“A PROSPECTIVE RANDOMISED CONTROL TRIAL COMPARING TISSUE ADHESIVE TO CONVENTIONAL SUTURING IN THE CLOSURE OF INGUINAL HERNIA SKIN INCISIONS”

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Dr. S. S. SHIMIKORE **MS**
Professor and Head,
Department of Surgery,
J. N. Medical College,
Nehru Nagar, Belagavi – 10

Date:
Place: Belagavi

Dr. N. S. MAHANTSHETTI **MD**
Principal,
J. N. Medical College,
Nehru Nagar, Belagavi – 10

Date:
Place: Belagavi

LIST OF ABBREVIATIONS USED

AD	-	Anno domini
BC	-	Before Christ
BP	-	Blood pressure
CDC	-	Centers for Disease Control
CFU	-	Colony-forming units
CGP	-	Chronic groin pain
cm	-	Centimeter
E. coli	-	*Escherachiae coli*
e.g.,	-	Exempli gratia (For example)
EHS	-	European Hernia Society
EPS	-	Extracellular polymeric material
e-PTFE	-	Polytetrafluoroethylene
F	-	Femoral
GPRVS	-	Giant prosthetic reinforcement of the visceral sac
h/o	-	History of
HAIs	-	Healthcare associated infections
HbSag	-	Surface antigen of the hepatitis B virus
HIV	-	Human immunodeficiency virus
i.e.,	-	That is,
IPOM	-	Intra-peritoneal onlay mesh
Kg	-	Kilogram
L	-	Lateral
M	-	Medial
MD	-	Multidirectional

mg	-	Milligram
mL	-	Millileter
mm Hg	-	Millimeters of mercury
mm	-	Millimeter
MPO	-	Myopectineal orifice
MRSA	-	Methicillin-resistant *S. aureus*
n	-	Total number
NNIS	-	National Nosocomial Infection Surveillance
P	-	Primary
p	-	Probability value
PDS	-	Polydioxanone
PHS	-	Prolene hernia system
PPM	-	Polypropylene mesh
R	-	Recurrent
s	-	Seconds
SD	-	Standard deviation
SSIs	-	Surgical site infections
TAPP	-	Trans-abdominal pre-peritoneal
TEP	-	Totally extra-peritoneal
UK	-	United Kingdom
US FDA	-	United States Food and Drug Administration
US	-	United States
vs	-	Versus

ABSTRACT

Background and Objectives

Wounds can be closed by a variety of methods. The data comparing tissue adhesive and conventional sutures for skin closure in the settings of open inguinal hernia is scant. This study was aimed to compare the incidence of post operative wound infection by Tissue adhesive versus conventional suturing in open inguinal hernia skin closure.

Methodology

This one year hospital based randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi. A total of 60 patients undergoing inguinal hernia repair from January 2015 to December 2015 were enrolled. Based on closed envelope method, these patients were randomly allocated into two groups method viz. Group A (skin closure with cyanoacrylate glue) and Group B (conventional skin closure).

Results

The clinical and demographic characteristics of the study population that is, sex, Mean Age, weight, pulse rate, systolic BP, and dialostic BP were comparable in group A and group B ($p>0.050$). Most of the patients in group A and group B had Right inguinal hernia (46.67%) and indirect inguinal hernia was note in 56.67% of the patients in Group A and 53.33% of the patients in group B (53.33%) ($p=0.795$). The mean duration of surgery was significantly low in group A (66.67±4.61 minutes) compared to group B (71.21±6.90 minutes) ($p=0.004$).

Swelling, fever and discharge was noted in 6.67% of the patients in group A while in group B, was present in 16.67% of the patients (p=0.228). Redness was seen in 6.67% of the patients in group A while in group B it was present in 10.00% of the patients (p=0.640).

Conclusion and interpretation

Closure of skin incision with tissue adhesive in the settings of inguinal hernia repair is a faster method of wound closure and equally safe as that of subcuticular sutures.

Keywords

Inguinal hernia; skin closure; Tissue adhesive; Subcuticular sutures;

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INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

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

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

Wounds can be closed by a variety of methods. Although the skill and technique of the surgeon are important, so is the choice of wound closure materials. The purpose of these materials is to maintain wound closure until a wound is strong enough to withstand daily tensile forces and to enhance wound healing when the wound is most vulnerable. The requirements of skin closure by any method is that it should hold the skin edges in apposition for sufficient length of time to allow healing to take place. There should be no movements between the skin edges and excessive tension on the wound margins must be avoided. The new aspect in securing mesh is with the use of skin staples instead of the usual polypropylene sutures. Staples are applied from a proximate plus MD (multidirectional) release skin stapler. Staples are quick to use and reduce the operating time and minimize the risk of wound infection.[10]

The latest trial in this aspect is securing mesh with use of skin staples instead of the usual polypropylene sutures. Staples are applied from a proximate plus MD (multidirectional) release skin stapler. Staples are quick to use and reduce the operating time and minimize the risk of wound infection.[11]

Despite the success of Lichtenstein hernioplasty in the management of inguinal hernia, the occurrence and handling of chronic groin pain (CGP) has posed a significant challenge to surgeons. The reported incidence of CGP varies from 0.7% to 62.9% in the medical literature. The origin of CGP can be divided into

neuropathic and non-neuropathic causes. Neuropathic causes of CGP include direct trauma to the nerves in the inguinal region or nerve entrapment secondary to mesh related fibrosis, postoperative fibrosis, suture fixation and the tacker fixation of the mesh. Non-neuropathic causes of CGP include the periosteal reaction of suture fixation at the pubic tubercle, the displacement of the mesh, an inflammatory reaction to the mesh and potentially the use of heavyweight mesh for hernia repair.[12]

A variety of techniques have been employed to tackle the issue of CGP. The use of lightweight mesh has been shown to reduce the incidence of chronic groin pain without increasing hernia recurrence rates. Use of a traumatic mesh fixation techniques such as fibrin or butyl-2-cynoacrylate glues have increased in popularity in recent years. It has been postulated that glue mesh fixation may decrease the operating time and reduce postoperative pain compared to suture or tacker fixation of mesh. Various non-randomised and randomised, controlled trials have been reported with variable incidence of CGP and recurrence.[12]

However, the data comparing on tissue adhesive and conventional sutures for skin closure in the settings of open inguinal hernia is scant. This prompted us to compare the incidence of post operative wound infection by Tissue adhesive versus conventional suturing in open inguinal hernia skin closure.

OBJECTIVES

The objective of this study was to find out the incidence of post operative wound infection by Tissue adhesive versus conventional suturing in open inguinal hernia skin closure

REVIEW OF LITERATURE

Historical notes

Inguinal hernia most probably has been a disease ever since mankind existed. In view of its existence in different kinds of animals, and in particular of primates, one can assume that already prehistoric human beings were affected with the disease. Inguinal hernia repair has made enormous progress throughout the ages. The main reasons for intervention however remained the same: continuous growth of the inguinal and/or scrotal swelling, the risk of incarceration of the hernia content and the poor results of conservative methods like truss placement. Surgical techniques have rapidly evolved since Eduardo Bassini proposed his first successful reconstruction of the inguinal floor. The various adaptations of his technique did however not result in a substantial reduction in the number of recurrences. The tension free repair, introduced by Irving Lichtenstein, caused a dramatic drop in the recurrence rate and became the procedure of choice. Laparoscopic repair of inguinal hernia is becoming increasingly popular.[13]

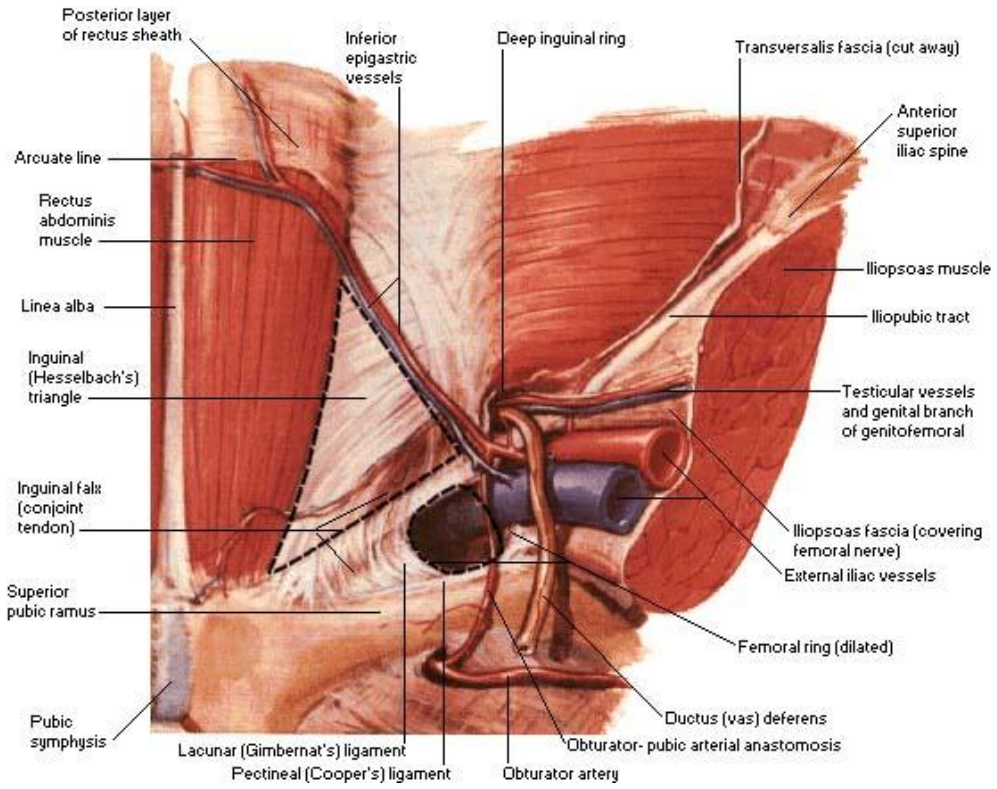


Figure 1. Anatomy of inguinal canal[14]

Anatomy[19]

Abdominal Wall Tissue

Tissues in the abdominal wall have different consistency and function, which also must be taken into account in hernia repair.[15]

- *Fascia* is a layered condensation of connective tissue (eg, Camper's, Scarpa's, Innominate, Cribriform).

- *Aponeurotic* tissue is connective tissue that is organized and has measurable strength (eg, crura of the external oblique).

Major muscles of the abdominal wall are the *external and internal obliques*, the *transversus abdominus* and the *rectus muscles*. Fascial sheaths cover them all.

- The *anterior rectus sheath* is composed of aponeuroses of both the oblique muscles and the transversus abdominus muscle.

- The *posterior rectus sheath* is composed of fibers from the transversus abdominus and internal oblique aponeuroses. Below the semicircular line described by Douglas (located midway between the pubis and the umbilicus), the posterior sheath lacks any strength, being only transversalis fascia.

- The *innominate fascia* covers the external oblique and the spermatic cord as it emerges between the crura of the external ring.

- The *external spermatic fascia* covers the pubic and scrotal portion of the spermatic cord.

- The *internal spermatic fascia* covers the spermatic cord within the inguinal canal.

- The *internal inguinal ring* is located 2 cm above the skin crease in the groin and midway between the pubic tubercle and the anterior superior iliac spine.

- The *inguinal ligament* is formed by fibers of the external oblique aponeurosis that swing posterior and medial after they insert on the pubic bone. It is held together by epitendineum and is attached at the anterior superior iliac spine and at the pubic tubercle, where it fans out to become the lacunar ligament.

- The *external ring* is formed by the intracrural fibers of the external oblique aponeurosis, between its medial and lateral crura. The reflected inguinal ligament on each side meets in the midline over the rectus sheath. Interparietal fascia separate the oblique and transversus muscles.

- The *conjoined tendon*, which exists in only 3% to 6% of patients, is a fused tendonous structure of the internal oblique and transversus abdominus muscles that reaches the pubic tubercle.

- The *cremasteric fascia* arises from the internal oblique muscle.

- The *endoabdominal fascia* in the pelvis is called the *endopelvic fascia*; in the groin it is called the *transversalis fascia.* The *transversalis fascia,* described as the Achilles tendon of the groin, covers the medial triangle of the groin (Hesselbach's, Hessert's).[16] The *transversalis fascia* gives rise to many structures in the groin: the superior pubic ligament, the iliopubic tract, the internal spermatic fascia, the interfoveolar ligament, the lacunar ligament, the anterior and posterior crura of the internal ring, and the anterior portion of the femoral sheath.

- The posterior wall of the inguinal canal is composed of 3 layers. The more superficial is the *aponeurosis of the transversus abdominus.* Deep in it are 2 thin layers of *transversalis fascia*. The *deep epigastric vessels* run between these 2 layers. Defects in the canal's posterior wall result from a deficiency in strong fibers of the transversus abdominus aponeurosis in the lower half of that triangle, just above the most vulnerable area of the abdomen.[17]

- The *superior pubic ligament* (Cooper ligament) is the periosteum of the superior pubic ramus.

- The *iliopubic tract* is an aponeurotic band of tissue within the transversus abdominus aponeurotic layer. It runs parallel to the inguinal ligament from the iliopectineal arch to the superior ramus of the pubis. It is more easily visualized from the posterior view, but often is difficult to discern from the anterior approach. It varies considerably in its thickness, thus making its identification from either approach questionable.[15,18]

The myopectineal orifice

The myopectineal orifice (MPO) is the site of indirect, direct, femoral and some interstitial hernias, and it has become the focus of many recent advances in hernia surgery.[18]

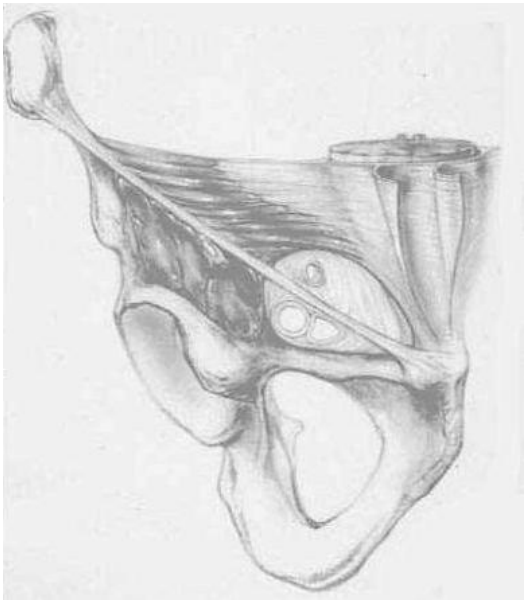


Figure 2. The myopectineal orifice. The passageway for the great vessels to the lower extremity, and for the testicle to reach the scrotum[18]

- The MPO is divided anteriorly by the inguinal ligament, and posteriorly by the iliopubic tract. It is bounded medially by the lateral border of the rectus muscle, superiorly by the arching fibers of the transversus abdominus and the internal oblique muscles, laterally by the iliopsoas muscle and inferiorly by the Cooper ligament.

- The MPO is perforated in its superior pane by the spermatic cord, and through its inferior pane by the femoral vessels.

- The MPO is protected only by the combined lamina of the aponeurosis of the transversus abdominus and the transversalis fascia.[18]

Vascularity

The arterial supply in the groin arises from the external iliac artery, which gives off the deep circumflex iliac and inferior epigastric arteries before becoming the common femoral artery. The internal spermatic (testicular) artery arises from the aorta. Venous drainage proceeds through the spermatic cord by way of the panpiniform plexus. This plexus of delicate veins is intertwined within the interstitial fat of the spermatic cord. The internal spermatic vein on the left side drains into the left renal vein. Venous drainage on the right is into the inferior vena cava.[18]

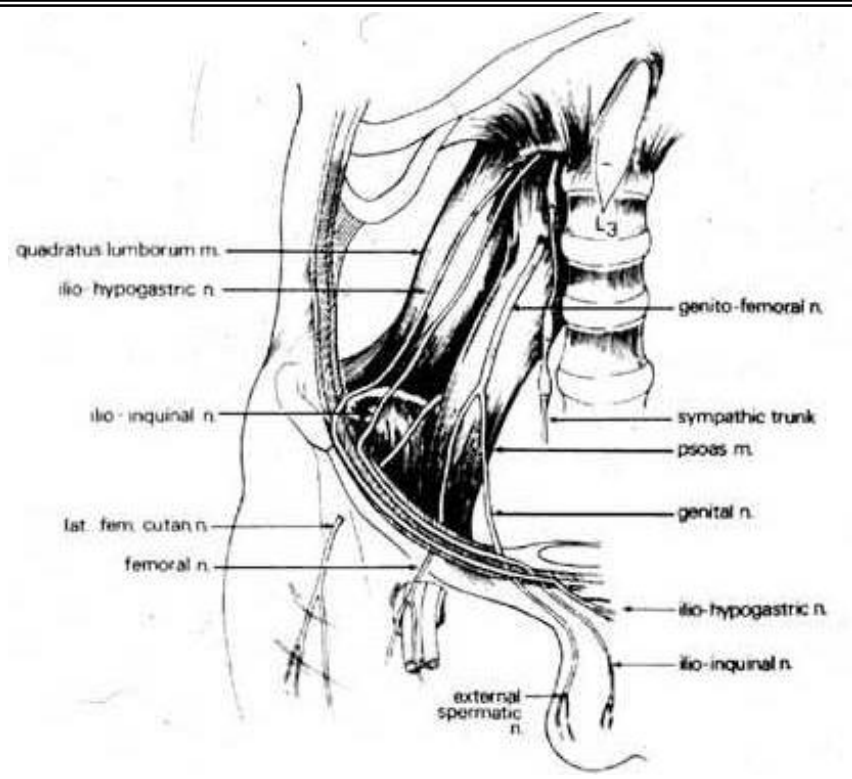


Figure 3. Nerve supply to the groin[18]

The *iliohypogastric nerve,* which arises from the 12th dorsal and 1st lumbar roots emerges into the groin as it perforates the posterior part of the transversus abdominus muscle and divides into lateral and anterior cutaneous branches. The anterior branch travels between the internal oblique and transversus muscles while supplying both muscles groups. It pierces the internal oblique muscle approximately 2 cm medial to the anterior superior spine. It perforates the external oblique muscle about 3 cm above the external ring and provides sensation to the skin of the abdomen above the pubis. The *Ilioinguinal nerve* arises from the 1st lumber nerve root. It perforates the transversus abdominus muscle near the anterior iliac spine, then pierces the internal oblique muscle and proceeds within the cremasteric fascia following the spermatic cord through the external ring. It provides sensation to the medial area of the thigh, over the base of the penis and the upper scrotal area. The

genital-femoral nerve arises from the 1st and 2nd lumbar nerves. It divides deep to the posterior wall where the genital branch perforates the posterior wall near the internal ring, then proceeds through the canal in the lateral bundle of the cremasteric fascia with the cremasteric vessels. The femoral branch passes behind the inguinal ligament and enters the femoral sheath lateral to the femoral artery. These three nerves are mainly sensory but do supply some motor function to the internal oblique and cremasteric muscles of the spermatic cord.[18]

Classification and symptoms of hernia in the groin

More than 10 classifications have been described to date. They have similarities and differences, but generally meet at complexity and difficulty in remembering. Probably the most frequently used classification is Nyhus classification.[22,23] It describes almost all types including pantaloon and femoral hernias, and gives attention to recurrent hernias. Gilbert classification is easier but lack the description of combined and femoral hernias.[19]

Aaachen classification that developed by Schumpelick and colleagues is based on an easy system.[25] It mentions both anatomical location (indirect or lateral vs. direct or medial) and size (<1.5 cm, 1.5-3.0 cm, >3 cm.) of hernia. The European Hernia Society (EHS) Board, including Prof. Schumpelick, recently agreed on a new classification based on Aachen system and asked all surgeons practicing hernia surgery to report the class of the hernia in the operative reports.[20]

The European Hernia Society (EHS) classification defines the location of hernia with L: lateral, M: medial, and F: femoral. The size of hernia is indicated with 1: ≤one finger, 2: one-two fingers, and 3: ≥three fingers. If the patient has two types

of hernia together (e.g., direct+indirect, direct+femoral, indirect+femoral) appropriate boxes in the table are ticked. In addition, P or R letter is encircled for a primary or recurrent hernia.[21]

No matter which classification system is used the type of hernia should be recorded according to intraoperative findings. It is important to describe each side separately and clearly for bilateral hernias.[21]

Management

The earliest record of inguinal hernia dates back to 1500 BC. In the middle ages, results of attempted repairs were poor. In the last decades of the 19th century along with the rapid advancement of the knowledge of anatomy, surgical asepsis and anesthesia there was refinements in the techniques of hernia repair as well.[22]

The early techniques relied on sutures to close the hernial defect. Conventional open herniorrhaphy is associated with high recurrence rate and slower return to unrestricted physical activities. The standard principles of inguinal hernia repair remained unchanged for decades and in fact, suture repair is still used in around 10 to 15% of inguinal hernia repairs.[23]

The modern age of hernia repair began about 45 years ago with the introduction of monofilament knitted polyethylene mesh to reinforce a previous sutured repair. The introduction of polypropylene mesh (PPM) as a synthetic biomaterial for hernia surgery soon followed. Most hernia repairs performed today involves the placement of some synthetic biomaterial. The most revolutionary developments occurred over the last 15 years with the development of laparoscopic surgery and its subsequent application in groin hernia repair. Refinements in

minimally invasive hernial repair techniques, along with evolving medical technologies have changed the present day scenario altogether.[22]

A high failure rate delayed return to normal activities and lastly a high overall cost involved will not only adversely affect the individual patients but will also have a negative impact on the society at large, in view of the re-operations, sick leave and the associated economic burden. Thus, a modest improvement in the surgical outcome has a significant impact on the surgical practice.[22]

With a better understanding of the anatomy and physiology of the inguinal area and knowledge of the most effective currently available techniques and materials, we are close to the ultimate goal of zero recurrence. However, the choice of repair remains controversial and no consensus has been reached regarding the surgical approach showing good cost effective clinical results.[22]

Open suture repair

Eduardo Bassini, the father of modern day hernia surgery, in 1887 with his pioneering work brought about radical changes in the concept of hernia repair.[24]

Bassini′s repair included high dissection and ligation of the peritoneal sac followed by division of the transversalis fascia. The split fascia was reconstructed along with the transversus aponeurosis and internal oblique (three layers) down to the inguinal ligament with interrupted sutures. Finally, the external oblique aponeurosis was closed of the over the cord.

Somehow his triple layer repair was corrupted over the years and he did not get due credit for his attention to the posterior inguinal wall,[25] a concept so commonly accepted in procedures of today.

Before Bassini′s aggressive approach of "radical cure of the inguinal hernia", (the title of his presentations at the Italian Surgical Society in 1887) the results of hernial surgery were very poor. Recurrence ranged from 30 to 40% in the1st postoperative year, to 100% within 4 years. Bassini recorded only eight recurrences out of 206 repairs during 3-year period.[24]

Other modifications of primary pure tissue repair by anterior approach were subsequently described by surgeons like Halsted, Tanner (relaxing incision to reduce suture line tension) and later by McVay (Cooper ligament repair) and these remained the mainstay of hernia surgery for decades. In 1948, Moloney introduced the nylon darn technique and it gained wide acceptance. The important drawback of pure tissue repair is the high failure rate and delayed return to normal activities stemming from the tension on the repair.[22]

In the "modified" or "North American" Bassini repair the posterior wall was not opened and sutures approximated the transversus arch and the inguinal ligament. The undue tension created resulted in recurrences.[22]

E. E. Shouldice in the second half of the 20th century revitalized Bassini′s original technique of herniorrhaphy.[31] Under local anesthesia, he performed a double layer repair of fascia transversalis followed by approximation of the conjoined tendon, iliopubic tract and inguinal ligament as third and fourth layers with non-absorbable sutures (originally stainless steel wire). Repaired flaps of external

oblique aponeurosis finally cover the later. The experience at the Shouldice Clinic, which later became a hospital devoted exclusively to the repair of abdominal wall hernias, was excellent with recurrence rate of < 1%. Surgeons here operate independently only after assisting in at least 100 cases and surgery on obese patients deferred until a targeted weight is reached. Shouldice repair remained the gold standard of hernia repair for the last 4 decades and has produced the best and most enduring results of any other pure tissue repair.

Porrero et al[32] conducted a recent prospective study on Shouldice repair on 775 patients. Average age of the patients was 52 years and 93% were males. They used local anaesthesia in 83% and regional anaesthesia in 13% of cases. 93% of the patients tolerated local anaesthesia well. The average duration of surgery was 57.5 (40-75) minutes. The most significant postoperative complications were urinary retention (8%), headache (7%) and ecchymosis (6%). While 20% of the interventions were on an outdoor basis, 76% of the patients were discharged within 1 day. Average absence from work was 20 days. Recurrence rate at 7 years was 2%.

Another recent randomized trial with Shouldice repair by Fleming et al[26] suggested a median operation time of 56 minutes, only 48% of the patients discharged from the hospital within 24 hours, rate of complications was 36%, median time taken to return to normal activities was 5 weeks and recurrence at 1 year was 4.3%.

Many other innovative surgeons have tried to improve the outcome of primary tissue repair. Annandale[27] first described the posterior approach to groin hernia repair. Cheatle[28] revitalized the issue of posterior preperitoneal approach.

Henry[29] began using it for femoral hernia repair and recently US surgeons Nyhus, Condon and Harkins effectively adapted the posterior preperitoneal approach for the repair of all types of groin hernias.[30] They employed only sutures for repair of type I, II and IIIC hernias.

Since the work of Bassini, not less than 81 operative techniques for inguinal hernia repair have been described. Such proliferation of techniques is the typical result of poor outcome. Recurrence rate of non-mesh suture repair of inguinal hernia vary between 0.2 and 33 percent.[24] Recurrence following Shouldice repair is in general less, the best reports are from Shouldice Clinic.

Open mesh repair

Different materials were tried in hernia surgery from native tissues like strips of external oblique aponeurosis, fascia lata grafts from thigh and even skin from the edges of the incision to metal and silk.[22]

The concept of hernia repair underwent a sea change with the introduction of monofilament knitted polyethylene plastic mesh in 1958 and later in 1962 of knitted, malleable polypropylene mesh (PPM). American surgeon Francis Usher fabricated and developed both the materials. Polypropylene mesh remains most popular both in open and laparoscopic surgery. However, the first popular nonmetallic mesh was a machine knitted polyester polymer called Dacron.[22]

In 1976, Gore by refining the technique of expanding polytetrafluroethylene developed the expanded PTFE or e-PTFE as a sheet. Its first use in hernia repair was in 1983.[22]

Recently some of the prosthetic biomaterials have been combined together to form various composite mesh in an attempt to minimize the undesirable side effects. Composix mesh is a combination of polypropylene with a thin coat of e-PTFE on one side used mainly in incisional hernia repair. The floppy, conformable Vypro mesh is another innovation in similar direction. It is light, large pore multifilamentous mesh composed of 50% polyglactin 910 (absorbable) and 50% polypropylene. Ingrowths of fibrous tissue and collagen provide strength to the repair.[22]

Different methods of repairs[20]

A. Tension-free prosthetic repairs
    a. Anterior repairs
        i. Lichtenstein repair and its a modifications
        ii. Plug repairs
        iii. Patch and plug repairs
        iv. Double-layer devices
    b. Posterior (preperitoneal) repairs
        i. Open techniques via inguinal incision
        ii. Stoppa repair
        iii. Laparoscopic/endoscopic repairs
            1. Transabdominal preperitoneal
            2. Total extraperitoneal
B. Tissue-Suture repairs
    a. Bassini-Shouldice technique and its modifications
    b. Marcy repair

Every type of tension free repair requires a mesh. Placement is either by open anterior, open posterior approach or by laparoscopic means.

Giant prosthetic reinforcement of the visceral sac (GPRVS)

Initially mesh prosthesis reinforced previous sutured repair. In 1975, René; Stoppa used a large Dacron prosthesis for the repair of groin hernias by the posterior pre-peritoneal approach via a low midline incision.[31] The entire peritoneal bag was wrapped with the mesh without suture fixation in a tension less manner. Expanding intraabdominal pressure held the graft in place just like the pressure of water in a bathtub holds the drain stopper in place (an application of Pascal′s hydrostatic principle). GPRVS is the "ultimate weapon" to repair recurrent hernia.[32] Stoppa was the first to demonstrate that permanent repair of the groin hernias do not require closure of the abdominal wall defect per se in presence of extensive reinforcement of fascia transversalis. Wantz[33] in 1989 furthered the works on GPRVS by using Dacron mesh for unilateral hernia repair. The mesh was draped between the peritoneum and the myopectineal orifice. The minimal access surgeons later utilized this concept of tension free repair.

Lichtenstein onlay patch repair

This is an example of open anterior tension free repair.[34] This is the most frequently performed hernia repair worldwide. In this tension free mesh hernioplasty a 12 x 7 cm piece of polypropylene mesh (tailored as per requirement) butresses the weak inguinal floor. The onlay graft is fixed by interrupted sutures to the transversus arch superiorly, inguinal ligament inferiorly and pubic tubercle medially. At the level of the cord, the mesh is slit creating two tails. The tails are crossed and

overlapped, effectively creating a neo-ring ring. The technique is simple, rapid, less painful and effective for primary hernia repair. The prime factor behind most herniorrhaphy failures is suturing together under tension of structures that are not normally in apposition. By Lichtenstein mesh hernioplasty, repair without suture line tension and distortion of anatomy is practicable.[22]

A survey[42] with 72 non-expert surgeons who performed more than 16,000 Lichtenstein repair showed a recurrence rate of < 0.5% and wound infection rate of 0.6%. Unlike Shouldice repair, Lichtenstein repair do not need a steep learning curve to obtain acceptable results in the hands on general surgeons.

Patch and plug repair

A preformed plug of polypropylene mesh (Atrium ® self-forming plug, Pre Fix ® plug) is placed within the internal ring (for indirect hernia) or into the direct hernial defect and sutured to the ring of the fascial opening. An onlay patch of the same material placed over the inguinal floor and around the spermatic cord lateral to the internal ring either free or sutured. This form of repair is ideally suited for small tight defects. It is pertinent to mention that the first attempt of this technique used a plug or cigarette made of mesh in the hernial defect and then the patch. The use of cigarette plug was eliminated because of the complications related to it. Later Rutkow modified the technique of the plug and patch repair.[22]

Gilbert′s sutureless[35] repair of inguinal hernia with an umbrella plug along with an onlay patch was an attempt in similar direction.

Kugel patch

It is an oval, flat piece of PPM with a "memory recoil ring" at the periphery, which allows it to flatten out in the preperitoneal space, to cover the entire inguinal floor. A single suture fixes it and it stays in place by the intra-abdominal pressure.[22]

The PROLENE polypropylene hernia system

It is a bilayer, three in one, patch device. It consists of a round disc (underlay patch) placed in the preperitoneal space of Bogros and an oblong shaped onlay component which needs to be placed over the inguinal floor. The internal ring accommodates a cylindrical connector joining these two components, producing the plug effect. It is useful in the repair of both direct and indirect inguinal hernias. The bilayered repair with PHS gives dual benefits of Lichtenstein repair (placement of the oblong onlay patch on the inguinal floor) and those of the laparoscopic approach (the round inlay component in the preperitoneal space).[22]

The results of a recent Indian trial with PHS,[36] conducted on 47 patients (mostly males) with the mean age of 55.8 years, having primary inguinal hernias (58% direct) was encouraging. The mean follow up period of this study was 6.24 months. The mean duration of operation was 35 minutes. Mean postoperative stay was 3.5 days. There were no postoperative complications except for transient neuralgia complained of by four patients, which resolved within one week. However, in spite of its favorable results the high cost of the PHS as compared to the conventional PPM is a definite deterrent to its wide spread use.

A randomized trial[37] comparing PHS, mesh plug repair and Lichtenstein method of open inguinal hernia repair on 334 patients did not show any clinically

significant difference in the postoperative pain and quality of life between the three types of mesh hernia repair.

Laparoscopic hernia repair

Ger in 1982[38] was the first to attempt minimal access groin hernia repair by closing the opening of an indirect inguinal hernial sac by Michel clips. Bogojavlensky in 1989 modified the technique[39] by intra-corporeal suture of the deep ring after plugging a PPM into the sac. Toy and Smoot in 1991[40] described a technique of intra-peritoneal onlay mesh (IPOM) placement, where an intra-abdominal piece of polypropylene or e-PTFE was stapled over the myopectineal orifice without dissection of the peritoneum. The IPOM had some major drawbacks like possibility of bowel adhesions and migration of the mesh. These initial attempts of laparoscopic repair did not meet with encouraging results. Ever since the early attempts by Ger, refinements of technique and innovations have changed the concept of hernia surgery forever and in spite of the longer learning curve and being more challenging than laparoscopic cholecystectomy or open herniorrhaphy, it became an increasingly popular procedure though controversies abound.[22]

The present day techniques of laparoscopic hernia repair evolved from Stoppa′s concept of pre-peritoneal reinforcement of fascia transversalis over the myopectineal orifice with its multiple openings by a prosthetic mesh.[22] In the early 1990′s Arregui and Doin[41,42] described the trans-abdominal pre-peritoneal repair (TAPP), where the abdominal cavity is first entered, peritoneum over the posterior wall of the inguinal canal is incised to enter into the avascular preperitoneal plane which is adequately dissected to place a large (15 x 10 cm) mesh over the hernial

orifices. After fixation of the mesh, the peritoneum is carefully sutured or stapled. 14% of the recurrences after open repair have been attributed to missed additional direct or femoral hernia. TAPP approach has the advantage identifying them during the first operation itself.[22]

Around the same time Phillips and McKernan[43,44] described the totally extra-peritoneal (TEP) technique of endoscopic hernioplasty where the peritoneal cavity is not breached and the entire dissection is performed bluntly in the extra-peritoneal space with a balloon device or the tip of the laparoscope itself. An advanced knowledge of the posterior anatomy of the inguinal region is imperative. Once the dissection is complete, a 15 x 10 cm mesh is stapled in place over the myopectineal orifice. The TEP method minimizes the potential for injury to the intra-abdominal organs while eliminating the exposure of the bowel to the prosthetic biomaterial. Experienced laparoscopists have increasingly favored it and it appears to be the most common endoscopic repair today.[22]

In both these repairs, the mesh is in direct contact with the fascia of the transversalis muscle in the pre-peritoneal space, allows tissue ingrowths leading to the fixation of the mesh (as opposed to being in contact to the peritoneum as in IPOM repair where it is prone to migrate).[22]

Laparoscopic repair is particularly appealing procedures for bilateral and recurrent hernias. In a prospective randomized study,[45] TAPP and TEP repairs were compared and found to give equally good results. TAPP is an easier procedure to learn and is less expensive than TEP repair done with balloon dissectors and their ports; however, the reverse is true if no balloon dissectors and staples are used

during TEP repair. Though TEP repair has a longer learning curve, Kald et al[46] concluded that it should be the preferred method, since intra-abdominal injury and postoperative adhesions and postoperative pain occurred more often in the TAPP group.

On the contrary, a study[47] on over 8000 patients has shown TAPP procedure can be performed without any serious morbidity.

A large multi-center study[48] comparing recurrences following TAPP and TEP repairs concluded, after a mean follow-up period of 13 months, the recurrence rates to be 0.7% and 0.4% respectively; another concluded that there was no significant difference.[49]

Certain guidelines prescribed by the UK National Institute of Clinical Excellence[50] on laparoscopic hernia repair are as follows:

- For primary inguinal hernia repair, open (mesh) should be the preferred.
- For recurrent and bilateral inguinal hernia repair, laparoscopic surgery should be preferred.
- TEP should be the preferred choice for laparoscopic repair.
- Laparoscopic inguinal hernia repair should be done in units manned by trained laparoscopic surgeons who regularly undertake these procedures.

New method of inguinal hernia repair

Desarda[51] from Pune, India has described a new technique of pure tissue repair for any type of inguinal hernia without a mesh, based on the concept of

constructing a strong and physiologically dynamic posterior wall to the inguinal canal with the help of the external oblique muscle and its aponeurosis. It has been developed because mesh is not easily available in rural or remote parts of many countries. After excision of the sac, a strip of the external oblique aponeurosis is partially separated from its medial leaf, keeping its continuity intact at either end. This undetached strip of external oblique aponeurosis is sutured to the inguinal ligament below and the muscular arch above, behind the cord, to form a new posterior wall. This strip is put under tension by muscular contraction and works as a shield to prevent recurrence. Thus the external oblique muscle gives additional strength to the weakened internal oblique and transverse abdominis muscles. Results were quite encouraging. Average hospital stay of 2-3 days and patients returned to work within 1-2 weeks. Out of 400 patients (followed up for more than10 years) there was only one recurrence. These results are comparable with operations performed with mesh. The operation is simple to perform, does not require mesh or extensive dissection and has produced excellent results. It may therefore be good alternative to mesh or other open or laparoscopic repairs.

An ideal hernia repair should be durable, produce low level of morbidity, allow rapid return to work or recreational pursuits and should be cost effective. The use of prosthetic mesh has emerged superior and the procedure of choice; it reduces recurrences by around 50%, regardless the method of placement and the incidence of both early and late persistent pain. The quality of life indicators for hernia repair as assessed by the postoperative pain and return to work strongly favors tension-free and laparoscopic approaches. Evidence-based practice indicates no advantage of non-mesh approach for patients above 18 years of age.[22]

If mesh is a better choice, then which is the best way of placing it (open or laparoscopic)? The place of laparoscopic inguinal hernia repair is a subject of intense debate and its routine use is controversial. The short-term benefits of laparoscopic repair in terms of less postoperative pain, marginal advantage in reducing time off work and its obvious advantages in recurrent and bilateral hernias are established. Recurrence rate are similar to that of open mesh repairs. However, even without the use of balloon dissectors, staples for fixation and disposable instruments, laparoscopy is associated with greater anesthetic (general anesthesia is usually necessary) and recovery room inputs and hence is not cost effective when compared to an open mesh under local anesthesia: a pertinent factor for a country like ours. In addition, the long learning curve of laparoscopic repair also deters many surgeons.[22]

Thus, there is no "best" form of hernia repair; it is to be tailored according to the nature of hernia, patient characteristic and the preference of the surgeon and the patient. It would be only apt to end with the words of Sir John Bruce of Edinburgh: "The final words on hernia repair will probably never be written".[52]

Complications[53]

In systematic reviews, the overall risk of complications after inguinal hernia surgery has been in the range of 15-28%. Complications may develop intraoperatively or postoperatively. Early postoperative complications include seroma formation and hematoma (8-22% of cases), urinary retention, and wound infection (1-7% of cases). Late postoperative complications include sensory loss,

hyperesthesia, chronic inguinal pain, mesh-related problems, hydrocele, testicular pain, testicular swelling, atrophy, and recurrence of hernia.

- *Vascular injuries*
- *Injuries to abdominopelvic structures*
- *Nerve injuries*

Postoperative complications

- *Urinary retention*
- *Seroma and hematoma*
- *Infection*
- *Pain*
- *Hydrocele*
- *Ischemic orchitis and thrombosis*
- *Recurrence*

SURGICAL SITE INFECTIONS

Definition

Surgical site infections (SSIs) are infections present in any location along the surgical tract after a surgical procedure. Surgical site infection involve postoperative infections occurring at any level (incisional or deep) of a specific procedure. Surgical site infection represents a significant burden in terms of patient morbidity and mortality, and cost to health services around the world. A multitude of risk factors influence the development of SSIs and awareness of these will help to promote effective preventive strategies. Assessment tools such as the Centers for

Disease Control (CDC) definitions, ASEPSIS and the Southampton Wound Assessment Scale are needed to accurately identify and classify SSIs.[54]

Over the past 50 years, increased interest in the discipline of surgical infection has resulted in advances in post-surgical infection control. Early investigations focused on the importance of anaerobic microflora to postoperative infection and paved the way for significant improvements in prophylactic and therapeutic antibiotic treatment of surgical patients. Later research centered on the identification of risk factors to better predict postoperative infection rates.[55]

Historical perspectives

Before the mid-19th century, surgical patients commonly developed postoperative "irritative fever," followed by purulent drainage from their incisions, overwhelming sepsis, and often death. It was not until the late 1860s, after Joseph Lister introduced the principles of antisepsis that postoperative infectious morbidity decreased substantially. Lister's work radically changed surgery from an activity associated with infection and death to a discipline that could eliminate suffering and prolong life.[56]

Until the middle of the 19th century, when Ignaz Semmelweis and Joseph Lister became the pioneers of infection control by introducing antiseptic surgery, most wounds became infected. Mortality rate in cases of the deep or extensive infection was around 70 to 80%.[57] Since then a number of significant developments, particularly in the field of microbiology, have made surgery safer. However, the overall incidence of healthcare associated infections (HAIs) remains high and represents a substantial burden of disease.

In 1992, the US CDC revised its definition of 'wound infection', creating the definition 'surgical site infection' (SSI)[58] to prevent confusion between the infection of a surgical incision and the infection of a traumatic wound. Most SSIs are superficial, but even so they contribute greatly to the morbidity and mortality associated with surgery.[58,59] Estimating the cost of SSIs has proved to be difficult but many studies agree that additional bed occupancy is the most significant factor. A review of the incidence and economic burden of SSIs in Europe estimated that the mean length of extended stay attributable to SSIs was 9.8 days, at an average cost per day of €325.[59]

In 1980, Cruse estimated that a SSI increased a patient's hospital stay by approximately 10 days and cost an additional $2,000.[60] A 1992 analysis showed that, each SSI resulted in 7.3 additional postoperative hospital days, adding $3,152 in extra charges.[61] Other studies corroborate that increased length of hospital stay and cost are associated with SSIs. Deep SSIs involving organs or spaces, as compared to SSIs confined to the incision, are associated with even greater increases in hospital stays and costs.[63]

Surgical wounds may heal by primary intention, delayed primary intention or by secondary intention. Most heal by primary intention, where the wound edges are brought together (apposed) and then held in place by mechanical means (adhesive strips, staples or sutures), allowing the wound time to heal and develop enough strength to withstand stress without support. The goal of surgery is to achieve healing by such means with minimal oedema, no serous discharge or infection, without separation of the wound edges and with minimal scar formation. On occasion, surgical incisions are allowed to heal by delayed primary intention where

non-viable tissue is removed and the wound is initially left open. Wound edges are brought together at about 4-6 days, before granulation tissue is visible.[64] This method is often used after traumatic injury or dirty surgery. Healing by secondary intention occurs when the wound is left open, because of the presence of infection, excessive trauma or skin loss, and the wound edges come together naturally by means of granulation and contraction.[64]

Classification

Classification of operative wounds based on degree of microbial contamination[65]

Classification	Criteria
Clean	Elective, not emergency, non-traumatic, primarily closed; no acute inflammation; no break in technique; respiratory, gastrointestinal, biliary and genitourinary tracts not entered.
Clean-contaminated	Urgent or emergency case that is otherwise clean; elective opening of respiratory, gastrointestinal, biliary or genitourinary tract with minimal spillage (appendicectomy) not encountering infected urine or bile; minor technique break.
Contaminated	Non-purulent inflammation; gross spillage from gastrointestinal tract; entry into biliary or genitourinary tract in the presence of infected bile or urine; major break in technique; penetrating trauma <4 hours old; chronic open wounds to be grafted or covered.
Dirty	Purulent inflammation (abscess); preoperative perforation of respiratory, gastrointestinal, biliary or genitourinary tract; penetrating trauma >4 hours old.

Classification of operative wounds based on CDC guidelines[65]

Superficial incisional SSI

- Infection involves only skin and subcutaneous tissue of incision.
- Superficial incisional SSI
    - Occurs within 30 days after the operation
    - Involves only the skin or subcutaneous tissue
    - At least 1 of the following:
        - Purulent drainage is present (culture documentation not required).
        - Organisms are isolated from fluid/tissue of the superficial incision.
        - At least 1 sign of inflammation (eg, pain or tenderness, induration, erythema, local warmth of the wound) is present.
        - The wound is deliberately opened by the surgeon.
        - The surgeon or clinician declares the wound infected.
    - Note: A wound is not considered a superficial incisional SSI if a stitch abscess is present; if the infection is at an episiotomy, a circumcision site, or a burn wound; or if the SSI extends into fascia or muscle.

Deep incisional SSI

- Infection involves deep tissues, such as fascial and muscle layers. This also includes infection involving both superficial and deep incision sites and organ/space SSI draining through incision.

- Occurs within 30 days of the operation or within 1 year if an implant is present
- Involves deep soft tissues (eg, fascia and/or muscle) of the incision
- At least 1 of the following:
    - Purulent drainage is present from the deep incision but without organ/space involvement.
    - Fascial dehiscence or fascia is deliberately separated by the surgeon because of signs of inflammation.
    - A deep abscess is identified by direct examination or during reoperation, by histopathology, or by radiologic examination.
    - The surgeon or clinician declares that a deep incisional infection is present.

Organ/space SSI

- Infection involves any part of the anatomy in organs and spaces other than the incision, which was opened or manipulated during operation.
- Occurs within 30 days of the operation or within 1 year if an implant is present
- Involves anatomical structures not opened or manipulated during the operation
- At least 1 of the following:
    - Purulent drainage is present from a drain placed by a stab wound into the organ/space.
    - Organisms are isolated from the organ/space by aseptic culturing technique.

- An abscess in the organ/space is identified by direct examination, during reoperation, or by histopathologic or radiologic examination.
- A diagnosis of organ/space SSI is made by the surgeon or clinician.

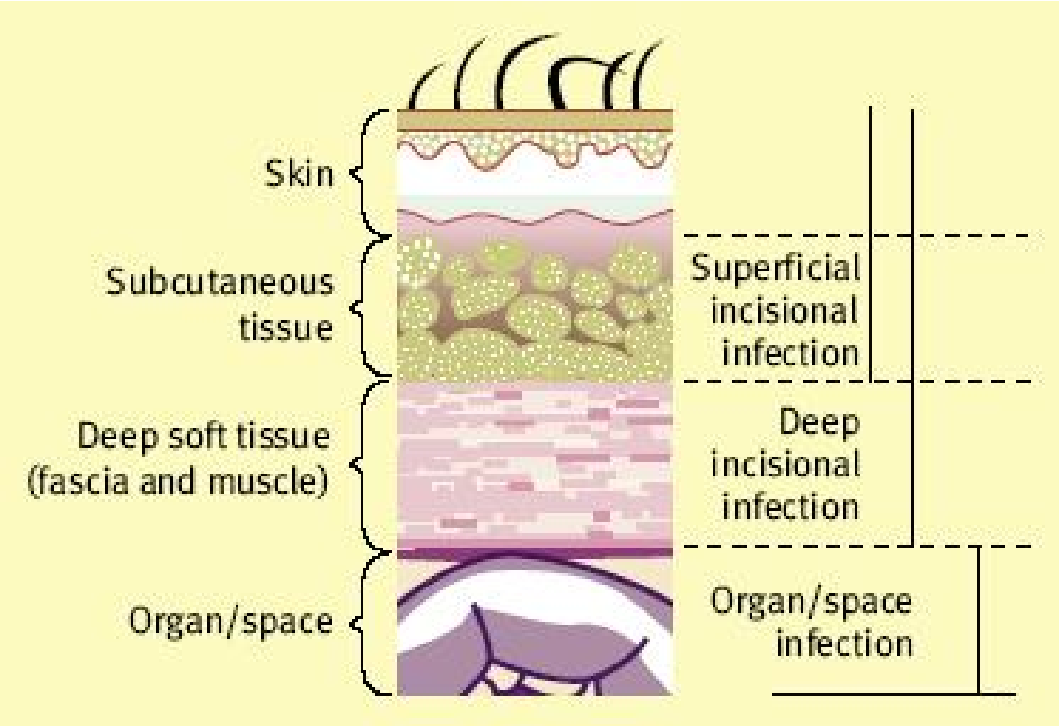


Figure 4. Schematic representation of the anatomical classification of surgical site infections[66]

Prevalence of SSIs

Infection rates in the four surgical classifications (clean, clean-contaminated, contaminated and dirty wounds) have been published in many studies but most literature refers as a benchmark for infection rates.[60] Before the routine use of prophylactic antibiotics infection rates were 1-2% or less for clean wounds, 6-9% for clean-contaminated wounds, 13-20% for contaminated wounds and about 40% for

dirty wounds.[72] Since the introduction of routine prophylactic antibiotic use, infection rates in the most contaminated groups have reduced drastically. Infection rates in United States National Nosocomial Infection Surveillance (NNIS) system hospitals were reported to be: clean 2.1%, clean-contaminated 3.3%, contaminated 6.4% and dirty 7.1%.[66] There is, however, considerable variation in each class according to the type of surgery being performed.[67]

An Indian study[68] was conducted at Himalayan Institute of Medical Sciences, Dehradun, India from November 2008 to October 2009 to determine the incidence of SSI in elective abdominal surgeries; to correlate the SSI with the nature of elective surgical procedure; to study the profile of bacterial isolates obtained from cases of SSI. The patients who underwent elective abdominal surgery were included in the study group. These patients were followed up for superficial incisional SSIs until complete wound healing occurred or on their discharge from the hospital. The incidence of SSI in elective surgeries was found to be five percent. E. coli was the most common organism isolated followed by Staphylococcus aureus. Risk factors like diabetes mellitus, smoking and duration of surgery play a significant role in causing SSI. The study concluded that, an effective surveillance programme for SSIs should be a critical component of any hospital infection control programme to reduce the rate of infection.

Risk factors

Risk factors associated with SSIs[69]

	Risk factors	
	Host related	**Procedure related**
Definite	Age	Pre-operative hair removal
	Obesity	Type of procedure
	Disease severity	Antibiotic prophylaxis
	Nasal carriage of Staph aureus	Duration of surgery
	Remote infection	
	Duration of pre-op hospitalization	
Likely	Malnutrition and low serum albumin	Multiple procedures
	Diabetes mellitus	Tissue trauma
		Foreign material
		Blood transfusion
Possible	Malignancy	Pre-op showers
	Immunosuppressive therapy	Emergency surgery
		Drains

Risk factors [69]

Patient factors

These include, extreme age, obesity, malnutrition, certain concurrent disease or conditions that is, diabetes, malignancy, chronic chest or heart disease and immunosuppression. Patients with pre-existing skin lesions or infection in another

site, and treatment with steroid and immunosuppressive drugs are more prone to get surgical wound infection due to impaired host defense mechanisms.

Surgical technique

The skill of the surgeon has a central role in minimizing surgical wound infection. Bad surgical practice must not be covered up with antibiotics. Expeditious surgery, gentle handling of tissue, reduction of blood loss or hematoma formation, elimination of dead tissue, debridement of devitalized tissue, removal of all foreign body materials from the wound are essential to minimize surgical wound infections in all patients.

Duration of operation

There is a direct link between the length of the operation and the infection rate with a clean wound which doubles every hour. This is because bacterial contamination increases over time and the operative tissue are damaged by drying and other surgical manipulations that is use of refractor, diathermy etc.

Pathogenesis

Microbial contamination of the surgical site is a necessary precursor of SSI. The risk of SSI can be conceptualized according to the following relationship:[70]

Dose of bacterial contamination X virulence = Risk of SSI.

Resistance of the host patient quantitatively has shown that if a surgical site is contaminated with >105 microorganisms per gram of tissue, the risk of SSI is markedly increased. However, the dose of contaminating microorganisms required

to produce infection may be much lower when foreign material is present at the site (100 staphylococci per gram of tissue introduced on silk sutures).[71]

Microorganisms may contain or produce toxins and other substances that increase their ability to invade a host, produce damage within the host, or survive on or in host tissue. For example, many gram-negative bacteria produce endotoxin, which stimulates cytokine production. In turn, cytokines can trigger the systemic inflammatory response syndrome that sometimes leads to multiple system organ failure.[72] One of the most common causes of multiple system organ failure in modern surgical care is intraabdominal infection.[73] Some bacterial surface components, notably polysaccharide capsules, inhibit phagocytosis,[74] a critical and early host defense response to microbial contamination. Certain strains of clostridia and streptococci produce potent exotoxins that disrupt cell membranes or alter cellular metabolism.[75] A variety of microorganisms, including gram-positive bacteria such as coagulase negative staphylococci, produce glycocalyx and an associated component called "slime,"[76] which physically shields bacteria from phagocytes or inhibits the binding or penetration of antimicrobial agents.[77] Although these and other virulence factors are well defined, their mechanistic relationship to SSI development has not been fully determined.

For most SSIs, the source of pathogens is the endogenous flora of the patient's skin, mucous membranes, or hollow viscera.[78] When mucous membranes or skin is incised, the exposed tissues are at risk for contamination with endogenous flora.[91] These organisms are usually aerobic gram-positive cocci (staphylococci), but may include fecal flora (anaerobic bacteria and gramnegative aerobes) when incisions are made near the perineum or groin. When a gastrointestinal organ is

opened during an operation and is the source of pathogens, gramnegative bacilli (*E. coli),* gram-positive organisms (enterococci), and sometimes anaerobes (*Bacillus fragilis)* are the typical SSI isolates.

Seeding of the operative site from a distant focus of infection can be another source of SSI pathogens,[79] particularly in patients who have a prosthesis or other implant placed during the operation. Such devices provide a nidus for attachment of the organism.[76]

Exogenous sources of SSI pathogens include surgical personnel (especially members of the surgical team),[80] the operating room environment (including air), and all tools, instruments, and materials brought to the sterile field during an operation. Exogenous flora is primarily aerobes, especially gram-positive organisms (staphylococci and streptococci). Fungi from endogenous and exogenous sources rarely cause SSIs, and their pathogenesis is not well understood.[81]

Microbiology

According to data from the NNIS system, the distribution of pathogens isolated from SSIs has not changed markedly during the last decade.[82]

Staphylococcus aureus, coagulase-negative staphylococci, *Enterococcus* spp., and *Escherichia coli* remain the most frequently isolated pathogens. An increasing proportion of SSIs are caused by antimicrobial-resistant pathogens, such as methicillin-resistant *S. aureus* (MRSA),[83] or by *Candida albicans.*[84] From 1991 to 1995, the incidence of fungal SSIs among patients at NNIS hospitals increased from 0.1 to 0.3 per 1,000 discharges.[84] The increased proportion of SSIs caused by resistant pathogens and *Candida* spp. may reflect increasing numbers of severely ill

and immunocompromised surgical patients and the impact of widespread use of broad-spectrum antimicrobial agents.

Outbreaks or clusters of SSIs have also been caused by unusual pathogens, such as Rhizopus oryzae, Clostridium perfringens, Rhodococcus bronchialis, Nocardia farcinica, Legionella pneumophila and Legionella dumoffii, and Pseudomonas multivorans. These rare outbreaks have been traced to contaminated adhesive dressings,[85] elastic bandages,[86] colonized surgical personnel,[87,88] tap water,[89] or contaminated disinfectant solutions.[90] When a cluster of SSIs involves an unusual organism, a formal epidemiologic investigation should be conducted.

Preventive techniques

The surgical technique used can affect the infection rate in various ways, for example in relation to skin preparation, shaving and wound closure.

Skin preparation

The skin is colonised by various types of bacteria, but up to 50% of these are *Staphylococcus aureus*.[91] In analyses of contamination rates after cholecystectomy, the main source of wound contamination was found to be the skin of the patient.[91] For this reason, preoperative preparation should be performed. Evidence has shown that the use of a preoperative wash containing chlorhexidine decreases the bacterial count on skin by 80-90%, resulting in a decrease in preoperative wound contamination.[91] The effect on SSI incidence has, however, been more difficult to demonstrate and it is possible that prolonged washing releases organisms from deeper layers of the skin.

Shaving

It is now recognized that shaving damages the skin and that the risk of infection increases with the length of time between shaving and surgery.[91] In one study, if the patient had been shaved more than two hours before surgery the clean wound infection rate was found to be 2.3%.[91] However, if patients had not been shaved but their body hair had been clipped the rate was 1.7%, and if they had not been shaved or clipped the rate dropped to 0.9%.[91] If shaving is essential, it should be performed as close to the time of surgery as possible.

Common types of skin closure techniques

- Simple suture
- Interrupted mattress suture
    - Vertical mattress
    - Horizontal mattress
- Continuous subcuticular suture
- Skin staples
- Adhesive paper strips

Identifying surgical site infections

The most widely recognised definition of infection, which is used throughout the United States of America and Europe, is that devised by Horan and colleagues and adopted by the CDC. This splits SSIs into three groups - superficial and deep incisional SSIs and organ-space SSIs - depending on the site and the extent of

infection. The CDC definition states that only infections occurring within 30 days of surgery (or within a year in the case of implants) should be classified as SSIs.[91]

In addition to sterile procedures and patient warming, prophylactic antibiotics have been shown to reduce SSI. Despite the widespread use of prophylactic antibiotics, however, SSI continues to occur and is devastating for patients. Many different wound irrigation solutions, including soaps, antibiotics and antiseptics, have been used to reduce SSI.[92]

Role of suture material

The role of suture material in the development of wound infections has been the subject of speculation among surgeons since the 1960s.[93] Sutures are a contributory factor in infection; in fact, 66% of SSIs are related to the incision.[94]

Microbial adherence to the surface of suture material has been reported in the surgical literature for many years. The presence of foreign materials in a wound enhances the susceptibility of surrounding tissues to infection. The number of bacteria needed to establish infection can be reduced 10,000-fold by the presence of a silk suture.[95]

In fact, it is postulated that in the presence of sutures, only 100 colony-forming units (CFU)/mg are necessary to produce infection.[96] Various bacteria may contaminate not only the tissue in the surgical wound, but the actual suture material. Once suture material becomes contaminated, local mechanisms of wound decontamination become ineffective.[97]

Sutures, that present virtually in all major operative procedures, may create a setting in which low numbers of bacteria proliferate while sequestered from host defenses. Any suture product of natural or synthetic composition and of mono- or multi-filament construction is susceptible to bacterial attachment and colonization. It is also clear that colonization is associated with surgical site infections.[98]

Sutures, like most other implants, have a non-shedding surface to which bacteria can adhere, form biofilms and potentiate SSIs. The adherence of bacteria to various sutures has been investigated, and variations in adherence-affinity correlated with infection. 'Biofilms' are ubiquitous and form whenever micro-organisms such as bacteria, yeasts, algae, fungi, or protozoa attach to surfaces.[99]

A study,[100] in 1985, reported that, percutaneous sutures approximating skin edges were often colonized from the body surface into the wound track by strains of *S epidermidis*.

Another recent study[101] in 2007, showed the presence of biofilms around the bacteria after 60 minutes, and this material appeared adhered to the sutures three hours after contamination. Once attached, free-living bacteria undergo a phenotypic change and, within minutes, deposit 'slime': extracellular polymeric material (EPS) or biofilms matrix.

At least 60% of human infections are believed to involve biofilms and the recognition that biofilms are the dominant mode of microbial growth, and that the majority of bacteria exist in biofilms, is still recent emphasized.[102]

Once established, in the environment or in infections, biofilms bacteria are difficult to treat because, shielded within the matrix, they are less susceptible to

antibiotics and antiseptics. A reason for the reduced susceptibility of biofilm-embedded organisms, compared with free living bacteria counterparts, and includes: heterogenecity of growth rates; cells being in a stationary physiological phase, present as recalcitrant 'persister' cells or able to degrade antimicrobials; and reduced rates of penetration of the biofilms by antibiotics. Biofilms can also shield their constituent micro-organisms from the body's immune system. The free-living form of the isolate was susceptible *in vitro* but in biofilms was resistant. Once a biofilm infection is established on an implant, it usually antibiotic treatment and needs removal.[102]

Classification of sutures

There are 3 main classifications of suture materials.[103]

Based on no. of strands

Monofilament

Plain catgut, chromic catgut, Maxon, PDS, Monocryl, Monocryl plus, Ethilon (Nylon), Prolene (polypropylene)

Multifilament

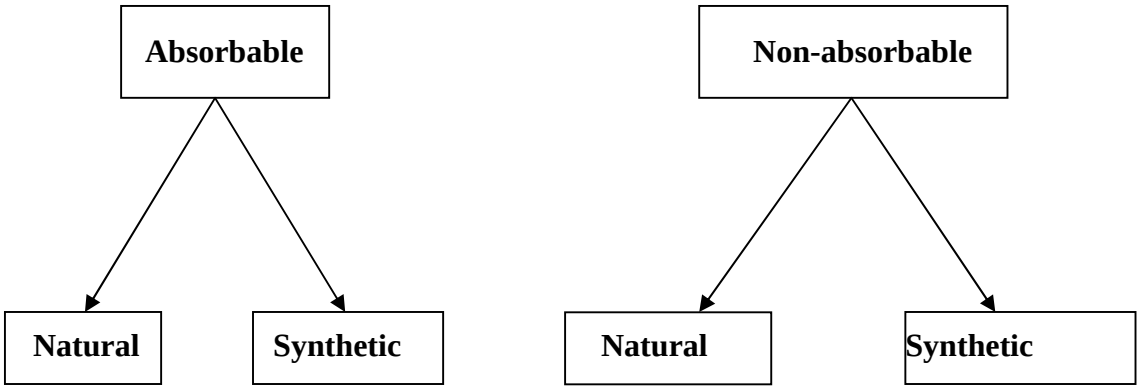
Vicryl (Polyglactin 910), Vicryl plus, Dexon (polyglycolic suture), Silk, Mersilene (Braided polyester)

Based on source

Natural or Synthetic

Based on absorption

Absorbable or Non-absorbable



Wound closure

Diagnostic or operative laparoscopy as a minimally invasive procedure is one of the most common operations in general surgery. The benefits of minimally invasive surgery as opposed to the traditional open surgical approach are reduced pain, quicker return of oral intake, shorter hospitalization, and improved cosmetic results due to decreased scarring.

There are several methods for skin closure of trocar wounds. The choice of material is often based on a surgeon's personal experience. Common procedures include closure with simple or subcuticular sutures, tapes and more recently, the tissue adhesive OCT. In addition to the above advantages of laparoscopic surgery,

acceptable wound cosmetic appearance and complication are also considered important outcomes following laparoscopic surgery.

The advantages and disadvantages of these different methods have been studied to some degree. Methods for closure of laparoscopic port sites vary in published series and are largely the result of surgeons' need for a rapid, economic, and reproducible technique of skin apposition.[104] Based on previous studies,[105,106] advantages of skin adhesives may include less time to apply and potentially good cosmetic outcomes.

The choice of wound closure after surgery whether major or minor procedure, there always exist lot of questions in many concerns. One of those concerns is how fast and comfortable will be the recovery. The recorded history of wound closure is as old as that of medicine. The Edwin Smith Surgical Papyrus, which was written in Egypt during the seventeenth century BC, was apparently an historical document when it was written, because it contained material dating back to 2500 to 3000 BC. This document is the first to mention surgical suturing in the passage interpreted, "Thou shouldst draw together for him his gash with stitching". Wound closure techniques have evolved from the earliest development of suturing materials to comprise resources that include synthetic sutures, absorbable, staples, tapes, and adhesive compounds.[107]

Sutures for wound closure

Traditionally, needle skin suturing with suture material is used because of cost-effective, nowadays surgeons are looking for faster, comfortable and cosmetically best technique for skin closure, more over 2-octylcyanoacrylate is

easier to use and provides a flexible, water resistant, sealed skin closure.[108] 2-octylcyanoacrylate provides a needle-free method of wound closure, an important consideration because of blood-borne viruses (e.g., HIV). It requires no bandaging due to its antimicrobial properties. For the patient side, it gives less pain during post operative period, patients can even have a shower, needs no suture or staple removal, disappears naturally as incision heals, leaves no mark.[107,108]

In traditional skin closure with suture material, Patients experiences more pain during post operative period, patient cannot have a shower; patient has to come for suture removal. Even after healing, there will be track marks of suture. Chances of infection of wound are also higher.

The technique of suturing is thousands of years old. Although suture materials and aspects of the technique have changed, the goals remain the same: closing dead space, supporting and strengthening wounds until healing increases their tensile strength, approximating skin edges for an aesthetically pleasing and functional result, and minimizing the risks of bleeding and infection.

The history of sutures begins more than 2,000 years ago with the first records of eyed needles. The Indian plastic surgeon, Susruta (AD 380- 450), described suture material made from flax, hemp, and hair.[107] At that time, the jaws of the black ant were used as surgical clips in bowel surgery. In 30 AD, the Roman Celsus again described the use of sutures and clips, and Galen further described the use of silk and catgut in 150 AD. Before the end of the first millennium, Avicenna described monofilament with his use of pig bristles in infected wounds. Surgical and suture technique evolved in the late 1800s with the development of sterilization procedures.

The first synthetics were developed in the 1950s, and further advancements have led to the creation of various forms. The different types of sutures offer different qualities in terms of handling, knot security, and strength for different purposes.

In ancient India, Egypt and the Greek and Roman societies wound treatments as well as suturing techniques and instruments were developed that strongly resemble those in our days. Hardly any progress is noted up to the nineteenth century. The improvement of catgut by Lister started in 1860. In the 19th century prototypes of mechanical suturing instruments (staplers) were developed. They were introduced into clinical practice in the early decades of the 20th century. The greatest progress in wound suturing started after World War II with the introduction of advanced semiautomatic stapler machinery and with the manufacture of synthetic non-resorbable and resorbable fibres.

Types of Suture Materials[107,109,110]

Suture materials can be broadly classified as naturally occurring and synthetic or Absorbable and non-absorbable .They can be further classified as monofilament or multifilament (braided), dyed or undyed, coated or uncoated.

Absorbable sutures

Type	Material	Duration at maximum strength	Complete absorption time (Days)	Colors available
Catgut	Sheep's intestine submucosa	3-4	Variable	Undyed
Chromic catgut	As above but tanned with chromic salts to delay absorption	10-14	>120	Undyed
Dexon	Polyglycolic	10-14	90-120	Undyed or green
Vicryl	Polyglactin 910	14-21	90	Undyed or purple
Polyglyconate	Glycolic acid and trimethylene carbonate	10-14	180	Undyed
Glycomer 631	Polyster of glycolide, dioxanone and trimethylene carbonate	12-20	90-110	Undyed
Polyglytone 6211	Polyster of glycolide caprolactone trimethylene carbonate and lactide	7-10	Variable	Undyed

Type	Material	Thread structure	Knots secure	Tissue reaction	Colour
Silk	Silk	Braided	Yes	++	Black
Nylon	Polymers of nylon 6	Braided and mono filament	Fair	±	Undyed / dyed blue or green
Prolene	Polypropylene	Monofilament	Fair	±	Blue / undyed
Polyster	Polyethylene terephthalate	Braided / multifilament	Fair	±	Undyed / dyed blue or green
Hexafluoro-propylene	Polyvinylidene fluoride and polyvinylidene fluoride-co-hexafluoropropylene				

Silk

Silk was first widely used as a suture material in the 1890s. It is a braided material formed from the protein fibers produced by silkworm larvae. Although silk is considered a non absorbable material, it is gradually degraded in tissue over 2 years. Silk has excellent handling and knot-tying properties and is the standard to which all other suture materials are compared. Its knot security is high, tensile strength low, and tissue reactivity high. Suture removal can be difficult and painful because the braided material becomes infiltrated with cells and encrusted with debris while the sutures are implanted in the skin.

Nylon

Introduced in 1940, nylon was the first synthetic suture available, and it is the most commonly used nonabsorbable material. It is available in both monofilamentous and multifilamentous forms. Nylon has a high tensile strength, and,

although it is classified as nonabsorbable, it loses tensile strength when buried in tissue. Multifilamentous forms retain no tensile strength after being in tissue for 6 months, whereas monofilamentous forms retain as much as two thirds of their original strength after 11 years. Monofilament nylon is stiff; therefore, handling and tying are difficult and knot security is low. The suture also may cut easily through thin tissue. Ethilon is monofilament nylon.

Multifilamentous forms have better handling properties but greater tissue reactivity. Monofilament nylon is relatively inexpensive and available as black, green, or clear. Although its greatest use is as a percutaneous suture, because of its low tissue reactivity, nylon (clear) can be used as a buried suture in situations in which prolonged dermal support is necessary.

Polypropylene

Polypropylene (Prolene; Ethicon) is a monofilament synthetic suture that was introduced in 1962. Its tensile strength is lower than that of the other synthetic nonabsorbable sutures. Its handling, tying, and knot security are poor as a result of its stiff nature and high memory. An additional throw is needed for adequate knot security. A method to improve security is the use of thermocautery to fuse the knots or transform the ends into small beads. Tissue reactivity is extremely low for polypropylene, and, unlike nylon, gradual absorption does not occur if it is buried in tissue. As a result, polypropylene is an excellent choice for a buried suture for long-term dermal support.

Polyglactin (vicryl)

It is a synthetic heteropolymer consisting of 90% of glycolide and 10% of lactide. These sutures are braided, multifilament, coated, absorbable synthetic sutures. This suture is degraded by hydrolysis. This suture can be supplied in an antibiotic form by impregnating with triclosan. In one study comparing the absorption of polyglactin 910 and polyglycolic acid, the absorption of former began approximately at 40 days, and was nearly complete by day 70. At 90 days, no polymer remained in the tissue.

Polyglycolic acid (Dexon)

This is an absorbable braided synthetic homopolymer of glycolic acid. Coated polyglycolic acid suture is undyed or dyed green, violet or bicolored. Since polyglycolic acid is not a naturally occurring organic substance, it elicits less inflammatory response than surgical gut. It is absorbed by hydrolysis. Polyglycolic acid possesses good tensile strength and excellent knot security. After two weeks of implantation, 65% of the initial tensile strength remains with polyglycolic acid suture, in contrast to 0% of surgical gut suture.[109]

Polyglyconate

It came in to market in 1985. It is synthetic monofilament absorbable suture, composed of glycolic acid and trimethylene carbonate. Polyglyconate has some advantages over other sutures, such as improved handling properties, lacks memory, passes easily through tissues and demonstrates superior strength. It retains 75% of original strength at two weeks of postimplantation. Absorption is essentially complete by 180 days.

Cyanoacrylate

The cyanoacrylates first were synthesized in 1949 by Coove A et al.[65] described their adhesive properties and suggested their possible use for surgical adhesives. In the early 1960s, various surgical applications were investigated for these adhesives. Cyanoacrylates can be synthesized by reacting formaldehyde with alkyl cyanoacetate to obtain a prepolymer that, by heating, is depolymerized into a liquid monomer. The monomer then can be modified by altering the alkoxycarbonyl (-COOR) group of the molecule to obtain compounds of different chain lengths. Upon application to living tissues (water or base), the monomer undergoes an exothermic hydroxylation reaction that results in polymerization of the adhesive. The shorter-chain derivatives tend to have a higher degree of tissue toxicity than the longer-chain derivatives. 2-Octylcyanoacrylate is a longer chain polymer which gives stronger bond. Until recently, 2-Butylcyanoacrylate skin adhesive is being used which is brittle in nature, after forming bond. The polymer 2-octyl cyanoacrylate was formulated to correct some of the deficiencies of the shorter-chain cyanoacrylate derivatives. The slower degradation of the octyl derivatives may result in lower concentrations of the cyanoacrylate polymer by-products in surrounding tissues, resulting in less inflammation. Additionally, plasticizers are added to produce a more pliable and tissue-compatible product that flexes with the skin and remains inherent for longer periods of time. The 3-dimensional breaking strength of 2-octyl cyanoacrylate is 3 times that of butyl-2 cyanoacrylate. This stronger flexible bond may allow its use on longer incisions.[107]

Cyanoacrylates are defined as solvent free, synthetic adhesives. They are reactive monomer liquids that polymerize into a film when initiated by moisture or

certain chemicals. A key property of cyanoacrylates is that the monomer liquid actually polymerizes directly on the surface where it is applied, creating a high quality and very tenacious polymer film. Cyanoacrylate is applied in a thin layer over the entire wound and extending 5-10 mm beyond the wound edge. The formation of the bond produces heat that the patient can feel. Once the layer is dried (10-30 seconds), a second layer is applied. Three to 4 layers are necessary. Cyanoacrylates typically fix within the minute and achieve full bond strength in 24 hours. No additional bandaging is required, and the patient is advised to not perform wound care at home. By 7-14 days, most of the adhesive sloughs with the epidermis and the remainder may be removed with soap and water or petroleum jelly.

Dermabond is quick and easy to apply; only one tenth to one fourth of the time required for suture placement is needed. It provides an antimicrobial and waterproof coating, but repeated washing removes the adhesive in a few days. The cosmetic outcome generally is good, and no postoperative visit is required for its removal.

2-Octylcyanoacrylate adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying adhesive in multiple thin layers (at least three) onto a dry wound and allowing time for polymerization between applications, heat is released slowly and the sensation of heat or pain experienced by the patient is minimized[111,112] If adhesive is applied so that large droplets of liquid are allowed to remain unspread, the patient may experience a sensation of heat or discomfort. Extra caution should be taken to avoid depositing any adhesive in the wound; the adhesive will not seep into the wound since it starts to polymerize instantaneously. A common mistake is to inadvertently

deposit the adhesive in the wound by pushing the tip of the vial into the wound and separating the wound edges.

Quinn J, et al[113] (1997) introduced a newer cyanoacrylate octy12 cyanoacrylate in his well designed, controlled study. Being combined with a plasticizer, this cyanoacrylate promises to have improved performance compared with other Cyanoacrylates. Being combined with a plasticizer, these long chain cyanoacrylates form a stronger bond than the other cyanoacrylate analogues after polymerization. This bond appears to be three times stronger than other cyanoacrylates. Because it is also flexible, it is less likely to fissure and fracture like other cyanoacrylates.

Quinn J, et al[113] (1997) conducted a randomised clinical trial comparing octy1 cyanoacrylate tissue adhesive and sutures in management of high tension lacerated wounds and concluded that this adhesive effectively closed selected lacerations and is a painless fast method of wound repair and can replace the need for suture of laceration.

Quinn J, et al[114] (1998) evaluated long term cosmetic outcome of octy1 cyanoacrylate tissue adhesive versus standard monofilament 5-0 suture and concluded no significant difference in the cosmetic value and that flue is a quick, faster way of closing lacerated wounds.

Octy1 cyanoacrylate and buty1 cyanoacrylate were compared by Osmond MH, et al[115] on facial laceration of 94 children. All lacerations were less than 4 cm. No difference was found between the groups when comparing cosmetic outcome, time to perform the procedure and complications.

Watson DP, et al[116] in (1989) conducted a prospective trial of cyanoacrylate tissue glue in closing facial lacerations in children less than 14 years and found that gluing is quick, atraumatic and cost effective. Furthermore cosmetic results were excellent and trouble of suture removal was avoided.

Eiferman RA et al[117] (1983) used buty1 cyanoacyrlate glue for the treatment of perforated corneal ulcers infected by gram positive organisms and concluded that bacteriostatic activity of glue was most pronounced against gram positive organisms and no activity against gram negative organism.

Bruns TB, et al[118] in 1996 conducted prospective randomized trial to compare long term cosmetic outcomes of n buty1 cyanoacrylate glue to conventional suturing for laceration repair in children at 1 month and 1 year. Outcome shows that glue alternative to conventional suture is comparable to conventional suture at 1 year for low-tension incision.

In 2001, Bernard L, et al[119] conducted a trial to compare the tissue adhesive with standard monofilament suture for closure of high tension excision wounds in children and adolescents. Cosmetic outcomes were evaluated two months later. They concluded that cosmetic outcome of high tension wound closed with glue were inferior to those closed with suture.

In one study by Bruns TB,[120] closure with sutures resulted in a cosmetically worse scar in lacerations that deviated by more than 20^0 from Langer's line in contrast to the closure with tissue adhesive who's scars were unaffected by wounds oriented with Langer's line.

The engineering of sutures in synthetic material along with standardization of traditional materials (eg, catgut, silk) has made for superior aesthetic results. Similarly, the creation of natural glues, surgical staples, and tapes to substitute for sutures has supplemented the armamentarium of wound closure techniques. Aesthetic closure is based on knowledge of healing mechanisms. Choosing the proper materials and wound closure technique ensures optimal healing. 2-Octyl Cyanoacrylate is the latest skin adhesive glue, used for faster skin closure. So it is essential to do a comparative study of the two techniques of skin closures.

Tissue glue to approximate the edges of the wound

In the modern time with the advent of elective surgery, more energy has been directed for achieving an efficient and uncomplicated healing of the deliberately inflicted wound. Every surgeon dreams of perfect wound healing while performing surgeries. Although spectacular achievements are made in science and technology in recent years, yet the oldest surgical problem of perfect wound closure still persists. The use of tissue adhesive as an attractive alternative to sutures has recently been invoked immense interest in the field of wound healing.[121]

The cyanoacrylate tissue glue has been claimed to have the advantages of being hemostatic,[122] bacteriostatic[123,124] and easy to use.

Kato Y et al,[125] in a study to investigate the efficacy of tissue adhesives for closing the orifice of inguinal hernia sac as an alternative method for treating inguinal hernia concluded that laparoscopic injection of derma bond into the inguinal hernial sac is simple, safe , reliable and virtually scarless It may be a reasonable alternative to standard open surgical inguinal hernia repair.

Sebesta M et al,[126] demonstrated that laparoscopic skin site skin closure with octyl cyanoacrylate is rapid and effective. The method yields cost saving and decrease in operative time of more than 9 minutes per case.

Zeplin et al,[127] concluded that if possible , the wound closure ,treated with common suturing techniques and especially with skin adhesive ,should be enhanced by an intracutaneous suture with an increasing length of the wound Under certain circumstances , skin adhesive , is an adequate substitute for common suturing material and method . The final decision about the method and material is as much closely related to the length and localization of the wound as to time of exposure .efficiency and comfort of the patient.

Switzer F[128] concluded that skin adhesives did result in faster wound healing and was an acceptable alternative to subcuticular suture closure in inguinal herniorrhaphy incisions though chanches of infections were higher .

Nowobilski W[129] in a study of Lichtenstein Inguinal Hernioplasty Using Butyl-2-Cyanoacrylate versus Sutures concluded that patients had significantly lower pain score after the first postoperative day and had a tendency to require less analgesic doses and to return earlier to their daily activity.

METHODOLOGY

The present study was carried out in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2015 to December 2015.

Study design: A hospital based randomized controlled trial.

Study period and duration: One year from January 2015 to December 2015.

Place: Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum attached to KLE University's Jawaharlal Nehru Medical College, Belgaum.

Source of Data: Patients undergoing unilateral and/or bilateral inguinal hernia repair.

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

Sampling procedure: the sample size was calculated based on the following formula

$$n = \frac{2(z\alpha + z\beta)^2 pq}{(p_0 - p_1)^2}$$

Where,

$z\alpha = 1.96$

$z\beta = 0.84$

$$p = \frac{p_0 + p_1}{2}$$

$$q = 100-p$$

Therefore,

$$n = \frac{2(1.96+0.84)^2 3x97}{6x6}$$

$$=60$$

Therefore a minimum sample size of total 60 patients divided into two groups of 30 each was considered for the study

Randomization

The patients were randomly allocated into two groups based on closed envelope method.

Selection criteria

Inclusion

- Patients undergoing unilateral and/or bilateral inguinal hernia repair and willing to participate in the study by giving and written informed consent.

Exclusion

- Patients who have not given the informed and written consent to participate in the trial.

- Patients with co-morbid conditions like renal failure, connective tissue disorders, peripheral vascular disease, infected wounds, substance abuse, malnourished and general debility.
- Patients with Metabolic disorders , drugs impairing wound healing coagulation disorders, steroids, chemotherapeutic drugs, Radiotherapy immuno-compromised status, collagen vascular disease , documented drug allergy, recurrent hernia strangulated hernia and obstructed hernia.
- Local causes like Burns, Keloids, Urticaria, Ulcers and h/o trauma.

Ethical clearance

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

Informed Consent

Patients fulfilling selection criteria were explained about the nature of study including risks and benefits of operation. A written informed consent was obtained prior to the enrolment (Annexure I).

Method of collection of data

The selected patients were interviewed and data such as age, presenting complaints were recorded. Further patients underwent clinical examination followed by systemic examination. These findings were noted on a predesigned and pretested proforma (Annexure II).

Investigations

Patients underwent following investigations

- Complete blood count
- Mini renal profile
- Liver function tests
- Chest X-ray
- Electrocardiogram
- Random blood sugar
- HIV HbSag

Procedure

Pre operative

In both the groups, shaving of the abdomen from nipple to mid-thigh prior to surgery was done. On the operation table the abdomen was cleaned with povidone iodine and spirit. Injection ciprofloxacin 100 mL IV and Inj. metronidazole 100 mL IV were given prior to skin incision. All the patients had standard analgesic and antibiotics protocol.

Surgical technique

Patients in both the groups underwent open abdominal surgeries using similar instruments and accepted general principles of surgery.

Closure technique

The closure of wound was done in monolayer.

Intervention

Group A

Patients in this group underwent skin closure with cyanoacrylate glue.

Group B

Patients in this group underwent conventional skin closure for inguinal hernias.

Post operative

The patients were postoperatively medicated with Inj. Ciprofloxacin 100 mL IV twice daily and Inj. metronidazole 100 mL thrice daily and if indicated and were changed to higher antibiotics accordingly.

Outcome variables

Patients wounds were inspected and evaluated for swelling, redness and discharge/pus from the wound, if any and fever, on postoperative day three.

Surgical site infection

The endpoint of the study was presence or absence of 'Postoperative surgical site infection'. An incisional surgical site infection was considered to be positive if surgical wound drained purulent material or if the surgeon judges it to be infected and opens it. The surgical wound infection was defined according to US Centre for Disease Control and Prevention (CDC) as SSI.[130]

Statistical analysis

The data was tabulated on Microsoft excel spread sheet (Annexure III). The data was analyzed using SPSS version 20.0 Categorical data was expressed as rates, ratios and percentages and continuous data was expressed as mean ± SD. Categorical data was compared using Chi-square test or Fisher's exact test and continuous data was compared using independent sample 't' test. A probability value of ≤ 0.050 at 95% confidence interval was considered as statistically significant.

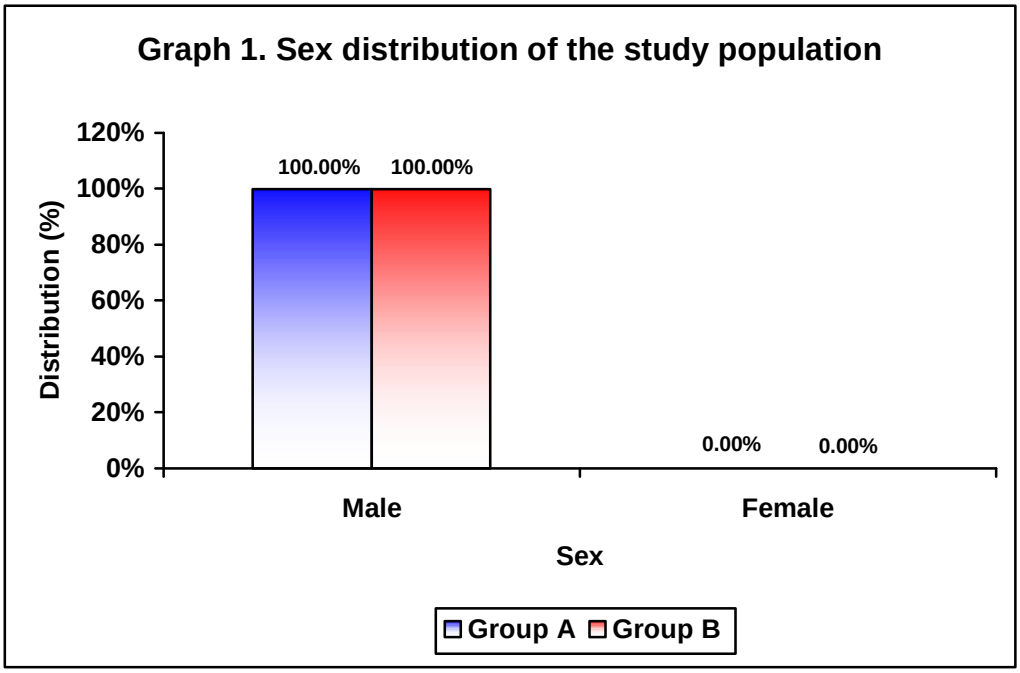
RESULTS

The present one year hospital based randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2015 to December 2015. A total of 60 patients undergoing unilateral and/or bilateral inguinal hernia repair were enrolled. Based on closed envelope method, these patients were randomly allocated into two groups method viz. Group A (Patients in this group underwent skin closure with cyanoacrylate glue) and Group B (Patients in this group underwent skin closure with conventional skin closure).

The data was analysed and the final results and observations were tabulated as below.

Table 1. Sex distribution of the study population

Sex	Group A (n=30)		Group B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
Male	30	100.00	30	100.00
Female	0	0.00	0	0.00
Total	**30**	**100.00**	**30**	**100.00**

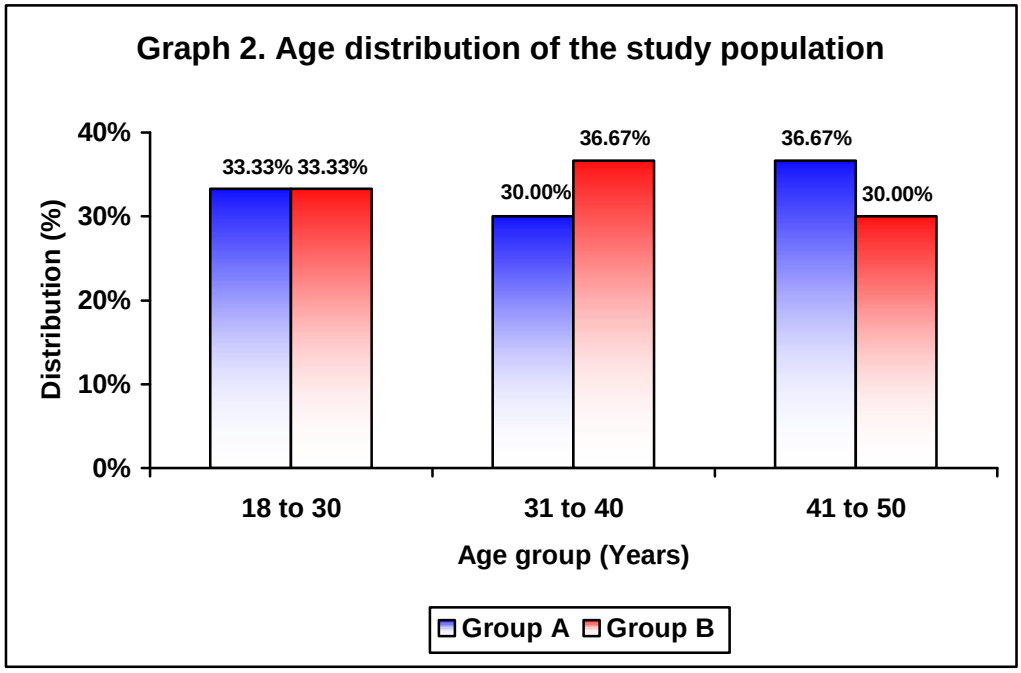


In the present study all the patients were males in group A as well as in Group B (100%).

Table 2. Age distribution of the study population

Age group (Years)	Group A (n=30)		Group B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
18 to 30	10	33.33	10	33.33
31 to 40	9	30.00	11	36.67
41 to 50	11	36.67	9	30.00
Total	**30**	**100.00**	**30**	**100.00**

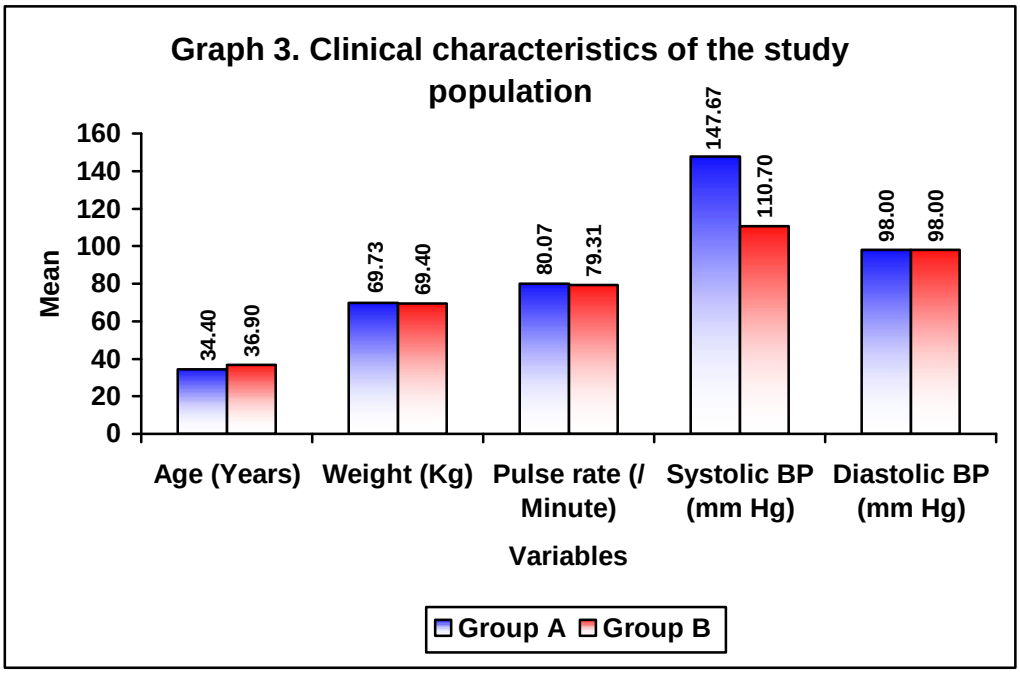
p = 0.861



In the present study most of the patients were aged between 41 to 50 years (36.67%) in group A while in group B, the commonest age group was 31 to 40 years (36.67). However this difference was statistically not significant (p=0.861).

Table 3. Clinical characteristics of the study population

Variables	Group A (n=30)		Group B (n=30)		p value
	Mean	SD	Mean	SD	
Age (Years)	34.40	7.99	36.90	7.87	0.174
Weight (Kg)	69.73	10.76	69.40	11.05	0.260
Pulse rate (/Minute)	80.07	6.16	79.31	5.19	0.791
Systolic BP (mm Hg)	147.67	204.60	110.70	8.80	0.296
Diastolic BP (mm Hg)	98.00	0.00	98.00	0.00	-



The comparison of clinical characteristics of the study population that is, Mean Age, weight, pulse rate, systolic BP, and dialostic BP are shown in Table 3 and graph 3. All these variables were comparable in group A and group B (p>0.050).

Table 4. Chief complaints

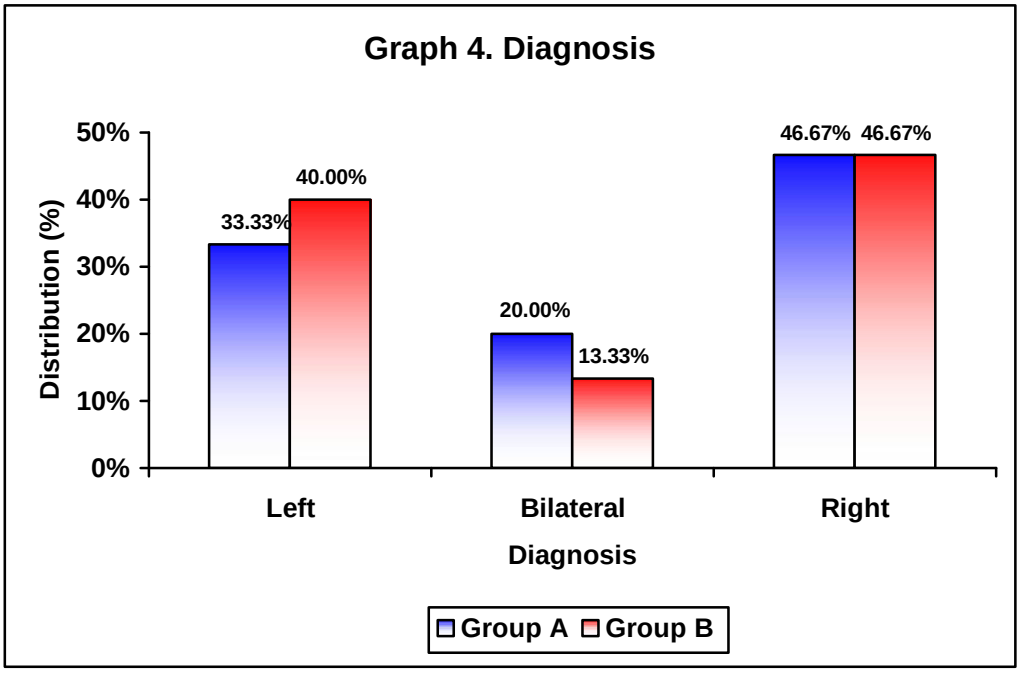
Chief complaints	Group A (n=30)		Group B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
Swelling in inguinal region	30	100.00	30	100.00
Total	**30**	**100.00**	**30**	**100.00**

In this study swelling in inguinal region was noted in all the patients of both the groups (100%).

Table 5. Diagnosis

Diagnosis	Group A (n=30)		Group B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
Left	10	33.33	12	40.00
Bilateral	6	20.00	4	13.33
Right	14	46.67	14	46.67
Total	**30**	**100.00**	**30**	**100.00**

p = 0.748

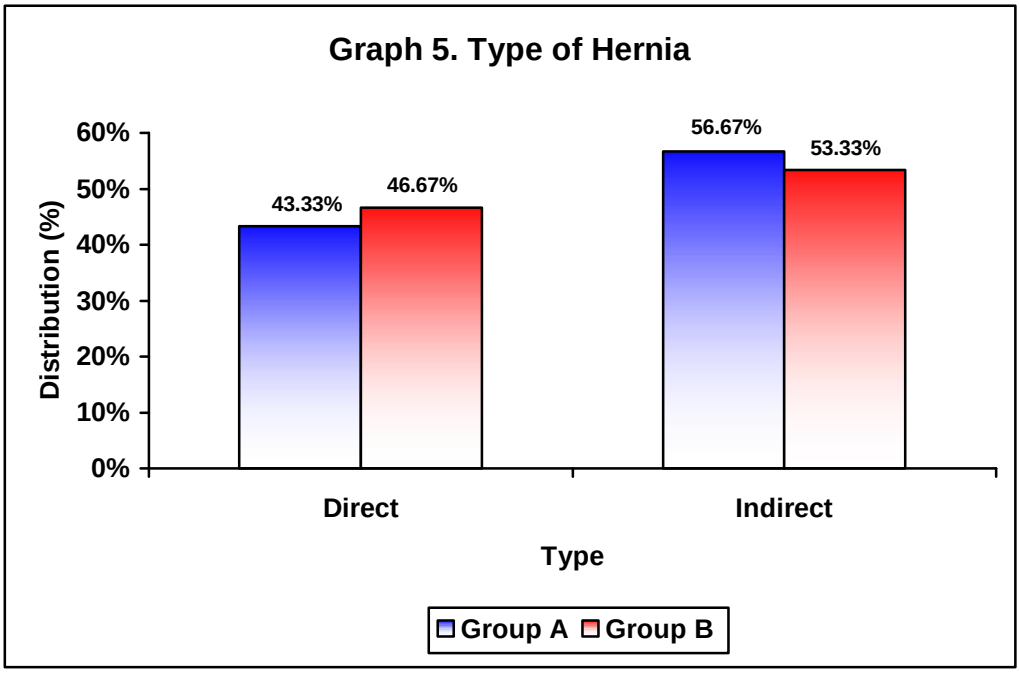


In the present study most of the patients in group A and group B had Right inguinal hernia (46.67%).

Table 6. Type of Hernia

Type	Group A (n=30)		Group B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
Direct	13	43.33	14	46.67
Indirect	17	56.67	16	53.33
Total	**30**	**100.00**	**30**	**100.00**

p = 0.795

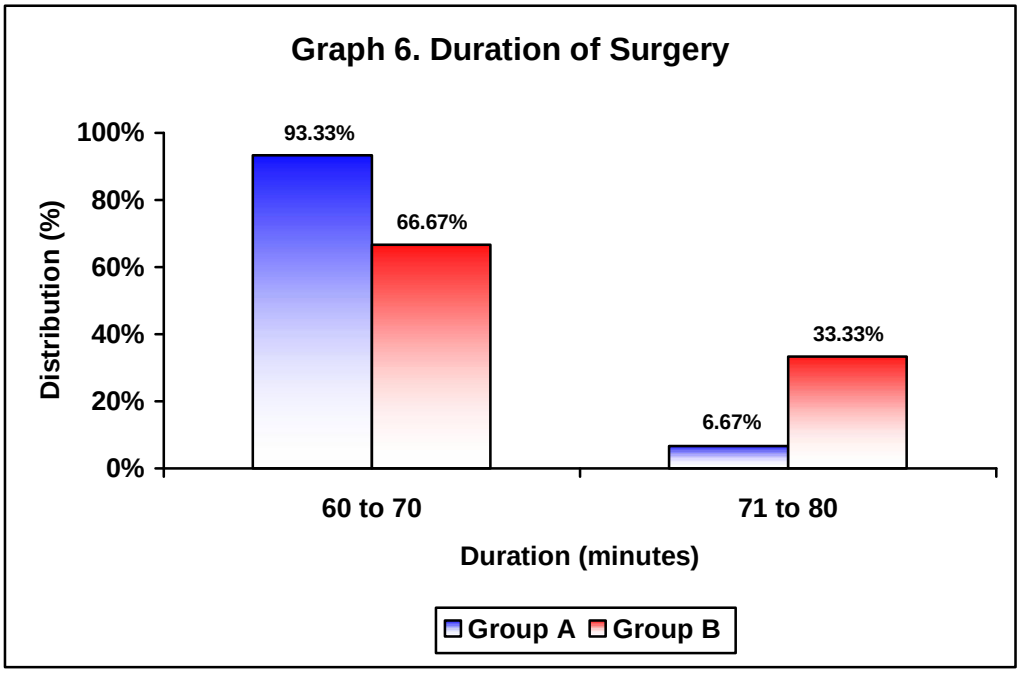


In the present study most of the patients in group A (56.67%) and group B (53.33%) had indirect inguinal hernia (p=0.795).

Table 7. Duration of Surgery

Duration (minutes)	Group A (n=30)		Group B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
60 to 70	28	93.33	20	66.67
71 to 80	2	6.67	10	33.33
Total	**30**	**100.00**	**30**	**100.00**

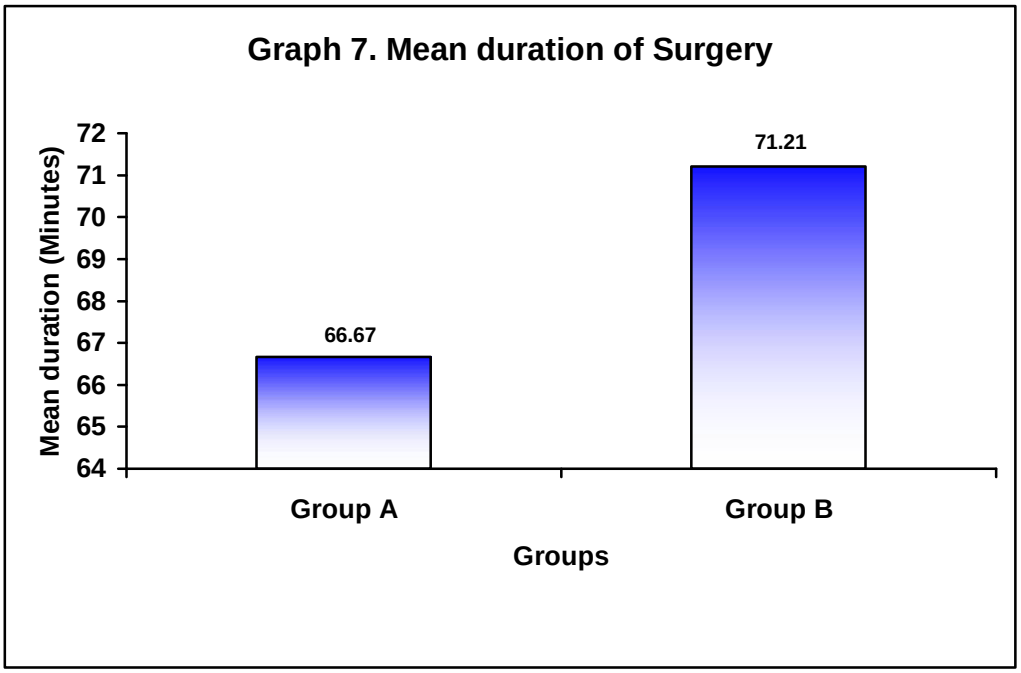
p = 0.010



In this study significantly higher number of patients in group A had duration of surgery between 60 to70 minutes (93.33%) compared to (66.67%) in group B (p=0.010).

Table 8. Mean duration of Surgery

Variables	Group A (n=30)		Group B (n=30)		p value
	Mean	SD	Mean	SD	
Duration of Surgery (Minutes)	66.67	4.61	71.21	6.90	**0.004**

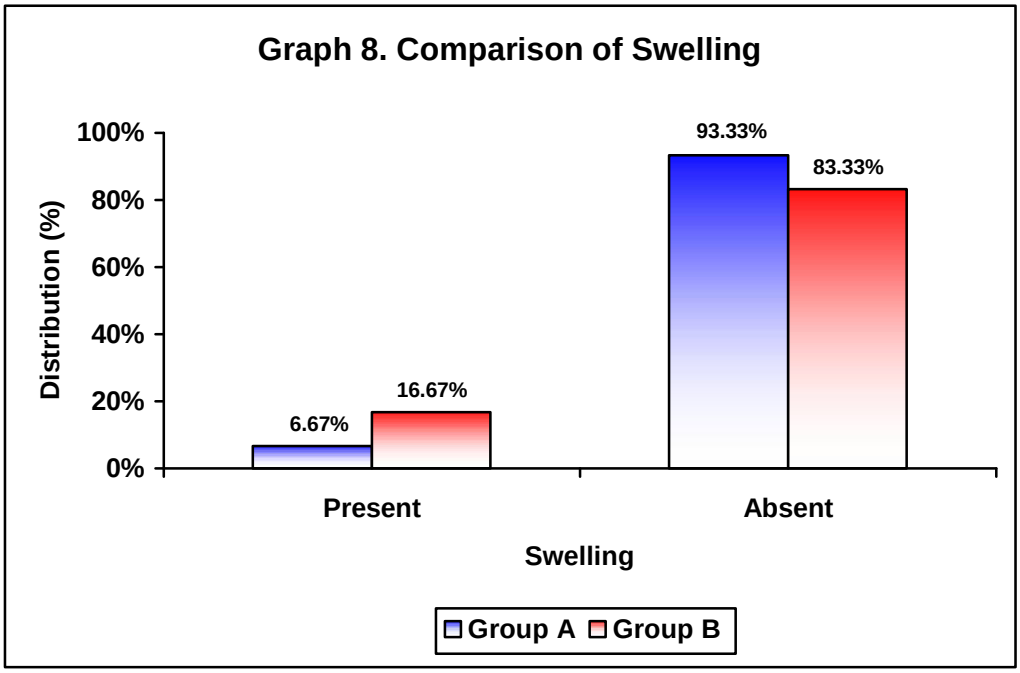


In this study the mean duration of surgery was significantly low in group A (66.67 ±4.61 minutes) compared to group B (71.21 ± 6.90 minutes) (p=0.004).

Table 9. Comparison of Swelling

Swelling	Group A (n=30)		Group B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
Present	2	6.67	5	16.67
Absent	28	93.33	25	83.33
Total	**30**	**100.00**	**30**	**100.00**

p = 0.228

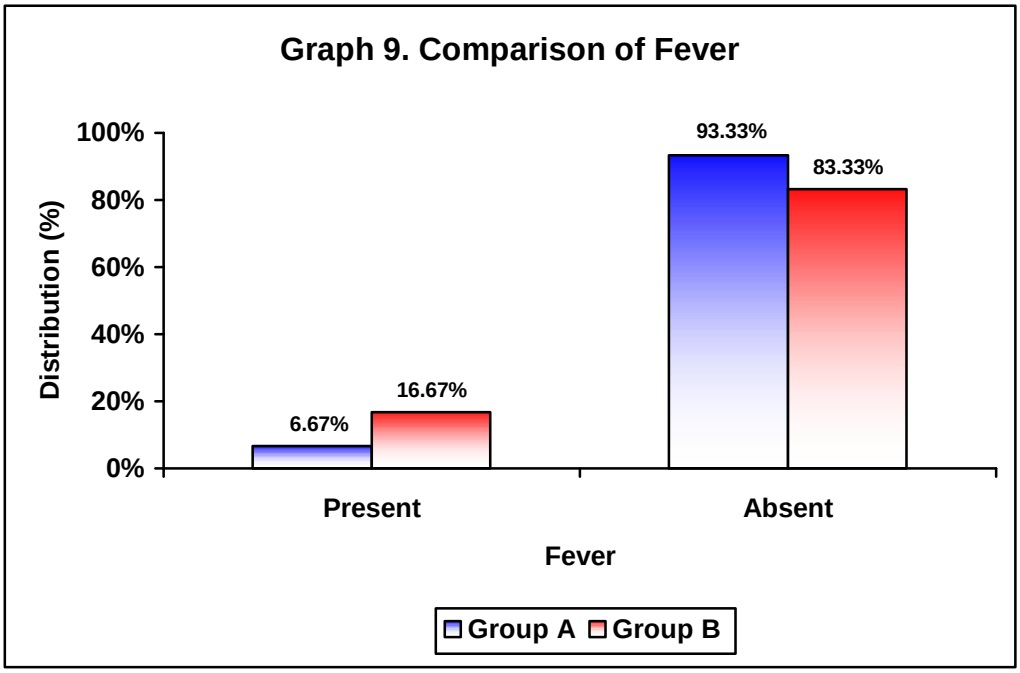


In this study swelling was noted in 6.67% of the patients in group A while in group B, swelling was present in 16.67% of the patients. However this difference was statistically not significant (p=0.228).

Table 10. Comparison of Fever

Fever	Group A (n=30)		Group B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
Present	2	6.67	5	16.67
Absent	28	93.33	25	83.33
Total	**30**	**100.00**	**30**	**100.00**

p = 0.228

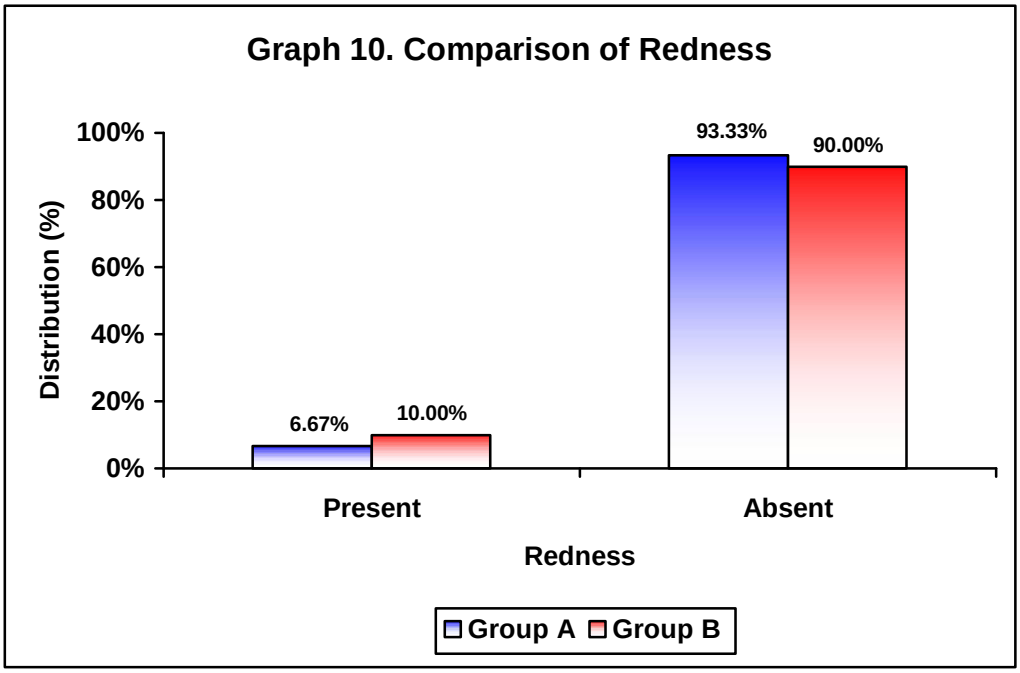


In the present study fever was present in 6.67% of the patients in group A while in group B, fever was present in 16.67% of the patients. However this difference was statistically not significant (p=0.228).

Table 11. Comparison of Redness

Redness	Group A (n=30)		Group B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
Present	2	6.67	3	10.00
Absent	28	93.33	27	90.00
Total	**30**	**100.00**	**30**	**100.00**

p = 0.640

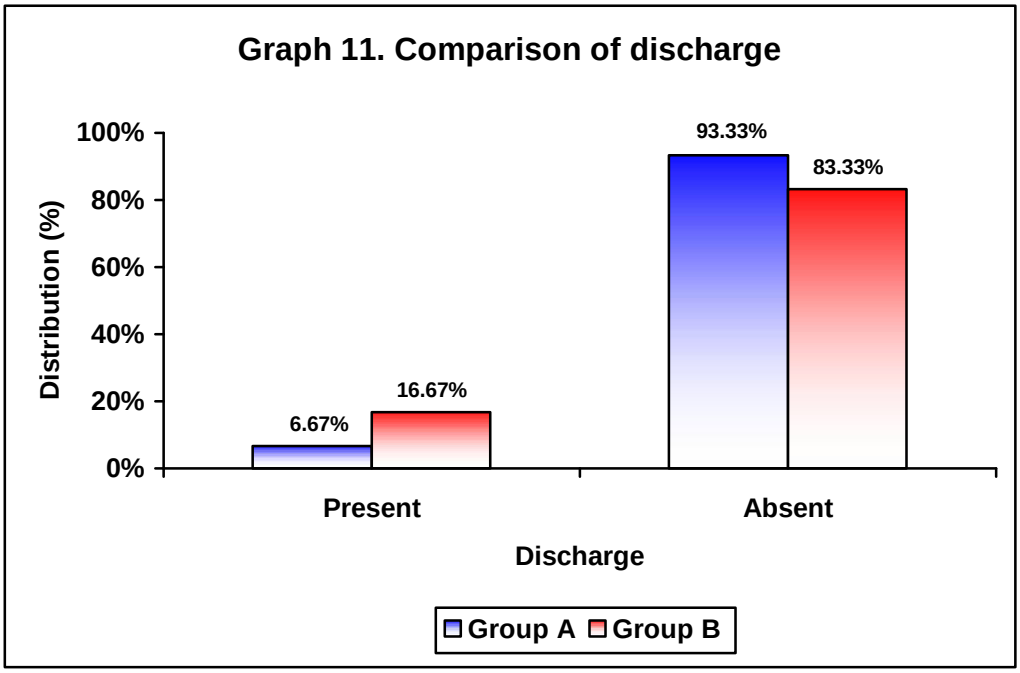


In this study redness was seen in 6.67% of the patients in group A while in group B, redness was present in 10.00% of the patients. However this difference was statistically not significant (p=0.640).

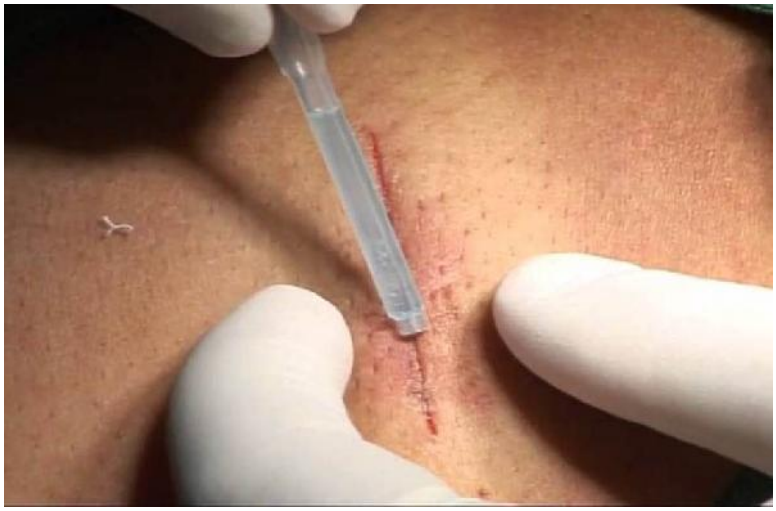
Table 12. Comparison of Discharge

Discharge	Group A (n=30)		Group B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
Present	2	6.67	5	16.67
Absent	28	93.33	25	83.33
Total	**30**	**100.00**	**30**	**100.00**

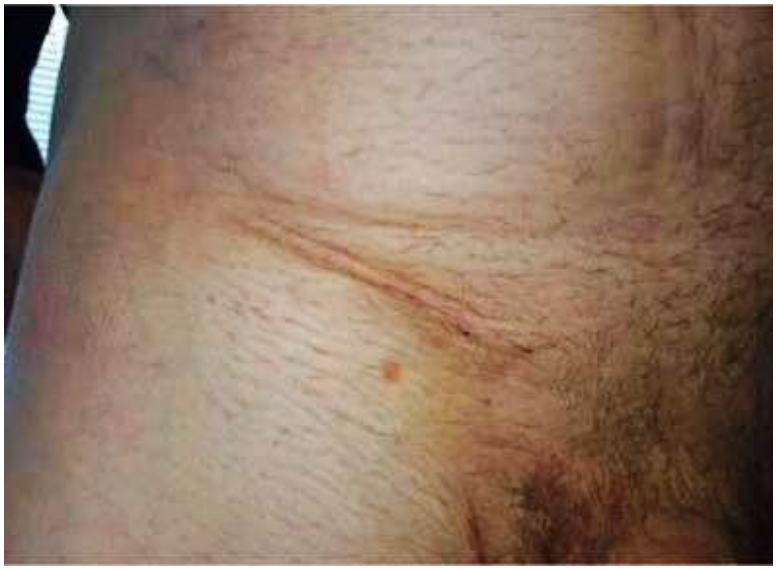
p = 0.228



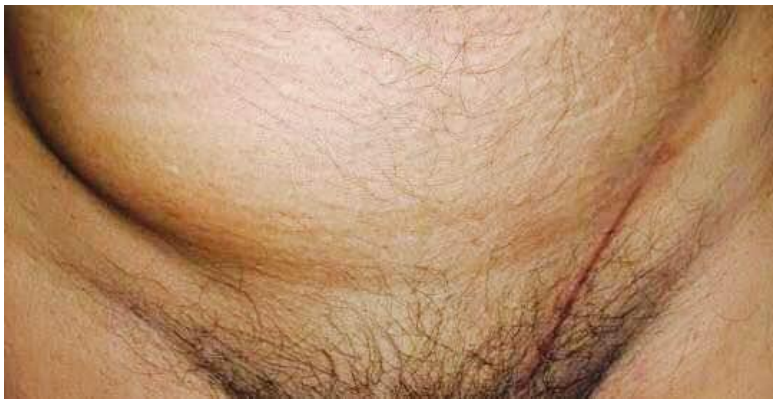
In the present study among the patients with group A discharge was noted in 6.67% of the patients. While in group B, it was present in 16.67% of the patients. However this difference was statistically not significant (p=0.228).



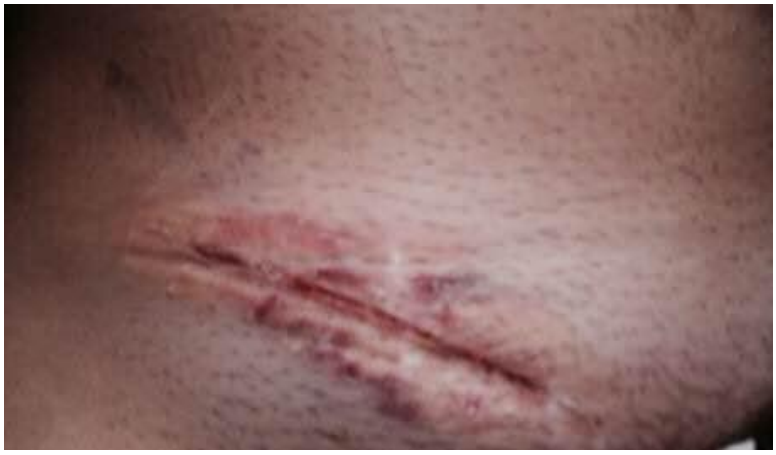
Photograph 1. Application of Cyanoacrylate glue



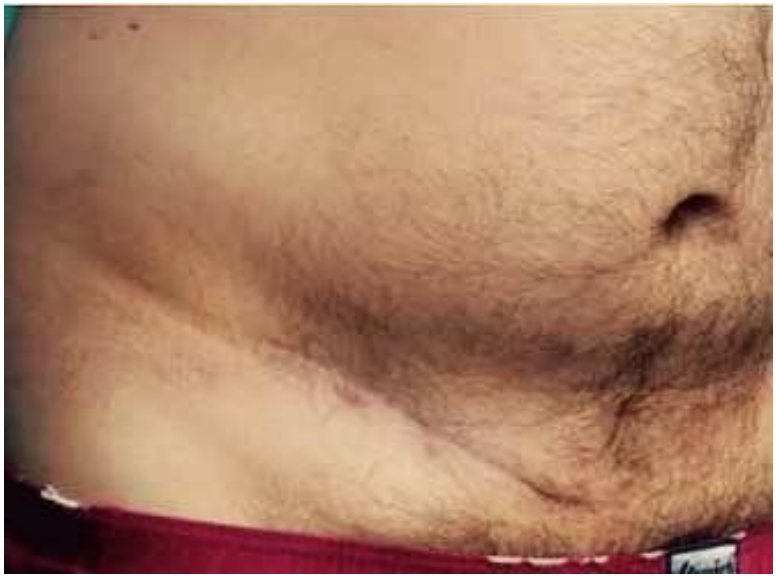
Photograph 2. Appearance of wound on post operative day 3 in group A.



Photograph 3. Appearance of wound on post operative day 7 in group A.



Photograph 4. Appearance of wound on post operative day 3 in group B.



Photograph 5. Appearance of wound on post operative day 7 in group B.

DISCUSSION

Wound closure has always attracted the attention of surgeons for improvement since ancient time. Surgeons in different era kept on devoting their best to fulfill the need for improvement. Wound closure techniques have evolved from the earliest development of suturing materials to comprise resources that include synthetic sutures, staples, tapes and adhesive compound. Aesthetic closure is based on knowledge of skin anatomy, healing mechanism and closure technique. Choosing the proper materials and wound closure technique ensure optimal healing. The field of tissue adhesive is an area of tremendous interest and research. Topical adhesives have been used quite successfully for minor incisions, thus sparing the patient the need for injection of local anesthesia for traumatic lacerations - a benefit of considerable importance especially for pediatric patients.[131]

In the past the options for wound closure have been limited largely to sutures (needle and thread) with other alternatives such as staples, adhesive tapes and tissue adhesives entering clinical practice more recently. Closure of wounds with sutures enables meticulous closure, but skin may react to sutures and they usually require removal. Tissue adhesives (glues) offer the advantages that suture removal is not required at a later date and there is no risk of needle stick injury to the surgeon or assistant.[132]

Tissue adhesives have been used in various forms for many years since the first cyanoacrylate adhesives were synthesised.[133] The early adhesives were appropriate for small superficial lacerations and incisions, but their limited physical properties prevented use in the management of other wounds. There were also

reports of acute and chronic inflammatory reactions. Further development led to the introduction of the n-2-butylcyanoacrlyates that were purer and stronger, but did not receive widespread acceptance because their clinical performance was limited by their low tensile strength and brittleness. More recently stronger tissue adhesives have been developed by combining plasticizer sand stabilizers to increase flexibility and reduce toxicity. Tissue adhesives have been used primarily in emergency rooms and there is increasing support in the literature for their effectiveness in the closure of various traumatic lacerations. Surgeons now also use tissue adhesives in the operating room for the closure of surgical skin incisions.[132]

The introduction of tissue adhesives was received enthusiastically as they may produce equivalent tensile strength, improved cosmetic appearance of the scar and a lower infection rate when compared with sutures, staples and adhesive tapes, while avoiding many of the risks and disadvantages of alternative methods. As with standard adhesives, tissue adhesives are applied to the wound in a liquid form - following application they undergo polymerisation and bonding and setting occurs.[132]

It is important that clinical decision-makers are able to make evidence-informed decisions regarding the use of tissue adhesives to close surgical incisions. As tissue adhesives become more widely used, more randomised controlled trials are conducted, and this update is required to incorporate this new evidence.[132]

In order to assess if tissue adhesive can be used as an alternative to subcuticular closure in elective surgical incisions as the data comparing on tissue adhesive and conventional sutures for skin closure in the settings of open inguinal

hernia is limited. The present study was undertaken compare to the incidence of post operative wound infection by Tissue adhesive VS conventional suturing in open inguinal hernia skin closure.

The present one year hospital based randomized controlled trial was done in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. A total of 60 patients undergoing unilateral and/or bilateral inguinal hernia repair from January 2015 to December 2015 were enrolled and studied. Based on closed envelope method, these patients were randomly allocated into two groups method viz. Group A (Skin closure with cyanoacrylate glue) and Group B (Skin closure with conventional suturing).

In the present study all the patients in both the groups were males (100%). The most common age group was between 41 to 50 years (36.67%) in group A while in group B, the most common age group was 18 to 30 years (33.33%). However this difference was statistically not significant (p=0.861). The comparison of clinical characteristics of the study population including mean Age (34.40 ± 7.99 vs 36.90 ± 7.87 years; p=0.174), weight (69.73 ± 10.76 vs 69.40 ± 11.05 Kg; p=0.260), pulse rate (80.07 ± 6.16 vs 79.31 ± 5.19 /Minute; p=0.791), systolic BP (147.67 ± 6.16 vs 79.31 ± 5.19 mm Hg; p=0.296), and diastolic BP (98.00 ± 0.00 vs 98.00 ± 0.00 mm Hg;) were comparable in group A and group B.. furthermore, clinical presentation including swelling in inguinal region, side of hernia, Type of hernia, extent of hernia were comparable in group A and group B (p>0.050). These findings show that the clinical demographic and clinical characteristics of the study population were comparable in group A and group B ruling out the possible bias in study results.

Goals of wound closure should be achieved with a simple rapid and cost effective. Use of surgical adhesives can simplify skin closure in that certain problems inherent to suture use can be avoided. Use of surgical adhesives can simplify skin closure in that certain problem inherent to suture use can be avoided. Application of a tissue adhesive is relatively painless for the patient. 2-octylcyanoacrylate is the only cyanoacrylate tissue adhesive approved by the U.S. Food and Drug Administration for superficial skin closure.[131]

In this study 93.33% of the patients in group A had surgical time between 60 to70 minutes in compared to 66.67% group B (p=0.010) this difference was statistically significant (p=0.010). Also, the mean duration of surgery was significantly low in group A compared to group B (66.67 ±4.61 vs 71.21 ± 6.90 minutes; p=0.004). These findings suggest that, skin closure with cyanoacrylate glue in patients undergoing inguinal hernia repair requires significantly less time compared to skin closure with conventional suturing. The direct head to head comparison of present study was not possible due to due lack of Randomised controlled trials in the settings of inguinal hernia repair comparing skin closure with cyanoacrylate glue and skin closure with conventional suturing.

It is reported that, an even greater difference in closure time would be expected for long wounds because an increase in wound length would not substantially increase the time for applying tissue adhesive but it would increase the time for subcuticular suture. The study of long wounds by Maw et al.[134] found an approximately 10 fold greater mean closure time for sutures versus tissue adhesive.

The overall results in the present study showed that the time required for closure of wound in the subcuticular vicryl 3-0 suture group was significantly higher than the tissue adhesive group.

Tissue adhesive is an effective barrier against microbial penetration also. United States Food and Drug Administration (US FDA) approved 2-octylcyanoacrylate in January 2001 for use as a barrier against common bacterial microbes including staphylococci, pseudomonas and *E. coli.* Tissue adhesive has been offered as a "safe and effective means of sutureless wound closure" in facial plastic surgery with insignificant tissue toxicity and may actually assist in reducing the surgical site infections.[135-137]

In this study with regard to incidence of post operative complications, swelling, fever and discharge were noted in slightly less number of patients (6.67%) in group A compared to group B (16.67%). But this difference was statistically not significant (p=0.228). However, redness was comparable in group A and group B (6.67% vs 10.00%; p=0.640). However the difference observed was statistically not significant. These findings suggest that, Skin closure with cyanoacrylate glue in patients undergoing inguinal hernia repair results in lower incidence of post operative complications including swelling, fever, redness and discharge. Though, the rate of incidence pertaining to swelling, fever, redness and discharge was low in patients who underwent skin closure with cyanoacrylate glue compared to those who underwent skin closure with conventional suturing no statistically significant differences were noted and hence the rate of incidence was comparable to that of skin closure with conventional suturing. It is difficult to comment on the findings of this study as there limited number of Randomised controlled trials in the settings of

inguinal hernia repair comparing skin closure with cyanoacrylate glue and skin closure with conventional suturing.

However, in contrast to the findings of this study Bansal AR et al.[131] in Rohtak., India reported wound discharge in significantly higher number of patients with cases in tissue adhesive that is, 6 out of 25 (24%) while only 2 out of 25 (8%) cases had wound discharge in subcuticular vicryl group (P<0.001). Wound infection in form of seropurulent discharge was observed in only one (4%) patient of the tissue adhesive group. However, the study by Bansal AR et al.[131] did not evaluated of complications fever, redness and swelling.

Considerable clinical experience exists with 2-octylcyanocrylate in the management of skin wound in many surgical fields. They have been used on skin, bone, cartilage graft, and middle ear surgery, repair of cerebrospinal fluid leak and repair of corneal ulcer.[138]

Various studies conducted on the use of tissue adhesive (2-octylcyanoacrylate) concluded that the only complication of tissue adhesive is a small increased risk of wound disruption.[139,140] Postoperative complications in the present study were in agreement with several other studies the studies conducted by Singer et al13; Switzer et al.[139] and at variance with Maw JL et al.[134] Ong CC et al[141] and Sebesta et al.[126] and Quinn JV et al.[138] despite of few methodological differences and different settings.

Ong CC et al.[141] conducted a prospective, randomised, controlled trial in 2002 to compare the tissue adhesive 2-octylcyanoacrylate standard subcuticular suture for closure of surgical incisions in children, looking at outcome measures of

time efficiency, cosmesis, and wound complications. All healthy patients undergoing unilateral or bilateral herniotomies were recruited prospectively with informed consent and randomly allocated to suture or glue. Time of wound closure was measured from the subcutaneous layer to application of the dressing. A total of 59 patients were recruited into the study with 26 in the glue group and 33 in the suture group. There was no difference in mean time of closure (glue 181 +/- 62 s vs suture 161 +/- 45 s, P = 0.18). No patient reported any rash, wound infection, or dehiscence. Authors concluded that, tissue glue is easy to use with no complications and has equivalent cosmetic results, but is not faster than a subcuticular suture.

Quinn JV et al.[138] compared the tissue adhesive Histoacryl Blue with suturing in the repair of pediatric facial lacerations in 1993 in a Prospective, randomized controlled trial. The two groups were similar for demographic and clinical characteristics. Photographs taken at three months were rated by two plastic surgeons blinded to the method of closure. There was no difference between groups for appearance scores on a visual analog scale (60.5 mm for Histoacryl Blue versus 57.2 mm for suture, P = .45) or on a categorical scale (Histoacryl Blue versus sutures: unacceptable, 11% versus 13%; acceptable, 59% versus 71%; excellent, 30% versus 16%; P = .76). Measures of observer agreement produced Pearson correlations of .72 and .94 on the visual analog scale and kappa coefficients of .46 and .73 on the categorical scale. Histoacryl Blue was assessed as less painful on a visual analog scale (24.7 versus 43.7 mm, P < .01) and faster (7.9 versus 15.6 minutes, P < .001). study concluded that, Histoacryl Blue is a faster and less painful method of facial laceration repair that has cosmetic results similar to the use of sutures.

Sebesta MJ et al.[126] in 2004 compared skin octylcyanoacrylate with subcuticular skin sutures to close laparoscopic trocar sites in their randomized, double-armed, prospective study was performed with 59 patients, in whom 228 trocar sites were closed. Twenty-nine patients underwent subcuticular closure of laparoscopic incisions, and 30 patients received closure with octylcyanoacrylate. Sutured trocar sites were closed with subcuticular 4-0 absorbable suture. Octylcyanoacrylate wounds received closure in accordance with the recommendations of the manufacturer (Ethicon, Somerville, NJ). The number of sutures or vials of octylcyanoacrylate used, closure times, and postoperative wound problems were recorded. Wounds were assessed 2 weeks postoperatively for healing complications. Closure costs were estimated using published operating room time per hour plus the cost of octylcyanoacrylate or suture. The Student paired *t* test was used for statistical analysis. he overall mean time for skin closure using octylcyanoacrylate and suture was 3.7 minutes and 14 minutes, respectively ($P<0.00001$). An average of 2.2 packets of suture were used to close all port sites, while those closed with octylcyanoacrylate required an average of 3.4 vials per patient. Wound complications consisted of subcuticular seroma with skin separation. No difference was noted in complication rates between the 2 groups. Study concluded that, Laparoscopic port-site skin closure with octylcyanoacrylate is rapid and effective. Closure with octylcyanoacrylate yields cost savings and a decrease in operative time of more than 9 minutes per case.

Maw JL et al.[134] in 1997 compared the tissue adhesive octylcyanoacrylate with subcuticular suture for the closure of head and neck incisions on 50 consecutive patients undergoing head and neck procedures at two University of Ottawa teaching

hospitals. The adhesive provided faster skin closure (29.7 seconds vs 289.0 seconds, $p < .0001$), and there were no differences in complications between the two groups. The primary outcome measure was the cosmetic appearance of the incision at 4 to 6 weeks. Although the adhesive group scored higher on both cosmesis scales, the visual analogue scale (octylcyanoacrylate 58.7 mm vs suture 53.2 mm) and the wound evaluation scale (57% vs 50% optimal wound scores), there were no statistical or clinically significant differences on either scale. The two facial-plastic otolaryngologists had good intraobserver and interobserver agreement when rating the cosmetic outcomes (0.87 and 0.71 respectively). Study concluded that, Octylcyanoacrylate was found to be an effective method of skin closure in clean head and neck incisions.

Primarily the ideal method of closure of surgical incision would be time saving without complication. Cosmetic outcome is the ultimate parameter by which we measure the quality of surgical incision repair. A number of prospective randomized controlled trials have been done for comparison of cosmetic outcome between tissue adhesive and subcuticular suture. Most of the studies have shown less wound closure time.

The present study demonstrated that tissue adhesive when used for closure of skin incision in a common surgical procedure like inguinal hernia is a faster method of wound closure when compared to suturing. But the frequency of complication using tissue adhesive is the same as that of subcuticular sutures.

CONCLUSION

Based on the findings of this study it may be concluded that, tissue adhesive when used for closure of skin incision in the settings of inguinal hernia repair is a faster method of wound closure when compared to suturing. Though the frequency of complication using tissue adhesive is less, statistically the frequency of complications is same as that of subcuticular sutures and equally safe as that of subcuticular sutures.

SUMMARY

Wounds can be closed by a variety of methods. Although the skill and technique of the surgeon are important, so is the choice of wound closure materials. However, the data comparing on tissue adhesive and conventional sutures for skin closure in the settings of open inguinal hernia is scant. This study was aimed to compare find out the incidence of post operative wound infection by Tissue adhesive versus conventional suturing in open inguinal hernia skin closure.

This one year hospital based randomized controlled trial was conducted in in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. A total of 60 patients undergoing unilateral and/or bilateral inguinal hernia repair from January 2015 to December 2015 were enrolled. Based on closed envelope method, these patients were randomly allocated into two groups method viz. Group A (skin closure with cyanoacrylate glue) and Group B (conventional skin closure).

All the patients were males in group A as well as in Group B (100%). Most of the patients were aged between 41 to 50 years (36.67%) in group A while in group B, the commonest age group was 18 to 30 years (33.33%) ($p=0.861$). The clinical characteristics of the study population that is, Mean Age, weight, pulse rate, systolic BP, and dialostic BP were comparable in group A and group B ($p>0.050$). Swelling in inguinal region was noted in all the patients of both the groups (100%). Most of the patients in group A and group B had Right inguinal hernia (46.67%) and indirect inguinal hernia was note in 56.67% of the patiente in Group A and 53.33% of the patients in group B (53.33%) ($p=0.795$). Significantly higher number of

patients in group A had duration of surgery between 60 to70 minutes in (93.33%) compared to (66.67%) group B (p=0.010). The mean duration of surgery was significantly low in group A (66.67 ±4.61 minutes) compared to group B (71.21 ± 6.90 minutes) (p=0.004). Swelling, fever and discharge was noted in 6.67% of the patients in group A while in group B, was present in 16.67% of the patients (p=0.228). Redness was seen in 6.67% of the patients in group A while in group B it was present in 10.00% of the patients (p=0.640).

Hence, closure of skin incision with tissue adhesive in the settings of inguinal hernia repair is a faster method of wound closure and equally safe as that of subcuticular sutures.

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ANNEXURE I – CONSENT FORM

Mr. /Mrs. /Miss. _____ we are requesting you to enroll yourself in study titled "a prospective randomised trial comparing tissue adhesive to conventional suturing in the closure of inguinal hernia skin incisions in KLES HOSPITAL & MRC, BELAGAVI" conducted by Dr. **** ***** ***** Post Graduate in M.S. General Surgery under the guidance of Dr. ******* ******* Associate Professor, Department of General Surgery, J. N. Medical College, Belagavi, under KLE university, Belagavi.

Respected Sir/Madam, We request you to enroll yourself to participate in our study as you are eligible for participating in the study. During the study your operative outcome will be accessed by some questions which will be answered by your operating surgeon.

Purpose of the study

In this study we are comparing tissue adhesive to conventional method of inguinal hernia skin incision closure. Purpose of study is to check post-operative skin infection and skin wound dehiscence.

Procedure Involved

If you agree to enroll your-self in my study, I will ask your present & past history You will undergo step wise physical examination and your routine blood and urine investigation will be carried out.

Risks and Benefits

Risk - There is no risk involved.

Benefits - Cyanoacrylate have more benefits over conventional suturing in inguinal hernia skin incision closure.

Alternatives

Even if you decline the participation in the study, your operative outcomes will not be documented. Your participation in this research is voluntary. You may choose not to enroll yourself in this study. Your decision will not change present or future health care services offered to you at K.L.E.S. Dr. Prabhakar Kore Hospital. If you decide to participate you are free to withdraw at any time.

Privacy and Confidentiality

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

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

Institutional/sponsors policy

There is no possibility of any harm or injury during your participation in this study.

Financial Incentives for participation

Financial incentives are being offered to enrolled patients. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator and provider.

Authorization to Publish Results

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

Questions

In case you have any questions related to the study, in future or in case of study related injury or illness, you can contact Dr. *** ***** ******, Department of General Surgery, KLES Hospital and MRC, Belagavi, phone number: **** *****. or Dr. ***** ****** ., Associate Professor, Dept Of General Surgery, KLES Hospital and MRC, Belagavi.

If you have any queries about your rights as a study subject, you may call Dr. **** ******* , Professor, Department of Pathology and Chairman, J. N. Medical College Institutional Ethical Committee for Human Subjects Research, Phone number- **** ****** , or extension **** at J. N. Medical College, Belagavi.

Consent for participation in prospective study

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

Subject Name : _____

Signature or the Left Thumb Print of Subject : _____

Date:

Witness Name: _____

Signature: _____

Date:

Investigators Name: _____

Signature: _____

Date:

Place: _____

ANNEXURE II – PROFORMA

"A PROSPECTIVE RANDOMISED CONTROL TRIAL COMPARING TISSUE ADHESIVE TO CONVENTIONAL SUTURING IN THE CLOSURE OF INGUINAL HERNIA SKIN INCISIONS IN KLES HOSPITAL & MRC,BELAGAVI." AT KLES DR. PRABHAKAR KORE HOSPITAL AND MRC, BELAGAVI."

Name & Address of the patient:

_____

_____

Age of the Patient : _____

In Patient Number : _____

Weight of Patient : _____

Sex : _____

Operating Surgeon : _____

History

Chief Complaints

Past History

History of Diabetes

Mellitus : Hypertension :

Asthma : Tuberculosis :

Previous surgeries

Other co-morbidities

Family History

General Physical Examination

Pulse :

Blood Pressure :

Temperature :

Systemic examination

Cardiovascular System: Respiratory System :

Central Nervous system: Per abdomen :

Investigations

Diagnosis

Proposed Surgery :

Inguinal hernia repair :

Inclusion Criteria :

All patients undergoing inguinal hernia repair who gives written consent for the study.

Exclusion Criteria

Patients who have not given the informed and written consent to participate in the trial.

Patients with co-morbid conditions like renal failure, connective tissue disorders, peripheral vascular disease, infected wounds, substance abuse, malnourished and general debility.

Patients with Metabolic disorders, drugs impairing wound healing ,coagulation disorders, steroids, chemotherapeutic drugs, Radiotherapy, immno-compromised status, collagen vascular disease , documented drug allergy, recurrent hernia strangulated hernia and obstructed hernia.

Local causes like Burns, Keloids, Urticaria, Ulcers and h/o Trauma.

Name :

Age / sex :

In Patient Number :

Operative outcome :

J) Duration of surgery : _____ minutes.

k) Open procedure : yes

Signature of operating surgeon:

ANNEXURE III-KEY TO MASTER CHART

BP	-	Blood pressure
Mm Hg	-	Millimeters of mercury
Kgs	-	Kilograms
/Minute	-	Per minute
^{0}C	-	Degree centigrade
M	-	Male
N	-	Normal
CI	-	Cough impulse
B/L	-	Bilateral
Lt	-	Left
Rt	-	Right
D	-	Direct
ID	-	Indirect
+	-	Present
-	-	Absent