"A ONE YEAR RANDOMIZED CONTROL STUDY TO COMPARE POST OPERATIVE PAIN IN LICHTENSTEIN TENSION FREE HERNIA REPAIR VERSUS LAPAROSCOPIC INGUINAL HERNIA REPAIR" AT A TERTIARY HOSPITAL

By

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Dissertation

Submitted to the
KLE Academy of Higher Education and Research,
Belagavi, Karnataka.

In partial fulfillment
of the requirements for the degree of

M.S.
in
GENERAL SURGERY

DEPARTMENT OF GENERAL SURGERY,
JAWAHARLAL NEHRU MEDICAL COLLEGE,
BELAGAVI, KARNATAKA.

APRIL - 2020

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH, BELAGAVI, KARNATAKA

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Sub: Acceptance Letter

Sir/Madam,

The softcopy of thesis entitled "A ONE YEAR RANDOMIZED CONTROL STUDY TO COMPARE POST-OPERATIVE PAIN IN LICHTENSTEIN TENSION FREE HERNIA REPAIR VERSUS LAPAROSCOPIC INGUINAL HERNIA REPAIR – AT A TERTIARY HOSPITAL" has been submitted for Anti-Plagiarism check through Turnitin software. The scan has been carried out and the scanned output reveals a match percentage of 5% (Five percentage) which is within the acceptable limits of 10% as per the guidelines given by UGC.

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LIST OF ABBREVIATIONS

ASIS	:	Anterior Superior Iliac Spine
cm	:	Centimeter
EOA	:	External Oblique Aponeurosis
TAPP	:	Trans Abdominal Pre Peritoneal
TEP	:	Totally Extra Peritoneal
IPOM	:	Intra Peritoneal Onlay Mesh
Mm	:	Millimetre
TLC.	:	Total leucocyte count
CXR	:	Chest X-Ray
ECG	:	Electrocardiogram
USG	:	Ultrasonography
Kg	:	Kilogram
P	:	Probability
mg	:	Milligram
min	:	Minute
mmHg	:	Millimetre of mercury
VAS	:	Visual analogue scale

GRS	:	Graphic Rating Scale
POD	:	Post operative day
DOD	:	Day of Discharge
ASA	:	American Society of Anaesthesiologists
LTHR	:	Lichtenstein tension free hernia repair
LHR	:	Laparoscopic hernia repair

ABSTRACT

"A ONE YEAR RANDOMIZED CONTROL STUDY TO COMPARE POST OPERATIVE PAIN IN LICHTENSTEIN TENSION FREE HERNIA REPAIR VERSUS LAPAROSCOPIC INGUINAL HERNIA REPAIR" AT A TERTIARY HOSPITAL.

BACKGROUND AND OBJECTIVES --

Inguinal hernia is a common disease condition requiring surgical procedure. Many techniques have evolved over past few decades from herniorraphy to the present day hernioplasty which is done both in open and in laparoscopic methods either TAPP or TEP. Many cases of recurrences of inguinal hernia were reported with the conventional hernioplasty. Hence newer concept of tension free meshplasty came into action. The present study is aimed to compare the post-operative pain scores between Lichtenstein tension free repair versus laparoscopic repair of inguinal hernias in patients along with evaluation of postoperative complications, hospital stay and time to return to normal activities.

MATERIALS AND METHODS –

A one year randomized control trial was done between January 2018 and December 2018. Patients who had inguinal hernia, satisfying the inclusion criteria and willing to participate in the study were included in this study. Group A had 20 patients who underwent Lichtenstein tension free hernia repair and Group B had 20 patients who underwent laparoscopic inguinal hernia repair. Pain scores in both groups was calculated with visual analogue scale at different time intervals. Also hospital stay in

number of days, time to resume normal activities post surgery and post operative complications were recorded if any and assessment done.

RESULTS –

In our study we found that the VAS score was less in laparoscopic group when compared to open group measured at 24 hrs, 72 hrs and 1 week post surgery and it was showing a significant difference ($p<0.0001$) between the groups. There was also a significant difference found in median of time that is required for normal activity and it was significantly more in open surgery group as compared to laparoscopic group ($p<0.0001$). The median of hospital stay in open group is significantly more (4.35 ± 1.81) than laparoscopic group (2.8 ± 0.89). Even the complications were found more in open group (10%) than in laparoscopic group (5%).

INTERPRETATION AND CONCLUSION –

Apart from the complications, which were found to be similar, laparoscopic hernia repair was found to be more suitable, safe and efficient in all the above mentioned aspects except when there is contraindication for general anesthesia. However, the data is insufficient to conclude which surgery is better overall, as long-term follow up and large population sample are required to evaluate for chronic pain, recurrence and learning curve in laparoscopic hernia repair.

KEYWORDS: Inguinal hernia, Lichtenstein repair, Laparoscopic hernia repair, post operative pain.

CONTENTS

LIST OF TABLES

LIST OF GRAPHS

LIST OF FIGURES

INTRODUCTION

Inguinal hernia continues to be the most common elective surgical condition presenting to the outpatient department, since then many changes in the treatment have taken place. Over past few years various techniques have evolved in the repair of inguinal hernia treatment from just observation to open surgery and advanced laparoscopic surgery and the present day robotic surgery. No single procedure is ideal and each of it have its own advantages and disadvantages over others. However evidence based medicine is the most scientific way to conclude the superiority of one technique over another. In our hospital the most widely performed surgeries are for inguinal hernias and cholelithiasis. Till date laparoscopic inguinal hernia repair is not widely accepted in surgical community as compared to laparoscopic cholecystectomy which is the gold standard of cholelithiasis.

Inguinal hernia is defined as a "Abnormal Protrusion of a viscus or part of the viscus through a defect in the walls of the cavity containing it in the inguinal canal".[1] Inguinal hernias are diagnosed clinically and can be either congenital or acquired. Etiology can be due to factors causing the weakness of anterior abdominal wall due to raised intra abdominal pressure. Other factors includes smoking, chronic cough, previous surgical scars can lead to laxity of abdominal wall which in turn leads to inguinal hernia.[2]

Usually patients can present with swelling in inguinal region or pain. The swelling can be either asymptomatic or symptomatic. If symptomatic, the symptoms may be either minimal (discomfort/pain) or interfere with their daily activities. Further some patients may also present with strangulation where the contents cannot be reduced back and further leads to obstruction if left untreated and requires emergency surgery.[3]

Postoperative pain is important factor in the determination of post operative convalescence after inguinal hernia repair, in that matter any surgery. Many studies have proved the inflammatory reaction and scar formation caused due to the placement of mesh is responsible for high chances of post-operative pain in open inguinal hernia repair[4]. The laparoscopic repair is gaining popularity in recent years due to its potential benefit of less convalescence period and post operative pain than with the open repair group.[5,6]Convalescence is defined as the number of days away from work or main activity post-surgery.[7] However there are many controversies in the repair of inguinal hernias using laparoscopic methods which include debate about the ideal indications for the use of laparoscopic approach and also debate regarding options for mesh fixation which can be usage of glue, tacks, suture fixation or no fixation at all in the view of chronic pain and recurrences.[8]

A study conducted by Prasad et al compared the incidence of post-operative complications between open repair versus laparoscopic repair and concluded that the post-operative pain and mean duration of hospital stay was less in laparoscopic group.[9] Similar study was done by Palanivelu to measure duration of hospital stay in Laparoscopic inguinal hernia patients.[10] Some studies were conducted to compare chronic pain following surgery and study conducted by Kumar S, et al compared the operative time between open and laparoscopic hernia repair.[11]

However, very few studies are conducted in this part of country on laparoscopic inguinal hernias and our study was one of the first of its kind in this region and intended to evaluate and compare post-operative morbidity between Lichtenstein tension free hernia repair and laparoscopic repair of inguinal hernias in patients at a tertiary care hospital.

OBJECTIVES

Primary objective:

The primary objective is to compare post-operative pain among Lichtenstein tension free hernia repair versus Laparoscopic inguinal hernia repair.

Secondary objectives:

1. Hospital stay in number of days,

2. Time to return to normal activities which is defined as "the time taken to achieve the same level of activity post operatively of which they were capable preoperatively, which may include minor discomfort and the use of simple oral analgesics".[7]

3. Post-operative complications like seroma, urinary retention, wound infection.

REVIEW OF LITERATURE

It is well established fact that the most common elective surgical procedures are the inguinal hernia repairs. With the use of newer prosthetic materials and detailed anatomy the surgical techniques have been improved with better outcomes.

Approximately 30 % of them presents asymptomatically, of which around half of them are unaware of having inguinal hernia.[12]

Different types of inguinal hernias are

1. **Indirect hernia**: sac is lateral to inferior epigastric vessels and hernia passes through the deep inguinal ring.
2. **Direct hernia**: it occurs most commonly in elderly people due to defect in posterior wall of inguinal canal and swelling arises medial to epigastric vessels.
3. **Pantaloon's hernia**: patient having both direct and indirect hernia on the same side is Pantaloon's hernia, also known as Saddle hernia or Romberg hernia. One sac will be medial and other sac is lateral to the epigastric vessels.

ANATOMY[13]

The inguinal area of the human abdomen is bounded inferiorly by thigh, medially by pubic tubercle and superolaterally by anterior superior iliac spine (ASIS). The inguinal canal lies obliquely with in this area connecting intraperitoneally with the scrotum. It lies between the deep inguinal ring and the superficial inguinal ring. The inguinal rings in infants are thought to overlie, which separates in superolateral and inferomedial direction in adults. The length of inguinal canal is around 4-5 cm in an average adult and directed downwards, forwards and medially.

Transversalis fascia condenses to form deep inguinal ring which is half an inch above the midpoint of inguinal ligament, that is between ASIS and pubic tubercle. It is oval in shape and marked as an entry into inguinal canal.

The superficial inguinal ring also known as external ring which is a triangular shaped opening in the external oblique aponeurosis (EOA) which lies one cm superior and lateral to pubic tubercle. It is considered as the exit of the canal.

The inguinal region is formed from outside to inside by:

1. Skin.
2. Superficial fasciae - Camper's layer.
3. Scarpa's fascia.
4. External oblique aponeurosis.
5. Spermatic cord in males and round ligament in females.
6. Internal oblique and conjoined tendon.
7. Fascia transversalis and transversus abdominis muscle.
8. Preperitoneal pad of fat.
9. Peritoneum.

The inguinal canal boundaries:

• **Anteriorly** - formed by skin, superficial fascia and EOA in its whole extent and internal oblique in lateral one third.

• **Posteriorly** - formed by conjoint tendon medially and transversalis abdominis muscle laterally.

• **Superiorly (Roof)** - internal oblique and transversus abdominis muscle fibers arches to form roof of inguinal canal.

• **Inferiorly (Floor)** – inguinal ligament and medially by lacunar ligament. Lateral third by iliopubic tract forms the floor of inguinal canal.

The structures which pass through the inguinal canal are:

Spermatic cord in males and round ligament in females

Vas deferens and its artery

Testicular artery

Cremasteric artery

Pampiniform plexus of veins

Genital branch of genitofemoral nerve

Ilioinguinal nerve

The ilioinguinal nerve is a branch of first lumbar nerve which enters the inguinal canal by piercing internal oblique muscle and travels along the spermatic cord in males and round ligament in females through the superficial ring. It gives innervations to root of penis and upper part of scrotum. Injury to this nerve should be prevented in open repairs as it is the cause for inguinodynia.

In 1814 Hesselbach described a triangle which is formed laterally by inferior epigastric vessels, inferiorly by inguinal ligament and medially by the lateral border of rectus muscle. Its clinical significance is that direct hernias occurs through this triangle.[13]

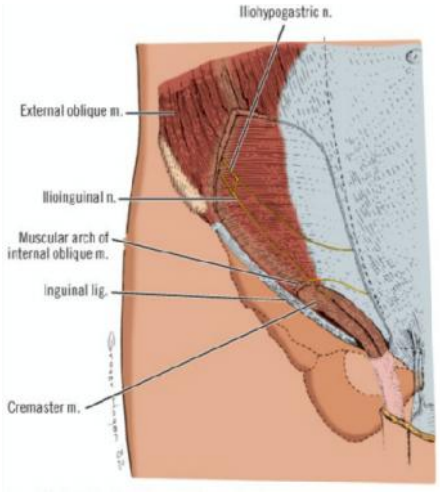


Figure 1: inguinal region showing ilioinguinal and iliohypogastric nerves[13]

Laparoscopic anatomy:

In Trans abdominal pre peritoneal (TAPP) repair, the first thing to be identified are the peritoneal folds or ligaments. They are

1. Median umbilical ligament which is an obliterated urachus.

2. Two medial umbilical ligaments also known as obliterated umbilical artery. These ligaments forms the important landmark for the laparoscopic inguinal hernia repair.

3. Two lateral umbilical ligaments which contains the inferior epigastric artery. This structure forms the lateral boundary of the Hesselbach's triangle and is used to differentiate direct and indirect hernias. Defect medial to this is direct hernia and defect lateral to this is indirect inguinal hernia.

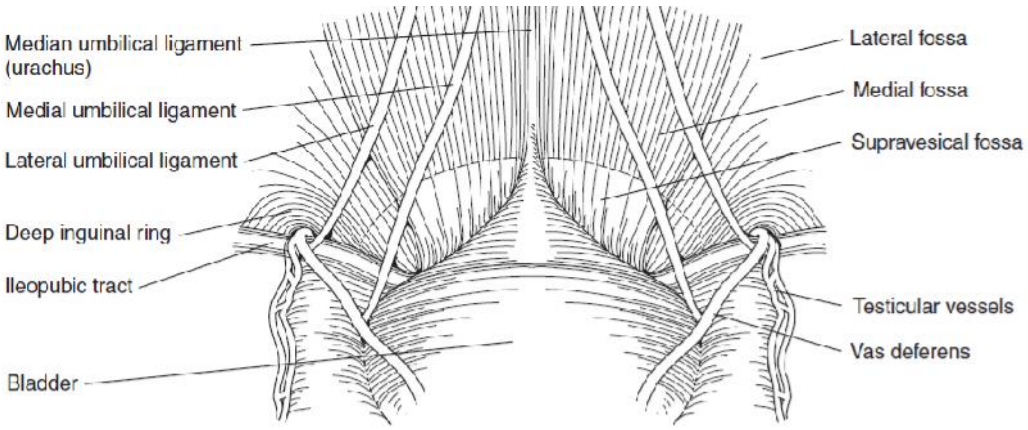


Figure 2: Laparoscopic view of inguinal region and ligaments

Important landmarks in Totally extraperitoneal repair (TEP) include musculo-aponeurotic layers of abdomen, iliopubic tract, bladder and cooper's ligament. The space first entered in TEP repair is Retzius's space which is between pubic symphysis and urinary bladder. On either side is space of Bogros which is extraperitoneal space situated deep to inguinal ligament between peritoneum and fascia transversalis and laterally by iliac fascia. During laparoscopic inguinal hernia repair, these spaces are identified and dissection done to fix the mesh flat.[14]

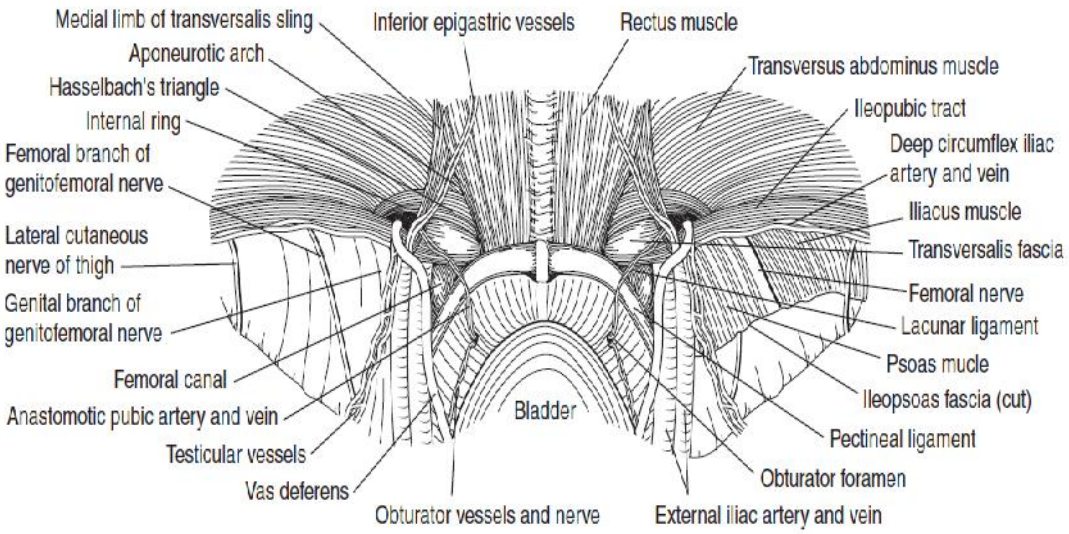


Figure 3: The pre peritoneal pelvic anatomy

TRIANGLE OF DOOM:

It is important landmark in TAPP repairs and formed medially by vas deferens, laterally by spermatic vessels and inferiorly by the peritoneal fold and contains external iliac vessels, genital branch of genitofemoral nerve and deep circumflex iliac vein. Staplers or tackers should be avoided in this triangle due to high chances of vessels getting injured leading to high chances of bleeding and mortality.

TRIANGLE OF PAIN:

It is seen during laparoscopic hernia repair and is bounded medially by gonadal vessels, laterally by iliopubic tract and inferiorly formed by the edge of the skin. Femoral branch of genitofemoral nerve and lateral femoral cutaneous nerve passes through this triangle which should be avoided during stapling causing nerve entrapment and neuralgia.

CIRCLE OF DEATH:

Also known as corona mortis which means crown of death in Latin. It is a vascular connection formed by the anastomosis of obturator artery from the internal

iliac artery with the aberrant artery arising from the branch of external iliac artery. This may be torn during laparoscopic repair which leads to profuse bleeding and death.

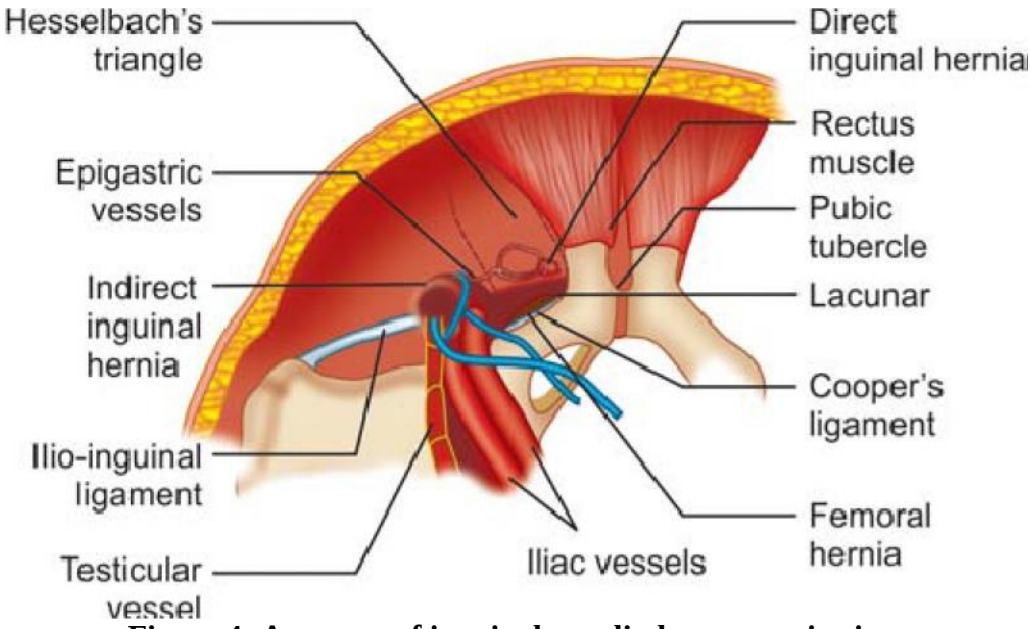


Figure 4: Anatomy of inguinal canalin laparoscopic view

These are some important anatomical landmarks should be identified during laparoscopic inguinal hernia repair.

HISTORY OF HERNIA REPAIR

With the works of Bassini the modern era of surgery for inguinal hernia began. He proposed the correct procedure is to dissect in layers from skin to preperitoneal space and all the structures like vessels, nerves and cord structures to be identified, preserved and then reconstruction of posterior wall of inguinal canal is done. Then the four layers of muscle sutured to external oblique and inguinal ligament and closure had done after placing cord back to normal position. Thus he created the obliquity of canal. The results found were excellent compared to surgeries performed by others during his time. He followed up to 90% of his patients and stated his failure rate to be

less than 3%.[15] However both short and long term results showed failure and recurrences due to tension in the tissues.

The works on Bassini's inguinal hernia repair has been reintroduced by a Canadian surgeon named Shouldice, who under local anaesthesia dissected inguinal hernia and opened posterior wall and then reconstructed using stainless steel wire in continuous manner. The results of these surgeries were found impressive.[16]Shouldice techniques using local anaesthesia lead to early mobilization of the patients. Other significant works on posterior repair of inguinal hernia are done by Rives and Stoppa from France, also Nyhus and Condon from USA.

Initially the mesh usage was not for routine inguinal hernia repairs and had been used only for complicated cases that are recurrent hernias. In 1984 mesh was used in less than 5% of hernia repairs, reached to about 10% by 1987 and by 1989 it reached about 15%. At 1991 meeting and 1993 meetings, mesh has gained acceptance for almost all hernia repairs both open and laparoscopic. In developing countries the use of mesh was slow for both open and laparoscopic repairs.[17] In France Stoppa used polyester and Rives used nylon type of mesh for preperitoneal inguinal hernia repairs and has been popular by the name of ***"Giant Prosthetic Reinforcement of the Visceral Sac* (*GPRVS*)"**.[18] However it was mainly used to repair bilateral recurrent inguinal hernias and giant scrotal hernias.

"Lichtenstein's tension free hernia repair" became popular with the works done by Lichtenstein of California with the use of marlex mesh in the repair of inguinal hernia. He did this procedure initially under local anaesthesia by approximating conjoined tendon to reflected part of inguinal ligament and then placing a mesh over this and then fixed it.[19] Lichtenstein deserves the credit for

popularizing the term "tension-free" concept that is now used in all aspects of inguinal hernia repairs.

Era of minimal access surgery:

There has been development of laparoscopic inguinal hernia repairs since the past two decades. Ger repaired indirect inguinal hernia laparoscopically in 1982.

Among the laparoscopic repairs are the following:

- **IPOM** – IntraPeritoneal Onlay Mesh, described by Filipi in 1992. The mesh is placed intraperitoneally covering the hernial orifice with a minimal dissection.[20]

- TAPP – Trans Abdominal Pre Peritoneal repair was first described by Arregui in 1991. Here mesh is placed preperitoneally, covering the inguinal and femoral hernial orifices via a transabdominal approach.[21]

- **TEP** – Totally Extra Peritoneal repair, in 1993 described independently by two surgeons, McKernan and Phillips. The mesh is placed preperitoneally as in TAPP, but without entering the abdominal cavity.[22]

Ger, Shultz, Corbitt, and Filipi et al had first described the technique of laparoscopic inguinal herniorraphy. Because of the high cost, need for general anaesthesia, steep learning curve, the use of laparoscopic inguinal hernia by many surgeons is in debate.[23]

A study conducted by Myers et al compared the same and concluded that there was a significant difference between the laparoscopic and open repair in terms of physical function, physical role, bodily pain and general health.[24]

A study conducted by Brunt LM et al revealed that laparoscopic repair can be performed efficiently and without major complications compared to open repair even when the learning curve is included.[25]

A study conducted by Ielpo B et al compared post operative pain, chronic pain and quality of life between laparoscopic and open repair and concluded that laparoscopic repair was effective in reducing the aforesaid complications.[26]

A study conducted by Elma A. O'Reillyet al proved that for unilateral inguinal hernia, TEP is associated with an increased risk of recurrence relative to open repair but not TAPP. And also TAPP is associated with increased risk of operative complications compared to open repair.[27]

LICHTENSTEIN TENSION FREE HERNIOPLASTY

After giving spinal anaesthesia, the incision of around 5-6 cm is taken over the inguinal region half inch above the mid inguinal point obliquely providing exposure from the deep ring to pubic tubercle. The subcutaneous tissues are separated using electric cautery source. The external oblique aponeurosis (EOA) is identified and incised till the superficial ring over the inguinal floor. The upper and lower leaves of EOA are separated using blunt dissection from the internal oblique to visualize the inguinal canal to place a mesh. Important nerves coming in this region are ilioinguinal and iliohypogastric nerves, identified and preserved to prevent chronic post operative pain caused by its entrapment or injury. A cord holding ring is placed around the lifted spermatic cord and retracted using this.

The cremasteric box is opened and cord structures identified and carefully looked for the indirect hernia sac and should be separated away from cord structures

till the preperitoneal pad of fat. The sac is then opened and held with mosquito forceps and contents to be reduced. Then transfixation and ligation of sac using absorbable suture is done and excess sac is transected and removed. In the case of a huge hernias extending till the scrotum, the proximal part of sac is transfixed, ligated and removed and distal part is left to prevent hydrocele formation. If direct hernia is seen with a large sac, it should be inverted and strengthening of posterior layer is done using monofilament non absorbable suture material and then mesh is placed over it. A 6 X 11 cm sized polypropylene mesh is fashioned by placing slit in the lateral third to accommodate cord. The first bite taken to pubic tubercle and mesh fixed using nonabsorbable monofilament suture both medially and laterally. Medially the mesh is sutured over to the conjoined tendon and laterally over to the reflected part of inguinal ligament in intermittent fashion. Then at this point the tails created using the slit over the mesh are passed around the cord and sutured creating the new internal inguinal ring. Care should be taken to prevent entrapment of genital branch of genitofemoral nerve and ilioinguinal nerve while fixing mesh. These sutures should proceed superiorly till the internal inguinal ring. Care must be taken to avoid injury to the iliohypogastric nerve which runs a sub-aponeurotic course. Then hemostasis achieved and closure of EOA done using absorbable suture in continuous fashion forming new external inguinal ring and then subcutaneous layer and skin closure done.[28] This tension free principle makes the Lichtenstein hernia repair better than other tissue repairs in inguinal hernia described earlier. This technique had been progressed over last few years and has best effects in view of easy learning curve and low cost. This technique compares homogeneously to other hernia repair in view of recurrence, less pain and fewer complications. Thus the Lichtenstein tension free hernia repair is

considered the procedure of choice for repair of primary, unilateral inguinal hernias and in patients contraindicated for the general anaesthesia.

TAPP (TRANS ABDOMINAL PRE PERITONEAL REPAIR)

The patient is positioned supine on the operating table with both arms tucked. Foley catheter inserted after induction of anaesthesia. The parts painted and draped. Pneumoperitoneum achieved using verres needle. The intraabdominal pressure of 14-16 mmHg is achieved and then table is tilted to trendelenberg position for better visualization of inguinal region. Then 10 mm umbilical port inserted and a 30° 10 mm scope is placed and inguinal region inspected bilaterally for the presence of hernias. Two additional 5 mm ports placed under direct vision at the level of the umbilicus in bilateral midclavicular lines. Anatomical landmarks like median, medial umbilical ligaments, inferior epigastric vessels and bladder are noted. Using a hook with monopolar cautery and grasper, a generous peritoneal opening made from the medial umbilical fold out laterally towards ASIS. The dissection carried out laterally to raise inferior peritoneal flap and sufficient working space created by mobilizing the peritoneum off from preperitoneal pad off fat using both blunt and sharp dissection. Using grasper the peritoneum is grasped and retracted towards the contralateral side and by using maryland dissecting forceps the preperitoneal fat is separated from the underlying peritoneum. The prime structures of importance to be seen are gonadal vessels in males and round ligaments in females. Vas deferens will be seen lateral to the gonadal vessels. The hernia sac is identified and to be skeletonised from the cord and ligated. Peritoneal flap is raised sufficiently in the inferior side till the divergence of vas and internal spermatic vessels so that the prosthesis will not be folded once the peritoneum is closed. Prolene mesh of size 15 x 11 cms is folded and inserted to

peritoneal cavity through umbilical cannula and is placed to cover myopectineal orifice to include direct, indirect and femoral rings. The mesh was anchored using either sutures or tacks superiorly away from epigastric vessels, then to cooper's ligament and pubic tubercle. Inferior margin no tacks was placed to avoid nerve injury. Peritoneum closed either with suture or tacks. Hemostasis achieved and gas deflated. Skin closed and patient is reversed from general anaesthesia.[28]

TOTALLY EXTRAPERITONEAL REPAIR (TEP):

Here dissection and placement of prosthesis is carried without entering peritoneal cavity. TEP is relatively difficult with around 60 procedures learning curve.[29, 30] Here the patient is placed in supine position and after induction with general anaesthesia, parts painted and draped. 10mm umbilical incision taken and subcutaneously separated and rectus sheath is incised and rectus muscle pushed laterally. Umbilical port is inserted and working space is created and preperitoneal space is filled with gas under direct vision of 10 mm laparoscope. Other two 5mm ports inserted one in midline 5cm above symphysis pubis and other port midway between the umbilicus and pubic symphysis. The intra operative complications like breach in the peritoneum which creates pneumoperitoneum and dissection of rectus muscle fibers leading to hemorrhage can occur. Then the prolene mesh of size 15 x 10 cm is placed through the umbilical port and covered over the myopectineal orifice and hemostasis is achieved. Under direct vision the gas is deflated from the preperitoneal space and looked for the flat placement of mesh. The ports are removed and closure done as described above.[28]

COMPLICATIONS OF HERNIA SURGERY:

1. **Seroma:** "Collection of serous fluid in the wound after the surgery". Commonly seen after repair of large indirect hernias with extensive dissection of cord structures. Most of them resolve spontaneously. It can be of clinical seroma, minor complication and major complication.

Clinical seroma: defined as "Those seromas which are detected during physical examination of patients and not causing any problem, or just a minimum discomfort that allows normal activity".

Minor complication: defined as "Associated with discomfort and does not allow normal activity to the patient, pain, superficial infection like cellulitis, or seroma lasting for more than 6 months".

Major complication: defined as "Infection, mesh rejection, recurrence or need to be punctured".

2. **Urinary retention:** This is seen frequently in elderly patients and those with symptoms of prostatism. This can be prevented usually by catheterising patients before surgery and removing one day after surgery.

3. **Neuralgias:** Pain occurring due to entrapment of nerve either due to mesh induced fibrosis or by tacks. Commonly involved nerves being genital branch of genitofemoral nerve and lateral cutaneous nerve of thigh.

4. **Mesh infection:** Very serious complication. So proper aseptic precautions must be taken while handling mesh and avoiding unhygenic practices.

5. **Hematoma:** Excessive handling of cord structures to be prevented and proper hemostasis to be achieved before closure.

6. Injury to vas: Correct identification of the vas deferens from the cord structures and proper handling to be done.

7. Wound infection: ranges from minimal pus discharge to extended hospital stay requiring intravenous antibiotics.

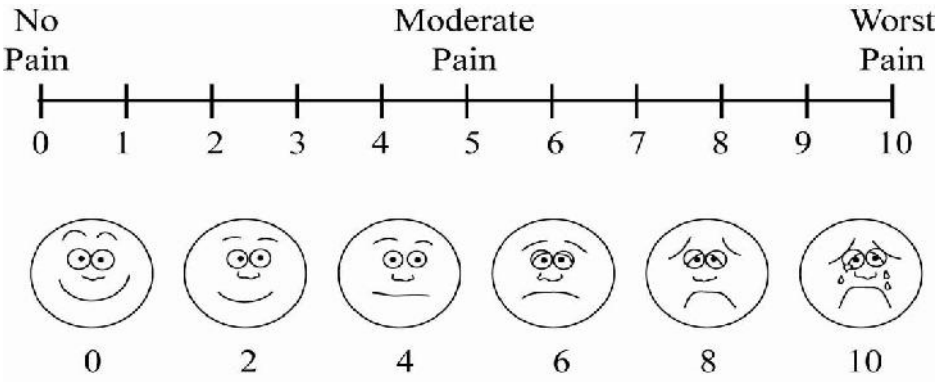
POST OPERATIVE PAIN:

Pathophysiology of post operative pain in inguinal hernia repair:

- This includes many factors such as either partial or complete transaction of nerves resulting in neuroma formation. Also mesh has been considered as the cause for pain due to nerve entrapment due to edema and fibrosis. Also excessive handling of operative area due to chronic and large inguinoscrotal hernias increases pain in the post operative region in the open hernia surgeries.
- The pathophysiology in the causation of post operative pain in the laparoscopic inguinal hernia repair are mainly due to extensive pre peritoneal dissection, placement of staples or tacks in the area of triangle of pain causing injury to nerves.

Visual Analogues Scale (VAS)

The visual analogue scale (VAS) is commonly used for measuring the intensity of pain in post operative patients. It is a 10 points horizontal line by which the patient's pain intensity is represented by a point between 0 to 10 that is "no pain at all" and "worst pain imaginable." It's very simple, reliable and easy for the patients to express their pain severity. When the descriptions like 'mild', 'moderate', 'severe' are added to the VAS, it is called as Graphic Rating Scale (GRS).[29]



Visual Analogue Scale

METHODOLOGY

This study was conducted among patients admitted for elective inguinal hernia repair in the department of general surgery at K.L.E.S Dr. PK Hospital and MRC, Belagavi during time period of January to December 2018.

Study design

It is a Randomized Controlled Trial (RCT).

Place

This study was done in the Department of General Surgery, K.L.E.S Dr. PK Hospital and MRC, Belagavi a tertiary care hospital attached to Jawaharlal Nehru Medical College (JNMC), Belagavi.

Sample size:

Calculated from the formula

$$n = \frac{2(Z\alpha+Z\beta)^2 S^2 = 20}{(x_1-x_2)^2}$$

Where, n= sample size

$Z\alpha = 1.96$

$Z\beta = 0.84$

S= standard deviation

x_1-x_2=effect size

As per the calculation sample size was 20 in each group.

Group A- 20 (Patients who are undergoing Lichtenstein tension free hernia repair)

Group B- 20 (Patients who are undergoing laparoscopic inguinal hernia repair)

Sampling method:

Every patient who fulfills the inclusion criteria will be included and the computer generated random table method will be used to assign patients to each group.

Selection criteria:

Inclusion criteria:

Patients aged above 12 years of age.

Patients with uncomplicated inguinal hernias.

ASA I, II categories.

Unilateral/bilateral inguinal hernias.

Exclusion criteria:

Patients with bleeding diathesis.

ASA III, IV, V categories.

with complicated inguinal hernias.

Uncooperative and unwilling patients.

Ethical clearance

The Ethical Clearance from the Institutional Ethics Committee, JNMC, Belagavi was obtained prior to the commencement.

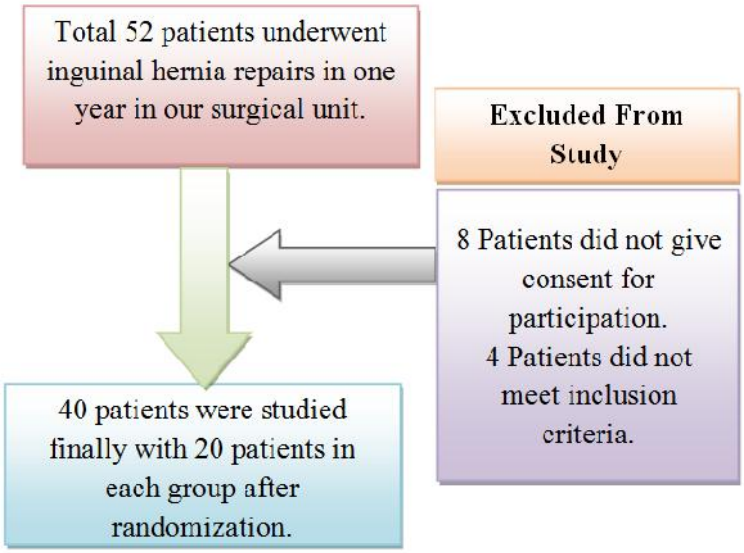
Informed Consent (Annexure I)

Those patients who fulfilled selection criteria were explained about the nature of study and the procedures. The patients who were not willing for the study and control groups were excluded.

Method of collection of data

Patients presenting with inguinal hernia and willing to participate in the study were included and data about the patients were tabulated. Clinical examination done and investigations were sent and noted in the proforma and consent taken. (Annexure III).

Randomization



Patients who were undergoing surgery for inguinal hernia were enrolled for this study and patients who were not willing for the study were excluded. Total of 52 patients underwent inguinal hernia repairs but 4of them did not meet the inclusion criteria and 8 patients did not give consent. Total of 40 cases were included. Patients were randomized and assigned to either of the two groups as below.

Group A (Lichtenstein tension free hernia repair patients): 20 patients

Group B (Laparoscopic inguinal hernia repair patients): 20 patients

All the surgeries in both groups were done by a single operating surgeon in a single surgical unit.

Operative procedure:

- **Lichtenstein tension free hernia repair:** Under spinal anesthesia the inguinal canal is opened after opening EOA and ilioinguinal nerve identified and retracted. Cord is lifted by using blunt dissection and hernia sac is identified and separated from the cord structures till preperitoneal pad of fat. For indirect hernia sac opened and contents reduced, transfixation and ligation of sac done using 2-0 vicryl and for direct hernia herniorraphy with mesh repair was done. Using aseptic

precautions a 6 x 11 cmsprolene mesh is placed after making slit in the lateral third to place cord. Mesh is fixed using prolene suture in intermittent fashion starting with first bite on pubic tubercle and laterally to reflected part of inguinal ligament carefully. Lateral and medial slit is overlapped below the spermatic cord and suture placed. Medially mesh fixed to conjoined tendon. Hemostasis achieved and EOA is closed in continuous fashion with vicryl forming a new external ring and leaving behind the ilioinguinal nerve. Skin closed in subcuticular fashion.

Figure 5: opening external oblique aponeurosis

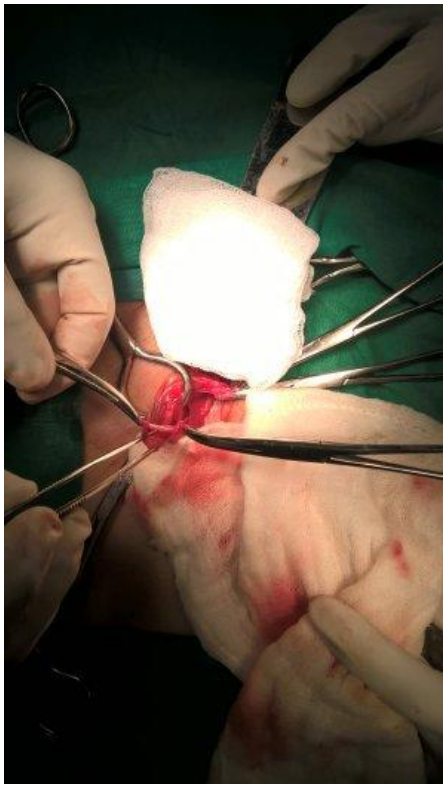


Figure 6: separating indirect sac from the cord

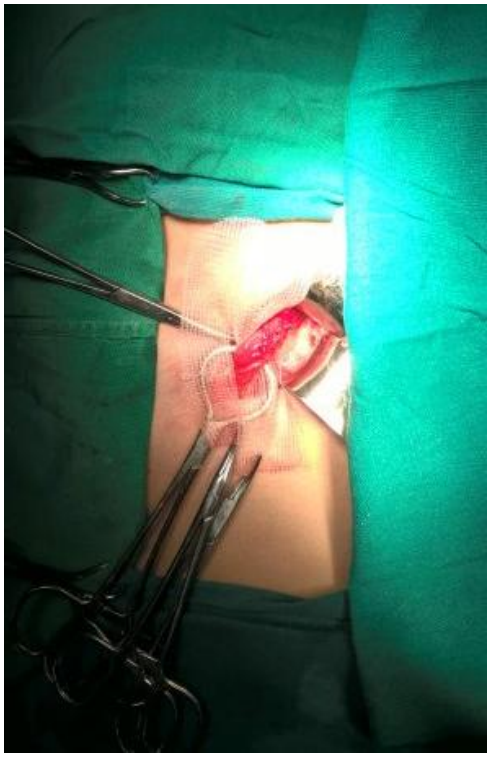


Figure 7: placing prolene mesh 6 x 11 cm size

Figure 8: fixing the mesh with prolene sutures

Laparoscopic inguinal hernia repair:

- **Trans abdominal pre peritoneal repair (TAPP):** Under general anesthesia and patient in supine position pneumoperitoneum created using verres needle and one 10 mm umbilical port and two 5 mm working ports placed lateral to umbilical port (midclavicular line). Bilateral inguinal regions noted for hernias. Transverse peritoneal incision made from medial umbilical ligament to ASIS. Then a preperitoneal plane is created using both sharp and blunt dissection, the cord structures are separated from hernial sac and sac ligated. Sufficient space created by raising peritoneum to place 15 x 10 cm polypropylene mesh. The mesh is properly spread flat without folds and the peritoneal flaps are closed using vicryl suture in continuous fashion..Hemostasis achieved and pneumoperitoneum deflated and ports are removed under vision and skin closed.

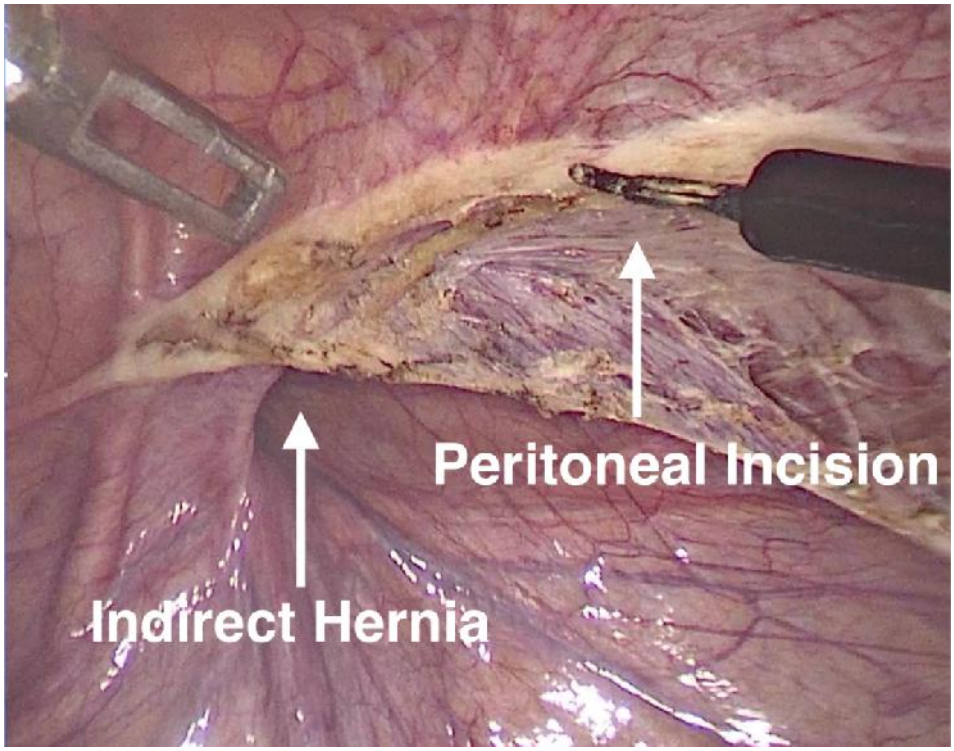


Figure 9: Incision of peritoneum from medial umbilical fold to ASIS

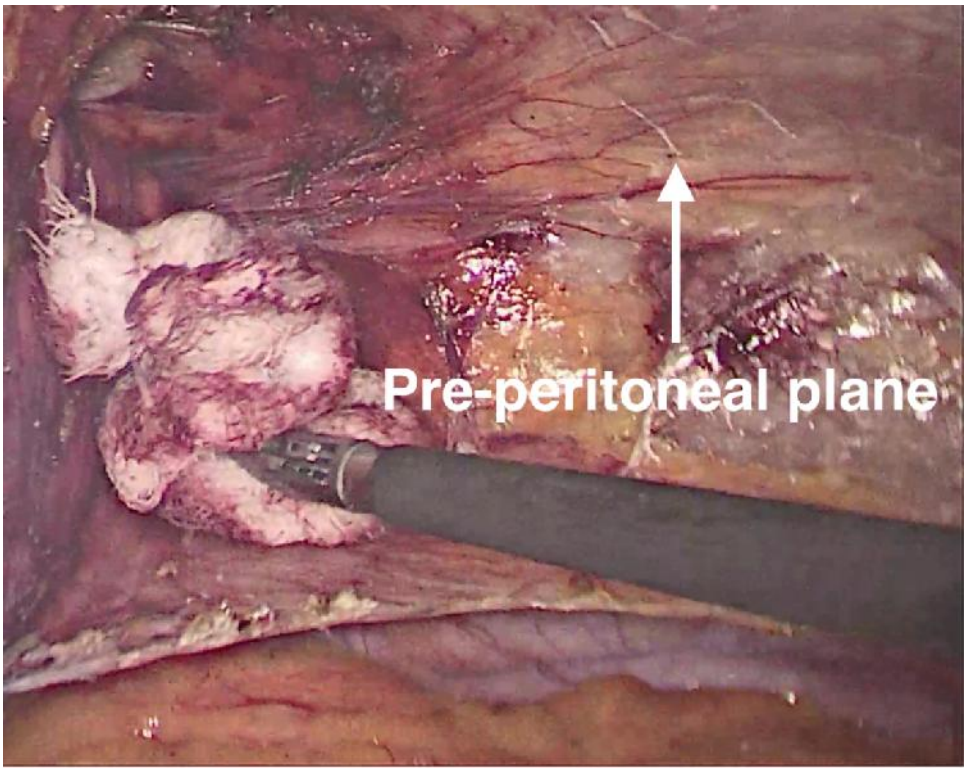


Figure 10: creating a pre peritoneal plane

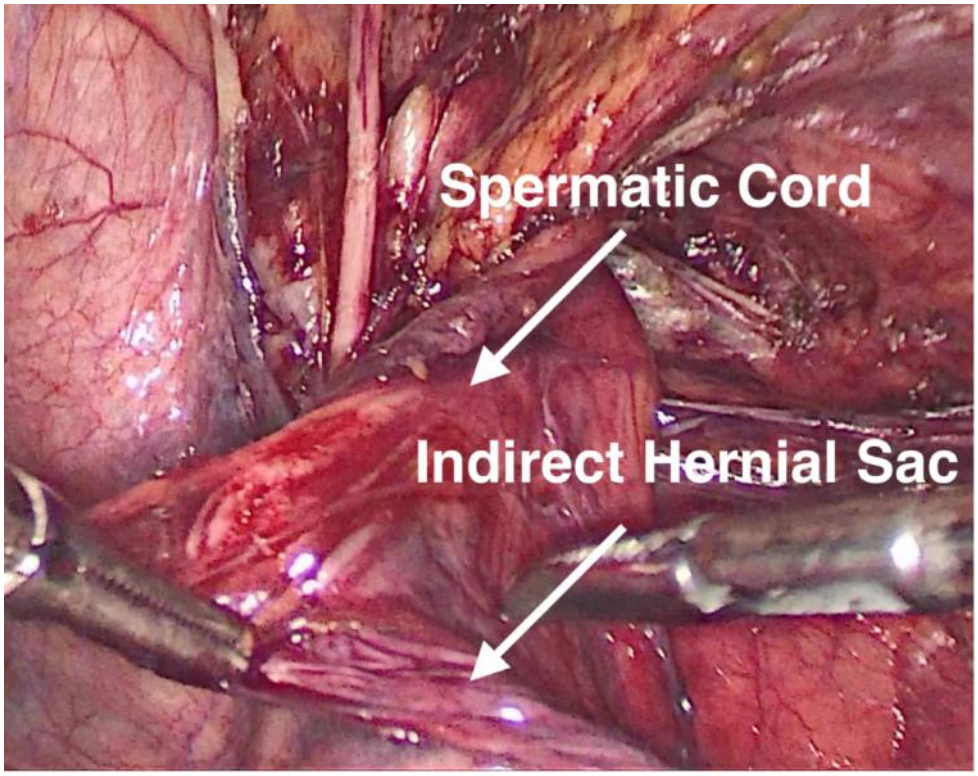


Figure 11: separating cord structures from hernia sac

Figure 12: ligating the hernia sac

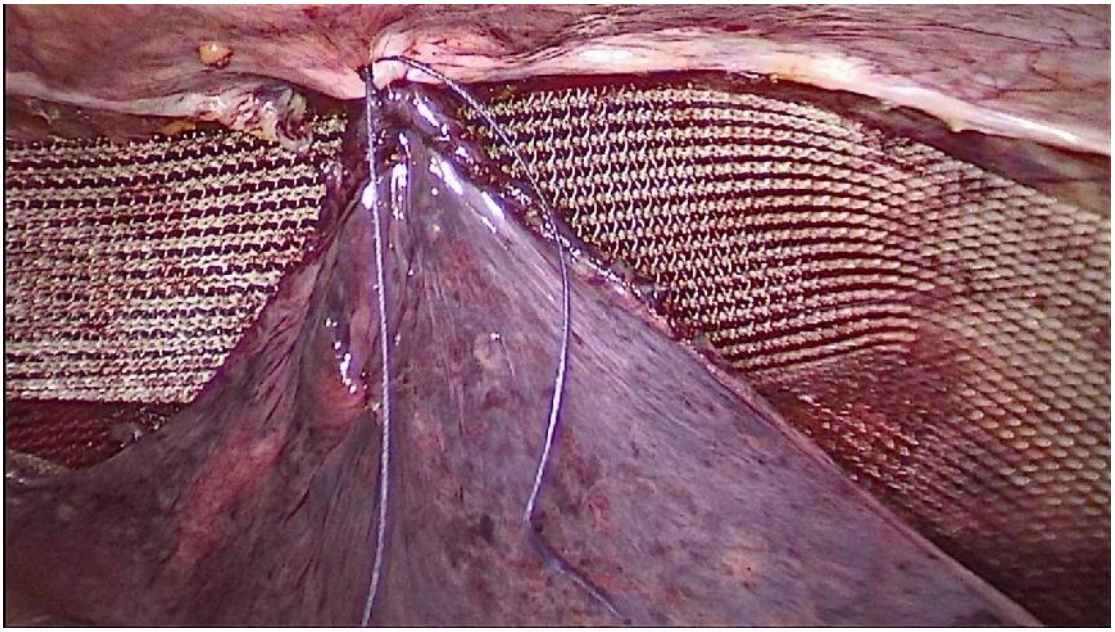


Figure 13: placing a 15 x 10 cm polypropylene mesh without folds in the pre peritoneal space

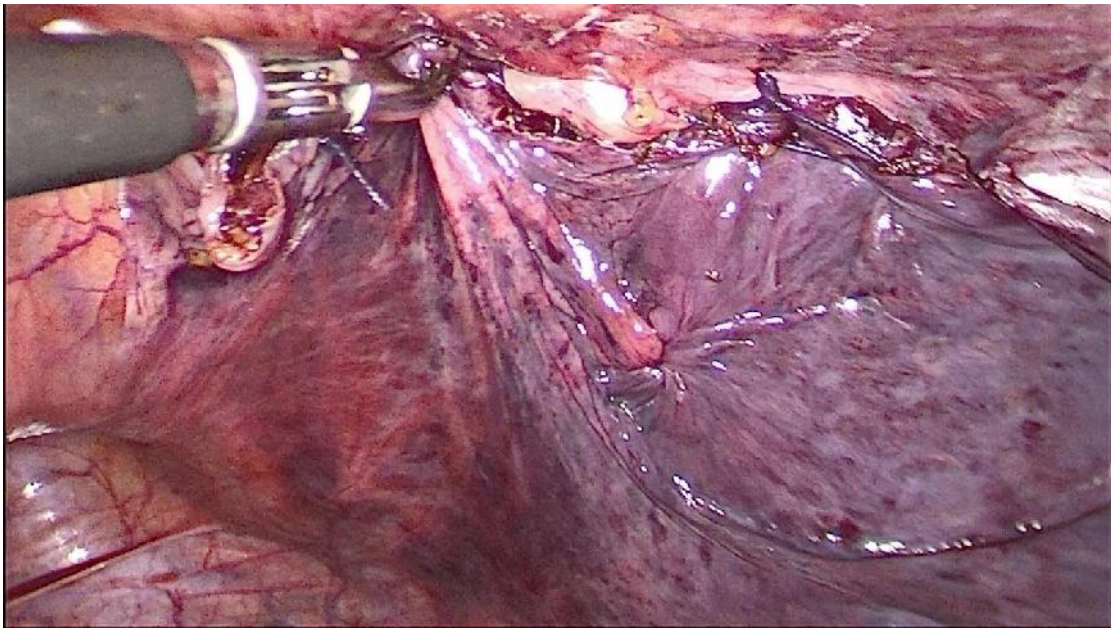


Figure 14: closure of peritoneal flaps using vicryl

Totally extra peritoneal repair(TEP): In TEP approach, the three ports (One 10 mm camera port and other two 5 mm working ports) were placed typically in line from pubic symphysis to umbilicus. Then, preperitoneal space was created by blunt dissection using zero degree scope under vision. Subsequently, the mesh was placed such that it covered the entire myopectineal orifice.

- After the surgery all the patients were monitored in post operative ward for pain, bleeding, hypotension and urinary catheter is removed on post operative day 1 and patients were advised to mobilize from bed.
- All the patients have been given standard analgesic tramadol injection 1 ampoule in the post operative period every 8^{th} hourly for two days and then analgesia of paracetemol tablet 500 mg twice a day is given for 5 days.
- Any time if severe pain was there then patient was given rescue analgesia with paracetemol injection 1gm IV.
- Patients are evaluated for post operative pain at 24 hrs, 72 hrs and 1 week by visual analogue scale and scores recorded. If patients are discharged the VAS scores were collected on telephone.
- Hospital stay is calculated in number of days from the day of surgery to day of discharge.
- Time to resume normal activities as defined earlier is calculated in number of days by asking the patients.
- Post operative complications like seroma, wound infection and urinary retention in patients were recorded.

- The patients were discharged and asked to keep a regular follow up either directly or by telephonic contact.

Statistical Analysis

Master chart was prepared in the Microsoft excel sheet (Annexure IV). The statistical analysis was made using data SPSS software. The results were obtained using Mann Whitney U test and Wilcoxon matched pairs test. Numerical data compared by student t test. A 'p' value less than/equal to 0.05 is considered as statistically significant at 95% confidence interval.

OBSERVATIONS AND RESULTS

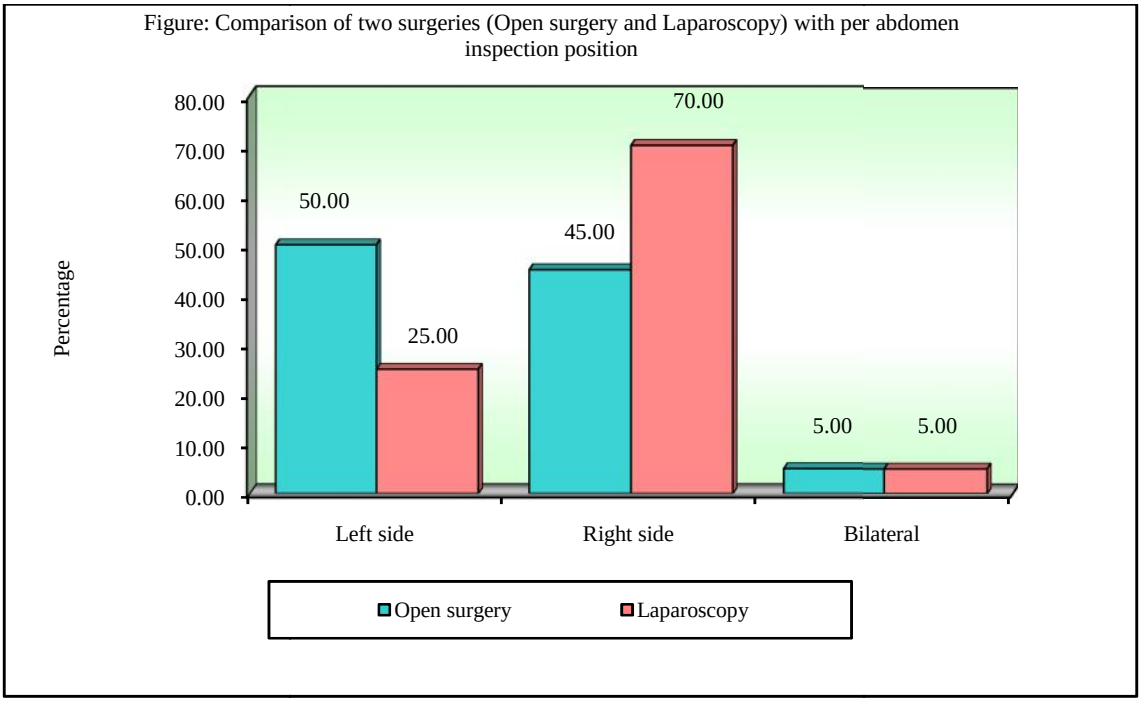
Table 1: Comparison of two surgeries (Open surgery and Laparoscopy) with mean age of patients by t test

Two surgeries	n	Mean	SD	SE	t-value	P-value
Open repair	20	51.05	15.58	3.48	0.9986	0.3243
Laparoscopy	20	45.65	18.50	4.14		

The age distribution of the subjects ranged from 12 to 78 years. The mean age of patients of laparoscopy group was 45.65±18.50 years and the mean age for Lichtenstein repair group was 51.05±15.58 years.

Table 2: Comparison of two surgeries (Open surgery and Laparoscopy) with per abdomen inspection position

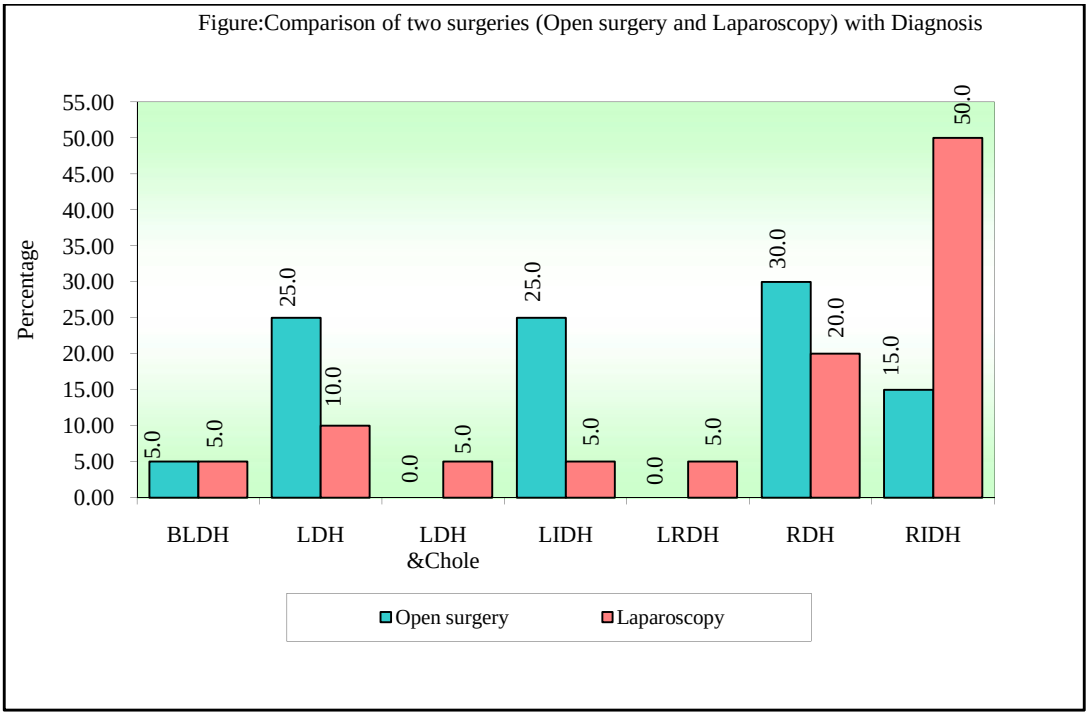
Position	Open repair	%	Laparoscopy	%	Total	%
Left side	10	50.00	5	25.00	15	37.50
Right side	9	45.00	14	70.00	23	57.50
Bilateral	1	5.00	1	5.00	2	5.00
Total	20	100.00	20	100.00	40	100.00
Chi-square2.7541 P = 0.2522						



Graph 1: comparison of two groups based on side of hernia on inspection

Out of the total 20 cases in open group 10 cases are on left side and 9 cases are on right side and 1 case has bilateral hernia, and out of 20 cases of laparoscopic group 5 cases are on left side, 14 cases on right side and 1 case has bilateral inguinal hernia.

In open group out of 11 direct hernias 8 were operated with both posterior wall repair and meshplasty and 3 for only meshplasty and rest all were indirect hernias proceeded with meshplasty. In laparoscopic group only 2 patients with direct hernia were operated with TEP repair and rest all by TAPP repair of which 11 were indirect and 6 were direct hernias.



Graph 2: Comparison of two surgeries (Open surgery and Laparoscopy) based on Diagnosis

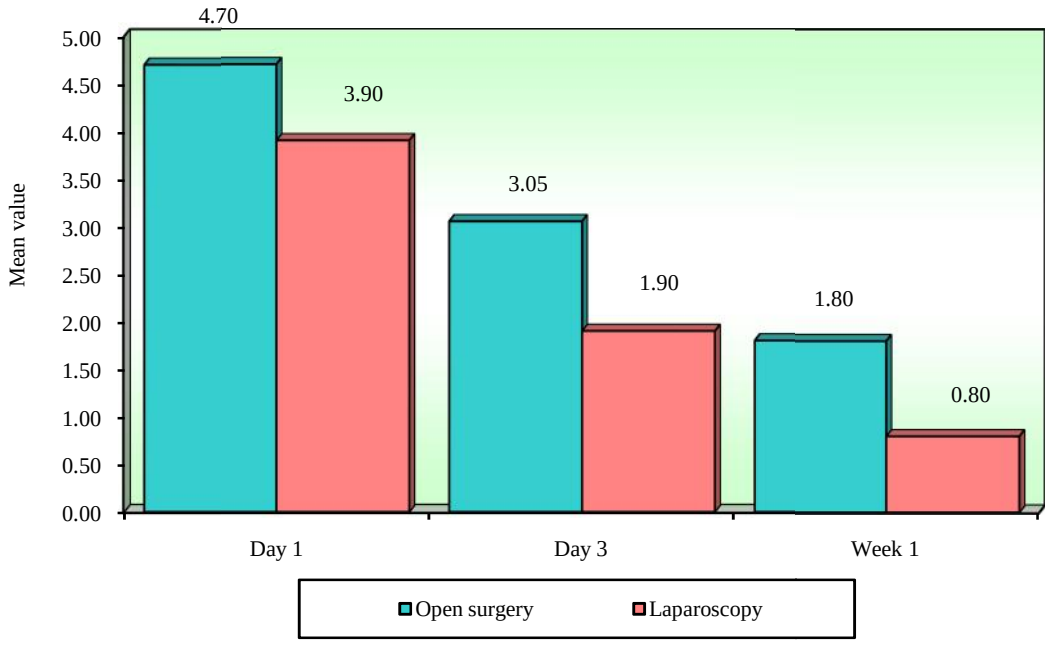
Out of 20 cases in open group 5 cases are left direct hernia and 5 are left indirect hernia, 6 cases are diagnosed with right direct hernia and 3 cases are of right indirect hernia, with 1 case bilateral direct hernia, and of 20 cases in laparoscopic group 3 cases are diagnosed with left direct hernia with simultaneous cholelithiasis in one patient among them. 1 case is left indirect hernia and 1 case is left recurrent hernia. 4 cases diagnosed with right direct hernia and 10 cases with right indirect hernia with 1 case of bilateral direct hernia.

Table 3: Comparison of two surgeries (Open surgery and Laparoscopy) with postoperative pain scores at day1, day3 and 1 week time points by Mann Whitney U test

Time	Open surgery			Laparoscopy			U-value	Z-value	p-value
	Mean	SD	Sum of ranks	Mean	SD	Sum of ranks			
Day 1	4.70	1.34	479.00	3.90	0.79	341.00	131.00	-1.8665	0.0620
Day 3	3.05	1.15	519.00	1.90	0.79	301.00	91.00	-2.9485	0.0032*
Week 1	1.80	1.01	520.50	0.80	0.77	299.50	89.50	-2.9890	0.0028*
Day 1 vs Day 3	1.65	0.49	347.00	2.00	0.46	473.00	137.00	-1.7042	0.0884
Day 1 vs Week 1	2.90	0.79	373.00	3.10	0.64	447.00	163.00	-1.0009	0.3169
Day 3 vs Week 1	1.25	0.55	428.00	1.10	0.55	392.00	182.00	-0.4869	0.6263

*p<0.05

Figure: Comparison of two surgeries (Open surgery and Laparoscopy) with pain scores at day1, day3 and 1 week time points



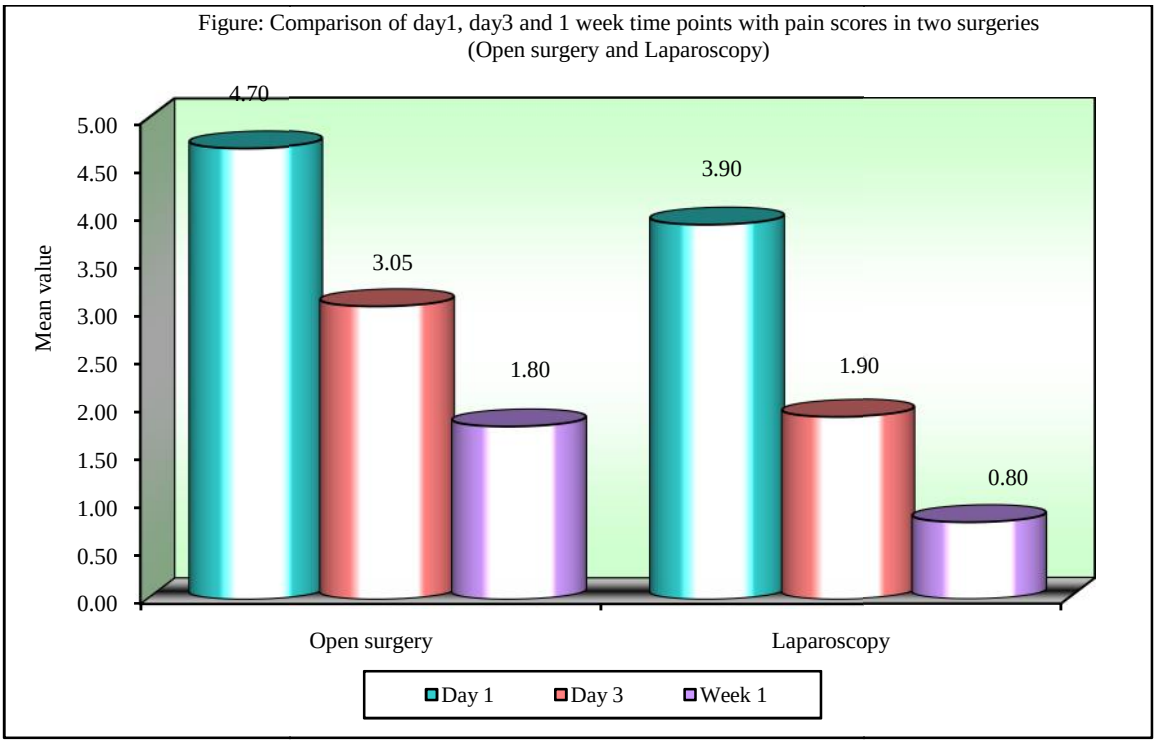
Graph 3: showing post operative pain scores between two groups

The postoperative pain is compared using VAS scores at 1st day, 3rd day and 1 week. Here the mean values of VAS score are 4.70 and 3.90 for open and laparoscopy group at day 1, 3.05 and 1.90 at day 3 and 1.80 and 0.80 at 1 week time points. The p value is significant at day 3 and 1 week time points for laparoscopic group. Also pain scores were compared between day 1 and day 3, between day 3 and 1 week and day 1 and 1 week time points by Mann-Whitney U test

Table 4: Comparison of day1, day3 and 1 week time points with pain scores in two surgeries (Open surgery and Laparoscopy) by Wilcoxon matched pairs test

Surgeries	Timepoints	Mean	SD	Mean Diff.	SD Diff.	% of effect	Z-value	p-value
Open repair	Day 1	4.70	1.34					
	Day 3	3.05	1.15	1.65	0.49	35.11	3.9199	0.0001*
	Day 1	4.70	1.34					
	Week 1	1.80	1.01	2.90	0.79	61.70	3.9203	0.0001*
	Day 3	3.05	1.15					
	Week 1	1.80	1.01	1.25	0.55	40.98	3.9199	0.0001*
Laparoscopy	Day 1	3.90	0.79					
	Day 3	1.90	0.79	2.00	0.46	51.28	3.9202	0.0001*
	Day 1	3.90	0.79					
	Week 1	0.80	0.77	3.10	0.64	79.49	3.9209	0.0001*
	Day 3	1.90	0.79					
	Week 1	0.80	0.77	1.10	0.55	57.89	3.7236	0.0002*

*p<0.05



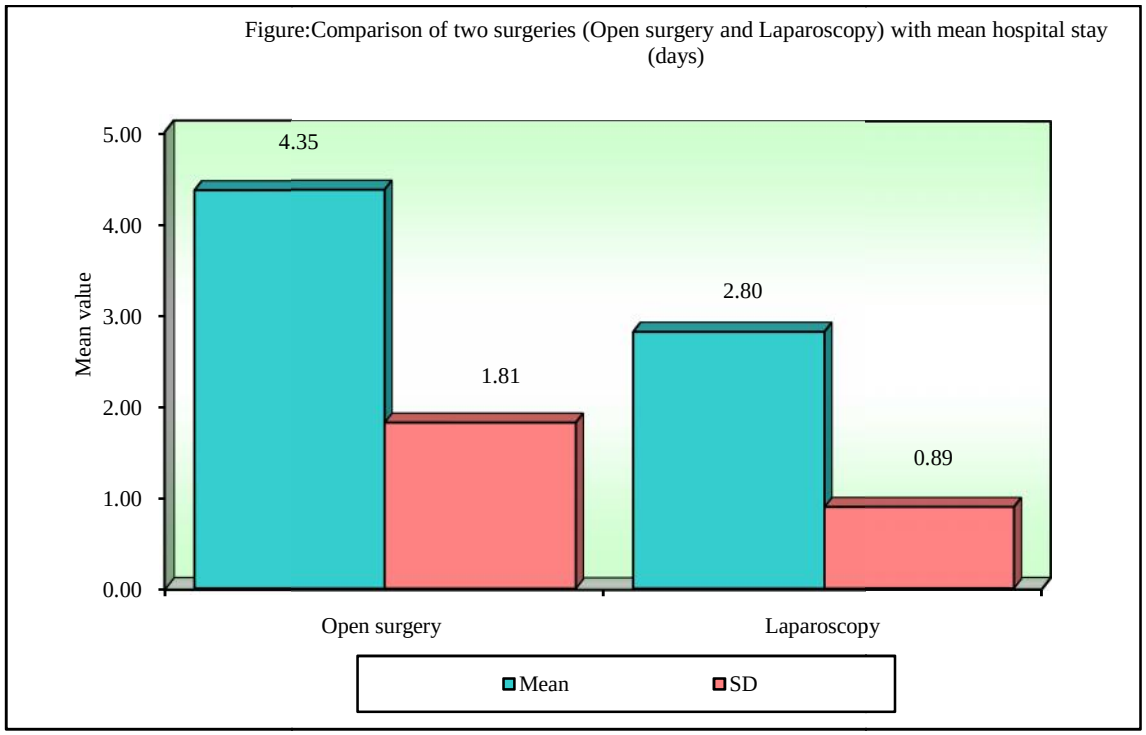
Graph 4: comparison of pain scores with in the groups

Also comparison of pain scores with in the groups at day 1, day 3 and 1 week time points is significant with $p<0.05$ by using Wilcoxon matched pairs test, with mean difference of 1.65, 2.90 and 1.25 between day 1 and day 3, day 1 and 1 week and day 3 and 1 week time points in open group and similarly mean difference of 2.00, 3.10 and 1.10 in laparoscopic group.

Table 5: Comparison of two surgeries (Open surgery and Laparoscopy) with mean hospital stay (days) by t test

Two surgeries	n	Mean	SD	SE	t-value	P-value
Open surgery	20	4.35	1.81	0.41	3.4267	0.0015*
Laparoscopy	20	2.80	0.89	0.20		

*p<0.05



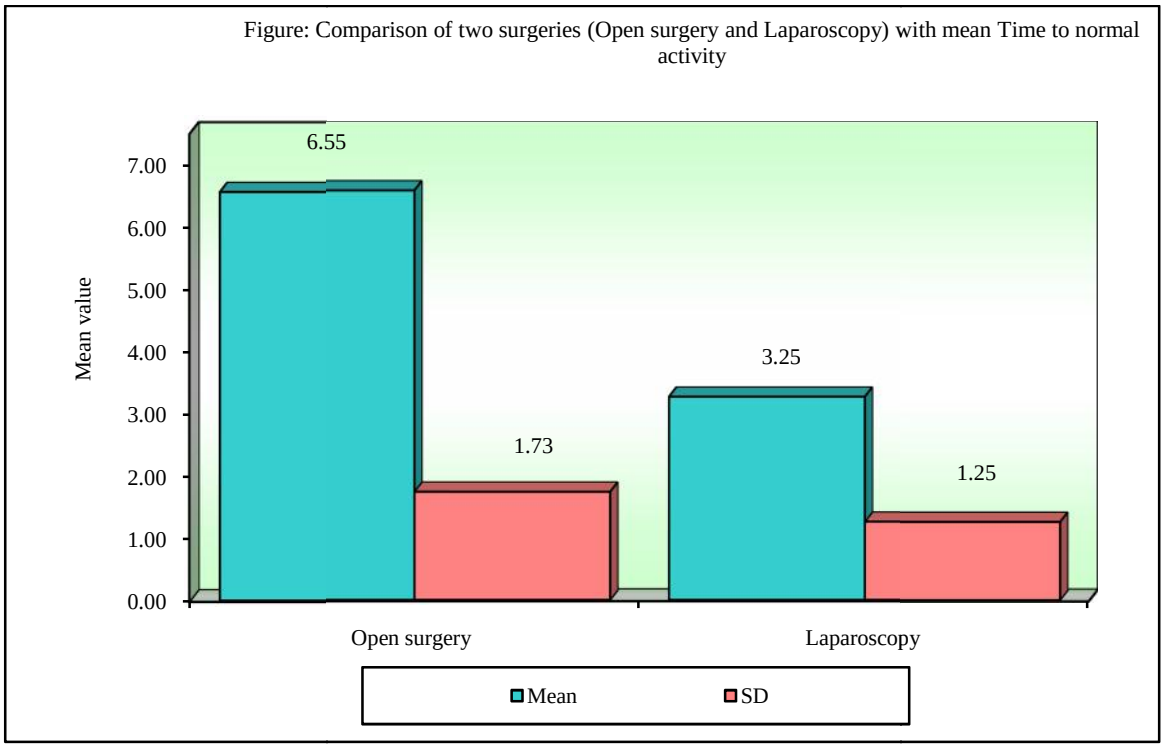
Graph 5 : comparison of mean hospital stay

The mean hospital stay between two groups is compared in number of days using t test which is found to be significantly less in laparoscopic group with mean of 2.80 when compared to open group with mean of 4.35.

Table 6: Comparison of two surgeries (Open surgery and Laparoscopy) with mean Time to normal activity in days by t test

Two surgeries	n	Mean	SD	SE	t-value	P-value
Open surgery	20	6.55	1.73	0.39	6.9087	0.0001*
Laparoscopy	20	3.25	1.25	0.28		

*p<0.05

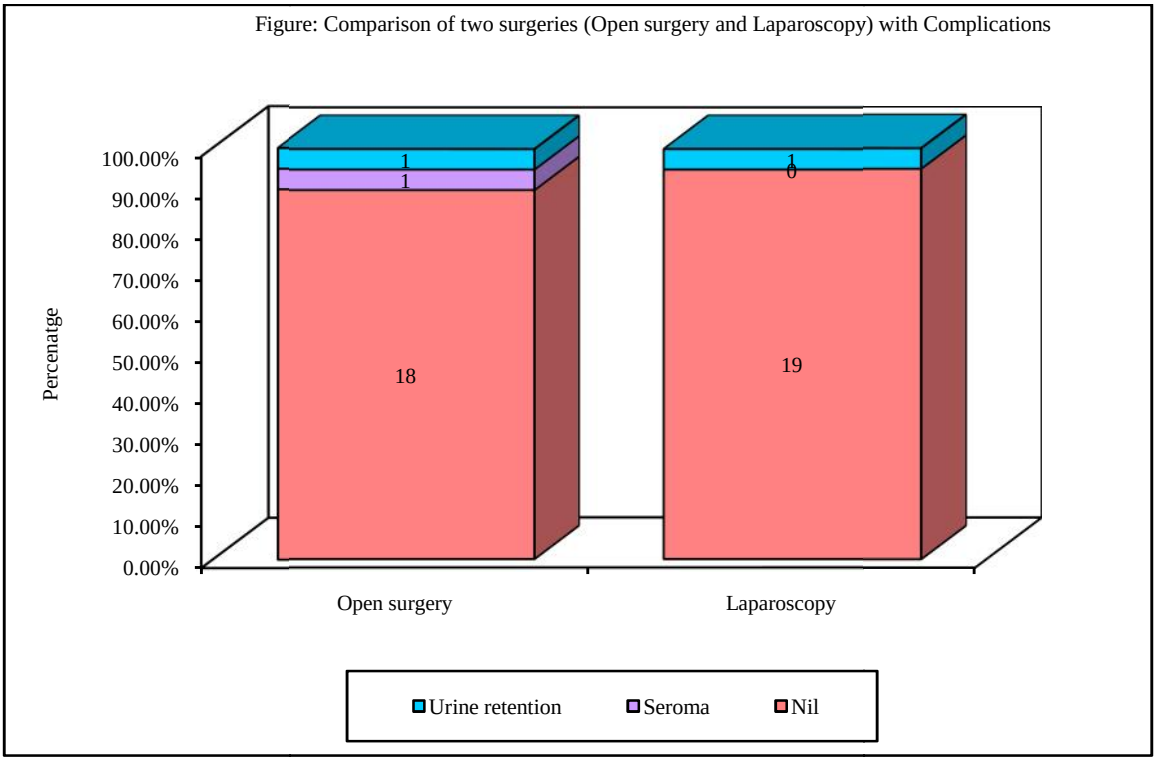


Graph 6 : comparison of time to return to normal activity

The mean time to return to normal activities is found to be 6.55 days in open group and 3.25 days in laparoscopic group and is significant with p<0.05

Table 7: Comparison of two surgeries (Open surgery and Laparoscopy) with Complications

Complications	Open surgery	%	Laparoscopy	%	Total	%
Nil	18	90.00	19	95.00	37	92.50
Seroma	1	5.00	0	0.00	1	2.50
Urine retention	1	5.00	1	5.00	2	5.00
Total	20	100.00	20	100.00	40	100.00



Graph 7: bar diagram showing comparison of complications

Post operativeseroma was observed in 1 case in open group for which no intervention was done. Post operative urine retention was observed in each 1 case in both open group and laparoscopic group after removal of foley's catheter, for which reinsertion of catheter has been done and removed later on.

DISCUSSION

The successful inguinal hernia repair depends on a tension free closure of hernia defect to achieve the lowest possible recurrence rate.[31] The most frequently utilized open techniques includedwere Shouldice, Bassini and the Lichtenstein repairs.[1] Lichtenstein tension free repair became popular when the scope for tissue-based repairs such as Bassini's repair and Shouldice repair became limited with increased recurrence rate.[32,33] The ideal technique still remains debatable and is individualized to person for inguinal hernia repair. Although open tension free mesh repair offer good outcome but the superiority of laparoscopic technique to be considered in view of reduced postoperative pain, discomfort and earlier resuming of normal activities.[33] Therefore, in our study we have compared both the techniques to analyse which one is more suitable and safer for operating inguinal hernia.

In this study, the mean age was 48.35±17.10 years, ranging from 12-78 years. 51.05±15.58 years in Lichtenstein tension free hernia repair (LTHR) group and 45.65±18.50 years in the Laparoscopic hernia repair (LHR) groupwhich can be compared to a study conducted by Pooraneson K.et al.,(2018)[34] where the mean age was 43.62+10.51 years with a range from 20 to 60 years with the mean for Lichtenstein Mesh Repair group being 45.24±10.05 years and laparoscopic technique group (TEP) was 42.00±10.92 years.

Inguinal hernias are more common in men with relatively around 90% of them are performed in males.[35] In a study conducted by Ira M Rutkow[36] 90% cases were male and remaining 10 % cases were females. Our study included 40 patients of which 100 % of them are males.

Many studies are made in the literature to know the precipitating factors for the causation of inguinal hernias like coughing, heavy physical work and activities that involve increase in intra abdominal pressure are studied. However it is still unclear about the mechanism of causation. We considered occupation in the demographic variables majority of them being farmers and some were students with normal activity in our study.

The comparison of different types is made with maximum of right indirect hernia being 32.5 % and right direct hernia being 25 % in our study group. Left sided hernias being 20% direct and other 15 % indirect type. A study conducted by I M Rutkow also showed comparison of different types of hernia based on diagnosis.[37]

In the present study of 40 cases, all of them satisfied the inclusion criteria and so included in the study. 20 cases underwent Lichtenstein tension free repair and 18 cases TAPP repair and 2 cases TEP repair. The biggest advantage of TAPP repair is that any other surgery can be performed in the same sitting. In our study one patient has associated cholelithiasis for which laparoscopic cholecystectomy was done in the same sitting.

Post operative pain has become an important measurable outcome in the field of inguinal hernia repairs. Many studies have been conducted on the post operative pain in the field of this surgeries and the proportion of pain ranges from 0 to 63 % which they divided into mild, moderate and severe depending on factors like using analgesics and frequency of visiting pain clinics and interfering to normal routine activities.

In our study, Visual analogue scale (VAS) was used to measure the pain score in the patients measured on post operative day 1, day 3 and on 1 week. The mean of postoperative VAS score was less in the LHR group than LTHR group at each time points ($p<0.05$) which is similar in a study conducted by Neumayer L et al,(2008)[38] where it was noted that the group undergoing surgery with laparoscopic technique has less pain than the group undergoing surgery with Lichtenstein technique.

In our study mean of VAS score at day 1 was 4.7 and 3.9 for LTHR and LHR groups respectively where p value was not significant. On day 3 it was 3.05 and 1.9 and on 1 week it was 1.8 and 0.8 respectively for both the groups with p value being significant.

Also the study conducted by Ielpo B et al compared post operative pain, chronic pain and quality of life between laparoscopic and open inguinal hernia repair and concluded that laparoscopic repair was effective in reducing the pain.[26]

The study conducted by Hallan et al compared open inguinal mesh repair with TEP and concluded higher patients in TEP group with testicular pain than in open group.[39] Stoker et al study concluded less pain for the first 4 hours post surgery for open hernia probably due to effect of local anaesthesia[40]. The meta analysis conducted by Berndsen F et al have shown that LHR is superior to open repair due to less post operative pain and short convalescence in early phase but long term results are not clear.[41] The post operative pain in laparoscopic repair is less compared to open group also because we did not use tacks or staples for fixation of mesh but used simple absorbable suture to just close the peritoneal flaps as done in many centers.

The duration of hospital stay in our study is calculated from the day of surgery to day of discharge. In our study the patients in LTHR group had longer duration of hospital stay that is 4.35 days, compared to the LHR group of 2.8 days which is similar to a study conducted by K. Pooraneson et al.,[34]where the length of hospital stay was more in Lichtenstein mesh repair 7.2 days than the laparoscopic repair group 4.6 days showing a statistical difference between the groups ($P<0.05$). While in a study conducted by Eker HH et al.(2009) [42]there was so significance found in duration of hospital stay between the two groups. This decrease in the duration of stay is attributed to less post operative pain of laparoscopic surgery due to less dissection.

The time to get back to the normal activity was shorter in Laparoscopic group which is 3.25 days when compared to open group mean being 6.55 days. The study conducted by a Kouhia ST et al,(2009)[43] showed the similar results that the group repaired with Laparoscopic technique (5.08±0.28 days) took shorter time to get back to normal activities than the Lichtenstein Mesh Repair group (10.08±0.76 days).

In our study, the complications were comparable among the LTHR group (10%) compared to the LHR (5%) group that is two patients have complications like seroma and urinary retention in post operative period in open group. While only one patient has urinary retention in laparoscopy group. In a study conducted by Vidović D et al.,(2007)[44] it was noted that there was no significant difference found in terms of postoperative complication rates between the two groups.Also in a study conducted by Liem MS et al.,(1997)[45] the results were in favour of the laparoscopic technique which showed fewer complications compared to the open mesh surgical repair. The post operative urinary retention rate ranges from 2.0% to 10.9% after laparoscopic

repair because of the pre peritoneal dissection and use of general anaesthesia.[46] Study conducted by Udwania et al, for wound infection rates were less for laparoscopic repairs (1%) compared to open repairs (2.7%).[47]A study conducted by Prasad et al., compared the incidence of post operative complications between open and laparoscopic repair and concluded that post operative pain and mean duration of hospital stay was less in laparoscopic group[9]. However our study did not compare recurrence rates and chronic pain after surgery.

The high cost of laparoscopic surgery and training can be balanced with the reduced costs in the form of less hospital stay, reduced complications and early return to normal activity and work.

CONCLUSION

The present study compared Lichtenstein tension free hernia repair with laparoscopic inguinal hernia repair in terms of post operative pain, hospital stay, early return to normal activities and complications.

As compared with the open repair, laparoscopic repair is much better in terms of early resumption of work and less pain post operatively. The cost burden also decreases for the patients in terms of less hospital stay, early return to work post surgery and better cosmesis. Also the complications of both the groups were comparable. But the operative time and learning curve is more for laparoscopic group.

Hence according to this study I would like to support laparoscopic hernia repair in terms of feasibility, efficiency and is safe in experienced surgeon's hands and is nearly scar less surgery. However long-term follow up is needed to evaluate for the chronic pain, recurrence rates.

SUMMARY

Inguinal hernia is a common disease condition requiring surgical procedure. Many techniques have evolved over past few decades from herniorraphy to the present day hernioplasty which is done both in open and in laparoscopic methods either TAPP or TEP. Many cases of recurrences of inguinal hernia were reported with the conventional hernioplasty. Hence newer concept of tension free meshplasty came into action. The present study is aimed to compare the post-operative pain scores between Lichtenstein tension free repair versus laparoscopic repair of inguinal hernias in patients along with evaluation of postoperative complications, hospital stay and time to return to normal activities.

A one year randomized control trial was done between January 2018 and December 2018. Patients who had inguinal hernia, satisfying the inclusion criteria and willing to participate in the study were included in this study. Group A had 20 patients who underwent Lichtenstein tension free hernia repair and Group B had 20 patients who underwent laparoscopic inguinal hernia repair. Pain scores in both groups was calculated with visual analogue scale at different time intervals. Also hospital stay in number of days, time to resume normal activities post surgery and post operative complications were recorded if any and assessment done.

In our study we found that the VAS score was less in laparoscopic group when compared to open group measured at 24 hrs, 72 hrs and 1 week post surgery) and it was showing a significant difference ($p<0.0001$) between the groups. There was also a significant difference found in median of time that is required for normal activity and it was significantly more in open surgery group as compared to laparoscopic group ($p<0.0001$). The median of hospital stay in open group is significantly more (4.35 ± 1.81) than laparoscopic group (2.8 ± 0.89). Even the

complications were found more in open group (10%) than in laparoscopic group (5%).

Apart from the complications, which were found to be similar, laparoscopic hernia repair was found to be more suitable, safe and efficient in all the above mentioned aspects except when there is contraindication for general anesthesia. However, the data is insufficient to conclude which surgeryis better overall, as long-term follow up and large population sample are required to evaluate for chronic pain, recurrence and learning curve in laparoscopic hernia repair.

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INFORMED CONSENT

Dear Mr./Mrs./Dr. _____, you are kindly requested to enroll yourself in a research study tilted,

"A ONE YEAR RANDOMIZED CONTROL STUDY TO COMPARE POST OPERATIVE PAIN IN LICHTENSTEIN TENSION FREE HERNIA REPAIR VERSUS LAPAROSCOPIC INGUINAL HERNIA REPAIR" AT A TERTIARY HOSPITAL.being conducted by Dr. _____, a post graduate student in M.S. General Surgery and the study will be carried out under the direct supervision and guidance of Dr. _____**,** Professor, Department of General Surgery, Jawaharlal Nehru Medical College, Belagavi.

You have been requested to participate in this as you fit into the laid out criteria for a study 'subject'/ participant.

Your participation in study is voluntary. During the study you will be asked some questions and you are supposed to answer to the best of your knowledge. Your decision whether or not to participate in the study will not affect your treatment in any form during your hospital stay. If you decide to participate you are free to withdraw at any time.

TITLE OF THE STUDY:

"A ONE YEAR RANDOMIZED CONTROL STUDY TO COMPARE POST OPERATIVE PAIN IN LICHTENSTEIN TENSION FREE HERNIA REPAIR VERSUS LAPAROSCOPIC INGUINAL HERNIA REPAIR" AT A TERTIARY HOSPITAL.

PURPOSE OF THE STUDY:

To compare the outcomes such as postoperative pain, post operative complications (seroma and surgical site infections), hospital stay and time to return to normal activities of Lichtenstien tension free hernia repair versus laparoscopic inguinal hernia repair.

PROCEDURES INVOLVED:

If you agree to enroll yourself in my study, you will be interviewed regarding your present, past and family history then you will be clinically examined in detail and investigated accordingly.

You will be grouped into group A and group B and either Lichtensteins repair or laparoscopic repair will be done by a consultant general surgeon under general anesthesia.

Post operative analgesia is standardized in both groups. On admission.Pain management will be standardized in both the groups. Both group patients receives Injection Tramadol 1 amp I.V in 100 ml NS infusion in case of severe pain and Tab. Ultracet for mild to moderate pain.

RISKS AND BENEFITS:

There is no increased risk involved in becoming a part of this study and the complications are those which are normally anticipated. This study will help us to estimate the incidence of post operative pain in comparison with the two techniques involved. The results derived at the end of study will benefit all similar patients admitted in this hospital.

Benefits of taking part in this research:

Both the treatment modalities are individualized according to patient factors. So, the chosen treatment modality will ensure the maximum efficacy, minimal side effects, and minimize dosing of the drug. Patient will get the benefit of maximum compliance.

No bias will be done to the patients who are not willing to participate in the study from the treatment point of view.

VOLUNTARY PARTICIPATION / WITHDRAWAL FROM THE STUDY:

Taking part in the study is voluntary. You may choose not to enroll yourself in this study and may choose to leave the study anytime in between.

ALTERNATIVES:

Your decision regarding participation in study will not change present or future health care services offered to you at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.You would simply be excluded from the study if youwish to, and all your details shall be kept confidential and you will get the routine line of management.

PRIVACY AND CONFIDENTIALITY:

All data collected or disclosed by you during the course of participation of study, will be kept fully confidential. If however during the course it becomes necessary for the progress of the course to disclose the identity, it would be done so only after your informed & written consent.

The only people to know that you are a research subject are members of the research team. No information about you will be disclosed to other without your written permission except:

- In emergency to protect your rights AND welfare.
- If required by law.

AUTHORIZATION TO PUBLISH RESULT:

The results of the study may be used to publish an article. When the results of research published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information obtained in connection with this study and that can be identified with you will remain confidential.

FINANCIAL INCENTIVES FOR PARTICIPATION:

No additional costs shall be incurred upon you for the purpose of this study.

It is purely being done with the idea of research and all the cost of study will be borne by the investigator.

COMPENSATION:

In the event that you become injured as a result of taking part in this study, treatment will be offered to you at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, or you will be given information about where to receive medical care. However, no reimbursement,compensation or free medical care will be given.

QUESTIONS/CONTACT DETAILS:

You shall be free to contact the below mentioned name & addresses anytime during the study period for any clarification or help as you may desire for.

Dr._____
MS(Post Graduate Student)
Department of General Surgery
Jawaharlal Nehru Medical College,
Nehru Nagar, KLE Hospital Road,
Belagavi 590010

Dr._____
MBBS, MS GENERAL SURGERY,
Professor,Department of General Surgery
Jawaharlal Nehru Medical College,
Nehru Nagar, KLE Hospital Road,
Belagavi 590010

In case you need any further information regarding your rights as study participant you may contact:

Dr. ROOPA BELLAD M D
Professor of Pediatrics& Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
Jawaharlal Nehru Medical College
Nehru Nagar, KLE Hospital Road.

CONSENT STATEMENT:

I the undersigned Mr/Mrs/Dr_____ do hereby give consent for my participation in this research study after being explained in-depth about the important elements of this study in my own vernacular language.

I give this consent voluntarily in my sound mind and good faith, knowing very well the risks involved and been given enough time to clear my doubts and other queries to participate as a 'subject' in this study. I do hereby also give consent for publication of this article in any media / journal and have no objections whatsoever.

Signature or left thumb print of participant or legally authorized representative

Participants name: _____

Signature: _____

Witness/guardian name: _____

Signature_____

Investigator's name:

Signature_____

Guide's name:

Signature_____

Date: ___/___/_____Place: _____

ANNEXURE II.ETHICAL CLEARANCE.

K.L.E.UNIVERSITY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
(Accredited 'A' Grade by NAAC)

Website: http://www.jnmc.edu
E-Mail : dome@jnmc.edu

Phone: (+ 91-(0)831 Office : 2471350
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 16 **Date: 22/11/2017**

To,

Dr. M Shashidhar Reddy,
PG student in Surgery,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"A ONE YEAR RANDOMIZED CONTROL TRIAL TO COMPARE POST OPERATIVE PAIN IN LAPAROSCOPIC INGUINAL HERNIA REPAIR VERSUS LICHTENSTEIN TENSION FREE HERNIA REPAIR – A SINGLE CENTRIC HOSPITAL BASED STUDY"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

73

ANNEXURE III – PROFORMA

PROFORMA OF CLINICAL EXAMINATION OF INDIVIDUAL PATIENT

Name

Age

Sex Address

Occupation

Socioeconomic

IP.No

Date of admission

Clinical diagnosis

Clinical details

HISTORY

1) Pain

2) Swelling

3) Systemic symptoms

4) Other complaints

5) Past history of operation

6) Personal history

GENERAL PHYSICAL EXAMINATION

1) Vitals
2) Appearance
3) Attitude

LOCAL EXAMINATION

Position of patient

1) standing
2) Supine

Inspection

1) Swelling
2) Skin over the swelling
3) Impulse on coughing
4) Position of penis

Palpation

1) Impulse on coughing
2) Reducing

Percussion

Auscultation

INVESTIGATION

1) CBC

2) Urine routine

3) Serum urea and creatinine

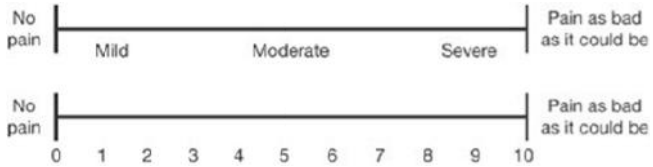
4) USG abdomen and pelvis

POST OPERATIVE PERIOD:

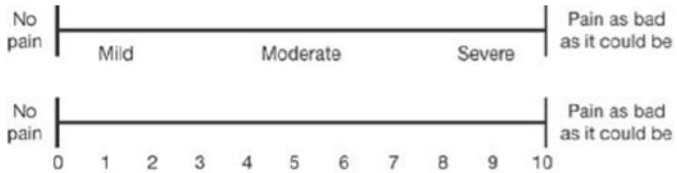
1)Evaluation of pain on visual analogue scale.

EVALUATION OF PAIN:

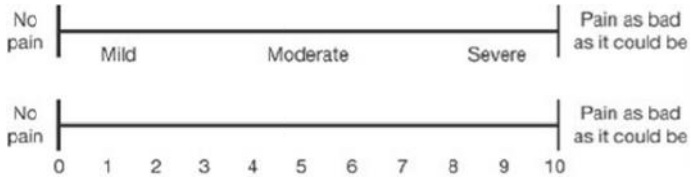
POSTOPERATIVE DAY 1:



POSTOPERATIVE DAY 3:



AFTER 1 WEEK: [before discharge]



2)Hospital stay and time to return to normal activities.

3) Postoperative complications (seroma and surgical site infection).

ANNEXURE IV - KEY TO MASTERCHART

GROUP A	:	LICHTENSTEIN TENSION FREE REPAIR GROUP
GROUP B	:	LAPAROSCOPIC INGUINAL HERNIA GROUP
L	:	LEFT
R	:	RIGHT
BL	:	BILATERAL
LDH	:	LEFT DIRECT HERNIA
RDH	:	RIGHT DIRECT HERNIA
LIDH	:	LEFT INDIRECT HERNIA
RIDH	:	RIGHT INDIRECT HERNIA
BLDH	:	BILATERAL DIRECT HERNIA
LRDH	:	LEFT RECURRENT DIRECT HERNIA
CHO	:	CHOLELITHIASIS
M	:	MALE
m	:	months
y	:	years