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Comparative Study of Skin Staples and Polypropylene Sutures for Securing the Mesh in Lichtenstein's Inguinal Hernia Repair: A Prospective Randomized Controlled Clinical Trial

Authors
Dr Kaushal K. Gupta, Dr Ramgopal Meena, Dr Romil Singh, Dr Rakesh K. Sharma
Department of Surgery, Government Medical College, Kota, Rajasthan, India
Corresponding Author
Dr Ramgopal Meena
Email: *ramgopalmeena16@gmail.com, Mobile no. -09462655110*

ABSTRACT

Background: *Fixation of the mesh in Lichtenstein's inguinal hernioplasty is traditionally performed with polypropylene sutures. A modification of this technique uses skin staples for securing of the mesh. This study compared two methods of mesh fixation.*

Material and Methods: *Forty six patients undergoing fifty repairs were randomized into two groups. In control group polypropylene mesh was secured with 2/0 polypropylene sutures and skin closed with 2/0 ethilon. In study group polypropylene mesh was secured with skin staples and skin was closed with staples from the same stapler. Duration of surgery, post-operative complications, recurrence and costs were compared.*

Results: *The operation was significantly shorter when staples were used (mean 36 minute versus 52 minute, P < 0.001). There was no significant difference in the incidence of postoperative complications. There were no recurrences in either group in the follow up period (median 3 months).*

Conclusion: *The use of skin staples to secure mesh in Lichtenstein inguinal hernioplasty significantly reduced the duration of surgery and was as effective as conventional mesh fixation with polypropylene in the short term One more advantage of using skin stapler for mesh fixation in HIV and hepatitis B positive patients is to reduces the operating time thus reduces the duration of exposure to infected blood as well as it reduces the chances of needle prick injury.*

KEY WORDS: *Inguinal hernia, Lichtenstein hernioplasty, Skin staples, Polypropylene sutures.*

Introduction

The Lichtenstein repair is a tension-free inguinal hernia repair which takes account of the important factors identified in the successful outcome of inguinal hernia operation-supplementing the strength of transversalis fascia without disturbing the anatomy and a tension free repair.[1,2]

The standard way of securing the mesh in position on the posterior wall of inguinal canal is with polypropylene sutures. This trial was conducted to assess the efficacy of anchoring the mesh in position with skin staples which was quicker when used and should reduce the operating time and deal with problem of infection by minimizing the risk of wound colonization.

With this aim this study had been conducted to compare the present one with the standard prolene suture fixation of mesh (Lichtenstein repair) in the term of time saving for placement of mesh, complications rate, postoperative recovery, cost and recurrence rate.

Material and Methods

This study was a single-centre, prospective randomised controlled trial. The study was carried out at Govt. Medical College Kota. The study was conducted for eighteen months between January 2013 and June 2014 in the department of surgery Govt. Medical College and associated hospitals, Kota (Rajasthan). A total of 46 Patients including 4 patients having bilateral inguinal hernia who underwent hernia surgery,(total 50 repair) included for this prospective comparative study. These were divided in two random group . In each group 25 repairs were done.

Inclusion criteria

1. All adult patient of any sex over 18 years of age having an uncomplicated unilateral or bilateral inguinal hernia.
2. Only electively repaired hernias were taken
3. Written signed informed consent

Exclusion criteria

1. Recurrent inguinal hernia
2. Complicated inguinal hernias like obstructed or strangulated hernias.
3. Impaired mental state and were unable to give consent and to give an accurate assessment

Methodology

An informed written consent was obtained from the participant. The visual analogue scale for pain assessment was carefully explained to each participant. All the patients were subjected to routine pre-anaesthetic workup which includes haemoglobin, urine examination, fasting blood sugar, blood urea, serum creatinine, BT, CT, chest X-ray and ECG. Participants part were prepared , kept on fasting overnight, injection of tetanus toxoid and a preoperative single dose of of intravenous antibiotic in the morning on the day of operation was given.

After taking the informed written consent, patients were randomized and divided into two groups A and B. In each group 25 repair were done.

In Group A - where mesh was fixed with skin staples

In Group B - where mesh was fixed with polypropylene sutures

All the procedures were carried under standardized spinal anesthesia.

All patients were operated for Lichtenstein hernioplasty.

In Group A mesh was fixed with multiproximate skin staple. One staple over pubic tubercle, two staples along inguinal ligament, two staples over conjoint tendon and one staples lateral to deep inguinal ring. External oblique aponeurosis was closed with vicryl 2-0. Subcutaneous tissue then approximated. Skin closure was completed using staples from same staple gun and these were removed 7 days after surgery.

In Group B mesh was fixed with polypropylene suture material 2-0RB. First bite was taken over the pubic tubercle, then mesh was fixed to the inguinal ligament followed by fixing mesh to conjoint tendon and finally one stitch lateral to deep inguinal ring. External oblique aponeurosis closed with vicryl 2-0. Skin closure was completed using interrupted sutures of 2/0 Ethilon.

The time taken from the skin incision to the beginning of the mesh fixation, beginning to completion of the mesh fixation and total duration of surgery was recorded to the nearest 30 seconds

Follow up

Patient discharged 2^{nd} to 7^{th} postop day. Dressing removed on 2^{nd} postoperative day after that wound remained open and sutures removed on 7^{th} postoperative day.

Instructions to immediately report back if excessive pain at the incision site, blood, wound discharge, or foul smell arising from the wound.

Instructions on how to fill the Visual Analogue Scale for pain at home on the 3rd Post operative day were given and the patient asked to repeat them for to ensure that they had been understood.

The first follow up was done one to two hours after the operation, where pain was assessed using the Visual Analogue Scale. The Patient was then given a copy of Visual Analogue Scale to note the level on the third day at home.

The second follow up was done on the 7th postoperative day. At this visit pain Visual Analogue Scale and any complications present noted. The stitches were then removed and the wound was cleaned with Chlorhexidine solution.

Any complications such as haematoma and scrotal or labial swelling were managed accordingly.

Patient was followed at 1 and 3 month for pain score (Visual Analogue Scale) and any complications if present noted.

RESULTS

Total 46 patients with 50 inguinal hernia were randomized prospectively to either skin staple group or polypropylene group for fixation of mesh in Lichtenstein's Hernioplasty. In each group 25 repairs were done .Following observations were made in both groups. The distribution of age, type of hernia, duration of hernia, distribution according to symptoms, given in table 1

Table 1: Clinical Details

	Staples Group	Polypropylene Group
Mean (range) age	49.24 (23-85)	46.04 (22-70)
Type of Hernia		
Direct : Indirect	8 : 17	9 : 16
Complete: incomplete	10 : 15	11 : 14
Duration of hernia		
<6month	3	5
6-12 month	5	4
>12 month	17	16
Symptoms		
Pain + swelling	13	14
Only swelling	12	11.

Duration of Surgery

The mean duration of operation was 35.52 ± 3.99 min in the stapler group compared with 51.96 ± 3.19 minutes in polypropylene group (Table 2.) This difference was accounted for by the difference in time from the beginning of the mesh insertion to the complete fixation of mesh. The difference in time from the start of surgery to insertion of mesh was not significant (P>0.05) between both groups, but the difference in time from mesh insertion to complete fixation of mesh between the two groups was significant (P<0.0001). The difference in total operative time between the two groups was also significant (P<0.0001).

Distribution of case according to mean time of surgery(In min)

Mean Time	Stapler Group	Polypropylene Group	P	T
From skin incision to beginning of mesh fixation(A)	22.44 min	24.16 min	0.0801	1.7878
SD	3.50	3.3		
From beginning to complete fixation of mesh(B)	3.38min	12.92 min	P<0.0001	40.82
SD	0.68	0.95		
Total duration of surgery(C)	35.52 min	51.96 min	P<0.0001	16.09
SD	3.99	3.19		

3: Postoperative hospital stay

4 patients had bilateral inguinal hernia were included in both groups ,out of which one patient stayed for 7 days and rest three were discharged between 3 to 5 days.

Most of the patients in both the groups were discharged in between 3-5 days. (table 3)

Table 3: Postoperative hospital stay

Duration(days)	Stapler Group		Polypropylene Group	
	No.	%	No.	%
1-2	5	20	4	16
3-5	18	72	18	72
6-8	2	8	3	12
Total	25	100	25	100
Mean	3.84		4.136	
SD	1.4		1.42	
t	0.7422			
P	0.4616			

Follow Up

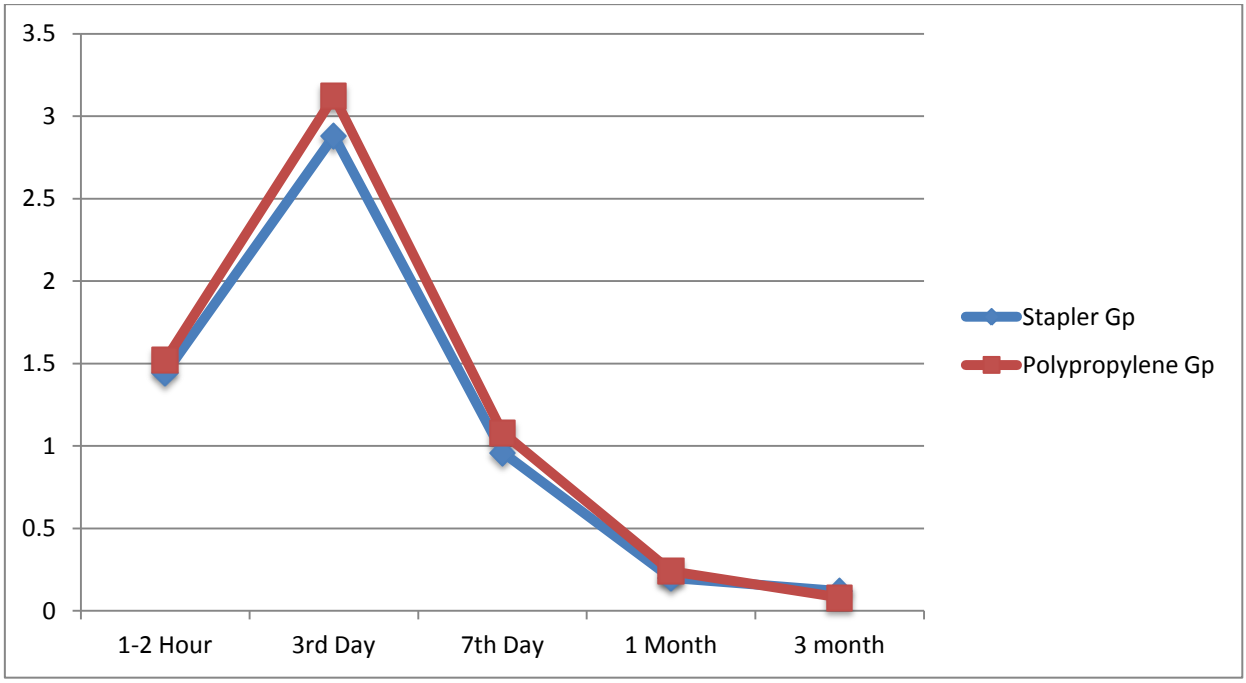
Post operative pain, postoperative complications compared between two groups.

Postopertaive pain

There was generally no significant statistical difference in mean pain scores at the five time points between the two intervention groups (P>0.05).

The general trend shows an increase in pain score on the 3rd postoperative day, followed by a marked decline in scores on the 7th day, and the pain score was nearly zero at 1 month (graph 1)

Graph - pain score trend



Complications

Four out of 25 hernia repairs in stapler group and seven out of 25 hernia repairs in polypropylene group developed swelling and induration of the wound which was transient and settled without intervention, the difference was statistically insignificant (P = 0.278). While one patients in staple group and two patients in prolene group developed seroma, difference was statistically insignificant (P = 0.096). There were no cases of mesh infection. No patient had wound hematoma. There were no hernia recurrences during the follow up period in either group.(table 4)

Table 4: postoperative complications

Complication	Stapler Group		Polypropylene Group	
	No.	%	No.	%
Urinary retention	2	8	6	24
Induration and Swelling	4	16	7	28
Seroma	1	4	2	8
Haematoma	0	0	0	0
Wound gaping	0	0	1	4
Mesh Infection	0	0	0	0
Recurrence	0	0	0	0

Discussion

The present study was conducted in department of Surgey at Govt. Medical College, Kota from January 2013 to June 2014. Our results with this technique of using skin stapler for mesh fixation in comparison with the conventional method of mesh fixation using polypropylene suture though with a small sample of patients has been very encouraging and confirming to the latest world wide experience with this technique.

The age of the patient in the stapler group and polypropylene group ranged from 20-85 year and 20-70 years with a mean of 49.24 and 46.04 years respectively. The two groups were statistically comparable in relation to age (p>0.05).

There were 100% male patients in the presented study. Egger et al reported 47:2 male to female ratio in their study of 49 patients.[3] In the series of 50 patients done by Mills et al the male to female ratio was same as our study (100% males)[4]

In the present study, most of the cases had incomplete hernial sac 29 (58%) with incomplete to complete hernia sac ratio was 1.4:1 in entire series

The two groups were comparable in relation to the symptoms and duration of symptoms (p>0.05). Egger et al 5 first reported the use of skin staples for securing the mesh in hernia repair. Janu et al 6 reported duration of surgery as "operating room time" of 111+/- 2 min. The results in his series were achieved in the setting of a surgical residency program with a steady turnover of residents being instructed in the Lichtenstein's mesh plasty technique, without the use of staples.

Mills et al4 reported a similar study to compare skin staples and polypropylene sutures for securing the mesh in inguinal hernioplasty. He reported fifty elective, unilateral, primary inguinal hernia repair done under general anaesthesia.

In our study the mean time of operation was almost 12.6 min shorter when staples were used whereas it was 09 minutes[4] shorter in Mills' study whereas it was 10 minutes shorter in Roshanlal's study.[7] In chaitanya et al study they were able to reduce the operating time up to 12 minutes.[8]

According to Mills this difference maybe important because shorter operations maybe associated with a reduced risk of wound infection and because this keeps the risk of anaesthesia to a minimum.

Pain was scored on a visual analogue scale of 0 to 10. The pain experienced by the participants in the two study arms was similar at the five time points (1-2hours, 3rd day, 7th day, 1month and 3 month). The mean pain score was highest on the 3rd POD in both arms.

The overall trend showed lower scores among the stapler group each point of time, but this was not statistically significant (P>0.05). Chaitanya P. Garg, Ashok M Bhatnagar and Chetan D.Parmar et al[8] also showed similar results

There were no significant difference between the two study arms with regard postoperative complications .The main complications in our study were swelling and induration of wound . 4 patient in stapler group and 7 patient in polypropylene group developed induration and swelling of wound . In present study 8 cases (16%) developed urinary retention (two in stapler group and 6 cases in polypropylene group). This may be due spinal anaesthesia .No patient developed hematoma, wound gaping, or mesh infection in stapler group. One patient in polypropylene group developed wound gaping (Table –X) .

Chaitanya P.Garg[8] also reported a similar results plus one patient developed wound gaping. Mills[4] reported four hematomas, which were not encountered in our study. Egger et al reported 3 cases of haematoma out of 53 cases[3] ·Concerns had been expressed, that the use of staples may lead to entrapment neuropathy[9,10] increased rate of wound infection and potential vascular injury.[10,11,12.] But, no such complications were encountered in this study.

There was no statistical significant difference in postoperative hospital stay in both groups (p>0.05).

There were no recurrence in present study with the follow-up of 3 months. Egger et al also

reported no recurrence in their study with short period of follow-up (median 105 days) [3] .Mills study also had a short follow-up (12 weeks) with no recurrences [4] and Chaitanaya et al also reported no recurrences with the follow up of 3-24 months.[8]

Conclusions

The technique of Lichtenstein tension-free repair is simple, relatively easier to learn and less technically demanding. A different way of securing the polypropylene mesh, as described by Egger, has been used in our study. The staples placement was done by a routine skin stapler, providing good penetration into the tissues, including the pubic tubercle, with secure fixation of the mesh, making this method technically easier.

- This study demonstrates that the technique of mesh fixation with skin stapler is as effective as conventional fixation with polypropylene sutures with an important added advantage of significant reduction in the operative time.
- It is safer to use new technique in HIV and Hepatitis B patients as it reduces the operative time, so it reduces the duration of exposure to the infected blood.
- It also reduces the needle prick injuries.

However the sample size and the follow up period in the current study is relatively short , A larger study sample and longer follow-up may be needed before any further conclusion can be made

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