COMPARATIVE STUDY BETWEEN CONVENTIONAL VERSES UNDER VISION CLOSURE FOR LAPAROSCOPIC PORT SITE- PROSPECTIVE STUDY

Submitted by

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in

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Under the guidance of

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DR.ROSHNI DEVI PATIL

LIST OF ABBREVATIONS

- Mm -Millimiter
- TSH Trocar site hernia
- CT -Computed tomography

ABSTRACT

Introduction

Incisional hernia can occur after any abdominal surgery and laparoscopic surgery is not immune to this complication. The hernia that follows laparoscopy usually occurs through the larger ports (size greater than 10mm ports), especially from the umbilical port. The trocar insertion and trocar site are associated with much complication.

Port site hernia's is a important and unrecognized complication in laparoscopy which carries a high risk of strangulation due to the small size of defect involved. Hence the port closure is a important step after the surgery.

Aims and Objectives

Comparative study Between Conventional Verses under Vision Closure For

- Comparison of closure time
- Port site related infection
- Port site incisional hernia
- Port site bleeding

Material and Method

Patients were randomly allotted to both case and control groups. The parameter's such as port site bleeding, port site infection, intra operative complication, time required for closure and follow up after 3 months for port site hernia was done.

Results

Total of 198 cases were considered out of which, the complications were tabulated and was seen that port site bleeding was seen in 5.1% in case and 7.1% in

control. Port site infection was seen in 9.2% in case and 14.3% in control. Port site hernia was seen in only 1 case in the control group.

Conclusion

Port site complications are very minimally associated with laparoscopic surgeries. Percentage wise the complications were more in control group. Port site infection was seen more in control group. Hernia at port site was seen in 1 laparoscopic cholecystectomy which belonged to control group.

All the complications were managed with minimal intervention, and morbidity. Consideration of meticulous surgical technique during closure of the port can minimize these complication s. There were 0.14% laparoscopic port site hernias, which is less. But designing a method for port closure, will reduce the incidence still further.

Key words: port site hernia, trocar site, port site infection

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INTRODUCTION

Laproscopy was introduced in the year 1987, by Mouret, now it is widely been accepted and applied in all branches of surgery. Incisional hernia can occur after any abdominal surgery and laparoscopic surgery is not immune to this complication. The hernia that follows laparoscopy usually occurs through the larger ports (size greater than 10mm ports), especially from the umbilical port.

Laproscopy has a huge impact on patients and their post operative outcome. Other name for laparoscopy is minimal access surgery wherein there are specialized instruments to operate, hence it is evolving in this era.

Initial step to start a laproscopy would be to create pneumoperitoneum by carbon di oxide insuffalation, so that the abdominal wall and viscera is visualized clearly. This can be achieved through veress needle or trocar.

The trocar insertion and trocar site are associated with many complication, specially while introducing the trocar blindly the great vessels/viscera are more susceptible to get injured,50% of intial bowel wall and great vessels injuries are during entry, and they are prone for trocar site hernia's post operatively. Incidence of port site bleeding is 0.7%.⁽¹⁾

Port site hernia's is a important and unrecognized complication in laproscopy which carries a high risk of strangulation due to the small size of defect involved. Hence the port closure is a important step after the surgery. Hence many methods have been tried to adequately close the port site.

Among all these factors, the single most important factor remains the improper closure of the fascial defects at the port sites. Computed tomography scans are helpful in its diagnosis and treatment. The incidence of incisional hernia occuring at the port sites lies between 0.02-3.6% and usually remains unreported, until the development of complications.⁽²⁾

Predisposing factors include:

- 1. Previous laparoscopies
- 2. Extensive manipulation during surgery
- 3. Increased intra –abdominal pressure
- 4. Obesity
- 5. Use of sharp cutting-tip trocars
- 6. Rapid abdominal deflation at the end of surgery
- 7. Poor port removal technique
- 8. Wound extension
- 9. Male sex and infection of the wound.⁽³⁾

To avoid the complications associated with port site closure, over the period of time many techniques have been developed to ascertain that the fascial layer of the larger ports such as 10mm and 12mm are closed completely.

In 1968, Fear was the first to report ventral hernia at a trocar site after laproscopy. Trocar complications occur in approximately 1 to 6% of patients. He also mentioned that by incorporating the peritoneum into the fascial layer the incidence of trocar site hernia's reduce.⁽⁴⁾

This study was undertaken to compare between conventional verses undervision closure for laparoscopic port site.

AIM'S AND OBJECTIVES

Comparative study Between Conventional Verses Under Vision Closure for Laparoscopic Port Site-Prospective cross sectional interventional study.

OBJECTIVES OF THE STUDY:

- Comparison of closure time
- Port site related infection
- Port site incision
- Port site bleeding

REVIEW OF LITERATURE

Before placing any trocar it is very important to know the anatomy because the underlying structures are very crucial and important. While closing the port site, if closed blindly then there are likely chances to injure the bowel and incomplete closure, hence closing undervision and ensuring that all the layers are taken is very important.

The umbilicus is considered as the best site for trocar placement because the skin is attached to the fascia and the anterior peritoneum with minimal intervening muscle or fat. This is not the case above and below umbilicus.

The structure of the abdominal wall is almost similar to the thoracic wall. Their are three layers external, internal and innermost layer. The vessels lie between internal and innermost layer.

ANATOMY OF ANTERIOR ABDOMINAL WALL

Anatomy of the anterior abdominal wall there is fascia, the superficial fascia, which is further divided into superficial fatty layer that is camper s and a deep fibrous layer scarap's fascia. The rectus abdominis extends from the xiphoid process of the sternum and the 5,6,7 costal cartilage to the pubic symphisis and the pubic crest.

There are nine layers to the abdominal wall:

- 1) Skin
- 2) Subcutaneous tissue
- 3) Superficial fascia
- 4) External oblique muscle

- 5) Internal oblique muscle
- 6) Transversus abdominis muscle
- 7) Transversalis fascia
- 8) Preperitoneal adipose and areolar tissue
- 9) Peritoneum. Nerves, blood vessels, and lymphatics are present throughout.

RECTUS ABDOMINIS

The rectus abdominis muscle, also known as the "abdominal muscles" is a paired muscle running vertically on each side of the anterior wall of the abdomen. There are two parallel muscles, separated by a midline band of connective tissue called the linea alba. It extends from the pubic symphysis, pubic crest and pubic tubercle inferiorly, to the xiphoid process and costal cartilages of ribs V to VII superiorly. The proximal attachments are the pubic crest and the pubic symphysis. It attaches distally at the costal cartilages of ribs 5-7 and the xiphoid process of the sternum.

The rectus abdominis muscle is contained in the rectus sheath, which consists of the aponeuroses of the lateral abdominal muscles. Bands of connective tissue called the tendinous intersections traverse the rectus abdominus, which separates this parallel muscle into distinct muscle bellies

The rectus abdominis is a long flat muscle, which extends along the whole length of the front of the abdomen, and is separated from its fellow of the opposite side by the linea alba. Tendinous intersections further subdivide each rectus abdominis muscle into a series of smaller false muscle bellies. The upper portion, attached principally to the cartilage of the fifth rib, usually has some fibers of insertion into the anterior extremity of the rib itself.

Blood supply

First, the inferior epigastric artery and vein (or veins) run superiorly on the posterior surface of the rectus abdominis, enter the rectus fascia at the arcuate line, and serve the lower part of the muscle.

Second, the superior epigastric artery, a terminal branch of the internal thoracic artery, supplies blood to the upper portion. Finally, numerous small segmental contributions come from the lower six intercostal arteries as well.

Nerve supply

The muscles are innervated by thoraco-abdominal nerves, these are continuations of the T7-T11 intercostal nerves and pierce the anterior layer of the rectus sheath. Sensory supply is from the 7-12 thoracic nerves

The rectus sheath is formed by the aponeuroses of the transverse abdominal and the external and internal oblique muscles. It contains the rectus abdominis and pyramidalis muscles.

It can be divided into anterior and posterior laminae.

The arrangement of the layers has important variations at different locations in the body or context, above the sheath are the following two layers:

- 1. Camper's fascia (anterior part of the Superficial fascia)
- 2. Scarpa's fascia (posterior part of the Superficial fascia)

Within the sheath, the layers vary:

Above the arcuate line

At the lateral margin of the rectus, the aponeurosis of the internal oblique divides into two lamellae:

- One of which passes in front of the rectus, blending with the aponeurosis of the external oblique as well as the aponeurosis of the anterior half of the internal oblique.
- The other, behind it, blending with the aponeurosis of the transversus as well as the posterior half of the internal oblique, and these, joining again at the medial border of the rectus, are inserted into the linea alba.⁽⁴⁾



Below the arcuate line:- Below this level, the aponeuroses of all three muscles (including the transversus) pass in front of the rectus.⁽⁴⁾





Among all the factors mentioned previously, the single most important factor remains the improper closure of the fascial defects at the port sites. Computed tomography scans are helpful in its diagnosis and treatment. The incidence of incisional hernia occuring at the port sites lies between 0.02-3.6 % and usually remains unreported, until the development of complications.⁽³⁾

Mouret introduced Laparoscopy surgery in 1987. Laparoscopy is associated with specific complication such as incisional hernia through the trocar site which may cause small bowel obstruction.

"Trocar sit hernia (TSH) is defined as an incisional hernia which occurs after minimally invasive surgery on the trocar incision site".⁽⁵⁾

In 2004 Tonouchi classified trocar site hernia into 3 type:-

- Early onset type:- Separation of anterior and posterior fascial plane and peritoneum, it is seen after surgery, within 30 days. We see small bowel obstruction.
- Late onset type:- Separation of anterior and posterior fascial plane .Peritoneum constitutes the hernia sac. Hernia usually develops several months after surgery.
- Special type:- Separation of the whole abdominal wall. Intestine or omentum protrusion. It is immediately seen after surgery.⁽⁶⁾

"According to DR. R.K.Mishra

PORT CLOSURE SHOULD HAVE FOLLOWING CHARACTERS

- Effective surgical wound closure
- Faster wound closure
- Good scar cosmesis
- Occlusive microbial wound dressing
- Less tissue trauma, reduced inflammatory reaction
- Easy to use simple learning curve
- Cost effective
- Reduced risk of needle stick injury"⁽²⁾

In this study by conventional method we mean, the rectus muscle is held with allis forceps and blindly suture is taken, in this technique their is risk of bowel injury and incomplete closure of ports, whereas when a port is closed under vision a 5mm scope is passed from 5mm port and the 10mm port is visualised and cobbler needle is inserted with vicryl 2-0 and from other side of port, the suture material is reterived, ensuring the port site is closed completely and their is no bowel injury.

Port site closure can be divided into 2 types

1st type:-needle must be seen through telescope (laproscopic visualisation)

2nd type:-needle must be seen by surgeon and no telescope is required for it (no laproscopic visualisation)

Different technique for port closure

These techniques include

- 1. Grice needles
- 2. The maciol needle
- 3. Catheter or spinal needles
- 4. The endoclose device, and the Gor-Tex device
- 5. Reverdin, Deschamps needles
- 6. Semm's emergency needle with adistal eyelet
- 7. The modified Veress needle with as litmade in there trac table brunt tip
- 8. Dental awl with aneye
- 9. Prolene 2/0 on a straight needle aided by a Veress needle; a straight needle armed with suture; Auto stitch (United states surgical), a modified Veress needle bearing a crochet hook at the tip, veress needle loop technique.⁽⁶⁾

1)Grice needle's used by Stringer et al, A Grice

- a)Needle was inserted at an angle along the side of a lateral trocar. Under direct laparoscopic visualization, the needle was placed through both the peritoneum and the fascia.
- b) Within the abdomen, the suture was grasped and removed from the Grice

needle with a grasper inserted from the opposite trocar. The Grice needle then was removed and reinserted opposite the previous puncture, again at an angle along the trocar.

c) The suture was regrasped with the Grice needle and pulled out of the abdomen. After complete removal of the trocar, the suture was tied under direct laparoscopic visualization".⁽⁷⁾



2) Maciol needles. Contarini reported using Maciol needles (Core Dynamics,

Inc. Jacksonville, FL, USA, Maciol needles area set of three needles:

- a) Two black handled introducers, one straight and one curved, and a goldenhandle retriever.
- b) The introducer needle (needle with an eye) is used to pass the suture through the abdominal wall into the peritoneal cavity from the subcutaneous tissue.
- c) The retriever needle (needle with a barb)is next passed into the abdomen on the opposite side of the defect to retrieve the suture, then pulled back through the tissue.
- d) The procedure is performed under direct laparoscopic visualization before trocar withdrawal and does not require any enlargement of the skin incision".⁽⁸⁾



3) Vein catheter, angiocath needle, and spinal cord needle.



a) Nadler et al. used a venous catheter, direct laparoscopic visualization to secure the abdominal wall fascia and peritoneum. A continuously running nonabsorbable 0-polypropylene suture is inserted through a 15 gauge needle, which penetrates all subcutaneous layers including the fascia, going around the umbilical opening at a 45 degree angle to create purse string.

- b) The needle penetrates the fascia at a distance of 0.5 to 1cm from the trocar site. After the first insertion of the needle, an endograsp forceps is used to pull the free suture edge into the abdomen. Then the needle, still holding the suture, is reinserted at the next point and, with the use of the forceps, the free intra-abdominal edge of the suture is locked through the loop that has been created.
- c) This maneuver is repeated another three times until the pursestring is fashioned. In the final step, the suture edge, which is pulled by the last loop, and the needle are withdrawn outside the abdomen near the site of first needle insertion, and both edges of the suture are tied up onto the fascia, angiocath needle to perform the same closure technique.
- d) The large 10 mm trocar is removed, and the pneumoperitoneum is maintained in all abdominaltrocarwounds10mmorlargersimplybyplacement of a gloved finger over the top of the wound. A 14 gauge angiocath needle with the sheath removed is preloaded with a 50 cm length of 0- braided polyglactin suture.
- e) The angiocath and suture are inserted through all fascia layer soon one side of the laparoscopic wound with laparoscopic visualization. Carefully, the needle and suture are placed in the exact middle of one side of the trocar wound. The surgeon or surgical assistant grasps the suture through a previously made 5 mm port. The needle is removed, and the suture is pulled a short distance(10-15cm)intotheabdominalcavity.A5mmgrasping instrument is inserted directly through the subxiphoid or any large trocar wound, and the suture is grasped.
- f) The 5mm grasping instrument and suture are removed from the abdominal cavity. The four steps are repeated by passing another preloaded angiocath

needle and suture through the midpoint of the other side of the trocar wound. The suture is brought out through the same trocar hole. The ends of the suture are tied to get her with several square knots. The knot is reduced into the peritoneal cavity by pulling on one or both ends of the tied suture. The knot may be removed by pulling it through the fascia, thereby leaving a single strand of suture for closure of the fascia. The fascia is then closed, and the suture is tied under direct vision through the laparoscope".⁽⁹⁾

4)Endoclose suture device.

- a) This is a disposable endoclose device (Tyco Auto Suture International, Inc. Norwalk, CT,USA) with a spring-loaded suture carrier is loaded with a 0absorbable suture and introduced into the abdomen between the edge of the skin and the port.
- b) The suture is released and dropped in the abdominal cavity, after which the device is removed.
- c) The spring-loaded suture carrier is then passed through the fascia and peritoneum 180° degree from the original insertion site between the skin incision and the port. With the assistance of a 5 mm grasping forceps through a secondary port, the suture is reloaded onto the opened notch in the endoclose needle.
- d) The device and suture are brought out of the abdomen. The port is removed, and the suture is tied to approximate the fascia and peritoneum".(10)(11)



5)THE GORE-TEX SUTURE PASSER

- a. Chapman used the Gore-Tex suture passer (WL Gore and Associates, Phoenix, AZ, USA), which is a reusable trocar closure device. With the trocar still in place and the abdomen distended by the pneumoperitoneum, the laparoscope is used to view the trocar site to be closed. The end of the trocar should still be visible within the peritoneal cavity.
- b. The suture is loaded into the Gore-Tex Suture passer, then passed through the subcutaneous tissue and fascia on one side of the trocar.
- c. The suture is released from the passer by pushing down on the handle, then grasped intraperitoneally with a blunt grasper. The suture passer is then removed and inserted through the subcutaneous space and fascia on the opposite side of the trocar. The suture is placed back in the jaw of the suture passer and locked into position by pulling back on the handle. The suture is then removed by pulling the passer out. Next, the trocar may be removed and the suture tied down".⁽¹²⁾



6)CARTER-THOMASON DEVICE

The Carter-Thomason close-sure system (Inlet Medical, Inc., Eden Prairie, MN, USA) is of two parts:

- a) The Pilot guide and the Carter-Thomason suture passer. Closure of the port incision requires four easy steps:
 - Use the suture passer to push suture material through the Pilot guide, fascia, muscle, and peritoneum into the abdomen, then drop the suture and remove the suture passer)
 - (2) Push the suture passer through the opposite side of the pilot guide and pick up the suture
 - (3) Pull the suture up through the peritoneum, muscle, fascia, and guide and
 - (4) Remove the Pilot guide and tie.
- b) Designed specifically for bariatric patients. The suture passer and Pilot guides have been lengthened to reach through the peritoneum in the larger patient to provide full-thickness closure in this at-risk group".⁽¹³⁾



7) ENDO-JUDGE DEVICE

- a) "The Endo-Judge wound closure device a 14 gauge hollow J-shaped needle that serves as a carrier for suture material and a device for performing the fascial closure. The suture is mounted on a reel at the proximal end of the device and fed to the hollow needle until it is delivered out the needle tip.
- b) The plastic oval shield (olive) at the J-portion of the needle maintains pneumoperitoneum and prevents injury to underlying structures. Reverdin and Deschamps needle can also be used same way to close the port. It is controlled by a sliding ring located on the shaft of the instrument. The device should be used under direct visualization.
- c) The Endo-Judge is passed into the abdomen until the olive is visible below the peritoneum. The instrument is then positioned in a plane perpendicular to the trocar incision to expose the needle and pass it through the peritoneum and fascia until it exits the skin incision. The end of the suture is grasped and tagged with a hemostat.

d) The needle is dropped back into the olive, and the instrument is rotated180°. The olive is again dropped to expose the needle, which is again passed through the peritoneum and fascia. After removal of the Endo-Judge, the suture is tied, creating a secure, air tight fascial and peritoneal closure".⁽¹³⁾



8) The 2 mm trocar technique.

- a) "Reardon et al. A 2 mm trocar and sleeve are introduced adjacent to the port whose entry site will be closed. A mono filament heavy-gauge suture with the needle removed is passed through the lumen of the 2mm sleeve.
- b) The 2 mm sleeve is then removed over the suture, after which the 2 mm trocar and sleeve are reintroduced through the opposingfascialedge180° from the original insertion site. The trocar is removed, and a 2 mm grasper is passed through the sleeve and used to retrieve the intra-abdominal end of the suture".⁽¹⁵⁾

9) THE 5 mm TROCAR TECHNIQUE

- a) "Rastogi and Dy developed a simple technique using the regular curved needle and sutures for closure of peritoneal and rectus sheath defects at the port site.
- b) Using a 5 mm telescope, they inspect the defect from the inside, and then pass a haemostat through the incision.
- c) Under direct telescopic vision, the peritoneum and rectus sheath are grasped at both the upper and lower edges and pulled through the incision, facilitating the passage of the needle. Chatzipapaset et al developed a similar closure technique using standard sutures with straight needles, a 5mm laparoscopic grasper, and a 4mm hysteroscope".⁽¹⁶⁾

10) TAHOE SURGICAL INSTRUMENT LIGATURE DEVICE

- a) "It is disposable. Initially, the laparoscopic cannula is removed. A0-absorbable suture is placed into the hollow delivery Tahoe needle without extension beyond the distal end of the needle.
- b) The device is introduced into the abdomen after the needles are first inserted through the two holes on an introduction disk. The needle tip's are then guided to pierce the fascia on either side of the port site. The lock is released, and the handle is depressed until the metal retrieval loop is extended and encompasses the tip and distal shaft of the delivery needle.
- c) The suture is fed into the delivery needle until it lies several inches beyond the distal end of the delivery needle and through the retrieval loop. The handle is released, allowing the retrieval loop to retract, there by securing the suture in the closed metal loop.

d) The entire device is withdrawn from the abdomen, thus delivering the tow ends of the suture onto the abdominal wall. The suture is tied, approximating the peritoneum and fascia".⁽¹⁷⁾

11)EXIT DISPOSABLE PUNCTURE CLOSURE DEVICE

- a) "A 10mm instrument with are accessed right-angle needle that can be exposed by rotating a dial at the top of the instrument. The device is introduced through the12mmlaparoscopicport.
- b) When laparoscopically visualized in the abdomen, the right-angle needle assembly is rotated to the open position, thereby exposing the needle carrier. The device is then pulled back up through the port, there by drawing the needle up through the peritoneum and fascia between the skin and the port.
- c) The skin is pulled away from the tip of the needle to avoid puncture of the skin. When the needle is seen coming through the subcutaneous fat, a 0-absorbable suture is loaded through the hole in the needle.
- d) The needle and suture, along with the entire device, are pushed back down through the port into the abdomen, thereby passing the suture down through the fascial and peritoneal layers. The exit device is then rotated 180° to the opposite side of the port, and the needle carrying the suture is again delivered through the fascia and peritoneum. The needle is identified in the subcutaneous tissue, and the suture is pulled from the tip of the needle. The device is returned back into the abdomen; the needle is closed; and the closed device is removed through the port. The port is removed, and the suture is tied, securing the peritoneum and fascia".⁽¹³⁾



11) Veress needle loop technique; used by R K Mishra,

a) "Making a loop by passing nylon suture to veress needle and tied it, then loadge the vicryl suture to the tip of veress needle, then push the veress needle with the loop, through the abdominal wall, without piercing the skin, 3mm away from the trocar site, then remove the veress, leaving the vicryl in side, by putting your finger on the vicryl, grasp the vicryl by grasper, and pass it to the other side of the trocar, to push it in side the veress loop, after piercing the abdominal wall, leaving the skin, and then remove the trocar, and close the wall by knotting".⁽¹⁸⁾

SECOND GROUP

Port closure should be performed under direct visualization of the surgeon, which requires good insufflations of the abdomen. When desufflation is performed, a tactile sense should be used to close the port. These techniques are applicable during insufflations or after desufflation. These techniques include the suture carrier, the dual hemostat technique, the Lowsley retractor, application of bioabsorbable hernia plug in trocar sites. Preliminary placement off fascial stay sutures above and below the prospective trocar site; Foley catheter threaded through the port hole for the elevation of fascial edge upon traction; fish-hook needle improvised out of a hypodermic needle by bending it 180°; Grooved director; U-shaped purse-string suture placed in the fascia around the port hole.⁽³⁾

1) SUTURE CARRIER

- a) "Jorge et al and Li and Chung developed a hook suture carrier for closure of trocar wounds, making use of the vertical rather than the horizontal space. The suture carrier is a hook suture carrier modified from a simple hook retractor with an eye drilled into the tip through which suture material can be threaded.
- b) The handle is 24 cm long, and the size of the hook approximates the size of the general closure needle (CT needle; Ethicon, Somerville, NJ, USA). To begin closure, the fascial edge is lifted vertically with a hook retractor, and the suture carrier is partially inserted into the wound to catch the peritoneum and fascia under direct vision, piercing it from the undersurface.
- c) A suture (such as 0-polypropylene) is threaded into the exposed eye of the carrier and brought beneath the fascia. This same suture is then carried to the opposite edge of the wound using the carrier, executing a stitch from inside out. After the suture is disengaged from the carrier, a simple stitch is accomplished with the knot on the surface when tied".⁽¹⁹⁾


2) DUAL-HEMOSTAT TECHNIQUE

- a) "Spalding et al reported the dual-hemostat technique, which is very simple, using two hemostats and a needle driver with suture and needle.
- b) The firs themostat is placed into the wound, after which the tips are spread open and the fascia is lifted up away from the underlying abdominal viscera.
- c) The second hemostat is used to retract the overlying subcutaneous tissue. Then the suture needle is driven through the fascia to exits between the splayed tips. The procedure is repeated at the opposite side of the wound".⁽²⁰⁾



3)LOWSLEY RETRACTOR WITH HAND CLOSURE

- a) "This technique uses the straight Lowsley retractor (Circon ACMI, Stanford, CT, USA), a regular needle driver, and a 0-absorbable suture on a curved needle. The closed straight Lowsley retractor is passed through the 12 mm port and into the peritoneal cavity.
- b) The blades of the Lowsley retractor are next opened maximally to 180°. The port then is removed from the abdomen along the shaft of the Lowsley retractor, leaving only the retractor in the wound.
- c) There tractor and the port are pulled upward. The fascia is tented toward the skin surface and exposed. A standard hand-sutured closure with0-absorbablesuturethenisperformed".⁽²¹⁾



FIGURE 14:- LOWSELY RETRACTOR WITH HAND CLOSURE

4)PORT PLUG TECHNIQUE

"In this technique using the bioabsorbable hernia plug hernia in trocar site, the device was implanted in the umbilical trocar (10mm)implantation of the bioabsorbable hernia plug device by the safe port possible in all cases".⁽²²⁾

According to Abdulzahra hussain et al⁽³⁾ has done a retrospective study 0f 5541 patients undergoing laparoscopic procedure shows that port site incisional hernia is reported in 124 patients, complicated hernia occurred before post operative day 30 and uncomplicated hernia occurred after 30 days. He has considered closure with a J shaped needle which is associated with bowel loop injury, omental injury or any other abdominal organ. This may result in less optimum closure and subsequent complication. The risk factors associated with occurrence of TSH are related both to patients and surgical technique. An important predisposing factor is obesity because obese patients have thicker peritoneum. There are surgical related technique such as herniation by widening the fascial defect, use of fascial screws to secure the port within the abdominal wall, longer procedure that causes excessive manipulation of port site ,large ports, cutting trocars, undected bowel or omental entrapment.⁽³⁾

In a study done by Somu Karthik et al⁽¹⁾, has done a descriptive study to analyse laparoscopic port site complication. This study was done in 570 patients from August 2009 to July 2011 which showed 17 had developed port site complication in a follow up period of 3months out of which port site complication were seen in 10 (1.8%) and port site bleeding in 4 (0.7%) omentum pluging related complication in 2 (0.35%) and port site metastasis in 1 (0.175%). Among bleeding at port site commonly involved was umbilical

port. To prevent port site bleeding U-Stiches can be placed in the abdominal wall under direct laparoscopic vision.⁽¹⁾

- In a study done by Somu Karthik et al⁽¹⁾, has done a descriptive study to analyse laparoscopic port site complication. This study was done on 570 patients from August 2009 to July 2011, which showed 1.8% of the patients had developed port site infection.⁽¹⁾
- In a study done by Shetty et al⁽²³⁾ in 2014 in Kerla, considered 200 patients undergoing laparoscopic donor nephrectomy were selected and divided into 2 groups considering the port closure technique, one group underwent closure by Carter-Thoamson needle and other conventionally they proved that closure by Carter-Thoamson is better method than conventionally with respect to reduced time, wound and bowel related complication.⁽²³⁾
- In a study done by Ahmed e. Lasheen et al⁽²⁴⁾, says that port site hernias are a well-known postoperative complication associated with laparoscopic surgery. Studies show that the incidence of port incisional hernia ranges from 1 to 6%. Trocar diameter and design, pre-existing facial defects, certain surgical procedures and patient related factors have been identified as risk factors for port site hernias. Meticulous closure of laparoscopic ports is important to prevent the incidence of port site incisional hernia, incorporation of bowel in port site closures, and their complications. Failure to adequately suture the facial defect, infection or suture disruption may lead to an incisional hernia or to ascitic fluid leakage in the case of patients with cirrhosis.⁽²⁴⁾

The port closure techniques were classified by Shaher into 3 groups: (a) techniques that use assistance from inside the abdomen (requiring 2 additional ports), (b) techniques that use extracorporeal assistance (requiring 1 additional

port), and (c) closure techniques that can be performed with or without visualization (without additional ports).⁽¹⁰⁾

- According a study done by P R Shah et al⁽²⁵⁾ defines conventional closure as, the lateral 10mm to 12mm ports are closed using vicryl with the help of a skin hook and a retractor(small Langenbach right angled retractor or skin hook). Skin hook is now inserted in the corner of the wound under the sheath. This can now be palpated with the fingers very easily as the sheath is taught. This also causes approximation of the sheath which can now be accessed by using another retractor above the sheath at 90 degrees to the hook to retract skin and subcutaneous tissue. The edge of the sheath is picked up with toothed forceps and a stitch is taken via one leaf of the sheath and the procedure is repeated by moving the retractor to the opposite edge to identify the other leaf of the sheath.⁽²⁵⁾
- A study conducted by Edward Phillips⁽²⁶⁾ in the year 2011 at Cedar-Sinai Medical centre, Los Angeles, california shows that port site hernias were reported in 124 patients: 26 were uncomplicated hernias, 14 were complicated and 84 were unknown outcomes. Of the 26, 2 cases were observed and 24 were treated with incisional hernia repair. All the 14 complicated cases were treated surgically. One patient required bowel resection, and one patient diet of multi-organ system failure directly resulting from bowel strangulation. All the complicated hernia occurred before post operative day 30, whereas uncomplicated cases (5-6) occurred within 30 post operative day.

Hence they conclude that high vigilance should be maintained and early signs of a complicated port-site hernia can be excessive pain, swelling at the site, and discoloration similar to a haematoma. Delay, in diagnosis may cause small bowel obstruction result in bowel resection.⁽²⁶⁾

• Sheik Firoj Kabir et al⁽²⁷⁾, conducted a retrospective study of 100 cases that underwent laparoscopic cholecystectomy, he concluded that 10mm ports are more vulnerable to port site hernia if not closed optimally. He found two patients with hernia (uncomplicated).⁽²⁷⁾

METHODOLOGY

Source of data

 All patients admitted in Department of Surgery Shri B. M. Patil Medical College, Hospital and Research Centre, Vijayapur between September 2016 to August 2018.

Sample size

TOTAL SAMPLE SIZE: 196(Each group consists of 98 patients)

With 95% level of confidence and margin of error $\pm 1\%$.Considering 80% of admitted patients.

METHOD OF COLLECTION OF DATA :

- The patient will be divided under 2 groups-the first group will undergo closure conventionally and second under vision.
- Operative time will be noted in the groups, port site bleeding, infection and follow up for 3 months for port site associated hernia

Mode of selection of cases and method of analysis

Study design:- Prospective study

Study type:- Interventional

INCLUSION CRITERIA

Patients undergoing all abdominal laparoscopic surgery.

INVESTIGATION

Investigations or interventions required in this study are routine standardized procedures.

There are no animal experiments involved in this study.

These routine investigations are required and necessary for routine postoperative follow-up (after 3 months):

1. Ultrasonography of abdomen.

METHOD:-

Detailed history of the patient is taken, after explaining the procedure to the patient in detail, the consent is taken from the patient and if the patient is minor consent is taken from the parent/guardian.

Preoperatively chest ultrasonography of the abdomen is done to confirm the pathology and the surgery is planned.

Method for cases to be closed under vision:-

At the end of surgery and removal of specimen, confirming that the operated site is clean. The 10mm umbilical port is visualized using a 4mm scope which is passed from the 5mm port. It is ensured that no adhesions and vessels are present at the 10mm port site, it is visualized clearly. Using cobbler needle and vicryl 2-0 one side of the port is pierced and the end is left inside, care should be taken not to injure the bowel. From the other end the cobbler needle is again pierced from the other side, care should be taken not to injure bowel. And also ensure that all the layers are included. Once it is ensured that no bowel is included and all the layers are included, the trocar is removed and the two end's of the vicryl are tied outside. The time is started from the piercing of cobbler needle till vicryl is tied outside. Intraopertively we look for any port site bleeding and intraopertive complication like bowel injury, injury to vessels .if any they are tackled and noted, the time for port site closure is also noted in by this method we confirm that all the layers are included and post operative hernia chances are also reduced.

Post operatively the patient is followed up till 1 month to look for port site infection, followed by at 3 months for port site hernia.



Figure 15 : visualization of adhesions at port site



Figure 16:- Releseof adhesions at port site



Figure 17:- The cobbler needle is pierced at the port and the vicryl 2-0 is left inside



Figure 18:- The vicryl 2-0 is extracted from the other side



Figure 19:- Both ends of vicryl are held outside ensuring that no bowel is taken and all layers of peritoneum are involved



Figure 20:- Both the ends are tied outside



Figure 21:- Port site closed under vision

Method for port site closure in control:-

At the end of surgery and removal of specimen, confirming that the operated site is clean. Haemostasis is achieved, the 10mm port is removed, and using allis forceps, both the side of rectus sheath are held and a deep bite is taken using vicryl 2-0, to close the port site. The time needed to close the port is noted, and if there is any port site bleeding and any intraoperative complications. As this is a blind procedure, we are not sure if we have taken any bowel underneath and also if the port site is completely closed.

Post operatively the patient is followed up till 1 month to look for port site infection, followed by at 3 months for port site hernia.



Figure 22:- Conventional method of port closure with allis forceps



Figure 23:- Port site bleeding

STATISTICAL METHOD APPLIED

All characteristics were summarized descriptively. For continuous variables, the summary statistics of mean, standard deviation (SD) were used. For categorical data, the number and percentage were used in the data summaries. Chi-square (χ^2) /Freeman-Halton Fisher exact test was employed to determine the significance of differences between groups for categorical data. The difference of the means of analysis variables between two independent groups was tested by unpaired t test. If the p-value was < 0.05, then the results were considered to be statistically significant. Data were analyzed using SPSS software v.23.0.and Microsoft office.

RESULTS

During the period September 2016 to august 2018, 196 laparoscopic cases were taken and randomly assigned case and control group, and were evaluated

DISTRIBUTION OF AGE AND SEX AMONG CASES

Total number of cases taken were 98, out of which 57 were male and 41 were female. The p value was found to be 0.387. The distribution of age and sex among cases is presented in table 1 and graph 1

TABLE 1:-DISTRIBUTION OF AGE AND SEX AMONG CASES

AGE (YRS)		MALE	FEMALE		
	Ν	%	N	%	p value
≤10	1	1.8	1	2.4	
11-20	12	21.1	10	24.4	
21-30	15	26.3	14	34.1	
31-40	14	24.6	7	17.1	0.207
41-50	5	8.8	4	9.8	0.387
51-60	4	7.0	5	12.2	
>60	6	10.5	0	0.0	
Total	57	100.0	41	100.0	

Graph 1: Distribution of age and sex among cases



DISTRIBUTION OF AGE AND SEX AMONG CONTROLS

Total number of control's were 96 out of which 35 were male and 63 were female. The p value is calculated to be 0.553. The distribution of age and sex among control is presented in table 2 and graph 2

		MALE	FEMALE		
AGE (YKS)	Ν	%	N	%	p value
≤10	1	1.8	2	4.9	
11-20	10	17.5	14	34.1	
21-30	9	15.8	8	19.5	
31-40	8	14.0	16	39.0	0.553
41-50	3	5.3	12	29.3	
51-60	1	1.8	4	9.8	
>60	3	5.3	7	17.1	
Total	35	61.4	63	153.7	

TABLE 2:-DISTRIBUTION OF AGE AND SEX AMONG CONTROLS

Graph 2: DISTRIBUTION OF AGE AND SEX AMONG CONTROLS



DISTRIBUTION OF AGE ACCORDING TO CASES AND CONTROLS

According to age distribution maximum number of cases was seen in 21-30 yrs in case group and in control they were seen in between 31-40 yrs. The p value was calculated as 0.29. It is depicted in graph 3 and table 3

TABLE 3:-DISTRIBUTION OF AGE ACCORDING TO CASES ANDCONTROLS

AGE (VRS)		CASES	(CONTROL	n value
	Ν	%	Ν	%	p vulue
≤10	2	2.0	3	3.1	
11-20	22	22.4	24	24.5	
21-30	29	29.6	17	17.3	
31-40	21	21.4	24	24.5	0.297
41-50	9	9.2	15	15.3	
51-60	9	9.2	5	5.1	
>60	6	6.1	10	10.2	
Total	98	100.0	98	100.0	

Graph 3: DISTRIBUTION OF AGE ACCORDING TO CASES AND CONTROLS



MEAN AGE ACCORDING TO CASES AND CONTROLS

Mean of the age was calculated in both the groups, mean of the cases is 33.1 and standard deviation is 16.4 and mean of control group is 34.5 with standard deviation of 17.5. The p value was calculated to be 0.57.

 Table 4:- MEAN AGE ACCORDING TO CASES AND CONTROLS

PARAMETER	CASE	ES	CONT	p value	
	Mean	SD	Mean	SD	-
AGE (YRS)	33.1	16.4	34.5	17.5	0.57

Graph 4: MEAN AGE ACCORDING TO CASES AND CONTROLS



DISTRIBUTION OF SEX ACCORDING TO CASES AND CONTROLS

According to sex distribution total number of male's in case group were 57 followed by females 41, whereas in control group males were 35 and females were 63. The p value was calculated to be 0.002 which is significant. It is showed in table 5 and graph 5

 TABLE 5:- DISTRIBUTION OF SEX ACCORDING TO CASES AND

 CONTROLS

SEX	CASES		CC	ONTROL	p value	
~	N	%	N	%	P	
Male	57	58.2	35	35.7		
Female	41	41.8	63	64.3	0.002*	
Total	98	100.0	98	100.0		

Graph 5: DISTRIBUTION OF SEX ACCORDING TO CASES AND CONTROLS



MEAN DURATION OF PORT CLOSURE ACCORDING TO CASES AND CONTROLS

The mean duration of port closure in cases is $2\min$ and standard deviation is 0.9, whereas in control the mean is 1.5 and standard deviation is 0.6. The p value was found to be <0.001 which is significant. It is depicted in table 6 and graph 6

TABLE 6: MEAN DURATION OF PORT CLOSURE ACCORDING TOCASES AND CONTROLS

PARAMETER	CASI	ES	CONTI	p value	
	Mean	SD	Mean	SD	
DURATION OF PORT CLOSURE	2.0	0.9	1.5	0.6	<0.001*

Note: * significant at 5% level of significance (p<0.05)

Graph 6: MEAN DURATION OF PORT CLOSURE ACCORDING TO CASES AND CONTROLS



DISTRIBUTION OF DIAGNOSIS ACCORDING TO CASES AND CONTROLS

The total number of cases was 98 out of which maximum number of cases were acute appendicitis followed by cholelithiasis. In control group 98 cases were considered out of which maximum number of cases were cholelithiasis followed by acute appendicitis. The p value showed 0.013 which is significant. It is shown in table 7 and graph 7

TABLE 7:-DISTRIBUTION OF DIAGNOSIS ACCORDING TO CASES AND

CONTROLS

DIAGNOSIS		CASES		ONTROL	n voluo
	Ν	%	Ν	%	p value
ACUTE ABDOMEN	0	0.0	1	1.0	
ACUTE APPENDICITIS	39	39.8	21	21.4	
ACUTE CHOLECYSTITIS	3	3.1	4	4.1	
APPENDICITIS WITH CHOLECYSTITIS	1	1.0	1	1.0	
CA STOMACH	0	0.0	1	1.0	
CHOLELITHIASIS	15	15.3	22	22.4	
CHRONIC APPENDICITIS	12	12.2	2	2.0	
CHRONIC CHOLECYSTITIS	0	0.0	1	1.0	
CHRONIC PAIN ABDOMEN	0	0.0	2	2.0	
DIAGNOSTIC LAPROSCOPY	5	5.1	2	2.0	
DUB	0	0.0	1	1.0	
HCC	1	1.0	0	0.0	
HYDATID CYST OF LIVER	1	1.0	0	0.0	0.013*
HYPERSPLENISIM	0	0.0	2	2.0	
LEFT OVARIAN CYST	0	0.0	1	1.0	
LIVER MASS	1	1.0	0	0.0	
OBSTRUCTIVE JAUNDICE	0	0.0	1	1.0	
PARAUMBILICAL HERNIA	1	1.0	0	0.0	
PRIMARY PERITONITIS	1	1.0	0	0.0	
RECTAL PROLAPSE	0	0.0	1	1.0	
RECURRENT APPENDICITIS	11	11.2	26	26.5	
RECURRENT CHOLECYSTITIS	4	4.1	3	3.1	
RT OVARIAN CYST	1	1.0	0	0.0	1
UMBILICAL HERNIA	2	2.0	6	6.1	1
Total	98	100.0	98	100.0	1

Note: * significant at 5% level of significance (p<0.05)

Graph 7: DISTRIBUTION OF DIAGNOSIS ACCORDING TO CASES AND

CONTROLS



TABLE 8: DISTRIBUTION OF TYPE OF SURGERY ACCORDING TOCASES AND CONTROLS

According to the total number of surgeries maximum were laparoscopic appendicectomy (67) followed by laparoscopic cholecystectomy (21). In control maximum number of cases were laparoscopic cholecystectomy (53) followed by laparoscopic appendicectomy (31). The p value was found to be 000.042 and was found to be significant.

SUD CEDV		CASES	CC	ONTROL	
SURGERY	Ν	%	Ν	%	p value
DIAGNOSTIC LAPAROSCOPY	3	3.1	2	2.0	
LAPAROSCOPIC APPENDICECTOMY	67	68.4	53	54.1	
LAPAROSCOPIC CHOLECYSTECTOMY	21	21.4	31	31.6	
LAPAROSCOPIC HERNIA REPAIR	3	3.1	0	0.0	
LAPAROSCOPIC HERNIOPLASTY	0	0.0	1	1.0	
LAPAROSCOPIC HYSTRECTOMY	0	0.0	1	1.0	0.042*
LAPAROSCOPIC MESH REPAIR	0	0.0	5	5.1	
LAPAROSCOPIC RECTOPEXY	0	0.0	1	1.0	
LAPAROSCOPIC SPLENECTOMY	0	0.0	2	2.0	
RUPTURE OF CYST	4	4.1	2	2.0	
Total	98	100.0	98	100.0	1

Note: * significant at 5% level of significance (p<0.05)

Graph 8: DISTRIBUTION OF TYPE OF SURGERY ACCORDING TO CASES

AND CONTROLS



Table 9:-DISTRIBUTION OF COMPLICATIONS ACCORDING TO CASES AND CONTROLS

The complications were tabulated and was seen that port site bleeding was seen in 5.1% in case and 7.1% in control, the p value was calculated to be 0.267. Port site infection was seen in 9.2% in case and 14.3% in control, the p value was calculated as 0.316. Port site hernia was seen in only 1 case in the control group, p value was found to be 0.551.

COMPLICATIONS		CASES		ONTROL	n value
COMILICATIONS	Ν	%	Ν	%	p value
PORT SITE BLEEDING	5	5.1	7	7.1	0.267
INTRA OPERATIVE COMPLICATIONS	0	0.0	0	0.0	0.316
PORT SITE INFECTION	9	9.2	14	14.3	-
PORT SITE HERNIA	0	0.0	1	1.0	0.551
Total	98	100.0	98	100.0	

Graph 9: DISTRIBUTION OF COMPLICATIONS ACCORDING TO CASES AND CONTROLS



DISCUSSION

Port site complications can be divided into

- 1) Access-related complications
- 2) Postoperative complications,

They have been reported in all age groups and in both genders. The literature shows that obesity is associated with increased morbidity related to port site due to various factors like the need for longer trocars, thick abdominal wall, need for larger skin incision to expose fascia adequately, and limitation in mobility of the instrument due to increased subcutaneous tissue.⁽¹⁾

The rapid advancement in science in CCD cameras and the flexible light sources have made the laparoscopic surgery more affordable and widely available. As a result, the use of laparoscopy has expanded to more sophisticated surgeries as well as management of malignancies. ⁽²⁸⁾

In our study we included total of 196 cases, which included 98 in each group, that is control and case study.

Comparison of total number of cases and sex:-

We compared the Total number of cases taken were 98, out of which 57 were male and 41 were female. The p value was found to be 0.387. And in control group 35 were male and 63 were female. The pvalue is calculated to be 0.553.

In a study conducted by Somukarthik et al⁽¹⁾ total number of cases were 570 which included 307 male nad 263 female.⁽¹⁾

Comparison of distribution of age:-

According to age distribution maximum number of cases were seen in 21-30 yrs in case group and in control they were seen in between 31-40 yrs. The p value was calculated as 0.29. Mean of the age was calculated in both the groups, mean of the cases is 33.1 and standard deviation is 16.4 and mean of control group is 34.5 with standard deviation of 17.5. the p value was calculated to be 0.57.

Ina study conducted by Somukarthik et al ⁽¹⁾the age of the patients were between 13 to 80 years.⁽¹⁾

Comparison of sex according to cases and controls:-

According to sex distribution total number of male patient in case group were 57 followed by 41 female patient. In control group male patient's were 35 and female's were 63. The p value was calculated to be 0.002 which is significant.

In study conducted by Somukarthik et al⁽¹⁾ 307 were male patient s and 263 were female patients.⁽¹⁾

In a study conducted by G.G.Ravindranath et $al^{(28)}$ which had 328 patients, 229 (69.8%) were females and 99 (30.2%) were males.⁽²⁸⁾

Comparison mean duration of port closure according to cases and controls

The mean duration of port closure in cases is $2\min$ and standard deviation is 0.9, whereas in control the mean is 1.5 and standard deviation is 0.6. The p value was found to be <0.001 which is significant.

In a study conducted by Abijit Shetty et al⁽³³⁾, compared the time taken for port closure using hand closure technique and carter thomsan needle which showed mean of 15min in hand closure and 8min in carter thomsan, by which he concluded that the time taken is less for carter thomsan, but in our study the time taken is more in under vision facial closure.⁽³³⁾

Comparison of diagnosis according to cases and controls

The total number of cases were 98 out of which maximum number of cases were acute appendicitis (n=39) followed by cholelithiasis (n=15). In control group 98 cases were considered out of which maximum number of cases were cholelithiasis (n=22) followed by acute appendicitis (n=21). So in total 60 cases were acute appendicitis and cholelithiasis were 37 cases. The p value showed 0.013 which is significant.

In a study conducted by Somu Karthik et al⁽¹⁾ it was found that total number of cholelithisis were 207 whereas appendicitis were 169.⁽¹⁾

Comparison of type of surgery according to cases and controls

According to the total number of surgeries maximum were laparoscopic appendicectomy (n=67) followed by laparoscopic cholecystectomy (n=21). In control maximum number of cases were laparoscopic cholecystectomy (n=53) followed by laparoscopic appendicectomy(n=31). The p value was found to be 0.042 and was found to be significant.

In a study conducted by SomuKarthik et al⁽¹⁾ it was found that total number of cholelithisis were 207 whereas appendicitis were 169.⁽¹⁾

Comparison of port site bleeding

Port site bleeding was seen in 5.1% in case group and 7.1% in control, the p value was calculated to be 0.267. In laparoscopic surgeries if their are any subcutaneous vessels which are not visualized properly, their are chances of injury, hence while removing trocar their can be intraoperative bleeding, in this technique these vessels are closed with the port and hence it can be assured that their is no port site bleeding.

In a study done by Somu Karthik et al⁽¹⁾ which showed to have "Incidence of port site bleeding is 0.7%. Injury to epigastric vessels can be related to carelessness during the operative procedure usually during the placement of secondary trocars which should be placed under direct vision and with prior illumination of the abdominal wall. Bleeding from the abdominal wall may not become apparent until after the port is removed because the port may tamponade muscular or subcutaneous bleeding. In addition to visually inspecting the access site upon its creation, the site should also be inspected during and following removal of the port. Bleeding points can usually be identified and managed with electrocautery. On occasion, the skin incision may need to be enlarged to control the bleeding. If persistent bleeding continues, a Foley catheter can also be inspected, inflated, and gentle traction applied to tamponade the site. Also, U-stitches can be placed into the abdominal wall under direct laparoscopic visualization using a suture passer with absorbable braided sutures. A number of specialized instruments have been devised for fascial closure at the port site and these may also be useful for managing abdominal wall bleeding".⁽¹⁾

Comparison of port site infection

Port site infection was seen in 9.2% in case group and 14.3% in control, the p value was found to be 0.316.

In a study conducted by Somu Karthik et al ⁽¹⁾which showed 10 cases to have port site infection out of 570 cases, and among 10 cases port site infection was found in laparoscopic cholecystectomy, and total extra peritoneal repair.⁽¹⁾ In a study conducted by Abhijit Shetty et al ⁽³³⁾showed port site infection in 2 cases in hand closure technique and 1 case in carter thomsan needle.⁽³³⁾

Similar was the case in a study by Adisa et al,⁽²⁹⁾⁽³⁰⁾⁽³¹⁾ where 75% of the cases had superficial infections. Similar cases were reported form other studies.⁽²⁹⁾⁽³⁰⁾⁽³¹⁾

Comparison of intra operative complication:-

In our study we did not encounter any intraoperative complication s in both case and control.

In a study conducted by Somu Karthik et al⁽¹⁾ which showed, omentum related complications, which accounted for 0.4%. These complications are attributed to

- 1) Prior to removing the port the gas must be deflated completely
- 2) Inadequate closure
- 3) Larger incision than port.

This can be avoided by

- 1) All the ports should removed under vision
- 2) After release of gas the primary port should be removed with the camera
- 3) Appropriate size of incision
- 4) To adequately close the port.

Two patients had omentum-related complications at the port site (11.8%, n = 2). Those were immediate postoperative herniation/ entrapment of the omentum from the site of umbilical (camera) port and late (3 months post surgery) herniation of the omentum from the umbilical port site scar (port site hernia). Both were associated with 10 mm ports and the fascia was closed by the conventional method.

Other documented omental complication include laceration, penetrating injury, omental bleeding and post operatively granulomas of the omentum.⁽¹⁾

Comparison of port site hernia's.

Port site hernia was seen in only 1 case in the control group, p value was found to be 0.551.

Sl no	Type of case	Number of cases of	Total number of
		port site hernia	cases
1	Nissen's fundoplication	1	456
2	Laparoscopic cholecystectomy	2	1621
3	Groin hernia repair	5	1833

In a study conducted by Abdul Zahra Hussain et al ⁽³⁾which showed ⁽³⁾

In other study conducted by Somu Karthik et al ⁽¹⁾which showed 1 port site hernia in laparoscopic appendicectomy out of 570 patients. The hernia was seen at umbilical port. ⁽¹⁾

In other study conducted by Abhijit Shetty et $al^{(33)}$, which showed port site hernia in only 1 case p value was found to be 0.003.⁽³³⁾

CONCLUSION

Port site complications are very minimally associated with laparoscopic surgeries. Complication at port site include

- 1) Wound infection
- 2) Herniation of small bowel
- 3) Bleeding
- 4) Entrapment of omentum.⁽⁶⁾

Percentage wise the complications noted in our study was 5.1% in case and 7.1% in control, there were no intraoperative complications, port site infection was seen in 9.2% in case and 14.3 in control group and hernia at port site was seen in 1 laproscopic cholecystectomy which belonged to control group.

All the complication's were managed with minimal intervention, and morbidity. Consideration of meticulous surgical technique during closure of the port can minimize these complication's. There were 0.14% laparoscopic port site hernias, which is less. But designing a method for port closure, will reduce the incidence still further.
SUMMARY

The present study entitled "COMPARATIVE STUDY BETWEEN CONVENTIONAL VERSES UNDER VISION CLOSURE FOR LAPAROSCOPIC PORT SITE- PROSPECTIVE STUDY" was undertaken at B.L.D.E.(deemed to be) Shri B M Patil Medical College, Hospital and Research Centre Vijayapur from September 2016 to October 2018

Laparoscopic under vision port closure was compared with conventional method of port closure. In this study 98 cases were included in both the groups which were randomly allotted.

In our study we found that port site bleeding was seen in 5.1% in case and 7.1% in control group, the p value was calculated to be 0.267. Port site infection was seen in 9.2% in case and 14.3% in control group, the p value was calculated as 0.316. Port site hernia was seen in only 1 case in the control group, p value was found to be 0.551.

By this we are ensured that their is no bowel involvement, port site infection are reduced and the incidence of port site hernia s are also less.

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ANNEXURES

ETHICAL CLEARANCE CERTIFICATE



SAMPLE INFORMED CONSENT FORM

B.L.D.E. (DEEMED TO BE UNIVERSITY) SHRI B. M. PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE, BIJAPUR-586 103

TITLE OF THE PROJECT : COMPARATIVE STUDY BETWEEN CONVENTIONAL VERSES UNDER VISION CLOSURE FOR LAPROSCOPIC PORT SITE-PROSPECTIVE STUDY

PRINCIPAL INVESTIGATOR: Dr.ROSHNI DEVI PATIL DEPARTMENT OF GENERAL SURGERY

PG GUIDE : Dr. GIRISH K. KULLOLLI M.S. GENERAL SURGERY ASSOCIATE PROFESSOR DEPARTMENT OF GENERAL SURGERY

PURPOSE OF RESEARCH:

I have been informed that this study will analyse the comparison of closure of port site under laparoscopic vision and conventional method. I have been explained about the reason for doing this study and selecting me/my ward as a subject for this study. I have also been given free choice for either being included or not in the study.

PROCEDURE:

Patient will be explained about the need of the surgery and posted for surgery and patient will also be explained about the required investigations as per standard protocol.

RISKS AND DISCOMFORTS:

I understand that I/my ward may experience some pain, may be pain at the operated site. There many risks involved in both conventional closure as well as under vision closure such as plugging of omental patch, bowel obstruction secondary to trocar site hernia.

ALTERNATIVES:

Even if you decline in participation, you will get the routine line of management.

CONFIDENTIALITY:

I understand that medical information produced by this study will become a part of this hospital records and will be subjected to the confidentiality and privacy regulation of this hospital. Information of a sensitive, personal nature will not be a part of the medical records, but will be stored in the investigator's research file and identified only by a code number. The code key connecting name to numbers will be kept in a separate secure location. If the data are used for publication in the medical literature or for teaching purpose, no names will be used and other identifiers such as photographs and audio or video tapes will be used only with my special written permission. I understand that I may see the photograph and videotapes and hear audiotapes before giving this permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time. Dr.Roshni deviPatil is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of this study, which might influence my continued participation.

If during this study, or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me.

And that a copy of this consent form will be given to me to keep it and for careful reading.

REFUSAL OR WITHDRAWL OF PARTICIPATION:

I understand that my participation is voluntary and I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital.

I also understand that Dr.Roshni devi Patil will terminate my participation in this study at any time after he has explained the reasons for doing so and has helped arrange for my continued care by my own physician or therapist, if this is appropriate.

INJURY STATEMENT:

I understand that in the unlikely event of injury to me/my ward, resulting directly to my participation in this study, if such injury were reported promptly, then medical treatment would be available to me, but no further compensation will be provided.

I understand that by my agreement to participate in this study, I am not waiving any of my legal rights.

I have explained to ______ the purpose of this research, the procedures required and the possible risks and benefits, to the best of my ability in patient's own language.

Date:

Dr.Girish Kullolli (Guide) Dr.Roshni devi Patil (Investigator)

STUDY SUBJECT CONSENT STATEMENT:

I confirm that Dr.Roshni devi Patil has explained to me the purpose of this research, the study procedure that I will undergo and the possible discomforts and benefits that I may experience, in my own language.

I have been explained all the above in detail in my own language and I understand the same. Therefore I agree to give my consent to participate as a subject in this research project.

(Participant)

Date

(Witness to above signature)

Date

PROFORMA

SL NO	
NAME	CASE NUMBER
AGE	IP NO
SEX	UNIT
OCCUPATION	DATE OF ADMISSION
	DATE OF SURGERY
ADDRESS	DATE OF DISCHARGE
	DIAGNOSIS

Chief Complaints:

History of presenting illness

Past history: History of any previous surgery

Personal history:

GENERAL PHYSICAL EXAMINATION

BUILT: WELL/MODERATE/POOR

NOURISHMENT: WELL/MODERATE/POOR [BMI= kg/m²]

PALLOR, ICTERUS, CYANOSIS, CLUBBING, PEDAL EDEMA, GENERALISED LYMPHADENOPATHY

VITALS DATA:

TEMPERATURE^{: 0}c

PULSE: bpm

RESPIRATORY RATE: cpm

BLOOD PRESSURE: mm/Hg

SYSTEMIC EXAMINATION

PER ABDOMEN:

RESPIRATORY SYSTEM:

CARDIOVASCULAR SYSTEM:

CENTRAL NERVOUS SYSTEM:

PER RECTAL EXAAMINATION:

CLINICAL DIAGNOSIS:

LABORATORY TESTS

CHEST X RAY:

ULTRASONOGRAPHY OF ABDOMEN AND PELVIS:

OTHERS: OPERATIVE PROCEDURE (DATE AND TIME):

INTRA-OPERATIVE FINDING:

DURATION OF PORT SITE CLOSURE-

PORT SITE BLEEDING-

INTRA OPERATIVE COMPLICATION-

OTHER VARIABLES

PORT SITE INFECTIONS

PORT SITE HERNIA

FOLLOW UP-

FOLLOW UP FOR 1 MONTH TO LOOK FOR PORT SITE INFECTION AND 3 MONTH FOR PORT SITE HERNIA.

KEY TO MASTER CHART

- Sl. No : Serial Number
- Ip No : In Patients
- M : Male
- F : Female