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A Randomised Control Trial in Comparison of Polypropylene Mesh Versus Polyester Mesh in Open Inguinal Hernia Repair

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ABSTRACT

One of the most common surgical problems presenting to the surgical OPD is Inguinal Hernia. Surgery being the main treatment for hernia, surgical techniques of inguinal hernia have undergone great development over centuries and decades. Lichtenstein's tensionless hernia repair has revolutionized the procedure. It is one of the first surgeries learnt by a surgery resident. While hernia recurrence rates have drastically been brought down by the placement of mesh, post operative pain has become more troublesome in herniorrhaphy. Polyester is a softer pliable material than the routinely used polypropylene mesh offering the benefit of less post operative pain and improved quality of life Prospective single blinded randomized control trial involving 144 patients assigned to receive lichtenstein repair with polyester mesh (n=72) or polypropylene mesh (n=72). All the patients were operated on by a single surgeon to maintain uniformity and made sure that ilioinguinal, iliohypogastric and genitofemoral nerves were identified intraoperatively and preserved. Patients were observed in the hospital and visual analogue score for pain was recorded postoperatively at 12 hours, 24 hours, 48 hours, 1 week, 1 month and 3 months complications were also noted down and analyzed using two sample t test for continuous variable and Chi-square test for categorical variables. The conclusion from this study is that usage of Polyester mesh is comparable and slightly superior to that of Polypropylene in view of Post operative Pain, duration of Stay in the Hospital and patient acceptance. Further studies are needed to find the optimal mesh for inguinal hernia repair.

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INTRODUCTION

Hernia means to bud or to protrude, to off shoot in Latin. Hernia is the protrusion of an organ or part (such as the intestine) through connective tissue or through a wall of the cavity in which it is enclosed. Among abdominal wall hernias, inguinal hernia remains the commonest variety which accounts for about 75% due to the presence of the natural weakness of internal inguinal ring and cord structures. Inguinal hernia shows a bimodal peak, the first peak before age of 1 year and the second peak found after the age of 40 years. Surgical techniques for inguinal hernia have undergone an evolution over the centuries. From the initial days of conservative man-

agement with TRUSS to an era of surgical procedures reserved for complicated hernias to present day open and laparoscopic procedures. The advent of mesh has made it possible to bridge the gaps without tension and to repair all hernias irrespective of size and shape. The most commonly used open technique for hernia repair is Lichtenstein's tension free repair with mesh placement. It is one of the first surgeries mastered by the junior resident owing to its easy learning curve and safety. Tension free mesh placement techniques have resulted in a decrease in the recurrence rates, but post operative pain continues to be a foregoing problem. New mesh products offer the potential to decrease pain without compromising the recurrence rate. There are three main groups of mesh available: polypropylene, polyester and polytetrafluroethylene. Polypropylene meshes used in hernia repair, being a hydrophobic material causes a certain degree of contraction and scar formation which results in an increased incidence of post operative pain due to scarring and contracture [1, 2]. Polyester being hydrophilic and pliable material is associated with increased tissue ingrowth and lesser fibrous encapsulation and better post operative tolerance in terms of pain.

Polyester also has been used as an implant material in form of vascular grafts with good safety record [3]. The main aim of the study was to collate the post procedure outcomes of the usage of polypropylene and polyester mesh in open inguinal hernia repair in terms of post operative pain, post operative complications like seroma, infection, recurrence and duration of hospital stay and determine which mesh is associated with a better outcome.

MATERIALS AND METHODS

A prospective single blinded randomized control trial involving 144 patients who underwent Lichtenstein tension free repair was divided equally into 2 groups Group A - polypropylene mesh (n=72) and Group B polyester mesh (n=72). The study was initiated after institutional ethical committee clearance [IEC 1944(A) dated 29/05/2020]. The sample size was calculated according to the number of patients with a diagnosis of inguinal hernia being reported to SRM Hospital General Surgery OPD and being operated on in a month by applying the same size on the formula $n=(Z\alpha+Z1-\beta)^2$ (P1Q1 +P2Q2)/$(P1-P2)^2$ n= 7.84 (475+1600)/ 225 gave the sample size as 72 in each group. Patients were blinded to the mesh they received and remained blinded throughout the follow up. Patients older than 18 years, without any previous surgical history and who were willing to participate were included in the study. Ultrasonogram was done in all the male patients beyond 40 years of age to look for prostate volume and post voidal residual urine to rule out benign prostatic hyperplasia. After anaesthesia clearance, the patients underwent elective inguinal hernia repair under spinal anaesthesia.

All the patients were administered a single dose of intravenous antibiotic for surgical site infection prophylaxis. In the post operative period, T. Paracetamol 500 mg BD was given for 2 days and additional analgesics were given according to requirement and recorded. The pain was recorded in all patients using a visual analogue scale at 12 hours, 24 hours, 48 hours in the hospital and 1 month, 3 months and 6 months on an outpatient basis. At any time postoperatively if a patient reported intractable nausea/vomiting, pain or signs of wound infection he or she was scheduled for visit evaluation.

Statistical Analysis

The statistical analysis was done using SPSS software version 21. The statistics were done using Levene's test (for equality of variances and t-test for equality of means), Pearson Chi-square test and Mann-Whitney test and Wilcoxon test.

RESULTS

A total of 144 patients were enrolled and randomized to receive either polyester or polypropylene mesh, with 72 patients in each group. Table 1 shows the Chi square test for the pain scale comparing polypropylene and polyester mesh after 12 hours of the procedure showed that pain was slightly higher in the polypropylene mesh group but statistically insignificant as the Pearson Chi square value was 0.215.

Table 2 shows the Chi square test for the pain scale among the mesh groups after 24 hours of the procedure showed that the pain was more among the polypropylene mesh group than the polyester and it was statistically significant as the Pearson Chi square value was .00.

Table 3 shows the Chi square test for the pain scale among both the mesh groups after 48 hours of the procedure showed that the pain was more among the polypropylene mesh group than the polyester and it was statistically significant as Pearson Chi square value was .00.

Table 4 shows a Pain comparison of the polypropylene and polyester mesh group 1 week post operatively in which 70 patients out of 72 patients 97.2% in the polyester mesh group had no pain and 38

Table 1: Summary Statistics — 12 hours of pain

			Mesh Type		Total
			Polypropylene (Group A)	Polyester (Group B)	
12 Hours	Mild To Moderate Pain	Count	62	68	130
		% within Mesh Type	86.1%	94.4%	90.3%
	Moderate Pain	Count	6	3	9
		% within Mesh Type	8.3%	4.2%	6.3%
	Moderate To Severe Pain	Count	4	1	5
		% within Mesh Type	5.6%	1.4%	3.5%
Total		Count	72	72	144
		% within Mesh Type	100.0%	100.0%	100.0%

Table 2: Summary Statistics – 24 hours pain

			Mesh Type		Total
			Polypropylene (Group A)	Polyester (Group B)	
24 Hours	Mild Pain	Count	22	58	80
		% within Mesh Type	30.6%	80.6%	55.6%
	Mild To Moderate Pain	Count	49	14	63
		% within Mesh Type	68.1%	19.4%	43.8%
	Moderate Pain	Count	1	0	1
		% within Mesh Type	1.4%	.0%	.7%
Total		Count	72	72	144
		% within Mesh Type	100.0%	100.0%	100.0%

Table 3: Summary Statistics – 48 hours of pain

			Mesh Type		Total
			Polypropylene (Group A)	Polyester (Group B)	
48 Hours	No Pain	Count	4	39	43
		% within Mesh Type	5.6%	54.2%	29.9%
	Mild Pain	Count	63	33	96
		% within Mesh Type	87.5%	45.8%	66.7%
	Mild To Moderate Pain	Count	5	0	5
		% within Mesh Type	6.9%	.0%	3.5%
Total		Count	72	72	144
		% within Mesh Type	100.0%	100.0%	100.0%

patients out of 72 patients 52.8% in the polypropylene mesh group had no pain and it was statistically significant as Pearson Chi square value was .00.

Table 5 depicts the pain comparison of the polypropylene and polyester mesh group after 1month of the procedure revealed mild pain noted in 8.3% of the polyester mesh group and 9.7% of the polypropylene group, but it was statistically insignificant as the Pearson Chi square value was .771

None of the patients of the polypropylene and polyester mesh groups was found to be having pain at 3 months and 6 months.

Figure 2 depicts the Additional pain requirements among the mesh groups where 31.9 % of patients in the polypropylene mesh group and 26.4% of patients in the polyester mesh group required additional analgesics during the post operative period

Table 4: Summary Statistics – 1-week pain

			Mesh Type		Total
			Polypropylene (Group A)	Polyester (Group B)	
1 Week	No Pain	Count	38	70	108
		% within Mesh Type	52.8%	97.2%	75.0%
	Mild Pain	Count	34	2	36
		% within Mesh Type	47.2%	2.8%	25.0%
Total		Count	72	72	144
		% within Mesh Type	100.0%	100.0%	100.0%

Table 5: Summary Statistics – 1-month pain

			Mesh Type		Total
			Polypropylene (Group A)	Polyester (Group B)	
1 Month	No Pain	Count	65	66	131
		% within Mesh Type	90.3%	91.7%	91.0%
	Mild Pain	Count	7	6	13
		% within Mesh Type	9.7%	8.3%	9.0%
Total		Count	72	72	144
		% within Mesh Type	100.0%	100.0%	100.0%

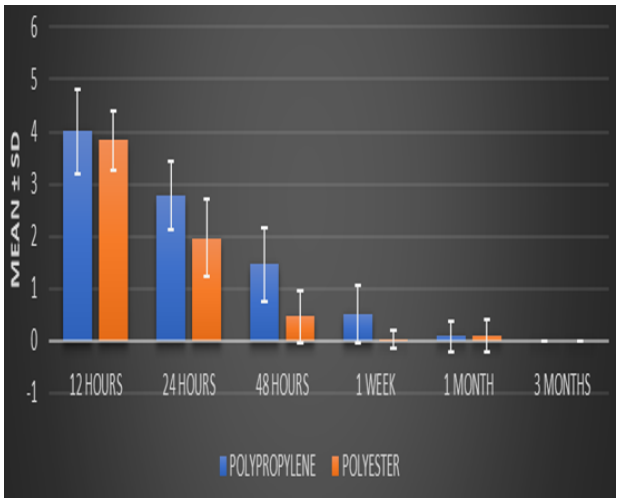

Figure 1: Overall comparison of post operative pain among polypropylene and polyester mesh groups

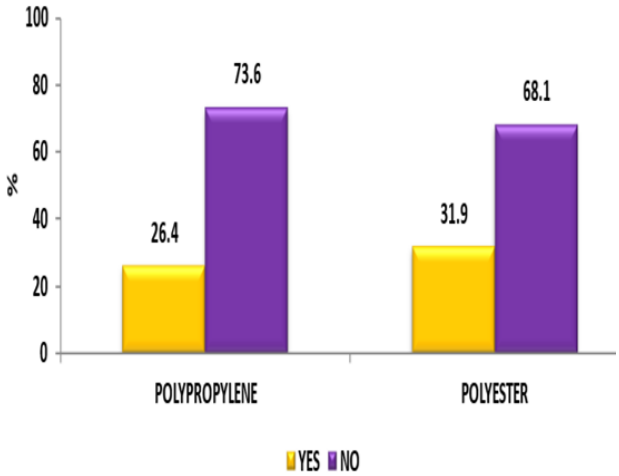

Figure 2: Comparison of additional pain requirements and mesh type

but it was statistically insignificant.

Figure 3 depicts the seroma between two mesh groups. There was no statistical significance noted in seroma formation among the two mesh groups (Figure 3). No wound infection or recurrence was noted among both the mesh groups during the period of the study.

The mean duration of hospital stay was found to be more in the polypropylene mesh group when compared to that of the polyester mesh group as shown in Figure 4.

DISCUSSION

Around 20 million groin hernia repairs are performed per year worldwide. Almost 100 years following Bassini's description, Lichtenstein tension-free Onlay mesh placement has been considered the standard care. Great progress has been made with respect to the recurrence rate among hernioplasty

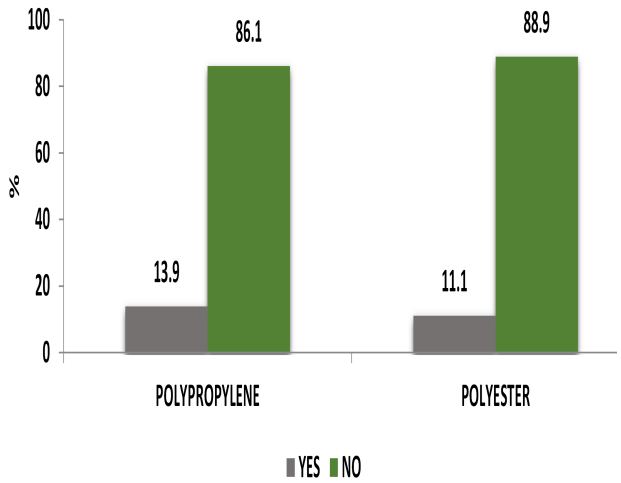

Figure 3: Comparison of seroma between two mesh groups

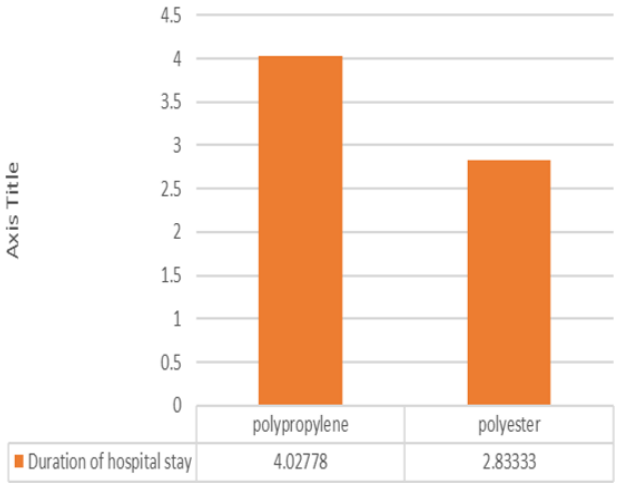

Figure 4: Comparison of duration of hospital stay

with the introduction of prosthetic meshes. The prosthetic mesh was first used in 1944 by D.E.

Acquaviva of Marseille (France). He presented the first use of a synthetic mesh - nylon in a manner that eliminated hernia and tension while leaving a defect intact. He tried different materials and finally arrived to use polypropylene, introduced as Marlex 50. The prosthetic mesh used in surgery induces an inflammatory reaction and scarring [4]. The societal costs in terms of lost productivity due to post operative pain and work hours loss are potentially great. More than 50% of patients reported that postoperative pain has affected their social activities [5, 6]. Newer mesh products are associated with reduced pain than conventional polypropylene mesh. Polyester mesh is a soft, pliable material which was initially used for hernia repair in the united states. Polyester meshes have been considered to initiate an early intense inflammatory reaction that stimulates greater tissue ingrowth and integration. Higher connective tissue is associated with lesser mesh contraction and lesser fibrous encapsulation and lesser stiffness around the mesh than the polypropylene mesh. This resulted in the sensory nerves being less likely to be pulled, stretched or constantly irritated by a firm piece of mesh or capsule surrounding the mesh thus resulting in lesser pain postoperatively [7]. In this study, the polyester mesh was compared to standard polypropylene mesh in Lichtenstein tension free hernia repair. The study was single-blinded and randomized, performed in an effective study format, which aims to compare results that would be expected in real world practice. Well validated outcome measures to evaluate the post operative pain were carried out. Groups were well matched through the randomization process.

Figure 1 shows, the polyester mesh group was found to have reduced post operative pain at 24 hours, 48 hours and 1 week post surgery with a significant difference in pain when compared to polypropylene group. B Sadowski et al [7]. Similarly compared polypropylene versus polyester mesh with respect to post operative pain and concluded that there was no significant difference in the post operative pain at 2 weeks and 3 months.

Several studies have shown that handling of ilioinguinal, iliohypogastric and genitofemoral nerves may affect post operative pain while a study by Wilfred Lik-Man Mui et al showed less post-operative pain in the routine division of the ilioinguinal nerve [8]. However, our study did not dictate how to handle the nerves rather it described how they were handled. In every case in our study attempt was made to identify ilioinguinal, iliohypogastric and genitofemoral nerve intraoperatively and were preserved.

Even though there was a significant difference in pain scores with lesser post operative pain among polyester 24 hours, 48 hours and 1 week post operatively, at 1 month there was no statistical significance between the pain scores of both mesh groups.

7 patients in the polyester mesh group and 8 patients in the polypropylene mesh group developed seroma which was statistically insignificant as the p value was .614 and most of the patients with seroma were managed conservatively. There were no recurrences or wound infections in both group during the study period. Michael.J.Rosen et al [9] studied polyester meshes and their long-term follow-up and concluded that there was no increased risk of recurrence or mesh infection.

The average hospital stay was higher among the

polypropylene group than the polyester group in our study of 144 patients which were similarly noted in a study conducted by Akshay Sutaria et al [10] who compared the post operative hospital stay duration among polypropylene mesh and polyester mesh concluded that the duration of hospital stay was seen to be slightly longer in polypropylene mesh group patients.

CONCLUSION

The usage of polyester mesh in open inguinal hernia repair has been associated with lesser early and intermediate post operative pain and shortens the duration of hospital stay. There were reduced additional analgesic requirements in the polyester group when compared to the polypropylene group. There was no difference in seroma formation, wound infection or recurrence rate among the study groups. Polyester meshes can be considered a safe and effective alternative to polypropylene mesh with good overall post operative outcomes.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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