"COMPARISON OF POST OPERATIVE PAIN AFTER PORT CLOSURE USING SPINAL NEEDLE AND PORT CLOSURE NEEDLE IN PATIENTS UNDERGOING LAPAROSCOPIC APPENDECTOMY – A HOSPITAL BASED RANDOMISED CONTROLLED TRIAL"

By

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Endorsement

This is to certify that the dissertation entitled **"COMPARISON OF POST OPERATIVE PAIN AFTER PORT CLOSURE USING SPINAL NEEDLE AND PORT CLOSURE NEEDLE IN PATIENTS UNDERGOING LAPAROSCOPIC APPENDECTOMY –A HOSPITAL BASED RANDOMISED CONTROLLED TRIAL"** is a bonafide research work done by **(REG NO. BH0117012)**.

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Yours sincerely,

Coordinator
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LIST OF ABBREVIATIONS

ERAS	:	ENHANCED RECOVERY AFTER SURGERY
CT	:	COMPUTED TOMOGRAPHY
CO2	:	CARBON DIOXIDE
ATP	:	ADENOSINE TRIPHOSPHATE
LC	:	LAPAROSCOPIC CHOLECYSTECTOMY
VAS	:	VISUAL ANALOG SCALE
GRS	:	GRAPHIC RATING SCALE
NRS	:	NUMERIC RATING SCALE
SA	:	SINGLE PORT APPENDECTOMY

ABSTRACT

Background and Objectives

Acute appendicitis is the most common cause of acute abdominal pain that requires surgical intervention. While history taking and clinical examination continue to be a cornerstone for the diagnosis of the disease, modern imaging techniques and minimally invasive surgery, has brought about a vast difference in the management of acute appendicitis, with appendectomy still being the gold standard treatment. Since the advent of minimally invasive surgery, laparoscopic appendectomy has become the procedure of choice. Despite the advantages associated with laparoscopy, considerable postoperative pain still remains a major cause of concern to the patients. There have been numerous methods that have been investigated to minimalize the post-operative pain, the technique of port closure being one of it. The objective of this was to study compare the incidence of postoperative pain after port closure using commonly available spinal needle and port closure needle following laparoscopic appendectomy.

Materials and Methods

The present study was conducted on patients admitted with the diagnosis of appendicitis in the Department of General Surgery of KLES Dr. Prabhakar Kore Hospital and Medical Research Centre from January 2018 to December 2018. Relevant data was collected by a detailed interview with the patient, clinical examination and blood investigations. The patients were then divided into two groups - Group A and Group B pre-operatively for port closure with Group A undergoing closure with an 18-gauge Spinal Needle Technique and Group B undergoing closure with Port closure needle technique. Pain was then assessed using Visual Analogue

Scale at 6 hours, 12 hours and 18 hours post-surgery. Statistical analysis was done using Independent t-test, Mann-Whitney U test and Wilcoxon matched pairs test.

Results

Of the 60 patients enrolled in the study, the mean age in group A was 29.50 years and that in Group B was 30.70 years with equal number of males and females in each group. There was found to be no significant difference in pain by VAS in the two groups at 6 hours and 12 hours, but at 18 hours post-operative, the pain was significantly less in the patients of Group A who underwent closure with 18-gauge Spinal Needle technique (p value 0.0321). The pain reduction between 6-12 hours and 6-18 hours was statistically more in Group A (p value 0.0211 and 0.0184 respectively).

Conclusion

Laparoscopic surgeries do cause pain post-operatively and addressing it is a major factor in determining the patient's recovery post the surgery. There have been numerous techniques that have been described for port closure, standard not being defined yet. The technique chosen should minimise the tissue damage at the same time achieve adequate fascial closure. The spinal needle technique was found to be more effective in reducing the incidence of pain in the immediate post-operative period.

CONTENTS

LIST OF TABLES

LIST OF GRAPHS

LIST OF PHOTOGRAPHS

16	Free end of the suture material entangled within the loop using Maryland forceps	**33**
17	The loop tightened, and the needle withdrawn	**34**
18	Both ends of the suture material brought out	**34**
19	Knot tied over the facial defect	**34**

Acute appendicitis, the most common cause of acute abdominal pain that requires surgical intervention, has been a commonly treated disease.[1] [2] . A lifetime risk of developing acute appendicitis has been found to be 7–8% with peak incidence occurring in the second and third decade, after which it is noted to decline with age[3–6].

History taking and clinical examination continues to be a cornerstone for the diagnosis of the disease[7]. Owing to the modern imaging techniques and minimally invasive surgery, the management of acute appendicitis has noted a paradigm shift [8].

The efficacy, low morbidity and mortality rate associated with appendectomy, makes it the gold standard of treatment for appendicitis [9,10].

Reduced postoperative pain, duration of hospital stay, faster return to normal activity and a lower frequency of wound infection has made laparoscopic appendectomy as the standard of care [11].

The most common reasons for delayed discharge post-surgery are: concern for abscess, postoperative pain, nausea or inability to tolerate oral intake, uncontrolled hypertension or comorbidities, inability of the patient to access healthcare facility post discharge[12,13].

Although minimally invasive, laparoscopic appendectomy still causes considerable postoperative pain [14]. A pain free post-operative period is an important aspect that aids in early recovery of the patient.

Post-operative pain following laparoscopy can be due to several factors[15]. Umbilical port site pain is one of the commonest complaints of the patients after

laparoscopic surgery. The puncture wounds created are at times difficult and time consuming to close[16].

With the implementation of ERAS protocols and the development of good analgesics, the concept of Ambulatory Surgery has been increasingly accepted for Laparoscopic Appendectomy.

The port site pain following laparoscopic surgeries can be minimalised by using effective, less traumatic techniques for closure.

Various techniques have been described for port closure, which offer good technical advantage to the operating surgeon and lesser discomfort to the patients in terms of decreased incidence of post-operative pain and early recovery.

The need now arises to study which amongst the techniques of port closure can be easily performed and causes minimal discomfort to the patient.

This study compares “the incidence of postoperative pain after port closure using commonly available spinal needle and port closure needle following laparoscopic appendectomy”.

The Spinal needle, due to its lesser diameter, looks promising in decreasing the post-operative pain in individuals as compared to port closure needle.

To compare the post-operative pain, using Visual Analog Scale, after closure of 10mm Port site with Spinal Needle Technique and Port Closure Needle Technique in patients undergoing Laparoscopic Appendectomy.

I. **Appendicitis: an overview**

II. **Laparoscopy**

III. **Laparoscopic appendectomy**

IV. **Port closure techniques**

V. **Spinal needle**

VI. **Vicryl- suture material**

VII. **Post-operative pain after Laparoscopy**

VIII. **Pain assessment**

I. APPENDICITIS: an overview

Ever since the first description of appendicitis as a surgical condition in 1886 by Reginald Fitz and its clinical manifestations by Charles McBurney, the understanding and management of the disease has evolved over the decades.

The appendix is an intraperitoneal organ that arises at the confluence of the taenia coli over the caecum. It measures around 9 cm in length, with volume of around 1ml. The horizontal arrangement of the collagen fibres in the wall of the appendix and the absence of mucosal folds, restricts its passive expansion. Vascular supply to the appendix is provided by the appendiceal artery which is an end artery, hence an increased susceptibility for ischemia and perforation in the setting of acute inflammation.

There have been numerous etiological factors that have been proposed in the causation of appendicular inflammation[1,2]:

- Faecolith
- Hyperplasia of the lymphoid tissue
- Stool impaction
- Foreign body
- Parasites
- Malignant change
- Trauma
- Infection

The main pathologic process involved in appendicitis is luminal obstruction leading to rise in the pressure within the appendicular lumen, vascular compromise, and resultant gangrene and perforation.

The clinical manifestation of appendicitis can be varied, posing a diagnostic dilemma to the examining clinician. Pain that is periumbilical to begin with, which eventually migrates to the lower abdomen on the right side; is usually the main presenting complaint of the patient. The other associated features include fever, anorexia, nausea and vomiting; the intensity of which depends upon the severity of the disease process[2]. The diagnostic accuracy with history and physical examination alone is about 80%[1].

There are various scoring systems that have been developed to assess the severity of the disease and aid in clinical decision making – the Alvarado score and the Appendicitis Inflammation Response score being the most accepted ones.

The diagnostic ability has increased with the addition of imaging modality. Transabdominal ultrasonography is a widely available, inexpensive imagining technique that has a sensitivity of 86% and specificity of 81%[3]. Though being operator dependent, it helps in identifying other causes of right lower quadrant pain in the absence appendicitis. Inflamed appendix is seen as a blind-ending, aperistaltic, non-compressible, tubular structure with laminated wall and circumferential colour on duplex scanning[3].

Computed Tomography (CT) is the preferred imaging technique for appendix. The presence of phlegmon, appendicular abscess and occult appendicular malignancy can be picked up readily on CT scan. Magnetic Resonance Imaging has an advantage of no radiation exposure and is useful

when imaging is required in pregnancy. With the use of these imaging techniques, evidence based early diagnosis of the disease is possible which results in reduced disease morbidity and mortality. However, the imaging modalities cannot reliably predict the sequelae of the disease process[2].

Antibiotic treatment alone has a failure rate at 1 year of around 25–30% with need for readmission or surgery cannot be side-lined [3]. Surgical removal of the appendix has now become the standard of treatment for cases with appendicitis[9,10].

II. LAPAROSCOPY:

The term "laparoscopy: was coined by Hans Jacobaeus. The evolution of laparoscopy dates to as early as the beginning of the 19th century. The credit to developments in the modern day laparoscopy go to von Ott(1901), Georg Kelling(1902) and Hans Christian Jacobaeus(1912)[17,18].

The use of air to insufflate peritoneal and throracic cavity and the use of trocars and endoscopes to visualize these cavities were the initial experiments of Georg Kelling and Hans Christian Jacobaeus.

Figure 1- Hans Christian Jacobeus (1879-1937) and Georg Kelling (1866-1945) : pioneers in the field of Laparoscopy

Since then, there have been numerous inventions and experiments that have been done to build up the era of modern laparoscopy [17].

It was in the late 1970s and early 1980s that Dr. Camran Nezhat developed a video system for laparoscopic surgery.

Kurt Semm, in 1983 performed the first Laparoscopic Appendectomy.[19]

The advantages with advent of laparoscopy such as reduced operative morbidity, early return to regular activities, shorter duration of hospital stay, reduction in the overall healthcare expenditure, better cosmesis; has undoubtedly revolutionised surgery.

III. LAPAROSCOPIC APPENDECTOMY:

Laparoscopic appendectomy is a safe and preferred method for both complicated and uncomplicated appendicitis.[20,21]

PROCEDURE:[22]

→ Anesthesia: General Anesthesia is preferred

→ Position: Supine; may be combined with Trendelenberg's position; with 10-15 degree left lateral tilt; with left arm tucked in.

→ Preoperative preparation: Foley placement followed by routine preparation of the abdomen.

→ Surgery: As per Zollinger's Atlas of Surgical Operations the steps of Laparoscopic Appendectomy are as follows-

- "The access ports are placed at the umbilicus, left lower quadrant, and lower midline
- Videoscope port is created first – Veress needle technique or Hasson's open technique.
- CO2 is insufflated- gas pressure maintained at 14mmHg.
- The videoscope introduced through the umbilical port.
- Under direct vision using the videoscope, two additional 5-mm ports are placed in the abdomen.

- The appendix is visualized by tracing the longitudinal taeniae over the caecum to their confluence.
- Laparoscopic removal begins with dissection of the mesoappendix using diathermy or stapling instrument.
- The base of the appendix is divided using various techniques like: ligation, Roeder's knot, liga clips, hemolock, stapler.
- The appendicular specimen is then retrieved through the 10mm port.
- The appendicular stump and the divided mesoappendix are examined for security and hemostasis.
- Lavage and suctioning done as per the requirement.
- The abdomen is desufflated and the port site closed. Fascial closure done for the 10mm umbilical port.
- Dressing applied".

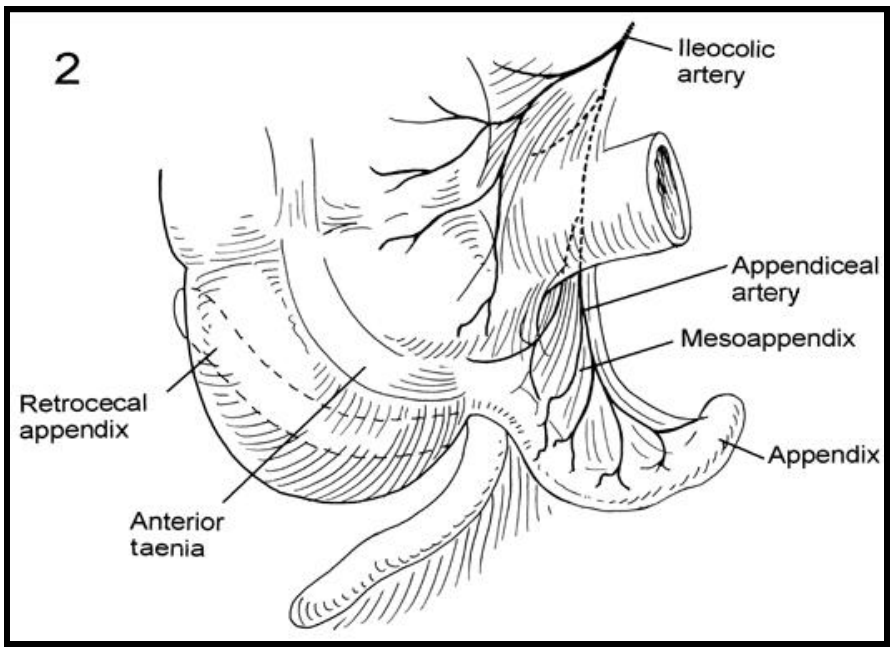


Figure 2 - Anatomical relationship of appendix to caecum[22]

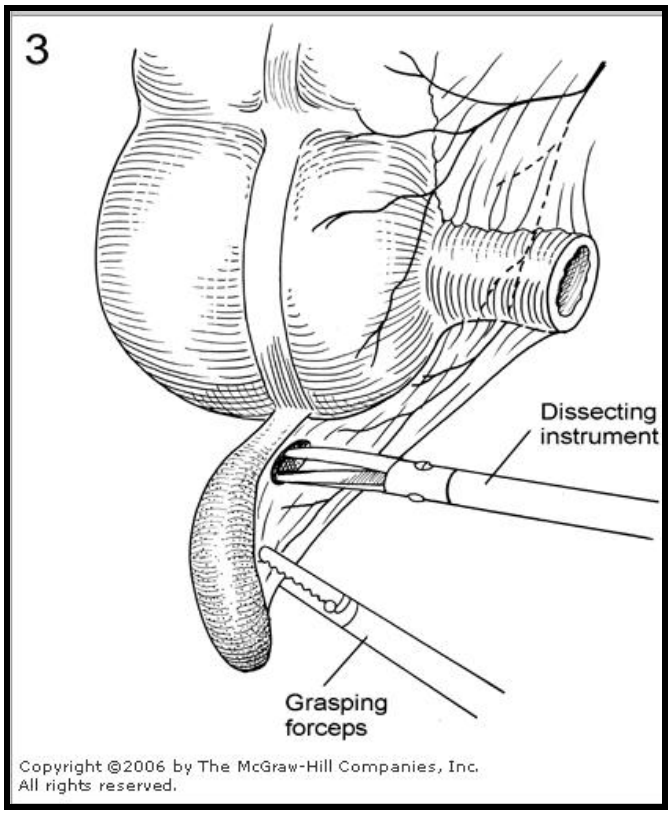


Figure 3 - Dissection at the mesoappendix[22]

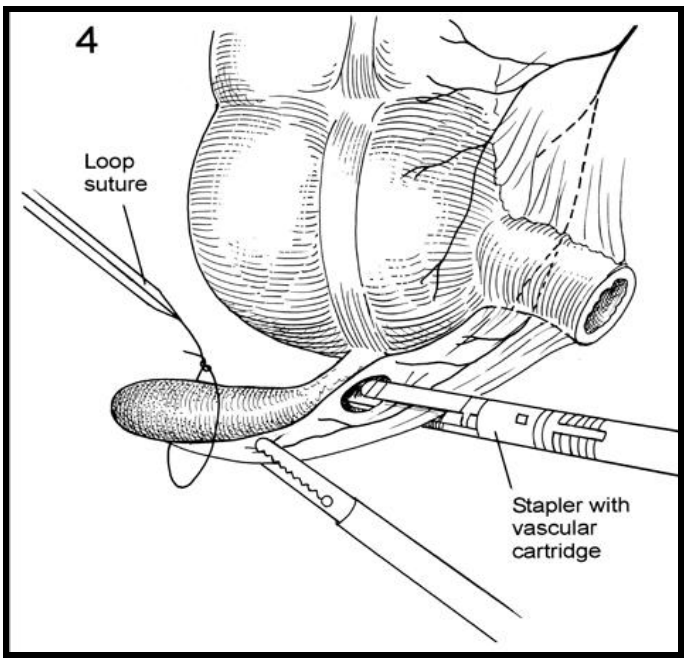


Figure 4 : Dividing the mesoappendix – in the image using a stapling device[22]

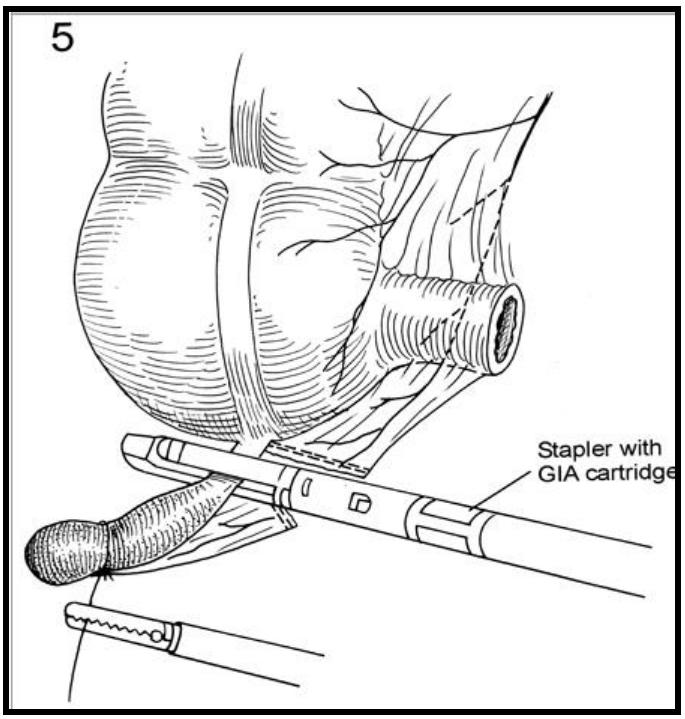


Figure 5 : Dividing the appendix at the base – in the image using a stapling device[22]

IV. PORT CLOSURE TECHNIQUES:

The puncture wounds created are at times difficult and time consuming to close[16].

The method of port closure should ideally be[23] :

- Fast
- Technically easier - without the need to enlarge the skin incision
- Safe
- Inexpensive
- Causing minimal post-operative pain
- Ensuring secure closure of the fascia

Based on the technique of closure, port closure methods can be classified as[24]:

1. "Techniques that use assistance from inside abdomen (i.e., requiring two additional ports: one for the laparoscope and one for the grasper),
2. Techniques that use extracorporeal assistance (i.e., needing only one additional port for the laparoscope),
3. Closure techniques that can be performed with or without visualization."

There are numerous methods and instruments described for port closure [24,25]:

- Grice needle technique
- Maciol needle technique
- Veress needle technique
- Vein catheter, Angiocath technique
- Spinal needle technique
- Deschamps needle technique
- 5mm Trocar Technique
- Port closure needle technique
- Carter-Thomason device
- Port plug technique
- Dual Hemostat technique
- Gore-Tex suture passer technique
- Endoclose suture device technique
- Endo-judge device technique
- Tahoe surgical instrument ligature device technique.
- Exit disposable puncture closure device technique.
- Suture carrier technique
- Lowsley retractor with hand closure technique

No gold standard method has been defined yet.

Closing the port site with pneumoperitoneum intact reduces the likelihood of iatrogenic injuries as the anterior abdominal wall is pushed away from the viscera. Apart from ensuring adequacy of the closure, it also allows

visualisation of the port site from the inside ensuring safety of the technique especially with respect to any visceral injury[25].

The closures that are performed without visualization are likely to cause more tissue damage (due to handling or requirement of widening the incision).

Most of the techniques described requires additional instrumentation, that further increases the cost of the surgery.

Hence, the choice of technique depends on the available resources, preference of the operating surgeon and the ease of the procedure.

V. SPINAL NEEDLE:

Most of the spinal needles that are manufactured are made of stainless-steel alloys. Their size ranges from 16G to 30G[26]. There are various modifications that have been made in the spinal needle since its invention. The Quinke's spinal needle has a bevelled edge, is sharp and hollow. These properties confer it the required tensile strength at the same time minimising tissue damage[27]. It is available in various sizes (based on the luminal diameter) and is colour coded.

Gauge (mm)	Color Code
16G (1.6mm)	White
18G (1.2mm)	Pink
19G (1.1mm)	Cream
20G (0.9mm)	Yellow
21G (0.8mm)	Deep Green
22G (0.7mm)	Black
23G (0.6mm)	Deep Blue
25G (0.5mm)	Orange
26G (0.45mm)	Brown
27G (0.40mm)	Grey

Figure 6: Colour coding of the spinal needle

The spinal needle has following parts: the tip, the body, the hub and the stylet.

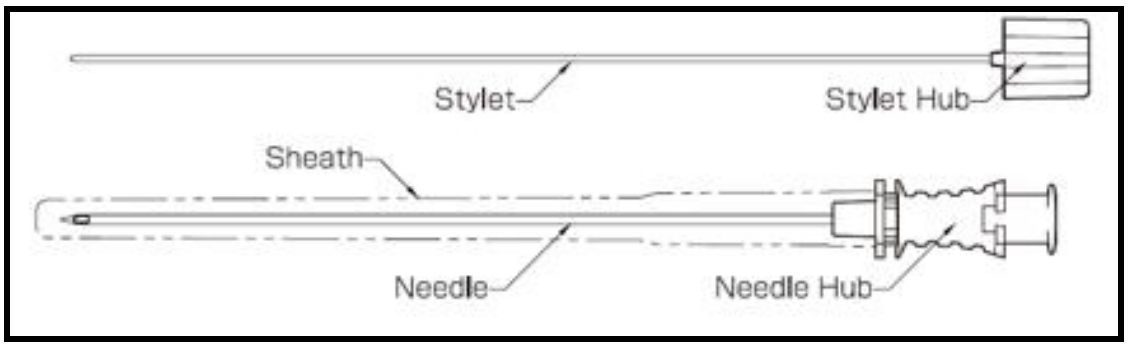


Figure 7: Parts of a spinal needle

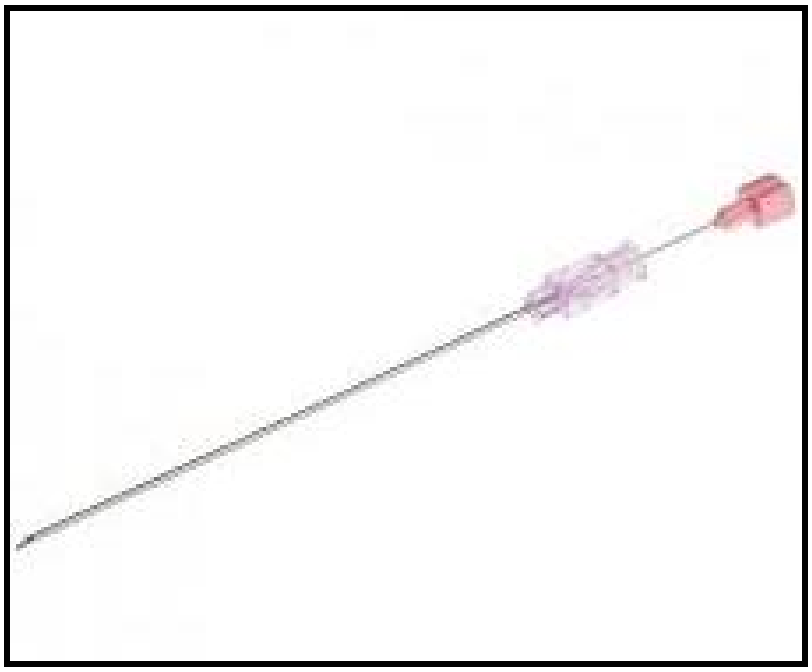


Figure 8: 18-gauge spinal needle

The 18-gauge spinal needle used in the study is Quincke needle 3.50 inches in length and has a diameter of 1.20mm. The stylet hub is coded pink in colour.

VI. VICRYL – suture material

Polyglactin 910 are synthetic absorbable sutures. They are polymers made of lactic acid and glycolic acid. The suture fibres are coloured violet for their visibility in the body. The braiding of filaments further increases the tensile strength. They are pliable and pass through the fascial layers and muscle without causing and pull or damage. They do not split or twist when tied and cut. They have a high initial tensile strength, both when the sutures are tied and after implantation. They are degraded by hydrolysis which is completed in 60-70 days.

CHARACTERISTIC OF VICRYL[28]

SUTURE	TYPE	RAW MATERIAL	TENSILE STRENGTH RETENTION IN VIVO
Coated Vicryl	Braided, Monofilament	Glycolide and L-Lactide coated with a copolymer of lactide and calcium	≅75% remains at 2 weeks ≅50% remains at 3 weeks 25% remains at 4 weeks

The material used in this study is the “VICRYL PORTT” needle

(ETHICON NW 2826).

Figure 9: Vicryl Portt needle

VII. POST-OPERATIVE PAIN AFTER LAPAROSCOPY

Pain is an unpleasant sensation experienced by individuals that has associated emotional and psychological components and may be associated with ongoing or potential tissue damage. Pain is a protective mechanism that helps to identify the site of damage for appropriate response.

Tissue damage leads to release of numerous factors which lead to the activation of receptors of pain. These include:

- Arachidonic acid
- Potassium
- Serotonin
- Histamine
- Bradykinin
- Lactic acid
- ATP

Many of these factors are also proinflammatory and lead to acute inflammation in the area of damage. The pain receptors are free nerve endings. They are classified based on the modality of pain that they perceive: thermal, mechanical or polymodal.

Pain sensation is subjective and varies between patients. Hence, measuring pain , analysing it and formulating a protocol for pain management is difficult[29]. Reduced pain post-operatively has been one of the greatest advantages of laparoscopy compared with open surgery. Despite being minimally invasive, pain continues to be the major cause of morbidity to the patients post laparoscopic surgeries.

Postoperative pain requires prompt attention as it amplifies the surgical stress responses thereby delaying the recovery[30,31]. The intensity of pain escalates during the first postoperative hours and usually subsides over the following days, hence there has been great emphasis laid on postoperative pain management as a fundamental for any surgical procedure outcome assessment [32,33].

Pain experienced by the patients after laparoscopy are frequently described to be subdiaphragmatic, shoulder tip or at the port-site incisions. More than 80% of patients post laparoscopic surgery required opioid analgesia. [34]

Post-operative pain following laparoscopy can be due to several factors[15,34]

- Gas insufflation in the abdomen- increases the pressure within the abdomen causing diaphragmatic irritation.
- Prolonged insufflation time
- Use of high insufflation pressure
- Injury to abdominal wall caused by the trocars at port site and its closure.
- The application of electrocautery.
- The possibility of peritoneal contamination by spilling of contents of bowel

Improved management of post laparoscopic pain is still an area of upcoming research as:

- With better pain control, the otherwise masked advantages of laparoscopic surgery in terms of earlier discharge and recovery time will be better appreciated.

- The post-operative pain reduction leads to reduced post-opertaive stress reaction which contributes to early recovery.

- With better pain control, the patients can be discharged early, thereby reducing the healthcare costs.

There are several methods that have been described and are also being investigated to reduce post-operative pain[34,35]:

- Pre-operative infiltration of local anesthetic at the trocar site.

- Reducing the insufflation pressure, the total duration and volume of insufflation.

- Humidifying the insufflated gas.

- Warming the gas prior to insufflation.

- Minimizing the use of drains

- Using better tissue sealing systems.

- Reducing the number of ports.

- Adequate removal of the insufflated gas.

- Using a better technique for port closure.

- Providing a combination of analgesic/ formulation of a standard analgesic protocol.

There have been studies that have positively concluded that reduction in postoperative pain could be achieved by reducing either the size or the number of ports in patients undergoing .[36–38]

A study by Papagiannopoulou et al suggested "Local tissue infiltration with levobupivacaine is more effective than ropivacaine in reducing the postoperative pain associated with laparoscopic cholecystectomy (LC)."[39]

A study by Lee et al concluded that "Incisional pain dominated during the first two postoperative days after LC. Preoperative somato-visceral or somatic local anesthesia reduced incisional pain during the first three postoperative hours. A combination of somato-visceral local anesthetic treatment did not reduce intraabdominal pain, shoulder pain or nausea more than somatic treatment alone. Preoperative incisional infiltration of local anesthetics is recommended".[40]

A review titled "Pain After Laparoscopy" by Mouton et al, enlisted the causes of post-surgical pain and gave recommendations of methods of reductions and management.[34]

Based on the above studies and many more done in the field of laparoscopy, it is evident that pain after surgery is still an area of upcoming research.

There have been no studies done so far to our knowledge that has compared the post -operative pain between two closure techniques.

VIII. PAIN ASSESSMENT:

"….. The investigator who would study pain is at the mercy of the patient, upon whose ability and willingness to communicate, he is dependent"

-LOUIS LASAGNA,1960

Pain is a subjective feeling. The intensity and severity of it varies in between every patient. There is no universally accepted classification of pain. It has been classified in several ways.

Categorically, pain can be acute, acute recurrent, chronic or chronic progressive - an aspect that is crucial for the management[41].

Pain assessment is necessary to understand the mechanism of pain and to evaluate the methods of pain control.

Assessment of pain can be done based on variable parameters that could be:

- Objective like-
    - Facial expression,
    - Behavior of the patient,
    - Physiological markers etc.

- Subjective (self-reported) like-
    - Intensity assessment
    - Assessment of functional capacity.

The experience of pain is influenced by numerous factors such as:

- Cultural background
- Ethnicity
- Personality of the individual
- Previous experience
- Level of consciousness
- Individual threshold
- Emotional state of the individual

Hence, using a single parameter to assess pain may not be reliable.

Of all the parameters, intensity of pain remains a salient aspect, measurement of which has shown to be reliable and accepted in most studies.

Assessment of the intensity of acute pain at rest after surgery is important for making the patient comfortable in the immediate post-operative period. Reduction in the intensity of pain by appropriate use of analgesics or any other intervention, helps in early recovery of the patient from the surgical process.[42]

There are numerous scales formulated to asses acute pain, of which, the Visual Analog Scale has been found to be more sensitive in detecting small differences in pain.[29,43]

"The Visual Analogue Scale (VAS) consists of a straight line with the endpoints denoting the end limits such as 'no pain at all' and 'pain as bad as it could be'. The patient is asked to mark his pain level on the line. The distance between 'no pain at all' and the mark defines the pain experienced by the patient".

This tool was used in psychology by Freyd for the first time in 1923.

"If descriptive terms like 'mild', 'moderate', 'severe' or a numerical scale is added to the VAS, it is referred to as Graphic Rating Scale (GRS) or Numerical Rating Scale (NRS)". Least measurement error has been noted with a line of 10-15cms, hence used in the scale.[42]

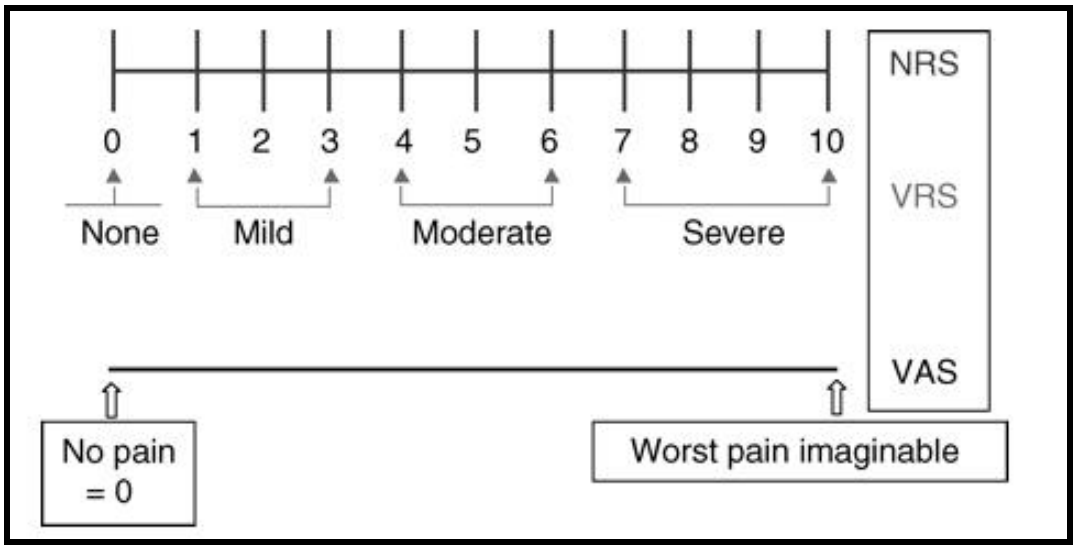


Figure 10: Scoring scale for pain assessment

Study Design	:	Randomized Controlled Trial
Study Period	:	January 2018 - December 2018
Source of data	:	All patients who were admitted to KLES PRABHAKAR KORE HOSPITAL AND MRC, BELGAUM with diagnosis of Appendicitis
Sample Size	:	Since there have not been studies done related to this topic, as a rule of thumb, the sample size of 60 is taken. (30- Spinal Needle; 30- Port Closure Needle)
Randomization Technique	:	Sequentially Numbered Opaque Sealed Envelopes (SNOSE)
Inclusion Criteria	:	All patients between 18-60years of age undergoing Elective Appendectomy.
Exclusion Criteria	:	All emergency cases. Patients with Diabetes.

Methodology:

- After admission, a detailed history was taken, and clinical examination was done for all the patients.
- The following investigations were done for the admitted patients for confirmation of diagnosis and as a part of the pre-operative work up:
    - Hemoglobin
    - Total and Differential Leucocyte count

- Platelet count
- Blood grouping
- PT/INR
- Urine Routine
- Blood Urea and S. Creatinine
- HIV and HBsAg
- ECG
- Chest X-ray
- USG-Abdomen and Pelvis

- The patients were then divided into two groups pre-operatively for port closure (allocated by random sampling - SNOSE), as:
    - **Group A**: Closure using 18-gauge Spinal needle technique
    - **Group B**: Closure using Port closure needle technique

- Following Laparoscopic Appendectomy, the ports were closed using the allotted technique.

  Group A-

    - At the termination of the case with pneumoperitoneum intact, the intra-abdominal side of the 10mm port site was visualized using a 5mm telescope.
    - Vicryl suture material was threaded through 18-gauge spinal needle and the needle was pushed at an angle by the side of the

trocar site through the abdominal wall without piercing the skin.

- The needle was then removed, leaving the vicryl inside.
- A loop of vicryl suture was then made by passing it through the spinal needle and the needle was pushed at an angle by the side of the trocar site through the other side of the defect.
- The free end of the vicryl suture was entangled in the loop of the spinal needle.
- The loop was tightened, and the Spinal needle was retracted along with the suture.
- Knot was tied over the fascial defect after removing the 10mm trocar.

Group B-

- The abdomen was decompressed, and the umbilical port removed.
- The edges of the fascial defect were grasped with Alli's Forceps and closed using Vicryl port needle.

- Post-operative pain was assessed at 6hours, 12 hours and 18 hours after surgery using the Visual Analog Scale.

PORT CLOSURE USING SPINAL NEEDLE TECHNIQUE:

Figure 11: 18-Gauge Spinal Needle

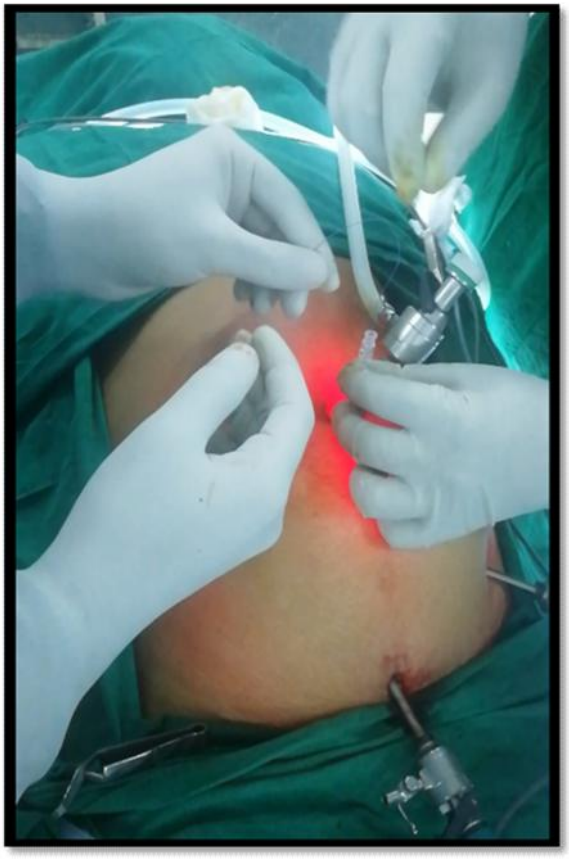


Figure 12: Threading of suture material through the needle

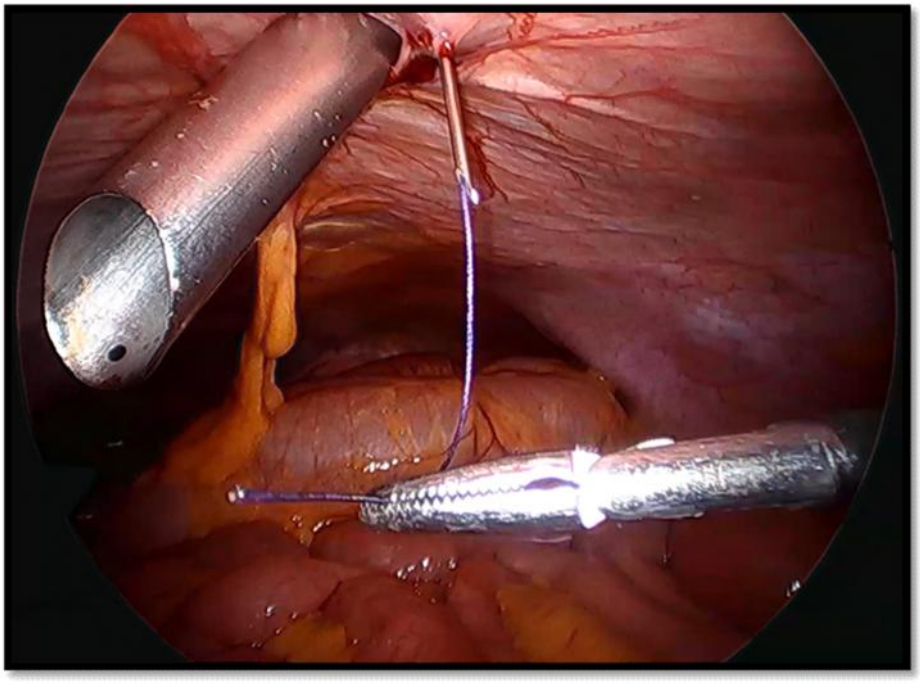


Figure 13: Intra-abdominal view of threading of suture material through the needle. The end is grasped with Maryland forceps.

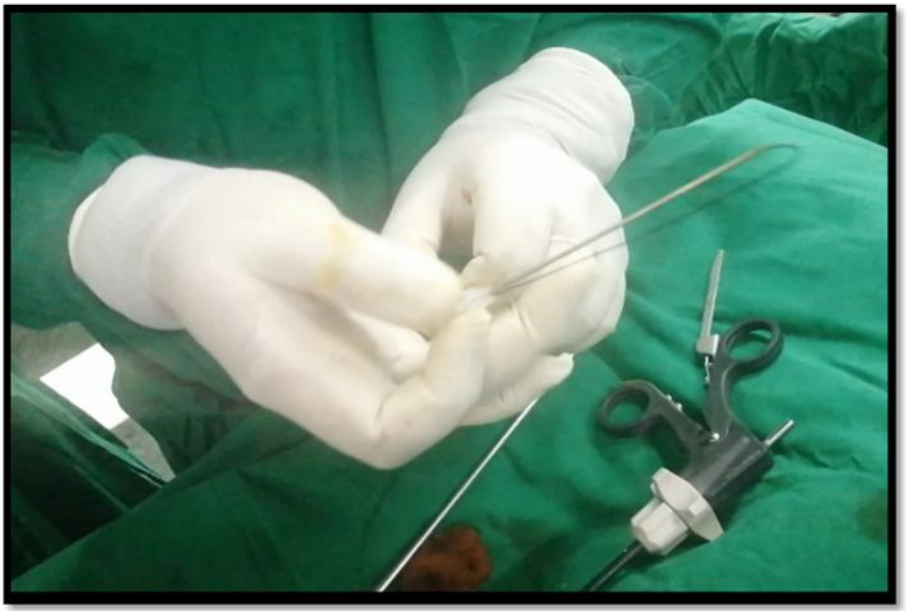


Figure 14 : Forming a loop of through the distal end of the suture material

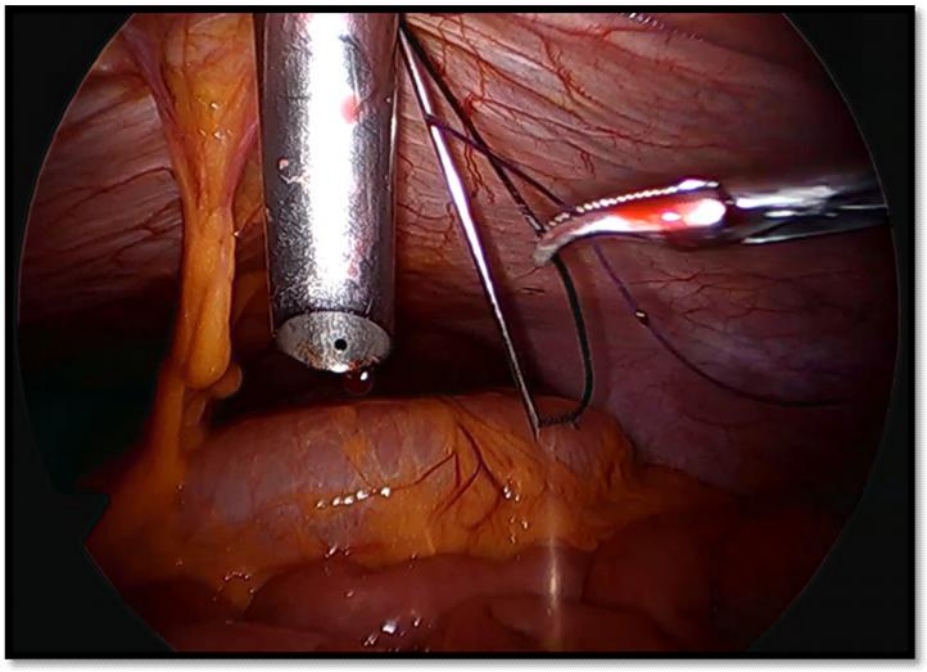


Figure 15: Intra-abdominal view of the two ends of the suture material

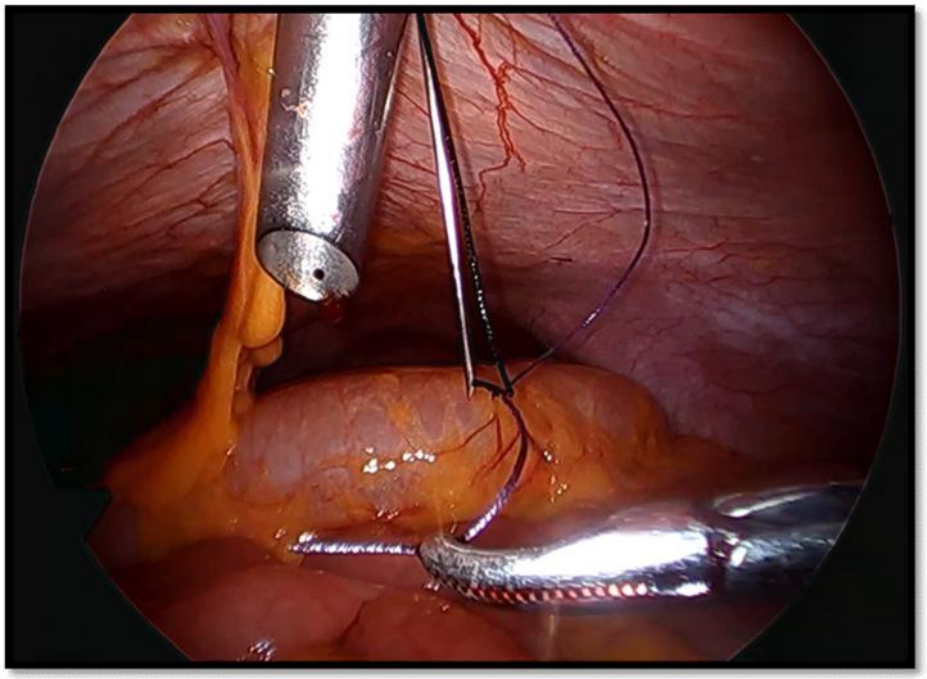


Figure 16: Free end of the suture material entangled within the loop using Maryland forceps

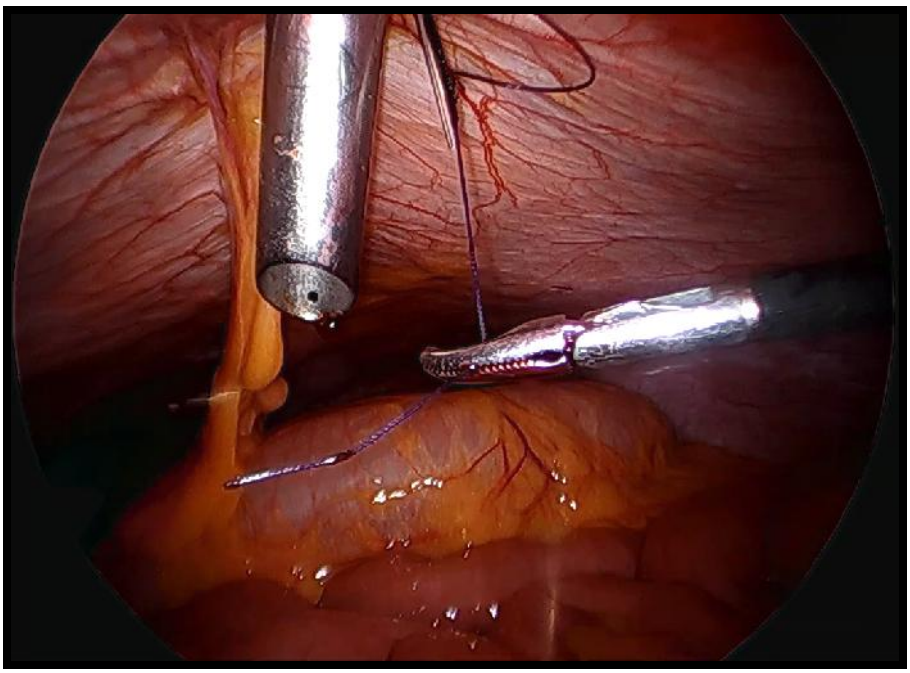


Figure 17: The loop tightened, and the needle withdrawn

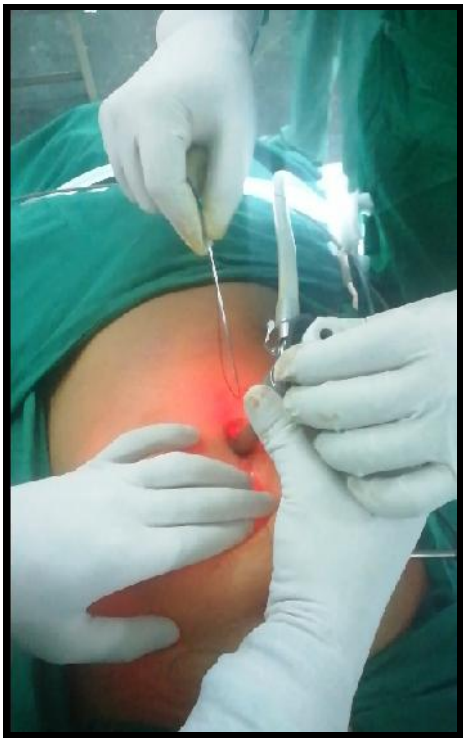


Figure 18: Both ends of the suture material brought out

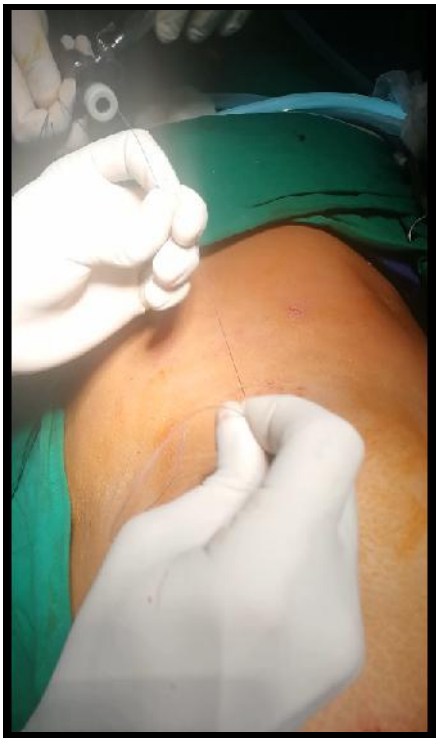


Figure 19: Knot tied over the facial defect

A total of 60 patients were enrolled for the study in the Department of General Surgery at KLES Dr Prabhakar Kore Hospital and MRC, Belagavi, between January 2018 to December 2018.

Allocation into two groups was randomized.

Demographic profile of the study population in terms of age and sex distribution was assessed.

The Visual Analog Scale scores for time intervals of 6hour, 12 hours and 18 hours after surgery was analyzed.

Independent t-test, Mann-Whitney U test and Wilcoxon matched pairs test were used for data analysis.

P value of <0.05 was significant.

DEMOGRAPHIC PROFLIE:

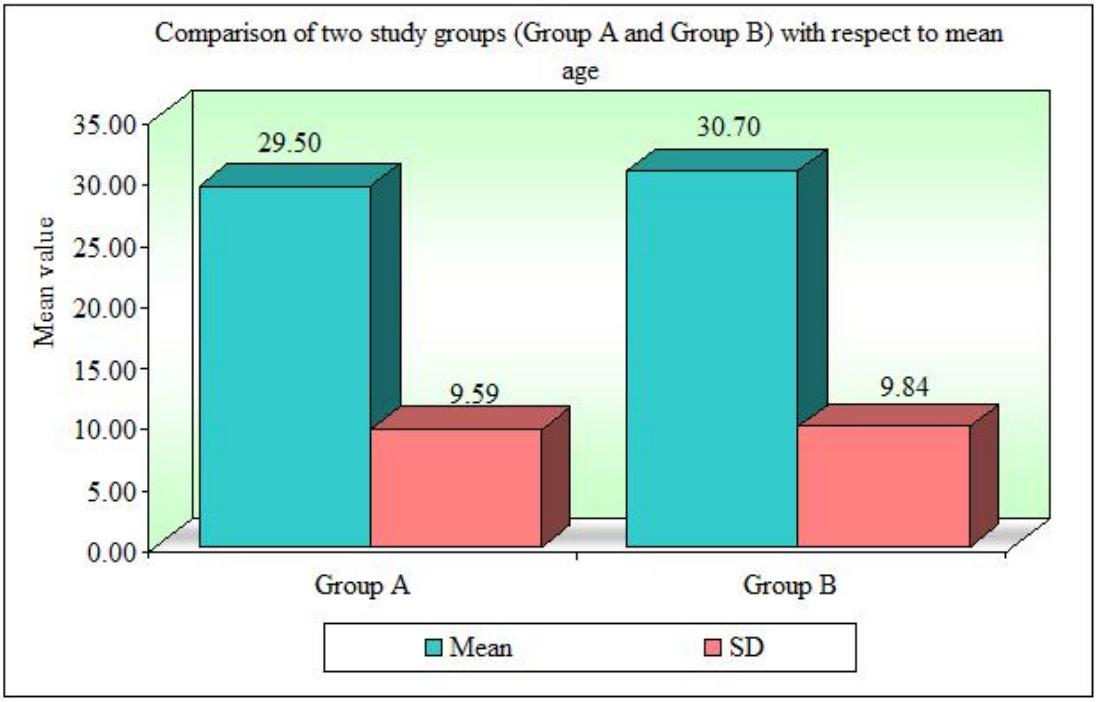
Age distribution:

Patients of age groups between 18years to 60 years were included in the study.

In the study population, the mean age of the patients in group A was 29.50 years and that in Group B was 30.70 years.

Table 1: Comparison of two study groups (Group A and Group B) with respect to mean age by independent t test

Groups	n	Mean	SD	SE	t-value	P-value
Group A	30	29.50	9.59	1.75	-0.4784	0.6342
Group B	30	30.70	9.84	1.80		



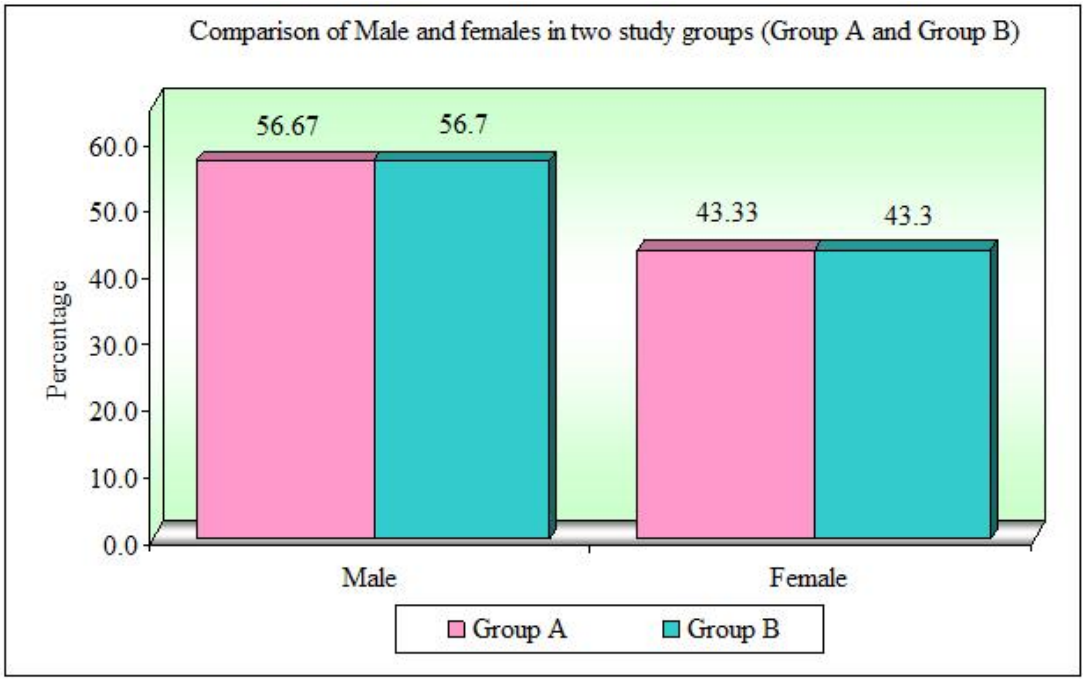
The above graph is a representation of the age distribution of the study population between the two groups.

Sex distribution:

As shown in the table below, there was equal sex distribution in both groups of the study population.

Table 2: Male and females in two study groups (Group A and Group B)

Sex	Group A	%	Group B	%	Total
Male	17	56.67	17	56.67	34
Female	13	43.33	13	43.33	26
Total	30	100.00	30	100.00	60



Graphical representation of the sex distribution of the study population between the two groups

COMPARISON OF VAS SCORES:

Table 3: Comparison of two study groups (Group A and Group B) with respect to VAS score at different time points by Mann-Whitney U test

Time point	Groups	Mean	SD	Sum of ranks	U-value	Z-value	P-value
6 hours	Group A	8.30	0.65	906			
	Group B	8.30	0.75	924	441	-0.1331	0.8941
12 hours	Group A	6.53	1.11	788			
	Group B	7.10	1.09	1042	323	-1.8776	0.0604
18 hours	Group A	5.07	1.26	770			
	Group B	5.70	1.09	1060	305	-2.1437	0.0321*
6 -12 hours	Group A	1.77	0.90	1071			
	Group B	1.20	0.76	759	294	-2.3064	0.0211*
6 -18 hours	Group A	3.23	1.14	1074.5			
	Group B	2.60	1.00	755.5	290.5	-2.3581	0.0184*
12 -18 hours	Group A	1.47	0.82	927			
	Group B	1.40	0.93	903	438	-0.1774	0.8592

*$p<0.05$

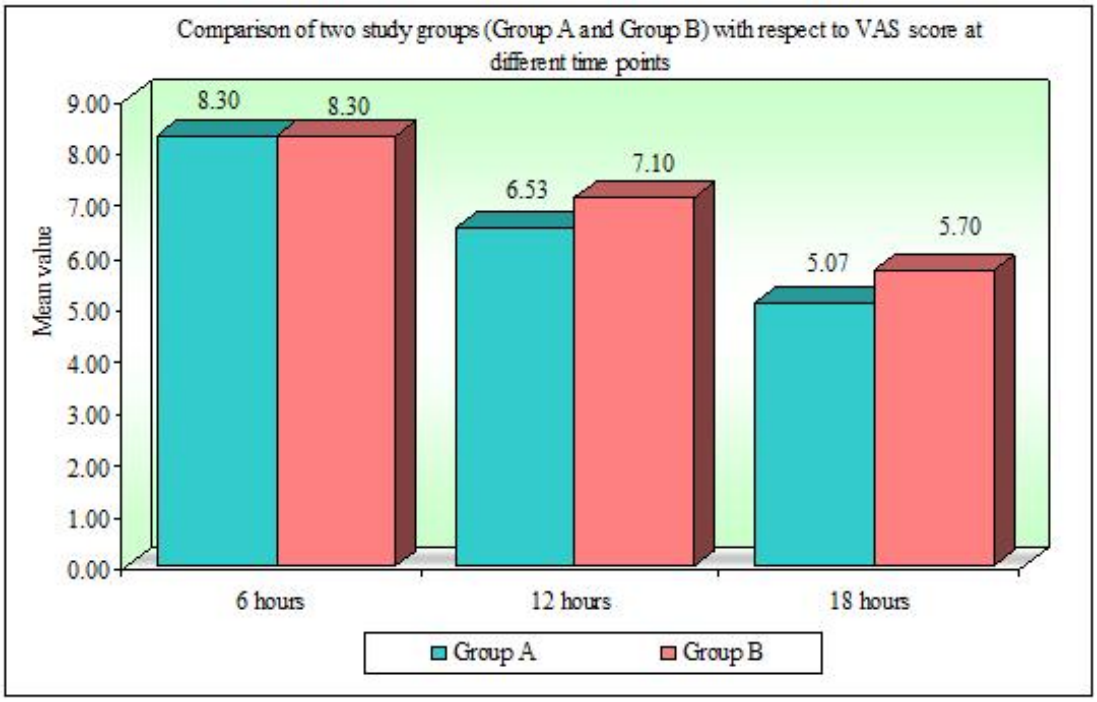
As noted in the table above, the maximum reduction in the VAS score was noted 18 hours after the surgery in Group A, mean score of 5.07($p<0.05$)

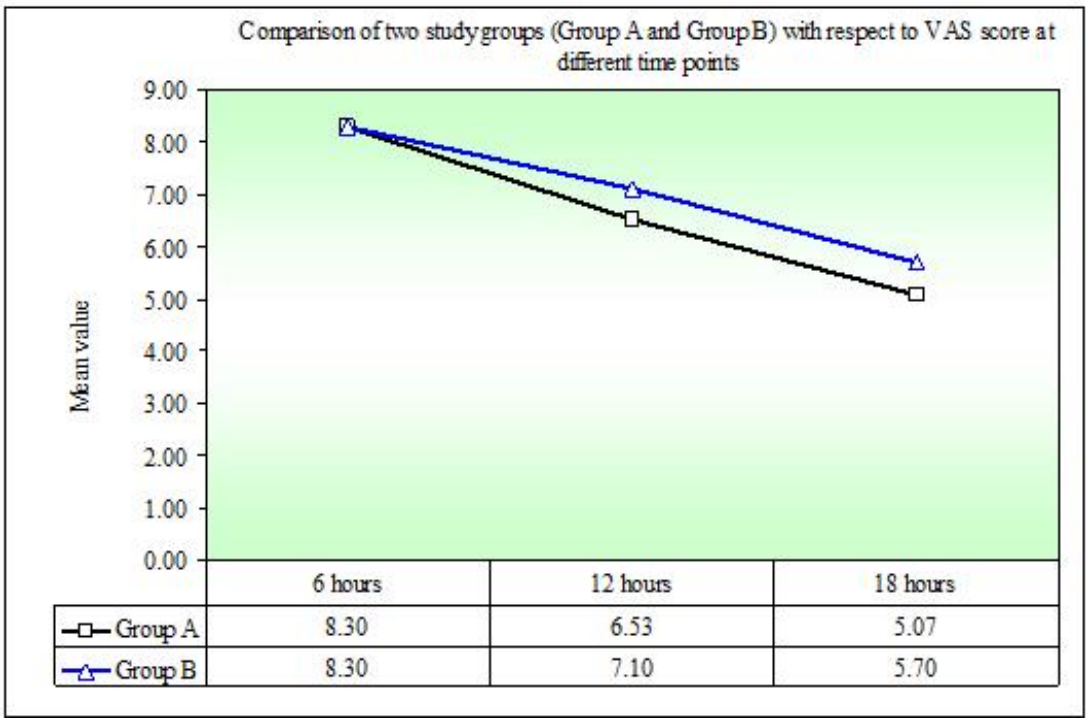
No significant difference was noted in the VAS scores at 6 and 12 hours post the surgery in both the groups.

While comparing the VAS scores at different time periods, significant reduction in the score was noted between 6-12 hours after the surgery in Group A as

compared to Group B. The VAS scores of Group A in the 6-18 hours period was also significant.

The above analysis deduces that pain reduction was more significant with the use of Spinal needle in the immediate post-operative period than Port closure needle.





	6 hours	12 hours	18 hours
Group A	8.30	6.53	5.07
Group B	8.30	7.10	5.70

The above graphs depict how the VAS scores of Group A showed significant reduction as compared to Group B.

The above analysis states that the “technique used in Group A was effective in reducing the VAS scores significantly as compared to Group B”.

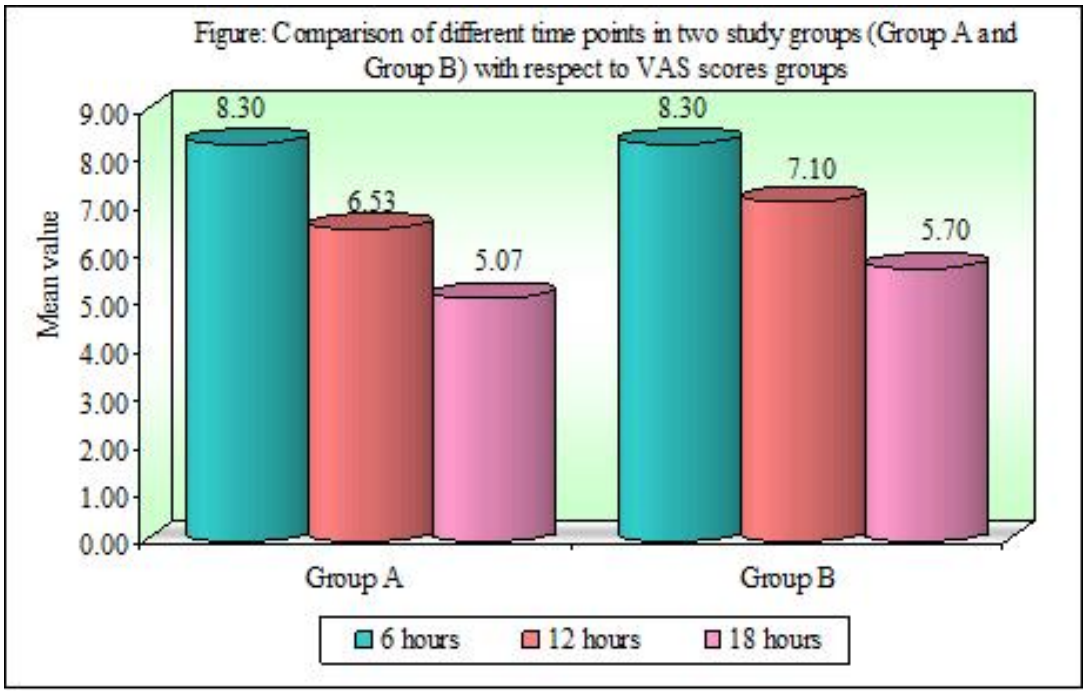
Table 4: Comparison of different time points in two study groups (Group A and Group B) with respect to VAS scores by Wilcoxon matched pairs test

Group	Time points	Mean	Std.Dv.	Mean Diff.	SD Diff.	% of change	Z-value	P-value
Group A	6 hours	8.30	0.65					
	12 hours	6.53	1.11	1.77	0.90	21.29	4.6226	0.0001*
	6 hours	8.30	0.65					
	18 hours	5.07	1.26	3.23	1.14	38.96	4.7821	0.0001*
	12 hours	6.53	1.11					
	18 hours	5.07	1.26	1.47	0.82	22.45	4.5407	0.0001*
Group B	6 hours	8.30	0.75					
	12 hours	7.10	1.09	1.20	0.76	14.46	4.3724	0.0001*
	6 hours	8.30	0.75					
	18 hours	5.70	1.09	2.60	1.00	31.33	4.7821	0.0001*
	12 hours	7.10	1.09					
	18 hours	5.70	1.09	1.40	0.93	19.72	4.2857	0.0001*

*$p<0.05$

The above table compares the VAS scores at 6hrs, 12hrs and 18hrs time points and the percentage of reduction in pain at each of these time period in each group.

Although there is statistically significant reduction of pain percentage in both the groups, the percentage of change of the VAS scores in Group A is significantly higher as compared to Group B.



The above table is a graphical representation of the reduction in the VAS scores over time periods of 6, 12 and 18 hours between two groups.

Reduced postoperative pain, duration of hospital stay, faster return to normal activity and a lower frequency of wound infection has made laparoscopic appendectomy as the standard of care for management of appendicitis [11].

Although minimally invasive, laparoscopic appendectomy still causes considerable postoperative pain [14]. Postoperative pain requires prompt attention as it amplifies the surgical stress responses thereby delaying the recovery[30,31]. The pain after laparoscopic surgery in the immediate postoperative period can be varied due to factors such as visceral, parietal, and shoulder pain, all having different intensities[35].

Our study has highlighted the proven fact that the intensity of pain escalates during the first postoperative hours and usually subsides over the following days, thus making pain evaluation a fundamental requisite in the outcome assessment following any surgery[32,33].

In a study done by Lee et al, it is reported that "incisional pain is more intense than visceral pain and is dominant during the first 48 hours after laparoscopic cholecystectomy"[40].

Papagiannopoulou et al emphasised on importance of establishing a pain free postoperative period and its relevance in reducing the discomfort to the patient and the duration of stay in the hospital[39].

A study done by Hyung Ook Kim et al comparing transumbilical single port laparoscopic appendectomy(SA) with conventional three port laparoscopic appendectomy found that "pain score in the 24 hours after surgery was higher in

patients who underwent SA (p = 0.009)" suggesting that size of the port and the trauma caused to the abdominal wall are a major determinant of post-operative pain [44].

Bisgaard et al in their study on mini laparoscopic cholecycsectomy concluded that "both incisional pain and overall pain were reduced with mini laparoscopy, which suggests that incisional pain is a significant component of overall pain after laparoscopic cholecystectomy"[37] further highlighting the role of port site incision length and intensity of post-operative pain.

"Patients undergoing the procedure with the shorter incisions experienced significantly less pain" was the conclusion of a study by Leggett et al on reducing the number of ports in Laparoscopic Cholecystectomy.[38]

With the implementation of ERAS protocol and the introduction of the concept of Ambulatory surgery, a lot of previously inpatient procedures are being done on an outpatient basis/ day care basis.

A study by Skattum et al on different outpatient surgeries concluded that "benefits of elective ambulatory surgery, not only for health care costs, but also for patients, are well documented"[45]

The concept of ambulatory / outpatient surgery has been applied for laparoscopic cholecystectomy, laparoscopic adrenalectomy, laparoscopic splenectomy, laparoscopic fundoplication[45–47].

A study by Cassandra et al evaluated the efficacy of an out-patient protocol for patients undergoing laparoscopic appendectomy for acute appendicitis. The authors concluded that the protocol set by the institution led to effective out patient

management of the operated patients on an outpatient basis without any significant rise in morbidity. They have further stated that their protocol is now being implemented as a standard of care for all patients with acute appendicitis[48].

Alvarez et al in their study have concluded that even perforated appendicitis could be treated on an ambulatory basis.[12]

Since one of the main factors that aid in early recovery post-surgery is pain, its assessment is crucial in the era of Ambulatory Surgery.

In this study, the incidence of somatic pain/ umbilical port site pain after closing the port with two techniques post laparoscopic appendectomy was analysed.

There have been various studies that have compared port closure techniques and the incidence of port site complications, especially port site hernia [23,49–54].

There are recommendations that have been made for closing of laparoscopic port:[23]

→ "All ports greater than 10 mm (midline and lateral) should be closed at the fascial level.

→ It is advised that 5-mm ports may need to be closed if the peritoneal and/or fascial defect has enlarged significantly during the procedure as a result of lengthy or extensive manipulation during the procedure. This is more likely to be necessary when the port is in the midline.

→ Enlarging the incision to allow proper closure should take precedence over obtaining a good cosmetic result.

→ Port closure should include fascia and peritoneum.

→ In thin patients, midline port sites can be closed using standard methods via the skin wound.

→ Where possible, it is advised to view the abdominal side of each wound during fascial closure via the laparoscope."

To our knowledge, no studies have been conducted to compare the incidence of post-operative port site pain between two port closure techniques.

In our study, we have found that the incidence of umbilical port site pain following laparoscopic appendectomy was reduced when the port was closed using 18-gauge spinal needle. Major reduction in postoperative pain was noted in the 6-18-hour period post-surgery.

Though minimally invasive, laparoscopic surgeries do cause pain post-operatively. Addressing pain as a major factor in determining the patient's recovery post the surgery is crucial as it tends to mask the other associated advantages associated with laparoscopy.

The pain post laparoscopy could be somatic, visceral or due to pneumoperitoneum.

The trocar site, especially >10mm, pose a technical challenge to the operating surgeon for their fascial closure. At times, the incision may have to be widened to achieve closure thereby increasing the trauma to the abdominal wall and increasing the post-operative pain. There have been numerous techniques that have been described for port closure, standard not being defined yet. The technique chosen should minimise the tissue damage at the same time achieve adequate fascial closure.

This study compared the incidence of post-operative pain at the umbilical port site following closure using two methods – spinal needle technique and port closure needle technique. The spinal needle technique was found to be more effective in reducing the incidence of pain in the immediate post-operative period.

Hence, we feel it is worth considering this study with large sample sizes to look for a correlation as it will help in establishing a standard of care protocol and help the patient to have an uneventful post-operative recovery.

This study was conducted at KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Belagavi between January 2018 to December 2018.

A total of sixty patients who were undergoing Laparoscopic Appendectomy were included in the study of whom, thirty patients underwent closure of the umbilical port with 18-gauge spinal needle and the remaining thirty with vicryl portt needle

The two groups were almost similar with respect to age and sex distribution.

There was significant reduction in the post-operative pain in the patients undergoing port closure using Spinal needle that was noted in this study. We feel this reduction is due to minimal tissue handling that is seen with spinal needle.

However, how effective these port closure techniques are in their ability to reduce the post-operative port site pain needs to be studied further with large sample size with a defined pain management protocol.

We also recommend the formulation and adoption of a protocol for post-operative pain management, especially for Laparoscopic cases, as they are now being done on Day care basis.

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ANNEXURE I – CONSENT FORM

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr/Mrs/Miss. _____, we are requesting you to enroll yourself in study titled **"COMPARISON OF POST OPERATIVE PAIN AFTER PORT CLOSURE USING SPINAL NEEDLE AND PORT CLOSURE NEEDLE IN PATIENTS UNDERGOING LAPAROSCOPIC APPENDECTOMY - A HOSPITAL BASED RANDOMISED CONTROLLED TRIAL",** conducted by **_____,** Post Graduate in M.S. General Surgery under the guidance of _____. Professor, Department of General Surgery, J.N. Medical College, Belagavi under KLE University, Belagavi.

Respected Sir/Madam,

We request you to participate in our study. Your participation in the research is voluntary. Your decision to participate in the study or otherwise will not affect the relationship with KLE Hospital. If you decide not to participate, you are free to withdraw at any time. During the study, your operative outcome will be assessed by some questions.

Purpose of the study:

This research is intended to compare the post-operative pain following port closure using two methods in patients undergoing Laparoscopic Appendectomy. The principal investigator of the study is _____, under the guidance of _____.

Procedure Involved:

If you agree to enroll yourself in this study, your detailed history will be taken and you will be clinically examined in detail. Investigations like Hemoglobin, Total Count, Differential Count, Platelet Count, RBS, Blood Urea, Serum Creatinine, Blood Grouping, Chest X-ray, ECG, USG Abdomen and Pelvis, required for confirmation of your diagnosis and for your pre-operative work up will be done accordingly. You will be assigned to either of the two groups of port closure, i.e., Group A – Spinal Needle, Group B – Port closure needle, by SNOSE [Sequentially Numbered Opaque Sealed Envelope].

You will undergo Laparoscopic Appendectomy under General Anesthesia.

Three abdominal ports will be placed-

- 10mm infra umbilical
- 5mm supra pubic
- 5mm left iliac fossa

The 10mm port will be closed using the needle allotted. The 5mm ports will be closed using Ethilon in both the groups. Following the surgery, you will be shifted to the recovery for post-operative monitoring.

Post-operative pain will be assessed using Visual Analogue Scale (3) (VAS) and graded at 6 ,12 and 18 hours. Intensity of pain will be assessed by using 10-point VAS representing various intensity of pain from '0' (No pain) to 10 (Worst possible pain).

Risks and Benefits:

There is no increased risk involved in being a part of this study and the complications are those which are normally anticipated. This study will help to estimate the incidence of postoperative pain in comparison with the two needles involved. The results derived at the end of study will benefit all similar patients admitted in this hospital.

Withdrawing/removal from the study:

The participant has freedom to withdraw from the study whenever he/she wishes and without any prior notice. Even if you decline to participate, there will not be any change in the line of your management or the relationship with your doctor. You will be told about all the information that affects your decision to participate in the study. The investigator may also exclude a participant from the study at any point of time.

Privacy and Confidentiality:

The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to other without your written permission except:

1. In emergency to protect your rights and welfare.

2. If required by law.

Institutional/sponsors policy:

If any unforeseen complications or injury occurs during the period of study the participant will be given treatment within the limitations of KLE's Prabhakar Kore Hospital.

Financial Incentives for participation:

The participant neither gets any financial incentives during the period of study nor will be asked to pay for this study.

Authorization to Publish Results:

When the results of the research are published, or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in this study that can be associated with your identity will remain confidential.

CONSENT STATEMENT:

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

Subject Name : _____

Signature or Left Thumb Print of Subject : _____

Witness Name: _____ Signature: _____

Investigators Name: _____ Signature: _____

Date: _____

Place: _____

ANNEXURE-II

PROFORMA

Group:

Name: IP no.:

Sex: Age:

Address: Religion:

Education: Date of admission:

Occupation: Date of discharge:

CHIEF COMPLAINTS:

HISTORY OF PRESENTING COMPLAINTS:

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; Febrile/Afebrile

SYSTEMIC EXAMINATION:

Abdomen:

Inspection:

Palpation:

Percussion:

Auscultation:

Cardio Vascular System:

Respiratory System:

CLINICAL IMPRESSION:

INVESTIGATIONS:

Hb: Total Leucocyte Count: Platelet count:

Random blood sugar : Blood Group:

Blood urea: Sr. Creatinine: PT/INR:

Urine routine and microscopy:

HIV: HBsAg:

ECG: Chest Xray:

USG-Abdomen and Pelvis:

OPERATION DETAILS:

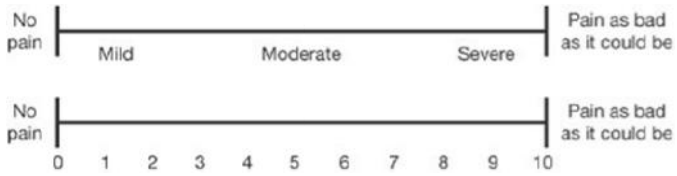
Date of Surgery:

Anesthesia: General Anesthesia

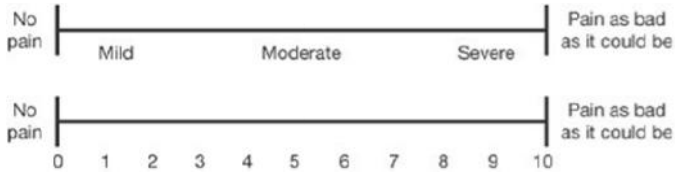
Duration of Surgery:

ASSESSMENT OF POST OPERATIVE PAIN BY VISUAL ANALOGUE SCALE(VAS)

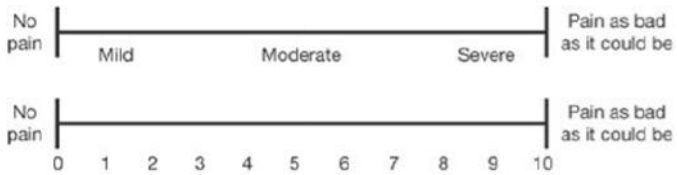
VAS AFTER 6 HOURS:



VAS AFTER 12 HOURS:



VAS AFTER 18 HOURS:



ANNEXURE-III- ETHICAL CLEARANCE LETTER

K.L.E.UNIVERSITY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
(Accredited 'A' Grade by NAAC)

Website: http://www.jnmc.edu
E-Mail : dome@jnmc.edu

Phone: (+ 91-(0)831 Office : 2471350
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 17 **Date: 22/11/2017**

To,

REG NO: BH0117012

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"COMPARISON OF POST OPERATIVE PAIN AFTER PORT CLOSURE USING SPINAL NEEDLE AND PORT CLOSURE NEEDLE IN PATIENTS UNDERGOING LAPAROSCOPIC APPENDECTOMY – A HOSPITAL BASED RANDOMIZED CONTROLLED TRIAL"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

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

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

67

ANNEXURES IV - MASTER CHART

S. No	IP Number	Age	Sex	Group	Post-Operative Pain (VAS)		
					After 6 Hours	After 12 Hours	After 18 Hours
1	881756	30	M	A	9	8	8
2	851111	18	F	A	8	5	4
3	854395	25	M	A	8	5	4
4	866848	32	M	A	9	7	5
5	890502	26	M	A	8	7	5
6	894907	23	F	A	9	8	5
7	866047	26	F	A	9	8	6
8	897196	20	F	A	8	7	5
9	877802	42	F	A	9	8	8
10	894273	32	M	A	8	7	5
11	891021	22	M	A	8	6	5
12	877065	23	F	A	8	6	5
13	887374	38	M	A	9	7	4
14	886908	27	M	A	7	5	3
15	870391	21	F	A	7	7	6
16	872520	32	F	A	8	7	7
17	918882	23	M	A	8	6	5
18	871206	22	M	A	9	6	5
19	879822	29	F	A	8	5	3
20	889359	18	M	A	9	6	5
21	885336	46	M	A	9	8	6
22	886063	36	M	A	7	6	4
23	863146	29	F	A	8	6	5
24	887398	58	F	A	8	6	5
25	899045	28	F	A	9	9	7
26	870954	50	F	A	8	5	4
27	915842	24	M	A	8	6	4
28	912268	35	M	A	8	5	4
29	881085	20	M	A	9	7	6
30	876128	30	M	A	9	7	4

S. No	IP Number	Age	Sex	Group	Post-Operative Pain (VAS)		
					After 6 Hours	After 12 Hours	After 18 Hours
1	917353	22	M	B	7	6	5
2	859542	25	M	B	7	5	5
3	891400	42	F	B	8	6	5
4	861908	20	F	B	8	8	6
5	861984	27	F	B	8	8	6
6	918599	41	M	B	7	6	6
7	895333	18	F	B	9	8	6
8	856638	34	M	B	9	8	8
9	854198	25	M	B	9	8	8
10	863488	21	F	B	8	7	7
11	855153	48	M	B	9	9	7
12	878492	45	F	B	8	8	6
13	857039	36	F	B	7	5	4
14	908750	22	M	B	8	6	5
15	919363	41	M	B	9	6	4
16	905964	38	M	B	7	6	4
17	910259	27	F	B	9	8	5
18	857570	42	M	B	8	7	5
19	913325	26	M	B	9	8	6
20	900084	28	M	B	9	7	7
21	917634	18	F	B	9	7	5
22	917291	38	M	B	9	8	7
23	899812	19	F	B	9	8	5
24	893680	27	M	B	8	6	5
25	902552	38	F	B	8	6	5
26	886981	32	F	B	9	9	7
27	906489	34	M	B	8	7	5
28	910559	18	M	B	8	7	6
29	913172	19	M	B	9	8	5
30	869292	50	F	B	9	7	6

Introduction

Objectives

Review of Literature

Methodology

Results

Discussion

Conclusion

Summary

Bibliography

Annexure-I

Annexure-II

Annexure-III

Annexure-IV