"COMPARISON OF SUTURES WITH N-BUTYL 2-CYANOACRYLATE GLUE FOR MESH FIXATION DURING PRIMARY INGUINAL HERNIA REPAIR- A ONE YEAR RANDOMIZED CONTROL TRIAL"

By

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Endorsement by the HOD/Principal/ Head of the Institution

This is to certify that the dissertation entitled **"COMPARISON OF SUTURES WITH N-BUTYL 2-CYANOACRYLATE GLUE FOR MESH FIXATION DURING PRIMARY INGUINAL HERNIA REPAIR- A ONE YEAR RANDOMIZED CONTROL TRIAL"** is a bonafide research work done by **Reg. No. BH0115010**.

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LIST OF ABBREVIATIONS

BP	-	Blood pressure
BPH	-	Benign Prostatic Hypertrophy
BL	-	Bilateral
BIH	-	Bilateral Indirect Inguinal Hernia
BDH	-	Bilateral Direct Inguinal Hernia
BTFH	-	Bilateral Tension Free Hernioplasty
CBC	-	Complete blood count
cm	-	Centimeter
CNS	-	Central nervous system
CVS	-	Cardiovascular system
D.O.A.	-	Date of admission
D.O.D.	-	Date of discharge
D.O.S.	-	Date of surgery
e.g.	-	For example
Hb	-	Haemoglobin
Hr	-	Hour
I.P.	-	In patient
i.e	-	That is
Kgs	-	Kilograms
KLES	-	Karnataka Lingayat Education Society
LDH	-	Left sided Direct Inguinal Hernia
LIDH	-	Left sided Indirect Inguinal Hernia
LTFH	-	Left Sided Tension free Hernioplasty
min	-	Minute

n	-	Total number
NBCA	-	N-butyl, 2-cyanoacrylate Glue
RIDH	-	Right sided Indirect Inguinal Hernia
RTFH	-	Right Sided Tension free Hernioplasty
RTDA	-	Return To Daily Activities
VAS	-	Visual Analog Scoring

ABSTRACT

Background: The Lichtenstein technique for open hernia repair is associated to a high rate of postoperative groin pain, mainly related to the mesh fixation technique. This randomized controlled trial was aimed to compare the conventional suture fixation with glue fixation of the mesh.

Methods: Sixty patients with primary inguinal hernia were randomized to undergo open hernia repair with suture fixation (Group A) or n butyl 2-cyanoacrylate glue fixation of the mesh (Group B). Primary outcome was to compare the short-term outcomes (post operative Inguinal pain and time to return to daily activities) in patients who underwent a mesh procedure for open groin hernia repair with sutures and N-butyl-2-cyanoacrylate for mesh fixation.

Results: Postoperative pain significantly lower in Group B compared to Group A and days taken to return to daily activities in group B is less than the days taken to return to daily activities in Group A. Total duration of surgery is less in Group B compared with Group A.

Conclusion: This study demonstrates that mesh fixation with glue is a safe procedure, effective and less time consuming when compared with conventional method of suture mesh fixation during primary inguinal hernia repair.

Keywords: Inguinal hernia; Hernia repair; Cyanoacrylate glue; Mesh fixation

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INTRODUCTION

The word “hernia” is derived from the Latin word for rupture. According to the definition hernia is an abnormal protrusion of an organ or tissue through a defect in the walls of its containing cavity[1].

An Inguinal 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 groin surgeries in any surgical units[3].

Hernioplasty is most commonly performed surgery for hernia[4].

Success of groin hernia repair is measured primarily by the permanence of the operartion, fewest complications, minimal costs and earliest return to daily activities[5].

The most important advance in hernia surgery has been the development of tension free repairs.

In 1958, Usher described a hernia repair using Marlex mesh and benefits of that repair he described as “tension eliminating” or “tension free” [6].

Every type of Tension free repairs requires a mesh, whether it is done open repair or laparoscopic route.

In adult patients, most inguinal hernias are treated by implanting a prosthetic mesh. To prevent mesh dislocation and thus recurrence, different types of fixation have been proposed. In contrast to penetrating fixation known to cause acute or chronic pain, adhesive fixation is becoming increasingly popular as it reduces markedly the risk of injury and pain.

Mesh fixation is an important step in hernioplasty surgeries. Conventionally mesh is fixed with non-absorbable prolene sutures which accounts to 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.

The primary goals of hernia repair include prevention of a potential strangulation, minimizing chance of recurrence, early return to normal activity and avoidance of acute and chronic pain.

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 or by suturing at pubic tubercle causing peri-osteitis hence these complications have prompted surgeons to use atraumatic method of fixation by tissue compatible glues like cyanoacrylate glue.

The Lichenstein technique for inguinal hernia repair is the standard open tension free mesh onlay method that is widely popular and produces low rates of complications and recurrence. Sutures are generally used to secure the prosthetic mesh but may contribute to pain, or other problems such as groin numbness or groin discomfort.

To improve post-operative life quality of patients, medical adhesive mesh fixation methods emerged which are less invasive patch fixation methods and got satisfactory effects[7.]

The lateral chains cyanoacrylates are the best choice for mesh fixation in open mesh repair of inguinal hernia[8]. This randomized controlled trial is designed to evaluate the impact of the mesh fixation method on postoperative pain and in particular to demonstrate that the use of cyanoacrylate glue can reduce post-herniorraphy pain with respect to the usual method of mesh fixation i.e using the sutures for mesh fixation.

OBJECTIVE

- **PRIMARY OBJECTIVE:** To compare the short-term outcomes (post operative Inguinal pain and time to return to daily activities) in patients who underwent a mesh procedure for open groin hernia repair with sutures and N-butyl-2-cyanoacrylate for mesh fixation.

- **SECONDARY OBJECTIVE:** To study the efficacy of N-butyl 2 cyanoacrylate glue in mesh fixation in patients who underwent open Inguinal hernia repair.

REVIEW OF LITERATURE

➢ HISTORY [9]

Evidence of surgical repair of inguinal hernias can be traced back to ancient civilizations of Egypt and Greece. Early management of inguinal hernias often involved a conservative approach with operative management reserved only for complications.Surgery often involved routine excision of the testicle and wounds were closed with cauterization or left open to granulate on their own.From the late 1700s to the early 1800s, physicians indentified vital components of the inguinal region.

Based on the comprehensive understanding of inguinal anatomy, Bassini (1884-1924) transformed inguinal hernia repair into a successful venture with minimal morbidity. The success of the Bassini repair over its predecessors ushered in the era of tissue based repairs. Modifications of the Bassini repair were manifest in the McVay and Shouldice repairs. All three of these techniques, as well as modern variations such as Desarda operation are currently practised.

In the early 1980s, Lichenstein popularised the tension free, supplanting tissue based repairs with the widespread acceptance of the prosthetic materials for hernioplasty. This technique was superior to previous tissue based repair in that mesh could restore the strength of the transversalis fascia, thereby avoiding tension in the defect closure.

With the advent of minimally invasive surgery, inguinal hernia repair underwent its most recent transformation. Laparoscopic inguinal hernia repair offers an alternative approach, minimises post-operative pain and improves recovery.

Furthermore, an array of prosthetic materials has been introduced to minimise recurrence and improve quality of life.

➢ SURGICAL ANATOMY OF THE INGUINAL CANAL[10]:

As the testis descends from the abdominal cavity to the scrotum in the male it first passes through a defect called the deep inguinal ring, located in the transversalis fascia, just deep to the abdominal muscles. This ring lies midway between the anterior superior iliac spine and the pubic tubercle, approximately 2-3 cms above the femoral artery pulsations in the groin. The inferior epigastric vessels lie just medial to the deep inguinal ring passing from the iliac vessels to the rectus abdominus muscle. Muscle fibres of the innermost two layers of the lateral abdominal wall, the transversus muscle and the internal oblique muscle, arch over the deep inguinal ring from lateral to medial before descending to become attached to the pubic tubercle.

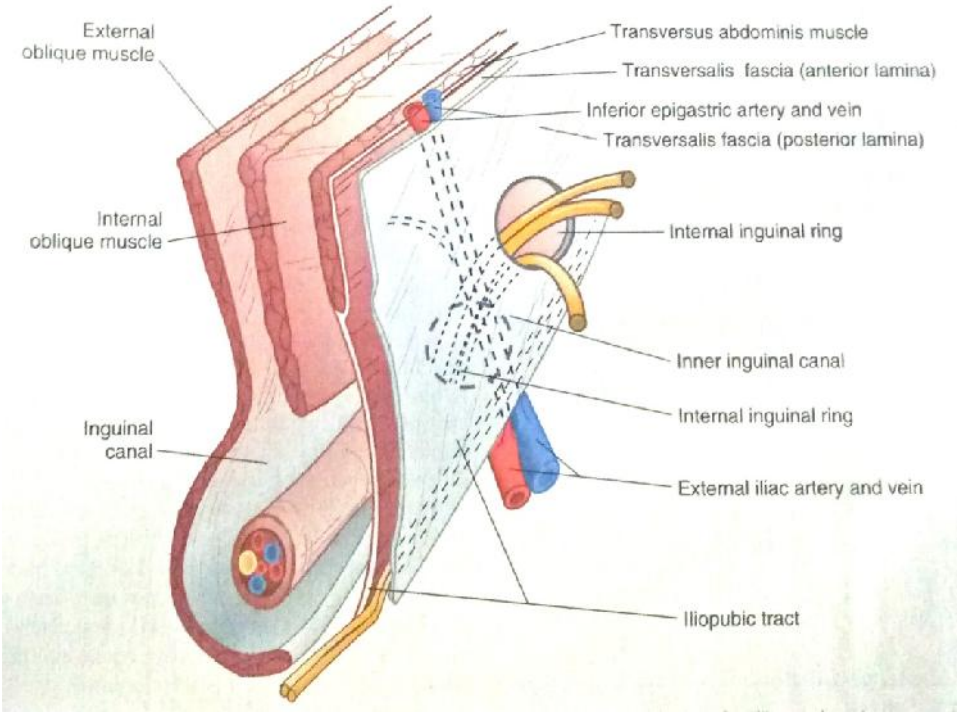


FIGURE 1. ANATOMY OF INGUINAL CANAL

The two muscles then fuse and become tendinous, hence this arch is referred to as Conjoint tendon. Below this arch there is no muscle but only transversalis fascia and external oblique aponeurosis resulting in weakness.

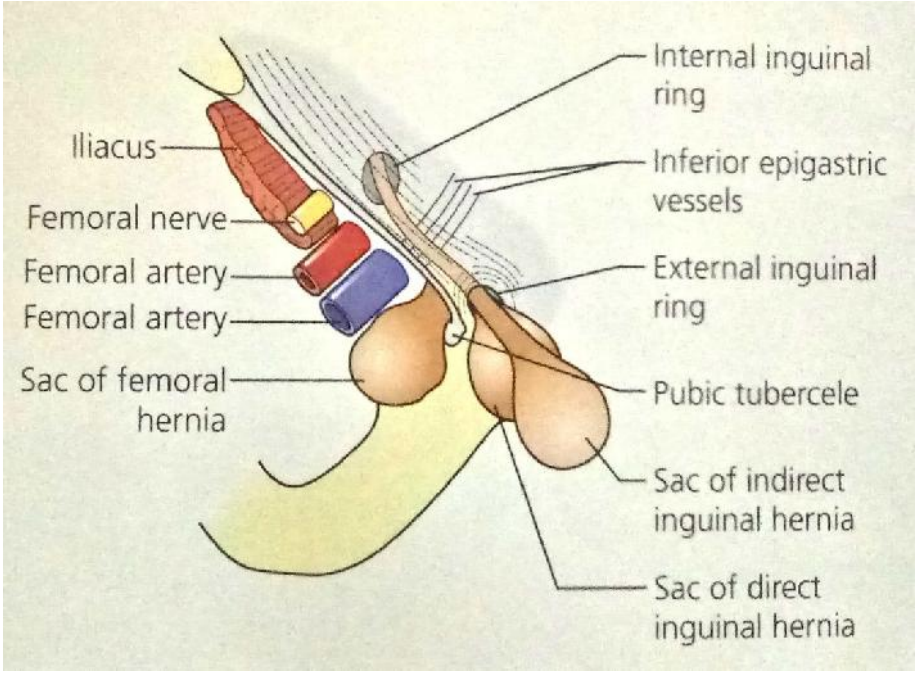


FIGURE 2: SHOWING RELATIONSHIP OF DIRECT AND INDIRECT SAC WITH VESSELS

Anterior to the canal is the aponeurosis of the external oblique muscle whose fibres run downwards and medially. The testis finally emerges through a v-shaped defect in the aponeurosis, the superficial inguinal ring, and descends into the scrotum.

The inguinal canal is roofed by the conjoint tendon, its posterior wall is transversalis fascia, an anterior wall is the external oblique aponeurosis and a floor which is also external oblique which rolls inwards at its lower margin and thickens to become the inguinal ligament (Poupart's Ligament).

INGUINAL CANAL[11]:

The inguinal is about 4 cm in length and is located just cephalad to the inguinal ligament. The canal extends between the internal ring (Deep ring) and external ring (Superficial inguinal ring). The inguinal canal contains the spermatic cord in men and the round ligament of the uterus in women.

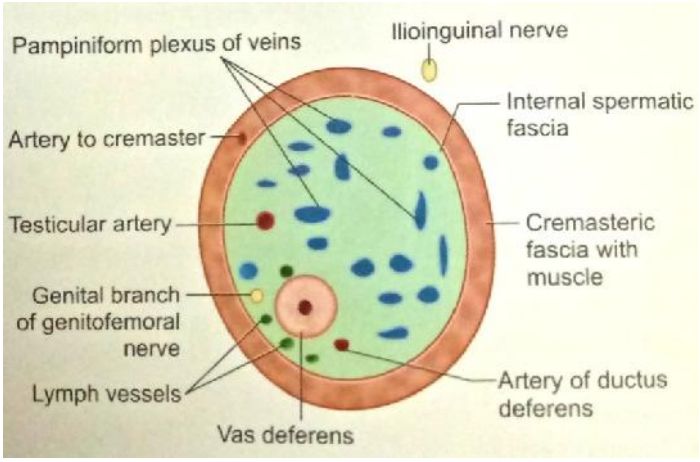


FIGURE 3: CONTENTS OF SPERMATIC CORD

The contents of Inguinal canal are:

- Spermatic cord
- Ilioinguinal nerve.

The spermatic cord is composed of:-

- cremaster muscle fibres and vessels
- the testicular artery and accompanying veins
- genital branch of the genitofemoral nerve
- Vas deferens
- Lymphatics and processus vaginalis

The boundaries of the inguinal canal are:

- Anterior: External oblique in its whole length. Internal oblique in its lateral third
- Posterior: Fascia transversalis and the aponeurosis of the transverses abdominis muscle in its whole lengt with Conjoint tendon (falx inguinalis) in its inner half
- Floor : The upper surface of the inguinal ligament which forms a furrow (Poupart's Ligament)

DEFENSE MECHANISM OF INGUINAL CANAL [12]:

- *Obliquity* of inguinal canal
- *Arching* of the Conjoint tendon
- *'Shutter mechanism'* of internal oblique
- *'Ball valve mechanism'* due to contraction of cremaster muscle which plugs to superficial ring
- When external oblique muscle contracts, intercrural fibres of superficial ring appose causing *' slit valve mechanism'*

FRUCHARD'S MYOPECTINEAL ORIFICE:

It is an osseo-myo-aponeurotic tunnel. It is through this tunnel all groin hernias occur.

It is bounded:

- *Medially* : lateral border of rectus sheath
- *Superiorly:* arched fibres of internal oblique and transverses abdominus muscle.
- *Laterally* : iliopsoas muscle
- *Inferiorly:* pectin fibres and fascia covering it.

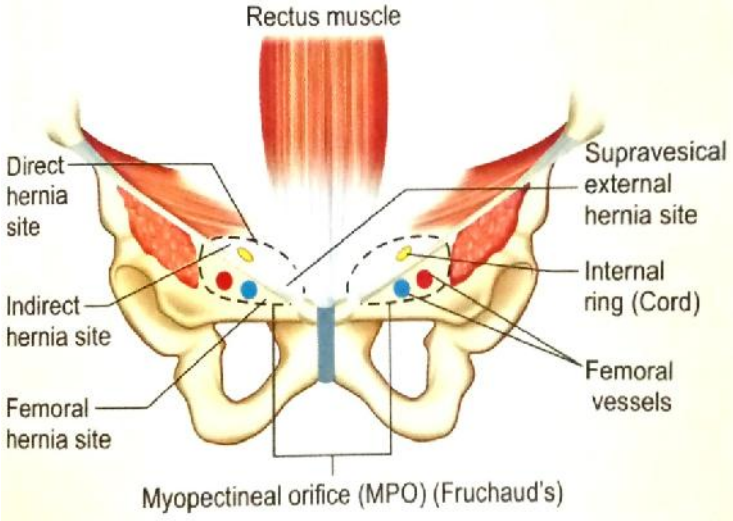


FIGURE 4: MYOPECTINEAL ORIFICE

CLASSIFICATION OF INGUINAL HERNIA[12]

- **CLASSIFICATION OF INGUINAL HERNIA I :**

Anatomical classification:

- *Indirect Inguinal Hernia*: Hernia through internal ring along with the spermatic cord. It is **lateral** to the *inferior epigastric artery*.
- *Direct Inguinal Hernia*: It occurs though the posterior wall of the inguinal canal through '***Hesselbach's triangle'***. It is **medial** to the *inferior epigastric artery.*

Hesselbach'sTriangle

- *Laterally* –inferior epigastric artery.
- *Medially*-outer border of rectus
- *Lower boundary* – inguinal ligament
- Hesselbach's triangle is divided into medial and lateral halves by the obliterated umbilical artery (Lateral umbilical ligament).

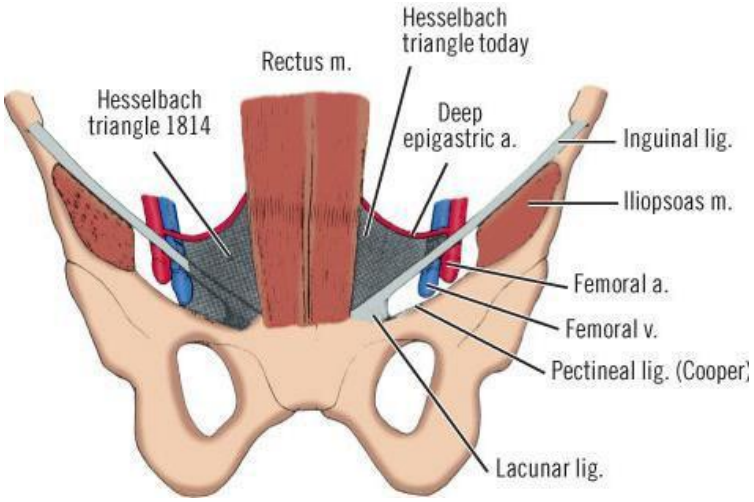


FIGURE 5 HESSELBACH'S TRIANGLE

Parts of hernia:

- Covering
- Sac
- Content

ETIOLOGY:

- ❖ Straining
- ❖ Lifting of heavy weights
- ❖ Chronic cough
- ❖ Chronic constipation
- ❖ BPH, carcinoma prostate
- ❖ Stricture urethra, phimosis, meatal stenosis
- ❖ Obesity
- ❖ Smoking
- ❖ Ascites
- ❖ Previous appendicectomy through McBurney's incision, may injure the ilio-inguinal nerve causing right sided direct inguinal hernia.

Types of indirect inguinal hernias[13]:

A. Congenital hernia

1. Congenital Vaginal hernia

The processus vaginalis has failed to become occluded in any part of its course. The hernia thereforedescends to the base of the scrotum and the test isbehind andmay be difficult to locate.

2. Congenital Funicular hernia

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.

B. Acquired hernia:

It is secondary to any causes which raise the intra-abdominal pressure leading into weakening of the area like in direct inguinal hernia.

Types of direct inguinal hernia[14]

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

a. Lateral direct hernia

b. Medial direct hernia

❖ **CLASSIFICATION OF INGUINAL HERNIA II :**

A. Incomplete :

- *Bubonocoele*: here sac is confined to the inguinal canal

-*Funicular:* here sac crosses the superficial inguinal ring but doesn't reach the bottom of the scrotum.

B. Complete: here sac descends to the bottom of the scrotum. saddle bag r pantaloon hernia sac has got both medial and lateral components.

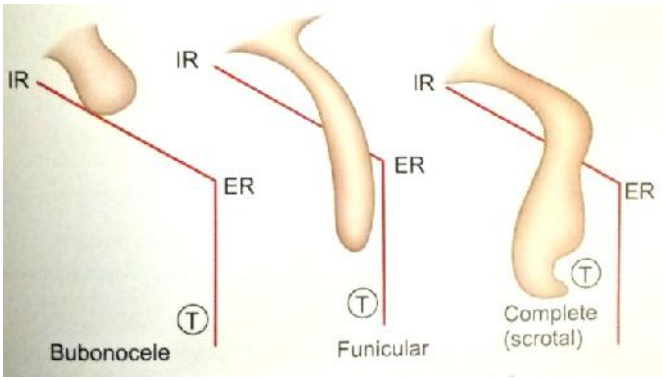


FIGURE 6 TYPES OF INGUINAL HERNIA

Newer classifications of hernia

- **Nyhus classification**[15]**:**
    a) *Type I:* Indirect hernia with normal deep ring
    b) *Type II:* Indirect hernia with dilated deep ring
    c) *Type III:* Posterior wall defect
        i. Direct
        ii. Pantaloon hernia
        iii. Femoral hernia
    d) *Type IV:* Recurrent Hernia

- **CLINICAL TYPES**[16]

1. Reducible
2. Irreducible
3. Obstructed/ Incarcerated
4. Strangulated[complication of irreducible hernia]
5. Inflamed

Reducible hernia

The hernia either reduces itself when the patient lies down, orcan 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, incontrast,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.

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 overcrowding within the sac. Irreducibility predisposes to strangulation.

Obstructed / Incarcerated hernia

This is an irreducible hernia containing intestine which is obstructed from outside 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.

Strangulated hernia

A hernia becomes strangulated when the blood supply of its contents is seriously impaired, rendering the contents ischaemic. Diagnosis is made when the hernia is irreducible, without any cough impulse, extremely tense and tender, followed by feature of intestinal obstruction.

Inflammed hernia

A rare condition and mimics strangulated hernia Inflammation can occur from inflammation of the contents of the sac (ie, acute appendicitis or salphingitis) or from external causes. The hernia is usually tender but not tense and the overlying skin is red and oedematous.

Rare varieties of hernia are:

1. *Sliding Hernia / Hernia-en-glissade*: In this type of hernia a piece of extra-peritoneal bowel, usually the caecum on the right side or the pelvic colon on the left side or the urinary bladder on either sides slides down outside the hernia sac forming a part of its wall being covered by the peritoneum on the hernia aspect only.
2. *Richter's hernia*: In this condition only a portion of the circumference of the bowel becomes strangulated. intestinal obstruction may not be present until and unless half of the circumference of the bowel is involved.
3. *Littre's hernia*: it is a type of hernia which contains Meckel's diverticulum.
4. *Maydl's hernia (Hernia-en-W)*: in this condition two loops of bowels remain in the sac and the connecting loop remains within the abdomen and becomes strangulated. The loops of the hernia look like a 'W'. the loop within the abdomen becomes first strangulated and can only be suspected when tenderness is elicited above the inguinal ligament along with presence of intestinal obstruction.

Physical findings[17]

The patient should be examined in both supine position and standing position and look for site, size of the swelling in the groin region. The examiner should look for cough impulse. The two cardinal signs of hernia is *cough impulse* and *reducibility* .The examiner should also look for any evidence of obstruction or strangulation.

"*Cough impulse* is defined as appearance of a new swelling or increase in the size of an existing swelling, synchronous with the act of coughing"

1. Zieman's technique

A clinical method to find out whether the inguinal hernia is one of direct, indirect (oblique) or femoral hernia is to place the index finger over the deep inguinal ring (1/2 inch above the mid-inguinal point, which is the midpoint between anterior superior iliac spine and symphysis pubis), the middle finger over the superficial inguinal ring and the ring finger over the saphenous opening (4 cm below and lateral to the pubic tubercle). This technique can only be applied when the hernia has been completely reduced. The patient is asked to cough. When impulse is felt on the index finger the case is one of indirect hernia, when impulse is felt on the middle finger the case is one of direct hernia and when it is felt on the ring finger the case is one of femoral hernia.

2. Finger Invagination test

After reduction of the hernia this test may be performed to palpate the hernial orifice. It is better to perform this test in recumbent position of the patient. Little finger should be used to minimize hurting the patient. But if it becomes inconvenient, one can use the index finger. Invaginate the skin from the bottom of the scrotum and

the little finger is pushed up to palpate the pubic tubercle. Right hand should be used for the right side and left hand for the left side. The finger is then rotated and pushed further up into the superifical inguinal ring. The nail will be against the spermatic cord and the pulp will feel the ring. Normal ring is a triangular slit which admits only the tip of a finger. If more than one finger can be easily introduced, the ring is abnormally large. But this will not always be associated with hernia. The patient is asked to cough. Normally the examining finger will be squeezed by the approximation of the two pillars. A palpable impulse will confirm the diagnosis.

The finger is rotated so that the pulp of the finger looks backwards. The patient is again asked to cough. If the impulse is felt on the pulp of the finger the hernia is a direct one and if the impulse is felt on the tip it is an indirect inguinal hernia.

3. Ring occlusion test:

This test is performed in standing position and the hernia must be reduced first. This is a confirmatory test to differentiate an indirect inguinal hernia from a direct inguinal hernia. Since an indirect hernia comes out through the deep inguinal ring and a direct hernia medial to the ring, pressure over the deep inguinal ring will occlude the indirect hernia but not the direct hernia. A thumb is pressed on the deep inguinal ring (1/2 inch above the mid-point between the anterior superior iliac spine and the symphysis pubis). The patient is asked to cough. A direct hernia will show a bulge medial to the occluding finger but an indirect hernia will not show any bulge. In case of a child, to make visible such a hernia the child is asked to jolt or jump from the examining table or deliberately make it cry according to its age.

Examination of the tone of the abdominal muscles:

The tone can be examined in two ways:

a. Undue protrusion of the lower abdomen denotes loss of tone.
b. In recumbent position the patient is asked to raise his shoulders against resistance. When the abdominal muscles are weak this test will demonstrate the Malgaigne's bulging in the inguinal region or just above it

External genital examination holds important in examination of hernia.

Thorough examination must be performed to exclude chronic bronchitis, enlarged prostrate, stricture urethra, chronic constipation etc which will induce chronic strain as to cause hernia to develop.

The Chest must be thoroughly examined to exclude any cause of chronic cough. Rectal examination is obligatory to exclude chronic constipation and enlarged prostrate.

Abdomen should be examined to exclude presence of intestinal obstruction.

Routine blood investigations, urine investigations to rule out associated illness.

USG of abdomen and pelvis is done to look for the fascial defect size and contents present in the sac at the time of scan and to rule out prostatomegaly.

SURGICAL PROCEDURE:

Selection of patient:

Treatment of inguinal hernia should be advised for all hernia that carry a significant risk of strangulation. Hernia that are difficult to reduce, and all hernia in infancy, are in this category. Repair is, however, recommended for the majority of hernia in younger people because even if they are asymptomatic and unlikely to strangulate, the natural history is for them to increase in size.

Elective surgery is the common and simple operation for inguinal hernia and can be done under local, spinal or general anaesthesia with minimal risk even in high-risk patients.

Herniotomy

In children who have lateral hernias with a persistent processus it is sufficient only to remove and close the sac. This is called herniotomy. In adult surgery, herniotomy alone has a high recurrence rate and some form of muscle strengthening is added i.e herniorrhaphy.

Open suture repair

In 1890, Eduardo Bassini described repair for inguinal hernia[18]. This was a massive leap forward and has been the basis of open repair for over 100 years.

The surgeon enters the inguinal canal by opening its anterior wall, the external oblique aponeurosis. The spermatic cord is dissected free and the presence of lateral or medial hernia is confirmed. The sac of the lateral hernia is separated from the cord, opened and the contents reduced.

The sac is then sutured closed at its neck and excess sac removed. If there is a medial sac then it is inverted and the fascia transversalis is suture plicated. Sutures are now placed between the conjoint tendon above and the inguinal ligament below, extending from the pubic tubercle to the deep inguinal ring. The posterior wall of the inguinal canal is then strengthened.

Open flat mesh repair

Synthetic mesh has been used since 1950s to reinforce hernia repair, and in 1980s Lichenstein described a tension free[19], simple, flat, polypropylene mesh repair for inguinal hernia. The initial part is identical to that of Bassini's repair.

Once the hernia sac has been removed and any medial defect is closed , a piece of mesh measuring 8X15 cms, is placed over the posterior wall , behind the spermatic cord, and is split to wrap around the spermatic cord at the deep inguinal ring. Loose sutures hold the mesh to the inguinal ligament and conjoint tendon.

Two major advantages are claimed:

- Lowered hernia recurrence rate
- Accelerated post operative recovery.

The Halsted procedure

William S. Halsted briefly first wrote about his repair method 1889 [20] and then made a more complete publication on it in 1893. In many aspects it was performed like the Bassini method but the cord excised of its superficial veins and transposed to a position above the external oblique aponeurosis. He later modified his method and omitted the transposition of the cord and instead covered it with both the internal and external oblique muscles.

The Shouldice repair

Described in 1953 by Earle Shouldice in his only bibliographied publication[21]. In fact the description in that publication is not similar to the modern repair method bearing his name. This was basically a Bassini modification. The posterior repair was done using the same layers but the adaption was made by a series of at least 3 nonabsorbable running sutures. The technique is regarded as the best of the sutured repairs. The Shouldice Hospital.

Open plug/ device/ complex mesh repair

Shaped mesh plugs have gained much attention being simple to insert into the defect and requiring little if any fixation. However, there can be meshoma and also migrate. The surgeon introduces a finger through the deep inguinal ring and bluntly opens the pre-peritoneal space deep to the inguinal canal into which a mesh is introduced. To date, there is little evidence to show any of those techniques is superior to Lichenstein's repair.

Open pre-peritoneal repair

This approach was first described by Annandale in 1880, but in 1950s Stoppa, a French surgeon, described it with mesh reconstruction. It is useful in multiple attempts at open standard surgery have failed and the hernia keeps recurring. It may be superseded by the totally extraperitoneal laparoscopic approach which is modelled on the Stoppa operation and first described by Ger, also French[22].

Laparoscopic inguinal hernia repair

Two techniques are described and have been extensively studied in randomised trials. The totally extra-peritoneal approach (TEP) is more widely used than the transabdominal preperitoneal approach[23] (TAPP).

In both, the aim of surgery is to reduce the hernia and hernia sac within the abdomen and then place a mesh just deep to the abdominal wall, extending across the midline into the retro-pubic space and 5 cm lateral to the deep inguinal ring. The mesh covers Hesselbach's triangle, the deep inguinal ring and the femoral canal.

Complications of inguinal hernia surgery

- ***Immediate (< 24 hours of surgery):***acute pain, bleeding, urinary retention, anaesthetic related complications.

- ***Medium (< 1 week of surgery):*** seroma formation, SSI (Surgical Site Infection).
- ***Late (>3months):*** chronic pain, Testicular atrophy.

Chronic pain (inguinodynia), defined as pain present three months after surgery, is common after all forms of surgery this may result due to nerve injury at the time of surgery or chronic irritation of nerves by sutures material used or mesh.

Mesh-related problems after inguinal hernia surgery[24]

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

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

n-Butyl 2- Cyanoacrylate glue`

Tissue glues are in existence for over 20 years and used in surgery for a variety of indications including abdominal skin wound closure, haemostasis during liver resection and endoscopic treatment of gastro-oesophageal bleeding and varices[25]. 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.

During the 1960s, cyanoacrylate was sold to Loctite, which in turn repackaged and distributed it under a different brand name "Loctite Quick Set 404". In 1971 Loctite called it “Super Bonder"[26].

Chronic pain, post hernia repair surgery is eliminated, mesh fixation with glue (tissue adhesive) seems an optimal choice to reduce postoperative pain[27,28]. 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, as NBCA is biologically inert.

Using a surgical glue whose essential function consists in its high binding capacity, which is easy to apply, dries rapidly, and is bio-absorbable[29]. In an attempt to find the ideal surgical technique for mesh fixation during primary open inguinal hernia repair, we evaluate the use of a synthetic surgical glue (N-butyl-cyanoacrylate) to reduce post operative pain and the complications associated with the use of conventional sutures for mesh fixation[30].

NBCA is used as an alternative to the conventional sutures in mesh fixation during an primary open inguinal hernia repair[31]. Mesh fixation with NBCA glue occurs because of polymeric bonds which seals off tissues and allows perfect fixation under bacteriostatic cover[32].

MATERIALS AND METHOD

This one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum over a period, from January 2016 to December 2016.

Source of Data

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.

Inclusion criteria:

- All patients with age 20 years and above with evidence of primary uncomplicated Inguinal Hernia.

Exclusion criteria:

- Patients who refuse to give consent.
- Patients with recurrent or giant hernias or femoral hernia or hernia with complications.
- Patients with History of coagulation disorder.
- Patients with connective tissue disorders and psychological or physical disorders that could affect the ability to feel and elaborate pain.

METHOD OF COLLECTION OF DATA

STUDY DESIGN:-

TYPE OF STUDY: Randomized Controlled trial

STUDY PERIOD: 1st January, 2016 to 31st December, 2016

Ethical clearance

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

Informed Consent

The patients fulfilling selection criteria were informed in detail about the nature of the study, especially the benefits of using the n- butyl 2 cyanoacrylate glue in mesh fixation during Lichenstein's mesh repair and a written informed consent was obtained (Annexure I).

SAMPLE SIZE AND SAMPLE SIZE CALCULATION:

Sample size: 30 in each group

It is calculated by using following formula:

$$n = \frac{2(Z\alpha+Z\beta)^{2}(S1^{2+}S2^{2})}{(x_1-x_2)^2} = 30$$

Where n= sample size

α= Type I Error = 0.5

$Z\alpha$= 1.96

β= Type II Error =0.2 or Power of 50%

$Z\beta$=0.84

$x_{1=}$ 4.3 (from previous study)[12]

Effect size- To reduce the post operative pain by 2 units as compared to Suture mesh fixation method

x2= 2.3

Standard Deviation S1= 1.9

S2= 1.7

According to this formula sample size comes to 25 rounded upto 30 in each group.

SAMPLING PROCEDURE:-

All consecutive patients fulfilling the criteria and who give informed consent during the period of study will be the sample of this study. After enrolling into the study Demographic data, clinical examination and findings, investigation done are entered into the proforma. (Annexure II)

METHOD:-

Randomization is to be performed using numbered and sealed envelopes that are to be opened at the beginning of the operation. If a bilateral hernia was present, the patient was assigned to one group and both hernias received the same treatment**.**

GROUP A: Suture Mesh Fixation

GROUP B: Glue Mesh Fixation

The first part of the operation was the same in the two groups, according to the original description by Lichtenstein ie. Incison is made 2.5 cms above and parallel to the medial three-fifths of the inguinal ligament. One or more superficial epigastric veins cross the line of incision in the subcutaneous fat and require ligation or diathermy coagulation. The incision is deepened until the aponeurosis of external oblique is exposed. The superficial inguinal ring through which cord emerges, is identified. The external oblique aponeurosis is divided along the

direction of fibres., the incision is then extended so as to open the superficial inguinal ring. Forceps applied to both the cut edges and elevated. The ilio-inguinal nerve identified and preserved.

Cord structures identified and cord clamp applied. The coverings of the spermatic cord are incised longitudinally and searched for indirect sac. Sac appears to be pearly white in appearance. Presence of direct hernia is looked for. Dissection in inguinal region done and Inguinal canal opened, alongside with the anatomical landmarks – pubic tubercle, conjoined area, inguinal ligament identified. The hernia sac was identified, contents of the sac reduced and transfixed. The mesh was shaped according to size of the fascial defect and inguinal canal and put in place. In Group A the mesh was fixed with two running sutures both starting from the first stitch passed on the tissue above the pubic tubercle (avoiding the periosteum and with a 2 cm overlap of the mesh above the tubercle) and passed on the conjoined area and the inguinal ligament. The two posterior wings of the mesh were sutured together with two single prolene stitches.

In Group B the mesh was fixed with n-butyl-2-cyanoacrylate tissue adhesive on the pubic tubercle, the inguinal ligament and the conjoined area. Attention was paid to avoid dripping the glue on the nerves. Only one vial of glue was used for each patient. The two posterior wings of the mesh were stitched with a single vicryl stitch paying attention to take only the mesh and not any tissue. All patients had the same polypropylene kind of mesh, irrespective of the fixation method.

All surgeries were performed under spinal anaesthesia.

Investigations

The following tests were subjected to the following investigations.

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

Outcome variables

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

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

VAS is usually a 100 mm in length, anchored by word descriptors at each end. The patient marks on the line the point that they believe represents their perception of their current state. The VAS score is determined by measuring in milimeters from the left hand end of the line to the point that the patient marks taiwan

Time to return to daily activities in patients who underwent open inguinal hernia repair with Mesh fixation with N-butyl 2 cyanoacrylate glue and with those with Mesh fixation with conventional sutures.

Additionally, total duration of surgery in primary open inguinal hernia repair with mesh fixation using NBCA glue and with those with mesh fixation using conventional suture.

Surgical site infection also noted in the form of inflammation, infection and gaping in both the groups.

Follow up

Patients were followed up at following intervals;

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

During follow up post-operative pain was assessed according to VAS score, Return to daily activities, surgical site infection and total duration of surgery is compared between the two groups.

STATISCAL ANALYSIS

By using unpaired t Test and Mann Whitney U test. The data collected was coded and entered in Microsoft Excel Spreadsheet, categorical data was expressed as Rate, Ratio and Percentages. The continuous data was expressed as Mean +/- SD then apply the tests.

RESULT

The present one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2016 to December 2016.

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

GROUP A: Patients in this group underwent Suture Mesh Fixation during primary open inguinal hernia repair

GROUP B: Patients in this group underwent Glue Mesh Fixation during primary open inguinal hernia repair.

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

Statistical methods:

Severity of pain as assed by VAS score was considered as primary outcome parameter. Return to daily activity study group (Glue Vs Suture) was consider as primary explanatory parameter.

Descriptive analysis: Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Data was also represented using appropriate diagrams like bar diagram, pie diagram and box plots.

Inferential statistics:

Quantitative outcome;

The association between categorical explanatory variables and quantitative outcome was assessed by comparing the mean values. Since the variables were non normally distributed, it was decided to compare median and IQR between the two groups. Non parametric tests like Mann-Whitney U test and Independent sample median test were used to test statistical significance. Appropriate like bar diagram and comparative Box plot were used.

Categorical outcome:

The association between explanatory variables and categorical outcomes was assessed by cross tabulation and comparison of percentages. Chi square test was used to test statistical significance.

P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.(1)

RESULTS:

A total of 60 subjects were included in the analysis.

Table 1: Descriptive analysis of Study Group in study population (N=60)

Study Group	Frequency	Percentage
Glue	30	50.00%
suture	30	50.00%

There were 30 subjects in glue group and 30 subjects in suture group

(Table1&figure1)

Figure 1: Bar chart of Study Group distribution in study population (N=60)

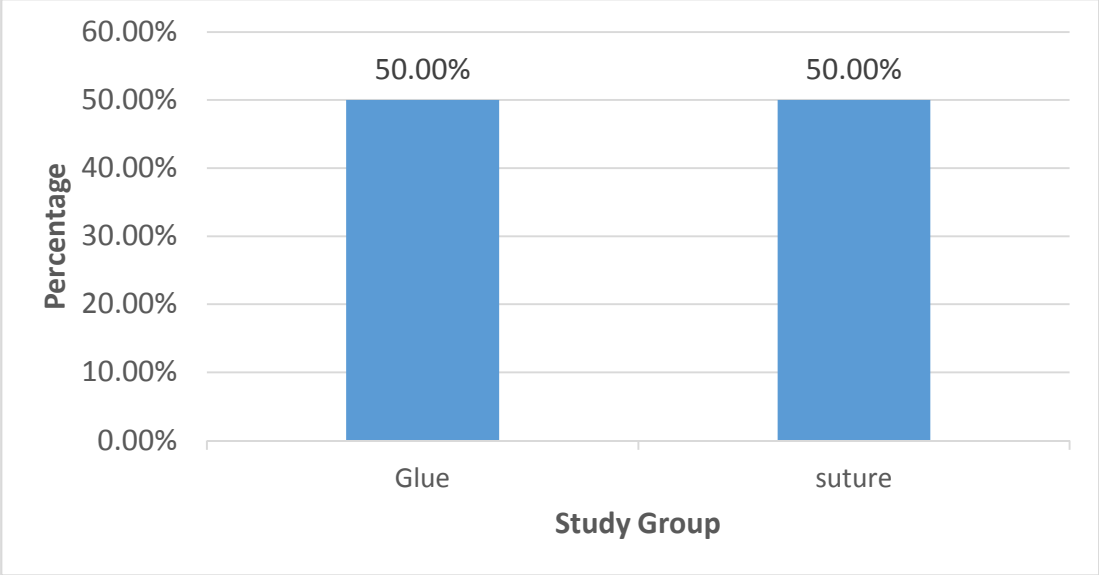


Table 2: Comparison of mean Age across study groups (N=60)

Parameter	Study Group		P value
	Glue (N=30)	suture (N= 30)	
Age	48.2 ± 16.92	50.5 ± 12.46	0.551

The mean age of subjects in glue group **was** 48.2 ± 16.92years and in suture group, it was 50.5 ± 12.46 years. The difference in the age between the two groups was statistically not significant (P Value=0.919) (Table2

Table 3: Association of Study Group with Gender of study population (N=60)

Gender	Study Group	
	Glue	suture
Male	29 (96.7%)	30 (100%)
Female	1 (3.3%)	0 (0%)

- No statistical test was applied –due to 0 subjects in one of the cells

In glue group, 29 (96.7%) were males and there was 1 (3.3%) female. In suture group all were males. (Table 3)

Figure 2: Bar chart of gender distribution in study population (N=60)

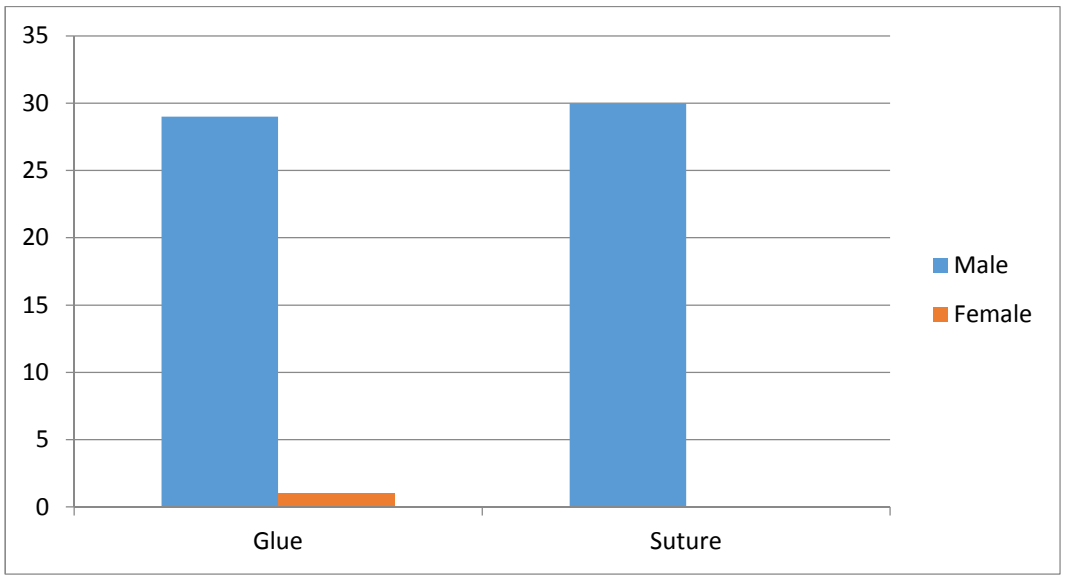


Table4: Comparison of mean Duration in month across study groups (N=60)

Parameter	Study Group		P value
	Glue (N=30)	suture (N= 30)	
Duration in month	14.67 ± 13.98	13.73 ± 11.18	0.776

The mean duration in month of subjects in glue group was14.67 ± 13.98 months and in suture group, it was 13.73 ± 11.18 months. The difference in the duration in month between the two groups was statistically not significant (P Value=0.776) (Table4&figure2).

Figure 3: Box and whisker plot of Duration in month between study group distribution in study group (N=60)

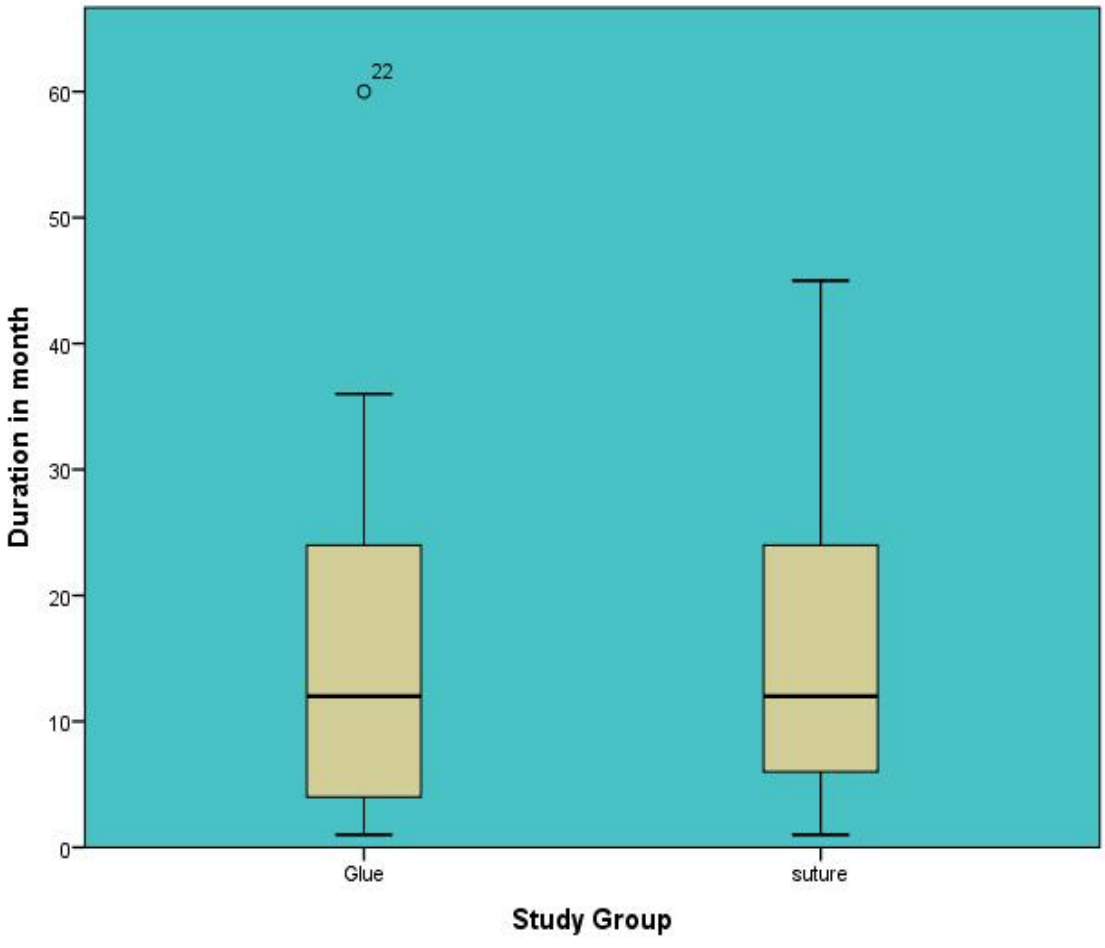


Figure 4: Bar chart of Duration in month distribution in study population (N=60)

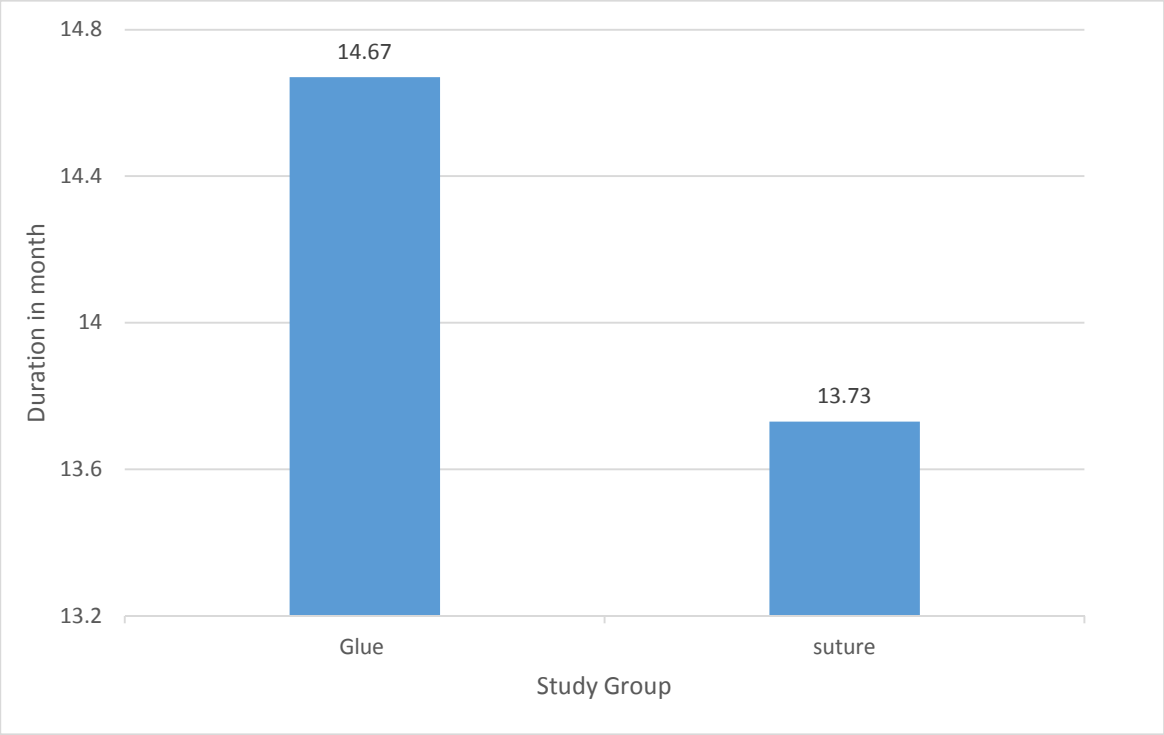


Table 5: Comparison of mean Systolic BP mm Hg GPE across study groups (N=60)

Parameter	Study Group		P value
	Glue (N=30)	suture (N= 30)	
Systolic BP mm Hg GPE	116.67 ± 8.64	118.93 ± 8.72	0.316

The mean Systolic BP of subjects in glue group was 116.67 ± 8.64 and in suture group, it was 118.93 ± 8.72. The difference in the Systolic BP between the two groups was statistically not significant (P Value=0.316) (Table5).

Table 6: Comparison of mean Diastolic BP mm Hg GPE across study groups (N=60)

Parameter	Study Group		P value
	Glue (N=30)	suture (N= 30)	
Diastolic BP mm Hg GPE	74.2 ± 5.34	74.33 ± 5.33	0.923

The mean Diastolic BP of subjects in glue group was74.2 ± 5.34 and in suture group, it was 74.33 ± 5.33. The difference in the diastolic BP between the two groups was statistically not significant (P Value=0.923) (Table6).

Table 7: Comparison of mean Hernia area in Cms across study groups (N=60)

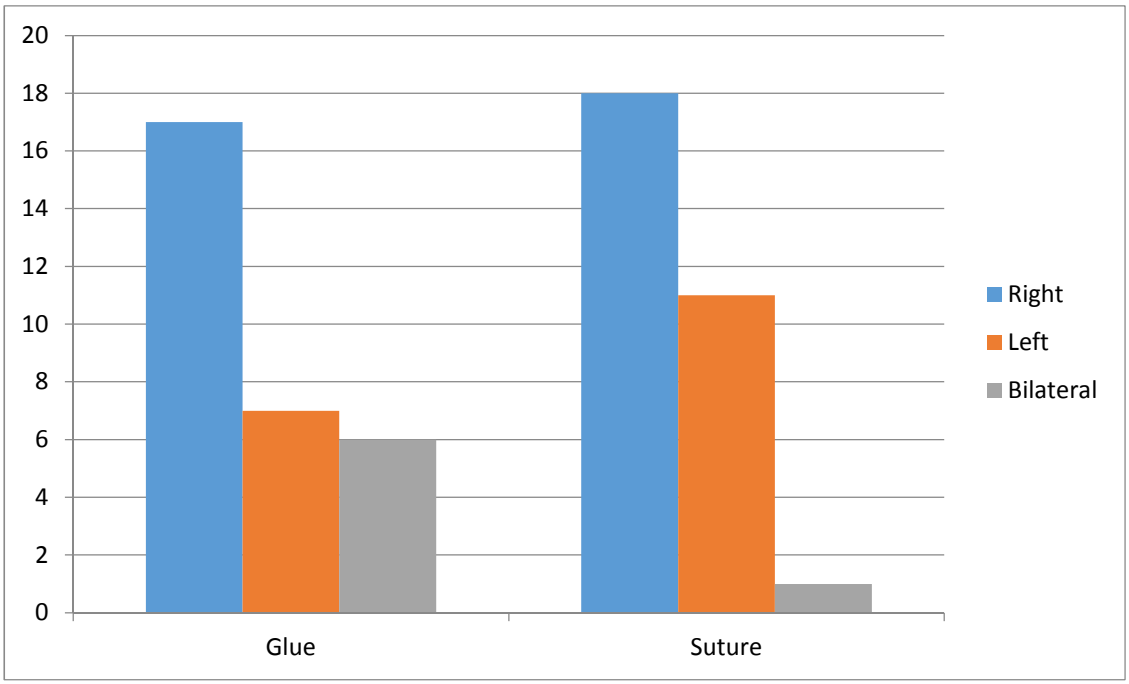
Parameter	Study Group		P value
	Glue (N=30)	suture (N= 30)	
Hernia inCms	10.3 ± 5.18	10.3 ± 6.1	1.000

The mean size of Hernia in Cms in glue group was10.3 ± 5.18and in suture group, it was 10.3 ± 6.1cms. The difference in the Hernia in Cms between the two groups was statistically not significant (P Value=1.000) (Table7).

Table 8: Association of Study Group with Position (N=60)

Position	Study Group		Chi square	P-value
	Glue	suture		
BL	6 (20%)	1 (3.33%)	4.489	0.106
L	7 (23.33%)	11 (36.67%)		
R	17 (56.67%)	18 (60%)		

Figure 5: Bar diagram showing association of study group with position



Among the glue subjects 20% had Bilateral disease, and in suture group this proportion was 3.33%. Among the glue subjects 23.33% had only left sided disease, and in suture group this proportion was 36.67%. Among the glue subjects 56.67% had right side disease and in suture group this proportion was 60%. The difference in side of the hernia between the two groups was statistically not significant (P value=0.106)

Table 9: Association of Study Group with Diagnosis of study population (N=60)

Diagnosis	Study Group		Chi square	P-value
	Glue	suture		
BIH	6 (20%)	1 (3.33%)	**6.323**	**0.176**
LDH	2 (6.67%)	6 (20%)		
LIDH	5 (16.67%)	5 (16.67%)		
RDH	10 (33.3%)	8 (26.67%)		
RIDH	7 (23.33%)	10 (33.33%)		

Figure 6: Bar diagram showing association of Study Group with Diagnosis of study population in Glue (group B)

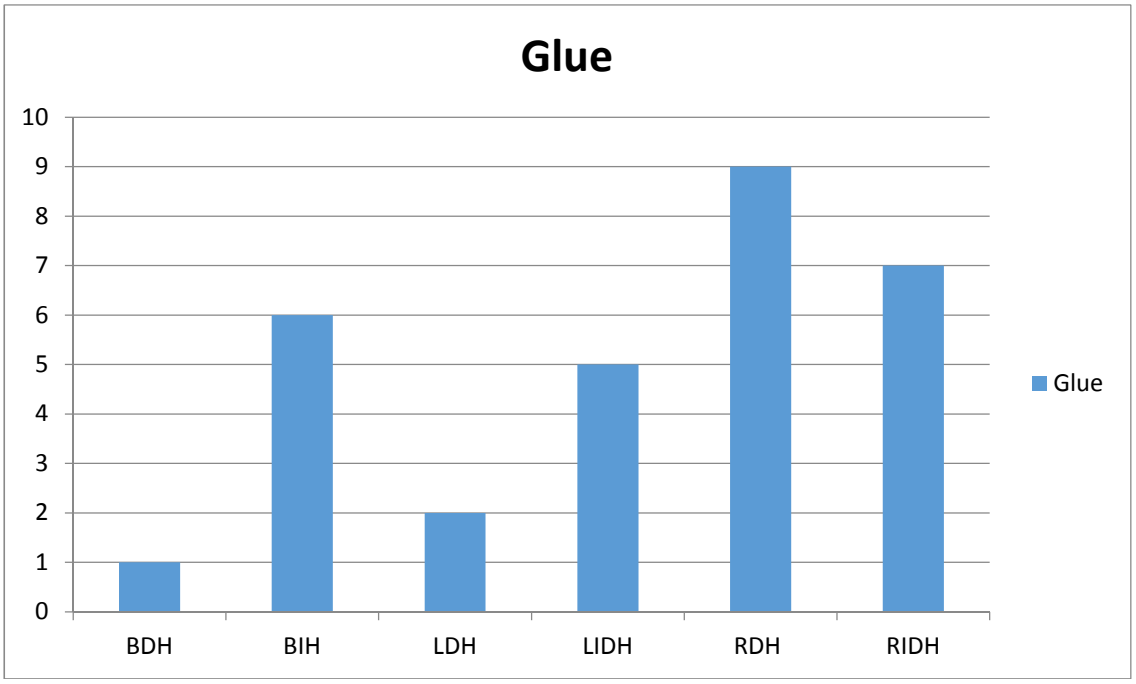
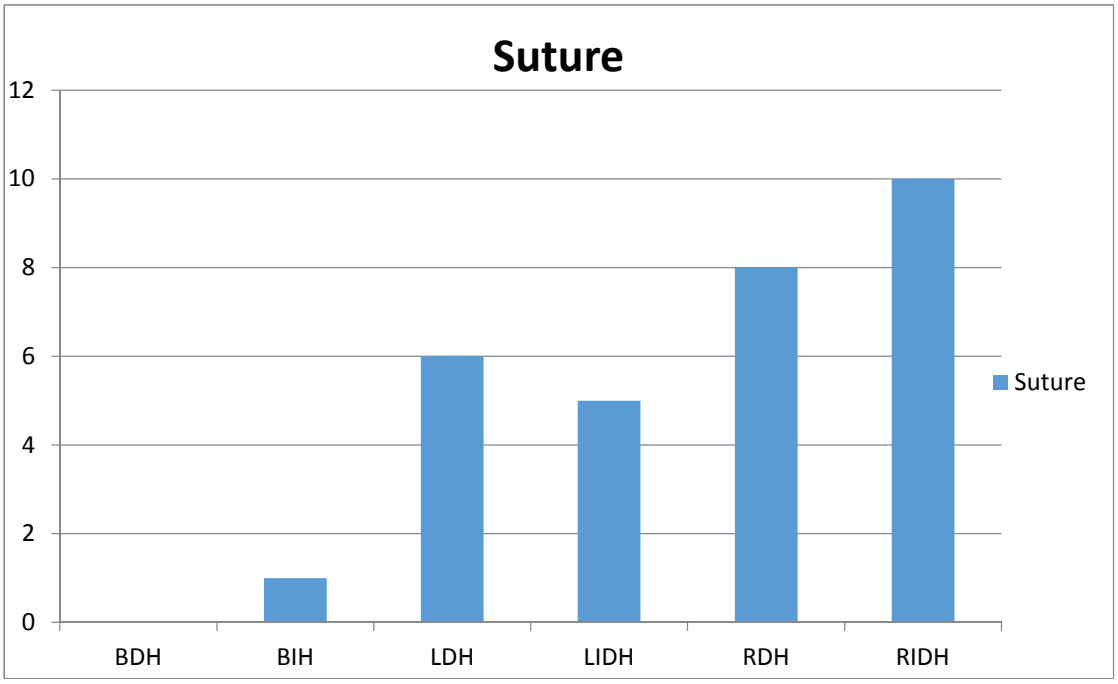


Figure 7: Bar diagram showing association of Study Group with Diagnosis of study population in Suture (group A)



Among the glue subjects 20% BIH, and in suture group this proportion was 3.33%. Among the glue subjects 6.67% LDH, and in suture group this proportion was 20% Among the glue subjects 16.67% LIDH and in suture group this proportion was 16.67%.Among the glue subjects 33.3%RDH and in suture group this proportion was 26.67% and Among the glue subject 23.33% RIDH and in suture group this proportion was 33.33%. The difference in diagnosis between the two groups was statistically not significant. (p value=0.176)

Table 10: Association of Study Group with Name of Surgery of study population (N=60)

Name of Surgery	Study Group		Chi square	P-value
	Glue	suture		
RTFH	17 (56.67%)	18 (60%)	4.489	0.106
LTFH	7 (23.33%)	11 (36.67%)		
BTFeIH	6 (20%)	1 (3.33%)		

Among the glue subjects 56.67% RTFH, and in suture group this proportion was 60%. Among the glue subjects 23.33%LTFH, and in suture group this proportion was 36.67%and Among the glue subjects 20% BTFeIH and in suture group this proportion was 3.33%. The difference in name of surgery between the two groups was statistically not significant (P value=0.106)

Figure 8: Bar diagram showing association of Study Group with Name of Surgery performed in the study population (N=60)

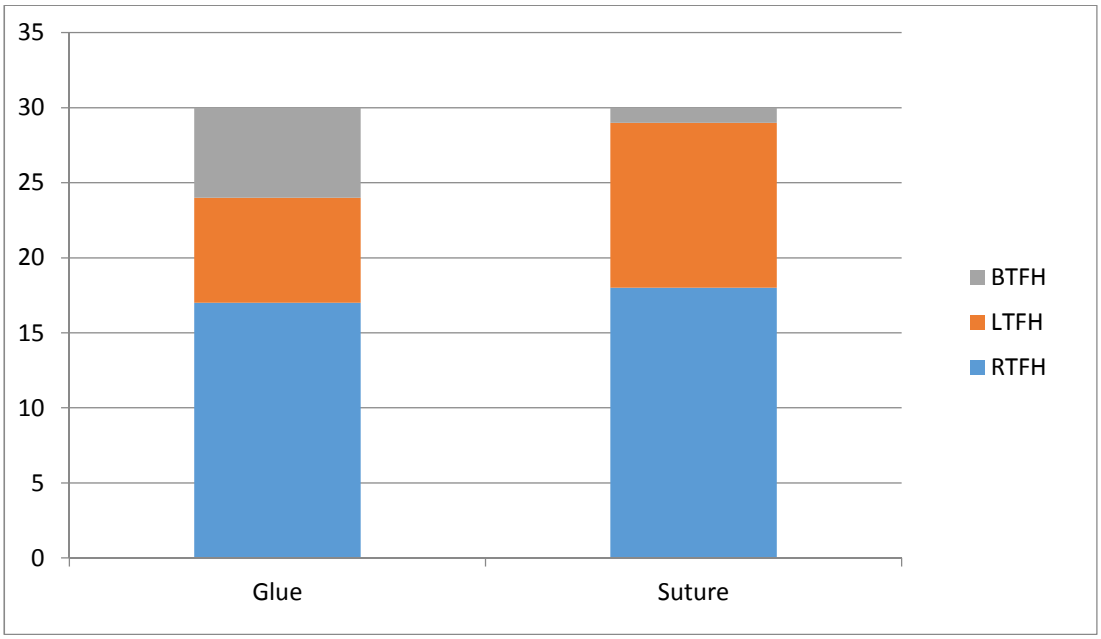


Table 11: Comparison of VAS score Between two study groups (N=60)

Parameter	Mean ±SD		P value
	Glue (N=30)	suture (N=30)	
Day1 Aop VAS score	3.43 ± 0.97	6.2 ± 1.27	<0.001
Da 3 Aop VA Score	2.2 ± 1.06	4.13 ± 0.68	<0.001
Day5 Aop VAS score	1.2 ± 0.76	2.73 ± 0.69	<0.001
Day7 Aop VAS score	0.5 ± 0.57	1.7 ± 0.65	<0.001
Day15 Aop Vas score	0.17 ± 0.38	0.9 ± 0.55	<0.001
Day30 Aop Vass core	0.03 ± 0.18	0.63 ± 0.56	<0.001

The mean day1 vas score of subjects in glue group was3.43 ± 0.97and in suture group, it was 6.2 ± 1.27. The mean day3 vas score of subjects in glue group was2.2 ± 1.06and in suture group, it was 4.13 ± 0.68.The mean day5 vas score of subjects in glue group was1.2 ± 1.06 and in suture group, it was 2.73 ± 0.69. The mean day7vas score of subjects in glue group was0.5 ± 0.57and in suture group, it was 1.7 ± 0.65.The mean day15vas score of subjects in glue group was0.17 ± 0.38and in suture group, it was 0.9 ± 0.55.The mean day30vas score of subjects in glue group was0.03 ± 0.18and in suture group, it was 0.63 ± 0.56. The difference in the daily activity of vas score parameter between the two groups was statistically significant (P Value<0.001) (Table11&figure4).

Figure 9: Bar chart of VAS score between study group at different follow up periods (N=60)

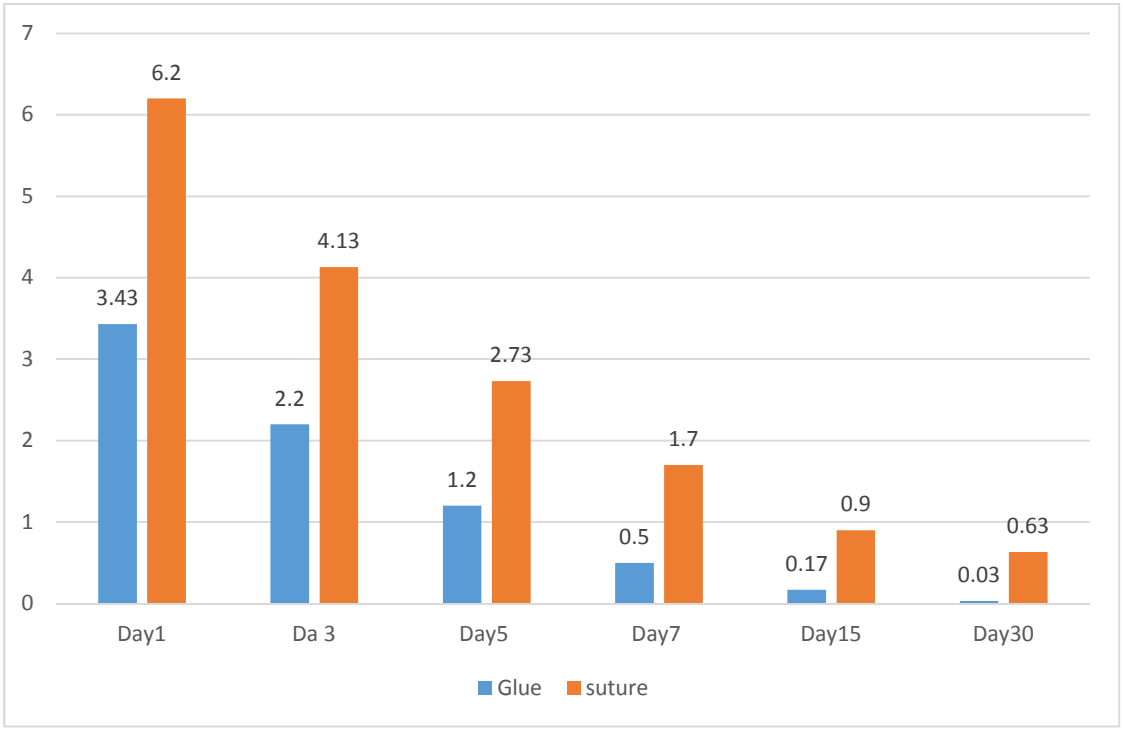


Table 12: Comparison of mean RTDA DAYS Aop VAS score across study groups (N=60)

Study Group	RTDA DAYS Mean± STD	Mean difference	95% CI		P value
			Lower	Upper	
Glue	22.33 ± 5.53	-6.03	-8.22	-3.85	<0.001
suture	28.37 ± 2.3				

The Mean of RTDA days was 22.33± 5.53in subjects with glue group and mean of RTDA days was28.37 ±2.3in subjects suture. The mean difference between the Group was (-6.03). It was statistically significant (P Value<0.001) (Table 12).

Figure 10: Bar diagram showing association of Study Group with Return to Daily Activities (RTDA) in days in the study population (N=60)

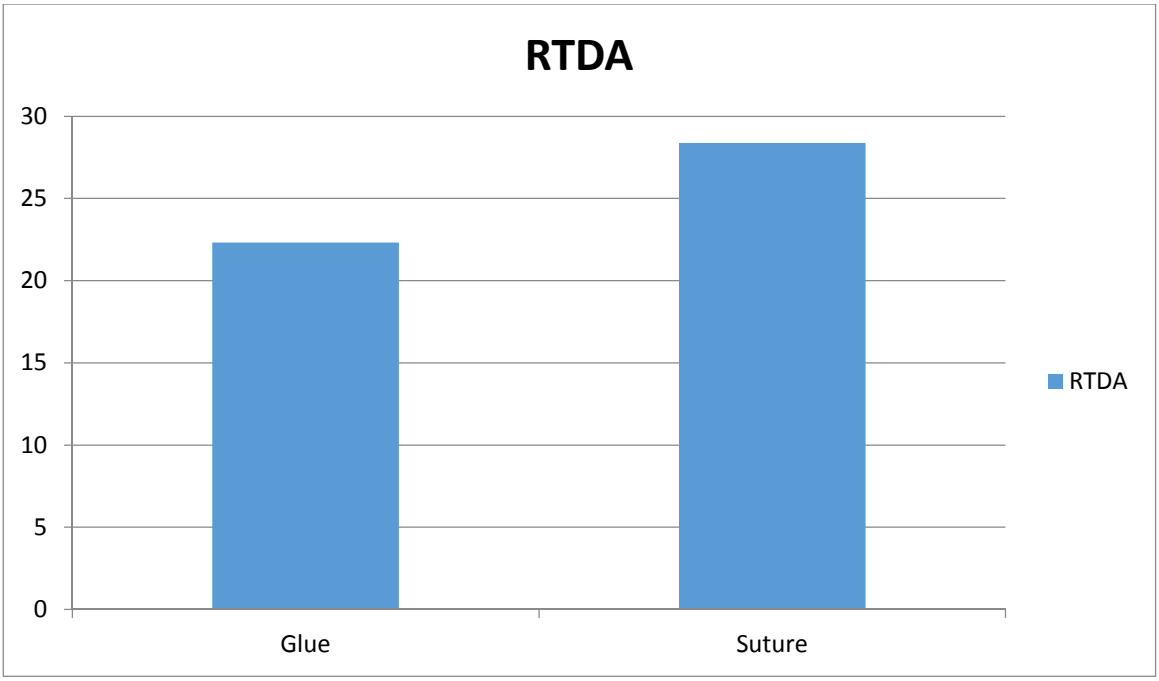


Table 13: Comparison of VAS score between two study groups (N=60)

Assessment of pain (VAS score)	Glue Median (IQR)	suture Median (IQR)	Mann Whitney U test
Day1	3(3,4)	6(5,7)	**<0.001**
Day 3	2(1,3)	4(4,5)	**<0.001**
Day5	1(1,2)	3(2,3)	**<0.001**
Day7	0(0,1)	2(1,2)	**<0.001**
Day15	0(0,0)	1(1,1)	**<0.001**
Day30	0(0,0)	1(0,1)	**<0.001**

The Median VAS **score** of day1 subjects in glue group was3 and IQR (3,4) and in suture group, it was 6and IQR (5,7).The Median VAS **score** of day3 subjects in glue group was 2 and IQR (1,3) and in suture group, it was 4and IQR (4,5). The Median vas score of day5 subjects in glue group was 1 and IQR (1,2) and 3and IQR (2,3).The Median vas score of day7 subjects in glue group was 0 and IQR (0,1) and 2and IQR (1,2).The Median vas score of day15 subjects in glue group was 0 and IQR (0,0) and 1and IQR (1,1).The Median vas score of day30 subjects in glue group was 0 and IQR (0,0) and 1and IQR (0,1). The difference in the VAS **score** between the two groups was statistically significant (P Value<0.001) (Table13).

Table 14: Association of Study Group with surgical site infection of study population (N=60)

surgical site infection	Study Group		Chi square	P-value
	Glue	suture		
Yes	5 (16.67%)	8 (26.67%)	0.884	0.347
No	25 (83.33%)	22 (73.33%)		

Among the glue subjects 16.67% surgical site infection and in suture group this proportion was 26.67%. The difference in surgical site infection between the two groups was statistically not significant (P value=0.347)

Figure 11: Bar diagram showing association of Study Group with SSi of study population (N=60)

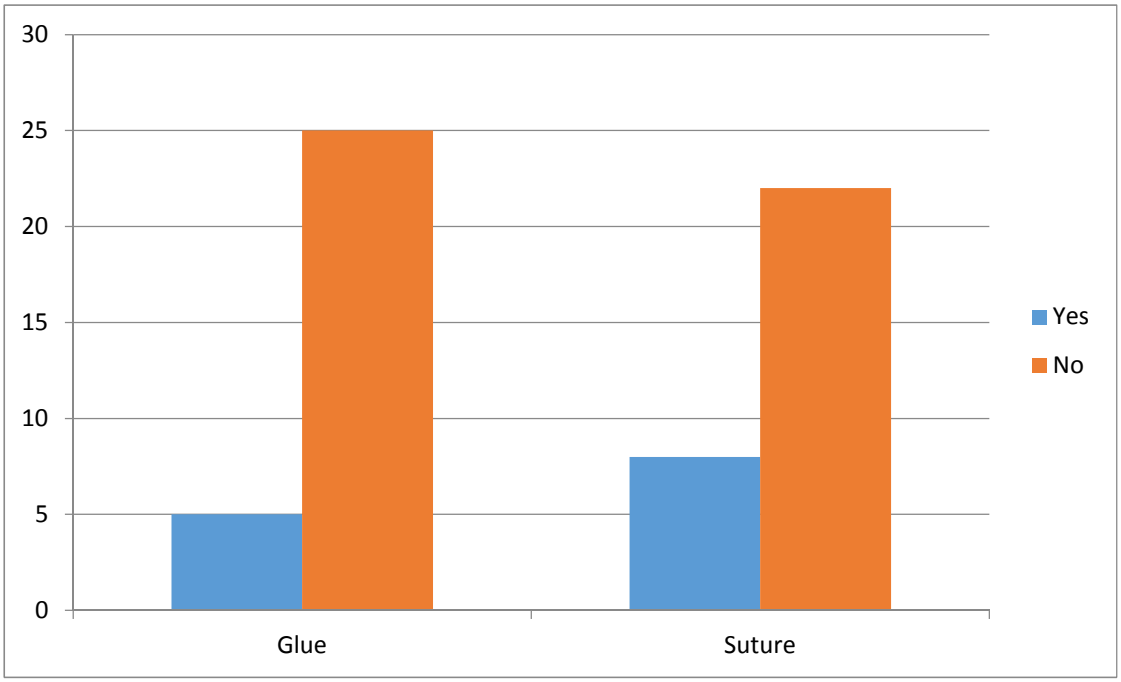
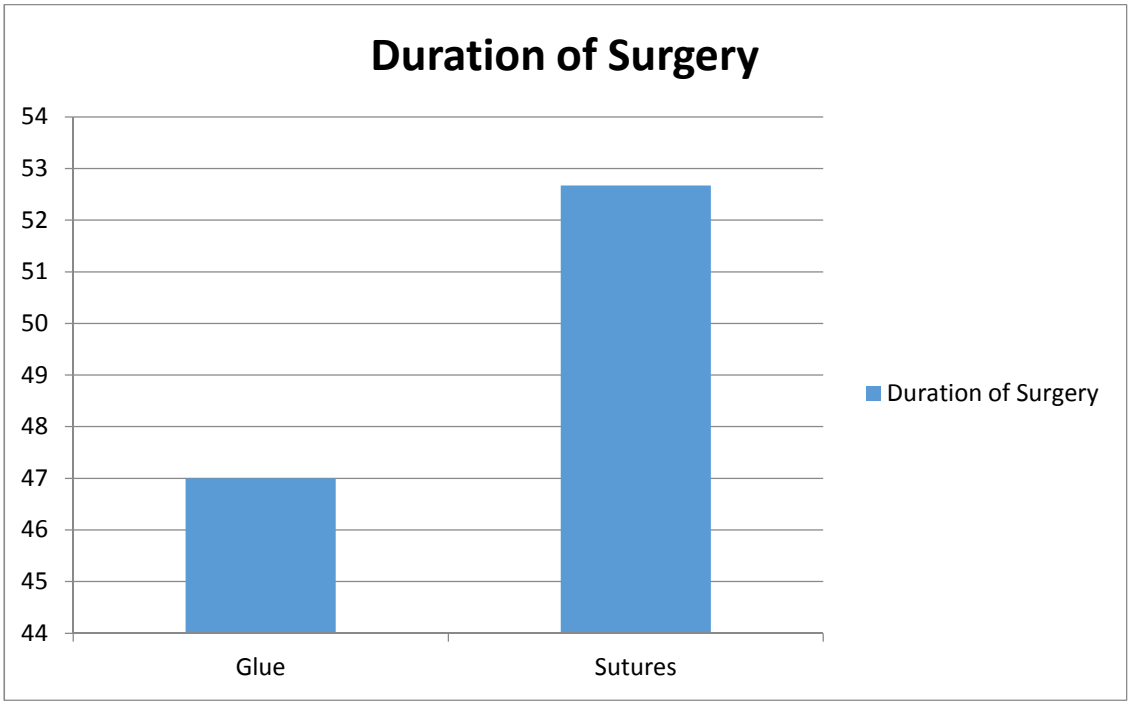


Table 15: Association of Study Group with Duration of Surgery in study population (N=60)

Parameter	Study Group		P value
	Glue (N=30)	suture (N= 30)	
Duration of Surgery (in mins)	47.33 ± 6.66	52.67 ± 5.53	0.0013

Figure 12: Bar diagram showing association of Study Group with mean Duration of Surgery of study population (N=60)



Among the glue subjects 47.33±6.66 mins is the mean duration of surgery and in suture group this mean duration of surgery was 52.67 ± 5.53 mins The difference in mean duration of surgery between the two groups was statistically significant (P value=0.0013)

DISCUSSION

The Lichenstein's tension free hernioplasty is the most preferred surgery for the inguinal hernia worldwide[33]. Conventional suture fixation of the mesh is time consuming and tedious work and invasive technique and thus the incidence of post operative groin discomfort, chronic pain at operated site is most common[34], can be because of the nerve entrapment.

Nevertheless its cause of chronic pain, discomfort and reduced quality of life in many cases.

Different methods of mesh fixation have been studied. The use of tissue adhesives has had the most promising result in terms of clinical efficacy and reduction of post-operative pain[35].

For a common pathology such as inguinal hernia, the goal is to have no defects. Thus, for primary inguinal hernia by the Lichtenstein's operation, we should aim for the following:

(a) mesh repair

(b) tension-free and suture-less;

(c) early ambulation;

(d) decreased duration of hospital stay

(e) rapid return to work

(f) recurrence rate of <1 % and

(g) absence of patient discomfort, numbness, or neuralgia.

This one year randomized controlled trial was conducted on a total of 60 patients admitted with inguinal hernia requiring mesh repair under the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2016 to December 2016. These patients were further randomized into two groups of 30 each as group A (Mesh fixation in an open inguinal hernia using conventional sutures) and Group B (Mesh fixation in an open inguinal hernia repair using NBCA glue)

In this study the mean age group in the Group B (NBCA glue) is 48.2 ± 16.92 years and the Group A (Suture group) is 50.5 ± 12.46 years with p-value 0.551, association of gender of study population includes 49.15% male in Group B and 50.85% male in Group A with Chi square value of 1.017 and p value 0.313. Comparison of mean duration in months, in Group B is 14.67 ± 13.98 and 13.73 ± 11.18 in Group A with p value 0.776. Comparison of mean systolic BP(mm HG) in Group B is 116.67 ± 8.64 and 118.93 ± 8.72 in Group A with p value of 0.316 and mean Diastolic BP (mm Hg) in Group B 74.2 ± 5.34 and 74.33 ± 5.33 in Group A with p value 0.923. Comparison of mean hernia size (in cms) in Group B is 10.3 ± 5.18 and 10.3 ± 6.1 in Group A with p value 1.000. In this study, in Group B there were 6 bilateral hernias where as there were 7 left sided hernias and 17 right sided hernias and in Group A, there were 1 bilateral hernias where as there were 11 left sided hernias and 18 right sided hernias. In Group B, 6 were Bilateral inguinal hernia, 2 were left direct inguinal hernia, 5 were left indirect inguinal hernia, 9 were right direct inguinal hernia and 7 were right indirect inguinal hernia. In Group A, 1 was Bilateral inguinal hernia, 6 were left direct inguinal hernia, 5 were left indirect inguinal hernia, 8 were right direct inguinal hernia and 10 were right indirect inguinal hernia.

In Group B, 17 underwent Right sided Lichenstein's tension free hernioplasty, 7 underwent Left sided Lichenstein's tension free hernioplasty and 6 underwent bilateral tension free hernioplasty and in Group A,18 underwent Right sided Lichenstein's tension free hernioplasty, 11 underwent Left sided Lichenstein's tension free hernioplasty and 1 underwent bilateral tension free hernioplasty.

Comparison of the visual analogue scale in the study group (N=60) mean score of the VAS score in Group B (NBCA Glue) on post op Day 1 was 3.43, on POD7 was 0.5 and 0.03 on POD30 whereas in Group A (Suture Group) on post op Day 1 mean VAS score was 6.2, on POD7 it was 1.7 and on POD30 it was 0.63, was statistically significant in this study (p value <0.05). Return to daily activities in Group B with mean of 22.33 and in Group A mean of 28.37, was statistically significant in this study (p value<0.05).

The incidence of Surgical site Infection, in the form of inflammation, infection and gaping , in group B, 5 of them had SSI and in Group A, 8 of them had SSI , was statistically not significant (p value > 0.05) in this study and SSI in both the groups it was treated by daily dressings.

Comparison of total duration of surgery in the two groups , among the glue subjects 47.33±6.66 mins is the mean duration of surgery and in suture group this mean duration of surgery was 52.67 ± 5.53 mins The difference in mean duration of surgery between the two groups was statistically significant (P value=0.0013)

In Karigoudar et al, the advantages of fibrin glue over Prolene suture in fixation of the mesh in open inguinal hernia repair was assessed[33]. Sixty-four cases of inguinal hernia underwent hernia repair by the Lichtenstein method.

In group A, fibrin glue was used for mesh fixation, and in group B, Prolene suture was used for mesh fixation. The mean age of patients in group A was 44.5

years and that of group B patients was 44.2 years. There was a significant difference in the duration of surgery, with the mean duration in fibrin glue group being 30.6 min and that of the suture group was 43.3 min.

The mean visual analogue pain score of postoperative pain at 1, 6, 12, and 24 h was significantly higher in the suture group than in the fibrin glue group ($p<0.001$). At the end of the first month, 25%of subjects in the suture group presented with mild groin pain (p value=0.0048). The present prospective trial has confirmed the observation of the earlier studies that the use of fibrin glue for mesh fixation significantly decreases postoperative pain as evidenced by the marked difference in the mean visual analogue pain scale score of the two groups.

In a systematic review and meta-analysis, study conducted 2010-2011[25], seven randomised controlled trials encompassing 1259 patients with 628 patients in suture mesh fixation group and 653 patients in Glue mesh fixation group . In the meta-analysis, post-operative complications, with follow up from 3-60 months the mean post-operative pain in the intervention groups was 0.31 in a total of 720 studies and post-operative complications with follow up of 3-60 months in 945 studies with RR 1.27, the study concluded that Glue method of mesh fixation comparable with suture method of mesh fixation groups in terms of post-operative pain, post-operative complications and return to daily activities.

In a study conducted in 2017 Ghonimi WAM, Elhorbity MA et al, with 60 as the sample size (30 in each group) they found out that the mean operating time in glue mesh fixation was ranged from 30 to 45 minutes compared to 40 to 60 mins in conventional method of mesh fixation using sutures. No SSI found in the study group. Return to daily activities in glue mesh fixation group was between 10 days to 2 weeks post-operative compared to 2 weeks to 6 weeks in suture mesh fixation[29].

Tebala GD, Tognoni V et al Forty-five male patients with primary unilateral groin hernia were randomized to undergo open hernia repair with suture fixation or cyanoacrylate glue fixation of the mesh (Group B). Primary outcome was early and late postoperative pain. Secondary endpoints were use of painkillers after 24 hours, morbidity rate and recurrence rate. Early postoperative pain and pain between 48 hours and 1 month after surgery were significantly lower in Group B. Only two patients had chronic pain, and both were in Group A. Clinical recurrences were two, both in suture fixation group[36]

In Wong JU, Leung TH, Huang CC, Huang CS et al, a study of 6 months, compared the postoperative pain, complications recurrence after bilayer polypropylene mesh inguinal hernioplasty (two types of Mesh used, PHS and Modified Kugel patch) using fibrin sealant versus sutures for mesh fixation, in this study 56 patients were randomly assigned to either of the groups, compared to 60 patients in the present study. Pain was measured by Visual Analogue Scale (VAS) same as compared to the present study. The primary end point was late post-operative pain at 1^{st} 7^{th} 30^{th} and 90^{th} days post-operatively compared to the present study were post-operative pain compared to post operative day 1^{st}, 3^{rd}, 5^{th}, 7^{th} ,15^{th} and 30^{th} days post operatively . There were no statistically significant differences between the mesh fixed with suture and fibrin sealant groups, unlike the present study where post operative pain and return to daily activities showed statistical significance. In the study it was concluded that use of fibrin sealant, in open inguinal hernia repair was associated with similar rates of complications and recurrence as mesh fixation using sutures[37].

CONCLUSION

In our study, comparison between conventional suture fixation and NBCA glue use in mesh fixation during open inguinal hernia repair was done and we found that:-

- Use of N butyl cyanoacrylate glue for Lichtenstein hernia repair is more efficacious than regular prolene suture mesh fixation and also has the potential to reduce the incidence of inguinodynia and discomfort at operated site.
- There is less pain after post operative day 30 in n-butyl cyanoacrylate group mesh fixation.
- Less number of cases of surgical site infection in N butyl cyanoacrylate group of mesh fixation.
- Return to daily activities is much earlier, seen in patients who underwent NBCA group of mesh fixation in primary open inguinal hernia repair.
- Total duration of surgery using NBCA glue in mesh fixation is much quicker, in primary open inguinal hernia repair.
- Hence Lichtenstein tension free hernioplasty with mesh fixation done using N butyl cyanoacrylate is safe, effective and less time consuming , when compared with suture fixation.

SUMMARY

Lichtenstein hernia repair is standard recommended surgery in the management of primary open inguinal hernia and, post operative pain is considered the most important complication[39]. The present study was aimed to compare the sutures versus NBCA glue in method of mesh fixation.

The present one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2016 to December 2016. A total of 60 patients requiring mesh repair were randomized into two groups of 30 each based on the type of glue used for mesh fixation, as group A (Sutures) and group B (NBCA glue).

Comparison of the visual analogue scale in the study group (N=60) mean score of the VAS score in Group B (NBCA Glue) on post op Day 1 was 3.43, on POD7 was 0.5 and 0.03 on POD30 whereas in Group A (Suture Group) on post op Day 1 mean VAS score was 6.2, on POD7 it was 1.7 and on POD30 it was 0.63, was statistically significant in this study (p value <0.05). Return to daily activities in Group B with mean of 22.33 and in Group A mean of 28.37, was statistically significant in this study (p value<0.05). The incidence of Surgical site Infection, In group B 5 of them had SSI and in Group A 8 of them had SSI , was statistically not significant (p value > 0.05) in this study and SSI in both the groups was treated by daily dressings.

Lastly, additional finding from this study is duration of surgery (in mins) compared between both the groups. Among the glue subjects 47.33±6.66 mins is the mean duration of surgery and in suture group this mean duration of surgery was

52.67 ± 5.53 mins .The difference in mean duration of surgery between the two groups was statistically significant (P value <0.05)

Overall, the present study showed that, the pain scores were significantly less in NBCA glue fixation group compared to Suture mesh fixation. Thus the use of NBCA glue in mesh fixation reduces the chances of peri-osteitis caused due to suture fixation at pubic tubercle and by reducing the entrapment of nerves resulting in lowering the possibility of inguinodynia in post-operative patients of Lichensteins tension free hernioplasty.

To summarise, considerable alteration has taken place from conventional suture fixation using prolene suture fixation method to the new era of tissue adhesives[40], which will minimise the tissue trauma, reduces the duration of surgery and post-operative pain and return to daily activities is much earlier with use of tissue adhesives in mesh fixation in open inguinal hernia repair.

Thus tissue adhesives/ glues (n-butyl 2-cyanoacrylate glue) in mesh fixation during open inguinal hernia repair was found to be safe, effective and less time consuming.

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ANNEXURE I – CONSENT FORM

***Title of Research Study*:**

COMPARISON OF SUTURES VERSUS N-BUTYL 2-CYANOACRYLATE GLUE FOR MESH FIXATION DURING PRIMARY INGUINAL HERNIA REPAIR - A ONE YEAR RANDOMIZED CONTROL TRIAL

Principal Investigator: -

DR. _____

Post Graduate Student,

Department Of General Surgery,

J. N. Medical College, Belagavi .

Co-investigator:-

DR. _____

Professor

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 N butyl 2-cyanoacrylate glue in mesh fixation during an open inguinal hernia repair in comparison with the conventional method of mesh fixation that is suture mesh fixation.

Our study is basically about the use of N-butyl 2-cyanoacrylate glue in Mesh fixation during open inguinal hernia repair. And compare it with the conventional method of mesh fixation during open inguinal hernia repair which is by using sutures. We are going to compare the Outcome of the new method of mesh fixation that is by using N-butyl 2-cyanoacrylate glue versus the conventional method of mesh fixation that is by using sutures, in terms of post operative pain in patients who underwent Meshplasty for inguinal hernia.

There has been sincere effort to study the effectiveness of N-butyl 2-cyanoacrylate glue in mesh fixation during open inguinal hernia repair compared to the conventional method of mesh fixation, as the former gives advantages over the latter in terms of reduced incidence of Post operative pain and less time taken to complete the surgery. In this study we are going to compare the outcome in terms of incidence of post-operative pain with the use of N-butyl 2-cyanoacrylate glue.

In this study, there will be comparison of the Glue Mesh Fixation technique versus Suture Mesh Fixation technique.

This study will be conducted by Dr. _____ , Post Graduate in Department of Surgery, under the direct supervision and guidance of Dr. _____, Professor, Department of Surgery, J. N. Medical College, 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 Glue Mesh Fixation technique or Suture Mesh Fixation Technique. You will be monitored after surgery until hospital discharge and evaluated by physical examination on days 3, 7 and 15 and at 1 month.

At the follow-up physical examinations, postherniorrhaphy pain is to be evaluated using a questionnaire that described the localization, frequency and level (slight, moderate, severe) according to the Visual Analog Scale [VAS], Return to daily activities and Surgical site infection has to be recorded.

BENEFITS: - May cause less post-operative herniorrhaphy pain compared to the conventional method of mesh fixation

RISK INVOLVED:- There is no side effects of this technique recorded till now.

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. 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. _____ and Dr. _____ 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 Kore Hospital, Belagavi. The alternative that you have is to undergo the traditional procedure that is carried out in KLES Dr.Prabhakar Kore Hospital, Belagavi.

If you have any queries about the study, you may contact:

Dr. _____

Professor,

(Post Graduate Student)

Department of Surgery

Jawaharlal Nehru Medical College

Nehru Nagar,

Belgaum 590010

Mobile- _____

Dr. _____

Dept. of General Surgery.

Jawaharlal Nehru Medical College

Nehru Nagar,

Belgaum 590010

Mobile - _____

In case you need any further information regarding your rights as study participant you may contact:

Dr. _____

Chairman

College Ethical Dissertation

And Research Committee,

Jawaharlal Nehru Medical College

Nehru Nagar, KLE Hospital Road

Belgaum 590 010

Mobile –_____

CONSENT TO PARTICIPATE IN THE STUDY

I Mr./Ms._____ have been explained about the research study, the need of the study, the intervention, their risks, benefits and alternatives available in my own vernacular language.

I voluntarily agree to participate in this study by signing up this form below. I understand that I may withdraw at any time from this study. I have been given adequate time to clarify my doubts about the study and my rights as a study participant.

My signature / thumb impression below indicates that I have read or information in the consent been read to me including the risks and benefits and have cleared my doubts.

Name of participant: Signature/LTI:

Name of legally authorized Signature/LTI:

Representative (if applicable):

Relationship with participant:

ame of witness: Signature:

Name of investigator: Signature:

Date:

Place:

ANNEXURE II

PROFORMA / QUESTIONNAIRE TO BE USED FOR DATA COLLECION

The proposed proforma / questionnaire to be used for data collection for the study titled **"COMPARISON OF SUTURES VERSUS N-BUTYL 2-CYANOACRYLATE GLUE FOR MESH FIXATION DURING PRIMARY INGUINAL HERNIA REPAIR - A ONE YEAR RANDOMIZED CONTROL TRIAL"**-is as follows:-

1. PATIENT IDENFICIATION DATA

Group:	Ward:
Name:	IP No.:
Age:	Sex:
D.O.A:	Address:
D.O.S:	D.O.D:
Education:	Religion:
Marital Status:	Occupation: \
Socio-Economic Status:	

CHIEF COMPLAINTS:

HISTORY OF PRESENTING COMPLAINTS:

Past History:

Personal History:

Family History:

GENERAL PHYSICAL EXAMINATION:

Built and Nourishment:

Weight:

Pallor / Icterus / Cyanosis / Clubbing / Edema / Lymphadenopathy

Vital Signs: PR: /min; BP: mmHg; RR: /min; Temp:

LOCAL EXAMINATION

SYSTEMIC EXAMINATION

Abdomen:

CNS:

CVS:

R S:

CLINICAL IMPRESSION:

INVESTIGATIONS:

OPERATION DETAILS: -

DATE OF SURGERY:

NAME OF SURGERY:

ANAESTHESIA: _____

QUESTIONNAIRE:

Name of the Patient_____ IP no._____

Group_____ Date_____

DAY 1(24 HRS): Any complaints of pain? YES NO

If yes Site of Pain_____ Severity_____

DAY 3: Any complaints of pain? YES NO

If Yes, Site of Pain_____ Severity_____

Dressing Soaked YES NO

DAY 5: Any complaints of pain? YES NO

If Yes, Site of Pain_____ Severity_____

Dressing Soaked YES NO

Returned to daily activities YES NO

If Yes Since how many days_____

DAY 7

If Yes, Site of Pain_____ Severity_____

Dressing Soaked YES NO

Returned to daily activities YES NO

If Yes Since how many days_____

Sutures removed? YES NO

DAY 15

If Yes, Site of Pain_____ Severity_____

Returned to daily activities YES NO

If Yes Since how many days_____

DAY 30

If Yes, Site of Pain_____ Severity_____

Returned to daily activities YES NO

If Yes Since how many days_____

ANNEXURE III – PHOTOGRAPHS

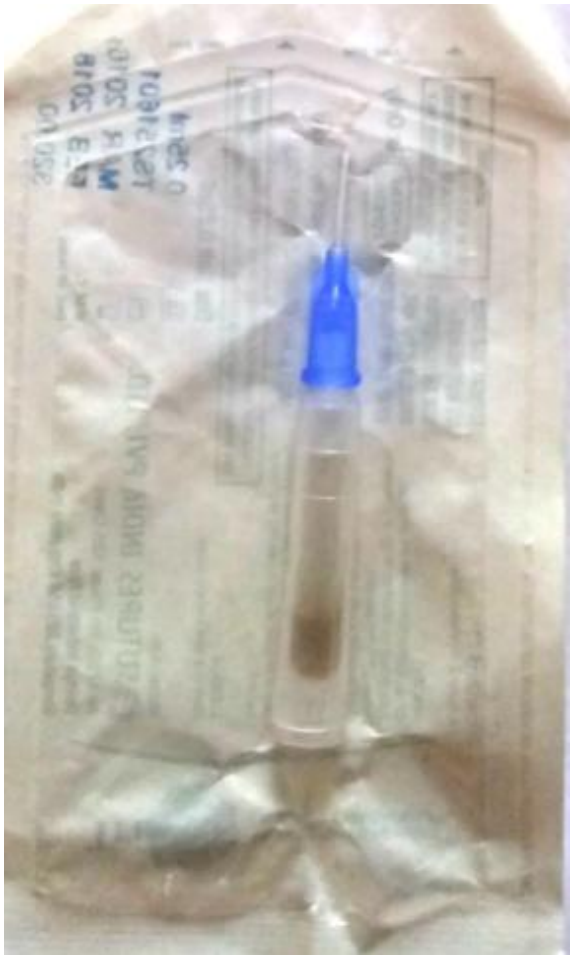

IMAGE 1: Showing Sterile Packing of Commercially Available NBCA Glue

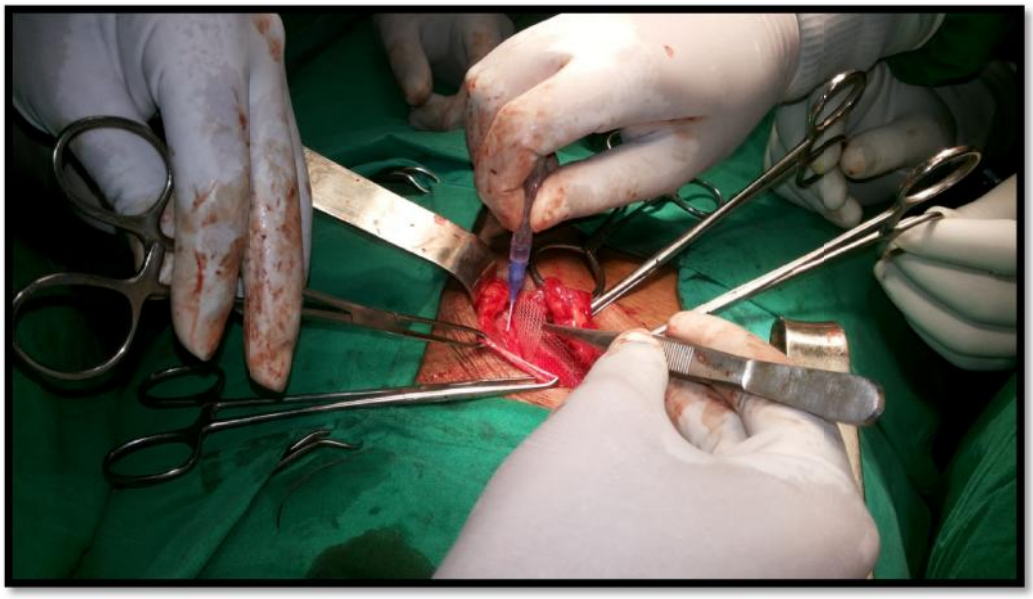

IMAGE 2: SHOWS APPLICATION OF NBCA GLUE FOR MESH FIXATION IN LEFT OPEN INGUINAL HERNIA REPAIR.

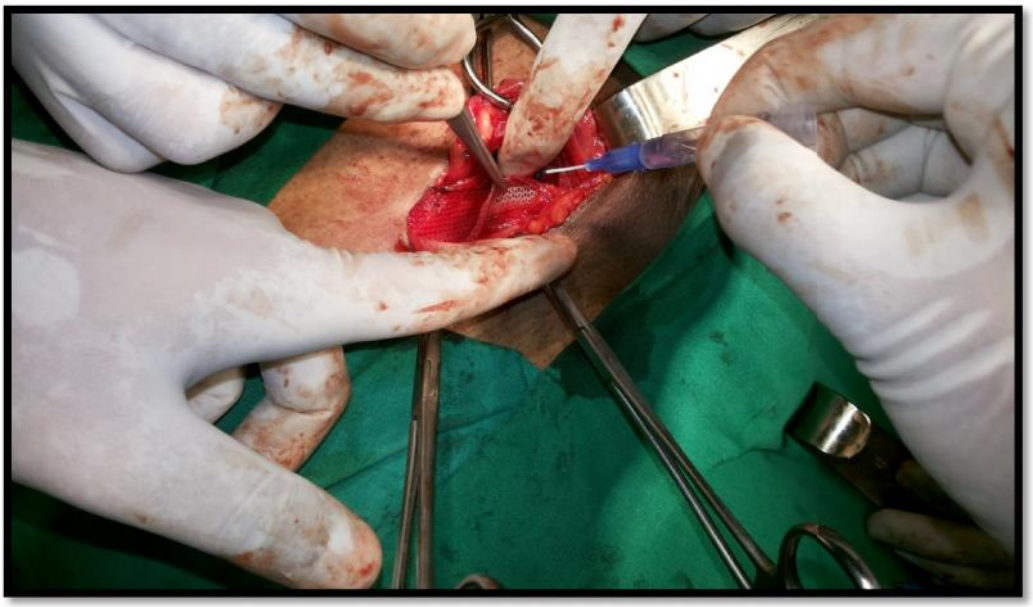

IMAGE 3: SHOWS APPLICATION OF NBCA GLUE IN RIGHT OPEN INGUINAL HERNIA REPAIR

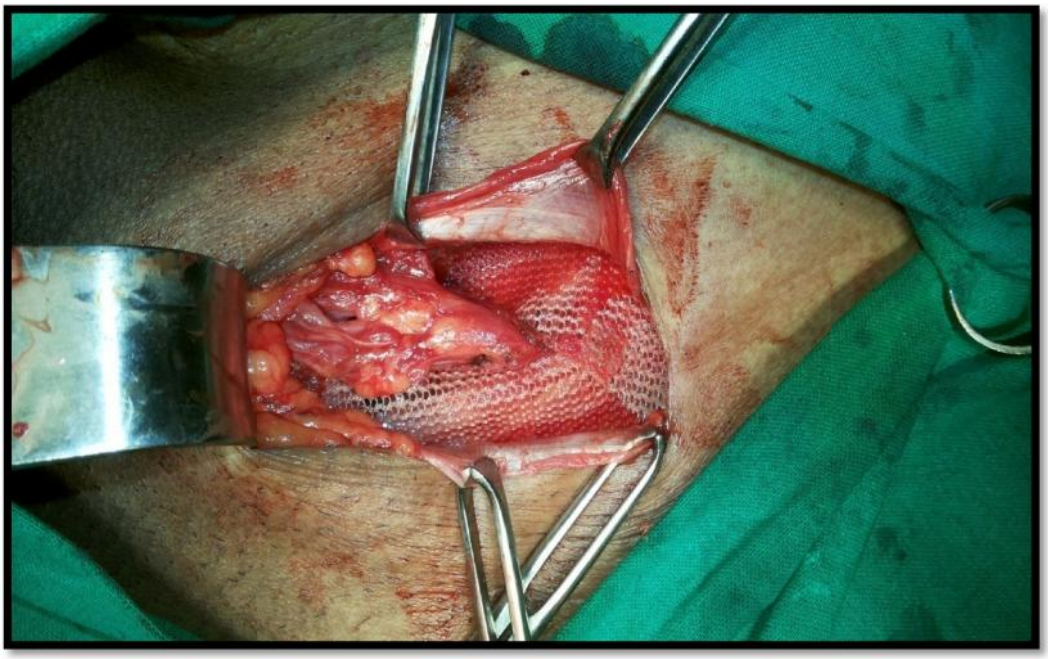

IMAGE 4: SHOWS PLACEMENT OF MESH AND FIXATION DONE WITH NBCA GLUE IN LEFT OPEN INGUINAL HERNIA REPAIR.

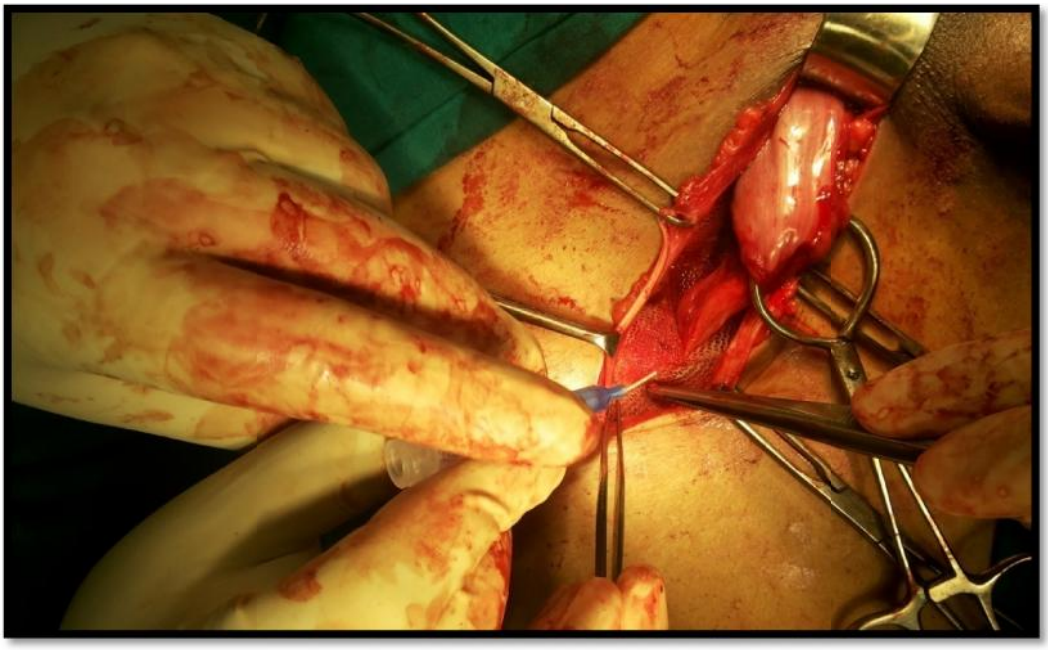

IMAGE 5: SHOWS APPLICATION OF NBCA FOR MESH FIXATION IN RIGHT SIDED OPEN INGUINAL HERNIA

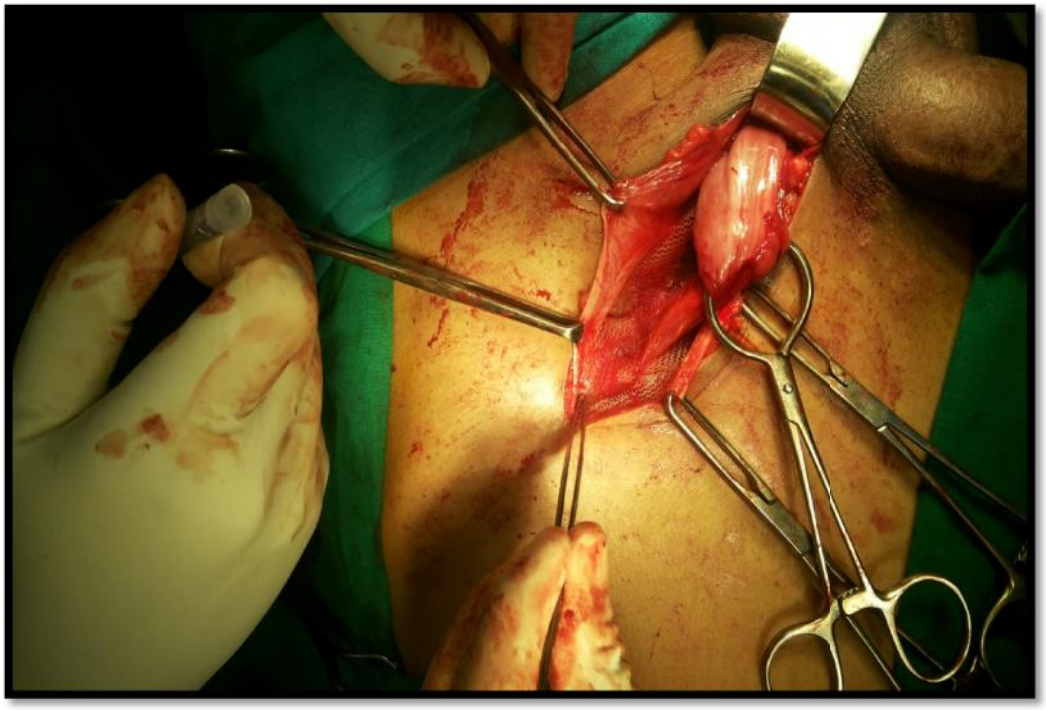

IMAGE 6: SHOWS MESH FIXATION IN RIGHT SIDED OPEN INGUINAL HERNIA USING NBCA

KEY TO MASTERCHART

B.P - Blood pressure

BL - Bilateral

BIH - Bilateral Indirect Inguinal Hernia

BDH - Bilateral Direct Inguinal Hernia

BTFH - Bilateral Tension Free Hernioplasty

F - Female

I.P - In patient

L - Left sided

LDH - Left sided Direct Inguinal Hernia

LIDH - Left sided Indirect Inguinal Hernia

LTFH - Left Sided Tension free Hernioplasty

M - Male

mm Hg- Millimetres of mercury

N - No

R - Right sided

RDH - Right sided Direct Inguinal Hernia

RIDH - Right sided Indirect Inguinal Hernia

RTFH - Right Sided Tension free Hernioplasty

RTDA - Return To Daily Activities

SA - Spinal Anaesthesia

SSI - Surgical Site Infection

VAS - Visual Analogue score

y - Duration in years

m - Duration in months

Y - Yes

\+ - Present

\- - Absent

ANNEXURE IV - MASTER CHART - GROUP SP

Serial Number	In patient Number	Sex	Age (Years)	Duration	General physical examination		Per abdomen					Diagnosis			Assessment of pain (VAS score)								
							Inspection			Palpation														
					Pulse Rate	BP(mm Hg)	Size (Cms)	Cough impulse	Position	Reducibility	Tenderness		Name of Surgery	Type of Anaesth	Day 1	Day 3	Day 5	Day 7	Day 15	Day 30	RTDA(DAYS)	SSI	OT Time (mins)
1	735499	M	77	2y	80	120/70	3*6	+	L	+	-	LIDH	LTFH	SA	4	2	1	1	0	0	20	N	45
2	710733	M	65	2y	70	130/80	3*4	+	R	+	-	RDH	RTFH	SA	2	1	0	0	0	0	15	N	40
3	705306	M	60	8m	82	110/70	6*4	+	R	+	-	RDH	RTFH	SA	3	1	1	0	0	0	20	N	45
4	710550	M	18	2m	80	120/80	3*4	+	L	+	-	LDH	LTFH	SA	4	1	1	0	0	0	15	N	40
5	714369	M	27	4m	78	120/70	3*4	+	BL	+	-	BIH	BLTFH	SA	3	1	1	1	0	0	20	Y	60
6	726898	M	50	1y	80	126/80	3*2	+	L	+	-	LIDH	LTFH	SA	4	3	2	1	0	0	25	N	45
7	726899	M	45	4m	82	110/80	5*4	+	R	+	-	RIDH	RTFH	SA	2	1	0	0	0	0	15	N	40
8	728124	M	75	4m	84	120/70	4*2	+	BL	+	-	BIH	BLTFH	SA	5	4	2	1	1	0	25	N	60
9	717718	M	35	3m	80	110/70	3*2	+	R	+	-	RDH	RTFH	SA	3	2	1	0	0	0	15	N	45
10	716498	M	40	1y	78	130/86	4*5	+	R	+	-	RIDH	RTFH	SA	4	2	0	0	0	0	15	N	40
11	716623	M	36	2m	80	120/70	4*3	+	L	+	-	LDH	LTFH	SA	3	1	1	0	0	0	20	N	50
12	747140	M	42	5m	80	140/70	4*2	+	L	+	-	LIDH	LTFH	SA	4	3	1	1	0	0	25	Y	45
13	715466	M	27	3y	76	110/80	3*2	+	R	+	-	RDH	RTFH	SA	3	2	1	0	0	0	15	N	40
14	715201	M	80	1y	78	120/80	4*4	+	L	+	-	LIDH	LTFH	SA	5	4	1	1	1	0	30	N	45
15	713747	M	70	4m	70	110/70	2*3	+	R	+	-	RDH	RTFH	SA	2	1	1	0	0	0	25	N	45
16	711801	F	48	1y	80	120/70	2*2	+	R	+	-	RDH	RTFH	SA	2	1	0	0	0	0	20	Y	50
17	744521	M	38	1y	78	108/80	3*3	+	R	+	-	RIDH	RTFH	SA	3	2	1	0	0	0	30	Y	45
18	743988	M	52	2y	70	120/70	3*5	+	BL	+	-	BIH	BLTFH	SA	4	3	2	1	1	0	30	N	40
19	742932	M	42	2y	80	110/70	4*3	+	R	+	-	RIDH	RTFH	SA	3	2	1	0	0	0	25	N	50
20	743321	M	44	1y	86	110/70	2*2	+	R	+	-	RDH	RTFH	SA	4	3	2	1	0	0	30	N	45
21	743480	M	18	6m	80	110/80	3*3	+	R	+	-	RDH	RTFH	SA	2	1	1	0	0	0	15	N	45
22	744873	M	61	5y	76	130/80	2*5	+	BL	+	-	BIH	BTFH	SA	5	4	3	2	1	1	30	N	50
23	749014	M	70	3y	80	110/70	2*4	+	BL	+	-	BIH	BTFH	SA	5	4	2	1	0	0	20	N	60
24	756252	M	51	3y	70	110/70	3*3	+	R	+	-	RIDH	RTFH	SA	3	2	1	1	0	0	30	N	45
25	772236	M	36	2y	86	120/70	3*2	+	R	+	-	RIDH	RTFH	SA	3	2	1	0	0	0	25	N	40
26	778488	M	42	1m	70	110/80	2*2	+	R	+	-	RDH	RTFH	SA	3	2	1	0	0	0	20	N	50
27	774717	M	62	10m	76	116/80	2*3	+	R	+	-	BDH	RTFH	SA	4	3	2	1	0	0	20	N	60
28	741074	M	31	2y	72	110/70	3*4	+	L	+	-	LIDH	LTFH	SA	3	2	1	1	0	0	25	Y	45
29	690013	M	61	2m	70	100/70	3*2	+	BL	+	-	BIH	BTFH	SA	5	4	3	1	1	0	20	N	60
30	704480	M	43	1m	80	120/70	3*3	+	R	+	-	RIDH	RTFH	SA	3	2	1	0	0	0	30	N	50
31	766433	M	46	1y	80	130/80	3*3	+	R	+	-	RDH	RTFH	SA	6	4	3	2	1	1	25	N	50
32	763823	M	55	45	90	110/70	3*2	+	L	+	-	LIDH	LTFH	SA	6	3	2	1	0	0	30	N	60

ANNEXURE IV - MASTER CHART - GROUP SP

Serial Number	In patient Number	Sex	Age (Years)	Duration	General physical examination		Per abdomen					Diagnosis			Assessment of pain (VAS score)								
							Inspection			Palpation														
					Pulse Rate	BP(mm Hg)	Size (Cms)	Cough impulse	Position	Reducibility	Tenderness		Name of Surgery	Type of Anaesth	Day 1	Day 3	Day 5	Day 7	Day 15	Day 30	RTDA(DAYS)	SSI	OT Time (mins)
33	760415	M	78	2y	70	116/70	3*2	+	R	+	-	RIDH	RTFH	SA	5	4	2	2	1	1	30	N	50
34	760182	M	60	2y	80	110/70	4*2	+	L	+	-	LDH	LTFH	SA	7	5	3	2	1	0	28	N	55
35	759268	M	72	3y	78	120/70	4*5	+	R	+	-	RIDH	RTFH	SA	5	4	2	1	1	0	30	Y	50
36	751382	M	42	6m	80	130/70	5*6	+	R	+	-	RDH	RTFH	SA	7	4	3	2	1	1	30	Y	45
37	749986	M	32	6m	70	120/78	2*4	+	R	+	-	RIDH	RTFH	SA	8	4	3	2	1	1	30	N	50
38	752304	M	40	1y	76	110/68	2*3	+	L	+	-	LDH	LTFH	SA	7	4	2	1	1	0	30	N	50
39	751386	M	44	1y	86	130/78	2*2	+	R	+	-	RDH	RTFH	SA	6	3	2	1	1	0	30	Y	55
40	779110	M	62	6m	78	130/80	4*2	+	R	+	-	RIDH	RTFH	SA	7	4	3	2	1	1	25	Y	50
41	777877	M	52	2y	96	120/70	3*4	+	L	+	-	LIDH	LTFH	SA	5	4	2	1	1	0	30	N	50
42	777180	M	58	2m	80	130/80	3*2	+	R	+	-	RDH	RTFH	SA	8	5	4	3	2	1	25	N	60
43	773190	M	60	6m	74	110/70	5*4	+	R	+	-	RIDH	RTFH	SA	8	4	3	2	1	1	30	N	50
44	770916	M	48	1y	56	120/80	4*2	+	R	+	-	RDH	RTFH	SA	5	4	2	1	0	0	25	N	50
45	770101	M	48	1y	80	120/70	3*2	+	R	+	-	RIDH	RTFH	SA	7	5	3	2	1	1	28	N	60
46	768871	M	40	4m	90	126/80	4*5	+	L	+	-	LDH	LTFH	SA	5	4	3	2	1	1	25	Y	50
47	769929	M	52	1y	56	110/80	4*3	+	BL	+	-	BIH	BTFH	SA	8	5	4	3	2	2	30	N	70
48	768507	M	46	1y	68	120/70	4*2	+	R	+	-	RIDH	RTFH	SA	5	4	2	2	1	1	30	N	50
49	760595	M	30	1y	72	110/70	3*2	+	L	+	-	LDH	LTFH	SA	4	3	2	1	0	0	30	N	45
50	749954	M	56	1m	62	130/86	4*4	+	L	+	-	LIDH	LTFH	SA	6	5	3	2	1	1	30	Y	60
51	726766	M	48	2m	60	120/70	2*3	+	R	+	-	RIDH	RTFH	SA	7	5	4	2	1	1	30	N	50
52	729373	M	42	2y	82	140/70	2*2	+	L	+	-	LDH	LTFH	SA	5	4	2	1	0	0	30	N	50
53	729371	M	60	1y	88	110/80	3*3	+	R	+	-	RDH	RTFH	SA	6	5	3	2	1	1	25	N	50
54	729357	M	52	3y	84	120/80	3*5	+	R	+	-	RIDH	RTFH	SA	8	5	3	2	1	1	30	N	55
55	732018	M	24	2y	92	110/70	4*3	+	L	+	-	LIDH	LTFH	SA	5	4	3	1	1	1	25	Y	50
56	732132	M	65	1y	62	120/70	2*2	+	L	+	-	LIDH	LTFH	SA	6	4	3	1	0	0	30	N	55
57	730504	M	50	4m	60	108/80	3*3	+	R	+	-	RDH	RTFH	SA	4	3	2	1	0	0	25	N	50
58	736214	M	48	4m	58	110/70	3*5	+	L	+	-	LDH	LTFH	SA	5	3	2	1	1	0	30	Y	55
59	736579	M	70	1y	60	120/70	4*3	+	R	+	-	RDH	RTFH	SA	7	4	3	2	1	1	30	N	45
60	741074	M	35	2m	78	108/80	2*2	+	R	+	-	RIDH	RTFH	SA	8	5	4	3	2	1	25	N	60

ANNEXURE IV - MASTER CHART - GROUP RP

Serial Number	In patient Number	Sex	Age (Years)	Duration	General physical examination		Per abdomen					Diagnosis	Assessment of pain (VAS score)					Duration of surgery	
							Inspection			Palpation									
					Pulse	BP(mm Hg)	Size (Cms)	Cough impulse	Position	Reducibility	Tenderness		Day 1	Day 3	One Week	4 Weeks	3 Months	Right	Left
1	746786	M	64	6m	70	130/80	3*6	+	R	+	-	RDH	8	6	6	4	4	38	
2	745342	M	60	6m	80	120/70	3*3	+	L	+	-	LDH	2	2	2	1	1		34
3	743694	M	70	2y	78	120/70	4*6	+	L	+	-	LDIH	6	4	1	1	1		37
4	743984	M	70	2m	82	130/80	2*4	+	R	+	-	RDIH	2	2	2	1	0	37	
5	723413	M	70	3y	80	130/80	4*5	+	R	+	-	RDIH	6	6	5	5	4	38	
6	725877	M	56	1y	70	120/70	3*3	+	L	+	-	LDH	2	2	2	1	1		35
7	728311	M	41	1y	78	110/70	2*3	+	BL	+	-	BDH	4	4	3	1	1	35	34
8	729331	M	54	6m	88	100/70	4*5	+	L	+	-	LDH	7	6	2	1	0	30	
9	729355	M	55	1y	72	120/70	3*3	+	R	+	-	RDH	3	3	2	2	1	35	
10	730110	M	50	2y	80	120/78	4*2	+	BL	+	-	BDH	7	7	5	5	4	34	38
11	728650	M	80	2y	80	110/80	3*3	+	L	+	-	LDIH	3	2	2	2	1		37
12	734994	M	38	2y	80	108/70	2*2	+	L	+	-	LDH	5	5	2	1	0		35
13	735217	M	65	2m	76	108/70	1*5	+	BL	+	-	BDH	3	2	2	2	1	35	30
14	734424	M	39	2y	80	130/80	3*3	+	L	+	-	LDH	4	3	2	0	0		35
15	735377	M	55	1y	90	110/70	3*2	+	R	+	-	RDH	9	7	6	5	4	35	
16	743488	M	62	2y	70	116/70	3*2	+	BL	+	-	BDH	4	2	1	0	0	36	35
17	743348	M	25	2y	80	110/70	4*2	+	L	+	-	LDH	6	4	2	2	1		38
18	744028	M	55	5m	78	120/70	4*5	+	R	+	-	RDIH	4	4	1	0	0	40	
19	744328	M	40	1y	80	130/70	5*6	+	R	+	-	RDH	5	5	2	0	2	30	
20	746511	M	50	6m	70	120/78	2*4	+	L	+	-	LDIH	9	5	1	1	1		38
21	736371	M	35	1y	76	110/68	2*3	+	BL	+	-	BDH	5	5	2	1	0	32	36
22	736718	M	75	2y	86	130/78	2*2	+	R	+	-	RDH	9	6	5	1	1	35	
23	736383	M	56	6m	78	130/80	4*2	+	R	+	-	RDH	5	4	2	1	0	35	
24	737030	M	70	2y	80	108/70	4*2	+	L	+	-	LDIH	5	5	2	2	0		36
25	737333	M	70	1y	80	140/88	4*5	+	R	+	-	RDH	8	5	2	1	0	36	

ANNEXURE IV - MASTER CHART - GROUP RP

Serial Number	In patient Number	Sex	Age (Years)	Duration	General physical examination		Per abdomen					Diagnosis	Assessment of pain (VAS score)					Duration of surgery	
							Inspection			Palpation									
					Pulse	BP(mm Hg)	Size (Cms)	Cough impulse	Position	Reducibility	Tenderness		Day 1	Day 3	One Week	4 Weeks	3 Months	Right	Left
26	736103	M	55	2y	76	11076	4*2	+	R	+	-	RDH	6	5	1	1	1	35	
27	737090	M	35	6m	80	100/70	3*4	+	L	+	-	LDH	8	5	1	1	1		25
28	737826	M	75	1y	80	130/80	4*2	+	R	+	-	RDH	6	5	1	1	1	32	
29	738110	M	60	2y	78	120/70	4*4	+	R	+	-	RDIH	7	4	2	0	0	36	
30	738445	M	64	1y	86	120/80	4*6	+	L	+	-	LDH	6	4	2	2	1		30
31	738512	M	35	4m	70	110/70	2*3	+	R	+	-	RDH	4	3	2	0	0	22	
32	738645	M	60	8m	80	120/70	2*2	+	R	+	-	RDH	9	7	6	5	4	25	
33	739504	M	49	1y	78	108/80	3*3	+	L	+	-	LDH	4	2	1	0	0		20
34	739586	M	70	2y	70	120/70	3*5	+	R	+	-	RDIH	6	4	2	2	1	27	
35	740913	M	72	1y	80	110/70	3*3	+	L	+	-	LDH	4	4	1	0	0		24
36	741177	M	36	2y	86	110/70	2*2	+	L	+	-	LDH	5	5	2	0	2		25
37	741217	M	64	1y	80	110/80	3*3	+	R	+	-	RDH	9	5	1	1	1	20	
38	742224	M	64	2y	76	130/80	2*5	+	BL	+	-	BDH	5	5	2	1	0	22	26
39	746786	M	28	1y	80	110/70	2*4	+	L	+	-	LDIH	9	6	5	1	1		28
40	747315	M	65	6m	70	110/70	3*3	+	R	+	-	RDH	5	4	2	1	0	24	