“COMPARISON BETWEEN THE COMPOSITE HEAVY WEIGHT PROLENE MESH VERSUS THE PROLENE SOFT MESH FOR THE REDUCTION IN POST-OPERATIVE PAIN IN PATIENTS UNDERGOING LICHENSTEINS MESH REPAIR FOR INGUINAL HERNIAS” A ONE YEAR RANDOMIZED CONTROL TRIAL AT KLES DR PRABHAKAR KORE HOSPITAL AND MRC, BELGAUM

REG.NO. BH0111001

Dissertation

Submitted to the
KLE University, Belgaum, Karnataka

In Partial Fulfillment
of the requirements for the degree of

M. S.
in
GENERAL SURGERY

DEPARTMENT OF SURGERY,
JAWAHARLAL NEHRU MEDICAL COLLEGE,
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ENDORSEMENT BY THE HOD/PRINCIPAL/ HEAD OF THE INSTITUTION

This is to certify that the dissertation entitled **"COMPARISON BETWEEN THE COMPOSITE HEAVY WEIGHT PROLENE MESH VERSUS THE PROLENE SOFT MESH FOR THE REDUCTION IN POST-OPERATIVE PAIN IN PATIENTS UNDERGOING LICHENSTEINS MESH REPAIR FOR INGUINAL HERNIAS" A ONE YEAR RANDOMIZED CONTROL TRIAL AT KLES DR PRABHAKAR KORE HOSPITAL AND MRC, BELGAUM** is a bonafide research work done by **THE CANDIDATE REG. NO. BH0111001.**

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LIST OF ABBREVIATIONS USED

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

mm Hg	-	Millimeters of mercury
N	-	Newtons
n	-	Total number
ng	-	Nanogram
NHS	-	National Health Service
NMDA	-	N-methyl-D-aspartate
NRS	-	Numerical Rating Scale
NSAID	-	Non-steroidal anti-inflammatory drug
OR	-	Odds ratio
p	-	Probability
PVB	-	Paravertebral blocks
RCT	-	Randomised controlled trials
RP	-	Control group
SD	-	Standard deviation
SP	-	Study group
TAPP	-	TransAbdominal PrePeritoneal
TEP	-	Totally ExtraPeritoneal
UK	-	United Kingdom
VAS	-	Visual Analogue Scale
VRS	-	Verbal Rating Scale
vs	-	Versus

ABSTRACT

Background and Objectives

Lichtenstein hernia repair is commonly recommended in the management of inguinal hernia and currently, pain is considered the most important complication. The present study was aimed to compare the heavyweight composite polypropylene mesh versus the prolene soft mesh [lightweight macro-porous polypropylene mesh] for the reduction of post-operative pain.

Methodology

The present one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2012 to December 2012. A total of 60 patients requiring mesh repair were randomized into two groups of 30 each based on the mesh type as group SP (Prolene soft mesh [light-weight mesh]) and group RP (Polypropylene mesh [Heavy-weight mesh]).

Results

In the present study 96.67% of patients in group SP and all (100%) in group RP were males. The mean age (51.93±18.73 vs 49.50±14.03 years; p=0.571) and duration of disease (12.67±9.85 vs 15.10 ± 8.98 months; p=0.321) in group SP and RP was comparable. During first follow up, all the patients in group SP reported moderate pain compared to 60% patients in group RP (p<0.001). During second follow up, majority of the patients (90%) in group SP reported mild pain compared to 26.67% patients in group RP (p<0.001). At the third follow up, all the patients (100%) in group SP reported mild pain compared

to 53.33% patients in group RP ($p<0.001$). The mean pain scores in group SP during first (4.50±0.57 vs 5.97±1.07), second (2.30±0.88 vs 4.27±1.48) and third (0.63±0.72 vs 2.57±1.79) were significantly less compared to group RP ($p<0.001$) but mean reduction in pain score from first follow up to third follow up was comparable in group SP (3.90±0.97) and RP (3.40±1.33) ($p=0.092$).

Conclusion and interpretation

Overall, the present study showed that, the prolene soft mesh (lightweight macro-porous polypropylene mesh) significantly reduced the post-operative pain in patients undergoing lichensteins mesh repair for inguinal hernia as compared to heavyweight composite polypropylene mesh.

Keywords

Heavyweight composite polypropylene mesh; Inguinal hernia; Lightweight macro-porous polypropylene mesh; Pain; Prolene soft mesh;

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Chapter 1

Introduction

INTRODUCTION

An inguinal hernia is a protrusion of abdominal cavity contents through the inguinal canal. There are two types of inguinal hernia, direct and indirect, which are defined by their relationship to the inferior epigastric vessels. Direct inguinal hernias protrude medial to the inferior epigastric vessels when abdominal contents herniate through the weakened posterior wall of the inguinal canal. Indirect inguinal hernias occur when abdominal contents protrude through the deep inguinal ring, lateral to the inferior epigastric vessels; this may be caused by failure of embryonic closure of the processus vaginalis.[1]

Inguinal hernia is among the most common problems encountered by general surgeons and may have significant complications.[2] Globally, inguinal hernia is the most common type of hernia, comprising of approximately 75% of all abdominal wall hernias.[2-4] Inguinal hernia repair is one of the most common general surgical operations worldwide accounting for 10 to 15% of all surgical procedures and is the second most common surgical procedure after appendicectomy.[3-5] It has been estimated that worldwide over 20 million repairs of inguinal hernia are carried out each year, the specific operation rates varying between countries from around 100–300 per 100 000 population per year.[6] Data from developing countries is limited hence the exact prevalence and incidence is not known.

Inguinal hernias may be congenital or acquired, with latter being the common presentation. Essentially any risk factors that either increases intra-abdominal pressure or weakens the anterior abdominal wall may lead to the

formation of an inguinal hernia. Known risk factors associated with hernia occurrence are smoking, positive family history, patent processus vaginalis, collagen disease, previous appendicectomy (open) and prostatectomy, patients with ascites, peritoneal dialysis, after long term heavy work and chronic obstructive pulmonary disease (COPD). It is interesting to note that occasional lifting, constipation and prostatism has not been proven to increase risk of inguinal hernias.[7]

With regards to clinical features, typically, patient may present with 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 cannot be reduced into the abdominal cavity which may lead to strangulation or ileus.[1]

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

Since Bassini published his original description of inguinal hernia repair in 1887, many techniques for hernia repair such as Shouldice, Darning, Desarda, Modified Bassini, Lichtenstein mesh repair and the more recent laparoscopic repair have been published.[5,6] Laparoscopic and Lichtenstein mesh repair are

becoming popular in recent days[10] as they are associated with rapid return to normal activities with low recurrence rates.[11]

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

Emphasizing the Halstead principle of no tension, the Lichtenstein repair advocated the routine use of mesh in 1984. The prosthesis used to reinforce the weakened posterior inguinal wall is placed between the transversalis fascia and the external oblique aponeurosis and extends well beyond the Hesselbach triangle. Mesh implants do not actively shrink, but they are passively compressed by the natural process of wound healing. Shrinkage of mesh occurs only to the extent to which the tissue contracts.[14]

Although the use of traditional microporous or heavyweight polypropylene meshes in the last 2 decades have reduced the incidence of recurrence after hernia surgery to less than 1%, a major concern has been the formation of a rigid scar plate causing patient discomfort and chronic pain, impairing quality of life. More than 50% of patients with a large mesh prosthesis in the abdominal wall complain of paresthesia, palpable stiff edges of the mesh, and physical restriction of abdominal wall mobility.[15]

It was assumed that flexibility of the abdominal wall is restricted by implantation of excessive foreign material and by excessive scar tissue formation. Better understanding of the biomechanics of the abdominal wall and the influence of mesh on those mechanics has led to our current understanding that “less is more.” In other words, less-dense, lighter-weight mesh of larger pore size, while still stronger than the abdominal wall, will result in less inflammation, better incorporation, better abdominal wall compliance, greater abdominal wall flexibility, less pain, and possibly less scar contraction and will therefore lead to a better clinical outcome.[7,16]

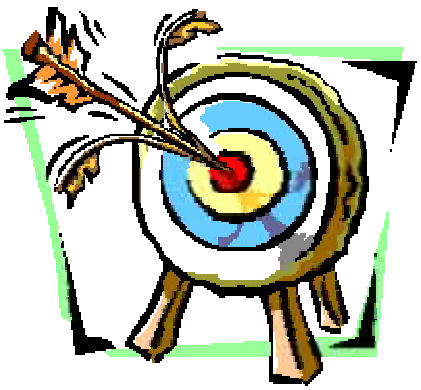
Light-weight, composite mesh thus was developed with the conviction that the ideal mesh should be just strong enough to handle the pressure of the abdominal wall and still be low in mass and as thin as possible. The advantage of large pore size mesh is that tissue is able to grow through the large pores of the mesh and create a thinner, more integrated scar. The new light-weight, composite meshes offer a combination of thinner filament size, larger pore size, reduced mass, and a percentage of absorbable material. Thus, there is less foreign body implanted, the scar tissue has greater flexibility (with almost physiologic abdominal wall mobility), there are fewer patient complaints, and the patient's quality of life is better.[14]

The use of light-weight mesh for Lichtenstein hernia repair did not affect recurrence rates, but it did improve some aspects of pain and discomfort 3 years after surgery.[17] According to data from current randomized, controlled trials and retrospective studies, light meshes seem to have some advantages with respect to postoperative pain and foreign body sensation.[7,18]

However, there is paucity of published data about the advantages of light weight macro-porous mesh in comparison with heavy weight mesh especially in India. Also, so far, no such study has been done in our hospital setting. Hence the present study was undertaken to compare the heavyweight composite polypropylene mesh versus the prolene soft mesh [lightweight macro-porous polypropylene mesh] for the reduction of post-operative pain in patients undergoing lichensteins mesh repair for inguinal hernia.

Chapter 2

Objectives



OBJECTIVES

The objectives of the present study were to compare the heavyweight composite polypropylene mesh versus the prolene soft mesh [lightweight macro-porous polypropylene mesh] for the reduction of post-operative pain in patients undergoing lichensteins mesh repair for inguinal hernia.

Chapter 3

Review of Literature

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.[20]

Since that time, many different types of abdominal wall hernias have been identified, along with a larger number of associated eponyms. This article reviews the pathophysiology, evaluation, and treatment of most of these hernias. Hernias are brought to the attention of an emergency physician either during a routine physical examination for other medical complaints or when the patient has developed a complication associated with the hernia.[21]

Approximately 96% of all groin hernias are inguinal hernias, with the remaining 4% being femoral. Hernias are bilateral in 20% of cases. The most common abdominal wall hernia is an inguinal hernia with a male to female preponderance of 9 to 1. Femoral hernias are more common in women.[22]

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.[23] 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.[24]

EMBROYLOGY[25]

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.[26]

SURGICAL ANATOMY[26-30]

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

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

Inguinal canal

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.

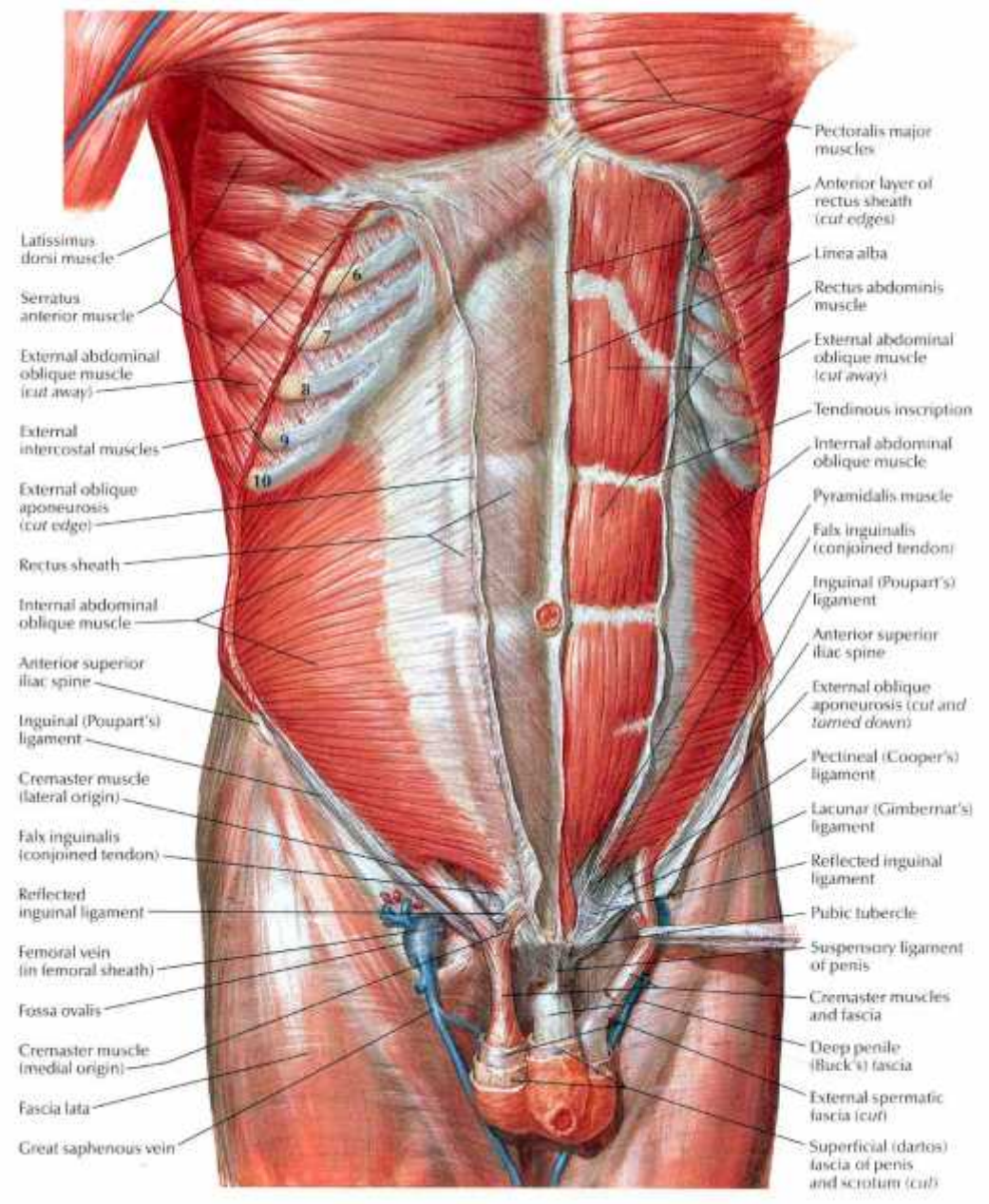


Figure 1. Muscles of the anterior abdominal wall

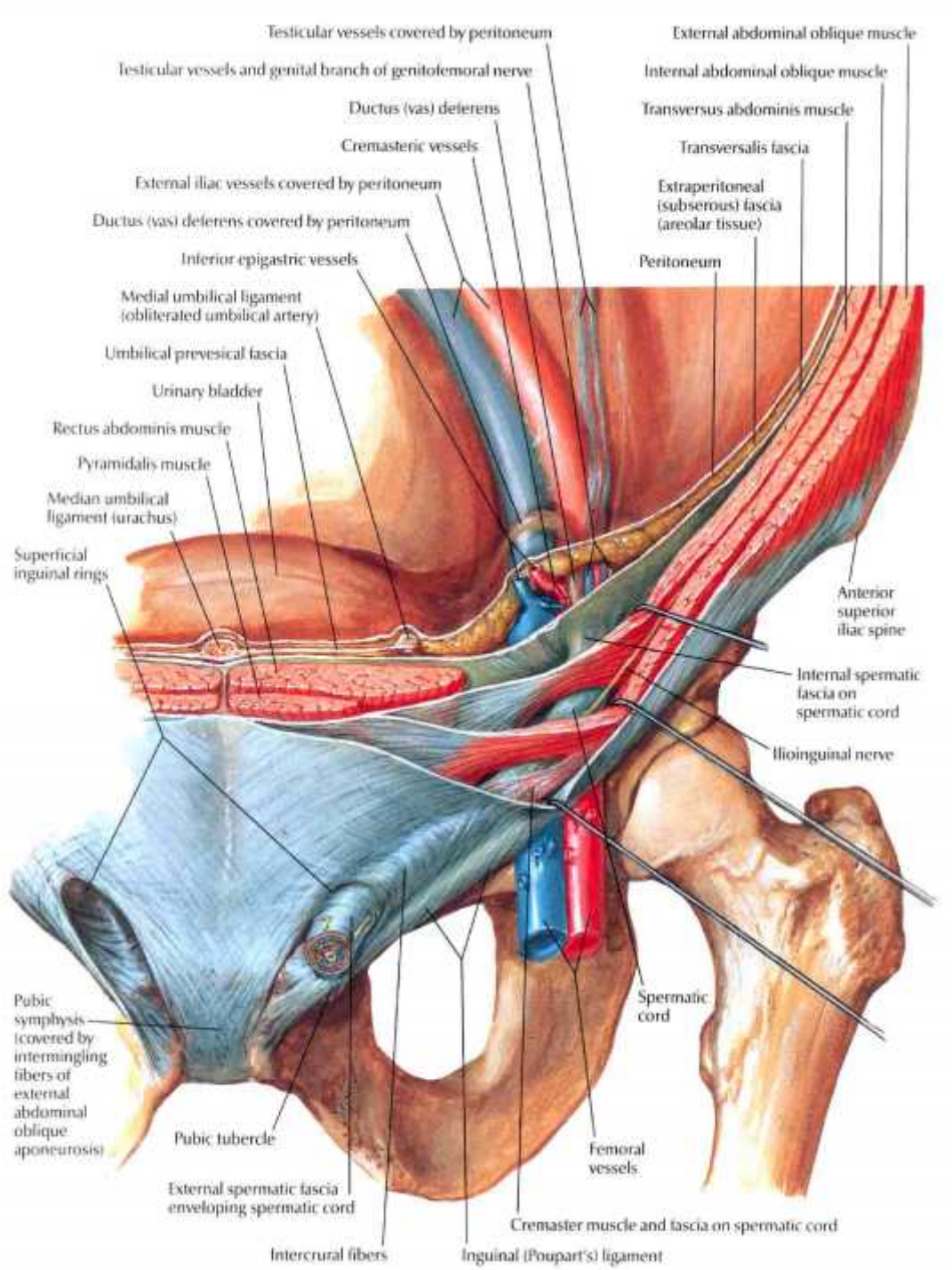


Figure 2. Inguinal canal in the male

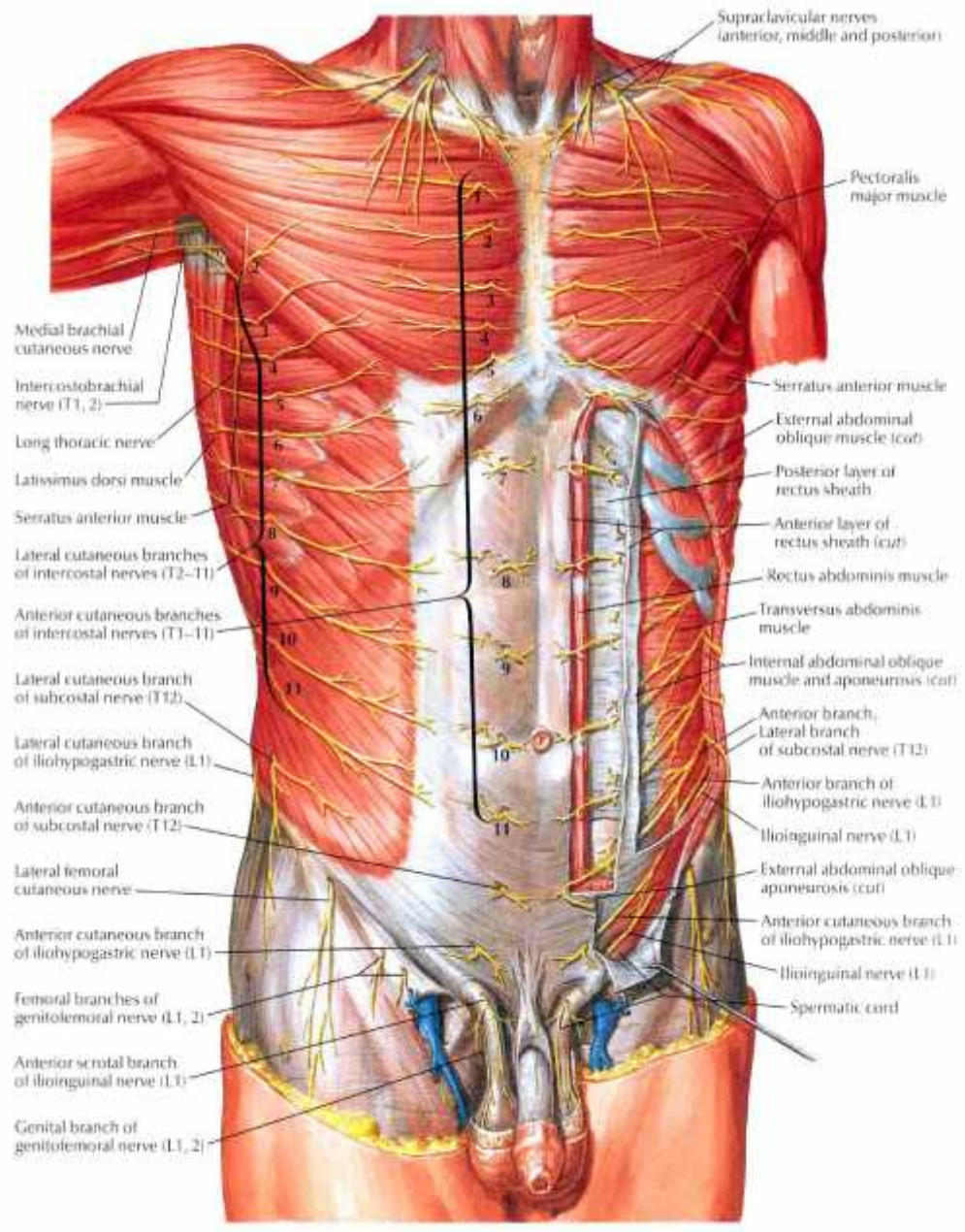


Figure 3. Nerve supply of the anterior abdominal wall in the male

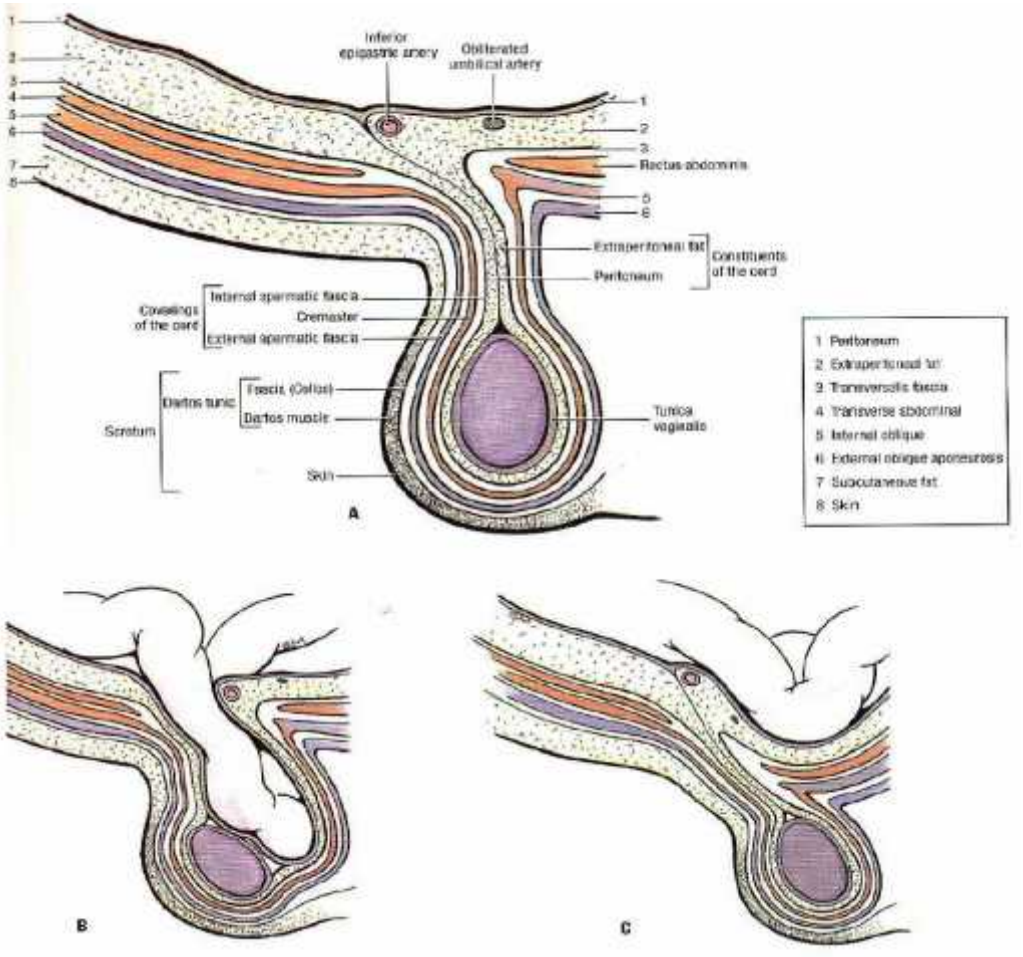


Figure 4. Labelled diagrams: A-Coverings of spermatic cord and testes; B-Indirect inguinal hernia; C-Direct inguinal hernia.

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.[32,33] Approximately 25% of males and 2% of females have inguinal hernias in their lifetimes representing the most common hernia in males and females.[22] Approximately 75% of all hernias occur in the groin; two thirds of these hernias are indirect and one third direct.[35] 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.[36] 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.[33,35] The incidence of incarcerated or strangulated hernias in pediatric patients is 10-20%; 50% of these occur in infants younger than 6 months.[33]

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.[22]

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.

A groin hernia is defined as a protrusion of abdominal contents or preperitoneal fat through a defect in the groin area, irrespective of whether this is preformed (congenital) or acquired. 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. 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.

History and presentation

Inguinal hernias present with a lump in the groin that goes away with minimal pressure applied over the lump or when the patient is lying down. Most cause mild to moderate discomfort that increases with activity. A third of patients scheduled for surgery have no pain, and severe pain is uncommon (1.5% at rest and 10.2% on movement).[37,38]

Inguinal hernias are at risk of irreducibility or incarceration, which may result in strangulation and obstruction; however, unlike with femoral hernias,

strangulation is rare. National statistics from England identified that 5% of repairs of primary inguinal hernia were emergency operations in 1998-9. Older age and longer duration of hernia and irreducibility are risk factors for acute complications. Gallegos and colleagues studied the presentation of inguinal hernias with a "working diagnosis of strangulation." Only 14 of their 22 patients with an acute hernia had compromised tissue at operation, with one of 439 patients requiring bowel resection.[39] Though the study numbers are small, these findings emphasise the rarity of strangulation. A recent larger study estimated the lifetime risk of strangulation at 0.27% for an 18 year old man and 0.03% for a 72 year old man.[40]

Patients with hernias present to the emergency department (ED) due to a complication associated with the hernia. Hernias also may be detected in the ED on routine physical examination. However, in relation to the chief complaint, the following clinical issues must be considered:

- Asymptomatic hernia
    - Presents as a swelling or fullness at the hernia site
    - Aching sensation (radiates into the area of the hernia)
    - No true pain or tenderness upon examination
    - Enlarges with increasing intra-abdominal pressure (coughing, sneezing, valsalva) and/or standing
- Incarcerated hernia
    - Painful enlargement of a previous hernia or defect
    - Cannot be manipulated (either spontaneously or manually) through the fascial defect

  - Nausea, vomiting, and symptoms of bowel obstruction (possible)
- Strangulated hernia
  - Symptoms of an incarcerated hernia present combined with a toxic appearance
  - Systemic toxicity secondary to ischemic bowel is possible
  - Strangulation is probable if pain and tenderness of an incarcerated hernia persist after reduction
  - Suspect an alternative diagnosis in patients who have a substantial amount of pain without evidence of incarceration or strangulation

Further anatomic considerations must be assessed in relation to the above clinical findings. The location of the underlying hernia may provide a unique constellation of symptoms with or without specific anatomic findings.

- Femoral hernia
  - Medial thigh pain as well as groin pain are possible because of the position of this hernia
- Obturator hernia
  - Because this hernia is hidden within deeper structures, it may not present as a swelling
  - The patient may complain of abdominal pain or medial thigh pain, weight loss, or recurrent episodes of bowel or partial bowel obstruction
  - Pressure on the obturator nerve causes pain in the medial thigh that is relieved by thigh flexion. This same pain may be

exacerbated by extension or external rotation of the hip (Howship-Romberg sign)

- Incisional hernia
    - As these are usually asymptomatic, patients present with a bulge at the site of a previous incision
    - Lesion may become larger upon standing or with increasing intra-abdominal pressure (coughing, sneezing, valsalva)

Physical 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.[21]

- 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

1. Zieman's technique[41]

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. Invagination test[41]

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:[41]

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.

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[21]

Assessment

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).[37]

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.[37]

Diagnosis

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.[21]

Imaging Studies

- Imaging studies are not required in the normal workup of a hernia.[36,42]
- 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

Management

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

Indications

Surgery is the only curing treatment for an inguinal hernia. Hernia symptoms in patients that can not be operated on, due to poor health or an unwillingness to be operated on, can sometimes be reduced by a hernia bandage (truss). Trusses are however not very comfortable and do not prevent strangulation. All hernias do not need surgery. Asymptomatic inguinal hernias in men can most often be left without surgical intervention. Conservative management and delay of surgery until symptoms occur is termed watchful waiting.[47] The only important reason to operate an asymptomatic inguinal hernia is to reduce the risk of strangulation. In men this risk is low but since that risk is considerably higher in women, due to the higher frequency of and often misdiagnosed femoral hernias, it is often recommended that women with inguinal hernias are operated upon. On the other hand many patients who undergo an

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

Repair techniques

Bandages (truss) have been used for 3000 years. Inguinal hernia surgery can at least be traced back to Alexandria 300 BC. At that time the anatomical knowledge was limited and the surgical techniques seem to have included closing of the hernial sac with or without removing the ipsilateral testis. 150 years ago the surgical repairs were performed subcutaneously including ligation of the sac, narrowing of the external opening and reinforcement of the anterior wall. The recurrence rates were depressingly high, almost 100%. Many authorities stated that hernia surgery should not be performed. Technical improvements like better sutures together with improved anatomical knowledge as well as new anaesthetic and antiseptic methods helped introducing "modern" repair techniques for inguinal hernia surgery. Between 1870 and 1900 a lot of new repair methods were introduced, often accompanied with very promising results.

The sutured repairs

The Marcy repair: Described12 in its initial form by Henry O. Marcy[44] 1871 who also promoted the aseptic technique in surgery. It consists of high ligation of the hernial sac and narrowing of the deep ring. Nowadays the technique is sometimes used for lateral hernias in children and in growing youths.

The Bassini's repair

Initially reported in Italian[45] by Eduardo Bassini 1887. Two years later he published a large monograph in Italian[46] on his technique, including many beautiful pictures, but the method was more widely recognized when his monograph was translated to German and republished[47] again 1890. Dissection of the inguinal canal, defining of the hernial sac, high ligation in case of a lateral sac and incision of the posterior floor were essential. The posterior floor was then reconstructed by interrupted nonresorbable suturing of the internal oblique muscle, the transverse abdominis and the transverse fascia to the iliopubic tract and the inner parts of the inguinal ligament. This also led to a narrowing of the internal ring. Bassini included follow up results10 for up to 4½ years with a recurrence rate of 3%.

The Halsted procedure

William S. Halsted18 briefly first wrote about19 his repair method 1889 and then made a more complete publication20 on it in 1893. In many aspects it was performed like the Bassini method but the cord excised of its superficial veins and transposed to a position above the external oblique aponeurosis. He later modified his method and omitted the transposition of the cord and instead covered it with both the internal and external oblique muscles21. Halsted's recurrence rate was 4% after at least four years of follow-up.

The McVay hernioplasty

It was first described by Georg Lotheissen[48] in 1898 but described again and popularized by Chester B. McVay[49] in 1941. The posterior wall was repaired by interrupted suturing. Medially the rectus sheet was adapted to Cooper's ligament and laterally the transversalis fascia was adapted to the femoral sheath. By this both the femoral and the internal ring were narrowed. McVay recommended the use of this method for medial, femoral, large lateral and recurrent hernias. He reported a recurrence rate of less than 1% after 1-11 years of follow-up.[50]

The Shouldice repair

Described in 1953 by Earle Shouldice in his only bibliographied publication.[51] In fact the description in that publication is not similar to the modern repair method bearing his name, described and published four years after his death.[52] This was basically a Bassini modification. The posterior repair was using the same layers but the adaption was made by a series of at least 3 nonabsorbable running sutures. The technique is regarded as the best of the sutured repairs. The Shouldice Hospital has reported a recurrence rate of 0.6% after 17 years.[53]

Nyhus original posterior preperitoneal operation

Lloyd M. Nyhus first described his preperitoneal repair method[54] in 1959. After opening the inguinal preperitoneal space the hernia was reduced and the transversalis fascia reapproximated to the iliopubic tract. This method was

especially suitable for recurrent hernias and those involving incarcerated or strangulated bowel. Nyhus frankly reported that for primary hernias his results could not compete with the results from the Shouldice hospital.[55]

The Lichtenstein hernioplasty

In 1986 Irving Lichtenstein introduced the term tension-free hernioplasty[56] and in 1987 he published a personal series of more than 6000 repairs[57] reporting a recurrence rate of 0.7%. At that time he recommended invagination of an indirect hernia sac and suturing of the transversus abdominis aponeurosis to the inguinal ligament including narrowing of the internal opening medially to the cord and in case of a direct or recurrent hernia the posterior wall should also be reinforced by a mesh.

In 1989 Lichtenstein published his improved, and nowadays often called original method,[58] where he no longer performed a sutured repair of the posterior wall, he just reinforced it by bridging the defect with a mesh that was sutured with a continuous monofilament nonabsorbable suture. The method was further improved in the early nineties[59] with recommendations of larger, slightly relaxed mesh, medial mesh overlap, crossing and suturing of the tails of the mesh lateral to the cord and only interrupted absorbable sutures on the upper edge of the mesh. The reported recurrence rate was further decreased.

As all popular methods it has been further modified not only by Lichtenstein's successor Amid[60] but also by many other surgeons. An EHS guideline published in 2009, states that it can be advisable to close a large direct hernia defect of the posterior wall, tension-free with continuous absorbable

sutures until a flat posterior wall has been created with a normal internal ring38. It is still debated whether surgeons should use the original method or the modified ones.

Plug and Patch or Rutkow-Robbins technique

The plug technique was developed and described by Alan Robbins and Ira Rutkow[61] in 1993. An umbrella shaped polypropylene plug was inserted into the hernia defect of the posterior wall acting as a sublay mesh and combined with an onlay flat mesh. They reported a recurrence rate of 1% for primary hernias on follow-up of upto to six years. It is well worth noting that Dr Rutkow has retired from clinical practice and now works as an author of medical history. He has written at least six publications on hernia history.[62]

Open posterior mesh repairs

The Stoppa method: This technique developed by many but popularized by René Stoppa[63] was performed by a low abdominal midline incision into the preperitoneal space. This gave the surgeon access to the entire bilateral myopectineal orifice of Fruchaud and a large mesh could be inserted completely overlapping all inguinal and femoral orifices.

Nyhus modified posterior preperitoneal operation: Later on in his life Nyhus modified his original method[54] by applying a mesh in the preperitoneal space after repairing the defect in the transversalis fascia.[55] He recommended this procedure especially for recurrent hernias.

Endoscopic posterior mesh repairs IPOM (IntraPeritoneal Onlay Mesh): In 1992 Charles Filipi described a laparoscopic technique in which a mesh is placed intraabdominal, covering all inguinal and femoral orifices.[64]

TAPP (TransAbdominal PrePeritoneal repair): Maurice Arregui[65] described the method in 1992. By a transabdominal laparoscopic technique a preperitoneal mesh is placed covering all inguinal and femoral orifices.

TEP (Totally ExtraPeritoneal repair): Described in French[66] by Jean-Louis Dulucq in 1992. By the extraperitoneal laparoscopic technique a preperitoneal mesh is applied covering all inguinal and femoral orifices.

The development of meshes

Synthetic sutures have been developed since the late 1930s. Nylon (polyamid) was the first such fabric. The polyester multifilament mesh Dacron (Mersilene) was the first popular synthetic mesh[67] and it is still available for clinical use49. Polyethylene was developed in the fifties. The synthetic suture had many improved properties e.g. it was strong, inert, nonwettable, temperature resistant and could be used as monofilament. When knitted as mesh it was strong and stretchable. In 1958 the use of polyethylene mesh (Marlex 50) in hernia surgery was first reported by Francis Usher.[68] He further supervised the development of the polyethylene mesh prosthesis and how to use it in different hernia repairs. In 1963 an improved version was introduced under the name of Marlex mesh (Bard). This was made of polypropylene. It was more temperature resistant, could be cut without frying and was two-way stretchable. Other similar products are nowadays sold under different names (Prolene mesh, Surgipro etc.).

The use of polypropylene meshes in all sorts of hernia repairs has increased enormously during the last 50 years. When incorporated in the tissue, polypropylene mesh induces an inflammatory reaction. The resulting fibrosis that develops around the mesh helps enhancing the strength of the repaired tissue.[67,69] Usher suggested the mesh could be used not only to strengthen or buttress a sutured repair but also to bridge the defect. By the latter the relaxing incision became unnecessary and the tension became eliminated.

The properties of the polypropylene mesh have continuously been improved. The manufacturers now provide such meshes with low weight, large pores (macroporous), different coatings, more flexibility but still with a good memory, combinations with resorbable parts and preshaped forms including plugs. Large pores permit local tissue growth in the pores. This and the monofilament are believed to be the factors that have made it possible to keep it in place even in most cases of infection. The size of the meshes used have increased over time, due to the knowledge that larger meshes than those initially used probably result in a lower recurrence rate.[70]

Nowadays, meshes are used for all sorts of hernia repairs. The different hernias and repair techniques require meshes with different properties. For example a large ventral hernia requires a mesh with more strength than a small inguinal hernia. New mesh devices usually promise improved properties but to a higher cost.

The definition of what is a lightweight mesh has been unclear.[71] This fact and the increased amount of different mesh devices have motivated a

classification system. The benefit of such a system would be to improve the quality control. The knowledge about the classification of the mesh system would help the surgeons to decide what mesh device is best for the patient. Uwe Klinge has recently suggested a new classification were the different mesh devices are grouped regarding to their biological and clinical response.[72]

- Class I: Large pore meshes (often low weight)
- Class II: Small pore meshes (heavy weight mesh)
- Class III: Porous meshes with special features
- Class IV: Meshes with films (no porous or micro porous)
- Class V: Three-dimensional meshes (preshaped, preformed, plugs etc)
- Class VI: Biologicals

Complications after inguinal hernia surgery

During the last 20 years the recurrence rates after the repair of inguinal hernia, have gradually decreased and surgeons are nowadays focused on other complications associated with inguinal hernia. The primary goal for most of the surgeons of the last century was always the maintenance of the repair. Today's goal apart from maintenance of repair, also includes the term "return to normal physiology".[71] In surgery there are obvious technical complications during the operation like damage to the bowel, the structures of the spermatic cord and the vessels(the femoral vessels during fixing mesh). The estimated incidence of injury to the vas deference is 0.3% in adult hernia repair,[73] on the other hand, the

endoscopic repair methods have their own specific complications including pneumatic problems and trocar site hernias.

Early postoperative complications after hernia repair include infection, severe pain, hematomas, seromas and post operative urinary retention. Late complications include post herniorraphy pain syndrome or inguinodynia, loss of sensation in the medial side of thigh, scrotum and recurrence of hernia. Chronic pain (inguinodynia) has probably been the most studied complication for the last 10 years. The prevalence of chronic pain affecting normal activities or work is 0.5-6%58. Nerve damage is proposed to be the main reason for chronic pain.[74]

Sexual problems secondary to an inguinal hernia repair surgery are also described. Sexual problems related to an inguinal hernia repair have been studied on males registered in the Danish Hernia Database. The identified problems were ejaculatory pain, genital pain, groin pain, pain related sexual impairment and erectile dysfunction.[75]

Mortality is the most extreme complication in an inguinal hernia repair. The risk in elective hernia surgery is almost zero. In emergency hernia surgery there is a substantial risk.[76]

Mesh-related problems after inguinal hernia surgery

Most of the meta-analysis and guidelines that summarize RCT's within the literature states that inguinal hernia surgery with mesh results in lower recurrence rates and less problems with chronic pain.[77]

The latter is probably partly due to the possibility for the surgeon to perform a tension-free repair. The question of chronic pain occuring after performing a TEP (total extraperitoneal repair) does not depends upon the fixation of mesh and is not finally answered.[78]

There are specific problems and adverse effects of placing a mesh in the inguinal hernia repair surgery. Postoperative local infections at the site of the mesh are more difficult to cure compared to sutured repairs. The mesh-induced foreign body reaction and the resulting fibrosis can give the patient a diversity of proven or suggested problems. These problems are partly related to the weight and the pore size of the mesh, to where the mesh is placed (anterior or posterior) and to the eventual fixation of the mesh. Among these problems are:[49]

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

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

Meshes and fixation

Different materials have been tested in the search for an ideal prosthetic substance to reinforce the groin and facilitate a good hernia repair. Theodor Billroth stated: "*if we could artificially produce tissues of the density and toughness of fascia and tendon, the secret for the radical cure of hernia would be discovered*".[72]

Among those materials that have been tested are silver filigree in the late 19th century,[79] homologic materials such as tendon from kangaroo, whale, ox and deer, and autologic materials such as fascia lata and the aponeurosis of the rectus muscle. Biological materials have the disadvantage of undergoing complete phagocytotic degeneration over time. Metal meshes made of titanium and stainless steel have been abandoned due to fragmentation, fracturing, sinus formations and recurrences.[80]

The early synthetic material that was used for hernia repair was nylon. This was first introduced by French surgeons in Marseille in 1944 and performed a hernia repair in method similar to the Lichtenstein technique56. Other synthetic materials such as polyvinyl alcohol, Silastic, Teflon and carbon fibre have been tested but are no longer in use.[80]

During the last two decades of the 20th century, three synthetic meshes have mainly been used in the hernia repair : polypropylene, polyester and expanded polytetrafluoroethylene (e-PTFE). Polypropylene (Marlex®, Prolene®) was synthesised in 1954 and has been used for hernia repair since 1958.[81] Polyester (Mersilene®) was synthesised in 1939 and introduced into hernia repair

in 1956.[79] Patented in 1976, e-PTFE (Gore-Tex®) has mainly been used for vascular prosthesis but to some extent also for hernia repair. The most commonly used material today is polypropylene, followed by polyester.

The mesh repair technique has progressed from small to large implants. For laparoscopic repair, mesh size has increased in order to avoid recurrence[82] and to compensate for possible shrinkage. Presently mesh size is approximately 13 by 15 cm to overlap the inguinal and femoral regions in all directions. For the Lichtenstein repair, mesh size has increased accordingly. Early meshes were 5 by 10 cm[83] or even smaller. The recommended size now is 7 by 15 cm. The mesh should overlie the pubic tubercle by approximately 2 cm medially, 3-4 cm above the Hesselbach´s triangle superiorly and by 5-6 cm laterally to the internal ring.[75]

The most commonly used and studied mesh, polypropylene, has been developed further during the last decade. Meshes are now categorised as heavyweight or lightweight. There is no clear definition for these two, but a composition of polypropylene below 50g/m2 is generally referred to as lightweight. The concept of lightweight meshes is that less foreign material is deposited in the wound, thus reducing any chronic inflammatory response. One effect of this is a reduction of the scar plate formed thus reducing the entrapment of adjacent nerves, possibly leading to a reduced risk of chronic pain.

This was indicated by some studies after Lichtenstein repair,[84] but data are somewhat inconsistent64. To lower the weight of the meshes, pore size and fibre thickness have been modified. A pore size of at least 75 microns is an important property of the mesh, facilitating the ingrowth of vessels and collagen

fibres as well as the admission of macrophages.[64] The pore size also influences the character and amount of adhesions between the mesh and intestines.[85] Some lightweight meshes are manufactured with an absorbable component in addition to polypropylene to make them easier to handle during the operation.[86] There are two commonly used absorbable components, polyglactin and polyglecaprone.

The impact of the mesh coating or whether it is multi- or monofilamentous presently remains unclear.[87] The regular prolene mesh (heavy weight) is constructed of knitted filaments of extruted polypropylene identical in composition to that used in the prolene suture. This mesh is about 0.020 inches thick and pore size of 75 micrometer. The mesh is knitted by a process which interlinks each fiber junction which provides elasticity in both directions. This type of construction permits the mesh to be cut in the desired shape and size without unraveling. The fiber junctions are not subject to the same work fatigue exibhited by more rigid metallic meshes. This bi-directional elastic property allows adaption to various stresses encountered in the body.

On the other hand light weight meshes are also constructed in the same format of heavy weight, but the foregin material (prolene) incorporated is less, about 50ng/m2 and have large pore size ranging from 1300-1500 micrometer. Blue prolene monofilaments are have been incorporated into the mesh to produce contrast striping. This mesh has been constructed, so as to reduce the diameter of the monofilament fiber, knitted into a unique design that results in a mesh that is 50% more flexible than the standard prolene mesh.

Whether a mesh should be fixed or not is debatable. In the original Lichtenstein repair the mesh was fixed with both interrupted stitches and a running suture of non-absorbable material (usually a prolene suture). The need for this has been questioned due to the risk of chronic pain. The use of an absorbable suture has not resulted in less chronic pain68. Human fibrin glue for fixation seems effective69, but the effect on chronic pain is still unclear. An international RCT on this issue is currently ongoing[88] and results are awaited.

In accordance with the initial description of the TEP repair, fixation of the mesh with staples or titanium screws was commonly used. It has been discussed whether these staples could cause chronic pain due to nerve injury, injuries to the deep muscle layers or to the pubic area.[89]

To overcome this, the mesh can be left in place without fixation or it can be fixed with human fibrin glue. Both methods appear effective but their impact on chronic pain is unclear.[90]

The most novel method for fixation is a “self-gripping” mesh with micro hooks made of polylactic acid. This mesh is also semi-absorbable (polylactic acid) and is therefore also considered to be a lightweight mesh. This material has so far only been used in one published prospective trial including 52 patients with 70 hernias. The mesh was placed with an open technique in an anterior position. After 24 months, no recurrences were found and only one patient reported discomfort.[91]

There are two RCTs currently underway comparing this new implant with a sutured lightweight mesh.[92] With the introduction of the laparoscopic technique

it was of interest to study the early postoperative period to see if there were any patient benefits in comparison with conventional open techniques. One factor of major importance in this respect is postoperative pain which is considered to reflect the amount of surgical trauma caused by the repair. It is also the main determinant for postoperative recovery, including length of sick leave. When interpreting postoperative pain, one must consider that several variables correlate with its degree, such as patient age, the amount of preoperative pain, gender, length of incision and type of operation.[93]

In order to evaluate short-term results and time to full recovery, several methods can be used. One objective way to evaluate impairment due to surgical trauma is to use functional tests resembling ordinary daily activities. Among these are: the treadmill test, raising straight legs, curled sit-ups, squatting, raising from a bed and climbing stairs. These tests are generally all in favour of laparoscopically operated patients one week after surgery.[94]

It is, however, not common to use functional tests in hernia trials. Instead, a proxy such as “time to recovery”, “performs usual activities” or “takes part in social activities” are used. The amount of time to achieve this is stated by the patient. This makes it difficult to compare the results from different studies, even if the proxy is well-defined. Several reports, however, indicate that the postoperative course for patients operated with the laparoscopic technique is more favourable.[61]

Length of sick leave is another way to measure physical impairment after surgery. Over the last few decades, there have been tremendous changes in

recommendations for the length of sick leave. A duration of seven to eight weeks was normal 30 years ago, four to six weeks 15 years ago and one week five years ago. The interpretation of the length of sick leave has its pitfalls, however, since it is influenced by several factors such as patient expectations, personality, information from friends and colleagues, the type of compensation system, if there is pain or other complications from the wound, and recommendations from the medical profession itself.[95]

Meta-analyses may reduce doubts arising from single studies, and the most recent one reports on an earlier return to work after laparoscopic compared with open repair.[61]

Chronic pain

The International Association for the Study of Pain (IASP) defines pain as an "unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage". This definition declares that pain, as well as having a physiological basis has a very real psychological or subjective component.[96]

Difference between acute and chronic pain is defined by most authors in terms of time.[96] The two most commonly used chronological markers to denote chronic pain have been three and six months since the initiation of pain, however these distinctions are arbitrary. The IASP provides one of the most referenced definitions of chronic pain. Chronic pain is that which persists beyond the normal time frame for healing, usually taken to be 3 months. The IASP considers a further characteristic related to the "appropriateness" of the disorder. In acute

pain there is an advantage to the individual, i.e. it allows rest and the inflammatory process of healing to occur. In chronic pain there is no biological value, i.e. there is no advantage to the individual in experiencing persistent pain. The Clinical Standards Advisory Board for the National Health Service (NHS) defines chronic pain "as that which persists beyond the expected time frame for healing or that which occurs in disease processes in which healing may never occur".[97]

The Practice Guidelines of the American Society of Anaesthesiologists for Chronic Pain Management considered chronic pain as a "persistent or episodic pain of a duration or intensity that adversely affects the function or well being of the patient, attributable to any non-malignant aetiology".[98]

Thus chronic pain may be as a result of the healing process gone awry. It may be persistent and unrelenting and conveys no benefit to the individual who experiences it. Sternbach has emphasized the differences between acute and chronic pain and argues that while acute pain is a symptom of disease, chronic pain itself is the disease.[99]

It is not easy to classify pain. At best the classification is ambiguous and variable. As there is no consensus of agreement, there are a wide variety of classifications of pain. Pain can be classified based on anatomy, duration, aetiology, body system or severity. Portenoy categorised both acute and chronic pain as nociceptive, neuropathic or psychogenic.[100]

Nociceptive pain is due to chronic activation of nociceptive afferent neurones and can be 3 somatic or visceral. In nococeptive pain and pain due to

tissue inflammation, the sensory experience reflects the normal, adaptive functioning of the pain system.[101] Neuropathic pain is defined by the IASP as pain initiated or caused by a primary lesion or dysfunction in the nervous system.[102]

It is due on the other hand to central reorganisation of sensory processing after injury to an afferent pathway. It may be sustained by mechanisms that involve disturbances in the peripheral nerve or nerve root, i.e. peripheral neuropathic pain, or the reorganisation of nociceptive information processing by the central nervous system, deafferentation syndrome.[103]

Niv and Devor see neuropathic pain as a fundamental paradox, as injury to a sensory conduction pathway should decrease the signal transmitted not increase it.[101]

They argue that it is important to remember that what we describe as conduction pathways are in fact protoplasmic extensions of living structures, neurones, and that these cells will respond actively to injury with changes in biological properties.

Chronic pain and inguinal hernia repair

Inguinal hernia surgery has advanced considerably over the past two decades. Despite this, the average general surgeon is still uncertain as how best to manage patients with an inguinal hernia both pre and post operatively. Over the years inguinal hernia repair has evolved from sutured to mesh repair. Mesh repair

brings with it the advantage of low recurrence rate (<5%) and is the most common method of repair.[104]

There is less postoperative pain following mesh rather than sutured repair of an inguinal hernia.[105] One of the perceived disadvantages of this type of repair appears to be an increase in the reporting of post-operative pain (chronic pain or inguinodynia) and discomfort.[106]

Chronic postoperative inguinal hernia pain can be severe and debilitating with neuralgia, parasthesia, hypoaesthesia and hyperesthesia. It has a negative effect on the individual in terms of lifestyle and work. This may also have a negative effect on the economy when one considers the number of repairs performed. Inguinal hernia repair has an annual procedural rate of 2,800 per million people in the United States alone. Approximately 70,000 hernias are performed in the UK in a given year.[107]

Given the frequency of post herniorrhaphy pain, it is not entirely clear whether the surgeon should be repairing inguinal hernias in all patients.[108]

More recently in 1987, Ralph Ger first described laparoscopic hernia repair and since then there have been numerous modifications and advances on his original technique.[109]

In 1999 Callesen et al published a prospective consecutive case series study that examined the incidence of chronic postoperative pain at one-year post elective day case local anaesthetic hernia repair. Pain was scored at rest, on coughing and at mobilisation as none, mild, moderate and severe at one year and

compared with data collected at one and four weeks post repair. Just fewer than 20% of patients reported some degree of pain at one year. The incidence of moderate to severe pain was higher after repair of a recurrent hernia. Those patients who complained of persistent pain at one year were more likely to have high pain scores at one week and four weeks post surgery. Thus they concluded that the intensity of early postoperative pain is a good predictor of long term chronic pain.

Another study in 1999 compared long-term outcome following local anaesthetic open mesh repair with the size of the hernia as found at operation. In total 220 hernias were repaired and the average followup was 15 months. Most patients (approximately 90%) were able to do sports and perform usual activities of daily living including driving within 4 weeks of surgery. Chronic unpleasant postoperative sequelae were classed as mild or moderate pain, local hypoaesthesia, and weather dependent changes in sensitivity and hyperaesthesia. This study found that those patients most likely to complain of moderate pain at one-year follow-up were those that had a small intra-operative hernia. The authors did not find a relation between pain of any sort and age and sex of the patient. They conclude that patients with small intraoperative hernias are not necessarily well served by surgery.[111]

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

of long term post operative pain include, absence of visible bulge preoperatively, numbness in the immediate postoperative period and the need for the patient to spend4 36 weeks or more off work postoperatively.[112]

In 2003, Poobalan et al reviewed all studies to date on chronic pain post inguinal hernia repair.[113] In their own follow up study they identified a cumulative prevalence of chronic pain of 30% at 3 years post surgery. One third of this 30% reported moderate to unbearable pain. The definition of chronic pain used by these authors was that used by the IASP. As stated by these authors standardization of definition, length of follow up and quantification of chronic pain is lacking. Direct comparisons between studies to tease out causative factors are therefore difficult if not impossible. This is illustrated in the study by Amid et al.[114]

The descriptor of chronic pain that they used was neuralgia and among other reasons is an explanation for their low chronic pain result 146. Pain during sexual activity and subsequent sexual dysfunction represent a clinically significant problem in about 3% of younger male patients with previous inguinal herniorrhaphy.[115]

Intraoperative nerve damage and disposition to other chronic pain conditions are the most likely pathogenic factors. Chronic pain post inguinal hernia repair ranges from 0 – 63% and is usually broadly classified into three categories mild, moderate and severe. Severity may be determined by extent of interference with social, daily and work related activities, number of painkillers used and attendance at chronic pain clinics. Perkins looked at post herniorrhaphy

pain in the context of their chronic pain model and estimated that it may be as high as 50% at one year.[116] They believe that the presence and extent of preoperative pain may influence the degree of postoperative pain. Some authors would argue that it is not imperative to repair all hernias as soon as they are detected. In the context of postoperative chronic pain there is a defined point where the surgeon must intervene, quantifying this point however is not clear. Repair of recurrent hernia and type of mesh used may be related to long-term chronic postoperative pain.

Preoperative factors that may contribute to post herniorrhaphy chronic pain

Chronic groin pain, as well as being a consequence of inguinal hernia repair, may also be as a result of a previously undiagnosed hernia. A small bulge in the posterior wall of the inguinal canal may not be large enough to be clinically detected but may account for chronic groin pain. Surgical mesh repair of this small direct hernia has been reported to alleviate in 87% and improve in the remainder of cases, previously unexplained chronic groin pain.[117] This study had fit sportsmen as its population base.

In another similar study surgical exploration and repair of a previously undiagnosed inguinal hernia should be undertaken in sports people unable to compete due to chronic groin pain. That is, when all other explanations of chronic groin pain are exhausted, a clinically silent groin hernia may be the explanation for chronic groin pain.[118]

As many as 66% report pain at the time of initial presentation and this increases to 90% in those patients that have their hernia for 10 years or more.[119]

What degree of preoperative pain needed to make repair worthwhile is not clear. For the patient to believe that the surgical experience has been worthwhile, the reduction in preoperative symptoms has to be greater than the risk of severe postoperative chronic pain and more than chronic pain per se. Arguments supporting repair are based on alleviating symptoms and avoiding the risk of an acute hernia accident, the latter being often estimated at between 4 and 6%.[120] However because large population based studies detailing the natural course of an untreated hernia are scarce, this commonly held assumption that the life time risk of strangulation is between 4 and 6% is more likely one of speculation than fact.

In the study by Hair et al the incidence of bowel resection was 0.3% , indicating that the risk of strangulation is approximately 1 in 300.[119]

Intraoperative factors that may contribute to post herniorrhaphy chronic pain

Chronic pain can be neuropathic or nociceptive in origin. Neuropathic pain is believed to be as result of nerve damage and is usually described as electric, sharp and shooting pain. Nociceptive pain on the other hand is as a result of tissue damage and is described as aching, heavy and dragging.[121]

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

Ducic et al believe that severe and chronic postoperative testicular pain after inguinal surgery can be treated by a designed approach that identifies the genital branch of the genitofemoral nerve in the proximal inguinal canal, resects it proximal to the previous operative field and subsequently places it behind the peritoneum.[122]

From cadaveric anatomical studies that highlighted the variability in the course of this nerve as it exited the external ring, they showed that proximal ligation of this nerve provides relief of chronic scrotal pain. Despite this being a small study, all four patients had relief of subjective symptoms and evidence of objective improvement with reduction in level and frequency of pain postoperatively.

Al-Dabbagh et al reviewed the anatomical variations in the course of the ilioinguinal and iliohypogastric nerves in 110 hernia repairs.[123] They found that the course of both nerves was consistent with that found in anatomical textbooks in just fewer than 50% of cases. This difference in the variation of the nerve along its pathway may leave it susceptible to injury at operation. However these differences in the course of the nerves can be readily appreciated and should be easily identified by the surgeon.

Since the early 1980's peripheral nerve entrapment syndrome following common surgical procedures to the lower abdominal wall have been recognised. Ilioinguinal or iliohypogastric nerve entrapment is typically diagnosed as a burning pain near the incision that radiates to the area supplied by the nerve with associated impaired sensory perception. Resolution occurs, albeit temporarily,

when the two nerves are infiltrated with local anaesthetic as they leave the internal oblique. Surgical repair of the scar and resection of the nerve was advocated as the method of treatment for this condition.[124] It is important to note that this early study involved very small numbers and that at least 25% of their patients had persistent chronic pain following the proposed treatment.

In 1996 Bower et al reported that severe chronic postoperative inguinal hernia neuralgia was rare.[125] They suggested that in the small number of patients in whom non operative methods of treatment were refractory, the involved nerve should be mapped out prior to its surgical high ligation and division.[125]

Understanding the typical nerve anatomy and variation, is fundamental in treating this rare but debilitating postoperative complication. A larger series of just under 500 patients, this time confining the surgical procedure to the sutured Shouldice repair of an inguinal hernia, states that inguinal entrapment syndrome can be reduced to below 2% if the genital branch of the genitofemoral nerve is deliberately dissected free or cut cleanly.[126]

The early postoperative complication rate or the recurrence rate is not affected.[126] Again, identifying the nerve and ligating it is advocated as a solution for severe chronic neuralgic pain which these authors state is uncommon but debilitating following hernia repair.[125]

Dittrick et al reviewed 90 patients who underwent Lichtenstein inguinal hernia repair over a seven year period. The two surgeons who performed the operations differed in the fact that one preformed ilioinguinal neurectomy on a routine basis. Neuralgia and paraesthesia were assessed through telephone and

personal patient interviews at 1 month, 6 months, 1 year and 3 years post surgery. There was no data recording preoperative symptoms or no data on potential confounding conditions e.g., stroke, diabetes etc. They concluded that the incidence of postoperative neuralgia was significantly lower in the neurectomy group versus the nerve preservation group at 1 month and 1 year but there was no significant difference in postoperative neuralgia at 3 years, though they did admit that numbers followed up at 3 years were small. At the same time the incidence of postoperative paraesthesia was not significantly higher in the neurectomy group versus the nerve preservation group at 1 month, 1 or 3 years. Those that reported postoperative paraesthesia in the neurectomy group at one month and six months had lower mean scores on the visual analogue scale than those in the nerve preservation group. These authors argue that routine division of the ilioinguinal nerve is a reasonable option during inguinal hernia repair.[127] The drawback of this study was that it was retrospective and that small numbers of patients were used.

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

transection even at one year follow up.[128] The problem with nerve studies is that in the main they evaluate the lack of function of one nerve only whereas there are three nerves involved in the sensory innervations of the groin.

In a second Italian study the identification and preservation of all three nerves during open mesh repair was associated with a reduction in chronic incapacitating groin pain and in the majority of these patients with chronic pain at six months the pain was resolved with conservative or medical management at 1 year.[129]

Madura et al state that the incidence of post herniorrhaphy neuropathies is not well known but is estimated to be in the region of 0 to 30%.[130] They argue that the most successful treatment is surgical resection of the nerve with good pain relief. Complete pain relief was seen in 72% of patients in their study and 10% reported a marked decrease in their symptoms. The only difference between patients who had complete relief and those who had partial relief of their symptoms was previous repair of a recurrent hernia. This seems to be the only available indirect evidence of chronic pain post repair of a recurrent inguinal hernia. To date there are no available studies that look at the incidence of post herniorrhaphy pain in patients who have had recurrent hernias repaired. One would assume that there is a higher incidence of chronic pain in these patients as tissue and nerve damage is twice as likely second time round. As an indirect result of our first study we found that patients who had a recurrent hernia repaired were no more likely to report pain at three months post surgery than those who had a primary hernia repaired. Therefore one can argue that chronic postoperative pain is partly explained by nerve damage at initial surgery. When any of the

nerves are not recognised and as a result traumatised, chronic postoperative pain can ensue. However it would appear that the situation is not clear. While cleanly dividing the nerves does not exacerbate postoperative pain it does play a role in disturbed sensory changes after repair. On the other hand clean nerve division can also be a solution for severe chronic neuropathic pain. It has been postulated that when these nerves are caught or trapped in permanent stitches or tacks or bound up in the mesh during the various methods of repair it is then that postoperative chronic neuropathic pain may result.

Characteristics of mesh types

Successful treatment of abdominal wall hernias and the prevention of recurrence is largely due to the insertion of a mesh. Meshes are synthetic alloplastic materials and are thought to work by mechanical sealing or by induction of a strong scar plate. Irrespective of which way the groin hernia is approached, meshes are necessary and indeed paramount to ensuring the low recurrence rates of less than 4%.[131]

The incorporation of a large amount of biomaterial can lead to seroma development, wound contracture and reduction in abdominal wall mobility. Meshes show migration and erosion of bladder and bowel with the formation of fistulas and bowel obstruction. It has been postulated that the very structure of the mesh and its inflammatory characteristic may contribute to post herniorrhaphy discomfort and pain. The host reaction is influenced by the mesh type used, particularly the amount of mesh used and the pore size. The optimum amount of material and pore size needed to adequately treat the hernia and avoid recurrence

is unclear. Textile analysis of the various mesh types available show variations in weight, structure, stiffness and strength. There is an asymmetry to meshes in that different strain properties are seen in the horizontal and vertical direction. The basic mesh type is composed of polyprolene monofilament and this has a high bending stiffness. Increasing the size of the pores 167 and reducing the polypropylene content will reduce the foreign body reaction and less scarplate formation resulting in less chances of entrapment of adjacent nerves. It is this modification in the lightweight mesh (prolene Soft) which has been optimally designed to cope with the physiological stresses of the abdominal wall and also supposedly reduce the post herniorraphy pain. The main purpose of implantable meshes is their tensile strength. This can be defined by the modified Law of La Place, which states that F = P x d / 4, where F = force (in Newtons, N) per cm2, P = intra abdominal pressure (in kiloPascals, kPA) and d = diameter (cm).[132]

Laparoscopic hernia repair and chronic pain

In the year 2001/2 95.9% of patients in the UK had their primary hernia repaired at open surgery, only 4.1% of patients with a hernia had a laparoscopic repair 137. The first report of a hernia repaired laparoscopically was in 1982 by Ralph Ger.[133] Since then many surgeons have contributed to modifications and improvements on the original technical description but only 5% of surgeons have adopted this technique into routine surgical practice.[134]

Laparoscopic hernia repair can be done either transabdominally or extraperitoneally, using either general or regional anaesthesia. The advantage of laparoscopic inguinal hernia surgery lies in the fact that the whole of the inguinal

floor on both sides is exposed and as a result direct, indirect, contralateral and femoral hernias can be detected and repaired. It also has the advantages of laparoscopic surgery in general, in terms of recovery period and incision length. The last decade has witnessed enthusiastic investigation comparing laparoscopic versus open inguinal surgery repair. Approximately four meta-analyses, two systematic reviews, nearly 70 randomised controlled trials (RCT) and numerous retrospective reviews have been published.[134]

The problem with many of the RCTs is poor quality. Many are not well designed and have been found to be underpowered.[134] Patients recruited to both open and laparoscopic repair groups were not necessarily homogeneous. End points that are easily measured i.e.; hernia recurrence, length of operation, are usually reported accurately but more subjective endpoints i.e.; postoperative pain, type of pain and return to normal activities are not usually reported in a standard quantified manner except in a few circumstances.[134]

The European Union (EU) hernia trialists' collaboration has organised the most extensive metaanalysis to date and continues to accrue data to constantly refine its conclusions. In the Group's 2000 review, recurrence rates for open and laparoscopic repairs were not significantly different. In 2002, the Groups' opinion was that return to normal activity is faster after laparoscopic repair and that persistent pain is less.[135]

In a five year follow up study laparoscopic hernia repair is shown to be associated with less long-term numbness and probably less pain in the groin than open mesh repair.[136]

Kumar et al found that chronic pain or discomfort was reported by 30% of patients after groin hernia repair and was significantly more common after open mesh repair than after laparoscopic total extra peritoneal repair (TEP) repair 175. It restricted physical or sporting activities in 18% of patients and specifically more so after open mesh repair.[137]

Postoperative neuralgia following laparoscopic repair was examined by Fitzgibbons et al, and they found that leg pain decreased significantly from 7% to 1.8% after the surgeon preformed 30 cases.[138]

Chronic pain and neuralgia occurs with an incidence of 0.5% and 4.6% respectively depending on the laparoscopic method used and as the surgeon becomes more familiar with the normal anatomy and its variants this incidence decreases.[134]

Postoperative factors that may influence post herniorrhaphy chronic pain

Adequate analgesia in the postoperative period is a priority in enabling the post-surgical patient to cope with the tissue damage of surgery. Irrespective of whether the hernia is repaired under local, regional or general anaesthesia, the patient will not be deemed fit for discharge until the pain of surgery is controlled with appropriate analgesia. Inguinal hernias have been repaired under general, regional or local anaesthesia. It is well established, for example that open inguinal hernia repair can be conducted under local anaesthesia, regardless of comorbidity and with minimal morbidity.[139]

Paravertebral blocks (PVB) have recently been used as the sole anaesthetic technique and randomized against general anaesthetic (GA) fast tracking for inguinal hernia repair. Patients who had their hernia repaired using PVB were discharged sooner, ambulated earlier, had less postoperative adverse events including acute postoperative pain than those in the GA group.[140]

Patients' general fitness for anaesthesia and preference are important in determining what type of anaesthesia is ultimately chosen. Despite this and despite the fact that local or regional anaesthesia is safe, cost effective and shown to decrease postoperative pain in inguinal hernia repair, the majority of anaesthetists choose GA to facilitate this surgical procedure.

In a randomised controlled trial comparing post operative pain following inguinal hernia repair under general or local anaesthesia (LA), the only difference noted between the two groups was a reduction in pain scores noted at six hours in the LA group. All patients underwent psychometric testing and pain score assessments at 6, 24 hrs, 3 months and one-year post repair. Regional anaesthesia is also an option but appears to be used exclusively only by hernia specialists.[141]

It is thought that acute post inguinal hernia surgery pain, that is pain in the first few days and weeks following surgery can influence the development of long term chronic pain. Therefore adequate and effective immediate postoperative pain control not only determines timing of discharge but may also contribute to a reduction in chronic pain. It has been suggested that treatment designed to prevent pain in advance of surgical trauma may be more effective than simply instituting analgesic therapy in response to the pain after surgery.[142]

The benefit of local anaesthetic field block before hernia surgery has been investigated by Tverskoy et al.[143] They reported that constant pain and incident pain were less severe for 48 hours after surgery in patients who received a preoperative field block with bupivicaine compared with patients who received no local anaesthetic at all. Inguinal field block is superior to local anaesthetic skin infiltration in terms of less pain postoperative pain until day 7, increased patient satisfaction, faster mobilization and lower analgesic consumption.[144] Analgesia in advance of the pain stimulus prevents central sensitisation and neuronal hyperexcitability i.e., "wind-up". Central sensitisation is thought to be dependent on painful stimuli acting on NMDA receptors located within the central neuraxis.[145] Pre-emptive treatment with local anaesthetics, anti-inflammatories or NMDA inhibitors have all been proposed as methods of inhibiting transmission of noxious stimuli thereby preventing stimulation of NMDA receptors and central sensitisation.[145]

Fitzgibbons et al.[146] and O'Dwyer et al.[147] both investigated pre- and postoperative pain in asymptomatic and mild symptomatic patients in a randomized setting. Both studies compare watchful waiting with standard open tension-free mesh repair. Fitzgibbons et al.[148] randomized inguinal hernia patients that were either completey asymptomatic or minimally symptomatic without interference with normal activity. Pain limiting activities were similar for watchful waiting vs surgical repair (5.1% vs 2.2%, respectively; P=0.52) after two years although a trend is visible in favour of surgical repair that might be significant in an adequately powered group.

O'Dwyer randomized patients without inguinal pain at rest or movement. Visual analogue pain scores at rest or movement after one year did not dier between observative or operative management (3.7 and 5.2 mm (P=0.34) at rest; 7.6 and 5.7 mm (P=0.39) on movement, respectively).[147]

Page et al.[150] followed up 63% of in total 323 patients at one year of whom preoperative pain scores at rest and on movement were reported. Severity of preoperative pain was no inclusion criterium. While overall the group showed a significant reduction in pain scores at rest and moving, this was due mainly to the large selected observed in patients with high preoperative values. Patients not reporting any pain preoperatively at rest had significant pain scores at one year (p=0.001).

The lightweight and large porous concept published by Bernd Klosterhalfen, Karsten Junge and Uwe Klinge, institute of pathology, Duren- in the year 2002, concluded that large porous construction of mesh reveals a significantly improved integration of mesh into recipient tissues. In lightweight and large porous mesh there is less foreign body reaction and reduced scar plate formation and hence reduce post-operative pain.

Study done in the year 2006, at St. Josef hospital, in the department of general surgery wherein appraisal of different types implants used for inguinal hernias was done, showed that there is no difference between the heavy-weight composite prolene mesh and light weight large-porous mesh [prolene soft] in terms of reduction in post–operative pain outcome in patients undergoing Lichensteins mesh repair for inguinal hernia.[19]

Study done by Agarwal BB, et al.[150] Department of General Surgery, Sir Ganga Ram Hospital, New Delhi in the year 2009 showed Lightweight polypropylene mesh was associated with significantly better pain scores, patient comfort in totally extraperitoneal repair of inguinal hernia.

Chapter 4

Methodology

METHODOLOGY

This one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum over a period, from January 2012 to December 2012.

Study design

The study design was randomized controlled trial.

Study period and duration

This study was conducted for the period of one year from January 2012 to December 2012.

Place

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

Source of Data

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

Sample size

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

Sampling procedure

The effect size is not available, hence the sample size was taken as 60, with 30 in study group [lightweight macro-porous – prolene soft] and 30 in control group [heavy weight composite prolene mesh].

Selection criteria

Inclusion

- All patients with inguinal hernia undergoing mesh repair.

Exclusion

- Pregnancy
- Subjects with pulmonary tuberculosis.
- Subjects with uncontrolled diabetes mellitus.
- Subjects with chronic cough
- Subjects with strangulated/obstructed hernia

Ethical clearance

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

Informed Consent

The patients fulfilling selection criteria were informed in detail about the nature of the study, especially the benefits of using the heavy weight and the light

weight mesh in lichensteins mesh repair and a written informed consent was obtained (Annexure I).

Randomization

The patients were randomized by asking them to pick an opaque brown concealed envelop which furnished the information regarding the choice of mesh for their hernia repair. Based on the option picked up, the patients were divided into two groups of 30 each as below;

- Patients who selected prolene soft mesh [light-weight mesh] in lichensteins repair of inguinal hernia formed group SP [study group].
- Those who selected composite polypropylene mesh [Heavy-weight mesh] were assigned to group RP [control group].

Method of collection of data

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

Investigations

The following tests were subjected to the following investigations.

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

Pain management

Post operatively patients of both the groups were given the same analgesics that is, Injection Diclofenac 50mg IM 1-0-1.

Outcome variables

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

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

Follow up

Patients were followed up at following intervals;

- From post operative 1week [before discharge]
- 2 weeks follow up

- 4 weeks follow up

Statistical analysis

The data obtained was coded and entered in Microsoft Excel Spreadsheet. The categorical data was expressed as rates, ratios and percentages and comparison was done using Fishers exact test and chi-square test. Continuous data was expressed as mean ± standard deviation. A 'p' value of less than or equal to 0.05 was considered as statistically significant.

Chapter 5

Results

RESULTS

The present one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2012 to December 2012.

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

- Patients who underwent lichensteins repair of inguinal hernia with prolene soft mesh [light-weight mesh] formed group SP.

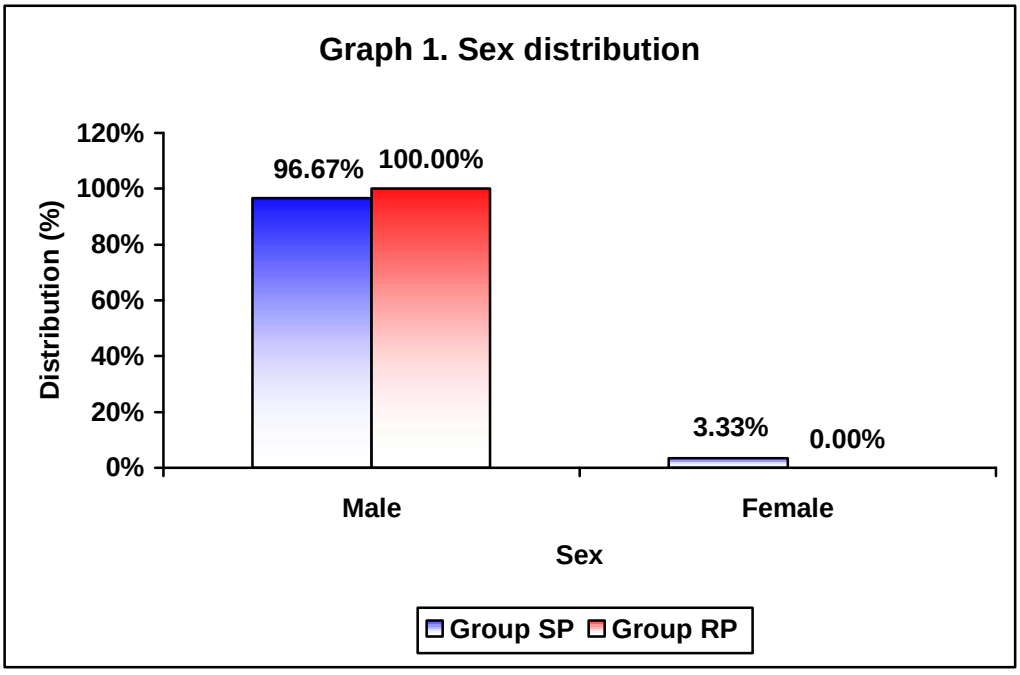
- Patients who underwent lichensteins repair of inguinal hernia with polypropylene mesh [Heavy-weight mesh] formed group RP.

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

Table 1. Sex distribution

Sex	Group SP (n=30)		Group RP (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
Male	29	96.67	30	100.00
Female	1	3.33	0	0.00
Total	**30**	**100.00**	**30**	**100.00**

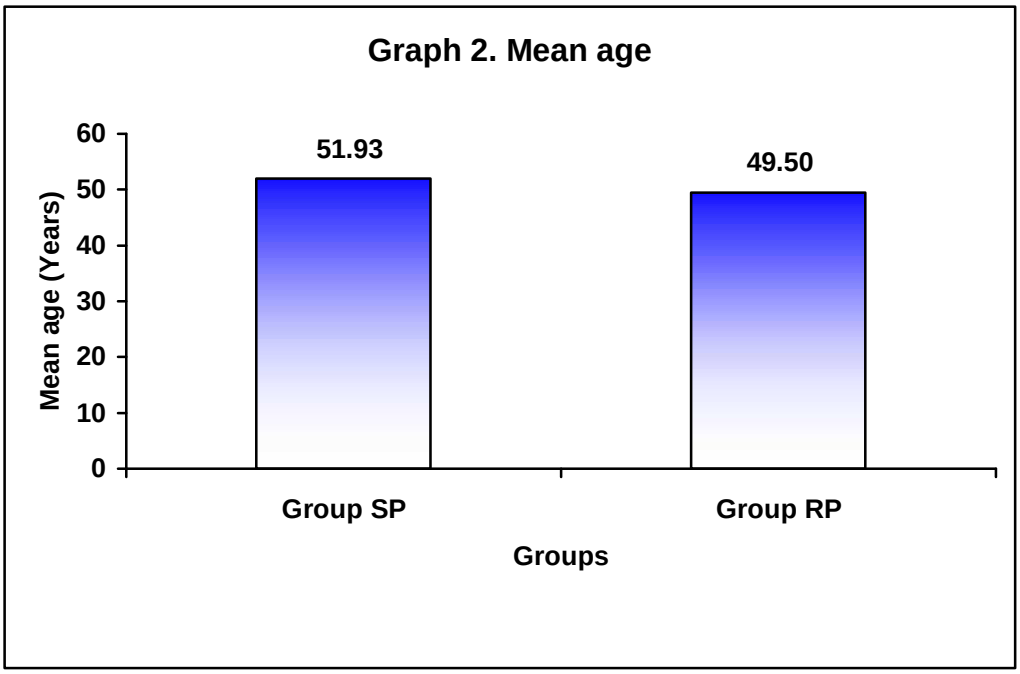
p=1.000



In the present study 96.67% of patients in group SP and all (100%) in group RP were males.

Table 2. Mean age

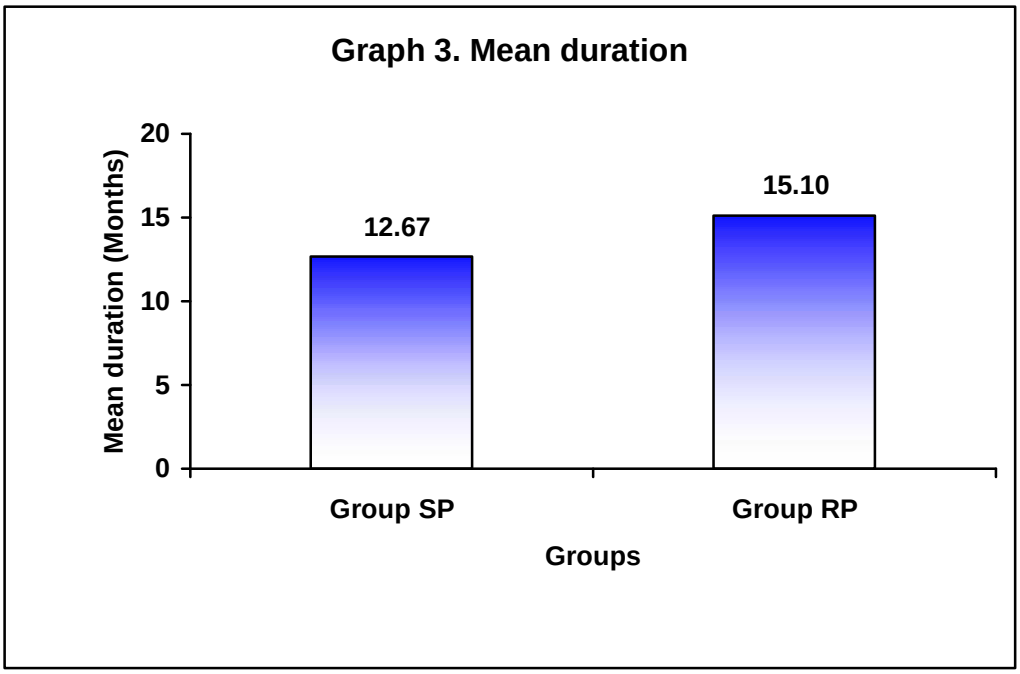
Variables	Group SP (n=30)		Group RP (n=30)		p value
	Mean	SD	Mean	SD	
Age (Years)	51.93	18.73	49.50	14.03	0.571



In the present study, group SP the mean age was 51.93 ± 18.73 years compared to 49.50 ± 14.03 years in group RP. However the difference was statistically not significant (p=0.571).

Table 3. Mean duration

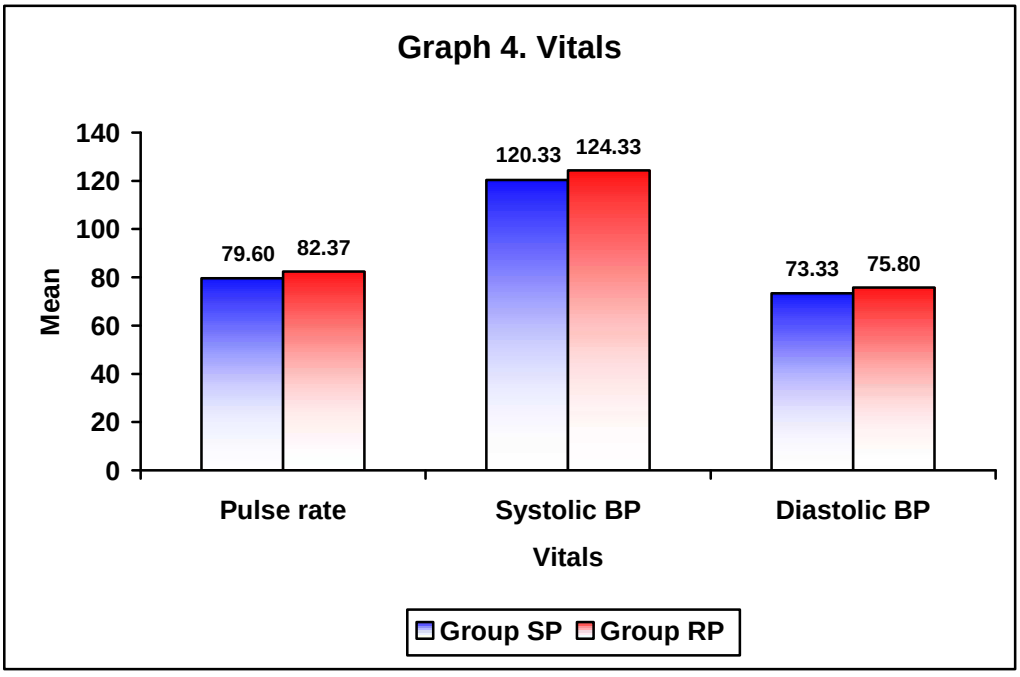
Variables	Group SP (n=30)		Group RP (n=30)		p value
	Mean	SD	Mean	SD	
Duration (Months)	12.67	9.85	15.10	8.98	0.321



In the present study the mean duration of the disease was 12.67 ± 9.85 months in group SP whereas in group RP it was 15.10 ± 8.98 months. However, this difference was statistically not significant (p=0.321).

Table 4. Vitals

Vitals	Group SP (n=30)		Group RP (n=30)		p value
	Mean	SD	Mean	SD	
Pulse rate (/min)	79.60	5.64	82.37	5.46	0.059
Systolic BP (mm Hg)	120.33	9.99	124.33	11.94	0.165
Diastolic BP (mm Hg)	73.73	6.76	75.80	8.59	0.305

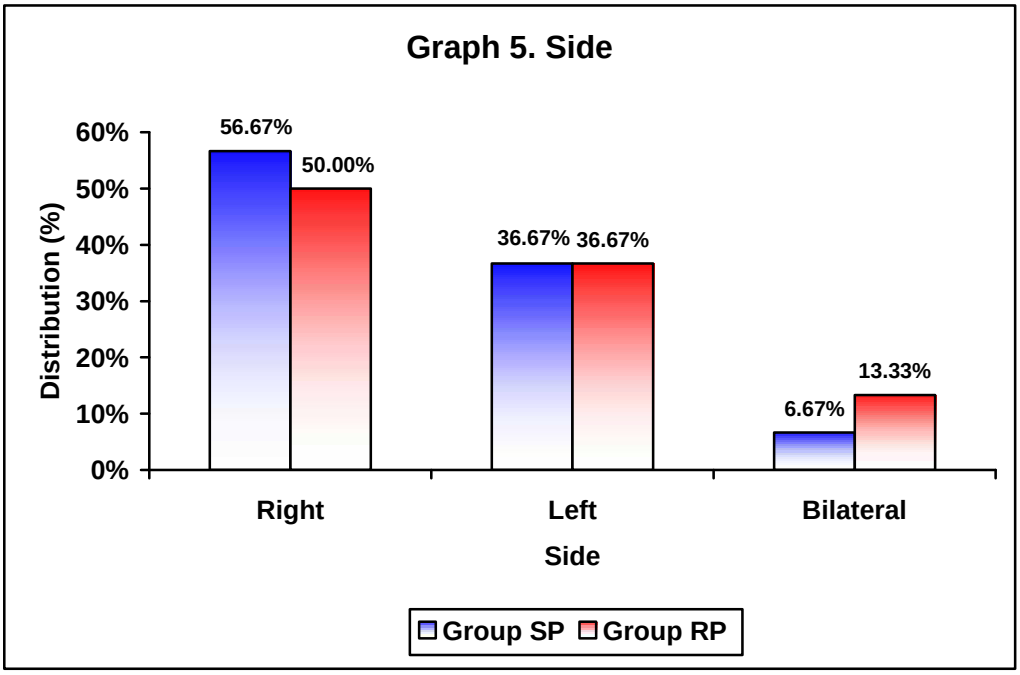


In this study, the mean pulse rate in group SP and RP (79.60 ± 5.64 vs 82.37 ± 5.46 /min; p=0.059), systolic blood pressure (120.33 ± 9.99 vs 124.33 ± 11.94 mm Hg; p=0.165) and diastolic blood pressure (73.73 ± 6.76 vs 75.80 ± 8.59 mm Hg; p=0.305) were comparable.

Table 5. Side

Side	Group SP (n=30)		Group RP (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
Right	17	56.67	15	50.00
Left	11	36.67	11	36.67
Bilateral	2	6.67	4	13.33
Total	**30**	**100.00**	**30**	**100.00**

p=0.673

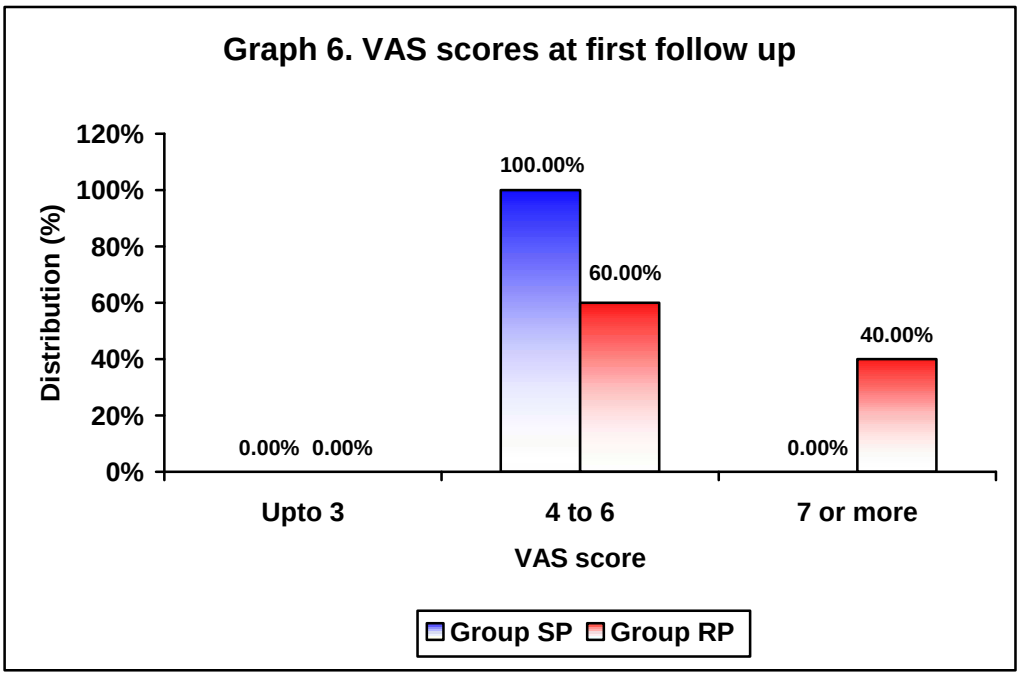


In the present study right position was noted in 56.67% of patients in group SP compared to 50% of patients in group RP. However this difference was statistically not significant (p=0.673).

Table 6. VAS scores at first follow up

VAS score	Group SP (n=30)		Group RP (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
upto 3	0	0.00	0	0.00
4 to 6	30	100.00	18	60.00
7 or more	0	0.00	12	40.00
Total	**30**	**100.00**	**30**	**100.00**

p<0.001

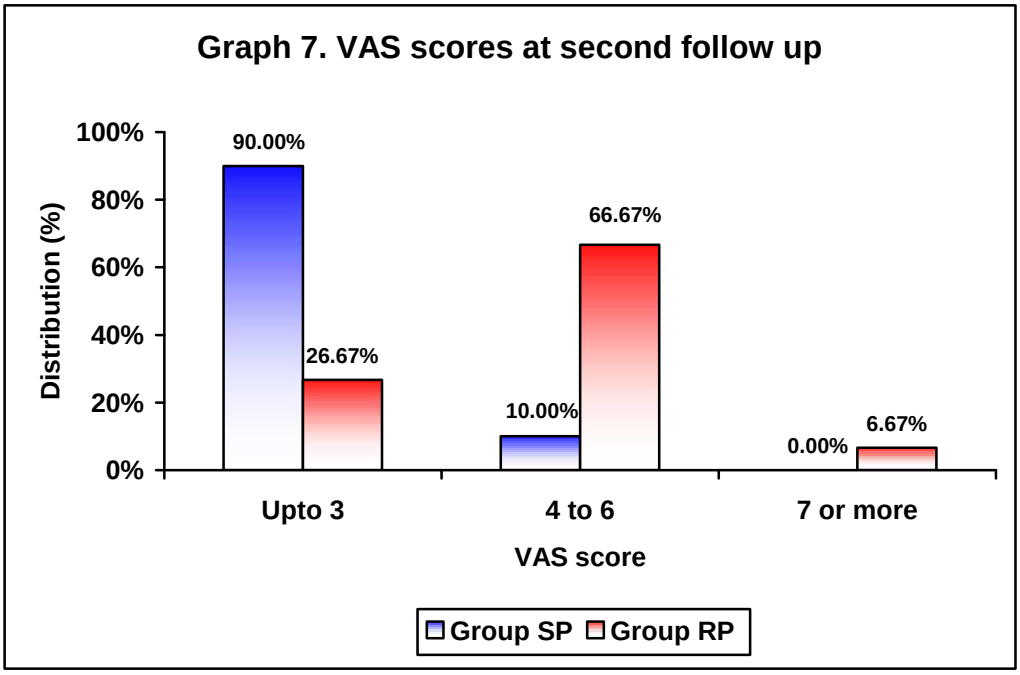


In this study during first follow up, all the patients in group SP reported pain scores between 4 to 6 (moderate pain) compared to 60% patients in group RP and 40% of patients reported pain scores of > 7 (sever pain) in group RP. This difference was statistically significant (p<0.001).

Table 7. VAS scores at second follow up

VAS score	Group SP (n=30)		Group RP (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
upto 3	27	90.00	8	26.67
4 to 6	3	10.00	20	66.67
7 or more	0	0.00	2	6.67
Total	**30**	**100.00**	**30**	**100.00**

p<0.001

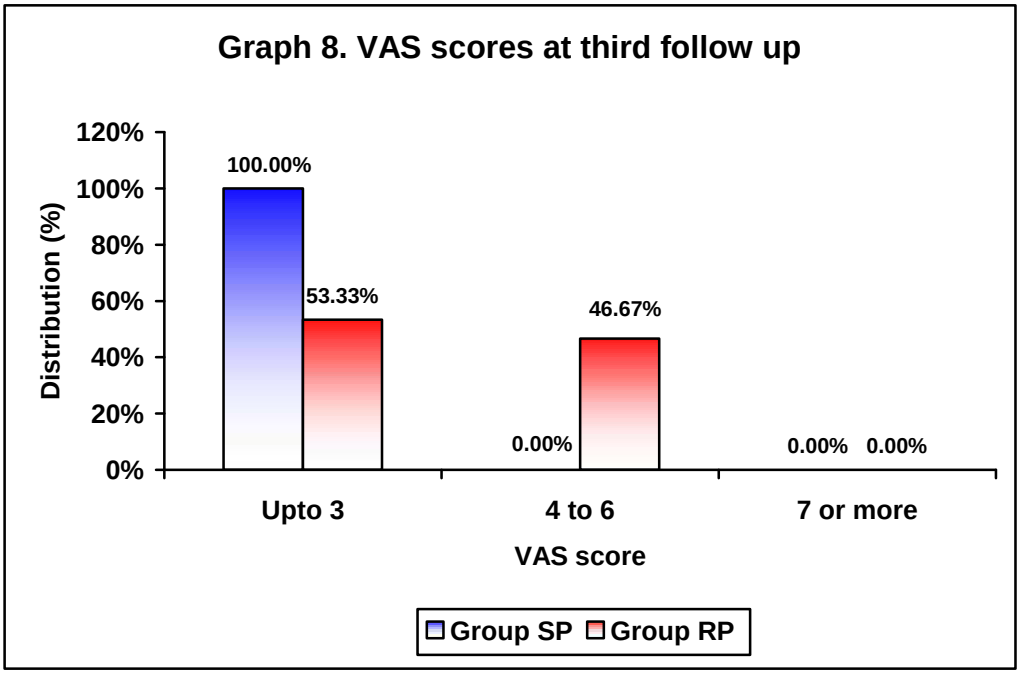


In this study during second follow up, majority of the patients (90%) in group SP reported pain scores ≤ 3 (mild pain) compared to 26.67% patients in group RP. Pain score between 4 to 6 (moderate pain) were seen in 10% of patients in group SP compared to 66.67% of patients in group RP and 6.67% of patients reported pain scores of > 7 (severe pain) in group RP. This difference was statistically significant (p<0.001).

Table 8. VAS scores at third follow up

VAS score	Group SP (n=30)		Group RP (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
upto 3	30	100.00	16	53.33
4 to 6	0	0.00	14	46.67
7 or more	0	0.00	0	0.00
Total	**30**	**100.00**	**30**	**100.00**

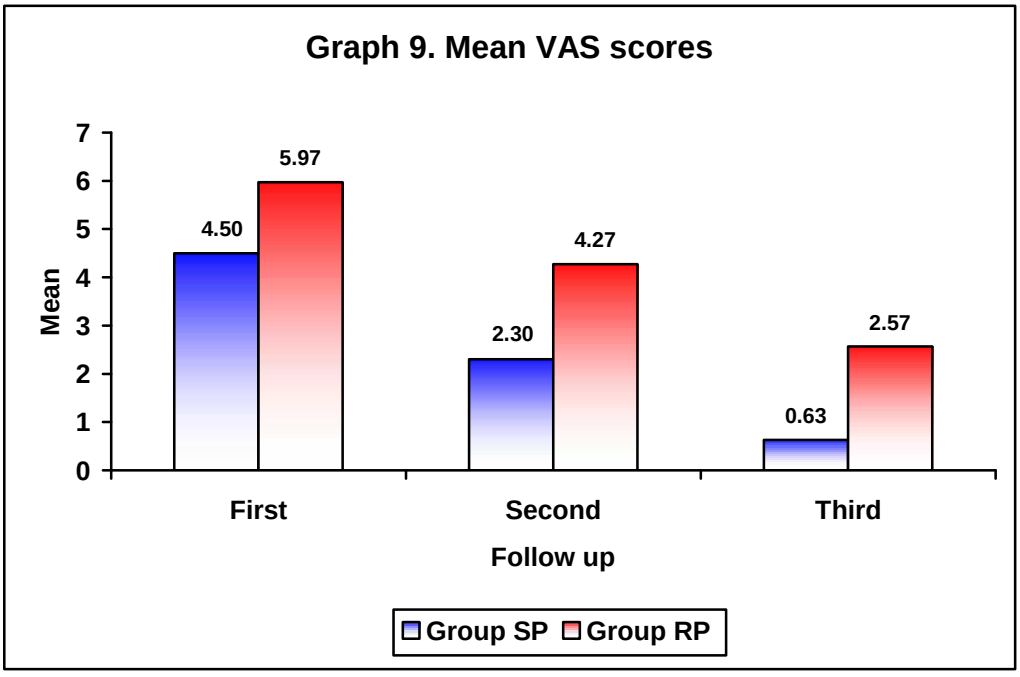
p < 0.001



In the present study during third follow up, all the patients (100%) in group SP reported pain scores ≤ 3 (mild pain) compared to 53.33% patients in group RP. In group SP, 46.67% of patients had pain scores between 4 to 6 (moderate pain). This difference was statistically significant ($p<0.001$).

Table 9. Mean VAS scores

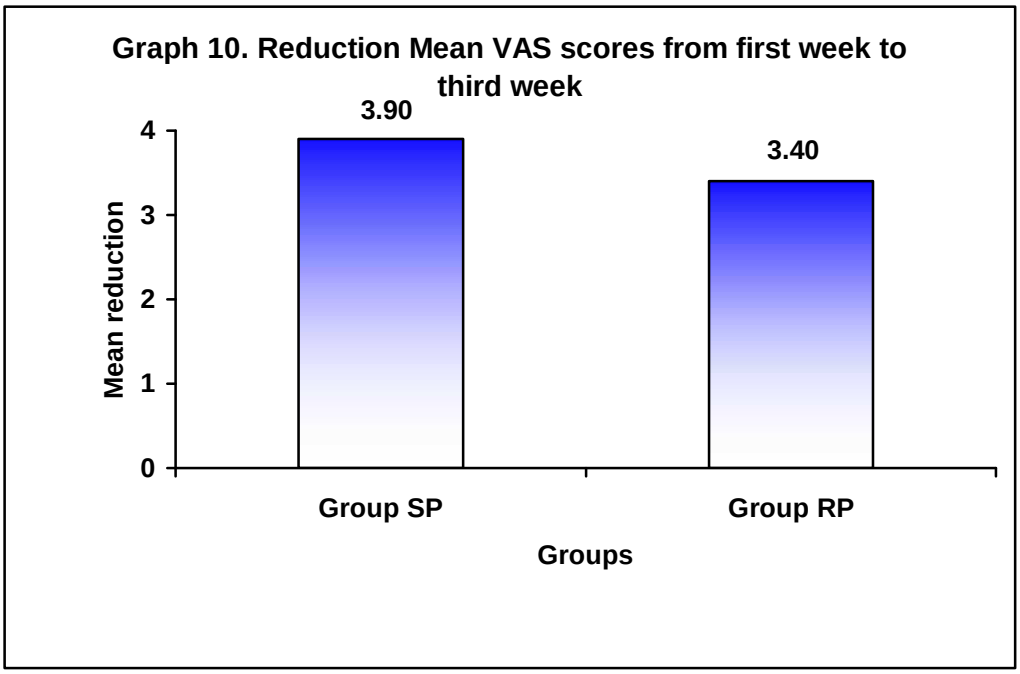
Follow up	Group SP (n=30)		Group RP (n=30)		p value
	Mean	SD	Mean	SD	
First	4.50	0.57	5.97	1.07	<0.001
Second	2.30	0.88	4.27	1.48	<0.001
Third	0.63	0.72	2.57	1.79	<0.001



In the present study the mean pain scores in group SP during first (4.50 ± 0.57 vs 5.97 ± 1.07), second (2.30 ± 0.88 vs 4.27 ± 1.48) and third (0.63 ± 0.72 vs 2.57 ± 1.79) were significantly less compared to group RP ($p<0.001$).

Table 10. Reduction Mean VAS scores from first week to third week

Pain	Group SP (n=30)		Group RP (n=30)		p value
	Mean	SD	Mean	SD	
Mean reduction	3.90	0.97	3.40	1.33	0.092



In this study, the mean reduction in pain score from first follow up to third follow up was comparable in group SP (3.90 ± 0.97) and RP (3.40 ± 1.33) (p=0.092).

Chapter 6

Discussion

DISCUSSION

The evidence-based inguinal hernia guidelines recommends a Lichtenstein hernia repair in case of a primary unilateral inguinal hernia; in this repair the inguinal floor is reinforced by means of a polypropylene mesh.[151] After the introduction of hernia repair with mesh the incidence of a recurrent inguinal hernia decreased from 15-20% to less than 5%.[152] As a result of this decline, currently chronic postoperative pain is the main subject of investigation. Although the incidence of chronic postoperative pain might have been the same over the years, not much attention was being paid to this since prevention of recurrence was main priority.

Currently, pain is considered the most important complication. Three months postoperatively 20% of patients still have pain and 12% experience pain that limits daily activity. One year postoperatively 1-3% still experiences invalidating pain.[152]

Pain is considered chronic when lasting longer than 3 months after operation.[153] Chronic pain is suggested to be of neuropathic, somatic or visceral origin. The commonest types of pain are somatic and neuropathic. The cause of pain is sometimes difficult to determine and therefore difficult to treat. Additionally, the incidence and severity of pain seems to be underestimated.[154]

Studies investigating the influence of light-weight versus heavy-weight meshes on pain show a slight advantage towards light-weight meshes.[155] The present study was aimed to compare the heavyweight composite polypropylene mesh versus the prolene soft mesh [lightweight macro-porous polypropylene

mesh] for the reduction of post-operative pain in patients undergoing lichensteins mesh repair for inguinal hernia.

This one year randomized controlled trial was conducted on a total of 60 patients admitted with inguinal hernia requiring mesh repair under the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2012 to December 2012. These patients were further randomized into two groups of 30 each as group SP (Lichensteins repair with prolene soft mesh [light-weight mesh]) and group RP (Lichensteins repair of inguinal hernia with polypropylene mesh [Heavy-weight mesh] formed group RP).

In the present study male preponderance was seen with 96.67% of patients in group SP and all (100%) patients in group RP were males. The mean age in group SP was 51.93 ± 18.73 years compared to 49.50 ± 14.03 years in group RP (p=0.571). The mean duration of the disease was 12.67 ± 9.85 months in group SP whereas in group RP it was 15.10 ± 8.98 months (p=0.321). The mean pulse rate in group SP and RP (79.60 ± 5.64 vs 82.37 ± 5.46 /min; p=0.059), systolic blood pressure (120.33 ± 9.99 vs 124.33 ± 11.94 mm Hg; p=0.165) and diastolic blood pressure (73.73 ± 6.76 vs 75.80 ± 8.59 mm Hg; p=0.305) were comparable. Right position was noted in 56.67% of patients in group SP compared to 50% of patients in group RP (p=0.673). These findings suggest that, the pre operative characteristics of the study population such as age, duration of disease, vitals and position were comparable in both the groups (p>0.050).

The Lichtenstein open tension-free mesh hernioplasty, performed under local anesthesia, is a simple technique and trained surgical residents are able to perform it without compromising the patient's care and long-term outcome. The procedure is time tested, safe, and economical, as well as being quick and easy to perform. In addition, it carries fewer complications and has become the gold standard in open tension-free hernioplasties.[14]

Indeed, postoperative pain after a Lichtenstein hernioplasty is minimal; according to a meta-analysis of all reported randomized studies, the pain is comparable to that occurring after laparoscopic repair.[14]

In this study during first follow up, all the patients (100%) in group SP reported pain scores between 4 to 6 compared to 60% patients in group RP and 40% of patients reported pain scores of > 7 (sever pain) in group RP. Also, the mean pain scores were significantly less in group SP compared to group RP (4.50 ± 0.57 vs 5.97 ± 1.07; $p<0.001$). These findings suggest that, significantly higher number of patients who underwent lichensteins repair of inguinal hernia under prolene soft mesh [light-weight mesh] had mild and/or moderate pain but in those who had lichensteins repair of inguinal hernia under polypropylene mesh [Heavy-weight mesh] had moderate and/or severe pain ($p<0.001$).

Similarly During second follow up, majority of the patients (90%) in group SP reported mild pain compared to 26.67% patients in group RP. The moderate pain in group RP was present in 66.67% of patients and 6.67% of patients reported severe pain ($p<0.001$). Also, the mean pain scores in group SP during second followed up were suggestive of mild pain (2.30 ± 0.88) compared

to moderate pain in group RP (4.27 ± 1.48) and this difference was statistically significant (p<0.001). These findings showed significantly higher number of patients with mild pain in those who underwent Lichensteins repair of inguinal hernia under prolene soft mesh [light-weight mesh]).

A the third follow up, all the patients (100%) in group SP reported mild pain compared to 53.33% of the patients in group RP. In the remaining, 46.67% of patients had moderate pain in group RP and this difference was statistically significant (p<0.001). Similarly the mean pain scores in group SP were suggestive of minimal pain (0.63 ± 0.72) compared to group RP (2.57 ± 1.79) (p<0.001). These findings suggest that, the patient who underwent Lichensteins repair of inguinal hernia under prolene soft mesh [light-weight mesh]) had very mild pain compared to those who had Lichensteins repair of inguinal hernia under polypropylene mesh [Heavy-weight mesh].

The concept of using a mesh to repair hernias was introduced over 50 years ago. Mesh repair is now standard in most countries and widely accepted as superior to primary suture repair. As a result, there has been a rapid growth in the variety of meshes available and choosing the appropriate one can be difficult.

Meshes are associated with a reduced risk of chronic pain compared to suture repair. This is thought to be related to the ability to use tension-free technique rather than the mesh itself. However, pain remains a serious complication of mesh repair and can occur for a variety of reasons. With regards to acute postoperative pain, there is little difference in the type of mesh used. Chronic pain following hernia repair has gained increased recognition, with a

quoted risk of over 50%. When it starts in the immediate postoperative period, it is usually due to nerve damage at the time of operation. In contrast, pain due to foreign body reaction (FBR) typically presents after 1 year. Explants removed for chronic pain are found to have nerve fibres and fascicles around the foreign body granulomata within the mesh. Neuromas can also be found at the interface of mesh and host tissue suggesting mechanical destruction of nerves by mesh. It follows that meshes with small pores and greater FBR, will cause higher rates of chronic pain. This is supported by most studies, although disputed by some. Some authors have also suggested that absorbable meshes may have a role in reducing chronic pain.[156]

The use of light-weight mesh for Lichtenstein hernia repair did not affect recurrence rates, but it did improve some aspects of pain and discomfort 3 years after surgery.[14] According to data from current randomized, controlled trials and retrospective studies, light meshes seem to have some advantages with respect to postoperative pain and foreign body sensation.[22]

In a study patients were assessed for pain at 1, 3 and 12 months by questionnaire, and were examined clinically at 12 months. 321 patients were included in an intention-to-treat analysis, 162 in the LW group and 159 in the HW group. At 12 months, significantly fewer patients in the LW group than in the HW group had pain of any severity: 39.5 versus 51.6 per cent (difference-12.1 (95 per cent confidence interval-23.1 to-1.0) per cent; P = 0.033). Study concluded that, use of lightweight mesh was associated with less chronic pain.

A randomized trial examined whether lightweight (LW) polypropylene mesh (large pore size, partially absorbable) could have long-term benefits in reducing chronic pain and inflammation after inguinal hernia repair. Six hundred men with a primary unilateral inguinal hernia were randomized to Lichtenstein repair using a standard polypropylene mesh or a LW mesh in one of six centres. Of the 590 men who had surgery, 243 (82.7 percent) of 294 in the standard mesh group and 251 (84.8 percent) of 296 in the LW mesh group were examined in the clinic, a median of 37 (range 30-48) months after hernia repair. Patients who had LW mesh had less pain on examination, less pain on rising from lying to sitting, fewer miscellaneous groin problems and felt the mesh less often than patients with standard mesh. Study concluded that, use of LW mesh for Lichtenstein hernia repair improved some aspects of pain and discomfort 3 years after surgery.[18]

A study evaluated whether patients noticed any difference between lightweight and standard polypropylene mesh for the repair of inguinal hernia. Patients scheduled for elective repair of unilateral or bilateral, primary or recurrent inguinal hernia by the Lichtenstein technique were randomized to receive either a conventional densely woven polypropylene mesh (100-110 g/m(2)) or a lightweight composite multifilament mesh (polypropylene 27-30 g/m(2)). Pain was assessed by means of a visual analogue scale 2 days and 6 months after surgery. Some 122 hernias were randomized; 117 were included in the analysis of perioperative data, and 106 were re-examined after 6 months. Use of lightweight mesh was associated with significantly less pain on exercise after 6

months (P = 0.042). Study concluded that, lightweight polypropylene mesh may be preferable for Lichtenstein repair of inguinal hernia.[157]

A systematic review and a meta-analysis of RCTs were carried out to determine whether the use of lightweight meshes influenced the pain. To assess the value of the lightweight mesh, an extensive literature search was performed. The random-effect meta-analysis model was used to correct for clinical diversity and methodological variations between studies. Eight prospective RCTs of good quality were identified. No significant difference was observed concerning severe pain (OR, 0.99; 95 % CI, 0.48-2.02; p = 0.97). Description of any pain resulted in a significant improvement in the lightweight group (OR, 0.65; 95 % CI, 0.50-0.84; p = 0.001). Study concluded that, use of lightweight mesh did not neither increase the recurrence rate nor reduce the incidence of severe pain. However study recommended that, lightweight meshes could be considered as a material of choice in primary inguinal hernioplasty.[158]

A study was conducted to use meta-analysis to compare lightweight and heavyweight mesh for Lichtenstein inguinal hernia repair. Information was gathered from randomized controlled trials that compared lightweight and heavyweight mesh for Lichtenstein inguinal hernia repair. The Cochrane Library, Medline, EMBASE, trial registries, conference proceedings and reference lists were searched. Primary outcome measures were chronic pain. Secondary outcome measures were mean visual analogue scale (VAS) pain scores. Six trials with 1936 hernias were included. Lightweight mesh was associated with reduced chronic pain (OR = 0.67, 95% CI = 0.50-0.90; p < 0.01). Lightweight mesh was also associated with lower VAS pain scores at 3 months after surgery (WMD = -

0.35, 95% CI = -0.39 to -0.31; $p < 0.0001$). Study concluded that, use of lightweight mesh in Lichtenstein inguinal hernia repair is associated with less chronic pain, and foreign body sensation compared with heavyweight mesh.[159]

Another study aimed to compare the outcomes of lightweight mesh and heavyweight mesh in inguinal hernia repair undertook a comprehensive literature search to identify studies comparing the influence of lightweight and heavyweight meshes on inguinal hernia. This meta-analysis pooled the effects of outcomes of a total 5,389 patients enrolled into 16 randomized controlled trials and 5 comparative studies. Lightweight mesh repair was associated with a significant less incidence of chronic postoperative pain [OR = 0.72, 95 % CI (0.57, 0.91)]. The study concluded that, lightweight mesh repair do have advantages in terms of chronic postoperative pain and recommended further well-structured trials with improved standardization of hernia types, operative techniques are necessary.[160]

The results of the present study were in agreement with the other studies which showed the role of lightweight mesh in reducing immediate and long term post operative pain. However, interestingly the mean reduction in pain score from first follow up to third follow up was comparable in group SP (3.90 ± 0.97) and RP (3.40 ± 1.33) ($p=0.092$) which again prompts the validation of lightweight mesh in the assessment of immediate pain following the Lichtenstein inguinal hernia repair. However, this disparity between the significantly lower pain scores and lack of significance in mean reduction in pain scores could be attributed to the smaller sample size.

Chapter 7

Conclusion

CONCLUSION

Based on the findings of the present study it may be concluded that, the the prolene soft mesh (lightweight macro-porous polypropylene mesh) significantly reduced the post-operative pain in patients undergoing lichensteins mesh repair for inguinal hernia as compared to heavyweight composite polypropylene mesh.

Chapter 8

Summary

SUMMARY

Lichtenstein hernia repair is commonly recommended in the management of inguinal hernia and currently, pain is considered the most important complication. The present study was aimed to compare the heavyweight composite polypropylene mesh versus the prolene soft mesh [lightweight macro-porous polypropylene mesh] for the reduction of post-operative pain.

The present 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 2012 to December 2012. A total of 60 requiring mesh repair were randomized into two groups of 30 each based on the mesh type as group SP (Prolene soft mesh [light-weight mesh]) and group RP (Polypropylene mesh [Heavy-weight mesh]).

In the present study 96.67% of patients in group SP and all (100%) in group RP were males. The mean age (51.93±18.73 vs 49.50±14.03 years; p=0.571) and duration of disease (12.67±9.85 vs 15.10 ± 8.98 months; p=0.321) in group SP and RP was comparable. During first follow up, all the patients in group SP reported moderate pain compared to 60% patients in group RP (p<0.001). During second follow up, majority of the patients (90%) in group SP reported mild pain compared to 26.67% patients in group RP (p<0.001). At the third follow up, all the patients (100%) in group SP reported mild pain compared to 53.33% patients in group RP (p<0.001). The mean pain scores in group SP during first (4.50±0.57 vs 5.97±1.07), second (2.30±0.88 vs 4.27±1.48) and third (0.63±0.72 vs 2.57±1.79) were significantly less compared to group RP

($p<0.001$) but mean reduction in pain score from first follow up to third follow up was comparable in group SP (3.90±0.97) and RP (3.40±1.33) ($p=0.092$).

Overall, the present study showed that, the pain scores were significantly less in prolene soft mesh (lightweight macro-porous polypropylene mesh) group as compared to heavyweight composite polypropylene mesh group. Thus the use of prolene soft mesh is associated with a less foreign body reaction, reducing the scarplate formation and reducing the entrapment of nerves resulting in lowering the possibility of inguinodynia in post-operative patients of Lichensteins hernioplasty.

Chapter 9

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Annexures

Annexure I

ANNEXURE I – CONSENT FORM

Mr./Mrs._____we are requesting you to enroll yourself in study titled**" Comparison between the composite heavy weight prolene mesh versus the prolene soft mesh for the reduction in post-operative pain in patients undergoing lichensteins mesh repair for inguinal hernia's. A one year randomized control trial at KLES Dr Prabhakar Kore Hospital Belgaum"**.

Conducted by **** ******, postgraduate student in MS GENERAL SURGERY under the guidance of **Dr. *** ******, MS** at J.N Medical College, Belgaum.

Objective / purpose of the study:

You have been requested to participate in research because we find your profile matching with our study group. During the study you will be asked some questions and you are supposed to answer to the best of your knowledge.

Your participation in the research is absolutely voluntary. Your decision to participate in the study or otherwise will not affect your

relationship with J.N.M.C. if you decide to participate, you are free to withdraw at any time.

The purpose of this trial is to study the post-operative pain outcome after undergoing lichensteins mesh repair using heavy weight[composite polypropylene mesh] or prolene soft mesh [light weight polypropylene mesh].

Procedure:

Depending on the group heavy weight or light weight polypropylene mesh will be used in lichensteins mesh repair.

Risk and benefits:

There is no risk involved in becoming a part of this study and the complications are those which are normally anticipated. This study will help us to estimate the efficacy of the prolene soft mesh [light weight polypropylene mesh] in comparison with heavy weight mesh in post- operative pain outcome after lichensteins mesh repair. The result at the end of the study will benefit all similar patients admitted in this hospital.

Withdrawing / removal from the study:

The participant has full freedom to withdraw from the study whenever he/ she wishes and without prior notice. Even if you decline to participate, there will not be any change in the line of your management or relationship with your doctor. You will be told about all the new information that may affect your decision to participate in the study. The investigator may also exclude a participant from study at anytime.

Privacy and confidentiality:

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

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

Institutional / sponsors policy:

If any unforeseen complications or injury occurs during the period of study the participant will be given treatment within the limitations of KLE's Prabhakar Kore Hospital General ward.

Financial incentives for participation:

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

Authorization to publish results:

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

Contact details:

The participant can contact the following people at any time during the study period for clarification of doubts or any questions.

Dr. **** *******
Post-Graduate in General surgery
J.N Medical college.
Belgaum.
Ph.**** ******

Dr. ***** *******
Professor
Department of General surgery
J.N Medical college,
Belgaum.
Ph. ***** *******

Dr. **** *******
Principal
J.N Medical college,
Belgaum.
Ph. ****** ******

Consent statement:

I, the undersigned, have been explained in my own vernacular language about the study. I am aware that my participation in this study is voluntary and I could withdraw at any time. Also I had been given enough time to comprehend and clarify my doubts about the study and my rights as a study participant.

Signature or left thumb impression of participant or legally authorized representative.

Participant's name:_____

Signature:_____

Witness's name:_____

Signature:_____

Investigator's name:_____

Signature:_____

Place:_____

Date:_____

Annexures

Annexure II

ANNEXURE II – PROFORMA

PROFORMA

Name : Age :

Address : IP no.:

Sex : Religion:

Education : Date of admission:

Occupation: Date of discharge:

HISTORY

When did the patient notice the lump:

Initial size of the lump :

Present size of the lump :

Associated features :Abdominal pain [colicky/dragging sensation]

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

Other complaints :

Past History:

Family History:

GENERAL PHYSICAL EXAMINATION:

Built and Nourishment:

Weight :

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

Vital Signs :

PR: RR:

BP: Temperature:

SYSTEMIC EXAMINATION:

Per Abdomen:

Respiratory System:

Central Nervous System:

Cardio-Vascular System:

LOCAL EXAMINATION: patient examined in standing and supine postion.

INSPECTION:

Size: Visible peristalisis:

Shape: Cough impulse:

Position: Position of the penis:

PALPATION:

Local rise of temperature: Cough impulse:

Tenderness: Reducibility of the swelling:

Consistency:

DIAGNOSIS:

INVESTIGATION:

PROCEDURE DONE:

EVALUATION OF PAIN:

After I week [before discharge]

AFTER 2 WEEKS:[During follow up in OPD]

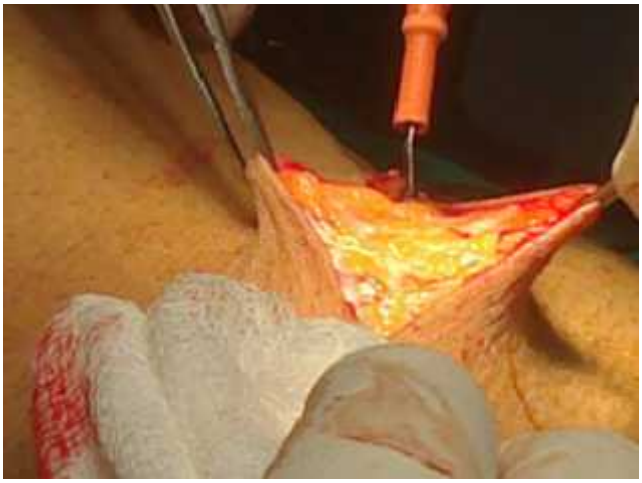
AFTER 4 WEEKS:

Annexures

Annexure III

ANNEXURE III – PHOTOGRAPHS

Photograph 1. Incision through skin and subcutaneous tissue



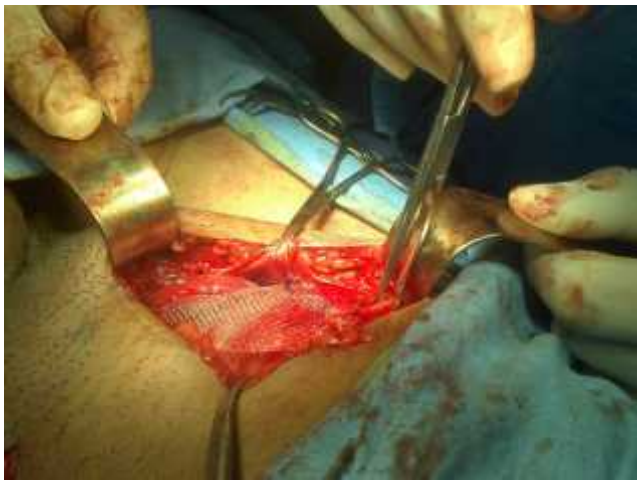
Photograph 2. Dissection carried through camphor and scarpa's fascia

Photograph 3. Identification of external oblique aponeurosis

Photograph 4. Identifying cord after opening up of external oblique aponeurosis cord is held with cord holding forceps.

Photograph 5. Opening of cremasteric box to identify the indirect sac.

Photograph 6. Reflected part of inguinal ligament, to which prolene mesh is fixed by a continuous running suture by a prolene suture-(lichenstein's mesh repair)

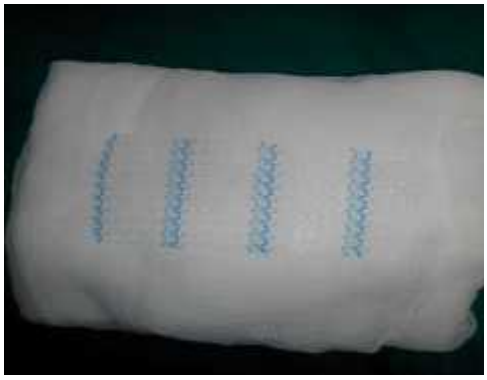


Photograph 7. Heavy weight polypropylene mesh placed and fixed

Photograph 8. Light weight polypropylene mesh placed and fixed

Photograph 9. Closure of the abdominal defect in layers, the post surgical scar

Photograph 10. The heavy weight composite polypropylene mesh. Microporous knitted polypropylene mesh with pore size of 75 micrometer and prolene content of 95-100ng/m^2



Photograph 11 A and B. The light weight prolene soft mesh. Macroporous with pore size of 1300-1500 micrometer and prolene content of less than 45ng/m^2. Blue prolene monofilaments have been incorporated into the mesh to produce contrast striping.

ANNEXURE IV - MASTER CHART - GROUP SP

Serial Number	In patient Number	Sex	Age (Years)	History				General physical examination			Systemic examination											Diagnosis	Assessment of pain (VAS score)		
				Lump				Pulse rate (bpm)	BP (mm Hg)		Respiratory	Cardiovascular	CNS	Per abdomen												
				Swelling duration (Wks)	Size		Reducibility		Systolic	Diastolic				Inspection				Palpation					One week	Two weeks	Four weeks
					Initial	Present								Size (Cms)	Visible peristalisis	Cough impulse	Position	Rise of temperature	Cough impulse	Reducibility	Tenderness				
1	466495	M	37	6m	2*2	3*4	+	82	130	70	N	N	N	3*6	+	+	R	-	+	+	-	RIIH	5	2	0
2	453917	M	60	2y	1*2	4*5	+	86	130	90	N	N	N	4*5	-	+	L	-	+	+	-	LDIH	4	2	0
3	467534	M	33	2m	2*2	3*2	+	70	120	70	N	N	N	3*3	-	+	L	-	+	+	-	LIIH	4	4	1
4	435378	M	60	1y	2*3	3*5	+	80	130	70	N	N	N	3*5	-	+	L	-	+	+	-	LDIH	5	2	1
5	457383	M	70	1y	2*2	4*5	+	86	130	90	N	N	N	4*5	-	+	R	-	+	+	-	RDIH	4	3	3
6	445062	M	25	3m	2*2	3*3	+	80	130	70	N	N	N	3*3	-	+	R	-	+	+	-	RIIH	4	2	0
7	457689	M	70	6m	3*2	5*4	+	82	130	90	N	N	N	5*4	-	+	L	-	+	+	-	LDIH	5	2	0
8	465078	M	56	1m	1*1	4*2	+	86	130	70	N	N	N	4*2	-	+	L	-	+	+	-	LIIH	6	3	0
9	482836	M	56	1y	2*1	2*3	+	80	110	70	N	N	N	2*3	-	+	L	-	+	+	-	LDIH	4	1	0
10	473998	M	50	2y	2*3	4*5	+	88	130	70	N	N	N	4*5	-	+	R	-	+	+	-	RIIH	4	1	1
11	485360	M	47	4m	2*3	4*4	+	80	130	70	N	N	N	4*3	-	+	R	-	+	+	-	RDIH	4	2	1
12	486792	M	55	6m	2*2	4*2	+	86	130	70	N	N	N	4*2	-	+	R	-	+	+	-	RDIH	5	4	1
13	453589	M	22	4m	2*3	2*3	+	70	120	82	N	N	N	2*3	-	+	R	-	+	+	-	RIIH	4	3	2
14	480438	M	80	3y	2*2	4*4	+	80	130	70	N	N	N	4*4	-	+	R	-	+	+	-	RDIH	5	2	1
15	482133	M	19	4m	2*2	2*3	+	80	130	70	N	N	N	2*3	-	+	L	-	+	+	-	LIIH	4	1	1
16	487808	F	16	2m	1*1	2*2	+	80	110	70	N	N	N	2*2	-	+	R	-	+	+	-	RIIH	4	2	0

ANNEXURE IV - MASTER CHART - GROUP SP

Serial Number	In patient Number	Sex	Age (Years)	History				General physical examination			Systemic examination											Diagnosis	Assessment of pain (VAS score)		
				Lump				Pulse rate (bpm)	BP (mm Hg)		Respiratory	Cardiovascular	CNS	Per abdomen												
					Size									Inspection				Palpation							
				Swelling duration (Wks)	Initial	Present	Reducibility		Systolic	Diastolic				Size (Cms)	Visible peristalisis	Cough impulse	Position	Rise of temperature	Cough impulse	Reducibility	Tenderness		One week	Two weeks	Four weeks
17	490628	M	80	1y	2*1	3*3	+	80	110	70	N	N	N	3*3	-	+	L	-	+	+	-	LDIH	4	3	1
18	490326	M	70	2y	3*2	3*5	+	78	120	70	N	N	N	3*5	-	+	BL	-	+	+	-	BLIH	5	3	1
19	492315	M	72	1y	3*3	3*3	+	70	120	70	N	N	N	3*3	-	+	L	-	+	+	-	LDIH	4	2	0
20	493108	M	36	2y	1*2	2*2	+	76	110	80	N	N	N	2*2	-	+	L	-	+	+	-	LIIH	5	2	0
21	496214	M	64	1y	2*2	3*2	+	88	110	70	N	N	N	3*3	-	+	R	-	+	+	-	RIIH	4	3	1
22	498456	M	64	2y	1*6	2*5	+	80	130	70	N	N	N	2*5	-	+	BL	-	+	+	-	BLIH	5	4	1
23	504034	M	28	1y	1*2	2*4	+	80	110	70	N	N	N	2*4	-	+	L	-	+	+	-	LIIH	5	3	0
24	504021	M	65	6m	2*3	3*3	+	72	110	70	N	N	N	3*3	-	+	R	-	+	+	-	RDIH	5	2	1
25	503349	M	52	2y	3*2	3*2	+	80	130	80	N	N	N	3*2	-	+	R	-	+	+	-	RDIH	5	1	0
26	509437	M	27	6m	2*1	2*2	+	80	110	80	N	N	N	2*2	-	+	R	-	+	+	-	RIIH	4	2	0
27	509881	M	50	6m	2*2	2*3	+	80	110	70	N	N	N	2*3	-	+	R	-	+	+	-	RDIH	5	3	1
28	511568	M	65	3y	3*2	3*4	+	70	110	80	N	N	N	3*4	-	+	R	-	+	+	-	RIIH	5	2	1
29	510327	M	60	1y	2*3	3*2	+	70	100	70	N	N	N	3*2	-	+	R	-	+	+	-	RDIH	4	2	0
30	516490	M	69	1y	3*3	3*3	+	88	110	70	N	N	N	3*3	-	+	R	-	+	+	-	RDIH	4	1	0

ANNEXURE IV - MASTER CHART - GROUP RP

Serial Number	In patient Number	Sex	Age (Years)	History				General physical examination			Systemic examination										Diagnosis	Assessment of pain (VAS score)		
				Lump					BP (mm Hg)					Per abdomen										
				Swelling duratiion (Wks)	Size		Reducibility	Pulse rate (bpm)	Systolic	Diastolic	Respiratory	Cardiovascular	CNS	Inspection				Palpation					One week	Two weeks	Four weeks
					Initial	Present								Size (Cms)	Visible peristalisis	Cough impulse	Position	Rise of temperature	Cough impulse	Reducibility	Tenderness				
1	496707	M	57	6m	3*3	3*3	+	82	130	90	N	N	N	3*3	-	+	R	-	+	+	-	RDIH	4	2	1
2	506626	M	32	6m	2*2	2*4	+	80	130	90	N	N	N	2*4	-	+	BL	-	+	+	-	BLDH	4	2	1
3	506237	M	38	2y	3*2	3*3	+	80	130	70	N	N	N	3*3	-	+	R	-	+	+	-	RDIH	4	2	0
4	461119	M	24	2m	2*2	2*3	+	80	110	72	N	N	N	2*3	-	+	L	-	+	+	-	LIIH	4	4	2
5	492203	M	49	3y	3*2	3*3	+	72	130	80	N	N	N	3*3	-	+	R	-	+	+	-	RIIH	5	3	1
6	492212	M	50	1y	2*3	3*3	+	80	110	70	N	N	N	3*3	-	+	R	-	+	+	-	RIIH	5	2	0
7	495962	M	65	1y	2*2	1*5	+	70	110	70	N	N	N	1*5	-	+	L	-	+	+	-	LDIH	5	2	0
8	493673	M	60	6m	3*3	3*3	+	80	130	70	N	N	N	3*3	-	+	R	-	+	+	-	RDIH	5	3	0
9	505007	M	62	1y	2*3	3*2	+	80	140	70	N	N	N	3*2	-	+	R	-	+	+	-	RDIH	5	2	0
10	461606	M	28	2y	2*2	4*5	+	88	130	80	N	N	N	4*5	-	+	R	-	+	+	-	RIIH	6	4	0
11	463459	M	40	2y	2*4	5*6	+	80	140	90	N	N	N	5*6	-	+	L	-	+	+	-	LIIH	6	5	1
12	480430	M	40	2y	2*2	2*3	+	86	110	70	N	N	N	2*3	-	+	L	-	+	+	-	LIIH	6	5	4
13	478645	M	38	2m	2*2	2*2	+	80	130	70	N	N	N	2*2	-	+	L	-	+	+	-	LIIH	6	5	2
14	474685	M	56	2y	2*1	4*2	+	88	130	90	N	N	N	4*2	-	+	R	-	+	+	-	RDIH	6	4	4
15	474282	M	60	1y	2*2	4*2	+	80	130	70	N	N	N	4*2	-	+	L	-	+	+	-	LDIH	6	5	4
16	484551	M	45	2y	2*2	4*2	+	78	110	70	N	N	N	4*2	-	+	R	-	+	+	-	RIIH	6	5	4

ANNEXURE IV - MASTER CHART - GROUP RP

Serial Number	In patient Number	Sex	Age (Years)	History				General physical examination			Systemic examination										Diagnosis	Assessment of pain (VAS score)		
				Lump					BP (mm Hg)					Per abdomen										
				Swelling duratiion (Wks)	Size		Reducibility	Pulse rate (bpm)	Systolic	Diastolic	Respiratory	Cardiovascular	CNS	Inspection				Palpation					One week	Two weeks	Four weeks
					Initial	Present								Size (Cms)	Visible peristalisis	Cough impulse	Position	Rise of temperature	Cough impulse	Reducibility	Tenderness				
17	471296	M	56	2y	2*2	4*2	+	86	130	70	N	N	N	4*2	-	+	R	-	+	+	-	RDIH	6	5	5
18	435653	M	70	5m	2*2	4*6	+	88	130	82	N	N	N	4*6	-	+	L	-	+	+	-	LDIH	6	4	4
19	460172	M	70	1y	2*2	4*5	+	88	140	90	N	N	N	4*5	-	+	R	-	+	+	-	RDIH	7	5	4
20	468582	M	64	6m	2*2	4*6	+	80	120	70	N	N	N	4*6	-	+	L	-	+	+	-	LDIH	7	4	1
21	481448	M	25	1y	2*2	4*2	+	86	110	70	N	N	N	4*2	-	+	L	-	+	+	-	LIIH	7	4	4
22	473625	M	60	2y	2*2	4*4	+	80	130	70	N	N	N	4*4	-	+	R	-	+	+	-	RDIH	7	4	3
23	476812	M	50	6m	2*2	4*2	+	83	130	70	N	N	N	4*2	-	+	BL	-	+	+	-	BIIH	7	7	5
24	486179	M	50	2y	2*3	4*5	+	88	100	70	N	N	N	4*5	-	+	L	-	+	+	-	LDIH	7	6	4
25	460172	M	70	1y	2*2	4*5	+	98	140	90	N	N	N	4*5	-	+	R	-	+	+	-	LDIH	7	5	4
26	513544	M	63	2y	2*3	3*6	+	80	130	90	N	N	N	3*6	-	+	BL	-	+	+	-	BDIH	7	6	5
27	513432	M	32	6m	2*2	3*4	+	80	110	70	N	N	N	3*4	-	+	R	-	+	+	-	RIIH	7	5	3
28	513870	M	31	1y	2*2	2*2	+	80	110	70	N	N	N	2*2	-	+	R	-	+	+	-	RIIH	7	6	4
29	519677	M	55	2y	2*1	3*2	+	90	110	70	N	N	N	3*2	-	+	BL	-	+	+	-	BDIH	7	7	4
30	519695	M	45	1y	2*2	2*4	+	80	140	70	N	N	N	2*4	-	+	L	-	+	+	-	LDIH	7	5	3

Annexures

Annexure IV

ANNEXURE IV – MASTER CHART

-	-	Absent
+	-	Present
BIIH	-	Bilateral Indirect Inguinal Hernia
BL	-	Bilateral
BLDH	-	Bilateral direct hernia
BLIH	-	Bilateral inguinal hernia
BP	-	Blood pressure
Cms	-	Centimeters
CNS	-	Central nervous system
F	-	Female
L	-	Left
LDIH	-	Left Direct Inguinal Hernia
LIIH	-	Left Indirect Inguinal Hernia
M	-	Male
m	-	Month
mm Hg	-	Millimeters of mercury
N	-	Normal
R	-	Right
RDIH	-	Right Direct Inguinal Hernia
RIIH	-	Right Indirect Inguinal Hernia
VAS	-	Visual analog scale
Wks	-	Weeks
y	-	Year
Y	-	Yes