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COMPARISON OF STAPLES AND POLYPROPYLENE SUTURES FOR SECURING THE MESH IN LICHTENSTEIN'S TENSION-FREE INGUINAL HERNIA REPAIR IN TERMS OF POSTOPERATIVE PAIN

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Abstract

Background: *For securing the mesh in Lichenstein tension free inguinal hernia mesh repair, polypropylene suture has been used traditionally. However, the staples made from stainless steel, offers advantage of easier placement and result in remarkable reduction in wound closure time and postoperative pain.*

Objective: *To compare the outcomes of staples and polypropylene suture for mesh fixation in patients undergoing elective Lichtenstein tension free mesh repair for inguinal hernia in terms of post-operative pain.*

Material and Methods: *From November 2023 to July 2024, this randomized controlled trial was conducted with 168 male patients with age 20-60 years who were randomly assigned to either staples (Group-A) or suture (Group-B). Post-operative pain was assessed using Visual Analogue Scale over one-week follow-up. Data were analyzed using SPSS, employing Chi-square tests to compare pain intensity between groups.*

Results: *The Group-A, with a mean age of 47.33±13.79 years, showed lower pain levels compared to Group-B (47.10±11.60 years). Pain on the first postoperative day was notably higher in Group-B, with 89.3% reporting moderate pain, compared to 66.7% in Group-A ($p<0.001$). By the seventh day, 100% of Group-A patients reported mild pain, whereas 31% of Group-B continued to experience moderate pain ($p<0.001$).*

Conclusion: *Performing Lichtenstein inguinal hernioplasty and anchoring the mesh with staples in comparison with polypropylene suture results in reduction in both the average operative time and postoperative pain.*

INTRODUCTION

Hernia repair is a prevalent surgical procedure performed worldwide (1-3). Inguinal hernia accounts for 73% of all different types of hernia cases, with a lifetime risk 27% in males and 3% in females (2,4). More than 20 million patients undergo inguinal hernia repair per annum globally (5). In Pakistan, the prevalence of inguinal hernias is considerable, impacting both males and females (6).

The notion of "Tension-Free hernioplasty," has transformed hernia management by reducing tension in the inguinal canal structures which was pioneered by French surgeons J. Rives and R. Stoppa (7,8). For the first time, a polymer mesh was employed during the hernia repair procedure to separate the peritoneum and the transversalis fascia. In 1993, Lichtenstein modified this approach by introducing

polypropylene mesh above the transversalis fascia based on his study of 3,125 hernioplasties (9). Hence, Lichenstein tension free inguinal hernia mesh repair is, therefore, considered as the gold standard procedure for inguinal hernia by American College of Surgeons. (10)

The basic principle of inguinal hernia surgery is the tension-free closure of defect preferably by using mesh (11). Lichtenstein hernia repair involves reducing the herniated viscus back into the peritoneal cavity and then reinforcing the inguinal canal floor with a Polypropylene mesh (12). The conventional method to place the mesh over the defect is by polypropylene suture, which is a complex and important surgical step to prevent migration, wrinkling and curling the mesh. (13-14) Innovations in surgical interventions are continually evolving to reduce operative time and postoperative complications. One notable advancement is the use of staples in Lichtenstein inguinal hernioplasty (17-18). The first author to describe staple modification to this technique, Egger et al. emphasized the advantage of shorter operating time (15). Mills et al. prospectively studied 50 patients that were operated using sutures or staples (16). This technique significantly reduces operating time and postoperative pain compared to traditional sutures, benefiting both patients and hospitals by decreasing workload and improving recovery times (19-21).

A study by Khan reported the mean operative time was 42.44 +/-2.55 minutes in the prolene suture group while it was 37.44 +/- 2.69 minutes in the staples group, the difference between the two groups being statistically significant ($p<0.001$). The difference between the two groups for postoperative pain was statistically significant ($p=0.026$); hence, reduced postoperative pain in the staples group (22).

Another study conducted by Damani stated that after 1 week of the surgery, 12 patients (37.5%) had no pain, 15 patients (46.8%) had mild, 4 patients (12.5%) with moderate and 1 patient (3.1 %) had severe pain in staples group. ln prolene suture group, 10 patients (31.25%) reported no pain, 14 patients (43.75%) had mild, 5 patients (15.6%) had moderate and 3 patients (9.37%) with severe pain (23).

There are limited studies comparing sutures versus staples regarding the frequency of post-operative pain in Lichtenstein hernioplasty. The rationale of this study was to find a better option for mesh securing during inguinal hernia repair in terms of procedure time and post-operative pain. This will help formulate an institutional protocol for inguinal hernia repair in hospital patients.

The rationale of this study was to compare staples with polypropylene sutures for mesh fixation in patients undergoing Lichtenstein tension free mesh repair in terms of post-operative pain. Moreover, previous studies have reported no significant difference on comparing both techniques in terms of postoperative pain; however, these studies were done on smaller group of patients (17). In the current era of evidence based surgical practices, the findings of this study will not only help in ascertaining the better technique out of the two but will also serve to generate interest for further studies on the topic.

MATERIAL AND METHODS:

The study was conducted in the Department of General Surgery at Liaquat National Hospital, Karachi, and spanned a duration of nine months. This was a randomized controlled trial involving 168 patients, divided into two equal groups of 84 each. Patients were randomly divided into two groups using sequentially numbered opaque sealed envelopes. Group A, consisting of 84 patients, underwent mesh fixation with staples, while Group B, also consisting of 84 patients, underwent mesh fixation using polypropylene suture.

The inclusion criteria specified male patients aged between 20 to 60 years, undergoing elective Lichtenstein mesh repair for unilateral uncomplicated inguinal hernia, with a body mass index (BMI) between 19-30 kg/m², and classified as ASA Class I, II, or III. Exclusion criteria included diabetic patients, recurrent or bilateral inguinal hernia, complicated inguinal hernia, and those unwilling to participate or unable to complete follow-up visits.

Patients were admitted to the surgical ward one day before the procedure after meeting the inclusion and exclusion criteria. A thorough history and detailed physical examination were conducted for all patients. Pre-operative workup was performed based on age and co-morbidities, and pre-anesthesia assessments were completed by an anesthetist. A written

informed consent was obtained from all patients enrolled in the study.

On the day of surgery, patients underwent Lichtenstein tension-free mesh repair under spinal or general anesthesia, with a single dose of prophylactic intravenous 1.2 grams amoxicillin/ clavulanic acid administered at the induction of anesthesia. Surgery of all patients will be performed by a consultant with minimum 3 years post fellowship experience assisted by postgraduate trainees. Operative time was recorded by an operation theatre assistant, defined as the duration from the start of mesh fixation until the last staple or stitch was applied. Skin closure was achieved using absorbable sutures. Post-operative pain was assessed using the Visual Analogue Scale (VAS), where patients were asked to mark the severity of their pain on a scale of 1 to 10. Pain scores were further classified into mild (1-3), moderate (4-6), or severe (7-10). Follow-up visits were scheduled on the 1st day, 3rd day, and one week postoperatively. Reminders were sent to patients to ensure compliance with follow-up visits. The observer assessing post-operative pain was blinded to the intraoperative findings to avoid bias. The exclusion criteria were strictly followed to minimize confounding factors and bias in the study.

Data were entered into and analyzed using SPSS version 25.0. Demographic data including age, gender, hospital record number, height, weight, BMI, operative time, and pain scores were meticulously documented. The normality of the data was assessed using the Shapiro-Wilk test. Quantitative variables such as age, BMI, operative time, and pain score were analyzed using mean and standard deviation or median with inter-quartile range if not normally distributed. Qualitative variables like gender, ASA class, laterality, type of hernia, and pain intensity were expressed as frequency percentages. The Chi-square test was applied to compare the intensity of pain between the two groups. Data were stratified for effect modifiers such as age, BMI, gender, ASA class, laterality, and type of hernia. Post-stratification Chi-square tests and Fisher exact tests were applied where appropriate to compare the intensity of pain between the groups. A P-value of ≤0.05 was considered statistically significant.

RESULTS

In our study, the demographic and clinical characteristics of patients stratified by study groups. The mean age of patients in Group A was 47.33±13.79 years, while in Group B, it was 47.10±11.60 years. Patients with age ≤45 years were 28(33.3%) and 56(66.7%) with age >45 years in group A and patients with age ≤45 years were 43(51.2%) and 41(48.8%) with age >45 years in group B. BMI was significantly higher in Group B (25.60±1.79 kg/m²) compared to Group A (24.47±2.16 kg/m²) (p<0.001). The distribution of ASA classification was similar between groups, with ASA A being the most common (58.3% in Group A vs. 59.5% in Group B), followed by ASA II (33.3% vs. 31%) and ASA III (8.3% vs. 9.5%). The distribution of hernia types revealed that indirect hernias were more common in Group B i.e., 50(59.5%) than in Group A i.e., 35(41.7%), whereas direct hernias were more common in Group A i.e., 49(58.3%) than Group B i.e., 34(40.5%). Laterality was noted as right sided hernia was found in 49(58.3%) in Group A vs. 42(50%) in Group B, but left-sided hernias were found in 35(41.7%) of Group A patients and 42(50%) of Group B patients. Neurectomy was performed in all patients in Group A i.e., 84(100%) but only in 59(70.2%) of those in Group B. Notably, 25(29.8%) of Group B patients did not get a neurectomy. The results are also presented in **Table-1**.

There was a similar duration of the study in Group A and Group B, which was observed as 46.66±4.27 days and 47.85±5.10 days, respectively, (p=0.103). The pain levels differed significantly in both groups at every time point. While none of the patients in Group B reported minor pain on the first postoperative day, 21(25%) of the patients in Group A did. Moderate pain was more common in Group B, 75(89.3%) than in Group A, 56(66.7%) while 7(8.3%) and 9(10.7%) of patients in Group A and Group B experienced severe pain, respectively, (p<0.001).

The pain assessment on the third postoperative day was noted as, mild pain was more common in Group A (i.e., 63(75%) vs. 17(20.2%)), but moderate pain was much greater in Group B (i.e., 67(79.8%) vs. 21(25%) (p<0.001). None of the patients in either group reported severe pain. There was also a

significant difference between the groups (p<0.001) on the seventh postoperative day, all patients in Group A 84(100%) reported mild pain, while in Group B, 58(69%) reported mild pain and 26(31%) reported moderate pain. There were no reports of significant pain at this time. On the seventh postoperative day, all patients in Group A (100%) reported mild pain, whereas in Group B, 69% had mild pain, and 31% continued to experience moderate pain, with a significant difference between groups (p<0.001). No cases of severe pain were recorded at this time point. These associations of demographic, operative and pain severity with study groups is presented in **Table-2**.

Table-3 shows significant differences in postoperative pain across various groups, with p-values indicating statistical significance. For patients aged ≤45 years, Group A reported mild pain on day 1 (50%), reducing to 100% mild pain by day 7. Group B had 79.1% moderate pain on day 1, decreasing to 79.1% mild pain by day 7 (p-values: 1st day <0.001, 3rd day 0.003, 7th day 0.010). For patients >45 years, Group A had 87.5% moderate pain on day 1, reducing to 100% mild pain by day 7 (p-values: 1st day 0.019, 3rd day <0.001, 7th day <0.001). ASA I patients in Group A had 28.6% mild and 57.1% moderate pain on day 1, improving to 100% mild pain by day 7 (p-values: 1st day <0.001, 3rd day <0.001, 7th day 0.003). Group B showed more moderate pain on all days (p-values: 1st day <0.001, 3rd day <0.001, 7th day 0.003). Indirect hernias in Group A had 60% mild pain on day 1, with 100% mild pain by day 7 (p-values: 1st day <0.001, 3rd day <0.001, 7th day <0.001). Direct hernias in Group B had 100% moderate pain on day 1, improving by day 7 (p-values: 1st day <0.001, 3rd day <0.001, 7th day <0.001). Neurectomy in Group A showed significant pain reduction, with 66.7% moderate pain on day 1, and 100% mild pain by day 7 (p-values: 1st day <0.001, 3rd day <0.001, 7th day <0.001). Group B without neurectomy had higher pain levels, especially on the 1st and 3rd days (p-values: 1st day <0.001, 3rd day <0.001, 7th day <0.001).

DISCUSSION

The management of inguinal hernia has undergone continuous evolution for more than 150 years (24). Numerous modifications for repair of inguinal hernia from the original approach by Bassini to Shouldice, Darning, Desarda, Modified Bassini and now Lichenstein mesh repair have been implemented, demonstrating varying levels of effectiveness (25). Among these advancements, Lichtenstein introduced the tension-free inguinal hernioplasty, which has proven to be a highly effective and safe technique with a lower recurrence rate (26, 27). Initially, the mesh fixation on the posterior inguinal canal wall was performed using polypropylene 2/0 suture. However, this method significantly impacted patients' quality of life and recovery (28). In recent decades, a new approach has emerged, utilizing staples instead of polypropylene sutures for mesh fixation. This innovative method has been associated with reduced operative time and complications such as wound infection and postoperative pain (17,29).

In our study comparing the outcomes of staples versus polypropylene sutures for mesh fixation in patients undergoing elective Lichtenstein tension-free mesh repair for inguinal hernia, we found significant differences in postoperative pain between the two groups. The demographic and clinical characteristics, such as age, ASA classification, and hernia type, were similar between the groups. However, Group A, which underwent neurectomy, reported significantly less pain at all postoperative time points. On the first postoperative day, 89.3% of Group B patients experienced moderate pain, compared to 66.7% in Group A (p<0.001). By the seventh postoperative day, all patients in Group A (100%) reported mild pain, whereas 31% of Group B patients continued to experience moderate pain (p<0.001). Additionally, pain was significantly reduced in patients aged ≤45 years and those with indirect hernias in Group A (p<0.001). These results suggest that the addition of neurectomy in Group A led to better pain management postoperatively, highlighting its importance in improving patient comfort following inguinal hernia repair.

In a study conducted by Ali et al. found that most of the patients undergoing inguinal hernia mesh repair were males, and had a mean BMI of 35.7 kg/m^2 (1). The predominance of male patients with higher mean BMI in all studies, may suggest possible gender and BMI-related factors contributing to inguinal hernia occurrence (30-32). Ali et al. found a similar

proportion of post-operative pain in both groups (p=0.544) (1). Furthermore, Garg and colleagues reported no difference in pain duration in both groups (33,34).

According to the findings of a research, the mean age of those in polypropylene group (Group-A) was 36.52+9.41 years, while those in staples group (Group-B) were 38.63+8.76 years old. Mean postoperative pain was 2.16+1.98 in Group-A and 1.46+1.24 in Group-B, both of which had p values of 0.0001. Mean postoperative duration in Group-A was 48.54+4.38 and 39.44+5.68 minutes in Group-B, both of which had p values of 0.0001. The results of this study showed reduction in both the average amount of time needed for the operation as well as the amount of postoperative pain experienced by the patient in staples group (8).

In another study of Lichtenstein inguinal hernioplasty, Awais Ali Khan and his colleagues (22) examined the use of polypropylene suture and staples for fastening mesh. The overall postoperative pain was lower (p= 0.026) when staples were used to anchor mesh in Lichenstein nguinal hernioplasty. In addition, the duration of the operation was shorter in the staple group (37.42+2.69 minutes) compared to the duration of the operation in the polypropylene group (42.44+2.55 minutes). These findings are in agreement with the results of previous study (8).

In the correction of Lichtenstein hernias, Anand Munghate and his colleagues (17) examined the amount of time needed for surgery as well as the postoperative outcomes of two different methods for fastening mesh: staples and polypropylene sutures. In this particular study, a total of 96 patients with an inguinal hernia who were having Lichtenstein mesh treatment were randomly randomized into two groups. In order to anchor the mesh, either staples from group I or polypropylene sutures were used (Group II). The operation time was considerably decreased from mesh insertion to completion of skin closure in group I (mean 20.7 min) as compared to group II (mean 32.7 min), with a significant P value (P 0.0001) and fewer complication rate in group I as compared to group II. This was shown by a significant difference in the mean operating times between the two groups.

A study by Ahmad et al. reported post-operative pain in inguinal hernia mesh repair in 29.3% patients of group A (Staple group) and in 44.4% patients of group B (polypropylene group). Statistically significant (P = 0.0155) difference between the frequency of post-operative pain was noted (35).

The study has a few limitations. One limitation of the study is that it was conducted at a single center, which may limit the generalizability of the findings to other healthcare settings or populations. Additionally, the follow-up period for assessing complications was relatively short, which might not capture delayed-onset complications. A longer follow-up duration could have provided a more comprehensive understanding of the outcomes.

CONCLUSION

When performing a Lichtenstein inguinal hernioplasty, anchoring the mesh with staples rather than polypropylene suture results in a reduction in both the average amount of time needed for the operation as well as the amount of postoperative pain experienced by the patient. These findings underscore the potential benefits of incorporating staples into hernioplasty procedures, not only for enhancing patient outcomes but also for optimizing healthcare resource utilization.

Further research and clinical studies are warranted to validate these findings and solidify the case for this innovative technique as a standard practice in hernia surgery.

Table-1: The summary of patients between study groups

	Study Group	
	Group A	**Group B**
Age groups		
≤45 years	28(33.3)	43(51.2)
>45 years	56(66.7)	41(48.8)
ASA classification		

ASA I	49(58.3)	50(59.5)
ASA II	28(33.3)	26(31)
ASA III	7(8.3)	8(9.5)
Hernia Type		
Indirect	35(41.7)	50(59.5)
Direct	49(58.3)	34(40.5)
Laterality		
Right	49(58.3)	42(50)
Left	35(41.7)	42(50)
Neurectomy		
Yes	84(100)	59(70.2)
No	0(0)	25(29.8)

Table-2: Association of patient's demographic, operative and pain severity with study groups

	Study Group		P-values
	Group A	Group B	
Age in years	47.33±13.79	47.10±11.60	0.909
BMI in Kg/m²	24.47±2.16	25.60±1.79	<0.001*
Duration of surgery	46.66±4.27	47.85±5.10	0.103
Pain on 1st operative day			
Mild	21(25)	0(0)	<0.001*
Moderate	56(66.7)	75(89.3)	
Severe	7(8.3)	9(10.7)	
Pain on 3rd operative day			
Mild	63(75)	17(20.2)	<0.001*
Moderate	21(25)	67(79.8)	
Severe	0(0)	0(0)	
Pain on 7th operative day			
Mild	84(100)	58(69)	<0.001*
Moderate	0(0)	26(31)	
Severe	0(0)	0(0)	

Chi square test was applied
*P<0.05 considered as significant

Table-3: Association of patient's severity of pain and study groups with respect to clinical factors.

			Pain on 1st operative day			Pain on 3rd operative day			Pain on 7th operative day		
			Mild	Moderate	Severe	Mild	Moderate	Severe	Mild	Moderate	Severe
Age groups	≤45 years	Group I	14(50)	7(25)	7(25)	21(75)	7(25)	0(0)	28(100)	0(0)	0(0)
		Group II	090)	34(79.1)	9(20.9)	17(39.5)	26(60.5)	0(0)	34(79.1)	9(20.9)	0(0)
		P-value	<0.001*			0.003*			0.010*		
	>45 years	Group I	7(12.5)	49(87.5)	0(0)	42(75)	14(25)	0(0)	56(100)	0(0)	0(0)
		Group II	0(0)	41(100)	0(0)	0(0)	41(100)	0(0)	24(58.5)	17(41.5)	0(0)
		P-value	0.019*			<0.001*			<0.001*		
ASA	ASA I	Group I	14(28.6)	28(57.1)	7(14.3)	42(85.7)	7(14.3)	0(0)	49(100)	0(0)	0(0)
		Group II	0(0)	41(82)	9(18)	17(34)	33(66)	0(0)	42(84)	8(16)	0(0)
		P-value	<0.001*			<0.001*			0.003*		
	ASA II	Group I	7(25)	21(75)	0(0)	14(50)	14(50)	0(0)	28(100)	0(0)	0(0)
		Group II	0(0)	26(100)	0(0)	0(0)	26(100)	0(0)	8(30.8)	18(69.2)	0(0)
		P-value	0.006*			<0.001*			<0.001*		
	ASA III	Group I	0(0)	7(100)	0(0)	7(100)	0(0)	0(0)	7(100)	0(0)	0(0)
		Group II	0(0)	8(100)	0(0)	0(0)	8(100)	0(0)	8(100)	0(0)	0(0)
		P-value	-			<0.001*			-		
Hernia Type	Indirect	Group I	21(60)	14(40)	0(0)	21(60)	14(40)	0(0)	35(100)	0(0)	0(0)
		Group II	0(0)	41(82)	9(18)	8(16)	42(84)	0(0)	33(66)	17(34)	0(0)
		P-value	<0.001*			<0.001*			<0.001*		
	Direct	Group I	0(0)	42(85.7)	7(14.3)	42(85.7)	7(14.3)	0(0)	49(100)	0(0)	0(0)
		Group II	0(0)	34(100)	0(0)	9(26.5)	25(73.5)	0(0)	25(73.5)	9(26.5)	0(0)
		P-value	0.038			<0.001*			<0.001*		
Laterality	Right	Group I	0(0)	42(85.7)	7(14.3)	49(100)	0(0)	0(0)	49(100)	0(0)	0(0)
		Group II	0(0)	42(100)	0(0)	17(40.5)	25(59.5)	0(0)	25(59.5)	17(40.5)	0(0)
		P-value	0.011*			<0.001*			<0.001*		
	Left	Group I	21(60)	14(40)	33(78.6)	14(40)	21(60)	0(0)	35(100)	0(0)	0(0)
		Group II	0(0)	0(0)	8(21.4)	0(0)	42(100)	0(0)	33(78.6)	9(21.4)	0(0)
		P-value	<0.001*			<0.001*			<0.001*		
Neurectomy	Yes	Group I	21(25)	56(66.7)	7(8.3)	63(75)	21(25)	0(0)	84(100)	0(0)	0(0)
		Group II	0(0)	59(100)	0(0)	9(15.3)	50(84.7)	0(0)	41(69.5)	18(30.5)	0(0)
		P-value	<0.001*			<0.001*			<0.001*		
	No	Group I	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)
		Group II	0(0)	16(64)	9(36)	8(32)	17(68)	0(0)	17(68)	8(32)	0(0)
		P-value	<0.001*			<0.001*			<0.001*		

Chi square test was applied
*P<0.05 considered as significant

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