



RANDOMIZED CONTROLLED TRIAL BETWEEN TENSION FREE OPEN HERNIA REPAIR (LICHTENSTEIN'S) AND LAPAROSCOPIC TRANSABDOMINAL PREPERITONEAL (TAPP) REPAIR OF INGUINAL HERNIA FOR COMPARISON OF POST OPERATIVE PAIN AND HOSPITAL STAY

Dr. Neeraj Kumar Banoria

Associate Professor, Department of Surgery, Maharani Laxmi Bai Medical College, Jhansi- 284128

Dr. Pankaj Kumar Saunakiya*

Assistant Professor, Department of Surgery Maharani Laxmi Bai Medical College, Jhansi*Corresponding Author

Dr. Mata Prasad Upadhyay

Junior Resident, Department of Surgery Maharani Laxmi Bai Medical College, Jhansi-

ABSTRACT

Objective: To compare the open Lichtenstein repair and laparoscopic mesh repair for direct inguinal hernias in terms of immediate post operative pain and length of hospital stay. **Methods:** This randomized control trial was conducted at Maharani Laxmi Bai Medical College, Jhansi, Uttar Pradesh from December 2017 to June 2019. All patients presenting in the surgical OPD with inguinal hernia (Direct & Indirect) were randomly divided in two equal groups. Group-I, patients underwent Lichtenstein's repair and Group-II had hernioplasty by laparoscopic method (TAPP). Post operative pain intensity assessed by VAS and hospital stay measured in hours. **Results:** A total 84 patients of inguinal hernia (Direct & Indirect) were studied. The mean age was 43.48 ± 17 years. The range of postoperative pain experienced was 5.35 as per VAS among all patients. In group-I (open hernioplasty) majority of patients (42.86%, n=18) experience severe type of pain where as in group-II, moderate severity of pain was reported by large number of patients (76.19%, n=32) The mean post operative pain intensity as per VAS was 6.05 in group-I and 4.67 in group-II patients. The mean length of hospital stay was slightly less (5.64 days) in group-I as compared to group-II (4.55days). **Conclusion:** There is definitely less post operative pain & less post operative hospital stay after laparoscopic repair.

KEYWORDS : Inguinal Hernia; Laparoscopic hernioplasty; Lichtenstein's repair; Post operative pain.

INTRODUCTION

More than 20 million inguinal hernia repair surgeries are performed every year worldwide. In India, the estimated annual incidence of inguinal hernias is 1,957,8501 This is a multifactorial disease affecting individuals of all ages and of both sexes. Thirty percent of patients with inguinal hernia are asymptomatic, and up to 50% are aware of their hernia. Three percent of the patients present incarceration. Indirect hernia corresponds to more than 70% of cases among adults. The recurrence after surgery ranges from 3 to 8%².

There have been various methods for inguinal hernia repair, but recently, so called 'tension-free repair' is the procedure of choice³ due to its low recurrence rate. These tension-free repair procedures can be roughly categorized into two groups; laparoscopic and open anterior approach. As laparoscopic hernia repair, total extraperitoneal (TEP) repair, transabdominal preperitoneal (TAPP) repair, and intraperitoneal onlay mesh (IPOM) repair are well known. Among them, TAPP is accepted as the most ideal method because its easy learning curve. And among open tension-free methods, such as Lichtenstein's operation, repair using mesh plug or prolene hernia system (PHS), PHS repair is becoming an accepted and popular technique because of shorter operating time, about 10%, and its low recurrence rate^{4,5}.

There is a constant discussion among surgeons about which hernia repair technique is better: open or laparoscopic? The National Institute for Health and Care Excellence guidelines recommend open surgical approaches for the treatment of primary unilateral inguinal hernias. However, there is a trend among surgeons to perform a laparoscopic procedure. Surgeons performing laparoscopic hernioplasty claim that there is decreased post operative pain and short postoperative hospital stay as compared to open hernioplasty.^{6,7}

The objective of the present study was to compare the

postoperative pain intensity, and the rate of complications between open inguinal hernia repair (Lichtenstein) and the laparoscopic (transabdominal preperitoneal - TAPP) technique.

METHODS:

The objective of the study was to compare the open Lichtenstein repair and laparoscopic mesh repair for inguinal hernias in terms of immediate post operative pain and length of hospital stay. This Randomized controlled trial was conducted in Department of Surgery, Maharani Laxmi Bai Medical College, Jhansi, Uttar Pradesh from December 2017 TO June 2019. A total of 100 patients were studied and divided between the 2 equal groups. Patients were selected through Simple random sampling (computer generated) technique. Inclusion Criteria consist of male presenting to general-surgery clinic with a diagnosis of inguinal hernia (Indirect or Direct). Exclusion Criteria comprised of Patients with contraindications to pelvic laparoscopy, history of repair with mesh, recurrent inguinal hernia, previous pelvic surgery or history of Transvesical prostatectomy. Routine baseline of all patients was checked. After obtaining approval by the hospital ethical committee, informed consent was taken from each patient. Pre-anesthetic evaluation was done before operation. All the procedures were performed by surgeon. The patients were divided in two groups by simple random sampling (computer generated) to minimize the selection bias. No blinding possible. Group-I includes Patients underwent hernioplasty by laparoscopic method (TAPP). Group-II includes Patients underwent hernioplasty by open method (Lichtenstein's repair).

Laparoscopic repair was performed by Transabdominal preperitoneal (TAPP) approach by 3 port technique, 1st at the umbilicus, and the other two at lateral border of Rectus muscle at the level of umbilicus on both sides. Classical Open Lichtenstein's repair was performed in the other group.

Postoperatively, patient's perception of pain was assessed by

Visual Analogue Scale (VAS) about four hours after surgery. All patients received analgesia in the form of Inj. Diclofenac sodium 75mg I/M immediately after surgery and it was repeated only after 06 hours. No preoperative or peroperative analgesia was given to any patient. All the patients were given standardized postoperative instructions not to restrict their activities unless the activities cause pain. All patients were assessed for postoperative analgesia requirements and hospital stay. Length of postoperative hospital stay was calculated in terms of hours after surgery till the time when patient was discharged. The discharge time was the time mentioned in patients' notes.

All the data was entered on SPSS for windows version 10. Mean and standard deviation will be calculated for all quantitative data (age, postoperative pain, length of hospital stay). Frequencies and percentages were calculated for qualitative data (age). Comparison of Quantitative data in both groups was analyzed by student T- test. Comparison of Quantitative data in both groups was analyzed by chi-square test in both groups. A p-value ≤ 0.05 was considered statistically significant.

RESULTS

A total of 84 patients having inguinal hernia admitted through the surgical OPD from December 2017 TO June 2019. The age varies between 20-75 years with a mean age of 43.48±17 years (Table-I). Patients were similar in demographic characteristics.

The range of postoperative pain experienced by the patients as per VAS was between 2-9 whereas mean was 4.70 (Table-II). The postoperative pain severity (ranked as mild, moderate and severe) showed severe type of pain experienced in 42.86% patients (n=18) in open hernioplasty group followed by moderate severity in 50.00% (n=21) Patients. In Laparoscopic repair group majority of patients experienced moderate (76.19%, n=32) and mild (21.43%, n=9) severity of pain respectively.

The mean post operative pain intensity as per VAS was 6.12 in open hernioplasty group and 4.34 in Laparoscopic repair group patients.

The mean hospital stay was 4.86 days and range was between 2 to 8 days in both groups. (Table-III). Table-IV, shows that the mean length of hospital stay was less (3.86 days) in laparoscopic group as compared to open group (5.86 days).

Table I: Severity of mean postoperative pain in all patients (n=84).

Minimum (VAS)	Maximum (VAS)	Mean	Std. Deviation
2	9	5.35	1.56

Table II: Comparison of mean severity of Post operative pain in both groups (n=84), p-value=0.0141

Procedure Postop pain	N	Mean	Std. Deviation	Std. Error Mean
Open hernioplasty	42	6.05	1.43	0.221
Laparoscopic hernioplasty	42	4.67	1.36	0.209

Table III: Mean Hospital Stay in all patients (n=84).

Minimum	Maximum	Mean	Std. Deviation
2	8	5.09	1.240

Table IV: Comparison of mean length of Hospital Stay in both groups (n=84) p-value =0.0106

Procedure	N	Mean	Std. Deviation	Std. Error Mean
-----------	---	------	----------------	-----------------

Open hernioplasty	42	5.64	1.13	0.174
Laparoscopic hernioplasty	42	4.55	1.09	0.168

DISCUSSION

According to several authors, laparoscopic surgical treatment of bilateral inguinal hernia apparently shows a lower rate of postoperative pain, reduction of the time of disability, reduction of hospital stay, and low postoperative complications, therefore allowing a better quality of life.⁸ Although open hernioplasty operation can be performed as day care procedure in selected cases with the use of local anesthesia but it has been presumed that open hernioplasty is associated with increased postoperative pain, prolonged hospital stay, more recurrence and a delayed return (four to six weeks) to full physical activity and employment. The rates of hernia recurrence after open repair reported in literature are low (less than 2%) in specialized centers, but recurrence rates in regionalized studies of heterogeneous populations have averaged 5 to 10 % for primary hernias and 5 to 30 % for recurrent hernias.⁹ With regard to postoperative pain and complications, in the present study of unilateral hernias, we found significant difference between groups.

Laparoscopic inguinal hernia repair has been around since 1990s.^{10,11} Principal advantages of the laparoscopic approach over traditional surgeries reported in literature are, reduced postoperative pain, shorter hospital stays, and shorter periods of disability.¹²

In contrast with the open repair, Laparoscopic repair of inguinal hernias is performed with the use of general anesthesia and three laparoscopic ports. Several techniques for laparoscopic herniorrhaphy have been used, including closure or plugging of the hernia and various types of patch repairs. Patch repair is currently the most common method and entails placing a large prosthetic patch internally to cover the hernia and inguinal floor.^{13,14,15} Conceptually, this operation is similar to the open preperitoneal approach advocated by Stoppa et al., who used a large "tension-free" patch to cover the entire inguinal floor, with a subsequent recurrence rate of 1.4 percent.¹⁵ It appears, however, that laparoscopic hernia repair is associated with less postoperative pain and an earlier return to full physical activity than conventional herniorrhaphy.¹⁶ Despite the favourable early results, the procedure is controversial. Although the operation is similar to the repair described by Stoppa et al, the different method for fixation of the mesh laparoscopically adds an element of uncertainty to long-term stability and security.

The p value for postoperative pain is 0.0141 in our study which is significant and concludes that the patient who had laparoscopic hernioplasty experienced less pain postoperatively as compared to those having open herniorrhaphy. The same results were also concluded from the review of 41 Cochrane studies,¹⁷ TULIP Trial¹⁸ and other studies.¹⁹ On the contrary, a multicenter trial conducted at Austria concludes no significant difference in complications and recurrence rate between laparoscopic and open hernioplasty.²⁰ Similarly, a meta analysis conducted at Aberdine, UK conclude that the open and laparoscopic hernia repair are equally effective procedures and choice between them should be made on a case to case basis depending on patient preference and other characteristics such as age, work, health status etc.¹⁷ Many national and international studies also conclude no significant difference in morbidity and recurrence between both modalities but operating time is more in laparoscopic herniorrhaphy.^{16,21,22}

Regarding hospital stay, our results shows that there is significant statistical difference (p value=0.0106) regarding

postoperative hospital stay in between open or laparoscopic hernia repair. These findings are consistent with the many other studies carried out at different centers.^{16, 20, 21, 23, 24} and also with Cochrane database review of 41 studies.¹⁷ Literature search showed that there are many trials which have reported contrary results for example Pironi D et al.²⁵, Neumayer et al.¹³ and Mahon et al.¹² A recent audit published in 2009 have shown over all averaged 3.7 days hospital stay, averaging 3.3 and 3 days for bilateral and unilateral repairs respectively and any added procedures lengthened the hospital stay from 4 to 10.6 days.²⁴

Laparoscopic hernia repair also requires a general anesthesia, with its associated risks, for a procedure that can be done conventionally with local anesthesia in selected cases. There is a small but definite risk of serious injury to intra-abdominal organs that is not associated with traditional inguinal herniorrhaphy. Also, costs may be higher because of the need for expensive equipment and other supplies related to laparoscopic instrumentation.^{14, 22} Unlike those for laparoscopic cholecystectomy, these increased costs are not offset by decreased hospital charges, since hernia operations are routinely outpatient procedures regardless of the method of repair. A recent comparison of conventional with laparoscopic herniorrhaphy indicated an average increase in cost of 135 percent with the laparoscopic approach. Whether these direct costs may be partially offset by an earlier return to employment is not known.^{22, 25}

The safety and efficacy of laparoscopic inguinal hernia repair have recently been evaluated in two multi-institutional reports.²⁶ In a multi-institutional trial, Fitzgibbons et al. reported 2.2 percent definite recurrences of hernia and 1.2% possible recurrences, whereas, in long term follow up, about 0.5% patients has reported thigh pain or hypoesthesia.²⁷

CONCLUSION

This study shows that there is less post operative pain after laparoscopic repair and hospital stay than open (Lichtenstein's) hernioplasty procedures.

REFERENCES

1. Primatesta P, Goldacre MJ. Inguinal hernia repair: Incidence of elective and emergency surgery, readmission and mortality. *Int J Epidemiol* 1996;25:8359.
2. The HerniaSurge Group International guidelines for groin hernia management. *Hernia*. 2018;22(1):1-165. doi: 10.1007/s10029-017-1668-x.
3. Eklund AS, Montgomery AK, Rasmussen IC, Sandbue RP, Bergkvist LA, Rudberg CR. Low recurrence rate after laparoscopic (TEP) and open (Lichtenstein) inguinal hernia repair: a randomized, multicenter trial with 5-year follow-up. *Ann Surg*. 2009;249:33-38.
4. Kingsnorth AN, Wright D, Porter CS, Robertson G. Prolene Hernia System compared with Lichtenstein patch: a randomised double blind study of short-term and medium-term outcomes in primary inguinal hernia repair. *Hernia*. 2002;6:113-119.
5. Gilbert AI, Graham MF, Voigt WJ. A bilayer patch device for inguinal hernia repair. *Hernia*. 1999;3:161-166.
6. Gould J. Laparoscopic versus open inguinal hernia repair. *Surg Clin North Am*. 2008;88:1073-1081. doi:10.1016/j.suc.2013.06.013.
7. Gray SH, Hawn MT, Itani KMF. Surgical progress in inguinal and ventral incisional hernia repair. *Surg Clin N Am*. 2008;88:17-26. doi:10.1016/j.suc.2007.11.007.
8. Ielpo B, Duran H, Diaz E, Fabra I, Caruso R, Malavé L, Ferri V, Lazzaro S, Kalivaci D, Quijano Y, Vicente E. A prospective randomized study comparing laparoscopic transabdominal preperitoneal (TAPP) versus Lichtenstein repair for bilateral inguinal hernias. *Am J Surg*. 2018;216 (1):78-83. doi: 10.1016/j.amjsurg.2017.07.016.
9. Bekker J, Keeman JN, Simons MP, Aufenacker TJ. A brief history of the inguinal hernia operation in adults. *Ned Tijdschr Geneesk*. 2007;151(6):924-931.
10. Gray SH, Hawn MT, Itani KMF. Surgical progress in inguinal and ventral incisional hernia repair. *Surg Clin N Am*. 2008;88:17-26. doi:10.1016/j.suc.2007.11.007.
11. Tai HC, Lin CD, Chung SD, Chueh SC, Tsai YC, Yang SS. A comparative study of standard versus laparoendoscopic single-site surgery (LESS) totally extra peritoneal (TEP) inguinal hernia repair. *Surg Endosc*. 2011;25:2879-2883.
12. Mahon D, Decadt B, Rhodes M. Prospective randomized trial of laparoscopic (Transabdominal Preperitoneal) vs. open (mesh) repair for bilateral and recurrent inguinal hernia. *Surg Endosc*. 2003;17:1386-1390.
13. Neumayer L, Giobbie-Hurder A, Jonasson O, Fitzgibbons R, Dunlop D, Gibbs J, et al. Open Mesh versus Laparoscopic Mesh Repair of Inguinal Hernia. *N Engl J Med*. 2004;350:1819-1827.
14. Legutko J, Pach R, Solecki R, Matyja A, Kulig J. The history of treatment of groin hernia. *Folia Med Cracov*. 2008;49:57-74.

15. Stoppa RE. The midline preperitoneal approach and prosthetic repair of groin hernias. In: Fitzgibbons RJ Jr, Greenburg AG, editors. *Nyhus and Condon's Hernia*. 5th ed. Vol. 199. Philadelphia: Lippincott Williams & Wilkins; 2009.
16. Wright D, Paterson C, Scott N, Hair A, O'Dwyer P J. Five-Year Follow-Up of Patients Undergoing Laparoscopic or Open Groin Hernia Repair: A Randomized Controlled Trial. *Ann Surg*. 2002;235:333-337.
17. McCormack K, Scott NW, Go PM, Ross S, Grant AM. EU Hernia Trialists Collaboration. Laparoscopic techniques versus open techniques for inguinal hernia repair. *Cochrane Database Syst Rev*. 2003;1:CD001785.
18. Koning GG, de Schipper HJ, Oostvogel HJ, Verhofstad MH, Gerritsen PG, van Laarhoven KC, et al. The Tilburg double blind randomised controlled trial comparing inguinal hernia repair according to Lichtenstein and the transinguinal preperitoneal technique. *Trials*. 2009;10:89.
19. 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.
20. Pokorny H, Klingler A, Schmid T, Fortelny R, Hollinsky C, Kawji R, et al. Recurrence and complications after laparoscopic versus open inguinal hernia repair: results of a prospective randomized multicenter trial. *Hernia*. 2008;12(4):385-389.
21. Aly O, Green A, Joy M, Wong CH, Al-Kandari A, Cheng S, et al. Is laparoscopic inguinal hernia repair more effective than open repair? *J Coll Physicians Surg Pak*. 2011;21(5):291-296.
22. Kuhry E, Van Veen RN, Langeveld HR, Steyerberg EW, Jeekel J, Bonjer HJ. Open or endoscopic total extra peritoneal inguinal hernia repair? A systematic review. *Surg Endosc*. 2007;21:161-166.
23. Memon MA, Cooper NJ, Memon E, Memon MI, Abrams KR. Meta-analysis of randomized clinical trials comparing open and laparoscopic inguinal hernia repair. *Br J Surg*. 2003;90:1479-1492.
24. Tatulli F, Chetta G, Caputi A, Mastrototaro P, Ruggieri T. Laparoscopic inguinal hernia repair: audit of our experience with laparoscopic transabdominal pro-peritoneal repair (TAPP) *Chir Ital*. 2009;61:47-53.
25. Pironi D, Palazzini G, Panarese A, La Gioia G, Vendettuoli M, Romani AM, et al. Open mesh technique versus laparoscopic Transabdominal preperitoneal (TAPP) approach in inguinal hernia repair. Our experience. *G Chir*. 2008;29:497-504.
26. Onofrio L, Cafaro D, Manzo F, Cristiano SF, Sgromo B, Ussia G. Tension-free laparoscopic versus open inguinal hernia repair. *Minerva Chir*. 2004;59:369-377.
27. Fitzgibbons RJ, Jr, Giobbie-Hurder A, Gibbs JO. Watchful waiting vs. repair of inguinal hernia in minimally symptomatic men: a randomized clinical trial. *JAMA*. 2006;295:285-292.