"A COMPARISON OF POLYPROPYLENE (prolene) VERSUS POLYGLACTIN SUTURES (vicryl) FOR MESH FIXATION IN ASSESSING POSTOPERATIVE CHRONIC PAIN USING VISUAL ANOLOGUE SCALE IN INGUINAL HERNIA REPAIR- A ONE YEAR RANDOMISED CONTROL TRIAL AT KLES DR PRABHAKAR KORE HOSPITAL AND MRC, BELAGAVI"

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This is to certify that the dissertation entitled **"A COMPARISON OF PROLENE VERSUS POLYGLACTIN SUTURES (vicryl) FOR MESH FIXATION IN ASSESSING POSTOPERATIVE CHRONIC PAIN USING VISUAL ANOLOGUE SCALE IN INGUINAL HERNIA REPAIR A ONE YEAR SINGLE BLINDED RANDOMIZED CONTROL TRIAL AT KLES DR PRABHAKAR KORE HOSPITAL AND MRC, BELAGAVI** is a bonafide research work done by **REG. NO. BH0118011**

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LIST OF ABBEVIATIONS USED

BUN	–	blood urea nitrogen
Cms	–	centimetres
COPD	–	chronic obstructive pulmonary disorder
ECG	–	electrocardiogram
Hb	–	hemoglobin
HIV	–	human immune virus
INR	–	international normalized ratio
n	–	number
SNOSE	–	Sequentially Numbered Opaque Sealed velopes
RBC	–	red blood cells
RBS	–	random blood sugar
RCT	–	randomized controlled trial
VAS	–	visual analogue scale
v/s	–	versus

ABSTRACT

Background and Objectives

Chronic pain in the groin is a critical issue in the wake of an open hernia repair with mesh, notwithstanding the pain is seldom pesky, various studies have verified that regardless of intensity chronic pain adversely affect daily activities. Lichtenstein hernia repair has become a benchmark modality for management of inguinal hernia. Galore of evidence point towards chronic pain attributing to the persistent pubic tubercle periosteal mangle. Routine usage of absorbable sutures such as polyglactin which gets absorbed and thus preventing persistent periosteal insult, fibrosis and inflammation and hence chronic pain. On the same account, this study was ventured upon to appraise post operative groin pain in the patients with vicryl sutures (group A) v/s using prolenesutures (group B) in Lichtenstein's repair for inguinal hernia.

Methodology

The present one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2019 to December 2019. A total of 60 patients undergoing Lichtenstein hernia repair were randomized into two groups of 30 each as group A (mesh fixed with polyglactin) and group B (mesh fixed with polypropylene).

Results

In this current study both males and females participated although majority was men. The mean age (53.87 ± 20.17 v/s 48.97 ± 19.27; p =0.7310) and duration of the symptoms (26.87 ± 66.25 v/s 15.73 ± 31.29; p=0.9332) in group A and group B was comparable. Upon comparing the VAS on all the four follow ups, there were

significant lower pain scores in group A as compared to the group B in the last two follow-ups, although the first two follow-ups didn't show any significant difference in terms of pain scores. The results showed the incidence of postoperative groin pain with mean severity scores of1.37 ± 0.49 v/s 1.43 ± 0.50; 1.40 ± 0.50 v/s 1.57 ± 0.73; 1.03 ± 0.61 v/s 1.50 ± 0.057; 0.77 ± 0.63 v/s 1.30 ± 0.79; at post operative day 1, 3 in both groups were similar and statistically not significant where as the 1 week and 3 months follow up in group A and B respectively, were significant ($p<0.05$). The results showed the incidence of decrease in postoperative groin pain with mean severity score of 0.33 ± 0.55 v/s -0.07 ± 0.74 (day 1 to 1 week; $p = 0.0287$); 0.60 ± 0.56 v/s 0.13 ± 0.78 (day 1 to 3 months; $p = 0.0276$ in group A and B respectively were significant, showing the use of polyglactin sutures to fix the mesh reduces post operative chronic pain remarkably as compared to using polypropylene sutures to fix the mesh in lichtenstien's repair. Our study also showed the occurrence of some of the common post-operative complications such as hematoma or seroma was also marginally higher in case of group B (3.33% v/s 6.67% ; 3.33% v/s 10.00%) respectively.

Conclusion and Interpretation:

Based on the findings of the present study we can conclude that, the routine usage of polyglactin sutures to fix a mesh is a safe and effective alternative to polyglactin sutures to fix a mesh in Lichtenstein hernia repair. However the duration of follow up and sample size in this study is relatively short, a substantial study sample and extensive follow-up can be required before we can make any further conclusions.Although the study sample and follow period is short in this present study than the previous studies, it is still wise to recommend usage of polyglactin (vicryl)

suture material in fixing the mesh for patients undergoing anterior inguinal hernia mesh repair. So when performing Lichtenstein inguinal hernia repair, routine fixation of the mesh with vicryl sutures is a plausible option.

Keywords:

Polyglactin (vicryl) sutures; polypropylene (p sutures; inguinal hernia; Lichtenstein hernia repair; mesh; chronic groin pain.

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INTRODUCTION

Inguinal hernia, usually the most frequently occurring type of hernia globally, with an approximate of 75% of all hernias of abdominal wall.[1–3] Repairing inguinal hernia is a common general surgical operation around the world that accounts for 10 to 15% of all surgeries and after Appendicectomy, is the next most frequently done surgical procedure.[2–4]

It has been evaluated that worldwide around 20 million inguinal hernia repairs are done each year.[5]

Hernias can be defined as a "Protrusion of a viscus or part of the viscus through an abnormal opening in the walls of its containing cavity".[6] Inguinal hernias can be congenital or acquired, and the latter is common.

Necessarily, a risk factor that either leads to an increase in the intra-abdominal pressure or that weakens the anterior abdominal wall can develop into inguinal hernia. Risk factors affiliated with hernia occurrence can be positive family history, smoking, patent processusvaginalis, previous appendicectomy (open) and prostatectomy, collagen disease, obstructive lung diseases. It is fascinating to observe that infrequent lifting of heavy weights, prostatism and constipation has no substantial evidence to increase risk of inguinal hernias.[7]

In patients with inguinal hernia typical presentation is either groin pain or swelling/lump. The swelling can be asymptomatic with routine activities. If symptomatic, the symptoms can be either minimal (pain / intermittent discomfort) or may interfere with the everyday activities. Moreover they can present with incarceration wherein a hernia can't be reduced back into the abdominal cavity that can proceed to strangulation.

Bassini had published his primary description of an inguinal hernia repair in 1887, ever since this, various techniques for a hernia repair like Shouldice, Desarda, Darning, Modified Bassini, Lichtenstein mesh repair and the latest laparoscopic repair[4,5] have been documented and practiced. Laparoscopic and Lichtenstein mesh repair are well known in present days[8]as they are linked with faster return to normalcy also having lower recurrence rates.[9]

For ages now, long-term evaluation of results of a hernia repair focused on post-operative pain as well as recurrence rates. Chronic groin pain (Inguinodynia) post hernioplasty can be defined as pain lasting for > 3 months post surgery. It's a very important complication that occurs after inguinal hernia repair. The incidence of Inguinodynia changes among different studies, that ranges between 0% and 62.9% and about 10% of the patients fit in the moderate to severe pain groups.[10] Nevertheless, only 2% - 4% of patients are severely affected by chronic groin pain in their daily life and has a remarkable impact on the quality of life.[11]

The basic mechanism of pain after the surgery still needs research. It could be related to nerve mangling while operating.[12] mesh repair can lead to an inflammatory reaction over a period of time, though it still needs ground work to find out exact cause of pain.[13]

The synthetic mesh is usually secured to the surrounding tissue by non absorbable or absorbable suture. The possible influence of different suture materials on chronic groin pain after inguinal hernia repair has not been studied in depth.[14]

We hypothesize that the use of polyglactin for mesh fixation lessens the severity and decrease the rate of chronic pain compared to the polypropylene suture in patients undergoing inguinal repair**.**

OBJECTIVES

The objective of the present study is to compare the effectiveness of polyglactin (vicryl) versus prolene in reducing the post operative pain measured by the visual analogue scale in inguinal hernia repair as the primary objective.And to compare the effectiveness of prolene v/s vicryl in reducing the postoperative complications apart from post operative chronic pain as the secondary objective.

REVIEW OF LITERATURE

Astley Cooper, in 1804 defined "hernia as a protrusion of any viscus from its proper cavity". "The protruded parts usually contained in a sac-like structure, that is formed by a membrane with which the cavity is lined naturally with".[15]

Out of all the known hernias 96% have been found to be inguinal and the remaining are femoral, its seen more in male which is nine times higher, and twenty percent are present on both sides.[16]

Historical notes.

The earliest possible data related to inguinal hernia have come to the top from the Ebers papyrus (1552 BC) also the mummy of Merneptah (1224-1214 BC), which leads us to plausible signs of hernia surgery.[17]

The fundamental reasons for any intervention continues to be the same: risk of strangulation/ incarceration/ obstruction of the content of the sac, continuous growth of the inguinal/ scrotal swellings and comparatively poor outcomes with the conservative methods. In the subsequent years, many documented descriptions of the anatomy and management of inguinal hernias by both surgical and non-surgical methods have been observed. The results were not very satisfactory because of poorly developed techniques.

At the fall of the 19th century, along with the emergence of anesthesia and antiseptic techniques, surgeries for hernias have transformed for good. EdoardoBassini, revolutionized the management of inguinal hernia by starting the 'Bassini's repair' in Padua, Italy.[18-19]

EMBRYOLOGY[20]

Gestational week 6, the somatopleure is invaded by the mesoderm from the myotomes that lie on either side of the vertebral column (primitive wall of the abdomen). The body stalk occupies this area and the open midgut. The mesoderm gives rise to a sheet like embryologic entity. The migration is usually in lateral and ventral direction, this forms the right and left rectus. Around the 12th week, they approximate in the midline, thus closing the body wall. The mesodermal layer gives rise to lower abdominal wall, the so-called "secondary mesoderm". This envelops and invades the cloaca, thus separating ectoderm from endoderm craniocaudally. The embryology of inguinal canal is peculiar. It's a highly synergistic mechanism, the skin, peritoneum, and embryologic and anatomic entities, the future pathway of the testes are between them. In males the skin will form the scrotum (scrotal folds) and in females labia (labial folds). The processes vaginalis is produced by the parietal peritoneum. This peritoneal diverticulum is more important to the male fetus as it will permit the descent of testes.

The inguinal canal is formed by the penetration of processusvaginalis through embryologic entities between skin and peritoneum, so as to facilitate the downward journey of the testicle into the scrotum. In females, the ovarian descent outside the peritoneal cavity is forbidden. The ovarian exodus obstruction is by closed processusvaginalis, but this leaves the formation of the inguinal canal in-situ. The extensions of the abdominal wall layer are carried by "Processes vaginalis, which forms the walls of inguinal canal". The spermatic cord and testes coverings are formed by these layers in males. Transversalis fascia opening, formed by the vaginal process turns into the deep inguinal ring and the external ring is formed by External oblique aponeurosis aperture.[21]

SURGICAL ANATOMY[21–24]

The anterior abdominal wall's extent is from the xiphoid process and costal margins superiorly to, the pubis, iliac crests and pubic symphysis inferiorly. The anterior abdominal wall has a portion below the level of the anterior superior iliac spines that's commonly known as groin.

Soft tissue of the anterior abdominal wall

Superficial fascia

"The superficial fascia of the abdominal wall is present between the muscles of anterior abdominal wall and the skin. In the lower half, the fascia metamorphose into superficial layer that is the camper's fascia and deeper membranous layer known as scarpa's fascia between which the superficial vessels and nerves and, in the groin region, superficial inguinal lymph nodes are present".[21]

a) "Camper's fascia is thick and areolar in nature that contains variable amounts of fat tissue. This is quite thickened in obese individuals. It is superficial to inguinal ligament, inferiorly continuous with the superficial fascia of thigh, also the outer layer of fascia covering the perineum, penis and scrotum".[21]

b) "Scarpa's fascia usually contains a lot of elastic fibers so it is loosely connected by areolar tissue to the external oblique aponeurosis, but it is adherent to linea alba and pubic symphysis in the middle".[21] In males, it further forms superficial ligament of the penis and is continuous medially as well as inferiorly over the penis and also scrotum, here it continues with membranous layer of the perineal superficial fascia.

Transversalis fascia

"This is a connective tissue that lies between the inner surface of extraperitoneal fat and transversus abdominis"[22]. It's a dense covering. "It is flimsy, glued to pubis, medial to femoral vessels. Few fibers also spread laterally along the anterior superior iliac spine, other fibers go medially at the back of rectus abdominis, and some go down to pubis at the rear of conjoint tendon thus forming deep crural arch".[22] "The fibers of this arch strengthen the inferomedial rim of deep inguinal ring. The spermatic cord in men, the round ligament of uterus in women, pass via transversalis fascia near deep ring. The transversalis fascia now becomes internal spermatic fascia and it covers these structures as the surrounding the testes and blends with areolar tissue on the parietal layer of tunica vaginalis".[22]

Lymphatic drainage

"The lymphatic vessels lie superficial and also deep to the deep fascia. Superficial lymphatics from the infra-umbilical region travel along with superficial epigastric vessels. The gluteal and lumbar regions goes with the superficial circumflex iliac vessels and so drains into superficial inguinal nodes.

The deep lymphatic vessels give company to deep arteries. The vessels of posterior part of the abdominal wall accompany the lumbar arteries thus draining into lateral aortic and retro-aortic nodes. Vessels of upper abdominal wall go with superior epigastric vessels and so drain into parasternal nodes. Vessels from lower abdominal wall drain into inferior epigastric, circumflex iliac, external iliac nodes".[23]

Innervations

"The 7th to 12th thoracic ventral rami run in front of the intercostal spaces goes into the abdominal wall. The external oblique and rectus muscle are innervated by the lower intercostal as well as the subcostal nerves (T7 – T12), and internal oblique and transverses by the same nerves with an addition of ilioinguinal and iliohypogastric nerves (L1). The ilio-inguinal nerve runs with the spermatic cord, goes via the superficial inguinal ring, to innervate the medial thigh proximal to inguinal ligament, upper anterior scrotum and root of penis. In women, the nerve leaves the superficial ring to innervate labia majora and mons pubis. Iliohypogastric nerve has few fibers in common with ilioinguinal and subcostal nerve".[23]

The genitofemoral nerve appears anteriorly to psoas major muscle. Its genital branch leaves the pelvis along the deep inguinal ring and travels with the spermatic cord, innervating the cremaster muscle. On the other hand the femoral branches of the genitofemoral nerves (L1, L2) goes below the inguinal ligament, runs across the lateral to the saphenous opening, and then travel a short distance in the femoral sheath innervating the skin above it.

Inguinal canal

It is an oblique passage situated just over the medial part of inguinal ligament. It is around 4 cm long. The size varies according to the age, although present in both sexes, is well developed in males. It spans between deep and superficial inguinal ring. The ilioinguinal nerve goes via the inguinal canal in both the sexes.

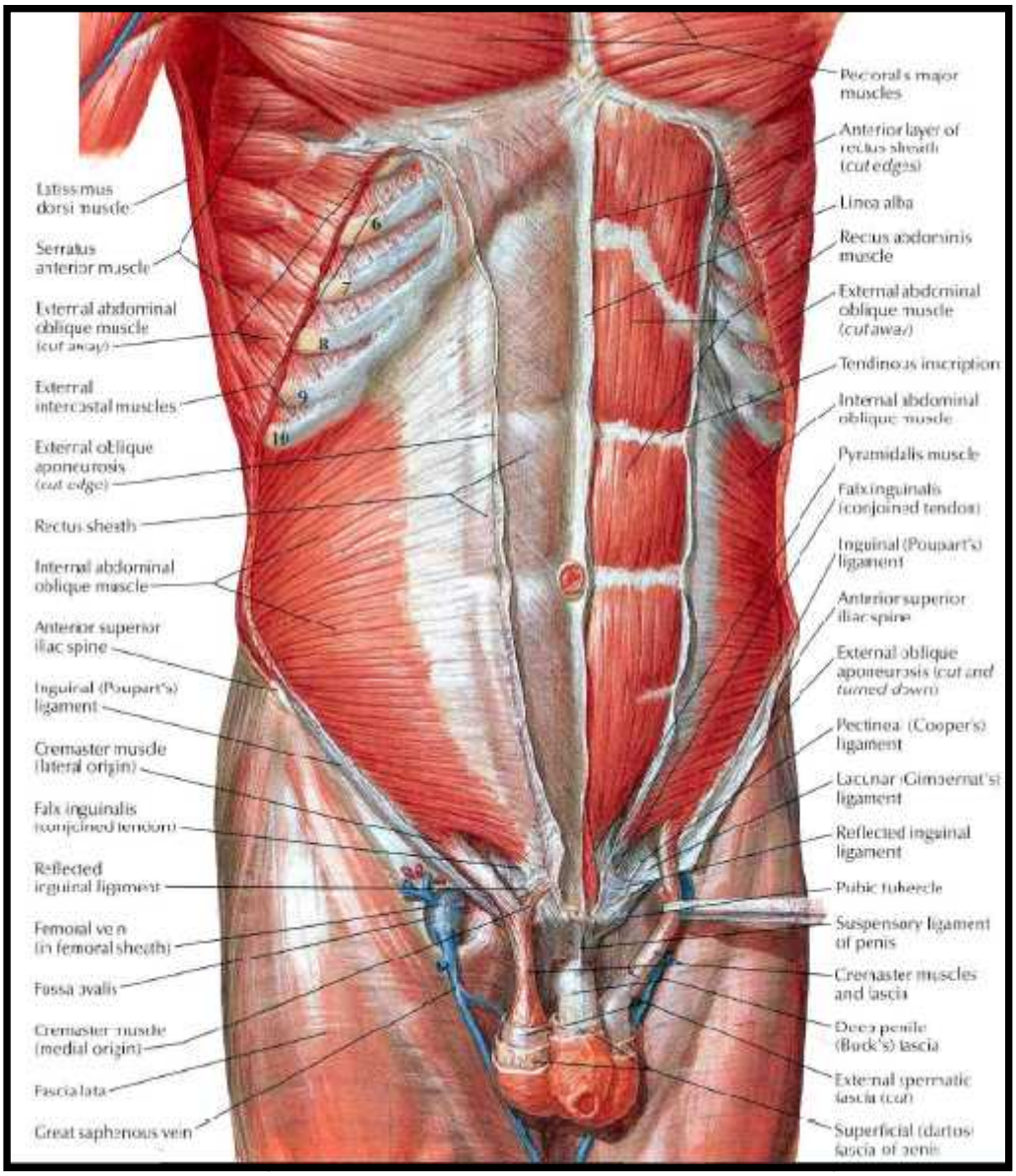


Figure 01: Muscles of the anterior abdominal wall.

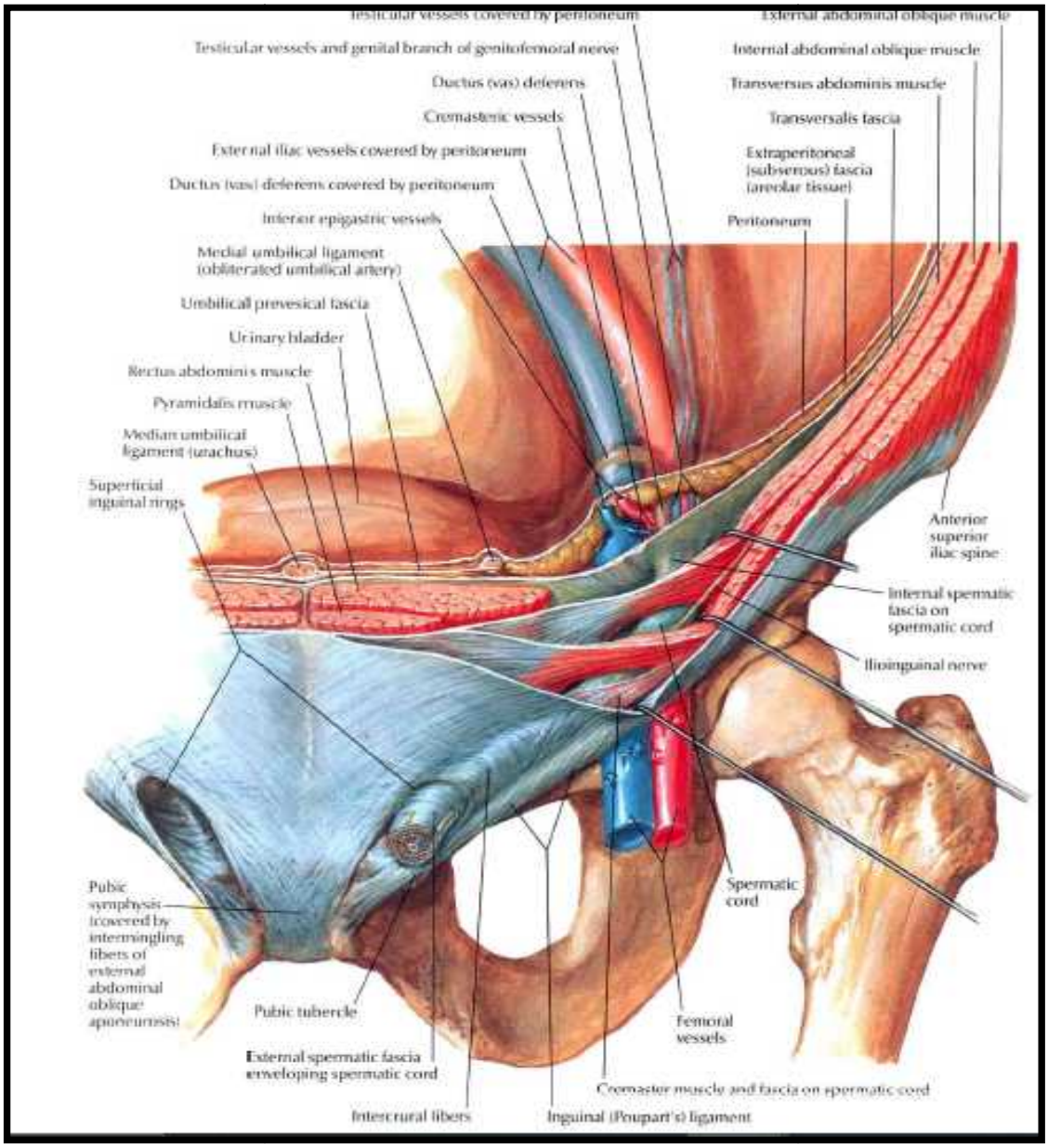


Figure 02: Inguinal canal in the male.

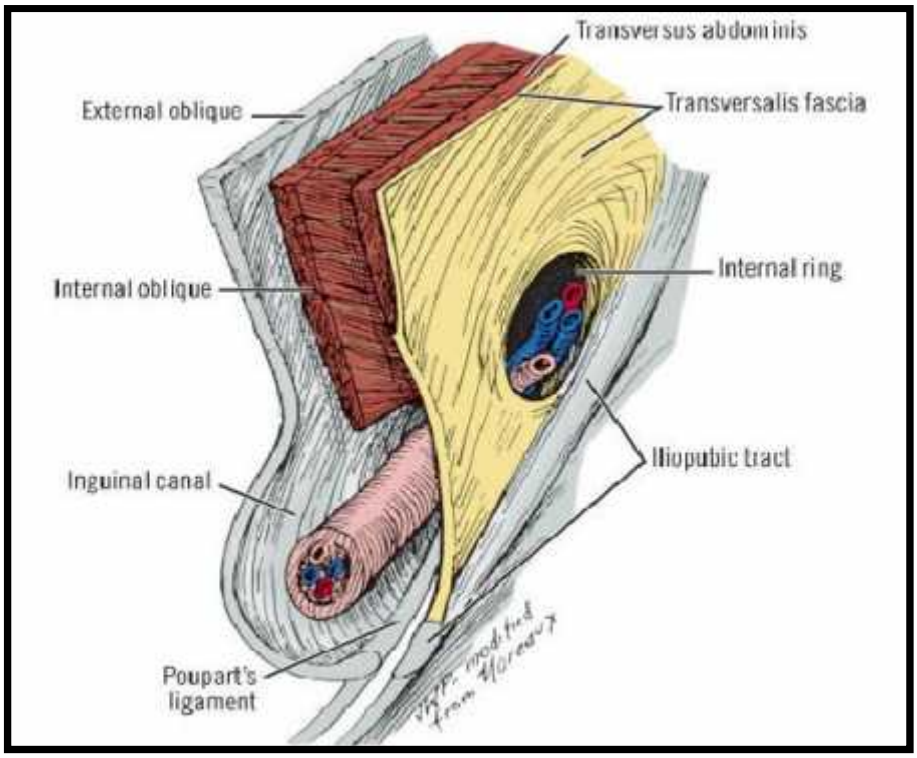


Figure 03: Parasagittal section through right mid-inguinal region, illustrating separation of musculoaponeurotic lamina into anterior and posterior inguinal walls

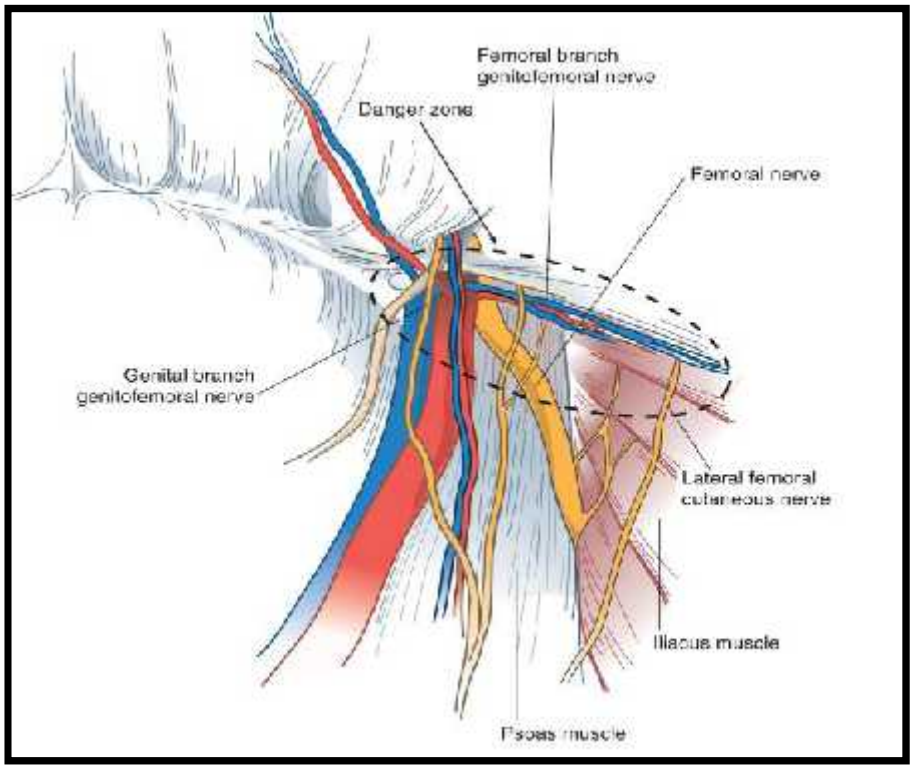


Figure 04: Important nerves and their relationship to the inguinal structures (right side).

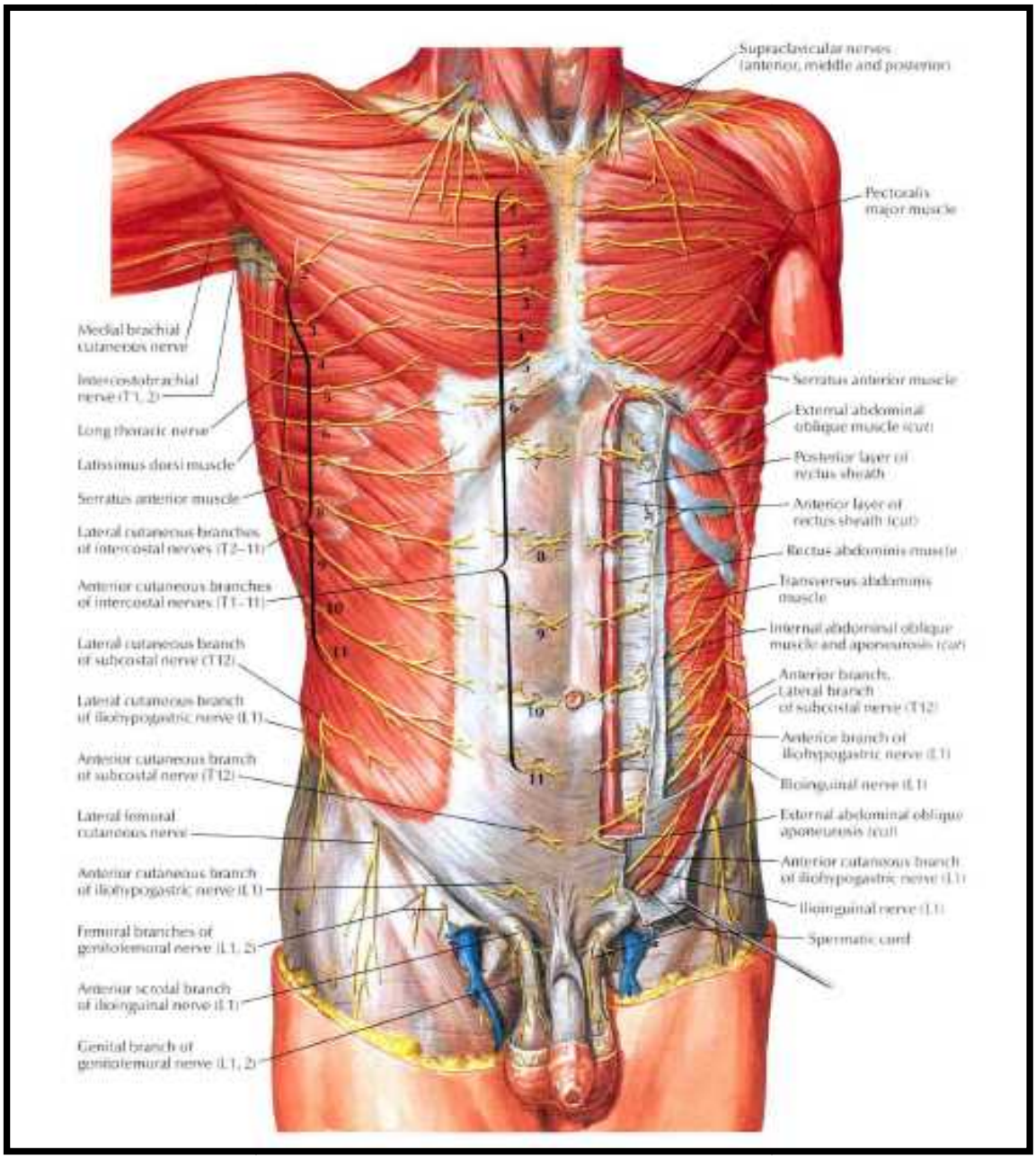


Figure 05: Nerve supply of the anterior abdominal wall in males.

Superficial inguinal ring

It is a triangular space in the aponeurosis of external oblique muscle that lays superolateral to the public crest, with apex directing along the line of deeper fibers of aponeurosis. The base is accompanied by crest of pubis, while sides are the crura. The stronger one is the lateral crus as its reinforced by fibers of inguinal ligament that inserts into pubic tubercle. The medial crus, which is thin and is attached to pubis symphysis and interlace with fibers from the opposite side. A few fibers arch above apex of the ring becoming the intercruralfibers. In men, the lateral crus curve to produce a groove and spermatic cord sits in it.

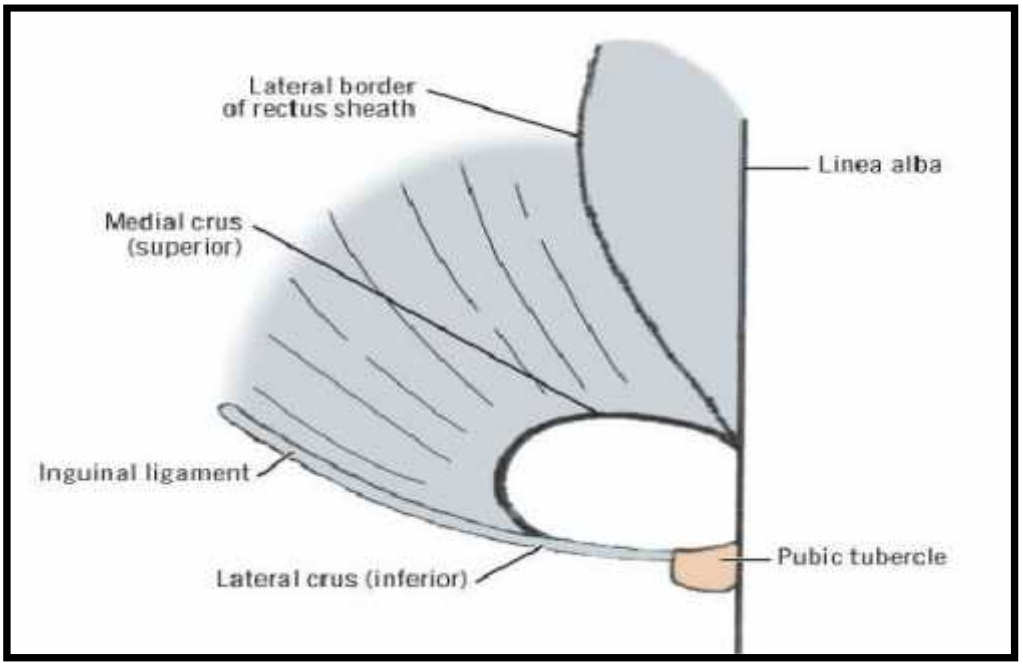


Figure 06: Diagrammatic representation of the external inguinal ring

Deep inguinal ring

Midway between symphysis pubis and the anterior superior iliac spine, is an oval opening from the fascia transversalis, located about 1.25 cm superior to the inguinal ligament. It is bounded, superolateral, by the transversalis fascia's arched lower margin, inferiorepigastric vessels forms its inferomedial border.

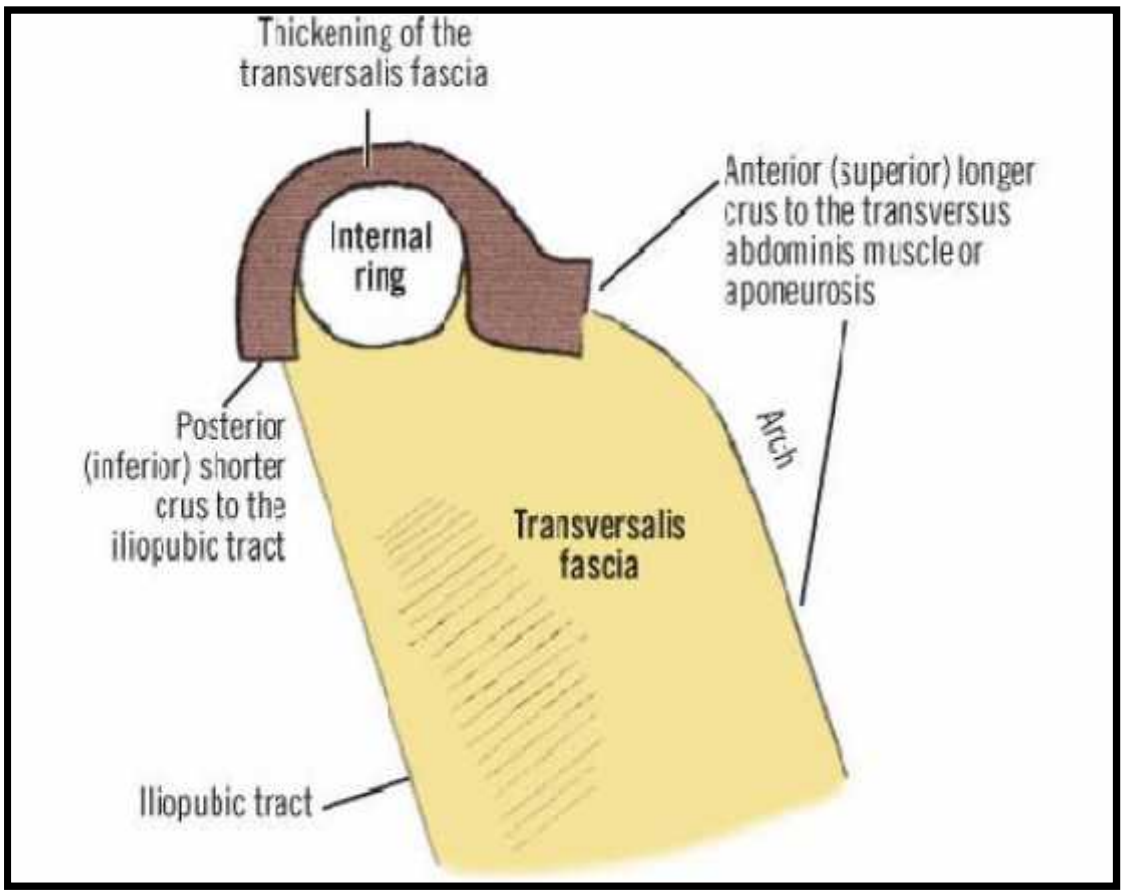


Figure 07: Surgical anatomy of the internal inguinal ring

Boundaries of the inguinal canal[25–28]

Anterior wall

"The inguinal canal is anteriorly bounded by skin, superficial fascia and the external oblique aponeurosis. The anterior wall, one-third laterally is reinforced by the fibers of internal oblique just above the inguinal ligament's origin".[24]

Posterior wall

The Medial part of posterior wall comprises of a powerful conjoint tendon which is a condensation transversusabdominis and internal oblique muscle. The reflected part of the inguinal ligament and transversalis fascia are present lateral to the conjoint tendon, this separates the inguinal canal from the extraperitoneal connective tissue also the peritoneum. The transversalis fascia laterally is made strong by tendinous muscle fibers which are derived from transverse abdominis that constitutes the interfoveolar ligament.

Roof of the canal

It is an arch and made by fibers of transverse abdominis muscles and internal oblique. The lateral $2/3^{rd}$ of the inguinal ligament gives rise to the internal oblique fleshy fibers.

Floor

The union of inguinal ligament with the transversalis fascia and by lacunar ligament medially, forms the floor. A thick triangular band of tissue is the lacunar ligament, which lies posterior to the medial limit of inguinal ligament. It is made from the fascia lata fibers of thigh and fibers of medial inguinal ligament. The inguinal fibers goposterolaterally to the medial limit of the pectineal line also continues with

the pectineal fascia. The apex is fixed to the pubic tubercle. Pectineal or the cooper ligament is a strong, fibrous band that is it stretches laterally through pectineal line. Fascia lata fibers join the posteroinferior edge of inguinal ligament; the latter, in combination with fibers from transversalis fascia, fuses with pectineal fascia while it joins the periostium of the pectineal line.

Relations

The inferior epigastric vessels lay posteromedially to the inguinal canal. They rest on transversalis fascia, as they tower obliquely at the back of the conjoint tendon and travel posterior to rectus sheath.

The Hesselbach's triangle, the inferior boundary is by the medial half of inguinal ligament, the lower lateral border of rectus sheath forms the medial border and laterally by inferior epigastric artery. "It is said to be an indirect hernia when a sac passes lateral to the vessel, and the one passing medial to the artery through the Hesselbach's triangle is a direct hernia".[22]

Fruchaud'smyopectineal orifice

This area in the groin has boundaries are as follows

Superior: transversusabdominis muscle and arch of internal oblique muscle

Inferior: Pecten pubis

Medial: rectus muscle (lateral border) and its anterior lamina

Lateral: Iliopsoas muscle

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

Spermatic cord

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

1. “Internal spermatic fascia –obtained from transversalis fascia at the deep inguinal ring”.

2. “Cremaster muscle and cremasteric fascia – It arises from transverse abdominis and internal oblique muscle. The fibers spiral down the cord and loop back to get inserted to public tubercle”.

3. “External spermatic fascia – obtained from the aponeurosis of external oblique as the cord passes between the crura of superficial ring”.

“The cremaster muscle can raise the testes forwards and also into the inguinal canal; although the fibers are skeletal, this action is reflex more than voluntary. Hence cremasteric reflex is especially active in younger population and ought to be kept in mind while examining scrotum in young to prevent a misdiagnosis of an undescended testis”.

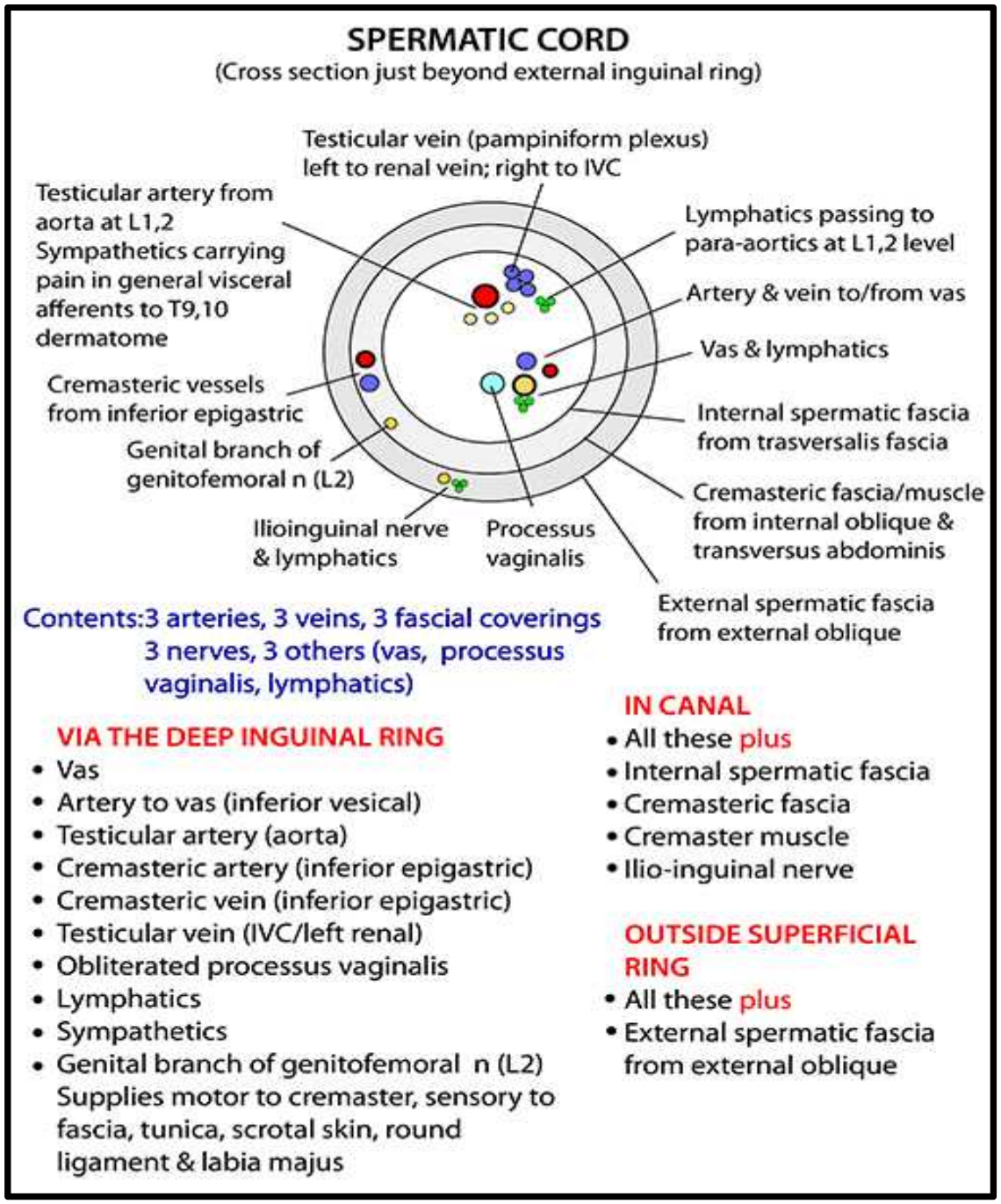


Figure 08: Contents of spermatic cord.

CLASSIFICATION OF INGUINAL HERNIAS[30,31]

Clinical Classification

This is based on the clinical presentation of hernia:

- Reducible hernia
- Irreducible hernia
- Obstructed hernia (Incarcerated hernia)
- Strangulated hernia
- Inflamed hernia

Gilbert's Classification

It is based on functional and anatomical defects that are established in the intra-operative period, classified groin region hernias in to 5 types. Type1, 2 and 3 were grouped as indirect whereas type 4 and 5 as direct.

Nyhus Classification of Groin Hernias

It merits a strict anatomic criterion that focuses on functional entity of the deep ring and inguinal canal's posterior wall.

Type I: Indirect inguinal hernia -- deep inguinal ring is normal (Congenital hernia).

Type II: Indirect inguinal hernia -- internal ring is dilated but posterior wall intact, inferior deep epigastric vessels undisplaced.

Type III: Posterior wall defects

A. Direct inguinal hernia.

B. Indirect inguinal hernia - deep ring is dilated, on medial side it encroaches or destroys the transversalis fascia of the Hesselbach's triangle. (E.g. Massive scrotal, Pantaloon or Sliding hernia).

C. Femoral hernia.

Type IV: Recurrent hernias

Classification as per the Patency of Processus Vaginalis

A.Vaginal hernia:

B.Infantile hernia:

C.Funicular hernia:

BENDAVID TSD CLASSIFICATION

Type:

1) Anterolateral (indirect)

2) Anteromedial (direct)

3) Posteromedial (femoral)

4) Posterolateral (perivascular)

Stage:

I. Sac in canal

II. Sac outside external ring

III. Sac into scrotum

Anatomical Classification

a. Direct hernia

b. Indirect hernia

c. Femoral hernia

Classification according to Descent of the Sac

A. Bubonocele

B. Funicular

C. Complete

INVESTIGATIONS[32,33]

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

Ultrasonography

- Ultrasonography is used to differentiate masses in the abdominal wall or groin or to differentiate testicular origins of swelling.
- If strangulated or an incarcerated hernia is suspected, the imaging studies which can be performed are
- erect abdominal x ray to exclude free air (extremely rare)
- Flat and erect abdominal x ray for a small bowel obstruction.

MANAGEMENT

Non operative management

A RCT was conducted by Fitzgibbons with his associates on expectant management strategy forasymptomatic patients as well as patients with mild symptoms.[35] They randomized over 700 men to either an expectant management or a surgery. The risk of incarceration in the expectant management group was considerably low at 1.8 per thousand patient-years, or 0.03% of study participants. Hence it provides us substantial evidence that a strategy for wait and watch policy for old patients who are not symptomatic or those who have minimal symptoms is viable.

Truss is used with insignificant success (30%), predominantly used in European countries. Complications related to truss include inflammation of ilioinguinal nerve, incarceration and atrophy of the testis

Operative Management

Surgery is the treatment of choice, various techniques have been introduced from a nylon darn, layered repair, open mesh to a laparoscopic repair.[19]

Indications

Surgery is the only modality that offers a cure to an inguinal hernia. Asymptomatic hernias can still be operated so as to lower strangulation possibilities. Strangulated hernia merits immediate intervention.

Techniques:

Anterior repairs

Sutured repairs

"Henry O. Marcy[36] described the Marcy repair in its initial form in 1871 who also promoted the aseptic technique in surgery. It consists of high ligation of hernial sac and narrowing of the deep ring. Nowadays the technique is used for lateral hernias in children and in growing youths".

The Bassini's repair

"Eduardo Bassini In 1887.[37] Dissection of inguinal canal, defining of the hernial sac, high ligation in case of a lateral sac and incision of the posterior floor were essential. Reconstruction of the posterior floor was then done by interrupted non

absorbable suturing of internal oblique, transverse abdominis and transverse fascia to iliopubic tract and the inner parts of inguinal ligament".

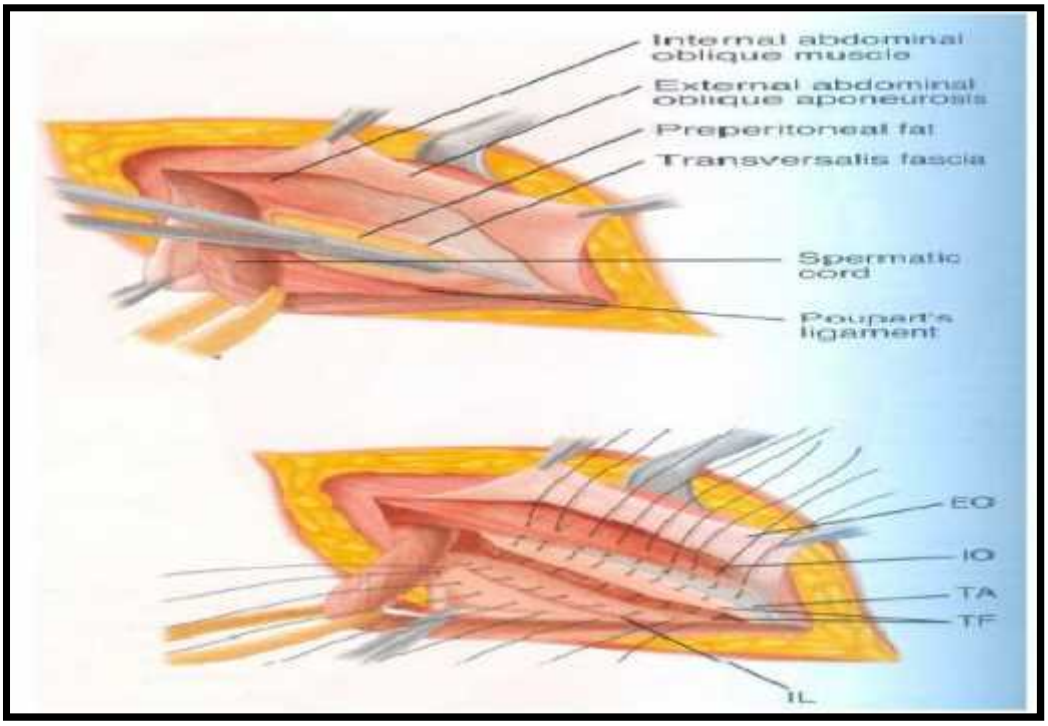


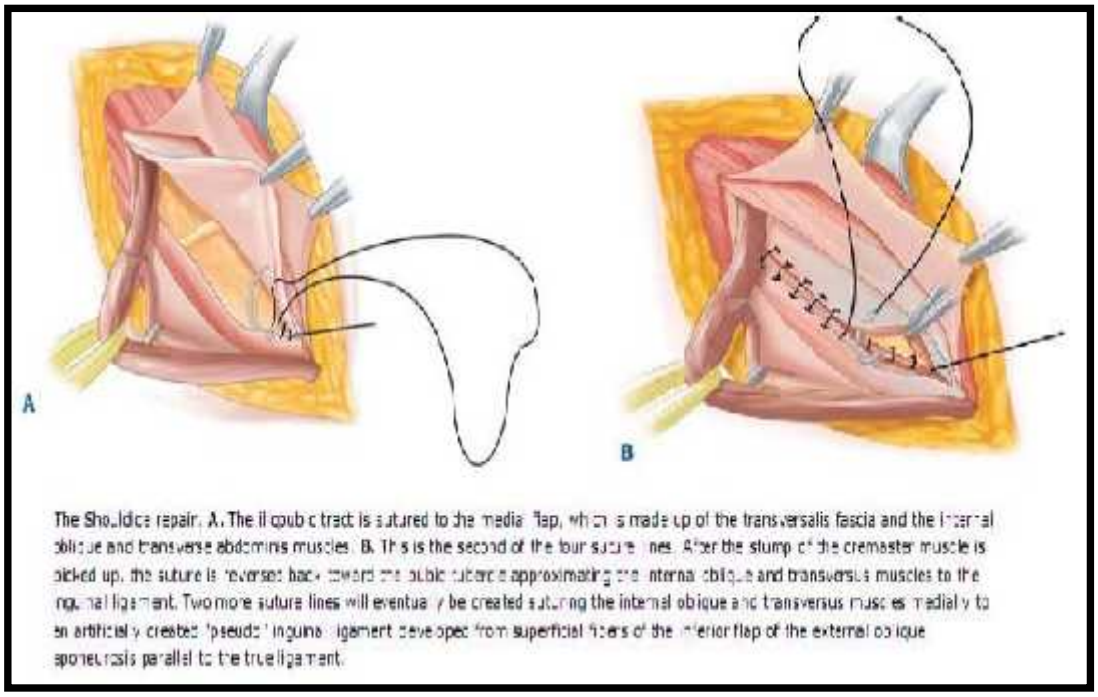
Figure 09: BASSINI S REPAIR

The Halsted procedure

"William S Halsted in 1889, similar to Bassini method but the cord excised of its superficial veins and transposed to a position above the aponeurosis of external oblique. He later modified his method and omitted the transposition of the cord and instead covered it with both the external and internal oblique muscles. After at least four years of follow-up, recurrence rate was 4%".[42]

Shouldice repair[40,41]

"Here transversalis fascia is divided to from superior and inferior flaps, from internal ring towards medial end near pubic tubercle. The primary layer of repair commences at pubic tubercle where iliopubic tract is anchored to lateral edge of the rectus sheath, later progresses laterally. The inferior flap includes iliopubic tract, this should be sutured in continuous fashion to posterior part of superior flap until internal ring is visualized. The suture is not knotted here, but is continued back over itself medially. At deep ring, a second layer is re-approximated off upper edge of transversalis fascia to inferior fascial margin also the shelving edge of inguinal ligament. The suture is later knotted to tail of original stitch. A third suture is begun at the tightened inguinal ring that joins the transversusabdominis and internal oblique aponeurosis to external oblique aponeurosis just above inguinal ligament. This layer to be continued till pubic tubercle, here it folds upon itself forming a fourth suture line".



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

Figure 10: Shouldice repair

The Mcvayhernioplasty

"1898 Georg lotheissen[42] first described this technique but popularized by Mcvay[43]. The posterior wall was repaired by interrupted suturing. Medially the rectus sheet was adapted to cooper's ligament and on the lateral side transversalis fascia was adapted to the femoral sheath".

The Lichtenstein hernioplasty

"Irving Lichtenstein introduced the term tension-free hernioplasty in the year 1986.[44] In 1989 Lichtenstein published his improved technique and nowadays often called original method[46] where he no longer performed a sutured repair of posterior wall, he just reinforced it by bridging the defect with a mesh that was sutured with a continuous monofilament non absorbable suture. The method was further improved in the early nineties[47] with recommendations of larger, slightly relaxed mesh, medial mesh overlap, crossing and suturing of tails of mesh lateral to the cord and only interrupted absorbable sutures on upper edge of the mesh". It has been modified by Lichtenstein.[48]

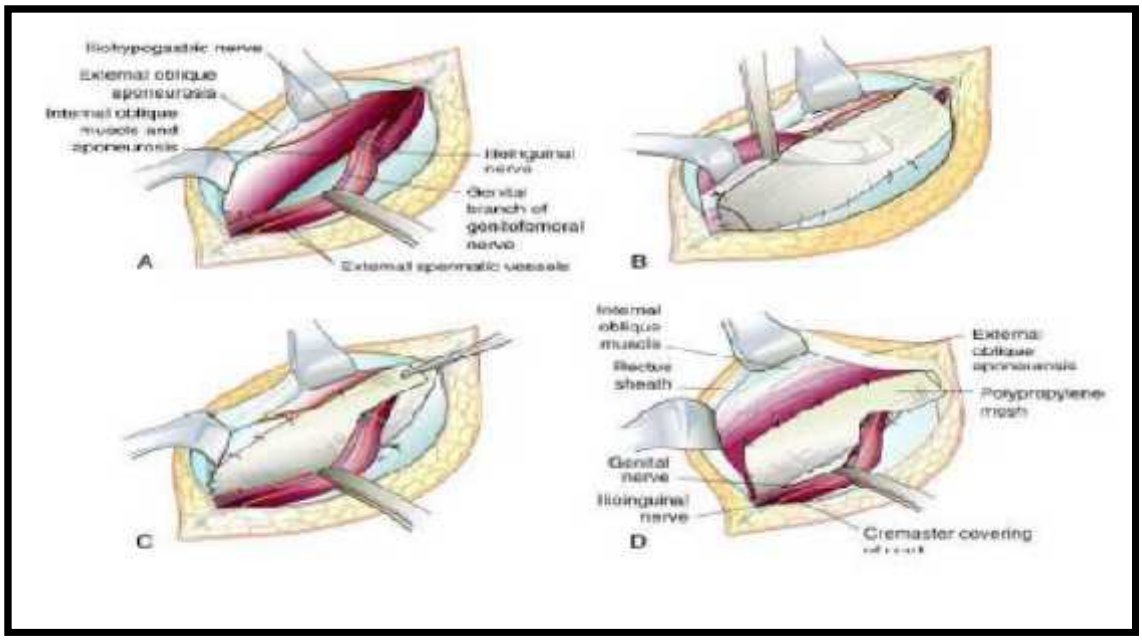


Figure 11: Lichtenstein repair

Plug and Patch or Rutkow-Robbins technique

Alan Robbins and Ira Rutkow[49] described the plug technique in 1993. An umbrella shaped plug made with polypropylene was placed in a hernia defect in posterior wall that acted as a sublay mesh added with a mesh over anterior rectus.

Open posterior mesh repairs

The Stoppa method[50]: the advantage of this technique is, it's able to treat every type of hernias, primary, recurrences too. In this method a deep dissection of bogros' space will recognize femoral hernias also all structures that pass through obturator orifice. After rives, stoppa outlined the concept of overlapping the peritoneum with a large preperitoneal mesh. Nyhus modified his original method[51] it as after repairing the defect in transversalis fascia , he placed a preperitoneal mesh.[52]

IPOM (Intraperitonealonlay mesh): "in 1992 Charles Filipi described a laparoscopic technique in which a mesh is placed intraabdominal, covering all inguinal and femoral orifices".[53]

TAPP (Transabdominalpreperitoneal repair):

"Maurice Arregui[54] described the method in 1992. By a transabdominal laparoscopic technique a preperitoneal mesh is placed covering all inguinal and femoral orifices".

TEP (Totally extraperitoneal repair): "by Jean-Louis dulucq[55] described this technique in 1992. By the extraperitoneal laparoscopic technique a preperitoneal mesh is applied covering all inguinal and femoral orifices".

Complications of inguinal hernia surgery[56,57]

Intra operative complications

- Hemorrhage
- Severance of nerves
- Nerve-entrapment by sutures
- Severance of testicular blood supply
- Trauma to vas deferens
- Damage to intestine
- Injury to the bladder
- Transection of spermatic cord

Post operative complications[57]

- General: systemic complications occur at a rate comparable with that after other surgical procedures of the same magnitude. Atelectasis and pneumonitis were most frequent followed by thrombophlebitis and urinary retention.
- Scrotal ecchymosis.
- Swollen testis
- Ischemic orchitis and testicular atrophy
- Hydrocele
- wound infection

Others:

- Urinary retention,
- Neuroma,
- Hematoma,
- Seroma,
- Sinus formation,

Persistent post operative pain:

- Groin pain. Common causes are nerve entrapment, neuroma, periostitis of pubic tubercle.
- Numbness.
- Paraesthesia
- Sexual dysfunction.

Physiology and anatomy of chronic groin pain after inguinal herniorrhaphy and hernioplasty[22,59,60]

Definition of pain "an unpleasant sensory and emotional experience with actual or potential tissue damage or described in terms of such damage".[61]

"Chronic pain can be defined as pain lasting for > 3 months post surgery".[10]If it's less than 3 months it can be considered as acute pain.

Nociceptive pain: "nociceptive pain is a dull, burning, tugging, type of pain which is brought on by lifting or stretching. It is akin to ligamentus or tendon injury".

"It can be visceral or somatic in origin, and the nervous conducting system is intact".

Neuropathic pain: "neuropathic pain presents as a jabbing, electrical, or brief, sharp pain can be provoked by movement or it can occur spontaneously. There is an abnormality in conduction".

Osteitispubis, and ilioinguinal nerve entrapment are common causes for chronic pain. "Postoperative pain is assessed using a 4- point verbal scale (none, mild, moderate, severe) assigning numerical values of 0 to 3".

"Mild pain was defined as an occasional disturbance that did not limit normal activities".

"Moderate pain: pain that interferes with normal – day life activities".

"Severe pain as pain that rendered the patient unable to perform normal activities".[62]

Grant and colleagues noted that 9·7 per cent of patients reported chronic pain 5 years after open inguinal hernia repair. Other studies have put the proportion with chronic pain as high as 34 per cent.[63]

SUTURE MATERIALS:[19]

Suture characteristics

STRUCTURE: "Suture material can be multifilament or monofilament".

"Monofilament - smooth and slides through tissues easily without any sawing action, but difficult knotting".[19]

"Multifilament or braided sutures – knotting comes easily, but have a surface area of few thousand folds to a monofilament sutures".[19] Chances of bacteria getting wedged are more. Silicon can be coated thus addressing this issue, known as braided sutures.

STRENGTH: "The strength of a suture material relies on its thickness its constituent material and how it is handled within tissues"[19].

Metric (EurPh)	Range of diameter (mm)	USP ('old')
1	0.100–0.149	5–0
1.5	0.150–0.199	4–0
2	0.200–0.249	3–0
3	0.300–0.349	2–0
3.5	0.350–0.399	0
4	0.400–0.499	1
5	0.500–0.599	2

Table 01: Thickness expressed in 10th of a millimeter

The force sufficient to break a suture when pulled the two ends apart is expressed as tensile strength but is only a mere approximation as the actual strength of the suture is its tissue strength in vivo.

TENSILE BEHAVIOR: How flexible or deformable a suture material is an important aspect. Either its "elastic" i.e. "the material returns to its primary length once all the tension is released", while others may be "plastic". Property of 'memory' is also a significant factor. It is imperative to acknowledge that sutures usually lose 50 per cent of the primary strength at the knot.

ABSORBABILITY: Suture materials can be either absorbable or non-absorbable and this property ought to be valued when choosing a suture material for a particular wound closure or anastomosis. Sutures utilized for urinary tract or biliary must be absorbable so as to reduce the risk of developing stones. Nevertheless, a vascular anastomosis necessitates the non absorbable element also sagacious to avoid braided thread as it can pave way to distal embolisation due to platelet adherence. Whenever constant strength is needed, non absorbable suture material is preferred and, prosthesis or an artificial graft never integrates into a host artery nor heals fully, so monofilament suture materials, like polypropylene, is universally preferred.

BIOLOGICAL BEHAVIOUR: The primary material is an important factor here. "Biological sutures, like catgut, are usually proteolysed, but it involves a process which is not very predictable and may cause local irritation and such materials are hence rarely used". Synthetic polymers are hydrolyzed and so are better predicted. Malignant cells might organize in biological materials giving raise to local recurrence. So synthetic threads can be predicted better with little tissue reactivity also no cancer seeding.

POLYGLACTIN (VICRYL)

"It's a braided multifilament Copolymer of lactide and glycolide in a ratio of 90:10, coated with polyglactin and calcium stearate. The tensile strength retention in vivo is approximately 60% remains at 2 weeks, approximately 30% remains at 3 weeks. The absorption rate i.e. the hydrolysis of the suture material is minimal until 5 to 6 weeks, complete resorption by 60 to 90 days".

Indications: gut anastomosis, vascular ligatures, ophthalmic surgery, subcuticular wound closures.

Figure 12: polyglactin suture material

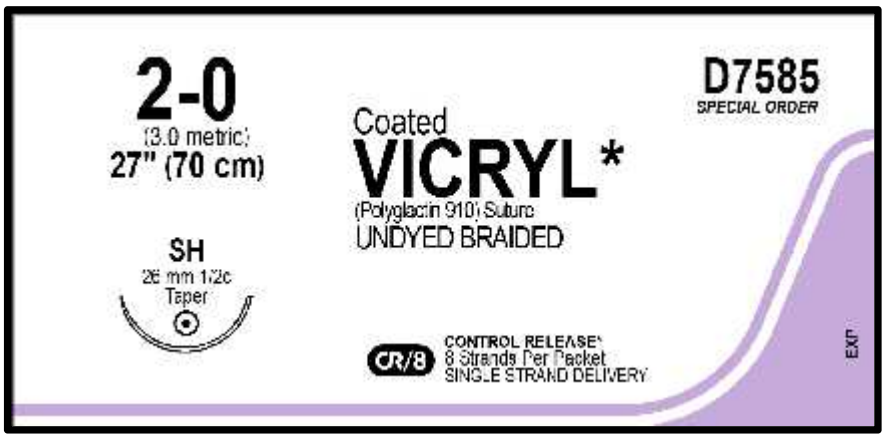


Figure 13: vicryl suture

POLYPROPYLENE (PROLINE) (CH2-CH(CH3-)n[64]

It is a monofilament suture material and is chemically extruded from a purified and dyed polymer which is neither adsorbed nor weakened by the action of tissue enzymes. Polypropylene is a thermoplast based on propane. It's molecular weight of 100000 g/mol. It is supposed to resist physical decay even after being implanted.

Filaments made of polypropylene have similar strength to steel although they have only 1/8th the density of iron.

It has an extremely high tensile strength which it retains indefinitely on implantation. This paucity of adherence to the tissue facilitates its use as permanent sutures. It can be extended up to 30% before it breaks and hence is useful in situations where postoperative tension is required from the suture to accommodate the postoperative swelling and they help to prevent tissue strangulation. Handling is good and knotting is secure as the material deforms no coefficient of friction. It is inert and non biodegradable. It is sterilized by ethylene dioxide.

Figure 14: polypropylene suture material

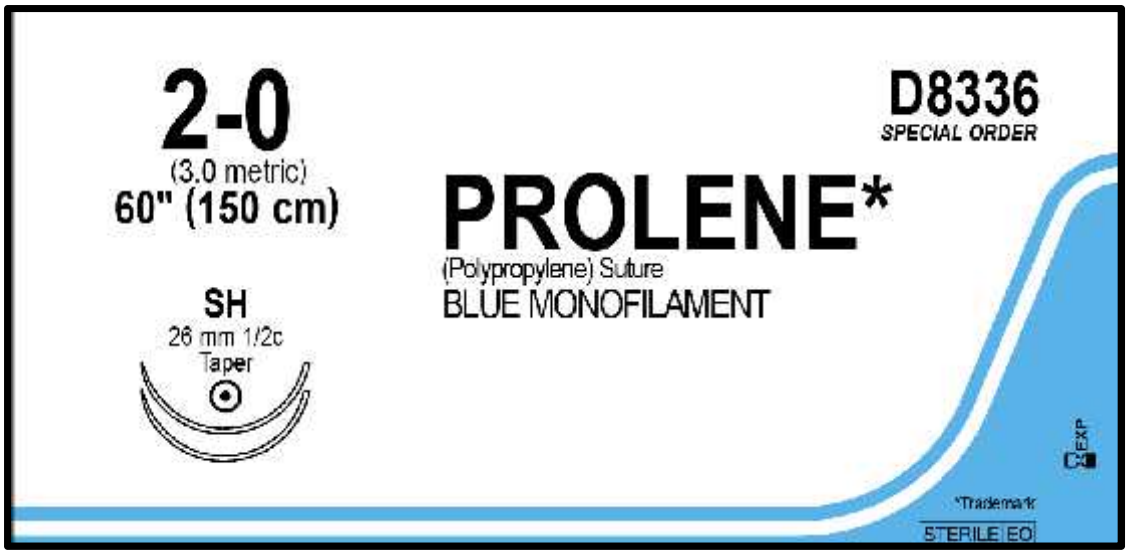


Figure 15: prolene sutures

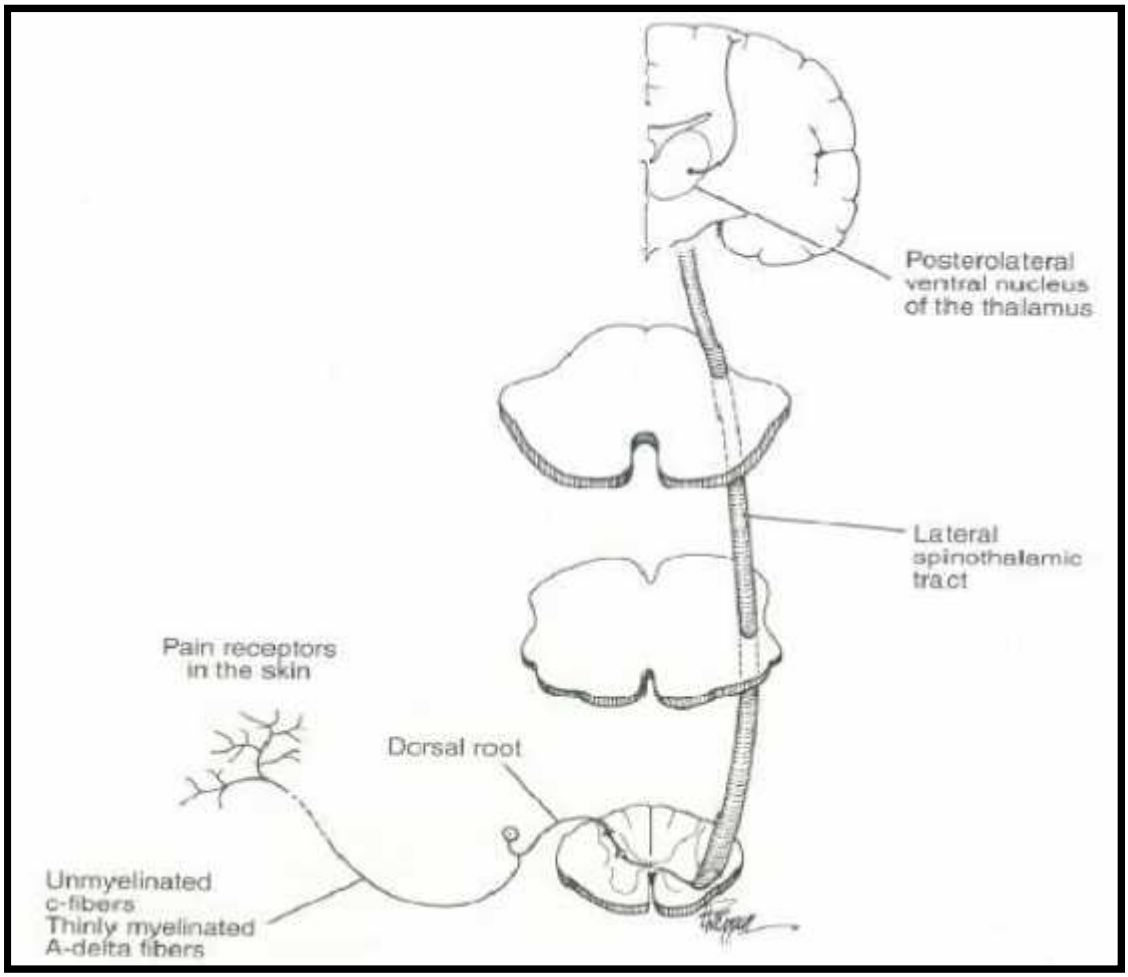


Figure 16: Physiology of pain

Anatomic considerations:

During exploration of groin by an anterior approach, encountering the ilioinguinal nerve, iliohypogastric nerve and genital branch of genitofemoral nerve is expected.

1. Ilioinguinal nerve (T12 – L1)

"This nerve appears from back of the psoas accompanying the iliohypogastric nerve. It travels obliquely over quadratuslumborum, perforates transvesusabdominus muscle close to the anterior tip of the iliac crest, it further penetrates internal oblique and traverses the inguinal canal only to leave the external ring or by entering the fascia just next to the superficial ring".

Innervation: "motor - internal oblique, sensory – upper 1/3rd thigh, upper scrotum and root of penis in men, mons pubis and labia majora in women".

-major culprit for chronic pain as demonstrated in ample of studies.

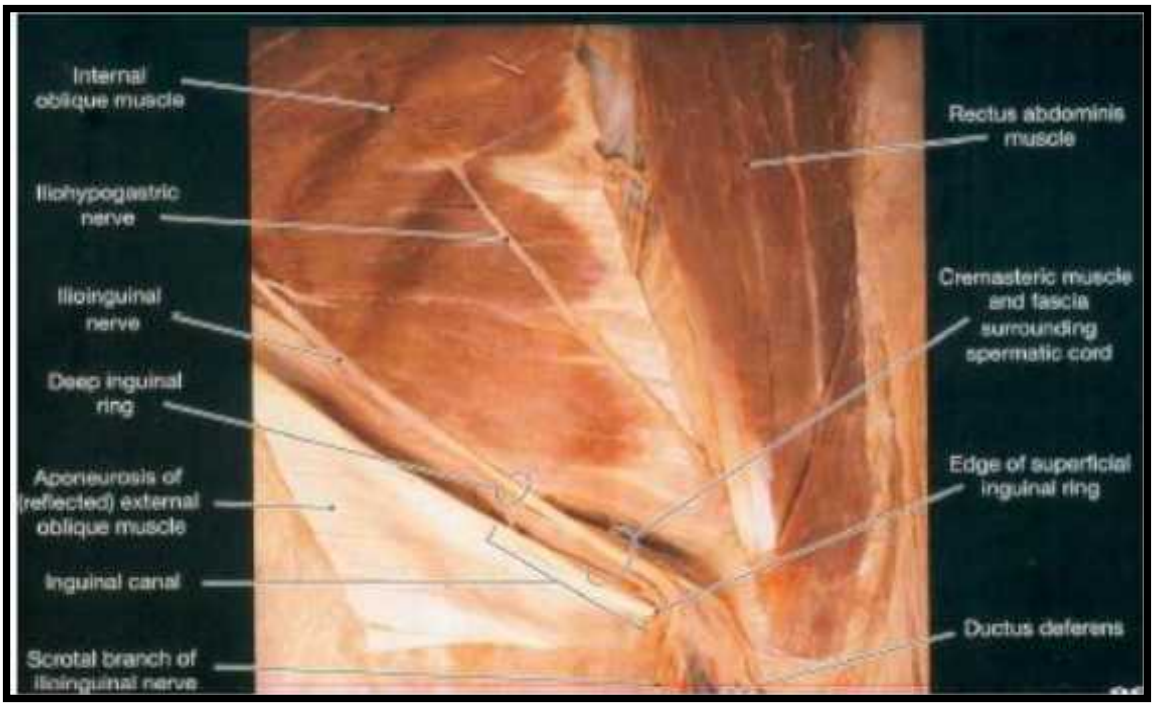


Figure 17: Ilioinguinal Nerve

2. Genitofemoral nerve (L 1– L 2)

"It's oblique to psoas muscle, it grips the L - 4 spinous process on the medial side. It then travels at the back of ureters, splits above the inguinal ligament. The genital branch goes behind external iliac artery, passes via deep ring into inguinal canal and supplies the cremasteric muscle and scrotal skin in men or mons pubis and labia majora in women. Lateral femoral branch innervates anterolateral part of thigh".

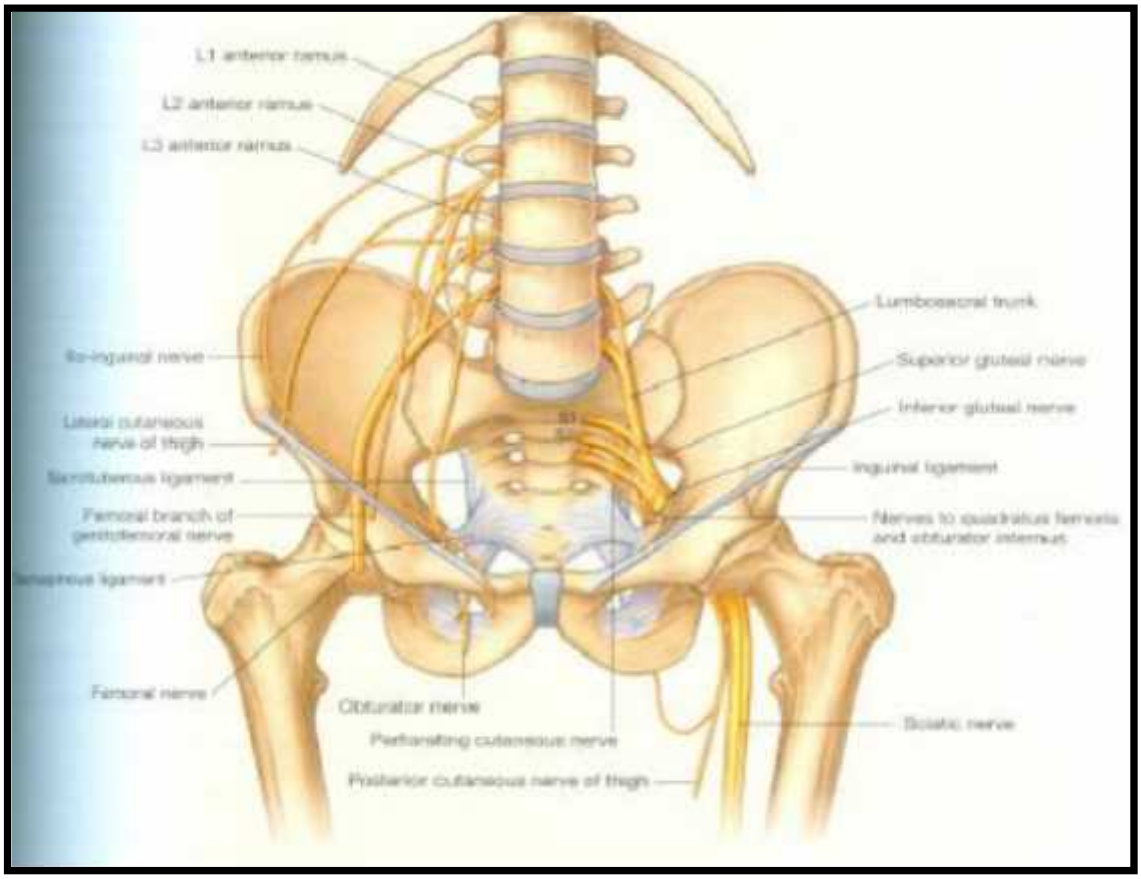


Figure 18: nerve plexus in the lumbar region

3. Iliohypogastric nerve (T12 - L1)

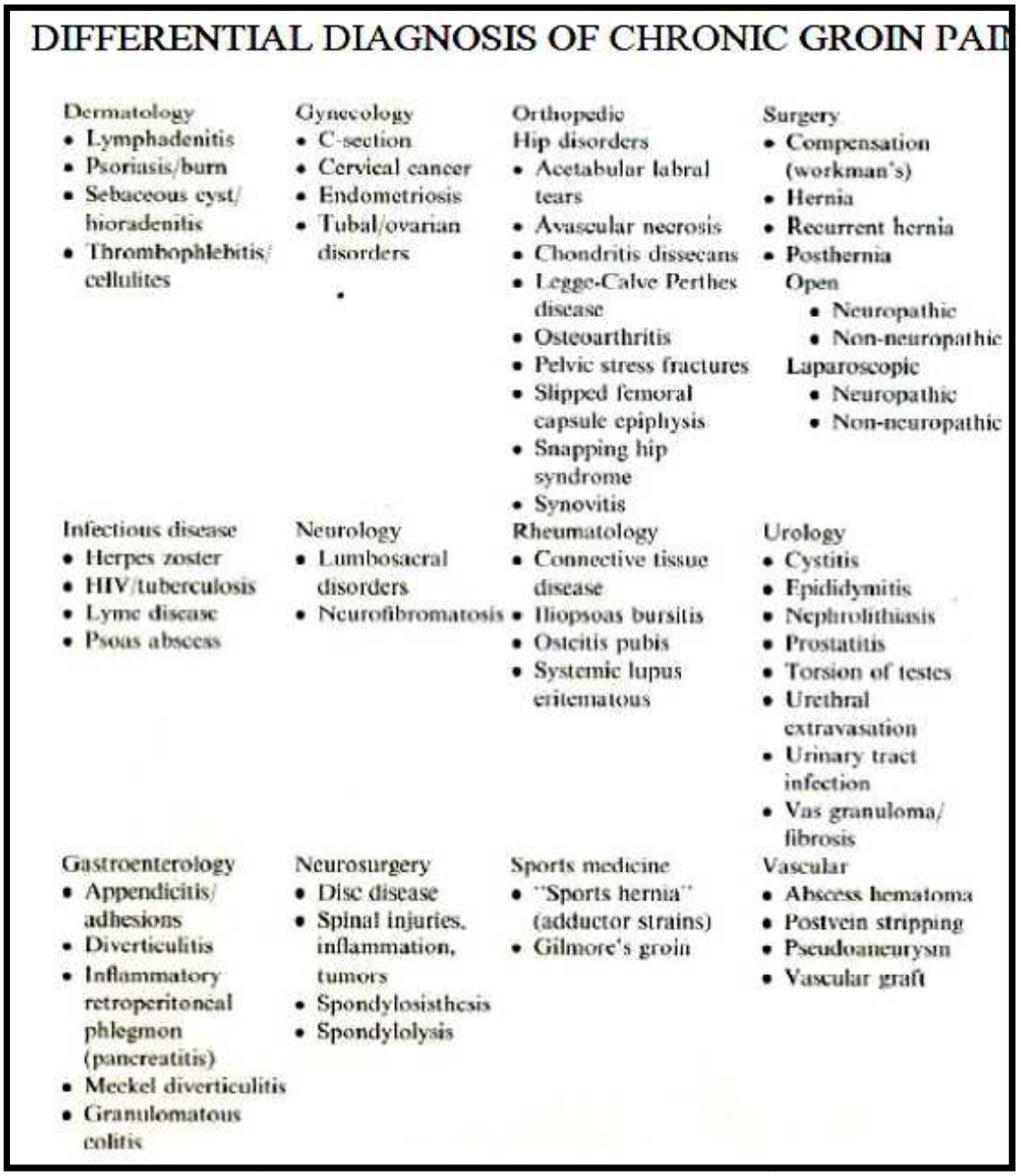
"It appears laterally to psoas muscle and travels anteriorly to quadrates lumborum. Over the iliac crest, it innervates transversusabdominus. Anterior cutaneous nerve branch dashes betwixt transversusabdominis and internal oblique till

about 2 cm medial to ASIS where it perforates internal oblique. It further advances medially and penetrates aponeurosis of external oblique over external ring. It supplies the suprapubic skin and branches itself to Ilioinguinal nerve".

Chronic pain following herniorrhaphy and its risk factors[22,60]

Even before surgery chances of entrapment, stretching or neuritis, may be seen complicated disease pathology must be of strong suspicion. This may also point to the existence of psychological predisposition or lowered pain threshold in such patients thus increases chances resultant pain after surgery. Mangling of nerves can pave way for formation of neuroma and contusion. Cautery damage, crushing, suture compression may progress to the development of chronic pain. "It has been shown peripheral nerve tissue can react with polypropylene mesh upon contact leading to, edema locally, degeneration of the myelin, and fibrosis causing neuralgia also peripheral neuropathy".[65]

The mesh and suture material implantation which leads scar formation by aggravated inflammation, can also be implicated as a cause of neuropathic pain.



DIFFERENTIAL DIAGNOSIS OF CHRONIC GROIN PAI

Dermatology
- Lymphadenitis
- Psoriasis/burn
- Sebaceous cyst/ hioradenitis
- Thrombophlebitis/ cellulites

Gynecology
- C-section
- Cervical cancer
- Endometriosis
- Tubal/ovarian disorders

Orthopedic
Hip disorders
- Acetabular labral tears
- Avascular necrosis
- Chondritis dissecans
- Legge-Calve Perthes disease
- Osteoarthritis
- Pelvic stress fractures
- Slipped femoral capsule epiphysis
- Snapping hip syndrome
- Synovitis

Surgery
- Compensation (workman's)
- Hernia
- Recurrent hernia
- Posthernia

Open
- Neuropathic
- Non-neuropathic

Laparoscopic
- Neuropathic
- Non-neuropathic

Infectious disease
- Herpes zoster
- HIV/tuberculosis
- Lyme disease
- Psoas abscess

Neurology
- Lumbosacral disorders
- Neurofibromatosis

Rheumatology
- Connective tissue disease
- Iliopsoas bursitis
- Osteitis pubis
- Systemic lupus erithematous

Urology
- Cystitis
- Epididymitis
- Nephrolithiasis
- Prostatitis
- Torsion of testes
- Urethral extravasation
- Urinary tract infection
- Vas granuloma/ fibrosis

Gastroenterology
- Appendicitis/ adhesions
- Diverticulitis
- Inflammatory retroperitoneal phlegmon (pancreatitis)
- Meckel diverticulitis
- Granulomatous colitis

Neurosurgery
- Disc disease
- Spinal injuries, inflammation, tumors
- Spondylosisthesis
- Spondylolysis

Sports medicine
- "Sports hernia" (adductor strains)
- Gilmore's groin

Vascular
- Abscess hematoma
- Postvein stripping
- Pseudoaneurysm
- Vascular graft

Table 2: differential diagnosis of chronic groin pain

Altered Groin Skin Sensations

At the 1-year evaluation, rates of neuropathic abnormalities including hypoesthesia, hyperesthesia, and allodynia.[66]

Avoiding Chronic Pain Following Inguinal Herniorrhaphy / hernioplasty.[10,22,67]

Judicious clinical discernment advice speedy intervention with cautious dissection to prevent nerve injury, subsequently reducing a potential crippling morbidity. Adequate measures to be taken while placing sutures to prevent inguinal ligament tightness. Avoid haphazard division of subcutaneous tissue. Avoid excision of the cremasteric muscle. To avoid suture placement in the lower part of internal oblique, to avoid excessive tightening the external ring.

Arct trial conducted to probe into the chronic pain postoperatively in ProGrip™ self-gripping mesh v/s standard sutured lightweight polypropylene mesh in 557 patients. It was evident that a substantial number of patients had reduced early post operative chronic pain in ProGrip™ self-gripping group.[63]

Nerve injury intaoperatively and disposition to other conditions of chronic pain are the having high chances to be the pathogenic factors. In repair of inguinal hernia chronic pain postoperatively ranges between 0 – 63% and is commonly classified as “mild, moderate, severe”. “Perkins looked at post herniorrhaphy pain in the context of their chronic pain model and estimated that it can be as high as 50% at one year”.[68] On an average 66% complained of pain during initial presentation , about 90% in patients having hernia for atleast 10 years.[69] The degree of pain preoperatively required to result in a worthwhile repair is unclear. For a patient to

experience a worthwhile surgery, the preoperative symptoms reduction should be given importance over chronic pain.[70]

"Ducic et al came to a conclusion that chronic, severe testicular pain postoperatively may be managed by a structured approach which recognizes genital branch of the genitofemoral nerve in inguinal canal proximally, resection proximal to the primary operative field and later placing it at the back of the peritoneum".[71]

A number of studies have been conducted on absorbable as well as non absorbable sutures used subsequently the mesh fixation, a study by Igor Jeroukhimov, et al. (2014) rate of chronic pain post surgery was more so in the non absorbable suture group, as in comparison with the absorbable suture (37 v/s 26; p ¼ 0.056). Pain disappeared much slower in non absorbable monofilament suture v/s the absorbable suture group (115.3 days; 95% CI, 88 142.7 v/s 77.4 days; 95% CI, 54.3 100.3; p ¼ 0.038, respectively. This implicates that a non absorbable suture usage in a inguinal hernia repair is affiliated with a higher chronic pain rate and a longer time to pain disappearance as compared with absorbable sutures.[14,72,61]

Evaluating and Treating the Chronic Pain.[54,71,73,74]

Uncurbed scar formation, hernia recurrence, and pressure due to the bulk of mesh can cause neuropathic pain. Some of the factors are entrapment of nerves either by staples sutures and formation of neuroma. This can also result in pain in the testis or pain in the labia when genitofemoral nerve is involved.[71,11,75]

" If the Ilioinguinal nerve is entrapped it can be elicited by having a patient hyper extended and twist the trunk to the other side of hernia repair".[73]

Treatment includes:

1. Pain killers

2. Nerve blocks

3. Revision surgery and removal of mesh, and

4. Surgical neurectomy: exploration and neurectomy, possibility of removal of mesh. On a documented case series, a total of 54 underwent inguinal exploration and triple neurectomy. About 68% were of them had pain relief. Same was agreed upon by another study, which showed that triple neurectomy results in about 72% complete relief of 25% partial relief.[73]

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 one year period, from January 2019 to December 2019

Study design: The study design was single blinded randomized controlled trial.

Study period and duration: This study was conducted for the period of one year from January 2019 to December 2019.

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.

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

Sampling procedure

Computer generated random numbers were used to assign the type of surgery to the patients that is, group A (patients undergoing mesh fixation with vicryl) and group B (mesh fixation with prolene) in Lichtenstein inguinal hernia repair, Patients wereblinded to the intervention. The sample size was taken as 60, with 30 in each group by applying the formula,

The mean d_1 and standard deviation $S_{2\ for}$ group 1 is 3.80 and 3.163.

The mean d_2 and standard deviation S_2 for the second group is 6.23 and 4.031.

Z alpha = 1.96 at 5% alpha error

Z beta = 0.842 at 20% beta error

S is average of $S_{1\ and}$ S_2

d is the difference between d1and d_2

$$N = \frac{2S^2 \{z\ alpha + z\ beta\}^2}{d^2}$$

N is 31.443 participants in each group, Rounded off to 30

Substituting these values in the formula, N= 30 and enrollment ratio is 1:1 hence, the sample size estimated was a minimum of 60 patients. Accordingly 30 patients each were included in vicryl repair & 30 in prolene repair.

Randomization technique: Sequentially Numbered Opaque Sealed Envelopes (SNOSE).

Selection criteria

Inclusion:

1. Written informed consent
2. Age group- 18-70 years
3. Unilateral / bilateral Inguinal hernia
4. Primary inguinal hernia
5. Uncomplicated hernia

Exclusion:

1. Irreducible hernias
2. Bleeding disorders
3. Patients on anticoagulant treatment
4. Pregnancy
5. Emergency repair
6. HIV and HbsAg

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 and demerits of using polyglactin as the suture material to fix the polypropylene mesh in Lichtenstein mesh repair and a written informed consent was obtained (**Annexure I)**.

Randomization

The patients were randomized by computer generated random numbers which were used to assign the type of surgery; the patients were divided into two groups of 30 each as below; Patients undergoing mesh fixation with polyglactin as suture material in Lichtenstein mesh repair formed group A [study group]. Patients undergoing mesh fixation with polypropylene suture material in Lichtenstein mesh repair formed group B [control group].

Investigations

The following tests were subjected to the following investigations.

Complete hemogram – Hb, total leukocyte counts, RBC count.

BUN, Serum creatinine, RBS, serum electrolytes.

Prothombin time and INR

Chest X-ray and ECG.

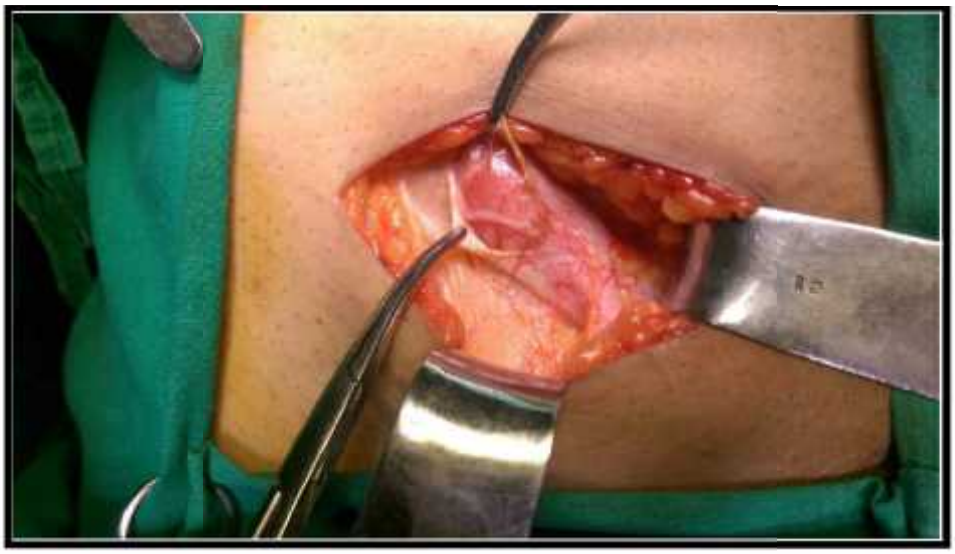
Ultrasonography of abdomen and pelvis

viral markers (HIV & HbsAg).

Surgical procedure

The skin and subcutaneous tissue (camper's and scarpa's fascia) was incised. The external oblique aponeurosis was opened. The cord was identified. The ilioinguinal nerve was identified. The direct inguinal hernial sac was reduced back without opening it. The indirect ones were divided, transfixed & excised. Then behind

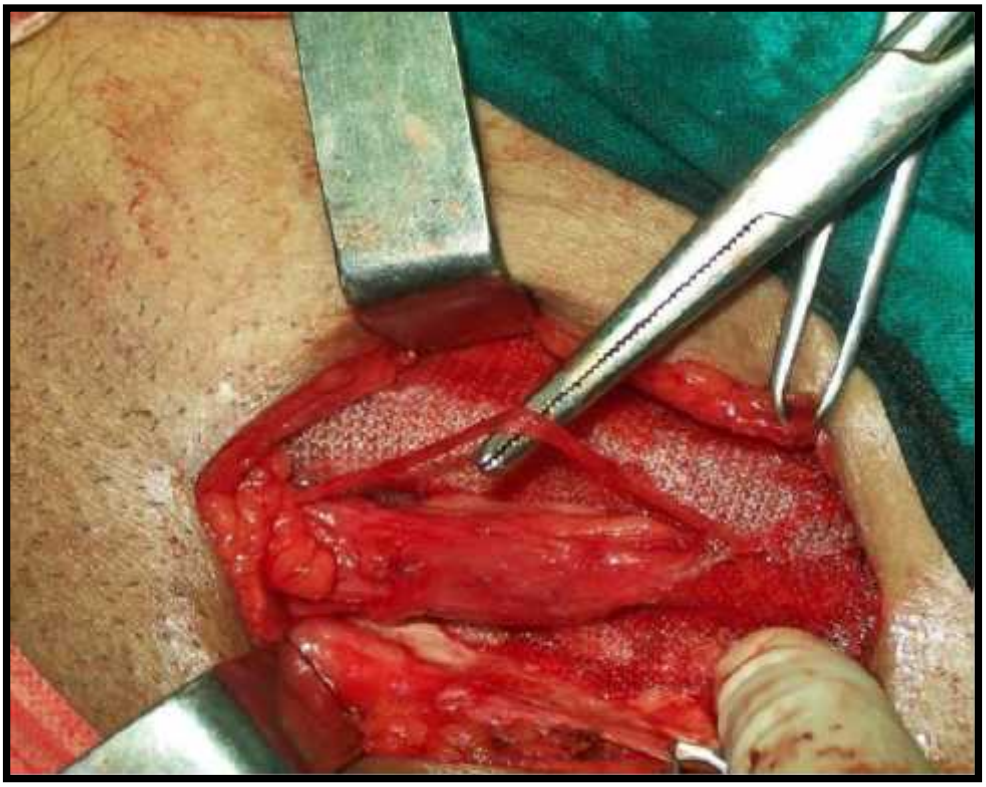
the cord, a polypropylene mesh was placed over the posterior wall. The mesh was fixed in an interrupted fashion to the conjoint tendon and inguinal ligament with the first stitch being taken 1 cm lateral to the pubic tubercle in order to prevent periostitis. Mesh was fixed using vicryl 2-0 for one set of patients (group A) and prolene 2-0 for another set of patients (group B). The external oblique aponeurosis & subcutaneous tissues were approximated by continuous absorbable sutures. Skin closure wasdone by non absorbable sutures.



Photograph 1:External oblique aponeurosis

Photograph 2: Fixing the mesh to the inguinal ligament with polyglactin

Photograph 3: Fixation of mesh with polypropylene sutures



Photograph 4: Mesh fixation complete, ilioinguinal nerve preserved

Pain management

Post operatively patients of both the groups were given the same analgesics that is, Injection paracetamol 1gm IV 12th hourly. Later oral paracetamol 650 mg was given as per requirement.

Outcome variables

We categorized post operative pain on day 1, day 3 and day 7 as acute and after 3 months as chronic pain.

"Pain was assessed based on Visual Analogue Score ranging from 0 to 10 considering 0 as no pain and 10 as maximum pain".

"Mild – VAS score = 3"

"Moderate – VAS score between 4 to 6"

"Severe – VAS score = 7"

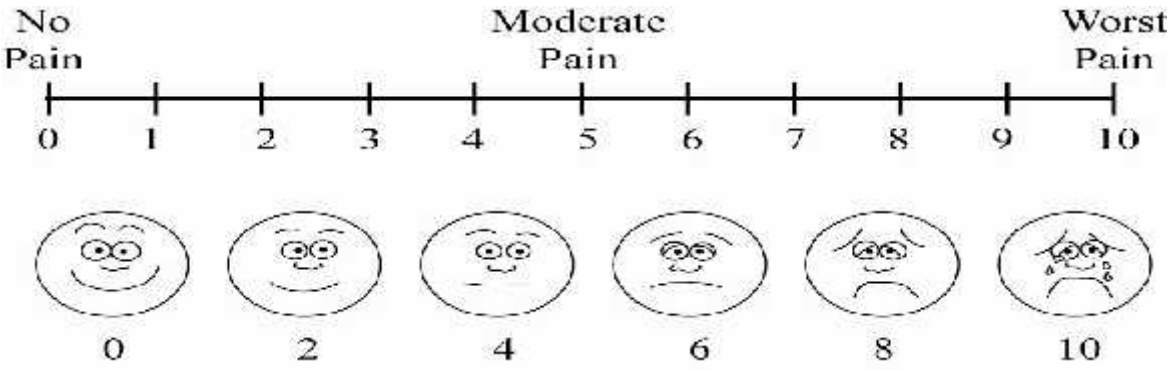


Fig 20: VISUAL ANALOGUE SCALE

Follow up

Patients were followed up at following intervals;

Postoperative day1

Postoperative day3

Postoperative day 7

3 months follow up

Statistical analysis

The data obtained was coded and entered in Microsoft Excel Spreadsheet. The categorical data was expressed as rates, ratios and percentages and comparison was carried out with chi–square tests, Mann-Whitney U tests, Wilcoxon matched pairs 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.

RESULTS

The present one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2019 to December 2019.

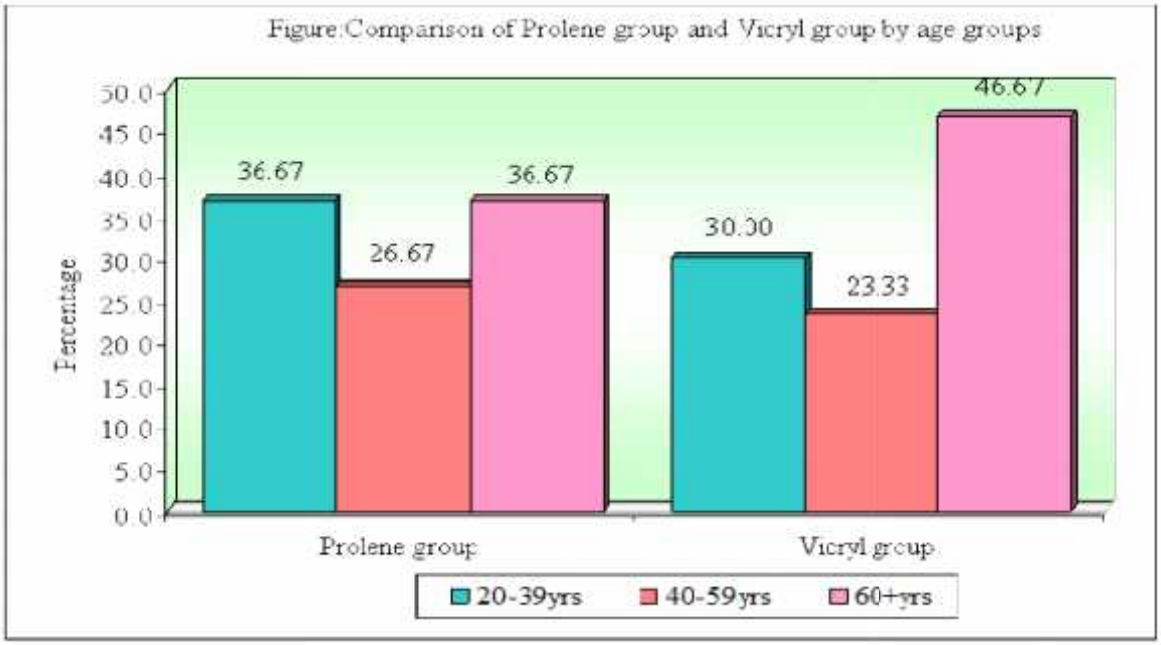
A total of 60 patients admitted with inguinal hernia requiring mesh repair were included in the study. Randomization of the patients was done, 2 groups were made 30 of each as below;

- **Group A**: Patients for whom mesh was fixed with polyglactin in Lichtenstein's hernia repair.
- **Group B**: Patients for whom mesh was fixed with polypropylene in Lichtenstein's hernia repair.

The data obtained was coded and entered in Microsoft Excel Spread sheet. The data was analyzed and the observations were tabulated as below.

Age groups	Group B (Prolene)	%	Group A (Vicryl)	%	Total	%
20-39yrs	11	36.67	9	30.00	20	33.33
40-59yrs	8	26.67	7	23.33	15	25.00
60+yrs	11	36.67	14	46.67	25	41.67
Total	30	100.00	30	100.00	60	100.00
Mean age	48.97		53.87		51.42	
SD age	19.27		20.71		19.99	
Chi-square test= 0.6271, P = 0.7310						

Table 03: Comparison of Prolene group and Vicryl group by age groups



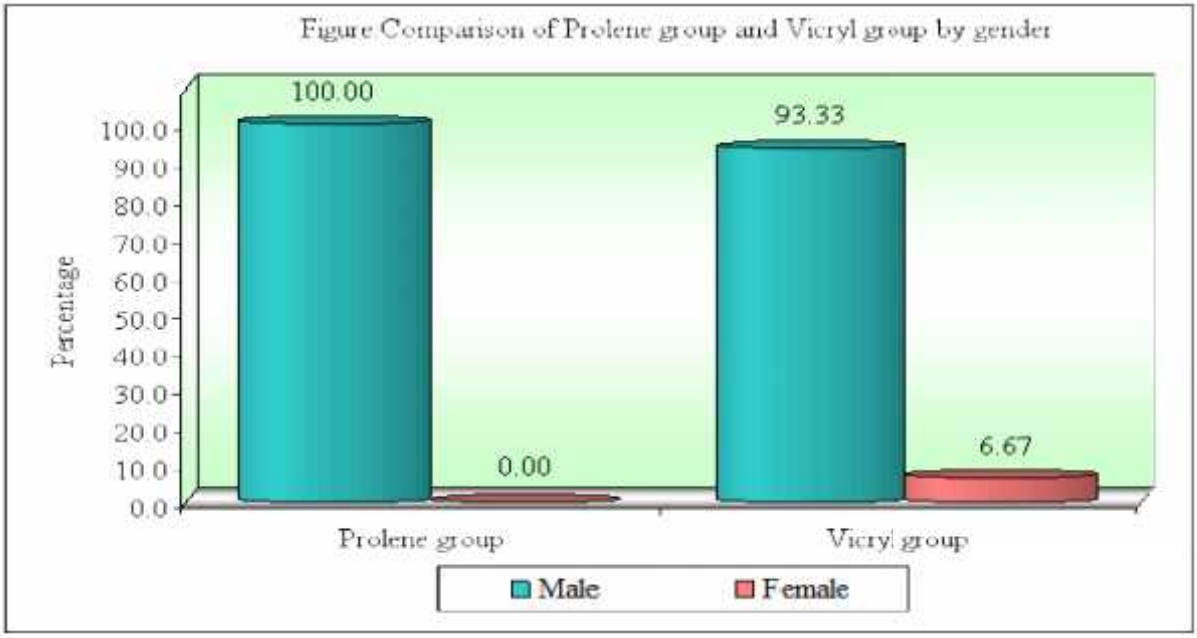
Graph 01

In the present study, distribution of age groups in group A(vicryl) and group B(prolene) are 30% v/s 36.77% between 20-29yrs,23.33% v/s 26.67% between 40-49yrs,46.67% v/s 36.67% between 60 yrs and above respectively are comparable.

In the present study, the mean age in group A was 53.87 ± 20.17 years compared to 48.97 ± 19.27 years in group B, the youngest patient being 19 years of age. However the difference was statistically not significant (p=0.7310).

Gender	Group B (Prolene)	%	Group A (Vicryl)	%	Total	%
Male	30	100.00	28	93.33	58	96.67
Female	0	0.00	2	6.67	2	3.33
Total	30	100.00	30	100.00	60	100.00
Chi-square test with Yates's correction = 0.5170 P = 0.4720						

Table 04: Comparison of Prolene group and Vicryl group by gender

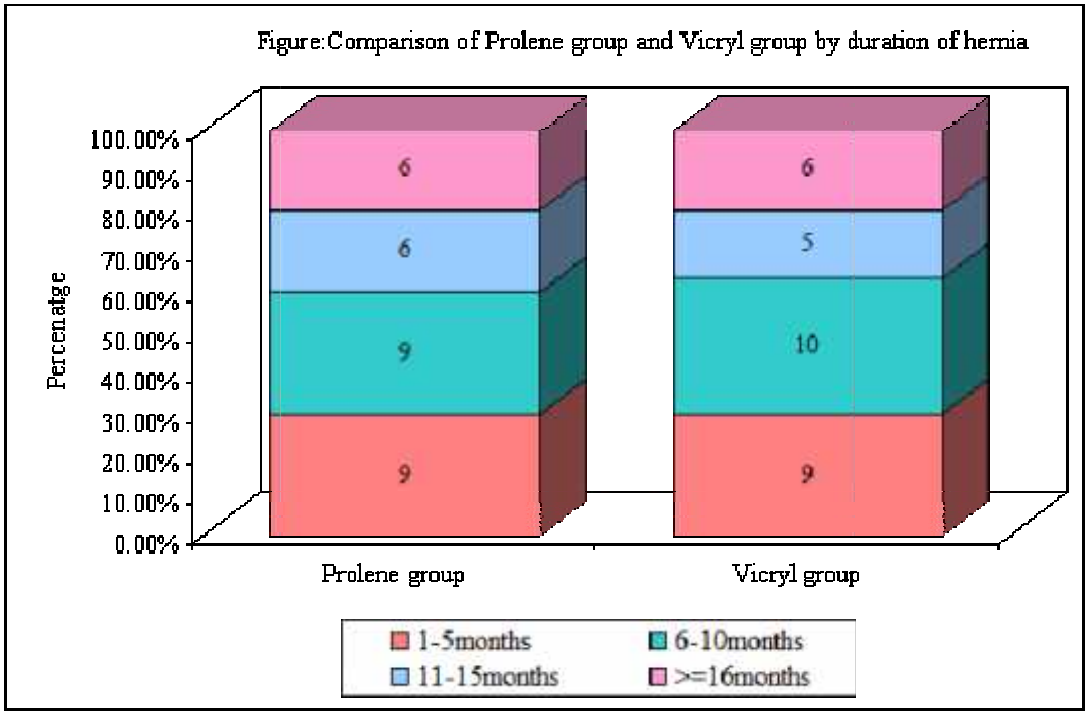


Graph 02

In the present study, 93.33% were males and only 6.67% were females group A and group B all patients were males.

Duration of hernia	Group B (Prolene)	%	Group A (Vicryl)	%	Tota l	%
1 5months	9	30.00	9	30.00	18	30.00
6-10months	9	30.00	10	33.33	19	31.67
11-15months	6	20.00	5	16.67	11	18.33
>=16months	6	20.00	6	20.00	12	20.00
Total	30	100.0 0	30	100.0 0	60	100.0 0
Mean age	15.73		26.87		21.30	
SD age	31.89		66.25		51.85	
Chi-square test= 0.4361 P = 0.9332						

Table 05: Comparison of Prolene group and Vicryl group by duration of hernia

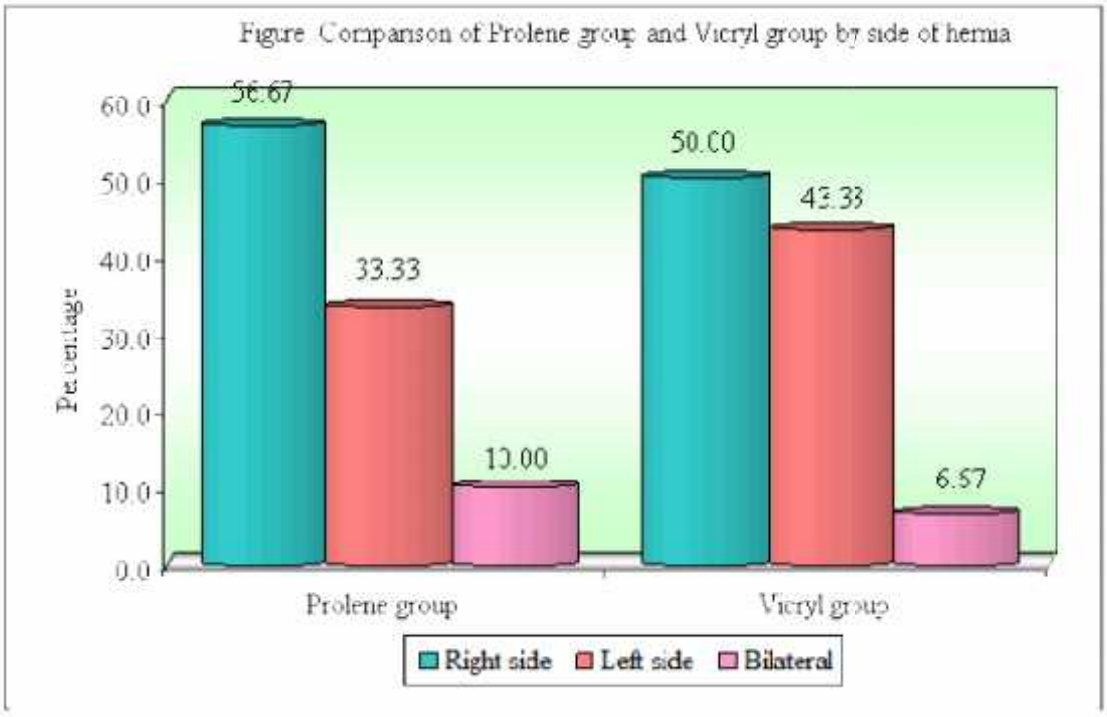


Graph 03

In the present study, the duration of hernia in prolene and Vicryl was 30% v/s 30% since 1 – 5 months, 30% v/s 33.67% since 6 – 10 months, 20% v/s 16.67% since 11 - 15 months, 20% v/s 20% >= 16 months respectively.In the present study the mean duration of the disease was 15.73± 31.29 months in group prolene whereas in group vicryl it was 26.87 ± 66.25 months. However, this difference was not statistically significant (p=0.9332).

Side of hernia	Group B (Prolene)	%	Group A (Vicryl)	%	Tota l	%
Right side	17	56.67	15	50.00	32	53.33
Left side	10	33.33	13	43.33	23	38.33
Bilateral	3	10.00	2	6.67	5	8.33
Total	30	100.0 0	30	100.0 0	60	100.0 0
Chi-square test= 0.7163 P = 0.6990						

Table 06: Comparison of Prolene group and Vicryl group by side of hernia



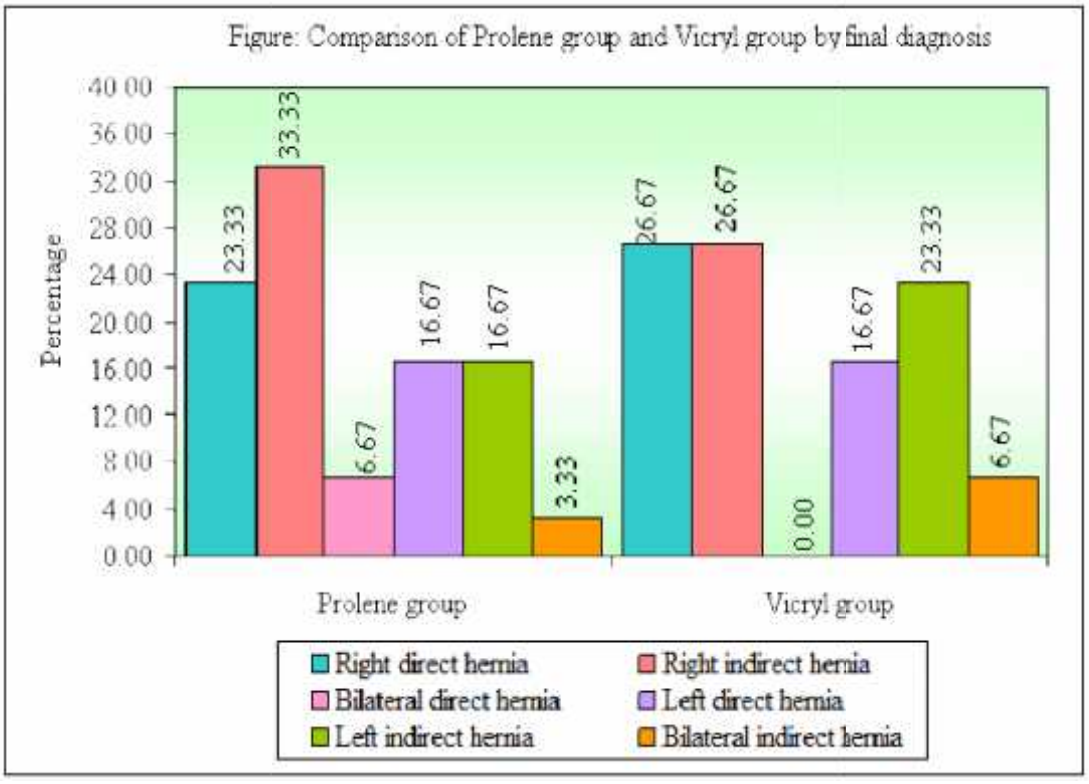
Graph 04

In the present study, 56.67% of patients in prolene group presented with a right-sided swelling compared to 50.00% of patients in vicryl group. 33.33% of patients in prolene group presented with a left-sided swelling compared to 43.33% of patients in vicryl group, 10% of prolene group and 6.67% of vicryl group presented with swelling on both sides. However this difference was statistically not significant (p=0.6990).

Final diagnosis	Group B (Prolene)	%	Group A (Vicryl)	%	Total	%
Right direct hernia	7	23.33	8	26.67	15	25.00
Right indirect hernia	10	33.33	8	26.67	18	30.00
Bilateral direct hernia	2	6.67	0	0.00	2	3.33
Left direct hernia	5	16.67	5	16.67	10	16.67
Left indirect hernia	5	16.67	7	23.33	12	20.00
Bilateral indirect hernia	1	3.33	2	6.67	3	5.00
Total	30	100.00	30	100.00	60	100.00

Chi-square test= 2.9564 P = 0.7075

Table 07: Comparison of Prolene group and Vicryl group by final diagnosis

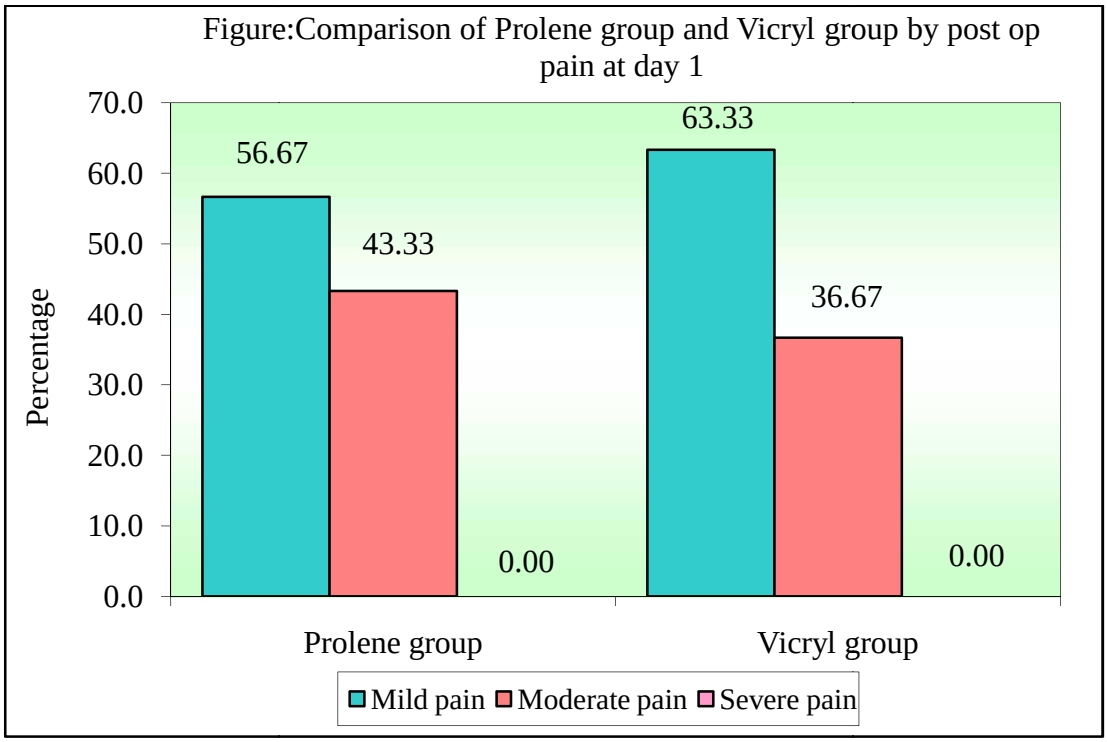


Graph 05

In the present study, 23.3% v/s 26.67% of right direct hernias in prolene group as compared to vicryl group. 33.3% v/s 26.67% of right indirect hernias in prolene compared to vicryl group. Only prolene group had patients with bilateral direct hernias. 16.67% v/s 16.67% of patients had left direct hernia in prolene group as compared to vicryl group. 16.67% v/s 23.33% had left indirect hernia in prolene group against Vicryl group. Just 1 patient had bilateral indirect hernia as compared to 2 patients having the same in vicryl group. However this difference was statistically not significant (p=0.7075).

Post op pain at day 1	Group B (Prolene)	%	Group A (Vicryl)	%	Total	%
Mild pain	17	56.67	19	63.33	36	60.00
Moderate pain	13	43.33	11	36.67	24	40.00
Severe pain	0	0.00	0	0.00	0	0.00
Total	30	100.00	30	100.00	60	100.00
Chi-square test= 0.2780 P = 0.5981						

Table 08: Comparison of Prolene group and Vicryl group by post op pain at day1

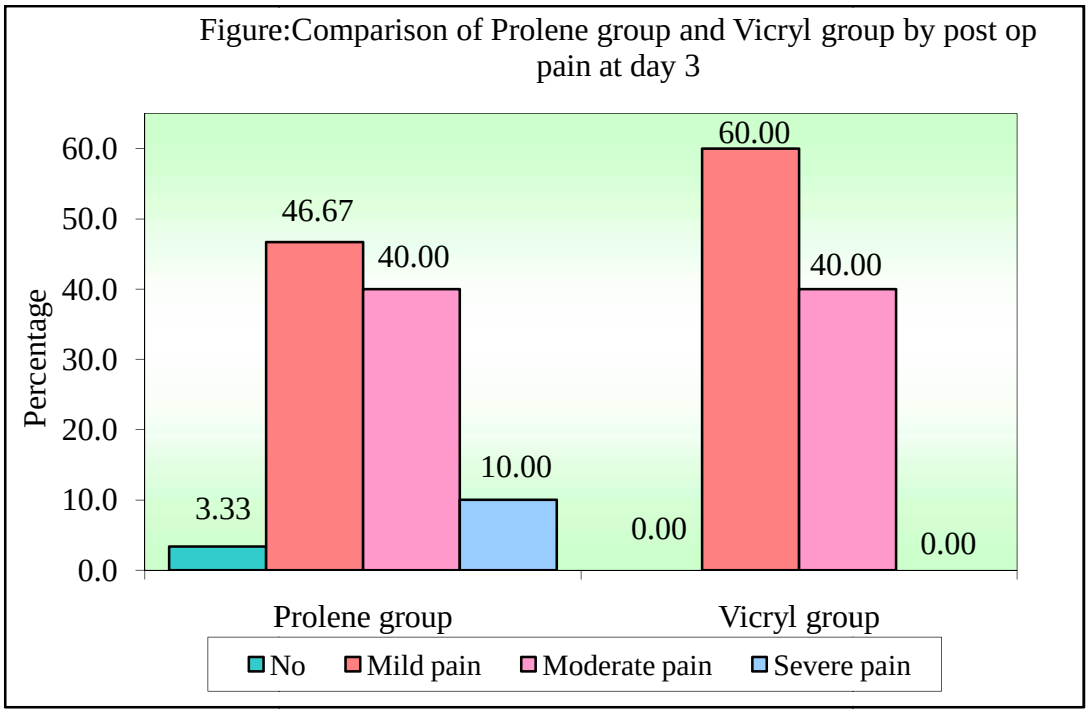


Graph 06

In the present study, out of total of 30 patients in each group, in which, 56.67% have mild pain and 43.33% have moderate pain in post op pain at day 1 in Prolene group as compared to 63.33% have mild pain and 36.67% have moderate pain in post op pain at day 1 in Vicryl group. The difference or association is found as statistically not significant (Chi-square test= 0.2780 P = 0.5981) at 5% level of significance. So, the post op pain at day 1 is similar in Prolene group as compared to Vicryl group.

Post op pain at day 3	Group B (Prolene)	%	Group A (Vicryl)	%	Total	%
No	1	3.33	0	0.00	1	1.67
Mild pain	14	46.67	18	60.00	32	53.33
Moderate pain	12	40.00	12	40.00	24	40.00
Severe pain	3	10.00	0	0.00	3	5.00
Total	30	100.00	30	100.00	60	100.00
Chi-square test= 4.5000 P = 0.2120						

Table 09: Comparison of Prolene group and Vicryl group by post op pain at day 3



Graph 07

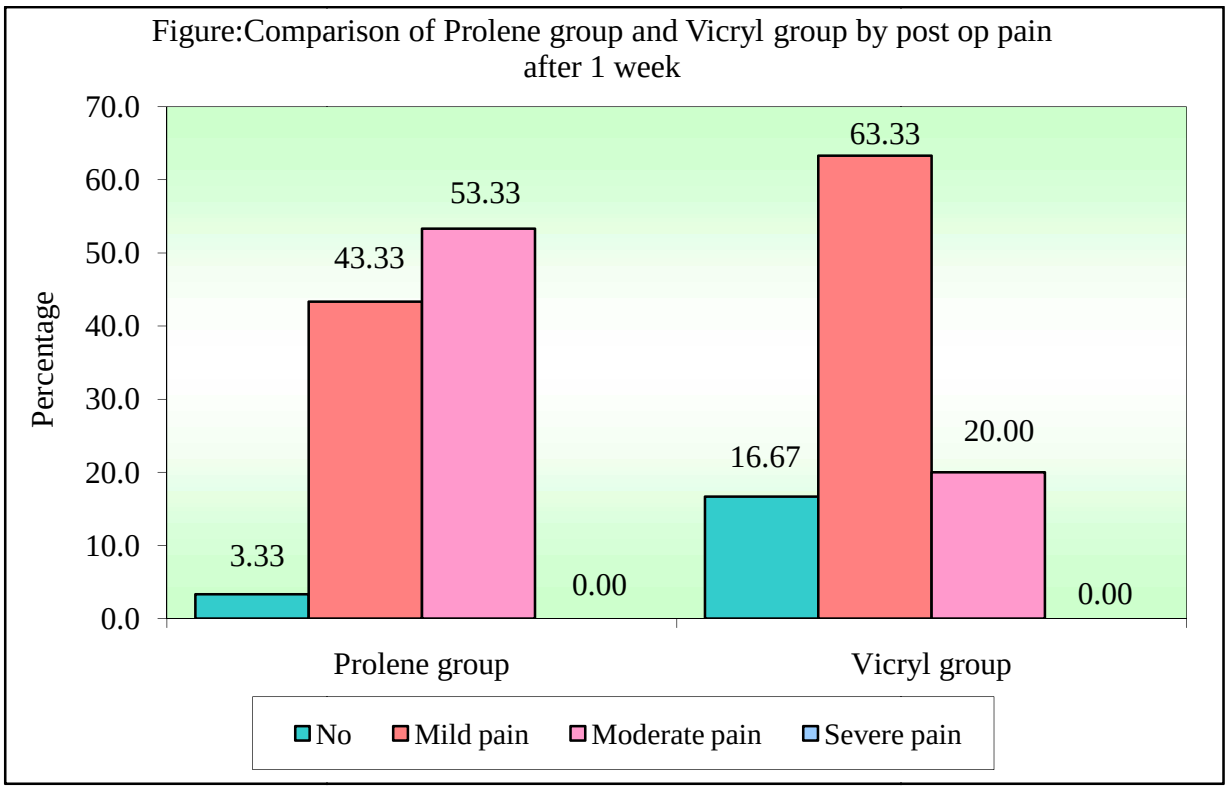
In the present study, out of total of 30 patients in each group, in which, 46.67% have mild pain and 40.00% have moderate pain in post op pain at day 3 in Prolene group as compared to 60.00% have mild pain and 40.00% have moderate pain in post op pain at day 3 in Vicryl group. The difference or association is found as statistically not significant (Chi-square test= 4.5000, P = 0.2120) at 5% level of

significance. So, the severity on post op pain at day 3 is similar in Prolene group and Vicryl group.

Post op pain after 1 week	Group B (Prolene)	%	Group A (Vicryl)	%	Total	%
No	1	3.33	5	16.67	6	10.00
Mild pain	13	43.33	19	63.33	32	53.33
Moderate pain	16	53.33	6	20.00	22	36.67
Severe pain	0	0.00	0	0.00	0	0.00
Total	30	100.00	30	100.00	60	100.00
Chi-square test= 8.3372 P = 0.0150*						

*p<0.05

Table 10: Comparison of Prolene group and Vicryl group by post op pain after 1 week



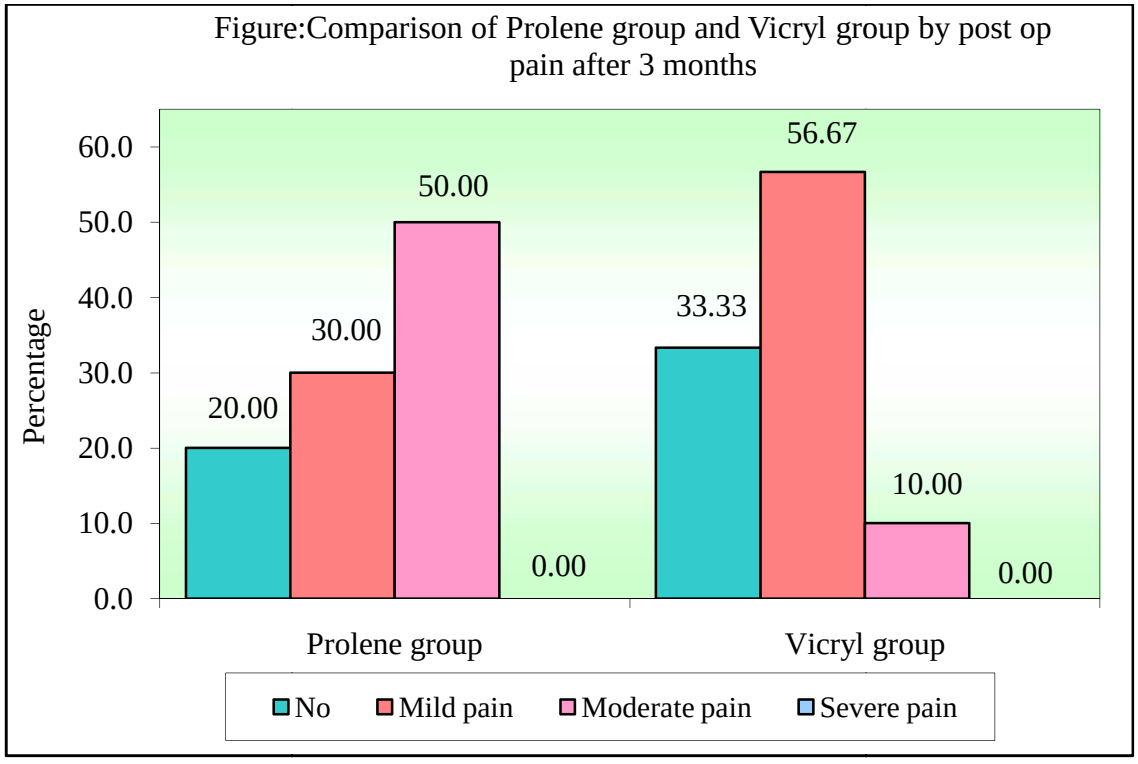
Graph 8

In the present study, out of total of 30 patients in each group, in which, 43.33% have mild pain, 53.33% have moderate pain, but 3.33% have no pain after 1 week in Prolene group as compared to 63.33% have mild pain, 20.00% have moderate pain, but 16.67% have no pain after 1 week in Vicryl group. The difference or association is found as statistically significant (Chi-square test= 8.3372 P = 0.0150) at 5% level of significance. So, the severity on post op pain at 1 week is significantly higher in Prolene group as compared to Vicryl group.

Post op pain after 3 months	Group B (Prolene)	%	Group A (Vicryl)	%	Total	%
No	6	20.00	10	33.33	16	26.67
Mild pain	9	30.00	17	56.67	26	43.33
Moderate pain	15	50.00	3	10.00	18	30.00
Severe pain	0	0.00	0	0.00	0	0.00
Total	30	100.00	30	100.00	60	100.00
Chi-square test= 11.4620 P = 0.00300*						

*p<0.05

Table 11: Comparison of Prolene group and Vicryl group by post op pain after 3 months



Graph 9

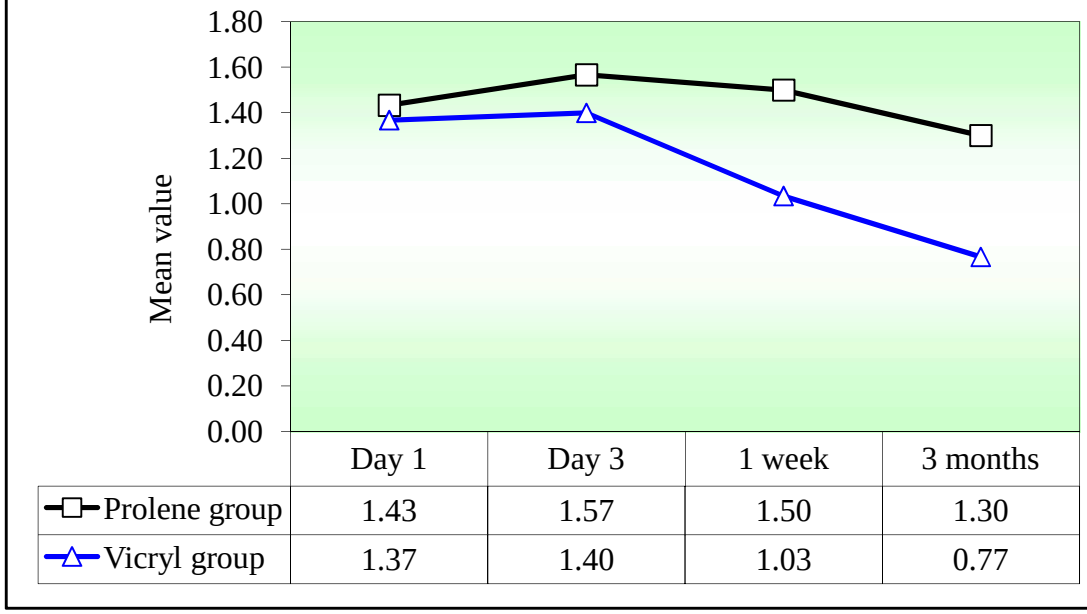
In the present study, out of total of 30 patients in each group, in which, 30.00% have mild pain, 50.00% have moderate pain, but 20.00% have no pain after 3 months in Prolene group as compared to 56.67% have mild pain, 10.00% have moderate pain, but 33.33% have no pain after 3 month in Vicryl group. The difference or association is found as statistically significant (Chi-square test= 11.4620 P = 0.00300) at 5% level of significance. So, the severity on post op pain at 3 months is greater in Prolene group than Vicryl group.

Time points	Group B (prolene)			Group A (Vicryl)			U-value	Z-value	P-value
	Mean	SD	Mean rank	Mean	SD	Mean rank			
Day 1	1.43	0.50	31.50	1.37	0.49	29.50	420.00	-0.4435	0.6574
Day 3	1.57	0.73	32.30	1.40	0.50	28.70	396.00	-0.7984	0.4247
1 week	1.50	0.57	36.27	1.03	0.61	24.73	277.00	-2.5577	0.0105*
3 months	1.30	0.79	36.30	0.77	0.63	24.70	276.00	-2.5725	0.0101*
Day 1 to Day 3	-0.13	0.82	28.40	-0.03	0.18	32.60	387.00	-0.9314	0.3516
Day 1 to 1 week	-0.07	0.74	25.57	0.33	0.55	35.43	302.00	-2.1881	0.0287*
Day 1 to 3 months	0.13	0.78	25.53	0.60	0.56	35.47	301.00	-2.2029	0.0276*
Day 3 to 1 week	0.07	0.58	26.73	0.37	0.49	34.27	337.00	-1.6706	0.0948
Day 3 to 3 months	0.27	0.78	26.40	0.63	0.49	34.60	327.00	-1.8185	0.0690
1 week to 3 months	0.20	0.48	29.63	0.27	0.45	31.37	424.00	-0.3844	0.7007

*p<0.05

Table 12: Comparison of Prolene group and Vicryl group with pain scores at different time points by Mann-Whitney U test

Figure:Comparison of Prolene group and Vicryl group with pain scores at different time points



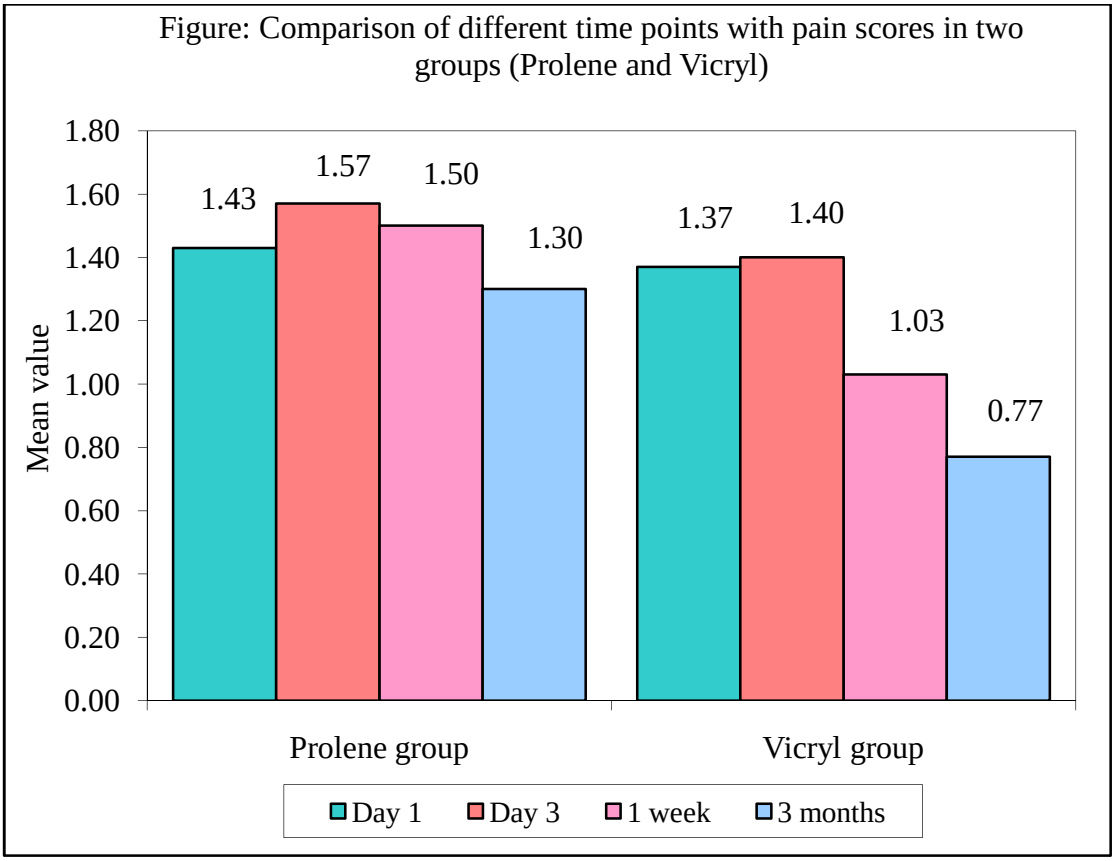
Graph 10

From the above table, a significant difference in pain scores not was not seen in both groups (Prolene v/s Vicryl) on day 1 and day 3 postoperatively. A significant difference in pain scores was observed between two groups with respect to pain scores at 1^{st} week ($p<0.05$) and at 3^{rd} month ($p<0.05$) at 5% level of significance.

Groups	Time points	Mean Diff.	% of change	Z-value	P-value
Group B (Prolene)	Day 1 to Day 3	-0.13	-9.30	0.8047	0.4210
	Day 1 to 1 week	-0.07	-4.65	0.4543	0.6496
	Day 1 to 3 months	0.13	9.30	0.8275	0.4080
	Day 3 to 1 week	0.07	4.26	0.5606	0.5751
	Day 3 to 3 months	0.27	17.02	1.6095	0.1075
	1 week to 3 months	0.20	13.33	1.8904	0.0587
Group A (Vicryl)	Day 1 to Day 3	-0.03	-2.44	0.0000	1.0000
	Day 1 to 1 week	0.33	24.39	2.5495	0.0108*
	Day 1 to 3 months	0.60	43.90	3.5279	0.0004*
	Day 3 to 1 week	0.37	26.19	2.9341	0.0033*
	Day 3 to 3 months	0.63	45.24	3.8230	0.0001*
	1 week to 3 months	0.27	25.81	2.5205	0.0117*

*$p<0.05$

Table 13: Comparison of different time points with pain scores in two groups (Prolene and Vicryl) by Wilcoxon matched pairs test

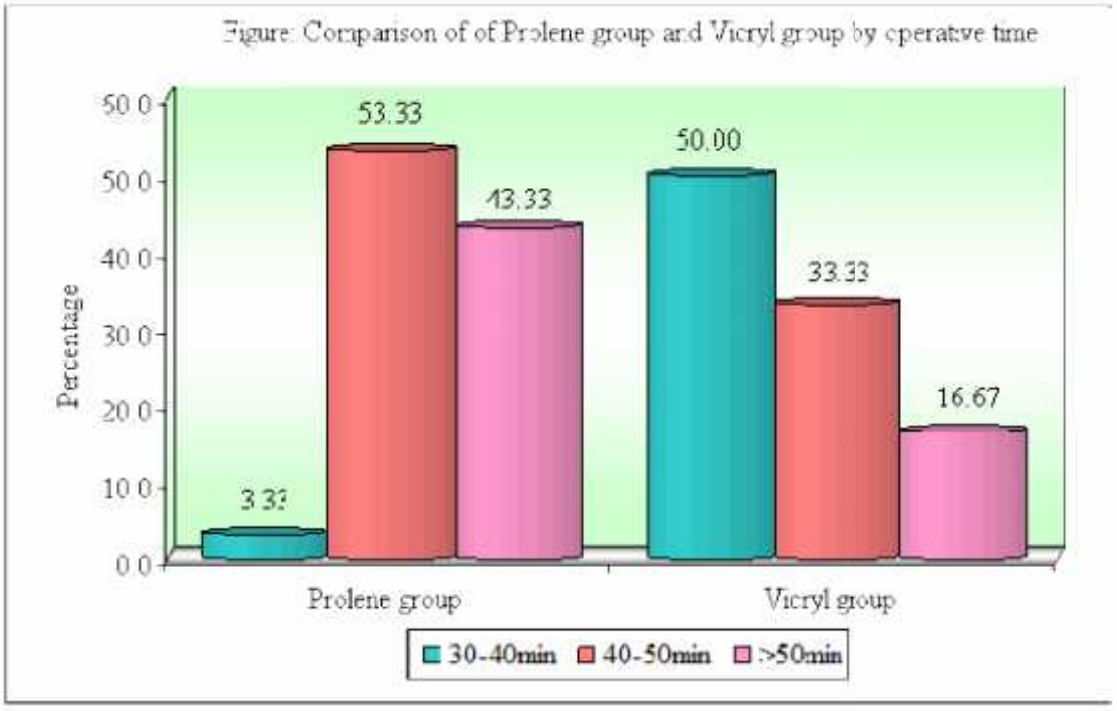


Graph 11

A significant of 4.06%, 17.02% , 13.33% pain reduction was seen respectively day3 , 1 week and 3 months treatment in Prolene group, but a significant 9.03% increase in pain scores after day 3 in Prolene group. However, a significant of 26.19%, 45.24% and 25.81% pain reduction was seen respectively after day 3, after 1 week and 3 months treatment and a 2.44% increase in pain scores after day in Vicryl group. It clearly shows that, the pain reduction little higher in Vicryl group as compared to Prolene group.

Operative time	Group B (Prolene)	%	Group A (Vicryl)	%	Tota l	%
30-40min	1	3.33	15	50.00	16	26.67
40-50min	16	53.33	10	33.33	26	43.33
>50min	13	43.33	5	16.67	18	30.00
Total	30	100.0 0	30	100.0 0	60	100.0 0
Chi-square test=17.1905 P = 0.0001*						

Table 14: Comparison of Prolene group and Vicryl group by operative time

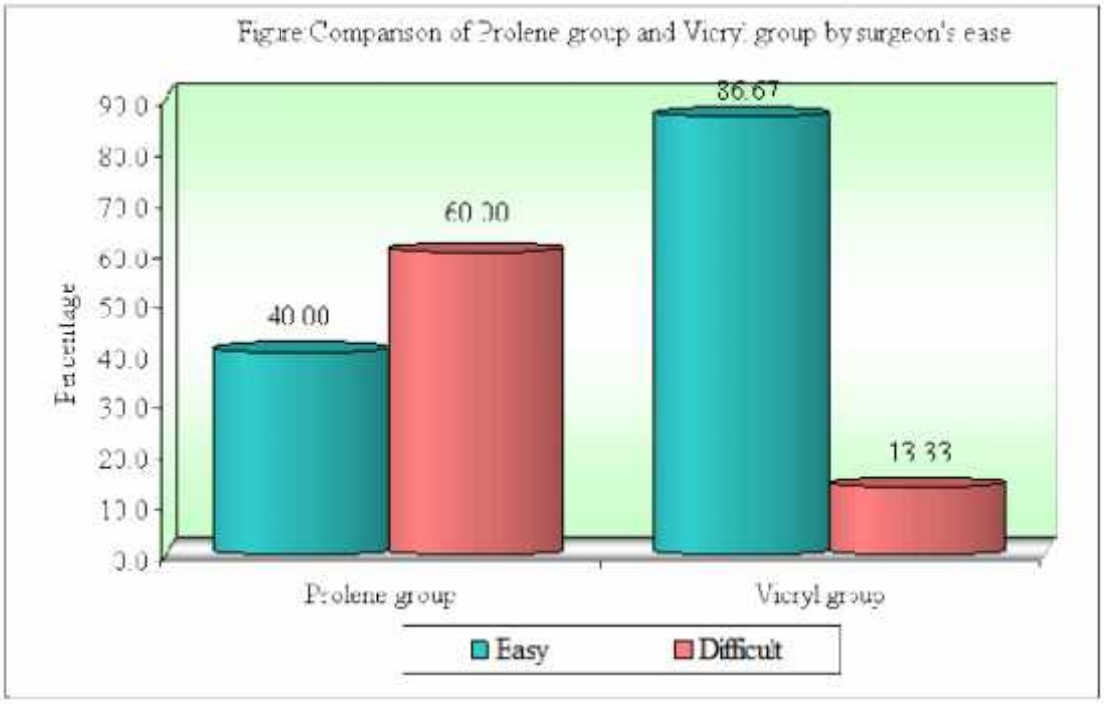


Graph 12

In this study, out of a total of 30 patients in each group, in which, 53.33% have a operative time of 40-50min and 43.330% have a operative time of >50min in Prolene group as compared to 50.00% have a operative time of 30-40min and 33.33% have a operative time of 40-50min in Vicryl group. The difference or association is found as statistically not significant (Chi-square test= 17.1905 P = 0.0001) at 5% level of significance.

Surgeon's ease	Group B (Prolene)	%	Group A (Vicryl)	%	Tota l	%
Easy	12	40.00	26	86.67	38	63.33
Difficult	18	60.00	4	13.33	22	36.67
Total	30	100.0 0	30	100.0 0	60	100.0 0
Chi-square test=14.0670 P = 0.0001*						

Table 15: Comparison of Prolene group and Vicryl group by surgeon's ease

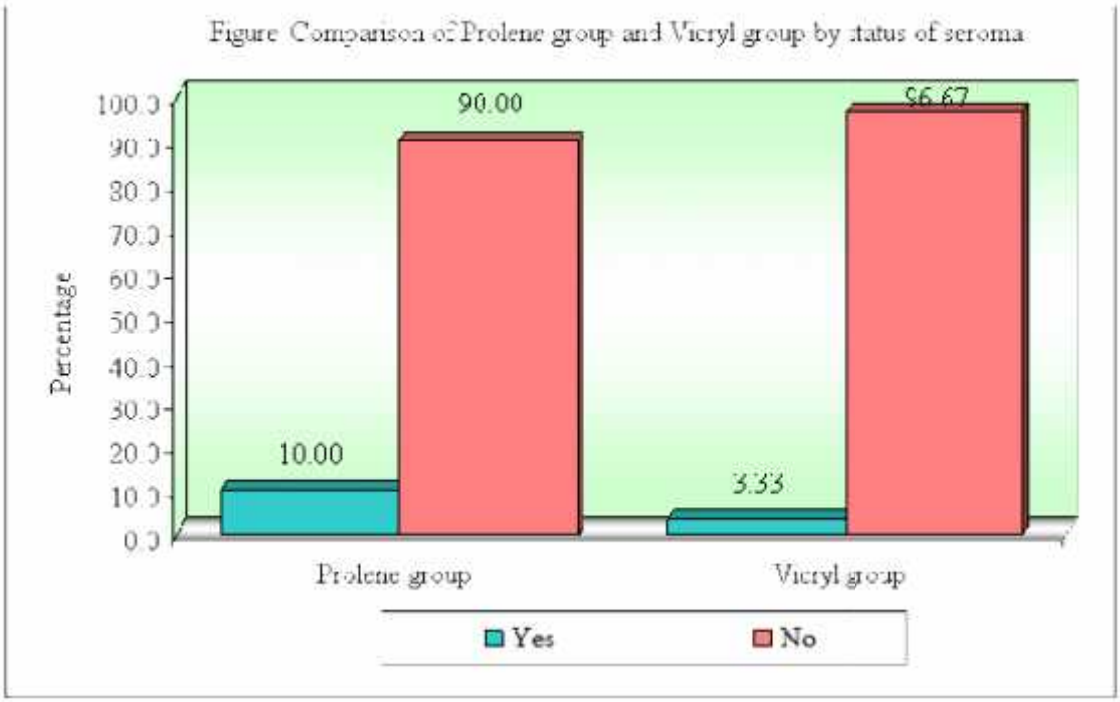


Graph 13

In this study, out of a total of 30 patients in each group, in which, 60% of the surgeons experienced some form of difficulty in fixing the mesh with prolene sutures while only 12.33% of surgeons have experienced difficulty in fixing the mesh with vicryl suture material. Although the numbers show substantial variation. The difference or association is found as statistically not significant (Chi-square test= 14.0670 P = 0.0001) at 5% level of significance.

Seroma	Group B (Prolene)	%	Group A (Vicryl)	%	Total	%
Yes	3	10.00	1	3.33	4	6.67
No	27	90.00	29	96.67	56	93.33
Total	30	100.00	30	100.00	60	100.00
Chi-square with Yates's correction = 0.2685 P = 0.6054						

Table 16: Comparison of Prolene group and Vicryl group by status of seroma

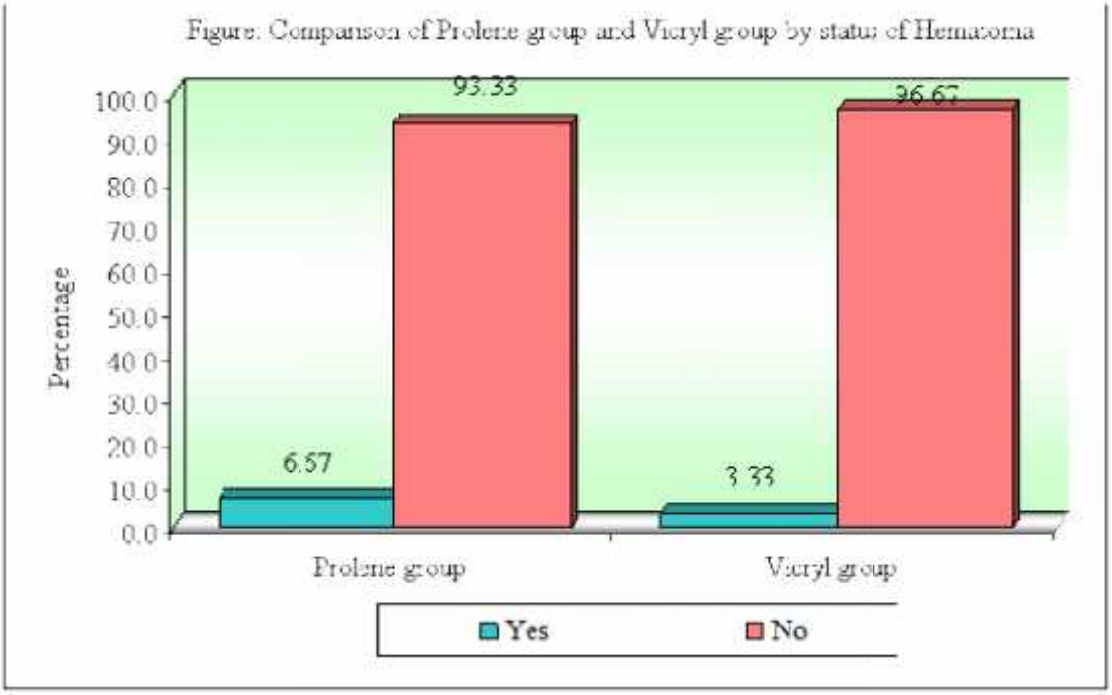


Graph 14

In this study, out of a total of 30 patients in each group, in which, only 10% of the patients developed seroma as a post operative complication in prolene group while just 3.33% developed seroma postoperatively in vicryl group. The difference or association is found as statistically significant (Chi-square test= 0.2685 P = 0.6054) at 5% level of significance.

Hematoma	Group B (Prolene)	%	Group A (Vicryl)	%	Total	%
Yes	2	6.67	1	3.33	3	5.00
No	28	93.33	29	96.67	57	95.00
Total	30	100.00	30	100.00	60	100.00
Chi-square with Yates's correction = 0.0001 P = 1.0000						

Table 17: Comparison of Prolene group and Vicryl group by status of hematoma

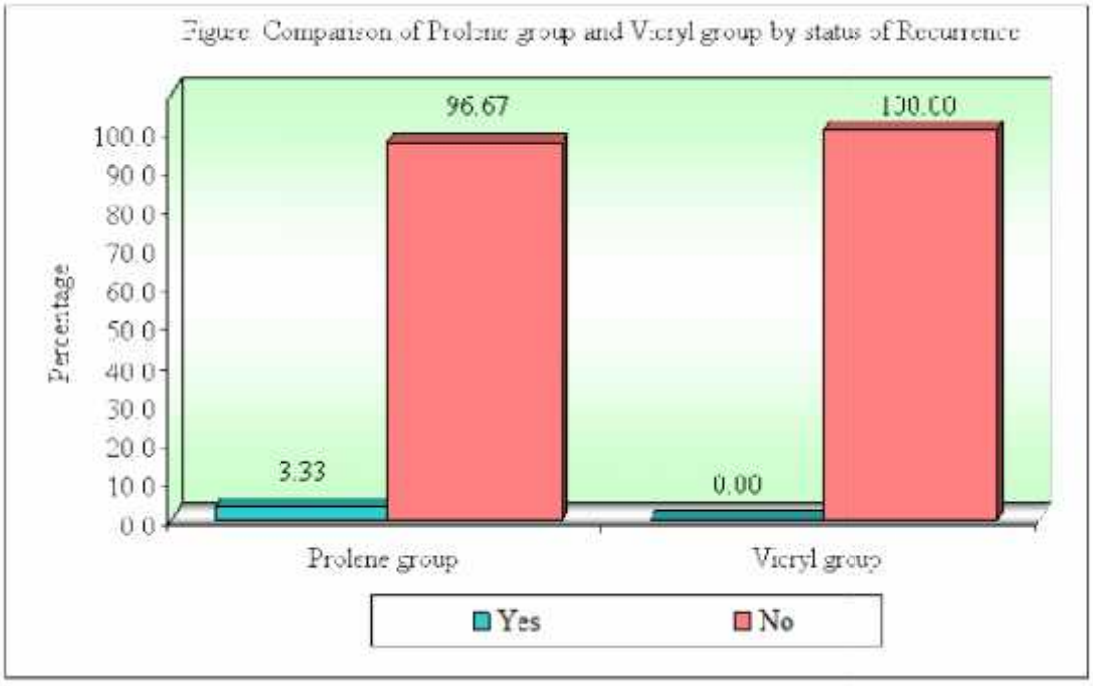


Graph 15

In this study, out of a total of 30 patients in each group, in which, only 6.67% of the patients developed hematoma as a post operative complication in prolene group while just 3.33% developed hematoma postoperatively in vicryl group. The difference or association is found as statistically significant (Chi-square test=0.0001 P = 1.0000) at 5% level of significance.

Recurrence	Group B (Prolene)	%	Group A (Vicryl)	%	Total	%
Yes	1	3.33	0	0.00	1	1.67
No	29	96.67	30	100.00	59	98.33
Total	30	100.00	30	100.00	60	100.00
Chi-square with Yates's correction = 0.0000 P = 1.0000						

Table 18: Comparison of Prolene group and Vicryl group by status of recurrence

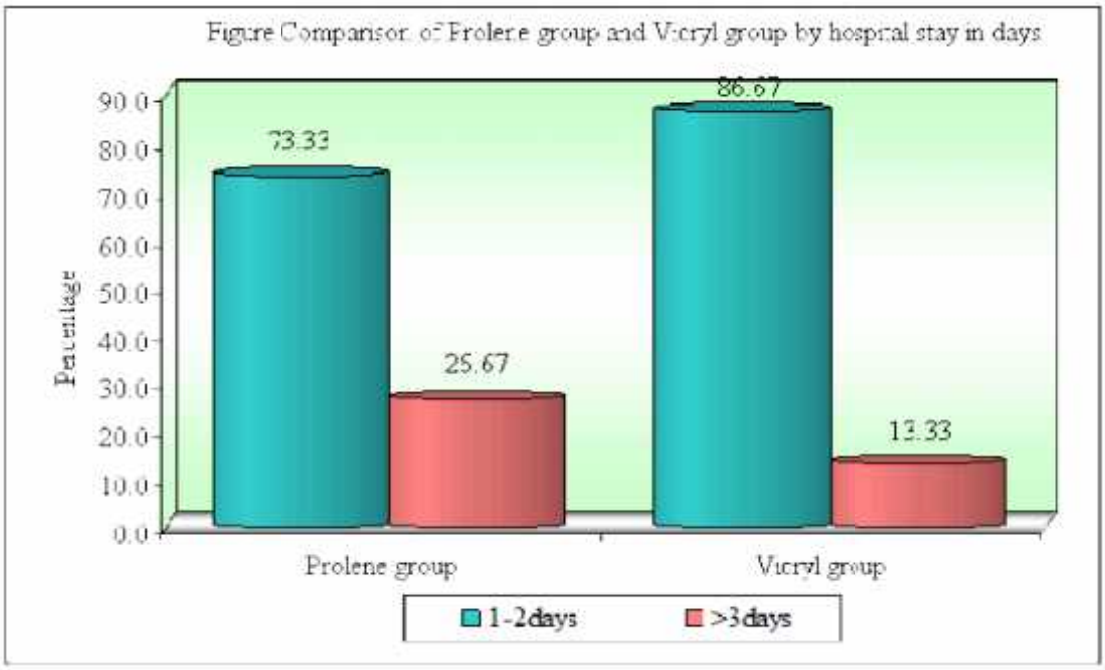


Graph 16

In this study, out of a total of 30 patients in each group, in which, only 3.33% of the patients had recurrence as a post operative complication in prolene group while no patients developed recurrence postoperatively in vicryl group. The difference or association is found as statistically significant (Chi-square test= 0.0000 P = 1.0000) at 5% level of significance.

Hospital stay	Group B (Prolene)	%	Group A (Vicryl)	%	Total	%
1-2days	22	73.33	26	86.67	48	80.00
>3days	8	26.67	4	13.33	12	20.00
Total	30	100.00	30	100.00	60	100.00
Chi-square test= 1.6676 P = 0.1977						

Table 19: Comparison of Prolene group and Vicryl group by hospital stay in days



Graph 17

In this study, out of a total of 30 patients in each group, in which, 73.33% of the patients were discharged within 2 days with post operative complication in prolene group while 86.67% of the patients got discharged within 2 days in Vicryl group. Similarly 26.67% of the patients from prolene group stayed in the hospital beyond 3 days whereas only 13.33% of patients had a stay over 3 days in the hospital postoperatively in vicryl group. The difference or association is found as statistically significant (Chi-square test= 1.6676 P = 0.1977) at 5% level of significance.

DISCUSSION

Chronic pain in the groin is a notable problem post lichtenstien's repair, even though the pain is usually mild, studies have revealed that irrespective of the severity, chronic pain may considerably hamper day to day activity.[69]Chronic pain is the principle issue linked with the Lichtenstein technique with a conclusive rate between 15% and 40%.[11,75–77]

Cunningham et al, the pioneers in raising the problem of chronic pain[78]. Subsequently, pain took a primordial focus in the field of research in hernia repair. Poobalan et al critique the incidence of chronic groin pain post inguinal repair up to 2000 and found prevalence from 0% to 63% a year after surgery.[10]

Routine usage of non absorbable sutures to fix mesh in lichtenstien's repair have resulted in reduce post operative chronic pain, yet controversies persist. So we took up this study to appraise post operative groin pain in the patients where polyglactin sutures were used to fix the mesh (group A) v/s polypropylene sutures in doing the same(group B) in Lichtenstein inguinal hernia repair.

In group A polyglactin was used to fix the mesh and in group B polypropylene sutures were used for the same, entrapment of nerve was kept in mind and utmost caution was exercised while operating while placing the mesh also during placing the sutures.

Postoperative day one, day three, seven and 3 months post surgery was the follow up to assess pain.

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

"Numerous retrospective as well as prospective studies which have been published have reported an incidence between six% and twenty nine% for pain after surgery".[10,79]

Several pioneers and researchers have corroborated and laid down algorithm to manage the chronic pain syndrome, others focused on prevention rather than tackling it.

One plausible theory is pain after surgery persists for a long period due to is inflammatory changes, fibrosis , subsequently entrapment of nerve, induced either by mesh or suture material , that's in proximity of ilioinguinal nerve.[79,80]

Apart from this untimely mangling to nerve at the time of dissection may contribute as well to this.

"Vicryl (polyglactin) is a synthetic, absorbable, braided suture which can sustain its tensile strength for nearly 3 to 4 weeks in tissues. It's entirely absorbed by hydrolysis within 60 days".[18,21]

In our study 60 patients who presented with groin swelling were divided in to two groups of 30 each. All patients in group A were males 2 patients in group B were females. The mean age, standard deviation and mean duration of the disease in group A and group B were comparable.

In our study there was a significantly lesser scores of pain in group A compared to other group. The mean pain scores in group A during first and 3rd day showed no significant difference all though the percentage of people experiencing pain on these two points on the timeline was more in polypropylene than polyglactin group. However in the third and fourth follow up the pain scores were significantly less compared to group B and the mean reduction in pain score from first follow up to fourth follow up was significantly higher in group A (0.77±0.63) compared to group B (1.30±0.79) (p=0.0101).

"In a single-blind randomized clinical trial comparing absorbable (ABS) with non absorbable (NAMS) suture material in 200 patients undergoing tension-free

inguinal hernia repair study by Igor Jeroukhimov et al in 2008[14], it was found that the incidence of severe pain after 1 week of surgery was more in the NAMS group as compared with ABS group (14 v/s 5 patients, p= 0.026)".

The rate of chronic pain following surgery was lower in the ABS group when compared to NAMS group (26 v/s 37 patients, p= 0.056).

A study by Ashish Kharadi, Viral Shah in 2014[81], 100 male patients underwent Lichtenstein tension free inguinal hernioplasty, comparing absorbable sutures against delayed absorbable sutures to fix the showed that there wasn't any statistical significant difference was found between two groups except for the appearance of the post-operative pain after 1 month (12 v/s 4, p= 0.02).

Paajanen study[82] demonstrated that in 168 patients who underwent Lichtenstein hernia repair with a two year follow-up, absorbable sutures (Dexon 2.0) were used to fix the mesh in 84 of them. They deduced that there wasn't any difference in incidence of chronic groin pain when using these sutures.

We have also compared few of the common post operative complications encountered in case of lichtenstien's repair. The incidence of seroma (3.3% v/s 10%) and hematoma (3.3% v/s 6.67%) formation is slightly higher in polypropylene group. There was also one recurrence seen in the prolene group but none in group A, although this wasn't significant, and various other patient factors could influence the development of complications. This could be attributed to the nature of the suture material which leads to lesser tissue reaction, lesser tissue damage, hence lower incidence of complications.

Surgeon factors such as operative time and ease of surgery was also analyzed and our study showed that the operative time was marginally less in polyglactin catagory against the polypropylene category (50% of the surgeries took 30-40 mins in

group A and 53.33% of the surgeries were done in 40-50 mins in group B) nonetheless it wasn't found to be statistically significant. When it came to surgeon's ease of fixing the mesh 86.67 % surgeons felt vicryl was easier to fix where as only 40% of the surgeons vouched for prolene.

Similar picture was noted in number of days the patients stayed in the hospital, in group A 86.67% of the patients were discharged within 2 days and in group B slightly lesser percentage i.e. 73.33 of the patients were discharged within day 2 and again the delayed resolution of the post operative pain, as well as the presence of complications can be attributed for the above results. Thus our study has shown the presence of chronic pain in the groin is quite less in group A (fixing the mesh with polyglactin sutures) compared to group B (fixing the mesh with polypropylene sutures) and statistically significant ($p<0.05$).

However our sample size and duration of follow up is considerably less. Hence requirement of a bigger sample size and extensive period of follow up is desired.

CONCLUSION

Based on the findings of the present study it may be concluded that, using polyglactin suture material to fix mesh is a safe, simple as well as an effective alternative to the conventional usage of polypropylene sutures for fixing the mesh in Lichtenstein hernia repair. The post operative pain on day 1 and day 3 is similar with both vicryl and prolene sutures but on the day 7 and after 3 months it is significantly less, as well as lesser post operative complications such as hematoma, seroma but not significant statistically.

The vicryl sutures are also easier to handle and to fix the mesh but yet again not statistically significant as our sample size and duration of follow up is considerably less, hence requirement of a bigger sample size and extensive period of follow up is desired to draw out better conclusions. Despite this polyglactin sutures can be recommended to fix the mish in lichtenstien's hernioplasty. So, routine usage of polyglactin (vicryl) sutures for mesh fixation in a lichtenstien's hernioplasty is a reasonable option.

SUMMARY

Chronic pain in the groin is quite bothersome for a patient after undergoing lichtenstien's hernioplasty. Though pain is less in intensity, studies have clearly revealed that chronic pain regardless of the intensity will remarkably interfere with everyday activity. Chronic groin pain hence assumes utmost importance as a problem with the Lichtenstein procedure. It has occurrence rate between 15% and 40%. Many studies have advocated the routine usage of polyglactin sutures to fix the mesh. Even so it still remains a moot point. Hence, this study was given a whirl.

The objective of the present study was to compare the incidence of postoperative chronic pain following Lichtenstein inguinal hernia repair using polyglactin sutures to fix the mesh versus using polypropylene sutures for the same.

The present one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2019 to December 2019. A total of 60 patients undergoing Lichtenstein hernia repair were randomized into two groups of 30 each as group A (polyglactin sutures for fixing the mesh) and group B (polypropylene sutures for fixing the mesh).

In the present study all the patients, both males and females participated, although males having the majority. The mean age (53.87 ± 20.71 v/s 48.97 ± 19.27 years; p=0.7310) and duration of the symptoms (26.87 ± 66.25 months v/s 15.73 ± 31.89 months; p=0.5334) in group A and group B was comparable. In this study comparing the VAS, initial two of the follow ups were comparable in both groups and no statistical significance was noted. While the other two follow ups done, the was lower rates of incidence of pain in patients who underwent mesh fixation with polyglactin sutures.

The results revealed the incidence of post operative inguinal pain with mean severity score of 1.37 ± 0.49 v/s 1.43 ± 0.50; 1.40 ± 0.50 v/s 1.57 ± 0.73; 1.03 ± 0.61 v/s 1.50 ± 0.057; 0.77 ± 0.63 v/s 1.30 ± 0.79; at post operative day 1, 3 in both groups were similar and statistically not significant, where as the 1st week and 3 months follow up, were significant ($p<0.05$).

The results have shown the decrease in postoperative pain in groin with mean severity score of 0.33 ± 0.55 v/s -0.07 ± 0.74 (day 1 to 1 week; $p = 0.0287$); 0.60 ± 0.56 v/s 0.13 ± 0.78 (day 1 to 3 months; $p = 0.0276$) were significant, suggesting that polyglactin sutures when used to fix the mesh, reduces post operative chronic pain remarkably as compared to using polypropylene sutures to fix the mesh in lichtenstien's repair.

This study also showed the occurrence ofsome of the common post operative complications such as hematoma or seroma was also marginally higher in case of group B (3.33% v/s 6.67% ; 3.33% v/s 10.00%) respectively.

Although the sample size and duration of follow up is considerably less. Hence requirement of a bigger sample size and extensive period of follow up is desired to draw out better conclusions. Despite this polyglactin sutures can be recommended to fix the mish in lichtenstien's hernioplasty. So, routine use of polyglactin sutures as a simple and safe alternative to polypropylene sutures to fix the mesh in patients undergoing anterior inguinal hernia mesh repair.

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ANNEXURE I

CONSENT STATEMENT

INFORMED CONSENT

Title of Research Study **A COMPARISON OF PROLENE VERSUS POLYGLACTIN SUTURES (vicryl) FOR MESH FIXATION IN ASSESSING POSTOPERATIVE CHRONIC PAIN USING VISUAL ANOLOGUE SCALE IN INGUINAL HERNIA REPAIR- A ONE YEAR RANDOMISED CONTROL TRIAL :Study in KLE'S Dr. Prabhakar Kore Charitable Hospital, Belagavi**

Principal Investigator: -
DR. _____
Professor,
Department Of General Surgery,
J. N. Medical College, Belagavi.

Co-investigator:-
REG NO BH0118011
Post Graduate Student,
Department Of General Surgery,
J. N. Medical College, Belagavi.

INTRODUCTION AND PURPOSE: You are requested to participate in a study that is an attempt to find out the effectiveness of Vicryl in comparison to prolene suture in mesh fixation in inguinal hernia repair that is lichensteins technique.

.With attention to patient outcome after open inguinal hernia chronic inguinal region pain and discomfort are major complains due to nerve compression by sutures used for mesh fixation. Since traditionally mesh is fixed with non-absorbable suture material, so this study planned with the objective to compare post-operative outcomes of mesh fixation with prolene versus vicryl suture material. About 60 patients with inguinal hernia will be enrolled in this study.

This study will be conducted by **REG NO BH0118011**, Post Graduate in Department of Surgery, under the direct supervision and guidance of Dr. , Professor, Department of Surgery, J. N. Medical College, Belagavi.

You need to be eligible, meeting all the selection criteria to participate in this study. You should be willing to provide information about yourself. 60 subjects will be enrolled in this study who will then be randomized in either of 2 groups (details below).

PROCEDURE: If you agree to participate in this study, you will be randomly allotted into a group (A or B) and accordingly receive either the standard treatment (prolene suture mesh fixation) or the newer treatment (vicryl).you will be admitted in the hospital for 5 to 7 days. Inital two days for blood investigations cheshx ray and ultrasound abdomen and pelvis, 3 to 5 days for post operative management and monitoring. Intra operatively, the operative time, surgeons ease along with any other problems faced during surgery will be noted. Postoperative complications will be noted until you are discharged, and follwed up for 3 months.

BENEFITS: The benefits of the procedure under study is to reduce post op chronic pain and associated complications.

RISKS: There is no additional risk compared to the standard treatment.

COMPENSATION: Taking part in the study will not affect the cost of treatment i.e. it will be similar to the cost of standard procedure. In the event that you become injured as a result of taking part in this study, treatment will be offered to you or you will be given information about where to receive medical care: but you/your insurance company will be responsible for the costs. However, no reimbursement, compensation or free medical care will be given.

CONFIDENTIALITY: Every effort will be made to protect the confidentiality of the information you provide. This means that the researchers will not let anyone, not a part of the study, see the information you provide. Only Dr. Nikhil M and Dr. A.S.

Gogate will have access to the information collected. Results of this study may be published but your name will not be revealed.

VOLUNTARY PARTICIPATION / WITHDRAWAL: Taking part in this study is voluntary; you may choose not to enroll in this study. Your decision will not change the present or future health care services offered to you at KLES Dr. Prabhakar Hospital, Belagavi. The alternative that you have is to undergo the traditional procedure that is carried out in KLES Hospital.

If you have any queries about the study, you may contact **REG NO BH0118011**or Dr. .If you need any further information regarding your rights as a study participant, you may also contact Dr. ROOPA BELLAD, Chairman of Institutional Ethics Committee, JNMC, Belagavi.

CONSENT FOR PARTICIPATION IN RESEARCH TRIAL

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

Subject Name : _____

Signature or the Left Thumb Print of Subject: _____

Date:

Witness Name : _____ Signature: _____

Date:

Investigators Name: _____ Signature: _____

Date:

Place : _____

ANNEXURE II.ETHICAL CLEARANCE.

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed – to- be- University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
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Ref: MDC/DOME/02 **Date: 24/11/2018**

To

REG NO BH0118011

PG student in Surgery,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"A COMPARISON OF PROLENE VERSUS POLYGLACTIN SUTURES (VICRYL) FOR MESH FIXATION IN ASSESSING POSTOPERATIVE CHRONIC PAIN USING VISUAL ANOLOGUE SCALE IN INGUINAL HERNIA REPAIR – A ONE YEAR RANDOMISED CONTROL TRIAL",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

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

(Dr. Roopa M Bellad)
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ANNEXURE III - PROFORMA

"A COMPARISION OF POLYGLACTIN VERSUS PROLENE SUTURES FOR MESH FIXATION IN ASSESSING POSTOPERATIVE CHRONIC PAIN USING VISUAL ANOLOGUE SCALE IN INGUINAL HERNIA REPAIR- A ONE YEAR RANDAMISED CONTROL TRIAL in KLE'S Dr. Prabhakar Kore Charitable Hospital, Belgaum."

Name & Address of the patient:

_____

_____

Age of the Patient: _____ IP. No. _____

Weight of Patient: _____ Sex.

Anaesthesiologist: _____ Surgeon: _____

Chief Complaints:

Past History:

- History of
- Diabetes Mellitus:- YES/NO
- Hypertension:- YES/NO
- Asthma:- YES/NO
- PREVIOUS SURGERIES:- YES/NO
- Drug Therapy: YES/NO

Family History:

General Physical Examination:

Weight: Temperature: Pallor: Height:

Cyanosis: Pedal Edema: Clubbing:

Pulse : B.P: RR:

SYSTEMIC EXAMINATION:

Cardiovascular System:

Respiratory System:

Per Abdomen:

Central Nervous system:

Spine assessment:

INVESTIGATIONS:

Hb%: Urine Routine:

Any Other:

USG Abdomen &Pelvis:

Diagnosis:

Proposed Surgery

Observations:

Group: _____.

Age:

Sex:

Operative time:

Surgeons ease:

Post operarive pain:

Post operative Complications:

Other findings:

Any other problems faced:-

Signature of staff in charge:

Variables of the two techniques

	vicryl	**prolene**
1)Operative Time		
2)surgeons ease		
3)difficulty in fixing the mesh		
4) post op pain		
5)seroma		
6)post op chronic pain		
7)hospital stay		

ANNEXURE IV - KEY TO MASTERCHART

1. GENDER: M- MALE, F- FEMALE
2. SIDE OF HERNIA: R- RIGHT, L- LEFT, B- BILATERAL
3. FINAL DIAGNOSIS: RDH- RIGHT DIRECT HERNIA, RIH- RIGHT INDIRECT HERNIA, BDH – BILATERAL DIRECT HERNIA, LDH- LEFT DIRECT HERNIA, LIH – LEFT INDIRECT HERNIA, BIH- BILATERAL INDIRECT HERNIA.
4. PAIN: M- MILD, O- MODERATE, S- SEVERE N- NO PAIN
5. SURGEON'S EASE: E- EASY, D- DIFFICULT
6. DIFFICULTY IN FIXING THE MESH: Y- YES, N – NO
7. SEROMA: Y- YES, N- NO
8. HEMATOMA: Y- YES, N- NO
9. RECURRENCE Y- YES, N- NO

VICRYL

sl no	Age	gender m-1/f-2	duration of hernia in months	side of hernia r-1/l-2/b-3	final diagnosis rdh-1/ rih 2 / bdh-3 / ldh-4 / lih-5 / bih-6 / both-7	post op pain at 1 day m-1/o-2/s-3	post op pain at day 3 m-1/o-2/s-3	post op pain after 1 week n-0/ m-1/o-2/s-3	post op pain after 3 months n-0/ m-1/o-2/s-3	operative time in mins (30-40-1)(40-50-2)(>50-3)	surgeon's ease e-1/d-2	difficulty in fixing the mesh y-1/n-2	seroma y-1/n-2	hematoma y-1/n-2	recurrence y-1 /n-2	hospital stay in days (1-2- 1) (>3-2)
1	56	1	6	1	2	2	2	1	1	1	1	2	2	2	2	1
2	45	1	10	2	5	1	1	1	1	2	1	2	1	2	2	2
3	62	1	8	1	2	2	2	1	1	1	1	2	2	2	2	1
4	34	1	7	2	5	2	2	1	1	2	2	1	2	2	2	1
5	34	1	15	1	2	1	1	1	1	1	1	2	2	2	2	2
6	21	1	5	2	5	1	1	0	0	1	1	2	2	2	2	1
7	76	1	360	1	2	2	2	2	2	3	2	1	2	2	2	2
8	54	2	14	2	5	1	1	1	0	1	1	2	2	2	2	1
9	85	1	14	1	1	1	2	2	2	1	1	2	2	2	2	1
10	21	1	3	2	5	1	1	0	0	1	1	2	2	2	2	1
11	45	1	1	1	1	1	1	1	1	2	1	2	2	2	2	1
12	69	1	8	2	4	1	1	1	1	1	1	2	2	2	2	1
13	35	1	3	1	2	1	1	0	0	1	1	2	2	2	2	1
14	75	1	3	2	4	2	2	1	1	1	1	2	2	1	2	2
15	78	1	24	2	4	1	1	1	1	1	1	2	2	2	2	1
16	28	1	5	3	6	1	1	1	0	3	1	2	2	2	2	1
17	64	1	3	2	1	1	1	1	1	1	1	2	2	2	2	1
18	50	1	7	1	1	1	1	0	0	1	1	2	2	2	2	1
19	78	1	5	1	1	1	1	1	1	2	1	2	2	2	2	1
20	41	1	15	1	1	2	2	2	2	3	2	1	2	2	2	1
21	70	1	7	3	6	2	2	2	1	3	2	1	2	2	2	1
22	55	1	10	1	1	1	1	1	1	2	1	2	2	2	2	1
23	21	2	5	2	4	2	2	2	1	3	1	2	2	2	2	1
24	83	1	96	2	5	2	2	1	1	2	1	2	2	2	2	1
25	21	1	7	2	5	1	1	1	0	2	1	2	2	2	2	1
26	64	1	12	1	1	2	2	1	1	2	1	2	2	2	2	1
27	76	1	60	1	2	1	1	1	0	2	1	2	2	2	2	1
28	76	1	60	1	2	2	2	2	1	2	1	2	2	2	2	1
29	61	1	24	1	2	1	1	1	0	1	1	2	2	2	2	1
30	38	1	9	2	4	1	1	0	0	1	1	2	2	2	2	1

PROLENE

sl no	Age	gender m-1/f-2	duration of hernia in months	side of hernia r-1/l-2/b-3	final diagnosis rdh-1/ rih 2 / bdh-3 / ldh-4 / lih-5 / bih-6 / both-7	post op pain at 1 day m-1/o-2/s-3	post op pain at day 3 m-1/o-2/s-3	post op pain after 1 week n-0/ m-1/o-2/s-3	post op pain after 3 months n-0/ m-1/o-2/s-3	operative time in mins (30-40-1)(40-50-2)(>50-3)	surgeon's ease e-1/d-2	difficulty in fixing the mesh y-1/n-2	seroma y-1/n-2	hematoma y-1/n-2	recurrence y-1/n-2	hospital stay in days (1-2- 1) (>3-2)
1	21	1	3	1	1	2	1	1	1	3	2	1	2	2	2	1
2	19	1	180	1	1	1	2	1	1	2	2	1	1	2	2	1
3	48	1	15	1	2	2	2	2	2	3	1	2	2	2	2	1
4	65	1	8	1	2	2	1	2	2	2	1	2	2	2	2	1
5	38	1	12	2	4	1	2	2	2	2	1	2	2	2	2	2
6	49	1	20	2	5	1	1	1	0	2	1	2	2	2	2	1
7	24	1	8	1	2	2	2	2	2	2	2	1	2	2	2	1
8	65	1	12	2	5	1	2	2	2	2	2	1	2	1	2	2
9	65	1	6	1	2	1	1	2	2	2	2	1	2	2	2	1
10	52	1	5	2	4	1	1	1	0	3	2	1	2	2	2	1
11	71	1	12	1	2	2	1	1	1	2	1	2	2	2	2	1
12	66	1	6	1	1	1	1	1	1	1	1	2	2	2	2	1
13	59	1	3	2	4	1	2	1	0	3	2	1	2	2	2	1
14	22	1	2	1	2	2	0	0	1	2	1	2	2	2	2	1
15	56	1	5	1	1	1	2	2	2	2	2	1	2	1	2	2
16	20	1	6	2	5	1	1	1	0	3	2	1	2	2	2	1
17	26	1	5	1	1	1	1	1	1	3	2	1	1	2	2	2
18	75	1	9	3	3	2	3	2	2	3	2	1	2	2	2	2
19	54	1	4	2	5	1	2	2	2	3	2	1	2	2	2	1
20	29	1	2	1	2	2	1	2	2	2	1	2	2	2	2	1
21	70	1	7	3	3	2	3	2	2	3	2	1	2	2	1	2
22	60	1	6	1	1	1	1	2	2	2	2	1	1	2	2	2
23	25	1	3	1	2	2	1	1	1	2	1	2	2	2	2	1
24	78	1	12	3	6	2	3	2	2	3	2	1	2	2	2	2
25	45	1	9	1	2	1	2	2	1	2	1	2	2	2	2	1
26	69	1	26	2	4	2	2	1	1	3	2	1	2	2	2	1
27	29	1	17	2	5	1	1	1	0	2	1	2	2	2	2	1
28	38	1	13	1	2	2	2	2	2	2	1	2	2	2	2	1
29	59	1	26	1	1	1	1	1	0	3	2	1	2	2	2	1
30	71	1	30	2	4	1	2	2	2	3	2	1	2	2	2	1
											2					