"COMPARATIVE STUDY OF SKIN STAPLES AND POLYPROPYLENE SUTURES FOR SECURING THE MESH IN LICHTENSTEIN'S TENSION FREE INGUINAL HERNIA REPAIR: A RANDOMIZED CONTROLLED TRIAL"

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ENDORSEMENT

This is to certify that the dissertation entitled **"COMPARATIVE STUDY OF SKIN STAPLES AND POLYPROPYLENE SUTURES FOR SECURING THE MESH IN LICHTENSTEIN'S TENSION FREE INGUINAL HERNIA REPAIR: A RANDOMIZED CONTROLLED TRIAL"** is a bonafide research work done by **CANDIDATE REG NO. BH0112004**.

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LIST OF ABBREVIATIONS USED

BC	-	Before Christ
BUN	-	Blood urea nitrogen
cm	-	Centimeters
COPD	-	Chronic obstructive pulmonary disease
CT	-	Computed tomography
ECG	-	Electrocardiogram
EHS	-	European Hernia Society
ePTFE	-	Polytetrafluoroethylene
ESR	-	Erythrocyte sedimentation rate
i.e.	-	That is
MD	-	Multidirectional
mm	-	Millimeters
MRI	-	Magnetic resonance imaging
n	-	Total number
p	-	Probability
PP	-	Polypropylene
RCT	-	Randomized controlled trial
TAPP	-	Trans abdominal preperitoneal
TEP	-	Total extraperitoneal
VA	-	Veteran Affairs

// ABSTRACT

ABSTRACT

Background and objectives

Lichtenstein technique of inguinal hernia repair is an effective and safe method with low recurrence rate. This study was designed to compare the two methods for securing the mesh in Lichtenstein tension free inguinal hernia repair so as to draw the benefits of skin staples in terms of total operation time, post operative complications and cost of the operation.

Methodology

This one year randomized controlled trial was done from January 2013 to December 2013 under the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. A total of 60 patients undergoing lichtenstein tension free inguinal hernia repair divided into two groups of 30 each viz., group S (securing the mesh using skin staples) and group P (polypropylene sutures) were studied.

Results

In this study 43.33% of the patients were aged between 46 to 60 years in group P compared to 36.67% in group S ($p=0.839$). The mean age in group P was 49.00±13.71 years compared to 54.23±16.18 years in group S ($p=0.182$). The mean part A operative time was comparable in group P and S (29.82±1.76 vs 29.23±1.48; $p=0.169$). The mean Part B operative time was significantly low in group S compared to group P (17.16±1.61 vs 24.34±1.24; $p<0.001$). Post operative complication of induration and seroma were comparable in both the

groups. None of the patient was observed to have hematoma and infection in both the groups.

Conclusion and interpretation

The skin staples can be applied much more quickly than sutures for mesh fixation thereby saving the operating time without any increase in complications, as compared to the use of sutures. The advantages of speed and convenience of skin staples outweigh marginal extra cost.

Keywords

Inguinal hernia repair; Skin staples; Sutures;

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INTRODUCTION

Hernia is defined as a protrusion of a viscus or a part of viscus through an abnormal opening in the wall of its containing cavity. The most frequent of all hernia is inguinal hernia.[1] An inguinal hernia is a protrusion of abdominal contents into the inguinal canal through an abdominal wall defect.[2]

Inguinal hernias occur in 73% of all the hernia cases and is 20 times more frequent in males than females.[3] The lifetime rate of inguinal hernia is 25% in males and 2% in females. The risk of inguinal hernia increases with age, and the annual incidence is around 50% in men by the age of 75. Approximately two-thirds of inguinal hernias are indirect, and one-third are direct. Approximately 10% of cases are bilateral. Recurrence occurs in about 1% to 5% of cases.[2]

A direct inguinal hernia protrudes through the deep inguinal ring, whereas an indirect inguinal hernia protrudes through the internal inguinal ring and may descend through the inguinal canal. Direct hernias typically develop only in adulthood and are more likely to recur than indirect hernias.[4] If the hernia is severe enough to restrict blood supply to the intestine, it is termed a strangulated hernia, and immediate corrective surgery is necessary. Most inguinal hernias, however, are less dangerous, and elective surgery is often performed to correct the defect. Symptoms include abdominal pain and a lump in the groin area, which is most easily palpable during a cough. Some inguinal hernias, however, are asymptomatic.[5]

Numerous classification systems have been proposed for groin hernias. One commonly used system was introduced by Nyhus in 1993.[6] This system employs

several clinical factors including direct/indirect, degree of enlargement of the internal inguinal ring, and degree of posterior wall weakness. Specifically, it comprises six types of increasing severity: (1) indirect inguinal hernia with a normal internal ring; (2) indirect inguinal hernia with an enlarged internal ring; (3a) direct inguinal hernia; (3b) indirect inguinal hernia causing posterior wall weakness; (3c) femoral hernia; and (4) recurrent hernia.[6] Stoppa[7] proposed that aggravating factors such as obesity or abdominal distension should upgrade the patient by one Nyhus level.[7] Higher severity generally means a higher risk of recurrence, and an appropriate classification may support the management approach.[2]

Surgical repair of hernias is the most commonly performed general surgical procedure. In 2003, an estimated 770,000 surgical repairs of inguinal hernia were performed in United States alone. This large volume of procedures suggests that even modest improvements in patient outcomes would have a substantial impact on population health.[2]

The primary goals of surgery include repairing the hernia, minimizing the chance of recurrence, returning the patient to normal activities quickly, and minimizing postsurgical discomfort and the adverse effects of surgery. The various surgeries present different constellations of benefits and risks, which presents some clinical uncertainty in the choice among approaches. Balancing these factors is a difficult yet critical process in an effort to make the best possible medical decisions.[2]

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

than a hundred repairs have been described for inguinal hernia and practiced at some time or the other over the past century are a testimony to the fact that none has been considered distinctly superior to the others. In recent years, however, the use of mesh for repair of inguinal hernia has become a norm. Reduction in the recurrence rate from more than 15% with tissue repairs to less than 1%, reduction in the postoperative pain and a shorter convalescence have all contributed to the popularity and widespread use of the tension-free mesh repairs.[8]

Surgical procedures for inguinal hernia repair generally fall into three categories: open repair without the use of a mesh implant (i.e., sutured), open repair with a mesh, and laparoscopic repair with a mesh. Within each of these categories, several specific procedures have been employed. Until the 1980s, open suture repair was the standard; however, the resulting tension along the suture line yielded relatively high rates of recurrence and patient discomfort. Nonsutured “tension-free” surgical mesh gained in popularity, and many specific open procedures were used.[2]

Lichtenstein et al. (1989) reported that excessive tension on the suture line resulted in the high recurrence rate after the primary repair. In 1989, Lichtenstein et al. concluded that with tension free mesh repair of hernia, recurrence can be completely avoided. Although many new techniques are available today for hernia repair (plug and patch, TEP, TAPP, PHS), Lichtenstein tension free repair is the most commonly used technique due to cost effectiveness, low recurrence rate, and better patient satisfaction.[9]

The Lichtenstein repair takes into account the important factors identified in the successful outcome of hernia operation—supplementing the strength of

transversalis fascia and a tension free repair. The only disadvantage of the mesh operation is that it requires the use of prosthetic material with attendant risk of infection. Any modification which reduces this threat would be useful.[1]

The main cause for recurrence of hernia is “Suture line tension” brought by suturing of overcasting between annular and ligamentous flap which are not normally in apposition. Needle hole and the tension created by suture material on tissue destroy the valuable sling and shutter mechanism.[1]

The latest trial in this aspect is securing mesh with use of skin staples instead of the usual polypropylene sutures. Staples are applied from a proximate plus MD (multidirectional) release skin stapler. Staples are quick to use and reduce the operating time and minimize the risk of wound infection.[1]

However, there is scanty data exploring the use of skin staples and polypropylene sutures for securing the mesh in lichtenstein tension free inguinal hernia repair. Hence the present study was designed to compare the two methods for securing the mesh in lichtenstein tension free inguinal hernia repair so as to enlighten the benefits in terms of total operation time, post operative complications and cost of the operation.

OBJECTIVES

The objectives of the present study were to compare the skin staples and polypropylene sutures for securing the mesh in lichtenstein tension free inguinal hernia repair in respect to

1. Total operation time.
2. Post operative complication in skin staple group and polypropylene group.
3. Cost of the operation.

REVIEW OF LITERATURE

A hernia, as defined in 1804 by Astley Cooper, is 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.[10]

Historical notes

Some of the earliest data regarding inguinal hernia come from the Ebers papyrus (approx. 1552 BC) and the mummy of Merneptah (1224-1214 BC), which shows possible remaining signs of hernia surgery.[11] 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. What can be termed modern inguinal hernia surgery started in the 1880s, with the anatomical repair introduced by Eduardo Bassini in Padua, Italy.[12]

ANATOMY

Embroylogy[13]

During the sixth week of gestation, mesoderm from the myotomes which lie on either side of the vertebral column invade the somatopleura (primitive wall of the abdomen). 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 embryologic entities between skin and peritoneum permit the processes vaginalis to penetrate them 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 processes 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.[14]

Surgical anatomy[14-18]

The anterior abdominal wall extends 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 and deep layers between which lie superficial vessels and nerves and, in the groin region, superficial inguinal lymph nodes.

a) Superficial layer (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) Deep membranous layer (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

This is a thin layer of connective tissue lying between the inner surface of transverse abdominis and extraperitoneal fat. In the inguinal region, it is thick and dense, and augmented by the aponeurosis of transverses 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 of the anterior abdominal wall 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 7th to 12th 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

The inguinal canal is a passage in the anterior abdominal wall which in men conveys spermatic cord and in women the round 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 illioinguinal nerve passes through the inguinal canal in both the sexes.

Its anterior wall is formed by the external oblique aponeurosis, and laterally by the internal oblique muscle. Its floor is the inrolled lower edge of the inguinal ligament, reinforced medially by the lacunar ligament. Its roof is formed by the lower edges of the internal oblique and transverses muscle, which arch over in front of the cord laterally and behind the cord medially, where their conjoined aponeurosis constitutes the conjoint tendon, which is inserted into the pubic crest and the pectineal line of the pubic bone. The posterior wall of the canal is formed by the strong conjoint tendon medially and weak transversalis fascia throughout.

Figure 1. Muscles of the anterior abdominal wall

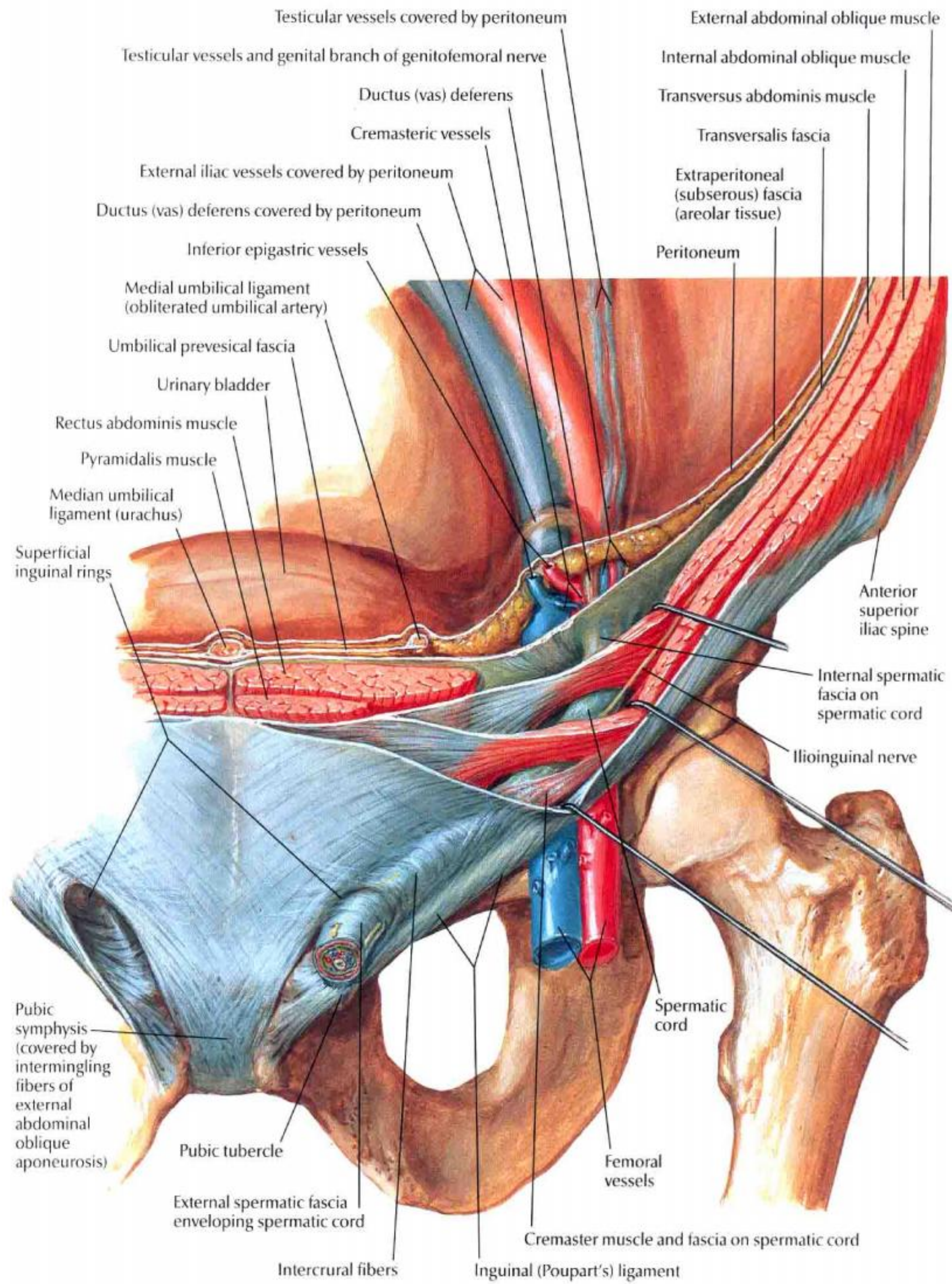


Figure 2. Inguinal canal in the male

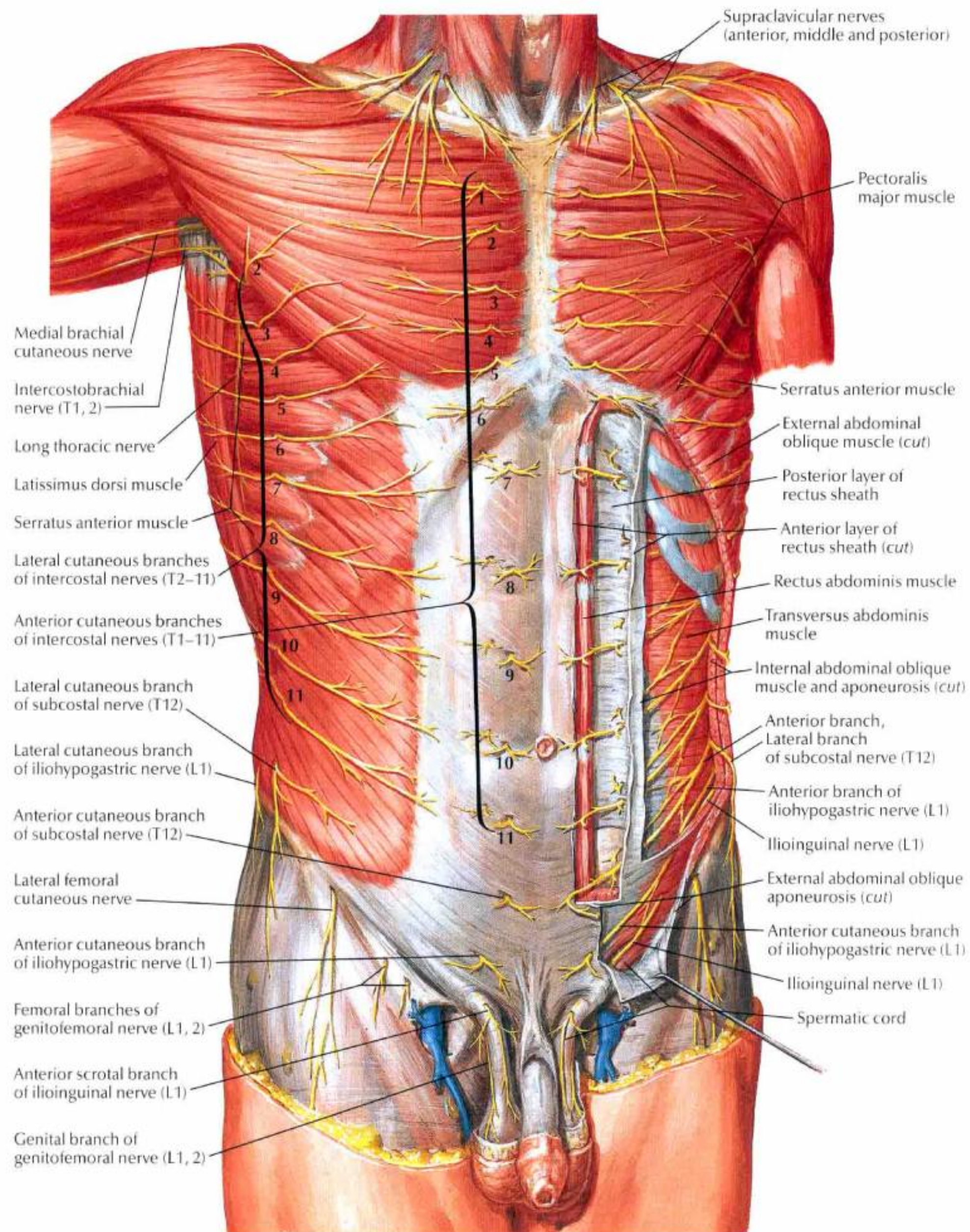


Figure 3. Nerve supply of the anterior abdominal wall in the male

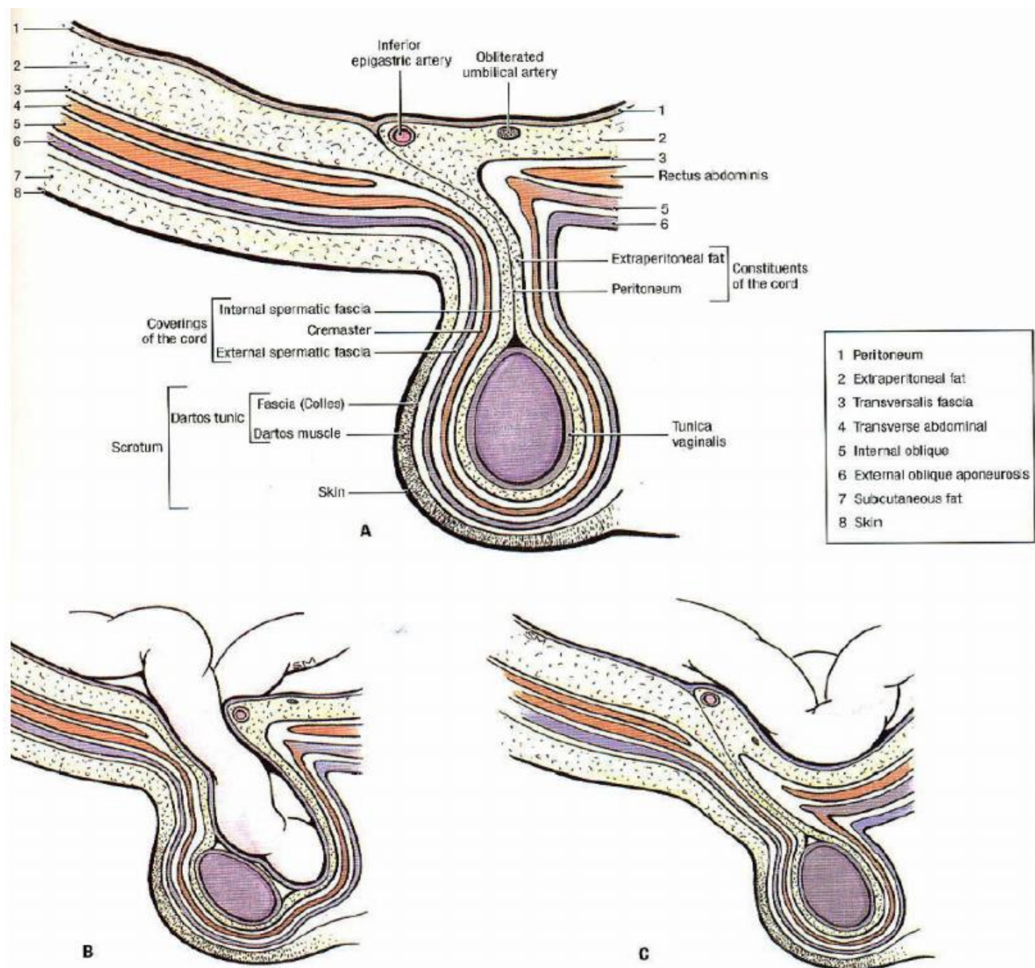


Figure 4. Labelled diagrams: A-Coverings of spermatic cord and testes; B-Indirect inguinal hernia; C-Direct inguinal hernia.

Superficial inguinal ring

It is an opening in the external oblique aponeurosis, which lies above and lateral to the public crest. The ring is triangular in shape with 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 public 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. Fibres from external oblique aponeurosis extends downwards as a tubular fibrous tissue around the spermatic cord and testes forming, external spermatic fascia.

Deep inguinal ring

It is an oval opening in the fascia transversalis, anatomically 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. Traction on this fascial ring exerted by internal oblique may constitute a valve – like safety mechanism when intra-abdominal pressure is increased. Thus preventing the herniation of the intra-abdominal contents.

Boundaries of the inguinal canal

Anterior wall

The inguinal canal is bounded anteriorly by the skin, superficial fasica 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. The integrity of the inguinal canal mainly depends upon the strength of the anterior wall in its lateral part and of the posterior wall in the medial part, and provided the abdominal muscles are of good tone and their aponeurosis unyielding, no direct herniation of viscera can take place.

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.

Throughout its course in the groin, the internal oblique muscle is closely attached to the underlying fibres of transverses abdominis aponeurosis. The internal oblique has a free lower border, which arches over spermatic cord: laterally the margin consists of muscle fibres in front of the cord; medially the margin consists of tendinous fibres in front of the cord; medially the margin consists of tendinous fibres behind the cord. These lower most fibres of internal oblique and transversus are supplied by iliohypogastric and ilioinguinal nevers (L1). Their contraction tightens the conjoint tendon and lowers the roof of the canal, like pulling down a shutter. Thus division of ilioinguinal nerve above this level (as in a muscle-splitting incision of appendectomy) leads to a direct inguinal hernia.

But damage to the ilioinguinal nerve within the canal does not paralyse these muscle fibres; at this level the nerve is sensory, having already given off its motor fibres, and injury here will only cause some sensory loss over anterior part of scrotum in males and labium majus in females and adjacent thigh.

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 transverses 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

It has three covering and six contents. It 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 – This is a loosely arranged layer consisting of striated muscle bundles united by areolar tissue and 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 – derrived 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 constituents 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 lymphnodes, 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. Processes 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.

Epidemiology

More than 1 million abdominal wall hernia repairs are performed each year, with inguinal hernia repairs constituting nearly 770,000 of these cases.[19,20] Approximately 25% of males and 2% of females have inguinal hernias in their lifetimes representing the most common hernia in males and females.[14] Approximately 75% of all hernias occur in the groin; two thirds of these hernias are indirect and one third direct.[21] 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.[22] 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.[20,21] The incidence of incarcerated or strangulated hernias in pediatric patients is 10-20%; 50% of these occur in infants younger than 6 months.[20]

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. Inguinal hernia is most common in men. In the western world 27% of all men but only 3% of all women undergo an inguinal hernia repair during their lifetime.[23]

Classification and symptoms of hernia in the groin

The normal and pathological anatomy of the groin is very complex and has been studied for about 2000 years. In the 18th and 19th century the knowledge improved and most anatomical structures of the groin were described.

The difficulty in understanding the anatomy of the groin is due to four different factors: The three-dimensional relationship between the muscular, fascial and aponeurotic layers and the way they are changed due to the hernia disease.

- The role and the vulnerability of the structures that are passing through the inguinal canal like the vessels, the nerves and the vas deference.
- The dynamic anatomical changes due to body position, abdominal pressure, diseases and previous operations.
- The need to recognize the anatomical structures, whether seen from the anterior or the posterior side of the abdominal wall.

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 epigastic artery and above the inguinal ligament through Hasselbach's triangle. 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. There is no singular Swedish term that corresponds to the English term groin hernia. 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 a irreducible hernia the contents of the hernia sac cannot be reduced into the abdomen.

The irreducible hernias can be chronic (accreta) or acute (incarcerated). 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. Sometimes both situations occur at the same time. Groin hernias can be asymptomatic. When symptoms occur, pain and discomfort are the most common. Large hernias can also give cosmetic problems due to their size. Most other symptoms are connected with complications of the hernia. A previously known hernia that becomes incarcerated often means increased local pain. If it is also strangulated it can give symptoms due

to intestinal obstruction, ischemia of the hernia contents and organ perforation. The symptoms of a severe hernia complication include nausea, vomiting, abdominal pain, local groin swelling and pain. Depending on the severity of the acute general symptoms the local groin symptoms are quite often unnoticed not only by the patient but also by the examiner.

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[24]

Risk factors

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
- 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.[4]

Clinical presentation

Typically, patients may present complaining of either groin pain or swelling/lump. The presence of swelling/lump may be asymptomatic with respect to their activities of daily living. If symptomatic, they may be either minimally symptomatic (intermittent discomfort/pain) or symptomatic with interference with their activities of daily living. Furthermore they may present with incarceration where the hernia is unable to be reduced into the abdominal cavity which may lead to strangulation or ileus.[25]

Clinical examination should reveal a reducible lump in the groin with a positive cough impulse. It is important to identify patient with recurrent hernias as evidenced by previous groin incision/ laparoscopic incisions. Previous lower abdominal scar must be noted as they may influence the approach to repair. Tenderness, signs of inflammation and irreducibility of the hernia may point to strangulation which will require urgent surgery.[25]

Although classically taught to differentiate direct vs. indirect hernias, generally clinical examination has been shown to be inaccurate and does not usually

influence management. It is more important to identify and differentiate femoral hernias from inguinal hernias as the former may require a more emergent repair.[25]

DIFFERENTIAL DIAGNOSIS

Several differential diagnoses to be considered in the diagnosis of groin hernias depend on the presenting symptom. If presenting with swelling in the groin:[25]

- Incisional hernia
- Lymph gland enlargement
- Femoral artery aneurysm
- Saphena varix
- Soft tissue tumour
- Abscess
- Genital abnormalities such as ectopic testis

If presenting with pain without swelling:

- Adductor tendonitis
- Pubic osteitis
- Hip artrosis
- Bursitis Ileopectinea
- Low back pain
- Endometriosis

Physical examination findings

In general, 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. This allows proper direction of pressure for reduction of hernia contents. The examiner should also look for any evidence of obstruction or strangulation.[26]

- When attempting to identify a hernia, look for a swelling or mass in the area of the fascial defect.
    - Place a fingertip into the scrotal sac and advance up into the inguinal canal. If the hernia is elsewhere on the abdomen, attempt to define the borders of the fascial defect.
    - If the hernia comes from superolateral to inferomedial and strikes the distal tip of the finger, it most likely is an indirect hernia.
    - If the hernia strikes the pad of the finger from deep to superficial, it is more consistent with a direct hernia.
- A bulge felt below the inguinal ligament is consistent with a femoral hernia.
- Strangulated hernias are differentiated from incarcerated hernias by the following:
    - Pain out of proportion to examination findings
    - Fever or toxic appearance
    - Pain that persists after reduction of hernia

Investigations

Laboratory Studies

- Complete blood count
  - Results from CBC are nonspecific.
  - Leukocytosis with left shift may occur with strangulation.
- Electrolytes, BUN, creatinine levels
  - Assess the hydration status of the patient with nausea and vomiting.
  - These tests are rarely needed for patients with hernia except as part of a preoperative workup.
- Urinalysis: This test assists with narrowing the differential diagnosis of genitourinary causes of groin pain in the setting of associated hernias.[26]

Imaging Studies

- Imaging studies are not required in the normal workup of a hernia.[27,28]
- 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 (neither sensitive or specific).
- CT scan or ultrasonography may be necessary in the following cases:
  - To diagnose a spigelian or an obturator hernia
  - Inability to obtain a good examination because of body habitus

Generally, patient who present with typical symptoms and signs of groin hernia do not require further imaging for confirmation. The diagnosis is clinical. However, in cases where the diagnosis is unclear, the patient may benefit from ultrasound of the groin which is non invasive and dynamic. The specificity of ultrasound in relation to surgical exploration is 81-100%, its sensitivity is 33% and up to 100% in clinical diagnosis of a groin hernia.[25]

MRI has a role in the diagnosis of groin hernia if the ultrasound done is non-diagnostic. MRI is especially useful for patients who present with pain that may be related to sports pathologies and for soft tissue differentiation of tumour or inflammation.[25]

Furthermore MRI allows for scanning to be done in any plane and dynamically during straining for further accuracy. Its sensitivity has been quoted to be about 94.5% and specificity about 96.3%.[29]

The role of CT is limited in the non acute setting even though it has a sensitivity of 83% and specificity of 67-83%. The role of CT may be useful in the rare case of involvement of the urinary bladder and for the evaluation of intra abdominal pathologies that may cause increased intra abdominal pressure causing hernia formation.[30]

Herniography has been touted as a safe, sensitive (100%) and specific (98-100%) in the diagnosis of the occult hernia. However in our local context it is not widely used secondary to its invasive nature and risk of complications of 0-4.3%, including contrast allergy, intestinal perforation, abdominal wall haematoma and pain.[30]

Assessment

1. <u>Zieman's technique</u>[31]

A distinguished method to find out whether the case is one of direct, indirect (oblique) or femoral hernia is to place the index finger 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.

2. <u>Invagination test</u>[31]

After reduction of the hernia this test may be performed to palpate the hernial orifice. It is better to perform this test in recumbent position of the patient. Little finger should be used to minimize hurting the patient. But if it becomes inconvenient, one can use the index finger. Invaginate the skin from the bottom of the scroutum and the little finger is pushed up to palpate the pubic tubercle. Right hand should be used for the right side and left hand for the left side. The finger is then rotated and pushed further up into the superifical inguinal ring. The nail will be against the spermatic cord and the pulp will feel the ring. Normal ring is a triangular slit which admits only the tip of a finger. If more than one finger can be easily introduced, the ring is abnormally large. But this will not always be associated with hernia. The

patient is asked to cough. Normally the examining finger will be squeezed by the approximation of the two pillars. A palpable impulse will confirm the diagnosis.

When the finger enters the ring – does it go directly backward (direct hernia) or upwards, backwards and outwards (indirect hernia)? The finger is again rotated so that the pulp of the finger looks backwards. The patient is again asked to cough. If the impulse is felt on the pulp of the finger the hernia is a direct one and if the impulse is felt on the tip it is an oblique hernia.

3. Ring occlusion test:[31]

This test is performed in standing position and the hernia must be reduced first. This is a confirmatory test to differentiate an indirect inguinal hernia from a direct inguinal hernia. Since an indirect (oblique) hernia comes out through the deep inguinal ring and a direct hernia medial to the ring, pressure over the deep inguinal ring will occlude the indirect hernia but not the direct hernia. A thumb is pressed on the deep inguinal ring (1/2 inch above the mid-point between the anterior superior iliac spine and the symphysis pubis). The patient is asked to cough. A direct hernia will show a bulge medial to the occluding finger but an indirect hernia will not find access.

A hernia is reducible if it occurs intermittently (such as on straining or standing) and can be pushed back into the abdominal cavity, and irreducible if it remains permanently outside the abdominal cavity. A reducible hernia is usually a longstanding condition, and diagnosis is made clinically, on the basis of typical symptoms and signs. The condition may be unilateral or bilateral and may recur after treatment (recurrent hernia).[32]

Inguinal hernias are often classified as direct or indirect, depending on whether the hernia sac bulges directly through the posterior wall of the inguinal canal (direct hernia) or passes through the deep inguinal ring alongside the spermatic cord, following the course of the inguinal canal (indirect hernia). However, there is no clinical merit in trying to differentiate between direct or indirect hernias.[32]

Management

Once surgical treatment is decided, the operating surgeon has a variety of surgical techniques to choose from. The repair of the inguinal hernia consists of three major components:[31]

1. Dissection of the hernia sac from the spermatic cord structures
2. Reduction of the hernia sac contents and resection of reduction of the hernia sac
3. Repair and/or reinforcement of the fascial defect in the posterior wall of the inguinal canal

While 1-2 are common in almost all hernia repairs, the variation comes from the method chosen to deal with the resultant posterior wall and fascial defect. Essentially repair methods can be considered under broad categories below:[33]

Open

a. Suture based: e.g. Bassini, McVay, Shouldice
b. Mesh based:
    a. Anterior approach: Lichtenstein, “plug and patch”, Hertra sutureless mesh (Trabucco)

b. Posterior approach: Stoppa, Kugel

Laparoscopic

a. Total extraperitoneal (TEP): split mesh, rectangular mesh, preformed mesh, 3D mesh
b. Trans abdominal preperitoneal (TAPP)

Open suture based methods

Bassini first described his technique in 1884 and since then several other have followed with variations of the open suture method all bearing their name. Of all the open suture based methods, the Shouldice technique has been shown to be the best with recurrence rates of 0.7-1.7% in specialized centers. In the Shouldice technique, the posterior wall of the inguinal canal and the internal ring were repaired by means of suture in several layers with continuous non–soluble monofilament suture.[25]

However it is important to note that the Shouldice technique done in general surgical practice have poorer results with long term recurrence rates between 1.7-15%6. Indeed the criticism of the suture based repair is the application of tension over the repair site. This may result in ischemia, causing pain, necrosis and ultimately tearing of sutures and recurrence of the hernia.[31]

Open mesh based methods

The principle behind the open mesh method is the tension free reinforcement of the fascial defect in the posterior wall. This may be done via 2 fundamentally

different methods of either blocking the defect with a plug or reinforcement with a flat mesh of non-absorbable material e.g. polypropylene.[25]

By far the Lichtenstein technique, introduced in 1984, has been the best studied and the method of choice in the open mesh technique. The technique, in brief, involves positioning the mesh between the internal oblique muscle and the aponeurosis of the external oblique and suturing to the inguinal ligament with a 2cm medial overlap of the pubic tubercle. This technique's popularity has been largely attributed to its reproducibility with minimal perioperative morbidity, low recurrence rates in the long term and ability to be performed under local anaesthesia as a day surgery.[31]

The most well known of the open posterior approach mesh repair is the Stoppa technique. This involves the dissection of the preperitoneal plane via an abdominal incision to expose the myopectineal orifice of Fruchaud with the insertion of a large mesh covering all the orifices. This method can be considered a precursor to the laparoscopic mesh repair that we have today and is still the procedure of choice in complex hernias.[34]

Another technique described is the open preperitoneal mesh placement of the Kugel patch with short-term results comparable to the Lichtenstein technique.[35]

Laparoscopic methods

The laparoscopic inguinal hernia repair was first performed by Ger and colleagues[36] in 1982 with the simple closure of the internal ring with a stapler. Arregui then reported his trans-abdominal preperitoneal (TAPP) technique in 1991. This involved the incision of the peritoneum to reveal the myopectineal orifices, the

hernia sacs dissected out and reconstitution of the peritoneum after placement of a large prosthesis to cover the hernia defects. However the need to transverse the abdomen cavity to reach the preperitoneal space has led to concerns about potential visceral injury and adhesions.

This led to the evolution of the totally extraperitoneal (TEP) technique. In TEP the access to the preperitoneal space is achieved with a dissecting balloon, a laparoscope or blunt dissection without entry into the peritoneal cavity. A mesh prosthesis is inserted into the preperitoneal space and the pneumopreperitoneum is evacuated under direct vision. Variations in technique generally exist in fixation methods (Tacks, no tacks, Fibrin glue) and mesh configuration (Wrapped around cord, 3D mesh).[37]

Unilateral hernias

Mesh or no mesh

Results from a systemic review of RCTs by the Cochrane collaboration/EU Hernia trialist Collaboration in 2002 and 2003 showed strong evidence that fewer hernias recur after mesh repair than following non mesh repair. Furthermore the chance of chronic pain is reduced with mesh repair.[31]

Following that, 3 RCTs comparing Shouldice and Lichtenstein techniques showed that recurrences were clearly higher in the Shouldice technique.[38-40] In the authors own analysis done as part of the European Hernia Society guidelines (EHS),[31] they performed an additional meta-analysis comparing the Shouldice repair with different mesh techniques in all trials with follow-up of more than 3 years.

Their results show that mesh technique is superior regarding recurrence but not at the expense of more pain.

If mesh, what mesh is best?

While the use of mesh in hernia repair is relatively well established in the literature, the type of mesh to be used is still a matter of debate. Since the first described use of polypropylene prosthetics in inguinal hernia repair by Usher in late 1950s,[41] the types of prosthetics available has been bewildering. The variability in terms of classification of lightweight vs. heavyweight, pore size and the myriad raw materials used for meshes make direct comparisons between meshes difficult.

Generally mesh prosthetics can be considered based on its characteristics15. They may be synthetic non absorbable, coated non absorbable, partially absorbable or biologic. Furthermore, they can be considered based on their material density ("weight") porosity and strength. The flat synthetic non-absorbable polypropylene mesh is the best-studied mesh with the longest experience and most articles in the literature. It is the mesh of choice of most surgeons in open inguinal hernia repairs. The monofilament nature of the mesh also reduces the chance of incurable chronic sinus formation or fistula, which can happen in patients complicated by deep infection. Weight reduced, macroporous (<1000 um) oligofilament prosthetics seem to shrink less, induce less scar formation and inflammatory reaction therefore causing less long term discomfort and foreign body sensation when used in open hernia repairs. However this must be balanced against increased risk of hernia recurrences especially if they are not adequately fixed or overlapping as suggested in literature.[31]

A recent review article suggest that indeed the selection of the appropriate mesh prosthetics should be based on the sound understanding of properties of the mesh selected, the technique used and for the appropriate clinical scenario.[42]

Perhaps the answer then is not a "best mesh" for all inguinal hernia repairs but the right mesh for the right technique in the right patient.

Open mesh or laparoscopic mesh?

Several recent meta-analysis of RCTs[43,44] done including a recent systemic review18 showed several benefits of laparoscopic mesh repair over open. These include Less wound infection; Less haematoma; Less chronic pain/numbness; Earlier return to normal activities or work; and Shorter hospital stay;

Benefits of the Lichtenstein repair however included Shorter operation time; Lower incidence of seroma; and Lower recurrences. This benefit of lower recurrences however is debated as most of the recurrences in the laparoscopic group were strongly influenced by the Veteran Affairs (VA) Multicenter trial[45] where the minimum sized mesh was 7.6x15cm, which some experts feel may have been undersized. When this trial was excluded, there was no difference between open and endoscopic surgery.

Clear benefit of Lichtenstein repair however is observed in patients who have large scrotal irreducible inguinal hernias, after pelvic irradiation or major lower abdominal surgery or who are not able to undergo general anaesthesia.[25]

Complications were higher in the laparoscopic group – particularly of rare but serious complications of major vascular and visceral (bladder) injuries.[25]

If open mesh repair, what anaesthetic method is best?

Open hernia repair may be performed under general, regional or local anaesthesia. In contrast, in local centres, all laparoscopic hernia surgery is done under general anaesthesia. The type of anaesthesia used for open hernia repair is important because many postoperative side effects and prolonged hospital stay are often related to effects of anaesthesia.[25]

Local anesthesia has been show to be superior to general/regional anaesthesia in terms of less postoperative pain, less anesthesia related complaints, less micturation difficulties with faster discharge and short-term recovery. However, this may not be suitable for patients who are very young, anxious, morbidly obese and complex or complicated hernias.[25]

Furthermore, surgeons need to be familiar with the infiltration technique. Indeed most of the dissatisfaction with local anaesthesia involved intraoperative pain experienced by the patient.[25]

General anaesthesia provides the surgeon with optimal operating conditions with patient immobility and muscle relaxation. Currently, general anaesthesia with short acting agents combined with local infiltration of analgesics is considered safe and fully compatible with day surgery. However this may be complicated by risk of airway complications, cardiovascular instability, nausea/vomiting and urinary complications, which may prolong hospital stay.[25]

Nevertheless, general anaesthesia is a valid alternative to local anaesthesia especially when used in combination with local anaesthesia. Regional anaesthesia may be administered either with spinal or epidural techniques. This is viable options

especially when the patient has significant risk of general anaesthesia and not suitable for local anaesthesia.[25]

However, in the latest EHS guidelines there is level 1b evidence to suggest that regional anaesthesia, especially when using high dose and/or long acting agents, has no documented benefits in open hernia repair, increases the risk of urinary retention and should be avoided.[31]

Laparoscopic mesh – TEP or TA PP

Although operating in the same preperitoneal plane, the access to the plane is different comparing TEP versus TAPP and hence the complications. TAPP had a higher proportion of major vascular and visceral injuries compared with TEP and open surgery (0.65% vs. 0-0.17%). Furthermore TAPP may cause more intra abdominal adhesions leading to intestinal obstruction in a small number of cases.[31]

A specific meta-analysis comparing TAPP versus TEP stated that there was insufficient data to allow conclusions to be drawn but suggest that TAPP is associated with higher rate of port site hernias and visceral injuries although TEP was associated with higher number of conversions.[44]

Once mesh in place for TEP, do we need fixation

Studies of laparoscopic hernia recurrences have shown that medial or lateral recurrences are caused by rolling up of the mesh thus prompting some authors to use mesh fixation either with sutures or tacks.[46,47] However, the use of tacks has been associated with postoperative pain and nerve injury particularly to the femoral branch of the genitofemoral nerve and lateral femoral cutaneous nerve.

In recent times there has been a move away from mesh fixation in laparoscopic TEP. A large retrospective study had shown no significant increase in recurrences and furthermore less pain at 4 weeks, shorter hospital stay, lower rates of urinary retention and seroma formation and earlier return to normal activities.[48]

A recent meta-analysis of outcomes of staple fixation vs. non fixation of mesh by Tam et al however did not demonstrate any significant difference in post operative pain. The study did however demonstrate a significant decrease operative cost and reduced operative time and inpatient stay with no significant difference in complications and recurrences.[49]

Bilateral hernias

In bilateral hernias limited data exist comparing open vs. laparoscopic mesh repair. Data suggest that there is no significant difference with recurrences and persisting pain between the 2 methods. However laparoscopic methods (TAPP/ TEP) may offer reduced time to return to normal activities compared with open mesh repair.[25]

Recurrent hernias

In general, recurrent hernias would benefit from another plane of dissection from the initial method of repair. Thus if the initial repair was done laparoscopically (where dissection was done in the preperitoneal plane), recurrences would be better done handled via the open anterior method e.g. Lichtenstein technique. This is also true vice versa where recurrences from previous anterior approach would benefit from repair via the posterior preperitoneal method.[25]

Evidence points to reduced perioperative complications, post operative pain, analgesia requirements and time to return to normal activities with laparoscopic approach (both TEP/TAPP) compared with repeat open anterior approach (Lichtenstein) in recurrent inguinal hernias.[50] Further evidence comparing TAPP versus Lichtenstein showed less postoperative pain and shorter sick leave for the laparoscopic group with comparable recurrences and chronic pain.[51]

Complications of inguinal hernia surgery[52-55]

Surgical complications

Hemorrhage

Serious haemorrhage can occur after trauma to pubic branch of obturator artery, deep circumflex iliac vessels and inferior deep epigastric. Damage to first three is troublesome. The vessels may be ligated with impunity. External iliac vessels must not be ligated and haemostasis achieved by applying pressure.

Transection of spermatic cord

In rare instances in which unintentional transaction of the spermatic cord occurs during an operation. Fever, tenderness and swelling of the testis follow in two third of the patients. But one third of patients are asymptomatic.

Severance of nerve

The ilioinguinal, Iliohypogasrtic and both the genital and femoral branches of the genitomoral nerve are vulnerable to injury during groin hernia repair. Ilioinguinal nerve provides sensory innervations to base of penis and upper scrotum

and adjacent thigh. Iliohypogastric nerve provides sensation to the supra public area. The genitofemoral nerve provides motor innervations to cremastric muscle and sensory innervation to skin of the penis and scrotum.

Fortunately, there are multiple cross connections between peripheral nerves in the groin and considerable central segmental overlap in their sensory representation. Prolonged anaesthesia of skin does not follow injury to one of these nerves. Anaesthesia if present in immediate postoperative period regress by 6th postoperative month. In genitofemoral branch injury patient may complain of testis on the side operated rests in somewhat more dependent position. It is impractical to attempt anastomosis. The nerve ends should be ligated to close the neuronal sheath and enforce development of the inevitable post-traumatic neuroma with in nerve sheath.

Nerve entrapment by a suture result in prolonged post operative symptoms to avoid this careful identification of nerves and protect them during dissection.

Severance of testicular blood supply

Internal spermatic or testicular artery arises from aorta and is the main arterial supply to testis. External spermatic artery a branch of inferior epigastric artery which supplies scremastric muscle. Potentially a rich collateral circulation exists at the upper end of the testis between end branches of the vesicle and prostatic arteries and the internal spcrmatic and differential arteries also have free anastomotic connections to vessels of spermatic cord just external to the superficial inguinal ring.

Every precaution should be taken to prevent damage to vessels of cord. If damage occurs, repair being impractical ligation is necessary. Ligation of the major

artery to the testis at the level of the deep inguinal ring does external collateral circulation is undisturbed. Preservation of this collateral circulation is accomplished by not dissecting the testis from the scrotum during repair.

Trauma to vas deferens

Trauma to vas deferens can be one of transaction or obstruction. Transaction is a mishap that usually occurs through open repairs, particularly in recurrent hernial repairs. Because there are two vas diferentia, transaction of a single vas may be considered minimal importance by the surgeon but rarely by the patient. Unless permission for transaction obtained preoperatively. Reanastomosis should be attempted with ‘O’ prolene as stent and with interrupted 3/0 chromic catgut approximately 50% usually are considered to function after repair.[56] Obstruction can result from handling of vas with forceps causing fibrosis and adherent to posterior inguinal wall leading to outflow obstruction and dysejaculation in 0.04% of herniorrhapies.

Damage to intestine

Complications relating to bowel during open technique of hernia are limited in two situations that is, freeing of incarcerated or strangulated segment of bowel and inadvertent laceration of large bowel in presence of sliding hernia.

During high ligation blind suturing is never acceptable because of the possibility of incorporating a loop of intestinal within the suture leading to obstruction, abscess within the intestinal wall or fecal fistula. The bowel may be injured either by entering it directly or by devitalizing it through interrupting its blood supply. Incised bowel should be immediately repaired with interrupted

seromuscular sutures of fine silk. Devitalised bowel must be dealt with either by exteriorization or resection. If resection is necessary in unprepared bowel, the anatomises in the sigmoid should be protected by a temporary diverting transverse colostomy.

Injury to bladder

Medical side of direct inguinal hernia often contains a sliding portion of bladder wall. If injury to bladder wall occurs the defect should be closed in two layers with interrupted chromic catgut sutures and an indwelling urethral catheter inserted for 5 days. Repair of hernia should be completed after the bladder injury has been treated.

Post operative complications[55]

General causes

Systemic complication occurs at a rate comparable with that after other surgical procedures of the same magnitude. Atelectasis and pneumonitis were most frequent followed by thrombophlebitis and urinary retention.

Scrotal Ecchymosis

It manifests during 2nd of 3rd post operative day. The skin of the scrotum has become discoloured by a dark purple ecchymosis. This complication results from dissection of blood from the inguinal canal in to the scrotum following the path of spermatic cord. Usually there is little or no haematoma palpable in the scrotum or the inguinal canal. The usual cause of scrotal ecchymosis is a small vessel

overlooked intra-operatively. Ecchymosis resolves spontaneously within few weeks post operatively.

Swollen Testis

Most common cause is that the tissues of the deep ring are closed too tightly. About the spermatic cord less frequently interruption of venous and lymphatic vessels has occurred in the course of the dissection of an indirect inguinal hernial sac or the spermatic cord as it passes through the deep inguinal ring or thrombosis of pampinform plexus has occurred.

Collateral lymphatic and venous channels usually develop in this situation and the swelling eventually subsides. Support of swollen testis and to restrict the activity to reduce the degree of discomfort.

Ischemic orchitis and testicular atrophy

Ischemic orchitis is a syndrome that can occur after inguinal hernioplasty consists of painful, tender, and swollen testiele and spermatic cord. Fever precedes testicular manifestations. The testicular abnormality is apparent only on 2nd or 3rd days after the operation.

The complication usually develops as the result of Arterial insufficiency or venous insufficiency or combination of both. Testicular atrophy is especially prone to occur after repair of an indirect complete scrotal hernia.

Ischemic orchitis may resolve completely or progress to testicular atrophy. Only rarely does the testicle become gangreneous. The fever disappears promptly but pain and tenderness may last for several weeks. It takes 4-5 months for size and

shape to come to normal. In most cases atrophy is apparent within few months of surgery.

Although atrophy of one testis does not diminish a patient's fertility or sexual potency such reassurances are often not completely satisfying to many patients.

It can be minimized by careful, non traumatic dissection of the spermatic cord by attention to preservation of venous and lymphatic drainage and by avoidance whenever possible of dissection of the testis and the distal portion of the spermatic cord from the scrotum.

Hydrocele

Collection of fluid in the scrotum or along the spermatic cord may result from leaving portion of distal hernial sac in situ. Hydrocele like collections of fluid also may form if lymphatic or venous drainage is unduly interrupted in the course of hernial repair. Mild swelling disappears within few days after the operation. Most of the large swelling due to fluid collection respond to simple aspiration of the fluid by syringe.

Wound infection[57-60]

The incidence of wound infection after primary repair of groin hernia is approximately 1% and in recurrent hernia up to 3%. If the infection extends below external oblique aponeurosis, recurrence becomes very high. Wound infection managed by early recognition, reopening of wound to permit drainage, and appropriate local care, systemic antibiotic indicated if symptoms of invasive sepsis.

Recurrence[61,62]

A weakness in the operation area necessitating further operation. There is no question that both through anatomical knowledge and skilled technique necessary for successful repair. One technical point deserves particular emphasis absence of tension in the completed hernial repair is essential to success.

Although recurrence of hernia is related in a small minority of patients to inadequacy of the patients fascial structures, the reason which accounts for the vast majority of hernial recurrences following operative repair is a technical failure on the surgeon. The most common mistake is the creation of too much tension in the wound. A hernia repaired under tension will not heal normally and is subject to disruption throughout the period of wound healing

Recurrence after 6 months is due to factors other than technical error or selection of inferior proceducer.[63] Recurrence is also due to decreased collagen synthesis. Other causes of recurrence are infection, too much tension during repair. Prevention of recurrence is done by supplementing the basic repair with additional support by prosthetic mesh.

Missed hernia

A missed hernia is a hernial defect present at the time of primary hernial repair but unrecognized by the operator and appearing subsequently as a new hernia. From the patient’s point of view this is recurrence. Missed hernias can be avoided by careful inspection and palpation of all potential hernial areas in the groin when the primary hernial repair is being conducted.

Other complications

Other complications include urinary retention, neuroma (Ilioinguinal and femoral neuritis caused by entrapment by sutures or the actual formation of symptomatic neuroma. Most syndromes can be expected to resolve spontaneously without treatment. Those with persistent symptoms can be treated by nerve block. After 1st post operative month rarely wound re-explored to localize neuroma and excision), hematoma, seroma, sinus formation, numbness and paraesthesia, sexual dysfunction and groin pain. Common causes are abdominal muscle strain, nerve entrapment, neuroma, periostitis of public tubercle and adductor tendenitis

History of Surgical meshes

The history of surgical meshes is an outstanding example for the progression in hernia surgery and possible benefit for patients from the use of biomaterials in general. The idea of strengthening of abdominal wall and in particular, surgical hernia repair with autologus material has been claimed in the last century, although meshes were first commercially available 40 years ago.[64]

It was Billroth who at the end of last century dreamed of strengthening the repair : “If we could artificially produce tissue of density and toughness of fascial & tendons, the secrete of radical cure of hernia would be discovered”. Artificial material was introduced in 1889 By Witzel, who used a mesh of silver wire for abdominal wall hernia repair. Busse in 1901 even used a gold wire. In 1931 Fieschi proposed implantation of rubber sponges. In 1940 Ogilvie published the use of cloth mesh of metallic wire to treat hernia patients. The triumphant progress of meshes had its beginning after World War II, with the development of synthetic polymers

for medical purposes, particularly with the construction of the polyester mesh mersilene in 1954 and the polypropylene mesh marlex in 1962.[64]

In 1958, Horwich used a prosthetic material made of elasticated nylon in patients with large or recurrent inguinal hernias. He recognized that any recurrence would occur at the edge of the prosthesis and that an implant of sufficient size to widely overlap the deficiency is required.[65]

In 1959, Usher et al reported a successful implantation of surgical mesh at first time in 13 dogs and afterwards in patients with abdominal wall hernia. They used relative thin strip (2.5 * 7 cm) of marlex as an additional buttress to reinforce conventional repairs and his initial experience was favourable with no infective complications.[65] He also commented on the benign postoperative course of these patients who had remarkably little postoperative pain. In 1963, an improved version of marlex was introduced by Usher based on new knitted mesh of polypropylene monofilament fibres, used initially as a suture material and this remains the prosthesis used today, polypropylene mesh has had an enormous impact on surgery over the past 35 years and countless patients have had their lives extended or improved by its application to numerous surgical problems. It is quite clearly and justifiably the most popular prosthetic mesh available today for surgical implantation.

In 1970, mainly French surgeon elaborated further technical details to cure various hernias with the help of mesh prosthesis, but it was in the 1990, that the use of meshes spread unimaginably due to the simple Lichtenstein's tension free repair

and newly developed laparoscopic technique, which are based on the obligate use of meshes.[64]

History of surgical stapling

Surgical stapling was developed in 1908 by Hulti Hummer in Austria. The original instrument was massive by today standard weighing 7.5 pounds. Modifications performed by Von Petz provided a lighter and simpler stapling device, and 1934 Fredrick of Ulm designed an instrument that resembles the modern linear stapler. The next major advances came from Russia after World War II. In 1958, Ravich, whose thorough research and development, refined the instrument to their current status and wide spread use today.

The most significant modification has been a introduction of absorbable staples when these are used in gynaecological operation, morbidity related to infectious granuloma and dysperunia has been diminished. Now a day disposable skin staplers are available. Stapler use also causes considerably less damage to wound defences.

Skin Staplers[66,67]

The PROXIMATE PLUS MD Skin Stapler is a sterile, single patient use instrument designed to deliver rectangular, stainless steel staples for routine wound closure. The PROXIMATE PLUS MD Skin Stapler is supplied sterile and preloaded for single patient use. It should be discarded after its use.

Figure 5. Stapler

Features

- Improved kick-off spring design
- Ergonomic design
- Alignment indicator
- Staples are coated with lubricant

Benefits

- Multi-directional release
- Comfortable for smaller hands
- Improves visibility
- Easy staple extraction

Regular staples have a diameter of 0.53 mm, a span of 5.7 mm, and a leg length of 3.9 mm. The staples are made from stainless steel with an inert coating. The length of the prongs on the staples is 3.9 mm, which appears sufficient to provide good penetration into the tissue, with secure fixation of the mesh.

When it is not possible to maintain at least a 5mm distance from the stapled skin to underlying bones, vessels, or internal organs, the use of staples for skin closure is contraindicated. Instrument should not be resterilised. It may compromise the integrity of the instrument which may result in unintended injury.

POLYPROPYLENE (PROLENE) (CH2-CH (CH3) -) n[66]

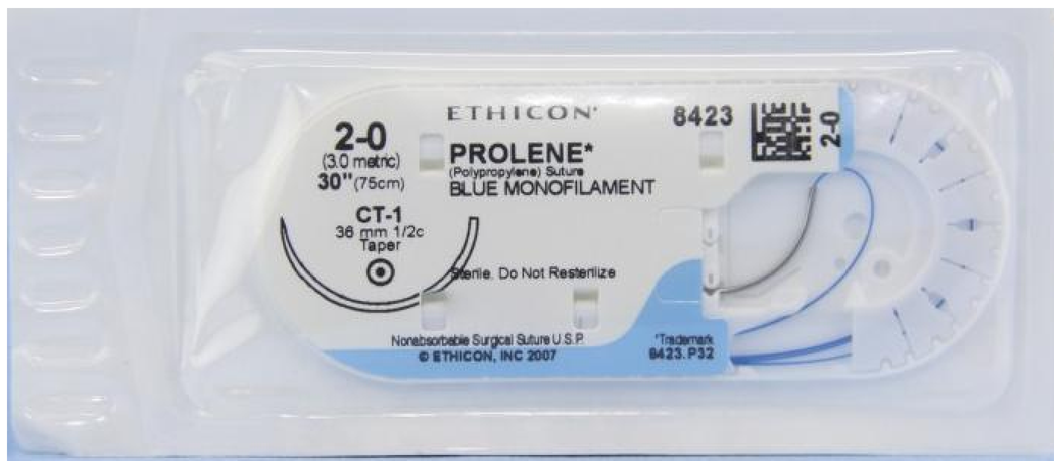


Figure 6. Prolene suture

It is a monofilament suture material and is chemically extruded from a purified and dyed polymer which is neither absorbed nor weakened by the action of tissue enzymes.

It is supposed to resist physical decay even after years of being implanted. Filaments made of polypropylene have similar strength to steel, although they are only one eighth the density of iron. It has an extremely high tensile strength which it retains indefinitely on implantation. This lack of adherence to tissue facilitates its use as permanent suture. It can extend up to 30% before breaking and hence is useful in situations where postoperative some give and take is required on the part of the suture to accommodate the postoperative swelling and they help to prevent tissue

strangulation. Handling is good and knotting is very secure since the material deforms on knotting and allows knot to bend down on itself. It has no coefficient of friction and slides through the tissue readily.

It is extremely smooth and it is less thrombogenic as compared to silk. It is inert and non-biodegradable. Being monofilament it should be carefully handled during surgery as rough handling and inadvertent crushing will damage it. Rough handling may cause fracture on strand which may break later in the post-operative period. It is sterilized by Ethylene dioxide.

PROPERTIES OF SURGICAL MESH[64]

Non absorbable meshes are knit, fabricated, net like material with high strength at the cut border, or almost a film like sheet, usually made of polypropylene (PP), polyester, ePTFE, till today, the superiority of either material has been controversial. The various meshes differ largely in their basic polymers, their weight from < $30g/m^2$ to > $100g/m^2$ and their pore size (from < 100 micron to >5 mm) implying considerable differences of their textile and mechanical properties. A pore size of at least 100 micron is required to permit an in growth connective tissue.[64]

According to international textile standard, a complete examination of surgical meshes consist of description of basic filament, weight, pore size (measurement of pore size is difficult, for the complex combination of several filaments prevent a uniform pore size), pulling force at strips, recovery angle and a test pressing through stamp that reflects best the in vivo strain.

After implantation; this polymer initiates a subacute inflammatory reaction of the host tissue with a consecutive fibrosis and high mechanical stability. Direct

contact with the intestine has to be prevented very carefully because polypropylene mesh tends to form intense adhesion and later fistula.

As a consequence of physiological wound contracture depending largely on the extent of inflammation, the polypropylene meshes show a considerable shrinkage of about 20% in length and 40% of surface area, sometimes folding and forming sharp edges. Polypropylene regularly causes, as do the other materials the development of the oedema around the implant, so that the drainage for 2 – 7 days is usually advisable. The induction of intense fibrosis entirely embedding the mesh into a scar plate is frequently followed by restriction of abdominal wall mobility and complaints of patients.

Properties of ideal prosthetic material[68]

In 1950s, Cumberland and scales developed criteria for ideal implantable biomaterial. These have been enumerated more recently by Homes, Hodges and Scott. The material should be

- Not be physically modified by tissue fluids
- Be clinically inert
- Not excite an inflammatory or foreign body reaction
- Be non-carcinogenic
- Not produce a state of allergy or hypersensitivity
- Be capable of being fabricated in the form required
- Be capable of being sterilized

Future biomaterial must be the additional criteria to a nearly match the Cumberland and scales requirement for the ideal prosthetic material

- They must be resistant to the infection.
- Must provide barrier to adhesion on the side of the material placed adjacent to the abdominal viscera
- They must respond in vivo more like autologus tissue, allowing tissue incorporation for good fixation and strong lasting repair without encouraging the scarring and encapsulation problems seen with today prosthesis

Lichtenstein tension – free hernioplasty

A 5cm skin incision which starts from the pubic tubercle and extends laterally within Langer's line is made. External oblique aponeurosis is opened and its lower leaf freed from spermatic cord and upper leaf from underlying internal oblique muscle. The cord with its cremasteric covering is separated from the floor of inguinal canal and pubic bone.[69] Cremasteric sheath is incised longitudinally and indirect hernial sac is freed from the cord to a point beyond the neck of sac and inverted into the abdomen. In complete scrotal hernia, the sac is transected at the midpoint of the canal leaving the distal section in place and anterior wall of distal sac is incised to prevent postoperative hydrocele. In case of direct hernias, the large sacs are inverted with absorbable suture. A thorough exploration of groin is necessary to rule out co- existing femoral hernia.

A sheet of 6 x 11 cm of mesh[69] is used. The medial end of the mesh is cut to the shape of the medial corner of inguinal canal with the cord retracted upwards, the rounded corner is sutured with non absorbable monofilament suture material to the

anterior rectus sheath on the public bone and overlapping the rectus sheath and periosteum by 1 to 1.5 cm. This is a crucial step in the repair, because failure to cover this bone with the mesh can result in recurrence. This suture is continued to attach the lower edge of the mesh to the inguinal ligament up to a point just lateral to internal ring. If there is a concurrent femoral hernia, the mesh is also sutured to Cooper's ligament 1 to 2 cm below its suture line with the inguinal ligament to close the femoral ring.

A slit is made at the lateral end of the mesh, creating two tails, a wide (2/3) one above and a narrower (1/3) below. The upper wide tail is grasped with hemostat 41 and passed underneath the spermatic cord; this positions the cord between two tails of the mesh. The wider upper tail is crossed and placed over the narrower one and held with hemostat and sutured to the inguinal ligament lateral to the deep ring. The upper edge of the patch is sutured in place with two interrupted absorbable suture, one to rectus sheath and other to the internal oblique aponurosis just medial to the internal ring.

Upward retraction of upper leaf of external oblique during this phase of repair is important because it results in the appropriate amount of laxity in giving a dome like configuration for the patch when the retraction is released. This laxity assures a true tension free repair.

Using a single nonabsorbable monofilament suture the lower edges of each of the two tails are fixed to inguinal ligament just lateral to completion knot of the lower running suture. This creates new internal ring made of mesh and maintains normal integrity of internal ring. The excess mesh on lateral side is trimmed, leaving

at least, 5cm beyond the internal ring. This is tucked underneath the external oblique aponeurosis which is then closed over the cord with an absorbable suture.

Historical Review of studies

Egger B et al[70] studied the use of skin staples for securing the mesh in the Lichtenstein repair of inguinal hernia. 49 patients underwent inguinal hernia repair using a modification of mesh repair described by Lichtenstein et al. A single hernia repair was performed in 45 patients and bilateral repairs were performed in 4 patients. A proximate rotating head skin stapler was used to anchor the mesh in position, starting at pubic tubercle and working round the margins of the mesh. He concluded that operating time was reduced. Average operating time was 29 minutes and very few complications occurred. And in the short period of follow up no recurrent hernia have been reported.

Mills IW et al[71] conducted a prospective randomized trial to compare skin staple and polypropylene for securing the mesh in inguinal hernia repair. 50 men undergoing unilateral primary Lichtenstein repair were randomized in to two groups. In control group polypropylene mesh was secured with 2/0 polypropylene sutures. In study group mesh was secured with skin staples Duration of operation was recorded. Follow was done till 12 weeks. They found that operation time was significantly shorter when staples were used (median 20 minutes versus 29 minutes, $p<0.01$). There was no difference in the incidence of postoperative pain score and complication. The study group reported earlier return to normal activity (4 weeks versus 6 weeks, 2 days $p<0.010$) although there was no difference in the time taken to return to work or driving. So they concluded that use of skin staples in fixation of

mesh reduces operation time and it is as effective conventional mesh fixation with polypropylene in the short term.

Garg CP et al[72] also compared the skin staples versus polypropylene sutures for securing mesh in Lichtenstein repair of hernia. 54 patients undergoing sixty repairs were randomized into two groups. In control group polypropylene mesh was secured with 2/0 polypropylene sutures. In study group mesh was secured with skin staples. Duration of operation was noted. They found that operation was significantly shorter when staples were used (median 42min 30s versus 54 min 30s , p<0.010). There were no significant differences in the incidence of postoperative complications or pain. There were no recurrences in either group in the follow up period (12 months).

A retrospective comparative study performed by van der Zwaal P et al.[73] 67 patients undergoing mesh fixation using sutures and 82 patients undergoing staple fixation were compared Operating time, recurrence, postoperative pain, complications and costs were studied. Seven recurrences (11%) occurred in the polypropylene group as compared to one recurrence (1%) in the staple group (P < 0.01). There was a trend of fewer complications in the staple group. Operative time and long-term postoperative pain did not differ significantly between the two groups. The costs per surgery for mesh fixation and skin closure were euro 11.13 for the suture group and euro 24.35 for the staple group. Study concluded that, staple fixation of the mesh in Lichtenstein's inguinal hernioplasty can be considered equal to traditional fixation with sutures with regard to operating time and postoperative pain. However, staple fixation seems to show fewer recurrences and fewer complications.

Lall RC et al[74] used skin stapler technique to secure a mesh in inguinal hernia repair and showed that this method is much quicker. They were able to reduce operating time by 10 min. The repair proved equally effective as that with polypropylene sutures and has not shown any greater complication in the short term.

Amid PK[75] also supported the use of stapler fixation of mesh and suggested 1) placement of suture and / or stapler into the pubic bone is a potential cause for chronic postoperative pain. 2) suturing or stapling of mesh to inguinal ligament lateral to internal ring is unnecessary and in fact a potential cause of femoral nerve injury. 3) Similar to suturing technique, not more than four to five points of fixation are necessary for securing mesh to the inguinal ligament and not more than two are required for fixation of mesh to the rectus sheath and internal aponeurosis.

According to Mills et al,[71] staples are made up of non-ferromagnetic stainless steel with an inert coating and he never envisaged a problem with their use in hernia repair. The current product information doesn’t state any contraindication to use skin stapler internally. Potential complication of osteitis pubis which has been described after insertion of monofilament sutures through the periostium of pubic bone, is uncommon and has not developed in any of his patients who has undergone repair with stapler.

Recently Khan AA et al[76] compared polypropylene suture and skin staples for securing mesh in Lichtenstein inguinal hernioplasty in terms of mean operating time and postoperative pain. They concluded that, mean operating time and postoperative pain is less in securing mesh with skin staples as compared to polypropylene suture in Lichtenstein inguinal hernioplasty.

Gomez-Leon JF[77] opined that, the use of skin stapler for fixation of mesh in inguinal hernia repair reduces the total operative time but there is no reduction in complication rates in staple group as compared to polypropylene group. In addition use of skin staple increases the total cost. So the traditional use of sutures for fixing the mesh should not be abandoned in terms of improving operative time.

Doctor HG[78] observed that, because the femoral vessels are underlying the inguinal ligament it is preferable to use prolene sutures in this area to fix the mesh to avoid injury to these vessels. Broad head of the stapler is definitely cumbersome to manoeuvre but can be managed by retraction of the skin flap. Formerly an end on skin stapler was available and that was very convenient and ideal to use. Once the staples are applied they remain in place, which can be confirmed by X-ray taken after few months.

Chauhan A[79] used staple for mesh fixation in 10 cases of Lichtenstein's hernia repair and concluded that, it is extremely difficult, if not impossible, to staple the mesh to pubic tubercle as there is virtually no 'give' in the periosteum for staple to hold. Broad head of the stapler is definitely cumbersome to manoeuvre especially during fixation of inferior edge of mesh to upturned portion of inguinal ligament. In both the above situation he had to resort to applying prolene sutures additionally to secure the mesh. The mean operative time was noted from insertion of the mesh to the placement of the last prolene suture / staple. The mean time in 10 cases of staple was 14 min. while in 10 cases of prolene suture was 11 min.

Gould SWT[80] says that the use of skin stapler for hernioplasty is rapid and safe method but he mentioned two notes of caution viz. 1) chances of femoral vessel

injury, for which he advised staple fixation of mesh little higher up on the ligament than one might with sutures. 2) periostium above the pubic tubercle, for this he advised to fix the mesh only to inguinal ligament and avoid periostium overlying the pubic tubercle to avoid troublesome postoperative pain from periostitis.

Fligelstone L[81] mentioned the disadvantages associated with the use of skin staple in hernioplasty. The advantages were 1) Use of surgical stapling device to secure the prolene mesh to the free edge of the inguinal ligament lead to the injury to femoral vessels (especially to femoral vein) as the depth of penetration of the staple cannot be judged as accurately as the path of needle. 2) The use of metal staples in benign conditions should be considered carefully, as their presence cause distortion of images obtained by computer tomography and magnetic resonance imaging, compromising future investigation of this area. 3) And the operating time for inguinal hernioplasty with staple is not very different from using prolene suture.

Sakorafas GH[82] studied open tension free repair of inguinal hernias; the Lichtenstein technique. 540 tension free inguinal hernia repairs were performed in 510 patients, using a polypropylene mesh and follow up was completed in 408 patients. Average follow up period was 3.8 years (1-6 years). There was only one recurrence of hernia (recurrence rate =0.2). Postoperative neuralgia in 5 patients (1%) They concluded that Lichtenstein tension free inguinal hernia repair is a simple, safe, with extremely low morbidity and remarkably low recurrences. Therefore it is the preferred method for hernia repair since 1994.

Kingsnorth AN[83] raised concern about the increasing cost with the use of skin stapler for fixation of mesh in hernioplasty.

van Veen RN et al,[40] conducted study on long term follow-up of a randomized clinical trial of non-mesh versus mesh repair of primary inguinal hernia. 10 years cumulative recurrence rates were 17 and 1 per cent respectively. Result of this study is mesh repair is still superior to non-mesh hernia repair. Recurrence rate may be underestimated as recurrence continues to develop for up to 10 years after surgery.

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 from January 2013 to December 2013.

Study design

The study design is randomized controlled trial.

Study period and duration

This study conducted for the period of one year from January 2013 to December 2013.

Place

The present study was carried out in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.

Source of Data

Patients undergoing elective uncomplicated inguinal hernia in the 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 calculated from the formula as below

$n = 2(Z \quad + Z \quad)^2 (S)^2 / (X_1\text{-}X_2)^2$

Where, n=Sample size

= Type I error = 0.05

=Type II error = 0.20

Hence, Z =1.96 and Z =0.84

X_1-X_2 (Difference in operative time between the two groups) Effective size was taken as 10

S=Common standard deviation taken as 8

By applying the above formula a sample size of 30 in each group was considered.

Selection criteria

<u>Inclusion</u>

- All cases of elective uncomplicated inguinal hernia.

<u>Exclusion</u>

- Complicated inguinal hernia
- Paediatric (age less than 18 years) and geriatric (more than 65 years) patients

Ethical clearance

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

Informed Consent

The patients fulfilling selection criteria were informed about the nature of study and a written informed consent was obtained (Annexure I).

Randomization

The patients were randomized into two groups of 30 each based on computer generated randomization as below;

- Group P: Patients undergoing mesh fixation with prolene sutures.
- Group S: Patients undergoing mesh fixation with skin staples.

Method of collection of data

Data such as age and type of hernia were noted and the findings were noted on a predesigned and pretested proforma (Annexure II).

Investigations

The patients 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
- HIV/HbsAg
- Random Blood Sugar
- Chest X-ray and ECG

Procedure

All the procedures are carried under standard spinal anaesthesia. Intravenous antibiotics, ciprofloxacin 100 mL and metronidazole 100 mL was given in both the groups. All patients were operated for lichtenstein's tension free hernioplasty.

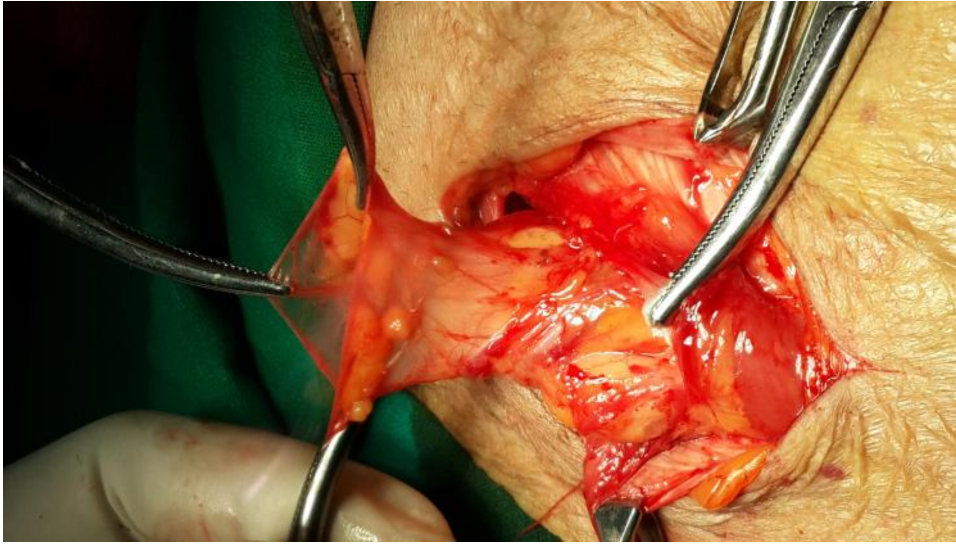
Skin closure

Group S

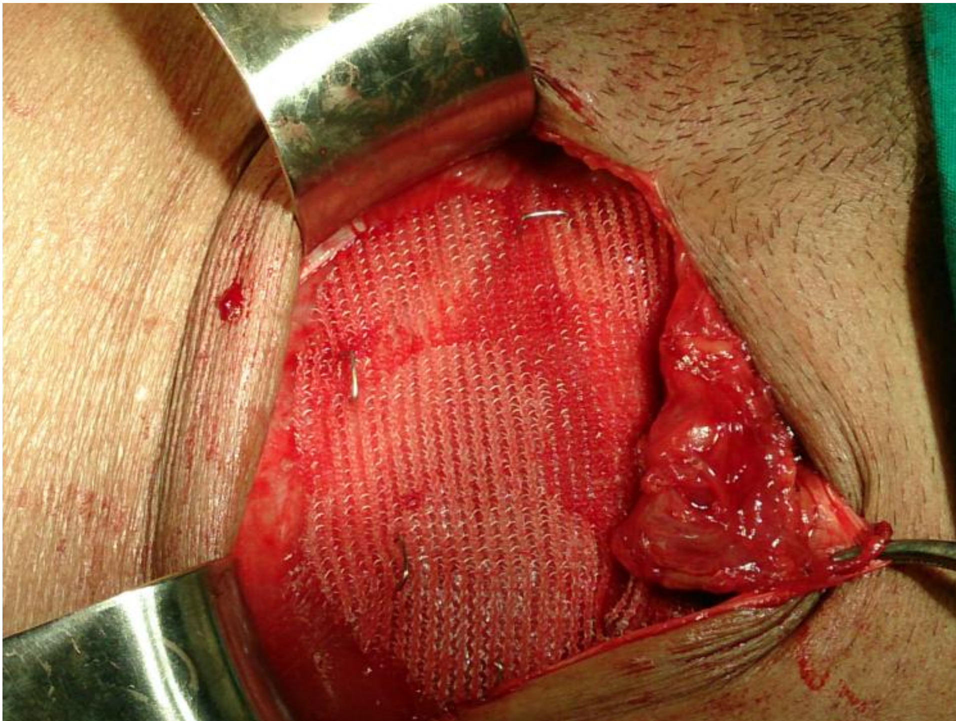
In Group S mesh was fixed with multi proximate skin staples and external oblique aponeurosis was closed with vicryl 2-0. The sub-cutaneous tissue was approximated. Skin closure was done by using ethilon 2-0 suture material which were removed after seven days.

Group P

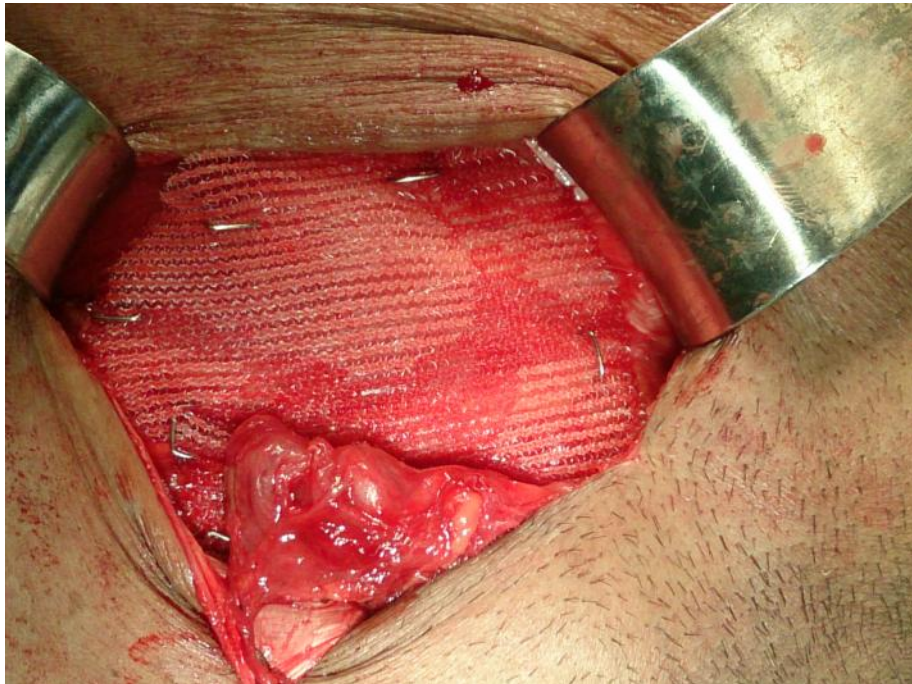
In Group P, mesh was fixed using polypropylene 1-0 and External oblique aponeurosis was closed using vicryl 2-0. The sub-cutaneous tissue was approximated. Skin closure was done by using ethilon 2-0 suture material which were removed after seven days.



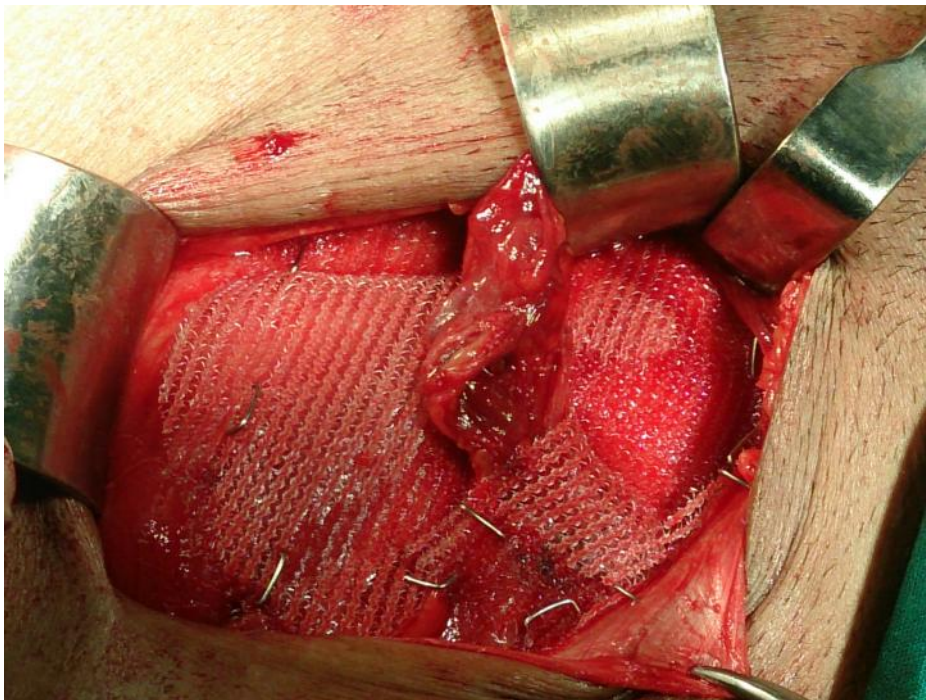
Photograph 1. Sac dissection



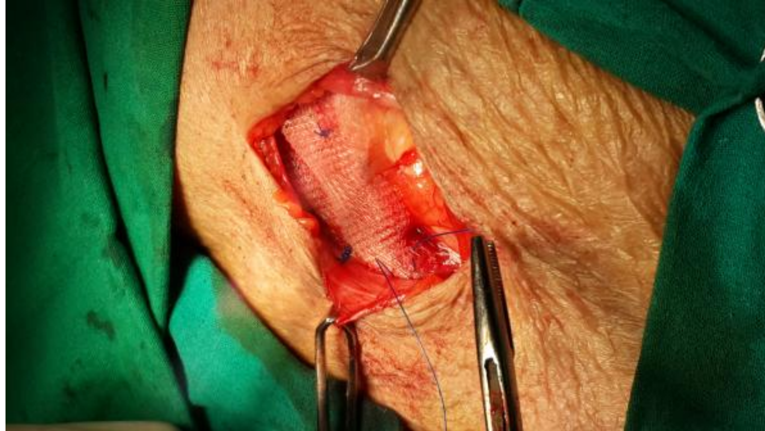
Photograph 2. Mesh fixation with skin stapler



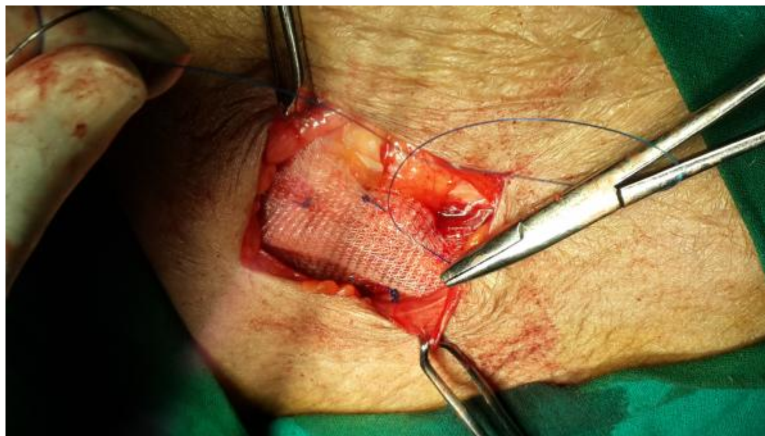
Photograph 3. Mesh fixation with skin stapler



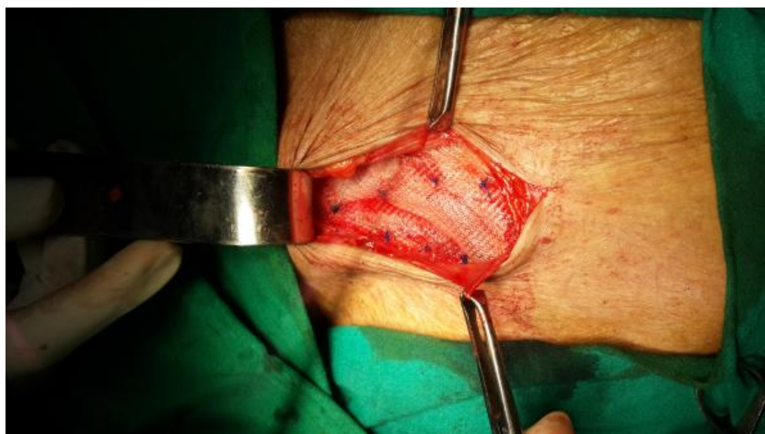
Photograph 4. Mesh fixation with skin stapler



Photograph 5. Mesh fixation with prolene



Photograph 6. Mesh fixation with prolene



Photograph 7. Mesh fixation with prolene

Outcome variables

Total operative time

The time taken from the skin incision to the beginning of the mesh fixation and from the beginning of the mesh insertion to completion of skin closure was recorded.

Complications

During post operative period (upto seven days) following complications were noted as below.

- Induration and swelling of operation site
- Seroma-collection of serous discharge.
- Haematoma-collection of blood clots.
- Infection-collection of purulent discharge.

Cost of operation

Total cost of operation was calculated

Statistical analysis

The data obtained was coded and entered in Microsoft Excel Spreadsheet (Annexure III). The categorical data was expressed as rates, ratios and percentages and comparison was done using Fishers exact test and chi-square test. Continuous data was expressed as mean ± standard deviation and comparison was done using independent sample t test. A 'p' value of less than or equal to 0.050 was considered as statistically significant.

RESULTS

The present one year randomized controlled trial was done from January 2013 to December 2013. A total of 60 patients undergoing surgery uncomplicated hernia repair under the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum were studied.

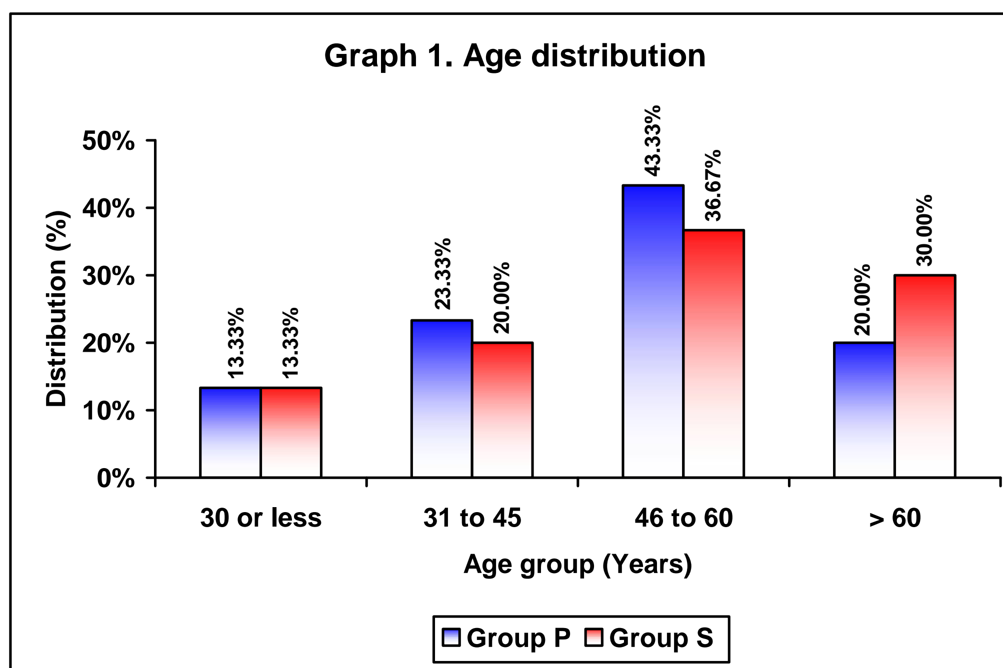
The patients were randomized into two groups of 30 each based on computer generated randomization that is, Group P (Mesh fixation with prolene sutures) and Group S (Mesh fixation with skin staples).

The data obtained was coded and master chart was prepared. The data was analysed and the final results and observations were tabulated as below.

Table 1. Age distribution

Age group (Years)	Group P (n=30)		Group S (n=30)	
	Number	Percentage	Number	Percentage
30 or less	4	13.33	4	13.33
31 to 45	7	23.33	6	20.00
46 to 60	13	43.33	11	36.67
> 60	6	20.00	9	30.00
Total	**30**	**100.00**	**30**	**100.00**

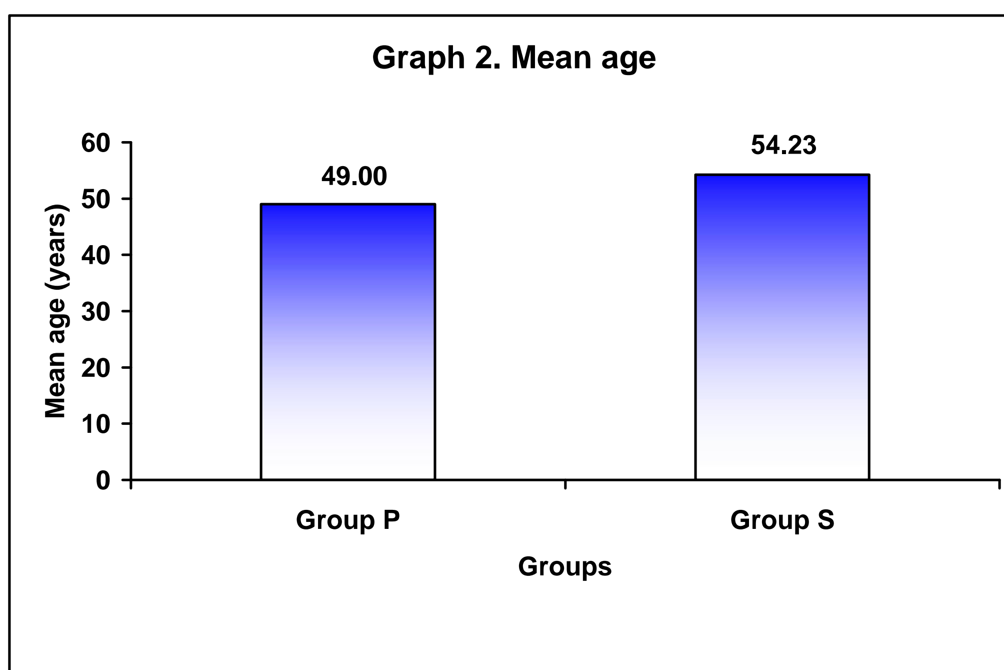
p = 0.839



In the present study most of the patients presented with age between 46 to 60 years that is, 43.33% from group P and 36.67% from group S. However the age distribution in group P and S was comparable (p=0.839).

Table 2. Mean age

Variables	Group P (n=30)		Group S (n=30)		p value
	Mean	SD	Mean	SD	
Age (Years)	49.00	13.71	54.23	16.18	0.182

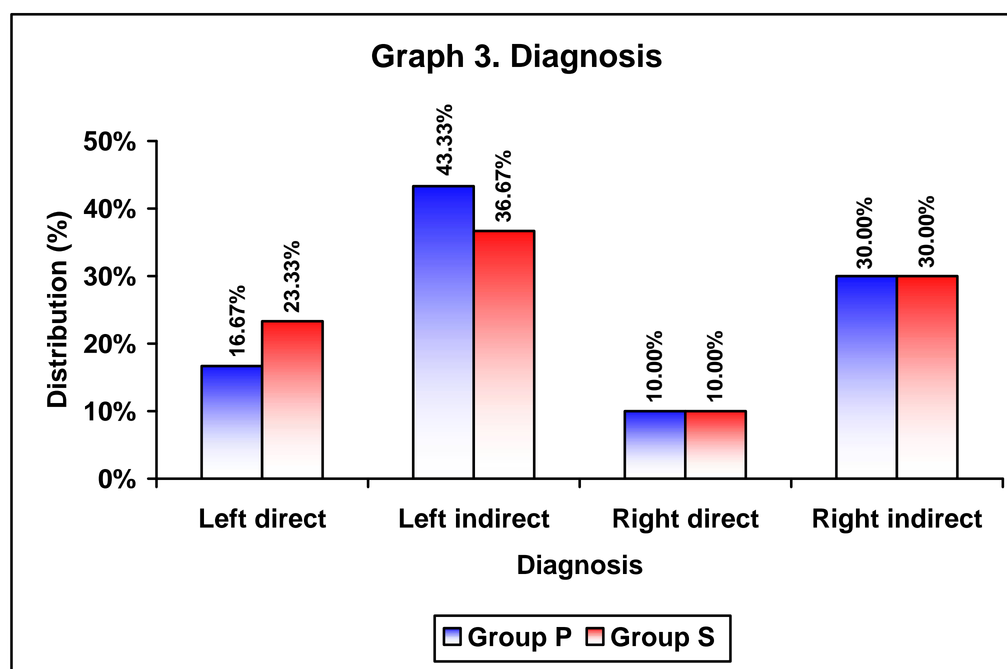


In this study the mean age in group P was slightly less (49.00 ± 13.71 years) compared to group S (54.23 ± 16.18 years) but the difference was statistically not significant (p=0.182).

Table 3. Diagnosis

Diagnosis	Group P (n=30)		Group S (n=30)	
	Number	Percentage	Number	Percentage
Left direct	5	16.67	7	23.33
Left indirect	13	43.33	11	36.67
Right direct	3	10.00	3	10.00
Right indirect	9	30.00	9	30.00
Total	**30**	**100.00**	**30**	**100.00**

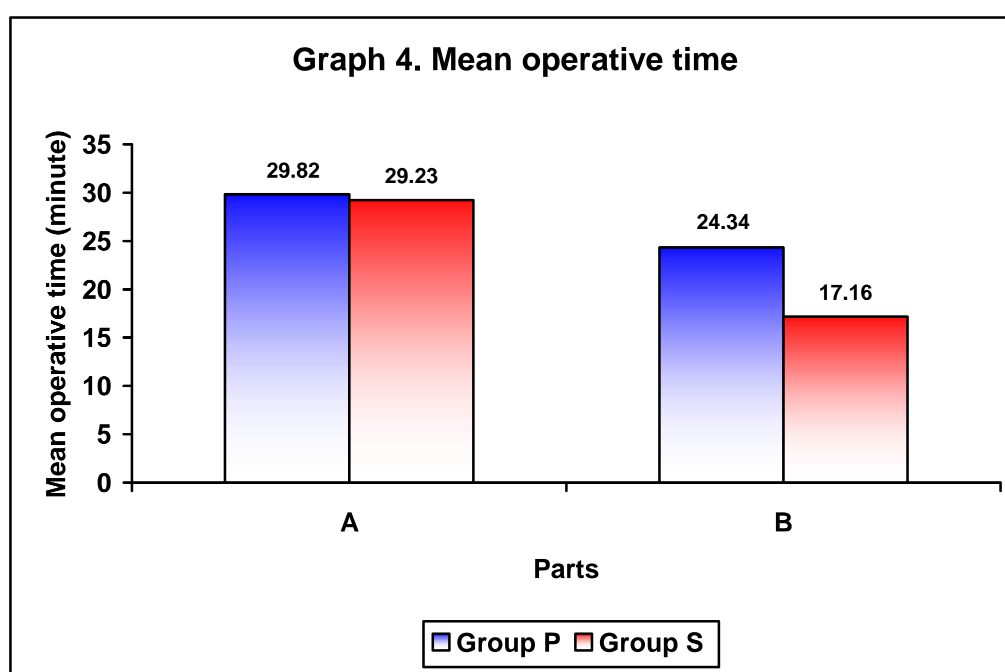
p = 0.919



In the present study most of the patients presented with diagnosis of left indirect (that is, 43.33% in group P and 36.67% in group S). The diagnosis among the patients with group P and S was comparable (p=0.919).

Table 4. Mean operative time

Parts	Group P (n=30)		Group S (n=30)		p value
	Mean	SD	Mean	SD	
A	29.82	1.76	29.23	1.48	0.169
B	24.34	1.24	17.16	1.61	<0.001

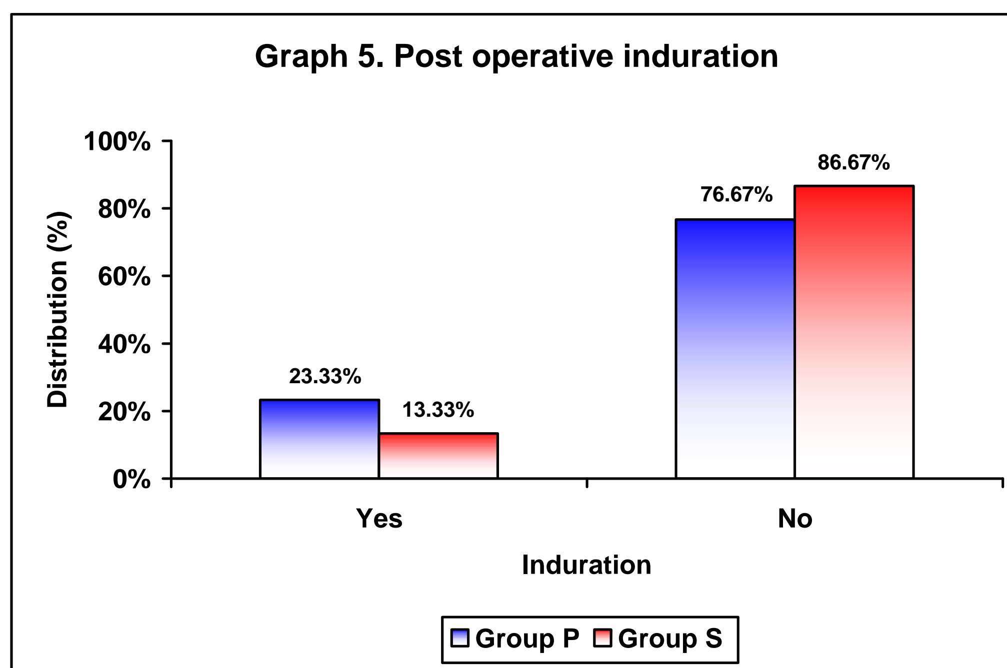


In this study the mean part A operative time was comparable in group P and S (29.82 ± 1.76 vs 29.23 ± 1.48; respectively; p=0.169) but mean Part B operative time was significantly low in group S compared to group P (17.16 ± 1.61 vs 24.34 ± 1.24; respectively; p<0.001).

Table 5. Post operative induration

Induration	Group P (n=30)		Group S (n=30)	
	Number	Percentage	Number	Percentage
Yes	7	23.33	4	13.33
No	23	76.67	26	86.67
Total	**30**	**100.00**	**30**	**100.00**

p = 0.317

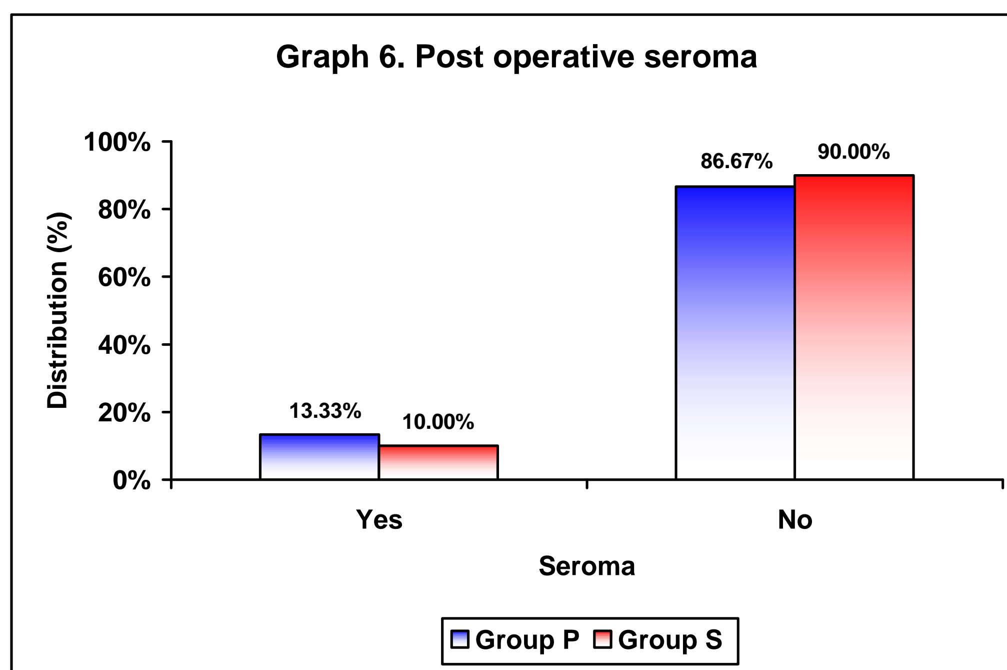


In the present study post operative complication of induration was noted in 13.33% of the patients in group S compared to 23.33% in group P. But this difference was statistically not significant (p=0.317)

Table 6. Post operative seroma

Seroma	Group P (n=30)		Group S (n=30)	
	Number	Percentage	Number	Percentage
Yes	4	13.33	3	10.00
No	26	86.67	27	90.00
Total	**30**	**100.00**	**30**	**100.00**

p = 0.688



In this study the post operative complication of seroma was comparable in both the groups (13.33% in group P and 10% in group S; p=0.688).

None of the patient was observed to have hematoma and infection in both the groups.

DISCUSSION

The treatment of inguinal hernia has evolved over the past 150 years from truss support with operation reserved for life-threatening situations to elective outpatient repair. Pure tissue repairs have suture line after closure, which is under tension because of the defect, edges are approximated instead of being bridged. Suture line tension is at the heart of failed hernia repair and solving this problem would largely eliminate the recurrence. Excessive tension on the suture line and the surrounding tissue leads to tissue ischemia and suture cut-out leading to recurrence.[1]

In tension free or mesh based repair, synthetic mesh is usually used to strengthen the transversalis fascia to create a strong and tensionless repair. Open mesh hernioplasty appears to be gold standard when managing inguinal hernia.[1]

Lichtenstein technique of inguinal hernia repair has been proved to be an effective and safe method with low recurrence rate. Surgeons use it successfully with good results. The Lichtenstein mesh technique takes account of the important factors identified in the successful outcome of inguinal hemia operation-supplementing the strength of the transversalis fascia and a tension-free repair.[1]

The only disadvantage of the mesh operation is that it requires the use of prosthetic material for mesh fixation with attendant risk of infection. Although this has not emerged as a major complication, modifications with staple fixation reduce this threat.[1]

But to date very few studies have assessed the use of skin staples for securing the mesh in Lichtenstein tension free inguinal hernia repair. This prompted

us to compare the two methods for securing the mesh in Lichtenstein tension free inguinal hernia repair so as to draw the benefits of skin staples in terms of total operation time, post operative complications and cost of the operation.

A total of 60 patients undergoing lichtenstein tension free inguinal hernia repair during the study period that is, from January 2013 to December 2013 were divided and studied. Based on computer generated randomization chart, patients were divided into two groups of 30 each viz., group S where patients underwent Lichtenstein tension free inguinal hernia repair with securing the mesh using skin staples and group P in which mesh was secured using polypropylene sutures.

In the present study the commonest age at presentation was between 46 to 60 years (43.33% in group P and 36.67% in group S; p=0.839). The mean age in group S was slightly high (54.23 ± 16.18 years) compared to group P (49.00 ± 13.71 years) but this difference was statistically not significant (p=0.182). These findings were comparable with a recent study[1] done in Punjab where the median age in patients with staple group was 48 years compared to 46 years in suture group.

In this study 43.33% of the patients in group P and 36.67% in group S presented with diagnosis of left indirect hernia. However the distribution of patients diagnosis in group P and S was comparable (p=0.919). These findings suggest that, the demographic and clinical characteristics of the study population were comparable in group P and S ruling out the bias of the confounding variables.

Lichtenstein technique of inguinal hernia repair is proved to be an effective and safe method and surgeons use it successfully with good results. The first author to describe staple modification to this technique, Egger et al.,[70] emphasized the

advantage of shorter operating time. Similarly in the present study the mean part A operative time in group P was 29.82 ± 1.76 minutes and in group S it was 29.23 ± 1.48 minutes. The comparison showed no statistically significant difference in part A operative time between two groups ($p=0.169$). With regard to Part B operative time, it was significantly low in group S (17.16 ± 1.61 minutes) compared to group P (24.34 ± 1.24 minutes) ($p<0.001$). The present study showed that, application of staples results in significantly lower operative time for securing the mesh in Lichtenstein repair. The difference observed was 11 minutes between the groups. These findings indicate the use of staples can be applied much more quickly than sutures and save operating time, reducing tissue handling, risk of wound infection, and risk associated with prolonged anaesthesia.[71] These findings were in accordance with the similar studies[72] from Baroda, India in 2003 and two recent studies[1,84] from Patiala, India which also reported a reduction of 12 minutes in surgical time in Part II. Another recent study[76] from Rawalpindi to compare polypropylene suture and skin staples for securing mesh in Lichtenstein inguinal hernioplasty in terms of mean operating time also concluded that, mean operating time is less in securing mesh with skin staples as compared to polypropylene suture.

The staples are made from stainless steel with an inert coating. The length of the prongs on the staples is 3.9 mm, which appears sufficient to provide good penetration into the tissue, with secure fixation of the mesh. Further Proximate RH (Rotating Head) skin stapler in which accurate staple placement is facilitated by the design of the stapler, whose head rotates 360 degrees, thereby allowing maximum visibility and improved access.

Wound infection is a major cause of hernia recurrence.[1] However, in the present study post operative complications of induration and seroma were noted and none of the patient had hematoma and infection in both the groups. Induration and seroma were noted in 13.33% and 10% of the patients in group S compared to 23.33% and 13.33% in group P. However the difference was statistically not significant ($p>0.050$). Garg et al.[72] also reported seroma formation and it was almost equal in both groups. Van der Zwaal et al.[73] reported that no post-operative wound infection. They suggested that it could possibly be attributed to the inert coating covering the stainless steel staples. Thus, it may be inferred that the rate of wound infection is significantly less with the use of staples, but further studies are needed to confirm these findings. Mills reported four haematomas, which were not encountered in our study.[71]

Overall the present study showed that securing the mesh with staples instead of sutures might reduce the mean operative time. From our study, we believe that the advantages of speed and convenience of skin staples are more economical and the disposable instruments can be reused until empty after due sterilization. Further studies with longer follow-up for assessment of pain, rate of recurrence are needed to comment accurately on use of skin staples.

CONCLUSION

Based on the findings of this study it may be concluded that, the skin staples can be applied much more quickly than sutures for mesh fixation thereby saving the operating time in patients undergoing hernia repair with Lichtenstein tension-free repair. The use of staples is not associated with any increase in complications, as compared to the use of sutures. The advantages of speed and convenience of skin staples outweigh marginal extra cost. Thus staples may be a better option for fixation of mesh than conventional sutures.

SUMMARY

Lichtenstein technique of inguinal hernia repair is an effective and safe method with low recurrence rate. However, it requires the use of prosthetic material for mesh fixation with attendant risk of infection. Modifications with staple fixation may reduce this threat. This study was aimed to compare the two methods for securing the mesh in Lichtenstein tension free inguinal hernia repair so as to draw the benefits of skin staples in terms of total operation time, post operative complications and cost of the operation.

This one year randomized controlled trial was done from January 2013 to December 2013 under the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. A total of 60 patients undergoing lichtenstein tension free inguinal hernia repair divided into two groups of 30 each viz., group S (securing the mesh using skin staples) and group P (mesh was secured using polypropylene sutures) were studied.

In this study 43.33% of the patients were aged between 46 to 60 years in group P compared to 36.67% in group S (p=0.839). The mean age in group P was 49.00 ± 13.71 years compared to 54.23 ± 16.18 years in group S (p=0.182). Most of the patients presented with diagnosis of left indirect hernia (group P-43.33%; group S-36.67%; p=0.919). The mean part A operative time was comparable in group P and S (29.82 ± 1.76 vs 29.23 ± 1.48; respectively; p=0.169). The mean Part B operative time was significantly low in group S compared to group P (17.16 ± 1.61 vs 24.34 ± 1.24; respectively; $p<0.001$). Post operative complication of induration was noted in 13.33% of the patients in group S compared to 23.33% in group P

(p=0.317) and complications of seroma were comparable in both the groups (13.33% in group P and 10% in group S; p=0.688). None of the patient was observed to have hematoma and infection in both the groups.

The skin staples can be applied much more quickly than sutures for mesh fixation thereby saving the operating time without any increase in complications, as compared to the use of sutures. The advantages of speed and convenience of skin staples outweigh marginal extra cost. Hence staples may be a better option for fixation of mesh than conventional sutures in patients undergoing hernia repair with Lichtenstein tension-free repair.

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ANNEXURE I – CONSENT FORM

COMPARATIVE STUDY OF SKIN STAPLES AND POLYPROPYLENE SUTURES FOR SECURING THE MESH IN LICHTENSTEIN'S TENSION FREE INGUINAL HERNIA REPAIR: A RANDOMISED CONTROLLED TRIAL

Principal Investigator:-
Dr. **** *****
Professor ,
Department Of General Surgery,
J. N. Medical College, Belgaum.

Co-investigator:-
Dr. ***** ****
Post Graduate Student,
Department Of General Surgery,
J. N. Medical College, Belgaum.

You are kindly requested to participate in a comparative study of skin staples and polypropylene sutures for securing the mesh in lichtenstein's tension free inguinal hernia repair.

Objective/purpose of study

Mesh repair has become a must for all the patients undergoing hernia repair. Traditionally mesh is secured using polypropylene sutures .In this study we plan to use skin staples to secure the mesh. As it is effective in reducing the operative time. The incidence of seroma wound infection, haematoma formation and the cost factor will be compared.

This study will be conducted by Dr. **** ******, Post Graduate in Department of Surgery, under the direct supervision and guidance of Dr. **** ****, Professor, Department of Surgery, J. N. Medical College, Belgaum.

You need to be eligible, meeting all the selection criteria to participate in this study. You should be willing to provide information about yourself. Sixty subjects will be enrolled in this study that will then be randomized in either of 2 groups (details given below).

Procedures

If you agree to participate in this study, you will be randomly allotted into a group (A or B) and accordingly receive either the standard management (securing the mesh with polypropylene sutures) or the newer management (securing the mesh with skin staples). Operative time, postoperative complications and cost will be compared. There is no observable risk associated with this study.

Financial incentives/compensation

No financial incentives are being offered to enrolled subjects. It is purely being done with the idea of research purpose and all cost of the study will be borne by the investigator. In the event that you become injured as a result of taking part in this study, treatment will be offered to you at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum by the investigator. In the event that you will be given information about where to receive medical care in which case you/your insurance company will be responsible for the costs. However, no reimbursement, compensation or free medical care will be given.

Privacy/confidentiality

Every effort will be made to protect the confidentiality of the information you provide. Only Dr. *** ***** and Dr. **** ***** will have access to the information provided by you. Results of this study may be published but your identity will not be revealed. Taking part in this study is voluntary; you may choose not to enroll in this study. Your decision will not change the present or future health care services offered to you at KLES Dr. Prabhakar Hospital, Belgaum. The alternative that you have is to undergo the traditional procedure that is carried out in KLES Hospital.

Contact details

If you have any queries about the study, you may contact Co-investigator, Dr. ***** (***** *****) / Dr. **** ***** (***** *****) Professor, Department of Surgery, J. N. Medical College, Belgaum., without any hesitation. In case you need

any further information regarding your rights as a study participant, you may contact Dr. **** *****, Prof of Pathology and HOD and Chairman of College Ethical Dissertation and Research Committee, JNMC, Belgaum, phone no: ****-******.

CONSENT TO PARTICIPATE IN A RESEARCH STUDY:

I, Mr./Mrs. ____

voluntarily agree to take part in this study, by signing this consent form I am not giving up my legal rights. I may withdraw at any time. I am signing after having been explained to me in my vernacular language including risks and the benefits and having all queries cleared.

Subject Name: ______________________________

Signature of the participant
Or Left thumb print ______________________________

Witness name: ____

Signature: ______________________________

Investigator's name: ____

Place: ____________________

Date:____________________ **Signature of the investigator**

ANNEXURE II – PROFORMA

1. PATIENT IDENTIFICATION DATA

GROUP:	CASE NO. :
I.P/ O.P.D NO.:	D.O.A:
NAME :	D.O.S:
SEX :	D.O.D:

OCCUPATION:

ADDRESS :

2. CHIEF COMPLAINTS:

3. HISTORY OF PRESENTING COMPLAINTS:

4. PAST HISTORY:

5. FAMILY HISTORY:

6. PERSONAL HISTORY

GENERAL PHYSICAL EXAMINATION

Pulse:_/min ;	B.P:_/_mmhg;	Temp:_
Pallor:+/- ;	Icterus:+/-;	Cyanosis:+/-;
Clubbing:+/-;	Lymphadenopathy:+/-;	Oedema:+/-;

LOCAL EXAMINATION

Inspection:

Palpation:

Percussion:

Auscultation:

SYSTEMIC EXAMINATION

Abdomen:

Rectal:

CVS:

Respiratory system:

CLINICAL IMPRESSION:

INVESTIGATIONS:

1) CBC: Hb_; TLC_; DLC_; Platelets_;

2) S.UREA_; S.CREATINE_;

3) BLEEDING TIME_; CLOTTING TIME_;

4) CHEST X-RAY;

5) ECG;

ANNEXURE III – KEY TO MASTER CHART

LTD	-	Left direct
LTID	-	Left indirect
Rs.	-	Rupees
RTD	-	Right direct
RTID	-	Right indirect

ANNEXURE III - MASTER CHART - GROUP S

Serial number	In patient number	Age (Years)	Diagnosis	Operative time (Minutes)		Post operative complications				Cost (Rs.)
				Part A	Part B	Induration	Haematoma	Seroma	Infection	
1	515620	44	LTID	28.21	17.48	-	-	-	-	1800
2	515850	56	LTD	27	16.04	+	-	-	-	1800
3	523439	29	RTID	28.4	17.02	-	-	-	-	1800
4	524989	56	RTID	31.5	17.89	-	-	-	-	1800
5	531505	62	LTID	30.02	20.06	-	-	-	-	1800
6	536542	65	LTID	29.4	18.06	+	-	-	-	1800
7	538080	60	RTID	31.06	22.01	-	-	-	-	1800
8	547927	60	LTID	28.04	18.1	-	-	-	-	1800
9	560312	30	RTD	28.56	17.5	-	-	-	-	1800
10	555681	70	LTD	27.5	16.5	-	-	+	-	1800
11	559332	37	LTD	27.5	17.4	-	-	-	-	1800
12	559301	46	RTID	31.21	19.26	-	-	-	-	1800
13	563130	71	LTD	29.27	17.51	-	-	-	-	1800
14	569586	48	LTID	25.4	14.48	+	-	-	-	1800
15	572116	42	RTID	28.56	15.45	-	-	-	-	1800
16	565721	60	RTD	28.46	17.4	+	-	-	-	1800
17	551301	28	LTID	30.06	16.46	-	-	+	-	1800
18	535446	60	LTD	30.2	17.05	-	-	-	-	1800
19	55443	89	LTD	28.46	15.5	-	-	-	-	1800
20	535252	85	LTD	30.42	17.4	-	-	-	-	1800
21	537679	50	RTID	29.25	16.45	-	-	-	-	1800
22	522355	38	LTID	29.1	18.24	-	-	-	-	1800
23	544895	38	RTID	32.26	19.27	-	-	-	-	1800
24	526139	75	RTD	28.32	14.46	-	-	-	-	1800
25	519695	45	RTID	28.56	17.36	-	-	-	-	1800
26	520853	60	LTID	29.26	16.14	-	-	+	-	1800
27	552090	65	RTID	29.5	16.4	-	-	-	-	1800
28	553473	30	LTID	29.56	16.4	-	-	-	-	1800
29	562019	60	LTID	30.6	15.06	-	-	-	-	1800
30	558937	68	LTID	31.3	16.37	-	-	-	-	1800

ANNEXURE III - MASTER CHART - GROUP P

Serial number	In patient number	Age (Years)	Diagnosis	Operative time (Minutes)		Post operative complications				Cost (Rs.)
				Part A	Part B	Induration	Haematoma	Seroma	Infection	
1	510320	51	RTID	29.17	22.21	-	-	-	-	1520
2	515502	42	LTD	31.27	25.02	+	-	-	-	1520
3	521710	35	RTID	29	24.5	-	-	-	-	1520
4	524954	18	LTID	32.04	25.56	-	-	-	-	1520
5	525901	71	RTID	29.56	23.05	-	-	-	-	1520
6	531914	31	LTID	27.56	23.4	-	-	-	-	1520
7	536556	40	LTD	34.06	24.5	+	-	-	-	1520
8	539444	51	LTID	29.56	26.21	-	-	-	-	1520
9	547312	51	LTID	32.56	24.56	-	-	-	-	1520
10	571412	30	LTID	31.56	24.5	-	-	-	-	1520
11	555680	44	RTD	28.41	22.02	-	-	-	-	1520
12	559220	68	LTD	29.51	24.04	-	-	+	-	1520
13	560642	51	LTID	30.08	24.26	+	-	-	-	1520
14	564779	58	LTID	28.3	23.41	-	-	-	-	1520
15	570637	51	LTID	26.02	26.96	+	-	-	-	1520
16	544551	29	LTID	29.46	23.27	-	-	-	-	1520
17	551277	38	RTID	31.05	26.52	-	-	-	-	1520
18	551727	65	RTD	28.5	24.25	-	-	-	-	1520
19	535445	55	LTID	29.46	23.45	-	-	-	-	1520
20	535059	50	RTID	29.05	24.23	-	-	-	-	1520
21	551065	65	LTID	30.1	23.36	+	-	-	-	1520
22	522279	55	LTD	30.1	25.5	-	-	-	-	1520
23	552445	60	RTD	31.15	25.5	-	-	-	-	1520
24	522841	55	LTID	27.05	22.4	-	-	+	-	1520
25	519677	55	LTD	27.4	24.04	+	-	-	-	1520
26	519559	35	LTID	30.06	23.36	-	-	-	-	1520
27	552009	55	RTID	31.37	25.06	-	-	+	-	1520
28	553624	67	RTID	28.4	24.48	+	-	-	-	1520
29	553408	29	RTID	31.2	26.02	-	-	-	-	1520
30	553417	65	RTID	31.45	24.5	-	-	+	-	1520

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REG NO. BH0112004

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BELGAUM, KARNATAKA

APRIL - 2015

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Annexure-III