“COMPARISON OF SELF RETAINING FREEDOM PROFLOR MESH REPAIR VERSUS LICHTENSTEIN MESH REPAIR FOR THE REDUCTION OF POSTOPERATIVE PAIN IN INGUINAL HERNIA” A ONE YEAR RANDOMIZED CONTROL TRIAL AT KLES DR PRABHAKAR KORE HOSPITAL AND MRC, BELAGAVI

By

(REG.NO. BH0114004)

Dissertation

Submitted to the
KLE University, Belagavi, Karnataka

In Partial Fulfillment
of the requirements for the degree of

M. S.

in

GENERAL SURGERY

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

APRIL - 2017

KLE UNIVERSITY, BELAGAVI, KARNATAKA

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LIST OF ABBREVIATIONS USED

A	-	Study group
Approx.	-	Approximately
B	-	Control group
BC	-	Before Christ
BP	-	Blood pressure
BUN	-	Blood urea nitrogen
CI	-	Confidence interval
cm	-	Centimeter
COPD	-	Chronic obstructive pulmonary disease
CT	-	Computed tomography
ECG	-	Electrocardiogram
ED	-	Emergency department
e-PTFE	-	Expanded polytetrafluoroethylene
ESR	-	Erythrocyte sedimentation rate
EU	-	European Union
FBR	-	Foreign body reaction
GA	-	General anaesthetic
i.e.	-	That is
IASP	-	International Association for the Study of Pain
IPOM	-	IntraPeritoneal Onlay Mesh
IPQ	-	Inguinal Pain Questionnaire
kPA	-	Kilopascals
LA	-	Local anaesthesia
min	-	Minute

mm Hg	-	Millimeters of mercury
N	-	Newtons
n	-	Total number
ng	-	Nanogram
NHS	-	National Health Service
NMDA	-	N-methyl-D-aspartate
NSAID	-	Non-steroidal anti-inflammatory drug
p	-	Probability
RCT	-	Randomized controlled trials
SD	-	Standard deviation
TAPP	-	TransAbdominal PrePeritoneal
TEP	-	Totally ExtraPeritoneal
UK	-	United Kingdom
VAS	-	Visual Analogue Scale
VRS	-	Verbal Rating Scale
Vs.	-	Versus

ABSTRACT

Background and Objectives

Lichtenstein hernia repair is commonly recommended in the management of inguinal hernia and currently, pain is considered the most important complication. The present study was aimed to compare self retaining freedom proflor mesh repair versus Lichtenstein mesh repair for the reduction of postoperative pain in inguinal hernia.

Methodology

The present one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgavi from January 2015 to December 2015. A total of 60 patients requiring mesh repair were randomized into two groups of 30 each based on the type of surgery as group A (freedom proflor mesh repair) and group B (lichtenstein repair).

Results

In the present study all the patients in both the groups were males. The mean age (53.57±14.31 vs 56.47±13.85 years; p=0.4284) and duration of the symptoms (13.07±9.6 months vs 15.10 ± 8.98 months; p=0.401) in group A and group B were comparable. In this study comparing the VAS on all the five follow ups there were significant lower pain scores in group A than group B. The mean pain scores in group A during first (3.53 ± 1.36 vs. 5.47 ± 2.11), second (1.37 ± 1.5 vs. 4.3 ± 1.51), third (0.47 ± 0.57 vs. 2.37 ± 1.47), fourth (0.3 ± 0.47 vs. 1.53 ±1.43) and fifth (0.2±0.41 vs. 1.07±1.28) follow up were significant compared to

group B ($p<0.0001$). In this study, the mean reduction in pain score from first follow up to fifth follow up was significant in group A (3.3 ± 1.24) compared to group B(4.40 ± 2.04) ($p=0.029$). All the patients in group A were operated on in less than 30 minutes. In group B only 3.33% were operated upon in the same time period. The rest of the patients from group B (96.67%) were operated on within 31-60 minutes with none in group A The operative time was significantly less in group A compared with group B. In all the patients in the group A the operative time is less than 30 minutes ($p<0.05$).

Conclusion and interpretation

Based on the findings of the present study it may be concluded that, the freedom proflor hernia repair significantly reduced the post-operative pain as compared to Lichtenstein hernia repair. There is statistically significant reduction in the operative time in freedom proflor mesh repair group, required less pain medication postoperatively and for shorter time compared to Lichtenstein group. In this study there were no recurrences in one year. However further long term studies are required for documenting hernia recurrences.

Keywords

Freedom proflor mesh; Inguinal hernia; Self retaining mesh; Pain;

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Chapter 1

Introduction

INTRODUCTION

Globally, inguinal hernia is the most common type of hernia, comprising of approximately 75% of all abdominal wall hernias.[1-3] Inguinal hernia repair is one of the most common general surgical operations worldwide accounting for 10 to 15% of all surgical procedures and is the second most common surgical procedure after appendicectomy.[2-4] It has been estimated that worldwide over 20 million repairs of inguinal hernia are carried out each year.[5]

Inguinal hernias may be congenital or acquired, with latter being a common presentation. Essentially any risk factors that either increases intra-abdominal pressure or weakens the anterior abdominal wall may lead to the formation of an inguinal hernia. Known risk factors associated with hernia occurrence are smoking, positive family history, patent processus vaginalis, collagen disease, previous appendicectomy (open) and prostatectomy, patients with ascites, peritoneal dialysis, after long term heavy work and chronic obstructive pulmonary disease (COPD). It is interesting to note that occasional lifting, constipation and prostatism has not been proven to increase risk of inguinal hernias.[6]

In inguinal hernia patients may typically present with either groin pain or swelling/lump. The presence of swelling may be asymptomatic with respect to their daily activities. If symptomatic, they may be either minimally symptomatic (intermittent discomfort/pain) or symptomatic with interference with their daily activities. Furthermore they may present with incarceration where the hernia cannot be reduced into the abdominal cavity which may lead to strangulation.[7]

The management of inguinal hernia poses therapeutic challenges to general surgeons practicing in resource-limited countries.[8] Late presentation of the disease coupled with lack of modern therapeutic facilities such as laparoscopy and mesh are among the hallmarks of the disease in developing countries.[8,9]

Since Bassini published his original description of inguinal hernia repair in 1887, many techniques for hernia repair such as Shouldice, Darning, Desarda, Modified Bassini, Lichtenstein mesh repair and the more recent laparoscopic repair have been published.[4,5] Laparoscopic and Lichtenstein mesh repair are becoming popular in recent days[10] as they are associated with rapid return to normal activities with low recurrence rates.[11]

The concept of hernia repair underwent a sea change with the introduction of monofilament knitted polyethylene plastic mesh in 1958[12] and later in 1962 of knitted, malleable PPM[13] Prolene mesh. American surgeon Francis Usher fabricated and developed both the materials. His innovations paved the way for advances that are accepted without question today. PPM remains most popular both in open and laparoscopic surgery. However, the first popular nonmetallic mesh was a machine knitted polyester polymer called Dacron.

Emphasizing the Halstead principle of no tension, the Lichtenstein repair advocated the routine use of mesh in 1984. The prosthesis used to reinforce the weakened posterior inguinal wall is placed between the transversalis fascia and the external oblique aponeurosis and extends well beyond the Hesselbach triangle. Mesh implants do not actively shrink, but they are passively compressed

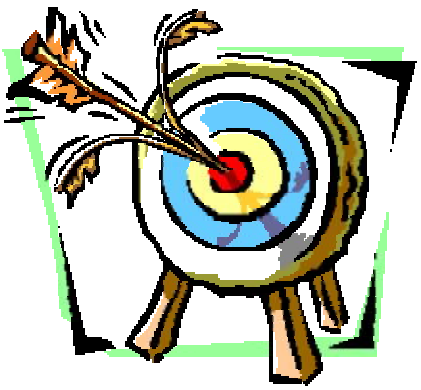
by the natural process of wound healing. Shrinkage of mesh occurs only to the extent to which the tissue contracts.[14]

The new prosthetic materials have significantly improved outcomes for many patients. Inguinal hernia repair historically was challenging and recurrence rates were high. To reduce the incidence of recurrence rate, Lichtenstein tension free mesh repair or similar procedures were introduced into open inguinal hernia. This showed a dramatic reduction in recurrence rates.[15] However, mesh fixation with sutures, to avoid dislocation has been reported in the literature as a cause of chronic pain and discomfort. According to the literature, perioperative nerve damage, postoperative fibrosis, and mesh related fibrosis are the main reasons for chronic groin pain.[16]

For decades, long-term analysis of results of hernia repair concentrated on post operative pain and recurrence rates. More recently however, several studies have focused on aspects of chronic pain and quality of life after hernia repair. However, mesh fixation with sutures to avoid dislocation has been considered as a cause of chronic pain and discomfort .Here we use a new self–gripping 3-D prosthesis for inguinal hernia repair, which does not require suture point fixation. Hence the study has been taken as an initiative to compare the post-operative pain after conventional Lichtenstein's meshplasty against Freedom proflor hernia repair.

Chapter 2

Objectives



OBJECTIVES

The objectives of the present study were to compare the incidence of postoperative pain following hernia repair with freedom proflor versus lichenstein mesh repair and to compare duration of surgery in freedom proflor mesh repair versus Lichtenstein mesh repair.

Chapter 3

Review of Literature

REVIEW OF LITERATURE

In 1804, Astley Cooper defined hernia as a protrusion of any viscus from its proper cavity. The protruded parts are generally contained in a sac-like structure, formed by the membrane with which the cavity is naturally lined.[17]

Approximately 96% of all groin hernias are inguinal hernias, with the remaining 4% being femoral. Hernias are bilateral in 20% of cases. The most common abdominal wall hernia is an inguinal hernia with a male to female preponderance of 9 to 1.[18]

Historical notes

The earliest data regarding inguinal hernia have appeared from the Ebers papyrus (approx. 1552 BC) and the mummy of Merneptah (1224-1214 BC), which shows possible remaining signs of hernia surgery.[19] Over the following centuries, several documents described the anatomy and treatment of inguinal hernias with both surgical and non-surgical methods. Results were generally poor as surgical ability was fragmentary or even non-existent. Most people therefore received no treatment at all or, at best, employed the use of a truss. It was not until the second half of the 19th century, together with the introduction of anaesthesia and antiseptic techniques, that hernia surgery evolved. Edoardo Bassini, revolutionized the treatment of inguinal hernia by introducing the 'Bassini's repair' in Padua, Italy.[20]

EMBRYOLOGY[21]

During the 6th week of gestation, mesoderm from the myotomes which lie on either side of the vertebral column invades the somatopleure (primitive wall of the abdomen). This area is occupied by the body stalk and the open midgut. The mesoderm forms a sheet like embryologic entity. After migrating laterally and ventrally, it differentiates to form the right and left rectus. Around 12th week, they approximate in the midline, closing the body wall. The lower abdominal wall is formed by a mesodermal layer, the so-called "secondary mesoderm". It envelops and invades the cloaca, thereby separating ectoderm from endoderm cranial to the cloaca. The embryology of inguinal canal is peculiar. In a highly synergistic way, the skin, parietal peritoneum, and embryologic and anatomic entities between them produce the future pathway of the testes. The skin will form the scrotum (scrotal folds) in male and labia (labial folds) in the female. The parietal peritoneum will produce the processes vaginalis. This peritoneal diverticulum is more important to the male fetus as it will permit the descent of the testes.

The processus vaginalis penetrate through embryologic entities between skin and peritoneum and form the inguinal canal, so the downward journey of the testicle to the scrotum is allowed. In girls, the descent of the ovary outside the peritoneal cavity is forbidden. The processus vaginalis finally closes to obstruct ovarian exodus but leaves the formation of the inguinal canal in-situ.

The vaginal process caries extensions of the layers of the abdominal wall before it, which form the walls of the inguinal canal. In males, these layers also

form the coverings of the spermatic cord and testes. The opening in the transversalis fascia, produced by the vaginal process becomes the deep inguinal ring and the opening created in External oblique aponeurosis forms the superficial inguinal ring.[22]

SURGICAL ANATOMY[22-26]

The extent of the anterior abdominal wall is from the costal margins and xiphoid process superiorly to the iliac crests, pubis and pubic symphysis inferiorly. The groin is a portion of the anterior abdominal wall below the level of the anterior superior iliac spines. Anterior abdominal wall tissues form the inguinal canal that connects the abdominal cavity to the scrotum in men, or the labia majora in women.

Soft tissue of the anterior abdominal wall

Superficial fascia

The superficial fascia of the abdominal wall lies between the skin and muscles of anterior abdominal wall. In the lower part, the fascia differentiates into superficial layer (camper's fascia) and deep membranous layer (scarpa's fascia) between which lie superficial vessels and nerves and, in the groin region, superficial inguinal lymph nodes.

a) Camper's fascia is thick, areolar in nature and contains variable amount of fat and is often greatly thickened in obese individuals. Inferiorly, it lies superficial to inguinal ligament and is continuous with superficial fascia of thigh, and the outer layer of fascia covering the perineum, penis and

scrotum. In this region, it is generally thin with very little adipose tissue and in the scrotum contains smooth muscle fibres, which form the dartos muscle. In females, it continues from the suprapubic skin of the abdomen into the labia majora and perineum.

b) Scarpa's fascia contains more elastic fibres and is loosely connected by areolar tissue to the aponeurosis of external oblique muscle, but in the midline it is adherent to linea alba and pubic symphysis. In males, it extends to form superficial ligament of the penis and continues medially and inferiorly over penis and scrotum where it becomes continuous with membranous layer of the superficial fascia of the perineum.

Transversalis fascia

It is a thin layer of connective tissue lying between the inner surface of transversus abdominis and extraperitoneal fat. In the inguinal region, it is thick and dense, and augmented by the aponeurosis of transversus abdominis muscle. Medial to the femoral vessels it is thin and fused to pubis behind conjoint tendon. Some fibres spread laterally towards the anterior superior iliac spine, some fibres run medially behind rectus abdominis, and some descend to pubis behind conjoint tendon, forming deep crural arch. The curved fibres of this arch thicken the inferomedial part of the rim of the deep inguinal ring. The spermatic cord in male, or the round ligament of uterus in female, pass through the transversalis fascia at the deep ring. The transversalis fascia spreads onto these structures as the internal spermatic fascia surrounding the testes and blends with areolar tissue on the parietal layer of tunica vaginalis.

Superficial vessels

The anterior abdominal wall receives its blood supply from paired superior epigastric artery (terminal branch of internal thoracic artery), and inferior epigastric artery (from the external iliac artery posterior to inguinal ligament) running vertically through the tissues, and from paired posterior intercostal, subcostal and lumbar vessels running obliquely around the anterolateral aspects of the abdomen.

The other vessels are the superficial circumflex iliac and external pudendal vessels which arise from femoral artery. All the arteries are accompanied by their respective veins and form tributaries to the femoral vein.

Lymphatic drainage

The lymphatic vessels lie both superficial and deep to the deep fascia. Superficial lymphatics from the infra-umbilical region run with the superficial epigastric vessels and vessels from lumbar and gluteal regions run with the superficial circumflex iliac vessels and drain into the superficial inguinal nodes.

The deep lymphatic vessels accompany the deep arteries. The vessels from the posterior part of the abdominal wall run with the lumbar arteries to drain into lateral aortic and retro-aortic nodes. Vessels from upper abdominal wall run with superior epigastric vessels to drain into the parasternal nodes. Vessels of the lower abdominal wall drain into circumflex iliac, inferior epigastric and external iliac nodes.

Innervation

The 7^{th} to 12^{th} lower thoracic ventral rami run anteriorly from the intercostal spaces into the abdominal wall. The rectus muscle and external oblique are supplied by lower intercostal and subcostal nerves (T7 – T12), and the internal oblique and transverses by those same nerves with the addition of iliohypogastric and ilioinguinal nerves (L1). The ilio-inguinal nerve accompanies the spermatic cord and runs through the superficial inguinal ring, to supply the medial thigh proximal to the inguinal ligament, the root of the penis and upper anterior scrotum. In the female, the nerve exits the superficial ring to supply the mons pubis and labium majora. Iliohypogastric nerve has some fibres in common with subcostal and ilioinguinal nerve.

The genitofemoral nerve emerges onto the anterior surface of psoas major muscle and its genital branch exits the pelvis via the deep inguinal ring and courses with the spermatic cord, supplying the cremaster muscle. The femoral branches of the genitofemoral nerves (L1, L2) pass under the inguinal ligament, travel across the thigh lateral to the saphenous opening, and then travel a short distance in the femoral sheath to supply the skin overlying it.

Inguinal canal

This is an oblique passage in the lower part of the anterior abdominal wall situated just above the medial half of inguinal ligament. It is about 4 cm long lying above the medial half of inguinal ligament. Its size varies with age, and although present in both sexes, is well developed in males. It extends from the

deep inguinal ring, to the superficial inguinal ring. The ilioinguinal nerve passes through the inguinal canal in both the sexes.

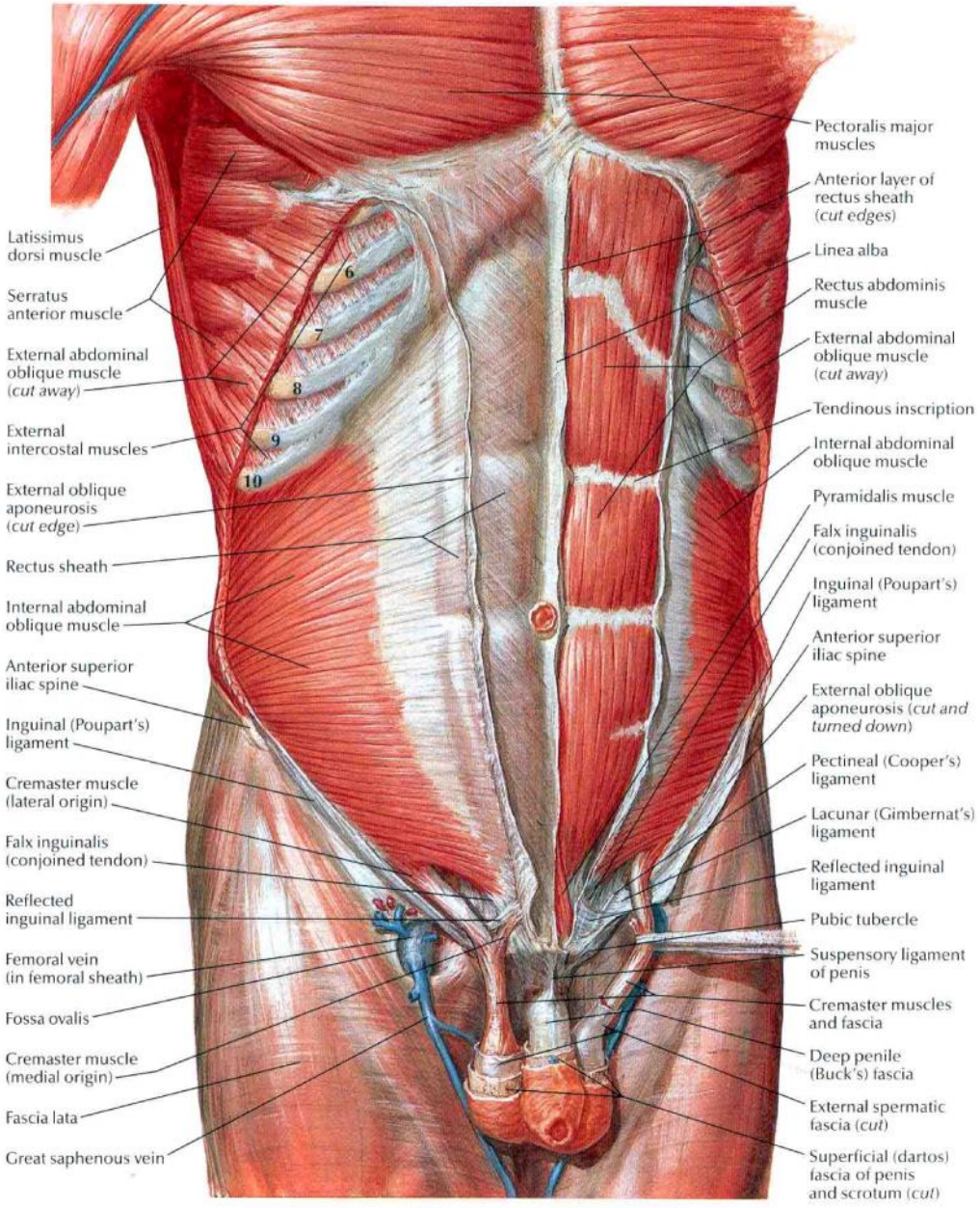


Figure 1. Muscles of the anterior abdominal wall.

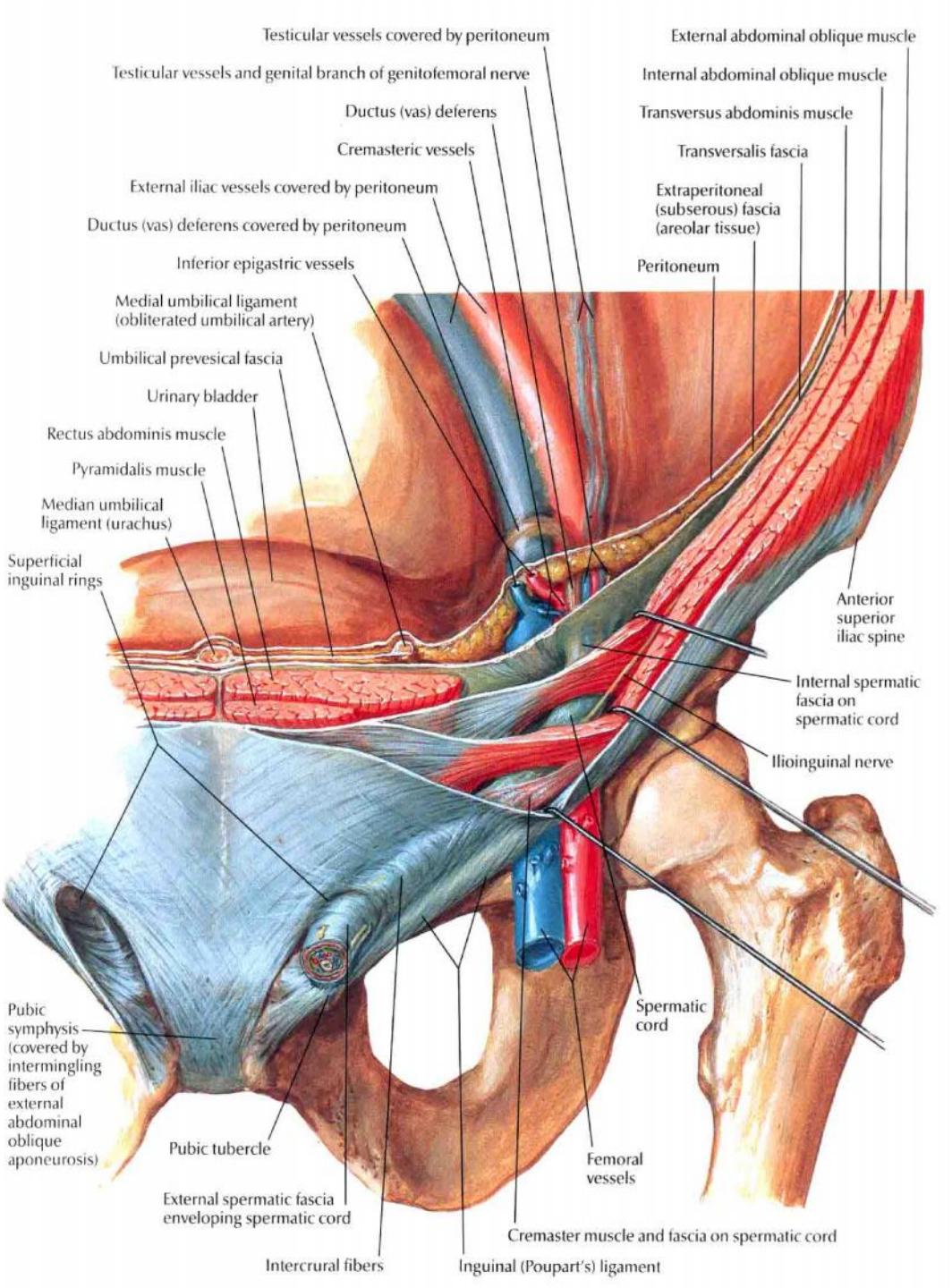


Figure 2: Inguinal canal in the male.

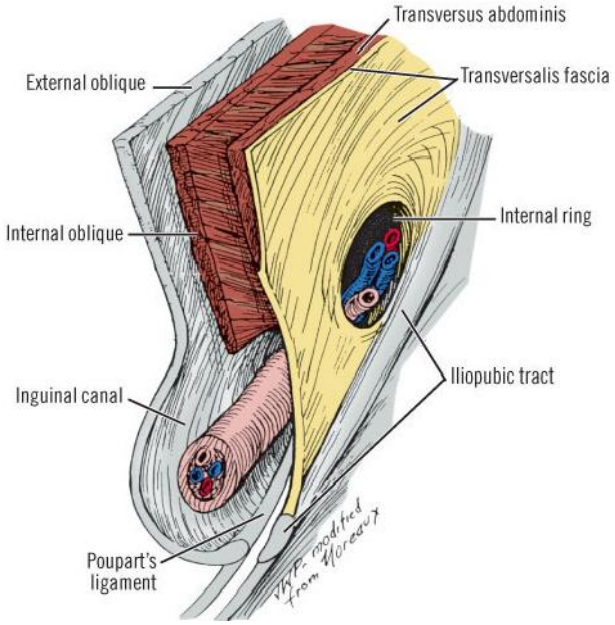


Figure 3: Parasagittal section through right mid-inguinal region, illustrating separation of musculoaponeurotic lamina into anterior and posterior inguinal walls.

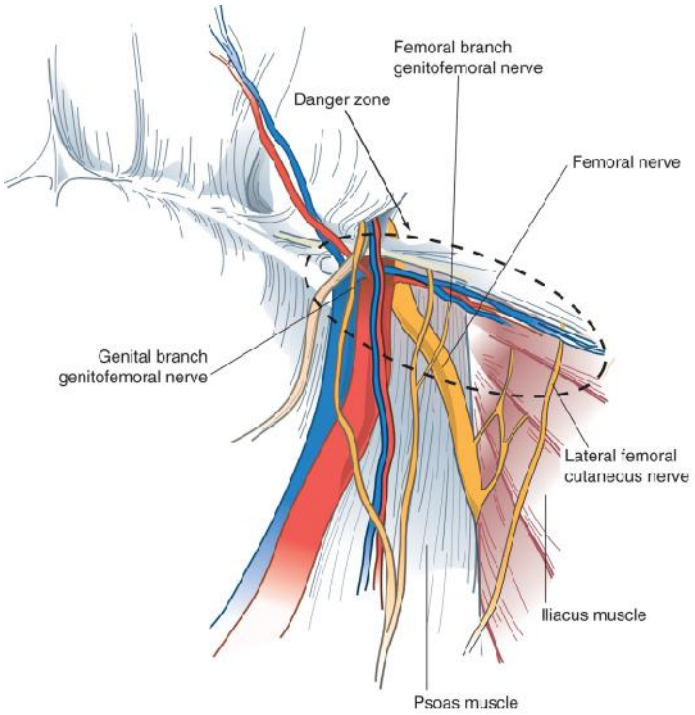


Figure 4: Important nerves and their relationship to the inguinal structures(right side).

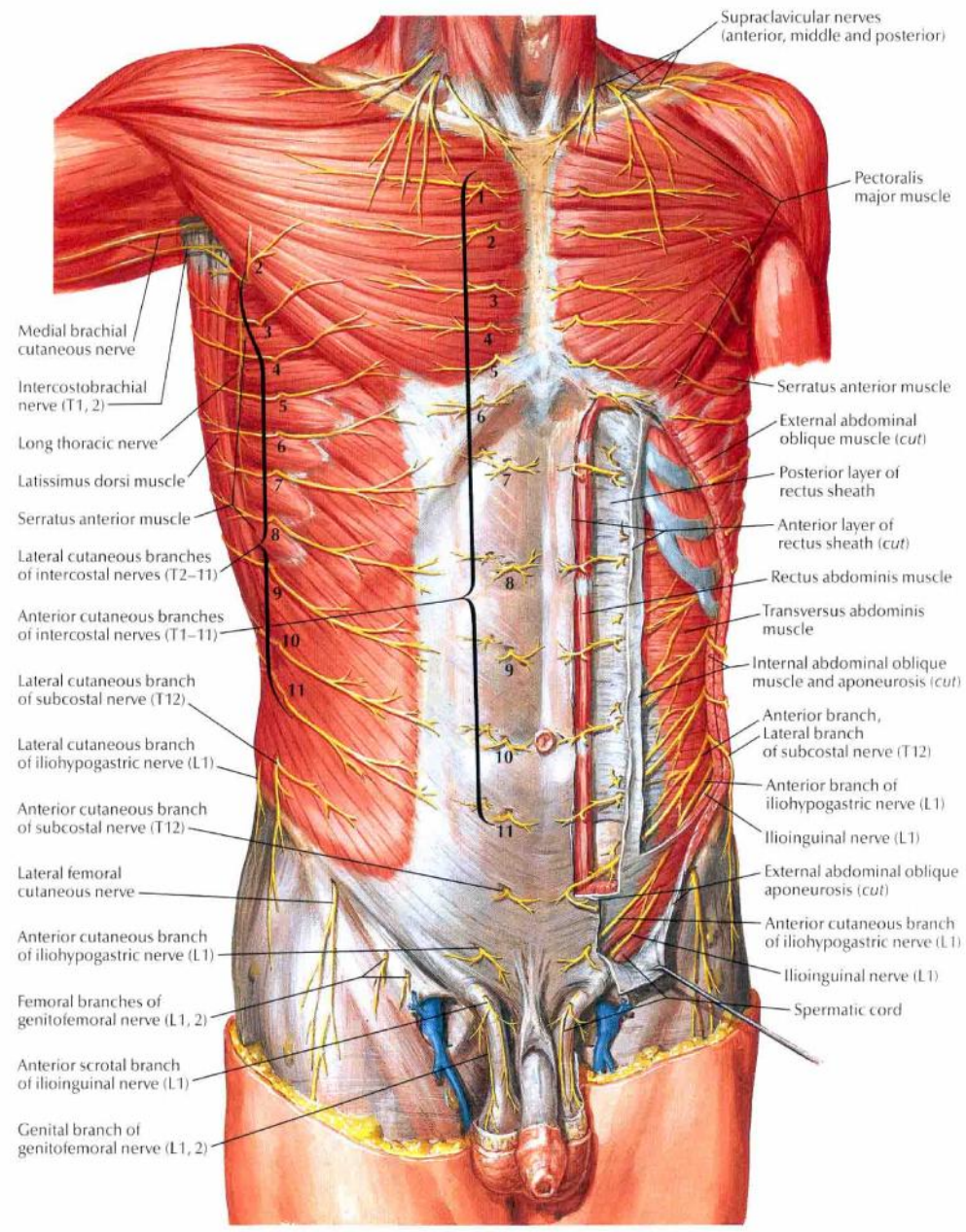


Figure 5. Nerve supply of the anterior abdominal wall in the male.

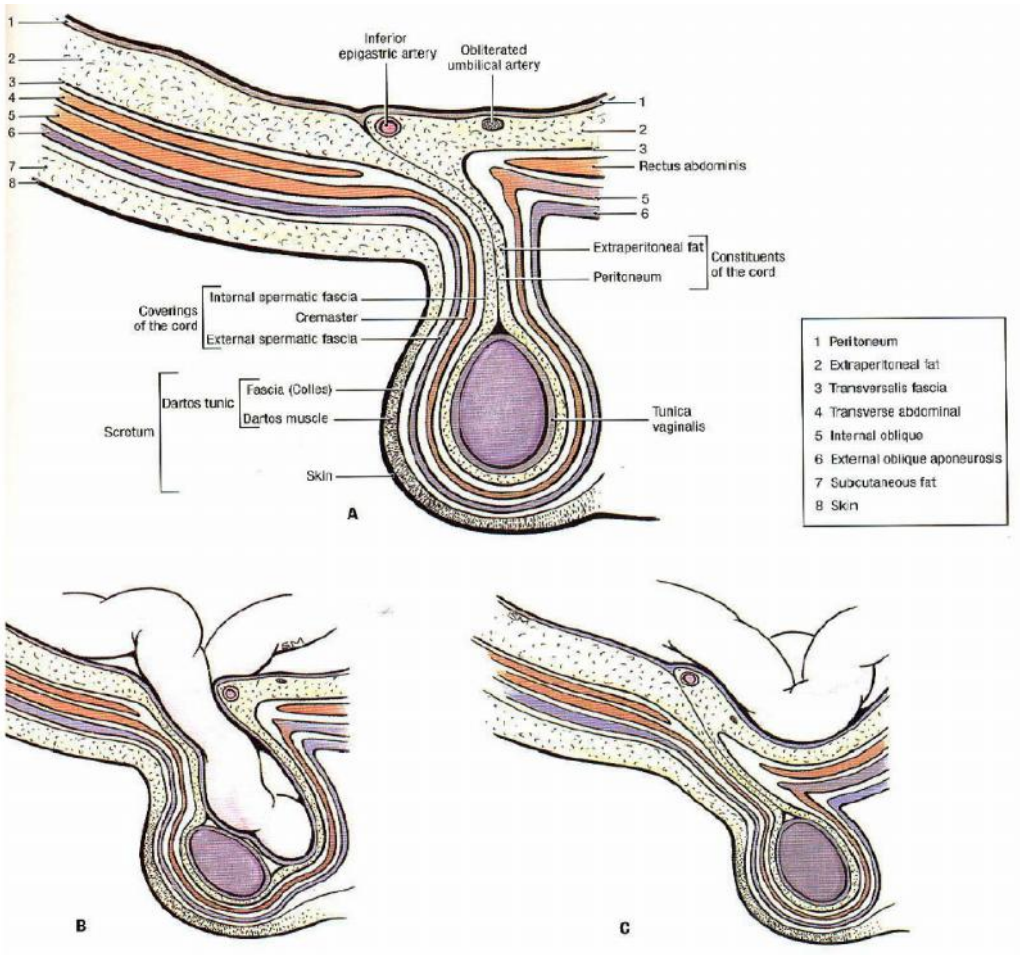


Figure 6: Labeled diagrams: A-Coverings of spermatic cord and testes; B-Indirect inguinal hernia; C-Direct inguinal hernia.

Superficial inguinal ring

It is a triangular gap in the external oblique aponeurosis, which lies above and lateral to the public crest. Its apex pointing along the line of the deep fibres of the aponeurosis. The base lies along crest of the pubis and its sides are the crura. The lateral crus is stronger and is reinforced by fibres of the inguinal ligament inserted into the pubic tubercle. The medial crus is thin and attached to the pubis symphysis and interlace with fibres from the opposite side. A few fibres arch over the apex of the ring as intercrural fibres. In males, the lateral crus is curved to form a groove in which the spermatic cord vests.

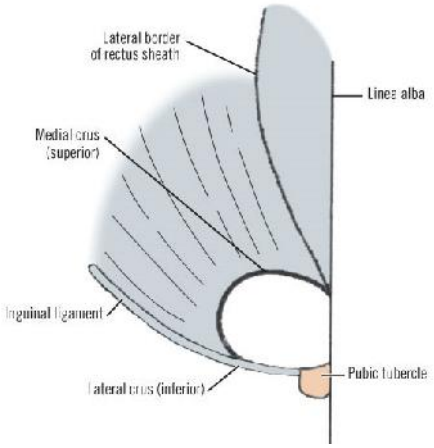


Figure 7: Diagrammatic representation of the external inguinal ring

Deep inguinal ring

It is an oval opening in the fascia transversalis, located midway between the anterior superior iliac spine and symphysis pubis approximately 1.25 cm above the inguinal ligament. It is bounded, above and laterally, by the arched lower margin of the transversalis fascia; below and medially, by the inferior epigastric vessels.

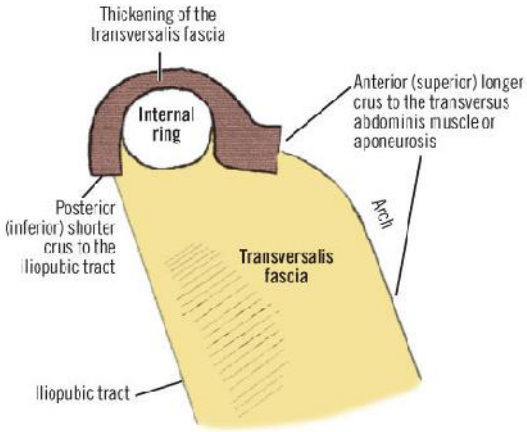


Figure 8: Surgical anatomy of the internal inguinal ring

Boundaries of the inguinal canal

Anterior wall

The inguinal canal is bounded anteriorly by the skin, superficial fascia and the aponeurosis of the external oblique. In the lateral one-third, the anterior wall is reinforced by the muscular fibres of internal oblique muscle just above the origin from the inguinal ligament.

Posterior wall

Medially the posterior wall consists of a strong conjoint tendon, formed by internal oblique muscle and transversus abdominis muscle. Lateral to the conjoint tendon, lies the transversalis fascia and reflected part of the inguinal ligament, which separate the inguinal canal from extraperitoneal connective tissue and peritoneum. Laterally the transversalis fascia in the posterior wall is

strengthened by the tendinous muscle fibres derived from transverse abdominis muscle constituting the interfoveolar ligament.

Roof of the canal

This is formed by the arched fibres of internal oblique and transverse abdominis muscles. The fleshy fibres of internal oblique arise from lateral two thirds of the inguinal ligament. The fibres that arise from the inguinal ligament continues as a aponeurosis that is attached to the crest of the pubic bone, and laterally, to the pectineal line.

Floor

It is formed by the union of the transversalis fascia with the inguinal ligament and medially by the lacunar ligament. The lacunar ligament is a thick triangular band of tissue lying posterior to medial end of inguinal ligament. It is formed from fibres of medial inguinal ligament and fibres from the fascia lata of thigh. The inguinal fibres run posteriorly and laterally to the medial end of the pectineal line and are continuous with the pectineal fascia. The apex of the triangle is attached to the pubic tubercle.

A strong, fibrous band, the pectineal ligament of Astley cooper extends laterally along the pectineal line. Fibres from the fascia lata join the inferior posterior border of the inguinal ligament; the latter, in combination with fibres from the transversalis fascia, fuses with the pectineal fasica as it joins the thickened periosteum of the pectineal line.

Relations

The inferior epigastric vessels lie posterior to the inguinal canal medially. They lie on the transversalis facia, as they ascend obliquely behind the conjoint tendon and pass posterior to the rectus sheath.

The Hesselbach's triangle is bounded inferiorly by medial half of inguinal ligament, medially by lower lateral border of rectus sheath and laterally by inferior epigastric artery. A hernial sac passing lateral to the artery (i.e. through the deep ring) is an indirect hernia, one passing medial to the artery through the Hesselbach's triangle is a direct hernia.

Fruchaud's myopectineal orifice

This area in the groin is bounded as follows

Superior:	Arch of internal oblique muscle and transversus abdominis muscle
Inferiorly:	Pecten pubis
Medial:	Lateral border of rectus muscle and its anterior lamina
Lateral:	Iliopsoas muscle

All the hernias of the groin begin within the groin through this myopectineal orifice.

Spermatic cord

The spermatic cord begins in the preperitoneal space with the confluence of testicular artery and vein and ductus deferens, traversing through the deep inguinal ring. Three coverings of spermatic cord from inside out are:

1. Internal spermatic fascia – derived from the fascia transversalis at the deep inguinal ring.
2. Cremaster muscle and cremasteric fascia – It arises from the internal oblique and transverse abdominis muscle. The fibres spiral down the cord and loop back to get attached to public tubercle.
3. External spermatic fascia – derived from the external oblique aponeurosis as the cord passes between the crura of the superficial ring.

The cremaster muscle can elevate the testes forwards or even into the inguinal canal; though the fibres are skeletal, the action is reflex rather than voluntary. This cremasteric reflex is particularly active in infants and children and must be kept in mind when examining the scrotum in young to avoid a misdiagnosis of an undescended testis. The contents of the cord;

1. The Ductus deferens, lies in the lower and posterior part of the cord.
2. Arteries – Testicular artery, artery to duct, and the cremasteric artery.
3. Veins – pampiniform plexus of veins, cremasteric veins, veins of ductus deferens.
4. Lymphatics – especially those from the testis draining to para-aortic and interaortocaval lymph nodes, but some from the coverings of the cord draining into external iliac nodes.

5. Nerves – genital branch of genitofemoral nerve supplying the cremaster muscle. Other nerves are sympathetic twigs which accompany the arteries.
6. Processus vaginalis –this is the obliterated remains of the peritoneal connection with the tunica vaginalis of the testis. If patent it forms the sac of an indirect inguinal hernia.

Mechanisms which prevent hernia in inguinal region[27]

The defensive mechanisms which prevent hernia to occur are -

1) The obliquity of the inguinal canal - When there is rise in intrabdominal pressure, the posterior wall is apposed against the anterior wall and thus prevents coming out of the abdominal content, through inguinal canal.
2) The shutter mechanism - The arched fibers of the internal oblique and the transverse abdominis will bring down these muscles towards the floor, when they contract during the rise of intra abdominal pressure.
3) The ball valve action of cremaster muscle - Cremaster pulls up the spermatic cord into the canal, which plugs it during a rise in intra abdominal pressure.
4) In floor of deep inguinal ring, there are strong fibers of internal oblique muscle; these prevent entry of the any abdominal contents through deep inguinal ring.
5) The strong conjoint tendon in front of Hesselbach's triangle prevents direct inguinal hernia.

EPIDEMIOLOGY

We found that 97% of all groin hernia repairs were inguinal hernias and 3% femoral hernias. Data showed that inguinal hernia surgery peaked during childhood and old age, whereas femoral hernia surgery increased throughout life[28]. More than 1 million abdominal wall hernia repairs are performed each year, with inguinal hernia repairs constituting nearly 770,000 of these cases.[29,30] Approximately 25% of males and 2% of females have inguinal hernias in their lifetimes representing the most common hernia in males and females.[18] Approximately 75% of all hernias occur in the groin; two thirds of these hernias are indirect and one third direct.[31] Indirect inguinal hernias are the most common hernias in both men and women; a right-sided predominance exists. Incisional and ventral hernias account for 10% of all hernias.[32] Only 3% of hernias are femoral hernias. The incidence of inguinal hernias in children ranges up to 4.5%, while umbilical hernias occur in approximately 1 out of every 6 children.[30,31] Data from developing countries is limited, therefore, an accurate occurrence value is unavailable. Current epidemiologic assessments postulate that gender and anatomic distribution are similar. However, inguinal hernia repair is one of the most common operations performed by general surgeons.

Classification and symptoms of hernia in the groin

There are several classifications for groin hernias but the most commonly used is based on the anatomy of the hernia. Within this simple classification, there are three groups of hernias in the groin. A medial or direct hernia is one that protrudes medially to the epigastric artery and above the inguinal ligament. A lateral or indirect hernia protrudes laterally to the epigastric artery, above the inguinal ligament. A femoral hernia protrudes just below the inguinal ligament medial to the femoral vein.

The term inguinal hernia refers to the direct and indirect variety, but excludes the femoral hernia. Although the femoral hernia is regarded as a separate entity, in the clinical situation it is usually considered together with the direct and indirect inguinal hernias. This is because it is situated in almost the same anatomical region. During clinical examination it is often difficult to differentiate between an inguinal hernia and a femoral hernia, especially in women. The two terms inguinal hernia and groin hernia are often wrongly used as synonyms. The groin hernias can also be divided into primary and recurrent hernias. Depending on the findings during the clinical examination hernias can be divided into reducible and irreducible. In an irreducible hernia the contents of the hernia sac cannot be reduced into the abdomen.

The irreducible hernias can be acute (incarcerated) or chronic (accreta). The irreducible acute hernia is called strangulated in two different situations, i.e. when the content of an incarcerated hernia is deprived of its vascular blood flow and becomes ischemic or when an incarcerated intestine becomes obstructed.

NYHUS classification[33]

Type I – Indirect hernia with an internal ring of normal size, configuration, and structure. The hernial sac is contained within the inguinal canal and the floor is intact.

Type II – Indirect hernias characterized as having an enlarged and distorted internal ring, without disruption or encroachment into the direct floor of the inguinal canal. The sac can occupy the entire inguinal canal but does not extend into scrotum.

Type III

III A – contains all direct hernias wherein "the protrusion does not herniate through the internal ring".

III B – Large indirect hernias where the defect has expanded medially and encroaches on posterior inguinal wall or direct floor. The sac is inguino-scrotal in size.

III C – Hernias consist of femoral hernia that emerges through the femoral ring.

Type IV – Recurrent hernias

IV A – Direct

IV B – Indirect

VI C – Femoral

VI D – Combination of A, B and C.

Modified Gilbert's classification[34]

Type 1: indirect inguinal hernia, tight internal ring through which passes a peritoneal sac of any size

Type 2: Indirect inguinal hernia, moderately enlarged internal ring that measures no more than 4 cm

Type 3: Indirect inguinal hernia, patulous internal ring of more than 4 cm

Type 4: direct inguinal hernia, essentially the entire floor of the inguinal floor is defective

Type 5: Direct inguinal hernia, diverticular defect of no more than 1 cm or 2 cm in diameter

Type 6: Both indirect and direct inguinal hernia (Pantaloon hernia)

Type 7: Femoral hernia

Halverson and MCVAY classification

Small indirect

Medium indirect

Large indirect & direct

Femoral

Combined – any mixture of above

HISTORY AND PRESENTATION

The patient presents with a lump in the groin that goes away with minimal pressure applied over the lump or when the patient is lying down. Most cause mild to moderate discomfort that increases with activity. A third of patients scheduled for surgery have no pain, and severe pain is uncommon (1.5% at rest and 10.2% on movement).[35,36]

Many hernias present as an asymptomatic swelling in the groin. The patient complains of a dragging or aching type of pain in the groin. This is often noticed when there is a tendency for a hernia to develop, so the pain appears long before lump is noticed. When a hernia becomes very painful and tender, it is probably strangulated. If the hernia is obstructing the lumen of the bowel (incarcerated hernia), the cardinal symptoms of intestinal obstruction will appear, colicky abdominal pain, vomiting, abdominal distension and absolute constipation. The causes of hernia may be present like, whooping cough or chronic bronchitis, dysuria due to BPH or urethral stricture and with the past history of appendicectomy, previous hernia repair.

Physical findings

The physical examination should be performed with the patient in both the supine and standing positions, both with and without the Valsalva maneuver. The examiner should attempt to identify the hernia sac as well as the fascial defect through which it is protruding. The examiner should also look for any evidence of obstruction or strangulation.[37]

1) **Position and Extent –** When the hernia is confined to the groin, it should be differentiated from femoral hernia. An inguinal hernia is positioned above the inguinal ligament and lateral to the pubic tubercle, whereas femoral hernia lies below the inguinal ligament and lateral to pubic tubercle.

2) **To get above the swelling –** This examination differentiates a scrotal swelling from an inguino-scrotal swelling. In case of inguinal hernia one cannot get above the swelling, whereas in case of pure scrotal swelling one can get above the swelling.

3) **Consistency –** If the inguinal hernia contains omentum the swelling feels doughy and granular. If it contains intestine it feels elastic. A strangulated hernia feels tense and tender.

4) **Impulse on coughing –** This is a classical sign of an uncomplicated hernia.

5) **Reducibility –** This is another classical sign of an uncomplicated hernia

6) **Invagination test –** After reduction of hernia one can perform this test. If the palpable impulse is felt on the pulp of the finger then it is a direct hernia and if impulse is felt on the tip it is an indirect hernia.

7) **Ring occlusion test** – This is done after occlusion of the deep inguinal ring, (1/2 inch above the mid-point between the anterior superior iliac spine and the symphysis pubis) the direct hernia will show a bulge medial to occluding finger but an indirect hernia will show no bulge on coughing.

8) **Zieman's technique**[38]– The index finger is placed over the deep inguinal ring (1/2 inch above the mid-inguinal point, which is the midpoint between anterior superior iliac spine and symphysis pubis), the middle finger over the

superficial inguinal ring and the ring finger over the saphenous opening (4 cm below and lateral to the pubic tubercle). This technique can only be applied when there is no obvious swelling or after the hernia has been completely reduced. The patient is asked to cough. When impulse is felt on the index finger the case is one of indirect hernia, when impulse is felt on the middle finger the case is one of direct hernia and when it is felt on the ring finger the case is one of femoral hernia.

ETIOLOGY

Any condition that increases the pressure in the intra-abdominal cavity may contribute to the formation of a hernia, including the following:

- Marked obesity
- Heavy weight lifting
- Coughing
- Straining with defecation or urination
- Ascites
- Chronic obstructive pulmonary disease (COPD)
- Family history of hernias

INVESTIGATIONS

Routine investigations like complete blood counts, urine examination, blood sugars and renal function tests.

Ultrasonography

- Ultrasonography can be used in differentiating masses in the groin or abdominal wall or in differentiating testicular sources of swelling.
- If an incarcerated or strangulated hernia is suspected, the following imaging studies can be performed:
    - Upright chest radiograph to exclude free air (extremely rare)
    - Flat and upright abdominal films to diagnose a small bowel obstruction.

MANAGEMENT

Non operative management

Fitzgibbons and colleagues recently reported the first prospective randomized trial of a watchful waiting strategy for patients with asymptomatic or minimally symptomatic inguinal hernias.[40] These investigators randomized more than 700 men to either a watchful waiting or open tension-free hernia repair. The risk for hernia incarceration in the watchful waiting group was extremely low at 1.8 per thousand patient-years, or 0.03% of study participants. This study provides conclusive evidence that a strategy of watchful waiting is safe for elderly patients with asymptomatic or minimally symptomatic inguinal hernias, and that even though almost 25% of patients eventually undergo repair, when they do, the

operative risks and complication rates are no different than those of patients undergoing prophylactic repair.

Patients electing non-operative management can occasionally have symptomatic improvements with the use of a truss. This approach is more commonly used in Europe. Correct measurement and fitting are important. Hernia control has been reported in about 30% of patients. Complications associated with the use of a truss include testicular atrophy, ilioinguinal or femoral neuritis, and hernia incarceration.

Operative Management

Surgery is the treatment of choice varying from a nylon darn, Shouldice layered, Lichtenstein mesh to a laparoscopic repair. The optimal repair has been assessed by randomized clinical trials and population based studies.[37]

Indications

Surgery is the only curing treatment for an inguinal hernia. Hernia symptoms in patients that cannot be operated on, due to poor health or an unwillingness to be operated on, can sometimes be reduced by a hernia bandage (truss). The only important reason to operate an asymptomatic inguinal hernia is to reduce the risk of strangulation. In men this risk is low but since that risk is considerably higher in women, due to the higher frequency of and often misdiagnosed femoral hernias, it is often recommended that women with inguinal hernias are operated upon. On the other hand many patients who undergo an

emergency operation due to a strangulated hernia do not know that they have a hernia or in case they know, this has not bothered them at all.

Repair techniques:

Anterior repairs

Inguinal hernia surgery can at least be traced back to Alexandria 300 BC. At that time the anatomical knowledge was limited and the surgical techniques seem to have included closing of the hernial sac with or without removing the ipsilateral testis. 150 years ago the surgical repairs were performed subcutaneously including ligation of the sac, narrowing of the external opening and reinforcement of the anterior wall. The recurrence rates were depressingly high, almost 100%. Many authorities stated that hernia surgery should not be performed. Technical improvements like better sutures together with improved anatomical knowledge as well as new anaesthetic and antiseptic methods helped introducing “modern” repair techniques for inguinal hernia surgery. Between 1870 and 1900 a lot of new repair methods were introduced, often accompanied with very promising results.

Sutured repairs

Henry O. Marcy[41] described the Marcy repair in its initial form in 1871 who also promoted the aseptic technique in surgery. It consists of high ligation of the hernial sac and narrowing of the deep ring. Nowadays the technique is used for lateral hernias in children and in growing youths.

The Bassini's repair

Eduardo Bassini Initially reported in 1887[42]. A large monograph was published two years later in Italian[43] on his technique which included many beautiful pictures, but the method gained wide recognition when his monograph was translated to German and republished[44] again in 1890. Dissection of the inguinal canal, defining of the hernial sac, high ligation in case of a lateral sac and incision of the posterior floor were essential. Reconstruction of the posterior floor was then done by interrupted nonreabsorbable suturing of the internal oblique muscle, the transverse abdominis and the transverse fascia to the iliopubic tract and the inner parts of the inguinal ligament.

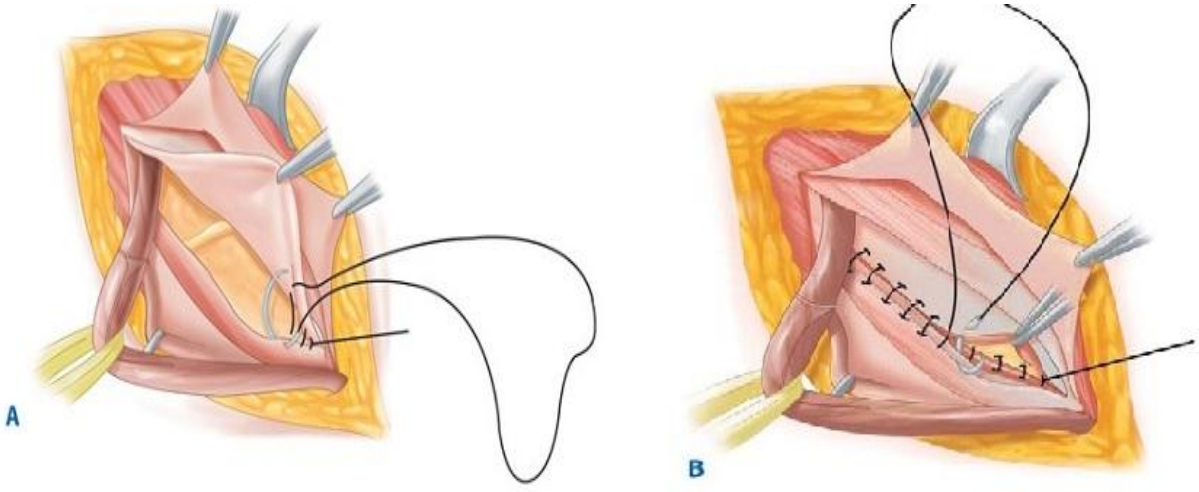
The Halsted procedure

William S. Halsted described this method in 1889. In many aspects it was performed like the Bassini method but the cord excised of its superficial veins and transposed to a position above the external oblique aponeurosis. He later modified his method and omitted the transposition of the cord and instead covered it with both the internal and external oblique muscles. After at least four years of follow-up, recurrence rate was 4%.

Shouldice repair[45,46]

The Shouldice technique is the most popular pure tissue hernia repair. In this technique the transversalis fascia is incised from the deep inguinal ring to medially as far as possible near pubic tubercle. The first layer of repair begins at the pubic tubercle where the iliopubic tract is sutured to the lateral edge of the

rectus sheath, then progressing laterally. The inferior flap of the transversalis fascia, which includes the iliopubic tract, is sutured continuously to the posterior aspect of the superior flap of the transversalis fascia until the internal ring is encountered. The suture is not tied here, but rather is continued back upon itself in the medial direction. At the internal ring, the second layer is the re-approximation of the superior edge of the transversalis fascia to the inferior fascial margin and the shelving edge of the inguinal ligament. The suture is then tied to the tail of the original stitch. A third suture is started at the tightened inguinal ring, joining the internal oblique and transversus abdominis aponeuroses to external oblique aponeurotic fibers just superficial to the inguinal ligament. This layer is continued to the pubic tubercle where it reverses upon itself to create a fourth suture line.



The Shouldice repair. **A.** The iliopubic tract is sutured to the medial flap, which is made up of the transversalis fascia and the internal oblique and transverse abdominis muscles. **B.** This is the second of the four suture lines. After the stump of the cremaster muscle is picked up, the suture is reversed back toward the pubic tubercle approximating the internal oblique and transversus muscles to the inguinal ligament. Two more suture lines will eventually be created suturing the internal oblique and transversus muscles medially to an artificially created "pseudo" inguinal ligament developed from superficial fibers of the inferior flap of the external oblique aponeurosis parallel to the true ligament.

Figure 9: Shouldice repair

The McVay hernioplasty

Georg Lotheissen first described this technique in 1898[47] but described again and popularized by Chester B. McVay[48] in 1941. The posterior wall was repaired by interrupted suturing. Medially the rectus sheet was adapted to Cooper's ligament and laterally the transversalis fascia was adapted to the femoral sheath. By this both the femoral and the internal ring were narrowed. McVay recommended the use of this method for medial, femoral, large lateral and recurrent hernias. He reported a recurrence rate of less than 1% after 1-11 years of follow-up.[49]

The Lichtenstein hernioplasty

Irving Lichtenstein introduced the term tension-free hernioplasty[50] in the year 1986 and in 1987 he published a personal series of more than 6000 repairs[51] reporting a recurrence rate of 0.7%. At that time he recommended invagination of an indirect hernia sac and suturing of the transversus abdominis aponeurosis to the inguinal ligament including narrowing of the internal opening medially to the cord and in case of a direct or recurrent hernia the posterior wall should also be reinforced by a mesh.

In 1989 Lichtenstein published his improved technique and nowadays often called original method[52] where he no longer performed a sutured repair of the posterior wall, he just reinforced it by bridging the defect with a mesh that was sutured with a continuous monofilament nonabsorbable suture. The method was further improved in the early nineties[53] with recommendations of larger, slightly relaxed mesh, medial mesh overlap, crossing and suturing of the tails of

the mesh lateral to the cord and only interrupted absorbable sutures on the upper edge of the mesh.

As all popular methods it has been further modified not only by Lichtenstein's successor Amid[54] but also by many other surgeons. An EHS guideline published in 2009, states that it can be advisable to close a large direct hernia defect of the posterior wall, tension-free with continuous absorbable sutures until a flat posterior wall has been created with a normal internal ring.

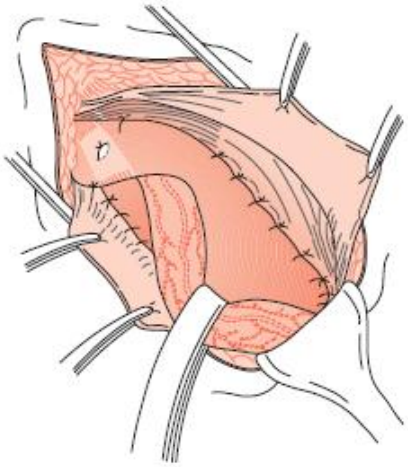


Figure 10: Lichtenstein repair.

Plug and Patch or Rutkow-Robbins technique

Alan Robbins and Ira Rutkow[55] described the plug technique in 1993. An umbrella shaped polypropylene plug was inserted into the hernia defect of the posterior wall acting as a sublay mesh and combined with an onlay flat mesh. They reported a recurrence rate of 1% for primary hernias on follow-up of upto to six years.

Open posterior mesh repairs

The Stoppa method[56]: The advantage of this operation is able to cure all types of hernias: primary as well as recurrences. In this technique the deep dissection of Bogros' space identifies femoral hernias and any structures passing through the obturator orifice. The concept of a large preperitoneal mesh overlapping the peritoneum has been outlined by Stoppa after Rives. But the so-called Stoppa operation by midline incision,this gave the surgeon access to the entire bilateral myopectineal orifice of Fruchaud and a large mesh could be inserted completely overlapping all inguinal and femoral orifices.

Nyhus modified posterior preperitoneal operation: Nyhus modified his original method[57] by applying a mesh in the preperitoneal space after repairing the defect in the transversalis fascia.[58] He recommended this procedure especially for recurrent hernias.

Endoscopic posterior mesh repairs IPOM (IntraPeritoneal Onlay Mesh): In 1992 Charles Filipi described a laparoscopic technique in which a mesh is placed intraabdominal, covering all inguinal and femoral orifices.[59]

TAPP (TransAbdominal PrePeritoneal repair): Maurice Arregui[60] described the method in 1992. By a transabdominal laparoscopic technique a preperitoneal mesh is placed covering all inguinal and femoral orifices.

TEP (Totally ExtraPeritoneal repair): by Jean-Louis Dulucq[61] described this technique in 1992. By the extraperitoneal laparoscopic technique a preperitoneal mesh is applied covering all inguinal and femoral orifices.

Tension – free hernioplasty using a bilayer prosthesis[62,63,64]

It is a bi-layer polypropylene device known as prolene hernia system (PHS), introduced in 1998 and is constructed in a three in one model. The inguinal canal is approached from an anterior approach after dividing the skin, Scarpa's fascia and the external oblique aponeurosis. The cord is examined for any indirect sac. In indirect hernias, sac is inverted and pocket created in the pre-peritoneal space. The underlay of the PHS is then deployed in the pre-peritoneal space. The onlay is secured by using 3 interrupted sutures to pubic tubercle, the conjoint tendon and the shelving edge of the inguinal ligament. A lateral slit is made in the mesh to accommodate the cord structures and to recreate the internal ring.

For direct hernias the attenuated transversalis fascia of the floor of the inguinal canal is opened and the hernia sac and contents reduced. The underlay of the PHS mesh is placed in the pocket created in the pre-peritoneal space and the onlay is sutured to the pubic tubercle, conjoint tendon and the shelving edge of the inguinal ligament.

Figure 11: Prolene Hernia System

Its underlay component is designed to protect the canal's posterior wall. Inferiorly it reaches beyond Cooper's ligament to protect the femoral triangle and superiorly it reaches well above the transverse arch, medially it reaches behind the pubic ramus and laterally it reaches to well beyond the internal ring. It is flat and pliable, and it covers and protects the entire myopectineal orifice. Its 2cm diameter connector will sit within the defect or internal ring. The onlay component of the device covers and protects the entire posterior wall. Laterally, it is positioned between the internal and external oblique muscles, and medially, it extends over the transverse arch and the pubic bone. It extends along the shelving edge of the inguinal ligament, protecting the entire Hesselbach's triangle.

Freedom proflor self retaining mesh technique

This is a new 3D ProFlor self-retaining implant has been developed by G Ameto from Italy. The 3D autostatic prosthetic device was specifically designed to be placed fixation free. This was achieved using its inherent radial recoil, vertical buffering and friction within the hernia edge. The absence of postoperative complications such as bleeding, chronic pain and discomfort could be interpreted as the effect of the fixation free implant placement. A secondary benefit of this "dynamic" design is that the implant moves in a three dimensional way in unison with the movements of the myotendineal structures of the groin. In conventional static meshes the loss of surface area induced by the shrinkage (sometimes up to 30%) is considered an important factor of recurrence.[65]

It achieved excellent outcomes in the porcine model[66], and demonstrated that the dynamic compliant movement and recoil of the 3D prosthetic structure within the groin's natural tissues allowed for the critical cyclical physiologic

loading that is missing with other implants. The use of this new 3D implant represented a faster and simpler surgical approach to inguinal hernia repair. The procedure was based on the centrifugal expansion of the device, whose design features converted ejection forces into gripping forces, and avoided the need for suturing the implant.

After opening the skin, subcutaneous tissue, externus aponeurosis, the cord was identified and the indirect sac if present was ligated and reduced inside. The fascia transversalis was opened and space created in the preperitoneal area posterior to fascia transversalis. This blunt dissection of the preperitoneal area was done with a finger or with the help of gauze to accommodate the placement of the preperitoneal disc of the freedom profor self retaining mesh. The implant was compressed with the thumb and forefinger and implant core was compressed with the applicator while the preperitoneal disk was fully deployed in extra peritoneal space. The freedom proflor self retaining mesh is available in two sizes of dynamic core (25mm and 40mm). Depending on the size of the defect appropriately sized proflor mesh was delivered into the opening of fascia transversalis with the applicator. The preperitoneal disk was spread into the preperitoneal space with the help of spatula. The cord is placed over it and external oblique aponeurosis was closed. The subcutaneous tissue and skin was closed.

Figure 12: Freedom Proflor mesh with delivery device

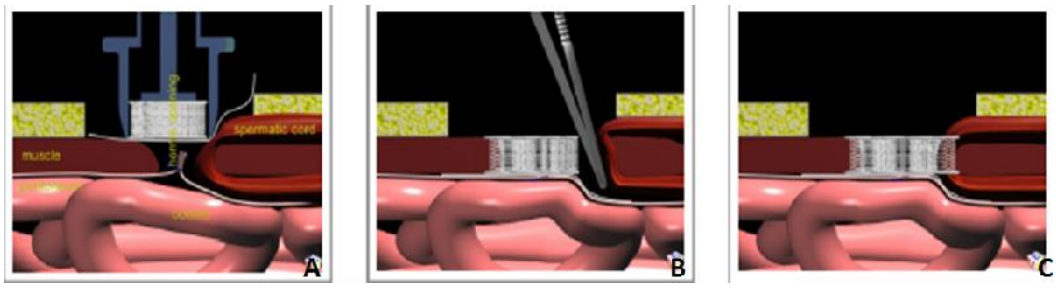


Figure 13: Proflor mesh repair

A) Deploying proflor mesh B) Spreading preperitoneal disc C) Implant holding the defect

The development of meshes

The polyester multifilament mesh Dacron (Mersilene) was the first popular synthetic mesh[67]. Polyethylene was developed in the fifties. In 1958 the use of polyethylene mesh (Marlex 50) in hernia surgery was first reported by Francis Usher.[68] In 1963 an improved version was introduced under the name of Marlex mesh (Bard). This was made of polypropylene. It was more temperature resistant, could be cut without frying and was two-way stretchable. Other similar products are nowadays sold under different names (Prolene mesh, Surgipro etc.). The use of polypropylene meshes in all sorts of hernia repairs has increased enormously during the last 50 years. When incorporated in the tissue, polypropylene mesh induces an inflammatory reaction. The resulting fibrosis that develops around the mesh helps enhancing the strength of the repaired tissue.[67,69]

Complications after inguinal hernia surgery

In surgery there are obvious technical complications during the operation like damage to the bowel, the structures of the spermatic cord and the vessels (the femoral vessels during fixing mesh). The estimated incidence of injury to the vas deferens is 0.3% in adult hernia repair[70]. Early postoperative complications after hernia repair include infection, severe pain, hematomas, seromas and post operative urinary retention. Late complications include post herniorraphy pain syndrome or inguinodynia, loss of sensation in the medial side of thigh, scrotum and recurrence of hernia. Chronic pain (inguinodynia) has probably been the most studied complication for the last 10 years. The prevalence of chronic pain affecting normal activities or work is 0.5-6%[58]. Nerve damage is proposed to be

the main reason for chronic pain.[70]Ejaculatory pain, genital pain, groin pain, pain related sexual impairment and erectile dysfunction.[71] are some sexual problems secondary to inguinal hernia

The mesh-induced foreign body reaction and the resulting fibrosis can give the patient a diversity of proven or suggested problems. These problems are partly related to the weight and the pore size of the mesh, to where the mesh is placed (anterior or posterior) and to the eventual fixation of the mesh. Among these problems are:[48]

- Foreign body sensation.
- Adherences to adjacent organs for example the bowel.
- Perforation of adjacent organs.
- Neuralgic pain due to induced fibrosis causing the entrapment of the adjacent nerves

Strangulation or obstruction of structures passing through or adjacent to the mesh due to induced fibrosis and mesh shrinkage, for example the structures of the spermatic cord.

Meshes and fixation

Theodor Billroth stated: "*if we could artificially produce tissues of the density and toughness of fascia and tendon, the secret for the radical cure of hernia would be discovered*".[73]Among those materials that have been tested are silver filigree in the late 19th century[74], homologic materials such as tendon from

kangaroo, whale, ox and deer, and autologic materials such as fascia lata and the aponeurosis of the rectus muscle. Biological materials have the disadvantage of undergoing complete phagocytic degeneration over time.

Metal meshes made of titanium and stainless steel have been abandoned due to fragmentation, fracturing, sinus formations and recurrences.[75] Nylon was first introduced by French surgeons in Marseille in 1944 and performed a hernia repair in method similar to the Lichtenstein technique. Other synthetic materials such as polyvinyl alcohol, Silastic, Teflon and carbon fibre have been tested but are no longer in use.[75]

During the last two decades of the 20th century, three synthetic meshes have mainly been used in the hernia repair: polypropylene, polyester and expanded polytetrafluoroethylene (e-PTFE). Polypropylene (Marlex®, Prolene®) was synthesized in 1954 and has been used for hernia repair since 1958.[70] Polyester (Mersilene®) was synthesized in 1939 and introduced into hernia repair in 1956.[76] Patented in 1976, e-PTFE (Gore-Tex®) has mainly been used for vascular prosthesis but to some extent also for hernia repair. The most commonly used material today is polypropylene, followed by polyester.

Whether a mesh should be fixed or not is debatable. In the original Lichtenstein repair the mesh was fixed with both interrupted stitches and a running suture of non-absorbable material (usually a prolene suture). The need for this has been questioned due to the risk of chronic pain. The use of an absorbable suture has not resulted in less chronic pain. Human fibrin glue for fixation seems effective, but the effect on chronic pain is still unclear. To

overcome this, the mesh can be left in place without fixation or it can be fixed with human fibrin glue. Both methods appear effective but their impact on chronic pain is unclear.[76]

The most novel method for fixation is a "self-gripping" mesh with micro hooks made of polylactic acid. This mesh is also semi-absorbable (polylactic acid) and is therefore also considered to be a lightweight mesh. This material has so far only been used in one published prospective trial including 52 patients with 70 hernias. The mesh was placed with an open technique in an anterior position. After 24 months, no recurrences were found and only one patient reported discomfort.[77]

Chronic pain

The IASP[78] provides one of the most referenced definitions of chronic pain. Chronic pain is that which persists beyond the normal time frame for healing, usually taken to be 3 months. The Clinical Standards Advisory Board for the National Health Service (NHS) defines chronic pain "as that which persists beyond the expected time frame for healing or that which occurs in disease processes in which healing may never occur".[79]

Portenoy categorized both acute and chronic pain as nociceptive, neuropathic or psychogenic.[80]Nociceptive pain is due to chronic activation of nociceptive afferent neurons and can be 3 somatic or visceral. In nociceptive pain and pain due to tissue inflammation, the sensory experience reflects the normal, adaptive functioning of the pain system.[81] Neuropathic pain is defined by the

IASP as pain initiated or caused by a primary lesion or dysfunction in the nervous system.[82]

Mesh repair brings with it the advantage of low recurrence rate (<5%) and is the most common method of repair.[83] There is less postoperative pain following mesh rather than sutured repair of an inguinal hernia.[84] One of the perceived disadvantages of this type of repair appears to be an increase in the reporting of post-operative pain (chronic pain or inguinodynia) and discomfort.[85]

In 1999 Callesen et al[86] published a prospective consecutive case series study that examined the incidence of chronic postoperative pain at one-year post elective day case local anaesthetic hernia repair. Pain was scored at rest, on coughing and at mobilization as none, mild, moderate and severe at one year and compared with data collected at one and four weeks post repair. Just fewer than 20% of patients reported some degree of pain at one year. The incidence of moderate to severe pain was higher after repair of a recurrent hernia. Those patients who complained of persistent pain at one year were more likely to have high pain scores at one week and four weeks post surgery. Thus they concluded that the intensity of early postoperative pain is a good predictor of long term chronic pain.

The Cooperative hernia study assessed postoperative pain in a prospective trial as part of a larger study looking at the recurrence rate and other morbidity of the Bassini, McVay and Shouldice repair. Just over three hundred patients were randomized to one of the repairs. At two years 50% of patients had some degree of pain and 10% had moderate to severe pain. They concluded that the predictors

of long term post operative pain include, absence of visible bulge preoperatively, numbness in the immediate postoperative period and the need for the patient to spend 36 weeks or more off work postoperatively.[87]

Intraoperative nerve damage and disposition to other chronic pain conditions are the most likely pathogenic factors. Chronic pain post inguinal hernia repair ranges from 0 – 63% and is usually broadly classified into three categories mild, moderate and severe. Severity may be determined by extent of interference with social, daily and work related activities, number of painkillers used and attendance at chronic pain clinics. Perkins looked at post herniorrhaphy pain in the context of their chronic pain model and estimated that it may be as high as 50% at one year.[88] They believe that the presence and extent of preoperative pain may influence the degree of postoperative pain. Some authors would argue that it is not imperative to repair all hernias as soon as they are detected. In the context of postoperative chronic pain there is a defined point where the surgeon must intervene, quantifying this point however is not clear. Repair of recurrent hernia and type of mesh used may be related to long-term chronic postoperative pain.

As many as 66% report pain at the time of initial presentation and this increases to 90% in those patients that have their hernia for 10 years or more.[89] What degree of preoperative pain needed to make repair worthwhile is not clear. For the patient to believe that the surgical experience has been worthwhile, the reduction in preoperative symptoms has to be greater than the risk of severe postoperative chronic pain and more than chronic pain per se. Arguments supporting repair are based on alleviating symptoms and avoiding the risk of an

acute hernia accident, the latter being often estimated at between 4 and 6%.[90] However because large population based studies detailing the natural course of an untreated hernia are scarce, this commonly held assumption that the life time risk of strangulation is between 4 and 6% is more likely one of speculation than fact.

Chronic pain can be neuropathic or nociceptive in origin. Neuropathic pain is believed to be as result of nerve damage and is usually described as electric, sharp and shooting pain. Nociceptive pain on the other hand is as a result of tissue damage and is described as aching, heavy and dragging.[91]

There are three nerves of anatomical and physiological importance in the groin area that may contribute to chronic post inguinal herniorraphy pain of neuropathic origin. These are the ilioinguinal, iliohypogastric nerves and the genital branch of the genitofemoral nerve.

Ducic et al believe that severe and chronic postoperative testicular pain after inguinal surgery can be treated by a designed approach that identifies the genital branch of the genitofemoral nerve in the proximal inguinal canal, resects it proximal to the previous operative field and subsequently places it behind the peritoneum.[91]

Al-Dabbagh et al reviewed the anatomical variations in the course of the ilioinguinal and iliohypogastric nerves in 110 hernia repairs.[92] They found that the course of both nerves was consistent with that found in anatomical textbooks in just fewer than 50% of cases. This difference in the variation of the nerve along its pathway may leave it susceptible to injury at operation. However these

differences in the course of the nerves can be readily appreciated and should be easily identified by the surgeon.

Since the early 1980's peripheral nerve entrapment syndrome following common surgical procedures to the lower abdominal wall have been recognized. Ilioinguinal or iliohypogastric nerve entrapment is typically diagnosed as a burning pain near the incision that radiates to the area supplied by the nerve with associated impaired sensory perception. Resolution occurs, albeit temporarily, when the two nerves are infiltrated with local anaesthetic as they leave the internal oblique. Surgical repair of the scar and resection of the nerve was advocated as the method of treatment for this condition.[93]

In 1996 Bower et al reported that severe chronic postoperative inguinal hernia neuralgia was rare. They suggested that in the small number of patients in whom non operative methods of treatment were refractory, the involved nerve should be mapped out prior to its surgical high ligation and division.[94]

Understanding the typical nerve anatomy and variation, is fundamental in treating this rare but debilitating postoperative complication. A larger series of just under 500 patients, this time confining the surgical procedure to the sutured Shouldice repair of an inguinal hernia, states that inguinal entrapment syndrome can be reduced to below 2% if the genital branch of the genitofemoral nerve is deliberately dissected free or cut cleanly.[95]

Dittrick et al reviewed 90 patients who underwent Lichtenstein inguinal hernia repair over a seven year period. The two surgeons who performed the operations differed in the fact that one preformed ilioinguinal neurectomy on a

routine basis. Neuralgia and paraesthesia were assessed through telephone and personal patient interviews at 1 month, 6 months, 1 year and 3 years post surgery. They concluded that the incidence of postoperative neuralgia was significantly lower in the neurectomy group versus the nerve preservation group at 1 month and 1 year but there was no significant difference in postoperative neuralgia at 3 years, though they did admit that numbers followed up at 3 years were small. At the same time the incidence of postoperative paraesthesia was not significantly higher in the neurectomy group versus the nerve preservation group at 1 month, 1 or 3 years. Those that reported postoperative paraesthesia in the neurectomy group at one month and six months had lower mean scores on the visual analogue scale than those in the nerve preservation group. These authors argue that routine division of the ilioinguinal nerve is a reasonable option during inguinal hernia repair.[96] The drawback of this study was that it was retrospective and that small numbers of patients were used.

Recently a double blind randomized controlled study was published in the Archives of Surgery from Italy. In four centres, 813 patients were randomized to inguinal hernia repair with either preservation or elective transection of the ilioinguinal nerve. The primary outcome was chronic pain at one year. At one year pain was absent in 76% of those with nerve preservation and in 73% of those with nerve transection. The majority of patients that reported pain had mild to moderate pain. However at 1 and 6 months postoperatively loss of pain and touch sensation were significantly greater in the group with the ilioinguinal nerve transected. Touch sensation remained decreased in the group with nerve transection even at one year follow up.[97]

In a second Italian study the identification and preservation of all three nerves during open mesh repair was associated with a reduction in chronic incapacitating groin pain and in the majority of these patients with chronic pain at six months the pain was resolved with conservative or medical management at 1 year.[98]

Madura et al state that the incidence of post herniorrhaphy neuropathies is not well known but is estimated to be in the region of 0 to 30%.[99] They argue that the most successful treatment is surgical resection of the nerve with good pain relief. Complete pain relief was seen in 72% of patients in their study and 10% reported a marked decrease in their symptoms. The only difference between patients who had complete relief and those who had partial relief of their symptoms was previous repair of a recurrent hernia. This seems to be the only available indirect evidence of chronic pain post repair of a recurrent inguinal hernia. To date there are no available studies that look at the incidence of post herniorrhaphy pain in patients who have had recurrent hernias repaired. One would assume that there is a higher incidence of chronic pain in these patients as tissue and nerve damage is twice as likely second time round. As an indirect result of our first study we found that patients who had a recurrent hernia repaired were no more likely to report pain at three months post surgery than those who had a primary hernia repaired. Therefore one can argue that chronic postoperative pain is partly explained by nerve damage at initial surgery. When any of the nerves are not recognized and as a result traumatized, chronic postoperative pain can ensue. However it would appear that the situation is not clear. While cleanly dividing the nerves does not exacerbate postoperative pain it does play a role in

disturbed sensory changes after repair. On the other hand clean nerve division can also be a solution for severe chronic neuropathic pain. It has been postulated that when these nerves are caught or trapped in permanent stitches or tacks or bound up in the mesh during the various methods of repair it is then that postoperative chronic neuropathic pain may result.

Adequate analgesia in the postoperative period is a priority in enabling the post-surgical patient to cope with the tissue damage of surgery. Irrespective of whether the hernia is repaired under local, regional or general anaesthesia, the patient will not be deemed fit for discharge until the pain of surgery is controlled with appropriate analgesia. Inguinal hernias have been repaired under general, regional or local anaesthesia. It is well established, for example that open inguinal hernia repair can be conducted under local anaesthesia, regardless of comorbidity and with minimal morbidity.[101]

Fitzgibbons et al.[102] and O'Dwyer et al.[103] both investigated pre- and postoperative pain in asymptomatic and mild symptomatic patients in a randomized setting. Both studies compare watchful waiting with standard open tension-free mesh repair. Fitzgibbons et al.[104] randomized inguinal hernia patients that were either completey asymptomatic or minimally symptomatic without interference with normal activity. Pain limiting activities were similar for watchful waiting vs. surgical repair (5.1% vs. 2.2%, respectively; P=0.52) after two years although a trend is visible in favour of surgical repair that might be significant in an adequately powered group. O'Dwyer randomized patients without inguinal pain at rest or movement. Visual analogue pain scores at rest or movement after one year did not dier between observative or operative

management (3.7 and 5.2 mm (P=0.34) at rest; 7.6 and 5.7 mm (P=0.39) on movement, respectively).[103]

Chapter 4

Methodology

METHODOLOGY

This one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum over a period, from January 2015 to December 2015.

Study design

The study design was randomized controlled trial.

Study period and duration

This study was conducted for the period of one year from January 2015 to December 2015.

Place

This study was done in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum attached to KLE University's Jawaharlal Nehru Medical College, Belgaum.

Source of Data

Patients admitted with inguinal hernia requiring mesh repair under Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum were studied.

Sample size

A total of 60 patients divided into two groups of 30 each were studied.

Sampling procedure

The sample size was taken as 60, with 30 in group A [freedom proflor self retaining mesh repair] and 30 in group B [conventional Lichtenstein mesh repair] according to thumb rule.

Selection criteria

Inclusion

- All patients with inguinal hernia undergoing mesh repair.

Exclusion

- Immunocompromised patients
- Patients with pulmonary tuberculosis
- Patients with recurrent hernia
- BPH

Ethical clearance

The study was approved from the Ethical and Research Committee, Jawaharlal Nehru Medical College, Belgaum prior to the commencement.

Informed Consent

The patients fulfilling selection criteria were informed in detail about the nature of the study, especially the benefits of using freedom proflor self retaining mesh repair and Lichtenstein mesh repair and a written informed consent was obtained (Annexure I).

Randomization

The patients were randomized by computer generated random numbers which were used to assign the type of surgery; the patients were divided into two groups of 30 each as below;

- Patients undergoing proflor mesh repair formed group A [study group].
- Patients undergoing conventional Lichtenstein mesh repair formed group B [control group].

Method of collection of data

Demographic data such as age, sex and history was obtained through an interview. Details such as duration, lump size were noted. These patients were subjected to clinical examination and the findings such as size, cough impulse, position were noted on a predesigned and pretested proforma (Annexure II).

Investigations

The following tests were subjected to the following investigations.

- Routine blood counts – Hemoglobin, total leucocyte counts, differential counts, red blood cell counts and ESR.
- Blood urea nitrogen, Serum creatinine
- Bleeding and clotting time
- Urine Routine and Microscopy
- Chest X-ray and ECG
- Ultrasonography- to rule out BPH

Surgical procedure

Group A

In group A the procedure was performed using freedom proflor self retaining mesh. The skin and subcutaneous tissue was incised. The external oblique aponeurosis was opened (Annexure III, photograph1). The cord was identified (Annexure III, photograph2) and the indirect sac if present was ligated and reduced inside. The fascia transversalis was opened and space created in the preperitoneal area posterior to fascia transversalis(Annexure III, photograph3). This blunt dissection of the preperitoneal area was done with a finger or with the help of gauze to accommodate the placement of the preperitoneal disc of the freedom profor self retaining mesh. The implant was compressed with the thumb and forefinger and implant core was compressed with the applicator while the preperitoneal disk was fully deployed in extra peritoneal space. The freedom proflor self retaining mesh is available in two sizes of dynamic core (25mm and 40mm). Depending on the size of the defect appropriately sized proflor mesh was delivered into the opening of fascia transversalis with the applicator (Annexure III, photograph4). The preperitoneal disk was spread into the preperitoneal space with the help of spatula (Annexure III, photograph5). The cord is placed over it and external oblique aponeurosis was closed. The subcutaneous tissue and skin was closed.

Group B

In this group the skin and subcutaneous tissue was incised. The external oblique aponeurosis was opened. The cord was identified and the indirect sac if

present was ligated and pushed inside. The floor was reinforced with flat polypropylene mesh (7 x15 cm) and was sutured to the pubic tubercle and a continous suture was taken to fix the mesh to the reflected part of the inguinal ligament. Mesh was fixed to the conjoint tendon by interrupted sutures. A slit was created for the cord structures and internal ring is recreated. Mesh is overlapped and fixed. The external oblique aponeurosis was closed. The subcutaneous tissue and skin was closed.

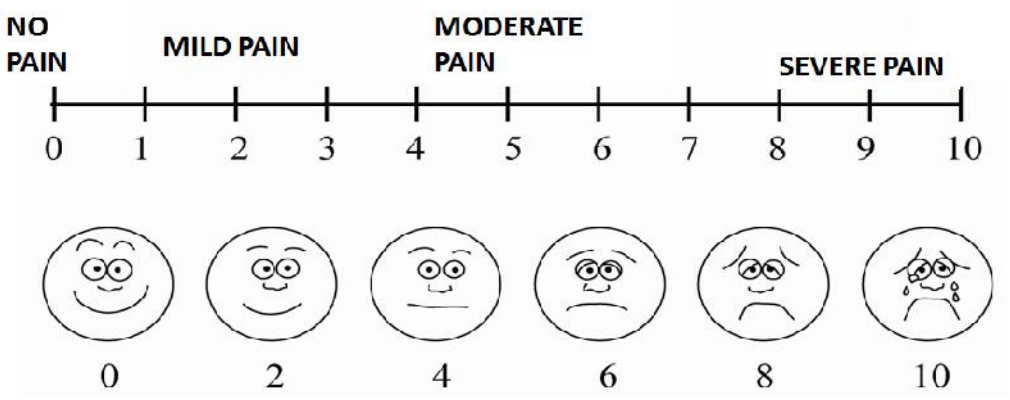
Pain management

Post operatively patients of both the groups were given the same analgesics that is, Injection Diclofenac 50mg IM BD. Later oral diclofenac 50mg was given as per requirement.

Outcome variables

Pain was assessed based on Visual Analogue Score ranging from 0 to 10 considering 0 as no pain and 10 as maximum pain. Further the pain was divided into 3 categories.

- Mild – VAS score ≤ 3
- Moderate – VAS score between 4 to 6
- Severe – VAS score ≥ 7



Follow up

Patients were followed up at following intervals;

- Postoperative day1
- Postoperative day3
- Post operative 1week
- 4 weeks follow up
- 3 months follow up

Statistical analysis

The data obtained was coded and entered in Microsoft Excel Spreadsheet. The categorical data was expressed as rates, ratios and percentages and comparison was done using Mann whitney test and‘t’ test. Continuous data was expressed as mean ± standard deviation. A ‘p’ value of less than or equal to 0.05 was considered as statistically significant.

Chapter 5

Results

RESULTS

The present one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2015 to December 2015.

A total of 60 patients admitted with inguinal hernia requiring mesh repair were included in the study. These patients were further randomized into two groups of 30 each as below;

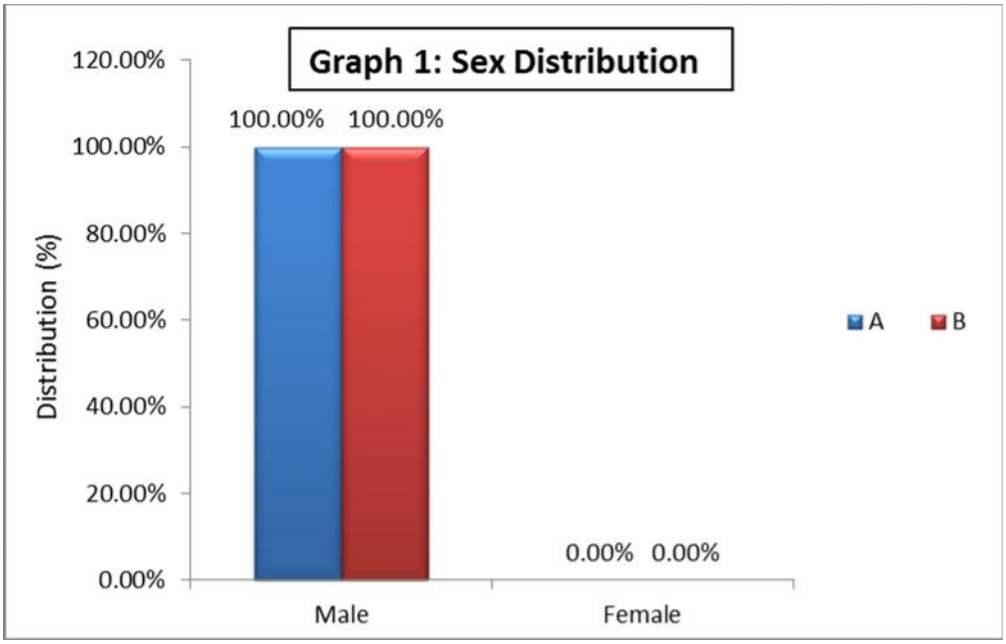
- Patients who underwent proflor mesh repair formed group A.
- Patients who underwent lichensteins repair formed group B.

The data obtained was coded and entered in Microsoft Excel Spreadsheet. The data was analysed and the observations were tabulated as below.

Table 1. Sex distribution

Sex	A (n=30)		B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
Male	30	100.00	30	100.00
Female	0	0.00	0	0.00
Total	**30**	**100.00**	**30**	**100.00**

p=1

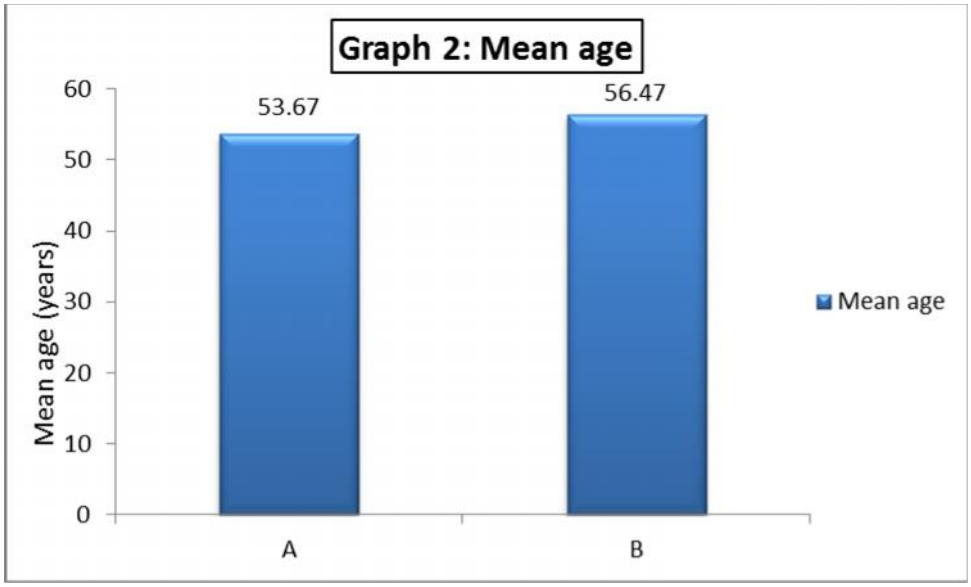


In the present study, all the patients in group A and group B were males.

Table 2. Mean age

Variables	A (n=30)		B(n=30)	
	Mean	**SD**	**Mean**	**SD**
Age (Years)	53.67	14.311	56.47	13.85

P=0.4284

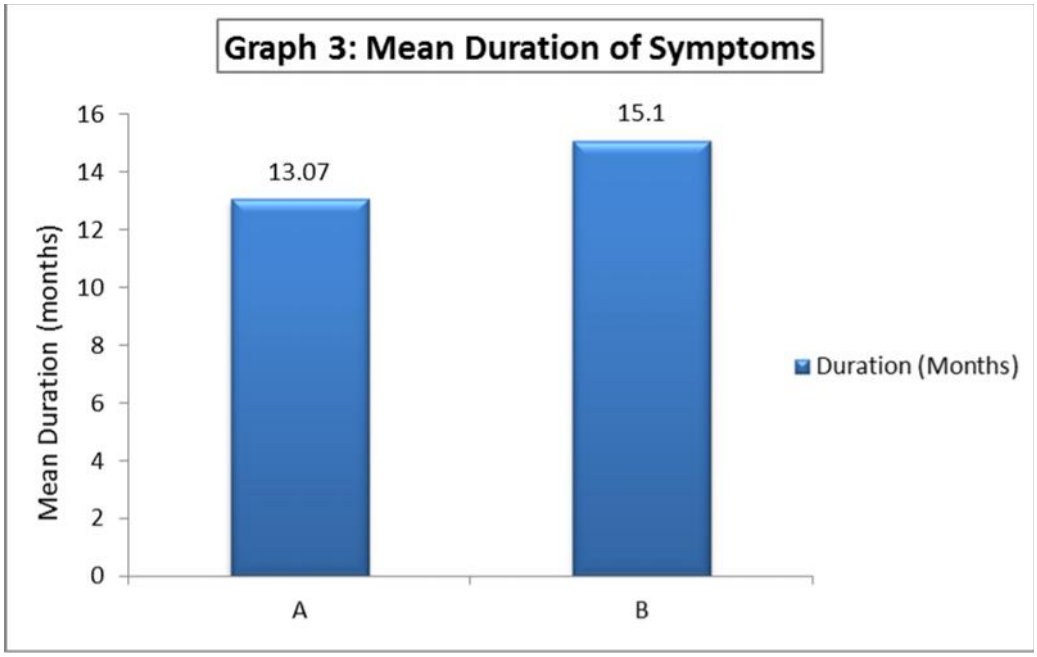


In the present study, the mean age in group A was 53.57 ± 14.31 years compared to 56.47 ± 13.85 years in group B, the youngest patient being 25 years of age. However the difference was statistically not significant (p=0.4284).

Table 3. Mean duration of Symptoms

Variables	A (n=30)		B (n=30)		p value
	Mean	SD	Mean	SD	
Duration (Months)	13.07	9.6	15.1	8.98	0.401

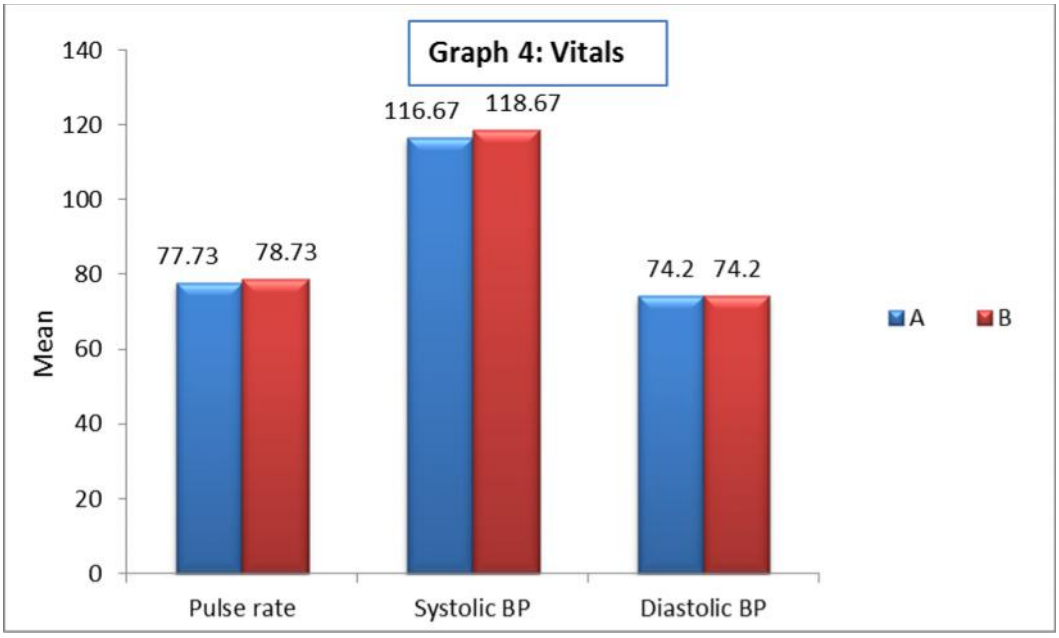
P=0.401



In the present study the mean duration of the disease was 13.07 ± 9.6 months in group A whereas in group B it was 15.1 ± 8.98 months. However, this difference was not statistically significant (p=0.401).

Table 4. Vitals

Vitals	A (n=30)		B (n=30)		p value
	Mean	SD	Mean	SD	
Pulse rate (/min)	77.73	4.81	78.73	4.99	0.432
Systolic BP (mm Hg)	116.67	8.64	118.67	10.16	0.415
Diastolic BP (mm Hg)	74.2	5.34	74.2	5.34	1

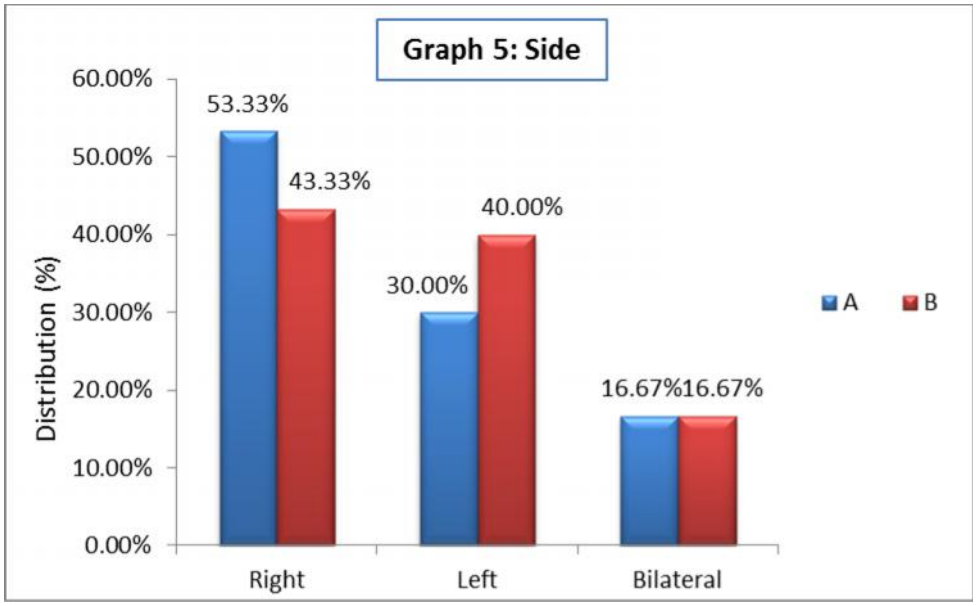


In this study, the mean pulse rate in group A and group B (77.73 ± 4.81 vs 78.73 ± 4.99 /min; p=0.432), systolic blood pressure (116.67 ± 8.64 vs 118.67 ± 10.16 mm Hg; p=0.165) and diastolic blood pressure (74.2 ± 5.34 mm Hg in both; p=1) were comparable.

Table 5. Side of hernia

Side	A (n=30)		B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
Right	16	53.33	15	43.33
Left	9	30	11	40
Bilateral	5	16.67	5	16.67
Total	**30**	**100.00**	**30**	**100.00**

p=0.691

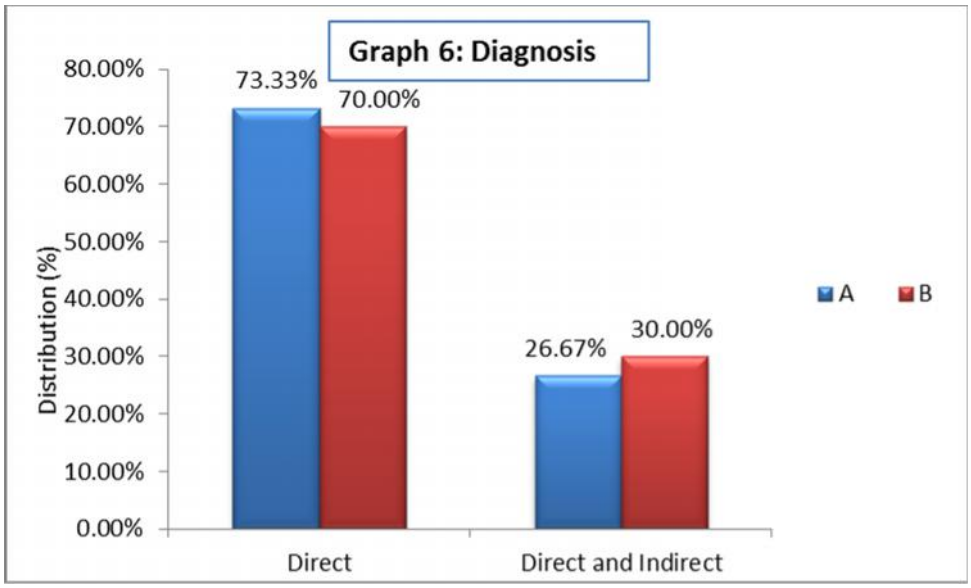


In the present study, 53.33% of patients in group A presented with a right-sided swelling compared to 43.33% of patients in group B. 30% of patients in group A presented with a left-sided swelling compared to 40% of patients in group B and 16.67% of the patients from both groups presented with swelling on both sides. However this difference was statistically not significant (p=0.691).

Table 6. Diagnosis

Diagnosis	A (n=30)		B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
Direct hernia	22	73.33	21	70.00
Direct and Indirect hernia	8	26.67	9	30.00
Total	**30**	**100.00**	**30**	**100.00**

p=0.774

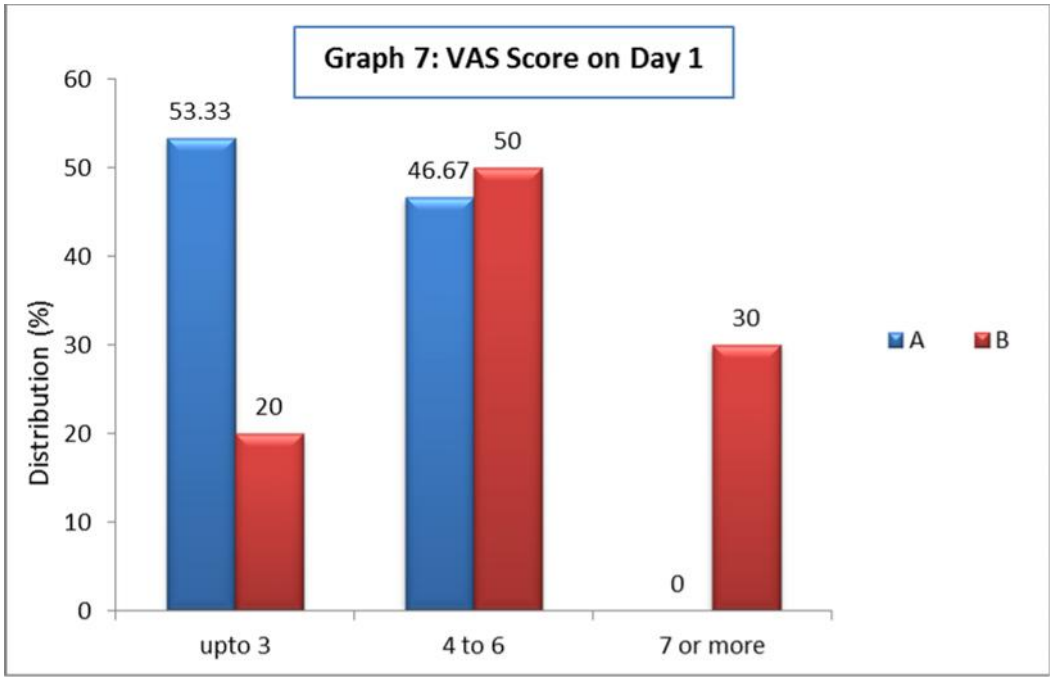


In the present study, all the patients in group A and group B had direct hernias. In group A 26.67% of patients had indirect hernia along with direct hernia whereas 30% of group B had indirect hernia along with direct hernia. However this difference was statistically not significant (p=0.774).

Table 7. VAS scores on Day 1

VAS score	A (n=30)		B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
upto 3	16	53.33	6	20.00
4 to 6	14	46.67	15	50.00
7 or more	0	0.00	9	30.00
Total	**30**	**100.00**	**30**	**100.00**

p= 0.001125

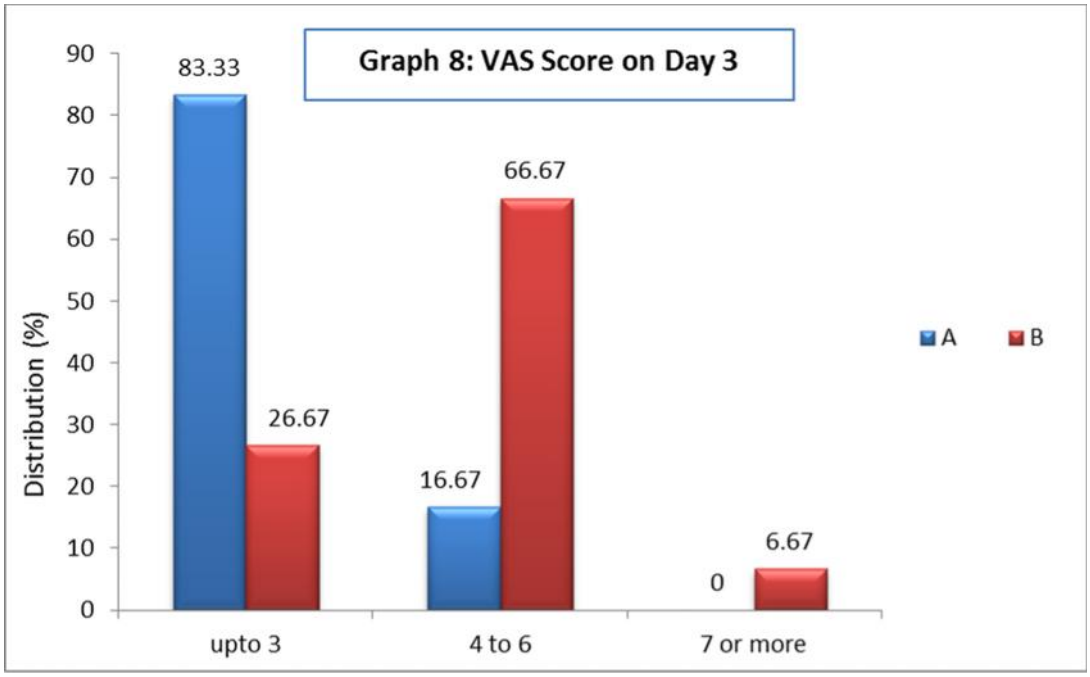


In this study during first follow up, 53.33% of the patients in group A reported pain scores between 1 to 3 (mild pain) compared to 20% patients in group B, 46.67% of patients from group A reported pain scores of 4-6 (moderate pain) compared to 50% in group B and 30% of group B reported pain scores of 7-9 (severe pain) compared to none from group A. This difference was statistically significant (p=0.001125).

Table 8. VAS scores on Day 3

VAS score	A (n=30)		B(n=30)	
	Number	**Percentage**	**Number**	**Percentage**
upto 3	25	83.33	8	26.67
4 to 6	5	16.67	20	66.67
7 or more	0	0.00	2	6.67
Total	**30**	**100.00**	**30**	**100.00**

p<0.001

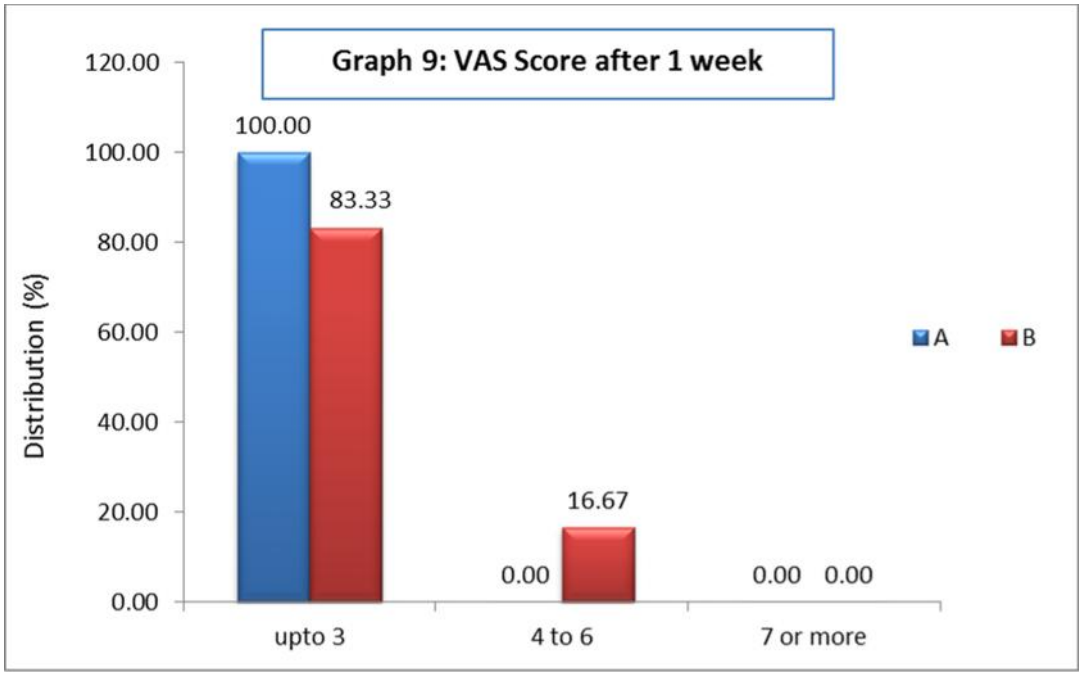


In this study during second follow up, majority of the patients (83.33%) in group A reported pain scores ≤ 3 (mild pain) compared to 26.67% patients in group B. Pain score between 4 to 6 (moderate pain) were seen in 16.67% of patients in group A compared to 66.67% of patients in group B and 6.67% of patients reported pain scores of > 7 (severe pain) in group B with none in group A. This difference was statistically significant (p<0.001).

Table 9. VAS scores after 1 week

VAS score	A (n=30)		B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
upto 3	30	100.00	25	83.33
4 to 6	0	0.00	5	16.67
7 or more	0	0.00	0	0.00
Total	**30**	**100.00**	**30**	**100.00**

p =0.02

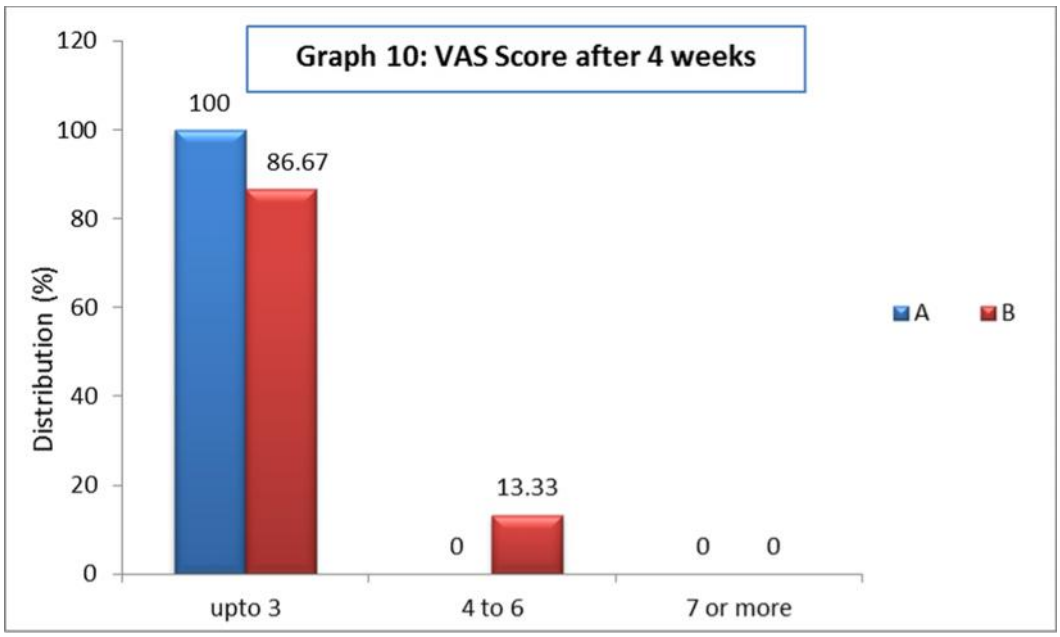


In the present study during third follow up, all the patients (100%) in group A reported pain scores ≤ 3 (mild pain) compared to 83.33% patients in group B. In group B, 16.67% of patients had pain scores between 4 to 6 (moderate pain) with none in group A. This difference was statistically significant ($p<0.001$).

Table 10. VAS scores after 4 weeks

VAS score	A (n=30)		B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
upto 3	30	100.00	26	86.67
4 to 6	0	0.00	4	13.33
7 or more	0	0.00	0	0.00
Total	**30**	**100.00**	**30**	**100.00**

p =0.035

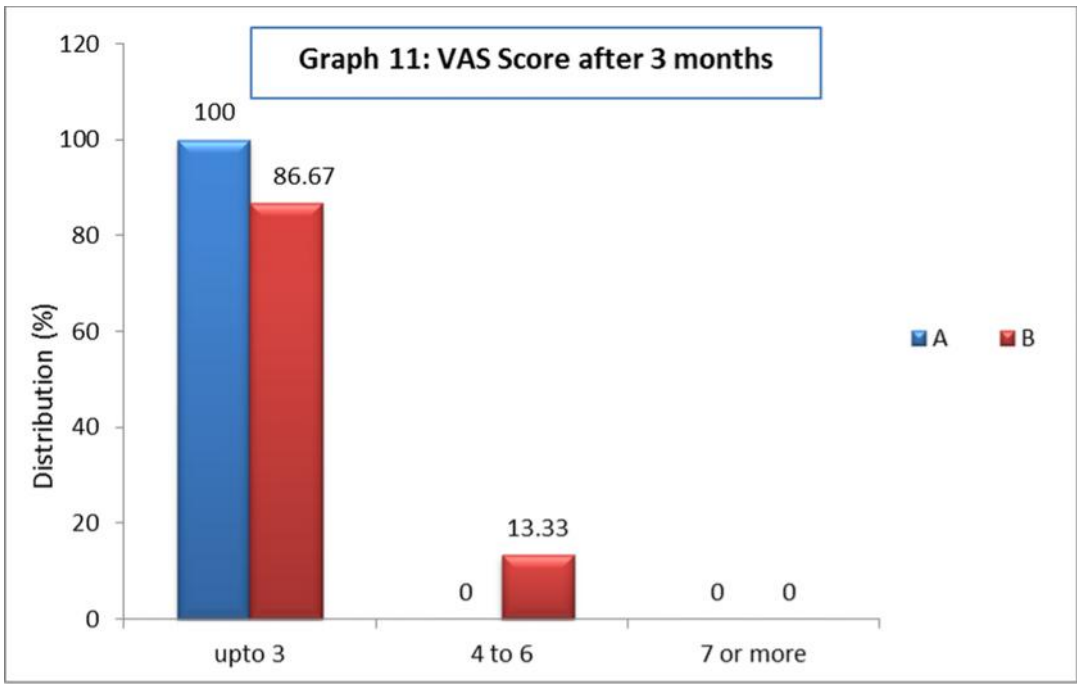


In the present study during the fourth follow up, all the patients (100%) in group A reported pain scores ≤ 3 (mild pain) compared to 86.67% patients in group B. In group A, no patient had pain scores between 4 to 6 (moderate pain).in group B 13.33% had pain scores between 4 to 6(moderate pain). This difference was statistically significant (p=0.035).

Table 11. VAS scores after 3 months

VAS score	A(n=30)		B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
upto 3	30	100.00	26	86.67
4 to 6	0	0.00	4	13.33
7 or more	0	0.00	0	0.00
Total	**30**	**100.00**	**30**	**100.00**

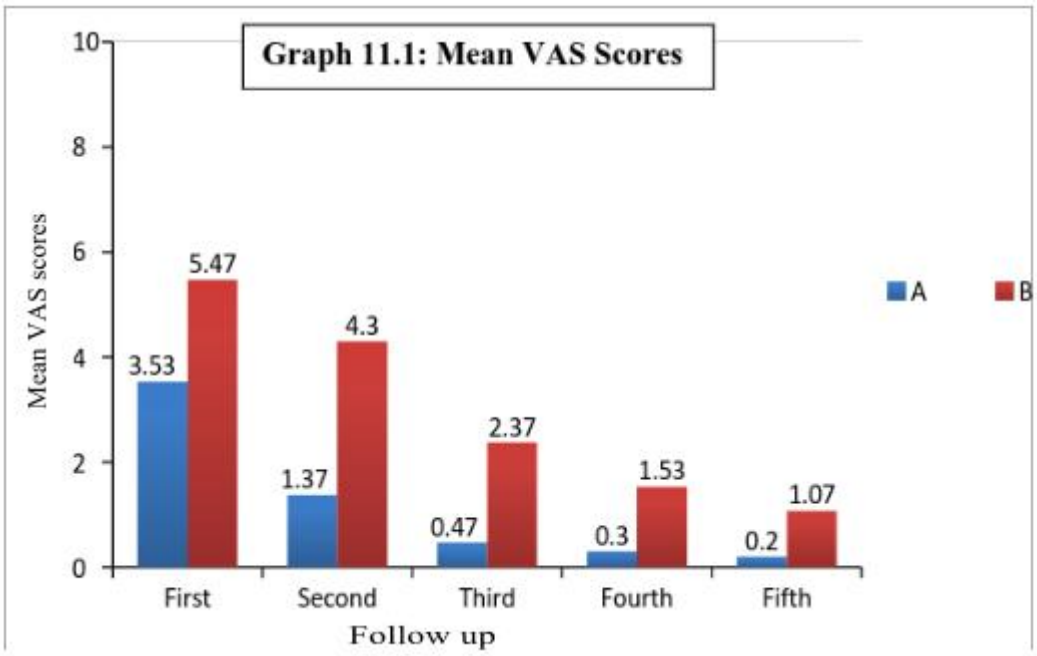
p =0.035

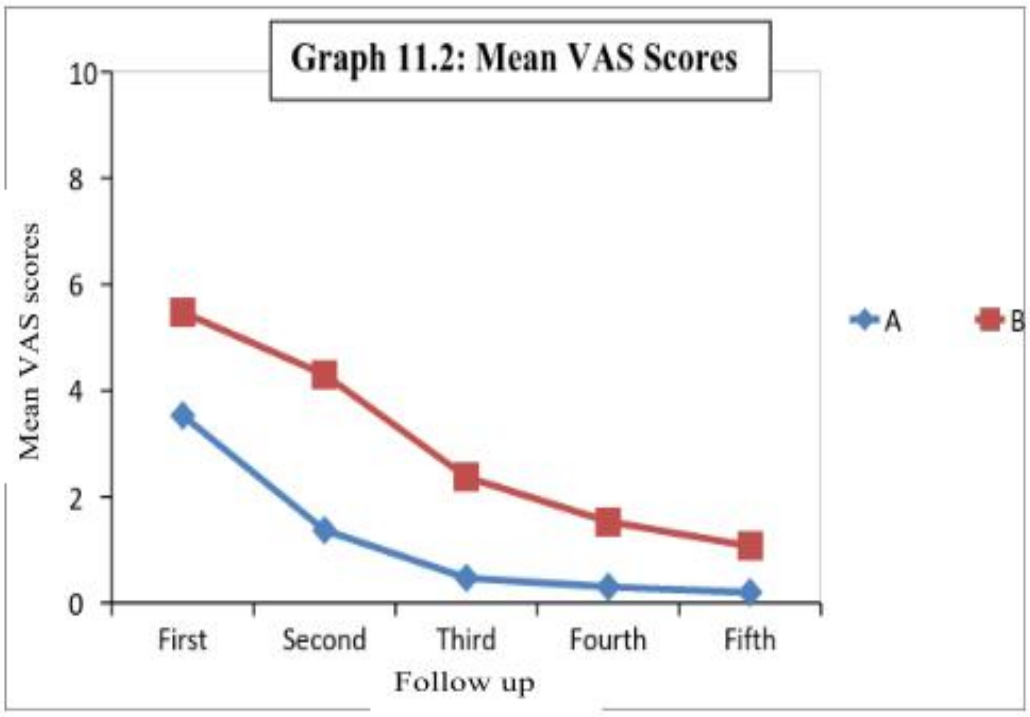


In the present study during the fifth follow up, all the patients (100%) in group A reported pain scores ≤ 3 (mild pain) compared to 86.67% patients in group B. In group A, no patient had pain scores between 4 to 6 (moderate pain) with 13.33% in group B. This difference was statistically significant (p=0.035).

Table 12. Mean VAS scores

Follow up	A (n=30)		B (n=30)		p value
	Mean	SD	Mean	SD	
First	3.53	1.36	5.47	2.11	<0.0001
Second	1.37	1.5	4.3	1.51	<0.0001
Third	0.47	0.57	2.37	1.47	<0.0001
Fourth	0.3	0.47	1.53	1.43	<0.0001
Fifth	0.2	0.41	1.07	1.28	<0.0001

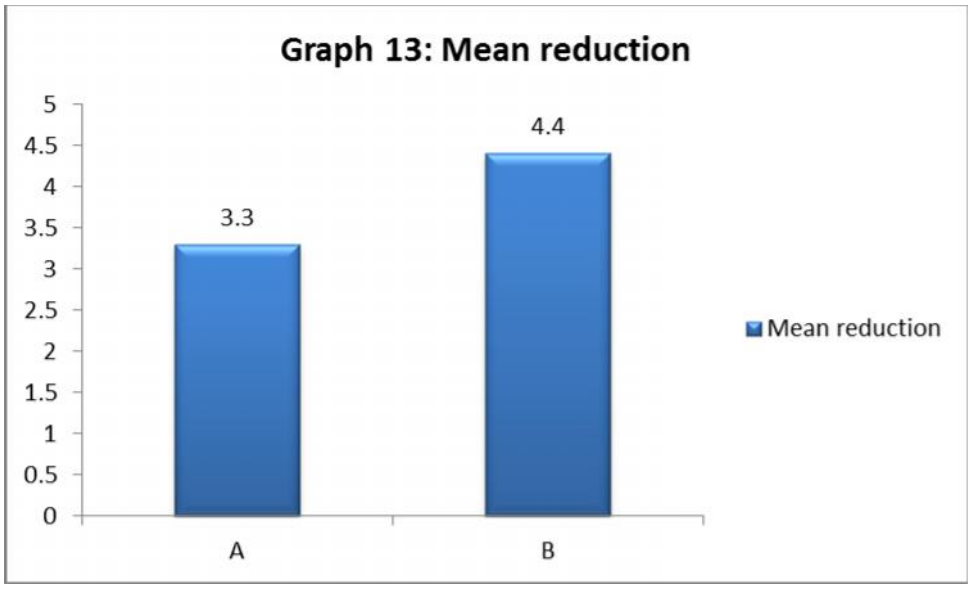




In the present study the mean pain scores in group A during first (3.53 ± 1.36 vs. 5.47 ± 2.11), second (1.37 ± 1.5 vs. 4.3 ± 1.51), third (0.47 ± 0.57 vs. 2.37 ± 1.47), fourth (0.3 ± 0.47 vs. 1.53 ±1.43) and fifth (0.2±0.41 vs. 1.07±1.28) follow up were significant compared to group B ($p<0.0001$).

Table 13. Mean Reduction VAS scores from the first follow up to the fifth follow up

Pain	A (n=30)		B (n=30)		p value
	Mean	SD	Mean	SD	
Mean reduction	3.3	1.24	4.4	2.04	0.029

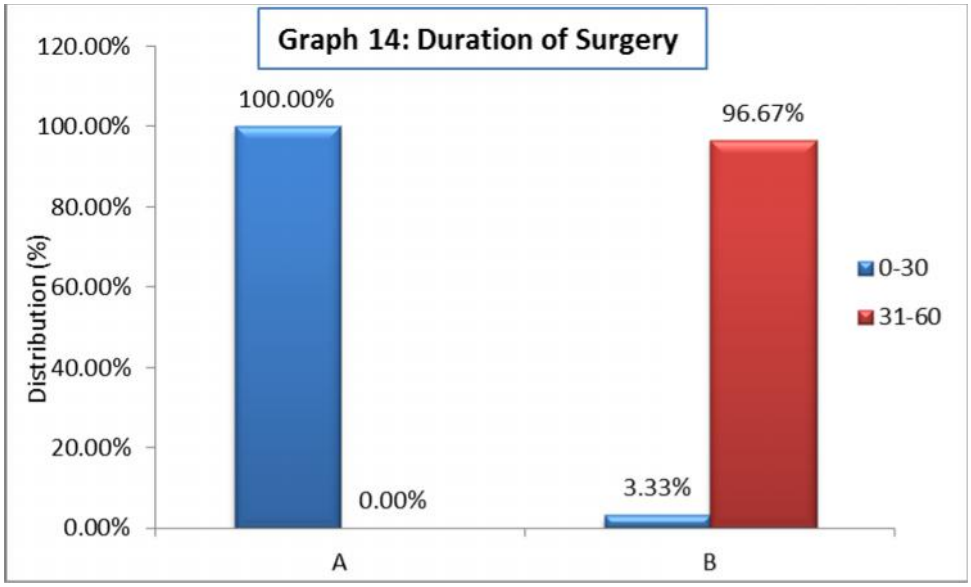


In this study, the mean reduction in pain score from first follow up to fifth follow up was significant in group A (3.3 ± 1.24) compared to group B (4.40 ± 2.04) (p=0.029).

Table 14. Duration of Surgery

Duration of Surgery (in minutes)	A (n=30)		B (n=30)	
	Number	Percentage	Number	Percentage
0-30	30	100.00	1	3.33
31-60	0	0	29	96.67
Total	**30**	**100.00**	**30**	**100.00**

p< 0.05



In the present study, all the patients in group A were operated on in less than 30 minutes while only 3.33% of group B were operated on in the same time period. The rest of the patients from B (96.67%) were operated on within 31-60 minutes with none in group A. The difference was statistically significant ($p<0.05$)

Chapter 6

Discussion

DISCUSSION

Inguinal herniorraphy is an evolving surgical solution to an age-old problem. Since Bassini first described repairing an inguinal hernia by suturing the conjoint tendon to the inguinal ligament in 1889. The initial Bassini repairs that were later modified by Halstead and McVay were performed under tension because of the direct approximation of tissue with resultant high recurrence rates reported to be between 5% and 21%[105,106]. In 1958, Usher et al[107] was the first to perform inguinal herniorraphy by using prosthetic mesh, thereby eliminating the tension associated with tissue approximation. However, mesh repair did not gain widespread acceptance until Lichtenstein et al[108] coined the term "tensionfree" repair and advocated this approach in 1986.

One of the most frequently used open techniques is the Lichtenstein herniorraphy. Nowadays, chronic pain is the main problem associated with the Lichtenstein procedure with a reported rate of 15% to 40%.[109,110] The reason of the postoperative pain was complex, and the position of the mesh is probably 1 factor. Furthermore, this anterior method needs extensive dissection of the inguinal wall and the fixation of the mesh.[111]

Later Alan Robbins and Ira Rutkow[55] described the plug technique in which plug is placed in the defect which required little fixation. However there is occurrence of meshoma and also migrate. A two layered mesh (hernia system) was developed which also gaining popularity. To date, there is little evidence to show any these techniques superior to the Lichtenstein operation

Cunningham et al were the first to bring up the issue of chronic pain[87]. Thereafter, pain became an important outcome in the field of hernia repair

research. Poobalan et al reviewed the incidence of chronic pain after inguinal repair up to 2000 and found prevalence from 0% to 63% a year after surgery[112].

In our study we used a new 3D autostatic prosthetic device was specifically designed to be placed fixation free. This was achieved using its inherent radial recoil, vertical buffering and friction within the hernia edge. The procedure was based on the centrifugal expansion of the device, whose design features converted ejection forces into gripping forces, and avoided the need for suturing the implant.

The present study was aimed to compare postoperative pain and duration of surgery in freedom proflor mesh repair (group A) versus Lichtenstein mesh (group B) repair for inguinal hernia.

The groin pain was assessed by Visual Analogue Scale on a scale of 1 to 10 with 1-3 being mild pain, 4-7 being moderate pain and 8-10 being severe pain.

All the patients presented with groin swelling in both groups. All patients in both groups were male. The mean age, standard deviation and mean duration of the disease in group A and group B were comparable.

In this study comparing the VAS scores on all the five follow ups there were significantly lower pain scores in group A compared with group B. The mean pain scores in group A during first, second, third, fourth and fifth follow up were significantly less compared to group B and the mean reduction in pain score from first follow up to fifth follow up was significant in group A (3.3 ± 1.24) compared to group B(4.40 ± 2.04) ($p=0.029$).

The lower pain scores in Proflor were due to its self retaining property of the mesh (no fixing sutures), lesser tissue dissection and placement of mesh behind the fascia transversalis which is free of nerves. The complications such as bleeding, nerve entrapment, hematoma, pain, discomfort were absent in the group B which arise as a direct result of fixation of the implants.

Chandra Kant Paliwal et al[113] followed up 260 cases with Proflor implant for the period of 2 weeks to 3 years. They observed mild to Moderate pain during first three days which became nil to mild after 4 days. The patient was able to go back to work in 3 days to One week .Only one case of reoccurrence was observed.

The patients in group A required less pain medication and for a shorter period of time than group B. All the patients are followed up for the study period of one year. There are no recurrences seen in both the groups till the study period of one year.

During this study, one individual complained of feeling the core of implant in the groin in the group A. This patient was thin. However there is no pain or discomfort.

In the present study, the operative time was significantly less in group A compared with group B. In all the patients in the group A the operative time is less than 30 minutes. ($p<0.05$)

The significant reduction of operative time in group A is due to the minimal anterior dissection required. The specifically designed mesh requires no point fixation. Thus there is a decrease in overall operative time

In the study conducted by Murphy JW, Porwal A[114], the average OR time for the Lichtenstein repair was 43 minutes. The average OR time for the Proflor repair was 24 minutes. This represented an average reduction in skin-to-skin surgical time of 19 minutes or 43% which is comparable to our study.

Studies show that the mean duration of surgery was shorter in the patients in which the mesh was placed behind the fascia transversalis. This technique gained widespread acceptance due to its advantages, including the fact that there is no tension, there is less pain and rate of recurrence is lower compared to other techniques[115].

The results of the present study showed the role of proflor mesh in reducing immediate and short term postoperative pain. The mean reduction in pain score from first follow up to fifth follow up is significant in group A than group B. The patients operated with freedom proflor mesh had statistically better VAS, a shorter operative time, and required less pain medication.

This present study is only limited to post-operative pain and operative time. Further long term studies need to be done to assess recurrences.

Chapter 7

Conclusion

CONCLUSION

Based on the findings of the present study it may be concluded that, the freedom proflor hernia repair significantly reduced the post-operative pain as compared to Lichtenstein hernia repair. There is statistically significant reduction in the operative time in freedom proflor mesh repair group, required less pain medication postoperatively and for shorter time compared to Lichtenstein group. In this study there were no recurrences in one year. However further long term studies are required for documenting hernia recurrences.

Chapter 8

Summary

SUMMARY

Lichtenstein tension-free mesh repair is the most commonly used technique for open inguinal hernia. However, mesh fixation with sutures to avoid dislocation has been considered as a cause of chronic pain and discomfort. The present study was aimed to compare self retaining freedom proflor mesh repair versus Lichtenstein mesh repair for reduction of postoperative pain in inguinal hernia.

The present one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2015 to December 2015. A total of 60 requiring mesh repair were randomized into two groups of 30 each based on the type of surgery as group A (Proflor mesh repair) and group B (Lichtenstein repair).

In the present study all the patients in both the groups were males. The mean age (53.57±14.31 vs 56.47±13.85 years; p=0.4284) and duration of the symptoms (13.07±9.6 months vs 15.10 ± 8.98 months; p=0.401) in group A and group B was comparable. In this study comparing the VAS on all the five follow ups there was significant lower pain scores in Proflor mesh repair group than Lichtenstein repair group. The mean pain scores in group A during first (3.53 ± 1.36 vs. 5.47 ± 2.11), second (1.37 ± 1.5 vs. 4.3 ± 1.51), third (0.47 ± 0.57 vs. 2.37 ± 1.47), fourth (0.3 ± 0.47 vs. 1.53 ±1.43) and fifth (0.2±0.41 vs. 1.07±1.28) follow up were significant compared to group B (p<0.0001). The mean reduction in pain score from first follow up to third follow up was significant in group A

(3.3 ± 1.24) than group B(4.40 ± 2.04) (p=0029). All the patients in group A were operated on in less than 30 minutes. In group B only 3.33% were operated upon in the same time period. The rest of the patients from group B (96.67%) operated upon required 31-60 minutes with none in group A. The operative time was significantly less in group A compared to group B ($p<0.05$).

Overall, the present study showed that, the pain scores were significantly less in proflor mesh repair group as compared to Lichtenstein repair group. There is significant reduction in the operative time in proflor mesh repair group and requires less pain medication and for shorter time compared to Lichtenstein group.

Chapter 9

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Annexures

Annexure I

ANNEXURE I – CONSENT FORM

Mr/Mrs/Miss. _____ we are requesting you to enroll yourself in study titled **" "**COMPARISON OF SELF RETAINING FREEDOM PROFLOR MESH REPAIR VERSUS LICHTENSTEIN MESH REPAIR FOR THE REDUCTION OF POSTOPERATIVE PAIN IN INGUINAL HERNIA:A ONE YEAR RANDOMISED CONTROLLED TRIAL AT KLE DR. PRABHAKAR KORE HOSPITAL**"** conducted by Dr._____ , Post Graduate in M.S. General Surgery under the guidance of Dr._____ M.S. Professor, Department of General Surgery, J.N. Medical College, Belagavi under KLE university, Belagavi.

Respected Sir/Madam, We request you to participate in our study as you are eligible for participating in the study. Your participation in the research is absolutely voluntary. Your decision to participate in the study or otherwise will not affect the relationship with KLE hospital. If you decide not to participate, you are free to to withdraw at any time. During the study your operative outcome will be assessed by some questions which will be answered by your operating surgeon.

Purpose of the study:

Lichtenstein tension-free mesh repair is the most commonly used technique for open inguinal hernia. However, mesh fixation with sutures to avoid dislocation has been considered as a cause of chronic pain and discomfort. This study is being done to compare two techniques used in the repair of inguinal hernia viz. freedom proflor mesh repair vs. conventional mesh repair to assess the postoperative pain in both techniques.

Procedure Involved:

If you agree to enroll yourself in my study, you will be asked your detail history. Then you will be clinically examined in detail and routine investigations like HB, TC, DC, PLATELET COUNT, RBS, BLOOD UREA, SERUM CREATININE, BLOOD GROUPING, CHEST X RAY, ECG,USG will be done accordingly. Computer generated random numbers are used to assign the type of surgery to the patients that is, group A and group B. Two techniques are used in the repair of hernia viz. Freedom proflor hernia repair (group A) and the conventional Lichtenstein mesh repair (group B) are compared in the study. The patients are monitored for pain by visual analogue scale ranging from 0 to 10 considering 0 as no pain and 10 as maximum pain postoperatively from day1, day3, 1st week, 4th week and 3rd month.

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 to estimate the incidence of postoperative 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.

Withdrawing/removal from the study

The participant has freedom to withdraw from the study whenever he/she wishes and with prior notice. Even if you decline to participate, there will not be any change in the line of your management or the relationship with your doctor. You will be told about all the new information that affects your decision to participate in the study. The investigator may also exclude a participant from the study at anytime.

Privacy and Confidentiality:

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

1. In an emergency to protect your rights and welfare.
2. If required by the law.

Institutional/sponsors policy:

If any unforeseen complications or injury occurs during the period of study, the participant will be given treatment within the limitations of KLE's Dr. prabhakar kore hospital general ward.

Financial Incentives for participation:

The participant neither gets any financial incentives during the period of study nor will be asked to pay for the purpose of this study.

Authorization to Publish Results:

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with your identity remaining confidential.

Contact details

The participant can contact me at any time during the study period for clarification of doubts or any questions. In case of any queries, you can contact the following:

DR. _____

Professor,

Department of Surgery

J.N.Medical College,

KLE University, Belagavi-10

DR. _____

Postgraduate student,

Department of Surgery,

J.N.Medical College,

KLE University, Belagavi-10

Ph no: _____

In case of queries regarding your right as participant you may contact :

DR. _____

Chairperson, College Ethical Dissertation and Research committee,

J.N.Medical College,

KLE University, Belagavi-10

Ph no: _____ Ext no: ____

CONSENT STATEMENT:

I, Mr/Ms/Mrs. _____ voluntarily agree for the participation as a subject of study. By signing this consent form I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in my vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name : _____

Signature or the Left Thumb Print of Subject : _____

Witness Name: _____ Signature:

Investigators Name: _____ Signature:

_____

Date: _____

Place: _____

Annexures

Annexure II

ANNEXURE II – PROFORMA

PROFORMA OF CLINICAL EXAMINATION OF INDIVIDUAL PATIENT

Name : Age :

Address : IP no.:

Sex : Religion:

Education: Date of admission:

Occupation: Date of discharge:

HISTORY

When did the patient notice the swelling:

Initial size of the swelling :

Present size of the swelling :

Associated features : Abdominal pain[colicky/dragging sensation]

Does the swelling automatically disappear on lying down: Yes / No

Other complaints :

Past History:

Family History:

GENERAL PHYSICAL EXAMINATION:

Built and Nourishment:

Weight :

Pallor / Icterus / Cyanosis / Clubbing / Edema / Lymphadenopathy:

Vital Signs :

PR: RR:

BP: Temperature:

SYSTEMIC EXAMINATION:

Per Abdomen:

Respiratory System:

Central Nervous System:

Cardio-Vascular System:

LOCAL EXAMINATION: patient examined in standing and supine position.

INSPECTION:

Size: Visible peristalsis:

Shape: Cough impulse:

Position: Position of the penis:

PALPATION:

Local rise of temperature: Cough impulse:

Tenderness: Reducibility of the swelling:

Consistency:

PERCUSSION:

AUSCULTATION:

Per rectal examination:

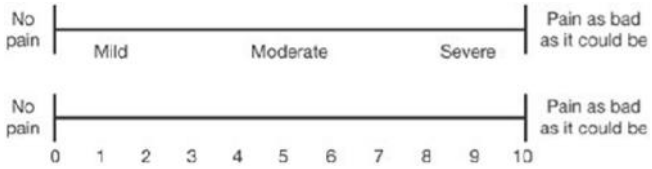
DIAGNOSIS:

INVESTIGATION:

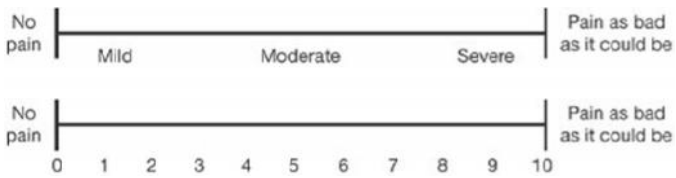
PROCEDURE DONE:

EVALUATION OF PAIN:

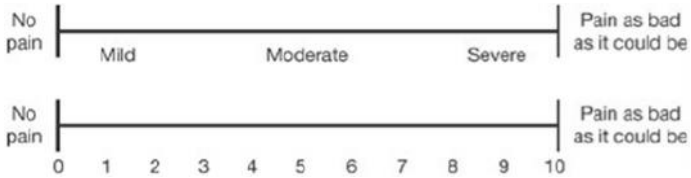
POSTOPERATIVE DAY 1:



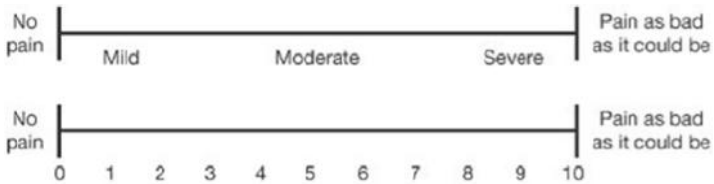
POSTOPERATIVE DAY 3:



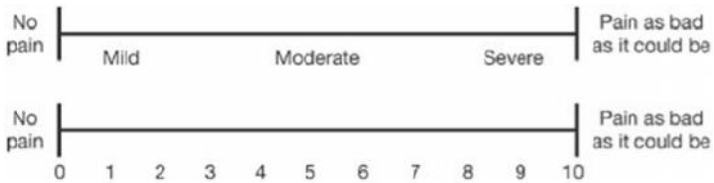
AFTER 1 WEEK: [before discharge]



AFTER 4 WEEKS:



AFTER 3 MONTHS:



DURATION OF SURGERY: **1) Right side: _____** minutes**.**
2) Left side: _____ minutes

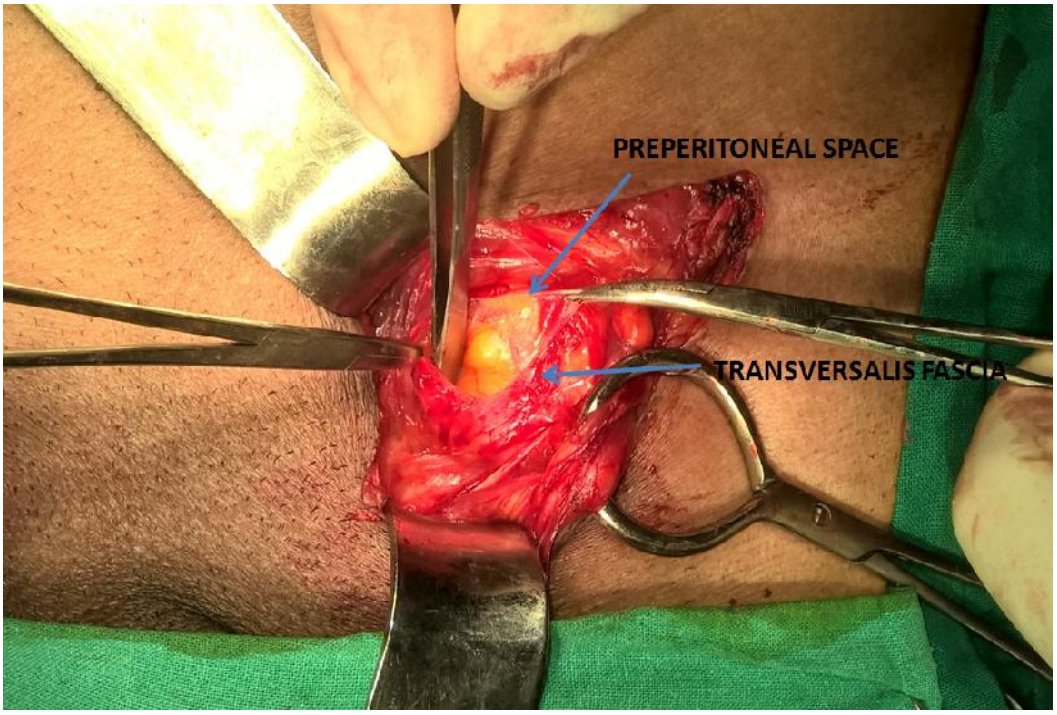
Annexures

Annexure III

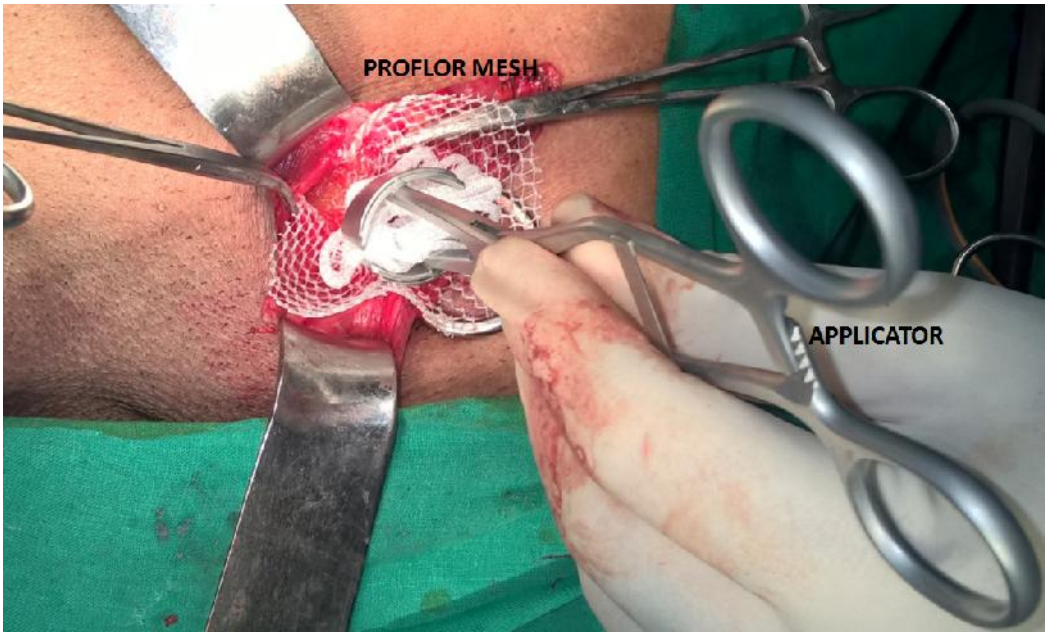
ANNEXURE III – PHOTOGRAPHS

Photograph 1. Opening of external oblique aponeurosis

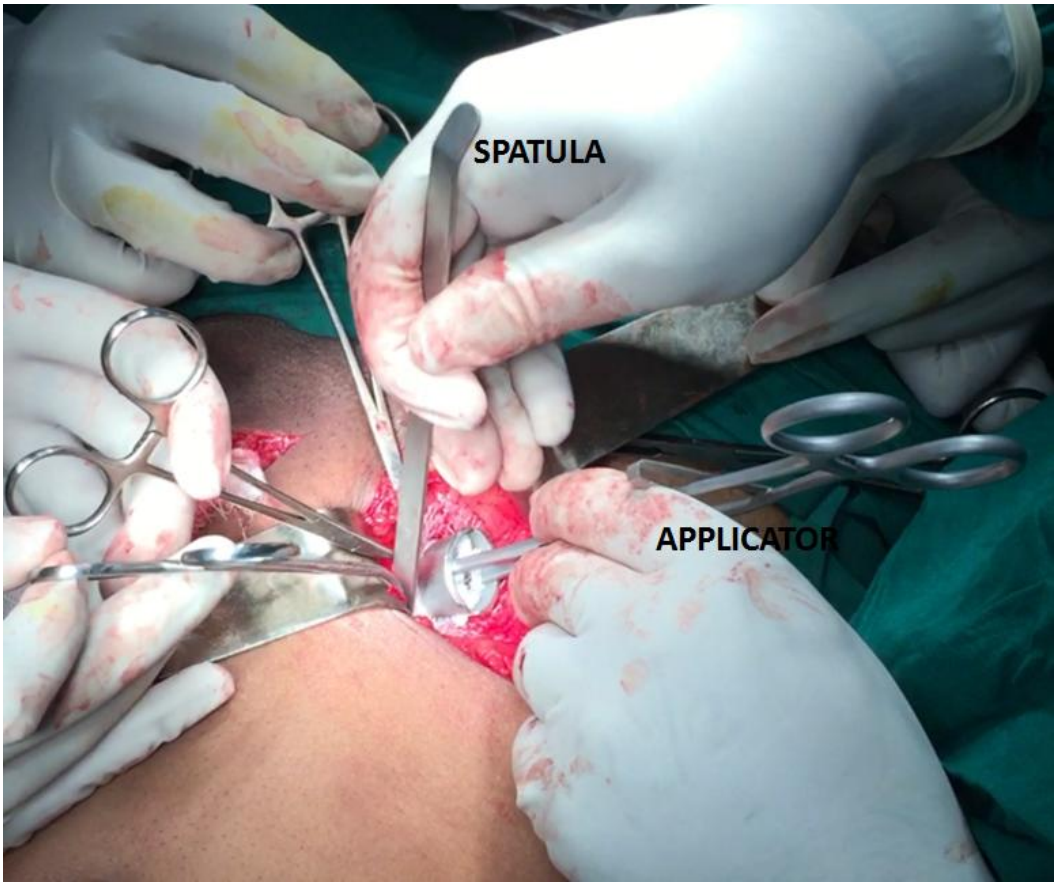
Photograph 2. Identifying cord after opening up of external oblique aponeurosis cord is held with cord holding forceps.



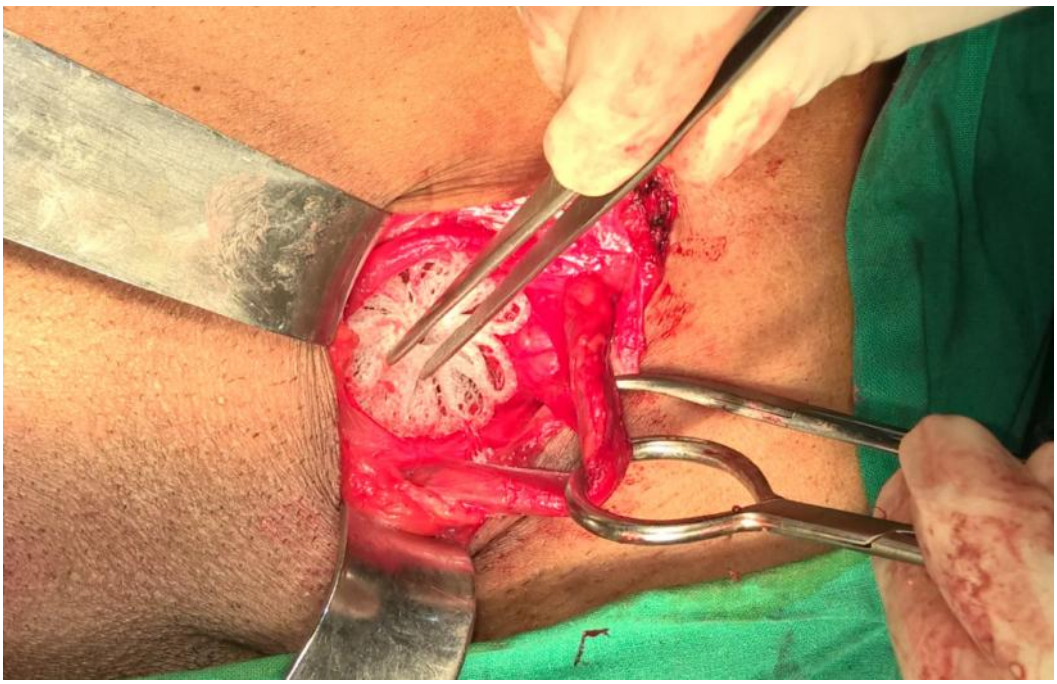
Photograph 3. Preperitoneal space



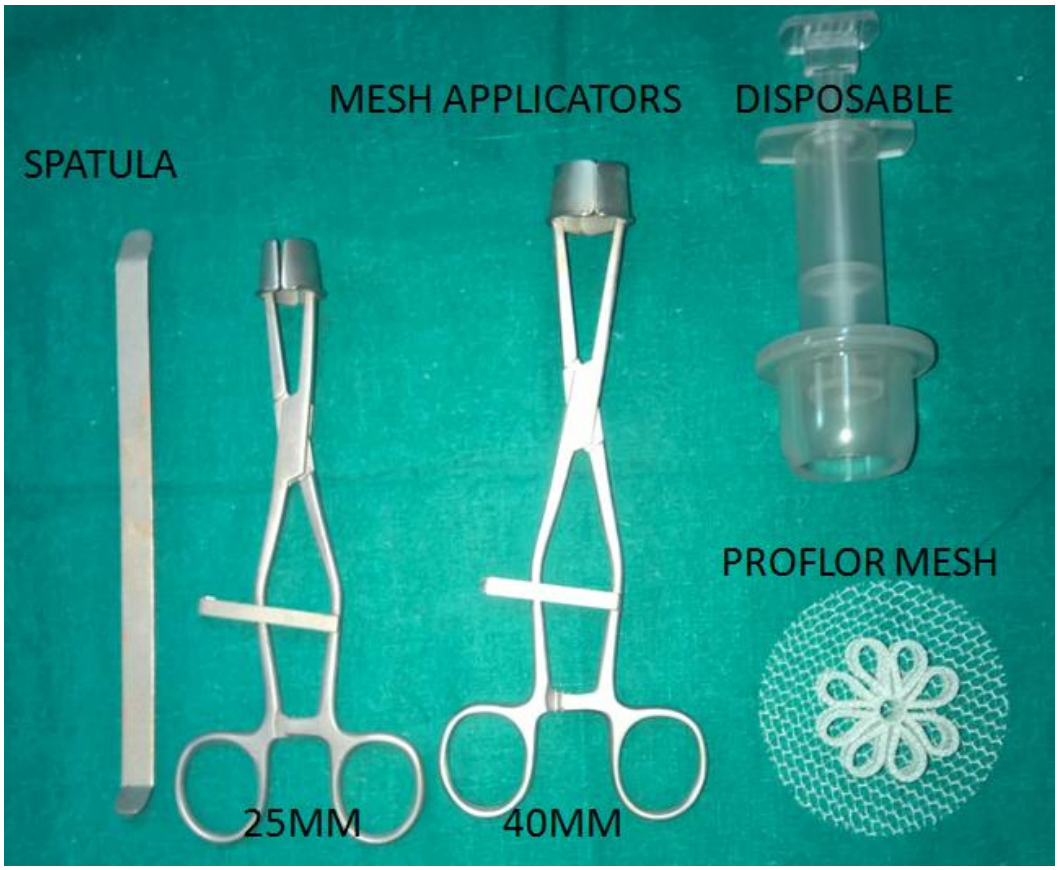
Photograph 4. Deployment of proflor mesh in preperitoneal space with the applicator



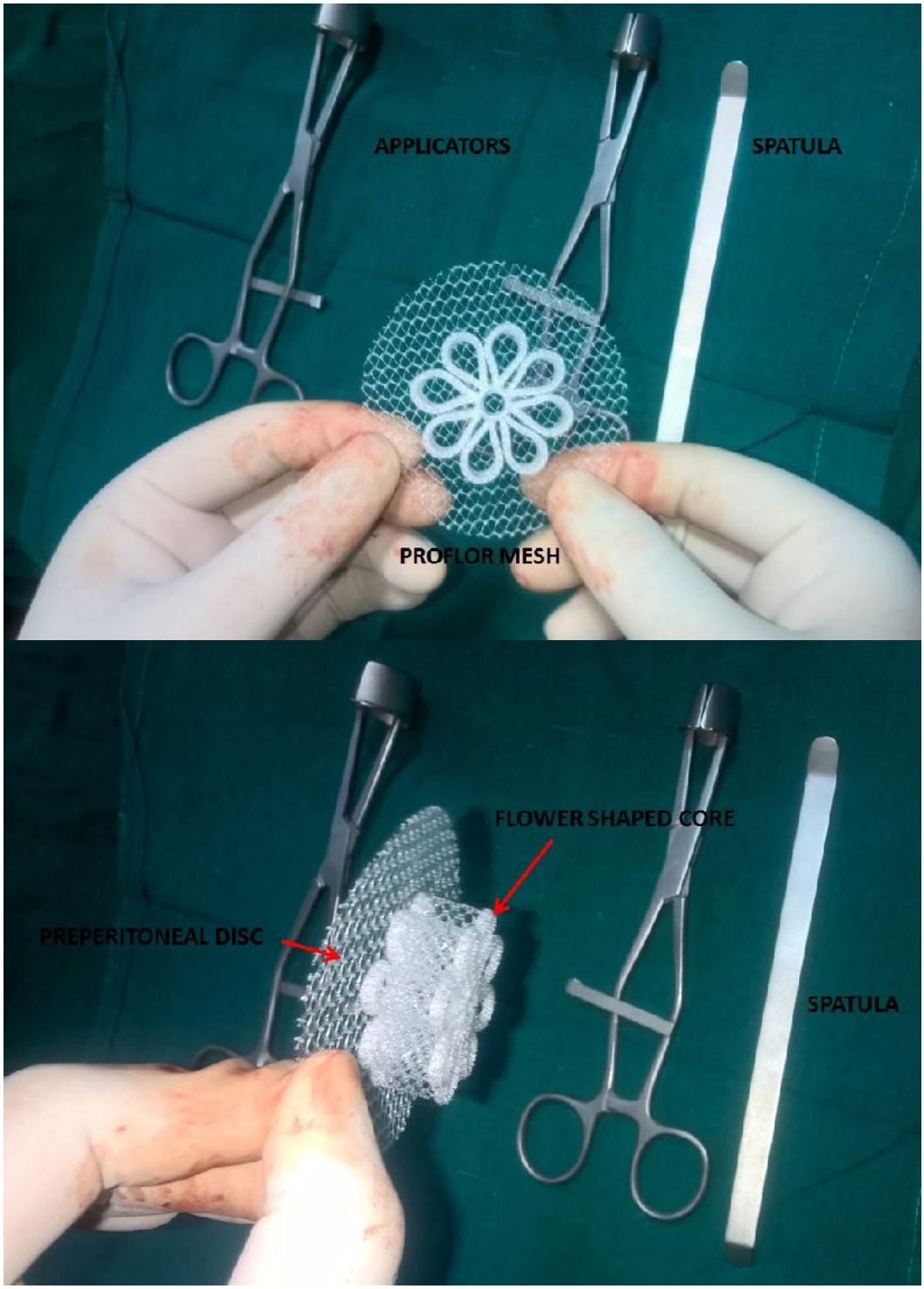
Photograph 5. Spreading preperitoneal disc into preperitoneal space with spatula



Photograph 6. Proflor mesh holding the defect in fascia transversalis



Photograph 7. Proflor mesh with applicators and spatula



Photograph 8. Profor mesh

Annexures

Annexure IV

ANNEXURE IV – MASTER CHART

-	-	Absent
+	-	Present
BL	-	Bilateral
BDH	-	Bilateral direct hernia
BP	-	Blood pressure
Cms	-	Centimeters
L	-	Left
LDIH	-	Left Direct Indirect Hernia
M	-	Male
m	-	Month
mm Hg	-	Millimeters of mercury
R	-	Right
RDIH	-	Right Direct Indirect Hernia
VAS	-	Visual analog scale
Wks	-	Weeks
y	-	Year