"COMPARISON OF ABSORBABLE MULTIFILAMENT SUTURE (VICRYL™) AND NON-ABSORBABLE MONOFILAMENT SUTURE (PROLENE™) IN LAPAROSCOPIC PORT SITE CLOSURE USING SPINAL NEEDLE - A HOSPITAL BASED RANDOMISED CONTROLLED TRIAL"

BY

REG NO: BH0118010

Dissertation

Submitted to the
KAHER, Belagavi, Karnataka

In partial fulfillment
of the requirements for the degree of

MASTER OF SURGERY (M.S.)
in
GENERAL SURGERY

JAWAHARLAL NEHRU MEDICAL COLLEGE
BELAGAVI, KARNATAKA

APRIL – 2021

KLE Academy of Higher Education and Research
Belagavi, Karnataka

Endorsement

This is to certify that the dissertation entitled **"COMPARISON OF ABSORBABLE MULTIFILAMENT SUTURE (VICRYL™) AND NON-ABSORBABLE MONOFILAMENT SUTURE (PROLENE™) IN LAPAROSCOPIC PORT SITE CLOSURE USING SPINAL NEEDLE - A HOSPITAL BASED RANDOMISED CONTROLLED TRIAL"** is a bonafide research work done by **REG NO. BH0118010.**

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Date: 14-09-2020

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The softcopy of thesis entitled: **"COMPARISON OF ABSORBABLE MULTIFILAMENT SUTURE (VICRYL) AND NON ABSORBABLE MONOFILAMENT SUTURE (PROLENE) IN LAPAROSCOPIC PORT SITE CLOSURE USING SPINAL NEEDLE."** has been submitted for Anti-Plagiarism check through Turnitin software. The scan has been carried out and the scanned output reveals a match percentage of **03%** which is within the acceptable limits of **10%** as per the guidelines given by UGC.

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LIST OF ABBREVIATIONS

BMI – Body Mass Index

BP – Blood Pressure

CDC – Centre for Disease Control

cm - centimetre

ECG – Electrocardiogram

GI – Gastrointestinal

HBsAg – Hepatitis B Surface Antigen

HIV – Human Immunodeficiency Virus

H/O – History of

INR – International Normalized Ratio

KAHER – KLE Academy of Higher Education and Research

KLES – Karnataka Lingayat Education Society

MIS – Minimally Invasive Surgery

mm – millimetre

PR – Pulse Rate

PT – Prothrombin Time

RR – Respiratory Rate

SNOSE – Sequentially Numbered Opaque Sealed Envelope

SSI – Surgical Site Infection

Temp. - Temperature

TSH – Trocar Site Hernia

USA – United States of America

USG – Ultrasonography

VAS – Visual Analogue Score

ABSTRACT

Background and Objectives

The importance of a proper technique in closing the port sites in laparoscopic surgery is well established, and to prevent complications, fascial closure is recommended for ports of size more than 10 mm. This study compared the post-operative port site complications (pain, surgical site infection, and hernia), after the fascial closure of 10 mm port sites with an absorbable multifilament suture (Vicryl^{TM}) and a non-absorbable monofilament suture (Prolene^{TM}) using spinal needle in subjects undergoing laparoscopic gastrointestinal surgeries.

Methodology

This study was conducted at KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Belagavi between January 2019 and December 2019. A total of sixty patients who were undergoing laparoscopic gastrointestinal procedures were included in the study of whom thirty patients underwent closure of the 10 mm port sites with Vicryl^{TM} and the other thirty with Prolene^{TM}.

Results

The two groups were almost similar with respect to age and sex distribution. Subjects in the prolene suture group experienced significantly lesser post-operative pain scores at 12 hours, when compared with the vicryl suture group. The post-operative complications like seroma formation and surgical site infection were also lesser in the prolene suture group, as compared to vicryl suture group, but these differences did not attain statistical significance.

Conclusion

There was a significant reduction in the post-operative pain after first 12 hours in the patients who underwent port closure with Prolene. Hence, there is a need for further prospective studies with a larger sample size.

Key words

laparocopy, port site closure, fascial closure, vicryl, prolene, pain, surgical site infection

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The modern era of laparoscopic surgery was ushered in when a miniature video camera was attached to the eyepiece of the laparoscope, which allowed multiple observers to view an operative field from the same vantage point. [1] Although the first published reports of laparoscopy were of the early 20th century, its use was limited to diagnostics and the ligation of the fallopian tubes for many decades. French surgeons first performed laparoscopic cholecystectomy in 1987, and since then, laparoscopic techniques are being used in a wide variety of abdominal and thoracic operations.

Many technological advancements have led to rapid progress in laparoscopic techniques. These new techniques allow for more intricate procedures to be performed with comparatively smaller abdominal incisions, which result in a reduced hospital stay and lesser post-operative complications as compared to open procedures.

It is an accepted fact that laparoscopic surgery has positively impacted both patients as well as the healthcare systems. Patients experience lesser pain, lesser complications and can resume their daily routine quickly. Healthcare systems have more savings and less drain on its manpower and resources. Thus, the shift towards laparoscopic surgeries year after year. Annually, over 1.5 crore laparoscopic procedures are performed worldwide.

But even these minimally invasive techniques are not without their associated complications, and port site related complications have been reported in upto 6.3% of the patients.[2] These range from surgical site infection and wound dehiscence to bowel herniation, omental entrapment and incarcerated Richter's hernia.[3] The incidence of these complications increase with the port size.

The importance of a proper technique in closing the port sites is well established, and to prevent these complications, fascial closure is recommended for ports of size more than 10 mm in adults and more than 5 mm in children.[4] Fascial closure with sutures helps reduce the chance of developing a port site hernia. Re-approximation of the fascia can be accomplished using a number of specialised instruments that have been devised for the same.

The two major factors which influence the outcomes are the suturing technique and the suture material. Various types of port closure techniques emerged, ranging from the conventional hand suturing to the utilization of specialized devices.[5] The use of spinal needle to close the port sites under vision was proven to be a simple yet effective technique, in many a series.[6]

Studies have also been done to identify the optimal suture material, but they have yielded conflicting results. Rucinski et al. in their "meta-analysis comparing absorbable with non-absorbable sutures for closure of a median abdominal wound, concluded that the use of absorbable sutures was associated with a significantly lower incidence of stitch abscess than that of non-absorbable sutures."[7]

van'tRiet et al. in their "meta-analysis comparing the onset of abdominal wall incisional hernia among different types of sutures, indicated that the incidence of abdominal wall incisional hernia was significantly higher following the use of absorbable sutures with a short duration of retention of the tensile strength."[8]

There is no consensus at present on which suture material is better for the fascial closure in abdomen, absorbable or non-absorbable. In this background, the current study is done with the purpose of comparing the efficacy of an absorbable multifilament suture (Vicryl^{TM}) and a non-absorbable monofilament suture

(Prolene^{TM}) for fascial closure of port sites in preventing various port site complications.

Controlled trials comparing the efficacy of various interventions are extremely vital in this regard. Hence, we carried out this study to compare an absorbable multifilament suture (Vicryl^{TM}) and a non-absorbable monofilament suture (Prolene^{TM}) for the closure of port sites in laparoscopic gastrointestinal surgeries.

To compare the post-operative port site complications (pain, surgical site infection, and hernia), after the fascial closure of 10 mm port sites with an absorbable multifilament suture (Vicryl^{TM}) and a non-absorbable monofilament suture (Prolene^{TM}) using spinal needle in patients undergoing laparoscopic gastrointestinal surgeries.

HISTORY OF LAPAROSCOPIC SURGERY

The rise of minimally invasive surgery (MIS) is among the most recent phenomena to be called a revolution in the field of surgery. Also known as minimal-access or keyhole surgery, MIS came of age in the field of general surgery in late-1980s, and ushered in significant changes for practitioners and patients alike. [9]

Endoscopy is the central technology of MIS. An endoscope is an instrument for visualising the interior of a human body, either through an existing orifice (such as cystoscopes for the bladder), or percutaneously through a surgical incision (such as thoracoscopes for the pleural cavity or culdoscopes for the female pelvic organs). Endoscopy is an umbrella term for a range of visualisation techniques, prominent among them being laparoscopy, defined as the endoscopic visualisation of the peritoneal cavity. [9]

Hans Christian Jacobaeus, a Swedish surgeon coined the term "laparoscopy" ("laparothorakoskopie"). He experimented on animals, inserting cystoscopes with no pneumoperitoneum. Subsequently he reported his experience of 17 laparoscopies and 2 thoracoscopies in 1910.[10]

Beginning in the early nineteenth century, an Italian obstetrician working in Frankfurt, Philippe Bozzinni, created a candlelit device comprising of mirrors and tubes to glimpse inside the human bladder. Later that century a French surgeon named Antoine Jean Desormeaux published De l'endoscope, a treatise describing an instrument for exploring the bladder and urethra. It was adapted in 1879 by the German urologist Max Nitze, then working in Berlin, who used burning platinum wires to improve illumination.[9]

In the early twentieth century, Georg Kelling of Dresden explored the abdominal cavity of living dogs with a Nitzecystoscope; he applied the term 'celioscopy' for what is today considered the first laparoscopic examination.[10] The twentieth century saw various technical improvements that refined and expanded endoscopic applications.[9]

Fig.1,2

Semm is credited with the first incidental laparoscopic appendicectomy in 1981 and Muhe with the first laparoscopic cholecystectomy in 1985.[11]Mouret Philippe of France removed a diseased gallbladder in 1987 and the portahepatis was clearly exposed by a forceful cephalad retraction of the fundus of gallbladder, using a laparoscopic video camera.[9]

The introduction of laparoscopic cholecystectomy was the single most important stimulus to the expansion of operative laparoscopy in surgery. As surgeons became skilled in laparoscopic cholecystectomy, they began performing other abdominal operations ranging from those on the esophagus to those on the rectum, and from those involving the abdominal wall to those involving the retroperitoneum.

LAPAROSCOPY IN INDIA

Within 50 years of Kelling′s experiment, Dr F.P. Antia of Mumbai's KEM Hospital did a laparoscopy (diagnostic) on a patient with hepatic cirrhosis using very basic instruments and room air insufflated using a sigmoidoscope pump for creation of pneumoperitoneum.[12]

From these humble beginnings, laparoscopic surgery has grown in a phenomenal way in our country. In India, the 1st laparoscopic cholecystectomy was performed by Dr Tehemton E Udwadia in 1990 at Mumbai's JJ Hospital.[12] The first workshop in laparoscopic surgery in an academic institute was held by Dr AbhayDalvi and Dr J. B. Agarwal at Mumbai's KEM Hospital.[12] Even though it was viewed with scepticism and apprehension in the starting days by patients and surgeons alike, the success of the initial cases soon transformed the medical community into ardent believers, which was largely propelled by the patient demand.

India is at the forefront of the countries practising minimal access surgery, in terms of wide national spread, the high volume and superior quality of high end laparoscopic surgery, technical expertise, and cost-effective outcomes.

PORT SITE COMPLICATIONS

These include persistent pain, surgical wound infection, implantation of tumour and incisional hernia.

The risk of surgical site infection in laparoscopic surgery is very less and is related to the case being operated. Infection can be identified by the sentinel signs of erythema, pain, and discharge from the wound. The modalities of treatment are topical or systemic antibiotics, wound dressings and drainage if a collection or an abscess is present. Different ways to prevent the surgical site infections are by giving

appropriate prophylactic antibiotics for the procedure being performed, removing all contaminated specimens through the skin using protective pouches and port site irrigation before closure of the incision.

Implantation of the tumour cells in trocar sites was reported for almost all the malignancies that are treated by laparoscopic surgery. Their incidence is very less, around 1% for lower GI and 2.3 % for gynaecological cancers.[13] Likely cause can be a poor operative technique such as wrong handling of the tissues. Other mechanisms were also investigated, including aerosolization, haematogenous spread and direct implantation. Many preventative techniques have been tried including wound protectors, protective bags for specimens, intra-peritoneal chemical agents, alternative insufflation techniques, trocar site excision and closure of the peritoneal wound.

Incidence of incisional hernia is usually seen many years after the surgery, but can even present early. The incidence rate of trocar site incisional hernias is 21 in 100,000.[14] Today's prevalent concept is that fascial closure should be done for all port sites that are more than 10 mm in size. Uslu et al "found that age greater than 60, BMI greater than 25, and duration of procedure greater than 90 min increased the risk in laparoscopic cholecystectomy patients. There is no consensus on closure of port sites and the means to do this. Many feel that the new dilating trocars allow the fascia to be left alone. There are various devices being proposed for closure but none that have gained widespread acceptance."[15]

TECHNIQUES FOR PORT SITE CLOSURE

Traditional suturing techniques can be difficult and time consuming, often leading to a blind closure of the fascia. Numerous devices and techniques have evolved facilitating the fascial closure. The technique for port site closure should

ideally be fast, technically easier - without the need to enlarge the skin incision, safe, inexpensive, ensuring secure closure of the fascia, and causing minimal post-operative pain.

"In addition to classical hand-sutured closure, other techniques could be classified from a technical point of view into three main groups based on the review of literature:

(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."[5]

There are numerous methods and instruments described for port closure [16]:

- 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
- 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 trocar site from the inside, ensuring safety of the technique especially with respect to any visceral injury. 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 require additional instrumentation, which further increase 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.

SPINAL NEEDLE

Most of the spinal needles that are manufactured are made of stainless-steel alloys. Their size ranges from 16G to 30G.[17] 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.[18] 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

Table. 1 Colour coding of the spinal needle

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

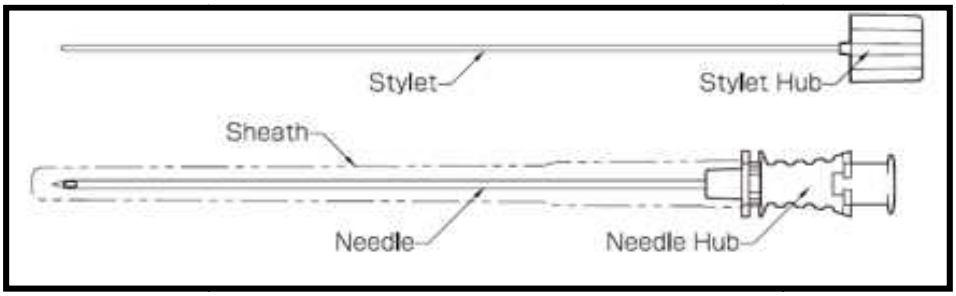


Fig.3

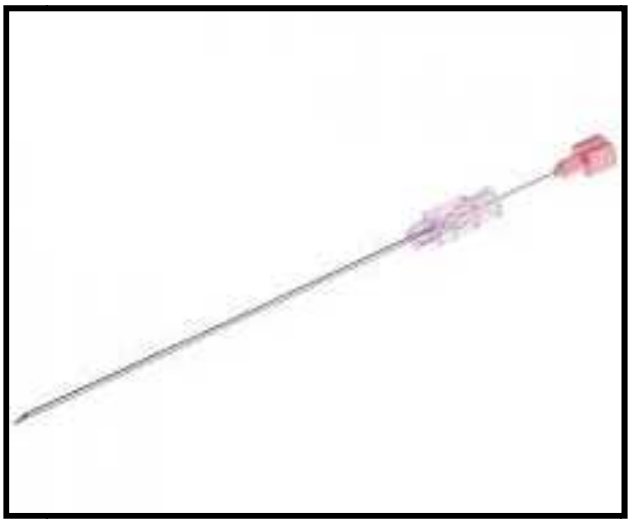


Fig.4 18-gauge spinal needle

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

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 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.

SUTURE	TYPE	RAW MATERIAL	RETENTION OF TENSILE STRENGTH IN VIVO
Vicryl (Coated)	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

Table2**Characteristics of Vicryl**[19]

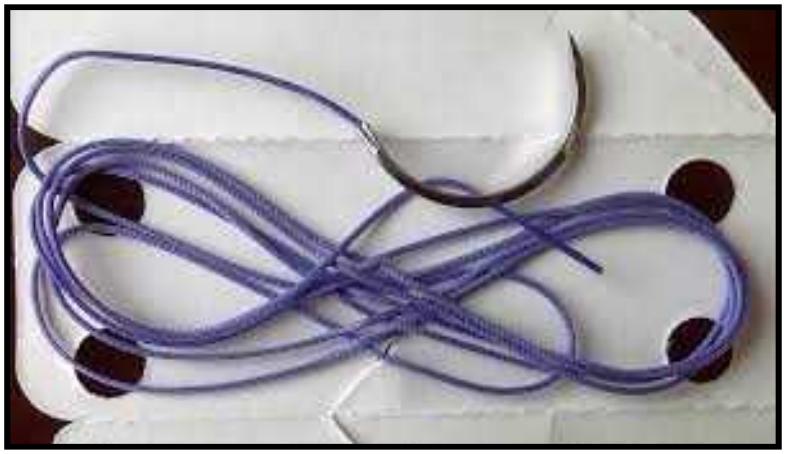


Fig.5

The material used in this study is the "VICRYL 2-0" (ETHICON NW 2382).

PROLENE – SUTURE MATERIAL

Prolene is a monofilament, synthetic, non-absorbable surgical suture composed of an isotactic crystalline stereoisomer of polypropylene, which is a synthetic linear polyolefin. It is usually dyed blue to enhance the visibility against the surrounding tissues. It is used in general for soft tissue ligation and approximation. Its advantages are durability and minimal tissue reaction. Disadvantages are high plasticity, fragility, high cost, and difficulty of use when compared to traditional nylon sutures.

SUTURE	TYPE	RAW MATERIAL	RETENTION OF TENSILE STRENGTH IN VIVO
Prolene	Monofilament	Isotactic crystalline stereoisomer of polypropylene	Not subject to degradation or weakening by action of tissue enzymes

Table 3 Characteristics of Prolene[19]

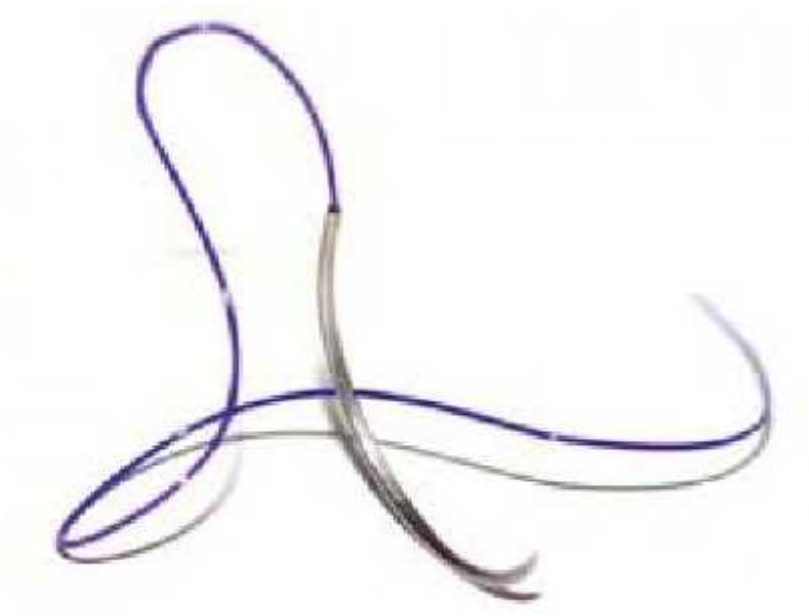


Fig.6 The material used in this study is the "PROLENE 2-0"(ETHICON NW 863).

POST-OPERATIVE PAIN

Tissue damage leads to the release of numerous chemical factors which in turn lead to the activation of receptors of pain. Many of these factors are also pro-inflammatory and lead to acute inflammation in the area of damage. The pain receptors are free nerve endings.

Pain sensation is subjective and varies between patients. Hence, measuring pain, analysing it and formulating a protocol for pain management is difficult.[20] 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.

Post-operative pain requires prompt attention as it amplifies the surgical stress responses thereby delaying the recovery.[21, 22] The intensity of pain escalates during the initial post-operative hours and usually subsides over the following days, hence a

great emphasis has been laid on post-operative pain management as a fundamental outcome assessment for any surgical procedure.[23, 24]

Pain experienced by the patients after laparoscopy is frequently described to be sub-diaphragmatic, shoulder tip or at the port-site incisions. Pain following laparoscopy can be due to several factors[25, 26]:

- 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.

There are several methods that have been described and also being investigated to reduce post-operative pain[26, 27]:

- Pre-operative infiltration of local anaesthetic 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 site closure.

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

SURGICAL SITE INFECTION

Post-operative wound infections are common and also morbid. They are the most common of all the hospital acquired infections, and account for almost 20% of all the hospital acquired infections.[28]

The most widely used definition for surgical site infection (SSI) has been provided by the Centre for Disease Control, USA. Accordingly, "SSIs are classified by depth and tissue spaces involved. A superficial incisional SSI involves only the skin or subcutaneous tissue, a deep incisional SSI involves the fascia or muscle layers, and an organ space SSI involves any part of the body opened or manipulated during a procedure, excluding the previously mentioned layers."[29]

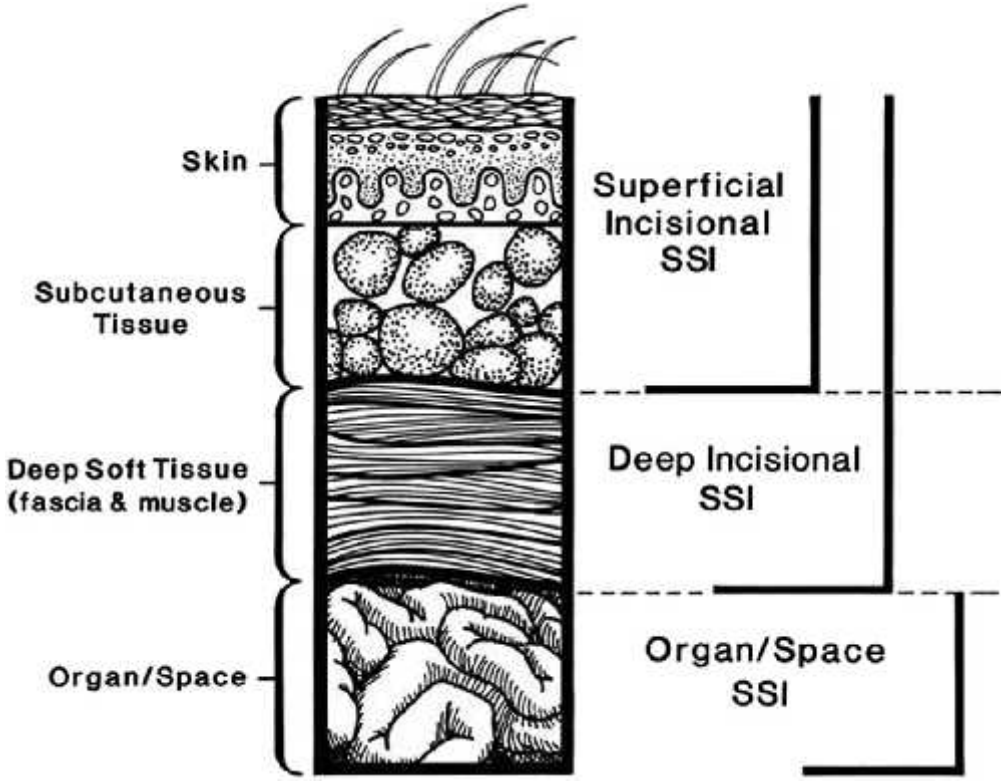


Fig. 7

Various risk factors for the development of post-operative wound infection have been identified. “These risk factors can be broadly separated into intrinsic (patient) factors that are modifiable or non-modifiable, as well as extrinsic (eg.procedure, facility, pre-operative, and operative) factors.”

“Potentially modifiable patient risk factors include glycemic control and diabetic status, dyspnea, alcohol and smoking status, pre-operative albumin<3.5 mg/dL, total bilirubin >1.0 mg/dL, obesity, and immunosuppression. Non-modifiable patient factors include increasing age, recent radiotherapy, and history of skin or soft tissue infection.”

“Procedure related factors include emergency and more complex surgery and wound contamination. Facility risk factors include inadequate ventilation, increased operating room traffic, and appropriate sterilization of equipment. Preoperative risk factors include presence of a pre-existing infection; inadequate skin preparation; hair removal; and antibiotic choice, administration, and duration. Intraoperative risk factors include duration of surgery, blood transfusion, maintenance of asepsis, poor-quality surgical hand scrubbing and gloving, hypothermia and poor glycemic control.”[30-32]

Post operative wound infection is a major problem affected by many factors, out of which only a few are under the control of the surgeon. The various strategies to reduce the wound infection are multifactorial and occur across a wide range of patient and hospital settings. The key to the success of reduction in the rate of wound infections is in ensuring a high compliance of the risk reduction strategies.

PORT SITE HERNIA

"Port site hernia (PSH), also called as trocar site hernia (TSH) has been defined by Crist and Gadacz as the development of hernia at the canula insertion site. Tonouchi et al have classified TSH into three types:

1. Early (dehiscence of fascial planes and peritoneum)
2. Late (dehiscence of fascial plane with intact peritoneal hernia sac)
3. Special (dehiscence of whole abdominal wall)"[33]

"Early and late onset types represent failure of fascial suturing. In both these varieties the skin sutures remain intact. While early onset type presents in the peri-operative period, late onset type presents several months later. Special type indicates dehiscence of the entire abdominal wall with protrusion of the intestine or greater omentum through the skin."[33]

By far the umbilicus was the most common trocar site associated with incisional hernia. However, incisional hernias were seen to occur at all the other sites as well involving every abdominal quadrant.[34, 35]

Risk factors for the development of trocar site hernias include the site of trocar insertion, diameter of the trocar, design of the trocar, direction of trocar insertion, any pre-existing defects in the fascia, patient and procedure related factors and the use of a drain. Various comorbidities were also linked to incisional hernias, which include diabetes mellitus, renal impairment, pulmonary insufficiency, and immune deficiency status.[34-36]

The risk of port site hernia is more in bariatric and overweight patients due to a greater intra-abdominal pressure and large pre-peritoneal space.[36, 37] Thus, closure of fascia alone is not sufficient, and the port size is another major factor, and many authors have advised for the fascial closure of ports more than 5 mm. Tonouchi et al

in their review of more than 60 studies related to port site incisional hernias concluded that a defect of more than 10 mm requires closure at the fascial level, while there are varied opinions as to whether a defect of 5-mm should be closed.[33]

It is difficult to anticipate which patient will develop a trocar site incisional hernia during the follow-up period. By considering all the potential risk factors for the development of a trocar site hernia, focus can be on the reduction of its incidence and thus the serious complication of intestinal strangulation can be prevented.

Study site: The study was conducted in the Department of General Surgery at KLES Dr.PrabhakarKore Hospital and Medical Research Centre, Belagavi, Karnataka, India.

Study population: Patients who were admitted to KLES Dr.PrabhakarKore Hospital and Medical Research Centre and underwent laparoscopic gastrointestinal surgery.

Study design: Randomised Controlled Trial.

Study Period: January 2019 - December 2019.

Sample Size: The sample size was 60 patients, and 30 patients each were included in group A and group B.

(The mean d_1 and standard deviation S_1 for group A is 3.80 and 3.163. The mean d_2 and standard deviation S_2 for group B is 6.23 and 4.031.

Z alpha = 1.96 at 5% alpha error

Z beta = 0.842 at 20% beta error

S is average of S_1 and S_2

d is the difference between d_1 and d_2

$N = 2S^2\{z\ alpha + z\ beta\}^2 / d^2$

N is 30.3 participants in each group. Rounding off to 30. Substituting these values in the formula, N= 30 and enrolment ratio is 1:1.)

Randomization technique: Sequentially Numbered Opaque Sealed Envelopes (SNOSE).

Inclusion Criteria:

1. Patients admitted and undergoing any laparoscopic gastrointestinal surgery.
2. Age – 18 years and above.

Exclusion Criteria:

1. Immune-compromised patients.
2. Patients with peritonitis.

Ethical clearance

The study was approved by the JNMC Institutional Ethics Committee on Human Subjects Research.

Informed consent

Annexure I

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:

    - Haemoglobin
    - Total and differential leucocyte count
    - Platelet count
    - Blood grouping
    - PT/INR
    - Urine routine
    - Blood urea and Serum creatinine
    - HIV and HBsAg
    - ECG
    - Chest X-ray
    - USG-Abdomen and Pelvis

- The patients were then allocated into either of the two groups pre-operatively for port closure (allocated by random sampling - SNOSE), as:

Group A: Closure with absorbable multifilament polyglactin 910 (Vicryl^{TM}) using an 18 gauge spinal needle.

Group B: Closure with non-absorbable monofilament polypropylene (Prolene^{TM}) using an 18 gauge spinal needle.

PROCEDURE:

- All patients underwent laparoscopic surgery under general anaesthesia.
- Following the surgery, the 10 mm ports were closed using the allotted technique.

Group A-

- At the completion of the case, with pneumoperitoneum intact, 10 mm scope is removed and a 5 mm scope introduced, and the intra-abdominal side of the 10 mm port sites visualized.
- Vicryl suture material is threaded through an 18-gauge spinal needle and the needle is pushed at an angle by the side of the trocar site through the abdominal wall without piercing the skin.
- The needle is then removed, leaving the vicryl inside.
- A loop of vicryl suture is then made by passing it through the spinal needle and the needle is 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 is entangled in the loop of the spinal needle.
- The loop is tightened and the Spinal needle is retracted along with the suture end.

- Knot is tied after removing the 10 mm trocar.

Group B-

- Same procedure was followed as in Group A, but using a prolene suture material.

- Skin closure for all the port sites (both 10 mm and 5 mm) was done using 3-0 Ethilon in both the groups.
- Post-operatively, patients in both the groups received Paracetamol 1 gram IV 8th hourly for analgesia.

ASSESSMENT:

The patients from both the groups were assessed for post-operative pain after 12 hours, 24 hours, and 48 hours, using the Visual Analogue Scale (VAS).

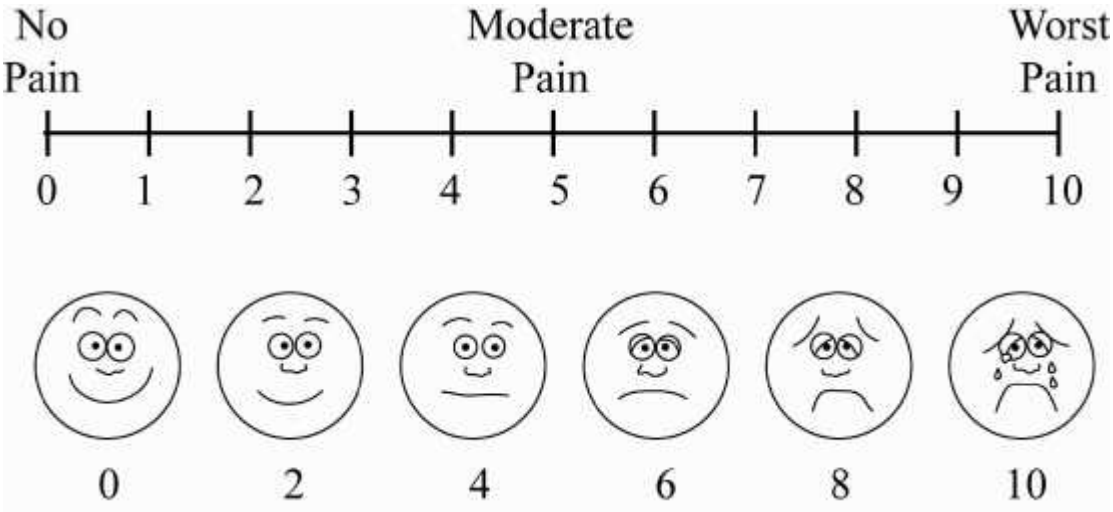


Fig. 8

The patients in both the groups were assessed for any seroma, hematoma and surgical site infection (SSI), using the Southampton Wound Scoring System. (After discharge, they were asked to report to the hospital if there are any signs of surgical site infection.)

They were assessed for port site hernia, in the long term during follow-up visits.

PORT CLOSURE USING SPINAL NEEDLE - TECHNIQUE:

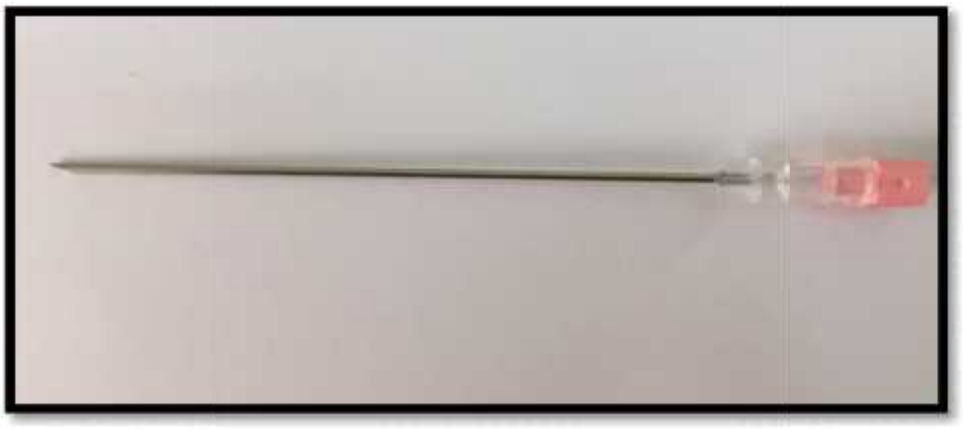


Fig. 9 18-Gauge Spinal Needle

Fig.10 2-0 Vicryl passed through an 18-gauze spinal needle

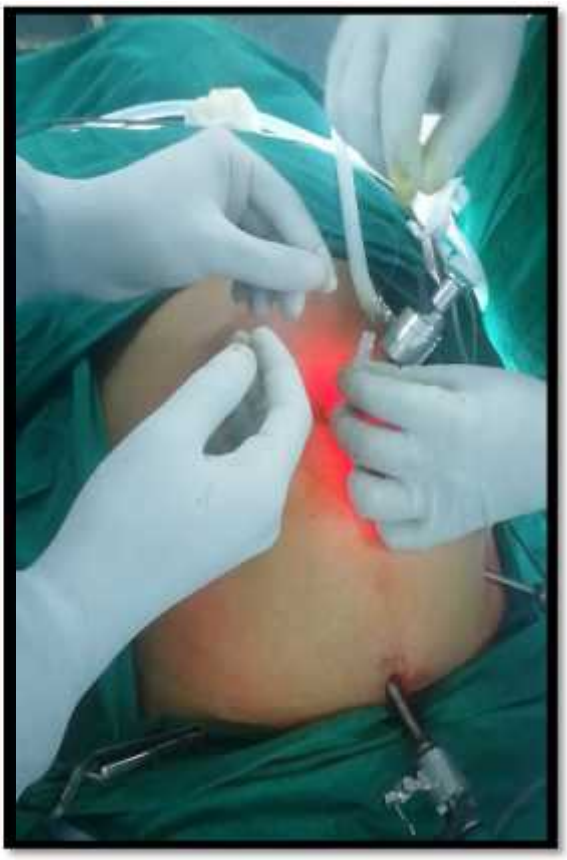


Fig.11 Threading of suture material through the needle

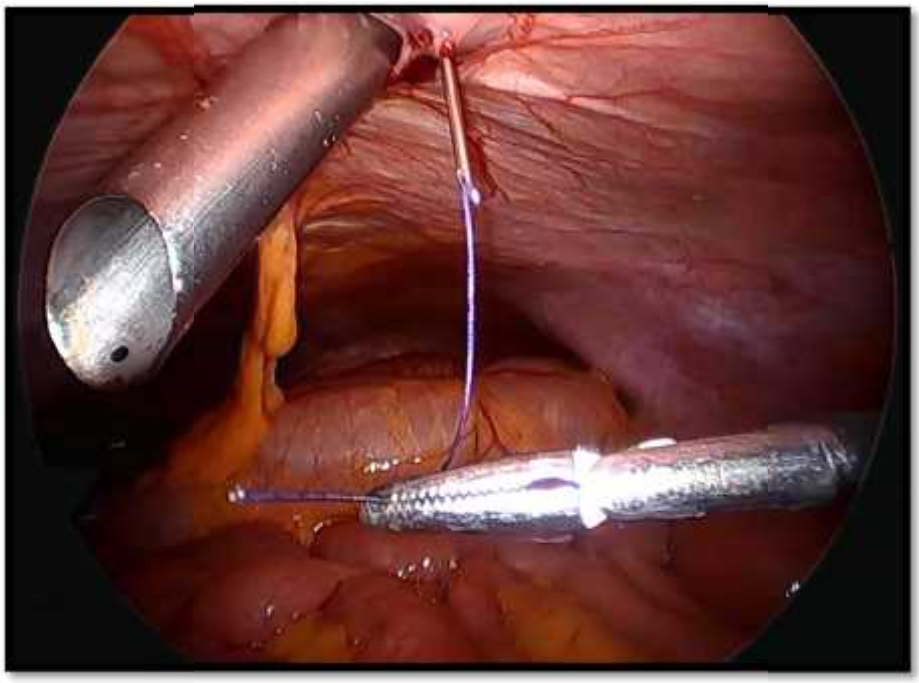


Fig.12 Intra-abdominal view of threading of the suture material through the needle. The end is grasped with Maryland forceps.

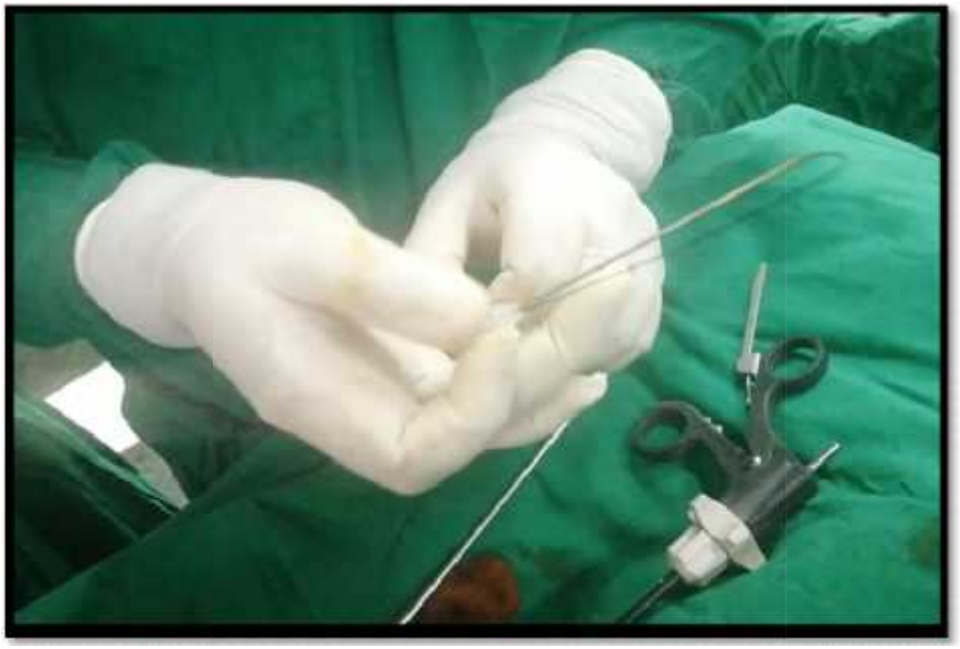


Fig.13 Forming a loop of through the distal end of the suture material

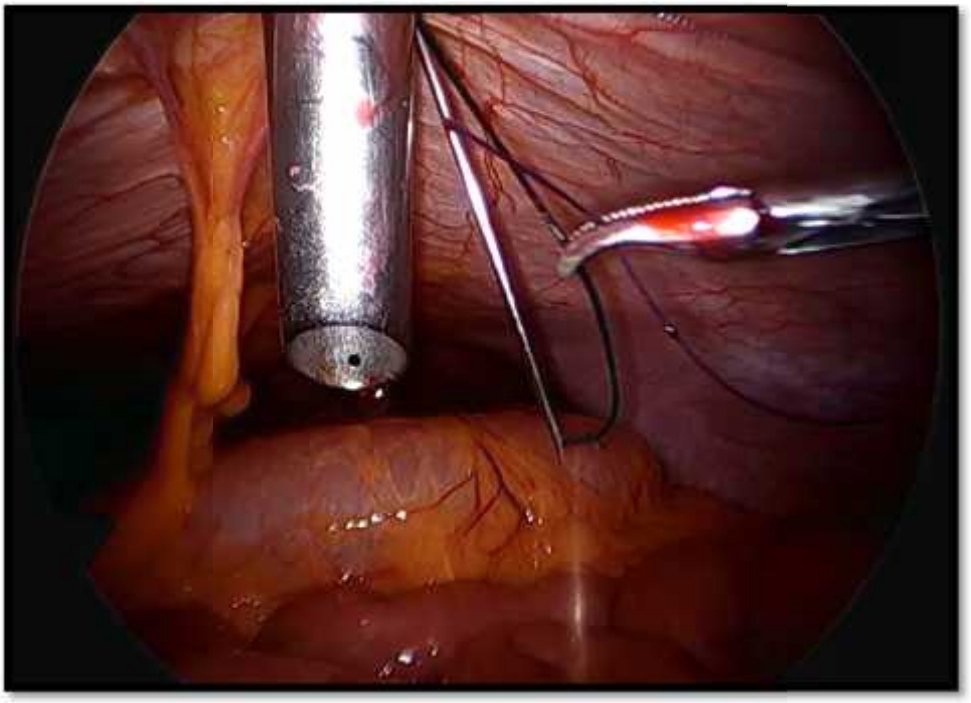


Fig. 14 Intra-abdominal view of the two ends of the suture material

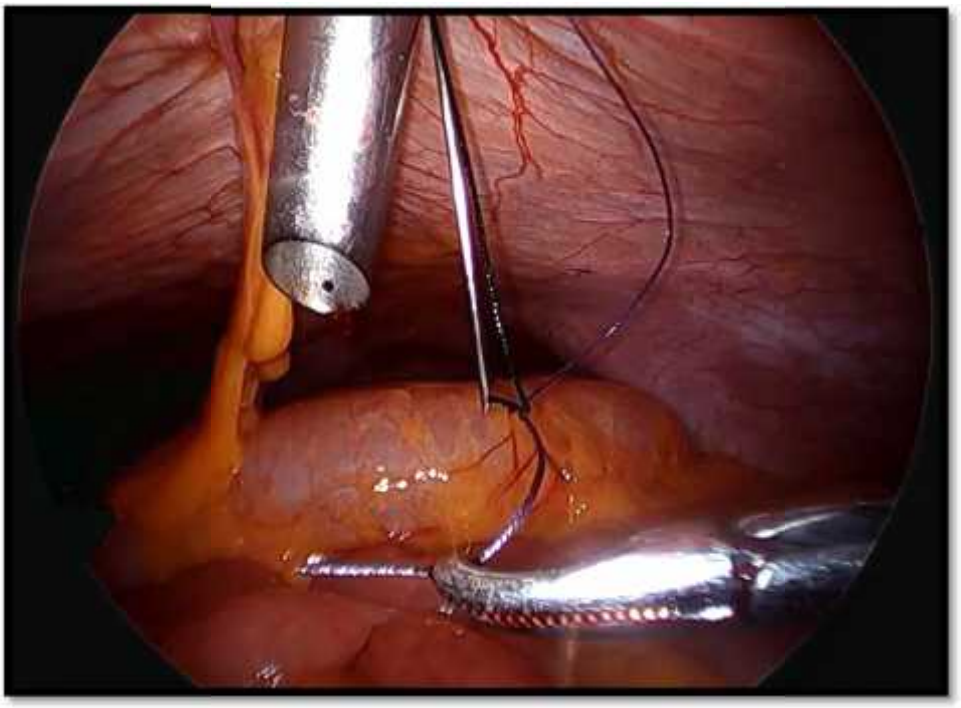


Fig. 15 Free end of the suture material entangled within the loop using Maryland forceps.

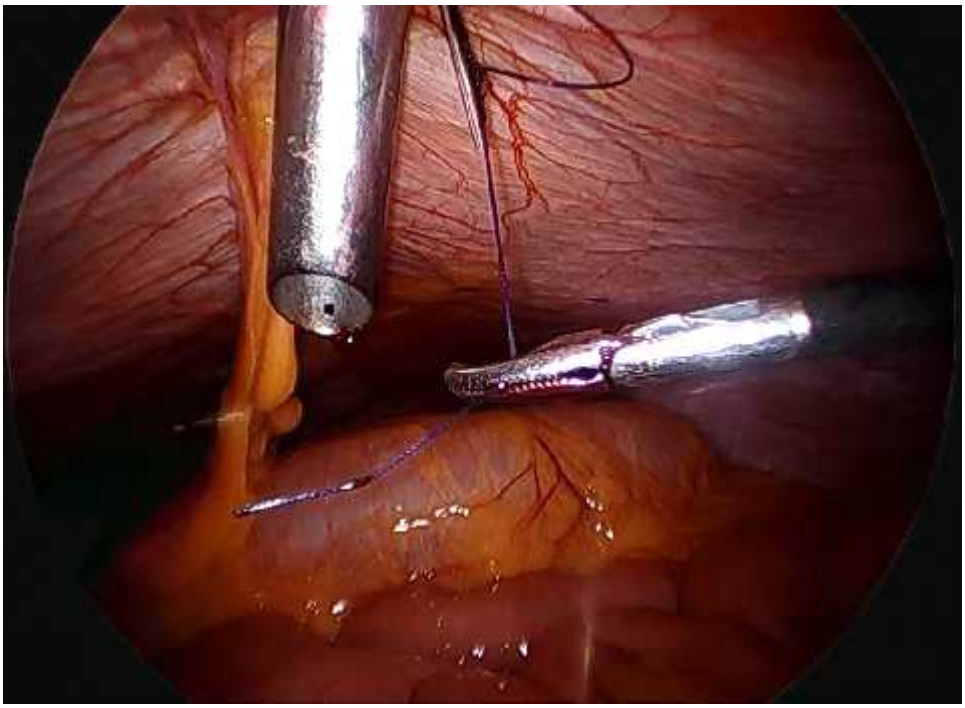


Fig.16 The loop is tightened and the needle withdrawn

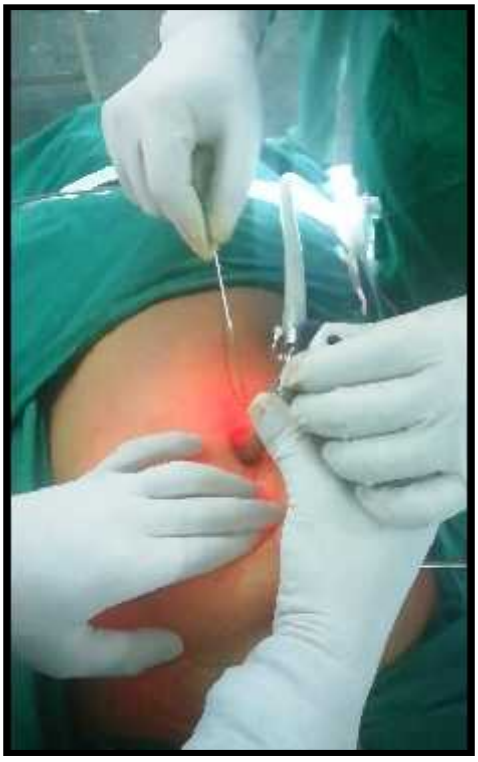


Fig.17 Both ends of the suture material brought out

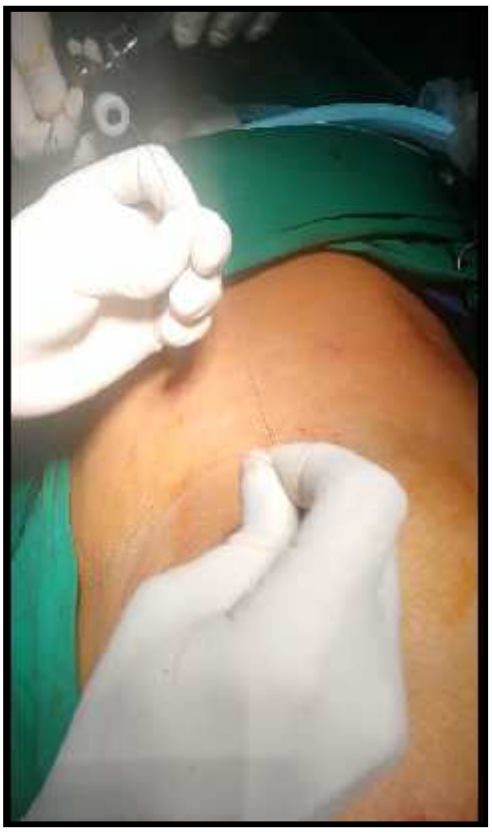


Fig.18 Knot tied approximating the facial defect

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 2019 and December 2019.

Allocation into two groups was randomised.

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

The Visual Analog Scale scores for time intervals of 12 hours, 24 hours and 48 hours after surgery were analysed.

The incidence of seroma, hematoma, surgical site infection and port site hernia were analysed.

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

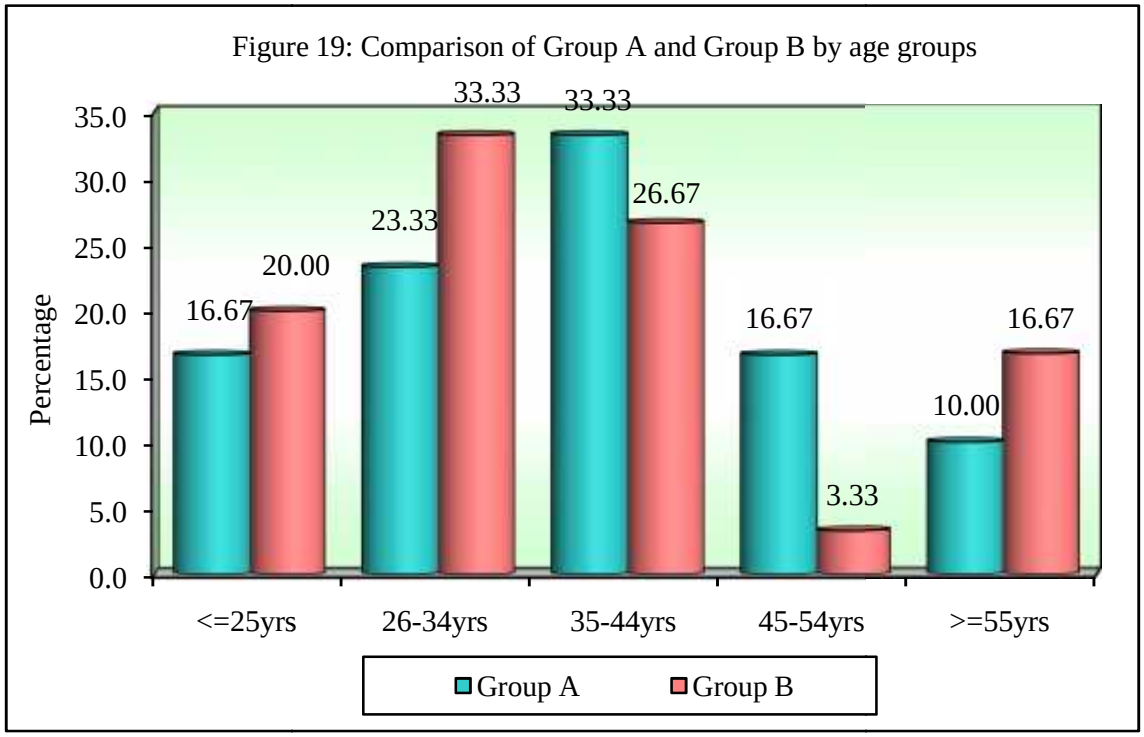
P value of <0.05 was significant.

1. <u>Age distribution:</u>

Patients above 18years of age were included in the study.In the study population, the mean age of the patients in group A was 38.57 years and that in Group B was 36.13 years.

Table 4: Comparison of the two study groups (Group A and Group B) with respect to mean age

Age groups	Group A	%	Group B	%	Total	%
<=25yrs	5	16.67	6	20.00	11	18.33
26-34yrs	7	23.33	10	33.33	17	28.33
35-44yrs	10	33.33	8	26.67	18	30.00
45-54yrs	5	16.67	1	3.33	6	10.00
>=55yrs	3	10.00	5	16.67	8	13.33
Total	30	100.00	30	100.00	60	100.00
Mean age	38.57		36.13		37.35	
SD age	15.09		13.65		14.32	
Chi-square test= 4.009, P = 0.4050						



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

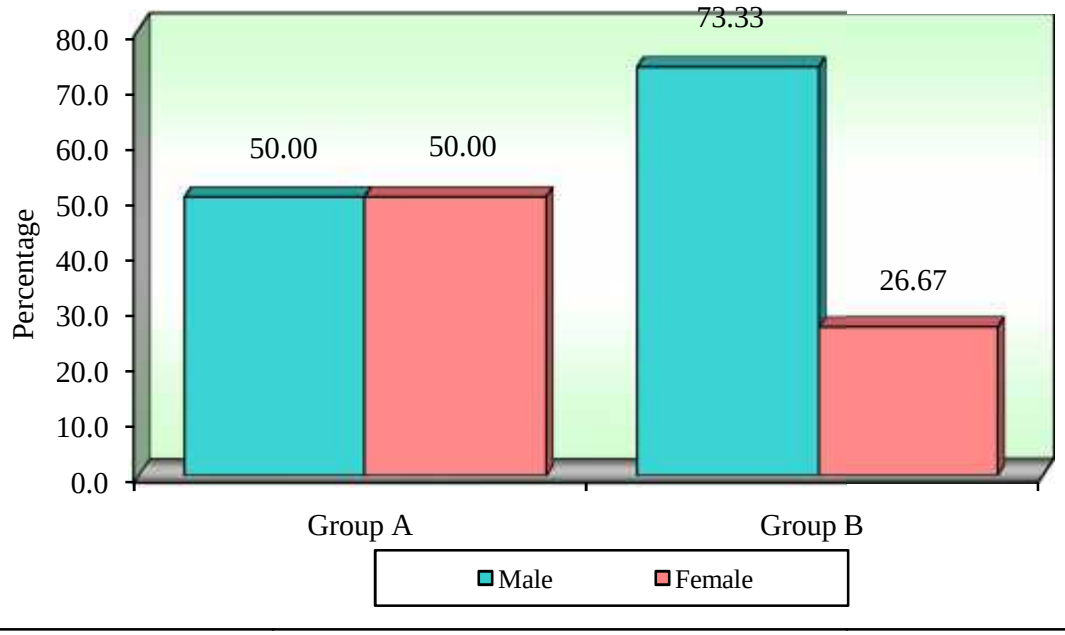
2. <u>Sex distribution</u>:

The table below, shows the sex distribution in both groups of the study population.

Table 5: Male and Female gender distribution in the two study groups (Group A and Group B)

Gender	Group A	%	Group B	%	Total	%
Male	15	50.00	22	73.33	37	61.67
Female	15	50.00	8	26.67	23	38.33
Total	30	100.00	30	100.00	60	100.00
Chi-square test 3.455 , P = 0.0630						

Figure 20: Comparison of Group A and Group B by gender



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

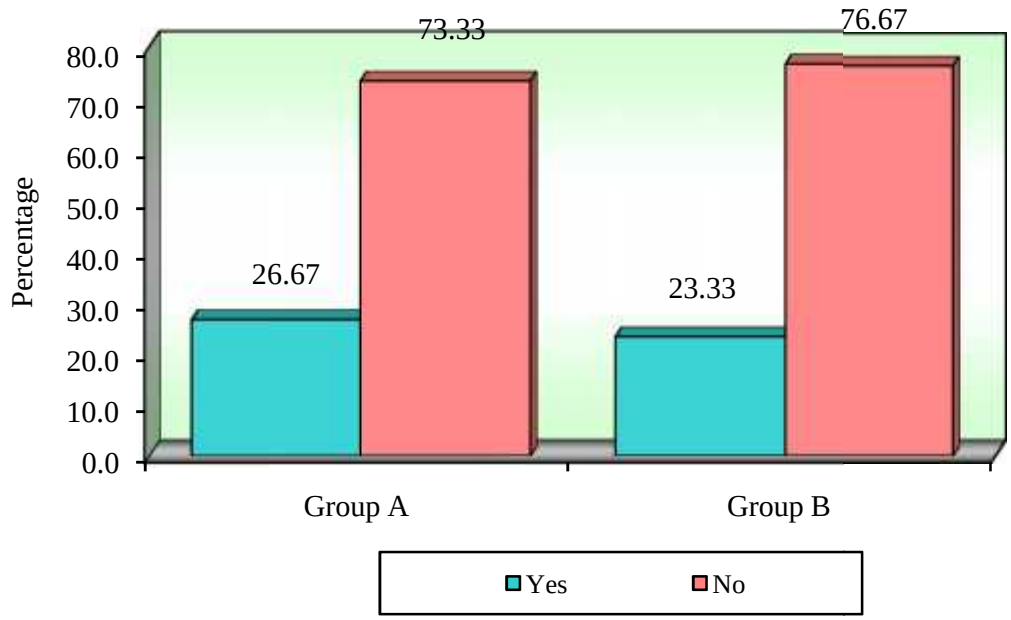
3. Diabetes Mellitus

The table below, shows the incidence of Diabetes mellitus in both groups of the study population.

Table 6: Comparison of Group A and Group B by the presence of diabetes mellitus

Diabetic mellitus	Group A	%	Group B	%	Total	%
Yes	8	26.67	7	23.33	15	25.00
No	22	73.33	23	76.67	45	75.00
Total	30	100.00	30	100.00	60	100.00
Chi-square test= 0.0890, P = 0.7660						

Figure 21: Comparison of Group A and Group B by presence of diabetes mellitus



4. Comparison of Post-Operative Pain by VAS scores:

Table 7: Comparison of Group A and Group B with post-operative pain scores at different time points by Mann-Whitney U test

Time points	Group A			Group B			U-value	Z-value	P-value
	Mean	SD	Mean rank	Mean	SD	Mean rank			
12 hours	5.93	1.01	35.23	5.33	1.12	25.77	308.00	-2.0994	0.0358*
24 hours	2.93	1.08	30.82	2.93	1.36	30.18	440.50	-0.1405	0.8883
48 hours	1.87	0.63	31.80	1.77	0.68	29.20	411.00	-0.5766	0.5642
12 hrs to 24 hrs	3.00	1.49	34.08	2.40	1.52	26.92	342.50	-1.5893	0.1120
12 hrs to 48 hrs	4.07	1.17	33.57	3.57	1.19	27.43	358.00	-1.3602	0.1738
24 hrs to 48 hrs	1.07	1.11	30.35	1.17	1.32	30.65	445.50	-0.0665	0.9470

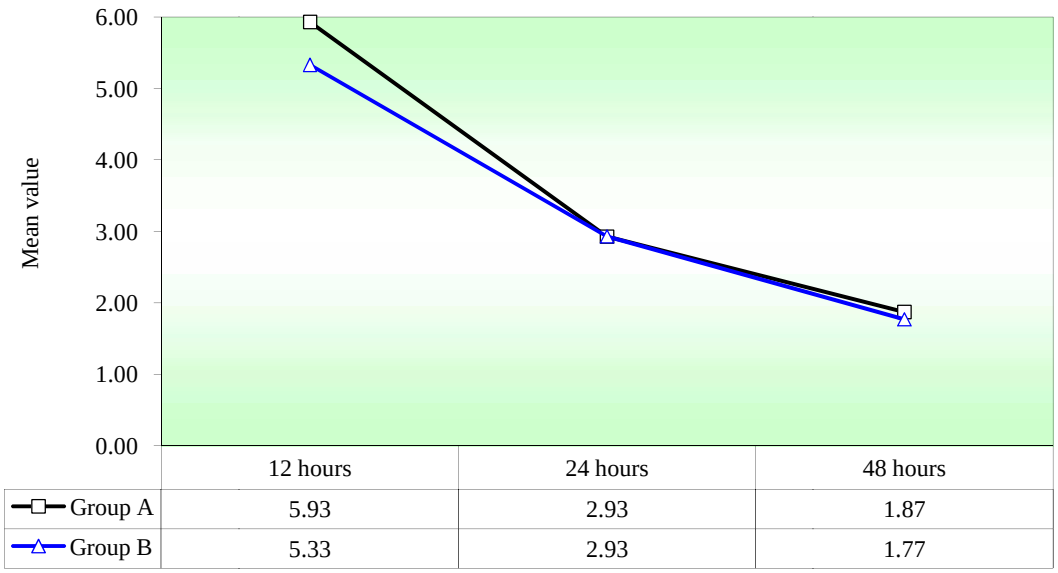
***p<0.05**

From the results of the above table, a significant difference was observed between Group A and Group B with respect to mean post operative pain scores at 12 hours (t=-2.0994, $p<0.05$) at 5% level of significance. It means that, **the post operative pain score is significantly higher in Group A as compared to Group B.** However, no significant difference was observed between the two groups with mean post operative pain scores at 24hrs and 48hrs of treatment ($p>0.05$).

Similarly, no significant difference was observed between the two groups with changes in mean post operative pain scores from 12hrs to 24hrs, 12hrs to 48hrs and 24hrs to 48hrs of treatment ($p>0.05$). It means that the performance in reducing the pain after different time points is same in the two groups ($p>0.05$).

Figure22

Figure:Comparison of Group A and Group B with post-operative pain scores at different time points



	12 hours	24 hours	48 hours
Group A	5.93	2.93	1.87
Group B	5.33	2.93	1.77

Figure 23

Figure:Comparison of Group A and Group B with post-operative pain scores at different time points

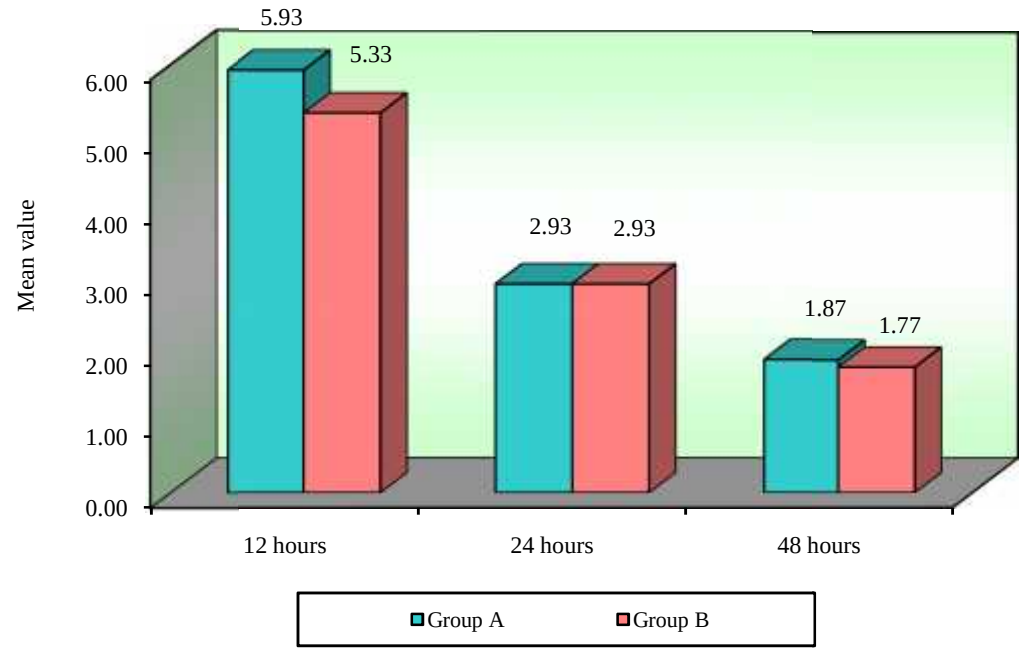


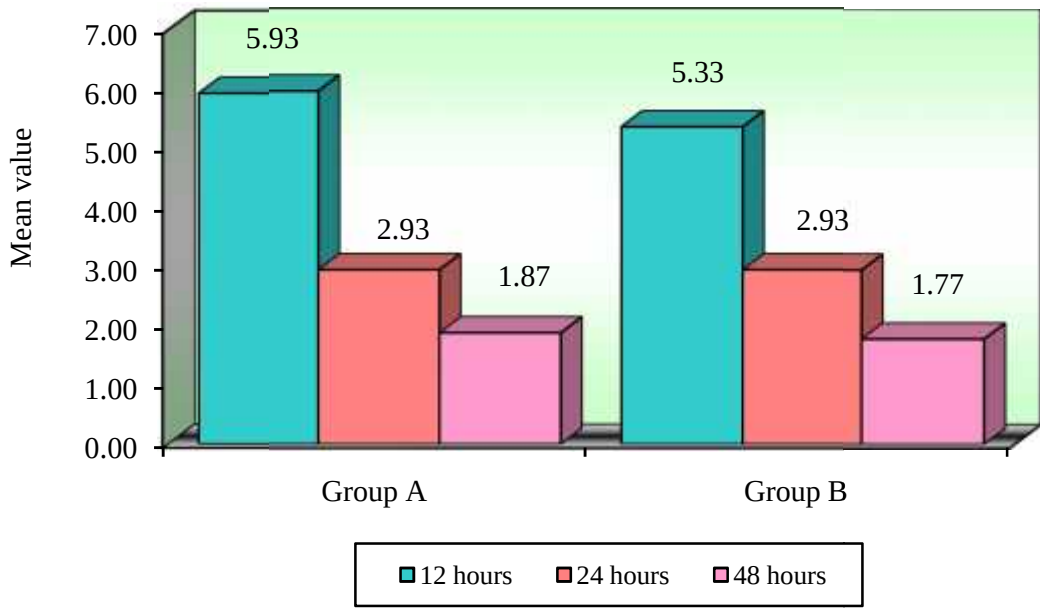
Table 8: Comparison of different time points with post-operative pain scores in Group A and Group B by Wilcoxon matched pairs test

Groups	Time points	Mean	SD	Mean Diff.	SD Diff.	% of change	Z-value	p-value
Group A	12 hours	5.93	1.01	3.00	1.49	50.56	4.6226	0.0001*
	24 hours	2.93	1.08					
	12 hours	5.93	1.01	4.07	1.17	68.54	4.7821	0.0001*
	48 hours	1.87	0.63					
	24 hours	2.93	1.08	1.07	1.11	36.36	3.7716	0.0002*
	48 hours	1.87	0.63					
Group B	12 hours	5.33	1.12	2.40	1.52	45.00	4.4573	0.0001*
	24 hours	2.93	1.36					
	12 hours	5.33	1.12	3.57	1.19	66.88	4.7821	0.0001*
	48 hours	1.77	0.68					
	24 hours	2.93	1.36	1.17	1.32	39.77	3.6322	0.0003*
	48 hours	1.77	0.68					

***p<0.05**

A significant reduction of 50.56% and 68.54% in post operative pain was seen after 24hours and 48 hours of treatment respectively in Group A, butonly a significant decrease of 36.36% in post operative pain scores from 24hours to 48hours of treatment in group A. However, a significant reduction of 45.00% and 66.88% post operative pain reduction was seen after 24hours and 48 hours of treatment respectively in Group B, but only a significant decrease of 39.77% in post operative pain scores from 24hours to 48hours of treatment in group B. It shows that, the pain reduction is higher in group A as compared to group B.

Figure 24: Comparison of different time points with post-operative pain scores in Group A and Group B

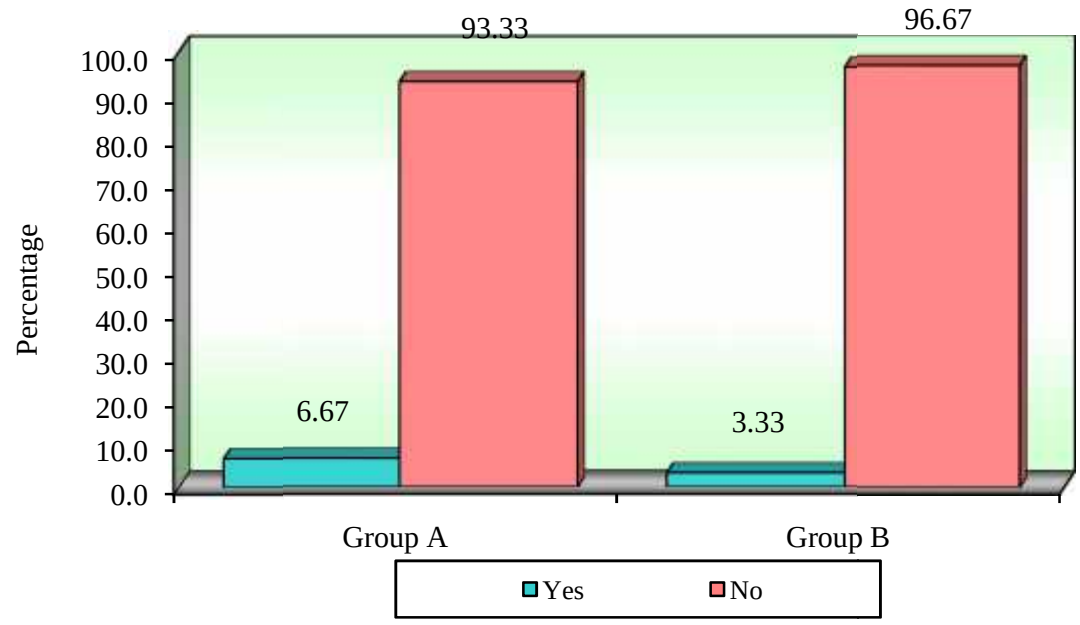


5. Seroma

Table 9: Comparison of Group A and Group B by status of Seroma

Seroma	Group A	%	Group B	%	Total	%
Yes	2	6.67	1	3.33	3	5.00
No	28	93.33	29	96.67	57	95.00
Total	30	100.00	30	100.00	60	100.00
Yates Chi-square = 0.0001 P = 1.0000						

Figure 25: Comparison of Group A and Group B by status of Seroma



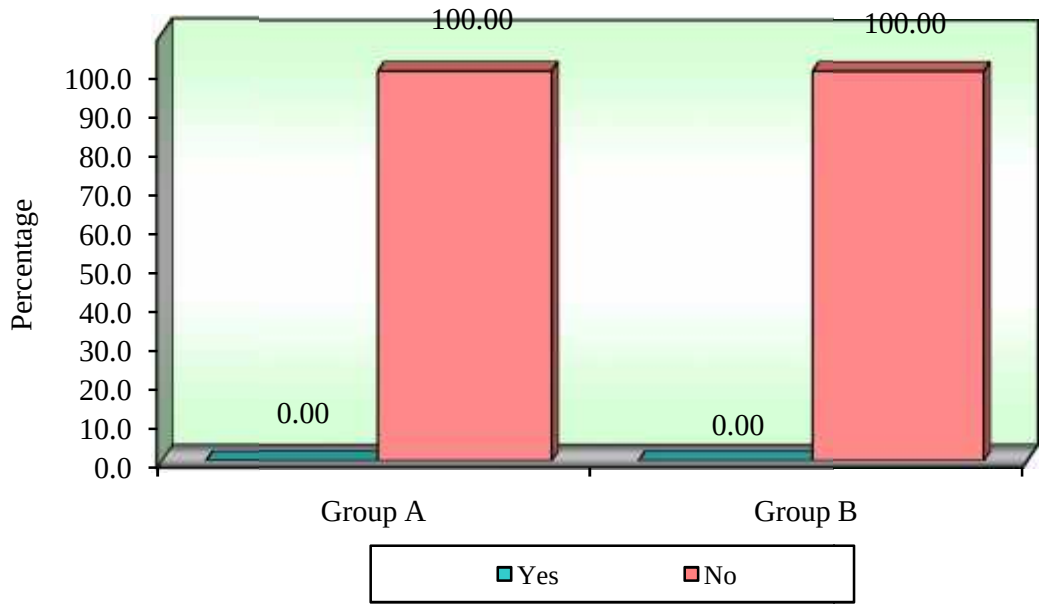
From the results of the above table, it can be seen that out of a total of 30 subjects in each group, 2 (6.67%) developed seroma in group A while just 1 (3.33%) developed seroma in group B. The difference or association is found to be statistically significant (Chi-square test = 0.0001, P = 1.0000) at 5% level of significance.

6. Hematoma

Table 10: Comparison of Group A and Group B by status of Hematoma

Hematoma	Group A	%	Group B	%	Total	%
Yes	0	0.0	0	0.0	0	0.0
No	30	100.00	30	100.00	60	100.00
Total	30	100.00	30	100.00	60	100.00
Chi-square test=0.0000 P = 1.0000						

Figure 26:Comparison of Group A and Group B by status of Hematoma



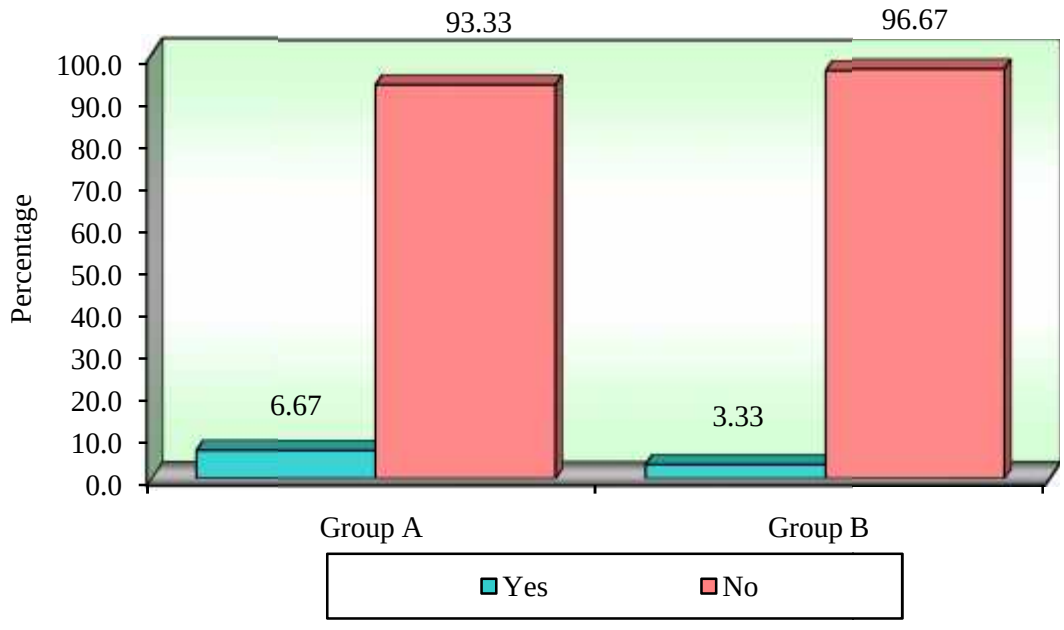
From the above table, it can be seen that out of a total of 30 subjects in each group, none have developed a hematoma.

7. Surgical Site Infection

Table 11: Comparison of Group A and Group B by Surgical Site Infection

Surgical Site Infection	Group A	%	Group B	%	Total	%
Yes	2	6.67	1	3.33	3	5.00
No	28	93.33	29	96.67	57	95.00
Total	30	100.00	30	100.00	60	100.00
Yates Chi-square =0.0001 P = 1.0000						

Figure 27: Comparison of Group A and Group B by Surgical Site Infection



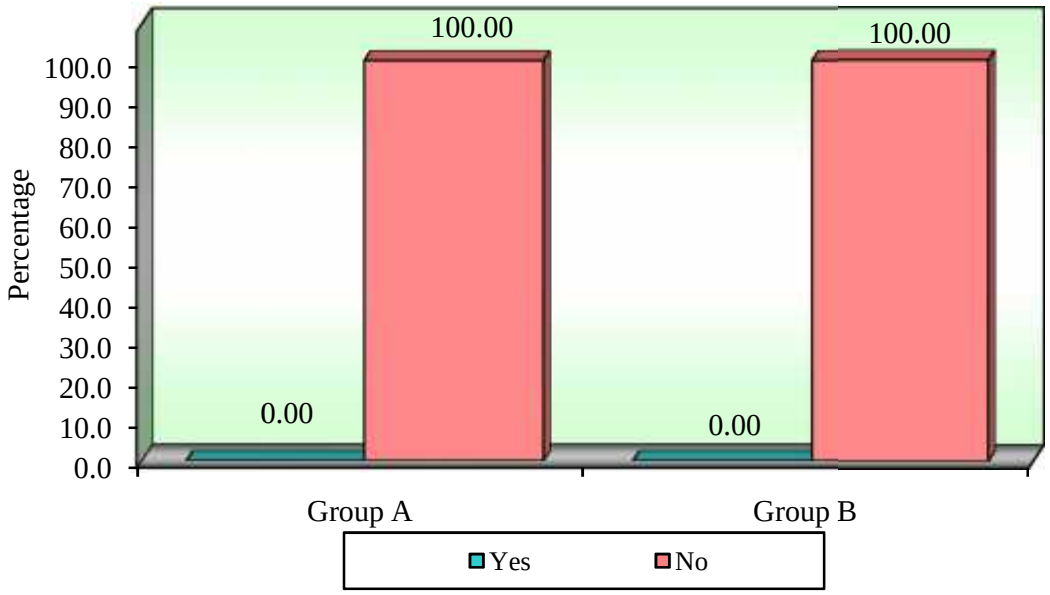
From the results of the above table, it can be seen that out of a total of 30 subjects in each group, 2 (6.67%) developed surgical site infection in group A while just 1 (3.33%) developed surgical site infection in group B. The difference or association is found to be statistically significant (Chi-square test = 0.0001, P = 1.0000) at 5% level of significance.

8. Port site hernia

Table 12: Comparison of Group A and Group B by status of Port site hernia

Port site hernia	Group A	%	Group B	%	Total	%
Yes	0	0.0	0	0.0	0	0.0
No	30	100.00	30	100.00	60	100.00
Total	30	100.00	30	100.00	60	100.00
Chi-square test=0.0000 P = 1.0000						

Figure 28:Comparison of Group A and Group B by status of Port site hernia



From the above table, it can be seen that out of a total of 30 subjects in each group, none has developed a port site hernia.

Reduced post-operative pain, decreased duration of hospital stay, quick return to normal activity, and a lower frequency of wound infection and other complications have made laparoscopic surgery a preferred choice in gastrointestinal procedures.

With the implementation of ERAS protocol and the introduction of the concept of ambulatory surgery, a lot of previous inpatient procedures are being done on an outpatient/ day care basis at present. 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."[38]Any post-operative complications will act as a setback in this regard, and hence their assessment is crucial in the era of Ambulatory Surgery.

The operative process is not considered complete until all the port sites larger than 10 mm are closed with a fascial suture. Closure of these wounds generally is quite difficult and rarely complete due to the small opening in the skin. The complications which occur most commonly at the port sites are persistent post-operative pain, surgical site infection and port site hernia. They depend on the technique used for the closure and also the suture material. Various types of port closure techniques have evolved, parallel to the evolution of the laparoscopic surgery.[2]

We did a randomised controlled trial with two different suture materials, Vicryl™ and Prolene™ using the spinal needle technique in 60 subjects undergoing laparoscopic procedures, with one group of 30 subjects undergoing fascial closure with vicryl and the other group of 30 subjects with prolene. The demographic parameters and the incidence of diabetes mellitus in both the groups were compared,

and the difference found to be statistically insignificant, and hence the groups were comparable.

In our study, a significant difference was observed between vicryl group and prolene group with respect to mean post-operative pain scores at 12 hours ($t=-2.0994$, $p<0.05$) at 5% level of significance. It means that the post-operative pain score is significantly higher in vicryl group as compared to prolene group. Our study also highlighted the proven fact that the intensity of pain escalates during the initial post-operative hours and usually subsides over the following days, thus making pain evaluation a fundamental requisite in the outcome assessment following any surgery.[23, 24]

In a study done by Lee et al, it is reported that the pain at the incision site is more intense than the visceral pain, even more during the first two days after a laparoscopic cholecystectomy.[39]Papagiannopoulou et al emphasized 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.[40] A study by Leggett et al concluded that "patients undergoing the procedure with the shorter incisions experienced significantly less pain".[41]

In our study, among the vicryl group, 2 (6.67%) subjects had seroma formation while in the prolene group, 1 (3.33%) subject had seroma formation. Even though the incidence of seroma was higher in vicryl group, the difference was not statistically significant ($P = 1.0000$). Also, among the vicryl group, 2 (6.67%) subjects had surgical site infection while in the prolene group, 1 (3.33%) subject had surgical site infection. Even though the incidence was higher in vicryl group, this difference was also not statistically significant ($P = 1.0000$).

Similar to our study, Bloemen et al in their trial comparing prolene and polydioxanone (absorbable) for midline fascial closure found that, in the prolene group 6.3% developed surgical site infection, lower than the 7.7% in polydioxanone (absorbable) group. But their result was also not statistically significant.[42]

In our study, port site hernias could not be assessed for more than 6 months as our study period was limited to one year. No early onset port site incisional hernias were reported in our study. Further evaluation needs to be done for assessment of late-onset port site hernias. Various comorbidities were also linked to incisional hernias, which include diabetes mellitus, renal impairment, pulmonary insufficiency and immune deficiency status,which have already been studied extensively.[34-36]

Though minimally invasive, laparoscopic surgeries are not without their associated complications. Addressing these as a major factor in determining the patient's recovery post-surgery is crucial as they tend to mask the other associated advantages associated with laparoscopy. The incidence of these complications increase with the port size.

The importance of a proper technique in closing the port sites is well established, and to prevent complications, fascial closure is recommended for ports of size more than 10 mm in adults and more than 5 mm in children.[4] There is no consensus at present whether the absorbable sutures are better or the non-absorbable sutures.

This study compared the post-operative port site complications (pain, surgical site infection, and hernia), after the fascialclosure of 10 mm port sites with an absorbable multifilament suture (Vicryl^{TM}) and a non-absorbable monofilament suture (Prolene^{TM}) using spinal needle in subjects undergoing laparoscopic gastrointestinal surgeries. Subjects in the prolene suture group experienced significantly lesser post-operative pain scores at 12 hours, when compared with the vicryl suture group. The post-operative complications like seroma formation and surgical site infection were also lesser in the prolene suture group, as compared to vicryl suture group, but these differences did not attain statistical significance.

Hence, we feel that there is a need for further large scale prospective studies to understand the efficacy and safety in different population sub groups to look for a correlation as it will help in establishing a standard of care protocol and also help the patients to have an uneventful post-operative recovery.

This study was conducted at KLES Dr PrabhakarKore Hospital and Medical Research Centre, Belagavi between January 2019 and December 2019.

A total of sixty patients who were undergoing laparoscopic gastrointestinal procedures were included in the study of whom thirty patients underwent closure of the 10 mm port sites with absorbable multifilament suture (Vicryl^{TM}) and the other thirty with non-absorbable monofilament suture (Prolene^{TM}).

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

There was a significant reduction in the post-operative pain after first 12 hours in the patients who underwent port closure with Prolene. There was also lower incidence of seroma formation and surgical site infections in the Prolene group, but this was not statistically significant.

Hence, there is a need for further prospective studies with a larger sample size to come to a conclusion regarding the superiority of a particular suture material for port site fascial closure.

1. Soper N, Brunt L, Kerbl K. Laparoscopic General Surgery. New England Journal of Medicine. 1994;330(6):409-419.
2. Elashry OM, Nakada SY, Wolf JS, Jr., Figenshau RS, McDougall EM, Clayman RV. Comparative clinical study of port-closure techniques following laparoscopic surgery. J Am Coll Surg. 1996;183(4):335-44.
3. Rastogi V, Dy V. Simple technique for proper approximation and closure of peritoneal and rectus sheath defects at port site after laparoscopic surgery. J Laparoendosc Adv Surg Tech A. 2001;11(1):13-6.
4. Di Lorenzo N, Coscarella G, Lirosi F, Gaspari A. Port-site closure: a new problem, an old device. Jsls. 2002;6(2):181-3.
5. Shaher Z. Port closure techniques. Surgical Endoscopy. 2007;21(8):1264-1274.
6. Critchlow JT. Trocar site closure: a simple, inexpensive technique. JSLS. 1997;1(3):273-5.
7. Rucinski J, Margolis M, Panagopoulos G, Wise L. Closure of the abdominal midline fascia: meta-analysis delineates the optimal technique. Am Surg. 2001;67(5):421-6.
8. van 't Riet M, Steyerberg EW, Nellensteyn J, Bonjer HJ, Jeekel J. Meta-analysis of techniques for closure of midline abdominal incisions. Br J Surg. 2002;89(11):1350-6.
9. Thomas Schlich. The Palgrave Handbook of the History of Surgery. 1st ed. London: Palgrave Macmillan; 2018.
10. Litynski GS. Laparoscopy - The Early Attempts: Spotlighting Georg Kelling and Hans Christian Jacobaeus. JSLS. 1997;1(1):83–5.

11. Nezhat F. Triumphs and controversies in laparoscopy: the past, the present, and the future. Jsls. 2003;7(1):1-5.
12. Udwadia T. Laparoscopy in India - A personal perspective. Journal of Minimal Access Surgery. 2005;1(2):51.
13. Nagarsheth NP, Rahaman J, Cohen CJ, Gretz H, Nezhat F. The incidence of port-site metastases in gynecologic cancers. JSLS. 2004;8(2):133-9.
14. Sirito R, Puppo A, Centurioni M, Gustavino C. Incisional hernia on the 5-mm trocar port site and subsequent wall endometriosis on the same site: A case report. American Journal of Obstetrics and Gynecology. 2005;193(3):878-880.
15. Uslu HY, Erkek AB, Cakmak A, Kepenekci I, Sozener U, Kocaay FA, Turkcapar AG, Kuterdem E. Trocar site hernia after laparoscopic cholecystectomy. J Laparoendosc Adv Surg Tech A. 2007;17(5):600-3.
16. Hamood MA MR. Different port closure techniques in laparoscopy surgery. World J Laparosc Surg. 2009(2(3)):29–38.
17. Tsen L, Hepner D. Needles used for spinal anesthesia. Expert Rev Med Devices. 2006 Aug 1;3:499–508.
18. Calthorpe N. The history of spinal needles: getting to the point. Anaesthesia. 2004;59(12):1231–41.
19. Md Cmt Jr, Md Kenneth L Mattox,, B. Mark Evers, Md Rdb Md. Sabiston Textbook of Surgery: The Biological Basis of Modern Surgical Practice. 19th ed. Phladelphia: Elsevier Saunders; 2012.
20. Wills VL, Hunt DR. Pain after laparoscopic cholecystectomy. Br J Surg. 2000 Mar 1;87(3):273–84.

21. Power I, Barratt S. Analgesic agents for the postoperative period: Nonopioids. Surg Clin North Am. 1999 Apr 1;79(2):275–95.

22. Wilmore DW, Kehlet H. Management of patients in fast track surgery. BMJ. 2001 Feb 24;322(7284):473–6.

23. Ure BM, Troidl H, Spangenberger W, Dietrich A, Lefering R, Neugebauer E. Pain after laparoscopic cholecystectomy. Intensity and localization of pain and analysis of predictors in preoperative symptoms and intraoperative events. Surg Endosc. 1994 Feb;8(2):90–6.

24. Pain after laparoscopic cholecystectomy - Slim - 2000 - BJS - Wiley Online Library [Internet]. [cited 2020 Aug 21]. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1046/j.1365-2168.2000.01522-3.x?sid=nlm%3Apubmed

25. Preincisional local infiltration of levobupivacaine vs ropivacaine for pain control after laparoscopic cholecystectomy | SpringerLink [Internet]. [cited 2020 Aug 21]. Available from: https://link.springer.com/article/10.1007/ s00464-002-9256-1

26. Mouton WG, Bessell JR, Otten KT, Maddern GJ. Pain after laparoscopy. Surg Endosc. 1999 May 1;13(5):445–8.

27. Berberoğlu M, Dilek ON, Ercan F, Kati I, Özmen M. The Effect of CO2 Insufflation Rate on the Postlaparoscopic Shoulder Pain. J Laparoendosc Adv Surg Tech. 1998 Oct 1;8(5):273–7.

28. Reichman DE, Greenberg JA. Reducing surgical site infections: a review. Rev Obstet Gynecol. 2009;2(4):212-21.

29. Ban K, Minei J, Laronga C, Harbrecht B, Jensen E, Fry D et al. American College of Surgeons and Surgical Infection Society: Surgical Site Infection Guidelines, 2016 Update. 2020.
30. Anderson DJ, Podgorny K, Berrios-Torres SI, et al. Strategies to prevent surgical site infections in acute care hospitals: 2014 update. Infect Control Hosp Epidemiol 2014;35:605e627.
31. Neumayer L, Hosokawa P, Itani K, et al. Multivariable predictors of postoperative surgical site infection after general and vascular surgery: results from the patient safety in surgery study. J Am Coll Surg 2007;204:1178e1187.
32. Campbell DA Jr, Henderson WG, Englesbe MJ, et al. Surgical site infection prevention: the importance of operative duration and blood transfusion-results of the first American College of Surgeons-National Surgical Quality Improvement Program Best Practices Initiative. J Am Coll Surg 2008;207:810e820.
33. Tonouchi H, Ohmori Y, Kobayashi M, Kusunoki M. Trocar site hernia. Arch Surg. 2004;139(11):1248-56.
34. Coda A, Bossotti M, Ferri F, Mattio R, Ramellini G, Poma A, et al. Incisional hernia and fascial defect following laparoscopic surgery. Surg Laparosc Endosc Percutan Tech 2000;10(1):34-8.
35. Nassar A, Ashkar K, Rashed A, Abdulmoneum M. Laparoscopic cholecystectomy and the umbilicus. Br J surg. 1997;84(5):630-3.
36. Azurin DJ, Go LS, Arroyo LR, Kirkland ML. Trocar site herniation following laparoscopic cholecystectomy and the significance of an incidental preexisting umbilical hernia. Am Surg. 1995;61(8):718-20.

37. Hussain A, Mahmood H, Singhal T, Balakrishnan S, Nicholls J, El-Hasani S. Long-term study of port-site incisional hernia after laparoscopic procedures. JSLS. 2009;13(3):346.

38. Skattum J, Edwin B, Trondsen E, Mjåland O, Raeder J, Buanes T. Outpatient laparoscopic surgery: feasibility and consequences for education and health care costs. Surg Endosc Interv Tech. 2004 May 1;18(5):796–801.

39. Lee I-O, Kim S-H, Kong M-H, Lee M-K, Kim N-S, Choi Y-S, et al. Pain after laparoscopic cholecystectomy: the effect and timing of incisional and intraperitoneal bupivacaine. Can J Anesth. 2001 Jun 1;48(6):545–50.

40. Papagiannopoulou P, Argiriadou H, Georgiou M, Papaziogas B, Sfyra E, Kanakoudis F. Preincisional local infiltration of levobupivacaine vs ropivacaine for pain control after laparoscopic cholecystectomy. Surg Endosc Interv Tech. 2003 Dec 1;17(12):1961–4.

41. Leggett PL, Churchman-Winn R, Miller G. Minimizing ports to improve laparoscopic cholecystectomy. Surg Endosc. 2000 Jan 1;14(1):32–6.

42. Bloemen A, van Dooren P, Huizinga B, Hoofwijk A. Randomized clinical trial comparing polypropylene or polydioxanone for midline abdominal wall closure. British Journal of Surgery. 2011;98(5):633-639.

ANNEXURE I – CONSENT FORM

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr/Mrs/Miss. _____, we are requesting you to enroll yourself in the study titled **"COMPARISON OF ABSORBABLE MULTIFILAMENT SUTURE (VICRYL^{TM}) AND NON-ABSORBABLE MONOFILAMENT SUTURE (PROLENE^{TM}) IN LAPAROSCOPIC PORT SITE CLOSURE USING SPINAL NEEDLE - A HOSPITAL BASED RANDOMISED CONTROLLED TRIAL",**conducted by **REG NO: BH0118010,** Post Graduate student in M.S. General Surgery, under the guidance of **Dr ,** Professor,Department of General Surgery, Jawaharlal Nehru Medical College, KAHER, 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 KLESDr Prabhakar Kore Hospital and Medical Research Centre. If you decide not to participate, you are free to withdraw at any point of time, even after the start of the study. 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 port site complications (pain, infection, and hernia), following port closure using two methods in patients

undergoing laparoscopic gastrointestinal surgeries. The principal investigator of the study is **REG NO: BH0118010**, under the guidance of **Dr**. _____

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 – absorbable multifilament polyglactin 910 (Vicryl^{TM}); Group B –non-absorbable monofilament polypropylene (Prolene^{TM}), by SNOSE (Sequentially Numbered Opaque Sealed Envelope).

You will undergo laparoscopic surgery under General Anesthesia.The 10mm ports will be closed using the suture material allotted. The skin closure for all ports will be done using Ethilon 3-0 in both the groups. Following the surgery, you will be shifted to the recovery area for post-operative monitoring.

Post-operative pain will be assessed using Visual Analogue Scale (VAS) and graded at 12, 24 and 48 hours. Intensity of pain will be assessed by using 10-point VAS score representing various intensities 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 complications in comparison with the two suture materials involved. The results derived at the end of this study will benefit all similar patients admitted to this hospital and elsewhere.

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/ hospital. You will be givenall the information that might affect your decision to participate in the study. The investigator may also exclude any 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 any others 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 complication or injury occurs during the period of study, the participant will be given treatment within the limitations of KLESDr 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 in the study. By signing this consent form, I am not giving up any of my legal rights. I may withdraw from the study at any point of time. I am signing the consent form after having read or having been read to me all the information regarding the study 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:

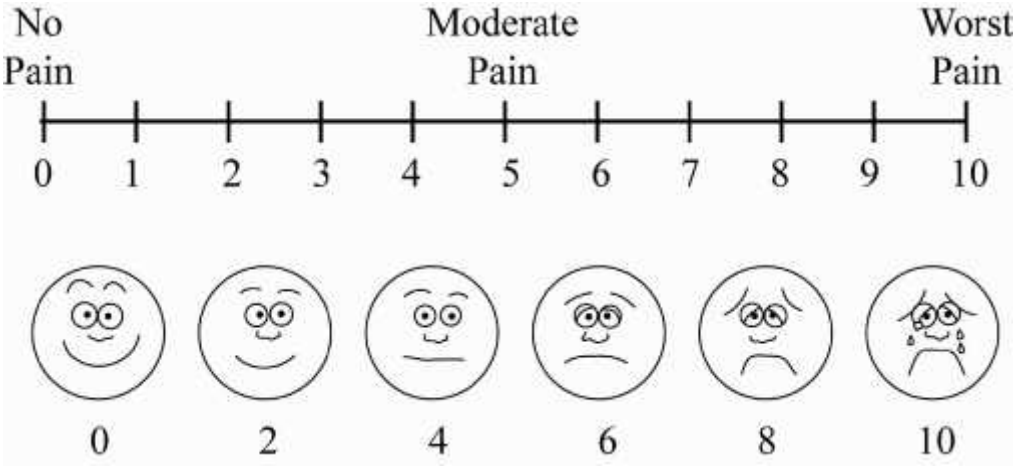
Date of Surgery:

Anesthesia: General Anesthesia

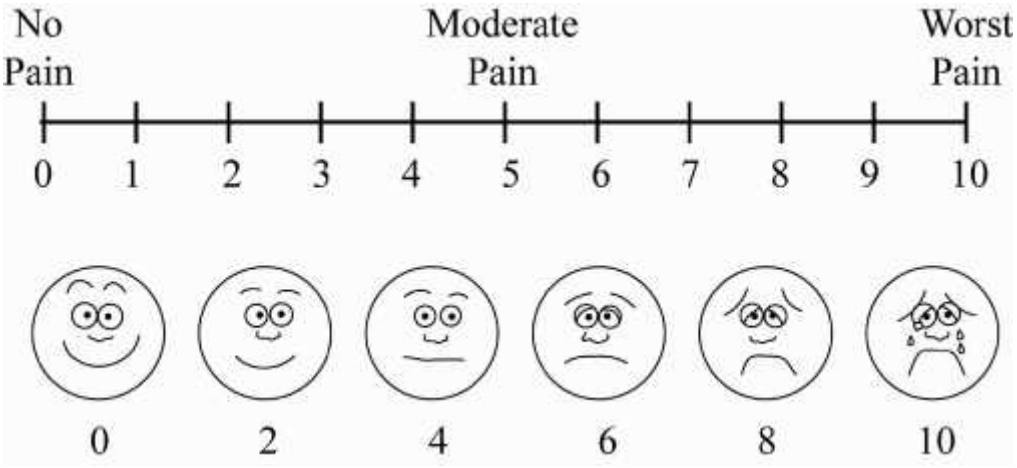
Duration of Surgery:

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

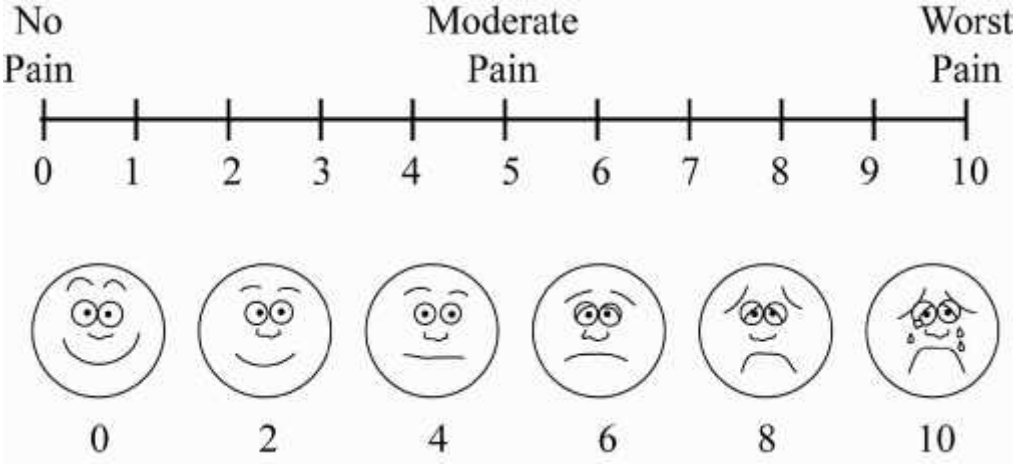
VAS AFTER 12 HOURS:



VAS AFTER 24 HOURS:



VAS AFTER 48 HOURS:



ASSESSMENT OF POST OPERATIVE WOUND

The patients in both the groups were assessed for any seroma, hematoma and surgical site infection (SSI), using the Southampton Wound Scoring System. (After discharge, they were asked to report to the hospital if there are any signs of surgical site infection.)

Southampton Wound Scoring System

GRADE 0 Normal Healing

GRADE I Normal Healing with mild bruising or erythema

A Some bruising

B Considerable bruising

C Mild erythema

GRADE II Erythema plus other signs of inflammation

A At one point

B Around sutures

C Along wound

D Around wound

GRADE III Clear or Haemoserous discharge

A At one point only (<2cm)

B Along wound (>2cm)

C Large volume

D Prolonged (>3days)

GRADE IV Pus

A At one point only (<2cm)

B Along wound (>2cm)

GRADE V Deep or severe wound infection with or without tissue breakdown; hematoma requiring aspiration

They were also assessed for port site hernia, in the long term during follow-up visits.

ANNEXURE III.

ETHICAL CLEARANCE.

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed – to- be- University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu
Phone: (+ 91-(0)831 Office : 2472550
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/02 **Date: 24/11/2018**

To,

REG NO: BH0118010
PG student in Surgery,
J.N.Medical College,
BELAGAVI.

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 ABSORBABLE MULTIFILAMENT SUTURE (VICRYL™) AN NON-ABSORBABLE MONOFILAMENT SUTURE (PROLENE™) IN LAPAROSC(PORT SITE CLOSURE USING SPINAL NEEDLE - A HOSPITAL BASED RANDOM CONTROL 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.

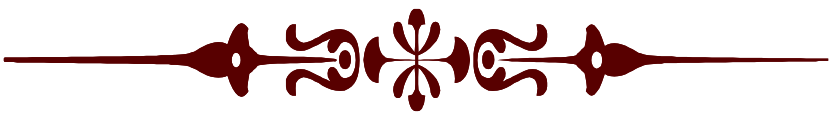
GROUP A

S. No	Group	Age	Sex	Diabetes Mellitus	Post-Operative Pain (VAS)			Seroma	Hematoma	Surgical Site Infection	Port site hernia
				Y-1/N-2	After 12 Hours	After 24 Hours	After 48 Hours	Y-1/N-2	Y-1/N-2	Y-1/N-2	Y-1/N-2
1	A	50	F	2	7	4	3	2	2	2	2
2	A	49	M	2	5	3	2	2	2	2	2
3	A	30	M	2	4	3	2	2	2	2	2
4	A	38	M	1	6	4	1	2	2	2	2
5	A	30	F	2	6	4	2	2	2	2	2
6	A	21	M	2	7	3	1	2	2	2	2
7	A	50	F	1	7	2	2	2	2	2	2
8	A	68	F	1	6	3	2	2	2	2	2
9	A	42	F	2	6	3	2	2	2	2	2
10	A	26	F	2	5	2	1	2	2	2	2
11	A	35	F	2	5	3	2	2	2	2	2
12	A	82	M	2	6	2	2	1	2	2	2
13	A	39	F	1	8	4	2	2	2	2	2
14	A	26	F	2	5	2	1	2	2	2	2
15	A	39	M	2	6	3	2	2	2	1	2
16	A	49	F	1	7	2	1	2	2	2	2
17	A	35	F	2	5	5	3	2	2	2	2
18	A	25	M	2	6	6	2	2	2	2	2
19	A	28	M	2	6	2	3	2	2	2	2
20	A	68	M	1	6	3	1	1	2	2	2
21	A	35	F	2	7	2	2	2	2	2	2
22	A	24	M	2	5	3	2	2	2	2	2
23	A	38	F	1	6	4	3	2	2	1	2
24	A	19	F	2	5	3	2	2	2	2	2
25	A	28	F	2	8	2	2	2	2	2	2
26	A	35	M	2	5	1	2	2	2	2	2
27	A	29	M	2	6	3	2	2	2	2	2
28	A	44	M	2	4	3	1	2	2	2	2
29	A	54	M	1	6	1	2	2	2	2	2
30	A	21	M	2	7	3	1	2	2	2	2

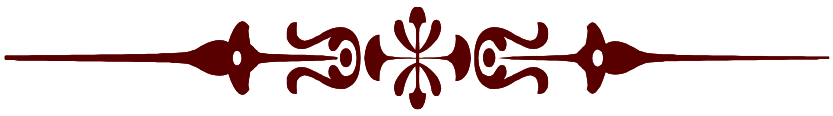
GROUP B

S. No	Group	Age	Sex	Diabetes Melitus	Post-Operative Pain (VAS)			Seroma	Hematoma	Surgical Site Infection	Port site hernia
				Y-1/N-2	After 12 Hours	After 24 Hours	After 48 Hours	Y-1/N-2	Y-1/N-2	Y-1/N-2	Y-1/N-2
1	B	40	M	2	5	3	2	2	2	2	2
2	B	29	F	2	4	4	3	2	2	2	2
3	B	35	F	2	5	3	1	2	2	2	2
4	B	19	M	2	7	4	2	2	2	2	2
5	B	30	M	2	5	5	2	2	2	2	2
6	B	27	M	2	6	2	1	2	2	2	2
7	B	39	F	1	5	3	2	2	2	2	2
8	B	56	M	1	8	3	3	2	2	2	2
9	B	27	M	2	5	4	2	2	2	2	2
10	B	70	M	2	6	1	1	2	2	2	2
11	B	58	F	1	5	3	1	2	2	1	2
12	B	35	M	2	4	2	2	2	2	2	2
13	B	18	M	2	6	4	1	2	2	2	2
14	B	30	M	2	5	3	2	2	2	2	2
15	B	55	M	1	4	2	2	2	2	2	2
16	B	29	M	2	5	2	1	2	2	2	2
17	B	65	M	2	7	7	3	2	2	2	2
18	B	26	F	2	6	2	2	1	2	2	2
19	B	32	M	2	5	1	1	2	2	2	2
20	B	22	M	2	6	3	3	2	2	2	2
21	B	30	F	2	5	2	2	2	2	2	2
22	B	36	M	2	7	4	1	2	2	2	2
23	B	42	F	1	5	5	2	2	2	2	2
24	B	40	M	2	4	2	2	2	2	2	2
25	B	42	M	1	5	3	1	2	2	2	2
26	B	23	F	2	4	1	2	2	2	2	2
27	B	25	M	2	3	2	1	2	2	2	2
28	B	51	M	1	6	3	2	2	2	2	2
29	B	32	M	2	7	1	2	2	2	2	2
30	B	21	M	2	5	4	1	2	2	2	2

Introduction



Aim and Objectives



Review of Literature

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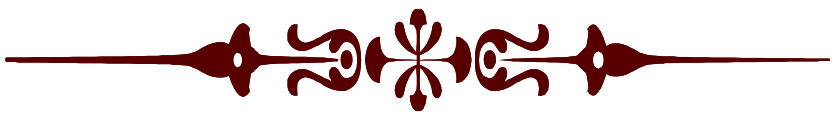
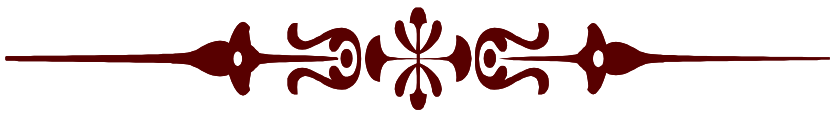
Materials and Methods

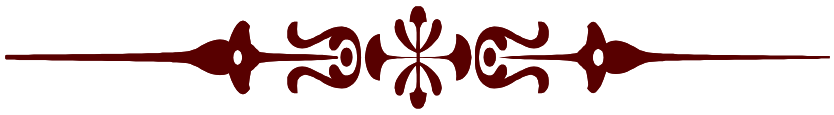
Results



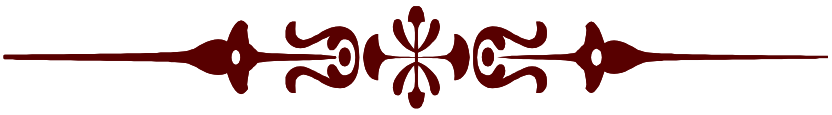
Discussion



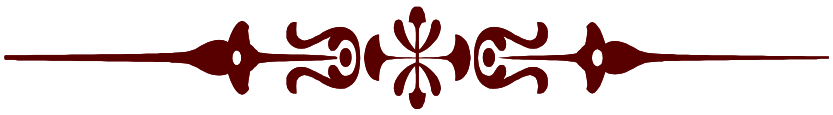
Conclusion



Summary



Bibliography



Annexures

Master Chart