"A RANDOMISED CONTROL TRIAL TO DETERMINE THE NEED FOR POST OPERATIVE ANTIBIOTICS AFTER LAPAROSCOPIC APPENDICECTOMY IN NON PERFORATED APPENDICITIS"

By

REG NO. BH0114009

Dissertation

Submitted to the
KLE University Belagavi, Karnataka

In partial fulfillment
of the requirements for the degree of

MASTER OF SURGERY (M.S.)

In

GENERAL SURGERY

DEPARTMENT OF SURGERY

J. N. MEDICAL COLLEGE, NEHRU NAGAR

BELAGAVI-590010

APRIL - 2017

KLE UNIVERSITY, BELAGAVI, KARNATAKA

ENDORSEMENT

This is to certify that the dissertation entitled **"A RANDOMISED CONTROL TRIAL TO DETERMINE THE NEED FOR POST OPERATIVE ANTIBIOTICS AFTER LAPAROSCOPIC APPENDICECTOMY IN NON PERFORATED APPENDICITIS"** is a bonafide research work done by **REG NO. BH0114009**

Dr. S. S. Shimikore MS
Professor and Head,
Department of Surgery,
J. N. Medical College,
Nehru Nagar, Belagavi – 10

Date:
Place: Belagavi

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

Date:
Place: Belagavi

LIST OF ABBREVIATIONS USED

USG	-	Ultrasonography
CT	-	Computed Tomography
NNIS	-	National Nosocomial Infection Surveillance
CDC	-	centre for Disease Control
SSIs	-	Surgical site infections
cm	-	centimeters
ml	-	mililiter
E. coli	-	*Escherachiae coli*
^0C	-	Centigrade
^0F	-	Fahrenheit
RLQ	-	Right lumbar quadrant
WBC	-	White blood cells
mm	-	Millimeters
RIF	-	Right iliac fossa
Co_2	-	Carbondioxide
ASIS	-	Anterior superior iliac spine
HAIs	-	healthcare associated infections
MIC	-	Minimum inhibitory concentration
e.g.	-	For example
SCIP	-	Surgical care improvement project
MDR	-	Multi drug resistance
MRSA	-	Methicillin resistant staphylococcus aureus
MSSA	-	Methicillin sensitive staphylococcus aureus
Inj	-	Injection

Iv	-	Intravenous
IP No	-	In Patient number
gm	-	gram
hrs	-	hours
mg/dL	-	Milligram per deciliter
mm Hg	-	Millimeters of mercury
n	-	Total number
p	-	Probability valure
RCT	-	Randomized controlled trial
SD	-	Standard deviation
F	-	Female
M	-	Male
PT	-	Probe tenderness
INF	-	Inflammed appendix
AA	-	Acute Appendicitis
CA	-	Chronic Appendicitis
SA	-	Sub acute Appendicitis
RA	-	Recurrent Appendicitis
HPR	-	Histo pathological report

ABSTRACT

Background and objectives

Acute Appendicitis is one of the most common cause of acute pain in abdomen. The appropriate use of prophylactic antibiotics prevents risk of postoperative SSIs. However there are no definitive guidelines regarding duration of antibiotic usage. A single preoperative prophylactic dose has been recommended by many randomized control trials. This study was aimed to determine the need for post operative antibiotics after laparoscopic appendicectomy for non perforated appendicitis.

Methodology

This randomized controlled trial was done in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi over a period, from January 2015 to December 2015. A total of 100 patients with non perforated appendicitis undergoing laparoscopic appendicectomy were enrolled. These patients were divided into two groups of 50 each that is First group (Group A) who received single dose of preoperative antibiotic and Second group (Group B) who received preoperative dose as well as three post operative doses of antibiotics.

Results

In the present study, 44% of the patients in group A and 64% of the patients in group B were females. (p=0.0453) The mean age in group A was 30.74 ± 10.69 years compared to 30.72 ± 9.56 years (p=0.757). All the patients in study presented with right iliac fossa pain. It was observed that total of 3 patients

in group A (6%) and 2 patients in Group B (4%) had grade 3 SSIs, which were managed conservatively. The difference between both the groups for incidence of SSIs is statistically insignificant (p=1.000).

Conclusion and interpretation

Prophylactic postoperative doses of antibiotics confer no additional benefit over a single preoperative dose in preventing the postoperative SSIs after laparoscopic appendicectomy.

Keywords

Surgical site infections (SSIs); Laparoscopic appendicectomy; Non perforated appendicits; Prophylactic antibiotics.

CONTENTS

LIST OF TABLES

LIST OF GRAPHS

LIST OF FIGURES

LIST OF PHOTOGRAPHS

Chapter 1

Introduction

INTRODUCTION

Acute appendicitis is the most common causes of acute surgical emergency, and laparoscopic appendicectomy is one of the most frequently performed emergency operations. The early surgical intervention following acute appendicitis improves the outcome. Approximately 8% of those in western countries have appendicitis at some point during their life time, with peak incidence between 10 and 30 years of age[1].

The diagnosis of appendicitis can be elusive, and high index of suspicion is required in preventing the serious complications of acute appendicitis. However the introduction of diagnostic imaging aids like abdominal ultrasound (USG) and computed tomography (CT), has allowed more accurate diagnosis of appendicitis. If untreated the acute appendicitis leads to perforation, abscess formation or secondary peritonitis with bacteraemia and septicemia.

The most important determinant of post operative surgical site infection following appendicectomy is the pathological state of appendix[2, 3]. The patients with perforated or gangrenous appendicitis (complicated appendicitis) are associated with four to five times greater incidence of surgical site infections than those with non perforated appendicitis[4].

Surgical site infection following appendicectomy is major cause of post operative morbidity like pain, anxiety, inconvenience. It also increases post operative hospital stay and increases financial cost.

From the very beginning of medicine, major and continuous efforts have been made by surgeons to prevent sepsis. Inspite of all, even today post operative wound infection is one of the major limiting factors in surgery. As per the National Nosocomial Infection Surveillance (NNIS) report of the centre for Disease Control (CDC), the prevalence rate of SSI, though preventable, is still high.

Surgical site infections (SSIs) are infections after any surgical procedure, and are present in any location along the surgical tract, which may involve superficial tissues or deeper tissues or organ or an intra – abdominal spaces. SSIs are one of the most common nosocomial infections and constitute 38% of the all infections in surgical patients. Superficial incisional infections are the most common of SSIs and they account for 60% to 80% of all and have a better prognosis than organ or space – related SSIs[5].

The appropriate use of antibiotics reduces risk of post operative surgical site infection by 40-60%[6-10]. Prospective clinical trials have established guidelines for choice of prophylactic antibiotics, route of administration and it's timing following emergency appendicectomy[11]. However there are no definitive guidelines regarding duration of antibiotic usage[12-13].

Nearly 45-50% of antibiotics used are either not needed or are given in inappropriate doses. Antibiotic misuse occurs most in surgical prophylaxis due to which many resistant strains are emerging[14]. Infection with these emergent strains leads to higher morbidity and mortality.

The use of preoperative antibiotics achieves adequate serum and tissue levels at time of maximum bacterial contamination i.e. during the course of surgery. Most of the bacterial contamination in clean and clean contaminated surgeries usually occurs during the procedure, so antibiotic given preoperatively plays an important role in prevention of wound infection.

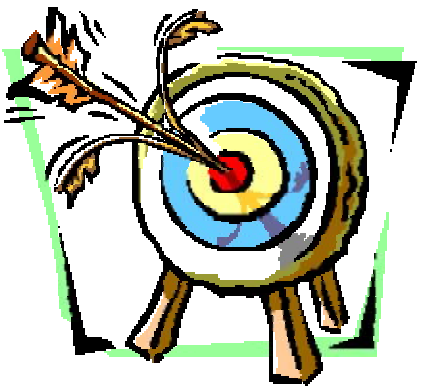
The cases of non perforated appendicitis are categorized as clean contaminated, while those with perforated appendicitis are categorized as contaminated cases. Patients undergoing appendicectomy for perforated appendicitis are universally treated with variable course of postoperative therapeutic antibiotics because of heavy contamination of peritoneal cavity and wound. However the role of postoperative antibiotics in reducing the surgical site infections in non perforated cases is still controversial[15].

The single dose antibiotic prophylaxis has been recommended for majority of the elective general surgical procedures, however in reality this practice is not followed and multiple dose regimens are still in use at many centers[4]. Many randomized control trials have supported use of single preoperative dose of second generation cephalosporins and metronidazole to reduce surgical site infection in patients with non perforated appendicitis[16, 17].

This study was carried out to determine the need for post operative antibiotics in reducing surgical site infection after laparoscopic appendicectomy for non perforated appendicitis.

Chapter 2

Objective



OBJECTIVE

The objective of the present study was to determine the need for post operative antibiotics in reducing surgical site infections after laparoscopic appendicectomy for non perforated appendicitis.

Chapter 3

Review of Literature

REVIEW OF LITERATURE

HISTORICAL BACKGROUND OF APPENDICITIS

The appendix was not mentioned in earlier anatomical studies, probably because these studies were performed on animals having no such organs. In 1521, Jacopo Berengario Dacarpi first described appendix as an anatomical structure. French physician Jean Fernel first reported case of perforative appendicitis at autopsy in 1554.[18]

Lorenz Heister a professor of medicine and a practicing surgeon was first to describe the pathology of appendicitis (1711)[19]. Later in 1719, Morgagni published studies with little additional information regarding gross anatomy of appendix[20]. John Hunter described gangrenous appendix, encountered at an autopsy that he performed on Colonel Dalrymple in 1767. A description of perforation of appendix containing a faecolith with a normal caecum, found in autopsy of a 5 year boy was published by Parkinson[21] in 1812.

The 19th century pathological concept is based on the notion "Perityphilitis", which is inflammation of the caecum. The caecum was considered as the site of disease rather than appendix. The term appendicitis became a surgical problem once it was obvious that the starting point of the disease was vermiform appendix. Reginald Heber Fitz the Harvard university pathologist was first to described this, who communicated his findings at the first meeting of the Association of American Physician in 1886.

Fitz, in his paper pointed out that the frequent abscesses in the right iliac fossa were not due to typhilitis, perityphilitis or epityphilitis but due to perforation of vermiform appendix. Hence he gave the condition name 'appendicitis' to avoid the possibility of misunderstanding and to localize the disease in its usual place of origin.[22] Richard Hall reported the first survival of a patient following removal of a perforated appendix.

Chester McBurney in 1889 described the characteristic migratory pain and the localization of the pain along the oblique line from anterior superior iliac spine to the umbilicus. In 1894 McBurney described a right lower quadrant muscle splitting incision for removal of appendix.

DEVELOPMENT OF APPENDIX

At an early embryonic stage it has the same caliber as the caecum and is in line with it. It is formed by excessive growth of the right wall of the caecum which pushes appendix to the inner side. Congenital absence of appendix is extremely rare.[23]

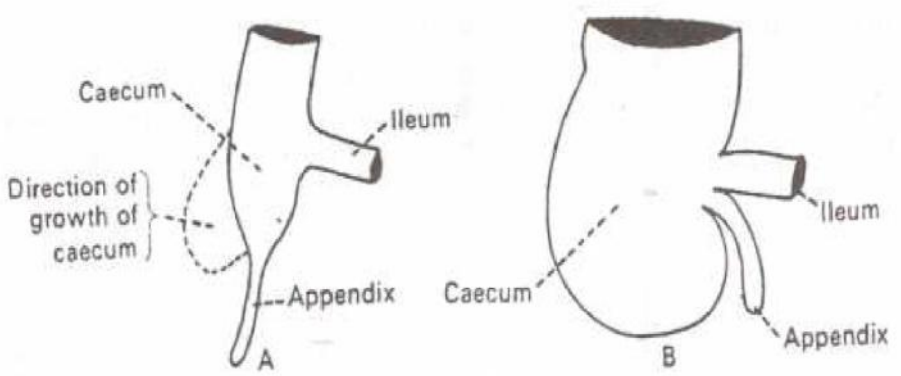


Figure 1: Development of appendix[23]

Abnormalities in development

Although these are quite rare they can occur in form of agenesis, duplication, diverticula and left sided appendix.

I. **Agenesis** – Absence of vermiform appendix. Occasionally during appendicectomy following acute appendicitis, the appendix may not be seen. It is due to sloughing of the appendix.

II. **Duplication** – There are few cases which has been reported where there is double appendix.

III. **Diverticula** – They are seen very rarely in appendix.

IV. **Left sided appendix** – Seen in case of situs inversus, where there is transposition of thoracic and abdominal viscera, in which case the appendix with ceacum will be seen on the left side. In some of the cases with non rotation of midgut, the appendix and ceacum may be seen either as a midline structure or on the left side.

ANATOMY OF THE VERMIFORM APPENDIX

The appendix lies at the commencement of the large gut and has the same basic structure. It is a blind muscular tube with mucosal, submucosal, muscular and serosal layers. Its wall contains much of the lymphoid tissue. The appendix is approximately 7.5 to 10 cm long. At birth, appendix is short and broad at its junction with caecum, but differential growth of caecum produces the typical tubular structure by about age of 2 years. In children it is longer than in adults, it may atrophy and become smaller in the middle age.

The appendix has a small lumen which communicates with the caecum by an orifice placed little behind and below the ileocaecal opening. The appendicular orifice is occasionally guarded by an indistinct semilunar fold of mucous membrane. The luminal capacity of the normal vermiform appendix is about 0.1 ml, although there is no real lumen. The secretion as little as 0.5 ml distal to the block can increase intraluminal pressure to about 60 cm of water.

Microscopic anatomy:

The appendix has an irregular lumen being encroached upon by multiple longitudinal folds of mucous membrane lined by columnar cell intestinal mucosa of colonic type. It has crypts which are not numerous. The argentaffin cells (Kulchitsky cells) lie in the base of the crypts, which may give rise to carcinoid tumors. The submucosa of appendix contains numerous lymphatic follicles, but there is no discernible change in immune function following appendicectomy.

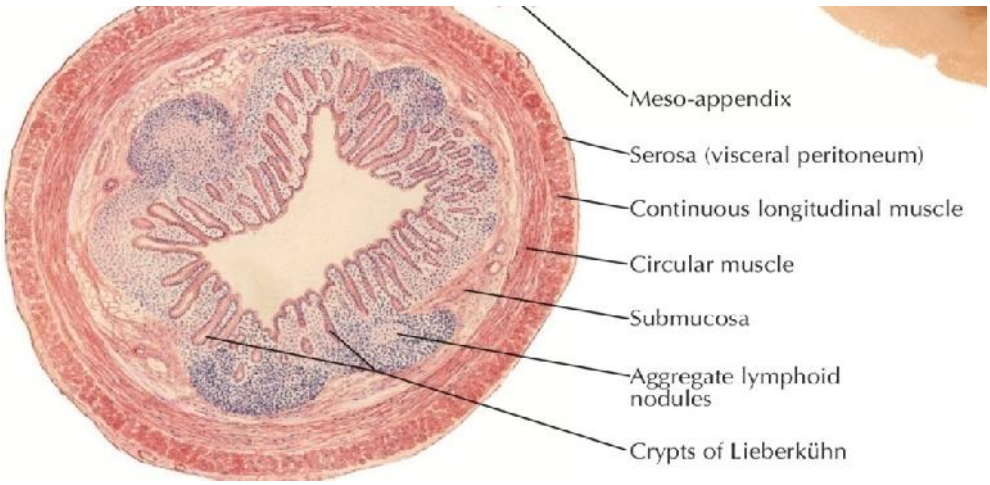


Figure 2: Microscopic anatomy of appendix[25]

Position of the Appendix:

The vermiform appendix is a narrow tubular, worm shaped structure arising from the postero medial wall of the caecum. Though the base of the vermiform appendix is fixed, its tip can point in any direction and it may occupy any of the several following positions.

1) **Retrocaecal Appendix (74%):** Behind the caecum and lower part of the ascending colon.
2) **Pelvic Appendix (21%):** It may descend over the brim of the lesser pelvis (Pelvic or descending appendix) in which case it lies in close relation to the right ureter in males and ovary and right uterine tube in females.
3) **Paracaecal Appendix (2%):** on the outer side of the caecum.
4) **Subcaecal Appendix (1.5%):** Below the caecum.
5) **Preileal Appendix (1%):** In front of the terminal part of the ileum and it may be in contact with the anterior abdominal wall.
6) **Postileal Appendix (0.5%):** Behind the terminal part of the ileum.

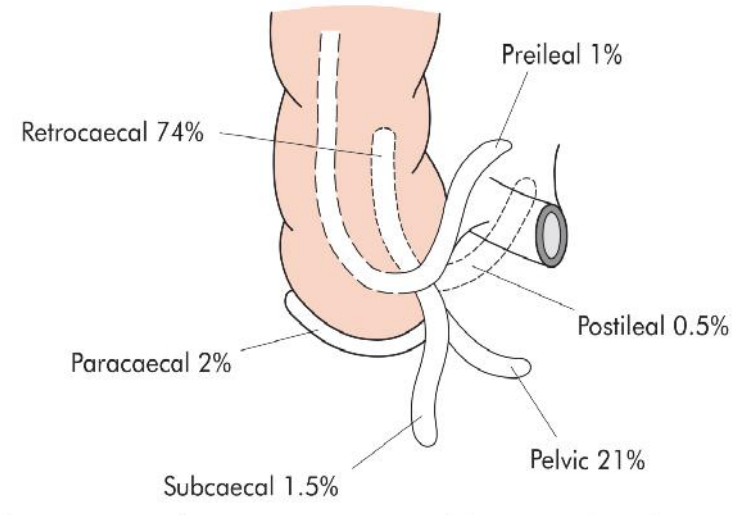


Figure 3: Positions of appendix[24]

Retrocaecal is the most common position followed by Pelvic, subcaecal, paracaecal, preileal and postileal in descending order.

The three taenia coli of the ascending colon and the caecum converge on the base of the appendix, where they merge into the longitudinal muscular layer of appendix. The anterior taenia of the caecum is distinct and it can be easily traced to the base of appendix.

The Mesoappendix:

It is the triangular fold of the peritoneum around the vermiform appendix, and it is attached to the lower end of the mesentry close to the ileocaecal junction. In the complete variety the mesentry usually extends upto the tip of the appendix. Sometimes the mesentry fails to reach the distal third of the appendix and is called incomplete mesentry.

The appendicular artery reaches the appendix along this mesentry. When the mesentry is incomplete the artery lies on the wall of the appendix in its distal part, the wall of this vessel may be eroded in suppurative appendicitis or it may lead to the thrombosis of the appendicular blood vessel.

In children the mesoappendix is so transparent that the contained blood vessels can be seen easily. The layers of the mesoappendix enclose the blood vessels, nerves, lymph vessels and lymph node of the appendix[24, 25].

VASCULAR SUPPLY AND THE LYMPHATIC DRAINAGE OF THE APPENDIX

Appendicular artery:

The appendicular artery is a branch of the lower division of the ileo – colic artery. It passes behind the terminal ileum to enter the mesoappendix a short distance from the base of the appendix, where it gives a recurrent branch which anastomoses with a branch of the posterior caecal artery at its base.

The main appedicular artery runs towards the tip of the appendix lying at first near to and then in the free border of the mesoappendix. In most individuals once the appendicular artery reaches the wall of the appendix, it becomes an end artery. The terminal part of the artery lies on the wall of the appendix which may get thrombosed as a result of appendicitis leading to distal gangrene and necrosis.

Many individuals possess an accessory appendicular artery described by SESHACHALAM[25].

Figure 4: Mesoappendix with appendicular artery[24].

Appendicular Veins:

The appendicular veins drain into the ileocolic or posterior caecal vein which then drains into superior mesenteric vein[25].

Lymphatic drainage of the appendix:

The appendix has numerous lymphatic vessels. From the tip and the body of the appendix around 8 – 15 lymphatic vessels reaches the mesoappendix, one or the two of which are interrupted by nodes lying in peritoneal fold. They unite to form three to four lymphatic vessels which end in the superior and inferior nodes of the ileocolic chain[25].

Nerve Supply of the appendix:

The appendix and overlying visceral peritoneum derives its sympathetic nerve supply from the coeliac and superior mesenteric ganglia and the parasympathetic supply is from the plexus around the artery supplying the appendix[25].

SURFACE MARKING

The surface marking for the base of the appendix is at the junction of the lateral and middle one thirds of the line joining the right anterior superior iliac spine to umbilicus (Mc Burney's point) [25].

AETIO - PATHOGENESIS OF ACUTE APPENDICITIS

There is no unifying hypothesis regarding the aetiology of acute appendicitis. Decreased dietary fiber and increased consumption of refined carbohydrates may play an important role. The incidence is lowest in societies with a high dietary fiber intake.

In the developing countries which are adopting a more refined western type of diet, the incidence of acute appendicitis continues to rise. This is in contrast to the dramatic decrease in the incidence of acute appendicitis in western countries observed during period of past 30 years. There are no reasons established for this paradoxical change; however increased hygiene and a change in the pattern of childhood gastrointestinal infection related to the increased use of antibiotics may be responsible[24, 26].

Obstruction of the lumen is believed to be the major cause of acute appendicitis[27]. This may be caused by inspissated stools (fecalith or appendicolith), vegetable matter or seeds, lymphoid hyperplasia, parasites or neoplasm. The lumen of appendix is small in relation to its length which may predispose to closed loop obstruction. Obstruction of the appendiceal lumen leads to bacterial overgrowth and continued secretion of mucus causes intra luminal distention and increased wall pressure.

A periumbilical pain experienced by the patient during episode of acute appendicitis is a visceral pain due to luminal distention. Subsequent impairment of venous and lymphatic drainage may lead to mucosal ischemia, which may progress to gangrene and perforation. Inflammation of the adjacent peritoneum

causes localized pain in right lower quadrant. Although there is considerable variability, perforation usually occurs after at least 48 hours from the onset of symptoms.

Rarely free perforation of the appendix occurring into peritoneal cavity leads to peritonitis and septic shock and can be complicated by the subsequent formation of multiple intra peritoneal abscesses.

Sub acute appendicitis

Some episodes of acute appendicitis may apparently subside spontaneously before they reach the acute stage, this is called sub acute appendicitis. It is milder form of acute appendicitis. However this condition may recur. Presumably obstruction of the lumen may spontaneously be relieved allowing subsidence of appendicular inflammation and its attendant symptoms[28].

Recurrent appendicitis

There are occasional patients who have one or more attacks of what appears to be acute appendicitis. Between attacks this patients are free of symptoms and the physical examination is normal. Repeated attacks of non obstructive appendicitis produce adhesions and fibrosis causing recurrent appendicitis. If repeated examination during an attack provides evidence of recurrent appendicitis, elective appendicectomy should be undertaken[29].

Chronic appendicitis

Although rare, chronic appendicitis can explain persistent abdominal pain in some patients. Patients do not present with typical symptoms of acute appendicitis, instead they complain of weeks to years of right lower quadrant (RLQ) pain and may have had multiple medical evaluations in past, and may describe an initial episode with more classic symptoms of acute appendicitis. At time of surgical exploration clinical and pathological changes of chronic inflammation are identified in the region of appendix[30, 31].

BACTERIOLOGY

Table 1: Common organisms seen in patients with acute appendicitis[31].

Aerobic and facultative	**Anaerobic**
Gram negative bacilli	**Gram negative bacilli**
E. coli	Bacteroides fragilis
Pseudomonas aeruginosa	Bacteroides species
Klebsiella species	Fusobacterium species
Gram positive cocci	**Gram positive cocci**
Streptococcus anginosus	Peptostreptococcus species
Streptococcus species	**Gram positive bacilli**
Enterococcus species	Clostridium Species

CLINICAL FEATURES

Symptoms

Pain

Pain is present in almost all the patients with acute appendicitis. Poorly localised colicky abdominal pain is the classical feature of acute appendicitis. The pain is due to mid-gut visceral discomfort in response to appendiceal inflammation and obstruction. The pain is initially located in the peri-umbilical region and is similar to, but less intense than, the colic of small bowel obstruction. Gradually the pain is localised in the right lower quadrant. It takes about 1 to 12 hours for such localisation. In some of the patients the pain begins in the right lower quadrant and remains there.

Anorexia

It is almost always complained of with acute appendicitis. It is one of the constant clinical features, and diagnosis should be questionable if patient is not anorectic.

Nausea and Vomiting

Nausea of some degree is present in at least 9 out of 10 patients with acute appendicitis. Vomiting usually appears after onset of pain. If vomiting precedes pain the diagnosis should be questioned.

Constipation or diarrhea

An ileus may develop as appendicitis progresses leading to constipation or decreased frequency of normal bowel habit. Diarrhea is not a common component, and is more common in children and in postileal appendix[24, 26].

Signs

1) **Pyrexia:** Appendicitis may cause rise of temperature, although pyrexia is uncommon with uncomplicated appendicitis. Rise in temperature is usually restricted to 90 or 100^0F (39^0C). Even patients with complicated appendicitis often presents with normal temperature.

2) On systemic gentle palpation of abdomen the area of maximum tenderness will correlate to the position of appendix and is usually located in right lower quadrant or near Mc Burney's point[24].

3) **Muscle guarding** or resistance to the palpation usually parallels the severity of the inflammatory process. Early in the course of disease resistance if present is usually due to voluntary guarding. As peritoneal irritation progresses it is eventually replaced by reflex involuntary rigidity. One should be able to differentiate the voluntary guarding from involuntary rigidity. Involuntary rigidity will not diminish during expiration as seen with voluntary guarding.

4) **Cutaneous hyperesthesia** can be appreciated by light stroking of the skin of right and left side of the abdomen**.** In acute appendicitis hyperesthesia is

found over Sherren's triangle formed by the anterior superior iliac spine, the symphisis pubis and the umbilicus.

5) **Pointing test:** When the patient is asked to point the site of pain, it usually corresponds to site of localized tenderness in Mc Burney's point that is at the junction of lateral third with medial two thirds of the spino – umbilical line (Mc Burney's sign)[32].
6) **Rovsing's sign:** When pressure is exerted on left lower quadrant on palpation, pain is complained of in the right lower quadrant. It is also called 'referred rebound tenderness'. Probable explanation for this is retrograde displacement of the colonic gas that strikes the base of inflamed appendix[26].
7) **Psoas sign:** It is performed by having the patient lie on his left side. The examiner then slowly extends the patients right thigh, thus stretching the iliopsoas muscle which produces pain. This test indicates the presence of inflammed appendix in close proximity to the psoas muscle. This is positive in the retrocaecal appendicitis.
8) **Rebound tenderness:** This is a classical sign of peritoneal inflammation. A sudden pressure is exerted over the inflamed area and sudden release of hand will produce extreme pain.
9) **Cope's obturator test:** Flexion and internal rotation of hip in a patient with pelvic appendicitis initiates pain as it lies over the obturator internus muscle.

10) **Dunphy's sign:** When patient coughs vigorously and holds his or her right lumbar quadrant (RLQ) or refuses to cough because of pain, RLQ peritonitis is suspected.
11) **Blumberg's sign (Release sign):** Rebound tenderness in RLQ suggests localized peritonitis.
12) **Baldwin's sign:** A hand is placed over the right flank and patient is asked to raise the right lower limb with knee extended, this initiates pain in retrocaecal appendicitis[32].

LABORATORY STUDIES

Laboratory study demonstrates elevated acute phase reactants secondary to acute inflammation.

- Total white blood cell (WBC) count
- Differential count
- C – reactive protein

The WBC count is usually elevated above 12,000cells/mm^3. On differential count there is increase in percentage of neutrophils, the left shift with normal leucocyte count supports clinical diagnosis of acute appendicitis. A normal leucocyte count and differential count although is uncommon in appendicitis, but it can be seen[31].

The C – reactive protein has also been studied and correlated with clinical and pathological findings of appendicitis but it is non – specific and is not a clinically useful laboratory study.

The laboratory studies can be helpful in diagnosis of appendicitis but no single test is definitive. A white blood cell (WBC) count is the most useful laboratory test. However the WBC count can be normal in patients with acute appendicitis, specifically in early cases. Serial WBC measurements can improve the diagnostic accuracy as the rising value over time is commonly seen in patients with acute appendicitis[31].

IMAGING STUDIES

The ideal imaging study for the diagnosis of appendicitis should be relatively non invasive, quick and should be accurate in those patients with high risk of complications. It should be easily obtained at any hour, easily reproducible and should be free of ineterobservor variability. Ideally, imaging should reveal inflammation of appendix when it is located at a site that is anatomically troublesome to evaluate.

The potential imaging modalities for diagnosis of acute appendicitis include abdominal ultrasound (USG) and Computed tomography (CT) [31].

Abdominal ultrasonography (USG)

The normal appendix on abdominal USG is compressible with wall thickness of less than or equal to 3 mm. The size of an appendix can differentiate the normal appendix from the acutely inflammed appendix.

The hallmark of appendicitis on USG is direct visualization of inflammed appendix. The characteristic appearance is that of concentrically layered, incompressible, sausage like structure demonstrated at the site of maximium tenderness.[33]

The usual findings of appendicitis on USG are:

- Visualization of non compressible appendix as aperistaltic, blind ending tubular structure.
- The target appearance of more than or equal to 6 mm in total diameter on cross section or maximum mural wall thickness of more than or equal to 2 mm.
- The lumen of appendix may be distended with anechoic or hyperechoic material.
- Diffuse hypoechogenicity is associated with higher incidence of perforation.
- Loss of wall layers.
- Visualization of appendicolith.
- Prominent hyperechoic mesoappendix / paracaecal fat.
- Localized periappendicular fluid collections.

If the inflammed appendix becomes non tender on pressure, one should consider diagnosis of the spontaneous resolving appendicitis. Many clinical look alikes of appendicitis can be reliably differentiated by Ultrasound. The most frequently encountered among this is bacterial ileocaecitis caused by yersinea, salmonella or campylobacter. Secondly important conditions are gynaecological conditions such as ovarian cyst, ectopic pregnancy, tubo-ovarian abscess and adnexal torsion. Other ultrasonographically detectable conditions are sigmoid and caecal diverticulitis, perforated peptic ulcer, cholecystitis, crohn's disease, urological disease and small bowel obstruction.

The appendix may be relatively thickened in patients with perforated peptic ulcer, crohn's disease or sigmoid diverticulitis due to adjacent extrinsic inflammatory disease, which can lead to a false positive diagnosis of appendicitis. In experienced hand the inflammed appendix can be visualized in 90% of patients with non-perforated appendicitis, 85% of those with appendiceal mass and 55% of those with free perforation[34].

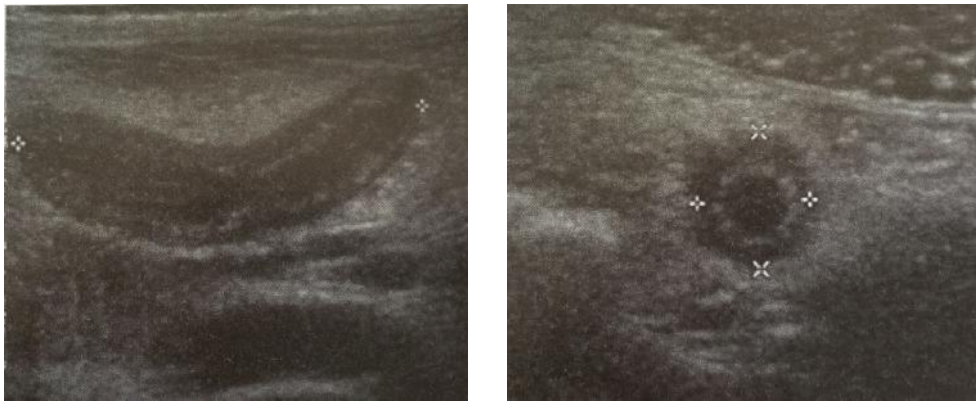


Figure 5: Longitudinal and transverse sonogram showing an enlarged tubular appendix (between calipers) that was non-compressible[35].

Computed tomography (CT)

CT has high diagnostic accuracy for appendicitis and can also diagnose many of other causes of pain in abdomen that can be confused with appendicitis[39].

The radiographic findings of appendicitis on CT include thick walled, dilated (>6 mm) appendix that does not fill with enteric contrast or air, and also the surrounding fat stranding to suggest inflammation. In various prospective studies CT has demonstrated a sensitivity of 0.94 and specificity of 0.95.[42] CT has a high negative predictive value, making it useful in excluding appendicitis in patients for whom the diagnosis is in doubt.

Figure 6: CT scan showing a typically distended appendix (arrow) with diffuse wall thickening and peri appendiceal fluid (arrowhead) [26].

ALVARADO SCORE

A number of clinical and laboratory based scoring system have been devised to assist the diagnosis of appendicitis. The most widely used is Alvarado score (Table 2). A score of 7 or more is strongly predictive of acute appendicitis[24].

Table 2: Alvarado (MANTRELS) score[24]

Symptoms	Score
Migratory RIF pain	1
Anorexia	1
Nausea and Vomiting	1
Signs	
Tenderness (RIF)	2
Rebound tenderness	1
Elevated temperature	1
Laboratory	
Leucocytosis	2
Shift to left	1
Total	10

RIF: right iliac fossa; MANTRELS: migratory pain, anorexia, nausea and vomiting, tenderness, rebound tenderness, elevated temperature, leucocytosis, shift to left (segmented neutrophils).

DIFFERENTIAL DIAGNOSIS

Because many of its signs and symptoms are nonspecific, the differential diagnosis of acute appendicitis is extensive and includes almost all the possible abdominal causes of pain, as well as some non abdominal causes. However, some of the diagnoses are more likely than others in certain patient groups. For instance, in young males with a suggestive history and physical examination, acute appendicitis is the most likely cause of right lower quadrant pain. Meckel's diverticulitis causes similar symptoms, but is relatively uncommon. In women of childbearing years, the diagnosis of right lower quadrant pain can be even more difficult. A complete history including recent menstrual history and pelvic examination can be helpful in differentiating these causes of pain from acute appendicitis. Nonetheless, appendicitis can be difficult to diagnose in this patient population, and higher rates of misdiagnosis have been described in women of childbearing age.[31]

Table3: Differential diagnosis of acute appendicitis[31]

Gastrointestinal Causes	Genitourinary Causes
Cecal diverticulitis	Pyelonephritis / perinephric abscess
Sigmoid diverticulitis	Nephrolithiasis
Meckel's diverticulitis	Hydronephrosis
Epiploica appendicitis	Urinary tract infection
Mesenteric adenitis	**Nonabdominal Causes**
Omental torsion	Rectus muscle hematoma
Crohn's disease	Lower lobe pneumonia
Cecal carcinoma	Streptococcal pharyngitis
Appendiceal neoplasm	**In Women**
Lymphoma	Ovarian cyst
Typhlitis	Corpus luteal cyst
Small bowel obstruction	Ovarian torsion
Perforated duodenal ulcer	Pelvic inflammatory disease
Intussusception	Endometriosis
Acute cholecystitis	Tubo-ovarian abscess
Hepatitis	**In Pregnancy**
Pancreatitis	Ectopic pregnancy
Infectious Causes	Round ligament pain
Infectious terminal ileitis	Chorioamnionitis
Gastroenteritis	Placental abruption
Cytomegalovirus colitis	Preterm labor

SURGERY FOR APPENDICITIS

The first ever appendicectomy was performed by a French surgeon **Claudius Amyand** in 1736 at St. George's hospital, London, when he described the presence of a perforated appendix within the hernia sac in an 11 year old boy. The appendix was perforated by a pin the boy had apparently swallowed[37].

Charles Mc Burney was one of the surgeons pioneering the diagnostics and operative treatment of appendicitis. He presented a classical report on early operative interference in case of appendicitis which was presented before the New York Surgical Society in 1889. In it he described the area of maximum abdominal pain in this disease process, now known as MC Burney's Point. Five years later in his another paper he described the incision that he used in case of appendicitis, now known as Mc Burney's Incision[38].

Figure 7: Charles Mc Burney

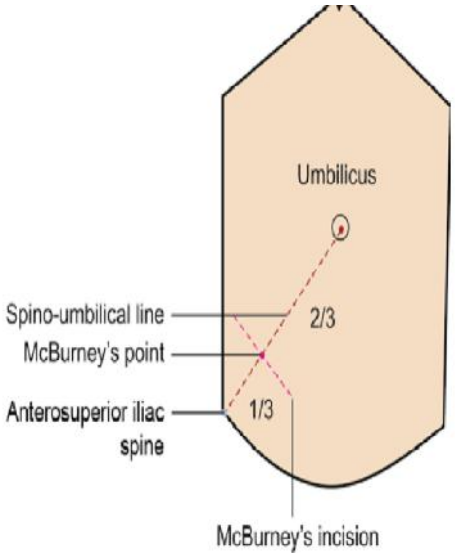


Figure 8: Mc Burney's point and incision

OPEN VS LAPAROSCOPIC APPENDICECTOMY

Several prospective randomized studies have compared laparoscopic and open appendicectomy, and overall differences in outcome remains the same. The percentage of appendicectomy performed laparoscopically continues to increase[39]. One situation in which laparoscopic appendectomy may be advisable is when the diagnosis of appendicitis is in doubt. Laparoscopy can be both diagnostic and therapeutic.

Table 4: Laparoscopic VS Open Appendicectomy

Laparoscopic appendicectomy	Open Appendicectomy
Diagnosis of other conditions	Shorter operating room time
Decreased pain after surgery	Lower operating room costs
Reduced length of stay	Lower hospital costs
Fewer wound infections	Fewer intra-abdominal abscesses
Quicker return to usual activities	
Lower societal cost	

LAPAROSCOPIC APPENDICECTOMY

Before the surgery begins all the equipments must be checked for the proper working capacity. All the methods of laparoscopic appendicectomy require standard laparoscopic equipments which are as follow:

- Trocars
- Blunt graspers
- Electro cautery
- Laparoscope, 30^0, 10 mm
- Veress needle
- Co_2 insufflator
- Light source

Positioning of the patient

The patient is placed in supine position. A monitor is placed at the right side of the patient, upon abdominal insufflation and laparoscope insertion, steep Trendelenburg position facilitates the proper placement of the last two trocars. After placing all trocars, placing the patient left side down aids gravity in relocating the small bowel away from the appendiceal field of vision.

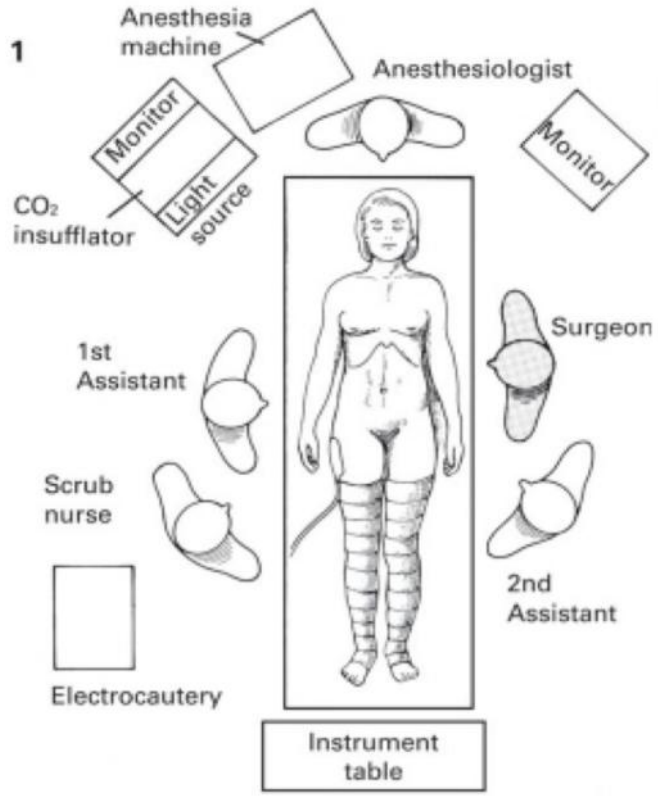


Figure 9: Postion of patient for laparoscopic appendicectomy

Technique

- Once the patient is positioned as described above, parts are painted and draped in sterile fashion.
- Insertion of Foley catheter is helpful in decompressing the bladder and thereby maximizing the viewing field and improving the working space.
- A 2-cm sub-umbilical curvilinear incision is made, directly below the umbilicus.

- A meticulous dissection should be performed through the subcutaneous tissue, beyond the scarpa fascia, down to lineaalba, skeletonizing the fascia.
- Continue the blunt dissection till the visualization of the peritoneum. Grasp the peritoneum with two straight clamps, side by side in a horizontal manner. Palpate the grasped peritoneum with the fingertips for any intra - abdominal contents.
- Cut 2 cm longitudinal incision by Metzenbaum scissors for entry into the peritoneal cavity. Now gently introduce the hasson trocar through this defect and initiate Co_2 insufflation.
- Meticulously visualize the entire abdominal cavity.
- Place the patient into a steep Trendelenburg position for the placement of the next two 5 mm trocars.
- The first trocar is placed to the left of the midline, 1 cm above the pubic ramus, by making a 1 cm incision. Make sure to stay cephalad to the dome of the bladder, when the port enters the peritoneal cavity.
- Place the second 5 mm port, about 2 cm above and medial to the left ASIS. The vessels over anterior abdominal wall can be highlighted with the light of scope to provide an appropriate roadmap in entering the abdominal cavity.
- Once all the trocars have been placed patient can be rotated left side down while maintaining the steep Trendelenburg position to obtain the best visualization of the proposed target. This maneuver allows small bowel to retract away from the operating field via gravity.

- Place two atraumatic grasper through the 5 mm ports, to visualize the appendix, follow the taenia coli down to its confluence at the base of caecum.
- Clutch the tip of the appendix with grasper through the suprapubic port, retracting it up and out towards the left upper quadrant, this should provide good visualization of the mesoappendix and the appendiceal base.
- Skeletonize the appendix, by coagulating and transecting the entire mesoappendix.
- Put a rodder's knot over the base of the appendix.
- Appendix can be removed out through infra umbilical 10 mm port with help of grasper and reducer while using the 30^0 5 mm scope placed into the left ASIS port.
- Removed appendix should be sent for histopathological examination.
- Switch the scopes again by substituting the 5 mm for 10 mm and again visualize the appendiceal stump for any abnormalities.
- Irrigate and suction this area as well as pelvis, if required, once the irrigation and suction are complete remove all the instruments from the abdominal cavity.
- Remove all the ports beyond fascia under direct visualization, cease the abdominal insufflation and turn off the light source. Release the hasson trocar and remove it from the abdominal cavity.
- Place a vicryl 0 stitch, in a figure of eight fashion, through the linea alba/fascia to close the infra umbilical port[31].

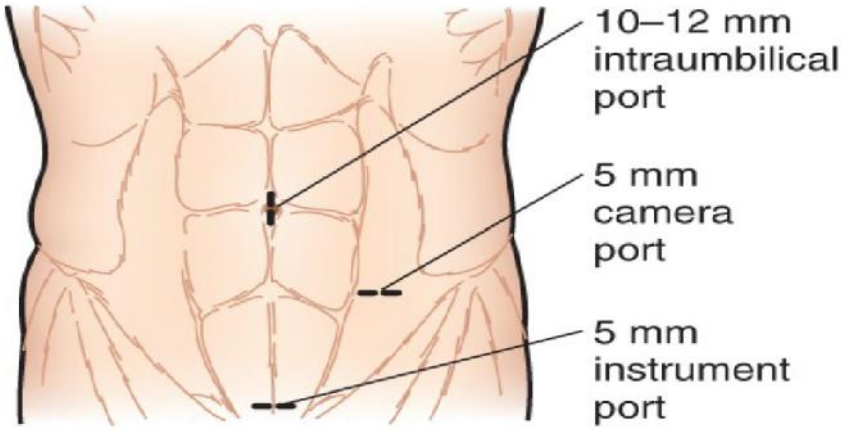


Figure 10: Position of ports for laparoscopic appendicectomy

Complications of appendicectomy

The several complications which can occur following appendicectomy are mentioned as below[35]

A. Surgical site infection
B. Appendix stump complications
C. Bowel obstruction
D. Post operative bleeding
E. Fecal fistula
F. Incisional hernias

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, ASEPSIS and Southampton Wound Assessment scale are required to identify and classify SSIs[40].

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 lead 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.[41]

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 women who died of puerperal fever, presumably as the proof of his tenets[42].

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[43]. 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[41]. Most surgical site infections are superficial, but still they contribute greatly to the morbidity and mortality associated with the surgery[45, 46].

Cruse in 1980, estimated that a SSI increases a patient's hospital stay by approximately 10 days and cost to an additional $2,000 [47, 48]. There are other studies which also show the increased length of hospital stay and cost associated with SSIs[46, 47]. As compared to superficial SSIs, Deep SSIs involving organs or spaces are associated with even greater increases in hospital stay and costs[51, 52].

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[53]. Another large systematic review of 147 clinical trials demonstrated an overall incidence of 11% following colorectal surgeries[54].

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[55]. Previous Indian studies also concur with similar rates of SSIs ranging from 10.06% to 45% in clean – contaminated cases[56-58].

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[44].

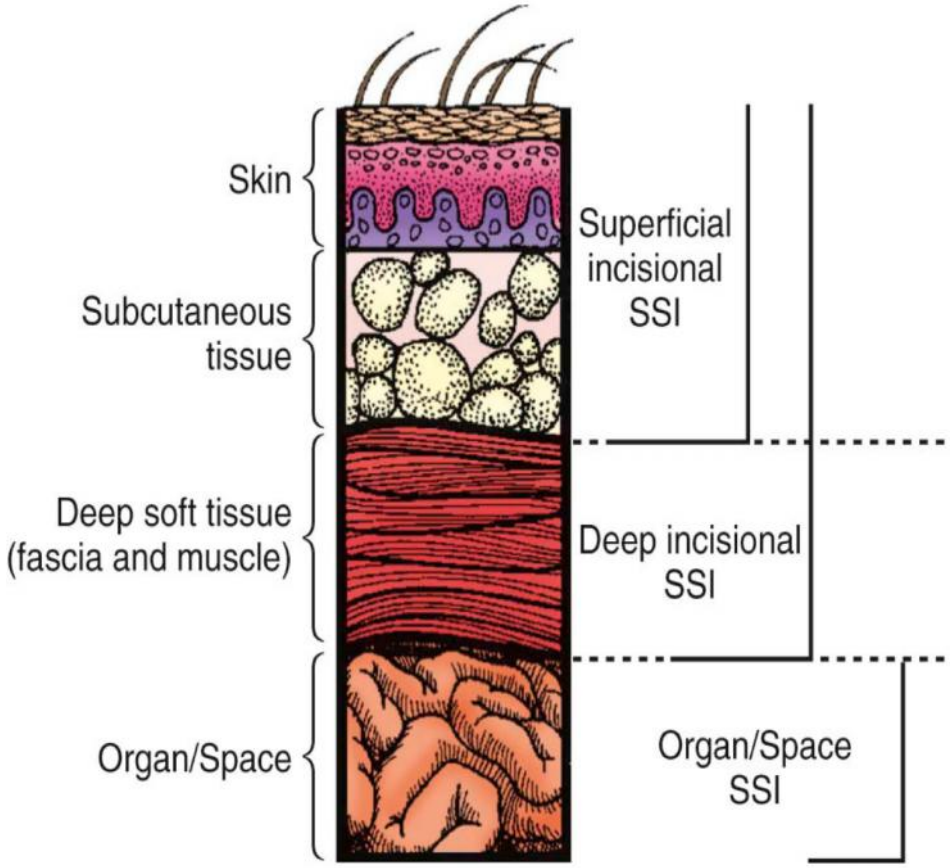


Figure 11: Surgical site infection as per CDC guidelines[26]

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
    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, or heat, and superficial incision deliberately opened by surgeons and culture positive or not culture.
    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, and
- Patient has at least 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. The differentiation between major and minor and the definition of SSI is important in audit or trial of antibiotic prophylaxis. 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.[24]

SOUTHAMPTON SCORING SYSTEM

Table 5: Southampton scoring system[59]

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)
Major Complication: 4 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	

The wound grading system used was simplified for the use of analysis.

By using the worst wound score recorded and information about any treatment instituted either in hospital or the community, wounds were regarded in four categories:

A. Normal healing;
B. Minor complication;
C. Wound infection – wounds graded 4 or 5 or wounds treated with antibiotics after discharge from hospital, irrespective of the wound grading given to them by the nurse; and major haematoma – wound or scrotal heamatomas requiring aspiration or evacuation.[59]

ANTIBIOTIC PROPHYLAXIS IN SURGERY

Prophylactic antibiotics are used most often to prevent infection of a surgical incision. It is well recognized that pre operative antibiotics reduces the risk of postoperative surgical site infection, whenever a patient undergoes any abdominal surgeries, and is especially important in clean – contaminated (appendicectomy) or contaminated cases (perforated duodenal ulcer), which constitute a majority of the abdominal surgeries.

There is a delay before host defences can become mobilized after a breach in an epithelial surface, whether caused by trauma or surgery. The acute inflammatory, humoral and cellular defences take up to 4 hours to be mobilized. This is called the 'decisive period', and it is the time when the invading bacteria may become established in the tissues. It is therefore logical that prophylactic antibiotics should be given to cover this period and that they could be decisive in preventing an infection from developing. The tissue levels of antibiotics should be above the minimum inhibitory concentration (MIC_{90}) for the pathogens likely to be encountered.[24]

It is widely accepted fact that the first dose should be given preoperatively, whenever prophylactic antibiotics are used in abdominal surgeries, which is based on the experimental wok of Burke who studied the effective period of preventive antibiotic action in dermal lesions and experimental incisions[60-62].

Chodak and Plaut in a critical review of the literature on prophylactic systemic antibiotics concluded that any study in which therapy was not begun pre

operatively was inadequate[63]. Stone and Hooper in their study have confirmed that postoperative antibiotics are ineffective as prophylaxis in gastric, biliary and colonic surgery[64]. Once it was concluded that postoperative antibiotics do not achieve significant prophylaxis in reducing surgical site infection, a timing of antibiotic administration was questionable, whether to be administered prior to the incision, during surgery or after the conclusion of surgery before closing the abdomen. Several studies were undertaken to the results of these.

Classen et al analysed 2847 patients prospectively who were undergoing clean or clean-contaminated surgeries with regard to timing of antibiotic administration and wound infection. The patients were divided in four groups according to timing of antibiotic administration: 'Early' – 2 to 24 hours before incision; 'preoperative' – within 2 hours of placing the incision; 'Perioperative' – within 3 hours after placing the incision; 'Postoperative' – within 3 to 24 hours after placing incision. The rates of surgical site infection were 14%, 0.6%, 1.4% and 3.3% respectively. So, the conclusion was that preoperative antibiotic administration was most beneficial in preventing the postoperative surgical site infection[65].

Prophylactic administration of antibiotic can reduce Post operative morbidity, reduces duration of hospital stay and reduces the overall costs attributable to surgical site infections. A review article by Page et al concludes that preoperative prophylactic antibiotics are helpful in certain clean cases and the selection should be based on local infection surveillance data, specific contraindications and the results of clinical trials[66].

Mc Donald et al systematically reviewed 28 clinical trials with 9478 patients which compared a single dose versus multiple doses antibiotic prophylaxis, the study concluded that there is no clear advantage of either single or multiple dose regimens in preventing SSI[67].

Song et al published a systemic review of 147 patients which concluded that single dose regimen are as effective and may be associated with less toxicity, less risk of developing bacterial resistance and fewer adverse effects[54].

Four principles to guide the administration of antimicrobial agents for prophylaxis[68]

1. Safety.
2. An appropriate narrow spectrum of coverage of relevant pathogens.
3. Little or no reliance on the agents for therapy of infection (because of the possible induction of resistance with heavy usage)
4. Administration within 1 hour before surgery and for a defined brief period thereafter (no longer than 24 hours, 48 hours for cardiac surgery, and ideally a single dose)

Antibiotic prophylaxis is designed to achieve effective antibiotic serum/tissue concentration at the time of initial surgical incision, and is maintained throughout the “vulnerable period” of procedure (i.e., time between skin incision and skin closure). If prophylaxis is given too early, antibiotic levels will be sub optimal/non existence when protection is needed. Properly timed pre operative antibiotic prophylaxis is desirable for optimal effectiveness since antibiotics given after skin closures are unlikely to be effective. When no

infection exists prior to surgery (clean/clean – contaminated surgery), single dose prophylaxis is preferred. When infection is present likely prior to surgery ("dirty surgery", e.g., perforated colon), antibiotics are given for more than one day and it represents early therapy, not true prophylaxis.[69]

Most SSIs are caused by gram – positive cocci, so prophylaxis should be directed primarily against staphylococci for clean cases and for high risk, clean – contaminated, elective biliary and gastric surgery. Cephalosporins are preferred in all circumstances. If gram negative or anaerobic coverage is required a second or third generation cephalosporins plus metronidazole are expert's first choice regimens[26, 68].

Even though SCIP (Surgical care improvement project) specifies a 24 hour limit for prophylaxis, a single dose prophylaxis is equivalent to multiple doses for prevention of SSI[64]. Unfortunately, excessively prolonged antibiotic prophylaxis is pervasive and potentially harmful. Prolonged antibiotics increases the risk of nosocomial infections unrelated to surgical site and of the emergence of MDR pathogens. Pneumonia and vascular catheter related infections have been associated with prolonged antibiotic use[70, 71], as has emergence of SSI caused by MRSA[72].

Evidence has shown that only 40% of patients who receive antibiotic prophylaxis do so for less than 24 hours[73]. As a result of ischemia caused by surgical hemostasis, antibiotic penetration into the incision immediately after surgery is questionable until neovascularization occurs (24 to 48 hours).

Antibiotics should not be given to cover indwelling drains or catheters, in lavage or irrigation fluid, or as a substitute for poor surgical technique.

Commonly used prophylactic antibiotics for surgical procedures are as follow[26, 69]

Table 6: Commonly used antibiotic prophylaxis:

Procedure	Usual organism	Preferred prophylaxis	Alternative prophylaxis
Stomach, upper small bowel surgery	S. aureus, (MSSA) Group A streptococci	Ceftriaxone 1 gm (IV) × 1 dose or Cefazolin 1 gm (IV) × 1 dose	Cefotaxime 2 gm (IV) × 1 dose or Ceftizoxime 2 gm (IV) × 1 dose
Distal small bowel, colon surgery	E. coli Klebsiella B. fargilis	Oral Neomycin plus either Erythromycin base or Metronidaole Parenteral Ertapenem 1gm (IV) × 1 dose	Piperacilin 3 gm (IV) × 1 dose Or Cefoxitin 2 gm (IV) × 1 dose Or combination therapy with Metronidazole 1 gm (IV) × 1 dose Plus either Ceftriaxone 1 gm (IV) × 1 dose Or Levofloxacin 500 mg (IV) × 1 dose Or Gentamycin 240 mg (IV) × 1 dose
Appendectomy, non perforated	Enteric gram negative bacilli, Anaerobes, enterococci	Cefoxitin 1-2 gm (IV) × 1 dose Or Cefazolin 1 gm (IV) × 1 dose plus Metronidazole 0.5 gm (IV) × 1 dose	Ampicilin – sulbactum 3 gm (IV) × 1 dose

Hepatic surgery	E.coli Klebsiella E.faecalis B.fragilis	Ampicillin / sulbactum 3 gm (IV) × 1 dose Or Piperacillin 4 gm (IV) × 1 dose	Meropenem 1 gm (IV) × 1 dose Or Moxifloxacin 400 mg (IV) × 1 dose
Biliary tract surgery	E.Coli Klebsiella E.faecalis	Meropenem 1 gm (IV) × 1 dose Or Piperacillin 4 gm (IV) × 1 dose	Ampicillin / sulbactum 3 gm (IV) × 1 dose
Pelvic (OB/GYN) surgery	Aerobic gram negative bacilli, Anaerobic streptococci B.fragilis	Ceftriaxone 1 gm (IV) × 1 dose plus Metronidazole 1 gm (IV) × 1 dose	Cefotetan 2 gm (IV) × 1 dose or Cefoxitin 2 gm (IV) × 1 dose or Ceftizoxime 2 gm (IV) × 1 dose
Urological implant surgery	S. aureus (MSSA) Aerobic gram negative bacilli	Ceftriaxone 1 gm (IV) × 1 dose	Cefotaxime 2 gm (IV) × 1 dose or Ceftizoxime 2 gm (IV) × 1 dose

CEFOTAXIME

It is the prototype of third generation cephalosporin antibiotic. It has a potential activity against gram positive and expanded gram negative compared to the first two generations of cephalosporins. It is highly resistant to the bacterial beta lactamases.

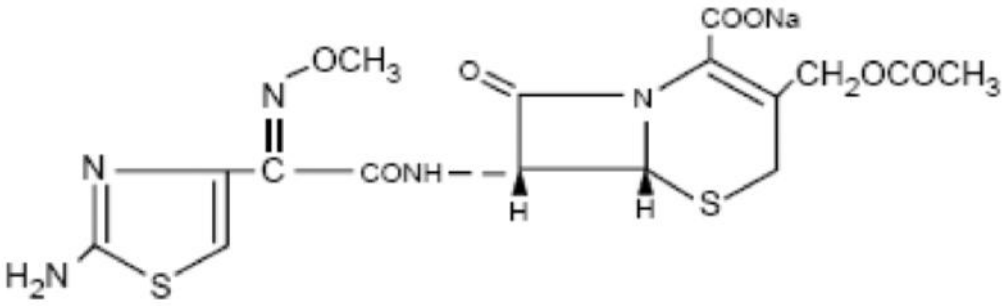


Figure 12 : Molecular structure of Cefotaxime

It has a plasma half life of about 1 hour. It is metabolized in the body to deacetylated form which exerts a weaker but synergistic action with parent drug. The plasma half life is longer for its deacetylated metabolite. Cefotaxime has been effectively used for meningitis caused by H. influenza, penicillin-sensitive S. pneumonia and for N. meningitides. It is routinely administered intravenously in a dose of 1-2 gm, 8-12 hourly.

As with all other cephalosporins, cefotaxime may elicit a variety of hypersensitivity reactions including anaphylaxis, fever, skin rashes, nephritis, granulocytopenia and hemolytic anemia. Renal toxicity occurs rarely with high doses[74, 75].

METRONIDAZOLE

It is the prototype of nitroimidazole introduced in 1959 for trichomoniasis and later found to be a highly active amoebicide. It has a broad spectrum cidal activity against protozoa and many anaerobic bacteria.

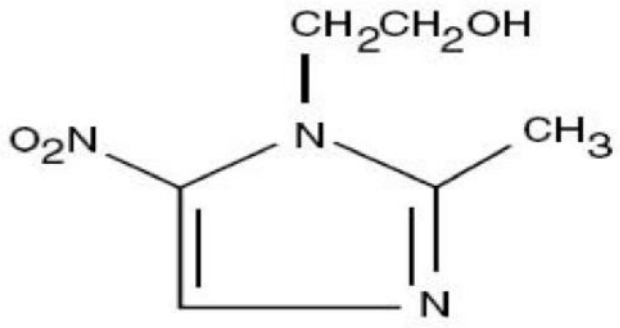


Figure 13: Molecular structure of Metronidazole

It has a plasma half life of about 8 hours, which is increased in patients with impaired renal functions. The parent drug and its metabolites are excreted in urine.

Metronidazole is a drug of choice for extraluminal amoebiasis and giardiasis. It is an effective drug for treating anaerobic bacterial infections such as brain abscess, endocarditis and infections occurring after colorectal surgery or appendicectomy where it is generally used with other antibiotics. It is given in a dose of 400mg tds.

The most frequently observed adverse effects of metronidazole are: nausea, vomiting, metallic taste and epigastric distress. Other less frequent side effects are headache, dryness of mouth, dizziness, rashes and transient neutropenia[74, 75].

Chapter 4

Methodology

METHODOLOGY

The present study was conducted in Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum over a period from January 2015 to December 2015 on patients undergoing laparoscopic appendicectomy for non perforated appendicitis.

Study design:

Open label Randomized control trial

Study Period:

The present one year study was conducted during the period of 1st January 2015 to 31st December 2015.

Place of study:

Department of General surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.

Source of Data:

All patients clinically diagnosed with appendicitis and admitted for Laparoscopic appendicectomy under department of General Surgery, KLES Dr. Prabhakar kore Hospital and MRC, Belgaum.

Sample Size:

A total of 100 patients admitted with non perforated appendicitis at KLES Dr. Prabhakar kore Hoapital and MRC, Belgaum were studied.

Sampling Procedure:

The sample size was calculated based on the formula mentioned below.

$$N = 2 (Z\alpha + Z\beta)^2 pq/ (P_0 – P_1)^2$$

Where

P_0 = surgical site infection rate with conventional three dose antibiotics.

P_1 = surgical site infection rate with single dose antibiotics.

$P = P_0+P_1/2$

$Q = 100-P$

So n= 16x7x93/4

=2604

The sample size was calculated considering the literature review[76] and by substituting the values to the above equation the sample size i.e., n = 2604.

Due to limitation of the patients with non perforated appendicitis in the hospital, the sample size was considered to be 100, with 50 patients in each group by the “Rule of Thumb”

Selection criteria

Inclusion criteria:

- Patients presenting with appendicitis and admitted in KLES Dr. Prabhakar Kore Hospital and MRC and who give consent for the participation in study
- Age 18 – 50 years
- Both Male/Female patients
- Clinically diagnosed as uncomplicated appendicitis

Exclusion Criteria:

- Complicated (Gangrenous or perforated appendicitis)
- Patients who have additional co – morbidities including diabetes; Immuno-suppression; cardiac, renal or liver failure.
- Patients allergic to Cephalosporins
- Patients who has taken antibiotics outside before participating in this study
- Patients who refuse to give consent

Ethical Consideration:

The study was approved by the Ethical and Research committee, Jawaharlal Nehru Medical College, Belgaum.

Informed consent

All the patients presenting with appendicitis and admitted in surgery wards were screened for eligibility. Patients fulfilling selection criteria were explained about the nature of the study and a written informed consent was obtained from all the participants before enrollment (Annexure II).

METHOD OF COLLECTION OF DATA AND SAMPLING PROCEDURE:

- All patients attending General Surgery OPD, who are clinically diagnosed as having an appendicitis and getting admitted to KLES Dr. Prabhakar Kore Hospital and MRC, belgaum for Laparoscopic appendicectomy were eligible for the study.
- After excluding the patients based on the above criteria, the first consecutive hundred patients who fulfilled the inclusion criteria were included in the study.
- A written and informed consent was taken from each patient enrolled in the study after briefing them about nature of surgery, required investigations, proposed interventions and possible untoward outcomes (Annexure I).
- The data concerning the demography, history of illness and details of the clinical examination were recorded onto a predesigned proforma (Annexure II).
- Routine investigations such as complete blood count, blood urea, serum creatinine and other investigations such as ultrasound of abdomen were done as required.
- Patients were randomized according to randomization procedure.

Randomization:

The study patients were randomized into two groups by an opaque envelope method. Hundred opaque envelopes containing a card inside were made. Fifty of these envelopes contained a card mentioning Group A and the remaining fifty had a card mentioning Group B. Patients were asked to pick up an envelope randomly and depending on the group mentioned in the envelope they were allocated into either one of the two groups.

Intervention

Group A (Study group): To receive a single dose of pre operative antibiotics Inj. Cefotaxime 1gm iv + Inj. Metronidazole 100ml iv. at the time of induction of anesthesia. No postoperative antibiotics.

Group B (Control group): To receive a pre operative antibiotics Inj. Cefotaxime 1gm iv + Inj. Metronidazole 100ml iv. at the time of induction of anesthesia as well as three more doses of same antibiotics post operatively 8 hrs, 16 hrs and 24 hrs from the time of index surgery.

Pre operatively:

- The written and informed consent was taken.
- Shaving of the abdomen was done from nipple to mid thigh, a day prior to surgery.
- No antibiotics were given to patients before induction of anesthesia.

Intra operatively:

- All the patients were given General anesthesia.
- All the patients in both the groups underwent painting of abdomen with 10% povidone iodine followed by re cleaning with spirit on the operation table.
- The surgical field was draped appropriately taking all aseptic precautions.
- Patients in both the groups received injection Cefotaxime 1 gm and injection Metronidazole 100 ml iv at the time of induction of anesthesia and prior to the incision.

- Patients in both the groups underwent laparoscopic appendicectomy as per the standard procedures.
- Appendix specimen was sent for histopathological examination.
- Similar instruments and suture materials were used in both the groups.
- Basic principles of surgery like adequate hemostasis and no undue traction on the tissues were followed in both the groups.

Post operatively:

- Group A: did not receive any post operative antibiotics other than a single dose of pre operative antibiotics at the time of induction of anesthesia.
- Group B: received three more doses of same antibiotics post operatively 8 hrs, 16hrs and 24 hrs from the index surgery.
- Intravenous fluids, analgesics and other supportive treatments were given as per the surgeon's advice.
- Surgical wound was inspected after 48 hrs, 72 hrs and on 7^{th} day to look for any signs of post operative wound infection.
- The scores at each dressing were charted in a pre-formed table to assess wound infection as per the Southampton scoring system (Grade 0 to 5).
- Sutures were removed on the 7^{th} post operative day.
- Wound healing was taken as normal for grades 0, 1 and 2. Infection of wound was categorized as minimal for grade 3 and as major for grades 4 and 5.

STATISTICAL ANALYSIS:

- The statistical analysis of data was descriptive using SPSS version 20.0 (SPSS Inc, Chicago, IL)
- The comparison of demographic characteristics was done using chi-square test, infection rates were compared using Fisher's exact test and the mean duration of hospital stay was compared using un-paired "t" test.
- A 'p' value of less than 0.05 was considered as statistically significant.

Chapter 5

Results

RESULTS

The present study was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and MRC, Belgaum over a period from January 2015 to December 2015 on 100 patients with non perforated appendicitis undergoing laparoscopic appendicectomy. Based on the envelope method patients were divided into two groups namely;

Group A: Received a single dose of pre operative antibiotics Inj. Cefotaxime 1gm iv + Inj. Metronidazole 100ml iv. at the time of induction of anesthesia.

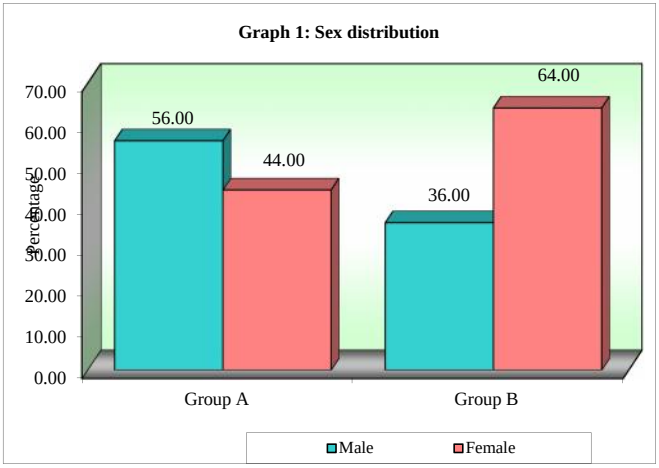
Group B: Received a pre operative antibiotics Inj. Cefotaxime 1gm iv + Inj. Metronidazole 100ml iv. at the time of induction of anesthesia as well as three more doses of same antibiotics post operatively 8 hrs, 16 hrs and 24 hrs from the time of index surgery.

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

Table 7: Sex distribution

Sex	Group A	%	Group B	%	Total
Male	28	56.00	18	36.00	46
Female	22	44.00	32	64.00	54
Total	50	100.00	50	100.00	100
P = 0.045*					

*p<0.05



A total of 46 (46%) males and 54 (54%) females participated in the study. Group A had 28 (56%) males and 22 (44%) females. Group B had 18 males (36%) and 32 (64%) females. The comparison showed statistically significant difference (p= 0.045) in distribution of patients between both the groups.

Table 8: Age distribution

Age groups	Group A	%	Group B	%	Total
<=20yrs	11	22.00	11	22.00	22
21-30yrs	18	36.00	17	34.00	35
31-40yrs	9	18.00	13	26.00	22
41-50yrs	12	24.00	9	18.00	21
P = 0.757					
Total	50	100.00	50	100.00	100
Mean age	30.74		30.72		30.73
SD age	10.69		9.56		10.09

In the present study the patients in both the groups were of age between 18 – 50 years. Majority of patients in both groups, Group A(36%) and Group B(34%) were of age between 21 – 30 years. The mean age in Group A was 30.74 ± 10.69 years and in Group B it was 30.72 ± 9.56 years.

However the difference between the age of both the group was not statistically significant (p = 0.757).

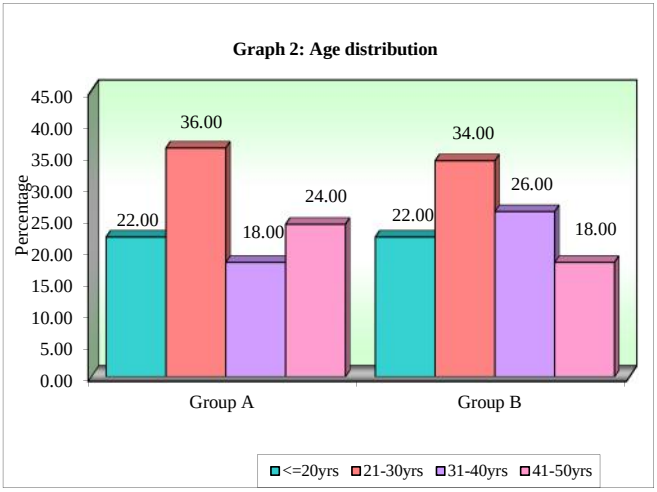


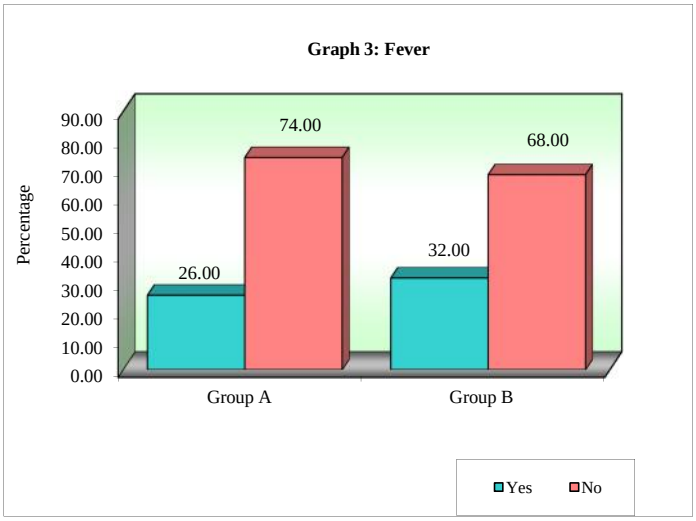
Table 9: Pain

Status of pain	Group A	%	Group B	%	Total
Yes	50	100.00	50	100.00	100
No	0	0.00	0	0.00	0
Total	50	100.00	50	100.00	100
p=1.000					

All the patients in both the groups, Group A (100%) and Group B (100%) had complains of pain in abdomen in right iliac fossa.

Table 10: Fever

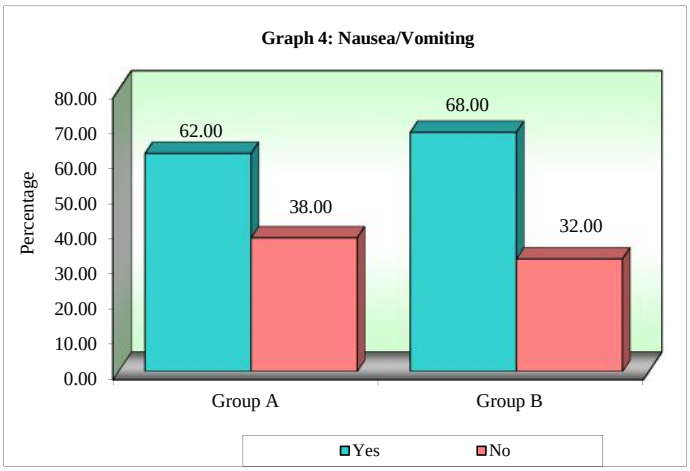
Status of fever	Group A	%	Group B	%	Total
Yes	13	26.00	16	32.00	29
No	37	74.00	34	68.00	71
Total	50	100.00	50	100.00	100
P = 0.509					



Total of 13 patients in Group A (26%) and 16 patients in Group B (32%) had complain of fever and the comparison showed that the difference between both the group was not statistically significant (p = 0.509).

Table 11: Nausea/Vomiting

Status of Nausea/Vomiting	Group A	%	Group B	%	Total
Yes	31	62.00	34	68.00	65
No	19	38.00	16	32.00	35
Total	50	100.00	50	100.00	100
P = 0.529					



Total of 31 patients in Group A (62%) and 34 patients in Group B (68%) had complain of nausea or vomiting and the difference between both the group was not statistically significant (p = 0.529).

Table 12: Mc burney's Tenderness

Status of Mc burney's Tenderness	Group A	%	Group B	%	Total
Yes	50	100.00	50	100.00	100
No	0	0.00	0	0.00	0
Total	50	100.00	50	100.00	100
p=1.000					

All the patients in both Group A and Group B had Mc burney's tenderness.

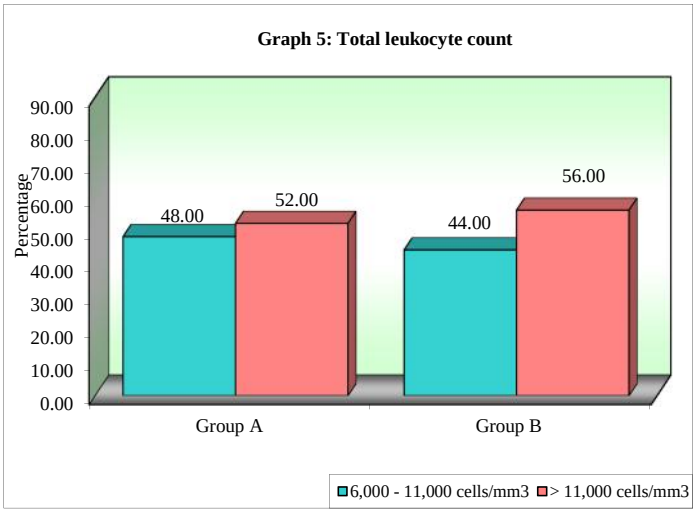
Table 13: Bowel Sounds

Status of Bowel Sounds	Group A	%	Group B	%	Total
Yes	50	100.00	50	100.00	100
No	0	0.00	0	0.00	0
Total	50	100.00	50	100.00	100
p=1.000					

The normal bowel sounds were present in all the patients in both Group A and Group B.

Table 14: Total leukocyte count

Total Leukocyte Count (cells/mm^3)	Group A	%	Group B	%	Total
6,000 – 11,000	24	48.00	22	44.00	46
>11,000	26	52.00	28	56.00	54
Total	50	100.00	50	100.00	100
P = 0.688					

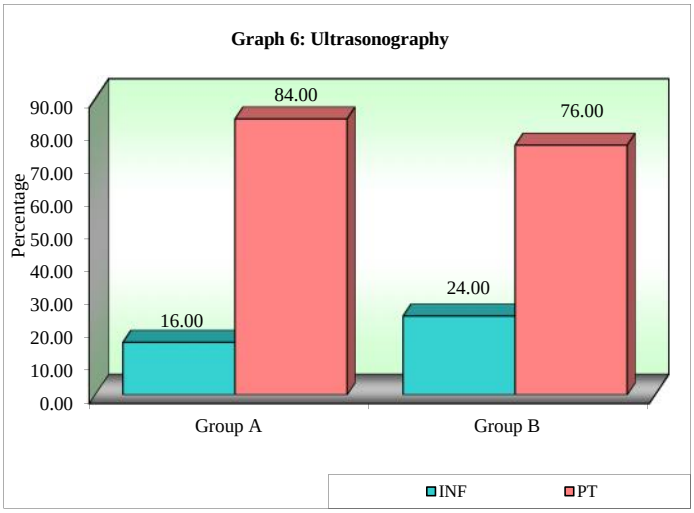


Total of 24 patients in Group A (48%) and 22 patients in Group B (44%) had total leukocyte count between 6,000-11,000 cells/mm^3; while 26 patients in Group A (52%) and 28 patients in Group B (56%) had leukocytosis (>11,000 cells/mm^3); and the difference between both the group was not statistically significant (p = 0.688).

The mean leukocyte count for Group A was 10,482 ± 1807 cells/mm^3 and for Group B was 10,518 ± 2028 cell/mm^3 with p value of 0.926 which was statistically insignificant.

Table 15: Ultrasonography

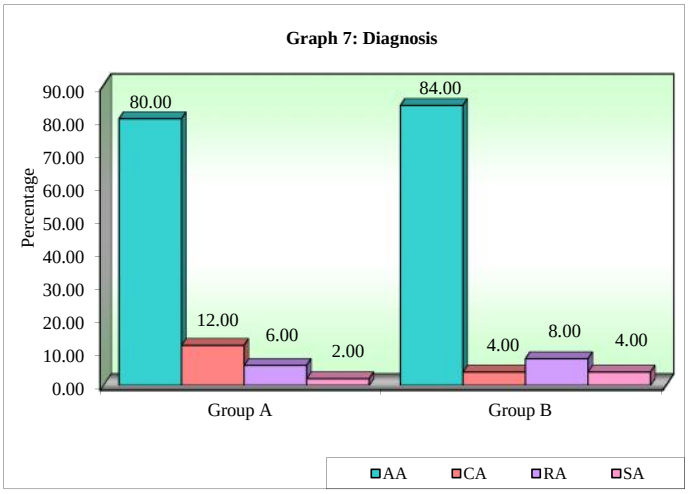
Ultrasonography	Group A	%	Group B	%	Total
INF	8	16.00	12	24.00	20
PT	42	84.00	38	76.00	80
Total	50	100.00	50	100.00	100
P = 0.317					



Total of 8 patients in Group A (16%) and 12 patients in Group B (24%) showed inflammed appendix; while 42 patients in Group A (84%) and 38 patients in Group B (76%) showed probe tenderness on ultrasonography, and the difference between both the group was not statistically significant (p = 0.317)

Table 16: Diagnosis

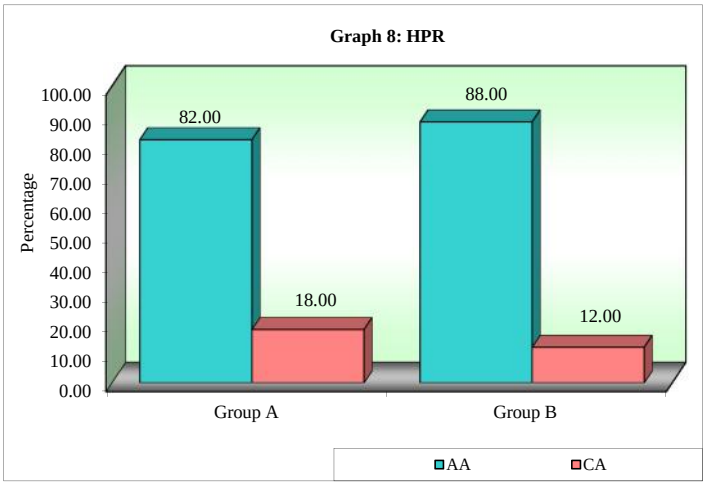
Status of diagnosis	Group A	%	Group B	%	Total
AA	40	80.00	42	84.00	82
CA	6	12.00	2	4.00	8
RA	3	6.00	4	8.00	7
SA	1	2.00	2	4.00	3
Total	50	100.00	50	100.00	100
P = 0.294					



Total of 40 patients in Group A (80%) and 42 patients in Group B (84%) had acute appendicitis; while 6 patients in Group A (12%) and 2 patients in Group B (4%) had chronic appendicitis; total of 3 patients in Group A (6%) and 4 patients in Group B (8%) had recurrent appendicitis; and 1 patient in Group A (2%) and 2 patients in Group B (4%) had sub acute appendicitis; the difference between both the group in terms of diagnosis was not statistically significant (p = 0.294).

Table 17: HPR

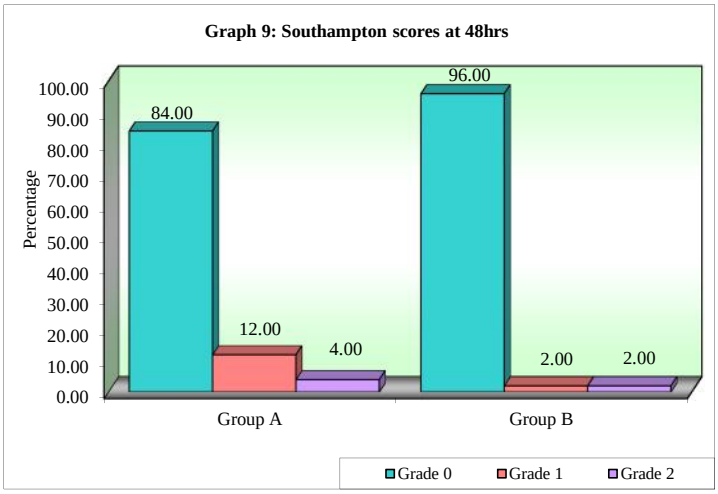
Status of HPR	Group A	%	Group B	%	Total
AA	41	82.00	44	88.00	85
CA	9	18.00	6	12.00	15
Total	50	100.00	50	100.00	100
P = 0.401					



The histopathology report was suggestive of acute appendicitis in total of 41 patients in Group A (82%) and 44 patients in Group B (88%); while it was suggestive of chronic appendicitis in 9 patients in Group A (18%) and 6 patients in Group B (12%), and the difference between both the group was not statistically significant (p = 0.401).

Table 18: Southampton scores at 48hrs

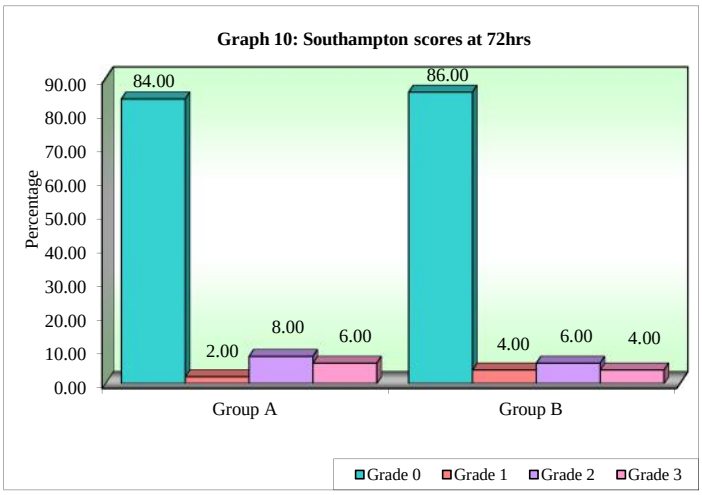
Status of wound at **48 hrs**	Group A	%	Group B	%	Total
Grade 0	42	84.0	48	96.0	90
Grade 1	6	12.0	1	2.0	7
Grade 2	2	4.0	1	2.0	3
P= 0.108					



At the end of 48 hours, on wound inspection 42 patients in Group A (84%) and 48 patients in group B (96%) had Grade 0 (Normal healing); while 6 patients in Group A (12%) and 1 patient in Group B (2%) had Grade 1 (Normal healing with mild bruising) and 2 patients in Group A (4%) and 1 patient in Group B (2%) had Grade 2 (erythema) and the difference between both the group was not statistically significant ($p = 0.108$).

Table 19: Southampton scores at 72hrs

Status of wound at **72 hrs**	Group A	%	Group B	%	Total
Grade 0	42	84.0	43	86.0	85
Grade 1	1	2.0	2	4.0	3
Grade 2	4	8.0	3	6.0	7
Grade 3	3	6.0	2	4.0	5
P= 1.000					

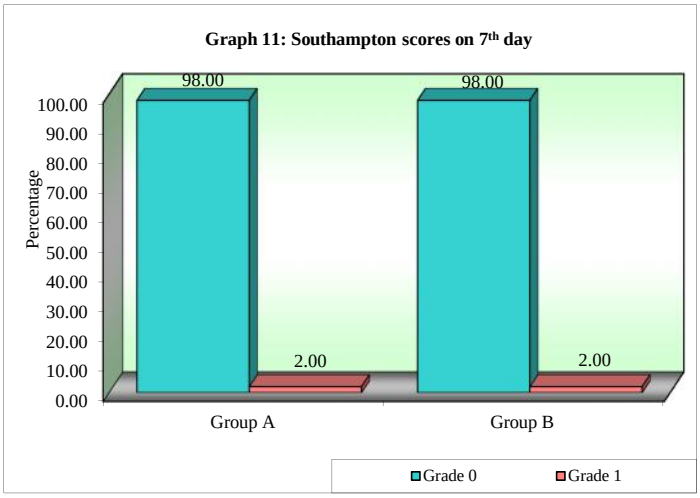


At the end of 72 hours, on wound inspection 42 patients in Group A (84%) and 43 patients in group B (86%) had Grade 0 (Normal healing); while 1 patient in Group A (2%) and 2 patient in Group B (4%) had Grade 1 (Normal healing with mild bruising) and 4 patients in Group A (8%) and 3 patient in Group B (6%) had Grade 2 (erythema); and 3 patients in Group A (6%) and 2 patients in Group B (4%) had

Grade 3 (Clear or haemoserous discharge) and the difference between both the group was not statistically significant (p = 1.000).

Table 20: Southampton scores on 7th day

Status of wound on **7th day**	Group A	%	Group B	%	Total
Grade 0	49	98.0	49	98.0	98
Grade 1	1	2.0	1	2.0	2
P= 1.000					



On 7th day total of 49 patients in group A (98%) and 49 patients in Group B (98%) had Grade 0 (Normal healing); while 1 patient in Group A (2%) and 1 patient in Group B (2%) had Grade 1 (Normal healing with mild bruising). and the difference between both the group was not statistically significant (p = 1.000).

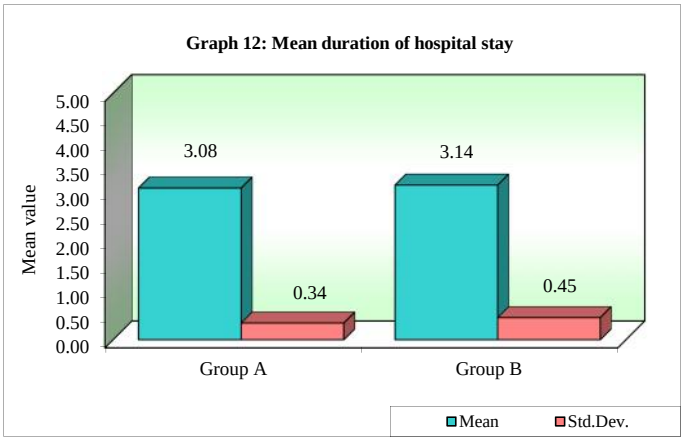
Table 21: Summary of Southampton scoring

Duration	Group	N	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4 & 5	P Value
48 hrs	A	50	42(84%)	6(12%)	2(4%)	0	0	0.108
	B	50	48(96%)	1(2%)	1(2%)	0	0	
72 hrs	A	50	42(84%)	1(2%)	4(8%)	3(6%)	0	1.000
	B	50	43(86%)	2(4%)	3(6%)	2(4%)	0	
7^{th} day	A	50	49(98%)	1(2%)	0	0	0	1.000
	B	50	49(98%)	1(2%)	0	0	0	

None of the patients in present study had Grade 4 or Grade 5 SSIs. The wound healing was taken as normal for grades 0, 1 and 2. The patients with grade 3 were considered as having wound infection[4]. Total of 3 patients in group A (6%) and 2 patients in group B (4%) had grade 3 SSIs (at 72 hrs) and they were managed conservatively with daily cleaning and dressing.

Table 22: Mean duration of hospital stay

Groups	Mean	Std.Dev.	p-value
Group A	3.08	0.34	0.455
Group B	3.14	0.45	



The mean duration of hospital stay for Group A was 3.08 ± 0.34 days; while for group B it was 3.14 ± 0.45 days, with 'p' value of 0.455, which suggests that there was no statistically significant difference in mean duration of hospital stay between both the groups.

Table 23: Comparison with other similar studies

Sl No.	Study	Sample size	Infection rate in study group	Infection rate in control group	P value
1	Abdullah et al[4]	100	11%	9%	0.986
2	Tiono et al[88]	110	7.3%	5.5%	1.000
3	Mohammad et al[76]	291	8.2%	6.25%	0.673
4	Kumar et al[89]	57	6%	5%	0.616
5	Chandra et al[90]	102	7%	6%	0.824
6	Present study	100	6%	4%	1.000

As evident from the above table the result obtained in present study are comparable to other studies.

Chapter 6

Discussion

DISCUSSION

Surgical site infections (SSIs) account for approximately 15% of nosocomial infections and are associated with increased cost and prolonged hospital stay. Infection usually develops when endogenous flora are translocated to a normally sterile site. Factors influencing development of SSI's include bacterial inoculum and virulence, host defenses, perioperative care, and intraoperative management[77]. The incidence of postoperative SSIs after appendicectomy for patients with non perforated appendicitis has been reported to range from 0% to 11%. The use of appropriate prophylactic antibiotics and the stage of the disease process at the time of operation significantly affects the risk for postoperative SSIs in addition to patient's factors[78, 79].

The goal of prophylactic antibiotics is to reduce the incidence of postoperative wound infection. It is important to recognize the difference between *prophylactic* and *empirical* therapy. *Prophylaxis* is indicated for procedures associated with high infection rates, those involving implantation of prosthetic material, and those in which the consequences of infection are serious. The antibiotic should cover the most likely contaminating organisms and be present in the tissues when the initial incision is made. Therapeutic concentrations should be maintained throughout the procedure. *Empiric* therapy is the continued use of antibiotics after the operative procedure based upon the intra-operative findings[77].

Inappropriate prophylaxis is characterized by unnecessary use of broad-spectrum agents and continuation of antibiotics beyond the recommended time period. These practices can increase the risk of adverse effects and promote the emergence of resistant organisms.

A systematic review by Daskalakis K et al in 2013 concluded that all patients with acute appendicitis should receive preoperative broad-spectrum antibiotics. For patients with non perforated appendicitis, pre operative treatment is enough and the use of post operative antibiotic treatment is not recommended. Whereas in case of perforated appendicitis, post operative broad spectrum antibiotics are recommended[80].

A Cochrane systematic review by Andersen BR et al have shown that the use of antibiotics in patients having uncomplicated appendicitis is superior to placebo in reducing postoperative complications but concluded that no specific recommendations can be made regarding the duration of antibiotic use. However for patients with complicated appendicitis, comprehensive antibiotic regime is to be continued, as they have quite high risk of infective complications[81].

The present study was undertaken to determine the need for post operative antibiotics after laparoscopic appendicectomy in patients with non perforated appendicitis for prevention of surgical site infection.

This study was conducted in Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum over a period from January 2015 to December 2015 on 100 patients undergoing laparoscopic appendicectomy for non perforated appendicitis. Based on envelope method, patients were divided into two groups namely group A (received a single dose of pre operative antibiotics at the time of induction of anesthesia) and group B (received pre operative antibiotics as well as three more doses of same antibiotics post operatively).

In the present study, there was an overall female preponderance in patients who presented with appendicitis. However, males (56%) outnumbered females (44%) in Group A, and females (64%) outnumbered males (36%) in Group B.

A total of 100 patients (50 in each group) participated in this study. The age of participants ranged from 18 to 50 years. The majority of patients in both the groups were of age between 21 to 30 years. The mean age in Group A was 30.74 ± 10.69 years compared to 30.72 ± 9.56 years in group B. However the difference between the age of both the groups was statistically not significant (p=0.757).

These findings were consistent with literature showing that the appendicitis is seen more frequently in patients in their second through fourth decades of life with mean age of 31.3 years[82].

All the patients with diabetes mellitus, cardiac, renal or liver failure and patients with immunodeficiency were excluded from the study. To reduce the confounding bias the patients who had history of consumption of antibiotics before participating in the study were also excluded. Patients diagnosed with complicated appendicitis (gangrenous or perforated) were also excluded from the study.

All the patients presented with multiple symptoms. A history of pain in abdomen in right iliac fossa was present in all the patients (100%) of both groups. Complain of fever was present in 13 patients (26%) in group A and 16 patients (32%) in group B, however the difference between both the groups was not statistically significant (p=0.509). Total of 31 patients (62%) in group A and 34 patients (68%) in group B had nausea and vomiting with P value of 0.529 suggesting it to be statistically not significant.

On examination all patients in both the group had tenderness in right iliac fossa (Mc burney's tenderness) on abdominal examination, as provided in literature it is one of the important signs that suggests appendicitis[31]. None of the patients in any of the group had either local guarding or rigidity on abdominal examination, as only

patients with uncomplicated appendicitis were selected for the study. The normal bowel sounds were present in all the patients in both the groups.

In a present study 48% patients in group A and 44% patients in group B had normal leukocyte count whereas leukocytosis was seen in 52% patients in group A and 56% patients in group B, and the difference between both the groups was statistically insignificant (p=0.688). Mild leukocytosis, ranging from 10,000 to 18,000 cells/mm^3 is usually seen in patients with acute uncomplicated appendicitis, however the white blood cell counts are variable[83].

In the present study abdominal USG was done in all the patients and majority of the patients (84% in group A and 76% in group B) had probe tenderness over right iliac fossa which was highly suggestive of appendicitis, while 16% patients in group A and 24% patients in group B showed inflammed appendix, however the difference between both the group was not statistically significant (p=0.317).

In this study, the majority of the patients (80% in group A and 84% in group B) had acute appendicitis, followed by chronic appendicitis in 12% patients in group A and 4% patients in group B. 6% patients in group A and 8% of patients in group B had recurrent appendicitis, while 2% patients in group A and 4% patients in group B had sub acute appendicitis. There was no statistical significance between both the groups (p=0.294).

The histopathological examination of removed appendix revealed features of acute appendicitis in 82% patients in group A and 88% patients in group B, while 18% patients in group A and 12% patients in group B had features of chronic appendicitis, and the difference between both the groups was statistically insignificant (p=0.401).

In the present study, on wound inspection by Southampton scoring system at the end of 48 hours, 12% patients in group A and 2% patients in group B had grade 1 SSIs (normal healing with mild bruishing), while 4% patients in group A and 2% patients in group B had grade 2 SSIs (erythema), and the rate of SSIs between two group was not statistically significant (Fishers exact p=0.108).

On wound inspection at the end of 72 hours, 2% patients in group A and 4% patents in group B had grade 1 SSIs (normal healing with mild bruishing), 8% patients in group A and 6% patients in group B had grade 2 SSIs (erythema), while 6% patients in group A and 4% patients in group B had grade 3 SSIs (serous discharge), and the rate of SSIs between two group was statistically insignificant (Fishers exact p=1.00).

On wound inspection at 7^{th} day only 2% patients in both the groups had grade 1 SSIs (normal healing with mild bruising) with Fishers exact p value of 1.00 which was statistically insignificant.

None of the patients in any of the groups had grade 4 or grade 5 SSIs. The wound healing was taken as normal for grades 0, 1 and 2. The patients with grade 3 were considered as having wound infection[4]. Total of 3 patients in group A (6%) and 2 patients in group B (4%) had grade 3 SSIs (serous discharge) and they were managed conservatively with daily cleaning and dressing, none of the patient in either group required antibiotics for management of SSIs.

These findings suggest that the rate of SSIs in both the groups is comparable and there is no statistically significant difference in rate of SSIs in both the groups. These findings accord with the findings of similar studies in the literature[84-87]

In the present study, the mean duration of hospital stay in group A was 3.08 ± 0.34 days, while in group B it was 3.14 ± 0.45 days. The difference in duration of the mean hospital stay between both the groups was not statistically significant (p=0.455).

A randomized control trial by Mui et al concluded that the single dose of perioperative antibiotic is adequate for prevention of infective wound complications in patients undergoing surgery for uncomplicated appendicitis. They also concluded that the prolonged antibiotic administration was cost-ineffective and leads to unnecessary complications[87].

Mohammad Taghi et al conducted a randomized control trial in Iran including 291 patients and divided them into three groups, group A received no postoperative antibiotics, group B received three more doses of antibiotics postoperatively and group C received 3 day course of antibiotics postoperatively, and showed SSIs rate of 8.2% in group A, 6.25% in group B and 5.2% in group C which was not statistically significant and concluded that single dose of prophylactic antibiotic is enough to prevent infective complications following appendicectomy for non perforated appendicitis[76].

A randomized control trial conducted by Sheik Abdullah et al compared single versus three doses of cefazolin as prophylaxis for non perforated appendicitis in one hundred patients and showed postoperative wound infection rate of 11% in those who received single dose compared to 9% in those who received three doses, which was statistically insignificant[4].

Tiono B.G. et al conducted a randomized study in Indonesia comparing risk of SSIs between single dose and multiple doses of prophylactic antibiotic group in 110

patients and showed rate of SSIs being 7.3% in single dose group compared to 5.5% in multiple dose group, which was not statistically significant[88].

A study conducted by Kumar A et al. including 57 patients showed incidence of SSIs being 6% in those who received single preoperative dose compared to 5% in those who also received post operative antibiotics, which was statistically insignificant and concluded that single dose of pre operative antibiotics was sufficient in controlling the SSIs after appendicectomy for non perforated appendicitis and post operative antibiotics do not provide significant additional clinical benefit[89].

A randomized control trial conducted by Chandra S et al and Venkateshwar P et al also showed the similar findings and concluded that the use of post operative antibiotics dose not reduce the rate of surgical infection in non perforated appendicitis[90, 91].

All the above studies support the results of the present study indicating that the prophylactic post operative doses of antibiotics has no additional benefit over a single pre operative dose of antibiotic and it has no any significant effect on risk of developing SSIs following appendicectomy. However the other parameters like maintenance of asepsis, good surgical technique and a good post operative care also plays an important role in reducing the risk of post operative SSIs and thereby reducing the morbidity.

Overall results of this study suggest that, the use of single pre operative dose of prophylactic antibiotics cefotaxime and metronidazole at the time of induction is sufficient to reduce the risk of post operative SSIs and additional post operative doses has no statistically significant benefits. However these findings are limited to a single procedure that is laparoscopic appendicectomy. Further studies on a larger scale with

various other abdominal surgeries are required to determine the actual need for post operative prophylactic antibiotics to reduce the SSIs.

Chapter 7

Conclusion

CONCLUSION

The surgical site infections (SSIs) following appendicectomy is one of the major cause of postoperative morbidity and the role of prophylactic antibiotics in preventing the postoperative SSIs is well established. Despite of recommendation for use of single preoperative prophylactic antibiotic, multiple doses are still at use.

The present study was conducted in department of General surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre on 100 patients undergoing laparoscopic appendicectomy for non perforated appendicitis with aim of determining the need for post operative antibiotics after laparoscopic appendicectomy.

The result of the present study showed that the incidence of SSIs in individuals who received single preoperative dose of prophylactic antibiotics and those who received additional postoperative doses was not statistically significant (p=1.000).

Thus we concluded that the prophylactic postoperative dose of cefotaxime and metronidazole confer no additional benefit over single preoperative dose for prevention of postoperative SSIs after laparoscopic appendicectomies. However further studies are required on a larger scale with bigger sample size.

Chapter 8

Summary

SUMMARY

Acute appendicitis is one of the most common causes of acute surgical emergency, with peak incidence between 10 and 30 years of age. The incidence of postoperative surgical site infection for patients undergoing appendicectomy for non perforated appendicitis ranges from 0% to 11%. The use of preoperative prophylactic antibiotics helps in reducing the incidence of postoperative surgical site infection. The present study was undertaken to determine the need for post operative antibiotics in reducing surgical site infection after laparoscopic appendicectomy for non perforated appendicitis.

This one year randomized control trial was conducted in the department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgavi over a period from January 2015 to December 2015 on 100 patients undergoing laparoscopic appendicectomy for non perforated appendicitis. Based on the envelope method, patients were divided into two groups namely group A (received a single dose of pre operative antibiotics at the time of induction of anesthesia) and group B (received pre operative antibiotics as well as three more doses of same antibiotics post operatively). A thorough clinical examination was conducted and the findings were recorded. Routine investigations such as complete blood count and special investigation such as abdominal ultrasonography was done for all the patients. Wound infection was identified and graded according to Southampton wound scoring system.

In the present study, there was an overall female preponderance in patients who presented with appendicitis. However, males (56%) outnumbered females (44%) in Group A, and females (64%) outnumbered males (36%) in

Group B. The mean age in Group A was 30.74 ± 10.69 years compared to 30.72 ± 9.56 years in group B

In the present study on wound inspection at the end of 48 hours, 12% patients in group A and 2% patients in group B had grade 1 SSIs (Normal healing with mild bruising), while 4% patients in group A and 2% patients in group B had grade 2 SSIs (erythema), (p=1.08). At the end of 72 hours, 2% patients in group A and 4% patents in group B had grade 1 SSIs (Normal healing with mild bruising), 8% patients in group A and 6% patients in group B had grade 2 SSIs (erythema), while 6% patients in group A and 4% patients in group B had grade 3 SSIs (serous discharge) (p=1.00). On wound inspection on 7^{th} day only 2% patients in both the groups had grade 1 SSIs (Normal healing with mild bruising).

The wound healing was taken as normal for grade 0, 1 and 2. Patients with grade 3 were considered as having wound infection, total of 3 patients in group A (6%) and 2 patients in group B (4%) had grade 3 SSIs (serous discharge), however the rate of SSIs between two groups was not statistically significant (p=1.00). The mean duration of hospital stay in group A (3.08 ± 0.34 days) and group B (3.14 ± 0.45 days) was also statistically insignificant (p=0.455).

The result of the present study show that the use of single pre operative dose of prophylactic antibiotics cefotaxime and metronidazole at the time of induction is sufficient to reduce the risk of post operative SSIs and additional post operative doses has no statistically significant benefits.

REFERENCES

1. Addiss DG, Shaffer N, Fowler BS et al. The epidemiology of appendicitis and appendectomy in the united states. Am J Epidemiol 1990; 132: 910-25
2. Bennion RS, Thompson JE, Baron EJ et al. Gangrenous and perforated appendicitis with peritonitis: treatment and bacteriology. Clinical Ther 1990; 12 Suppl C: 31-44
3. Browder W, Smith JW et al. Nonperforative appendicitis: a continuing surgical dilemma. J Infect Dis 1989; 159: 1088-94.
4. Abdullah S, Vaithianathan R et al. Randomized clinical trial of single versus three doses of cefazolin as prophylaxis for nonperforated acute appendicitis. Int J Cur Res Rev, Dec 2012; Vol 04 (23):124-30.
5. Daniel AA, Dellinger EP. Surgical infections and choice of antibiotics. In: Townsend CM, Beauchamp RD, Evers BM, Mattox KL, (eds). Sabiston Textbook of surgery. 18th ed. Philadelphia: Elsevier; 2008: 229-306.
6. Koch A, Zippel R et al. Prospective multicenter study of antibiotic prophylaxis in operative treatment of appendicitis. Dig Surg 2000; 17:370-78.
7. Lau WY, Fan ST, Chu KW, Suen HC, Yiu TF, Wong KK. Randomized, prospective, and double-blind trial of new betalactams in the treatment of appendicitis. Antimicrob Agents Chemother 1985; 28:639-42.
8. Nguyen BL, Raynor S, Thompson JS. Selective versus routine antibiotic use in acute appendicitis. Am Surg 1992; 58: 280-83.
9. Tonz M, Schmid P, Kaiser G. Antibiotic prophylaxis for appendectomy in children: critical appraisal. World J Surg 2000; 24:995-98.

10. alDhohayan A, al Sebayl M et al. Comparative study of augmentin versus metronidazole/gentamicin in the prevention of infections after appendicectomy. EurSurg Res 1993; 25:60-64.
11. Antimicrobial prophylaxis in surgery. Med Lett Drugs Ther 1999; 41:75-80.
12. Danziger L, Hassan E. Antimicrobial prophylaxis of gastrointestinal surgical procedures and treatment of intra-abdominal infections. Drug IniellClin Pharm 1987; 21:406-16.
13. Fry DE. Antibiotics in surgery. An overview. AmjSurg 1988; 155(5A):11-5.
14. Rosemond GP et al. One of the neglected factors related to wound infection. Surg.1959; 45:354-55.
15. Bauer T, Vennits BO, Holm B, Pederson J, Lysen D, Galatius H et al. Danish multicenter study group III. Antibiotics prophylaxis in acute non – perforated appendicitis. Ann Surg 1989; 209: 307-11.
16. Busuttil RW, Davidson RK, Fine M, Tompkins RK. Effect of prophylactic antibiotics in acute nonperforated appendicitis: a prospective, randomized, double-blind clinical study. Ann Surg 1981; 194: 502-9.
17. Charlotte Haldane et al. The Alvarado scoring system is an accurate diagnostic tool in acute appendicitis. Bests Medline 2008; 1-3.
18. Wolff H. Medical history aspects of appendicitis treatment. ZentralblChir 1998; 123 (4): 2-5.
19. Reith HB. Appendicitis and Perityphylitis: HistorischeruberblickchirGastroenterol 1993; 9: 184-96.
20. Williams R et al. Presidential address: A history of appendicitis. Ann. surgery 1983;191:495-05.
21. Cope Z. A History of the acute abdomen. Oxford university press, London 1965.

22. Fitz RH. Perforating inflammation of the vermiform appendix, with special reference to its early diagnosis and treatment. Trans Ass AmerPhys 1886; 1: 107-44
23. Decker GA, Du Plessis DJ. Lee McGregor's synopsis of surgical anatomy. 12th edition, Bristol: Verghese publishing house; 1986.
24. Williams NS, Bulstrode CJK, O'connell PR. Bailey & Love's short practice of surgery 25th edition; London. Hodder Arnold publication; 2008.
25. Standring S. Gray's Anatomy: The anatomical basis of clinical practice. 40th edition; UK Elsevier Churchill Living stone: 2008.
26. Townsend CM, Beauchamp RD, Evers BM, Mattox KL. Sabiston Textbook of Surgery: The biological basis of modern surgical practice. 19th edition; New Delhi: Elsevier; 2012.
27. Prystowsky JB, Pugh CM, Nagle AP: Current problems in surgery. Appendicitis. CurrProblSurg 42:688-742, 2005.
28. Somen Das. A concise textbook of surgery. 9th edition; Kolkata 2016; 43: 1006
29. Dempsey DT, Klein AS, Pemberton JH, Peters JH. Shackelfod's surgery of the alimentary tract. 6th edition; Vol 2: 2150
30. Becker JM, Stucchi AF. Essentials of surgery. Elsevier publication 2006; 15: 145
31. Zinner MJ, Ashley SW. Maingot's abdominal operations. 11th edition; New York: McGraw Hill; 2007.
32. Lumley JS. Hamilton Bailey's demonstration of physical signs in clinical surgery. 18th edition. Oxford: Hodder Arnold publication; 1997.
33. Abu – Yousef MM, Bleacher JJ, Macer J et al. High resolution sonography of acute appendicitis. AJR 1987; 149: 53-8.

34. BorushokKF, Jeffrey RB at el. Sonographic diagnosis of perforation in patients with aute appendicitis. AJR Am J Roentgenol 1990; 154: 275-8.
35. SamiranNundy, Sanjay Nagral. The Appendix: ECAB clinical update – surgical gastroenterology and liver transplantation. Elsevier publication 2012: 75-90
36. Rao PM, Rhea JT, Novelline RA at el. Effect of computed tomography of the appendix on treatment of patients and use of hospital resources. N Engl J Med 1998; 338(3): 141-6.
37. D'Alia C, Lo Schiavo MG, Tonanto A, Gagliano E et al. Amyand's hernia: case report and review of the literature. Hernia 2003; 7: 89-91.
38. Mc Burney C. The incision made in the abdominal wall in case of Appendicitis, with a description of a new method of operating. Ann Surg 1894; 20: 38-43.
39. Nguyen NT, Zainabadi K, Mavandadi S, et al. Trends in utilization and outcomes of laparoscopic versus open appendectomy. Am J Surg 2004; 188: 813-20
40. Gottrup F, Meling A, Hollander DA. Worlwide wounds: An overview of surgical site infections: aetiology, incidence and risk factors.URL:http://www.worldwidewounds.com/2005/september/Gottrup/Surgical-site-infections-overview.html Access Date: 05.04.2010
41. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for prevention of surgical site infections, 1999. Infect Control HospEpidemiol. 1999; 20(4): 250-78; quiz 279-80.
42. Nuland SB: The doctor's Plague: Germs, Childbed fever and the strange story of IgnazSemmelweis. New York: WW Norton & Co; 2003, P1.
43. Altemeier WA. Sepsis in surgery. Presidential address. Arch Surg 1982; 117(2): 107-12.

44. Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. Infect Control HospEpidemiol 1992; 13(10): 606-8.
45. Leaper DJ, Van Goor H, Reilly J, Petrosillo N, Geiss HK, Torres AJ, et al. Surgical site infection – a European perspective of incidence and economical burden. Int Wound Journal 2004; 1(4): 247-73.
46. DiPiro JT, Martindale RG, Bakst A, Vacani PF, Watson P, Miller MT. Infections in surgical patients: effects on mortality, hospitalization and post discharge care. Am J Health Syst Pharm 1998; 55(8): 777-81.
47. Cruse P. Wound infection surveillance. Rev Infect Dis 1981; 4(3): 734-7.
48. Cruse PJ, Foord R. The epidemiology of wound infection: a 10-year prospective study of 62,939 wounds. SurgClin North Am 1980; 60(1): 27-40.
49. Boyce JM, Potter-Bynoe G, Dziobek L. Hospital reimbursement patterns among patients with surgical wound infections following open heart surgery. Infect Control HospEpidemiol 1990; 11(2): 89-93.
50. Poulsen KB, Bremmelgaard A, Sorensen et al. Estimated costs of post operative wound infection. A case-control study of marginal hospital and social security costs. Epidemiol Infect 1994; 113(2): 283-95.
51. Vegas AA, Jodra VM, Garcia ML. Nosocomial infections in surgery wards: a controlled study of increased duration of hospital stay and direct cost of hospitalization. Eur J Epidemiol 1993; 9(5): 504-10.
52. Albers BA, Patka P, Haarman HJ, Kostense PJ. Cost effectiveness of preventive antibiotic administration for lowering risk of infection by 0.25%. [German]. Unfallchirurg 1994; 97(12): 625-8.

53. Suchitra JB, Lakshmidevi N. Surgical site infections: Assessing risk factors, outcomes and antimicrobial sensitivity patterns. African Journal of Microbiology Research 2009; 3(4): 175-9.
54. Song F, GlennyAM. Antimicrobial prophylaxis in colorectal surgery: a systemic review of randomized controlled trials. Br J Surg 1998; 85: 1232-41.
55. Lilani SP, Jangale N, Chowdhary A, Daver GB. Surgical Site Infection In Clean and Clean – Contaminated Cases. Indian J Med Microbiol 2005; 23:249-52.
56. Rao AS, Harsha M. Postoperative wound infection. J Indian Med Assoc 1975; 64: 90-3.
57. Tripathy BS, Roy N. Post – operative wound sepsis. Indian J Surg 1984; 47: 285-8.
58. Anvikar AR, Deshmukh AB, Karyakarte RP. A one year prospective study of 3280 surgical wounds. Indian J Med Microbiol 1997; 17: 129-32.
59. Bailey IS, Karran SE, Toyn K, Brough P, Ranaboldo C, Karran SJ. Community surveillance of complications after hernia surgery. BMJ 1992; 304(6825): 469-71.
60. Nichols RL. Use of prophylactic antibiotics in surgical practice. Am J Med 1981; 70: 686-92.
61. Dellinger EP, Lennard ES. The use of antibiotics for the prevention of postoperative infection. Surgical Rounds 1981; 48-54.
62. Burke JF. The effective period of preventive antibiotic action in experimental incisions and dermal lesions. Surgery 1961; 50: 161-8.
63. Chodak GW, Plaut ME. Use of systemic antibiotics for prophylaxis in surgery: a critical review. Arch Surg 1977; 112: 326-34.

64. Stone HH, Hooper CA, Kolb LD. Antibiotic prophylaxis in gastric, biliary and colonic surgery. Ann Surg 1976; 184: 443-52

65. Classen DC, Evans RS, Pestonik SL, Horn SD, Menlove RL, Burke JP. The timing of prophylactic administration of antibiotics and the risk of surgical wound infection. N Eng J Med 1992; 30: 281-6

66. Page CP, Bohnen JM, Fletcher JR, McManus AT, Solomkin JS, Wittmann DH. Antimicrobial prophylaxis for surgical wounds. Guidelines for clinical care. Arch Surg 1993; 128: 79-88

67. McDonald M, Grabsch E, Marshall C, Forbes A. Single versus multiple dose antimicrobial prophylaxis for major surgery: a systematic review. Aust N Z J Surg 1998; 68: 388-96.

68. Bratzler DW, Houck PM. Antimicrobial prophylaxis for surgery: an advisory statement from the national surgical infection prevention project. Am J Surg 2005;189:395-404

69. Burke A Cunha. Antibiotic essentials 14th edition: Jaypeebrothers medical publishers 2015: 354-7.

70. Namias H, Harvill S, Ball S et al. Cost and morbidity associated with antibiotic prophylaxis in ICU. J Am CollSurg 1999;188:225-30

71. Fukatsu K, Saito H, Matsuda T et al. Influences of type and duration of antimicrobial prophylaxis on an outbreak of methicillin – resistant staphylococcus aureus and on the incidence of wound infection. Arch Surg 1997;132:1320-25

72. Manian FA, Meyer PL, Setzer J et al. Surgical site infections associated with methicillin – resistant staphylococcus aureus: Do post operative factors play a role? Clin Infect Dis 2003;36:863-68

73. Bratzler DW, Houck PM, Richards C et al. Use of antimicrobial prophylaxis for major surgery: Baseline results from the national surgical infection prevention project. Arch Surg 2005;140:174-82
74. Sharma HL, Sharma KK. Principles of pharmacology 2nd edition; Paras publication;2012
75. Tripathi KD. Essentials of Medical Pharmacology 6th edition; Jaypee brothers medical publishers;2008
76. Mohammad Taghi RM, Seyed HM et al. Optimum duration of perioperative antibiotic therapy in patients with acute non-perforated appendicitis: a prospective randomized trial. Asian Biomedicine 2012;6(6):891-94
77. Antibiotic prophylaxis in surgery: Department of surgical education, Orlando regional medical center guidelines; October 2006: 1-4.
78. Ravari H, Jangjoo A, Motamedifar J, Moazzami K. Oral metronidazole as antibiotic prophylaxis for patients with nonperforated appendicitis. ClinExperimenlGastroenterol 2011; 4:273-6.
79. Coakley BA, Sussman ES, Wolfson TS, Bhagavath AS, Choi JJ, Ranasinghe NE, et al. Postoperative antibiotics correlate with worse outcomes after appendectomy for non perforated appendicitis. J Am CollSurg 2011; 213:778-83.
80. Daskalakis K, Juhlin C, Pahlman L. The use of pre or post operative antibiotics in surgery for appendicitis: A systemic review. Scandinavian journal of surgery 2013; 0: 1-7.

81. Andersen BR, Kallehave FL, Andersen HK. Antibiotics versus placebo for prevention of postoperative infection after appendicectomy. Cochrane Database Syst Rev 2005; 3: CD001439.

82. Flum DR, Morris A, Koepsell T, Dellinger EP. Has misdiagnosis of appendicitis decreased over time? A population based analysis. JAMA 2001; 286:1748

83. Bower RJ, Bell MJ, Ternberg JL. Diagnostic value of the white blood count and neutophil percentage in the evaluation of abdominal pain in children. SurgGynecolObstet 1981; 152: 424.

84. Liberman MA, Greason KL, Frame S, Ragland JJ. Single dose of cefotetan or cefoxitin versus multiple dose cefoxitin as prophylaxis in patients undergoing appendectomy for acute non perforated appendicitis. J Am CollSurg 1995; 180: 77-80

85. Le D, Rusin W, Hill B, Langell J. Postoperative antibiotic use in non perforated appendicitis. Am J Surg 2009; 198: 748-52

86. Tsang TM, Tam PK, Saing H. Antibiotic prophylaxis in acute non perforated appendicitis in children: single dose of metronidazole and gentamicin. J R CollSurgEdinb 1992; 37: 110-2

87. L.M. Mui, E.K.W. Ng, D.W.H. Lee, Y.H. Lam et al. A Prospective randomized trial to compare one dose preoperative, three doses perioperative and 5 day full course antibiotics for nonperforated acute appendicitis. Ann College Surg Hong Kong 2000; 5: 19-20

88. Tiono BG, Sudartana K, Widiana R. There is no difference of surgical site infection between single dose and multiple dose of prophylaxis antibiotic in open appendicectomy of non perforated acute appendicitis. Bali medical journal (BMJ) 2012; 1(3): 121-24

89. Kumar A, Noaman A. Efficacy of postoperative antibiotics after appendectomy in patients with non perforated appendicitis – A clinical study. Journal of Advanced medical and dental sciences research 2016; 4(2): 146-48.

90. Sarath Chandra A, Rajalingam K, Rao RM. Use of antibiotics in non – perforated appendicitis. MRIMS journal of health sciences 2015; 3(2):89-91

91. Venkateshwar P, Shalini T. Post operative use of antibiotics in non perforated appendicitis. IOSR Journal of Dental and Medical Sciences 2015; 14(10): 51-54.

Annexures

Annexure I - Consent Form

ANNEXURE I – CONSENT FORM

TITLE OF THE STUDY: **"A randomized control trial to determine the need for post operative antibiotics after Laparoscopic Appendicectomy in non perforated appendicitis.**

You are invited to participate in this research as you are a patients suffering from Acute Appendicitis. The study is being done to determine the role of post operative antibiotics after laparoscopic appendectomy in non perforated appendicitis as mentioned in the objectives. Dr. _____ is the principal investigator and the study will be conducted under the direct supervision of Dr. _____ .

PROCEDURE:

If you consent to be in this study, the relevant data is collected as per the pro forma provided to you. And then you will be allocated randomly into two different groups. Patient in group A will receive only single doses of Inj. Cefotaxime 1gm Iv + Inj. Metronidazole 100ml Iv at the time of induction while patient in group B will receive 3 doses of similar antibiotics post operatively also.

BENEFITS

To the community at large.

1. The data obtained from the study will help to provide information on the role of post operative antibiotics in case of non perforated appendicitis..
2. **RISKS**

   There are no risks associated with this study.

ALTERNATIVES

If you decline to participate in the study, your decision will not change the present or future health care or other services that you will receive. The treatment given out to you will be the standard treatment for your condition.

WITHDRAWING / REMOVAL FROM THE STUDY:

You can withdraw from the study during anytime you want and you will not be penalized for the same. You can be removed from the study if you do not fulfill the inclusion criteria.

PRIVACY AND CONFIDENTIALITY:

All information about the subject during the course of the study will be kept confidential to the extent permitted by law. The code numbers will identify the subject in this research record. Information from this study may be published but the subject's identity will be confidential in any publication.

COSTS

The patient will not have to pay any extra amount for the proposed intervention

QUESTION:

In case you have any questions related to the study, in future or in case of study related injury or illness, you can contact Dr. Rampurwala Jakiyuddin Zoeb, Department of General Surgery, KLE'S DR. PRABHAKAR KORE HOSPITAL & MRC, BELAGAVI. Phone number: _____or Dr. _____ . Professor in the Department of General Surgery, KLE'S DR. PRABHAKAR KORE HOSPITAL & MRC, BELAGAVI.

If you have any queries about your rights as a subject, you may call Dr. _____ , Professor, Department of Pathology and Chairman J. N. Medical College Institutional Ethical Committee for Human Subjects Research, Phone number: _____ or extension _____ at Jawaharlal Nehru Medical College, Belagavi**.**

STATEMENT OF CONSENT:

The details of the research study in which I am expected to participate, for which I have to undergo a randomized control trial have been explained to me.

I willingly, under no pressure from the researcher agree to take part in this study, and agree to participate in all investigations. I may withdraw at any time. I am not giving up any of my legal rights by signing this form.

My signature below indicates that I have read this entire consent form or it has been read to me, and had all my questions answered. I will be given a copy of this consent form.

Signature of the participant or legally authorized representative.

Participants Name :

Signature :

Name of the legally authorized representative :

Signature :

Witness's name :

Signature :

Investigators Name and signature :

Date and Place :

Annexures

Annexure II - Proforma

ANNEXURE II – PROFORMA

TITLE: ""A randomized control trial to determine the need for post operative antibiotics after Laparoscopic Appendicectomy in non perforated appendicitis."

I.P/ OPD NO:

Name: Age:

Sex: Occupation:

Address: Religion:

I. How Long have you been having complains of pain in the abdomen?

II. Are you currently taking any drugs for your present complains?

III. Do you have any of the following complaints?

1. Nausea.
2. Vomiting.
3. Fever.
4. Others specify.

_____

IV. Are you on any medications?

1. Yes
2. No

If yes then specify_____

V. Have you been diagnosed with any of the following conditions?

1. Chronic liver diseases
2. Chronic kidney diseases
3. Cardiac diseases
4. Diabetes mellitus
5. Hypertension
6. Malignant conditions

VI. Have you ever had any reactions to any of IV antibiotics?

1. Yes
2. No

_____.

Chief Complains:

History of Present illness:

Past History:

Family history:

General Physical Examination:

Built and Nourishment –

Vitals -

PR:

BP:

Temperature:

Pallor / Icterus / Cyanosis / Clubbing / Lymphadenopathy / Edema:

Systemic Examination:

Per Abdominal Findings:

Respiratory system:

Cardiovascular system:

Central nervous system:

Investigations:

Intervention:

Antibiotics Used	At Time Of Induction	8 Hrs After Surgery	16 Hrs After Surgery	24 Hrs After Surgery
Inj Cefotaxime 1gm IV				
Inj Metronidazole 100 ml iv				

ASSESSMENT OF WOUND:

SOUTHAMPTON GRADE	48 hrs After Surgery	72 Hrs After Surgery	On 7th Post-op day
0 : Normal Healing			
1 : Normal Healing With Mild Bruising			
2 : Erythema			
3 : Clear Discharge			
4 : Purulent Discharge			
5 : Deep Wound Infection			

Annexures

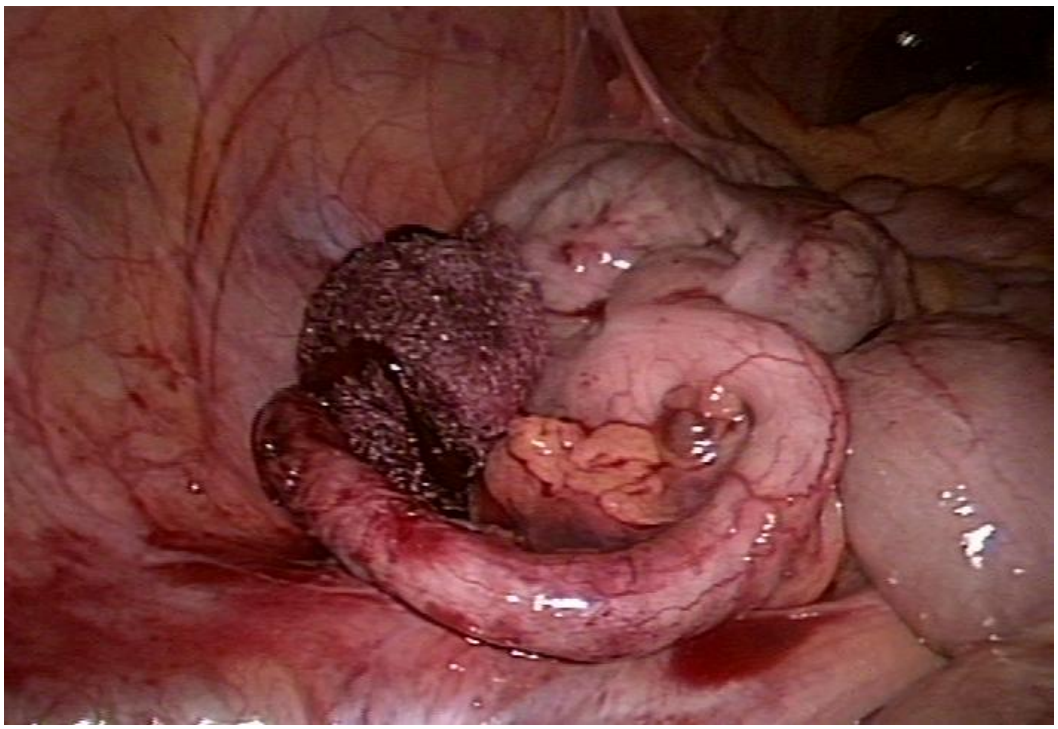
Annexure III – Photographs

ANNEXURE III – PHOTOGRAPHS

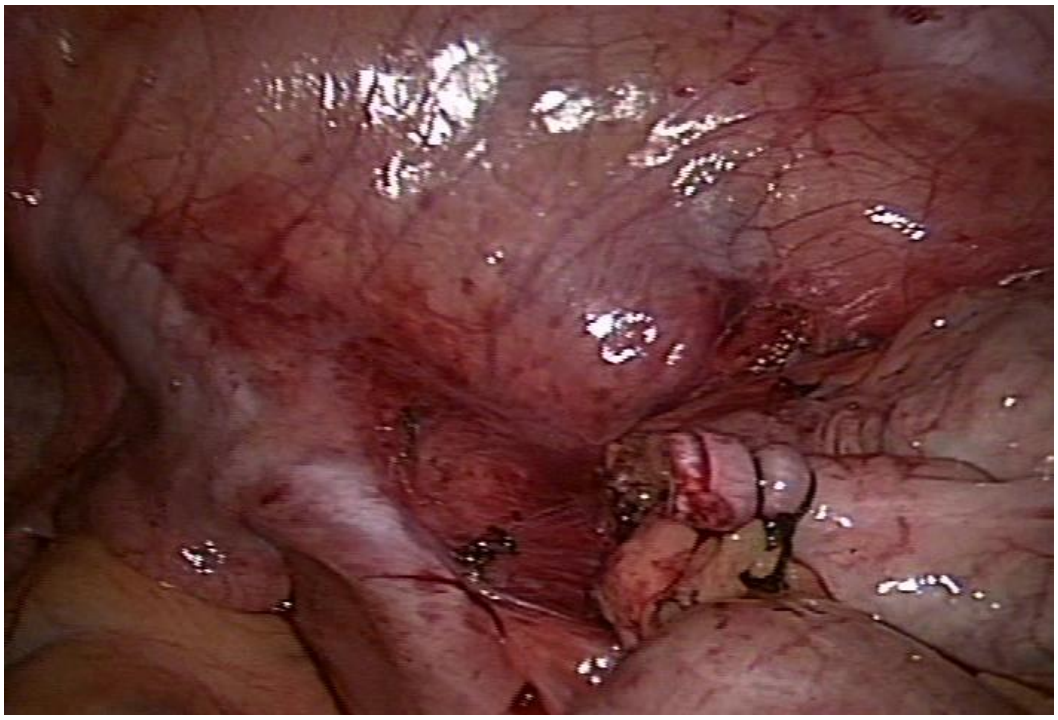
Photograph 1: Cefotaxime injection

Photograph 2: Metronidazole injection

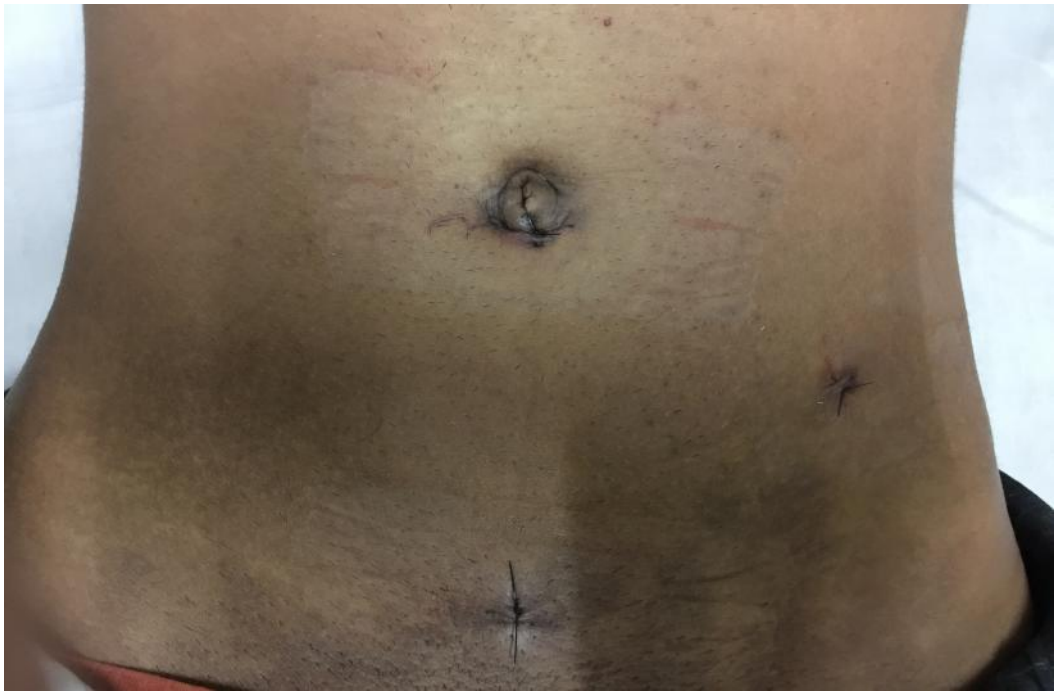
Photograph 3: Port placement



Photograph 4: Intra operative image of inflammed appendix



Photograph 5: Intra operative image of appendicular stump



Photograph 6: Patient having normal wound healing

Photograph 7: Patient with serous discharge at umbilical wound site

Photograph 8: Patient with normally healed umbilical wound

Annexures

Annexure IV – Master Chart

ANNEXURE IV – KEY TO MASTER CHART

F	-	Female
M	-	Male
+	-	Present
-	-	Absent
PT	-	Probe tenderness
INF	-	Inflammed appendix
AA	-	Acute Appendicitis
CA	-	Chronic Appendicitis
SA	-	Sub acute Appendicitis
RA	-	Recurrent Appendicitis
HPR	-	Histo pathological report

Southampton Score

Grade 0	-	Normal healing
Grade 1	-	Normal healing with mild erythema
Grade 2	-	Erythema
Grade 3	-	Clear discharge