A ONE YEAR RANDOMISED CONTROL TRIAL TO COMPARE APPENDICEAL STUMP CLOSURE TECHNIQUE WITH LIGA-CLIPS v/s HEM-O-LOK IN LAPAROSCOPIC APPENDECTOMY IN KLE'S DR PRABHAKAR KORE HOSPITAL, BELAGAVI.

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LIST OF ABBREVIATIONS.

No.	Abbreviation		Meaning
1.	AA	-	Acute appendicitis
2.	ASIS	-	Anterior Superior Iliac Spine
3.	CAS	-	Closure of the Appendiceal Stump
4.	CBC	-	Complete Blood Count
5.	Cm	-	centimetre
6.	$CO2$	-	Carbon Dioxide
7.	CT	-	Computed Tomography
8.	DKA	-	Diabetic Ketoacidosis
9.	ECG	-	Electrocardiogram
10.	GA	-	General Anaesthesia
11.	GE	-	Gastroenteritis
12.	HbsAg	-	Hepatitis B surface Antigen
13.	HIV	-	Human Immunodeficiency Virus
14.	H-o-L	-	Hem-o-Lok
15.	IgG	-	Immunoglobulin G
16.	IV	-	Intravenous
17.	LA	-	Laparoscopic Appendectomy
18.	MHz	-	Megahertz
19.	Mm	-	millimeter
20.	OA	-	Open Appendectomy
21.	PID	-	Pelvic Inflammatory Disease
22.	RIF	-	Right Iliac Fossa
23.	RLQ	-	Right Lower Quadrant
24.	SD	-	Standard Deviation
25.	SE	-	Standard of Error
26.	SSI	-	Surgical Site Infection
27.	TLC	-	Total Leucocyte Count
28.	USG	-	Ultrasonography
29.	UTI	-	Urinary Tract Infection
30.	WBC	-	White Blood Cells

ABSTRACT

INTRODUCTION: Although surgical technique for LA has been well established, concerns and controversy exists regarding CAS, which is a crucial step in the procedure. It is considered so because most grievous complications following LA occur due to leak of the stump. The risk of developing life-threatening complications like enterocutaneous fistulas, postoperative peritonitis, sepsis is dreaded and undesired. An ideal technique for appendiceal stump closure is considered the one that is safe, more feasible, simpler to use, and relatively economical. Recent studies have established the use of endoclips simpler and quicker as special laparoscopic skills are not required and hence seamlessly adapted.

METHODS: A total of 60 patients diagnosed with appendicitis without complications planned for LA were enrolled for the study. They were divided into two groups, A & B, of 30 each. Liga Clips were used for CAS in group A and Hem-o-Lok in group B and operative time, intra-op and post op events were recorded.

RESULTS: The mean operative time (time from skeletonisation of appendix to retrieval of the appendix) in group A was noted to be 376.03 seconds (~6.27 minutes) and that in group B was noted to be 345.50 seconds (~5.75 minutes)(p~0.2873). None of the patients enrolled in the study developed stump leak or intra- abdominal abscess and none of them had to undergo reoperation.

CONCLUSION: In conclusion, the use of both endoclips like Liga Clips and Hem-o-Lok for CAS in LA is quicker, safe, secure and feasible technique in cases of appendicitis (Acute or Chronic) without increased risk of complications. In our experience, it is suggested that Hem-o-Lok is more efficient in securing the

appendiceal stump due to it’s lock engagement system giving a sense of security and ease of application.

KEYWORDS: Laparoscopic appendectomy, Closure of appendicealstump, Liga clips, Hem-o-Lok.

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INTRODUCTION

In recent times laparoscopic surgery or minimal access surgery is frequently used in elective procedures as well as acute abdominal emergencies like AA. The most common cause of patients presenting with acute abdomen is AA with a lifetime incidence between 8 and 16% and invariably requires surgical treatment as main line of management(1). Incidence of appendicitis is as high as around 11 cases per 10,000 population per year. There have been remarkable changes regarding the approaches to any surgical condition in this new era of Laparoscopy.

A German gynaecologist, Kurt Semm was the first to describe LA in 1983 and the procedure has gained wide popularity over the period of time. It is now considered a safe and effective mode of treatment in surgical management of AA with or without complications(2). Decreased pain, faster recovery, fewer complications and better cosmetic outcome are the established advantages of laparoscopic surgery when compared to the open approach. It is a preferred approach in all patients but especially females, obese and elderly patients. However, disadvantages like a greater chances of developing intra-abdominal abscess, stump leak, longer operative time, and higher costs have been noted(3). Although the surgical technique for LA has been well established, concerns and controversy exists regarding the closure of the appendiceal stump (CAS), which is a crucial step in the procedure(4). It is considered so because most grievous complications of the procedure occur due to leak of the stump(5). The risk of developing life-threatening complications like enterocutaneous fistulas, postoperative peritonitis and sepsis is dreaded and undesired(6). This crucial step could be made easier by deciding on the suitable size of clip, endoloop or stapler length based on the average diameter of the diseased appendix(7).

An ideal technique for appendiceal stump closure is considered the one that is safe, more feasible, simpler to use, and relatively economical(8). Hence a variety of techniques have been tried and tested for closure of appendiceal stump during LA, including the use of intracorporeal knotting, Endoloops- Roeder's knot (Pre-knotted loops), mechanical endo staplers, bipolar endo- coagulation- Ligasure, ultrasonically activated scalpel- Harmonic scalpel, endoclips- LigaClips (titanium clips) and H-o-L (polymeric clips). However, the best method for the CAS is still debatable. All these alternatives have advantages and disadvantages during the different clinical stages of the AA(9).

Recent studies have established the use of endoclips simpler and quicker as special laparoscopic skills are not required and hence seamlessly adapted. Initially intracorporeal suturing was adopted which was soon replaced with extracorporeal pre tied loops like Roeder's knot and was soon widely accepted. Laparoscopic training, experience and dexterity is required for the application of Endoloops. Soon endo staplers were introduced and found to have a shorter operative time with decreased risk of postoperative complications, but highly expensive hence not a feasible option in all patients(10).

Hem-o-Lok is a non absorbable polymer clip with a lock engagement system that provides good security. It was introduced in 1999(11).

Metal endoclips were first used in CAS in 1999. One of such endoclips, Liga clips are made up of titanium and are widely used in numerous Laparoscopic procedures because of their safety and ease of application and shorter operative time(12). Both Liga clips and Hem-o-Lok were first used in ligation of cystic duct/ artery in Laparoscopic Cholecystectomy and soon found application in appendiceal

stump closure with shorter operative time and ease of application in comparison to Roeder's knot(5,13).

Now that it has been established that the use of endoclips is safer, simpler and quicker than that of endoloops we further intend to establish comparison among the endoclips and find the best solution among the available options. Hence the study aims to compare the results of application of Liga Clips and Hem-o-Lok for the CAS in LA in cases of Appendicitis without complications.

AIMS &OBJECTIVES

AIM: To compare the results of application of Liga Clips and Hem-o-Lok for the CAS in LA in cases of Appendicitis without complications.

OBJECTIVES:

1) Operative time

2) Intraoperative findings:

   a). Ease of passing the clip/ removing clipped specimen through 10 mm port

   b). Dropped clip

   c). Ease of clip application

3) Postoperative complications:

   a). Stump leak

   b). Intra- abdominal abscess

REVIEW OF LITERATURE

HISTORICAL REVIEW

It seems necessary to enlighten one's mind with historic moments of surgery and its evolution, which are fascinating. Credit must be given to those who have contributed for the benevolence of mankind. The pioneer works of the legendary clinicians and surgeons are an inspiration to the new generations.

The history related to appendix and appendicitis has evolved over the past two centuries

It is suspected that Appendicitis was recorded by Aryataeus of Cappadocia in 30 AD and is thought to have described accurately appendicular abscesses and cured the patient by incision and drainage of the abscess through the abdominal wall.

Appendix was described as an 'Orchid' in the anatomical drawings of Leonardo da Vinci in 1492, literally meant to denote the auricular appendage of the caecum

The first appendectomy was performed successfully by Claudius Amyanda Sergeant Surgeon to Queen Ann, King George I, and King George II in 1735 at St. Georges Hospital in London, when he found a perforated appendix in a scrotal hernia sac. In his honor, a hernia containing appendix till date is known as Amyand's hernia.

A pathologist-physician Reginald Fitz's public lecture in 1886 became a prominent event in the evolution of appendix. He introduced the term "appendicitis". He then published a study on appendicitis and named the procedure an appendectomy.

Charles McBurney described the McBurney's point as the area of maximal tenderness in appendicitis in 1889. It is described as one third of the distance from the ASIS to the umbilicus in the RLQ of the abdomen. He proposed his original muscle splitting operation to the New York surgical society in 1893(14). McBurney's incision for appendectomy was named after him in 1894. Charles McBurney was the one who diagnosed and suggested early operative intervention of appendicitis for the first time.

In 1905, Murphy clearly demonstrated Murphy's triad which comprised of pain abdomen in RLQ, vomiting associated with nausea and fever.

In the surgical management of acute and chronic appendicitis, LA is gradually being considered as a gold standard after it was first performed by a German gynaecologist Kurt Semm in 1981.

A.J. Oschner advocated for a non-operative treatment of peritonitis, as he stated that "After my first operation I was completely disgusted because after cutting my patient lengthwise and crosswise, I found, behind the ascending colon, an inoffensive looking, shriveled up remains of what had been an appendix. I felt that I had subjected my patient to a very grave operation without a corresponding benefit"(15). It is also emphasised in literature that A. J. Ochsner originally advocated the conservative management of appendicular peritonitis followed by subsequent removal of appendix and not J. B. Murphy.

LA became a 'fashionable' surgery after a surgeon from London, Treves, performed appendectomy on King Edward VII.

In the 20th century, with the advent of penicillin and other antibiotics, improvements in fluid resuscitation and safer anaesthesia, the mortality due to

appendicitis fell significantly. Diagnostic delay remained the main cause of death following appendicitis by 1990(16).

In 1991 Pier A. et al, demonstrated that LA is suitable in most cases of appendicitis with high success rate, lesser complications, longer operative time compared to traditional open surgery which was published in the first large series of LAs for AA(17).

In 1992 Attwood sehill and et al in his study concluded that LA is superior to open appendectomy and is recommended as a treatment preferred in case of AA(18).

In 1997 Gurbas at, Peetz me et al concluded in pregnant women that laparoscopic appendectomy does not increase in maternal and fetal morbidity or mortality as compared to open appendectomy.

EMBRYOLOGY

Appendix develops during the descent of colon, as a narrow diverticulum from the distal end of the caecal bud. It appears at about 6th week of intra uterine life as a small conical dilatation of caudal limb of the midgut. The caeum is inline with the appendix and has the same calibre at the early embryonic stage. It is then formed when the right wall of caecum grows asymmetrically and pushes the appendix medially. This causes the appendix to find its adult position on the posterior medial wall of the caecum, just below the ileocecalvalve(19).

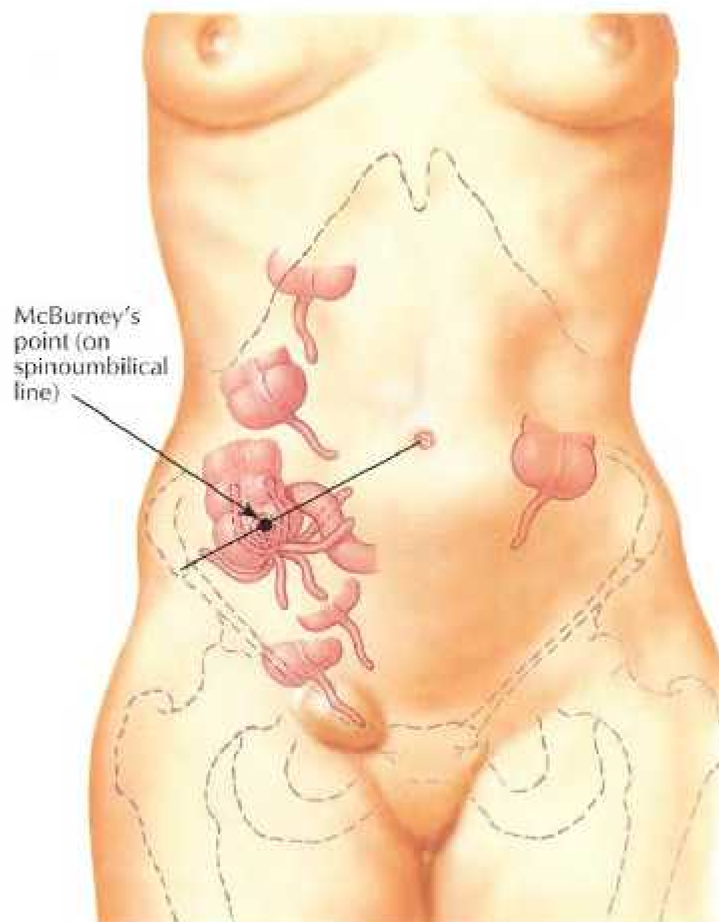

Figure1: Variation in position of appendix

ANATOMY

A narrow tubular structure arising from posteriomedial wall of caecum is the vermiform appendix. The different positions in which the appendix maybe identified are retrocaecal, retrocolic, pelvic, subcaecal, preileal, postilel and subhepatic. Intraoperatively the appendix is identified by tracing the three taeniae coli converging at the base of the appendix. The length of the appendix may vary from 2 cms to 20 cms and diameter 5-7 mm. It is usually suspended by the triangular fold of mesoappendix. The opening of the appendicular lumen into the caecum may be guarded by the Valve of Gerlach which is a semilunar mucosal fold.

VASCULAR SUPPLY AND LYMPHATIC DRAINAGE

The arterial supply to the appendix is by the appendicular artery which is a branch of ileocolic artery. It usually runs along free border of mesoappendixupto the tip. The venous drainage is through the Appendicular veins which in turn drain into the ileocolic vein. The appendicular wall is rich in lymphoid tissue and the lymphatics drain into the mesenteric lymph nodes.

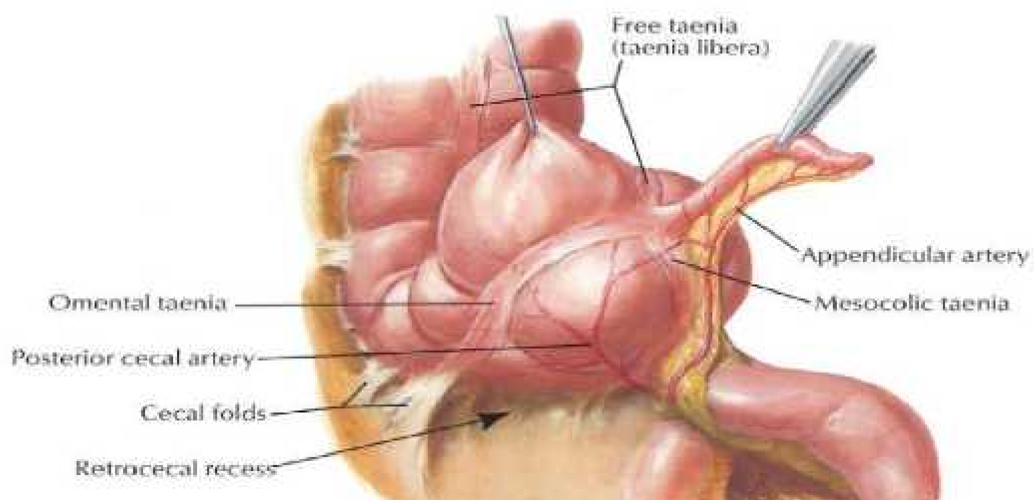

Figure 2: Anatomy of Vermiform Appendix

APPENDICITIS

Incidence:

Appendicitis is a common and an urgent surgical illness with protean manifestations, generous overlap with other clinical syndromes, and significant morbidity, which increases with diagnostic delay. Around 7% of the population undergo appendectomy for AA during their lifetime. The life time rate of appendicectomy is 12% for men and 25% for women. There is slight male predominance (1.2 to 1.3 :1).

AETIOLOGY

The etiological factors still remain unknown and obscure although appendix is a common disease. It is or has been, universally rare prior to the adoption of western standards of living. The riddle of appendicitis, its actual causes and its meteoric rise from an insignificant disease to the most common serious intra-abdominal inflammatory affection of western civilized areas-has been a matter of much speculation. It is rare in rural communities in economically less developed countries and its incidence is rising with economic development, migration to urban area and emigration to western countries. No individual with an appendix seems immune from the risk of developing appendicitis, but many contributory factors may be responsible.

1. Age and Sex: No age is immune from the risk of developing appendicitis, which has been reported in new born (Shinaberger) and also at the extremes of age. It is rare under the age of four year and after the age of 50 years. About 65% of the patients are under the age of 30 years and only 2% are 60 years and above. The incidence of appendicitis is maximum between 20 to 30 years.

2. Familial susceptibility: There are instances of appendicitis occurring in families, suggesting an inherited susceptibility. A report by Downs (1942) is consisting. He operated upon 16 cases out of 22 closely related individual for appendicitis. In each case appendix was sharply kinked at the base by a fibrous band binding it to the lateral aspect of the caecum

3. Seasonal factors: There is particularly in children, a possible association between seasonal respiratory tract infection and AA. The lymphoid tissue in the appendix and tonsils may be simultaneously affected.

4. Race and Diet: In general, appendicitis is associated with non- roughage diet and with the consumption of a high proportion of meat. It is common in highly industrialized countries, such as Great Britain, United States, France and Germany.

5. Faecoliths: Non-calcified inspissated faecal masses are a common finding in a large proportion of appendices removed for acute disease. Ulceration or perforation usually occurs at or near a faecoliths may turn diffuse inflammatory lesion into gangrene.

6. Parasites: Blackadder (1824) reported a case in which a man died suddenly after a very severe bout of pain in the abdomen and who was found at autopsy to have a round worm impacted at the appendiceal junction. Other parasites like thread worm injure mucus membrane or at times cause obstruction of the lumen of the appendix and cause acute inflammation of the appendix.

7. Bacterial factors: The lumen of the appendix harbors variable and mixed flora. Epithelial erosion may admit organisms to the sub mucosal layers and progressive inflammation will occur with pathogenic organisms, if there is no local or general resistance to the organism. Organisms in the blood stream may enter the wall of the

appendix and the lymphoid follicles and may be the primary site of acute inflammation. An established AA is certain to involve bacterial activity and usually the organ is attacked by mixed organisms commonly found in the bowel.

8. Bands and Adhesions: Various abnormal peritoneal attachments of congenital origin have been described and if these cause kinking of the appendix, it results into obstruction. Inflammatory or acquired adhesions due to repeated attacks of appendicitis may induce final acute obstructive picture.

9. Strangulation within a hernial Sac: Strangulation or trauma of the appendix, which lies in an interval or external hernial sac, may induce progressive changes similar to strangulated small bowel. Diffuse inflammation of an appendix in hernialsac may be aggravated by the obstructive effect at the neck of the sac.

10. AA secondary to metastatic carcinoma: Kenneth (1966)reviewed total 13 cases from the literature, of these 7 cases have presented as AA and in 5 of them, the cases showed appendiceal perforation at operation. In 5 cases breast was the site of primary Carcinoma. Metastatic carcinoma of the appendix due to the encroachment of the growth presents as acute obstructive appendicitis leading to perforation and other complications.

13. Epidemic Form: AA may occur as an epidemic and the portal of entry for the infection is the nasopharynx and the organisms are usually streptococci.

14. Vascular factors: The appendicular artery is basically an end artery. It is possible that extramural ischemia may play a role in this disorder. Any thing that compromises the blood supply could therefore contribute to ischemia, inflammation and hence secondary infection in the appendix.

Pathogenesis of Appendicitis :

Appendicitisiscaused due to obstructive or non obstructiveetiologies.

The events that follow obstruction of the appendix depend upon the interactions among four factors:

a. The contents in the lumen

b. Degree of obstruction

c. Continued secretion by the mucosa

d. Inelastic character of the appendiceal serosa

In obstructive causes like fecoliths if there's obstruction in the appendicular lumen proximally which causes collection of secretions in the the lumen and thereafter increasing the intraluminal pressures. This further causes edema of the appendicular wall which progresses to compromise the venous drainage further causing congestion and eventually compromise the arterial supply (mostly by thrombosis) of the appendix. Finally the appendix undergoes ischemic changes and turn gangrenous which makes it susceptible to perforation/ sloughing out. Simultaneously there could be inflammatory response and translocationof the enteric bacteria into the blood stream causing bacteremia, sepsis and septic shock.

The greater omentum tries to limit this process by sealing off the inflamed region failing which might cause peritonitis. If the omentum succeeds to limit the pathology, it leads to the formation of appendicular mass.

In cases of non obstructive causes, the inflammation usually starts at the mucosal level which eventually leads to inflammatory response of the lymphoid follicles of the

appendix. This process may eventually end into:

1. Resolution
2. Ulceration
3. Suppuration
4. Fibrosis
5. Gangrene.

Different types of appendicitis are as follows:

a. Acute catarrhal appendicitis

b. Acute focal appendicitis

c. Acute suppurative appendicitis

d. Gangrenous appendicitis

e. Perforative appendicitis.

CLINICAL FEATURES:

The most common complaint the patients present with is pain abdomen. It typically starts in the periumbilical region and eventually migrates to the RLQ. the location of pain and its presentation may vary depending on the position of the appendix. Pain may be radiating to the back.

The other symptoms patient presents with maybe fever, nausea, vomiting, loss of appetite, loose stools in uncomplicated cases. Atypical symptoms like dysuria, increased frequency of micturition.

In complicated cases the patient may present with an appendicular mass, septicaemia, septic shock, signs of peritonism, intestinal obstruction

In cases of developmental anomalies, appendicitis may present with vague symptoms and may cause diagnostic dilemmas. Diagnostic laparoscopy is the preferred option.

SIGNS:

1. Mc Burney's Sign:

Mc Burney's point was described in 1890 as point of maximum tenderness at the junction of lateral 1/3rd and medial 2/3rd of a line joining the right ASIS to umbilicus. This point corresponds to the base of appendix.

2. Rebound tenderness or Blumberg's sign:

A hand kept in the RIF is progressively pressed with each movement of expiration. It is then removed suddenly, the patient will wince or cry with pain, if the

sign is positive. This indicates inflammation of the parietal peritoneum. It is useful sign in the absence of guarding or rigidity.

3. Rovsing's sign:

This sign is positive as a result of pressure on the left side of the colon, forcing the gas into the caecum distending the caecum and surrounding of the inflamed focus resulting in pain (Hamilton Bailey)

4. Cope's Sign (obturatorinternus test):

Pain in the hypogastrium due to spasm of theiliacus and obturatorinternus muscle caused by the inflamed appendix. This is elicited by flexing and internally rotating the right thigh

5. Psoas sign:

The patient is made to lie on his left side and asked to extend the right thigh. Due to inflamed retrocaecal appendix, pain is experienced This is due to irritation of the psoas muscle in retrocaecal inflamed appendix.

6. Hyperaesthesia in Sherren's Triangle

Sherren in 1925, pointed out this Sherren's triangle is defined as the triangle bounded by lines joining umbilicus, right ASIS and pubic symphysis. If hyperesthesia is present it indicates the perforation of the appendix.

7. Baldwin's test for retrocaecal appendix:

After identifying the tender spot in the right flank, light pressure is maintained over the spot and the patient is asked to lift the right lower limb keeping the knee in

straight position. This produces increased pain in the loin and the patient drops the leg with pain. This is a positive sign of retrocaecal appendicitis.

8. Pointing test:

Patient is asked to point out the site of maximum pain on coughing. It if corresponds to point of maximum tenderness. It may also be certainly the site of inflammation.

9. Shifting Tenderness (Alder's):

The most tender spot is marked first, the patient is put in left lateral position and point of maximum tenderness is marked again. If the tender spot shifts probably it is not a case of appendicitis. This sign is useful to differentiate appendicitis from mesenteric lymphadenitis and painful uterine conditions in pregnancy.

Differential diagnosis :

Acute abdomen causes form the differential diagnosis for appendicitis.

Differential diagnosis of appendicitis

Surgical

- Perforated peptic ulcer
- Meckel's diverticulitis
- Mesenteric adenitis
- Intestinal obstruction
- Intussusception
- Acute cholecystitis
- Appendicular or colonic diverticulitis
- Rectus sheath haematoma
- Pancreatitis

Urological

- ureteric colic on the right side
- Right pyelonephritis
- UTI

Gynaecological

- Ectopic pregnancy
- Ruptured ovarian follicle
- Torted ovarian cyst
- Salpingitis or PID

Medical

- GE
- Pneumonia
- Terminal ileitis
- DKA
- Preherpetic pain on the right 10th and 11th dorsal nerves
- Porphyria

INVESTIGATIONS

Laboratory tests:

1. CBC: The majority of the patients undergoing evaluation for acute abdominal pain have a CBC as a component of the evaluation. The leukocyte count is elevated to more than 10,000 / mm3 around the range of 12,000 to 18,000 / mm. In addition an increase in the percentage of neutrophils (the "Left shift") with a normal

TLC supports the clinical diagnosis of appendicitis. Other laboratory indices of inflammation have been studied as adjuncts of appendicitis. C- reactive protein has been studied and correlated with the clinical and pathologic features in general; this is not a clinically useful laboratory study because this is non- specific.

2. Urine analysis: A urine analysis is often obtained in the evaluation of patients with abdominal pain to determine the presence of genitourinary tract inflammation. The urine analysis may show mild pyuria with appendicitis owing to the proximity of the ureter to the inflamed appendix.

Radiographic evaluation:

1. **Abdominal radiography**:

- Appendicolith (0.5-6cm)
- Sentinel loop sign
- Dilated caecum

2. Barium enema: In the past it was recommended for evaluation of possible appendicitis. Findings suggestive of appendicitis include spasm of the terminal ileum or caecum, external compression of the caecum, and non fillingorpartial filling of the appendix.

3. **Ultrasound**: the graded compression technique for examination with a 7MHz probe over the point of maximum tenderness in the RLQ is used.

Ultrasound findings:

Non compressible, non peristaltic, Blind ending tubular structure, at the point of maximum tenderness

Diameter of 6 mm or greater,

Appendicolith casting an acoustic shadow,

High echogenicity, non compressible surrounding fat,

Surrounding fluid or abscess,

Edema of caecal pole.

4. **Computerized Tomography**: findings suggestive of appendicitis are:

Diameter of the appendix measuring >6mm, no contrast enhancement in the lumen (oral contrast) or the wall of the appendix (iv contrast), appendicolith. Adjacent inflammation maybe noted as changes fluid collection, adjacent periappendiceal fat stranding, phlegmon formation, abscess formation, extraluminal air pockets and lymphadenopathy, caecal thickening. CT scan is a preferred imaging study over USG to visualise normal appendix. Sensitivity and specificity approach l00%.

6. **Nuclear Medicine**: Nuclear medicine studies can be used to evaluate patients with suspected appendicitis. Two types of imaging studies are used: radiolabelled white blood cells (Tc 99m WBC) and immunoglobulin G (Tc 99m IgG). The studies take 1 to 3 hours to perform. These techniques rely on the localization of the leukocyte or IgG at the site of appendiceal inflammation; with use of scintigraphy, the inflamed tissue is observed in the right lower quadrant.

7. **Diagnostic Laparoscopy**: this investigation has a useful role in equivocal cases of appendicitis.

8. **Others**;

- Chest X-ray Postero-anterior view
- ECG
- HIV
- HbsAg

"Alvarado Score"
It is the most widely used scoring system for the diagnosis of appendicitis

	Score
Symptoms:	
Migrating pain to the RIF	1
Anorexia	1
Nausea and vomiting	1
Signs:	
Tenderness at the RIF	2
Rebound tenderness	1
Elevated temperature	1
Laboratory:	
Leucocytosis	2
Shift to left	1
Total score:	**10**

Strongly predictive of AA: Score >7.

TREATMENT:

The gold standard in the treatment of appendicitis is surgery. "Appendectomy is the ultimate cure for appendicitis". There are various methods in which the diseased appendix can be removed and the pathology eliminated all together. The approach also depends on the clinical presentation of the patient, presence or absence of signs of complications in which case the approach is more emergent and exploratory.

With the emerging research there are evidences supporting conservative management in cases of uncomplicated appendicitis. 80-90% remission is documented but the chances of recurrence within an year are approximately 15%. Hence this approach is usually reserved in patients with high surgical risks (multiple comorbidities). And of course underlying malignancy needs to be ruled out in elderly patients presenting with appendicular mass.

Conservative management mostly involves IV antibiotics (3rd- generation Cephalosporins and metronidazole), rehydration and bowel rest. Patient needs to be followed up explained regarding the possible complications

SURGERY: Before taking up for surgery, the patient needs to be resuscitated and optimized adequately. A pre operative dose of antibiotics is known to be associated with fewer post operative complications like intra- abdominal abscess, SSI.

"OPEN APPENDECTOMY" (OA):

The oldest technique is that of Open Appendectomy (OA) which has evolved over time. It can be performed under spinal anaesthesia or epidural anaesthesia or general anaesthesia.

Here the appendix can be approached in the RLQ using various approaches:

1. Grid iron incision
2. Lanz incision
3. RockeyDewis horizontal incision
4. Rutherford morrison
5. Right paramedian incision
6. Lower midline laparotomy.

Once the incision is placed, dissection is continued through the subcutaneous tissue, Camper's and Scarpa's fasciae to reach the external oblique aponeurosis which is then incised. The underlying muscles are then split or incised to reach the peritoneum which is then opened to reach the abdominal cavity.

The appendix can then be traced from the ileocaecal junction or by the confluence of the three taenia coli at the base of the appendix.

The mesoappendix is then identified and the appendicular artery closely related to it. The dissection of the mesoappendix is started from the tip up to the base of the appendix. Appendicular artery identified and ligated. The ligation of the stump is again one of the most crucial parts of the surgery which is conventionally done by transfixing and ligating the stump using silk sutures and then severing the appendix at the stump. Purse string invaginating sutures were previously used to invert the appendiceal stump but was found to have no additional benefits.

The abdomen is then closed in layers and then skin sutured.

In complicated cases with perforation, abscess formation or localised/ general peritonitis exploratory laparotomy is usually taken up and thorough lavage is given with placement of drainage tube

LAPAROSCOPIC APPENDECTOMY (LA):

With the established benefits of laparoscopic approach over open surgery, LA is gradually being considered as a Gold standard in the management of appendicitis with or without complications. This approach again can be executed employing a variety of techniques at various stages like methods of port insertion, types, number of ports, energy sources for dissection, techniques to close the appendiceal stump, extraction of the specimen, techniques for port closure. These techniques further affect the ease of surgery for the surgeon and the postoperative outcome for the patient.

LA is usually done under GA. Patient is then placed supine with the left arm tucked in and the right extended. Ryle's tube maybe place to decompress the stomach and Foley's self retaining catheter to empty the bladder and prevent injury at the time port insertion. The first port is usually placed at the umbilicus using open (Hasson's) or closed (using Veres' needle) techniques. Pneumoperitoneum is then created with carbon dioxide insufflation with optimum flow rate and intra abdominal pressure. After introducing the telescope, a diagnostic scopy is done to grossly identify the abdominal structures and the rest of the ports are placed under vision as per surgeon's preferences.

The appendix is then looked for by identifying the three taeniae converging at its base and its lie and position are made a note of. The mesoappendix is then identified by lifting the appendix by its tip. Dissection is then carried out to identify the stump and appendicular artery. The CAS is a crucial step and various techniques are employed for the purpose to prevent untoward complications.

Initially intracorporeal suturing, knotting was taken up and soon pre tied extracorporeal knots were widely used. The above mentioned techniques need extensive laparoscopic training and dexterity. Soon endo staplers were introduced and were found to be safe and effective even in cases with gangrenous stump but were an expensive option. Soon endo clips were introduced which were initially used for ligating the cystic duct and artery in lap cholecystectomy. Soon the technique was adopted in LA and were deemed quick, easy, safe and effective technique for CAS without significant difference in the incidence of complications. Thereafter studies were conducted to compare conventional pre tied extracorporeal knots with endo clips showing significant decrease in the operative time and easier to use.

COMPLICATIONS:

1. Bleeding
2. Retained fecoliths
3. Incomplete appendectomy- stump appendicitis
4. Post operative abscess
5. Stump leak
6. Surgical site infection
7. Intra abdominal abscess

MATERIALS AND METHODOLOGY.

STUDY DESIGN: Randomized Controlled Trial

STUDY PERIOD: One year from January 2018 to December 2018

STUDY POPULATION: Patients diagnosed with Appendicitis (Acute or Chronic) without complications admitted in General Surgery Ward of KLE's Dr. Prabhakar Kore Hospital from January 2018 to December 2018 planned for Laparoscopic Appendectomy.

INCLUSION CRITERIA:

1. Diagnosed cases of Appendicitis (Acute or Chronic), willing for Laparoscopic Appendectomy.
2. Age between 18 to 60 years.
3. Clinically diagnosed as Appendicitis without complications.

EXCLUSION CRITERIA:

1. Patients with acute perforated appendicitis and local or diffuse peritonitis were excluded from the study.
2. Patients found to have gangrenous appendiceal stump intra operatively.
3. Patients who did not consent to participate in the study.
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SAMPLE SIZE:

A total of 60 patients were divided into two groups (A and B) of 30 patients each.

DIAGNOSIS: Appendicitis was diagnosed on the basis of patient history (RIF pain, vomiting, nausea, anorexia, fever), clinical signs (tenderness at McBurney's point, Rebound Tenderness), and laboratory tests (elevated leukocyte count).

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2) Group B in which Hem-o-lok was used for CAS

Both the groups were explained the details of the surgical procedure & enrolled to the study after a written informed consent was taken.

PROCEDURE:

The surgery was performed under general anesthesia. The patient placed in a supine position, combined with the Trendelenburg position and left lateral position (10–15º, inclined towards the surgeon). The surgeon and an assistant stood on the left side, and the monitor on the right side of the patient.

The urinary bladder was decompressed with a Foley's catheter.

Through the umbilicus, a 10 mm port was inserted using Hasson's Open Technique and pneumoperitoneum created by CO_2 insufflation and another 10 mm port inserted in the suprapubic region and one 5-mm trocar inserted in the left lower quadrant under vision. Additionally a 5 mm port was inserted at the right lower quadrant if necessary. Suprapubic 10mm port used as camera port. Further, Diagnostic scopy done and abdominal cavity examined to locate the appendix in the RIF by the confluence of the three tenia coli.

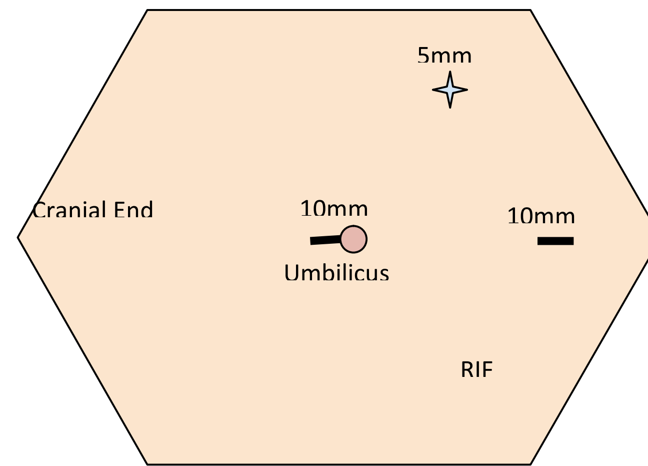

Figure 3: Diagram showing the laparoscopic port placement for LA.

TECHNIQUE OF LAPAROSCOPIC APPENDECTOMY:

To visualise the mesoappendix, the appendix is held at its tip using a dissector or grasper. The mesoappendix is skeletonized from the tip to the stump using cautery/ dissection. Appendicular artery identified and ligated using clips or diathermy. The approximate diameter of the appendix assessed with the blades of the Maryland dissector which measure ~10mm.

INTERVENTION:

Operative time was noted from the time of complete skeletonisation of appendix upto the time when the specimen is retrieved from the 10 mm port.

In group A, Liga clips were passed through the 10 mm port and applied at the base of the appendix. 2 clips were applied 5 mm apart & a third one distal to the two. In group B, H-o-L was introduced through the 10 mm port. H-o-L Clips were applied in the similar pattern as liga clips in most of the cases. After a few cases, as per the surgeon's discretion only 2 polymer clips were applied in few cases as The appendix

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After tracing the small bowel, pneumoperitoneum was deflated and the ports removed. 10mm port sites closed using 2-0 vicryl suture and skin closed with 3-0 Ethilon suture with mattress sutures. Wound cleaned and dressing done.

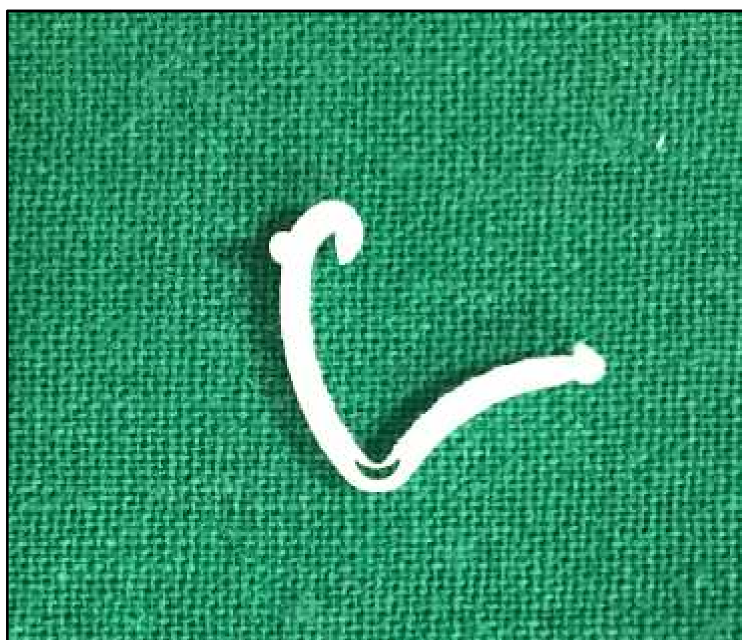
Photograph 1: Liga Clip (400)- cartridge & loaded in the applicator.

Photograph 2: Liga clip.

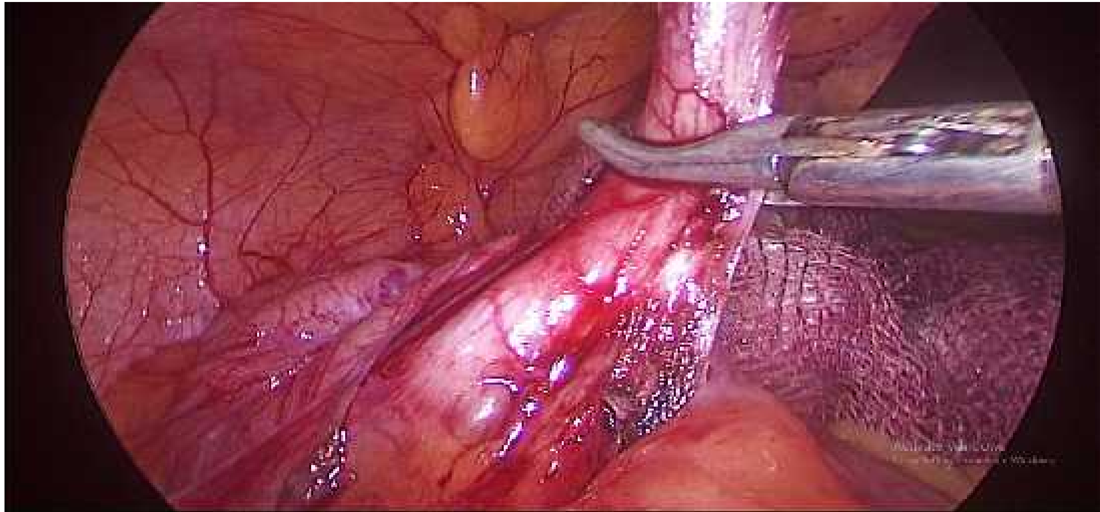
Photograph 3: Hem-o-Lok clips cartridge (Purple- Large) with applicator.

Photograph 4: Hem-o-Lok clips cartridge (Purple- Large) with applicator.

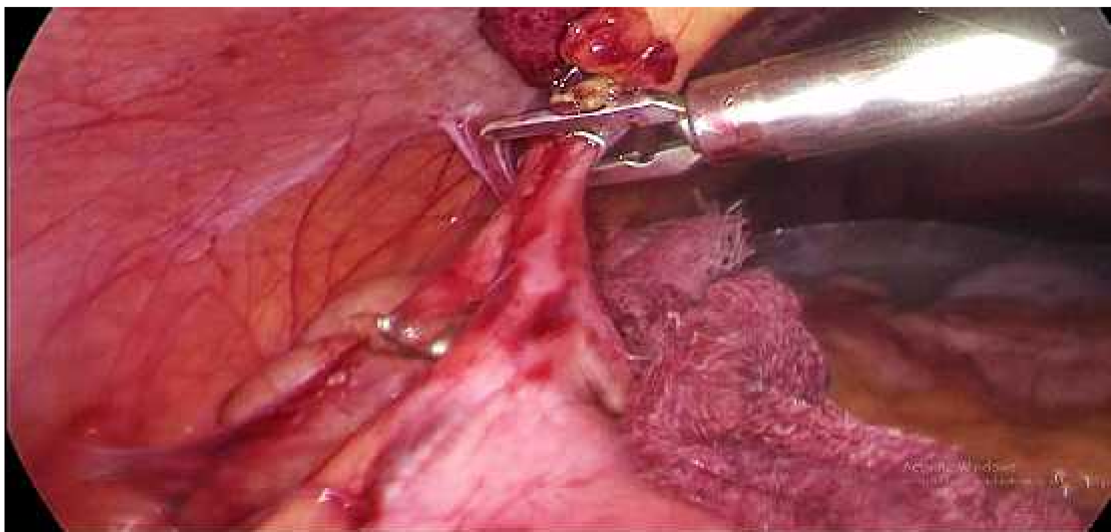
Photograph 5: Hem-o-Lok loaded in the applicator.



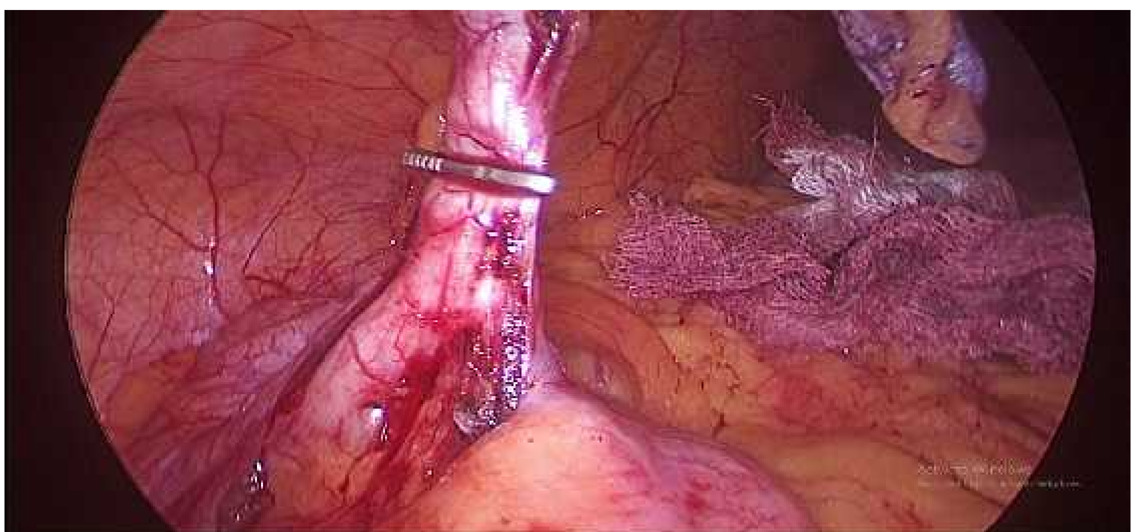
Photograph 6: Open Hem-o-Lok with Lock engagement system



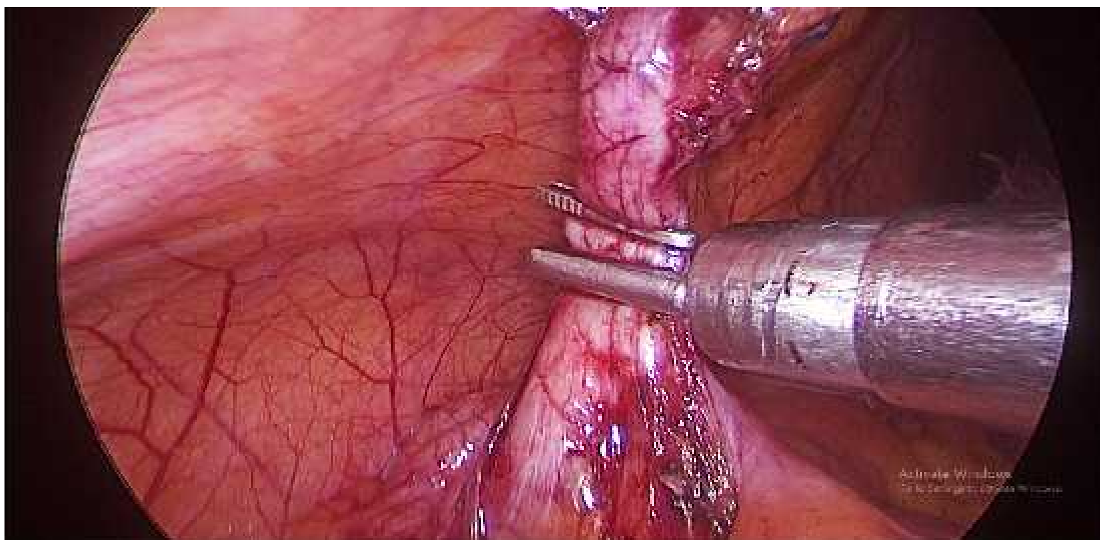
Photograph 7: approx. diameter of Appendiceal stump being measured by the blades of Maryland dissector (~10 mm).



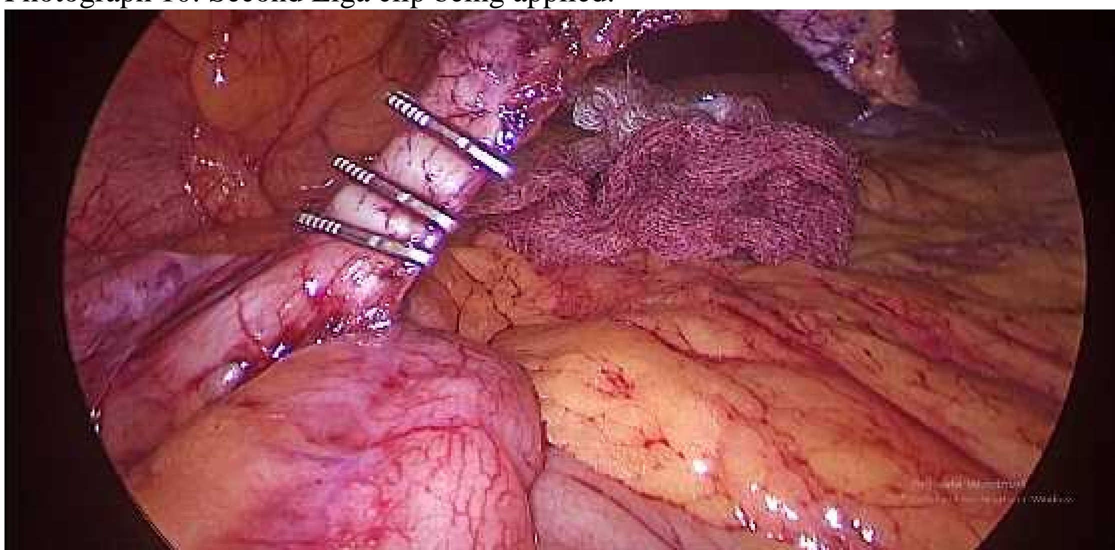
Photograph 8: First Liga clip being applied at the base of the appendix.



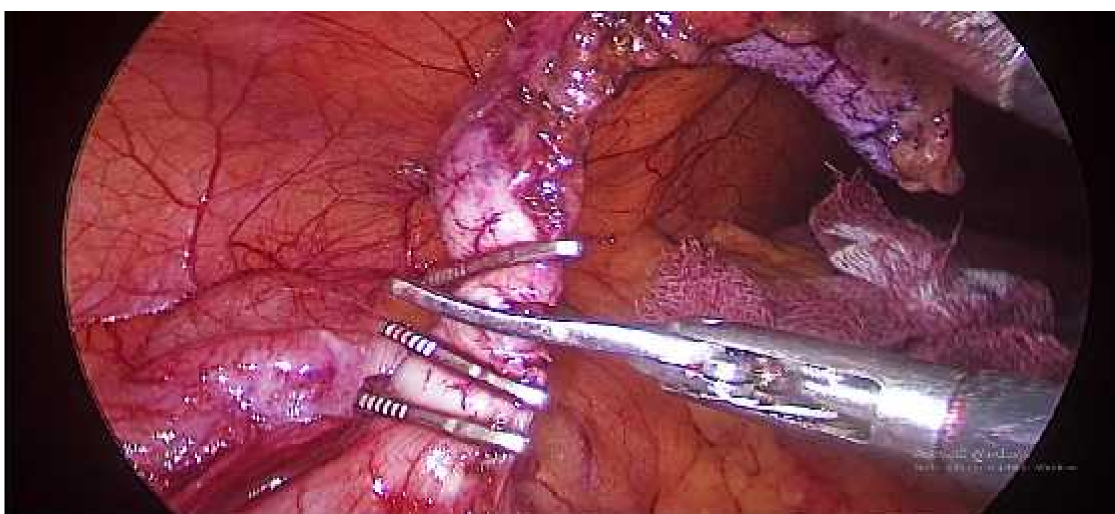
Photograph 9: Liga clip in place.



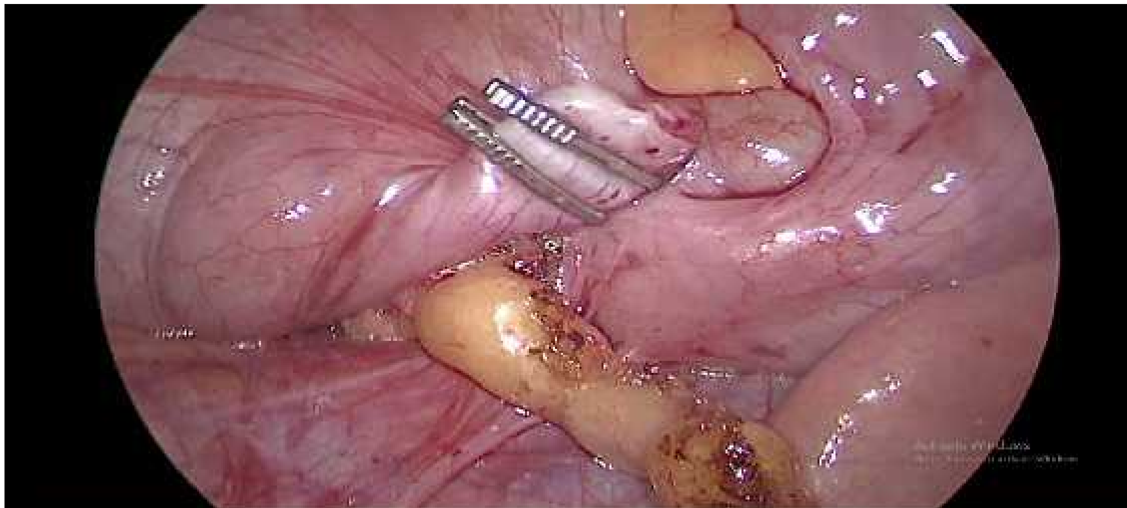
Photograph 10: Second Liga clip being applied.



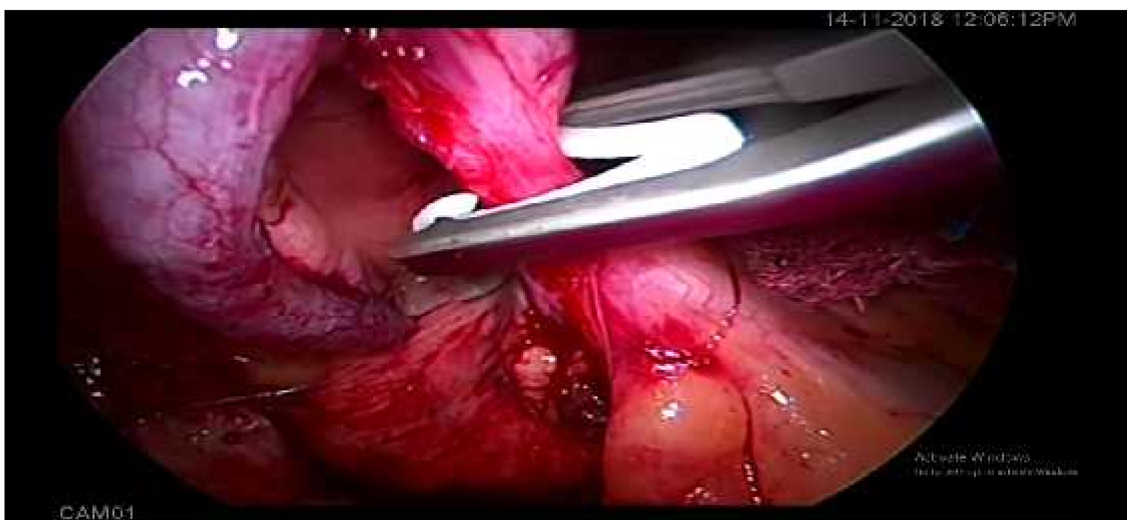
Photograph 11: Three Liga Clips in place.



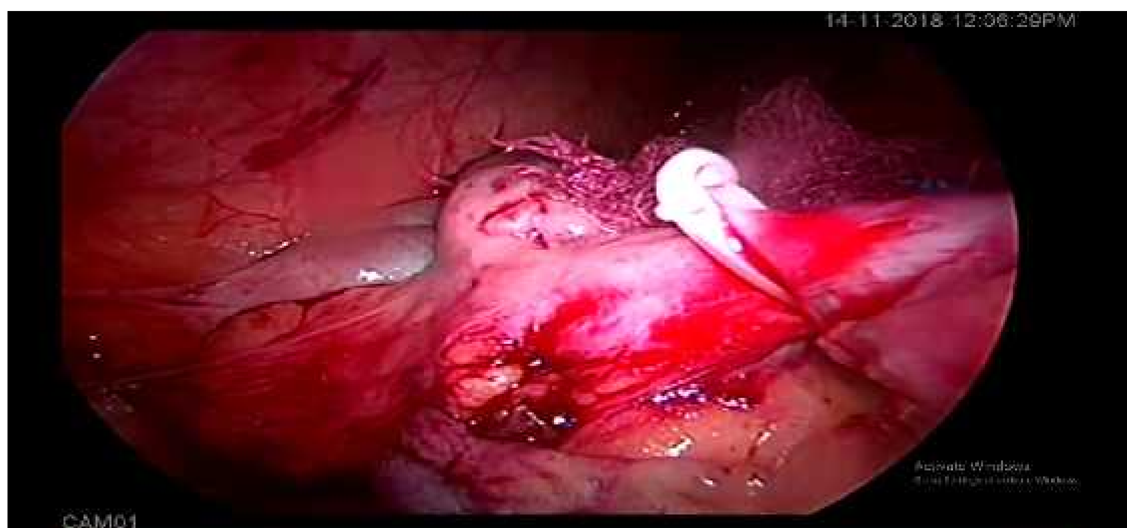
Photograph 12: Appendix being cut between distal two clips.



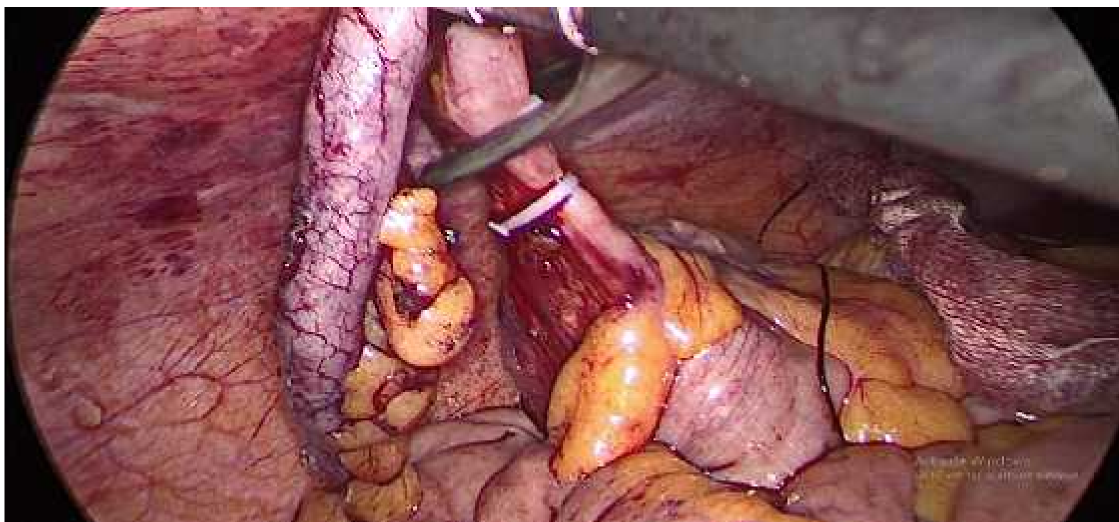
Photograph 13: Two clips left at the caecal end of appendiceal stump after appendectomy. No stump leak noted.



Photograph 14: First Hem-o-Lok polymer clip being applied at the base of appendix.



Photograph 15: Hem-o-Lok clip in place. Note the Lock engagement system.



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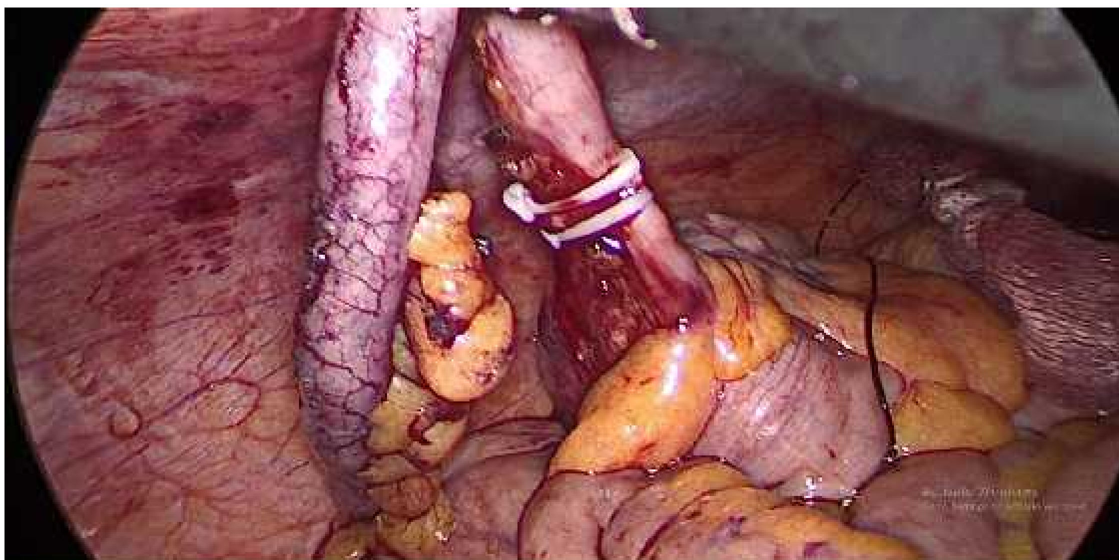

Photograph 17: Two Hem-o-Lok clips in place.

POST- OPERATIVE PERIOD:

Both the groups had similar Postoperative management. Monitoring was done for patients in both groups, looked for any signs of complications and further evaluated accordingly until discharge and in the follow up period. The skin wound was assessed and sutures removed between postoperative days 7-10. Patients were advised follow up for a period of 2 months after surgery.

Diagnosis was correlated histopathologically.

At the time of follow- up if the patient was found to be symptomatic and stump leak or intra- abdominal abscess were suspected, vitals were noted to look for tachycardia, abdomen examined for guarding, total count repeated to look for neutrophilia and an Ultrasound of the abdomen and pelvis were done to look for any localised collection in RIF/ diffuse collection intra peritoneally.

STATISTICAL ANALYSIS:

The collected data was entered in spread sheets and the Master- chart was prepared. The data was then subjected to statistical analysis: Student unpaired-t test and chi-square test were used to compare data from both groups. The categorical data was expressed as rates, ratios and percentages and comparison was done using chi-square test. Continuous data was expressed as mean ± standard deviation and the comparison was done using independent sample t test. A p-value <0.05 was considered statistically significant.

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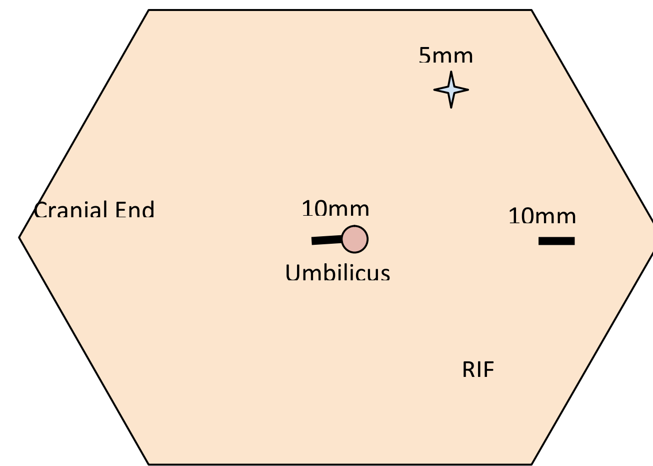

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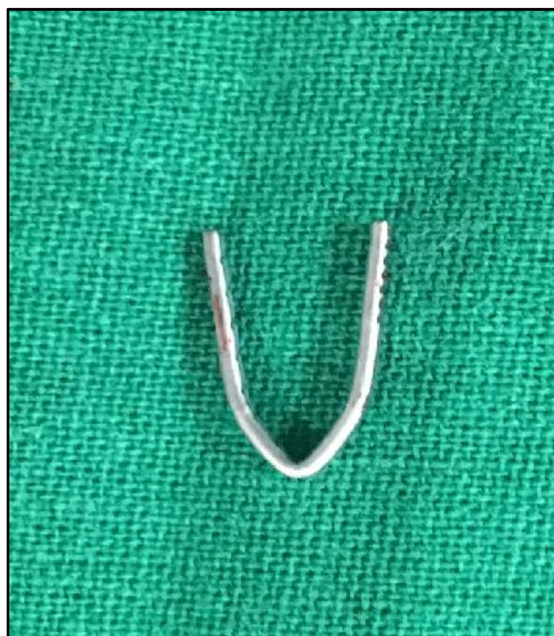

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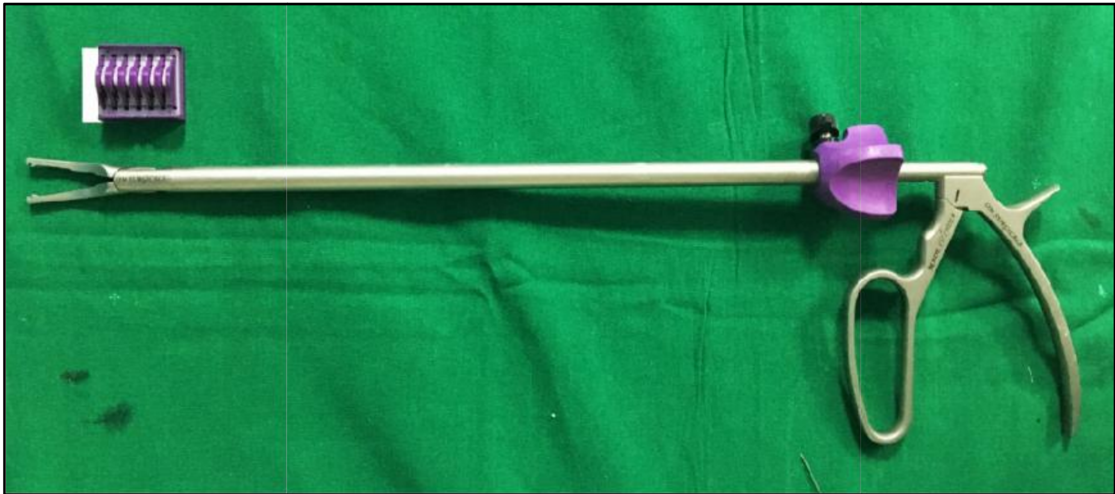

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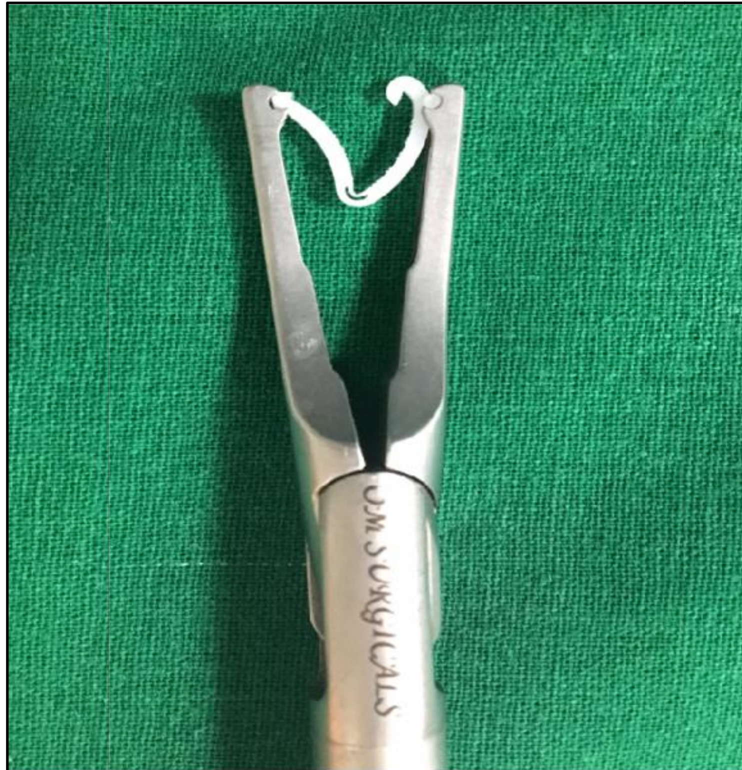

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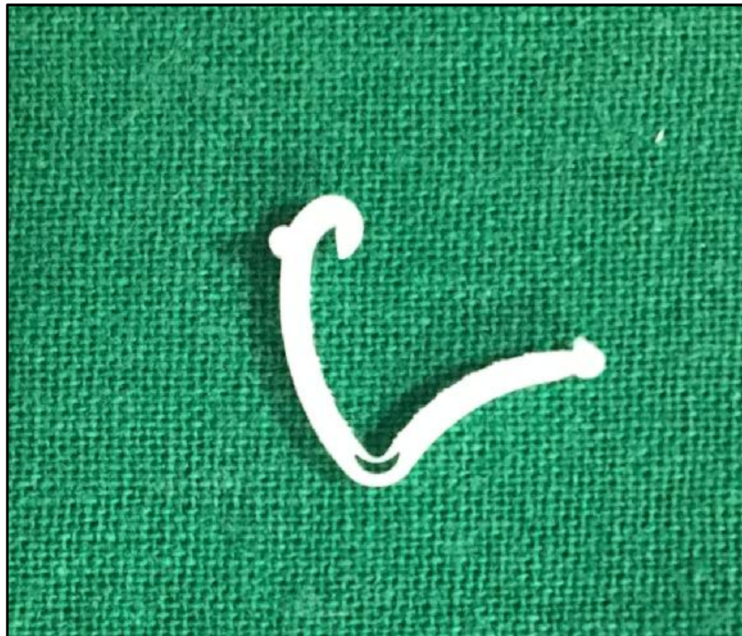

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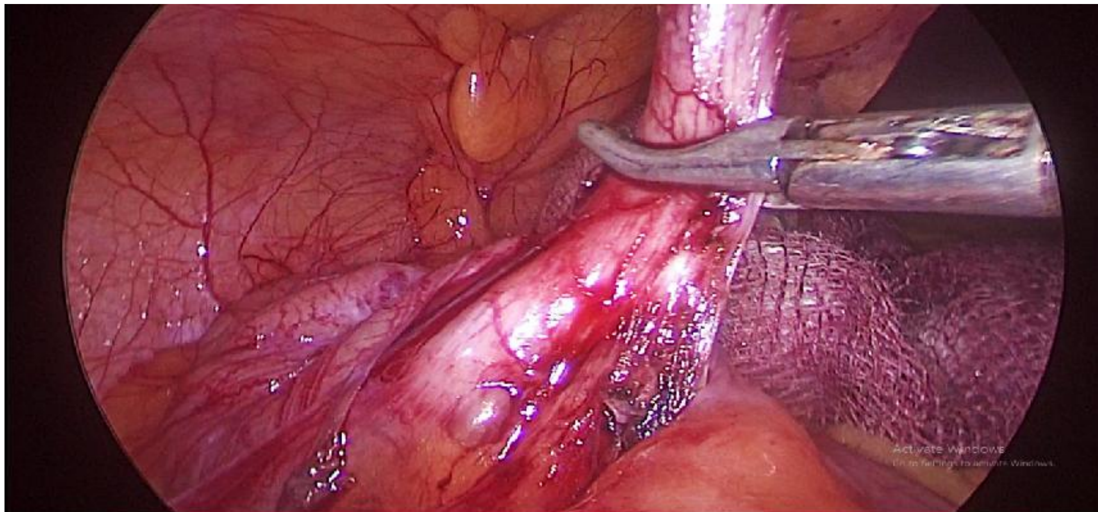

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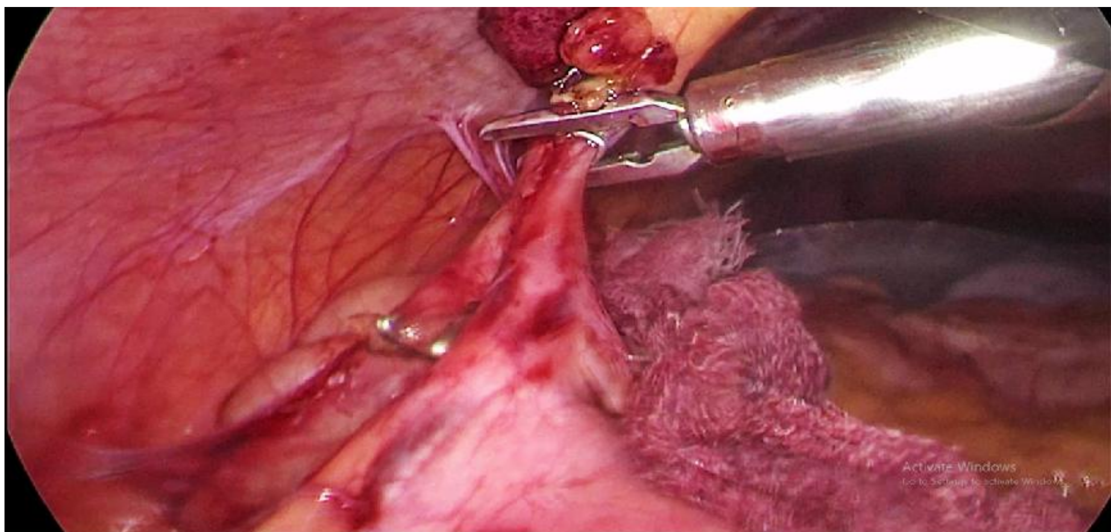

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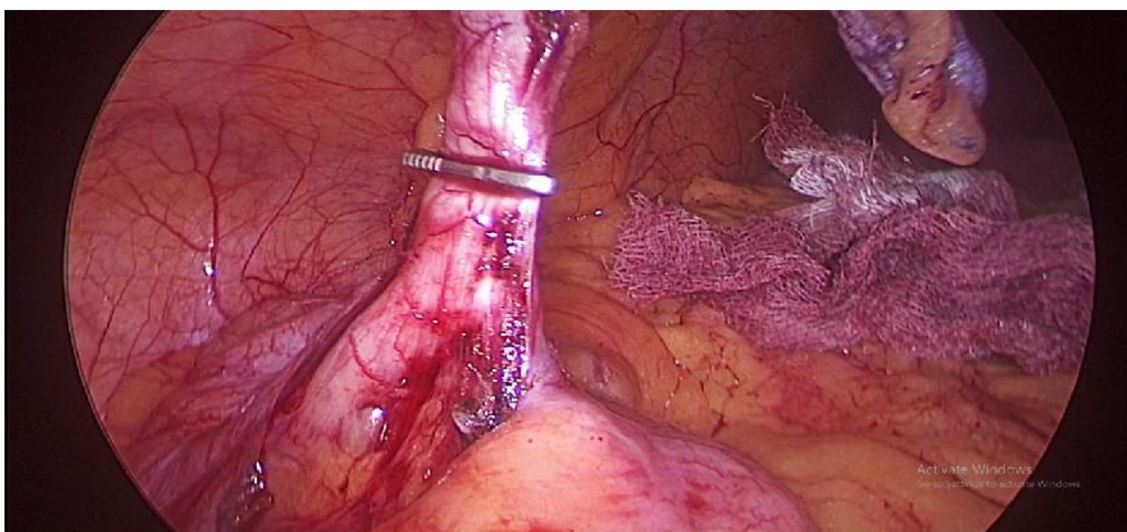

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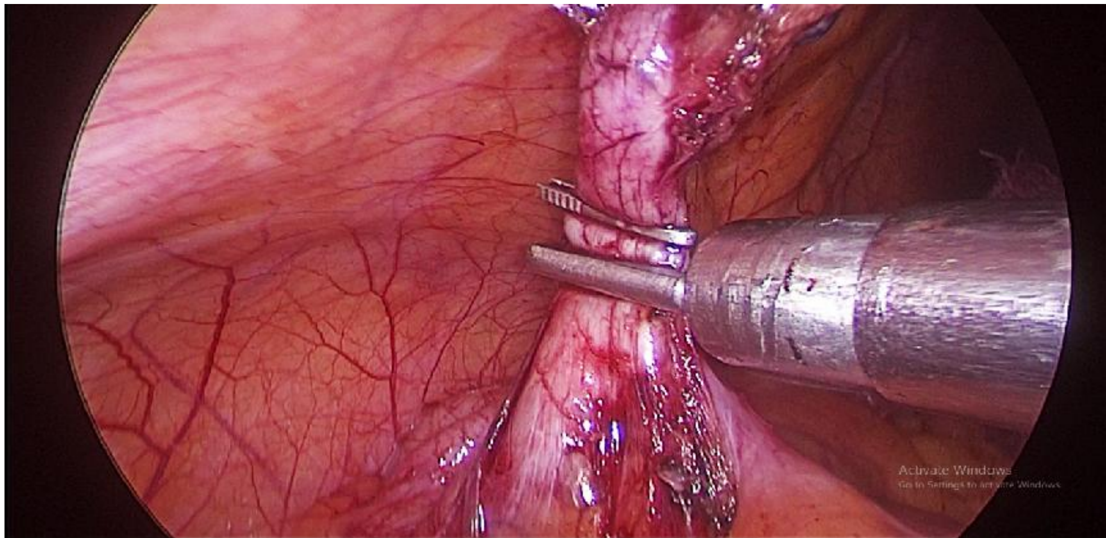

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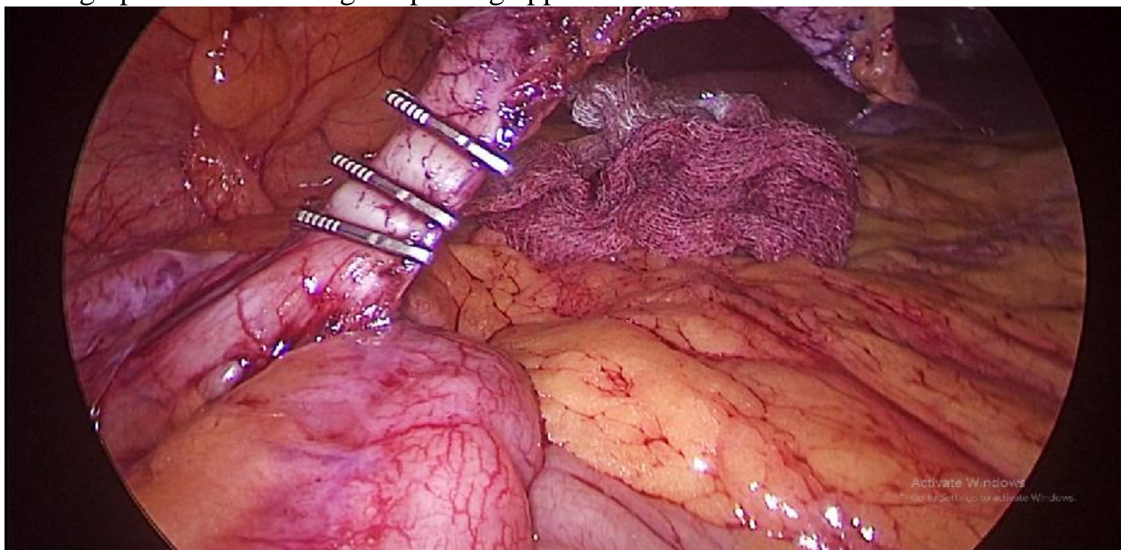

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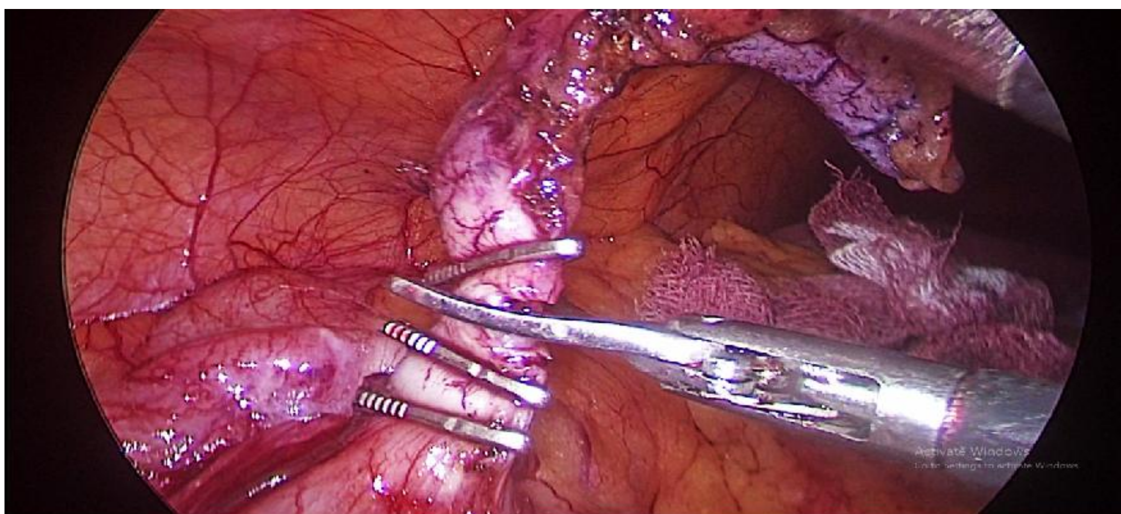

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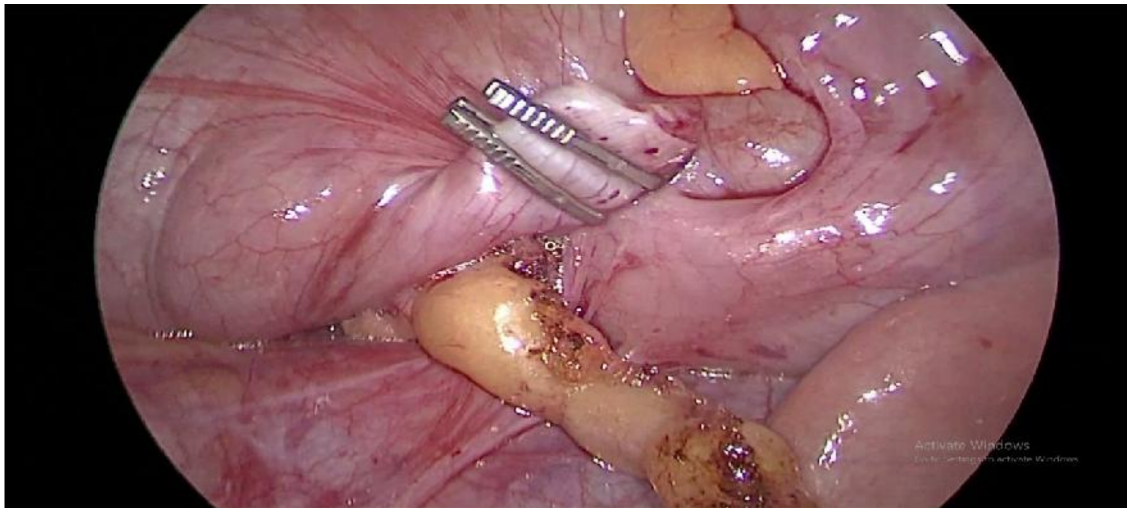

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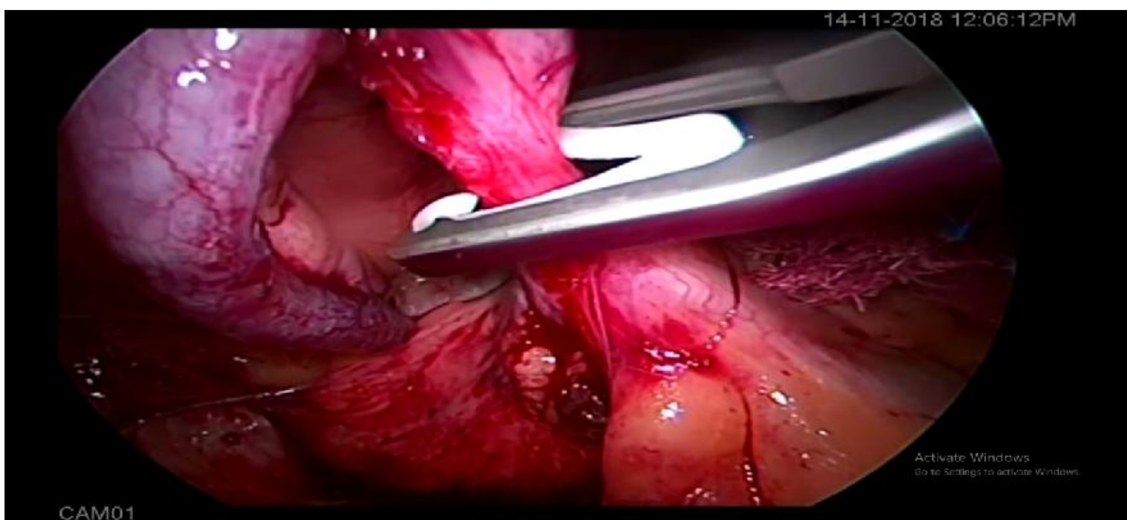

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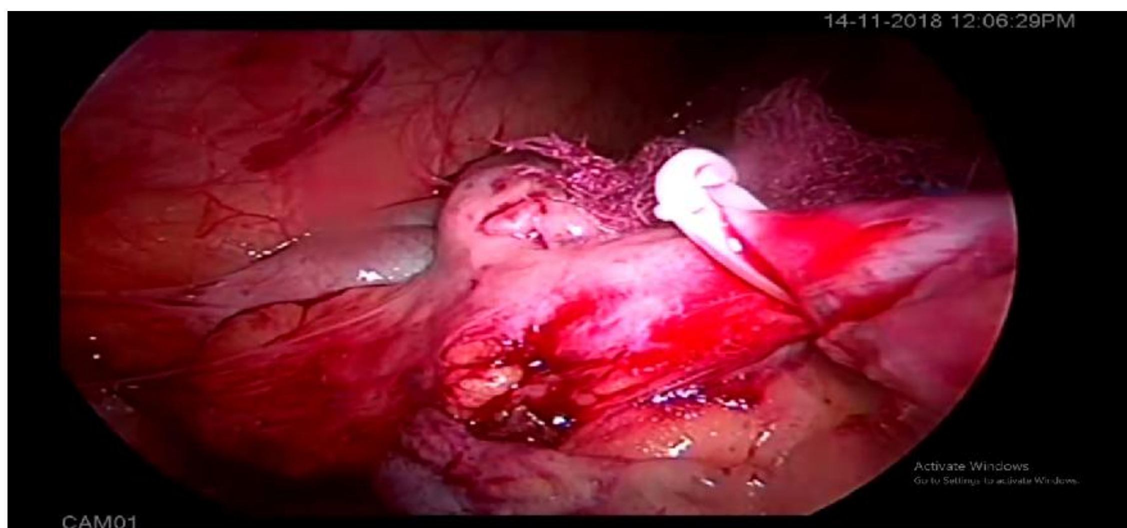

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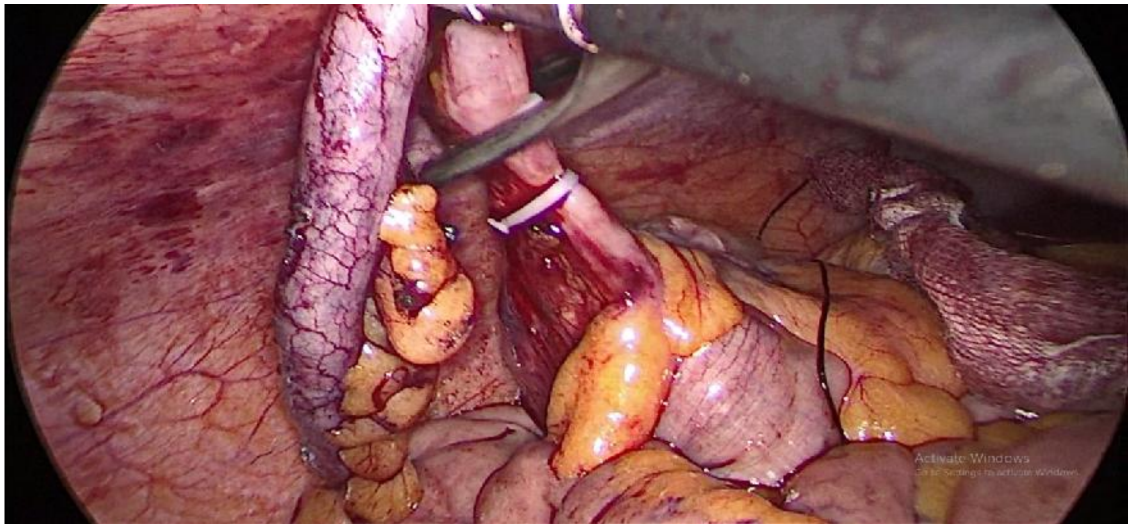
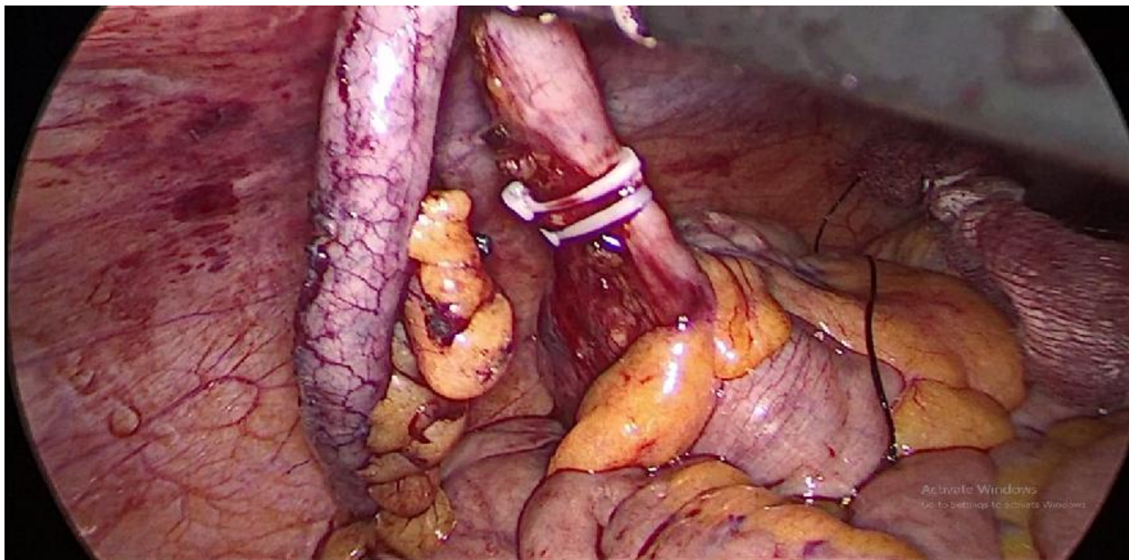


Photograph 16: Second Hem-o-Lok clip being applied distally.



Photograph 17: Two Hem-o-Lok clips in place.

POST- OPERATIVE PERIOD:

Both the groups had similar Postoperative management. Monitoring was done for patients in both groups, looked for any signs of complications and further evaluated accordingly until discharge and in the follow up period. The skin wound was assessed and sutures removed between postoperative days 7-10. Patients were advised follow up for a period of 2 months after surgery.

Diagnosis was correlated histopathologically.

At the time of follow- up if the patient was found to be symptomatic and stump leak or intra- abdominal abscess were suspected, vitals were noted to look for tachycardia, abdomen examined for guarding, total count repeated to look for neutrophilia and an Ultrasound of the abdomen and pelvis were done to look for any localised collection in RIF/ diffuse collection intra peritoneally.

STATISTICAL ANALYSIS:

The collected data was entered in spread sheets and the Master- chart was prepared. The data was then subjected to statistical analysis: Student unpaired-t test and chi-square test were used to compare data from both groups. The categorical data was expressed as rates, ratios and percentages and comparison was done using chi-square test. Continuous data was expressed as mean ± standard deviation and the comparison was done using independent sample t test. A p-value <0.05 was considered statistically significant.

RESULTS

The present study is a Randomised Controlled Trial conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi. A total of 60 patients diagnosed with Appendicitis (Acute or Chronic) without complications and undergoing Laparoscopic Appendectomy (LA) from January 2018 to December 2018 were considered in this study

The cases were divided into two groups using Sequentially Numbered Opaque Sealed envelope (SNOSE) method:

1) Group A- 30 cases in which Liga clips was used for CAS
2) Group B- 30 cases in which Hem-o-lok was used for CAS

The data collected was analysed and the results obtained were tabulated and interpreted as follows:

AGE AND GENDER:

The demographic data w.r.t. age and gender distribution of the 60 patients was as shown in Table 1. In both the groups, 40% in Group A and 50% in Group B, the majority of the patients belonged to the 21- 30 years age group with a mean age of 28 years and 27 years respectively. Also there was an equal distribution of male and female patients in Group A (50% each), whereas the number of female patients was slightly more (53.33%) than that of males in Group B. It was noted that the age and gender distribution had no significant association with the outcome in either of the groups (Table 2).

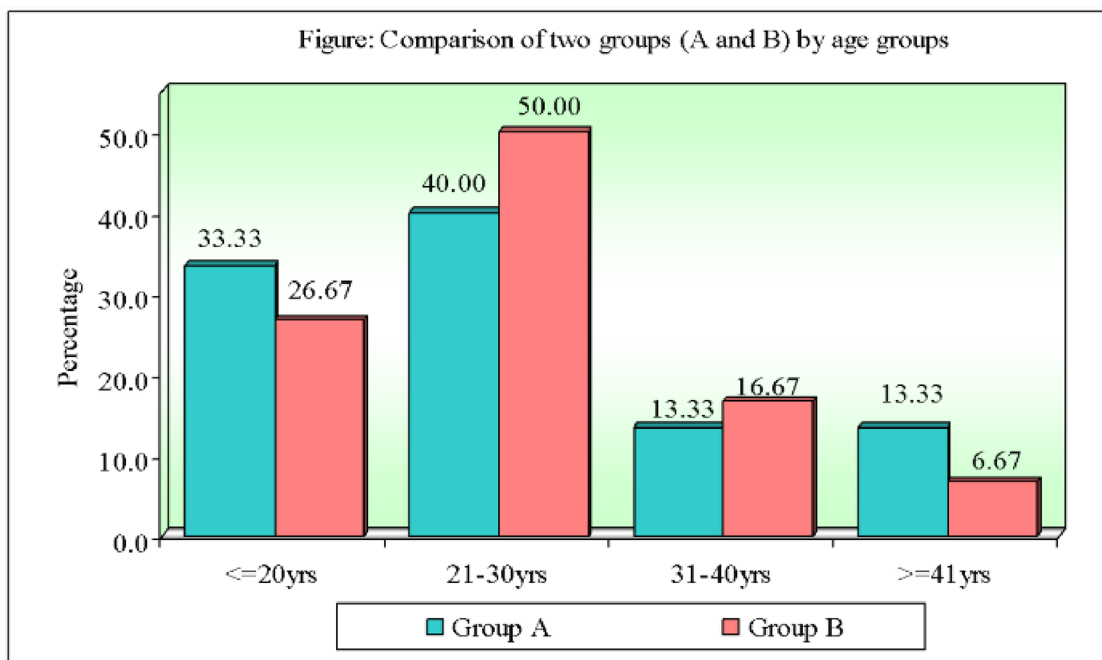
Table 1: Age and gender wise distribution of respondents in two groups (A and B) with age groups and gender

Demographic profile	**Group A**	%	**Group B**	%	**Total**	%	Chi-square	**p-value**
Age groups								
<=20yrs	10	33.33	8	26.67	18	30.00	1.3330	0.7212
21-30yrs	12	40.00	15	50.00	27	45.00		
31-40yrs	4	13.33	5	16.67	9	15.00		
>=41yrs	4	13.33	2	6.67	6	10.00		
Gender								
Male	15	50.00	14	46.67	29	48.33	0.0672	0.7961
Female	15	50.00	16	53.33	31	51.67		
Total	30	100.0	30	100.0	60	100.0		

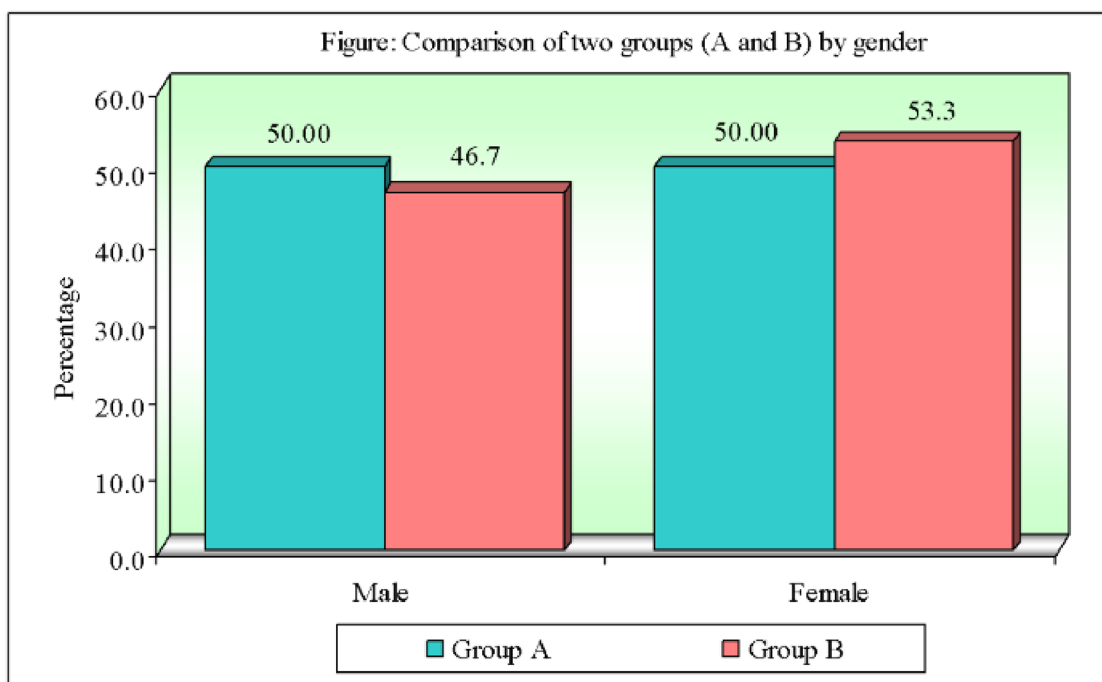
Table 2: Comparison of two groups (A and B) with mean age by independent t test

Groups	n	Mean	SD	SE	t-value	P-value
Group A	30	28.13	12.17	2.22	0.3177	0.7519
Group B	30	27.27	8.67	1.58		

Graph 1



Graph 2



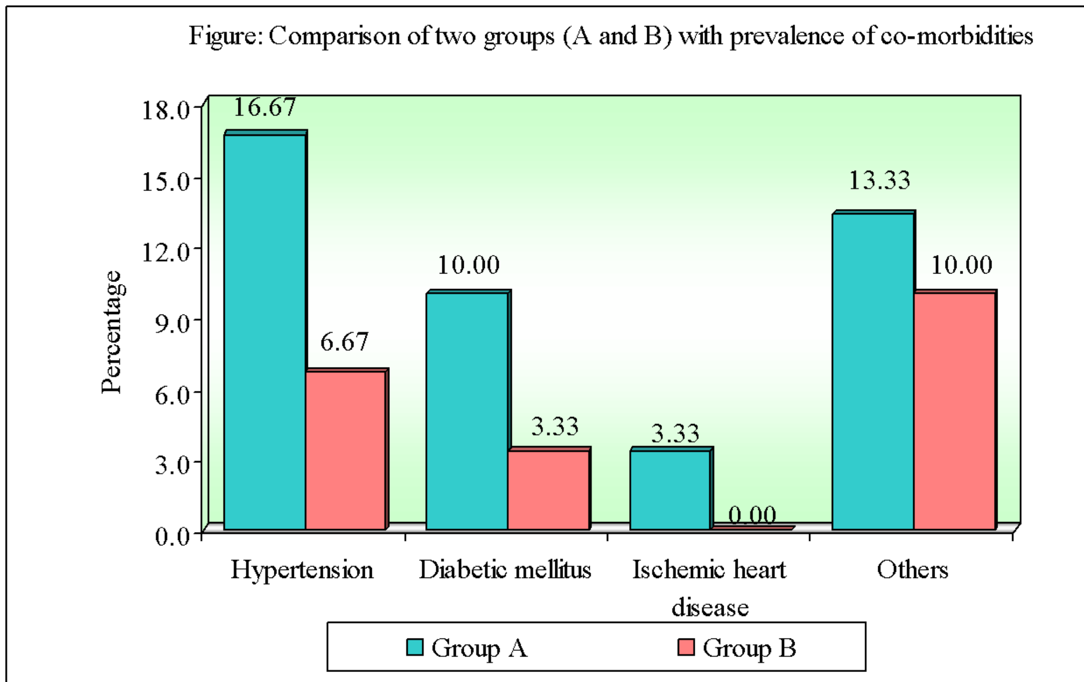
COMORBIDITIES:

The prevalence of co morbid conditions in the enrolled patients were as shown in Table 3. There was no significant correlation between the existence of co-morbidities and the outcomes of this study.

Table 3: Comparison of two groups (A and B) with prevalence of co-morbidities

Co-morbidities	**Group A**	%	**Group B**	%	**Total**	%	Chi-square	**p-value**
Hypertension								
Yes	5	16.67	2	6.67	7	11.67	1.4561	0.2276
No	25	83.33	28	93.33	53	88.33		
Diabetic mellitus								
Yes	3	10.00	1	3.33	4	6.67	1.0712	0.3006
No	27	90.00	29	96.67	56	93.33		
Ischemic heart disease								
Yes	1	3.33	0	0.00	1	1.67	1.0173	0.3132
No	29	96.67	30	100.00	59	98.33		
Others								
Yes	4	13.33	3	10.00	7	11.67	0.1620	0.6876
No	26	86.67	27	90.00	53	88.33		
Total	30	100.00	30	100.00	60	100.00		

Graph 3



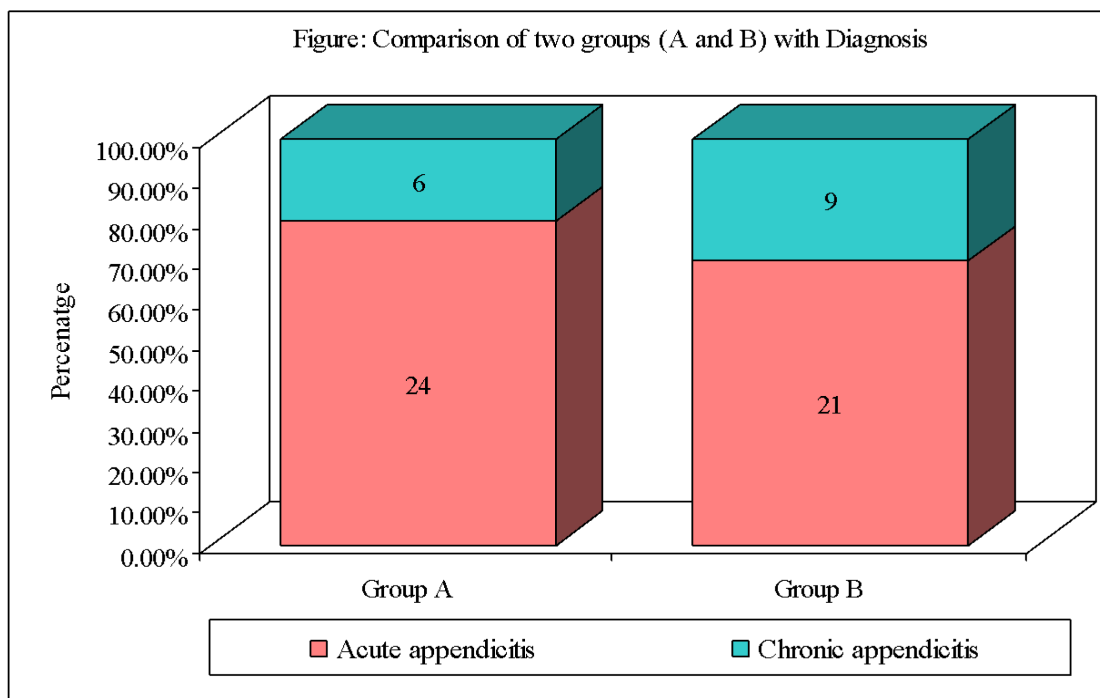
DIAGNOSIS:

The incidence of AA was more in both the groups in comparison to chronic appendicitis but it had no significant relation with the intra op and post operative findings. Of the 30 cases in each group 24 (80%) in group A and 21 (70%) in group B were that of AA (Table 4).

Table 4: Comparison of two groups (A and B) with Diagnosis

Diagnosis	Group A	%	Group B	%	Total	%	Chi-square	p-value
Acute appendicitis	24	80.00	21	70.00	45	75.00	0.8000	0.371 0
Chronic appendicitis	6	20.00	9	30.00	15	25.00		
Total	30	100.00	30	100.00	60	100.00		

Graph 4



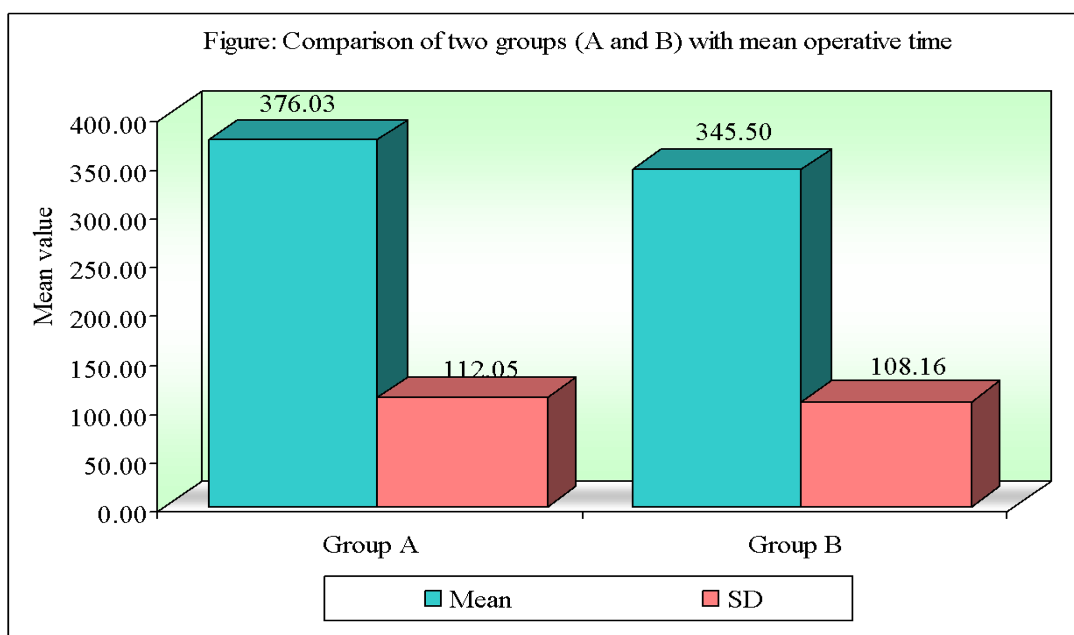
OPERATIVE TIME:

Operative time in this study was considered from the time of complete skeletonisation of appendix upto the time when the specimen is retrieved from the 10 mm port. The mean operative time in group A was noted to be 376.03 seconds (~6.27 minutes) and that in group B was noted to be 345.50 seconds (~5.75 minutes) (Table 5). Although the operative time was slightly more in group A when compared to group B, it was not found to be statistically significant (p~0.2873) . Hence one can say there is not much difference in the operative time with the use of Liga clips or H-o-L.

Table 5: Comparison of two groups (A and B) with mean operative time by independent t test

Groups	n	Mean	SD	SE	t-value	P-value
Group A	30	376.03	112.05	20.46	1.0738	0.2873
Group B	30	345.50	108.16	19.75		

Graph 5



INTRAOPERATIVE FINDINGS:

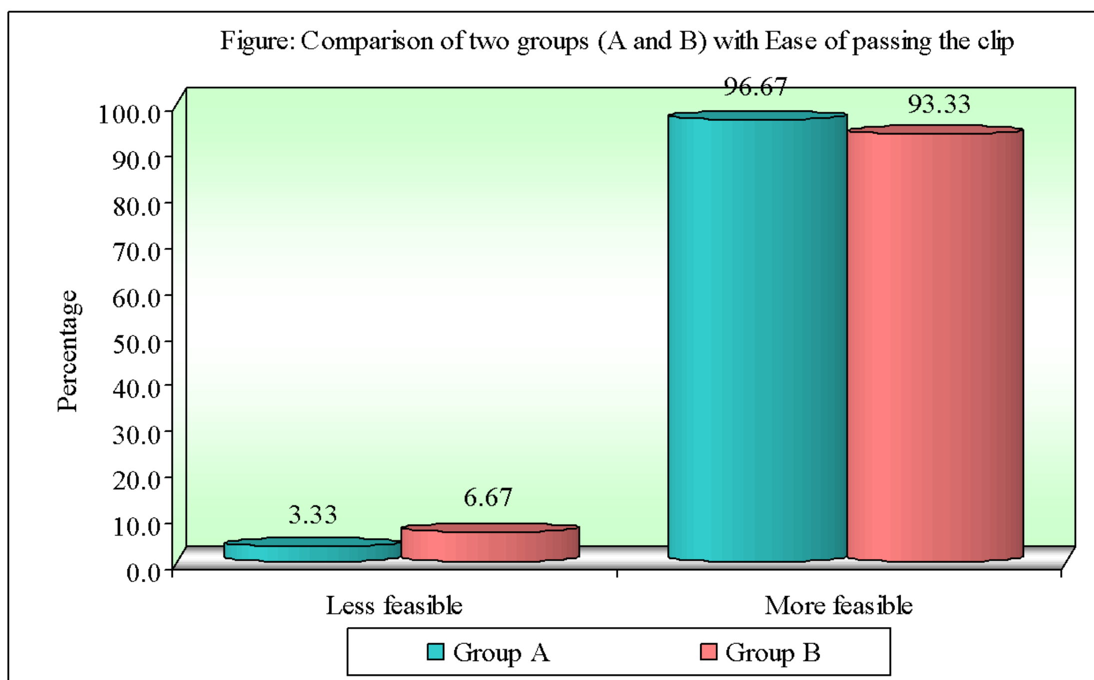
Table 6: Comparison of two groups (A and B) with Intraoperative findings

Intraoperative findings	Group A	%	Group B	%	Total	%	Chi-square	p-value
Ease of passing the clip								
Less feasible	1	3.33	2	6.67	3	5.00	0.0001	1.0000
More feasible	29	96.67	28	93.33	57	95.00		
Dropped clip								
Zero	28	93.33	27	90.00	55	91.67	2.0180	0.3650
Dropped	2	6.66	3	10.00	5	8.34		
Ease of clip application								
Less feasible	4	13.33	1	3.33	5	8.33	0.8730	0.3500
More feasible	26	86.67	29	96.67	55	91.67		
No. of clips used								
Two	0	0.00	4	13.33	4	6.67	2.411	0.1210
Three	30	100.00	26	86.67	56	93.33		
Position of the appendix								
Pelvic	6	20.00	4	13.33	10	16.67	0.7550	0.6860
Preileal	1	3.33	1	3.33	2	3.33		
Retrocaecal	23	76.67	24	80.00	47	78.33		
Subhepatic	0	0.00	1	3.33	1	1.67		
Total	30	100.00	30	100.00	60	100.00		

EASE OF PASSING THE CLIP:

In this study the ease of passing the clip along with the applicator through the umbilical 10mm port was assessed by the surgeon as more or less feasible. In the initial few cases passage of the clips through the port was assessed less feasible until the surgeon gained practice and fluency eventually. The feasibility was considered more in 96.67% of cases in group-A and 93.33% of cases in group-B but the difference was not noted to be statistically significant (Table 6). It was noticed to be less feasible in group B because the Hem-o-lok clip (12mm) along with the applicator had to be partially closed while passing through the port and at times initially would get accidentally clipped and locked prior to its passage through the 10 mm port.

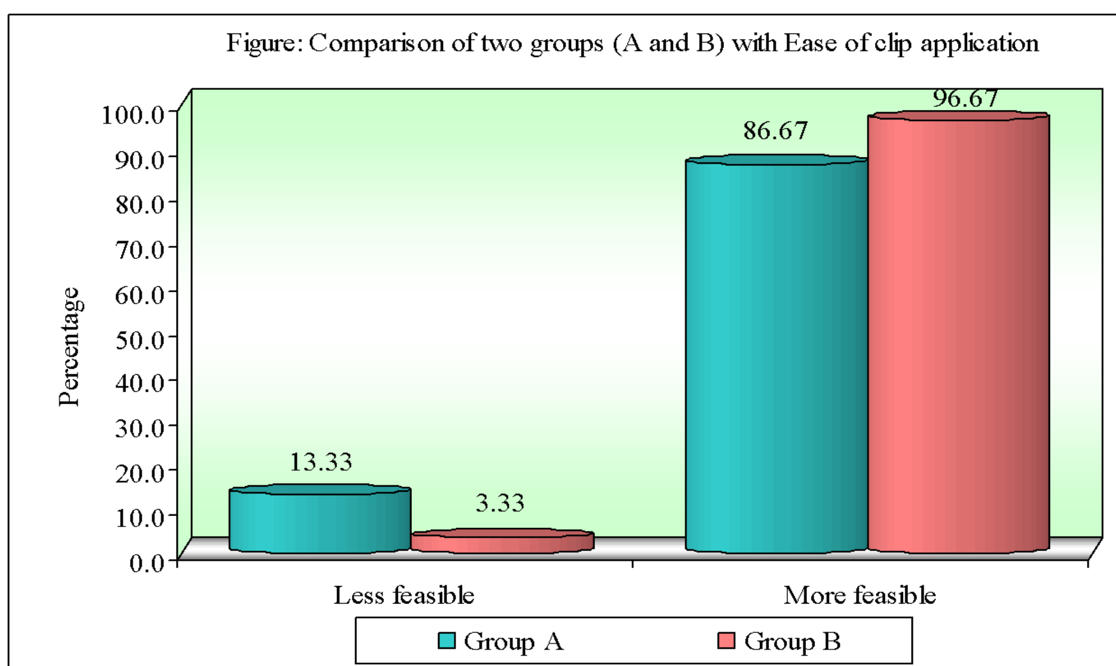
Graph 6



EASE OF CLIP APPLICATION:

The ease with which the two clips were applied were also assessed by the operating surgeon as more feasible and less feasible. More feasibility was seen with 86.67% of cases in group- A and 96.67% of cases in group- B but the difference was not statistically significant (Table 6). This difference was noted in favour of Hem-o-lok because of its wider length ie 12mm which makes it suitable for inflamed, edematous appendix with a wider stump as well and the engaging lock system on clipping which seems to provide more security from the clip loosening or slipping.

Graph 7



NUMBER OF CLIPS USED:

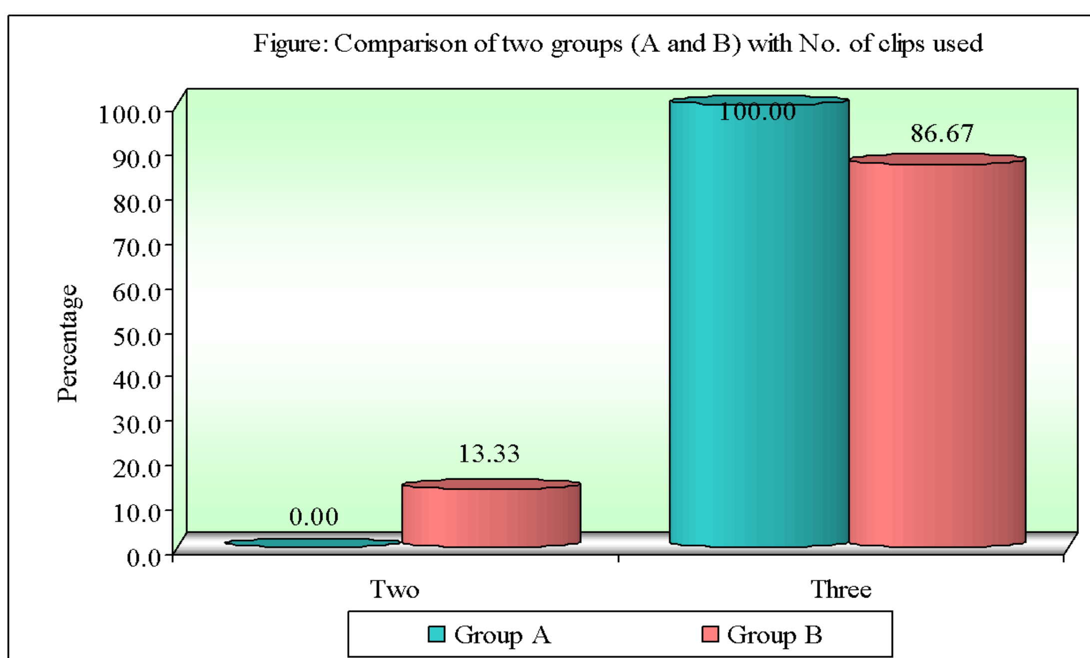
In this study as per the designed protocol three clips were proposed to be used; two at caecal end and one at appendix specimen end. But with the progression of the study, as the surgeon gained more confidence in the engaging locking system of the H-o-L clip, only two clips were used in a few cases; one at caecal end and another at specimen end. Two clips were used in 4 of the 30 cases of group B. When the two groups were compared in this respect using independent t test, a p-value of 0.039 (<0.05) was obtained which is statistically significant (Table 7). This again goes in favour of H-o-L clips as the decrease in the no. of clips used will also improve it's cost effectiveness and the operative time as well.

Table 7: Comparison of two groups (A and B) with mean no of clips used by independent t test

Groups	n	Mean	SD	SE	t-value	P-value
Group A	30	3.00	0.00	0.00	2.1122	0.0390*
Group B	30	2.87	0.35	0.06		

*p<0.05

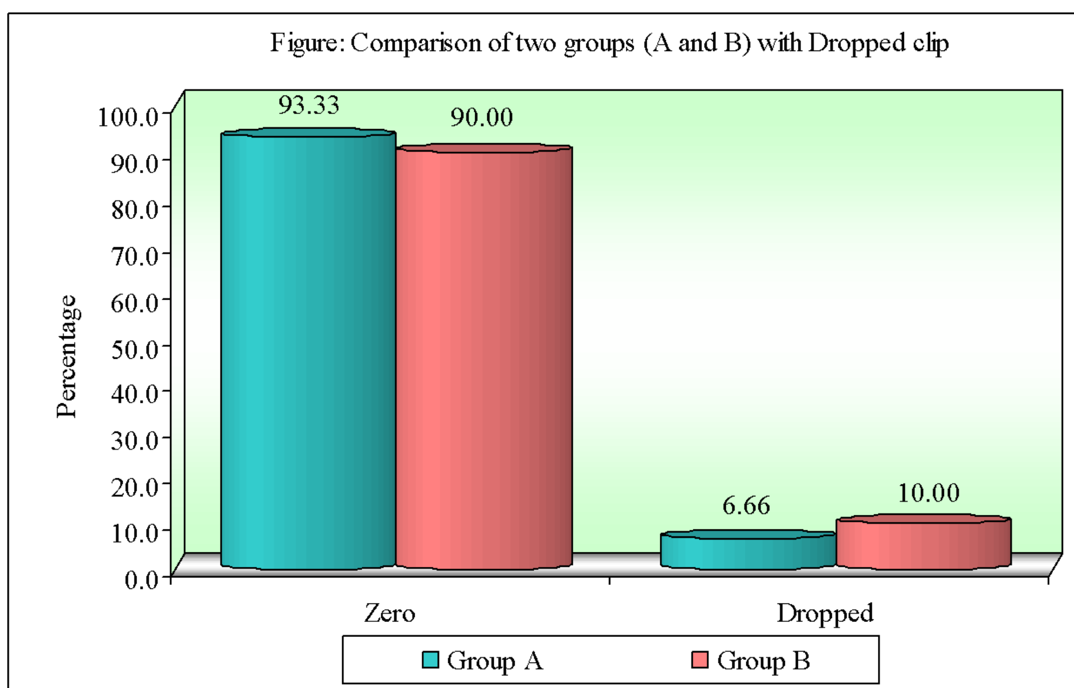
Graph 8



DROPPED CLIPS:

In this study along with the operative time, other technical difficulties faced by the surgeon intraoperatively were also taken into consideration. Hence the number of clips dropped or slipped during the procedure were made a note of. It also seems to prolong the operative time in such situations. In group A, this difficulty was faced in 2 cases out of 30 and 3 cases in Group B but the difference did not attain statistical significance. This problem was again noted in the initial phase of the study.

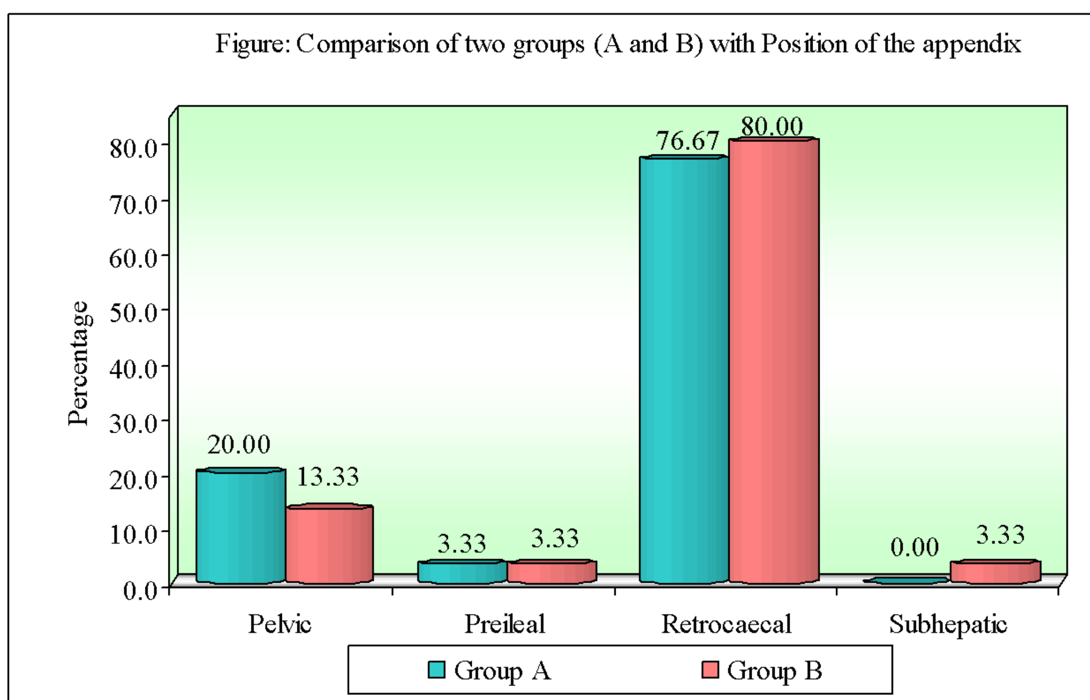
Graph 9



POSITION OF THE APPENDIX:

In majority of the cases in both the groups, the position of the appendix was noted to be retrocaecal which is in sync with previous literature; 76.67% in group- A and 80% in group- B (Table 6). However there was no significant statistical association of the position of the appendix with the outcomes measured in this study.

Graph 10



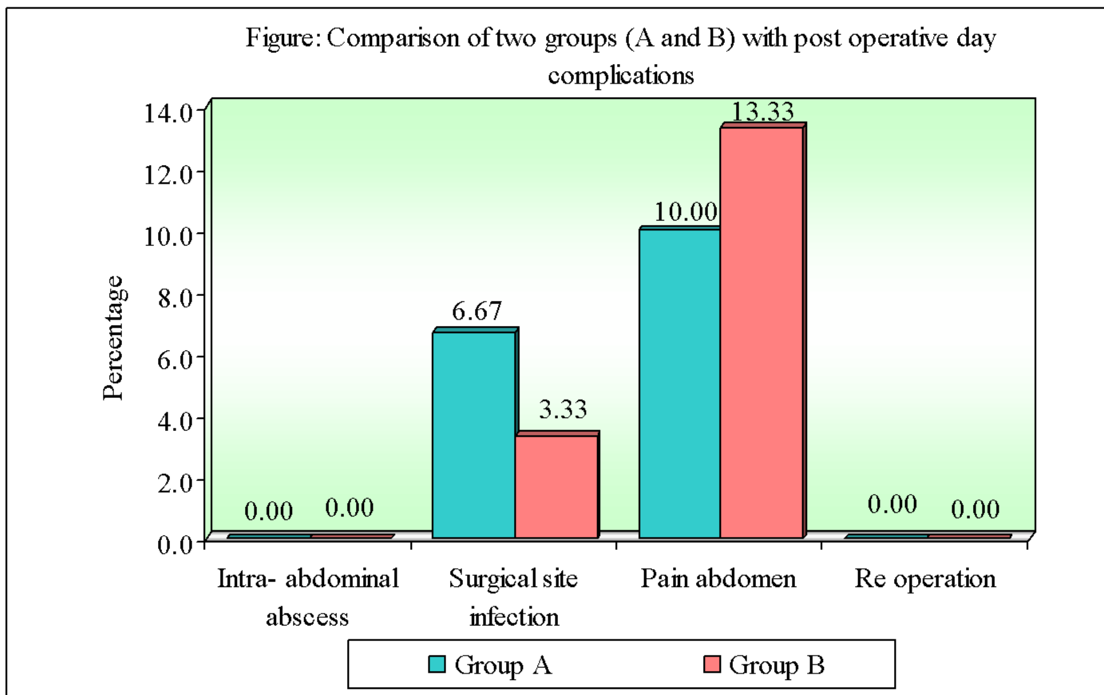
POSTOPERATIVE FINDINGS:

In this study a few postoperative parameters or rather complications were looked for pertaining to appendiceal stump closure especially stump leak and intra-abdominal abscess formation over the follow up period. It was noted that none of the patients enrolled in the study developed stump leak or intra- abdominal abscess and none of them had to undergo reoperation. There were a few incidences of surgical site infection, 2 cases in group A and 1 case in group B but not statistically significant. And not associated with appendiceal stump closure technique. Few patients had complaints pain abdomen which were due to non specific causes but no significant association to the technique of appendiceal stump closure. (Table 8).

Table 8: Comparison of two groups (A and B) with postoperative complications

Post operative complications	Group A	%	Group B	%	Total	%	Chi-square	p-value
Surgical site infection								
Yes	2	6.67	1	3.33	3	5.00	0.0001	1.0000
No	28	93.33	29	96.67	57	95.00		
Pain abdomen								
Yes	3	10.00	4	13.33	7	11.67	0.1620	0.6880
No	27	90.00	26	86.67	53	88.33		

Graph 11



HOSPITAL STAY:

Since one of the inclusion criteria of this study was appendicitis without complications, all the patients were discharged on POD 2 or 3 (i.e. 3-4 days of Hospital stay) 90% of the patients in groupA and 86.67% in group B were discharged after 3 days of hospital stay and the rest after 4 days. This too had no significant statistical value and hence the hospital stay was similar in either of the techniques of appendiceal stump closure. (Table 9, 10)

Table 9: Comparison of two groups (A and B) with Hospital stay

Hospital stay	Group A	%	Group B	%	Total	%	Chi-square	p-value
3 days	27	90.00	26	86.67	53	88.33	0.1620	0.6880
4 days	3	10.00	4	13.33	7	11.67		
Total	30	100.00	30	100.00	60	100.00		

Table 10: Comparison of two groups (A and B) with mean hospital stay by independent t test

Groups	n	Mean	SD	SE	t-value	P-value
Group A	30	3.10	0.31	0.06	-0.3959	0.6936
Group B	30	3.13	0.35	0.06		

Graph 12

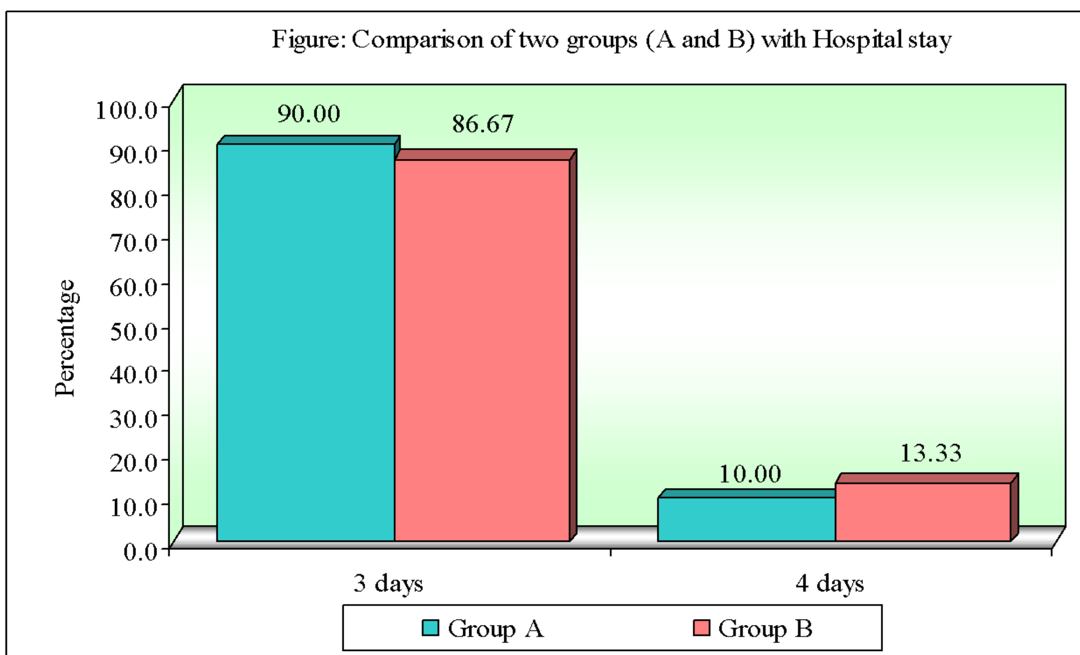


Table 10: Comparison of two groups (A and B) with complications at POD1, POD7 and 2 months post OP

Post operative complications	Group A	%	Group B	%	Total	%	Chi-square	p-value
POD 1								
None	26	86.67	25	83.33	51	85.00	0.1620	0.9220
Pain	3	10.00	4	13.33	7	11.67		
Vomiting	1	3.33	1	3.33	2	3.33		
POD 7								
None	28	93.33	28	93.33	56	93.33	0.0000	1.0000
Fever	2	6.67	2	6.67	4	6.67		
2 months								
None	30	100.00	30	100.00	60	100.00	-	-
Total	30	100.00	30	100.00	60	100.00		

DISCUSSION

Till date, Surgery i.e appendectomy is the treatment of choice for appendicitis. Even then, unlike laparoscopic cholecystectomy, LA is still an evolving procedure in the treatment of appendicitis and yet to be considered a gold standard but is been widely practiced in most cases of appendicitis with or without complications(20). There are several established techniques in this procedure at different stages which can be executed in hundreds of different ways(21). One such crucial step is the CAS in LA which can be carried out in several effective ways including the use of intracorporeal knotting, Endoloops- Roeder’s knot (Pre-knotted loops), mechanical endo staplers, bipolar endo- coagulation- Ligasure, ultrasonically activated scalpel- Harmonic scalpel, endoclips- LigaClips (titanium clips) and Hem-o-Lok (polymeric clips). This, if not done appropriately can lead to untoward complications like stump leak, intra-abdominal abscess which can further complicate into life threatening conditions like localised or diffuse peritonitis, enterocutaneous fistulas, sepsis which are undesired(6). Hence the quest for an ideal method for appendiceal stump closure in LA still continues.

In a study by Kiudelis et al., it was concluded that use of endoloops significantly decreased the operative time and did not have significant differences in overall complications and hence was considered safe in comparison to intracorporealinvaginating sutures for CAS(22). Soon endoloops like pre-knotted Roeder’s knot gained popularity and were being widely used.

In another study comparing CAS with endoloops and linear endostaplers(23), the latter were found to have fewer complications and a shorter

operative time but higher cost of surgery(24). Endo- staplers are still preferred in cases where the appendiceal stump is found to be necrosed or gangrenous.

Initially endoclips were introduced and proved safe and effective for securing the cystic duct and cystic artery in laparoscopic cholecystectomy(13). This practice was then adapted in LA for CAS.

The hem-o-lok clip is a non absorbable polymer clip which was introducedin 1999. It features a lock engagement system, and also serrations in the jaws that provide good security. When compared to other devices, it has been tested to withstand supraphysiologicalpressures(11). Even though it has been observed that these clips may be used up to a 16 mm diameter of the appendix, the reliability is decreased in cases where the appendix base diameter is over 1 cm(25). The safety of Hem-o-lok clip use has been demonstrated for ligating the cystic duct, ureter, and vessels up to 16 mm in diameter. The sizes of Hem-o-lok clips available are M (blue), ML (green), L (purple), to XL (brown) capable of ligating tissue bundle sizes up to 16 mm. The laparoscopic applicator for Hem-o-lok clips can be used through a 10-mm port and is easy to deploy (26).

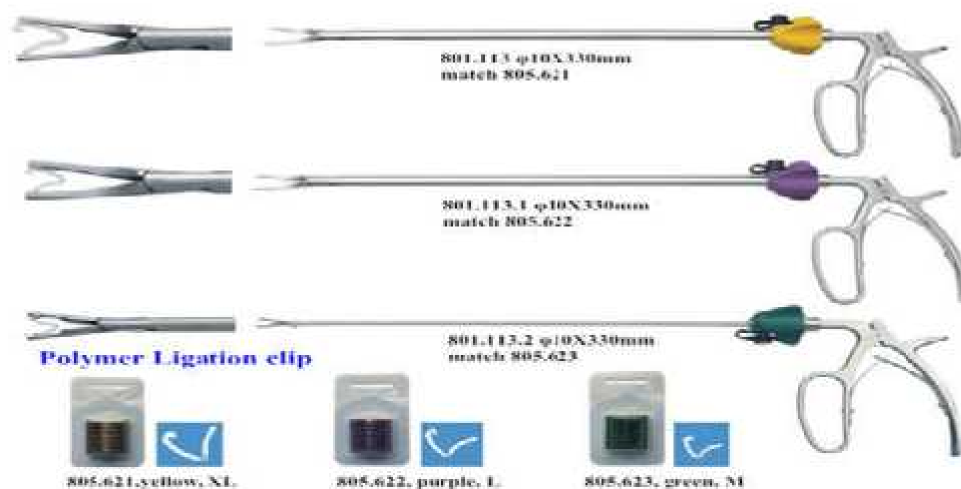


Figure 4: Hem-o-Lok clips and applicators in different sizes.

Metal endoclips were first used in CAS in 1999. One of such endoclips, Liga clips are made up of titanium and is widely used in numerous Laparoscopic procedures (12). It is a biocompatible implant material that allows for a good adaptation to the tissue as well as a constant and high closing force. Non-clinical testing has demonstrated the implantable clips made of titanium in these devices are MR Conditional. A patient with the implanted titanium clips can be scanned safely immediately after placement of the clips, under controlled conditions (27)

The following precautions need to be followed for effective use of the metal clips:

Complete dissection around the circumference of the structure

Clip of appropriate size

Visualising the curved tip of Maryland around &beyond the structure

No cross clipping

Feeling of tactile snap when the clip latched

Placement of clip at 90 degrees to the structure

Examination of the ligated site after clip application to ensure security & proper closure (28).

A number of studies have concluded the safety, efficacy of endoclips is comparable to that of endoloops but has significantly shorter operative time(29,30). Adequate laparoscopic training, experience and dexterity are required for the application of endoloops which could be time consuming, whereas the

application of endoclips is much simpler, quicker and comparably efficient and cost effective(31).

Since the safety, efficacy and shorter operative time of the endoclips has been established over endoloops, through this study we aimed at comparing the two endoclips widely used in laparoscopic surgeries i.e. Liga Clips and H-o-L for CAS in LA.

This RCT was conducted in Dr. PK Hospital, Belagavi, and 60 patients diagnosed with appendicitis without complications undergoing LA were considered during a period of one year duration. In a cohort of 60 patients, they were divided into two groups of 30 each; Group A in whom Liga Clips were used and Group B in whom Hem-o-Lok was used for appendiceal stump closure. Various outcomes were then compared among the two groups.

As far as demographic data is concerned, there was no significant difference between the two groups in the distribution of the patients based on gender. The male to female ratio was almost equal in the two groups (1:1 in group A & 1:0.83 in group B). In either of the groups, major proportion of the patients belonged to 21 to 30 years age group which is consistent with previous literature. However it was found unlikely to affect the outcome of this study. Similarly comorbidities didn't seem to affect the post op outcomes in the two groups.

Based on the clinical diagnosis, majority of the patients in both the groups (80 and 70% respectively in group A and B) were diagnosed and undertaken for surgery for Acute appendicitis.

The primary outcome recorded in this study was the operative time which was considered from the time of complete skeletonisation of the appendix to the time when the specimen is retrieved from the 10mm port. This time was noted to be shorter in group B cases probably due to the ease with which the H-o-L along with its applicator was handled, the reassuring lock engagement system and hence fewer number of clips used. Though this finding did not reach a point of statistical significance a notable difference in the operative time was seen in favour of H-o-L clips.

With the progression of this study and the practice & experience gained by the surgeon over time, it was noted that the ease of passing either of the clips along with their applicators became more feasible, the clip drop rates decreased. However the number of clips used for the stump closure decreased significantly subsequently in group B using H-o-L probably because of the sense of security, which the surgeon developed over the study period. This factor also helps to cut down on the cost of the clips as well as the operative time as fewer of them are used.

When the postoperative events are compared there was no significant difference between the two groups in regards to complications like stump leak or intra-abdominal abscess or need for reoperation as none of these were recorded in either of the groups.

CONCLUSION

In conclusion, the use of both endoclips like Liga Clips and Hem-o-Lok for CAS in LA is quicker, safe, secure and feasible technique in cases of appendicitis (Acute or Chronic) without increased risk of complications. In our experience, it was found that Hem-o-Lok is more efficient in securing the appendiceal stump due to it's lock engagement system giving a sense of security and ease of application.

SUMMARY

Appendiceal stump closure during laparoscopic appendectomy is a most important step as stump leak may result in life threatening events. Recent studies have established the use of endoclips simpler and quicker in comparison to pre tied extracorporeal knots, as special laparoscopic skills are not required and hence seamlessly adapted. Hence this study aimed to compare the outcomes on application of the two endo clips Liga clips and Hem-o-Lok in LA for CAS.

In this randomised controlled trial a total of 60 patients diagnosed with appendicitis without complications planned for LA were enrolled for the study. They were divided into two groups, A & B, of 30 each. Liga Clips were used for CAS in group A and Hem-o-Lok in group B and operative time, intra-op and post op events were recorded.

In the results of this study, the mean operative time (time from skeletonisation of appendix to retrieval of the appendix) in group A was noted to be 376.03 seconds (~6.27 minutes) and that in group B was noted to be 345.50 seconds (~5.75 minutes)(p~0.2873). Hence suggesting both modalities are quick and easy to use.

None of the patients enrolled in the study developed stump leak or intra- abdominal abscess and none of them had to undergo reoperation. More so implying no increased risk of postoperative complication.

Also, with the progression of this study and the practice & experience gained by the surgeon over time, it was noted that the ease of passing either of the clips along with their applicators became more feasible, the clip drop rates decreased. However the number of clips used for the stump closure decreased significantly subsequently in group B using H-o-L probably because of the sense of security, which the surgeon developed over the study period, owing to the lock engagement system of H-o-L. This

factor also helps to cut down on the cost of the clips as well as the operative time as fewer of them are used.

Hence concluding, the use of both endoclips like Liga Clips and Hem-o-Lok for CAS in LA is quicker, safe, secure and feasible technique in cases of appendicitis (Acute or Chronic) without increased risk of complications. In our experience, it is suggested that Hem-o-Lok is more efficient in securing the appendiceal stump due to it's lock engagement system giving a sense of security and ease of application.

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ANNEXURE I

INFORMED CONSENT

<u>Title of Research Study</u>:A ONE YEAR RANDOMISED CONTROL TRIAL TO COMPARE APPENDICEAL STUMP CLOSURE TECHNIQUE WITH LIGA CLIPS v/s HEM-O-LOK IN LAPAROSCOPIC APPENDECTOMY IN KLE'S DR PRABHAKAR KORE HOSPITAL, BELAGAVI.

Principal Investigator: -
DR. ________________
Professor & Head,
Department Of General Surgery,
J. N. Medical College, BELAGAVI.

Co-investigator:-
DR. _______________
Post Graduate Student,
Department Of General Surgery,
J. N. Medical College, BELAGAVI.

<u>INTRODUCTION AND PURPOSE</u>: You are requested to participate in a study that is an attempt to find out the effectiveness of Liga clips in comparison to Hem-o-Lok in Appendiceal stump closure in Laparoscopic Appendectomy.Although the surgical technique of laparoscopic appendectomy has been well established, concerns & controversy exists regarding the closure of appendiceal stump, which is a key point in the procedure. Therefore, several modifications to the original technique with new materials have been introduced for optimizing and controlling the appendiceal stump closure. Controversies about the efficacy and safety of the materials still exist, and the need to evaluate this through new research has become important.

In an effort to solve the above mentioned problems, this study has been undertaken to evaluate the efficacy of alternate techniques of Appendiceal stump closure using Liga Clips and Hem-o-Lok. About 60 patients with appendicitis will be enrolled in this study.

This study will be conducted by Dr. ———————, Post Graduate in Department of Surgery, under the direct supervision and guidance of Dr. ___, Professor, Department of Surgery, J. N. Medical College, BELAGAVI.

You need to be eligible, meeting all the selection criteria to participate in this study. You should be willing to provide information about yourself. 60 subjects will be enrolled in this study who will then be randomized in either of 2 groups (details below).

PROCEDURE: If you agree to participate in this study, you will be randomly allotted into a group (A or B) and accordingly receive treatment with either Liga Clips or Hem-o-Lok. Intra operatively, the operative time, position of the appendix & complications will be noted along with any other problems faced during surgery. Postoperative complications will be noted until you are discharged.

BENEFITS: The benefits of the procedure under study are early recovery time, better cosmesis& minimum complications.

RISKS: There is no additional risk compared to the standard treatment.

COMPENSATION: Taking part in the study will not affect the cost of treatment i.e. it will be similar to the cost of standard procedure. In the event that you become injured as a result of taking part in this study, treatment will be offered to you or you will be given information about where to receive medical care: but you/your insurance company will be responsible for the costs. However, no reimbursement, compensation or free medical care will be given.

CONFIDENTIALITY: Every effort will be made to protect the confidentiality of the information you provide. This means that the researchers will not let anyone, not a part of the study, see the information you provide. Only Dr. Pronoti Patil and Dr. A.S.

Gogate will have access to the information collected. Results of this study may be published but your name will not be revealed.

VOLUNTARY PARTICIPATION / WITHDRAWAL: Taking part in this study is voluntary; you may choose not to enroll in this study. Your decision will not change the present or future health care services offered to you at KLES Dr. Prabhakar Hospital, BELAGAVI. The alternative that you have is to undergo the traditional procedure that is carried out in KLES Hospital.

If you have any queries about the study, you may contact Dr. __________ or Dr. __________ If you need any further information regarding your rights as a study participant, you may also contact the Chairman of Institutional Ethics Committee, JNMC, BELAGAVI.

Consent for participation in research trial

I, Mr. /Ms/Mrs. ________________________________ voluntarily agree for the participation as a subject of study. By signing this consent form I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name : ______________________

Signature or the Left Thumb Print of Subject: _______________________

Date:

Witness Name : ______________________ Signature: ________________

Date:

Investigators Name: ___________________ Signature: ________________

Date:

Place : ________________

ANNEXURE II.

PROFORMA

"A ONE YEAR RANDOMISED CONTROL TRIAL TO COMPARE APPENDICEAL STUMP CLOSURE TECHNIQUE WITH LIGA CLIPS v/s HEM-O-LOK IN LAPAROSCOPIC APPENDECTOMY IN KLE'S DR PRABHAKAR KORE HOSPITAL, BELAGAVI."

Name & Address of the patient: ___________________________________

Age of the Patient:

IP. No. ___________________

Weight of Patient: _________________ Sex.

Anaesthesiologist: _________________ Surgeon: _________________

PRE OPERATIVE EVALUATION:

Chief Complaints:

Past History:

- History of
- Diabetes Mellitus:- YES/NO
- Hypertension:- YES/NO
- Asthma:- YES/NO
- PREVIOUS SURGERIES:- YES/NO
- Drug Therapy: YES/NO

Family History

General Physical Examination:

Weight:	Temperature:	Height
Pallor:	Present/ Absent	Cyanosis: Present/ Absent
Pedal Oedema:	Present/ Absent	Clubbing: Present/ Absent
Pulse :	B.P:	RR:

<u>SYSTEMIC EXAMINATION</u>:

Cardiovascular System:

Respiratory System:

Per Abdomen:

Central Nervous system:

Spine assessment:

<u>INVESTIGATIONS</u>:

Hb%: Urine Routine:

Any Other:

USG Abdomen & Pelvis:

Diagnosis:

Proposed Surgery

Inclusion Criteria:

1. Diagnosed Appendicitis cases, willing for Laparoscopic Appendectomy.
2. Age between 18 to 60 years.
3. Clinically diagnosed as Appendicitis without complications.

Exclusion Criteria:

1. Patients with acute perforated appendicitis and local or diffuse peritonitis will be excluded from the study.
2. Patients found to have gangrenous appendiceal stump intra operatively.
3. Patients who do not consent to participate in the study.
4. Patients with bleeding disorders.

Observations:

Readings were recorded in the following manner:

Group: ____.

Age: **Sex: Male/ Female**

Operative time:

Localization of Appendix:

Intraoperative Complications:

Postoperative Complications:

Other findings:

Any other problems faced:-

Signature of staff in charge:

ANNEXURE III.ETHICAL CLEARANCE

K.L.E.UNIVERSITY'S

JAWAHARLAL NEHRU MEDICAL COLLEGE,

NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)

(Accredited 'A' Grade by NAAC)

Website: http//www.jnmc.edu
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Phone: (+ 91-(0)831 Office : 2471350
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 11 **Date: 22/11/2017**

To,

PG student in Surgery,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"ACUTE ABSCESS MANAGEMENT – A PROSPECTIVE 1-YEAR SINGLE – CENTRIC RANDOMIZED CONTROL TRIAL FOR COMPARISON BETWEEN PRIMARY CLOSURE OF SUPREFICIAL ABSCESS VERSUS HEALING OF ABSCESS BY SECONDARY INTENTION",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

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