"RANDOMISED CONTROL TRIAL OF STERI STRIPS VERSUS SUBCUTICULAR SUTURING IN SKIN CLOSURE OF OPEN INGUINAL HERNIA"

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ENDORSEMENT

This is to certify that the dissertation entitled **"RANDOMISED CONTROL TRIAL OF STERI STRIPS VERSUS SUBCUTICULAR SUTURING IN SKIN CLOSURE OF OPEN INGUINAL HERNIA"** is a bonafide research work done by **CANDIDATE REG NO. BH0114003**.

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LIST OF ABBREVIATIONS USED

NAS	-	Non-absorbable suture
AS	-	Absorbable stitches
eg,	-	For example,
cm	-	Centimeter
MPO	-	Myopectineal orifice
EHS	-	European Hernia Society
L	-	Lateral
M	-	Medial
F	-	Femoral
P	-	Primary
R	-	Recurrent
BC	-	Before Christ
PPM	-	Polypropylene mesh
CDC	-	Centers for Disease Control
SSIs	-	Surgical site infections
HAIs	-	Healthcare associated infections
NNIS	-	National Nosocomial Infection Surveillance
US	-	United States
E. coli	-	*Escherachiae coli*
CFU	-	Colony-forming units
mg	-	Milligram
EPS	-	Extracellular polymeric material
PDS	-	Polydioxanone
SD	-	Standard deviation

p	-	Probability value
h/o	-	History of
HIV	-	Human immunodeficiency virus
HbSag	-	Hepatitis B surface antigen
mL	-	Milliliter
n	-	Total number
Kg	-	Kilogram
BP	-	Blood pressure
mm Hg	-	Millimeters of mercury
CI	-	Confidential interval
vs	-	Versus

ABSTRACT

Background and objectives

The skin closure with steri strips can reduce the complications like wound infection. The present study was aimed to compare the frequency of post operative wound infection by steri strips and subcuticular suturing in open inguinal hernia skin closure.

Methodology

The one year present hospital based randomized controlled trial 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. A total of 60 patients undergoing inguinal hernia repair were enrolled. These patients were randomly allocated into two groups based on simple randomization that is Group A (subcuticular skin closure group) and Group B (skin closure was done by steri strips).

Results

The clinical and demographic characteristics of the study population that is, sex, Mean Age, weight, pulse rate, systolic BP, and dialostic BP did not differ significantly in group B and group A ($p>0.050$). All the patients in group A and group B had Swelling in inguinal region (100%). Most of the patients in group A and group B had Right inguinal hernia (46.67%) ($p=0.748$) while 56.67% of the patients in group A (56.67%) and group B (53.33%) had indirect hernia ($p=0.795$). The mean duration of surgery was significantly less in group B (64.00 ± 2.32 minutes) compared to group A (69.3 ± 7.28 minutes) ($p<0.001$). The rate

of post operative wound infection including swelling (p=0.148), fever (p=0.421), redness (p=0.148) and discharge (p=0.421) were comparable in Group A and Group B.

Conclusion and interpretation

There is no statistical significance of wound infection in either of groups i.e subcuticular skin suturing group (Group A) & Steri Strips group (Group B). The study probably will need a larger sample size.

Keywords

Open inguinal hernia repair; Steri strips; Skin closure; Subcuticular suture; Surgical site infection;

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INTRODUCTION

A Hernia is defined as protrusion of whole or a part of a viscus through the wall that contains it.[1] Many different types of abdominal wall hernias have been identified, along with a larger number of associated eponyms and are brought to the attention of a physician either during a routine physical examination for other medical complaints or when the patient has developed a complication associated with the hernia.[2]

Inguinal hernias are common throughout the world. Inguinal hernias occur in about 15% of the adult population, and inguinal hernia repair is one of the most commonly performed surgical procedures in the world.[3] These account for almost 75% of all forms of hernias. These are more common in males than females in a ratio of 20:12.[4] In developed countries like United States, approximately 800,000 mesh hernioplasties are performed each year,[5] 100,000 in France, and 80,000 in the United Kingdom.

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.[6]

A number of studies have been reported in search of improving the skin closure related outcome measures following various surgical procedures, and due to this fact the skin closure techniques are evolving vastly and immensely, predominantly over the last few decades. Innumerable skin closure methods reported in medical literature include continuous stitch closure, interrupted stitch closure, full thickness closure, sub-cuticular closure, primary closure, secondary closure, vacuum assisted closure, glue assisted closure, skin clips or staples closure, simple suture *vs* mattress sutures, steri-strips closure, absorbable or non-absorbable suture (NAS) closure and other innovative methods.[7] These manifold practices of skin approximation after surgical procedures can jointly be classified into two groups. Group I includes the use of NAS for skin closure requiring additional clinical care due to the need of removal of stitches or metallic staples. Group II includes the use of absorbable stitches (AS) or glue which does not require additional clinical care like the groupI. The proponents of the use of NAS for skin closure claim that an increased tensile strength of NAS keep wound margins adequately coapted resulting in optimal wound and skin healing.[8-10] The supporters of AS advocate similar effectiveness in wound healing without the requirement of additional clinical care in addition to the benefits of an improved cosmetic outcome and the reduced risk of surgical site infection.[11-14] Due to significant differences in the opinion, the general consensus about the use of either absorbable AS or NAS is still lacking.[7]

Though subcuticular sutures are used conventionally since many years, they are associated with disadvantages like needle puncture marks, suture canal scaring and wound infection. It was observed that these complications can be reduced by not introducing suture material in to the wound. Which can be done by using steri strips. It is also reported that steri strips are cost effective compared to staplers and the time taken for skin closure using steri strips is less compared to that of subcuticular sutures.[15] The advantages of tapes include ease of use, comfort to the patient, and avoidance of tissue strangulation, infection, and crosshatch marks.[16]

This prompted us to find out the incidence of post operative wound infection by steri strips versus subcuticular 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 steri strips versus subcuticular 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.[17]

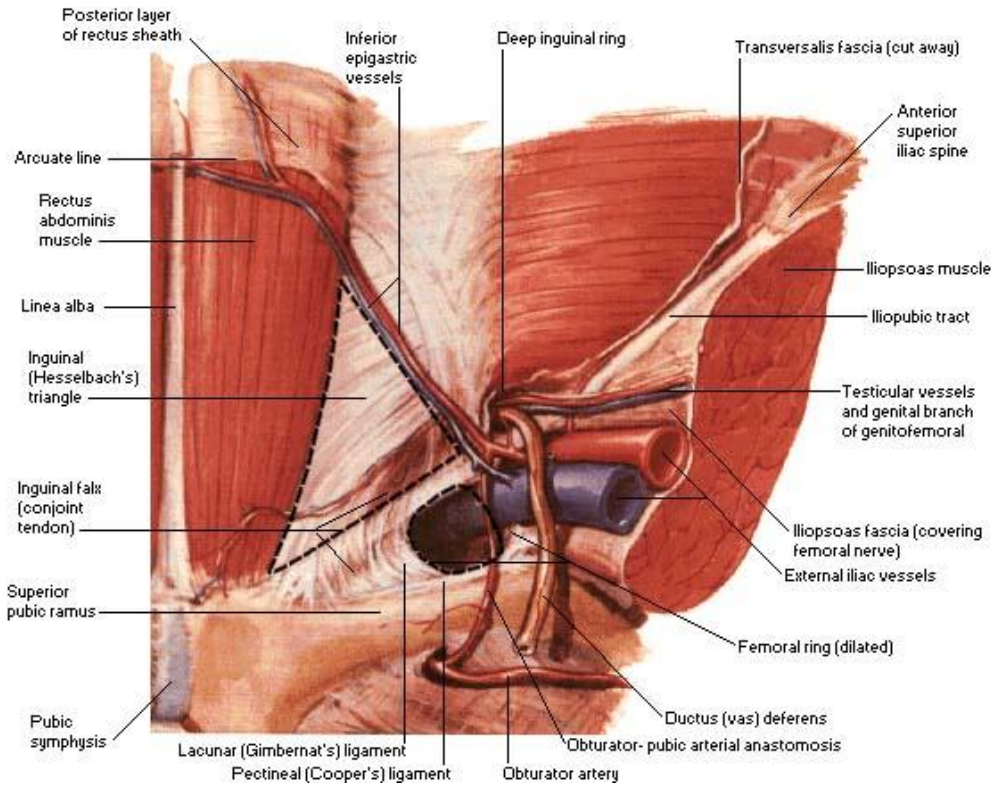


Figure 1. Anatomy of inguinal canal[18]

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.[19]

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

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

Major muscles of the abdominal wall are the *external and internal oblique muscles*, 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), there is deficient of posterior sheath, 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 inguinal ligament 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 *conjoint 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).[20] 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 there 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.[21]

- 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 dissect from the anterior approach. It varies considerably in its thickness, thus making its identification from either approach questionable.[19]

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.[19]

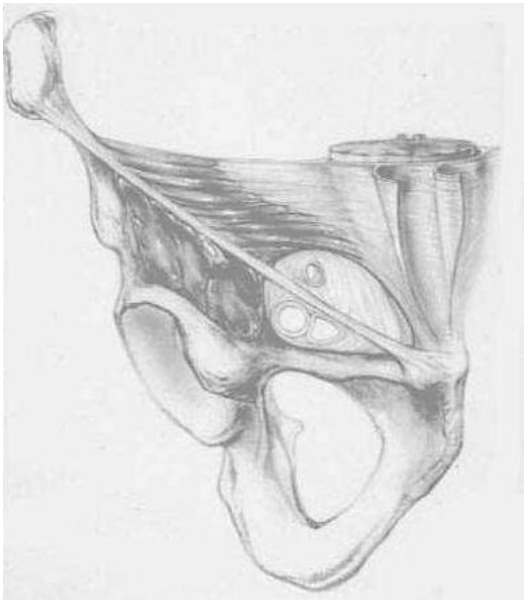


Figure 2. The myopectineal orifice. The passageway for the great vessels to the lower extremity, and for the testicle to reach the scrotum[19]

- 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 plane by the spermatic cord, and through its inferior plane by the femoral vessels.

- The MPO is protected only by the combined lamina of the aponeurosis of the transversus abdominus and the transversalis fascia.[19]

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 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.[19]

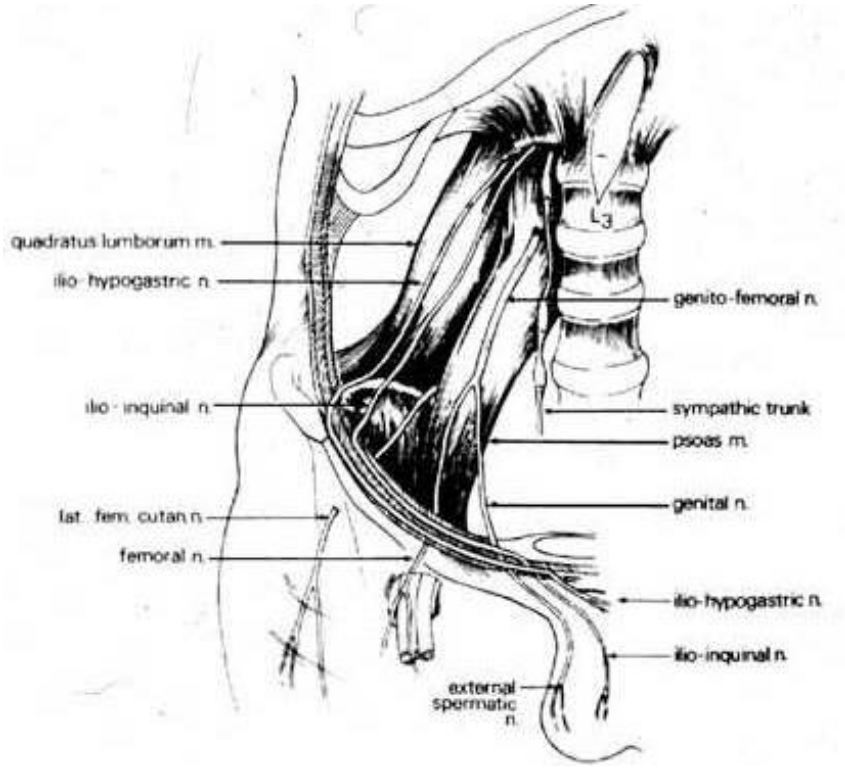


Figure 3. Nerve supply to the groin[19]

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 muscle 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 lumbar 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 3 nerves are mainly sensory but do supply some motor function to the internal oblique and cremasteric muscles of the spermatic cord.[19]

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 of description of combined and femoral hernias.[24]

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.[26]

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.[22]

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.[22]

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.[27]

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.[28]

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 inguinal hernia repair. Refinements in minimally invasive hernial repair techniques, along with evolving medical technologies have changed the present day scenario altogether.[27]

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.[27]

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.[27]

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.[29]

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,[30] 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.[29]

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.[27]

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.[27]

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[33] 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[34] first described the posterior approach to inguinal hernia repair. Cheatle[35] revitalized the issue of posterior preperitoneal approach. Henry[36] 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 inguinal hernias.[37] 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.[29] Recurrence following Shouldice repair is in general less, the best reports are from Shouldice Clinic.

SURGICAL SITE INFECTIONS

Definition

Surgical site infections are infections present in any location along the surgical tract after a surgical procedure. SSIs involve postoperative infections occurring at any level (incisional or deep) of a specific procedure. SSI 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.[38]

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 has shown 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.[39]

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.[40]

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%.[41] 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)[70] 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.[70,71] 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.[71]

In 1980, Cruse estimated that a SSI increased a patient's hospital stay by approximately 10 days and cost an additional $2,000.[72] A 1992 analysis showed that, each SSI resulted in 7.3 additional postoperative hospital days, adding $3,152 in extra charges.[45] Other studies corroborate that increased length of hospital stay and cost are associated with SSIs.[46] 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.[47]

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.[48] 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.[49]

Classification

Classification of operative wounds contamination[50]

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[50]

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.

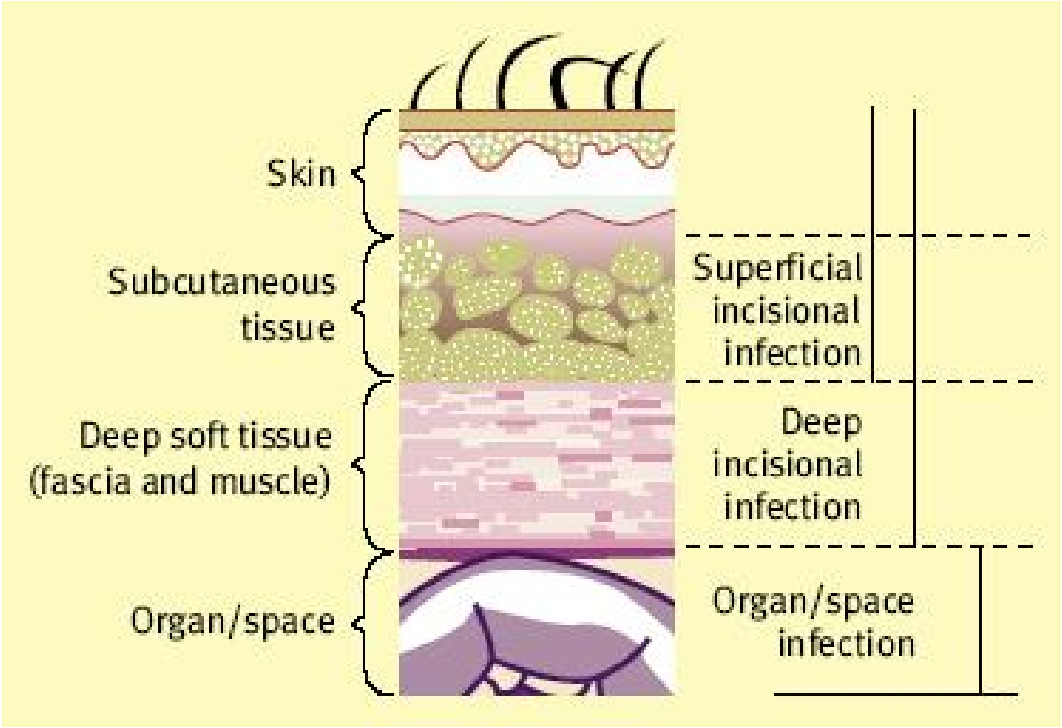


Figure 4. Schematic representation of the anatomical classification of surgical site infections[51]

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.[44] 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%.[51] There is, however, considerable variation in each class according to the type of surgery being performed.[52]

An Indian study[53] 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.

isk factors

Risk factors associated with SSIs[54]

	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 [54]

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 retractor, 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:[55]

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).[56]

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.[57] One of the most common causes of multiple system organ failure in modern surgical care is intraabdominal infection.[58] Some bacterial surface components, notably polysaccharide capsules, inhibit phagocytosis,[59] 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.[60] A variety of microorganisms, including gram-positive bacteria such as coagulase negative staphylococci, produce glycocalyx and an associated component called "slime,"[61] which physically shields bacteria from phagocytes or inhibits the binding or penetration of antimicrobial agents.[62] Although

these and other virulence factors are well defined, their 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.[63] When mucous membranes or skin is incised, the exposed tissues are at risk for contamination with endogenous flora.[64] These organisms are usually aerobic gram-positive cocci (staphylococci), but may include fecal flora (anaerobic bacteria and gram-negative 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, gram-negative 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,[65] particularly in patients who have a prosthesis or other implant placed during the operation. Such devices provide a nidus for attachment of the organism.[61]

Exogenous sources of SSI pathogens include surgical personnel (especially members of the surgical team),[66] the operating room environment (including air), and all tools, instruments, and materials brought to the sterile field during an operation. Exogenous flora are 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.[67]

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*. In analyses of contamination rates after cholecystectomy, the main source of wound contamination was found to be the skin of the patient. 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.[68] 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. 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%. 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%.[68] If shaving is essential, it should be performed as close to the time of surgery as possible.

Skin closure

Incision care and/or skin closure refers to a series of procedures and precautions related to closing a wound or surgical incision; protecting the cut or injured tissues from contamination or infection; and caring properly for the new skin that forms during the healing process. It begins in the hospital or outpatient clinic and is continued by the patient during recovery may be at home. There are several reasons for caring properly for an incision or wound. These include lowering the risk of postoperative complications, particularly infection avoiding unnecessary pain or discomfort. minimizing scarring, preventing blood loss

Proper skin closure begins with knowing what material or technique is used to close incision. There are four major types of closure used viz. surgical sutures, staples, steri strips and liquid tissue glues

Surgical sutures

Sutures, or stitches, are the oldest method still in use to close an incision. The surgeon uses a sterilized thread, which may be made of natural materials (silk or catgut) or synthetic fibers, to stitch the edges of the cut together with a special curved needle. There are two major types of sutures, absorbable and non-absorbable. Absorbable sutures are gradually broken down in the body, usually within two months. Absorbable sutures do not have to be removed. They are used most commonly to close the deeper layers of tissue in a large incision or in such areas as the mouth. Nonabsorbable sutures are not broken down in the body and must be removed after the incision has healed. They are used most often to close the outer layers of skin or superficial cuts.[69]

Sutures have several disadvantages. Because they are made of materials that are foreign to the body, they must be carefully sterilized and the skin around the incision cleansed with Betadine or a similar antiseptic to minimize the risk of infection. Suturing also requires more time than newer methods of closure. If the patient is not under general anesthesia, the surgeon must first apply or inject a local anesthetic before suturing. Lastly, there is a higher risk of scarring with sutures, particularly if the surgeon puts too much tension on the thread while stitching or selects thread that is too thick for the specific procedure.[69]

Surgical staples

Surgical staples are a newer method of incision closure. Staples are typically made of stainless steel or titanium. They are used most commonly to close lacerations on the scalp or to close the outer layers of skin in orthopedic procedures. They cannot be used on the face, hand, or other areas of the body where tendons and nerves lie close to the surface. Staples are usually removed seven to 10 days after surgery.[69]

Staples are less likely to cause infections than sutures, and they also take less time to use. They can, however, leave visible scars if the edges of the wound or incision have not been properly aligned. In addition, staples require a special instrument for removal.[69]

Steri-strips

Steri-strips are pieces of adhesive material that can be used in some surgical procedures to help the edges of an incision grow together. They have several advantages, including low rates of infection, speed of application, no need for local

anesthesia, and no need for special removal. Steri-strips begin to curl and peel away from the body, usually within five to seven days after surgery. They should be pulled off after two weeks if they have not already fallen off. Steri-strips, however, have two disadvantages: they are not as precise as sutures in bringing the edges of an incision into alignment; and they cannot be used on areas of the body that are hairy or that secrete moisture, such as the palms of the hands or the armpits.[69]

Liquid tissue glues

Tissue glues are the newest type of incision closure. They are applied to the edges of the incision and form a bond that holds the tissues together until new tissue is formed. The tissue glues most commonly used as of 2003 belong to a group of chemicals known as cyanoacrylates. In addition to speed of use and a low infection rate, tissue glues are gradually absorbed by the body. They are less likely to cause scarring, which makes them a good choice for facial surgery and other cosmetic procedures. They are also often used to close lacerations or incisions in children, who find them less frightening or painful than sutures or staples. Like Steri-strips, however, tissue glues cannot be used on areas of high moisture. They are also ineffective for use on the knee or elbow.[69]

Although, during the last half century, there has been plenty of evidence that the healing of skin wounds is hindered by suture closure and fostered by the use of surgical tapes, the latter technique has not been widely practiced, because the adhesiveness of surgical tapes has been deemed too unreliable. When used at all, tapes have generally been applied only over subcuticular and subcutaneous sutures. The author describes his experience in using a new transparent adhesive tape for

primary wound closure of 37 surgical incisions without underlying sutures. The series involved a wide range of surgical wounds, in various portions of the body. In all cases, the results were excellent; neither major nor minor complications were observed. Compared with suture closure, this method was associated with a reduced potential for infection, faster renewal of tensile strength, greater cost effectiveness, and better cosmetic effects.[70]

The absorbable continuous subcuticular suture is frequently used to close surgical incisions where the aim is healing by primary intention. A form of adhesive surgical tape is commonly also placed over the wound but this combination closure seems to have its development based on anecdotal, rather than experimental evidence.[71]

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.[68]

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.[72]

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.[73] Sutures are a contributory factor in infection; in fact, 66% of SSIs are related to the incision.[74]

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.[75]

In fact, it is postulated that in the presence of sutures, only 100 colony-forming units (CFU)/mg are necessary to produce infection.[76] 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.[77]

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.[78]

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 microorganisms such as bacteria, yeasts, algae, fungi, or protozoa attach to surfaces.[79]

A study[80] 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 study[81] 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.[82]

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.[82]

Classification of sutures

There are 3 main classifications of suture materials.[83]

Based on no. of strands

Monofilament

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

Multifilament

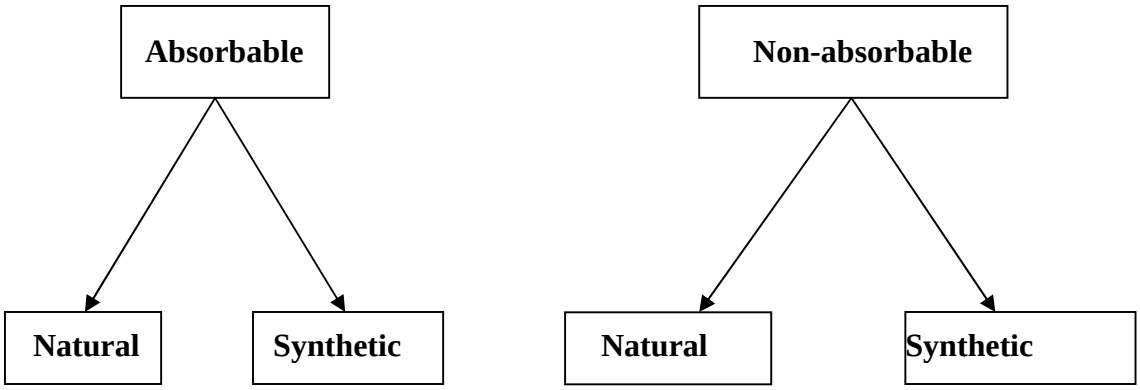
Vicryl (Polyglactin 910), Vicryl plus, Dexon (polyglycolic suture), Silk, Mersilene (Braided polyester)

Based on source

Natural or Synthetic

Based on absorption

Absorbable or Non-absorbable



New devices and technologies are constantly emerging in the market, and they are often widely adopted before scientific comparison to the preexisting accepted standard. For many of the operations performed by surgeons, the lengthy closure time of the procedure adds significantly to the costs, increases anesthetic time, and potentially increases patient risk. New approaches to wound closure that result in shortened operative time, while improving or at least not compromising quality, may be justified despite the apparent increase in device cost compared with standard suturing techniques. Technological innovations are often adopted before scientific comparison to an accepted standard.[84]

Van De Gevel et al.[85] demonstrated that the Steri-Strip™ brand of coaptive film is a reasonable and safe alternative to sutures without incidence of wound

infection, dehiscence or skin irritation. Kerrigan and Homa found that Steri-Strips™ permits faster wound closure than suture,[84] and Lazar et al.[86] reported that Steri-StripTM decreases erythema. These above mentioned studies were performed by cardiothoracic surgeons[84-86] or plastic surgeons.[85]

Rebello and colleagues conducted a randomized controlled trial comparing coaptive film (Steri-Strip™) and sutures in children with cerebral palsy undergoing soft tissue releases,[87] and concluded that Steri-Strips™ takes less time to close the skin than sutures; they reported no wound complications and the resulting scars produced similar cosmetic results. These findings were further supported by Grottkau et al who used Steri-Strips™ compare to sutures in children undergoing posterior spinal fusion with instrumentation.[88] They concluded that Steri-Strips™ are time-savers for skin closure following paediatric spine surgery, and produced comparable cosmetic results with no increase in complication rates. We found no reports comparing coaptive film (Steri-StripsTM) to sutures for skin closure in routine orthopaedic trauma surgery.

The difference in skin thickness between the limbs and trunk[89] can affect wound dehiscence and infection in orthopaedic surgery.[90]

Earlier in 1987 Pederson VM et al.[91] performed skin closure Following 264 non-contaminated abdominal operations, after randomization to Steri-Strip tape suture or conventional continuous 3-o or 4-o Dermalon suture. The cosmetic results were evaluated six and 46 months after the operation. In the six-month review Steri-Strip tape suture showed advantages over conventional suturing. However, follow-

up of 217 patients revealed no significant differences in late cosmetic results after about four years.

Papicello J. et al.[92] in 1989 carried out a retrospective, five year analysis of 350 wounds from intra-abdominal operations, using Steri-Strip (3M) skin closures as the sole method of skin closure. No subcutaneous or subcuticular sutures were used. The average age of the patients was 53.5 years, and the average duration of follow-up study was 194 days. The rate of wound infection was 1.14 per cent, far lower than that in any other historical trails used for comparison. The over-all complication rate that was attributed solely to the method of skin closure was 4.57 per cent. This compares favorably with those in historical trials. Advantages of a taped skin closure are lower rates of infection and over-all morbidity, a lower cost and a reduction in time in the operating room when compared with conventional methods. Foreign body granulomas and cellulitis were avoided. Strangulation and necrosis of tissue were eliminated because of gentle handling of tissue. Needle puncture marks and suture canal scarring were eliminated. These factors lead to a better cosmetic result.

Kolt JD et al.[71] in 2003, reviewed the scientific literature on the development of sutureless wound closure and presents the current evidence for the use of combination wound closure. Review was undertaken of the medical literature using the PubMed Internet database and cross-referencing major -articles on the subject. The following combinations of key words were searched: skin closure, wound closure, suture technique, sutureless, adhesive tape, op-site, staples, subcuticular suture, complication, infection and scars. Taped closure alone has advantages of lower wound infection rates and greater wound tensile strength, but disadvantages of

epidermal reaction, skin edge inversion, doubtful safety and time required for meticulous surgical technique. The use of the continuous absorbable subcuticular suture allows accurate skin edge approximation, which increases the safety margin. The combination closure has a slightly superior cosmetic result to sutureless techniques but no study has been performed to compare the results of combination subcuticular suture and tape, with tape or subcuticular suture alone. Study opined that, there is no evidence in the scientific literature to justify or support the practice of closing a surgical wound with both subcuticular suture and adhesive surgical tape.

In 2010, Kerrigan CL. and Homa K.[84] compared suture with a new coaptive film device, 3M Steri-Strip S Surgical Skin Closure, on linear incisions. Patients undergoing Wise-pattern breast reduction or abdominal procedures had paired incisions randomly assigned to Steri-Strip S or suture closure. Key outcome measures were closure time, patient comfort, and scar quality at 6 months by patients and surgeons using a new scar evaluation tool, visual assessment of linear scars. Statistical differences between the two closure techniques were assessed by Wilcoxon signed rank test. Of 59 patients, eight were excluded from randomization (a surgeon judged Steri-Strip S to be a nonviable closure technique for mismatched wound edges). Fifty-one patients (breast, n = 24; abdomen, n = 27) were randomized. Operative time with Steri-Strip S for breast was 2.0 minutes (SD = 1.1) versus suture closure at 4.6 minutes (SD = 1.5; $p < 0.001$). Similarly, Steri-Strip S versus suture for the abdomen was faster ($p < 0.001$; 4.9 minutes, SD = 2.3 versus 10.1 minutes, SD = 3.4). Comfort scores did not differ between closures [5.8 (SD = 2.7) versus 6.9 (SD = 2.0), respectively, on breast ($p = 0.142$) and 7.7 (SD = 1.8) versus 7.7 (SD = 2.3) on abdomen ($p = 0.903$)]. Complication rates did not differ between closure

types. Patients' visual assessment of linear scars rating of breasts was 3.8 (SD = 2.9) for Steri-Strip S and better at 2.6 (SD = 2.9) for suture (p = 0.008). One surgeon rated breast Steri-Strip S scars worse than suture scars (4.3 versus 3.7; p = 0.014). For abdominal scars, there was no difference in the patient or surgeon ratings. Study concluded that, Steri-Strip S permits faster wound closure than suture. On the basis of patient reports of comfort and scar quality, surgeons increase efficiency and maintain quality with the use of Steri-Strip S on abdominal wounds but not on breast wounds.

A Liew S, Haw CS[93] conducted a study in which steri strips were used for skin closure in intra abdominal operations. It was proved that taped skin closure has lower rate of infection,lower cost and reduction in time while closing skin.Needle puncture marks and suture canal scarring are eliminated.

A study was done by Traub AC and Quattlebaum FW[94] mentioning the cosmetic result cost effectiveness and complication rate of three different types of skin closures : staples,tapes and interrupted sutures. It was proved that tapes were most cost effective because they are cheapest.

Rcently a prospective randomized study by Lazar HL et al.[86] was undertaken to compare the use of the 3M Steri-Strip™ S Surgical Skin closure system with a running absorbable subcuticular suture technique for skin closure following a mediansternotomy for cardiac surgical procedures. Thirty-six patients undergoing a mediansternotomy for a cardiac surgical procedure were prospectively randomized to either Steri-Strip S or subcuticular suture for wound closure. The wounds were evaluated on postoperative days 7 and 21 for erythema, edema, pain, cosmesis, and

the time taken to close the incision. Skin closure with Steri-Strip S was faster (5.33 ± 1.32 minutes steri-strips vs. 6.07 ± 0.91 sutures; p = 0.06) and resulted in significantly less erythema and edema, but no difference in pain or cosmesis after seven days. Following 21 days, there was no difference in pain, edema, or cosmesis between the groups. However, patients receiving steri-strips continue to have less erythema. Study concluded that, both Steri-Strip S and absorbable sutures are effective techniques for skin closure following a mediansternotomy incision for cardiac surgical procedures. Steri-Strip S can decrease the amount of erythema, but results in no significant difference in pain, cosmesis, or edema compared to the traditional subcuticular wound closure technique.

More recently, Ramdhan IMA et al.[95] reported that, the use of coaptive film for wound closure after long bone fracture fixation has not been well documented in the literature. *Methods:* The aim of this prospective, randomized controlled trial comparing coaptive film with sutures for wound closure after long bone fracture fixation was skin closure time, incidence of wound complications and scar width at 12 week follow-up. Forty-five patients underwent femur fracture fixation (22 patients' wound closed with sutures, 23 with coaptive film). *Results:* The mean time for skin closure using coaptive film was 171.13 seconds compared to 437.27 seconds using suture. The mean wound lengths in the coaptive film group and suture group were 187.65 mm and 196.73 mm, respectively. One patient in each group had wound complications. *Conclusion:* Coaptive film is a time-saving procedure for skin closure following long bone fracture fixation. There is no difference in the incidence of wound complications and scar width between these two methods of skin closure.

METHODOLOGY

The present study was carried out in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi 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, Belagavi attached to KLE University's Jawaharlal Nehru Medical College, Belagavi.

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,

$$n = \frac{2(1.96+0.84)^2 3x97}{4x4}$$

$$=60$$

Therefore 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 simple randomization.

Selection criteria

Inclusion

- Patients undergoing unilateral and/or bilateral inguinal hernia repair.

Exclusion

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

- Patients with co-morbid conditions like diabetes, immunocomprimised, recurrent hernia, strangulated hernia and obstructed hernia.
- Local causes like Burns, Keloids, Urticaria, Ulcers and h/o trauma.

Ethical clearance

The study was approved from the Ethical and Research Committee, Jawaharlal Nehru Medical College, Belagavi.

Informed Consent

The 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 inguinal hernia repair using similar instruments and accepted general principles of surgery.

Closure technique

The closure of wound was done in two layers.

Intervention

Group A

Patients in this group underwent subcuticular skin closure.

Group B

Patients in this group underwent skin closure with steri strips.

Photograph 1. Application of steri strips

Photograph 2.Subcuticular suturing

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 wound was inspected and evaluated for swelling, redness and discharge/pus from the wound, if any and fever, on postoperative day 3.

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.[23]

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 $\leq$ 0.050 at 95% confidence interval was considered as statistically significant.

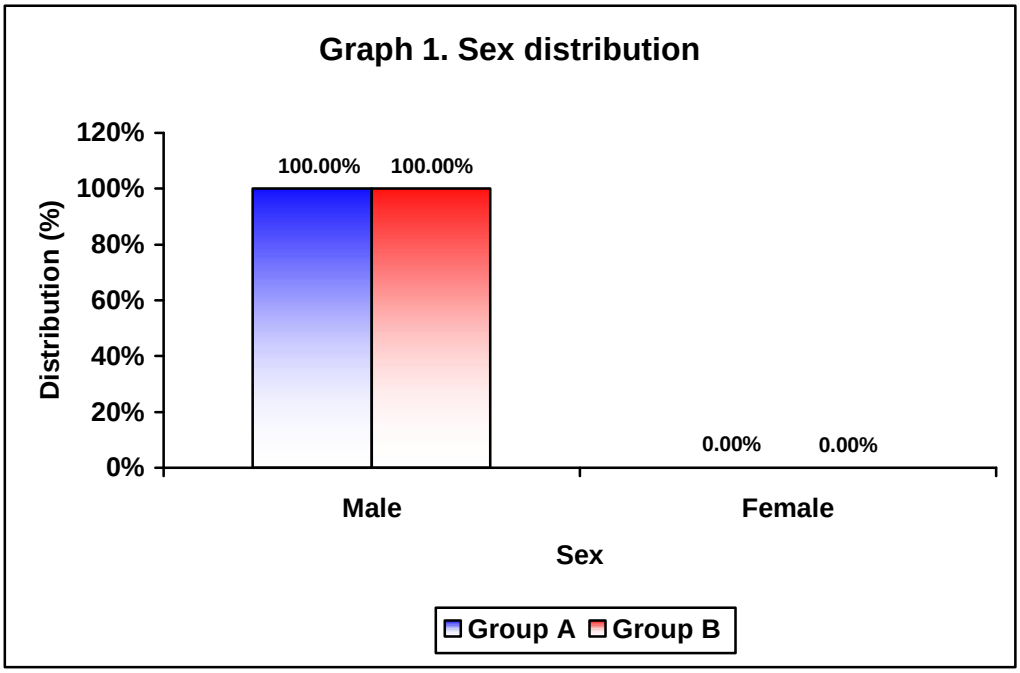
RESULTS

The one year present hospital based randomized controlled trial was carried out in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2015 to December 2015. A total of 60 patients undergoing unilateral and/or bilateral inguinal hernia repair were enrolled. These patients were randomly allocated into two groups based on simple randomization that is Group A (Patients in this group underwent subcuticular skin closure) and Group B (Patients in this group underwent skin closure with steri strips).

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

Table 1. Sex distribution

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**

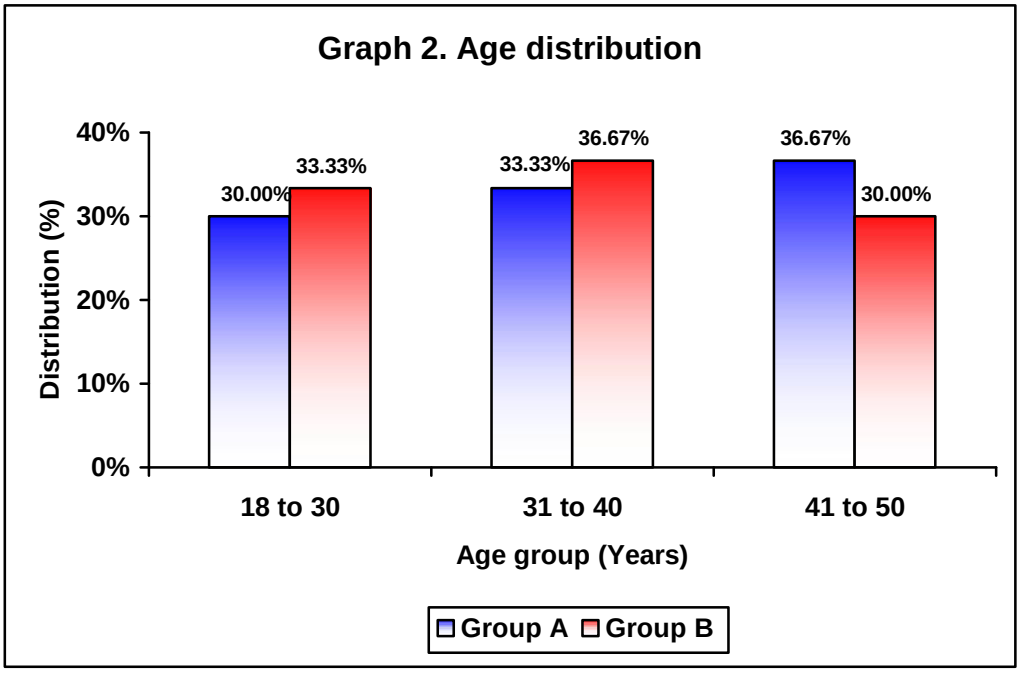


In the present study all the patients were males in group A as well as Group B (100%).

Table 2. Age distribution

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

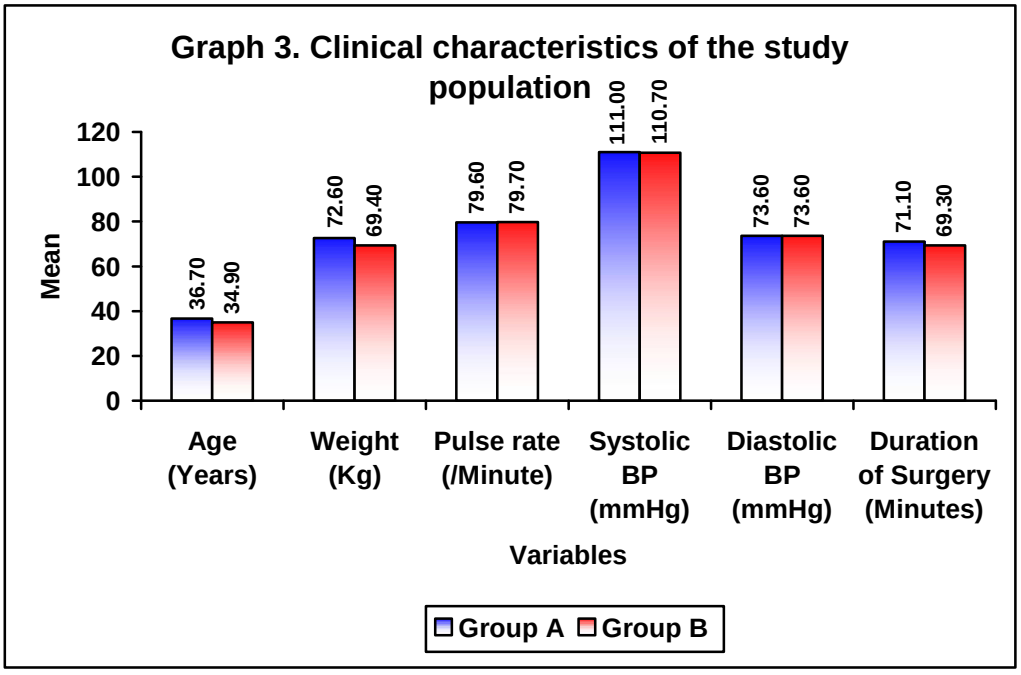
p = 0.861



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)	36.70	8.05	34.90	8.04	0.399
Weight (Kg)	72.60	8.78	69.40	11.05	0.219
Pulse rate (/Minute)	79.60	5.46	79.70	6.42	0.966
Systolic BP (mm Hg)	111.00	10.61	110.70	8.80	0.927
Diastolic BP (mm Hg)	73.60	9.63	73.60	8.50	1.000
Duration of Surgery (Minutes)	71.10	6.78	69.30	7.28	0.317



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. However, all these variables did not differ and comparable in group B and group A ($p>0.050$).

Table 4. Chief complaints

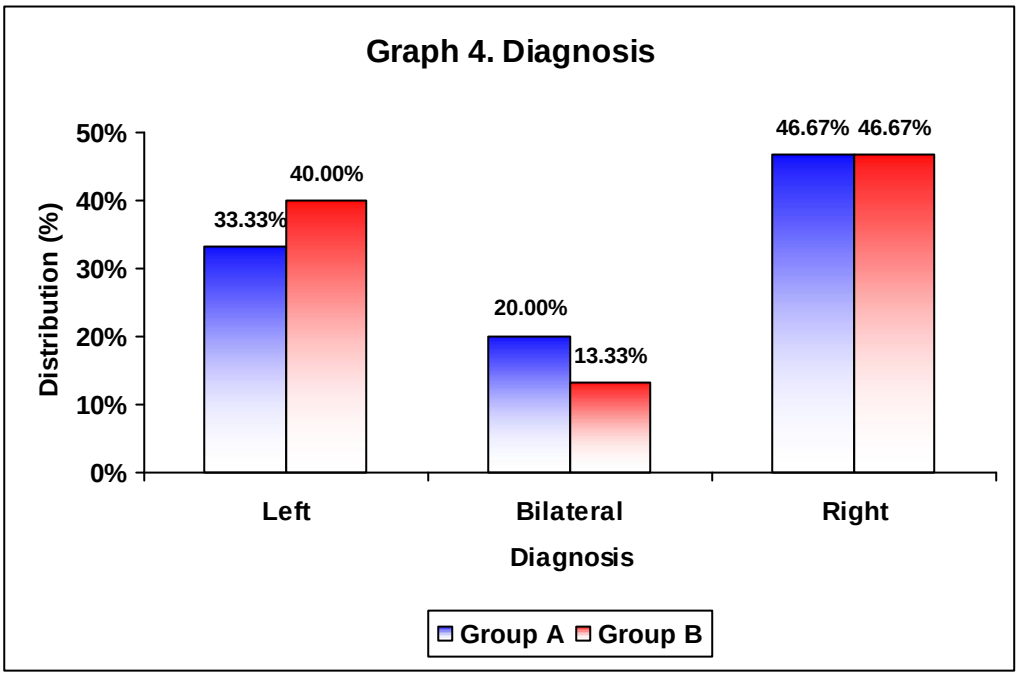
Chief complaints	Group A (n=30)		Group B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
Swelling in inguinal region	30	100.00	30	100.00
Total	**30**	**100.00**	**30**	**100.00**

In this study all the patients in group A and group B had swelling in inguinal region (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

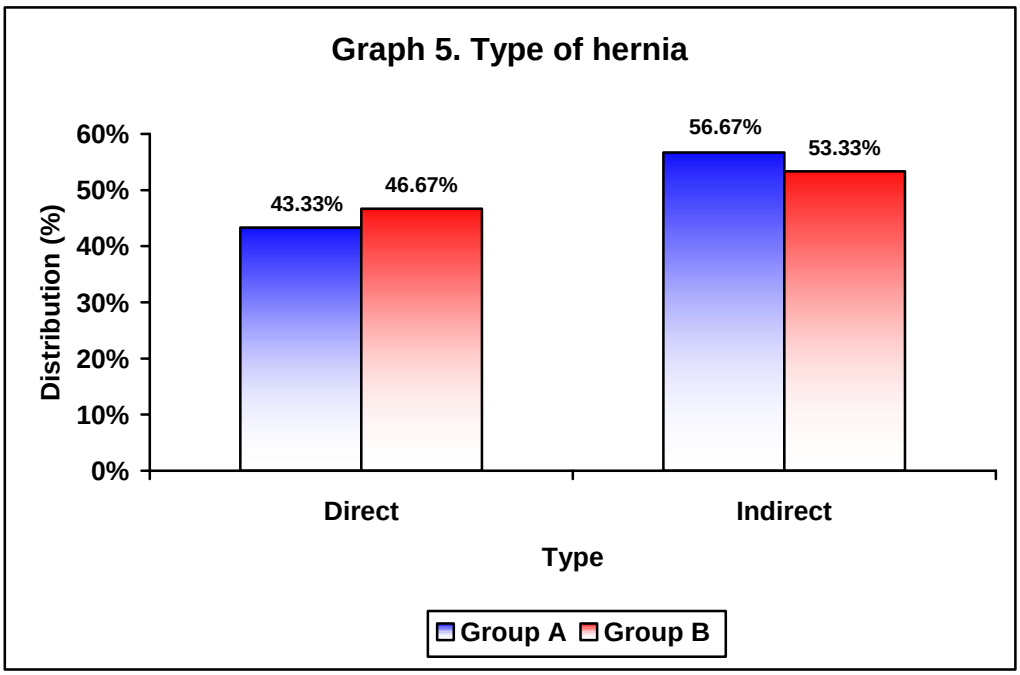


In the present study most of the patients in group A and group B had right inguinal hernia (46.67%) (p=0.748).

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

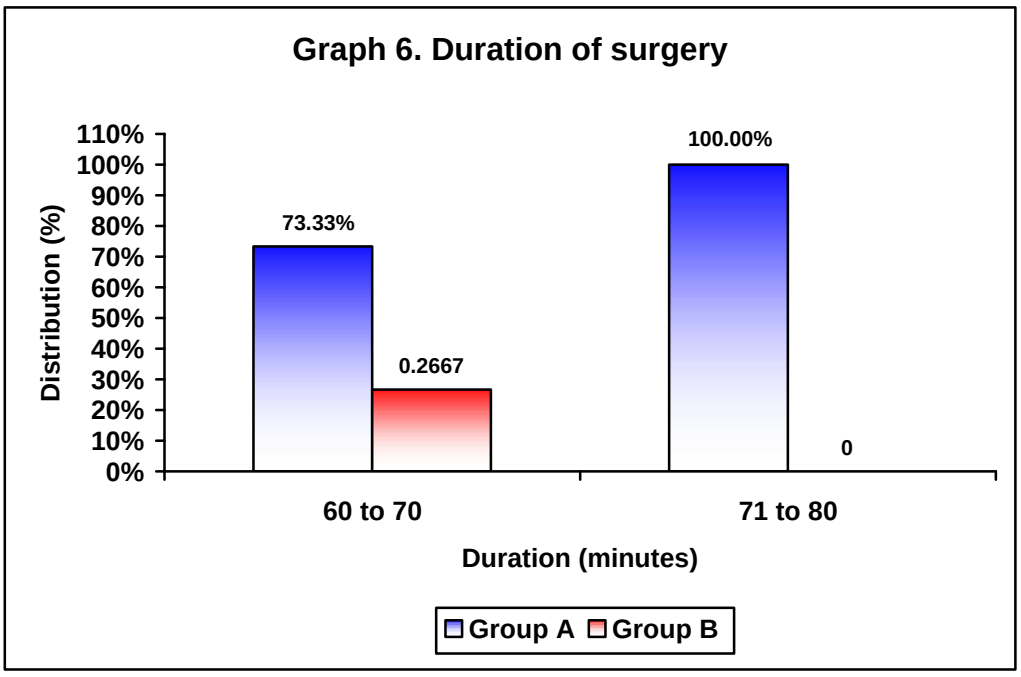


In the present most of the patients in group A (56.67%) and group B (53.33%) has indirect hernia (p=0.795).

Table 7. Duration of surgery

Duration (minutes)	Group A (n=30)		Group B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
60 to 70	22	73.33	30	100.00
71-80	8	26.67	0	0.00
Total	**30**	**100.00**	**30**	**100.00**

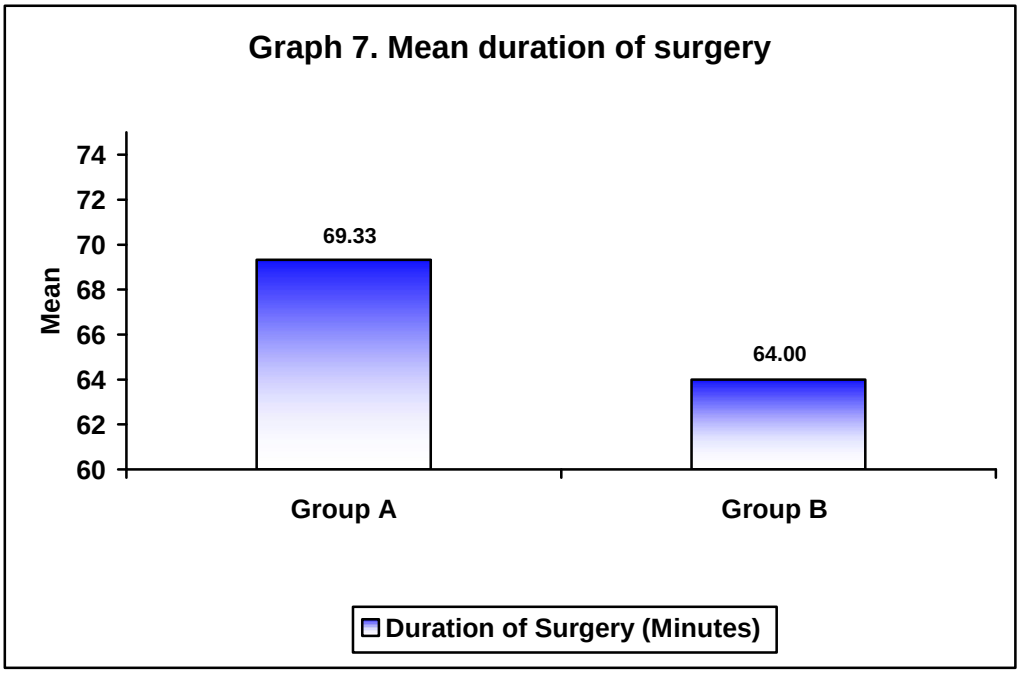
p = 0.002



In this study all the patients in group B had duration of surgery between 60 to 70 minutes (100%) while in group A, 73.33% of the patients had duration of 60 to 70 minutes and 26.67% of the patients had 71 to 80 minutes. This difference was statistically significant (p=0.002).

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)	69.33	7.28	64.00	2.32	0.001

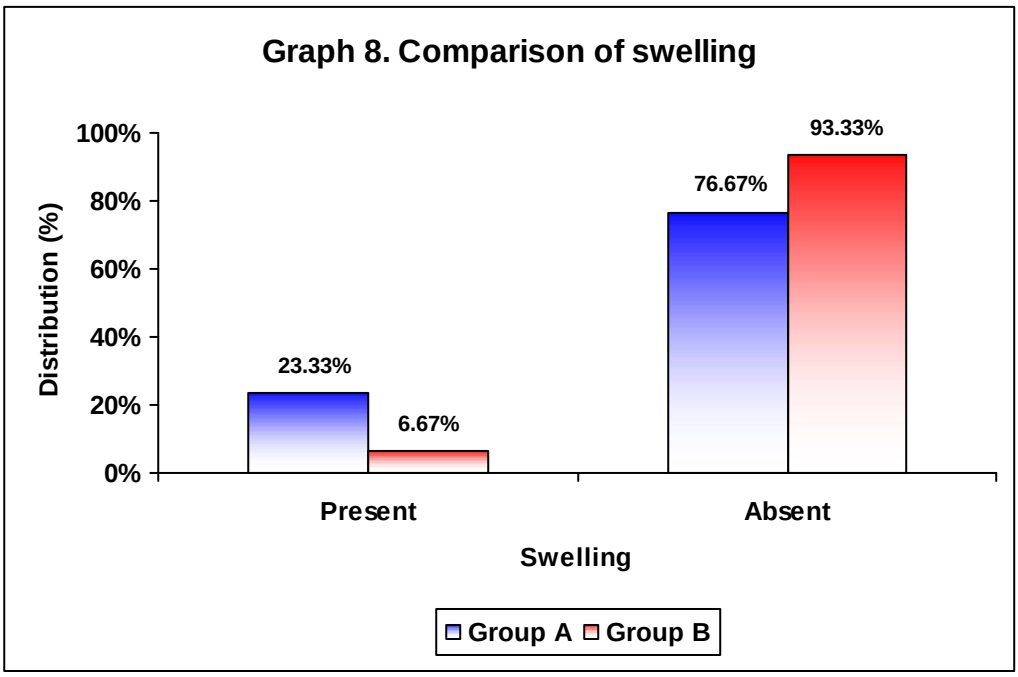


In this study the mean duration of surgery was significantly less in group B (64.00 ± 2.32 minutes) compared to group A (69.3 ± 7.28 minutes) ($p<0.001$).

Table 9. Comparison of swelling

Swelling	Group A (n=30)		Group B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
Present	7	23.33	2	6.67
Absent	23	76.67	28	93.33
Total	**30**	**100.00**	**30**	**100.00**

p = 0.148

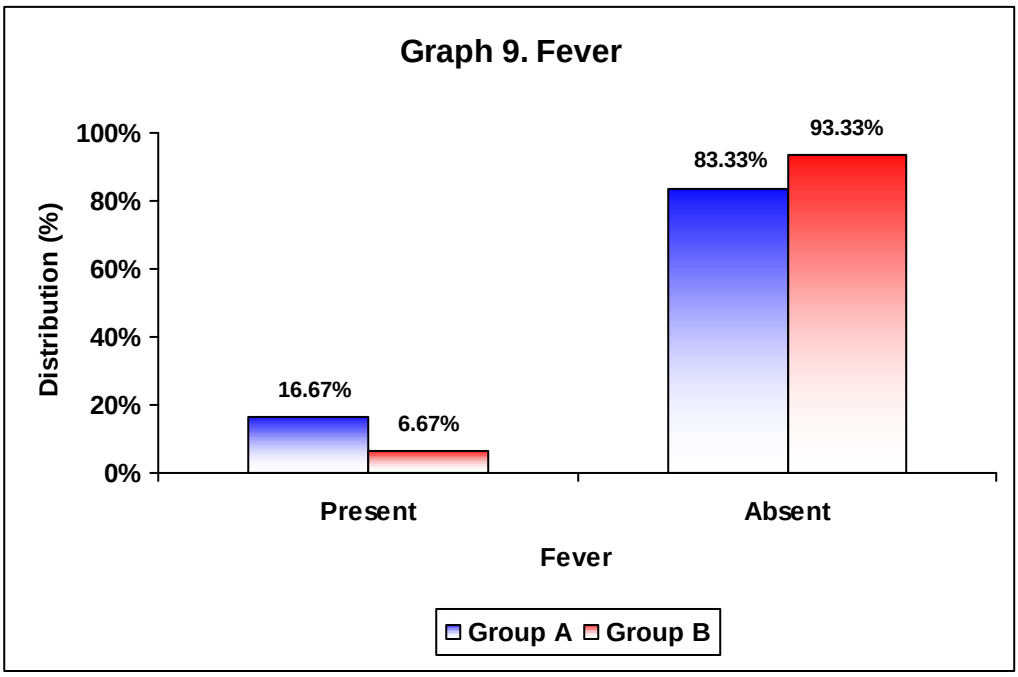


In this study swelling was present in 23.33% of the patients in group A while in group B, swelling was noted in 6.67% of the patients. However this difference was statistically not significant (p=0148).

Table 10. Fever

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

p = 0.421

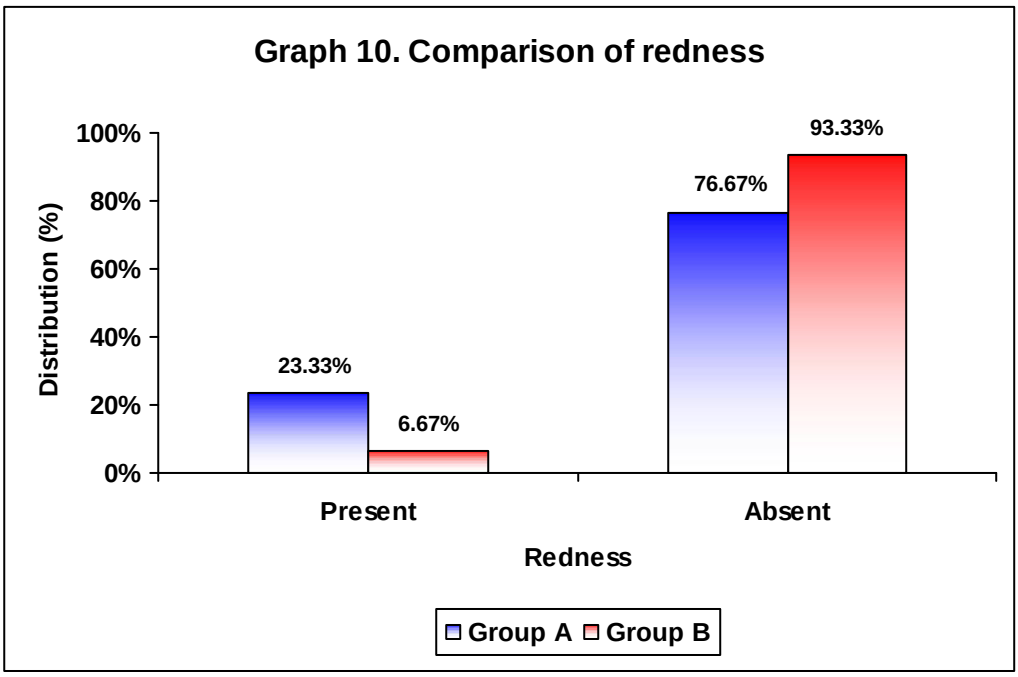


In the present study fever was noted in 16.67% of the patients in group A while in group B, fever was present in 6.67% of the patients. However this difference was statistically not significant (p=0.421).

Table 11. Comparison of Redness

Redness	Group A (n=30)		Group B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
Present	7	23.33	2	6.67
Absent	23	76.67	28	93.33
Total	**30**	**100.00**	**30**	**100.00**

p = 0.148

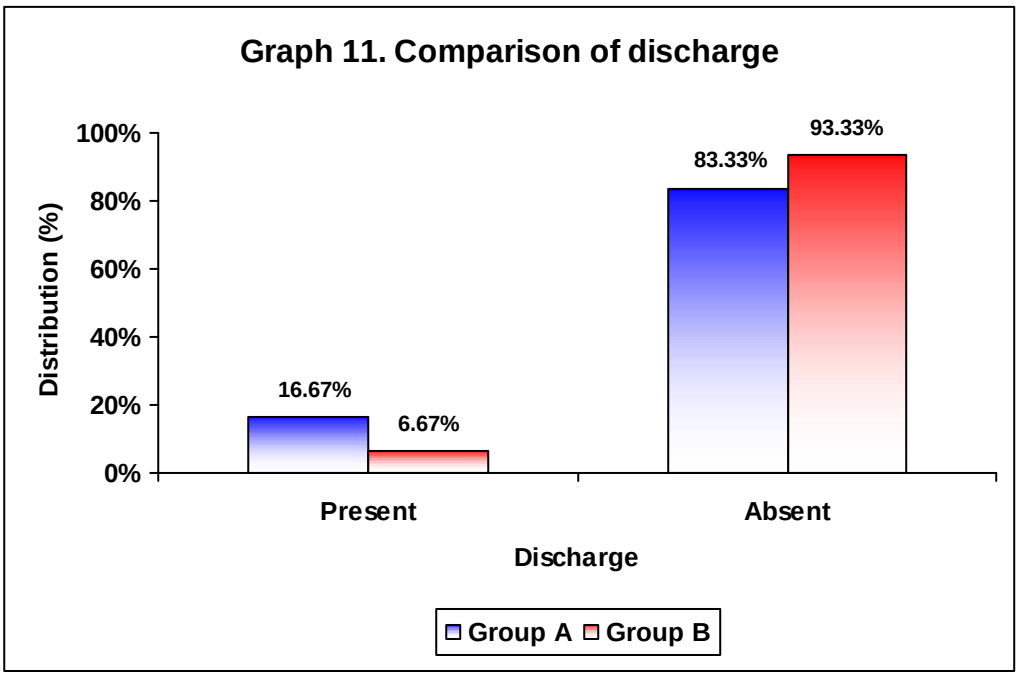


In this study redness was seen in 23.33% of the patients in group A while in group B, redness was present in 6.67% of the patients. However this difference was statistically not significant (p=0.148).

Table 12. Comparison of Discharge

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

p = 0.421



In the present study among the patients with group A discharge was noted in 16.67% of the patients. While in group B, it was present in 6.67% of the patients. However this difference was statistically not significant (p=0.421).

DISCUSSION

The treatment of inguinal hernia has evolved over the past 150 years from truss support with operation reserved for life-threatening situations to elective outpatient repair.[96] Pure tissue repairs have suture line after closure, which is under tension because the defect edges are approximated instead of being bridged. Suture line tension is at the heart of failed hernia repair and solving this problem would largely eliminate the recurrence.[97] Excessive tension on the suture line and the surrounding tissue leads to tissue ischemia and suture cut-out leading to recurrence.[98]

Wounds can heal by secondary intention, or they 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.[16]

For many of the operations performed by surgeons, the lengthy closure time of the procedure adds significantly to the costs, increases anesthetic time, and potentially increases patient risk. New approaches to wound closure that result in shortened operative time, while improving or at least not compromising quality, may be justified despite the apparent increase in device cost compared with standard suturing techniques.[84]

Though subcuticular sutures are used conventionally since many years, However, subcuticular sutures have certain limitations disadvantages like needle

puncture marks, suture canal scaring and wound infection. These complications can be reduced by alternative to the suture material in to the wound which can be accomplished by using steri strips in this study. Another advantage of steri strips is that they are cost effective and requires less time for skin closure compared to that of sub- cuticular sutures. In an effort to increase efficiency in the operating room without sacrificing quality the present study was undertaken to find out the incidence of post operative wound infection by steri strips versus subcuticular suturing in open inguinal hernia skin closure.[84]

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, Belagavi from January 2015 to December 2015. A total of 60 patients undergoing unilateral and/or bilateral inguinal hernia repair were studied. These patients were randomly allocated into two groups based on simple randomization that is Group A (This group underwent subcuticular skin closure) and Group B (This group underwent skin closure with steri strips).

In the present study all the patients (100%) were males in group A and Group B. However, The most common age group was 41 to 50 years (36.67%) in group A comprised of 36.67% of the patients compared to 18 to 30 years comprised of 33.33% of the patients in group B. However this difference was statistically not significant (p=0.861). the mean age of the patients in group A was slightly high (36.70 ± 85 years) compared to group B (34.90 ± 8.04 years). But statistically the mean age in group A and group B were comparable (p=0.399). Further other clinical characteristics of the study population that is, weight (p=0.219), pulse rate (p=.966), systolic BP (p=0.927), and dialostic BP (p=1.000) did not differ and were

comparable in group B and group A (p>0.050). with regard to clinical signs and symptoms all the patients in group A and group B had Swelling in inguinal region (100%). Most of the patients in group A and group B had right inguinal hernia (46.67%) (p=0.748) and indirect hernia was noted in 56.67% of the patients in group A compared to 53.33% in group B (p=0.795).

These findings suggest that, the study population comprised in Group A and Group B was comparable in terms of demographic, clinical characteristics and characteristics of hernia that is side, extent and type of hernia ruling out the possible bias in the study results.

In this study the duration of surgery in all the patients of group B was between 60 to 70 minutes (100%) compared to 73.33% in group A. However, in Group A 26.67% of the patients required slightly higher time that is 71 to 80 minutes. This difference was statistically significant (p=0.002). Also, the mean duration of surgery was significantly low in group B (64.00 ± 2.32 minutes) compared to group A (69.30 ± 7.28 minutes) (p<0.001) These findings suggest that, a potential time saving of 5.3 minutes for skin closure with steri strips requires significantly less time compared to subcuticular skin closure with suturing.

Thus the application of steri strips in skin closure of inguinal hernia repair reduces the operative time. Reduction of operative time causes less exposure of wound therefore reducing the risk of wound infection. Difference of 5.3 minutes was found between the groups A and B which was significant (p<0.001).

These findings were consistent with a review by Kerrigan CL et al.[84] in 2007 to compare suture with a new coaptive film device, 3M Steri-Strips Surgical Skin

Closure, on linear incisions. The mean time for closure of abdominal incision segments with Steri-Strips was 4.9 minutes (SD=2.3; 95% CI =4.0 to 5.8) and with suture was 10.1 minutes (SD =3.4; 95% CI =8.7 to 11.5). The mean difference of 5.2 minutes between closure techniques was significantly different (p= 0.001). The mean time for closure of the full abdominal incision would thus be 9.9 minutes using Steri-Strips and 19.6 minutes using suture. This would thus save 9.7 minutes of operative time by choosing to use Steri-Strips for closure over suture.

Wound infection is a major cause of hernia recurrence.[99] In this study post operative complications including swelling (23.33% vs16.67%; p=0.148), fever (16.67% vs 6.67%; p=0.421), redness (23.33% vs 6.67%; p=0.148) and discharge (16.67% vs 6.67%; p=0.421) were high Group A compared to Group B. the overall incidence of wound infection in group A was 23.33% compared to 6.67% in group B but the difference was statistically not significant suggesting comparable outcome in both the groups.

A review by Kerrigan CL et al.[84] in 2007 to compare suture with a new coaptive film device, 3M Steri-Strips Surgical Skin Closure, on linear incisions reported that, of the 27 patients with abdominal surgery, two patients had reported wound healing complications. One with cellulitis at the drain site and incision segment closed with sutures. The other with cellulitis in the suprapubic region at the juncture of sutures and Steri-Strips closed wounds. However, these complications were not observed in the present study.

Photograph 3. Infected wound with serous discharge

Photograph 3. Infected wound with redness

In our study, it was concluded that the steri strips can be applied much more quickly than sutures for skin closure thus saving the operating time. This technique of skin closure is as effective as skin closure with subcuticular sutures.

Thus, steri strips are far better option for skin closure as compared to subcuticular sutures. The limitations of this study were smaller sample size and single centre study. Also the recruited patients with elective inguinal hernia only. However, the findings observed in the present study need further evaluation in a larger group of patients involving multi centre hospitals to explore the impact of reduced operative time on postoperative complications.

CONCLUSION

This study demonstrates that there is no statistical significance of wound infection in either of groups i.e subcuticular skin suturing group (Group A) & Steri Strips group (Group B).the study probably will need a larger sample size.

SUMMARY

Since many years, subcuticular sutures are used for skin closure but they are associated with disadvantages like suture canal scaring and wound infection. The skin closure with steri strips can reduce these can complications. The present study was aimed to compare the frequency of post operative wound infection by steri strips and subcuticular suturing in open inguinal hernia skin closure.

The one year present hospital based randomized controlled trial was carried out in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2015 to December 2015. A total of 60 patients undergoing undergoing unilateral and/or bilateral inguinal hernia repair were enrolled. These patients were randomly allocated into two groups based on simple randomization that is Group A where subcuticular skin closure was done and Group B skin closure was done by steri strips.

In the present study all the patients were males in group A and 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 did not differ significantly and were comparable in group B and group A ($p>0.050$). All the patients in group A and group B had Swelling in inguinal region (100%). Most of the patients in group A and group B had Right inguinal hernia (46.67%) ($p=0.748$) while 56.67% of the patients in group A (56.67%) and group B (53.33%) had indirect hernia ($p=0.795$). All the patients in group A had duration of surgery between 60 to 70 minutes (100%) while in group B

73.33% had duration of 60 to 70 minutes and 26.67% had 71 to 80 minutes (p=0.002). All the patients in group B had duration of surgery between 60 to 70 minutes (100%) while in group A 73.33% of the patients had duration of 60 to 70 minutes and 26.67% of the patients had duration of 71 to 80 minutes. This difference was statistically significant (p=0.002). Also the mean duration of surgery was significantly less in group B (64.00 ± 2.32 minutes) compared to group A (69.3 ± 7.28 minutes) (p<0.001). The post operative complications including swelling (23.33% vs 16.67%; p=0.148), fever (16.67% vs 6.67%; p=0.421), redness (23.33% vs 6.67%; p=0.148) and discharge (16.67% vs 6.67%; p=0.421) were high Group A compared to Group B. but the difference was statistically not significant suggesting comparable outcome in both the groups.

Overall, there is no statistical significant difference in wound infection rates using subcuticular skin suturing group and steri Strips group. However, skin closure with steri Strips seems to be advantageous as the operative time required is less compared to subcuticular skin suturing group. Hence this technique of skin closure is as effective as skin closure with 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 Steri strips to subcuticular suturing in the closure of inguinal hernia skin incisions in KLES HOSPITAL & MRC, BELAGAVI" conducted by Dr. HIMA BINDU KAKARLA, Post Graduate in M.S. General Surgery under the guidance of Dr. M. S. SANGOLI M.S. Professor, Department of General Surgery, Jawaharlal Nehru 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 Steri strips to subcuticular suturing 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:

1. In emergency to protect your rights and welfare.
2. 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. HIMA BINDU. KAKARLA, Department of General Surgery, KLES Hospital and MRC, Belagavi, phone number: 7026800033. Or Dr. M. S. SANGOLI$_{M.S.}$, 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. Ganga Pilli, Professor, Department of Pathology and Chairman, J.N. Medical College Institutional Ethical Committee for Human Subjects Research, Phone number- 9480275601, or extension 4052 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 RANDOMISEDCONTROL TRIAL COMPARING STERI STRIPS TO SUBCUTICULAR 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	-	
B/L	-	Bilateral
Lt	-	Left
Rt	-	Right
D	-	Direct
ID	-	Indirect
+	-	Present
-	-	Absent