A PROSPECTIVE ONE YEAR COMPARATIVE STUDY OF COMPLICATIONS IN LAPAROSCOPIC SURGERIES IN CREATION OF PNEUMOPERITONEUM BY VEREES NEEDLE(CLOSED) VERSUS HASSON'S(OPEN) TECHNIQUE", IN KLE'S DR. PRABHAKAR KORE CHARITABLE HOSPITAL, BELAGAVI-590010:- A RANDOMIZED CONTROLLED TRIAL

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LIST OF ABBREVIATIONS USED

ASA	-	AMERICAN SOCIETY OF ANESTHESIOLOGISTS
ADH	-	ANTIDIRUETIC HORMONES
BMI	-	BODY MASS INDEX
CO	-	CARDIAC OUTPUT
CO_2	-	CARBON DIOXIDE
CM	-	CENTIMETER
CVP	-	CENTRAL VENOUS PRESSURE
DTI	-	DIRECT TROCAR INSERTION
EAES	-	EUROPEAN ASSOCIATION FOR THE ENDOSCOPIC SURGERIES
$ETCO_2$	-	END TIDAL CARBON DIOXIDE
FRC	-	FUNCTIONAL RESIDUAL CAPACITY
GBP	-	GASTRIC BYPASS
GFR	-	GLOMERULAR FILTRATION RATE
HR	-	HEART RATE
IAP	-	INTRA-ABDOMINAL PRESSURE
KG/M^2	-	KILOGRAM PER METER^2
LIT/MIN	-	LITRES/MINUTES
LVEDV	-	LEFT VENTRICULAR END DIASTOLIC VOLUME
MAP	-	MEAN ARTERIAL PRESSURE

MM	-	MILIMETER
MMHG	-	MILIMETER OF MERCURY
O2	-	OXYGEN
$PACO_2$	-	PRESSURE OF ARTERIAL CARBON DIOXIDE
PAWP	-	PULMONARY ARTERIAL WEDGE PRESSURE
PCWP	-	PULMONARY CAPILLARY WEDGE PRESSURE
PEEP	-	POSITIVE END EXPIRATORY PRESSURE
PTINR	-	PROTHROMBIN TIME INTERNATIONALIZED RATIO
RBF	-	RENAL BLOOD FLOW
RR	-	RESPIRATORY RATE
SOGC	-	SOCIETY OF OBSTETRICIANS AND GYNAECOLOGISTS OF CANADA
SV	-	STROKE VOLUME
SVR	-	SYSTEMIC VASCULAR RESISTANCE
TV	-	TIDAL VOLUME
VR	-	VENOUS RETURN

LIST OF ABBREVIATIONS USED IN RESULTS

AA	-	ACUTE APPENDICITIS
AC	-	ACUTE CHOLECYSTITIS
A CARDIA	-	ACHALASIA CARDIA
BI	-	BOWEL INJURY
CA	-	CHRONIC (RECURRENT) APPENDICITIS
CP	-	CHRONIC PAIN ABDOMEN
DL	-	DIAGNOSTIC LAPAROSCOPY
EI	-	EXTRA-PERITONEAL INSUFFLATION
FOT	-	FAILURE OF TECHNIQUE
GL	-	GASTRIC LEAKAGE
HVP	-	HOLLOW VISCUS PERFORATION
LA	-	LAPAROSCOPIC APPENDECTOMY
LC	-	LAPAROSCOPIC CHOLECYSTECTOMY
LCG	-	LAPAROSCOPIC CYSTOGASTROSTOMY
LHM	-	LAPAROSCOPIC HELLER'S MYOTOMY
LPC	-	LAPAROSCOPIC PERFORATION CLOSURE
M	-	MORTALITY
NOC	-	NEED FOR CONVERSION
PA	-	PERFORATED APPENDICITIS
PCP	-	PSEUDOCYST OF PANCREAS
PSH	-	PORT SITE HEMATOMA
SE	-	SUBCUTANEOUS EMPHYSEMA
VI	-	VASCULAR INJURY

ABSTRACT

Background

One of the challenges in laparoscopy is access into the abdomen, specifically insertion of surgical instruments through small incisions.In most cases major complications occur during insertion of primary umbilical trocar prior to commencement of intended surgery (about 50%).Finding a safe entry technique is a priority for the life of the patients. Two most commonly used techniques to create pneumoperitoneum is Closed (Verees needle) technique and Open (Hasson's) technique.

Objective:

Primary-To evaluate safety, efficacy of two laparoscopic entry techniques Closed (Verees needle) and Open (Hasson's) techniques, their associated complications.

Secondary-Assess the access time to establish pneumoperitoneum by techniques.

Materials and Method:

It is a randomized controlled trial, done in patients undergoing any laparoscopic surgeries in department of general surgery at KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehrunagar, Belagavi, between Jan 2014 to Dec 2014, with age group ≥16 years and ≤65 year's patients and those with previous history of abdomen surgery included. The patients were randomized into two study groups. In group A, Verees needle was used, in group B Hasson's cannula or 10mm trocar without blade was used. Variables comparing the safety and efficacy of the two methods and access time were studied.

Results:

The time to establish pneumoperitoneum was much less in the Hasson's cannula technique (5.28 ± 1.1 minutes) as compared to the Verees needle technique (6.02 ± 0.7 minutes, P value <0.001). Pneumoperitoneum was achieved in 128 cases except in 2 cases in closed group. In the open group, gas leakage occurred in 14 (21.53%) cases, no patient had gas leak in closed group, bowel injury occurred in 2(1.53%) patients ,one(1.5%) in each group, extra-peritoneal insufflations in 3 patients(2.30%), with 2(3.1%) in closed group & one(1.5%) in open group, 3 (2.3%) patients had need for conversion,2(3.1%) closed group and one(1.5%) in open group, failure of technique in 2(3.1%) both in closed group, port-site hematoma occurred in 2(1.53%) ,one in each group case. There were no vascular injury, subcutaneous emphysema in either of the study group and there were no perioperative mortalities. Only access time and gas leakage had significance difference with P-value < 0.001, other complication had no significant difference between both groups and were comparable. In our present study we analyzed our results comparing patients with BMI< or >25 kg/m ^{2} and on patients with presence or absence of previous history of abdomen surgery irrespective of techniques used. In this analysis major and minor complication were more in patients with BMI> 25Kg/m^2 and with previous history of abdomen surgery, but this finding was not statistically significant.

Conclusion:

The study concludes that there is still controversy exists to support the superiority of one technique over the other and this view is supported by the literature. Further studies are needed in multiple centers and on larger samples for conclusive evidence.

Keywords: Laparoscopy, Pneumoperitoneum, Hasson's, Verees Needle

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INTRODUCTION

Abdomen is a magic box, filled with uncertain findings. In laparoscopic surgery, initial and most important step is gaining access to create a space for operability. Laparoscopy (Laparo– abdomen, scope in-to examine) is the art of examining the abdominal cavity and its contents.[1]In present days of clinical practice laparoscopy is widely used for both diagnostic and therapeutic purposes. It has become choice of approach for most benign abdomen conditions that requires surgery. With introduction of video-camera and other sophisticated instrument, laparoscopy has progressed from being a mere diagnostic procedure to eventually performing many surgical procedures with a wide variety of indications.

Laparoscopy initially needs insertion of cannula through abdominal wall and insufflation of the abdominal cavity with gas or air (pneumoperitoneum) for visualization of abdominal contents with illuminated telescope. The formation of pneumoperitoneum provides an unobstructed, wide view of whole abdomen in its all glory and clarity with accuracy. Objective of creating this space is for surgical dissection, suturing, achieving hemostasis and completion of procedure with satisfaction and success. But there is a steep fall in literature explaining iatrogenic complications during achieving pneumoperitoneum. So it is important to find safe and sure path for success.

Inspite of technical advances in laparoscopic surgery, the creation of pneumoperitoneum and introduction of instruments is associated with lethal first step that can lead to serious injuries to the viscera and major retroperitoneal vessels. The reported incidence of vascular and bowel injuries ranges between approximately 0.05

to 0.5/100 laparoscopic procedures.[2,3] But documented incidence of trocar injuries are under estimated of the true incidence, since a lot of accidents are not mentioned for obvious reasons.

The event of major vascular and undetected bowel injuries is serious usually leading to morbidity and mortality. The overall mortality reported to be 4% is increasing to 21% for unrecognized bowel injuries.[4, 5] Since last 25 years the incidence of complications has remained unchanged, [1] so it is important to have knowledge on possible complication, risk factor, prevalence of bowel and vascular injuries in view to prevent, establish an early diagnosis and treat these complications properly, thus decreasing morbidity and mortality rates. In addition it has been estimated that one half of all laparoscopic complications are due to entry technique.[1, 6]

There are two most commonly used techniques to create pneumoperitoneum and enter into abdominal cavity. First is with Verees needle (closed) technique, blind procedure to create pneumoperitoneum followed by trocar insertion. Another is Hasson's (open) technique, in this trocar is inserted without creation of pneumoperitoneum. In this method, small laparotomy is done and layer by layer skin, subcutaneous, rectus sheath, peritoneum are incised under direct vision followed by blunt Hasson's or usual trocar insertion and subsequently pneumoperitoneum created.[2, 7]

The complications are unique to laparoscopic surgery and rarely seen in open surgeries. Both techniques are not backed up by strong evidence and there is ongoing debate between gynecologists who favor closed technique and surgeons who prefer open entry technique.[2, 8] Critics of the verees needle states that there is a high risk of vascular injury compared to open technique, but cannot be completely avoided.[9]

Studies state visceral injuries are same in both techniques, but open technique has an added advantage of detection of injuries immediately under vision.[10] In a study done after gynecological surgery concluded that minor complications reduces by 40% with laparoscopy compared to laparotomy, but major complications are same, the overall risk of complications is 8.9% with laparoscopy compared to 15.2% with laparotomy. There is no difference between laparoscopy and laparotomy in the risk of major complications 1.4% in each group, but minor complications were significantly less frequent with laparoscopy 7.5% vs. 13.8%.[1]

Because of shortage of evidence, practical clinical guidelines on the creation of pneumoperitoneum cannot be framed, which entry technique is preferred. Each technique is preferred according to surgeons training, experience and regional, interdisplinary variability. Evidence indicates that younger generation surgeon prefer open technique.

Various studies have shown advantage and disadvantage of both techniques. Based on current available data, European Association for the Endoscopic Surgeries (EAES) concluded that no technique can be considered superior over other.[1, 11]With this uncertainty choice of technique is left on surgeon's preference. This works for experienced surgeons but there is area of confusion for residents and younger surgeons.

To answer these questions with a high level of evidence a randomized comparison of the open and closed access techniques is required to reduce the complications. Therefore it is important to continue to report on this topic because one has to rely on accumulating evidence of a lower level.

This study was conducted to compare the two techniques in terms of access related complications and time spent on creation of pneumoperitoneum. As there is no similar study published in our college and hospital comparing these two techniques. Thus, no local,evidence-based guidelines can be formulated. In view of the mentioned confusions and the paucity of literature there is a need for local guidelines to be drafted.

AIMS AND OBJECTIVES

The objectives of the present study are:

Primary-To evaluate safety, efficacy of two laparoscopic entry techniques Closed (Verees needle) technique and Open (Hasson's) technique, their associated complications.

Secondary- Assess the access time to establish pneumoperitoneum by two techniques.

REVIEW OF LITERATURE

Laparoscopy is at present most commonly used in the practice of medicine, for both diagnostic and therapeutic purposes.[12, 13] One of the challenge in laparoscopy is access into the abdomen specifically for the insertion of surgical instruments through small incisions.[1, 13] In most cases major complications (at least 50%) occur prior to commencement of intended surgery.[1,14]The majority of injuries is due to insertion of primary umbilical trocar.[1] Finding a safe entry technique is a priority for the life of the patients.

In the last three decades, rapid advances in laparoscopic surgery have made it an invaluable part of general surgery, but there remains no clear consensus as on an optimal method of entry into the peritoneal cavity.[13]

Commonly two techniques used are Verees needle (closed) and Hasson's (Open) method.

Verees Needle:.The Verees needle is the oldest method, developed by Dr. Verees in 1938. Commercially available Verees needles vary from 12 to 15cm in length, with an external diameter of 2 mm.[13]

Hasson's Technique: Hasson first described open laparoscopy in 1971 and it remains the favourite entry method for many laparoscopic surgeons.

Most of the studies are done only on virgin abdomen; studies on non-virgin abdomen are less. Most of studies are retrospective studies with few prospective, as in retrospective studies many findings like minor injuries, bleeding are not noted. So

these studies show less incidence of complications, leading to bias, in other hand prospective study overcome this bias.

There have been many studies comparing the efficacy and safety of the numerous access techniques although meta-reviews of these have turned out to be inconclusive, warranting the need for further evidence.[14]

Levison in 1974 first reported complication of major vascular injury during laparoscopic surgeries. Mac Donald and colleague in 1978 had two cases of major retroperitoneal vascular injury with touhy needle out of 400 laparoscopic surgeries (0.5% incidence). This was the first highlight on significant and potentially catastrophic complication with laparoscopy while entry. Following this many studies conducted in different countries like Germany, French, USA, Canada found that Verees needle cause more vascular accident.[15]

A study conducted in Department of Surgery, Federal University of Sao Paulo included 696,502laparoscopies, with 1,575 injuries (0.23%), 126 (8%) of which involved blood vessels or hollow viscera (0.018% of all laparoscopies). Of the 98 vascular injuries, 8 (8.1%) were injuries to major retroperitoneal vessels. There were 34 other reported retroperitoneal injuries, but the authors were not specific as to which vessel was injured. Of the 28injuries to hollow viscera, 17 were considered major injuries, i.e. 60.7% (0.0024% of the total cases assessed).[12]

A study conducted in Department of Surgical Sciences, Organ Transplantation, and Advanced Technologies, University of Catania, Cannizzaro Hospital in which a meta-analysis of 760,890 closed laparoscopy and 22,465 open laparoscopy cases reported that the incidence of vascular injury rate in closed

laparoscopy was 0.44%compared with 0% in open laparoscopy. The incidenceof bowel injury was 0.7% compared to 0.5%, respectively.[13, 16]

The study also reported that complication rates during introduction of Verees needle at one attempt 0.8–16.3%, two attempts 16.31–37.5%, three attempts 44.4–64%, and more than three attempts 84.6–100%. The complications associated were extra-peritoneal insufflations, omental and bowel injuries, and failed laparoscopy.[13]

Hasson reports his experience on 5,284 women who were subjected to open technique for laparoscopic surgery and have developed complications related to primary access. Twenty-one patients had minor wound infections, four had minor haematomas, one developed an umbilical hernia that required surgery, and one had an inadvertent injury to the small bowel that was repaired intraoperatively without adverse outcome.[13, 16]

Chapron et al. reported on a nonrandomized comparison of open versus closed laparoscopic entry practiced by university affiliated hospital teams. The bowel and major vessel injury rates were 0.04% and 0.01% in the closed technique and 0.19% and 0% in the open technique, respectively. They concluded that open laparoscopy does not reduce the risk of major complications during laparoscopic access.[1, 13, 14]

Catarci et al. analysed a multicentre questionnaire survey of general surgeons (57% responding) reported a relatively high incidence of major injuries with the closed technique (0.18%, used 82% of the time) than with the open technique (0.09%).[13]

Until 1997, no case of major retroperitoneal vessel injury had been reported with the use of a blunt Hasson's cannula, which therefore was considered to be

absolutely safe, while the rate of vascular injury was from 0.02% to 0.24% for closed technique. The rate of visceral injury with closed technique varied from 0.03% to 0.15% with prevalence of injury to the gastrointestinal tract (80%) greater than that for urinary tract (20%). With the open technique, the same figure varied from 0% to 0.12%. High rates of mortality related to major injury (10–50%) were reported in gynaecologic series, associated mainly with delayed diagnosis and treatment.[13]

Studies have reported placing the Verees needle into the peritoneal cavity on the first attempt at frequencies of 85.5-86.9%; two attempts required in 8.5-11.6%, three attempts in 2.6-3.0% and more than three attempts in 0.3-1.6%.[13]

Complication rates associated are: one attempt 0.8-16.3%, two attempts 16.31-37.5%, three attempts 44.4-64% and more than three attempts 84.6-100%. The complications associated were extra peritoneal insufflation, omental and bowel injuries and failed laparoscopy.[1]

Jansen et al. in clinical trials that compared closed and open entry techniques, the complication rates were 0.07% and 0.17% for the closed and open techniques, respectively. The number of entry-related complications with the open technique was significantly higher than with the closed technique by university affiliated hospital teams. The bowel and major vessel injury rates were 0.04% and 0.01% in the closed technique and 0.19% and 0% in the open technique, respectively. They concluded that open laparoscopy does not reduce the risk of major complications during laparoscopic access.[1, 13, 14]

Schafer et al. analysed 26 major vascular injuries and reported that only four of them (15%) had been caused by inexperienced surgeons (surgeons who had

performed fewer than 50 laparoscopic procedures). The other 22 injuries (85%) had been caused either by experienced surgeons (those who had performed between 51 and 100 procedures) or very experienced surgeons (over 100 procedures performed). [1, 14]

In Finland after 70,607 laparoscopic procedures, 256 complications were reported to the national patient insurance association. The overall rate of major complications was 1.4 per 1,000 procedures. This included 0.6 per 1,000 intestinal injuries, 0.3 per 1,000 urological injuries and 0.1 per 1,000 vascular injuries.[16]

In the Netherlands, a multicentre prospective study from 72 hospitals revealed the overall incidence of intestinal injuries and major complications was 5.7 per 1,000 procedures. 70% of these were related to the primary port entry. The overall incidence of laparoscopic entry injuries was 3.3 per 1,000. There were 29 cases of gastrointestinal damage (1.3 per1000) and 27 cases of abdominal vessel injuries (1.05 per 1000).[16]

F. Agresta et al, in his case series of 2175 different laparoscopic procedures pneumoperitoneum was established with DTI, study had no injuries, either minor or major. Peritoneal access and the creation of a laparoscopic workplace were obtained quickly and efficiently by DTI, they concluded DTI is a fast, safe, and reliable alternative to traditional techniques for pneumoperitoneum establishment.[17]

Jamie Kroft et al, in University of Toronto, Toronto conducted national wide survey to determine entry locations, and to collect information about complications by various laparoscopic entry techniques in gynecology and reported that in 72.9% of respondents, the clinical practice does not compulsorily coincide with current

recommendations by recent SOGC clinical practice guideline. These variance increases the need for further educational studies to ensure that the evidence from research is used to make clinical practice safer.[18]

Department of Obstetrics and Gynecology, Chang Gung Memorial Hospital, Linkou, Tao-Yuan Taiwan, Long JB et al, retrospectively reviewed 2010 patients undergoing laparoscopic surgery with open access method reported complications related to entry i.e. enterotomy (0.1%), failure to enter (0.1%) with no vascular injury, (2.5%), hematoma (0.05%). These complications were statistically significant in obese and previous abdominal surgery. It was concluded that blind technique of Verees needles is potential for visceral and vascular injuries. The open technique is a safe and effective method of obtaining access to the abdominal cavity with no associated vascular injury.[19]

Study done in Dr. RML Hospital New Delhi with a total of 4014 patients where pneumoperitoneum was created with verees needle, had total 27 complications like abdominal emphysema, omental injuries, small bowel injuries but majority were in patient with BMI >30kg/m^2 and they concluded that verees needle is comparative with open technique particular in patient with BMI<30kg/m^2.[20]

HISTORY OF LAPAROSCOPY

The Greek word “Lapara” meaning soft part of body between ribs, hips, flanks and loin, skope in, meaning to observe, were combined to give the word “laparoscopy” , its other name being “key hole” surgery. In earlier days it was used as a diagnostic procedure by gynecologists. But with development of video-camera and the introduction of laparoscopic cholecystectomy performance of many laparoscopic surgeries led to revolution of general surgery.

Laparoscopy has transformed the area of general surgery more rapidly than any surgical milestones. The privilege of introduction of word laparoscopy goes to Jacobeous, a Swedish surgeon, in 1910 who was the first to introduce the term laparoscopy in his work. He published the descriptions of the human peritoneal, thoracic and pericardial cavities.[21] The German Physician, Kelling was the first to visualize the peritoneal cavity. He experimented the procedure on a dog using cystoscope and filtered air to create pneumoperitoneum.[22]

In next few decades there were major developments, Korbsch in 1921 created pneumoperitoneum with needle for the first time. This achievement was in conjunction with first insufflators reported by Goetze.[23]Kalk in 1929 introduced first angled viewing scope with the central viewing axis that can be angled by 45-50 degree from the longitudinal axis. This invention helped to have better orientation, better visualization of organ and improved diagnostic ability. Kalk is also credited for being the first to introduce 2nd trocar incision.[24]

Laparoscopy was used as diagnostic tool initially. With improvement in light conduction, lens and electricity, operative procedures are now possible. Some of the

early operative procedures were adhesiolysis and diagnostic biopsy. Ferres in 1933 was the first to use cauterization for intra-abdominal adhesions and also first to introduce use of CO_2.[24] In 1938 O_2 was replaced by CO_2 as gas of choice for insufflation. Borsch in Germany was the first to laparoscopically conduct tubal sterilization using monopolar electrocoagulation. Around this year Verees needle was introduced for initial access to abdominal cavity followed by Hasson's open technique under direct vision in 1978.[25]

With the advancement in the technique and instruments, demand for laparoscopic procedures increased. Drastic improvement in the illumination was seen with introduction of fibre optic light source in 1960. Maintenance of hemostasis is more important in complicated procedures. With development of bipolar endoscopic electro cauterization, there was further excellence in laparoscopic surgeries.[26]

Kurt Semm, has given major contribution in development of laparoscopy. He has designed instruments like laparoscopic scissor, pre-tied suture loop, irrigation and aspiration devices. He also has been credited for creating, pelvi-trainer to teach surgeons hand to eye co-ordination skill as he was the one to recognize the importance of this training in laparoscopy.

Laparoscopic appendectomy was the first general laparoscopic surgery performed by Semm in 1982. Although it was successful, but operative laparoscopy was slow to gain acceptance. The landmark surgery was laparoscopy cholecystectomy done by Muhe in 1985, on animal, but his publication met with several critricism.[27] Laparoscopy as a technique became properly integrated into the discipline of general surgery, with introduction of video camera and computer chip which allowed projection of images on the television screen in 1986.

Encouragement received for laparoscopic cholecystectomy led to application of laparoscopic technique to other major procedures like nephrectomy, splenectomy, inguinal hernia repair etc. Compared to open procedure, many studies have documented advantages in terms of postoperative pain, recovery and length of hospital stay with laparoscopy rapidly.[28, 29, 30]

Laparoscopy continued to be inculcated into regular operating schedule of general surgeons and it is becoming technique of choice for future.

Some of the milestones in development of laparoscopic surgery,[31]

In 1806, Philip Bozzini, built an instrument that could be introduced in the human body to visualize the internal organs. He called this instrument "LICHTLEITER". Bozzini used an aluminium tube to visualize the genitourinary tract. The tube, illuminated by a wax candle, had fitted mirrors to reflect images.

In 1853, Antoine Jean Desormeaux, a French surgeon first introduced the 'Lichtleiter" of Bozzini to a patient. For many surgeons he is considered as the "Father of Endoscopy".

Kussmaul in 1868, performed the first esophagogastroscopy on a professional sword swallower.

Commander Pantaleoni in 1869, used a modified cystoscope to cauterize a hemorrhagic uterine growth.

In 1901, The first experimental laparoscopy was performed in Berlin in 1901 by German surgeon Georg Kelling, who used a cystoscope to peer into the abdomen

of a dog after first insufflating it with air. He also proposed a high pressure insufflation of abdominal cavity called as “air-tamponade

In 1920, Zollikofer of Switzerland discovered the benefit of CO2 gas used for insufflation.

In 1929, Heinz Kalk, a German gastroenterologist developed a 135 degree lens system and a dual trocar approach. He used laparoscopy as a diagnostic method for liver and gallbladder diseases.

In 1938, Janos Verees of Hungary developed a specially designed spring-loaded needle. But he developed this for induction of pneumothorax rather than to be used in laparoscopic procedures.

In 1944, Raoul Palmer, of Paris performed gynaecological examinations using laparoscopy, placing the patients in the Trendelenberg position, so air could fill the pelvis.

Kurt Semm introduced an automatic insufflation device capable of monitoring intra-abdominal pressures in 1966,

H.Coutnay Clarke in1972, first time showed laparoscopic suturing technique for hemostasis.

In 1983, Semm, a German gynaecologist, performed the first laparoscopic appendicectomy.

The first documented laparoscopic cholecystectomy was performed by Erich Mühe in Germany, 1985.

Harry Reich in 1989 described first laparoscopic hysterectomy using bipolar dessication.

In 1990, Bailey and Zucker in USA popularized laparoscopic anterior highly selective vagotomy combined with posterior truncalvagotomy.

In 1994, A robotic arm was designed to hold the telescope with the goal of improving safety and reducing the need of skilled camera operator.

In 1996, First live telecast of laparoscopic surgery performed remotely via the Internet.

ANATOMY

The abdominal wall is defined superiorly by the costal margins, inferiorly by the symphysis pubis and pelvic bones, and posteriorly by the vertebral column. Surgical implications of abdominal wall structure become apparent during the course of managing primary abdominal wall diseases or gaining access to the peritoneal cavity. A surgeon must have a thorough understanding of the arrangement of abdominal wall muscles and aponeuroses.[32]

There are nine layers to the abdominal wall: skin, subcutaneous tissue, superficial fascia, external oblique muscle, internal oblique muscle, transversusabdominis muscle, transversalis fascia, preperitoneal adipose and areolar tissue, and peritoneum.[33]

Skin

The integument of the anterior abdominal wall comprises skin, soft tissues, lymphatic and vascular structures, and segmental nerves. The outer layer is formed by the skin and subcutaneous fat. The skin is non-specialized and variably hirsute.[34]

Subcutaneous Tissues

The subcutaneous tissue consists of Camper's and Scarpa's fascia. Camper's fascia is the superficial layer that contains the bulk of the subcutaneous fat; Scarpa's fascia is a denser layer of fibrous connective tissue contiguous with the fascia lata of the thigh. Approximation of Scarpa's fascia aids in the alignment of the skin after surgical incisions in the lower abdomen.[33]

The anterior abdominal wall can be considered to have two parts: anterolateral and middle (or midline). The anterolateral portion is composed of the external oblique, the internal oblique, and the transverses abdominis muscles. The middle portion is composed of the rectus abdominis and pyramidal muscles.[35]

Anterolateral portion of abdominal wall

Lateral to the rectus sheath are three muscular layers with oblique fiber orientations relative to one another. These layers are derived from the laterally migrating mesodermal tissues during the sixth to seventh week of fetal development, before fusion of the developing rectus abdominis muscles in the midline.[32]

The external oblique muscle runs forward inferiorly and medially, but its upper fibres are nearly horizontal 4 arising from the margins of the lowest eight ribs and costal cartilages. The external oblique muscle originates laterally on the latissimus dorsi and serratus anterior muscles. Its lower fibres, inserting into the iliac crest, are nearly vertical. Medially it forms a tendinous aponeurosis, which is contiguous with the anterior rectus sheath.[32]

The inguinal ligament is the inferior most edge of the external oblique aponeurosis, reflected posteriorly in the area between the anterior superior iliac spine and pubic tubercle.[32]

The internal oblique muscle lies immediately deep to the external oblique muscle and arises from the lateral aspect of the inguinal ligament, the iliac crest, and the thoracolumbar fascia. Its fibers course superiorly and medially, but its lowest fibres, which descend to the pubis, are almost vertical.[36]

They form a tendinous aponeurosis that contributes components to both the anterior and posterior rectus sheath. The lower medial and inferior-most fibers of the internal oblique course may fuse with the lower fibers of the transverses abdominis muscle (the conjoined area).[32]

Transversus abdominis is the deepest muscle, and runs mainly horizontally, although its lowest fibres run downwards along with those of internal oblique as the conjoint tendon. Its deep surface is lined by transversalis fascia; between this and the peritoneum there is a layer of extraperitoneal fat of variable thickness.[36]

Middle portion of abdominal wall

Rectus abdominis lies alongside the linea alba, extending above from the 5th, 6th, 7th costal cartilages and the xiphoid process, below it attaches to the pubic crest, to the ligamentous tissue at the symphysis pubis, and the superior ramus of the pubis. Its lateral border may be visible on the surface of the anterior abdominal wall as a curved groove, the linea semilunaris, which extends from the tip of the ninth costal cartilage to the pubic tubercle It is broader but thinner superiorly. Its substance is traversed by three horizontal tendinous intersections, one opposite the umbilicus, another near the xiphoid, and a third midway between these. Studies by Milloy et al. demonstrate that three inscriptions are the most common pattern (58%), and four inscriptions the next most common (35%).[35]

Vascular supply-

Rectus abdominis is supplied principally by the superior and inferior epigastric arteries. The inferior epigastric artery tends to be larger in caliber than the superior. Small terminal branches from the lower three posterior intercostal arteries, the

subcostal artery, the posterior lumbar arteries and the deep circumflex artery may provide some contributions.[34]

Nerve supply

Rectus abdominis is innervated by the terminal branches of the ventral rami of the lower six or seven thoracic spinal nerves via the lower intercostal and subcostal nerves.[34]

Pyramidal muscle

The pyramidal muscle attaches to the pubic crest and symphyseal ligamentous tissues and inserts into the linea alba. The pyramidal muscle is absent on one or both sides in 10 to 20 percent of subjects. When present, its insertion into the linea alba is a landmark for an accurate midline incision.[35]

Vascular supply

Pyramidalis is supplied by branches of the inferior epigastric artery, with some contribution from the deep circumflex iliac artery. A small artery frequently crosses the midline posterior to the belly of the muscle to anastomose with the contralateral vessel. This may cause troublesome bleeding during surgical incisions that run down as far as the lower rectus sheath above the symphysis pubis. [34]

Nerve supply

Pyramidalis is supplied by the terminal branches of the subcostal nerve, which is the ventral ramus of the twelfth thoracic spinal nerve.[34]

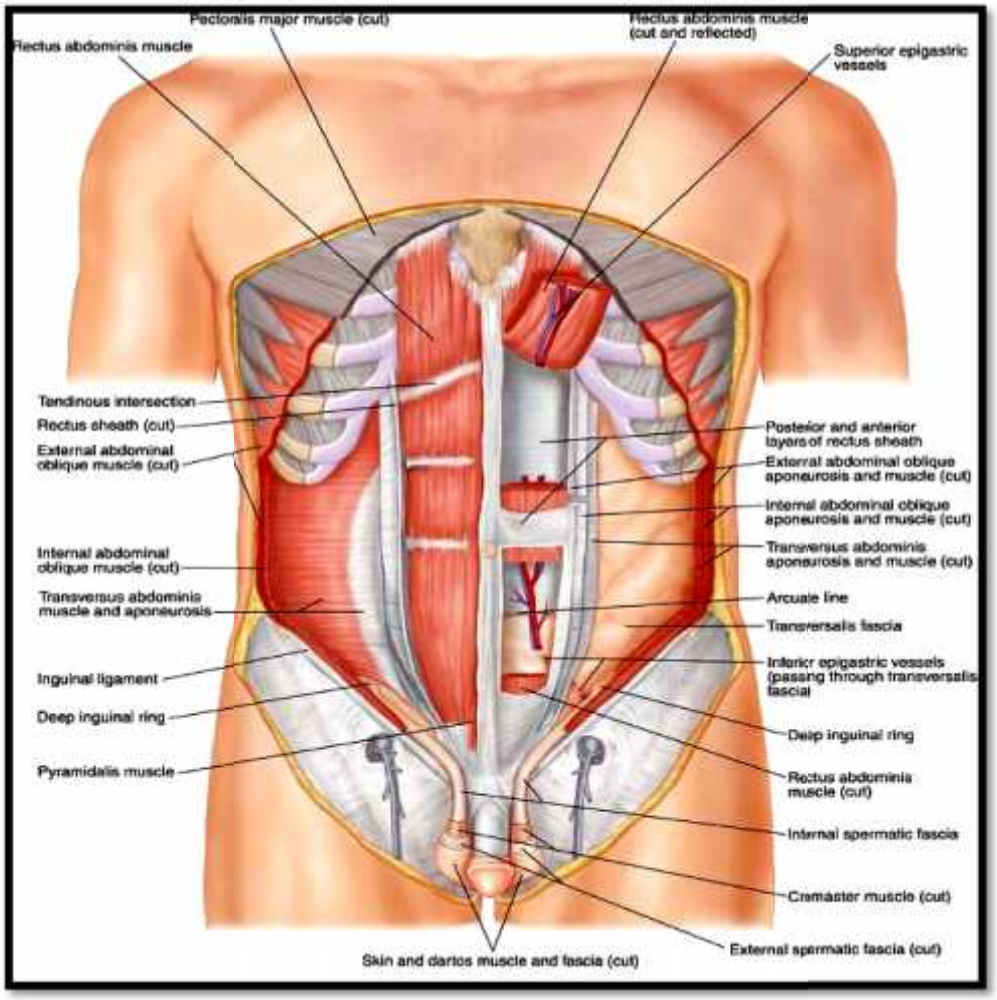


Figure No.1: A, Showing Layers Of Anterior Abdominal Wall

RECTUS SHEATH

This is formed by the aponeuroses of external oblique, internal oblique and the transverses abdominis, the last two of which are arranged in a somewhat complicated manner. The anterior sheath is complete from rib margin to pubis. In its upper three-quarters it is formed by external oblique and by the anterior lamina of internal oblique. In the lower one-quarter it is formed by all three aponeuroses. It is adherent to the tendinous intersections of the rectus muscle.[36]

The posterior sheath is complete only as far down as a point midway between umbilicus and pubis, where it ends as a free border, called the arcuate line (semicircular line of Douglas), which lies roughly at the level of the anterior superior iliac spines . Below this level the sheath is deficient, the rectus being separated from the peritoneum by transversalis fascia alone. The posterior sheath is formed by the posterior lamina of internal oblique fused with transversus. The tendinous intersections do not extend to the posterior surface of the rectus abdominis.[36]

Because of this arrangement, both the anterior and posterior layers of the rectus sheath consist of three layers of fibres with the middle layer running obliquely at right angles to the other two. At the midline, the anterior and posterior layers are closely approximated. Fibres of each layer decussate to the opposite side of the sheath, forming a continuous aponeurosis with the contralateral muscles.[34]

Fibres also decussate anteroposteriorly, crossing from anterior sheath to posterior sheath. The dense fibrous line caused by this decussation is called the linea alba. These decussating fibres maybe used to identify the midline during surgical incisions, since they can be seen as oblique fibres crossing at right angles. Below the level of the arcuate line, the fibres forming the posterior rectus sheath rapidly cease running behind the rectus and all leaves pass into the anterior rectus sheath.[34]

Linea alba

The linea alba is a tendinous raphe extending from the xiphoid process to the symphysis pubis and pubic crest. It lies between the two recti and is formed by the interlacing and decussating aponeurotic fibres of external oblique, internal oblique and transverses abdominis. It is visible only in the lean and muscular, as a slight

groove in the anterior abdominal wall. A fibrous cicatrix, the umbilicus, lies a little below the midpoint of the linea alba, and is covered by an adherent area of skin. Below the umbilicus, the linea alba narrows progressively as the rectus muscles lie closer together. Above the umbilicus, the rectus muscles diverge from one other and the linea alba is correspondingly broader. The linea alba has two attachments at its lower end: its superficial fibres are attached to the symphysis pubis, and its deeper fibres form a triangular lamella that is attached behind rectus abdominis to the posterior surface of the pubic crest on each side. This posterior attachment of linea alba is named the 'adminiculum lineae albae'. The linea alba is crossed from side to side by a few minute vessels.[34]

According to Askar, there is a single decussation of fibers of both the anterior and posterior rectus sheath laminae in 30% of cases. A single decussation of anterior rectus sheath laminae and a triple decussation of posterior rectus sheath laminae is found in 10% of cases. A triple decussation of aponeurotic fibers of both anterior and posterior rectus laminae occurs in 60% of cases. Subjects in the group with single fibrous crossings of both the anterior and posterior rectus sheath laminae may be more susceptible to linea alba herniation.[35]

Linea semicircularis

The semicircular line of Douglas marks the lower level of the aponeurotic posterior lamina. This concavity of the arcuate line is usually directed downward or downward and laterally. If the change from aponeurosis to transversalis fascia is gradual, the line is poorly defined. If the change is abrupt, the line is well marked.[35]

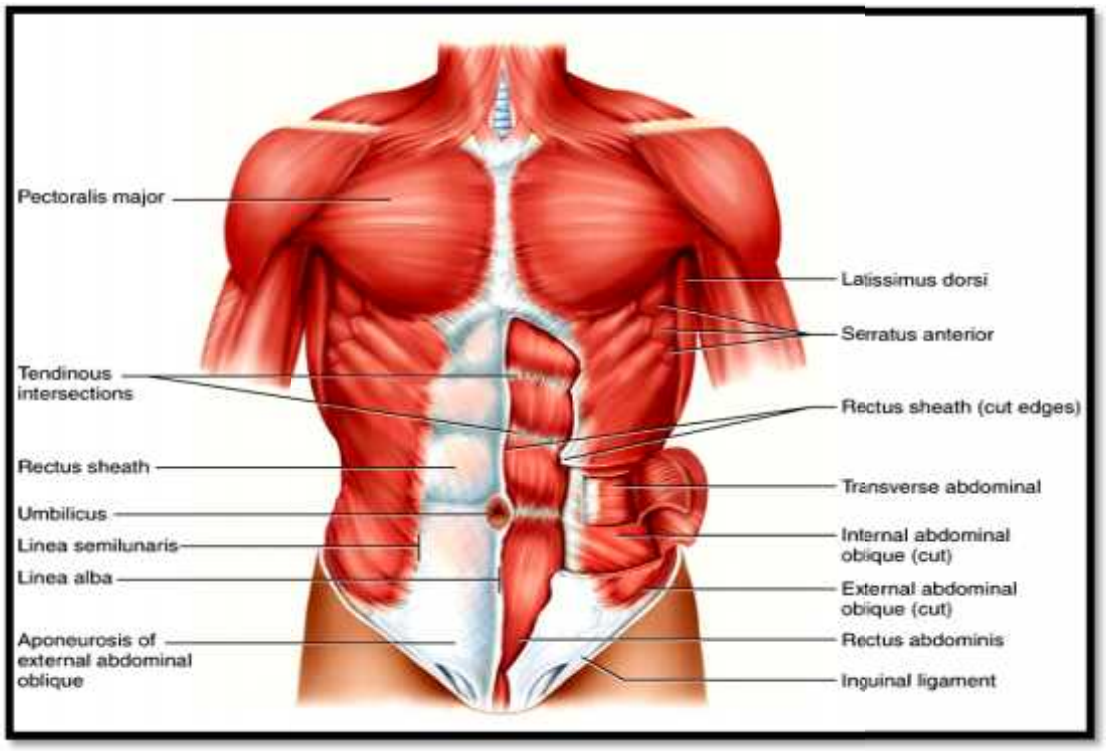


Figure No.1: B, Showing Layers Of Anterior Abdominal Wall

Transversalis fascia

It covers the deep surface of the transverses abdominis muscle and with its various extensions forms a complete fascial envelope around the abdominal cavity. This fascial layer regionally covers the iliopsoas fascia, obturator fascia, and inferior fascia of the respiratory diaphragm. The transversalis fascia binds together the muscle and aponeurotic fascicles into a continuous layer and reinforces weak areas where the aponeurotic fibers are sparse. This layer is responsible for the structural integrity of the abdominal wall, and by definition, a hernia results from a defect in the transversalis fascia.[33]

Extraperitoneal connective tissue

The extraperitoneal connective tissue is a layer of areolar tissue lying between the peritoneum and the fasciae lining the abdominal and pelvic cavities. The amount of extraperitoneal tissue varies. It is variable in thickness on the anterolateral wall. It is scanty in the suprapubic region, above the iliac crest and in the pelvis. Extraperitoneal tissue is continuous with the epimysium of muscles of the abdominal wall.[34]

Peritoneum

The peritoneum is the innermost layer of the abdominal wall anteriorly, laterally, and posteriorly. It is loosely connected with the transversalis fascia in most areas, except at the internal ring, where the connection is stronger. It can also be fused rather tightly to the posterior lamina of the rectus sheath, rendering their separation difficult.[35]

Blood supply

The majority of the blood supply to the muscles of the anterior abdominal wall is derived from the superior and inferior epigastric arteries. The superior epigastric artery arises from the internal thoracic artery, whereas the inferior epigastric artery arises from the external iliac artery. The two vessels have anastomotic connections within the belly of the muscle.[36]A collateral network of branches of the subcostal and lumbar arteries also contributes to the abdominal wall blood supply.[32]

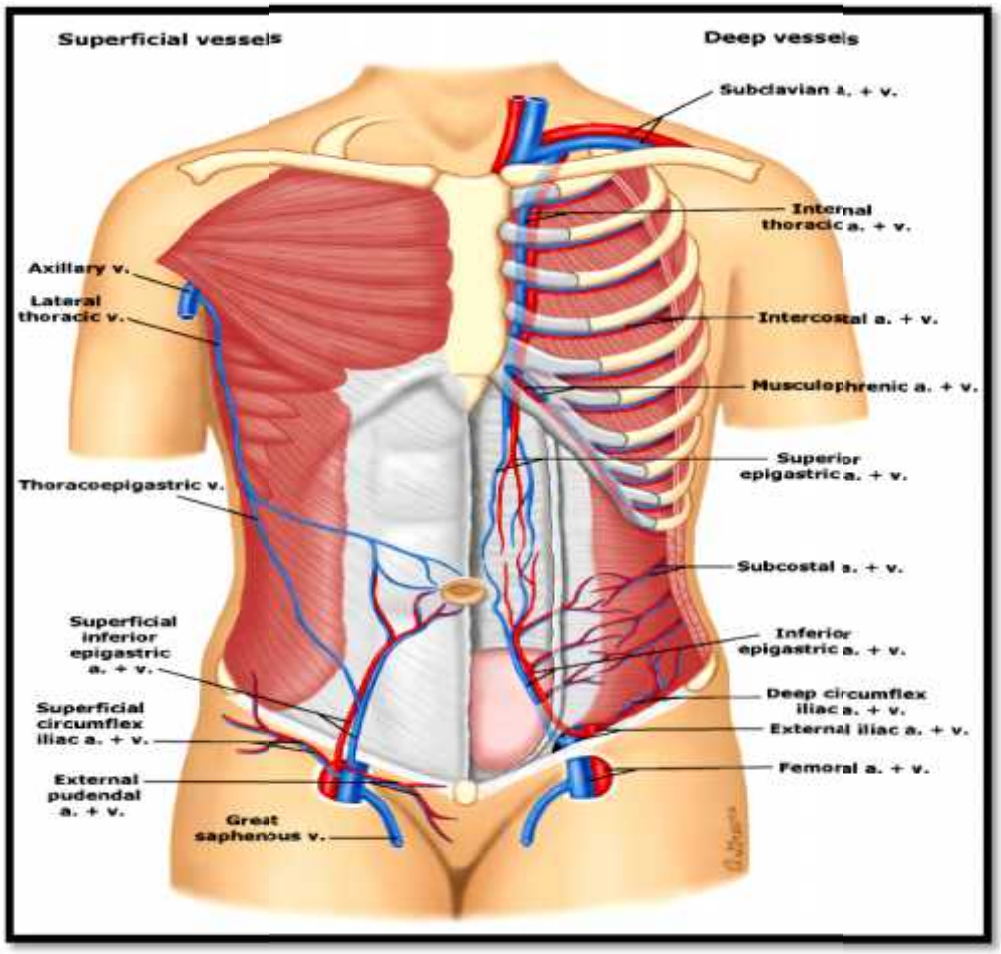


Figure No.2 : Showing Blood Supply To Anterior Abdominal Wall

Lymphatic drainage

The lymphatic vessels of the anterior abdominal wall lie both superficial and deep to the deep fascia. The lymphatic drainage of the abdominal wall is predominantly to the major nodal basins in the superficial inguinal and axillary areas.

Superficial vessels

The superficial lymphatic vessels accompany the subcutaneous blood vessels. Vessels from the lumbar and gluteal regions run with the superficial circumflex iliac vessels. Those from the infra-umbilical skin run with the superficial epigastric

vessels. Both drain into the superficial inguinal nodes. The supra-umbilical region is drained by vessels running obliquely up to the pectoral and subscapular axillary nodes, and there is some drainage to the parasternal nodes.[34]

Deep vessels

The deep lymphatic vessels accompany the deep arteries. The vessels from the posterior portion of the abdominal wall pass with the lumbar arteries to drain into the lateral aortic and retro-aortic nodes. Vessels from the upper anterior abdominal wall run with the superior epigastric vessels to the parasternal nodes. Vessels of the lower abdominal wall drain into the circumflex iliac, inferior epigastric and external iliac nodes.[34]

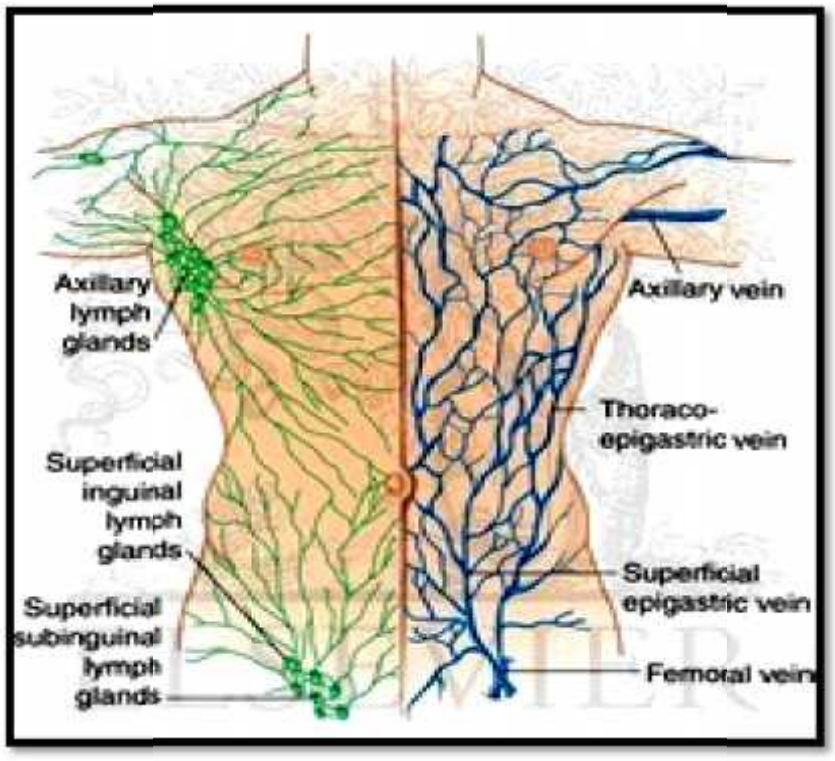


Figure No.3 : Showing Lymph Node And Lymphatics Of Anterior Abdominal Wall.

Nerve supply

Innervation of the anterior abdominal wall is segmentally related to specific spinal levels. The motor nerves to the rectus muscles, the internal oblique muscles, and the transverses abdominis muscles run from the anterior rami of spinal nerves at the T6 to T12 levels. The overlying skin is innervated by afferent branches of the T4 to L1 nerve roots, with the nerve roots of T10 sub serving sensation of the skin around the umbilicus.[32]

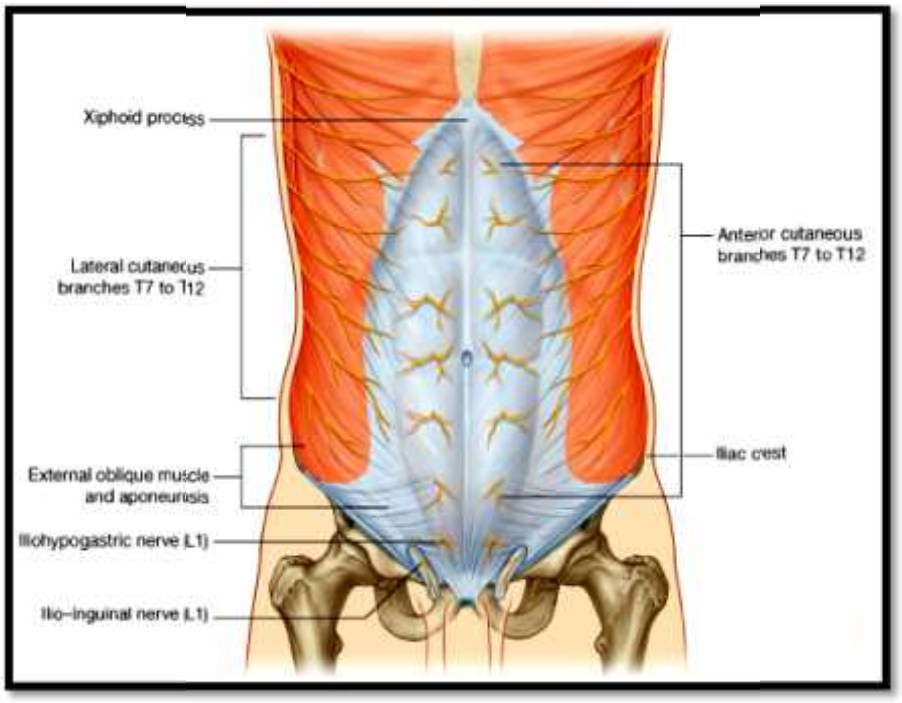


Figure No.4 : Showing Nerve Supply To Anterior Abdominal Wall

PATHOPHYSIOLOGY OF PNEUMOPERITONEUM

Pathophysiology of pneumoperitoneum

Laparoscopic surgery in today's date is a routinely performed procedure worldwide, replacing many types of open surgeries. It has the benefits of small incision, improved cosmetic aspects, less postoperative pain, and quick recovery time to normal activities. The most commonly used gas for insufflation is carbon dioxide. Carbon dioxide CO_2 pneumoperitoneum and increased intraabdominal pressure can induce many pathophysiologic disturbances, requiring the anesthesiologist to be well alert during the operation for necessary management. Moreover, advanced laparoscopic surgeries are being used also on older patients and in critically ill patients, requiring technically demanding anesthesia.

Pathophysiologic changes

Respiratory changes

The normal function of respiratory system is affected by pneumoperitoneum. Total volume of the lungs is decreased as the diaphragm is pushed cephalad leading to stiffness of the chest wall, caused by an increase in intraabdominal pressure with insufflations. Therefore pulmonary compliance is reduced to 35–40% and maximum respiratory system resistance also increased significantly.[37, 38, 39, 40]There is high chance of ventilation perfusion mismatch and intrapulmonary shunting leading to hypoxemia but is rare in healthy patients.[41]Hypercapnia and acidosis may occur as carbon dioxide is a highly soluble gas. It is easily absorbed into the circulation through the peritoneum.

One study comparing laparoscopic Roux-en-Y gastric bypass (GBP) against open surgery found that $ETCO_2$ was raised from 35 mmHg to 40 mmHg, i.e. by 14%, whereas PaCOv also was raised by 10%, from 38 mmHg to 42 mmHg.[42]Demiroluk et al reported $PaCO_2$ levels were initially 34 mmHg and increased to 42 mmHg with pneumoperitoneum.[43]Wittgen et al concluded that there is significant increase in $ETCO_2$ and $PaCO_2$ with decrease pHa value in ASA III and IV patients compared to ASA I and II patients group in a study comparing ventilator effects on laparoscopic cholecystectomy.[44]

Carbon dioxide is mainly excreted by lungs depending on alveolar and mixed venous carbon dioxide exchange rate which are themselves controlled by cardiac output, alveolar ventilation and respiratory quotient.[45] Normal excretion of carbon dioxide is 100-200 ml and may increase by 12-48 ml/min with administration of CO_2 intraperitoneally.[46, 47, 48, 49] Usually it will take few hours after desufflation to have normal CO_2 level after prolonged laparoscopic surgery, since high use of peripheral storage capacity will lengthen the duration of increased $PaCO_2$.[51, 52]

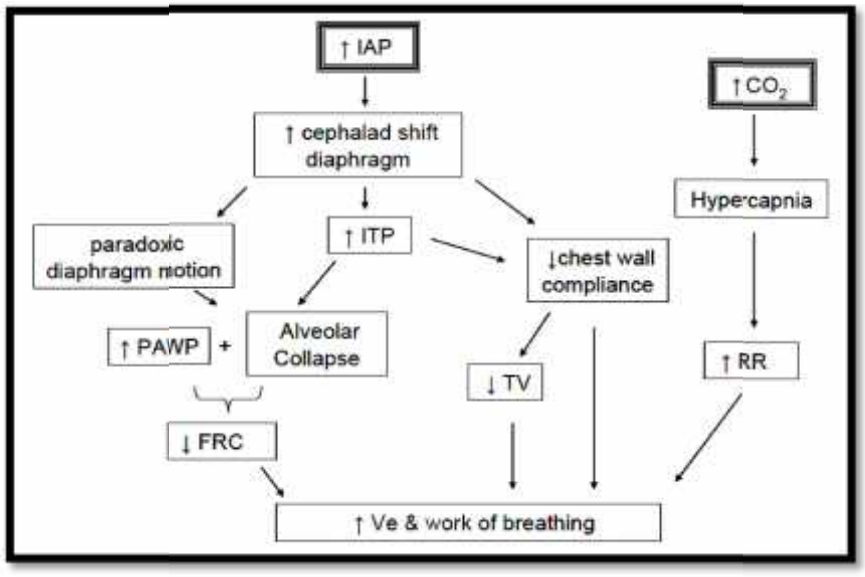


Figure no. 5 : Effect Of Pneumoperitoneum On Respiratory System

Cardiovascular changes

During pneumoperitoneum, cardiovascular system is affected so to attenuate any possibility of cardiac untoward events due to reduced preload caused by pneumoperitoneum, it is important to maintain euvolumic status of the patients prior to surgery. Cardiac effects are mainly caused by increased intra-abdominal pressure and hypercarbia followed by acidosis. Cardiovascular function is affected by stimulation of sympathetic system, directly or indirectly by hypercarbia. With mild hypercarbia ($PaCO_2$ 45-50 mmHg) effect is not significant but with moderate to severe hypercarbia, it hampers the function of cardiac by acting as myocardial depressant with vasodilator effect.[52] During CO_2 pneumoperitoneum side effects are caused mainly by hypercarbia followed by acidosis and increased intra-abdominal pressure. A euvolumic status is of great importance prior to surgery to reduce any cardiac depression via reduced preload caused by the pneumoperitoneum.

Dexter et al compared two groups of patients, one with pneumoperitoneum of 7 mmHg and the other with a pressure of 15 mmHg, concluded that both groups have an increase in heart rate and mean arterial pressure, but the cardiac output and stroke volume were more significantly decreased in the 15 mmHg group.[53]Westerban et al studies showed a cardiac index depressed by 30% in patients during laparoscopic cholecystectomy.[54] Kraut et al, concluded that combination of increased IAP and PEEP should be avoided as study showed mild decrease in cardiac output and stroke volume with 15mmHg but addition of 10 cm of PEEP showed prominent reduction in cardiac and stroke volume.[55]Joris et al said that with a post-inflation IAP of 15 mmHg after deflation MAP increased by 35% and systemic vascular resistance increased by 65%, pulmonary vascular resistance increased by 90%, and a decrease in cardiac

index by 20%. The authors suggested that increased vascular resistance could partly increase the cardiac index.[56]

Bradyarrythmia is also seen in pneumoperitoneum. These arrhythmias are due to peritoneal stretching on insufflation.[57]In one study with patients undergoing laparoscopic urology surgery, bradycardia was developed in 28% of patients compared to 0% of patients who received dose of atropine prior to pneumoperitoneal insufflation.[58]

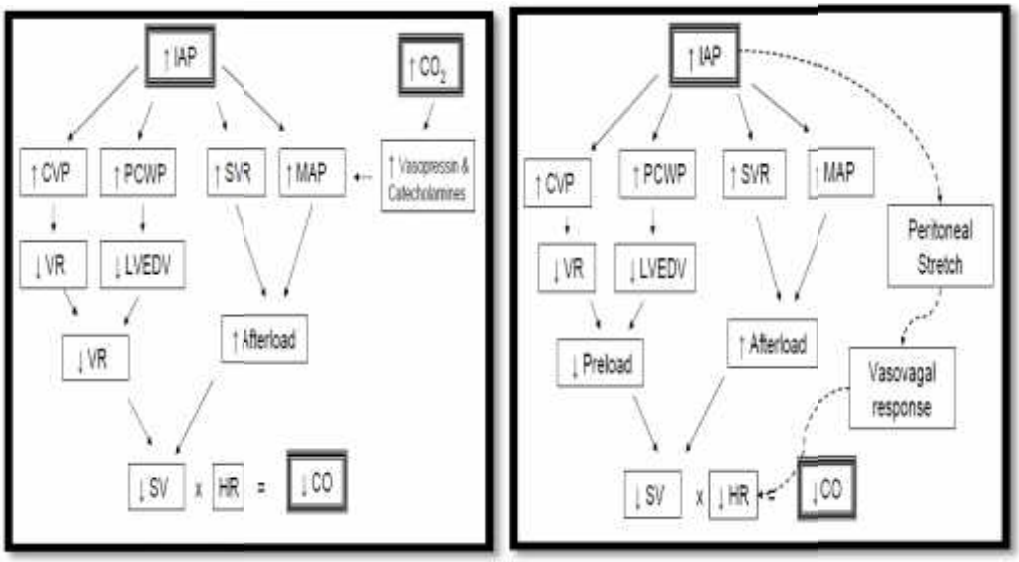


Figure No. 6 : Effect Of Pneumoperitoneum On Cardiovascular System.

Renal changes

Main renal effect of pneumoperitoneum is oliguria.[59, 60, 61] Renal normal functioning is affected by different mechanisms during increased intraabdominal pressure. Shuto et al stated that renal blood flow (RBF) decreased considerably with pressure of 20mmHg insufflation due to compression of the renal vessels and parenchyma.[62] There is renal cortical vasoconstriction due to renin-angiotensin-aldosterone activation following decreased renal perfusion caused by increased IAP.

Nguyen et.al stated that the level of ADH, renin, and aldosterone significantly increased during laparoscopic GBP.[63] Chui et.al, reported a decrease of 60% in renal cortical flow, which however returned to normal after desufflation.[64] Ortega et.al reported a precipitous rise in ADH concentration during laparoscopic cholecystectomy, which was not seen in open cholecystectomy. There is no proven mechanism of disturbance in renal blood flow and needs to be studied. During increased IAP, renal blood flow has been quantified and shows gradual decrease in RBF up to 75% on reaching pressure of 15mmHg. There are controversial studies also stating no significant changes in RBF during pneumoperitoneum.[65]

Yavuz et al & Ali et al, did studies on pig concluded no significant changes in RBF. Many studies monitoring serum creatinine concluded that there is rise in serum creatinine.[66, 67]Krisch et al, studied on rat with 5mmHg and 10mmHg of IAP to observe significant increase in serum creatinine but it returned to normal within a couple of hours.[68] Miki et al compared IAP and wall lifting technique during cholecystectomy laparoscopy. They reported a decrease in urine output and GFR, with effective renal plasma flow, during laparoscopy but these changes were not seen with the abdominal wall lift device technique.[69]

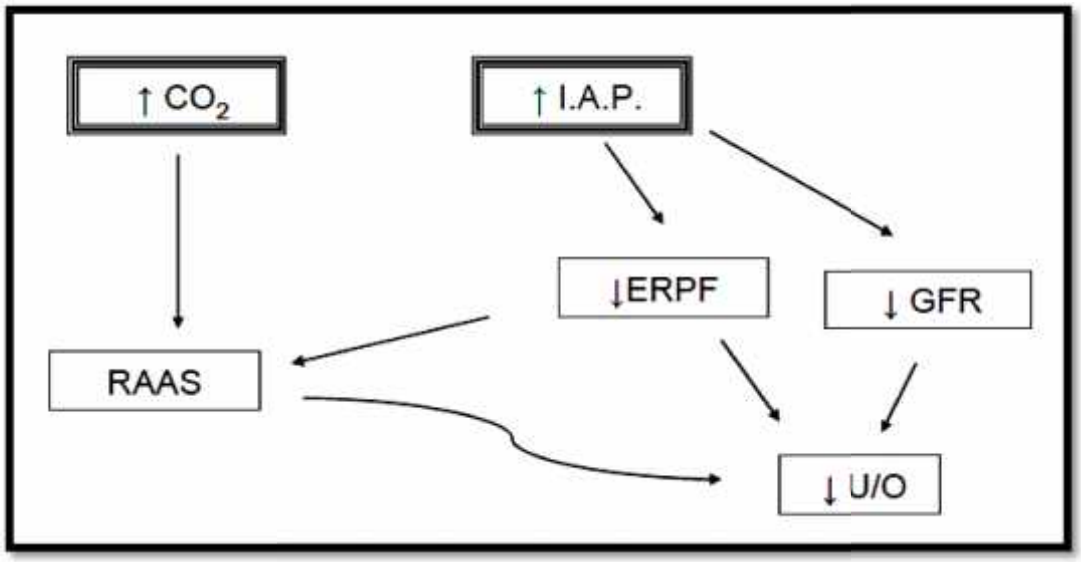


Figure No. 7 : Effect Of Pneumoperitoneum On Renal System

Splanchnic changes

The studies have shown that splanchnic circulation is also changed during increased IAP. During raised IAP of 10 to 15 mmHg shows decrease in blood flow of 40 to 50% in stomach, 32% in jejunum, 44% in colon, 39% in liver, and 60 % in peritoneum.[70] Studies on animals showed decrease in splanchnic macro and micro-circulation.[71, 72] Pneumoperitoneum decreased hepatic blood flow in a manner similar to renal flow. This may lead to acute hepatocellular injury with transient increase with normalization within 72 hours. Hepatic injury can be decreased by keeping IAP less than 15 mmHg, minimizing traumatic liver retraction and avoiding anesthesia that could worsen liver function.

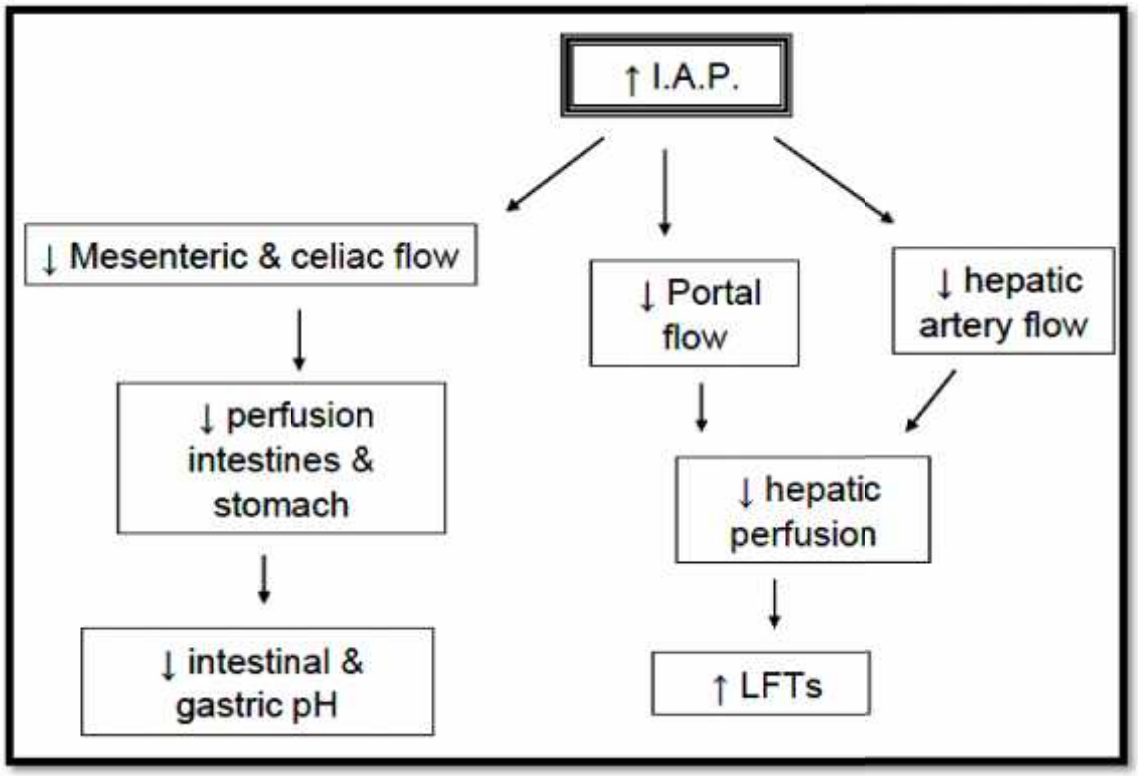


Figure No.8 : Effect Of Pneumoperitoneum On Biliary Hepatic And Gastrointestinal System.

TECHNIQUES OF ABDOMINAL ACCESS

Gases used

The most common gas used for laparoscopy is carbon dioxide. Nitrous oxide, argonium, helium, xenon, and also room air are other gases that are used for insufflation. There are significant differences between these in physical matter. Several studies reported the various effects on tumor biology during the laparoscopic procedure, helium and xenon seem to decrease tumor volume. Helium and argonium are also found to be safer for the cardio-circulatory system.[73]

Techniques of abdominal access

There are two techniques of abdominal entry with some modifications in laparoscopic surgeries

1) Verees needle (closed) technique, most traditional and oldest method
2) Hasson's (open) technique- under direct vision by doing mini-laparotomy initial trocar can be placed.

Verees needle (closed) technique:

Verees needle technique is the widely used method in present days. In this technique space is created in abdominal cavity between abdominal wall and intraabdominal as well as retro-peritoneal organs by insufflating adequate volume of gas. After complete formation of space, sharp trocar is placed in peritoneal cavity. This is a blind technique in the absence of direct vision as trocar is inserted into insufflated peritoneal cavity. This needle was developed by Janos Verees of Hungary.[74]It is specially designed spring loaded needle.

Verees needle is 12 to 15 cms long with external diameter of 2mm. The needle consists of sharp outer sheath which has beveled needle point to dissect through tissues. The inner stylet is blunt spring loaded located within outer cannula designed to guard obturator against injury on penetration. The blunt inner stylet is pushed into shaft of outer sheath when direct pressure is applied and inner stylet springs out on entering a space as peritoneal cavity.[75] It is available in both disposable and reusable forms.

Photograph No.1: Verees Needle

Technique

The insertion of verees needle into abdominal wall relies on various factors. It depends on previous incision scar, body habitus, type of surgery etc.[75]A gastric tube is put to decompress the stomach before inserting verees needle as often stomach is insufflated during induction of anesthesia and there is high chance of injury.

The best site for location of initial needle insertion is periumbilical region where abdominal wall is comparatively thin and fascia is adherent to umbilicus. If earlier midline incision is present near umbilicus, alternate location or different technique is preferred.[75] In case of presence of scar due to previous midline surgery left upper quadrant site is preferred for verees needle insertion to reduce the risk of injury to viscus due to intra-abdominal adhesion.[76, 77] This site is known as palmer point, located 3cm below the middle of left costal margin.[78] It is reported that at this region distance between skin and retroperitoneal structure is more than 11cms.[79]

Photograph No.2 : Taking Incision Before Insertion Of Verees Needle

Photograph No.3 : (A) Technique Of Verees Needle Insertion

Periumbilical verees needle insertion is done through vertical/ transverse stab incision made with knife. No.11 needle is held in position keeping distal length of needle tip adequate to transverse whole thickness of abdominal wall. Towel clip can be placed near skin incision to elevate abdominal wall. This act will help to make a cavity between anterior aspect of peritoneum and intra-abdominal content as well as retroperitoneal structure. In obese patients, skin and subcutaneous is lifted by towel clip maneuver. The abdominal wall is grasped and lifted and verees needle advanced at 45 degree caudal angle or perpendicular in obese to abdominal wall.[31]The needle is pushed till appreciable change in force is felt as needle advances into peritoneal cavity. A surgeon should feel two clicks as needle is pushed. The first click felt as needle passes through anterior rectus fascia and second on entering and traversing peritoneal cavity.[1]

Photograph No.3 : (B) Technique Of Verees Needle Insertion

Confirmation of needle position

To confirm proper placement of needle following tests are made, [31]

1. Hiss test- due to negative intraabdominal pressure atmospheric air is sucked into the abdomen with hiss sound, to confirm needle tip is in the peritoneal cavity.
2. Aspiration test- Half filled saline syringe attached to top of verees needle and aspirated. If any blood, bowel content, urine seen on aspiration, it indicates needle is in vessel, bowel or bladder.
3. Re-aspiration test- 5ml saline is instilled into peritoneal cavity and if saline flows inside without resistance and does not enter the syringe on re-aspiration,

it means tip is in the cavity. Aspiration of fluid indicates needle is into organ or in between layers of abdominal cavity.

4. Drop test- Saline drop kept over top of verees needle is sucked into the peritoneal cavity due to negative intra-peritoneal pressure.
5. Percussion over the quadrant- liver dullness obliterated with 5-10 cc insufflation CO_2 indicating proper position of needle in peritoneal cavity.

Other method for confirmation is Waggle test- In this Verees needle should move freely over a fulcrum point located within anterior abdominal wall. Lack of this movement suggests needle is into intra or retro peritoneal structure.[75]

Insufflator

Insufflator (laparoflator) is a machine used for introduction of the gas under specified volume and pressure into abdominal cavity. Initially devices were set manually, but in present days mainly automatic electronically controlled insufflators are available. The devices will allow a specified flow of the introduced gas (in lit/min), and at a constant pressure (12-14 mmHg). Some of the devices are available with bacteriological filters, and an endothermic system to maintain adequate temperature of insufflated gas. In some cases a controlled desufflation is also used to remove a surgical smoke.[73]

Photograph No.4 : Insufflator

Insufflation

After confirming the position of tip of verees needle with tests mentioned before gas tubing is connected, insufflation is started at low rate of less than 3mmHg. During insufflation flow rate and intraabdominal pressure has to be monitored.[31] If there is zero flow and high pressure of more than 20 mmHg, it indicates needle tip is in the abdominal wall, bowel, omentum. The needle is withdrawn and reinserted, as should not be advanced further.[75]

In the beginning of insufflation, initial filling pressure of less than 10mmHg is best indicator of intraperitoneal placement.[80] During insufflations following parameter has to be monitored , i.e. abdominal morphology, volume of gas insufflated, intraabdominal flow rate and vitals. Flow rate can be set to higher rate, if intraabdominal pressure is low, flow rate can be set up to 40lit/ min but usually rarely exceeding 1 to2 lit/ min.[75]

Open technique

This technique was developed by H M Hasson. In this technique first trocar is inserted before creating pneumoperitoneum by dissecting abdominal wall under vision. Visceral injuries due to blind penetration of abdominal cavity were high. To decrease this incidence open technique was developed. In this technique mini-laparotomy is to be done. For this technique, Hasson developed a device which consists cannula and blunt obturator to prevent injuries during penetrating and specific sealing cone with tab to fix the sutures.[75] alternatively standard 10mm trocar without blade can be used with adequate sealing sutures.

Photograph No.5 : Hasson's Cannula

Photograph No. 6 : 10mm Trocar

In open technique abdominal cavity is entered under vision so there is decreased chance of injury to adherent bowel. This technique is likely to minimize major vascular injuries.[77, 81] but disadvantages are increased port related complication like hematoma, wound infection, hernia, leakage of gas around cannula.[79]

Technique

Infra or supraumbilical region is preferred site. Incision of appropriate size is taken. Subcutaneous tissue is bluntly dissected and abdominal fascia seen. Linea alba seen and held on either side with Kocher's clamp and lifted. Linea alba incised vertically in midline about 0.5 to 1 cm.[75] A defect is created, too big defect will lead to air leakage. Preperitoneal plane should not be dissected in excess because peritoneum may fall away from fascia and surgeon may be lost in this plane.[31]After confirming the entry into abdominal cavity visually, on either side of the fascial defect, two heavy absorbable sutures should be placed before taking out Kocher's clamp. Hasson cannula or 10mm trocar without blade is advanced into abdominal cavity and suture is firmly attached to create seal with fascia. Then abdominal cavity

is insufflated with gas and laparoscope inserted. If gas leakage is present, penetrating towel clip or stay sutures are removed and resutured firmly to secure cannula.

Photograph No. 7: (A) Showing Open Technique Port Placement

Photograph No. 7: (B) Showing Open Technique Port Placement

METHODOLOGY

Source of Data –

In patients undergoing laparoscopic surgeries in Department of General Surgery at KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi, between January 2014 to December 2014.

Method of collection of data

a) Study design:

A randomized controlled trial

b) Study Period-

1 year January 2014 to December 2014.

c) Study population-

Patients undergoing laparoscopic surgeries in Department of General Surgery

i) Place:

KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Jawaharlal Nehru Medical College, Belagavi.

d) Selection criteria

i) Inclusion criteria

1. Age: - ≥ 16 YEARS, ≤ 65 YEARS

2. Patient who give consent for study
3. ASA grade I & II
4. Virgin and non-Virgin abdomen

Operations performed by experienced surgeons senior / junior residents, post graduate doctors and the series include the learning curve of any surgeons involved.

ii) Exclusion criteria

1. Patient who refuses to give consent to study.
2. Co-morbid conditions like

   Chronic liver disease,

   Chronic renal failure,

   Malignancy
3. Immunocompromised patient.

e) Sample size calculation-

Total sample size of 130 cases, 65 in group A and the other 65 in group B.

The sample was calculated by considering of incidence of complication in two technique 14%(p_1) with Verees needle and 0.9% (1%)(p_2) with Hasson's open method.

with type I error $\alpha = 0.05$ and

type II error rate $\beta = 0.02$

with a power of 80% and using the formula-

$$n = \frac{2(Z\alpha + Z\beta)^2 pq}{(p_1 - p_2)^2}$$

n= number of sample

$Z\alpha = 1.96$

$Z\beta = 0.84$

$P_{1} = 14\%$

$P_{2} = 1\%$

Ethical clearance

Prior to the commencement of the study ethical clearance was obtained from the Institutional Ethical committee, Jawaharlal Nehru Medical College, Belagavi.

Informed Consent

Patients who were undergoing laparoscopic procedure for some surgical abdominal conditions are screened for eligibility by detailed history, physical examination, investigations and indication for surgery by trained residents in the Department of General surgery. Those fulfilling the selection criteria were explained about the purpose of the study, its complications and the need for randomization. A written informed consent was obtained from all the participants before the enrollment (Annexure I).

Method of collection of data

After enrollment, demographic data, history, previous surgical history details, BMI and indication for surgery is obtained. Routine physical examination and per abdominal examinations was carried out. Variable outcomes after creation of pneumoperitoneum by two techniques were obtained. The data was recorded on a predesigned and pretested proforma (Annexure II).

Randomization

By using sequential numbered brown opaque envelop method patients who were undergoing laparoscopic procedure were randomized into groups as below.

- Closed (group A) (n = 65): included patients who underwent laparoscopic procedure with pneumoperitoneum created by Closed (Verees needle) method.
- Open (Group B) (n = 65): included patients who underwent laparoscopic procedure with pneumoperitoneum created by Open (Hasson's) method.

Methodology-

After obtaining the approval of the ethical committee and written informed consent, a total of 130 patients undergoing laparoscopic surgeries for any clinical conditions will be included in the study.

There was no specific indication for a particular technique to be used in favor of other one and patient were allotted randomly into closed and open group using sequential numbered brown opaque envelop method.

All insertion done through infraumbilical OR supraumbilical 1 cm to 1.5 cm transverse incision. Patients will be randomly divided into two groups. Variables taken into consideration includes the ability to create pneumoperitoneum, the time taken to establish it, leakage of carbon dioxide gas from the margins of the access site, conversion to laparotomy, mortality and the known complications of laparoscopic surgeries which include abdominal wall hematoma, subcutaneous insufflations of gas, failures, penetrating injuries to blood vessels and intraabdominal

viscera. Complications will be prospectively recorded and retrieved from the database.

All patients are taken under general anesthesia. The guidelines for asepsis and antisepsis are maintained. The surgeries will be performed by experienced surgeon, senior and junior residents, post graduate doctors, observing for intraoperative complications and assessing the time to establish pneumoperitoneum.

Observation: Look for

i) Complications:-

1) Bowel perforation
2) Vascular injuries
3) Subcutaneous emphysema
4) Gas leakage
5) Extraperitoneal insufflations
6) Need for conversion
7) Port site hematoma
8) Failure of technique
9) Mortality

ii) Access time to establishing pneumoperitoneum

Statistical analysis

The data obtained was coded and entered into Microsoft Excel Worksheet. The categorical data was expressed as rates, ratios and proportions and continuous data was expressed as mean ± standard deviation (SD). Data were statistically described as mean ± standard deviation or % as appropriate. The comparison of quantitative variables was done with the use of student t test for independent samples. For comparing categorical data, chi- square test was performed. The data was analysed using chi-square test and Fischer's exact test. A probability value ('P' value) of less than or equal to 0.05 was considered as statistically significant. All statistical calculations were done with the use of the computer programs Microsoft Excel 2007 and SPSS version 17 for Microsoft windows.

RESULTS

This present study was conducted in the Department of GENERAL SURGERY, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, KLE University's teaching hospital attached to Jawaharlal Nehru Medical College Belagavi, during the period of January 2014 to December 2014.

A total of 130 patients undergoing laparoscopic surgeries in Department of General Surgery were included in the study. Using sequential numbered brown opaque envelop method, patients were randomized into groups as below.

- (Closed) Group A (n=65): includes patients who underwent laparoscopic procedure with pneumoperitoneum created by closed (Verees needle) method.
- (Open) Group B (n=65): includes patients who underwent laparoscopic procedure with pneumoperitoneum created by open (Hasson's) method

The data obtained was coded and entered into Microsoft Excel Worksheet and the data was analyzed and results were tabulated as below.

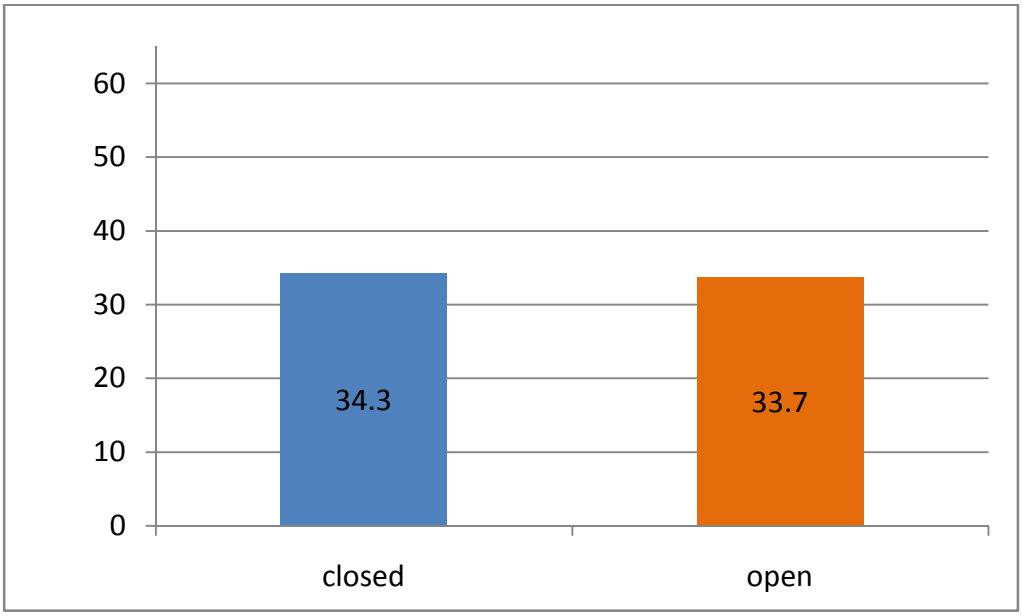
Table 1-Distribution of Demographic Data in two groups

Parameters	Closed (Group A)(Mean ± SD)	Open (Group B)(Mean ± SD)	P Value
Age(years)	34.3±13.79	33.7 ± 13.47	0.792
Height(meters)	1.62 ± 0.08	1.63 ± 0.09	0.626
Weight(Kg)	60.4 ± 13.44	64.63 ± 0.09	0.54
Sex(Male/Female)	32/33	31/34	
ASA (Grade I/II)	58/7	59/6	

All demographic parameter age, weight, height, sex distribution is comparable in two groups, with no significant difference as shown in table no.1.

Demographic Data Age

Bar graph no.1 showing average ages of patient in two groups.



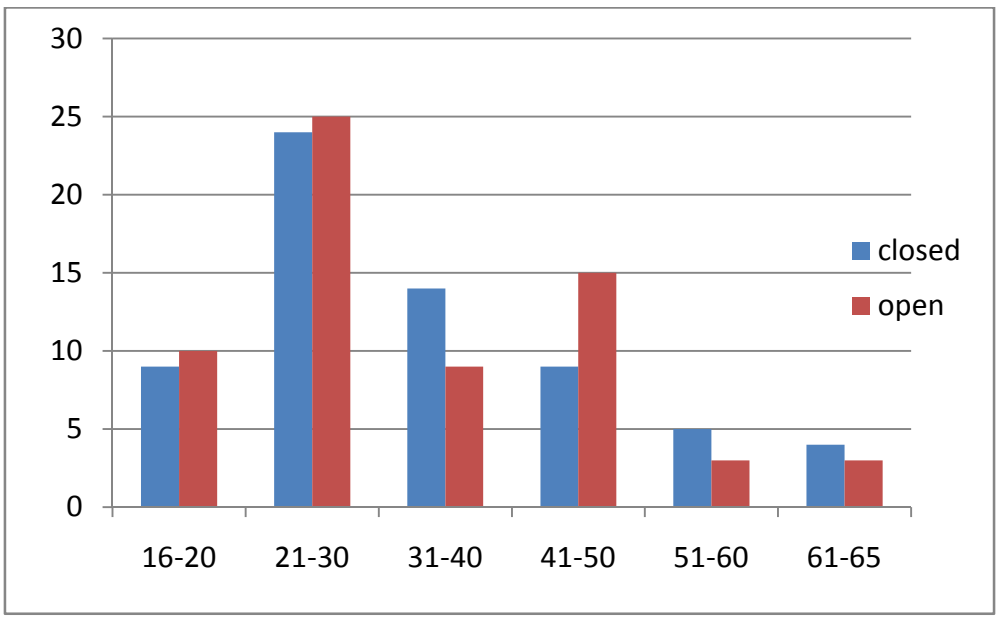
Average ages in the closed group was 34.3 years, in open group 33.7 years, with t=0.265, P value 0.792 no significant difference. Both groups ages comparable.

Age Distribution

Table no.2 showing distribution of age in two groups.

Age (Groups) Years	Closed (Group A)		Open (Group B)		Total	
	(No.	%)	(No.	%)	(No.	%)
16-20	9	13.80%	10	15.30%	19	14.60%
21-30	24	36.90%	25	38.40%	49	37.60%
31-40	14	21.50%	9	13.80%	23	17.60%
41-50	9	13.80%	15	23.07%	24	18.40%
51-60	5	7.60%	3	4.60%	8	6.10%
61-65	4	6.10%	3	4.60%	7	5.30%

Bar graph no.2 showing distribution of age (years) in two groups.



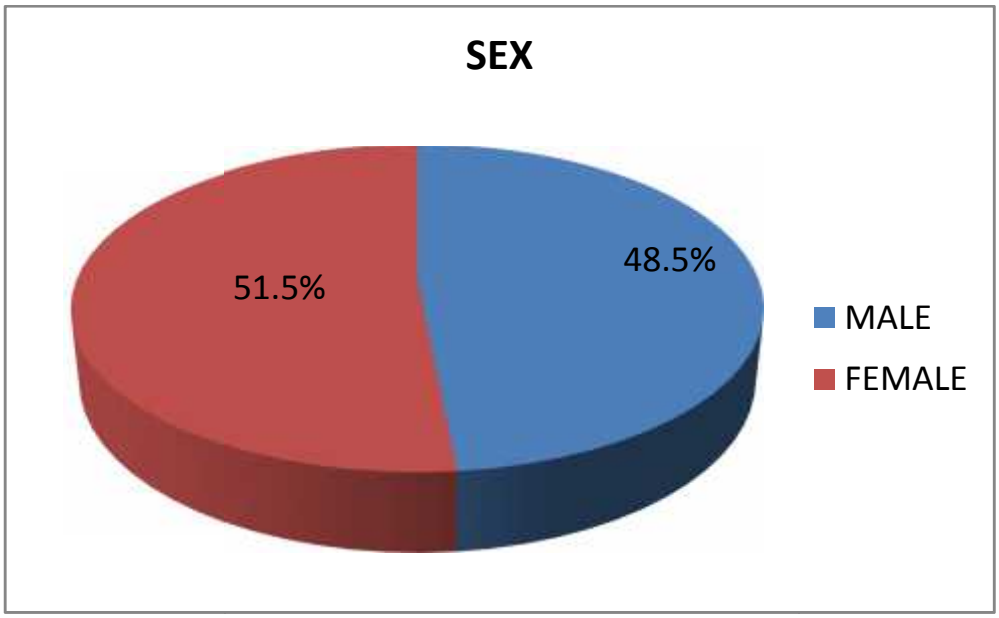
Maximum patients were in age group between 21 to 50 years.

Table no.3 showing sex distribution in two groups.

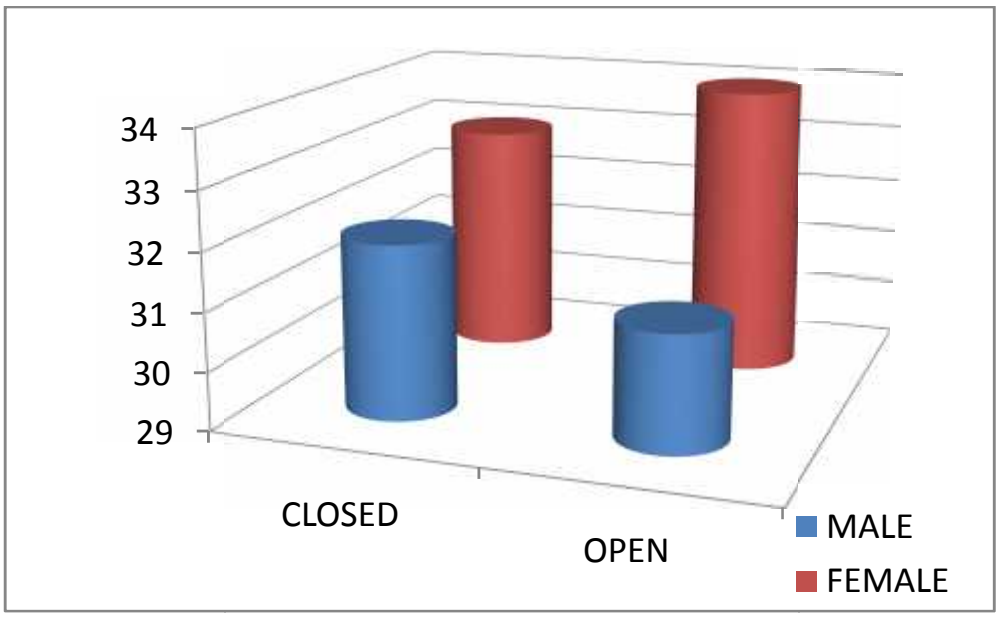
Sex	Closed (Group A)No. (%)	Open (Group B)No. (%)	TotalNo. (%)
Male	32 (49.2%)	31 (47.7%)	63 (48.5%)
Female	33 (50.8%)	34 (52.3%)	67 (51.5%)

Out of total 130 patients 63(48.5%) were male, 67(51.5%) female (graph), in closed group 32(49.3%) male and 33(50.76%) female patients, in open group 31(47.7%) male and female 34(52.3%) patients. Two groups were comparable with no significant difference P value 0.861.

Pie graph no.3 showing sex distribution in study.



Bar graph no.4 showing distribution of sex in each group.



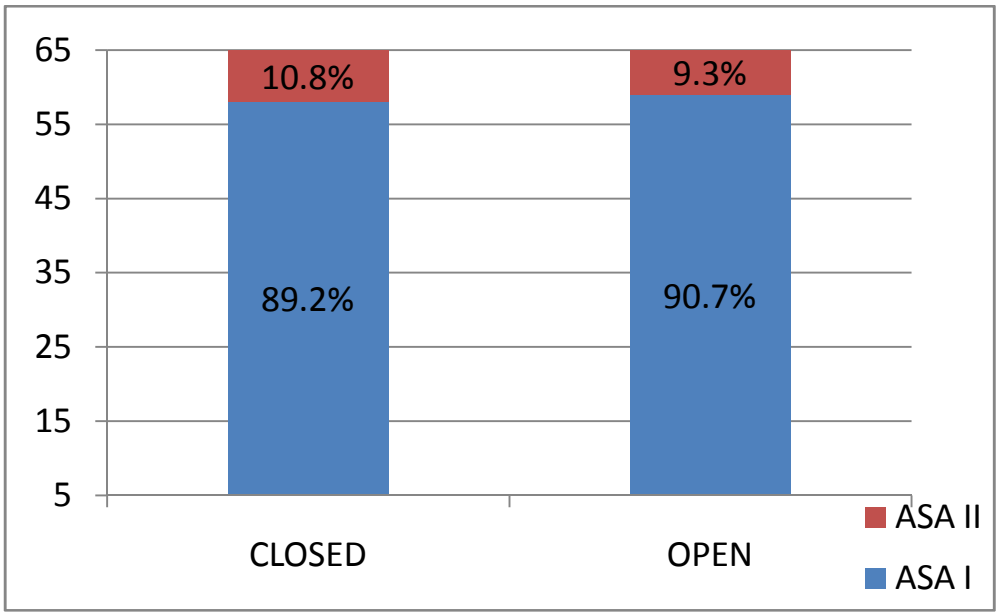
ASA STATUS

Table no. 4 showing distribution ASA I and II in two groups

ASA(Grade)	Closed (Group A) No. (%)	Open (Group B) No. (%)
I	58 (89.2%)	59 (90.7%)
II	7 (10.8%)	6 (9.3%)

Both groups were comparable in distribution of ASA status.

Bar graph no. 5 showing distribution ASA I and II in two groups.



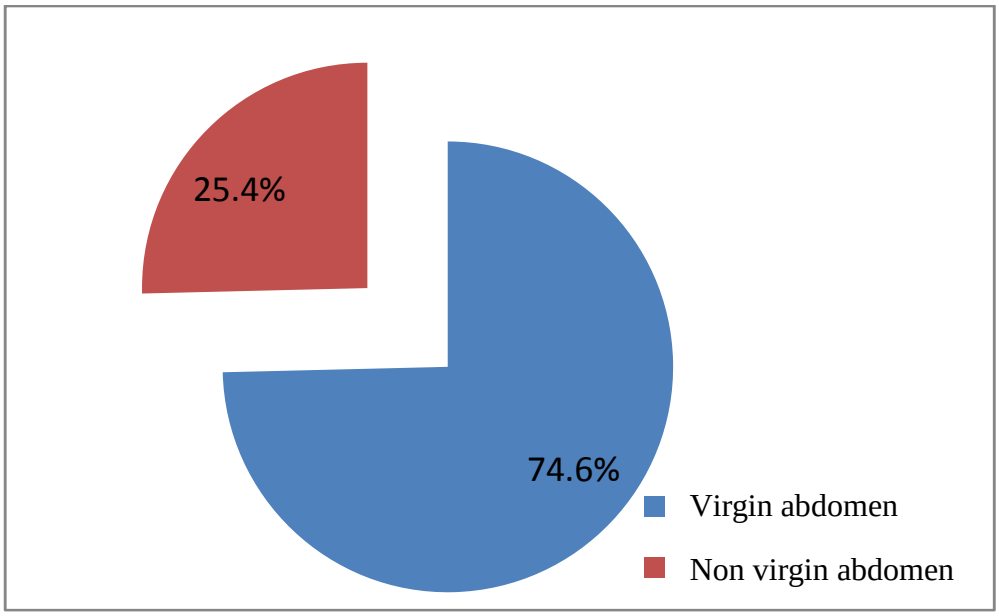
In both closed and open group 58(89.2%), 59(90.7%) patients were of ASA I and remaining 7(10.8%), 6(9.3%) patients were of ASA II status respectively. Both groups were comparable.

Table no.5 showing distribution of patient with virgin & non-virgin abdomen

Previous history of surgery	Closed (Group A) No. (%)	Open (Group B) No. (%)	Total No. (%)
No (Virgin abdomen)	49 (75.4%)	48 (73.8%)	97 (74.6%)
Yes (Non-virgin abdomen)	16 (24.6%)	17 (26.2%)	33 (25.4%)

Out of total 130, 33 (25.4%) patients had history of previous abdominal surgery, remaining 97 (74.6%) patient had no history i.e. virgin abdomen.

Pie graph no.6 showing distributions of patient with previous history of abdomen surgery absent (Virgin) or present (Non-virgin) abdomen.



With 16 (24.6%) patients in closed group and 17(26.2%) in open group had previous history of surgery out of 65 patients in each group. There was no significant difference with p value 0.840 and were comparable.

Bar graph no.7 showing distribution of patient with virgin & no virgin abdomen

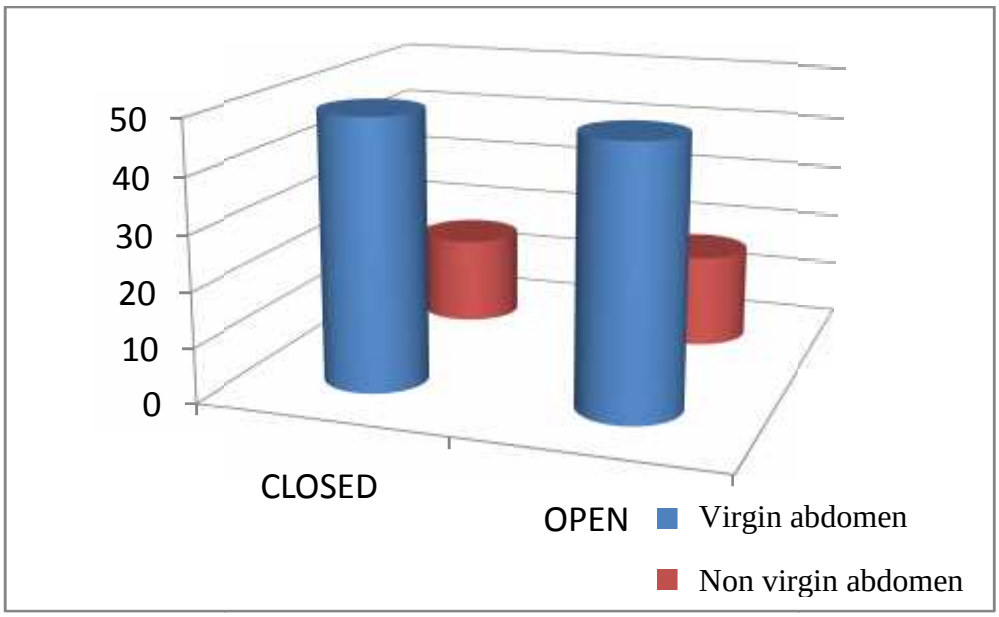


Table no.6 showing distribution of patient with BMI< or > 25Kg/m^2

BMI (Kg/m^2)	Closed (Group A)No. (%)	Open (Group B)No. (%)	TotalNo. (%)
<25 (Kg/m^2)	48 (73.8%)	36 (55.4%)	84 (64.6%)
>25 (Kg/m^2)	17 (26.2%)	29 (44.6%)	46 (35.4%)

In total 130 patients 84(64.6%) patients had BMI of less than 25kg/m^2 and 46(35.4%) patients had BMI more than 25Kg/m^2(overweight).

Pie graph no.8 showing distribution of patient with BMI< or > 25Kg/m^2

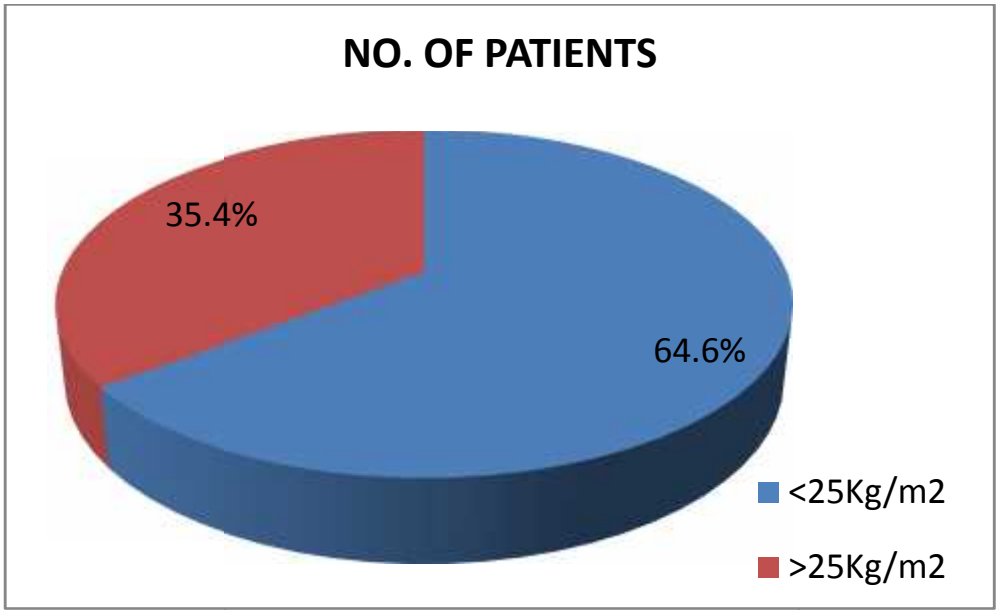


Table no.7 showing average BMI in two groups

Groups	BMI Kg/m^2 (Mean ± SD)
Closed (Group A)	22.6 ± 3.34
Open (Group B)	23.9 ± 3.86

Bar graph no.9 showing average BMI in two groups

Both group were comparable with no significant difference mean BMI in closed group 22.6 ± 3.34 and open group 23.9 ± 3.86.

Table no.8 provides a comparison of baseline parameters between two groups.

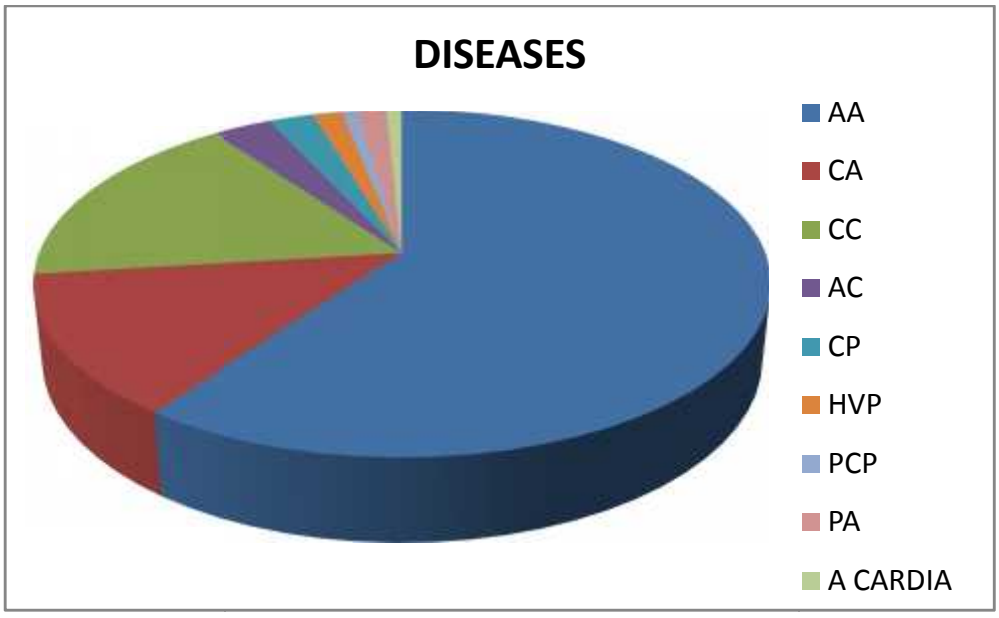
Parameters	Closed (Group A) Mean ± SD	Open(Group B) Mean ± SD	T130	P value
Pulse (beats/min)	89.9 ± 13.25	92.4 ± 14.46	1.018	0.311
Respiratory Rate (cycles/min)	16.8 ± 2.18	18.1 ± 3.19	2.826	0.006*
Temperature(^{o}F)	99.2 ± 0.98	99.1 ± 0.84	1.014	0.312
Haemoglobin (g%)	12.58 ± 1.83	12.24 ± 1.76	0.407	0.685
TLC (Count/mm^3)	9617 ± 2907	9957 ± 2986	0.658	0.512
Platelet(Lac/mm^3)	3.75 ± 1.08	3.95 ± 1.09	1.021	0.309
PT INR	1.3 ± 0.25	1.3 ± 0.17	1.255	0.212

The groups were comparable for parameters like pulse rate, temperature, haemoglobin, total leucocytes count, platelet count, PT INR with no significant difference was noted. Except respiratory rate which had significant difference, with P value 0.006.

Table no.9 showing distribution of diseases included into study in both groups

Diseases	Closed (Group A) No. (%)	Open (Group B) No. (%)	Total No.(%)
Acute appendicitis	35(53.8%)	43(66.2%)	78(60%)
Chronic(recurrent)appendicitis	8(12.3%)	9(13.8%)	17(13.1%)
Cholelithiasis	13(20%)	9(13.8%)	22(16.9%)
Chronic pain abdomen	2(3.1%)	1(1.53%)	3(2.3%)
Hollow viscus perforation	2(3.1%)	0(0%)	2(1.5%)
Acute cholecystitis	2(3.1%)	2(3.1%)	4(3.07%)
Pseudocyst pancreas	1(1.5%)	0(0%)	1(0.7%)
Perforated appendicitis	2(3.1%)	0(0%)	2(1.5%)
Achalasia cardia	0(0%)	1(1.53%)	1(0.7%)

Pie graph no.10 showing distribution of diseases included into study



In study most of patients were acute appendicitis 78(60%), chronic(recurrent) appendicitis 17(13.1%), cholelithiasis 22(16.9%), chronic pain abdomen 3(2.3%), hollow viscus perforation 2 (1.5%), acute cholecystitis 4(3.1%), pseudocyst of pancreas 1(0.7%), perforated appendicitis 2(1.5%),achalasia cardia (0.7%).

In both the groups as mentioned in table no.9 were comparable with fisher exact test, no significant difference P value 0.507 seen in two groups.

Bar graph no.11 showing distribution of diseases included into both groups.

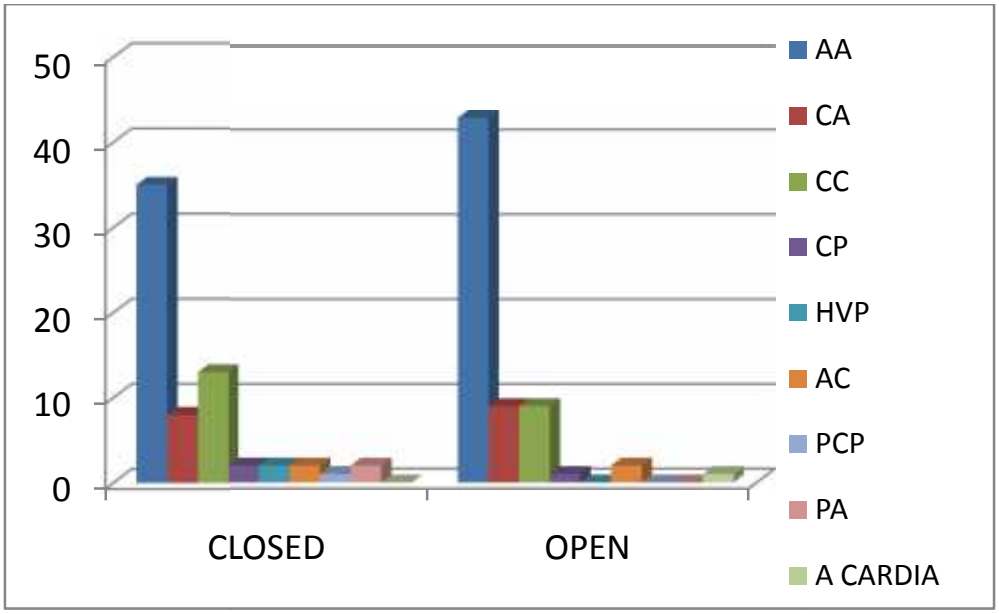
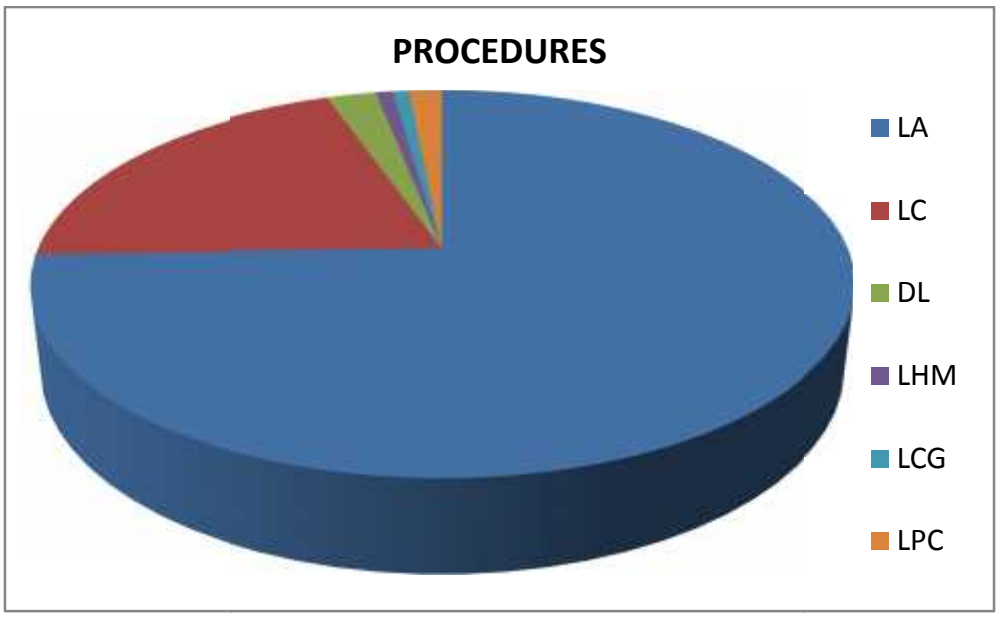


Table no. 10 showing various laparoscopic surgeries undertaken in the study

Procedure	Closed (Group A) No. (%)	Open (Group B) No. (%)	Total No. (%)
Laparoscopic Appendectomy	45 (69.2%)	52 (80%)	97(74.6%)
Laparoscopy Cholecystectomy	15 (23.1%)	11 (16.9%)	26(20%)
Diagnostic Laparoscopy	2 (3.1%)	1 (1.5%)	3(2.3%)
Laparoscopic Heller's Myotomy	0 (0%)	1 (1.5%)	1(0.7%)
Laparoscopic Cystogastrostomy	1(1.5%)	0(0%)	1(0.7%)
Laparoscopic Perforation Closure	2(3.1%)	0(0%)	2(1.5%)

In study total 97 (76.4%) laparoscopic appendectomy, laparoscopic cholecystectomy 26 (20%), diagnostic laparoscopy 3 (2.3%), laparoscopic perforation closure 2(1.5%) laparoscopic Heller's myotomy and laparoscopic cystogastrostomy 1(0.7%) each.

Pie graph no.12 showing distribution of surgeries undergone in study



Calculating with Fischer exact test, there was no significant difference with P-value 0.303 between the two groups with respect to various laparoscopic surgeries included in the study and groups were comparable.

Bar graph no.13 showing distribution of surgeries undergone in two groups

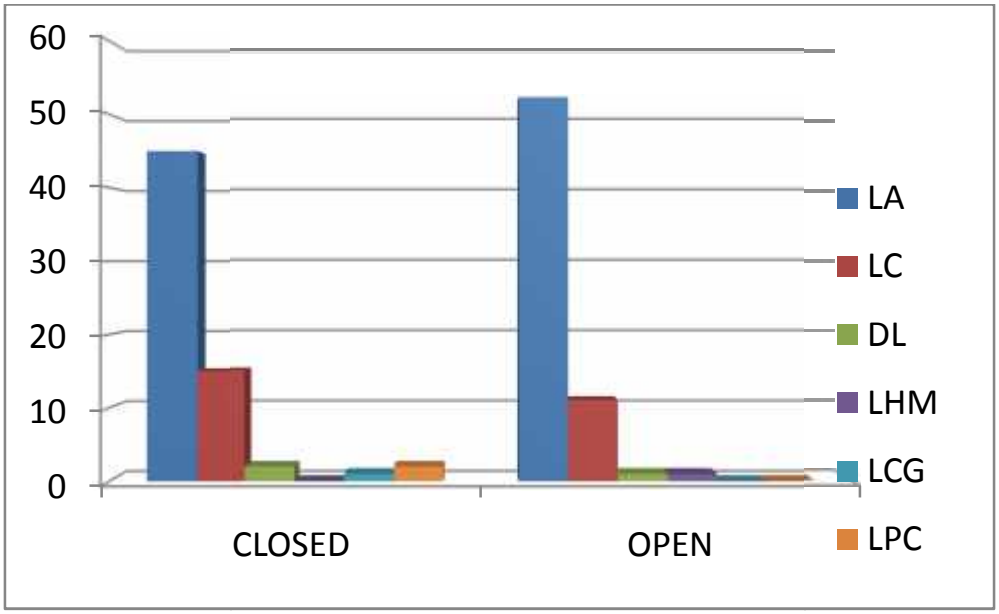
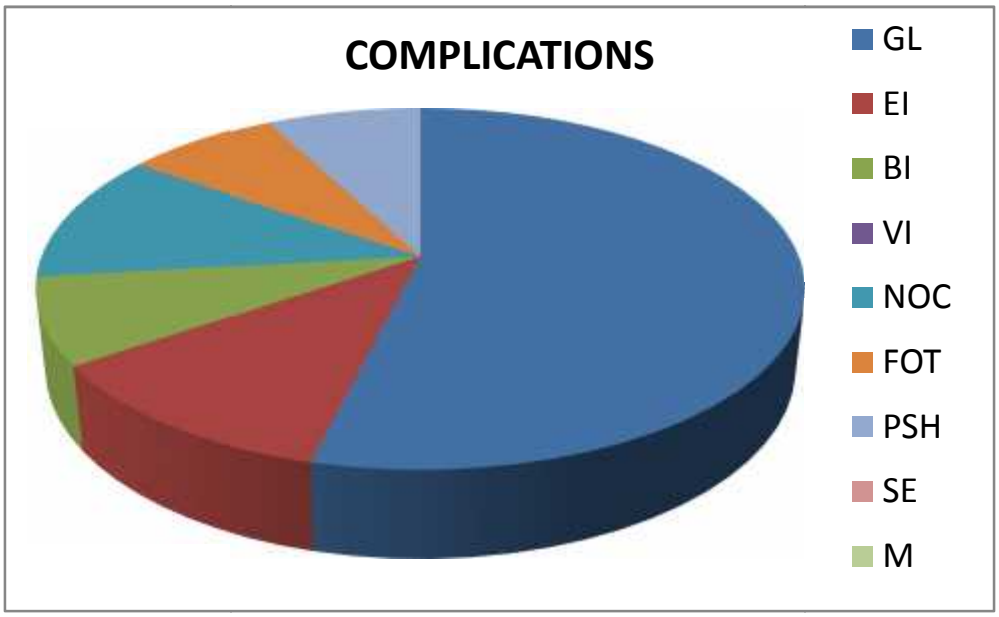
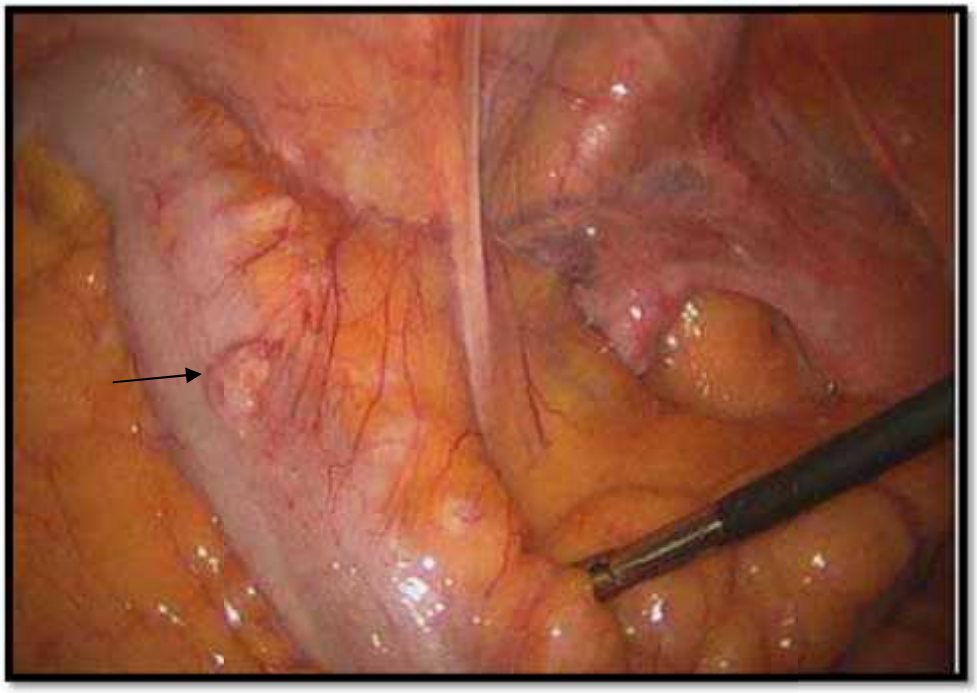


Table no.11 showing major and minor complications, access time in two groups

Complication	Closed (Group A) No. (%)	Open(Group B) No. (%)	TOTAL	P value
Gas Leakage	0(0%)	14(21.5%)	14(10.7%)	<0.001*
Extra-peritoneal Insufflation	2(3.1%)	1(1.5%)	3(2.3%)	1
Bowel Injury	1(1.5%)	1(1.5%)	2(1.5%)	1
Vascular Injury	0(0%)	0(0%)	0(%)	-
Need For Conversion	2(3.1%)	1(1.5%)	3(2.3%)	1
Failure Of Technique	2(3.1%)	0(0%)	2(1.5%)	0.496
Port Site Hematoma	1(1.5%)	1(1.5%)	2(1.5%)	1
Subcutaneous Emphysema	0(0%)	0(0%)	0(%)	-
Mortality	0(0%)	0(0%)	0(%)	-
Av. Time To Access	6.02±1.4 mins	5.28±0.94 mins	-	<0.001*

Pie graph no.14 showing distribution of major and minor complications in study



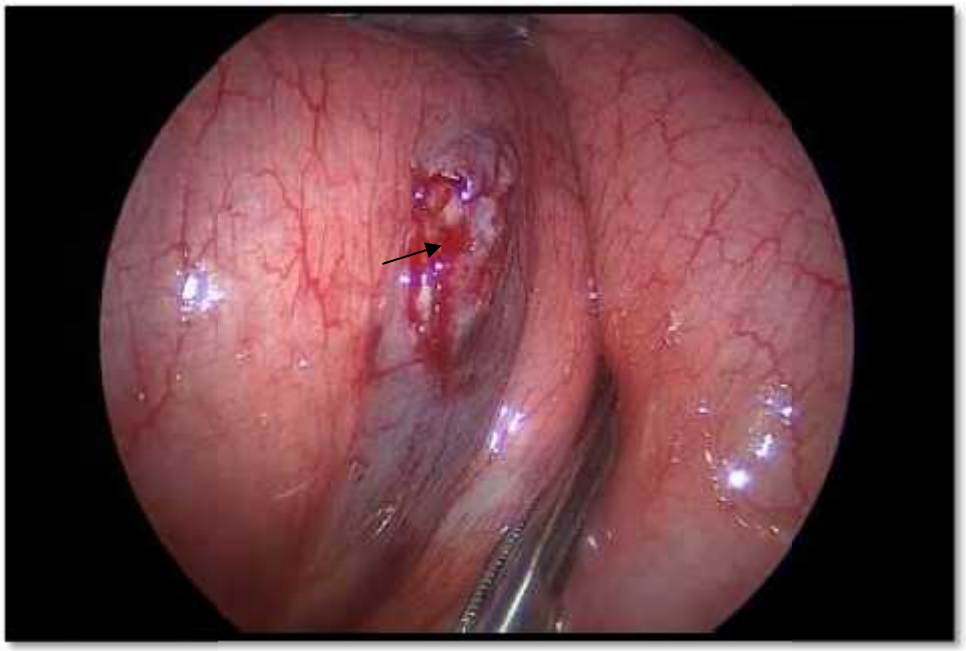


Photograph No.8 Shows Trocar Injury To Colon

The comparative analysis of the study variables are presented in Table no.11. The time to establish pneumoperitoneum was much less in the Hasson cannula technique (5.28±1.1 minutes) as compared to the Verees needle technique (6.02 ± 0.7

minutes, p = < 0.001). Pneumoperitoneum was achieved in 128 cases except in 2 cases in closed group; there was failure of technique in one patient due to malfunctioning of Verees needle and other due to intra-abdominal adhesions. In the open group, gas leakage occurred in 14 (21.53%) cases and zero in closed group, bowel injury occurred in 2(1.53%) patients, one(1.5%) in each group (in open group- trocar injury to transverse colon , closed group- Verees needle perforated the stomach), extra-peritoneal insufflations in 3 patients(2.30%) with 2(3.1%) in closed group & one(1.5%) in open group, 3 (2.3%)patients had need for conversion one(1.5%) in open group due to transverse colon injury and 2(3.1%) in closed group ; one due to Verees needle perforating the stomach, another due to dense intra-abdominal adhesion, port-site hematoma occurred in 2 (1.53%) one in each group.

There were no vascular injury and subcutaneous emphysema and mortality in either of the study group and there were no peri-operative mortalities.

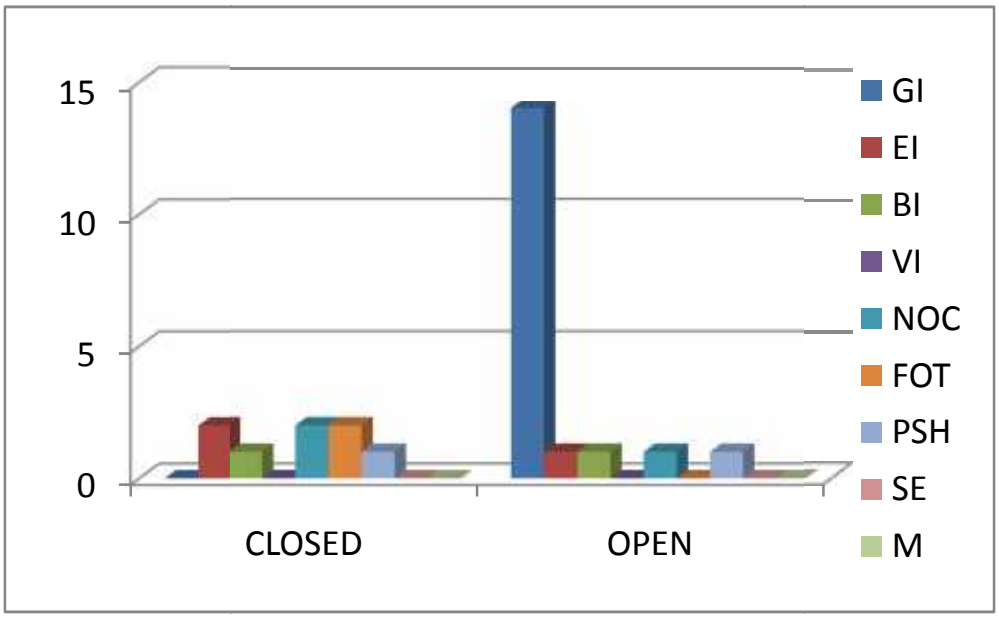


Photograph No. 9 Showing Verees Needle Injury In Stomach.

Only access time and gas leakage had a significant difference with P-value < 0.001. Other complications had no significant difference between both the groups and were comparable.

Photograph No.10 Showing Port Site Hematoma

Bar graph no.15 showing distribution of complications in both groups



Bar graph no.16 showing average access time in minutes in each group

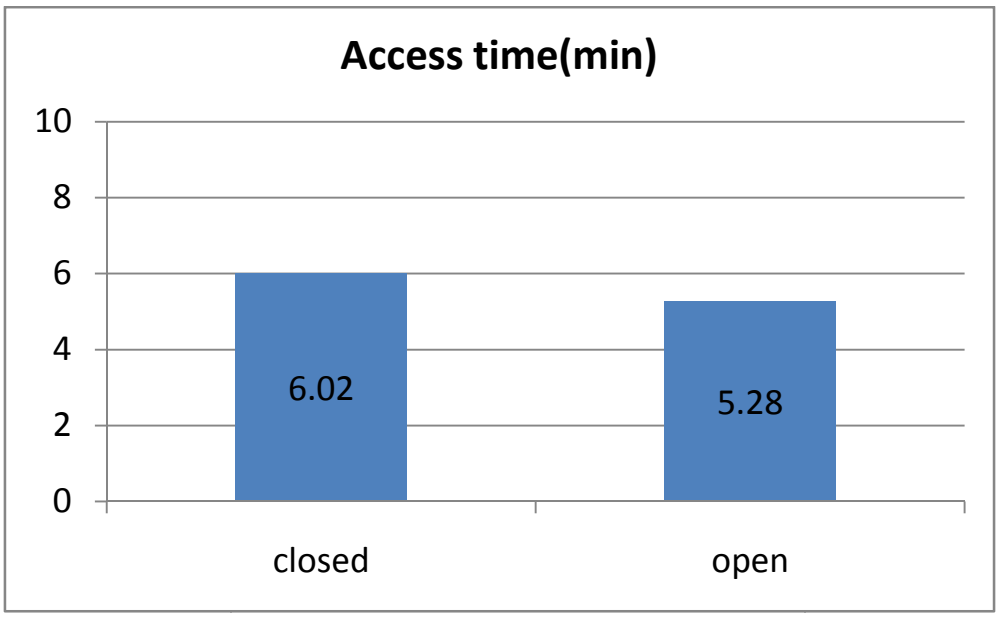
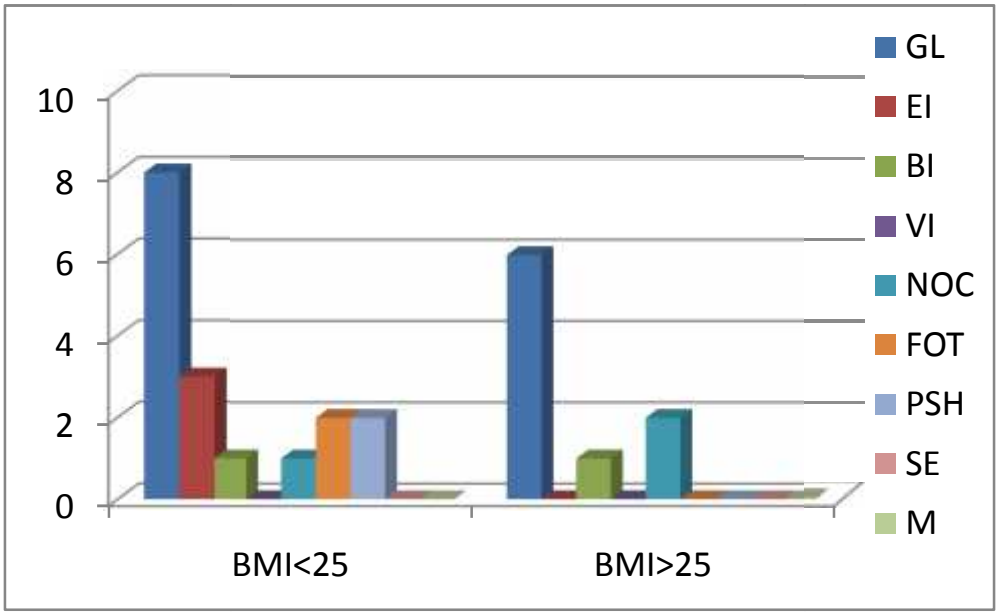


Table no.12 showing distribution of complications in two groups; one with BMI < 25 Kg/m^2 and other > 25 Kg/m^2

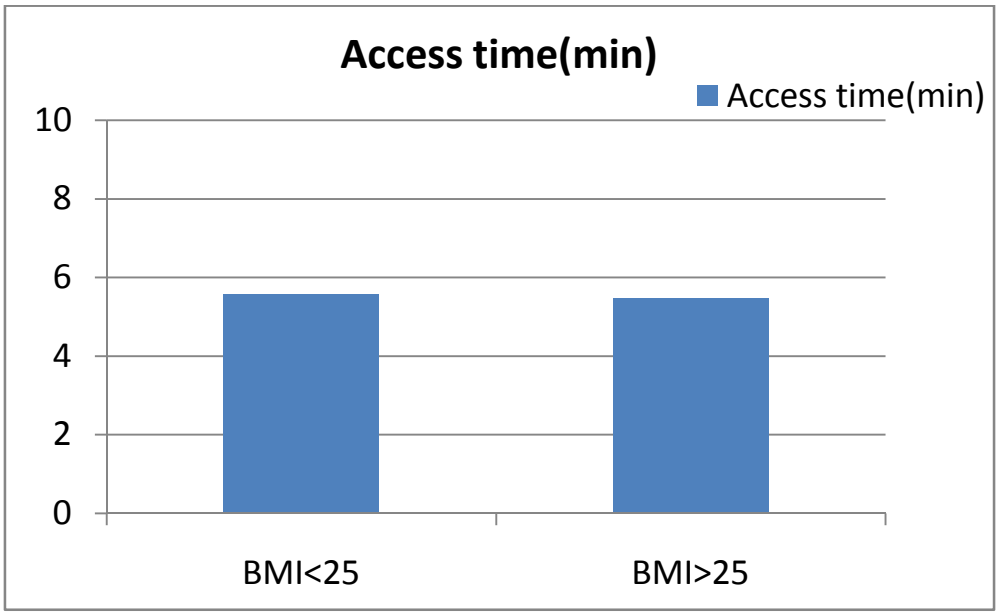
Complications	BMI<25 Kg/m^2 No. (%)	BMI>25 Kg/m^2 No. (%)	P Value
Gas Leakage	8(9.5%)	6(13.04%)	0.714
Extra-peritoneal Insufflation	3(3.5%)	0(0%)	0.551
Bowel Injury	1(1.1%)	1(2.1%)	0.349
Vascular Injury	0(0%)	0(0%)	-
Need For Conversion	1(1.1%)	2(4.3%)	1
Failure Of Technique	2(2.3%)	0(0%)	0.542
Port Site Hematoma	2(2.3%)	0(0%)	0.542
Subcutaneous Emphysema	0(0%)	0(0%)	-
Mortality	0(0%)	0(0%)	-
Av. Time To Access-	5.57 ± 1.38	5.47 ± 1.04min	0.242

Bar graph no.17 showing distribution of complications in two groups; one with BMI < 25 Kg/m^2 and other > 25 Kg/m^2



Of 130 patients, 84 patients have BMI< 25 Kg/m^2 and 46 patients with BMI> 25 Kg/m^2, as per table no.12 mentioned above both minor and major complications more in obese/ overweight group i.e. patients with BMI >25 Kg/m^2 compared to patients with BMI < 25 Kg/m^2, but this finding was not statistically significant.

Bar graph no.18 showing access time in group with BMI<25 Kg/ m^2& BMI > 25 Kg/m^2

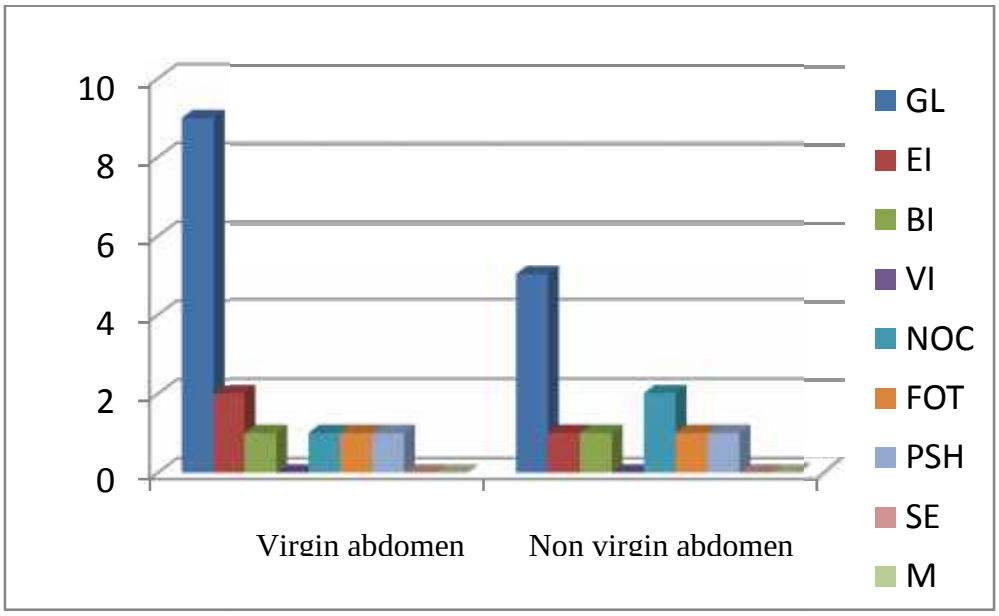


In group less than 25 Kg/m^2 average access time is 5.57 ± 1.38minutes and 5.47 ± 1.04 minutes in group more than 25 Kg/m^2.

Table no.13 showing comparison of complications in two groups; one with previous history of abdominal surgery present and in other with no history of abdominal surgery

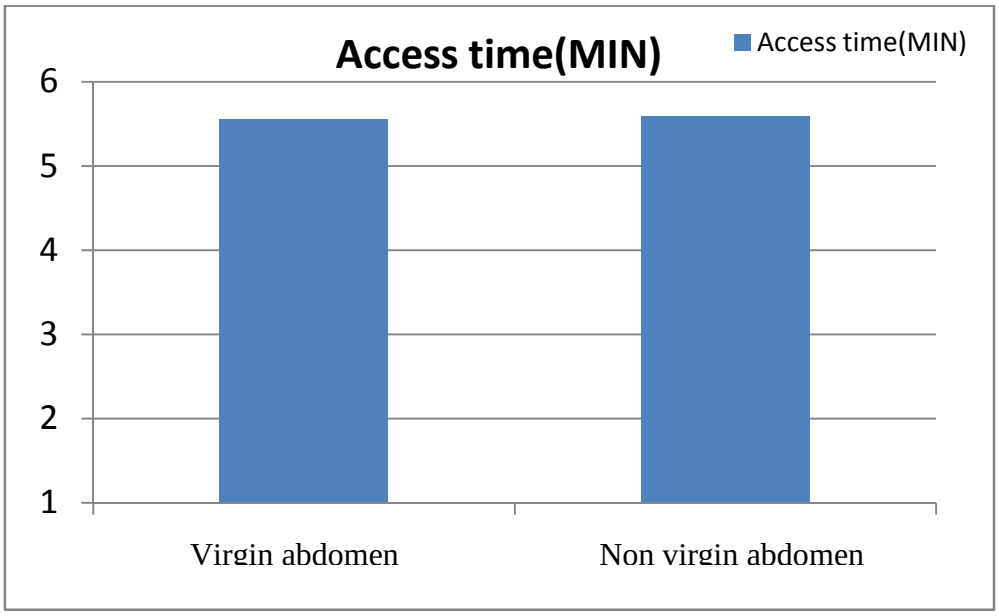
Complications	Virgin abdomen No. (%)	Non-virgin abdomen No. (%)
Gas Leakage	9(9.2%)	5(15.1%)
Extra-peritoneal Insufflation	2(2.1%)	1(3.03%)
Bowel Injury	1(1.03%)	1(3.03%)
Vascular Injury	0(0%)	0(0%)
Need For Conversion	1(1.03%)	2(6.06%)
Failure Of Technique	1(1.03%)	1(3.03%)
Port Site Hematoma	1(1.03%)	1(1.03%)
Subcutaneous Emphysema	0(0%)	0(0%)
Mortality	0(0%)	0(0%)
Av. Time To Access-	5.56±1.29	5.59±1.27

Bar graph no.19 showing distribution of complications in two groups; virgin and non-virgin abdomen.



In patients with previous history of abdomen surgery gas leakage was seen in 5 (15.1%), need for conversion 2 (6.06%), bowel injury, extraperitoneal insufflation, failure of technique, port site hematoma were 1(3.03%) compared to patients with no history of previous surgery gas leak was 9 (9.2%), extra-peritoneal insufflation 2(2.1%), need for conversion, bowel injury, failure of technique, port site hematoma were 1(1.03%). According to table no.13 mentioned above, both major and minor complication were more in patient with previous history abdominal surgery when compared to patient with no history of previous abdominal surgery, access time is less in virgin abdomen compared to non-virgin abdomen group.

Bar graph no. 20 showing access time in group with virgin and non-virgin abdomen



In group with virgin abdomen average access time is 5.56±1.29 minutes and non-virgin abdomen 5.59±1.27 minutes.

DISCUSSION

In last couple of decades, laparoscopic surgery has advanced rapidly to be considered a well-established procedure. But still laparoscopy is comparatively a newer technique, leading to controversy, especially with respect to the ideal method for the creation of the pneumoperitoneum.[13] The two most commonly used basic techniques to achieve access into the peritoneal cavity during laparoscopic procedures are blind Verees needle/trocar insertion and the open technique by placement of the trocar under direct vision. Both of these techniques have positive and negative points with various advantages and disadvantages. The most serious and life-threatening complication during insertion of a Verees needle or of the first trocar is major vascular injury, with a mortality of 15%.[82] Hasson about 3 decades ago described the advantages of the open technique for achieving access into the abdominal cavity.[82] Direct vision gives option of safe entry by preventing bowel injury, and even if it occurs, allows immediate recognition and surgical repair. The learning curve had to be passed simultaneously by many surgeons resulting in an increase in major complications.[83] In a pursuit to minimize the complications that occur during gaining access into the abdominal cavity, studies using modified techniques of both open and closed basic approaches have been carried out while others are underway.

In the present study we compared these two methods in terms of time required to induce pneumoperitoneum, complications associated with each method in study, also we compared complications and time required to induce pneumoperitoneum in patient with previous history of abdominal surgery as one group and patients with no history as another group irrespective of technique used. Similarly same were compared in patients with BMI< 25Kg/m^2 and patients with BMI> 25Kg/m^2.

In our study both groups demographic parameters like age, height, weight, sex were comparable. Age distribution was evenly distributed in both groups. In our study 51.5% of female and 45.5 % male participated, with both groups comparable in sex ratio. In this study ASA grade I and II patients were included with 90% and 10% respectively. The study also included patients with history of previously undergoing abdomen surgeries like appendectomy, inguinal hernia repair, tubectomy and other abdominal surgeries. All baseline parameter like pulse rate, temperature, haemoglobulin, total leucocyte count, platelet, PT INR were comparable in both groups. Most of diseases included were appendicitis amounting for approximately $3/4^{th}$ of study sample, other diseases were Cholelithiasis, Chronic pain abdomen, Hollow viscus perforation, Acute cholecystitis, Pseudo cyst pancreas, Achalasia cardia. Procedures undergone in our study were total (76.4%) laparoscopic appendectomy, laparoscopic cholecystectomy (20%), diagnostic laparoscopy (2.3%), laparoscopic perforation closure (1.5%), laparoscopic Heller's myotomy and laparoscopic cystogastrostomy (0.7%) each.

Most of previous studies we have only considered major complications, but in our study not only major complications like major vascular injury and bowel injury associated with methods in creation of pneumoperitoneum but also minor complication such as gas leakage, extraperitoneal insufflations, need for conversion, failure of technique, port site hematoma, subcutaneous emphysema, mortality were compared.

In our study only two bowel injuries in each group and no vascular injuries were noted as major complications, with zero mortality and rate of bowel injury 1.5%, vascular injuries 0.0% in both groups were comparable with no significance

difference. This study contradicts previous studies conducted by Bonjer et al. who demonstrated visceral and vascular injury as 0.08% ,0.07% in closed group and 0.05% , 0%in open group with significant difference(P- 0.0002). Mortality rates after closed and open laparoscopy were respectively 0.003% and 0% (NS).[1, 14]

Similarly Garry et al analyzed six reports, one survey of open laparoscopy and 6 reports of closed laparoscopy conducted by gynecologists. With rates of bowel and major vessel injury in the closed entry technique, were 0.04% and 0.02% and in the open entry technique 0.5% and 0% respectively. When he excluded survey report (n = 8000) the bowel injury rate decreased to 0.06% with the open technique. Garry concluded that open laparoscopy can be used as an adorable alternative technique that has reported to prevent the chance of major injury almost nil in anatomically normal positioned intra-abdominal structures.[1]

A meta-analysis conducted in 2002 of English language studies from both the gynecological and general surgical literature, study took in consideration of only major complications defined as bowel or vascular injury in open method of abdomen entry and stated that major vessel injuries can be avoided almost completely by the open technique (4.7/100 000). But there are many cases reporting vascular injuries with open technique and published. In this study reported 23 bowel injuries in 21547 procedures (0.1%) and only one vascular injury out of 21292 surgeries (0.005%).[1]

Merlin et al in his systemic review reported bowel injuries 0–1.3% using the open technique and 0.04% with closed technique, vascular injuries 0– 0.03% using open technique, whereas 0.003–1.33% in closed technique. This meta-analysis indicates a trend towards a decreased risk of major complications with open access technique.[83]

Hasson et al. conclude "In laparoscopy there is no proof to favor abandoning the closed entry technique, however, the selection of patients for an open or alternative procedure is still recommended".[1]

Champault et al described rate of bowel injuries of 0.06% and major vessel injuries of 0.04% in more than 100 000 patients using the Verees technique.[83]

Joao Luiz et al in there systemic review stated that verees needle insertion in the abdominal midline, may cause serious chance injury to major vessel, viscera and risk to the life of patients and need more studies to investigate alternate sites for verees needle insertion.[11]

But there are other studies which has similar result as in our study like Swiss Association for Laparoscopic and Thoracoscopic Surgery (SALTS) studied on patients undergoing various laparoscopic surgeries in between 1995 and 1997 reporting total 8 bowel injury with six in closed group, two in open group and stated that open method is not superior when compared to closed method and failed to show any advantage.[12]

Chandler et al. stated that visceral injuries are not less common with open method and still could be undiagnosed. They reported 594 organs injured during laparoscopic access in 566 patients.[1]

In 18 primary entry injuries associated with Hasson-type entries 4 patients had small bowel injury, two recognized late and death, and with another four patients had retroperitoneal vessels injuries, in that one patient's died. In the remaining 10 patients, there were four instances of colon injuries, three of abdominal wall vessel laceration, and one each of liver, urinary bladder, or mesenteric vessel injury.[1] Most

of major injuries goes undiagnosed, many studies suggest that 30% to 50% of bowel injuries and 13% to 50% of vascular injuries goes undiagnosed during the time of surgery. As bowel injury is more often than vascular injury, it is more likely to produce serious consequences because of the delay in diagnosis. The mortality rate from bowel injury is 2.5% to 5%.[1]

Penfield reported a bowel injury rate of 0.06%, but these injuries were partial and recognized immediately because of the proximity of the bowel to the wound.[13]

European Association for Endoscopic Surgery in its clinical practice guideline on the pneumoperitoneum for laparoscopic surgery stated that, in the randomized controlled trials no difference was found in major complications between open and closed group with inadequate sample but in large studies showed less complications in the closed group.[1, 14] They found that the use of either techniques may have advantages in specific patient subgroups.[1, 83] However, most of major vascular injuries occur with the Verees approach. The panel conclusion cannot support the use of either technique in access to abdomen.[83]

But Molloy et al. in their studies saw that bowel injuries are more in Hasson's method than with closed technique 0.11%, 0.04% respectively. But they also stated that this may be due to selection bias in choosing patients as most who had previous abdominal surgery preferred open method, also smaller number of surgeon were involved in open technique which was also potential bias. Thus concluding that ideal method of laparoscopic entry in the low-risk patient remains unclear.[1]

Many meta-analysis studies comparing open technique with closed technique failed to state any safety advantage of an open technique, in terms of both visceral and

major vascular injury and randomized controlled trials had insufficient power to effectively demonstrate an advantage.

But in nonrandomized studies the risk of bowel injury was higher with the open technique than with closed technique, but selection bias may be the major factor influencing the outcome. The evidence on the comparative safety and effectiveness of the different access methods was not definitive, but trends in the data merit further exploration.[13]

So still there are controversies on defining which ideal, safe technique to creating pneumoperitoneum, with many studies having selection bias, inadequate sample size, experience of surgeons

In our study open technique is faster in achieving pneumoperitoneum i.e. access time compared to closed technique, with significance difference with P value < 0.001.

European Association for Endoscopic Surgery also reported that open approach is faster and associated with a lower incidence of minor complications.[1, 14]

Petigen *et al.* concluded that the open technique requires half the time compared to closed technique in abdomen access and they preferred its use.[14]

Sigman *et al.* also reported that less time was required for the open method and advocated its use on this basis.[14]

But Moberg et al. in their study showed Verees technique requires 214–300 seconds for abdominal cavity access, which was shorter (median 93 seconds) compared to other studies (240–300 seconds) were open access has been used.[83]

According to a study by Hurd et al, an access time of 300 seconds was required in open technique compared to 230 sec using the Verees technique.[83]

In our study minor complications like gas leakage had a significant difference when compared between open (21.53%) and closed (0%) technique, with P valve <0.001.Other complications like extraperitoneal insufflation & need for conversion occurred 3.1% in closed group and 1.5% open group, failure of technique 3.1% in closed group with 0% in open group, port site hematoma 1.5% in both group, no subcutaneous emphysema in both groups.

Similarly Hurd et al demonstrated gas leakage in 14% with modification of the Hasson's technique without using special instruments and recommended to use Verees technique routinely.[83]

Nezhat et al, in there randomized prospective study, reported 22%, 6%, and 0% rates of minor complications in closed technique, direct conventional laparoscopic trocar insertion, and direct disposable shielded trocar insertion, respectively in 200 patients.[84]

In our study we also compared time required to induce pneumoperitoneum, complications between patients with history of previous abdomen surgery present and absent irrespective of technique. Our study found that there was no significant difference between patients with history of previous abdomen surgery present or absent with respect to access time, major and minor complication mentioned in our study.

In contrast Toro et al, in their experience with 750 laparoscopic surgical procedures, out of which 50 patients had history of previously undergoing abdominal

surgery. In his study had one minor intestinal injury during closed technique and concluded that Hasson technique is preferred in previously operated patients.[13]

Brill *et al*.analyzed women who underwent previous laparotomy, undergoing operative laparoscopy about 360 patients. Out of which 58 of 102 with midline incision had significantly more adhesions than those with Pfannenstiel incisions i.e. 70 of 258 patients. Direct injury to the adherent omentum and bowel seen in 28 % (21) of patients during the laparoscopic procedure. Concluding that this group of patients clearly represents a risk factor for adhesion.[16]

Moberg et al, concluded, that open access technique is applicable in all patients without a previous laparotomy. It is fast and easy to learn with very few associated problems. They strongly recommend this technique for laparoscopic procedure.[83]

Long JB et al, in review of 2010 patients open laparoscopic access technique concluded that there is no association between failed entry and previous surgery or obesity. Previous abdominal surgery and obesity are not contraindications to an open laparoscopic entry, but in fact open approach has some advantage over the closed technique in this patients.[19]

Although in our study complications rate were high in group with history of previously abdominal surgery compared to patient with no history but it was not statistically significant.

In our study we also compared complications between patients with BMI less than 25 kg/m^2 and more than $25kg/m^2$ irrespective of technique. Study found that

there is no significant difference between patients with BMI less than 25 kg/m^2 and more than $25kg/m^2$ with respect to access time, major and minor complication mentioned in our study.

Zaraca et al, reported in patients with a BMI above 30 had access time of 570 sec in with their technique. They concluded open technique is more applicable to obese patients.[83]

In another study conducted in Department of Surgery, University Hospital of Malmo, Malmo, Sweden showed that median time for access was 93 seconds , entrance time in patients with BMI>30 was 100 sec and with BMI < 30 it was 90sec ($p = 0.71$). The median time forconsultants was 88 sec and for residents 120 sec ($p = 0.003$), no gas leakage was seen.Prolonged time for access was seen in three patients, two equipment failures and one obese patient. In conclusion, the open access technique used in this study is applicable in all patients without a previous laparotomy. It is fast and easy to learn with very few associated problems. They strongly recommend this technique for laparoscopic procedures.[83]

In present day many newer techniques to create pneumoperitoneum are developed, but verees needle (closed) technique and hasson's(open) technique are the two techniques used most commonly especially in developing country like India, where there is limitation of resources, facilities and cost. Thus it is important to have a standard technique to which is cost effective, safe, and efficient. So we tried to compare techniques in respect time required to induce pneumoperitoneum, major and minor complication, results of our study gives an impression that both techniques are good in some aspect like open technique safer in patients with previously abdomen surgery, obese and verees needle is better to virgin abdomen , will avoid mini-

laparotomy, less gas leakage. In our study comparing major complications like vascular and bowel injury in two techniques, the sample size is not adequate to give a conclusion still further studies are required with large sample size to comment on which technique is better.

CONCLUSION

Based on the findings of this study, we conclude that there is still controversy exist to support the superiority of one technique over the other and this view is supported by the literature like European Association for Endoscopic Surgery (EAES)[1, 14], Swiss Association for Laparoscopic and Thoracoscopic Surgery (SALTS)[12] and many meta-analysis studies comparing closed technique and open technique. According to this study open technique had a time advantage over the closed method, but gas leakage was significantly more in open group. While complications are more in patient with history of previous abdomen surgery and in overweight, obese patients during gaining access into the peritoneal cavity irrespective of method used. Further studies are needed in multiple centers, on larger samples for conclusive evidence and surgeons should be competent in both techniques.

SUMMARY

This present studywas conducted in the Department of General Surgery, KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, KLE's University's teaching hospital attached to Jawaharlal Nehru Medical College Belagavi, during the period of January 2014 to December 2014.

A total of 130 patients undergoing laparoscopic surgeries in Department of General Surgery were included in the study. Closed group includes patients who underwent laparoscopic procedure with pneumoperitoneum created by closed (Verees needle) method and Open group B includes patients with pneumoperitoneum created by open (Hasson's) method

All demographic parameter age, weight, height, sex distribution was comparable in two groups, with no significant difference. Average ages in the closed group was 34.3 years, in open group 33.7 years, with t 0.265, P value 0.792 no significant difference. Maximum patients were age group between 21 to 50 years. The groups were comparable for parameters like pulse rate, temperature, hemoglobin, total leucocyte count, platelet count, PT INR with no significant difference.

Out of total 130 patients 63(48.5%) were male, 67(51.5%) female, in closed group 32(49.3%) male and 33(50.76%) female patients, in open group 31(47.7%) male and female 34(52.3%) patients. Out of total 130, 33 (25.4%) patients had history of previous abdominal surgery, remaining 97 (74.6%) patient had virgin abdomen. With 16 (24.6%) patients in closed group and 17(26.2%) in open group had previous history of surgery out of 65 patients in each group. In total 130 patients 84(64.6%)

patients had BMI of less than 25kg/m^2 and 46(35.4%) patients had BMI more than 25Kg/m^2.

In study most of patients included were diagnosed with acute appendicitis 78(60%), chronic (recurrent) appendicitis 17(13.1%), cholelithiasis 22(16.9%) chronic pain abdomen 3(2.3%), hollow viscus perforation 2(1.5%), acute cholecystitis 4(3.1%), pseudocyst of pancreas 1(0.7%), perforated appendicitis 2(1.5%), achalasia cardia (0.7%) both the groups as comparable with no significant difference P value 0.507 seen in two groups.

In study total 97(76.4%) laparoscopic appendectomy, laparoscopic cholecystectomy 26 (20%), diagnostic laparoscopy 3 (2.3%), laparoscopic perforation closure 2(1.5%) laparoscopic Heller's myotomy and laparoscopic cystogastrostomy 1(0.7%) each, were performed with no statistically significance with P value 0.303, with respect to various laparoscopic surgeries included in the study.

The comparative analysis of the study variables are, the time to establish pneumoperitoneum was much less in the Hasson cannula technique (5.28 ± 1.1 minutes) as compared to the Verees needle technique (6.02 ± 0.7 minutes, $P < 0.001$). Pneumoperitoneum was achieved in 128 cases except in 2 cases in closed group; there was failure of technique in one patient due to malfunctioning of Verees needle and other due to intra-abdominal adhesions. In the open group, gas leakage occurred in 14 (21.53%) cases and zero in closed group, bowel injury occurred in 2(1.53%) patients one(1.5%) in each group, (open group- trocar injury to transverse colon , closed group-Verees needle perforated the stomach), extra-peritoneal insufflation in 3 patients(2.30%) with 2(3.1%) in closed group & one(1.5%) in open group, 3 (2.3%)patients had need for conversion one(1.5%) in open group due to transverse

colon injury and 2(3.1%) in closed group ; one due to Verees needle perforating the stomach, another due to dense intra-abdominal adhesion, port-site hematoma occurred in 2 (1.53%) one in each group.

There were no vascular injury, subcutaneous emphysema and mortality in either of the study group and there were no peri-operative mortalities.

Only access time and gas leakage had a significant difference with P-value < 0.001. Other complications had no significant difference between both the groups.

In present study we analyzed our results comparing on patients with BMI< or >25 kg/m ^{2} and on patients with presence or absence of previous history of abdomen surgery irrespective of techniques used. Both minor and major complications were more in obese/ overweight group i.e. patients with BMI >25 Kg/m^2 compared to patients with BMI < 25 Kg/m^2, with no significant difference. In group less than 25 Kg/m^2 average time is 5.57±1.38 minutes and 5.47±1.04 minutes in group more than 25 Kg/m^2.

In patients with previous history of abdomen surgery, gas leakage was seen in 5 (15.1%), need for conversion 2 (6.06%), bowel injury, extra peritoneal insufflation, failure of technique, port site hematoma were 1(3.03%) compared to patients with no history of previous surgery gas leakage was 9 (9.2%), extra peritoneal insufflation 2(2.1%), need for conversion, bowel injury, failure of technique, port site hematoma were 1(1.03%). In group with virgin abdomen average access time is 5.56±1.29 minutes and non-virgin abdomen 5.59±1.27 minutes.

Both major and minor complication were more in patient with previous history abdominal surgery when compared to patient with no history of previous abdominal surgery, access time less in virgin abdomen compared to non-virgin abdomen groups**.**

In this analysis major and minor complication were more in patients with BMI> 25Kg/m^2 and with previous history of abdomen surgery, but no statistically significance.

We conclude that there is still controversy exists to support the superiority of one technique over the other and this view is supported by the literature. According to this study open technique had a time advantage over the closed method, but gas leakage was significantly more in open group. Further studies are needed in multiple centers, on larger samples for conclusive evidence and surgeons should be competent in both techniques

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ANNEXURE-I

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr/Mrs/Miss. _____ we are requesting you to enroll yourself in study titled **"A PROSPECTIVE ONE YEAR COMPARATIVE STUDY OF COMPLICATIONS IN LAPAROSCOPIC SURGERIES IN CREATION OF PNEUMOPERITONEUM BY VEREES NEEDLE (CLOSED) VERSUS HASSON'S (OPEN) TECHNIQUE", IN KLE'S DR. PRABHAKAR KORE CHARITABLE HOSPITAL, BELAGAVI-590010:-:- A Randomized Controlled Trial** conducted by

Respected Sir/Madam we request you to enroll yourself to participate in our study as you are eligible for participating in the study. During the study you will be asked some questions regarding your present complaint and you are supposed to answer to the best of your knowledge.

Your participation in this research is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J.N.Medical College. If you decide to participate you are free to withdraw at any time.

The purpose of research is to know safety and efficacy of techniques in creation of pneumoperitoneum in laparoscopic surgeries by comparing the complications by this technique.

Purpose of the study:

There have been many studies comparing the efficacy and safety of the numerous access techniques although meta-reviews of these have turned out to be inconclusive, warranting the need for further evidence.

No study has been in our institution comparing these two techniques. Thus, no local, evidence-based guidelines can be formulated.

In view of the mentioned confusions and the paucity of literature there is a need for local guidelines to be drafted.

This study is conducted to compare the safety and efficacy of the Hasson cannula and Verees needle techniques for gaining entry and establishing pneumoperitoneum.

Procedure Involved:

If you agree to enroll yourself in my study, I will ask your present past and family history. Then you will be clinically examined in detail and routine investigations like Hb, TC, DC, Platelet Count, RBS, Blood Urea, Serum Creatinine, Blood Grouping, Chest X-ray, ECG,will be done accordingly. You will be allotted into one of the two groups randomly using sequential numbered brown opaque envelop method.

One group pneumoperitoneum is created by Verees needle(closed) technique and the other group by Hasson's(open) technique, observed for any difficulties, efficacy,complications and time taken for establishment of pneumoperitoneum

Risks:

There are few rare risk involved with use either two technique. It may include minor complication like the port site infection, subcutaneous emphysema, or bleeding from the epigastric vessels to major complications, the major vascular injury (0,003-1,33%), or visceral injury (0,04-4%) and are rather rare . Management depends on the

type of the complication. Major complications are an indication for an urgent laparotomy and minor are managed conservatively.

Benefits:

By laparoscopic surgery, patients recovery will be early, hospital stay will be less, cosmetically good than any laparotomy. Open technique has less major complication than close.

Voluntary Participation/Withdrawal:

Taking part in the study is voluntary. You may choose not to enroll yourself in this study. Your decision will not change present or future health care services offered to you at K.L.E. hospital.

Alternatives:

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

Privacy and Confidentiality:

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

1. In emergency to protect your rights and welfare.
2. If required by law.

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 connection with this study and that can be identified with your identity remaining confidential.

Financial Incentives for participation:

No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator.

Compensation:

In the event of injury related to the study, treatment will be made available through KLES' Hospital &MRC, Belagavi. There is no compensation or payment for such medical treatment by law. If you are injured you may contact at Department of General Surgery, KLES Hospital& MRC, Belagavi.

Questions:

If you have any queries about your rights as a study subject, you may call Dr. Ganga Pilli, Professor, Department of Pathology and Chairman, J.N. Medical College Institutional Ethical Committee for Human Subjects Research, Phone number-9448863866, or extension 4052 at J.N. Medical College, Belagavi.

CONSENT FOR PARTICIPATION IN RESEARCH TRIAL

"A PROSPECTIVE ONE YEAR COMPARATIVE STUDY OF COMPLICATIONS IN LAPAROSCOPIC SURGERIES IN CREATION OF PNEUMOPERITONEUM BY VEREES NEEDLE(CLOSED) VERSUS HASSON'S(OPEN) TECHNIQUE", IN KLE'S DR. PRABHAKAR KORE CHARITABLE HOSPITAL, BELAGAVI-590010:-.:- A Randomized Controlled Trial

Consent for participation in research trial

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

Subject Name : _____

Signature or the Left Thumb Print of Subject:_____

Date :

Witness Name : _____ Signature:_____

Investigators Name: _____ Signature:_____

Signature: _____

Date :

Place : Belagavi

ANNEXURE-II

PROFORMA

"A PROSPECTIVE ONE YEAR COMPARATIVE STUDY OF COMPLICATIONS IN LAPAROSCOPIC SURGERIES IN CREATION OF PNEUMOPERITONEUM BY VEREES NEEDLE(CLOSED) VERSUS HASSON'S(OPEN) TECHNIQUE", IN KLE's DR. PRABHAKAR KORE CHARITABLE HOSPITAL, BELAGAVI-590010:-:- A RandomizedControlled Trial.

Name: _____

Address _____

_____

Age of the Patient: _____ IP. No. _____

Weight of Patient: _____

Sex. Male/Female

Anaesthesiologist: _____ Surgeon unit/ Designation: _____

PRE OPERATIVE EVALUATION :

Chief Complaints:

	YES/NO	DURATION
PAIN ABDOMEN		
SITE OF PAIN		
TYPE OF PAIN: RADIATING	YES / NO	
THROBBING	PRICKING	DULL ACHING

INTENSITY:	MILD	MODERATE	SEVERE

VOMITING:	PRESENT	ABSENT

FEVER:	PRESENT	ABSENT

DURATION:	

TYPE OF FEVER:	CONTINUOUS	INTERMITTENT	SPIKING

DEGREE OF FEVER:	MILD	MODERATE	SEVERE

PREVIOUS SURGERIES :	YES	NO

If, yes

What surgery has been done	

Past History:

- History of
- Diabetes Mellitus:-

YES	NO

- Hypertension:-

YES	NO

- Asthma:-

YES	NO

- Drug Therapy:

YES	NO

Family History

General Physical Examination:

Weight:	
Temperature:	
Pallor:	
Height	
Cyanosis:	
Pedal Oedema:	
Clubbing:	
Lymphadenopaty:	
Icterus	

BMI Weight in kgs/ height in metres^2

= _____

Pulse :	
B.P :	
RR :	

SYSTEMIC EXAMINATION :

Per Abdomen:

TENDERNESS:	PRESENT	ABSENT

IF PRESENT,

SITE	

BOWEL SOUND	PRESENT	ABSENT

	NORMAL	ABNORMAL FINDINGS
Cardiovascular System:		
Respiratory System:		
Central Nervous system:		

INVESTIGATIONS:

Hb%:

TLC:

DLC: N L E M B

Urine Routine:

Platelet:

Creatinine:

Urea:

PTINR:

LFT: Total bilirubin:

Direct bilirubin:

A**SA STATUS:** Grade I / II

Diagnosis:

Proposed Surgery

Inclusion Criteria:

1. ASA physical status I and II.

2. Age between 16 to 65 years.

3. Virgin and Non virgin abdomen

Exclusion Criteria:

1. Patients not willing to give consent

2. Co-morbid conditions of

Chronic liver disease,

Chronic renal failure,

Malignancy

3. Immunocompromised

Methodology:

After obtaining the approval of the ethical committee and written informed consent, a total of 130 patients undergoing laparoscopic surgeries for any clinical conditions will be included in the study.

Patients will be randomly divided into two groups by using sequential numbered brown opaque envelop method.

Variables taken into consideration included the ability to create pneumoperitoneum, the time taken to establish it, leakage of carbon dioxide gas from the margins of the access site, conversion to laparotomy, mortality and the known complication of laparoscopic surgeries these include abdominal wall hematoma, subcutaneous insufflations of gas, failure, penetrating injuries to blood vessels and intraabdominal viscera.

All patients will be taken under general anesthesia covered.

Following the guidelines for asepsis and antisepsis are maintained.

The patients will be randomly selected to one of two groups .The surgeries will be performed by experienced surgeon, senior and junior residents, post graduate doctors, observed for intraoperative complications, access time, while establishing pneumoperitoneum.

Group A Verees needle (closed) technique will be used in creating pneumoperitoneum.

Group B Hasson's(open) technique will be used.

Gases used

The most popular gas used for laparoscopy is carbon dioxide.

Insufflator

Insufflator is a device used for introduction of the gas under specified volumeand pressure into peritoneal cavity. It is automatic electronically controlled insufflators are used. These allow to set a precise flow of the introduced gas (in lit/min), and at a constant pressure (12-14 mmHg).

Closed laparoscopic access

The Verees needle is undoubtedly the most characteristic instrument for a closedlaparoscopic entry. They are available in many sizes, also equipped with the movable blunt tip to avoid incidental injuries. The Verees needle is connected through the isolated cord, often equipped with bacterial filters to an insufflator. It is possible to

close the gas flow with the valve placed on the stalk of the needle. It must be also equipped with a gas valve which allows passing the gas inside.

In the first step of this technique a small (up to 1.5 cm) incision, above, under or lateral (most often left side) of the umbilicus is made. Then to lift the anterior abdominal wall or stabilize it before the Verees needle is inserted.

The Verees needle should be inserted in angle from 45° in non-obese to 90° in obese patients. There are various methods like hanging drop of saline test, the “hiss” sound test, aspiration and syringe test, that are believed to prove correct localization of the needle, however in view of recent findings these do not have any support in evidence.

The last step of the blind laparoscopic entry is the introduction of the first trocar, the manoeuvre especially critical in an aspect of potential major vessels, or organ injuries. The anterior abdominal wall is elevated with the hand, during the trocar insertion, which helps to avoid major complications. The insertion should be made just after the removal of the Verees needle to avoid escape of the insufflated gas. The trocar should be gripped for its handle 90° angle to the surface of abdominal wall, and introduced carefully with the rotary motion. Just after the insertion of the first trocar, the insufflation cord should be connected to maintain the pneumoperitoneum.

Open laparoscopic access

Open laparoscopic access was developed by HM. Hasson as the alternative for the closed laparoscopic entry. The notable difference between techniques is, that the first trocar isinserted before the pneumoperitoneum is established, and with a prior

dissection of theanterior abdominal cavity wall, with an incision of the fascia and the peritoneum under thecontrol of the sight.

The most specific part of the instrumentation used in open laparoscopic entry is Hasson trocar. It consists of a cannula and a blunt obturator, which helps to avoid injuries during an insertion, and a specific sealing cone with tabs to fix the sutures. Alternatively a standard 10 mm trocar, without its blade may be used. The insufflation equipment remains the same as in the closed method.

The first step in the open laparoscopic entry is the dissection of the anterior abdominal cavity wall. The skin incision is rather longer than in a closed laparoscopic entry, so it has to fit the wider Hasson trocar, it is localized typically as in closed technique. After the incision subcutaneous tissue, the fascia (up to 5mm) and peritoneum dissected. After the exposition of the prepared hole, and optional finger control of the space, the Hasson trocar is placed into the peritoneal cavity.

Sample size - As proven prevalence of complication not available, the effect size cannot be calculated. Therefore sample size of 130 with each group 65 samples is studied.

Parametric data will be analysed by student unpaired-t test. Non- parametric data was analysed by using Chi square Test. P value of less than 0.05 is considered significant

Observations:

a)Complications

1) Gastric perforation
2) Vascular injuries
3) Subcutaneous emphysema
4) Gas leakage
5) Extra peritoneal insufflations
6) Failure of technique
7) Need for conversion
8) Port site hematoma

b) Access time for establishment of pneumoperitoneum

Readings were recorded in the following manner:

Laparoscopic access technique: _____.

Group: _____.

Complications	**Present**	**Absent**
Gas leakage		
Extra peritoneal insufflation		
Bowel injuries		
Vascular injuries		
Need for conversion		
Failure of technique		
Port site hematoma		
Mortality		
Subcutaneous emphysema		

2) Access time: - _____ minutes

Any other complication noted_____.

Signature of staff in charge:

KEY TO MASTER

1	-	ASA II
A	-	ABSENT
BMI	-	BODY MASS INDEX
b/min	-	BEATS PER MINUTE
Count/mm^3	-	COUNT PER CUBIC MILIMETER
c/min	-	CYLCES PER MINUTE
F	-	FEMALE
˚F	-	FAHRENHITE
g%	-	GRAM%
IP.NO	-	IN PATIENT
Kg/m^2	-	KILOGRAM PER SQUARE METERS
lac/mm^3	-	LACS PER CUBIC MILIMETERS
M	-	MALE
m	-	METER
min	-	MINUTES
mmHg	-	MILIMETER OF MERCURY
N	-	NO
P	-	PRESENT
SL NO.	-	Serial number
Y	-	YES