

**COMPARATIVE STUDY BETWEEN N-BUTYL-2
CYANOACRYLATE GLUE VERSUS SUTURED MESH
FIXATION IN LICHTENSTEINS HERNIA REPAIR**

By

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In partial fulfillment of the requirements for the degree of

MASTER IN SURGERY

in

GENERAL SURGERY

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DR.ASHRITH I. M.

LIST OF ABBREVIATIONS USED

| | | |
|-------|---|------------------------------|
| SL NO | - | SERIAL NUMBER |
| N | - | NAME |
| A | - | AGE IN YEARS |
| S | - | SEX |
| M | - | MALE |
| F | - | FEMALE |
| IP NO | - | IN PATIENT NUMBER |
| DOA | - | DATE OF ADMISSION |
| DOS | - | DATE OF SURGERY |
| DOD | - | DATE OF DISCHARGE |
| FUAOM | - | FOLLOW-UP AFTER ONE MONTH |
| P | - | PAIN |
| HEM | - | HEMATOMA |
| SE | - | SEROMA |
| INF | - | INFECTION |
| FUATM | - | FOLLOW-UP AFTER THREE MONTHS |
| CP | - | CHRONIC PAIN |
| FBS | - | FOREIGN BODY SENSATION |
| FUATM | - | FOLLOW-UP AFTER THREE MONTHS |
| MIN | - | MINUTES |

ABSTRACT

BACKGROUND AND OBJECTIVES:

A hernia is a protrusion of a viscus or part of a viscus through an abnormal opening in the walls of its containing cavity.¹

A hernia is the bulging of part of contents of the abdominal cavity through a weakness in the abdominal wall.²

Inguinal hernia repair is the most frequently performed operation in any general surgical unit.³

Hernioplasty is most commonly performed surgery for hernia.

Mesh fixation is a major step in hernioplasty regularly mesh is fixed with non-absorbable prolene sutures, as there is longer operative time, more pain during post-operative period and foreign body sensation, sutures are replaced by N-butyl-2-cyanoacrylate glue mesh fixation in Lichtenstein hernia repair.

Evidence of surgical repair of inguinal hernias can be traced back to civilizations of ancient Egypt and Greece.⁴

In 1989, repair for inguinal hernia was first described by Lichtenstein.⁵

However chronic pain after inguinal hernia repair remains a frequent complication with reported incidence of up to 63 percent.⁶

Complications associated with sutured mesh fixation following open groin hernia repair, such as chronic irritation and pain are probably due to tension or nerve compression by sutures hence these complications have prompted surgeons to use atraumatic method of fixation by cyanoacrylate glue.⁷

METHODS:

All patients presenting to B.L.D.E.U's Shri B.M. Patil Medical College Hospital and Research Centre Bijapur and admitted patients in whom the diagnosis of primary inguinal hernia is considered from October 2013 to June 2015

- Two groups are made, standard suture fixation for one group and glue fixation to another group.
- Minimum of 50 cases with permissible error in each group will be taken up for the study.

Results were interpreted with respect to pain, operative time, complications and foreign body sensation.

RESULTS:

- Operating time was significantly less that is 36.52 min in cases and 48.32 in control group.
- Hospital stay in cases group was 4.82 days and in control group was 6.48 days
- Pain after 3 month was seen only in 5 patients in N butyl cyanoacrylate mesh fixation group and whereas it was more in Standard Prolene Mesh fixation group i.e.16 patients.
- There were only 4% cases with complaints of seroma and none with complaints of infection or hematoma in the case group, whereas 18% of controls presented with complaints of seroma and 10% with hematoma. Hence, the case group is superior to control group.
- Foreign body sensation is significantly less in cases group

CONCLUSION:

N butyl cyanoacrylate glue Mesh fixation is far superior option to be used in standard Lichtenstein tension free repair for mesh fixation.

Key Words : N butyl cyanoacrylate glue, mesh fixation, Lichtenstein, Operating Time, Hematoma, Chronic Pain, Foreign Body sensation

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INTRODUCTION

A hernia is a protrusion of a viscus or part of a viscus through an abnormal opening in the walls of its containing cavity.¹

A hernia is the bulging of part of contents of the abdominal cavity through a weakness in the abdominal wall.²

Inguinal hernia repair is the most frequently performed operation in any general surgical unit.³

Hernioplasty is most commonly performed surgery for hernia.

Mesh fixation is a major step in hernioplasty regularly mesh is fixed with non-absorbable prolene sutures, as there is longer operative time, more pain during post-operative period and foreign body sensation, sutures are replaced by N-butyl-2-cyanoacrylate glue mesh fixation in Lichtenstein hernia repair.

Evidence of surgical repair of inguinal hernias can be traced back to civilizations of ancient Egypt and Greece.⁴

In 1989, repair for inguinal hernia was first described by Lichenstein.⁵

However chronic pain after inguinal hernia repair remains a frequent complication with reported incidence of up to 63 percent.⁶

Complications associated with sutured mesh fixation following open groin hernia repair, such as chronic irritation and pain are probably due to tension or nerve compression by sutures hence these complications have prompted surgeons to use atraumatic method of fixation by cyanoacrylate glue.⁷

AIM OF THE STUDY

To study the outcome of N-butyl-2-cyanoacrylate glue versus sutured mesh fixation in Lichtenstein hernia repair with respect to pain, operative time and foreign body sensation.

OBJECTIVES

To compare the outcome of N-butyl-2-cyanoacrylate glue versus sutured mesh fixation in Lichtenstein hernia repair with respect to pain, seroma, hematoma and infection within 1 month of follow-up, chronic pain using visual analogue scale(VAS) (3mths) and foreign body sensation.

REVIEW OF LITERATURE

EMBRYOLOGY^{8,9}

In a highly synergistic way the skin, the parietal peritoneum and the embryologic and anatomic entities between them produce the future pathway for the testes. The skin will form the scrotum in male and the labia in female. The embryologic entities between the skin and peritoneum permit the processus vaginalis to penetrate them and form the inguinal canal. The downward journey of the testis to the scrotum is thus allowed and descent of the ovary outside the peritoneal cavity however is forbidden.

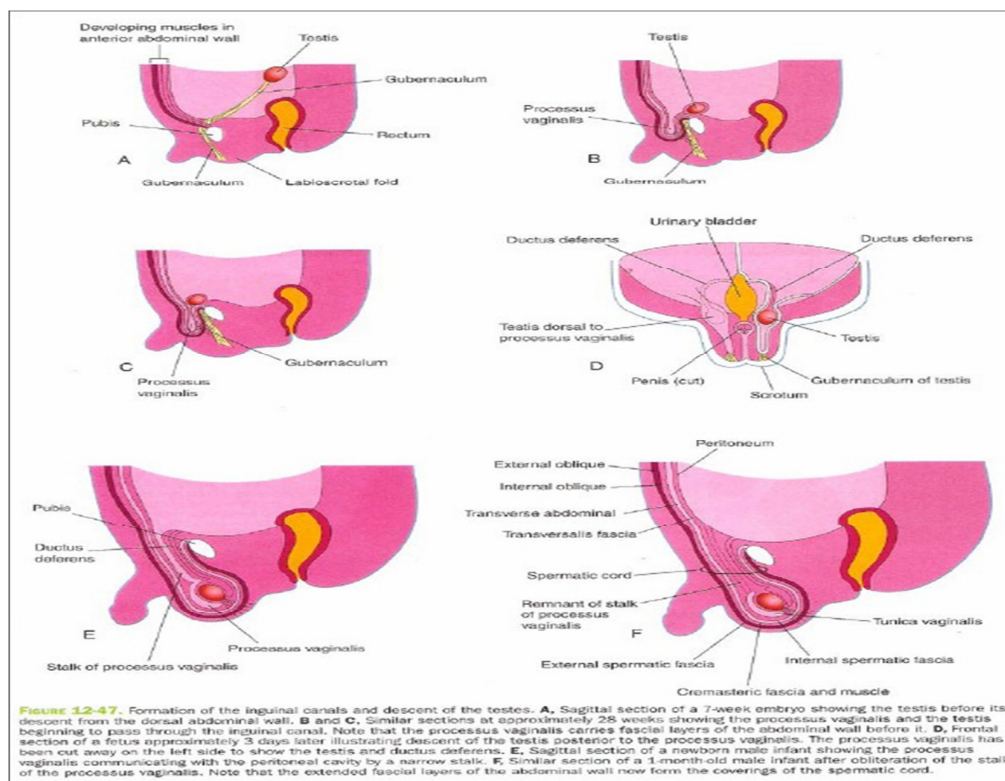


Figure 1 Embryology

ANATOMY^{10,11,12}

“No disease of the human body belonging to province of surgeon required in its treatment, a better combination of accurate, anatomical knowledge with surgical skill, than hernia in all its varieties”.

Sir Astley Patson Cooper, (1804)

A hernia is a protrusion of a viscus or part of a viscus through an opening in the wall of the cavity in which it is contained.

The inguinal canal is an oblique intermuscular slit about 4cm long lying above the medial half of the inguinal ligament. It commences at the deep inguinal ring and ends at the superficial inguinal ring. It is directed downwards, forwards, and medially. In infants, the superficial and deep inguinal rings are almost superimposed and obliquity of canal is slight.

The deep inguinal ring is a U shaped condensation of the transversalis fascia and it lies 1.25 cm above the inguinal ligament (Poupart's ligament) mid way between the symphysis pubis and the anterior superior iliac spine.

The superficial inguinal ring is a triangular aperture in the aponeurosis of external oblique and lies 1.25cm above the pubic tubercle. The ring is bounded by supero medial and infero lateral crus joined by criss cross intercrural fibres. Normally, the ring will not admit the tip of little finger. The inguinal ligament is the thick folded lower border of the aponeurosis of the external oblique presenting a grooved superior abdominal surface (The floor of the inguinal canal), and which stretches from the anterior superior iliac spine to the pubic tubercle. It has variously been called the crural arch, the superficial crural arch, and Poupart's ligament.

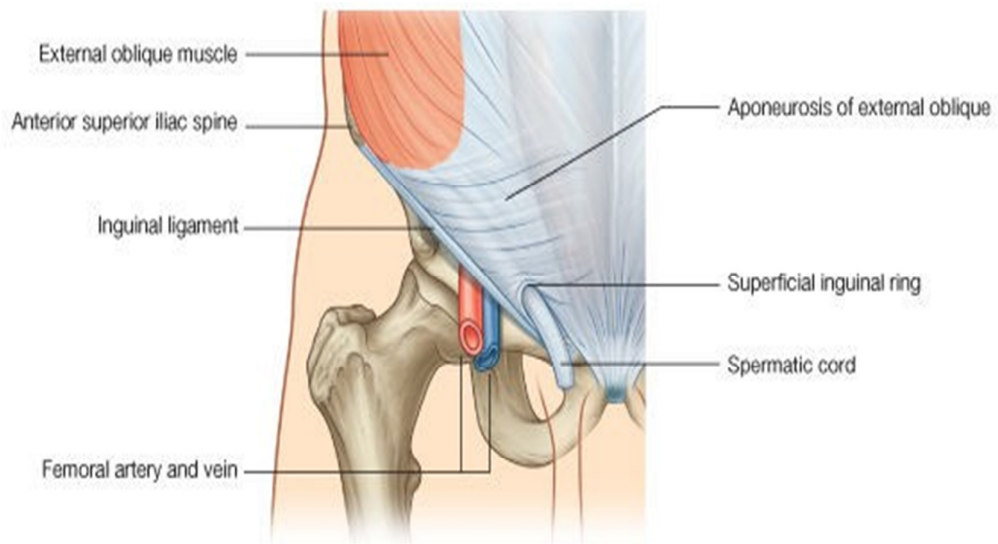
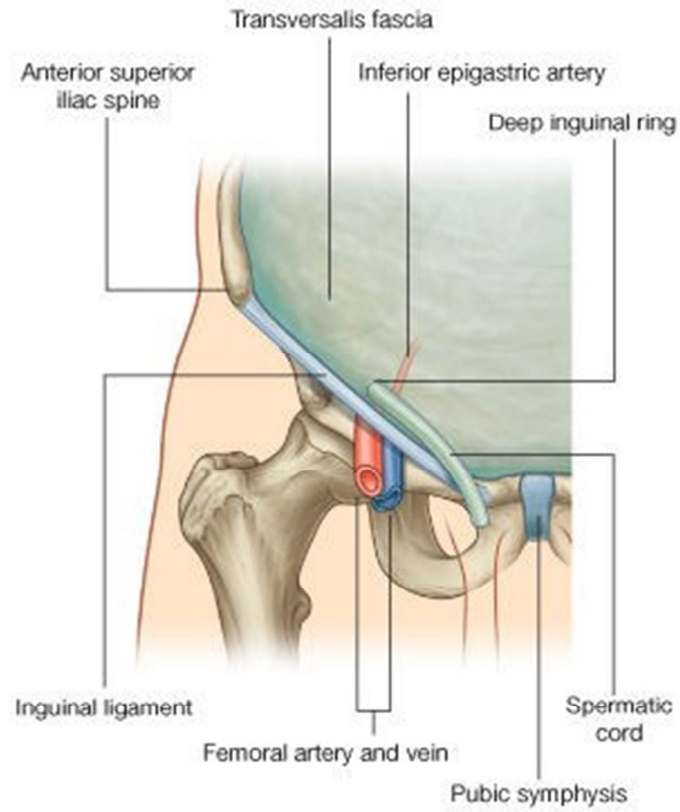


Fig.2: Anatomy of the Inguinal Canal

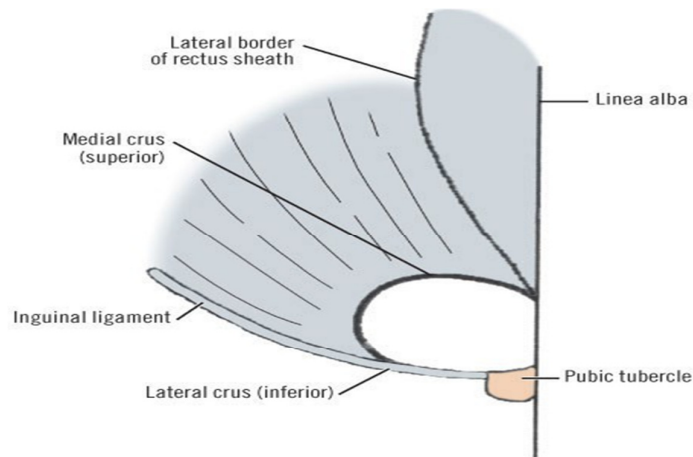


Fig3:Superficial Inguinal Ring¹³

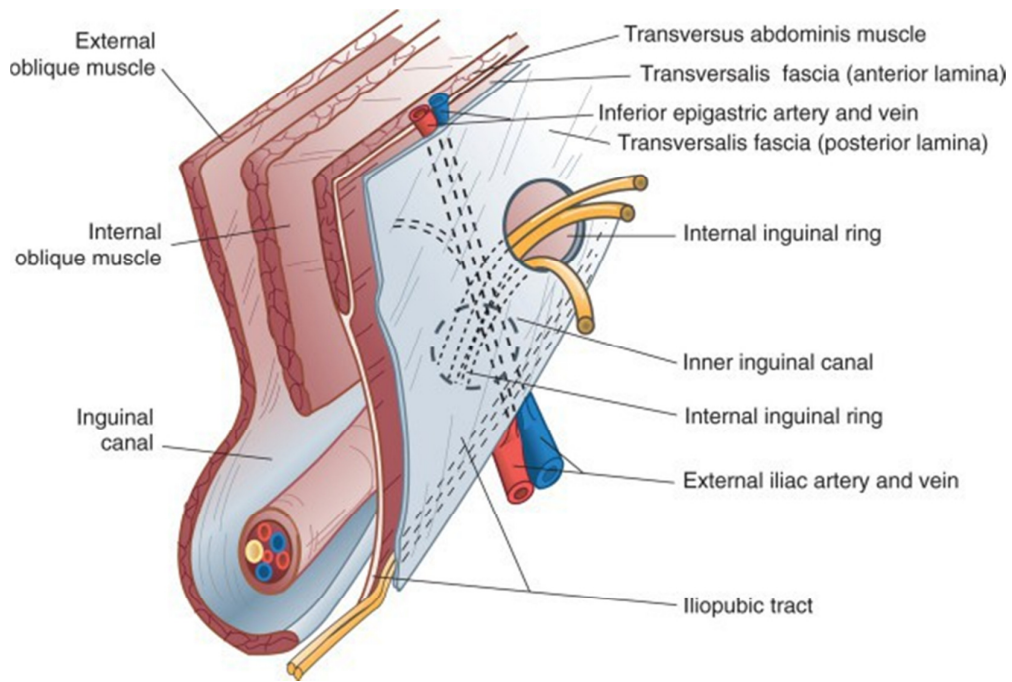


Fig4:Inguinal Canal¹⁴

Boundaries

Anterior wall is formed by the following In its whole extent

1. Skin
2. Superficial fascia
3. External oblique aponeurosis

In its lateral 1/3rd

Fleshy fibres of internal oblique muscle.

Posterior wall

In its whole extent

1. Fascia transversalis
2. Extra peritoneal tissue
3. Parietal peritoneum

In its medial 2/3rd

Conjoint tendon.

Reflected part of inguinal ligament (Medial end)

In its lateral 1/3rd

Inter foveolar ligament { When present }

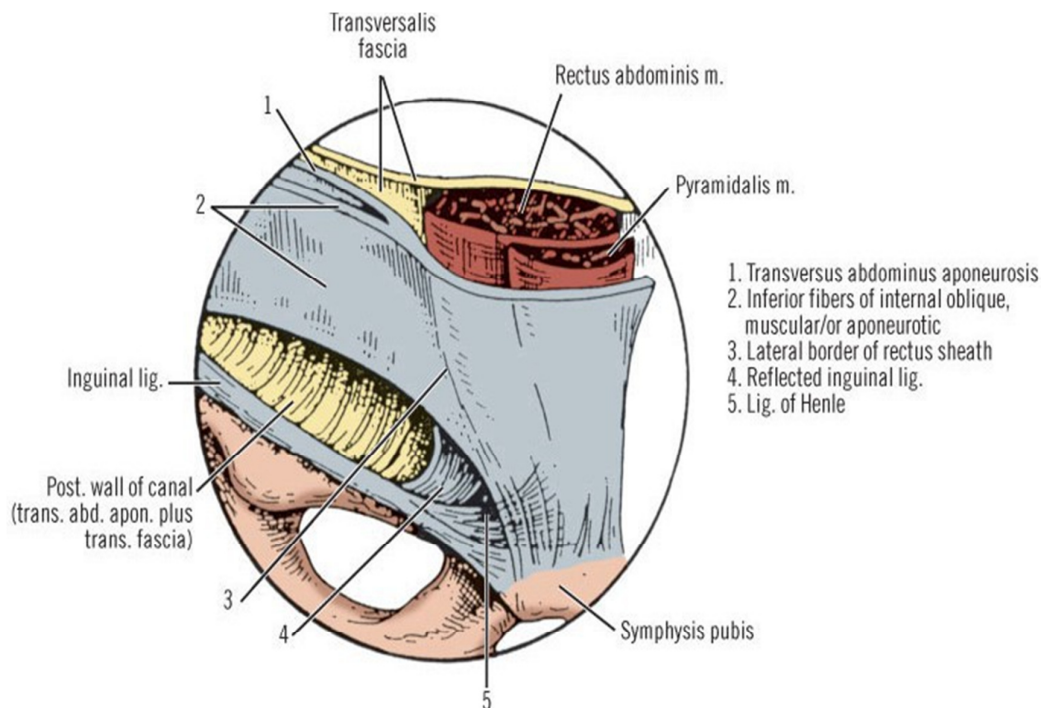


Fig5:Conjoined Area

Roof

Arched fibres of internal oblique and transversus abdominis muscles.

Floor

Grooved upper surface of the inguinal ligament and at the medial end by the lacunar ligament

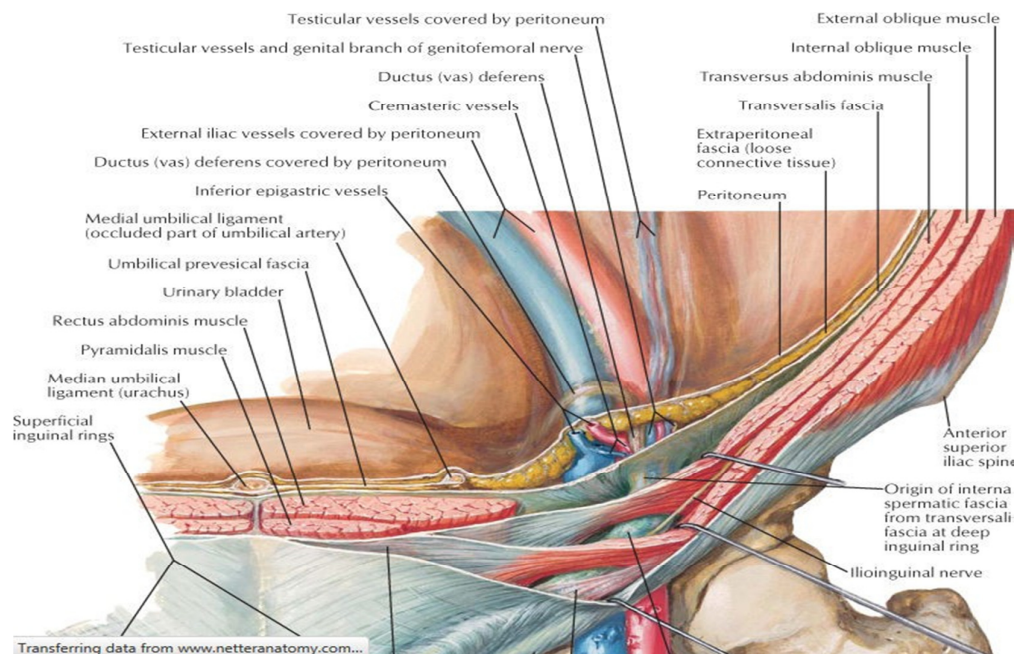


Fig.6 : Boundaries of Inguinal Canal¹⁵

Structures passing through the canal

In males

Spermatic cord

Vas deference and its artery

Testicular artery¹⁶

Cremasteric artery¹⁶

Pampiniform plexus of veins

Obliterated remains of processus vaginalis

Genital branch of genito femoral nerve

Autonomic nerves

Lymphatics

In females,

Obliterated Processes vaginalis

Round ligament

Lymphatics from the uterus

The ilio inguinal nerve, although is a content of the inguinal ring, doesnot enter the canal through the deep ring, but by piercing the internal oblique muscle i.e. it slips into the canal from the side not from the back. The nerve lies infront of the cord and leaves the canal through the superficial ring¹⁹.

Hasselbach's Triangle¹⁷

Laterally –inferior epigastric artery.

Medially - outer border of rectus

Lower boundary – inguinal ligament

Hasselbach's triangle is divided into medial and lateral halves by the obliterated umbilical artery (Lateral umbilical ligament).

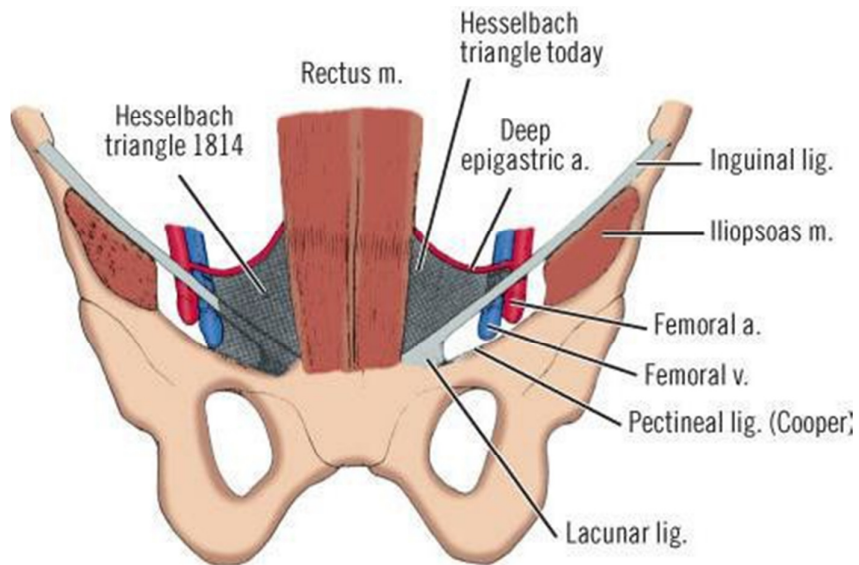


Fig7:Hasselbach's triangle^{14,18}

PHYSIOLOGY

Mechanism of inguinal canal

The presence of the inguinal canal is a cause of weakness in the lower part of the anterior abdominal wall. This weakness is compensated for by the following factors.

1. Flap valve mechanism

The deep and superior inguinal rings lie at opposite ends of inguinal canal and the intervening part of the canal is pressed flat when the aponeurosis are under tension and the intra abdominal pressure raised.

2. Ball valve mechanism

Contraction of the cremaster helps the spermatic cord to plug the superficial inguinal ring.

3. Slit valve mechanism

Contraction of the external oblique results in approximation of two crura of the superficial inguinal ring. The integrity of the superficial inguinal ring is greatly increased by inter crural fibres.

4. Shutter mechanism of internal oblique

This muscle has a triple relation to the inguinal canal. It forms the anterior wall, the roof and the posterior wall of the canal. When it contracts the roof is approximated to the floor, like a shutter. The arching fibres of the transversus also take part in the shutter mechanism.

5. The superficial inguinal ring is guarded from behind by the conjoint tendon and by the reflected part of the inguinal ligament.

6. The deep inguinal ring is guarded from the front by the fleshy fibres of the internal oblique.

7. Hormones may play a role in maintaining the tone of the inguinal musculature.

Whenever there is a rise in intra abdominal pressure (as in coughing, sneezing, lifting heavy weights) all these mechanisms come into play, so that the inguinal canal is obliterated, its openings are closed and herniation of abdominal viscera is prevented.

ETIOLOGY

The cause of hernia is probably multifactorial. It is assumed that 3 main factors are involved. The presence of preformed sac, repeated elevation in the intra abdominal pressure, and weakening of the body muscles and tissues with time.

Principle etiologic factors

A. Congenital

Predisposing factors for indirect inguinal hernia genesis is anatomic configuration and patent processus vaginalis. But, it is not the sole cause for hernia genesis as many persons at postmortem had patent process vaginalis without suffering from hernia during life. The descent of testis carries along with it, the processes, hence predisposes to hernia. Sex wise males are common sufferers from inguinal hernia.

Subtle variants in attachment and arrangement of abdominal muscles also play a role in hernia genesis as direct hernias do not occur in females because of narrowness between inguinal ligament and transverses arch.

Congenital defects in tissue metabolism, relating to enzyme deficiency also suffer from hernia. There are deranged collagen synthesis disorders such as **Ehler's-Danlos syndrome**, where the tissues are defective. This leads to direct hernia formation. Similarly, persons with high arched lower border of transversus abdomen also develop direct hernia because of congenital posterior inguinal wall weakness.

B. Contributory factors: They are

1. Age

As age advances, abdominal muscle tissue weakness develops because of gradual tissue breakdown, hence most common in elderly persons. The reason for hernias in elderly people may be linked to findings of Rodrigues, who in 1990, reported a decrease in Oxytatum fibers and an increase in the amorphous substance elastic fibers as a function of age, which may be responsible for alterations in the resistance of transversalis fascia.

2. Females are particularly free of direct inguinal hernia^{14,20,21}:

The narrowness of the interval between the transverses arch and the inguinal ligament is an important factor protecting women against direct hernia. On the other hand, musculo aponeurotic attachments in women are such that they frequently develop femoral hernia. Other factors that are significant in the etiology are the number of aponeurotic fibers in the transversus aponeurosis, which determines the intrinsic strength of the layer.

3. Obesity

Increased fat content in the various layers of abdominal wall leads to weakness of these layers, predisposing to hernia formation.

4. Pulmonary causes

Emphysema, chronic bronchitis, pneumonitis causes laborious and difficult respiration which leads to raise in intra abdominal pressure.

5. Genitourinary.

Prostatism, constipation, diverticular disease, colonic carcinoma, all lead to straining to expel the excreta, causing raised intra abdominal pressure. Other genitourinary problems such as cystitis, cystocele, and urethrocele play role in female to hernia formation.

6. Cardiac problems

Patients suffering from congestive heart failure will have ascites, which opens up dormant patent processus leading to hernia.

7. Pregnancy

Stretching of abdominal wall in pregnancy disrupt muscles and later replaced by collagen tissue which prevents effective action of these muscles thus predisposing to hernia.

C. Precipitating and exciting causes

1. Sudden increase in intra abdominal pressure as occurs with coughing, straining, heavy weight lifting, sneezing, crying.
2. Trauma- severe sudden blow or crush injury may lead to hernia formation.

D. Biological factors

1. Malnutrition

Sailors who suffer from scurvy had hernias and rupture of healed scars. This is because of vitamin 'C' deficiency which is essential for collagen synthesis. Similarly protein malnutrition are also essential for collagen synthesis and healing.

2. Environmental toxins

Smokers had the potentially undesirable combination of increase in proteolytic and reductions in alpha- antitrypsin, the major naturally occurring circulating protease. This combination could set the stage for the evolution of a hernia by affecting the synthesis- degradation equilibrium of groin collagen and could be a pathologic sequence initiated by excessive smoking

E. Iatrogenic factors: Previous operations

1. Appendectomy may predispose to the later appearance of ipsilateral inguinal hernia. The presumptive mechanism is that damage to the innervation of the muscular constrictors of the internal ring shutter mechanism.
2. Increased intra abdominal pressure associated with chronic ambulatory peritoneal dialysis frequently results in hernia. Incidence varies from 1% to 30%.

CLASSIFICATION OF GROIN HERNIA ANATOMICAL TYPES

Indirect inguinal hernia

An indirect hernial sac is actually a dilated persistent processus vaginalis. It passes through the deep ring, lies within the spermatic cord and follows the indirect course of the cord to the scrotum.

Direct inguinal hernia

The direct inguinal hernial sacs originate through the floor of the inguinal canal i.e., Hesselbach's triangle, they protrude directly and they are contained by the aponeurosis of the external oblique muscle.

Types of indirect inguinal hernias

1. Vaginal

The processus vaginalis has failed to become occluded in any part of its course. The hernia therefore descends to the base of the scrotum and the testis is behind it and may be difficult to locate.

2. Funicular

The processus is obliterated above the testis. The testis can be felt separately from the hernia below it.

3. Infantile

A process of peritoneum of the processus vaginalis is found in front of the hernia as high up as the external ring. Therefore, at operation, a peritoneal sac is found in front of the hernia sac.

4. Encysted

As (1), but a process of peritoneum lies in front of the sac up to the external ring. Types (3) and (4) are due to a diverticulum of the processus vaginalis being caught up at the external ring during development.

5. Intestinal

In this type, a diverticulum of the processus vaginalis has been caught between the layers of the developing abdominal wall.

The sac may be,

- Proparietal or extraparietal (superficial) between the superficial fascia and external oblique.

Intraparietal (intramuscular) between the internal and external oblique muscles.

Retroparietal or intraparietal (properitoneal) between the fascia transversalis and peritoneum. This type of hernia is rare and is usually found in association with an imperfectly descended testis¹⁹

Types of direct inguinal hernia

A direct hernia leaves the Hesselbach's triangle through its outer or inner part and is therefore

- a. Lateral direct hernia
- b. Medial direct hernia²²

CLINICALTYPES

1. Reducible
2. Irreducible
3. Obstructed
4. Strangulated(complication of irreducible hernia)
5. Inflamed

Reducible hernia

The hernia either reduces itself when the patient lies down, or can be reduced by the patient or the surgeon .The intestine usually gurgles on reduction and the first portion is more difficult to reduce than the last . Omentum, in contrast, is described as doughy and the last portion is more difficult to reduce than the first. A reducible hernia imparts an expansile impulse on coughing.



Fig. 8 :Right Sided Indirect reducible Inguinal Hernia

Irreducible hernia

Here the contents cannot be returned to the abdomen, but there is no evidence of other complications. It is usually due to adhesions between the sac and its contents or from over crowding within the sac.

Obstructed hernia

This is an irreducible hernia containing intestine which is obstructed from without or within, but there is no interference to the blood supply to the bowel. The symptoms (Colicky abdominal pain and tenderness over the hernia site) are less severe and the onsets more gradual than is the case in strangulation, but more often than not the obstruction culminates in strangulation.

Incarcerated hernia

This term is correctly employed only when it is considered that the lumen of that portion of the colon occupying the hernia sac is blocked with faeces.

Strangulated hernia

A hernia becomes strangulated when the blood supply of its contents is seriously impaired, rendering the contents ischaemic. Gangrene may occur as early as 5 to 6 hours after the onset of first symptoms. Although inguinal hernia may be 10 times more common than femoral hernia, a femoral hernia is more likely to strangulate because of the narrowness of the neck and its rigid surroundings.

Inflamed hernia

Inflammation can occur from inflammation of the contents of the sac (i.e., acute appendicitis or salpingitis) or from external causes (Eg. the trophic ulcers which develop in the dependent areas of large umbilical or incisional hernias). The hernia is usually tender but not tense and the overlying skin is red and edematous.

OPERATIVE PROCEDURES

Position of the patient

The patient is placed on his back on the operating table. Access is improved if the head of the table is tilted downwards by about 15°.

Incision 23, 24, 25



Figure 9 Incision for inguinal hernia

The incision is placed 1.25 cm above medial 3/5th of the inguinal ligament. Laterally the incision begins over the deep inguinal ring, runs to the pubic tubercle, then curves caudally (vertically) and runs down over the pubic tubercle.

Exposure

After the skin has been divided the subcutaneous fat is opened in the length of the incision down to the external oblique aponeurosis. The superficial pudendal and superficial epigastric vessels are dealt with cautery. The deep fascia of the thigh is opened to allow access to the femoral canal exposed below the inguinal ligament and checked to make sure it is intact.

Dissection throughout the operation must be meticulous and careful haemostasis must be observed to avoid haematomas and infection.

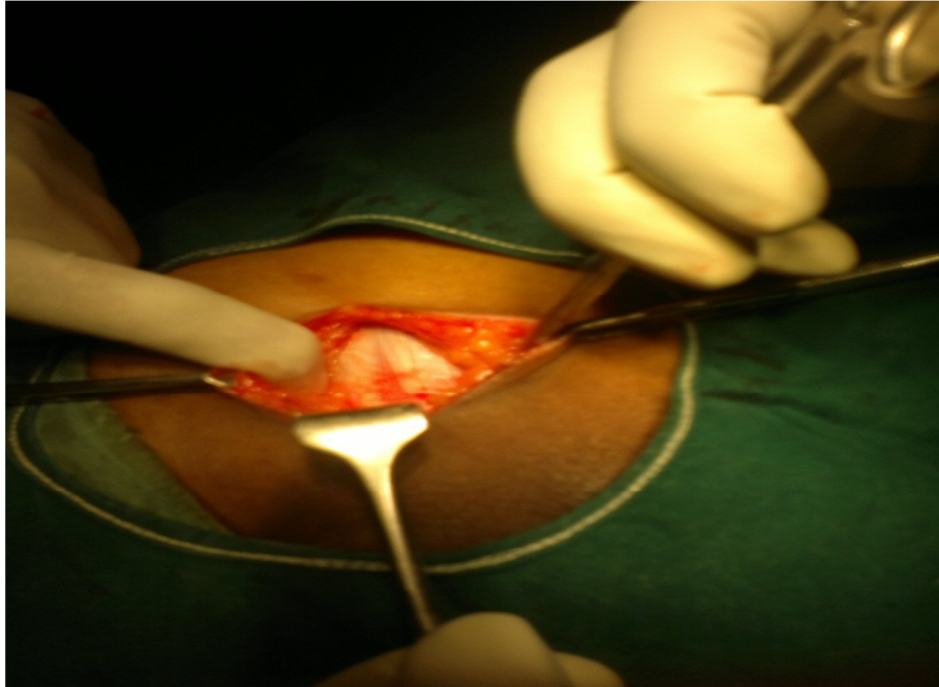


Figure 10- Exposing external oblique aponeurosis

Dissection of the canal

The external oblique aponeurosis is next opened in the long axis of the inguinal canal. This incision extends down to the external inguinal ring, the margin of which is divided. The condensation of the transversalis fascia about the emerging cord is the deep ring and it must be identified accurately

Forceps are applied to the two cut edges, the upper leaf is retracted to expose the conjoined muscles arching over the cord and the lower to expose the upper surface of the inguinal ligament. The ilioinguinal and iliohypogastric nerves are identified and safeguarded.

The cord, with which is included the hernial sac is lifted up from the medial part of the incision and is spread out on the finger. Its coverings are incised longitudinally and are further separated by blunt dissection, care being taken to avoid injuring the spermatic veins. The sac appears as a pearly white structure lying on the anterosuperior aspect of the cord structures. The sac is separated by gauze stripping. As the separation proceeds traction is applied to the sac and the stripping is continued until the neck comes into view. This is identified from the presence of an adherent pad or collar of fat. The inferior epigastric vessels lie to the medial side of indirect and lateral to direct hernia and care should be taken that they are not injured. When separation is complete the sac is opened at some distance from its neck and a finger is introduced into its interior to ensure that it is empty of its contents. Adherent contents are freed from the sac and returned to the abdomen.

In the case of scrotal hernia, where the fundus of the sac may not come easily into view, there is no objection to leaving the distal part of the sac in situ. This obviates the dissection required to deliver the sac from the depth of the scrotum and greatly reduces the risk of subsequent testicular atrophy and haematoma formation.

The sac is now drawn strongly downwards and is twisted at its neck in order to occlude it before the ligature is applied. The sac is amputated 1cm below the ligature prior to cutting the ligature so that there is adequate control of the stump in the event of bleeding. If the ligature has been applied at a sufficiently high level the stump will immediately retract well above the deep inguinal ring to lie flush with the general peritoneum.

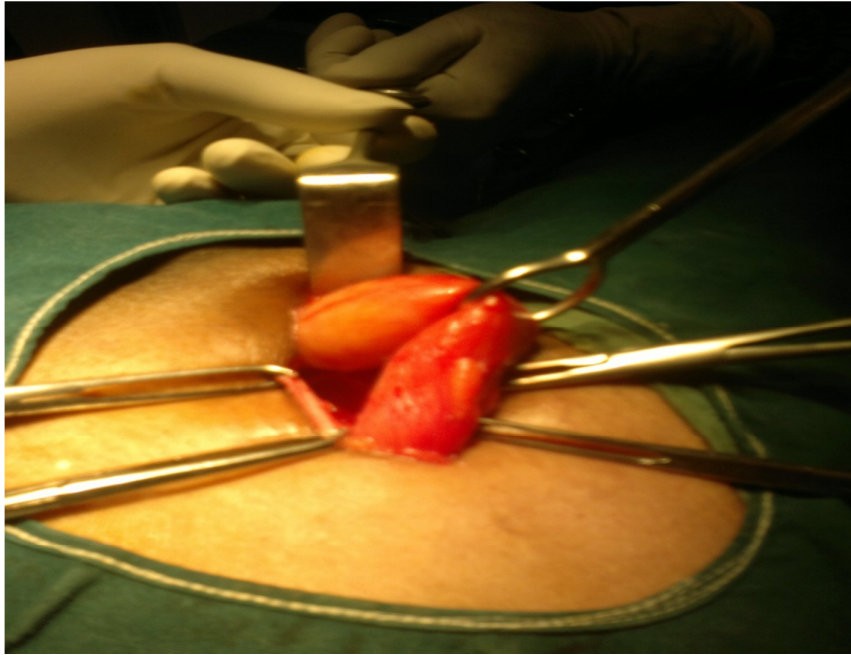


Figure 11 Cord and its structures

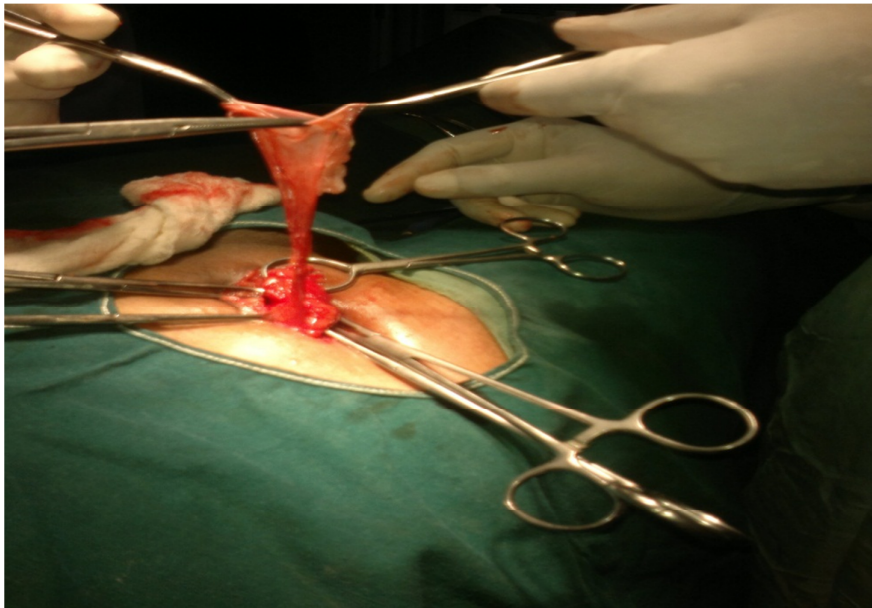


Figure 12 Identification of sac

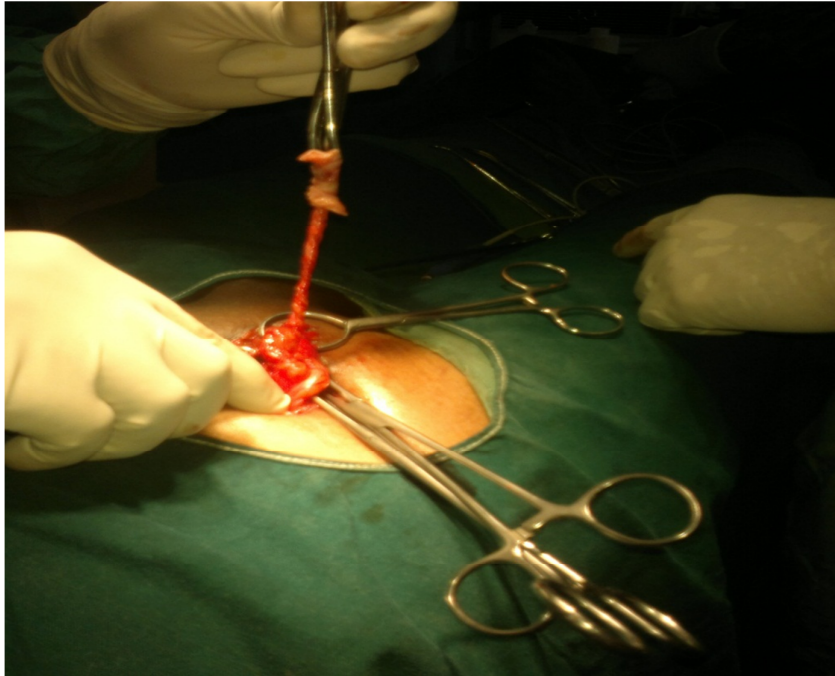


Figure 13 Twisting and ligation of sac

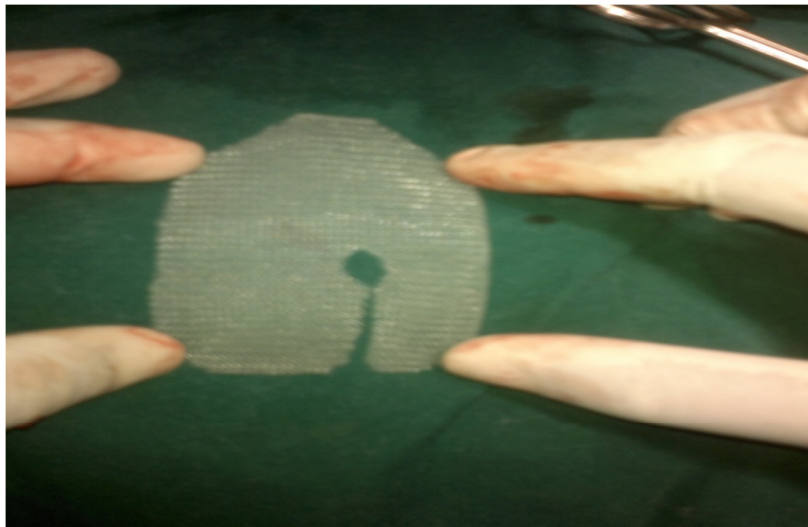


Figure 14 Prepared mesh

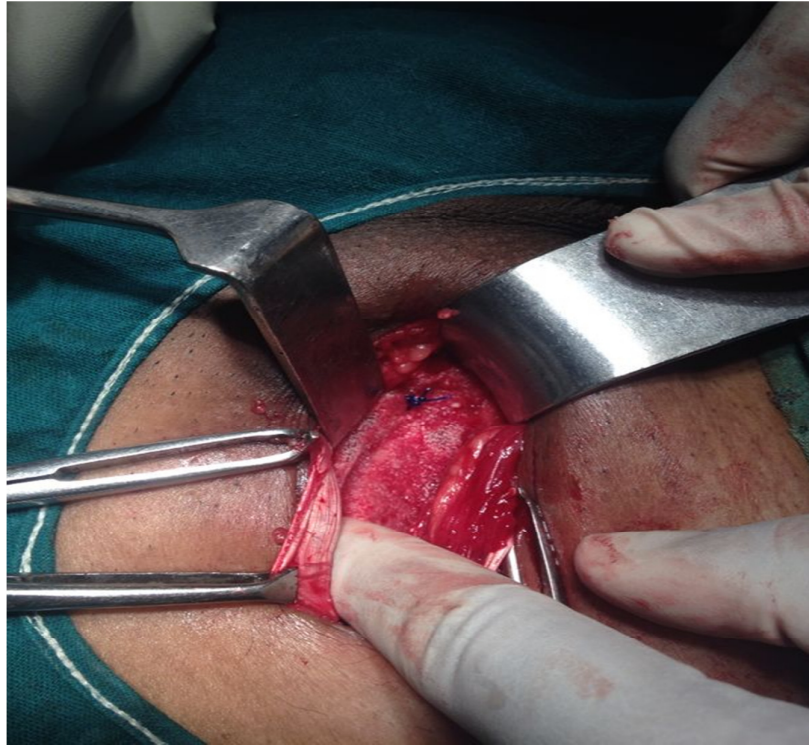


Figure 15 Mesh placement and fixation with sutures

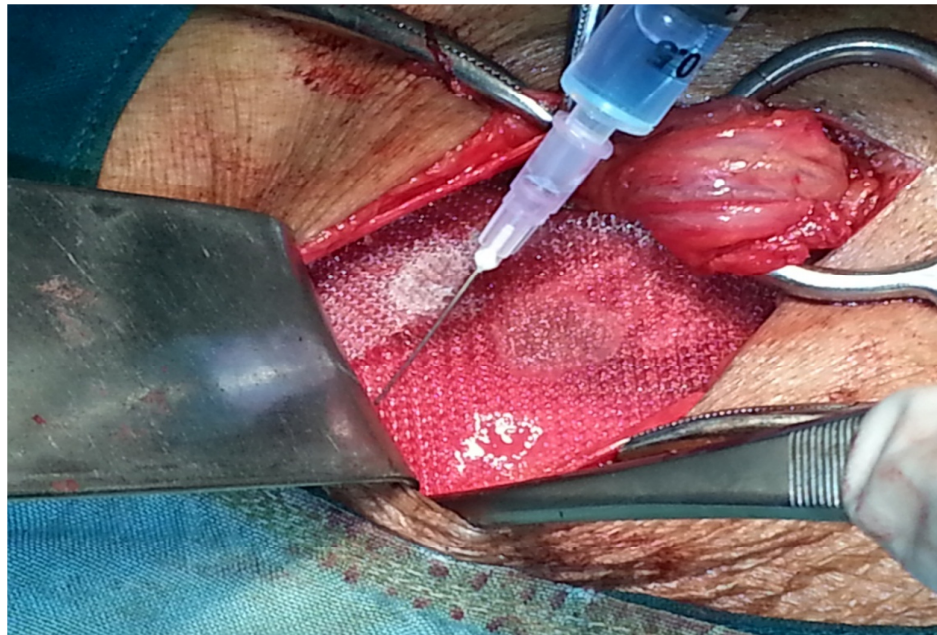


FIGURE 16 Mesh placement and fixation with N butyl cyanoacrylate glue



Figure 17 After mesh fixation with glue

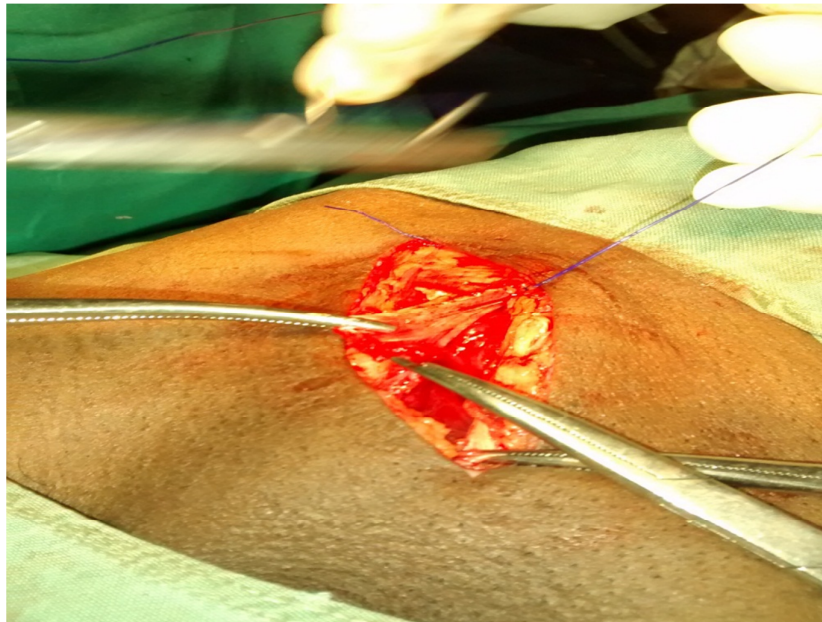


Figure 18 Closure of external oblique



Figure 19 Closure of skin with sutures



Figure 20 Closure of skin with glue

RECONSTRUCTIVE PROCEDURES

The Lichtenstein Tension-free repair

Since the early 1980s, the surgical techniques used in repairing groin hernias has undergone a profound transformation. These changes are highlighted by the fact that in 1996 over 50% of all groin hernia repairs incorporated a mesh prosthesis as part of the repair. In the tension-free repair the mesh prosthesis is not utilized to buttress or support a primarily sutured herniorraphy, but is the actual repair²⁶.

After reducing the sac, a sheet of polypropylene mesh measuring approximately 6x11 cms is trimmed to fit the area exposed and used to reconstruct the entire floor of the inguinal canal without any attempt to close the defect by suture. The mesh is sutured along its lower edge to the pubic tubercle, the lacunar ligament and the inguinal ligament to beyond the internal ring with a continuous 3-0 polypropylene suture. The superior edge is tacked down to the aponeurosis or muscle of the internal oblique with a few interrupted sutures. The lateral edge of the mesh is slit and the two tails passed around to embrace the cord at the internal ring, they then are crossed over each other and tacked down to the inguinal ligament with one polypropylene suture. This creates a new internal ring and shutter mechanism. The external oblique aponeurosis is then sutured in front of the cord. This is a completely tensionless repair and requires no formal reconstruction of the canal floor; it is a revolutionary departure from the tissue repairs used for the past 100yrs since Bassini.²⁷

INTRODUCTION TO CYANOACRYLATE

The original cyanoacrylates (the chemical name for the glue) were discovered in 1942 in a search for materials to make clear plastic gun sights during World War II, when a team of scientists headed by Harry Coover Jr. stumbled upon a formulation that stuck to everything that it came in contact with; it was rejected for the application. In 1951 cyanoacrylates were rediscovered by Eastman Kodak researchers Harry Coover Jr. and Fred Joyner, who recognized their true commercial potential; "Eastman #910" (later "Eastman 910") was the first cyanoacrylate adhesive to be sold, in 1958.²⁸

During the 1960s, Eastman Kodak sold cyanoacrylate to Loctite, which in turn repackaged and distributed it under a different brand name "Loctite Quick Set 404". In 1971 Loctite developed its own manufacturing technology and introduced its own line of cyanoacrylate, called "Super Bonder". Loctite quickly gained market share, and by the late 1970s it was believed to have exceeded Eastman Kodak's share in the North American industrial cyanoacrylate market. National Starch and Chemical Company purchased Eastman Kodak's cyanoacrylate business and combined it with several acquisitions made throughout the 1970s forming Permabond. Other manufacturers of cyanoacrylate include LePage (a Canadian company acquired by Henkel in 1996), the Permabond Division of National Starch and Chemical, Inc., which was a subsidiary of Unilever. Together, Loctite, Eastman and Permabond accounted for approximately 75% of the industrial cyanoacrylate market²⁸. As of 2013 Permabond continued to manufacture the original 910 formula.²⁸

The Lichtenstein hernia repair is a common surgical procedure worldwide. First described in 1989, it has changed hernia surgery drastically^{29,30}. The implantation of a mesh graft to stabilize the transverse fascia according to Lichtenstein is an operation of low complexity and is associated with a low rate of complications and recurrences²⁹⁻³². Because the operation can be performed under local anaesthesia it is well suited to outpatient surgery. Nevertheless, the rare occurrence of chronic pain after Lichtenstein hernia repair was recognized as an issue in the late 1980s³³. In the 1990s, several authors published studies finding up to 50% of patients having postoperative groin discomfort³⁴. The main causes identified as contributing to groin discomfort include: inflammatory reaction to the mesh, nerve lesion or nerve irritation and/or nerve entrapment by fixative sutures³⁴. Because hernia repair with or without mesh implantation resulted in similar rates of chronic groin discomfort, suture-induced irritation of nerves is considered a major underlying factor. This is why alternative, suture less mesh fixation techniques are of major interest: to date only preliminary data for the use of skin staples (rotating skin stapler)³⁵, spiral tacks or tissue adhesives have been published³⁵.

Because direct nerve irritation or nerve entrapment is eliminated, mesh fixation with glue (tissue adhesive) seems an optimal choice to reduce postoperative pain. Our choice in the use of this glue was considered according to the following criteria: Choosing a synthetic glue, thus avoiding the minimum but unavoidable risk inherent in the use of biological glue.

Using a surgical glue whose essential function consists in its high binding capacity, which is easy to apply, dries rapidly, and is bio absorbable. In an attempt to find the ideal surgical technique for mesh fixation during laparoscopic total extra peritoneal inguinal hernia repair, we evaluate the use of a synthetic surgical glue (N-

butylcyanoacrylate—Glubran 2) in an effort to reduce postoperative pain and the complications associated with the use of staples

Technique for Lichtenstein's Hernioplasty:

After thoroughly painting with betadine 10%v/v, drapes were put. A 5cm incision was made starting from the pubic tubercle medially to the position of the internal ring laterally (1.25cm above medial 3/5th of the inguinal ligament). The skin incision was deepened. The external oblique aponeurosis was opened and its lower leaf freed from the spermatic cord. The upper leaf of the external oblique was freed from the underlying internal oblique muscle and aponeurosis. The spermatic cord was mobilised by hooking an index finger around it near pubic tubercle. A thorough search was made for any direct sac. If present the direct sac was inverted and imbricated using a non absorbable suture (Prolene2-0) to flatten the posterior wall. The cremasteric sheath was incised longitudinally and the cord structures separated out and a search for any indirect sac was made.

The indirect sac, if found, was freed from the cord to a point beyond the neck of the sac. The sac was opened. Any contents of peritoneal cavity present were removed by twisting the sac. The sac was then transligated and excised. To minimize the risk of postoperative ischemic orchitis, complete non sliding scrotal hernia sacs were transacted at the midpoint of the canal, leaving the distal section in place.

A sheet of 2.4"x 4.3" polypropylene { Prolene } onlay mesh was sutured with polypropylene 2-0 continuous sutures into place or fixed with n butyl cyanoacrylate glue. The medial end of the mesh was cut out to the shape of the medial corner of the inguinal canal. The infero medial border of the mesh was sutured to the soft tissues

overlying pubic tubercle after obtaining 2-3 cms of overlap here or fixed with 2- 3 drops of glue . The periosteum of the bone was avoided.

The inferior border of the mesh was attached to the inguinal ligament with a loose continuous polypropylene suture or with d intermittent drops of N butyl cyanoacrylate glue. A slit was made at the lateral end of the mesh, creating two tails a wider above and a narrower below. A 3mm circular piece of mesh was removed at the medial end of the slit for positioning the cord. The wider upper tail was passed around the cord, and sutured or adhered with glue along with the narrower tail to the inguinal ligament with loose continuous suture or fixed with glue using 2 cc sterile syringe. Similarly the upper end of mesh was sutured or glued at different sites of conjoint tendon.

During the procedure every care was taken to prevent entrapment of ilioinguinal as well as iliohypogastric nerves in the sutures.

The external oblique aponeuroses was closed using prolene 2-0 and skin closed by interrupted sutures with ethylon 2-0.

All inguinal hernias share the common feature of emerging through the myopectinaeal orifice of Fruchaud, the opening in the lower abdominal wall bounded above by the myoaponeurotic arch of the lower edges of the internal oblique and the transverse abdominis muscle. And below by the pectineal line of the superior pubic ramus.

METHODOLOGY

SOURCE OF DATA:

All patients presenting to B.L.D.E.U's Shri B. M. Patil Medical College Hospital and Research Centre Bijapur and admitted patients in whom the diagnosis of primary inguinal hernia is considered from October 2013 to June 2015

Method of collection of data:

- This is a randomised controlled trial study in which patients presenting with unilateral primary uncomplicated indirect and direct inguinal hernias in B.L.D.E.U's Shri B. M. Patil Medical College Hospital will be taken up into study.
- Two groups are made, standard suture fixation for one group and glue fixation to another group.
- Minimum of 50 cases with permissible error in each group will be taken up for the study.
- The period of study is from October 2013 to June 2015.
- Diagnosis of unilateral primary uncomplicated indirect and direct inguinal hernia was made on the basis of thorough clinical examination, appropriate laboratory and radiological investigations.
- A pretested structural proforma will be used to collect relevant information for each individual patient selected.
- Data will be entered on master chart for analysis.
- The data will be analysed by using student t- test, Chi square test, Mann Whitmy test, & Fischer exact tests wherever needed respectively.
- Cases will be selected consequently with following inclusion and exclusion criteria.

Inclusion criteria:

- Men 20 years of age or older with unilateral/bilateral primary inguinal hernia.

Exclusion criteria:

- Any recurrent hernias.
- Presence of bowel obstruction, strangulation, peritonitis or perforation.
- Associated femoral hernia.
- Patients undergoing orchidectomy in the same procedure.

Follow up:

- Early complications (within 1 month): Pain, seroma formation, hematoma, wound infection rate.
- Late complications: Chronic pain using visual analogue scale {3 to 6mths}, foreign body sensation.

Research hypothesis:

N-butyl-2-cyanoacrylate glue mesh fixation in Lichtenstein hernia repair is having better outcomes when compared with standard suture mesh in terms of operating time, postoperative pain, foreign body sensation, seroma, surgical site infection, haematoma and time taken to return back to normal work after 3 months.

Sampling:

Study period from: October 2013 to June 2015.

All the patients admitted during this period, who fulfil the inclusion criteria, will be included in this study.

For control group mesh was fixed to the pubic tubercle, inguinal ligament and conjoint tendon by standard prolene 2-0.

For case group mesh was fixed to the pubic tubercle, inguinal ligament and conjoint tendon by (ENDOCRYL) that is N butyl cyanoacrylate glue.

A single dose of Inj.Ceftriaxone + Sulbactam 1.5 gm was given intravenously immediately before the surgery.

The note was taken of the contents of the sac, and any technical difficulty encountered during the surgery.

Postoperatively patient was put on Inj. Ceftriaxone + Sulbactam 1.5 gm BD intravenously for five days and injection Dynapar aq iv BD for 2 days . The patients were followed up for postoperative pain which was evaluated using visual analogue scale, wound hematoma, wound seroma, wound infection.

Sutures were removed on the 7th postoperative day and the patients discharged if there was no wound infection, were ambulatory, were taking orally and felt comfortable. Patients were called to the outpatient department and follow up was done at 1 and 3 months for complications like chronic groin pain (inguinodynia), foreign body sensation. Patients were assessed for postoperative pain using visual analogue scale after 1 & 3 months after surgery. Visual analogue scale consists of a 10 cm line anchored at one end by a label as no pain and at the other end by a label such a severest pain patient experienced in his life time. We translated this for documentation as a 1-3 mild pain, 3-7 moderate pain, 7-10 severe pain.

RESULTS

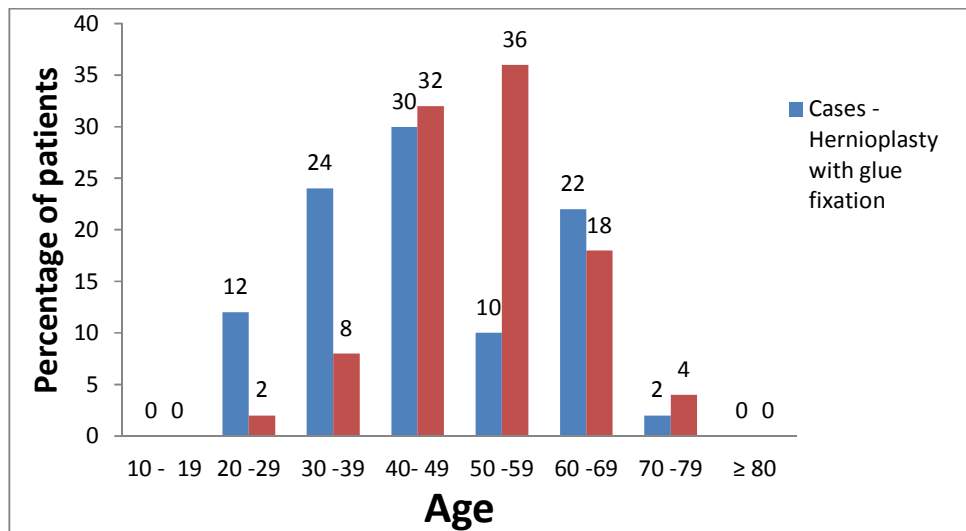
Comparison of age-wise distribution of cases

Table 1

| Age in years | Cases - Hernioplasty with glue fixation n (%) | Control - Lichtenstin's hernioplasty with sutures n (%) | Total |
|----------------|--|--|-----------|
| 20 - 29 years | 6 (12) | 1 (2) | 7 (7) |
| 30 -39 years | 12 (24) | 4 (8) | 16 (16) |
| 40 -49 years | 15 (30) | 16 (32) | 31 (31) |
| 50 -59 years | 5 (10) | 18 (36) | 23 (23) |
| 60x` -69 years | 11 (22) | 9 (18) | 20 (20) |
| 70 -79 years | 1 (1) | 2 (4) | 3 (3) |
| Total | 50 (100) | 50(100) | 100 (100) |

Number in parenthesis indicate percentages

Chart 1



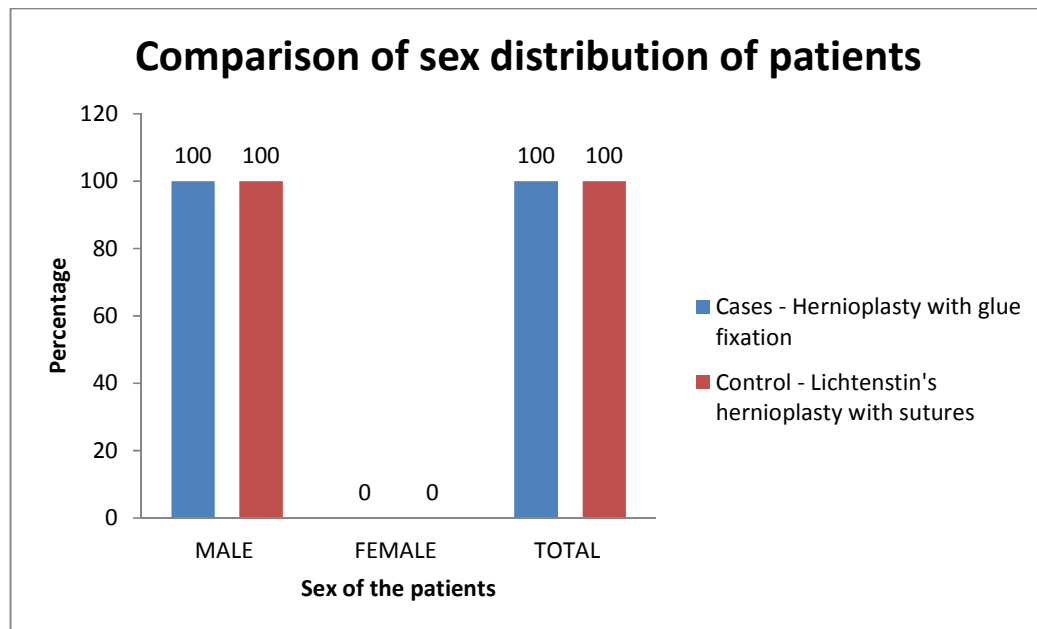
Comparison of sex distribution of patients

Table 2

| SEX | Cases - Hernioplasty with glue fixation n (%) | Control - Lichtenstin's hernioplasty with sutures n (%) | Total |
|---------------|--|--|--------------|
| MALE | 50 (100) | 50 (100) | 100 (100) |
| FEMALE | 0 | 0 | 0 (0) |
| TOTAL | 50 | 50 | 100 (100) |

Number in parenthesis indicate percentages

Chart 2



Comparison of Presenting complaints

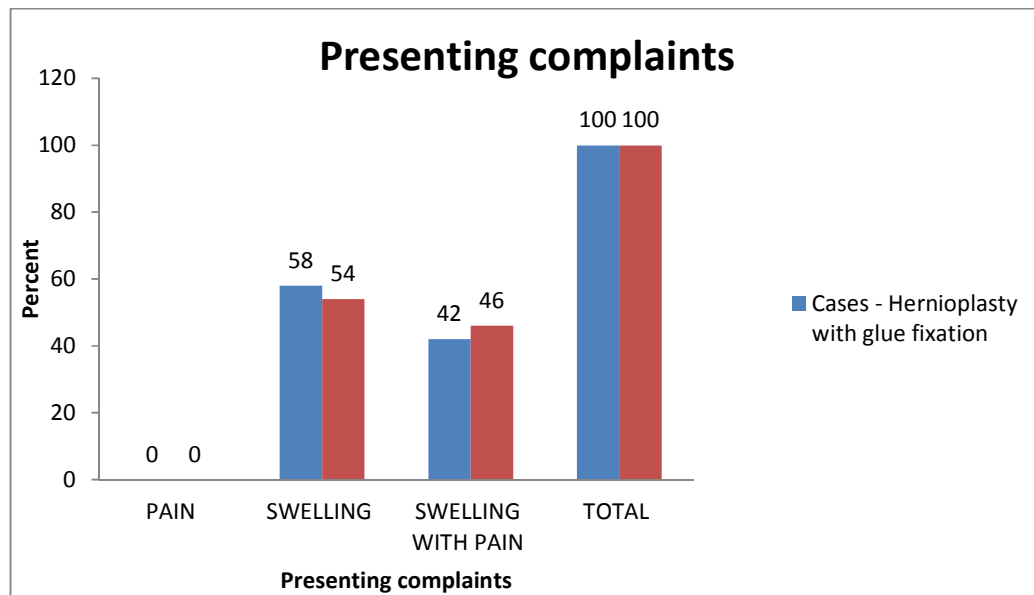
Table 3

| COMPLAINTS | Cases - Hernioplasty with glue fixation n (%) | Control - Lichtenstin's hernioplasty with sutures n (%) | TOTAL | p value |
|--------------------|--|--|------------|-------------------|
| PAIN | 0 | 0 | 0 (0) | p value = 0.69 |
| SWELLING | 29 (58) | 27 (54) | 56 (56) | |
| SWELLING WITH PAIN | 21 (42) | 23 (46) | 44 (44) | |
| TOTAL | 50 (100) | 50 (100) | 100 | |

Number in parenthesis indicate percentages

The result is *not* significant at $p < 0.05$.

Chart 3



Comparison of Duration of Swelling

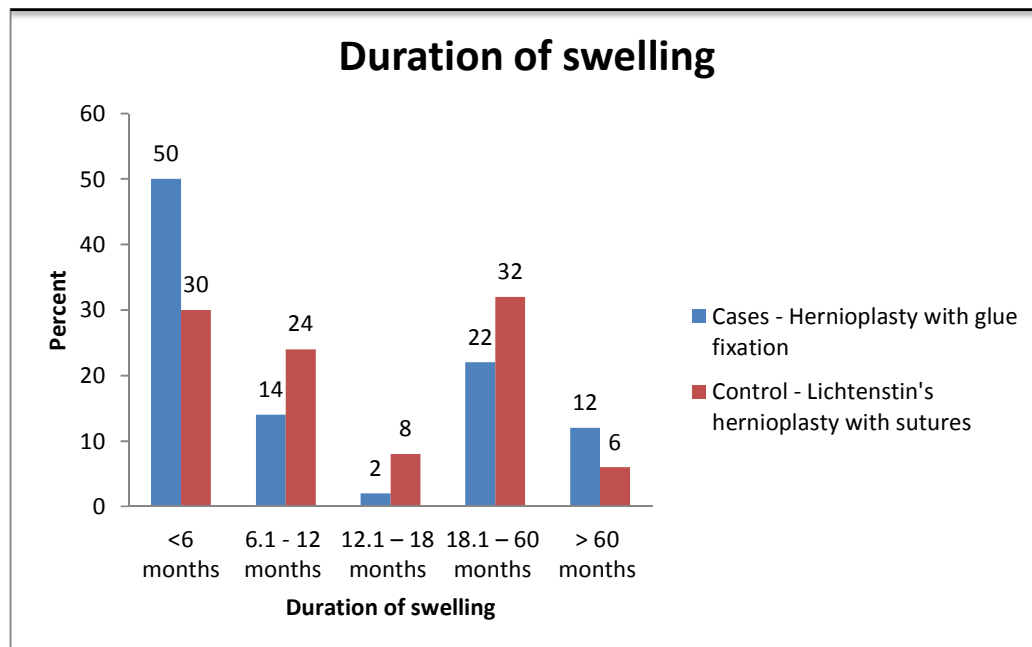
Table 4

| Duration of SWELLING | Cases - Hernioplasty with glue fixation n (%) | Control - Lichtenstin's hernioplasty with sutures n (%) | Total | χ^2 value and p value |
|-----------------------|--|--|------------------|--|
| <6 MONTHS | 25 [50] | 15 [30] | 40 (40) | χ^2 value = 7.5417 p value= 0.109* |
| 6.1 MONTHS- 12 months | 7 [14] | 12[24] | 19 (19) | |
| 12.1 – 18 months | 1 [2] | 4 [8] | 5 (5) | |
| 18.1 – 60 months | 11[22] | 16 [32] | 27 (27) | |
| > 60 months | 6 [12] | 3 [6] | 9 (9) | |
| TOTAL | 50 (100) | 50 (100) | 100 (100) | |

Number in parenthesis indicate percentages

*The result is *not* significant at $p < .05$.

Chart 4



Comparison of side affected

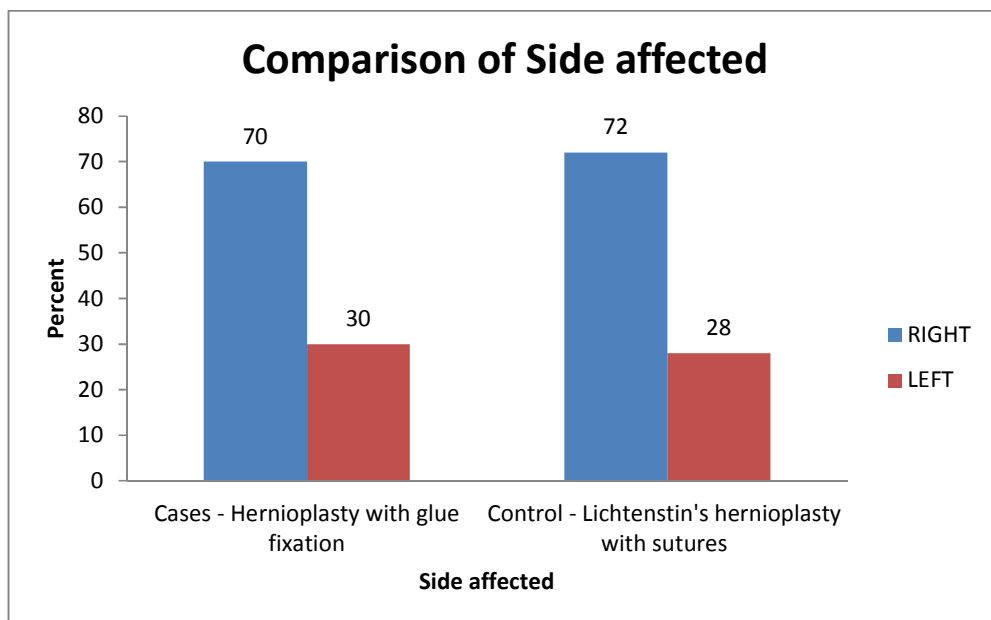
Table 5

| SIDE affected | Cases - Hernioplasty with glue fixation n (%) | Control - Lichtenstin's hernioplasty with sutures n (%) | Total | χ^2 value and p value |
|----------------------|--|--|------------------|--|
| RIGHT | 35 [70] | 36 [72] | 71 (71) | χ^2 value = 0.0486 p value= 0.826* |
| LEFT | 15 [30] | 14 [28] | 29 (29) | |
| TOTAL | 50[100] | 50[100] | 100 (100) | |

Number in parenthesis indicate percentages

*The result is *not* significant at $p < 0.05$.

Chart 5



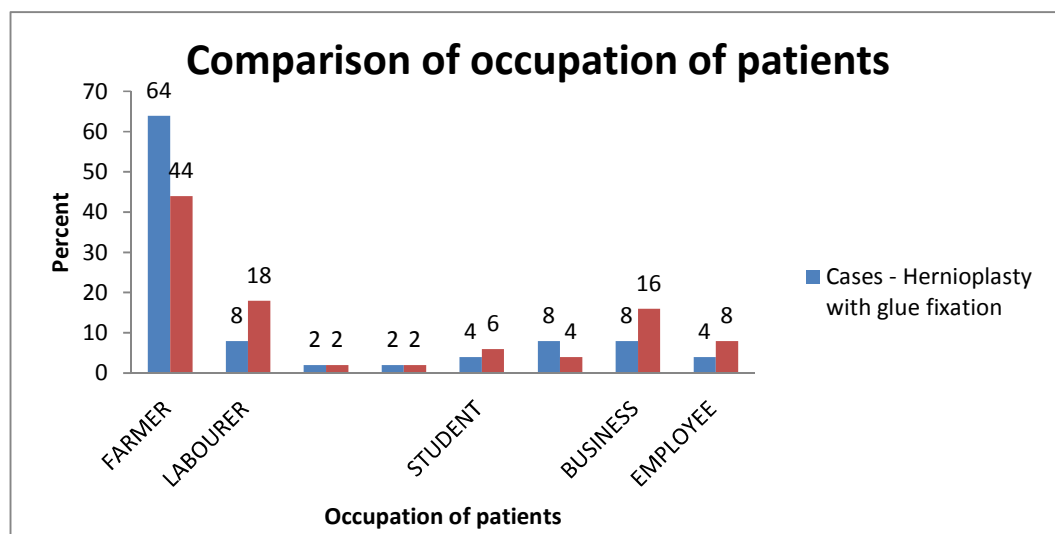
Comparison of occupation of patients

Table 6

| OCCUPATION | Cases - Hernioplasty with glue fixation n (%) | Control - Lichtenstin's hernioplasty with sutures n (%) | Total |
|-------------------|--|---|------------------|
| FARMER | 32[64] | 22[44] | 54 (54) |
| LABOURER | 4[8] | 9[18] | 13 (13) |
| TEACHER/DOCTOR/SN | 1[2] | 1[2] | 2 (2) |
| DRIVER/CONDUCTOR | 1[2] | 1[2] | 2 (2) |
| STUDENT | 2[4] | 3[6] | 5 (5) |
| RETIRED EMPLOYEE | 4[8] | 2[4] | 6 (6) |
| BUSINESS | 4[8] | 8[16] | 12 (12) |
| EMPLOYEE | 2[4] | 4[8] | 6 (6) |
| TOTAL | 50[100] | 50[100] | 100 (100) |

Number in parenthesis indicate percentages

Chart 6



Comparison of type of hernia (direct or indirect hernia)

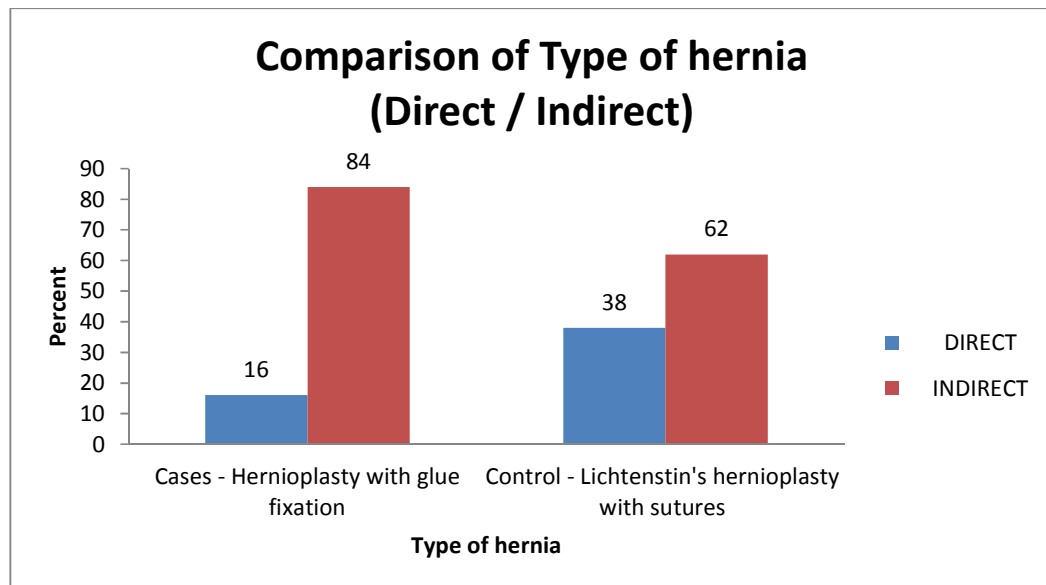
Table 7

| | Cases - Hernioplasty with glue fixation n (%) | Control - Lichtenstin's hernioplasty with sutures n (%) | Total | χ^2 value and p value |
|----------|--|--|--------------|--|
| DIRECT | 8 (16) | 19 (38) | 27 (27) | χ^2 value = 6.139 p value= 0.013* |
| INDIRECT | 42 (84) | 31 (62) | 73 (73) | |
| TOTAL | 50 (100) | 50 (100) | 100 | |

Number in parenthesis indicate percentages

The result is significant at $p < 0.05$.

Chart 7



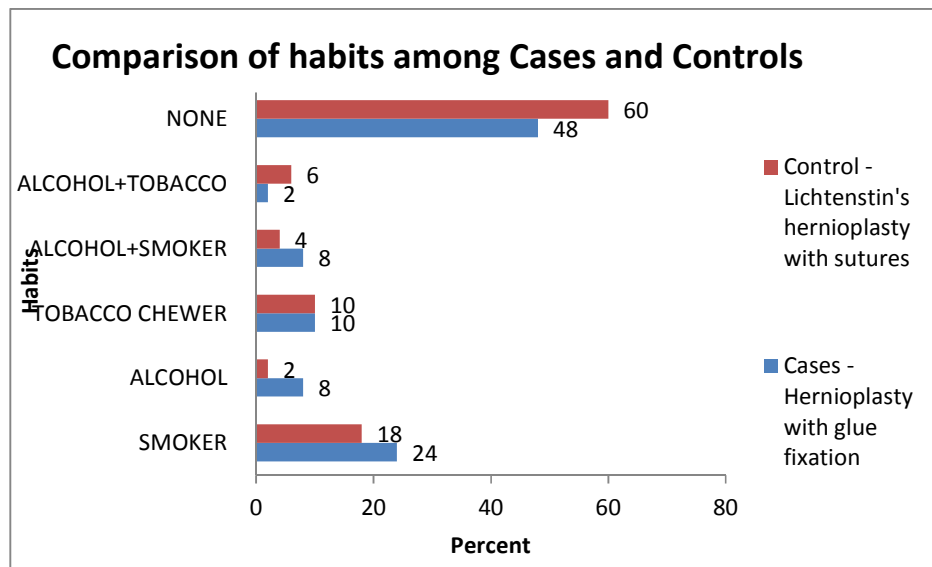
Personal History (Habits)

Table 8

| HABITS | Cases - Hernioplasty with glue fixation n (%) | Control - Lichtenstin's hernioplasty with sutures n (%) | Total n (%) |
|------------------------|--|--|------------------------|
| SMOKER | 12[24] | 9[18] | 21 (21) |
| ALCOHOL | 4[8] | 1[2] | 5 (5) |
| TOBACCO CHEWER | 5[10] | 5[10] | 10 (10) |
| ALCOHOL+SMOKER | 4[8] | 2[4] | 6 (6) |
| ALCOHOL+TOBACCO | 1[2] | 3[6] | 4 (4) |
| NONE | 24[48] | 30[60] | 54 (54) |
| TOTAL | 50[100] | 50[100] | 100 (100) |

Number in parenthesis indicate percentages

Chart 8



Comparison of associated illnesses

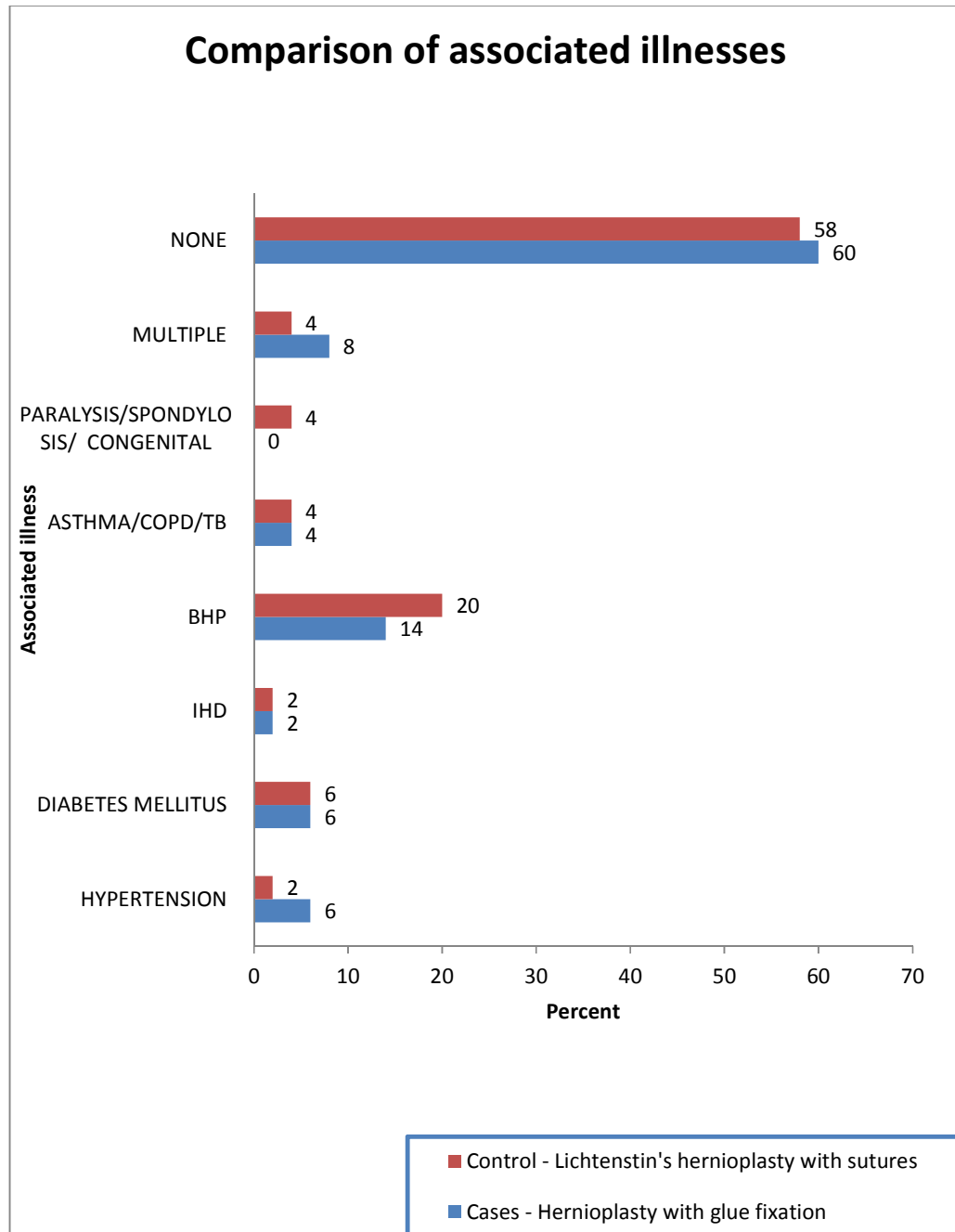
Table 9

| Associated illness | Cases - Hernioplasty with glue fixation n (%) | Control - Lichtenstin's hernioplasty with sutures n (%) | Total n (%) | p value |
|---|--|--|------------------------|----------------|
| HYPERTENSION | 3[6] | 1[2] | 4 (4) | p = 0.755* |
| DIABETES MELLITUS | 3[6] | 3[6] | 6 (6) | |
| IHD | 1[2] | 1[2] | 2 (2) | |
| BHP | 7[14] | 10[20] | 17 (17) | |
| ASTHMA/COPD/TB | 2[4] | 2[4] | 4 (4) | |
| PARALYSIS/ SPONDYLOSIS/ CONGENITAL | 0[0] | 2[4] | 2 (2) | |
| MULTIPLE | 4[8] | 2[4] | 6 (6) | |
| NONE | 30[60] | 29[58] | 59 (59) | |
| TOTAL | 50[100] | 50[100] | 100 (100) | |

*Result is not significant at $p < 0.05$

Number in parenthesis indicate percentages

Chart 9



Comparison of abdominal tone

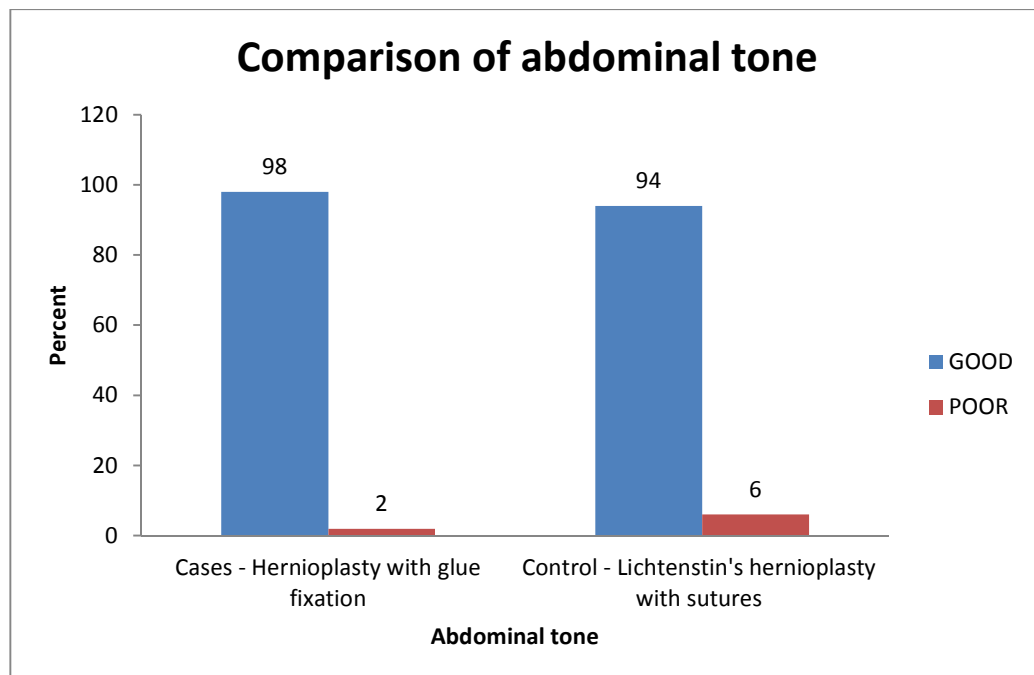
Table 10

| ABDOMINAL MUSCLE TONE | Cases - Hernioplasty with glue fixation n (%) | Control - Lichtenstin's hernioplasty with sutures n (%) | Total n (%) | χ^2 value and p value |
|-----------------------|--|--|----------------|---|
| GOOD | 49 (98) | 47 (94) | 96 (96) | χ^2 value = 1.402 p value = 0.307 |
| POOR | 1 (2) | 3 (6) | 4 (4) | |
| TOTAL | 50 (100) | 50 (100) | 100 (100) | |

Number in parenthesis indicate percentages

*Result is not significant at $p < 0.05$

Chart 10



Comparison of Operating time

Table 11

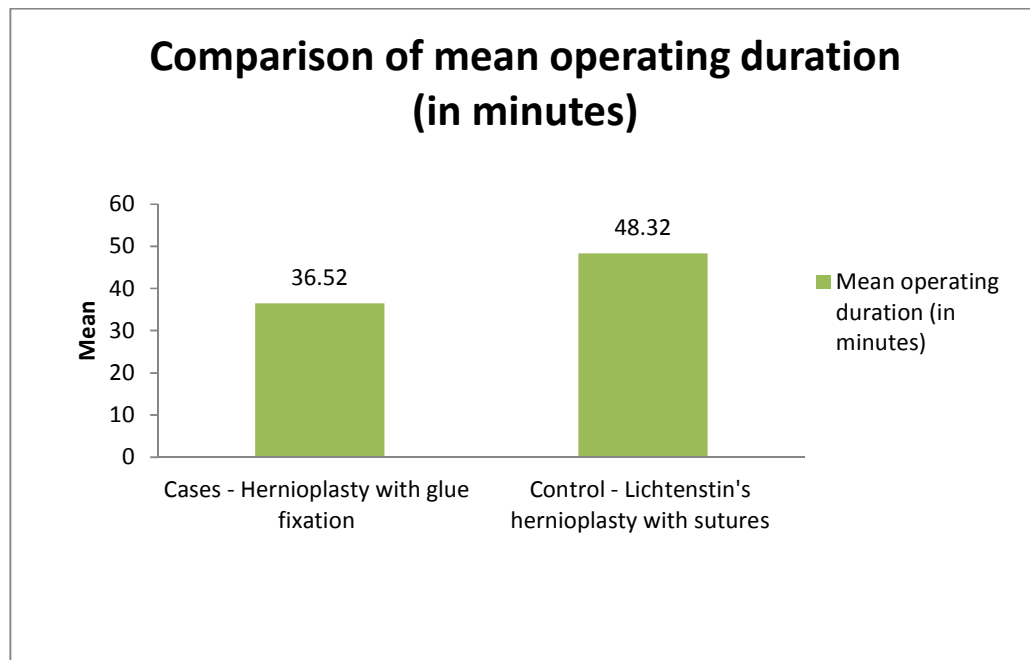
| | Cases - Hernioplasty with glue fixation | | Control - Lichtenstin's hernioplasty with sutures | | |
|----------------------------------|---|--------------------|---|--------------------|-----------------------------------|
| Operating time in minutes | Mean | Standard Deviation | Mean | Standard Deviation | p value |
| | 36.52 | 3.11 | 48.32 | 5.93 | 0.01* (p value is significant) |

The mean operating time required for the cases is 36.52 ± 3.1 minutes.

The mean operating time required for the controls is 48.32 ± 5.9 minutes.

There is a significant difference between the time required for the two procedures.

Chart 11



Comparison of Duration of hospital stay

Table 12

| | Cases - Hernioplasty with glue fixation | | Control - Lichtenstin's hernioplasty with sutures | | |
|-----------------------|---|--------------------|---|--------------------|---------|
| Hospital stay in days | Mean | Standard Deviation | Mean | Standard Deviation | p value |
| | 4.82 | 1.30 | 6.48 | 1.39 | 0.00* |

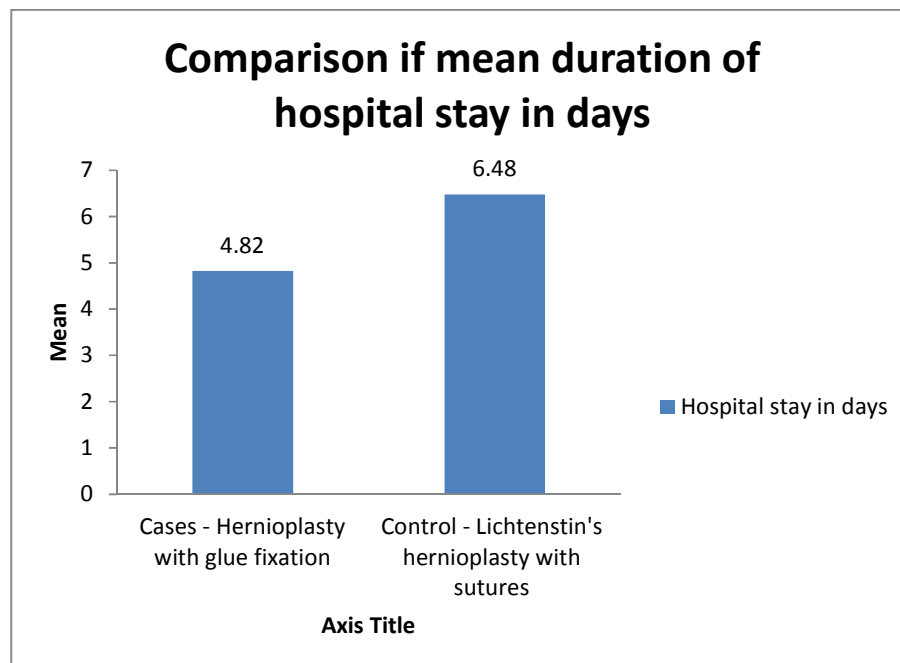
* Significant with $p < 0.05$

The mean duration of hospital stay required for the cases is 4.82 ± 1.3 days .

The mean duration of hospital stay required for the controls is 6.48 ± 1.39 days.

There is a significant difference between the time required for the two procedures.

Chart 12



Comparison of Chronic Pain

Table 13

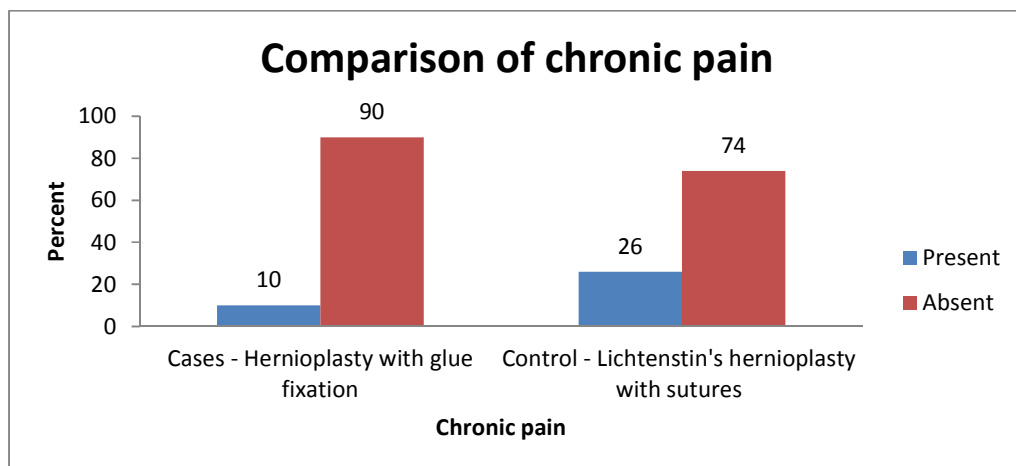
| Chronic pain | Cases - Hernioplasty with glue fixation n (%) | Control - Lichtenstin's hernioplasty with sutures n (%) | Total n (%) | χ^2 value and p value |
|--------------|--|--|----------------|--------------------------------|
| Present | 5 [10] | 13 [26] | 18 [18] | $\chi^2 = 4.336$ p = 0.037* |
| Absent | 45 [90] | 37 [74] | 82 [82] | |
| Total | 50 [100] | 50 [100] | 100 [100] | |

* result is Significant with p < 0.05

Number in parenthesis indicates percentages

The number of patients with chronic pain who underwent hernioplasty with glue fixation is less (10%) when compared to number of patients with chronic pain who underwent Lichtenstin's hernioplasty with sutures (26%). This association is found to be statistically significant.

Chart 13



Comparison of grades of pain

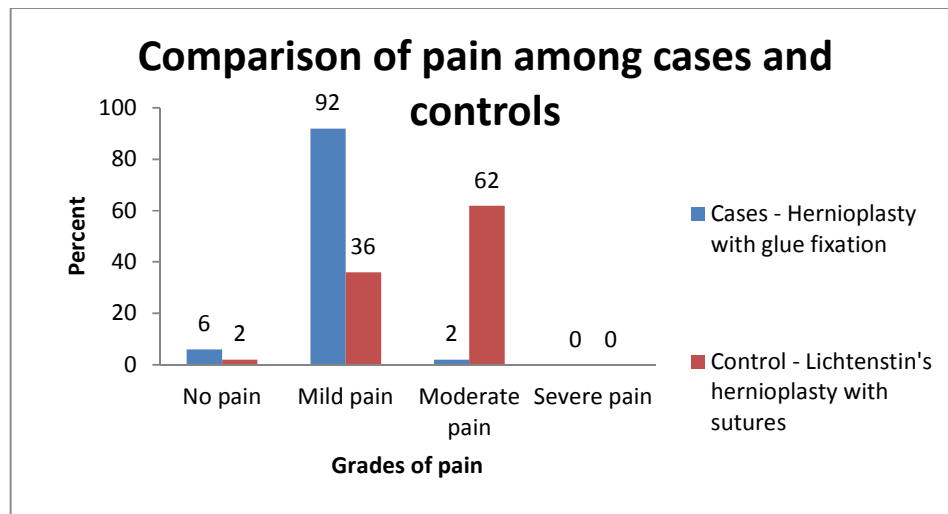
Table 14

| Grades of pain | Cases - Hernioplasty with glue fixation n (%) | Control - Lichtenstin's hernioplasty with sutures n (%) | Total n(%) | χ^2 value and p value |
|----------------|---|---|------------|----------------------------------|
| No pain | 3 (6) | 1 (2) | 4 (4) | $\chi^2 = 41.38$ p = 0.001* |
| Mild pain | 46 (92) | 18 (36) | 64 (64) | |
| Moderate pain | 1 (2) | 31 (62) | 32 (32) | |
| Severe pain | 0 (0) | 0 (0) | 0 (0) | |
| Total | 50 (100) | 50 (100) | 100 (100) | |

* Result is significant with p < 0.05

Number in parenthesis indicates percentages

Chart 14



The case group has lesser number of patients suffering from moderate pain (2%) compared to control group (62%) and this association is found to be statistically significant.

Comparison of Visual analogue scale

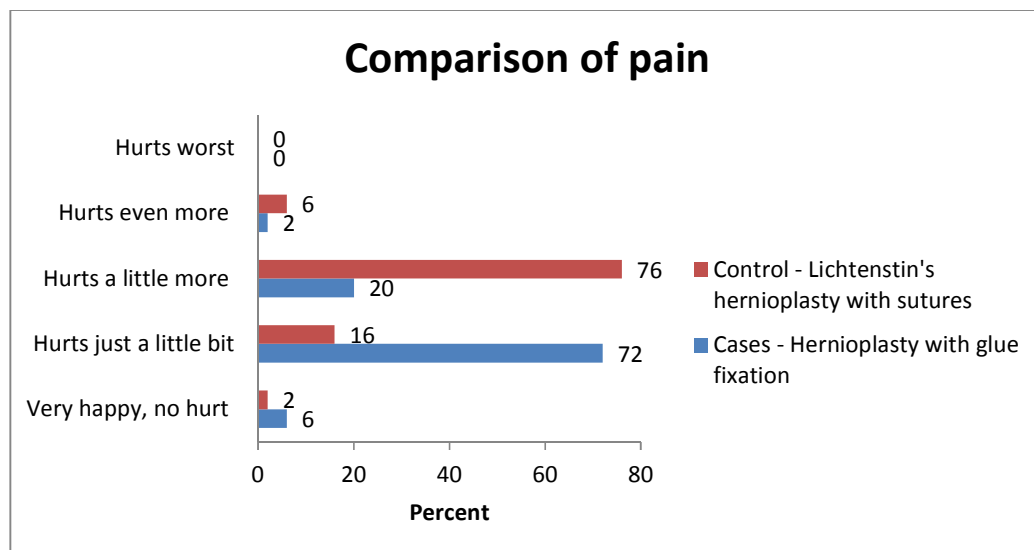
Table 15

| Categories of pain | Cases - Hernioplasty with glue fixation n (%) | Control - Lichtenstin's hernioplasty with sutures n (%) | Total n(%) | χ^2 value and p value |
|-------------------------|---|---|---------------|----------------------------------|
| Very happy, no hurt | 3 (6) | 1 (2) | 4 (4) | $\chi^2 = 36.15$ p = 0.001* |
| Hurts just a little bit | 36 (72) | 8 (16) | 44 (64) | |
| Hurts a little more | 10 (20) | 38 (76) | 48 (32) | |
| Hurts even more | 1 (2) | 3 (6) | 4 (4) | |
| Total | 50 (100) | 50 (100) | 100 (100) | |

* Result is significant with p < 0.05

Number in parenthesis indicates percentages

Chart 15



The case group has lesser number of patients suffering from moderate pain (2%) compared to control group (62%).

Duration of Hospital Stay

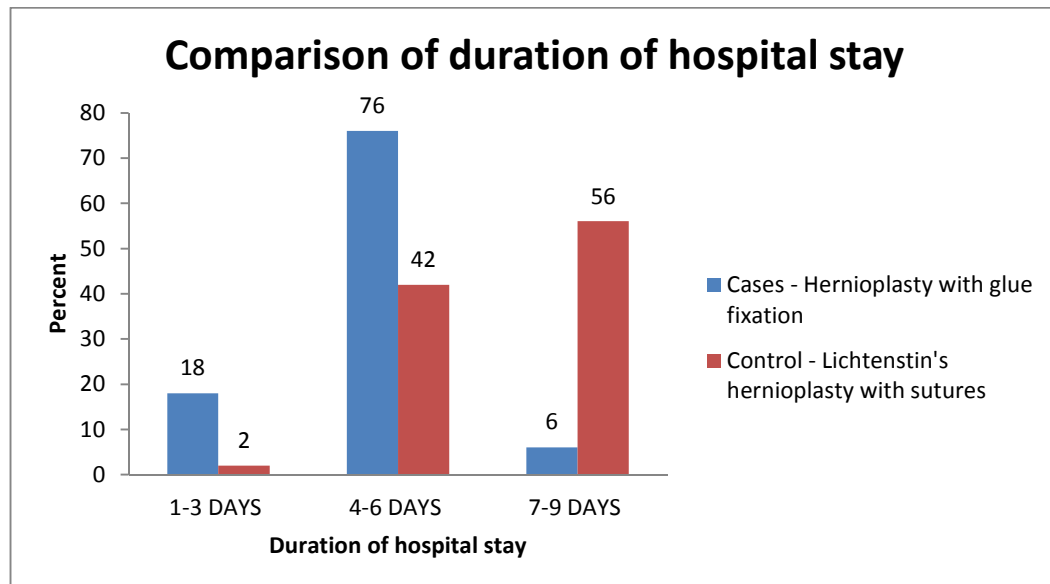
Table 16

| HOSPITAL STAY | Cases - Hernioplasty with glue fixation n (%) | Control - Lichtenstin's hernioplasty with sutures n (%) | Total | χ^2 value and p value |
|---------------|--|--|-----------|--------------------------------|
| 1-3 DAYS | 9 [18] | 1 [2] | 10 (10) | $\chi^2 = 36.46$ p = 0.001* |
| 4-6 DAYS | 38 [76] | 21 [42] | 59 (59) | |
| 7-9 DAYS | 3 [6] | 28 [56] | 31 (31) | |
| TOTAL | 50[100] | 50[100] | 100 (100) | |

* Result is significant with p < 0.05

Number in parenthesis indicates percentages

Chart 16



Comparison of Seroma, Hematoma, Wound infection after 1 month

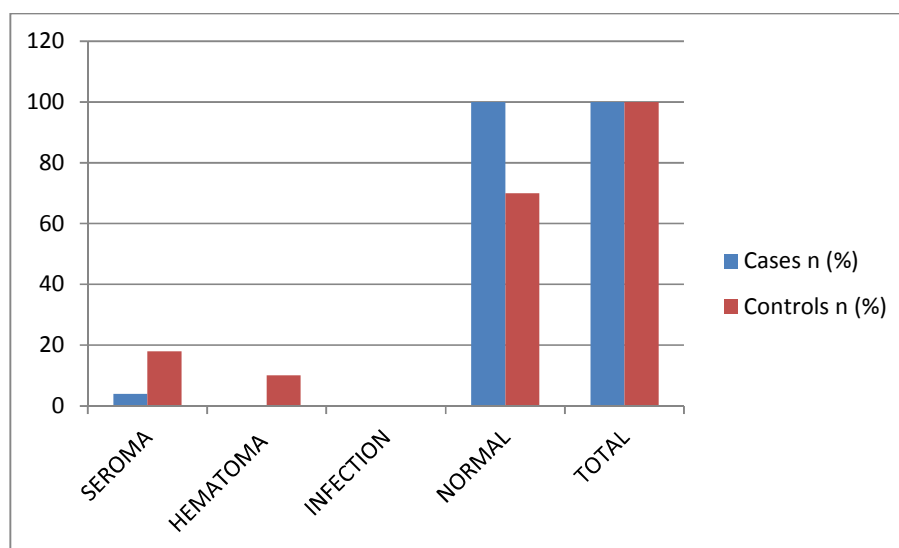
Table 17

| | Cases n (%) | Controls n (%) |
|-----------|-------------|----------------|
| SEROMA | 2 [4] | 9 [18] |
| HEMATOMA | 0 [0] | 5 [10] |
| INFECTION | 0 [0] | 0 [0] |
| NORMAL | 50 [100] | 35 [70] |
| TOTAL | 50 [100] | 50 [100] |

Number in parenthesis indicates percentages

There were only 4% cases with complaints of seroma and none with complaints of infection or hematoma in the case group, whereas 18% of controls presented with complaints of seroma and 10% with hematoma. Hence, the case group is superior to control group.

Chart 17



DISCUSSION

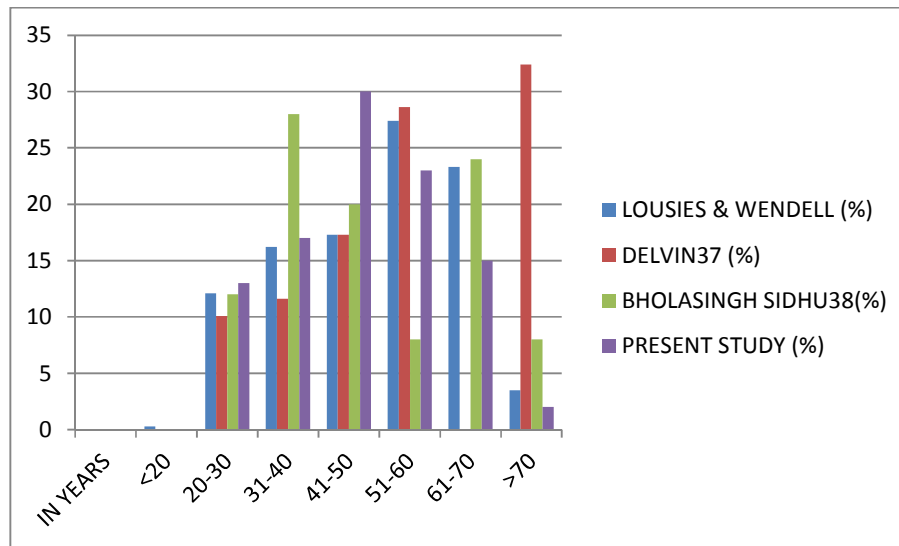
Age at Presentation (Comparison with other studies)

Table 18

| AGE GROUP IN YEARS | LOUSIES & WENDELL (%) | DELVIN ³⁷ (%) | BHOLASINGH SIDHU ³⁸ (%) | PRESENT STUDY (%) |
|-----------------------|--------------------------|-----------------------------|---------------------------------------|----------------------|
| <20 | 0.3 | - | - | 0 |
| 20-30 | 12.1 | 10.1 | 12 | 13 |
| 31-40 | 16.2 | 11.6 | 28 | 17 |
| 41-50 | 17.3 | 17.3 | 20 | 30 |
| 51-60 | 27.4 | 28.6 | 8 | 23 |
| 61-70 | 23.3 | - | 24 | 15 |
| >70 | 3.5 | 32.4 | 8 | 2 |

Chart 18

Comparison of Age With Other Studies



The incidence of age at presentation of Inguinal hernia was maximum between 30-60 years of life . (Louies & Wendell, Delvin, Bhol Singh). These results are comparable with present study with highest number of patients between 30-60 years.

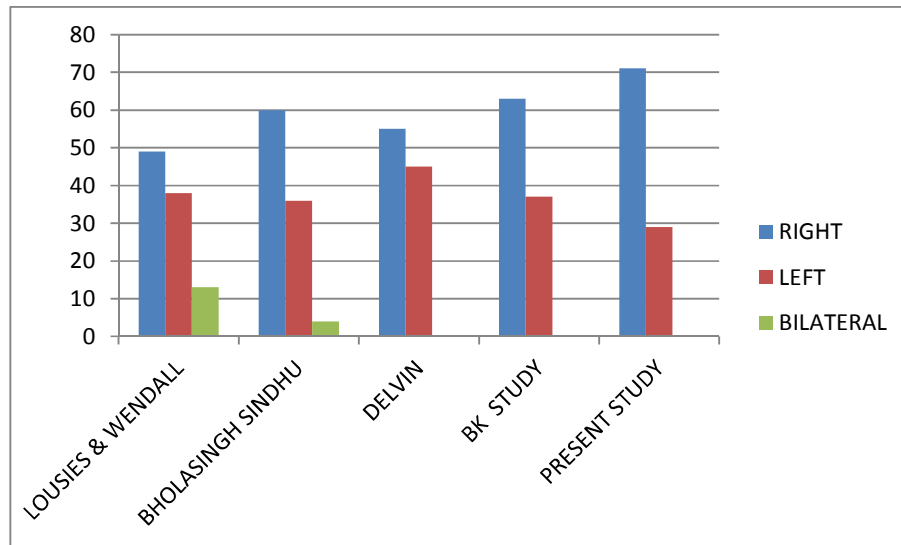
Location of Hernia (Comparison with other studies)

Table19

| LOCATION | LOUSIES & WENDALL | BHOLASINGH SINDHU ³⁸ | DELVIN ³⁷ | BK STUDY ³⁹ | PRESENT STUDY |
|-----------|-------------------|---------------------------------|----------------------|------------------------|---------------|
| RIGHT | 49% | 60% | 55% | 63% | 71% |
| LEFT | 38% | 36% | 45% | 37% | 29% |
| BILATERAL | 13% | 4% | - | - | 0% |

Chart 19

Comparison of location of hernia with other studies



Present study group is comparable with B.K³⁹ Study with 71% right sided Inguinal hernias and 29% left sided Inguinal hernias.

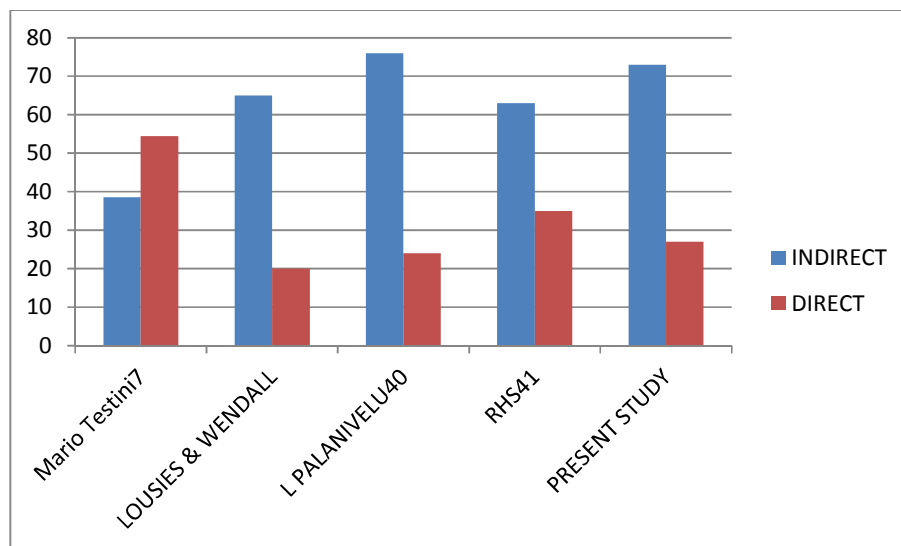
Comparison of type of hernia with other studies (Direct or Indirect hernia)

Table 20

| TYPE | Mario Testini⁷ | LOUSIES & WENDALL | L PALANIVELU⁴⁰ | RHS⁴¹ | PRESENT STUDY |
|-------------|----------------------------------|------------------------------|----------------------------------|-------------------------|----------------------|
| INDIRECT | 38.5 % | 65% | 76% | 63% | 73% |
| DIRECT | 54.5% | 20% | 24% | 35% | 27% |

Chart 20

Comparison of type of hernia



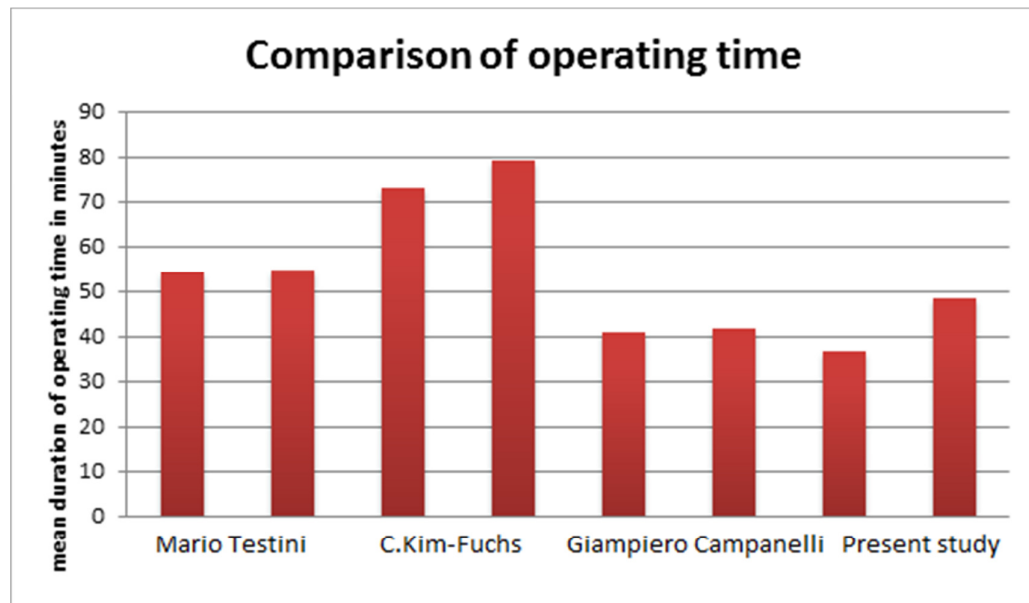
Present study is comparable with L.Palanivelu ⁴⁰ with 73% having Indirect component and 27% Percent having Direct component

Comparison of Operating time (Comparison with other studies)

Table 21

| Mario Testini ⁷ (Mean duration in minutes) | | C.Kim-Fuchs ⁵ | | Giampiero Campanelli ³⁵ | | Present study* (Mean duration in minutes) | |
|--|----------|---|----------|------------------------------------|----------|---|----------|
| Cases | Controls | Cases | Controls | Cases | Controls | Cases | Controls |
| 54.2 | 54.5 | 73 | 79 | 40.7 | 41.5 | 36.52 | 48.32 |
| Not significant | | Significant difference in time duration | | Not significant | | Significant difference in operating time duration | |

Chart 21

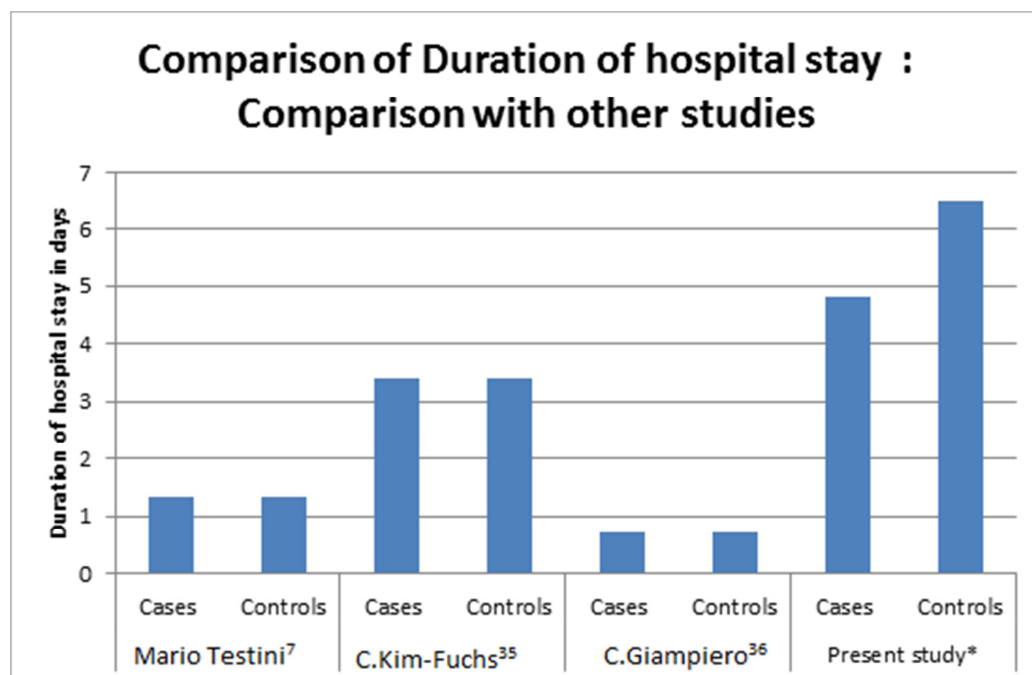


Comparison of Duration of hospital stays (Comparison with other studies)

Table 22

| Mario Testini ⁷ | | C.Kim-Fuchs ⁵ | | Giampiero Campanelli ³⁵ | | Present study* | |
|----------------------------|------------------------|--------------------------|----------|------------------------------------|---------------------|---|----------|
| Cases | Controls | Cases | Controls | Cases | Controls | Cases | Controls |
| 1.33 days (32 hrs) | 1.36 days (32.6hrs) | 3.4 | 3.4 | < 1day (17 hrs) | < 1 day (17 hrs) | 4.82 | 6.48 |
| Not significant | | Not significant | | Not significant | | Significant difference in operating time duration | |

Chart22



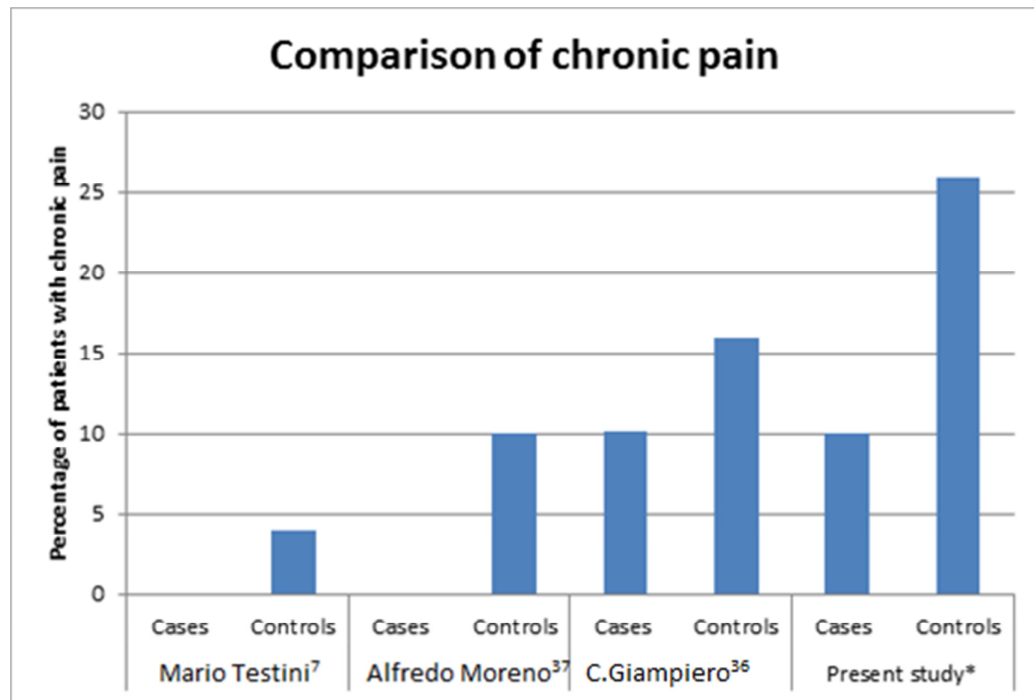
Comparison of chronic pain (Comparison with other studies)

Table 23

| Mario Testini ⁷ | | Alfredo Moreno ³⁶ | | Giampiero Campanelli ³⁵ | | Present study* | |
|----------------------------|----------|------------------------------|----------|------------------------------------|----------|---|----------|
| Cases | Controls | Cases | Controls | Cases | Controls | Cases | Controls |
| 0 (0) | 2 (4) | 0 (0) | 2 (10) | 13 (10.1) | 21 (16%) | 5 (10) | 13 (26) |
| Not significant | | Not significant | | Not significant | | Significantly less pain among the cases | |

Number in parenthesis indicate percentage.

Chart 23



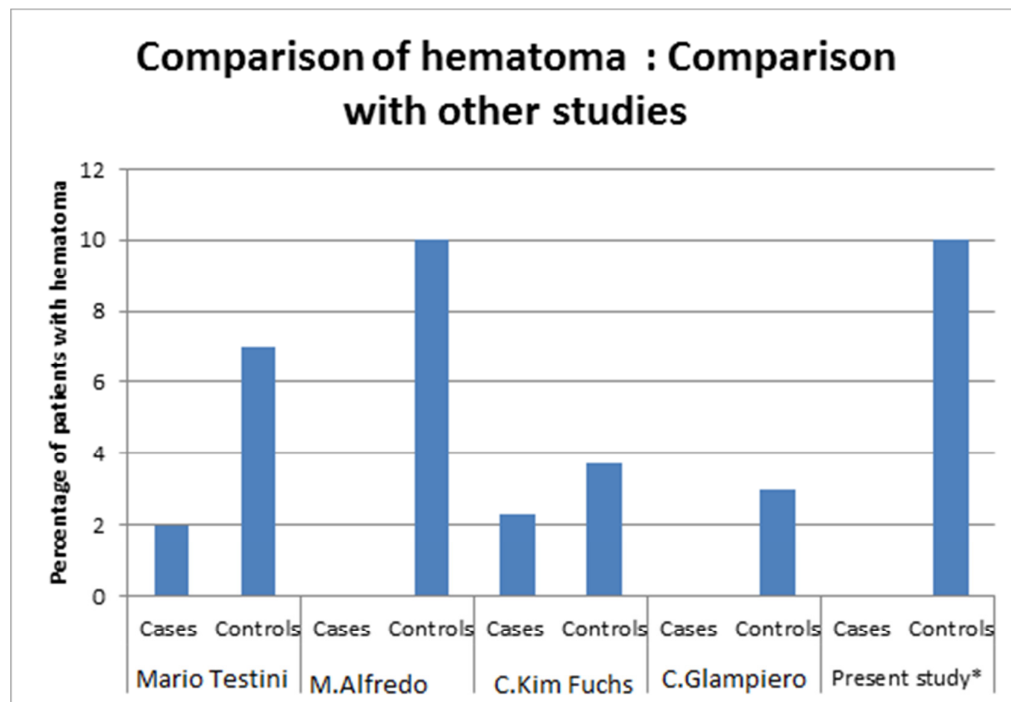
Comparison of Hematoma (Comparison with Other Studies)

Table 24

| Mario Testini ⁷ | | Alfredo Moreno ³⁶ | | C.Kim-Fuchs ⁵ | | Giampiero Campanelli ³⁵ | | Present study* | |
|----------------------------|----------|------------------------------|----------|--------------------------|----------|------------------------------------|----------|----------------|----------|
| Cases | Controls | Cases | Controls | Cases | Controls | Cases | Controls | Cases | Controls |
| 1 (2) | 4 (7) | 0 (0) | 2 (10) | 3 (2.3) | 5 (3.7) | 0 (0) | 1 (3%) | 0 (0) | 5 (10) |

Number in parenthesis indicate percentage.

Chart 24



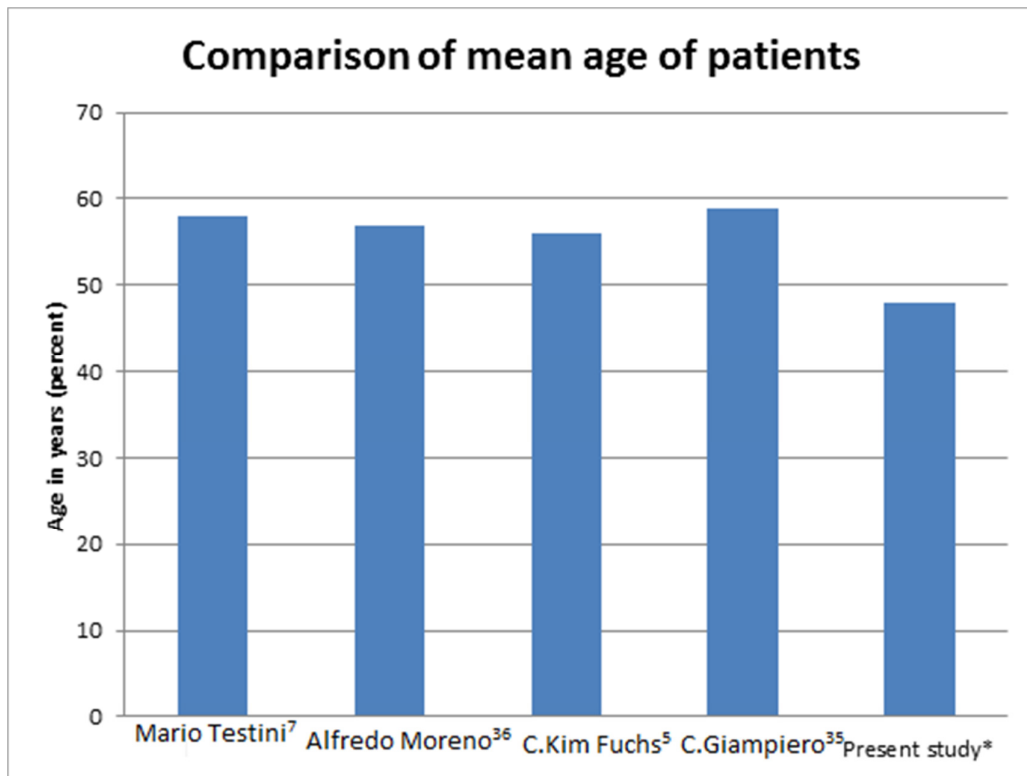
Present study is comparable with Alfredo Moreno³⁶ with 10% of hematoma formation in post operative period.

Comparison of mean age of the study population (Comparison with other studies)

Table 25

| Mario Testini ⁷ | Alfredo Moreno ³⁶ | C.Kim-Fuchs ⁵ | Giampiero Campanelli ³⁵ | Present study* (Mean age in completed years) |
|----------------------------|------------------------------|--------------------------|------------------------------------|---|
| 58 | 57 | 56.1 | 59 | 47.9 |

Chart 25



SUMMARY

- In our study of comparison between use of N butyl cyanoacrylate glue versus prolene suture mesh fixation in Lichtenstein hernia repair, we found that out of total 100 patients ,50 in N butyl cyanoacrylate group & 50 in standard prolene suture mesh fixation group ,mean age was of 50.88 ± 9.67 years in standard prolene suture group & 44.9 ± 14.3 years in N butyl cyanoacrylate group.
- Patients presented with swelling in the groin with or without pain or only with pain ranging from <6 months to >5 years.
- Highest number of patients was in the age group of 40-49 years in N butyl cyanoacrylate group and in the age group of 50-59 years in standard prolene fixation of mesh group.
- Zero females underwent Lichtenstein's tension free hernioplasty.
- Majority of patients were farmers by occupation.
- Majority of the patients had Incomplete inguinal hernia in both the groups.
- Smoking was the most common associated factor in both the groups with 12% in N butyl cyanoacrylate fixation group and 9% in standard prolene mesh fixation group.
- Majority of patients had benign hyperplasia of prostate as associated illness with 14% in Nbutyl cyanoacrylate mesh fixation group and 20% in standard prolene mesh fixation group.
- Abdominal muscle tone was poor only in 2% of the patients in cases and 6% in control group.

- Operating time was significantly less that is 36.52 min in cases and 48.32 in control group.
- Hospital stay in cases group was 4.82 days and in control group was 6.48 days
- Pain after 3 month was seen only in 5 patients in N butyl cyanoacrylate mesh fixation group and whereas it was more in Standard Prolene Mesh fixation group i.e.16 patients.
- There were only 4% cases with complaints of seroma and none with complaints of infection or hematoma in the case group, whereas 18% of controls presented with complaints of seroma and 10% with hematoma. Hence, the case group is superior to control group.
- Foreign body sensation is significantly less in cases group.
- N butyl cyanoacrylate glue Mesh fixation is far superior option to be used in standard Lichtenstein tension free repair for mesh fixation.

CONCLUSION

- Use of N butyl cyanoacrylate glue for Lichtenstein hernia repair is more efficacious than regular prolene suture mesh fixation and has the potential to reduce the incidence of chronic inguinodynia and foreign body sensation.
- There is less chronic pain after 3 months in n butyl cyanoacrylate group mesh fixation.
- Less number of cases of seroma, hematoma and infection in N butyl cyanoacrylate group of mesh fixation were observed.
- Operating time is significantly reduced in glue fixation group compared to standard prolene suture fixation.
- Foreign body sensation is less in glue fixation group
- Hence Lichtenstein tension free hernioplasty is always better option if mesh fixation done with N butyl cyanoacrylate when compared with Lichtenstein's tension free hernia repair with standard prolene suture fixation.

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ETHICAL CLEARANCE CERTIFICATE



B.L.D.E. UNIVERSITY'S
SHRI.B.M.PATIL MEDICAL COLLEGE, BIJAPUR-586 103
INSTITUTIONAL ETHICAL COMMITTEE

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this college met on 13-11-2013 at 3-30pm to scrutinize the Synopsis of Postgraduate Students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected & revised version synopsis of the Thesis has been accorded Ethical Clearance.

Title "Comparative Study between N-Butyl-2-cyanoacrylate glue versus sutured mesh fixation in Lichtensteins hernia repair"

Name of P.G. student Dr Ashroith, I. M.

Department of Surgery.

Name of Guide/Co-investigator Dr. M. B. Patil,

professor of Surgery.

DR. TEJASWINI VALLABHA
CHAIRMAN
INSTITUTIONAL ETHICAL COMMITTEE
BLDEU'S, SHRI.B.M.PATIL
MEDICAL COLLEGE, BIJAPUR.

SAMPLE INFORMED CONSENT FORM

**B.L.D.E.U's SHRI B.M. PATIL MEDICAL COLLEGE, HOSPITAL AND
RESEARCH CENTRE, BIJAPUR – 586103, KARNATAKA.**

TITLE OF THE PROJECT : COMPARATIVE STUDY BETWEEN
N-BUTYL-2-CYANOACRYLATE
GLUE VERSUS SUTURED MESH
FIXATION IN LICHTENSTEINS
HERNIA REPAIR

PRINCIPAL INVESTEGATOR : Dr. ASHRITH I M
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Professor of Surgery
B.L.D.E. University's
Shri B.M. Patil Medical College Hospital
& Research Centre, Sholapur Road,
BIJAPUR - 586103

PURPOSE OF RESEARCH:

I have been informed that this study will analyse COMPARATIVE STUDY
BETWEEN N-BUTYL-2-CYANOACRYLATE GLUE VERSUS SUTURED MESH
FIXATION IN LICHTENSTEINS HERNIA REPAIR.

I have been explained about the reason for doing this study and selecting me/my ward as a subject for this study. I have also been given free choice for either being included or not in the study.

PROCEDURE:

I understand that relevant history will be taken. I will undergo detailed clinical examination after which necessary investigations will be done whenever required, which would help the investigator for appropriate management.

RISKS AND DISCOMFORTS:

I understand that I/my ward may experience some pain and discomfort during the examination or during my treatment. This is mainly the result of my condition and the procedure of this study is not expected to exaggerate these feelings which are associated with the usual course of treatment.

BENEFITS:

I understand that I/my wards participation in this study will help to analyse the effectiveness of n butyl cyanoacrylate glue in reducing post operative pain and complications.

CONFIDENTIALITY:

I understand that medical information produced by this study will become a part of this Hospital records and will be subjected to the confidentiality and privacy regulation of this hospital. Information of a sensitive, personal nature will not be a part of the medical records, but will be stored in the investigator's research file and identified only by a code number. The code key connecting name to numbers will be kept in a separate secure location.

If the data are used for publication in the medical literature or for teaching purpose, no names will be used and other identifiers such as photographs and audio or

video tapes will be used only with my special written permission. I understand that I may see the photograph and videotapes and hear audiotapes before giving this permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time. Dr. ASHRITH I M is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of this study, which might influence my continued participation.

If during this study or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me and that a copy of this consent form will be given to me for careful reading.

REFUSAL OR WITHDRAWAL OF PARTICIPATION:

I understand that my participation is voluntary and I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital.

I also understand that Dr. ASHRITH I M will terminate my participation in this study at any time after he has explained the reasons for doing so and has helped arrange for my continued care by my own physician or therapist, if this is appropriate.

INJURY STATEMENT:

I understand that in the unlikely event of injury to me/my ward, resulting directly to my participation in this study, if such injury were reported promptly, then medical treatment would be available to me, but no further compensation will be provided.

I understand that by my agreement to participate in this study, I am not waiving any of my legal rights.

I have explained to _____ the purpose of this research, the procedures required and the possible risks and benefits, to the best of my ability in patient's own language.

Date:

Dr. M.B. PATIL

Dr. ASHRITH I M

(Guide)

(Investigator)

STUDY SUBJECT CONSENT STATEMENT:

I confirm that Dr. ASHRITH I M has explained to me the purpose of this research, the study procedure that I will undergo and the possible discomforts and benefits that I may experience, in my own language.

I have been explained all the above in detail in my own language and I understand the same. Therefore I agree to give my consent to participate as a subject in this research project.

(Participant)

Date

(Witness to above signature)

Date

ANNEXURE IX

PROFORMA

CASE NO:

1. Name : IP No :
2. Age/sex: DOA:
3. occupation DOS:
Address: DOD:

4. CHIEF COMPLAINTS:

Swelling in the inguinoscrotal region:

- Onset
- Duration
- Progress
- Size and extent when appeared
- Aggravating factors
- Relieving factors

Pain in the inguinal region :

- Mode of onset
- Duration
- Character
- Aggravating factors
- Relieving factors

Risk factors:

- Chronic cough
- Smoking
- Constipation

- Difficulty in passing urine

Past history:

5. Personal history:

- Diet
- Appetite
- Bowel/Bladder
- Sleep
- Habits

6. Family history

7. GENERAL PHYSICAL EXAMINATION:

1. Obese / Not Obese
2. Nutritional status: Poor / Average / Good
3. Pallor
4. Icterus
5. Cyanosis / Clubbing
6. General – Lymphadenopathy
7. PR
8. BP

Systemic examination

Per Abdomen:

Inspection

1. Abdominal obesity
2. Swelling – size
3. Shape
4. Position & Extent

5. Skin over the swelling
6. Expansile impulse on coughing
7. Visible Intestinal Peristalsis

Palpation:

1. Tenderness
2. Local rise in temperature
3. Size
4. Shape
5. Position and Extent
6. To get above the swelling
7. Shape and size of defect
8. Consistency
9. Content
10. Reducibility
11. Invagination test
12. Ring occlusion test
13. Ziemann's test
14. Abdominal tone: Straight Leg Raising test and Neck raising test

Percussion: Dull / Resonant

Auscultation: Bowel sounds

Per Rectal Examination:

Chronic constipation

Enlarged prostate

Respiratory System:

Inspection

Palpation

Percussion

Auscultation

Cardiovascular System:

Inspection

Palpation

Percussion

Auscultation

Central Nervous System:

Higher Mental functions

Diagnosis

INVESTIGATIONS:

- Hb TC DC
- Blood Grouping & Rh Typing
- Blood Urea, Serum Creatinine
- RBS
- Urine analysis
- ECG
- Chest X-ray

Management

Preoperative treatment

- 1) Correction of anaemia.
- 2) Weight reduction if obese.
- 3) Improvement of nutritional status.
- 4) Treatment of respiratory infection if any.

- 5) Abstinence from smoking / alcohol.
- 6) Advice regarding breathing exercises.

Operative procedure

Type of surgery

Anaesthesia GA / SA

Prophylactic antibiotic

Drains

Type of mesh fixation

Operating time

Post operative period

Pain

Respiratory infection

Seroma formation

Hematoma

Wound infection

Drain removal

Suture removal

Follow up at : 1month

3months

Inference:

Comments:

VISUAL ANALOG SCALE (VAS)

Faces Pain Scale



| 0 | 2 | 4 | 6 | 8 | 10 |
|---------------------|-------------------------|---------------------|-----------------|-------------------|---|
| Very happy, no hurt | Hurts just a little bit | Hurts a little more | Hurts even more | Hurts a whole lot | Hurts as much as you can imagine (don't have to be crying to feel this much pain) |

Visual Analog Scale (VAS)

