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Original Research Article

Totally extra peritoneal repair under general anesthesia versus Lichtenstein repair under local anesthesia for unilateral inguinal hernia: a prospective randomized controlled study

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Abstract: A hernia is defined as an abnormal protrusion of a viscus, in part or in whole, through a normal or abnormal-congenital or acquired-defect in the wall through the region of the abdominal wall that contains it. Inguinal hernia is the most common variety accounting for approximately 75% of all hernias. Laparoscopic hernia repairs and open Lichtenstein hernioplasty both have same recurrence rate according to multiple studies. This study was conducted to know the pros and cons of laparoscopic unilateral inguinal hernia repair by Total Extra-Peritoneal [TEP] approach under general anesthesia in comparison to that of open Lichtenstein inguinal hernia repair under local anesthesia in terms of Operating time, Post operative pain and analgesic requirement, Intra operative and post operative Complications, Duration of hospital stay, Cost effectiveness. 200 cases were randomly selected according to selection criteria and randomized for Lichtenstein repair and laparoscopic TEP. Two groups were compared as per aims. Suitable statistical test were applied. The Random study conducted over 200 patients showed that laparoscopic hernia repair had less post operative pain, less hospital stay, decreased seroma and infection rate of incision, more cosmetically acceptable by patients in comparison with open Lichtenstein hernia repair under local anesthesia. Lichtenstein open hernioplasty under local anesthesia was cost effective and devoid of post operative adverse affects of general anesthesia. The laparoscopic hernia repair is better than Lichtenstein hernia repair for unilateral inguinal hernia repair except for the long duration of surgery and cost effectiveness.
Keywords:TEP, less complications, less post operative pain, cost effective

INTRODUCTION:

A hernia is defined as an abnormal protrusion of a viscus, in part or in whole, through a normal or abnormal-congenital or acquired-defect in the wall through the region of the abdominal wall that contains it. The inguinal region is a weak part of the abdominal wall by the presence of the inguinal canal, the deep inguinal ring and the superficial inguinal ring. All groin hernias emerge through the myopectineal orifice of Fruchaud, the opening in the lower abdominal wall bounded by the transverse abdomen arch and superior public ramus. [1] Inguinal hernia is the most common variety accounting for approximately 75% of all hernia. Inguinal hernioplasty is the most common surgical procedure performed by general surgeons these days. In the 1990s, mesh hernioplasties became widely used, the widely used Bassini procedure was almost entirely replaced by tension free Lichtenstein hernioplasty [5], because Bassini repair was associated with high recurrence rate as compared to Lichtenstein repair [6]. Since, laparoscopic inguinal hernia repair was first reported by Ger and colleagues in 1990 [7]. After the introduction of laparoscopic techniques, it was evident that the Lichtenstein procedure and the laparoscopic approach of treating primary inguinal hernias were equal in the means of recurrence [2,3] . For the management of unilateral hernias, the base- case analysis and most of the sensitivity analysis suggests that open flat mesh is the least costly option but provides less quality adjusted life years(QALYs) than Totally extra peritoneal repair. It is likely that , for management of symptomatic bilateral hernias, laparoscopic repair would be more cost effective as differences in operation time(a key cost driver) may be reduced and differences in convalescence time are more marked (hence QALYs will increase) for laparoscopic compared with open mesh repair. [8].

MATERIAL AND METHOD:

This prospective randomized controlled study was conducted in the Department of General Surgery, S.P. Medical College and P.B.M. and Associated Group of Hospitals, Bikaner, from January 2015 to December 2015. Minimum 200 patients of hernioplasty were considered. Half of these patients were undergoing, laparoscopic TEP [group-A] and another half undergoing Lichtenstein hernioplasty under local anesthesia [group- B] was studied and their outcomes were compared in accordance with the aims and objectives of the study.

Totally extra peritoneal repair under general anesthesia and Lichtenstein repair under local anesthesia for unilateral inguinal hernia.

Inclusive criteria:

1. Age between 16 -75 years
2. Clinically diagnosed primary unilateral direct and indirect inguinal hernia
3. Exclusive criteria:
4. Patients with strangulated, incarcerated and obstructed inguinal hernia
5. Recurrent and bilateral inguinal hernia
6. Patient with previous operation scars for pelvic surgery previous laparotomy with possibility of adhesions to underling parietal peritoneum
7. Patient with history of pelvic irradiation
8. Patients who were unfit from cardiopulmonary point of view

Patients were grouped in to either laparoscopic or Lichtenstein group on the basis of their admission to the hospital, Fully informed consent was obtained from the patient and relatives about participation in the study. Consent for conversion of laparoscopic to open repair was taken for every laparoscopic hernia surgery. All patients were given a VAS (Visual analogue scale) pain score chart preoperatively. The y-axis of the VAS score was numbered 0-100 at one centimeter interval. Number 100 denotes worst imaginable pain and 0 denote no pain. The x-axis of the scale was numbered as 12hr, 24hr to record postoperative pain at those times. All open Lichtenstein repair were operated with 6-3 inches polypropylene mesh (prolene) fixed with 2-0 polypropylene sutures. Laparoscopic group patients were operated on using large 15*15 cm meshes of prolene. Fixation device like endotackers were used only if patients could afford the costs. In those patients not affording the cost for endotackers, then mesh were not fixed. Around 50 ml of xylocaine 0.5% was used with adrenaline or without adrenaline. Plain xylocaine dose was 3mg/kg body weight. Xylocaine with adrenaline-dose was 7mg/kg body weight. For local anesthesia we used field block method (Shouldice Method).

RESULTS AND DISCUSSION:

Data was analyzed for descriptive statistics like Mean, Median Mode and Mean Standard deviation and inferential statistics by Chi test and relevant statistics.

Table 1: Distribution of patients by age in group A & group B

Age (years)	TEP Repair Group A (n=100)	Lichtenstein Repair Group B (n=100)
≤ 20	4	4
21-35	48	16
36-50	40	24
51-75	8	56

All patients were male in this study. The patients were in the age group 16 to 75 years. Most of patients were between the age of 21 to 35 yrs in group A and in the age group of 51 to 75 yrs group B.

Table 2: Distribution of patients age profile (mean, S.D., Range) in group A and group B

Age (years)	TEP Repair Group A (n=100)	Lichtenstein Repair Group B (n=100)
Mean	35.24	51.68
Range	20-60	13-75
S.D.	11.91	17.05
t- test value	3.952	
P- value	0.0003***	

The mean age in group A was 35.24 years and the group B was 51.68 years. These age difference was statistically significant (p=0.0003***).

Table 3: Shows the sides of hernia operated in each group

Sides	**TEP Repair Group A (n=100)**	**Lichtenstein Repair Group B (n=100)**
Right	72 (72%)	60 (60%)
Left	28 (28%)	40 (40%)
Total	100	100
χ^2	0.357	
p value	0.550	

Majority of patients were right sided inguinal hernia 72 (72%) in group A and 60 (60%) in group B. In our study the sides of hernia are statistically non significant (p=0.550).

Table 4: Operating Time (Mean, Median, range & S.D) in two groups

Operating time (Minutes)	**TEP Repair Group A (n=100)**	**Lichtenstein Repair Group B (n=100)**
Mean	77.64	48.84
Median	80	46
Range	60-120	40-62
S.D	±15.04	±7.723
T	8.517	
P- value	<0.0001***	

The study showed statistically significant difference between the groups (p<0.0001***) with respect to operating time.

Table 5: Show the Intra-operative complication in two groups

Complication	**TEP Repair Group A (n=100)**	**Lichtenstein Repair Group B (n=100)**
Nil	80	80
Minor Bleeding	12	20
Peritoneum Breach	8	0
Total	100	100
χ^2	2.500	
p value	0.287	

The study showed statistical insignificance (p=0.287) with respect to complications in these two groups.

Table 6: Show the Visual Analogue Scale (VAS) for pain after operation in two groups

Time After Operation	**TEP Repair (n=100) Mean ± S.D**	**Lichtenstein Repair (n=100) Mean ± S.D**	**P-Value**	**t value**
12 Hour	3.280±0.9798	3.840±1.519	0.1279	1.549
24 Hour	1.760±1.332	2.720±0.9798	0.0056*	2.903

The mean pain at 12 hour was 3.280±0.9798 in group A & 3.840±1.519 in group B. These was statistically insignificant (p= 0.1279**). The mean pain score of group A & group B at 24 hour was 1.760±1.332 & 2.720±0.9798 respectively, these were statistically significant (p=0.0056**).

Table 7: Show the Post-operative complications in two groups

Complication	TEP Repair Group A (n=100)	Lichtenstein Repair Group B (n=100)	χ^2	p value
Seroma	8	16	0.115	0.734
Wound Infection	0	8	0.444	0.505
Neuralgia	4	8	0.001	0.973
Pneumoscroteum	8	0	0.444	0.505
Retention of Urine	8	0	0.444	0.505
Nil	72	68	0.008	0.928

The study did not show any statistical significant difference between the complications of group A and group B.

Table 8: Show the Post-operative Hospital Stay in two groups

Postoperative Time at discharge	TEP Repair Group A (n=100)	Lichtenstein Repair Group B (n=100)
≤48 Hrs	68 (68%)	44 (44%)
>48 Hrs	32 (32%)	56 (56%)

Table 9: Comparison of patient's opinion about surgery

Opinion About Surgery	TEP Repair Group A (n=100)	Lichtenstein Repair Group B (n=100)
Very Satisfied	76 (76%)	64 (64%)
Satisfied	24 (24%)	36 (36%)
Not Satisfied	0 (0%)	0 (0%)
χ^2	0.381	
p value	0.537	

In our study, the patient's opinion about surgery were statistically insignificant (p=0.537).

DISCUSSION:

The study entitled "Totally extra peritoneal repair under general anesthesia versus Lichtenstein repair under local anesthesia for unilateral inguinal hernia: a prospective randomized controlled study" was carried out on 200 patients (100 patients TEP repair and 100 patients Lichtenstein Repair) were admitted in, Department of Surgery, S.P. Medical College & AG Hospital, Bikaner with the clinical diagnosis of inguinal hernia from January 2015 to December 2015.

Demographic data:

Age:

All the patients in both groups were male. The majority of patients were between 21-50 years in Group A and 36- 75 years in Group B. The mean age in group A was 35.24 years and the group B was 51.68 years.

Sides of inguinal hernia (Right and Left):

Most of the patients in Group A and Group B had right sided hernia 72 (72%) and 60 (60%). The prevalence of hernia is stated to be more in males by ratio 7:1 to female. The incidence of hernia in males were clearly age dependent and right side groin hernia were common than the left. In our study the sides of hernia were statistically insignificant in the groups (p=0.550)

Operating time:

The mean operative time in Group A repair was 77.64 minutes (range 60- 120 minutes). This was significantly longer than the operative time for Group B repair (Mean 48.84 minutes, range 40-62 minutes). In our study operative time was statistically significant (p<0.0001***) in between groups. The mean operative time Group A of 77.64 minutes in our series was comparable to the operative time Dhankhar *et al.;* [9] who observe that TEP Repair were significantly had longer operation time (75.99 + 13.68 vs 64.77 + 12.66 min, p=0.002) compare to Lichtenstein repair. Yasser Hamaza *et al.;* [10] who observed that laparoscopic operations were significantly longer than open operations (54.5 + 13.2, 34.21 + 23.5 versus 96.12 + 22.5, 77.4 + 43.21; t = 3.891, p < 0.001). Langeveld Hester *et al.;* [11] observed that mean operating time for a unilateral hernia with TEP was longer (54 vs. 49 minutes, P=0.03), After TEP, patients had a faster recovery of daily activities (ADL) and less absence from work (P=0.01).Our result for operative time for Group A \ group B (75.40 Vs 48.64 minute

respectively) were comparable and similar to result of Anderson *et al.;* [12] (81±27 minute Vs 59±20).

The current study demonstrated significant variation of the operating time in favor of open repairs. Group B repair was significantly faster to perform. This reflects the relative simplicity of the latter approach, so laparoscopic Group A repair was significantly lengthier procedure than open Group B especially in the learning phase.

Post operative pain:

The post operative pain was recorded at 12 hour and 24 hour after operation using Visual Analogue Scale (VAS) pain scoring system. The mean pain out at 12 hour was 3.280±0.9798 in group A & 3.840±1.519 in group B. These were statistically insignificant (p= 0.1279). The mean pain score of group A & group B at 24 hour was 1.760±1.332 & 2.720±0.9798 respectively, these were statistically significant (p=0.0032**). There was however significant evidence to support that laparoscopic approach causes less postoperative pain at least immediate postoperative period.Eklund A *et al.;* [13] in 2006 stated that TEP was associated with less postoperative pain, a shorter period of sick leave and a faster recovery, compared with open Lichtenstein hernia repair.

Intra-operative complication:

All complications were recorded during both operations. Eight case of peritoneal breach were noted in Group A in which four were managed with verses needle insertion in the peritoneal cavity. Minor bleeding occurred in 12 (12%) cases, all of which were controlled by pressure. There were no conversions of laparoscopic Group A repair to open Group B repair. The rate conversion of laparoscopic to an open technique varies from 0-1.7% in most series. Lal P, Kajla RK *et al.;* [14] reported conversion rate at 0% and 2% in Eklund *et al.;* [15] study. Eker HH, Langeveld HR *et al.;* [16] found that intraoperative complication were more frequent in Group A v/s Group B. Overall Group A had more intra operative complications were minor and had no major impact on patient short term recovery.

Postoperative complication:

All the complication in both groups were noted and evaluated. In the Group A seroma formation was 8% (8 cases) and in Group B 16% (16 cases) In our study post operative seroma formation were statistically insignificant (p=0.734) among the groups. The incidence of neuralgia was 4% (4 cases) in Group A and 8% (8 cases) Group B. This may be due to in advertant nerve trauma during dissection or mesh fixation. Pneumo scrotum developed in 8% cases and was resolved spontaneously in TEP repair group. Wound infection was prevented by routine antibiotic prophylaxis in every case on morning of surgery but still wound infection was a major worry in open repair due to large incision in inguinal region and using prosthetic material. Eight cases (8%) had wound infection in Group B and no patient had wound infection in group A. In our study post operative wound infection was statistically insignificant (p=0.505). Langeveld *et al.;* [11] also found wound infection rate higher in open Group B than Group A, this indicates Group B has higher postoperative complication in the form of wound infection.Retention of Urine was 8% (8 cases on group A) and no patient had this complain in group B, in our study post operative retention of urine were statistically insignificant (p=0.505).

Duration of hospital stay:

Post operative hospital stay was less in Group A than Group B repair. This results in comparable to the result of Langeveld *et al.;* [11], Sanna TH Kouhiya *et al.;* [17] who showed similar result that Group A repair patient had less postoperative stay than Group B repair.

Cost effectiveness:

Laparoscopic repair had cost more than open repair. The laparoscopic operation needs larger mesh, general anesthesia and fixation devices in comparison to open surgery, which uses only small sized mesh, local anesthesia and no fixation device. All these factors between these operations makes open repair as cost effective one.

Patients Satisfaction about surgery:

Patient opinion about surgery was evaluate by a 3 point scale and it was found that 76% of patients were very satisfied with their group A as compared to 64% in the group B. Lal P, Kajla RK *et al.;*[97] reported that 100% patients were very satisfied with surgery in TEP group while the figure was 28 in Lichtenstein group.

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 decrease but still more than open operation ($p < 0.0001$).

Postoperative pain is significantly less in TEP repair as compared to Lichtenstein repair. The p value for post operative period pain (at 24 hours) period (p is 0.0032) Postoperative seroma formation is less in TEP group but it is statistically insignificant. Postoperative wound infection is more in open repair due to large incision in inguinal region and using prosthetic material, but it is statistically insignificant. Numbness and neuralgia at inguinal region are less in laparoscopic TEP repair as compared to Lichtenstein repair but it is

statistically insignificant. This is the major limitation of open hernia surgery including Lichtenstein repair.

Post operative hospital stay is less in TEP repair than Lichtenstein repair, because TEP group patients have lesser post operative pain score. Most of the patients in TEP group are satisfied with their surgery and cosmetic results with less pain, less wound infection and better cosmesis. Patient satisfaction with TEP repair is higher than open Lichtenstein repair.

Lichtenstein repair under local anesthesia is as good as TEP under general anesthesia. The shorter operating room time, smaller mesh size, and lower cost of local anesthetic drugs all contribute to make Lichtenstein repair the better choice for repair of uncomplicated unilateral inguinal hernia, especially in developing nations with scarce resources. Moreover, TEP is significantly less painful in the early postoperative period, leading to earlier ambulation than open repair. As well as significantly better cosmetic results.TEP repair for the hernia surgery is also a good procedure when experienced surgeon and good operative setup is available still, TEP can be recommended for those patients who demand for laparoscopy surgery.

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