

## COMPARATIVE STUDY OF INGUINAL HERNIA REPAIR BY LICHTENSTEIN METHOD V/S OPEN PRE-PERITONEAL MESH REPAIR- A PROSPECTIVE STUDY

Shadab Asif<sup>1</sup>, Ankit Modi<sup>2</sup>, Aakash Bora<sup>3</sup>, Ateev Singh<sup>4</sup>, Nikhil Mehrotra<sup>5</sup>, Faisal Moin Ansari<sup>6</sup>

<sup>1</sup>Assistant Professor, Department of General Surgery, Era's Lucknow Medical College & Hospital, Lucknow.

<sup>2</sup>Junior Resident, Department of General Surgery, Era's Lucknow Medical College & Hospital, Lucknow.

<sup>3</sup>Junior Resident, Department of General Surgery, Era's Lucknow Medical College & Hospital, Lucknow.

<sup>4</sup>Junior Resident, Department of General Surgery, Era's Lucknow Medical College & Hospital, Lucknow.

<sup>5</sup>Junior Resident, Department of General Surgery, Era's Lucknow Medical College & Hospital, Lucknow.

<sup>6</sup>Junior Resident, Department of General Surgery, Era's Lucknow Medical College & Hospital, Lucknow.

### ABSTRACT

#### BACKGROUND

Inguinal hernias constitute an important public health problem and often pose a surgical dilemma even for the most skilled surgeon.<sup>1</sup> They are the most common form of abdominal wall hernias. The present prospective study was proposed to compare inguinal hernia repair by Lichtenstein method Vs. Open pre-peritoneal mesh repair regarding drawbacks such as complications, early recurrence and benefits like lower severity of pain and time of hospital stay/surgery.

#### MATERIALS AND METHODS

The present study was a prospective randomised study in the Department of General Surgery at Era's Lucknow Medical College and Hospital from October, 2013. All the patients were followed up for 6 months. Out of 100 patients, 50 underwent Lichtenstein procedure and other 50 underwent open pre-peritoneal mesh repair.

#### RESULTS

Mean duration of surgery was 51.60±7.03 min. in Group I and 71.50±8.03 in Group II, thus showing a significant difference between two groups ( $p < 0.001$ ). Mean duration of hospital stay was 6.72±0.83 days in Group I and 5.52±1.04 days in Group II.

#### CONCLUSION

The findings of present study suggested that post-operative complications, pain and recurrence rates were lower in pre-peritoneal repair group as compared to Lichtenstein repair group, hence open pre-peritoneal hernia repair is recommended as a surgical procedure of choice.

#### KEYWORDS

Hernia, Pre-peritoneal, Lichtenstein, Hernioplasties.

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#### BACKGROUND

The subject of repair of inguinal hernia has been full of controversy ever since Eduardo Bassini of Padua University described his method of repair in the manuscript 'Radical Cure of Inguinal Hernias' way back in 1887.

Nyhus and Stoppa developed the concept of pre-peritoneal repair of inguinal hernia in an effort to reduce the high recurrence rates associated with the anterior repairs popular around that time- most of which in fact were tissue, as against, prosthetic repairs. Around the same time, Lichtenstein<sup>2</sup> and others started performing anterior tension-free mesh repairs, also in an attempt to reduce the recurrence rate, postoperative pain and long convalescence associated with traditionally performed Bassini, Shouldice and McVay repairs. Ironically, Lichtenstein's concept of tension-free

repair by routine implantation of a mesh, which was scathingly criticised as late as 1990,<sup>3</sup> is today considered the 'gold standard' in the open treatment of groin hernias.

Approximately 20 million groin hernioplasties are performed each year worldwide, over 17000 operations in Sweden, over 12000 in Finland, over 80000 in England and over 800000 in the USA<sup>4,5,6,7</sup> Recurrence of inguinal hernia was initially a significant problem; however, with the advent of the tension-free mesh repair as described as Lichtenstein repair (LR),<sup>8</sup> recurrence rate has consistently been reported as low as 1-4%,<sup>9,10,11,12,13</sup> a drop from up to 50-60%.

Some of the common methods of choice for inguinal hernia repair include (Rehman et al 2010):<sup>14</sup>

1. Lytle repair.
2. Bassini repair.
3. Shouldice repair.
4. Darn repair (Moloney's).
5. Lichtenstein repair (Mesh repair).
6. Stoppa's repair.
7. Laparoscopic extraperitoneal and intraperitoneal mesh hernioplasty.

In the recent years, the polypropylene mesh has been extensively used with encouraging results. During 1980s, modern herniologists like Lichtenstein and Gilbert simply laid

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Corresponding Author:

Dr. Shadab Asif,

#592K/34, Subhami Khera,

Telebagh, Lucknow-226002.

E-mail: drshadab.asif@rediffmail.com

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a swatch of mesh without sutures deep to or in front of fascia transversalis with good results (Legutko et al., 2008; Yaghoobi et al., 2007; Deysine, 2008).<sup>15,16,17</sup>

Recently the Health Services Research Unit, Institute of Applied Health Sciences, University of Aberdeen, carried out an extensive review of literature to address whether laparoscopic methods were more effective and cost-effective than open mesh methods of inguinal hernia repair.<sup>18</sup>

Bhandarkar et al (2006)<sup>19</sup> in a meta-analysis study of 14 studies concluded that the laparoscopic repair was costlier than open mesh in all but 2 studies. In the review for the management of unilateral hernias, the open flat mesh was considered the least costly option, but provided less quality adjusted life years than TEP or TAPP. TEP was preferred over TAPP as TEP was found to be less costly and more effective. For management of symptomatic bilateral hernias, laparoscopic repair was considered to be more cost-effective as the operation time was reduced and differences in convalescence time are more marked for laparoscopic compared with open mesh repair. The study also addressed the issue of training costs. If the surgeon were to adopt cost-containment strategies such as use of reusable laparoscopic instruments (which is more or less the norm in India) as against disposable ones, use of indigenous balloons devices rather than commercially available ones, sparing use of fixation devices and reliance on sutures for fixation of the mesh, the cost of the laparoscopic hernia repair should be comparable to the open repair. It is likely that many surgeons are already practising these strategies and passing on the benefits of laparoscopic repair to their patients. They suggested that high-volume centers in India undertake prospective studies to carefully document and analyse data related to the cost-effectiveness of laparoscopic hernia repair.

Therefore, the present prospective study was proposed to compare inguinal hernia repair by Lichtenstein method Vs. Open pre-peritoneal mesh repair regarding drawbacks such as complications, early recurrence and benefits like lower severity of pain and time of hospital stay/surgery.

### Aim and Objectives

1. To study the benefits and drawbacks of hernial repair by Lichtenstein method and open peritoneal mesh repair.
2. To study and compare the intra-operative and post-operative findings of Lichtenstein method and open peritoneal mesh repair of hernia.

### MATERIALS AND METHODS

The present study was a prospective randomised study in the Department of General Surgery at Era's Lucknow Medical College and Hospital from October, 2013. All the patients were followed up from the time of admission till six months from the day of surgery at monthly intervals.

### Inclusion Criteria

Patients undergoing elective hernial surgery.

### Exclusion Criteria

Patients undergoing emergency surgeries.  
Patient affected with HIV, HCV, HBsAg or Diabetes mellitus.

### Duration of Study

Eighteen months starting from October, 2013.

### Sample Size and Randomisation

A total of 100 patients falling in sampling frame were enrolled in the study. They were randomly allocated to one of the following two groups:

Group I (n=50)- Patients in this group underwent hernia repair using Lichtenstein procedure.

Group II (n=50)- Patients in this group underwent hernia repair using open pre-peritoneal mesh procedure.

Randomisation was done through computerised random number generation. Both the procedures were performed as per standard guidelines.

### Assessment- The following factors were assessed.

#### Operative-

Duration of Operation.

#### Intra-Operative

- Haemorrhage.
- Injury to nerve.
- Urinary bladder injury.
- Others.

#### Post-Operative Complications

##### Immediate (0-7 Days)

- Haematoma.
- Wound infection.
- Urinary retention.
- Numbness in inguinal area.

##### Early (7-30 Days)

- Wound healing problems/wound gapping.
- Chronic infection/sinus tract.

##### Late (30 Days and Beyond)

- Chronic pain.
- Reoccurrence.
- Scrotal swelling/local swelling/testicular swelling.
- Seroma/hydrocoele.

#### Other Factors

- Total cost.
- Total duration of hospital stay.
- Returned to work.

#### Duration of Surgery

Total duration of surgery was noted.

#### Chronic Pain

Chronic pain was assessed by Visual analogue scale (VAS) where pain was graded 0-10 on the basis of facial expression, where 0 denotes no pain and 10 as worst imaginable pain.

#### Materials

##### Polypropylene Mesh

Polypropylene mesh of 6×3 was used in Lichtenstein method and 6×6 was used in pre-peritoneal mesh repair.

#### Sutures

Prolene 2.0 RB was used for mesh fixation and Vicryl 2.0 RB was used for external aponeurosis.

One dose of antibiotic was given pre-operatively and scrotal support was given in all the patients. Necessary

laboratory and radiographic investigations were done before planning for operative procedure.

**RESULTS**

The present study was conducted in the Department of Surgery, Era's Lucknow Medical College, Lucknow to study

the benefits and drawbacks of hernial repair by Lichtenstein method and open pre-peritoneal mesh repair and to compare the intra-operative and post-operative findings of both the operative procedures.

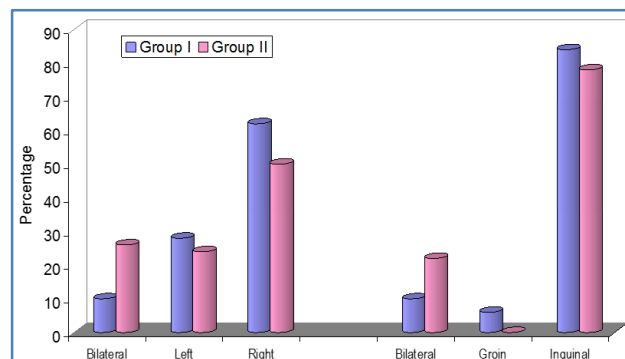
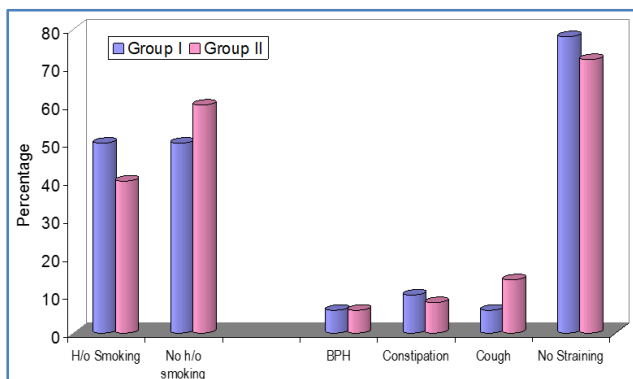
100 patients were randomly administered two different operative procedures as shown below.

Variables	Total Subjects	Group I (n=50)		Group II (n=50)		Statistical Significance	
		No.	%	No.	%	$\chi^2$	P
Lt. Inguinal Hernia	25	13	26.00	12	24.00	7.233	0.124
Rt. Inguinal Hernia	57	32	64.00	25	50.00		
B/L Inguinal Hernia	18	5	10.00	13	14.00		

*Table 1. Between Group Comparison of Diagnosis*

Variables	Total Subjects	Group I (n=50)		Group II (n=50)		Statistical Significance	
		No.	%	No.	%	$\chi^2$	P
History of Smoking							
Positive	45	25	50.00	20	40.00	1.010	0.315
Negative	55	25	50.00	30	60.00		
History of Straining							
BPH	6	3	6.00	3	6.00	1.831	0.608
Constipation	9	5	10.00	4	8.00		
Cough	10	3	6.00	7	14.00		
No Straining	75	39	78.00	36	72.00		

*Table 2. Between Group Comparison of Personal Habits & History of Straining*



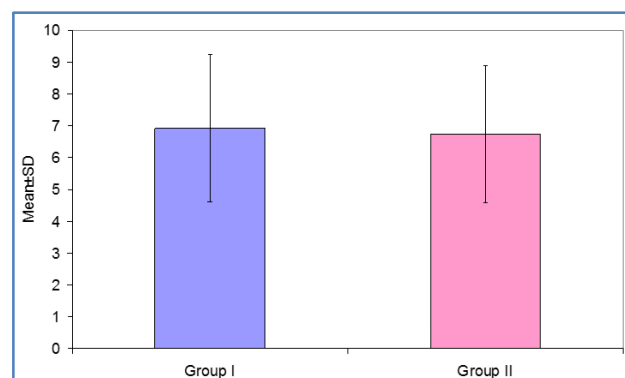
Variables	Total Subjects	Group I (n=50)		Group II (n=50)		Statistical Significance	
		No.	%	No.	%	$\chi^2$	P
Side of Swelling							
Bilateral	16	5	10.00	13	26.00	4.352	0.113
Left	26	14	28.00	12	24.00		
Right	58	31	62.00	25	50.00		
Site of Swelling							
Bilateral	16	5	10.00	11	22.00	5.361	0.069
Inguinal	84	45	90.00	39	78.00		

*Table 3. Between Group Comparison of Side and Site of Swelling*

Group	No. of Subjects	Minimum	Maximum	Mean	S.D.
Group I	50	2	12	6.92	2.31
Group II	50	3	12	6.74	2.15
<b>Total</b>	<b>100</b>	<b>2</b>	<b>12</b>	<b>6.83</b>	<b>2.22</b>

*Table 4. Between Group Comparison of Duration of Swelling (Months)*

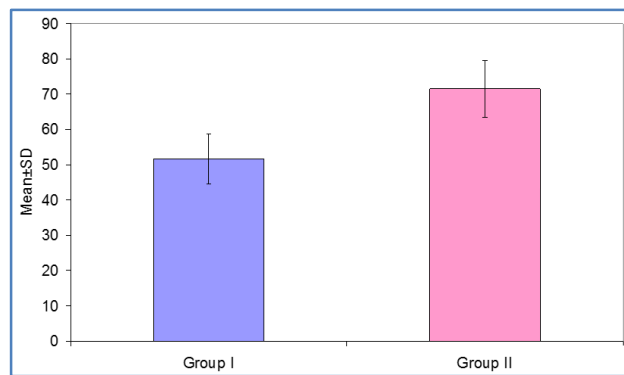
t'=0.404; p=0.687



Group	No. of Subjects	Minimum	Maximum	Mean	S.D.
Group I	50	45	75	51.60	7.03
Group II	50	50	90	71.50	8.03
<b>Total</b>	<b>100</b>	<b>45</b>	<b>90</b>	<b>61.55</b>	<b>12.51</b>

**Table 5. Between Group Comparison of Duration of Surgery (Minutes)**

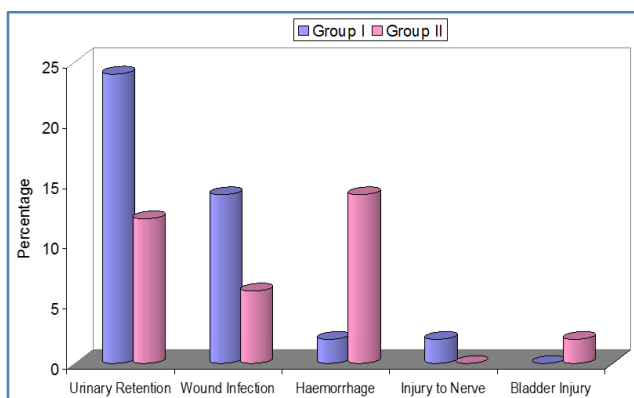
't'=13.181; p<0.001 (Significant)



Variables	Total Subjects	Group I (n=50)		Group II (n=50)		Statistical Significance	
		No.	%	No.	%	$\chi^2$	P
Urinary Retention	18	12	24.00	6	12.00	2.439	0.112
Wound Infection	10	7	14.00	3	6.00	1.778	0.182
Haemorrhage	8	1	2.00	7	14.00	4.891	<b>0.012</b>
Injury to Nerve	1	1	2.00	0	0.00	1.010	0.315
Bladder Injury	1	0	0.00	1	2.00	1.010	0.315

**Table 6. Between Group Comparison of Complications during Surgery and Post-operative Complications (Immediate)**

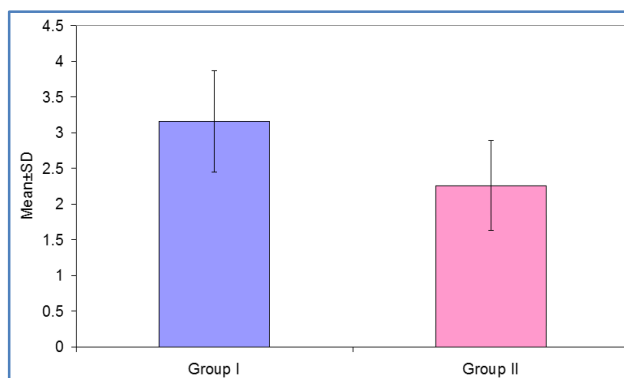
\*Significant



Group	No. of Subjects	Min	Max	Mean	S.D.	Median
Group I	50	1	4	3.16	0.71	3
Group II	50	1	4	2.26	0.63	2
<b>Total</b>	<b>100</b>	<b>1</b>	<b>4</b>	<b>2.71</b>	<b>0.81</b>	<b>3</b>

**Table 8. Between Group Comparison of Chronic Pain at 3 Months (VAS Score)**

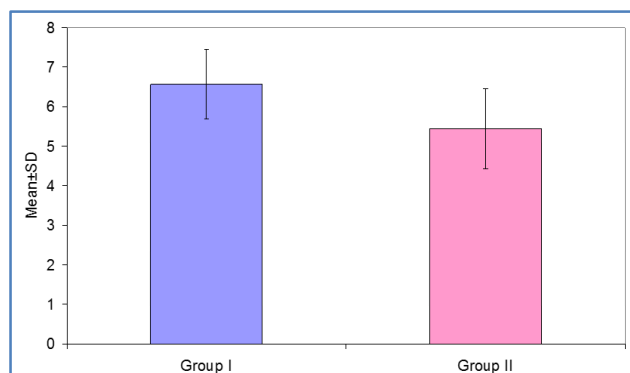
'z'=5.740; p<0.001 (Mann-Whitney U test) (Significant)



Group	No. of Subjects	Min	Max	Mean	S.D.	Median
Group I	50	4	8	6.56	0.88	7
Group II	50	3	7	5.44	1.01	6
<b>Total</b>	<b>100</b>	<b>3</b>	<b>8</b>	<b>6.00</b>	<b>1.10</b>	<b>6</b>

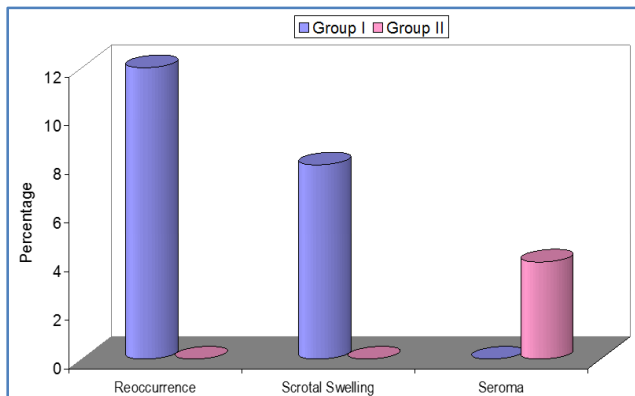
**Table 7. Between Group Comparison of Pain at 1st week (VAS Score)**

'z'=5.365; p<0.001 (Mann-Whitney U test) (Significant)



Variables	Total Subjects	Group I (n=50)		Group II (n=50)		Statistical Significance	
		No.	%	No.	%	$\chi^2$	P
Recurrence	6	6	12.00	0	0.00	6.383	0.012
Scrotal Swelling	4	4	8.00	0	0.00	4.167	0.041
Seroma	2	0	0.00	2	4.00	2.041	0.153

**Table 9. Between Group Comparison of late Post-operative Complications 30 days and beyond**



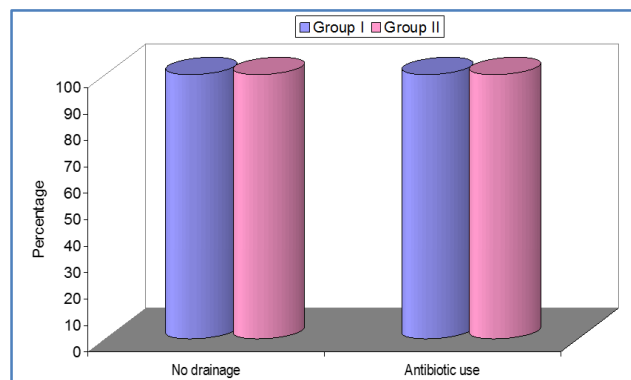
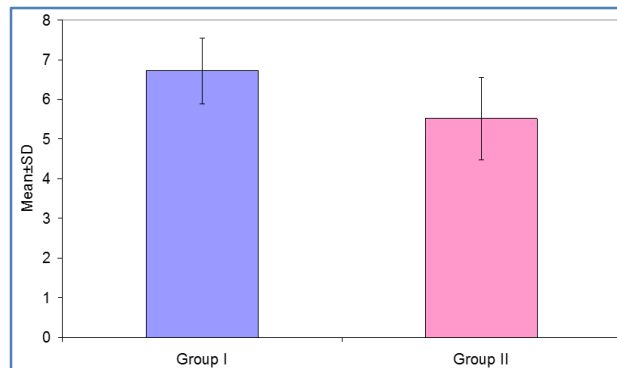
Group	No. of Subjects	Min	Max	Mean	S.D.	Median
Group I	50	4	8	6.72	0.83	7
Group II	50	4	8	5.52	1.04	6
<b>Total</b>	<b>100</b>	<b>4</b>	<b>8</b>	<b>6.12</b>	<b>1.11</b>	<b>6</b>

**Table 12. Between Group Comparison of Duration of Stay at Hospital (Days)**

't'=6.384; p<0.001 (Significant)

Variables	Total Subjects	Group I (n=50)		Group II (n=50)		Statistical Significance	
		No.	%	No.	%	$\chi^2$	P
No Drainage	100	50	100.00	50	100.00	-	-
Antibiotic Use	100	50	100.00	50	100.00	-	-

**Table 10. Between Group Comparison of Drainage and Use of Antibiotics**



**DISCUSSION**

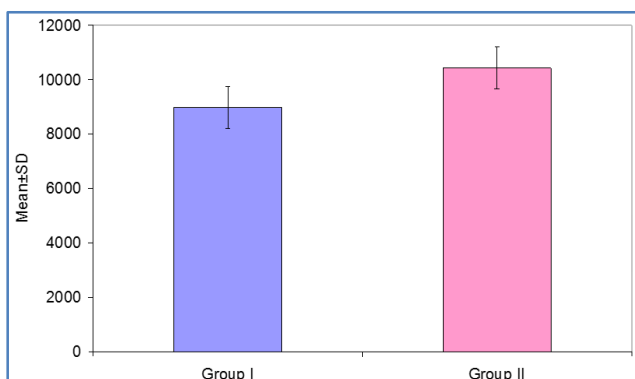
Inguinal hernias constitute an important public health problem and often pose a surgical dilemma even for the most skilled surgeon. They are the most common form of abdominal wall hernias. The incidence of inguinal hernia is unknown, but about 500,000 cases come to medical attention each year.<sup>20</sup> In international and US surveys conducted 25 or more years ago, the prevalence of non-surgically treated inguinal hernia among men was 5–7 percent, and a similar number of men had a history of hernia repair. Inguinal hernias are painful, cause discomfort and impair the activities of life.<sup>21</sup> There are a number of surgical techniques to perform hernia repair, viz., tension-free prosthetic repairs done through anterior approach (Lichtenstein repair, plug repair, patch and plug repair and double-layer devices) or posterior/pre-peritoneal approach (Open technique, Stoppa, Laparoscopic/endoscopic repairs) and tissue-suture repairs that include Bassini-Shouldice technique and its modifications and Marcy repair.

Group	No. of Subjects	Min	Max	Mean	S.D.	Median
Group I	50	7500	11000	8970.00	785.13	9000
Group II	50	9000	12000	10425.00	766.40	10500
<b>Total</b>	<b>100</b>	<b>7500</b>	<b>12000</b>	<b>9697.50</b>	<b>1063.21</b>	<b>9000</b>

**Table 11. Between Group Comparison of Cost of Surgery (Rs.)**

Today, some strong recommendations exist in favour of Lichtenstein repair. American College of Surgeons choose this technique for "gold standard", while National Institute of Clinical Excellence [NICE] from UK<sup>22</sup> and The National Agency for Accreditation and Evaluation in Health [ANAES] from France<sup>23</sup> recommended it for inguinal hernia repair. It is easy to learn and perform.<sup>24</sup> However, a recent Cochrane review has shown that open pre-peritoneal mesh repair is as good as Lichtenstein procedure<sup>25</sup> while some of the workers are of the view that open pre-peritoneal procedure not only has similar success rate but also has lesser acute and chronic pain. The Cochrane review study has also recommended randomised controlled trials for this purpose. Hence, the present study was undertaken.

't'=9.3773; p<0.001 (Significant)



In the present study, a total of 100 patients proposed to undergo hernia repair were enrolled in the study. The patients were randomly allocated to two groups– Group I had 50 patients in whom hernia repair was performed using Lichtenstein procedure whereas Group II had 50 patients in whom hernia repair was performed using Open pre-

peritoneal mesh repair. Demographic profile, clinical presentation, risk exposures, anaesthetic needs, duration of surgery, intraoperative and post-operative complications of procedure, post-operative pain, antibiotic use, cost of procedure, duration of hospital stay, duration of resumption of activities and recurrence rates of two procedures were compared. The demographic and pre-operative clinical profile of two groups was matched.

In the present study, age of patients ranged from 17 to 85 years. Majority of patients (59%) were above 40 years of age. Mean age of patients was 44.65±16.33 years.

In the present study, majority of cases were male (87%). Male to female ratio was 6.69:1. 92% patients in Group I and 82% in Group II were males.

In the present study, majority of cases had unilateral hernia (82%). Right side was more commonly involved (57%) as compared to left side (25%). Bilateral involvement was seen in 18% cases.

In the present study, history of smoking was noticed in 50% of Group I and 40% of Group II patients. Statistically, this difference was not significant ( $p=0.315$ ). Smoking is a known risk factor for recurrence of hernias.<sup>26,27</sup> History of BPH, Constipation and Cough was seen in 6%, 9% and 10% cases respectively.

In the present study, no significant difference between two groups was observed with respect to side and site of swelling. Duration of swelling ranged from 2 to 12 months.

In Lichtenstein group, all the patients were operated under spinal anaesthesia (100%). However, in open pre-peritoneal mesh approach, only 10% cases were operated under spinal anaesthesia, in remaining cases general anaesthesia was used.

In the present study, duration of surgery ranged from 45 to 90 min. Mean duration of surgery was 51.60±7.03 min. in Lichtenstein repair group as compared to 71.50±8.03 in Open pre-peritoneal repair group, thus showing a significant difference between two groups ( $p<0.001$ ).

In the present study, intraoperatively and immediate post-operatively, urinary retention, wound infection, haemorrhage, nerve injury and bladder injury was observed in 12, 7, 1 and 0 patients respectively in Group I and 6, 3, 7 and 1 patients respectively in Group II. A significant difference between two groups was observed for haemorrhage ( $p=0.012$ ).

In the present study, one week post-operative pain was significantly higher in Lichtenstein group as compared to open pre-peritoneal repair group. Similar chronic pain observed at 3 months was also significantly higher in Lichtenstein group as compared to open pre-peritoneal repair group. In a recent Cochrane review, it was shown that pre-peritoneal repair causes less or comparable acute and chronic pain compared to the Lichtenstein procedure. The findings in present study showed a better response to open pre-peritoneal repair as compared to Lichtenstein repair.

In the present study, scrotal swelling, seroma formation and recurrence was seen in 4, 2 and 6 patients respectively. All the recurrences took place in Lichtenstein group only. Scrotal swelling was also seen in Lichtenstein group only. Seroma formation was seen in open pre-peritoneal repair group only. Statistically, the difference between two groups was significant with respect to recurrence and scrotal swelling.

In the present study, mean cost of procedure was Rs 8970±785 for Lichtenstein repair and Rs 10425±766 for Open pre-peritoneal repair. However, one must not forget that Lichtenstein repair group had 6 cases of recurrence (12%), thus after adjusting for this failure rate, the actual direct cost goes up by 12% to reach at Rs 10764/-. In the present study, mean duration of hospital stay and resumption of work was 6.72±0.83 and 13.92±1.31 days respectively in Lichtenstein repair group and 5.52±1.04 and 11.44±1.73 days respectively in pre-peritoneal repair group.

The finding of present study suggested that post-operative complications, pain and recurrence rates were lower in pre-peritoneal repair group as compared to Lichtenstein repair group, hence open pre-peritoneal hernia repair is recommended as a surgical procedure of choice.

## CONCLUSION

1. Age of patients ranged from 17 to 85 years. Majority of patients (59%) were above 40 years of age. Mean age of patients was 44.65±16.33 years. The age of patients in two groups was comparable.
2. Majority of cases had unilateral hernia (82%). Right side was more commonly involved (57%) as compared to left side (25%). Bilateral involvement was seen in 18% cases.
3. History of smoking was noticed in 50% of Group I and 40% of Group II patients. Statistically, this difference was not significant ( $p=0.315$ ).
4. History of BPH, Constipation and Cough was seen in 6%, 9% and 10 cases respectively. Statistically, there was no significant difference between two groups with respect to these findings.
5. Duration of surgery ranged from 45 to 90 min. Mean duration of surgery was 51.60±7.03 min. in Group I and 71.50±8.03 in Group II, thus showing a significant difference between two groups ( $p<0.001$ ).
6. Intraoperatively and immediate post-operatively, urinary retention, wound infection, haemorrhage, nerve injury and bladder injury was observed in 12, 7, 1 and 0 patients respectively in Group I and 6, 3, 7 and 1 patients respectively in Group II. A significant difference between two groups was observed for haemorrhage ( $p=0.012$ ).
7. One week post-operative median pain score was 7 in Group I and 6 in Group II, thus showing a significant difference between two groups ( $p<0.001$ ).
8. At 3 months, median pain score was 3 in Group I and 2 in Group II, thus showing a significant difference between two groups ( $p<0.001$ ).
9. Scrotal swelling, seroma formation and recurrence was seen in 4, 2 and 6 patients respectively. All the recurrences took place in Group I. Scrotal swelling was also seen in Group I only. Seroma formation was seen in Group II only. Statistically, the difference between two groups was significant with respect to recurrence and scrotal swelling.
10. Mean cost of procedure was Rs 8970±785 in Group I and Rs 10425±766 in Group II. Statistically, the difference was significant. However, considering the recurrence rate of 12% in Group I, the burden of average cost reaches to Rs 10764 which is comparable to that in Group II.

11. Mean duration of hospital stay was  $6.72 \pm 0.83$  days in Group I and  $5.52 \pm 1.04$  days in Group II. Statistically, the difference between two groups was significant.
12. Mean duration of resumption to work was  $13.92 \pm 1.31$  days in Group I and  $11.44 \pm 1.73$  days in Group II. Statistically, the difference between two groups was significant ( $p < 0.001$ ).
13. Considering the post-operative complications, pain and recurrence rate as the determinants of choice for selection of a surgical procedure for hernia repair, open pre-peritoneal hernia repair remains to be the surgery of choice.

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