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Randomized trial to compare efficacy of polyester mosquito net mesh with polypropylene mesh in inguinal hernia surgery in northwestern India

Sanchit Jain[1], Abhishek Agarwal[2], Lakshman Agarwal[3], Laxmi Narayan Meena[3], Sumita Jain[3], Mohit Jain[3]

ABSTRACT

Objectives: Lichtenstein repair using mesh prosthesis is one of the most common repairs for inguinal hernia. In our country, the price of mesh contributes to a major portion of the total cost of the procedure. The study was conducted to compare the incidence of postoperative complications of using low-cost polyester mosquito net mesh with that of commercially available polypropylene mesh for inguinal hernia surgery by Lichtenstein repair and taking into consideration the cost of the operation.

Methods: The study was a prospective randomized double-blind single-centre (government medical college) study. The study was conducted at SMS Medical College and Hospital, Jaipur, India, on 170 patients with inguinal hernia (45 bilateral and 125 unilateral) undergoing inguinal hernia surgery. Patients were randomly assigned to receive either of the meshes, and study of postoperative complications was carried out with follow-up of up to 1 year. The average cost of the procedure was also calculated. Chi-square test and Student's t-test were applied for significance testing (p-value ≤ 0.05, significant; p-value < 0.001, highly significant).

Results: No significant difference in incidence of postoperative complications between the two groups was observed. However, the cost of the operative procedure using the polyester net mesh was significantly lower (p-value < 0.0001).

Conclusions: The results of the short-term follow-up clearly demonstrate that the incidence of postoperative complications from using polyester net mesh is well comparable with that of commercial polypropylene mesh. Using polyester mesh significantly reduces the cost of surgery and therefore it has a role in resource-limited settings.

Key words: *Inguinal hernia, mosquito net, lichtenstein repair, low cost*

Introduction

Inguinal hernia surgery remains one of the most commonly performed general surgeries. Lichtenstein first popularized the concept of employing synthetic mesh prosthesis to bridge the defect, as it was recognized that tension in hernia repair is the chief cause of recurrence [1]. The purpose of surgical mesh in hernia repair is to reinforce and replace tissue for long-term stabilization of the abdominal wall. Over the years, it has been proven that mesh repair procedures reduce hernia recurrence rates by 50–75% in comparison to non-mesh techniques [2, 3].

The use of synthetic mesh was a milestone in hernia repair and led to the development of many other mesh products of various polymer types, densities and elasticity. Various types of prosthetic materials are used

Author affiliations : *Department of General Surgery, [1]RUHS College of Medical Sciences, Jaipur, India [3]SMS Medical College, Jaipur, India [2]Department of GI Surgery, AIIMS, New Delhi, India*

Correspondence : *Sanchit Jain, MS, Department of General Surgery, RUHS College of Medical Sciences, Jaipur, India. e-mail: sanchit4088@gmail.com*

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in the tension-free Lichtenstein repair. All these materials cause an early and late inflammatory response after implantation, the quantity and quality of which is related directly to the material used. Since its inception in 1962, polypropylene has satisfied all the requirements of an ideal mesh and is the best material available today, but its cost continues to be a limiting factor [4]. Polyester (used and available as mosquito net) looks and feels like polypropylene mesh and is well comparable to it in terms of various properties.

There is a need to provide cost-effective inguinal hernia repair to decrease the unrecognized burden of this disease. Mosquito net made from 100% polyester is easily available and it may be used in place of conventional, costly commercial mesh for cost-effective repair. Many studies have evaluated the use of mosquito net mesh in inguinal hernia surgery (Tongaonkar et al. [5], Freudenberg et al. [6], Clarke et al. [7]).

The present study was carried out to assess and compare the occurrence of postoperative complications after the use of polypropylene mesh and polyester mosquito net mesh in inguinal hernia repair and the cost effectiveness of using polyester mesh in terms of total operative procedure cost (in Indian rupees, Rs). The study was registered with the Clinical Trial Registry of India (CTRI/2014/09/004985).

Materials and Methods

The study was conducted at the Department of General Surgery, SMS Medical College, Jaipur, India, with the permission of the Research Review Board and Ethical Committee of the hospital. The study was a hospital-based, double-blind randomized control interventional study. The study was conducted from October 2011 to August 2012. During this period, a total 170 cases with 215 inguinal hernias (125 unilateral and 45 bilateral) underwent reparative surgery and were included in the study. The eligibility criteria of the present study were as follows:

Inclusion Criteria

1. Patients were 14 years of age or older, irrespective of sex, and seen at the Department of General Surgery, SMS Hospital.
2. Patients with diagnosis of inguinal hernia confirmed during surgery irrespective of type.
3. Patients classified under American Society of Anaesthesiologists (ASA) Grade 1 and Grade 2.
4. Patients provided consent to undergo inguinal hernia surgery using either of the meshes.

Exclusion Criteria

1. Patients presenting with recurrent hernia irrespective of type of repair done previously.
2. Patients presenting with features suggestive of strangulated or obstructed hernia.
3. Immunocompromised patients.
4. Patients classified under ASA grade 3 or above.
5. Patients not providing consent.
6. Patients suffering from hemorrhagic tendency.

Randomization technique: A simple randomization technique through the chit box method was used to allocate random selection of a particular case to one of two groups, i.e., polyester or polypropylene. For bilateral hernias, the patients themselves acted as their own controls, with polyester mesh being placed on one side and polypropylene mesh on the other side.

The CONSORT (CONsolidated Standards of Reporting Trials) 2010 flow chart [8] depicting how the study population was recruited and managed during the study can be seen in Figure 1.

Materials used included:

- Polypropylene mesh: 7.5 × 15 cm mesh composed of commercially available, non-absorbable polypropylene material.
- Polyester net mesh: Polyester net is available in the market as knitted mosquito net (made of 100% polyester). The net was cut into 7.5 × 15 cm pieces. The pieces were cleaned with alcohol and water and then packed into cotton gauze. These packets were then sterilized in the hospital autoclave before use. The mesh underwent steam sterilization at 121°C for 20 min, and temperature-sensitive autoclave tape ensured adequate sterilization. The mosquito net used was not impregnated with insecticides. Preoperative consent forms were signed by every patient to indicate that they were willing to undergo surgery with either of the meshes. Lichtenstein hernioplasty was performed with some modifications under spinal anesthesia using 5% heavy lignocaine. Instead of suturing the mesh in a continuous running fashion, it was fixed at multiple places by interrupted sutures. All patients were operated on by the same team of general surgeons. Detailed operative

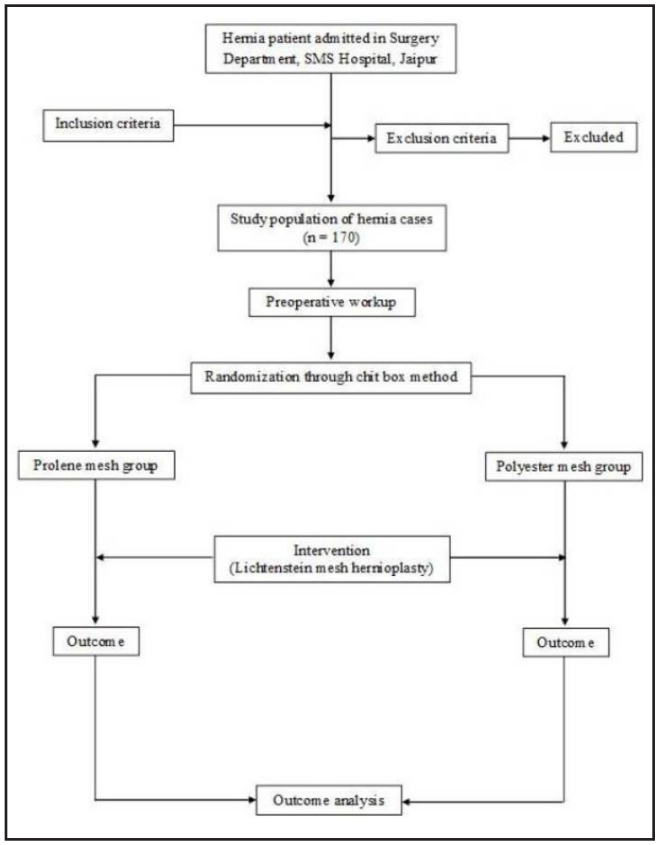

Figure 1. Flowchart depicting how the study population was recruited and managed.

notes were written, including information on the side on which the hernia was located and the type of hernia.

Postoperative pain in all patients was evaluated using the Visual Analogue Scale (VAS) at 6 hours and 24 hours. For patients with bilateral hernia, pain was evaluated for both sides separately. Patients were advised to carry out their day-to-day activities immediately after recovering from the effects of anesthesia. Patients were encouraged to sit up and move about in the evening. They were allowed to take nutrition orally from evening. Patients were discharged on postoperative day 1 and were given antibiotics and analgesics for 5 days.

All patients attended follow-up on postoperative day 8, when the sutures were removed, and on postoperative day 15, 1 month after surgery, 3 months after surgery and 1 year after surgery. In addition, patients were advised to report as and when required if they had any complaint. On each follow-up, a detailed local examination was performed to detect seroma, hematoma, stitch abscess, gross infection, signs of mesh rejection or recurrence of hernia.

Performa was filled up for each patient, and data were compiled using IBM-SPSS 20 software and were subjected to statistical analysis. An unpaired t-test was used to determine the significance in comparisons of the difference of means of both groups. The chi-square test was used to determine the significance in comparisons of the difference in proportions in the groups (p-value ≤ 0.05, significant; p-value < 0.001, highly significant).

Results

Out of 170 patients presenting with inguinal hernia during the study period, 168 were men and only 2 were women (1.17%). The 2 women were equally distributed in both groups. The variables evaluated in both groups are shown in Table 1.

Overall, both groups were well comparable in terms of demographic characteristics. The highest number of hernia cases was in the 61–70-year age group. Unilateral hernias had a bimodal peak in the 41–50- and 61–70-year age groups, while bilateral hernias were most common in patients aged 61–70 years. Hernias occurred more frequently on the right side in both groups. Overall, the ratio of right- to left-sided hernias was 1.15:1.

The most common type of hernia in both groups was direct hernia. Overall, the incidence of direct hernia was 48.83%, that of indirect hernia was 39.53%, and mixed or pantaloon hernia was found in 11.62% in the study population.

Postoperatively, pain was evaluated at 6 hours and 24 hours using VAS. In our study, there was a significant difference in the mean pain score between the two groups, with a higher mean score in the polypropylene mesh group at 6 hours but not at 24 hours.

The number of hernia cases developing urine retention in the postoperative period was 15 out of 215 (6.97%). No significant difference was noted in the groups with regard to postoperative urine retention.

Among the various complications, only minor complications were seen, and there was no major complication. Seroma was the most common minor complication. Overall, seroma incidence was 6.04% (13 out of 215 hernias). The incidence of seroma in the polyester group was 5.60% (6 out of 107 hernias) and incidence in the polypropylene group was 6.48% (7 out of 108). No significant difference was found between the two groups with regards to seroma formation. In our study, seroma was diagnosed clinically, and aspiration was performed under sterile precautions. None of the

Table 1. Various variables evaluated in the study groups.

S. No.	Variables		Polyester Group N=107	Polypropylene Group N=108	P-Value
1	Age (Mean ± SD)		51.56 ± 16.26	51.68 ± 16.91	0.959
2	M:F		106:1	107:1	0.995
3	Side	Right	59	56	0.629
		Left	48	52	
4	Type	Indirect	47	38	0.462
		Direct	50	55	
		Mixed	11	14	
5	Pain at 6 hr postoperatively (Mean ± SD)		4.18 ± 0.81	4.44 ± 0.82	0.02
6	Pain at 24 hr postoperatively (Mean ± SD)		2.50 ± 0.81	2.63 ± 0.90	0.253
7	Urine retention		8	7	0.776
8	Seroma		6	7	0.788
9	Hematoma		2	1	0.555
10	Superficial infection		2	4	0.414

Table 2. Comparison of results of studies based on mosquito net mesh.

Study	Mesh used (number)	Minor complications	Major complications
Tongaonkar et al[5]	Mosquito net – polypropylene with polyethylene (359)	25	1(Recurrence)
	Polypropylene (44) + Marlex (16)	6	None
Freudenberg et al[6]	Mosquito net – polyamide (18)	None in both groups	None
	Ultrapro® - polypropylene with polyglactin (18)		
Clarke et al[7]	Mosquito net – polyester (106)	7	None
Present study	Polypropylene (108)	12	None
	Polyester mosquito net mesh (107)	10	

patients developed recurrence of seroma formation or any other complication.

Another complication noted was hematoma formation. Overall, the incidence was 1.39% (3 out of 215 hernias). No difference was found between the two groups with reference to hematoma formation. In all 3 patients, the hematomas were aspirated, and compression dressing was applied. None of them had any further complications upon follow-up. In the polypropylene group, the incidence of hematoma was <1%; that in the polyester group was 1.86%.

Two types of infection may be described in relation to prosthesis repair: superficial subcutaneous infections and infections around the mesh. Superficial infection includes stitch abscess, while the second category requires vigorous antibiotic therapy and drainage of infected collection. Minor superficial infection was seen in 6 out of 215 hernias (2.79%). All cases were managed conservatively by antibiotic therapy. None of the patients required incision and drainage. None of these patients developed any other complications.

All patients reported for follow-up at 3 months. At 1 year, 16 patients were lost to follow-up, out of which 3 had bilateral hernia. None of the remaining patients in either group showed any signs of gross infection, mesh rejection or recurrence of hernia.

The total cost of surgery using polypropylene mesh was compared with that of polyester net mesh. The average cost of surgery using polypropylene mesh was about Rs 1700, while that for polyester mesh was Rs 605. The cost includes the cost of the mesh and other disposable items. This difference was highly significant, with a p-value < 0.001. It was noted that the most important factor limiting the use of mesh for hernia repair was its cost. Comparison of the various characteristics of polyester net mesh with that of polypropylene mesh

revealed that polyester mesh had a greater pore size (>2 mm) than polypropylene mesh (1–2 mm). Polyester mesh was thinner than polypropylene mesh, but it could withstand a higher bursting pressure.

Discussion

Hernia repair is among the most frequently performed surgical procedures around the world, yet many cases are left untreated due to the lack of adequate and affordable surgical care. This is especially the case in the developing and underdeveloped nations. The accumulation of chronic cases can lead to severe and emergent presentations such as incarceration, strangulation, and so on. Many patients cannot afford tension-free repair, the main constraint being the expensive surgical mesh. As health expenditures increase, there is a need to search for a low-cost alternative to commercially manufactured surgical mesh to render hernia repair widely available and cost-effective.

Of the various polymers, the predominantly used material for hernia repair is based on polypropylene or polyester. Between the two, polypropylene is preferred. Since its 1962 introduction, polypropylene has satisfied most of the criteria of an ideal mesh.

There have been many studies comparing the two meshes. Klosterhalfen et al. [9] studied the tissue reaction of these meshes in rats. They noted that although polyester has a tendency to form early seromas, its use appeared to be more favorable than polypropylene.

Sadowski et al. [10] compared quality of life and chronic pain after polypropylene and polyester mesh placement in inguinal hernia and found no difference between the two groups.

One of the first studies to be conducted using mosquito net mesh for hernia repair was by Tongaonkar et al. [5]. Mosquito net made of polypropylene with polyethylene was used in the study. The surgical results of the mosquito net mesh were compared with that of polypropylene and Marlex mesh. They concluded that mosquito net has properties similar to synthetic mesh and can be safely used for hernioplasty, and is a cost-effective replacement for routinely used mesh. Seroma formation occurred in 1.12% and hematoma in 0.84% of the mosquito net mesh group only. However, in our study, a higher incidence of seroma (6.04%) and hematoma (1.39%) were recorded. Interestingly, Clarke et al. [7] reported a much higher incidence of hematoma formation (4.71%).

Tongaonkar et al.[5] reported an incidence of superficial infection of 4.7% in the mosquito net group and 6.66% in the polypropylene+Marlex mesh group. However, this type of infection occurred less commonly in our study (2.79%).

Tongaonkar et al.[5] also reported gross infection in 0.28%, mesh rejection in none and hernia recurrence in a single patient only. It is pertinent to mention that none of these complications was noted in the present study.

Freudenberg et al. [6] compared the results of commercial Ultrapro mesh with mosquito net mesh made from 100% nylon and found no significant difference in the short-term outcomes of hernia treatment or surgeons' ease in handling the two materials. They concluded that nylon mosquito net may be an alternative to commercial mesh when the latter not available or not affordable.

Clarke et al. [7] conducted a 5-day 'Operation Hernia" mission in Ghana, where a total 95 patients underwent Lichtenstein repair using polyester mosquito net mesh. The surgeons' ease of handling and incidence of complications were evaluated at 6 weeks and 6 months postoperatively. Only 7 patients had minor complications. Ease of handling improved after the first 2–5 cases. They concluded that the mesh represents a cost-effective alternative to commercial meshes in developing countries, with a low rate of early complications and similar short-term recurrence rates.

It is noteworthy that the results of our study were well comparable to the abovementioned studies (Table 2).

Regarding the best method to safely sterilize mosquito net mesh, Stephenson and Kingsnorth [11] evaluated the various methods of mesh sterilization. The meshes used in the studies conducted by Tongaonkar et al. [5] and Clarke et al. [7] were evaluated. They found that most commercial companies use ethylene oxide for sterilizing polymer-based products but that steam sterilization is the most practical and widely available method for low-income countries if adequate temperature control is maintained. Even in our study, the steam-sterilized mesh produced successful results.

In a review article, Sorensen and Rosenberg [12]

concluded that both short-term and long-term outcomes with these non-commercial meshes appear good.

In the present study, the sample size used to compare the two meshes was small, so the results, although encouraging, require a more detailed study with a larger number of cases. Follow-up was performed only up to 1 year, although it is known that hernia recurrence can occur years later. Therefore, even though the results of using polyester net mesh in inguinal hernia repair are promising, a study with a large number of cases with a long follow-up over multiple centers is warranted.

Conclusions

The use of low-cost polyester mosquito net mesh for inguinal hernia repair is not only cost-effective, but also produces results that are well comparable with that of the commercially available polypropylene mesh, hence it should be considered for hernia repair where cost is a constraint factor. Therefore, it is recommended that the application of such products can not only help reduce government healthcare expenditure remarkably, but also reduce the accumulation of untreated hernias.

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Conflict of Interest

The authors declare no conflicts of interest.

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