A COMPARATIVE STUDY TO ASSESS THE IMPACT OF LOW PRESSURE VERSUS STANDARD PRESSURE PNEUMOPERITONEUM ON SHOULDER TIP PAIN AFTER LAPAROSCOPIC SURGERY

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LIST OF ABBREVATIONS

ABBREVATIONS	FULL FORM
AD	AFTER DEATH
B.C	BEFORE CHRIST
IAP	INTRAABDOMINAL PRESSURE
ICP	INTRACRANIAL PRESSURE
STP	SHOULDER TIP PAIN
PNP	PNEUMOPERITONEAL PRESSURE
USG	ULTRASONOGRAPHY
NOTES	NATURAL ORIFICE TRANSLUMINAL ENDOSCOPIC SURGERY.
LCH	LAPAROSCOPIC CHOLECYSTECTOMY
OCH	OPEN CHOLECYSTECTOMY
CT	COMPUTED TOMOGRAPHY
SD	STANDARD DEVIATION
V/Q	VENTILATION PERFUSION RATIO
CPP	CEREBRAL PERFUSION PRESSURE
CBD	COMMON BILE DUCT

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ABSTRACT

Background: Most frequently, carbon dioxide gas is insufflated into the peritoneal cavity, held there at constant pressure until the end of the procedure, then it is released at the time the ports are withdrawn, to establish pneumoperitoneum for laparoscopic procedures. In an effort to lessen the effect of pneumoperitoneum on human physiology while still giving appropriate working space, a new trend has been the use of low pressures for pneumoperitoneum in the range of 7–10 mm Hg. The advantages of low pressures during pneumoperitoneum appear to be a lower incidence of shoulder tip pain in the postoperative period and also better quality of life in the week following surgery.

Objectives

1. To study the advantages of low-pressure pneumoperitoneum and its impact on decreasing postoperative complications, especially shoulder tip pain.
2. Correlating the duration of laparoscopic surgery and its impact on shoulder tip pain.

Methods:

This is a prospective comparative study of patients undergoing laparoscopic surgeries in B.L.D.E.(D.U)'S Shri B.M.Patil Medical College Hospital and Research Centre with a sample size of 90.

Results:

Postoperative shoulder tip pain scores were significantly low in the low pneumoperitoneal pressure group, according to our study, with a p-value of < 0.00. The duration of surgery also had a significant impact on shoulder tip pain. Procedures that exceeded more than 1 hour were associated with more shoulder tip pain (p-value of <0.00). The analgesic requirement and duration of stay in hospital was also less in the low pneumoperitoneal pressure group.

1. INTRODUCTION:

Primum non nocere. Possibly, the Hippocratic impulse underlying the demand for moral action on the part of doctors was one of the many factors responsible for the introduction of minimally invasive surgery as we know it today.[1]

Endoscopic operations are now common practice across all surgical specialities and have become an essential component of all surgical specialities. Laparoscopic surgery is being used to execute an increasing variety of complicated surgical procedures. The dangers and complications of surgery have always been a top priority for surgeons and medical professionals.[1]

The use of robotic surgery has been added to conventional laparoscopy.
The development of complicated surgical methods as we know them now required a significant number of phases and people, as the history of laparoscopy demonstrates.[2]

The first person to explain the fundamentals of abdominal endoscopy was Georg Kelling. In a dog, Kelling carried out the surgery. The first endoscopy on a human was carried out by Jacobaeus almost exactly a century ago. Between the 1960s and the 1980s, significant improvements in endoscopy were made, along with a shift from diagnostic to surgical laparoscopy. These developments are inextricably tied to Kurt Semm in Kiel and Raoul Palmer in Paris.[2]

On September 13, 1980, Semm performed the first laparoscopic appendectomy at the University of Kiel's department of obstetrics and gynaecology. At the time, it was a complete rarity and a worldwide phenomenon.[2]

Semm, a gynaecologist and skilled toolmaker, transformed how conventional surgery was performed. He, however, drew the ire of numerous gynaecological and surgical colleagues. The medical community at the time, in his own words, responded with the worst hatred and opposition he had ever seen in his career: "Both surgeons and gynaecologists were unhappy with me; they practically stoned me. Such nonsense does not, and will never, belong in general surgery, was the reply made in response to each of my initial attempts to publish a study on laparoscopic appendectomy. As a result, his initial report on laparoscopic appendectomy was not published until 1983. His close associate Liselotte Mettler (born in 1939), in an interview, recalled how Semm was called from the operating area and required to undergo a computed tomography examination of his skull to demonstrate that he was in good health.[2]

Laparoscopy also grew well-established in other fields, including urology and surgery. A significant demand for surgeons and technology resources was matched by the interventions' increasing complexity.When doing endoscopic procedures for several hours, a surgeon approaches his or her physical and mental limits.[3]

Technical developments played a key role in the development of endoscopy later on. By further minimising the skin incision, laparoscopic procedures like NOTES (natural orifice transluminal endoscopic surgery) and surgery using a single trocar (single-port approach) aim to lessen access-related stress.[3]

The most innovative type of minimally invasive surgery available today is robot-assisted surgery. The use of minimally invasive surgery is possible even in difficult scenarios thanks to advances in 3D technology and the extension of surgical instruments to 7 degrees of freedom. During complex operations, robot-assisted guidance of the tools allows the surgeon to work without tremors and with a low level of tiredness, which is highly helpful for both the surgeon and the patient. The surgeon can also perform simultaneous tasks at two consoles. The learning curve is lowered, complications are less common, and surgical training is encouraged.[4]

One of the biggest triumphs in medical history is the adoption of endoscopy in surgical practice. There is currently no clear end in sight for the development of minimally invasive solutions.[4]

AIMS AND OBJECTIVES OF THE STUDY

The aim of this study is to determine the impact of low-pressure pneumoperitoneum and standard pressure pneumoperitoneum with duration of laparoscopic surgeries on postoperative shoulder tip pain.

Objectives of the study: To study

1. Advantages of low pressure pneumoperitoneum and its impact on decreasing post operative complications especially shoulder tip pain

2. Correlating the duration of laparoscopic surgery and its impact on shoulder tip pain.

3. A visual analogue scale for the measurement of shoulder tip pain post procedure.

4. Faster recovery and decreasing post operative complications and the Duration of stay in the hospital.

5. Better quality of Life in the week following surgery.

REVIEW OF LITERATURE

History and Pioneers

Endoscopy and laparoscopy are both Greek words that translate to "seeing the interior areas of the human body." The earliest documented records of medicine show that in addition to the standard inquiry techniques of palpation, auscultation, and percussion, doctors were always interested in the prospect of "looking into" (endoscopy) the human body.[5]

The chief exponent of the Kos school of medicine, Hippocrates II (born 460 B.C., died 375 B.C.), reported using a speculum to examine the rectum. Similar devices for examining the vagina have also been mentioned in other cultures and were discovered in the remains of Pompeii (which was destroyed in the year 70 A.D.). The necessity to clarify the subject of the probe, however, constrained the scope of the investigation. Lighting has been a problem with laparoscopy for a long time.[6]

An Arabian physician named Albukasim was the first to employ reflected light to see within the body (912–1013 A.D.). In front of the vulva, he held a glass mirror, reflecting light into the vaginal vault. The first person to employ a mechanical lamp was Cardan (1501-1576).[6]

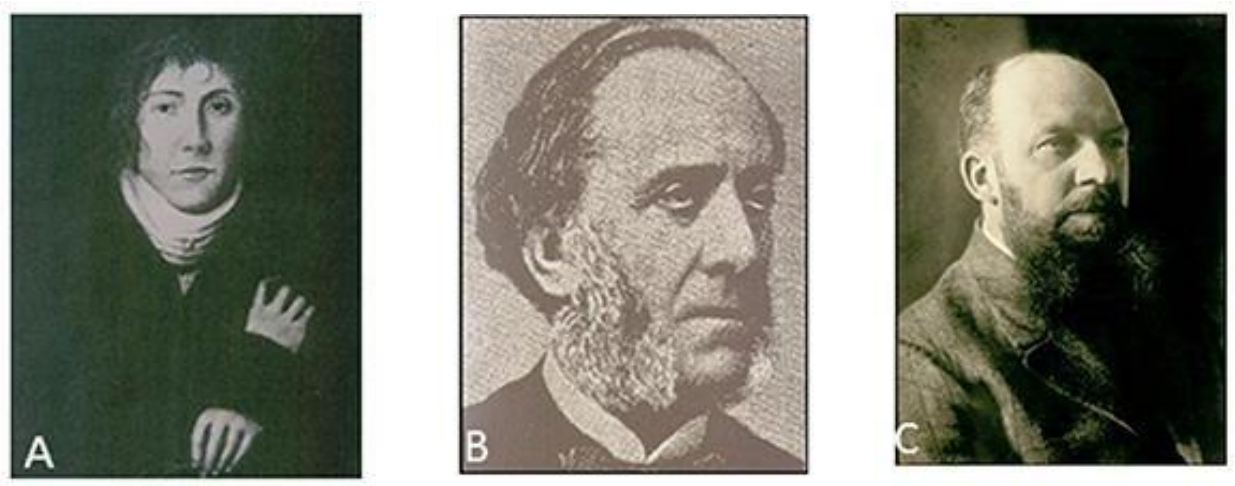
Aranzi (1530-1589), a Venetian, used a camera obscura to bundle light. The first endoscopic examination light with a shielded bulb was created in 1768 by the French gynaecologist and surgeon George Arnaud de Rosil (1698-1774). He was able to illuminate the vagina after it had been spread open with specula.[6]

Frankfurt physician Philipp Bozzini (1773–1809), who symbolises the shift from conventional to modern medicine, had a significant impact on the development of contemporary endoscopy. Bozzini's report on his light conductor, which consists of an optical component with lighting apparatus and a mechanical part positioned to match the anatomy of the body orifice, was published in 1806. As a result, he developed a device that could be used for inspection and, to a lesser extent, for performing surgery, on the vagina, the rectum, and the oral cavity. All subsequent attempts to conduct a cystoscopy over the course of the following 70 years were based on Bozzini's illumination principle, specifically that of a reflected light source, despite the fact that the light conductor was much too weak and the field of vision was too tiny.[7]

With the invention of the first portable endoscope in 1843, Antonin Jean Desormeaux (1815–1894) pushed this historical trend. Numerous people consider Antonin Jean Desormeaux to be the "father of endoscopy" because he was the first to use Bozzini's light conductor in a clinical setting. His endoscope, which consisted of a set of mirrors and lenses with an open flame as the light source, was largely employed to answer urological queries.[8]

Burns were caused by the light source's extreme heat, which was one of the drawbacks. Electric-lit endoscopes weren't created until Thomas Alva Edison's discovery of the light bulb in 1879 and the mignon lamp, a smaller counterpart of the bulb. Cystoscopy was the initial focus of later developments in endoscopy. Edison's lightbulb underwent modification by Maximilian Nitze (1848–1906).[8]

Nitze set the groundwork for clinical endoscopy in 1877 by developing the first urethroscope and cystoscope with an integrated light source for the illumination of body cavities. In 1881, Joseph Leiter, a Vienna-based instrument maker, and Johann Mikulicz-Radecki (1850–1905) utilised Nitze's rigid optical system idea and created the first gastroscope for therapeutic usage.[8]



(A) Philipp Bozzini (1773–1809) (B) Antonin Jean Desormeaux (1815–1894) (C) Georg Kelling (1866–1945)

(D) Maximilian Nitze (1848–1906) (E) Heinrich Kalk (1895–1973) (F) Raoul Palmer (1904–1985)

FIGURE 1: **Pioneers of laparoscopy.**

Era of Diagnostic Laparoscopy (1901–1933)

After his lecture on "About the Inspection of the Esophagus and the Stomach with Flexible Instruments," George Kelling (1866-1945), a surgeon and gastroenterologist from Dresden, introduced the first laparoscopy; he called the procedure "coelioscopy." Kelling concentrated on the gastrointestinal tract's anatomy and physiology in his doctoral thesis.[8]

He was the first to further develop the technique based on this information and his discoveries regarding the insufflation of air into the abdomen. Using a Nitze cystoscope, he examined the abdominal cavity of a dog whose body had previously been insufflated with filtered air. This intervention might be thought of as the laparoscopic procedure's birth hour.[8]

The term "laparothoracoscopy" was coined nine years later by the Swedish internist Hans-Christian Jacobaeus (1879–1937) during the first endoscopic examination of the chest and abdominal cavities of a human. In 1910, Jacobaeus wrote about his first 17 laparoscopies in the Münchner Medizinischen Wochenschrift (Munich Medical Weekly).[9]

"About the alternatives of utilising cystoscopy for the investigation of serous cavities" was the report's heading. Jacobaeus suggested using the method to do endoscopic examinations of other bodily cavities. Jacobaeus introduced the trocars without first generating a pneumoperitoneum, in contrast to Kelling. By using thoracoscopy to observe the body, Jacobaeus began to remove adhesions. He is considered the inventor of thoracoscopic procedures since he performed thoracoscopic investigations as early as 1913.[9]

Bertram M. Bernheim (1880–1958) carried out the country's first laparoscopy in 1911. Organoscopy was his method's name. A proctoscope and basic lighting made up the

tools. Without making a pneumoperitoneum, Bernheim inserted his device through a small incision. His first patient had an enlarged gall bladder, which he was able to find. But it wasn't until a subsequent laparotomy that the precise diagnosis of pancreatic cancer was made.[9]

The abdominal cavity was better insufflated. An article on abdominal cavity X-ray diagnosis was published in the Munich Medical Weekly one day after the First World War came to an end. Author and assistant surgeon Otto Goetze (1886–1957) concentrated on issues with radiology. To increase contrast on X-rays, he employed oxygen. In order to introduce oxygen safely into the abdomen, he developed a double-walled cannula in accordance with the “principle of solid displacement.”

He also created the phrase "pneumoperitoneum." Swiss gynaecologist Richard Zollikofer began insufflating patients with CO2 in place of air in 1924.[10]

Optics also got a boost. The German school of laparoscopy was founded by Berlin-based gastroenterologist Heinz Kalk (1895–1973), who also invented the 135-degree lens system and the twin trocar. Kalk employed laparoscopy to diagnose conditions affecting the liver and gall bladder. He spoke about more than 2,000 liver punctures performed under local anaesthetic in a book of his experiences in 1939 without mentioning a single fatality. Additionally, he removed adhesions using laparoscopic surgery.[10]

Era of Operative Laparoscopy

The surgical range was expanded as proficiency with the procedure grew, in addition to notable advancements in tools and technology. Carl Fervers successfully completed the first laparoscopic adhesiolysis in 1933, which is considered to be the first surgical laparoscopy in the modern definition of the word.[11]

J.C. Ruddock, an American, reported on more than 500 laparoscopic surgeries including biopsies, primarily from the liver, in 1937. This internist, whose work was published in surgical journals, employed electrically powered pincers for the purpose of coagulation.

The Hungarian internist and pulmonologist János Veres (1903-1979), who introduced his insufflation needle that had really been reported earlier by Goetze but had vanished into obscurity, set another significant milestone in the historical evolution of laparoscopy. A unique canula with a spring mechanism was created by Veress. It was used to treat tuberculosis, which was a common illness at the time, by inducing a pneumothorax. Even today, a pneumoperitoneum is safely created during laparoscopy using the Veress needle. When delivered through the abdominal wall, its spring mechanism enables gas insufflation with a low risk of problems and prevents damage to internal organs.[12]

The first simple surgical procedures were carried out in the 1960s, mostly by gynaecologists. The French gynaecologist Raoul Palmer (1904–1985) made significant contributions in this area. Palmer was primarily interested in the diagnosis and treatment of sterility. He carried out a laparoscopy in the Trendelenburg position in 1944. He also

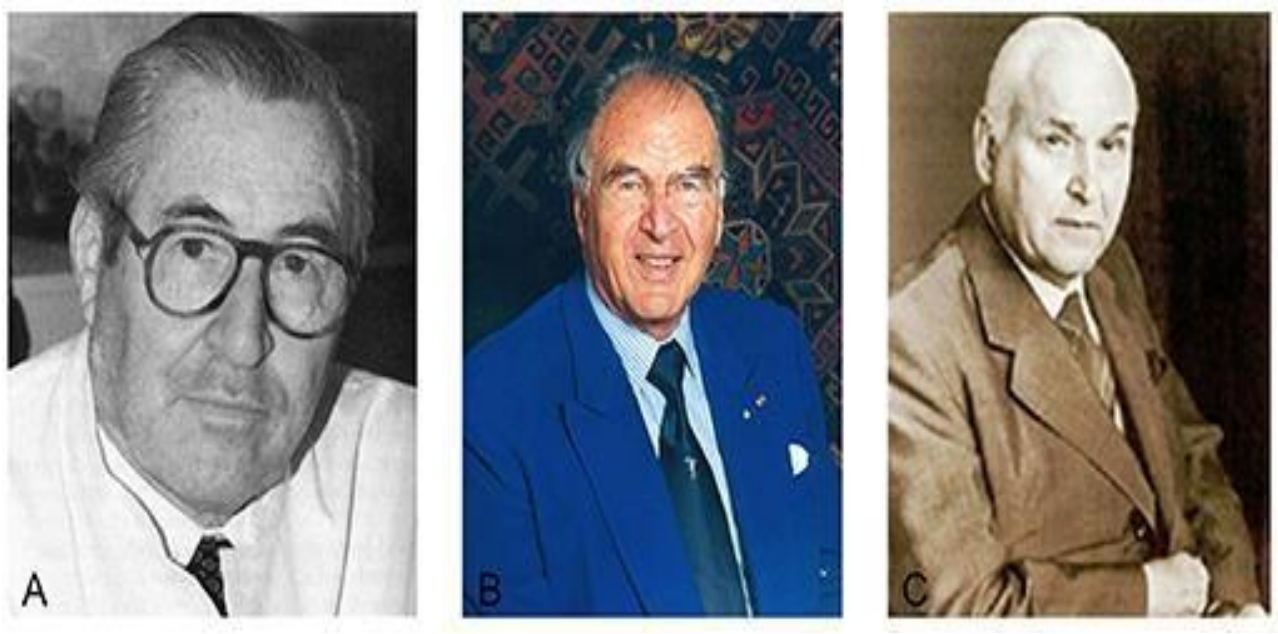
performed the first laparoscopic sterilisation. Palmer's name is attached to an incision location in the upper abdomen on the left costal border, however in 1946 he preferred making the incision in the navel. He used the term "coelioscopy," just like Kelling, to describe the endoscopic operation.[12]

In 1946, American Albert Decker (1895-1988) introduced the laparoscope transvaginally through the posterior vaginal vault since abdominal access was challenging due to the blind nature of insertion. He called the operation culdoscopy. However, from this standpoint, the diagnostic process was insufficient, and the technique, which was initially quite well-liked, lost popularity in the USA.[12]

Pioneers of Operative laparoscopic Surgery

Hans Frangenheim (1920–2001) and Kurt Semm are generally credited with the development of laparoscopy in Germany following World War II (1927–2003). When a tumour in the lower abdomen was found during endoscopy of the liver at the Medical Clinic of Cologne in 1952, Frangenheim underwent laparoscopy and had to determine the best course of action.[12]

He worked as Palmer's clerk in France in 1955 and learned that laparoscopy was preferable than culdoscopy, which was being practised at the time in Germany. A CO2 insufflator was created by Frangenheim in collaboration with the Dräger Company. He helped spread the method through his books, articles, and talks.[12]



(A)Hans Frangenheim (1920–2001) (B)Kurt Semm (1927–2003 (C)Karl Storz (1911–1996).

FIGURE 2. Pioneers of operative laparoscopy.

The contemporary laparoscopy was reportedly invented at the Kiel University Department of Obstetrics and Gynecology under Kurt Semm (1927–2003). He rose to prominence as the field's most productive researcher and creative equipment creator in endoscopic surgery today.[13]

Two significant events in the 1960s helped usher in a new era of endoscopy. The Hopkins optics were created in 1961 by the British scientist Harold Hopkins (1918-1994), who also made significant advancements in the field. This optical device was made out of "rod lenses." Sharper and brighter images were produced thanks to its increased field of vision and eighty times greater light transmission. German instrument maker Karl Storz became interested in the method and persuaded Hopkins to collaborate with him. The cold light source, which took the role of the bulb at the endoscope's tip, was created by the Karl Storz Company as early as 1960.[13]

The benefits of the cold light source were clear: it produced significantly less heat and offered much greater illumination. Intra-abdominal endoscopy was mostly used for diagnostic procedures until 1970. This restriction could be attributable to the lack of tools for stopping bleeding during surgical procedures. Semm wanted to go beyond just diagnosing with a laparoscopy. He gave his method the name "pelviscopy" to set it apart from internistic laparoscopy of the upper abdomen. 13 Semm personally created numerous instruments because he is a skilled precision mechanic. Since 1955, he has been involved with endoscopy. His motorised CO2 insufflator, built in 1963, improved the safety and comfort of abdominal surgery.

In order to stop bleeding, the Roeder loop was created in 1973 and thereafter thermocoagulation. In 1977, Semm created the first morcellator, an electronic insufflator, and a unique suction irrigation system. His variety of hemostasis tools and techniques, such as endosutures with intra- and extracorporeal knots, allowed surgeons to undertake ever-more intricate operations. These developments turned out to be essential building blocks for the later development of endoscopy.[14]

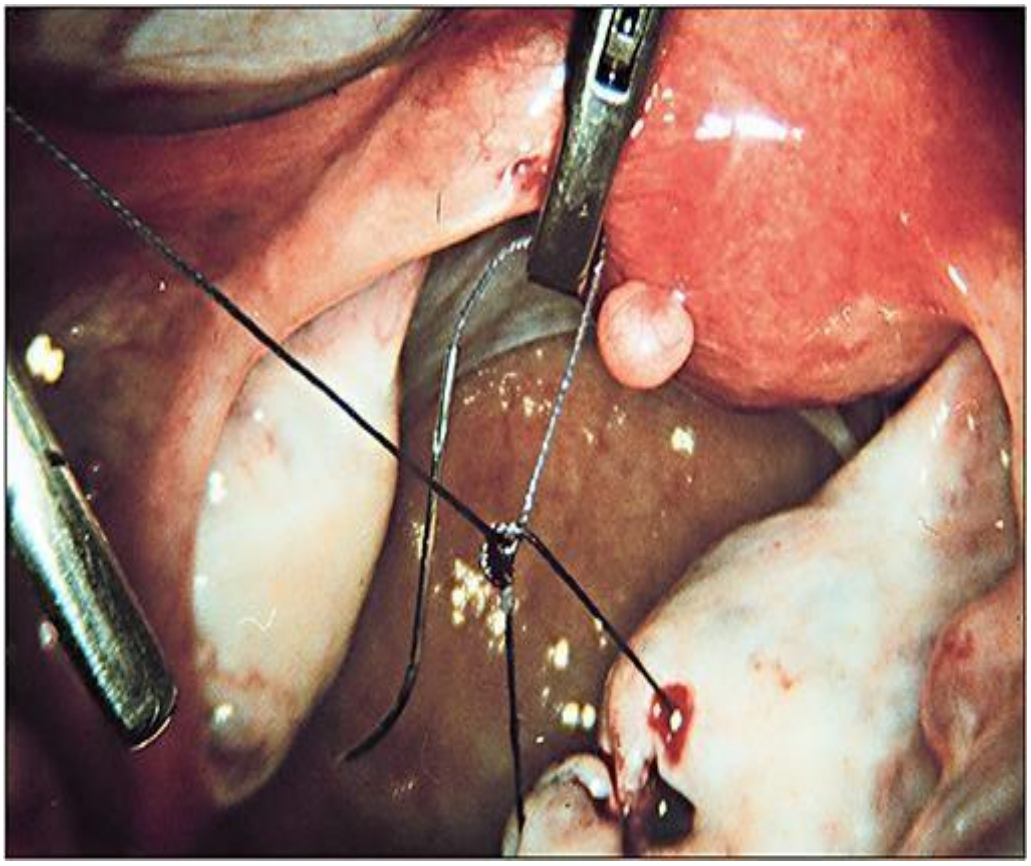


FIGURE 3: Introduction of intracorporeal knots (1974). Source: Department of Obstetrics and Gynecology, University Clinic of Kiel.

Many gynaecologists and surgeons, however, attacked Semm for his "keyhole surgery" and thought that laparotomy was no longer a concern because of contemporary anaesthetic techniques. Semm followed his work in laparoscopy with unwavering determination because he was aware of the enormous potential of endoscopic surgery, particularly in the field of surgery and not just gynaecology. In order to lessen surgical trauma for patients, he persisted in his efforts.[15]

Semm's goal was pursued by two German surgeons, Gotz and Pier, who popularised laparoscopic appendectomy. They used this method to execute hundreds of appendectomies and refine the technique as early as the early 1990s. Even individuals with acute appendicitis were included.[16]

Using the tools created by Semm, the German surgeon Erich Mühe (1938–2005) carried out the first laparoscopic cholecystectomy in 1985. He reported on 97 successful procedures using this technique in 1987. In 1989, Reich et al. described the first hysterectomy assisted by laparoscopy, and in 1991, Mouret carried out the first cholecystectomy using video laparoscopy. At that time, interest in laparoscopy increased as the industry recognised its significance and possible economic benefits.[17]

McKernan and Saye performed the first laparoscopic cholecystectomy in the USA in 1988 after being inspired by a film presentation of Semm's laparoscopic appendectomy at a gynaecologists' convention in Baltimore. They combined the laser technology with Semm's tools. Many endoscopists afterwards came to Nashville to study the novel method from the two surgeons. The information made it to the American media, and a television chat show promoted the method.[17]

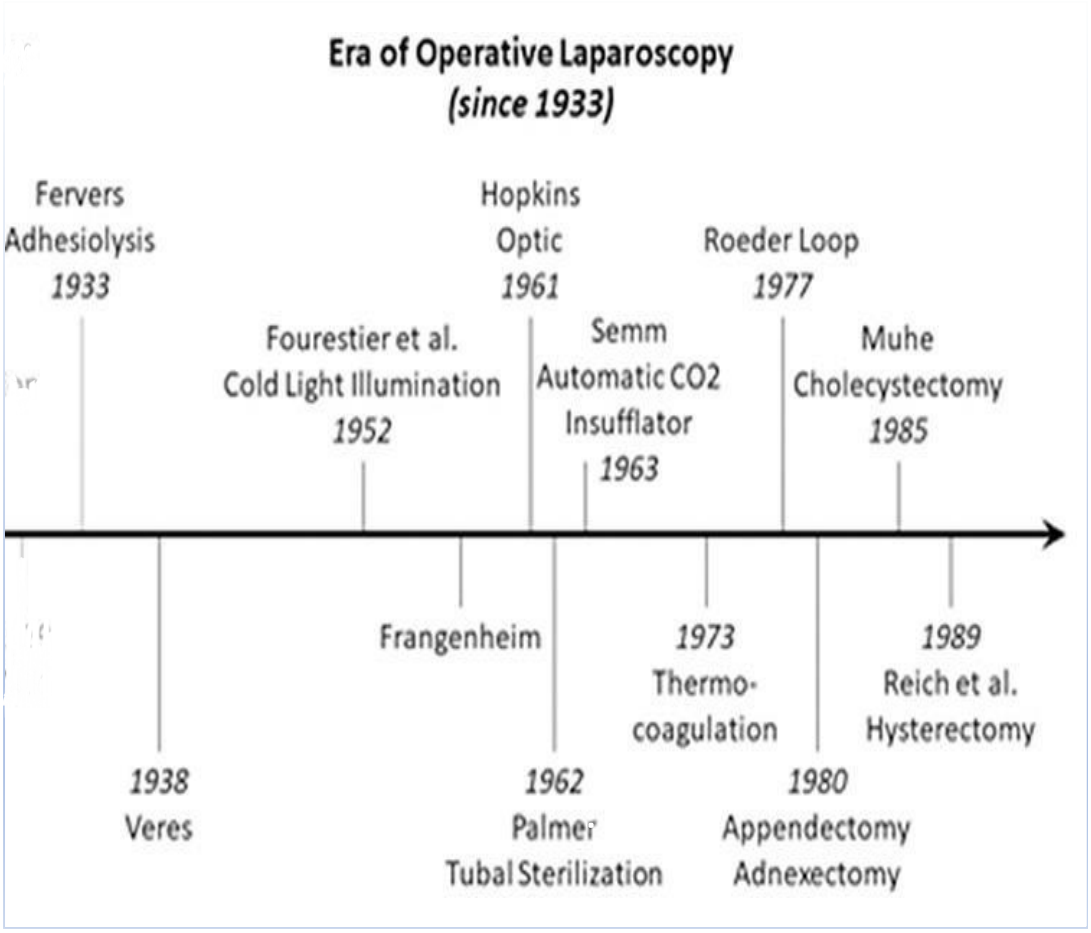


FIGURE 4: Summarizes the historical steps in the Era of Operative laparoscopy.

The further development and use of laparoscopy were delayed by developments in other medical professions. Many surgeons in the 1970s and 1980s disregarded the development of laparoscopy. The reasons for this were advancements in anaesthetic, intensive care, and the increased range of drugs that allowed surgeons to carry out lengthy operations. Endoscopic cholecystectomy and appendectomy were regarded as daredevil surgeon procedures that provided dangerous remedies to issues that could be safely treated.[18]

The idea that serious medical issues necessitate significant fixes, such as abdominal incisions, was instilled in surgeons' thoughts. This was false because laparoscopy's basic was the opposite idea.[18]

Modern Era of Laparoscopy(2001- 2021)

One of the biggest triumphs in medical history is the adoption of endoscopy in surgical practise. This historical perspective demonstrates how laparoscopy has advanced in the last 20 years at an amazing rate and given rise to surgical prospects that have never before existed.[19]

The major goals of current advances are to enhance and realistically portray images. Additionally, the development of innovative surgical techniques like single-trocar access or natural orifice transluminal endoscopic surgery (NOTES) and consistent advancements in robotic surgery (single-port technique). Marc Possover created the idea of "Neuropelveology" in clinical practise based on discoveries in pelvic neurofunctional anatomy and the introduction of laparoscopy in the dissection and imaging of the pelvic nerves. The International Society of Neuropelveology was established in 2014.[19]

The interdisciplinary approach is becoming more significant in a time when medical specialty is on the rise and presents potential for endoscopic surgery. Operations can now be shared more easily with surgeons of various specialisations thanks to the exceptional quality of digital imagery.[20] This advancement has been further supported by the development of innovative and user-friendly tools that may be utilised in different specialisations, and the simultaneous use of two consoles in robot-assisted surgery. Additionally, contemporary operating rooms allow for a quick switch of surgeons. Information may be exchanged over great distances thanks to contemporary communication technologies and telementoring. As a result, surgeons from different specialisations or locations can interact during surgery even when they are not physically together.[21]

The high cost of installation and maintenance in robot-assisted operations is one of their drawbacks. These procedures typically need lengthy operating periods, at least at first, and come with a new learning curve, even for experienced laparoscopists. Additionally, training in the usage of the robot system is required for both the medical staff and the nursing staff. In the beginning, docking, trocar placement, and the unfamiliar motions at the console require more time. Despite the current drawbacks of robot-assisted surgery, technological advancements in this area will likely increase the availability of compact, cost-effective integrated systems in the near future and broaden the range of minimally invasive surgical techniques.[22]

ANATOMY

The abdominal wall is complete Musculo-aponeurotic structure that is attached to the vertebral column posteriorly, the ribs superiorly and the bones of the pelvis inferiorly it is derived segmentally in a metameric manner and this is reflected in its blood supply and innervations.[22] The abdominal wall protects abdominal viscera and its musculature acts indirectly to flex the vertebral column, it's integrity is essential in the prevention of hernia. There are nine layers of the abdominal wall namely,

- Skin
- Subcutaneous tissue consists of fascia's (Camper's and Scarpa's fascia).
- The External oblique muscle
- The Internal oblique muscle
- The Transversus abdominis muscle
- The Transversalis fascia
- Extra peritoneal adipose and areolar tissue and
- Peritoneum

Skin:

Skin of the abdomen is the general body skin with hairs. It may be involved with other generalized cutaneous lesions, Langer's lines-the lines of tension of the abdominal skin are nearly transverse.[22]

Subcutaneous tissue: The subcutaneous tissue consists of superficial Camper's fascia and deep Scarpa's fascia.[23]

Camper's fascia: This is a superficial fatty layer of subcutaneous tissue gives roundness and contour to the abdomen. This layer is more prominent in lower part of abdomen. Below it is continuous with the superficial layer of thigh. The layer offers little strength in wound closure.[23]

Scarpa's fascia: This is a deep membranous layer of subcutaneous tissue composed of dense fibrous connective tissue and it continues as fascia lata of the thigh below the inguinal ligament, and as Colle's fascia over the penis and scrotum. Approximation of Scarpa's fascia aids in alignment of skin after surgical incisions.[24]

Muscles of the abdominal wall and aponeurosis: (FIGURE 5)

The abdominal wall is formed anterolaterally by five pairs of muscles and their aponeurosis. They are:

1. Two (2) external oblique muscles
2. Two (2) internal oblique muscles
3. Two (2) transversus abdominis muscles
4. Two (2) rectus abdominis muscles
5. Two (2) pyramidales muscles.

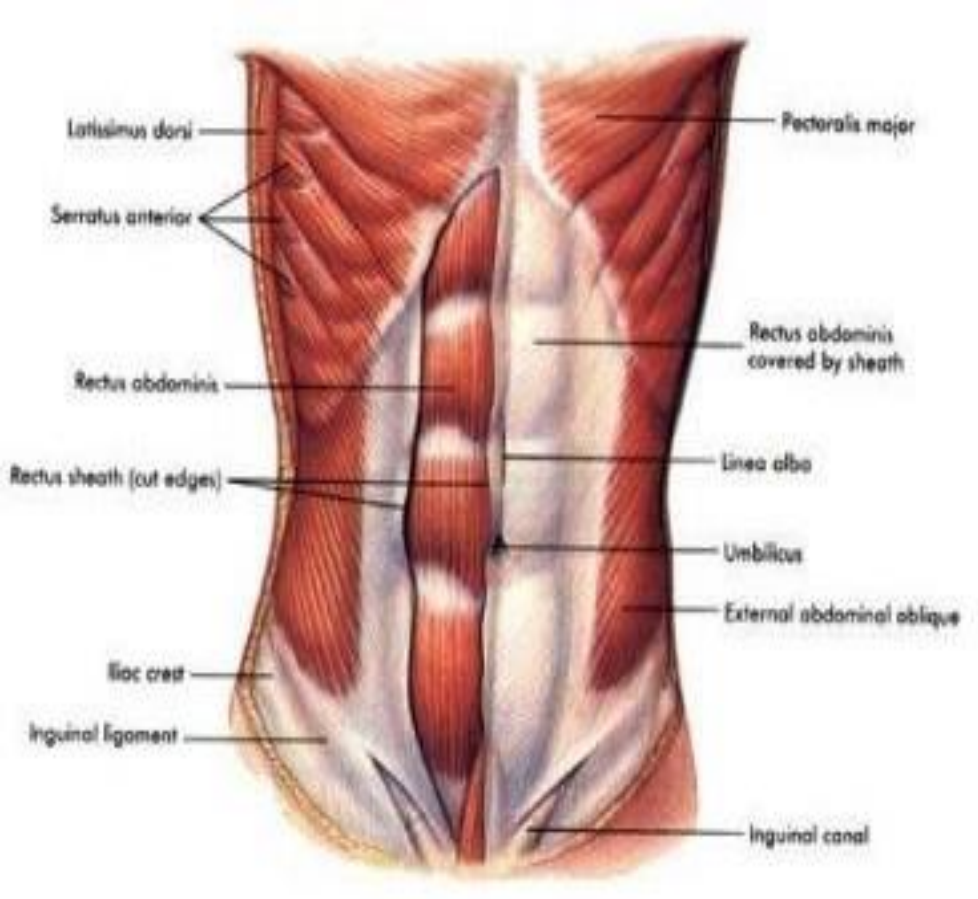


FIGURE 5: Muscles of Anterior Abdominal Wall

The External oblique muscle:

The External oblique muscles are the largest and the thickest of all the flat muscles of the abdomen. They originate from lower eight ribs and upper four digitations inter digitate with serratus anterior muscle and lower four with latissimus dorsi muscle. It courses in a superolateral to inferomedial directions to insert into anterior half of the outer lip of iliac crest at the mid clavicular line, the muscle fibers give rise to flat strong aponeurosis that passes anteriorly to rectus sheath to insert into the Linea alba.[25]

Internal oblique muscle:

The internal oblique muscle lies between external oblique and transversus abdominis muscles. It is a fan shaped muscle with narrow origin and broad insertion. It originates from lateral half of the inguinal ligament, intermediate line of the anterior two third of iliac crest and form intermediate lamina of thoracolumbar fascia. It is directed below upward and forwards. The central fibres form an aponeurosis at the semicircular line (of Douglas), and are separated into anterior and posterior lamella that encircle the rectus abdominis muscle. Its uppermost fibres are introduced to the lowest five ribs and their cartilages. The internal oblique muscle's aponeurosis runs anteriorly as a component of the anterior rectus sheath below the semicircular line. The lowermost internal oblique muscle fibres travel in a direction inferomedially similar to the spermatic cord before inserting into the pubis between the pubic symphysis and pubic tubercle. Some of the lower muscular fascicles go with the spermatic cord as the cremasteric muscle into the scrotum.[26]

The Transversus abdominis muscle

Transversus abdominis muscle is the smallest muscle of anterior abdominal wall. It arises from lateral one third of the inguinal ligament, from inner lip of iliac crest, from middle layer of the lumbosacral fascia, and from the lower six inter costal cartilages where it interdigitates with slips of diaphragm. Most of the fibers travel horizontally and gets inserted into Linea alba and through the conjoint tendon into the pubic crest. This muscle contributes to the posterior lamella of the rectus sheath up to the semicircular line below, which the fibres travel only anteriorly to linea alba in conjugation with aponeurosis of external and internal external oblique muscles.[26]

Rectus abdominis muscle (Figure 6)

Rectus abdominis muscles come in pairs and have the appearance of long, flat triangular ribbons that are wider at their origin on the anterior surface of the 5th, 6th, and 7th costal cartilages and xiphoid process than they are at their insertion on the pubic crest and symphysis pubis. Each muscle is made up of numerous long, parallel fascicles that are split up by three to five tendinous junctions. 28 attachments to the anterior rectus sheath of the rectus abdominis muscle are provided by these tendinous junctions. The posterior rectus sheath doesn't have a connection like that. The only thing separating these muscles from one another is the linea alba. The spinal column is flexed by the contraction of these muscles in addition to providing protection.[26]

Pyramidales muscle:

It is a smaller triangular muscle originating from the front of pubis and ligaments of symphysis. It is inserted into linea alba and it serves as tensor. The last thoracic nerve innervates it and it is absent in 11% of cases.[26]

Transversalis fascia:

This is extensive fascial tissue layer of stratum, which lines the entire abdominal wall. The fascia of one side is directly continuous with the other side behind the sheath of recti. It assumes the name of the structures which covers example-diaphragmatic fascia, iliac fascia etc. It is of varying density; it is well developed below the inferior margin of internal oblique and transversus abdominis muscle where it forms floor of the Hesselbach's triangle. It is separated from peritoneum and extra peritoneal adipose and areolar tissue. Inferiorly it is attached to the outer half of the inguinal ligament. It passes over the femoral vessels below the inguinal ligament as femoral sheath. Medial to femoral vessels it is attached to pectineal line of superior ramus of the pubis.[27]

Extra peritoneal adipose and areolar tissue:

Adipose and areolar tissue can be found in the preperitoneal area, which is located between the transversalis fascia and the parietal peritoneum. Before entering the rectus sheath, the inferior epigastric artery and vein travel through this region slightly above the hypogastrium. The three remaining foetal structures are located in this area (median umbilical ligaments which are the reminants of foetal umbilical arteries, midline fibrous cord representing foetal allontoic stalk, and the falciform ligament of liver).[28]

Parietal peritoneum:

The peritoneum is the thickest layer of the abdominal wall and is located at the interior of the abdominal cavity. It is made up of a single layer of squamous epithelium covering the inner surface of the peritoneum and a thin layer of thick, irregular connective tissue. It is innervated from TI to Ll and offers only little strength for wound closure, but it provides exceptional protection from infections.[29]

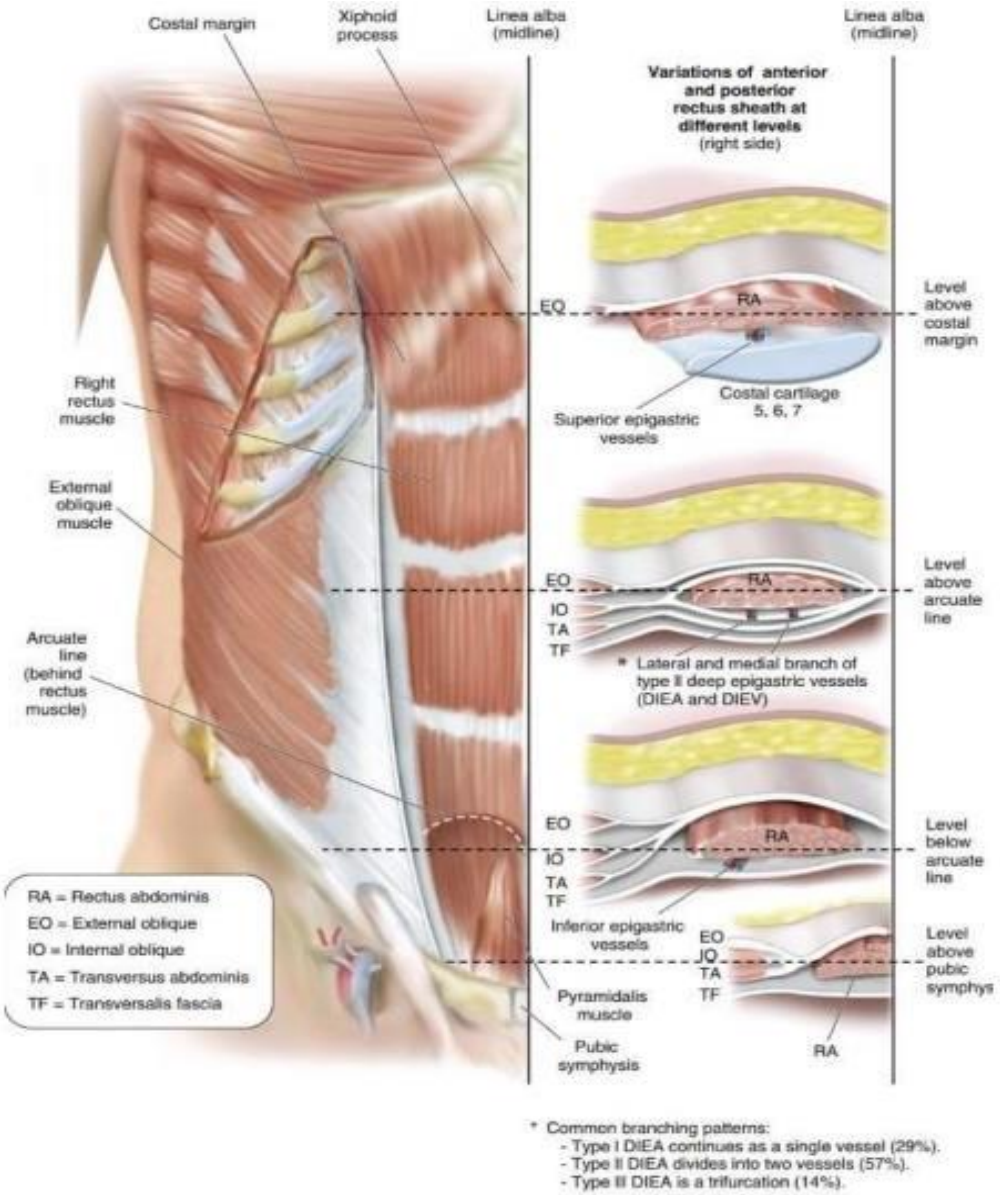


FIGURE 6

ANATOMY OF RECTUS SHEATH

GASES USED IN CREATING PNEUMOPERITONEUM.

Gas	Solubility/diffusion	Risk		Biological effects
		Burns	Gas embolism	
CO_2	+ + +	Yes	Very low	Many
He	– – –	No	Very low	Inert
N_2O	+ +	Yes	Low	Anesthesia
Air	O_2: –	Yes	High	Oxidation
	N_2: +	No	High	Inert

Table 1: Comparison of gases used during Laparascopy

Physiologic effects of CO2-pneumoperitoneum

Features of ideal gas for insufflation in laparoscopy

- Antiknock
- fireproof
- limited ability resorption
- Limited physiological effects on the body after absorption
- Rapid excretion from the body after absorption
- Does not support the occurrence of burns
- Limited physiological effects in the case of intravascular embolization
- Very soluble in blood.
- Colorless.

The body naturally produces CO2, which is an inert gas that is very affordable, more widely used, and more practical than nitrous oxide. Since gas is naturally eliminated from the body through the lungs, neither its diffusion nor decomposition within the body present a concern to the patient nor a risk of embolism. Since CO2 is not flammable, electrocoagulation is allowed.[30]

In some cases, carbon dioxide may cause peritoneal irritation and postoperative pain during prolonged laparoscopic procedures. It can occasionally cause laparoscopic acidosis after being absorbed from the stomach, which could result in cardiac arrhythmias.[30]

Some surgeons use nitrous oxide (N2O) for quick laparoscopic surgeries since it does not cause peritoneal irritation, resorption, or acidosis. It should be highlighted that additional nitrous oxide is not blood soluble and, theoretically, poses a very high danger of gas embolism. Due to the flammability of the gas, electrocautery is associated with a risk of burns during N2O-pneumoperitoneum.[30]

Although they are suited for insufflation due to their characteristics, other gases like helium, argon, xenon, and krypton were not used in routine laparoscopic procedures due to their high cost. Table 1 compares the gases used for PNP during laparoscopy.

Intraoperative acid-base balance changes.

Currently, the gas most frequently utilised to produce PNP is carbon dioxide. During CO2- pneumoperitoneum, there has been a discernible increase in the blood concentration of CO2 (pCO2) or end tidal CO2, as well as a concurrent decrease in the serum pH. The presence of pneumoperitoneum can change the acid-base balance and cause systemic CO2 absorption. The primary cause of hypercarbia is intraperitoneal CO2 absorption through the transperitoneal route.

During carboperitoneum, patients with significant cardiac or pulmonary disease have been linked to the development of more profound hypercarbia and acidemia than patients with normal cardiopulmonary function would normally experience.

PNP appears to have a minimal and clinically insignificant impact on alterations in oxygenation.[31]

Pulmonary changes

Due to the patient's elevated IAP, the abdominal wall physically shifts forward when patients breathe. The diaphragm, intercostal, and sternocostal muscles play a major role in this process, with the help of the pectoral muscles. With the exception of lung blockage, when the expiratory abdominal muscles are included in the process, the process of breathing out is passive. Respiratory compliance is reduced by 50% at a value of 15 mm Hg for intraabdominal pressure.[31]

Transient acidosis may result from hypoxemia and hypercapnia, which are both caused by CO2 absorption. Respiratory issues during laparoscopy can also be influenced by how the patient is positioned on the operating table. Patients with respiratory and heart disorders experience these changes more visibly. In cases of hypoxemia, acidosis, neuromuscular illness, undernutrition, or upper abdominal surgery, the diaphragm's ability to contract decreases. The exchange of gases, which is now limited due to disturbances, is directly impacted and shows up as a variety of ventilatory diseases.

Laparoscopic procedures result in substantially faster recovery and normalisation of spirometry and less intense changes to respiratory function. Problems that could arise from PNP, CO2 absorption, and the development of intraoperative acidosis and hypercapnia are swiftly resolved, necessitating the termination of gas. Postoperative pulmonary ventilation disorders have a restrictive character. To distinguish between restrictive anomalies and airflow restrictions, Tiffeneau index is used, which is calculated as the ratio of forced expiratory volume in 1 second (FEV1) to forced vital capacity (FVC). In comparison to the traditional open cholecystectomy, laparoscopic cholecystectomy is associated with a much shorter hospital stay and a quicker recovery.[31]

Cardiovascular and hemodynamic changes

The effects of elevated IAP on the heart and major blood arteries, as well as potential hemodynamic abnormalities, are typically well-tested. The physiological changes that occur in patients during laparoscopy include decreased venous flow to the heart, increased systemic vascular resistance, and increased intrathoracic pressure. Reduced venous flow to the heart is caused by intra-abdominal pressure supporting splanchnic vasoconstriction, reduction in blood flow through the inferior cava vein, renal vein, and portal vein.[31]

ADH secretion, sympathetic activity, and the renin-angiotensin-aldosterone system are examples of neurohumoral vasoactive systems that are engaged and cause an increase in systemic vascular resistance (SVR) (RAAS). IAP rises in conjunction with an increase in central venous pressure (CVP). Intrathoracic pressure rises as a result of PNP in the presence of somewhat increased IAP, raising the CVP. An rise in IAP that is significantly greater squeezes blood from intra-abdominal organs into the venous reservoir.[31]

An increase in CVP does not accurately represent the actual condition of effective blood volume in these circumstances. A rise in IAP causes the pulmonary vascular resistance to reach 65% of its usual level. An rise in intracranial pressure is caused by an increase in systemic artery pressure. Increased O2 intake at the level of the heart muscle results from the hemodynamic stress response to the CO2-pneumoperitoneum, which is extremely detrimental for people with heart disease. The increase of the same or no change in cardiac output is a result of CO2-pneumoperitoneum. The venous flow to the heart is even less in hypovolemic patients. A sufficient refill of the crystalloid volume may lessen the hemodynamic alterations and enhance venous return to the heart.

Arrhythmias can be triggered on by the insufflation of gas into the peritoneal cavity. They occur more frequently during laparoscopies—14 to 27% of them—than during "open" surgery. During laparoscopy, the blood's plasma renin activator level rises, which is crucial for controlling the body's blood flow. Antidiuretic hormone (ADH) regulates blood flow in the body during laparoscopy by acting on receptors in blood vessel walls to lower blood pressure.[31]

Hepatic function and changes in intraoperative portal venous flow

The IAP used during laparoscopic surgery is 12 mm Hg, which is greater than the typical portal blood pressure (7-10 mm Hg). Therefore, this PNP may decrease portal flow and impair liver function. Blood flow across several abdominal organs is significantly reduced in healthy people with elevated IAP of 10 mm Hg at l5 mm Hg: the stomach by 54%, the jejunum by 32%, the colon for 4%, the liver for 39%, the peritoneum for 60%, and the duodenum by 11%. Mesenteric ischemia can occasionally result from a decrease in blood flow in the mesenteric blood arteries.[31]

Reduced intra-abdominal organ perfusion can be seen as a temporary result of elevated abdominal pressure, which affects the liver and portal vein, splanchnic area, and kidneys. The "hepatic arterial buffer response" (HABR), which denotes the relationship between the flow via the portal vein and hepatic artery, is a special autoregulatory mechanism that characterises hepatic perfusion. Increasing the allocation of liver blood results from decreased flow through the portal vein, which reduces flow resistance through the hepatic artery, and vice versa.[31]

It has been demonstrated that the natural regulation of blood flow via the liver by this mechanism is adequate for appropriate IAP. It has been demonstrated in numerous investigations that the elevated IAP at 15 mm Hg reduces portal venous flow. When individuals have healthy liver function, these alterations are not clinically evident. However, these changes might be linked to a major clinical course in patients who already have liver impairment.

Jakimowicz et al. observed a 53% decrease in portal blood flow with abdominal insufflation to 14 mm Hg in a clinical investigation of lc. Hepatic hypoperfusion and transient hepatocyte damage may result from a decrease in portal venous blood flow during PNP. Hepatic hypoperfusion may cause a brief increase in liver enzymes. In patients with cirrhosis or hepatic dysfunction, laparoscopic cholecystectomy conducted under a low pressure PNP or gasless LC using abdominal wall retractors may be possible.

Changes in renal function

Renal function during laparoscopy is characterised by elevated vascular resistance, produced vasopressin, and decreased "cardiac output," which decreases renal blood flow and glomerular filtration. During laparoscopic surgery, the blood's plasma renin activator level rises, which is crucial for controlling the body's blood flow. It has been demonstrated that laparoscopy's elevated IAP changes renal function. During laparoscopic procedures, a decrease in intraoperative urine flow has been widely established.[32]

The acutely elevated IAP is connected to the oliguria process. In contrast to previous investigations, Micali et al. compared 28 patients treated using the open technique with 31 patients who received laparoscopic procedures. They discovered no variation in urinary N-acetyl-beta-(D)glucosaminidase levels and came to the conclusion that PNP does not significantly cause renal tubular damage. It is not apparent whether the well-documented decrease in renal blood flow has any clinical value.[32]

These alterations in renal blood flow are probably not noteworthy in healthy patients under most normal circumstances, but they might be crucial in situations where renal blood flow is already reduced. Although the data show that PNP reduces renal function, its clinical importance is uncertain because it seems that renal function returns to normal after PNP is released.[32]

Venous stasis during laparoscopic surgery

Although it is unknown if deep vein thrombosis occurs more frequently following laparoscopic surgery than after open surgery, several aspects of Virchow's triad (endothelial damage, hypercoagulability, and venous stasis) are changed during laparoscopy. Venous stasis is the key element that is negatively impacted during laparoscopy. It has been demonstrated that decreasing femoral venous flow during laparoscopy is caused by increased IAP and the reverse Trendelenburg position. Numerous research have looked at D-dimer postoperatively and during PNP. D-dimer readings were noticeably greater in the

LC examinees compared to the traditional technique patients. Every consecutive measurement showed an increase in those levels, which was especially evident in the laparoscopic patient group when tests were made after the fifth postoperative day.[32]

When there was no prophylaxis beyond the fifth day, the increase in D-dimer readings in LCH patients was significantly more pronounced than it was during the procedure and the first 24 hours following it, when active prevention was in effect. Increased IAP along with the reverse Trendelenburg's position (head up) patient, which is present throughout the majority of laparoscopic procedures, leads to an increase in venous stasis in the lower extremities and a 40% reduction in the blood return from those areas. These patients may be at risk for deep vein thrombosis..[32]

Intracranial pressure during PNP

Increased IAP during laparoscopic surgeries causes a rise in intracranial pressure (ICP), disturbs blood flow through the intracranial blood vessels, and causes aberrant cerebrospinal fluid resorption. After an abdominal gas release, the elevated ICP immediately returns to normal. It has not been demonstrated that elevated ICP during laparoscopy has any particular clinical repercussions. According to pathophysiological investigations, an increase in IAP causes aberrant venous drainage of the lumbar venous plexus, which directly affects how much cerebrospinal fluid can be absorbed when introducing gas into the abdomen.[33]

It is therefore likely that an increase in IAP causes an increase in ICP, which causes a rise in systemic pressure brought on by the action of the CNS. The precise pathophysiology of elevated ICP during PNP is still unknown, though. Experimental and clinical research has demonstrated that the body's hemodynamic alterations during PNPs are directly accompanied by rising ICP. In light of this, intraabdominal laparoscopic procedures are not appropriate for patients who have cerebral damage or high ICP for other causes.[33]

With the capacity to do a low-pressure procedure using gasless laparoscopy, these individuals may require laparoscopic treatment if necessary (6-8 mm Hg). When used during laparoscopy, CO2-pneumoperitoneum can cause hypercarbia and acidosis, which might affect brain circulation. ICP rises with hypoventilation and hypercarbia as opposed to hyperventilation and hypocarbia. Hyperventilation cannot successfully lower ICP during an acute rise. During laparoscopic surgery, intermittent pneumatic compression of the lower extremities raises brain oxygenation.[33]

TABLE 2:

Physiological effects of pneumoperitoneum(SUMMARY)

Cardiovascular		
	IAP < 10 mm Hg	↑ VR ⟶ ↑ CO
	IAP 10–20 mm Hg	↑ IAP ⟶ ↓ VR ⟶ ↓ CO
		↑ IAP ⟶ ↑ SVR
		BP = ↓ CO × ↑↑ SVR
		↔↑ BP
	IAP > 20 mm Hg	↓↓ VR ⟶ ↓↓↓ CO
		↓ BP
Respiratory		
	Lung volumes esp FRC	↓
	Airway resistance	↑
	Pulmonary compliance	↓
	Airway pressure	↑
	Risk of barotrauma	↑
	V/Q mismatch	↑
Renal		
	Renal function	↓
Gastrointestinal		
	Risk of regurgitation	↑

Cardiovascular	
Neurological	
ICP	↔↑
CPP	↔↓

Table 3:
Physiological effects of positioning

	Trendelenburg	Reverse Trendelenburg
Cardiovascular		
VR	↑	↓
CO	↑	↓
BP	↔	↓
Respiratory		
Lung volumes	↓	↔
V/Q mismatch	↑	↔
Atelectasis	↑	↔

METHODS OF CREATING PNEUMOPERITONEUM

1. Veress needle insertion method: Under general anaesthesia, a brief infraumbilical incision of 5 mm in the skin is done. Veress needle is inserted into the incision through the layers of the ventral wall when the abdominal wall at or around the umbilicus has been adequately lifted. Saline drop and aspiration tests are used to validate the position of the needle tip in the peritoneal cavity. Once the peritoneal cavity has inflated due to average intraabdominal pressure of around 10 to 12 mmHg or the introduction of 2.5 to 3 L of gas, the peritoneal cavity is insufflated with CO2. The trocar is then introduced followed by introduction of camera scope to inspect for any possible injuries. The intended operation is then carried out. Palmer's technique is particularly useful in cases where umbilical entry is contraindicated, it is preferred to use the left upper quadrate for entry of Veress needle. The Veress needle is introduced through left hypochondria, i.e Palmer's point 2 cm below the left subcostal margin in the midclavicular line.[34]

2. Direct trocar insertion method: This technique involves making an infraumbilical incision slightly over 10 mm long. The anterior abdominal wall is supported at or near the umbilicus, and a trocar is twisted into the general peritoneal cavity with a gradual advancement until it feels as though the peritoneum has been penetrated. The stop cock of the trocar canula is made to remain open during insertion in order to allow air to rush in on access to the peritoneum to counteract the negative pressure inside amplified by lifting of the anterior abdominal wall, hence reducing the risk of harm to important structures. Once the trocar has been inserted, the camera scope has also been inserted, and the targeted surgery has been completed.[34]

3. Hassans method: Hasson (open) entry technique was first described by Harrith Hasson in 1971. Hasson first asserted that his method eliminates Veress needle pneumoperitoneum and its accompanying consequences (gas embolism and vascular injury). By cutting the fascial layer and stabilising its margins with two lateral stay sutures, the cannula is stabilised in this procedure. Incision in the abdominal wall will be sealed to cone-shaped sleeve as a result. Omentum and bowel visualisations are followed by the introduction of the telescope and the start of insufflations. The best primary access mechanism is still a subject of long-standing debate. According to some experts, the Hasson open technique is better than the conventional closed entry technique since it is quicker, doesn't increase the danger of gas embolism, and considerably lessens vascular and intestinal damage from primary access.[35]

FIGURE 7

4.Optical Trocar: Allows visualisation of the tissues as the blade cuts through the layers of abdominal wall.

OT LAYOUT AND THEATRE ENGONOMICS.

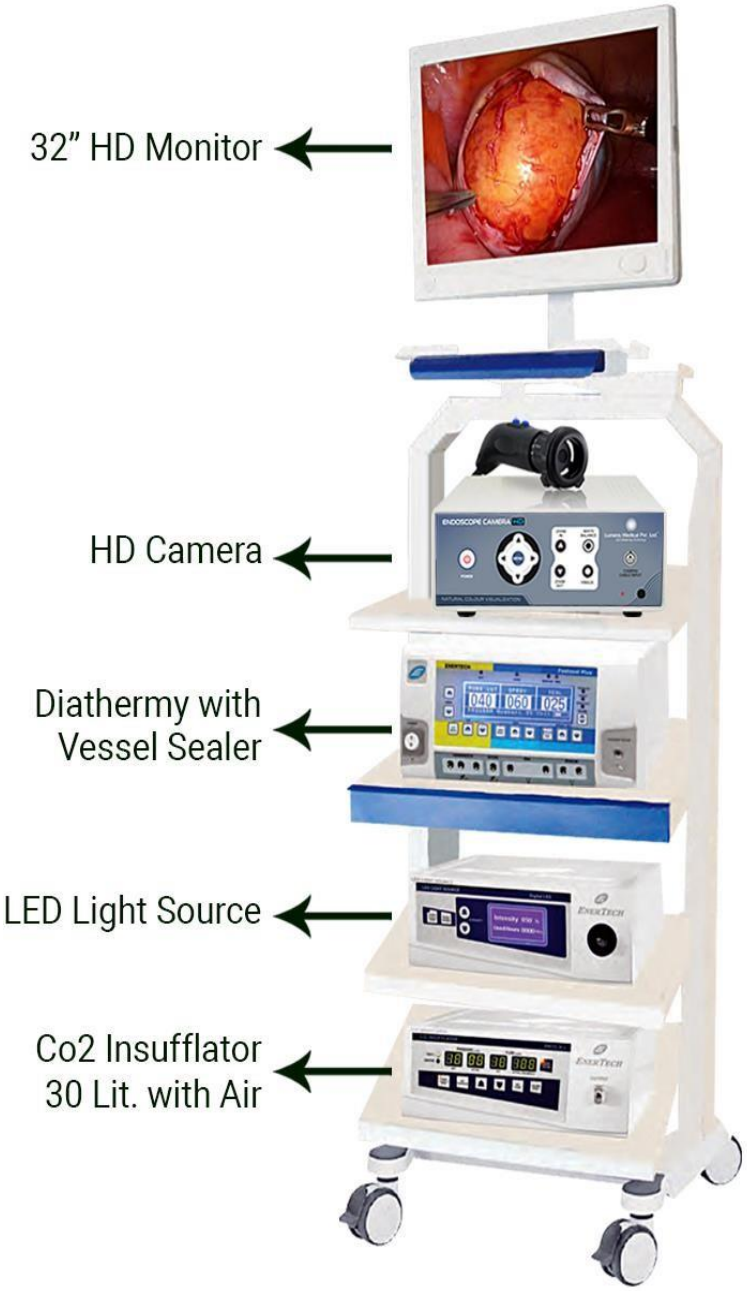


FIGURE 8 :Laparoscopy Instrument layout.

BODY POSTURE

The ideal position for the laparoscopic surgeon is with the arms slightly abducted, retroverted, and rotated inward at the shoulder level; the elbow should be bent at a 90° to 120° angle; the hands should grasp the instruments with the wrist slightly extended and with the distal interphalangeal joints almost extended; the metacarpophalangeal and proximal interphalangeal joints should be flexed at 30° to 50°; and the fingers should be abducted.[36]

THE MONITOR

A monitor that displays visual data from the surgical scenario must be set up before the procedure to prevent adopting uncomfortable postures for an extended amount of time. The monitor should be directly in front of the surgeon and parallel to the forearm-instrument motor axis in the horizontal plane. To prevent neck extension, it should be positioned below the surgeon's eye level in the sagittal plane.

The most comfortable viewing angle is roughly 15 degrees downward. The size of the monitor has a big impact on viewing distance. It should be far enough to prevent excessive eye accommodation and extraocular muscle contraction, yet close enough to prevent gazing and detail loss. The usage of a second monitor close to the work area is advised to complete precision jobs since it enhances hand-eye coordination.[36]

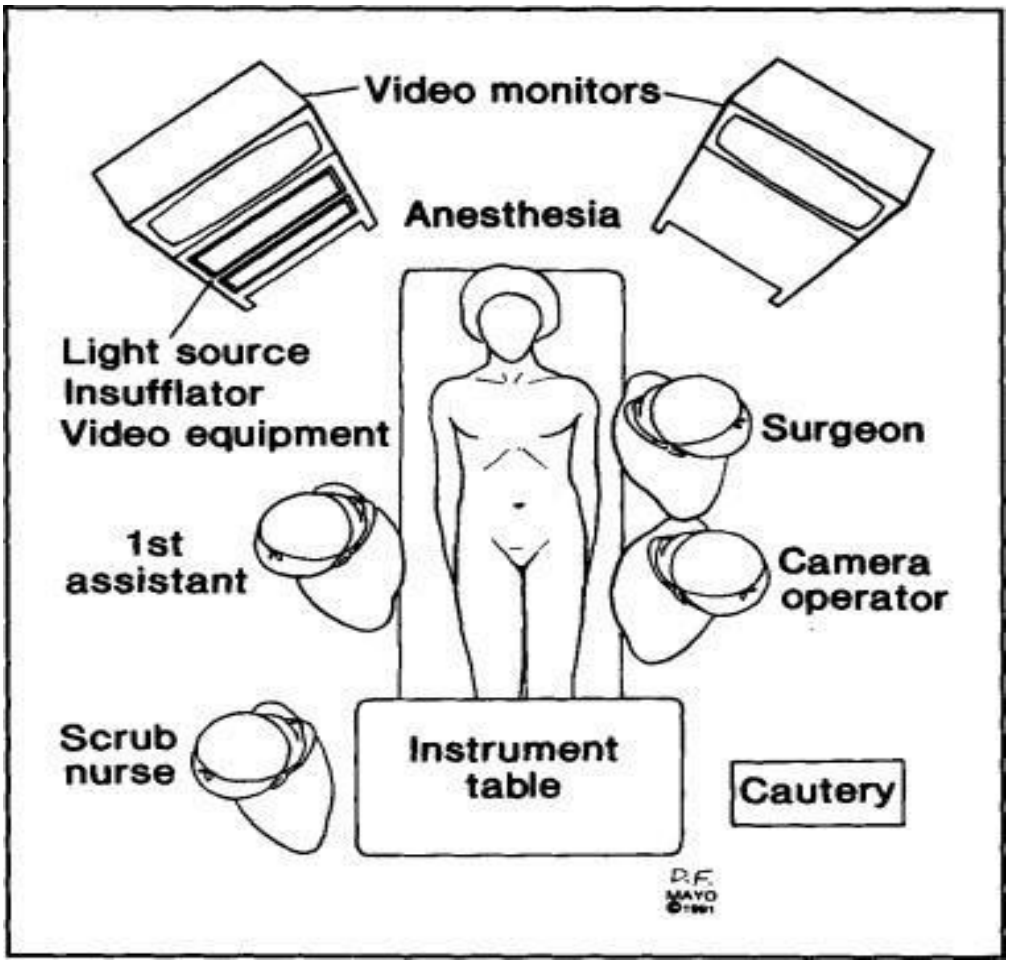


FIGURE 9: Laparoscopy theatre ergonomics.

Operating table

The operating table needs to be adjusted for the height and position of the surgeon (standing or sitting). In order to elevate and hold the shoulders and elbows, muscles must contract with a lot more energy if the operating table is too high. If that position is held for an extended amount of time, the shoulder muscles quickly become fatigued. The table's height should be set such that the surgeon's elbows are just over the handles of the laparoscopic instruments. When performing manual labour, the ideal table position keeps the shoulders

down and the angle between the lower and upper arm is between 90° and 120°. If the table cannot be lowered to a specified height, lifts may be employed.[37]

Foot pedals

During laparoscopic surgery, foot pedals are frequently used to operate tools like electrocauterization, ultrasonic shears, bipolar devices, or other tissue welding/dividing tools. They frequently require uncomfortable and out-of-character postures because of their inadequate positioning. Their primary issues during laparoscopic surgery are a lack of visual control, the surgeon's uneven stance, and the excessive use of pedals. Replace them wherever possible with hand controls as a potential remedy. Pedals should be positioned close to the foot and oriented toward the target quadrant and laparoscopic monitor, in the same plane as the instruments. As a result, surgeons may use the pedal without having to rotate their body or leg. It is advisable to use a pedal with a built-in foot rest.[38]

INSUFFLATORS USED DURING LAPAROSCOPY:

Pneumoperitoneum is created during laparoscopic surgery by introducing a gas, typically carbon dioxide, into the abdominal cavity. This raises the pressure inside the abdomen (IAP). A pressure of 10–20 mm Hg of carbon dioxide is insufflated into the peritoneal cavity at a rate of 4-6 litres per minute. A steady gas flow of 200–400 ml/min keeps the pneumoperitoneum in place.[39]

FIGURE 10.

SHOULDER TIP PAIN THEORIES:

The cause of post-MIS STP, which is thought to be complex and possibly referred pain, is not completely understood. There are at least three probable explained theories.

1. According to the first theory, the generation of carbonic acid lowers the pH of the peritoneal fluid, which damages and irritates the peritoneal and diaphragmatic nerves and causes STP. The conversion of carbon dioxide (CO) gas to carbonic acid by carbonic anhydrase, which takes place in the wet surface of the peritoneum and diaphragm, is what causes the irritation caused by carbonic acid on the peritoneum and diaphragm. Although similar results are not always replicated by other investigations, the use of carbonic anhydrate inhibitor acetazolamide in the substantial lowering of STP supports additional evidence.[40]

2.The second theory—also known as visceral ligament traction—is backed by the following facts:

(1) the presence of CO2 gas pockets between the liver and diaphragm, which results in loss of negative pressure in the peritoneal cavity and, consequently, the loss of suction support of the liver and diaphragm, allowing traction on the triangular and coronary ligaments of the liver, leading to sub-diaphragmatic pain and STP;

(2) a close correlation between the amount of residual gas or CO2 bubble volume under the right hemidiaphragm and STP;

(3) the positive correlation between delayed absorption of CO2 and longer STP; and

(4) the STP occurring generally more than four hours after the procedure.[40]

3. The tissue trauma theory is the final (also calling neuropraxia theory). Pneumoperitoneum causes the peritoneum and diaphragm to extend and/or get injured, which causes blood vessels to leak, nerves to become compressed (such as the phrenic nerve), and the production of inflammatory mediators that cause pain to radiate to the shoulder. The relationship between stretching and the severity of STP has already been documented.[40]

MATERIAL AND METHOD

SOURCE OF DATA

All patients admitted in the Department of surgery at Shri B.M.Patil Medical College, Hospital and Research centre, Vijayapur between October 2020 to November 2022 and underwent laparoscopic surgeries for different surgical ailments.

STUDY PERIOD

OCTOBER 2020 to NOVEMBER 2022.

METHOD OF COLLECTION OF DATA:

This is a prospective comparative study of patients undergoing laparoscopic surgeries in B.L.D.E.(D.U)'S Shri B.M.Patil Medical College Hospital.

. • All patients in IPD undergoing laparoscopic surgery were included in the study

• A pretested structural proforma was used to collect relevant information for each individual patient selected.

Patients were divided into two groups;

Group A included patients in whom the intra peritoneal pressure is above 10 mm of HG (i.e)standard pressure pneumoperitoneum group, and

Group B included patients in whom the intraperitoneal pressure is less than 10 mm of HG (i.e) low pressure pneumoperitoneum ,each group were then subdivided into two sub-groups depending on the duration of surgery

- In the first subgroup the duration of surgery was less than one hour.
- In the next subgroup included patients where the duration of surgery is more than one hour.

- Presence or absence of shoulder Tip pain was recorded within four hours, 12 hours ,24 hours and 48 hours

- Visual analogue pain scores of each individual patient selected were included.

• All routine investigations were done.

• Written informed consent was obtained from all the patients with detailed explanation of theprocedure going to be performed on them, the risk factors and complications involved and theadvantages and disadvantages of the same

• The duration of stay of each individual patient post operation is mentioned in the study

• Cases were selected consequently following the inclusion and exclusion criteria

INCLUSION CRITERIA

Patients admitted in B.L.D.E .(D.U) Shri BM Patil medical College and research Centre and underwent laparoscopic surgeries for different surgical conditions.

EXCLUSION CRITERIA –

- -Patients with Endocrine, Renal, Hepatic or Immunological disease
- -Pregnant patients and Gynaecological surgeries
- -Patients undergoing open conversion of a Laparoscopic surgery

SAMPLING

All the patients admitted during the study period (October 2020 to November 2022), who fulfill the inclusion criteria, were included in this study.

ESTIMATION OF SAMPLE SIZE:

With Anticipated Proportion of Shoulder tip pain in group A (12-14 mm hg pressure) among Laparoscopic surgeries 27.3 % and among group B (8-10 mm hg pressure) 12 % resp, the study sample size of: 45 per group. (i.e. a total sample size of 90 assuming equal group sizes), to achieve a power of 90% for detecting a difference in proportions between two groups at a two sided p-value of 0.05.

Formula used

• $n= (z\alpha+z\beta)2\ 2\ p*q\ MD2$

Where Z= Z statistic at a level of significance

MD= Anticipated difference between two proportions

P=Common Proportion

q= 100-p

STATISTICAL ANALYSIS

The data obtained was entered in a Microsoft Excel sheet, and statistical analysis was performed using statistical package for the social sciences (Verson 20).

Results are presented as Mean (Median) ±SD, Range, counts and percentages and diagrams. For normally distributed continuous variables, comparison using Independent t test was done. For not normally distributed variables ,Mann Whitney U test was used. The results of pre and post documentation were compared by Paired t test/ Wilcoxon signed rank test. Categorical variables were compared using Chi square/Fisher's Exact test. P value <0.05 was considered statistically significant. All statistical tests will perform two tailed.

INVESTIGATIONS:

Investigations or interventions required in this study are routine standardized procedures. There are no animal experiments involved in this study. These routine investigations were required and necessary for routine follow-up.

- ✓ Complete blood picture.
- ✓ Renal function tests.
- ✓ Random Blood glucose.
- ✓ Urine – sugar, albumin and microscopy.
- ✓ Electrocardiogram.
- ✓ Chest X-ray (when age of patient is >35yrs, or if necessary).
- ✓ Ultrasonography of abdomen.
- ✓ CT Abdomen and pelvis.
- ✓ Tests to detect infection with Human Immunodeficiency Virus and Hepatitis B Virus (in accordance to Universal Safety Precautions).
- ✓ Any other investigations as required.
- ✓ Intraoperative pneumoperitoneal pressure
- ✓ Post operative visual pain assessment score.

VAS SCALE

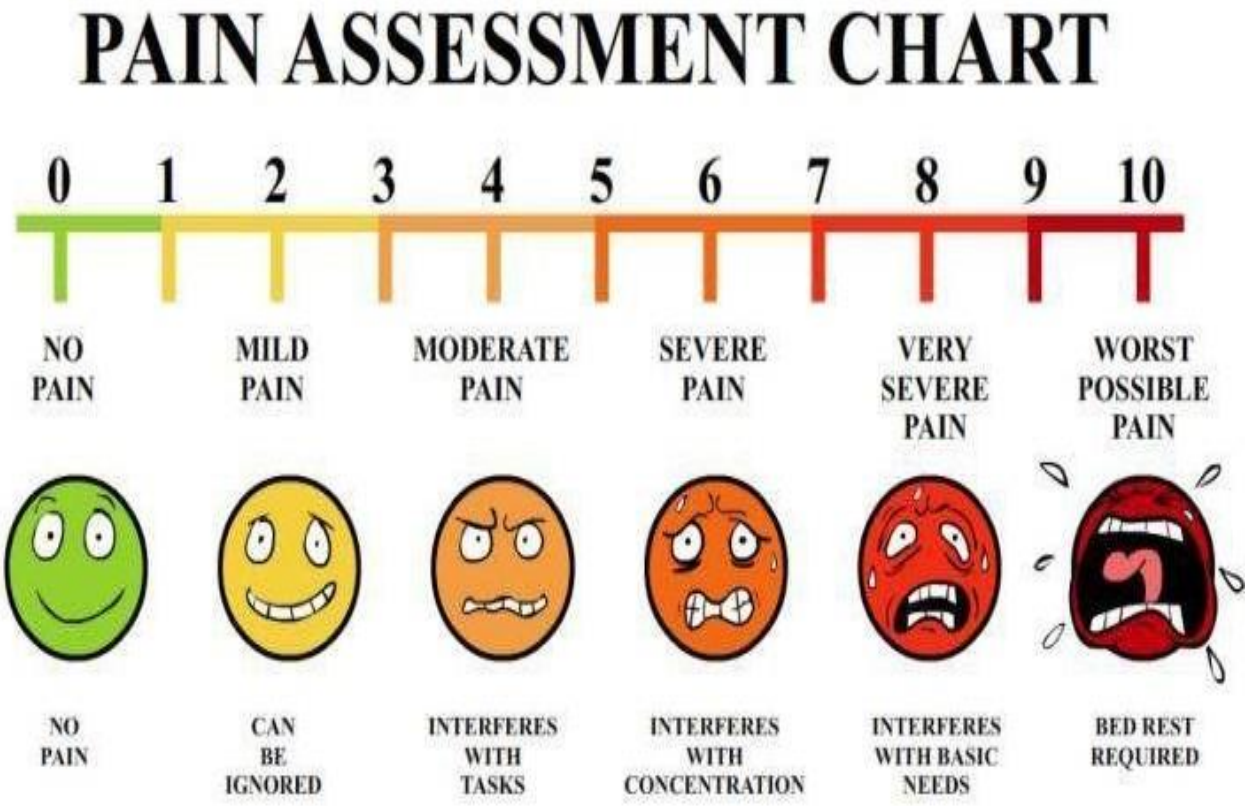


FIGURE 12. VAS SCALE

INTRAOPERATIVE PRESSURE SETTINGS

PICTURE 1. Laparoscopic Appendicectomy. (PNP-10)

PICTURE 2. Laparoscopic Appendicectomy. (PNP – 11)

PICTURE 3:Laparoscopic Cholecystectomy (PNP-13)

PICTURE 4: Laparoscopic Inguinal Hernia Repair. (PNP-12)

PICTURE 5 : Laparoscopic Hiatus Hernia Repair.(PNP-14)

PICTURE 6: Diagnostic Laparoscopy with adhesiolysis(PNP-10)

PICTURE 7.Laparoscopic Appendicectomy.(PNP-9)

PICTURE 8:Laparoscopic Hellers Cardiomyotomy.(PNP-10)

C 

PICTURE 9: Laparoscopic Hernia repair.(PNP-11)

PICTURE 10 :Laparoscopic Cholecystectomy.(PNP-13)

RESULTS:

In this prospective study, in comparison to assess the impact of low-pressure versus standard-pressure pneumoperitoneum on shoulder tip pain after Laparoscopic surgery various parameters were evaluated. Basic objectives such as advantages of low-pressure pneumoperitoneum and its impact on decreasing post-operative complications especially shoulder tip pain, correlating the duration of Laparoscopic surgery and its impact on shoulder tip pain.,a visual analogue scale for the measurement of shoulder tip pain post-procedure,.faster recovery and the duration of stay in the hospital were studied.

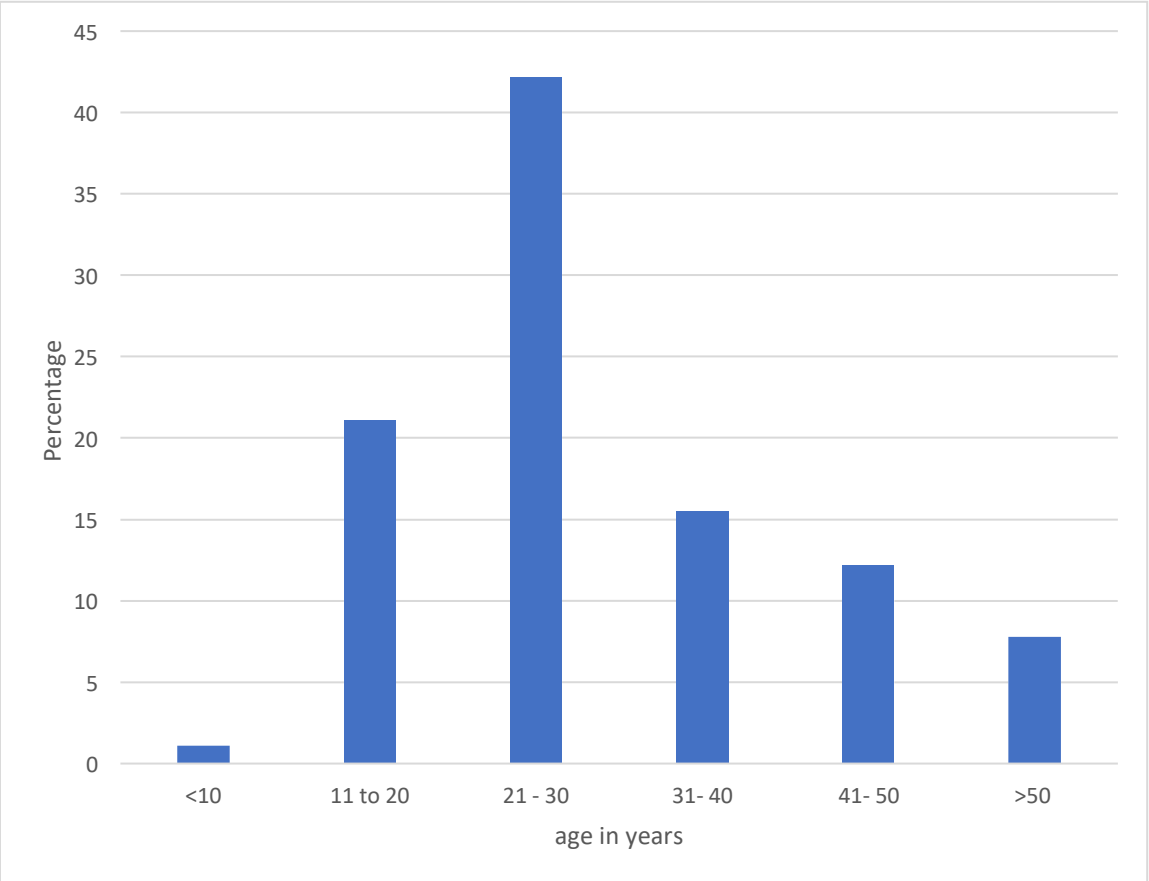
TABLE 4:Mean age of patients in the study.

	Age of patients in years
Total no of patients(N)	90
Minimum age	9
Maximum age	72
Mean	34

In this study total population included was 90 with which the maximum age of the patient being 72 years, and the minimum age being 9 years. The mean age of the population was 34 years.

AGE(In years)	No of patient	Percentage (%)
<10 years	1	1.1
10-20	19	21.1
21-30	38	42.2
31-40	14	15.5
41-50	11	12.2
>50 years	7	7.8

TABLE 5: Distribution according to age groups



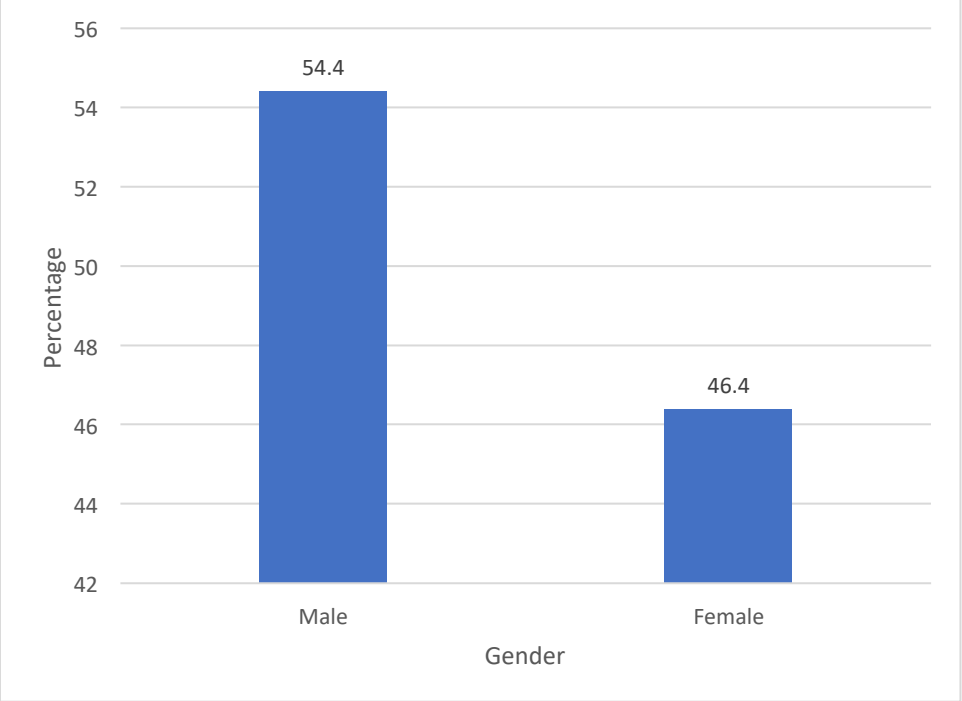
GRAPH 1: Distribution according to age groups.

The majority of the study population was in the age group of 21 - 30 years which accounts for around 42.2%, next common group were 11-20 years constituting 21.1 % (Table 6, Graph 1)

TABLE 6: Distribution according to Gender.

Gender	No of Patient	Percentage
Male	49	54.4
Female	41	46.4
Total	90	100

In our study of a total population of 90, male patients were more compared to females, with males being 54.4%, and Females being 46.4 %.



GRAPH 2: Distribution according to Gender.

TABLE 7: Distribution according to the type of surgical procedure performed.

Surgical procedure	Number
1.Laparoscopic Cholecystectomy.	39
2.Laparoscopic Appendicectomy	27
3.Laparoscopic hernia (inguinal and umbilical)repair.	12
4.Laparoscopic hiatus hernia repair(niessens)	5
5.Diagnostic laparoscopy	2
6.Laparoscopic hellers cardiomyotomy	1
7.Laparoscopic rectopexy	1
8.Laparoscopic rectovaginal fistula repair.	1
9.laparoscopic deroofing of hydatid cyst	1
10.Laparoscopic orchidopexy	1

The most common laparoscopic procedure was cholecystectomy i.e 43%, followed by appendicectomy i.e 29 %. Laparoscopic hernia repair accounted for 12 % of all the procedures performed.

Shoulder tip pain was assessed using a visual analogue score and the average of the scores was calculated:

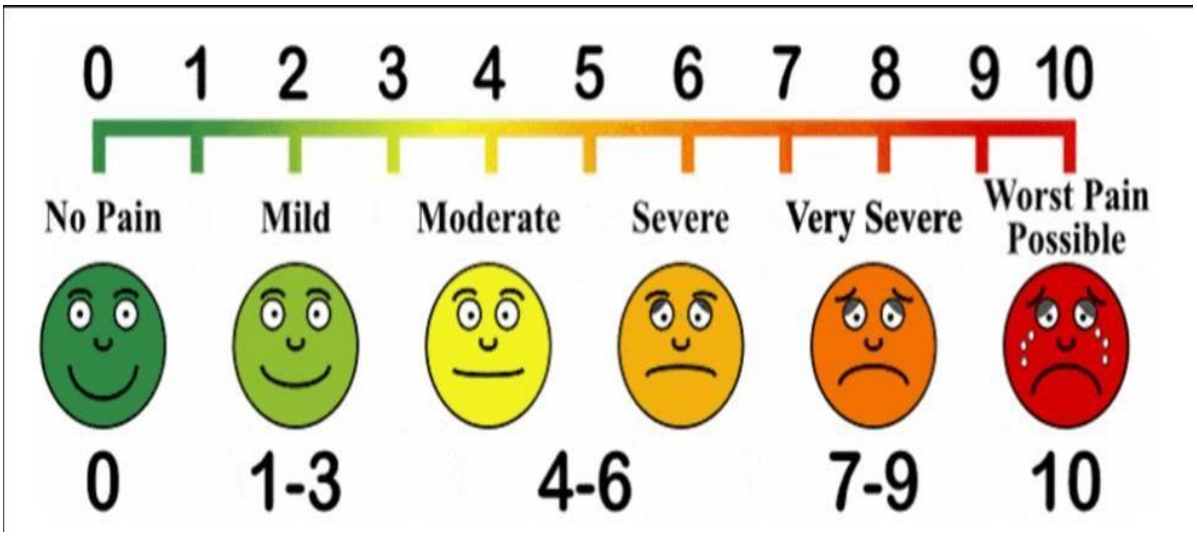


TABLE 8:Distribution according to PNP setting.

		Frequency	Percent
PNP	<=10	45	45
	> 10	45	45
	Total	90	100.0

In our study, with a total population of 90, 45 patients underwent surgery with low pneumoperitoneal pressure (i.e 45 %) and the remaining 45 % of patients underwent surgical procedures with pneumoperitoneal pressure above 10.

The population were randomized into two groups of 45 patients in group A and 45 in group B. Patients in group A had a pneumoperitoneal pressure of more than 10 and patients in group B had a pneumoperitoneal pressure of less than or equal to 10.

TABLE 9:Comparison of STP and Type of Surgery.

	Type of surgery	Group A (PNP > 10 mmhg)	Group B (PNP <=10 mmhg)
Average of shoulder tip pain scores	1.Laparoscopic Cholecystectomy.	5	3
	2.Laparoscopic Appendicectomy	3	3
	3.Laparoscopic hernia (inguinal and umbilical)repair.	4	2
	4.Laparoscopic hiatus hernia repair(niessens)	2	2
	5.Diagnostic laparoscopy	4	2
	6.Laparoscopic hellers cardiomyotomy	4	-
	7.Laparoscopic rectopexy	5	-
	8.Laparoscopic rectovaginal fistula repair.	4	-
	9.laparoscopic deroofing of hydatid cyst	4	-
	10.Laparoscopic orchidopexy	3	-

The average of the shoulder tip pain scores was calculated and it was seen that patients in Group A had more shoulder tip pain compared to the patients in Group B. The average shoulder tip pain scores were significantly higher in cholecystectomy and inguinal hernia repair patients.

GRAPH 3 :Comparison of STP and Type of Surgery.

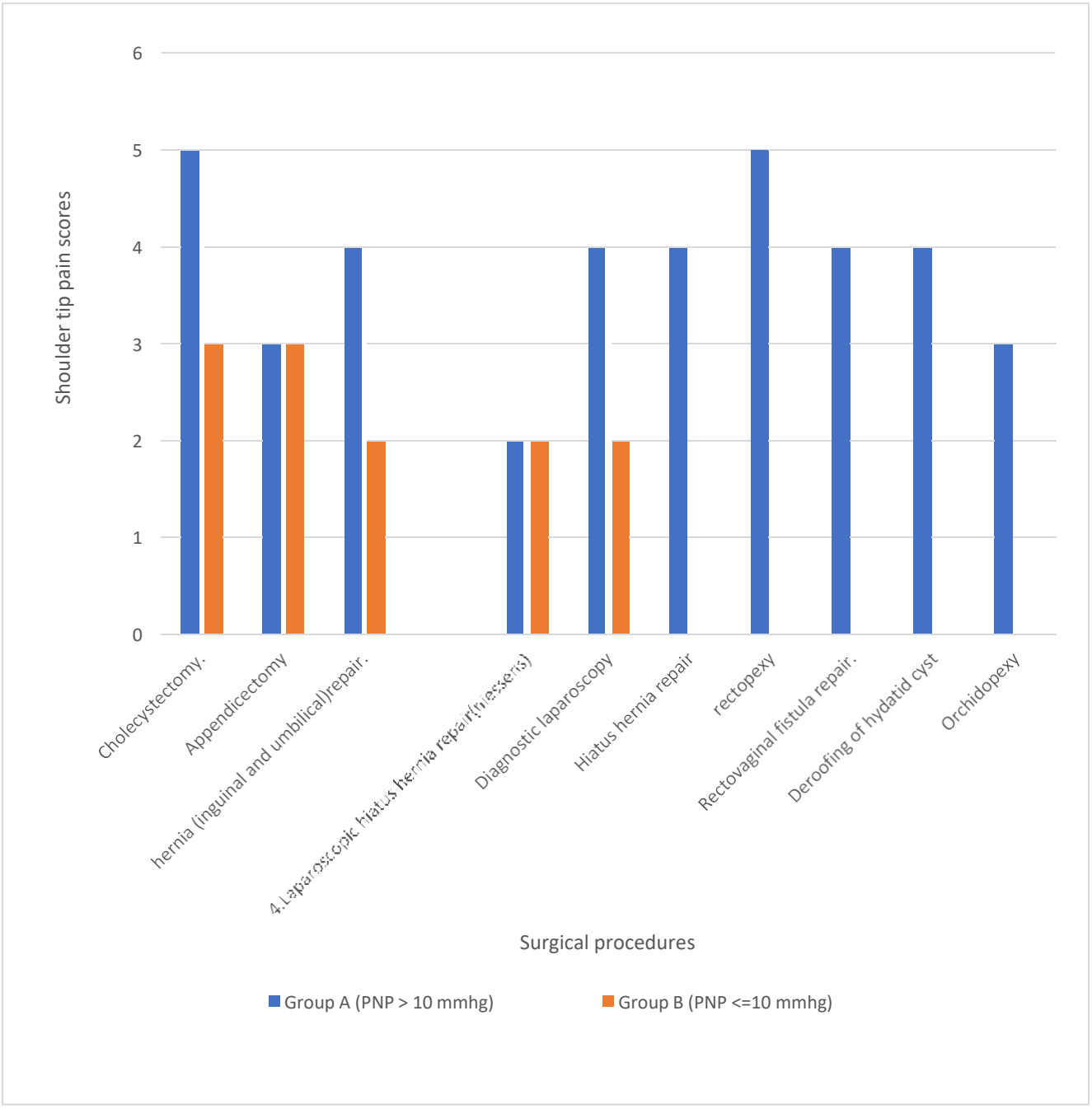


TABLE 10:Comparison with shoulder tip pain score and pressure

			cpressure		Chi-square Value	p-value
			≤10(Group B)	> 10(Group A)		
Shoulder tip pain score	0	Count	5	0	25.1999	**0.000**
		% within Shoulder tip pain score	100.0%	0.0%		
	1	Count	14	4		
		% within Shoulder tip pain score	77.8%	22.2%		
	2	Count	14	11		
		% within Shoulder tip pain score	56.0%	44.0%		
	3	Count	4	10		
		% within Shoulder tip pain score	28.6%	71.4%		
	4	Count	3	15		
		% within Shoulder tip pain score	16.7%	83.3%		
	5	Count	2	6		
		% within Shoulder tip pain score	25.0%	75.0%		
	6	Count	0	2		
		% within Shoulder tip pain score	0.0%	100.0%		
Total		Count	42	48		
		% within Shoulder tip pain score	46.7%	53.3%		

In our study, it was noted that patients in Group B had lower STP scores compared to patients in Group A with a significant p-value of 0.000 and a chi square value of 25.1999.

GRAPH 4 : Comparison with shoulder tip pain score and pressure

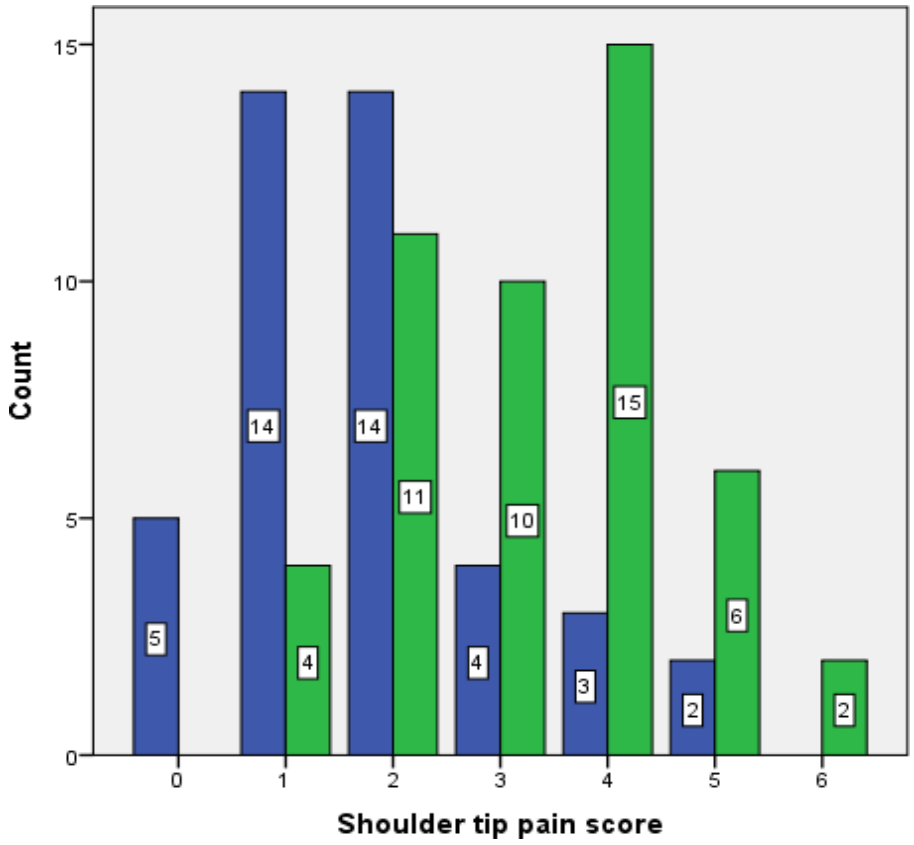
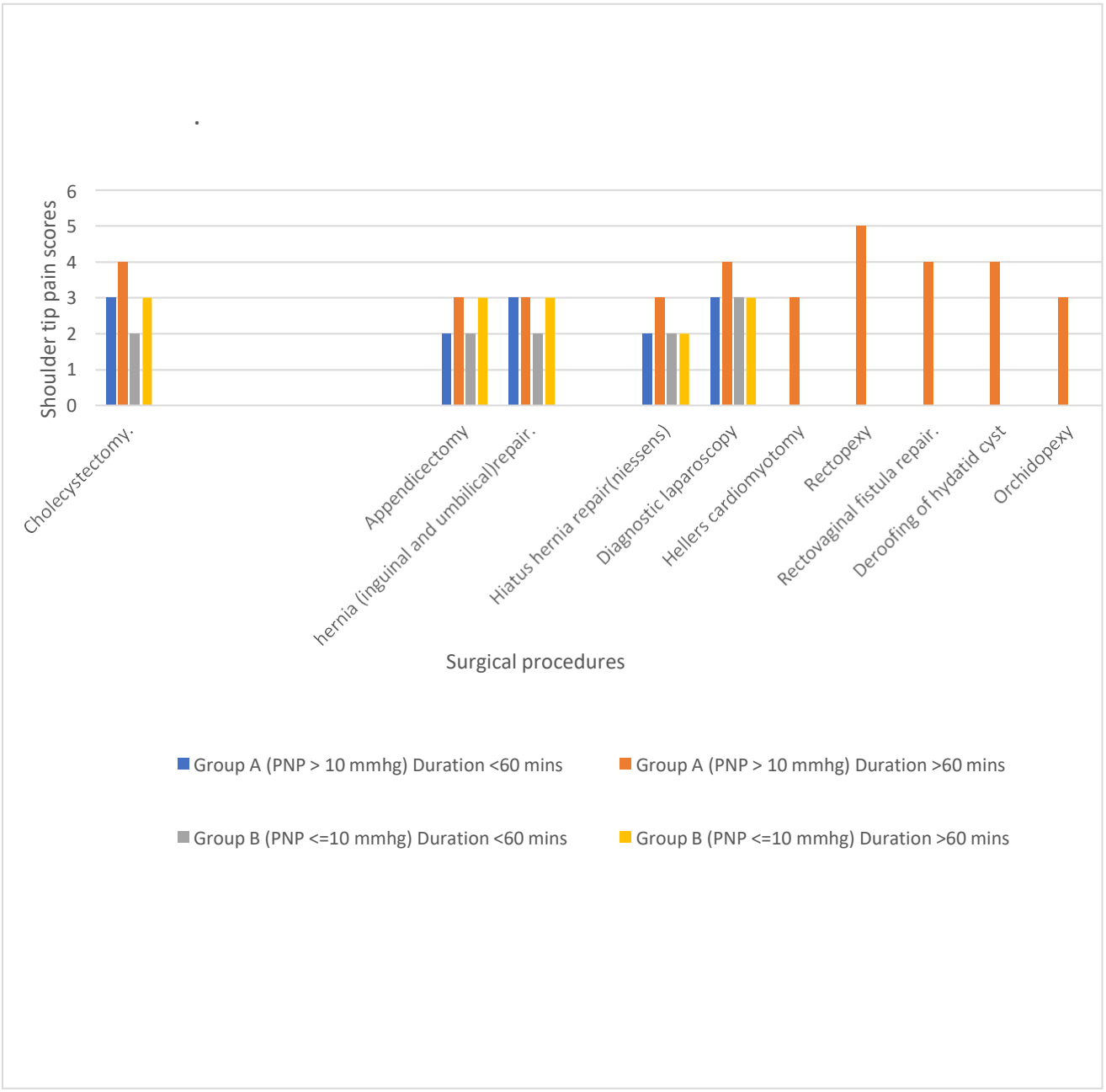


TABLE 11:Comparison of STP with Type and Duration of Surgery.

	Type of surgery	Group A (PNP > 10 mmhg)		Group B (PNP <=10 mmhg)	
		Duration <60 mins	Duration >60 mins	Duration <60 mins	Duration >60 mins
Average of shoulder tip pain scores	1.Laparoscopic Cholecystectomy.	4	5	3	4
	2.Laparoscopic Appendicectomy	3	4	3	3
	3.Laparoscopic hernia (inguinal and umbilical)repair.	4	4	2	4
	4.Laparoscopic hiatus hernia repair(niessens)	3	2	2	2
	5.Diagnostic laparoscopy	4	3	2	2
	6.Laparoscopic hellers cardiomyotomy	-	4	-	-
	7.Laparoscopic rectopexy	-	5	-	-
	8.Laparoscopic rectovaginal fistula repair.	-	4	-	-
	9.laparoscopic deroofing of hydatid cyst	-	4	-	-
	10.Laparoscopic orchidopexy	-	3	-	-

The study population were further subdivided into two groups depending on the duration of the procedure. (i.e less than 60 mins and more than 60 mins). Patients in the standard pneumoperitoneal group with procedures lasting more than 1 hour had more shoulder tip pain compared to the patients in the low pneumoperitoneal group and it was statistically significant. The pain scores were more in Cholecystectomy followed by Appendicectomy and Hernia repair.

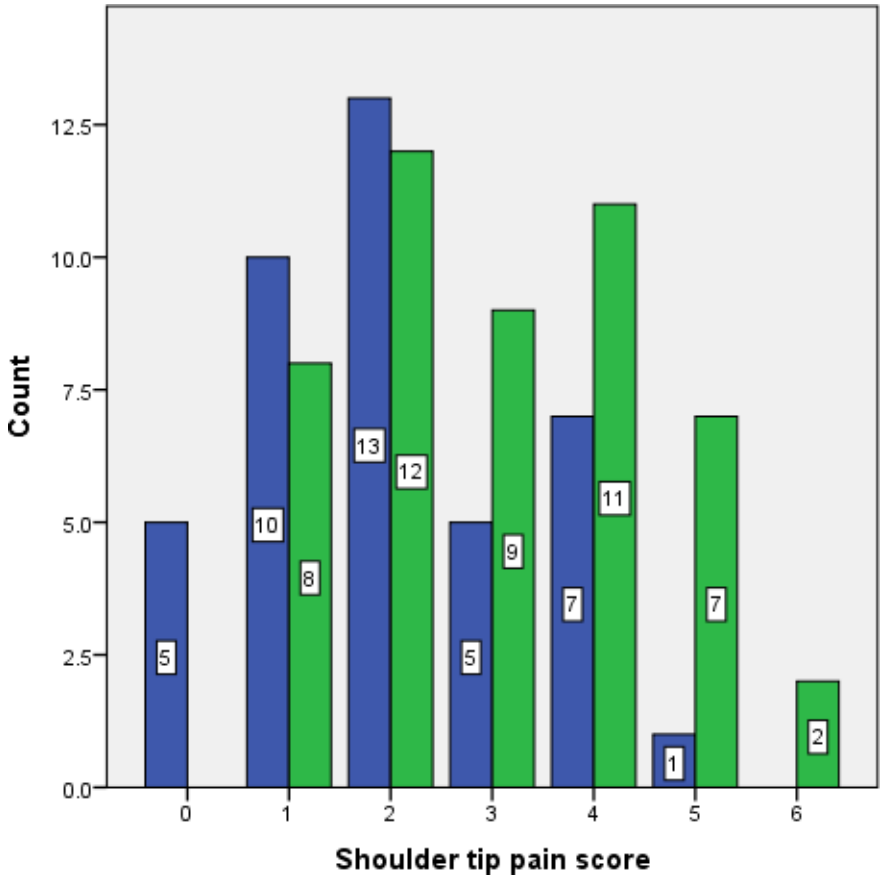
GRAPH 5 : Comparison of STP with Type and Duration of procedure.



			Duration of procedure		Total
			<= 60	> 60	
Shoulder tip pain score	0	Count	5	0	5
		% within Shoulder tip pain score	100.0%	0.0%	100.0%
	1	Count	10	8	18
		% within Shoulder tip pain score	55.6%	44.4%	100.0%
	2	Count	13	12	25
		% within Shoulder tip pain score	52.0%	48.0%	100.0%
	3	Count	5	9	14
		% within Shoulder tip pain score	35.7%	64.3%	100.0%
	4	Count	7	11	18
		% within Shoulder tip pain score	38.9%	61.1%	100.0%
	5	Count	1	7	8
		% within Shoulder tip pain score	12.5%	87.5%	100.0%
	6	Count	0	2	2
		% within Shoulder tip pain score	0.0%	100.0%	100.0%
Total		Count	41	49	90
		% within Shoulder tip pain score	45.6%	54.4%	100.0%

TABLE 12 : Comparison of Shoulder tip pain score with duration of procedure.

GRAPH 6: Comparison of Shoulder tip pain score with duration of procedure.



Duration of procedure (mins)

<=60

>60

In our study it was noted that high shoulder tip pain scores were noted in patients where the duration of procedure lasted more than 60 min with a chi-square value of 13.187, indicating that there is a positive association between the two variables and a significant p-value of

TABLE 13: Comparison of Duration of stay in Hospital with type and duration of procedure.

	Type of surgery	Group A (PNP > 10 mmhg)		Group B (PNP <=10 mmhg)	
		(a)Duration <60 mins	(b)Duration >60 mins	(a1)Duration <60 mins	(b1)Duration >60 mins
Duration of stay in Hospital. (Average days0	1.Laparoscopic Cholecystectomy.	3	4	2	3
	2.Laparoscopic Appendicectomy	2	3	2	3
	3.Laparoscopic hernia (inguinal and umbilical)repair.	3	3	2	3
	4.Laparoscopic hiatus hernia repair(niessens)	2	3	2	2
	5.Diagnostic laparoscopy	3	4	3	3
	6.Laparoscopic hellers cardiomyotomy	-	3	-	-
	7.Laparoscopic rectopexy	-	5	-	-
	8.Laparoscopic rectovaginal fistula repair.	-	4	-	-
	9.laparoscopic deroofing of hydatid cyst	-	4	-	-
	10.Laparoscopic orchidopexy	-	3	-	-

In the present study, the subdivided groups were further compared with the duration of stay in the hospital. It was noted that the average duration of stay in the hospital for group A patients was higher compared to Group B Patients. The average duration of stay of group A patients was 3-4 days, whereas in the average duration of stay for group B patients was 2-3 days.

GRAPH 7: Comparison of Duration of stay in Hospital with duration of procedure and PNP

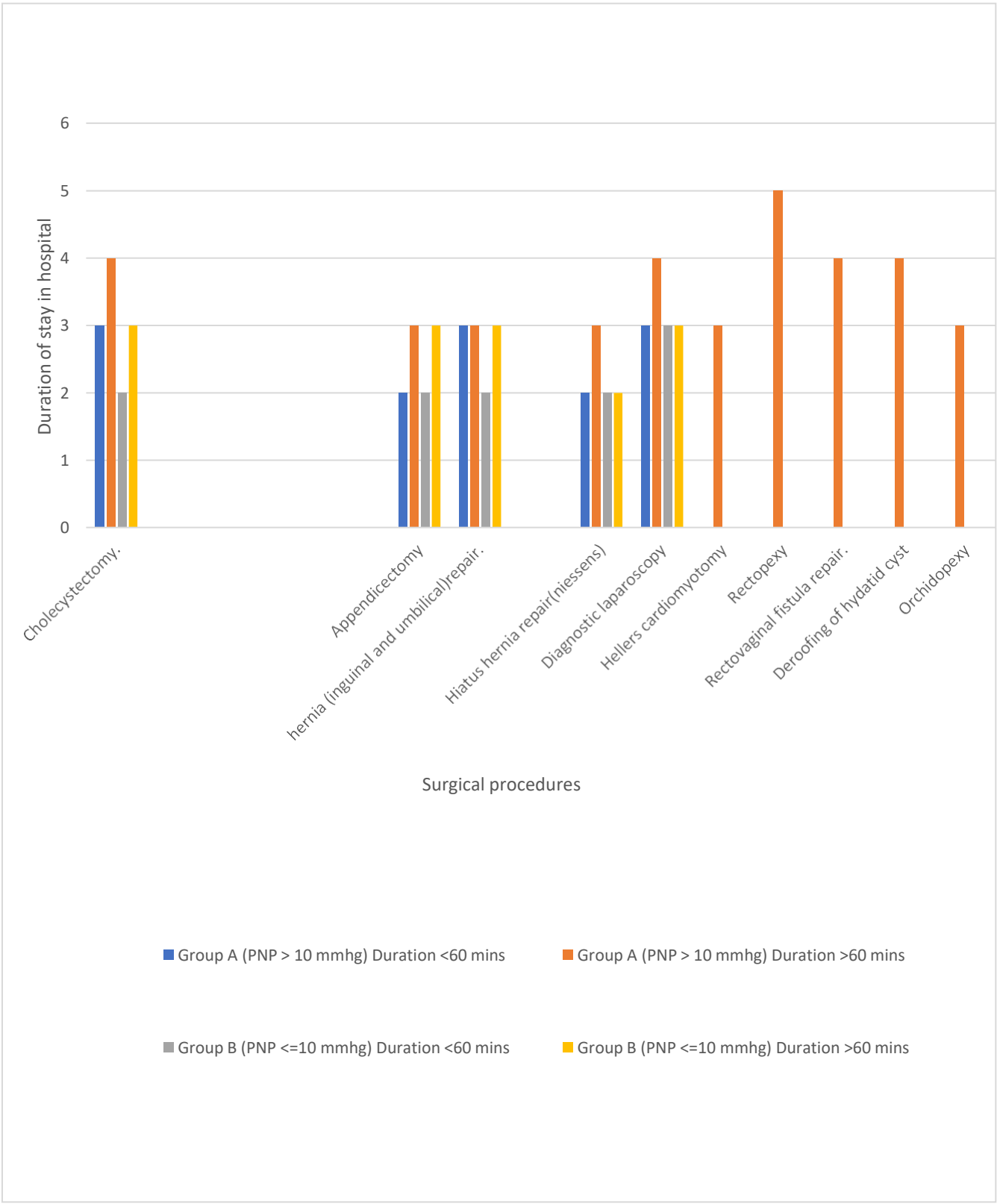


TABLE 14: Comparison of Post operative analgesic requirement in Both groups.

		Group A (PNP>10)	Group B (PNP<=10)
Post operative (opiods)analgesic requirement.	Given	30	20
	Not given	15	25
	Total	45	45

In our study, comparison of analgesic (opioids) requirement in the postoperative period was compared with the standard and low pneumoperitoneal pressure group. It was noted that 66.6% population in Group A needed additional analgesics whereas only 33.3 % of Group B patients needed analgesics for pain management.

GRAPH 8: Comparison of Post operative analgesic requirement in Both groups.

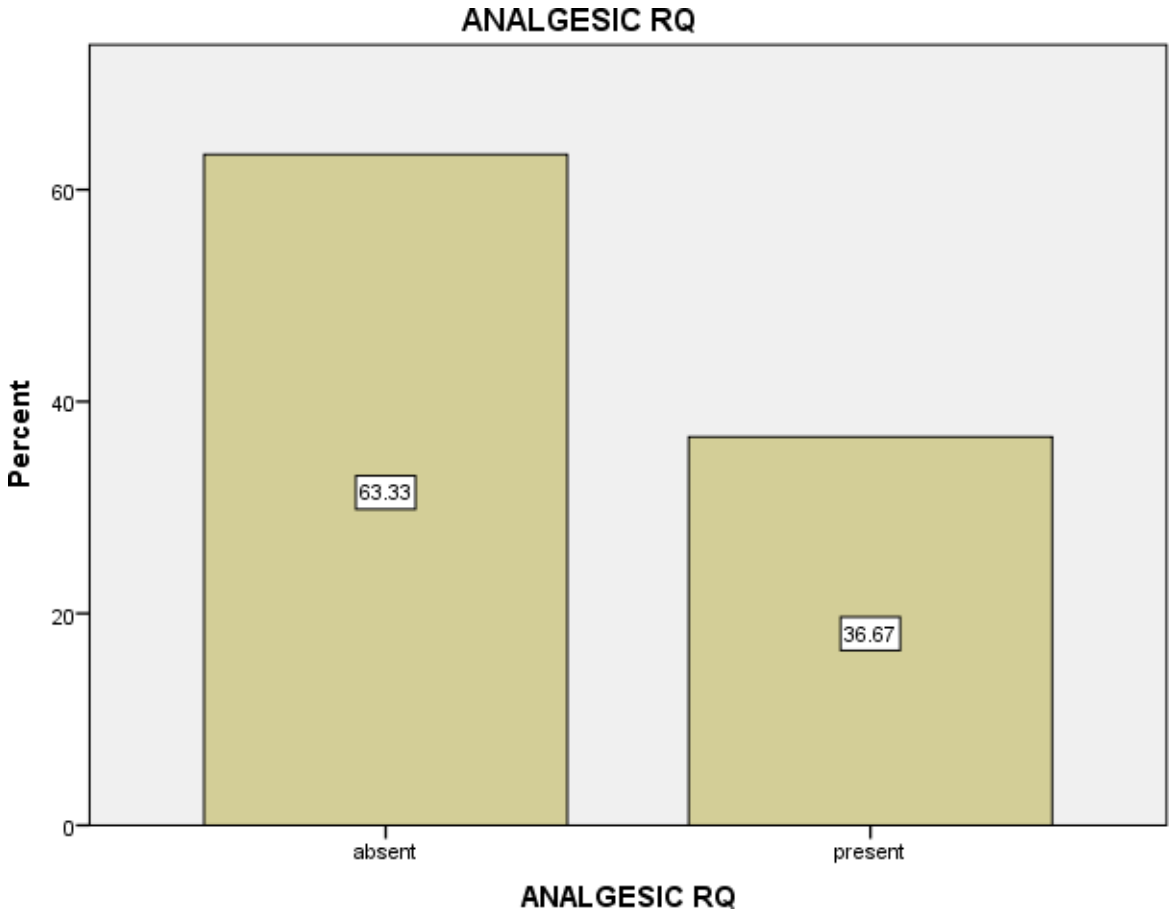
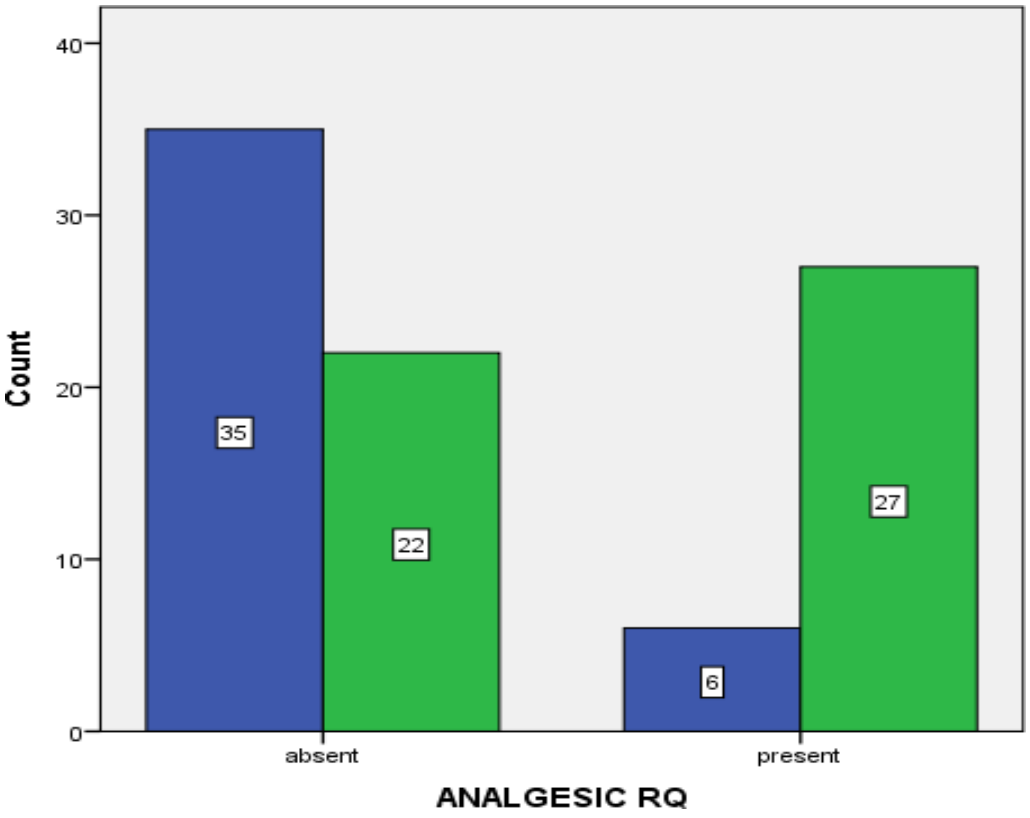


Table 15:Comparison of Analgesic requirement with Duration.

			Duration		Total
			<= 60	> 60	
ANALGESIC RQ	absent	Count	35	22	57
		% within ANALGESIC RQ	61.4%	38.6%	100.0%
	present	Count	6	27	33
		% within ANALGESIC RQ	18.2%	81.8%	100.0%
Total		Count	41	49	90
		% within ANALGESIC RQ	45.6%	54.4%	100.0%

In our study, out of the total population, it was noted that About 54.4 % of the patients need opioid analgesics when the duration of the procedure exceeded 1 hour with a p-value of 0.000.

GRAPH 9 : Comparison of Analgesic requirement with Duration.



Duration of procedure (mins)

>60

<=60

TABLE 16: Nonparametric Correlations.

Variables	Spearman's rho Correlation value	p-value
Pressure v/s Pain Score	**0.551**	**0.00**
Pressure v/s Duration	**0.654**	**0.00**
Pain score v/s Duration	**0.523**	**0.00**

The following table summarises the variables that were studied and their association and level of significance.

1. Comparison of PNP Pressure with shoulder tip pain score yielded a spearmans rho value of 0.551 indicating strong association with a p value of 0.00,stating that it is statistically significant.

2. Comparison of PNP Pressure with Duration of procedure yielded a spearmans rho value of 0.654 indicating strong association with a p value of 0.00,stating that it is statistically significant.

3. Comparison of Shoulder tip pain score with Duration of procedure yielded a spearmans rho value of 0.551 indicating strong association with a p value of 0.00,stating that it is statistically significant.

DISCUSSION

In our study of 90 patients, the maximum age of the patient was 72 years, whereas the minimum age was 9 years. The mean age of the population was 34 years.

The majority of the study population was in the age group of 21 - 30 years which accounts for around 42.2%, next common group were 11-20 years constituting 21.1 %.In our study, the majority of the patients were males, with the male being 54.4%, and the Females being 46.4 %.

The most common laparoscopic procedure was cholecystectomy i.e 43%, followed by appendicectomy i.e 29 %. Laparoscopic hernia repair accounted for 12 % of all the procedures performed.

Nasir et al 2011, in which 100 patients were studied, which majority of the study population was 30-40 years and the majority of the study population was females(63%) and the indication for surgery was Cholelithiasis.[43]

In a study done by Sarli et al in 2017, in which 90 patients were studied, which majority of the study population was 40-50 years and the majority of the study population was females(70%) and the indication for surgery was Cholelithiasis.[44]

In a study done by Guruswamy et al in 2021, in which 1092 patients were studied, which majority of the study population were females(60%) and the indication for surgery was Cholelithiasis.[45]

TABLE 17 : Comparison with other studies.(1)

SL NO	Name of study	Study Population(years)	Indication
1.	Nasir et al	30-40	Cholelithiasis
2.	Sarli et al	40-50	Cholelithiasis
3.	Guruswamy et al	30-40	Cholelithiasis
4.	Monica ortezi et al	30-40	Cholelithiasis
5.	Present study	21-30	Cholelithiasis >Appendicectomy>Hernia repair

In our study, it was noted that patients in Group B had lower Shoulder tip pain scores compared to patients in Group A with a p-value of 0.000 and chi-square value of 25.1999. The pain scores were more in Cholecystectomy followed by appendicectomy and hernia repair. In our study it was noted that high shoulder tip pain scores were noted in patients where the duration of the procedure lasted more than 60 min with a chi-square value of 13.187, indicating that there is a positive association between the two variables.

In a study done by Nasir et al 2011, Patients in Group A had higher scores compared to patients in Group B. The scores were initially higher post-procedure at 4hr, and 12 hr and gradually decreased over a period of time. The mean operative time was more in Group A compared to Group B.[43]

In the study conducted by Sarli et al 2017, Patients in Group A had higher scores compared to patients in Group B. The frequency was significantly lower in patients who underwent laparoscopic cholecystectomy with low-pressure pneumoperitoneum as compared to patients with standard-pressure pneumoperitoneum with a p-value of 0.05.[44]

In the study conducted by Guruswamy et al 2021, Patients in Group A had higher scores compared to patients in Group B. The frequency was significantly lower in patients who underwent laparoscopic cholecystectomy with low-pressure pneumoperitoneum as compared to patients with standard-pressure pneumoperitoneum with a p-value of 0.01.[45]

In the study conducted by Monica ortezi et al 2022, Patients in Group A had higher scores compared to patients in Group B. The frequency was significantly lower in patients who underwent laparoscopic cholecystectomy with low-pressure pneumoperitoneum as compared to patients with standard-pressure pneumoperitoneum with a p-value of 0.001.[46]

TABLE 17 : Comparison with other studies(2)

Study	Analgesic Req in low PNP group	Duration of stay(days) Group A	Duration of stay Group B(days)
Nasir et al	40%	2-3	1-2
Sarli et al	31%	NA	NA
Guruswamy et al	less	More compared to group b	More compared to group A
Monica ortezi et al	less	1-2	2-3
Present Study	33.3%	3-4	2-3

In our study, comparison of analgesic (opioids) requirement in the postoperative period was compared with the standard and low pneumoperitoneal pressure group. It was noted that 66.6% population in Group A needed additional analgesics whereas only 33.3 % of Group B patients needed analgesics for pain management.

In our study, out of the total population, it was noted that About 54.4 % of the patients need opioid analgesics when the duration of the procedure exceeded 1 hour with a p-value of 0.00. The average duration of stay of group A patients was 3-4 days, whereas the average duration of stay for group B patients was 2-3 days.

In a study by Nasir et al in 2011, the analgesic requirement in the postoperative period was more in group A patients compared to Group B patients. About 60% of Group A patients required post-operative analgesics, whereas only 40 % of Group B patients needed additional analgesics. The average duration of stay of group A patients was 2-3days, whereas the average duration of stay for group B patients was 1-2 days.[43]

In a study by Sarli et al in 2017, analgesic requirement in the postoperative period was more in group A patients compared to Group B patients. About 69% of Group A patients required post-operative analgesics, whereas only 31 % of Group B patients needed additional analgesics.[44]

In a study by Guruswamy et al in 2021, the analgesic requirement in the post-operative period was more in group A patients compared to Group B patients. The average duration of stay of group A patients was more compared to patients in Group B.[45]

In a study by Monica ortezi et al in 2022, the analgesic requirement in the postoperative period was more in group A patients compared to Group B patients. About 56% of Group A patients required post-operative analgesics, whereas only 44 % of Group B patients needed additional analgesics. The average duration of stay of group A patients was 1-2days, whereas the average duration of stay for group B patients was 2-3 days.[46]

SUMMARY

The prospective comparative study titled "**A COMPARATIVE STUDY TO ASSESS THE IMPACT OF LOW PRESSURE VERSUS STANDARD PRESSURE PNEUMOPERITONEUM ON SHOULDER TIP PAIN AFTER LAPAROSCOPIC SURGERY**" was conducted in the Department of General Surgery, BLDE (Deemed to be University)'s Shri B.M. Patil Medical College Hospital included 90 patients who underwent Laparoscopic surgeries from the period October 2020 to October 2022.

The patients were compared based on the pneumoperitoneal pressure and intensity of shoulder tip pain post-procedure. Shoulder tip pain scores were also correlated with the duration of the procedure.The majority of the patients were females, males being 54.4%, and Females 46.4 %. The study population in the age group of 21 - 30 years accounted for 42.2%, next common group was 11-20 years constituting 21.1 %. The most common laparoscopic procedure was Cholecystectomy i.e 43%, followed by Appendicectomy i.e 29 %. Laparoscopic hernia repair accounted for 12 % of all the procedures performed.

In our study, a comparison of PNP Pressure with shoulder tip pain score yielded a p-value of 0.00 indicating that low PNP pressure patients had low pain scores. Comparison of Pain scores with Duration of procedure yielded a p-value of 0.00 indicating that low shoulder tip pain scores were noted when the duration of the procedure was less than 60 mins. The Duration of hospital stay was also longer in the standard PNP group compared to the low PNP group.

CONCLUSION

The prospective comparative study of low pneumoperitoneal pressure versus standard pneumoperitoneal pressure showed significant low shoulder tip pain post-procedure in the low PNP group compared to the standard PNP group.

The Duration of surgery also had an impact on shoulder tip scores, when the procedure exceeded more than 60 mins pain scores were high as compared to procedures which lasted less than 60 mins.

The analgesic requirement in the postoperative period was also more in the standard PNP group compared to the Low PNP group.

Thus we would like to conclude that patients with low pneumoperitoneal pressure during laparoscopic surgeries had fewer complications especially lower shoulder tip pain scores and better quality of life post-procedure.

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ANNEXURES

SAMPLE INFORMED CONSENT FORM

B.L.D.E(D.U)'s SHRI B.M. PATIL MEDICAL COLLEGE, HOSPITAL ANDRESEARCH CENTRE, VIJAYAPUR – 586103, KARNATAKA.

TITLE OF THE PROJECT:

A COMPARATIVE STUDY TO ASSESS THE IMPACT OF LOW PRESSURE VERSUS STANDARD PRESSURE PNEUMOPERITONEUM ON SHOULDER TIP PAIN AFTER LAPAROSCOPIC SURGERY

PRINCIPAL INVESTIGATOR:

DR. VINAYAK PILLAI
Department of General Surgery
Email:pillai.vinayak11@gmail.com

PG GUIDE: DR. M.B.PATIL MS

Professor and H.O.D. of General Surgery
B.L.D.E. Deemed to be University's
Shri B.M. Patil Medical College & ResearchCentre, Sholapur Road,
Vijayapur 586103

PURPOSE OF RESEARCH:

- I have been informed that this study will compare and assess the impact of low pressure versus standard pressure pneumoperitoneum on shoulder tip pain after laparoscopic surgery

- I have been explained about the reason for doing this study and selecting me/my ward as a subject for this study. I have also been given free choice for either being included or not in the study.

PROCEDURE:

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

RISKS AND DISCOMFORTS:

I understand that I/my ward may experience some pain, may be pain at the operated site. There are many risks involved during anesthesia, operation and during postoperative period. If any complication occurs during the operation or during the post operative period, I/my ward will be treated with best of our knowledge. There is no compensation or payment for such medical treatment.

ALTERNATIVES:

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

CONFIDENTIALITY:

I understand that medical information produced by this study will become a part of this Hospital records and will be subjected to the confidentiality and privacy regulation of this hospital. Information of a sensitive, personal nature will not be a part of the medical records, but will be stored in the investigator's research file and identified only by a code number. The code key connecting name to numbers will bekept in a separate secure location.

If the data are used for publication in the medical literature or for teaching purpose, no names will be used and other identifiers such as photographs and audio or video tapes will be used only with my special written permission. I understand thatI may see the photograph and videotapes and hear audiotapes before giving this permission.

REQUEST FOR MORE INFORMATION:

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

If during this study, or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me and that a copy of this consent formwill be given to me for careful reading.

REFUSAL OR WITHDRAWL OF PARTICIPATION:

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

I also understand that DR VINAYAK PILLAI will terminate my participation in thisstudy at any time after he has explained the reasons for doing so and has helped arrange for my continued care by my own physician or therapist, if this is appropriate

INJURY STATEMENT:

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

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

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

Dr. M.B.PATIL Dr. VINAYAK P

(Guide) (Investigator)

STUDY SUBJECT CONSENT STATEMENT:

I confirm that Dr. VINAYAK PILLAI has explained to me the purpose of this research, thestudy procedure that I will undergo and the possible discomforts and benefits that I may experience, in my own language.
I have been explained all the above in detail in my own language and I understand the same. Therefore I agree to give my consent to participate as a subject in this research project.

_____

_____

(Participant) Date

_____

_____

(Witness to above signature) Date

PROFORMA

CASE NO:

Name:

IPNo:

Age/sex:

Occupation:

Address:

DOA:

DOO:

Address:

DOD:

CHIEF COMPLAINTS:

PAST HISTORY:

Diabetes Mellitus

Hypertension

Renal diseases

IHD

PERSONAL HISTORY:

- Diet
- Sleep
- Appetite
- Bowel & bladder

GENERAL PHYSICAL EXAMINATION:

-Mental Status

- Built
- Nourishment
- Pallor

-Icterus

- Cyanosis
- Clubbing
- Edema
- Pulse
- Blood Pressure
- Respiration
- Temperature
- Any Obvious Deformity

SYSTEMIC EXAMINATION

-PER ABDOMEN:

INSPECTION

PALPATION

PERCUSSION

AUSCULTATION

RESPIRATORY SYSTEM

CARDIOVASCULAR SYSTEM

CENTRAL NERVOUS SYSTEM

DIAGNOSIS

PROCEDURE

INTRAOPERATIVE PRESSURE:

DURATION OF PROCEDURE

INVESTIGATIPNS

FOLLOW-UP

-4 HOURS POST PROCEDURE

-12 HOURS POST PROCEDURE

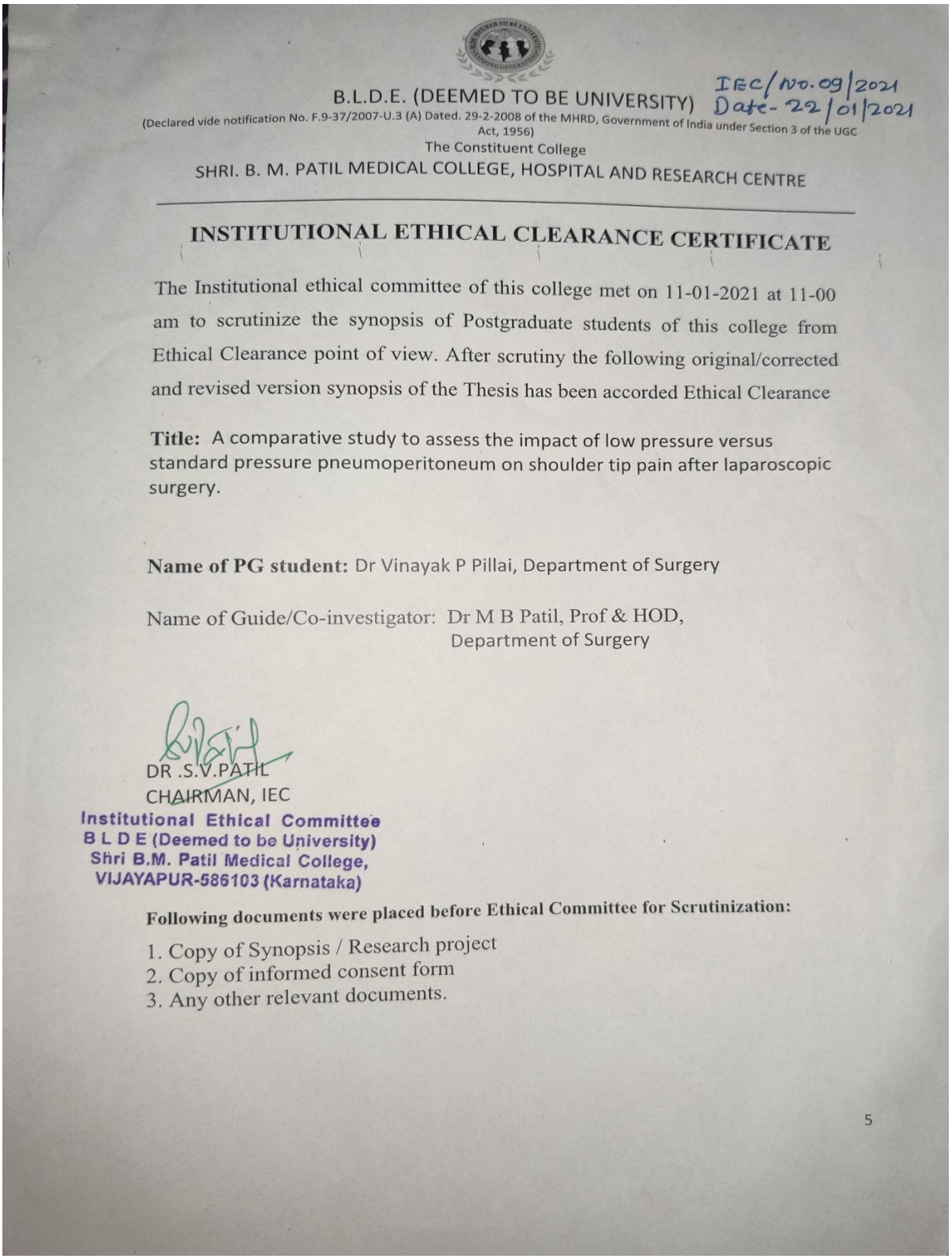
-24 HOURS POST PROCEDURE

-48 HOURS POST PROCEDURE

COMMENTS:

INFERENCE:

ETHICAL COMMITTEE CLEARANCE CERTIFICATE.



B.L.D.E. (DEEMED TO BE UNIVERSITY)

IEC/No.09/2021
Date- 22/01/2021

(Declared vide notification No. F.9-37/2007-U.3 (A) Dated. 29-2-2008 of the MHRD, Government of India under Section 3 of the UGC Act, 1956)

The Constituent College

SHRI. B. M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Institutional ethical committee of this college met on 11-01-2021 at 11-00 am to scrutinize the synopsis of Postgraduate students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected and revised version synopsis of the Thesis has been accorded Ethical Clearance

Title: A comparative study to assess the impact of low pressure versus standard pressure pneumoperitoneum on shoulder tip pain after laparoscopic surgery.

Name of PG student: Dr Vinayak P Pillai, Department of Surgery

Name of Guide/Co-investigator: Dr M B Patil, Prof & HOD, Department of Surgery

DR .S.V.PATIL
CHAIRMAN, IEC

Institutional Ethical Committee
B L D E (Deemed to be University)
Shri B.M. Patil Medical College,
VIJAYAPUR-586103 (Karnataka)

Following documents were placed before Ethical Committee for Scrutinization:

1. Copy of Synopsis / Research project
2. Copy of informed consent form
3. Any other relevant documents.

5

PLAGIARISM CERTIFICATE

Ouriginal
by Turnitin

Document Information

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MASTERCHART

SR. NO	NAME	AGE	SEX	IPNO	DIAGNOSIS	PROCEDURE	PRESSURE	Shoulder tip pain score	Duration of procedure(in mins)	ANALGESICRQ	Length of hospital stay
1	Bharati Biradar	36	F	13573	Cholelithiasis	Cholecystectomy	12	3	75	absent	4
2	Jyashree	46	F	21443	Cholelithiasis	Cholecystectomy	9	0	40	absent	2
3	Kasappa	72	M	28280	Cholelithiasis with hydatid cyst of liver recurrent	Cholecystectomy with cystectomy	12	2	90	present	4
4	Anand Kudagi	64	M	64715	appendicitis	appendicectomy	9	0	30	absent	3
5	Mala	39	F	72645	Cholelithiasis with umbilical hernia	Cholecystectomy	10	0	60	absent	3
6	Rangava	48	F	41669	Cholelithiasis	Cholecystectomy	10	1	45	absent	5
7	Bhimray	56	M	28212	Cholelithiasis	Cholecystectomy	10	2	60	absent	4
8	Kesu	60	M	56261	Cholelithiasis with ureteric calculi	Cholecystectomy	12	1	70	present	3
9	Bhagwant	45	M	66174	Cholelithiasis	Cholecystectomy	10	4	60	present	4
10	Prakash	50	M	55640	Cholelithiasis with recurrent appendicitis	Cholecystectomy with appendicectomy	12	4	105	present	5
11	Sumitra	27	F	16747	recurrent	appendicectomy	9	1	30	absent	3

					appendicitis						
12	Nisha	19	F	64712	Hydatid cyst of spleen	Deroofing of splenic cyst	11	4	60	present	7
13	Umesh	60	M	35244	Cholelithiasis recurrent	Cholecystectomy	9	2	45	absent	2
14	Pooja	20	F	11217	appendicitis	appendicectomy	10	3	45	absent	4
15	Savitri Patil	34	F	15968 2	Moderate ascitis	Diagnostic Laparascopy	9	0	30	absent	3
16	Annapurna	45	F	11301	Cholelithiasis recurrent	Cholecystectomy	10	1	40	absent	2
17	Chetan	16	M	4533	appendicitis	appendicectomy	9	0	30	absent	3
18	Abhinandan	29	M	13194 1	left indirect inguinal hernia	TAPP(Transabdominal preperitoneal repair)	13	3	90	present	2
19	Sharada	36	F	12040 3	Cholelithiasis	Cholecystectomy	11	2	60	absent	2
20	Sushasini	32	F	14159 2	Cholelithiasis	Cholecystectomy	11	4	40	absent	4
21	Sharanagouda	62	M	9424	left direct inguinal hernia	TAPP(Transabdominal preperitoneal repair)	12	4	90	absent	2
22	Lakshmi	45	F	42434	Cholelithiasis	Cholecystectomy	12	4	50	present	4
23	Hirachand	45	M	13571	Complete rectal prolapse recurrent	Rectopexy	14	5	60	present	8
24	Sumitra	35	F	13599 4	appendicitis	appendicectomy	10	1	40	absent	3
25	Bharati	53 5	F	24687	Cholelithiasis	Cholecystectomy	12	4	60	present	2
26	Gouramma	60	F	24924 9	Cholelithiasis	Cholecystectomy	14	5	90	absent	5

27	Kavita	12	F	29183	acute appendicitis recurrent	appendicectomy	10	1	45	absent	2
28	Ragavendra	35	M	29073	appendicitis	appendicectomy	9	1	50	present	1
29	Kaveri	17	F	29306	acute appendicitis	appendicectomy	9	1	70	absent	2
30	Shantabai	50	F	23726	Cholelithiasis recurrent	Cholecystectomy	12	2	65	present	3
31	Shashikala	59	F	23990	appendicitis	appendicectomy	10	1	60	absent	2
32	Rajshekar	40	M	24856	acute appendicitis	appendicectomy	10	1	55	absent	2
33	Mala	36	F	24816	Small bowel obstruction	Diagnostic Laparascopy with adhesiolysis	12	4	130	present	5
34	Kasturi	30	F	26940	Cholelithiasis recurrent	Cholecystectomy	10	1	80	absent	4
35	Jaffar	17	M	35781	appendicitis	appendicectomy	9	2	55	absent	2
36	Kulsambi	65	F	29707	Cholelithiasis umbilical	Cholecystectomy	12	5	90	present	5
37	Dasarth	40	M	30801	hernia recurrent	IPOM repair	12	3	90	present	4
38	Basavaraj	28	M	29203	appendicitis left indirect	appendicectomy	10	2	40	absent	2
39	Mallikarjun	35	M	31254	inguinal hernia	laproscopic IPOM repair	10	5	105	present	3
40	Nellawa	46	F	31574	Cholelithiasis subacute	Cholecystectomy	10	2	90	absent	3
41	Manjunath	27	M	7325	appendicitis	appendicectomy	10	4	60	absent	2

42	Mallangouda	22	M	8827	acute appendicitis	appendicectomy	10	3	65	absent	2
43	Vimala	60	F	14208	Cholelithiasis	Cholecystectomy	12	5	90	present	5
44	Lakshmi	32	F	23510	Cholelithiasis	Cholecystectomy	14	2	90	absent	4
45	Praveen	30	M	19017	acute appendicitis	appendicectomy	14	2	70	present	2
46	Appasab	58	M	4993	Umbilical hernia with cholelithiasis	Cholecystectomy With IPOM repair	14	5	130	absent	3
47	Muttanna	38	M	86095	left indirect inguinal hernia	TAPP(Transabdominal preperitoneal repair)	10	2	75	present	2
48	Sidanna	70	M	16171 3	right indirect inguinal hernia	TAPP(Transabdominal preperitoneal repair)	12	3	60	absent	3
49	Bhoomikka	19	F	30703	acute appendicitis	appendicectomy	14	2	90	present	2
50	Bharati	45	M	13790	Rectovaginal fistula	Rectovaginal fistula repair	15	4	195	present	7
51	Sunita	31	F	14908 2	Cholelithiasis	Cholecystectomy	12	4	105	present	3
52	Neeraj	23	M	14566	acute appendicitis recurrent	appendicectomy	14	2	90	present	2
53	Shabanam	26	F	16932 4	appendicitis	appendicectomy	12	1	55	absent	2
54	Gaddena	17	M	16873 1	acute appendicitis	appendicectomy	10	3	60	absent	3
55	Pinkidevi	33	F	17396 3	Cholelithiasis	Cholecystectomy	10	5	75	absent	3
56	Ismail	48	M	14025 5	Cholelithiasis	Cholecystectomy	14	4	90	present	4
57	Bhimaraya	70	M	16929 2	Cholelithiasis	Cholecystectomy	12	3	105	absent	3

58	Sushmita	23	F	180343	Cholelithiasis acute	Cholecystectomy	10	1	90	present	4
59	Shambuling	32	M	189386	appendicitis acute	appendicectomy	10	2	60	absent	2
60	Arati	12	F	190632	appendicitis recurrent	appendicectomy	10	1	70	absent	2
61	Mahantesh	30	M	190560	appendicitis	appendicectomy	10	2	60	absent	3
62	Manjula	37	F	211961	Umbilical hernia with recurrent appendicitis	appendicectomy with TARM repair	14	6	135	present	2
63	Pushpa	24	F	207192	Cholelithiasis	Cholecystectomy	14	6	80	present	3
64	Arman	13	M	207145	Left undescended testis acute	left orchidopexy	12	3	130	absent	3
65	Vidya	30	F	23009	appendicitis	appendicectomy	9	2	45	absent	2
66	Ratidevi	40	F	221536	Cholelithiasis	Cholecystectomy	10	3	60	absent	2
67	Mallapa	50	M	221370	Cholelithiasis recurrent	Cholecystectomy	14	3	130	present	5
68	Shivakumar	23	M	222261	appendicitis	appendicectomy	12	1	90	absent	4
69	Mallappa K	57	M	231358	Cholelithiasis	Cholecystectomy	12	2	70	absent	3
70	Nanagouda	70	M	232008	Cholelithiasis	Cholecystectomy	12	3	105	present	4
71	Suhas	18	M	981766	Cholelithiasis acute	Cholecystectomy	14	2	60	absent	2
72	Sangamesh	24	M	25224	appendicitis	appendicectomy	10	1	45	absent	2
73	Mahantesh	40	M	26107	Hiatus Hernia	Dors fundoplication	12	4	110	absent	4
74	Sangamma	45	F	270500	Umbilical	TARM	14	3	75	absent	1

					Hernia with oment ocle acute							
75	Shiv	21	M	70707	append icitis	appendicectomy	10	2	55	absent	2
76	Siddanagoida	52	M	28071	Cholelithiasis	Cholecystectomy	12	3	60	absent	3
77	Asha	38	F	19806	Cholelithiasis recurrent	Cholecystectomy	10	2	75	present	3
78	Archana	29	F	28088	append icitis	appendicectomy	10	4	60	absent	2
79	Sangamma	50	F	27673	Hiatus Hernia	Niessens dundoplication	14	4	120	present	3
80	Annappa	45	M	28091	Achalasia Cardia	Hellers cardiomyotomy with fundoplication	12	4	130	present	3
81	Abdulagi	42	m	65411	B/l inguinal Hernia	TAPP(Transabdominal preperitoneal repair)	12	4	110	absent	2
82	Gurupal	23	M	28150	Cholelithiasis	Cholecystectomy	12	1	90	present	3
83	Ashwini	27	F	31660	Cholelithiasis	Cholecystectomy	10	2	70	absent	2
84	Shilpa	26	F	23829	Cholelithiasis recurrent	Cholecystectomy	12	5	105	present	2
85	Rahul	31	M	31724	append icitis recurrent	appendicectomy	10	1	85	absent	2
86	Prem	26	M	31294	append icitis acute	appendicectomy	10	2	60	absent	2
87	Pavan	20	M	33464	append icitis acute	appendicectomy	12	2	55	absent	2
88	Anil	22	M	34667	append icitis	appendicectomy	12	2	115	absent	2
89	Fayaz	24	M	30202	Hiatus Hernia	Niessens fundoplication	14	4	75	absent	3

90	Sujata	23	F	352813	recurrent appendicitis	appendicectomy	10	2	60	absent	2