

A Prospective Randomized Comparative Study of Lichtenstein Open Tension-Free Versus Laparoscopic Totally Extraperitoneal Inguinal Hernia Repair

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Abstract

Background: The research for ideal technique for Hernia correction would have preferably less complication rates and low recurrences. In recent studies laparoscopic hernia repair has been preferred and has gained vast acceptance among surgeons. Both laparoscopic(TEP) repair and open hernia repair have shown to be better outcome in many studies.

Material and Methods: This was a hospital based prospective comparative observational study in which 100 (50 each) subjects with a diagnosis of inguinal hernia those were willing to participate were taken for each of two groups i.e. laparoscopic totally extra peritoneal (TEP group) and Lichtenstein open tension- free mesh repair (Lichtenstein group).

Results: TEP was associated with shorter operative time, shorter hospital stay and cosmetically better compared to Lichtenstein hernioplasty. The mean pain score in the TEP group was significantly less than the Lichtenstein group on all occasions up to 2nd week post- operatively. There was no conversion from TEP to open Lichtenstein repair. The hospital stay in Lichtenstein group was significantly longer compared to TEP group (p= 0.042).

Conclusion: Laparoscopic TEP repair may be done in all uncomplicated inguinal hernias by an experienced surgeon for those desiring less pain, better cosmetic results, less postoperative complications, less hospital stay and early return to work.

Keywords: Hernia, Lichtenstein hernioplasty, TEP

Introduction

Hernia is derived from the Latin word for rupture, defined as an abnormal protrusion of an organ or tissue through a defect in its surrounding walls. Hernia constitutes a major health-care drain. It is estimated that

27% of men and 3% of women develop inguinal hernia during their lifetime¹.

In 1984, Lichtenstein et al² coined the term “Tension- Free repair” which is routinely advocated for open inguinal hernia repair. This repair using tension free mesh technique gave better results than a conventional sutured repair³.

Even though hernia repairs were reported as early as 1982 by Ger⁴, the widespread interest in laparoscopic hernioplasty did not occur till the 1990`s. Disappointing early recurrence rates, general anesthesia, longer operative times, cost of the procedure and the steep learning curve were the major stumbling blocks which prevented the routine use of laparoscopy in the management of inguinal hernias. TEP (totally extra peritoneal) Laparoscopic inguinal hernia repair which was first described by Mc Kernan and Laws⁵ in 1993 is a popular

method in the present era. This has been possible because of advancement of modern instruments and increasing pressure from the industry as well as from patients who increasingly demand less invasive procedures, in the face of criticism from conventional surgeons.

Laparoscopic hernioplasty has several advantages over its open counterparts as evidenced by several studies⁶⁻⁸. First and foremost aspect from the patient point of view is the reduced post-operative pain and short recovery period. Second, the entire myopectineal orifice can be inspected, allowing repair of any unexpected hernias thereby reducing the chance of recurrence. Third, laparoscopic hernioplasty avoids the previous operative scar site in patient with recurrent hernias.

TEP repair has gained popularity in recent years because peritoneal sanctity is maintained, leading to a lower incidence of serious complications. Now TEP is considered as the standard laparoscopic Hernia repair.

The aim of this study is to assess and compare Lichtenstein's open tension-free and laparoscopic totally extra peritoneal mesh repair in relation to operative time, intra-operative complications, post-operative pain and neuralgia, post-operative hospital stay, time required for return to work and hernia recurrence.

Material and Methods

This was a hospital based prospective comparative observational study conducted at a tertiary care centre in Jaipur, India with prior approval of institutional ethical committee during the period of January 2017 to January 2018. 50 subjects were taken for each of two groups' i.e. laparoscopic totally extra peritoneal (TEP group) and Lichtenstein open tension-free mesh repair (Lichtenstein group). Sampling was done using systemic random sampling technique applied on all the cases of elective inguinal hernia coming to outdoor in a single surgical unit operated by a single surgeon in the given period which meet the inclusion and exclusion criteria.

Inclusion Criteria: All cases with a diagnosis of inguinal hernia those were willing to participate and follow-up for 3 month and gave written informed consent

Exclusion Criteria: Pregnancy; patient having bleeding disorder or on anticoagulants; any emergency surgery e.g. peritonitis, strangulated, incarcerated and obstructed inguinal hernias; patients unsuitable for general anaesthesia; patients with large, complete, indirect inguinal hernia which were only partially reducible or irreducible (SGRH classification grade V groin hernia); prior groin irradiation or other inflammatory process.

Patients undergoing TEP repair were operated under general anaesthesia with use of 12*15cm² Prolene mesh

which was fixed using endotack tacking device as and when required.

Patients undergoing Lichtenstein mesh hernioplasty were operated under local, spinal or general anaesthesia with use of 7.5*15 cm² Prolene mesh which was fixed using Prolene 2-0 interrupted sutures. All patients were given standard postoperative care and on demand analgesia.

The following variables were assessed for both groups – Mean duration of surgery, injury to vital structures, pain, incision site infection, seroma and hematoma formation, hydrocele formation, paraesthesia, mean duration of hospital stay, average time for return to work and recurrence (follow up for 3month). All the patients were encouraged to return to work, when they felt comfortable.

The operative time was noted in each case from the time of first incision to the last skin stitch applied. Postoperative Pain was recorded using Visual Analogue Scale (VAS) at 24h, 48h, 7th day and 14th day postoperatively. The data were compiled on the Microsoft Excel computer program and subjected to statistical analysis. The Mann–Whitney U test and Student's t test were used for comparison of the means (quantitative data). The chi-square test and Fisher's exact test were used for categorical data.

Results

Total 100 patients were included in this study; 50 in each groups out of which 99 were male and 1 female. The patients were in the age group of 15-76 years and there was no significant difference in the mean age between two groups. Majority of the patients had right sided inguinal hernia 49%, 52% in TEP group and 46% in the

Lichtenstein group (Table 1). Laparoscopic TEP procedure was significantly lengthy than Lichtenstein hernioplasty. The mean pain score in the TEP group

was significantly less than the Lichtenstein group on all occasions up to 2nd week post-operatively (Table 2). There were no major complications like bladder injury, bowel injury or major vascular injury except for one patient in Lichtenstein group had ilio-inguinal nerve injury. There was no conversion from TEP to open Lichtenstein repair. The hospital stay in Lichtenstein group was significantly longer compared to TEP group (p= 0.042). Patients in TEP group returned to work earlier than their counterparts (Table 1). There was no recurrence and no readmission in both groups during the period of follow up of 3 months.

Table 1. Comparison of demographic, clinical, intraoperative and postoperative observations between both groups

	TEP Group (n=50)	Lichtenstein Group (n=50)	p Value
Mean Age (±SD)	39.54 (15.989)	42.78 (17.258)	0.451
Sex distribution			
Male	49	50	
Female	1	0	
Side of Hernia			
Right	26	23	
Left	8	13	
Bilateral	16	14	
Mean Operative Time in min (±SD)	87.9(26.23)	55.54(16.37)	<0.001
Postoperative stay in hospital in days (±SD)	2.02 (0.14)	2.54 (1.77)	0.042
Return to work postoperatively in days (±SD)	11.34 (1.99)	17 (3.48)	<0.001

p Value < 0.05 = Significant

Table 2. Comparison of Visual Analogue Scale Score between both groups

Time	TEP Group (VAS ±SD)	Lichtenstein Group (VAS ±SD)	p Value
24 hrs.	2.96 ±0.63	3.60±0.96	<0.001
48 hrs.	1.88±0.48	2.30±0.61	<0.001

7 days	0.54±0.40	1.06±0.97	<0.001
14 days	0.40±0.10	0.59±0.36	<0.001
p Value < 0.05 = Significant			

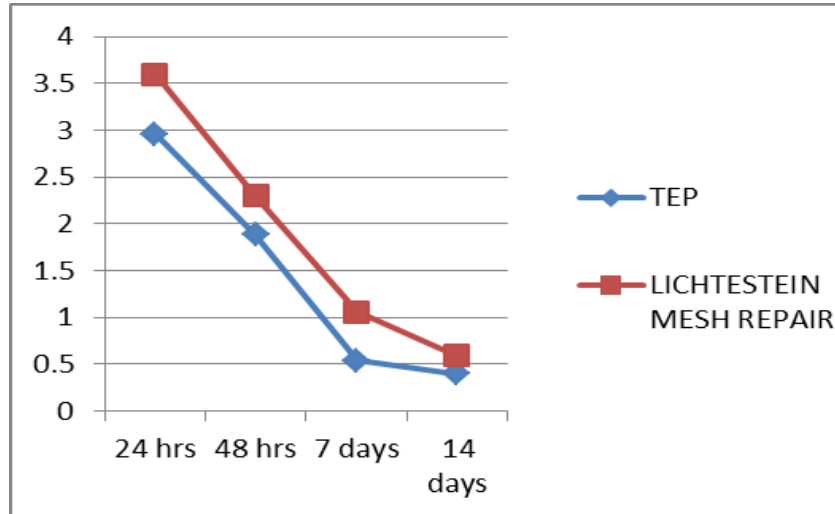


Figure 1: Trend line showing VAS score of two groups

COMPLICATION	TEP group(n=50)	Lichtenstein group(n=50)
NS		
Bladder Injury	0	0
Bowel Injury	0	0
Nerve Injury	0	1
Nausea	5	5
Seroma	0	7
Incision site induration	0	6
Numbness	0	1
Hematoma	0	1
Secondary Hydrocele	0	1

Discussion

All patients in both groups were male except one female in TEP group. This was unintentional. The mean age of patients in the laparoscopic TEP group was

39.54 years and was less than the age in Lichtenstein group i.e. 42.78 years. The difference in mean age of patients in both the groups was found statistically insignificant. The patients were equally distributed in different age groups. In TEP group, 26(52%) patients had Right sided hernia, 8(16%) Left sided hernia and

16(32%) had bilateral hernia. Overall 49% patients had Right sided hernia. In literature, the prevalence of hernia is stated to be more in males by ratio of 7:1. The prevalence of hernia in male is clearly age dependent and right sided groin hernias are more common than the left⁹.

The mean operative time of TEP repair was 87.90min (± 26.3). This was significantly longer than the operative time for Open Lichtenstein repair (55.54 ± 16.37). The operative time improved with the learning curve of the surgeon and assistant which holds laparoscope. The mean operative time of TEP repair in our series is slightly longer than all other published series⁹. This could be explained by the fact that we still need little more expertization and due to large indirect sac which took longer time to dissect. Expertization of the assistant is also necessary. Mean operative time in series by Andersson et al¹¹ was 81(± 27) min and Suter et al¹² 82 min. Other series had lesser mean operating times.

Our mean operative time for Lichtenstein repair

i.e. 55.54 min was slightly more than Wright et al¹³ (45 min) and nearer to Heikkinen et al¹⁴ (53 min) and Lal et al¹⁵ (54 min).

All patients in TEP group were operated under general anesthesia as it is the safest and most comfortable for the patient. There were no anesthetic complications however longer mean operative times resulting in longer anesthesia times, more doses of drugs, more costs and probably delayed recovery from anesthesia; all of which are detrimental to the patient.

Lichtenstein repair was mostly done under spinal block with its inherent complications due to convenience, lesser time needed and need of anesthesia for a short time.

There were no conversions of Laparoscopic TEP repair to open Lichtenstein repair (0%), which is equal or lower than any published series because of the experienced surgeon. Lal et al¹⁵ and Lau et al¹⁶ reported conversion rate at 0%. The conversion rate of laparoscopic to an open technique varies from 0 to 1.7% in most series. The conversion is most frequently performed for the management of complications (hemorrhage, digestive tract, injuries, etc.) and occasionally due to technical problems related to faulty surgical equipment (Liem et al¹⁷). Overall, in TEP group no major intraoperative complications occurred. The mean pain score were significantly low in TEP group as compared to Lichtenstein group in all readings up to 2 weeks postoperatively. This is consistent with the findings of other randomized studies. Lal et al¹⁵ had significant difference in pain scores after 12 and 24 hours but not thereafter, which was similar to results of Liem et al¹⁸ and Champault et al¹⁹.

Postoperative complications:- In the TEP group, seroma formation in the inguinoscrotal region was nil which was probably related to dissection of the space in avascular plane and delicate handling of the cord structures. In Open group seroma was present in 7 (14%) cases probably due to extensive dissection of the space, rough handling of cord and intraoperative oozing. However all cases were managed by reassurance and anti-inflammatory medication for 5-7 days. All resolved conservatively at various time periods. The seroma formation in our study was higher in comparison to Liem et al¹⁸ (1%) and Kald et al²⁰ (2%).

There were no major vessels, bladder or bowel injuries in laparoscopic TEP group due to careful meticulous technique of initial port insertion, preoperative routine urinary catheterization of all patients and secondary port insertion under vision. Bladder injuries were reported by Ramshaw et al²¹ (0.6%). Overall in TEP group no major intraoperative complications occurred. Incision site induration was present in 6 cases and only one case of each complication such as numbness, hematoma and secondary hydrocele was observed in Lichtenstein group.

Postoperative numbness/paresthesia was seen in any case in TEP group but in one (2%) case of Lichtenstein group. Lal et al¹⁵ reported 8% incidence of neuralgia in TEP group and Tamme et al²² 1.1%. This is reported in

various studies to be a cause of long term morbidity and lower quality of life in open repairs¹⁰.

Hematoma occurred in one case in the inguinal region in Lichtenstein group which resolved conservatively. Lal et al¹⁵ reported no incidence of hematoma formation in TEP and 8% in Lichtenstein group. Liem et al¹⁸ reported 1.8% hematoma in TEP group.

Duration of hospital stay: Postoperative hospital stay was significantly low in TEP group. Lal et al¹⁵, Khoury N²³ and Andersson et al¹¹ shows no significant difference in hospital stay but other studies showed significantly lesser hospital stay in TEP repair cases.

Duration to Return to work: Mean duration of return to work was longer in Lichtenstein group(17 days) than TEP group(11.34 days) which was significant. These can be explained by that less intraoperative and postoperative complications, and early recovery. Our findings were supported by Hekkinen et al¹⁴ (12 vs 17 days) and Liem et al¹⁸ (14 vs 21 days).

Better cosmetic result and low complication rate is an advantage of using laparoscopic hernia repair particularly in young patients who desire better scars.

Recurrence – There was no recurrence in the short term follow up of the patients (mean follow up 3 month). Longer follow up will be necessary to interpret this data.

Conclusions

Laparoscopic TEP repair is a significantly lengthier procedure than open Lichtenstein repair especially in the learning phase of the surgeon. Thereafter, the operative time decreases but still more than open procedure.

Good technique and knowledge about various potential complications with experience in TEP repair is essential to prevent serious complications like bladder injuries, bowel injuries and major vascular injuries etc. Increased patient satisfaction due to less pain, less wound complications and better cosmetic results and earlier return to work in TEP group makes this procedure a preferable one.

Laparoscopic TEP repair may be done in all uncomplicated inguinal hernias by an experienced surgeon for those desiring less pain, better cosmetic results, less postoperative complications, less hospital stay and early return to work.

Research involving Human Participants - All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments.

Informed consent - Informed consent was obtained from all individual participants included in the study.

References

1. Kingsnorth A, LeBlanc K. Hernias: inguinal and incisional. *Lancet* 2003; 362:1561-71.
2. Lichtenstein IL, Shulman AG, Amid PK, Montllor MM. The tension-free hernioplasty. *Am J Surg.* 1989 Feb. 157(2):188-93.
3. Nordin P, Bartelmess P, Jansson C, et al. Randomized trial of Lichtenstein versus Shouldice hernia repair general surgical practice. *Br J Surg.* 2002; 89:45–9.
4. Ger R, Monroe K, Duvivier R, et al. Management of indirect inguinal hernias by laparoscopic closure of the neck of the sac. *Am J Surg.* 1990; 159:370– 373.
5. McKernan JB, Laws HL. Laparoscopic repair of inguinal hernias using a totally extraperitoneal prosthetic approach. *Surg Endosc.* 1993;7:26–28
6. Kumar S, Wilson RG, Nixon SJ, Macintyre IM. Chronic pain after laparoscopic and open mesh repair of groin hernia. *Br J Surg.* 2002;89:1476– 1479
7. Memon MA, Cooper NJ, Memon B, Memon MI, Abrams KR. Meta-analysis of randomized clinical trials comparing open and laparoscopic inguinal hernia repair. *Br J Surg.* 2003;90:1479–1492
8. Youn SI, Kim BG, Cha SJ, Chang IT. The comparative analysis between laparoscopic inguinal herniorrhaphy and open inguinal herniorrhaphy. *J Korean Surg Soc.* 2005;69:166– 171
9. Rutkow IM, Robbins AW. Demographic, classificatory, and socioeconomic aspects of hernia repair in the United States. *Surg Clin North Am.* 1993; 73:413–26.
10. Kuhry, E., van Veen, R.N., Langeveld, H.R. et al. Open or endoscopic total extraperitoneal inguinal hernia repair? A systematic review. *Surg Endosc.* 2007;21:16.

11. Andersson B, Hallén M, Leveau P, Bergenfelz A, Westerdahl J. Laparoscopic extraperitoneal inguinal hernia repair versus open mesh repair: a prospective randomized controlled trial. *Surgery*. 2003;133: 464–472
12. Suter M, Martinet O, Spertini F. Reduced acute phase response after laparoscopic total extraperitoneal bilateral hernia repair compared to open repair with the Stoppa procedure. *Surg Endosc*. 2002;16: 1214–1219.
13. Wright Dm, Kennedy A, Baxter JN, Fullarton, GM, Fife LM, Sunderland GT, O Dwyer PJ. endoscopic tension-free hernioplasty: A randomized clinical trial. *Surgery*. 1996; 119: 552-557 .
14. Heikkinen TJ, Haukipuro K, Koiuvkangas P, Hulkko A. A prospective randomized outcome and cost comparison of totally extraperitoneal endoscopic hernioplasty versus Lichtenstein hernia operation among employed patients. *Surg. Laparosc Endosc*. 1998; 8: 338-344
15. Lal P, Kajla RK, Chander J, Saha R, Ramteke VK. Randomized controlled study of 2003; 17: 850–856.
16. Lau H, Patil NG, Yuen WK, Lee F. Management of peritoneal tear during endoscopic extraperitoneal inguinal hernioplasty. *Surg Endosc*. 2002;16:1474- 1477.
17. Liem MSL, Halsema JAM, van der Graaf Y, Schrijvers AJ, van Croonhoven TJ. Cost effectiveness of extraperitoneal laparoscopic inguinal hernia repair: a randomized comparison with conventional herniorrhaphy. *Ann Surg*. 1997; 6:668-676
18. Liem MS, Van der Graaf Y, van Steensel CJ, Boelhouwer RU, Clevers GJ, Meijer WS, Stassen LP, Vente JP, Weidema WF, Schrijvers AJ, van, vronhoven TJ. Comparison of conventional anterior surgery and laparoscopic surgery for inguinal hernia repair. *N Engl J Med* 1997;336:1541-1547.
19. Champault GG, Rizk N, Catheline JM, Turner R, Bouteliner P. Inguinal hernia repair: totally stoppa operation: randomized trial of 100 patients. *Surg laparosc Endosc*. 1997; 7:445-450.
20. Kald A, Anderberg B, Smedh K, Karlsson M. Transperitoneal or totally extraperitoneal Of 491 consecutive hernioplasty. *Surg Endosac*. 1997; 7:86-89.
21. Ramshaw B, Abiad F, Voeller G, et al. Polyester mesh for total extraperitoneal laparoscopic united states. *Endosc* 2003; 17:498-501.
22. Tamme, C., Scheidbach, H., Hampe, C. et al. Totally extraperitoneal endoscopic inguinal hernia repair (TEP). *Surg Endosc* 2003; 17: 190.
23. Khoury N. A randomized prospective controlled trial of laparoscopic extraperitoneal hernia repair and mesh-plug hernioplasty: a study of 315 cases. *J laparoendosc Adv Surg Tech*. 1998; 8:367-372.