ORIGINAL ARTICLE

Comparison of short- and long-term outcomes of skin stapples used for mesh fixation after Lichtenstein inguinal hernioplasty versus polypropylene suture fixation. – A multicentric randomized controlled trial

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ABSTRACT

Background: Open inguinal hernia repair is still one of the most commonly performed surgery globally. Chronic post inguinal pain and recurrence are the two most reported complications of the surgery. Mesh fixation technique is believed to have a role in both these complications.
Aim: To compare the short- and long-term outcomes associated with open hernia repair and mesh fixation using suture versus skin staples in terms of recurrence, post-operative pain and wound infection rates
Methods: A randomized control trial was designed with a sample size of 30 cases in each arm conducted at three teaching hospitals from December 2017 till June 2018. All eligible candidates were evaluated and randomized into two groups at the time of Lichtenstein open hernia repair for either fixation of mesh with staples or sutures. Short and long term outcome measures were compared using t-test and chi-square tests with a p-value <0.05 was taken as statistically significant.
Results: A total of 71 patients enrolled in study with 30 finally recruited in each arm (PS vs SS groups). Patients in each group were matched for age and gender mean operative time and mesh fixation times were calculated and compared (61.47±14.44 vs 53.17±10.23) and (17.70±2.26 versus 13.97±2.55); both variables were statistically significant. There was no statistical difference in other variables including post operative pain, seroma formation and long term pain.
Conclusion: Skin Staples can be safely used in the setting of primary repair of inguinal hernias. The short- and long-term outcomes are comparable to conventional polypropylene suture and there is no significant difference in the results when the procedure is performed by trained trainees or consultants.
Keywords: Inguinal hernia, Lichtenstein repair, Mesh fixation, Skin staples, polypropylene suture

INTRODUCTION

Open Tension free Lichtenstein hernia repair for inguinal hernia is one of the commonest operations being performed globally[1]. The procedure is based on using propylene mesh which is fixed on the posterior wall of inguinal canal eliminating its potential weak muscular layer[2].

The standard procedure as recommended by several hernia society guidelines is to use polypropylene thread of appropriate diameter for fixation of mesh. The sutures are place in a continuous as well as interrupted fashion[1,2]. Fixation of mesh is critical since data suggest its migration into surrounding anatomical structures and presenting with complications[3]. Other agents including fibrin glue, self-adhesive mesh and absorbable tackers have been used to fix the mesh in its position by other authors, however later agents are associated with higher operative cost and seroma formation[4].

Recent studies on ventral and inguinal hernia repairs with mesh have advocated use of skin staples for anchorage of mesh[5-9]. These studies suggest reduction in operative time as well as postoperative pain. The application of skin staples for mesh fixation has a steeper learning curve for less experienced trainee surgeons[10]. Literature for inguinal hernia repair using skins staples is scarce and there is no long-term evaluation of the skin staples in terms of corrosion, foreign body reactions and mesh infections.

This study was designed to compare the short and long term outcomes of use of skin staple in Lichtenstein hernioplasty in terms of minimum number of cases needed to teach the steps to trainee surgeons, changes in operative time and severity of early postoperative pain as well as development of long term complications in terms of frequency of recurrence of Hernia, development of sinuses and deep surgical site infections resulting in mesh infection leading to redo incisional hernia surgery and or mesh removal+) The study may have an impact in change of practice of hernial repair based on the final study outcomes.

The primary outcome of the study was to compare mean operative time for mesh fixation and total operative time while using polypropylene (proline ® 2/0) suture versus skin staple (covidien®) assisted fixation, to compare short term outcomes in terms of intraoperative bleeding, seroma formation and immediate postoperative pain score using visual analogue scale and to compare the 2 – year outcome of the technique in terms of recurrence, foreign

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body reactions, sinus formation and mesh infection and chronic pain syndromes.

MATERIALS AND METHODS

A randomized control trial conducted at three teaching institutions including Lahore medical and Dental College/ Ghurki Trust teaching hospital, King Edward Medical University/Mayo Hospital, Lahore and Services Institute of Medical Sciences, Lahore. The initial phase of the study was done from December 2017 till June 2018. The study was approved by local Institutional ethical review board. In this study, all consecutive cases presenting to the hospitals during the study periods were included across all the three centers. A minimum of 30 subjects were to be included in each group. Estimated sample size for power of study at 80% and Confidence Interval (CI) of 95% with effect size of 10% and P1 (37.44±2.69 min) versus P2 (42.44±2.55 min) for staples group versus Suture securing group a minimum of 30 cases were to be included[9].

All patients presenting to the outpatient department aged between 20–60 year with a clinically palpable swelling in either side in the inguinal region with a positive cough impulse and confirmed by using an Ultrasound abdomen and groin scan were offered to participate in the study. The patients who fulfilled the criteria were briefed regarding the trial and risk benefit ratio was explained in detail by one of the member of operating surgeons.

Once the subjects agreed to be part of the study a consent form was signed, and routine blood work and assessment was conducted. Patients with ASA grade I and II were included in the study whereas ASA III or higher were excluded to reduce the risk of bias. All types of uncomplicated primary hernias were included in the study. Obese patients with BMI more than 35, chronic smokers and or patients with urinary strictures were excluded from the study. All other patients with comorbidities including hypertension, ascites, bilateral hernias were also excluded from the study. Patient's workup was done including complete blood examination, Renal function tests and pre-operative assessment was done by anesthesia team for fitness for spinal anesthesia. All blood thinners and smoking were stopped before the surgery. Case report form A was filled including demographic details including Name, Age, Gender, Occupation, risk factors. Once included in the study patients were scheduled for next elective list and assigned either of two arms - Polypropylene Suture (PS) or Skin Staples (SS) based on ballot paper drawn at the time of surgery. All the patients underwent herniotomy and Hernioplasty using light weighted Polypropylene Mesh. The surgery was performed by year 4 General surgical trainees under direct supervision of a consultant surgeon. In PS (polypropylene suture group)low weight ultrapro® mesh size 6x11cm was spread under aseptic measures and fixed to inguinal ligament using short continuous sutures throughout the length of inguinal canal . The upper edges were fixed with five interrupted sutures fixing the mesh to the conjoined tendon and muscles. In this group skin was closed using the same suture in subcuticular fashion. .In second arm i.e.group Skin Staples (SS), the mesh was fixed with up to8 skin staples (Covedien®)evenly spreading the tension. Lower mesh line was secured with another 5 clips. In this group (SS) skin incision was approximated using the same stappling device. Time of operative surgery were noted for each case ata) time of incision, b) placement of mesh and c) application of last suture or last clips(in each case). Any patient requiring Surgical drains placement due to extensive dissection or bleeding was excluded from the study.

Patients were asked regarding the severity of pain at 6 hours after applying dressing to allow the effect of spinal anesthesia to wear off.The pain score recorded at 6 hours was be considered as a reference value and re-assessed after 24 hours of operation(prior to discharge), at 3rdpost-operative day (change of first dressing)and 7th post-operative day(removal of stiches or extraction of skin clips. These data points were also used to assess development of any seroma by clinical examination for any swelling, redness, or fluctuation. Any patient with suspicion of seroma was subjected to an ultrasound for confirmation of findings. Data was collected on specially designed case report forms. The assessor at 30 day documented any wound infection, seroma formation or hernial repair failure. The patients were then offered a follow-up program annually and were informed that they will be contacted through telephone calls and were asked to answer 5 questions regarding their operation every year up to24 months (upto December 2020).Patients were asked to comment for their pain at the site of hernia repair every 6 months for a duration of 2 years. The patients were also followed up for any case of hernia recurrence, chronic wound infection, mesh infection and chronic sinus formation.

Data analysis: Consort Statement[11] was duly filled in as a requirement of running clinical trials. on specially designed Case report forms and tabulated using Statistical Package for the Social Sciences (SPSS®) Software v 21.0. demographic variables including age, gender was analyzed using the descriptive analytics. The data was analyzed for normal distribution. Parametric tests of significance were applied to compare means. Central tendency was determined for all Quantitative variables with means and standard deviations were analyzed including duration of surgery, mesh placement and post-operative pain. Pain score was analyzed using means & Std Deviations on a scale of zero to 100. Seroma formation was analyzed in the form of frequency and percentages. A p-value of less than 0.05 was considered as statistically significant.

Operative surgery time and time to fix the mesh and closure was noted in minutes. Mean, standard deviation and ranges were calculated, and t-test applied to compare the means. Postoperative pain was measured using a100 mm visual analogue scale and were graded asnil (0–10mm), mild (11-30), moderate (40-70mm) or severe (80-100)in increasing intensity from no pain (00) to excruciating pain (100). Patients were clinically examined at day 30 for any collection of fluid (seroma formation) and suspicious swellings were evaluated using an ultrasound to determine the findings and quantity the seroma.

Post operatively the patients were contacted through telephone based questionnaire at 6,12, 18 and 24 months. Five simple questions were asked to determine a) recurrence of swelling b) wound infection c) Pain score d)

discharging sinus e) need for re-operation on same hernia site due to infection. In cases where the patients were not sure about the answers, they were asked to send a picture of the scar using mobile phone in daylight for assessment.

RESULTS

A total of 60 patients were included in the analysis as described on the CONSORT flowsheet (Figure 1). The mean age of the patients 39.3±12.053 with comparison of the two groups given in Table 1. Proportions of the patients based on gender was determined.

Mean operative time and time of mesh fixation were analyzed in both the groups and the two means were compared using independent t-test. There was statistically significant difference both quantitative continuous variables, suggesting shorter duration in the skin staples(SS) group.

Average cost estimation was done based on the number of sutures used in PS group and cost of stapples used in SS group. A mean value of PKR 1080 + 354 (PS group) as compared to PKR 907 + 244 (SS Group) was estimated. ($p<0.0001$).

Post-operative pain scores were extensively using the VAS Score at pre-specified times. There was a general trend in worsening of the pain at 6 hours which improves later. There was not statistically difference in pain scores across the two groups at any of four data set points suggesting no statistically significance difference in severity of pain when compared in both techniques. (Table 2)

Frequencies of long-term outcomes including chronic pain, non-healing granuloma and mesh infections were determined using a telephone-based questionnaire. Patients were asked to send back photographs of their wounds and reports if there is a problem. 10% (n=3/30) patients in the PS group as compared to 6.6% (n=2/30) patients in Staples group complained of chronic pain in absence of any infection or swelling at the operation site at the end of one year . The mean pain scores at the end of study duration at 24 months was 9% (range 0 – 33%) in PS group as compared to 7 % in SS group and a p value of 0.43.

The response rate decreased to 70% (n = 42/60 at 24 months and 57% (n= 34/60) by the end of study duration. (n=0/21) None of patients in the staples group at the end of study period complained of chronic discharge due to possible corrosion of the -staples or foreign body reactions leading to mesh failure requiring removal of mesh. Similarly, none of the patients complained of discharging sinus or wound hyperemia any time after 60 days after surgery in either groups. None of the patients reported recurrence of hernia during the study period.

Table 1: Demographic data for both groups

	Total	**Group A (Polyprolylene Suture)**	**Group B (Skin Staples)**	**P value (independent t-test)**
	N = 60	N= 30	N=30	
Age (in years)	39±12.053	42.10 ±10.340	36.5±13.13	0.72
Gender				
Male	58	30	28	
Females	02	00	02	
Operating Surgeon				
Consultant: Trainee ratio	1:1	1:1	1:1	
Operative time				
Mean Operative Time (Min)	57.32±13.09	61.47±14.44	53.17 ± 10.23	0.013
Mesh to Skin closure time (Min)	15.8 ±3.043	17.70 ±2.26	13.97± 2.55	<.0001*
Average cost of Mesh fixation (PKR)	907± 244	1080±354	735±259	<.0001*
Seroma formation				
Time of examination Day 03	8/ 60 (13%)	7/30(23.3%)	1/30 (3.3%)	0.02*
Day 07	5/60 (8.3%)	3/ 30 (10%)	2/ 30 (6.7%)	

Table 2: Mean Visual analogue pain score among the two groups .

	Total	**Group A (Polyprolylene Suture)**	**Group B (Skin Staples)**	**P value (independent t-test)**
Pain at time of end of surgery	34.07±19	33.7±15.93	34.43±21.93	0.88
Pain at 6 hours (Spinal Anesthesia effect wears off)	48.45±18.24	54.37±17.83	42.43 + 16.92	0.01
Pain score at 24 hours	29.6±14.5	29.77±15.44	29.43 + 13.73	.93
Pain Score at 07 days	19.9±10.22	20.04 ±9.42	19.96 + 9.96	0.90

Table 3: Telephone based Questionnaire for Long Term outcome Assessment

Did you had a hernia again during these years ?
Is there is any wound with seeping pus from the wound ?
Did you had to get your mesh removed due to infection ?
Do you feel Pain at the hernia site ?
If Yes for question 4 – How would you rate the pain from 00 to 100 ?

DISCUSSION

The Lichtenstein hernia repair is recommended treatment of inguinal hernias using open technique and is recommended by all the hernia societies and hernia management guidelines[1]. This repair includes proper placement of mesh strengthening the posterior wall. Two most common complications are recurrence of hernia and chronic pain. The primary reason for recurrence is poor surgical technique and improper mesh fixation[1,10]. It has

been postulated that lighter weighing meshes and less foreign body load in the form of suture fixation may have a beneficial effect on postoperative pain[6,7,8]. There is recent trend to use non suture materials to keep the mesh at the right place[12]. Our study suggests use of skin staples is associated with shorter operative time and better learning curve for trainee surgeons, quality assurance. Our study has also been able to report on long term outcome of skin staples on the mesh.

Our study reports a statistically significant reduction in the time of operation in the skin staples group when compared to suture fixation group without any associated statistically significant difference in the complications. Reported studies in the literature suggest that the operation time using the skin staples are shorter when surgery is performed by trained surgeons and consultants[1,2]. The time of operation using the suture fixation ranges from 40 minutes to 57 minutes[7-9,13] whereas in the staple fixation groups the time of surgery ranges from 27–53 minutes. Not all reported studies have reported the difference in the time taken to fix the mesh and final closure. Our study has accurately assessed the difference in the time taken to place and fix the mesh (17.7 minutes versus 13.97 min, p <000) mainly due to reduction in the steps of surgery including tissue handling suture cutting and change of retractions by the assistant.

The literature is scarce on the risk of corrosion and secondary infection of the mesh due to its long-term effect of foreign body (metal) on mesh. The authors failed to identify any research article which particularly has included corrosion, mesh failure, infection and chronic discharging sinus possibly caused by placement of skin staples for mesh fixation.Our study reports no instance of chronic non healing sinus associated with infection in the metals. We infer that there is low to minimal risk of getting the hernia mesh infected by use of skin staples and thus can be safely used for hernia repair.

This result in associate with the finding of lesser financial cost incurred to the patient in closure of skin as well as fixation of mesh when compared to suture fixed mesh hernioplasty suggests an opportunity to reduce the cost of surgery with no added risk to the patients. Our study estimates a statistically significant difference between the two groups in terms of financial cost of devices used for fixation and closure of wound (1080±354 versus 735±259; p value <0.0001) due to use of a single staples (26–35 staples) as compared to up to two polypropylene sutures for continuous mesh fixation and subcuticular skin closures. The study suggests that use of staples is cost-effective as well.

The learning curve for the trainee surgeons to be comparable to the consultant and reach a set benchmark ranges from 37 - 50 open surgeries (1,2). One of the important factors identified in these studies of failure to achieve excellence among the trainee residents is mesh fixation. Our study suggests the number of cases required to learn mesh fixation using skin staple device is easier to teach, standardized and better assessed intra-operatively.

Since there is no risk of injury to the vascular structures including iliacs vessels using the staples at pre-defined surgical anatomical landmarks makes it a safer option at the hand of younger trainee surgeons. Additionally, the skin staple has a fixed length and there is no risk of poor mesh fixation if the surgeon and assistant visual confirm its proper placement after placement.

Postoperative pain scores were evaluated at four key points i.e. at the end of surgery to have a baseline pain score, at 6 hours when the effect of spinal anesthesia wears off, 24 hours- at the time of discharge to determine whether analgesia is sufficient for discharge the patient on oral medication and at 7th day at the time of suture/staple removal to assess any localized collection or wound problems. The trend showed despite the best practices followed the pain score raised when the spinal anesthesia effect worn off. However, the difference between the two groups was not statistically significant at any time during these recordings. This suggests lack of evidence that there can be a difference in early post-operative pain after application of skin staples or the suture closure.

The seroma formation is another common early complication of the open hernia repairs irrespective of technique used for closure. This factor is more commonly associated with tissue handling and surgical technique. However, the suture closure can be associated with hematoma formation due to injury to small or large vessels in the vicinity of repair. The proportion of cases with seroma formation increased from 3.34% initially to 7 % in the staples group due to slower collection of serum in the wound and has a different mechanism of bleeding from the tissues while suture fixation of mesh is performed. (up to 10%)[5-9,13,14].

Our study could not identify any statistically difference in the pain scores on long term basis at 6 monthly basis. There is a concept of association of chronic pain with mesh shrinkage more common with tight suture closures. Advocates for this theory have suggested that the placement of skin staples may reduce the incidence of postoperative chronic pain[15,16]. However, our study failed to report on this concept and the pain score in both groups remained comparable throughout the study period. Although the mean pain score was less in Skin staples group but it did not reach a statistically significant value.

There was no statistical difference in rate of recurrence of hernia in the two groups suggesting effectiveness of both techniques with comparable results. The result also suggests a non-inferiority assumption that the two techniques are equally implementable[16,17].

The main limitation of the study was the minimum sample size which may affect the generalizability of the results. Our study did not assess the risk of migration of the mesh after both techniques and the question related to this complication was not included in the protocol. This area of our study remains to be re-evaluated.

CONCLUSION

Skin Staples can be safely used in the setting of primary repair of inguinal hernias. The short- and long-term outcomes are comparable to conventional polypropylene suture and there is no significant difference in the results when the procedure is performed by trained trainees or consultants. There is no evidence in our study that the skin staples erode and cause non healing chronic discharging sinuses or a cause of mesh failure. The use of staples is

cheap as compared to polypropylene since the same staples can be used to close the skin as well.

Author contribution: AAA and AUQ conceived the research questions. AK drafted the protocol. AUQ, AK and SSQ conducted the research at their respective centers. All authors contributed to data analysis and edited the final revision of manuscript. All authors agreed on the final manuscript.

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Figure 1: Comparison of short- and long-term outcomes of skin stapples used for mesh fixation after Lichtenstein inguinal hernioplasty versus polypropylene suture fixation. – A multicentric randomized controlled trial