"TO STUDY INCIDENCE OF SURGICAL SITE INFECTIONS USING TRICLOSAN COATED AND NON TRICLOSAN COATED SUTURE MATERIALS- A RANDOMIZED CONTROL STUDY."

By

Dr. RAHUL SINGH R

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Under the Guidance of

Dr. SHASHIREKHA C.A

PROFESSOR

DEPARTMENT OF GENERAL SURGERY,

SRI DEVARAJ URS MEDICAL COLLEGE,

TAMAKA, KOLAR-563101

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SRI DEVARAJ URS MEDICAL COLLEGE,

TAMAKA, KOLAR-563101

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Dr. RAHUL SINGH .R

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Date:

Place: Kolar

Signature of the Guide

Dr. SHASHIREKHA C.A

Professor
Department of General surgery,
Sri Devaraj Urs Medical College, &
Research Center,
Tamaka, Kolar.

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH CENTER, TAMAKA, KOLAR, KARNATAKA

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Dr. P.N.SREERAMULU
Professor & Head
Department of General Surgery,
Sri Devaraj Urs Medical College,
& Research Center, Tamaka, Kolar

Date:
Place: Kolar

Dr. P.N.SREERAMULU
Principal
Sri Devaraj Urs Medical College
& Research Center,
Tamaka, Kolar.

Date:
Place: Kolar

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH CENTER, TAMAKA, KOLAR, KARNATAKA

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Dr. RAHUL SINGH. R

Post graduate student

Department of General Surgery

Sri Devaraj Urs Medical College

Kolar.

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SIGNATURE OF THE CANDIDATE

Dr. RAHUL SINGH. R

LIST OF ABBREVATION

SSI: Surgical Site Infection

SSSI: Superficial Surgical Site Infection

CDC: Centre for Disease Control

NNIS: National Nosocomial Infection Surveillance

BMI: Body Mass Index

HRV: Human Retroviral Infection

POD: Post-Operative Day

FDA: Food and Drug Administration

SENIC: Study on the Efficacy of Nosocomial Infection Control

ASA: American Society of Anesthesiologists

AMP: Antimicrobial Prophylaxis

MIC: Minimum Inhibitory Concentration

EPS: Extracellular Polymeric Material

PGA: Polyglycolic Acid

ENR: Enoyl-acyl Carrier Protein Reductase Enzyme

NHSN: National Health Care Safety Network

HICPAC: Health Care Infection Control Practices Advisory Committee

AORN: Association of Operating Room of Nurses

Disclaimer

This study has not been funded by any pharmaceutical company

ABSTRACT

Background: Despite the use of prophylactic antibiotics, surgical site infections (SSI) are still a real risk of surgery and represent a substantial burden of disease for both patients and healthcare services in terms of morbidity, mortality and economic cost. It is one of the most frequently encountered nosocomial infections in hospitalized patients.

Aim: To prevent Surgical Site Infections (SSI) in patients undergoing Clean Surgeries.

Objectives:

1) To study the incidence of superficial surgical site infections developing in clean surgical wounds with bioactive suture material (coated polyglactin 910 with triclosan).
2) To study the incidence of superficial surgical site infections developing in clean surgical wounds using non Triclosan coated suture material.
3) To record surgical site infections in clean surgical wounds using Triclosan coated **v/s** non Triclosan coated suture materials.

Methods: In our prospective observational study, 146 patients were included and were divided into study and control group. In the study group, the subcutaneous layer of the wounds was closed using Triclosan coated suture materials in patients undergoing surgeries for clean wounds.

Results: Each group had 73 patients, in control group 7 cases developed SSI and in the study group 4 patients developed SSI. The incidence of SSI in the study group was less compared to the control group.

Interpretation and Conclusions:

1. All patients undergoing surgeries for 'clean wounds' were included in this study.

2. Most of the patients studied were in the age group of 51-60 years. Majority studied were males.

3. Majority of the patients included in this study were operated for Inguinal Hernia.

4. Use of Triclosan coated suture material in apposing the subcutaneous layer in clean surgeries, is useful in reducing the incidence of SSI's in the study group. These suture materials have reduced incidence of SSI's, in comparison to two groups.

5. There is a decrease in the post-operative hospital stay in the study group.

6. The post-operative day on which patients developed SSI in both study and control groups was almost the same (post-operative day 3).

7. The intensity of pain perceived in study group as analyzed by the visual analog scale is less than that in the control group.

Keywords: Surgical Site Infection, Literature, Triclosan, Subcutaneous Layer, Clean Surgeries

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INTRODUCTION

INTRODUCTION

Most common post-operative complications are the Surgical site infections (SSI)[1-5] .Even the well-equipped hospitals with modern facilities and strict standard protocols, to prepare a patient for a procedure, and laid down norms of antibiotic prophylaxis, are not free from these Surgical Site Infections (SSI)[1]. Among the most frequently encountered nosocomial infections, these are second in order, with urinary tract infection being the first. Among the patients who undergo elective surgeries 3-5% of them develop SSI's. Keeping in mind the region and the facilities available, 4.5% to 20% is the incidence globally[40]. Studies have revealed that among the patients undergoing surgeries in India 4% to 30% develop an SSI[20,21].

Though antibiotics are administered prophylactically, SSI's are still a real risk of surgery and represent a substantial burden of disease for both patients and health care providers. Innovations, inventions and surgeries being performed in this modern materialistic world is always increasing. The most frequently noticed, studied and discussed nosocomial infections are the surgical site infections, contributing substantially to the morbidity and financial burdens of those affected.

The various factors that increase a person's liability to developing a SSI can be divided into patient related factors and surgeon related factors[22-24]. Patient related factors can be modifiable or non-modifiable depending on the duration and the kind, but are difficult to change once a surgical intervention is planned. Therefore further efforts on the surgeon's side are needed to reduce the frequency of SSI's.

The rates of SSI vary depending on the type of surgery[22].

- For clean surgery = 2.1 of every 1000 operations
- For clean contaminated surgery = 3.3 of every 1000 operations
- For contaminated surgery = 6.4 every 1000 operations
- Dirty surgery = 7.1 of every 1000 operations.

Research has shown that surgical techniques, skin preparation, timing and type of wound closure are significant factors that decide the probability of developing subsequent infection. It is well recognized that sutures are an important part of surgeries and trauma management[6-8]. The primary purpose of sutures is to bring the apposing tissues together and hold them in close approximation to facilitate and hasten healing process with minimal or no scar formation following an injury or operation. The factors favoring use of a particular suture in day to day wound management are, closing the tissues layer wise, to have a good wound closure, tension across the wound that has been approximated using sutures, depth at which the suture is placed, presence or absence of edema, probable time of suture removal, time taken to acquire adequate strength, and show minimal or no inflammatory reactions. Sutures have to be significantly pliable and flexible for better handling.

A suture material itself can be one of the cause or a co-factor in post-operative SSI's, the extensive research in this field and latest developments have focused more on making them less susceptible to bacterial overgrowth[6-8]. Biologically active suture materials have been created by fixing drugs to sutures[9-10]. Coating sutures with antimicrobial has been considered since the early 1970's. Antibiotics such as gentamicin were the first to be considered but this was not pursued. Triclosan is an antiseptic, which has been chosen for incorporation into the sutures to give a local, broad spectrum antimicrobial effect to the wounds. And thus, an attempt to reduce perioperative surgical morbidity. There is

currently no clinical risk of triclosan resistance but recommended prudent use. Triclosan, as an antiseptic, has undergone scrutiny at various levels and is only then considered for incorporation into sutures in these respects[11-12]. The initial studies using triclosan coated suture materials have shown a decrease in the risk of SSI[13-19].

As surgeons, many of us have an intimate knowledge of the sequelae of surgical site infections. We utilize understanding of dressing properties in the role of meeting tissue requirements based on detailed wound assessment and patient specific needs such as causative pathogenic organism, documented sensitivities etc. identifying the type of SSI is not necessarily requisite for adequate management[14-16].

SSI is a social burden and adds to the agony of the patient and his/her spouse and family. Many studies have been conducted at various levels and all these studies have stressed on a systematic management of patients to prevent SSI both before and after the surgery. Antibacterial coated suture materials could be one such measures in reducing the risk of development of SSI's.

This study is to focus more on the method of wound closure with regards to suture material used. In this study, we compare the rates of SSI's in patients undergoing elective clean surgeries in whom the subcutaneous layer will be closed with TRICLOSAN coated polyglactin 910 v/s the wounds which will be closed with non-TRICLOSAN coated polyglactin 910. This satisfies the definition criteria of superficial SSI (limiting only to the skin and the underlying subcutaneous tissue).

A quote that seems to fit for the perpetual student in all of us –

" My mind rebels at stagnation: give me work, give me problems to solve." – Sherlock Holmes.

OBJECTIVES

OBJECTIVES OF THE STUDY

1) To study the incidence of superficial surgical site infections developing in clean surgical wounds with bioactive suture material (coated polyglactin 910 with triclosan).
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REVIEW OF LITERATURE

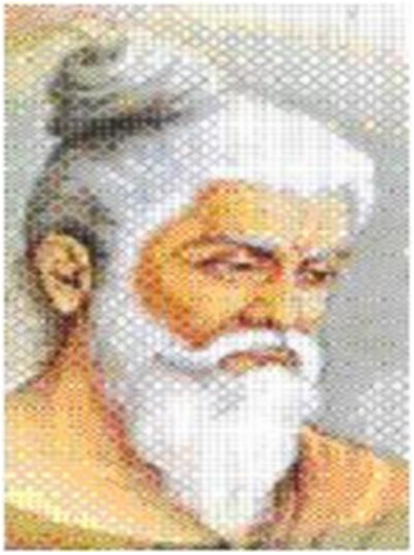
REVIEW OF LITERATURE

Historical aspects of suture approximation of wounds

Sushruta, an ancient surgeon of the recorded history (600 B.C) is said to be the pioneer to treat patients aesthetically and hence he is the "Father of Indian Plastic Surgery"[25,26]. Sushruta who lived nearly 150 years before Hippocrates vividly described the basic principles of plastic surgery in his famous ancient treatise 'Sushruta Samhita' (Sushruta's compendium) in 600 B.C.

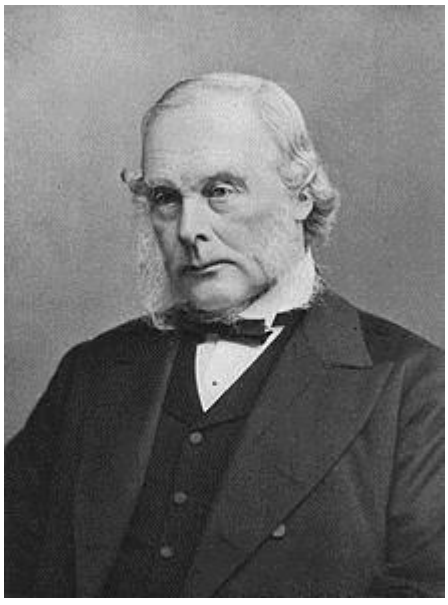
Shushruta described surgery under eight heads - *Chedya* (excision), *Lekhya*(scarification), *Vedhya* (puncturing), *Esya* (exploration), *Ahrya* (extraction), *Vsraya*(evacuation) and *Sivya* (Suturing).

In his writings he elaborates, the use of suture materials made of bark, tendon, hair and silk and needles of bronze or bone (circular, two finger-breadths wide and straight, triangular bodied, three finger - breadths wide)[27].



There is documentary evidence that the historical background of wound infection may be traced back to as far as 1st century AD when a Roman physician, Cornelius Celsus described the four cardinal signs of inflammation and used 'anti septic' solutions[26]. Claudius Galen (130-200 AD), another Roman physician had such an influence on the management of wounds that he is still thought by many as the "Father of Surgery"[27]. He and his followers investigated the 'laudable pus' theory. According to this theory, it was considered that having pus in a wound was good for the healing process. This went on till the 16th century when Ambroise Pare "encouraged wounds to suppurate"[27].

Before the mid 19th century, surgical patients commonly developed post-operative "irritative fever", followed by purulent drainage from their incisions, overwhelming sepsis, and often death. In the late 1860's, after Joseph Lister (1827-1912) introduced the principles of anti-sepsis, the postoperative infectious morbidity reduced substantially[27]. Lister's contribution radically changed surgery from being just an activity associated with death following infection, to a discipline that could eliminate suffering, improve the quality and longevity of life[27].



The "Germ Theory" was accepted in the 19th century and introduction of antisepsis through Semmelweiss (1818-1865), Pasteur (1822-1895). Mary Ayton, a nursing officer, defined terminologies like Wound infection, wound contamination, wound colonization, which are in current use.

Wound Contamination: bacterial presence within a wound without any host reaction.

Wound Colonisation: bacterial presence within the wound which do multiply or initiate a host reaction.

Wound Infection: an associated host reaction as the bacteria deposit and multiply in the tissue.

Vincent Falanga in 1994 identified the concept of 'critical colonisation' with fresh insights to chronic wound healing and non-healing wounds.

Critical Colonisation: delay in wound healing caused by multiplication of bacteria, usually associated with an exacerbation of pain not previously reported but still with no host reaction.

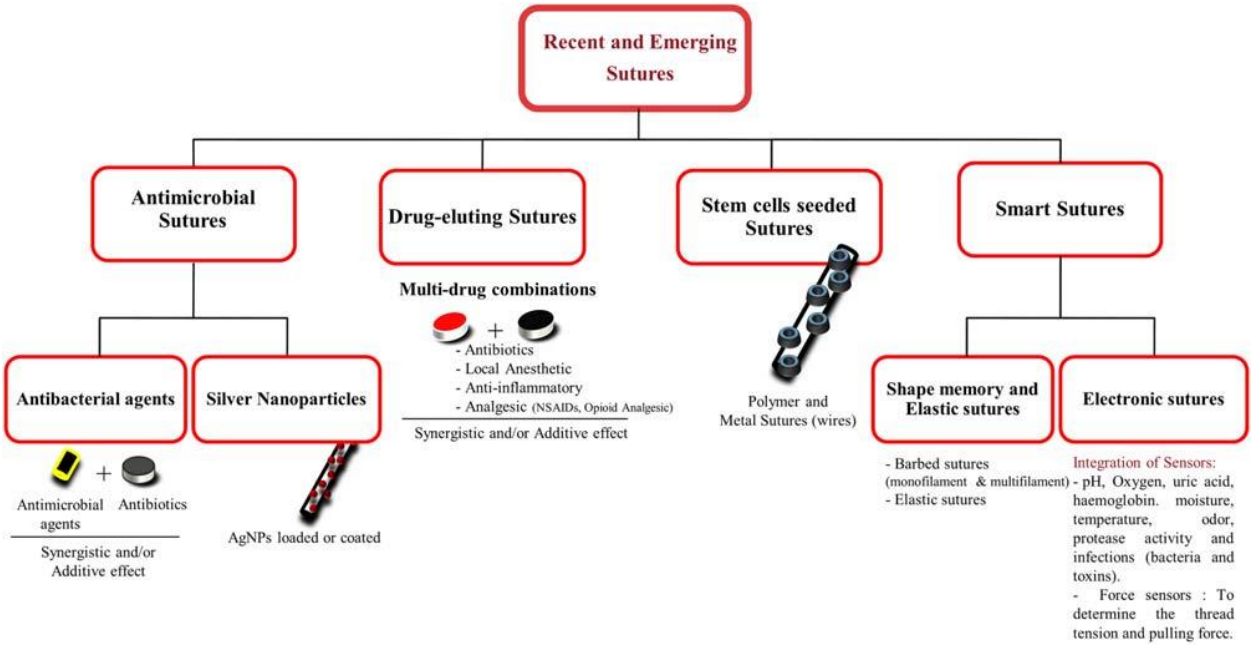
Introduction to Bioactive sutures

The era of surgical medicine has witnessed sutures being at the forefront throughout time[28]. Surgery and sutures have come a long way since ancient India. Sutures are surgeon friendly as these are readily available, cost effective, easy to use, efficient as they provide adequate strength to sustain closure[29]. Surgeon has the privilege to choose one best suited suture from a variety of suture materials that are available, to have the best possible outcome. The pros and cons to be considered when selecting an appropriate suture for

wound closure and achieve faster healing are, how tough the suture is, how well the host tissue can withstand it, risk of infection, critical time of absorption and the overwhelming inflammation. There is nothing wrong in saying that there is a suture for every occasion. We have witnessed that in this era of research and development, suture material has been polished and made more useful and a novel prospect has now been made available- BIOACTIVE SUTURE MATERIALS. The beneficial or adverse effects of a drug on living matter has been described in pharmacology based on its biological activity or pharmacological activity[30]. Bioactive sutures combine the bioactivity of the drug with the mechanical function of approximating a wound. Biologically activating surgical sutures by fixing the appropriate drugs onto them by means of chemical bonds has proven to be feasible. Blaker et al., coated both absorbable and non absorbable sutures with silver-doped glass powder in vitro , and showed that antibiotic and bactericidal properties can be imparted to the suture without affecting its dynamic and thermal properties and thus the first bioactive suture material was made commercially available[31]. They showed, in vitro, that antimicrobial bactericidal properties were imparted to the suture without affecting its dynamic and thermal properties. Adhesion of Staphylococcus epidermis to sutures coated with silver-doped bioactive glass was compared with control uncoated sutures and with sutures coated with Bioglass (NovaBone Products, LLC, Alachua, Fla.), another type of glass coating, in another study done by the same group. Bacterial adhesion to the silver-doped bioactive glass–coated suture reduced significantly when compared with the other two groups[32].

Numerous bioactive sutures have since been created including sutures with antibacterial agents, sutures with antimicrobial and anesthetic long acting, sutures smeared with chemotherapeutic agents, sutures with radioactivity and even sutures with stem cells which aid tissue regeneration[9,33]. Thus, numerous conditions stand to benefit from the

development of bioactive sutures. Anti-microbial surgical sutures, provide the wound with the antibiotics settled in their structure for a long period, and can aid in taking precautions and treatment of surgical sepsis. After an extensive work in the field of research and development the first antibacterial suture Vicryl plus (triclosan coated polyglactin 910 suture) was approved in 2002 by Food and Drug Administration (FDA) to lower the risk of surgical site infections. The first commercial preparation targeting SSI is Triclosan Coated polyglactin 910[34].



Surgical site infections

C.M.Green rightly quoted "virulent infection yields to no treatment, save the grace of God". This was believed to be true until the great pioneers in infection control – Ignaz Semmelweiz who successfully reduced maternal morbidity and mortality insisted that the examining hands should be cleaned with chlorinated water and Joseph Lister who popularized the use of 5% carbolic acid solution to wash hands and instruments, both before and after surgical procedures – when most wounds became infected[35]. When Alexander Fleming discovered penicillin in 1928, he changed the fate of millions and this set off the modern era of antibiotic discovery. This can be demonstrated by reviewing each surgical class of wound and comparing the incidence of infection before and after the use of prophylactic antibiotics[36,37].

(table i)

TYPE OF WOUND	RATES OF INFECTIONS	RATES OF INFECTIONS
Clean	1%-2%	2%
Clean contaminated	6%-9%	3.3%
Contaminated	13%-20%	6.4%
Dirty	40%	7.1%

Based on the data available, mortality rates, costs and relative changes in frequency of infections in recent years, nosocomial or hospital acquired infections are today by far the most common complication affecting patients in the hospital. Four commonly encountered infections - Urinary tract infection (usually catheter associated), blood stream

infections (usually follows an intravascular procedure), SSI and acquired pneumonia (common in patients on ventilator support) account for nearly 80% of all the nosocomial infections of which SSI are third in order (nearly 20%) and comparatively cost effective (third in cost). Urinary tract infections are the most commonly encountered infections (nearly 35%), these are easily treatable, cost effective and are not lethal[38]. Blood borne infections and respiratory infections like pneumonia are less common (nearly15%) – but are expensive to the patient and can be lethal at times[39]. SSI's are the third most frequently reported nosocomial infection, and are associated with morbidity that can endanger a patient's life, prolong the number of days of stay in the hospital, and increase the cost of health care.

Majority of the SSI's are confined to the site of incision, and the rest involve the organs or spaces that are accessed during the operation. When surgical patients with nosocomial SSI died, 77% of the deaths were reported to be related to the infection per se, and the majority (93%) were organ or space involving infections, accessed during the operation[40].

Curse estimated that an SSI increased a patient's hospital stay by approximately 10 days and also adding to the cost in 1980. An analysis in 1992 showed that each SSI resulted in 7.3 additional postoperative hospital days. Other studies also accept that increased length of hospital stay is associated with SSI's[41,42].

SSI's remain a substantial cause of morbidity and mortality in hospitalized patients. The most important reason being the emergence of antimicrobial resistant pathogens and the increased number of surgical patients who are elderly and/or have a wide variety of chronic, debilitating, or immuno-compromising underlying diseases[42]. This era has also

seen increasing number of prosthetic implants being used and organ transplantation operations being performed. Operative wound infection may not only retard normal healing but also may induce life threatening clinical situations, particularly in critically ill patients[41,42]. The probability of a post-operative surgical site infection developing in a patient is influenced by a wide range of intrinsic and extrinsic risk factors. Thus, to lower the risk of SSI, a systematic yet realistic protocol has to be applied with the awareness that this risk is influenced by characteristics of patient, procedure, personnel, and hospital.

Patients with SSI are two times likely to die, chances of admission to an ICU is 60%, more than five times more likely to have a readmission to the hospital after discharge. In 2002, 8205 deaths were encountered due to SSI. At a rate of 5 SSI's per 100 surgical procedures, the total annual cost of treating SSI's would be 3.2 to 10 billion dollars. A wide variations in the cost of health care reflect that, there is a difference in the severity of each SSI depending on the causative pathogen, type of surgery performed, patients health status and other factors[43,44].

Two SSI risk stratification systems have been developed. The Study on the Efficacy of Nosocomial Infection Control (SENIC) determined that the risk for an SSI increases for patients who fulfill the following –

- Abdominal surgery
- Operation lasting > 2 hours
- Class III or class IV wound classification (contaminated or dirty infected).
- Surgery performed on a patient with 3 or more discharge diagnoses.

the NNIS National Nosocomial Infections Surveillance System index assesses higher SSI risk when the following variables are present:

- Class III or class IV wound (contaminated or dirty infected).

- Length of operation >T hours, where T is the 75th percentile of the duration of the specific operation being performed.

The various risk factors that predispose development of SSI can be divided as-

1. Patient related factors:

- Age : more than 60 years

- Gender : Males > femles

- Obesity : BMI > 25 kg/m^2

- Co-morbidities : Diabetes mellitus, chronic ling disease, obstructive jaundice. Immuno suppression in organ transplant patients, chemotherapy and steroid therapy.

2. Surgery related factors :

- Emergency surgeries, bowel surgery, abdominal aortic aneurysm, stoma closure, operations for peritonitis, re-laparotomy.

- technique and suture material used for closure of the abdominal incisions.

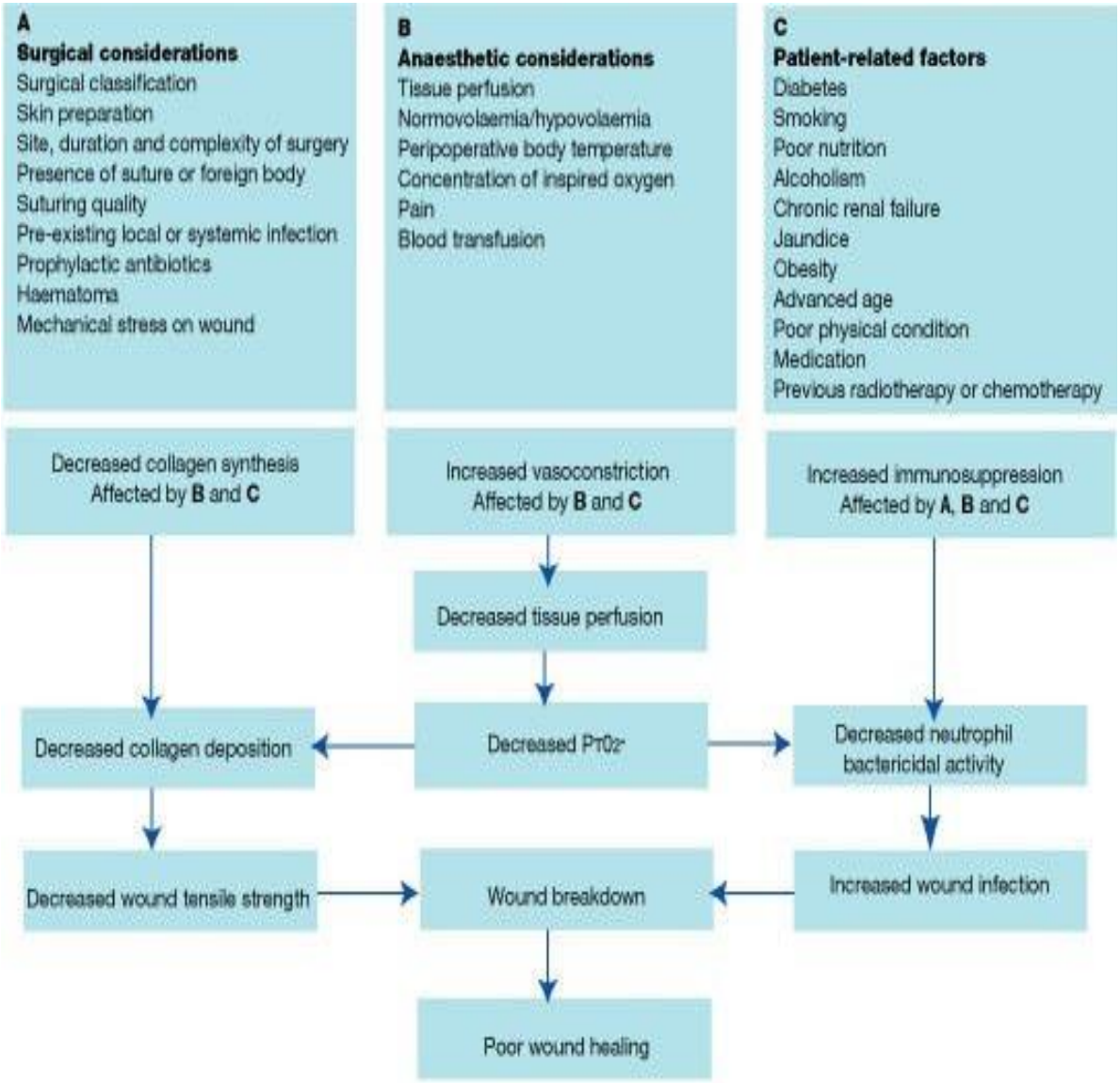
- wound infection, long operating time, increased blood loss, surgeon's experience.

3. Biological Factors :

- Collagen and metalloproteinases synthesis.

- Smoking

- Nutritional deficiencies.



Patient related, surgery related, and physiological factors which increase the risk of SSI include the following[45-48]:

1. Patient related factors include:

- AGE: Skin and muscle tissue lose their tone and elasticity with aging. Circulation may be impaired and metabolism also slows down. Aging and chronic disease states go together. Aging alone has no role in long term wound healing. There is delayed

cellular response to the stimulus of injury, delayed collagen deposition, and decreased tensile strength in the remodeled tissue. All of these factors lengthen the repair processes and healing time.

- WEIGHT: Excess fat at the wound site prevents securing a good closure. Obesity (>20% ideal body weight) makes the tissue vulnerable to trauma and infection, as fat does not have a rich blood supply. Melting fat from the wound leaks out, thus creating a nutritious medium for bacterial inoculation and infection.

- NUTRITIONAL STATUS: Adequate nutrition is essential to support cellular activity and collagen synthesis at the wound site. Overall deficiencies in carbohydrates, proteins, zinc, and vitamins A, B, and C impair wound healing process. These deficiencies are common in chronic diseases or cancer cachexia. When a major elective operation is planned in a severely malnourished patient, surgeons use their expertise in providing a good nutritional support to the patient in consideration of the major morbidity.

- DEHYDRATION: Depletion of fluids in patient's system can alter the electrolytes and can hamper the cardiac function, kidney function, cellular metabolism, oxygenation of the blood, and hormonal function. This invariably impairs the healing process and has an impact on patient's overall health status and recovery from surgery.

- INADEQUATE BLOOD SUPPLY TO THE WOUND SITE: Oxygen is necessary for cell survival and healing. Diabetic patients and those suffering from atherosclerosis have a compromised blood supply to the wound such as poor circulation to the limbs

with vascular compromise and will slow down and even seize the healing process. Skin healing takes place faster in the face and neck, which receive the greatest blood supply, and most slowly in the extremities.

- IMMUNE RESPONSES: Immunity plays an important role in protecting the patient from infection. Immunodeficiencies can manifest in any form, a patient infected with HIV, ongoing chemotherapy, using high doses of catabolic steroids, diabetes, which either affect directly or indirectly as a confounding factor in hampering the healing process and making the patient vulnerable to repeated infections. Some patients have allergies to specific suture materials, metal alloys or latex. These, on the other hand, will cause increased allergic reactions. This also interferes with the healing process. Therefore, the surgeon should check beforehand on a patient's allergies.

- CHRONIC DISEASES: Chronic illnesses, especially endocrine disorders, diabetes, malignancies, localized infection, or debilitating injuries will heal more slowly and will be more vulnerable to post surgical wound complications. For an already ongoing insult to the patient's system, delayed wound healing adds on to the agony. All of these conditions merit concern, as they negatively affect the tissues at the wound site, as well as their potential impact upon the patient's overall recovery from the procedure. Malignancies, in addition, may alter the cellular structure of tissue and influence the surgeon's choice of methods and closure materials. The overall management protocol will differ from patient to patient.

- RADIATION THERAPY — Radiation therapy to the surgical site prior to or shortly after surgery can produce considerable impairment of healing and lead to substantial

wound complications. The various harmful rays being emitted act as a double edged sword, that could heal locally but the rest of the system is not free from the damage. Therefore surgical procedures for malignancies must be planned to minimize the potential for these problems.

- NICOTINE USE: Delays primary wound healing and heightens the risk of SSI. Tobacco consumption (in any form) affects the sternal and /or mediastinal wounds following cardiac surgery, making it vulnerable to develop SSI. For elective procedures, patient's should be educated to stop tobacco products atleast 30 days prior to the proposed procedure.

- PROLONGED PREOPERATIVE HOSPITAL STAY: Is frequently suggested as a patient characteristic associated with an increased SSI risk. However, more the number of days spent in the hospital, more is the severity of illness and co-morbidities, requiring in-patient workup and / or a course of treatment before the procedure.

- THE PHYSICAL STATUS OF THE PATIENT: The American Society of Anaesthesiologists (ASA) has developed a graded, descriptive scale, to categorize patients based on preoperative comorbidity. The classification is independent of surgical procedure and is a standard method of addressing the patient's physical status to anesthesiologists and other health care providers. Patients are categorized as follows:

ASA I—No systemic, physiologic, biochemical, or psychiatric disturbance. An otherwise healthy patient.

ASA II—A patient with mild systemic insult, but no functional limitation. Examples are well-controlled hypertension and uncomplicated diabetes mellitus.

ASA III—A patient suffering with a debilitating severe systemic manifestation with non-incapacitating functional Impairment. Examples are vascular complications in diabetic patients, previous myocardial infarction, and uncontrolled hypertension.

ASA IV— A patient having constant threat to his/her life in the form of an incapacitating systemic disease.

Examples are congestive heart failure and unstable angina pectoris.

ASA V—A moribund patient, with no signs or expectations of survival for 24 hours with or without surgery. Examples are ruptured aortic aneurysm and intracranial hemorrhage with elevated ICP.

ASA VI— patient declared brain dead and whose organs are being harvested for transplantation.

E—Emergency surgery is required. For example, *ASA IE* represents an otherwise healthy patient undergoing emergency appendicectomy.

The CDC's National Nosocomial Infection Surveillance system (USA)

Operative characteristics:

2. Pre-operative issues:

- PRE-OPERATIVE ANTISEPTIC MEASURES: painting the surgeon's area of interest with an antiseptic, has shown to lower the number of microbial flora in the skin . The products that contain Chlorhexidine gluconate need repeated applications to achieve maximum antimicrobial effect. Though preoperative application of

antimicrobials, reduces the contamination of the skin, there is no acceptable evidence that they reduce SSI rates. Chlorhexidine gluconate reduces the microbial count by 9 fold. In one study, SSI rates were less among patients who used chlorhexidine gluconate (9%), compared to those with soap bar (12.8%) or placebo (11.7%). The Association of Operating Room Nurses (AORN) recommend that patients undergoing clean surgeries to take bath twice with 4% Chlorhexidine Gluconate the previous night of surgery. For procedures limited to the head, two preoperative shampoos with 4% chlorhexidine gluconate is advocated.

- PRE-OPERATIVE HAIR REMOVAL: Hair removal was once theorized to reduce the risk of post-operative infection and, accordingly, became routine practice in many operating rooms. . Removing hair the previous night (shaving) is associated with a significantly higher risk of SSI. Hair removal using a depilatory is not associated with SSI risk, but causes skin irritation. Shaving creates small cuts and micro abrasions the skin, that later serve as nidus for bacterial proliferation. Decreased rates of SSI's are seen if the hair in and around the operating area is shaven just prior to the procedure, compared to shaving the previous night; the rate of SSI was more than 20% if hair removal was performed >24 hours prior to the procedure. There is no valid reason that clipping hair immediately before operation lowers the risk of SSI than shaving or clipping the night before the operation (1.8% = SSI rates immediately before surgery v/s clipping the night before = 4%). Overall the risk of SSI is less with depilatories than shaving or clipping, but hypersensitivity reactions have been reported from its use. Thus, if hair removal is necessary, clipping rather than shaving have to followed and should be done immediately before the commencement of the procedure.

- PATIENT SKIN PREPARATION IN THE OPERATING ROOM: The most commonly used agents are iodophores (Povidone iodine), chlorhexidine gluconate and alcohol containing products. Alcohol is readily available, inexpensive and remains the most effective and rapid acting skin antiseptic, the only potential disadvantage is its flammability. Chlorhexidine gluconate compounds and iodophores both have broad spectrum antibacterial activity. Studies have compared the two and shown that chlorhexidine gluconate is better in reducing skin contamination than Povidone iodine. Also, unlike iodophores, chlorhexidine gluconate is not inactivated by blood or serum proteins. To the skin of the patient, which is free from gross contamination like (dirt, soil, debris) an antiseptic is applied in concentric circles, initiating from the site of the proposed incision. Enough place has to be left in order to extend the incision if needed or to create new incisions or for the drain sites. Preparing the skin of the intended site, can be modified depending on the condition of the skin (e.g, burns) or location (e.g., face).

- PREOPERATIVE HAND AND FOREARM ANTISEPTICS: The surgical team personnel who have direct access to the sterile operating field or sterile instruments or supplies used in the field, should reduce microbial counts on their own skin. Surgical team members should perform a traditional procedure known as scrubbing (or surgical scrub) immediately before wearing sterile gowns and gloves. An ideal antiseptic used for the scrub should be fast acting, have a broad spectrum of activity, and have a persistent effect. The antiseptic agent used, the scrubbing technique, the time taken to scrub, hand hygiene and condition and the techniques used to dry the hands and wear gloves, have a bearing on the imposed risk of SSI on the patient. Arms and hands should be scrubbed for atleast 5 minutes before the first procedure of the day. And 2 –

3 minutes for subsequent procedures. Adding alcohol to chlorhexidine gluconate has a positive effect on reducing SSI's. A study showed that adding alcohol to chlorhexidine gluconate reduced SSI by >50 folds, when compared to only 3 fold improvement in use of povidone – iodine alone.

- ANTIMICROBIAL PROPHYLAXIS: Surgical antimicrobial prophylaxis (AMP) refers to a very brief course of an antimicrobial agent started just before a procedure begins. AMP is not a step to sterilize tissues, but a critically timed adjunct used to reduce the microbial burden of intra-operative contamination to a level that cannot overwhelm host defences. The time of infusion of the initial dose of antimicrobial agent should be such that, the concentration of the drug is maintained at therapeutic levels by incision time. The dose has to be repeated if required to maintain the therapeutic levels of the AMP throughout the procedure.

  The principles to maximize the benefits of AMP are:

- In all operations or classes of operations those AMP agent's have to be used that have a substantial evidence from the clinical trials.
- An AMP agent that is safe, not expensive, is bactericidal and covers the most probable widest sterile surgical area with broad spectrum of activity has to be used.
- The time at which the first dose of antimicrobial agent is initiated has to be noted so that the drug concentration in the body is optimum by time of incision.
- The therapeutic levels of the drug has to be constant in the tissues and blood, all through the procedure and atleast, a few hours after the procedure.

3. Intraoperative issues:

- OPERATING ROOM ENVIRONMENT:

(1) VENTILATION- Microbial laden dust, skin, lint, squames, or respiratory droplets may be seen in the operation theatre. The level of contamination in the operating room is directly related to the number of people moving around in the room. Thus, the number of people moving around in the operating room has to be minimized. Corridors and adjacent areas has to be maintained at a positive pressure, that prevents air flow from less clean areas into more clean areas.

Parameters for operating room ventilation (table ii)

Temperature	68-73 F, depending on normal ambient temperatures.
Relative Humidity	30%-60%
Air Movement	From "clean to less clean" areas
Air changes	Minimum 15 total air changes per hour Minimum 3 air changes of outdoor air per hour.

(2) ENVIRONMENTAL SURFACES: Although rarely implicated as causative agents in SSI, environmental surfaces (tables, floors, walls, ceilings, and lights) should be routinely cleansed to re-establish a clean environment after each operation. Medical equipment left in operating room should be covered so that solutions used during cleaning and disinfecting do not come in contact with sterile devices or equipments.

(3) MICROBIAL SAMPLING: No standardized parameters are being followed to compare microbial levels obtained from cultures of ambient air or environmental surfaces in the

operating room. Such sampling should only be performed as part of an epidemiological investigation. Both endogenous and exogenous organisms have a role in SSI. But it is the endogenous indwelling organisms in the skin that have an upper hand in SSI risk.

(4) STERILIZATION OF SURGICAL INSTRUMENTS:

Majority of SSI outbreaks is due to the inadequate sterilization of surgical instruments. Thus, proven methods of sterilization such as steam under pressure, dry heat, ethylene oxide have to be used depending on the instrument. The need arises in the midst of any procedure to sterilize the instrument instantly (e.g., to reprocess an inadvertently dropped instrument). This method is called the Flash Sterilization, and this cannot be recommended as a routine method.

(4) SURGICAL ATTIRE AND DRAPES: Surgical attire refers to scrub, suits, caps/hoods, shoe covers, masks, gloves and gowns.

i. Every person who enters the operating room should ensure that his/her mouth and the nose is covered fully with a surgical mask.

ii. Surgical cap, should be worn such that all the scalp hair is well covered.

iii. Use of sterile gloves after scrubbing and wearing a sterile gown.

iv. Surgical gowns and drapes should be water proof..

(5) SURGICAL TECHNIQUE: Excellent surgical techniques include:

i. Achieving complete haemostasis while blood supply is preserved.

ii. Preventing hypothermia.

iii. Handling the tissues gently.

iv. Removal of dead tissues (necrotic or charred).

v. Appropriate use of drains and suture materials.

vi. Incision care.

4. Operative characteristics:

- POST OPERATIVE ISSUES:

(1) INCISION CARE: The type of postoperative incision care depends on closing the wound in the same sitting or kept open to close later or kept open to facilitate drainage and heal by secondary intention. All patients prefer wound closure that has minimal scarring, but not all wounds are to be closed. A primarily closed incision is covered with a sterile dressing for 24 to 48 hours. Delayed primary closure of wounds and for those which are kept open to completely drain and heal by secondary intention have to be filled with a sterile gauze and covered with a sterile dressing. A prospective study (Cohn SM et al 2001)[49], revealed higher incidence of SSI's when contaminated abdominal surgeries were closed primarily, compared to 3 days packing and evaluating for the signs of SSI and then decide on closure.

(2) DISCHARGE PLANNING: The procedure decides the number of days a patient has to stay in the hospital . Many patients are to be discharged very soon after their operation, before surgical incisions have fully healed. The intent of discharge is to maintain integrity of the healing incision, tell the patient about the signs and symptoms of infection, and advise them to report any problems.

5. SSI SURVEILLANCE:

An important component of various strategies to reduce SSI risk is, surveillance of SSI with feedback of appropriate data to surgeons. The use of epidemiologically sound

infection definitions and effective surveillance methods, stratification of SSI rates according to risk factors associated with SSI development, and data feedback are the components of a successful surveillance program.

The proven and reliable predictors of SSI risk are:

1. the ones that estimate the intrinsic degree of microbial contamination of the surgical site.
2. the ones that measure the duration of the procedure.
3. those that are considered as markers for host susceptibility.

Over the past decade, the shift from inpatient to outpatient surgical care (day care surgery) has been dramatic. Every procedure has its own protocol but the types of operations performed, the risk factors assessed, and the surveillance methods used may differ.

Surgeons and the infection control personnel jointly decide, which procedure to monitor, which infection to report and how to address various issues. The available literature suggests that observing and assessing the surgical sites is the most accurate method to detect SSI's.

Various methods for the surveillance of SSI have been designed.

a. Inpatient SSI surveillance:

- direct observation of the surgical site by the surgeon, trained nurse or infection control personnel.

- indirect detection by infection control personnel through review of laboratory reports, patients records, and discussions with primary care providers.

b. Post discharge SSI surveillance:

- examining the patient's wounds directly during follow up visits.

- reviewing the medical records and the records of previous admission.

c. Outpatient SSI surveillance:

Both direct and indirect methods have been used to detect SSI's that complicate outpatient operations (day care surgery).

CLASSIFICATION OF WOUNDS:

In 1964, US National Research Council group, developed a classification, based on the depth or severity of contamination of the wound. For better understanding and for good results four classes of wounds have been described in increasing order of risk of SSI's: clean, clean contaminated, contaminated and dirty. This system of classification is being widely used to predict the rate of infection after surgery[50].

1. CLEAN WOUNDS: Seventy-five percent of all wounds (which are usually elective surgical incisions) fall into the clean wounds category—an uninfected operative wound in which no inflammation is encountered and the viscera are not entered. Strict aseptic precautions are being followed for these elective incisions to prevent infections.

   Inflammation is a natural entity of wound healing, every wound has to go through this phase in the process of healing. Rubor (redness), calor (increased heat), dolor (pain), tumor (swelling), loss of function are the basic signs of any inflammatory process. There is no similarity between inflammation and infection, the latter is an activity in which bacteria is present and produce damage. Clean wounds are closed primarily and usually use of drains is not advocated. Closing the wound primarily is the most desirable method of closure, using the simplest surgical procedures and the lowest risk of postoperative complications. Sutures are not removed until the wound tensile strength is sufficient so that sutures or other forms of tissue apposition are no longer needed. A common and routinely performed operation "hernia repair" is a very good example of a clean operative procedure. Clean operated wounds have a SSI rate of less than 2% .

2. CLEAN-CONTAMINATED WOUNDS*:* These are the procedures in which viscera is entered under controlled conditions and without much contamination. Specifically, procedures pertaining to the biliary tract, appendix, vagina, and oropharynx are included in this category provided no evidence of infection or major break in technique is encountered. Appendectomies, cholecystectomies, and hysterectomies fall into this category, as well as routinely clean wounds which become infected by entry into a viscus resulting in minimal spillage of contents. 3 - 11% of SSI are recorded in clean contaminated wounds.

3. CONTAMINATED WOUNDS*:* These include open, traumatic wounds or injuries such as soft tissue lacerations, open fractures, and penetrating wounds; operative procedures in which gross spillage from the gastrointestinal tract occurs; those procedures of the genitourinary and biliary tracts, in the presence of infected urine or bile; and procedures in which failure of asepsis has occurred (as in emergency open cardiac massage). Multiplication of microorganisms occurs so rapidly that within 6 hours a contaminated wound can become infected. Even with preventive antibiotics, infection rate is greater than 10% .

4. DIRTY AND INFECTED WOUNDS: These wounds have been heavily contaminated or clinically infected prior to the operation. They include perforated viscera, abscesses, or chronic wounds secondary to trauma in which dead and devitalized tissue or foreign material have been retained. Infective foci, present at the time of surgery can increase the infection rate of any wound by an average of four times. This signifies that, the

organisms causing postoperative infections were present in the operative field before the operation.

This traditional classification of wounds was initially used to predict the patient's probability of developing a SSI. However, one of this system's major problems is its failure to account for the intrinsic patient risk of developing an SSI.

MAJOR AND MINOR SSI:

A wound that either discharges significant quantities of pus spontaneously or needs a secondary procedure to drain it, is known as a major SSI. Patients are systemically ill, and have a delayed return home.

Discharge of pus or infected serous fluid is regarded as minor wound infections, but excessive discomfort, systemic signs or delay in return home should not be associated.

Differentiating between major and minor and defining the SSI's is important in audit or trials of antibiotic prophylaxis. The scoring systems for the severity of wound infection, are particularly useful in surveillance and research.

Southampton Wound Grading System: (table iii)

GRADE	APPEARANCE
0	Normal healing.
1	Normal healing with erythema and/or bruises
2	Erythema and other signs of inflammation.
3	Discharge from the wound (clear or serous)
4	Pus discharge
5	Deep or severe wound infection with or without tissue breakdown; hematoma requiring aspiration.

In 1992, the US Centers for Disease Control (CDC) renamed 'wound infection', as 'surgical site infection' (SSI) to prevent confusion between the infection at the surgical site 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.

The USA Centres for Disease Control (CDC) states that only infections occurring within 1 month of surgery or within one year, if an implant or a foreign material (mesh, vascular graft, prosthetic joint and so on) is used should be classified as a Surgical Site Infection.
Factors that predict the wound infection are :

1) Host response.
2) Virulence and inoculum of infective agent.
3) Vascularity and health of the tissue being invaded (including local ischaemia and systemic shock).
4) Presence of dead, devitalized or foreign tissue.
5) Presence of antibiotics during the ‘decisive period’.

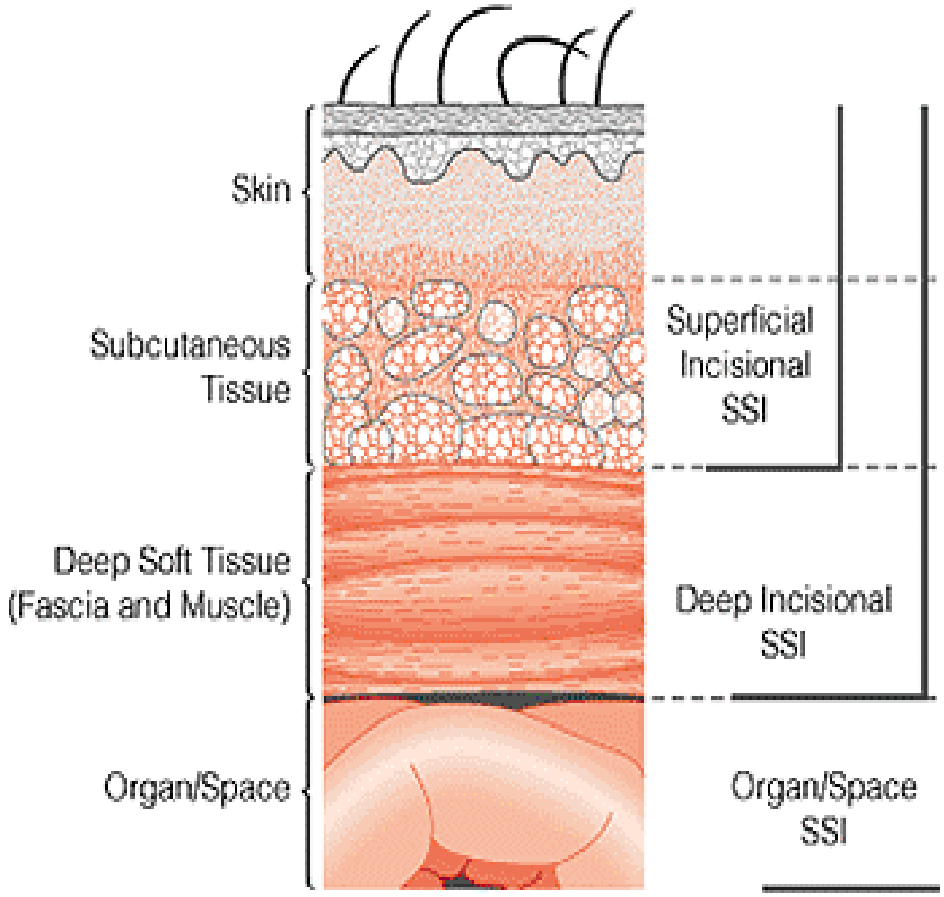
Decisive Period: the acute inflammatory, humoral and cellular defences take up to 4 hours to be mobilized. This is called the decisive period, and this is the time when the invading bacteria may become established in the tissues. Strategies aimed at preventing infection from taking a hold, become ineffective after this time period. It is hence proved, that the use of antibiotics prophylactically is necessary to cover this period and they could be decisive in preventing an infection from developing. The antibiotic levels in the tissue should be above the minimum inhibitory concentration (MIC 90) for pathogens likely to be encountered.

SSI's are studied in three groups.

1. Superficial SSI

2. Deep SSI

3. Organ Space SSI



Superficial or Incisional infections are the most common, accounting for 60% to 80% of all SSIs and the prognosis is better than what organ/space-related SSIs do, with the latter accounting for 93% of SSI related mortalities.

Superficial Incisional SSI

To diagnose a Superficial SSI the following two criteria must be met:

1. The infection must occur within 30 days of the procedure.

2. The infection must involve only the skin and subcutaneous tissue around the

Incision.

PLUS

Atleast one of the following criteria:

1. Purulent draining from the incision with or without diagnostic laboratory testing (culture).
2. Organisms isolated from an aseptically obtained culture of fluid / tissue fromthe incision
3. Either one of the following signs or symptoms of infection

a. Pain or tenderness at the incision site.

b. Edema.

c. Erythema or increased temperature.

4. Superficial incisional SSI diagnosed by a surgeon or attending physician.

The following are NOT considered Superficial SSI:

1. Stitch abscess (minimal inflammation and discharge confined to points of suture penetration).
2. Infection of an episiotomy site or neonatal circumcision site.
3. Infected burns.
4. Incisional SSI that extends into fascial and muscle layers (which are Deep SSI)
5. A localized stab wound or pin site infection. Such an infection can be considered as, skin or soft tissue infection, depending on its depth, but not an SSI.

Two specific types of Superficial incisional SSI's are being studies :

1. Superficial Incisional Primary – SSI noted in a primary incision in a patient. (for example, C-section incision or chest incision for CBGB)

2. Superficial Incisional Secondary – SSI noted in a secondary incision. (for example, donor site incision for CBGB).

Note: specific criteria are used to identify infected episiotomy and circumcision sites and burn wounds.

Deep Incisional SSI:

Those infections occuring within 30 days after the surgery without implant or
Within 1 year if implant is used and the infection appears to be related to the
Surgical procedure.

And

Infection involves deep soft tissues (eg: fascial and muscle layers) of the incision

And

Atleast one of the following:

1. Pus draining from the deep incision but not from the organ / space of the site.

2. Spontaneous dehiscence or deliberate opening by the surgeon from the deep incision when the patient has atleast one of the following signs or symptoms

a. Fever >38 C / 100.4 F

b. Localized pain or tenderness

UNLESS THE INCISION IS CULTURE NEGATIVE

3. Abscess or other evidence of infection involving the deep incision is found either on direct examination, or during re-operation, or by histopathology or radiological examination.

4. Deep incisional SSI diagnosed by a surgeon or attending physician.

Two specific types of Deep Incisional SSI.s are being studied :

1. Deep Incisional Primary – SSI noted in a primary incision, in a patient who has undergone a procedure before, with one or may incisions. (for example, C-section incision or chest incision for CBGB).
2. Deep Incisional Secondary - SSI noted in a secondary incision, in a patient who has undergone a procedure before, with one or may incisions. (for example, donor site incision for CBGB).

Note:

If both superficial and deep layers are involved, or if organ/space SSI drains through incision, classification will be deep incisional SSI.

Report an organ / space SSI that drains through the incision as deep incisional SSI .

Organ / Space SSI:

Infections occuring within 30 days after the surgery if no implant is used or within 1 year if implant is used and the infection appears to be directly related to the surgical procedure.

And

Infection involving any part of the anatomy (eg: organs or spaces), except the incision, which facilitated direct access during an operation.

And

Atleast one of the following:

1. Pus draining from a drain that is placed through a stab wound into the Organ/space (infection of drain site is not SSI).

2. The growth of organisms from an aseptically obtained culture of fluid or tissue in the organ/space.

3. Evidence of infection involving the organ / space that is found on direct examination , during reoperation, or by histopathologic or radiologic examination.

4. Organ / space SSI diagnosed by a surgeon or attending physician[51].

Sutures and SSI

Mary Ayton described wound infection as the deposition and multiplication of bacteria in tissue, with an associated host reaction[52]. This definition has remained unchanged since 1985.

The mere presence of bacteria in a wound is known as wound contamination, and it does not mean that wound will get infected. The risk of SSI markedly increases if a surgical site is contaminated with $>10^5$ microorganisms per gram of tissue[53]. ELEK and CONEN in their human experiments demonstrated that the concentration of microorganisms drastically reduces to as less as 100 cocci, when another foreign body such as a suture material is found in the same wound. Persistent skin antisepsis, meticulous operative technique, appropriate antimicrobial prophylaxis, and identification of strategies for decreasing wound contamination are effective and important for decreasing the risk of SSI[54].

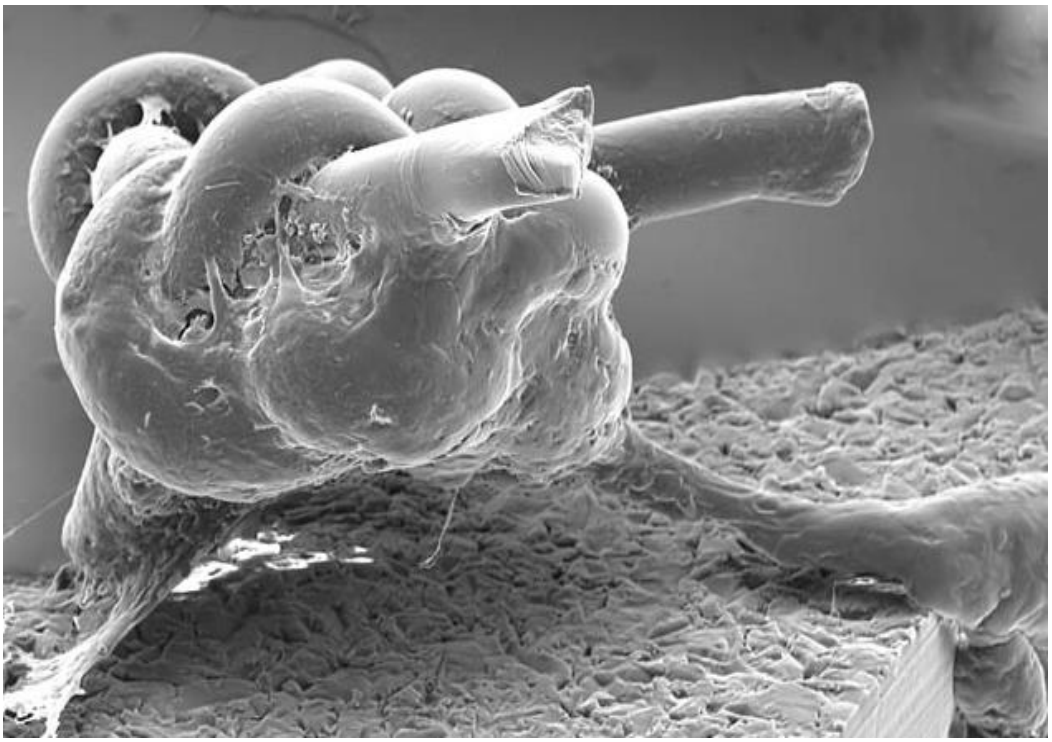
Foreign material in a wound enhances the susceptibility of surrounding tissues to infection. Sutures can also initiate infection in wounds, by the following mechanisms :

- Tissue damage by the needle evokes a significant inflammatory response.
- Surgeon's method of handling tissues.
- Sutures tied too tightly around the wound edges.

- The physical and chemical structure of the suture, are the factors that may play a role in development of wound infection[6-8].

Not only the surgical wound, but the actual suture may also be contaminated by various bacteria. Once the suture material itself is contaminated, the local mechanisms to decontaminate the wound are no longer effective. As less as 100 colony forming units (CFU)/mg are enough to contaminate a suture. Thus, sutures set up an environment in which less numbers of bacteria proliferate while sequestered from host defenses.

Like most other implants, sutures have no shedding surface to which bacteria can adhere, form biofilms and potentiate SSI's. be it natural or synthetic composition, mono or multi filament construction, any suture product is susceptible to bacterial attachment and colonisation[6-8].



'Biofilms' are ubiquitous and form whenever micro-organisms such as bacteria, yeasts, algae, fungi or protozoa attach to a surface. The free living bacteria, once attached, undergo a phenotypic change and, within minutes, deposit 'slime' : extracellular polymeric material (EPS) or biofilms matrix[55]. Biofilm formation around suture materials protects micro-organisms from host defence, interterfering with the normal healing, potentially resulting in complications. Laboratory susceptibility tests, do not identify this bacteria and even sensitivity to antibiotics is not shown, thus making it impossible to treat a biofilm. Once a biofilm infection is established on an implant, it usually needs removal and antibiotic treatment.

Antibacterial coated surgical sutures:

Assisting one's own host defenses, taking precautions against and treatment of surgical sepsis, anti-microbial surgical sutures can be of great use. The antibiotics settled in the structure of antimicrobial surgical sutures provide the wound with antibiotics for a long period. This has been done by biologically activating surgical sutures by fixing the appropriate drugs onto them by means of chemical bonds. Simultaneously, chemical bonds allow varying magnitudes and durations of biological action[9,56].

One such novel antimicrobial suture is the Triclosan coated polyglactin 910.

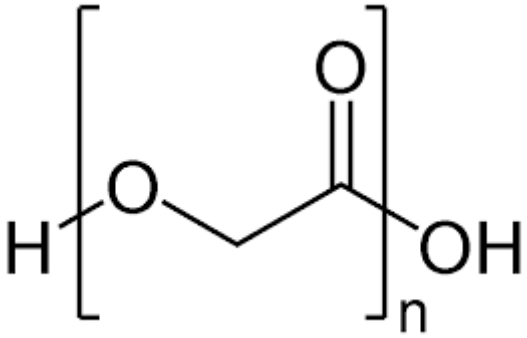
Triclosan coated polyglactin 910 suture material:

Polyglycolic acid suture material has been a surgeons favourite, since it's invention in the 1970's by Davis and Geck. Till its invention all the surgeons were using catgut suture, due to its different properties. Though not significant but it used to cause

irritant reactions in patients. PGA has reduced the dependence of a surgeon on catgut sutures.

PGA is sensitive to hydrogenolysis compared to other synthetic polymers, and this is the only little use known since 1954.

Among the elderly, anemic and malnourished patients, suture absorption occurs quickly. It either has a violet colour or remains undyed and it is sold in sizes USP 6-0 (1 metric) to USP 2 (5 metric). Very high initial tensile strength, smooth passage through tissue, easy handling, excellent knotting ability, and secure knot tying is an added advantage. It is commonly used for apposition of subcutaneous tissue, intra-cutaneous closures, abdominal and thoracic surgeries[57,58].



Polyglycolide

Triclosan: safety, Biocompatibility and Pharmacokinetics

Triclosan is a stable, synthetic, polychlorinated, aromatic hydrocarbon with broad, anti-microbial properties. It is lipophilic and active within a broad pH range. Before it is absorbed into the blood stream and widely distributed, triclosan passively dissipates from implanted sutures to the surrounding tissues, but not confined to any particular tissue or organ system. Maximum and rapid metabolism of triclosan takes place in the liver, by phase II metabolism to glucuronide and sulphate conjugates with an elimination half life of 13 hours after a single oral exposure. Therefore triclosan is cleared from the blood

stream in approximately 3.8 days. Conjugated triclosan is readily water soluble and is excreted from the body by the kidneys. There is no evidence that triclosan accumulates in the body over time and this pharmacokinetic profile makes it suitable for clinical use.

Some intravenous studies have been conducted to determine absolute bioavailability. Intravenous exposure by-passes the possibility of first pass metabolism and is considered to represent the worst case of what would happen after implantation of a suture. Overall, the similar metabolism of triclosan after intravenous exposure allows for the use of the extensive safety database available after oral exposure to support the safety of Vicryl plus.

SAFETY OF TRICLOSAN COATED OR TRICLOSAN IMPREGNATED SUTURES

1. Assessment of patient exposure

For triclosan coated suture, 69% of the triclosan content dissipates in the first 24 hours after implantation, with 99% dissipation by 36 days.

2. Potential for systemic toxicity

The maximal single day exposure to triclosan was calculated to be 0.03, 0.08 and 0.09 mg/kg body weight, respectively. When compared to the widespread use of triclosan containing oral and topical personal care products, the contribution of a maximal daily exposure to triclosan from vicryl plus is only 12% of daily background exposure.

3. Local irritant potential

Intramuscularly implanted plus sutures were comparable with sutures not containing triclosan based on the properties tissue reaction, absorption profile and impact on wound healing at the implantation site.

4. Impact on Wound Healing

Segments of plus sutures placed in experimental incisional skin wounds caused no adverse cosmetic effects or changes in multi-axial biomechanical wound strength over time.

5. Impact on reduction of infection

Coating sutures with triclosan was an effective strategy for reducing SSI's. Certain inevitable factors like, contamination of suture itself in a surgical wound, increases the probability of developing SSI. .

(table iv)

	% Dissipation in first 24 hours	**Days until 99% dissipated**
Vicryl plus	69	36
Monocryl plus	41	36
PDS plus	46	19

TRICLOSAN IN MEDICAL PRODUCTS

Triclosan is present in a broad range of consumer products. It has many medical uses including use in alcohol based scrubs, rubs and skin antiseptics; in ointments; and impregnated/coated in catheters and surgical sutures.

Biofilm formation around suture materials protects micro-organisms from host defence mechanisms and these infected sutures induce and maintain an inflammatory reaction, interfering with the normal healing process, potentially resulting in complications.

TRICLOSAN AND THE RISK OF RESISTANCE

Bacteria have evolved to survive natural and man-made stress phenomena, but there is no adverse effects of resistance caused by triclosan in the environment. There is apparently a disparity between what can be shown in laboratory studies and what happens in the real world environment for this molecule.

The term insusceptibility simply means, resistance that results because of innate/inbuilt physiological properties of a bacterium. Insusceptibility has been noted to some antiseptics and is based on alterations in bacterial physiology. There is no evidence that resistance once developed can be reversed. The term 'Resistance' means, the ability of a microorganism to withstand the effects of an antimicrobial agent. Microorganisms acquire resistance through evolution and adaptation.

Cross resistance (where exposure to an antiseptic causes antibiotic resistance) has also not been conclusively shown for triclosan in the clinical or other environments. The widely accepted and unambiguous cause of antibiotic resistance is the use and misuse of antibiotics.

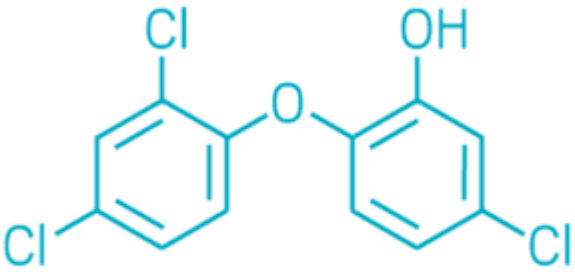
Antibiotics often target single or limited number of microorganisms, when it comes to pharmacological aspects. Where as, antiseptics have multiple targets based on the concentration. True antiseptic resistance is not frequently encountered and outcome altering changes in susceptibility are uncommon.

Antibiotic resistance refers to, a change from a susceptible phenotype to a less susceptible phenotype which results in clinical, therapeutic failure.

(table v)

Days Implantation	Approximate % original strength remaining
14 days	75
21 days	50
28 days	25

This suture elicits a minimal acute inflammatory reaction in tissue and ingrowth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption occurs by means of hydrolysis, where the copolymer degrades to glycolic acid and lactic acids, which are subsequently metabolized and absorbed in the body. Absorption starts as a loss of tensile strength followed by loss of mass.



Triclosan

TRICLOSAN- MECHANISM OF ACTION AND ANTIBACTERIAL PROFILE

It acts as a biocide, with multiple cytoplasmic and membrane targets. At lower concentrations, however, triclosan is bacteriostatic. It tackles the infection by targeting the bacteria mainly by inhibiting fatty acid synthesis. Triclosan inhibits FabI gene which encodes the enoyl-acyl carrier protein reductase enzyme (ENR).

Triclosan binds to bacterial enoyl-acyl-carrier protein reductase enzyme (ENR) which increases the enzyme's affinity for NAD+ resulting in the formation of a stable tertiary complex of **ENR-NAD-TRICLOSAN** which is unable to participate in fatty acid synthesis and thus, cell membranes can't be produced effectively. Triclosan disrupts the cell membrane and causes the cell contents to leak. Since humans don't have the ENR enzyme, they are not affected[59-61].

It was proved that treating polyglactin910 with triclosan was an effective strategy in decreasing SSI by proving decreased adherence of both Gram positive and Gram negative bacteria to Triclosan coated suture material.

The addition of Triclosan to polyglactin910 suture does not affect the physical handling properties or performance characteristics like the ease of passage through tissues, first throw knot holding, knot security and so on (physical and functional comparison of coated polyglactin910 and antibacterial suture-surgical infections[62,63].

The use of Triclosan coated polyglactin910 in subcutaneous closure, by inhibiting bacterial colonization of the suture decreased pain, which can be used as an indicator of subclinical infection.

At high concentrations triclosan appears to interact with multiple cytoplasmic and membrane targets. It enters cells through membranes / porins and can disrupt the cell

membranes (both the outer and inner cell membranes of gram negative cells) causing cell contents to leak. Once inside the cell triclosan may interact with the cytoplasmic components, and with the ENR[64,65].

Some bacteria have innate resistance to triclosan, such as pseudomonas aeruginosa which possesses multiple drug efflux pumps that remove triclosan from the cell, along with different versions of the ENR. Other gram negative organisms like E.coli remain susceptible to triclosan.

In short, acquired high level triclosan resistance is probably not a widespread phenomenon[66].

In terms of cross resistance, the proven cause of antibiotic resistance is antibiotic use and abuse. There is little or no evidence of antiseptic resistance or cross resistance.

INITIATIVES THAT HAVE BEEN PROMOTED AS A MEANS OF REDUCING SURGICAL SITE INFECTIONS :

Due to the deleterious effects on the patient, caregiver and institution involved in the patient care, numerous health care and regulatory organizations have launched large scale efforts aimed to impact the occurrence of SSI's. most have included various basic practices that institutions already widely utilize, while others have recommended the adoption of specialized approaches for when basic practices have not been sufficient in controlling SSI's[68].

From improving control of the physical care of the patient to information gathering efforts such as broader reporting, a lot of initiatives have been taken.

A. National Health Care Safety Network (NHSN) – a voluntary internet based surveillance system that gathers patient and health care providers. Data is collected from allover through the participating health care facilities. The NHSN conducts

research to gather information about the epidemiology of nosocomial infections, assess risk factors, evaluate preventive techniques.

B. Guidance on Public Reporting of HealthCare Associated Infections – the CDC's Health Care Infection Control Practices Advisory Committee (HICPAC) has an established guidelines to report healthcare associated infections. The HICPAC guidelines consider using outcome measures of surgical antimicrobial prophylaxis and SSI's .

C. AORN Perioperative Standards and Recommended practices – The Association of Operating Room of Nurses, has annually published guidelines, that includes recommendations on skin preparation procedures to reduce damage to tissues and decrease SSI.

- Thorough cleansing of the surgical site.
- Inspecting and assessing the surgical site with documentation if necessary.
- Trying to leave hair intact at the surgical site where ever possible to reduce skin damage.
- An antiseptic application to close vicinity of the surgical site as well.
- All measures to preserve skin integrity and prevent injury.

D. Institute for Healthcare Improvement 5 Million Lives Campaign -

This campaign was in effect between December 2006 – December 2008. To improve the healthcare quality, by protecting patients from 5 million incidents of medical harm.

- Judicious use of prophylactic antibiotics.
- Appropriate hair removal
- 6 a.m , controlled monitoring of serum glucose in cardiac surgery patients.
- Immediate postoperative normothermia for colorectal surgery patients.

"Bundles" are quite often used, which means packed group of interventions adopted to address patient risk factors systematically, and plan multitask prevention at different stages of patient care[69].

KEY PRINCIPLES FOR PREVENTION OF SURGICAL SITE INFECTIONS

A. Preoperative :

stop tobacco usage 30 days prior to the procedure.

Antimicrobial Prophylaxis :

- Administer minimum 30 – 60 minutes before the incision.
- Repeat if the surgery is delayed.
- Maintain at threshold levels all through procedure.
- To not discontinue more than 24 hours after the end of surgery.
- Preoperative showering with 4% chlorhexidine gluconate.
- Hair clipping instead of shaving.
- Preoperative use of broad spectrum antiseptics.
- Preoperative correct method and duration of scrubbing of arma and hands.

B. Perioperative :

- Prevent intraoperative hypothermia.
- HbA1c <7%
- Supplementing oxygen to avoid perioperative hyperoxia.
- Pack the wounds left open and weigh the possibilities of SSI.

If prevention of SSI's is not taken seriously -

Patients with SSI, are 2 times likely to die, 60% chances of ICU admission, 5 times likely to have a readmission, prolong hospital stay by 7-10 days, and add over to the cost of healthcare services.

MATERIALS & METHODOLOGY

MATERIALS AND METHODOLOGY

This prospective observational comparative study included 146 patients who underwent elective surgeries for clean wounds, in Sri Devaraj Urs Medical College Hospital, Tamaka, Kolar, between December 2016 and June 2018 satisfying all the inclusion criteria mentioned below. Clearance from the institutional ethics committee was obtained before initiating the study.

The Inclusion criteria were:

1) AGE GROUP-all patients in between 15-60 years of age.

2) **GENDER**- both male and female.

3) All patients undergoing surgeries for Clean Surgical Wounds like-

a. Uncomplicated inguinal and femoral hernia.

b. Elective Breast surgeries (Excision of Fibroadenoma).

c. Lipoma Excision.

d. Ventral Hernia.

e. Umbilical Hernia.

f. Thyroid Surgeries (for benign conditions).

g. Parotid Surgeries.

The Exclusion criteria were:

1). Patients with Clean Contaminated Wounds.

2). Patients with Contaminated Wounds.

3) Immuno-compromised individuals (diabetics, HIV, bleeding disorder, patients on steroid and immunosuppressive therapy.).

4). Gynecological Surgeries.

5). Patients with pre-existing SSI.

1). The pre-operative data collected will include the patient's demographics, co-morbidities, Elective& emergency indication, setting (emergency/elective) and class of wound. Intra-operative data will include the duration of the surgery, method of painting and draping, antibiotics received before and during surgery, intra-operative findings which will help in classifying the wound (eg: biliary contamination).

Post-operative data include development of SSI as per the standardized means of detecting and diagnosing surgical site infections, and how many days after the elective surgery was SSI noted.

2). The study planned is a Prospective Study. Division of all individuals admitted in General Surgical units will be into two groups

Group 1: 73 patients undergoing surgery will have closure of subcutaneous layer with coated polyglactin 910 with Triclosan.

Group 2: And the other 73will have closure of subcutaneous layer with coated polyglactin 910 without Triclosan. Post operatively the wound will be assessed using Southampton Wound Scoring System on post-operative day three, five, seven and ten as follows=

Grade 1- Normal Healing with mild bruising and Erythema.

Grade II- Erythema and signs of Inflammation.

Grade III- Clear or Homologous Discharge.

Grade IV- Pus discharge.

Grade V- Deep or Severe Wound Infection**.**

3). The SSI rates will be reported as percentages within each group and compared between the groups using student t-test for proportion. The time frame between surgery and development of SSI will be summarized as mean and standard deviation. Between the study and the control groups this data will be compared using independent sample t-test, if the data is normally distributed.

4). In the post-operative period, pain of the patient will be assessed based on the Visual Analog Scale, and categorized as mild, moderate and severe.

All tests with p</=0.05 level of significance, will be considered statistically significant.

All patients received similar standards of care in the operating room, with regards to pre-operative shaving, pre-operative skin preparation, intra-operative antimicrobial prophylaxis, use of sterile drapes, masks, gowns and gloves.

All the wounds were inspected every day from the third post-operative day onwards till the day of discharge and from then on, on weekly out-patient visits till 30 days after the date of surgery.

The CDC criteria for defining a superficial incisional surgical site infection was followed:

1.The infection must occur within 30 days of the procedure.

2.The infection must involve only the skin and subcutaneous tissue around the incision.

PLUS

Atleast one of the following criteria:

1. Pus draining from the incision with or without diagnostic laboratory testing (culture).

2. Growth of organisms from an aseptically obtained culture of fluid / tissue from the incision

3. Either one of the following signs or symptoms of infection

a. Pain or tenderness at the incision site.

b. Edema.

c. Erythema or increased temperature.

4. Superficial incisional SSI diagnosed by a surgeon or attending physician.

The following are NOT considered Superficial SSI:

1.Stitch abscess (minimal inflammation and discharge confined to points of suture penetration).

2.Infection of an episiotomy site or neonatal circumcision site.

3.Infected burns.

4.Incisional SSI that extends into fascial and muscle layers (which are Deep SSI).

Note: specific criteria are used to identify infected episiotomy and circumcision sites and burn wounds.

The following data was obtained

Patient demographics:

Age of the patient

Sex of the patient

Weight of the patient

Comorbidities of the patients:

Diabetes

Hypertension

Anaemia

Systemic steroid requirement

Nicotine abuse

Previous surgeries

Alcohol abuse

General physical examination:

Built of the patient

Nourishment of the patient

Pallor/icterus/cyanosis/clubbing/lymphadenopathy/edema

Diagnosis

Indication for surgery

Elective/Emergency

Perioperative transfusion of blood/blood products.

Pre operative antibiotic administration.

Intra-operative findings

Class of wound

Which postoperative day was the infection noted.

The results obtained were evaluated and tabulated statistically. The main parameters analyzed were:

- The incidence of superficial SSI in each group.
- The time period between date of surgery and diagnosis of a superficial SSI.
- To assess the length of hospital stay in both the groups.

Statistical Methods:

$$\text{Sample size} = \frac{r+1}{r}\frac{(p^*)(1-p^*)(Z_\beta + Z_{\alpha/2})^2}{(p_1 - p_2)^2}$$

r = Ratio of control to cases, 1 for equal number of case and control
p^* = Average proportion exposed = proportion of exposed cases + proportion of control exposed/2
Z_β = Standard normal variate for power = for 80% power it is 0.84 and for 90% value is 1.28. Researcher has to select power for the study.
$Z_{\alpha/2}$ = Standard normal variate for level of significance as mentioned in previous section.
$p_1 - p_2$ = Effect size or different in proportion expected based on previous studies. p_1 is proportion in cases and p_2 is proportion in control.

The Sample Size was estimated based on the difference in proportion of SSI between two groups. By using the formula at 95% confidence levels and 80% power a sample size of 73 was obtained in each group. Hence a total of 146 cases were included in the study.

Collected data was coded and entered in to an excel format. All quantitative measures were presented by Mean and standard deviation. Qualitative variables were presented by Proportions and confidence intervals. Significance of the difference between two groups was compared by using Student t test and Chi-square test. P value less than or equal to 0.05 was considered as statistically significant.

Randomization followed was **Block Randomization.**

The subjects were divided into subgroups called blocks, such that the variability within the blocks is less than the variability between blocks. Then, subjects within each block were randomly assigned to treatment conditions.

This technique is applied selecting a block size of 4 (totally 6 blocks of size 4). Each time a block is randomly selected and accordingly.

References for statistics:

1. Gaddis, ML, Gaddis, GM. Introduction to biostatistics: Part 4, Statistical inference techniques in hypothesis testing. *Ann Emerg Med*. 1990;19:820–825.
2. Patra P. Sample size in clinical research, the number we need. Int J Med Sci Public Health. 2012;1:5–9.
3. Sunder Rao P S S , Richard J (2006) : An Introduction to Biostatistics, A manual for students in health sciences , New Delhi: Prentice hall of India. 4th edition, 86-160.
4. Elenbaas, RM, Elenbaas, JK, Cuddy, PG. Evaluating the medical literature, part II: Statistical analysis.*Ann Emerg Med*. 1983;12:610–620.

Statistical analysis:

Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions. **Chi-square test** was used as test of significance for qualitative data. Continuous data was represented as mean and SD. **Independent t test or Mann Whitney U test** was used as test of significance to identify the mean difference between two quantitative variables and qualitative variables respectively.

Graphical representation of data: MS Excel and MS word was used to obtain various types of graphs such as bar diagram, Pie diagram and Scatter plots.

p value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

Statistical software: MS Excel**,** SPSS version 22 **(**IBM SPSS Statistics, Somers NY, USA) was used to analyze data..

RESULTS

OBSERVATION AND RESULTS:

Table 1: Age distribution:

		Group			
		Group A		Group B	
		Count	%	Count	%
Age	<30 years	12	16.4%	16	21.9%
	31 to 40 years	14	19.2%	15	20.5%
	41 to 50 years	14	19.2%	15	20.5%
	51 to 60 years	33	45.2%	27	37.0%

$\chi 2 = 1.24$, df = 3, p = 0.743

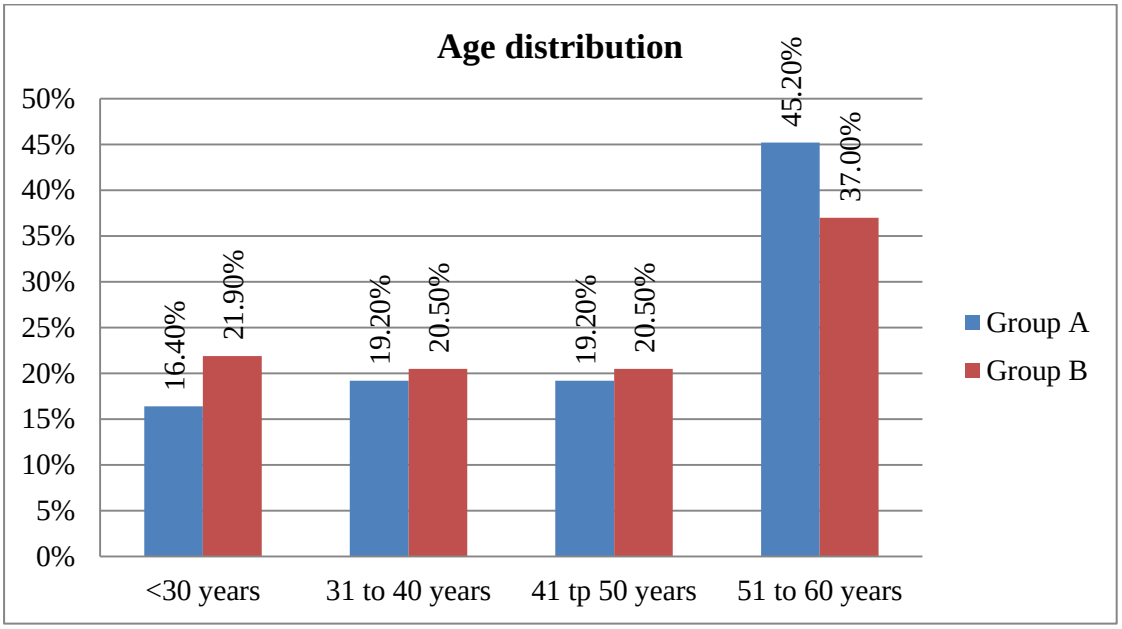


Figure 1: Bar diagram showing Age distribution between two groups

In Group A, majority of the patients were in the age group 51 to 60 years (45.2%). In Group B, majority were in the age group 51 to 60 years (37%). Thus, making this the vulnerable age group in this study. There was no difference in age distribution between two groups.

Table 2: Mean age distribution:

		Age		P value
		Mean	SD	
Group	Group A	45.89	12.12	0.333
	Group B	43.93	12.22	

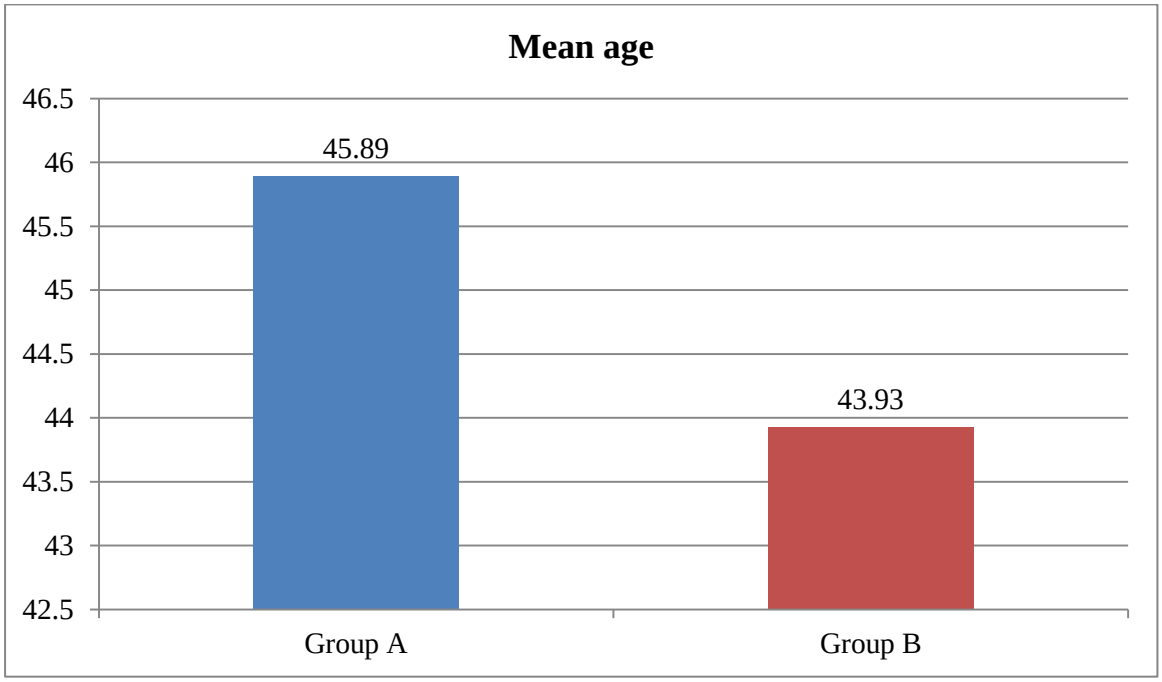


Figure 2: Bar diagram showing Mean age distribution between two groups

In Group A, mean age was 45.89 ± 12.12 years and in Group B was 43.93 ± 12.22. There was no difference in mean age between two groups. Patients are age matched with p=0.333.

Table 3: Gender distribution:

		Group			
		Group A		Group B	
		Count	%	Count	%
Gender	Female	28	38.4%	28	38.4%
	Male	45	61.6%	45	61.6%

χ 2 = 0.000, df = 1, p = 1.000

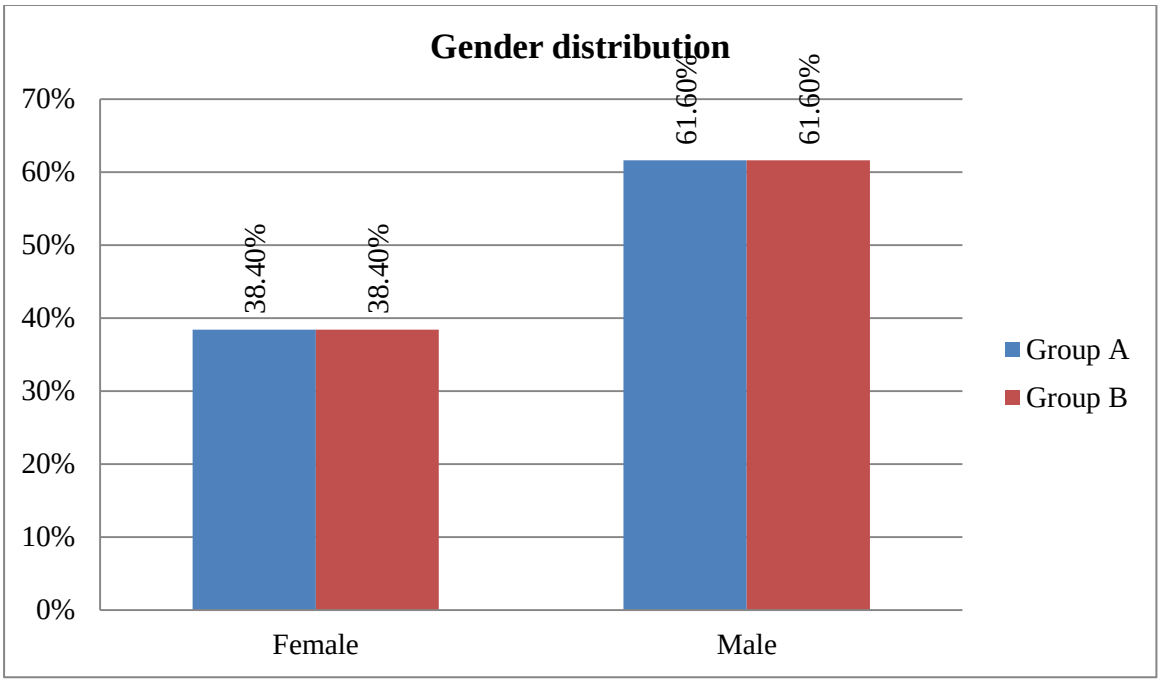


Figure 3: Bar diagram showing Gender distribution between two groups

In this study majority studied were males. In Group A, 38.4% were females and 61.6% were males. In Group B, 38.4% were females and 61.6% were males. There was no difference in gender distribution between two groups.

Table 4: Shows Distribution of patients in each group w.r.t their diagnosis:

		Group			
		Group A		Group B	
		Count	%	Count	%
Diagnosis	Inguinal Hernia	39	53.4%	31	42.5%
	Umbilical Hernia	10	13.7%	19	26.0%
	Incisional Hernia	8	11.0%	8	11.0%
	Epigastric Hernia	1	1.4%	4	5.5%
	Other Hernias	2	2.7%	1	1.4%
	Fibroadenoma	5	6.8%	4	5.5%
	MNG	5	6.8%	5	6.8%
	Lipoma	3	4.1%	1	1.4%

$\chi 2 = 6.952$, df = 7 , p = 0.434

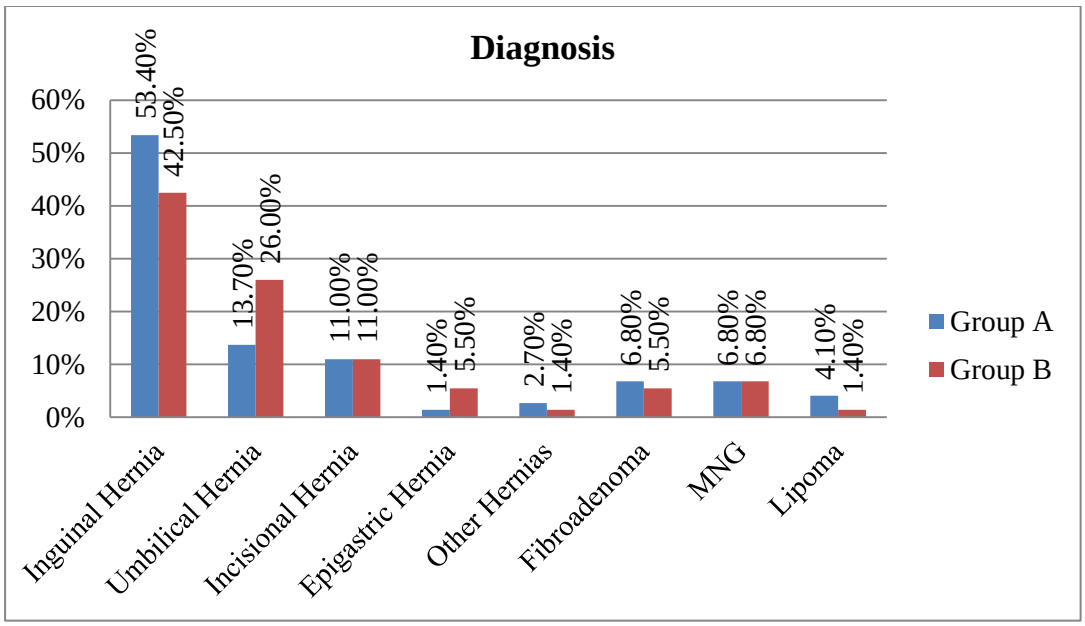


Figure 4: Bar diagram showing the distribution of patients w.r.t their diagnosis.

All patients undergoing surgeries for clean surgical wounds were included in this study. In Group A and Group B majority (n=70) were the patients who underwent surgeries for Inguinal Hernia followed by Umbilical Hernia, Incisional Hernia, MNG, Fibroadenoma, lipoma, Para-umbilical hernia, Femoral hernia and Epigastric hernia in decreasing order.

Table 5: Comparing the Incidence of SSI w.r.t the diagnosis in Group A:

		Post Op Wound			
		Clean Wound		SSI	
		Count	%	Count	%
Diagnosis	Inguinal Hernia	37	53.6%	2	50.0%
	Umbilical Hernia	10	14.5%	0	0.0%
	Incisional Hernia	7	10.1%	1	25.0%
	Epigastric Hernia	1	1.4%	0	0.0%
	Other Hernias	2	2.9%	0	0.0%
	Fibroadenoma	5	7.2%	0	0.0%
	MNG	4	5.8%	1	25.0%
	Lipoma	3	4.3%	0	0.0%
a. Group = Group A					

$\chi 2 = 4.024$, df = 7 , p = 0.777

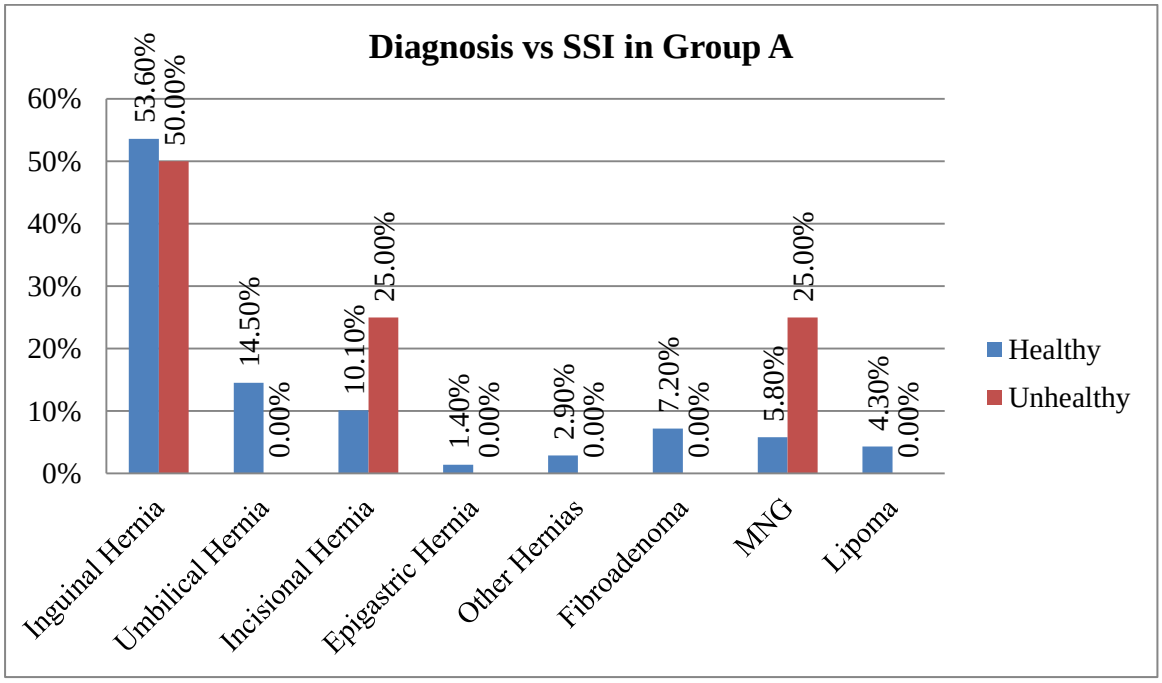


Figure 5: Bar diagram comparing the incidence of SSI w.r.t the diagnosis in Group A

In group A/ study group, of the 39 patients who were operated for Inguinal hernia, 2 patients (50.0%) developed SSI, of the 8 patients operated for Incisional hernia, 1 patient

(25%) developed SSI and of the 5 patients operated for MNG, 1 patient (25%) developed SSI. So, a total of 4 patients developed SSI among the 73 patients included in the study group.

Table 6: Comparing the incidence of SSI w.r.t the diagnosis in Group B:

		Post Op Wound			
		Clean Wound		SSI	
		Count	%	Count	%
Diagnosis	Inguinal Hernia	29	43.9%	2	28.6%
	Umbilical Hernia	16	24.2%	3	42.9%
	Incisional Hernia	8	12.1%	0	0.0%
	Epigastric Hernia	4	6.1%	0	0.0%
	Other Hernias	1	1.5%	0	0.0%
	Fibroadenoma	4	6.1%	0	0.0%
	MNG	3	4.5%	2	28.6%
	Lipoma	1	1.5%	0	0.0%
a. Group = Group B					

$\chi 2 = 8.43$, df = 7 , p = 0.296

In group B/ control group, of the 31 patients who were operated for Inguinal hernia, 2 patients (28.6%) developed SSI, of the 16 patients operated for Umbilical hernia, 3 patients (42.9%) developed SSI and of the 5 patients operated for MNG, 2 patients (28.6%) developed SSI. So, a total of 7 patients developed SSI among the 73 patients included in the control group.

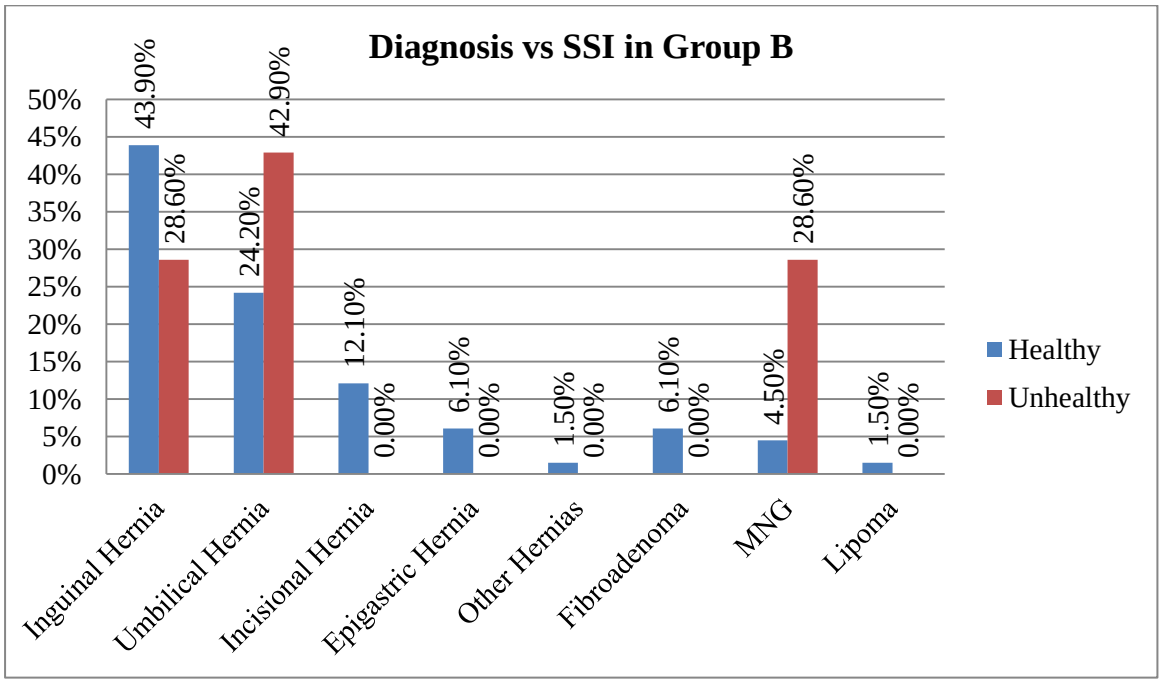


Figure 6: Bar diagram comparing the incidence of SSI w.r.t the diagnosis in Group B

Table 7: Association of Age with SSI in Group A:

		Age							
		<30 years		31 to 40 years		41 to 50 years		51 to 60 years	
		Count	%	Count	%	Count	%	Count	%
Post Op Wound	Clean Wound	12	100.0%	14	100.0%	12	85.7%	31	93.9%
	SSI	0	0.0%	0	0.0%	2	14.3%	2	6.1%
a. Group = Group A									

$\chi 2 = 3.625$, df = 3, p = 0.305

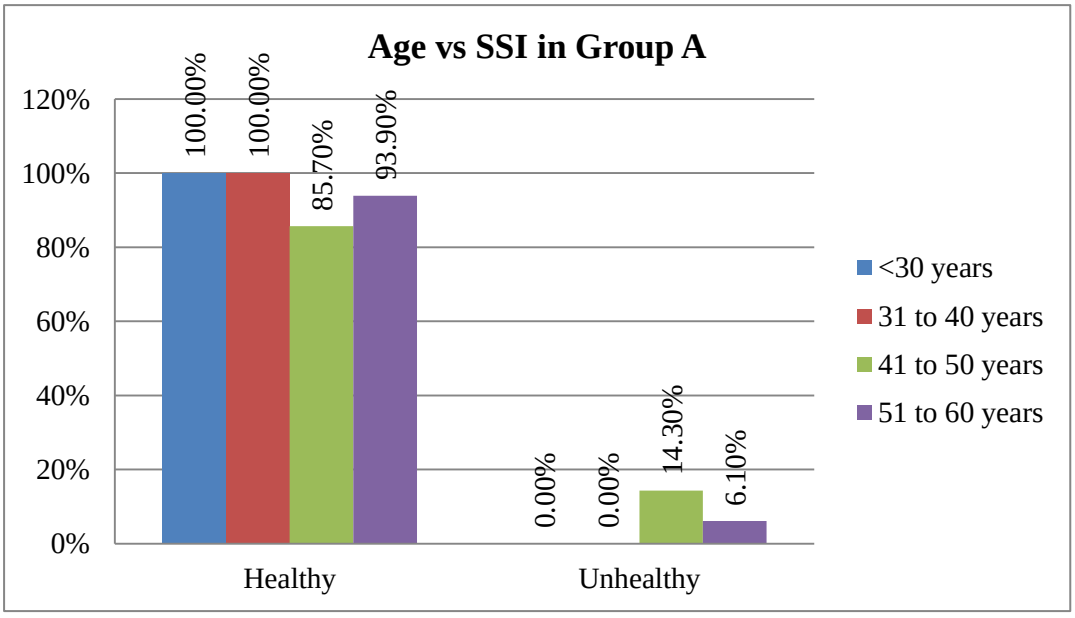


Figure7: Bar diagram showing association of Age with SSI in Group A

In Group A, among the patients <30 years and in the age group of 31 to 40 years 26 patients were studied and nobody developed SSI, in the age group of 41 to 50 years, 14.3% of patients developed SSI and in the age group of 51 to 60 years, 6.1% of patients developed SSI. The vulnerable age group was 41-60 years, where out of 43 patients studied, 4 patients (20.4%) developed SSI.

Table 8: Association of Age with SSI in Group B:

		Age							
		<30 years		31 to 40 years		41 to 50 years		51 to 60 years	
		Count	%	Count	%	Count	%	Count	%
Post Op Wound	Clean Wound	13	81.2%	14	93.3%	14	93.3%	25	92.6%
	SSI	3	18.8%	1	6.7%	1	6.7%	2	7.4%
a. Group = Group B									

$\chi 2 = 1.993$, df = 3, p = 0.574

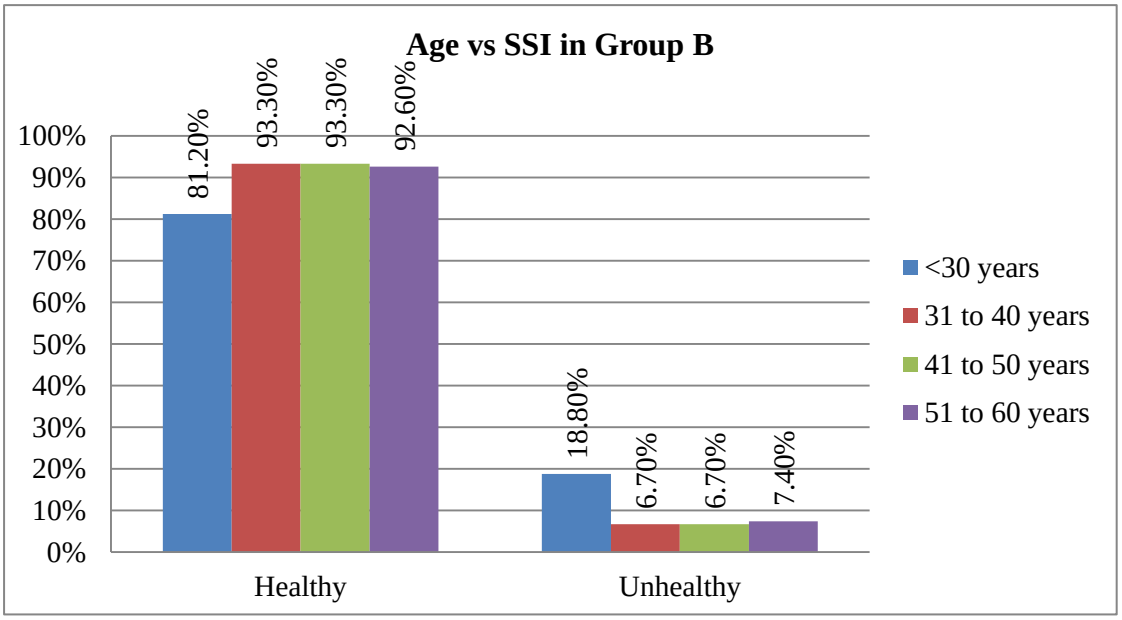


Figure 8: Bar diagram showing association of Age with SSI in Group B

In Group B, among the patients <30 years 18.8% of them developed SSI, in the age group of 31 to 40 years, 6.7% of patients developed SSI, in the age group of 41 to 50 years, 6.7% of patients developed SSI and in the age group of 51 to 60 years, 7.4% of patients developed SSI. From this table it is clear that patients in all the age groups developed SSI, majority being <30 years.

Table 9: Association of Gender with SSI in Group A:

		Gender			
		Female		Male	
		Count	%	Count	%
Post Op Wound	Clean Wound	26	92.9%	43	95.6%
	SSI	2	7.1%	2	4.4%
a. Group = Group A					

$\chi 2 = 0.243$, df = 1, p = 0.622

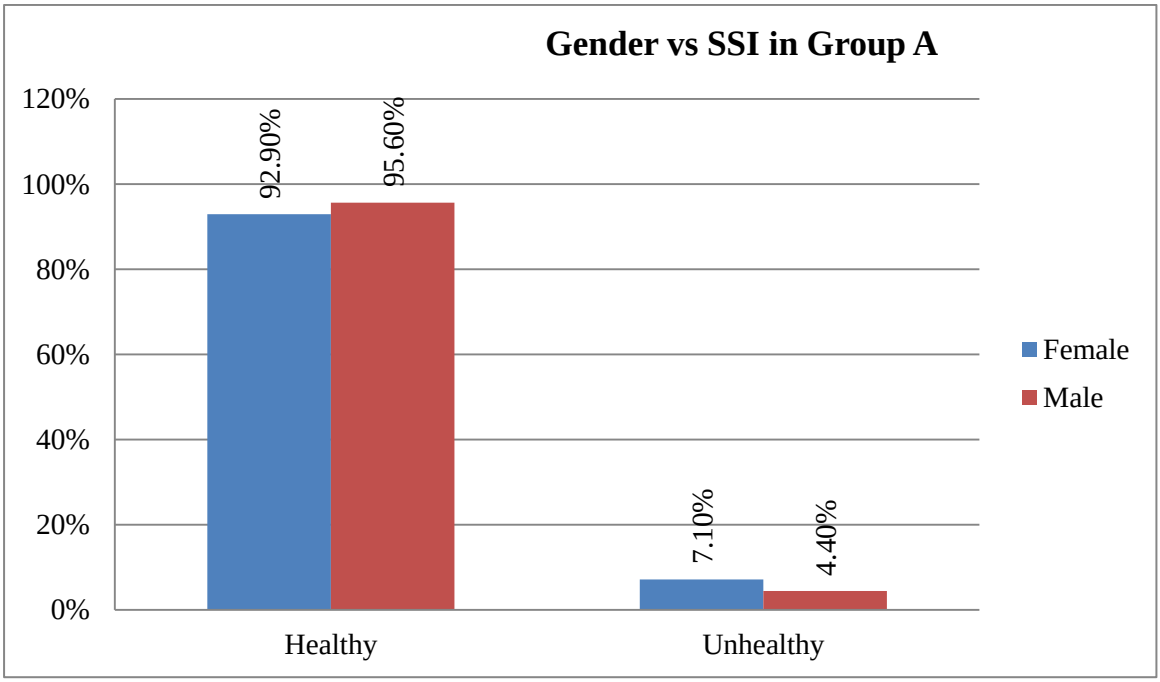


Figure 9: Bar diagram showing association of gender with SSI in Group A

In Group A, 45 patients (majority) were males. Out of 28 females studied, 2 patients (7.1%) showed signs of SSI and among 45 males studied 2 patients (4.4%) showed signs of SSI. The incidence of SSI was equal in both the genders.

Table 10: Association of Gender with SSI in Group B:

		Gender			
		Female		Male	
		Count	%	Count	%
Post Op Wound	Clean Wound	25	89.3%	41	91.1%
	SSI	3	10.7%	4	8.9%
a. Group = Group B					

$\chi 2 = 0.066$, df = 1, p = 0.797

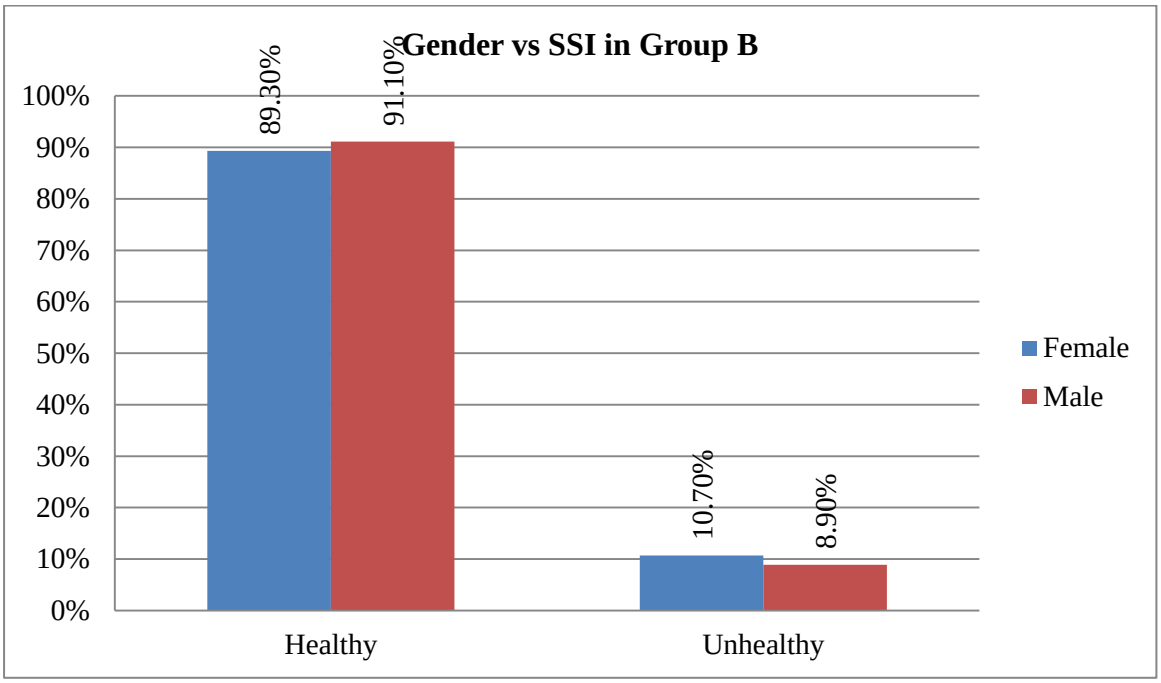


Figure 10: Bar diagram showing association of gender with SSI in Group B

In Group B, 45 patients (majority) were males. Out of 28 females studied, 3 patients (10.7%) showed signs of SSI and among 45 males studied 4 patients (8.9%) showed signs of SSI. The incidence of SSI was more in males compared to females.

Table 11: Mean Duration of Surgery (hrs) :

		Duration of Surgery (hrs)		P value
		Mean	SD	
Group	Group A	1.75	0.61	0.061
	Group B	1.94	0.57	

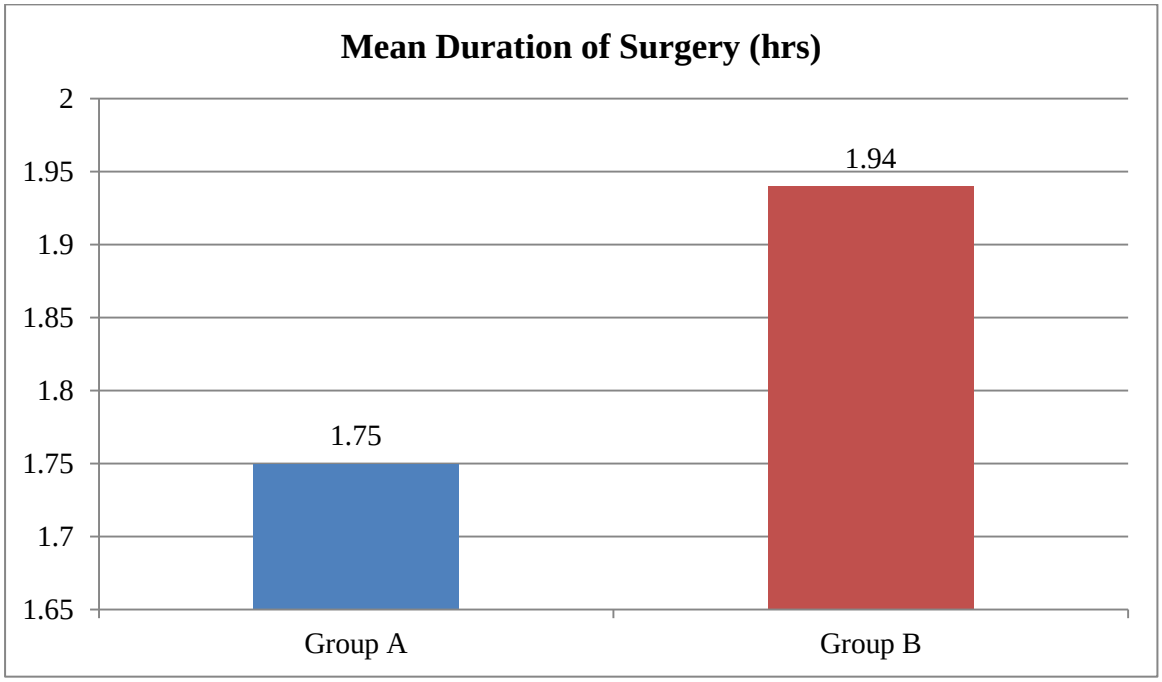


Figure 11: Bar diagram showing Mean Duration of Surgery (hrs).

Time taken for surgery, tissue handling technique adds to the incidence of SSI. In this study, in Group A, the mean duration of each surgery performed was 1.75 ± 0.61 hours and in Group B the mean duration of each surgery performed was 1.94 ± 0.57 hours. The time taken to perform surgery in group B was more compared to group A.

Table 12: Type of Wound:

		Group			
		Group A		Group B	
		Count	%	Count	%
Type of Wound	Clean	73	100.0%	73	100.0%

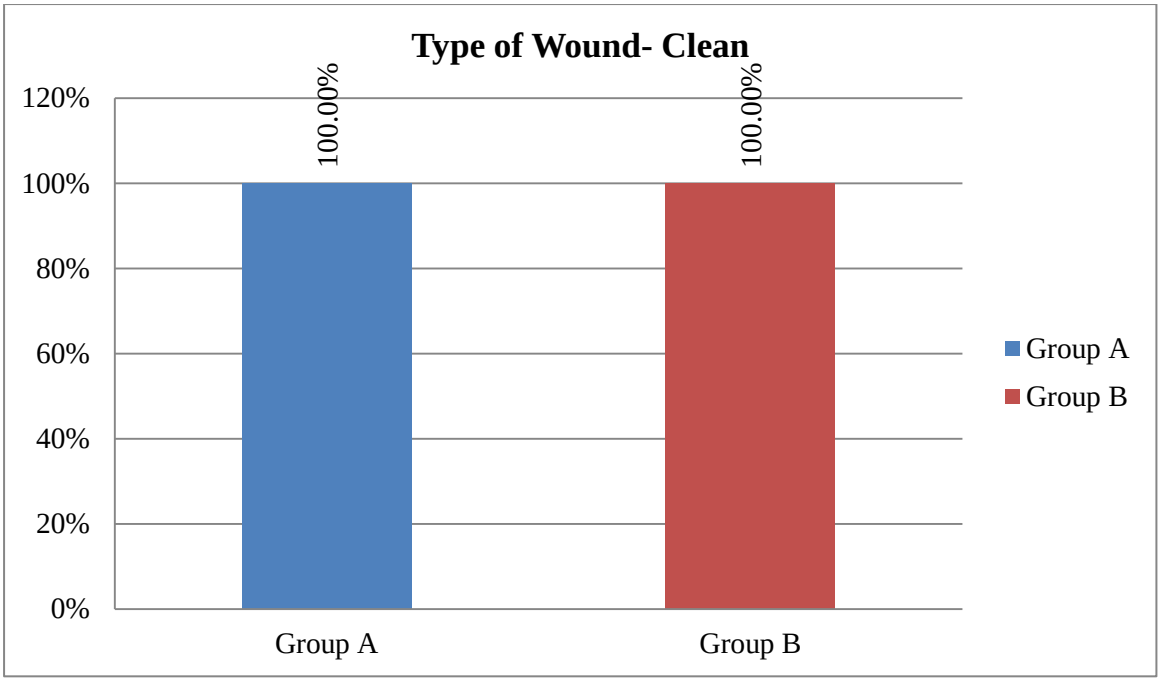


Figure 12: Bar diagram showing Type of Wound comparison between two groups

In this study a total of 146 patients undergoing surgeries for clean surgical wounds were included. Thus, in Group A and Group B, the type of wound of all patients was 'clean'. And all the surgeries performed were planned and 'elective' surgeries.

Table 13: Incidence of Superficial Surgical site infection (SSSI) in two groups studied:

		Group			
		Group A		Group B	
		Count	%	Count	%
SSSI	No	69	94.5%	66	90.4%
	Yes	4	5.5%	7	9.6%

χ 2 = 0.885, df = 1, p = 0.347

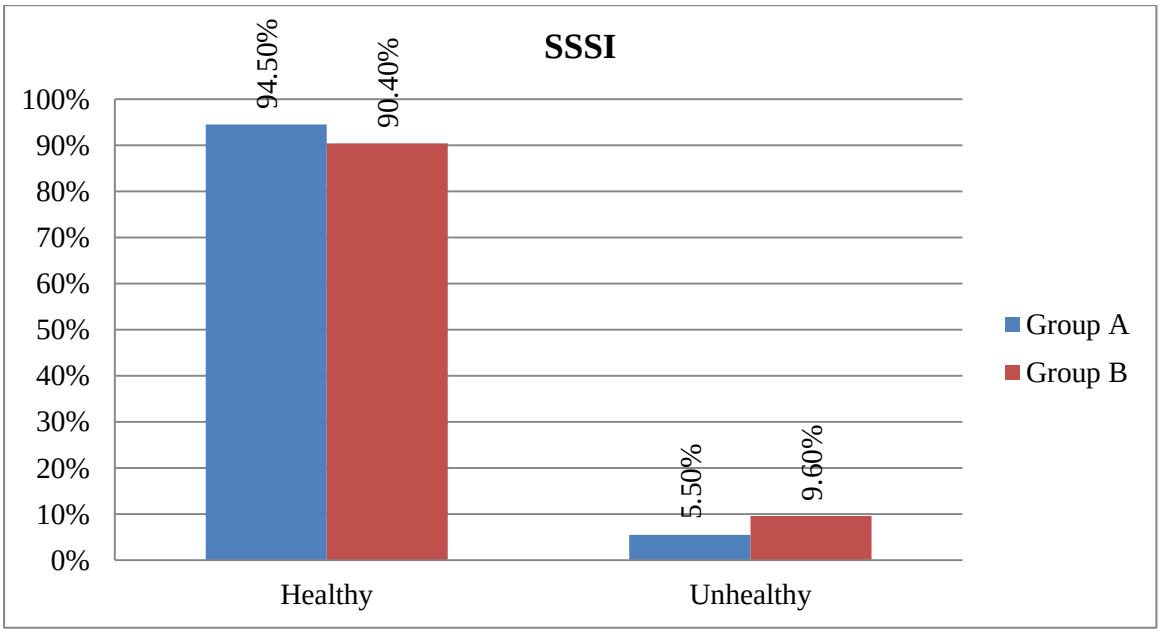


Figure 13: Bar diagram showing incidence of Superficial Surgical site infection (SSSI) in two groups.

In Group A, the wounds of 94.5% of patients did not show any signs of SSSI where as 5.5% of patients developed SSSI.

In Group B, the wounds of 90.4% of patients did not show any signs of SSSI where as 9.6% patients developed SSSI.

Lesser incidence of SSI was seen in Group A patients in whom Triclosan coated suture materials was used.

Incidence of SSSI is statistically similar in two groups with *p*=0.347.

Table 14: On which post-operative day was the diagnosis of superficial SSI made:

		Group			
		Group A		Group B	
		Count	%	Count	%
Post-operative Day	Nil	69	94.5%	66	90.4%
	3rd Day	4	5.5%	7	9.6%

$\chi 2 = 0.885$, df = 1, p = 0.347

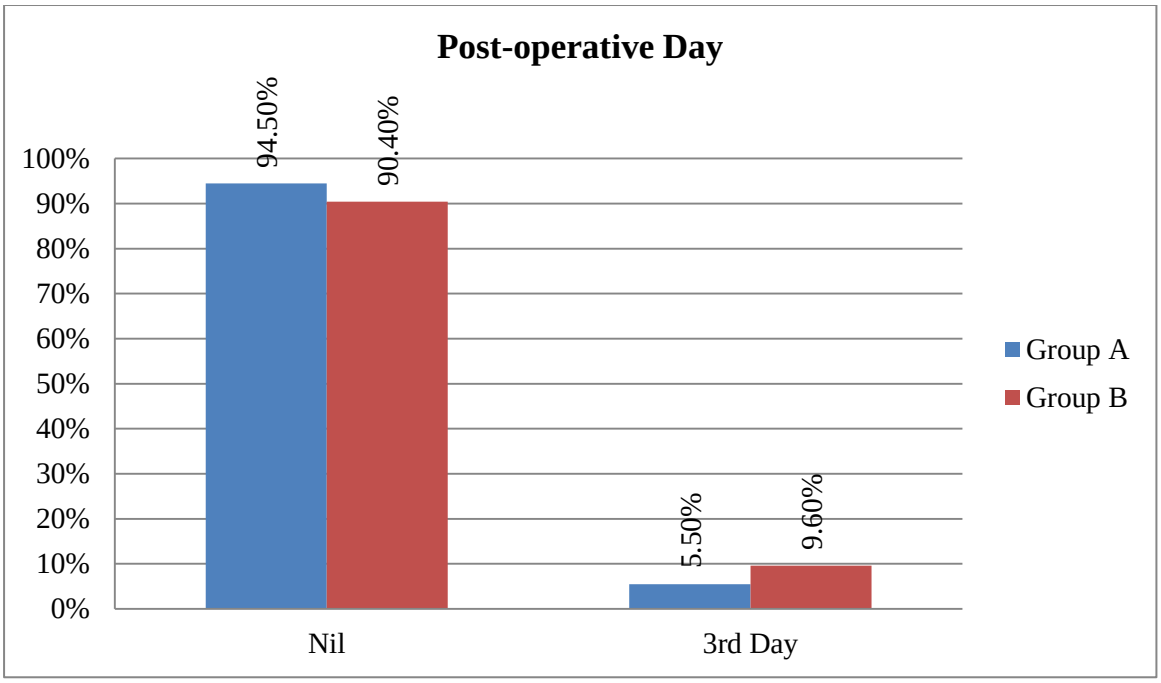


Figure 14: Bar diagram showing the post-operative day on which the diagnosis of superficial SSI was made.

In Group A, 5.5% patients showed signs of SSI on post-operative day 3. In Group B, 9.6% patients showed signs of SSI on post-operative day 3. In both the groups the day on which SSI's were noted was almost the same (day 3).

The post-operative day on which the diagnosis of SSSI was made is statistically similar in two groups with *p*=0.347.

Table 15: Comparing the patients in both the groups with SSI- based on Southampton Grading System:

		Group			
		Group A		Group B	
		Count	%	Count	%
Southampton Grading	Grade 1	0	0.0%	1	14.3%
	Grade 2	2	50.0%	3	42.9%
	Grade 3	2	50.0%	3	42.9%
a. Unhealthy = Present					

$\chi 2 = 0.629$, df = 2, p = 0.930

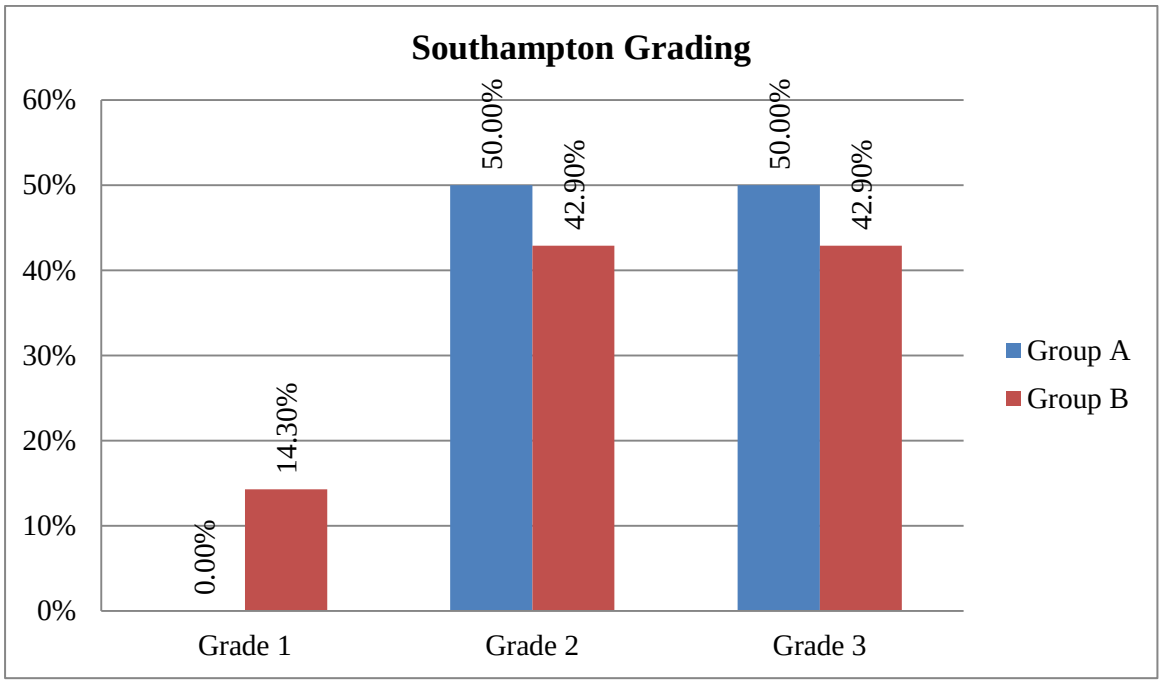


Figure 15: Bar diagram showing Southampton Grading Comparison among those with SSI between Two Groups

The patients who developed SSI were graded according to the Southampton grading system. The following was the observation.

Three grades were observed.

1 patient (14.3%) from the group B had Grade 1 infection. 2 patients (50%) from group A and 3 patients (42.9%) from group B had Grade 2 infections. 2 patients (50%) from group A and 3 patients (42.9%) from group B had Grade 3 infections.

Table 16: Post-Operative Pain Assessment between the two groups:

		Group			
		Group A		Group B	
		Count	%	Count	%
Post- Operative Pain	Nil	69	94.5%	64	87.7%
	Mild	3	4.1%	5	6.8%
	Moderate	1	1.4%	4	5.5%

$\chi 2 = 2.488$, df = 2, p = 0.288

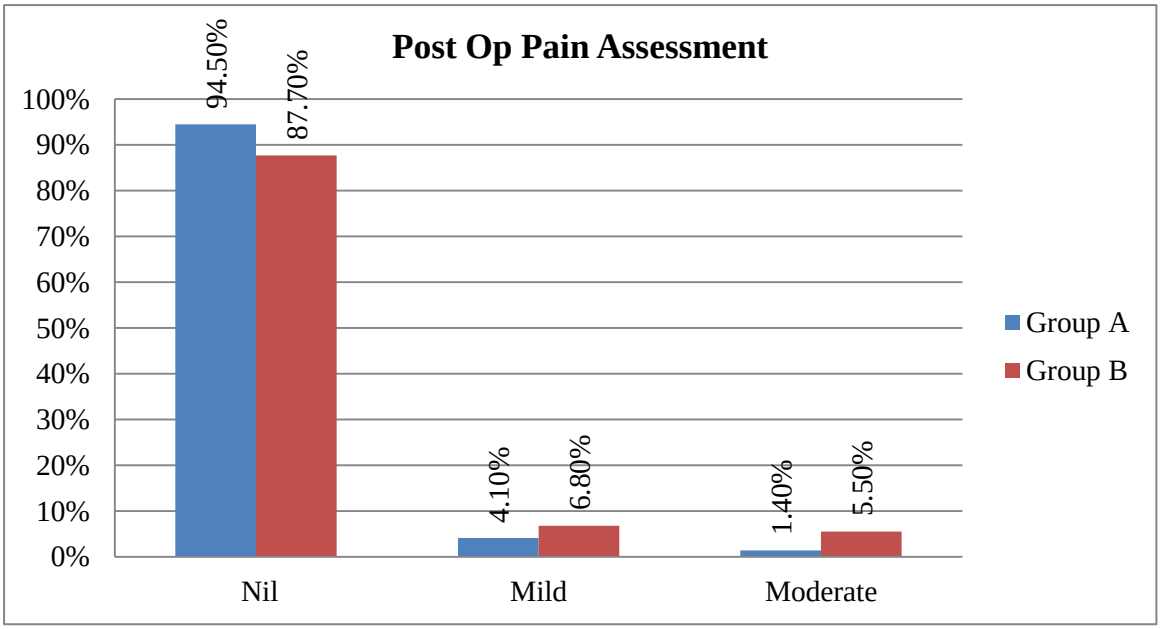


Figure 16: Bar diagram showing Post Op Pain Assessment between Two Groups

The number of patients complaining of pain in the Group A (4 patients) is less compared to the Group B (9 patients). The intensity of pain perceived in Group A as analyzed by the visual analog scale is less than that in the Group B.

Table 17: Comparing the Duration of post-operative hospital stay in the two groups:

		Duration of Stay		P value
		Mean	SD	
Group	Group A	10.32	1.55	0.745
	Group B	10.41	1.98	

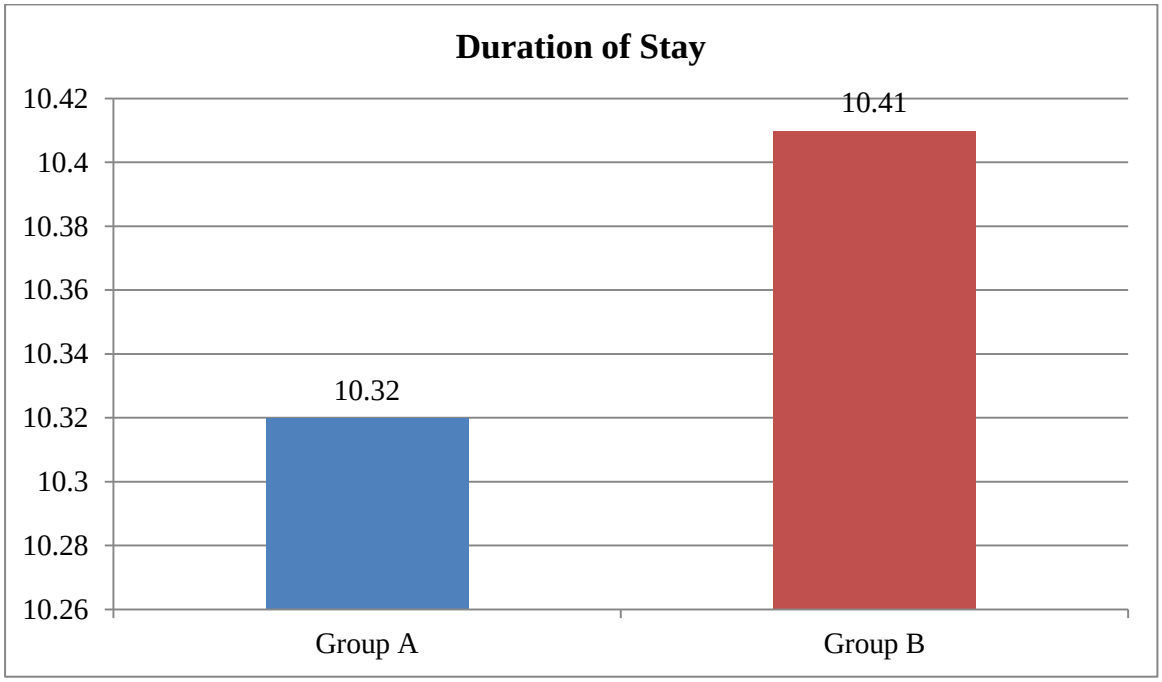


Figure 17: Bar diagram comparing Duration of post-operative hospital stay.

In Group A, the average number of days patients stayed in the hospital after surgery was 10.32 ± 1.55 days and in Group B the average number of days patients stayed in the hospital after surgery was 10.41 ± 1.98 days.

The duration for which patients stayed in the hospital in group A was comparatively lesser than that in group B.

Table 18: Co-morbidities Comparison between Two Groups

		Group				P value
		Group A		Group B		
		Count	%	Count	%	
DM	No	73	100.0%	73	100.0%	-
HTN	No	73	100.0%	73	100.0%	-
Systemic steroids	No	73	100.0%	73	100.0%	-
Anemia	No	64	87.7%	58	79.5%	0.180
	Yes	9	12.3%	15	20.5%	
Nicotine	No	51	69.9%	58	79.5%	0.183
	Yes	22	30.1%	15	20.5%	
Intra Op Antibiotics	Yes	73	100.0%	73	100.0%	-

In Group A, 12.3% had anemia, 30.1% had nicotine consumption. In Group B, 20.5% had anemia, 20.5% had nicotine consumption.

DISCUSSION

DISCUSSION

The study was conducted as a hospital based randomized prospective observational study. This study compares the effectiveness of the suture materials coated with an antiseptic Triclosan, in reducing the burden of SSI, among the patients undergoing surgeries for clean surgical wounds.

The study population includes 146 patients undergoing clean surgeries, in the Department of General Surgery at R.L.Jalappa hospital and research center attached to Sri Devaraj Urs Medical College, Kolar, during study period from November 2016 to September 2018. Patients with clean contaminated wounds, contaminated wounds, those undergoing gynecological surgeries, those with an already existing SSI, those who are immunocompromised are excluded from the study.

The study was approved by the Ethical Committee of the medical college. A total of 146 patients grouped into two were studied. Group A, includes patients undergoing clean surgeries in whom the subcutaneous layer closure is done using Triclosan coated suture material, and group B includes patients undergoing clean surgeries in whom the subcutaneous layer closure is done using conventional suture material. Patients were followed up on post-operative day 3,5,9,11,15 and 30. The primary end point was development of a superficial SSI.

1. AGE :

In our study it was observed that, in Group A, majority of the patients were in the age group 51 to 60 years (45.2%). In Group B, majority were in the age group 51 to 60 years (37%). Patients in the two groups are age matched with p= 0.743 (χ 2 = 1.24, df = 3, p =

0.743). In Group A, mean age was 45.89 ± 12.12 years and in Group B was 43.93 ± 12.22..

Similar findings were noted in a study conducted by Manisha Agarwal et al[75], triclosan coated suture materials were studied in preventing surgical site infection in perforation peritonitis.

In another double blinded prospective randomized control trial, conducted by Rozelle et al[19], it was observed that, no statistically significant difference was noted in between the groups studied, in terms of age.

All patients in between the age group of 15 – 60 years undergoing clean surgeries were included in this study.

2. **GENDER :**

In Group A, 38.4% were females and 61.6% were males. In Group B, 38.4% were females and 61.6% were males. There was no difference in gender distribution between two groups ($\chi 2 = 0.000$, df = 1, p = 1.000).

In groups A and B, out of 73 patients studied, 45 were males and 28 were females.

In our study, the majority of the patients studied were males, in both the groups. No statistical difference was noted in between the two groups in terms of gender.

3. **DIAGNOSIS :**

The patients included in this study had a variety of diagnoses. All patients undergoing clean surgeries were included in this study. The association of the superficial surgical site

infection with the age, gender of the patient, diagnosis for which patient underwent surgery will be as following -

3.1 Distribution of patients in each with respect to their diagnosis –

All patients undergoing surgeries for clean surgical wounds were included in this study. In Group A and Group B majority (n=70) were the patients who underwent surgeries for Inguinal Hernia (χ 2 = 6.952 , df = 7 , p = 0.434) followed by Umbilical Hernia, Incisional Hernia, MNG, Fibroadenoma, lipoma, Para-umbilical hernia, Femoral hernia and Epigastric hernia in decreasing order

Out of the 73 patients studied in group A and group B, 39 patients (53.4%) in group A and 31patients (42.5%) in group B, underwent surgery for Inguinal Hernia respectively, thus this was the maximum diagnosis studied in both the groups.

3.2 Association of the diagnosis with respect to age of the patient –

In Group A, there was significant association between age and diagnosis (χ 2 = 36.05 , df = 21 , p = 0.022*).

Out of 73 patients studied in group A, 39 patients were operated for Inguinal Hernia. Out of these 39 patients, maximum number, 20 patients (60.6%) were found in the age group of 51-60 years.

In Group B, there was significant association between Age and Diagnosis (χ 2 = 37.83 , df = 21 , p = 0.013*).

Out of 73 patients studied in group B, 31 patients were operated for Inguinal Hernia. Out of these 31 patients, maximum number, 16 patients (59.3%) were found in the age group of 51-60 years.

3.3 Association of Diagnosis with the incidence SSI in both the groups –

In Group A, out of the 73 patients studied, 4 patients developed SSI. Out of these, 2 patients (50%) who underwent surgeries for Inguinal Hernia, 1 patient (25%) for Incisional hernia, 1 patient (25%) for MNG developed SSI , (χ 2 = 4.024 , df = 7 , p = 0.777).

In Group B, out of the 73 patients studied in group B, 7 patients developed SSI. Out of these 7, 2 patients (28.6%) who underwent surgeries for Inguinal Hernia, 3 patients (42.9%) for Umbilical hernia, 2 patients (28.6%) for MNG developed SSI , (χ 2 = 8.43 , df = 7 , p = 0.296).

3.4 Association of age of the patient with the incidence of SSI –

In the patients among the age group of <40 years, nobody had SSI, in 41 to 50 years, 14.3% of patients developed SSI and in 51 to 60 years, 6.1% of patients developed SSI (χ 2 = 3.625, df = 3, p = 0.305).

Therefore the most vulnerable age group to have SSI was 41-60 years among the patients studied in group A.

In Group B, in patients <30 years, 18.8% of patients developed SSI, in 31 to 40 years, 6.7% of patients developed SSI, in 41 to 50 years, 6.7% of patients developed SSI and in 51 to 60 years, 7.4% of patients developed SSI (χ 2 = 1.993 , df = 3, p = 0.574).

Patients in the control group, in whom triclosan coated suture materials was not used developed SSI in all age groups.

4. MEAN DURATION OF SURGERY (HRS):

In Group A, mean duration of surgery was 1.75 ± 0.61 Hrs and in Group B was 1.94 ± 0.57 Hrs. The duration taken to perform surgery in both the groups is statistically similar with *p*=0.061.

In our study the duration of time taken to perform surgery in both groups was almost similar. Proper care was taken to administer the patient with a dose of antibiotic, with adequate time gap between the dose of antibiotic and incision. And whenever required, top up dose was also given to maintain the therapeutic levels of antibiotic in the body.

Similar results were noted by Renita Geneieve Lobo et al[82], where in no statistical difference was noted in between the two groups in terms of duration of surgery.

5. TYPE OF THE WOUND/TYPE OF SURGERY:

In Group A and Group B, 100% had clean wound.

In Group A and Group B, 100% were elective surgery.

In our study, only clean surgical wounds were studied, with all the patients being taken up for surgery on an elective basis.

6. **INCIDENCE OF SSI:**

In Group A, the post-operative wounds of 94.5% of patients did not show any signs of SSSI where as 5.5% of patients developed SSSI.

In Group B, the post-operative wounds of 90.4% of patients did not show any signs of SSSI where as 9.6% patients developed SSSI.

Lesser incidence of SSI was seen in Group A patients in whom Triclosan coated suture materials was used.

Out of 73 patients studied in Group A, post-operative wounds of 69 patients (94.5%), were healthy, whereas 4 patients (5.5%), developed SSI.

Out of 73 patients studied in Group B, post-operative wounds of 66 patients (90.4%), were healthy, whereas 7 patients (9.6%), developed SSI.

On an overall, there is 4.1% decrease in the incidence of SSSI in the study group compared to the control group.

Thus, in our study Triclosan coated suture materials have reduced the incidence of SSI.

Incidence of SSSI is statistically similar in two groups with p=0.347.

(χ 2 = 0.885, df = 1, p = 0.347.)

The use of Triclosan sutures has always been a topic of debate since its advent. There have been studies conducted in various scenarios. A few studies go in favour of Triclosan, whereas a few are against.

Here is a list of studies, and their results, comparing triclosan sutures with non-triclosan sutures.

Author	Yr	Location	Study Design	Population/Study number	End Point	Result	Verdict
Fleck et al[17]	'07	Vienna, Austria	Retrospective	479 pts/Cardiac Sx.	Sternal wound infection	0% SSI in bioactive group.	In favor of Triclosan
Rozelle et al[19]	'08	New York, USA	RCT	84 procedures/CSF shunt sx	Shunt infection	4% SSI in study group, 21% in control group	In favor of Triclosan
Mingmalairak et al[18]	'09	Pthumthani, Thailand	RCT	100 pts/ appendicectomy	SSI	10% SSI in study group, 5% in control group	No statistical difference (p=0.727)
Deliaret et al[16]	'09	Venlo, Netherlands	RCT	26 pts, breast reduction	Wound dehiscence	61% in study group, 21% in control group	Against Triclosan Sutures
Justinger et al[68]	'09	Homburg /Saag, Germany	Retrospective, diff time periods	2,088 pts, midline laparotomy	SSI	5% SSI in study group, 11% in control group	In favor of Triclosan
Justinger et al[14]	'11	Homburg /Saag, Germany	Retrospective, diff time periods	839 pts/ transverse abdominal incisions	SSI	4% SSI in study group, 9% in control group	In favor of Triclosan
Chen et al[15]	'11	Taipei, Taiwan	RCT	241 pts/wide excision of head/neck cancer & reconstruction	SSI	14.9% SSI in study group, 14.7% SSI in control group	No difference
Renita lobo et al[82]	'11	Bangalore, India	RCT	90 pts/ laparotomy incisions	Superficial SSI	41.2% SSI in study group, 30.1% in control group	Against Triclosan
Justinger et al[78]	'13	RCT	Homburg/SAAG German y	856 pts/ laparotomy, various abdominal Sx	SSI	6.3% SSI in study group, 11.3% SSI in control group	In favor of Triclosan
Daoud Fc et al[79]	'14	Meta Analysis	Paris, France	4800 patients	SSI	0.67% SSI, significantly low in study group	In favor of Triclosan

7. **Post-operative day on which the diagnosis of Superficial SSI was made:**

In group A, 4 patients (5.5%), showed signs of SSI on post-operative day 3.

In group B, 7 patients (9.6%) showed signs of SSI on post-operative day 3.

The post-operative day on which patients developed SSI was almost similar in the two groups.

(χ 2 = 0.885, df = 1, p = 0.347.)

POD is statistically similar in the two groups with *p*=0.347.

8. **SOUTHAMPTON GRADING SYSTEM:**

Among those post-operative wounds with signs of SSI, Southampton Grading was as follows

1 patient (14.3%) from the group B had Grade 1 infection. 2 patients (50%) from group A and 3 patients (42.9%) from group B had Grade 2 infections. 2 patients (50%) from group A and 3 patients (42.9%) from group B had Grade 3 infections.

(χ 2 = 0.629, df = 2, p = 0.930) Similar results were found by Karikazi MA et al[84], 2016 when they compared wounds based on Southampton Grading System.

9. **POST OPERATIVE PAIN ASSESSMENT:**

Out of 73 patients studied in group A, 69 patients (94.5%), did not complain of pain, where as 3 patients (4.1%), complained of mild pain and 1 patient (1.4%), complained of moderate pain.

In group B, out of 73 patients studied, 64 patients (87.7%), complained of no pain, where as 5 patients (6.8%), complained of mild pain, and 4 patients (5.5%), complained of moderate pain. The pain assessment of all the patients was done using a Visual Analog Scale.

There was no difference noted in between the two groups (χ 2 = 2.488, df = 2, p = 0.288).

12. **DURATION OF STAY IN THE HOSPITAL:**

In Group A, the average number of days patients stayed in the hospital after surgery was 10.32 ± 1.55 days and in Group B was 10.41 ± 1.98 days

Patients in the study group, in whom triclosan coated suture materials were used to approximate the sub-cutaneous layer, stayed for a shorter duration in the hospital compared to patients in the control group, in whom non-triclosan coated suture materials were used to approximate the sub-cutaneous layer.

13. **CO-MORBIDITIES:**

None of the patients included in the study had diabetes or hypertension. The patients on steroids, were not included in the study.

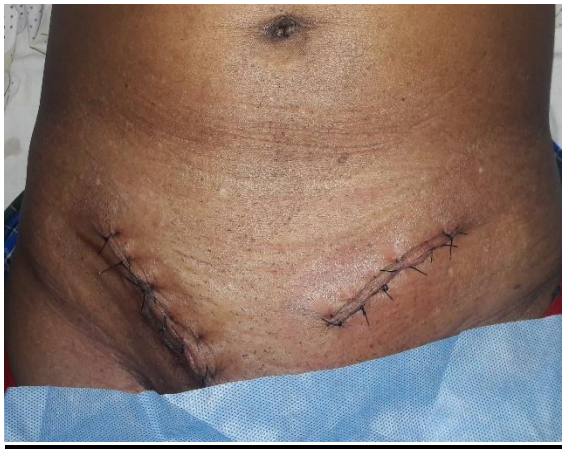
In group A, 9 patients (12.3%), had anemia, 30.1% had nicotine consumption.

In Group B, 15 patients (20.5%), had anemia, 20.5% had nicotine consumption.

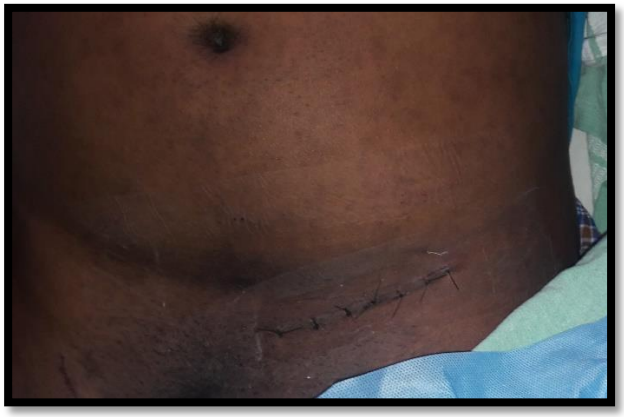
Anemia	**P value**	**Nicotine Use**	**P value**
Our Study	0.180	Our study	0.183
Renita Lobo et al[82]	0.545	Renita lobo et al[82]	0.415

PHOTO GALLERY

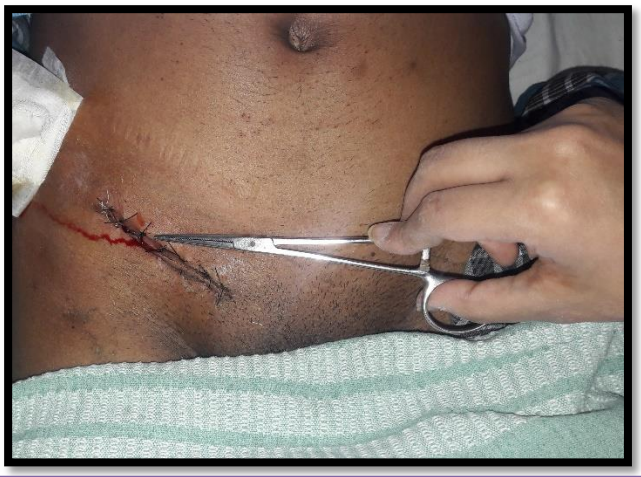
PHOTO GALLERY



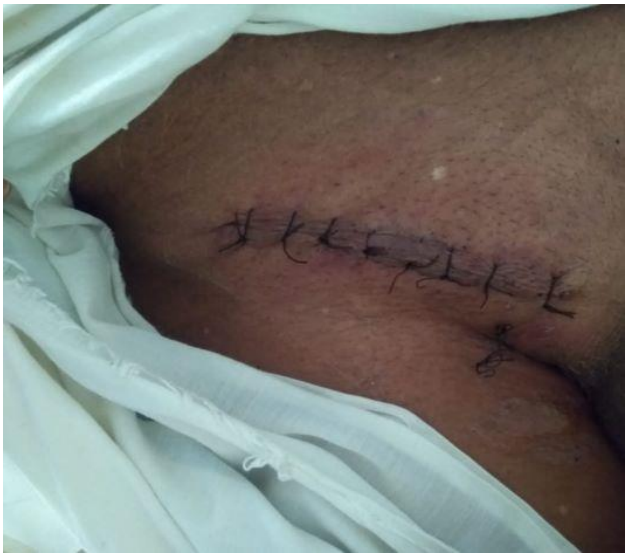
BILATERAL INGUINAL HERNIA- SOUTHAMPTON GRADE I



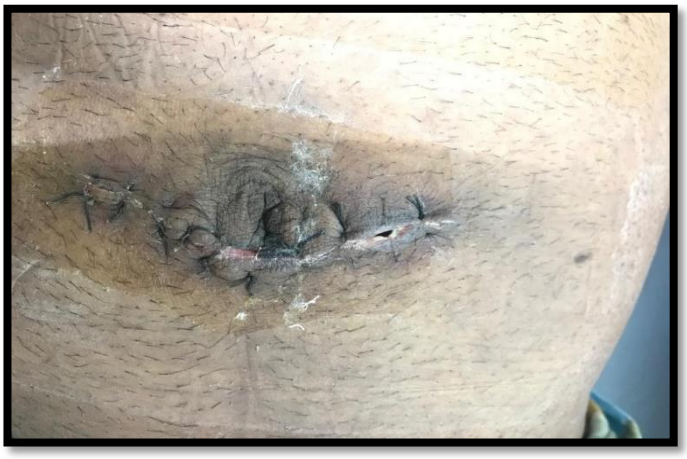
SOUTHAMPTON GRADE II- ERYTHEMA IS SEEN.



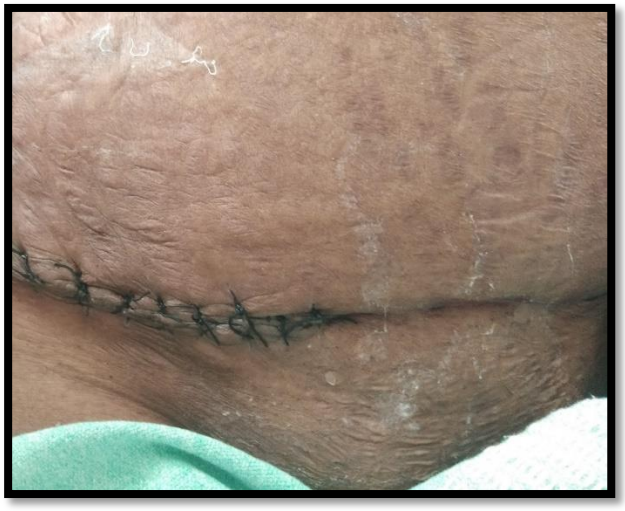
SOUTHAMPTON GRADE III. SEROUS DISCHARGE IS SEEN.



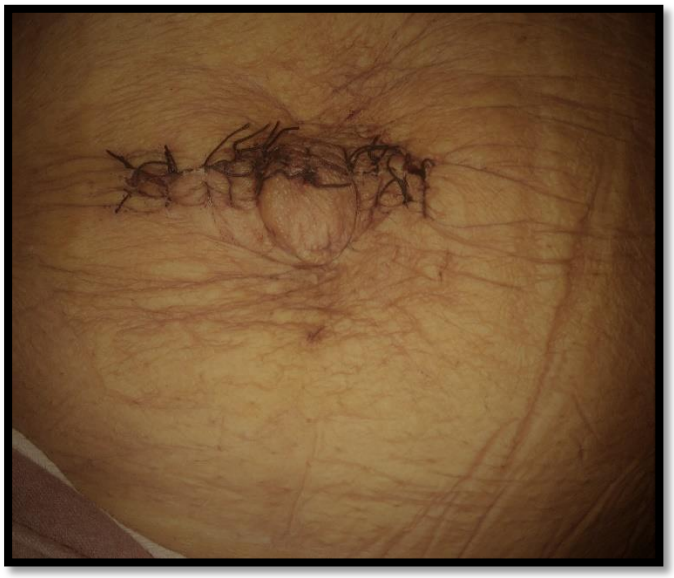
SOUTHAMPTON GRADE II – ERYTHEMA IS SEEN



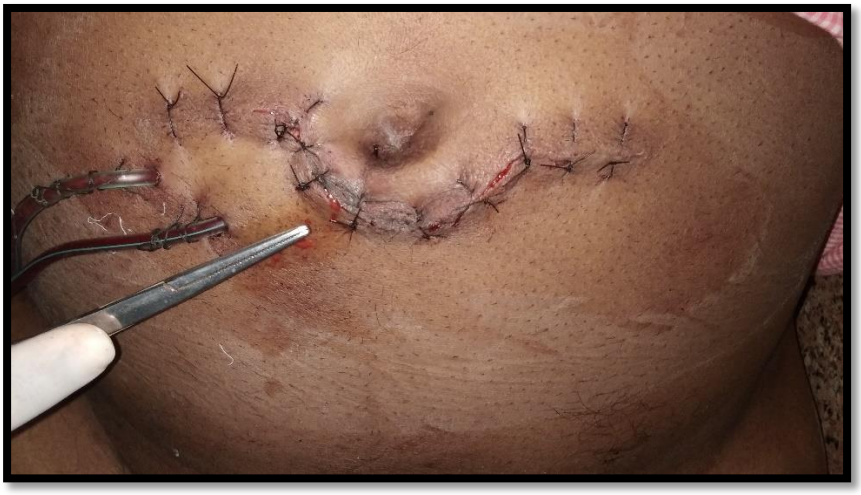
UMBILICAL HERNIA – SOUTHAMPTON GRADE III



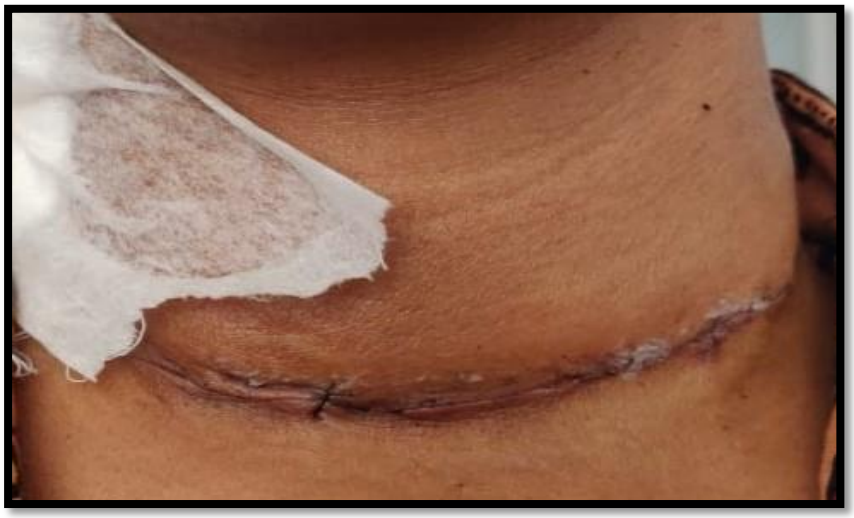
SOUTHAMPTON GRADING 0, NORMAL HEALING OF INCISIONAL HERNIA



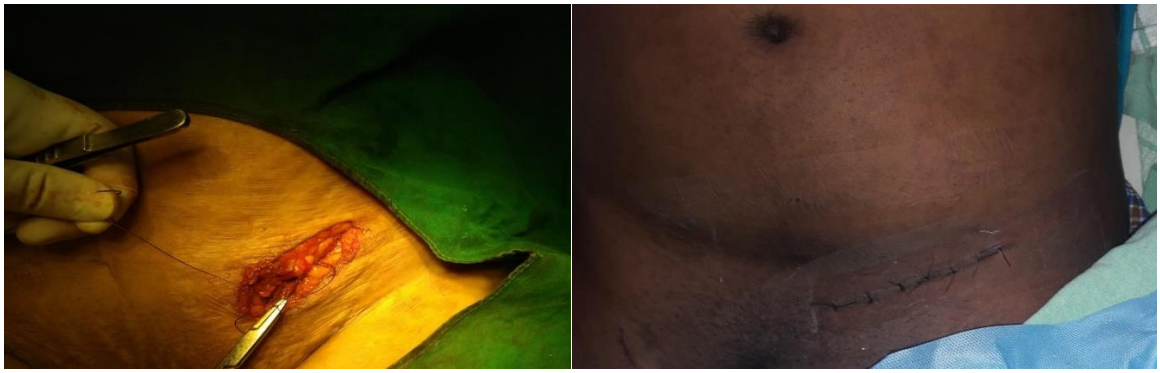
SOUTHAMPTON GRADING 0, NORMAL HEALING OF UMBILICAL

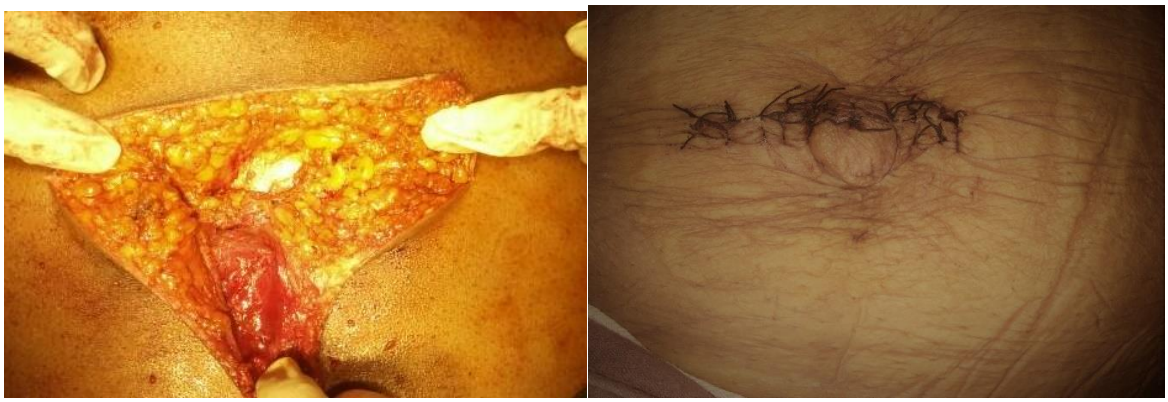


SOUTHAMPTON GRADING 3, UMBILICAL HERNIA, SHOWING HEMOSEROUS DISCHARGE.



SOUTHAMPTON GRADING 1, THYROIDECTOMY WOUND. MILD ERYTHEMA.





IMAGES SHOWING SUBCUTANEOUS CLOSURE IN INGUINAL AND UMBILICAL HERNIA INTRA-OPERATIVELY WITH TRICLOSAN COATED SUTURES, AND HEALTHY POST-OPERATIVE WOUND.

CONCLUSION

CONCLUSIONS

1. All patients undergoing surgeries for ‘clean wounds’ were included in this study.

2. Most of the patients studied were in the age group of 51-60 years. Majority studied were males.

3. Majority of the patients included in this study were operated for Inguinal Hernia.

4. Use of Triclosan coated suture material in apposing the subcutaneous layer in clean surgeries, is useful in reducing the incidence of SSI’s in the study group. These suture materials have reduced incidence of SSI’s, in comparison to two groups.

5. There is a decrease in the post-operative hospital stay in the study group.

6. The post-operative day on which patients developed SSI in both study and control groups was almost the same (post-operative day 3).

7. The intensity of pain perceived in study group as analyzed by the visual analog scale is less than that in the control group.

SUMMARY

SUMMARY

146 patients undergoing clean surgeries were included in this study to look for superficial surgical site infections. This study was intended, to know the effectiveness of triclosan coated suture materials and its role in reducing the incidence of SSI's. In this study we noted that Triclosan coated suture materials used for approximation of subcutaneous layer in clean surgeries, have reduced the incidence of SSI's.

Most of the patients in our study group, were in the age group of 51-60 years (45.2% in group A and 37% in group B). The variety of diagnosis included in our study were Inguinal Hernia, femoral hernia, Ventral Hernia's, Fibroadenoma, Multi Nodular Goiter and Lipoma. Majority of patients were operated for Inguinal hernia. All surgeries were performed under aseptic precautions.

The duration for which patients stayed in the hospital after surgery was studied using Triclosan coated suture materials. There was a decrease in the duration of post-operative hospital stay in the study group. Patients in whom Triclosan coated suture materials were used, stayed for a shorter duration in the hospital compared to the ones in whom it was not used.

The patients in both study group (triclosan coated) and control group (non-triclosan coated) showed signs of superficial surgical site infection on almost the same day after surgery (post-operative day 3).

In our study, among the patients in whom Triclosan coated sutures were used, only 5.5% patients showed signs of SSI. Among those in whom non Triclosan coated sutures were used, 9.6% patients showed signs of SSI, the difference being 4.1%.

Hence, Triclosan coated suture materials are 4.1% times superior to conventional suture materials in reducing the incidence of post-operative Surgical Site Infections.

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BIBLIOGRAPHY

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ANNEXURES

I. PATIENT INFORMATION SHEET

Study title: TO STUDY THE INCIDENCE OF SURGICAL SITE INFECTIONS USING TRICLOSAN COATED AND NON TRICLOSAN COATED SUTURE MATERIALS. A RANDOMIZED CONTROL STUDY.

Study site: R.L JALAPPA HOSPITAL, TAMAKA, KOLAR.

Aim: **To assess the incidence of Surgical Site Infections using Antibacterial Coated Suture Materials.**

Purpose of this study is to analyze the incidence of surgical site infections in various surgeries. With the acceptance of standardized criteria worldwide as the antibacterial coated suture materials would reduce the incidence of Surgical Site Infections. Thus, antibacterial coated suture materials can be superior to conventionally used suture materials in reducing SSI's.

Please read the following information and discuss with your family members. You can ask any question regarding the study. If you agree to participate in this study we will collect information (as per proforma) from you. Relevant blood investigations will be carried out if required. This information collected will be used for dissertation and publication only.

All information collected from you will be kept confidential and will not be disclosed to any outsider. Your identity will not be revealed. The expenses required for the above investigations will be funded by the study investigator. This study has been reviewed by the Institutional Ethics Committee and you are free to contact the member of the

Institutional Ethics Committee. There is no compulsion to agree to this study. The care you will get will not change if you don't wish to participate. You are required to sign/ provide thumb impression only if you voluntarily agree to participate in this study.

For any further clarification you can contact the study investigator:

Dr. Rahul Singh R

Mobile no: 9632417129

E-mail id: rahulsupercool.683@gmail.com

ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆ

ಅಧ್ಯಯನ ಶೀರ್ಷಿಕೆ: ಒಂದು ಯಾದೃಚ್ಚಿತ ನಿಯಂತ್ರಿತ ಪ್ರಯೋಗದಿಂದ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆ ಸ್ಥಳದಲ್ಲಿ ಕಂಡುಬರುವ ಸೊಂಕುಗಳ ಅಧ್ಯಯನಕ್ಕೆ ಟ್ರೈಕ್ಲೊಸನ್ ಲೇಪಿತ ಮತ್ತು ಟ್ರೈಕ್ಲೊಸನ್ ಲೇಪಿತ ರಹಿತ ಹೊಲಿಗೆಯ ಪದಾರ್ಥಗಳಿಗೆ ಹೊಂದಿಕೊಳ್ಳುವಿಕೆ .

ಅಧ್ಯಯನ ಸ್ಥಳ: ಆರ್. ಎಲ್. ಜಾಲಪ್ಪ ಆಸ್ಪತ್ರೆ, ಟಮಕ, ಕೋಲಾರ.

ಗುರಿ: ಈ ಅಧ್ಯಯನದ ಉದ್ದೇಶ – ಆಂಟಿಬ್ಯಾಕ್ಟೀರಿಯಲ್(ಜೀವಿ ವಿರೋಧಿ) ಲೇಪಿತ ಹೊಲಿಗೆಯ ವಸ್ತುಗಳನ್ನು ಬಳಸಿ ಶಸ್ತ್ರ ಚಿಕಿತ್ಸೆಯ ಸೊಂಕುಗಳ ಪ್ರಮಾಣವನ್ನು ವಿಶ್ಲೇಸಿಸಲು ನಿರ್ಣಯಿಸುವುದು.

ವಿಶ್ವದಾದ್ಯಂತ ಪ್ರಮಾಣಾನುಸಾರಿಯಾಗಿಸಿದ ಮಾನದಂಡಗಳ ಪ್ರಕಾರ ಆಂಟಿಬ್ಯಾಕ್ಟೀರಿಯಲ್(ಜೀವಿ ವಿರೋಧಿ) ಲೇಪಿತ ಹೊಲಿಗೆಯ ವಸ್ತುಗಳು ಶಸ್ತ್ರ ಚಿಕಿತ್ಸೆಯ ಸೊಂಕುಗಳು ಹಾಗೂ ಅದರ ವ್ಯಾಪ್ತಿಯನ್ನು ತಗ್ಗಿಸುವ ಜೊತೆಗೆ ಸಾಂಪ್ರದಾಯಕವಾಗಿ ಬಳಸಲಾಗುವ ಹೊಲಿಗೆ ವಸ್ತುಗಳಿಗಿಂತಲೂ ಆಂಟಿಬ್ಯಾಕ್ಟೀರಿಯಲ್(ಜೀವಿ ವಿರೋಧಿ) ಲೇಪಿತ ಹೊಲಿಗೆಯ ವಸ್ತುಗಳು ಎಸ್.ಎಸ್.ಐ(ಸರ್ಜಿಕಲ್ ಸೈಟ್ ಇನ್ಫೆಕ್ಷನ್) ಅನ್ನು ಕಡಿಮೆ ಮಾಡುತ್ತದೆ.

ಈ ಮಾಹಿತಿಯನ್ನು ಓದಿ ಮತ್ತು ನಿಮ್ಮ ಕುಟುಂದ ಸದಸ್ಯರೊಂದಿಗೆ ಚರ್ಚಿಸಿ ನೀವು ಈ ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಬಹುದು . ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವುದಾದರೆ ನಿಮ್ಮಿಂದ ನಮೂನೆ ಪ್ರಕಾರ ಮಾಹಿತಿ ಸಂಗ್ರಹಿಸಲಾಗುತ್ತದೆ.. ಸಂಗ್ರಹಿದ ಮಾಹಿತಿ ಪ್ರೌಢಪ್ರಬಂದದಲ್ಲಿ ಪ್ರಕಟಣೆಗೆ ಮಾತ್ರ ಬಳಸುವುದಾದರೆ ಸಂಭದಿತ ರಕ್ತ ಪರೀಕ್ಷೆಗಳನ್ನು ಕೈಗೊಳ್ಳಬೇಕಾಗುತ್ತದೆ.

ನಿಮ್ಮಿಂದ ಸಂಗ್ರಹಿಸಿದ ಎಲ್ಲಾ ಮಾಹಿತಿಯನ್ನು ಗೌಪ್ಯವಾಗಿ ಇಡಲಾಗುತ್ತದೆ. ನಿಮ್ಮ ಗುರುತನ್ನು ಯಾವುದೇ ಕಾರಣಕ್ಕೂ ಬಹಿರಂಗ ಪಡಿಸುವುದಿಲ್ಲ. ಈ ಅದ್ಯಯನಕ್ಕೆ ಅಗತ್ಯವಿರುವ ಖರ್ಚು ವೆಚ್ಚವನ್ನು ಸಂಶೊಧಕರೇ ವಹಿಸಿಕೊಳ್ಳುತ್ತಾರೆ. ಈ ಅದ್ಯಯನವು ನೈತಿಕ ಸಮಿತಿಯ ವಿಮರ್ಷೆಗೆ ಒಳಪಟ್ಟಿರುತ್ತದೆ. ಹಾಗೂ ನೀವು ನೈತಿಕ ಸಮಿತಿಯ ಸದಸ್ಯರನ್ನು ಉಚಿತವಾಗಿ ಸಂಪರ್ಕಿಸಬಹುದು.

ನೀವು ಈ ಅದ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪದಿದ್ದರೆ ಯಾವುದೇ ರೀತಿಯ ಕಡ್ಡಾಯವಿರುವುದಿಲ್ಲ ಹಾಗೂ ನಿಮಗೆ ಒದಗಿಸುವ ಆರೈಕೆಯಲ್ಲಿ ಯಾವುದೇ ರೀತಿಯ ಬದಲಾವಣೆ ಇರುವುದಿಲ್ಲ.

ನೀವು ಈ ಅದ್ಯಯನದಲ್ಲಿ ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿದರೆ ಮಾತ್ರ ನಿಮ್ಮ

ರುಜು/ ಹೆಬ್ಬೆಟ್ಟಿನ ಗುರುತನ್ನು ಓದಗಿಸುವ ಅಗತ್ಯವಿರುತ್ತದೆ.

ನೀವು ಯಾವುದೇ ರೀತಿಯ ಸ್ಪಷ್ಟೀಕರಣ ಬಯಸಿದ್ದಲ್ಲಿ ಈ ಅಧ್ಯಯನದ ಸಂಶೋಧಕರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ಅಧ್ಯಯನಕಾರರ ವಿಳಾಸ:–
ಡಾ॥ ರಾಹುಲ್ ಸಿಂಗ್. ಆರ್
ಮೊಬೈಲ್ ಸಂಖ್ಯೆ:– 9632417129
ಇ–ಮೇಲ್ ಐಡಿ:– rahulsupercool.683@gmail.com

II. INFORMED CONSENT FORM

TITLE OF THE STUDY- **To Study the Incidence of Surgical Site Infections Using Triclosan Coated and Non Triclosan Coated Suture Materials. A Randomized Control**

Patient name – Address -

Age –

Sex –

Hospital number – Ward –

Date – Time –

Study number –

If you agree to participate in the study we will collect information (as per proforma) from you or a person responsible for you or both. We will collect the treatment and relevant details from your hospital record. This information collected will be used for only dissertation and publication. This study has been reviewed by the institutional ethical committee. The care you will get will not change if you don't wish to participate. You are required to sign/ provide thumb impression only if you voluntarily agree to participate in this study.

I understand that I remain free to withdraw from the study at any time and this will not change my future care. I have read or have been read to me and understood the purpose of the study, the procedure that will be used, the risk and benefits associated with my involvement in the study and the nature of information that will be collected and disclosed during the study. I have had the opportunity to ask my questions regarding various aspects of the study and my questions are answered to my satisfaction. I, the undersigned agree to participate in this study and authorize the collection and disclosure of my personal information for dissertation.

Subject name-

(Parents / Guardians name)

DATE: SIGNATURE /THUMB IMPRESSION

Attendant'sname –

SIGNATURE /THUMB IMPRESSION

Relation to patient –

ಮಾಹಿಯುಕ್ತ ಸಮ್ಮತಿ ಪತ್ರ

ಅಧ್ಯಯನ ಶೀರ್ಷಿಕೆ:– ಯಾದೃಚ್ಛಿಕ ನಿಯಂತ್ರಿತ ಪ್ರಯೋಗದಲ್ಲಿ ಟ್ರೈಕ್ಲೊಸನ್ ಲೇಪಿತ ಮತ್ತು ಟ್ರೈಕ್ಲೊಸನ್ ಲೇಪಿತ ರಹಿತ ಹೊಲಿಗೆಯ ವಸ್ತುಗಳನ್ನು ಬಳಸಿ ಶಸ್ತ್ರ ಚಿಕಿತ್ಸೆ ಸೊಂಕುಗಳ ಅಧ್ಯಯನ .

ರೋಗಿಯ ಹೆಸರು– ವಿಳಾಸ– ವಯಸ್ಸು:

ಲಿಂಗ: ಗಂ/ಹೆ

ಆಸ್ಪತ್ರೆ ಸಂಖ್ಯೆ: ವಾರ್ಡ/ಕೊಠಡಿ:

ದಿನಾಂಕ: ಸಮಯ:

ಅಧ್ಯಯನ ಸಂಖ್ಯೆ:

ನೀವು ಈ ಅದ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿದರೆ ನಾವು ನಿಮ್ಮಿಂದ ಅಥವಾ ನಿಮ್ಮ ಪಾಲಕ/ ಪೊಷಕರಿಂದ ನಮೂನೆಯ ಪ್ರಕಾರ ನಿಮ್ಮ ಆಸ್ಪತ್ರೆಯ ದಾಖಲೆ ಚಿಕಿತ್ಸೆ ಮತ್ತು ಇತರೆ ಸಂಬಂದಿತ ವಿವರಗಳನ್ನು ಸಂಗ್ರಹಿಸುತ್ತೇವೆ. ಸಂಗ್ರಹಿದ ಈ ಮಾಹಿತಿಯನ್ನು ಪ್ರೌಢಪ್ರಬಂಧ ಮತ್ತು ಪ್ರಕಟಣೆಗೆ ಬಳಸಲಾಗುತ್ತದೆ. ಈ ಅದ್ಯಯನವು ಸ್ಥಾನಿಕ ನೈತಿಕ ಸಮಿತಿಯ ವಿಮರ್ಷೆಗೆ ಒಳಪಡಿಸಲಾಗಿದೆ. ನೀವು ಈ ಅದ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಇಚ್ಚಿಸದಿದ್ದರೆ ನೀವು ಪಡೆಯುವ ಕಾಳಜಿ, ಆರೈಕೆಯಲ್ಲಿ ಯಾವುದೇ ಬದಲಾವಣೆ ಇರುವುದಿಲ್ಲ. ನೀವು ಸ್ವಯಂ ಪ್ರೇರಣೆಯಿಂದ ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿದರೆ ಮಾತ್ರ ನಿಮ್ಮ ರುಜು/ ಹೆಬ್ಬೆಟ್ಟಿನ ಗುರುತು ಒದಗಿಸುವ ಅಗತ್ಯ ಇರುತ್ತದೆ.

ನಾನು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಅಧ್ಯಯನದಿಂದ ಹಿಂದಕ್ಕೆ ಸರಿಯಲು ಮುಕ್ತನಾಗಿರುತ್ತೇನೆ. ಹಾಗೆ ಹಿಂದಕ್ಕೆ ಸರಿದರೆ ನನ್ನ ಭವಿಷ್ಯದ ಕಾಳಜಿ ಹಾಗೂ ಆರೈಕೆಯಲ್ಲಿ ಬದಲಾಗುವುದಿಲ್ಲ ಎಂದು ತಿಳಿದಿದ್ದೇನೆ. ಅಧ್ಯಯನದ ಉದ್ದೇಶವನ್ನು ನಾನು ಓದಿ/ಓದಿಸಿ ಅರ್ಥೈಸಿಕೊಂಡಿದ್ದೇನೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಪಾಲ್ಗೊಳ್ಳುವಿಕೆ ಮತ್ತು ಇದರ ಅಪಾಯ ಉಪಯೋಗಗಳ ಬಗ್ಗೆ ನನಗೆ ಮನದಟ್ಟುಗೊಳಿಸಲಾಗಿದೆ. ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಸಂಗ್ರಹಿಸಿದ ಮಾಹಿತಿಯ ಬಗ್ಗೆ ನನಗೆ ತಿಳಿಸಲಾಗಿದೆ. ಒದಗಿಸಿದ ಮಾಹಿತಿ ಸ್ವರೂಪ ಸಂಬಂದಿತ ಪ್ರಯೋಗಗಳನ್ನು, ಶಸ್ತ್ರ ಚಿಕಿತ್ಸೆಯ ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ನನಗೆ ಮುಕ್ತ ಅವಕಾಶ ನೀಡಲಾಗಿದೆ ನನ್ನ ಪ್ರಶ್ನೆಗಳಿಗೆ ಪ್ರಬಂಧಕಾರರ ಉತ್ತರಗಳು ನನಗೆ ತೃಪ್ತಿ ನೀಡಿದೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಮತ್ತು ಸಂಗ್ರಹಿದ ವಿಷಯಗಳನ್ನು ಪ್ರೌಢಪ್ರಬಂಧದಲ್ಲಿ ಬಹಿರಂಗಪಡಿಸಲು ನನ್ನ ವೈಯಕ್ತಿಕ ಒಪ್ಪಿಗೆ ಇರುತ್ತದೆ ಎಂದು ಒಪ್ಪಿ ರುಜು/ ಹೆಬ್ಬೆಟ್ಟಿನ ಗುರುತು ನೀಡಿ ಅಧಿಕೃತಗೊಳಿಸಿರುತ್ತೇನೆ.

ಮೇಲಿನ ಮಾಹಿತಿಯನ್ನು ನೀಡಿದವರ ಹೆಸರು:–

1. ಪೊಷಕರ ಹೆಸರು
2. ಪಾಲಕರ ಹೆಸರು

ರೋಗಿಯ ಸಂಬಂದ: ಸಹಿ/ಹೆಬ್ಬೆಟ್ಟಿನ ಗುರುತು

ದಿನಾಂಕ:

III.PROFORMA

Name		Age	
UHID		Sex	
DOA		DOD	

CHIEF COMPLAINTS:

PAST HISTORY:

Diabetes Mellitus	
Hypertension	
Asthma	
Epilepsy	
Previous Surgeries	
Use of steroids	

PESONAL HISTORY:

Smoking	
Tobacco Chewing	
Alcohol	

GENERAL PHYSICAL EXAMINATION:

	Poor	Moderate	Well
Built			
Nourishment			

Pallor		Clubbing	
Icterus		Lymphadenopathy	
Cyanosis		Edema	
Weight			

DIAGNOSIS:

INDICATION FOR SURGERY:

NO. OF PRE-OPERATIVE DAYS STAY IN HOSPITAL:

ELECTIVE/EMERGENCY:

DATE OF SURGERY:

INTRA OPERATIVE FINDINGS:

TYPE OF WOUND:

Clean	
Clean Contaminated	
Contaminated	
Dirty	

POST OPERATIVE WOUND ASSESSMENT:

Post op day							
Fever							
Erythema							
Local rise of temperature							
Pain/Tenderness							
Local Swelling							
Discharge							
Inference=Wound	**Healthy**						
	Unhealthy						

DURATION OF STAY IN THE HOSPITAL:

CONDITION OF THE PATIENT AT DISCHARGE:

IV. KEY TO MASTER CHART

Sl No – Serial Number

M- Male

F- Female

UHID No- Unique Hospital Identification Number

DOA- Date of Admission

DOS- Date of Surgery

Elec- Elective

Emer- Emergency

No of Hrs- Number of Hours

DM- Type II diabetes mellitus

HTN- Hypertension

SSSI- Superficial surgical site infection

POD- Post-operative Day

ANNEXURE IV

MASTER CHART

SL.NO	A/B	UHID NO.	AGE/SEX	WEIGHT	DIAGNOSIS	DOA	DOS	SURGERY	NO. OF HRS OF SURGERY	ELEC/EMER	NO. OF PRE OP DAYS	CLASS OF WOUND	POST OP WOUND	ON WHICH POST OP DAY	SOUTHAMPTON GRADING	POST OP PAIN ASSESSMENT	DURATION OF STAY	DM	HTN	SYSTSTEROIDS	ANEMIA	NICOTINE	INTRA OP ANTIBIOTICS	
1	B	377501	40/M	60	UMBILICAL HERNIA	19/12/16	20/12/16	MESHPLASTY	1.5	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	0	1	
2	A	373365	49/M	65	INCISIONAL HERNIA	24/11/16	28/11/16	MESHPLASTY	2	ELEC	4	CLEAN	HEALTHY				10	0	0	0	0	0	1	
3	A	373753	31/M	50	INGUINAL HERNIA	12/12/16	13/12/16	HERNIOPLASTY	1	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	1	1	
4	A	360406	47/M	60	INGUINAL HERNIA	14/11/16	15/11/16	HERNIOPLASTY	1	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	1	1	
5	B	386082	60/M	68	INGUINAL HERNIA	9/1/17	10/1/17	HERNIOPLASTY	1	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	1	1	
6	B	110136	22/F	68	UMBILICAL HERNIA	16/1/17	18/1/17	MESHPLASTY	1.5	ELEC	2	CLEAN	UNHEALTHY	3	GRADE 3	MODERATE	18	0	0	0	0	0	1	
7	A	385962	45/M	55	INGUINAL HERNIA	9/1/17	11/1/17	HERNIOPLASTY	1	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	1	1	
8	A	383060	48/F	57	UMBILICAL HERNIA	9/1/17	11/1/17	MESHPLASTY	1	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
9	A	383050	26/M	70	INGUINAL HERNIA	16/1/17	18/1/17	HERNIOPLASTY	1	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
10	A	392471	60/F	70	UMBILICAL HERNIA	27/1/17	30/1/17	MESHPLASTY	1	ELEC	3	CLEAN	HEALTHY				10	0	0	0	0	0	1	
11	B	402303	35/F	58	MNG	20/2/17	1/3/17	SUB TOTAL THY	3	ELEC	12	CLEAN	UNHEALTHY	3	GRADE 2	MODERATE	15	0	0	0	1	0	1	
12	A	397168	55/F	63	LIPOMA	6/2/17	8/2/17	EXCISION	1	ELEC	2	CLEAN	HEALTHY				8	0	0	0	0	0	1	
13	B	404769	48/F	65	INCISIONAL HERNIA	6/2/2017	8/2/2017	MESHPLASTY	2	ELEC	2	CLEAN	HEALTHY				12	0	0	0	0	0	1	
14	A	330214	46/F	58	INCISIONAL HERNIA	6/2/17	8/2/17	MESHPLASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
15	B		38/M	75	INCISIONAL HERNIA	6/2/2017	8/2/2017	MESHPLASTY	2	ELEC	2	CLEAN	HEALTHY			MODERATE	12	0	0	0	0	0	1	
16	A	381749	51/M	76	INGUINAL HERNIA	11/2/17	15/2/17	HERNIOPLASTY	1.5	ELEC	4	CLEAN	HEALTHY				10	0	0	0	0	0	1	
17	B		42/M	72	UMBILICAL HERNIA	11/2/2017	15/2/17	MESHPLASTY	1.5	ELEC	3	CLEAN	HEALTHY				10	0	0	0	0	0	1	
18	A	400917	29/F	60	FIBROADENOMA	16/2/17	22/2/17	EXCISION	1	ELEC	5	CLEAN	HEALTHY				8	0	0	0	0	0	1	
19	A	407683	48/M	78	INGUINAL HERNIA	6/3/17	8/3/17	HERNIOPLASTY	1.5	ELEC	2	CLEAN	HEALTHY				12	0	0	0	0	0	1	
20	B	484478	60/M	70	INGUINAL HERNIA	8/3/17	10/3/17	HERNIOPLASTY	2	ELEC	3	CLEAN	HEALTHY				10	0	0	0	0	1	1	
21	A	385022	46/F	64	INCISIONAL HERNIA	18/3/17	22/3/17	MESHPLASTY	2.5	ELEC	4	CLEAN	HEALTHY				12	0	0	0	0	0	1	
22	A	417989	50/F	60	LIPOMA	2/4/17	12/4/17	EXCISION	1	ELEC	10	CLEAN	HEALTHY				8	0	0	0	0	0	1	
23	B	362219	25/F	50	MNG	10/4/17	19/4/17	SUB TOTAL THY	3.5	ELEC	8	CLEAN	UNHEALTHY	3	GRADE 2	MODERATE	15	0	0	0	1	0	1	
24	B	425070	30/M	68	INGUINAL HERNIA	20/4/17	24/4/17	HERNIOPLASTY	1.5	ELEC	4	CLEAN	HEALTHY				10	0	0	0	0	1	1	
25	B	426485	56/F	55	INCISIONAL HERNIA	24/4/17	26/4/17	MESHPLASTY	2.5	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
26	A	419928	51/F	48	MNG	10/4/17	12/4/17	SUB TOTAL THY	3.5	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
27	B	426331	48/F	65	INCISIONAL HERNIA	24/4/17	26/4/17	MESHPLASTY	2	ELEC	2	CLEAN	HEALTHY			MILD	12	0	0	0	0	0	1	
28	A	429225	60/M	68	INGUINAL HERNIA	8/5/17	10/5/17	HERNIOPLASTY	1	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
29	A	431228	60/F	58	FEMORAL HERNIA	6/5/17	10/5/17	HERNIOPLASTY	1.5	ELEC	5	CLEAN	HEALTHY				10	0	0	0	0	0	1	
30	A	433390	60/M	71	INGUINAL HERNIA	12/5/17	12/5/17	**HERNIOPLASTY**	**1.5**	**ELEC**	1	CLEAN	HEALTHY				10	0	0	0	0	0	1	
31	A	434414	35/F	58	UMBILICAL HERNIA	15/5/17	17/5/17	MESHPLASTY	2	ELEC	2	CLEAN	HEALTHY				12	0	0	0	1	0	1	
32	A	433859	37/F	68	UMBILICAL HERNIA	21/5/17	22/5/17	MESHPLASTY	2	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	0	1	
33	B	435524	60/M	68	INGUINAL HERNIA	25/5/17	25/5/17	HERNIOPLASTY	1.5	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	1	1	
34	A	434338	45/F	55	MNG	23/5/17	24/5/17	SUB TOTAL THY	4	ELEC	1	CLEAN	UNHEALTHY	3	GRADE 3	MODERATE	15	0	0	0	1	0	1	
35	B	390515	38/F	56	INCISIONAL HERNIA	25/5/17	29/5/17	MESHPLASTY	2.5	ELEC	4	CLEAN	HEALTHY				10	0	0	0	0	0	1	
36	A	409814	26/M	68	INGUINAL HERNIA	3/6/17	4/6/17	HERNIOPLASTY	1.5	ELEC	1	CLEAN	HEALTHY				12	0	0	0	1	0	1	
37	A	384083	60/F	60	MNG	1/6/17	6/6/17	SUB TOTAL THY	3	ELEC	5	CLEAN	HEALTHY				10	0	0	0	0	0	1	
38	A	442618	60/M	65	INGUINAL HERNIA	5/6/17	7/6/17	HERNIOPLASTY	1.5	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	1	1	
39	B	440890	60/M	70	UMBILICAL HERNIA	1/6/17	1/6/17	MESHPLASTY	2	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	0	1	
40	A	442050	38/M	68	INGUINAL HERNIA	3/6/17	8/6/17	HERNIOPLASTY	1.5	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	1	1	
41	A	444153	56/M	62	INGUINAL HERNIA	9/6/17	10/6/17	**HERNIOPLASTY**	**1.5**	**ELEC**	1	CLEAN	HEALTHY				10	0	0	0	0	1	1	
42	B	448314	19/F	50	FIBROADENOMA	19/6/17	20/6/17	EXCISION	1	ELEC	1	CLEAN	HEALTHY				8	0	0	0	0	0	1	

SL.NO	A/B	UHID NO.	AGE/SEX	WEIGHT	DIAGNOSIS	DOA	DOS	SURGERY	NO. OF HRS OF SURGERY	ELEC/EMER	NO. OF PRE OP DAYS	CLASS OF WOUND	POST OP WOUND	ON WHICH POST OP DAY	SOUTHAMPTON GRADING	POST OP PAIN ASSESSMENT	DURATION OF STAY	DM	HTN	SYSTSTEROIDS	ANEMIA	NICOTINE	INTRA OP ANTIBIOTICS	
43	B	446011	54/F	65	SPIGELIAN HERNIA	14/6/17	23/6/17	MESHPLASTY	2	ELEC	9	CLEAN	HEALTHY				13	0	0	0	0	0	1	
44	B	451156	55/M	78	EPIGASTRIC HERNIA	26/6/17	28/6/17	MESHPLASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
45	B	345676	28/F	56	FIBROADENOMA	28/6/17	29/6/17	EXCISION	1	ELEC	1	CLEAN	HEALTHY				6	0	0	0	0	0	1	
46	A	450641	40/M	70	INGUINAL HERNIA	9/7/17	11/7/17	HERNIOPLASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	1	1	1	
47	B	457165	54/F	65	UMBILICAL HERNIA	9/7/17	10/7/17	MESHPLASTY	2	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	0	1	
48	B	449285	45/F	65	UMBILICAL HERNIA	15/7/17	20/7/17	MESHPLASTY	2	ELEC	5	CLEAN	HEALTHY				10	0	0	0	0	0	1	
49	A	462942	60/F	55	INGUINAL HERNIA	24/7/17	25/7/17	HERNIOPLASTY	1.5	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	0	1	
50	A	465778	25/M	68	LIPOMA	27/7/17	31/7/17	EXCISION	1	ELEC	4	CLEAN	HEALTHY				8	0	0	0	0	0	1	
51	B	463768	56/M	70	INGUINAL HERNIA	22/7/17	24/7/17	HERNIOPLASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	1	1	
52	A	467557	37/M	72	INGUINAL HERNIA	30/7/17	2/8/17	HERNIOPLASTY	1.5	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	1	1	
53	A	467845	60/M	65	INGUINAL HERNIA	31/7/17	2/8/17	HERNIOPLASTY	1.5	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
54	A	467849	60/M	75	INGUINAL HERNIA	2/8/17	2/8/17	HERNIOPLASTY	2	ELEC	1	CLEAN	HEALTHY				12	0	0	0	0	1	1	
55	B	466925	31/F	54	UMBILICAL HERNIA	2/8/17	5/8/17	MESHPLASTY	2	ELEC	3	CLEAN	HEALTHY				10	0	0	0	1	0	1	
56	A	467984	60/M	65	INGUINAL HERNIA	31/7/17	5/8/17	HERNIOPLASTY	2	ELEC	5	CLEAN	HEALTHY				10	0	0	0	0	1	1	
57	A	471373	60/M	67	UMBILICAL HERNIA	8/8/17	9/8/17	MESHPLASTY	2	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	0	1	
58	A	472270	30/M	65	INGUINAL HERNIA	9/8/17	11/8/17	MESHPLASTY	2	ELEC	2	CLEAN	HEALTHY				12	0	0	0	0	0	1	
59	B	475324	35/M	70	EPIGASTRIC HERNIA	16/8/17	18/8/17	MESHPLASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
60	B	472110	30/F	70	UMBILICAL HERNIA	16/8/17	18/8/17	MESHPLASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
61	A	475404	32/M	75	INGUINAL HERNIA	16/8/17	18/8/17	HERNIOPLASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
62	B	481109	40/M	75	INGUINAL HERNIA	30/8/17	30/8/17	HERNIOPLASTY	1.5	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	0	1	
63	A	473190	55/M	60	MNG	11/8/17	22/8/17	SUB TOTAL THY	3	ELEC	10	CLEAN	HEALTHY				10	0	0	0	0	0	1	
64	A	477087	35/M	76	INGUINAL HERNIA	21/8/17	23/8/17	HERNIOPLASTY	1	ELEC	2	CLEAN	HEALTHY				11	0	0	0	0	1	1	
65	A	468994	60/M	75	INGUINAL HERNIA	21/8/17	23/8/17	HERNIOPLASTY	1.5	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	1	1	
66	A	477334	51/M	78	INGUINAL HERNIA	21/8/17	23/8/17	HERNIOPLASTY	1.5	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	1	1	
67	B	437960	48/M	70	INGUINAL HERNIA	10/9/17	11/9/17	HERNIOPLASTY	2	ELEC	1	CLEAN	HEALTHY				10	0	0	0	1	0	1	
68	A	426880	60/M	60	INGUINAL HERNIA	26/8/17	26/8/17	HERNIOPLASTY	2	ELEC	1	CLEAN	HEALTHY				12	0	0	0	0	1	1	
69	A	480559	43/M	65	INGUINAL HERNIA	28/8/17	9/9/17	HERNIOPLASTY	1.5	ELEC	10	CLEAN	HEALTHY				10	0	0	0	0	0	1	
70	A	482481	60/M	64	INGUINAL HERNIA	4/9/17	5/9/17	HERNIOPLASTY	1.5	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	1	1	
71	B	481966	27/M	78	INGUINAL HERNIA	31/8/17	2/9/17	HERNIOPLASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	1	1	
72	B	478465	60/M	67	INGUINAL HERNIA	5/9/17	8/9/17	HERNIOPLASTY	2	ELEC	3	CLEAN	HEALTHY				13	0	0	0	0	1	1	
73	B	481419	60/M	70	INGUINAL HERNIA	30/8/17	8/9/17	HERNIOPLASTY	2	ELEC	8	CLEAN	HEALTHY				10	0	0	0	1	0	1	
74	A	484108	31/M	65	INGUINAL HERNIA	5/9/17	11/9/17	HERNIOPLASTY	1.5	ELEC	6	CLEAN	HEALTHY				10	0	0	0	0	1	1	
75	A	492829	52/M	56	UMBILICAL HERNIA	25/9/17	26/9/17	MESHPLASTY	2	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	0	1	
76	B	489348	44/M	85	UMBILICAL + EPIGASTRIC HERNIA	16/9/17	21/9/17	MESHPLASTY	2.5	ELEC	4	CLEAN	**UH**	3	GRADE 2	MILD	14	0	0	0	1	0	1	
77	B	492328	60/M	78	INGUINAL HERNIA	23/9/17	28/9/17	HERNIOPLASTY	1.5	ELEC	5	CLEAN	HEALTHY				10	0	0	0	0	1	1	
78	A	492514	35/F	60	INCISIONAL HERNIA	26/9/17	27/9/17	MESHPLASTY	2	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	0	1	
79	A	492922	60/M	70	INGUINAL HERNIA	25/9/17	28/9/17	HERNIOPLASTY	1.5	ELEC	3	CLEAN	UH	3	GRADE 2	MILD	15	0	0	0	0	1	1	
80	B	493651	45/M	70	INGUINAL HERNIA	26/9/17	5/10/17	HERNIOPLASTY	1.5	ELEC	9	CLEAN	HEALTHY				10	0	0	0	0	0	1	
81	A	492305	23/F	54	FIBROADENOMA	27/9/17	28/9/17	EXCISION	1	ELEC	2	CLEAN	HEALTHY				6	0	0	0	0	0	1	
82	B	497081	45/M	69	INGUINAL HERNIA	4/10/17	6/10/17	HERNIOPLASTY	1	ELEC	2	CLEAN	HEALTHY				10	0	0	0	1	0	1	
83	B	491112	60/M	70	INGUINAL HERNIA	12/10/17	13/10/17	HERNIOPLASTY	2	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	1	1	
84	B	497001	42/M	78	INGUINAL HERNIA	11/10/17	12/10/17	HERNIOPLASTY	2	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	0	1	

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85	B	500367	52/M	76	INGUINAL HERNIA	12/10/17	16/10/17	HERNIOPLASTY	2	ELEC	4	CLEAN	HEALTHY				10	0	0	0	0	0	1	
86	A	355811	60/M	80	EPIGASTRIC HERNIA	28/9/17	3/10/17	MESHPLASTY	2.5	ELEC	4	CLEAN	HEALTHY				10	0	0	0	0	0	1	
87	B	498042	28/F	48	FIBROADENOMA	6/10/17	10/10/17	EXCISION	1	ELEC	4	CLEAN	HEALTHY				4	0	0	0	0	0	1	
88	B	500734	58/M	68	INCISIONAL HERNIA	13/10/17	16/10/17	MESHPLASTY	2	ELEC	3	CLEAN	HEALTHY				10	0	0	0	0	0	1	
89	B	499147	28/M	70	INGUINAL HERNIA	16/10/17	18/10/17	HERNIOPLASTY	1.5	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	1	1	
90	B	501300	45/M	70	UMBILICAL HERNIA	16/10/17	18/10/17	MESHPLASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
91	B	504925	52/M	75	INGUINAL HERNIA	23/10/17	25/10/17	HERNIOPLASTY	1.5	ELEC	2	CLEAN	UNHEALTHY	3	GRADE 3	MILD	15	0	0	0	1	0	1	
92	B	509729	47/M	76	UMBILICAL HERNIA	4/11/17	6/11/17	MESHPLASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
93	B	506073	52/M	75	UMBILICAL HERNIA	1/11/17	3/11/17	MESHPLASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
94	B	509044	25/M	70	INGUINAL HERNIA	1/11/17	3/11/17	HERNIOPLASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
95	B	510286	26/F	60	UMBILICAL HERNIA	6/11/17	21/11/17	MESHPLASTY	2	ELEC	12	CLEAN	HEALTHY				10	0	0	0	1	0	1	
96	A	495128	35/F	58	FIBROADENOMA	29/9/17	3/10/17	EXCISION	1	ELEC	4	CLEAN	HEALTHY				8	0	0	0	0	0	1	
97	B	510250	34/F	55	UMBILICAL HERNIA	6/11/17	21/11/17	MESHPLASTY	2	ELEC	15	CLEAN	HEALTHY				10	0	0	0	0	0	1	
98	A	521170	58/F	50	INCISIONAL HERNIA	3/1/18	12/1/18	MESHPLASTY	2	ELEC	8	CLEAN	HEALTHY				10	0	0	0	0	0	1	
99	A	530091	32/M	48	INGUINAL HERNIA	3/1/18	11/1/18	HERNIOPLASTY	1.5	ELEC	7	CLEAN	HEALTHY				12	0	0	0	0	0	1	
100	A	534363	28/F	45	FIBROADENOMA	11/1/18	20/1/18	EXCISION	1	ELEC	8	CLEAN	HEALTHY				6	0	0	0	0	0	1	
101	A	534750	51/M	70	INGUINAL HERNIA	12/1/18	24/1/18	HERNIOPLASTY	1.5	ELEC	12	CLEAN	HEALTHY				10	0	0	0	0	1	1	
102	A	534662	50/F	55	INCISIONAL HERNIA	3/2/18	9/2/18	MESHPLASTY	2	ELEC	5	CLEAN	HEALTHY				12	0	0	0	1	0	1	
103	B	536719	38/M	78	INGUINAL HERNIA	29/1/18	2/2/18	HERNIOPLASTY	2	ELEC	4	CLEAN	HEALTHY				10	0	0	0	0	1	1	
104	B	480283	40/F	65	INCISIONAL HERNIA	29/1/18	2/2/18	MESHPLASTY	2	ELEC	4	CLEAN	HEALTHY				10	0	0	0	0	0	1	
105	B	540767	53/M	70	INGUINAL HERNIA	6/2/18	17/2/18	HERNIOPLASTY	2	ELEC	10	CLEAN	HEALTHY				10	0	0	0	0	0	1	
106	B	551601	41/F	65	INCISIONAL HERNIA	26/2/18	8/3/18	MESHPLASTY	2	ELEC	10	CLEAN	HEALTHY				10	0	0	0	0	0	1	
107	A	530834	55/M	78	INGUINAL HERNIA	22/2/18	22/2/18	HERNIOPLASTY	2	ELEC	1	CLEAN	HEALTHY				12	0	0	0	0	1	1	
108	A	542297	57/F	57	MNG	26/2/18	27/2/18	SUB TOTAL THY	3	ELEC	1	CLEAN	HEALTHY				10	0	0	0	1	0	1	
109	A	546576	51/M	75	UMBILICAL HERNIA	28/2/18	1/3/18	MESHPLASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
110	B	637560	54/M	77	UMBILICAL HERNIA	10/10/18	12/10/18	MESHPLASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
111	A	549888	52/M	70	INGUINAL HERNIA	1/3/18	2/3/18	HERNIOPLASTY	1.5	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	0	1	
112	A	549417	25/F	45	UMBILICAL HERNIA	6/3/18	7/3/18	MESHPLASTY	2.5	ELEC	1	CLEAN	HEALTHY				12	0	0	0	0	0	1	
113	B	631811	26/M	75	RIGHT INGUINAL HERNIA	25/9/18	27/9/18	HERNIOPLASTY	1.5	ELEC	2	CLEAN	**UNHEALTHY**	3	GRADE 3	MILD	15	0	0	0	1	0	1	
114	B	582462	51/M	58	LEFT INGUINAL HERNIA	9/10/18	11/10/18	HERNIOPLASTY	1.5	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	1	1	
115	A	506826	30/F	65	UMBILICAL HERNIA	28/2/18	7/3/18	MESHPLASTY	2	ELEC	7	CLEAN	HEALTHY				10	0	0	0	0	0	1	
116	B	638143	60/M	57	LEFT INGUINAL HERNIA	15/10/18	16/10/18	HERNIOPLASTY	2	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	0	1	
117	B	555134	48/F	65	LIPOMA	7/3/18	9/3/18	EXCISION	1	ELEC	2	CLEAN	HEALTHY				6	0	0	0	0	0	1	
118	B	552961	40/F	50	MNG	1/3/18	6/3/18	NEAR TOTAL THY	4	ELEC	5	CLEAN	HEALTHY				10	0	0	0	0	0	1	
119	A	553413	58/M	65	INGUINAL HERNIA	13/3/18	16/3/18	MESHPLASTY	2	ELEC	3	CLEAN	HEALTHY				10	0	0	0	0	0	1	
120	B	610505	60/M	60	LEFT DIRECT INGUINAL HERNIA	30/7/18	3/8/18	HERNIOPLASTY	2	ELEC	4	CLEAN	HEALTHY				10	0	0	0	1	1	1	
121	B	595590	40/F	60	EPIGASTRIC HERNIA	9/7/18	13/7/18	MESHPLASTY	2	ELEC	4	CLEAN	HEALTHY				10	0	0	0	0	0	1	
122	B	598415	40/M	70	RIGHT DIRECT INGUINAL HERNIA	4/7/18	6/7/18	HERNIOPLASTY	1.5	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	1	1	
123	B	478084	36/F	60	UMBILICAL HERNIA	18/7/18	20/7/18	MESHPLASTY	2.5	ELEC	2	CLEAN	HEALTHY				10	0	0	0	1	0	1	
124	B	592586	28/M	75	RIGHT INDIRECT INGUINAL HERNIA	13/6/18	15/6/18	HERNIOPLASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
125	B	584146	60/M	75	RIGHT DIRECT INGUINAL HERNIA	23/5/18	29/5/18	HERNIOPLASTY	2	ELEC	5	CLEAN	HEALTHY				10	0	0	0	0	0	1	
126	A	570507	45/M	78	PARA UMBILICAL HERNIA	17/4/18	20/4/18	MESHPLASTY	2	ELEC	3	CLEAN	HEALTHY				10	0	0	0	0	0	1	

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127	A	574143	55/M	65	RIGHT IRREDUCIBLE INGUINAL HERNIA	26/4/18	2/5/18	HERNIOPLASTY	1.5	ELEC	7	CLEAN	HEALTHY				10	0	0	0	1	1	1	
128	B	577317	26/M	70	RIGHT INDIRECT INGUINAL HERNIA	10/5/18	18/5/18	HERNIOPLASTY	1.5	ELEC	5	CLEAN	HEALTHY				10	0	0	0	0	0	1	
129	B	565444	55/M	65	RIGHT RECURRENT INGUINAL HERNIA,LEFT DIRECT INGUINAL HERNIA	4/4/18	6/4/18	HERNIOPLASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	1	1	1	
130	B	565758	23/M	66	LEFT INDIRECT COMPLETE INGUINAL HERNIA	4/4/18	6/4/18	HERNIOPLASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	1	1	
131	A	559311	52/F	70	INCISIONAL HERNIA	17/3/18	29/3/18	MESHPLASTY	2	ELEC	9	CLEAN	UNHEALTHY	3	SOUTHAMPTON GRADE 2	MILD	13	0	0	0	1	0	1	
132	A	565438	48/M	60	RIGHT INDIRECT INGUINAL HERNIA	4/4/18	6/4/18	HERNIOPLASTY	2	ELEC	2	CLEAN	UNHEALTHY	3	SOUTHAMPTON GRADE 3	MILD	15	0	0	0	1	0	1	
133	A	563125	38/F	55	UMBILICAL HERNIA	16/3/18	19/3/18	MESHPLASTY	2.5	ELEC	3	CLEAN	HEALTHY				10	0	0	0	0	0	1	
134	B	559666	60/M	60	UMBILICAL HERNIA	19/3/18	21/3/18	ANATOMICAL REPAIR	2	ELEC	2	CLEAN	HEALTHY				12	0	0	0	0	0	1	
135	A	552256	60/M	60	B/L INGUINAL HERNIA	28-2-18	5-3-18	HERNIOPLASTY	2	ELEC	6	CLEAN	HEALTHY				10	0	0	0	0	1	1	
136	B	591487	51/F	50	UMBILICAL HERNIA	27-6-18	3-7-18	MESHPLASTY	2	ELEC	6	CLEAN	HEALTHY				10	0	0	0	0	0	1	
137	A	608894	25/F	55	LEFT INGUINAL HERNIA	25-7-18	27-7-18	HERNIOPLASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
138	B	594763	60/M	60	UMBILICAL HERNIA	19-6-18	28-6-18	MESHPLASTY	2	ELEC	10	CLEAN	UNHEALTHY	3	SOUTHAMPTON GRADE 1	MILD	12	0	0	0	0	0	1	
139	B	582575	30/F	65	FIBROADENOMA	19-5-18	24-5-18	EXCISION AND BIOPSY	1	ELEC	5	CLEAN	HEALTHY				8	0	0	0	1	0	1	
140	A	603564	42/F	70	INCISIONAL HERNIA	25-7-18	27-7-18	MESHPLASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	0	0	1	
141	B	561087	38/F	70	MNG	25-3-18	26-3-18	SUBTOTAL THY	3	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	0	1	
142	B	592516	50/F	60	MNG	13-6-18	4-7-18	TOTAL THY	4	ELEC	18	CLEAN	HEALTHY				10	0	0	0	0	0	1	
143	A	622896	28/M	70	RIGHT INGUINAL HERNIA	1-9-18	6-9-18	HERNIOPLASTY	2	ELEC	5	CLEAN	HEALTHY				10	0	0	0	0	0	1	
144	A	624521	29/F	50	FIBROADENOMA	6-9-18	7-9-18	EXCISION AND BIOPSY	1	ELEC	1	CLEAN	HEALTHY				10	0	0	0	0	0	1	
145	B	590691	40/M	70	RIGHT INGUINAL HERNIA	10-6-18	12-6-18	HERNIOPL;ASTY	2	ELEC	2	CLEAN	HEALTHY				10	0	0	0	1	0	1	
146	B	596540	50/M	65	EPIGASTRIC HERNIA	22-6-18	26-6-18	MESHPLASTY	2	ELEC	4	CLEAN	HEALTHY				10	0	0	0	0	0	1	