

Original Research Article

Prospective comparative study of laparoscopic totally extraperitoneal versus Lichtenstein's tension free open meshplasty for management of inguinal hernia

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ABSTRACT

Background: Since the advent of minimal access surgery, its application has been widespread starting from appendectomy to complex intestinal surgeries carried out laparoscopically. But hernia surgery is a major debatable section, to compare it with the commonly performed gold standard Lichtenstein repair. First laparoscopic transabdominal preperitoneal and then totally extra peritoneal (TEP) repair came into existence. In today's era of extended TEP repair laparoscopic TEP repair has emerged to be gold standard.

Methods: This is a prospective cohort study including 40 cases of Lichtenstein open meshplasty, against minimally invasive laparoscopic TEP procedure were compared. Patients operated in our department between January 2010 and September 2010 were included after consent and assessment. Procedures were carried out according to standard guidelines, and results compared for technical details, cosmesis, intra or post-operative complications, analgesia requirement, hospital stay, recovery and follow up and all results were analyzed.

Results: Operative time was less by 2 minutes, hospital stay less by 1 day, return to work earlier by nearly 20 days for strenuous work, analgesia requirement less for laparoscopic extra peritoneal repair.

Conclusions: Study showed that if the period of learning curve has been eliminated than an experienced surgeon performs laparoscopic procedure with better patient satisfaction, less hospital stay, faster recovery and earlier return to work with less operative time, analgesic consumption, and complication.

Keywords: Inguinal hernia, Laparoscopic totally extra peritoneal, Lichtenstein repair

INTRODUCTION

Inguinal hernia repair is one of the common surgical procedures performed worldwide. It usually presents as a lump, with or without discomfort, which may limit daily activities and work. They can occasionally be life-threatening if bowel strangulates or becomes obstructed, requiring emergency surgery.

Variety of repair exists for inguinal hernia. Surgery has transformed in the last decade by technology and by efforts to make surgical decision-making evidence based. But these changes were accelerated by the laparoscopic revolution, which promised less pain, improved cosmesis, and shorter disability.¹ One of the procedures to have benefited immensely from minimal access surgery has been the repair of inguinal hernias.

Since the original description of hernia repair by Bassini in 1889 hernia surgery underwent numerous refinements to reduce recurrence.^{2,3} Hernia repair using suture has paved way to synthetic meshes. The most effective method of repair is by means of a tension-free technique involving the use of prosthetic mesh to reinforce the abdominal wall in the region of the groin by open or laparoscopic techniques. Both laparoscopic and Lichtenstein open tension-free, hernia repairs have been shown to offer faster recovery and lower recurrence rates than the traditional methods.

Open techniques are here to stay, for the simple reasons that they are safe to perform on all patients of all ages, and do not require a general anesthetic and are cost efficient with rare and seldom life-threatening complications. At present stage also open repair is practiced nearly 70% compared to laparoscopy for treating inguinal hernia

But since wide-spread application of laparoscopy to various surgical procedures, inguinal hernia surgery received a new dimensional approach claiming equivalent or even better results than the available methodologies.^{4,5}

The objective for the study was to evaluate both procedures for effectiveness and superiority of one technique over the other in management of inguinal hernia by demographic and clinical data, operating time, operative complications, postoperative stay, pain, recovery and return to activity and requirement of analgesia as short term morbidity and recurrence, cosmesis, follow up complications as long term morbidity.

METHODS

After permission of institutional ethics committee, observational prospective comparative cohort study was carried out in 80 cases of inguinal hernia, admitted to department of general surgery in Medical College and General Hospital, Rajkot, from January 2010 till September 2010. Patients were examined and history and examination findings were filled in proforma. Uncomplicated unilateral, bilateral or recurrent inguinal hernia were included. Exclusion criteria were irreducible, obstructed, strangulated inguinal hernia and patient unfit for general anesthesia. Those having previous surgery in retro pubic space or requiring associated surgeries (orchietomy, circumcision, hydrocele) or emergency management, having previous lower midline or para median incision, local or systemic infection, active precipitating factors, also were excluded.

All underwent pre-operative investigation for anesthesia and those who were fit were explained both procedures-their advantages, disadvantages and risks. Those willing were divided alternatively in laparoscopic totally extra peritoneal (TEP) and Lichtenstein group and operated after taking written informed consent.

In the operating room all patients were given single dose of injectable ceftriaxone 1 gram at the time of induction. Spinal anesthesia was used for open procedures and general anesthesia after placing urinary catheter for TEP.

In open group the patient was placed in supine position, groin prepared and Lichtenstein hernia repair was performed using a technique that had been described by Lichtenstein and Amid.^{6,7}

An oblique incision was kept ½ inch above the medial part of inguinal ligament. Subcutaneous tissue dissected, external oblique apo-neurosis cut and flaps created. Cord lifted up from pubic tubercle, skeletonized and sac separated taking care of ilioinguinal and iliohypogastric nerves. Indirect sac was dissected, transfixed at the neck and cut. Direct sac was dissected and inverted. A 6×11 cm polypropylene mesh was placed. Monofilament non-absorbable suture was used in a continuous fashion beginning at the pubic tubercle than onto shelving edge of the inguinal ligament, to a point lateral to the internal inguinal ring. At this point, the tails created by the slit are sutured together around the spermatic cord snugly forming a new internal inguinal ring. The mesh is further sutured to transversus-abdominis muscle superiorly and conjoint tendon to end at the pubic tubercle. Sheath closed and superficial ring created such as it admits the tip of little finger. Skin approximated with non-absorbable suture.

In laparoscopic TEP patient was placed supine with arms by the side, after induction and preparation; single 10 mm sub umbilical transverse incision was kept towards the side of unilateral and on right for bilateral, cutting skin and dissecting subcutaneous tissue to expose anterior sheath which was incised transversely, rectus muscle retracted laterally to enter the space between muscle and posterior rectus sheath.⁸⁻¹¹ A tunnel was made in this space using a surgical glove finger as a balloon or telescope, towards pubic symphysis. Then with Hassan's cannula and CO₂ insufflation space was maintained. Two additional cannulas (5 mm) were placed in the midline under vision, first above the pubic symphysis and second midway between the first and umbilical.

Inadvertent rents in peritoneum were closed for maintaining pre-peritoneal space and to avoid contact of mesh with abdominal organs. CO₂ insufflation was continued to maintain 12 to 14 mm Hg pressure. The dissection was carried beyond midline medially, up to superior iliac spine and psoas laterally, inferiorly up till vas was turned medially, in order to involve entire myopectineal orifice. This was done by alternate blunt and sharp dissection with scissors or Maryland in right hand and blunt grasper in another hand. Sac was completely isolated from vas and testicular vessels. After dissection and complete reduction of contents the indirect sac was divided and ligated, either by sutures. Polypropylene mesh (15 × 12 cm) was introduced into the cavity through the 10-mm port. The mesh was placed

covering entire myopectineal orifice from opposite pubic tubercle medially to psoas laterally. No fixation, no slit was made. CO₂ drained by opening the 5mm port slowly and holding the mesh in position. Sheath closed for 10 mm port and all ports closed for skin with nonabsorbable suture.

Standard set up was used for both procedures.

Post operatively catheter was removed on table after reversal of general anesthesia for all Laparoscopic procedures. All were encouraged to pass urine as early as possible. Clear liquids started orally after 4-6 hours. Analgesics were given in form of injectable diclofenac sodium 50 mg immediate postoperatively and after 12 hour to all. After 24 hours oral administration of diclofenac 50 mg tablet according to requirement was given and all were educated and encouraged to get ambulatory as early as possible. Prophylactic oral amoxicillin clavulanic 625 mg was continued for 5 days in all, and definitive in those developing, wound complications was continued as per wound culture sensitivity.

Patients examined at 6 and 24 hours post operatively for pain assessment, requirement of analgesia and complications. They were encouraged for discharge as early as they were able to carry routine activities without discomfort. Dressings were opened on 7th postoperative day in both groups, unless there were indicators suggesting wound infection they were opened early. Sutures removed on 7th postoperative day, if no complication.

Follow-up examinations were performed after discharge, on OPD basis at 1, 2 weeks, 1, 3, 6 months and 1 year in person and telephonically at 3,5 and 7 years. Encouraged to start normal activities (work and social) as early as possible guided by minimal discomfort and pain. On follow up encouraged starting heavy work as per pain tolerance and discomfort level.

Both groups were compared for demographic data (age, sex, side of hernia, duration and presenting complaints) duration of surgery (from skin incision to last skin suture) and complications which include intraoperative (anesthesia related or injury to vessels, viscera, cord or nerves) and post-operative (immediate- urinary retention, hematoma, pain; early- pain, seroma, orchitis, wound infection and late- testicular atrophy, recurrence, pain).^{12-15,23-30}

Conversion, procedure initiated as TEP but converted to open or TAPP.

Requirement of analgesia, indicator of short-term morbidity, compared for both on basis of pain assessment and analgesia consumption.

Pain assessment was done on basis of mayo clinic pain assessment, the patient was asked direct and indirect questions to assess the severity of pain at that particular instance, at 6 hour, at 24 hour, 1, 2, 4 weeks, 3, 6 months and 1 year. At initial level upto 24 hours the pain assessment was with the use of analgesia.¹⁶ The scale used was, 0-1 no pain, 2-3 mild pain, 4-5 discomforting - moderate pain, 6-7 distressing - severe pain, 8-9 intense - very severe pain, 10 unbearable pain, for convenience we took severe pain as >6.

Analgesia consumption was counted as per patient's requirement to carry out his activities without pain, occasional analgesia requirement was not considered and only those requiring persistent analgesia for smooth working were considered as <1 week, 1-2 week, 2-3 week, >3 week.

Post-operative hospital stay

Day of surgery to the day of discharge.

Return to work was counted from the day of surgery

- **Routine:** defined as work of daily living, moving around, eating, drinking, going to toilet, light walking, standing, sitting.
- **Normal:** defined as activity of earning that is going to work and participating in social activities and shopping, light weight lifting.
- **Strenuous:** defined as activities requiring physical exertion (jogging, running, labor work) and lifting heavy weight.

Long term morbidity

- **Recurrence:** was defined as a detectable bulge in the operated groin by the examining doctor with or without symptoms at OPD follow up.
- **Chronic groin pain:** pain in groin persisting after 3 months.
- **Testicular complications:** Ischemic orchitis, testicular atrophy, damage to ductus deferens to be judged clinically and by Doppler.^{15,29}

Wound infection: Surgical site having signs of inflammation with discharge were considered infected. Discharge was sent for culture sensitivity.

Prosthetic complication: infection, sinus, erosion, rejection

Neuralgia: Sharp shooting pain associated with distribution of affected nerve. Immediate (<24 hours in development) considered for short term morbidity and late (days after) considered for long term morbidity at follow up.

All data was collected for analysis. Data analysis was done by Fisher's test and chi-square test, to assess

categorical variables. Student ‘t’ test were used for assessing the quantitative variables. A ‘p’ value of less than 0.05 was considered statistically significant.

RESULTS

The demographic and clinical data pertaining to study is as shown in (Table 1). The total number of subjects was 40, 31 had unilateral and 9 bilateral so total no of hernia was 49 in each group.

All the cases of comorbidities were under control for their illness and were taking medications regularly for the

same and were fit for anesthesia. Grade 4 and 5 ASA were excluded from study.

For TEP mean operating time was 59.46±18.84 minutes compared to 61.98±20.50 minutes for open with difference of 2.52 minutes and ‘p’ value of 0.5. Mean time for unilateral TEP turned out to be 53.32±19.53 minutes compared to 55.13±20.50 minutes in Lichtenstein with difference of 1.81 minutes and p value of 0.7. For bilateral hernia mean time in TEP was 80.40 ±19.50 minutes compared to 85.56±21.50 minutes for open with difference of 5.16 minutes and p value of 0.5. The above ‘p’ values are non-significant.

Table 1: Demographic and clinical parameters.

Parameter	Lichtenstein (n=40)	Laparoscopic TEP (n=40)	P value
Mean age in years	51.45±17.81	45.3±14.81	0.0486
Sex	All males		1.0
Symptoms	Pain	3	5
	Swelling	24	23
	Both	13	12
Unilateral hernia	31 (67.5%)	31	1.0
Unilateral hernia right	14	25	
Unilateral hernia left	17	6	
Bilateral hernia	9	9 (22.5%)	1.0
Direct hernia	35/49	29/49	0.0767
Indirect hernia	14/49	20/49	
Incomplete hernia	37/49	38/49	1.0
Complete hernia	12/49	11/49	1.0
Comorbidities	11	10	0.5874
Hypertension	4	2	
Diabetes	1	0	
COPD	3	6	
BPH	3	2	
ASA grade			0.18
ASA 1	6 (15%)	8 (20%)	
ASA 2	14 (35%)	20 (50%)	
ASA 3	20 (50%)	12 (30%)	

Table 2: Comparison of surgical outcome of both techniques.

Assessed parameters	Laparoscopic TEP	Lichtenstein	P value
Surgical time	59.46 min	61.98 min	0.5
Complications	12.5%	32.5%	-
Technique	Difficult	Easier	-
Postoperative hospital stay	1.25 days	2.55 days	0.7
Postoperative pain assessment (6 hrs)	Mild	Mild-moderate	0.04
Postoperative pain (24 hrs)	No pain	Mild	0.001
Postoperative pain (1week)	No pain	Mild	0.19
Postoperative pain (2 week)	No pain	No pain	0.13
Postoperative analgesia requirement	Avg. < 1 week	Avg. 1 to 2 weeks	0.007
Return to routine work	1.55 days	3.33 days	0.0001
Return to normal work	6.22 days	10.62 days	0.0001
Return to strenuous work	15.8 days	36.92 days	0.0001
Long term morbidity	0	7.5%	-
Cosmesis	Better	-	-

When both techniques were compared for complications; there were no intraoperative complications in both groups. There were 3 conversions out of 40 cases (7.5%), one due to inability to maintain an optimum SPO₂ due to CO₂ toxicity, leading to termination of laparoscopic TEP and conversion to Lichtenstein. Two having surgical difficulties, included dense adhesions resulting in failure to dissect space leading to conversion to Lichtenstein (large direct hernia) in one and inability to reduce contents in second which was completed by transabdominal preperitoneal approach (complete indirect sac with adhesions).

When compared for postoperative complications, 2 from TEP and 3 from Open group had urinary retention which was treated by overnight catheterisation which was removed next day morning. From Open 2 had scrotal hematoma as immediate, 3 had seroma and 2 (5%) patients had surgical site infection as early, 2 had chronic groin pain and 1 had testicular atrophy as late complications, all treated conservatively. None of TEP group had this complication. At the end of one year, in person follow up examination revealed no recurrence in any patient in both the groups. Readmission was required in 2 out of 40 cases (5%) of open group for mainly wound infection, increasing length of stay in Lichtenstein group. In TEP 5 (12.5%) had complication while in open it was 13 (32.5%) which was much higher, but both had minor complications with no major vascular, bladder, bowel injury.



Figure 1: Cosmesis, Lichtenstein vs. TEP, bilateral repair.

The average post-operative hospital stay was less in TEP repair, mean being 1.25±0.58 days compared to 2.55±2.19 days in open. 33 of 40 (82.50%) were discharged on next day compared to 17 (42.50%) in open which was significant. The overall 'p' value of 0.7 is non-significant. 2 patients with wound infection in Open group had average 5 days stay as they were readmitted for the purpose of better wound management.

At 6 hours post operatively 6, 27 and 7 patients out of 40 had no, mild and moderate pain in TEP group, compared

to 3, 20 and 17 patients of 40 for Lichtenstein group respectively. P value of 0.0448 is significant. None of the patient had severe pain. At 24 hours 25, 12 and 3 patients in TEP had no, mild, moderate pain compared to 10, 19 and 11 patients of Lichtenstein group. Thus 25 (62.5%) patients were pain free in TEP group than for Lichtenstein group where 30 (75%) still had pain at the end of 24 hours. This was time when the patients had started with their routine activities on their own. At 1 week and 2 week 31 and 38 respectively were pain free in laparoscopic group compared to 28 and 33 in open; 'p' value 0.19 was insignificant. Only 2 (5%) patients had pain for TEP, compared to 7 (17.5%) in open at end of 2 week. The 'p' value 0.13 was nonsignificant.

Following protocols as mentioned in methodology it was found that TEP group was able to leave analgesics earlier, 29 (72.5%) patients discontinued in less than one week compared to 16 in open. 11 (27.5%) required analgesia for >1 week in TEP which was 24, too higher for open group. Out of 11 cases in TEP group requiring analgesia >1 week, 3 were those who were converted to other procedures and others were from bilateral group. The 'p' value was 0.007 highly significant.

The values for return to routine, normal and strenuous work respectively were 3.33±2.19, 10.62±3.23 and 36.92±15.82 days for Lichtenstein and 1.55±1.19, 6.22±2.93 and 15.80±5.86 for TEP. The 'p' values were 0.0001 highly significant for all.

All 80 patients completed their follow up of one year. It showed long term morbidity in 3 (7.5%) cases of Lichtenstein- 2 had chronic groin pain, 1 had testicular atrophy as confirmed by ultrasound which was 0 for TEP. None had recurrence.

Follow up at end of 3 years done for 78 patients showed no recurrence. At the end of 7 years only 75 patients were traceable, and none had recurrence.

DISCUSSION

Laparoscopic cholecystectomy has been accepted as the gold standard for patients with gall stone disease.⁵ But unfortunately, laparoscopic hernia surgery attempting similar claims underwent controversies with conflicting results, because the patients', society's and surgeons' perspective varied widely from not only country to country but also among regions within the same country.^{17,18}

Lichtenstein repair of inguinal hernia is a time-tested option and is associated with the lowest rate of recurrence among the various methods for open repair of inguinal hernia with results equally reproducible from all quarters of the globe. Furthermore, laparoscopic TEP repair is associated with greater patient satisfaction and better cosmetic results, lesser-postoperative pain and hospital stay, earlier return to work when compared to

Lichtenstein, provided the long-term recurrence rates also are comparable. TEP has long learning curve, rare but major complication chances, requires General anaesthesia and setup is a bit costlier.^{6,7}

In our study of 80 subjects, the age distribution was concentrated between 41 to 70 years, 41 - 50 for TEP, and 51 - 70 for Lichtenstein, comparable to Eklund et al and Bringman et al with 1512 and 299 subjects respectively in both studies.^{19,20}

The presentation and selection criteria matched European hernia trialist.²¹ The presentation, side, type of hernia matched European union and study of constantinos Antonopoulos 2001.^{21,22} In associated medical problems like COPD, DM it matched other trials. ASA grade, classification, meshes used was comparative to European union hernia trial.²¹ When comparing laparoscopic TEP to Lichtenstein, Lichtenstein is easier to perform, as introduced during residency and routinely performed, while TEP is performed only by experts thus leaving definite learning curve. EHS guidelines show - introduction of this procedure early during learning phase under supervision reduces learning curve.

Swedish hernia registry data from 2006 showed mean operating time with Lichtenstein and TEP as 56 minutes and 39 minutes respectively.²⁰ EU trial states operating time to be 8 to 13 minutes lower for Lichtenstein. In our study we compared the operating time, as mean, for unilateral and bilateral repairs and found that TEP was relatively faster, more in bilateral repairs as in Dinko et al and Gokalp et al.^{23,24}

The overall risk of complications after inguinal hernia operations reported vary from 15 to 28% in systematic reviews. With active monitoring such as phone calls, questionnaires or clinical examination, the rates have been reported to be higher, ranging from 17 to 50%. The most frequent early complications were hematomas and seromas (8-22%), urinary retention and early pain, and late complications were mainly persistent pain and recurrences. Authors considered a list of complications and reviewed the results and found higher complications in Lichtenstein.²³⁻²⁶

In the case of open surgery, the risk of haematoma varies between 5.6 and 16%, the risk varies between 4.2 and 13.1% for laparoscopy. Here 2 cases of hematoma in Lichtenstein were treated conservatively.^{12,27,28}

Incidence of seroma formation varies between 0.5 and 12.2%, significantly higher for endoscopic techniques than for open repairs.^{12,27,28}

Most seromas disappear spontaneously within 6-8 weeks. If persist, it can be aspirated but chances of infection are high. There were 3 seroma with Lichtenstein, nil in TEP.

Infection risk is about 1-3% for open surgery and less than 1% after endoscopic surgery. Deep infections are rare and do not have to lead to the removal of the mesh when monofilament materials are used. Drainage and antibiotics are usually sufficient for superficial infections. Here rate of infection was 2/40 (5%), all superficial in Lichtenstein and none in TEP.^{12,27,28}

There were 2 cases of post-operative urinary retention with TEP (5%) and 3 cases with Lichtenstein.

Postoperative ischemic orchitis usually develops within 24-72 hours and may result in testicular necrosis within days or result in testicular atrophy over a period of several months. Minimizing cord dissection is recommended. Transection of the hernia sac leaving the distal part in situ is recommended to reduce the risk of ischemic orchitis.

Author encountered a single case of atrophy detected at 3 months in Lichtenstein group with no prior orchitis. There were no other major complications.

The conversion rates were 39/1074 (3.6%) according to NICE guidelines.³⁰ Another studies also matched our conversion rates.

Post-operative hospital stay was comparable with Lal et al and Liem et al.^{5,33}

Chronic pain after hernia repair, reported in 40 studies, ranged from 0 to 53%. Intraoperative nerve damage was related to the development of chronic pain. The risk of nerve damage is reduced at endoscopic surgery and thus the incidence of chronic pain is reported to be lower after TEP. Other manifestations of nerve lesions like numbness and paresthesia are also fewer following endoscopic surgery.^{12,14}

There were 2/40 (5%) cases of Lichtenstein with chronic pain compared to nil in TEP.

Recovery for both the techniques was compared in terms of return to routine, normal and strenuous activities. In other studies, the difference for routine activities was not that significant, but in our study it was. Return to strenuous activity matched Schneider et al which was 15 days for TEP and 34 days for open.^{31,32} Return to normal work was 5 days in TEP and 7 days in Lichtenstein in Bringman et al.¹⁹ The main cause of prolonged recovery is predominantly pain. In addition, co-morbidity and cultural background affect the time of recovery. Similar results were reported from other studies.³¹

Another study by Bringman et al of 299 patients showed two recurrence (0.7%) in TEP and two (0.7%) in open mesh repair.¹⁹ Xavier et al with 10 year follow up showed 2.2 % recurrence in TEP and 5.7 % in Lichtenstein.^{19,26}

The studies, Lal et al, Neumayer et al, MRC group and European union concluded the superiority of cosmesis of TEP as in our study.^{4,21,25,33}

CONCLUSION

Thus, laparoscopic TEP in trained and skillful hands is acceptable technique against Lichtenstein which is learned at basic level and is easy, requiring less skill than TEP. TEP was superior in terms of lesser postoperative hospital stay, less pain, less analgesia requirement, early recovery and less overall complications, cosmesis and less morbidity but had equivalent operating time and recurrence rate. It had a definite learning curve, required technical expertise and had propensity for rare but dreaded complications.

Drawbacks were limited subjects due to time bound study and single expert performing laparoscopy was compared to multiple experts performing Lichtenstein in this study.

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