
"A STUDY OF SINGLE HEM-O-LOK CLIP V/S
ROEDER'S KNOT IN LAPAROSCOPIC APPENDICEAL
STUMP CLOSURE: A ONE YEAR RANDOMIZED
CONTROLLED TRIAL STUDY IN KLE'S DR.
PRABHAKAR KORE CHARITABLE HOSPITAL,
BELGAVI"

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**KLE Academy of Higher Education and Research, Belagavi,
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**Endorsement by the HOD/ Principal/ Head
of the Institution**

This is to certify that the dissertation entitled “**A STUDY OF SINGLE HEM-O-
LOK CLIP V/S ROEDER’S KNOT IN LAPAROSCOPIC APPENDICEAL STUMP
CLOSURE: A ONE YEAR RANDOMIZED CONTROLLED TRIAL STUDY IN
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LIST OF ABBREVIATIONS USED

WBC	-	White Blood Count
CRP- C	-	reactive protein
HCG	-	Human chorionic gonadotropin
IL-6	-	Interleukin-6
LA	-	Laparoscopic Appendectomy
OA	-	Open Appendectomy
USG	-	Ultra Sonography

ABSTRACT

Background and Objectives:

Appendicitis is one of the most common abdominal condition emergencies in the world. Standard method of care is laparoscopic appendectomy (LA). In LA most important step is to secure base of the appendix. Now most commonly followed method is by using Roeder's knot, which is usually of silk material. With advancement in surgical approach and technology, there are various other methods to secure appendicular stump. In this study we are comparing standard Roeder's knot with Hem-o-lok polymeric clip. Through this study we would like to compare operative time, surgeons feasibility, pneumoperitoneum pressure gradient and post operative complications

Materials and Methods:

Patients diagnosed with Appendicitis (Acute, chronic or recurrent), who are willing to undergo LA were randomised in to two groups of 30 each. First group was named as Test Group and second with Control Group. Test group had patients in whom Hem-o-lok clips were used and in Control group standard Roeders knot was used.

Study was done in Dept of Gen. Surgery in Dr.Prabhakar Kore Charitable Hospital, Belagavi. Study period was between Jan 2017 to Dec 2017.

Results: In the present study 63.33% of the patients in Control group were males compared to 56.66% in Test group. The mean age in control group was 28.6 years and in Test group it was 29.76 ($p=0.7360$). Other variables including clinical presentation, medical history, anthropometry, vitals, clinical signs, diagnosis, haemoglobin and urine analysis were comparable. The time between insertion of clip applicator and retrieval of appendix in patients in Test group was between 239 to 598 seconds while in patients in Control group time between insertion of knot pusher and retrieval of appendix was between 480 to 740 seconds ($p<0.0001$). Surgeons feasibility in Test group was more feasible in 93.33% and 13.33 % in Control group ($p<0.0001$). The pneumoperitoneum pressure after insertion of clip applicator in Test group was between 12 to 14 mm of hg with mean value of 13.43 mm of hg and pressure after insertion of knot pusher and retrieval of appendix in Control group was between 7 to 11 of hg($p<0.0001$). Post operative complications in both Test and Control group were on POD 1, however on POD3 in Test group 3 patients had fever and in Control group 4 patients had fever.

Conclusion: Hem-o-lok clips to secure appendicular stump in LA is fast, feasible and safe as compared to standard Roeder's knot.

Key words: Laparoscopic Appendectomy, Appendectomy, Appendicitis, Hem-o-lok clip, Roeder's knot.

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INTRODUCTION

Appendicitis is the most common abdominal emergency in the world. The lifetime risk of developing appendicitis is around 7% and invariably requires surgical treatment as main line of management. Incidence of appendicitis is approximately 11 cases per 10,000 population per year. Acute appendicitis may occur at any age, although it is relatively rare at the extremes of age and more commonly in young adults. There is an increased incidence in white skin patients between the ages of 15 and 30 years during which time the incidence increases to 23 per 10,000 population per year. Appendicitis comprises approximately 25% of the surgical emergency admissions and 40% of the total laparotomy emergencies¹

Obstruction of the appendicular lumen is the main factor for acute appendicitis and fecoliths invariably cause the obstruction. Other causes of obstruction could be lymphoid hyperplasia, intestinal worms, tumors, or other conditions.^{2,3}

Since its first description by Fitz in 1886, there have been lot of papers about acute appendicitis and the prompt intervention required to prevent many serious consequences including that of perforation. Over the years, the surgical management of appendicitis has advanced from open techniques to minimal invasive ones. The gold standard for appendectomy, now, is Laparoscopic Appendectomy (LA), even for complicated appendicitis. Studies have shown that LA has significant advantages.^{4,5}

Laparoscopy appendectomy surgeries are increasing daily because of its facilities and advantages such as less postoperative pain, faster recovery, shorter hospital stay, less postoperative complications, and minimally sized incisions/scars. Patients who undergo Laparoscopic appendectomy, experience

reduced wound infections, reduced intra-operative and postoperative analgesia, reduced length of hospital stay, have a early return of normal bowel function, and good cosmeses, avoiding a large laparotomy scar.⁵ Intra-abdominal abscesses, higher costs and increased into operative time are some of its disadvantages.^{1,6}The technique of appendicular stump closure apparently influences chances of abscess formation.⁷

During a laparoscopic appendectomy, an important step in the procedure is the closure of the appendiceal stump. Postoperative complications can occur from its inappropriate closure. Development of dangerous consequences sometimes such as enterocutaneous fistulas, peritonitis, and sepsis is feared and undesirable.⁸

Although the surgical technique and management of laparoscopic appendectomy has been well established, but the key point in the procedure is closure of appendiceal stump which has attracted many controversies. The main concern in laparoscopic appendectomy is the matter of closure of the appendiceal stump or base. Therefore, many methods have been recommended and examined for its closure, some of these methods include endoloop, double endoloop, cutting with ultrasonic knife, tying with instrument, metal or plyometric clips, ligator and thread, hemolock, and linear endostapler. Currently, polymeric clips, pre-knotted loops and staplers are being used for stump closure. The finest method is not known and that topic is debatable.^{9,10}

Most commonly used procedure for ligation of the appendiceal stumps is the Roeder's knot. However, controversies about the efficacy and safety of these novel materials still exist, and the need to evaluate this through new research has become important.¹¹

An innovative appliance for appendicular stump closure is the Hem-o-lok clips. The Hem-o-lok Clip's non-absorbable polymer composition and it is a proven biocompatible implant material. It allows good adaptation to tissue with locking system. The design is characterized by curved parallel shanks with distal loc. The tissue is compressed, between the shanks during the closing process and a locking system so as to ensure no slippage of the clip. Scissoring is also prevented by the shanks.

This study was designed to assess the ease of use and safety of Hem-o-lok polymeric clips compared to Roeder's knot in the appendiceal stump closure and to compare operative time, post operative complications, hospital stay and follow up period among the patients undergoing laparoscopic appendectomy.

OBJECTIVE

The objectives of the present study were

Primary

To assess the operative time and surgeon's feasibility of Hem-o-lok clips compared to Roeder's knot in the appendiceal stump closure in laparoscopic appendectomy.

Secondary

To compare the following outcomes between Hem-o-lok clips and Roeder's knot appendiceal stump closure groups;

1. Pneumoperitoneum pressure gradient.
2. Post operative complications

REVIEW OF LITERATURE

Historical Review

Most of the history of appendicitis and appendectomy has been made during the past two centuries. Jacopo Berengario da Carpi gave the first description of this structure in 1522. Gabriele Fallopio, in 1561, appears to have been the first writer to compare the appendix to a worm. In 1579 Caspar Bauhin proposed the ingenious theory that the appendix served in intrauterine life as a receptacle for the faeces. Reginald J.¹² Fitz of Harvard University was the first person to officially describe appendicitis.⁹ The first inflamed appendix was removed by Claudius Amyand, a Sergeant Surgeon to Queen Ann, King George I, and King George II¹³

In 1886 Reginald Heber Fitz published a study on appendicitis and named the procedure an appendectomy. In 1889, Tait split open and just drained an inflamed appendix and did not perform appendectomy. Charles McBurney proposed his original muscle splitting operation in 1893 and this was modified by Robert Fulton Weir in 1900. Kurt Semm performed the first laparoscopic appendectomy in 1981 and it became the new gold standard in surgical treatment of acute and chronic appendicitis¹²

Ancient Egyptians were the first ones to know about the appendix. They referred to it as "the worm of the intestine" as found in their Coptic jars. In 1492, Leonardo da Vinci published the first ever drawing of the appendix. Jacopo Berengario Dan Carpi, an Anatomist, is known to have the first description of the appendix in 1521.¹² In his publication "De Humani Corporis Fabrica", Andrea Vesalius gave a clear picture of the appendix, in 1543.¹³

Jean Francois Fernel, a French doctor, is known to have given the first description of appendicitis in the early 1500's in the "Universa Medicina". He described it as "A girl of seven afflicted with diarrhoea passed for many days from the bowels a white putrid and foul material. She swelled up with increasingly severe pains and repeated loss of consciousness and vomiting of a fecal liquid. She died miserably two days later. On opening the body, the

caecum intestinum was narrowed and constricted....and material opened up itself an unusual route by necrosis and perforation".¹³

Describing his paper "Perforating Inflammation of the Vermiform Appendix" to the Association of American Physicians, American anatomist Reginald. J. Fitz, was the first person to provide a clear account of the pathology, diagnosis and treatment of appendicitis in 1886. The term "Appendicitis" for the first time was used then.¹³

In 1827 the idea that appendix could be surgically removed was given by Francois Melier in his most ignored paper. He was argued and opposed by Guillaume Dupuytren , a French surgeon who thought that the caecum was the prime cause of right lower quadrant inflammatory disease.² It was in early 1840s that Thomas Hodgkin, Voltz, Addison and Bright ,all suggested that appendix was the source of the disease.¹³

After Melier's paper, for 50 long years, there was no definitive treatment and the disease was called with multiple names like typhilitis, tumphloenteritis, perityphilitis,, iliac passion, paratyphilitis and caecitis.¹³

Claudius Amyand performed the first appendectomy at St. Georges Hospital in London, when a perforated appendix was found in a scrotal hernia sac. In his honor, a hernia containing appendix till date is known as Amyand's hernia.¹³

Charles McBurney was the one who diagnosed and suggested early operative intervention of appendicitis for the first time.¹⁴

In 1889 the McBurney's point was described, which was one-third of the distance from the anterior superior iliac spine to the umbilicus in the right lower quadrant of the abdomen. In 1894, the appendectomy incision, McBurney's incision was named.

A.J. Oschner debated for a non-operative treatment of peritonitis, and then 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

EMBRYOLOGY:

Appendix and cecum appear as out pouchings from the caudal limb of the midgut in the sixth week of human embryonic development. The appendiceal outpouching, initially noted in the eighth week, begins to elongate at about the fifth month to achieve a vermiform appearance in the foetus. The appendix maintains its position at the tip of the cecum throughout developmental period. The subsequent unequal growth of the lateral wall of the cecum causes the appendix to find its adult position on the posterior medial wall, just below the ileocecal valve. The base of the appendix can be located by following the longitudinally oriented taeniae coli to their confluence on the cecum. The tip of the appendix can be located anywhere in the right lower quadrant of the abdomen, pelvis, or retroperitoneum.¹⁶

Vermiform is Latin word which means “in the shape of a worm”. The appendix vermiformis is an approximately 2 to 20 cm long (average 9 cm in adults) and 0.5 to 1 cm wide blind ended tubular sac. Extending from the caecum, just distal to the ileocaecal junction, of the human large intestine.¹⁷

The appendix traced by the presence of convergence of three taenia coli at the junction of appendix with the caecum, where the base of appendix resides. This is a vital landmark in identifying and during operating (Appendectomy). The absence of appendix, duplication, and diverticula have all been described in many cases.¹⁸

For many years appendix was viewed wrongly as a vestigial organ without any sort of function. It is now known that the appendix has an immunological role, i.e., it takes part in the secretion of immunoglobulins particularly immunoglobulin A. Many recent studies have shown a relation between appendectomy and the development of inflammatory bowel disease, though there is no clear pathological role in human disease initiation. There appears to be a negative age related association between prior appendectomy and subsequent development of ulcerative colitis. In addition, comparative analysis shows a clear delay in onset of disease and a benign nature in ulcerative colitis in population with prior appendectomy. The association between appendectomy and Crohn's disease is less clear. Although studies done before suggested that appendectomy increases the chances or risk of developing Crohn's disease. However more recent studies that carefully assessed the timing of appendectomy in

relation to the onset of Crohn's disease demonstrated a no such correlation. So as per these data appendectomy may protect against the subsequent development of inflammatory bowel disease; however, the mechanism is unclear.¹⁸

Approximately around 2 weeks after birth, lymphoid tissue first appears in the appendix. This tissue increases till puberty and then begins to decrease with age. Lymphoid tissue does not remain within the appendix after 60 years of age and the lumen is completely obliterated around that age.¹⁸

ANATOMY:

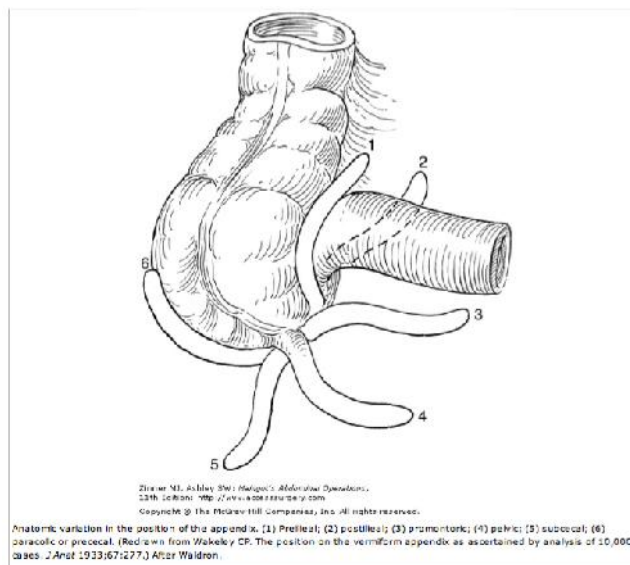


Figure 1. Different positions of appendix

The vermiform appendix is a narrow worm shaped tube, arising from posteromedial caecal wall, 2 cm or less below the end of the ileum. It can be found in any of the following position.¹⁹

1. Retrocaecal (12 O'clock) position – directed upwards in the retrocaecal recess. If the length is greater it may be retrocolic on hepatic.
2. Right Paracaecal (11 O'clock) position: lies on right side of caecum.
3. Left Paracaecal (10 O'clock) position: lies on left side of caecum. It may be preileal or postileal.
4. Splenic (2 O'clock) position: directed towards spleen.

5. Promontoric (3 O' clock) position: directed towards sacral promontory.
6. Pelvic (4 to 5 O'clock) position: Crosses the pelvic brim and lies in true pelvis.
7. 6 O'clock position: Appendix in mid inguinal position.

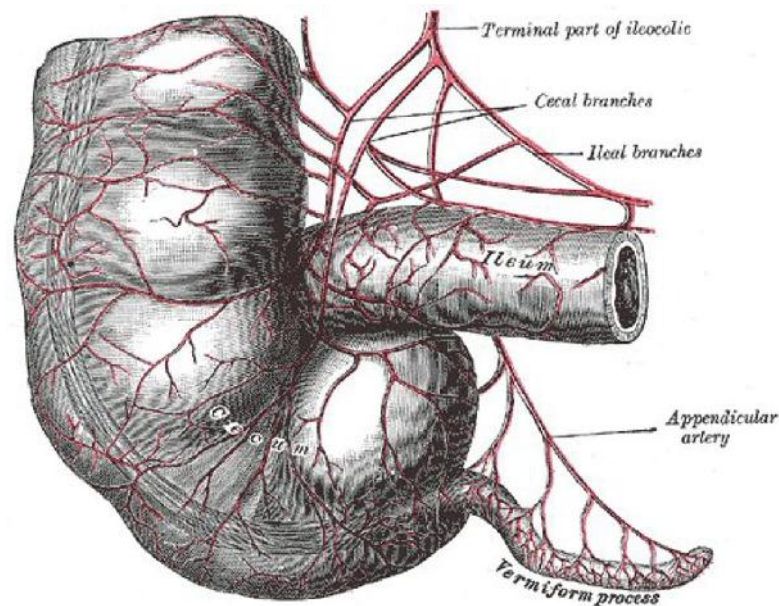
The location of appendix is as follows.¹⁹

Retrocaecal and retrocalic	:	74%
Pelvic	:	21%
Sub caecal	:	1.5%
Preileal	:	1%
Post ileal	:	0.5%

The appendicular orifice is situated at posteromedial aspect of the caecum 2 cms below the ileocaecal orifice. valve of Gerlach, a semi lunar fold of mucous membrane that is occasionally present guards appendicular orifice.

Appendix is suspended by mesoappendix, which the fold of peritoneum and is triangular in shape. In the free edges of mesoappendix often runs the appendicular artery, but may run closer to the base of the appendix as well .¹⁹

Blood supply

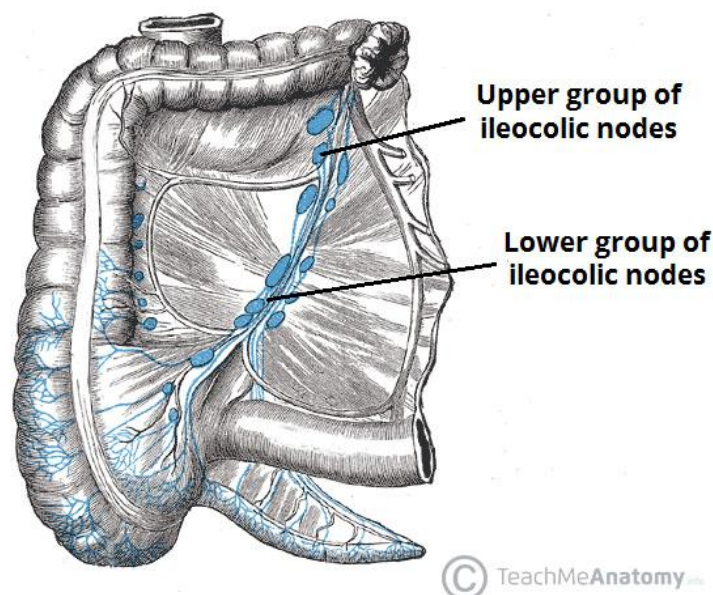


The caecum is supplied by the anterior and posterior caecal branches of the ileocolic artery of superior mesenteric artery.

The appendicular artery, a branch of ileocolic artery reaches the appendix through the mesoappendix. If the mesentery is incomplete, the artery lies on the wall of appendix in its distal part and may be thrombosed in acute appendicitis. There may be an accessory appendicular artery (artery of Seshachalam) arising from the posterior caecal artery.²⁰

Venous drainage

Venous drainage is brought about by the appendicular, ileocolic and superior mesenteric veins and is directed to the portal vein.²¹



Lymphatic drainage

The lymph vessels from caecum and appendix terminate in ileocolic nodes situated close to the ileocolic artery. Small appendicular nodes usually lie close to the mesoappendix and invariably enlarged in acute infections.²¹

Nerve supply

The nerve plexus consists of both sympathetic and parasympathetic fibres accompanying the arteries to reach the caecum and appendix. The plexus is an offshoot from

the superior mesenteric plexus. The sympathetic fibres are derived from T10 – T11 segment of the cord and the parasympathetic fibres are derived from vagi.²¹

Epidemiology

Addiss and associates estimated the incidence of acute appendicitis in the United States population to be 11 cases per 10,000 population annually. The disease is slightly more common in males, with a male:female ratio of 1.4:1.

In a lifetime, 8.6% of males and 6.7% of females can be expected to develop acute appendicitis. Young age is a risk factor, as nearly 70% of patients with acute appendicitis are less than 30 years of age. The highest incidence of appendicitis in males is in the 10- to 14-year-old age group (27.6 cases per 10,000 population), while the highest female incidence is in the 15- to 19-year-old age group (20.5 cases per 10,000 population). Patients at extremes of age are more likely to develop perforated appendicitis.

Overall, perforation was present in 19.2% of cases of acute appendicitis. This number was significantly higher, however, in patients under 5 and over 65 years of age. Although less common in people over 65 years old, acute appendicitis in the elderly progresses to perforation more than 50% of the time¹²

Decreased faecal viscosity, decreased bowel transit time and reduced faecolith formation is seen in people consuming dietary fibre. So in Asia and Africa, due to the diet, there is a lower incidence of appendicitis. Dietary factors predisposes appendix for lumen obstruction.²²

Lohar HP. et al.²³ in Pune during 2010 to 2011 did a retrospective study over 3 years excluding negative appendectomy cases, diagnosed a total of 130 cases with acute appendicitis based on clinical suspicion and investigations. In the 1st year, the incidence was

3.1 per 1000, 2nd year was 4.17 and 3rd year was 3.85. It remained almost stable during the study period of 3 years. The incidence of appendicitis was found to be the highest between 11-20 years of age which was 44.6%. 21-30 years age group constituted 36.1%, 31-40 years age group constituted 11.5% and 0-10 years age group was 3%. 41-50 years and 51-75 years of age group was 2.3% each. Incidence of appendicitis in both sexes were almost equal. Seasonal variation was seen as the incidence hit a peak in spring and found to be low in the summer. Non vegetarians were affected more in the study, which supported beneficial role of dietary fibres.

Etiology and Pathogenesis.

The etiology and pathogenesis of appendicitis are not completely understood until date. However obstruction of the lumen due to fecaliths or hypertrophy of lymphoid tissue is assumed to be main etiologic factor in acute appendicitis. The severity of the inflammatory process is directly proportional to the frequency of appendicular lumen obstruction. Fecaliths are found in 40% of cases of simple acute appendicitis, in 65% of cases of gangrenous appendicitis without rupture, and in nearly 90% of cases of gangrenous appendicitis with rupture.

The belief has been that there is a predictable rows of events that leads to appendiceal rupture. The proximal obstruction of the appendiceal lumen produces a closed-loop obstruction, and continuing normal secretion by the appendiceal mucosa rapidly produces distension which leads to distension of the appendix and stimulates the nerve endings of visceral afferent stretch fibres causing vague, dull, diffuse pain in the mid abdomen or lower epigastrium. Continued mucosal secretion causes continued distension and rapid multiplication of the resident bacteria of the appendix. These events causes reflex nausea and vomiting, and the visceral pain. As pressure in the organ increases, venous pressure increases too. Though capillaries and venules are

occluded but arterial inflow continues, resulting in engorgement and eventually vascular congestion. The inflammatory process soon involves the serosa of the appendix and in turn the parietal peritoneum. This produces the characteristic shift in pain to the right lower quadrant. Intraluminal pressure is increased to 60 cm H₂O due to continuous secretion in the appendicular lumen. Appendiceal distension stimulates the nerves. Visceral afferent fibers are stimulated to produce vague, dull, diffuse pain in the umbilical region.¹⁶

Diseases like appendicitis, diverticular disease, and colorectal carcinoma are more prone to occur in developed civilizations. Burkett et al found an increased incidence of appendicitis in Western countries compared to Africa, also in wealthy, urban communities as compared to rural areas. He attributed this issue to the Western diet habits, which are low in dietary fibres and high in refined sugars and fat. Hence he postulated that low-fiber diets leads to less bulky bowel contents, prolonged intestinal transit time leading to increased intraluminal pressure. Burkitt hypothesis stated that the combination of firm stool leading to appendiceal obstruction and increased intraluminal pressure causing bacterial translocation across the bowel wall resulting in acute appendicitis. In examining surgically resected appendixes for reasons other than appendicitis, Burkitt found fecaliths to be more prevalent in Canadian populations (32%) than in South African populations (4%) adults. In a group of patients with appendicitis, fecaliths were more common in Canadian populations (52%) than in South African populations (23%).He felt this was confirmation that appendiceal obstruction resulted in appendicitis. Of note, however, the majority of patients with appendicitis in his study did not have evidence of a fecalith.

The structure and function of the appendix and the role of obstruction in appendicitis was extensively studied by Wangensteen. Based on anatomic studies, Wangensteen postulated that mucosal folds and a sphincter like orientation of muscle fibers at the appendiceal orifice make the appendix susceptible to obstruction.

Wangensteen proposed the following sequence of events to explain events of appendicitis:

- (1) Swelling of the mucosal and submucosal lymphoid tissue at the base of the appendix due to closed loop obstruction is caused by a fecalith .
- (2) Fixed obstruction causes increase in the intraluminal pressure, which is elevated by appendiceal mucosal fluid secretions.
- (3) Increased pressure in the appendiceal wall exceeds capillary pressure leading to mucosal ischemia.
- (4) Inflammation, edema, and necrosis is a resultant of intra luminal bacterial overgrowth and translocation of bacteria across the appendiceal wall . If the appendix is not excised, perforation can occur.

Appendiceal obstruction is widely accepted as the primary cause of appendicitis but evidences suggest that this may be just one of many other possible etiologies. First, some patients with a fecalith have a histologically normal appendix and majority of patients with appendicitis shows no evidence of fecalith.

Arnbjornsson and Bengmark studied and analysed appendixes after excision at laparotomy in patients with suspected appendicitis. They found the intraluminal pressure of the appendix prior to removal was increased in only 8 of 27 patients with

nonperforated appendicitis. And found no signs of obstruction in the remaining patients with nonperforated appendicitis. Considering these studies together it implies that obstruction is but one of the many other possible etiologies of acute appendicitis.

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Bacteriology

In normal individuals appendiceal bacterial flora and colonic flora are similar. Except *Porphyromonas gingivalis*, the flora remain constant and same through out life time. This *Porphyromonas gingivalis* is seen in adults only. Colonic infections such as diverticulitis hence have the same bacterial cultures as appendicitis. The most common organisms found in appendicitis are *Escherichia coli* and *Bacteroides fragilis*. Other than these bacterias present in this condition are other anaerobic and facultative bacteria many a times with mycobacterium. Some series of studies reporting the culture of up to 14 different organisms in appendicitis, making it a polymicrobial infection of ten resulting in to perforation.¹⁸

Following are the common Organisms Seen in Patients with Acute Appendicitis

Aerobic and Facultative	Anaerobic
Gram-negative bacilli	Gram-negative bacilli
<i>Escherichia coli</i>	<i>Bacteroides fragilis</i>
<i>Pseudomonas aeruginosa</i>	Other <i>Bacteroides</i> species
<i>Klebsiella</i> species	<i>Fusobacterium</i> species
Gram-positive cocci	Gram-positive cocci
<i>Streptococcus anginosus</i>	<i>Peptostreptococcus</i> species
Other <i>Streptococcus</i> species	Gram-positive bacilli
<i>Enterococcus</i> species	<i>Clostridium</i> species

ROLE OF ANTIBIOTICS

As already discussed, the flora is known in appendicitis, and therefore broad-spectrum antibiotics are routinely indicated. With this patients often recovers from the illness by the time results are documented. Peritoneal culture should be taken for patients who are immunosuppressed, as a result of either illness or medication, and also for patients who develop an abscess after the treatment of appendicitis.¹⁸

In cases of nonperforated appendicitis, the coverage of antibiotics is limited to 24-48 hours only. It is recommended to give 7-10 days of antibiotics in perforated appendicitis cases. Intravenous antibiotics are usually given until the total count is normal and the patient has no fever for 24 hours. Antibiotic irrigation of the peritoneal cavity and the use of transperitoneal drainage through the wound are controversial. Postoperative wound infection and intra-abdominal abscess are as well prevented with this antibiotic therapy.¹⁸

Clinical features

Appendicitis is an acute inflammatory condition, where pain is the predominant complaint associated with other features like vomiting and fever, which may or may not found in all the patients.

Symptoms: Disease usually starts with periumbilical and diffuse pain that eventually localizes to the right lower quadrant (sensitivity, 81%; specificity, 53%). Although right lower quadrant pain is one of the most sensitive signs of appendicitis, but in the initial phase pain in an atypical location or minimal pain is the common complaint. Since appendix has Variations in the anatomic locations that may account for the differing presentations and location of the somatic phase of pain.²⁴

Appendicitis is also associated with gastrointestinal symptoms like nausea (sensitivity, 58%; specificity, 36%), vomiting (sensitivity, 51%; specificity, 45%), and anorexia (sensitivity, 68%; specificity, 36%).

SIGNS: Diagnosis of appendicitis is more valued with clinical examination than on any aspect of the history or laboratory investigation. Cardinal features are those of the patient who come with low grade fever, localised abdominal tenderness in right iliac fossa, muscle guarding and rebound tenderness. On abdominal inspection which may show limitation of respiratory movement in the lower abdomen. There are many signs to diagnose appendicitis but if the position is retrocaecal, these signs may be negative in many patients.²⁴

Following are the clinical signs and manoeuvre to diagnose appendicitis and also to know the position of appendix:

Pointing sign- The patient is then asked to point to where the pain began and where it moved. Gentle surface palpation of the abdomen, starting from left iliac fossa moving anticlockwise to the right iliac fossa will detect muscle guarding over the point of maximum tenderness, mainly in McBurney's point. Patient will elicit rebound tenderness when the patient is asked to cough or gentle percussion over the site of maximum tenderness.²⁴

Rovsing's sign-Deep palpation of the left iliac fossa may cause pain in the right iliac fossa,, which is the supporting clinical finding in diagnosis of appendicitis.²⁴

Psoas sign- Sometimes, an inflamed appendix lies on the psoas muscle, patient will lie with the right hip flexed for pain relief .

Obturator test; Zachary Cope-Spasm of the obturator internus is occasionally demonstrated if the hip is flexed and internally rotated. If an inflamed appendix comes

in contact with the obturator internus, this manoeuvre will cause pain in the hypogastrium.

Sometimes there may also be cutaneous hyperesthesia in Right iliac fossa but this doesn't have much of value in diagnosis.²⁴

Laboratory Investigations

As already mentioned appendicitis is the diagnosed mainly with clinical findings, specialist investigations are not required to make the diagnosis of appendicitis. Judicial use of simple bedside tests and laboratory markers of inflammation will suffice in providing additional evidence to support the diagnosis of acute appendicitis and exclude important differential diagnosis. Urine analysis and microscopy can exclude urinary tract infection but may be deranged in around 48% of patients undergoing appendectomy.²⁵

The most commonly used serological inflammatory markers to diagnose acute appendicitis are the leukocyte count(WBC) and C-reactive protein (CRP).But neither of them is of diagnostic value in acute appendicitis. Many studies have attempted to define potential thresholds values which are predictive of a diagnosis and disease severity.^{26,27} Sequential repeated tests may also be useful in assessing disease progression and response to initial antibiotic therapy.

Having said the above, in the presence of normal inflammatory markers CRP, WBC and neutrophil count the diagnosis of acute appendicitis is unlikely.^{28,29}

The performance of these tests is clearly related to the population under study and a meta-analysis of studies of reporting results on patients admitted to hospital with acute abdominal pain and those selected for appendectomy demonstrated that CRP performed better as a diagnostic test in those with an acute abdomen than in those selected already for surgery.²⁶

A meta analysis of studies reporting on patients with a suspicion of appendicitis on clinical examination concluded that the diagnosis of acute appendicitis was more likely when

two or more inflammatory variables [granulocyte count, proportion of polymorph nuclear blood cells, white blood cell count (WBC) and CRP] are elevated.²⁸

Studies on inflammatory markers in appendicitis showed that, in children notably increase in CRP and WBC count can support the diagnosis of acute appendicitis.^{30,31} These studies have all used different cut off levels to determine abnormal results and have generally been small single centre studies. Hence the authors, suggests that the use of inflammatory variables should be used to support a clinical diagnosis of acute appendicitis and to exclude other pathologies rather than using them as diagnostic modalities. All women of reproductive age group should have a serum or urine beta HCG tested to confirm pregnancy status and to exclude ectopic pregnancy. Considering the differential diagnosis of acute appendicitis other blood tests including amylase, lipase, liver function tests, and clotting studies may be needed to confirm or to exclude other differential diagnoses. Given the limitations of the current inflammatory markers there has been considerable research interest in identifying other potential biomarkers for the diagnosis of acute appendicitis and for predicting perforation. Interleukin-6 (IL-6) serum levels have not shown any aid in the diagnosis of appendicitis or reduce negative laparotomy rates. Hyperbilirubinemia has been shown to correlate with a diagnosis of perforated appendicitis³² but a stronger correlation has been recently reported for CRP.³³ The use of plasma D-lactate levels in the diagnosis of appendicitis is unclear with some studies suggesting it may³⁴ or may not be a useful adjunct test.³⁵

A study of 51 patients with appendicitis suggested plasma concentration of lactoferrin and calprotectin were elevated, but their role in diagnosis is unclear.³⁶

Laboratory tests have also been used to try and determine the need for further investigation in patients presenting with abdominal pain. Due to the non specific nature of most inflammatory variables, however, no single specific test has been able to predict the need for further radiological investigation.³⁷

Radiology can help with the diagnosis of appendicitis. Computed Tomography and ultrasonography are helpful in this context.

Scoring Systems

The diagnosis of acute appendicitis can sometime be difficult and any delay in definitive treatment with surgery can lead to an increase in mortality and morbidity as the disease progresses to appendiceal perforation which is the fatal status. This increase in morbidity and mortality has been used to justify the high rates of negative appendectomy which range from 14 to 75%.³⁸

Therefore there has been a drive to improve the diagnosis of appendicitis using different clinical scoring systems. These systems have been based on symptoms, signs and laboratory findings. In some circumstances they have been part of a computer-aided diagnostic algorithm.²⁶

The most commonly used scoring system in the diagnosis of acute appendicitis in adults is the Alvarado score.³⁸ Whereas, in paediatric age groups, the pediatric appendicitis score or Samuel score is most widely used scoring system.³² The scores have now been validated in a wide variety of populations, but still they have not made it into routine clinical practice in all settings.²⁶

A number of studies have also used computer aided diagnosis in patients with acute abdominal pain in an attempt to improve the management of patients presenting with acute abdominal pain. These systems have reported a diagnostic accuracy of 97.2% in acute appendicitis, improvement in time to surgery, with a reduction in the number of perforations over a 2 year period. But, not been introduced into routine clinical practice. In an aid to further improve diagnosis artificial neural networks have been suggested as adjuncts to diagnose appendicitis but this remains an area of research with only a small number of patients having had diagnoses made in this way.^{39,40}

Diagnosis

As the diagnosis of appendicitis is largely a clinical one, special investigations are not needed to confirm the diagnosis. Simple tests like blood and urine examination can allow to differentiate with other conditions and also to support the diagnosis, and there are no specific

tests to diagnose appendicitis. To help or aid in diagnosis of appendicitis, various scoring systems and algorithms have been introduced but are not being used in routine practice.

According to one meta-analysis and systematic review, it is concluded that in patients who cannot be clinically or laboratorial confirmed of appendicitis, computed tomography scanning and ultrasonography should be carried out. As ultrasonography is hugely operator dependent, it is recommended that a greater diagnostic accuracy is by the use of computed tomography when compared to ultrasonography in this select group of patients as per some authors.^{41,42}

Rates of negative appendectomy with the introduction of radiological scanning is still debatable. In a longitudinal study, it has been suggested that in spite of the advent of radiological tests, the rate of negative appendectomy have been the same.⁴³ A possible reason maybe because of the ultrasonography having moderate accuracy in diagnosis and operator dependent.⁴⁴ According to two prospective studies there is a decrease in the number of unnecessary admissions and appendectomies when the use of computed tomography is considered. Some authors have raised their opinion that there is a risk of ionizing radiation exposure in computed tomography scannings, and hence low or lower dose protocols have been encouraged.⁴¹

Differential diagnosis

Acute abdomen causes form the differential diagnosis for appendicitis.⁴¹

Differential diagnosis of acute appendicitis

Surgical

- Perforated peptic ulcer
- Meckel's diverticulitis
- Mesenteric adenitis
- Intestinal obstruction
- Intussusception
- Acute cholecystitis
- Colonic/appendicular diverticulitis

- Rectus sheath haematoma
- Pancreatitis

Gynaecological

- ✓ Ectopic pregnancy

Ruptured ovarian follicle

- ❖ Torted ovarian cyst

- 0. Salpingitis/pelvic inflammatory disease

Urological

(0) Right ureteric colic

- Right pyelonephritis
- Urinary tract infection

Medical

- Gastroenteritis
- Pneumonia
- Terminal ileitis
- Diabetic ketoacidosis
- Preherpetic pain on the right 10th and 11th dorsal nerves
- Porphyria

DIFFERENTIAL DIAGNOSIS AS PER AGE GROUPS ARE AS FOLLOWS²⁴

Children

Gastroenteritis

Mesenteric adenitis

Meckel's diverticulitis

Intussusception

Henoch-Schönlein purpura

Lobar pneumonia

Adults

Regional enteritis

Ureteric colic

Perforated peptic ulcer

Torsion of testis

Pancreatitis

Rectus sheath haematoma

Adult female

Mittelschmerz

Pelvic inflammatory disease

Pyelonephritis

Ectopic pregnancy

Torsion/rupture of ovarian cyst

Endometriosis

Elderly

Diverticulitis

Intestinal obstruction

Colonic carcinoma

Torsion appendix epiploicae

Mesenteric infarction

Leaking aortic aneurysm

Treatment

The fact always stays that, acute appendicitis needs early diagnosis and treatment/ surgery to avoid complications. Appendectomy was first published by Herbert Fitz.¹⁰ Pre operative antibiotics (1-3 doses) should be given, mostly broad spectrum, to prevent abscess and post-op wound infections.^{41,45}

Timing of surgery

Timing of surgery is considered one of the important factors in the out come of the patient. Early being less than 12 hours after presentation and late being 12-24 hours. However no significant differences were found in a recently done retrospective between early or late appendectomy.⁴⁶ But the rate of perforation can have a bearing effect if the actual time of symptom onset is taken into consideration, which wasn't done in this study. The rate of appendicular perforation on an average, is between 16% and 36% after 36 hours from symptom onset, and for every 12 hour thereafter, perforation risk is 5%. Surgical intervention should be done without much delay, after confirmation of diagnosis of appendicitis.^{47,11}

Operative procedure

There are mainly two types of procedures for appendicitis. Either open appendectomy or laparoscopic appendectomy. The open appendectomy has been done by a Gridiron incision or by a Lanz's incision. The Gridiron incision is taken at right angle to a line joining anterior superior iliac spine and umbilicus at the McBurney's point. The Lanz's incision is beneficial cosmetically. With the advancement of laparoscopic surgeries, the amount of open appendectomies have fallen. Open appendectomy Since first surgery by McBurney about 120 years ago, the approach to open appendectomy has not changed.^{48,49}

About one third between the right anterior-superior iliac spine and the umbilicus, just lateral of the right rectus muscle, an incision of around 5cm is taken along the skin fold, as per the conventional approach. By blunt dissection the muscle layers and the fascia are dissected and divided, along with that, electrocautery is used to achieve haemostasis. Then the peritoneum is opened. Caecum is seen and tainae coli are traced to find their convergence. The base of appendix is revealed at their convergence. The caecum is held with a Babcock's

forceps and along with the appendix it is brought out of the peritoneal cavity and the ligation of mesoappendix is done. A stump is left after excising at the base of the appendix.⁴⁸

Even after 30 years of laparoscopic approach there is still debate about the continued practice of Open Appendectomy. However in complicated appendicitis (gangrenous and perforated appendices), Open Appendectomy is considered the gold standard due to lesser complications in the postoperative period like abscess or infection. In case if laparoscopic dissection is not possible or difficult (inflammation or adhesions], then surgery will be converted to open. Conversion from LA to OA is found to be 8.6%, but this number too is steadily decreasing as surgeons are gaining more experience with LA.⁴⁸

Laparoscopic Appendectomy

Kurt Semm was the one to introduce the first described minimally invasive laparoscopic appendectomy (LA) in 1983, since then surgery slowly shifted away from the era of OA.⁵⁰ In the laparoscopic procedure, ports are placed to facilitate working space within the abdomen and to best visualise the appendix. A 10 mm port is placed at the umbilicus and two 5 mm ports in suprapubic and left iliac fossa. The appendix is visualized with same manoeuver as open and manipulated using a Grasper. Using endoscopic stapler or harmonic scalpel mesoappendix is divided from the appendix. The appendiceal base is ligated with either an endoscopic stapler or Endoloop. An Endobag is used to retrieve the appendix through the 10 mm port.⁴⁸

LA approach is advantageous over OA as it reduces chances of wound infections, require less intraoperative and postoperative analgesia, lesser hospital stay, quickened return of normal bowel function, and improved cosmetic outcome since it avoids a large scar.⁴⁸ This has been proved in a meta-analysis conducted by Sauerland et al.⁵¹ LA patients returned to work 5 days earlier, stayed in hospital 1.1 fewer days, had reduced pains by 8 mm on a 100mm visual analogue scale, and approximately had 1/2 the number of wound infections as compared to OA.

Since it is also a diagnostic tool laparoscopy also has an added benefit. This is beneficial in gynecological conditions. It was found out in a study, which looked at

unnecessary appendectomies in females, that if a simultaneous gynecological pathology was present, which was diagnosed in 73% in laparoscopic group compared to 17% in the open group.⁴⁸

A controversial area is what steps should be taken in a patient without a clear diagnosis and in a non inflamed appendix. In an Italian Consensus Conference, 60% of surgeons felt that the normal appendices should be removed.⁴⁸ When examined histologically, 1/3rd of all “normal looking appendices” will actually be inflamed, and it was described by Phillips et al.⁷⁰ Recently, potential dangerous consequences of “negative appendectomy, was published in a study by M. N. Anderson and R. E. Anderson.⁵² As per their study the morbidity and mortality nearly paralleled that of a perforated appendicitis. Which brings out whether this changes the opinions and practices of majority of the surgeons or not.⁴⁸

In most minimally invasive institutions, LA is the standard procedure in uncomplicated appendectomies. There is an increase in the rate of LA to approximately 58% of all appendectomies. It is surprising that in spite of LA acquiring majority of appendectomies, OAs are still performed, at an increasing amount.⁴⁸ A German study in 2009 questioned whether LA is the standard procedure in German hospitals as it reported that nearly half of all appendectomies were open procedures (46%).⁵⁰ This can be explained due to the fact that the conventional open approach hasn't yet been shown to be inferior to LA, and in an affordable way, it provides reliable clinical results compared to LA.⁴⁸

Special considerations

Pregnancy

Appendicitis is the most frequent non-obstetric emergency needing intervention/surgery in pregnancy with an incidence of 0.15 to 2.10 per 1000 pregnancies.⁵³ There is a reduced incidence in appendicitis during pregnancy, particularly during the third trimester, in contrast to earlier studies which suggested an equal incidence, according to a recent study.⁴¹

Presentation is atypical and may be mistaken for labour pains quite often. This can be explained by the gravid uterus pushing or displacing the appendix challenging the classical

presentation of pain. If tenderness along anywhere over the right side of the abdomen with an associated symptoms of nausea and vomiting are present, then appendicitis must be considered. Maternal mortality rises to 4% with advanced gestation and perforation in appendicitis whereas fetal mortality ranges from 20-35% in cases of perforation compared to 0.5-1% in uncomplicated cases.⁵³

Appendicular mass

A tender mass may be felt in the right iliac fossa with muscle rigidity, in patients with a delay in presentation. It can be confirmed with radiological scans like ultrasonography or computed tomography scan but in elderly population, neoplasia must be ruled out. The initial management of this condition is conservative, with appropriate resuscitation and intravenous broad spectrum antibiotics. As the inflammation resolves, the mass decreases in size, although patients need careful monitoring to detect early signs of progression and perforation. Interval appendectomy is carried out after resolution of the mass, as appendicitis can occur in the future.⁴¹

Appendicular abscess

Patients presenting with high grade fever, tachycardia, and leukocytosis associated with mass are said to have an appendicular abscess. Usually it is situated in the right iliac fossa on the lateral aspect, but sometimes it can be pelvic which is checked by a rectal examination. On ultrasonography or computed tomography, it can be confirmed. A percutaneous drainage under radiological guidance can be done. Appendectomy can be done if open drainage is planned. That is the added advantage.⁴¹ But with increased experience and techniques in laparoscopy, appendicular abscess can be drained.

Chronic (recurrent) appendicitis

Neuroimmune appendicitis is a new concept which has evolved after the introduction of neurogastroenterology. Altered visceral perception from the gut is resulted by subtle alterations in enteric neurotransmitters after bouts of intestinal inflammation; this has been

implicated in a wide range of gastrointestinal conditions. It remains an interesting area but further work and researches are required.⁴¹

Inflammatory bowel disease

Delayed disease onset and a benign type of ulcerative colitis is associated with patients having a history of appendectomy.^{41,54} The same association with Crohn's disease is not clear, but some studies suggest a delayed disease onset.⁴¹ There is contradictory evidence also which suggests an increased risk of developing this disease depending on the patient's age, sex, and diagnosis at the time of operation.⁴⁸

Complications

Appendectomy is a safer procedure as 0.8 per 1000 is the mortality rate associated with appendectomy (uncomplicated).⁴⁹ The mortality in complicated cases as in perforation is 5.1 per 1000. 30% is the average rate of perforation at presentation, due to delay in diagnosis this is increased in young children and elderly people, with the rate up to 97%.⁷

The increased rate of mortality and morbidity associated with perforation has been used as justification for high rates of negative appendectomy, quoted as between 20% and 25%.⁵⁵ Despite this, complications can occur after removal of a normal appendix, and the surgical community continues to strive to reduce the numbers of negative procedures.⁵⁶

A perforated appendix during childhood does not have a long term effect on subsequent female fertility, according to a large cohort study.⁵⁷ Low incidences of intraoperative and postoperative complications have been reported in association with laparoscopic appendectomy.⁴¹

Bleeding

Most conversions to open procedure is due to intra operative bleeding. It is usually overestimated due to the camera magnification in LA. Bleeding can occur from the mesoappendix secondary to aggressive dissection or through the retroperitoneum in a retrocaecal appendix which is inflamed. But careful dissection can prevent this complication. Suction, pressure of the site of bleeding with an instrument or gauze and an additional trocar facilitate identification and control of the site of bleeding. With various steps like

Coagulation, clips, or by an endoloop, the bleeding can be controlled. Very rarely, conversion to open procedure is needed due to bleeding.

Faecolith

This is a rare complication. During dissection of a distended, gangrenous appendix, a faecolith may drop into the peritoneal cavity. And this retained faecoliths may cause an intrabdominal abscess post operatively. Therefore, faecoliths should be avoided being lost between the loops of the intestine and the pelvis and should be carefully taken out . Faecoliths should be thrown into an endobag and a peritoneal lavage should be given. As laparoscopic appendectomy becomes a more common method of treatment, this complication will be found more often.⁵⁵ However with increased magnification chances of finding lost fecolith also increases in LA.

In order to treat faecolith adequately, surgeons should be aware of this complication, when recognized intra or postoperatively. This complication can be prevented by the gentle treatment of an inflamed, gangrenous appendix and the use of an endobag. Since in all described cases of a dropped faecolith after open appendectomy, an abscess develops, it is recommended to remove the faecolith when it is established that one has dropped intraoperatively. Removal by laparoscopy is possible in cases if the presence of a faecolith is confirmed postoperatively.⁵⁸ A retained faecolith which is manifested as an intra abdominal abscess is treated like any other abscess.⁵⁵

Incomplete appendectomy

After an incomplete appendectomy, delayed obstruction and inflammation of the residual tissue is called stump appendicitis.⁵⁷ This is a rare but serious complication due to recurrent appendicitis. Most reports published are for open appendectomy, though theoretically it is increased in laparoscopic cases.⁴¹

Stump appendicitis occurs when the appendix is excised from a point far away from the base. An important point is the clear visualization of the junction between the caecum and the appendix. Identification is carried out by tracing the taenia coli up to the base of the appendix. The base of the appendix can be alternatively marked by dissecting and ligating of

recurrent branches of the appendicular artery.⁵³ The base of the appendix should be dissected to avoid injury to the caecum. If a patient with history of appendectomy complains of similar pain, then stump infection must be considered.⁴¹

Postoperative abscesses

It is rarely seen after laparoscopic appendectomy as a good lavage and clear cleaning of the operative field with the help of a good camera decreases chances of retained infection. There is also a significant decrease in the incidence of post-operative abscess after laparoscopic appendectomy. Hypothesis is that infected fluid in the abdominal cavity causes subhepatic and subphrenic abscesses when the patient is in Trendelenburg's position. They are treated by image guided drainage along with antibiotic coverage.⁴⁵

Stump leak

When there is excessive coagulation of the stump or an inadequately placed endoloop, the tissue goes into necrosis and sluff out occurs. This is a rare complication and is characterized by an enterocutaneous fistula and managed similarly.

Wound infection

Even in gangrenous appendicitis, wound infection is rare after laparoscopic appendectomy when compared to open technique. The incidence of wound infection is reduced by the advent of the endobag and the maneuver of retrieving the appendix through a port.

Intra-abdominal abscess

In cases with gross contamination of the abdominal cavity, this complication may occur. The patient has fever and abdominal pain. It can be confirmed by a computed tomography or ultrasonography. Under image guided with a pigtail catheter, an abscess can be drained. But occasionally, open or rectal drainage may also be needed. The incidence of these abscesses are reduced by administering perioperative broad spectrum antibiotics.⁴⁵

On a whole, laparoscopic appendectomy has advantages, which are proven, over the open technique. There are lower risks of wound infection, lesser post-operative pain and shorter hospital stay. The most common reasons for unsuccessful procedures are the position

of the appendix, intra op bleeding and post op abscess. Surgeon's inexperience may add up to these factors. The procedure becomes challenging especially in cases of retrocaecal appendix and abscess. In these cases, approach is easier by laparoscopy which indicates the site of the incision. The abdominal cavity is cleansed completely, by laparoscopy in cases of generalized peritonitis with lavage and drainage. Important characteristics of laparoscopy are less irritation of the bowel, less trauma to tissues, lesser postoperative pain, short hospital stay, a faster recovery and return to everyday activities. The economic importance and its implications favoring this approach cannot be ignored.⁵⁹

Appendiceal Stump Closure during Laparoscopy

During a laparoscopic appendectomy, the closure of the appendiceal stump is an important step to avoid the potentially serious postoperative complications which arise from inappropriate stump closure. The development of dangerous events such as postoperative peritonitis, enterocutaneous fistulas, and sepsis are feared and unwanted which carry high morbidity and mortality. When Kurt Semm published his laparoscopic technique, he described and illustrated in detail all the steps taken in the operation. He opted for the endoligature with a surgical knot, for stump, followed by a purse-string suture, in addition to a Z-suture.⁶⁰ Endoligature and double surgical knotting requires high skills and experience from the surgeon side. There are chances of developing a mucocele and some anatomic alterations in the caecum, which may confuse future diagnosis.⁶¹

In 1985, Engstrom and Fenyo⁶² published a study, which was randomized prospective, with 735 patients who underwent an appendectomy within 5 years. There were 2 groups in the study. In the first group, endoligation and invagination through purse string suture followed by Z suture was carried out at the base of the appendix, in 357 patients. In group 2, endocoagulation of the extraverted mucosa was done after ligating the base with absorbable endoligature in 361 patients. Both groups were comparable in terms of sex, percent forms of complication, and antimicrobial treatment. In accordance to infectious complication rate, postoperative fever and hospital stay, there was no significant difference found when compared in both the groups. It was concluded that the procedure of choice is

single appendiceal stump endoligature during appendectomy and that the destruction of the mucosa, after an appendix section, may avoid mucocele.

The alternatives are mechanical endostapler, endoligature (endo-loop), metal clips, bipolar endocoagulation, polymeric clips, and intracorporeal suture.⁶¹ Various methods of the appendiceal closure haven't been fully assessed in randomized studies.⁶³

Mechanical endostaplers and simple endoligature, according to literature, is most used to manage the stump. There are many advantages of a mechanical endostapler include decreased enterocutaneous fistula rates and possible treatment of complicated forms of appendicitis. Costs, technical problems, rare cases of obstruction in adherence to the suture line are the disadvantages. Partial obstruction of the ileocecal valve can be produced when stapling the caecal-appendiceal transition, and the surgeon should be careful in this regard.⁶⁴

Benefits of the endoligature include 6- to 12-fold decreased costs and an easier procedure. If the patient comes back with necrosis at the insertion of the appendix into the caecum, this ligatured stump does not allow treatment. This is the major disadvantage. About only 3% of the cases have been observed but this has been discussed much in literature.⁶⁵ Intracorporeal caecorrhaphy can be carried out in this scenario or a video-assisted laparotomy as published by Browne.⁶⁶ Both require surgeons with experience in the laparoscopic treatment of complicated forms of the acute appendicitis. If endostapler is available, it can be definitely used however drawbacks can't be winked off.

A meta-analysis to compare the use of the endostapler with the endoligature in the appendiceal stump closure was done by Kazemier et al.⁹ Data from 427 patients enrolled in 4 prospective randomized studies were included. The variables were operative time, complication rate and in-hospital stay. After analyzing these details, it was concluded that endostapler was preferred.

A systematic review by comparing endostapler and endo-loop was carried out by Sajid et al.⁶⁷ They included 622 patients from 5 randomized studies. In the endo-loop group, it was observed that it had a longer operative time, compared to the endostapler and no significant difference between groups regarding hospital stay and intra-abdominal abscess.

But perioperative rate of complication was higher in the endoloop group. It was concluded that endoloops are safe to use.

Cristalli et al.⁶⁵ described the use of a metal clip (Ethnor T1300) to treat an uncomplicated appendiceal stump in appendicitis. In 20 patients who underwent laparoscopic appendectomy, the advantages and disadvantages were analyzed. Mean time for the procedure was found to be 36.5 minutes, conversion not required, and there were zero postoperative complications. This procedure is fast, feasible and indicated in patients with a right inferior quadrant pain bearing an uncomplicated acute appendicitis.

In 105 patients, metal clip (Ethicon T400) was used for the appendiceal stump closure by Gomes and Nunes⁶⁵ Mean operative time was found to be 31.4 minutes, complications of infection around 6.7%, and laparotomy was needed to complement the laparoscopic procedure in 1.9% cases. There were no complications directly related to the clip. The presence of necrosis at the junction of the appendix into the caecum and considerable appendiceal diameter were the main flaws. Laparoscopic knot using 3-0 polygalactin, caecorrhaphy, and video-assisted laparotomy were the alternatives.

Bipolar endocoagulation was the treatment of choice in 60 patients for the appendiceal stump by Khanna et al.⁶⁸ Located 3 to 5mm from the caecal wall, the appendix was subjected to endocoagulation. The time needed was between 60 to 180 seconds, with an average of 90 seconds, until bubbling of the tissue was no longer seen and a ring formed at the said point. The appendix is then sectioned with the help of a magnified image provided by laparoscopy. The basic principle is that in the presence of less intense heat (45 to 601C) for longer periods, the tissue protein denatures and determines the loss of its quaternary structure and solidification. This is widely used for hemostasis in laparoscopic procedures. 3 patients had complications but they were not described, and 1 case needed laparotomy. It was concluded that bipolar endocoagulation was simple and cost effective and makes unnecessary to use any material that is foreign to the body. Two studies compared nonabsorbable polymeric clip (Hem-o-lok MLX) and the treatment with an endostapler and evaluated the advantages and disadvantages.^{69,70}

The Hanssen trial⁶⁹ was comprised of 2 stages. 28 patients were divided into 2 groups of 14 patients in the first stage. One group used the clip and the other used the laparoscopic stapler. Variables such as operative time, hospital stay, complications, and costs were studied. Following the same pattern, 250 patients were evaluated in stage 2. The use of polymeric clip is safe, feasible and a cost-effective alternative to treat the appendiceal stump, it was found. A single nonabsorbable polymeric clip was compared to the endostapler and evaluated for feasibility, morbidity, and cost effectiveness of the same in appendiceal stump closure in the Partecke et al.¹⁵ study. It was a prospective nonrandomized study with 56 patients closed by endostaplers, and in 26 patients, a single Hem-o-lok MLX polymeric clip was used. The time of surgery, costs, time of hospitalization and complications were analyzed. It was noticed that the length of surgery was longer in the clip group because of the introductory phase. Morbidity was comparable and acceptable in both groups. The costs of 1 set of Hem-o-lok clips were negligible compared with endostaplers (19.94 vs. 356.43 Euros). It was concluded that the use of a single nonabsorbable polymeric clip is easy to use, safe and cost effective. Therefore it is suggested that a tactical modification of the appendiceal stump closure with a single appendiceal endoligature, replacing the invaginating suture, is the procedure of choice during an appendectomy whenever possible.

In selected cases only, the management of the appendiceal stump by an invaginating suture should be used. Studies suggest the use endostapler, endoligature (endoloop), metal clips, bipolar endocoagulation, and polymeric clips, which don't require an invaginating suture. All are having advantages and disadvantages up against the different clinical stages of appendicitis, and there are no prospective studies available that assess all of them. For a safe and more cost-effective procedure, knowledge about and appropriate use of the different forms of appendiceal stump closure are important.⁶¹ Roeders knot in appendiceal stump closure

Appendiceal stump closure is the most controversial issue in the laparoscopic appendectomy procedure. Despite the fact that many authors have described several modifications with new materials for appendiceal stump closure, an optimal closure material

has not yet been determined. Moreover, most of these materials may prolong the operation time or increase cost, which may limit the popularity of laparoscopic appendectomy.¹¹

Knot tying is challenging when performed during laparoscopy. A new horizon for laparoscopy has opened up by laparoscopic vessel ligation, suturing and performing anastomosis. Laparoscopic knots can be done extracorporeally or intracorporeally. The tumble square, Dundee, Aberdeen, Midship and blood knots are the most common intracorporeal knots. Decreased sensation of the tension applied to the tissues and the knot and difficulty in knotting because of technical requirements and limited space are the disadvantages. Duncan, Roeder, modified 4-S Roeder, Tayside, Yanni and Gea knots are the most common extracorporeal knots. It is much easier to tie than intracorporeal knot, but they can cause tissue trauma from pulling long lengths of suture through the needle tract, excessive tension on the tissue while pushing the knot into position, and loss of focus on the operative field during knotting. One kind of knot-pusher would not fit for all and hence use of different knot-pushers for different suture materials are suggested.¹¹

In routine cases, the intracorporeal knot-tying procedure requires 4 trocars. One holds the camera, 2 are for working to tie the suture, and the last is for holding and manipulating the appendix to be tied. If the fourth port is not used, the dissected appendix remains unsupported, and placing the knot precisely at the base becomes difficult. The percutaneous hanging technique was first introduced by Joshi et al.⁹¹ for laparoscopic appendectomy. This technique removed the need for the fourth trocar and reduced the operating time. This model is with a minor modification, that is, without the use of an epidural, and thus we do not need a fourth trocar for stabilization. Although this hanging method is ergonomic and useful for intracorporeal knot-tying, the operation time is still longer than that for the endoclip procedure.

The titanium endoclip is made of a nonabsorbable metal material used routinely in surgery. Various studies, especially in laparoscopic cholecystectomy, have demonstrated that titanium endoclips can be used safely and efficiently. With the widespread use of the titanium endoclip in surgery, endoscopic procedures have been greatly facilitated, and operation times

have been considerably shortened. Moreover, it can be applied easily and does not require advanced surgical skills on the part of surgeons.¹¹

The use of metal clips to close the appendicular stump was first described by Cristalli et al.⁶⁵ in 1991. However, it has not gained general acceptance despite the increased popularity of laparoscopic appendectomy. Nonabsorbable polymeric clips have lock systems that resemble the titanium endoclip, but they are expensive. Recently, some studies have compared the polymeric clip with the endoloop and stapler in appendiceal stump closure during laparoscopy and reported that the polymeric clip is safe, easy to use, and more cost effective.^{69,70,71}

The recent studies suggest that titanium endoclips are safe and they shorten the operation time and simplify the procedure. Thus, the endoclip can be a useful alternative to intracorporeal knot-tying for appendiceal stump closure. Knot-tying techniques, in contrast to the endoclip, require hanging the appendix, which entails an added intervention and increases the operation time significantly.¹¹

One concern is that a drawback of titanium endoclips may be abscess formation in the later period. There are no reports about abscess formation after appendectomy with endoclips; however, a few case reports of abscess formation associated with dropped metallic surgical clips after laparoscopic cholecystectomy have been reported, none of which has specified whether the clip was titanium.^{72,73}

Singh et al.⁷⁴ reported an important study of 26 cases in which surgical metal clips were dropped during cholecystectomy, and none was associated with increased risk of abscess. They pointed out that dropped gallstones, rather than dropped metal clips, was the main cause of abscess formation in their study.

A second drawback of titanium endoclips is the question of migration, as some studies have presented case reports showing that metal clips used in cholecystectomy may migrate into the common bile duct. No prospective study or case report has discussed the migration of titanium endoclips used in laparoscopic appendectomy into the intestines,

although some case reports have indicated the migration of the clip into the bile duct after cholecystectomy.¹¹

Despite the increasing number of cholecystectomies being performed annually, clip migration cases are still rare. The exact pathophysiology underlying the migration of endoclips into the bile duct is unknown. However post cholecystectomy clip migration into the bile duct has also been reported for absorbable clips. The most likely reason for migration is improper or erratic application of the clips, resulting in bile leakage. Secure and correct placement of the clips could help prevent this complication.¹¹ Beldi et al.⁷⁵ reported that 1 endoloop used in appendiceal stump closure is sufficient and safe.

Ates M. et al.¹¹ used double intracorporeal knot-tying sutures and double titanium endoclips, and there were no differences in the complication rate or length of hospital stay between these groups. Their experience in all 61 cases revealed no increased risk of complications and leakage in laparoscopic appendiceal stump closure with intracorporeal knot-tying, but the operation time is significantly longer than that with endoclip closure because the intracorporeal knot-tying is not as easy as endoclip application and requires extensive laparoscopic training.

The Double Shank (DS) Clip is an effective and safe device for closing the appendiceal base in laparoscopic appendectomy. In university and country hospitals the clip was applied in large number of patients. The complications are comparable to other methods. It is suitable as a standard tool for laparoscopic appendectomy in hospitals of different supply levels. There are limitations for the clip application in cases of severely inflamed or wide appendix base. When these conditions were met, a group of patients were excluded but nevertheless in a group of patients the clip was applied, even when the appendix base was estimated severely inflamed or extremely enlarged.¹¹

No significant difference was found in the incidence of intra-abdominal abscesses in some randomized and prospective clinical trials when staplers are compared to endoloops for appendiceal stump closure. Endoloop was an easy, safe, and cost-effective procedure.⁷⁶

Among 4489 patients with acute appendicitis, in a non-concurrent cohort study, it was found that the endoloop group had a significantly higher rate of intra-abdominal surgical-site infection and readmission compared with stapling.⁶⁴

The routine use of endoscopic staplers was favoured in a meta-analysis of 427 patients in four randomized controlled trials on appendix stump closure. When the appendix stump was secured with staplers, superficial wound infections and postoperative ileus were obviously less frequent but there was no significant difference in relation to intra-abdominal abscess.⁹

One or two proximal ligatures and one distal ligature are applied around the base of the appendix, which results in extraversion of the appendiceal stump mucosa in endoloops, as opposed to the inversion of the mucosa with stapling devices. Insufficient closure of the stump or exposure of the remaining contaminated mucosa to the abdominal cavity may be the cause of abscess formation after endoloop. Mucosal necrosis with loosening of the ligature could be postulated as another mechanism of leakage.⁹

METHODOLOGY

The present study was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgavi from January 2017 to December 2017.

Study design

The study design was a randomized controlled trial.

Study period and duration

The present study was conducted for one year from January 2017 to December 2017.

Place

The present study was carried out in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgavi a tertiary care teaching hospital attached to KLE Academy of Higher Education and Research centre (KAHER), Belgavi.

Source of Data

Patients diagnosed with appendicitis (Acute, chronic, recurrent and tip perforation) and undergoing laparoscopic appendectomy were included in this study.

Sample size

A total of 60 patients divided into two groups of 30 each undergoing laparoscopic appendectomy were studied.

Sampling procedure

Based on the rule of thumb a sample size of 60 divided into two groups of 30 each was planned due to the lack of proven data on prevalence for this study, the effect size could not be calculated.

Randomization

Patients were divided into two groups of 30 each as Test group and Control group by Sequential Numbered Opaque Envelope Method

Selection criteria

Inclusion

- Patients diagnosed with appendicitis and willing for laparoscopic appendectomy.
- Clinically diagnosed as appendicitis (Acute, chronic and recurrent)
- Patients aged between 12 to 70 years.

Exclusion

Patients with

- Appendicular base perforation
- Appendicular base more than 10 mm, which was assessed using Maryland dissector
- Immunocompromised state
- Bleeding disorders
- Pregnancy
- Patients who refused to participate in the study.

Ethical clearance

Prior to the commencement, the study was approved from the Ethical and Research Committee, Jawaharlal Nehru Medical College, Belgaum.

Informed Consent

The patients fulfilling selection criteria were informed in detail about the nature of the study and a written informed consent was obtained before enrollment (Annexure I).

Method of collection of data

Patients were interviewed and demographic data such as age, sex and the presenting symptoms were noted. These patients were subjected to clinical examination and evaluated for vitals and clinical signs. These findings were recorded on a predesigned proforma (Annexure II).

Investigations

The following investigations were done

- Routine blood investigations including:
 - o Complete blood count.
 - o Urine examination (routine and microscopy)
- Serum Urea
- Serum Creatinine
- Liver function test
- Ultrasound

Procedure

Diagnosis of appendicitis

Diagnosis of appendicitis was based on disease history (Right Iliac Fossa pain, vomiting, nausea, anorexia, fever) and clinical signs (McBurney's point tenderness, Rebound Tenderness), and laboratory tests (elevated leukocyte count in acute appendicitis). The preoperative diagnosis of appendicitis was confirmed by ultrasound

abdomen and pelvis revealing either probe tenderness in the right Iliac fossa or an aperistaltic, tubular appendix.

Patient positioning

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

Anaesthesia

All the surgeries were performed under general anaesthesia.

Surgical technique

All the laparoscopic appendectomies were performed in the same surgical unit. The bladder was decompressed with a Foley catheter to avoid injury during insertion of the supra-pubic ports. Through the umbilicus, a 10 mm port was inserted by Hasson's open technique and pneumoperitoneum was created and another 10 mm port was inserted in the midline lower pelvic (suprapubic) region. One 5 mm trocar was inserted in the left lower quadrant forming a triangle with the previous two ports. If necessary an additional 5 mm port was inserted at the right lower quadrant. After that, diagnostic laparoscopy was done.

The mesoappendix was skeletonized from the top to the base using cautery or at occasion using clips through the 10 mm umbilical port. The base of the appendix was then isolated.

Intervention

Test Group

Hem-o-lok clips were passed through the 10 mm port and secured at the base of the appendix. Two clips were placed at the base and a 3rd clip placed distally for 6 cases and for other 24 cases one clip placed at the base and other at the distal end. Using a Maryland grasper, the base of the appendix was measured and if < 10mm, Hem-o-lok clips were applied.

Control Group

Through the same port a Roeder's Knot (Silk suture, self made) is introduced in the same way. Three knots placed in 3 cases, two knots were applied in 27 cases and the appendix is transected between the two ties. After resection of the appendix, it was retrieved through a 10 mm trocar. Silk suture was used to carry out Roeder's knot.

Diagnosis was correlated with Histopathology report.



Photograph 1: Hem-o-lok clip applicator and clip with Roeder's knot pusher with knot



Photograph 2: Different sizes of Hem-o-lok Clips

Different sizes of Hem-o-lok clips are available and they are colour coded as follows:

Blue-Medium clip

Green-Medium Large clip

Purple/Violet-Large clip

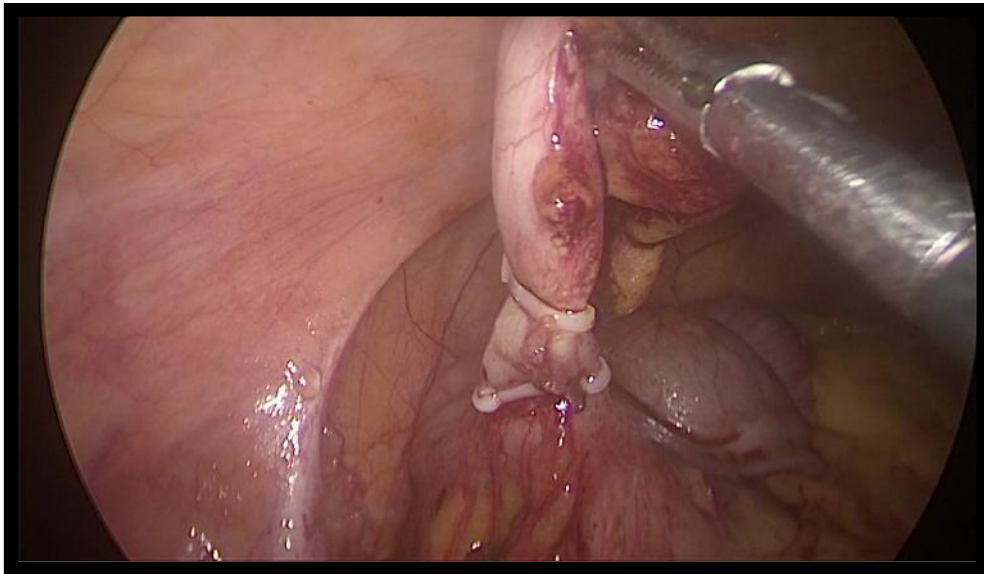
Brown-Extra Large

In our study we used Purple/ violet Large clip which can ligate up to 13mm of diameter.

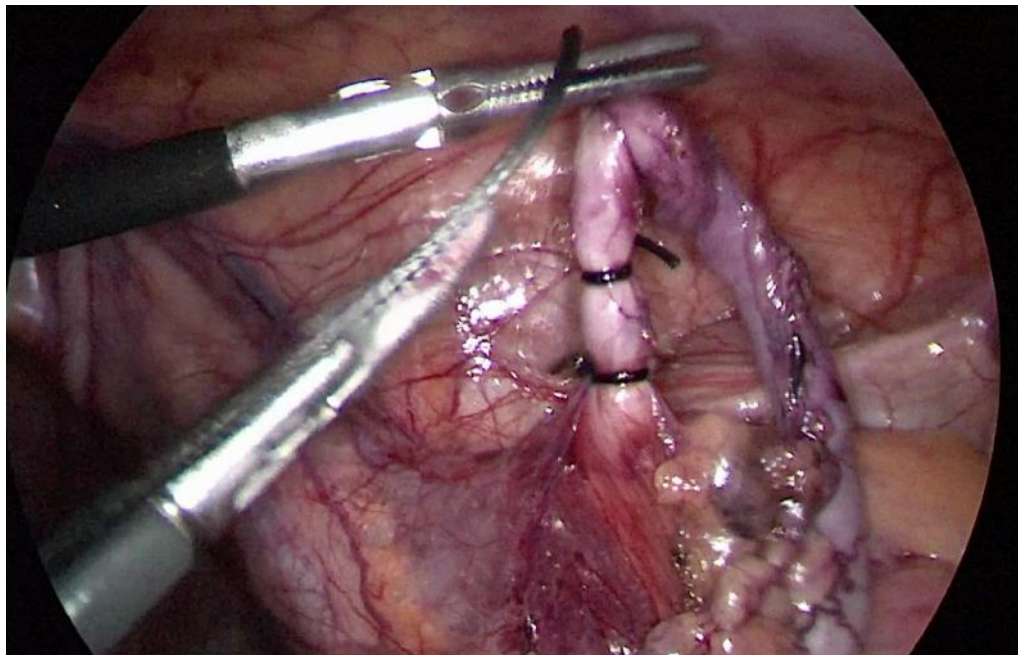


Photograph 3: Hem-o-lok clip with applicator

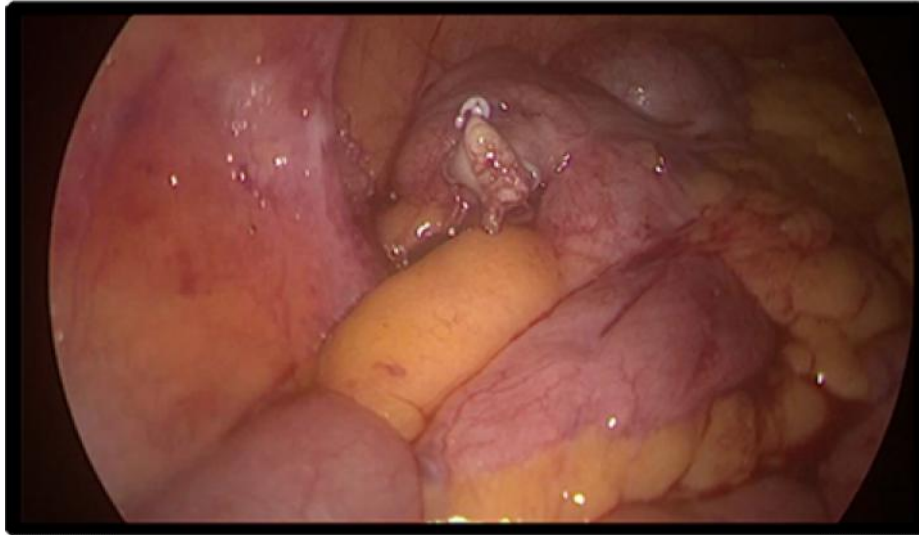
(Hem-o-lok clip has locking mechanism, it is inert, non conductive and radiolucent)



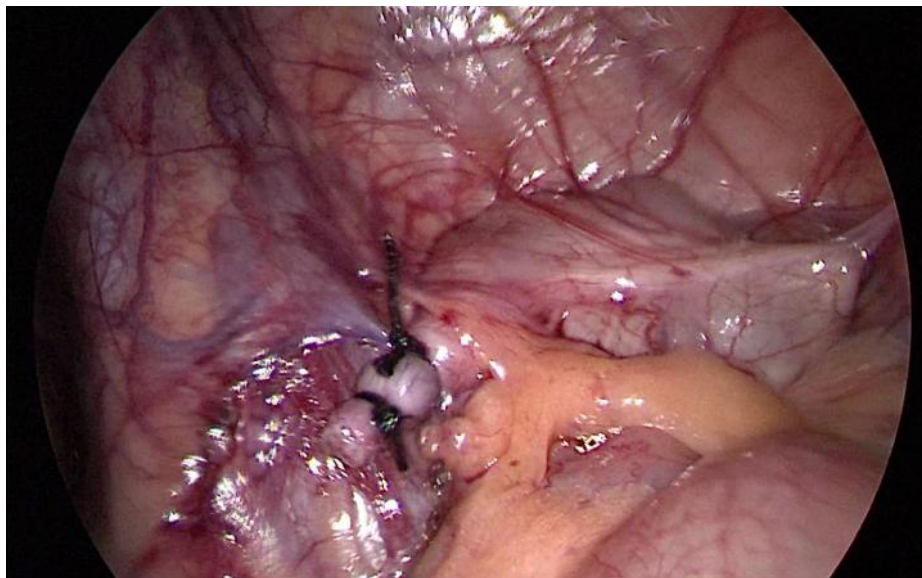
Photograph 4: Hem-o-lok clip ligation



Photograph 5: Roeder's knot ligation



Photograph 6: Post operative stump picture (Hem-o-lok Clip)



Photograph 7. Post operative stump picture (Roeder's Knot)

Post operative care

Post operative management was the same for both the groups. Both groups were monitored for any complications till discharge from the hospital. The skin sutures were removed between postoperative day seven to ten. Routine follow up examinations were ordered for all patients for first two months after surgery.

Outcome variables

The following variables were evaluated intra operatively and post operatively._

- Ease of use and safety of Hem-o-lok clips compared to Roeder's knot by operative time and pressure gradient respectively
- Intraoperative complications
- Post operative complications
- Hospital stay
- Follow up period

Statistical analysis

The data was entered into the Microsoft Excel Spreadsheet (Annexure III). The data was analyzed using MedCalc statistical software version 17.0. The categorical data was expressed as rates, ratios and percentages and comparison was done using chi-square test. Continuous data was expressed as mean \pm standard deviation and the comparison was done using independent sample t test. A probability ('p' value) of less than or equal to 0.05 at 95% confidence interval was considered as statistically significant.

RESULTS

The present one year randomized controlled trial was done in the the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgavi. A total of 60 patients diagnosed with appendicitis (Acute, chronic, recurrent and tip perforation) and undergoing laparoscopic appendectomy from January 2017 to December 2017 were enrolled. Based on the intervention, these patients were divided into two groups of 30 each based according to the opaque envelope method as below.

Control Group

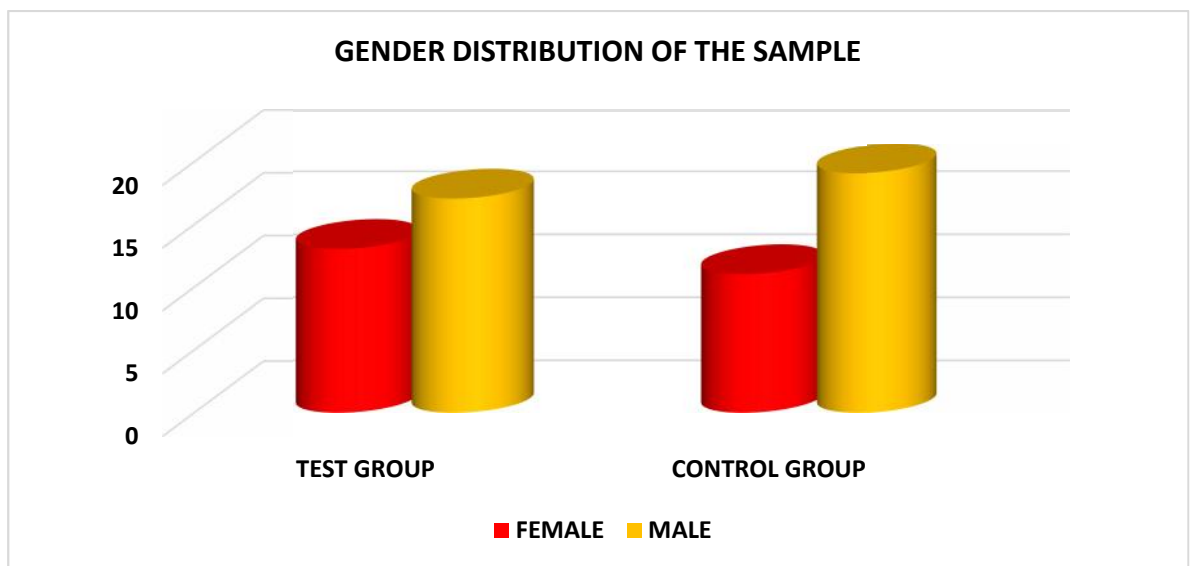
The appendiceal stump closure during laparoscopic appendectomy in this group was done using Roeder's Knot (Silk suture).

Test Group

Patients in this group underwent the appendiceal stump closure during laparoscopic appendectomy using Hem-o-lok clips.

The data obtained was analyzed and the final results and observations were tabulated and interpreted as below.

	TEST GROUP	CONTROL GROUP	TOTAL
FEMALE	13	11	24
MALE	17	19	36
TOTAL	30	30	60



In this study there was male preponderance in both test and control group.

	TEST GROUP				CONTROL GROUP					
	MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	P VALUE	INFERENCE
AGE	29.76	14.91	13	68	28.60	11.15	13	69	0.7360	NS

In test group age group is between 13-68 years with mean of 29.76 years. And in control group age group varied between 13-69 years with mean value of 28.60.p value 0.7360, which is statistically insignificant

	TEST GROUP		CONTROL GROUP	
HTN	NUMBER	PERCENTAGE	NUMBER	PERCENTAGE
N	28	93.33	29	96.67
Y	2	6.67	1	3.33
TOTAL	30	100.00	30	100.00

The p value using Chi-Square test is 0.5536 (NS)

Presence of HTN is not associated with a groups.

	TEST GROUP		CONTROL GROUP	
DM	NUMBER	PERCENTAGE	NUMBER	PERCENTAGE
N	26	86.67	28	93.33
Y	4	13.33	2	6.67
TOTAL	30	100.00	30	100.00

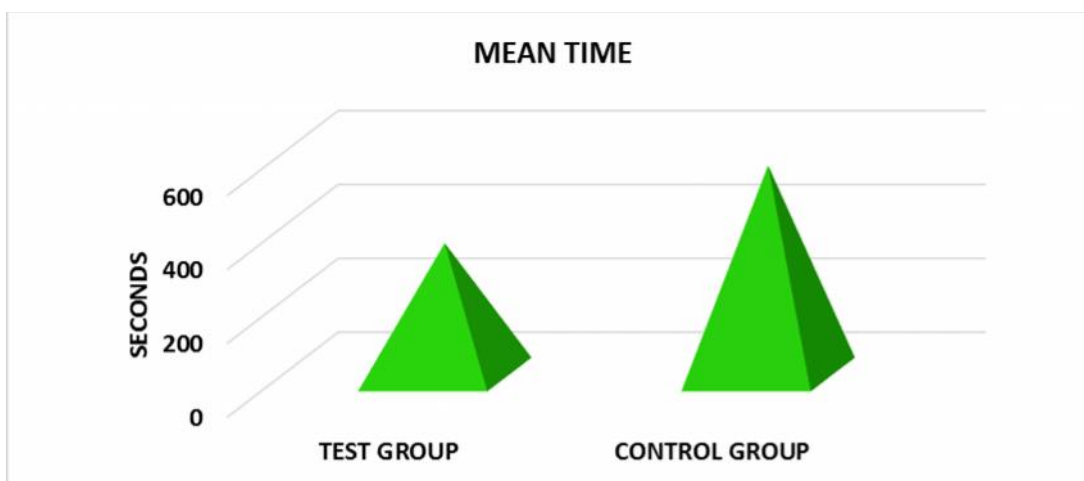
The p value using Chi-Square test is 0.3894 (NS)

Presence of DM is not associated with a groups.

IHD	TEST GROUP		CONTROL GROUP	
	NUMBER	PERCENTAGE	NUMBER	PERCENTAGE
N	30	100.00	30	100.00
Y	0	0.00	0	0.00
TOTAL	30	100.00	30	100.00

No association between IHD and test or control group

	TEST GROUP				CONTROL GROUP				P VALUE	INFERENCE
	MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX		
TIME	356.03	82.50	239	598	566.33	62.24	480	740	< 0.0001	HS



In the test group time varied between 239 sec to 598 sec with mean of 356.03. And in control group time varied between 480 sec to 740 sec with mean value of 566.33 sec. p value is < 0.0001 which is statistically highly significant.

SURGEON FEASIBILITY	TEST		CONTROL	
	NUMBER	PERCENTAGE	NUMBER	PERCENTAGE
LESS FEASIBLE	2	6.67	26	86.67
MORE FEASIBLE	28	93.33	4	13.33
TOTAL	30	100.00	30	100.00

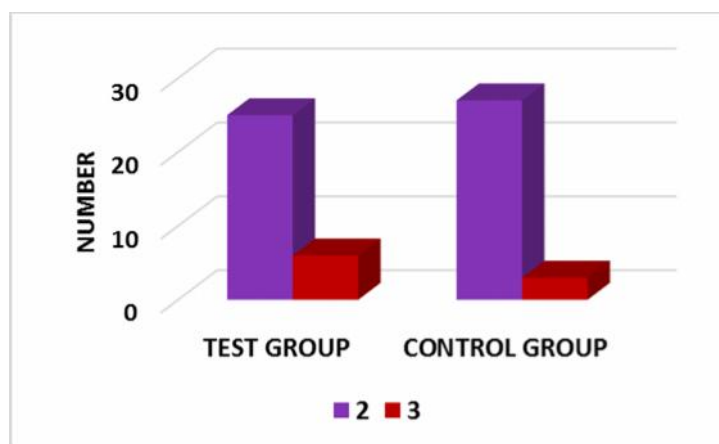
The p value using Chi-Square test is < 0.0001 (HS)

Surgeon feasibility is associated with groups.



Percentage of more feasibility in test group is 93.33 and in control group it is 13.33.

p value is < 0.0001 which is statistically highly significant.

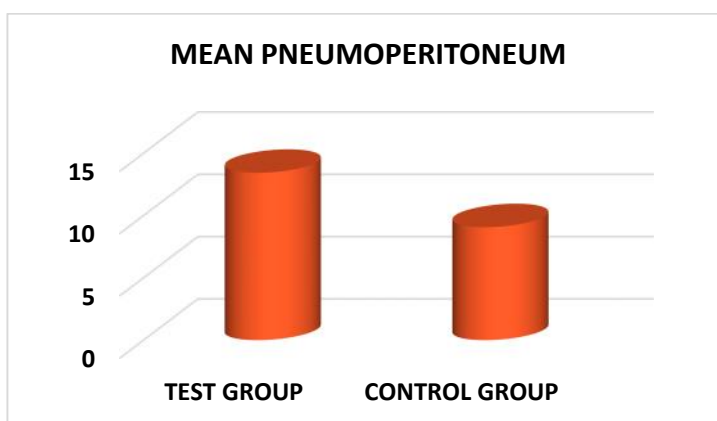


	TEST(HEM-O-LOK)		CONTROL(ROEDER'S KNOT)	
NUMBERS USED	NUMBER	PERCENTAGE	NUMBER	PERCENTAGE
2	24	80.00	27	90.00
3	6	20.00	3	10.00
TOTAL	30	100.00	30	100.00

The p value using Chi-Square test is 0.2781 (NS)

Number of Hem-o-lok clips in test group are 3 in 6 cases and 2 in 24 cases. And number of roeder's knot are 3 in 3 cases and 2 in 27 cases. p value is 0.2781 which is statistically insignificant.

	TEST GROUP				CONTROL GROUP				p VALUE	INFERENCE
	MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX		
PNEUMOPERITONEUM	13.43	0.68	12	14	9.07	0.83	7	11	< 0.0001	HS



Pneumoperitoneum pressure gradient varied between 12 to 14 mm of hg in Test group with mean value of 13.43 mm of hg. In control group pressure gradient varied between 7 to 11 mm hg with mean of 9.07 mm of hg. p value is <0.0001 which is statistically highly significant.

DISCUSSION

Treatment of appendicitis has remained unchanged since it was reported in 1889 by Charles McBurney⁴⁹. Kurt Semm described an alternative approach i.e., Laparoscopic appendectomy in 1983⁷⁰ and the first research series of large group of Laparoscopic appendectomy was done in 1990 by Pier et al.⁷⁷

Laparoscopic appendectomy (LA) for acute appendicitis has advantages over open appendectomy and it has gained wide acceptance in the past decade. Using the National Inpatient Sample (NIS) database, it was estimated that the use of LA had increased from 41% in 2003 to 80% in 2011⁷⁸

The standard technique for securing the base of the appendix in laparoscopic appendectomy is with absorbable endoloop ligature or Roeder's knot, though many clinical evidence favors the use of the end staplers, nonabsorbable polymer Hem-o-lok clips are an alternative technique, because laparoscopic appendectomy can be performed in less amount of time and inexpensive than the standard technique and has a locking mechanism. Hem-o-lok clips caused a milder reaction than endoloop clips did⁷⁹. If the inflammation of the appendix has involved the caecum or base of appendix is perforated, loops are not safe.⁸⁰

The most important point in LA is to choose the safest method for appendicular stump closure. There are various methods of stump closure by using Hem-o-lok clips, endoloop and titanium clips for appendicular stump closure. Studies suggested that use of the Hem-o-lok clip for appendicular stump in LA is a feasible, safe, fast, and cost-effective procedure in patients with a mild to moderately inflamed appendix base of less than 10 mm in diameter.⁸¹

Till date, few randomized clinical studies have been conducted to compare Roeder's knot and Hem -o-lok clips. This study was designed to assess the operative time, surgeon feasibility, pressure gradient and safety of Hem-o-lok clips compared to Roeder's knot in the appendiceal stump closure among the patient undergoing laparoscopic appendectomy.

The present one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgavi from January 2017 to December 2017. A total of 60 patients diagnosed with acute appendicitis or chronic appendicitis or recurrent appendicitis or appendicular tip perforations scheduled for laparoscopic appendectomy were studied. Based on the method of appendiceal stump closure, these patients were divided into two groups of 30 each by opaque envelope method as Control Group (Patient underwent appendiceal stump closure with Roeder's Knot) and Test Group (Patients underwent appendiceal stump closure using Hem-o-lok clips). The patients were evaluated for operative time, surgeons feasibility ,intra operative pnemuperitoneum pressure, intra-operative and post operative complications. In the present study frequency of males were slightly high in both the groups. In test group, 56.66% of the patients were males and in control group males constituted 63.33%. The male to female ratio in test group was 1.3:1 compared to 1.72:1 in control group . Ates M. et al.¹¹ which compared intracorporeal (polyglactin) knot-tying suture with titanium endoclips in appendiceal stump closure during laparoscopic appendectomy reported male preponderance.

The incidence of appendicitis gradually rises from birth, peaks in the late teen years, and gradually declines in the geriatric years.^{23,82} The mean age in test group was 29.76 years and in control group the mean age was 28.6 years (p=0.7360). These findings suggest that, most of the patients who presented with appendicitis were young. Many of the earlier studies^{23,82} in the literature have observed that appendicitis is common in the younger age group.

Further, the history of associated illness (including diabetes mellitus, hypertension and Ischemic heart diseases) did not have statistical significance as p value for HTN for both the groups was 0.5536, p value for Diabetes Mellitus was 0.3894 .

With each method having its advantages and disadvantages, various methods are being studied and tried for the same. An important step to avoid post-operative infectious complications is the appendiceal stump closure. Endoloops, endoclips and endostaplers are used for this procedure.

Any one of the methods cannot be preferred as the literature is mixed in this context. There are many studies where staplers are compared to endoloops. Routine use of endostaplers is preferred, in two reviews,^{10,66} especially in case of an inflamed appendix base, because complications were lesser compared to endoloops. In contrast, endoloops were considered superior because of similar complication rates compared to staplers but much lower costs in another review, consisting of five RCTs having 622 patients.⁹ Longer operation time associated with endoloops led to higher costs in these studies. Also for the placement and tightening of the loop around the appendiceal base experience is required. This can be counted as a disadvantage.⁶⁴

More than 20 years ago, the use of endoclips for appendicular stump closure was described. In spite of this, it is less investigated and less commonly used. The diameter of the appendix base and severity of inflammation limits the use of the endoclips. Clips can be used safely for closure of the appendiceal base in selected cases have been shown in small studies.⁷

In the present study intra operative time is calculated by mainly taking time in seconds between insertion of Hem -o- lok clip applicator and retrieval of appendix in test group and in control group time between insertion of Roeder's knot pusher to retrieval of appendix. In the present study significantly higher number of patients in test group had operative time between 300 and 400 seconds ($p < 0.0001$). The mean operative time in test group was significantly low compared control group (356.03 seconds vs 566.33, $p < 0.0001$). These findings suggest that, appendiceal stump closure during laparoscopic appendectomy requires significantly lower operative time using Hem-o-lok clips compared to Roeder's knot. As per the study done by Samir Delibegovic and Ervin Matovic , Mean operative time was 47.1 ± 6.7 min in the endoloop group and 38.7 ± 5.0 min in the hem-o-lok group (p value=0.00001). (35).According to Sabry AA et al use of the Hem-o-lok clip for CAS in LA is a feasible, safe, fast, and cost-effective procedure in patients with a mild to moderately inflamed appendix base of less than 10 mm in diameter.⁸¹

Comfort and feasibility with instruments while operating plays an important role in better outcome of the patients. If the better results or outcome are seen with newer techniques or instruments as well as if difficulty level is decreased for a surgeon during surgery it eventually benefits the patient and improves the outcome. In this study, operating surgeon was given an option after surgery, whether it was more feasible or less feasible with Hem -o-lok clip and Roeder's knot. In the test group for 28 cases surgeon found it more feasible and in

control group only in 4 cases surgeon found it more feasible (93.33% v/s 13.33% respectively) with p value <0.0001. As per Mohammed H. Al-Temimi et al, The Hem -o-Lok clip was effective and easy to use as compared to Roeder's knot. As per Sabry AA et al use of the Hem-o-lok clip for appendicular stump closure in LA is a feasible, safe, fast, and cost-effective procedure in patients with a mild to moderately inflamed appendix base of less than 10 mm in diameter.⁸¹

In the present study, initially for 3 clips were used in test group, however only two were for appendicular stump closure. Totally in 6 patients 3 hem-o-lok were used accounting for 20% of the cases (2 clips to secure appendicular stump and 1 for cut end to avoid spillage in the abdomen). In rest of 80% of the patients totally 2 clips were used, and only one was for securing appendicular stump and other for distal cut end. Similarly in control group 10% used 3 Roeders knot and rest 90 % used 2 Roeder's knot. However it was not statistically significant (p=0.2781).

Post-operatively on day 1 there were no recordable complications seen in either test or control group. However on POD 3 in test group 3 patient had fever in test group and 4 patients in control group. Patients were asked to followup on POD 7, there were no recordable complications noted in either of the groups. Patients were further followed up over telephonic conversation, however long term complications couldn't be followed up.

Overall the results of this study suggest that Hem-o-lok clips shorten the operation time, more feasible for operating surgeon, has minimal pressure gradient difference and simplifies the procedure with minimal post operative complications. Hence, Hem-o-lok clips can be used in alternative to Roeders knot for appendiceal

stump closure. However, there is a limitation of this study in that the follow-up period was not enough to discuss long-term side effects of Hem-o-lok clips.

CONCLUSION

Overall the present study of Hem-o-lok clips versus Roeder's knot in appendiceal stump closure showed that the Hem-o-lok clips had several advantages. Less operative time, surgeon's feasibility and lower pressure gradient (maintenance of pneumoperitoneum) are distinct which are statistically highly significant. So use of Hem-o-lok for appendicular stump closure in Laparoscopic Appendectomy is a feasible, fast and safe as compared to standard Roeders knot.

SUMMARY

Appendiceal stump closure during laparoscopic appendectomy is a most important step as stump leak may result in life threatening events. The present study was an attempt to evaluate the ease of use,operative time and safety of Hem-o-lok clips compared to Roeder's knot in the appendiceal stump closure in patients undergoing laparoscopic appendectomy by comparing operative time,surgeons feasibility ,pressure gradient and post operative complications .

This one year randomized controlled trial was done in under the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgavi from January 2017 to December 2017. A total of 60 patients undergoing laparoscopic appendectomy were enrolled. Based on the intervention, patients were divided into two groups of 30 each that is,Control Group (Roeder's Knot using Silk suture) and Test Group (Hem-o-lok clips).

In the present study 63.33% of the patients in Control group were males compared to 56.66% in Test group. The mean age in control group was 28.6 years and in Test group it was 29.76 (p=0.7360). Other variables including clinical presentation, medical history, anthropometry, vitals, clinical signs, diagnosis, haemoglobin and urine analysis were comparable. The time between insertion of clip applicator and retrieval of appendix in patients in Test group was between 239 to 598 seconds while in patients in Control group time between insertion of knot pusher and retrieval of appendix was between 480 to 740 seconds (p<0.0001). Surgeons feasibility in Test group was more feasible in 93.33% and 13.33 % in Control group (p<0.0001). The

pneumoperitoneum pressure after insertion of clip applicator in Test group was between 12 to 14 mm of hg with mean value of 13.43 mm of hg and pressure after insertion of knot pusher and retrieval of appendix in Control group was between 7 to 11 of hg($p<0.0001$). Post operative complications in both Test and Control group were on POD 1, however on POD3 in Test group 3 patients had fever and in Control group 4 patients had fever.

Based on the results of this study it may be concluded that, appendiceal stump closure with Hem-o-lok clips is advantageous since it is fast, feasible and safe($p<0.0001$) as compared to Roeder's knot in Control group.

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ANNEXURE I – CONSENT FORM

**TITLE OF RESEARCH STUDY: A STUDY OF SINGLE HEM-O-LOK CLIP
V/S ROEDER'S KNOT IN LAPAROSCOPIC APPENDICEAL STUMP
CLOSURE: A ONE YEAR RANDOMIZED CONTROLLED TRIAL STUDY
IN KLE'S DR. PRABHAKAR KORE CHARITABLE HOSPITAL, BELGAVI**

Under the supervision (Guide)

DR. _____
Professor & HOD,
Department Of General Surgery,
Jawaharlal Nehru Medical College,
Belagavi.

Principle-investigator

DR. _____
Post Graduate Student,
Department of General Surgery
Jawaharlal Nehru Medical College,
Belagavi.

Introduction and purpose A study of single Hem-o-lok clips v/s Roeder's knot in
Laparoscopic Appendiceal Stump closure : A One year Randomized Controlled Trial
Study in KLE'S Dr. Prabhakar Kore Charitable Hospital, Belgavi.

You are requested to participate in a study that is an attempt to find out the
effectiveness of single Hem-o-lok clips in comparison to Roeder's knot suturing in
Appendiceal 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 a alternate technique of Appendiceal stump closure in comparison to Roeder's Knot sutures. 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 and HOD, Department of Surgery, J. N. Medical College, Belgavi.

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 and B) and accordingly receive either the standard treatment (Roeder's knot suturing) or the newer treatment (Hem-o-lok Clips). Intra operatively, the operative time, surgeon's feasibility, Pressure gradients, number of clips and sutures used & complications will be noted along with any other problems faced during surgery. Postoperative complications will be noted until you are discharged and further followup is done if required through telephonic conversation.

Benefits

The benefits of the procedure under study are decreased length of surgery, better surgeon feasibility, minimal pneumoperitoneum pressure variability leading to decreased intra-operative complications, early recovery time, better cosmesis & minimum post operative 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. _____ and Dr. _____ 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, Belgavi. 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. _____(Mobile No. _____); or Dr. _____ (Mobile No. _____ .If you need any further information regarding your rights as a study participant, you may also contact Dr. _____ (Mobile no. _____, Chairman of Institutional Ethics Committee, JNMC, Belgaum.

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:

General Physical Examination

Weight: Temperature: Pallor: Height
Cyanosis: Pedal Oedema:
Clubbing: Pulse : Blood Pressure: RR:

Systemic examination

Cardiovascular System:

Respiratory System:

Per Abdomen:

Central Nervous system:

Spine assessment:

Investigations

Hb%: Urine Routine:

Any Other:

USG Abdomen & Pelvis

Diagnosis

Inclusion Criteria

- Diagnosed Appendicitis cases, willing for Laparoscopic Appendectomy
- Age between 12 to 70 years.
- Clinically diagnosed as Uncomplicated Appendicitis

Exclusion Criteria

1. Patients not willing to participate in the study

2. Complicated Appendicitis like perforated appendicular base AND local or diffuse peritonitis
3. Patients unfit/contraindicated for Laparoscopic Surgeries
4. Immunocompromised patients

Observations

Readings were recorded in the following manner

Group:

Age:

Sex:

Operative time (Time b/n insertion of clip applicator or roeder's knot pusher and retrieval of appendix):

Surgeon's feasibility:

Pneumoperitoneum pressure:

Localization of Appendix:

Perioperative Complications:

Post operative Complications:

Other findings:

Any other problems faced:

Signature of staff in charge:

ANNEXURE III – KEY TO MASTER CHART

N	-	Absent
Y	-	Present
HTN	-	Hypertension
DM	-	Diabetes Mellitus
IHD	-	Ischemic Heart Diseases
YRS	-	Years
SEC	-	Seconds
POD	-	Post Operative Day
MM HG	-	Millimeter of Mercury
B/N	-	Between
M	-	Male
F	-	Female

SL. NO.	IP NO.	AGE (YRS)	SEX	HTN	DM	IHD	OTHER CO-MORBIDITIES	DIAGNOSIS	SURGERY DONE	DATE OF SURGERY	TIME B/N INSERTION OF ROEDERS KNOT PUSHER AND EXCISION OF APPENDIX	SURGEON FEASIBILITY	PNEUMOPERITONEUM PRESSURE WITH ROEDER'S KNOT PUSHER INSERTION IN MM HG	NUMBER OF ROEDERS KNOT	POST-OP COMPLICATIONS		
															POD1	POD3	POD7
1	808885	21	F	N	N	N	N	APPENDICITIS	LAPROSCOPIC APPENDECTOMY	5/6/2017	578 SEC	FEASIBLE	10	2	N	N	N
2	822134	34	M	N	N	N	N	ACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	14/7/2017	602 SEC	LESS FEASIBLE	9	2	N	N	N
3	822314	18	M	N	N	N	N	ACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	18/8/2017	580 SEC	LESS FEASIBLE	9	2	N	FEVER	N
4	835258	20	M	N	N	N	N	RECURRENT APPENDICITIS	LAPROSCOPIC APPENDECTOMY	16/10/2017	732 SEC	LESS FEASIBLE	9	3	N	N	N
5	786714	69	F	N	Y	N	N	APPENDICITIS WITH LIVER ABSCESS	LAPROSCOPIC APPENDECTOMY WITH DRAINAGE OF LIVER ABSCESS	6/2/2017	662 SEC	LESS FEASIBLE	11	3	N	N	PORT SITE INFECTION
6	823774	22	F	N	N	N	N	ACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	13/9/2017	612	FEASIBLE	8	2	N	N	N
7	833424	35	F	N	N	N	HYPOTHYROID	RECURRENT APPENDICITIS	LAPROSCOPIC APPENDECTOMY	9/10/2017	740 SEC	LESS FEASIBLE	8	3	N	N	N
8	840310	28	M	N	N	N	N	ACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	14/11/2017	521 SEC	LESS FEASIBLE	9	2	N	N	N
9	830539	26	M	N	N	N	N	ACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	25/9/2017	536 SEC	LESS FEASIBLE	9	2	N	FEVER	N
10	843565	28	M	N	N	N	N	ACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	29/11/2017	570 SEC	LESS FEASIBLE	9	2	N	N	N
11	798277	28	F	N	N	N	N	ACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	13/4/2017	504 SEC	LESS FEASIBLE	10	2	N	N	N
12	811691	23	F	N	N	N	N	ACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	19/6/2017	622 SEC	LESS FEASIBLE	10	2	N	N	N
13	843080	38	M	N	N	N	N	ACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	27/11/2017	496 SEC	LESS FEASIBLE	9	2	N	N	N
14	821362	14	M	N	N	N	N	ACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	8/8/2017	534 SEC	LESS FEASIBLE	9	2	N	N	N
15	821347	18	M	N	N	N	N	ACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	8/8/2017	544 SEC	FEASIBLE	9	2	N	N	N
16	821501	20	M	N	N	N	N	SUBACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	11/8/2017	569 SEC	LESS FEASIBLE	9	2	N	N	N
17	827259	23	M	N	N	N	N	CHRONIC APPENDICITIS	LAPROSCOPIC APPENDECTOMY	8/9/2017	552 SEC	LESS FEASIBLE	9	2	N	FEVER	N
18	828318	28	M	N	N	N	N	ACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	11/9/2017	510 SEC	LESS FEASIBLE	9	2	N	N	N
19	829318	50	M	N	Y	N	N	ACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	21/9/2017	587 SEC	LESS FEASIBLE	8	2	N	N	N
20	834419	30	M	N	N	N	N	ACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	13/10/2017	539 SEC	LESS FEASIBLE	8	2	N	N	N
21	877802	13	F	N	N	N	N	ACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	8/2/2017	564 SEC	LESS FEASIBLE	10	2	N	N	N
22	789530	26	M	N	N	N	N	APPENDICITIS	LAPROSCOPIC APPENDECTOMY	20/2/2017	533 SEC	LESS FEASIBLE	7	2	N	N	N
23	809872	29	F	N	N	N	N	ACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	7/6/2017	502 SEC	LESS FEASIBLE	10	2	N	N	N
24	812338	28	M	N	N	N	N	SUBACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	23/6/2017	491 SEC	LESS FEASIBLE	9	2	N	N	N
25	817851	34	M	N	N	N	N	APPENDICITIS	LAPROSCOPIC APPENDECTOMY	21/7/2017	590 SEC	LESS FEASIBLE	9	2	N	N	N
26	804512	41	F	N	N	N	N	APPENDICITIS	LAPROSCOPIC APPENDECTOMY	11/5/2017	480 SEC	LESS FEASIBLE	8	2	N	FEVER	N
27	881756	27	F	N	N	N	N	APPENDICITIS	LAPROSCOPIC APPENDECTOMY	31/5/2017	572 SEC	LESS FEASIBLE	10	2	N	N	N
28	796166	20	F	N	N	N	N	ACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	27/3/2017	526 SEC	FEASIBLE	10	2	N	N	N
29	891654	29	M	N	N	N	N	ACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	8/2/2017	560 SEC	LESS FEASIBLE	9	2	N	N	N
30	831568	38	M	Y	N	N	N	ACUTE APPENDICITIS	LAPROSCOPIC APPENDECTOMY	27/9/2017	582 SEC	LESS FEASIBLE	9	2	N	N	N