

"A RANDOMISED CONTROL TRIAL TO COMPARE
OCTYL 2- CYANOACRYLATE VERSUS
CONVENTIONAL SUTURING OF PORT SITE SKIN
CLOSURE IN LAPAROSCOPIC APPENDICECTOMY
FOR 1 YEAR"

REG.NO. BH0112005

Dissertation

Submitted to the
KLE University, Belgaum, Karnataka

In Partial Fulfillment
of the requirements for the degree of

M. S.
in
GENERAL SURGERY

**DEPARTMENT OF SURGERY,
JAWAHARLAL NEHRU MEDICAL COLLEGE,
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**ENDORSEMENT BY THE HOD/PRINCIPAL/
HEAD OF THE INSTITUTION**

This is to certify that the dissertation entitled “**A RANDOMISED CONTROL TRIAL TO COMPARE OCTYL 2-CYANOACRYLATE VERSUS CONVENTIONAL SUTURING OF PORT SITE SKIN CLOSURE IN LAPAROSCOPIC APPENDICECTOMY FOR 1 YEAR**” is a bonafide research work done by **CANDIDATE REG. NO. BH0112005.**

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LIST OF ABBREVIATIONS USED

°C	-	Degree centigrade
AA	-	Acute appendicitis
AD	-	Anno Domini
BC	-	Before Christ
BP	-	Blood pressure
CECT	-	Contrast enhanced computed tomography
cm	-	Centimeters
-COOR	-	Alkoxy carbonyl
eg	-	For example
ESR	-	Erythrocyte sedimentation rate
FGF	-	Fibroblastic growth factor
HIV	-	Human immunodeficiency virus
IL	-	Interleukin
IP No.	-	In patient number
min	-	Minutes
mm	-	Millimeters
mmHg	-	Millimeters of mercury
MRI	-	Magnetic resonance imaging
n	-	Total number
OCA	-	Octyl-2-cyanoacrylate
OCT	-	Octyl
p	-	Probability
PDGF	-	Platelet-derived growth factor
PMNs	-	Polymorphonuclear leukocytes

PR	-	Pulse rate
RR	-	Respiratory rate
SD	-	Standard deviation
Temp	-	Temperature
TGF-b	-	Transforming growth factor beta
TNF	-	Tumor necrosis factor

ABSTRACT

Background and Objectives

Several methods are used for the skin closure of trocar wound. Skin incision closure using adhesives glues is one of the recent and advanced method. This study was aimed to compare port site wound closure using octyl-2-cyanoacrylate with conventional suture in patients undergoing laparoscopic appendicectomy with regard to complications, time taken for wound closure and cosmetic outcome.

Methodology

The present one year randomized controlled trial was done in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. A total of 60 patients who underwent laparoscopic appendicectomy from January 2013 to December 2013 were divided into two groups of 30 each based on Opaque envelope method. In Group A, port site wound closure was done using with octyl 2- cyanoacrylate and in Group B the same was carried out with non-absorbable sutures.

Results

In the present study 66.67% in group A and 50% in group B were males ($p=0.190$). The mean age in group A was 26.96 ± 6.80 years compared to 30.30 ± 9.69 years in group B ($p=0.129$). The clinical characteristics of the study population in group A and B were comparable ($p>0.050$). The mean surgical time in group A was significantly less compared to group B (123.30 ± 22.46 vs 186.90 ± 21.49 minutes; $p<0.001$) The complications including erythema, warmth,

tenderness, drainage and infection were comparable in group A and B at all the three follow ups ($p>0.050$). The Hollander Cosmesis score was optimal (score of 6) in majority of the patients with group A as well as group B at all the follow ups ($p>0.050$).

Conclusion and interpretation

Overall, the wound closure using octyl-2-cyanoacrylate requires significantly less time for skin closure and results in shorter operative time and the wound complications and cosmetic outcome using octyl-2-cyanoacrylate are comparable with conventional suture.

Keywords

Conventional suture; Laparoscopic appendicectomy; Octyl-2-cyanoacrylate;

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INTRODUCTION

Acute appendicitis is the most common cause of an 'acute abdomen' in young adults. Appendicitis is an inflammation of the inner lining of the vermiform appendix that spreads to its other parts. The condition is common and urgent surgical illness with variable manifestations, generous overlap with other clinical conditions and significant morbidity, which increases with diagnostic delay.¹ The dominant factor for acute appendicitis is obstruction of the lumen and the usual cause of obstruction are fecoliths. Other causes for obstruction are lymphoid hyperplasia, intestinal worms, tumors or other conditions.²

There is 7% lifetime risk of developing appendicitis among the individuals of industrialized countries. The highest frequency occurs at ages between 10 to 30 years and risk gradually decreases until age 50, where it stabilizes.³ In the past three decades, the incidence has fallen dramatically with individual lifetime risk of appendectomy being 8.6% and 6.7% among males and females respectively.⁴

The diagnosis of acute appendicitis relies on a thorough history and examination.⁵ Typical uncomplicated cases of acute appendicitis are easy to diagnose and treat. Unfortunately, 20-33% of the patients suspected of having acute appendicitis present with atypical findings.⁶ In recent years however with the availability of various cross-sectional imaging techniques viz. Ultrasonography, CECT and MRI, false positive diagnosis of acute appendicitis has reduced. The overall accuracy of cross-sectional imaging techniques in diagnosing acute appendicitis varies from 87%-98%.⁷

Since its first description by Fitz in 1886, much has been documented about the inflamed vermiform appendix and the need for prompt intervention to prevent the morbid consequences of perforation.⁸ In the 1880s, Billroth was credited with pioneering the field of abdominal surgical intervention in Vienna, opening the door for procedures to resect diseased appendices. McBurney's muscle splitting incision standardized this approach to an appendectomy upon its publication in 1894. Since then, mortality associated with acute appendicitis has been reduced to nearly 0.1% due to further improvements in medical and surgical management. Surgical operations have evolved over the decades from open appendectomies to increasingly minimally invasive procedures.⁹

Appendectomy is one of the most commonly performed surgical procedures of the abdomen in the world. This surgical procedure has been performed for over 100 years, after first being described by McBurney.¹⁰ With rapidly developing, minimally invasive surgery, the laparoscopic appendectomy has become a selectable method for appendectomy. Previous studies have reported that laparoscopic appendectomy has many advantages in comparison to open appendectomy, such as shorter hospital stays, reduced risks of complications, and better cosmetic satisfaction.¹¹ Therefore, the laparoscopic appendectomy, like laparoscopic cholecystectomy, is considered to be a favorable procedure for appendectomy present and future.¹²

In the ever-evolving world of medicine, continual research and new advances in technology have aided our care for patients for many years. With the recent changes in healthcare policies and procedures, our search for improved patient care has been directed at finding better ways to be cost-effective and time-efficient, while

still directing our treatment goals towards providing the highest quality patient care. One of the areas that have continually seen advances in cost and time efficiency is the treatment and closure of wounds and lacerations.

There are several methods for skin closure of trocar wound. In the past, surgical skin incisions were closed using sutures, and further staples and adhesive tapes were used. Recently since 1949, skin adhesive glues are also available.

Sutures have conventionally been the method of approximating wound edges due to their high tensile strength and favorable cosmetic outcomes. Sutures do, however, have some downfalls in that they require increased time and a skilled individual to accomplish good cosmetic outcomes. Over the past four decades, advances have seen other forms of wound closure methods emerge that address some of the disadvantages of sutures.¹³

Adhesives glues are most recent and advanced method available for closing surgical skin incisions. Tissue adhesive, octyl-2-cyanoacrylate (OCA) ('Dermabond') does not require a skilled person to apply, nor does it cause pain that requires anesthesia as with the suturing technique. Therefore, it can be applied in a much quicker manner and not cause any additional pain or anxiety to the patient.¹⁴

With these advantages and with continued improvement, tissue adhesives have become an ideal alternative to conventional sutures and could possibly become the preferred standard of care in many procedures. However, this concept remains unexplored due to scanty data comparing the use of adhesive glues and sutures. This prompted us to compare octyl-2-cyanoacrylate with conventional suturing of port

site wound closure in laparoscopic appendectomy in terms of wound complications, time taken for wound closure and cosmetic outcome.

OBJECTIVES

The objectives of the present study were to compare octyl-2-cyanoacrylate with conventional suturing of port site wound closure in laparoscopic appendicectomy in terms of -

1. Time taken for wound closure.
2. Wound complications.
3. Cosmetic outcome

REVIEW OF LITERATURE

Historical review

Caludius Amyrand in 1736 performed first appendicetomy on a boy of 11 years old who had right scrotal hernia accompanied by fistula (within the scrotum was found the perforated appendix).¹⁵

Heister in 1755 recognized that appendix might be sight of primary inflammation. Hamock in 1848 successfully drained an appendicular abscess in a pregnant female during her eight month of pregnancy. Lawson Tait in 1880 performed first abdominal appendicectomy.¹⁵

Reginald Fitz in 1886 first described acute appendicitis. He was also the first to use the term “Appendicitis”. McBurney in 1889 advanced the act of diagnosis sufficiently to remove the first unruptured appendix and also devised the muscle splitting incision named after him.¹⁵

Two hundred years after anatomical description, the appendix was observed to be the site of inflammatory disease. This was not widely accepted until the publication by Fitz 120 years later. American surgeons demonstrated that performing early appendectomy was safe and life saving. Perforation of the appendix with peritonitis continues to be a major problem, but the mortality rate has significantly declined. Appendiceal disease has clearly affected the course of history.¹⁶

Anatomy

The vermiform appendix is a narrow, vermian (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:¹⁷

1. Retrocaecal (12 O'clock) position – directed upwards in the retrocaecal recess. If the length is greater it may be retrocolic or 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 as follows.¹⁷

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

The length varies from 2 to 20 cm with an average of 9 cm. it is longer in children than adults. The diameter is about 5 mm. The lumen is quite narrow and may be obliterated after mid-adult life.¹⁷

The appendicular orifice is situated at posteromedial aspect of the caecum 2 cms below the ileocaecal orifice. The appendicular orifice is occasionally guarded by an indistinct semilunar fold of mucous membrane known as valve of Gerlach.¹⁷

The appendix is suspended by a small triangular fold of peritoneum, called mesoappendix. The appendicular artery often runs in its free edge, but may run closer to the base of the appendix.¹⁷

Blood supply

The caecum is supplied by the anterior and posterior caecal branches of the ileocolic artery which is a branch of superior mesenteric artery.¹⁸

The appendicular artery, a branch of ileocolic artery reaches the appendix through the mesoappendix. There may be an accessory appendicular artery (artery of Seshachalam) arising from the posterior caecal artery. If the mesentery is incomplete, the artery lies on the wall of appendix in its distal part and may be thrombosed in acute appendicitis.¹⁸

Venous drainage

Venous drainage is brought about by the appendicular, ileocolic and superior mesenteric veins and is to the portal vein.¹⁹

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.¹⁹

Nerve supply

A plexus of nerves consisting of both sympathetic and parasympathetic fibres accompany 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.¹⁹

Development

The caecum and appendix develop from the caecal bud of the midgut. Agensis of the appendix is extremely rare. A study reported an incidence of one in 1,00,000 laparotomies for suspected appendicitis.¹⁹

Histology

The structure of the appendix resembles that of large intestine. The lamina propria is extensively infiltrated with lymphocytes and the details of the mucosa are often obscured by the many lymphatic nodules that may fill the mucosa and submucosa. This profusion of lymph tissue has promoted the description of “abdominal tonsil” for the appendix, and draws attention to this features as relevant to the causes of appendicitis.¹⁹

Duplication of the appendix

Duplication of the appendix is an anomaly of extreme rarity, classified it into three types.²⁰

Type A: Partial duplication of the appendix on a single caecum.

Type B: Single caecum with two completely separate appendices.

B1 : Bird like appendix where there are two appendices symmetrically placed on either side of ileocaecal valve.

B2 : Along with the usual appendix another rudimentary appendix arises from the caecum along the line of one of the teniae coli.

Type C: There are two caeca, each of which bears an appendix.

Tinkler described a unique case of a triple appendix, associated with double penis and ectopia vesicae.²⁰

Epidemiology

Appendicitis is the most common acute surgical condition of the abdomen. Approximately 7% of the population will have appendicitis in their lifetime, with the peak incidence occurring between the ages of 10 and 30 years.²¹

Studies have demonstrated that AA is seen most commonly in western societies, particularly in youths and males.²² Consequently only 5% to 10% of acute appendicitis cases are seen in the elderly.²³ The lower incidence of AA and the less pronounced gender gap in regions such as Africa and Asia is worth mentioning.²⁴

Epidemiological and demographic studies report the appendicitis incidence to vary according to age, gender, race, socioeconomic status, food culture, and seasonal changes etc.^{22,24} Therefore, the frequency of AA is different in each country.

Appendicitis is most frequently seen in patients in their second to fourth decades of life, with a mean age of 31.3 years and a median age of 22 years.²⁵

The studies performed in the last decade have reported a decrease in the incidence of AA in western countries²⁶ but an increase in some African²⁷ and Asian²⁸ countries is interesting.

In California, the incidence of appendicitis was 137.5 per 1,00,000 for Caucasian males while this incidence was 162.7 for Hispanics, 98.0 for Asian/others, and 70.7 for blacks. The same was true in female patients with rates per 1,00,000 of 98.8, 97.5, 64.6, and 49.6 for the above groups respectively.²⁶

The effect of better socioeconomic conditions created as a result of improving water supplies and hygienic conditions, has been found to be the reason for this decrease in Western societies. A recent study from Spain found a decrease in appendicitis in the last 10 years.²⁹ A study from Greece evaluating the last 30 years found the age-standardized appendicitis rate to fall 75% from 652/1,00,000 to 164/1,00,000.³⁰

Pathogenesis

The appendix is a long diverticulum that extends from the inferior tip of the cecum. Its lining is interspersed with lymphoid follicles. Most of the time, the appendix has an intraperitoneal location (either anterior or retrocecal) and thus may

come in contact with the anterior parietal peritoneum when it is inflamed. Up to 30 percent of the time, the appendix may be “hidden” from the anterior peritoneum by being in a pelvic, retroileal or retrocolic (retroperitoneal retrocecal) position. The “hidden” position of the appendix notably changes the clinical manifestations of appendicitis.²¹

Obstruction of the narrow appendiceal lumen initiates the clinical illness of acute appendicitis. Obstruction has multiple causes, including lymphoid hyperplasia (related to viral illnesses, including upper respiratory infection, mononucleosis, gastroenteritis), fecoliths, parasites, foreign bodies, Crohn's disease, primary or metastatic cancer and carcinoid syndrome. Lymphoid hyperplasia is more common in children and young adults, accounting for the increased incidence of appendicitis in these age groups.²¹

Diagnosis

Diagnosis of acute appendicitis relies on a thorough history and examination.³¹

History

Abdominal pain is the primary presenting complaint of patients with acute appendicitis. The diagnostic sequence of colicky central abdominal pain followed by vomiting with migration of the pain to the right iliac fossa was first described by Murphy but may only be present in 50% of patients.³² Typically, the patient describes a peri-umbilical colicky pain, which intensifies during the first 24 hours, becoming constant and sharp, and migrates to the right iliac fossa. The initial pain represents a referred pain resulting from the visceral innervation of the midgut, and

the localized pain is caused by involvement of the parietal peritoneum after progression of the inflammatory process. Loss of appetite is often a predominant feature and constipation and nausea are often present.³¹

Profuse vomiting may indicate development of generalized peritonitis after perforation but is rarely a major feature in simple appendicitis. A meta-analysis of the symptoms and signs associated with a presentation of acute appendicitis was unable to identify any one diagnostic finding but showed that a migration of pain was associated with a diagnosis of acute appendicitis.³³

This classic presentation can be influenced by the age of the patient and anatomical position of the appendix. Patients at the extremes of the age spectrum can present with diagnostic difficulty because of non-specific presentation, often with subtle clinical signs. Infants and young children often seem withdrawn and elderly people may present with confusion. A high index of suspicion for acute appendicitis is needed in such patients.³¹

Anatomical considerations in the presentation of acute appendicitis

The vermiform appendix is a tubular structure attached to the base of the caecum at the confluence of the taeniae coli. It is approximately 8-10 cm long in adults and represents the underdeveloped distal end of the large caecum seen in other animals. In humans it is regarded as a vestigial organ, and acute inflammation of this structure is called acute appendicitis.³¹

Retrocaecal/retrocolic (75%)

Right loin pain is often present, with tenderness on examination. Muscular rigidity and tenderness to deep palpation are often absent because of protection from the overlying caecum. Irritation of psoas muscle in this position, leading to hip flexion and exacerbation of the pain on hip extension (psoas stretch sign)³¹

Subcaecal and pelvic (20%)

Suprapubic pain and urinary frequency may predominate. Diarrhoea may be present as a result of rectal irritation. Abdominal tenderness may be lacking, but rectal or vaginal tenderness may be present on the right. Microscopic haematuria and leucocytes may be present on urine analysis.³¹

Pre-ileal and post-ileal (5%)

Signs and symptoms may be lacking. Vomiting may be more prominent, and diarrhoea may result from irritation of the distal ileum.³¹

Examination

The patient is often flushed, with a dry tongue and an associated fetor oris. The presence of pyrexia (up to 38°C) with tachycardia is common. Abdominal examination reveals localised tenderness and muscular rigidity after localisation of the pain to the right iliac fossa. Rebound tenderness is present but should not be elicited to avoid distressing the patient. Patients often find that movement exacerbates the pain, and if they are asked to cough the pain will often be localised to the right iliac fossa. The site of maximal tenderness is often said to be over McBurney's point, which lies two thirds of the way along a line drawn from the

umbilicus to the anterior superior iliac spine. Findings on per rectal and vaginal examination may be normal, although tenderness to the right may be present particularly in a pelvic appendix. Tenderness on rectal examination may be suggestive but is not diagnostic of appendicitis. Percussion tenderness, guarding, and rebound tenderness are the most reliable clinical findings indicating a diagnosis of acute appendicitis.³³

Further examination techniques that may aid in the diagnosis of appendicitis are Rovsing's sign (palpation of the left iliac fossa causes pain in the right iliac fossa), psoas stretch sign, and the obturator sign.³¹

Investigations

Special investigations are rarely needed to confirm a diagnosis of acute appendicitis and the diagnosis is predominantly a clinical one. No specific diagnostic test for appendicitis exists, but the judicious use of simple urine and blood tests, particularly inflammatory response variables, should allow exclusion of other pathologies and provide additional evidence to support a clinical diagnosis of appendicitis.³¹

Investigation of acute appendicitis

- Urine analysis up to 40% can have abnormalities
- Pregnancy test in women to exclude pregnancy
- Full blood count - Neutrophil (>75%) predominant leucocytosis is present in 80-90%

- C reactive protein—raised concentration may be present, but its absence should not exclude a diagnosis of appendicitis

Scoring systems

Scoring systems and algorithms have been proposed to aid the diagnosis of acute appendicitis but have not been widely used.³¹

There are several clinical scoring systems that have been used in the diagnosis of acute appendicitis. Alvarado published his scoring system in 1986, also referred to as MANTRELS based on the mnemonic for remembering the combination of 8 signs and symptoms. The score ranges from 0-10; a patient with a score of 5 or 6 is typically observed, whereas a patient with a score of 7 or greater should undergo operation.³⁴ Since then, there have been several studies evaluating the diagnostic accuracy of the Alvarado score, modified versions of the Alvarado score such as the Pediatric Appendicitis Score³⁵ and other scores such as the Kharbanda³⁶ and Lintula scores.³⁷⁻³⁹

Alvarado or MANTRELS scoring system³⁴

Variable		Value
Symptoms	Migration	1
	Anorexia	1
	Nausea-vomiting	1
Signs	Tenderness in right lower quadrant	2
	Rebound of pain	1
	Elevation of temperature	1
Laboratory	Leukocytosis (White Blood count > 10,000 / μ L)	2
	Shift to the left	1
Total score		10

In general, these clinical scoring systems have better LRs than individual symptoms or signs alone. However, these scoring systems do not have sufficient discriminate or predictive ability to routinely be used alone to diagnose appendicitis. They have been used to determine the need for further radiologic studies⁴⁰ or as a guide for dictating clinical management.⁴¹

Radiological evaluation

Radiological tests can be used to aid the diagnosis of acute appendicitis. The table describes the role of these investigations, and the use of ultrasonography and computed tomography scanning may be considered.³¹

One meta-analysis and one systematic review on the role of ultrasonography and computed tomography scanning in the diagnosis of acute appendicitis have concluded that these investigations should be done only in patients in whom a clinical and laboratory diagnosis of appendicitis cannot be made. As ultrasonography studies are operator dependent and need careful examination, these authors also recommend the use of computed tomography in preference to ultrasonography in this group of patients as it has a greater diagnostic accuracy.^{43,44}

The impact of the introduction of imaging techniques on the negative appendectomy rate is still unclear. A study has suggested that ever after the introduction of ultrasonography and computed tomography scanning the rates of negative appendectomy have remained unchanged.⁴⁵ The moderate diagnostic accuracy of ultrasonography in such studies was stated as a possible reason for this.⁴³

Imaging and diagnosis of acute appendicitis³¹

Investigation	Diagnostic criteria	Evidence
Plain radiography	None	No role in diagnosis of acute appendicitis although in some cases a faecolith may shown
Ultrasonography	Aperistaltic and non compressible structure with diameter >6 mm	Sensitivity of 86%; specificity of 81%
Computed tomography	Abnormal appendix identified or calcified appendicolith seen in association with periappendiceal inflammation of diameter >6 mm	Sensitivity of 94% and specificity of 95% in diagnosis of acute appendicitis
Magnetic resonance imaging	Not confirmed	Restricted to cases in which radiation and diagnostic difficulties preclude use of other modalities (for example pregnancy)

However, two prospective studies have evaluated the use of computed tomography, and both showed a decrease in the number of unnecessary admissions and appendicectomies. Importantly, some authors have highlighted the risk of unnecessary exposure to ionising radiation caused by excessive use of computed tomography scans, and low dose protocols have been advocated.

Differential diagnosis

The differential diagnosis of appendicitis is that of an acute abdomen. At the extremes of age, the threshold for referral for further assessment should be low because of the high mortality associated with delayed presentation or diagnosis.³¹

Differential diagnosis of acute appendicitis³¹

Surgical

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

Urological

- Right ureteric colic
- Right pyelonephritis
- Urinary tract infection

Gynaecological

- Ectopic pregnancy
- Ruptured ovarian follicle
- Torsion of ovarian cyst
- Salpingitis/pelvic inflammatory disease

Medical

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

Treatment

Herbert Fitz was the first author to publish on the need for early diagnosis and surgery for acute appendicitis.⁸ Appropriate resuscitation followed by expedient appendicectomy is the treatment of choice. All patients should receive broad spectrum perioperative antibiotics (one to three doses), as they have been shown to decrease the incidence of postoperative wound infection and intra-abdominal abscess formation.⁴⁶

Timing of surgery

A recent retrospective study found no significant differences in complications between early (less than 12 hours after presentation) or later (12-24 hours) appendicectomy.⁴⁷ This does not, however take into account the actual time from the onset of symptoms to presentation, which can have a bearing on the rate of perforation.⁴⁸ After the first 36 hours from the onset of symptoms the average rate of perforation is between 16% and 36%, and the risk of perforation is 5% for every

subsequent 12 hour period.^{47,49} Once a diagnosis is made, appendectomy should therefore be done without any unnecessary delays.

Operative procedure

Traditionally, open appendectomy has been done through a muscle splitting gridiron incision over McBurney's point made perpendicular to a line joining the umbilicus and anterior superior iliac spine or through a more cosmetically acceptable Lanz's incision. The proportion of open procedures done has fallen with the increased use of laparoscopic techniques.³¹

Compared with open surgery, a systematic review found that laparoscopic appendectomy in adults reduces wound infections, postoperative pain, length of hospital stay, and time taken to return to work, although the number of intra-abdominal abscesses was higher after the laparoscopic approach.⁵⁰ However, this view is not shared by a recent study, which found no significant differences between the two procedures except higher quality of life scores at two weeks in the laparoscopic group.⁵¹

Although in the light of these findings laparoscopic appendectomy is becoming more common, it is often technically more demanding and requires special equipment. As a result, the method of approach for appendectomy is dictated by the level of expertise of the operating surgeon and the facilities available. An additional advantage of laparoscopic techniques is the ability to do diagnostic laparoscopy initially, which may show alternative pathology as the cause of the presentation.³¹

Spontaneous resolution of early appendicitis can occur and antibiotics alone can be used to treat appendicitis if no facilities for appendectomy are available. However, a 14-35% readmission rate was associated with antibiotic treatment and because of the high recurrence rate and relatively low morbidity and mortality associated with appendectomy early operative intervention remains the treatment of choice. This study nevertheless does provide support for the immediate starting of intravenous antibiotics once a diagnosis of appendicitis is made and the patient is waiting for theatre.³¹

Complications

Appendectomy is a relatively safe procedure with a mortality rate for non-perforated appendicitis of 0.8 per 1000.⁵² The mortality and morbidity are related to the stage of disease and increase in cases of perforation; mortality after perforation is 5.1 per 1000.²⁰ As stated above, the average rate of perforation at presentation is between 16% and 30%,^{47,49} but this is significantly increased in elderly people and young children, in whom the rate can be up to 97%, usually because of a delay in diagnosis. The increased mortality and morbidity associated with perforation has been used as justification for high rates of negative appendectomy, quoted as between 20% and 25%.⁵² 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. According to a large historical cohort study, a perforated appendix during childhood does not seem to have a long term detrimental effect on subsequent female fertility.⁵³

Wound infection

The rate of postoperative wound infection is determined by the intraoperative wound contamination. Rates of infection vary from < 5% in simple appendicitis to 20% in cases with perforation and gangrene. The use of perioperative antibiotics has been shown to decrease the rates of postoperative wound infections.³¹

Intra-abdominal abscess

Intra-abdominal or pelvic abscesses may form in the postoperative period after gross contamination of the peritoneal cavity. The patient presents with fluctuating pyrexia and the diagnosis can be confirmed by ultrasonography or computed tomography scanning. Abscesses can be treated radiologically with a pigtail drain, although open or per rectal drainage may be needed for a pelvic abscess. The use of perioperative antibiotics has been shown to decrease the incidence of abscesses.³¹

A systematic review of studies comparing laparoscopic and open appendectomies was performed by Sauerland et al¹¹ and published in 2002. The metaanalysis of 39 separate investigations concluded that wound infections were significantly reduced in laparoscopic appendectomy (odds ratio 0.5), but abscess formation was significantly increased (odds ratio 2.8).

Wound infection, which can be as high as 30% following open appendectomy, is reported to be about 0.1% following laparoscopic procedures.⁵⁵ Strict attention to cleansing the umbilicus of all debris and proper sterilization of laparoscopic instruments may lessen this incidence even further. The majority of studies suggest that wound infections occur infrequently, at rates similar to those of

open surgery, with most randomized studies demonstrating fewer infections in laparoscopic appendectomy than in the open cohort.^{56,57}

Wound healing

Wound healing is a complex and dynamic process with the wound environment changing with the changing health status of the individual. It is a complex series of events that begins at the moment of injury and can continue for months to years. Tremendous advancements have been made in understanding the processes of wound healing. The cell types and the order in which they appear in the wound have been established; many growth factors and their functions have been elucidated.⁵⁸

An incision created by a scalpel, trauma resulting from a bullet, or tissue death caused by a myocardial infarction all undergo a similar and predictable reparative process.⁵⁸

The 3 categories of wound closure are primary, secondary, and tertiary. Primary healing involves closure of a wound within hours of its creation, repairing a full-thickness surgical incision. Secondary healing involves no formal wound closure; the wound closes spontaneously by contraction and reepithelialization. Secondary healing results in an inflammatory response that is more intense than with primary wound healing. In addition, a larger quantity of granulosomatous tissue is fabricated because of the need for wound closure. Secondary healing results in pronounced contraction of wounds.⁵⁸

Tertiary wound closure, also known as delayed primary closure, and involves initial debridement of the wound for an extended period and then formal closure

with suturing or by another mechanism. This type of healing may be desired in the case of contaminated wounds. By the fourth day, phagocytosis of contaminated tissues is well underway and the processes of epithelization, collagen deposition, and maturation are occurring. Phases of wound healing have been identified and studied on the cellular and molecular level. These 4 distinct phases are Hemostasis, Inflammation, Tissue formation, and Tissue remodeling.⁵⁸

Hemostasis

It depends on an elaborate cascade of growth factors and cellular components interacting in a directed manner to achieve wound closure. The cascade of vasoconstriction and coagulation commences with clotted blood immediately impregnating the wound, leading to hemostasis. Following vasoconstriction, the initial injury leads to the recruitment of inflammatory cells into the wound, platelets adhere to damaged endothelium and discharge adenosine diphosphate (ADP), promoting thrombocyte clumping, which dams the wound. The inflammatory phase is initiated by the release of numerous cytokines by platelets. Alpha granules liberate platelet-derived growth factor (PDGF), platelet factor IV, and transforming growth factor beta (TGF-b), while vasoactive amines such as histamine and serotonin are released from dense bodies found in thrombocytes. PDGF is chemotactic for fibroblasts and along with TGF-b is a potent modulator of fibroblastic mitosis. Fibrinogen is cleaved into fibrin and the framework for completion of the coagulation process is formed. Fibrin provides the structural support for cellular constituents of inflammation. This process starts immediately after the insult, once a clot forms in response to disrupted blood vessels. This scenario entails a complex interaction between local tissue mediators and cells that migrate into the wound.⁵⁸

Inflammation phase

Within the first 6-8 hours, the next phase of the healing process is underway, with polymorphonuclear leukocytes (PMNs) engorging the wound. TGF- β facilitates PMN migration from surrounding blood vessels where they extrude themselves from these vessels. These cells “cleanse” the wound, clearing it of debris. The PMNs attain their maximal numbers in 24-48 hours and commence their departure by hour 72. Other chemotactic agents are released, including fibroblastic growth factor (FGF), transforming growth factors (TGF- β and TGF- α), PDGF and plasma-activated complements C3a and C5a (anaphylactic toxins). They are sequestered by macrophages or interred within the scab or eschar. As the process continues, monocytes also exude from the vessels. These are termed macrophages. The macrophages continue the cleansing process and manufacture various growth factors during days 3-4. The macrophages organize the multiplication of endothelial cells with the sprouting of new blood vessels, the duplication of smooth muscle cells and the creation of the environment created by the fibroblast. Many factors influencing the wound healing process are secreted by macrophages. These include TGFs, cytokines and interleukin-1 (IL-1), tumor necrosis factor (TNF), and PDGF. The inflammatory phase occurs in the first few days as inflammatory cells migrate into the wound. Migration of epithelial cells has been shown to occur within the first 12-24 hours, but further new tissue formation occurs over the next 10-14 days.⁵⁸

Granulation Phase

This phase consists of different subphases. These subphases do not happen in discrete time frames but constitute an overall and ongoing process. The subphases

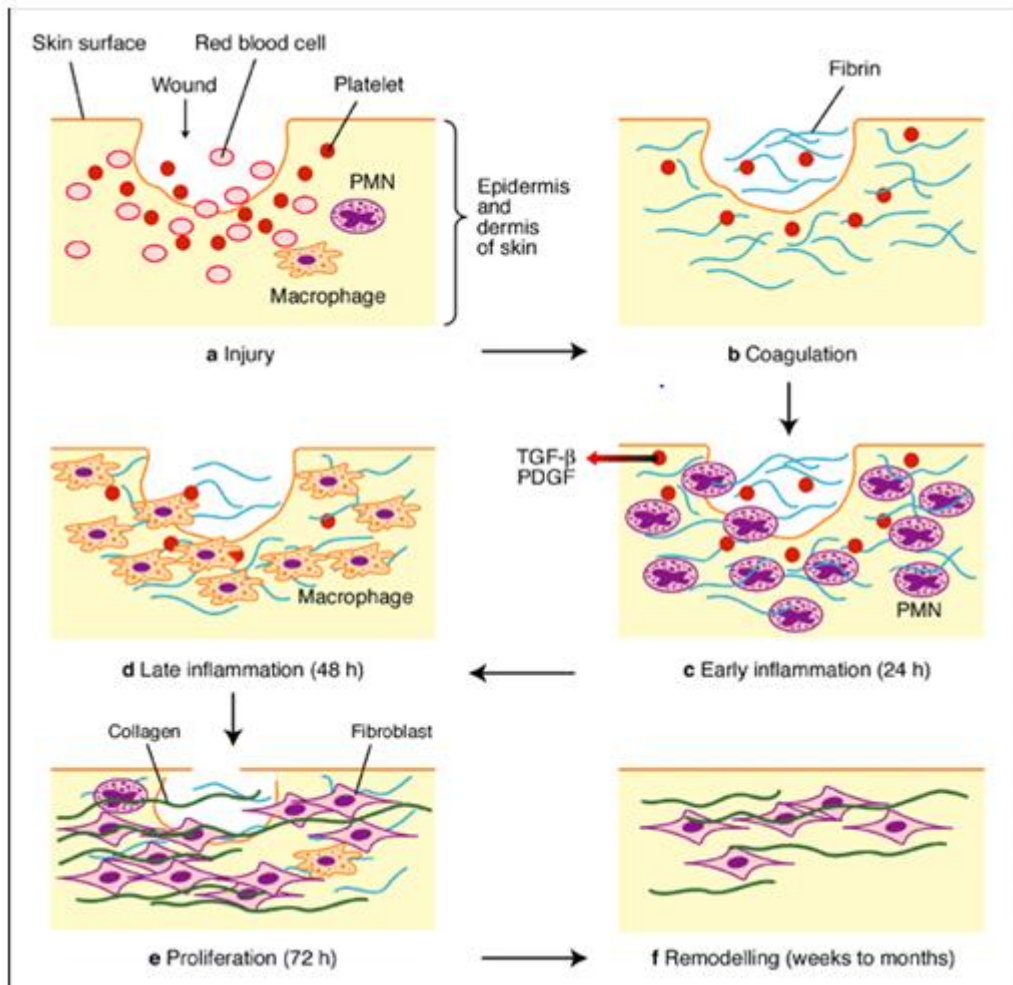
are fibroplasia, matrix deposition, angiogenesis and re-epithelialization. In days 5-7, fibroblasts have migrated into the wound, laying down new collagen of the subtypes I and III. Early in normal wound healing, type III collagen predominates but is later replaced by type I collagen.⁵⁸

The wound is immersed with GAGs and fibronectin produced by fibroblasts. These GAGs include heparan sulfate, hyaluronic acid, chondroitin sulfate and keratan sulfate. Proteoglycans are GAGs that are bonded covalently to a protein core and contribute to matrix deposition. Angiogenesis is the product of parent vessel offshoots. The formation of new vasculature requires extracellular matrix and basement membrane degradation followed by migration, mitosis and maturation of endothelial cells. Basic FGF and vascular endothelial growth factor are believed to modulate angiogenesis.⁵⁸

Re-epithelialization occurs with the migration of cells from the periphery of the wound and adnexal structures. This process commences with the spreading of cells within 24 hours. Division of peripheral cells occurs in hours 48-72, resulting in a thin epithelial cell layer, which bridges the wound. Epidermal growth factors are believed to play a key role in this aspect of wound healing. Epithelialization and neovascularization result from the increase in cellular activity. Stromal elements in the form of extracellular matrix materials are secreted and organized. This new tissue, called granulation tissue, depends on specific growth factors for further organization to occur in the completion of the healing process. This physiologic process occurs over several weeks to months in a healthy individual.⁵⁸

Remodeling Phase

Finally, tissue remodeling, in which wound contraction and tensile strength is achieved, occurs in the next 6-12 months. After the third week, the wound undergoes constant alterations, known as remodeling, which can last for years after the initial injury occurred. Collagen is degraded and deposited in an equilibrium-producing fashion, resulting in no change in the amount of collagen present in the wound. The collagen deposition in normal wound healing reaches a peak by the third week after the wound is created. Contraction of the wound is an ongoing process resulting in part from the proliferation of the specialized fibroblasts termed myofibroblasts, which resemble contractile smooth muscle cells. Wound contraction occurs to a greater extent with secondary healing than with primary healing. Systemic illness and local factors can affect wound healing.⁵⁸



Phases of wound healing

Wound closure

Diagnostic or operative laparoscopy as a minimally invasive procedure is one of the most common operations in general surgery. The benefits of minimally invasive surgery as opposed to the traditional open surgical approach are reduced pain, quicker return of oral intake, shorter hospitalization, and improved cosmetic results due to decreased scarring.

There are several methods for skin closure of trocar wounds. The choice of material is often based on a surgeon's personal experience. Common procedures

include closure with simple or subcuticular sutures, tapes and more recently, the tissue adhesive OCT. In addition to the above advantages of laparoscopic surgery, acceptable wound cosmetic appearance and complication are also considered important outcomes following laparoscopic surgery.

The advantages and disadvantages of these different methods have been studied to some degree. Methods for closure of laparoscopic port sites vary in published series and are largely the result of surgeons' need for a rapid, economic, and reproducible technique of skin apposition.¹⁴ Based on previous studies,^{59,60} advantages of skin adhesives may include less time to apply and potentially good cosmetic outcomes.

The choice of wound closure after surgery whether major or minor procedure, there always exist lot of questions in many concerns. One of those concerns is how fast and comfortable will be the recovery. The recorded history of wound closure is as old as that of medicine. The Edwin Smith Surgical Papyrus, which was written in Egypt during the seventeenth century BC, was apparently an historical document when it was written, because it contained material dating back to 2500 to 3000 BC. This document is the first to mention surgical suturing in the passage interpreted, "Thou shouldst draw together for him his gash with stitching". Wound closure techniques have evolved from the earliest development of suturing materials to comprise resources that include synthetic sutures, absorbable, staples, tapes, and adhesive compounds.⁶¹

Sutures for wound closure

Traditionally, needle skin suturing with suture material is used because of cost-effective, nowadays surgeons are looking for faster, comfortable and cosmetically best technique for skin closure, more over 2-octylcyanoacrylate is easier to use and provides a flexible, water resistant, sealed skin closure.⁶² 2-octylcyanoacrylate provides a needle-free method of wound closure, an important consideration because of blood-borne viruses (e.g., HIV). It requires no bandaging due to its antimicrobial properties. For the patient side, it gives less pain during post operative period, patients can even have a shower, needs no suture or staple removal, disappears naturally as incision heals, leaves no mark.^{61,62}

In traditional skin closure with suture material, Patients experiences more pain during post operative period, patient cannot have a shower; patient has to come for suture removal. Even after healing, there will be track marks of suture. Chances of infection of wound are also higher.

The technique of suturing is thousands of years old. Although suture materials and aspects of the technique have changed, the goals remain the same: closing dead space, supporting and strengthening wounds until healing increases their tensile strength, approximating skin edges for an aesthetically pleasing and functional result, and minimizing the risks of bleeding and infection.

The history of sutures begins more than 2,000 years ago with the first records of eyed needles. The Indian plastic surgeon, Susruta (AD 380- 450), described suture material made from flax, hemp, and hair.⁶¹ At that time, the jaws of the black ant were used as surgical clips in bowel surgery. In 30 AD, the Roman Celsus again

described the use of sutures and clips, and Galen further described the use of silk and catgut in 150 AD. Before the end of the first millennium, Avicenna described monofilament with his use of pig bristles in infected wounds. Surgical and suture technique evolved in the late 1800s with the development of sterilization procedures. The first synthetics were developed in the 1950s, and further advancements have led to the creation of various forms. The different types of sutures offer different qualities in terms of handling, knot security, and strength for different purposes.

In ancient India, Egypt and the Greek and Roman societies wound treatments as well as suturing techniques and instruments were developed that strongly resemble those in our days. Hardly any progress is noted up to the nineteenth century. The improvement of catgut by Lister started in 1860. In the 19th century prototypes of mechanical suturing instruments (staplers) were developed. They were introduced into clinical practice in the early decades of the 20th century. The greatest progress in wound suturing started after World War II with the introduction of advanced semiautomatic stapler machinery and with the manufacture of synthetic non-resorbable and resorbable fibres.

Types of Suture Materials^{61,63,64}

Suture materials can be broadly classified as naturally occurring and synthetic or Absorbable and non-absorbable .They can be further classified as monofilament or multifilament (braided), dyed or undyed, coated or uncoated.

Absorbable sutures

Type	Material	Duration at maximum strength	Complete absorption time (Days)	Colors available
Catgut	Sheep's intestine submucosa	3-4	Variable	Undyed
Chromic catgut	As above but tanned with chromic salts to delay absorption	10-14	>120	Undyed
Dexon	Polyglycolic	10-14	90-120	Undyed or green
Vicryl	Polyglactin 910	14-21	90	Undyed or purple
Polyglyconate	Glycolic acid and trimethylene carbonate	10-14	180	Undyed
Glycomer 631	Polyster of glycolide, dioxanone and trimethylene carbonate	12-20	90-110	Undyed
Polyglytone 6211	Polyster of glycolide caprolactone trimethylene carbonate and lactide	7-10	Variable	Undyed

Type	Material	Thread structure	Knots secure	Tissue reaction	Colour
Silk	Silk	Braided	Yes	++	Black
Nylon	Polymers of nylon 6	Braided and mono filament	Fair	±	Undyed / dyed blue or green
Prolene	Polypropylene	Monofilament	Fair	±	Blue / undyed
Polyster	Polyethylene terephthalate	Braided / multifilament	Fair	±	Undyed / dyed blue or green
Hexafluoro-propylene	Polyvinylidene fluoride and polyvinylidene fluoride-co-hexafluoropropylene				

Silk

Silk was first widely used as a suture material in the 1890s. It is a braided material formed from the protein fibers produced by silkworm larvae. Although silk is considered a non absorbable material, it is gradually degraded in tissue over 2 years. Silk has excellent handling and knot-tying properties and is the standard to which all other suture materials are compared. Its knot security is high, tensile strength low, and tissue reactivity high. Suture removal can be difficult and painful because the braided material becomes infiltrated with cells and encrusted with debris while the sutures are implanted in the skin.

Nylon

Introduced in 1940, nylon was the first synthetic suture available, and it is the most commonly used nonabsorbable material. It is available in both monofilamentous and multifilamentous forms. Nylon has a high tensile strength, and,

although it is classified as nonabsorbable, it loses tensile strength when buried in tissue. Multifilamentous forms retain no tensile strength after being in tissue for 6 months, whereas monofilamentous forms retain as much as two thirds of their original strength after 11 years. Monofilament nylon is stiff; therefore, handling and tying are difficult and knot security is low. The suture also may cut easily through thin tissue. Ethilon is monofilament nylon.

Multifilamentous forms have better handling properties but greater tissue reactivity. Monofilament nylon is relatively inexpensive and available as black, green, or clear. Although its greatest use is as a percutaneous suture, because of its low tissue reactivity, nylon (clear) can be used as a buried suture in situations in which prolonged dermal support is necessary.

Polypropylene

Polypropylene (Prolene; Ethicon) is a monofilament synthetic suture that was introduced in 1962. Its tensile strength is lower than that of the other synthetic nonabsorbable sutures. Its handling, tying, and knot security are poor as a result of its stiff nature and high memory. An additional throw is needed for adequate knot security. A method to improve security is the use of thermocautery to fuse the knots or transform the ends into small beads. Tissue reactivity is extremely low for polypropylene, and, unlike nylon, gradual absorption does not occur if it is buried in tissue. As a result, polypropylene is an excellent choice for a buried suture for long-term dermal support.

Polyglactin (vicryl)

It is a synthetic heteropolymer consisting of 90% of glycolide and 10% of lactide. These sutures are braided, multifilament, coated, absorbable synthetic sutures. This suture is degraded by hydrolysis. This suture can be supplied in an antibiotic form by impregnating with triclosan. In one study comparing the absorption of polyglactin 910 and polyglycolic acid, the absorption of former began approximately at 40 days, and was nearly complete by day 70. At 90 days, no polymer remained in the tissue.

Polyglycolic acid (Dexon)

This is an absorbable braided synthetic homopolymer of glycolic acid. Coated polyglycolic acid suture is undyed or dyed green, violet or bicolored. Since polyglycolic acid is not a naturally occurring organic substance, it elicits less inflammatory response than surgical gut. It is absorbed by hydrolysis. Polyglycolic acid possesses good tensile strength and excellent knot security. After two weeks of implantation, 65% of the initial tensile strength remains with polyglycolic acid suture, in contrast to 0% of surgical gut suture.⁶³

Polyglyconate

It came in to market in 1985. It is synthetic monofilament absorbable suture, composed of glycolic acid and trimethylene carbonate. Polyglyconate has some advantages over other sutures, such as improved handling properties, lacks memory, passes easily through tissues and demonstrates superior strength. It retains 75% of original strength at two weeks of postimplantation. Absorption is essentially complete by 180 days.

Cyanoacrylate

The cyanoacrylates first were synthesized in 1949 by Coove A et al.⁶⁵ described their adhesive properties and suggested their possible use for surgical adhesives. In the early 1960s, various surgical applications were investigated for these adhesives. Cyanoacrylates can be synthesized by reacting formaldehyde with alkyl cyanoacetate to obtain a prepolymer that, by heating, is depolymerized into a liquid monomer. The monomer then can be modified by altering the alkoxy carbonyl (-COOR) group of the molecule to obtain compounds of different chain lengths. Upon application to living tissues (water or base), the monomer undergoes an exothermic hydroxylation reaction that results in polymerization of the adhesive. The shorter-chain derivatives tend to have a higher degree of tissue toxicity than the longer-chain derivatives. 2-Octylcyanoacrylate is a longer chain polymer which gives stronger bond. Until recently, 2-Butylcyanoacrylate skin adhesive is being used which is brittle in nature, after forming bond. The polymer 2-octyl cyanoacrylate was formulated to correct some of the deficiencies of the shorter-chain cyanoacrylate derivatives. The slower degradation of the octyl derivatives may result in lower concentrations of the cyanoacrylate polymer by-products in surrounding tissues, resulting in less inflammation. Additionally, plasticizers are added to produce a more pliable and tissue-compatible product that flexes with the skin and remains inherent for longer periods of time. The 3-dimensional breaking strength of 2-octyl cyanoacrylate is 3 times that of butyl-2 cyanoacrylate. This stronger flexible bond may allow its use on longer incisions.⁶¹

Cyanoacrylates are defined as solvent free, synthetic adhesives. They are reactive monomer liquids that polymerize into a film when initiated by moisture or

certain chemicals. A key property of cyanoacrylates is that the monomer liquid actually polymerizes directly on the surface where it is applied, creating a high quality and very tenacious polymer film. Cyanoacrylate is applied in a thin layer over the entire wound and extending 5-10 mm beyond the wound edge. The formation of the bond produces heat that the patient can feel. Once the layer is dried (10-30 seconds), a second layer is applied. Three to 4 layers are necessary. Cyanoacrylates typically fix within the minute and achieve full bond strength in 24 hours. No additional bandaging is required, and the patient is advised to not perform wound care at home. By 7-14 days, most of the adhesive sloughs with the epidermis and the remainder may be removed with soap and water or petroleum jelly.

Dermabond is quick and easy to apply; only one tenth to one fourth of the time required for suture placement is needed. It provides an antimicrobial and waterproof coating, but repeated washing removes the adhesive in a few days. The cosmetic outcome generally is good, and no postoperative visit is required for its removal.

2-Octylcyanoacrylate adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying adhesive in multiple thin layers (at least three) onto a dry wound and allowing time for polymerization between applications, heat is released slowly and the sensation of heat or pain experienced by the patient is minimized.^{66,67} If adhesive is applied so that large droplets of liquid are allowed to remain unspread, the patient may experience a sensation of heat or discomfort. Extra caution should be taken to avoid depositing any adhesive in the wound; the adhesive will not seep into the wound since it starts to polymerize instantaneously. A common mistake is to inadvertently

deposit the adhesive in the wound by pushing the tip of the vial into the wound and separating the wound edges.

Quinn J, et al⁶⁸ (1997) introduced a newer cyanoacrylate octyl2 cyanoacrylate in his well designed, controlled study. Being combined with a plasticizer, this cyanoacrylate promises to have improved performance compared with other Cyanoacrylates. Being combined with a plasticizer, these long chain cyanoacrylates form a stronger bond than the other cyanoacrylate analogues after polymerization. This bond appears to be three times stronger than other cyanoacrylates. Because it is also flexible, it is less likely to fissure and fracture like other cyanoacrylates.

Quinn J, et al⁶⁸ (1997) conducted a randomised clinical trial comparing octyl1 cyanoacrylate tissue adhesive and sutures in management of high tension lacerated wounds and concluded that this adhesive effectively closed selected lacerations and is a painless fast method of wound repair and can replace the need for suture of laceration.

Quinn J, et al⁶⁹ (1998) evaluated long term cosmetic outcome of octyl1 cyanoacrylate tissue adhesive versus standard monofilament 5-0 suture and concluded no significant difference in the cosmetic value and that glue is a quick, faster way of closing lacerated wounds.

Octyl1 cyanoacrylate and butyl1 cyanoacrylate were compared by Osmond MH, et al⁷⁰ on facial laceration of 94 children. All lacerations were less than 4 cm. No difference was found between the groups when comparing cosmetic outcome, time to perform the procedure and complications.

Watson DP, et al⁷¹ in (1989) conducted a prospective trial of cyanoacrylate tissue glue in closing facial lacerations in children less than 14 years and found that gluing is quick, atraumatic and cost effective. Furthermore cosmetic results were excellent and trouble of suture removal was avoided.

Eiferman RA et al⁷² (1983) used butyl cyanoacrylate glue for the treatment of perforated corneal ulcers infected by gram positive organisms and concluded that bacteriostatic activity of glue was most pronounced against gram positive organisms and no activity against gram negative organism.

Bruns TB, et al⁷³ in 1996 conducted prospective randomized trial to compare long term cosmetic outcomes of n butyl cyanoacrylate glue to conventional suturing for laceration repair in children at 1 month and 1 year. Outcome shows that glue alternative to conventional suture is comparable to conventional suture at 1 year for low-tension incision.

In 2001, Bernard L, et al⁷⁴ conducted a trial to compare the tissue adhesive with standard monofilament suture for closure of high tension excision wounds in children and adolescents. Cosmetic outcomes were evaluated two months later. They concluded that cosmetic outcome of high tension wound closed with glue were inferior to those closed with suture.

In one study by Bruns TB,⁷⁵ closure with sutures resulted in a cosmetically worse scar in lacerations that deviated by more than 20° from Langer's line in contrast to the closure with tissue adhesive who's scars were unaffected by wounds oriented with Langer's line.

The engineering of sutures in synthetic material along with standardization of traditional materials (eg, catgut, silk) has made for superior aesthetic results. Similarly, the creation of natural glues, surgical staples, and tapes to substitute for sutures has supplemented the armamentarium of wound closure techniques. Aesthetic closure is based on knowledge of healing mechanisms. Choosing the proper materials and wound closure technique ensures optimal healing. 2-Octyl Cyanoacrylate is the latest skin adhesive glue, used for faster skin closure. So it is essential to do a comparative study of the two techniques of skin closures.

METHODOLOGY

This one year randomized controlled trial was carried out in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum over a period, from January 2013 to December 2013.

Study design

The study design was a randomized controlled trial.

Study period and duration

This study was performed for the duration of one year from January 2013 to December 2013.

Place

The present study was carried out at the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum a teaching hospital attached to KLE University's Jawaharlal Nehru Medical College, Belgaum.

Source of Data

Patients diagnosed to have appendicitis (Acute, chronic and recurrent) undergoing laparoscopic appendicectomy were studied.

Sample size

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

Sampling procedure

Considering as pilot study, the sample size was planned for a total of 60 patients divided into two groups of 30 each.

Selection criteria

Inclusion

- Patients diagnosed to have appendicitis and undergoing laparoscopic appendicectomy.
- Patients with age between 16 to 60 years.

Exclusion

Patients with/who have;

- Diabetes mellitus or immunodeficiency.
- Pre-existing systemic/local infection.
- Patients with appendicular abscess, gangrenous appendicitis, appendicular mass.
- Patients with perforation, peritonitis and/or other apparent foci of active abdominal infection.
- A known allergy to cyanoacrylate compound

Ethical clearance

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

Informed Consent

Patients undergoing laparoscopic appendicectomy were evaluated for the eligibility. Those who fulfilled the selection criteria were informed in detail about the study and a written informed consent was obtained (Annexure I).

Randomization

Based on 'Opaque envelope method' the cases were allotted to either of the two groups of 30 each that is,

- Group A – Patients underwent port site wound closure with octyl 2-cyanoacrylate.
- Group B - Patients underwent port site wound closure with non-absorbable sutures ie Ethilon 3-0.

Method of collection of data

The selected patients were interviewed and data such as age, sex, history and clinical presentation were obtained. These patients were subjected to clinical examination and the findings were noted on a predesigned and pretested proforma (Annexure II).

Investigations

The following tests were subjected to the following investigations.

- Routine blood counts – Hemoglobin, total leucocyte counts, differential counts, red blood cell counts and ESR.

- Urine Routine
- Serum urea
- Serum creatinine
- Purulent discharge from the wound, if any, to be sent for culture and antibiotic sensitivity.

Basic procedure

The operation was performed under general anaesthesia . Patients in both the groups underwent similar surgery that is laparoscopic appendicectomy, using similar instruments and under accepted general principles of laparoscopic surgery. Three ports were established at umbilicus, suprapubic region and near left anterior superior iliac spine . The patient is placed in a Trendelenberg position so that the small bowel falls into the upper abdomen. When the appendix is visualized, the first step in the dissection is release the adhesions so that appendix can be delivered. The caecum is grasped and retracted upwards to expose the base of the appendix. A window is then developed through the appendix mesentery, close to the base of the appendix. These two structures are secured separately. Diathermy coagulation of the appendix mesentery is done and is now generally preferred. Once hemostasis is achieved, A tissue grasper is then passed through the noose of a pre-tied suture to hold the appendix. The appendix is delivered through the noose which is then guided down to the base of the appendix and tightened. This maneuver is repeated and the appendix cut between the ligatures. Appendix is taken out with grasper through supra-pubic port and sent histo-pathological reporting.



Photograph 1. Dermabond (octyl 2- cyanoacrylate)



Photograph 2. Method of application



Photograph 3. Wound appearance on post operative day 7 in group A



Photograph 4 Wound appearance on post operative one month in group A



Photograph 5. Wound appearance on post operative three months in group A



Photograph 6. Wound appearance on post operative day 7 in group B



Photograph 7. Wound appearance on post operative one month in group B



Photograph 8. Wound appearance on post operative three months in group B

Wound closure

Group A

Patients underwent port site wound closure with octyl 2- cyanoacrylate.

Group B

Patients underwent port site wound closure- mattress sutures with non-absorbable suture ie Ethilon 3-0.

Follow up

The wound was assessed for wound complications on 3rd ,5th and 7th post-operative day, first and third month for cosmetic outcome. Discharge/pus from the wound, if any, was sent for culture and sensitivity.

Outcome variables

Intraoperatively both the groups were assessed in terms of time taken for the wound closure of all ports. Postoperatively, patients in both the groups were evaluated for wound in terms of erythema, warmth, tenderness, discharge and infection. Each patient was followed up until discharge post operatively and followed on out patients department basis after discharge.

The wound was assessed for cosmesis on seventh post-operative day and at the end of first and third month using Modified Hollander cosmesis scale which has six clinical variables as step off borders, edge inversion, contour irregularities, excess inflammation, wound margin separation and good overall appearance. Wound was assigned 0 or 1 point each for the presence or absence of the following.

- Step off the borders, (0 for yes, 1 for no)
- Contour irregularities – puckering, (0 for yes, 1 for no)
- Wound margin separation, (0 for yes, 1 for no)
- Wound edge inversion, (0 for yes, 1 for no)
- Excessive wound distortion, (0 for yes, 1 for no)
- Good overall appearance (0 for poor, 1 for acceptable)

The total score was calculated and wounds with a score of six were considered to have an optimal cosmetic appearance and others suboptimal appearance.

Statistical analysis

The data obtained was coded and entered in Microsoft Excel Spreadsheet. The categorical data was expressed as rates, ratios and percentages and comparison was done using chi-square test and Fisher's exact test. Continuous data was expressed as mean \pm standard deviation and the independent sample 't' test was used for comparison. A '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 Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. A total of 60 patients undergoing laparoscopic appendicectomy over a period one year from January 2013 to December 2013 were studied. Patients were divided into two groups of 30 each based on 'Opaque envelope method' as below;

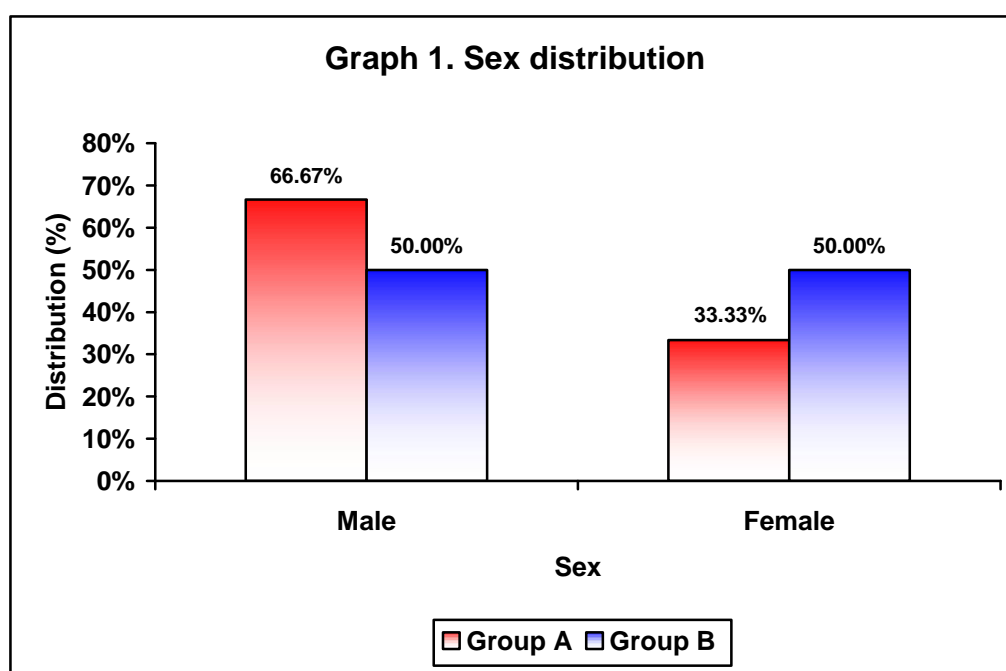
- Group A – Port site wound closure with octyl 2- cyanoacrylate.
- Group B - Port site wound closure with non-absorbable sutures ie Ethilon 3-0.

The data obtained was analysed and the final results and interpretations were presented as below.

Table 1. Sex distribution

Sex	Group A (n=30)		Group B (n=30)	
	Number	Percentage	Number	Percentage
Male	20	66.67	15	50.00
Female	10	33.33	15	50.00
Total	30	100.00	30	100.00

p = 0.190

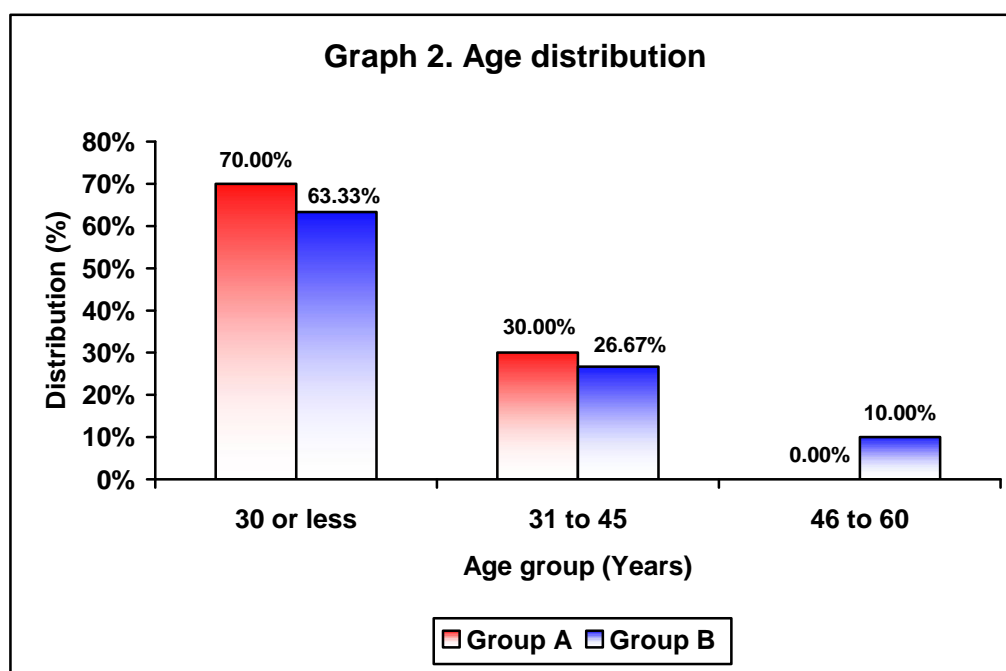


In the present study 66.67% in group A and 50% in group B were males. The male to female ratio was found to be 2:1 in group A and 1:1 in group B. However the sex distribution in group A and B was comparable (p=0.190).

Table 2. Age distribution

Age group (Years)	Group A (n=30)		Group B (n=30)	
	Number	Percentage	Number	Percentage
30 or less	21	70.00	19	63.33
31 to 45	9	30.00	8	26.67
46 to 60	0	0.00	3	10.00
Total	30	100.00	30	100.00

p = 0.300



In this study most of the patients presented with age less than 30 years that is 70% in group A and 63.33% in group B. However this difference was statistically not significant (p=0.300).

Table 3. Mean age

Variables	Group A (n=30)		Group B (n=30)		p value
	Mean	SD	Mean	SD	
Age (Years)	26.96	6.80	30.30	9.69	0.129

In the present study the mean age of the study population in group A was slightly low (26.96 ± 6.80 years) compared to group B (30.30 ± 9.69 years). However the difference was statistically not significant ($p=0.129$).

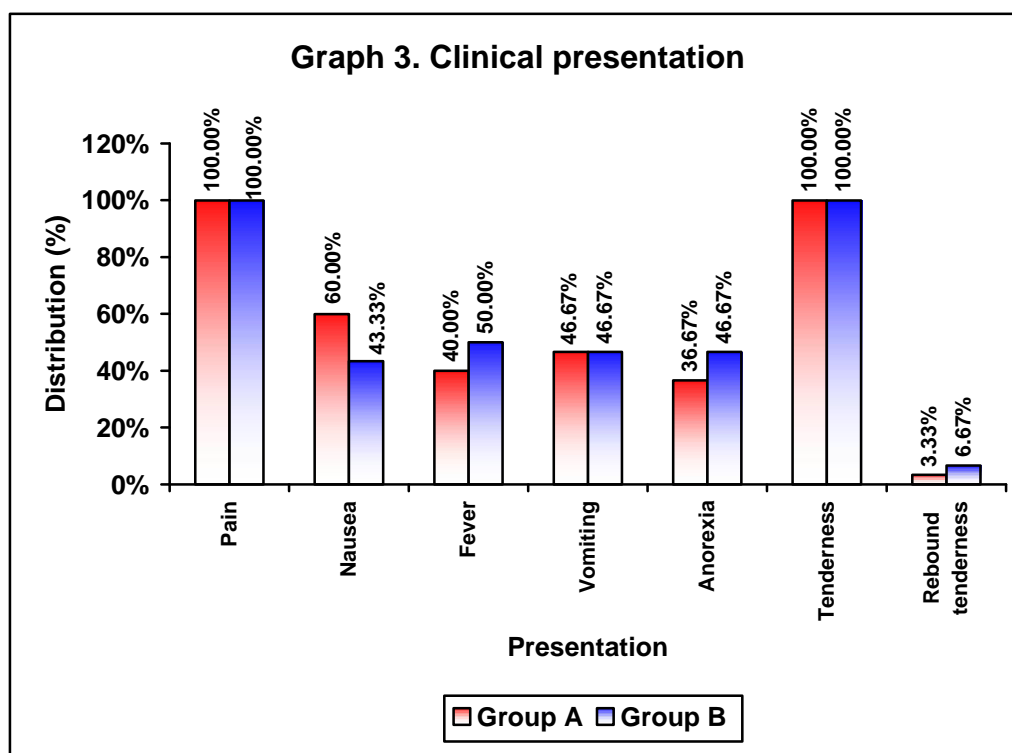
Table 4. Pulse rate

Variables	Group A (n=30)		Group B (n=30)		p value
	Mean	SD	Mean	SD	
Pulse rate (/minute)	91.63	8.33	91.06	10.24	0.815

Table 4. shows mean pulse rate in group A and B. It was observed that the mean pulse rate was comparable in both the groups ($p=0.815$)

Table 5. Clinical presentation

Presentation	Findings	Group A(n=30)		Group B(n=30)		p value
		No	%	No	%	
Pain	Present	30	100.00	30	100.00	-
	Absent	0	0.00	0	0.00	
	Total	30	100.00	30	100.00	
Nausea	Present	18	60.00	13	43.33	0.196
	Absent	12	40.00	17	56.67	
	Total	30	100.00	30	100.00	
Fever	Present	12	40.00	15	50.00	0.436
	Absent	18	60.00	15	50.00	
	Total	30	100.00	30	100.00	
Vomiting	Present	14	46.67	14	46.67	1.000
	Absent	16	53.33	16	53.33	
	Total	30	100.00	30	100.00	
Anorexia	Present	11	36.67	14	46.67	0.432
	Absent	19	63.33	16	53.33	
	Total	30	100.00	30	100.00	
Tenderness	Present	30	100.00	30	100.00	-
	Absent	0	0.00	0	0.00	
	Total	30	100.00	30	100.00	
Rebound tenderness	Present	1	3.33	2	6.67	0.500
	Absent	29	96.67	28	93.33	
	Total	30	100.00	30	100.00	



The clinical presentation of the study population in group A and B is as shown in Table 5 and Graph 3. However the clinical presentation was comparable in group A and B ($p > 0.050$).

Table 6. Temperature

Findings	Group A (n=30)		Group B (n=30)	
	Number	Percentage	Number	Percentage
Febrile	14	46.67	13	43.33
Afebrile	16	53.33	17	56.67
Total	30	100.00	30	100.00

p = 0.795

In this study 46.67% of the patients in group A and 43.33% in group B were febrile (p=0.795)

Table 7. Mean surgical time for wound closure

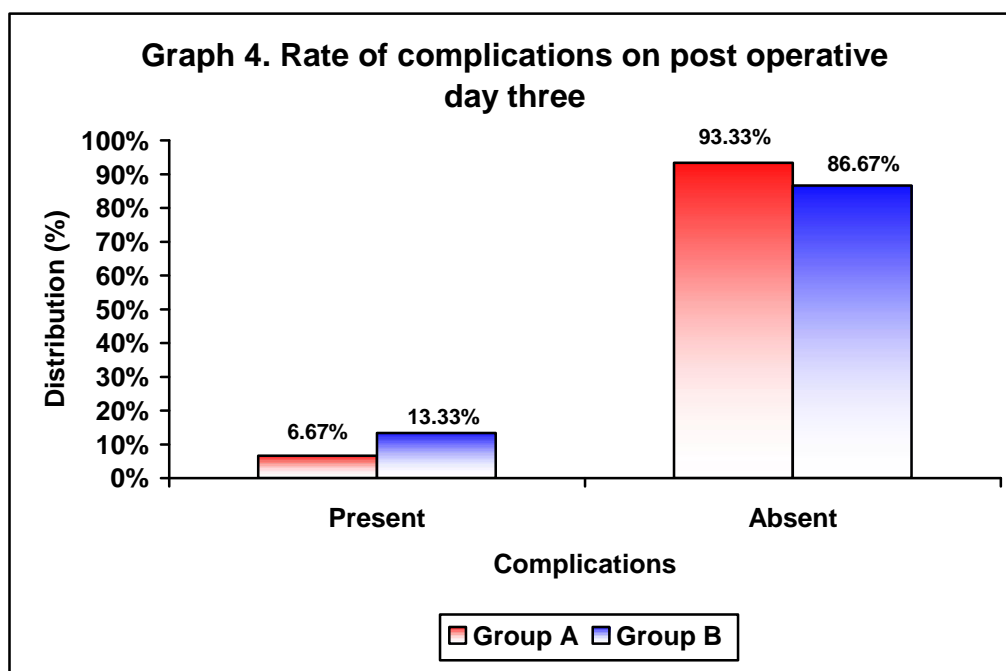
Variables	Group A (n=30)		Group B (n=30)		p value
	Mean	SD	Mean	SD	
Surgical time (seconds)	123.30	22.46	186.90	21.49	<0.001

In the present study the mean surgical time for closure of the wound in group A was significantly less compared to group B (123.30 ± 22.46 vs 186.90 ± 21.49 seconds; p<0.001).

Table 8. Rate of complications on post operative day three

Complications	Group A (n=30)		Group B (n=30)	
	Number	Percentage	Number	Percentage
Present	2	6.67	4	13.33
Absent	28	93.33	26	86.67
Total	30	100.00	30	100.00

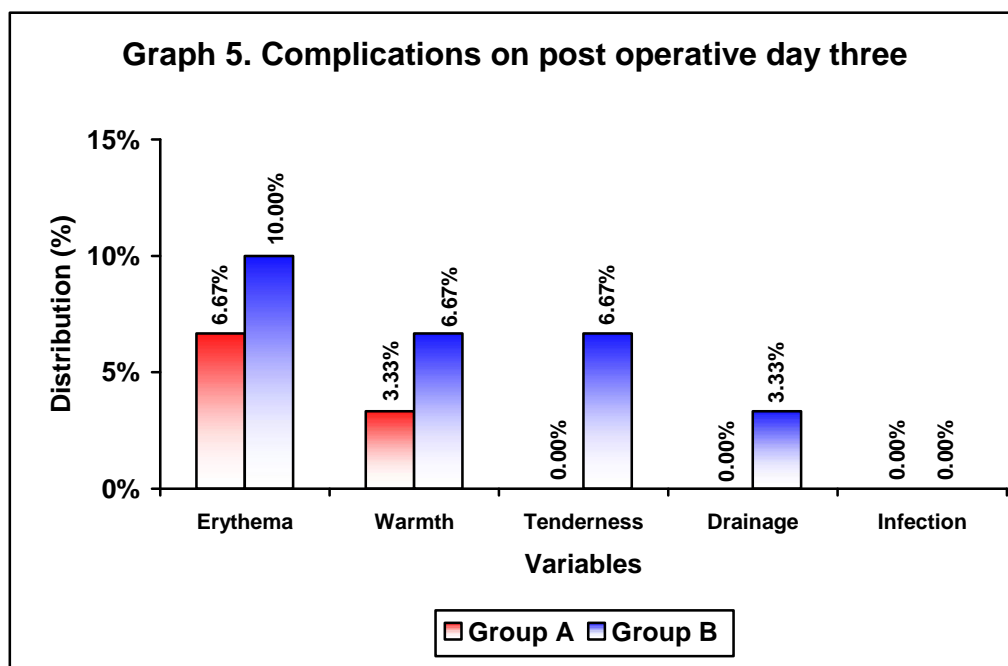
p=0.335



In the present study 6.67% of the patients in group A and 13.33% in group B had complication on post operative day three. However the difference was statistically not significant (p=0.335).

Table 9. Complications on post operative day three

Variables	Findings	Group A (n=30)		Group B (n=30)		p value
		No	%	No	%	
Erythema	Present	2	6.67	3	10.00	1.000
	Absent	28	93.33	27	90.00	
	Total	30	100.00	30	100.00	
Warmth	Present	1	3.33	2	6.67	1.000
	Absent	29	96.67	28	93.33	
	Total	30	100.00	30	100.00	
Tenderness	Present	0	0.00	2	6.67	0.492
	Absent	30	100.00	28	93.33	
	Total	30	100.00	30	100.00	
Drainage	Present	0	0.00	1	3.33	1.000
	Absent	30	100.00	29	96.67	
	Total	30	100.00	30	100.00	
Infection	Present	0	0.00	0	0.00	-
	Absent	30	100.00	30	100.00	
	Total	30	100.00	30	100.00	

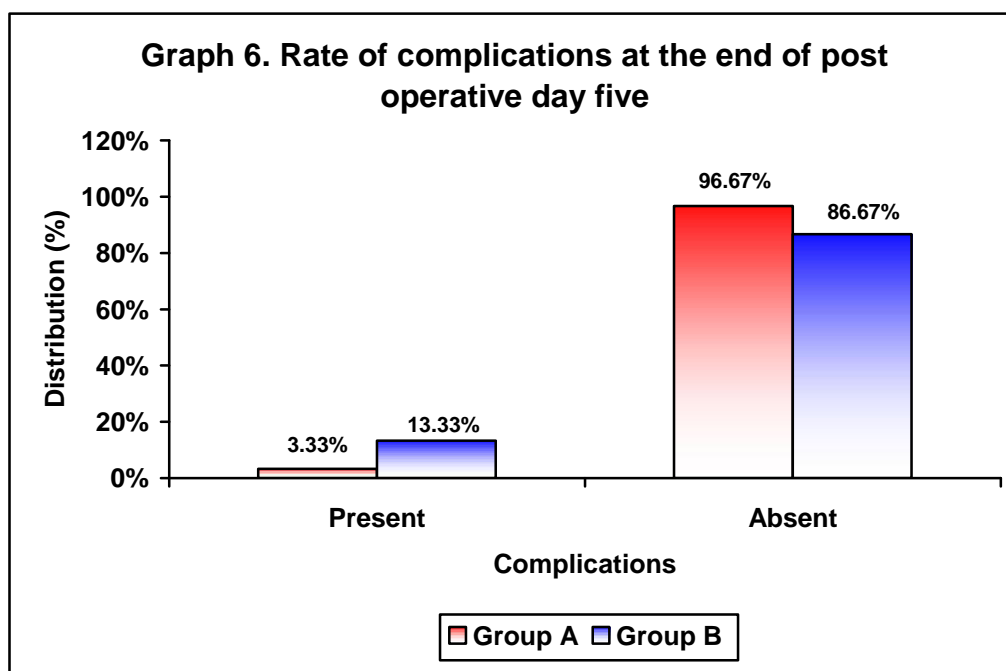


The complications on post operative day three are as shown in table 9 and graph 5. Erythema was noted in 6.67% of the patients in group A while the same was present in 10% of the patients in group B. However complications including erythema, warmth, tenderness, drainage and infections were comparable in group A and B ($p>0.050$).

Table 10. Rate of complications at the end of post operative day five

Complications	Group A (n=30)		Group B (n=30)	
	Number	Percentage	Number	Percentage
Present	1	3.33	4	13.33
Absent	29	96.67	26	86.67
Total	30	100.00	30	100.00

p = 0.177



In this study 3.33% of the patients in group A had complications on day five follow up compared to 13.33%. in group B. However the difference was statistically not significant (p=0.177).

Table 11. Complications at the end of post operative day five

Variables	Findings	Group A (n=30)		Group B (n=30)		p value
		No	%	No	%	
Erythema	Present	0	0.00	0	0.00	-
	Absent	30	100.00	30	100.00	
	Total	30	100.00	30	100.00	
Warmth	Present	0	0.00	0	0.00	-
	Absent	30	100.00	30	100.00	
	Total	30	100.00	30	100.00	
Tenderness	Present	0	0.00	2	6.67	0.492
	Absent	30	100.00	28	93.33	
	Total	30	100.00	30	100.00	
Drainage	Present	1	3.33	4	13.33	0.350
	Absent	29	96.67	26	86.67	
	Total	30	100.00	30	100.00	
Infection	Present	0	0.00	0	0.00	-
	Absent	30	100.00	30	100.00	
	Total	30	100.00	30	100.00	

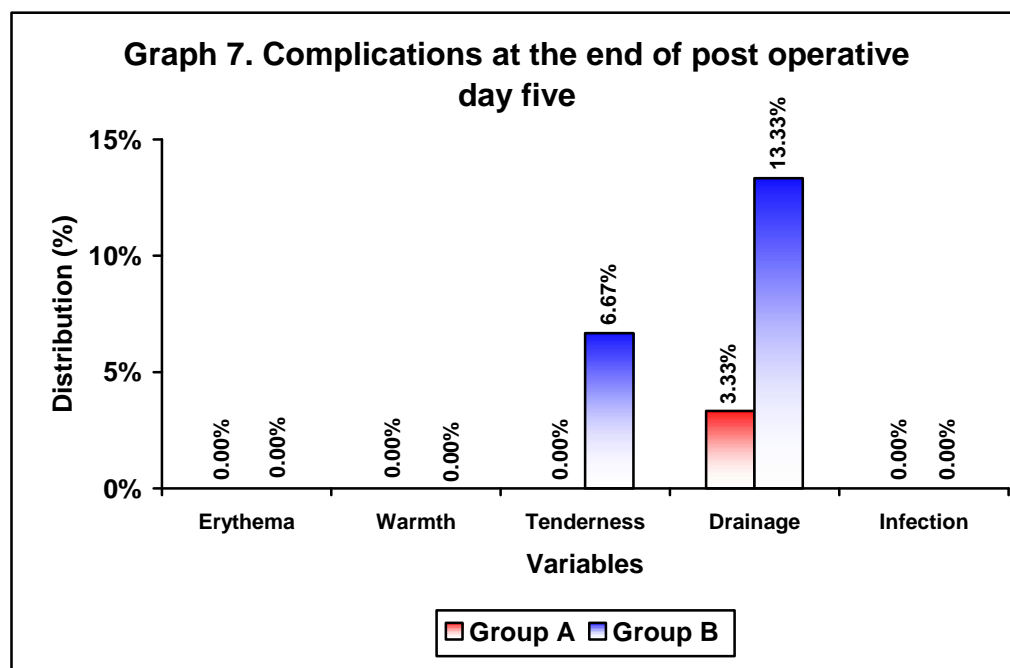
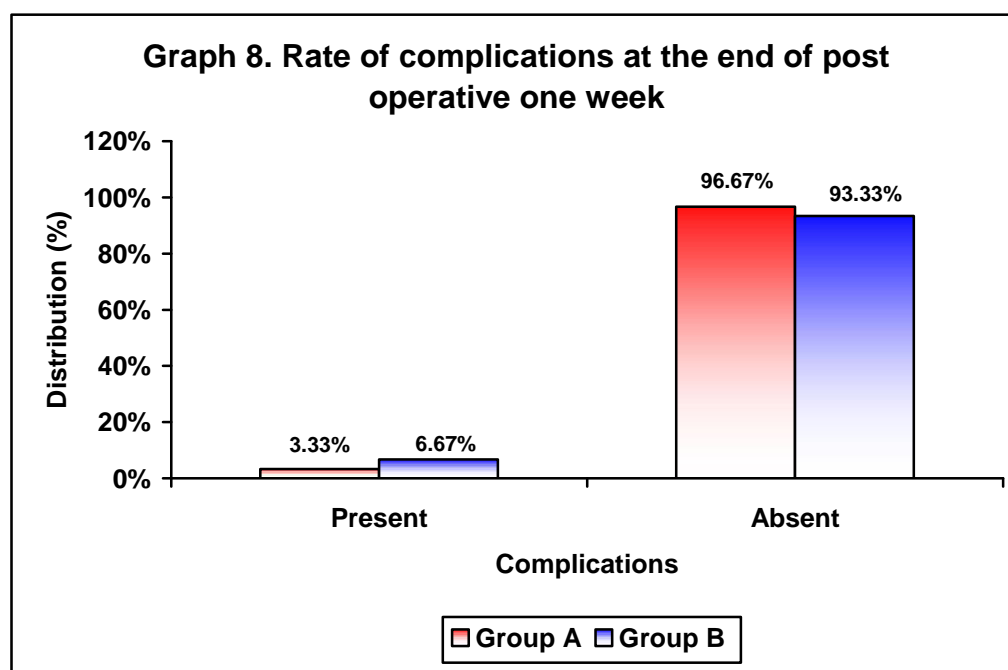


Table 11 and graph 7 shows complications at the end of post operative day five follow up. The complications of drainage were noted among 3.33% of the patients in group A compared 13.33% in group B. However complications including tenderness and drainage were comparable in group A and B ($p>0.050$).

Table 12. Rate of complications at the end of post operative one week

Complications	Group A (n=30)		Group B (n=30)	
	Number	Percentage	Number	Percentage
Present	1	3.33	2	6.67
Absent	29	96.67	28	93.33
Total	30	100.00	30	100.00

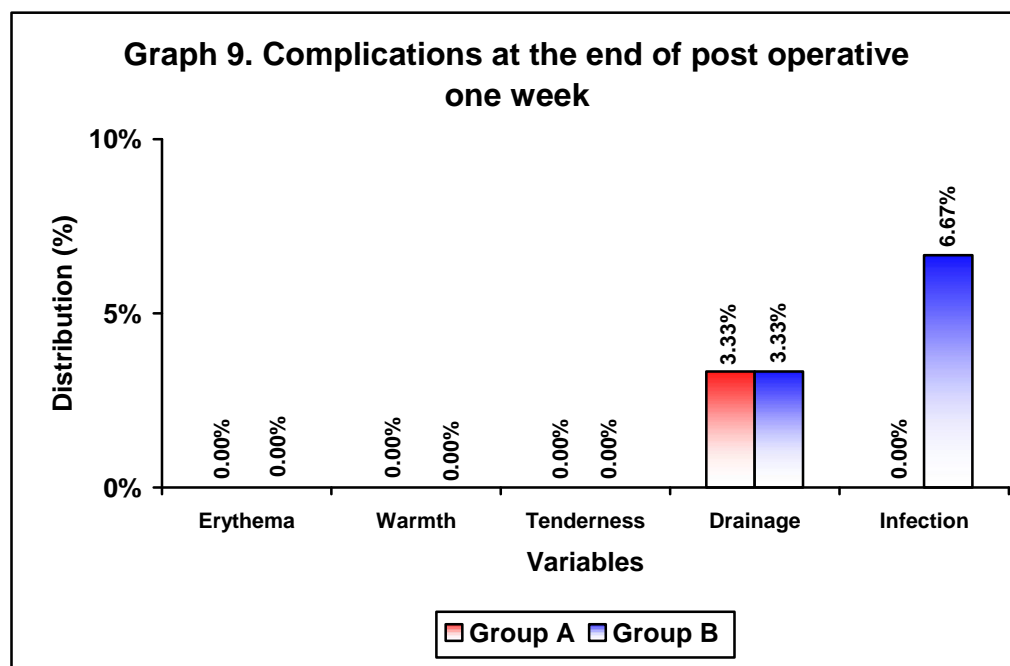
p = 0.500



In the present study, in group A, 3.33% of the patients had complications at the end of one week follow up compared to 6.67% in group B. However this difference was statistically not significant (p=0.500).

Table 13. Complications at the end of post operative one week

Variables	Findings	Group A (n=30)		Group B(n=30)		p value
		No	%	No	%	
Erythema	Present	0	0.00	0	0.00	-
	Absent	30	100.00	30	100.00	
	Total	30	100.00	30	100.00	
Warmth	Present	0	0.00	0	0.00	-
	Absent	30	100.00	30	100.00	
	Total	30	100.00	30	100.00	
Tenderness	Present	0	0.00	0	0.00	-
	Absent	30	100.00	30	100.00	
	Total	30	100.00	30	100.00	
Drainage	Present	1	3.33	1	3.33	1.000
	Absent	29	96.67	29	96.67	
	Total	30	100.00	30	100.00	
Infection	Present	0	0.00	2	6.67	0.492
	Absent	30	100.00	28	93.33	
	Total	30	100.00	30	100.00	



Complications observed at the end of post operative one week follow up are as depicted in Table 12 and graph 9. Drainage was noted among 3.33% of the patients each in group A and group B and infection was present in 6.67% of the patients in group B only and culture was positive. The organism isolated was staphylococcus aureus in 6.67% of the patients. However, complications including drainage and infections were comparable in group A and B ($p>0.050$).

Table 14. Hollander Cosmesis Score

Interval	Findings	Group A (n=30)		Group B (n=30)		p value
		No	%	No	%	
Day seven	Optimal (Score 6)	25	73.33	22	83.33	0.365
	Suboptimal (<6)	5	26.67	2	16.67	
	Total	30	100.00	30	100.00	
One month	Optimal (Score 6)	27	80.00	24	93.33	0.278
	Suboptimal (<6)	3	20.00	6	6.67	
	Total	30	100.00	30	100.00	
Three months	Optimal (Score 6)	28	90.00	25	83.33	0.228
	Suboptimal (<6)	2	10.00	5	16.67	
	Total	30	100.00	30	100.00	

In the present study the Hollander Cosmesis score was optimal (score of 6) in majority of the patients with group A as well as group B at all the follow ups ($p>0.050$)

DISCUSSION

Since the evolution of medicine, great strides have been taken in the field of advanced and minimal access surgeries. Diagnostic or operative laparoscopy as a minimally invasive procedure is one of the most common operations in general surgery. The benefits of minimally invasive surgery as opposed to the traditional open surgical approach are reduced pain, quicker return of oral intake, shorter hospitalization, and improved cosmetic results due to decreased scarring.

There are several methods for skin closure of trocar wound. In past the surgical skin incisions were closed using sutures, and then came the staples and adhesive tapes. Recently since 1949, skin adhesive glues are also available. With so many methods available for skin closure and each one of the methods having their own advantages and disadvantages, it becomes imperative to know which methods are better in what circumstances.

Closing surgical skin incision using adhesives glues is the most recent and advanced method. However there is scarcity of data regarding the surgical time, wound complications and cosmetic results in comparison to sutures. Hence the present study was undertaken to compare octyl-2-cyanoacrylate with conventional suturing of port site wound closure in laparoscopic appendicectomy in terms of wound complications, time taken for wound closure and cosmetic outcome.

This one year randomized controlled trial was carried out at Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2013 to December 2013. A total of 60 patients undergoing

laparoscopic appendectomy were divided into two groups of 30 each based on Opaque envelope method as Group A (patients in this group underwent port site wound closure with octyl 2- cyanoacrylate) and Group B (Where patients underwent port site wound closure with non-absorbable sutures ie Ethilon 3-0).

In the present study male preponderance was noted in group A 66.67% (male to female ratio 2:1) while in group B equal number of patients were males and females (50% each; male to female ratio 1:1). Despite the sex distribution in group A and B was comparable ($p=0.190$). In this study we encountered most of the patients with younger age that is, 70% of the patients in group A and 63.33% in group B presented with age less than 30 years. The mean age of patients in group A was slightly low (26.96 ± 6.80 years) compared to group B (30.30 ± 9.69 years). However the age distribution and mean age in group A and B were comparable ($p>0.050$).

In this study all the patients presented with pain and tenderness in both the groups (100%). The next common complaint in group A was nausea (60%), vomiting (46.67%), fever (40%), anorexia (36.67%) and rebound tenderness (3.33%). In group B, group B common complaints were noted as fever (50%), vomiting (46.67%), anorexia (46.67%) nausea (43.33%), and rebound tenderness (6.67%). However the difference was statistically not significant ($p>0.050$).

Overall the above findings suggest that the demographic characteristics and clinical presentation pattern of the study population was comparable in group A and B ($p>0.050$).

In the present study the mean surgical time for wound closure in group A was 123.30 ± 22.46 seconds compared to 186.90 ± 21.49 seconds in group B. ($p < 0.001$). These findings suggest that, port site wound closure using octyl-2-cyanoacrylate results in significantly lower surgical time compared to conventional suturing in patients undergoing laparoscopic appendectomy. These findings were consistent with several other studies.

In one of the first published studies evaluating Octylcyanoarylate, Quinn J, et al⁶⁸ performed a prospective randomized controlled trial comparing Octylcyanoarylate and sutures. One hundred and thirty patients were enrolled. Use of the skin adhesive was found to be significantly faster in this setting (220 seconds versus 744 seconds; $p < 0.001$). Similar observations were reported in a study by Matin SF, et al⁷⁷ that is, the mean time taken for skin closure in adhesive glue group was faster than skin suturing group (150 seconds versus 360 seconds). Torumi M et al⁷⁸ (1998) took 55 seconds for closure of lacerations with glue and 235 seconds sutures with difference being significant ($p < 0.0001$) Bruns TB et al⁷³ conducted a trial for closure of lacerations in children's emergency department in 1995 and concluded that there was significant time difference between glue application and suturing with glue needing lesser time for closure. The findings of the present study were consistent with these results though these studies were not conducted in the settings of laparoscopic appendectomy. Further the wide variation in the mean time would be explained by the different settings studied by the different authors.

In the present study no statistically significant difference was observed with regard to complications between group A and group B on post operative day three

(6.67% vs 13.33%; $p=0.335$) day five (3.33% vs 13.33%; $p=0.177$) and at one week (3.33% vs 6.67%; $p=0.500$). These findings suggest that wound closure using octyl-2-cyanoacrylate has lower rate of complications compared to conventional suturing in patients undergoing laparoscopic appendectomy but not statistically. Among the patient in group A, erythema and warmth were noted on post operative day three in 6.67% and 3.33% compared to 10% and 6.67% respectively. In addition, 6.67% of the patients in group B had tenderness and drainage was noted in 3.33%. During second follow up, in group A 3.33% of the patients had drainage and no other complications were noted compared to 13.33% in group B and in addition, 6.67% of the patients in group B had tenderness. At third follow up drainage was noted in 3.33% of the patients each while infection was present in 6.67% of the patients in group B only. The culture was positive for staphylococcus aureus in 6.67% of the patients. These patients were treated with antibiotics according to the sensitivity. However the rate of erythema, warmth, tenderness, drainage and infection were comparable in both the groups at all the follow ups. These findings suggest that, the possible complications using octyl-2-cyanoacrylate are mostly erythema, warmth and drainage and tenderness and infections are less likely to be seen.

It is known that cyanoacrylate glue has antibacterial properties. Quinn J et al in 1997⁶⁸ has shown the antibacterial property of glue in a contaminated wound model. The exact mechanism of antibacterial property is not known, but it is likely to be a cell wall mechanism because the sensitivities are restricted to gram positive organisms. Gram negative organisms are relatively less affected. Toruimi M et al⁷⁸ (1998) did not find any evidence of gaping in both groups of glue and sutures for laceration repair.

In the present study Hollander Cosmesis score showed optimal (score of 6) scorer in majority of the patients with group A as well as group B at all the follow ups ($p>0.050$). These findings were in agreement with a study by Jallali. N et al,⁷⁹ where authors compared the wound with Modified Hollander Cosmesis Scale and showed no significant difference in Cosmesis.^{69,78}

Overall the results from the present study show that skin closure by adhesive glue, Octylcyanoacrylate is better than traditional skin suturing method. The concept of a surgical tissue adhesive for superficial skin closure is an attractive alternative to the use of sutures for both surgeons and patients in terms of reduced surgical time for skin closure there by resulting in a shorter operative time, forms a flexible, water resistant, sealed skin closure, faster, comfortable and cosmetically best technique for skin closure, and is easier to use. Further, the watertight barrier formed by Octylcyanoacrylate allows patient to shower any time after surgery, no stitches to be removed and no need to apply bandages. Cosmetic benefits include that the glue disappears naturally as incision heals and leaves no mark resulting in better cosmetic outcome. Octylcyanoacrylate is non-irritating to skin and side effects are extremely less. Hence it can be used in surgical skin closure for the patients undergoing laparoscopic appendicectomy.

CONCLUSION

The present study showed that, wound closure using octyl-2-cyanoacrylate requires significantly less time for skin closure and results in shorter operative time compared to with conventional suturing in patients undergoing laparoscopic appendicectomy. Further the wound complications and cosmetic outcome using octyl-2-cyanoacrylate are comparable with conventional suture.

SUMMARY

Several methods are used for the skin closure of trocar wound. Skin incision closure using adhesives glues is one of the recent and advanced method. This study was aimed to compare port site wound closure using octyl-2-cyanoacrylate with conventional suture in patients undergoing laparoscopic appendectomy with regard to complications, time taken for wound closure and cosmetic outcome.

The present one year randomized controlled trial was done in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. A total of 60 patients who underwent laparoscopic appendectomy from January 2013 to December 2013 were divided into two groups of 30 each based on Opaque envelope method. In Group A, port site wound closure was done using with octyl 2- cyanoacrylate and in Group B the same was carried out with non-absorbable sutures.

In the present study 66.67% in group A and 50% in group B were males and the male to female ratio was 2:1 and 1:1 respectively ($p=0.190$). Most of the patients presented with age less than 30 years (70% in group A and 63.33% in group B; $p=0.300$). The mean age in group A was 26.96 ± 6.80 years compared to 30.30 ± 9.69 years in group B ($p=0.129$). The clinical characteristics of the study population in group A and B were comparable ($p>0.050$). The mean surgical time in group A was significantly less compared to group B (123.30 ± 22.46 vs 186.90 ± 21.49 minutes; $p<0.001$). In group A, 6.67% of the patients and 13.33% in group B had complication on post operative day three. On post operative day 5, 3.33% of the patients in group A had complications compared to 13.33% in group B. At the end

of one week follow up, in group A, 3.33% of the patients had complications compared to 6.67% in group B. However, complications were comparable in group A and B at all the three follows ($p>0.050$). The Hollander Cosmesis score was optimal (score of 6) in majority of the patients with group A as well as group B at all the follow ups ($p>0.050$).

Overall, the wound closure using octyl-2-cyanoacrylate requires significantly less time for skin closure and results in shorter operative time and the wound complications and cosmetic outcome using octyl-2-cyanoacrylate are comparable with conventional suture.

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ANNEXURE I – CONSENT FORM

Title of Research Study: “A randomised control trial to compare octyl 2-cyanoacrylate versus conventional suturing port site skin closure in laparoscopic appendicectomy for 1 year”

Principal Investigator:
Dr. *****
Professor,
Department Of General Surgery,
J. N. Medical College, Belgaum.

Co-investigator:
Dr. *****
Post Graduate Student,
Department Of General Surgery,
J. N. Medical College, Belgaum.

You are requested to participate in a study that is an attempt to find out the effectiveness of octyl2-cyanoacrylate (tissue adhesive) compared to conventional suturing of port site skin closure. In past the surgical skin incisions were closed using sutures, and then came the staples and adhesive tapes. So many methods available for skin closure and each one of the methods having their own advantages and disadvantage, it becomes imperative to know which methods are better in what circumstances.

Octyl-2 cyanoacrylate has been demonstrated to be an adequate replacement for the traditional suture closure of simple skin lacerations. According to previous few studies laparoscopic ports closed with Octyl cyanoacrylate had fewer early complications, such as wound erythema, tenderness and drainage. Ports closed with Octyl 2 cyanoacrylate had a better cosmetic appearance. About 60 patients with appendicitis who will be undergoing laparoscopic appendicectomy will be enrolled in this study.

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

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 randomised in either of 2 groups (details below).

If you agree to participate in this study, you will be randomly allotted into a group (A or B) and accordingly receive either port site skin closure with octyl 2 cyanoacrylate (tissue adhesive) or the conventional skin suturing (non absorbable). Postoperatively, your wound will be evaluated for erythema, warmth, tenderness, discharge and infection. There is no additional risk compared to the standard method of administration.

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.

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.

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, Belgaum. 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. **** *, Chairman of Institutional Ethics Committee, JNMC, Belgaum.

CONSENT TO PARTICIPATE IN THE STUDY

I Mr./Ms. _____ have been explained about the research study, the need of the study, the intervention, their risks, benefits and alternatives available in my own vernacular language.

I voluntarily agree to participate in this study by signing up this form below. I understand that I may withdraw at any time from this study. I have been given adequate time to clarify my doubts about the study and my rights as a study participant.

My signature / thumb impression below indicates that I have read or information in the consent been read to me including the risks and benefits and have cleared my doubts.

Name of participant: Signature/LTI:

Name of legally authorized Signature/LTI:

Representative (if applicable):

Relationship with participant:

Name of witness: Signature:

Name of investigator: Signature:

Date:

Place:

ANNEXURE II – PROFORMA

Title of Research Study: “A randomised control trial to compare octyl 2-cyanoacrylate versus conventional suturing port site skin closure in laparoscopic appendicectomy for 1 year”

Name: Age: Sex:
Address: IP No.:
Ward: Education: Religion:
Marital Status: Occupation:
Socio-Economic Status:

HISTORY

When did the patient first notice the pain:

Details:

Associated features and duration: Fever
Vomiting
Other -

Previous history of use of antibiotics/steroids:

Past History:

Personal History:

Family History:

GENERAL PHYSICAL EXAMINATION:

Built and Nourishment:

Weight:

Pallor / Icterus / Cyanosis / Clubbing / Edema / Lymphadenopathy

Vital Signs:	PR: /min;	BP: mmHg;
	RR: /min;	Temp:

SYSTEMIC EXAMINATION:

Per Abdomen examination:

Respiratory System:

Central Nervous System:

Cardio-Vascular System:

INVESTIGATIONS:

ANNEXURE III – KEY TO MASTER CHART

-	-	Absent
+	-	Present
A	-	Group A
B	-	Group B
F	-	Female
M	-	Male
RIF	-	Right iliac fossa
Sec	-	Seconds

