



ORIGINAL RESEARCH PAPER

Surgery

LAPROSCOPIC VS OPEN HERNIA REPAIR- RESULTS OF A PROSPECTIVE RANDOMISED CONTROL TRIAL

KEY WORDS:

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ABSTRACT

Background: Repair of an inguinal hernia is the most frequently performed operation in general surgery. Although laparoscopic approach to inguinal hernia surgery has been found to be safe and reliable, its superiority over open method is still controversial.

Methods: A prospective, open labelled, randomized, comparative, two armed study was conducted in Department of surgery, J.N. Medical College, AMU, Aligarh, India between June 2016 to July 2018. A total of 100 patients with uncomplicated inguinal unilateral direct or indirect, undergoing elective inguinal hernia surgery, who are fit for laparoscopy and general anaesthesia, were included in the study. The patients were randomly allocated into two groups consisting of 50 in each group. Group A were operated with open tension free Lichtenstein's hernioplasty. Group B operated by laparoscopic totally extraperitoneal repair using mesh. Surgical variables and clinical outcomes were measured.

Results: The duration of surgery for Group B is shown to be significantly higher than the Group A (p value =0.00). The VAS score (for pain) and (PNOV) values of Group B were Significantly lower than that of Group A at 0h, 6h and 24h (p value =0.00). The mean hospital stay in both groups were almost similar. The mean time taken by patients to execute their daily activities was 3.05±2.1 in Group B as compared to Group A 4.06±1.64 days and the difference was statistically significant. The postoperative seroma formation rate was found to be statistically significant in both Groups (p value=0.003), i.e more common in group B.

Conclusions: Laparoscopic hernia repair is safe and provide less postoperative morbidity in experienced hands compared to open hernia repair.

INTRODUCTION

Hernia repair is one of the most common operations performed by general surgeons¹⁻³. Despite the frequency of this procedure, no surgeon has ideal results, and complications such as postoperative pain, nerve injury, surgical site infection, and recurrence remain. True incidence is unknown. It is estimated that 5% of the population will develop an abdominal wall hernia, but the prevalence may be even higher. About 75% of all hernias occur in the inguinal region. Men are 25 times more likely to have a groin hernia than women. Advances in groin hernia repair in the century following Bassini have shared the primary goal of reducing long-term hernia recurrence rates. To this end, efforts have been directed at developing a repair that imparts the least tension on the tissues that are brought together to repair the hernia defect. Lichtenstein's tension free inguinal hernioplasty using a prosthetic mesh is preferred approach for open inguinal hernia repair. In the general population (i.e. not specific to the elderly) meta-analysis and systematic reviews; report patients undergoing laproscopic hernia repair suffered less acute pain, less chronic pain, less infection and a quicker return to work⁴⁻⁶. The laparoscopic approach to hernia repair has since evolved into a common and effective procedure. The most important difference between the laparoscopic and open approaches for inguinal hernia repair is anatomical: the laparoscopic approach uses mesh to repair the hernia defect in a plane posterior to the defect (either in the preperitoneal space or from within the perito-neal cavity), whereas the open approaches repair the hernia anterior to the defect. Laproscopic hernia repair increased risk of inferior epigastric injury and visceral injury in some studies, however data from all meta-analysis and reviews originated from the same clinical pool.⁴ This study was aimed to compare outcomes following laproscopic total extraperitoneal repair (TEP) with the standard open anterior tension free repair (Lichtenstein's)

METHODS:

A prospective, open labelled, randomized, comparative, two armed study was conducted in Department of surgery, J.N. Medical College, AMU, Aligarh, India between June 2016 to July 2018. A total of 100 patients with uncomplicated inguinal unilateral direct or indirect, undergoing elective inguinal hernia surgery, who are fit for laparoscopy and general anaesthesia, were included in the study. The patients were randomly allocated into two groups consisting of 50 in each group. Group A were operated with open tension free Lichtenstein's hernioplasty. Group B operated by laparoscopic totally extraperitoneal repair using mesh.

All patients with having complications like irreducible, strangulated & obstructed hernia, patients having cardiac/chronic respiratory disease, patients unfit for general anaesthesia and patients not giving consent were excluded from the study.

All patients underwent routine preoperative investigations and pre-anaesthetic check up for fitness. After taking written consent, patients were randomly assigned into one of the two arms of the study each group consisting 50 patients.

Group A operated by open tension free Lichtenstein's hernioplasty.

Group B were operated with laparoscopic totally extraperitoneal repair using mesh.

Preoperative antibiotic atleast 30min before surgery was given as per protocol (1gm ceftriaxone intravenous). patients were operated as per allotted group.

Postoperative analgesic was used in every patient (diclofenac sodium 75 mg I.V 12 hourly) and pain was recorded on visual analogue score (VAS) at 0 min, 6 hours, and 24 hours after surgery.

Patients were also evaluated for :

- Length of hospital stay
- Time taken to return daily activity after surgery
- Seroma formation
- Duration of surgery

Discharge after start of oral diet and without any sign of postoperative wound infection. If sign of wound infection were present then pus from wound was taken and sent for microbiological culture and sensitivity testing. Appropriate antibiotics started after reports and wound care taken accordingly. Follow up in opd for stitch removal after 7 days,if operative wound is healthy.

Descriptive statistics were expressed as means and standard deviations, as well as frequencies and percentages. Fisher's exact and Pearson's tests of chi-square were applied for categorical variables. Independent Sample 2-tailed T Test was used to compare the means among the continuous variables. P<0.05 was considered statistically significant.

RESULTS:

A total 100 patients were included in the study(50 patients in each group) allocated randomly. There was no mortality or surgery related major complications in any group.

Mean age of the patients among study were compared

Mean age of group A was 42.16±18.06 and group B was 44.44±15.01,p=0.61)



p>0.05 i.e statistically insignificant

Mean operative time taken to complete the procedure in both groups

On comparing the mean operative time taken in both groups, the time for group B is shown to be significantly higher than the group A (p value =0.000).

Table 1: Comparison of mean operative time taken in both groups.

	Group A	Group B	P-value
Mean duration of Surgery(in min)	55.24±14.26	145.34±23.14	0.00

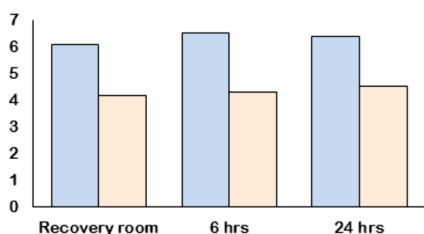
Postoperative pain score (VAS) among the study groups

VAS score of group B was significantly lower as compared to group A in terms of severity of post-operative pain (p<0.05).

Table 1. Postoperative pain score (VAS) among the study groups.

Comparison of VAS score in two groups of patients studied

Groups	Recovery Room	VAS at 6 hrs	VAS at 24 hrs
Group A	6.11±1.15	6.53±1.22	6.42±1.30
Group B	4.21±0.98	4.32±0.89	4.53±1.12
P- value	p=0.00	p=0.00	p=0.04



Graphical representation of VAS score in terms of post-operative severity of pain among study groups

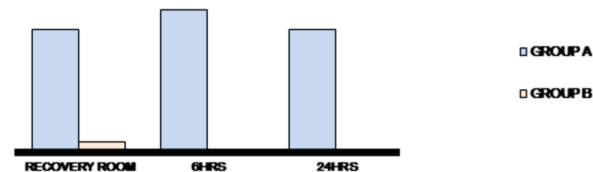
Incidence of post-op nausea and vomiting in both groups

Post-operative nausea and vomiting is significantly lower in group A as compared to group B(p<0.05).

Table 2. Comparisons of incidence of postoperative nausea and vomiting

Groups	In recovery room	6hrs	24hrs
Group A	4%	0%	0%
Group B	18%	20%	18%
P- value	P =0.00	P =0.00	P =0.00

Graphical representation of post-operative nausea & vomiting among study groups



Mean time taken to return to daily activity among study groups

The mean time taken by patients to return to their daily activities was 3.05±2.1 days in group B as compared to 4.06±1.64 days in group A and the difference was statistically significant.

Table 3.comparison of mean time taken to return to daily activity

	Group A	Group B	P-value
Return to daily activity(mean time in days)	4.06±1.64	3.05±2.1	0.03

Postoperative seroma formation among study groups

Postoperative seroma formation is more commonly seen in group A as compared to group B (12% vs 4%).it was statistically significant,p=0.00

Table 4. post operative seroma formation

	Group A	Group B	P-value
Post-operative seroma formation	12%	4%	0.00

The postoperative surgical site infection rate was not found to be statistically significant in both Groups(p value=0.061).

The mean hospital stay in both groups were almost similar.

DISCUSSION

A meta-analysis of 29 randomized trials in 2003 found that laparoscopic hernia repair was associated with earlier discharge from the hospital, quicker return to normal activity and work, and fewer postoperative complications than open repair.¹⁰

A more recent multicenter, randomized trial that analyzed long-term hernia results in over 2000 patients in 14 Veterans Affairs hospitals found that laparoscopic hernia repair was associated with a higher recurrence rate among primary hernias, but was equivalent to open repair in recurrent hernias.¹¹

In a randomized, multicenter trial comparing 665 TEP versus 705 Lichtenstein repairs with 5-year follow-up, authors initially found that the recurrence rate following TEP (3.5%) was significantly higher (p =0.008) than that following Lichtenstein (1.2%).¹² However, when they removed a single surgeon who was responsible for 33% of all the recurrences in the TEP group, the cumulative recurrence rate for TEP was lowered to 2.4% and was not statistically different from the Lichtenstein group. Finally, a recent study has reported a significant learning curve inherent in the laparoscopic approach.¹⁴ Clearly, more definitive mul-ticenter data from

surgeons experienced in both procedures are needed to reach formal conclusions about the utility of both hernia approaches.

In our study, time taken for laparoscopic inguinal hernia repair was more than the open inguinal hernia repair group. But the time taken to daily activities was significantly less in the laparoscopy group.¹³

In our study, postoperative pain following laparoscopic surgery was lower than that of open surgery at any given time and this difference was statistically significant $p < 0.00$ based on the VAS scores at 0 hour, 6 hours and 24 hours respectively.¹⁸ Incidence of post operative nausea and vomiting was significantly lesser in open hernia group as compared to laparoscopic hernia group.^{15,16,17}

In a large study, conducted on 1,542 patients charted into five randomized controlled trials and seven comparative studies, evaluated through modern meta-analytic methods showed less incidence of seroma formation in patients operated through laparoscopic technique as compared to open repair¹⁸. Same result was observed in our study.

The postoperative surgical site infection rate was not found to be statistically significant in both Groups (p value = 0.061). The mean hospital stay in both groups were almost similar.

The pros and cons of any procedures need to be weighed. Although many authors have over weighed the advantages of laparoscopic inguinal hernia repair, open repair still remains the mainstay for the clinicians operating at rural hospitals due to lack of modern equipments. Another limitation to this latest advancement is that it can be performed only under general anesthesia unlike open surgery which has options for both local anesthesia and general anesthesia. Findings comparing various studies demonstrate that the mastery in laparoscopic approaches can yield better outcomes with good results.

CONCLUSION

Laparoscopic hernia repair is safe and provide less postoperative morbidity in experienced hands compared to open hernia repair.

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