"A RANDOMIZED CONTROLLED TRIAL TO COMPARE EFFICACY IN REDUCING SURGICAL SITE INFECTION OF MONOCRYL PLUS VERSUS MONOCRYL IN SUBCUTICULAR SKIN SUTURING IN PATIENTS WITH ELECTIVE INGUINAL HERNIA REPAIR – A ONE YEAR STUDY"

REG NO. BH0112002

Dissertation

Submitted to the
KLE University, Belgaum, Karnataka

In Partial Fulfillment
of the requirements for the degree of

MASTER OF SURGERY (M.S.)
in
GENERAL SURGERY

DEPARTMENT OF SURGERY,
JAWAHARLAL NEHRU MEDICAL COLLEGE,
BELGAUM, KARNATAKA

APRIL - 2015

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ENDORSEMENT

This is to certify that the dissertation entitled **"A RANDOMIZED CONTROLLED TRIAL TO COMPARE EFFICACY IN REDUCING SURGICAL SITE INFECTION OF MONOCRYL PLUS VERSUS MONOCRYL IN SUBCUTICULAR SKIN SUTURING IN PATIENTS WITH ELECTIVE INGUINAL HERNIA REPAIR – A ONE YEAR STUDY"** is a bonafide research work done by **CANDIDATE REG NO. BH0112002**.

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LIST OF ABBREVIATIONS USED

^{0}F	-	Degree Fahreinheit
BC	-	Before Christ
BSA	-	Bovine Serum Albumin
CDC	-	Centers for Disease Control
CFU	-	Colony-forming units
cm	-	Centimeter
CNS	-	Central nervous system
CVS	-	Cardiovascular system
DPB	-	Diastolic blood pressure
E.coli	-	Escherichia coli
eg	-	For example
EHS	-	European Hernia Society
ESBL	-	Extended-spectrum beta-lactamase
FDA	-	Food and Drug Administration
g	-	Grams
GPRVS	-	Giant prosthetic reinforcement of the visceral sac
HAIs	-	Healthcare associated infections
Hb	-	Haemoglobin
HIV	-	Human immunodeficiency virus
Id. No	-	Identification number
IP No	-	In patient number
IPOM	-	Intra-peritoneal onlay mesh
M	-	Monocryl
mg	-	Milligram

Min	-	Minutes
mmHg	-	Millimeters of mercury
MP	-	Monocryl plus
MPO	-	Myopectineal orifice
MRSA	-	Methicillin-resistant Staphylococcus aureus
n	-	Total number
NNIS	-	National Nosocomial Infection Surveillance
p	-	Probability
PHMB	-	Polyhexamethylene biguanide
PHS	-	Prolene hernia system
PPM	-	Polypropylene mesh
RR	-	Respiratory rate
SBP	-	Systolic blood pressure
SD	-	Standard deviation
Sr.	-	Serum
SSI	-	Surgical site infections
TAPP	-	Trans-abdominal pre-peritoneal
TEP	-	Totally extra-peritoneal
TPI	-	Trigger point injection
UK	-	United Kingdom
US	-	United States

ABSTRACT

Background and objectives

Sutures are a contributory factor in surgical site infections. This study was undertaken to evaluate the efficacy of newly introduced antibacterial suture (monocryl plus) compared to traditional suture (monocryl) in reducing surgical site infections among the patients undergoing inguinal hernia and to see the use of antibiotics post operatively.

Methodology

The present 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 elective inguinal hernia repair from January 2013 to December 2013 were divided into two groups of 30 each that is, Group MP (wound closure using Monocryl plus suture) and Group M (wound closure using conventional monocryl).

Results

Most of the patients in group M were aged > 60 years (40%) compared to 31 to 45 years in group MP (33.33%) (p=0.341) and mean age in group M was 56.96±15.79 compared to 45.50±18.08 years in group MP (p=0.060). On post operative day three, grade IC SSI was noted in 3.33% of the patients each in group M and group MP (p=1.000). On day five, among the patients with group M, grade IA and IC (6.67% each) SSI was noted compared to grade IA and IIIC (3.33% each) in group MP (p=0.513). On day seven, grade IA and IC were present in 3.33% and 10% of the patients in group M and in group MP, grade IA

and IIIB were noted among 3.33% of the patients each (p=0.237). One patient (3.33%) in group MP had grade V SSI (p=1.000). The mean duration of antibiotic administration in group M and MP was comparable (2.20 ± 0.41 vs 2.13 ± 0.57 days; p=0.604).

Conclusion and interpretation

The efficacy of new antibacterial suture (monocryl Plus) is comparable with a traditional suture (monocryl). Also the requirement of antibiotics using monocryl plus is same as compared to conventional monocryl.

Keywords

Antibacterial suture; Inguinal hernia repair; Surgical site infections;

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INTRODUCTION

Hernia is a protrusion of any viscus from its proper cavity, the protruded parts are generally contained in a sac-like structure, formed by the membrane with which the cavity is naturally lined.[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.

However, wound infection is a potential complication for all inguinal hernia repairs.[6] Wound infection usually appears between the fifth and tenth day after surgery.[7] The incidence of mesh infection during open hernia repair has been reported to be as high as 3%.[8] Bacterial growth rate from wound cultures confirms the superficial surgical site infection rate in all groups.[9]

Surgical site infections (SSI) are the third most common hospital-acquired infection and account for 14% to 16% of all such infections.[10] The definition of

surgical site infections (SSIs) according to the criteria developed by the Centers for Disease Control and Prevention include every SSI up to 30 days after the operation.[11] Infections are categorized as incisional (superficial or deep) infections or organ–space infections. Superficial SSIs involve only skin and subcutaneous tissue and exclude stitch abscesses. Deep SSIs involve deeper soft tissues at the site of incision. Organ– space SSIs are defined as infections in any organ or space.

Potential sources of infection are the patient (especially contamination by alimentary tract bacteria), hospital environment, food, other patients, staff, infected surgical instruments, dressings, and even drugs and injections.[11] Despite of strict aseptic technique, antibiotic coverage (when indicated), and an adequate surgical technique, the infection rate remains high.[12] Surgical site infections are also related to suture.[13]

A suture is a biomaterial device, natural or synthetic, used to approximate tissues together following separation by surgery or trauma. It can also be used to denote the method used for mechanical wound closure. Although there are other methods for mechanical wound closure such as staples, tape and adhesives, sutures are the most widely used materials in wound closure.

Many strategies have been evaluated for reducing the surgical site infections. Use of antiseptic and antibiotic coated suture is one of such strategy to reduce the burden of surgical site infections. Antibiotics such as gentamicin were the first to be considered but this was not pursued. Triclosan is an antiseptic which has been widely studied and chosen for incorporation into sutures to give a local, broad-

spectrum antimicrobial effect in wounds and could provide an effective strategy for reducing surgical site infections, and surgical morbidity.[14]

Triclosan is a synthetic, polychlorinated, aromatic hydrocarbon with broad antimicrobial properties. Its lipophillic and active broad pH range (4-8) unlike other antiseptics. It passively dissipates from implanted suture to surrounding tissues where it is absorbed and widely distributed. Many studies have shown utility of these suture in decreasing both bacterial colonisation of suture and infections after surgery.[15]

Coating sutures with an antimicrobial has been considered since the early 1970s Monocryl sutures provide smooth even passage to tissue, causing less reaction than chromic gut suture. It is synthetic absorbable, monofilament suture made of Poliglecaprone 25. Monocryl suture has high pliability and passes smoothly through tissues. It provide high tensile strength for 21 days.

Recently a new antimicrobial suture Poliglecaprone 25 coated with triclosan (monocryl Plus) has been introduced. Triclosan has been widely used in humans for over 30 years.[16] *In vitro* study, showed efficacy against *S. aureus, S. epidermidis*, MRSA, MRSE, E.coli, Klebsiela Pneumoniae.

Not many studies have been done to compare the two sutures i.e. monocryl and monocryl plus suture in hernia repair surgery as it is postulated to be clean surgery. However, SSIs after hernia repair would increase the morbidity and also result in high cost of treatment. Hence the present study is undertaken to evaluate the efficacy of new antibacterial suture (monocryl plus) compared with traditional

suture (monocryl) in reducing surgical site infections in inguinal hernia surgery so as to reduce the use of antibiotics post operatively.

OBJECTIVES

The objectives of the study were;

1. To evaluate the efficacy of new antibacterial suture (monocryl Plus) compared with a traditional suture (monocryl) in reducing surgical site infection in patients with elective inguinal hernia repair.

2. Reducing use of antibiotics post operatively.

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]

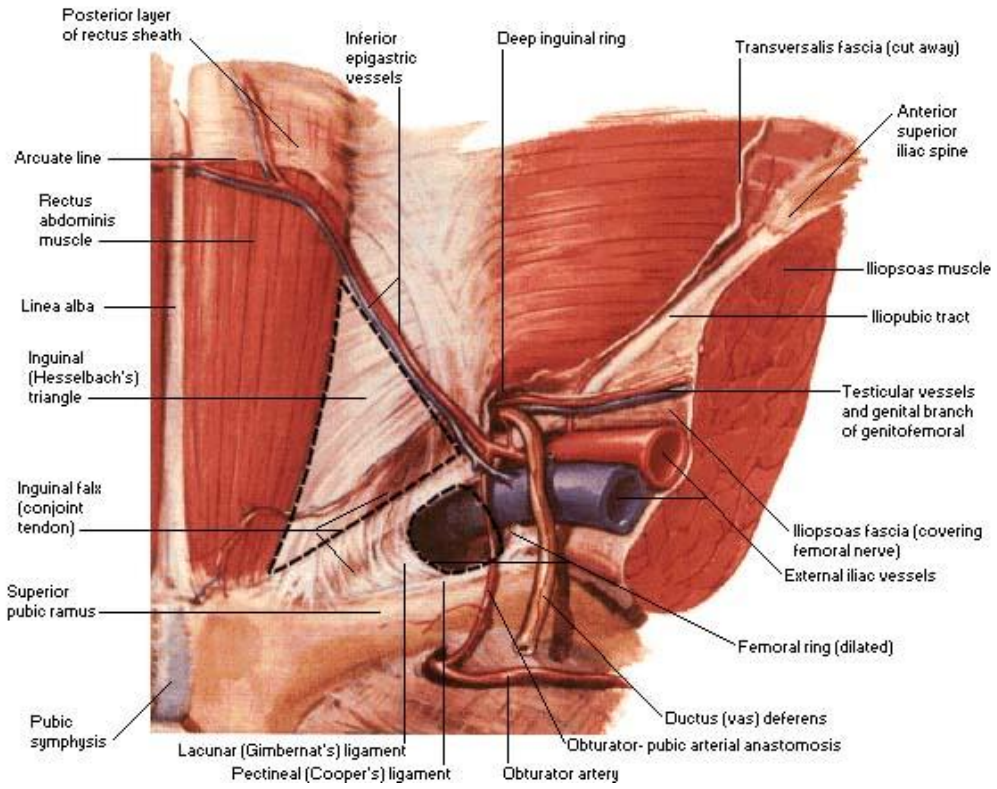


Figure 1. Anatomy of inguinal canal[18]

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 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).[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 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 discern 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]

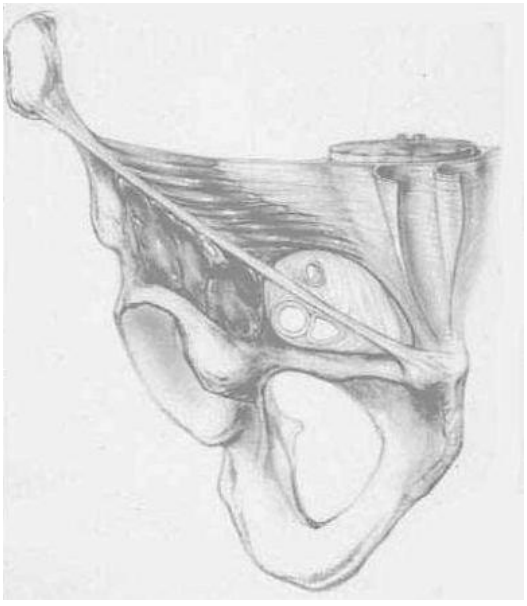


Figure 2. The myopectineal orifice. The passageway for the great vessels to the lower extremity, and for the testicle to reach the scrotum[19]

- 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 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.[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 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.[19]

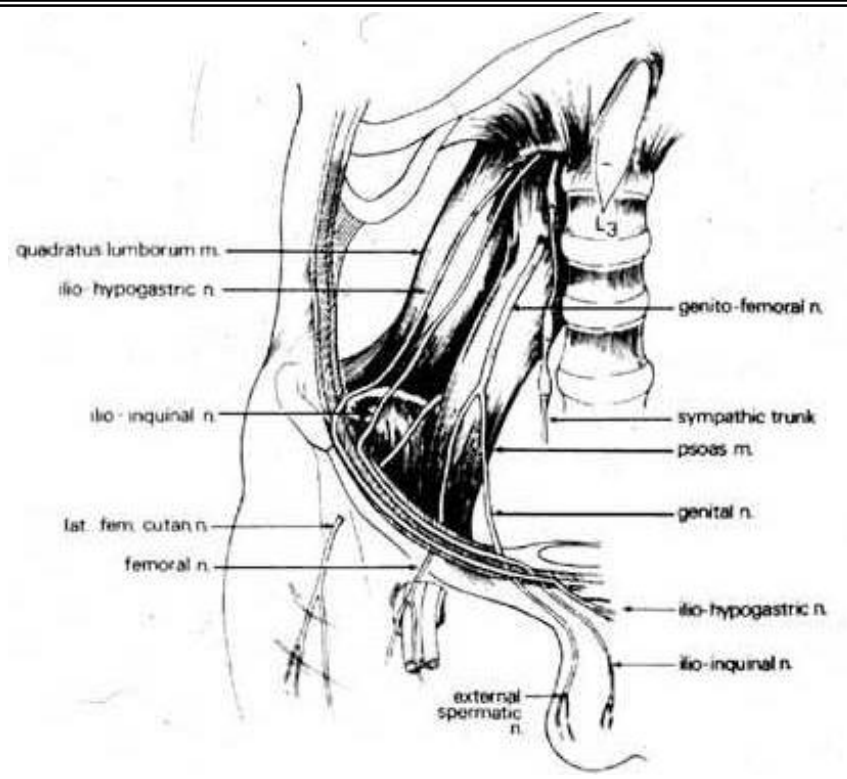


Figure 3. Nerve supply to the groin[19]

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 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 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 the description of combined and femoral hernias.[24]

Aachen 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 groin 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 groin 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 groin 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.

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.[27]

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.[27]

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.[27]

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.[27]

Different methods of repairs[26]

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.[38] 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.[39] 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[40] 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.[41] 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.[27]

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.[27]

Gilbert′s sutureless[43] 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.[27]

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).[27]

The results of a recent Indian trial with PHS,[44] 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[45] 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[46] 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[47] by intra-corporeal suture of the deep ring after plugging a PPM into the sac. Toy and Smoot in 1991[48] 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.[27]

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.[27] In the early 1990′s Arregui and Doin[49,50] 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.[27]

Around the same time Phillips and McKernan[51,52] 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.[27]

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).[27]

In a randomized study Fleming et al[53] had compared TEP (n=116) repair with Shouldice technique (n=115) on 200 patients. The comparative results are as follows (figures in brackets are those of Shouldice repair): median duration of operation 70 minutes (56 minutes), first day discharge 68% (48%), return to normal

life style within 1 month 77% (49%), rate of complications 16% (36%), recurrence within 1 year of follow up 2 (5). TEP repair costs 40% more than Shouldice repair.

A recent randomized study[54] on 123 patients comparing Lichtenstein repair (n=62) with TEP repair (n=61) concluded that there was no significant difference between the two groups in terms of postoperative pain, in hospital stay, resumption of normal activities and complications. TEP repair took 16 minutes longer and it was more expensive. The authors opined that for primary inguinal hernia repair Lichtenstein technique is preferable and TEP repair in recurrent and bilateral hernias. With gradual decrease in operating time, use of reusable instruments and reduction in the hospital stay, (many are performing it as an out patient procedure) laparoscopic repair is likely to become more cost effective.

Heikkinen et al[55] on the other hand opined that the total costs for *working patients* would be lower with laparoscopic repair if the cost of lost workdays were factored into the overall expenses.

A recent meta-analysis[56] of randomized trials comparing open with laparoscopic repair reported fewer complications following laparoscopic repair but all serious visceral and vascular complications were from this group.

The EU Hernia Trialists Collaboration found 4.7 serious injuries per 1000 procedures, especially of bladder and vessels.[57]

Laparoscopic repair is particularly appealing procedures for bilateral and recurrent hernias. In a prospective randomized study,[58] 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[59] 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[60] on over 8000 patients has shown TAPP procedure can be performed without any serious morbidity.

A large multi-center study[61] 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.[62]

Certain guidelines prescribed by the UK National Institute of Clinical Excellence[63] 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[64] 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.[27]

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.[27]

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".[65]

Complications[66]

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 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.[5]

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.[6]

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.[67]

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%.[68] 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.[73] Other studies corroborate that increased length of hospital stay and cost are associated with SSIs.[75] 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.[75]

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.[76] 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.[77]

Classification

Classification of operative wounds based on degree of microbial contamination[69]

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[69]

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.

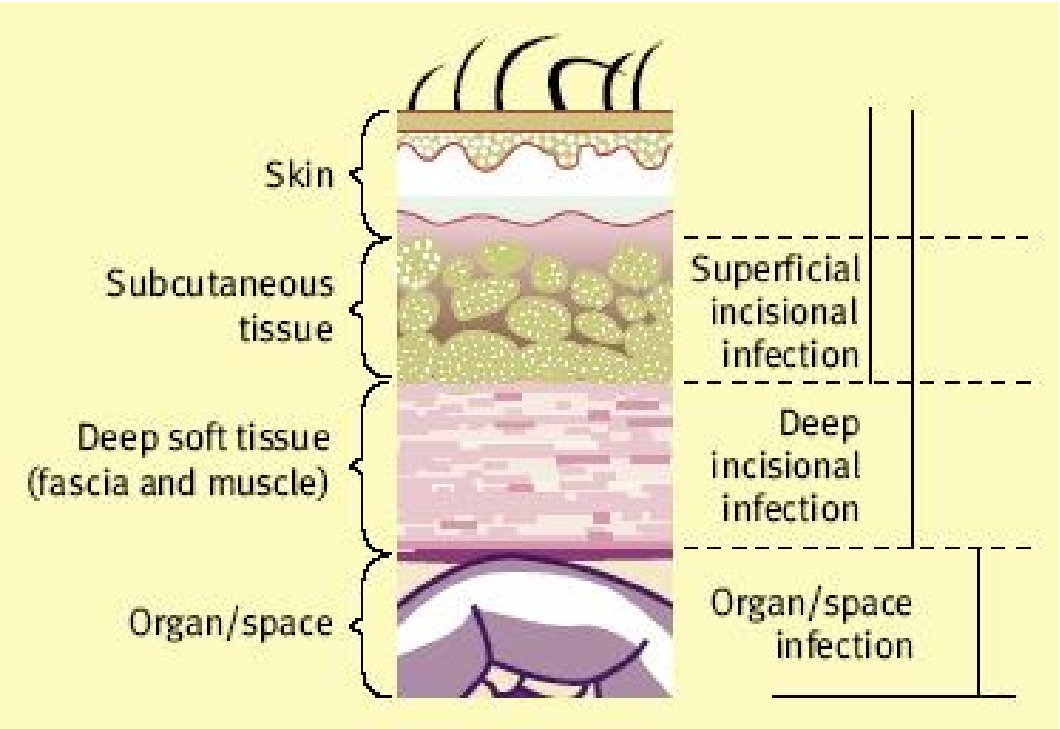


Figure 4. Schematic representation of the anatomical classification of surgical site infections[78]

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.[72] 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%.[78] There is, however, considerable variation in each class according to the type of surgery being performed.[79]

An Indian study[80] 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[81]

	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 [81]

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:[82]

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).[83]

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.[84] One of the most common causes of multiple system organ failure in modern surgical care is intraabdominal infection.[85] Some bacterial surface components, notably polysaccharide capsules, inhibit phagocytosis,[86] 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.[87] A variety of microorganisms, including gram-positive bacteria such as coagulase negative staphylococci, produce glycocalyx and an associated component called "slime,"[88] which physically shields bacteria from phagocytes or inhibits the binding or penetration of antimicrobial agents.[89] 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.[90] 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,[92] particularly in patients who have a prosthesis or other implant placed during the operation. Such devices provide a nidus for attachment of the organism.[88]

Exogenous sources of SSI pathogens include surgical personnel (especially members of the surgical team),[93] 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.[94]

Microbiology

According to data from the NNIS system, the distribution of pathogens isolated from SSIs has not changed markedly during the last decade.[95]

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),[96] or by *Candida albicans.*[97] 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.[97] 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,[98] elastic bandages,[99] colonized surgical personnel,[100,101] tap water,[102] or contaminated disinfectant solutions.[103] 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*.[104] In analyses of contamination rates after cholecystectomy, the main source of wound contamination was found to be the skin of the patient.[104] 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.[104] 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.[104] 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%.[104] 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%.[104] 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.[104]

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.[105]

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.[106] Sutures are a contributory factor in infection; in fact, 66% of SSIs are related to the incision.[107]

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.[108]

In fact, it is postulated that in the presence of sutures, only 100 colony-forming units (CFU)/mg are necessary to produce infection.[109] 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.[110]

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.[111]

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.[112]

A study,[113] 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[13] 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.[114]

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.[114]

Classification of sutures

There are 3 main classifications of suture materials.[115]

Based on no. of strands

Monofilament

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

Multifilament

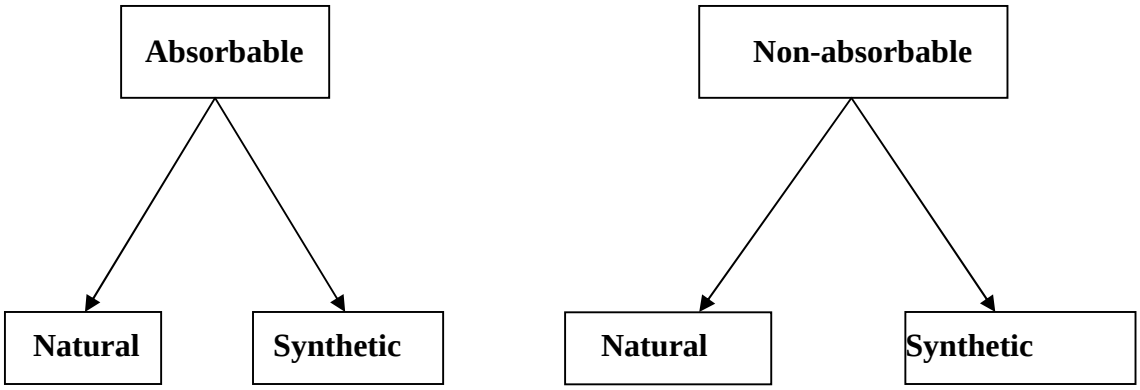
Vicryl (Polyglactin 910), Vicryl plus, Dexon (polyglycolic suture), Silk, Mersilene (Braided polyester)

Based on source

Natural or Synthetic

Based on absorption

Absorbable or Non-absorbable



Antimicrobial Sutures

The antimicrobial suture is interesting. Fowler,[116] in 1965, recommended that all suture materials be steeped in a 1/2,000 solution of chlorhexidine before suturing reduces surgical wound infections, although many manufacturers had argued against him.

The actual development of an antibacterial surgical suture has been under consideration since early 1980s.[117] Preventive strategies included prophylactic antibiotics before the biofilm can form, or 'intelligent' surfaces that prevent colonization or have antimicrobial properties. Potential antiseptics for coating surfaces include chlorhexidine, polyhexamethylene biguanide (PHMB), octenidine and triclosan. Compared with antibiotics, which generally have single

pharmacological targets, which select for resistance, antiseptics have several or multiple targets and true 'resistance' is rare. Antimicrobial-impregnated implants, which prevent bacterial adhesion and biofilms formation, can avoid long-term, ineffective, systemic antibiotics, reduce the risk of microbial resistance generation and need for implant removal. Ideally, antiseptics should have a rapid potent and broad microbicidal spectrum with long-lasting effects and no risk of developing antimicrobial resistance. They should be biocompatible with medical products, not impair healing processes and be well tolerated in wounds with no toxicity or systemic absorption.[118]

Recently, the only substance being used for impregnantion in suture is Triclosan. Triclosan 5-chloro-2 (2, 4-dichlorophenoxyphenol) is a broad-spectrum antimicrobial agent developed over 40 years ago.[119]

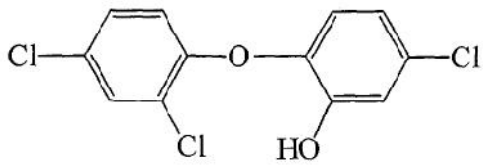


Figure 5. Chemical structure of Triclosan

The chemical structure is as shown in Figure 1. In the United States, triclosan has been used in underarm deodorants and deodorant soaps since 1960s. It was first introduced in the healthcare industry in a surgical scrub at 1% in 1972 and for oral care in toothpaste in Europe in 1985.[120]

In 1989, triclosan was approved for use in cosmetics, which can be used up to 0.3% by the European Community Cosmetic Directive.[121]

Over the last 20 years, the use of triclosan has grown rapidly in personal care products including soap, hand sanitizer, cosmetics, and toothpaste, as well as household products such as odour-fighting socks and germ-resistant sponges, kitchenware, and bedding. A 2001 U.S. study found triclosan in 76% of 395 commercial soaps examined.[122]

At the beginning, the mode of action was supposed to be through nonspecific disruption of the bacterial cell membrane. Newer studies, however, revealed that the target of triclosan is the Fab I gene, which blocks bacterial fatty acid synthesis (particularly the enzyme enoyl-acyl carrier protein reductase).[122]

The combined effect of triclosan with antibiotic, amoxicillin, gentamicin, nitrofurantoin and the fluoroquinolones was superior when considering significant increases in susceptibility. The synergistic effects of triclosan and several antibiotics are consistent with a triclosan-dependent metabolic strain and/or membrane disruptive effect, and offers important insight into the combined use of antimicrobial compounds in clinical practice.[123]

The antimicrobial spectrum and speed of activity of triclosan are well documented both as an active ingredient and in a wide array of formulations.[120]

A comprehensive submission of published, unpublished, and historical data was prepared for the FDA and includes in vitro and in vivo data on triclosan. These references include more than 1000 in vitro tests performed with triclosan formulations on a broad array of microorganisms such as fungi, *Clostridium dificile*, methicillin-resistant *Staphylococcus aureus* (MRSA), and vancomycin-resistant *Enterococcus*. The results indicate the formulations have similar broad-spectrum

antiviral activity on adenovirus 2, herpes simplex virus, type 1, HIV-l, influenza A, and rhinovirus 37 at both concentrations with a high level of activity on enveloped viruses such as herpes simplex virus, HIV-l, and influenza.[120]

As previous mentioned above, FDA (US) has approved polyglactin 910 sutures coated with triclosan for commercial used since 2002.[124]

The first report[125] was published in 2005 show prospective, randomized, controlled, open-label, comparative, single-center study was conducted on 147 pediatric patients (age 1-18 years) undergoing various surgical procedures with either polyglactin 910 sutures coated with antibiotic triclosan or polyglactin sutures without triclosan. The endpoints of this study focused on intraoperative handling and wound healing characteristics instead of surgical site infection that the aim of this investigated suture. For intra-operative handlings were favorable and not significantly different for both sutures, although coated polyglactin 910 sutures with triclosan received more “excellent” scores (71% vs. 59%). Wound healing characteristics were comparable for both sutures, except significantly fewer patients with triclosan sutures reported pain on day one compared with patients without triclosan sutures ($p=0.01$). The overall incidence of adverse events was 18%; none was device related, and there was no difference between treatment groups. This study was sponsored by industry for antimicrobial sutures.

Another retrospective study[122] to evaluate reduction of sternal wound infection was conducted in 2007. A total of 479 patients underwent a cardiac surgical procedure. One hundred and three patients were closed with triclosan-coated suture material, whereas the remaining 376 patients had their incision closed

with non-coated sutures. During the study period, 24 patients had superficial (n=10) or deep (n=14) sternal wound infections. All those patients were closed with conventional suture material. In the triclosan group, no wound infection or dehiscence was observed during hospital stay and follow-up visits. This study was also evaluated the cost-effective for this operation.

A prospective, double-blinded, randomized controlled trial[124] evaluate reduction of CSF shunt infection following shunt procedures was conducted in 2008. The study enrolled 61 patients, among whom 84 CSF shunt procedures were performed over 21 months. The shunt infection rate in the study group was 2 (4.3%) of 46 procedures and 8 (21%) of 38 procedures in the control group (p=0.038). There were no statistically significant differences in shunt infection risk factors between the groups (procedure type and time, age < 6 months, weight < 4 kg and recent history of shunt infection). No suture-related adverse events were reported in either group. Wound closure with antimicrobial suture was associated with a favor lower shunt infection risk than placebo suture wound closure in this study but statistic not significant due to small sample size.

A large cohort,[108] evaluated the effect of antibacterial-coated sutures for abdominal closure in 2009. The authors performed 2,088 operations between October 2004 and September 2006 via midline incision and prevent wound infections in different kinds of abdominal surgery, including colorectal, hepatopancreatic, and vascular surgery. In the first time period (October 2004 to September 2005= TP1), a PDS II loop suture was used. In the second time period (October 2005 to September 2006 =TP2), Vicryl plus was used. Using a PDS loop suture for abdominal wall closure in TP1, 10.8% of patients with wound infections

were detected. The number of patients with wound infections decreased in TP2 using Vicryl plus for abdominal wall closure to 4.9% ($P < .001$) despite no other changes in protocols of patient care. Other risk factors for the development of site infections were comparable in the two groups. The use of antibiotic-coated loop suture for abdominal wall closure can decrease the number wound infections after abdominal surgery. Although this study was done in a single center in Germany over two different time periods and using two different types of suture material with high volume of sample size. Although these findings of the study are impressive, the design and data analysis appear to be still sub-optimal because of no randomization of the patients, lack of microbial confirmation and multivariate analysis. Additionally, their strategies for the management of contaminated wounds are not shown, which greatly influence the outcomes of such wounds. Despite an increase in the rate of wound infection in the PDS group, the duration of hospital stay was not prolonged in this group, suggesting that complications other than wound infection might occur more frequently in the triclosan coated group. Abdominal wound dehiscence, which is a deep incisional surgical site infections and a very serious wound complication, appears to be more related to the suture materials used for transfascial mass closure when compared with the association between these suture materials and superficial incisional SSIs. So this study should show whether antibiotic coating of transfascial sutures could decrease the rate of wound dehiscence.[126]

However recently (in 2011), authors[108] extended their study between October 2003 and October 2007 (previous study reported between October 2004 and September 2006) and focused in transverse abdominal incision instead midline

incision as previous study.[127] 839 operations were performed using a transverse abdominal incision. In the first time period, a PDSII loop suture was used for abdominal wall closure. In the second time period, we used Vicryl plus. Wound infections after transverse laparotomy. 409 Using a PDSII loop suture for abdominal wall closure in the first time period, 9.2% of the patients developed wound infections. In the second time period, 430 using Vicryl plus, the number of wound infections decreased to 4.3% ($p< 0,005$). Both groups were comparable regarding risk factors despite no other changes in protocols of patient care. The major clinical finding of this study is the superiority of braided Vicryl plus sutures over PDS sutures in relation to wound infections after a two-layered closure of transverse laparotomy in patients undergoing hepatobiliary resections.

Two randomized control trials[12,128] showed no statistical difference in both group. First in trial[128] in 2009 was a prospective, randomized, controlled, double blind, comparative, a single center study which was conducted to to assess the efficacy of an antibacterial suture (polyglactin 910 coated with triclosan) compared to uncoated polyglactin 910 sutures in reducing rates of SSI in patients undergoing appendectomy. Surgeons and assistants were blinded to suture type as similarity in appearance made the two products indistinguishable. Baseline patient characteristics did not difference between both group. The rate of SSI was not statistically significantly different between the two treatment groups, nor was the complication rate after one year. The authors concluded that polyglactin 910 coated with triclosan was safe in surgical practice, with a comparable outcome to polyglactin 910 but that more study was needed to confirm this.

Second in 2011,[129] which was a prospective study was evaluated the effect of triclosan-coated sutures on surgical wide excision of a head or neck cancer and reconstructive procedures. 241 patients were included in this study, divided into two groups by flip of a coin. The Triclosan group contained 112 patients, whose surgical wounds were closed with Triclosan-coated sutures (Vicryl Plus). The control group included the remaining 129 patients, whose surgical wounds were closed with conventional Vicryl sutures. The results showed cervical wound infection rate was 14.9% (17/112) in the Triclosan group and 14.7% (19/129) in the control group, and these rates were not significantly different. Tumor stage and delayed intra-oral flap healing were independent risk factors for cervical wound infection. In this study, Triclosan-coated Vicryl sutures did not reduce the infection rate of cervical wounds after head or neck cancer surgery. The effectiveness of this suture material in head and neck cancer surgery should be considered with caution. The study showed negative result, which was also stated by another study in 2009.[129]

The study[129] investigated the effect of triclosan on wound healing a double blind prospective pilot study in women undergoing a breast reduction was performed. Each patient was her own control. After randomization the Triclosan-coated sutures were used either on the left or right side. The contralateral side was used as the control. The incidence of dehiscence was studied. The result showed twenty-six patients were included. In the triclosan breasts there was a wound dehiscence in 16 cases, whereas in the control breasts in seven cases a dehiscence was observed ($p=0.023$). These results suggest that triclosan-coated sutures should be used with caution. These sutures have already been introduced on to the market without good clinical studies and might have potential adverse effects as shown by these data. The

bilateral dehiscence in five cases found that four unilateral dehiscent cases in the triclosan group (p=0.023). The limitation of this study was small sample size but a double blind randomized design in which each patient was their own controls have value because each patient is her own control.

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 2013 to December 2013.

Study design: A randomized controlled trial.

Study period and duration: One year from January 2013 to December 2013.

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 elective inguinal hernia repair.

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

Sampling procedure: Based on the average three years hospital data the sample size of 60 cases undergoing elective inguinal hernia repair divided into two groups of 30 each was planned.

Selection criteria

Inclusion

- Patients undergoing elective inguinal hernia repair.
- Patients aged above 18 years.

Exclusion

- Immuno compromised individuals
    - Diabetics
    - Human immunodeficiency virus (HIV)
    - Bleeding disorders
    - Patients on steroid therapy
- Known hypersensitivity to suture or its components.

Ethical clearance

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

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).

Randomization

The patients were randomly allocated into two groups based on closed envelope method that is, patient was asked to pick an opaque brown concealed envelop containing the information regarding the type of suture material. Based on the option picked up, the patient was allocated to either group M or group MP.

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

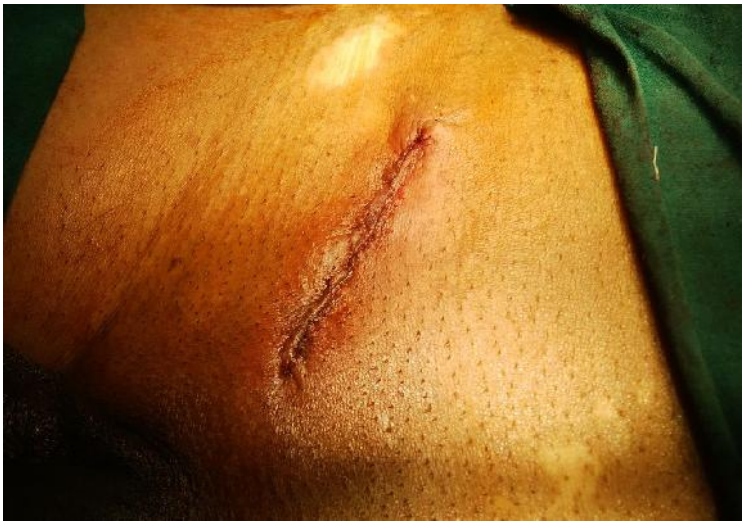
- Complete blood count
- Blood urea nitrogen
- Serum creatinine
- Bleeding time
- Clotting time
- Urine routine and microscopy

Procedure

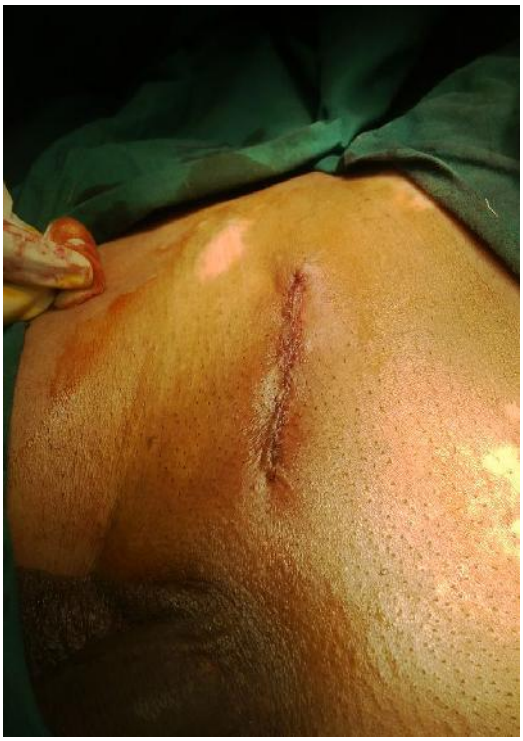
In both the groups patients received same antibiotic dose that is Injection Taxim 1g prior to surgery and same Inj. Taxim 1 gm IV BD was given for two days post operatively in all the patients. The patients who had grade I, II and III infection received antibiotics for three days without change in regimen. However, antibiotics were changed based on the severity of SSI, culture and sensitivity. Patients in group MP had wound closure using Monocryl plus and in group M, conventional monocryl was used. The Post-Operative care was similar for both the groups. Lichtenstein repair was done using prolene mesh (Ethilon) followed by subcuticular skin suturing.

Photograph 1. Conventional Monocryl suture

Photograph 2. Monocryl plus suture



Photograph 3. Appearance of wound on post operative day three in group M



Photograph 4. Appearance of wound on post operative day three in group MP

Outcome

The assessment of wound was carried out based on Southampton wound scoring system[6] on post operative day three, five and seven and fourteen.

Assessment of wound using Southampton Wound Scoring System[130]

Grades		Appearance
0		**Normal healing**
I		**Normal healing with mild bruising or erythema**
	A	Same bruising
	B	Considerable bruising
	C	Mild erythema
II		**Erythema plus other signs of inflammation**
	A	At one point
	B	Around sutures
	C	Along wound
	D	Around wound
III		**Clear or haemoserous discharge**
	A	At one point only (< 2 cm)
	B	Along wound (> 2 cm)
	C	Large volume
	D	Prolonged (> 3days)
IV		**Major complications**
	A	At one point (< 2 cms)
	B	Along wound (> 2 cm)
V		**Deep severe wound infection with or without tissue breakdown; haematoma requiring aspiration**

Statistical analysis

The data obtained was entered in Microsoft Excel Spreadsheet. The categorical data was expressed in terms of rates, ratios and percentages. Continuous

data was expressed as mean ± standard deviation. The comparison of categorical data was carried out using chi-square test Fisher's exact test. The comparison of continuous data was done using independent sample t test. A 'p' value of less than or equal to 0.05 was considered as statistically significant.

RESULTS

This study was done in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. A total of 60 patients undergoing elective inguinal hernia repair from January 2013 to December 2013 were studied. Patients were divided into two groups of 30 each as below.

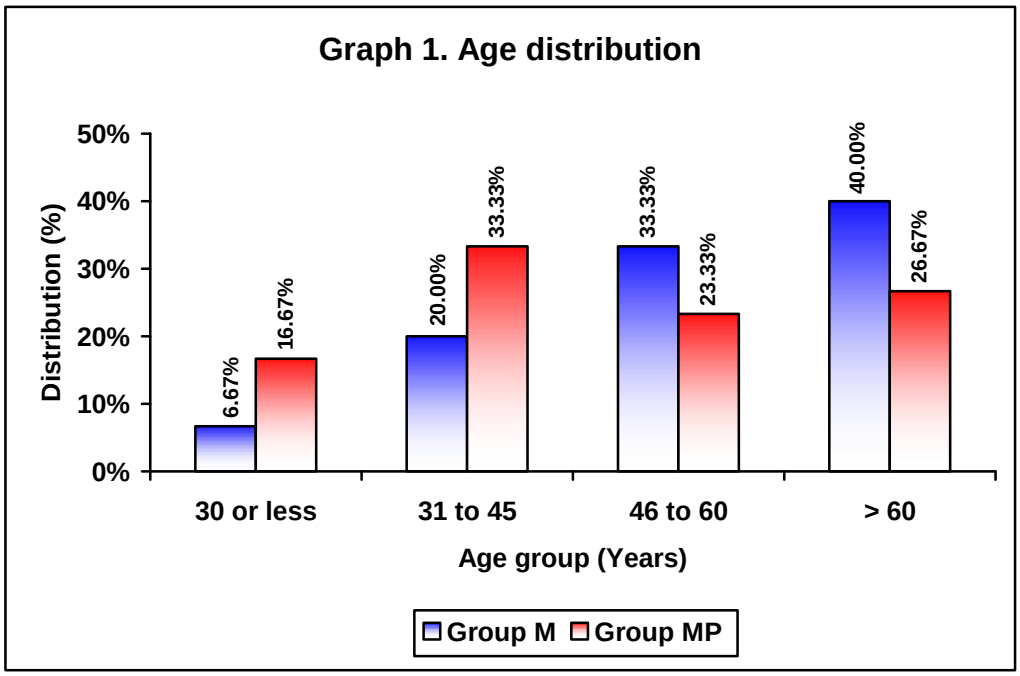
- Group MP – Patients in this group had wound closure using Monocryl plus
- Group M - Patients in this group had wound closure using conventional monocryl.

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

Table 1. Age distribution

Age group (Years)	Group M (n=30)		Group MP (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
30 or less	2	6.67	5	16.67
31 to 45	6	20.00	10	33.33
46 to 60	10	33.33	7	23.33
> 60	12	40.00	8	26.67
Total	**30**	**100.00**	**30**	**100.00**

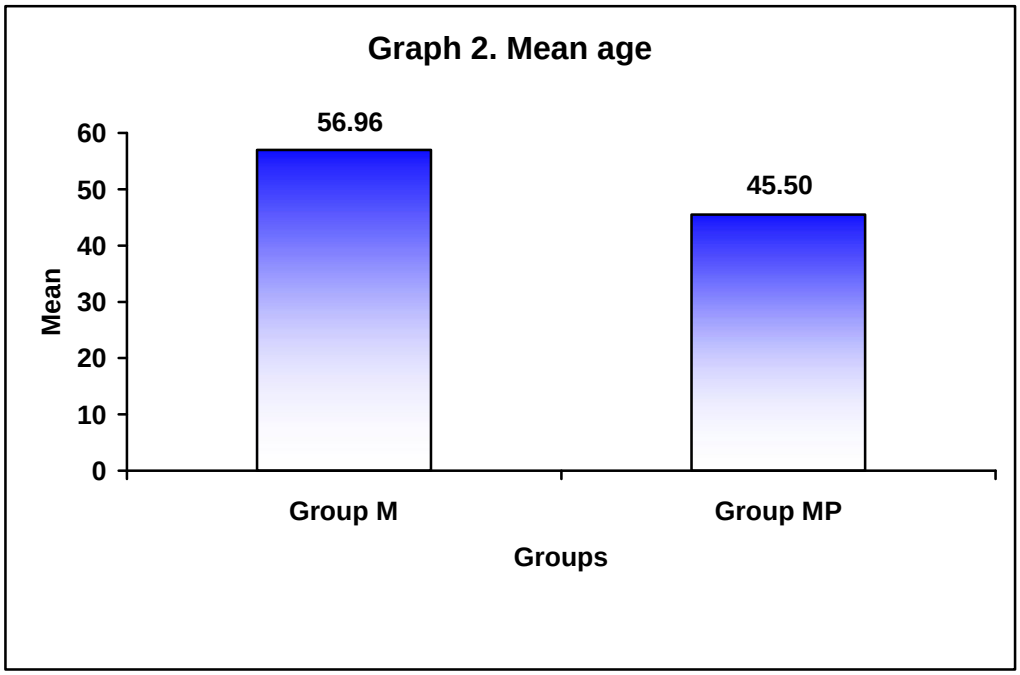
p = 0.341



In the present study most of the patients in group M were aged > 60 years (40%) compared to 31 to 45 years in group MP (33.33%). However the difference was statistically not significant (p=0.341).

Table 2. Mean age

Variables	Group M (n=30)		Group MP (n=30)		p value
	Mean	SD	Mean	SD	
Age (Years)	56.96	15.79	45.50	18.08	0.060



In this study the mean age in group M was 56.96 ± 15.79 years compared to 45.50 ± 18.08 years in group MP but the difference was statistically not significant (p=0.060).

Table 3. Comparison of vitals

Variables	Group M (n=30)		Group MP (n=30)		p value
	Mean	SD	Mean	SD	
Pulse rate (/Minute)	77.70	10.57	81.10	7.17	0.151
SBP (mm Hg)	120.00	7.43	118.67	9.73	0.553
DBP (mm Hg)	75.00	8.20	75.53	9.45	0.816
Respiratory rate (/Minute)	23.73	2.00	24.20	2.12	0.384

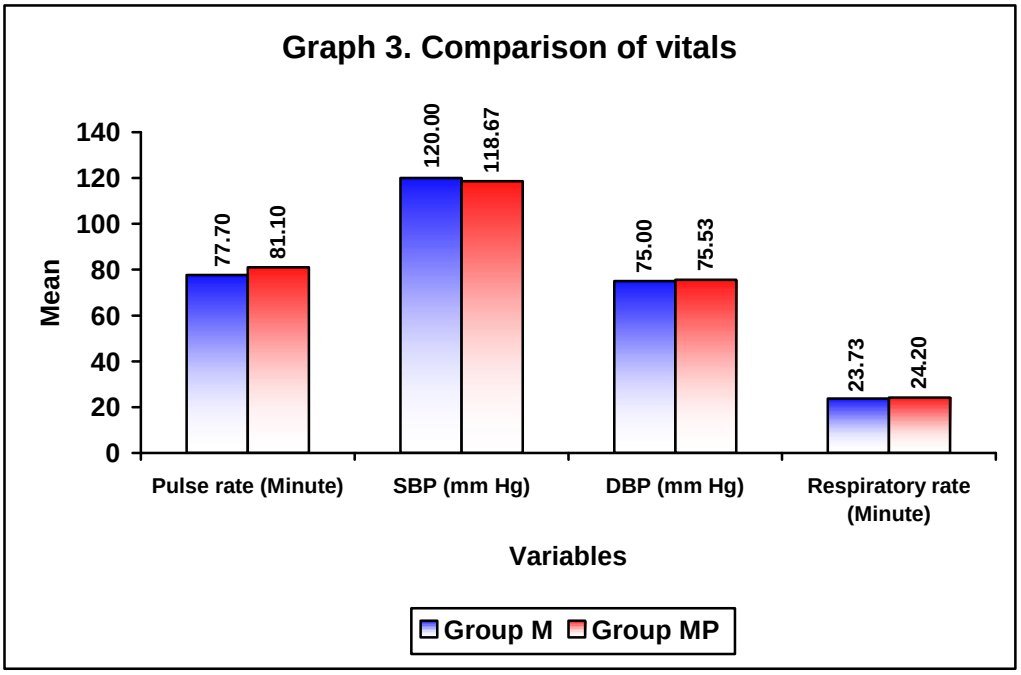
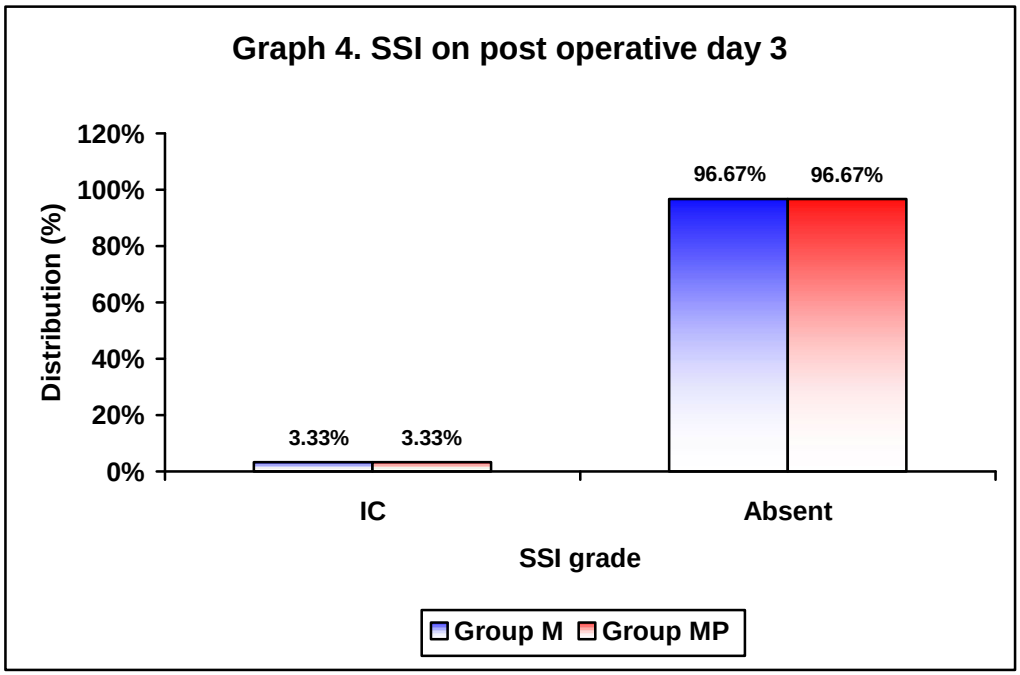


Table 3 and graph 3 shows comparison of mean pulse rate, systolic and diastolic blood pressure and respiratory rate. It was observed that, these variables were comparable in group M and MP (p>0.050)

Table 4. SSI on post operative day 3

SSI Grade	Group M (n=30)		Group MP (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
IC	1	3.33	1	3.33
Absent	29	96.67	29	96.67
Total	**30**	**100.00**	**30**	**100.00**

p = 1.000

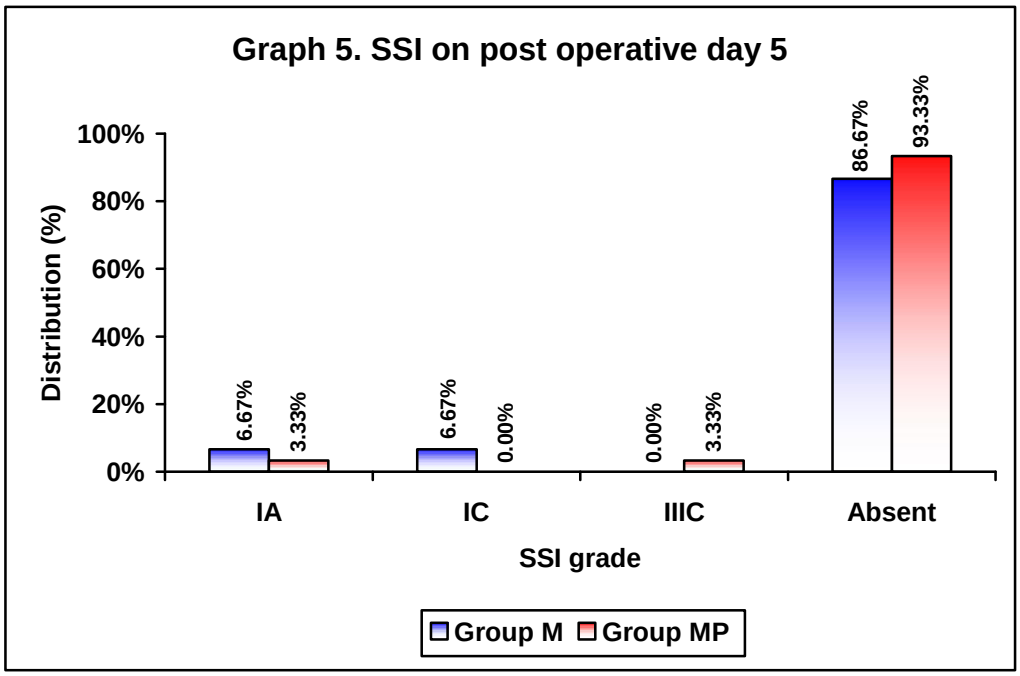


In the present study, on post operative day three, grade IC SSI was noted in 3.33% of the patients each in group M and group MP (p=1.000).

Table 5. SSI on post operative day 5

SSI Grade	Group M (n=30)		Group MP (n=30)	
	Number	Percentage	Number	Percentage
IA	2	6.67	1	3.33
IC	2	6.67	0	0.00
IIIC	0	0.00	1	3.33
Absent	26	86.67	28	93.33
Total	**30**	**100.00**	**30**	**100.00**

p = 0.513

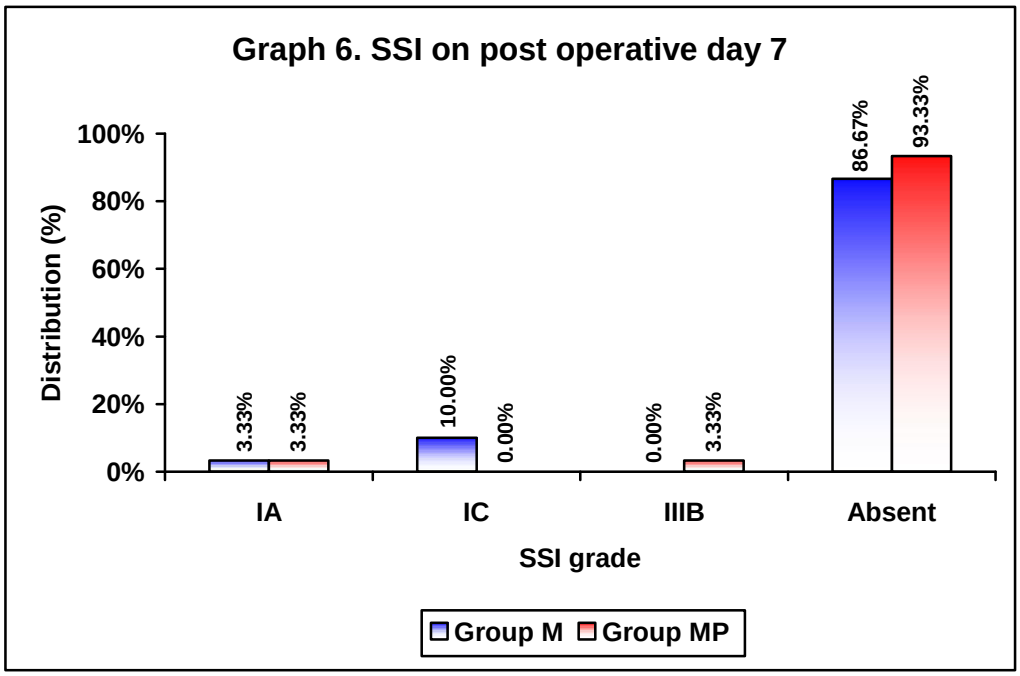


In this study, on post operative day five, among the patients with group M, grade IA (6.67%) and IC (6.67%) SSI was noted while in group MP grade IA (3.33%) and IIIC (3.33%) were present (p=0.513)

Table 6. SSI on post operative day 7

SSI Grade	Group M (n=30)		Group MP (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
IA	1	3.33	1	3.33
IC	3	10.00	0	0.00
IIIB	0	0.00	1	3.33
Absent	26	86.67	28	93.33
Total	**30**	**100.00**	**30**	**100.00**

p = 0.237

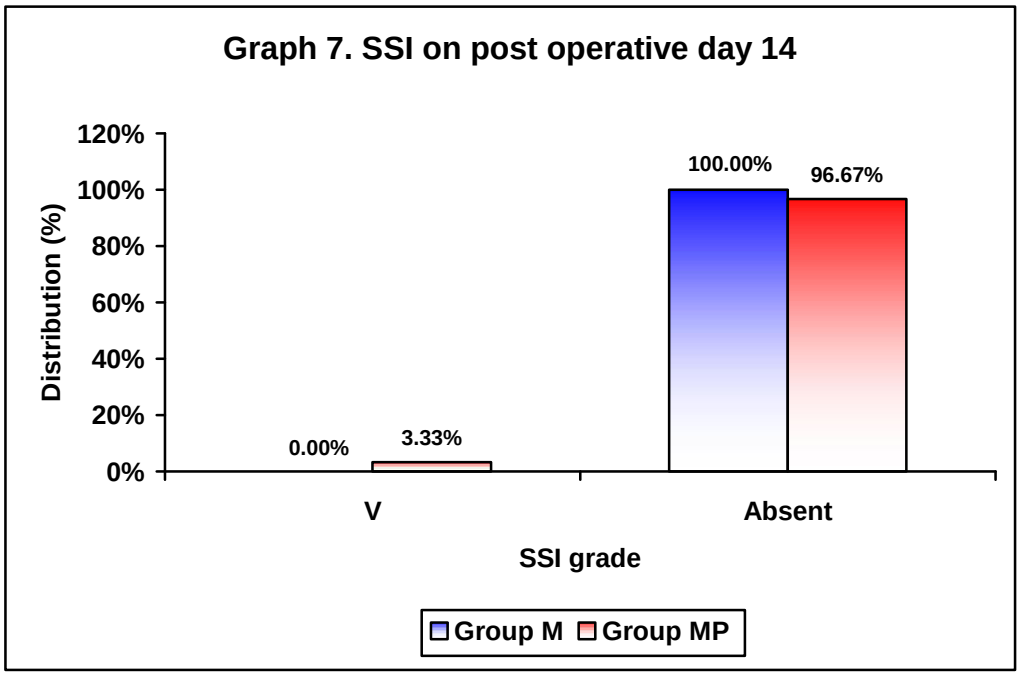


In the present study on post operative day seven, grade IA and IC were present in 3.33% and 10% of the patients who belonged to group M. In group MP, grade IA and IIIB were noted among 3.33% of the patients each (p=0.237).

Table 7. SSI on post operative day 14

SSI Grade	Group M (n=30)		Group MP (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
V	0	0.00	1	3.33
Absent	30	100.00	29	96.67
Total	**30**	**100.00**	**30**	**100.00**

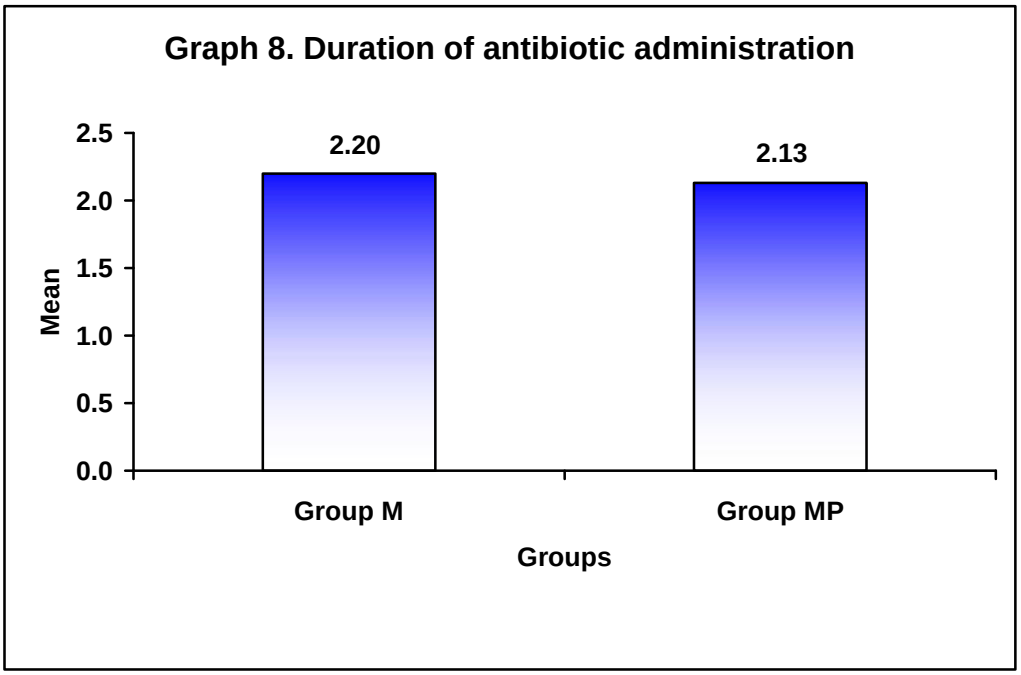
p = 1.000



In this study one patient (3.33%) in group MP had grade V SSI while none of the patient in group M had SSI (p=1.000).

Table 8. Duration of antibiotic administration

Variables	Group M (n=30)		Group MP (n=30)		p value
	Mean	SD	Mean	SD	
Duration (Days)	2.20	0.41	2.13	0.57	0.604



In the present study the mean duration of antibiotic administration in group M and MP was comparable (2.20 ± 0.41 compared to 2.13 ± 0.57 days; p=0.604).

DISCUSSION

Despite the advances made in asepsis, antimicrobial drugs, sterilization and operative techniques, surgical site infections (SSI) continue to be a major problem in all branches of surgery in the hospitals.[131] They have been responsible for the increasing cost, morbidity and mortality related to surgical operations and continue to be a major problem even in hospitals with most modern facilities and standard protocols of preoperative preparation and antibiotic prophylaxis. A major 30%-50% of antimicrobials prescribed in hospital practice are for surgical prophylaxis to prevent post-operative wound infection. A reduction in the infection rate to a minimal level could have significant benefits in terms of both patient comfort and medical resources used.[132]

The role of suture material in the development of wound infections has been the subject of speculation among surgeons since the 1960s.[12] Sutures are a contributory factor in infection. Most surgical site infections are related to suture. The superficial and deep reached 90% of SSI. Although efficacy against surgical infection: a strict aseptic technique, antibiotic coverage (when indicated), and an adequate surgical technique were applied, Infection rate remains high.[12]

Recently a new antimicrobial suture Poliglecaprone 25 coated with triclosan (monocryl Plus) has been introduced. Further few studies have compared monocryl and monocryl plus suture in hernia repair surgery as it is clean surgery. The present study was an attempt to evaluate the efficacy of new antibacterial suture (monocryl plus) compared with traditional suture (monocryl) in reducing surgical site

infections in inguinal hernia surgery so as to reduce the use of antibiotics post operatively.

This randomized controlled trial was carried out in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2013 to December 2013. A total of 60 patients undergoing elective inguinal hernia repair were divided into two groups of 30 each as Group MP where patients had wound closure using Monocryl plus suture and Group M in which wound closure done using conventional monocryl.

In the present study 40% of the patients in group M were aged more than 60 years whereas in group MP 33.33% of the patients were aged between 31 to 45 years ($p=0.341$). The mean age in group M was slightly high (56.96 ± 15.79 years) compared to group MP (45.50 ± 18.08 years) in group MP ($p=0.060$). However the difference observed in age distribution and the mean age was statistically not significant ($p>0.050$). The comparison of mean pulse rate, systolic and diastolic blood pressure and respiratory rate were also comparable in group M and MP ($p>0.050$). The findings rule out the bias as the demographic and clinical characteristics of the study population were comparable in group M and MP.

In the present study, on post operative day three, grade IC SSIs were present in 3.33% of the patients each in group M and group MP. On post operative day five, grade IA and grade IC SSIs were present in 6.67% each in group M whereas in group MP 3.33% of the patients each had grade IA and IIIC SSIs. During third follow up on post operative day seven, grade IA and IC were present in 3.33% and 10% of the patients in group M compared to 3.33% of the patients with grade IA and

IIIB in group MP. During last follow up one patient (3.33%) in group MP had grade V SSI while none of the patient in group M had SSIs. These findings suggest that, the efficacy of new antibacterial suture (monocryl Plus) is comparable with a traditional suture (monocryl) with regard to surgical site infection among the patients undergoing elective inguinal hernia repair. The exact reason for grade V SSI in the MP group could not be ascertained.

Monocryl Plus is a suture coated with triclosan (antiseptic) which inhibits bacterial colonization on the suture. In studies its been said that 5% of patients undergoing surgery may develop an SSI (surgical site infections), which may effect the quality of life of patients and their relatives and impose a considerable financial burden to health care providers.[12] Other consequences of (surgical site infection) SSIs are increased hospital readmission or longer stay, delay in ongoing treatments and decreased confidence in health care professionals.

Triclosan is a synthetic, polychlorinated, aromatic hydrocarbon with broad antimicrobial properties. Its lipophillic and active broad pH range (4-8) unlike other antiseptics. It passively dissipates from implanted suture to surrounding tissues where it is absorbed and widely distributed.

The susceptibility of the most common device-related pathogens combined with inherently low toxicity makes triclosan a favorable candidate for use in the clinical setting as antimicrobial suture. Many investigators have examined the relationship of suture construction and chemical composition as it relates to bacterial attachment and surgical infection. For example, Rothenburger et al,[133] 2002, report ability of coated polyglactin 910 sutures with triclosan to inhibit the growth of wild-

type and methicillin-resistant *Staphylococcus aureus* and *S. epidermidis* using several *in vitro* models. From these investigations, it is explicit that any suture product of natural or synthetic composition and of mono or multi-filament construction is susceptible to bacterial attachment and colonization. Explicitly, colonization is associated with surgical site infection. These data clearly support the conclusion that coated polyglactin 910 suture with triclosan provides an antimicrobial effect sufficient to prevent *in vitro* colonization of the suture by *S. aureus* included MRSA and *S. epidermidis* by using several *in vitro* models. For evaluated the effect of biofilms, Edmiston et al,[134] 2004, found the adherence of nosocomial surgical pathogens like MRSA, glycocalyx-producing *S. epidermidis*, VRE, *E. coli*, and *Pseudomonas aeruginosa* that produce biofilms that can prevent microbial adherence by coated polyglactin 910 suture with triclosan.

Edmiston et al,[117] 2006, reported that there are more studies to assess bacterial adherence and the antibacterial activity of a triclosan-coated polyglactin 910 (braided) suture against selected Gram-positive and Gram-negative clinical isolates from infect surgical wounds that reductions in both Gram-positive and Gram-negative bacteria such as *Staphyllococcus aureus* - methicillin-resistant *S aureus* (MRSA), *S epidermidis* (biofilm-positive), and *Escherichia coli* - extended-spectrum beta-lactamase (ESBL) or producer. The adherences were observed on triclosan-coated sutures compared with non-coated material. After insertion of antimicrobial suture, the inert surface is rapidly coated with tissue proteins, including fibrinogen, fibronectin, collagen, and other soluble substrates, all of which function as adhesions for microbial attachment. In this study was designed to provide an in vitro evaluation of contaminated suture material in an environment

mimicking the physiologic conditions within the surgical wound. For the suture material preconditioned in Bovine Serum Albumin (BSA), compared with non-conditioned suture material, there was approximately a 35% to 40% increased in staphylococcal and *E coli* adherence to the surface of both noncoated and triclosan-coated polyglactin 910 sutures. But, the BSA conditioning did not diminish the antiseptic activity of triclosancoated sutures compared with the non-coated devices.

After antimicrobial suture was developed successfully, a new type of antimicrobial sutures were established. The monofilament suture, Monocryl and PDS, was used instead of braided suture, Vicryl, for decreased the capillary effect of braided suture and may more improve rate of the SSIs.

In the present study, the mean duration of antibiotic administration was 2.20 ± 0.41 days in group M and the same was found to be 2.13 ± 0.57 days in group MP which comparable in both the groups (p=0.604). These findings suggest that, the infection control offered by monocryl plus is equal to that of conventional monocryl and there was no benefit in terms of reduction in antibiotic administration. This could be due to the smaller sample size. However The MP group showed less grade I, II and III SSIs. Only one infective case of monocryl plus group received different antiobiotic (Tab. Amoxyclav) for five days as organism growth was Staph Aureus and sensitive to Amoxiclav.

CONCLUSION

- Based on the findings of this study it may be concluded that, efficacy of new antibacterial suture (monocryl Plus) is comparable with a traditional suture (monocryl) in reducing surgical site infection among the patients undergoing elective inguinal hernia repair.

- In this study the requirement of antibiotics was similar in both groups.

- However further studies with larger sample size is required.

SUMMARY

Sutures are a contributory factor in surgical site infections. New antimicrobial suture Poliglecaprone 25 coated with triclosan (monocryl Plus) has been introduced recently. This study was undertaken to evaluate the efficacy of new antibacterial suture (monocryl plus) compared to traditional suture (monocryl) in reducing surgical site infections among the patients undergoing inguinal hernia and to see the use of antibiotics post operatively.

The present 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 elective inguinal hernia repair from January 2013 to December 2013 were divided into two groups of 30 each that is, Group MP (wound closure using Monocryl plus suture) and Group M (wound closure using conventional monocryl).

Most of the patients in group M were aged > 60 years (40%) compared to 31 to 45 years in group MP (33.33%) (p=0.341). The mean age in group M was 56.96 ± 15.79 years compared to 45.50 ± 18.08 years in group MP (p=0.060). Mean pulse rate, systolic and diastolic blood pressure and respiratory rate were comparable in group M and MP (p>0.050). On post operative day three, grade IC SSI was noted in 3.33% of the patients each in group M and group MP (p=1.000). On day five, among the patients with group M, grade IA (6.67%) and IC (6.67%) SSI was noted compared to grade IA (3.33%) and IIIC (3.33%) in group MP (p=0.513). On day seven, grade IA and IC were present in 3.33% and 10% of the patients in group M and in group MP, grade IA and IIIB were noted among 3.33% of the patients each

(p=0.237). One patient (3.33%) in group MP had grade V SSI while none of the patient in group M had SSI (p=1.000). The mean duration of antibiotic administration in group M and MP was comparable (2.20 ± 0.41 vs 2.13 ± 0.57 days; p=0.604).

The efficacy of new antibacterial suture (monocryl Plus) is comparable with a traditional suture (monocryl) in reducing surgical site infection among the patients undergoing elective inguinal hernia repair. Also the requirement of antibiotics using monocryl plus is same as compared to conventional monocryl.

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ANNEXURE I – CONSENT FORM

Id.No:-

You are requested to enrol yourself in study entitled, **"A RANDOMIZED CONTROLLED TRIAL TO COMPARE EFFICACY IN REDUCING SURGICAL SITE INFECTION OF MONOCRYL PLUS VERSUS MONOCRYL IN SUBCUTICULAR SKIN SUTURING IN PATIENTS WITH ELECTIVE INGUINAL HERNIA REPAIR – A ONE YEAR STUDY"** that is an attempt to find out effectiveness of triclosan coated suture in decreasing surgical site infections, which is being conducted by Dr. **** *****, post graduate in Surgery at Jawaharlal Nehru Medical College Belgaum, Karnataka. Under guidance of Dr. ****** ******** Professor, Department of Surgery, Jawaharlal Nehru Medical College, Belgaum, under KLE University, Belgaum.

Respected Sir/Madam, we request you to enroll yourself to participate in our study as you are eligible for participating in this study. During the study you will be asked some questions regarding your present complaints and you are suppose to answer to the best of your knowledge.

Your participation in research is voluntary. If you decide to participate you are free to withdraw at any time.

The purpose of research is to evaluate the efficacy of new antibacterial suture (Monocryl Plus) compared with a traditional suture (Monocryl) in reducing abdominal surgical site infection.

Procedure involved

If you agree to enroll yourself in my study, you will be interviewed regarding your present and past history then you will be clinically examined in detail and investigated accordingly. Computer generated blocked random numbers will be used to assign the type of surgery to the patients that is, Group A or Group B. If you are in Group-A monocryl plus suture will be used and if you are in Group-B conventional monocryl suture will be used. The Post-Operative care will be same for both groups of participants. The wound will be assessed on post operative day three, five and seven and ten.

Benefits and Risks

The benefits of taking part in this research are you will have reduced abdominal surgical site infection, avoiding post op. dose of antibiotics. There are no observable risks associated in this study.

Voluntary participation / Withdrawal

Taking part in the study is voluntary. You may choose not to enrol yourself in this study. Your decision will not change present or future health care services offered to you at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.

Alternatives

Even if you decline the participation in the study, you will get the routine line of management.

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 and if required by law.

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 you will remain confidential.

Financial Incentives for participation

No 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.

Compensation

In the event of injury, related to the study, treatment will be made available at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. There is no compensation or payment for such medical treatment by law.

Questions/Contact details

If you have any queries, in future or in case of study related injury or illness, you may contact. Dr. ***** ******** at Department of Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum Phone Number ***** ******** or on ****** ******.

If you have any queries rlated to case of study subject, you may call Dr. ***** ********, Professor, Department of General Surgery, J. N. Medical College, Belgaum, under whose guidance this study is conducted, contact no.**** ******

If you have any queries about your rights as a study subject, you may call Dr. ***** ******* Chairperson, Professor and head, Department of Pathology J. N. Medical College Institutional Ethical Committee for Human Subjects Research, Ph. **** ******* at J. N. Medical College, Belgaum.

CONSENT TO PARTICIPATE IN A RESEARCH STUDY:

I, Mr./Mrs. _____

voluntarily agree to take part in this study, by signing this consent form I am not giving up my legal rights. I may withdraw at any time. I am signing after having read, or been read to me in the vernacular language including risks and the benefits and having all queries cleared.

Subject Name: _____

Signature of the participant _____ Date _____
Or Left thumb print
Witness name: _____

Signature: _____ Date _____

Investigator's name: _____

Signature: _____ Date _____

Place: _____

ANNEXURE II – PROFORMA

STUDY: A RANDOMIZED CONTROLLED TRIAL TO COMPARE EFFICACY IN REDUCING SURGICAL SITE INFECTION OF MONOCRYL PLUS VERSUS MONOCRYL IN SUBCUTICULAR SKIN SUTURING IN PATIENTS WITH ELECTIVE INGUINAL HERNIA REPAIR – A ONE YEAR STUDY

PATIENT DETAILS

Name	:	IP No	:
Sex	:	Age	:
Date of admission	:	Date of Surgery:	
Address	:		

HISTORY

Chief Complaints

EXAMINATION

General Examination

Built and Nourishment: ***Weight:***

Pallor/Icterus/Cyanosis/Clubbing/Edema/Lymphadenopathy

Vitals

Pulse Rate	:	/Min	B.P.	:	mm Hg
Temperature	:	^{0}F	R. R.	:	/Min

Systemic Examination

Respiratory :

CVS :

CNS :

Local examination

Per abdomen :

INVESTIGATIONS

Blood - Routine : Hb: Total count: Platelet:

Random blood sugar :

Blood urea. :

Sr. Creatinine. :

Bleeding time :

Clotting time :

Urine routine and microscopy

OPERATION DETAILS

Group : Group A / Group B

Date of surgery :

Procedure done :

Anaesthesia Duration of the surgery :

Assessment of wound

Grades		Appearance	Interval			
			Day 3	**Day 5**	**Day 7**	**Day 14**
0		**Normal healing**				
I		**Normal healing with mild bruising or erythema**				
	A	Same bruising				
	B	Considerable bruising				
	C	Mild erythema				
II		**Erythema plus other signs of inflammation**				
	A	At one point				
	B	Around sutures				
	C	Along wound				
	D	Around wound				
III		**Clear or haemoserous discharge**				
	A	At one point only (< 2 cm)				
	B	Along wound (> 2 cm)				
	C	Large volume				
	D	Prolonged (> 3days)				
IV		**Major complications**				
	A	At one point (< 2 cms)				
	B	Along wound (> 2 cm)				
V		**Deep severe wound infection with or without tissue breakdown; haematoma requiring aspiration**				

ANNEXURE III – KEY TO MASTER CHART

BP	-	Blood pressure
m	-	Male
M	-	Monocryl
mm Hg	-	Millimeters of mercury
MP	-	Monocryl plus