"A ONE YEAR RANDOMISED CONTROLLED TRIAL TO COMPARE THE EFFICACY OF KNOTLESS BARBED SUTURES VS. SUBCUTICULAR MONOFILAMENT SUTURES FOR SKIN CLOSURE IN OPEN INGUINAL HERNIA REPAIR"

BY

REG NO. B H 0 1 1 6 0 1 2

Dissertation

Submitted to the

KLE Academy of Higher Education and Research, Belagavi, Karnataka

In partial fulfillment

of the requirements for the degree of

MASTER OF SURGERY(M.S)

IN

GENERAL SURGERY

DEPARTMENT OF GENERAL SURGERY,
J. N. MEDICAL COLLEGE
BELAGAVI- 590010. KARNATAKA

APRIL - 2019

KLE Academy of Higher Education and Research, Belagavi, KARNATAKA

Endorsement by the HOD/ Principal/ Head of the Institution

This is to certify that the dissertation entitled **"A ONE YEAR RANDOMISED CONTROLLED TRIAL TO COMPARE THE EFFICACY OF KNOTLESS BARBED SUTURES VS. SUBCUTICULAR MONOFILAMENT SUTURES FOR SKIN CLOSURE IN OPEN INGUINAL HERNIA REPAIR"** is a bonafide research work done by **REG NO. BH0116012**

Dr. A.S.GOGATE **M.S.**
Professor and Head,
Department of General Surgery,
J. N. Medical College,
Nehru Nagar, Belagavi – 10

Date:
Place: Belagavi

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

Date:
Place: Belagavi

LIST OF ABBREVIATIONS USED

VS	-	Versus
BC	-	Before Christ
BSA	-	Bovine Serum Albumin
CDC	-	Centers for Disease Control
CFU	-	Colony-forming units
cm	-	Centimeter
RS	-	Respiratory System
CVS	-	Cardiovascular system
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
TC	-	Total Count
HIV	-	Human immunodeficiency virus
IP No	-	In patient number
IPOM	-	Intra-peritoneal onlay mesh
mg	-	Milligram
Min	-	Minutes

mmHg	-	Millimeters of mercury
MPO – Myo	-	pectineal orifice
MRSA – Methicillin	-	resistant Staphylococcus aureus
n	-	Total number
NNIS	-	National Nosocomial Infection Surveillance
p	-	Probability
PHS	-	Prolene hernia system
PPM	-	Polypropylene mesh
Sr.	-	Serum
VAS	-	Visual Analogue Score
SSI	-	Surgical site infections
TAPP	-	Trans-abdominal pre-peritoneal
TEP	-	Totally extra-peritoneal
UK	-	United Kingdom
US	-	United States
p	-	Probability value

ABSTRACT

Backgrounds and Objectives

There exists a need to provide good wound closure in terms of low rates of SSI and acceptable cosmesis. The advent of the knotless barbed sutures has provided a novel approach to the same. This study was undertaken to evaluate the efficacy of knotless barbed sutures as compared to the subcuticular monofilament in reducing post-operative pain and SSI in patients undergoing open inguinal hernia repair.

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 2017 to December 2017 were divided into two groups of 30 each that is, Group A (wound closure using V-Loc^{TM} 90, Knotless barbed sutures) and Group B (wound closure using conventional Monocryl, subcuticular monofilament sutures).

Results

In this study all participants were males (100%). In Group A, the median age was 56 years (IQR 38, 70) and it was 46 years (IQR 31.75 to 65) in Group B. Median pain scores at 6 hrs were 4 (IQR 4, 5) and 5 (IQR 5, 6) in Group A and B (P value <0.001) , 12 hrs were 3 (IQR 3, 4) and it was 4 (IQR 4, 5) in Group A and Group B respectively (P Value< 0.001) at 24 hrs it was 4 (IQR 3, 4) and 5 (IQR 4, 5) in Groups A and B respectively (P value <0.001). The median pain score at 48 hrs, was 3 (IQR 3, 4) and 4 (IQR 3, 4) in Groups A and B respectively (P value 0.086) and at 72 hrs was 3 (IQR 2, 3) in Group A and it was 3 (IQR 2.75, 3) in Group B (P value of

0.147). On post-operative Day 3, SSI of grades of Ia and Ic was seen in 3.33% of patients in each group. (P value 1.000) On Day 8, Grade Ia, Ib, Ic and IIa was seen in 3.33% of patients each in Group A and was seen in 3.33% of patients each with Grade Ia, Ib and IIa healing and 6.67% with Grade Ic healing in Group B (P value 0.986) and on Day 10, Group A had 6.67% of patients with Grade Ia, 3.33% with Ib and 3.33% with Grade Ic. Group B had 10% of patients with Grade Ia, 6.67% of patients with Ib and Ic healing each P value (0.789)

Conclusion

The incidence of SSI with the Knotless barbed sutures (V-Loc™ 90) is comparable to the conventional monofilament subcuticular sutures (Monocryl). There was lesser early post-operative pain in the Knotless barbed suture group reported.

Keywords

Knotless barbed sutures; Monofilament subcuticular; Wound closure; Inguinal hernia repair; Surgical Site Infections.

CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF GRAPHS

LIST OF PHOTOGRAPHS

INTRODUCTION

Inguinal hernia occurs in 73% of all cases of hernia and is 20 times more common in males than in females[1]. Inguinal hernia repair is one of the most common surgical procedures performed worldwide. In developed countries like the United States, approximately 800,000 mesh hernioplasties are performed in a year.[2]

Post-operative pain is an important aspect in the inguinal hernia repair surgery. It depends on various aspects of the surgery. In the early post-operative period pain depends on modality used to incise skin, length of skin incision, type of analgesia received and local inflammation (nociceptive pain). Chronic inguinal pain is mostly neuropathic pain (nerve entrapment, neuroma or direct nerve injury).[3] The use of the ideal suture material plays a role in reducing local tissue irritation and subsequently inflammation and pain.

Wound infection in inguinal hernia repair is a potential complication.[4] It generally appears between fifth and tenth day following surgery.[4] The rate of mesh infection has been reported as high as 3% in open hernia repair.[5]

Surgical site infections are the third most common hospital acquired infection and account for 14 to 16% of all such infections.[6] The definition for SSI according Centre for Disease Control and Prevention include every SSI that occurs 30 days following an operation.[7] Infections can be categorised as incision (superficial or deep) infections or organ-space infection. Superficial SSI involve only infections of skin and subcutaneous tissue and exclude stitch abscess. Deep SSIs include infection of only the deeper soft tissues at the site of incision.

Potential sources of infection are the patient himself, other patients, food, staff, surgical instruments, dressing and even drugs or injections.[8] Despite adequate aseptic precautions, antibiotic coverage and good surgical technique there exists a risk of infection.[9] Suture material is also a known to be a nidus for infection.[10]

A suture is a biomaterial device, natural or synthetic, used to approximate tissue together following surgery or trauma. Although other methods for wound closure like staples, tissue adhesive and steri-strips have been used, suture remains the most widely used materials.

Many modifications in suture materials have been made to reduce the incidence of SSI. Use of antibiotic or antiseptic coated suture material and absorbable monofilament sutures to prevent suture granulomas are some methods to reduce incidence of infection and improve wound healing.[11] These measures also ensure better wound cosmesis.

A recent technical modification in suture material is the addition of barbs to the substance of the strand which creates an effective strategy to stabilize the suture and secure it. It also distributes the tensile strength of the material equally. Surgical knots have been identified to be a nidus for infection and predispose to seroma formation. The presence of the barbs eliminates the necessity for application of knots and hence infection. These barbs maybe unidirectional or bidirectional along the suture. They are designed to anchor within the tissue and distribute the tension throughout the wound equally ensuring better approximation.[12]

The application of barbed sutures has been studied for wound closure in gynaecological, orthopaedic, plastic surgery and cardiothoracic procedures. These

studies have shown decreased closure time, lesser incidence of wound infection and better cosmesis[13]

This study was undertaken to evaluate the efficacy of knotless barbed sutures as compared to monofilament subcuticular sutures (Monocryl) in reducing post-operative pain of inguinal hernia repair. Additionally, the incidence of Surgical site infection was also compared between the two groups.

OBJECTIVES

The objective of the study was to evaluate the efficacy of Knotless barbed sutures (V-Loc^{TM} -90) in comparison with conventional monofilament subcuticular sutures (Monocryl) in terms of reducing

1) Post-operative pain
2) Surgical Site Infection

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, one can assume that even prehistoric human beings were affected with the disease.

Inguinal hernia repair has made vast progress through 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 hernial contents 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 rates and became the procedure of choice. Laparoscopic repair of inguinal hernia is also gaining popularity.[14]

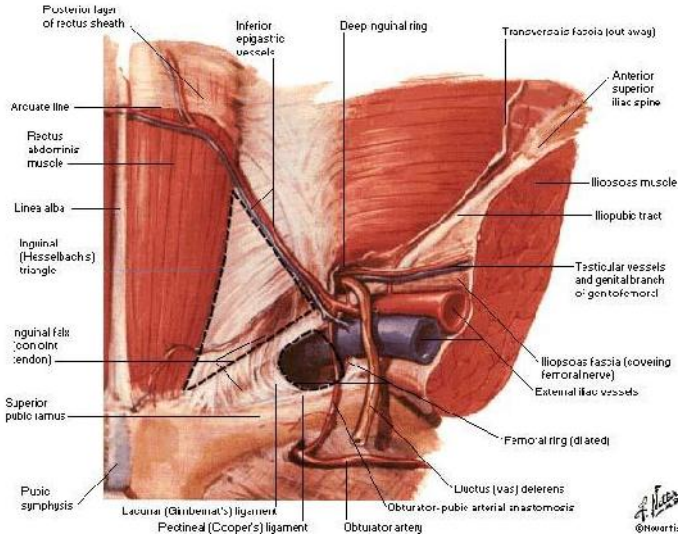


Figure 1: Anatomy of Inguinal Canal[15]

Anatomy[16]

Abdominal Wall Tissue

Tissues in the abdominal wall have different consistency and function, which also must be considered in hernia repair.[16]

- *Fascia* is a layered condensation of connective tissue (eg, Camper's, Scarpa's, Innominate, Cribriform).
- *Aponeurotic* tissue is connective tissue which has measurable strength (eg, crura of the external oblique).
- Major muscles of the abdominal wall are the *external and internal oblique muscles*, the *transversus abdominus* and the *rectus muscles*. Fascial sheaths cover them all.
- The *anterior rectus sheath* is composed of aponeuroses of both the oblique muscles and the transversus abdominus muscle.
- The *posterior rectus sheath* is composed of fibres from the transversus abdominus and internal oblique aponeuroses. Below the semi-circular line described by Douglas (located midway between the pubis and the umbilicus), there is deficient of posterior sheath, being only transversalis fascia
- The *innominate fascia* covers the external oblique and the spermatic cord as it emerges between the crura of the external ring.
- The *external spermatic fascia* covers the pubic and scrotal portion of the spermatic cord.
- The *internal spermatic fascia* covers the spermatic cord within the inguinal canal.

- The *internal inguinal ring* is located 2 cm above the inguinal ligament in the groin and midway between the pubic tubercle and the anterior superior iliac spine.
- The *inguinal ligament* is formed by fibres 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 fibres of the external oblique aponeurosis, between its medial and lateral crura. The reflected inguinal ligament on each side meets in the midline over the rectus sheath. Interparietal fascia separate the oblique and transversus muscles.
- The *conjoint tendon*, which exists in only 3% to 6% of patients, is a fused tendinous 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).[17]
- The *transversalis fascia* gives rise to many structures in the groin: the superior pubic ligament, the iliopubic tract, the internal spermatic fascia, the interfoveolar ligament, the lacunar ligament, the anterior and posterior crura of the internal ring, and the anterior portion of the femoral sheath.
- The posterior wall of the inguinal canal is composed of 3 layers. The more superficial is the *aponeurosis of the transversus abdominus.* Deep in it there

are 2 thin layers of *transversalis fascia*. The *deep epigastric vessels* run between these 2 layers. Defects in the canal's posterior wall result from a deficiency in strong fibres of the transversus abdominus aponeurosis in the lower half of that triangle, just above the most vulnerable area of the abdomen.[18]

- The *superior pubic ligament* (Cooper ligament) is the periosteum of the superior pubic ramus.
- The *iliopubic tract* is an aponeurotic band of tissue within the transversus abdominus aponeurotic layer. It runs parallel to the inguinal ligament from the iliopectineal arch to the superior ramus of the pubis.

  It is more easily visualized from the posterior view, but often is difficult to dissect from the anterior approach. It varies considerably in its thickness, thus making its identification from either approach questionable.[16]

The Myo-pectineal orifice of Fruchard

The Myo-pectineal 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.[16]

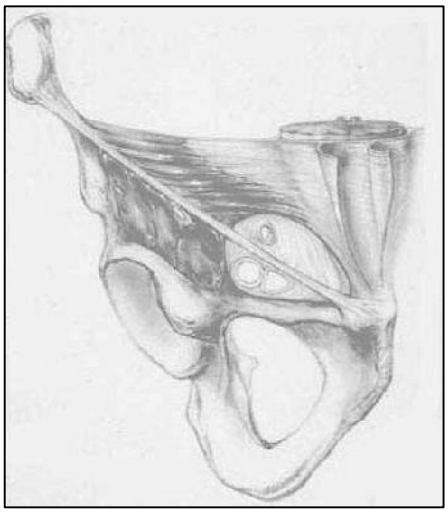


Figure 2. The Myo-pectineal orifice. The passageway for the great vessels to the lower extremity, and for the testicle to reach the scrotum[16]

- The MPO is divided anteriorly by the inguinal ligament, and posteriorly by the ilio-pubic tract. It is bounded medially by the lateral border of the rectus muscle, superiorly by the arching fibres of the transversus abdominus and the internal oblique muscles, laterally by the iliopsoas muscle and inferiorly by the Cooper ligament.
- The MPO is perforated in its superior plane by the spermatic cord, and through its inferior plane by the femoral vessels.
- The MPO is protected only by the combined lamina of the aponeurosis of the transversus abdominus and the transversalis fascia.[16]

Vascularity

The arterial supply in the groin arises from the external iliac artery, which gives off the deep circumflex iliac and inferior epigastric arteries before becoming the common femoral artery. The internal spermatic (testicular) artery arises from the aorta. Venous drainage proceeds through the spermatic cord by the pampiniform plexus. This plexus of delicate veins is intertwined within the interstitial fat of spermatic cord. The internal spermatic vein on the left side drains into left renal vein. Venous drainage on the right is into the inferior vena cava[16]

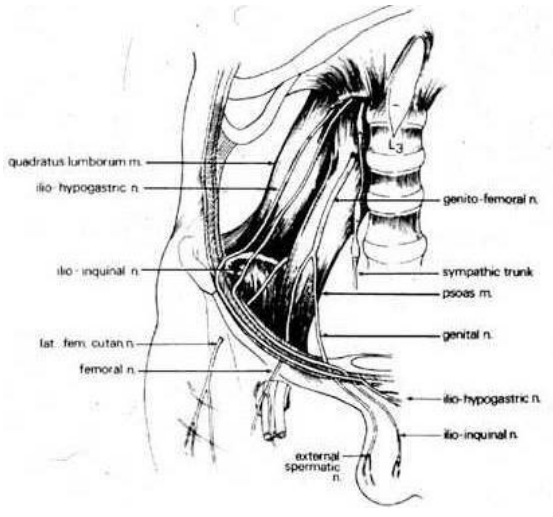


Figure 3. Nerve supply to the groin[16]

The *iliohypogastric nerve*, which arises from the 12th dorsal and 1st lumbar roots, emerges into the groin as it perforates the posterior part of the transversus abdominus muscle and divides into lateral and anterior cutaneous branches. The anterior branch travels between the internal oblique and transversus muscles while supplying both muscle groups. It pierces the internal oblique muscle approximately 2 cm medial to the anterior superior spine. It perforates the external oblique muscle about 3 cm above the external ring external ring and provides sensation to the skin of the abdomen above the pubis.

The *Ilioinguinal nerve* arises from the 1st lumbar nerve root. It perforates the transversus abdominus muscle near the anterior iliac spine, then pierces the internal oblique muscle and proceeds within the cremasteric fascia following the spermatic cord through the external ring. It provides sensation to the medial area of the thigh, over the base of the penis and the upper scrotal area. The *genital-femoral nerve* arises from the 1st and 2nd lumbar nerves. It divides deep to the posterior wall where the genital branch perforates the posterior wall near the internal ring, then proceeds through the canal in the lateral bundle of the cremasteric fascia with the cremasteric vessels. The femoral branch passes behind the inguinal ligament and enters the femoral sheath lateral to the femoral artery. These 3 nerves are mainly sensory but do supply some motor function to the internal oblique and cremasteric muscles of the spermatic cord.[16]

Classification and symptoms of hernia in the groin

More than 10 classifications have been described to date. The most frequently used is probably the Nyhus classification.[19,20] It describes almost all types including pantaloon and femoral hernias and pays attention to recurrent hernias. Gilbert classification is simpler but lacks in the description of combined and femoral

hernias.[21] Aaachen classification that was developed by Schumpelick and colleagues is based on an easy system.[22] 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.

EHS classification defines the location of hernia with reference to 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.[19]

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.[19]

Management

The earliest record of inguinal hernia dates to 1500 BC. In the middle ages, results of attempted repairs were poor.[23]

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.[24]

The modern age of hernia repair began about 45 years ago with the introduction of monofilament knitted polyethylene mesh to reinforce a previous sutured repair. The introduction of polypropylene mesh (PPM) as a synthetic biomaterial for hernia surgery soon followed. Most hernia repairs performed today involves the placement of some synthetic biomaterial. The most revolutionary

developments occurred over the last 15 years with the development of laparoscopic surgery and its subsequent application in inguinal hernia repair. Refinements in minimally invasive hernial repair techniques, along with evolving medical technologies have changed the present-day scenario altogether.[23]

A modest improvement in the surgical outcome has a significant impact on the surgical practice.[23]

With a better understanding of the anatomy and physiology of the inguinal area and knowledge of the most effective currently available techniques and materials, it has been possible to reduce recurrence rates greatly. However, the choice of repair remains controversial and no consensus has been reached regarding the surgical approach showing good cost-effective results.[23]

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.[23]
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 over the cord.

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. 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.[23]

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 with this method created resulted in recurrences.[23]

E. E. Shouldice in the second half of the 20th century revitalized Bassini's original technique of herniorrhaphy.[25] Under local anaesthesia, he performed a double layer repair of fascia transversalis followed by approximation of the conjoined tendon, ilio-pubic tract and inguinal ligament as third and fourth layers with non-absorbable sutures (originally stainless-steel wire). Repaired flaps of external oblique aponeurosis cover the latter.

Many other innovative surgeons have tried to improve the outcome of primary tissue repair. Annandale[26] first described the posterior approach to inguinal hernia repair.

Cheatle[27] revitalized the issue of posterior preperitoneal approach. Henry[28] began using it for femoral hernia repair and recently US surgeons Nyhus, Condon and Harkins effectively adapted the posterior preperitoneal approach for the repair of all types of inguinal hernias.[29] They employed only sutures for repair of type I, II and IIIC hernias.

Open mesh repair

Different materials have been 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.[23] The concept of hernia repair underwent a major 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 non-metallic mesh was a machine knitted polyester polymer called Dacron.[23]

In 1976, Gore by refining the technique of expanding polytetrafluorethylene developed the expanded PTFE or e-PTFE as a sheet. Its first use in hernia repair was in 1983.[23]

Recently some of the prosthetic biomaterials have been combined to form various composite mesh 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 multi-filamentous mesh composed of 50% polyglactin 910 (absorbable) and 50% polypropylene. Ingrowths of fibrous tissue and collagen within the mesh provide strength to the repair.[23]

Different methods of repairs[19]

A. Tension-free prosthetic repair

a. Anterior repairs

i. Lichtenstein repair and it's 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

All tension free repairs require placement of a mesh. This is made by either an anterior, posterior or laparoscopic approach

Giant prosthetic reinforcement of the visceral sac (GPRVS)

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.[30] 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).[31] Wantz[32] 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.

Lichtenstein onlay patch repair

This is an example of open anterior tension free repair.[33] 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) buttresses the weak inguinal floor. The on-lay 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. By Lichtenstein mesh hernioplasty, repair without suture line tension and distortion of anatomy is possible.[23]

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 on-lay 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. Initially, this technique used a plug or cigarette, made of mesh in the hernial defect and then the patch was applied. Later Rutkow modified the technique of the plug and patch repair.[23]

Gilbert′s sutureless[34] repair of inguinal hernia with an umbrella plug along with an on-lay patch was attempted in a similar technique.

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 due to the intra-abdominal pressure.[23]

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 on-lay 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 bi-layered repair with PHS gives dual benefits of Lichtenstein repair (placement of the oblong on-lay patch on the inguinal floor) and those of the laparoscopic approach (the round inlay component in the preperitoneal space).[23]

Laparoscopic hernia repair

Ger in 1982[35] 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[36] by intra-corporeal suture of the deep ring after plugging a PPM into the sac. Toy and Smoot in 1991[37] described a technique of intra-peritoneal onlay mesh (IPOM) placement, where an intraabdominal piece of polypropylene or e-PTFE was stapled over the myo-pectineal orifice without dissection of the peritoneum. The IPOM had some major drawbacks like possibility of bowel adhesions and migration of the mesh.

The present-day techniques of laparoscopic hernia repair evolved from Stoppa′s concept of pre-peritoneal reinforcement of fascia transversalis over the myo-pectineal orifice with its multiple openings by a prosthetic mesh.[23]

In the early 1990′s Arregui and Doin[38,39] 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 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.[23]

Around the same time Phillips and McKernan[40,41] described the totally extraperitoneal (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 essential. Once

the dissection is complete, a 15 x 10 cm mesh is stapled in place over the myo-pectineal 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 .[23]

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).[23]

Certain guidelines prescribed by the UK National Institute of Clinical Excellence[42] on laparoscopic hernia repair are as follows:

- For primary inguinal hernia repair, open (mesh) technique should be 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[43] 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 un-detached 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 have been quite encouraging.

An ideal hernia repair should be durable, produce low levels 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 preference between laparoscopic and open repair is still debatable and depends largely on the expertise of the surgeon. The use of General anaesthesia for laparoscopic repair is also a deterrent although there is lesser post-operative pain and early recovery observed with the same.

❖ **Common types of skin closure techniques**

- Simple suture
- Interrupted mattress suture
  - o Vertical mattress
  - o Horizontal mattress
- Continuous subcuticular suture
- Skin staples
- Adhesive paper strips
- Liquid tissue glues

Proper skin closure begins with knowing what material or technique is best suited to close incision. The choice of skin closure material depends on anatomical location of incision, type of surgery, length of incision and existing infection.

Surgical sutures

Sutures, or stitches, are the oldest method still in use to close an incision. The surgeon uses a sterilized thread, which may be made of natural materials (silk or catgut) or synthetic fibres, to stitch the edges of the cut together with a special curved needle. There are two major types of sutures, absorbable and non-absorbable.

Absorbable sutures are gradually broken down in the body, usually within two months. Absorbable sutures do not have to be removed. They are used most commonly to close the deeper layers of tissue in a large incision or in such areas as the mouth. Nonabsorbable sutures are not broken down in the body and must be removed after the incision has healed. They are used most often to close the outer layers of skin or superficial cuts.[44]

Sutures have several disadvantages. Because they are made of materials that are foreign to the body, they must be carefully sterilized and the skin around the incision cleansed with Betadine or a similar antiseptic to minimize the risk of infection. Suturing also requires more time than newer methods of closure. Lastly, there is a higher risk of scarring with sutures, particularly if the surgeon puts too much tension on the thread while stitching or selects thread that is too thick for the specific procedure.[44]

Surgical staples

Surgical staples are a newer method of incision closure. Staples are typically made of stainless steel or titanium. They are used most commonly to close lacerations on the scalp or to close the outer layers of skin in orthopaedic procedures. They

cannot be used on the face, hand, or other areas of the body where tendons and nerves lie close to the surface. Staples are usually removed seven to 10 days after surgery.[44] Staples are less likely to cause infections than sutures, and they also take less time to use. They can, however, leave visible scars if the edges of the wound or incision have not been properly aligned. In addition, staples require a special instrument for removal.[44]

Steri-strips

Steri-strips are pieces of adhesive material that can be used in some surgical procedures to help the edges of an incision grow together. They have several advantages, including low rates of infection, speed of application, no need for local anaesthesia, and no need for special removal. Steri-strips begin to curl and peel away from the body, usually within five to seven days after surgery. They should be pulled off after two weeks if they have not already fallen off. Steri-strips, however, have two disadvantages: they are not as precise as sutures in bringing the edges of an incision into alignment; and they cannot be used on areas of the body that are hairy or that secrete moisture, such as the palms of the hands or the armpits.[44]

Liquid tissue glues

Tissue glues are the newest type of incision closure. They are applied to the edges of the incision and form a bond that holds the tissues together until new tissue is formed. The tissue glues most commonly used as of 2003 belong to a group of chemicals known as cyanoacrylates. In addition to speed of use and a low infection rate, tissue glues are gradually absorbed by the body. They are less likely to cause scarring, which makes them a good choice for facial surgery and other cosmetic procedures. They are also often used to close lacerations or incisions in children, who find them less frightening or painful than sutures or staples. Like Steri-strips,

however, tissue glues cannot be used on areas of high moisture. They are also ineffective for use on the knee or elbow.[44]

- **Classification of sutures**

There are 3 main classifications of suture materials.[45]

Based on no. of strands

Monofilament

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

Multifilament

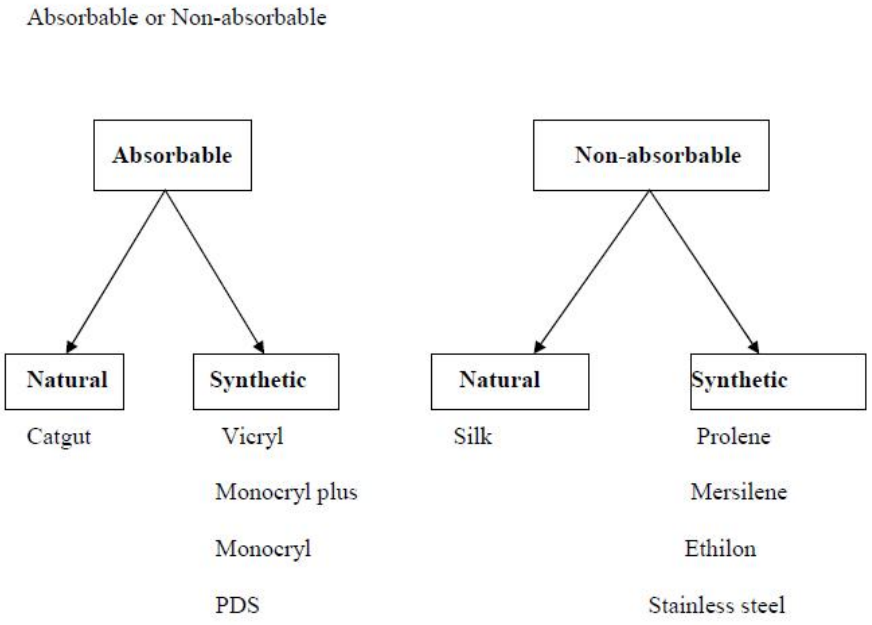
Vicryl (Polyglactin 910), Vicryl plus, Dexon(polyglycolic suture), Silk, Mersilene (Braided polyester)

Based on source

Natural or Synthetic

Based on absorption

Absorbable or Non-absorbable



New devices and technologies are constantly emerging in the market, and they are often widely adopted before scientific comparison to the pre-existing accepted standard. For many of the operations performed by surgeons, the lengthy closure time of the procedure adds significantly to the costs, increases anaesthetic time, and potentially increases patient risk. New approaches to wound closure that result in shortened operative time, while improving or at least not compromising quality, may be justified despite the apparent increase in device cost compared with standard suturing techniques. One such technical modification to the existing sutures in use for wound closure is the application of barbs to the suture material.

Barbed sutures are currently manufactured by Quill, Covidien (V-Loc) and Stratafix^{TM} (Ethicon). The manufacturing involves cutting of a strand of suture using a specialized blade. Although this method presents many manufacturing advantages, perhaps the most important drawback from a clinical perspective is that cutting barbs into suture reduces the tensile strength of the suture by weakening its core and narrowing its functional diameter. Thus, it is vital that clinicians understand the individual tensile strength of the particular suture being used rather than relying on synonymous measurements of traditional smooth sutures.[46]

Barbs maybe placed in a unidirectional or bidirectional manner. Quill^{TM} manufactures bidirectional barbed sutures which uses a back-cut in the strand of several types of monofilament sutures, both absorbable (polyglycolic acid/polycaprolactone [Monoderm] and polydioxanone [PDO]) and nonabsorbable (nylon and polypropylene).

Here, the basic strategy relies on a bidirectional approach, with a needle attached on either end of the suture. The directionality of the barbs then changes at the midpoint of the suture strand. As a result, wound closure using a Quill^{TM} device

begins at the midpoint of the wound. Several passes of the suture are made in 1 direction until there is lodging of the barbs into the soft tissue. This then acts as the anchor by resisting the pulling of the opposite end of the suture through the tissues, as tension is applied by passing the remaining half of the strand in the opposite direction. Both ends are then passed through the tissue running in opposite directions until the wound is closed. At the end of the suture, a small back pass is added to the closure to enhance the engagement of the barbs, and thus there is no need to incorporate a loop or other type of fixation method as the suture is locked into position. As a result, the suture is simply cut flush with the skin and the cut end retracts slightly below the skin level.[46]

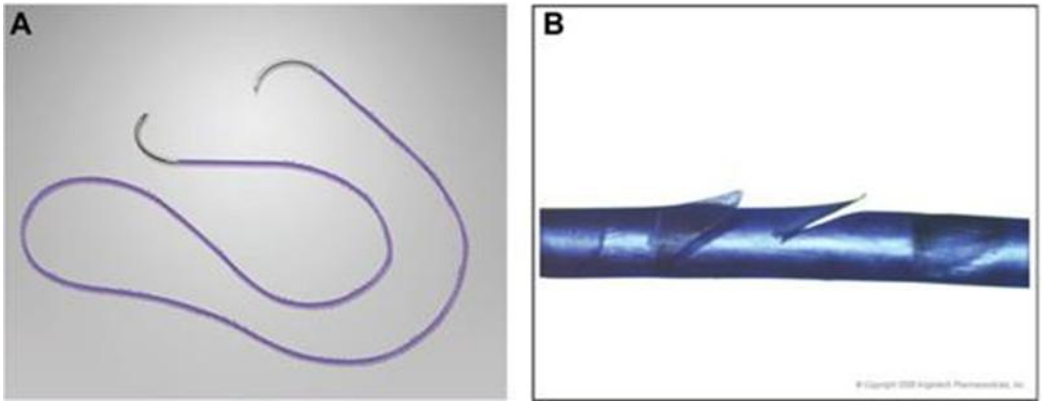


Figure 4[46] (A) The bidirectional suture has a needle at each end with the barbs switching directions at the midpoint. (B) Scanning electron micrograph of a Quill bidirectional suture

Covidien manufactures the V-Loc™ -90 and V-Loc™ 180 sutures whose nomenclature is based on their absorption, i.e., rapidly absorbable and delayed absorbable respectively. Currently, the V-Loc suture is available only in an absorbable form (combination of polyglycolic acid, 60%; polytrimethylene carbonate, 26%; and polydioxanone, 14%). The basic strategy with the V-Loc device is similar to that used with Quill, with the major difference being that the V-Loc is a unidirectional barbed suture. The V-Loc has a welded loop at 1 end of the suture

strand that is used to secure the beginning of the wound closure. Therefore, as opposed to starting in the middle of the wound as with Quill, closure with the V-Loc begins at either end of the wound. The suture is passed through the loop, and closure then proceeds along the length of the wound in a unidirectional fashion until the wound is closed.[46]

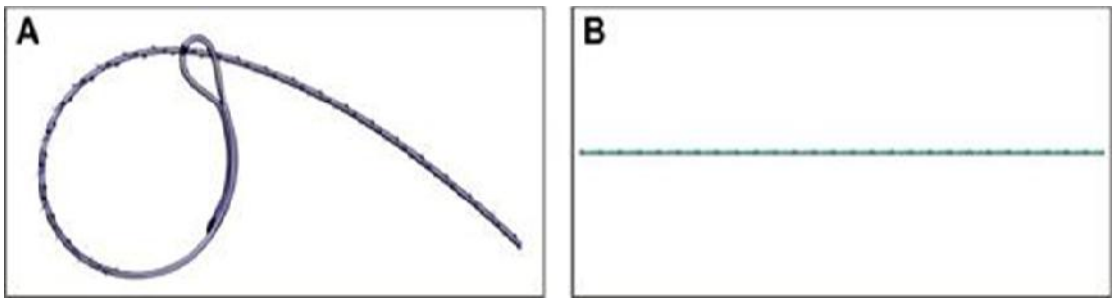


Figure 5[46] (A) The unidirectional suture features a needle at one end with a loop at the other and the barbs oriented in the same direction along the entire length of the suture strand. (B) Scanning electron micrograph of a unidirectional V-Loc suture.

- **Complications**[47]

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 abdomino-pelvic structures*
- *Nerve injuries*

Postoperative complications

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

PAIN[48-52]

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. Pain may be Acute or Chronic pain. Acute pain is usually seen in the post-operative period and is nociceptive in nature. Chronic pain is predominantly neuropathic. In most cases of Mesh repair for inguinal hernia it occurs mostly as a result of nerve entrapment i.e., of ilioinguinal, iliohypogastric and genital branch of genitofemoral nerve. Other causes maybe neuroma formation, direct nerve injury and adhesive scar tissue[53]

Post-operative pain can also be classified as Somatic (input from skin, subcutaneous tissue and mucous membranes) and Visceral pain (input from internal organs or its coverings)

Factors contributing to pain

There may be a multitude of factors involved in causation and intensity of post-operative pain. These include duration of surgery, length of incision, modality used to make incision (electrocautery or scalpel), type of anaesthesia, pre-operative condition of patient including psychology and general physical health and post-operative care including analgesia.[3]

Pre-emptive analgesia:

Pre-emptive analgesia is that which is administered to the patient prior to incision. This prevents the development of central sensitization from incisional injury and inflammatory.

The phenomenon of complete blockade of noxious stimuli provides maximum benefit here.[54]

Assessment of pain is done by 2 methods:

1) ***Type I method***

These are objective methods done by the physician where he assigns numbers about the patient's condition. It includes

Physiological indices

- Endocrinal
- Cardiovascular
- Respiratory

Neuro-pharmacological

- Beta-endorphin levels (low in painful conditions)
- Thermography (hypo-emission in chronic pain)

Neurological

- Nerve conduction velocity
- Evoked potentials
- Single positron emission tomography (SPET)

Behavioural

- Sighing, crying, trembling and shouting

2) ***Type 2 methods***

Can be broadly classified as

Single dimension methods

- Visual Analogue Scale
- Category Scale (Verbal rating scale)
- Graphic rating scale
- Numerical rating scale

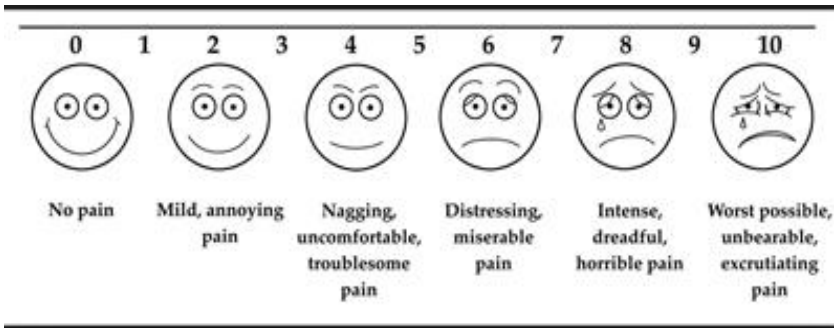
Multi-dimensional methods

- McGill pain Questionnaire (MPQ)
- Dartmouth pain Questionnaire (DPQ)
- West Haven Yale pain Questionnaire (WFYPQ)[55]

In clinical practice, assessment of pain is done by verbal communication between the doctor and patient. In research studies, a rating scale is required to evaluate and compare the data collected.

❖ **Visual Analogue Scale**

It is a simple scale and provides a quantification of pain perceived by patient. The visual analogue scale uses a straight line with extremities of pain intensity at one end. The line is typically 10 cms long with one end defined as no pain and the other end being excruciating unbearable pain. The patient is asked to place a mark on the line to describe the amount of pain that they are currently experiencing. The distance between the end labelled no pain and the mark placed by the patient is measured and rounded to nearest centimetre which gives the value of the scale.[47]



Management of Post-operative Pain

Prophylactic measures

The incidence, severity, duration of pain and suffering during the postoperative period can be reduced by good pre-operative and post-operative surgical and psychological care. Although the accepted definition of pain emphasises the cognitive, emotional response to tissue damage, the role of psychological techniques in the relief of acute pain has been minimised. Psycho-educational care has beneficial effects on recovery, post-operative pain and in psychological distress post-surgery. Psycho-educational care was classed as health-care information (information in preparation for surgery, timing of procedures, function and roles of health-care providers, self-care actions, and pain and discomfort information); skills teaching (coughing, breathing and bed exercises, relaxation, hypnosis); and psychosocial support (identifying and alleviating concerns, reassurance, problems solving, and encouraging questions).

Good surgical technique helps decrease the severity of post-operative pain. Skilled gentle handling of tissues, carrying out the operation under observance of good surgical principles promote minimal trauma. This is greatly influenced by the type of sutures used to close the wound and its nature to produce minimal irritation and inflammation of the tissues.

Post-operative Measures:

1. Systemic analgesics and adjuvants

- Narcotics
- Non-steroidal anti-inflammatory drugs
- Intravenous paracetamol
- NMDA antagonists
- Alpha-2 adrenergic agonists
- Miscellaneous non-opioid compounds

2. Local infiltration and field block - Regional analgesia with local anaesthetics

- Continuous segmental epidural block
- Interpleural analgesia
- Intraperitoneal analgesia

3. Regional analgesics with neuro-axial opioids

4. Regional analgesia with combined local anaesthetics and opioids

5. Electrical analgesia achieved with transcutaneous electrical stimulation or electroacupuncture.[49]

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.

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.[1]

Over the past 50 years, increased interest in the discipline of surgical infection has resulted in advances in post-surgical infection control. Early investigations focused on the importance of anaerobic microflora to postoperative infection and has shown the way for significant improvements in prophylactic and therapeutic antibiotic treatment of surgical patients. Later research centred on the identification of risk factors to better predict post-operative infection rates.[2]

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 made a huge impact in shifting the perception of surgery as a procedure leading to more morbidity to a process that prolongs life and reduces suffering.[56]

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

In 1992, the US CDC revised its definition of 'wound infection', creating the definition 'surgical site infection' (SSI)[58] to prevent confusion between the infection of a surgical incision and the infection of a traumatic wound. Most SSIs are superficial,

but even so they contribute greatly to the morbidity and mortality associated with surgery.[58,59]

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.[60] In 1980, Cruse estimated that a SSI increased a patient's hospital stay by approximately 10 days and cost an additional $2,000.[61]

A 1992 analysis showed that, each SSI resulted in 7.3 additional postoperative hospital days, adding $3,152 in extra charges.[62] Other studies corroborate that increased length of hospital stay and costs are associated with SSIs.[63] Deep SSIs involving organs or spaces, as compared to SSIs confined to the incision, are associated with even greater increases in hospital stays and costs.[63]

Surgical wounds may heal by primary intention, delayed primary intention or by secondary intention. Most heal by primary intention, where the wound edges are brought together (apposed) and then held in place by mechanical means (adhesive strips, staples or sutures), allowing the wound time to heal and develop enough strength to withstand stress without any support. The goal of surgery is to achieve healing by such means with minimal oedema, no serous discharge or infection, without separation of the wound edges and with minimal scar formation. On occasion, surgical incisions are allowed to heal by delayed primary intention where non-viable tissue is removed, and the wound is initially left open. Wound edges are brought together at about 4-6 days, before granulation tissue is visible.[64] This method is often used after traumatic injury or dirty surgery.

Healing by secondary intention occurs when the wound is left open, because of the presence of infection, excessive trauma or skin loss, and the wound edges some together naturally by means of granulation and contraction.[65]

Classification

Classification of operative wounds based on degree of microbial contamination[58]

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[58]

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.

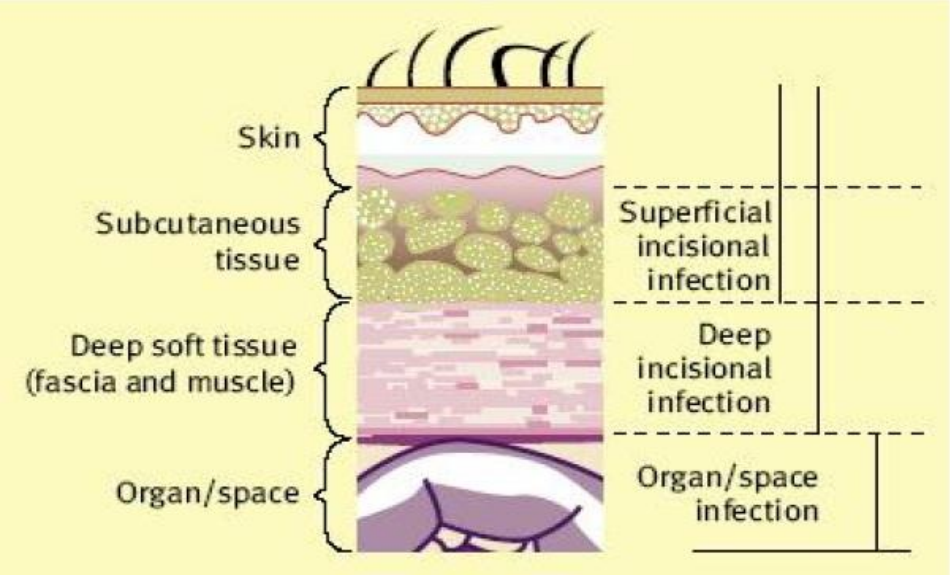


Figure 6. Schematic representation of the anatomical classification of surgical site infections[66]

Southampton Wound Scoring System[67]:

Grades	Appearance
0 Normal Healing	
I Normal healing with bruising or erythema	
A	Some bruising
B	Considerable bruising
C	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 (<2cm)
B	Along wound (>2cm)
C	Large volume
D	Prolonged
IV Pus	
A	At one point only (<2cm)
B	Along wound (>2cm)
V Deep or Severe wound infection	With or without tissue break-down haematoma requiring aspiration

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.[61] 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.[61] Since the introduction of routine prophylactic antibiotic use, infection rates in the most contaminated groups have reduced drastically. Infection rates in United States National Nosocomial Infection Surveillance (NNIS) system hospitals were reported to be: clean 2.1%, clean-contaminated 3.3%, contaminated 6.4% and dirty 7.1%.[66] There is, however, considerable variation in each class according to the type of surgery being performed.[68]

Risk factors

Risk factors associated with SSIs[69]

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

Risk factors[69]

Patient factors:

These include, extreme age, obesity, malnutrition, certain concurrent disease or conditions that is, diabetes, malignancy, chronic chest or heart disease and immunosuppression. Patients with pre-existing skin lesions or infection in another site, and treatment with steroid and immunosuppressive drugs are more prone to get surgical wound infection due to impaired host defence 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. Meticulous surgery, gentle handling of tissue, reduction of blood loss or hematoma formation, elimination of dead tissue, debridement of devitalized tissue, removal of all foreign body materials from the wound are essential to minimize surgical wound infections in all patients.

Duration of operation:

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

Pathogenesis

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

Dose of bacterial contamination X virulence = Risk of SSI. Resistance of the host patient quantitatively has shown that if a surgical site is contaminated with >105 microorganisms per gram of tissue, the risk of SSI is markedly increased. However,

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

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

For most SSIs, the source of pathogens is the endogenous flora of the patient's skin, mucous membranes, or hollow viscera.[78] When mucous membranes or skin is incised, the exposed tissues are at risk for contamination with endogenous flora.[79] These organisms are usually aerobic gram-positive cocci (staphylococci) but may include faecal flora (anaerobic bacteria and gram-negative aerobes) when incisions are made near the perineum or groin. When a gastrointestinal organ is opened during

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

Seeding of the operative site from a distant focus of infection can be another source of SSI pathogens,[80] particularly in patients who have a prosthesis or other implant placed during the operation. Such devices provide a nidus for attachment of the organism.[76]

Exogenous sources of SSI pathogens include surgical personnel (especially members of the surgical team),[81] 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.[82]

Microbiology

According to data from the NNIS system, the distribution of pathogens isolated from SSIs has not changed markedly during the last decade.[83]

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),[84] or by *Candida albicans.*[85] 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.[85] 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,[86] elastic bandages,[87] colonized surgical personnel,[88,89] tap water,[90] or contaminated disinfectant solutions.[91]

Preventive technique

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*.[92] In analyses of contamination rates after cholecystectomy, the main source of wound contamination was found to be the skin of the patient.[92] 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.[92] 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.[92] 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%.[92] 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%.[92] If shaving is essential, it should be performed as close to the time of surgery as possible.

Skin closure

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

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 colleague 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 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.[92]

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.[93]

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.[94] Sutures are a contributory factor in infection; in fact, 66% of SSIs are related to the incision.[95]

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.[96]

In fact, it is postulated that in the presence of sutures, only 100 colony- forming units (CFU)/mg are necessary to produce infection.[97] 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.[98]

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.[99]

Sutures, like most other implants, have a non-shedding surface to which bacteria can adhere, form biofilms and potentiate SSIs. The adherence of bacteria to various sutures has been investigated, and variations in adherence-affinity correlated with infection. 'Biofilms' are ubiquitous and form whenever microorganisms such as bacteria, yeasts, algae, fungi, or protozoa attach to surfaces.[100]

A study[101] 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*.

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.[100]

Results of conventional suture techniques depend on the technical expertise of the operator, with increased training requirements needed to obtain optimal results.[102] When interrupted sutures are placed along the length of an incision, the tension is concentrated at the individual suture loops, rather than divided equally along the entire wound length.[103] As tissue pressure within a loop rises, the resultant inflammatory response and enzymatic tissue degradation decrease the strength of the wound and increase the likelihood of wound dehiscence.[104,105] These constrictive suture loops may strangulate the vascular flow to the tissue they encircle, resulting in tissue necrosis due to microinfarctions.[106] Besides predisposing to wound infection, pressure induced ischemia and necrosis have been identified as the principal factors leading to wound dehiscence.[107] In addition to producing a biomechanically weaker wound,[108] higher wound tensions produce wider and more unsightly scars.[109]

Knotless barbed sutures have the advantage of possessing barbs in the substance of their strand which eliminate the necessity to knot the sutures at the ends and ensure equal distribution of tension throughout the wound and good approximation of the edges. Surgical knots applied to secure the suture are known to be a nidus for infection and lead to dehiscence of wound.[110]

Barbed sutures have been extensively used in various gynaecological procedures and to close different types of tissues including the uterus, muscle subcutaneous tissue and skin.[111]

These studies have shown shorter operative time with similar post-operative complications between barbed sutures and conventional suture material.

In a study conducted by Murtha et al,[112] wound closure for Pfannenstiel incision in cases of nonemergent caesarean section using barbed sutures were compared with conventional 3-0 polydioxanone sutures. This study showed that there was no significant difference in terms of wound cosmesis and rate of infection.

In a Randomized controlled trial conducted by Kristen Aliano et al,[113] the barbed sutures were compared with standard sutures in patients undergoing bilateral reduction mammoplasty or panniculectomy. The patients were their own controls and received bidirectional barbed sutures by Quill™ on one side and Monocryl or Vicryl sutures for the other side for wound closure. The results of this study showed shorter operative time and comparable cosmesis and post-operative complications.

Olga solavovya et al[114] conducted a review study on the use of barbed sutures for wound closure in hip and knee arthroplasty comparing the same with conventional suture, most of the studies having used Vicryl. The results showed shorter duration of surgery with the barbed sutures and no significant increase in post-operative complication rate. In a similar meta-analysis by Wei Zhang et al[115] comparing Knotless barbed sutures (KBS) with Knotted traditional sutures (KTS) for wound closure in knee arthroplasty, shorter operative time and reduced costs were noted with the barbed sutures. Their subgroup analysis also showed reduced complication rates with KBS.

Vladimir Grigoryants et al[116] conducted a randomized controlled trial to study patients undergoing lipo-abdominoplasty. The lipo-abdominoplasty wounds of 30 consecutive patients were divided into 2 equal halves, and the control and study halves of the wound were randomly assigned for each patient. On the control side, a conventional 3-layer wound closure (Scarpa's fascia, deep dermis, and upper dermis) was performed using polyglactin 910 and polyglecaprone 25 sutures. On the study

side, the wound was closed in 2 layers (Scarpa's fascia and upper dermis) using a running suture of V-Loc 90 sutures. Patients were followed for an average of 13 months postoperatively. Postoperative complications were recorded, and scar appearance was evaluated with the Vancouver Scar Scale (VSS). The mean closure time for each layer was faster with barbed sutures than with non-barbed sutures, and the total average closure time was 4.4 minutes (36.1%) faster using barbed sutures compared with conventional sutures (7.9 vs 12.3 minutes, respectively; $P < .0001$). Postoperative wound complications occurred in 4 (13.3%) control sides compared with 1 (3.3%) study side of the wound. The VSS scores were similar between the 2 sides. The lateral section of the scar received lower VSS scores than central sections. This study concluded that wound closure with barbed sutures may be financially and clinically advantageous in lipo-abdominoplasty patients as it requires less wound closure time.

Similarly, another multicentre randomized controlled trial was undertaken by Rubin et al[117] comparing absorbable barbed sutures versus conventional absorbable sutures for dermal closure in open surgical procedures. In this study, patients undergoing abdominoplasty, mastopexy and reduction mammoplasty were studied. Each patient received barbed sutures on 1 side of the body, with deep dermal sutures eliminated or reduced. Smooth sutures with deep dermal and subcuticular closure were used on the other side as a control. The primary endpoint was dermal closure time. Safety was assessed through adverse event reporting through a 12-week follow-up. A total of 229 patients were ultimately treated (115 with slow-absorbing polymer and 114 with rapid-absorbing polymer). Mean dermal closure time was significantly quicker with the barbed suture compared with the smooth suture (12.0 vs 19.2 minutes; $P < .001$), primarily due to the need for fewer deep dermal sutures. The

rapid-absorbing barbed suture showed a complication profile equivalent to the smooth suture, while the slow-absorbing barbed suture had a higher incidence of minor suture extrusion.

Krishnamoorthy et al[118] also conducted a randomized controlled trial to compare traditional monofilament knotted sutures with barbed knotless sutures for donor leg wound closure in coronary artery bypass surgery. Here, one hundred and forty-two patients were randomized into two groups. Group 1 (n = 70) received traditional monofilament sutures and Group 2 (n = 72) received barbed knotless sutures. All wounds were assessed on postoperative days 3 and 5 and weeks 2, 4 and 6 using a validated wound scoring system. Antibiotics usage and general practitioner and district nurse visits were recorded. Leg wound skin closure times were significantly shorter in Group 2 compared with Group 1 ($P < 0.001$). Group 1 demonstrated a greater incidence of excessive scarring ($P < 0.001$), itching ($P < 0.001$), irritation ($P < 0.001$) and adverse skin tissue reactions ($P < 0.001$) than Group 2. Fewer general practitioner visits were recorded in Group 1 compared with Group 2 ($P = 0.051$). This study thus concluded that knotless barbed suture usage significantly reduces the incidence of knot-related leg wound complications compared with traditional monofilament knotted sutures. This may be related to differences in the rate of absorption of the suture material or an associated decrease in the incidence of adverse skin tissue reactions that may delay postoperative wound healing. This study also used two different types of barbed sutures. The V-loc 180 with unidirectional barbs and the Stratafix^{TM} with spiral barbs. No significant difference was noted in the outcomes studied between the two types of barbed sutures

The safety profile and efficacy of using barbed sutures for other tissues has also been studied. This includes uterine closure following caesarean section and

myomectomy, vaginal cuff closure, vesicourethral anastomosis, prostatectomy, gastrointestinal anastomosis and for flexor tendon repair.

Its use has been extensively studied in the field of plastic and aesthetic surgery as seen in the above-mentioned studies.

Considering the large numbers of inguinal hernia repair procedures that are performed in our country, any minor improvement in terms of lesser post-operative pain and wound healing will lead to overall improvement in patient satisfaction and cost-effectiveness. This prompted us to study the efficacy of the barbed sutures for skin closure in inguinal hernia repair in comparison with the conventional subcuticular monofilament sutures.

MATERIALS AND METHODS

The present study was carried out in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2017 to December 2017.

Study design: A randomized controlled trial

Study period: One-year duration between January 2017 and December 2017

Place of Study: 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: the sample size was calculated using the following formula

$$n = \frac{2(z\alpha+z\beta)^2 pq}{(p0-p1)^2}$$

Where,

$z\alpha = 1.96$

$z\beta = 0.84$

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

$q = 100 - p$

Therefore,

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

$$= 60$$

Therefore, a sample size of 60 with 30 in each group was considered for the study

Selection criteria:

Inclusion:

- Patients undergoing elective inguinal hernia repair
- Aged above 18 years
- Those who were willing to participate in the study.

Exclusion:

- Diabetes Mellitus
- Immunocompromised
- Bleeding disorders
- Connective tissue disorders
- Known hypersensitivity to suture 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 willing to participate in this study were enrolled and randomly allocated into two groups based on closed envelope method, that is, patient was asked to pick an opaque brown concealed envelope containing the information regarding the type of suture material. Based on the option picked up, the patient was allocated to either Cases (Knotless barbed suture) or Control (Subcuticular monofilament sutures) group respectively.

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
- Urine routine and microscopy
- Electrocardiogram
- Random blood sugar
- HIV, HbSag

Procedure

Pre-operative:

In both the groups, patients were prepared as per pre-operative protocol. On the operation table the abdomen was cleaned with povidone iodine and spirit. Injection Cefotaxime 1g IV and Inj. metronidazole 100 ml IV were given prior to skin incision. All the patients had standard analgesic and antibiotics protocol.

Surgical technique:

Lichtenstein repair was done using prolene mesh as per standard prescribed surgical technique.

Closure:

Was done in two layers.

Group A:

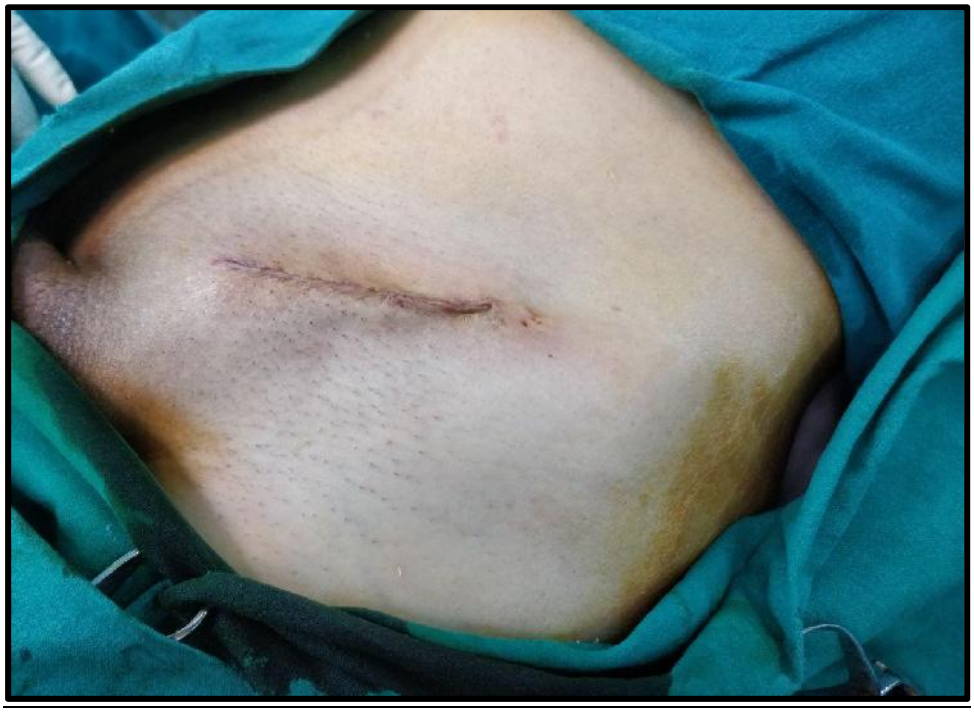
Covidien V-loc^{TM} 90 (Knotless barbed sutures) were applied for skin closure in the recommended manner, i.e., subcuticular closure without application of knots and cut flush to the skin at the end.

Group B:

Skin was closed using Monofilament (Monocryl 3-0) subcuticular sutures with knots applied at the two ends as per standard technique.

Photograph 1: Conventional Monofilament sutures

Photograph 2: V-Loc^{TM} 90 (Knotless barbed sutures)



Photograph 3: Appearance of wound after skin closure using barbed sutures (V-Loc 90) in Group A

Photograph 4: Appearance of wound after closure in Group B

Post-operative:

The patients were postoperatively medicated with Inj. Cefotaxime 1g iv twice daily and Inj. metronidazole 100 mL thrice daily for a period of three days and if indicated and were changed to higher antibiotics accordingly.

Inj. Paracetamol 1000mg iv 8^{th} hourly was given for post-operative analgesia for a duration of two days.

Inj. Tramadol 1 amp (200mg) diluted in 100 ml NS was given as rescue analgesia.

Outcome variables:

Post-operative pain was assessed at 6 hrs, 12 hrs, 24 hrs, 48 hrs and 72 hrs using Visual analogue scale (0-10)

The assessment of wound was carried out based on Southampton wound scoring system on post-operative day three, eight and ten. Assessment of wound using Southampton Wound Scoring System[137]

Photograph 5: Appearance of wound on Post-operative day 3 in Group A

Photograph 6: Appearance of wound on Post-operative day 3 in Group B

Statistical Analysis

The data obtained was entered in Microsoft Excel Spread sheet. Age, Post-operative pain (VAS scores at 6 hours, 12 hours, 24 hours, 48 hours, 3rd day) were checked for normal distribution within each category of explanatory variable by using visual inspection of histograms and normality Q-Q plots.

Shapiro- wilk test was also conducted to assess normal distribution and a p value of >0.05 was considered as normal distribution.

For non-normally distributed parameters i.e., age and post-operative pain (6 hrs, 12 hrs, 24 hours, 48 hours, 3rd day), Medians and Interquartile range (IQR) were compared between study groups using Mann Whitney u test (2 groups)

Healing status at different follow up periods (3rd day, 8th day, 10th day) was compared between study groups (cases vs control) using Chi square test. P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.

DISCUSSION

Inguinal hernia repair is a widely performed surgery worldwide. Over the years there have been many modifications to the originally described procedure. Bearing in mind the possibility of recurrence, pain and cosmesis a wide range of alternative procedures and techniques have been established. A very important aspect of this surgery is to ensure acceptable cosmesis of the wound.

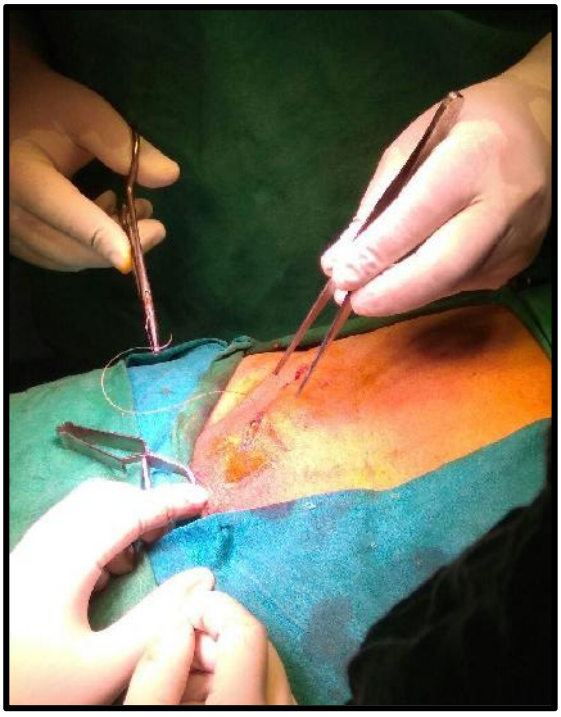
Many variations in skin closure techniques have been described to achieve the same[119]. Some of them include subcuticular absorbable sutures, staples, adhesives, tapes and steri-strips.

Subcuticular monofilament absorbable sutures for skin closure has been in use in the recent past. The advantage with this suture material was that it did not require removal and the subcuticular closure provided a good approximation. However, the need to knot the suture at the ends and the inherent nature of material predisposes the wound to SSIs.[120]

Other modalities of wound closure including steri-strips, skin staples, tapes and adhesives have been studied. These eliminate needle puncture and suture canal scarring, but the adequacy of tissue approximation and subsequently tensile strength of the wound may not be satisfactory. Weaker wounds are known to predispose to infections hence increasing the chances of SSI.[121]

The advent of the barbed sutures has provided a novel method for skin closure in various surgeries. The use of the same has been extensively studied for providing aesthetically better scars. Variations in the barbed sutures were seen in terms of barbs being placed in a unidirectional or bidirectional manner, rate of absorption and composition of the suture material.

Photograph 7: Intraoperative application of V-Loc™ 90



Photograph 8: Intraoperative wound closure using V-loc™ -90

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 2017 to December 2017. A total of 60 patients undergoing elective inguinal hernia repair were divided into two groups of 30 each as Cases where patients had skin closure using knotless barbed suture and Controls where Monocryl was used for subcuticular skin closure.

In the present study all the participants (100%) were males in both groups. In Group A, 10 (33.3%) participants were aged between 46 to 60 years and 10 (33.3%) participants were aged 61 years and above and in Group B, majority of patients i.e., 11 (36.7%) participants were aged 61 years and above. However, this difference in proportion of patients did not meet statistical significance (P value 0.276). Among the cases, the median age was 56 years (IQR 38, 70) and it was 46 years (IQR 31.75 to 65) in controls. The difference in the median age between the groups was statistically not significant (P Value 0.181)

Both the groups had 4(13.33%) cases of direct inguinal hernia and 26 (86.67%) indirect inguinal hernia in the two groups.

In Group A, 2 (6.7%) participants had right direct hernia, 2 (6.7%) participants had left direct hernia, 15 (50%) participants had right indirect hernia, 11 (36.7%) participants had left indirect hernia. In Group B, 3 (10%) participants had right direct hernia, 1 (3.3%) participants had left direct hernia, 14 (46.7%) participants had right indirect hernia, 12 (40%) participants had left indirect hernia. This difference in the proportion of clinical diagnosis between group was statistically not significant (P value 0.894).

Therefore, demographically and clinically the two study groups had comparable characteristics. All baseline investigations were sent on admission and vital signs (Blood Pressure, Pulse Rate and Respiratory Rate) were recorded. Patients were randomized after confirming that these parameters were within normal limits.

Post-operative pain was assessed at 6 hrs, 12 hrs, 24hrs, 48 hrs and 72 hrs after surgery using the Visual Analogue Score (VAS 1-10). The use of any rescue analgesia was also documented.

At 6 hrs, the median pain scores were 4 (IQR 4, 5) and 5 (IQR 5, 6) in Group A and B respectively. This difference was statistically significant (P value <0.001). It was observed to be 3 (IQR 3, 4) and it was 4 (IQR 4, 5) at 12 hrs in Group A and B respectively. This difference was also found to be statistically significant P value <0.001)

At 24 hrs, the median score was 4 (IQR 3, 4) and it was 5 (IQR 4, 5) in Groups A and B respectively. This was statistically significant (P value <0.001).
However, the median pain score at 48 hrs, was 3 (IQR 3, 4) and 4 (IQR 3, 4) in Groups A and B respectively. Here the P value was 0.086 and hence insignificant.

The 72 hr pain scores were 3 (IQR 2, 3) in Group A and it was 3 (IQR 2.75, 3) in Group B with a P value of 0.147 which was also insignificant.

Most studies conducted to evaluate the efficacy of barbed sutures for wound closure evaluated the operative time and surgical site complications. Our inclusion of post-operative as a parameter studied is mainly to establish if the barbs incite any tissue irritation and subsequently pain. Additionally, reactionary changes in the tissue due to impaired healing will also cause local inflammation and more pain. Our study showed significantly lower scores in Group A (Barbed sutures) as compared to Group

B in the 24 hrs following surgery. The 48 and 72 hr scores between the groups were not significantly different. However, none of the patients in either group required rescue analgesia in the post-operative period. This could be indicative of lesser reactionary inflammation in the tissue following skin closure in the barbed suture group.

Wound healing between the groups was compared using Southampton Wound Scoring System.

On post-operative Day 3, Wound grades of Ia and Ic was seen in 1(3.33%) patient in each group. (P value 1.000)

On Day 8, Grade Ia, Ib, Ic and IIa was seen in 1(3.33%) patient each in Group A and was seen in 1(3.33%) patient each in Grades Ia, Ib and IIa and 2(6.67%) patients with Grade Ic in Group B. (P value 0.986)

On day 10, Group A had 2(6,67%) patients with Grade Ia healing, 1(3.33%) with Ib and 1(3.33%) with Grade Ic healing. Group B had 3(10%) with Grade Ia, 2(6.67%) with Ib and 2(6.67%) with Ic healing. (P value 0.789)

Although there was a marginally higher number of patients in Group B with incidence of SSI, this did not meet statistical significance. This suggests that efficacy of the Knotless barbed sutures is comparable to the monofilament subcuticular sutures in terms of incidence of SSIs.

In the Randomized controlled trial by Krishnamoorthy et al,[118] barbed sutures were compared with monofilament braided sutures for skin closure of donor leg in cases of Coronary artery bypass grafting. Detailed wound assessments were recorded on postoperative days 3 and 5 for data analysis. Here, Patients in the barbed suture group demonstrated significantly reduced complications associated with the process

of healing compared with the knotted monofilament group (P < 0.001). An improvement in erythema outcomes was also demonstrated with knotless compared with knotted sutures (P < 0.001). Although our study did not show a significant difference in the rate of SSI. A similar increase in erythema was noted in the monofilament group. Infections were observed more often in the monofilament knotted group compared with the barbed suture group, although this did not reach significance (P = 0.129).

Similarly, in a study by Vladimir Grigoryants et al[116], the barbed sutures were used to compare closure times and clinical outcomes of 2-layer wound closure using V-Loc 90 barbed suture with conventional, 3-layer closure with non-barbed, nonlocking sutures in patients undergoing lipo-abdominoplasty. In this study, patients were their own controls were half of the wound was closed using the 3 layered closure and the other half using the V loc 90 barbed sutures. The incidence of infection was lower 4 (13.3%) controls compared with 1 (3.3%) study subjects.

In a study by Murtha at al,[112] a prospective, randomized, controlled trial was designed to show that the use of barbed suture in dermal closure of the Pfannenstiel incision during nonemergent caesarean delivery surgery produces scar cosmesis at 5 weeks that is no worse than that observed with conventional closure using 3-0 polydioxanone suture. Cosmesis was assessed by review of postoperative photographs by a blinded, independent plastic surgeon using the modified Hollander cosmesis score. Secondary endpoints included infection, dehiscence, pain, closure time, and other adverse events. Six subjects experienced surgical site infection, four (3.15 percent) in the barbed suture group and two (3.28 percent) in the control suture group (*p* value not significant). All surgical site infections were superficial in nature, and none required hospital admission. Pain scores and analgesic use did not significantly

differ between the barbed suture and control suture groups during the hospital stay or at the 5-week follow-up visit. The findings of this study were also in accordance with our study concluding that the rate of complications was comparable between the two groups studied.

Our additional observation during the use of the barbed sutures was that there is a uniform distribution of the tension along the suture line by the barbs which are lodged within the tissue. When subcuticular suturing of wound was done with Monocryl, there may be wrinkling of skin edges noted which is dependent on the tension applied at the knots placed.

Most of the above-mentioned studies have also concluded that the barbed sutures have resulted in an aesthetically better scar as compared to other conventional sutures used.

This study has established that the use of barbed sutures provides good approximation for skin closure and comparable post-operative infection rate as compared to the monofilament subcuticular sutures. Limitations of this study was the cost of the suture material and the fact that only skin closure in cases of open inguinal hernia repair. With routine use of the barbed suture material for skin closure we believe the cost will become more affordable.

Also, based on the studies demonstrating good cosmesis of wound, the barbed sutures can be studied on larger sample size for a wider range of clean surgeries to establish a clear safety profile and efficacy.

CONCLUSION

- There is significantly lesser early post-operative pain associated with the knotless barbed sutures.
- Based on the findings of this study it may be concluded that efficacy of the knotless barbed sutures is comparable to monofilament subcuticular sutures in terms of rates of SSI

SUMMARY

Sutures are known to be a contributory factor in SSI. The surgical knots applied during the skin closure with conventional sutures have been demonstrated to cause weakening of the tensile strength of the suture material and unequal distribution of tension. This causes a poor wound approximation and hence poor healing. The advent of Knotless barbed sutures eliminates the necessity for knotting and ensures good approximation of the wound edges.

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 2017 to December 2017 were divided into two groups of 30 each that is, Group A comprising of patients undergoing skin closure using the knotless barbed sutures (V-Loc 90) and Group B comprising of patients undergoing skin closure using subcuticular monofilament sutures (Monocryl).

In this study all participants were males (100%). In Group A, the median age was 56 years (IQR 38, 70) and it was 46 years (IQR 31.75 to 65) in Group B. This was statistically insignificant (P value 0.181)

Other parameters such as demographic variables and clinical diagnosis was comparable between the groups.

In this study, median pain scores at 6 hrs were 4 (IQR 4, 5) and 5 (IQR 5, 6) in Group A and B (P value <0.001) , 12 hrs were 3 (IQR 3, 4) and it was 4 (IQR 4, 5) in Group A and Group B respectively (P Value< 0.001) and 24 hrs was 4 (IQR 3, 4) and it was 5 (IQR 4, 5) in Groups A and B respectively (P value <0.001). The median pain

score at 48 hrs, was 3 (IQR 3, 4) and 4 (IQR 3, 4) in Groups A and B respectively (P value 0.086) and at 72 hrs was 3 (IQR 2, 3) in Group A and it was 3 (IQR 2.75, 3) in Group B with a P value of 0.147.

On post-operative Day 3, SSI of grades of Ia and Ic was seen in 3.33% of patients in each group. (P value 1.000)

On Day 8, Grade Ia, Ib, Ic and IIa was seen in 3.33% of patients each in Group A and was seen in 3.33% of patient each in Grades Ia, Ib and IIa and 6.67% of patients with Grade Ic in Group B. (P value 0.986)

On day 10, Group A had 6.67% of patients with Grade Ia, 3.33% with Ib and 3.33% with Grade Ic. Group B had 10% of patients with Grade Ia, 6.67% of patients with Ib and Ic healing each. (P value 0.789)

Thus, based on these results, the efficacy of knotless barbed sutures is superior in terms of lesser early post-operative pain and comparable to monofilament sutures in terms of incidence of SSI.

Studies with larger sample size and inclusion of wound cosmesis are required to establish a clear advantage of the knotless barbed sutures.

BIBLIOGRAPHY

1. Cuschieri A, Steele RJC, Moosa AR. Hernia. In: Cuschieri A, Steele RJC, Moosa AR, eds. Essential surgical practice. 4th ed., London: Arnold; 2002. p.174-5.
2. Scott NW, McCormack K, Graham P, Go PM, Ross SJ, Grant AM. Open mesh versus non-mesh for repair of femoral and inguinal hernia. Cochrane Database Syst Rev 2002;CD002197
3. Kehlet H, Jensen TS, Woolf CJ. Persistent postsurgical pain: risk factors and prevention. Lancet. 2006;367:1618-25
4. Fawole AS, Chaparala RP, Ambrose NS. Fate of the inguinal hernia following removal of infected prosthetic mesh. Hernia 2006;58-61
5. Moon V, Chaudry GA, Choy C, Ferzli GS. Mesh infection in the era of laparoscopy. J Laparoendosc Adv Surg Tech A 2004; 14: 349 –52.
6. Skarzynska J, Cienciala A, Madry R, Barucha P, Kwasniak M, Wojewoda T,Sroga J:Hospital infection in general surgery wards. Przegl Epidemiol 2000,54 (3-4):299-304
7. Burkitt JF. Identification of the sources of staphylococci contaminating the surgical wound during operation. Ann Surg 1963;158:898-904
8. Reichman DE, Greenberg JA. Reducing Surgical Site Infections: A Review. *Reviews in Obstetrics and Gynecology*. 2009;2(4):212-221.
9. Hranjec T, Swenson BR, Sawyer RG. Surgical Site Infection Prevention: How We Do It. *Surgical Infections*. 2010;11(3):289-294. doi:10.1089/sur.2010.021.
10. Kathju S, Nistico L, Tower I, Lasko L-A, Stoodley P. Bacterial Biofilms on Implanted Suture Material Are a Cause of Surgical Site Infection. *Surgical Infections*. 2014;15(5):592-600.

11. Leaper D, Assadian O, Hubner N-O, McBain A, Barbolt T, Rothenburger S, Wilson P. Antimicrobial sutures and prevention of surgical site infection: assessment of the safety of the antiseptic triclosan. Int Wound J2011;8(6):556-66.
12. Cortez, Roberto & Lazcano, Eric & Miller, Travis & Hein, Rachel & Constantine, Ryan & Anigian, Kendall & Davis, Kathryn & M Kenkel, Jeffrey. (2015). Barbed Sutures and Wound Complications in Plastic Surgery: An Analysis of Outcomes. Aesthetic surgery journal / the American Society for Aesthetic Plastic surgery. 35. 178-88
13. Lin, Y. *et al.* The Efficacy and Safety of Knotless Barbed Sutures in the Surgical Field:A Systematic Review and Meta-analysis of Randomized Controlled Trials. *Sci. Rep.* 6, 23425; doi: 10.1038/srep23425 (2016).
14. Van Hee R. History of inguinal hernia repair. Jurnalul de Chirurgie 2011;7(3):301-19.
15. Netter FH. Atlas of human anatomy. 4th ed., New York: Saunders; 2009.
16. Gilbert AI, Graham MF, Voigt WJ. Inguinal Hernia: Anatomy and Management. Available from: URL ttp://www.medscape.org/ viewarticle/420354_print Access Date: 18.04.2014
17. Hessert W. Some observations on the anatomy of the inguinal region, with special reference to absence of the conjoined tendon. Surg Gyneclol Obstet. 1913:566-8.
18. Nyhus LM. An anatomic reappraisal of the posterior inguinal wall. Surg Clin North Am 1964;44:1305.
19. Kulacoglu H. Current options in inguinal hernia repair in adult patients. Hippokratia 2011; 15(3): 223–31.

20. Nyhus LM, Klein MS, Rogers FB. Inguinal hernia. Curr Probl Surg.1991;28:403–50.
21. Gilbert AI. An anatomic and functional classification for the diagnosis and treatment of inguinal hernia. Am J Surg 1989;157:331-3.
22. Schumpelick V, Treutner KH, Arlt G. Classification of inguinal hernias. Chirurg 1994;65:877–9.
23. Bhattacharjee PK. Surgical options in inguinal hernia: Which is the best. Indian J Surg 2006;68(4):191-200.
24. Liem MS, van der Graaf Y, van Steensel CJ, Boelhouwer RU, Clevers GJ, Meijer WS et al. Comparison of conventional anterior surgery and laparoscopic surgery for inguinal hernia repair. N Engl J Med 1997;336:1541-7.
25. Shouldice EE. The treatment of Hernia. Ontario Med Rev 1953;20:670-84.
26. Annandale T. A case in which a reducible oblique and direct inguinal and femoral hernia existed on the same side and were successfully treated by operation. Edinburhg Med J 1876;21:1087-91.
27. Cheatle GL. An operation for the radical cure of inguinal and femoral hernia.Br Med J 1920;2:68.
28. Henry AK. Operation for femoral hernia by midline extraperitoneal approach: With a preliminary note of the use of this, route for reducible inguinal hernia. Lancet 1936;1:531-3.
29. Nyhus LM, Condon RE, Harkins HN. Clinical experiences with preperitoneal hernia repair for all types of hernia of the groin. Am J Surg 1960;100:234-44.

30. Stoppa R, Petit J, Henry X. Unsutured Dacron prosthesis in groin hernias. Int Surg 1975;60:411-2.

31. Stoppa RE, Rives JL, Warlaumont CR, Palot JP, Verhaeghe PJ, Delattre JF. The use of Dacron in the repair of hernias of the groin. Surg Clin North Am 1993;73:571-81

32. Wantz GE. Prosthetics: Their Complications and Management, Part I. In: Bendavid R (ed). Prosthesis in Abdominal Wall Hernias. Austin,Tex: RG Landes Co. 1994;326-9.

33. Lichtenstein IL, Shulman AG. Ambulatory (outpatient) hernia surgery including a new concept: introducing tension free repair. Int Surg 1986;11:1-4.

34. Gilbert AI. Inguinal hernia repair: biomaterials and sutureless repair. Perspect Gen Surg 1991;2:113-29

35. Ger R. The management of certain abdominal herniae by intra-abdominal closure of the neck of the sac. Ann R Coll Surg Engl 1982;64:342-4

36. Bogojavalensky S. Laparoscopic treatment of inguinal and femoral hernia (video presentation). 18th Annual Meeting of the American Association of Gynecological Laparoscopists. Washington, DC; 1989

37. Toy FK, Smoot RT Jr. Laparoscopic hernioplasty update. J Laparoendosc Surg (United States) 1992;2:197-205

38. Arregui ME, Davis CJ, Yucel O, Nagan RF. Laparoscopic mesh repair of inguinal hernia using a preperitoneal approach. A preliminary report. Surg Laparosc Endosc 1992:2:53-8.

39. Dion YM, Morin J. Laparoscopic inguinal herniorrhaphy. Can J Surg 1992;35:209-12

40. Phillips EH, Carroll BJ, Fallas MJ. Laparoscopic preperitoneal inguinal hernia repair without peritoneal incision: technique and early clinical results. Surg Endosc 1993;7:159-62.

41. McKernan BJ, Laws HL. Laparoscopic preperitoneal prosthetic repair of inguinal hernias. Surg Rounds 1992;7:579-610

42. National Institute of Clinical Excellence. Guidelines on the use of laparoscopic surgery for inguinal hernia. NICE: London, 2001.

43. Desarda MP. New method of inguinal hernia repair: a new solution. ANZ J Surg 2001;71:241-4

44. Incision care. Type of wound or incision closure. Available from: URL:http://www.surgeryencyclopedia.com/Fi-La/Incision-Care.html Access Date:15.06.2016

45. Doctor HG. Surgeons and sutures. 2nd ed., USA: Ethicon; 1999.

46. Zaruby J Gingas K Taylor J Maul D . An in vivo comparison of barbed suture devices and conventional monofilament sutures for cosmetic skin closure: biomechanical wound strength and histology. Aesthetic Surg J. 2011;31(2):232–240.

47. Kapoor VK, Roberts KE. Open inguinal hernia repair. Available from:URL:http://emedicine.medscape.com/article/1534281overview#aw2aab6b2b2 Access Date: 22.04.2014

48. Carr DB, Goudas LC. Acute pain. Lancet 1999;353:2051-62.

49. Miller RD. Miller's anaesthesia. 6th ed., Philadelphia: Elsevier, Churchill Livingstone; 2005

50. Morgan GE, Mikhail MS, Murray MJ. Clinical Anesthesiology. 4th ed., USA: McGraw Hill;2006.

51. Merskey H, Bogduk N. Classification of chronic pain - Descriptions of chronic pain syndromes and definitions of pain terms, 2nd ed. Seattle: IASP press;1994.

52. Merskey H, Bogduk N. Classification of chronic pain - Descriptions of chronic pain syndromes and definitions of pain terms, 2nd ed. Seattle:IASP press;1994.

53. Aasvang EK, Brandsborg B, Christensen B, Jensen TS, Kehlet H. Neurophysiological characterization of postherniotomy pain. Pain. 2008;137:173–81

54. Moiniche S, Kehlet H, Dahl JB, A qualitative and quantitative systemic review of pre-emptive analgesia for poetoperative pain relief: the role of timing of analgesia. Anaesthesiology 2002;96:725-41

55. Kehlet H. Acute pain control and accelerated postoperative surgical recovery. Surg Clin N Am 1999;79:431-45.

56. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for Prevention of Surgical Site Infection, 1999. Infect Control Hosp Epidemiol.1999; 20(4):250-78; quiz 279-80.

57. Altemeier WA. Sepsis in surgery. Presidential address. Arch Surg 1982;117(2): 107-12.

58. Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. Infect Control Hosp Epidemiol 1992; 13(10): 606-8.

59. Leaper DJ, van Goor H, Reilly J, Petrosillo N, Geiss HK, Torres AJ, et al. Surgical site infection - a European perspective of incidence and economical burden. Int Wound Journal 2004; 1(4): 247-273.

60. DiPiro JT, Martindale RG, Bakst A, Vacani PF, Watson P, Miller MT. Infection in surgical patients: effects on mortality, hospitalization, and post-discharge care. Am J Health Syst Pharm 1998; 55(8): 777-81.

61. Cruse PJ, Foord R. The epidemiology of wound infection: a 10-year prospective study of 62,939 wounds. Surg Clin North Am 1980; 60(1): 27-40.

62. Martone WJ, Jarvis WR, Culver DH, Haley RW. Incidence and nature of endemic and epidemic nosocomial infections. In: Bennett JV, Brachman PS, eds. Hospital Infections. 3rd ed. Boston: Little, Brown and Co; 1992. p. 577-96.

63. Albers BA, Patka P, Haarman HJ, Kostense PJ. Cost effectiveness of preventive antibiotic administration for lowering risk of infection by 0.25%. [German]. Unfallchirurg 1994; 97(12): 625-8.

64. Gottrup F. Wound closure techniques. J Wound Care 1999; 8(8): 397-400.

65. Thomas S. Wound Management and Dressings. London: Pharmaceutical Press, 1990.

66. Cruse PJE. Classification of operations and audit of infection. In: Taylor EW, editor. Infection in Surgical Practice. Oxford: Oxford University Press, 1992. p. 1-7.

67. Bailey, IS, Karran, SE, Toyn, K, Brough, P, Ranaboldo, C, Karran, SJ. Community surveillance of complications after hernia surgery. Br Med J. 1992; 304:469–471.

68. Culver DH, Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG, et al.Surgical wound infection rates by wound class, operative procedure, and patient risk index. National Nosocomial Infections Surveillance System. Am J Med 1991; 91(3B): 152S-157S.

69. Emmerson AM, Damani NN. Manual of infection control procedures. 2nd London: Greenwhich Medical Media; 2003.

70. Altemeier WA, Culbertson WR. Surgical infection. In: Moyer CA, Rhoads JE, Allen JG, Harkins HN, eds. Surgery, principles and practice. 3rd ed. Philadelphia: JB Lippincott; 1965. p. 51-77.

71. Elek SD, Conen PE. The virulence of Staphylococcus pyogenes for man: a study of problems with wound infection. Br J Exp Pathol 1957; 38: 573-86.

72. Morrison DC, Ryan JL. Endotoxins and disease mechanisms. Ann Rev Med 1987; 38: 417-32.

73. Eiseman B, Beart R, Norton L. Multiple organ failure. Surg Gynecol Obstet 1977; 14: 323-6.

74. Kasper DL. Bacterial capsule old dogmas and new tricks. J Infect Dis 1986;153: 407-15.

75. Fry DE, Pearlstein L, Fulton RL, Polk HC. Multiple system organ failure: the role of uncontrolled infection. Arch Surg 1980; 115: 136-40.

76. Goeau-Brissonniere O, Leport C, Guidoin R, Lebrault C, Pechere JC, Bacourt F. Experimental colonization of an expanded polytetrafluoroethylene vascular graft with Staphylococcus aureus: a quantitative and morphologic study. J Vasc Surg 1987; 5(5): 743-8.

77. Kaebnick HW, Bandyk DF, Bergamini TM, Towne JB. The microbiology of explanted vascular prostheses. Surgery 1987; 102: 756-61.

78. Altemeier WA, Culbertson WR, Hummel RP. Surgical considerations of endogenous infections sources, types, and methods of control. Surg Clin North Am 1968; 48: 227-40.

79. Wiley AM, Ha'eri GB. Routes of infection: a study of using tracer particles in the orthopedic operating room. Clin Orthop 1979; 139:150-5.

80. Valentine RJ, Weigelt JA, Dryer D, Rodgers C. Effect of remote infections on clean wound infection rates. Am J Infect Control 1986; 14: 64-7.

81. Calia FM, Wolinsky E, Mortimer EA Jr., Abrams JS, Rammelkamp CH Jr.Importance of the carrier state as a source of Staphylococcus aureus in wound sepsis. J Hyg (Lond) 1969; 67: 49-57.

82. Giamarellou H, Antoniadou A. Epidemiology, diagnosis, and therapy of fungal infections in surgery. Infect Control Hosp Epidemiol 1996; 17(8):558-64.

83. Nooyen SM, Overbeek BP, Brutel de la Riviere A, Storm AJ, Langemeyer JM. Prospective randomised comparison of single-dose versus multiple-dose cefuroxime for prophylaxis in coronary artery bypass grafting. Eur J Clin Microbiol Infect Dis 1994; 13: 1033-7.

84. Schaberg DR. Resistant gram-positive organisms. Ann Emerg Med 1994; 24(3): 462-4.

85. Jarvis WR. Epidemiology of nosocomial fungal infections, with emphasis on Candida species. Clin Infect Dis 1995; 20: 1526-30.

86. Centers for Disease Control. Nosocomial outbreak of Rhizopus infections associated with Elastoplast wound dressings Minnesota. MMWR 1978; 27:33-4.

87. Pearson RD, Valenti WM, Steigbigel RT. Clostridium perfringens wound infections associated with elastic bandages. JAMA 1980; 244: 1128-30.

88. Richet HM, Craven PC, Brown JM, Lasker BA, Cox CD, McNeil MM, et al. A cluster of Rhodococcus (Gordona) bronchialis sternal-wound infections after coronary-artery bypass surgery. N Engl J Med 1991; 324: 104-9.

89. Wenger PN, Brown JM, McNeil MM, Jarvis WR. Nocardia farcinica sternotomy site infections in patients following open heart surgery. J Infect Dis 1998; 178: 1539-43.

90. Lowry PW, Blankenship RJ, Gridley W, Troup NJ, Tompkins LS. A cluster of Legionella sternal-wound infections due to postoperative topical exposure to contaminated tap water. N Engl J Med 1991; 324: 109-13.

91. Bassett DC, Stokes KJ, Thomas WR. Wound infection with Pseudomonas multivorans: a water-borne contaminant of disinfectant solutions. Lancet 1970; 1: 1188-91.

92. Gottrup F, Meling A, Hollander DA. Worldwide wounds: An overview of surgical site infections: aetiology, incidence and risk factors. Available from: URL:http://www.worldwidewounds.com/2005/ september/Gottrup/ Surgical-Site-Infections-Overview.html Access Date: 25.04.2014

93. Chundamala J, Wright JG. The efficacy and risks of using povidone-iodine irrigation to prevent surgical site infection: an evidence-based review. Can J Surg. 2007; 50(6): 473-81.

94. Katz S, Izhar M, Mirelman D. Bacterial adherence to surgical sutures. A possible factor in suture induced infection. Ann Surg 1981;194:35-41.

95. Marco F, Vallez R, Gonzalez P, Ortega L, de la Lama J, Lopez-Duran L.Study of the efficacy of coated Vicryl plus antibacterial suture in an animal model of orthopedic surgery. Surg Infect (Larchmt) 2007;8:359-65

96. Justinger C, Moussavian MR, Schlueter C, Kopp B, Kollmar O, Schilling MK. Antibacterial [corrected] coating of abdominal closure sutures and wound infection. Surgery 2009; 145:330-4

97. Storch ML, Rothenburger SJ, Jacinto G. Experimental efficacy study of coated Vicryl plus antibacterial suture in guinea pigs challenged with Staphylococcus aureus. Surg Infect (Larchmt) 2004;5:281-8.

98. Uff CR, Scott AD, Pockley AG, Phillips RK. Influence of soluble suture factors on in vitro macrophage function. Biomaterials 1995;16:355-60.

99. Geiger D, Debus ES, Ziegler UE, Larena-Avellaneda A, Frosch M, Thiede A,. Capillary activity of surgical sutures and suture-dependent bacterial transport:a qualitative study. Surg Infect (Larchmt) 2005;6:377-83.

100. Leaper D, McBain AJ, Kramer A, Assadian O, Sanchez JL, Lumio J, et al. Healthcare associated infection:novel strategies and antimicrobial implants to prevent surgical site infection. Ann R Coll Surg Engl 2010;92:453-8.

101. Gristina AG, Price JL, Hobgood CD, Webb LX, Costerton JW. Bacterial colonization of percutaneous sutures. Surgery 1985;98:12-9.

102. Singer, A. J., Hollander, J. E., Valentine, S. M., et al. Association of training level and short-term cosmetic appearance of repaired lacerations. *Acad. Emerg. Med.* 3: 378, 1996.

103. Price, P. B. Stress, strain and sutures. *Ann. Surg.* 128: 408,1948.

104. Hogstrom, H., Haglund, U., and Zederfeldt, B. Tension leads to increased neutrophil accumulation and decreased laparotomy wound strength. *Surgery* 107: 215, 1990.

105. Jonsson, T., and Hogstrom, H. Effect of suture technique on early healing of intestinal anastomoses in rats. *Eur. J. Surg.* 158: 267, 1992.

106. Myers, M. B., and Cherry, G. Functional and angiographic vasculature in healing wounds. *Am. Surg.* 36: 750, 1970.

107. Bartlett, L. C. Pressure necrosis is the primary cause of wounddehiscence. *Can. J. Surg.* 28: 27, 1985.

108. Nilsson, T. Effect of increased and reduced tension on the mechanical properties of healing wound in the abdominal wall. *Scand. J. Plast. Reconstr. Surg.* 16: 101, 1982.

109. Burgess, L. P. A., Morin, G. V., Rand, M., et al. Wound healing: Relationship of wound closing tension to scar width in rats. *Arch. Otolaryngol. Head Neck Surg.* 116: 798, 1990

110. Ruff, G. L. The history of barbed sutures. Aesthet Surg J 33, 12s–16s, doi: 10.1177/1090820x13498505 (2013).

111. Greenberg JA. The Use of Barbed Sutures in Obstetrics and Gynecology. *Reviews in Obstetrics and Gynecology*. 2010;3(3):82-91.

112. Murtha, A. P. *et al.* Evaluation of a novel technique for wound closure using a barbed suture. *Plast Reconstr Surg* 117**,** 1769–1780, doi: 10.1097/01.prs.0000209971.08264.b0 (2006).

113. Kristen Aliano, Michael Trostler, Indira Michelle Fromm, Alexander Dagum, Sami Khan, and Duc Bui, "A Comparison of Barbed Sutures and Standard Sutures with regard to Wound Cosmesis in Panniculectomy and Reduction Mammoplasty Patients," Plastic Surgery International, vol. 2016, Article ID 7590396, 5 pages, 2016. https://doi.org/10.1155/2016/7590396.

114. Olga Solovyova and James Slover, The Use of Barbed Suture for Wound Closure in Hip and Knee Arthroplasty. Biomed J Sci & Tech Res. 2017; Volume 1 - Issue 5

115. Zhang, W. et al. Barbed versus traditional sutures for wound closure in knee arthroplasty: a systematic review and meta-analysis. Sci. Rep. 6, 19764; doi: 10.1038/srep19764 (2016)

116. Vladimir Grigoryants, MD; and Arpa Baroni, DO. Effectiveness of Wound Closure With V-Loc 90 Sutures in Lipoabdominoplasty Patients. Aesthetic Surgery Journal 33(1) 97–101

117. J. Peter Rubin, Joseph P. Hunstad, Alain Polynice, Jeffrey A. Gusenoff, Thomas Schoeller, Raymond Dunn, Klaus J. Walgenbach, Juliana E. Hansen; A Multicenter Randomized Controlled Trial Comparing Absorbable Barbed Sutures Versus Conventional Absorbable Sutures for Dermal Closure in Open Surgical Procedures, Aesthetic Surgery Journal, Volume 34, Issue 2, 1 February 2014, Pages 272–283, https://doi.org/10.1177/1090820X13519264

118. Krishnamoorthy B, Shepherd N, Critchley WR, Nair J, Devan N, Nasir A et al. A randomized study comparing traditional monofilament knotted sutures with barbed knotless sutures for donor leg wound closure in coronary artery bypass surgery. Interact CardioVasc Thorac Surg 2016;22:161–7.

119. Hsiao T, Council M. Wound, Closure Techniques. [Updated 2017 Nov 6]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2018 Jan.

120. Giddins GE. Experience with a knot-free absorbable subcuticular suture. Ann Roy Coll Surg Engl 1994;76:405–6.

121. Saalabian, Ali & Covi, Jennifer & Horch, Raymund. (2011). A review on wound closure techniques. Journal of Wound Technology.

INFORMED CONSENT FORM

You are requested to enrol yourself in study entitled, **"A ONE YEAR RANDOMIZED CONTROLLED TRIAL TO COMPARE EFFICACY OF KNOTLESS BARBED SUTURES VERSUS SUBCUTICULAR MONOFILAMENT SUTURES FOR SKIN CLOSUREIN OPEN INGUINAL HERNIA"** that is an attempt to find out efficacy of Knotless barbed sutures in decreasing post-operative pain and surgical site infections, which is being conducted by Dr. _____, post graduate in Surgery at Jawaharlal Nehru Medical College Belagavi, Karnataka. Under guidance of Dr. _____ Professor, Department of Surgery, Jawaharlal Nehru Medical College, Belgaum, under KLE University, Belagavi.

Respected Sir/Madam, we request you to enrol 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 supposed 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 Knotless barbed sutures (V- Loc^{TM}-90) compared with a monofilament subcuticular suture (Monocryl) in reducing post-operative pain and surgical site infection

Procedure involved

If you agree to enrol 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. Sequentially numbered opaque sealed enveloped 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 Knotless barbed suture (V-loc^{TM} 90) will be used and if you are in Group-B monofilament subcuticular (Monocryl) suture will be used. The Post-Operative care will be same for both groups of participants. Post-operative pain will be assessed at 24 hours, 48 hours and 72 hours. The wound will be assessed on post-operative day three, day eight and ten.

Benefits and Risks

The benefits of taking part in this research are you will have reduced post-operative pain and surgical site infection. 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, Belagavi.

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, Belagavi. 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, Belagavi Phone Number _____ or on _____.

If you have any queries related 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 having been read to me in my 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 _____

Date:

Place:

PROFORMA

Proforma for Clinical Evaluation of Individual Patient

Name:

Age:

Male	Female

Sex:

Address:

Occupation:

IP No:

Date of Admission:

Clinical Diagnosis:

Clinical Details:

History:

1) Pain
2) Lump:

Right	Left

3) Side:
4) Duration:
5) Systemic symptoms
6) Other complaints:
7) Past history of operation:
8) Personal history:

Smoker	Alcoholic	Tobacco chewing

9) Co-morbidities:

Diabetes Mellitus	Hypertensive	Others

General Physical Examination:

1) Vitals:

B.P:	PR:

2) Appearance:

Pallor	Icterus	Cyanosis	Clubbing	Lymphadenopathy	Oedema

3) Attitude:

Local Examination:

Position of patient:

Standing	Supine

Inspection:

1) Size of swelling:

2) Skin over swelling:

3) Impulse on coughing:

4) Position of penis:

Normal	Deviated

Palpation:

1) Impulse on coughing

2) Reducibility:

3) Tenderness:

4) Ring occlusion test:

No swelling	Present medial to ring

5) Finger invagination test:

Impulse at tip	Impulse on pulp

6) Ziemann's test

Internal ring	Superficial ring	Saphenous opening

Percussion:

Auscultation:

Respiratory Examination:

Cardiovascular Examination

Investigation:

1) CBC :

Hb	
TC	
RBC	
Platelet	

2) RBS:

3) Urine routine

Ph	
Pus cells	
RBC	
Others	

4) Renal function:

Blood Urea	
Serum creatinine	

5) USG Abdomen and Pelvis:

INTERVENTION USED:

Post-operative pain: based on Visual Analogue score

24hrs	48hrs	3rd day

Wound healing:

Grade	**Healing**	**DAY 3**	**DAY 8**	**DAY 10**
0 Normal Healing				
I Normal healing with mild bruising or erythema				
A	Some bruising			
B	Considerable bruising			
C	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 (<2cms)			
B	Along wound(>2cms)			
C	Large volume			
D	Prolonged (>3 days)			
IV Pus				
A	At one point (<2cms)			
B	Along wound (>2cms)			

							Post-operative Pain								
Sl. no	**Ipno**	**Group**	**Age**	**Age group**	**Gender**	**Clincal diagnosis**	**6 hours**	**12 hours**	**24 hours**	**48 hours**	**3rd day**	**Healing status**	**HS Day3**	**Hs Day8**	**HS Day10**
1	803,636	B	26	UP to 30	Male	Left indirect hernia	6	5	5	4	3.0	Normal	0	0	0
2	806,636	B	61	61 and above	Male	Right indirect hernia	5	5	5	3	3.0	Normal	0	0	0
3	807,291	B	35	31 to 45	Male	Right indirect hernia	6	4	4	4	3.0	Normal	0	0	0
4	810,374	B	72	61 and above	Male	Right direct hernia	6	4	5	3	3.0	Abnormal	0	0	1b
5	746,765	B	38	31 to 45	Male	Right indirect hernia	5	4	6	4	3.0	Normal	0	0	0
6	775,769	B	50	46 to 60	Male	Left direct hernia	5	4	5	4	3.0	Normal	0	0	0
7	807,696	B	65	61 and above	Male	Right indirect hernia	6	3	5	4	3.0	Normal	0	0	0
8	780,145	B	50	46 to 60	Male	Left indirect hernia	6	4	5	4	3.0	Normal	0	0	0
9	808,273	B	36	31 to 45	Male	Left indirect hernia	5	4	5	5	4.0	Normal	0	0	0
10	811,300	B	71	61 and above	Male	Right direct hernia	4	3	5	3	4.0	Normal	0	0	0
11	813,428	B	61	61 and above	Male	Left indirect hernia	4	4	4	3	3.0	Abnormal	1c	2a	1c
12	821,938	B	76	61 and above	Male	Left indirect hernia	5	4	4	4	4.0	Normal	0	0	0
13	822,589	B	78	61 and above	Male	Right direct hernia	6	5	4	3	3.0	Normal	0	0	0
14	816,393	B	55	46 to 60	Male	Right indirect hernia	6	5	5	4	2.0	Abnormal	0	1c	1a
15	857,207	B	35	31 to 45	Male	Right indirect hernia	5	5	4	3	3.0	Abnormal	0	1c	0
16	843,604	B	67	61 and above	Male	Left indirect hernia	5	4	5	3	4.0	Normal	0	0	0
17	838,101	B	35	31 to 45	Male	Left indirect hernia	6	4	4	4	3.0	Abnormal	1a	1a	0
18	768,154	B	23	UP to 30	Male	Right indirect hernia	5	4	5	4	4.0	Abnormal	0	0	1a
19	840,323	B	32	31 to 45	Male	Right indirect hernia	5	4	4	3	3.0	Normal	0	0	0
20	838,863	B	35	31 to 45	Male	Left indirect hernia	5	3	5	4	3.0	Abnormal	0	0	1a
21	827,680	B	24	UP to 30	Male	Right indirect hernia	5	4	5	4	2.0	Normal	0	0	0
22	801,518	B	42	31 to 45	Male	Right indirect hernia	6	5	4	3	2.0	Normal	0	0	0
23	781,235	B	65	61 and above	Male	Right indirect hernia	6	5	5	4	3.0	Normal	0	0	0
24	843,421	B	65	61 and above	Male	Left indirect hernia	5	5	4	4	3.0	Abnormal	0	0	1c
25	810,671	B	72	61 and above	Male	Right indirect hernia	5	4	4	3	2.0	Normal	0	0	0
26	822,273	B	24	UP to 30	Male	Left indirect hernia	5	4	4	3	2.0	Abnormal	0	1b	0
27	786,123	B	28	UP to 30	Male	Right indirect hernia	5	4	5	4	3.0	Normal	0	0	0
28	801,673	B	52	46 to 60	Male	Left indirect hernia	5	5	4	3	2.0	Normal	0	0	0
29	802,640	B	25	UP to 30	Male	Left indirect hernia	4	4	4	3	3.0	Normal	0	0	0
30	791,979	B	31	31 to 45	Male	Right indirect hernia	5	3	4	4	2.0	Abnormal	0	0	1b
31	797,706	A	53	46 to 60	Male	Left indirect hernia	4	4	3	3	2.0	Normal	0	0	0
32	843,573	A	40	31 to 45	Male	Left indirect hernia	4	4	4	4	3.0	Normal	0	0	0

							Post-operative Pain								
Sl. no	**Ipno**	**Group**	**Age**	**Age group**	**Gender**	**Clincal diagnosis**	**6 hours**	**12 hours**	**24 hours**	**48 hours**	**3rd day**	**Healing status**	**HS Day3**	**Hs Day8**	**HS Day10**
33	844,952	A	60	46 to 60	Male	Left indirect hernia	4	3	3	3	2.0	Normal	0	0	0
34	811,161	A	68	61 and above	Male	Right direct hernia	4	4	3	4	3.0	Normal	0	0	0
35	774,079	A	38	31 to 45	Male	Right indirect hernia	5	3	3	2	2.0	Normal	0	0	0
36	806,636	A	43	31 to 45	Male	Right indirect hernia	4	3	4	4	3.0	Normal	0	0	0
37	819,874	A	55	46 to 60	Male	Left indirect hernia	3	3	3	3	2.0	Abnormal	0	1b	1a
38	805,185	A	29	UP to 30	Male	Right indirect hernia	4	4	4	3	2.0	Abnormal	1c	0	0
39	795,431	A	78	61 and above	Male	Right direct hernia	4	4	4	3	3.0	Normal	0	0	0
40	795,123	A	23	UP to 30	Male	Right indirect hernia	5	4	4	4	2.0	Abnormal	0	0	1c
41	814,741	A	70	61 and above	Male	Left indirect hernia	4	3	4	4	3.0	Normal	0	0	0
42	793,803	A	75	61 and above	Male	Right indirect hernia	4	3	5	4	3.0	Normal	0	0	0
43	821,211	A	48	46 to 60	Male	Left indirect hernia	5	3	5	4	3.0	Abnormal	0	1c	0
44	822,394	A	38	31 to 45	Male	Left direct hernia	4	4	4	3	3.0	Normal	0	0	0
45	841,501	A	70	61 and above	Male	Right indirect hernia	3	4	4	3	2.0	Normal	0	0	0
46	821,538	A	78	61 and above	Male	Left direct hernia	4	4	3	3	3.0	Normal	0	0	0
47	815,143	A	35	31 to 45	Male	Right indirect hernia	4	3	3	3	3.0	Abnormal	0	2a	1a
48	800,936	A	24	UP to 30	Male	Right indirect hernia	5	4	4	4	3.0	Normal	0	0	0
49	782,124	A	48	46 to 60	Male	Left indirect hernia	5	3	4	3	3.0	Abnormal	1a	0	0
50	800,413	A	60	46 to 60	Male	Right indirect hernia	4	3	4	3	3.0	Normal	0	0	0
51	829,817	A	33	31 to 45	Male	Left indirect hernia	5	4	3	3	2.0	Normal	0	0	0
52	809,613	A	58	46 to 60	Male	Left indirect hernia	5	3	5	4	3.0	Normal	0	0	0
53	793,678	A	50	46 to 60	Male	Right indirect hernia	5	3	4	3	3.0	Normal	0	0	0
54	800,298	A	79	61 and above	Male	Right indirect hernia	4	4	5	4	3.0	Normal	0	0	0
55	804,288	A	59	46 to 60	Male	Left indirect hernia	4	3	4	3	3.0	Normal	0	0	0
56	806,518	A	57	46 to 60	Male	Right indirect hernia	4	4	3	4	2.0	Normal	0	0	0
57	838,657	A	68	61 and above	Male	Left indirect hernia	4	4	4	3	3.0	Normal	0	0	0
58	829,936	A	70	61 and above	Male	Right indirect hernia	5	3	4	3	3.0	Normal	0	0	0
59	826,440	A	38	31 to 45	Male	Right indirect hernia	4	3	3	3	3.0	Abnormal	0	1a	1b
60	830,311	A	70	61 and above	Male	Right indirect hernia	4	3	4	3	3.0	Normal	0	0	0