"COMPARISSION OF EFFICACY BETWEEN NON ABSORBABLE POLYMER CLIPS AND ENDOLOOP LIGATION FOR APPENDICULAR STUMP CLOSURE DURING LAPAROSCOPIC APPENDICECTOMY"

BY

Dr. SAILESH KUMAR S

DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, TAMAKA, KOLAR,KARNATAKA.

In partial fulfilment of the requirements for the degree of

M.S. GENERAL SURGERY

UNDER THE GUIDANCE OF

Prof. DR. KRISHNA PRASAD K

PROFESSOR

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SRI DEVARAJ URS MEDICAL COLLEGE

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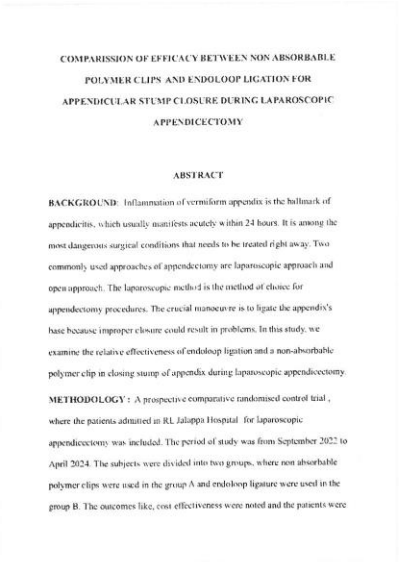

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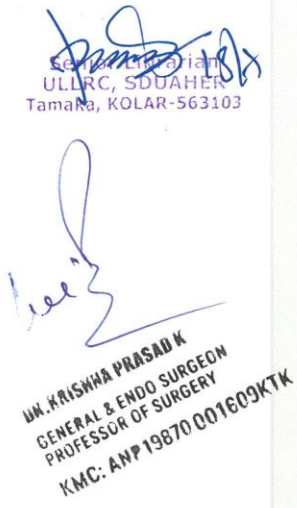
ABSTRACT

BACKGROUND: Inflammation of vermiform appendix is the hallmark of appendicitis, which usually manifests acutely within 24 hours. It is among the most dangerous surgical conditions that needs to be treated right away. Two commonly used approaches of appendectomy are laparoscopic approach and open approach. The laparoscopic method is the method of choice for appendectomy procedures. The crucial manoeuvre is to ligate the appendix's base because improper closure could result in problems. In this study, we examine the relative effectiveness of endoloop ligation and a non-absorbable polymer clip in closing stump of appendix during laparoscopic appendicectomy.

METHODOLOGY : A prospective comparative randomised control trial , where the patients admitted in RL Jalappa Hospital for laparoscopic appendicectomy was included. The period of study was from September 2022 to April 2024. The subjects were divided into two groups, where non absorbable polymer clips were used in the group A and endoloop ligature were used in the group B. The outcomes like, cost effectiveness were noted and the patients were



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COMPARISSION OF EFFICACY BETWEEN NON ABSORBABLE POLYMER CLIPS AND ENDOLOOP LIGATION FOR APPENDICULAR STUMP CLOSURE DURING LAPAROSCOPIC APPENDICECTOMY ABSTRACT BACKGROUND: Inflammation of vermiform appendix is the hallmark of appendicitis, which usually manifests acutely within 24 hours. It is among the most dangerous surgical conditions that needs to be treated right away. Two commonly used approaches of appendectomy are laparoscopic approach and open approach. The laparoscopic method is the method of choice for appendectomy procedures. The crucial manoeuvre is to ligate the appendix's base because improper closure could result in problems. In this study, we examine the relative effectiveness of endoloop ligation and a non-absorbable polymer clip in closing stump of appendix during laparoscopic appendicectomy. METHODOLOGY : A prospective comparative randomised control trial , where the patients admitted in RL Jaiappa Hospital for laparoscopic appendicectomy was included. The period of study was from September 2022 to April 2024. The subjects were divided into two groups, where non absorbable polymer clips were used in the group A and endoloop ligature were used in the group B. The outcomes like, cost effectiveness were noted and the patients were regularly followed up for any post op complications like intra-abdominal abcess , post operative pain and Surgical site infection.Time taken to apply non absorbable polymer clips / endoloop ligatures were noted and questionnaire was given to the surgeons performing the surgery to know how convineient each technique was. RESULTS : The surgeons were asked to score the ease of each technique from 1-3 , 1 being hard , 2 being moderately hard and 5 being very easy.The average score for applying non absorbable polymer clip was , and the average score for applying endoloop ligature was . The P value for this comparison was , indicating there is no much significant difference in ease of technique. The second entity of comparison between these 2 techniques was time taken to apply non absorbable polymer clip and endoloop ligature. Applying an endoloop ligature took an average of 5.16 minutes, while applying a non-absorbable polymer clip took 4.63 minutes.The average time taken to apply each approach varied significantly, as indicated by the P value of less than 0.05 for this comparison. The cost-effectiveness served as the third comparison entity. Two non-absorbing polymer clips were utilized in group A to ligate the closure of the appendicular stump. Each clip costed about 700 rupees, summing up 1400 rupees for each patient. In group B, 2 knots were made using polyglactin (vicryl 2-0 rb) ,each costing 800 rupees , summing up 1600 rupees per patient . The P value was zero, indicating that there is no discernible difference in the average cost between both the groups because the cost remained the same for every patient in each group.The 4th entity for the comparison was post operative complications. The patients were kept under observation for intra- abdominal abscesses, surgical site infections, fecal fistula, wound dehiscence and post-operative discomfort. The post operative pain was assessed using the VAS score.The average post operative pain score in group A where non absorbable polymer clips were used was 2 , and the average post operative pain score in group B , where endoloop ligature were used was 3 . The average pain score after surgery did not differ significantly, as indicated by the P value of 1 for the comparison mentioned above. Three of the thirty-three patients in group A, where non-absorbable polymer clips were used, experienced surgical site infections, and five of the thirty-three patients in group B, where endoloop ligatures were utilized, experienced the same outcome. Wound dehiscence was noted in one case where endoloop ligature was used and no cases of wound dehiscence was observed in non absorbable polymer clips group. There were no incidences of fecal fistula in both the groups. There was no significant difference in post operative hospital stay also. CONCLUSION: The amount of time required to apply the non-absorbable polymer clip was significantly less than that required to apply the endoloop ligature, which contributed to a shorter intraoperative stay.Use of non- absorbable polymer clips can be considered inlaparoscopic appendicectomy , to effectively reduce the intra operative time period. INTRODUCTION INTRODUCTION The inflammation of the vermiform appendix is the hallmark of appendicitis, which usually manifests acutely within 24 hours. It still remains as one of the most serious surgical illnesses requiring immediate surgical treatment.1 Even the most skilled surgeons may struggle to diagnose patients who appear with a variety of clinical symptoms.2 Early detection avoids consequences including perforation and the development of an abscess and gangrene thereby reducing the postoperative complications and hospital stay.3,4 Even with improvements in the management of acute appendicitis with antimicrobial therapy, surgery remains the main treatment option for acute appendicitis. An appendicectomy is the gold standard of care for a case of acute appendicitis.5 Two commonly used approaches of appendectomy are laparoscopic approach and open approach.5 The laparoscopic method is the method of choice for appendectomy procedures. The laparoscopic method is used to perform the majority of simple appendectomies.6 There are well-established procedures for laparoscopic appendectomy, and ligation of the appendix's base is a crucial move since improper closure can result in problems like severe postoperative pain, surgical infections, and stump appendicitis. 7 Appendicular stump closure has been accomplished thus far using a variety of methods, such as ligation by surgical knots, Endoloop Ligature, surgical clips, endoscopic staplers, and others.8 The ideal method should be safe, easily applicable and cheap. As a quicker and less expensive alternative, a non-absorbable polymer clip was demonstrated.9 Here, using this study, we compare the Efficacy between a non-absorbable polymer clip & endoloop ligation for closing stump of appendix during laparoscopic appendicectomy . AIM & OBJECTIVES AIM & OBJECTIVES Study's aim & objectives include: 1) To study efficacy of non absorbable polymer clips in terms of: • Ease of

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Dr. SAILESH KUMAR S

LIST OF ABBREVATIONS

SSI	surgical site infection
USG	ultrasound sonography
CT	computed tonography
MRI	magnetic resonance imaging
RB	round body
VAS	visual analogue scale

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METHODOLOGY : A prospective comparative randomised control trial , where the patients admitted in RL Jalappa Hospital for laparoscopic appendicectomy was included. The period of study was from September 2022 to April 2024. The subjects were divided into two groups, where non absorbable polymer clips were used in the group A and endoloop ligature were used in the group B. The outcomes like, cost effectiveness were noted and the patients were regularly followed up for any post op complications like intra-abdominal abcess , post operative pain and Surgical site infection.Time taken to apply non absorbable polymer clips / endoloop ligatures were noted and questionnaire was given to the surgeons performing the surgery to know how convineient each technique was.

RESULTS : The surgeons were asked to score the ease of each technique from 1-3 , 1 being hard , 2 being moderately hard and 5 being very easy.The average score for applying non absorbable polymer clip was , and the average score for applying endoloop ligature was . The P value for this comparison was , indicating there is no much significant difference in ease of technique. The second entity of comparison between these 2 techniques was time taken to apply non absorbable polymer clip and endoloop ligature. Applying an endoloop ligature took an average of 5.16 minutes, while applying a non-absorbable polymer clip took 4.63 minutes.The average time taken to apply each approach varied significantly, as indicated by the P value of less than 0.05 for this comparison. The cost-effectiveness served as the third comparison entity. Two non-absorbing polymer clips were utilized in group A to ligate the closure of the appendicular stump. Each clip costed about 700 rupees, summing up 1400 rupees for each patient. In group B, 2 knots were made using polyglactin (vicryl 2-0 rb) ,each costing 800 rupees , summing up 1600 rupees per patient .

The P value was zero, indicating that there is no discernible difference in the average cost between both the groups because the cost remained the same for every patient in each group.The 4th entity for the comparison was post operative complications. The patients were kept under observation for intra-abdominal abscesses, surgical site infections, fecal fistula, wound dehiscence and post-operative discomfort. The post operative pain was assessed using the VAS score.The average post operative pain score in group A where non absorbable polymer clips were used was 2 , and the average post operative pain score in group B , where endoloop ligature were used was 3 . The average pain score after surgery did not differ significantly, as indicated by the P value of 1 for the comparison mentioned above.

Three of the thirty-three patients in group A, where non-absorbable polymer clips were used, experienced surgical site infections, and five of the thirty-three patients in group B, where endoloop ligatures were utilized, experienced the same outcome.

Wound dehiscence was noted in one case where endoloop ligature was used and no cases of wound dehiscence was observed in non absorbable polymer clips group.

There were no incidences of fecal fistula in both the groups.

There was no significant difference in post operative hospital stay also.

CONCLUSION: The amount of time required to apply the non-absorbable polymer clip was significantly less than that required to apply the endoloop ligature, which contributed to a shorter intraoperative stay.Use of non-absorbable polymer clips can be considered inlaparoscopic appendicectomy , to effectively reduce the intra operative time period.

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INTRODUCTION

INTRODUCTION

The inflammation of the vermiform appendix is the hallmark of appendicitis, which usually manifests acutely within 24 hours. It still remains as one of the most serious surgical illnesses requiring immediate surgical treatment.[1]

Even the most skilled surgeons may struggle to diagnose patients who appear with a variety of clinical symptoms.[2] Early detection avoids consequences including perforation and the development of an abscess and gangrene thereby reducing the postoperative complications and hospital stay.[3]

Even with improvements in the management of acute appendicitis with antimicrobial therapy, surgery remains the main treatment option for acute appendicitis. An appendicectomy is the gold standard of care for a case of acute appendicitis.[4] Two commonly used approaches of appendectomy are laparoscopic approach and open approach.[5] The laparoscopic method is the method of choice for appendectomy procedures. The laparoscopic method is used to perform the majority of simple appendectomies.[6]

There are well-established procedures for laparoscopic appendectomy, and ligation of the appendix's base is a crucial move since improper closure can result in problems like severe postoperative pain, surgical infections, and stump appendicitis. [7]

Appendicular stump closure has been accomplished thus far using a variety of methods, such as ligation by surgical knots, Endoloop Ligature, surgical clips, endoscopic staplers, and others.[8]

The ideal method should be safe, easily applicable and cheap. As a quicker and less expensive alternative, a non-absorbable polymer clip was demonstrated.[9]

Here, using this study, we compare the Efficacy between a non-absorbable polymer clip & endoloop ligation for closing stump of appendix during laparoscopic appendicectomy .

AIM & OBJECTIVES

AIM & OBJECTIVES

Study's aim & objectives include:

1) To study efficacy of non absorbable polymer clips in terms of:

- Ease of technique
- Time taken to apply clips
- Cost effectiveness
- Post op complications like post operative pain , SSI , wound dehiscence , faecal fistula and intrabdominal abscess.

2)To study the efficacy of endoloop ligature in terms of:

- Ease of technique
- Time taken to apply ligature
- Cost effectiveness
- Post op complications like post operative pain , SSI , wound dehiscence , faecal fistula and intrabdominal abscess.

3) To compare the efficacy of a Non absorbable polymer clip and endoloop ligature in appendicular stump closure during a laparoscopic appendicectomy.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

ANATOMY

Situated at ileocecal valve, appendix is a real diverticulum that emerges from the posteromedial caecal boundary. Near the point where taenia coli converge, into caecum, is where the base of the appendix can be found. [10]

The Anatomical name is "Appendix Vermiformis". In Latin it means "worm-like," refers to its lengthy, tubular structure. [11]

In 1710, Verneys was the first to use the phrase "vermiform appendix".[12]

All of colon's layers, which is mucosa, submucosa, longitudinal & circular muscularis propria, & serosa, are present in this actual diverticulum.

Appendicular mucosa and submucosa have B & T lymphoid cells which is necessary for the histological separation of the appendix from the colon.[13]

The appendix can range in length from 5 to 35 cm. The development of B cells and the synthesis of IgA antibodies are mediated by lymphoid tissue in appendix. It is thought to play a role in immunity because lamina propria contains gut-associated lymphoid tissue.[14]

FIGURE 1 : HISTOLOGY OF APPENDIX

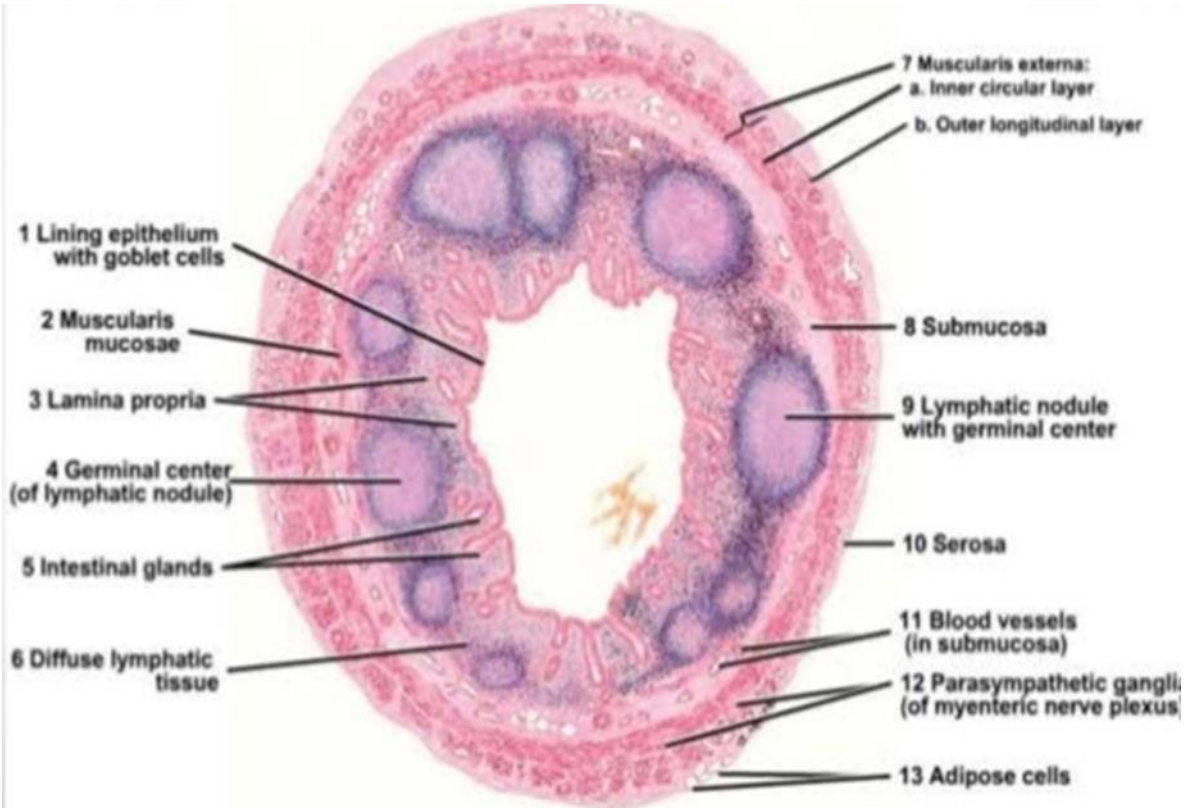
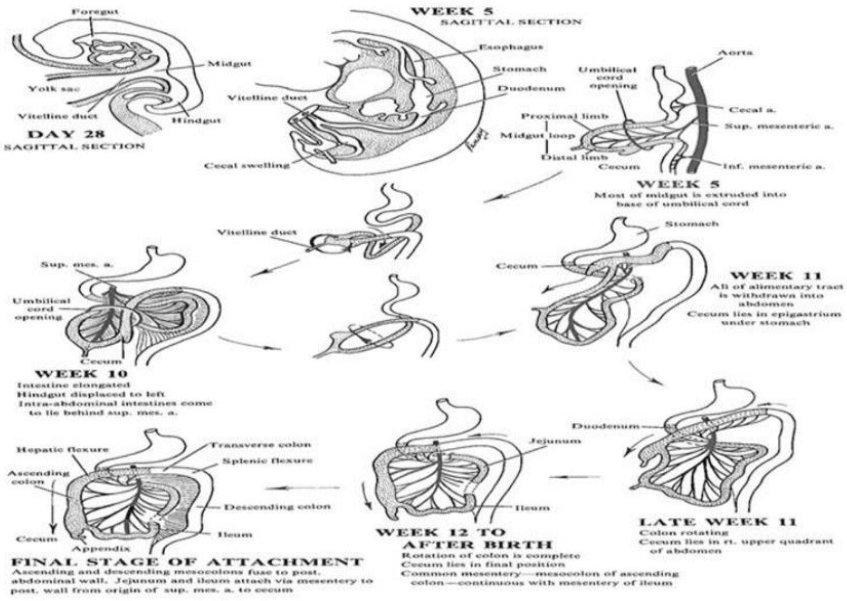


FIGURE 2 : EMBRYOLOGY OF APPENDIX

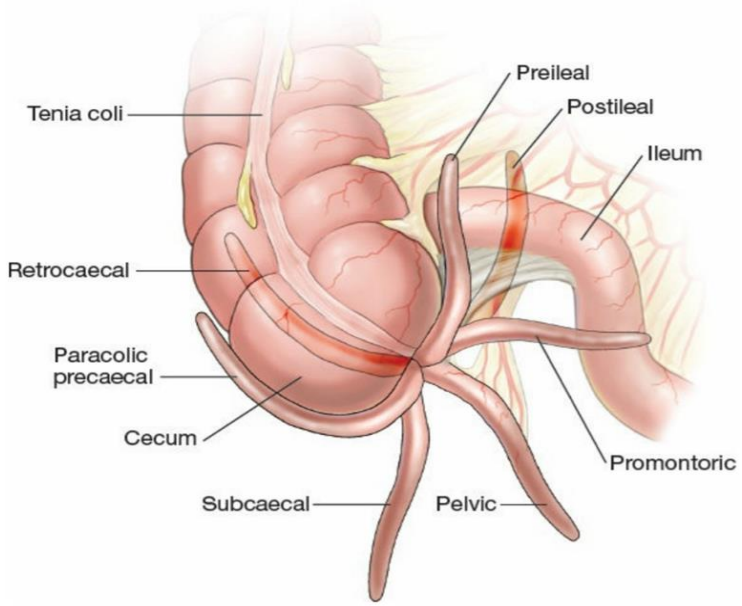
Midgut gives birth to the appendix. In week six, the cecal diverticulum emerges, which is precursor to cecum & appendix. Histologically, appendix is detectable in 8th week of gestation. Together with colon's elongation, cecum and appendix rotate medially, then descend into right lower abdomen. Appendix takes on different positions as it is forced ahead of cecum. Mucosa generates lymphoid tissue in weeks 14 and 15, which supports its role in immunity.[15]

FIGURE 2 : EMBRYOLOGY OF APPENDIX



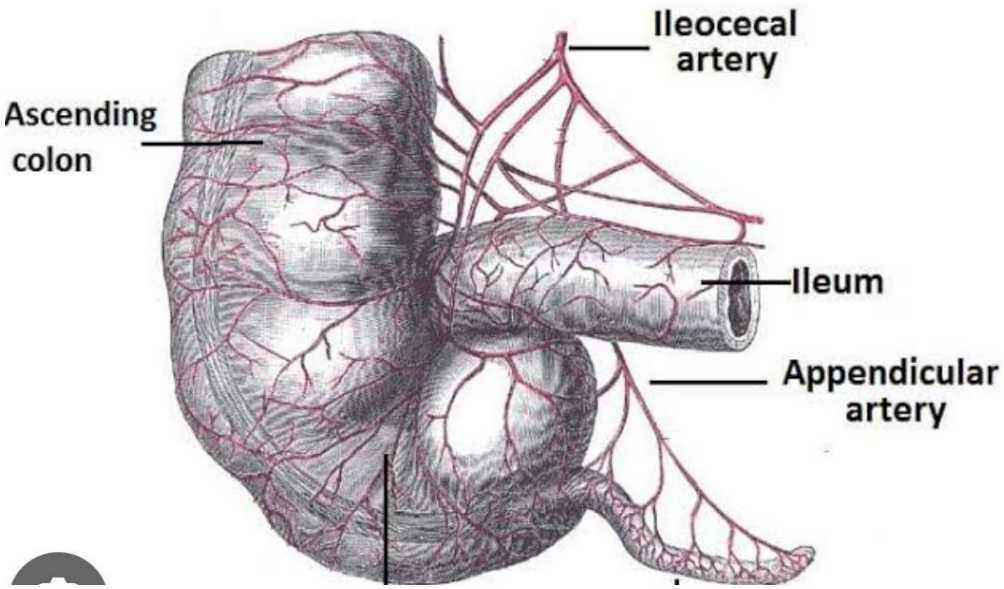
Appendix is found in various positions as depicted below. Retrocecal position is a most common position of appendix.[16]

FIGURE 3 : DIFFERENT ANATOMICAL POSITIONS OF APPENDIX



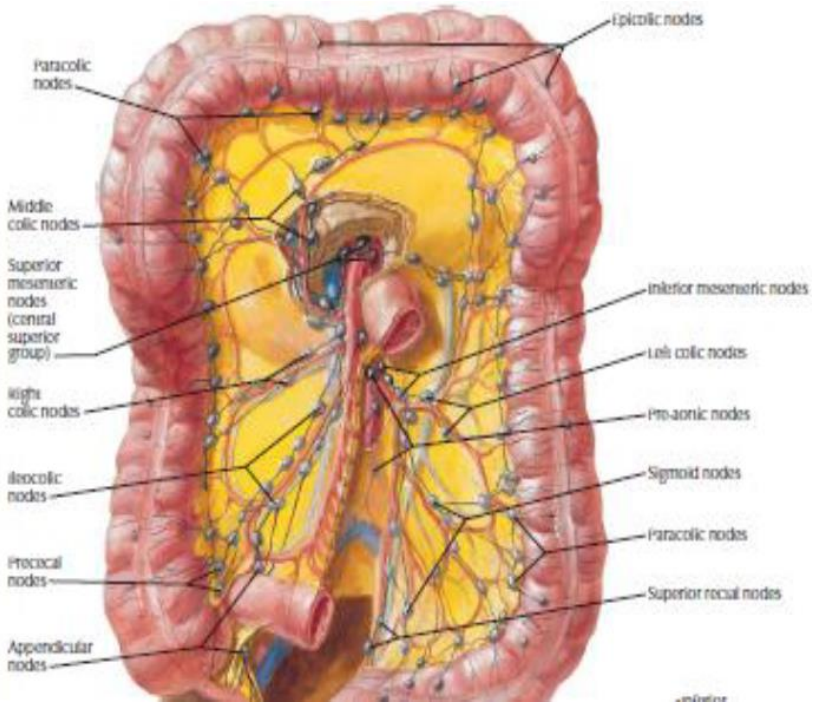
Appendicular artery, a branch of ileocecal artery, which is one of the branches of superior mesenteric artery, supplies blood to appendix.[17]

FIGURE 4 : ARTERIAL SUPPLY OF APPENDIX



Ileocolic lymph nodes receive lymph from appendix, which then drains to superior mesenteric nodes.[18]

FIGURE 5 : LYMPHATICS OF APPENDIX



Superior mesenteric plexus supplies the appendix's autonomic innervation. At T10, sympathetic nerve fibers carrying afferent sensory fibers from the appendix enter the spinal cord.[19]

ETIOPATHOGENESIS

Inflammation of appendix is appendicitis. Reginald Fitz discovered the appendix to be the main source of inflammation in right lower quadrant in 1886. He suggested early surgical treatment of the condition and created the name appendicitis.[20]

For men, lifetime rate of appendecitis is twelve percentage, whereas for women it is twenty-five percentage. This most common condition is encountered in patients in 2^{nd}-4^{th} decades of life is appendicitis.[21]

Luminal obstruction is the cause of appendicitis. The are several causes of luminal obstruction, amongst them, the most common cause is fecal stasis and fecaliths. In younger age groups, lymphoid hyperplasia is more frequently the cause of blockage. As intraluminal pressure rises above perfusion pressure, ischemia damage occurs. This promotes bacterial overgrowth and sets off an inflammatory reaction.[22]

The stimulation of visceral afferent fibers occurs when the appendiceal wall becomes inflamed. The classical diffuse periumbilical pain and nausea associated with development of appendicitis are caused by the fibers entering spinal cord at T8–T10. The parietal peritoneum becomes inflamed as inflammation worsens, stimulating the somatic nerve fibers and resulting in localized discomfort.[23] Location is determined by where the appendix's tip is located.

For instance:

• The patient may experience right flank pain due to a retrocecal appendix, which is triggered by extending their right hip. "Psoas sign" refers to pain felt by the patient when they are in the left lateral decubitus position and their hip extends, extending their iliopsoas muscle. [24]

• McBurney's sign is an additional discovery. The abdominal wall is palpated at this location to trigger this.[24]

- Rovsing's sign is seen in classic appendicitis with tip in retrocaecal position, where pain felt on right iliac fossa on palpation of left iliac fossa.[24]
- Obturator sign is when pain is felt on internal rotation of right hip due to impingement on inflamed obturator internus.[24]

Other clinical signs are:

- BLUMBERG'S SIGN (REBOUND TENDERNESS)- When compression is released over Mc Burney's point, patient cries out in agony or winces. This may indicate appendicitis-related inflammation of parietal peritoneum. This is not necessary if there is guarding. This test reveals peritoneal inflammation brought on by an inflammatory organ beneath the skin.[25]
- POINTING SIGN- On asking about the progression and radiation of pain, the patient points that the pain initially was at the umbilicus and then has shifted to the right lower quadrant at present. This migration of pain is called as Volkovich Kocher's sign.[24]

  Acute appendicitis symptoms include fever, nausea, vomiting, and a increased white blood cell count.

TYPES OF APPENDICITIS:-[26]

1) ACUTE NON-OBSTRUCTIVE APPENDICITIS:

In acute non obstructive appendicitis, there is no luminal obstruction but there is mucosal inflammation followed by secondary infection. Its sequelae can be resolution, fibrosis, recurrent appendicitis or obstructive appendicitis. Finally, obstructive appendicitis occurs when the bacteria translocates from submucosa to muscularis propria. As appendicular artery is an end artery, inflammation may lead to thrombosis of appendicular artery which causes necrosis and gangrene starting at the tip of appendix. Lymphoid hyperplasia can also be seen to cause obstructive appendicitis.

2) ACUTE APPENDICITIS - OBSTRUCTIVE

Fecolith is the commonest cause of obstructive appendicitis, being 40% in acute appendicitis,65% in gangrenous appendicitis and more than 90% in perforated cases. Other causes include lymphoid hyperplasia, foreign objects, such as seeds, infestations of roundworms or pinworms, etc.

3) RECURRENT APPENDICITIS

Fibrosis and adhesions from recurring episodes of non-obstructive appendicitis result in recurrent episodes of appendicitis.

4) SUBACUTE APPENDICITIS

It is an acute appendicitis that is less severe.

5) STUMP APPENDICITIS

Infection of the left-out stump if a long stump is left behind after appendicectomy.

Laboratory results should be utilized to corroborate the clinical picture and should be interpreted cautiously in cases of suspected appendicitis. Eighty percent of cases have leukocytosis, frequently with a "left shift."[27]

Urinalysis is mostly normal but there may be pyuria or trace leucocyte esterase due to vicinity of appendix with bladder. Isolated positive urinalysis does not rule acute appendicitis.[28]

Appendicitis is diagnosed by a range of radiographic investigations, including MRI, CT, USG & plain radiographs.

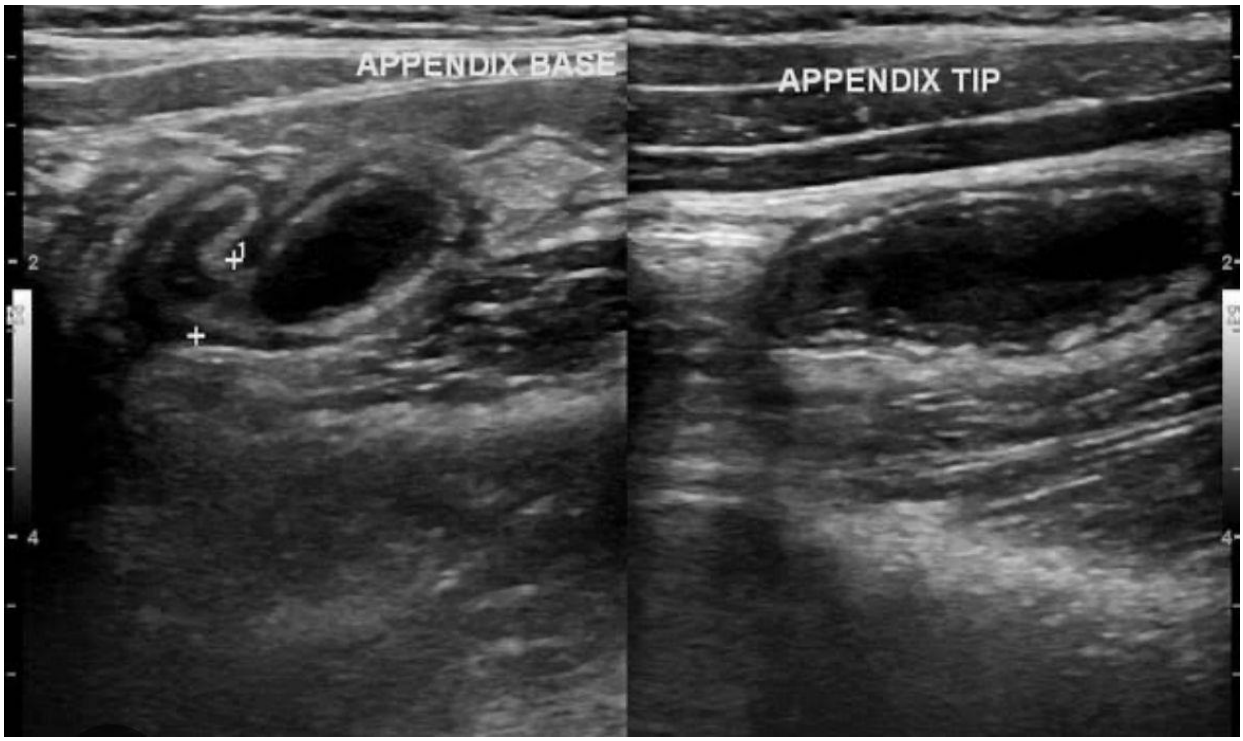
Plain radiographs have a low sensitivity & specificity A calcified fecolith in right iliac fossa is a finding that lends credence to the diagnosis.[29]

Most common imaging technique for diagnosing acute appendicitis is USG. Gradient compression is administered to collapse normal surrounding intestine and reduce interference caused by overlying intestinal gas after the USG probe is introduced to the painful location. Usually, an inflammatory appendix is noncompressible, swollen, and immovable.

The USG will reveal the following symptoms:

- Tender spot
- Non-compressible, blind-ending tubular structure
- Diameter more than or equal to 7 mm
- Absence of peristalsis
- Lith producing an acoustic shadow
- High echogenicity, non-compressible surrounding fat
- Surrounding fluid / abscess
- Edema of caecal pole

FIGURE 6 : USG IMAGE OF APPENDICITIS



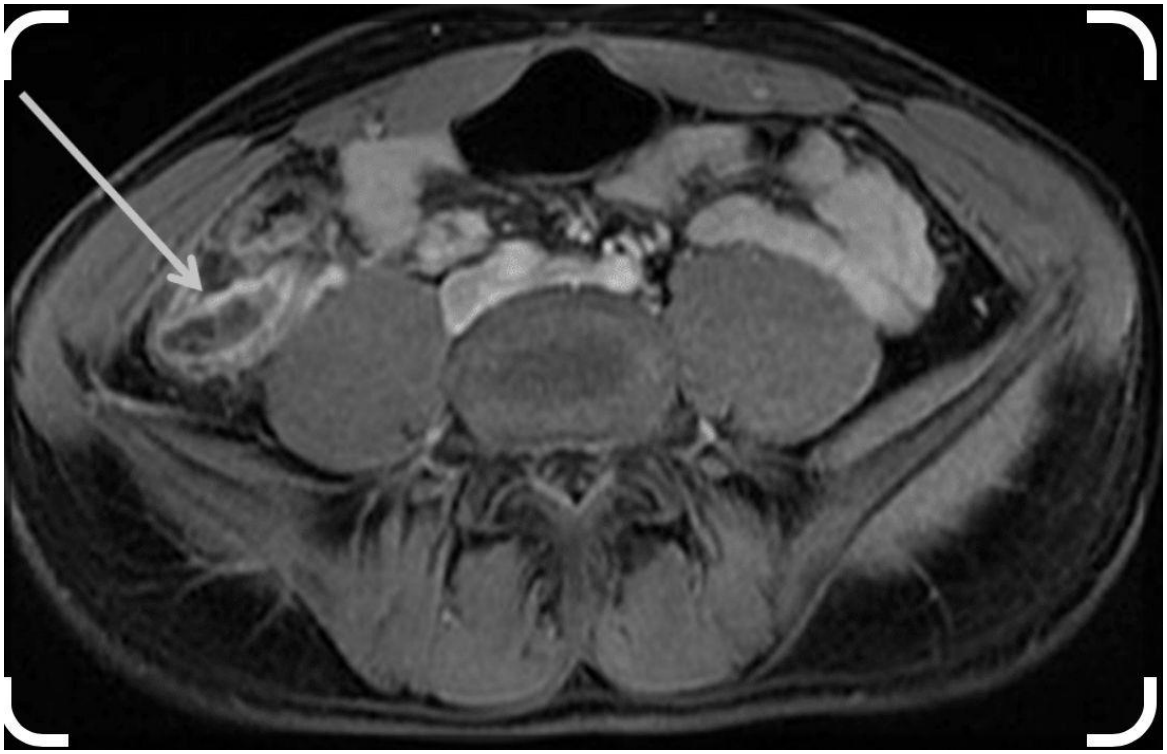
CT scans are simple to interpret and independent of the operator. CT has a 91–9% specificity and a sensitivity of 90–100%. When an enlarged, inflammatory appendix with surrounding "stranding" appears on CT, acute appendicitis is diagnosed. The appendix, also known as a "target sign," is usually more than 7 mm in diameter and has an inflammatory, thickened wall with mural enhancement. The absence of inflammatory signs on CT scans or the nonvisualization of the appendix indicate the absence of appendicitis. [31]

FIGURE 7 : CT IMAGE OF APPENDICITIS

MRI is typically used in the pregnant patients without any usage of contrast agents. The diagnosis of appendicitis with MRI is highly accurate and has good resolution. Diagnosis of acute appendicitis is by presence of inflammation, thickness of more than 2 mm, and appendiceal enlargement of more than 7 mm.

MRIs have a 100% sensitivity and a 98% specificity. The benefits of MRI include operator independence and very good outcomes. MRI's drawbacks include motion artifact, high expense, and significant difficulty for non-radiologists to understand results.[32]

FIGURE 8 : MRI IMAGE OF APPENDICITIS



An urgent appendicectomy is the recommended course of treatment for acute appendicitis. Fluid resuscitation should be performed on the patient, and intravenous broad-spectrum antibiotics that target gram-negative and anaerobic organisms should be started right away.[33]

A clinical grading system called Alvarado score is employed in diagnosis of appendicitis. Six clinical items and one laboratory measurement make up the score's nine points. [34]

1-4: Acute appendicitis highly unlikely

5-6: Maybe acute appendicitis, for observation.

7-8: probably acute appendicitis, operate.

9-10: definitely acute appendicitis, operate.

FIGURE 9 : ALVARADO SCORE

The Alvarado Score	
Signs	
Right lower quadrant tenderness	2
Elevated temperature (>99.1 F)	1
Rebound tenderness	1
Symptoms	
Anorexia	1
Nausea or vomiting	1
Migration of pain to right lower quadrant	1
Laboratory Values	
Leukocytosis (>10,000 WBC)	2
Left shift (>75% neutrophils)	1

Emergency appendectomy is mainly of 2 approaches:

- Open appendectomy
- Laparoscopic appendectomy

OPEN APPENDECTOMY:

In the supine posture, the patient is put. The surgeon's preference will determine which incision is used; typically, the McArthur-McBurney incision is an oblique muscle-splitting incision. [35]

Other incisions are :[36]

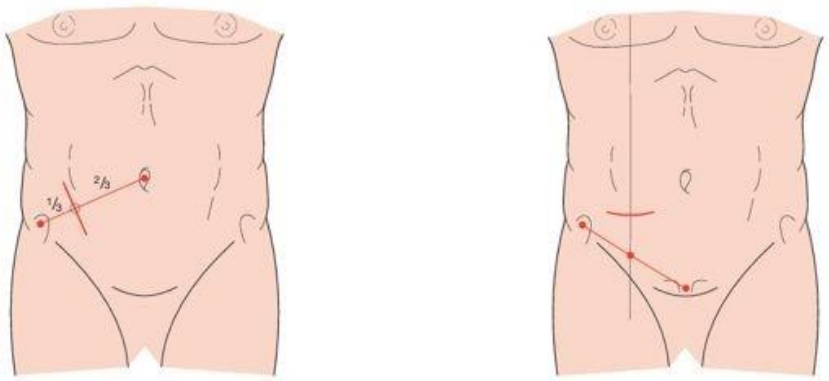
1. Gridiron incision: The gridiron incision, which McArthur originally described, is centered along the line which connects the anterior superior iliac spine to umbilicus and is put at a right angle to that line.

2. Lanz Incision: From 2 centimeters below umbilicus centering on midclavicular – midinguinal line, incision is performed onto the patient.

3. Rutherford Morison's Incision: Helpful when appendix is at paracaecal or retrocaecal. With its lower end covering McBurney's point & extending obliquely upwards & laterally as needed - oblique muscle-cutting incision.

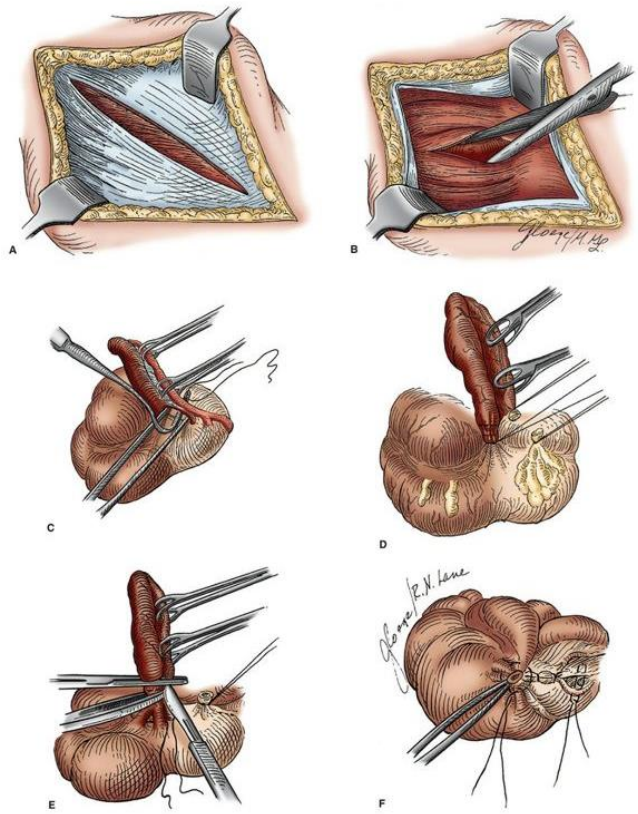
4. Lower midline incision: Utilized when, diagnosis is unclear, especially in cases where intestinal obstruction is present.

FIGURE 10 : A) MCBURNEY INCISION B) LANZ INCISION



On entering the peritoneal cavity, cecum is initially held by the taeniae and then brought into the wound, which allows clear picture of the base of appendix at convergence of tenia and delivery of tip of appendix. mesoappendix is then identified, divided & the base of appendix is transfixed, ligated with an absorbable suture, and divided. The appendiceal stump is chemically cauterized or inverted by purse-string / Z suture technique. Then, the peritoneal wash is given and the wound is closed in layers.[37]

FIGURE 11 : STEPS OF OPEN APPENDICECTOMY



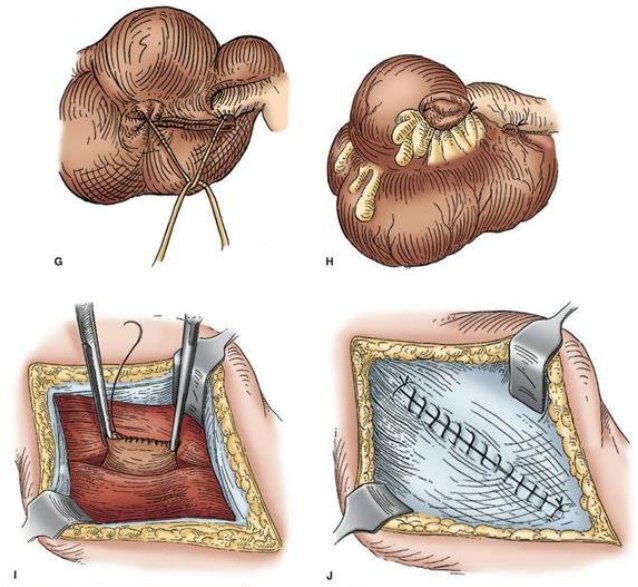


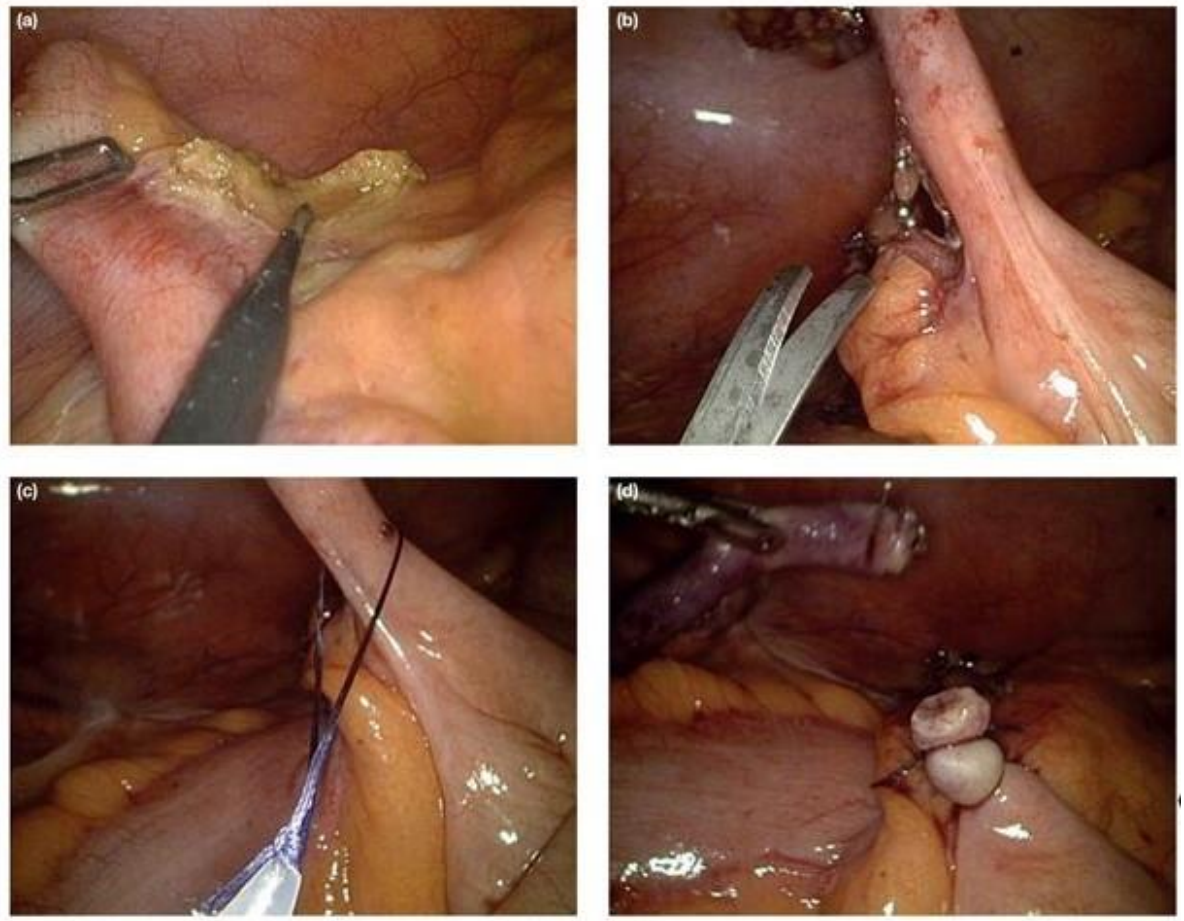
FIGURE 41-7 Open appendectomy technique.

LAPAROSCOPIC APPENDECTOMY

It is more commonly used nowadays than open technique. Advantages include better visualisation of abdomen and pelvis, faster recovery, less hospital stay, less wound infections, reduced pain and analgesic use, cosmetically better scar.

In the supine posture, the patient is put. A foley's catheter is used to empty the bladder, or the patient can void right before operation. The laparoscope is inserted during surgery to confirm the diagnosis, and the abdomen is entered at the umbilicus. Next, two more functioning ports are positioned in the suprapubic region and/or supraumbilical midline, as well as in left lower iliac fossa.It is advantageous for surgeon & assistant to stand on left side of patient with patients left upper limb tucked , as this position allows optimum triangulation of the camera and working instruments. Appendix is then elevated using atraumatic graspers and the mesoappendix is identified and carefully divided using the harmonic scalpel. Finally, the base is then secured and the appendix is finally divided. This process is done by burying the appendix stump into the cecum or by suture ligating the appendix base without inversion in open surgery.[38]

FIGURE 11 : STEPS OF LAPAROSCOPIC APPENDICECTOMY



The appendicular base is ligated in laparoscopic appendectomy using various methods which include:

- ligation by surgical knots
- Endoloop Ligature
- surgical clips
- endoscopic staplers

Retrieval of the appendix is usually done by the usage of a plastic retrieval bag. Then pelvic wash is given and the trocars are removed.The incisions are closed.[39]

Laparoscopic appendectomy in highly advanced centers are performed with single-site laparoscopic surgical technique.[40]

COMPLICATIONS OF LAPAROSOPIC APPENDICECTOMY[41]:

- bowel injury and blood vessels near ports
- Pneumoperitoneum
- Cautery injury
- Bleeding
- Perforation leading to peritonitis
- Slipping of base ligature leading to leak, peritonitis or fistula formation
- Stump appendicitis

During surgery, the base is secured by Endoloop ligature or by surgical knots. A non-absorbable polymer was proven technique which is less costly & faster.

Delibegovic'et al. proposed one prospective randomised trial which compared safety, operative time & difference in cost between three methods. Ninety patients were allotted to following groups

- Group one: base of appendix was secured using 1 Endoloop ligature
- Group two: base of appendix was secured using using a 45-mm stapler
- Group three: base was secured using only one non absorbable polymer clip.

Study conclusion was use of one non absorbable polymer clip was equally safe as Endoloop / stapler; but, time of procedure using non absorbable polymer clip was lesser in comparison with Endoloop, with cost being lowest.[42]

Hue et al. did one prospective randomized trial from May 2010 to August 2011. 105 patients were included in study. In 66 patients endoloop was used and non-absorbable polymer clip

for 39 patients. The aim was to investigate usefulness and safety of non-absorbable polymer clip for closing stump of appendix & its disadvantages. Conclusion of study was use of non-absorbable polymer clip for appendicular stump closure during lap appendicectomy is "easily available, safe, fast & less costing procedure" in patients with a mild to moderately inflamed base of less than 10 millimetre in diameter.[43]

Colak et al. proposed one prospective randomised trial, where 53 patients were divided into either non absorbable polymer clip or Endoloop groups. Twenty-six patients in non-absorbable polymer clip group and twenty-seven patients in Endoloops group. Aim is to evaluate clinical outcomes of non-absorbable polymer clip ligature method in laparoscopic closure of stump of appendix by comparing it to Endoloop method. Conclusion of study was mean surgery time was shorter for non-absorbable polymer clip group compared to Endoloop group; however, difference was not significant. Other findings are similar. Appendicular stump closure with non-absorbable polymer clip for laparoscopic appendectomy is a cheaper & simpler method .[44]

In the year 2016, Soll et al. observed the study where 813 patients who underwent laparoscopic appendicectomy. Non absorbable polymer clip was used in 435 patients for closing stump of appendix and Endoloop ligation was used in 378 patients. Aim was to identify how many cases developed intra-abdominal abscesses in non-absorbable polymer clip group and compare it with Endoloop ligature group. Study concluded that appendiceal stump closure using non-absorbable polymer clip showed lesser rate of intra-abdominal abscesses .[45]

Lucchi et al. in the year 2016 did one retrospective study which had 259 patients. Aim was to check safety & asses usefulness of non-absorbable polymer clip in closing stump of appendix, and comparing these data to Endoloop group. Endoloop ligature was used in 121

patients while non absorbable polymer clip was used in 138 patients. They concluded that both the Endoloop and non-absorbable polymer clip were safe for closing stump of appendix. But, non-absorbable polymer clip was to be better than Endoloop ligation in reference to easeness & cost while maintaining safety.[46]

Samuel Ho Ting Poon et al conducted a study which revealed that, While both non absorbable polymer clip and Endoloop ligation gives a safe and promising complication profile, the use of non-absorbable polymer clip shows a comparative state to endoloop ligation in terms of operative time and benefit on the complication profile. It is a reasonable alternative to endoloop ligature When taking financial and technical aspects into consideration.[47]

MATERIALS AND METHODS

MATERIALS AND METHODS

SOURCE OF DATA: Department of Surgery, R.L.Jalappa Hospital & Research Centre, Sri Devaraj Urs Medical College, Tamaka, Kolar.

STUDY POPULATION: Patients diagnosed with Appendicitis in R.L. Jalappa Hospital & Research Centre, Tamaka, Kolar, attached to Sri Devaraj Urs Medical College.

INCLUSION CRITERIA:

1. All cases of appendicitis undergoing laparoscopic appendicectomy

2.Patients between the age of 21-70 are included (arbitrary number)

EXCLUSION CRITERIA:

1. Perforated and gangrenous appendix.

2. Appendicular mass.

3.Incidental appendicectomy

DURATION OF STUDY: From September 2022 to August 2024

STUDY DESIGN: Prospective study

SAMPLING TECHNIQUE: Convenient sampling

SAMPLING SIZE : 66

MSJ Wilson et al. reported the average operative time was significantly reduced in non-absorbable polymer clip group (59± 13 minutes) than in endoloops group (68±13) minutes.

Assuming alpha error -> 5% (95% Confidence limit), Power > 80%, the ratio polymeric clip: endoloop is 1:1. Presuming standard deviation of the VAS scores to be 13 in both the groups, Minimum required sample size to find the difference in mean operative time between both study group is calculated as 66 subjects (33 subjects in polymeric clip group and 33 in the endoloops group). Sample size was derived using the following formula:

Sample size (n) = $\frac{2{S_p}^2\,[Z_{1-\frac{\alpha}{2}}+Z_{1-\beta}]^2}{{\mu_d}^2}$; ${S_p}^2 = \frac{{S_1}^2+{S_2}^2}{2}$

Where S_1: Standard deviation in group one

S_2: Standard deviation in group two

μ_d: Mean difference between samples

α: Significance level

1-β: Power

METHOD OF DATA COLLECTION:

- Data was collected using proforma, from the patients with appendicitis, complete history was taken, and relevant investigations were done.
- Patients within age group of 21-70 were included
- The purpose of study was explained to them and consent was taken.

- The subjects were divided into two groups based on odd-even method. Non absorbable polymer clips were used in the group A(odd group) and endoloop ligature were used in the group B(even group).
- The outcomes, cost effectiveness was noted.
- The patients were regularly followed up for any post op complications like intra-abdominal abscess using USG abdomen if the patient had symptoms, post operative pain, faecal fistula, Surgical site infection and wound dehiscence.
- Time taken to apply non absorbable polymer clips / endoloop ligatures were noted and questionnaire was given to the surgeons performing the surgery to know how convenient each technique was.
- Scoring of ease of technique :

  1- Difficult

  2- Moderately difficult

  3- Easy

    - The average number of days in hospital post operatively was also calculated in this study.

Following investigations were done to all patients:

- Complete blood picture
- Renal function test
- Se.electrolytes
- Chest radiograph
- USG abdomen and pelvis / CT abdomen and pelvis

Financial burden: All the investigations involved were part of the routine management of appendicitis. Hence it was borne by the patient party.

The costs for the endoloop ligature, non-absorbable polymer clips and the clip applicator were borne by the investigator.

STATISTICAL ANALYSIS:

Data is entered in Microsoft Excel & analysed in Statistical Package for Social Science (SPSS) standard version 20. Socio-demographic & clinical characteristics of patient will be summarized in Mean (SD) for continuous variables & proportions (%) for categorical variables. Comparison of continuous variables (age, BMI, operative time, duration of antibiotics, WBC count, duration of hospital stays) across both groups (polymeric clip group vs endoloops group) will be performed by student's t test. Comparison of categorical variables (sex, ASA score, need for intra-op and post-op antibiotics, intra-op and post-op complications etc.) across study groups will be done using Chi square test. P-value of <0.05 will be considered statistically significant.

GRAPHICAL REPRESENTATION OF DATA:

MS Excel & MS Word were used to obtain graphs such as bar diagrams & pie diagrams. A P value of <0.05 is considered statistically significant.

Statistical software: MS Excel, SPSS Version 22 (IBM, SPSS statistics, somer, NY, USA) were used in analysing data.

ETHICAL CONSIDERATION:

1. Institutional ethical approval was acquired well before the research starts.

2. Before the trial began, every patient who was included provided their informed permission.

3. Throughout the research and follow-up, all patients received the Standard of Care.

FIGURE 12 : NON ABSORBABLE POLYMER CLIP

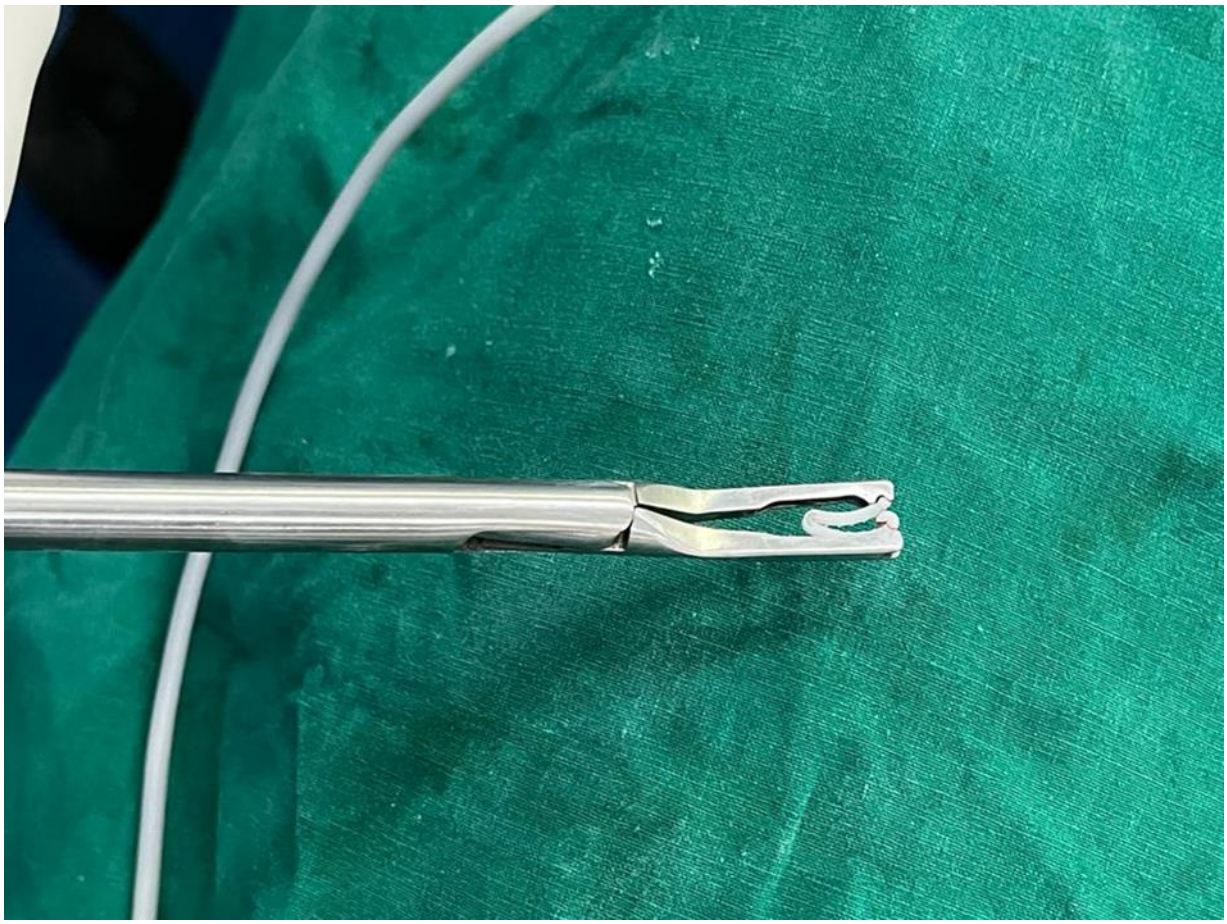
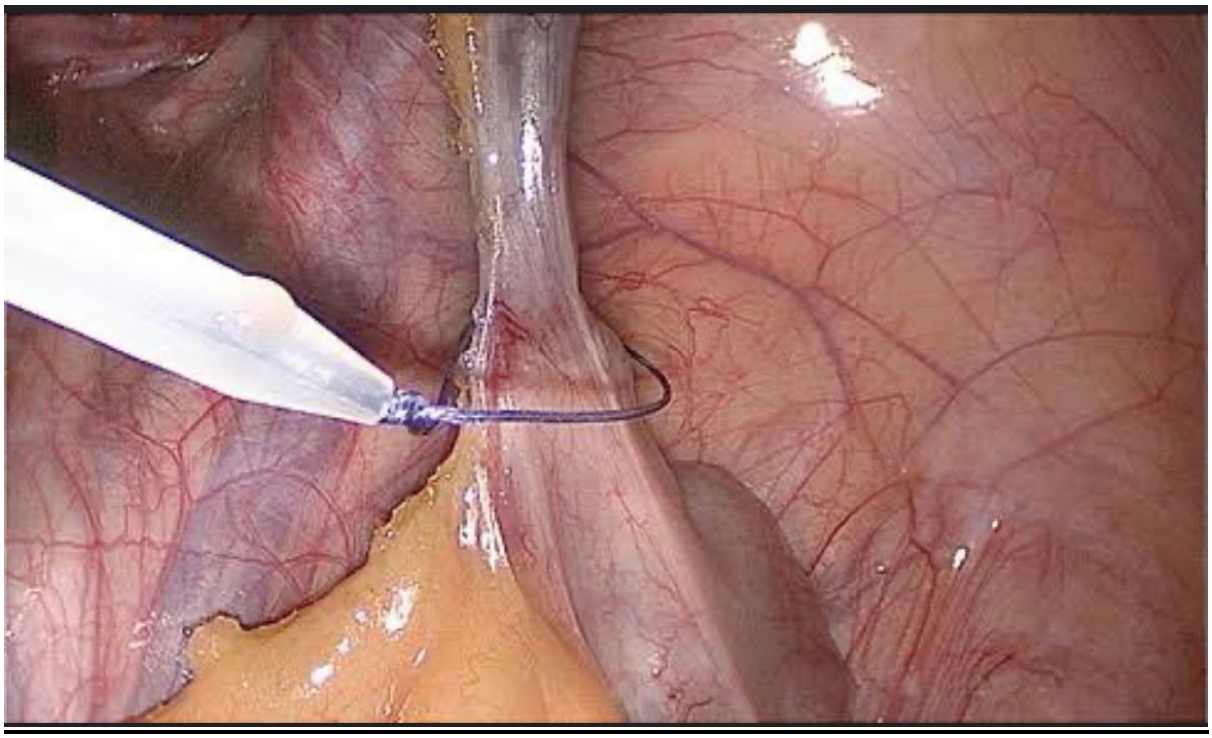


FIGURE 13 : INTR-OP PICTURES OF NON ABSORBABLE POLYMER CLIP

A) 

B) 

FIGURE 14 : INTRA-OP PIC OF ENDOLOOP LIGATURE



RESULTS

RESULTS

TABLE 1 : AGE DISTRIBUTION

AGE	COUNT	PERCENTAGE
21-30	21	31.8 %
31-40	17	25.7 %
41-50	19	28.7 %
51-60	6	0.9 %
61-70	3	0.04 %

The mean age was 29.33, and the majority of patients were in 21-30 age group. (31.8%)

GRAPH 1 : AGE DISTRIBUTION

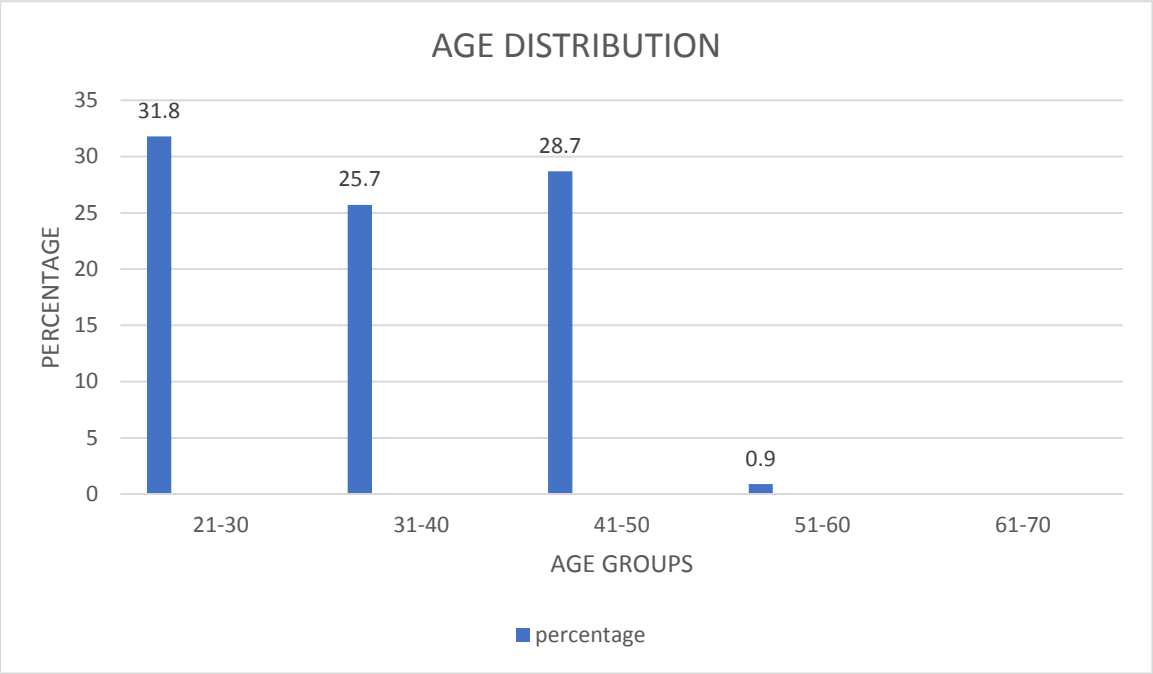


TABLE 2: SEX DISTRIBUTION

SEX	COUNT	PERCENTAGE
Male	37	56%
Female	29	44%

CHART 2 : SEX DISTRIBUTION

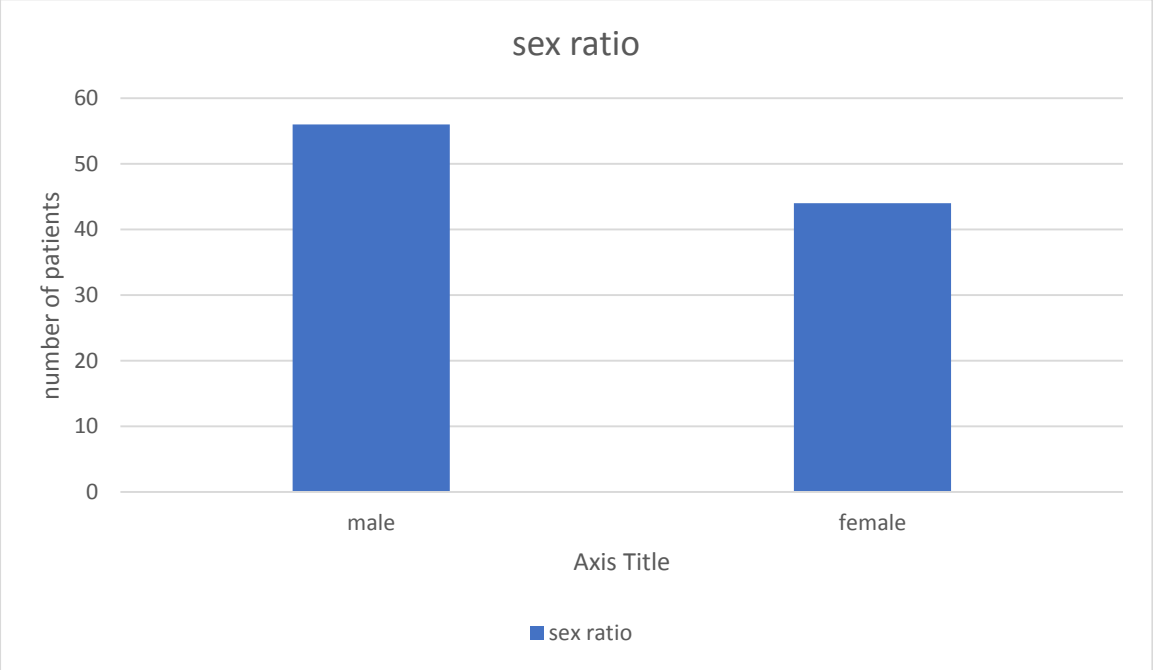


TABLE 3 : ASSOCIATED COMORBIDITIES

CO-MORBIDITIES	COUNT	PERCENTAGE
T2DM	9	13.6%
HTN	11	16.6%
T2DM AND HTN	4	6%
NIL	42	63.6 %
TOTAL	66	100%

CHART 3 : ASSOCIATED COMORBIDITIES

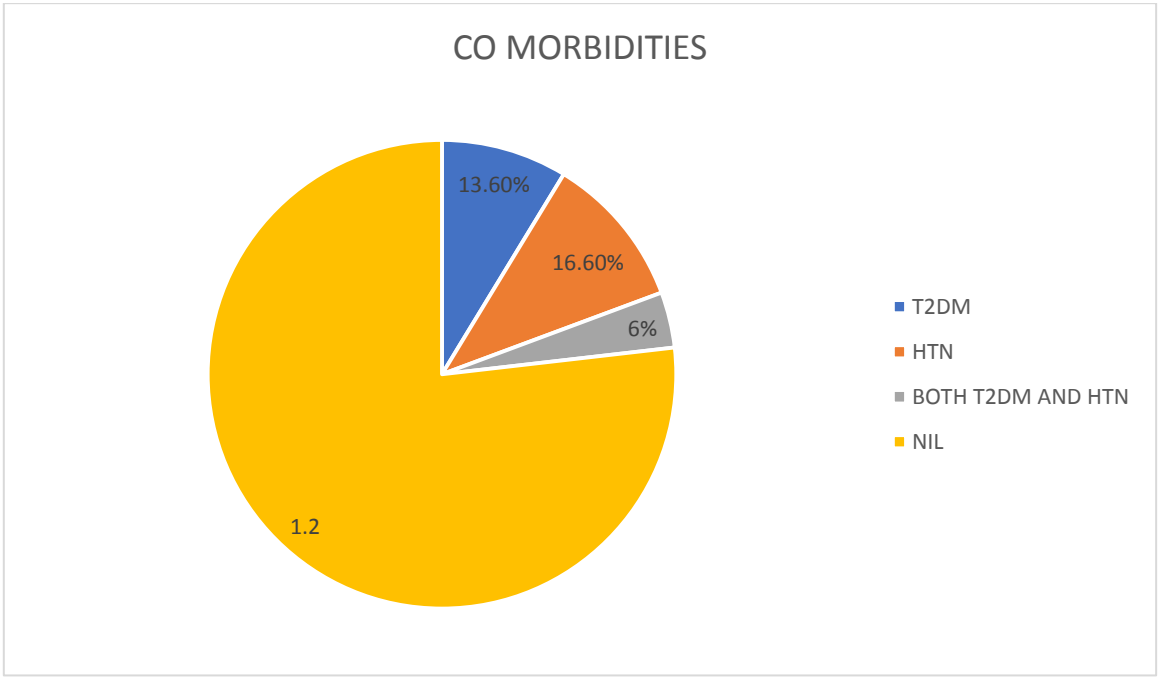


TABLE 4 : MODE OF PRESENTATION

PRESENTATION	COUNT	PERCENTAGE
Acute Appendicitis	32	48.4 %
Recurrent appendicitis	34	51.5 %

GRAPH 4 : MODE OF PRESENTATION

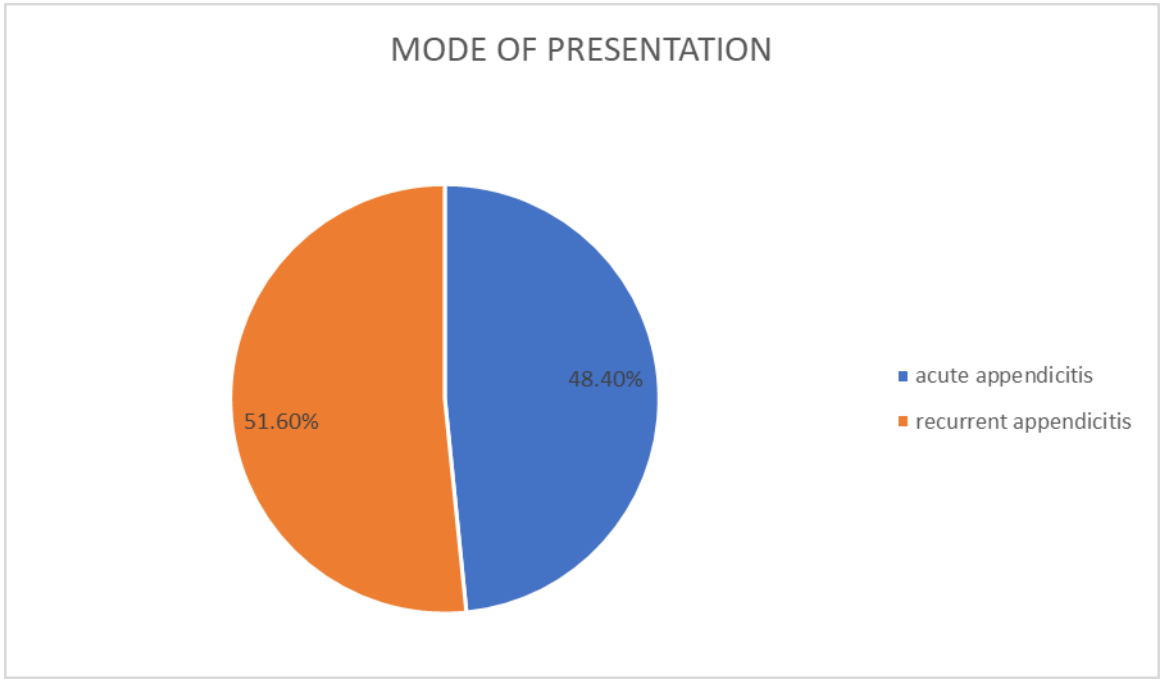


TABLE 5 : INTRA-OP FINDINGS

INTRA OP FINDING	COUNT	PERCENTAGE
Acute appendicitis	47	71.21%
Acute appendicitis with abscess	13	19.69%
Early mass formation	6	9.09 %

GRAPH 5 : INTRA-OP FINDINGS

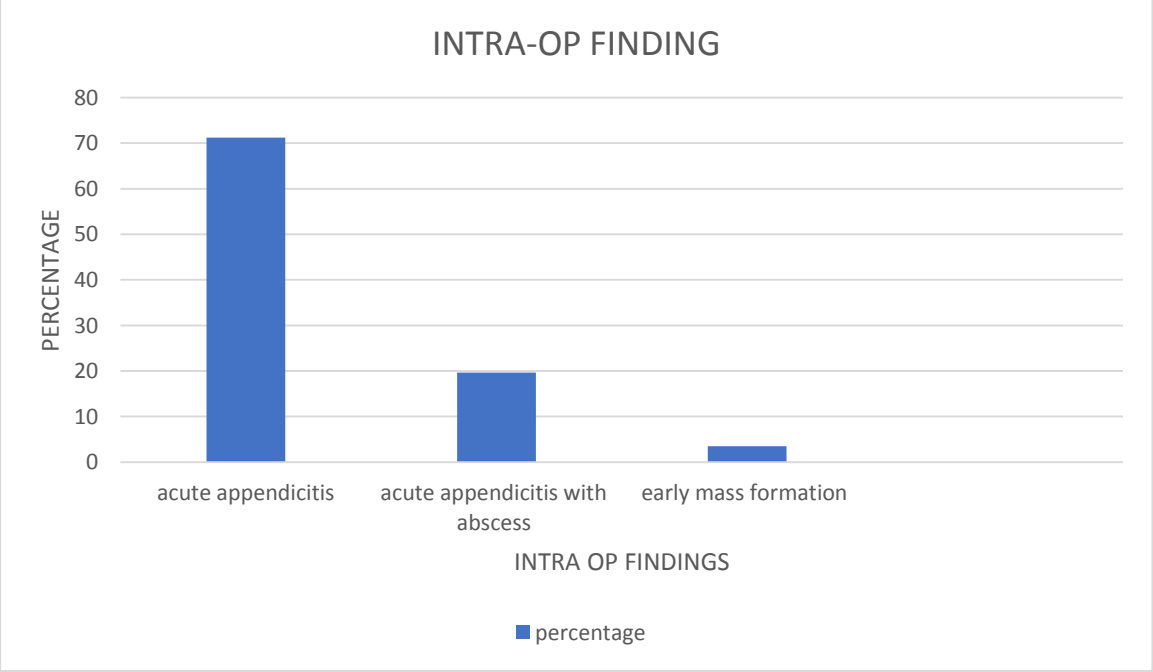


TABLE 6 : DIAGNOSIS AND METHOD USED

DIAGNOSIS	NON-ABSORBABLE POLYMER CLIPS	ENDOLOOP LIGATURE
ACUTE APPENDICITIS	21	11
RECURRENT APPENDICITIS	12	22

GRAPH 6 : DIAGNOSIS AND METHOD USED

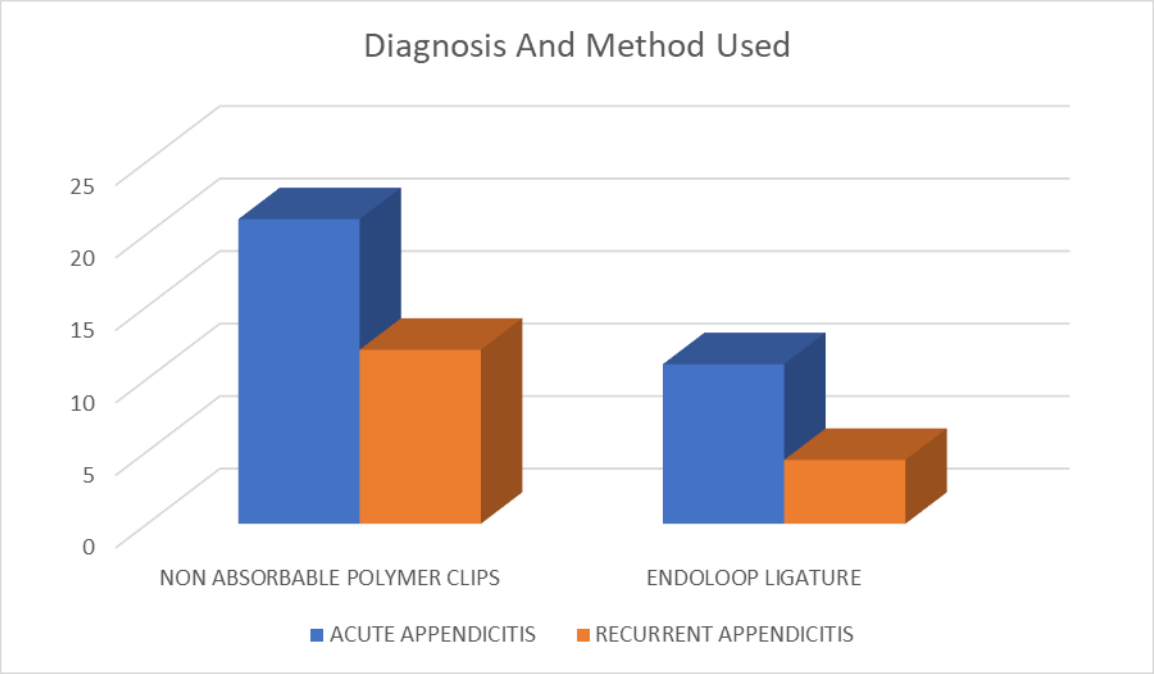


TABLE 7 : EASE OF TECHNIQUE:

The surgeons were asked to score the ease of each technique from 1-5, 1 being hard and 5 being very easy.

SCORE	NON-ABSORBABLE POLYMER CLIP(COUNT)	ENDOLOOP LIGATURE (COUNT)
1	5	9
2	13	14
3	15	10
MEAN:	2.303	2.0303
Standard deviation	1.041	0.758

P Value : 0.228

GRAPH 7 : EASE OF TECHNIQUE

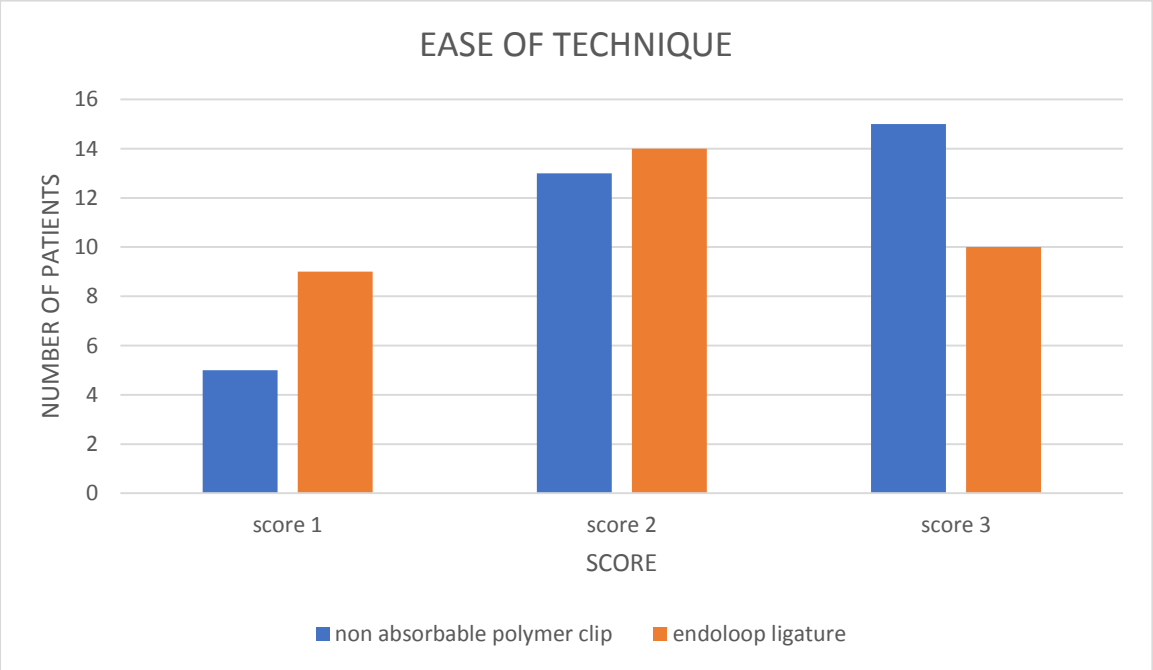


TABLE 8 : TIME TAKEN TO APPLY CLIPS AND ENDOLOOP LIGATURE

GROUP	COUNT	MEAN	STANDARD DEVIATION
Non absorbable polymer clips	33	4.63	0.718
Endoloop ligature	33	5.16	0.688

P VALUE = 0.0037

GRAPH 8 : AVERAGE TIME TAKEN TO APPLY CLIPS AND ENDOLOOP LIGATURE

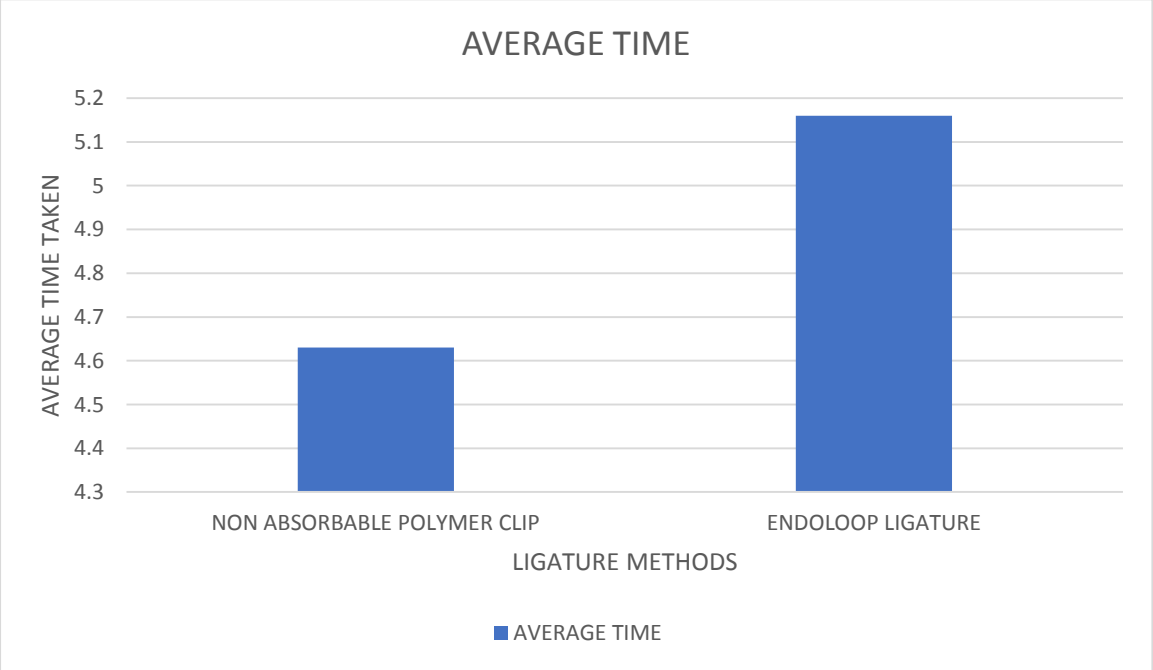


TABLE 8 : COST EFFECTIVENESS

GROUP	COUNT	MEAN COST
Non absorbable polymer clips	33	700x2 = 1400
Endoloop ligature	33	1600

As standard deviation is zero , p value is = 0

GRAPH 8 : AVERAGE COST

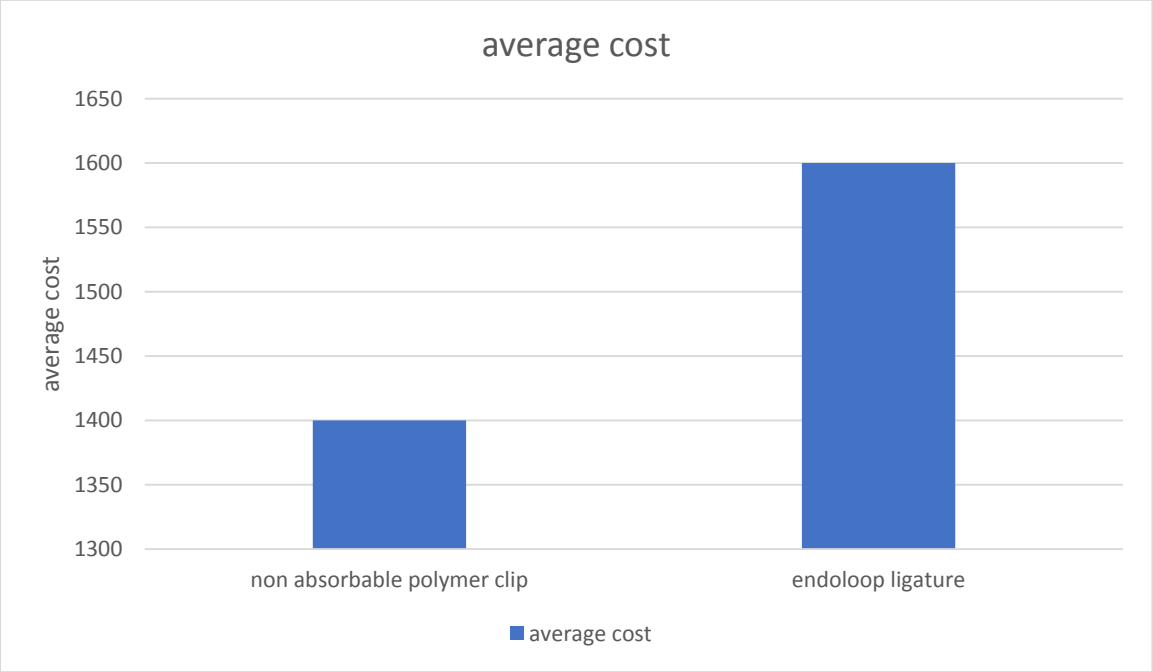
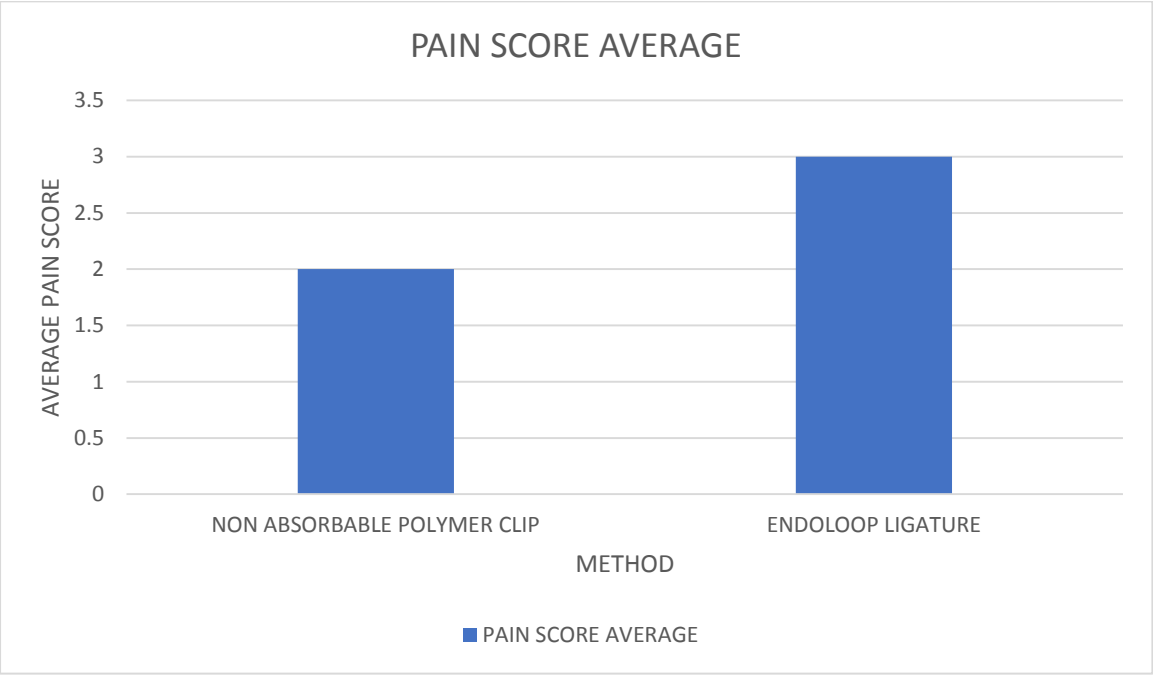


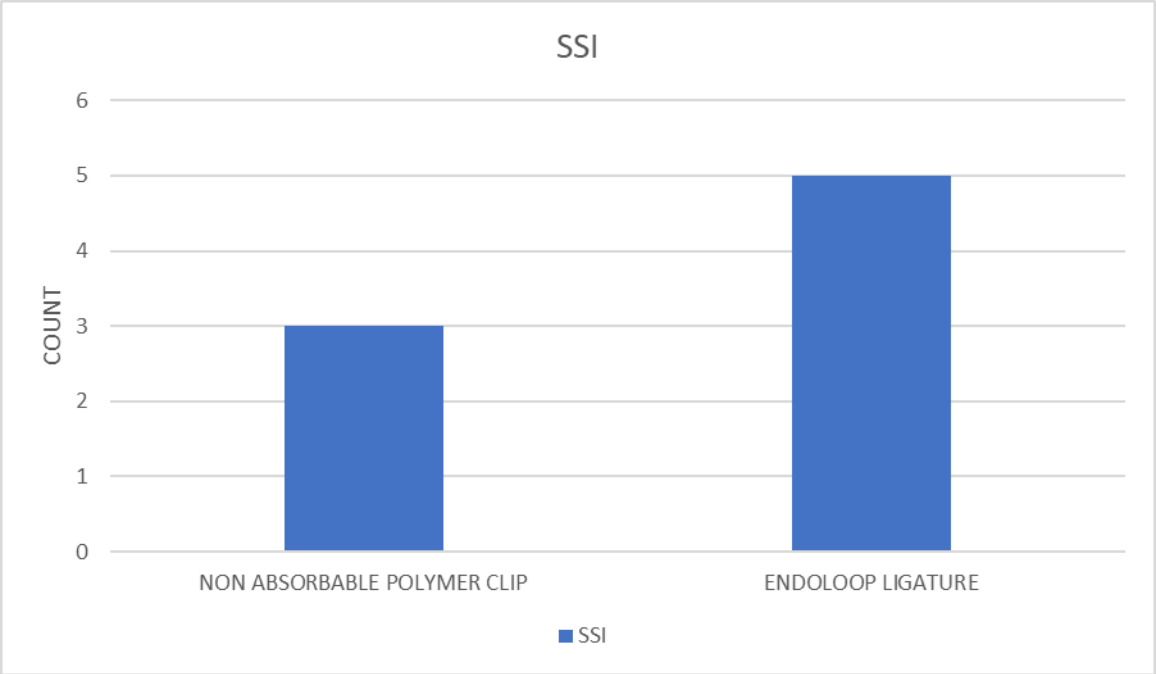
TABLE 10 : COMPLICATIONS

Complications	Method	
	Non absorbable polymer clip	Endoloop ligature
SSI	3(9%)	5(15%)
Faecal fistula	0	0
Post-op pain	2(mean VAS score)	3(mean VAS score)
Wound dehiscence	0	1(3%)
Intra-abdominal abscess	0	0

GRAPH 10 : AVERAGE PAIN SCORE



GRAPH 11 : RATE OF SSI



P VALUE FOR POST OP PAIN IS = 1

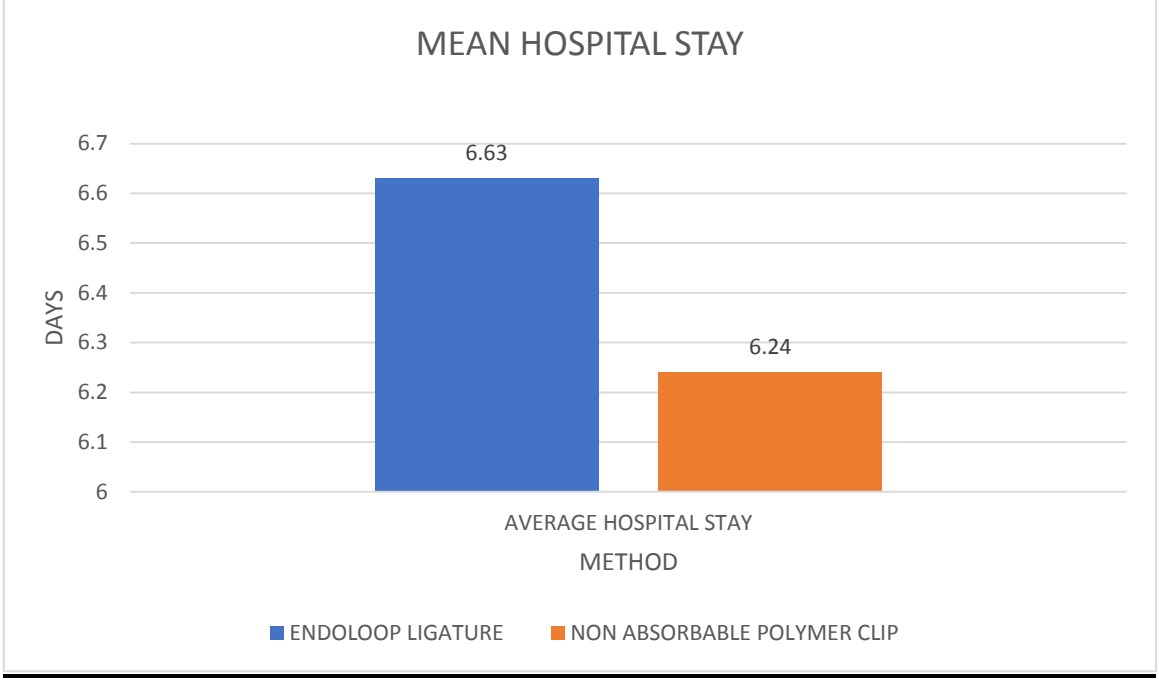
P VALUE FOR SSI = 0.906

TABLE 11: MEAN HOSPITAL STAY

METHOD	MEAN HOSPITAL STAY	STANDARD DEVIATION
Endoloop ligature	6.63 days	1.0855
Non absorbable polymer clip	6.24 days	1.2725

P VALUE : 0.2074

GRAPH 12: MEAN HOSPITAL STAY



DISCUSSION

DISCUSSION

Acute appendicitis is a common surgical emergency condition, and with advancement in technology laparoscopic appendectomy is a commonly chosen technique. base of appendix ligation is a critical maneuver and the various method.

Various techniques used for of base of appendix ligation are by surgical knots, Endoloop Ligature, surgical clips, endoscopic staplers, etc.

Of these, endoloop ligature have been more commonly used now, and is already proven to be better and an easier method when compared to surgical knots.

In this study, we have compared the the efficacy between a non-absorbable polymer clip and endoloop ligature for appendicular stump closure in laparoscopic appendicectomy in terms of Ease of technique,Time taken to apply clips, Cost effectiveness, Post operative complications and mean hospital stay.

Study population is divided into 2 groups, 33 participants in group A, where non absorbable polymer clips were used, 33 participants in group B, where endoloop ligature was used.

In this trial, the average age group of patients is 29.33 and the majority were within the group of 21-30 years.

Majority of the participants in this study were men, 37 males and 29 females participated in the study.

In the study population of 66 patients, 42 patients were free of any comorbidities, 9 had T2DM, 11 had hypertension alone and 4 had both T2DM and hypertension.

Of those 66 participants, 32 patients were cases of acute appendicitis and 34 patients were cases of recurrent appendicitis.

Intraoperatively, 47 patients were diagnosed as uncomplicated appendicitis, 13 patients were diagnosed as appendicitis with abscess and 6 patients were diagnosed as early mass formation.

Of the 32 patients who were diagnosed as acute appendicitis, non-absorbable polymer clips were used in 21 patients and endoloop ligature was used in 11 patients.

Of the 34 patients who were diagnosed as recurrent appendicitis, non-absorbable polymer clips were used in 12 patients and endoloop ligature was used in 22 patients.

The ease of technique of applying non absorbable polymer clip and endoloop ligature in ligation of appendiceal base during laparoscopic appendectomy was assessed using a questionnaire.

According to questionnaire given to the operating surgeons, both non absorbable polymer clip and endoloop ligature, were comparatively easier than the traditional surgical knots.

The surgeons were requested to score the ease of each technique from 1-3, 1 being difficult, 2 being moderately difficult and 3 being easy.

The average score for applying non absorbable polymer clip was 2.303, and the average score for applying endoloop ligature was 2.0303.

The P value for this comparison was 0.228, indicating there is no much significant difference in ease of technique.

The second entity of comparison between these 2 techniques was time taken to apply non absorbable polymer clip and endoloop ligature. The mean time taken to apply non absorbable polymer clip was 4.63 minutes and the meantime taken to apply endoloop was 5.16 minutes.

P value for the above comparison is < 0.05, indicating, there is a significant difference in mean time taken in applying each technique.

The 3rd entity for the comparison was the cost efficacy. In group A, 2 “non absorbable polymer clips” were used to ligate stump of appendix. Each clip costed about 700 rupees, summing up 1400 rupees for each patient. In group B, 2 knots were made using polyglactin (vicryl 2-0 rb),each costing 800 rupees , summing up 1600 rupees per patient .

The P value was zero, indicating that there is no discernible difference in average cost between both groups because the cost remained the same for every patient in each group.

The 4th entity for the comparison was post operative complications. The patients were monitored for post operative pain, SSI, wound dehiscence, faecal fistula and intra-abdominal collection.

The post-surgery pain was assessed using the VAS score.The average post operative pain score in group A where non absorbable polymer clips were used was 2 , and the average post operative pain score in group B , where endoloop ligature were used was 3 .

The P value for the above comparison was 1, indicating there is no significant difference in average pain score post operatively.

Out of 33 patients in group A, where non absorbable polymer clips were used, 3 patients had surgical site infection, and of the 33 patients of group B, where endoloop ligature was used 5 patients had Surgical site infection.

The P value of above comparison is 0.906, indicating that there is no significance in the rate of surgical site infection in both the groups.

One patient in endoloop ligature group developed wound dehiscence and no cases of wound dehiscence was observed in non absorbable polymer clip group.

There were no cases with intra-abdominal abscess and faecal fistula post operatively in both the study groups.

The average number of days the patient was in hospital postoperatively was also calculated in this study. It was found that the average hospital stay for the non-absorbable polymer clip group was 6.24 days , and for endoloop ligature was 6.63 days. The P value for this comparison was 0.2074 indicating there is no significant difference.

From the study by Hue et al., comparing ENDOLOOP® Ligature and polymeric clip, authors found no statistically significant difference between both methods regarding feasibility & safety of surgery. Operating time, which was found to be significantly shorter in our study, was not assessed in the report.[43]

In meta-analysis done by Knight et al. in the year 2019, operative time of polymeric clip was thirty-seven minutes and endoloop groups was thirty-nine minutes, without any signifcant diference between both groups (p=0.365).[48]

Strzalka et al. did one study comparing metal clip, suture & endostaplers in 307 patients; & found that there is hardly any difference in complications between these three techniques.[49]

Rickert et al., studied that the usefulness of clips made in titanium with comparison of other already available clips in similiar size, which allows closing base of appendix bigger than ten millimetres, but size of applicator for that purpose requires a twelve and half millimetre trocar. So, if Hem-o-loc clips are manufactured in bigger sizes, thickness of base of appendix will not be a limitation.[50]

CONCLUSION

CONCLUSION

As per the present study, it was noted that there is a significant difference in using non absorbable polymer clip in appendicular stump closure over endoloop ligature in terms of ease of technique and helps in reducing the intra-operative time.

It is also noted that there is a marginal difference in using non absorbable polymer clip in appendicular stump closure over endoloop ligature in terms of post operative pain , post operative complications and mean hospital stay , but there is no statistical significance for the same.

LIMITATIONS

LIMITATIONS

1. 1)The total number of patients involved in this study were few, and as a result, the results might well be biased. Hence future studies can be done on larger samples.
2. 2)Very few variants were included to the study to compare the efficacy between two methods.

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ANNEXURES

ANNEXURE 1 : PROFOMA

COMPARISSION OF EFFICACY BETWEEN NON ABSORBABLE POLYMER CLIPS AND ENDOLOOP LIGATION FOR APPENDECULAR STUMP CLOSURE DURING LAPAROSCOPIC APPENDICECTOMY

INVESTIGATOR: DR. SAILESH KUMAR S

NAME:

AGE/SEX:

UHID:

CHIEF COMPLAINTS:

HOPI:

PAST HISTORY:

PERSONAL HISTORY :

GENERAL PHYSICAL EXAMINATION:

SYSTEMIC EXAMINATION:

RS:

CVS:

CNS:

P/A:

DIAGNOSIS:

USG ABD AND PELVIS :

INTRA OPERATIVE FINDING:

TECHNIQUE USED: NON ABSORBABLE POLYMER CLIPS / ENDOLOOP

EASE OF TECHNIQUE:

TIME TAKEN:

POST OP COMPLICATIONS :

NUMBER OF DAYS IN HOSPITAL POST OPERATIVELY:

ANNEXURE 2 : PATIENT INFORMATION SHEET

"COMPARISION OF EFFICACY BETWEEN A NON ABSORBABLE POLYMER CLIP AND ENDOLOOP LIGATION FOR APPENDICULAR STUMP CLOSURE DURING LAPAROSCOPIC APPENDICECTOMY"

STUDY CONDUCTED BY DR.SAILESH KUMAR S

R L Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar.

The purpose of the study is explained in detail and all information collected is for study purpose only. The data collected is submitted to the department of surgery, SDUMC, Kolar and confidentiality ensured .

As you have been diagnosed with acute appendicitis, you will be included in this study. Patients in this study will undergo CBC, and usg abdomen and pelvis. You will be planned for laparoscopic appendicectomy and will be randomized in an odd-even manner and non absorbable polymer clips or endoloop ligature will be applied.

The cost of the non absorbable polymer clip / endoloop ligature will be beared by the primary examiner .

Please read the following information and discuss with your family members. You can ask any question regarding the study. If you agree to participate in the study, we will collect information (as per proforma) from you or a person responsible for you or both. Relevant history will be taken. This information collected will be used only for dissertation and publication.

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

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

For further information contact:

Dr.Sailesh kumar s [post graduate]

Department of General Surgery

SDUMC, Kolar

Phone number

7299303055.

ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆ

ಒಂದು ಹೀರಿಕೊಳ್ಳಲಾಗದ ಪಾಲಿಮರ್ ಕ್ಲಿಪ್ (ಹೆಮ್-ಒ-ಲೋಕ್ ಕ್ಲಿಪ್) ಮತ್ತು ಲ್ಯಾಪರೊಸ್ಕೋಪಿಕ್ ಅಪೆಂಡಿಕ್ಟಮಿ ಸಮಯದಲ್ಲಿ ಅಪೆಂಡಿಕ್ಯುಲರ್ ಸ್ಟಂಪ್ ಮುಚ್ಚುವಿಕೆಗಾಗಿ ಎಂಡೋಲೂಪ್ ಬಂಧನದ ನಡುವಿನ ಹೋಲಿಕೆ: ಗೈಡ್. ಕೃಷ್ಣ ಪ್ರಸಾದ್ ಕೆ

ಅಧ್ಯಯನವನ್ನು ಡಾ.ಶೈಲೇಶ್ ಕುಮಾರ್ ಎಸ್

ಅಧ್ಯಯನ ಸ್ಥಳ: ಆರ್ ಎಲ್ ಜಾಲಪ್ಪ ಆಸ್ಪತ್ರೆ ಮತ್ತು ಸಂಶೋಧನಾ ಕೇಂದ್ರವು ಶ್ರೀ ದೇವರಾಜ್ ಅರ್ಸ್ ಮೆಡಿಕಲ್ ಕಾಲೇಜಿಗೆ ಲಗತ್ತಿಸಲಾಗಿದೆ, ಟಮಕ, ಕೋಲಾರ.

ಅಧ್ಯಯನದ ಉದ್ದೇಶವನ್ನು ನಮಗೆ ವಿವರವಾಗಿ ವಿವರಿಸಲಾಗಿದೆ ಮತ್ತು ಸಂಗ್ರಹಿಸಲಾದ ಎಲ್ಲಾ ಮಾಹಿತಿಯು ಅಧ್ಯಯನ ಉದ್ದೇಶಕ್ಕಾಗಿ ಮಾತ್ರ. ಸಂಗ್ರಹಿಸಿದ ಡೇಟಾವನ್ನು ಶಸ್ತ್ರಚಿಕಿತ್ಸಾ ಇಲಾಖೆ, SDUMC, ಕೋಲಾರಕ್ಕೆ ಸಲ್ಲಿಸಲಾಗಿದೆ ಮತ್ತು ಗೌಪ್ಯತೆಯನ್ನು ಖಾತ್ರಿಪಡಿಸಲಾಗಿದೆ. ಅರ್ಹತೆ ಮತ್ತು ದೋಷಗಳನ್ನು ನಮಗೆ ಸಂಕ್ಷಿಪ್ತವಾಗಿ ವಿವರಿಸಲಾಗಿದೆ.

ತೀವ್ರವಾದ ಅಪೆಂಡಿಸೆಕ್ಟಮಿ ರೋಗನಿರ್ಣಯ ಮಾಡಿದ ಎಲ್ಲಾ ರೋಗಿಗಳನ್ನು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಸೇರಿಸಲಾಗುತ್ತದೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ರೋಗಿಗಳು ವಾಡಿಕೆಯ ತನಿಖೆಗಳಿಗೆ ಒಳಗಾಗುತ್ತಾರೆ, ಮತ್ತು usg ಹೊಟ್ಟೆ ಮತ್ತು ಸೊಂಟಕ್ಕೆ ಒಳಗಾಗುತ್ತಾರೆ. ಲ್ಯಾಪರೊಸ್ಕೋಪಿಕ್ ಅಪೆಂಡಿಸೆಕ್ಟಮಿಗೆ ಯೋಜಿಸಲಾದ ರೋಗಿಗಳನ್ನು ಯಾದೃಚ್ಛಿಕಗೊಳಿಸಲಾಗುತ್ತದೆ ಮತ್ತು ಹೀರಿಕೊಳ್ಳಲಾಗದ ಪಾಲಿಮರ್ ಕ್ಲಿಪ್ಗಳು ಅಥವಾ ಎಂಡೋಲೂಪ್ ಲಿಗೇಚರ್ ಅನ್ನು ಹಾಕಲಾಗುತ್ತದೆ.

ದಯವಿಟ್ಟು ಕೆಳಗಿನ ಮಾಹಿತಿಯನ್ನು ಓದಿ ಮತ್ತು ನಿಮ್ಮ ಕುಟುಂಬದ ಸದಸ್ಯರೊಂದಿಗೆ ಚರ್ಚಿಸಿ. ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದಂತೆ ನೀವು ಯಾವುದೇ ಪ್ರಶ್ನೆಯನ್ನು ಕೇಳಬಹುದು. ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಸಮ್ಮತಿಸಿದರೆ, ನಾವು ನಿಮ್ಮಿಂದ ಅಥವಾ ನಿಮ್ಮಿಂದ ಅಥವಾ ಇಬ್ಬರಿಗೂ ಜವಾಬ್ದಾರರಾಗಿರುವ ವ್ಯಕ್ತಿಯಿಂದ

(ಪ್ರೊಫಾರ್ಮಾ ಪ್ರಕಾರ) ಮಾಹಿತಿಯನ್ನು ಸಂಗ್ರಹಿಸುತ್ತೇವೆ. ಸಂಬಂಧಿತ ಇತಿಹಾಸವನ್ನು

ತೆಗೆದುಕೊಳ್ಳಲಾಗುವುದು. ಸಂಗ್ರಹಿಸಿದ ಈ ಮಾಹಿತಿಯನ್ನು ಪ್ರಬಂಧ ಮತ್ತು ಪ್ರಕಟಣೆಗೆ ಮಾತ್ರ ಬಳಸಲಾಗುತ್ತದೆ.

ನಿಮ್ಮಿಂದ ಸಂಗ್ರಹಿಸಿದ ಎಲ್ಲಾ ಮಾಹಿತಿಯನ್ನು ಗೌಪ್ಯವಾಗಿ ಇರಿಸಲಾಗುತ್ತದೆ ಮತ್ತು ಯಾವುದೇ ಹೊರಗಿನವರಿಗೆ ಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ. ನಿಮ್ಮ ಗುರುತನ್ನು ಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನವನ್ನು ಸಾಂಸ್ಥಿಕ ನೀತಿಶಾಸ್ತ್ರ ಸಮಿತಿಯು ಪರಿಶೀಲಿಸಿದೆ ಮತ್ತು ನೀವು ಸಾಂಸ್ಥಿಕ ನೀತಿಶಾಸ್ತ್ರ ಸಮಿತಿಯ ಸದಸ್ಯರನ್ನು ಸಂಪರ್ಕಿಸಲು ಮುಕ್ತರಾಗಿದ್ದೀರಿ.

ಈ ಅಧ್ಯಯನವನ್ನು ಒಪ್ಪಿಕೊಳ್ಳಲು ಯಾವುದೇ ಒತ್ತಾಯವಿಲ್ಲ. ನಿಮಗೆ ಸಿಗುವ ಕಾಳಜಿ ಇರುತ್ತದೆ

ನೀವು ಭಾಗವಹಿಸಲು ಬಯಸದಿದ್ದರೆ ಬದಲಾಗುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನೀವು

ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಒಪ್ಪಿಕೊಂಡರೆ ಮಾತ್ರ ನೀವು ಸಹಿ/ಹೆಬ್ಬೆರಳಿನ ಗುರುತನ್ನು ಒದಗಿಸಬೇಕಾಗುತ್ತದೆ.

ಹೆಚ್ಚಿನ ಮಾಹಿತಿಗಾಗಿ ಸಂಪರ್ಕಿಸಿ: ರೋಗಿಯ ಎಡ ಹೆಬ್ಬೆರಳಿನ ಗುರುತು/ಸಹಿ

ಡಾ.ಶೈಲೇಶ್ ಕುಮಾರ್ ಎಸ್ [ಸ್ನಾತಕೋತ್ತರ ಪದವಿ]

ಜನರಲ್ ಸರ್ಜರಿ ವಿಭಾಗ

ANNEXURE 3 : CONSENT

Title: "COMPARISION BETWEEN THE EFFICACY OF A NON ABSORBABLE POLYMER CLIP AND ENDOLOOP LIGATION FOR APPENDICULAR STUMP CLOSURE DURING LAPAROSCOPIC APPENDICECTOMY"

GUIDE: DR. KRISHNA PRASAD K

STUDY CONDUCTED BY DR.SAILESH KUMAR S

Study location: R L Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar.

I,MR/ Mrs. …….. have been explained in my own understandable language, that I will be included in a study which is COMPARISION BETWEEN A NON ABSORBABLE POLYMER CLIP AND ENDOLOOP LIGATION FOR APPENDICULAR STUMP CLOSURE DURING LAPAROSCOPIC APPENDICECTOMY"

I have been explained that my clinical findings, investigations, preoperative and post-operative findings will be assessed and documented for study purpose.

I have been explained my participation in this study is entirely voluntary and I can withdraw from the study any time and this will not affect my relation with my doctor or treatment for my ailment.

I have been explained about the risk of the study such as post operative pain , slip of ligature , intra abdominal abscess, faecal fistula, surgical site infection and wound dehiscence.

I understand that the medical information produced by this study will become part of institutional records and will be kept confidential by my said institute.

I agree not to restrict the use of any data or result that arise from this study provided such a use is only for scientific purpose(s).

I have principal investigator mobile number for enquiries.

I have been informed that standard of care will be maintained throughout the treatment period.

I in my sound mind give full consent to be added in the part of this study.

Investigator: Dr.SAILESH KUMAR S

Participant's signature/ thumb impression

ಶೀರ್ಷಿಕೆ:

"ಲ್ಯಾಪರೊಸ್ಕೋಪಿಕ್ ಅಪೆಂಡಿಸೆಕ್ಟಮಿ ಸಮಯದಲ್ಲಿ ಅಪೆಂಡಿಕ್ಯುಲರ್ ಸ್ಟಂಪ್ ಮುಚ್ಚುವಿಕೆಗಾಗಿ ಹೀರಿಕೊಳ್ಳಲಾಗದ ಪಾಲಿಮರ್ ಕ್ಲಿಪ್ (ಹೆಮ್-ಒ-ಲೋಕ್ ಕ್ಲಿಪ್) ಮತ್ತು ಎಂಡೋಲೂಪ್ ಬಂಧನದ ನಡುವಿನ ಹೋಲಿಕೆ"

ಮಾರ್ಗದರ್ಶಿ: ಡಾ. ಕೃಷ್ಣ ಪ್ರಸಾದ್ ಕೆ

ಅಧ್ಯಯನವನ್ನು ಡಾ.ಶೈಲೇಶ್ ಕುಮಾರ್ ಎಸ್

ಅಧ್ಯಯನ ಸ್ಥಳ: ಆರ್ ಎಲ್ ಜಾಲಪ್ಪ ಆಸ್ಪತ್ರೆ ಮತ್ತು ಸಂಶೋಧನಾ ಕೇಂದ್ರವು ಶ್ರೀ ದೇವರಾಜ್ ಅರ್ಸ್ ಮೆಡಿಕಲ್ ಕಾಲೇಜಿಗೆ ಲಗತ್ತಿಸಲಾಗಿದೆ, ಟಮಕ, ಕೋಲಾರ.

ನಾನು, MR/ ಶ್ರೀಮತಿ …….. ನನ್ನ ಸ್ವಂತ ಅರ್ಥವಾಗುವ ಭಾಷೆಯಲ್ಲಿ ವಿವರಿಸಲಾಗಿದೆ, ಹೀರಿಕೊಳ್ಳಲಾಗದ ಪಾಲಿಮರ್ ಕ್ಲಿಪ್ (HEM-O-LOK CLIP) ಮತ್ತು ENDOLOOP ನಡುವಿನ ಹೋಲಿಕೆಯ ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನನ್ನು ಸೇರಿಸಲಾಗುವುದು ಲ್ಯಾಪರೊಸ್ಕೋಪಿಕ್ ಅಪೆಂಡಿಸೆಕ್ಟಮಿ ಸಮಯದಲ್ಲಿ ಅಪೆಂಡಿಕ್ಯುಲರ್ ಸ್ಟಂಪ್ ಮುಚ್ಚುವಿಕೆಗಾಗಿ ಬಂಧನ"

ನನ್ನ ಕ್ಲಿನಿಕಲ್ ಸಂಶೋಧನೆಗಳು, ತನಿಖೆಗಳು, ಪೂರ್ವಭಾವಿ ಮತ್ತು ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ನಂತರದ ಸಂಶೋಧನೆಗಳನ್ನು ಮೌಲ್ಯಮಾಪನ ಮಾಡಲಾಗುತ್ತದೆ ಮತ್ತು ಅಧ್ಯಯನ ಉದ್ದೇಶಕ್ಕಾಗಿ ದಾಖಲಿಸಲಾಗುತ್ತದೆ ಎಂದು ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಭಾಗವಹಿಸುವಿಕೆಯು ಸಂಪೂರ್ಣವಾಗಿ ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿದೆ ಮತ್ತು ನಾನು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಅಧ್ಯಯನದಿಂದ ಹಿಂದೆ ಸರಿಯಬಹುದು ಮತ್ತು ಇದು ನನ್ನ ವೈದ್ಯರೊಂದಿಗಿನ ನನ್ನ ಸಂಬಂಧ ಅಥವಾ ನನ್ನ ಕಾಯಿಲೆಯ ಚಿಕಿತ್ಸೆಯ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ ಎಂದು ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ.

ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ನಂತರದ ನೋವು, ಅಸ್ಥಿರಜ್ಜು ಸ್ಲಿಪ್, ಇಂಟ್ರಾ ಕಿಬ್ಬೊಟ್ಟೆಯ ಬಾವು ಮತ್ತು ಶಸ್ತ್ರಚಿಕಿತ್ಸಕ ಸೈಟ್ ಸೋಂಕಿನಂತಹ ಅಧ್ಯಯನದ ಅಪಾಯ/ಪ್ರಯೋಜನದ ಕುರಿತು ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ.

ಈ ಅಧ್ಯಯನದಿಂದ ಉಂಟಾಗುವ ಯಾವುದೇ ಡೇಟಾ ಅಥವಾ ಫಲಿತಾಂಶದ ಬಳಕೆಯನ್ನು ನಿರ್ಬಂಧಿಸದಿರಲು ನಾನು ಒಪ್ಪುತ್ತೇನೆ, ಅಂತಹ ಬಳಕೆಯನ್ನು ವೈಜ್ಞಾನಿಕ ಉದ್ದೇಶ(ಗಳು) ಗಾಗಿ ಮಾತ್ರ ಬಳಸಲಾಗಿದೆ.

ವಿಚಾರಣೆಗಾಗಿ ನಾನು ಪ್ರಧಾನ ತನಿಖಾಧಿಕಾರಿಯ ಮೊಬೈಲ್ ಸಂಖ್ಯೆಯನ್ನು ಹೊಂದಿದ್ದೇನೆ.

ಚಿಕಿತ್ಸೆಯ ಅವಧಿಯುದ್ದಕ್ಕೂ ಆರೈಕೆಯ ಗುಣಮಟ್ಟವನ್ನು ನಿರ್ವಹಿಸಲಾಗುವುದು ಎಂದು ನನಗೆ ತಿಳಿಸಲಾಗಿದೆ.

ಈ ಅಧ್ಯಯನದ ಭಾಗದಲ್ಲಿ ಸೇರಿಸಲು ನನ್ನ ಉತ್ತಮ ಮನಸ್ಸಿನಲ್ಲಿ ನಾನು ಸಂಪೂರ್ಣ ಒಪ್ಪಿಗೆಯನ್ನು ನೀಡುತ್ತೇನೆ.

ತನಿಖಾಧಿಕಾರಿ: ಡಾ.ಸೈಲೇಶ್ ಕುಮಾರ್ ಎಸ್

ಭಾಗವಹಿಸುವವರ ಸಹಿ/ಹೆಬ್ಬೆರಳಿನ ಗುರುತು

ಹೆಸರು:

ANNEXURE 4 : MASTER CHART

S.NO	UHID	DIAGNOSIS	METHOD USED	EASE OF TECHNIQUE	TIME TAKEN	COST EFFECTIVENESS	SSI	WOUND DEHISCENCE	FAECAL FISTULA	VAS SCORE	HOSPITAL STAY
1	247140	RECURRENT APPENDICITIS	ENDOLOOP LIGATURE	1	5 MINS	1600	NO	NO	NO	3	7 DAYS
2	254133	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	2	6 MINS	1400	NO	NO	NO	2	8 DAYS
3	90609	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	2	6 MINS	1600	NO	NO	NO	4	8 DAYS
4	193949	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	3	6 MINS	1400	NO	NO	NO	2	6 DAYS
5	213205	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	2	4 MINS	1600	NO	NO	NO	4	7 DAYS
6	239302	RECURRENT APPENDICITIS	NON ABSORBABLE POLYMER CLIP	3	5 MINS	1400	NO	NO	NO	2	7 DAYS
7	195687	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	1	4 MINS	1600	YES	NO	NO	3	10 DAYS
8	270836	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	1	6 MINS	1400	NO	NO	NO	4	6 DAYS
9	160999	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	3	5 MINS	1600	NO	NO	NO	3	7 DAYS
10	44999	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	2	4 MINS	1400	NO	NO	NO	3	7 DAYS
11	175001	RECURRENT APPENDICITIS	ENDOLOOP LIGATURE	2	5 MINS	1600	NO	NO	NO	3	7 DAYS
12	264707	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	3	5 MINS	1400	YES	NO	NO	2	9 DAYS
13	265012	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	1	5 MINS	1600	NO	NO	NO	4	6 DAYS
14	265626	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	3	4 MINS	1400	NO	NO	NO	2	6 DAYS
15	279126	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	3	6 MINS	1600	NO	NO	NO	4	7 DAYS
16	277817	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	1	5 MINS	1400	NO	NO	NO	3	7 DAYS
17	251396	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	2	5 MINS	1600	NO	NO	NO	3	7 DAYS
18	184499	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	2	4 MINS	1400	NO	NO	NO	2	6 DAYS
19	239089	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	1	6 MINS	1600	NO	NO	NO	5	6 DAYS
20	221083	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	2	4 MINS	1400	NO	NO	NO	3	5 MINS
21	165161	RECURRENT APPENDICITIS	ENDOLOOP LIGATURE	3	5 MINS	1600	NO	NO	NO	3	6 DAYS
22	196962	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	1	4 MINS	1400	NO	NO	NO	2	6 DAYS
23	169020	RECURRENT APPENDICITIS	ENDOLOOP LIGATURE	3	5 MINS	1600	NO	NO	NO	4	7 DAYS
24	173725	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	3	5 MINS	1400	NO	NO	NO	2	6 DAYS
25	96609	RECURRENT APPENDICITIS	ENDOLOOP LIGATURE	1	4 MINS	1600	NO	NO	NO	3	6 DAYS
26	194304	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	2	5 MINS	1400	NO	NO	NO	2	7 DAYS
27	148358	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	2	6 MINS	1600	NO	NO	NO	3	6 DAYS
28	214586	RECURRENT APPENDICITIS	NON ABSORBABLE POLYMER CLIP	3	5 MINS	1400	NO	NO	NO	2	5 DAYS
29	357823	RECURRENT APPENDICITIS	ENDOLOOP LIGATURE	3	4 MINS	1600	NO	NO	NO	3	7 DAYS
30	311578	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	3	5 MINS	1400	NO	NO	NO	3	7 DAYS
31	354218	RECURRENT APPENDICITIS	ENDOLOOP LIGATURE	2	6 MINS	1600	NO	NO	NO	4	6 DAYS
32	355361	RECURRENT APPENDICITIS	NON ABSORBABLE POLYMER CLIP	1	4 MINS	1400	NO	NO	NO	4	7 DAYS
33	297325	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	2	5 MINS	1600	YES	YES	NO	5	6 DAYS
34	310973	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	2	4 MINS	1400	NO	NO	NO	3	5 DAYS
35	365422	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	3	5 MINS	1600	NO	NO	NO	3	6 DAYS
36	309249	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	3	5 MINS	1400	NO	NO	NO	2	6 DAYS
37	298952	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	2	6 MINS	1600	NO	NO	NO	3	7 DAYS
38	353366	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	2	4 MINS	1400	NO	NO	NO	2	6 DAYS
39	293990	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	1	6 MINS	1600	NO	NO	NO	4	6 DAYS
40	327218	RECURRENT APPENDICITIS	NON ABSORBABLE POLYMER CLIP	3	4 MINS	1400	NO	NO	NO	2	5 DAYS
41	371879	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	2	5 MINS	1600	NO	NO	NO	4	6 DAYS
42	304980	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	1	4 MINS	1400	NO	NO	NO	3	7 DAYS
43	336156	RECURRENT APPENDICITIS	ENDOLOOP LIGATURE	3	5 MINS	1600	NO	NO	NO	3	6 DAYS
44	368022	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	3	5 MINS	1400	YES	NO	NO	2	9 DAYS
45	299432	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	3	6 MINS	1600	NO	NO	NO	3	6 DAYS
46	355968	RECURRENT APPENDICITIS	NON ABSORBABLE POLYMER CLIP	2	4 MINS	1400	NO	NO	NO	4	5 DAYS
47	359536	RECURRENT APPENDICITIS	ENDOLOOP LIGATURE	2	5 MINS	1600	NO	NO	NO	3	7 DAYS
48	302652	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	3	4 MINS	1400	NO	NO	NO	4	6 DAYS
49	393584	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	2	6 MINS	1600	NO	NO	NO	3	6 DAYS
50	374865	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	3	5 MINS	1400	NO	NO	NO	2	5 DAYS
51	350847	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	1	4 MINS	1600	NO	NO	NO	4	6 DAYS
52	383945	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	2	4 MINS	1400	YES	NO	NO	2	8 DAYS
53	335184	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	3	5 MINS	1600	NO	NO	NO	3	6 DAYS
54	374776	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	2	4 MINS	1400	NO	NO	NO	2	5 DAYS
55	366814	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	2	6 MINS	1600	NO	NO	NO	4	6 DAYS
56	350417	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	2	5 MINS	1400	NO	NO	NO	2	5 DAYS
57	362511	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	1	5 MINS	1600	NO	NO	NO	3	6 DAYS
58	368044	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	3	6 MINS	1400	NO	NO	NO	2	6 DAYS
59	304570	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	2	5 MINS	1600	NO	NO	NO	3	5 DAYS
60	339100	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	2	4 MINS	1400	NO	NO	NO	3	5 DAYS
61	298316	ACUTE APPENDICITIS	ENDOLOOP LIGATURE	3	5 MINS	1600	NO	NO	NO	3	6 MINS
62	324367	RECURRENT APPENDICITIS	NON ABSORBABLE POLYMER CLIP	3	6 MINS	1400	NO	NO	NO	4	6 DAYS
63	383212	RECURRENT APPENDICITIS	ENDOLOOP LIGATURE	2	5 MINS	1600	YES	NO	NO	3	10 DAYS
64	343567	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	2	5 MINS	1400	NO	NO	NO	5	6 DAYS
65	282561	RECURRENT APPENDICITIS	ENDOLOOP LIGATURE	1	6 MINS	1600	YES	NO	NO	4	8 DAYS
66	367543	ACUTE APPENDICITIS	NON ABSORBABLE POLYMER CLIP	3	4 MINS	1400	NO	NO	NO	2	6 DAYS