



## Surgery

## A COMPARATIVE STUDY OF LAPAROSCOPIC TOTAL EXTRA-PERITONEAL REPAIR TECHNIQUE VERSUS OPEN TENSION-FREE(LICHTENSTEIN) REPAIR TECHNIQUE FOR UNCOMPLICATED PRIMARY UNILATERAL INGUINAL HERNIA

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### KEYWORDS :

#### INTRODUCTION

Groin hernias are the most common condition referred to Surgeons all over the world. Currently adult groin herniorrhaphy accounts for 15 percent of operations in General Surgery and is one of the most common procedures performed by any General Surgeon. <sup>(1)</sup>

Inguinal hernias, despite its frequency continue to present challenging problems for Surgeon. Although many recent technical advances have occurred in Surgery, current management of an inguinal hernia remains as controversial and diverse as it was in the time of *Bassini* and *Halsted*. <sup>(2)</sup>

A variety of procedures have been described for hernia repair. Controversy exists about which being the best procedure. A large number of randomized prospective studies are increasingly being reported. Operations on hernia have progressed from wound cauterization and hernial sac debridement in 15<sup>th</sup> century to laparoscopic repair in recent times. Surgery for hernia has evolved significantly after 1<sup>st</sup> surgical repair described by *Bassini* in 1890 which is a major breakthrough. From then onwards main aim of operation was to reduce morbidity and recurrence. <sup>(3)</sup>

Developments in management of an inguinal hernia have decreased post-operative disability and recurrence rates. Recurrent hernias accounted for 16 percent of hernia repairs which testifies to the fact that the perfect solution to this problem has not yet been developed.

The principal of open tension free mesh repair was championed by *Lichtenstein*. Physiological repair can be done in congenital hernia but not required in type where there is defect of posterior wall due to metabolic causes. The most important principle in reconstruction surgery is to avoid tension when restoring the muscular or elastic structures. Attempting to move muscular structure to an immovable structure is structurally destructive. A prosthetic reinforcement of weak posterior wall by mesh is physiological and structurally acceptable. Instead of opposing the anatomic structures under tension; reinforcement of defect is done by mesh. It repairs and protects the region of defect from future hernia. Today worldwide it is the method of choice. Mesh repair is easy to perform, with low recurrence and complication rates. <sup>(4)</sup>

Several factors contributed to the thought process, which culminated in the advent of laparoscopic repair of hernia. Important of these were the preperitoneal repair advocated by *Nyhus* and *Stoppa* and the clinical and experimental work by *Ralph Ger*.

Minimal invasive surgery is a marriage of technology and surgical

innovation that aims to accomplish surgical therapeutic goals with minimal somatic and psychological trauma. The word 'Laparoscopy' derives from the Greek word "*Laparo*" meaning flank and "*skopein*" meaning examination.

Laparoscopic inguinal hernia repair (LIHR) was introduced following the success of laparoscopic cholecystectomy on the premise that there would be less postoperative discomfort and pain, recovery time would be reduced, repair of recurrent hernia would be easier because the repair is performed in virgin tissue, concurrent treatment of bilateral hernias, simultaneous diagnostic Laparoscopy, high ligation of hernial sac would be feasible, and cosmesis would be improved.

The first Laparoscopic hernia repair was performed by Ger (1982). In 1989, *Bogojavalensky* revived this procedure by introducing the mesh-plug technique. Since then three laparoscopic procedures have been established, intra-abdominal (intra-peritoneal) on-lay mesh, the trans abdominal pre-peritoneal mesh (TAPP, *Arregui* 1991) and total extra-peritoneal mesh (TEP, *Duluca*, 1991).

In laparoscopic total extra-peritoneal mesh repair, the abdominal cavity is not entered, but instead extra-peritoneal space is created and endoscopic trocars and instruments are placed in this operating tunnel. Hence the risk of major complications of laparoscopy such as bowel perforation, potential for adhesion formation, major vascular injury and any obvious cardiopulmonary contraindications to a pneumoperitoneum is avoided.

The total extra-peritoneal (TEP) mesh repair (Preperitoneal) for inguinal hernia is generally considered to be a technically demanding, expensive and time-consuming procedure. However with experience it has been shown that the operation now take less time than open mesh repair in experienced hands, is associated with less post operative pain, faster recovery, postoperative complications are reduced, chronic and sometimes severe groin pain is significantly less. For these reasons, it has been recommended to surgeons who perform groin hernia surgery to seek out training in this important development in one of the most common conditions that we treat. <sup>(5)</sup>

With these perspectives, this prospective study was planned to assess the applicability of laparoscopic total extra-peritoneal (TEP) repair technique, compare it with open tension-free (Lichtenstein) repair technique for uncomplicated primary unilateral inguinal hernias and study the associated complications, advantages and disadvantages in our set-up.

#### AIMS AND OBJECTIVES

**AIMS:**

- To study advantages and disadvantages of Laparoscopic Total Extra-peritoneal (TEP) hernia repair technique in uncomplicated primary unilateral inguinal hernias.

**OBJECTIVES:**

- To study and compare the results of inguinal hernia repair by Laparoscopic Total Extra-peritoneal (TEP) repair technique with open tension-free (Lichtenstein) repair technique taking parameters like intra-operative complication rate, operative time, post-operative local complication rate, post-operative pain, time taken to return to normal work, surgery and cosmesis and recurrence rate at one year of follow-up into consideration.

**Some of the study results between laparoscopic TEP and Open (Lichtenstein) group are being high lightened under the following heads.**

**A) COMPLICATIONS:**

Studies by Bringman<sup>(65)</sup>, Anderson<sup>(67)</sup>, Subwongcharoen<sup>(68)</sup>, Lal<sup>(69)</sup> and Schneider<sup>(69)</sup> comparing results between TEP hernia repair and conventional open hernia repair (Lichtenstein) showed no significant difference in complication rates between the TEP group and the open group. However, a study by Neumayer et al<sup>(71)</sup> demonstrated a complication rate of 39% in the TEP group and 33.4% in the open group. A similar study by Lau et al<sup>(72)</sup> demonstrated that chronic groin pain in the open group was 21.7%, vis-a-vis in the TEP group (9.9%). A higher incidence of urinary retention was reported in a series by Vidovic et al<sup>(73)</sup> in the TEP group compared to the open group. A study by Hallen et al<sup>(77)</sup> study found significantly higher incidence of testicular pain in the TEP group and higher impaired inguinal sensation in the open group.

**B) LENGTH OF OPERATION (in minutes):**

Studies by Bringman et al<sup>(65)</sup>, Schneider et al<sup>(70)</sup> and Vidovic et al<sup>(73)</sup> found no difference in length of operation between TEP and open group. Lal et al<sup>(69)</sup> however found significant difference in length of operation between the two groups (**'p' value of <0.001**). Average operative time in the TEP group was 75.72+/- 31.6 minutes and in the open group were 54+/-15. Thus operation was lengthier in the TEP group. Similar results were also shown in a study by Subwongcharoen<sup>(68)</sup> stating that the average operative time in TEP group was more i.e. 67.85+/- 21.66 minutes as compared to open group, which was 55.85 minutes.

Conversely, a study by Lau et al<sup>(72)</sup> concluded that open repair technique took more time for operation than TEP repair technique. In this study TEP group average operative time was 50+/- 13.2 minutes and for open group it was 58+/-17.6 minutes.

**C) CONVERSION TO OPEN:**

Conversion from TEP to open repair technique were reported in a single case in each of the studies by Subwongcharoen<sup>(68)</sup> and Anderson et al<sup>(67)</sup> due to intra-operative difficulties. No conversion from TEP repair to open procedure were reported in studies by Lal et al<sup>(69)</sup> and Lau et al<sup>(72)</sup>.

**D) POST OPERATIVE SEROMA:**

Formation of seroma is one of the most common post-operative complications following TEP repair. Reported occurrence of seroma formation was 2% (Kald et al<sup>(74)</sup>), 6% (Cohen et al<sup>(75)</sup>) and 1.5% (Spitz et al<sup>(76)</sup>).

**E) POST OPERATIVE PAIN:**

It has been observed in numerous studies that the incidence of persisting post-operative pain is significantly less in laparoscopic herniorrhaphy patients as compared to open herniorrhaphy, which remains a principal reason behind the popularity of the former operation. Bringman et al<sup>(65)</sup> measured post operative pain on VAS (Visual Analogue Scale) and reported a score that was consistently lower in the TEP group and higher in the open group. In a study by Anderson et al<sup>(67)</sup>, it was reported that for post-operative pain control, significantly less analgesics were required by patients in the TEP group as compared to the open group, (**'p' value < 0.001**). A study by Lal et al<sup>(69)</sup> showed that average VAS score at 12 hours for the TEP group was 2.64+/- 1.4 and for the open group was 3.52+/- 1.7, which was significantly lower (**'p' value <0.04**). In the same study, average VAS score at 24 hours for TEP group was 1.76+/- 1.4 and for the open group was 3.52+/- 1.7, which was significantly lower (**'p'**

**value <0.01**). A similar study by Neumayer et al<sup>(71)</sup> showed that difference in mean score on VAS is 10.2 mm between the TEP and the open groups. Postoperative pain and chronic groin pain both were significantly less in a study done by Lau et al<sup>(72)</sup>.

**F) RETURN TO WORK:**

Return to work was earlier in TEP repair group which was demonstrated by several studies. In a study by Bringman et al<sup>(65)</sup>, average return to work was within 14 days of operation while in the open group it was 28.5 days. In a similar study by Lal et al<sup>(69)</sup>, the average return to work was 12.8+/-7.1 days which was significantly lower in open group taking 19+/-4.3 days (**'p' value <0.001**). In a study by Schneider et al<sup>(70)</sup>, average return to work period was 15 and 34 days for TEP and open group respectively (**'p' value <0.005**). Lau et al<sup>(72)</sup> study group took average 8.6 days in TEP repair technique as compared to 14 days in open group with significant **'p' value <0.006**. Elkund et al<sup>(78)</sup> study showed that TEP group took average 7 days for return to work when compared with 12 days in open group, showed significant difference (**'p' value <0.001**).

**G) RECURRENCE:**

Studies by Lal et al<sup>(69)</sup> and Lau et al<sup>(72)</sup> study showed no difference in recurrence rates between TEP and open group. Similar studies by Subwongcharoen<sup>(68)</sup> and Anderson et al<sup>(67)</sup> showed no recurrence in open group but had 1 recurrence out of 55 and 2 cases out of 81 respectively in the TEP groups. Hallen et al<sup>(77)</sup> showed 3% recurrence rate in TEP group and 4% recurrence rate in open group while Elkund et al<sup>(78)</sup> showed 3.5% recurrence rate in TEP group and 1.2% recurrence rate in open group. Study results of the Neumayer et al<sup>(71)</sup> reported a 10.1% recurrence after primary hernia repair and 10% recurrence after recurrent hernia repair in the TEP group. In the open group, a 4% recurrence after primary hernia repair and 14.1% recurrence after recurrent hernia repair was reported.

**MATERIALS AND METHODS****STUDY AREA:**

The study was conducted in the Department of Surgery, Vivekanand Institute of Medical Sciences, Ramakrishana Mission Seva Pratishthan, Kolkata-26. This prospective study was planned to assess the applicability of laparoscopic total extra-peritoneal (TEP) repair technique and compare it with open tension free (Lichtenstein) repair technique for uncomplicated primary unilateral inguinal hernia and study the associated complications, advantages and disadvantages in our set-up.

**STUDY POPULATION:**

The study was carried out in patients attending General Surgical Out Patient Department & admitted in General Surgical Wards having uncomplicated primary unilateral inguinal hernia between the age group of 18-80 years; operated in General Surgical operation theatres of Vivekananda Institute of Medical Sciences, Ramakrishna Mission Seva Pratishthan, Kolkata-26. During the study following inclusion & exclusion criteria were considered

**INCLUSION CRITERIA:**

- Patients aged 18 years and above.
- Male patients
- Suitable for General Anesthesia.
- Patients with primary unilateral hernia.
- Elective repair.

**EXCLUSION CRITERIA:**

- Patients unfit for General Anesthesia.
- Recurrence after previous preperitoneal mesh repair.
- Previous lower abdominal and pelvic surgeries.
- Suspected strangulation of hernia.
- Patients with coagulation disorders.

**STUDY PERIOD:**

The study was conducted in the time period of August 2007 to December 2008.

**SAMPLE SIZE:**

The study was conducted on thirty-four cases each for laparoscopic TEP repair technique and open (Lichtenstein) mesh repair technique.

**SAMPLE TECHNIQUE:**

The sample was randomly chosen, controlled and designed for

comparative study through informed consent including conversion to open if necessary.

**STUDY DESIGN:**

The study was a Prospective Observational Controlled Study.

**PARAMETERS TO BE STUDIED**

The study was conducted with the help of following parameters which defines the objectives of study.

- A) Duration of operation: The parameter is from skin incision to skin closure.
- B) Intra-operative complication:

The parameters are:-

1. Vascular injury:
  - I) Injury to the vessels of abdominal walls-inferior epigastric artery
  - ii) Vessels deep seated -like femoral, iliac.
2. Visceral injury:
  - I) Injury to Bladder
  - ii) Injury to intestine
  - iii) Others
3. Nerve injury: Complaints of tingling, numbness, pain along the groin, lateral aspect of thigh.
- C) Post-operative pain: It is assessed by Visual Analogue Scale (VAS).
- D) Post-operative local complication: Formation of seroma, haematoma both local and scrotal and wound infection.
- E) Time taken to return to normal work: Parameter was moving up and down the staircase, lifting a 5 Lit bucket full of water.
- F) Opinion about surgery and cosmesis: Assessed by asking patients opinion about surgery and cosmesis in the form of Very satisfied, Satisfied and Not satisfied.
- G) Recurrence: Assessed by visible cough impulse on the same side and or unequivocal evidence by radiological imaging like USG, CT or MRI.

**STUDY TOOLS:**

Pre-designed proforma was maintained to document patient particulars, history, clinical examination, relevant investigations, pre-anesthetic check-up, operative notes, intra-operative complications, post-operative and follow-up findings of patient. All the standard General Surgical instruments and laparoscopic instruments in the operation theatre of Vivekanand Institute of Medical Sciences, Ramakrishana Mission Seva Pratishthan, Kolkata-26, were used for study. The operative procedures were carried out under strict asepsis.

**STUDY COHORT:**

Patients attending out patient department fulfilling both inclusion and exclusion criteria were admitted in wards and informed consent was taken. Patients were followed up post-operatively at 1 week interval for 1 month, monthly interval for 3 months and then at 3 months interval for 1 year. Any patient developing complaints in between were requested to attend surgical out patient department or Emergency immediately.

Patients with inguinal hernia had groin swelling in either right or left groin. In all these cases swelling was reducible.

After admission detailed history was taken and every patient was thoroughly examined clinically. In every patient expansile cough impulse was noticed. Deep ring occlusion test was done to assess clinically the type of hernia. In patients with associated complaints of narrow stream of urine and constipation, digital rectal examination was done to assess the size of prostate and exclude any rectal and anal canal pathology.

**INVESTIGATIONS:**

All patients were asked to do following investigations:

- 1) Estimation of hemoglobin, total leukocyte count, differential leukocyte count.
- 2) Blood sugar both fasting and post prandial to exclude Diabetes Mellitus
- 3) Urine examination

- 4) Serum urea and creatinine, coagulation profile.
- 5) X-ray chest P-A view.
- 6) Electrocardiogram.
- 7) Ultrasonography of KUB region with detection of post void residual urine in patients with prostatomegally.

**PRE-ANESTHETIC CHECK-UP:**

These all investigations were done on out patient basis. Patients were sent to Anesthesia Department for pre-anesthetic check-up. Operations were arranged on scheduled dates after patient was declared fit for surgery from Anesthesia Department.

To conduct this study following measure were taken:

- 1) Patients were offered laparoscopic (TEP) and Open (Lichtenstein) repair randomly.
- 2) Informed consent was taken, including conversion to open procedure if necessary. Those who refused, were excluded from study.
- 3) All patients were operated under general anesthesia. This was to maintain uniformity in post operative assessment.
- 4) Regular follow-up of all the patients was done in out patient department for minimum one year.

**Pre-operative check-up of patients:**

The following checks of patients were done:

- Check if patient was correct.
- Check for correct side of hernia.
- Check if patient was nil per mouth for more than 6 hours.
- Check if patient had given consent for surgery.
- Check if patient had shaved from xiphoid to groin and mid-thigh.

**SURGEONS:**

Operations were performed by senior visiting surgeons or junior trainee surgeons under proper supervision.

**ANESTHESIA:**

All patients were operated under general anesthesia.

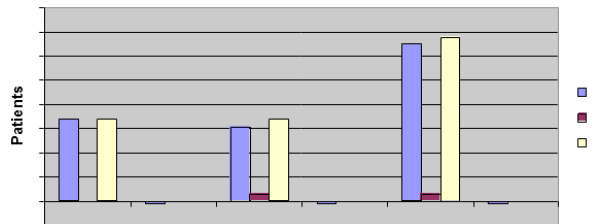
Each patient was given pre-operative injection Amoxicillin + Clavulanic acid 1.2g intravenous, after skin test, before induction of anesthesia.

**Plan for Analysis of Data:-**

Numerical variables were compared between the two groups by Student's t-test and Mann-Whitney U test.

Categorical variables were compared between the groups by Chi-square test, or Fisher exact test as appropriate.

Analysis would be two tailed and on an intention to treat bias. 'p' value <0.05 would be regarded as statistically significant.



**DISCUSSION**

Hernia is a disease that has been known to mankind since ancient times. Various techniques are being used to repair groin hernias like:

- Pure tissue repair by *Shouldice* repair, the *Cooper's* ligament repair.
- Darn repair.
- Mixed tissue + prosthetic repairs by Gilbert.

Recognizing the fact that tension in a repair is the principle cause of recurrence, management of hernia using synthetic mesh prosthesis to bridge the defect, a concept popularized by Lichtenstein gives excellent results with low recurrence and complication rates.

With the advent of Laparoscopic surgery, the tide has entered hernia operation. Increasing number of patients are being operated by preperitoneal approach.

Various articles and reviews have been published about the merits of laparoscopic hernia, while recurrence rate, operative time and cost are debatable when compared with open tension-free repair; the parameters of reduced pain, morbidity and earlier return to work have been said in its favour which is ideal from social perspective.

The present study was conducted to assess the effectiveness of the laparoscopic total extra-peritoneal (TEP) repair technique in comparison to open tension-free (Lichtenstein) repair technique of inguinal hernia.

The study was carried out on 68 male patients with a clinical diagnosis of inguinal hernia presenting to the Out Patient Department and were admitted in wards of Department of General Surgery, in Vivekananda Institute of Medical Sciences, Ramakrishna Mission Seva Pratishthan, Kolkata-26, during a span of 17 months. 34 patients were included in each group. Informed written consent was taken.

The patients were in the age group of 18 to 66 years. In the laparoscopic TEP group the mean age was 45.35 years and in the OPEN (Lichtenstein) group the mean age was 43.82 years. (Table No:-2)

All the patients operated were male patients. Major proportions of patients were involved in non-heavy jobs, supporting minimal role of strenuous work per se behind groin hernias. (Table No:-3)

Patients were presented with complaints of groin swelling, with or without pain. Of the 68 patients, 54 patients had no associated pain. All the patients had unilateral swelling. No patient had any history of hernia operation earlier. Of the 54 patients with no associated pain, 29 underwent TEP operation while 25 fell into OPEN (Lichtenstein) group. (Table No:-4)

The patients were suffering from hernia for a range of 4 to 28 months. In TEP group the symptom duration ranged from 4 to 25 months, with a mean of 12.14 months. In OPEN (Lichtenstein) group the patients were suffering from hernia from 6 to 28 months, with a mean of 14.32 months. (Table No:-5)

Co-morbid conditions like COPD (Chronic Obstructive Pulmonary Disease), LUTS (Lower urinary tract symptoms), DM (Diabetes Mellitus), HTN (Hypertension), CHF (Congestive heart failure) were found to be distributed similarly between the two groups. (Table No:-6)

Per-operatively it was found that 50 (73.52%) patients had indirect hernia, 9 (13.24%) had direct hernia, while 9 (13.24%) had pantaloon type of hernia. There were 26 (76.47%) patients with indirect hernia in TEP group and 24 (70.59%) with indirect hernia in OPEN group. 2 (5.88%) patients in TEP and 7 (20.59%) in OPEN group had direct hernia. 6 (17.65%) patients of TEP and 3 (8.82%) patients of OPEN group had pantaloon hernia. (Table No:-7)

#### Intra-operative Complications:

Intra-operative complications that occurred during the study were conversion from TEP technique to OPEN technique, nerve injury and cord structure injury, mainly. The complication rate in TEP group is 23.52% while that of OPEN is 17.64%. In TEP 6 (17.65%) patients had conversion to open, 1 (2.94%) patient had cord structure injury, and 1 (2.94%) patient had vessel injury. The results when compiled statistically, the complication rate was significant in TEP group (**'p' value 0.017**) (Table No:-8). These results were comparable to the results of MRC trial group<sup>(59)</sup> (1999) and Neumayer et al<sup>(71)</sup> (2004).

Conversions to OPEN technique were required because of dense adhesions, large indirect hernia sac, loss of clarity in the field, or inadvertent pneumo-peritoneum that couldn't be controlled otherwise. Conversion rate in our study was much higher than other studies given by Subwongcharoen<sup>(68)</sup> (2002), Anderson et al<sup>(67)</sup> (2003), Lal et al<sup>(69)</sup> (2003), Lau et al<sup>(72)</sup> (2006).

#### Operative Time:

The time taken for operation was noted. The mean operative time in TEP group was 113.38 minutes, which was statistically significant (**'p' value 0.000000**) and higher when compared to the mean of 57.05 minutes in OPEN group. The minimum and maximum time in TEP group was 60 and 180 minutes; while in that of OPEN was 40 and 90 minutes respectively. (Table No:-9)

The values given above resemble those results given by Subwongcharoen<sup>(68)</sup> (2002), Bringman et al<sup>(65)</sup> (2003) and Lal et al<sup>(69)</sup> (2003), where TEP group took a longer time than OPEN group. The result of our study is not comparable with most recent studies such as those done by Vidovic et al<sup>(73)</sup> (2007) where both the TEP and OPEN group took almost similar time to complete the operation.

#### Post-operative Pain:

Post-operative pain at 6 hours was measured by Visual Analogue Scale (VAS). Patients undergoing TEP repair technique had a mean pain score of 3.16 while those undergoing OPEN technique had a pain score with a mean of 3.7 (Table No:-10). At the end of 2 weeks the pain score in TEP group had a mean of 0.911 and the OPEN group had a mean of 1.10 (Table No:-15). The difference was statistically significant at these two intervals (**'p' value 0.003175** at 6 hours post operation and **'p' value 0.0328** after 2 weeks of operation). At the end of 3 months the VAS score in TEP and OPEN group had a mean of 0.10 and 0.16 respectively. This implies that there was no significant difference at that duration (**'p' value 0.34**) (Table No:-15).

The result in our study was comparable to those given by Bringman et al<sup>(65)</sup> (2003), Anderson et al<sup>(67)</sup> (2003), Lal et al<sup>(69)</sup> (2003), Neumayer et al<sup>(71)</sup> (2004), Lau et al<sup>(72)</sup> (2006) where patients undergoing TEP repair technique had a lesser pain score than OPEN technique.

#### Post-operative complication:

All post-operative complications were routinely noted. Seroma formation, urinary retention, and wound infection were the complications found. 5 patients (14.70%) in TEP group had post-operative complications. 2 patients (5.88%) were suffered from seroma formation; 1 patient (2.94%) had urinary retention, 1 patient (2.94%) suffered from wound infection and 1 patient (2.94%) had orchitis. (Table No:-11)

In OPEN group 7 patients (20.58%) had post-operative complications. 2 patients (5.88%) had seroma formation, 2 patients (5.88%) had urinary retention, 2 patients (5.88%) suffered from wound infection and 1 patient (2.94%) had orchitis. (Table No:-11)

These two groups when compared statistically, did not show any significant difference (**'p' value 0.752**). The result of our study was comparable to those given by Schneider et al<sup>(70)</sup> (2003), Subwongcharoen<sup>(68)</sup> (2002), Bringman et al<sup>(65)</sup> (2003), Anderson et al<sup>(67)</sup> (2003) and Lal et al<sup>(69)</sup> (2003) which also shows that there was no significant difference in post-operative complication rates between TEP and OPEN group.

The percentage of seroma formation was 5.88% (2 cases) in the TEP group. One case was treated conservatively while the other required aseptic needle aspiration. The seroma formation in our study was higher in comparison to Kald et al<sup>(74)</sup> (1997) and Spitz et al<sup>(76)</sup> (2000) but slightly lower than Cohen et al<sup>(78)</sup> (1998).

Our study also differed from the study done by Vidovic et al<sup>(73)</sup> (2007) in which there was urinary retention only in TEP group but not in OPEN group.

#### Time Taken to Return to Normal Work:

The time required to return to normal daily activities was evaluated. In the TEP group the minimum time required was 10 days while the maximum was 28 days with a Mean of 16.5 days. In OPEN group the minimum time recorded was 14 days and maximum of 30 days. The Mean was 21 days. (Table No:-16)

When compared statistically it was found that there was significant difference between the two groups (**'p' value 0.000006**). In the TEP group there was significant early return to work, when compared to OPEN group.

The above result had resemblance to those given by Bringman et al<sup>(65)</sup> (2003), Anderson et al<sup>(67)</sup> (2003), Lal et al<sup>(69)</sup> (2003), Schneider et al<sup>(70)</sup> (2003), Lau et al<sup>(72)</sup> (2006), Elkund et al<sup>(78)</sup> (2009).

From the above discussion it was proven undoubtedly that laparoscopic TEP repair technique help in saving the working days.

#### Opinion About Surgery and Cosmesis:

Patients opinion about the surgery was evaluated by a 3 point scale and it was found that in TEP group 73.53% patients were 'very satisfied'

about their surgery, as compared to 55.88% patients in OPEN group. (Table No:-17)

In TEP group, 82.35% patients were 'very satisfied' about the cosmetic result of the operation as compared to 55.88% in OPEN group. The data when compared statistically there was significant difference between the two groups, stating superiority of TEP repair technique as cosmetic surgery. [**Pvalue 0.0386**] (Table No:-18)

These results were comparable to the study by Lal et al<sup>(72)</sup>(2003).

#### Recurrence:

In both the groups patients were followed up for one year to see the recurrence of hernia. No patient in OPEN group had any recurrence while 3(8.82%) patients in TEP group had recurrence in follow up. (Table No:-19)

When compared statistically it was found that there was no significant difference between the two groups (**'p' value 0.239**).

The result in our study showing recurrence of 8.82% was higher than those given by Subwongcharoen<sup>(68)</sup> (2002), Anderson et al<sup>(67)</sup> (2003), Lal et al<sup>(69)</sup> (2003), Lau et al<sup>(72)</sup> (2006), Hallen et al<sup>(77)</sup> (2008), Elkund et al<sup>(78)</sup> (2009). But recurrence rate in our study was lower than that given by Neumayer et al<sup>(71)</sup> (2004).

The intra-operative morbidity and operative time in our study can be explained by the phenomenon of **Learning Curve**. It has been shown in previous studies that the surgeons with the experience of more than 300 laparoscopic hernia repair surgeries had consistently lower operative morbidity than the surgeons with experience of less than 300 laparoscopic hernia repair surgeries. It has also been shown that significant improvement in intra-operative morbidity and decrease in operative time can be expected after the initial learning phase<sup>(79)</sup>. In our study none of the operating surgeon had experience of more than 300 cases in laparoscopic hernia repair which possibly explains the higher morbidity and longer operative time, as compared to those reported in recent literature. Also due to constraints in follow-up time period, we could not review patients in both groups for more than a year after operation. Hence true recurrence rate in laparoscopic TEP group can not possibly be compared to those reported recently in literature.

#### SUMMARY AND CONCLUSION

The present Prospective Observational Controlled Study was conducted to compare laparoscopic total extra-peritoneal (TEP) repair technique with open tension-free (Lichtenstein) repair technique for uncomplicated primary unilateral inguinal hernia, in the Department of General Surgery, Vivekananda Institute of Medical Sciences, Ramakrishna Mission Seva Pratishthan, Kolkata-26, from August 2007 to December 2008 during the period of 17 months.

The study was carried out on 68 male patients with a clinical diagnosis of inguinal hernia presenting to the Out Patient Department fulfilling both inclusion and exclusion criteria and were admitted in wards of Department of General Surgery in our institute. In each group 34 cases were included.

Pre-designed proforma was maintained to document patient particulars, history, clinical examination, relevant investigations, pre-anesthetic check-up, operative notes, intra-operative complications, post-operative and follow-up findings. All the standard General Surgical instruments and laparoscopic instruments in the operation theatre were used for study. Operations were performed by senior visiting surgeons or junior trainee surgeons under proper supervision. The operative procedures were carried out under strict asepsis. All patients were operated under general anesthesia.

The aim of our study was to study advantages and disadvantages of Laparoscopic Total Extra-peritoneal-TEP hernia repair technique and to evaluate whether it should be preferred over open tension-free (Lichtenstein) repair technique as procedure of choice in uncomplicated primary unilateral inguinal hernias.

The objectives were divided into:

- 1) Intra-operative complication rate
- 2) Operative time
- 3) Post-operative local complication rate
- 4) Post-operative pain
- 5) Time taken to return to normal work
- 6) Surgery and Cosmesis

7) Recurrence rate at one year of follow up.

- i) Numerical variables were compared between the two groups by Student's t-test and Mann-Whitney U test.
- ii) Categorical variables were compared between the groups by Chi-square test, or Fisher exact test as appropriate.
- iii) Analysis was two tailed and on an intention to treat bias.
- iv) **p' value <0.05** was regarded as statistically significant.

After complete analysis and discussion, before arriving at the conclusion following were the '**Salient Findings**' of our study:

- All the patients operated were male patients.
- The patients were in the age group of 18 to 66 years. In the TEP group the mean age was 45.35 years and in the OPEN group the mean age was 43.82 years.
- Major proportion of patients had non-heavy jobs.
- Patients presented with complaints of groin swelling with or without pain. Of the 68 patients, 54 patients had no associated pain.
- The patients were suffering from hernia from a range of 4 to 28 months. In TEP group the mean symptom duration was 12.14 months, while in OPEN group it was 14.32 months.
- Co-morbid conditions were found to be distributed similarly between the two groups.
- Indirect type is the most common type of hernia on per-operative finding.
- Intra-operative complication rates were higher in TEP group (23.52%) than in the OPEN group (17.64%) [**p' value 0.017**].
- The average time taken for operation was much higher in TEP group (mean=113.38 minutes) than in OPEN group (mean=57.05 minutes) [**p' value 0.000000**].
- Post-operative pain measured by Visual Analogue Scale (VAS) was significantly lower in TEP group than in OPEN group at 6 hours and 2 weeks of post operation (**'p' value 0.003175** at 6 hours post operation and **'p' value 0.0328** after 2 weeks of operation). No significant difference of VAS score at 3 months of operation was noted between the two groups.
- There was no significant difference in post-operative complication rates between TEP and OPEN group [**'p' value 0.752**].
- Patients undergoing TEP repair technique returned to work earlier than patients in the OPEN repair group [**'p' value 0.000006**].
- TEP repair technique had better patient satisfaction and cosmetic results as compared to OPEN repair technique [**'p' value 0.0386**].
- There was no significant difference in recurrence rates at one year between the two groups [**'p' value 0.239**]. However it will require longer follow up to find out the true recurrence rates.

#### CONCLUSION

- 1] Intra-operative complication rates are higher in laparoscopic TEP group than OPEN (Lichtenstein) group.
- 2] Laparoscopic TEP repair is lengthier procedure than OPEN (Lichtenstein) repair.
- 3] There is no significant difference in post-operative complication between the two groups.
- 4] Post-operative pain score at 6 hours and 2 weeks after surgery are significantly less in laparoscopic TEP group as compared to OPEN (Lichtenstein) group.
- 5] There is no difference in post-operative pain score between the two groups at 3 month after operation.
- 6] Patients undergoing laparoscopic TEP repair technique returned to work earlier than patients in the OPEN (Lichtenstein) repair group.
- 7] Laparoscopic total extra peritoneal (TEP) inguinal hernia repair can be recommended to those desiring better cosmetic results.
- 8] Recurrence rates are not significantly different between the two groups and require longer follow up.

Overall it can be concluded that Laparoscopic total extra-peritoneal hernia repair technique is associated with less post-operative pain, earlier return to work and better patient satisfaction and cosmetic results than Open tension-free (Lichtenstein) hernia repair technique. However, intra-operative complication rates and length of operation are more in Laparoscopic TEP hernia repair. There is no difference in post-operative complication rates and recurrence rate between the two groups.