# **Original Research Article**

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# Laparoscopic transabdominal preperitoneal inguinal repair versus open Lichtenstein repair: a randomized control trial

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#### **ABSTRACT**

**Background:** There have been a plenty of evolution in surgical techniques of hernia repair. The current standard technique is tension-free repair. The different studies show different results with the use of laparoscopy in performing tension-free hernia repair. Hence a study was conducted to compare the laparoscopic transabdominal preperitoneal repair with open Lichtenstein repair regarding operative complications, pain, analgesic usage, and time to return to normal activities.

**Methods:** A randomized control trial was conducted in the Department of General Surgery in a tertiary center from December 2010 to May 2012. All patients underwent either open Lichtenstein repair or laparoscopic transabdominal preperitoneal repair (TAPP). Both the procedures included a recording of operative time, operative complications, pain, analgesic usage, hospital stay, surgical site infection (SSI), and time to return to normal activities. Mann Whitney U test, student 't' test and Fisher's exact test were used to study the significance of the difference. A p-value <0.05 was considered significant.

**Results:** The open Lichtenstein procedure was found to have a significantly less operative time compared to TAPP procedure (54±15 minutes vs. 75.7±31.6 minutes; p=0.001; CI=95%; Mann Whitney 'U' test). TAPP group had a significantly low pain at 12hrs and 24hrs postoperatively. There was no difference between the TAPP group and Lichtenstein group regarding the mean hospital stay (37.2±12.1 hours vs. 38.2±13.6 hours; p=0.7; CI=95%; Mann Whitney 'U' test). The mean time to return to work was 12.1±11.8 days in TAPP group, which was significantly lesser than the Lichtenstein group (20.9±4 days; p= 0.04; CI=95%; student 't' test). No recurrence was found.

**Conclusions:** Laparoscopic TAPP was a safe and effective procedure for inguinal hernia repair, and it can replace open procedure.

**Keywords:** Inguinal hernia, Laparoscopic transabdominal preperitoneal repair, Lichtenstein repair, Randomized control trial

## INTRODUCTION

Repair of an inguinal hernia is one of the most common surgeries performed by the surgeons worldwide. There have been a plenty of evolution in surgical techniques of hernia repair. The current standard technique is tension-free repair using a prosthetic mesh proposed by

Lichtenstein.<sup>1</sup> The use of laparoscopy in performing tension-free hernia repair was proposed to have benefits of reduced post-operative pain, early discharge from the hospital and early return to normal activities.<sup>2</sup> But a few studies found that laparoscopy in hernia repair was associated with major vascular injury, bowel obstruction, nerve injuries and bladder injury.<sup>3</sup> A Cochrane review by

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McCormack et al.<sup>2</sup> concluded that laparoscopic hernia repair is as effective as open mesh repair, but it was soon contradicted by multicentre trials such as Neumayer et al.<sup>3</sup> Hence we conducted a comparative study of laparoscopic transabdominal preperitoneal inguinal hernia repair (TAPP) and open Lichtenstein procedure in a tertiary center. Both the groups were compared for operative complications, pain, analgesic usage, and time to return to normal activities.

#### **METHODS**

A prospective randomized control trial was performed in a tertiary center over a period of 18 months, from December 2010 to May 2012.

#### Inclusion and exclusion criteria

A total of 50 patients were studied. All adults with uncomplicated inguinal hernias were included in the study. Patients with immunosuppression, anemia, infection, associated with other abdominal hernias, unfit for anesthesia, recurrent hernia, and intra-operative laparoscopy to open conversion were excluded. Patients with Nyhus type IIIc and type IV were excluded from the study.<sup>4</sup> Patients with previous groin irradiation, pelvic lymph node dissection, and open prostatectomy were also excluded.

#### **Procedure**

The study was started after approval from "Institute Ethics Committee." The patients presenting with an inguinal hernia to the Department of General Surgery were screened for eligibility. All eligible patients underwent preliminary investigations and pre-anaesthetic check-up.

All patients underwent either open Lichtenstein repair or laparoscopic transabdominal preperitoneal repair (TAPP). After obtaining consent from the patient, he/she was allocated randomly to one of the groups by using a sealed envelope, opened by a person other than the operative team. All the surgeries were performed in a single surgical unit under controlled conditions.

Both the procedures included a recording of operative time, operative complications such as bleeding, injury to vas, inferior epigastric vessels, nerve, and major visceral vascular injury. All the hernias were classified intra-operatively according to Nyhus classification.<sup>4</sup>

TAPP was performed under general anesthesia while open Lichtenstein procedure was done under the spinoarachnoid block. Each patient received 1gm Cefotaxime intravenously as a prophylaxis at the time of induction.<sup>5</sup> Polypropylene (Prolene®) mesh was used in both the groups.

In TAPP, the sac was reduced; the peritoneum was separated from vas and gonadal vessels. Preperitoneal space was dissected beyond the midline on the medial aspect, beyond the anterior superior iliac spine exposing the psoas muscle on the lateral aspect, inferiorly up to symphysis pubis and the level of obturator foramen and superiorly up to the level of the arcuate line. The polypropylene mesh was trimmed to fit the contours of the dissected preperitoneal area. Mesh was fixed with intracorporeal sutures using 1-0 polypropylene. Care was taken to avoid suturing in the triangle of Doom and the triangle of pain. Mesh was fixed only at the Cooper's ligament.

In open Lichtenstein procedure, the medial portion of the mesh was rounded to the shape of the medial corner of the inguinal canal. A slit was made at the lateral end of the mesh, creating a wider tail above the cord and narrow one below and the cord positioned between the two tails of the mesh. The mesh was sutured to the aponeurotic tissue over the pubic bone overlapping the bone with 2-0 polypropylene suture medially, with inguinal ligament inferiorly and to the conjoined tendon above. Laterally, two tails of the mesh were sutured to inguinal ligament thus creating a new internal ring. The excess mesh was trimmed laterally leaving 3-4 cm beyond the internal ring. Perfect hemostasis was ensured. External oblique aponeurosis was sutured with 2-0 prolene. The subcutaneous fat was sutured with 2-0 catgut and skin was approximated using staples/sutures.

Oral feeds were resumed once the patient recovered from anesthesia. All patients received intramuscular Diclofenac sodium (Voveran®) 75mg intramuscularly 8 hourly during first 24 hours, followed by oral Diclofenac (Voveran) 50mg sos for pain. The pain was assessed using the Visual Analogue Scale (VAS).<sup>6</sup> The continuum of pain was represented by a straight line, with no pain at one end and intolerable pain at the other end. The length of the line was 10cm. All patients received intramuscular diclofenac as analgesic every eight hours.

Surgical site infection (SSI) was defined as per CDC (Center for Disease Control) guidelines.<sup>5</sup> Infection occurring in an operative site within 90 days after the surgery having one of the following criteria was considered as SSI: A purulent drainage from the incision or aseptically obtained culture from the incision showed growth of a micro-organism or if the incision was dehisced or deliberately opened by the surgeon or attending physician or other designee and was culture positive or not cultured and patient had at least one of the following symptoms or signs: erythema; localized swelling; pain or tenderness; or heat.

Patients were evaluated for postoperative complications such as hematoma, seroma, wound infection, neuralgia, and recurrence. The total length of hospitalization, cost, and return to work were documented. All patients were discharged in 24 to 72hours. VAS pain score chart was

filled by each patient as explained at 12hours, 24hours, 48hours, 72hours and seven days after surgery. Patients were advised to attend OPD on the 7<sup>th</sup> postoperative day for review. The subsequent visits were at six weeks, three months, nine months, and at two years post-operative. They were also instructed to visit earlier in case of symptoms. Every patient was followed up for an at least 2-year period.

# Statistical analysis

All the data were compiled in Microsoft Excel and was subjected to statistical analysis. Outcome assessor and analysts were kept blinded. Mann Whitney U test, student 't' test and Fisher's exact test were used to study the significance of the difference of various parameters in the laparoscopic TAPP and open (Lichtenstein) inguinal hernia groups. A p-value less than 0.05 was considered significant.

## **RESULTS**

A total of 50 out of 64 patients met eligibility criteria (Figure 1). They were randomized into TAPP group and open Lichtenstein group, with 25 patients in each group. The youngest person was aged 21 years whereas the elder most was aged 65 years. Majority of the patients belonged to 21-35 years age group (44%). The mean age of study population was 37.1±12.3 years. Male to female ratio was 3:1.

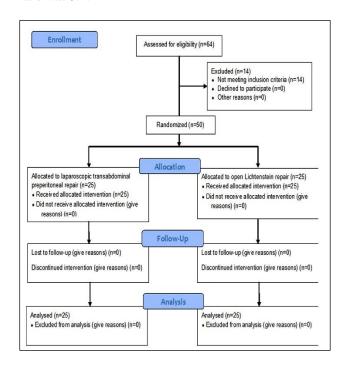


Figure 1: Consort diagram.

The age distribution was similar in both the groups. There was no difference in the mean age between the TAPP and the open Lichtenstein groups [36.4±12.1 years vs. 37.8±12.4 years; p=0.7; Confidence Interval (CI)=95%;

Mann Whitney 'U' test]. The open Lichtenstein procedure was found to have significantly less operative time compared to TAPP procedure (54±15 minutes vs. 75.7±31.6 minutes; p=0.001; CI=95%; Mann Whitney 'U' test). None of the TAPP procedures was converted to open procedure. TAPP group had a significantly low pain at 12hrs and 24hrs postoperatively, while there was no significant difference between the groups regarding pain at 48-hrs, 72-hrs and 7th day postoperatively (Table 1). The total number of patient's pain-free (VAS score=0) were significantly more in TAPP group at 24-hrs, 48-hrs, and 72hrs postoperative period (Table 2).

Table 1: VAS pain score. TAPP group had a significantly low pain at 12hrs and 24hrs postoperatively.

Timer after operation	TAPP (n=25)	Lichtenstein (n=25)	p (Mann Whitney U test)
12 hrs	2.64±1.4399	3.52±1.6613	0.04
24 hrs	1.76±1.3625	2.74±1.4866	0.01
48 hrs	1.40±1.5275	1.80±0.9574	0.06
72 hrs	$0.72\pm1.40$	1.08±1.1150	0.06
7 <sup>th</sup> day	0.36±0.7571	0.60±0.9574	0.5

Table 2: Number of patients pain-free in the postoperative period.

Time after operation	TAPP (n=25)	Lichtenstein (n=25)	p (Fischer's exact test)
24 hrs	5 (20)	0 (0)	0.02
48 hrs	8 (32)	2 (8)	0.04
72 hrs	17 (68)	9 (36)	< 0.05
7 days	19 (76)	16 (64)	>0.05

No intra-operative complication was noted in both the groups. TAPP group had one (4%) postoperative complication while the Lichtenstein group had six (24%) complications. But the difference wasn't statistically significant (p=0.1; CI=95%; Fischer's exact test). The open Lichtenstein group had three (12%) seroma formation while TAPP group had no cases of seroma formation, but the difference wasn't significant (p=0.2; CI=95%; Fischer's exact test). There were two cases of wound infection (both were superficial), one in each group. The Lichtenstein group had two (8%) cases of hematoma, and the TAPP group had no case of hematoma, but the difference wasn't statistically significant (p= 0.5; CI=95%; Fischer's exact test). All the complications were managed conservatively. No recurrence or any other complication was found in either of the groups at two years postoperative follow-up.

The mean analgesic (Voveran 50mg) consumption in TAPP group was significantly lesser than that of open Lichtenstein group (2.6±2.3 tablets vs. 5.8±3.5 tablets; p=0.001; CI=95%; Mann Whitney U test). There was no difference between the TAPP group and Lichtenstein

group regarding the mean hospital stay  $(37.2\pm12.1 \text{ hours vs. } 38.2\pm13.6 \text{ hours; p=0.7; CI=95\%; Mann Whitney 'U' test). The mean time to return to work was 12.1\pm11.8 days in TAPP group, which was significantly lesser than the Lichtenstein group <math>(20.9\pm4 \text{ days; p=0.04; CI=95\%; student 't' test)}$ . The total cost for TAPP surgery was 24,556 rupees while it was 8,932 rupees for open Lichtenstein procedure.

#### **DISCUSSION**

An inguinal hernia is one of the most common surgical afflictions worldwide. The repair of an inguinal hernia has evolved through various stages, and the current standard method is to repair with a synthetic mesh.<sup>2</sup> Mesh placement can be done either using an open approach or a minimal access approach. The standard landmark surgeries in this regard are tension-free repair invented by Irving Lichtenstein and transabdominal preperitoneal inguinal hernia repair proposed.7 But the better among these two is still a debate. A Cochrane meta-analysis favoured TAPP procedure, but a multicentre trial contradicted it soon.<sup>2.3</sup> There were a few more studies, but it was inconclusive whether to opt for an open Lichtenstein or a laparoscopic TAPP. Hence, we conducted a study to compare open Lichtenstein and laparoscopic TAPP procedure.

Present study had two groups, open Lichtenstein and laparoscopic TAPP. Both groups were matched regarding the number, age, and age group. The open Lichtenstein group was found to have lesser operating time compared to TAPP group (54±15 minutes vs. 75.7±31.6 minutes; p=0.001; CI= 95%; Mann Whitney 'U' test). The finding was consistent with other studies.<sup>3,8</sup> A few studies found no difference between the open Lichtenstein and TAPP groups regarding operative time.<sup>9-11</sup> Found laparoscopic TAPP was quicker than the open Lichtenstein procedure.<sup>12,13</sup> Hence, it is not the type of procedure but the learning curve in laparoscopy which decides the operative time.

The intra-operative complications include hemorrhage, technical failure, conversion, injury to vas deferens, injury to vessels, injury to viscus, and major vascular injury. None of our patients had any intra-operative complication. Found no difference between the two groups in terms intra-operative complications. <sup>10,12,13</sup> But a multicentre trial found intra-operative complications were more in a laparoscopic procedure. <sup>3</sup> Again, it's the surgeon's laparoscopic skill which makes a difference. Also found that the injury to spermatic cord structures was low in TAPP compared to the open group, possibly due to the magnified view of laparoscopy. <sup>3</sup>

TAPP being a minimal access procedure, the amount of tissue injury was less, hence lesser post-operative pain. Our patients with TAPP had a lesser pain score at 12hrs and 24hrs postoperatively, while there was no significant difference between the groups regarding pain at 48hrs,

72hrs and 7<sup>th</sup> day postoperatively (Table 1). The finding was universal as almost every study had the same findings concluding TAPP as a less painful procedure.<sup>3</sup>

The TAPP group had significantly more number of patients who were pain-free (VAS score= 0) compared to the open Lichtenstein group at 24hrs, 48hrs, and 72hrs postoperative period (Table 2). This was a unique finding regarding our study. To the best of our knowledge, none of the studies have mentioned this.

The postoperative complications of hernia repair include seroma, hematoma, wound infection (superficial and deep), neuralgia, urinary retention, urinary tract infection, and recurrence. In our study, TAPP group had only one (4%) postoperative complication while open Lichtenstein group had six (24%) postoperative complications, but the difference wasn't statistically significant (p=0.1; CI=95%; Fischer's exact test). found that the open Lichtenstein procedure was associated with increased incidence of seroma formation wound infection, while there were no significant differences observed for the other postoperative complications.<sup>8</sup> Found no significant differences between the two groups in terms.<sup>9,11</sup> Open Lichtenstein had increased incidence of wound infection in studies conducted. 10,12 There was also an increased incidence of postoperative neuralgia in open Lichtenstein procedure compared to TAPP as per. 12,13 These findings suggest laparoscopic TAPP is superior to open Lichtenstein procedure regarding postoperative complications. The incidence of vascular injuries and neuralgia can be avoided by avoiding suturing in the triangle of Doom and triangle of pain. Alternately, the mesh can be fixed by mechanical fixation devices such as tackers. But suturing is not only more effective but also reduces the cost of surgery.

Our study showed that the mean analgesic consumption was less in TAPP group and the finding was consistent with other studies such as.<sup>7-9,11</sup>

The patients who underwent TAPP resumed their work significantly earlier than those who underwent open Lichtenstein procedure as per our study. The same finding was found in studies conducted.<sup>2,3,7-13</sup>

We found no difference between the TAPP group and Lichtenstein group regarding the mean hospital stay (37.2±12.1 hours vs. 38.2±13.6 hours; p=0.7; CI=95%; Mann Whitney 'U' test). This was consistent with.<sup>8,10,13</sup> The laparoscopic TAPP patients were discharged early compared to open Lichtenstein group in studies.<sup>2,11,12</sup>

The mean time to return to work was  $12.1\pm11.8$  days in TAPP group, which was significantly lesser than the Lichtenstein group (20.9 $\pm4$  days; p=0.04; CI=95%; student 't' test). This was a universal finding as all other studies found laparoscopic TAPP had significantly less time to return to work.<sup>2,3,8,11-13</sup>

There was no recurrence in our study population. There was no difference between the two groups regarding the recurrences as per. found that the rate of recurrence was lesser in TAPP compared to open Lichtenstein group. <sup>2,3,8-13</sup> This finding makes the TAPP superior over open Lichtenstein procedure.

The other advantage of laparoscopic TAPP was that it could deal with bilateral hernias better than open Lichtenstein procedure.<sup>2</sup>

#### CONCLUSION

Laparoscopic TAPP was a safe and effective procedure for inguinal hernia repair. Laparoscopic TAPP was superior to open Lichtenstein procedure regarding preoperative and postoperative complications, postoperative pain, analgesic requirement, recurrence, and return to work. The laparoscopic TAPP can replace open Lichtenstein repair for inguinal hernias.

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Institutional Ethics Committee

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