"COMPARISON OF ALL THREE 5 MM PORTS LAPAROSCOPIC APPENDECTOMY WITH CONVENTIONAL LAPAROSCOPIC APPENDECTOMY - A HOSPITAL BASED RANDOMISED CONTROLLED TRIAL"

REG NO: BH0120015

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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 ALL THREE 5 MM PORTS LAPAROSCOPIC APPENDECTOMY WITH CONVENTIONAL LAPAROSCOPIC APPENDECTOMY – HOSPITAL BASED RANDOMISED CONTROLLED TRIAL ",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

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LIST OF ABBREVIATIONS

SILA - single incision laparoscopic appendectomy

DILA - Double incision laparoscopic appendectomy

NOTES – Natural Orifice Transluminal Endoscopic Surgery

NSAID – Non-steroidal anti-inflammatory drugs

BP – Blood Pressure

Cms – centimetres

Cc – cubic centimetres

Mm - millimetre

ECG – Electrocardiogram

RCT – Randomised Controlled Trial

pH – potential of hydrogen

CO_2 – carbon dioxide

^{0} C – degree of Celsius

HIV – Human Immunodeficiency Virus

COX – cyclo-oxygenase

PG – prostaglandin

IL – Interleukin

IV – intravenous

mg - milligrams

H/O – History of

HIV – Human Immunodeficiency Virus

AIDS – Acquired Immune Deficiency Syndrome

INR – International Normalized Ratio

HBsAg – Hepatitis B Surface Antigen

HCV – Hepatitis C Virus

JNMC - Jawaharlal Nehru Medical College

KAHER – KLES Academy of Higher Education and Research

KLES – Karnataka Lingayat Education Society

MIS – Minimally Invasive Surgery

POSAS - The Patient and Observer Scar Assessment Scale

PR – Pulse Rate

PT – Prothrombin Time

SNOSE – Sequentially Numbered Opaque Sealed Envelope

USG – Ultrasonography

VAS – Visual Analogue Scale

SD – Standard deviation

IQR - Interquartile range

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ABSTRACT

Background and objectives:

Acute appendicitis is one of the most common causes of acute abdomen. It ranges from subacute inflammation to perforation. Its management, appendectomy was initially described by Claudius Amyand in 1753 has evolved remarkably; from a large McBurney's incision to minimally invasive approach. Due to increased availability of laparoscopy, it is currently the preferred approach of choice for appendectomy. With advances in minimal access techniques, various attempts are being made and studied to reduce the invasiveness by reducing the number and size of ports, such as single incision laparoscopic appendectomy, double incision laparoscopic appendectomy and NOTES. However, there are several drawbacks i.e., the requirement of specialized instruments and skills, difficulty in triangulation of instruments, increased cost, a longer learning curve, increased incidences of incisional hernia and unsatisfactory cosmesis, and hence leading to various speculations and debates. Therefore, we hypothesize that the use of all three 5 mm ports technique can be used to reduce postoperative pain and achieve satisfactory cosmesis, while retaining the same skillset as conventional laparoscopic appendectomy. This study aims to compare patients undergoing all three 5 mm port laparoscopic appendectomy and conventional laparoscopic appendectomy terms of postoperative pain and cosmesis, and rate of conversion to a 10 mm port.

Materials and methods:

A total of 60 patients diagnosed with uncomplicated acute appendicitis were enrolled, in ages between 18 to 60, and planned to undergo laparoscopic appendectomy. They were assigned randomly into two groups: the all three 5 mm port laparoscopic appendectomy (group A) and conventional laparoscopic appendectomy (group B). Demographics, size of the appendix on ultrasonography, duration of surgery, conversion of the 5 mm umbilical port to 10 mm port

during specimen retrieval, and postoperative pain and cosmesis at serial intervals were recorded. Statistical analysis was done on Microsoft Excel and IBM SPSS v 20; Independent t-test, Shapiro-Wilk test and Mann-Whitney U test were applied. P value less than 0.05 was considered as significant.

Results:

In the study group, the mean age in group A was 34.1 years and in group B was 33.7, and 32 males and 28 females. On ultrasound imaging, the average size of the appendix in group A was 9.17 mm and in group B was 8.87 mm. The mean duration of surgery was significantly longer in all three 5 mm ports laparoscopic appendectomy, 79 minutes, which is significantly longer than in those undergoing. The rate of conversion to of the 5 mm umbilical port to 10 mm was 53%, i.e., 16 patients in group A, where the appendiceal size was more than 8 to 9 mm. Postoperative pain was significantly lower in group A at 1 hour and 12 hours postoperatively with $P < 0.001$ but was higher in patients who underwent conversion. Cosmetic outcome in group A was also significantly better at 1 week and 4 weeks, where $P < 0.05$) but was worse in patients who underwent conversion.

Interpretation and conclusion:

The all three 5 mm laparoscopic appendectomy technique is safe and feasible, where the diameter of appendix is less than 8-9 mm with significantly lower postoperative pain and a better surgical scar. Moreover, there was no compromise in surgical steps. The conventional technique can be used when the appendix is larger than 8-9 mm.

Key words: Acute appendicitis, laparoscopic appendectomy, 5 mm port laparoscopic appendectomy, minimal invasive surgery, cosmesis.

INTRODUCTION

Appendicitis and appendectomy were first formally described in 1886 by Reginald Heber Fitz. The procedure was first performed by Claudius Amyand in 1753. With progress in modern surgery, it has evolved, with notable advances in the incisions used. Laparoscopic approach was first used by Kurt Semm in 1982.[1]

Since its contraption, minimal access surgery has undergone explosive growth in the past three decades. It is being assessed and used for a substantial number of major surgical procedures. In most cases, although the access is minimal, the surgery itself is major. The merits of laparoscopic over open surgeries are better cosmesis, lesser postoperative pain, less analgesic use, lower postoperative infections, shorter hospital stay and faster recovery.[2]

Laparoscopic appendectomy is now largely acknowledged as the standard therapy for both difficult and simple acute appendicitis. Its disadvantages are intra-abdominal abscesses, higher costs, and prolonged operative time. Several efforts have been made to minimize the number and size of ports used in this method. i.e., single incision laparoscopic appendectomy (SILA) and "natural orifice transluminal endoscopic surgery (NOTES)." However, these require specialized and expensive instruments, which is difficult in a limited resource setting. It requires a challenging skillset, and presents with various complications such as the need for proper channels for instruments, spatial orientation, triangulation for dissection and retraction and closure techniques to prevent intraperitoneal infection.[2,3]

Postoperative pain is a major concern for patients undergoing major surgeries. Inadequate postoperative pain management leads to delayed recovery, reduced pulmonary function, longer hospital stay, restriction of mobility, delay in starting physiotherapy, and thromboembolic events which have adverse effects on the outcome

of the surgery, including the decision of discharging a patient and resuming daily activities. Opioids with NSAIDs are regarded as a part of multimodal approach. However, opioids are known to cause prolonged ileus, altered neurological examination and on chronic therapy, leads to drug abuse, addiction, and dependency. In laparoscopic surgery, early postoperative pain may be a parietal, visceral or pain in the right shoulder. Which can be attributed to lifting and stretching of the diaphragm, distension of abdominal muscles and noxious effects of leftover carbon dioxide within the peritoneal cavity.[4]

Another key factor in surgical outcome is the psychological nuances, which must be considered with sensitivity. Patients undergoing laparotomy have larger scars, where the scores of the postoperative pain, somatization, anxiety, depression, interpersonal sensitivity are higher. These have a negative outcome which can be reduced by minimal access methods, resulting in better patient satisfaction.[5]

Conventional laparoscopic appendectomy is done by using a 5 mm port and two 10 mm ports. Incisions more than 10 mm leave a larger fascial defect, which result in more postoperative pain and hernias. 5 mm laparoscopic appendectomy is done routinely in children, where all three ports are of 5 mm in diameter. This has been tried in laparoscopic cholecystectomy and anti-reflux surgeries with satisfying results.[6]

Minimal access techniques are now being developed and studied to decrease the number of ports, rather than the size, as it reduces post-operative pain and achieves better cosmesis. This could be the reason there are studies comparing conventional laparoscopic appendectomy with double incision laparoscopic appendectomy and single incision laparoscopic surgery.

Therefore, we hypothesise that the use of all three 5 mm ports technique can be used to reduce postoperative pain and achieve satisfactory cosmesis, while retaining the same skillset as conventional laparoscopic appendectomy.

AIMS AND OBJECTIVES

AIM:

To evaluate the efficacy of all three 5 mm ports laparoscopic appendectomy over conventional laparoscopic appendectomy.

OBJECTIVES:

Comparison of the two techniques of laparoscopic appendectomy with regards to:

Primary

- Post-operative pain and cosmesis of all three 5 mm ports in laparoscopic appendectomy with conventional laparoscopic appendectomy.

Secondary

- Evaluate the conversion of 5 mm port to a conventional 10 mm port during surgical specimen retrieval.

REVIEW OF LITERATURE

Embryology and anatomy of Appendix

Caecum and appendix develop from the superior mesenteric arterial segment of the midgut loop. It is seen as a protuberance of caecum at the 8th week of intrauterine life. During the final stages of rotation of the gut, the appendix moves to the right lower quadrant.

The average length of the appendix in adults is around 9 cms and 8 mm in diameter, with wall thickness of 2 mm. Along the inferior aspect of caecum, base of the appendix lies at the convergence of taeniae, facilitating identification during appendectomy.

Lumens of caecum and appendix communicate through an orifice which is guarded by semilunar mucosal valves and is lined by crypts and argentaffin (Kulchitsky) cells lie at the base. Appendiceal lumen is <0.1 ml, and when the luminal secretions increase to 0.5 ml, the intra luminal pressure increases to 60 cm of water.[9] The appendix lies in different anatomical positions. In one quarter of cases, it may lie in the pelvic, subcaecal and paracaecal position as a result of non-rotation of appendix. It may occasionally be found close to the gall bladder when caecum fails to rotate to its final position.

Most common variations:

1. Retrocecal: behind the caecum.
2. Pelvic: in true pelvis.
3. Paracaecal: on either side of caecum.
4. Subcaecal: below the caecum.
5. Preileal: anterior to terminal ileum.
6. Post-ileal: posterior to terminal ileum. [1]

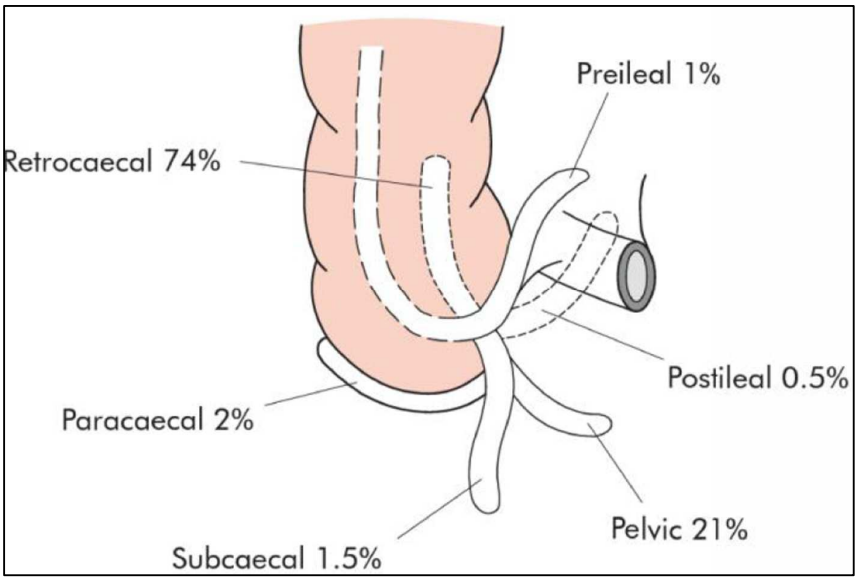


Figure 1: Positions of appendix [(1)]

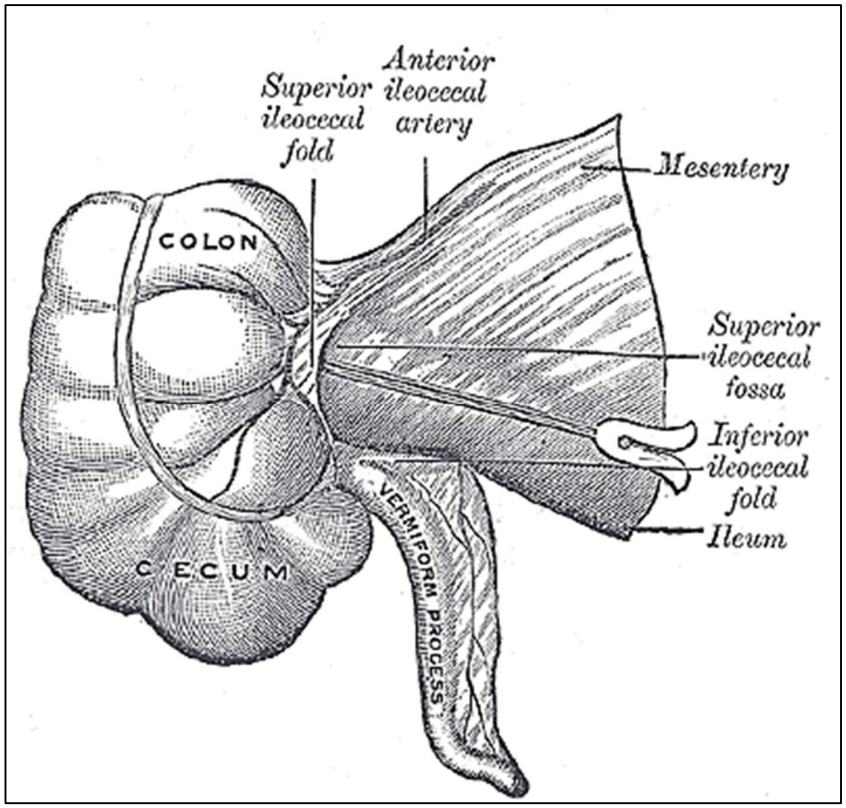


Figure 2: Ligament of Treves. [(10)]

The mesoappendix is a triangular fold of peritoneum that covers the whole organ, extending from the tip and attaches itself to the mesentery of the small bowel. It contains blood vessels, nerves and lymphatics. ***Ligament of Treves*** is an ileoceacal fold of peritoneum which adheres superiorly to ileum and inferiorly attaches to mesentery of appendix. It helps with a bloodless field during appendectomy.[10]

Blood supply and lymphatic drainage

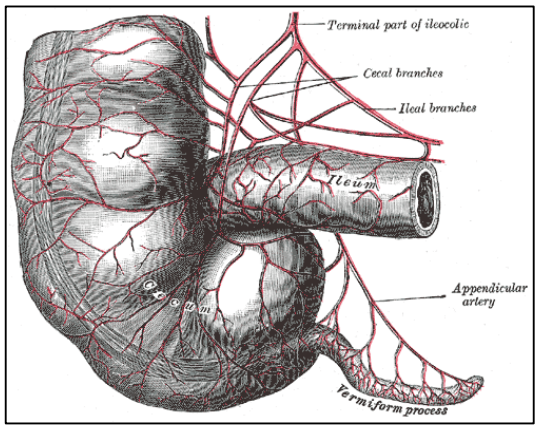
The appendicular artery, a branch of ileocolic artery, enters the mesoappendix close to the base, just behind the terminal ileum. Gangrenous appendicitis and perforated appendix are a result of appendicular artery thrombus. The appendicular vein drains into the ileocolic and posterior colic veins, which further drain in the superior mesenteric vein. The lymphatics of appendix drains into anterior ileocolic lymph nodes via multiple lymphatic channel that traverse mesoappendix.[1]

Nervous supply:

Sympathetic and the parasympathetic nerves by superior mesenteric plexus innervate appendix.

Histology:

Vermiform appendix contains the following layers - Serosa, Muscular, Submucous, Mucosa. Appendicular lumen is irregular, lined by multiple columnar cells. The serous layer completely invests the entire organ, except along the line of mesentery. Mucus secreting goblet cells are scattered throughout the longitudinal folds. Cells of Kulchitsky lie at the base of the crypts. Numerous lymphoid follicles lie in the submucosal layer, which are prominent in the young, hence one of the important etiological factors for acute appendicitis.[11]



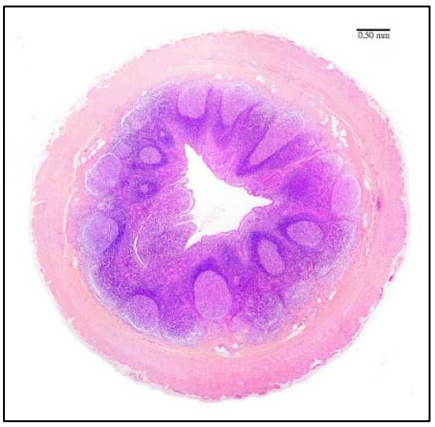


***Figure 3*: Appendicular artery [(10)]** ***Figure 4*: Normal histology of appendix.[(11)]**

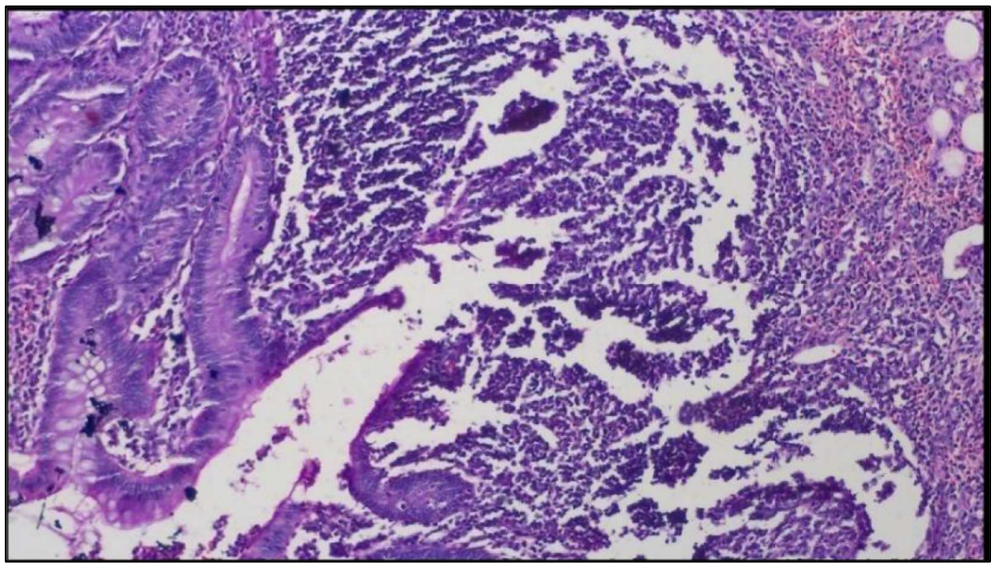


***Figure 5:* Histopathology of acute appendicitis.**

Appendicitis

Appendicitis usually occurs during the 2nd to 4th decade of life, with a female predominance. A major part of the population who suffer from chronic abdominal pain, have an incidence of chronic and recurrent appendicitis ranging between 7-10%. It is associated with ischemic changes, perforations and septicaemia. Incidence is also found to be higher in the western countries, major factors being genetic, environmental, and dietary factors. (12)

Etiopathogenesis:

Over half to three quarter of the population with an inflamed appendix have a secondary luminal obstruction, which includes the presence of a fecolith, a gall stone and worm infestations, thereby increase in luminal mucinous secretions and intra luminal pressures which compromises the venous drainage. The resulting ischemic injury becomes a focus for bacterial growth.

In the initial stages, neutrophils invade all the layers, leading to inflammation. The appendix appears dull, congested, and granular. With the worsening of inflammatory process there may be a production of firbropurulent exudate involving the serosa, eventually leading to an abscess. (1,12)

Clinical features

- Abdominal pain, localized in the right lower abdomen and the periumbilical region.
- Nausea and vomiting are also commonly seen.
- Fever, bowel disturbances and urinary tract irritations are frequently associated.
- Appendicitis is a clinical diagnosis, which is supported by radiological investigations. (12)

Examination

Inspection:

Pointing sign - the patient is asked to locate the course of the pain, starting with the point of occurrence, is due to the irritation of the parietal peritoneum.

Palpation:

- McBurney's tenderness: at McBurney's point.
- Dunphy's sign: An act of coughing, sneezing can cause increased abdominal pain.
- Blumberg's sign: In the right iliac fossa, rebound tenderness due to peritoneal irritation.
- Rovsing's sign: On deep palpation of left iliac fossa, pain is experienced in right iliac fossa; due to shift of ileal coils to the right iliac fossa in presence of local peritonitis.
- Psoas sign: Extension of the right hip causes pain, seen in retrocecal appendix due to irritation of an inflamed appendix lying over the psoas muscle.
- Cope's obturator test: Internally rotating the right hip causes pain in the hypogastrium secondary to the spasm of the obturator internus.
- Sherren's triangle of hyperesthesia: It is a triangle bound by the lines joining anterior superior iliac spine, umbilicus and symphysis pubis. By lifting the skin along with the subcutaneous tissue, a gentle stroke can elicit pain.[1,13]

Laboratory investigation:

- Total leucocyte count: > 10,000/cc/mm, with neutrophilia.
- C Reactive protein: Synthesized by liver in infections and inflammations, it is an acute phase reactant. The rise occurs between 6-12 hours of an acute attack and normalise within 12 hours. In appendicitis a normal level carries a negative predictive value of 97-100%.
- Urine analysis: To rule out other causes of pain in abdomen and check for associated urinary tract infection with appendicitis.

Imaging:

Plain X-ray abdomen:

Not a sensitive investigation for appendicitis but can be used to rule out other intestinal conditions.

Ultrasonography:

It is > 85% sensitive and > 90% specific. It is a non-invasive modality and requires no patient preparation. Therefore, it is widely being used.

Computer tomography:

Most commonly used imaging technique, with or without contrast in high resolution, the accuracy increases to 95% or more.

Diagnostic laparoscopy:

In most patients, diagnosis is established with history, clinical examination and investigation. But in a smaller population of patient in whom diagnosis remains elusive, diagnostic laparoscopy is the best preferred intervention. It allows the inspection of appendix and other abdominal organs.[13]

Management

Early diagnosis followed by prompt surgical intervention is known to be the most important principle in treating appendicitis.

Several RCTs that compared laparoscopic vs open appendectomies showed minimal to negligible amount of differences. Due to merits of minimal access surgery, laparoscopic appendectomies seem to progressively increase.[1,12,13]

Preoperative workup:

Surgical intervention should not be delayed for more than 6 hours from presentation.

- Keep patient nil per oral.
- Intravenous fluids are kept on maintenance.
- An antibiotic with anaerobic and aerobic cover is administered as a single dosage in uncomplicated appendicitis.
- Prepare for conversion to open.

Laparoscopic Appendectomy [13]

Anaesthesia: general.

Procedure:

1. Patient is in supine, Trendelenburg and left lateral position (10–15^{o} inclination toward the surgeon).
2. Parts from nipple to midthigh are painted and draped.
3. Pneumoperitoneum is created with either Veress needle or open Hanson's method.
4. A 10 mm umbilical port is inserted, following which a diagnostic laparoscopy is done to look for port entry injuries, gross pathologies in the abdomen and the pelvis.
5. Under vision, in the hypogastrium, the second 10 mm port is inserted, followed by a 5 mm port in the left iliac fossa.

6. The appendix is identified and inspected for signs of inflammation, fibrosis and turbidity.
7. With a non-traumatic grasper, the tip of the appendix is held to visualize the entire length and up to the base of the appendix.
8. Adhesiolysis is done, if required.
9. Mesoappendix is dissected and divided using clips, bipolar electric devices or ties.
10. Base of the appendix is identified at the convergence of taenia. Secure the base with a Roeder's knot, clips or linear stapling device, which is divided.
11. Specimen is retrieved from the umbilical port.
12. Peritoneal cavity is irrigated and suctioned.
13. Trocars are withdrawn under vision, followed by the laparoscope.
14. 2-0 absorbable suture is used to suture the rectus sheath at 10 mm port sites.
15. Skin is sutured with 2-0 nonabsorbable sutures.

Minimal access surgery [1,13]

Minimal access surgery, as coined by John Wickman, is a technique of performing surgeries through small incisions, often using mini instruments and coupled imaging systems, resulting in diminished surgical trauma; most of which is inflicted because the surgeon requires adequate exposure for vigilant dissection and organ removal. It seldom leads to morbidity i.e., surgical site infections, wound dehiscence, nerve entrapment, herniation and pain, which prolong time of recovery and contributes to other complications like lung atelectasis, pneumonia, paralytic ileus and deep vein thrombosis, due to reduced mobility. The aim is to accomplish surgical therapeutic goals and quick recovery with minimal somatic and psychological trauma. Some examples of minimal access approaches are laparoscopy, thoracoscopy and endoscopy.

Laparoscopy is a branch of minimal access surgery which involves surgery of abdominal and pelvic organs, through small incisions that are less than 1.5 cm. It requires the use of specialised instruments, light – camera system with display monitors, energy sources and distension of the peritoneal cavity with gas.

Due to the small size of incisions, laparoscopy has many advantages over open approach, i.e., reduced hospital stay, faster return to routine activity, lesser pain, good cosmesis and better outcomes, which have promoted the use of laparoscopy as the gold standard for many surgeries, such as cholecystectomy, appendectomy, prostatectomy, surgeries of small and large intestines, anti-reflux surgery, etc. It also has disadvantages, such as longer operative time, limited field of vision and degrees of freedom, a long learning curve, loss of organ tactile sensation and feedback, and increased cost. However, when feasible, it has proven to be superior.

The first appendectomy was performed on a 11 year old boy, by Claudius Amyand in 1753. The procedure has evolved and refined over time, with notable contributions from Reginald Heber Fitz, who recognized the pathology of the disease and coining the term appendectomy in 1886, and Charles McBurney for proposing the muscle splitting incision in 1893. Kurt Semm performed the world's first laparoscopic appendectomy in 1981, which has been widely endorsed ever since as the preferred approach for treatment of acute appendicitis, simple and complicated.

Various attempts are being made to decrease the number of ports, this has resulted in the introduction of double incision laparoscopic appendectomy, single incision laparoscopic appendectomy and NOTES. While these skills are innovative, there are accompanying challenges, such as – increase in the size of port to accommodate instruments, requirement of specialized instruments and training, longer operative time,

and increased cost, which can make the procedure less feasible, with increased postoperative pain and poor cosmesis.

Pain

As defined by the International Association for the Study of Pain, it is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage." It therefore perceives the correlation between objective, physiologic and sensory aspects of pain with other components, such as subjective, emotional and psychological. [14]

Postoperative pain occurs due to damage and inflammation of tissue, i.e., nociceptive. It is clinically divided into acute and chronic and is further enumerated based on the source, visceral and somatic. Somatic pain is from mucous membranes, skin and subcutaneous tissue, and is described as a well localized, sharp, pricking, or throbbing sensation. Whereas visceral pain is from internal organs and its coverings. It is a dull and diffuse pain, which is associated with abnormal autonomic system activity – hemodynamic changes, sweating, nausea and vomiting. [15]

Neurophysiology of pain

Nociceptors

Pain can also be characterized as noxious or protopathic, and non-noxious or epicritic. Where, epicritic components are transmitted by large, myelinated nerve fibres and senses temperature, fine touch, proprioception and pressure. And noxious components are divided into two as - a poorly localized, slow onset sensation, transmitted by C fibres; and a fast, sharp and well-localized sensation, transmitted by the Aδ nerve fibres. [16]

This pain has many types.

1. Nociceptors – somatic (skin, deep tissues) and visceral nociceptors (internal organs).
2. Mechano-nociceptors – sharp pain.
3. Mechano-heat receptors - excessive pressure, extreme temperature and pain producing substances.
4. Silent nociceptors - responds to inflammation.[17–19]

Pain pathway (*figure 6)*

Pain is transmitted to the pain centre in the cerebral cortex, from the periphery, along the three neurons pathway. [18]

First order neurons

Cells of these neurons are located in the dorsal root ganglia. Through the dorsal sensory root, the proximal end of these axons connect to the spinal cord. [18]

Second order neurons

The first order neurons then synapse with the second order neurons in the ipsilateral dorsal horn, through interneurons, which ascend or descend three segments in the Lissauer's tract. Most of the axons cross the midline to the contralateral side, forming the lateral spinothalamic tract and connects to thalamus, periaqueductal grey, nucleus raphe and reticular formation. [18]

Third order neurons

Located in the thalamus, send their fibres to somatosensory areas I and II in the cortex. [18]

Pain in laparoscopy

There are several reasons for pain in laparoscopy such as injury to the abdominal wall by the endoscope, handling of visceral organs with instruments and abdominal distention.[22]

A. Factors associated with gaseous pneumoperitoneum

Rapid distension with peritoneum may be attributed with traction of nerves, injury to blood vessels and release of inflammatory mediators.

1. Neuropraxia of the phrenic nerve, that transpires due to diaphragmatic distention during insufflation of gas, probably related to the C4 dermatome. [23]
2. The type of gas insufflated and intraabdominal pH**:** The use of CO_2 leads to acidic milieu and phrenic nerve neuropraxia. The intraperitoneal pH is found to be 6.0 immediately postoperatively and gradually increased to 6.4 to 6.7 on the first postoperative day, 6.8 to 6.9 on the second postoperative day and thereafter it normalizes to above 7.0.[22]
3. Residual intraabdominal gas**:** CO_2 dissolution, peritoneal irritation and intraabdominal acidosis occur if the gas is not adequately evacuated. Additional factors are loss of surface tension of peritoneum and support of abdominal organs. [24]
4. Temperature of gas**:** pain was significantly lower in whom warmed gas was used when compared to standard cold insufflation gas (20^0 C). [23]
5. Humidity of gas**:** significantly lower postoperative pain was observed in whom humidified gas was insufflated. It is proposed that dry gas insufflation causes ultrastructural damage to membranous linings.[25]

B. Operational factors

The number and size of incisions utilised differ across surgeries.[26]

Effect of postoperative pain

Acute pain has adverse effects on organ function and postoperative outcome. As, inefficient management of postoperative pain intervenes with routine activities, effective treatment plays a crucial role in patient care and improving quality of life.[28]

a. Cardiovascular effects:

There are several causes for perioperative cardiac events, especially from postoperative day one to three. This occurs due to mismatch in myocardial oxygen supply and demand, which can precipitate myocardial ischemia.[29,30]

b. Pulmonary effects:

The classical pulmonary response to abdominal surgery is similar to acute restrictive pulmonary disease, leading to clinically significant hypoxia and hypercarbia. An increase in total body oxygen consumption and carbon dioxide production is also seen.[4,31]l

c. Gastrointestinal effects:

Sympathetic overactivity leads to increased gastric acid secretion causing stress ulcers and decreases intestinal motility causing ileus.[32]

d. Endocrinal effects:

The dominant neuroendocrine responses to pain involve hypothalamo – pituitary - adrenocortical interactions, resulting in increased catecholamine and catabolic hormone release. This effect causes sodium and water retention, and increased

levels of blood glucose, free fatty acids and lactate. [33]

e. Haematological and immunological effects:

Surgery is a hypercoagulable state which can precipitate myocardial ischemia and deep vein thrombosis.[34] It also suppresses reticulo-endothelial function and potentiates immunosuppression.[16]

f. Psychogenic effects:

Anxiety, fear, and the loss of control due to tissue injury have effects on the hypothalamo-pituitary axis. Behavioural responses are disturbed sleep, poor morale and long-term emotional disturbances.[5]

Measurement of pain:

Objective assessment - performed by healthcare workers; numbers are assigned based on the patient's condition. These are:

Behavioural

- Crying, sighing, shouting.

Physiological

- Cardiovascular response - increased heart rate and blood pressure.
- Endocrine response - increased catecholamine and cortisol.
- Respiratory response - decreased tidal volume and increased respiratory rate.

Neuro-biochemical

- Decreased beta endorphin in acute pain.
- Hypo emission in thermography - chronic pain.

Neurological

- Nerve conduction study.
- Cortical evoked potential.

Subjective assessment

Single dimension scales

- Verbal rating (VRS).
- Numerical scale.
- Visual analogue scale (VAS).[35]

Multidimensional scales

- McGill pain Questionnaire, MPQ.
- Dartmouth pain Questionnaire, DPQ. [4]

As pain is a subjective experience, assessment between individuals is seldom challenging. Factors influencing these perceptions are age, sex, past experiences, ethnic background, anxiety and depression. Therefore, the quantification of pain has been extensively studied, including the differences in how individuals quantify pain. As a result, VAS and VRS are widely used, due to its ease of use. In routine clinical practice, assessment of pain depends on interaction between the healthcare worker and patient. Rating scales are appropriate for clinical data used in research projects.[35]

Visual analog scale (VAS)

A 10 centimetres long line is used, with extremities of intensity of pain on both ends. The scale is marked, ranging from “no pain” to “excruciating or unbearable pain;” words can be used to describe the intensity and orient the patient, such as (mild, moderate, severe). The patient is then asked to mark on the line, describing the intensity of pain they

are experiencing currently.[33] It can be used serially at regular intervals to provide patient centric management of pain.

Postoperative Pain Management

Prophylactic measures

Adept perioperative surgical and psychological care can reduce the duration, severity and incidence of pain. Psychological techniques play a little role in relief of acute pain, due to damage of tissues. However, it plays a significant role in subsequent recovery, psychological distress and chronic pain after surgery.[36]

Optimal and individual patient centred surgical care aids in reducing the severity of pain, these include the Early Recovery After Surgery (ERAS) programme i.e., postoperative psychological support, early ambulation and feeding, care of wounds and good nursing care. The inflammation and stress response can be modulated during surgery, i.e., gentle and skilful tissue handling, therefore causing the least trauma possible, have long-term effects in wound healing and cosmesis.[1,37]

Active measures [38]

Postoperative pain relief can be achieved partially or completely by the following methods:

1. Systemic analgesics and adjuvant

a. Opioids:

These are drugs that act on central and peripheral opioid receptors.

(1) Systemic opioids – These are effective analgesics and can be administered by various routes. The side effects are sedation, nausea, vomiting,

hypotension, bradycardia, pruritis, impaired return of bowel function and postoperative ileus, respiratory depression, and has a substantial risk of addiction and tolerance. It requires frequent reassessment of the patient. E.g. – morphine, meperidine, fentanyl. These usually have active metabolites, which leave undesirable side effects, such as seizures, delirium, psychosis. [39]

- Patient controlled analgesia – The patient can be relieved of pain without assessment by the healthcare worker, with fixed doses of drug being delivered on demand or as continuous intravenous infusion. These systems have failsafe mechanisms to prevent overdose. It is not suited for patients with high opioid tolerance, substance abuse and who develop reactions with opioids. E.g. – morphine and meperidine. [39–41]

- Oral opioids – used to rapidly wean patients off parenteral therapy. E.g. – oxycodone, tramadol.[17]

- Transdermal opioid patches – the drug is incorporated into an adhesive matrix, and is absorbed through the skin, therefore avoiding hepatic first-pass metabolism. It has a slow onset of action, but is steadily released, providing continuous analgesia. E.g. – buprenorphine patch. [17]

b. NSAIDs – these are agents that reduce mediators of pain and inflammation. Hence, these are less potent but have opioid sparing effects. When combined with opioids, synergistic effect is seen. Adverse effects are gastrointestinal haemorrhage, peptic ulcer disease, renal and platelet dysfunction.

- COX 2 inhibitors – reduces production of prostaglandins that cause inflammation and pain (PGI_2, IL-1). Adverse effects are thrombotic cardiovascular events, stroke and myocardial infarction. E.g. – celecoxib. [42]

c. Intravenous paracetamol (acetaminophen) – central antinociceptive effect due to central COX-3 inhibition, modulation of inhibitory descending serotonergic pathway and prevents prostaglandin production at transcriptional level.[17]

d. NMDA antagonists (used as adjuvants)

- Ketamine – IV anaesthetic drug with analgesic properties and is used as an adjuvant during local anaesthesia at low doses. [43]
- Dextromethorphan – Inhibits nociceptive responses in the dorsal horn. [44]

2. Local infiltration with field block – Local anaesthetics used in regional analgesia, usually involves anaesthetizing the lower half of the body or a particular limb.

- Central neuraxial blockade - epidural analgesia after surgery (continuous infusion) of cervical, thoracic, lumbar or sacral segments. In epidural analgesia, morphine is commonly used at dosage of 2 to 5 mg, provides analgesia in 15 - 30 minutes lasting for up to 24 hours. Adrenaline can also be used to prolong the analgesic effect of epidural opioids.[45]

- Peripheral techniques – brachial plexus block, peripheral nerve block, Bier block. [17]

3. <u>Nonpharmacologic techniques</u>:

The above pharmacological agents produce potential side effects, hence

alternative therapies have been introduced as adjuvants, which have varying success. Examples are Transcutaneous Electrical Nerve Stimulation (TENS), cryo-analgesia, ultrasound, laser stimulation and hypnotherapy.[46]

WHO analgesic ladder (1990)-

This is a patient centric guideline for management of postoperative pain, proposed by WHO in 1990. Pain needs to be assessed periodically and moved up or down the ladder as required.

a. Step 1 - mild pain – non opioids (acetaminophen, NSAIDs), adjuvants may be needed.

b. Step 2 - moderate pain - oxycodone, hydroxycodone, codeine (weak opioids) in addition to step 1.

c. Step 3 - pain is severe – fentanyl, morphine, hydromorphone (strong opioids) in addition to step 1. [47]

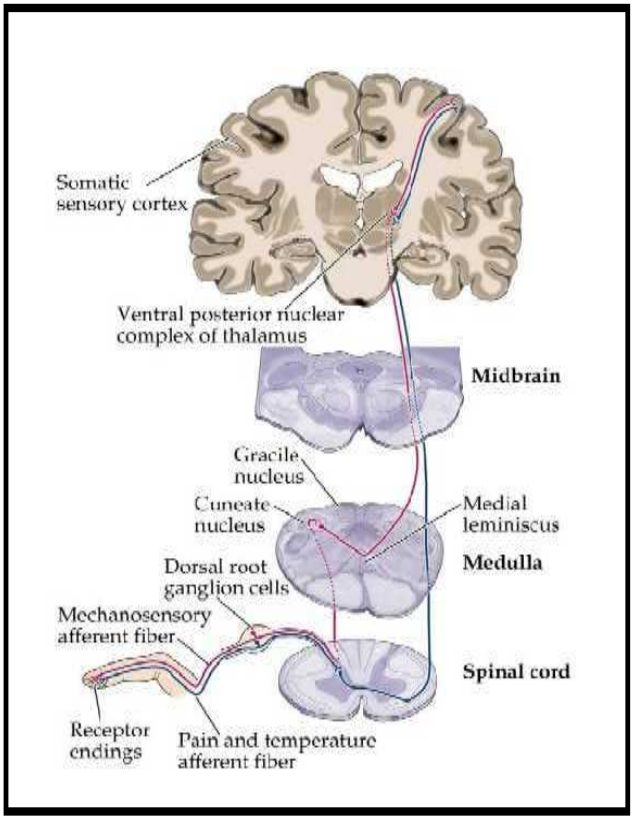


Figure 6: **Pain pathway.**

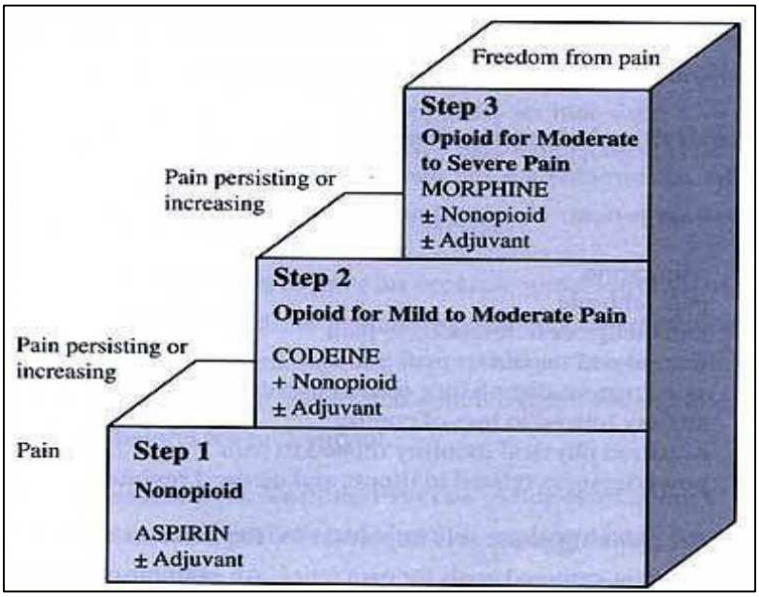


Figure 7**: WHO analgesic ladder.**

Cosmesis

Surgical wounds are usually clean cut incisions, without skin loss and heal by primary intention. When a surgery concludes, the subcutaneous layers and skin need to be closed, to restore normal anatomy, prevent operated site seroma and hematoma formation, and surgical site infection. This is achieved with various materials such as sutures, staples, tissue adhesive glue, etc.

Stages of wound healing

1. Haemostatic phase – immediately after trauma, macrophages cleanse the wound at a cellular level.[1]
2. Inflammatory phase – until 2-3 days, presence of redness, swelling, warmth and pain. Characterized by initial vasoconstriction and thrombus formation with macrophage and fibroblast activity.[1]
3. Proliferative phase – until three weeks, consists of collagen and ground substance production with angiogenesis, re-epithelialization, granulation tissue.
4. Remodelling phase – after three months, maturation of collagen and wound contracture occurs.

A deviation from the above process leads to abnormal wound healing, resulting in keloid and hypertrophic scars.

Factors affecting wound healing

a) Local factors
    - Site.
    - Mechanism of injury – avulsion, incision or crush.
    - Tissues involved.
    - Tissue lost during injury.
    - Contamination with bacteria or foreign body.

- Others -
    - Venous or arterial insufficiency.
    - Pressure over the wound
    - History of radiation.
- Sutures used
    - Type – monofilament, nonabsorbable.
    - Technique of suturing – vertical mattress, simple dermal and subcuticular sutures.

b) Systemic factors

- Non communicable diseases, such as diabetes mellitus.
- Immunomodulator drugs like steroids.
- Malnutrition and micronutrient deficiencies.
- Immune deficiencies - HIV-AIDS and chemotherapy.
- Habits - smoking. [(1)]

Of late, cosmesis has become important, as it has significant effects on patient and caregiver satisfaction, body image, quality of life, depression and anxiety. When present over joint creases, scar contracture leads to deformity and restriction of movement. (48) Therefore, it is critical to plan surgical incisions along Langer's lines or skin creases, adopt appropriate suturing technique and minimal handling of tissues.

Methods of assessing surgical scar -

- Manchester Scar Scale (MSS)
- Vancouver Scar Scale (VSS)
- Patient and Observer Scar Assessment Scale (POSAS)
- Seattle Scale
- Hamilton Scale

- Stony Brook Evaluation Scale (SBES)
- Matching Assessment of Scars and Photographs Scale (MAPS)

A retrospective study conducted by Donmez *et al* (2015), with 70 subjects, in whom conventional laparoscopic appendectomy was done on 38 subjects and 2-port laparoscopic appendectomy on 32, found that the 2-ports technique for laparoscopic appendectomy is comparable with the conventional technique, with respect to postoperative pain and cosmetic outcome, but with higher mean operative time and technique involved with double incision technique.[49] Though the results were desirable, a standardized scoring system (POSAS scale) was not used to evaluate postoperative cosmesis.

Another retrospective study conducted by Tiwari MM *et al* (2018) with 60 subjects, in whom conventional laparoscopic appendectomy was done on 29 subjects and double incision laparoscopic appendectomy on 31, found comparable results with double incision approach for laparoscopic appendectomy when compared with the conventional approach, with better cosmetic outcome. (3) Like the above study, a standardized scoring system was not used.

A study conducted by Golebiewski *et al* (2019) with 50 paediatric subjects, in whom single - port laparoscopic appendectomy was done on 25 subjects and three - port laparoscopic appendectomy was done on 25, it was found that single - port laparoscopic appendectomy has a longer operative time, higher surgical trauma and therefore more painful.[50]

In 2011, a study was conducted by Schill MR *et al* on 5 attending surgeons, 4 surgical residents and 18 medical students on competence in using multiport laparoscopy and single site access laparoscopy training modules. It was found that single site access are associated with a steeper learning curve, longer task performance. [51]

A study conducted by El-Dhuwaib *et al* (2002) with 17 subjects, in whom the all three 5 mm port technique was used, has found the technique to be safe and feasible in laparoscopic appendectomy.[6] A randomized comparison was however needed to evaluate post-operative pain, analgesic requirement, operative time and cosmesis.

The above described minimal access techniques were developed to lessen the number of ports, rather than the size, as it is speculated that it reduces postoperative pain and achieves better cosmesis. The above techniques have been studied and the results are either equivocal or inconclusive; therefore, requires further evidence. However, these techniques pose many challenges, such as longer operative time, increase in the size of port to accommodate instruments, requirement of specialized instruments and training, which are expensive and difficult in a low resource setting. It is also a challenging skillset, with other complications and limitations, such as viscus perforation, the need for proper channels for instruments, special orientation, triangulation for dissection and retraction and closure techniques to prevent intraperitoneal infection.

Therefore, we hypothesise that the all three 5 mm ports technique for laparoscopic appendectomy can be used, as there are ready availability of instruments with easy triangulation, no new skills and learning curve is required, lower chances of injury to abdominal organs, postoperative pain and satisfactory cosmesis can be achieved, as the size of the incisions are smaller when compared conventional laparoscopic appendectomy.

METHODOLOGY

Study Design: Randomized controlled trial

Study Period: January 2021 - December 2021

Study Population: Patients who were admitted to KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi and underwent laparoscopic appendectomy.

Inclusion Criteria:

- All patients between 18-50 years of age.
- Patients diagnosed with uncomplicated acute appendicitis clinically and radiologically.

Exclusion Criteria:

- Patients with generalized peritonitis.
- Patients diagnosed with complicated appendicitis.
- Patients with comorbidities such as diabetes mellitus, hypertension, thyroid disorders.
- Patients with bleeding disorders.
- Immunocompromised state.
- Pregnant women.
- Patients who have undergone previous major abdominal surgeries, such as exploratory laparotomy.

Sample Size:

Group A –

Mean $d_1 = 1.25$, standard deviation $S_1 = 0.44$.

Group B -

Mean $d_2 = 1.63$, standard deviation $S_2 = 0.49$.

Z alpha = 1.96 @ 5% α error.

Z beta = 0.842 @ 20% β error.

Where,

$d = (d_1 - d_2)$

S = average of S_1 and S_2.

$$N = \frac{2S^2\{Z\ alpha + Z\ beta\}^2}{d^2}$$

N is 23.4 participants in each group, rounding off to 24 in each group.

Substituting in the formula, N= 24, with enrolment ratio at 1:1, the estimated sample size was a minimum of 48 patients. Accordingly, 24 patients were enrolled in group A & group B, each.

Randomization Technique: Sequentially Numbered Opaque Sealed Envelopes (SNOSE)

Method:

- After admission, a detailed history and clinical examination was done for all the patients.
- The following investigations were done for all the admitted patients for preoperative work up:
    - Haemoglobin
    - Total and Differential Leucocyte count
    - Platelet count
    - Blood grouping

- PT/INR
- Urine Routine
- Blood Urea and Creatinine
- HIV, HBsAg and HCV
- ECG
- Chest X ray
- USG-Abdomen and Pelvis

- Informed consent was taken.
- The patients were then divided into two groups pre-operatively for the laparoscopic appendectomy technique, using SNOSE, as:

Group A: All three 5 mm ports laparoscopic appendectomy.

Group B: Conventional laparoscopic appendectomy (a 5 mm port and two 10 mm ports).

PROCEDURE:[7]

- All patients underwent laparoscopic appendectomy under general anaesthesia.
- The technique allotted was employed during the surgery.

Group A-

- The patient was placed in supine, Trendelenburg and left lateral position (10–15^{o} inclination toward the surgeon).
- For the all three 5 mm ports technique, pneumoperitoneum was established through the “open” technique (Hasson blunt port insertion).
- An umbilical 5 mm port was inserted for the laparoscope.
- Two 5 mm port ports were then placed in the suprapubic and left iliac fossa areas.

- The appendix was identified at the base of the caecum, with the convergence of caecal taeniae.
- With a laparoscopic tissue holding forceps, the appendix was held up and the mesoappendix was displayed.
- In the mesoappendix, a window was created using a dissecting forceps, and coagulation or ligation of appendicular vessels was done.
- The mesoappendix was separated from the appendix.
- The appendicular base was ligated with a Roeder's knot, using absorbable suture material, which was then divided.
- The appendix was extracted through the umbilical port, using a grasping forceps, with the port.
- During the retrieval of surgical specimen, if the appendix could not be removed, the infraumbilical port was converted to a 10 mm port and retrieved.
- Irrespective of the technique used, the rectus sheath at the umbilical port site was closed with polyglactin 2-0, followed by simple interrupted nylon 2-0 sutures.
- The remaining port sites were closed with simple nylon 2-0 suture.

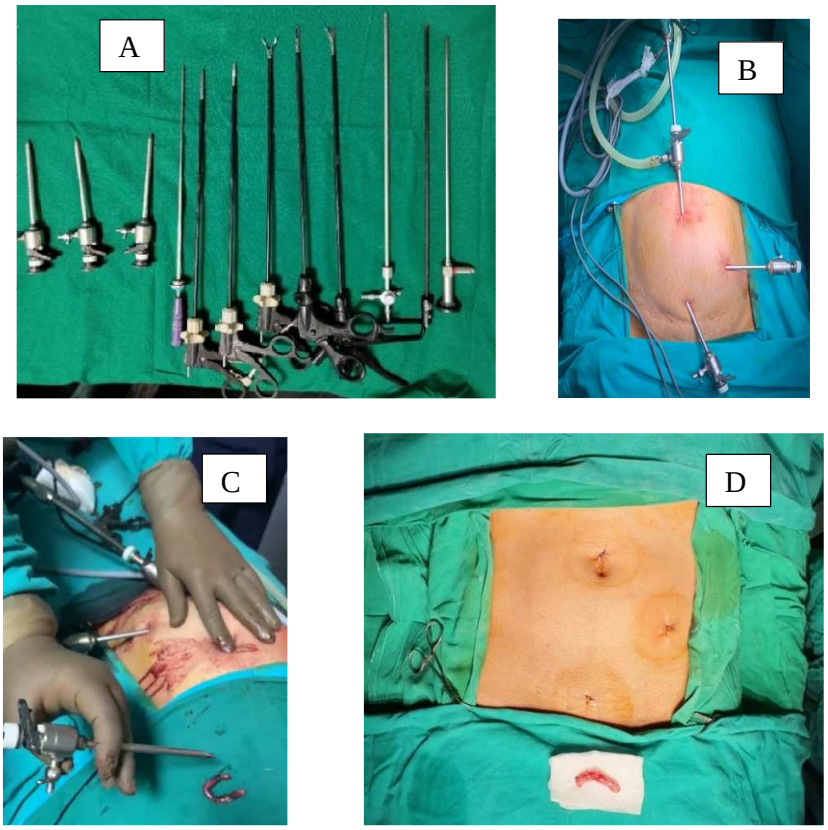


Figure 8: **Steps of all three 5 mm ports laparoscopic appendectomy. A- instruments used in all three ports laparoscopic appendectomy. B- All three 5 mm ports in-situ. C- the surgical specimen being retrieved through the 5 mm umbilical port. D – surgical wounds with specimen**

Figure 9: **Instruments used in conventional laparoscopic appendectomy.**

Group B-

- The patient was placed in supine, Trendelenburg and left lateral position (10–15^0 inclination toward the surgeon).
- For the conventional technique, pneumoperitoneum was established through the "open" technique (Hasson blunt port insertion).
- An umbilical 10 mm port was inserted for the laparoscope.
- Two working ports were placed, a 5 mm port in left iliac fossa and a 10 mm port in the suprapubic areas.
- The appendix was identified at the base of the caecum, with the convergence of caecal taeniae.
- With a laparoscopic tissue holding forceps, the appendix was held up and the mesoappendix was displayed.
- In the mesoappendix, a window was created using a dissecting forceps, and coagulation or ligation of appendicular vessels was done.
- The mesoappendix was separated from the appendix.
- The base of the appendix was ligated with titanium clips or haemolock, which was then divided.
- The appendix was then extracted through the umbilical port.
- In the 10 mm port sites, the rectus sheath is closed with polyglactin 2-0, followed by mattress nylon 2-0 suture, and the 5 mm port site using simple nylon 2-0 suture.

Assessment:

In patients of both groups, post-operative pain was assessed using visual analogue scale (VAS) (*figure 10*) serially, at 1, 12 and 24 hours postoperatively (where, 0 = no pain, to 10 = unbearable pain). The rescue analgesic used was injection paracetamol 1 gram in 100 ml normal saline intravenous infusion.

Cosmetic outcome was assessed serially at 3 days, 1 week and 4 weeks postoperatively, using the Patient and Observer Scar Assessment Scale (v. 2.0) (PSOAS Scale).(8)

Statistical Analysis:

All the variables were compared between the two study groups. For quantitative variables, standard deviation and average were used; for categorical variables, numbers and percentage were used. The quantitative outcome variables were compared using Mann-Whitney U test and Wilcoxan matched pairs test, depending on the distribution of data; qualitative variables were compared using Chi square test, using Microsoft Excel and SPSS (v. 20).

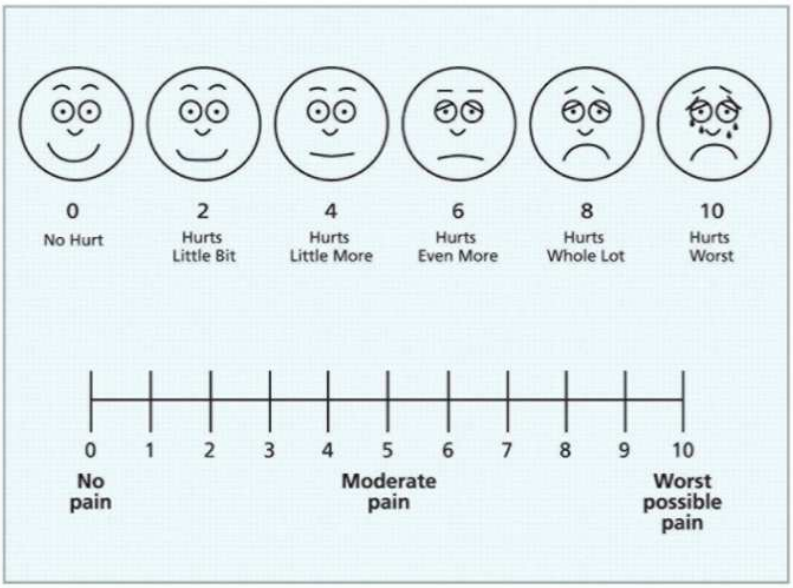


***Figure 10* – VAS chart to assess pain.**

Observer Scar Assessment Scale (OSAS)

	Normal skin 1 2 3 4 5 6 7 8 9 10 Worst scar imaginable
Vascularization	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
Pigmentation	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
Thickness	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
Relief	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
Pliability	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
Observer scar rating	– – – – – – – – – +

OSAS summary score: _____ (minimum, 5; maximum, 50)

Patient Scar Assessment Scale (PSAS)

	No, no complaints 1 2 3 4 5 6 7 8 9 10 Yes, worst imaginable
Is the scar painful?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
Is the scar itching?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○

	No, as normal skin 1 2 3 4 5 6 7 8 9 10 Yes, very different
Is the color of the scar different?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
Is the scar more stiff?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
Is the thickness of the scar different?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
Is the scar irregular?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
Overall patient scar satisfaction	– – – – – – – – – +

PSAS total score: _____ (minimum, 6; maximum, 60)

***Figure 11*: Patient and Observer Scar Assessment Scale (POSAS) chart for cosmesis.**

RESULTS

In the current study, 60 patients were enrolled. It was carried out in the General Surgery Department of KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi, during the time period of January 2021 to December 2021.

The allotment of the patients was done into two groups at random.

Group A: All three 5 mm laparoscopic appendectomy (all three 5 mm ports).

Group B: Conventional laparoscopic appendectomy (one 5 mm port and two 10 mm ports).

The parameters studied among the patients were demographic profile with respect to age and gender, and ultrasonography of abdomen with diameter of appendix.

The VAS scale was utilized to score pain from the time period of 1, 12 hours and 24 hours after the surgery.

The POSAS scale cosmesis scale was utilized to evaluate the cosmetic outcome on day 3, week 1 and 4 weeks after the surgery.

The study group was used for the primary explanatory variable. Post-operative pain and cosmesis were deemed as primary outcome variables and conversion of the 5 mm umbilical port to conventional as the secondary outcome variable.

For the quantitative variables, descriptive analysis was calculated as mean and standard deviation, and for categorical variables, proportion and frequency were used. Interquartile range (IQR) and median were used to summarize non normally distributed quantitative variables. Pictorial representation of the data was done using bar and pie diagrams and scatter plots.

By visually inspecting the normality Q-Q plots and histograms, normal distribution of quantitative variables was checked for, within each category of explanatory variable. To assess normal distribution, Shapiro- Wilk test was performed, and a P value of >0.05 was considered. Between the study groups, for normally distributed parameters, the comparison of mean values was done using independent sample t-test; for non-normal parameters, the IQRs and medians were compared using Mann Whitney U test. The comparison of categorical outcomes were done using Chi square test if the overall sample size was less than 20 or Fisher's Exact test was used if < 5.

Using Microsoft Excel and IBM SPSS V 22.0 (2013), the data was analysed. P value of <0.05 was considered as significant.

1. Age and sex distribution

Patients of ages between 18 and 60 years were included. The mean age in Group A was 34.1 years and in Group B was 33.7 years. Group A consisted of 14 males and 16 females (46.67% and 53.33% respectively), and 18 males and 12 females (60% and 40% respectively) in group B (figure 12). The results were not statistically significant.

Table 1: The comparison of age and sex between study groups.

Demographic Parameters	Study Group (Mean ± SD)		P value
	Group A (N=30)	Control (N=30)	
Age	34.1 ± 10.79	33.7 ± 12.37	0.894
Gender			
Male	14 (46.67%)	18 (60%)	0.301
Female	16 (53.33%)	12 (40%)	

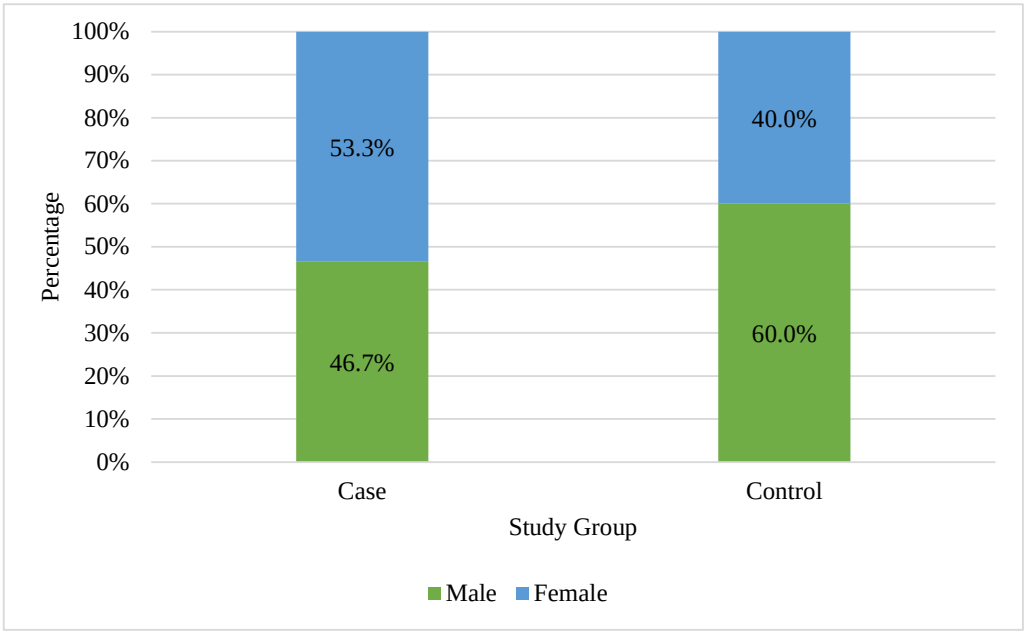


Figure 12: **Staked bar chart - comparison of study groups by sex. (N=60)**

2. <u>Comparison of ultrasonography and its findings.</u>

Table 2 represents comparison of ultrasound imaging done and its findings on presentation to the hospital with clinical features of acute appendicitis and diagnosed with it, between both groups. The mean appendicular diameter in the group A group was 9.17 mm and 8.87 mm in group B. No statistically significant result was found.

Table 2: Comparison of ultrasound imaging and its findings between study groups.

Investigations	Study Group		P value
	Group A (N=30)	Control (N=30)	
USG- f/s/o appendicitis (Yes)	30 (100%)	30 (100%)	-
Size of appendix (mm)	9.17 ± 1.42	8.87 ± 1.61	0.447

3. <u>Operative findings.</u>

Table 3: Rate of the 5 mm umbilical port being converted to 10 mm in group A (N=30)

Conversion to Conventional	Frequency	Percentages
Yes	16	53.33%
No	14	46.67%

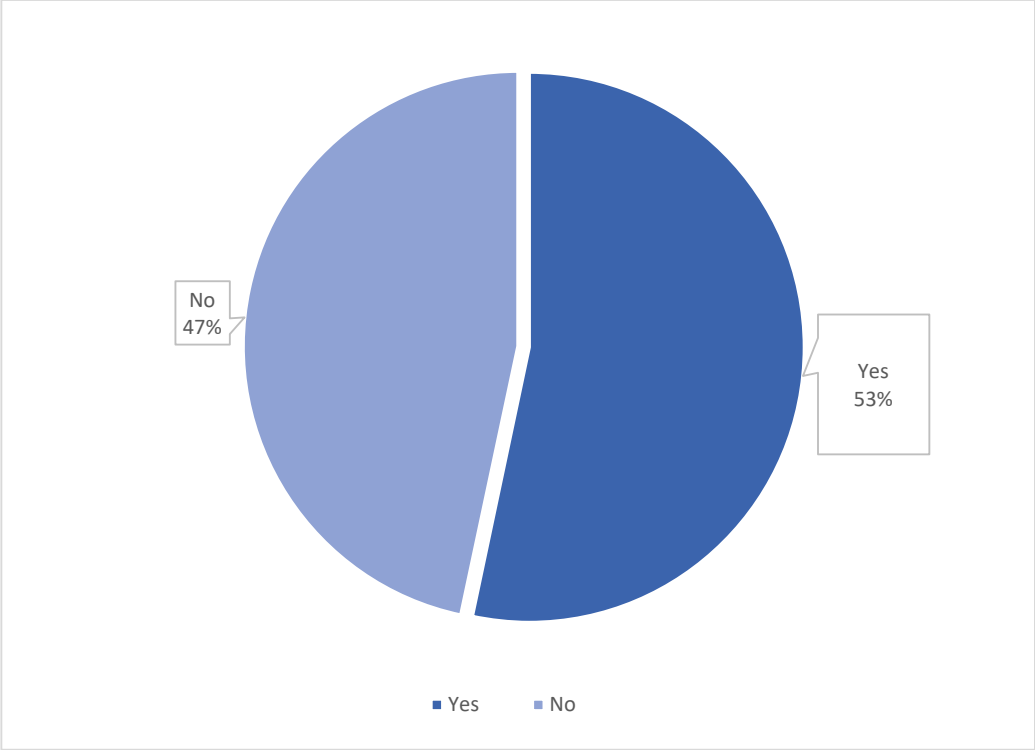


Figure 13: **Pie chart representing the rate of the 5 mm umbilical port being converted to 10 mm in group A**

In group A, the 5 mm umbilical port was converted to 10 mm in 16 patients during extraction of specimen (53.33 %), where the diameter of the appendix is more than 8 mm (table 3 and figure 13).

Table 4: Comparison of mean of duration of surgery (in minutes) between study groups (N=60)

Parameter	Study Group (Mean± SD)		P value
	Group A (N=30)	Group B (N=30)	
Duration of surgery (mins)	79.87 ± 7.83	70.23 ± 7.02	<0.001

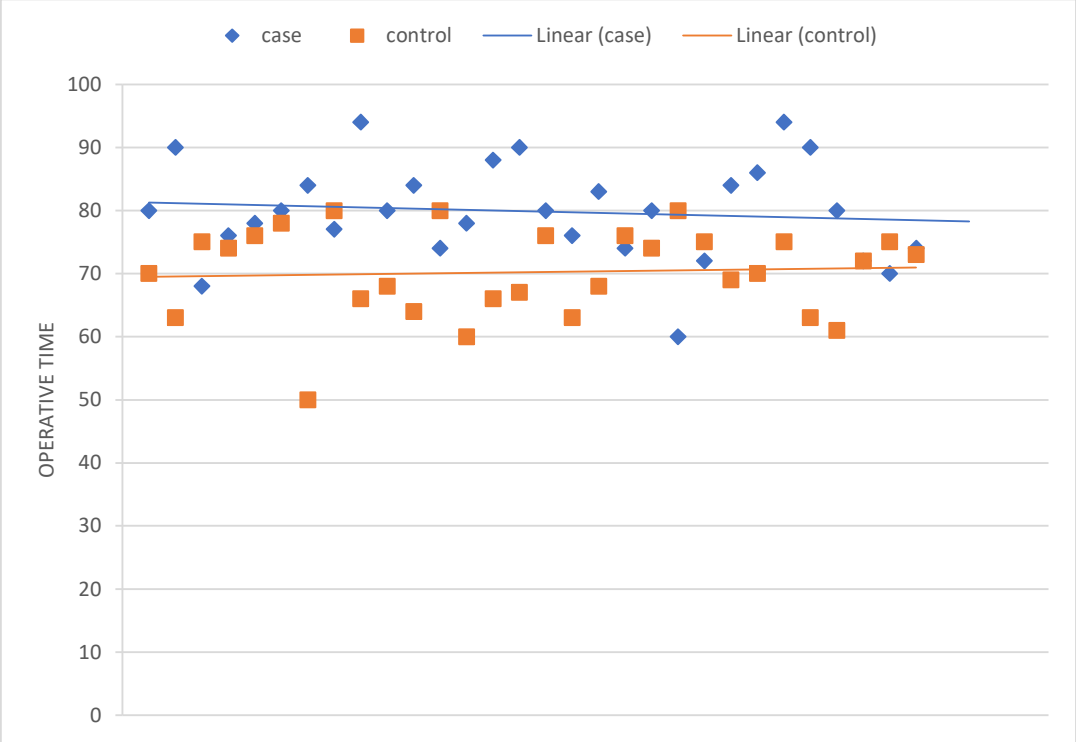


Figure 14: **Scatter plot diagram comparing the operative times in the study group.**

The mean duration of surgery was found to be significantly higher in group A (79 minutes) than group B (70 minutes), with a statistically significant result (P <0.001) (table 4 and figure 14). The increase in time can be ascribed to the conversion of the 5 mm umbilical port to 10 mm, extraction of surgical specimen, changing of trocars and closure of the rectus sheath in the umbilical port site.

4. <u>Comparison of Post-Operative Pain by VAS scores in the study group:</u>

Table 5: Comparison of post-operative pain by VAS scores at 1 hour, 12 hours and 24 hours postoperatively in the study group by median and Mann Whitney U test.

VAS (Pain score)	Median (IQR)		Mann Whitney U test (P value)
	Group A (N=30)	Group B (N=30)	
1 Hours	6 (6,7)	7 (7,7)	<0.001
12 Hours	4 (3,4)	4 (4,5)	<0.001
24 Hours	3 (2,3)	3 (2,3)	0.0013

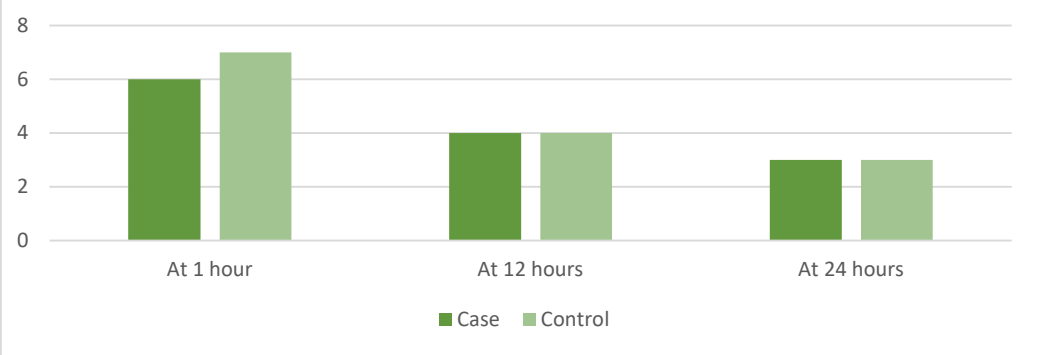


Figure 15: **Comparison of median postoperative pain VAS scores in between study groups at serial intervals (N=60).**

From the above results, a significant difference was observed between the study groups, in terms of post operative pain scores; measured at 1 hour (median - 6), 12 hours (median - 4) and 24 hours (median - 3) in group A, when compared to group B, it measured at 1 hour (median - 7), 12 hours (median - 4) and 24 hours (median - 3) (table 5 and figure 15). Therefore, this suggests that in both groups postoperative pain was similar, but with significantly lesser scores in group A at 1 and 12 hours ($p < 0.001$).

Table 6: Comparison of post operative pain (VAS) Scores in group A group, between patients who had undergone conversion to conventional and who had not. (N=30) [Mann Whitney U Test]

Post-op pain	Conversion to 10 mm		P Value
	Yes (N=14)	No (N=16)	
1 hour	7.00(6.0 to 7.0)	6.00(5.0 to 6.0)	0.0017
12 hours	4.00(3.25 to 4.0)	3.00(3.0 to 4.0)	0.0582
24 hours	2.00(2.0 to 3.0)	2.00(2.0 to 2.0)	0.0827

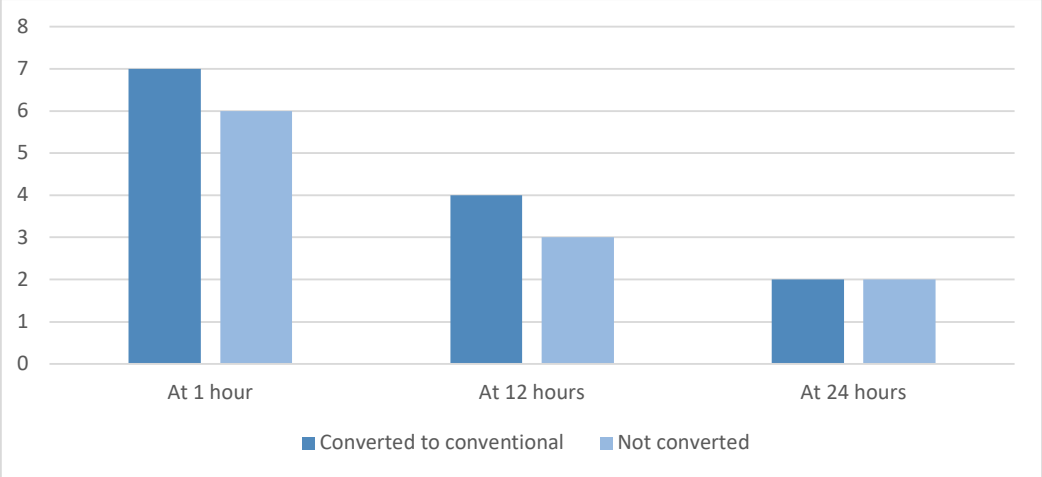


***Figure 16*: Comparison of post operative pain (VAS) Scores in group A group, between patients who had undergone conversion to conventional and who had not (N=30)**

In group A, the patients who had undergone conversion of the 5 mm umbilical port to 10 mm, had more post-operative pain, with VAS scores at 1 hour (7, 6 respectively, P = 0.0017), 12 hours (4,3 respectively, P= 0.0582) and at 24 hours (2, 2 respectively, P= 0.0827) (table 6 and figure 16). Therefore, pain is higher in patients who have undergone conversion to a 10 mm port, though not statistically significant.

5. Cosmetic Appearance by POSAS scores.

Table 7: Comparison of the study group with cosmetic appearance (POSAS) scores at 3 days, 1 week and 4 weeks post-operatively, by Mann-Whitney U test. (N= 60)

POSAS scores at	Study Group (Mean± SD)		P value
	Group A (N=30)	Group B (N=30)	
3 days			
OSAS	25.93 ± 7.62	28.73 ± 6.31	0.126
PSAS	25.33 ± 6.12	31.17 ± 4.07	<0.001
Total	**51.27 ± 12.93**	**60.20 ± 9.64**	**0.0036**
1 Week			
OSAS	17.83 ± 5.18	20.33 ± 3.63	0.0346
PSAS	16.73 ± 6.38	19.97 ± 3.09	0.0153
Total	**34.57 ± 11.02**	**40.30 ± 4.76**	**0.0113**
4 Weeks			
OSAS	9.95 ± 3.90	13.40 ± 3.00	0.0028
PSAS	11.00 ± 3.77	13.80 ± 2.61	0.0084
Total	**20.95 ± 7.35**	**27.20 ± 4.89**	**0.0026**

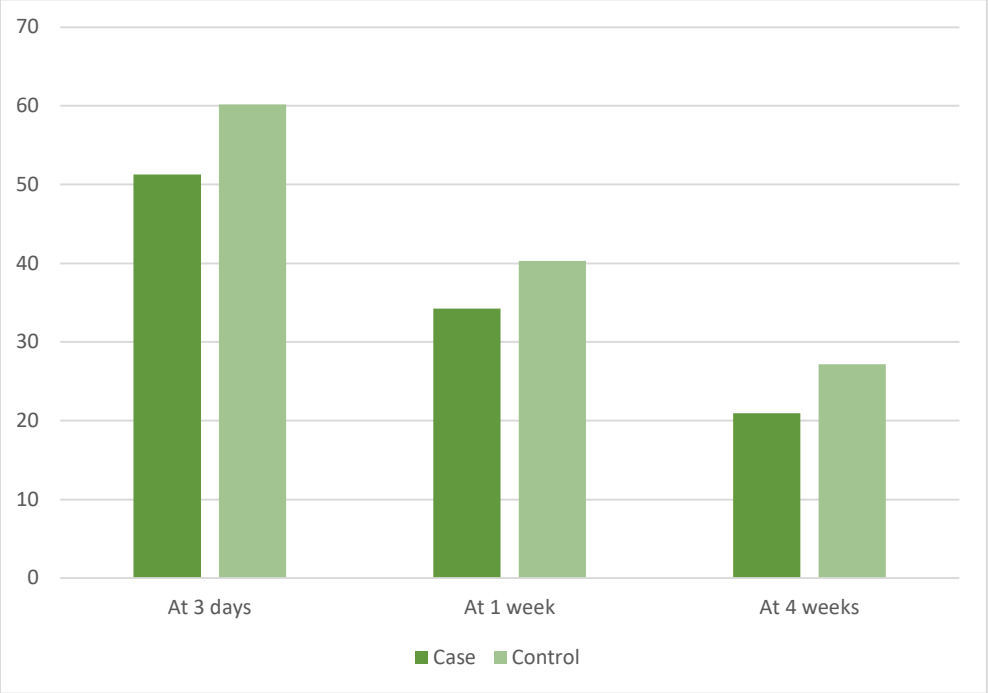


Figure 17: **Comparison of surgical scar cosmetic appearance (POSAS) total scores in the study group. (N= 60)**

From table 7 and figure 17, a significant difference was observed in terms of cosmetic appearance of surgical site, observed on post operative day 3 (51.27, 60.20 respectively, p = 0.0036), 1 week (34.57, 40.30 respectively, p = 0.0113) and 4 weeks (20.95, 27.20 respectively, p = 0.0026). This suggests that group A had a better cosmetic outcome, though not statistically significant.

Table 8: Comparison of cosmesis scores in group A, between patients who had undergone conversion to a 10 mm port and who had not. (N=30)

POSAS scores at	Conversion to 10 mm (Mean± SD)		P Value
	Yes (N=14)	No (N=16)	
3 days			
OSAS	33.36 ± 3.18	19.44 ± 2.63	<0.001*
PSAS	20.94 ± 2.89	30.36 ± 4.80	<0.001*
Total	**40.38 ± 5.23**	**63.71 ± 5.34**	**<0.001***
1 week			
OSAS	14.06 ± 2.69	22.14 ± 3.74	<0.001*
PSAS	11.56 ± 2.10	22.64 ± 3.89	<0.001*
Total	**25.63 ± 4.21**	**44.79 ± 6.28**	**<0.001***
4 weeks			
OSAS	14.00(13.0 to 15.0)	7.00(6.0 to 8.0)	<0.001†
PSAS	8.46 ± 1.33	14.67 ± 3.00	<0.001*
Total	**28.00(26.0 to 30.0)**	**16.00(14.0 to 17.0)**	**<0.001†**

Legend: † = independent t test, * = chi-square test

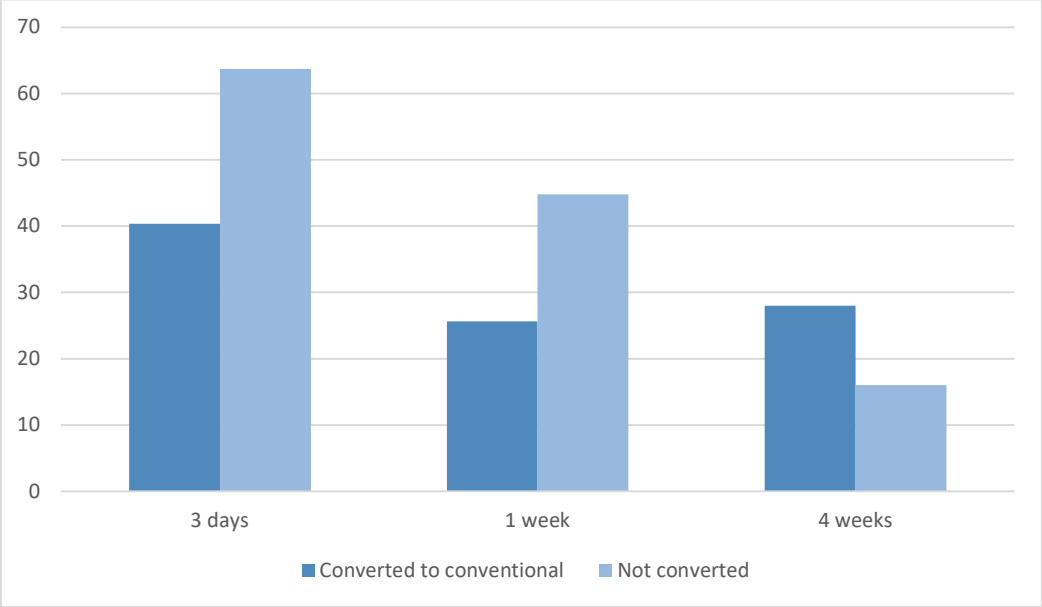


Figure 18: **Comparison of cosmesis scores in group A group, between patients who had undergone conversion to conventional and who had not (N= 30).**

From table 8 and figure 18, a significant difference was observed in terms of cosmetic appearance of surgical site, observed on post operative day 3 (40.38, 63.71 respectively, p <0.001), 1 week (25.67, 44.79 respectively, p <0.001) and 4 weeks (28, 16 respectively, p <0.001). This suggests that the patients who had undergone conversion to 10 mm had a worse cosmetic outcome, which was statistically significant.

3. Table 9: Comparison of duration of hospital stay (no. of days) with study group.

Duration of hospital stay	**Study Group (Mean± SD)**		**Mann Whitney U Test (P Value)**
	Group A (N=30)	**Group B (N=30)**	
No. of days	4.37 ± 0.85	4.57 ± 1.14	0.443

In the study groups, the number of days of hospital stay was almost equal, not statistically significant.

DISCUSSION

Minimal access surgery has revolutionized modern surgery tremendously with numerous advantages that outweigh all else. It has changed the patients' and the surgeons' perspectives of surgery. Despite initial obstacles, its various advantages have proven to it be the superior technique.

Currently, the preferred method of treatment of acute appendicitis is laparoscopic appendectomy. This has led to the introduction of various forms of minimal access surgery, such as double incision laparoscopic appendectomy, single incision laparoscopic appendectomy and NOTES, which have been extensively studied. However, these have several disadvantages, such as, the need for specialized and expensive equipment, a long learning curve and require a specialized set of skills, for both the surgeon and nursing staff.[52]

Single incision laparoscopic appendectomy was introduced and proposed to have better cosmetic outcome when compared to multiple incisions, but the incision required for the trocar was around 15-20 mm, which yielded a poor scar and sometimes, a deformed umbilicus. It was also noted to have higher pain scores. [53]

Numerous studies have been conducted on double incision laparoscopic appendectomy and minilaparoscopic appendectomy, the techniques have been described by *Pattanshetti et al (2017)* and *Shimikore S et al (2014)* respectively. These have resulted in similar postoperative pain and aesthetically acceptable surgical scars. However, there was an increase in operative time, required a new skillset and specialized instruments, and also had a long learning curve. Difficulty in handling tissues was also noted with the minilaparoscopic technique.[2,54]

Our study was prompted by the debates over the merits of various techniques of laparoscopic appendectomy. The present study was designed to compare all three 5 mm ports laparoscopic appendectomy and conventional laparoscopic appendectomy, with respect to postoperative, cosmesis and the rate of the 5 mm umbilical port being converted to 10 mm during the extraction of surgical specimen.

A one year randomized controlled trial was conducted in the Department of General Surgery at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2021 to December 2021. A total of 60 patients diagnosed with acute appendicitis underwent laparoscopic appendectomy, were randomly assigned into two study groups i.e., all three 5 mm ports laparoscopic appendectomy and conventional laparoscopic appendectomy.

In our study, a female preponderance was noted in group A at 53.33% and male preponderance was found in group B at 60%, with a P value of 0.301. The average ages of patients were comparable; 34.1 years in group A and 33.7 in group B, P value being 0.894.

The patients underwent ultrasonography of the abdomen to verify the diagnosis and note the diameter of the appendix, the average size of which was comparable, 9.17 mm in group A and 8.87 in group B.

During the surgery, there was no disparity in the quality of picture with 10 mm and 5 mm laparoscopes, and no new skill was required. In group A, in 16 patients, the 5 mm umbilical port was converted to 10 mm when retrieving the surgical specimen (53.33%). The duration of surgery was significantly longer in group A, taking an average of 79 minutes and 70 minutes when compared to group B (P = 0.001). This

extra time can be attributed to the conversion of the 5 mm port to 10 mm, changing of trocars and closure of the rectus sheath in the umbilical port site.

In group A, the port was converted where the appendicular diameter was 8 to 9 mm and more. While in the remaining patients, it was retrieved with the port trocar, which could be possible due to oozing of appendicular contents and collapse of the organ. The higher rate of conversion can be attributed to the average diameter of the appendix being 9 mm, which is comparatively bigger than 8 mm in group B.

The postoperative pain in both groups was compared serially by VAS, at 1 hour, 12 hours, and 24 hours, which was significantly lower in group A at 1 and 12 hours, with median scores of 6 and 7 ($P < 0.001$), and 4 and 4 ($P<0.001$) respectively. However, in group A, pain was noted to be higher in patients who underwent conversion of the 5 mm umbilical port to 10 mm, especially at 1 hour ($P = 0.0017$) and gradually reduces.

For cosmetic outcome, the surgical scar assessment was done serially with POSAS scale at 3 days, 1 week and 4 weeks postoperatively. A significantly better scar was observed in Group A when compared to group B, with mean total scores of 51 and 60 at 3 days, and 11 and 13 at 4 weeks, respectively. Likewise, patient scores were found to be significantly better. However, the surgical scar was worse in patients who underwent conversion of the 5 mm port to 10 mm in group A, with P value less than 0.001.

Hence, we infer that the use of all three 5 mm ports laparoscopic appendectomy technique is safe and feasible in patients with the appendicular diameter of 8 to 9 mm or less, with significantly lower postoperative pain and better cosmesis, while retaining the same skillset of conventional laparoscopic appendectomy.

CONCLUSION

- We conclude that all three 5 mm laparoscopic appendectomy technique is safe and feasible, with no compromise in surgical steps.
- This technique results in significantly lower postoperative pain and better surgical scar in appendiceal diameter less than 8-9 mm.
- Conventional laparoscopic appendectomy can be used when the diameter is more than 9 mm.

SUMMARY

Laparoscopic appendectomy is the treatment of choice for acute appendicitis, complicated and uncomplicated. Since its contraption, it has evolved rapidly to SILA, DILA and NOTES. Though these techniques have been extensively studied, there are several drawbacks and have either equivocal or unfavourable results. Hence, we hypothesize that the use of all three 5 mm ports for laparoscopic appendectomy can overcome these drawbacks, in terms of postoperative pain and cosmesis, and the rate of conversion of the 5 mm umbilical port to 10 mm during surgical specimen retrieval.

A randomised controlled trial was conducted in KLES Dr Prabhakar Kore Hospital & MRC, with 60 patients undergoing laparoscopic appendectomy. They were divided equally into two groups i.e., A – all three 5 mm ports laparoscopic appendectomy and B – conventional laparoscopic appendectomy. The results were as follows.

No statistically significant differences were found in the demographic parameters. The patients in group A had a larger appendiceal diameter of 9.17 mm when com-pared to group B, 8.87 mm. In group A, 16 (53%) patients underwent conversion of the 5 mm umbilical port to 10 mm, where the appendiceal diameter was more than 8-9 mm, they also had a significantly longer operative duration of 79.87 minutes, which is around 10 minutes longer than group B. This can be attributed to conversion of the port and trocar, and closure of the rectus sheath. While in remaining patients, the appendix could be extracted through the 5 mm umbilical port with the trocar. This could be possible due to the shrinkage of the organ and oozing of the contents.

The postoperative pain was significantly better in group A, especially at 1 and 12 hours, and so is the surgical scar cosmesis at 1 and 4 weeks. In group A, in patients who had undergone conversion, the post operative pain and the surgical site cosmesis were worse. Other noteworthy observations were, that there was no difference between the quality of picture through both the laparoscopes, no new skillset nor instruments were required to perform this procedure.

In conclusion, the all three 5 mm port laparoscopic appendectomy technique is a safe and feasible technique, which can be used in patients with the diameter of appendix less than 8-9 mm. It results in lower postoperative pain and satisfactory cosmesis.

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ANNEXURE 1: CONSENT FORM

Study title: **COMPARISON OF ALL THREE 5 MM LAPAROSCOPIC APPENDECTOMY WITH CONVENTIONAL LAPAROSCOPIC APPENDECTOMY - A HOSPITAL BASED RANDOMISED CONTROLLED TRIAL.**

(i) I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions. ☐

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

(iii) I understood that doctor of the clinical trial, others working on the doctor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understood that my identity will not be revealed in any information released to third parties or published.

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

(v) I agree to take part in the above study.

In case of queries related to the study, during and in future, please contact **Dr_____** Department of General Surgery, KLES Hospital and MRC, Belagavi, Phone number- 8217414008 or **Dr, _____** Department of General Surgery, KLES Hospital and MRC, Belagavi, Phone number- 9844001879.

In case of queries about the rights as a study subject, please contact **Dr Harsha Hegde,** CHAIRPERSON, JNMC, IEC & Scientist D, ICMR, National Institute of Traditional Medicine, Belagavi – 9480422500

Subject name: _____

Signature or thumb impression of the subject: _____

Date (dd-mm-yyyy): ☐☐ ☐☐ ☐☐☐☐

Name of the person obtaining informed consent: _____

Signature of the person obtaining informed consent: _____

If a patient has limited ability to read and write, In these instances the patient his/her thumb impression in the place of the signature.

Patient's Legally Acceptable Representative's Statement:

I, as the patient's legally acceptable representative, was present during the consenting procedure and understand the preceding information describing this study. All of the questions regarding the study and the patient's participation in it have been answered to my satisfaction and that of the patient. I state that all aspects of the study were clearly presented during the consent procedure. The patient is willing to participate in the study and I sign below on his/her behalf testifying to this effect.

Name of the patient: _____

Name of the Legally Acceptable Representative: _____

Relationship to the patient: _____

Signature of the Legally Acceptable Representative: _____

Date (dd-mm-yyyy): ☐☐ ☐☐ ☐☐☐☐

ANNEXURE 2: PROFORMA

The proposed proforma / questionnaire to be used for data collection for the study titled **"COMPARISON OF ALL THREE 5 MM LAPAROSCOPIC APPENDECTOMY WITH CONVENTIONAL LAPAROSCOPIC APPENDECTOMY - A HOSPITAL BASED RANDOMISED CONTROLLED TRIAL."** is as:

1. Unique Participant ID no.: | | | | | | | |
2. Applicant is willing to give consent (1 = Yes, 2 = No): | |
3. Date of admission | | | | | | | | | (dd/mm/yyyy):
4. Date of discharge | | | | | | | | | (dd/mm/yyyy):
5. Date of interview | | | | | | | | | (dd/mm/yyyy):
6. Sex (1 = M, 2 = F): | |
7. Age (in | | | years):
8. Height | | | | (in cms):
9. Weight | | | (in kgs):
10. Address (1 = Belagavi, 2 = Outside Belagavi): | |
11. Occupation (1 = Unemployed, 2 = Unskilled, 3 = Semiskilled, 4 = Skilled, 5 = Professional): | |
12. Education (1 = Illiterate, 2 = Primary (1st - 7th std), 3 = High school (8th-10th std), 4 = Intermediate, 5 = Degree and above) | |
13. Socio-economic status (1 = Low, 2 = Middle, 3 = High): | |

History:

14. Pain abdomen (no. of days): | |

15. Nature of pain (1 = colicky type, 2 = dull aching type):

16. Location of pain (1 = periumbilical, 2 = right iliac fossa): ☐

17. Nausea and vomiting: (1 = yes, 2 = no): ☐

If yes, no. of episodes: ☐

18. Fever - No. of episodes: ☐

On examination:

Per abdomen:

19. Distended (1 = yes, 2 = no): ☐

20. Guarding (1 = yes, 2 = no): ☐

21. Rebound tenderness (1 = yes, 2 = no): ☐

22. Right iliac fossa (McBurney's point) tenderness (1 = yes, 2 = no): ☐

23. Other signs (1= Rovsing's sign, 2 = psoas sign, 3 = Obturator sign): ☐

24. Bowel sounds (1 = present, 2 = sluggish, 3 = absent): ☐

25. **INVESTIGATIONS:**

USG Abdomen and Pelvis shows features of appendicitis (1 = yes, 2 = no): ☐

OPERATION DETAILS:

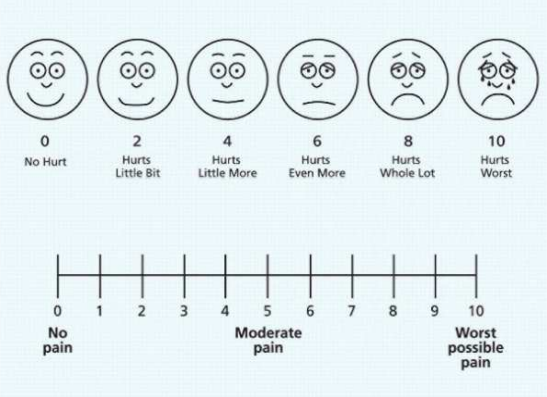
26. Date of Surgery (dd/mm/yyyy): ☐☐☐☐☐☐☐☐

27. Duration of Surgery (in minutes): ☐☐☐

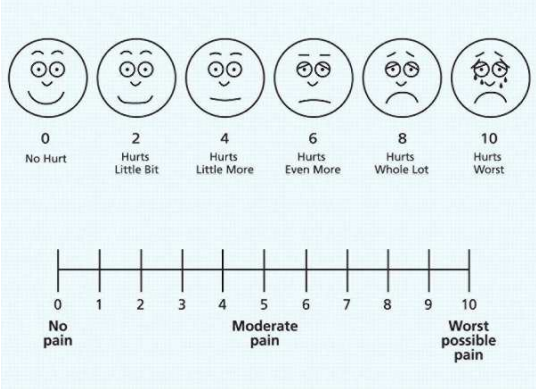
28. Conversion of the 5 mm umbilical port to 10 mm (1 = yes, 2 = no, 3 = N/A): ☐

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

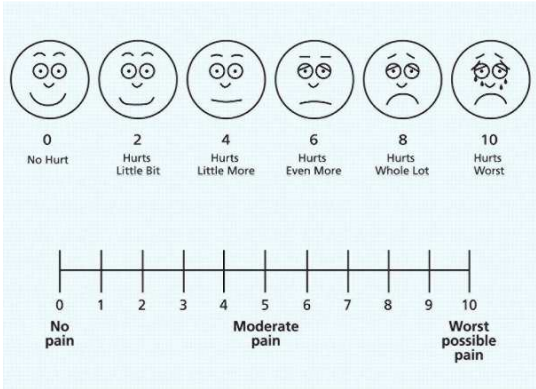
29. VAS AFTER 1 HOUR:



30. VAS AFTER 12 HOURS:



31. VAS AFTER 24 HOURS:



SERIAL ASSESSMENT OF POST OPERATIVE WOUND COSMESIS USING POSAS SCALE

32. POSAS Scale after 3 days:

Observer Scar Assessment Scale (OSAS)

	Normal skin 1 2 3 4 5 6 7 8 9 10	Worst scar imaginable
Vascularization	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Pigmentation	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Thickness	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Relief	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Pliability	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Observer scar rating	– – – – – – – – – +	

OSAS summary score: _____ (minimum, 5; maximum, 50)

Patient Scar Assessment Scale (PSAS)

	No, no complaints 1 2 3 4 5 6 7 8 9 10	Yes, worst imaginable
Is the scar painful?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Is the scar itching?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
	No, as normal skin 1 2 3 4 5 6 7 8 9 10	**Yes, very different**
Is the color of the scar different?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Is the scar more stiff?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Is the thickness of the scar different?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Is the scar irregular?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Overall patient scar satisfaction	– – – – – – – – – +	

PSAS total score: _____ (minimum, 6; maximum, 60)

33. POSAS Scale after 1 week:

Observer Scar Assessment Scale (OSAS)

	Normal skin 1 2 3 4 5 6 7 8 9 10	Worst scar imaginable
Vascularization	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Pigmentation	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Thickness	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Relief	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Pliability	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Observer scar rating	– – – – – – – – – +	

OSAS summary score: _____ (minimum, 5; maximum, 50)

Patient Scar Assessment Scale (PSAS)

	No, no complaints 1 2 3 4 5 6 7 8 9 10	Yes, worst imaginable
Is the scar painful?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Is the scar itching?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
	No, as normal skin 1 2 3 4 5 6 7 8 9 10	**Yes, very different**
Is the color of the scar different?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Is the scar more stiff?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Is the thickness of the scar different?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Is the scar irregular?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○	
Overall patient scar satisfaction	– – – – – – – – – +	

PSAS total score: _____ (minimum, 6; maximum, 60)

34. POSAS Scale after 4 weeks:

Observer Scar Assessment Scale (OSAS)

	Normal skin	1	2	3	4	5	6	7	8	9	10	Worst scar imaginable
Vascularization		○	○	○	○	○	○	○	○	○	○	
Pigmentation		○	○	○	○	○	○	○	○	○	○	
Thickness		○	○	○	○	○	○	○	○	○	○	
Relief		○	○	○	○	○	○	○	○	○	○	
Pliability		○	○	○	○	○	○	○	○	○	○	
Observer scar rating		–	–	–	–	–	–	–	–	–	+	

OSAS summary score: _____ (minimum, 5; maximum, 50)

Patient Scar Assessment Scale (PSAS)

	No, no complaints	1	2	3	4	5	6	7	8	9	10	Yes, worst imaginable
Is the scar painful?		○	○	○	○	○	○	○	○	○	○	
Is the scar itching?		○	○	○	○	○	○	○	○	○	○	

	No, as normal skin	1	2	3	4	5	6	7	8	9	10	Yes, very different
Is the color of the scar different?		○	○	○	○	○	○	○	○	○	○	
Is the scar more stiff?		○	○	○	○	○	○	○	○	○	○	
Is the thickness of the scar different?		○	○	○	○	○	○	○	○	○	○	
Is the scar irregular?		○	○	○	○	○	○	○	○	○	○	
Overall patient scar satisfaction		–	–	–	–	–	–	–	–	–	+	

PSAS total score: _____ (minimum, 6; maximum, 60)

ANNEXURE 3: MASTER CHART

Group A

Sl. No	Age	Sex	size of appendix on USG (mm)	duration of surgery (mins)	conversion to 10 mm	VAS at 1 hr	VAS at 12 hrs	VAS at 24 hrs	OSAS at 3 days	PSAS at 3 days	OSAS at 1 week	PSAS at 1 week	OSAS at 4 weeks	PSAS at 4 weeks
1	33	F	8	80	no	4	3	2	17	18	9	7	7	7
2	29	F	9	90	yes	7	4	3	38	32	17	19	13	13
3	42	M	11	68	yes	7	5	3	38	24	17	20	11	15
4	37	F	8	76	no	6	4	2	18	14	12	10	N/A	N/A
5	23	F	10	78	yes	6	4	2	36	30	19	22	15	11
6	42	M	8	80	no	6	3	3	18	20	14	14	N/A	N/A
7	21	F	8	84	no	5	4	2	16	18	12	12	8	9
8	34	M	9	77	no	7	5	2	18	20	14	14	8	9
9	43	M	11	94	yes	7	4	3	35	28	20	24	N/A	N/A
10	26	F	12	80	yes	6	4	2	33	20	22	20	14	12
11	48	M	9	84	yes	6	5	2	33	30	22	22	13	15
12	23	F	11	74	yes	7	4	3	34	26	25	18	15	17
13	32	F	10	78	yes	7	3	2	34	35	25	16	N/A	N/A
14	19	F	9	88	no	5	4	3	18	20	12	10	6	9
15	25	M	7	90	no	6	3	2	20	24	16	14	7	9
16	37	M	8	80	no	5	4	2	22	23	18	12	8	8
17	26	M	9	76	no	6	3	2	24	25	16	10	6	8
18	25	F	10	83	yes	7	4	3	30	30	22	25	N/A	N/A
19	41	M	11	74	yes	7	4	2	33	35	23	27	17	13
20	53	F	8	80	no	7	3	2	16	20	10	10	6	6
21	55	F	7	60	no	6	3	2	18	20	12	12	6	7
22	24	M	9	72	no	6	3	2	20	22	16	14	8	9
23	43	M	8	84	no	6	2	2	22	24	18	14	8	10
24	46	M	8	86	no	5	4	3	24	24	16	10	7	11

25	18	F	9	94	yes	7	3	2	28	29	18	22	17	21
26	54	F	12	90	yes	5	4	3	36	37	30	26	N/A	N/A
27	26	M	8	80	no	6	3	2	18	20	14	12	6	8
28	40	M	9	72	yes	7	3	2	29	34	26	30	N/A	N/A
29	32	F	11	70	yes	6	3	2	30	35	24	26	13	15
30	26	F	8	74	no	5	4	2	22	23	16	10	N/A	N/A

Group B

Sl. No	Age (years)	Sex	size of appendix on USG (mm)	duration of surgery (mins)	VAS at 1 hr	VAS at 12 hrs	VAS at 24 hrs	OSAS at 3 days	PSAS at 3 days	OSAS at 1 week	PSAS at 1 week	OSAS at 4 weeks	PSAS at 4 weeks
1	52	F	9	70	7	4	3	29	32	22	26	14	15
2	18	M	8	63	7	5	3	19	37	18	21	12	15
3	33	M	10	75	7	5	2	28	26	16	20	N/A	N/A
4	51	F	8	74	8	4	2	38	32	17	19	13	13
5	30	F	7	76	8	5	2	38	24	17	20	11	15
6	19	M	7	78	7	3	2	18	27	19	25	N/A	N/A
7	40	F	9	50	6	4	2	22	23	19	10	5	6
8	45	F	8	80	7	5	2	24	27	19	21	N/A	N/A
9	35	M	9	66	7	4	3	27	28	19	21	13	15
10	18	M	10	68	7	4	1	24	32	19	23	16	17
11	43	M	11	64	8	4	2	24	29	14	20	14	15
12	23	M	12	80	7	6	4	37	35	28	24	N/A	N/A
13	23	M	11	60	7	3	3	13	25	12	22	N/A	N/A
14	34	F	10	66	8	4	3	33	34	20	18	16	14
15	54	F	7	67	7	4	3	34	35	25	16	N/A	N/A
16	67	M	6	76	7	5	4	36	34	19	20	15	14
17	24	M	11	63	7	4	2	32	35	22	21	13	15
18	45	M	10	68	6	5	4	25	29	24	20	15	16
19	32	F	8	76	7	4	3	26	29	21	24	N/A	N/A
20	25	F	7	74	7	3	3	34	36	22	18	13	11
21	35	M	6	80	7	3	3	28	30	18	19	11	12
22	37	M	8	75	7	4	3	25	28	23	17	N/A	N/A
23	22	F	8	69	6	5	4	33	35	24	20	15	13

24	19	M	9	70	6	4	3	36	37	26	21	N/A	N/A
25	44	M	11	75	7	5	4	27	30	27	19	20	11
26	21	F	10	63	6	4	2	24	29	18	19	N/A	N/A
27	33	M	8	61	7	5	3	29	32	19	20	10	11
28	35	M	11	72	8	5	3	30	33	20	17	12	15
29	32	F	8	75	7	5	4	36	37	21	22	14	16
30	22	M	9	73	8	6	4	33	35	22	16	16	17

ANNEXURE 4 – KEY TO MASTER CHART

Sl. no – serial number

M – male

F – female

Mm – millimetres

Mins – minutes

VAS – Visual Analog Scale

OSAS – Observer Scar Assessment Scale

PSAS – Patient Scar Assessment Scale

N/A – not applicable