene Hernia System in Terms of-

- Cost and affordability of PHS.
- Effectiveness of Pascal Law and patient acceptance.
- Postoperative pain.
- Postoperative complications.
- Duration of hospital stay.
- Duration of return to normal activities.
- Recurrence.

MATERIALS AND METHODS

Source of Data

The prospective observational study comprises of 30 patients presenting with inguinal hernia attending OPD and admitted to Surgical Unit-I of Mahatma Gandhi Memorial Hospital, Warangal Urban during the study period of January 2016 to September 2017.

Method of Collecting Data

In this study, 30 patients presenting with inguinal hernia were selected by random sampling technique.

Inclusion Criteria

1. All cases > 18 years.
2. Uncomplicated inguinal hernia.

Exclusion Criteria

Complicated hernia like obstructed and strangulated inguinal hernias presenting as emergencies.

These patients presented with either swelling in the groin/ pain in the groin area of varying duration. Patients with these symptoms were admitted to surgical ward with the diagnosis of direct or indirect uncomplicated inguinal hernia. A detailed relevant clinical history was taken and physical examination including general, systemic and local examination was done as the proforma approved by the guide.

Investigations were carried out to assess the Fitness of Patients for Surgery. These include-

1. Blood: Hb percentage/ Total and Differential White Cell Count/ Bleeding time and Clotting time/ Fasting/ Random Blood Sugar/ Blood Urea and Serum Creatinine.
2. Urine: Albumin/ Sugar/ Microscopy.
3. Electrocardiogram.
4. X-ray of the chest was done to rule out any lung pathology.
5. Ultrasound of the abdomen and pelvis was done to rule out benign enlargement of the prostate.
6. Cardiac evaluation such as 2D Echo and Pulmonary function test.

After routine investigations, patients were informed about the various techniques and advantages of the PHS

mesh. In those patients who agreed, consent was taken and patients were prepared for surgery. Patients were subjected to prolene hernia system repair.

All patients were given preoperative antibiotic prophylaxis with injection. Ceftriaxone/ Sulbactam 1.5 gm IV. Spinal anaesthesia was administered.

Operative Technique

A classical incision was used for hernia repair, i.e. above and parallel to the medial 3/5th of the inguinal ligament and then the fascia of the external oblique muscle was incised to open the inguinal canal. For indirect hernia repair, a high dissection of the neck of the hernia sac is performed. Creation of a "Posterior Space" was done by the use of a 2 x 2 cm gauge and blunt dissection and/ or sponge manipulated into the preperitoneal space. Then using the forefinger, sweep circumferentially medial, then laterally to actualise the preperitoneal space. The PHS mesh is folded as shown in figure and is inserted through the internal ring allowing the mesh to expand to underlay position. No sutures were used for the bottom underlay patch, as it is taken care in its position as per Pascal's law. The top onlay patch, which is designed to cover the posterior wall is then modified as needed to accommodate the cord structures. If one end of the oval onlay patch is longer than the other, the PHS is positioned so that the longer end covers the posterior wall and overlaps the pubic tubercle. Sutures may be used to secure the top onlay patch in place. The cord structures then lie on the top of medial portion of the onlay patch. Drain was kept if needed and the wound was closed in layers using Vicryl and Ethilon sutures.

In the postoperative period, Inj. Diclofenac 1 – 2 mg/kg body wt. IM BD/ Inj. Tramadol 50 – 100 mg IV was given as analgesia for 48 hours and Inj. Ceftriaxone - Sulbactam 1.5 gm IV BD was also given for 48 hrs. Postoperatively, patients were monitored carefully and details regarding patient complications, incapacity to work and complications were noted. Patients were evaluated for immediate complications like urinary retention, postoperative pain, haematoma and wound infection. Pain was evaluated by patient's own perception of pain based on visual analogue score. Seroma was evacuated when required. Infection: Confirmed by culture and sensitivity and treated by drainage and proper antibiotics. Drain was removed usually within 48 hrs. or when daily drainage was < 20 mL. Patients were discharged between 3rd and 5th day when considered fit to go about their normal routine. Sutures were removed on the 8th to 10th postoperative day. Follow-up: Patients were followed up on 1 month, 3 months and 6 months after surgery. They were advised to come earlier in case they noted any complications. During the follow-up, late complications like chronic groin pain and recurrence was evaluated.

RESULTS

The present study which is a prospective observational study was carried out in the Department of Surgery, MGM Hospital/ Kakatiya Medical College, Warangal. 30 cases of inguinal hernia were included in the study after explaining about the new PHS technique, advantages and cost effectiveness and their consent was taken. They were subjected to the Onlay-Inlay mesh repair. Evaluation of all the patients included in the study was done regarding the history, physical findings, operative details and postoperative complications. The

patients were followed up at one month, three months and six months postoperatively for any complication, chronic groin pain or recurrence.

The following observations were made during the course of the study.

In this study, patients ranged in the age from 20 - 80 years with about 63% of them being above 51 years of age. The greatest incidence was in the 51 - 60 years' age group (30%). All patients presented with swelling in the groin (100%) and pain was present in 12 of the patients (40%). Pain was of dragging type except in one patient where the pain was colicky in a case of irreducible hernia. More than half of the patients presented with hernia on the right side (53.33%) followed by left (33.33%). Bilateral hernias were fewer accounting to 13.33%. Moderate-to-high activity workers (farmers, labourers, conductor) accounted for 60% of the total no. of cases. Sedentary activity workers were found to be 40%. Most common associated co-morbidity found in the population was BPH, present in 10 cases accounting for 33.33% followed by HTN 23.33%. The most common straining factor associated with inguinal hernia in this group of patients was chronic cough (30%) followed by BPH (23%). Severe pain was present in only 2 cases (7%) and most of patients 25 (83.33%) had moderate pain during the first 24 hours. Majority of patients had minimal pain for 48 and 72 hours, i.e. 50% and 90% respectively. Mean VAS score of cases in 24 hours was 3.6. Mean VAS score of cases in 48 hours was 2.5. Mean VAS score of cases in 72 hours was 1.6.

Most common immediate postoperative complication was urinary retention comprising of 4 cases, which accounted for 13.33% of total no. of cases. 1 (3.33%) case had seroma which was managed by aspiration and evacuation followed by compression dressing. 1 (3.33%) case had wound infection, which was managed by daily dressing, antibiotics based on culture and sensitivity report. Majority (53.4%) of patients had a hospital stay of 4 days or less. Due to associated comorbid conditions and patients from rural areas with lack of health care facilities, some patients had longer duration of hospital stay before they were deemed to be fit for discharge-

- 5 cases had minimal pain after 1 month, which accounted for 16.67%.
- Whereas, 25 cases had Nil pain in the groin after 1-month accounting for 83.33%.
- At 6 months, 100% of the cases were pain free with no case reporting any chronic groin pain. Amongst all 30 cases studied, none of the patients reported of recurrence after a minimum follow-up of 6 months.

DISCUSSION

Inguinal hernia repair is one of the most common surgical procedures theoretically, Onlay-Inlay Mesh (PHS) has an ideal structure to reinforce and maintain the posterior wall of the inguinal canal without any tension, which should minimise the risk of recurrence and complications; however, these theoretical advantages have not been fully evaluated especially in developing countries like India.

As a surgeon, we want techniques easy to master with short learning curves, but we still want to attain results comparable to the specialist hernia surgeons.

Patients on the other hand want their period of hospital stay, convalescence and rehabilitation to be uneventful in

both the short and the long term, so as to early return to their normal daily activities and get best quality of life.

A Study with regard to following Parameters were made-

- Effectiveness of Pascal law and patient acceptance.
- Postoperative pain.
- Postoperative complications.
- Duration of hospital stay.
- Duration to return to normal activities.
- Recurrence.
- Cost and affordability of PHS.

The observations and calculated means were subjected to statistical analysis. The statistical analysis used was mean, proportion and Chi-square test.

The results and observations discussed and compared with those of the available literature are as follows.

Age at Presentation

Age (in yrs.)	Louies and Wendell ⁸	Present Study
< 20	0.3%	
21-30	12.1%	6.6%
31-40	16.2%	13.2%
41-50	17.3%	16.5%
51-60	27.4%	30.0%
61-70	23.3%	20.0%
71-80	3.5%	13.2%

Table 1. Comparison at Age at Presentation with Other Studies

In this study, the mean age was calculated to be 54.8 years and maximum number of patients (30%) belonged to the age group of 51 - 60 years. This study is comparable with the studies conducted by Louies and Wendell et al.

Symptoms

Most common presentation of hernia is swelling. In the present study without exception, all patients presented with swelling in the inguinal region. Swelling only was present in 60% of patients as compared to swelling associated with pain in 40%.

The history of pain came forth only on direct questioning. The type of pain was described to be of dragging sensation in 36.3% and of colicky type in one patient with irreducible hernia. This was excluding complicated hernias.

Symptoms	Present Study				Alan Hair ⁷ et al
	Position			Total (%)	
	Right	Left	B/L		
Swelling	9	8	1	18 (60%)	78%
Swelling with Pain	7	2	3	12 (40%)	66%
Table 2. Comparison of Symptoms with Other Studies					

In a study by Alan Hair, 66% of patients presented with pain along with the swelling. The difference in the rate of presentation with pain between the two studies may be due to the fact that pain is a subjective phenomenon and varies from person to person, each having a different pain threshold level.

Side of Hernia

Side	Present Study (n=30)	Shinich ⁸ Hasegawa, et al (n=367) 2006	Bahadir Kulah ⁹ et al (2001)	O. Yener et al ¹⁰ 2011 (n=300)
Right	53.33%	50.4%	63%	60%
Left	33.33%	42%	37%	40%
Bilateral	13.3%	7.6%	0	0

Table 3. Comparison of Side of Hernia with Other Studies

As can be expected, the incidence of hernia is more common on the right side owing to the embryological fact that right testis descends later than the left and higher incidence of patent processus vaginalis on the right side.

The following table compares the findings of the present study with previous studies and gives consistent results. Present study is comparable with other studies. Higher bilaterality in the present study is attributed to smaller sample size.

Gender Distribution

All the patients in our study were males. This represents the low incidence of inguinal hernia in female in general population.

Occupational Incidence

In a study by M Bay Nielsen, the Various Occupations were classified as-

- Sedentary work.
- Walking, no heavy lifting.
- Intermittently strenuous work.
- Constantly strenuous work.
- Unspecified.

In a present series of 30 cases, hernia was most common in group of intermittently and continuous strenuous workers-farmers, manual labourers and conductors (60%). It was relatively less among sedentary workers group- shopkeepers, teachers and students (40%). This suggests that hernias occur more commonly in people involved in strenuous work, which could be the precipitating factor by increasing the intra-abdominal pressure.

The study made by Laue H et al (Surgery 2007 in Journal Royal College of Surgeons, Vol. 141 (20: 262-66) concluded that presence of hernia was associated with a higher work activity index and a higher total activity index.

Duration of Surgery

	Present Study 2016	Kingsnorth et al 2009	The BOOP ¹¹ Study 2008	Nienhuijs ⁹ S et al 2004	Chandir- amani ¹² VA et al 2003
Mean * SD	41 ± 4.7	34.1±9.6	37.4 ±1	42.0±24.6	35
Range	32-55 min		20-110 min		20-90 min

Table 4. Comparison of Duration of Surgery with Other Studies

The mean duration of surgery was 41 minutes for PHS repair.

This has been found to be more or less similar in other comparative studies.

Postoperative Pain

In this study, immediate postoperative pain was evaluated and scored based on visual analogue scoring. Patients with PHS repair had a score range of 1/10 to 5/10 requiring lesser number and dose of analgesics. The differences in the above-mentioned studies could be due to individual variation in the threshold of pain.

Post	Day 1 VAS-Mean	Day 2 VAS-Mean	Day 7 VAS-Mean
CS Huang et al ¹³ et al 2005 (n=218)	3	2.19	0.77
AJS ¹⁴ 2007 (n=321)	-	2.5	2
J Dalenback ¹⁵ et al 2009	3.5	2.5	2
Present Study	3.6	2.5	1.3

Table 5. Comparison of Postoperative Pain with Other Studies

Postoperative Complications

Wound Infection

Infection represents a dreaded complication for all types of surgeries and it is no different for inguinal hernia surgeries. Inguinal hernia surgeries complicated by infections have a higher rate of recurrence as the repairs are destroyed along with tissues.

In our study, there was 1 case (3.33%) of wound infection. This was managed by daily dressing and antibiotics based on culture sensitivity.

Seroma

1 case had seroma, which accounted for 3.33% of total population. This was managed by aspiration and evacuation of seroma and compression dressing. Suture removal was also delayed in this case.

Post	Wound Infection	Haematoma	Seroma	Scrotal/ Testicular Complications
Claudio Cord ¹⁶ et al 2011 (n=96)	1(1.04%)	1(1.04%)	2(2.08%)	2(2.08%)
The BOOP study ¹¹ : 2008 (n=1550)	6(3.8%)	14(9%)	0	0
Samir S. Awad AJS (n=193) 2007	2.8%	6.9%	0	0
Shinichi Hasegawa ⁸ et al 2006	9(2.3%)	6(1.5%)	6(1.5%)	0
Present Study (n=30)	1(3.33%)	0	1(3.33%)	0

Table 6. Comparison of Postoperative Complications with Other Studies

The rate of complications as compared to various other studies is found to be similar as in our study. The little differences in the complication rate obtained in our study could be due to a smaller sample size as compared to the other studies.

Duration of Hospital Stay

Mean duration of hospital stay was 4.6 days for PHS repair.

These results are attributed to less postoperative pain and wound infection experienced by patients undergoing PHS repair.

Return to Normal Activities

Study	Median (Days)	Mean (Days)
J Vironen et al BJS 2006	7	10.4
Present Study	9	10.6

Table 7. Comparison of Return to Normal Activities with Other Studies

AN Kingsnorth et al experienced that the use of the PHS mesh results in a better postoperative recovery in patients undergoing primary inguinal hernia repair. J Vironen et al conducted a randomised clinical and experienced that with PHS group of patient's time to return to daily activities ranged between 3 and 11 days.

Chronic Groin Pain

Chronic Pain	Nil	Minimal	Moderate	Severe
1 Month	25 (83.33%)	5 (16.67%)	0	0
3 Months	29 (96.67%)	1 (3.33%)	0	0
6 Months	30 (100%)	0	0	0

Table 8. Comparison of Chronic Groin Pain with Other Studies

A study by Berende¹⁷ CA (2007) demonstrated lower rates of persisting pain following PHS mesh repair. In a review article by Aasnang E, Kehlet H (in British Journal of Anaesthesia. Vol. 95, No.1, pp. 69 - 76) concluded that chronic groin pain is less after mesh repair when compared with non-mesh repair of hernia. However, Van Veen et al¹⁸ (2007) found that chronic postoperative pain seems to dissipate over time, thus requiring a longer duration of follow-up before drawing any conclusion.

Recurrence

Study	No. of Patients	Follow-Up Duration	Recurrence Rate
Kingsnorth et al 2009	206	6-12 months	0%
D Faraj ¹⁹ et al 2009	158	5.5 years	5 (2.3%)
The BOOP ¹¹ study 2008	155	3 years	2 (1.3%)
Samir Awad et al AJS ¹⁴ 2007	321	17 months	0.6%
Huang ¹³ 2005	234	25.8 months	0%
Hasegawa 2005	395	19.3 months	7 (1.8%)
Chandiramani ¹² et al 2003	46	6 months	0%
Present Study	30	6 months	0%

Table 9. Comparison of Recurrence with Other Studies

Recurrences are a burden to patients and occasionally prove ruinous in their lives. Financially, a recurrence represents not only wasted resources of the first operation, but also added financial and emotional expense of a second or

more operation (s). It frequently alters personal activities and for some patients it becomes the root of prolonged loss of time from gainful and productive employment, which requires expensive job rehabilitation. Based on the above chart, it is provided beyond doubt the PHS repair has the least recurrence rate and an ideal method in the treatment of inguinal hernia. However, judging the success of a hernia repair solely in terms of recurrence rates is too limiting.

Effectiveness of Pascal's Law

As Pascal's law states that "pressure in a closed space, when increased is distributed equally in all the directions." This holds good here in stabilising the underlay patch of Prolene hernia system.²⁰ If the patch or mesh is of larger size than the defect, the patch is then forced up against the inner surface of anterior abdominal wall and is stabilised in position by the very forces that tend to push the patch through the defect as during increased intra-abdominal pressure, eg. when the patient stands or strains will enhance deployment by flattening the underlay mesh against the inside of abdominal wall. By virtue of this law no suture fixation of the mesh is needed in PHS repair and it is kept in position by Pascal's law.

Cost Effectiveness

Prolene Hernia System mesh manufactured by PHS; Ethicon, Somerville, NJ, USA was used which was procured for Rs. 5,000/- to the patients. The cost of single layered prolene mesh used for Lichtenstein repair is available for Rs. 1,500/- to 3,000/-.

Though the cost of PHS mesh is expensive, the considerably lesser expenses incurred in procuring lesser number of analgesics and antibiotics owing to be decreased postoperative pain and wound infection and the possibility of reoperation due to one of least recurrence rates. Because of nil or minimal suturing required in fixation of the mesh, patient experience minimal postoperative pain. Also, it helps in faster healing and recovery with a much stronger wound. This leads to the conclusion that PHS repair is a cost-effective method in the inguinal hernia repair, where affordability is not a concern.

Due to its ability to completely obliterate the myopectineal orifice, it provides an added benefit of reducing femoral hernia, a property that gives an additional edge over the commonly employed Lichtenstein repair and other open methods.

Summary

- The mean age of the patients presenting with inguinal hernia was 54.8 years with majority of patients in the age group of 51 - 60 years.
- Farmers (36.67%) and labourers (20%) were commonly affected owing to their strenuous work.
- The most common presenting symptom was swelling along with accounting for 60% followed by swelling with pain 40%.
- Right-sided inguinal hernia (53.3%) was common compared to left (33.3%) with indirect inguinal hernia being more common than direct hernia.
- Chronic cough and BPH causing straining symptoms were the most common associated factors in 30% and 23.3% of cases respectively.
- The mean duration of surgery was 41 minutes.

- Immediate postoperative pain was 3.6 (mean) at 24 hrs. scored on a visual analogue scale.
- Patients with PHS repair experienced postoperative pain of lesser intensity and hence requiring fewer analgesics.
- Postoperative wound infection was seen in 1 case (3.3%).
- Postoperative seroma formation was seen in 1 case (3.3%).
- The mean duration of hospital stay was 4.6 days and the patients resumed normal activities by 10 days (mean) after Onlay-Inlay Mesh (PHS) repair.
- None of the patients had chronic groin pain at 6 months follow-up.
- Patient's acceptance with Onlay-Inlay Mesh (PHS) repair is good.
- Hence, the repair of inguinal hernia with the Onlay-Inlay (PHS) mesh appears to be a safe and a feasible procedure in our Indian population with lower rates of complications recurrence and late symptoms.

CONCLUSION

The repair of a simple inguinal hernia or a recurrent hernia is no longer just the sewing together of a defect in the musculature. Present day hernia operations require that the surgeon fully understand the function anatomy and pathophysiology of the abdominal wall and groin, and the mechanism that help in prevention of recurrence of hernias. The ideal inguinal hernia repair should provide effective coverage of the myopectineal orifice, have the lowest possible recurrence rate, have minimal operative and postoperative discomfort and allow rapid return to normal activities. Furthermore, it should be cost effective and ideally should be applicable to most types of hernias encountered.

The Onlay-Inlay Mesh tension free mesh repair is a simple, straight forward technique without the need for complex instrumentation without compromising the safety or the long-term success of the procedure.

It permits a repair at the level of transversalis fascia with added security of only patch to reduce the likelihood of recurrence by protecting the entire myopectineal orifice.

Preperitoneal dissection is technically demanding in the initial cases of learning curve. But the procedure is technically easy to master and likely to lend to fewer recurrences.

The PHS techniques have shown acceptable short-term results. This procedure is characterised by a short learning curve, short duration of the procedure, low complication rate and is applicable for all types of inguinal hernias.

This technique can well be used in all patients more than 20 years of age and it being a soft and pliable mesh incidence of chronic groin pain is reduced.

Results among general surgeons utilising the PHS are equivalent to those of hernia specialists.

The PHS is, therefore, an exceptionally fit procedure to implement in a regional surgical training facility. These acceptable results are getting more pronounced during long-term follow-up, as both the recurrence rate and the presence of chronic pain are consistently low.

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