A ONE YEAR RANDOMIZED CONTROL TRIAL TO COMPARE THE EFFECT OF EARLY VERSUS LATE POST-OPERATIVE SHOWERING ON LAPAROSCOPIC PORT SITE WOUND INFECTION RATES AT KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI.

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LIST OF ABBREVATIONS USED

OC	–	Ovarian Cyst
AA	–	Acute Appendicitis
C	–	Cholelithiasis
ACC	–	Acute Calculous Cholecystitis
CA	–	Chronic Appendicitis
GBP	–	Gall Bladder Polyp
DL	–	Diagnostic Laparoscopy
LA	–	Laparoscopic Appendicectomy
LC	–	Laparoscopic Cholecystectomy
POD	–	Postoperative Day
DOA	–	Date of Admission
DOD	–	Date of Discharge
PSI	–	Port Site Infection
SSI	–	Surgical Site Infection
NICE	–	National Institute for Health and Care Excellance
Eg.	–	Example
mmHg	–	Millimeters of Mercury
^{o}F	–	Fahrenheit
BP	–	Blood pressure
CDC	–	Centre for Disease Control
LS	–	Laparoscopic Surgery
MAS	–	Minimal Access Surgery
SD	–	Standard deviation

p	-	Probability value
m	-	Centimeters
ml	-	Milliliter
mm	-	Millimeters
IP No	-	In Patient number
gm	-	gram
hrs	-	hours
mg/dL	-	Milligram per deciliter
NS	–	Not significant

ABSTRACT

Background and Objectives

The question of whether patients should be permitted to shower or bathe in the early post-operative period appears to have only recently been addressed in surgical literature. Opinion amongst surgeons varies, with the majority favouring delay of showering until suture removal because of the possibility of increased risk of infection. Nonetheless, some studies have shown that early postoperative showering or bathing is safe and post-operative dressings are not necessary for wound care. There is currently no guidance regarding when a wound can be made wet by post-operative bathing or showering. The objective of the present study was to compare the effect of early versus late post-operative showering on laparoscopic port site wound infection rates.

Methodology

The present one year hospital based randomized controlled trial was done in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2017 to December 2017. A total of 80 patients undergoing elective laparoscopic surgery were studied. These patients were randomly allocated into two groups based on simple randomization that is Group A (Shower Group – Patients are instructed to shower starting 48 hours after surgery) and Group B (Non-shower Group – Patients are prohibited from showering till after stitch removal).

Results

The study population comprised in Group A and Group B was comparable in terms of demographic and clinical characteristics, ruling out the possibility of bias in the study results. Patients having a variety of diagnosis such as acute appendicitis, cholelithiasis, acute calculous cholecystitis, chronic appendicitis, ovarian cyst and gall bladder polyp were included in the study. The wound infection rate was 5% in the shower group (2 out of 40 patients) and 7.5% (3 out of 40 patients) in the nonshower group. The p value was 0.6442, which indicated that the incidence of surgical site infection between the two groups was not statistically significant.

Conclusion and Interpretation

Our study showed that laparoscopic port site wounds may be safely showered and left uncovered 48 hours after surgery. Postoperative showering did not increase the risk of surgical site complications. It may increase patients' satisfaction and lower the cost of wound care.

Keywords

Postoperative Showering / Bathing, Laparoscopic port site infection, Postoperative wound care

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INTRODUCTION

The question of whether patients should be permitted to shower or bathe in the early post-operative period appears to have only recently been addressed in surgical literature. Opinion amongst surgeons varies, with the majority favouring delay of showering until suture removal because of the possibility of increased risk of infection.[1]

Showering after surgery is a controversial issue for wound care providers and patients. The optimal timing and indications for showering after surgery for clean-contaminated wounds remains inconclusive. There is currently no guidance regarding when a wound can be made wet by post-operative bathing or showering.[2]

Post-operative bathing and showering may remove dead skin cells, dirt, micro-organisms and sweat that has collected around the wound edges, and so may reduce risk of infection and promote wound healing. It also makes the patient more comfortable. Furthermore, early showering or bathing may encourage early mobilization of the patient, which prevents development of deep vein thrombosis and encourages deep breathing, which can prevent chest infections. Early mobilization is encouraged after most operations. However, early washing of the surgical wound may affect healing adversely by irritating or macerating the wound and disturbing the healing environment. Exposure to the external environment may also introduce infection.[3]

Traditionally postoperative wounds were cleansed with a sterile solution and maintained dry and covered by a dressing until stitches were removed. Nonetheless, some studies have shown that early postoperative showering or bathing is safe and post-operative dressings are not necessary for wound care.[2]

According to the 2008 NICE guidelines, patients may safely shower 48 hours after surgery, and saline or tap water is equally effective to clean the wound after surgery with comparable wound infection rates. Studies have shown that tap water is effective for wound cleansing and early postoperative showering; it is also conducive to personal hygiene and cost effectiveness.[2]

A study by Ajao et al. showed that the use of sterile bandages for longer than 24 to 36 hours postoperatively was not necessary and that using sterile bandages for longer than 36 hours did not reduce the number of surgical wound infections. The traditional advice has been to cover the wound with a dressing for a period of at least 48 hours, since this is the period during which epithelialization of the wound occurs. Additional data have shown that no increase in the incidence of surgical site infection occurred when surgical wounds were not covered with bandages at all after surgery.[4]

Thus a study proving the results of the above studies is needed inorder to shed clarity on the best time for post-operative showering. None of the studies have specifically concentrated on showering after laparoscopic surgeries, hence such a study would be useful as a large number of abdominal surgeries are done by laparoscopic techniques nowadays. Results favouring early postoperative showering will help in removing the taboo associated with early postoperative showering from the minds of patients and doctors, along with enhancing patient satisfaction with wound care.

In this study, the effect of early versus late postoperative showering on laparoscopic port site wound infection rates is compared.

OBJECTIVES

The objective of this study is to compare the effect of early versus late post-operative showering on laparoscopic port site wound infection rates.

REVIEW OF LITERATURE

ANATOMY OF ANTERIOR ABDOMINAL WALL

The abdominal wall is defined superiorly by the costal margins, inferiorly by the symphysis pubis and pelvic bones, and posteriorly by the vertebral column. Surgical implications of abdominal wall structure become apparent during the course of managing primary abdominal wall diseases or gaining access to the peritoneal cavity. A surgeon must have a thorough understanding of the arrangement of abdominal wall muscles and aponeuroses.[5]

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.[6]

Skin

The integument of the anterior abdominal wall comprises skin, soft tissues, lymphatic and vascular structures, and segmental nerves. The outer layer is formed by the skin and subcutaneous fat. The skin is non-specialized and variably hirsute.[7]

Subcutaneous Tissues

The subcutaneous tissue consists of Camper's and Scarpa's fascia. Camper's fascia is the superficial layer that contains the bulk of the subcutaneous fat; Scarpa's fascia is a denser layer of fibrous connective tissue contiguous with the fascia lata of the thigh. Approximation of Scarpa's fascia aids in the alignment of the skin after surgical incisions in the lower abdomen.[6]

The anterior abdominal wall can be considered to have two parts: anterolateral and middle (or midline). The anterolateral portion is composed of the external oblique, the internal oblique, and the transverses abdominis muscles. The middle portion is composed of the rectus abdominis and pyramidal muscles.[8]

Anterolateral portion of abdominal wall

Lateral to the rectus sheath are three muscular layers with oblique fiber orientations relative to one another. These layers are derived from the laterally migrating mesodermal tissues during the sixth to seventh week of fetal development, before fusion of the developing rectus abdominis muscles in the midline.[5]

The external oblique muscle runs forward inferiorly and medially, but its upper fibres are nearly horizontal; arising from the margins of the lowest eight ribs and costal cartilages. The external oblique muscle originates laterally on the latissimus dorsi and serratus anterior muscles. Its lower fibres, inserting into the iliac crest, are nearly vertical. Medially it forms a tendinous aponeurosis, which is contiguous with the anterior rectus sheath.[5]

The inguinal ligament is the inferior most edge of the external oblique aponeurosis, reflected posteriorly in the area between the anterior superior iliac spine and pubic tubercle.[5]

The internal oblique muscle lies immediately deep to the external oblique muscle and arises from the lateral aspect of the inguinal ligament, the iliac crest, and the thoracolumbar fascia. Its fibers course superiorly and medially, but its lowest fibres, which descend to the pubis, are almost vertical.[9]

They form a tendinous aponeurosis that contributes components to both the anterior and posterior rectus sheath. The lower medial and inferior-most fibers of the internal oblique course may fuse with the lower fibers of the transverses abdominis muscle (the conjoined area).[5]

Transversus abdominis is the deepest muscle, and runs mainly horizontally, although its lowest fibres run downwards along with those of internal oblique as the conjoint tendon. Its deep surface is lined by transversalis fascia; between this and the peritoneum there is a layer of extraperitoneal fat of variable thickness.[9]

Middle portion of abdominal wall

Rectus abdominis lies alongside the linea alba, extending above from the 5th, 6th, 7th costal cartilages and the xiphoid process; below it attaches to the pubic crest, to the ligamentous tissue at the symphysis pubis, and the superior ramus of the pubis. Its lateral border may be visible on the surface of the anterior abdominal wall as a curved groove, the linea semilunaris, which extends from the tip of the ninth costal cartilage to the pubic tubercle. It is broader but thinner superiorly. Its substance is traversed by three horizontal tendinous intersections, one opposite the umbilicus, another near the xiphoid, and a third midway between these. Studies by Milloy et al. demonstrate that three inscriptions are the most common pattern (58%), and four inscriptions the next most common (35%).[8]

Vascular supply

Rectus abdominis is supplied principally by the superior and inferior epigastric arteries. The inferior epigastric artery tends to be larger in caliber than the superior. Small terminal branches from the lower three posterior intercostal arteries, subcostal

artery, the posterior lumbar arteries and the deep circumflex artery may provide some contributions.[7]

Nerve supply

Rectus abdominis is innervated by the terminal branches of the ventral rami of the lower six or seven thoracic spinal nerves via the lower intercostal and subcostal nerves.[7]

Pyramidalis muscle

The pyramidal muscle attaches to the pubic crest and symphyseal ligamentous tissues and inserts into the linea alba. The pyramidal muscle is absent on one or both sides in 10 to 20 percent of subjects. When present, its insertion into the linea alba is a landmark for an accurate midline incision.[8]

Vascular supply

Pyramidalis is supplied by branches of the inferior epigastric artery, with some contribution from the deep circumflex iliac artery. A small artery frequently crosses the midline posterior to the belly of the muscle to anastomose with the contralateral vessel. This may cause troublesome bleeding during surgical incisions that run down as far as the lower rectus sheath above the symphysis pubis.[7]

Nerve supply

Pyramidalis is supplied by the terminal branches of the subcostal nerve, which is the ventral ramus of the twelfth thoracic spinal nerve.[7]

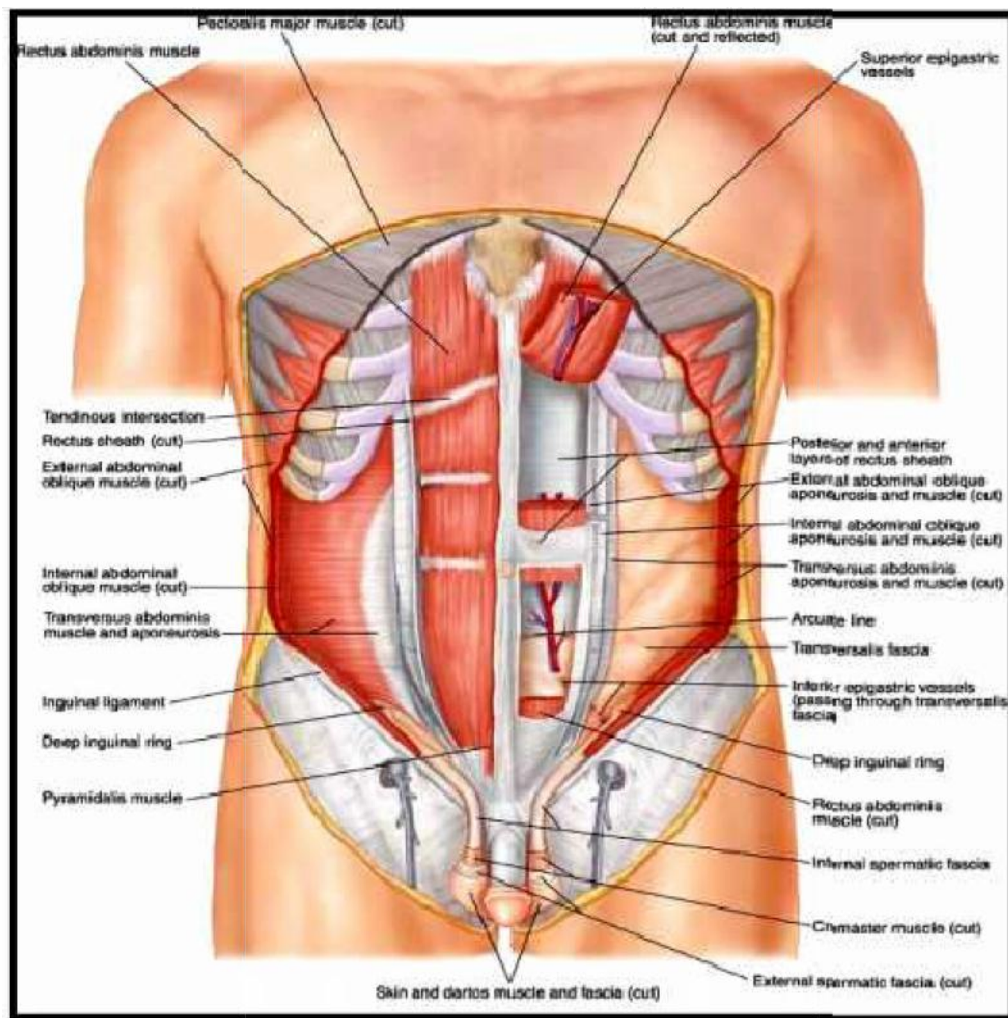


Figure No.1: Layers of Anterior Abdominal Wall

Rectus Sheath

This is formed by the aponeuroses of external oblique, internal oblique and the transversus abdominis, the last two of which are arranged in a somewhat complicated manner. The anterior sheath is complete from rib margin to pubis. In its upper three-quarters it is formed by external oblique and the anterior lamina of internal oblique. In the lower one quarter it is formed by all three aponeuroses. It is adherent to the tendinous intersections of the rectus muscle.[9]

The posterior sheath is complete only as far down as a point midway between umbilicus and pubis, where it ends as a free border, called the arcuate line

(semicircular line of Douglas), which lies roughly at the level of the anterior superior iliac spines . Below this level the sheath is deficient, the rectus being separated from the peritoneum by transversalis fascia alone. The posterior sheath is formed by the posterior lamina of internal oblique fused with transversus. The tendinous intersections do not extend to the posterior surface of the rectus abdominis.[9]

Because of this arrangement, both the anterior and posterior layers of the rectus sheath consist of three layers of fibres with the middle layer running obliquely at right angles to the other two. At the midline, the anterior and posterior layers are closely approximated. Fibres of each layer decussate to the opposite side of the sheath, forming a continuous aponeurosis with the contralateral muscles.[7]

Fibres also decussate antero-posteriorly, crossing from anterior sheath to posterior sheath. The dense fibrous line caused by this decussation is called the linea alba. These decussating fibres maybe used to identify the midline during surgical incisions, since they can be seen as oblique fibres crossing at right angles. Below the level of the arcuate line, the fibres forming the posterior rectus sheath rapidly cease running behind the rectus and all leaves pass into the anterior rectus sheath.[7]

Linea alba

The linea alba is a tendinous raphe extending from the xiphoid process to the symphysis pubis and pubic crest. It lies between the two recti and is formed by the interlacing and decussating aponeurotic fibres of external oblique, internal oblique and transverses abdominis. It is visible only in the lean and muscular, as a slight groove in the anterior abdominal wall.

A fibrous cicatrix, the umbilicus, lies a little below the midpoint of the linea alba, and is covered by an adherent area of skin. Below the umbilicus, the linea alba narrows progressively as the rectus muscles lie closer together. Above the umbilicus, the rectus muscles diverge from one other and the linea alba is correspondingly broader. The linea alba has two attachments at its lower end: its superficial fibres are attached to the symphysis pubis, and its deeper fibres form a triangular lamella that is attached behind rectus abdominis to the posterior surface of the pubic crest on each side. This posterior attachment of linea alba is named the 'adminiculum lineae albae'. The linea alba is crossed from side to side by a few minute vessels.[7]

According to Askar, there is a single decussation of fibers of both the anterior and posterior rectus sheath laminae in 30% of cases. A single decussation of anterior rectus sheath laminae and a triple decussation of posterior rectus sheath laminae is found in 10% of cases. A triple decussation of aponeurotic fibers of both anterior and posterior rectus laminae occurs in 60% of cases. Subjects in the group with single fibrous crossings of both the anterior and posterior rectus sheath laminae may be more susceptible to linea alba herniation.[8]

Linea semicircularis

The semicircular line of Douglas marks the lower level of the aponeurotic posterior lamina. This concavity of the arcuate line is usually directed downward or downward and laterally. If the change from aponeurosis to transversalis fascia is gradual, the line is poorly defined. If the change is abrupt, the line is well marked.[8]

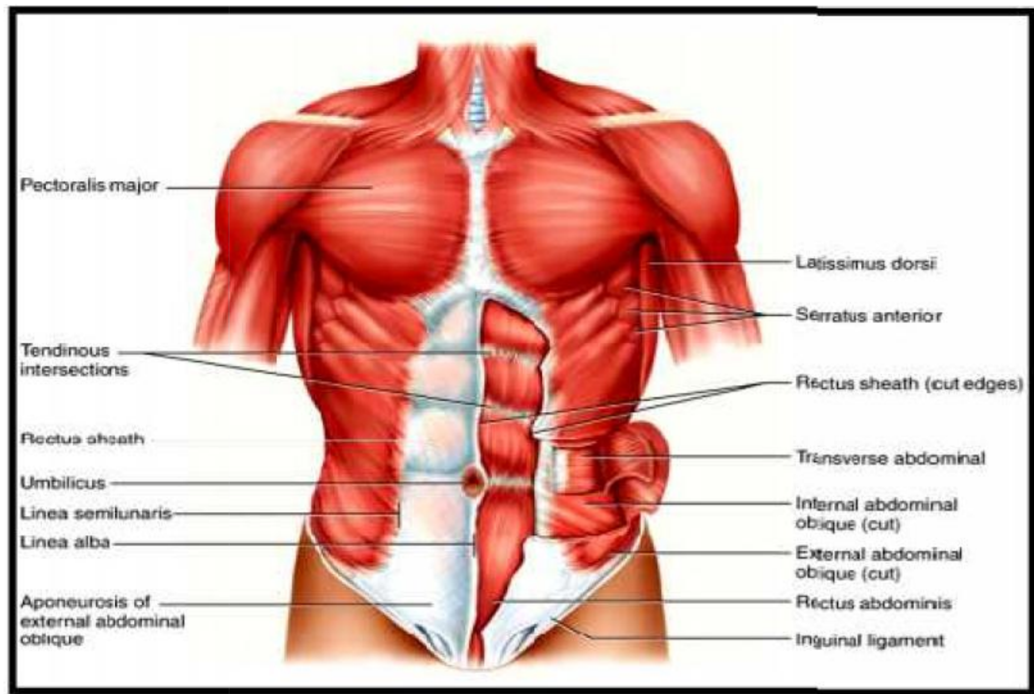


Figure No.2: Layers of Anterior Abdominal Wall

Transversalis fascia

It covers the deep surface of the transversus abdominis muscle and with its various extensions forms a complete fascial envelope around the abdominal cavity.

This fascial layer regionally covers the iliopsoas fascia, obturator fascia, and inferior fascia of the respiratory diaphragm. The transversalis fascia binds together the muscle and aponeurotic fascicles into a continuous layer and reinforces weak areas where the aponeurotic fibers are sparse. This layer is responsible for the structural integrity of the abdominal wall.[6]

Extraperitoneal connective tissue

The extraperitoneal connective tissue is a layer of areolar tissue lying between the peritoneum and the fasciae lining the abdominal and pelvic cavities. The amount of extraperitoneal tissue varies. It is variable in thickness on the anterolateral wall. It is scanty in the suprapubic region, above the iliac crest and in the pelvis. Extraperitoneal tissue is continuous with the epimysium of muscles of the abdominal wall.[7]

Peritoneum

The peritoneum is the innermost layer of the abdominal wall anteriorly, laterally, and posteriorly. It is loosely connected with the transversalis fascia in most areas, except at the internal ring, where the connection is stronger. It can also be fused rather tightly to the posterior lamina of the rectus sheath, rendering their separation difficult.[8]

Blood supply

The majority of the blood supply to the muscles of the anterior abdominal wall is derived from the superior and inferior epigastric arteries. The superior epigastric artery arises from the internal thoracic artery, whereas the inferior epigastric artery arises from the external iliac artery. The two vessels have anastomotic connections within the belly of the muscle. A collateral network of branches of the subcostal and lumbar arteries also contributes to the abdominal wall blood supply.[5]

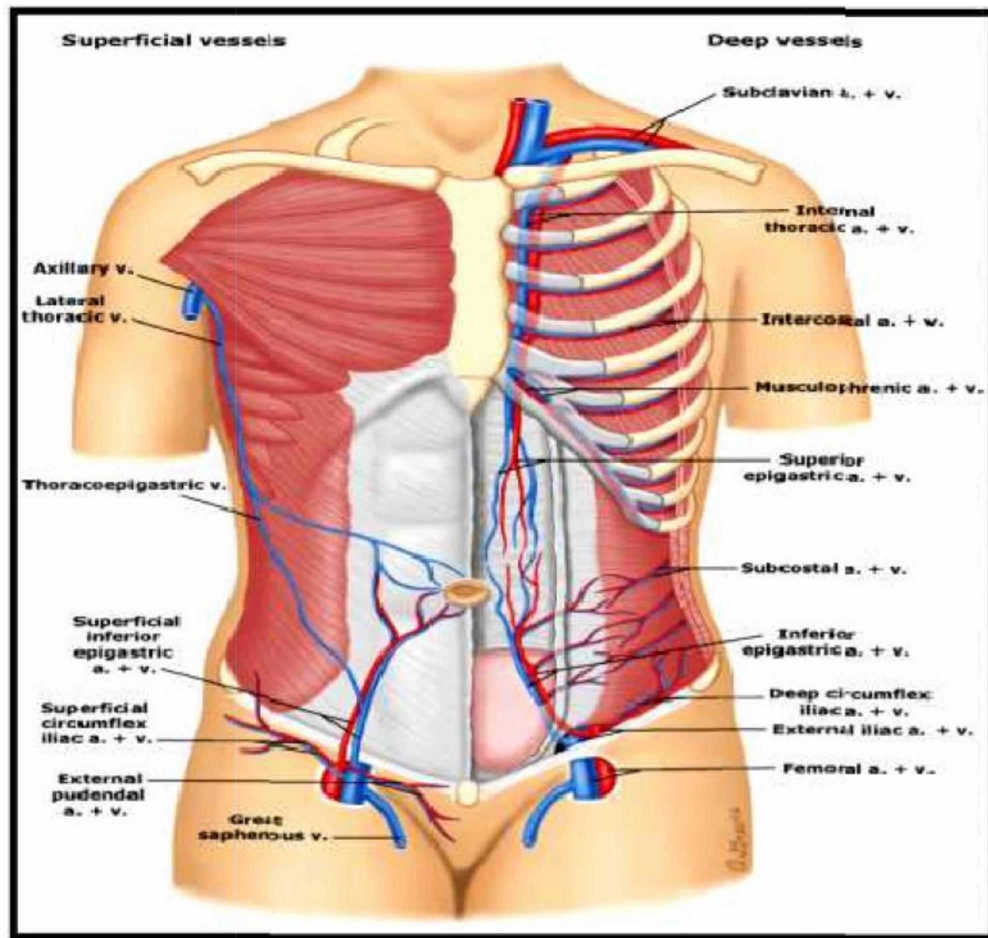


Figure No.3: Blood Supply to Anterior Abdominal Wall

Lymphatic drainage

The lymphatic vessels of the anterior abdominal wall lie both superficial and deep to the deep fascia. The lymphatic drainage of the abdominal wall is predominantly to the major nodal basins in the superficial inguinal and axillary areas.

Superficial vessels

Vessels from the lumbar and gluteal regions run with the superficial circumflex iliac vessels. Those from the infra-umbilical skin run with the superficial epigastric vessels. Both drain into the superficial inguinal nodes. The supra-umbilical

region is drained by vessels running obliquely up to the pectoral and subscapular axillary nodes, and there is some drainage to the parasternal nodes.[7]

Deep vessels

The deep lymphatic vessels accompany the deep arteries. The vessels from the posterior portion of the abdominal wall pass with the lumbar arteries to drain into the lateral aortic and retro-aortic nodes. Vessels from the upper anterior abdominal wall run with the superior epigastric vessels to the parasternal nodes. Vessels of the lower abdominal wall drain into the circumflex iliac, inferior epigastric and external iliac nodes.[7]

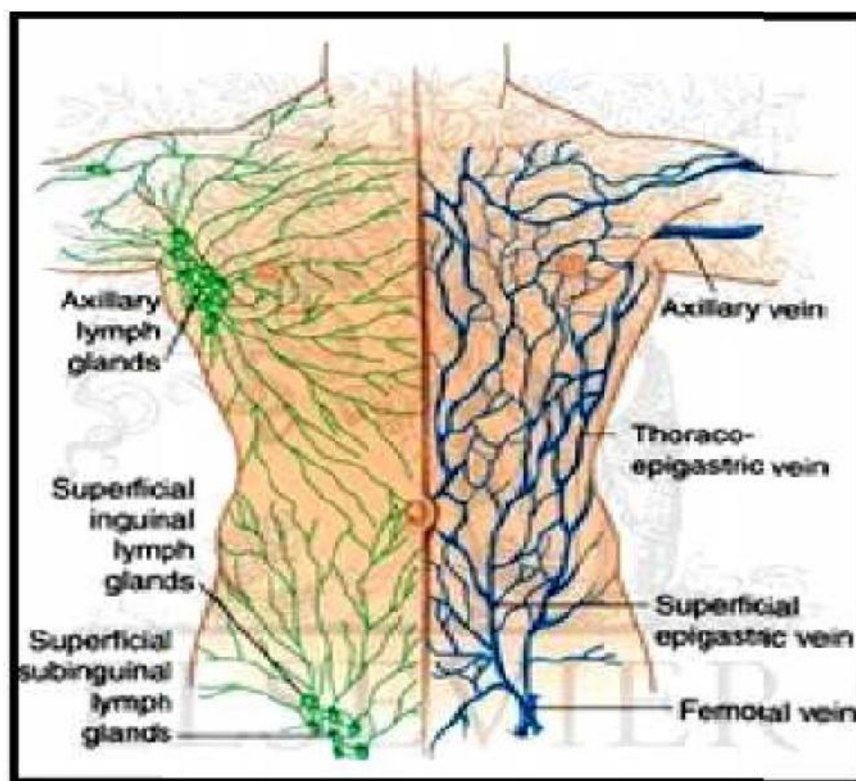


Figure No.4: Lymph Nodes and Lymphatics of Anterior Abdominal Wall.

Nerve supply

Innervation of the anterior abdominal wall is segmentally related to specific spinal levels. The motor nerves to the rectus muscles, the internal oblique muscles, and the transversus abdominis muscles run from the anterior rami of spinal nerves at the T6 to T12 levels. The overlying skin is innervated by afferent branches of the T4 to L1 nerve roots, with the nerve roots of T10 sub serving sensation of the skin around the umbilicus.[5]

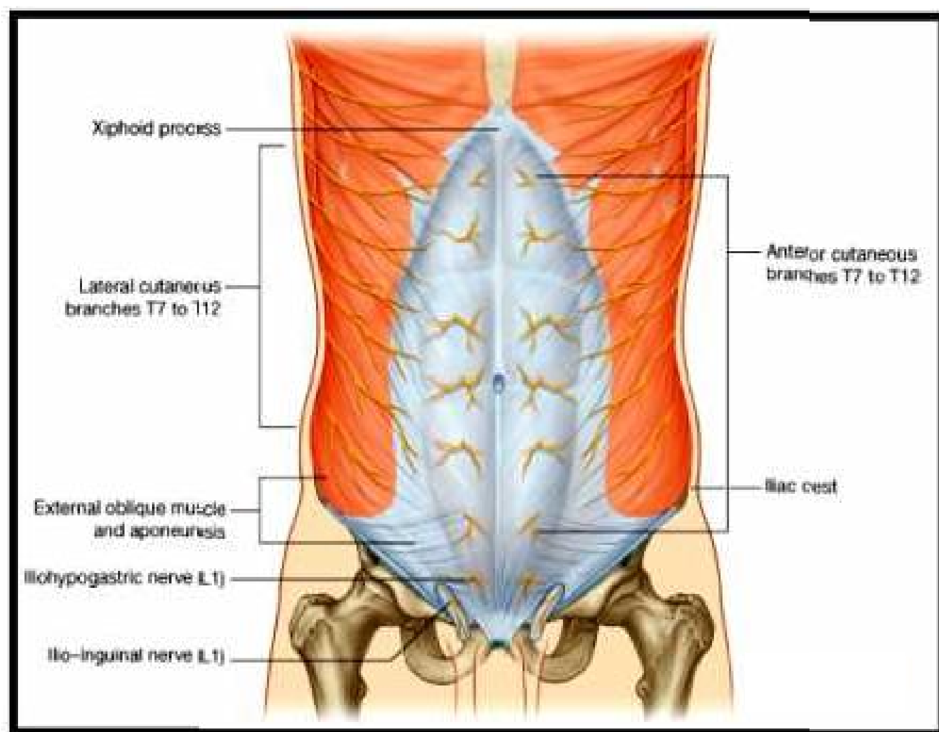


Figure No.5: Nerve Supply to Anterior Abdominal Wall

SURGICAL SITE INFECTION

Definition

Surgical site infections are infections present in any location along the surgical tract after surgical procedure. SSIs involve postoperative infections occurring at any level (incisional or deep) after a specific procedure. Surgical site infections represent a significant burden in terms of patient morbidity and mortality, and cost of health services. Assessment tools such as the Centers for Disease Control (CDC) definitions and Southampton Wound Assessment scale are required to identify and classify SSIs.[10]

Historical review

Depending upon the state of knowledge concerning bacteria and bacterial disease, the concept to solve problem of surgical infections have been varying since long time. In earlier days practice was to identify the bacteria and eliminating them from the surgical environment. This has led to the present day method of sterile and aseptic technique based on simple philosophy that if there are no bacteria around the surgical field there is no infection.

This was followed by better understanding of bacterial metabolism and development of antibacterial substances. With the increasing information about the natural resistance of patient against bacteria, the concept of prophylactic antibiotics was evolved. With the modern sterile techniques, bacterial contamination of surgical wounds can be reduced to very small amount. These small numbers of bacteria gaining entrance to wounds will be immediately eliminated by patient's natural antibacterial mechanism supplemented or augmented by externally administered antibiotics.

Before the mid-19th century, surgical patients commonly developed postoperative fever followed by purulent discharge from their incisions, overwhelming sepsis and often death. It was not until the late 1860s, when Joseph Lister introduced principles of antisepsis that substantially lead to decreased postoperative infectious morbidity. Lister's work had changed surgery radically from an activity associated with infection and death to a discipline that could eliminate suffering and prolong life.[11]

In 1846, Ignaz Semmelweis, a Magyar physician noticed that the mortality from puerperal fever was much higher in the teaching ward than in the ward where patients were delivered by midwives. He introduced a practice of rinsing hands thoroughly in chlorine water before entering. This simple intervention had reduced mortality drastically. Unfortunately Semmelweis's ideas were not accepted by the authorities of that time, so he committed suicide in 1865 by intentionally cutting his finger during an autopsy of a woman who died of puerperal fever, presumably as the proof of his tenets.[12]

Ignaz Semmelweis and Joseph Lister became the pioneers of the infection control during the mid-19th century, by introducing antiseptic surgery. Mortality rate was as high as 70 to 80% for patients with deep or extensive infections.[13] Since then number of developments have been made, particularly in the field of microbiology, which have made surgery safer. However the overall incidence of healthcare associated infections (HAIs) still remains high and represents a substantial burden of disease.

In 1992, the US CDC revised the definition of 'wound infection', creating the definition of 'surgical site infection' (SSI) to prevent confusion between the infection

of a traumatic wound and infection of a surgical incision.[11] Most surgical site infections are superficial, but still they contribute greatly to the morbidity and mortality associated with the surgery.[15,16]

Cruse in 1980, estimated that a SSI increases a patient's hospital stay by approximately 10 days and cost to an additional $2,000.[17,18] There are other studies which also show the increased length of hospital stay and cost associated with SSIs.[16,17] As compared to superficial SSIs, Deep SSIs involving organs or spaces are associated with even greater increases in hospital stay and costs.[21,22]

The incidence of post-operative surgical site infection ranges from 4% (in developed countries and in clean cases) to 45% (in developing countries and in contaminated surgeries). An Indian study demonstrated an incidence of 12% after a retrospective analysis of 1125 patients with abdominal surgeries.[23] Another large systematic review of 147 clinical trials demonstrated an overall incidence of 11% following colorectal surgeries.[24]

Another Indian study conducted in Mumbai by Lilani and colleagues evaluated SSIs in 190 consecutive patients undergoing clean and clean – contaminated surgeries, and found that 8.95% developed SSIs.[25] Previous Indian studies also concur with similar rates of SSIs ranging from 10.06% to 45% in clean – contaminated cases.[26-28]

Classification of Surgical Site Infection based on CDC guidelines

As per CDC guidelines, surgical site infections have been classified into three types, which are as follows.[14]

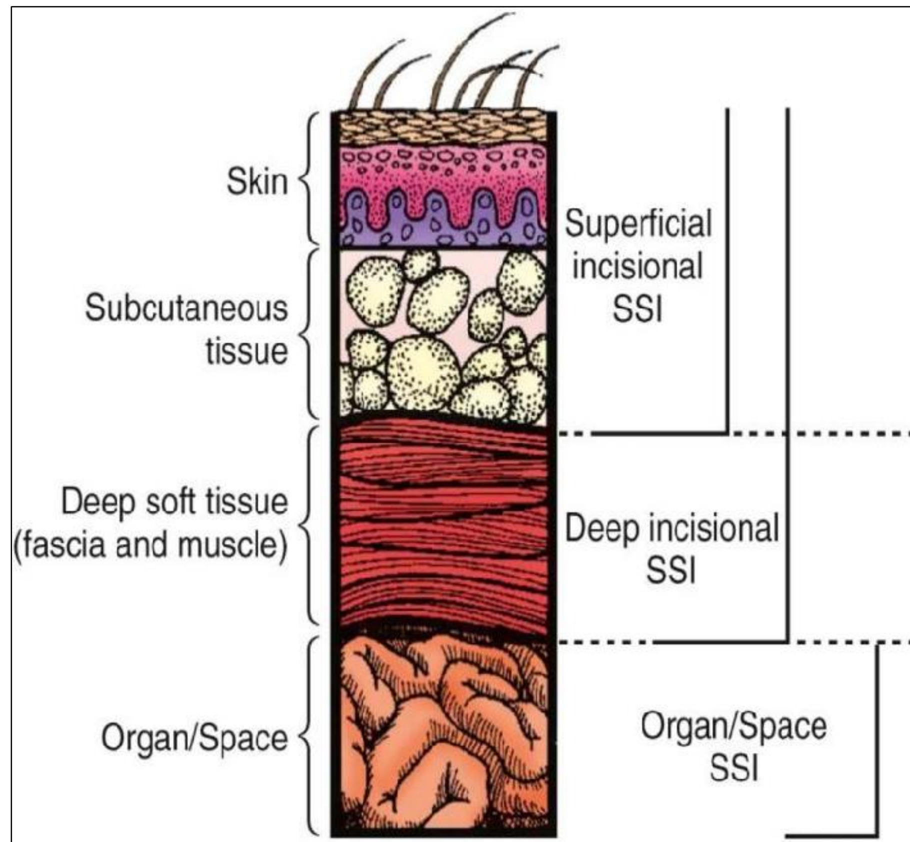


Figure No.6: Surgical Site Infection as per CDC guidelines

1. **Superficial incisional SSI**

It should meet the following criterion:

- Infection occurring within 30 days after the operative procedure
- Involves only skin and subcutaneous tissue of the incision
- Patient has any one of the following:

a. Purulent drainage from the superficial incision (culture documentation not required)

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

c. Presence of at least one of the following signs or symptoms of infection: Pain or tenderness, localized swelling, redness, warmth, and superficial incision deliberately opened by surgeons.

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

2. Deep incisional SSI

It should meet the following criterion:

- 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 related to the operative procedure
- Involves deep soft tissues (eg, fascial and muscle layers) of the incision
- Patient has one of the following:

a) Purulent drainage from the deep incisions 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 one of the following signs or symptoms: fever, or localized pain or tenderness. A cultured 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 histopathological or radiological examination

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

3. Organ / Space SSI

It involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure. It should meet the following criterion:

- 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 related to the operative procedure, and
- Patient has at least one of the following:

a. Purulent drainage from the 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 histopathological or radiological examination

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

Major and Minor surgical site infections

A major SSI is defined as a wound that either discharges significant quantities of pus spontaneously or needs a secondary procedure to drain it. The patient may have systemic signs such as pyrexia, tachycardia and a raised WBC count.

Minor wound infections may discharge pus or infected serous fluid but should not be associated with excessive discomfort, systemic signs or delay in return home.

There are scoring systems for the severity of wound infection, which are particularly useful in surveillance and research, example of which is Southampton scoring system.

Southampton Scoring System[29]

GRADE	APPEARANCE
0	Normal healing
1	Normal healing with mild bruising or erythema
	A - Some bruising B - Considerable bruising C - Mild erythema
2	Erythema plus other signs of inflammation
	A - At one point B - Around sutures C - Along wound D - Around wound
3	Clear or haemoserous discharge
	A - At one point only (<2mm) B - Along wound (>2cm) C - Large volume D - Prolonged (>3 days)
4	Major Complication: Pus
	A - At one point only (<2cm)
	B - Along wound (> 2cm)
5	Deep or Severe wound infection with or without tissue breakdown: haematoma requiring aspiration

Risk factors associated with SSIs[30]

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

Classification of operative wounds contamination[31]

Classification	Criteria
Clean	Elective, not emergency, non-traumatic, primarily closed; no acute inflammation; no break in technique; respiratory, Gastrointestinal, biliary and genitourinary tracts not entered.
Clean – contaminated	Urgent or emergency case that is otherwise clean; elective opening of respiratory, gastrointestinal, biliary or genitourinary tract with minimal spillage (appendicectomy) not encountering infected urine or bile; minor technique break.
Contaminated	Non-purulent inflammation; gross spillage from gastrointestinal tract; entry into biliary or genitourinary tract in the presence of infected bile or urine; major break in technique; penetrating trauma <4 hours old; chronic open wounds to be grafted or covered
Dirty	Purulent inflammation (abscess); preoperative perforation of respiratory, gastrointestinal, biliary or genitourinary tract; penetrating trauma >4 hours old

Port Site Infection

Port site infection (PSI), although infrequent, is one of the bothersome complications which undermine the benefits of minimal invasive surgery. Not only does it add to the morbidity of the patient but also spoils the reputation of the surgeon. Despite the advances in the field of antimicrobial agents, sterilization techniques, surgical techniques, operating room ventilation, PSIs still prevail. PSIs are preventable if appropriate measures are taken preoperatively, intraoperatively and postoperatively. PSIs can often be treated non-surgically, with early identification and appropriate management.

Incidence

Incidence of SSI after elective laparoscopic cholecystectomy is less than that after open elective cholecystectomy due to shorter length of incision.[32] The technique of primary port entry to the peritoneum does not show any difference in umbilical PSIs in patients undergoing laparoscopic cholecystectomy.[33] The umbilical PSI rate in LS has been reported to be 8% with 89% of the infections occurring after laparoscopic cholecystectomy, whereas 11% after laparoscopic appendectomy.[34] Francis et al[35] studied the factors predicting 30 day readmission after laparoscopic colorectal cancer surgery. Out of 268 patients in their study who underwent laparoscopic colorectal surgery, 48 (18%) were readmitted with surgical site infection (SSI).[35] Several other authors have found that SSI rate is much higher in conventional surgical procedures than in MAS.[36-38] The immune functions are less affected in LS as compared to open surgery.[39]

Risk factors for PSIs

A number of contributing factors are somewhat responsible for the emergence of postoperative PSIs. Antibiotics always may not be the answer to this problem. Thus, using them irrationally, as is often done will only result in the emergence of multidrug resistant microbes. The majority of the reports of postoperative wound infection are of SSIs. PSIs following LS have been less reported. The risk factors for SSIs, however, may be applicable to PSIs.

Lilani et al[36] reported a significant increase in the incidence of SSIs with preoperative stay of more than 2 days for surgical procedures. The study by Lilani et al also reported a nil infection rate in surgeries of less than 30 minute duration. There was a significant increase in SSIs for operations of prolonged duration for two hours or more.

Obesity, prophylactic antibiotics, and drains have no effect on the rate of SSIs following laparoscopic cholecystectomy.[44] Factors like emergency/multi-procedure surgery and surgery in acutely inflamed organs adversely affect the rate of SSIs.[41,42] The risk of SSIs increases in patients with a history of nicotine or steroid usage, diabetes, malnutrition, long preoperative hospital stay, preoperative colonization of nares with *Staphylococcus aureus*, or perioperative blood transfusion.[45,46]

PSIs are more common in the umbilical port[38]; the infection rate may depend upon the port through which the specimen is extracted. The infected specimen should be removed in an endobag in order to prevent wound infection and accidental spillage of contents or occult malignant cells.[40]

Microbial flora causing PSIs

PSIs occur due to exposure of surgical wound to microbes which may be from an endogenous or exogenous source. The source of endogenous flora usually is from the patient's skin, mucous membranes or any of the viscera. The exogenous flora may be from any contaminated sources present in the sterile surgical field including surgeon and team, instruments, room air, *etc*.[47]

The pathogenic organisms causing SSIs differ with the surgical procedure performed. Clean surgical wounds usually harbor *Staphylococcus aureus* which may have an exogenous origin or may be from the patient's native flora. Infections in clean-contaminated, contaminated and dirty surgical wounds are polymicrobial, resembling the endogenous flora of the target organ.[48]

PSIs are of two broad varieties based on the timing when they are present. The more common type manifests early, within a week of the surgical procedure. Gram positive or negative bacteria are the usual offending organisms which are contracted from the native skin or infected surgical site. They usually respond well to the commonly used antimicrobial agents. The other variety is caused by rapid growing atypical mycobacterium species, which has an incubation period of 3 to 4 weeks. They show a poor response to the usual antimicrobial agents.[49]

Non-mycobacterial isolates: Kownhar et al[50] reported superficial SSIs as the most common in both MAS and open surgical procedures, with *Staphylococcus aureus* as the most common isolate. They studied the SSIs and found various common bacteria isolated as *Staphylococcus aureus* (37%) and *Pseudomonas aeruginosa* (37%), followed by *Klebsiella pneumonia* (8%), *Acinetobacter spp*. (3.2%), *Proteus spp*. (4.8%), *Escherichia coli* (4.8%), *Citrobacter freundii* (1.6%), *Edwardsiella tarda*

(1.6%) and *Enterococcus faecalis* (1.6%). *Klebsiella sp.* is the most common offending organism in deep SSIs irrespective of the surgical approach.[50] Usually hospital acquired skin flora cause superficial SSIs. Organisms causing deep SSIs usually are endogenous in origin or may be the skin commensals which reach the fascia or muscle layers through surgical incision.[43]

Mycobacterial isolates: Several reports have established the role of rapid growing mycobacteria (RGM), particularly *M. fortuitum* and *M. chelonae* which together have been termed as *M. fortuitum-chelonae complex* that is known to cause disease in humans as well as animals. This often cause localized skin infections 3-4 weeks post-surgery.[51,52]

Clinical presentations of PSIs

Wound discharge and erythema around the port site are the most common presentation of non-mycobacterial infection usually occurring within a week of the surgery. They are usually limited to the skin and subcutaneous tissue.[38] There may be surrounding tissue inflammation with pain or tenderness and low grade fever.[47]

The delayed type of presentation commonly caused by mycobacteria manifests nearly a month after surgery, in the form of persistent multiple discharging sinuses or lumps/nodules, not responding to antibiotics. There may be pigmentation and induration at the port site starting in a single port and spreading to others.

Diagnosis and Treatment of PSIs

Gram stains and culture sensitivity of the pus from port site wounds are to be taken. The swabs obtained are processed aerobically and anaerobically by standard methods to find the non-mycobacterial isolates. *Staphylococcus aureus* strains are

usually isolated from clean wounds. Their status of -lactamase production and methicillin resistance needs to be assessed.[36] Daily dressing, cleaning of the wound and a course of empirical antibiotic are started. Specific antibiotics as per the culture and sensitivity report are to be given subsequently. Drainage and debridement may sometimes be required for assisting in wound healing. Management of PSIs with atypical mycobacteria lacks consensus. They respond poorly to first line anti-tubercular drug treatment. Second line anti-tubercular drugs including macrolides (clarithromycin), quinolones (ciprofloxacin), tetracyclines (doxycycline) and aminiglycosides (amikacin and tobramycin) in various combinations have been used with promising results.[51]

Prevention of PSIs

Ten commandments for preventing PSI[53-56]

(1) Use of disposable trocars and instruments, and adequate availability of properly sterilised reusable trocars to cover all the surgical procedures in a day.

(2) Use of autoclavable laparoscopic hand instruments.

(3) Use of instruments with good ergonomics, limited joints and facility for proper cleaning of the debris collected in its crevices.

(4) A proper cleaning of the instrument is best achieved by ultrasonic technology. Use of autoclaved water for cleaning the instruments after dismantling.

(5) Proper guidelines should be followed regarding the concentration, contact time and cycles of use for instrument sterilization with liquid sterilizing agents.

(6) Use of plasma sterilizer or ethylene oxide in between the consecutive surgery for instrument sterilization.

(7) Avoiding inter-departmental sharing of instruments, such as using instruments used for gynecological or urological procedures.

(8) Avoiding spillage of bile or gut content in the operative area or the port site.

(9) Use of non-porous specimen retrieval bags for retrieving the specimen.

(10) Thorough irrigation and cleaning of the port site before wound closure.

In a study conducted by Pei-Yin Hsieh et al., in Department of Surgery, National Taiwan University Hospital, between May 1, 2013 to March 18, 2014,

wound infection rates were evaluated starting 48 hours after surgery for clean & clean contaminated wounds. Patients were randomized into the shower & non-shower groups having 222 patients each. Superficial surgical site infection in shower group – 1.8%. Superficial surgical site infection in non-shower group – 2.7%. The study showed that clean and clean contaminated wounds may be safely showered and left uncovered 48 hours after surgery. Postoperative showering did not increase the risk of surgical site complications. It may increase the patient's satisfaction and lower the cost of wound care.[2]

A trial was conducted by Toon CD et al., including 857 patients undergoing minor skin excision surgeries. The wounds were sutured after the excision. Patients were randomized into early and delayed post-operative bathing groups. The only outcome of interest reported in this trial was surgical site infection. The proportions of patients who developed surgical site infection were 8.5% in the early bathing group and 8.8% in the delayed bathing group. There was no statistically significant difference in the proportion of patients who developed surgical site infection between the two groups. The author stated that there is currently no conclusive evidence available from randomized trials regarding the benefits or harms of early versus delayed post-operative showering or bathing for the prevention of wound complications. The author recommended running further randomized controlled trials to compare early versus delayed post-operative showering or bathing.[3]

A study was conducted by Borkar NB et al., to determine whether or not the routine use of postoperative dressings prevents surgical site infection. Patients with clean or clean-contaminated sutured surgical wounds were randomized into two

groups: those who did not receive postoperative dressings (the study group) and those who did (the control group). Wounds were assessed after 6 and 24 hours, and on the third and fifth postoperative days for clinical signs of infection. A total of 123 patients with clean surgical wounds were recruited into the study. There was no significant difference in the rate of wound complications between the two groups: 4.76% for the study group and 4.92% for control. Based on these preliminary data, surgical wounds left open do not have an increased incidence of surgical site infection compared with similar types of wounds dressed postoperatively.[57]

A prospective randomized study was designed to determine the effect of postoperative water contact on tissue healing by Riederer SR et al. A total of 121 patients undergoing open hernia repair was divided into two groups. The first group was permitted to shower postoperatively, allowing the wound to come into direct contact with the water, the second group was instructed to keep the incision dry. Water contact, wound healing and patient satisfaction were assessed. There was no difference in wound healing between the two groups and no manifest infection.[58]

In a study conducted by Ellwood G. Voorhes et al., eighty two patients who underwent surgery at Walter Reed Army Medical Centre from August 1978 to May 1979, were randomly assigned to a showering or a non-showering group according to whether their social security number ended in even or odd digits. The skin was closed with monofilament nylon in both the groups. Members of the shower group were encouraged to shower with ordinary bath soap on the second postoperative day. Patients in the non-shower group were permitted to shower 1 day after suture removal. Two wound complications occurred in the showering group whereas 4 wound complications were present in the non-shower group. The results between the

two groups were not significant and there was no indication that early postoperative showering causes infection or delays wound healing.[1]

Paul Dayton et al., undertook a systematic review of electronic databases and other relevant sources regarding the incidence of infection when patients had been allowed to wet their surgical incision site by showering or bathing before suture removal. Nine studies involving 2150 patients met the inclusion criteria. A total of 2150 patients were included, of whom 1639 subjects (76.23%) were allowed to bathe or shower and wet the surgical site before suture or staple removal. The period ranged from immediately postoperatively to 5 days postoperatively. Of the remaining 511 patients (23.77% of the total), 295 (13.72% of the total and 57.73% of the remaining patients) were not allowed to wet the incision site until after suture or staple removal, and 216 (10.05% of the total, 42.27% of the remaining patients) were not allowed to wet their wound immediately, but a specific period was not noted in the methods section. The anatomic site, surgical procedure, and method of closure varied in the included studies. The studies all appeared to use tap water. This was mentioned specifically in several studies, and the others did not state anything to the contrary. All the patients allowed to bathe or shower were instructed to do so with the bandage off. No increased incidence of infection was found in the patients allowed to shower or bathe as a part of their normal daily hygiene before suture removal compared with those who were instructed to keep the site dry until suture removal.[4]

METHODOLOGY

The present study was carried out in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.

TYPE OF STUDY: Randomized Controlled Trial

METHOD OF RANDOMIZATION: Sealed Envelope Method

STUDY PERIOD: 1st January, 2017 to 31st December, 2017

SOURCE OF DATA: All patients of elective laparoscopic surgery attending General Surgery OPD and getting admitted to KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi.

SAMPLE SIZE: Total – **80** patients

40 patients in each group

(According to **Thumb Rule**)

INCLUSION CRITERIA:

1) Patients willing to give written informed consent for participation.
2) Adult patients undergoing elective laparoscopic surgeries.

EXCLUSION CRITERIA:

1) Patients not willing to give consent.
2) Patients with contaminated and infected wounds (eg. Peritonitis)
3) Patients with diabetes mellitus.
4) Patients with other immunosuppressive conditions.

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

INFORMED CONSENT: The patients fulfilling selection criteria were explained about the nature of study including risks and benefits of operation. A written informed consent was obtained prior to the enrolment.

METHOD OF COLLECTION OF DATA: The selected patients were interviewed and data such as age, presenting complaints were recorded. Further patients underwent clinical examination followed by systemic examination. These findings were noted on a predesigned and pretested proforma.

INVESTIGATIONS: The patients underwent following investigations:

Complete Blood Count

Blood Sugar

Blood Urea

Sr. Creatinine

Liver Function Test

Urine Routine Microscopy

USG Abdomen

PROCEDURE:

After surgery eligible patients were randomized to the shower group or the non-shower group.

Group A – Shower Group – Patients were instructed to shower starting 48 hours after surgery.

Group B – Non-shower Group – Patients were prohibited from showering till after stitch removal.

Wound care during 48 hours after surgery was the same for all patients. Briefly, the wounds were covered with dressings and remained unchanged if no significant discharge was observed. The dressing material used was simple gauze piece or primapore bandages.

Photograph 1: Primapore dressing

Shower Group

- Showering was encouraged starting 48 hours after surgery with the wounds undressed.

  Instead of showering, using a bucket and tumbler to have a bath was also acceptable as the water just runs over the wounds just as in showering. However soaking the wounds in water (eg. Bathtub, swimming pool) was discouraged.
- Tap water used.
- Frequency, duration and amount of water used were according to patient's preference.
- The wounds were left open without any dressing until the stitches were removed.

Non-Shower Group

- Wounds were covered with dressings until the stitches were removed.
- Showering or bathing was prohibited.
- The dressings were changed every alternate day and the wounds were cleaned using sterile normal saline solution.

Follow Up:

Patients were examined for port site wound infection, 10 days after surgery, at the time of stitch removal. Wounds were evaluated for infection, which was defined as the presence of **redness** and **swelling** or the presence of **purulent exudate** or a **positive bacterial culture**.

STATISTICAL ANALYSIS

The data was tabulated on Microsoft excel spread sheet. The data was analyzed using SPSS version 20.0. Categorical data was expressed as rates, ratios and percentages and continuous data was expressed as mean ± SD. Categorical data was compared using Chi-square test or Fisher's exact test and continuous data was compared using independent sample 't' test. A probability value of 0.050 at 95% confidence interval was considered as statistically significant.

RESULTS

The present one year hospital based randomized controlled trial was done in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2017 to December 2017. A total of 80 patients undergoing elective laparoscopic surgery were studied. These patients were randomly allocated into two groups based on simple randomization that is Group A (Shower Group – Patients are instructed to shower starting 48 hours after surgery) and Group B (Non-shower Group – Patients are prohibited from showering till after stitch removal).

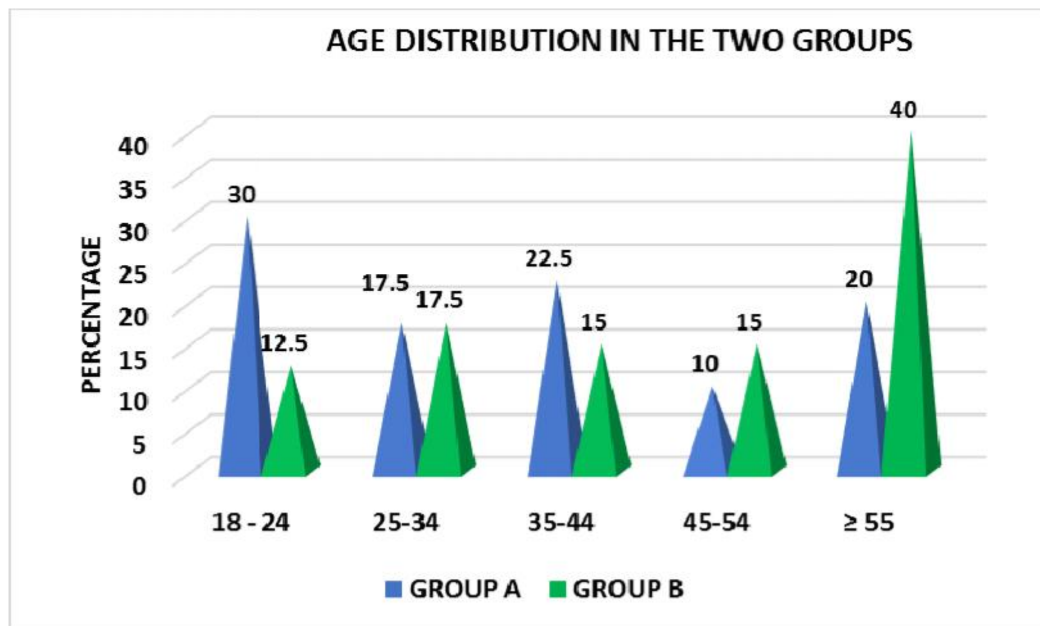
The data obtained was analyzed and the final results were tabulated as follows:

Age Distribution

Table No. 1

	GROUP A		GROUP B	
AGE	**NUMBER**	**PERCENTAGE**	**NUMBER**	**PERCENTAGE**
18 - 24	12	30.00	5	12.50
25-34	7	17.50	7	17.50
35-44	9	22.50	6	15.00
45-54	4	10.00	6	15.00
55	8	20.00	16	40.00
TOTAL	40	100	40	100

Graph No. 1



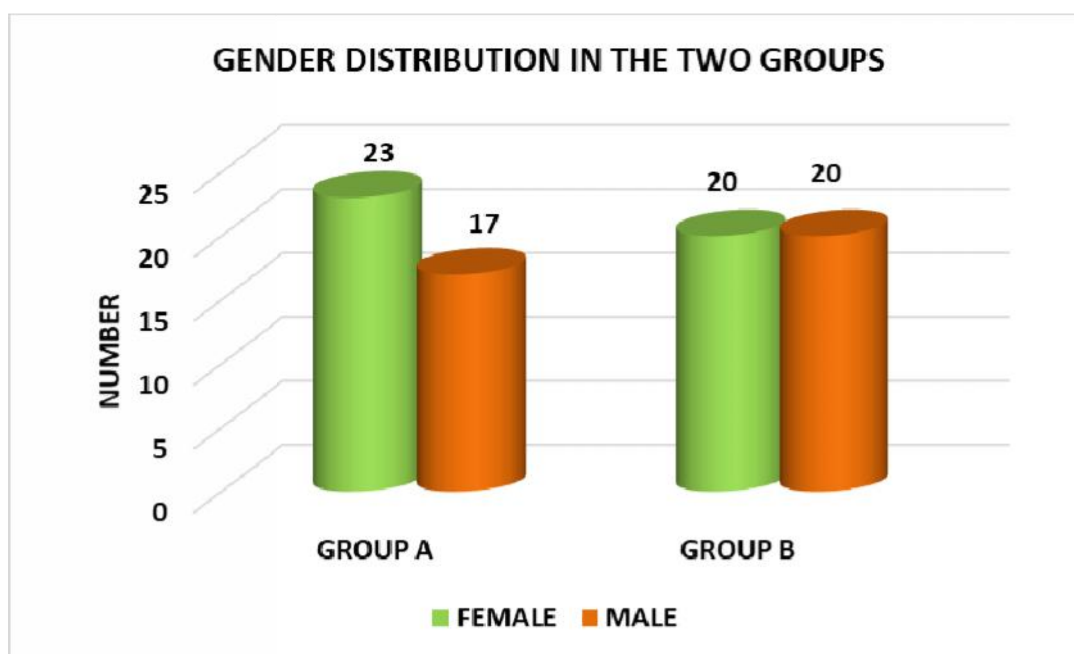
All the patients included in the study were adults above the age of 18 years. The most common age group was 18-24 years in Group A comprising 30% of the patients whereas in Group B, the most common age group was above 55 years comprising 40% of the patients.

Gender Distribution

Table No. 2

	GROUP A		GROUP B	
	NUMBER	PERCENTAGE	NUMBER	PERCENTAGE
FEMALE	23	57.50	20	50.00
MALE	17	42.50	20	50.00
TOTAL	40	100	40	100

Graph No. 2



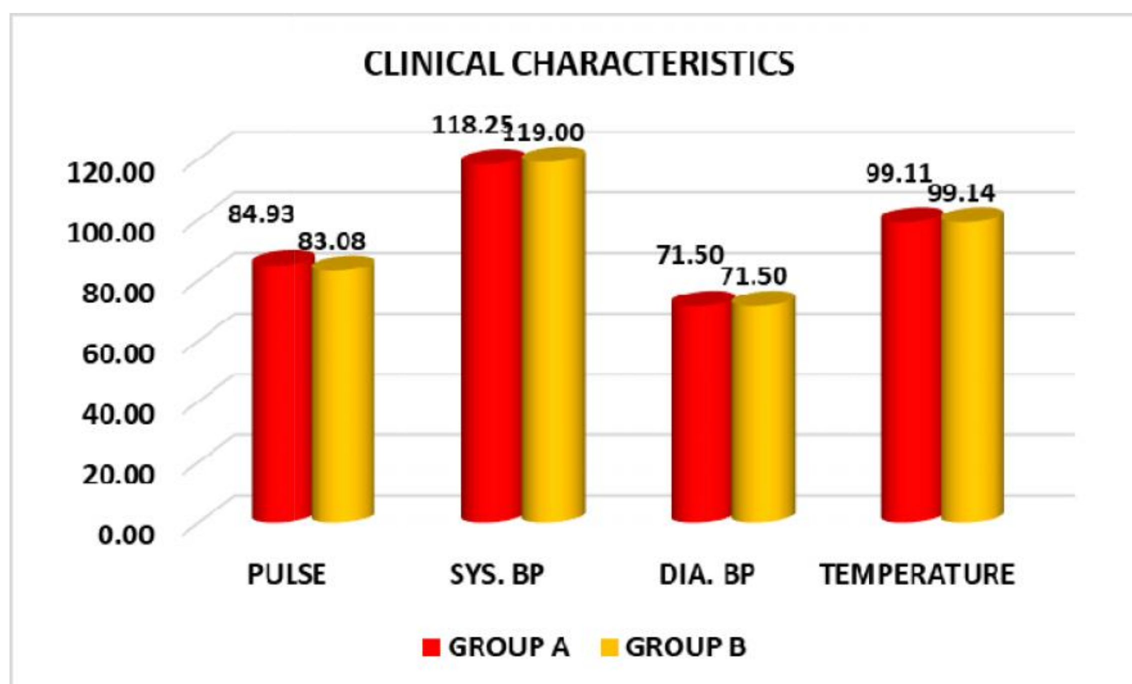
In the present study, there were 23 females (57.5%) and 17 males (42.5%) in Group A whereas there were 20 females (50%) and 20 males (50%) in Group B. There were no statistically significant differences in age and gender between the two groups.

Clinical Characteristics

Table No. 3

	GROUP A		GROUP B			
CLINICAL CHARACTERISTICS	**MEAN**	**S.D.**	**MEAN**	**S.D.**	**p VALUE**	**INFERENCE**
PULSE (/min)	84.93	6.22	83.08	6.15	0.1849	NS
SYSTOLIC BP (mmHg)	118.25	8.74	119.00	9.00	0.7064	NS
DIASTOLIC BP (mmHg)	71.50	6.22	71.50	4.27	1.0000	NS
TEMPERATURE (^{o}F)	99.11	0.75	99.14	0.74	0.8691	NS

Graph No. 3



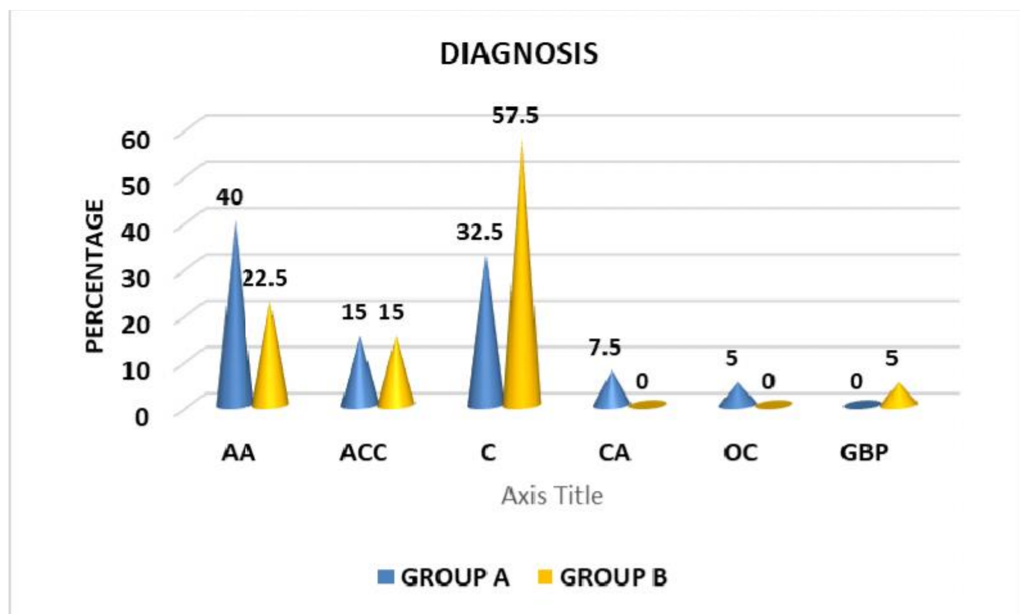
Clinical characteristics of the study population that is pulse rate (p= 0.1849), systolic BP (p= 0.7064), diastolic BP (p= 1.0000) and temperature (p=0.8691) did not differ and there was no statistically significant difference between the two groups.

Diagnosis

Table No. 4

	GROUP A		GROUP B	
DIAGNOSIS	**NUMBER**	**PERCENTAGE**	**NUMBER**	**PERCENTAGE**
AA	16	40	9	22.5
ACC	6	15	6	15
C	13	32.5	23	57.5
CA	3	7.5	0	0
OC	2	5	0	0
GBP	0	0	2	5
TOTAL	40	100	40	100

Graph No. 4



Patients having a variety of diagnosis such as acute appendicitis, cholelithiasis, acute calculous cholecystitis, chronic appendicitis, ovarian cyst and gall bladder polyp were included in the study. The most common diagnosis was cholelithiasis (45% of all patients) followed by acute appendicitis (31.25% of all patients).

Operation Performed

Table No. 5

	GROUP A		GROUP B	
Operation Performed	**NUMBER**	**PERCENTAGE**	**NUMBER**	**PERCENTAGE**
DL	2	5	0	0
LA	19	47.5	9	22.5
LC	19	47.5	31	77.5
TOTAL	40	100	40	100

Graph No. 5

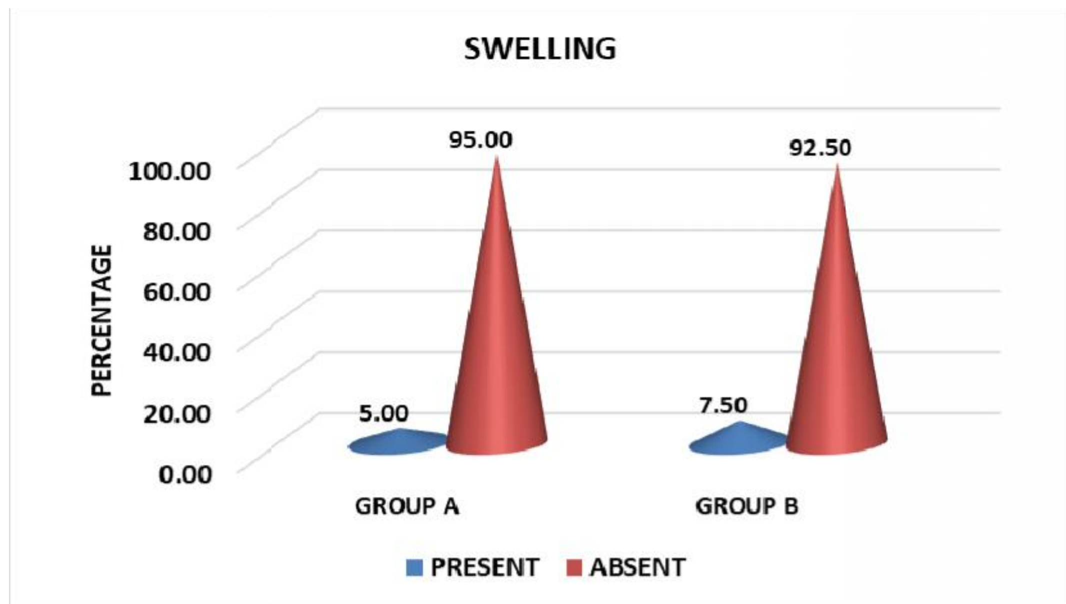
The surgeries performed to treat the patients included laparoscopic cholecystectomy, laparoscopic appendicectomy and diagnostic laparoscopy. In Group A a total of 19 LA (47.5%), 19 LC (47.5%) and 2 DL (5%) were performed. In Group B a total of 9 LA (22.5%), 31 LC (77.5%) and 0 DL (0%) were performed.

Swelling

Table No. 6

	GROUP A		GROUP B			
SWELLING	NUMBER	PERCENTAGE	NUMBER	PERCENTAGE	p VALUE	INFERENCE
PRESENT	2	5.00	3	7.50	0.6442	NS
ABSENT	38	95.00	37	92.50		
TOTAL	40	100	40	100		

Graph No. 6



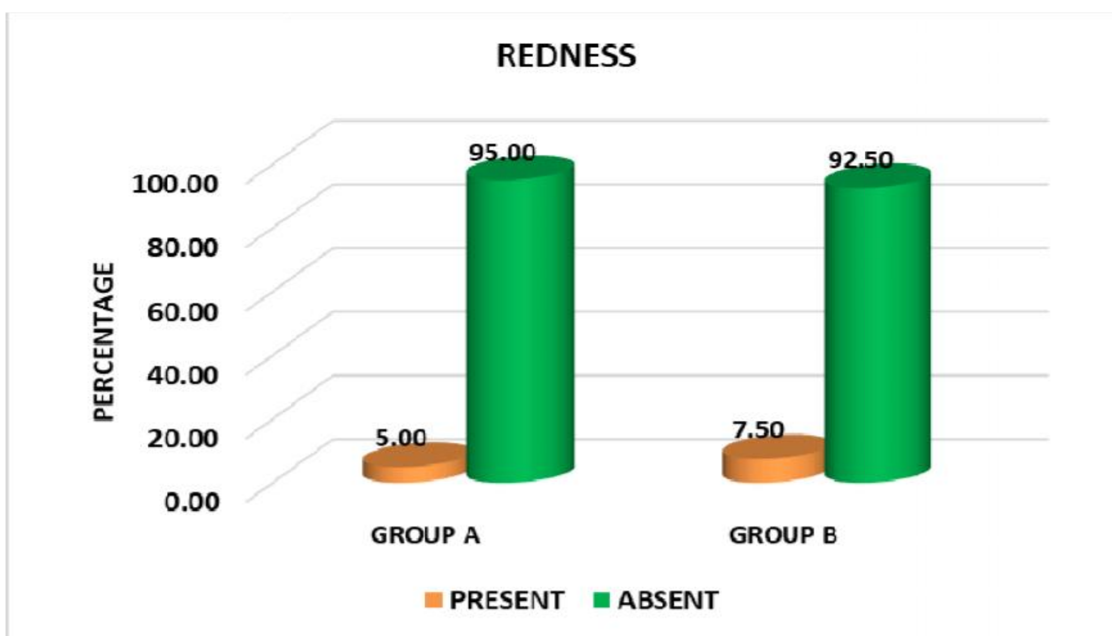
In this study, swelling was present in 5% of patients in Group A whereas in Group B it was present in 7.5% of the patients. The p value was 0.6442, thus there was no statistically significant difference between the two groups.

Redness

Table No. 7

	GROUP A		GROUP B			
REDNESS	**NUMBER**	**PERCENTAGE**	**NUMBER**	**PERCENTAGE**	**p VALUE**	**INFERENCE**
PRESENT	2	5.00	3	7.50	0.6442	NS
ABSENT	38	95.00	37	92.50		
TOTAL	40	100	40	100		

Graph No. 7



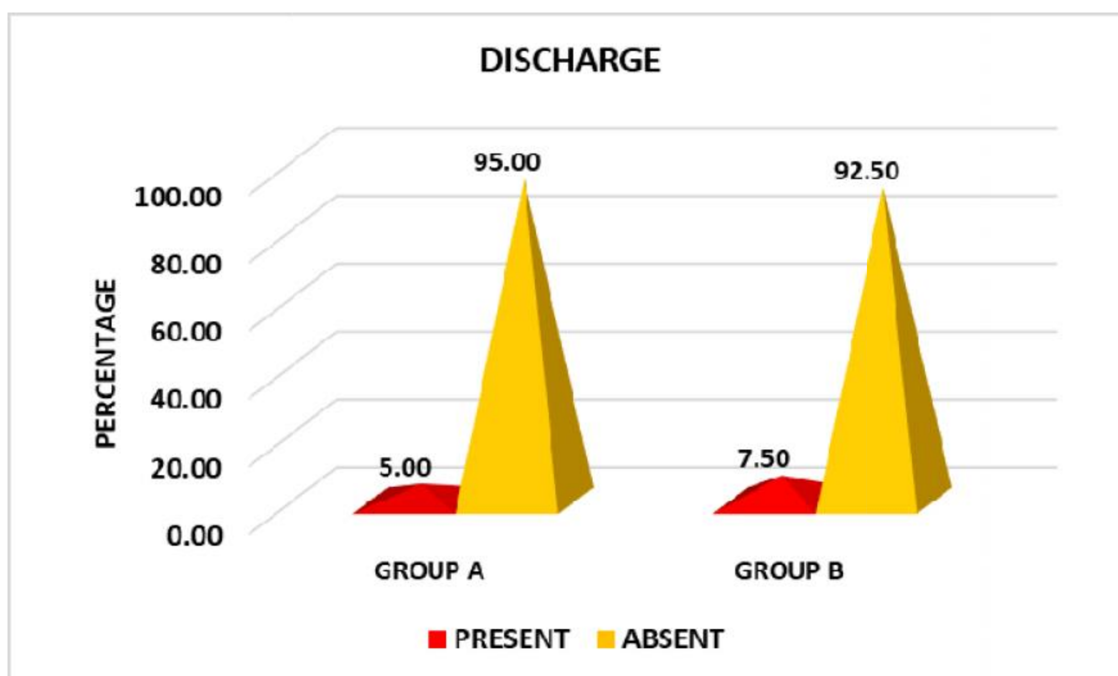
In this study, redness was present in 5% of patients in Group A whereas in Group B it was present in 7.5% of the patients. The p value was 0.6442, thus there was no statistically significant difference between the two groups.

Discharge

Table No. 8

	GROUP A		GROUP B			
DISCHARGE	**NUMBER**	**PERCENTAGE**	**NUMBER**	**PERCENTAGE**	**p VALUE**	**INFERENCE**
PRESENT	2	5.00	3	7.50	0.6442	NS
ABSENT	38	95.00	37	92.50		
TOTAL	40	100	40	100		

Graph No. 8



In this study, discharge was present in 5% of patients in Group A whereas in Group B it was present in 7.5% of the patients. The p value was 0.6442, thus there was no statistically significant difference between the two groups. No patient had a purulent exudate or positive bacterial culture.

DISCUSSION

Proper cleansing to create an environment optimal for wound healing is a key component of postoperative wound management. Cleansing methods and solutions may differ among individual health care providers and institutions.[2]

Showering after surgery is a controversial issue for surgeons and patients. The optimal timing and indications for showering after surgery remains inconclusive. Majority surgeons favour delay of showering until suture removal because of the possibility of increased risk of infection. However, some studies have shown that early postoperative showering or bathing is safe and post-operative dressings are not necessary for wound care.

Once the edges of the most superficial part of the wound (the epidermis) are clean and viable, the body starts to bridge the gap. Within 48 hours, most wounds are epithelialized, meaning there is at least one layer of cells covering the wound. This is why, ideally, surgical dressings are left on for 48 hours after which they can be removed. Epithelialization is sealing the internal wound off from the outside world. Once it’s occurred, fluid can’t get out, therefore water can’t get in. At this point patients can shower safely.[59]

The present one year hospital based randomized controlled trial was done in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2017 to December 2017. A total of 80 patients undergoing elective laparoscopic surgery were studied. These patients were randomly allocated into two groups based on simple randomization that is Group A (Shower Group – Patients are instructed to shower starting 48 hours after surgery) and

Group B (Non-shower Group – Patients are prohibited from showering till after stitch removal).

In the present study, there were 23 females (57.5%) and 17 males (42.5%) in Group A whereas there were 20 females (50%) and 20 males (50%) in Group B. All the patients included in the study were adults above the age of 18 years. The most common age group was 18-24 years in Group A comprising 30% of the patients whereas in Group B, the most common age group was above 55 years comprising 40% of the patients. There were no statistically significant differences in age and gender between the two groups.

Further, other clinical characteristics of the study population that is pulse rate (p= 0.1849), systolic BP (p= 0.7064), diastolic BP (p= 1.0000) and temperature (p=0.8691) did not differ and there was no statistically significant difference between the two groups. None of the patients in either group had any co-morbidities. These findings suggest that the study population comprised in Group A and Group B was comparable in terms of demographic and clinical characteristics, ruling out the possibility of bias in the study results.

Patients having a variety of diagnosis such as acute appendicitis, cholelithiasis, acute calculous cholecystitis, chronic appendicitis, ovarian cyst and gall bladder polyp were included in the study. The most common diagnosis was cholelithiasis (45% of all patients) followed by acute appendicitis (31.25% of all patients).

The surgeries performed to treat the patients included laparoscopic cholecystectomy, laparoscopic appendicectomy and diagnostic laparoscopy. In Group A a total of 19 LA (47.5%), 19 LC (47.5%) and 2 DL (5%) were performed. In Group B a total of 9 LA (22.5%), 31 LC (77.5%) and 0 DL (0%) were performed.

The wound infection rate was 5% in the shower group (2 out of 40 patients) and 7.5% (3 out of 40 patients) in the nonshower group. The p value was 0.6442, which indicated that the incidence of surgical site infection between the two groups was not statistically significant. All infections were superficial surgical site infections characterized by redness, swelling and serous discharge. No patient had a purulent exudate or positive bacterial culture.

The specimen was retrieved through the umbilical port in all the surgeries performed in this study. A total of 5 out of 80 patients had port site infection and in all 5 cases the umbilical port was affected. There was no evidence of infection in any of the other port sites. These results are consistent with previous studies which state that umbilical port site is the most common site of port site infection possibly due to the role of umbilical flora in the development of infection. Emphasis is also there on the increased frequency of port site infection and the trocar site of extraction.

In India most people are used to daily bathing. Along with cleaning the body, bathing promotes a sense of health and well-being along with improving patients' subjective comfort, satisfaction, and quality of life after surgery. Also the cost of wound care was reduced in the shower group as dressing materials were not required in the postoperative period as wounds were left open after showering was initiated starting 48 hours after surgery.

The results of our study are consistent with the results of previously done similar studies.

Hsieh et al. in a clinical trial compared wound related outcomes in two groups of 222 patients each, after undergoing general surgery procedures. 222 patients were allowed to get the surgical wound wet 48 hours after surgery and 222 patients delayed

washing until stitches removal. They demonstrated that clean and clean-contaminated wounds can be safely showered 48 hours after surgery. Postoperative showering didn't increase the risk of surgical site complications. Increase in patients' satisfaction and lower cost of wound care are two benefits reported regarding early wound washing.[2]

Heal et al. conducted a large prospective randomized controlled trial for minor skin excisions in general practice. They concluded that wounds can be allowed to get wet in the first 48 hours after minor skin excision without increasing the incidence of infection.[60]

In a systematic review, Dayton et al found 9 randomized clinical trials which showed that there was no reason to avoid showering or bathing the surgical wound as part of routine hygiene during the healing period. The wound was even able to be wet 12 hours after surgery without increasing the risk of surgical wound infection.[4]

In two Cochrane database reviews Toon et al and Chang reported that no conclusive evidence is currently available regarding the benefits or harms of early versus delayed post-operative showering or bathing for the prevention of wound complications. They recommended further randomized controlled trials to compare early versus delayed post-operative showering or bathing.[3, 61]

Several other studies not directly related to arthroplasty, including general surgical incisions, sutured wounds, spinal surgical sites and foot and ankle surgeries have failed to demonstrate increased infection rates when early showering is allowed.[62]

Nevertheless, published data also demonstrate similar rates of surgical site infection in surgical wounds that remained covered or uncovered and washed with tap water in the first 48 hours following surgery.[63, 64] Additionally, cleaning with tap water versus sterile saline was found to have no effect on the incidence of infection.[65]

Keeping the results of our study and previously done studies as mentioned above in mind, we suggest that for laparoscopic port site wounds, showering at 48 hours is as safe as keeping the wound dry and dressed. Postoperative showering does not increase the risk of surgical site complications. It may increase patients' satisfaction and lower the cost of wound care.

The limitations of this study are small sample size and single centre study. The long-term effects of early showering for wounds were not evaluated in this study because standardization of long-term wound care after stitches removal would be difficult.

CONCLUSION

Our study showed that laparoscopic port site wounds may be safely showered and left uncovered 48 hours after surgery. Postoperative showering did not increase the risk of surgical site complications. It may increase patients' satisfaction and lower the cost of wound care.

The findings observed in the present study need further evaluation in a larger group of patients involving multi centre hospitals to explore the effect of early versus late postoperative showering on laparoscopic port site wound infection rates.

SUMMARY

The question of whether patients should be permitted to shower or bathe in the early post-operative period appears to have only recently been addressed in surgical literature. Opinion amongst surgeons varies, with the majority favouring delay of showering until suture removal because of the possibility of increased risk of infection. Nonetheless, some studies have shown that early postoperative showering or bathing is safe and post-operative dressings are not necessary for wound care. There is currently no guidance regarding when a wound can be made wet by post-operative bathing or showering.

The present one year hospital based randomized controlled trial was done in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2017 to December 2017. The objective of the present study was to compare the effect of early versus late post-operative showering on laparoscopic port site wound infection rates. A total of 80 patients undergoing elective laparoscopic surgery were studied. These patients were randomly allocated into two groups based on simple randomization that is Group A (Shower Group – Patients are instructed to shower starting 48 hours after surgery) and Group B (Non-shower Group – Patients are prohibited from showering till after stitch removal).

The study population comprised in Group A and Group B was comparable in terms of demographic and clinical characteristics, ruling out the possibility of bias in the study results. Patients having a variety of diagnosis such as acute appendicitis, cholelithiasis, acute calculous cholecystitis, chronic appendicitis, ovarian cyst and gall bladder polyp were included in the study. The wound infection rate was 5% in the shower group (2 out of 40 patients) and 7.5% (3 out of 40 patients) in the nonshower

group. The p value was 0.6442, which indicated that the incidence of surgical site infection between the two groups was not statistically significant.

Our study showed that laparoscopic port site wounds may be safely showered and left uncovered 48 hours after surgery. Postoperative showering did not increase the risk of surgical site complications. It may increase patients' satisfaction and lower the cost of wound care.

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INFORMED CONSENT

Dear Mr. /Mrs./Dr. ______________________________, you are kindly requested to enroll yourself in a research study tilted, “A ONE YEAR RANDOMIZED CONTROLLED TRIAL TO COMPARE THE EFFECT OF EARLY VERSUS LATE POST-OPERATIVE SHOWERING ON LAPAROSCOPIC PORT SITE WOUND INFECTION RATES AT KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI” 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 and HOD, Department of General Surgery, Jawaharlal Nehru Medical College, Belagavi.

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:

“A ONE YEAR RANDOMIZED CONTROLLED TRIAL TO COMPARE THE EFFECT OF EARLY VERSUS LATE POST-OPERATIVE SHOWERING ON LAPAROSCOPIC PORT SITE WOUND INFECTION

RATES AT KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI."

PURPOSE OF THE STUDY:

To compare the effect of early versus late post-operative showering on laparoscopic port site wound infection rates.

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 the envelope method into Group A (shower group) and Group B (non-shower group).

Group A – Shower Group – Patients are instructed to shower starting 48 hours after surgery.

Group B – Non-shower Group – Patients are prohibited from showering till after stitch removal.

Wound care during 48 hours after surgery is the same for all patients. Briefly, the wounds are covered with dressings and remained unchanged if no significant discharge is observed.

Shower Group

-Showering is encouraged starting 48 hours after surgery with the wounds undressed.

-Tap water used.

-Frequency, duration and amount of water used are according to patients preference.

-The wounds are left open without any dressing until the stitches are removed.

Non-Shower Group

-Wounds are covered with dressings until the stitches are removed.

-Showering or bathing is prohibited.

-The dressings are changed every alternate day and the wounds are cleaned using sterile normal saline solution.

Follow Up:

Patients are examined for port site wound infection, 10 days after surgery, at the time of stitch removal. Wounds are evaluated for infection, which is defined as the presence of redness and swelling or the presence of purulent exudate or a positive bacterial culture.

RISKS AND BENEFITS:

Risks

Laparoscopic port site wound infection can occur in either group. In case infection does occur, adequate treatment will be provided in the form of daily cleaning and dressing along with antibiotics and analgesics.

No other major risks are expected in this study.

Benefits

Early post-operative showering is likely to increase the patient's satisfaction with wound care as the patient would be able to maintain good personal hygiene by bathing daily. Also it would reduce the cost of wound care, as wounds are left open without any dressing after showering.

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. ____________________

Post Graduate Student,

Department of General Surgery,

Jawaharlal Nehru Medical College,

Nehru Nagar, KLE Hospital Road,

Belgaum 590010

Mobile – ______________

Dr. ____________________

Professor and HOD,

Department of General Surgery,

Jawaharlal Nehru Medical College,

Nehru Nagar, KLE Hospital Road,

Belgaum 590010

Mobile - ______________

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

Dr. ______________________

Professor of Pathology & Chairman,

JNMC Institutional Ethics Committee

on Human Subjects Research,

Jawaharlal Nehru Medical College

Nehru Nagar, KLE Hospital Road

Mobile – ____________________

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.

Participants name: __________________________________

Signature/ Left Thumb Print of Participant: ____________________

Witness/guardian name: ______________________________

Signature/Left Thumb Print ____________________

Investigator's name: **Dr.** ______________________

Signature____________________

Guide's name: **Dr.** ______________________

Signature____________________

Date: ___/___/_____Place: ____________

PROFORMA / QUESTIONNAIRE TO BE USED FOR DATA COLLECTION

The proposed proforma/questionnaire to be used for data collection for the study titled, "A ONE YEAR RANDOMIZED CONTROLLED TRIAL TO COMPARE THE EFFECT OF EARLY VERSUS LATE POST-OPERATIVE SHOWERING ON LAPAROSCOPIC PORT SITE WOUND INFECTION RATES AT KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI," is as follows:

PATIENT DETAILS:

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

NAME: D.O.D:

AGE:

SEX:

ADDRESS:

CHIEF COMPLAINTS:

1.) PAIN IN ABDOMEN

Yes / No	Duration

2.) SITE OF PAIN

Right Hypochondrium / Left Hypochondrium / Right Lumbar Region / Left Lumbar Region/ Right Iliac Fossa / Left Iliac Fossa / Epigastrium / Umbilical Region/ Hypogastrium

3.) TYPE OF PAIN:

Radiating / Localised
Colicky / Pricking / Dull aching

4.) ASSOCIATED WITH FOOD INTAKE

Yes / No

5.) FEVER

Yes / No Duration

Degree of Fever – Mild / Moderate / Severe

Type of Fever – Continuous / Intermittent

6.) VOMITTING

Yes / No
Duration and frequency:
Contents:

7.) LOSS OF WEIGHT

Yes / No

8.) HISTORY OF SIDE EFFECT OR INTOLERANCE TO ANY DRUG

Yes / No
Name of drugs:

GENERAL EXAMINATION:

Built and Nourishment:

Weight:

PULSE :

BP :

R/R :

TEMPERATURE:

SYSTEMIC EXAMINATION:

	NORMAL	ABNORMAL FINDINGS
CVS:		
RS:		
CNS:		
PA:		

INVESTIGATIONS:

CBC:

Blood Sugar:

Blood Urea:

Sr. Creatinine:

LFT:

Urine Routine Microscopy:

USG ABDOMEN:

OPERATION DETAILS:

Date of Surgery:

Name of Surgery:

Anesthesia:

ASSESSMENT FOR LAPAROSCOPIC PORT SITE WOUND INFECTION

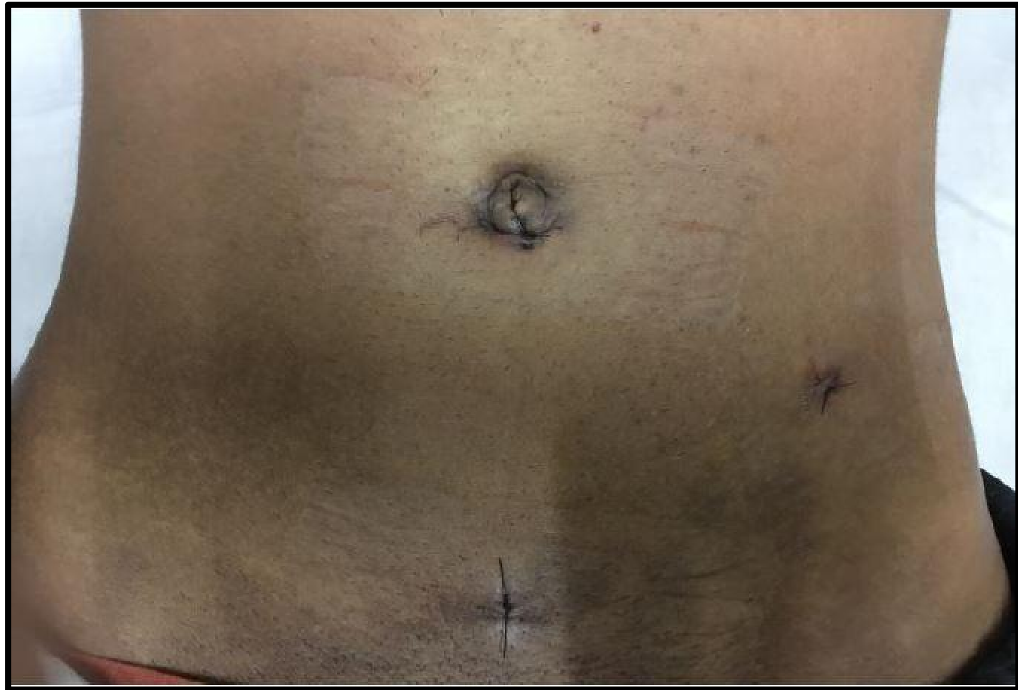
PORT SITE AFFECTED:

	YES	NO
REDNESS	☐	☐
SWELLING	☐	☐
DISCHARGE	☐	☐
POSITIVE BACTERIAL CULTURE	☐	☐

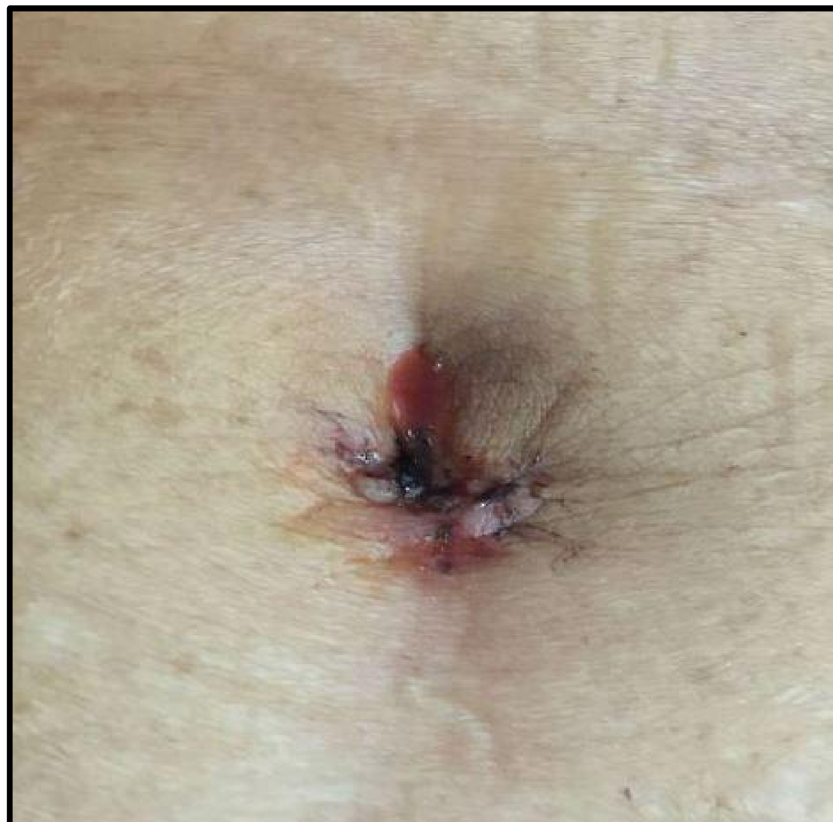
(Only when discharge is present)

Organism Isolated:

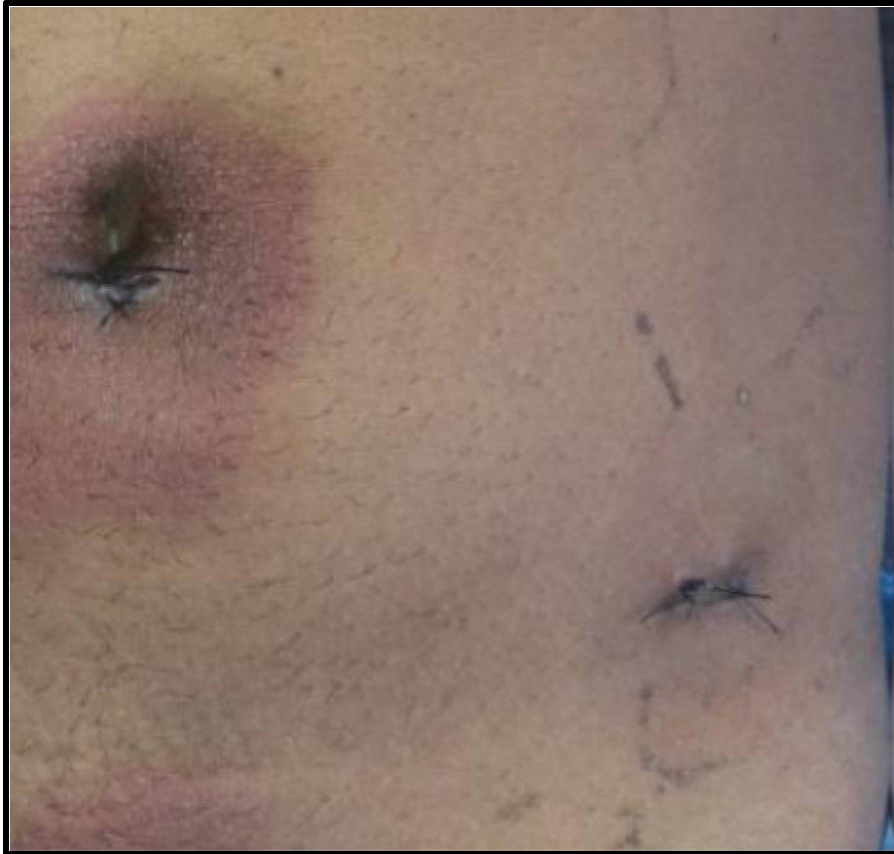
ANNEXURE III - PHOTOGRAPHS



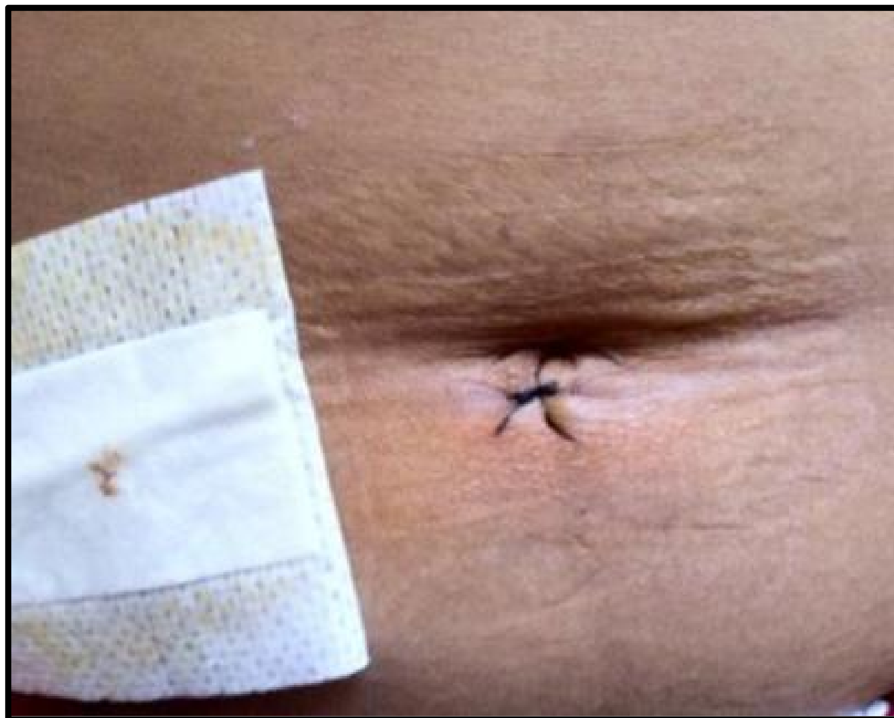
Photograph 2: Normal Portsite Wound Healing



Photograph 3: Infected Umbilical port site with discharge



Photograph 4: Infected Umbilical port site with redness



Photograph 5: Infected Umbilical port site

KEY TO MASTER CHART

M	–	Male
F	–	Female
OC	–	Ovarian Cyst
AA	–	Acute Appendicitis
C	–	Cholelithiasis
ACC	–	Acute Calculous Cholecystitis
CA	–	Chronic Appendicitis
GBP	–	Gall Bladder Polyp
DL	–	Diagnostic Laparoscopy
LA	–	Laparoscopic Appendicectomy
LC	–	Laparoscopic Cholecystectomy
POD	–	Postoperative Day
(+)	–	Present
(-)	-	Absent

Sr.No.	IP No.	Group	Age	Sex	Diagnosis	Operation Performed	Assessment for port site wound infection (POD-10)				
							Port affected	Redness	Swelling	Discharge	Culture
1	784018	A	36	F	OC	DL	-	-	-	-	-
2	798254	A	35	F	AA	LA	Umbilical	(+)	(+)	(+)	Negative
3	799609	A	26	F	C	LC	-	-	-	-	-
4	802594	A	62	F	C	LC	-	-	-	-	-
5	790517	A	20	F	OC	DL	-	-	-	-	-
6	782053	A	19	M	AA	LA	-	-	-	-	-
7	786077	A	18	F	AA	LA	-	-	-	-	-
8	786045	A	38	F	AA	LA	-	-	-	-	-
9	792720	A	42	M	AA	LA	-	-	-	-	-
10	792639	A	28	F	C	LC	-	-	-	-	-
11	799180	A	45	F	C	LC	-	-	-	-	-
12	800557	A	21	F	AA	LA	-	-	-	-	-
13	805943	A	19	F	AA	LA	-	-	-	-	-
14	805960	A	35	F	C	LC	-	-	-	-	-
15	811868	A	52	M	ACC	LC	-	-	-	-	-
16	814100	A	20	F	C	LC	-	-	-	-	-
17	822003	A	24	M	ACC	LC	-	-	-	-	-
18	821954	A	28	M	AA	LA	-	-	-	-	-
19	823253	A	57	M	C	LC	-	-	-	-	-
20	829055	A	21	M	AA	LA	Umbilical	(+)	(+)	(+)	Negative
21	829080	A	43	M	C	LC	-	-	-	-	-
22	831433	A	69	M	C	LC	-	-	-	-	-
23	831829	A	19	M	AA	LA	-	-	-	-	-
24	840147	A	25	F	ACC	LC	-	-	-	-	-
25	843034	A	50	F	ACC	LC	-	-	-	-	-
26	845166	A	57	F	C	LC	-	-	-	-	-
27	811726	A	30	F	AA	LA	-	-	-	-	-
28	813233	A	21	M	AA	LA	-	-	-	-	-
29	815676	A	42	F	ACC	LC	-	-	-	-	-
30	817086	A	39	F	C	LC	-	-	-	-	-
31	821858	A	43	F	AA	LA	-	-	-	-	-
32	823746	A	65	F	CA	LA	-	-	-	-	-
33	836859	A	70	F	ACC	LC	-	-	-	-	-
34	843580	A	62	M	C	LC	-	-	-	-	-
35	847352	A	55	M	C	LC	-	-	-	-	-
36	849145	A	46	M	CA	LA	-	-	-	-	-
37	849168	A	21	M	AA	LA	-	-	-	-	-
38	816843	A	20	M	AA	LA	-	-	-	-	-
39	810943	A	30	M	CA	LA	-	-	-	-	-
40	809731	A	30	F	AA	LA	-	-	-	-	-

Sr.No.	IP No.	Group	Age	Sex	Diagnosis	Operation Performed	Assessment for port site wound infection (POD-10)				
							Port affected	Redness	Swelling	Discharge	Culture
41	783811	B	57	F	C	LC	-	-	-	-	-
42	785131	B	60	M	C	LC	-	-	-	-	-
43	791742	B	56	F	ACC	LC	-	-	-	-	-
44	794417	B	38	M	C	LC	-	-	-	-	-
45	795826	B	54	M	C	LC	-	-	-	-	-
46	796937	B	45	F	C	LC	Umbilical	(+)	(+)	(+)	Negative
47	798123	B	36	M	AA	LA	-	-	-	-	-
48	797955	B	75	F	C	LC	-	-	-	-	-
49	800358	B	68	F	C	LC	-	-	-	-	-
50	800948	B	68	M	C	LC	-	-	-	-	-
51	800671	B	80	F	ACC	LC	-	-	-	-	-
52	794083	B	27	M	GBP	LC	-	-	-	-	-
53	794861	B	22	M	AA	LA	-	-	-	-	-
54	802754	B	61	M	ACC	LC	-	-	-	-	-
55	803150	B	39	F	AA	LA	-	-	-	-	-
56	804663	B	62	F	ACC	LC	-	-	-	-	-
57	813849	B	57	F	ACC	LC	-	-	-	-	-
58	815371	B	47	F	C	LC	-	-	-	-	-
59	815887	B	18	M	AA	LA	-	-	-	-	-
60	815910	B	59	M	C	LC	-	-	-	-	-
61	817484	B	29	M	ACC	LC	Umbilical	(+)	(+)	(+)	Negative
62	819254	B	60	F	C	LC	-	-	-	-	-
63	819251	B	62	M	GBP	LC	-	-	-	-	-
64	819487	B	24	F	C	LC	-	-	-	-	-
65	820405	B	75	F	C	LC	-	-	-	-	-
66	821224	B	39	F	C	LC	-	-	-	-	-
67	822330	B	25	F	AA	LA	Umbilical	(+)	(+)	(+)	Negative
68	821340	B	57	M	C	LC	-	-	-	-	-
69	823403	B	42	M	C	LC	-	-	-	-	-
70	823457	B	29	M	AA	LA	-	-	-	-	-
71	823599	B	46	M	C	LC	-	-	-	-	-
72	824395	B	31	F	C	LC	-	-	-	-	-
73	825277	B	55	M	C	LC	-	-	-	-	-
74	826195	B	23	F	AA	LA	-	-	-	-	-
75	828465	B	45	F	C	LC	-	-	-	-	-
76	829490	B	30	M	AA	LA	-	-	-	-	-
77	830585	B	52	M	C	LC	-	-	-	-	-
78	838399	B	25	F	C	LC	-	-	-	-	-
79	843930	B	20	M	AA	LA	-	-	-	-	-
80	843684	B	35	F	C	LC	-	-	-	-	-