"SUBCUTANEOUS WOUND DRAINAGE VS CONVENTIONAL CLOSURE IN REDUCING SURGICAL SITE INFECTION AFTER LAPAROTOMY FOLLOWING PERITONITIS- A RANDOMISED CONTROL TRIAL"

BY

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

Dissertation

Submitted to the

KLE Academy of Higher Education and Research, Belagavi, Karnataka

In partial fulfillment

of the requirements for the degree of

MASTER OF SURGERY(M.S)

IN

GENERAL SURGERY

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

APRIL - 2019

KLE Academy of Higher Education and Research, Belagavi, KARNATAKA

Endorsement by the HOD/ Principal/ Head of the Institution

This is to certify that the dissertation entitled **"SUBCUTANEOUS WOUND DRAINAGE VS CONVENTIONAL CLOSURE IN REDUCING SURGICAL SITE INFECTION AFTER LAPAROTOMY FOLLOWING PERITONITIS- A RANDOMISED CONTROL TRIAL"** is a bonafide research work done by **Dr. SHETTY VIVEK RAGHURAM** under the guidance of **Dr. S. S. SHIMIKORE** **M.S** Professor, Department of General Surgery, Jawaharlal Nehru Medical College, Nehru Nagar, Belagavi-590010.

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LIST OF ABBREVIATIONS USED

SSI	:	Surgical Site Infection
SBO	:	Small Bowel Obstruction
BMI	:	Basal Metabolic Rate
ASA	:	American Society of Anaethesiologists
SIRS	:	Systemic Inflammatory Response Syndrome
MODS	:	Multi Organ Dysfunction Syndrome
CDC	:	Center for Disease Control and Prevention
CDC-NHSN	:	Center for Disease Control and Prevention- National Healthcare Safety Networks
NNIS	:	National Nosocomial Infection Surveillance
IPA	:	Isopropyl Alcohol
TRAPE	:	Trial to Reduce Anti-microbial Prophylaxis Errors

ABSTRACT

Background and objectives

Surgical site infection is one of the most common complications of laparotomy for perforation peritonitis with delayed recovery, increased cost of treatment, mental trauma to the patient and the possibility of future complications. The study undertaken aimed to determine which is a better method of closure of the abdomen post laparotomy for perforation peritonitis with regards to seroma formation, wound infection and wound dehiscence.

Methodology

This one year randomized controlled trial was done with the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, from January 2017 to December 2017. A total of 100 patients operated for laparotomy for perforation peritonitis were studied. The patients were divided into two groups of 50 each as Group A (Placement of negative suction subcutaneous drain) and Group B (Conventional closure)

Results

In the present study we noted that the incidence of seroma formation, wound infection(SSI) and wound dehiscence were significantly lower with a *P* value of <0.0001 measured for all the three parameters in patients in whom negative suction subcutaneous drain was placed as compared to conventional closure of the abdomen post laparotomy for perforation peritonitis.

Conclusion and Interpretation

Overall, we noted that subcutaneous wound drainage is a better method of abdominal closure as compared to conventional abdominal closure post laparotomy for perforation peritonitis with regards to seroma formation, wound infection and wound dehiscence.

Key words

Negative suction, perforation peritonitis, surgical site infection, wound dehiscence.

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INTRODUCTION

Peritonitis is one of the most commonly encountered surgical emergencies in tropical countries like India[1]. It is more commonly seen in males as compared to females and usually seen in the middle aged and older age group. In countries like India, peritonitis of the proximal gastro-intestinal tract is more common whereas in developed countries perforations of the distal gastro-intestinal tract are found to be more common[2].

In spite of advances in surgical techniques, intensive care and newer antibiotics, the management of perforation peritonitis continues to be challenging. Along with these factors, due to unavailability of emergency support in rural areas and the shortage of quality care, majority of these patients present to the hospital after delay when peritonitis has already set in. In these cases, there is established generalized peritonitis with faecal/ purulent contamination and septicaemia of varying degree. The signs and symptoms are usually typical and a diagnosis of peritonitis can be made in almost all patients.

Perforation peritonitis usually presents with gross contamination of the peritoneal cavity and falls in the class IV of wound classification and hence the probability of post-operative wound contamination is high[3,4,5].

Surgical Site Infection (SSI) are defined as wound infection following an invasive surgical procedure[6]. They are one of the most common complication following any invasive procedure. Laparotomies carry a higher risk compared to other surgeries[7] and amongst laparotomies the risk is even higher when laparotomy is done for perforation peritonitis.

SSIs lead to increased hospital stay, increased morbidity and mortality, decreased health related quality of life, increased cost of treatment and unnecessary patient suffering[8].

SSIs have also been shown to be a factor in developing late complications like incisional hernias[9], which in turn has been shown to be associated with increased morbidity, decreased quality of life and economic hardships. Studies have also been undertaken to find out the relationship between SSIs and small bowel obstruction (SBO)[9].

Various risk factors have been identified for the development of SSIs such as smoking, high BMI and obesity[10]. Other factors include nutrition, diabetic control, other comorbidities, ASA class, operating time and the level of intra-abdominal contamination[11,12].

Various interventions have been proposed to reduce SSIs. They include routinely used techniques like hand washing, minimising shaving, preoperative antibiotics and skin preparation[13,14,15,16].

However, the use of drains to reduce SSIs is not routinely followed[17,18]. It is believed that the presence of haematoma, bacterial load, dead space and serous fluid in surgical incisional wounds increases the risk of SSIs as this acts as a culture medium[19,20]. Hence by using subcutaneous drains with negative suction it is attempted to tackle the above mentioned factors for reducing surgical site infection[21].

OBJECTIVES

The objective of this study is to evaluate and compare the seroma formation, wound infection and wound dehiscence following conventional closure of the abdomen with and without negative suction subcutaneous drain following laparotomy for peritonitis.

REVIEW OF LITERATURE

Abdominal wall

Anatomy

There are nine layers to the abdominal wall: skin, subcutaneous tissue, superficial fascia, external oblique muscle, internal oblique muscle, transversus abdominis muscle, transversalis fascia, preperitoneal adipose and areolar tissue, and peritoneum[22]

Subcutaneous Fascia

The subcutaneous tissue consists of Camper and Scarpa fasciae-

Camper is the superficial adipose layer that contains the bulk of the subcutaneous fat and Scarpa fascia is a deeper, denser layer of fibrous connective tissue contiguous with the fascia lata of the thigh. Approximation of Scarpa fascia aids in the alignment of the skin after surgical incisions in the lower abdomen.

Muscle and Investing Fascia

The muscles of the anterolateral abdominal wall include the external and internal oblique and transversus abdominis. These flat muscles enclose most of the circumference of the torso giving rise to a broad flat aponeurosis investing the rectus abdominis muscles, termed the *rectus sheath.*

The external oblique are the thickest and largest of the flat abdominal wall muscles. Their origin is from the lower seven ribs and travel in a superolateral to inferomedial direction. The posterior of the fibers run vertically downward to insert

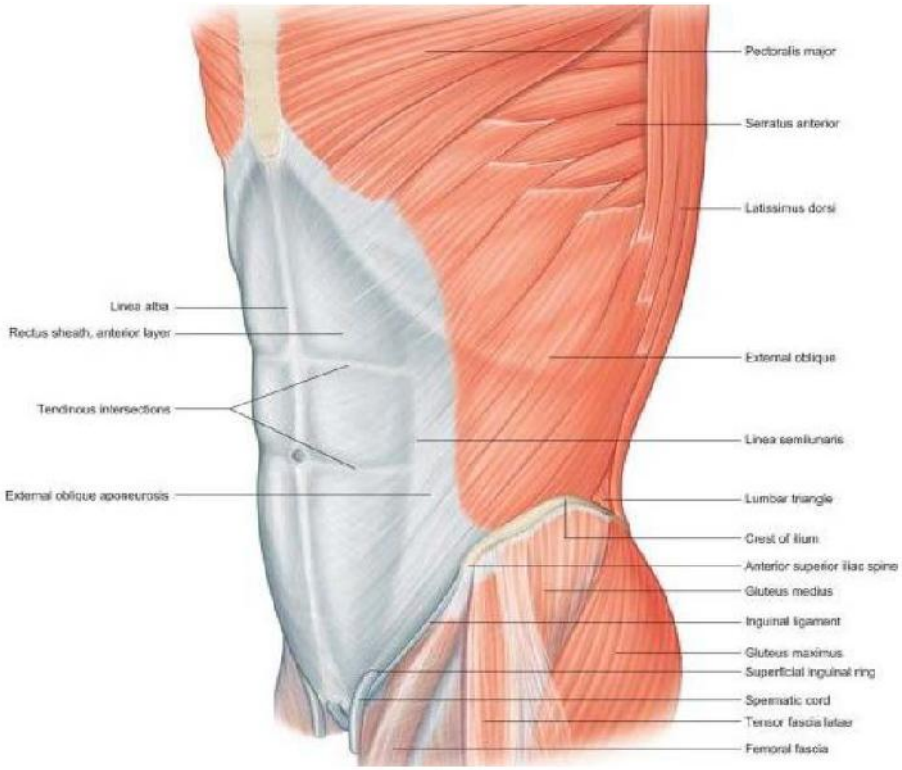
into the anterior half of the iliac crest. At the midclavicular line, the muscle fibers give rise to a strong, flat aponeurosis that courses anteriorly to the rectus sheath to insert medially into the linea alba. The lower part of the external oblique aponeurosis is rolled posteriorly and superiorly on itself to form a groove which contains the spermatic cord. This portion of the external oblique aponeurosis that extends from the anterior superior iliac spine to the pubic tubercle is termed the inguinal or Poupart ligament[23]. The inguinal ligament is the lower edge of the external oblique aponeurosis posterior to which pass the femoral artery, vein, and nerve and the iliacus, psoas major, and pectineus muscles.

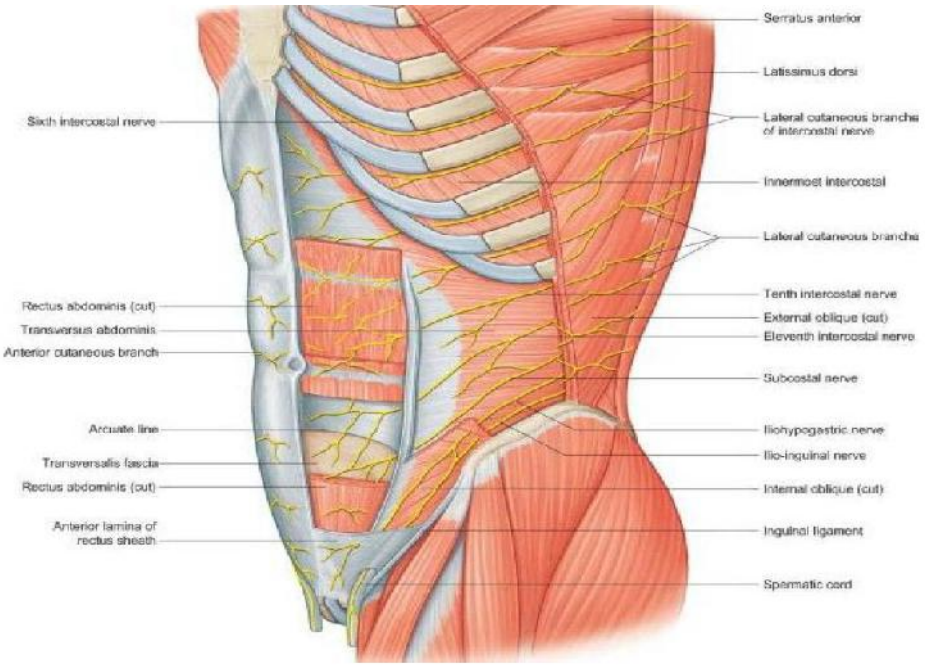
The rectus abdominis are paired muscles that appear as flat, long, triangular ribbons wider at their origin on the anterior surfaces of the fifth, sixth, and seventh costal cartilages and the xiphoid process than at their insertion on the pubic crest and pubic symphysis. The muscle is composed of long parallel fascicles interrupted by three to five tendinous inscriptions, which attaches the rectus abdominis muscle to the anterior rectus sheath. There is no attachment to the posterior rectus sheath. These muscles lie adjacent to each other, separated by the linea alba. In addition to supporting the abdominal wall and protecting its contents, contraction of these powerful muscles also flexes the vertebral column.

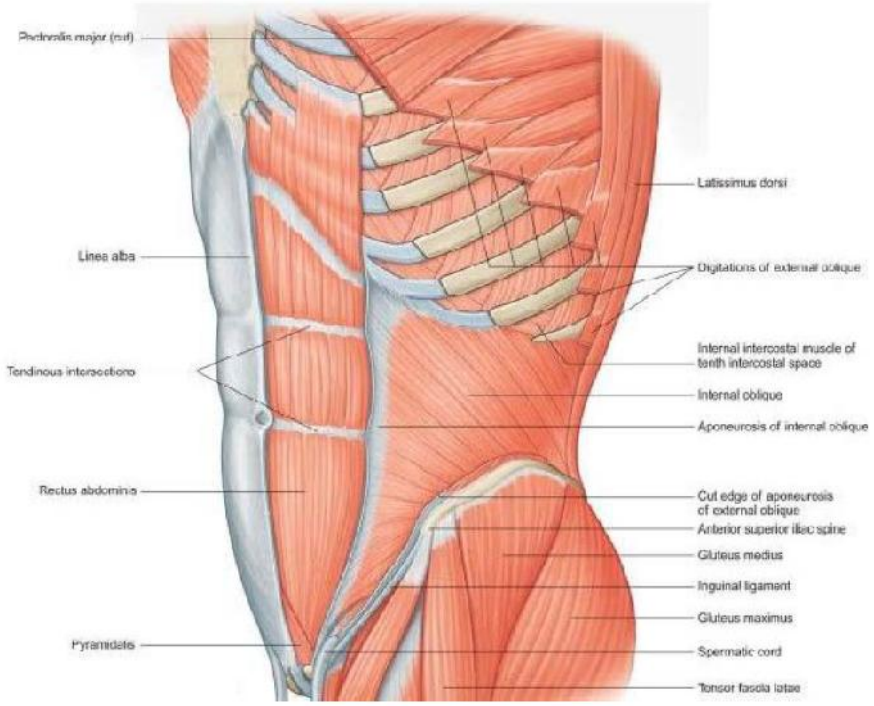
The rectus abdominis muscles are contained within the rectus sheath, which is formed from the aponeuroses of the three flat abdominal muscles. Superior to the semi-circular line, this fascial sheath completely envelops the rectus abdominis muscle, with the external oblique and anterior lamella of the internal oblique aponeuroses passing anterior to the rectus abdominis and aponeuroses from the posterior lamella of the internal oblique muscle, transversus abdominis muscle, and

transversalis fascia passing posterior to the rectus muscle. Below the semi-circular line, all these fascial layers pass anterior to the rectus abdominis muscle, except the transversalis fascia. In this location, the posterior aspect of the rectus abdominis muscle is covered only by transversalis fascia, preperitoneal areolar tissue, and peritoneum. The rectus abdominis muscles are held closely in apposition near the anterior midline by the linea alba.

The linea alba consists of a band of dense, crisscrossed fibers of the aponeuroses of the broad abdominal muscles that extends from the xiphoid to the pubic symphysis. It is much wider above the umbilicus than below, thus facilitating the placement of surgical incisions in the midline without entering the right or left rectus sheath[24].




Serratus anterior
Latissimus dorsi
Sixth intercostal nerve
Lateral cutaneous branches of intercostal nerve
Innermost intercostal
Lateral cutaneous branches
Rectus abdominis (cut)
Transversus abdominis
Anterior cutaneous branch
Tenth intercostal nerve
External oblique (cut)
Eleventh intercostal nerve
Subcostal nerve
Arcuate line
Transversalis fascia
Rectus abdominis (cut)
Anterior lamina of rectus sheath
Iliohypogastric nerve
Ilio-inguinal nerve
Internal oblique (cut)
Inguinal ligament
Spermatic cord


Pectoralis major (cut)
Latissimus dorsi
Linea alba
Digitations of external oblique
Internal intercostal muscle of tenth intercostal space
Tendinous intersections
Internal oblique
Aponeurosis of internal oblique
Rectus abdominis
Cut edge of aponeurosis of external oblique
Anterior superior iliac spine
Gluteus medius
Inguinal ligament
Gluteus maximus
Pyramidalis
Spermatic cord
Tensor fasciae latae

Perforation Peritonitis

Peritonitis is defined as inflammation of the peritoneum and maybe generalised or localised. It occurs when the capacity of the peritoneum to localise infection is exceeded[25].

Types

Generally classified as primary and secondary peritonitis.

Primary Peritonitis- It occurs as a result of haematogenous spread to the peritoneal cavity in the absence of hollow viscous perforation[26].

Secondary Peritonitis- It occurs as a result of contamination of the peritoneum by perforation of a hollow viscous. Intraperitoneal leakage of bile, food particles or faeces are responsible for the development of peritonitis.

Tertiary Peritonitis- It is the result of persistent diffuse peritonitis usually following the initial treatment of secondary peritonitis. It represents both the failure of host response and super infection

Causes-

Bacterial- gastrointestinal and non-gastrointestinal.

Chemical- Bile, barium

Traumatic- Operative, external trauma

Ischaemic- Strangulated bowel, vascular occlusion

Allergic- Starch peritonitis

Routes of Peritoneal Infection

Gastrointestinal Perforation- Perforated ulcer, diverticulum, appendix

Transmural translocation (without perforation) - primary bacterial peritonitis, pancreatitis

Exogenous contamination- Surgery, drains, trauma, peritoneal dialysis.

Infection from the female genital tract

Haematogenous spread.

Microorganisms in peritonitis-

Gastrointestinal source-

Eschericia coli

Enterococci

Bacteroides spp.

Streptococci

Clostridium spp.

Klebsiella pneumoniae[27]

Other sources

Chlamydia trachomatis

Neisseria gonorrhoeae

Haemolytic streptococci

Staphylococci

Streptococcus pneumoniae

Fungal infections

Mycobacterium tuberculosis and other spp.

Clinical Features

Abdominal pain, increases on movement, deep respiration and coughing

Anorexia, fever, malaise

Pyrexia

Nausea with ± vomiting

Tachycardia

Hypotension

Tenderness ± guarding/rigidity/rebound of abdominal wall

Reduced or absent bowel sounds

Pain/tenderness on rectal/ vaginal examination in pelvic peritonitis

Septic Shock(SIRS with MODS) in later stages[28]

Investigations

Complete blood count

Urea, creatinine and electrolytes

Erect X-Ray of the abdomen for air under diaphragm

Computed tomography to diagnose pneumoperitoneum and to find out cause of peritonitis

Management

Surgery is an important part of treatment for perforation peritonitis but it must be timed correctly after a period of few hours of active resuscitation and optimization of the patients condition.

1) Water, electrolyte and protein replacement to compensate for the considerable losses that have occurred since the onset of the condition.
2) Antibiotic therapy whenever there is suspicion of bacteremia or peritonitis secondary to bacterial infection.
3) Ventilation- Patients with severe peritonitis will have poor diaphragmatic movement and impairment of tissue perfusion and hence oxygen should be given.
4) Analgesia
5) Renal function should be monitored specially in the older age group for signs of pulmonary oedema and cardiac failure by measuring hourly urine output.[28]

Surgery

The choice of the surgical procedure depends on the underlying pathology.

The generalised basis of surgical approach for perforation peritonitis is as-

1) A long vertical incision that allows access to all parts of the peritoneal cavity.
2) Pus and debris is mopped and suctioned out. Pus should be sent for culture and antibiotic sensitivity.

3) The peritoneum is irrigated with warm saline containing antibiotic or an antiseptic
4) A gastric or duodenal perforation is usually closed with a patch repair. After placing sutures across the perforation, the sutures are gently tied and the long ends are retained. Then, a small portion of the omentum is placed along the suture line and the ends of the sutures are loosely tied, therefore anchoring the omentum over the perforation site. In the presence of a perforated gastric ulcer, biopsy of the ulcer edge is taken because of the possibility of malignancy. Vagotomy and pyloroplasty for perforated duodenal ulcer is preferred by some surgeons in a high risk patient.
5) In the case of ileal perforation which occurs secondary to enteric fever, primary closure or resection and anastomosis is commonly done.
6) Peritoneal lavage is given to the entire peritoneal cavity and drains are placed, usually 2 in no. One at the subdiaphragmatic space and the other in the pelvis to drain the collection and prevent post-operative abcess formation.
7) Abdomen incision is sutured using mass closure technique using loop polydiaxanone or ethilon sutures. The subcutaneous space is irrigated and skin is closed with interrupted with mattress sutures. Local anaesthetic maybe injected to reduce immediate post-operative pain.

Post-operative care

1) Patient is transferred to the intensive care unit
2) Respiratory assistance may need to be continued and the cardiac and renal functions need to be closely monitored.
3) Nasogastric suction is continued
4) Intravenous fluids have to be continued with supervision to give adequate amounts and prevent overloading
5) Systemic antibiotics are continued.
6) Analgesics to control pain and prevent respiratory limitations due to pain
7) Physiotherapy to prevent respiratory complications.

Complications

Abdominal complications

1) Paralytic ileus
2) Residual or recurrent abcess
3) Portal pyaemia/liver abcess
4) Small bowel obstruction secondary to adhesions
5) Surgical site infection[29]

Systemic complications

1) Septic shock
2) Systemic inflammatory response syndrome
3) Multi-organ dysfunction syndrome
4) Death

Surgical Site Infection

Surgical site infections (SSIs) have played a major role in the evolution of medical care throughout history. Wound complications contributed significantly to the historical surgical mortality rates before the development of Lister's aseptic approach in the nineteenth century[30]. The impact of the antiseptic/aseptic techniques was readily apparent in its adaptation to battlefield medicine. During the Civil War in America, surgeons routinely operated bare-handed, with wound suppuration considered to be a beneficial aspect of wound healing[31]. With the gradual acceptance of the principles of antisepsis, and the usage of sterile dressings and aseptic surgical technique, there was a dramatic reduction in mortality from wounds to 7.4% in the Spanish-American War[32]. Despite nearly two centuries of medical progress, the management of surgical infection remains a pressing concern, and SSIs continue to be a leading component of nosocomial morbidity and mortality. SSIs require a multifaceted and multidisciplinary approach, which are a critical aspect of infection control outcomes.

DEFINITIONS

The Center for Disease Control and Prevention (CDC) established the National Healthcare Safety Network (NHSN) to monitor quality control measures, including SSIs, and has defined widely used definitions for SSI[33].

Centers for Disease Control and Prevention–National Healthcare Safety Network definitions for surgical site infections

1) Superficial incisional surgical site infection

Infection occurs within 30 days after the operative procedure and

Involves only skin and subcutaneous tissue of the incision and

Patient has at least 1 of the following:

a. Purulent drainage from the superficial incision

b. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision

c. At least 1 of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, and superficial incision is deliberately opened by surgeon and is culture positive or not cultured. A culture-negative finding does not meet this criterion

d. Diagnosis of superficial incisional SSI by the surgeon or attending physician

2) Deep incisional surgical site infection

Infection occurs within 30 days after the operative procedure if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operative procedure and

Involves deep soft tissues (eg, fascial and muscle layers) of the incision and

Patient has at least 1 of the following:

a. Purulent drainage from the deep incision but not from the organ/space component of the surgical site

b. A deep incision spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or not cultured when the patient has at least 1 of the following signs or symptoms: fever (>38_C) or localized pain or tenderness. A culture-negative finding does not meet this criterion

c. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination

d. Diagnosis of a deep incisional SSI by a surgeon or attending physician

3) Organ/space surgical site infection

Infection occurs within 30 days after the operative procedure if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operative procedure and infection involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure and

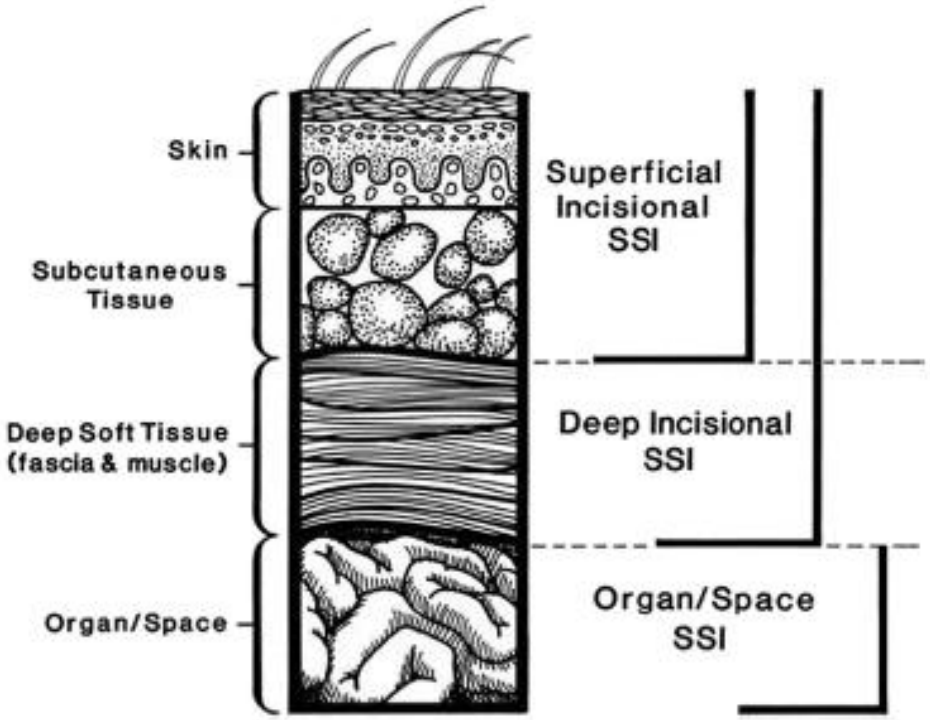
Patient has at least 1 of the following:

a. Purulent drainage from a drain that is placed through a stab wound into the organ/space

b. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space

c. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination

d. Diagnosis of an organ/space SSI by a surgeon or attending physician.



SSI are classified based on the depth of involvement of the infection, which may be confined to the skin and subcutaneous tissues (superficial incisional SSI), involve the deep soft tissue, such as the fascial and muscular layers (deep incisional SSI), or extend further beyond these anatomic boundaries (organ/space SSI)[34]. Incisional SSIs are further subdivided into primary and secondary for cases with more than one incision. For instance, a primary incisional SSI involves the primary incision (eg, chest incision for coronary artery bypass grafting), and a secondary incisional SSI involves secondary incisions (eg, leg incision for donor site in coronary artery bypass grafting).

EPIDEMIOLOGY

Before the antisepsis era, the risk of surgery was exceedingly high due to the enormous rates of surgical infection. Compounded by the absence of the effective anaesthesia, early surgical procedures had limited success compared with the modern era. Acknowledgment of the aseptic approach made a significant impact on outcomes.

The simple introduction of hand washing by Semmelweis resulted in a decrease in mortality due to puerperal sepsis from 12% to 2%[35]. The development of multiple aspects of modern surgical care has led to significant improvements in the historical context described. Nevertheless, SSIs remain a frequent postoperative complication, developing in 3% to 20% of surgical procedures[36]. The rate of SSI is highly variable depending on the specific operative procedure, with rates that can be even higher depending on the number of risk factors present. There is a substantial impact of SSI on both morbidity and mortality. However, establishing the exact impact of SSI is difficult because of the dependence on accuracy of reporting and the variability of patient follow-up.

In the 1980s, it was observed that SSI led to a 10-day increase in hospital length of stay[37]. Even a decade later, another study reported persistent delayed discharge from hospital and increased requirement for post-discharge care[38]. In a study of 288,906 patients, in-hospital mortality for the patients with SSIs was 14.5% versus 1.8% of patients with no SSI. SSIs are estimated to be responsible for more than 8000 deaths annually in the United States[36]. SSIs may be of even greater consequence in developing countries, because surveillance rates of SSI in a study conducted by the International Nosocomial Infection Control Consortium were higher for most surgical procedures compared with CDC-NHSN rates[39].

RISK FACTORS FOR SURGICAL SITE INFECTION

From a general perspective, the microbes responsible for infection of surgical wounds originate from either the surrounding skin or associated structures that are contiguous with the regions of the surgical procedure. The logical extension of this principle is that the risk of wound contamination and subsequent SSI depends on location, the nature of the surgical wound/incision, and the procedure performed. The CDC wound classification system defines wound class based on risk and is divided into 4 categories: clean, clean-contaminated, contaminated, and dirty[34]. With clean wounds, the expected risk is from microbes located directly on the surface of the skin, or introduced from the external environment. With increasing wound class, there is increased exposure to microorganisms that are present on internal structures of the body, such as epithelial surfaces of the gastrointestinal tract and genitourinary tract. In the early epidemiologic studies, the SSI rate increased with wound class (I, 2.1%; II, 3.3%; III, 6.4%; IV, 7.1%)[40]. Appropriate risk stratification for SSI cannot be limited to the wound alone. There are a variety of patient-related factors and perioperative factors that can significantly affect the risk of SSI in a surgical patient. One system of risk stratification is the National Nosocomial Infection Surveillance (NNIS) System risk score, based on 3 factors. These factors are

(1) an American Society of Anaesthesiology preoperative assessment score of greater than or equal to 3;

(2) an operation with a wound classification as contaminated or dirty; and

(3) an operation longer than the 75th percentile in duration for the specific procedure[40].

In the original development of the NNIS risk score, each additional risk factor resulted in increasing rates of SSI, even within the same traditional wound class. In

the most recent publication of aggregate data from the NHSN SSI surveillance system, the effects of risk factors remain apparent, with escalating SSI rates with the number of risk factors. The NNIS score has been further modified to account for some specific instances of laparoscopic cases, as the risk for SSI can be lower. The risk factors identified in the NNIS risk scoring system are useful from surveillance and monitoring perspectives. However, prevention requires identification of risk factors that are more readily modifiable than those listed in the NNIS scoring system. An approach to the risk factors of SSIs can be categorized into a schematic of microbial factors, patient factors, and perioperative factors.

Surgical wound classification

Class Type Description

I) Clean-

An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tract is not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow nonpenetrating (blunt) trauma should be included in this category if they meet the criteria.

II) Clean contaminated-

An operative wound in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered.

III) Contaminated-

Open, fresh, accidental wounds. In addition, operations with majorbreaks in sterile technique (eg, open cardiac massage) or grossspillage from the gastrointestinal tract, and incisions in which acute, nonpurulent inflammation is encountered are included in this category.

IV) Dirty-

Infected old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.

MICROBIAL FACTORS

The predominant source of microbes involved in SSIs originate from either the skin or the surrounding tissues of the incision, or from deeper structures involved in the operative procedure (eg, enteric organisms in bowel-related surgeries. The most frequently identified pathogens were, in order, Staphylococcus aureus, Coagulase-negative Staphylococci, Escherichia coli, Enterococcus faecalis, and Pseudomonas aeruginosa[41]. The overall distribution of pathogens associated with SSI has changed to some extent over the past couple decades[41,42,43]. The proportion of gram negative bacilli has decreased coinciding with a relative increase in the proportion of S aureus–related infection.

PATIENT FACTORS

Patient comorbidities can contribute significantly to the potential risk of SSIs. These factors include age, obesity, smoking, diabetes mellitus, malnutrition, dyslipidemia, and immunosuppression [44]. These factors can contribute significantly to the risk of SSI. Identification of these risk factors with appropriate preoperative history and physical examination is critical.

The core principle for management of these patient-related risk factors is preoperative optimization. Because many of the patient comorbidities are non-modifiable, there can be a substantial increase in SSI risk. Particularly in urgent or emergent situations, there may not be an opportunity to optimize a patient's comorbid status fully.

The rate of SSI is expected to be much higher in emergency surgery, as opposed to elective cases, which has been demonstrated in many studies[44,45,46]. The higher SSI rate in emergency cases also signifies patients that are more critically ill, with greater physiologic compromise, and expectedly, worse outcome. Other patient-related risk factors are also often non-modifiable in the timeline of preoperative planning. Although age is clearly a non-modifiable risk factor, other comorbidities, such as diabetes, obesity, and immunosuppression, are not easily reversible in a short-term time frame. Optimization of these risk factors is critical. For diabetes, optimization of glucose control has been clearly demonstrated to have efficacy in reduction of SSI rates[44,47,48].

Smoking results in significantly increased risk of SSI because of its effects on local tissue perfusion. Large numbers of studies have consistently shown that smoking results in at least a 2-fold increased risk of SSI[47]. In one trial by Møller and colleagues[49] of 120 patients, smoking cessation therapy resulted in a reduction of

wound-related complications from 31% to 5%. This finding has been confirmed by additional studies, and in meta-analyses of trial data[50,51]. Recommendations are for smoking cessation at least 30 days before operation[44,47,48]. For patients that have significantly elevated risk because of risk factors that cannot be modified, additional preventative measures need to be considered and can include the use of altered protocols for antimicrobial prophylaxis, or consideration of additional risk reduction measures.

PERIOPERATIVE FACTORS

Preventative measures in the preoperative period have changed rapidly over the past few decades. A large volume of research has established the importance of a host of preventative measures in the operative period. Examples include skin decontamination, perioperative warming, and antimicrobial prophylaxis[44,47,48].

Skin Decontamination-The use of antiseptic agents topically has long been recommended for use in skin decontamination[34]. The 2 broad classes of topical agents include chlorhexidine based preparations and iodophor-based agents. In addition, these agents can be combined with isopropyl alcohol (IPA) in solution. Several studies have sought to address potential differences in efficacy between the various available agents, although there has been significant inconsistency of results, which have been also been confounded by methodological differences between the studies. Among multiple studies that were reviewed, there was minimal incremental benefit for chlorhexidine-based agent in their specific subset of clean-contaminated cases. As one prospective European study highlighted, there was no direct correlation between the residual bacterial flora following disinfection and subsequent SSI in a variety of

surgical cases[52], suggesting that in certain surgical disciplines, the choice of skin antisepsis has less effect, particularly when the cause lies in non-cutaneous sources, such as enteric sources for general surgical procedures.

Antibiotic Prophylaxis

From a historical perspective, routine antibiotic prophylaxis was questioned for its usefulness. With demonstrated clinical benefit in the clinical trials conducted separately by Polk and Lopez-Mayor and Stone and colleagues[53,54], there has been tremendous improvement in SSI as an outcome. From the outset, the development of antibiotic prophylaxis has undoubtedly led to a clear reduction in rates of SSI.

The antimicrobial agent should be safe. An appropriate antimicrobial agent should be selected that has a narrow spectrum of coverage for the expected relevant pathogens. Antimicrobial prophylaxis should be administered in the preoperative period to allow serum and tissue concentrations to reach appropriate levels at the time of incision. Last, the antimicrobial agent should be administered for the shortest effect period, with appropriate discontinuation of the agent.

Clinical practice guidelines for antimicrobial prophylaxis were updated in 2013 in a joint publication by the American Society of Health-System Pharmacists, the Infectious Diseases Society of America, the Surgical Infection Society, and the Society for Healthcare Epidemiology of America[55]. The revised guidelines replaced the previously published 1999 guidelines[56] and highlighted several focuses including timing of preoperative dosing, weight-based dosing, and duration of postoperative prophylaxis. Selection of antibiotics for prophylaxis should be made with the primary consideration of the spectrum of coverage required. This consideration should be made because of the wound classification and the overall risk of infection. For

example, in clean surgical procedures, the risk of SSI is relatively low and, in several cases, antimicrobial prophylaxis is not indicated[44].

Consideration of intrinsic patient-related factors associated with increased risk of SSI (eg, age, malnutrition, immunosuppression) is relevant and appropriate justification for the use of antimicrobial prophylaxis[55,56]. A meta-analysis conducted by Bowater and colleagues[57] demonstrated that the relative risk reduction was the same across wound classes.

In clean procedures, the primary coverage is for the likely Staphylococcus sp. That will be the predominant cause. For clean-contaminated procedures, similar spectrum of coverage for Staphylococcus sp. is required, with additional coverage as needed depending on the site of surgery. As such, first-generation and second-generation cephalosporins remain the recommended prophylactic antibiotics for a large number of surgical procedures[55,56]. For contaminated and dirty wound classes, prophylaxis is typically not indicated, because therapeutic antibiotic management is required. Preoperative dosing of antibiotic prophylaxis is optimized to allow serum and tissue concentrations to reach sufficient levels at the time of incision. Several studies have studied the precise timeline for preoperative administration of prophylaxis to achieve maximal benefit.

In 1992, Classen and colleagues[58] showed a decreased SSI rate to 0.59% with administration within 2 hours of incision, compared with 3.8% for early (2–24 hours before incision) and 3.3% for postoperative administration. In the Trial to Reduce

Antimicrobial Prophylaxis Errors (TRAPE) study of 4722 patients undergoing cardiac, arthroplasty, or hysterectomy procedures, the effect of specific windows of antibiotic prophylaxis (in 30-minute intervals, preceding and following incision) was examined[59]. The lowest rate of SSI was in the 30-minute window immediately before

incision. The potential incremental benefit of an earlier antibiotic window is likely small and would be difficult to detect without significantly larger sample sizes. Current guidelines emphasize prophylaxis administration within 60 minutes of incision, or within 120 minutes for antibiotics requiring longer infusion times[55]. In the updated clinical practice guidelines, weight-based dosing is an additional focus[55]. Particularly in obese patients, studies have shown the pharmacokinetics of antibiotic administration are significantly altered.

Adequate redosing of antibiotics for longer operative procedures is necessary for risk reduction. With longer procedures, serum and tissue concentrations can drop below adequate levels, particularly in antibiotics with shorter half-lives (eg, cefazolin, cefoxitin, gentamicin)[55,60]. In the study by Morita and colleagues[61] of 131 patients undergoing colorectal procedures, the SSI rates in procedures longer than 4 hours were 8.5% and 26.5%, in groups with or without redosing, respectively. In the TRAPE trial, the rate of SSI was increased with an absence of redosing, 5.5% versus 1.8%[59]. Guidelines emphasize repeated dosing at intervals of 2 half-lives of the antibiotic used[55].

Additional Measures

Several additional measures have been investigated for implementation in the prevention of SSI. As a prime example, perioperative oxygenation was shown in 2 early trials to lead to a reduction in SSI rates with the use of 80%oxygen intraoperatively and immediately postoperatively. Further investigations have been mixed, with 2 prominent studies showing negative findings for efficacy[62,63]. In the PROXI trial, a large Danish randomized controlled trial studied 1400 patients undergoing abdominal surgery, who received either 80% oxygen or 30% oxygen during and for 2 hours after surgery[64]. There was no significant difference in SSI rates

with increased perioperative oxygen fraction. Several conducted meta-analyses of these trials do suggest an overall reduction of SSI rates[65,66,67]. There is significant heterogeneity of the trials performed, with variability of the type of surgical procedures, perioperative care, and delivery protocol for hyperoxia. Perioperative hyperoxia has been included in some recommendations for the prevention of SSIs. Perioperative measures with considerably less controversy include perioperative warming, hair removal, and optimization of the operating room environment. Perioperative hypothermia is associated with significantly increased risk of SSI. With regards to hair removal, the lowest risk of SSI has always been associated with not removing hair. If hair needs to be removed because of interference with the procedure, then hair removal should be done immediately before the surgery with a clipper rather a razor.

THERAPY

The general principle of SSI therapy remains control of the source of infection. For superficial SSI, the standard management remains the use of incision and drainage[68].The wound should be sufficiently sized to promote adequate drainage. For uncomplicated superficial SSIs, simple incision and drainage, with local wound care, are appropriate, with no antibiotic therapy required[69,70]. Identification of deep SSI or complicated skin and soft tissue infection requires adequate clinical suspicion. The presence of systemic features (eg, fever or leukocytosis) with an absence of local signs of wound infection should raise suspicion for organ/ space SSI, or for an infection arising from an alternate site. In addition, consideration should be made for antibiotic therapy in SSIs in patients with systemic features, or widening erythema (>5 cm in diameter)[70]. Direct clinical examination should follow to ensure an

appropriate clinical response, with consideration of alternative diagnoses, if atypical features were to appear. For more complicated skin and soft tissue infections, antibiotic therapy is appropriate, particularly in patients demonstrating signs of systemic shock. The principle of source control remains important, with the appropriate selection of antibiotics based on the type of surgical procedure performed, and the expected microbial causes for the infection[68]. As highlighted earlier, the growing impact of MDR organisms will greatly increase the difficulty of treatment of SSIs. Effective prevention will help to limit the potential impact of increasing resistance.

THE ECONOMIC AND QUALITY OF CARE IMPACT OF SURGICAL SITE INFECTIONS

The economic costs of SSIs are significant. There is a wide variance in estimates of the attributable costs of SSI infection that depends heavily on the type of surgical procedure and the geographic region[71]. No studies have been conducted in India to determine the economic impact of surgical site infection, although they have been done in countries like Canada and the United States.The estimates vary from $3937 per infection (Canadian tertiary care hospital)[72] to about $20,000 per infection (American surgery population)[73]. These analyses may underestimate the economic impact, through a combination of underestimation of surgical infection rates, and the costs of the worst manifestations of SSI, such as organ/space SSI with accompanying sepsis and septic shock, which can exceed $22,100 per case[74]. The rates of SSI are increasingly being used as outcome and surrogate measures for examining the quality of surgical care. The National Surgical Infection Prevention Project was developed in 2003 with the goal to standardize quality improvement measure to decrease the

incidence of SSI in major surgical procedures nationally. In some countries these quality indicators have become pay-performance measures. For example, in the United States, the Centers for Medicare and Medicaid Services linked Medicare payments to hospitals on their compliance to performance indicators[75]. The 2014 hospital payment rule finalized the general framework for the Hospital-Acquired Condition Reduction Program to be implemented in 2015[76]. The rule updated measures and financial incentives with the following areas related to SSI: postoperative sepsis rate, wound dehiscence rate, central line–associated bloodstream infection, and catheter-associated urinary tract infection.

SUMMARY

SSIs remain a very important component of patient outcome, contributing to substantial patient morbidity. From a historical perspective, there has been a significant improvement in postsurgical outcomes, but these incremental gains have slowed in the recent decades. The translation of basic and clinical research has expanded the complexity of evidence-based guidelines for SSI prevention. The importance of SSI prevention has been heightened because of its association with institutional and regulatory quality control measures. Sustained research in multiple aspects of SSI prevention needs to continue to realize further gains in SSI prevention. A multidisciplinary and multifaceted approach to SSI is absolutely necessary to continue to improve these critical outcomes of surgery.

Drains

Drains are commonly used after surgical procedures and can be classified as either active or passive.

Active drains use negative pressure to remove accumulated fluid from a wound. Passive drains depend on the higher pressure inside the wound in conjunction with capillary action and gravity to draw fluid out of a wound (i.e, the difference in pressure between the inside and the outside of the wound forces the fluid out of the wound). Passive drains, such as a Penrose drain, do not require special attention; the dressing is changed when it becomes saturated, or, if the drain is attached to a reservoir, then the reservoir is emptied or changed when it is full. Active drains, however, do require special maintenance. The collection reservoir of an active drain expands as it collects fluid drainage by exchanging negative pressure for fluid. The drain becomes ineffective if the vacuum is lost.

USE OF DRAINS

Drains are used both prophylactically and therapeutically. The most common use is prophylactic after surgery to prevent the accumulation of fluid (eg, blood, pus) or air. In any surgery in which a dead space (eg, a cavity) is created, the body has a natural tendency to fill this space with fluid or air. Use of a prophylactic drain is not routinely recommended after clean surgical procedures[77,78], although some articles claim that use of drains results in seroma reduction[79,80], and results of research have shown that use of vacuum drains may not influence the outcome after tissue expander use in breast surgery[81]. Surgical drains commonly are used after procedures on the thyroid[77], breast[82], and axillary area as well as after abdominal procedures and joint

replacements[83,84]. Vacuum drains may be used to drain perirectal wounds[85], and certain special vacuum drains (ie, endoluminal) are available to treat anastomotic leaks that may occur after intestinal resection and anastomosis[86,87].

DRAIN INSERTION

Typically, when a drain is required, it is inserted at the end of a surgical procedure. Frequently, the drain is inserted through a separate hole a few centimeters from the main incision to decrease the risk of a postoperative wound infection. There are two methods to insert a vacuum-type drain. The first method is used with drains that have a sharp trocar attached to the tube. The surgeon uses the trocar with some drains attached to pierce the skin from the inside of the wound at the desired site and pulls the attached tube out through the stab wound. The surgeon places the inner end of the tube at the required site and detaches the trocar. The surgeon may secure the drain to the skin with a stay-stitch. After the wound is closed, the scrub person connects the tube to the reservoir. Suction may be attached to the reservoir to facilitate wound drainage. The second method for drain insertion is used when a trocar is not attached to the drainage tube. In this case, the surgeon uses a forceps to pierce the abdominal wall from the inside of the wound and pushes the forceps through the subcutaneous tissue. He or she then incises the overlying skin with a scalpel. The surgeon opens the tip of the forceps to grasp the end of the drain tube and pulls the drain into the wound to the desired location. The surgeon may secure the tube to the patient's skin with a stay-stitch. The scrub person connects the tube to the reservoir after the wound is closed. Vacuum drains are classified according to the degree of pressure used. Typical bottled vacuum drains (eg, Redi-vac) use high

negative pressure. Bulb-shaped suction devices (eg, Jackson-Pratt) and collapsible four-channel vacuum drains (eg, J Vac, Blake) use low negative pressure.

DRAIN REMOVAL

The negative pressure in the reservoir should be released by removing the plug from the exit valve, and the bulb or reservoir should be disconnected before the drain is removed. After cutting the stay-stitch, if there is one, the drain is pulled out. Drain removal can be painful for some patients, so the patient may wish to take an oral analgesic before removing the drain. After removing the drain, drain-tube site is cleaned with antiseptic and a gauze. If the site is oozing, then a gauze dressing may be applied. If there is a large quantity of drainage, then a stoma bag may be applied.

COMPLICATIONS OF VACUUM DRAINS

Drains serve an important function, there are potential complications with their use. The complications include the following:

1) Breakage—Drains are made of strong silicone or polyvinyl chloride plastic and, therefore, are not likely to break, but breakage can occur[89]. Laparoscopic removal may be required if part of a drain breaks off inside the patient's abdomen during removal[90].

2) Difficulty in removal—If a drain remains inserted for a long period of time, it may become difficult to remove. On occasion, the drain has been stitched to the wound during closure of deeper layers. The wound may need to be temporarily opened to remove the drain.

3) Inadvertent removal—Drains may get entangled in the patient's other lines (eg, IV tubing, electrocardiogram leads) or become tangled in clothing or linen and accidentally be pulled out. This might cause bleeding or pain.

4) Infection—Although one purpose of surgical drains is to evacuate excessive fluid accumulation to prevent bacterial proliferation, drains can increase the risk of infection via retrograde bacterial migration. Therefore, drains should be removed when they are draining a negligible amount (eg, less than 25 mL per day; less than 1 mL per hour) to minimize this risk.

5) Occlusion—Drain tubes can become occluded by clot, tissue, or omentum. This can lead to the formation of a hematoma and subsequent discomfort and increased risk for infection.

6) Pain—Drain sites can be painful and may prevent the patient from lying on the side where the drain is inserted. Furthermore, some patients are apprehensive about moving with a drain in place after surgery; lack of movement can potentially increase the risk of postoperative immobility complications (eg. Deep vein thrombosis).

7) Unsightly scar—A drain site is left to heal by secondary intention so the site may form a puckering scar. When possible, the surgeon may place the drain in a skin crease to help improve cosmesis[91].

8) Visceral perforation—Drains left in place for a long period of time can erode into the bowel and lead to visceral perforation[92].

Review of Articles

A study done by Sumi et al to determine effects of subcutaneous closed suction drain for the prevention of incisional SSI in patients with colorectal perforation concluded that a subcutaneous closed suction drain is effective in preventing incisional SSI in high risk patients undergoing emergency operations for a colorectal perforations[93].

In another study conducted in Japan by Fujii et al to determine effects of subcutaneous drain for prevention of incisional SSI in high risk patients undergoing colorectal surgery concluded that subcutaneous drain is effective for preventing incisional SSI in patients with thick subcutaneous fat in colorectal surgery[94].

A study conducted in Mysore by Thrishuli et al to determine the role of negative suction for abdominal closure in the presence of sepsis(acute abdomen) concluded that it is an effective method of abdominal wall closure in cases of peritonitis when compared to conventional primary skin closure as it significantly reduces the incidence of SSI, wound dehiscence, wound secondary suturing and duration of hospital stay[95].

A study of subcutaneous negative pressure closure versus simple closure in laparotomy wound of ileal perforation conducted by Vaghani et al at Surat concluded that although this method had no impact on mortality but did have an impact with data showing improved rate of recovery, less SSI and decreased morbidity in terms of hospital stay[96].

A meta-analysis done by Manzoor et al to review the role of subcutaneous wound drainage in reducing surgical site infections after laparotomy considered two thousand eight hundred and sixty-four patients undergoing laparotomies in nine different trials concluded that although there was no role for subcutaneous drain placement in all laparotomies, there may be potential benefit in higher risk patients, patients with deeper subcutaneous fat and patients with contaminated or dirty wounds[97].

Another study conducted at Lucknow by Saraswat et al to determine role of negative suction drain in subcutaneous space during closure of wound of perforation peritonitis concluded that placing negative suction drain had a positive impact on outcome of perforation peritonitis in terms of reduction in infection rate and duration of hospital stay. With respect to wound dehiscence too, negative pressure suction showed a trend towards reducing the adverse events[1].

A study conducted at Dallas, Texas by Murray eta al to study the impact of surgical site infection on the development of incisional hernia and small bowel obstruction in colorectal surgery concluded that patients with an SSI were 1.9 times more likely to have an incisional hernia than those without an SSI. An SSI after colorectal surgery was a risk factor for the development of incisional hernia but not for small bowel obstruction[9].

Another study conducted by Baier et al at Freiburg, Germany to determine the role of subcutaneous redon on surgical site infections after laparotomy concluded that there was no indication for prophylactic subcutaneous suction drains after laparotomy as their study could not demonstrate a reduction of SSI by the use of redon drains[98].

An evidence based value of subcutaneous surgical wound drainage: Systemic review and Meta-analysis conducted by Kosins et al at the Aesthetic and Plastic

Surgery Institute, University of California, Irvine concluded that many surgical operations can be performed safely without prophylactic drainage and surgeons can consider omitting drains after caesarean section, breast reduction, abdominal wounds, femoral wounds, and hip and knee joint replacement. They also suggested that surgeons should consider not placing drains prophylactically in obese patients. They however suggested that drain placement following a procedure is the surgeon's choice and can be based on multiple factors beyond the type of procedure being performed or the patient's body habitus[99].

METHODOLOGY

The present study was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, from January 2017 to December 2017 on 100 patients undergoing midline incision laparotomy for perforation peritonitis

Study design

The study design was a randomised control trial

Study period and duration

The present study was carried out for a period of one year from January 2017 to December 2017

Place

This study was done under the Department of General Surgery of a tertiary care teaching hospital attached to KAHER's Jawaharlal Nehru Medical College, Belagavi.

Source of Data

All patients undergoing midline incision laparotomy for perforation peritonitis were included in the study.

Sample size

The study sample was comprised of 100 patients, 50 in the first group(Patients without negative suction subcutaneous drain) and the other group(Patients with negative suction subcutaneous drain)

Formula:

$n = 2(Z\alpha+Z\beta)^2 \times PQ(P1-P2)^2$

where,

$\alpha=0.05$, $\beta=0.2$, $Z\alpha=1.65$, $Z\beta=0.84$, P1=12, P=30, Q=(1-P)

Statistical analysis: Pearson's Chi Square test

Sampling procedure

Systematic Random Sampling

SELECTION CRITERIA

Inclusion criteria

- Patients aged between 18 and 75 years
- Patients of either sex.
- Patients undergoing midline incision laparotomy for perforation peritonitis.
- Patients willing to give consent.

Exclusion criteria

- Age <18 and >75 years.
- All immunocompromised patients.
- Patients requiring stoma for surgical reasons.
- Patients suffering from malignancies.
- Patients refusing to give consent.

Diagnostic criteria for peritonitis

Clinically-

Patients presenting with

1) Pain abdomen (acute), nausea, vomiting.
2) Fever, tachycardia.
3) Guarding, Rigidity on abdominal examination.
4) Decreased or absent bowel sounds.

Investigations

1) Leucocytosis.
2) X-Ray of the erect abdomen- Free air under the diaphragm
3) USG abdomen- Free fluid in the peritoneal cavity
4) CT abdomen- Pneumoperitoneum

Ethical clearance

The Ethical Clearance was obtained from the Institutional Ethics Committee, Jawaharlal Nehru Medical College, Belagavi prior to the commencement.

Informed Consent

Those patients who fulfilled selection criteria were briefed about the nature of study and a written informed consent regarding the study, investigations sent and procedure involved was obtained (Annexure I) prior to the enrolment.

Method of collection of data

Patients satisfying selection criteria were interviewed and the demographic data such as age and sex, presenting complaints were noted. Further the patients were subjected to clinical and systemic examination and the findings were noted on a predesigned and pretested proforma (Annexure II).

Procedure

1) Midline incision was taken for all patients.
2) Exploratory laparotomy was undertaken and the cause of perforation was identified and appropriate surgical management depending on the cause and the site of perforation was done.
3) Peritoneal lavage was given and intra-abdominal drain was placed for all patients.

4) Closure of abdominal wound was done with the same technique in all cases (Mass closure done with ethilon loop no.1, subcutaneous tissue approximated with vicryl 2.0 and skin closed with ethilon 2.0)
5) 10 no. negative suction romovac drain was placed in patients of the second group in the subcutaneous plane before approximation of subcutaneous tissue was done.
6) Dressing was done with gauze and dynaplast and negative suction was connected to the subcutaneous drain.
7) De-clotting of the drain was done everyday.
8) Drain was removed if drainage was nil or on post-operative day 3, whichever was earlier.

Analysis of outcomes

The outcomes measured were seroma formation, wound infection and wound dehiscence.

Seroma formation was defined as the collection of sterile serous fluid in the subcutaneous plane.

Wound infection was defined as a break in the skin or mucous membrane with discharge of purulent fluid requiring suture removal to allow free drainage followed by daily wound dressing.

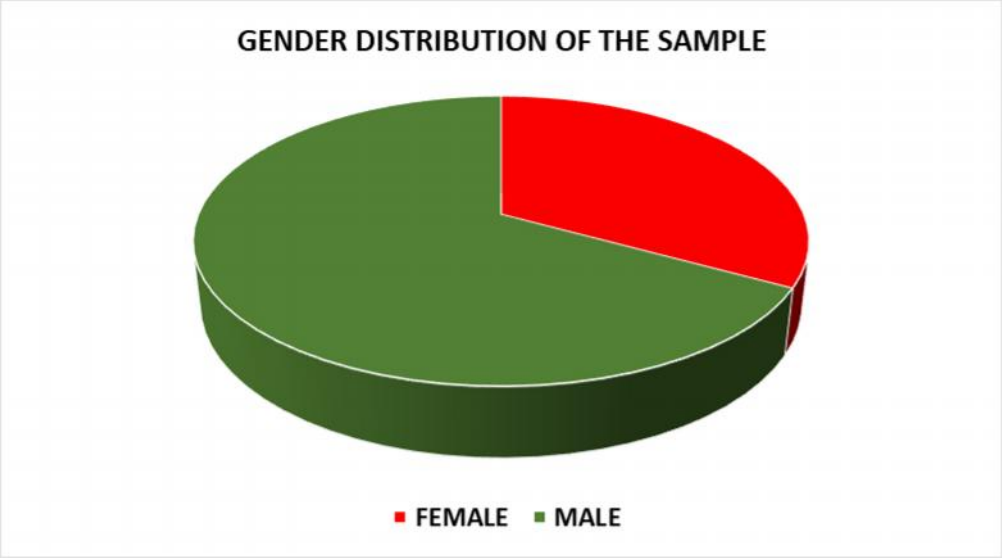
Wound dehiscence was defined as a break in the continuity of the wound requiring secondary suturing at a later date.

Statistical Analysis

All the relevant data was tabulated. The presence or absence of seroma formation, wound infection or wound dehiscence was examined in patients with or without drain. Using Pearson's chi square test statistical significance was identified and a *P* value <0.05 was considered statistically significant.

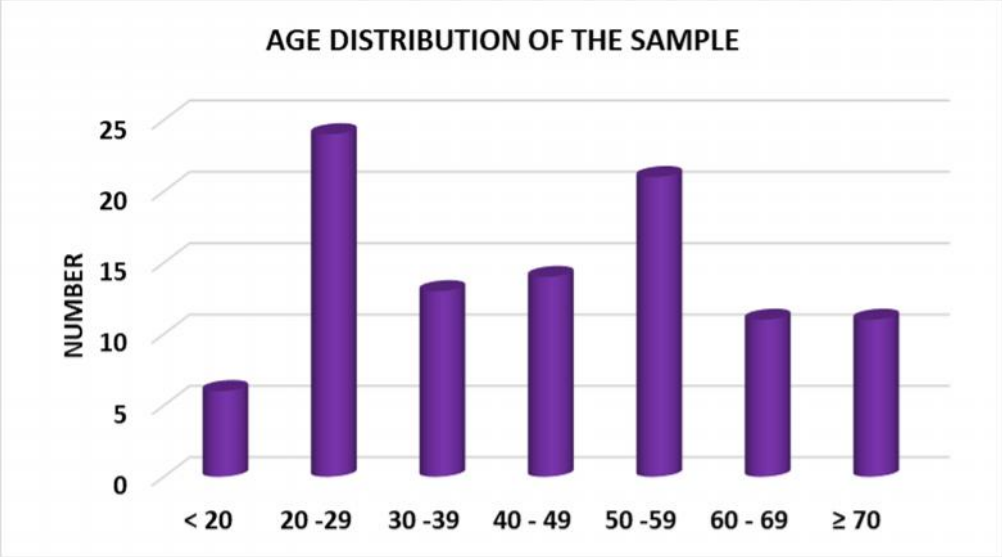
RESULTS

1) Demography



GENDER	NUMBER
FEMALE	33
MALE	67
TOTAL	100

A total of 100 patients were included in the study with 50 patients in the drain group and 50 in the no drain group which includes 33 females and 67 males.



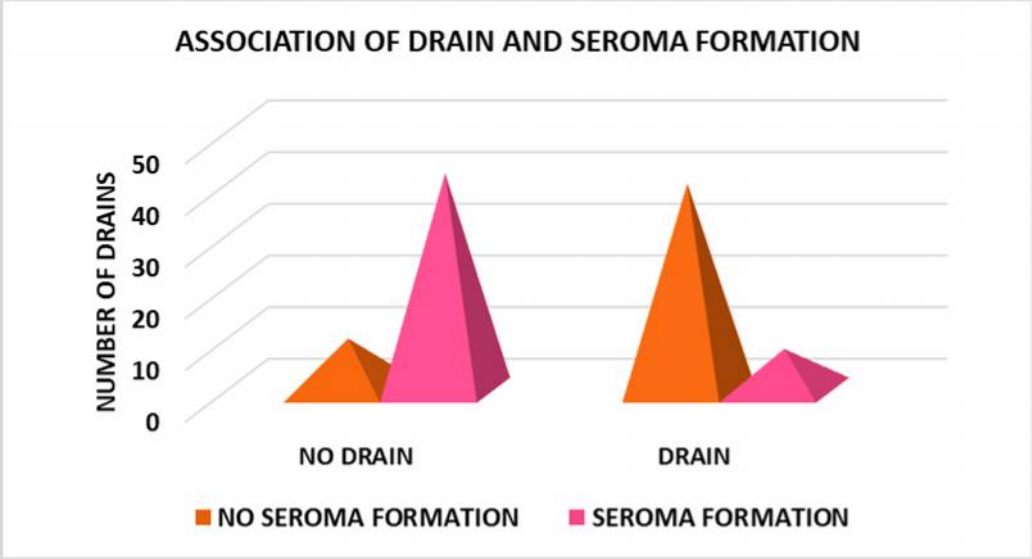
AGE	NUMBER
< 20	6
20 -29	24
30 -39	13
40 - 49	14
50 -59	21
60 - 69	11
≥ 70	11
TOTAL	100

	MEAN	S.D.	MIN	MAX
AGE	43.57	17.25	18	75

The *P* value using chi square test is <0.0001(HS)

The minimum age in the study is 18yrs with a maximum age of 75yrs and a mean age group of 43.5yrs.

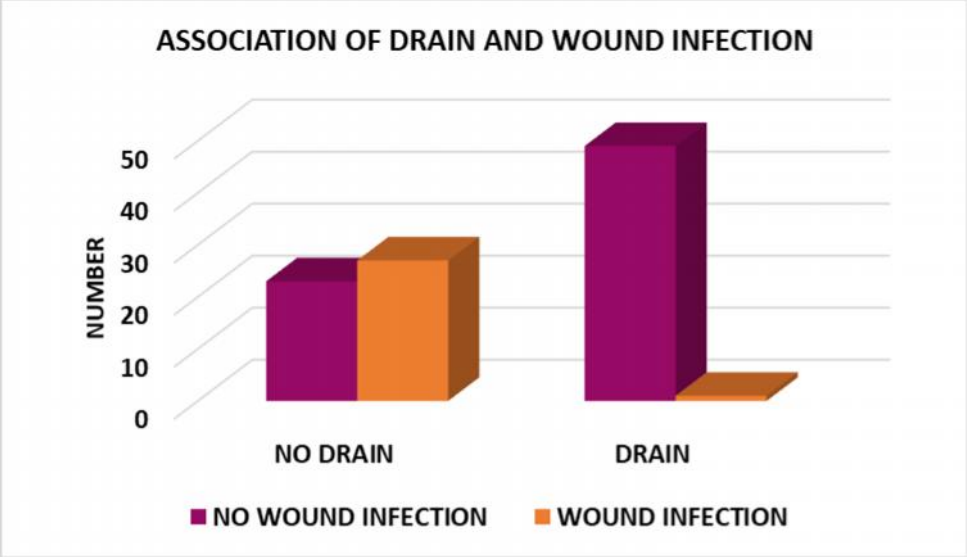
Seroma formation



	DRAIN		
SEROMA FORMATION	**NO**	**YES**	**TOTAL**
NO	10	42	52
YES	40	8	48
TOTAL	50	50	100

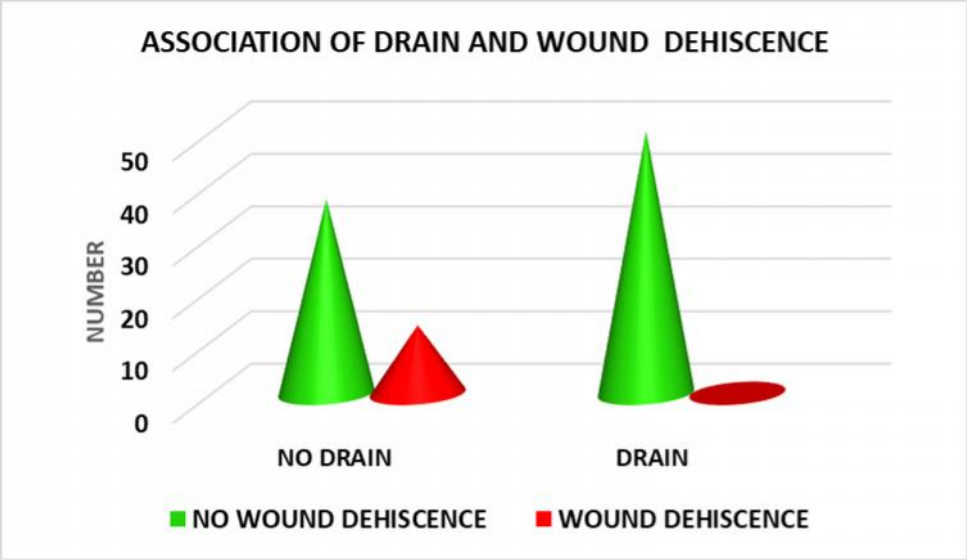
The *P* value using chi-Square test is < 0.0001 (HS)

With respect to seroma formation in the no drain group 40 patients out of 50 developed a seroma , whereas in the drain group 8 patients developed a seroma with a *P* value of <0.0001. Hence it shows that drain help to reduce seroma formation.



	DRAIN		
WOUND INFECTION	**NO**	**YES**	**TOTAL**
NO	23	49	72
YES	27	1	28
TOTAL	50	50	100
The p value using chi-Square test is < 0.0001 (HS)			
There is close association			

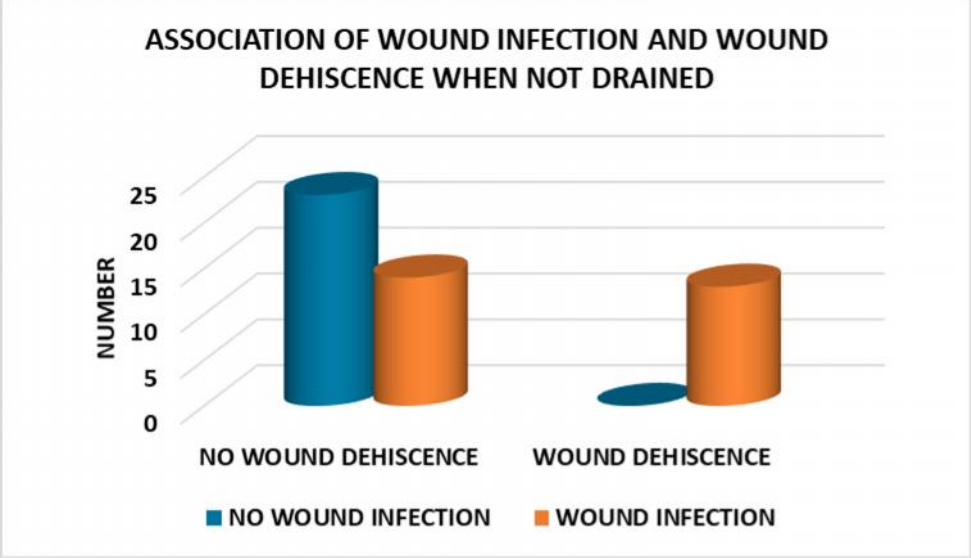
With respect to wound infection in the no drain group 27 patients out of 50 developed a superficial surgical site infection , whereas in the drain group 1 patient developed a surgical site infection with a *P* value of <0.0001. Hence it shows that drain helps in reducing surgical site infections.



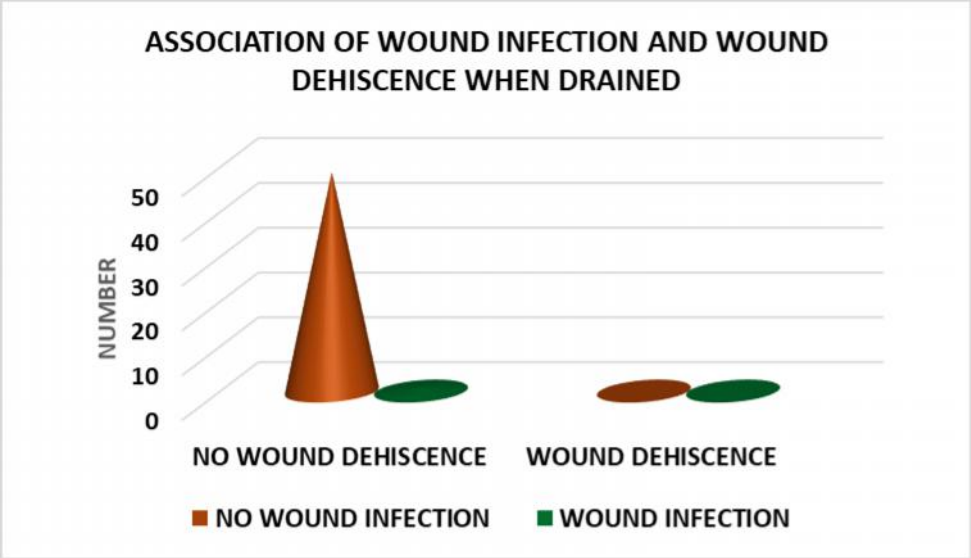
	DRAIN			
WOUND DEHISCENCE	**NO**	**YES**	**TOTAL**	
NO	37	50	87	
YES	13	0	13	
TOTAL	50	50	100	
The p value using chi-Square test is 0.0001 (HS)				

With respect to wound dehiscence in the no drain group 13 patients out of 50 developed wound dehiscence, whereas in the drain group no patient developed wound dehiscence with a *P* value of 0.0001. Hence it shows that wound dehiscence is significantly lower with drain than without drain.

WHEN NOT DRAINED			
	WOUND DEHISCENCE		
WOUND INFECTION	**NO**	**YES**	**TOTAL**
NO	23	0	23
YES	14	13	27
TOTAL	37	13	50
The p value using chi-Square test is 0.0001 (HS)			
There is close association			



In patients with no drain in the subcutaneous space, 27 patients developed a wound infection, of which 13 developed wound dehiscence.



In patients with a drain in the subcutaneous space, 1 developed a wound infection and no patients developed wound dehiscence.

WHEN DRAINED			
	WOUND DEHISCENCE		
WOUND INFECTION	**NO**	**YES**	**TOTAL**
NO	49	0	49
YES	1	0	1
TOTAL	50	0	50
There is perfect association			

DISCUSSION

Perforation peritonitis is one of the most common emergencies encountered in general surgery[1]. The outcome depends on multiple factors such as age of the patient, associated co-morbidities, nutrition, diabetes control, ASA class, cause and site of the perforation, the condition of the patient at presentation, the level of peritoneal contamination, operating time, intra-op management and the post-operative outcome and management[11,12]. One of the most common complications of surgery for perforation peritonitis is the development of SSI. Multiple interventions have been proposed with the intention of reducing SSIs. Many of these interventions are being used in clinical practice such as hand washing, skin preparation, minimising shaving, preoperative antibiotics, good glycaemic control, cessation of smoking prior to surgery[10,13-16]. Factors such as good glycaemic control and cessation of smoking cannot be followed in emergency surgeries such as for perforation peritonitis. All the other factors mentioned however have gained acceptance in the surgical community.
The use of drains however has not gained acceptance among surgeons[17,18]. Use of drains after surgery has decreased in recent times. It has been shown that drains provide no advantage after appendicectomies, cholecystectomies, hernia repair and various other surgeries[78,79,80]. Abdominal drains are still used though after surgeries for perforation peritonitis and major resections. They are also used in major plastic surgery procedures as they are believed to reduce the collection in closed spaces.

It has been put forth that the presence of serous fluid, haematoma, and dead space in surgical wounds increases the risk of infection as it acts as a culture medium[19,20]. Subcutaneous drains have been used to reduce the risk of SSIs. However, this intervention has not been universally accepted by surgeons owing to

the fact that drains may not be efficacious and may cause discomfort and increased hospital stay on their own. Many studies have been conducted regarding the efficacy of subcutaneous drains and a few of them have put forth that drains do not help in reducing SSIs. However, most of these studies were not limited to high risk patients.
In the current study, we have used a 10 no. romovac suction drain in the subcutaneous plane and removed it on POD3 or when the collection was nil. We found that the incidence of seroma formation, wound infection and wound dehiscence was significantly lower in the drain group as compared to the no drain group.

SSI has some of the following causes: haematoma formation, bacterial load, subcutaneous dead space, subcutaneous effusion, local ischaemia of the skin and subcutaneous tissue. In addition to closing the subcutaneous space with vicryl sutures, we placed a drain in the subcutaneous plane which is effective in reducing the incidence of SSI as because of the continuous suction of the subcutaneous effusion, haematoma and bacteria and it also helps in the reduction in the dead space of the subcutaneous wound.

In a study done in Mysore by Thrishuli[95] et al from September 2015 to September 2017, they studied the effect of negative suction subcutaneous drainage in cases of peritonitis due to any cause such as cholecystitis, liver abscess, enteric perforations, parietal wall abscess and found that subcutaneous suction drainage is an effective method of abdominal wall closure in cases of peritonitis when compared to conventional primary skin closure as it significantly reduces the risk of SSI, wound dehiscence, wound secondary suturing and duration of hospital stay.

In a study conducted by Fujii[94] et al in Japan, they studied the effects of subcutaneous drain for the prevention in incisional SSI in high risk patients undergoing colorectal resection and concluded that subcutaneous drains were

effective for preventing incisional SSI in patients with thick subcutaneous fat in colorectal surgery.

A study of subcutaneous negative pressure closure versus simple closure in laparotomy wound of ileal perforation done by Vaghani[96] et al in Surat from November 2012 to June 2013 studied the effects of negative suction drainage in patients undergoing laparotomy for ileal perforation and concluded that negative pressure closure removes serous discharge and bacterial colonization from laparotomy wounds and avoids wound infection and helps in reducing hospital stay and morbidity.

A review of subcutaneous wound drainage in reducing SSI after laparotomy was conducted by Manzoor[97] et al at the University of Manchester, studied two thousand eight hundred and sixty-four patients undergoing laparotomies in nine different trials and concluded that although there was no role for subcutaneous drain placement in all laparotomies, there may be potential benefit in higher risk patients, patients with deeper subcutaneous fat and patients with dirty or contaminated wounds. In a study conducted by Saraswat[1] et al in Lucknow, they studied the role of negative suction drain in the subcutaneous space during closure of wound of perforation peritonitis in 70 patients and found that it had a positive impact on outcome in terms of reduction in infection, wound dehiscence and duration of hospital stay.

Ina a study conducted by Sumi[93] et al in Japan, they studied the effects of subcutaneous closed suction drain for the prevention of incisional SSI in patients with colorectal perforation in 47 patients and concluded that it is effective in preventing SSI.

In our study we have studied the effects of negative suction subcutaneous drainage vs conventional closure in cases of perforation peritonitis due to any cause or

any part of the abdominal gastro-intestinal tract. We noted that the incidence of seroma formation was significantly lower 8 out of 50 in the drain group vs 40 out of 50 in the no drain group with a *P* value of <0.0001. Seroma formation is one of the causative factors for surgical site infection. Hence if the rate of seroma formation is lowered, the rate of surgical site infection will also go down.

Even with respect to wound infection, only 1 patient out of 50 developed wound infection in the drain group, whereas 27 out of 50 in the no drain group developed surgical site infection with a *P* value of <0.0001.

With respect to wound dehiscence, no patient in the drain group developed wound dehiscence, whereas 13 patients out of 50 developed wound dehiscence in the no drain group, with a *P* value of 0.0001.

Few studies have mentioned rates of infection lower than those seen in our study, but a lot of those studies were done either for all laparotomy incisions in general or peritonitis due to any cause. It is seen that the contamination in cases of perforation peritonitis is more than any other cause as there is spillage of gastro-intestinal contents into the peritoneum. As this centre is the biggest tertiary care centre in the region, we have also noticed that the patients coming to our centre have a history of 2-4 days on average, in which cases, gross contamination of the abdominal cavity is noted and hence the incidence of surgical site infection is higher. In our study, we have seen that the incidence of seroma formation, wound infection and wound dehiscence is significantly reduced with negative suction drain placement in the subcutaneous space compared to those patients in whom drain was not placed. Limitations in this study were that ours was a single centric study with a sample size of 100. We suggest multi centric, larger sample size studies to support a similar hypothesis.

Drains do have their disadvantages such as the chance of infection and inconvenience, but the advantage of not developing a possible surgical site infection and avoiding future surgery, prolonged hospital stay and the economic implications as also the increased chances of developing an incisional hernia in the future far outweigh their disadvantages and hence it is advisable to place a negative suction subcutaneous drain post laparotomy for perforation peritonitis.

CONCLUSIONS

Based on the findings of this study, it may be concluded that placing a negative suction drain in the subcutaneous plane post laparotomy for perforation peritonitis is better than conventional closure in terms of reducing seroma formation, wound infection (surgical site infection) and wound dehiscence and should be done in cases of perforation peritonitis. Multicentric studies with larger sample size should be done to support this hypothesis.

SUMMARY

The study undertaken aimed to determine which is a better method of closure of the abdomen post laparotomy for perforation peritonitis with regards to seroma formation, wound infection and wound dehiscence.

This one year randomized controlled trial was done with the Department of Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, from January 2017 to December 2017. A total of 100 patients operated for laparotomy for perforation peritonitis were studied. The patients were divided into two groups of 50 each as Group A (Placement of negative suction subcutaneous drain) and Group B (Conventional closure).

In the present study we noted that the incidence of seroma formation, wound infection(SSI) and wound dehiscence were significantly lower with a *P* value of <0.0001 measured for all the three parameters in patients in whom negative suction subcutaneous drain was placed as compared to conventional closure of the abdomen post laparotomy for perforation peritonitis.

Overall, we noted that subcutaneous wound drainage is a better method of abdominal closure as compared to conventional abdominal closure post laparotomy for perforation peritonitis with regards to seroma formation, wound infection and wound dehiscence.

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ANNEXURE I – CONSENT FORM

Dear Mr./Mrs./Dr. _____, you are kindly requested to enroll yourself in a research study tilted, "**SUBCUTANEOUS WOUND DRAINAGE VS CONVENTIONAL CLOSURE IN REDUCING SURGICAL SITE INFECTION AFTER LAPAROTOMY FOLLOWING PERITONITIS- A RANDOMISED CONTROL TRIAL**" being conducted by Dr. , a post graduate student in M.S. General Surgery and the study will be carried out under the direct supervision and guidance of Dr. _____, Professor, Department of General Surgery, Jawaharlal Nehru Medical College, Belgaum.

You have been requested to participate in this as you fit into the laid out criteria for a study 'subject'/ participant.

Your participation in study is voluntary. During the study you will be asked some questions and you are supposed to answer to the best of your knowledge. Your decision whether or not to participate in the study will not affect your treatment in any form during your hospital stay. If you decide to participate you are free to withdraw at any time.

TITLE OF THE STUDY:

"**SUBCUTANEOUS WOUND DRAINAGE VS CONVENTIONAL CLOSURE IN REDUCING SURGICAL SITE INFECTION AFTER LAPAROTOMY FOLLOWING PERITONITIS- A RANDOMISED CONTROL TRIAL**"

PURPOSE OF THE STUDY:

To compare surgical site infection with and without subcutaneous drain in cases of laparotomy following peritonitis

PROCEDURES INVOLVED:

If you agree to enroll yourself in my study, you will be interviewed regarding your present, past and family history then you will be clinically examined in detail and investigated accordingly.

You will be randomly allocated using computer generated numbers into group A (with drain) and group B (without drain).

On admission with complaints of pain abdomen, constipation and general physical and systemic examination with features of peritonitis, X Ray erect abdomen will be done to look for air under the diaphragm. USG abdomen and pelvis and if required CT scan of abdomen will be done. In the case of perforation, midline incision laparotomy will be done to look for site of perforation and its management. During closure of abdomen following successful surgery, after closure of peritoneum, rectus sheath layer will be closed using ethilon loop 1, subcutaneous layer using vicryl 2.0 and skin using ethilon 2.0

Drain will be placed in the subcutaneous layer

Daily observation of surgical site and drain quantity will be done

Drain will be removed on post op day 3 or when drain collection is nil

Time of observation: Daily until Post Operative day 3 or when drain is nil

RISKS AND BENEFITS:

Benefits of taking part in this research:

Some studies have shown that negative suction drain in the subcutaneous space has shown to reduce surgical site infection in the post op period.

No bias will be done to the patients who are not willing to participate in the study from the treatment point of view.

VOLUNTARY PARTICIPATION / WITHDRAWAL FROM THE STUDY:

Taking part in the study is voluntary. You may choose not to enroll yourself in this study and may choose to leave the study anytime in between.

ALTERNATIVES:

Your decision regarding participation in study will not change present or future health care services offered to you at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. You would simply be excluded from the study if you wish to, and all your details shall be kept confidential and you will get the routine line of management.

PRIVACY AND CONFIDENTIALITY:

All data collected or disclosed by you during the course of participation of study, will be kept fully confidential. If however during the course it becomes necessary for the progress of the course to disclose the identity, it would be done so only after your informed & written consent.

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

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

AUTHORIZATION TO PUBLISH RESULT:

The results of the study may be used to publish an article. When the results of research published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information obtained in connection with this study and that can be identified with you will remain confidential.

FINANCIAL INCENTIVES FOR PARTICIPATION:

No additional costs shall be incurred upon you for the purpose of this study.

It is purely being done with the idea of research and all the cost of study will be borne by the investigator.

COMPENSATION:

In the event that you become injured as a result of taking part in this study, treatment will be offered to you at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum, or you will be given information about where to receive medical care. However, no reimbursement, compensation or free medical care will be given.

QUESTIONS/CONTACT DETAILS:

You shall be free to contact the below mentioned name & addresses anytime during the study period for any clarification or help as you may desire for.

Dr. _____

MS (Post Graduate Student)

Department of General Surgery

Jawaharlal Nehru Medical College,

Nehru Nagar, KLE Hospital Road,

Belagavi 590010

Mobile – _____

Dr. _____

MBBS, MS GENERAL SURGERY,

Professor,

Department of General Surgery

Jawaharlal Nehru Medical College,

Nehru Nagar, KLE Hospital Road,

Belagavi 590010

Mobile - _____

In case you need any further information regarding your rights as study participant you may contact:

Dr. GANGA. S. PILLI

Professor of Pathology & Chairman,

JNMC Institutional Ethics Committee

on Human Subjects Research,

Jawaharlal Nehru Medical College

Nehru Nagar, KLE Hospital Road

Mobile – 9480275601

CONSENT STATEMENT:

I the undersigned Mr/Mrs/Dr._____ do hereby give consent for my participation in this research study after being explained in-depth about the important elements of this study in my own vernacular language.

I give this consent voluntarily in my sound mind and good faith, knowing very well the risks involved and been given enough time to clear my doubts and other queries to participate as a 'subject' in this study. I do hereby also give consent for publication of this article in any media / journal and have no objections whatsoever.

Signature or left thumb print of participant or legally authorized representative

Participants name: _____

Signature: _____

Witness/guardian name: _____

Signature_____

Investigator's name:

Signature_____

Guide's name:

Signature_____

Date: ___/___/_____ Place: _____

ANNEXURE-II PROFORMA

PROFORMA / QUESTIONNAIRE USED FOR DATA COLLECION

Proforma/questionnaire used for data collection for the study tilted, "**SUBCUTANEOUS WOUND DRAINAGE VS CONVENTIONAL CLOSURE IN REDUCING SURGICAL SITE INFECTION AFTER LAPAROTOMY FOLLOWING PERITONITIS- A RANDOMISED CONTROL TRIAL**" is as follows:

PATIENT DETAILS:

I.P.D/O.P.D NO.: **D.O.A:**

NAME: **D.O.D:**

SEX:

AGE:

ADDRESS:

Chief Complaints

GENERAL EXAMINATION:

Built and Nourishment:

Weight:

BMI:

	PULSE:
	BP :
	R/R :
	TEMPERATURE:

	NORMAL	*ABNORMAL FINDINGS*
CVS:		
		RESPIRATORY:
CNS:		

P/A:

INVESTIGATIONS:

CBC:

RBS:

Blood Urea:

Sr. Creatinine:

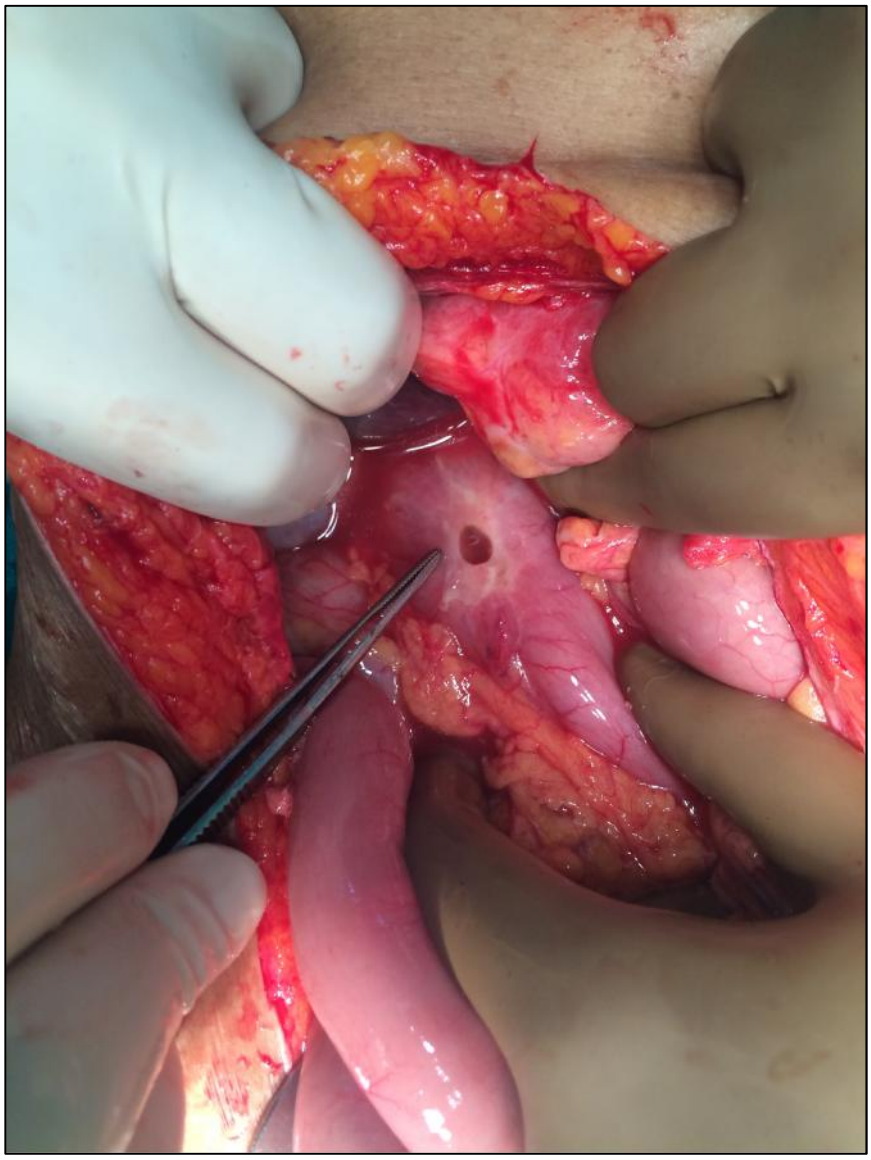
X-RAY Erect Abdomen:

USG Abdomen and Pelvis:

ASSESSMENT OF SURGICAL SITE INFECTION:

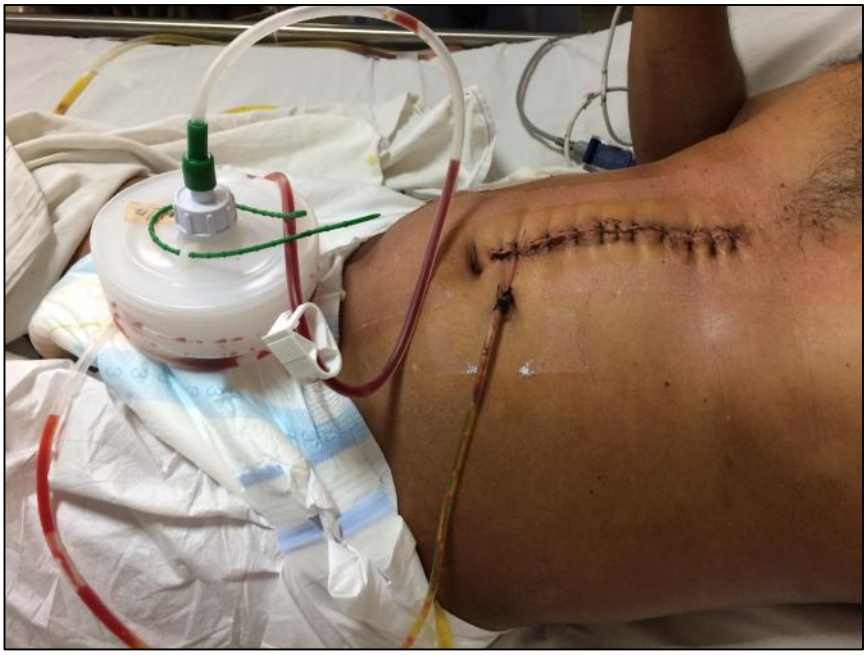
1) Seroma Formation
2) Surgical Site Infection:
3) Wound dehiscence:

ANNEXURES III: PHOTOGRAPHS

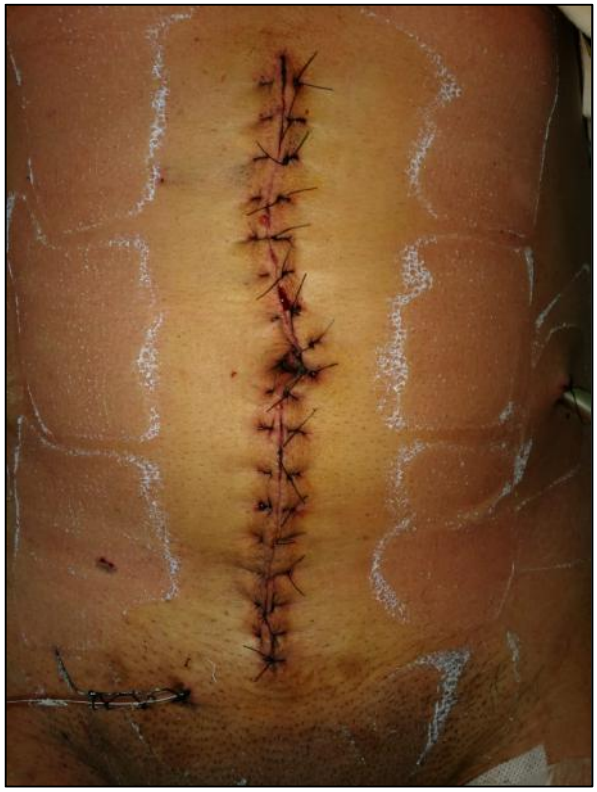


Pre-pyloric Gastric perforation intra-op image

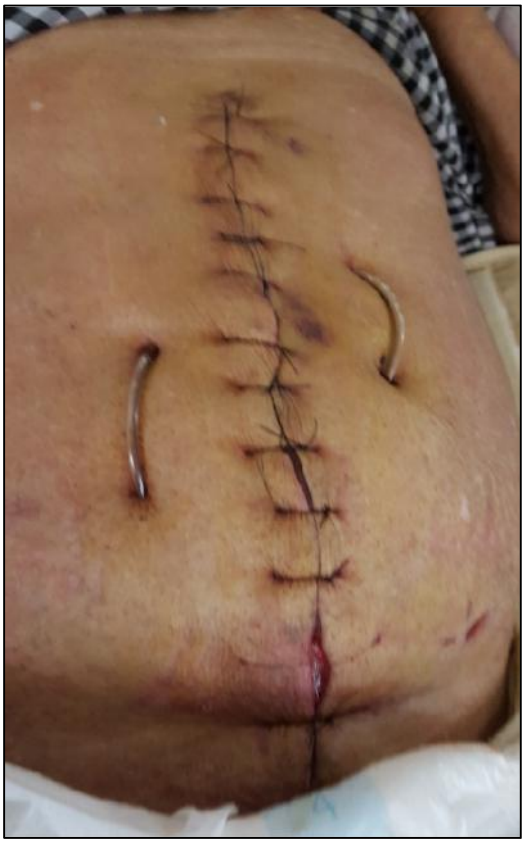
Negative suction subcutaneous drain Romovac No. 10



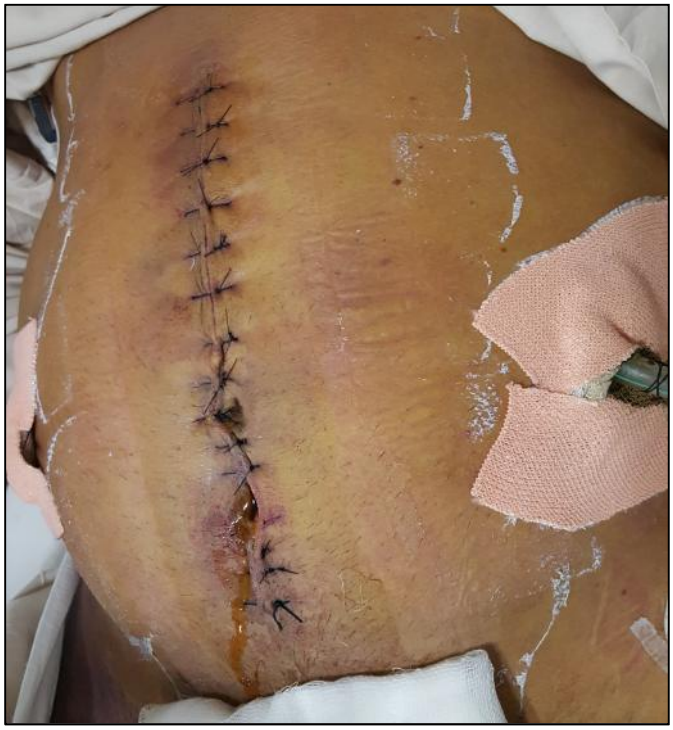
Negative suction subcutaneous drainage with seroma and debris



POD3 with Drain



Surgical Site Infection



Seroma

Wound Dehiscence

KEY TO MASTERCHART

Sex

Male- M

Female- F

Drain

Yes: Inserted

No : Not inserted

Seroma Formation

Yes : Present

No: Absent

Wound Infection

Yes: Present

No: Absent

Wound Dehiscence

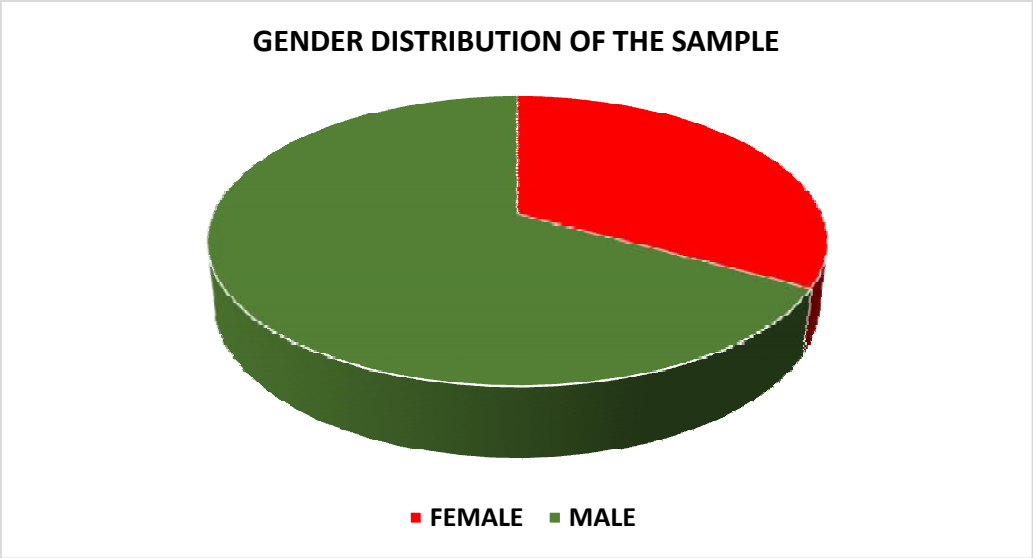
Yes: Present

No : Absent

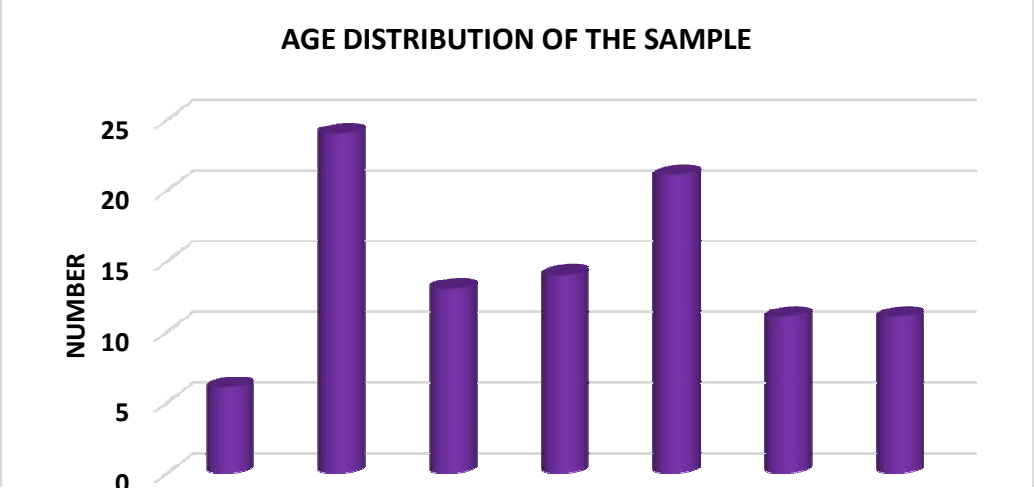
SRL. NO	IP.NO	AGE	SEX	DRAIN	SEROMA FORMATION	WOUND INFECTION	WOUND DEHISCENCE
2	776346	68	M	NO	YES	YES	NO
4	786071	45	M	NO	YES	YES	YES
5	788746	30	M	NO	YES	YES	NO
7	788156	26	F	NO	YES	NO	NO
8	801955	24	F	NO	YES	NO	NO
9	796180	55	M	NO	YES	YES	YES
12	797143	26	F	NO	NO	NO	NO
15	800682	55	M	NO	YES	YES	NO
16	802667	35	F	NO	NO	NO	NO
17	803076	50	F	NO	YES	YES	NO
21	808223	38	M	NO	NO	NO	NO
22	809706	60	M	NO	YES	NO	NO
24	811034	40	F	NO	YES	YES	YES
26	815046	56	F	NO	YES	YES	NO
28	817715	67	M	NO	YES	YES	YES
30	819123	42	M	NO	YES	YES	NO
32	820041	28	M	NO	NO	NO	NO
34	820772	24	M	NO	YES	NO	NO
36	821445	22	M	NO	YES	NO	NO
39	823031	60	M	NO	YES	YES	YES
42	828713	55	M	NO	YES	YES	YES
44	824449	45	M	NO	YES	YES	NO
45	825805	18	F	NO	YES	NO	NO
48	831487	37	M	NO	YES	YES	YES
52	833785	52	F	NO	NO	NO	NO
53	835024	40	F	NO	YES	NO	NO
54	832446	65	M	NO	YES	YES	YES
56	835218	28	M	NO	YES	YES	NO
58	837640	30	M	NO	YES	YES	NO
62	842670	20	F	NO	NO	NO	NO
67	844451	55	M	NO	YES	NO	NO
70	871290	29	F	NO	YES	YES	YES
72	865650	32	M	NO	YES	YES	YES
74	876601	24	M	NO	YES	NO	NO
75	876789	50	M	NO	YES	NO	NO
76	884061	25	M	NO	YES	YES	NO
78	890856	75	M	NO	NO	NO	NO
81	871632	50	F	NO	YES	YES	NO
82	875196	18	M	NO	NO	NO	NO
83	879438	42	M	NO	YES	NO	NO
85	880690	72	M	NO	YES	YES	NO
86	886059	45	F	NO	YES	NO	NO
89	864578	19	F	NO	YES	NO	NO
90	864164	41	M	NO	YES	YES	YES
91	850519	21	M	NO	YES	YES	NO
93	859377	68	M	NO	NO	NO	NO
95	875547	55	F	NO	YES	YES	YES
97	884769	70	M	NO	NO	NO	NO
98	885593	65	M	NO	YES	YES	NO
100	892791	65	M	NO	YES	YES	YES
1	783234	27	M	YES	NO	NO	NO
3	784806	26	F	YES	NO	NO	NO
6	766821	54	M	YES	YES	NO	NO
10	795814	70	M	YES	YES	YES	NO
11	796034	60	F	YES	NO	NO	NO
13	798572	26	M	YES	NO	NO	NO
14	800011	59	M	YES	NO	NO	NO
18	805413	45	M	YES	NO	NO	NO
19	805039	42	M	YES	NO	NO	NO
20	814266	56	M	YES	NO	NO	NO
23	810311	19	F	YES	NO	NO	NO
25	811210	55	M	YES	NO	NO	NO
27	815484	27	F	YES	NO	NO	NO
29	819016	18	M	YES	NO	NO	NO
31	819365	22	F	YES	NO	NO	NO
33	820122	24	F	YES	NO	NO	NO
35	821058	74	M	YES	YES	NO	NO
37	821831	30	M	YES	NO	NO	NO

SRL. NO	IP.NO	AGE	SEX	DRAIN	SEROMA FORMATION	WOUND INFECTION	WOUND DEHISCENCE
38	820003	55	M	YES	YES	NO	NO
40	823528	50	F	YES	NO	NO	NO
41	828079	25	M	YES	NO	NO	NO
43	830308	33	M	YES	NO	NO	NO
46	834546	24	M	YES	NO	NO	NO
47	876214	70	M	YES	NO	NO	NO
49	832100	28	F	YES	NO	NO	NO
50	832165	18	M	YES	NO	NO	NO
51	831800	63	F	YES	YES	NO	NO
55	838613	50	M	YES	NO	NO	NO
57	836020	23	M	YES	NO	NO	NO
59	839016	60	M	YES	NO	NO	NO
60	838618	26	F	YES	NO	NO	NO
61	836130	24	M	YES	NO	NO	NO
63	842006	75	M	YES	YES	NO	NO
64	843547	45	M	YES	NO	NO	NO
65	843667	40	M	YES	NO	NO	NO
66	843790	45	M	YES	NO	NO	NO
68	847446	70	M	YES	NO	NO	NO
69	848055	70	F	YES	YES	NO	NO
71	891609	70	F	YES	NO	NO	NO
73	875373	30	F	YES	NO	NO	NO
77	888555	38	F	YES	NO	NO	NO
79	842133	70	F	YES	YES	NO	NO
80	866431	50	F	YES	NO	NO	NO
84	896089	52	M	YES	NO	NO	NO
87	890123	35	M	YES	NO	NO	NO
88	847346	32	M	YES	NO	NO	NO
92	854320	50	M	YES	NO	NO	NO
94	873480	45	M	YES	NO	NO	NO
96	883030	38	M	YES	NO	NO	NO
99	873628	54	F	YES	NO	NO	NO
	MEAN	43.54	33	50	10	23	37
	S.D.	17.11956	67	50	40	27	13
	MIN	18			42	49	50
	MAX	75			8	1	0

GENDER	NUMBER
FEMALE	33
MALE	67
TOTAL	100



AGE	NUMBER
< 20	6
20 -29	24
30 -39	13
40 - 49	14
50 -59	21
60 - 69	11
≥ 70	11
TOTAL	100



< 20 20 -29 30 -39 40 - 49 50 -59 60 - 69 ≥ 70

	MEAN	S.D.	MIN	MAX
AGE	43.57	17.25	17	80

FEMALE	33
MALE	67

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