"A COMPARISON OF POST OPERATIVE PORT SITE PAIN WHEN GALL BLADDER IS RETRIEVED FROM UMBILICAL PORT VERSUS EPIGASTRIC PORT FOLLOWING LAPAROSCOPIC CHOLECYSTECTOMY. A ONE YEAR RANDOMIZED CONTROL TRIAL: SINGLE CENTRIC HOSPITAL BASED STUDY"

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Endorsement by the HOD/Principal/ Head of the Institution

This is to certify that the dissertation entitled **"A COMPARISON OF POST OPERATIVE PORT SITE PAIN WHEN GALL BLADDER IS RETRIEVED FROM UMBILICAL PORT VERSUS EPIGASTRIC PORT FOLLOWING LAPAROSCOPIC CHOLECYSTECTOMY. A ONE YEAR RANDOMIZED CONTROL TRIAL: SINGLE CENTRIC HOSPITAL BASED STUDY"** is a bonafide research work done by **Reg. No. BH0115007**

Dr. S. S. SHIMIKORE **M.S**
Professor and Head,
Department of General Surgery ,
J. N. Medical College,
Nehru Nagar, Belagavi – 10
Date:
Place: Belagavi

Dr. N.S. MAHANTHSHETTI **MD**
Principal,
J. N. Medical College,
Nehru Nagar, Belagavi – 10

Date:
Place: Belagavi

LIST OF ABBREVIATIONS

BP	-	Blood pressure
CBC	-	Complete blood count
cm	-	Centimeter
Co2	-	carbon dioxide
CNS	-	Central nervous system
CT	-	Computed tomography
CVS	-	Cardiovascular system
D.O.A.	-	Date of admission
D.O.D.	-	Date of discharge
D.O.S.	-	Date of surgery
DBP	-	Diastolic blood pressure
DLC	-	Direct leukocyte count
DPQ	-	Dartmouth pain Questionnaire
e.g.	-	For example
FBS	-	Fasting blood sugar
Hb	-	Haemoglobin

Hr	-	Hour
I.P.	-	In patient
Kgs	-	Kilograms
LC	-	Laparoscopic cholecystectomy
min	-	Minute
ml	-	Milliliter
mm	-	Millimeter
MPQ	-	Mc Gill pain Questionnaire
n	-	Total number
NMDA	-	N-methyl-D-aspartate receptor
OC	-	Open cholecystectomy
O.P.D	-	Out patient department
USG	-	Ultrasonography
WHYPQ	-	West Haven-Yale pain Questionnaire,
WDR	-	wide dynamic range

ABSTRACT

Background and objectives

Postoperative pain remains one of the main causes of delay in resumption of activities after laparoscopic cholecystectomy (LC). The study undertaken aimed to determine which is a superior port when the gall bladder (GB) was retrieved via the epigastric port versus umbilical port in terms of lesser post operative pain.

Methodology

This one year randomized controlled trial was done with the Department of Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, from January 2016 to December 2016. A total of 40 patients posted for elective cholecystectomy were studied. The patients were divided into two groups of 20 each as Group A (GB retrieved via the Epigastric port) and Group B (GB retrieved via the Umbilical port)

Results

In the present study mean duration of surgery was 73.55 ± 10.6 minutes in group A and in group B it was 68.9 ± 10.3 minutes. However the difference was statistically not significant (p=0.1676) in patients with group B.

The mean pain scores at all the intervals were significantly low (p<0.050) Rescue analgesia was required in 25% of the patients in group A at the 6 hour and 12 hour intervals and 55% at the 24 hour interval. However, in group B, no requirement of rescue analgesia was required.

In group A, 45% of the patients had mild pain, 55 % of the patients had moderate pain when compared to group B, where all the patients had mild pain only.

Conclusion and Interpretation

Overall, Umbilical port could be a better port for retrieval of Gall Bladder in Laparoscopic Cholecystectomy in terms of lesser post operative port site pain and lesser requirement of analgesia.

Key words

Laparoscopic cholecystectomy, Post operative Pain, Gall bladder retrieval, Epigastric port, Umbilical port.

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INTRODUCTION

Cholecystectomy is the most commonly performed operation of the biliary tract and the second most common operative procedure performed at present[1]. LC was introduced in 1987 and is now the preferred method for cholecystectomy[2]. This surgical procedure has been a milestone in the management of GB disease by reducing postoperative pain, risk of surgical site infection and incisional hernia[3].This surgery is still evolving with time and the size, number of ports is reducing day by day.

Acute postoperative pain as with all other types of pain is an extraordinarily complex sensation which may be described as an interpretation of these signals by higher centres involving past experiences of painful situation, and an affective component which generally comprises anxiety and or depression[4]. Uncontrolled postoperative pain has an adverse sequel of delayed resumption of normal pulmonary function, restricted mobilization (thus contributing to thromboembolic complications), nausea and vomiting, increase in the systemic vascular resistance, cardiac work, and myocardial oxygen consumption through an increase in the catecholamine release induced by the stress response[5]. Pain is the most frequent complaint after LC and the main reason for staying overnight at hospital on the day of operation[6].

Pain after LC depends on multiple factors including rupture of blood vessels caused by rapid distension of the peritoneum, traumatic traction on the nerves, trauma to the abdominal wall during port insertion and GB retrieval and pneumoperitoneum created by use of Carbon dioxide (CO2) to maintain high abdominal pressure. It is noted that incisional pain is more intense than visceral pain and is dominant during the first 48 hours after LC[7].

It was proved that following LC, the site of most severe pain was in the right upper quadrant and port wounds during first 24 hours[8]. Adequacy of postoperative pain control is one of the most important factors in determining when a patient can be safely discharged from a surgical facility and has a major influence on the patient's ability to resume their daily chores[9].

Retrieval of GB is an important terminal step of LC and is hypothesized to be one of the factors affecting postoperative port site pain and infection. GB is either retrieved from the epigastric or umbilical port. Both the ports have been recommended for retrieval of GB in LC, and are always selected as per surgeon's preference[10-12]. Till date, there is very little evidence to support any one port being superior to the other for GB extraction while considering postoperative-port site pain.

This trial is being undertaken to determine which port is a superior port in terms of lesser post operative pain when GB is retrieved from umbilical port versus the epigastric port in adult patients undergoing four port elective LC at a tertiary care hospital.

OBJECTIVE

To determine whether post-operative port site pain is lesser when gall bladder is retrieved via the epigastric port versus umbilical port following a four port elective laparoscopic cholecystectomy at a tertiary care hospital.

REVIEW OF LITERATURE

LC has become a gold standard procedure for surgical treatment of symptomatic gallstone disease[13-14]. The eminence of LC reflects advantages in surgical morbidity, systemic complications, quality of life, and postoperative pain[15]. LC decreases postoperative pain, decreases need for postoperative analgesia, shortens hospital stay from 1 week to less than 24 hours, and returns the patient to full activity within 1 week compared to 1 month after open cholecystectomy (OC) [16].

HISTORICAL REVIEW:

During the 1980s, the preferred surgical procedure for cholecystectomy changed from the classical open procedure to LC. In 1985 Muhe performed the first LC and the following year he presented to the German Surgical Congress but was greeted with outright hostility[17-18].

In 1985 first laparoscopically assisted cholecystectomy was performed by Muhe, Boblingen, Germany. In 1987, French surgeon in Lyon, Phillipe Mouret, performed the first video LC[19].

SURGICAL ANATOMY OF GALL BLADDER

The GB is pyriform in shape and is present in the GB fossa on the inferior surface of right lobe of liver. It projects from the right end of the porta hepatic to the inferior border of liver[20]. It is 7 to 10 cm long, 3 cm broad at its widest and has 30-50ml capacity.

Parts of the GB are fundus, body, neck and infundibulum. The fundus, extends down, forwards and to the right. It is visible below the inferior border of liver and comes in contact with the anterior abdominal wall at the junction of the ninth right costal cartilage and the lateral edge of the right rectus abdominis muscle. Posteriorly it

is related to transverse colon. The body is directed medially, towards the right end of the porta hepatis and it is continuous with neck. It is related above to the liver, below to the transverse colon and further back to the first and upper end of second segment of duodenum. The neck is narrow, directed upwards and forwards and then abruptly backwards and downwards, joins the cystic duct. Thin areolar tissue containing cystic artery connects the neck to the liver. The mucosa of the neck shows a spiral valve which gives its surface a spiral grove when the neck is distended. Hartmann's pouch (originally described by Broca) is a small recess going down and backwards.

The cystic duct is 3 to 4 cm long; projecting backwards, downwards and medially. It begins from the neck of the GB and joins the common hepatic duct to form the common bile duct. The junction is located just below the porta hepatis. But may occur at a lower level, where the cystic duct lies along the right edge of lesser omentum. Its mucosa shows 5-10 concentric folds projecting obliquely in regular succession, like a spiral valve, referred as the "valve of Heister"[20-23].

LAPAROSCOPIC ANATOMY OF GALL BLADDER

The advent and popularity of LC has led to a new look and insights into biliary anatomy especially of the Calot's triangle area and the term 'laparoscopic anatomy' has actually found a place even in anatomy texts. Although a detailed discussion of all the factors peculiar to laparoscopy that contribute to an increased incidence of injuries is beyond the scope of this review, the different anatomical 'laparoscopic view' of the area around the GB especially the Calot's triangle does contribute to misidentification of structures. The method of retraction during the laparoscopic procedure tends to distort the Calot's triangle by actually flattening it rather than opening it out[24.] Also, the reluctance to (or difficulty in) performing a fundus first cholecystectomy during the laparoscopic procedure as opposed to the open procedure also contributes to the

same lack of exposure of the Calot's triangle. Finally, the 'posterior' or 'reverse' dissection of the Calot's triangle, which is popular during a LC, again gives a different view of the area and since the GB is flipped over during this method may lead to further anatomical distortion[25].

The Rouviere's sulcus is a fissure on the liver between the right lobe and caudate process and is clearly seen during a LC during the posterior dissection in a majority of patients. It corresponds to the level of the porta hepatis where the right pedicle enters the liver. It has hence been recommended that all dissection be kept to a level above (or anterior) to this sulcus to avoid injury to the bile duct. Also, this being an 'extrabiliary' reference point it does not get affected by distortion due to pathology. Similarly, a clear delineation of the junction of the cystic duct with the GB along with the demonstration of a space between the GB and the liver clear of any other structure other than the cystic artery (safety window or critical view) is also recommended as an essential step to prevent bile duct injury[25].

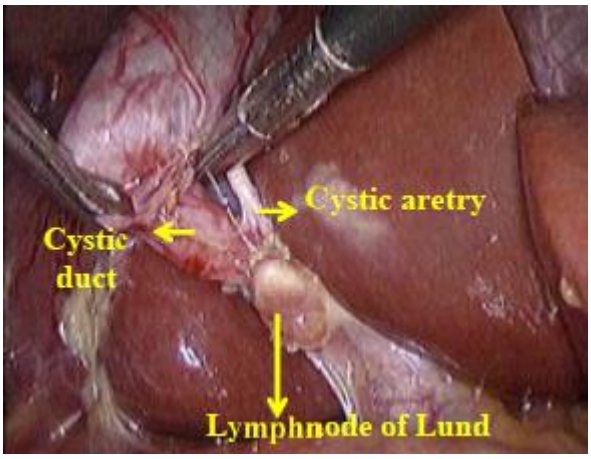


Illustration 1: Laparoscopic view of Calots triangle [25]

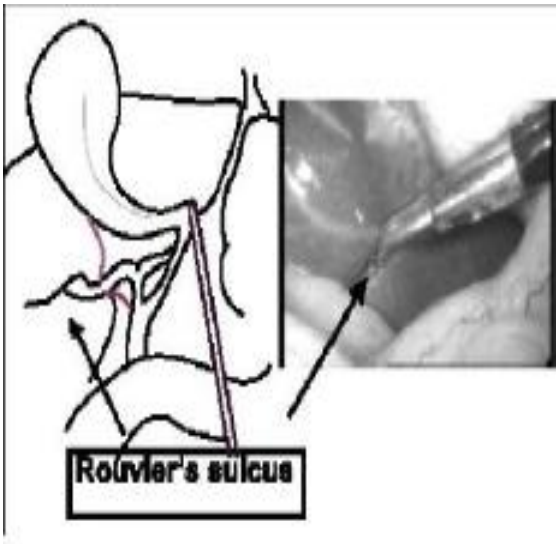


Illustration 2: Rouvier's sulcus[25]

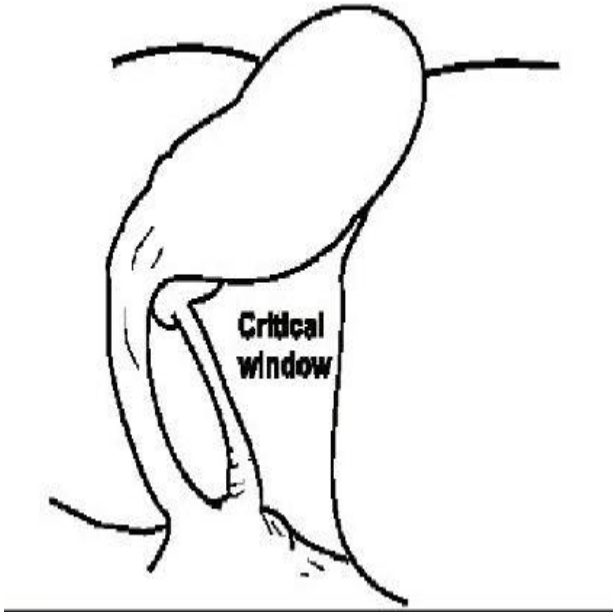


Illustration 3: Critical view of safety[25]

UMBILICUS IN LAPAROSCOPY

Typically the umbilicus is at the same level as the highest point of the iliac crest, i.e. at the 3rd - 4th lumbar disc. The prominence of the umbilicus and the depth of the umbilical pit (cicatrix) are extremely variable[26]. The central location and ability of the umbilicus to camouflage scars makes it an attractive trocar site for laparoscopic

surgery. However, it poses its own problems as it is naturally a weak area, given to overt surreptuous congenital defects[27-28]. Biliary pain is described to be episodic, severe in nature, felt in the upper abdomen which lasts more than 30 minutes and nocturnal in onset; Associated with nausea and vomiting; radiating through to the back[28].

PAIN AFTER LAPAROSCOPY

The International Association for the Study of Pain defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage." This definition suggests association between the objective, physiologic sensory aspects of pain and its subjective, emotional and psychological components [29] .Pain following laparoscopy, is usually less severe and is for a shorter duration compared to pain following laparotomy. The reduction in pain has an advantage of lesser hospital stay, provided that the control of the residual pain is possible with drugs or other techniques like transdermal patches used for analgesia are safe[30]. Pain may occur in the upper quadrants of the abdomen or lower abdomen, back, or shoulders. Upper abdominal quadrants are known to be the site with the greatest incidence of pain. Pain after laparoscopy may be transient or it may last for at least two days. Following LC, it was observed that predominant pain in the first 24 hours was due to visceral pain, whereas shoulder pain, was mild in severity on the first day, increased and becomes significant on the following day[31].

Pain is divided clinically into, acute pain which is primarily due to nociception and chronic pain, which may also be due to nociception, but in which psychological and behavioral factors definitely play a role. Postoperative pain is a type of acute pain and can be further differentiated based on the origin into somatic and visceral pain. Somatic pain is due to nociceptive input arising from skin, subcutaneous tissues, and

mucous membranes and is characterized by being well-localized and described as sharp, pricking, throbbing or burning sensation. Visceral pain also is due to nociceptive input arising from internal organ or its capsule. It is usually dull diffuse pain which is commonly associated with abnormal sympathetic or parasympathetic activity causing nausea, vomiting, sweating and /or changes in blood pressure or heart rate[32].

Many factors influence the quality, intensity, occurrence and duration of postoperative pain like the site, type of incision (thoracic and upper abdominal operations are associated with the most severe pain), nature and duration of operation, the preoperative psychological, physical and pre operative medications of the patient, anaesthetic management and the quality of post operative care[32].

NEURO-PHYSIOLOGY OF PAIN

Nociceptors

Sensation is commonly described as either protopathic (noxious) or epicritic (nonnoxious). Epicritic sensation (light touch, pressure, temperature discrimination and proprioception) is characterized by low-threshold receptors (specialized endorgans on the afferent neurons) and conducted by large myelinated nerve fibers while; protopathic sensation (pain) is perceived by high-threshold receptors (free nerve endings)[33.] Noxious sensations are divided into two components: a fast, sharp, and well-localized sensation "first pain" which is conducted by Aδ fibers; and a duller, slower onset, and poorly localized sensation "second pain" which is conducted by C fibers. This protopathic pain is transmitted primarily by free nerve endings that sense mechanical or chemical tissue damage[34-35]. Various types of this pain is described;

a. Mechano-nociceptors, which respond to pinprick.

b. Silent nociceptors, which respond only on the presence of inflammation.

c. Polygonal mechano-heat receptors which is more common and respond to excessive pressure, extreme of temperature, and pain producing agents[36].

Nociceptors are either somatic that include those in skin and deep tissues (muscle, tendons, joints), or visceral nociceptors that include those in internal organs[34-36].

PAIN PATHWAY

Pain is conducted along three neuron pathways; from the periphery to the cerebral cortex[34-36].

First order neuron: Cells of these neurons are located in the dorsal root ganglia (for the body) and specific cranial nerve ganglia (for the head and neck) for example, Gasserian ganglion for trigeminal nerve. The Proximal end of their axons reach spinal cord via the dorsal sensory root of cervical, thoracic, lumbar, and sacral level (for the body) and through the cranial nerves (for head and neck)[34-36].

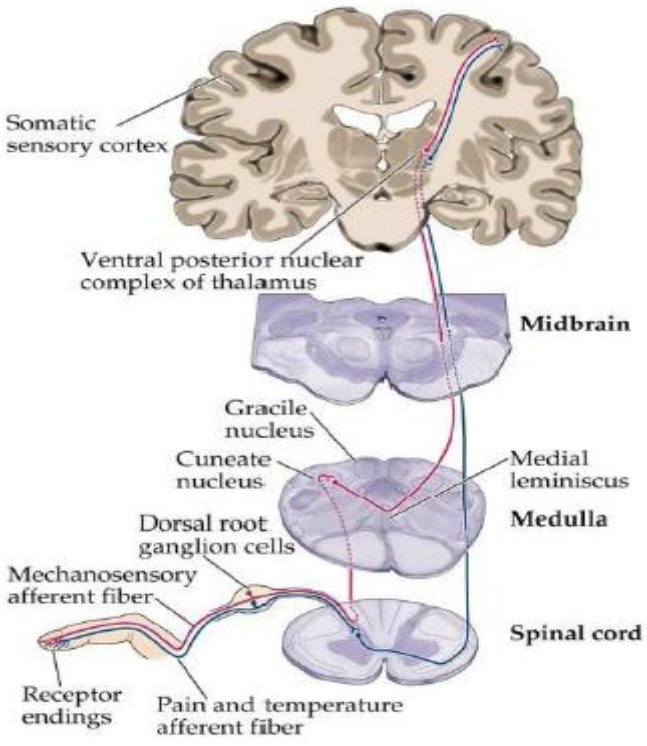


Illustration 4. Pain pathway[34-36].

Second order neurons: Pain fibers may ascend or descend three spinal cord segments in the Lissauer's tract before synapsing with the second order neuron in the gray matter of the ipsilateral dorsal horn, this synapsing may be through interneurons. Second order neurons are either; nociceptive specific which serves only noxious stimuli and are normally silent or wide dynamic range (WDR) neurons that can receive also non-noxious afferent input. WDR neurons are more prevalent in the dorsal horn and are responsible for the increased intensity of firing in response to same stimulus "windup"[34-35]. Lamina II of the gray matter of the dorsal horn of the spinal cord, (also called the substantia gelatenosa) contains many interneurons and is believed to play a role in processing and modulating nociceptive input [34-35]. Axons of most of the second order neurons cross the midline to the contralateral side of the spinal cord forming the lateral spinothalamic tract that send its fibers to the thalamus, the reticular formation, nucleus raphe and periaqueductal gray matter[34-35].

Third order neurons: These neurons are located in the thalamus and send their fibers to the somato-sensory area I and II in the cerebral cortex[34-35].

MECHANISM OF PAIN IN LAPAROSCOPY

Rapid distension of the peritoneal layer can be associated with tearing of blood vessels, traumatic traction of the nerves and release of inflammatory mediators. Peritoneal inflammation is probably also the origin of the upper abdominal pain after lower abdominal surgery or after diagnostic laparoscopy which can persist for at least three days.

A study has shown that a Peritoneal biopsy performed two to three days after laparoscopy showed inflammation and neuronal rupture, and there was a linear inverse relationship between abdominal compliance at the time of laparoscopy and

severity of postoperative pain[31]. Hence, distension of the abdomen should be gradual with adequate muscle relaxation to ensure suitable abdominal compliance. The prolonged presence of shoulder tip pain is due to stimulation of the phrenic nerve that is caused by the persistence of gas in the abdomen (pneumoperitoneum). There is a statistically significant correlation between the width of the gas bubble and pain score, and this pain can be reduced by the aspiration of the gas under the diaphragm[31].

FACTORS ASSOCIATED WITH GASEOUS PNEUMOPERITONEUM:

a. Neuropraxia of the phrenic nerve

It has been suggested that distention of the diaphragm during gas insufflations and the resultant phrenic nerve neuropraxia plays a role in contributing to Post operative pain, which may include the related C4 dermatome[37].

b. Type of insufflated gas and intra-abdominal pH

The phrenic nerves may be damaged by the acid milieu created by the dissolution of CO2. The intraperitoneal pH when CO2 gas is insufflated has been measured at 6.0 immediately postoperatively. On the first postoperative day, the pH rises to 6.4 to 6.7, and on the second postoperative day to 6.8 to 6.9. Thereafter it normalizes to above 7.0. Similar values were found when argon gas was substituted[38].

c. Retained intra-abdominal gas

Several reports have indicated that residual or retained intraabdominal gas after laparoscopy causes pain. Carbon dioxide dissolution, intra abdominal acidosis, and the consequent peritoneal irritation occur for a longer duration if the gas is not evacuated at the end of the laparoscopic procedure. Residual gas also may result in a loss of peritoneal surface tension and support to the abdominal organs, thus contributing to postoperative pain[38].

d. Temperature of gas

According to studies, pain reduction was significantly greater where warmed gas was used, especially with respect to diaphragmatic and shoulder tip pain, with the lasting effect of three days[37].

e. Humidity of gas

A prospective randomized controlled trail was conducted at the Queen Elizabeth Hospital, Adelaide, to investigate the outcome when humidified gas was insufflated during LC instead of standard dry gas[39]. The results of this study suggested significantly reduced postoperative pain in patients who underwent humidified gas insufflation. The humidified insufflations showed a trend of less postoperative analgesic consumption, along with shorter hospital stay and earlier return to work. The exact relation between dry gas and postoperative pain is not yet determined, but other animal studies have observed that dry gas insufflations is implicated in ultrastructural damage to exposed membranes, an effect that was not seen with the use of humidified gas[40].

PAIN AFTER LAPAROSCOPIC CHOLECYSTECTOMY

Postoperative pain in patients who have preoperative pain was more severe than those without preoperative pain. Studies have shown there is a positive association between fear of surgical procedure and postoperative LC pain intensity[41-42].

The severity of pain after laparoscopic cholecystectomy peaks within the first four to eight hours and reduces in the subsequent 48-72 hours. It involves three different components with different intensity, time course and pathophysiological mechanisms. These pain components are incisional sharp pain (parietal pain component); deep intraabdominal diffuse pain (visceral pain component) and shoulder

tip pain (presumed referred visceral pain.) The intensity of visceral pain dominates in the immediate postoperative period[41-42].

EFFECTS OF POST OPERATIVE PAIN

Moderate to severe acute pain, regardless of its site, can affect nearly every visceral function and may adversely influence postoperative morbidity and mortality. Acute pain is classically associated with neuroendocrine stress response that is proportional to pain intensity, and it has been hypothesized that a reduction in surgical stress responses (endocrine, metabolic and inflammatory) will lead to a reduced incidence of postoperative organ dysfunction and thereby lead to a better outcome[43].

a. Cardiovascular effects

It is observed that Perioperative myocardial ischemia is most likely to occur after surgery (from day 1-3 postoperatively), which has led to formulating Strategies regarding its management in order to prevent its development[44]. In addition to the various factors that contribute to the development of postoperative myocardial ischemia, including hypothermia, anaemia, anxiety, and tracheal intubation / suctioning, responses to poorly controlled pain play a prominent role in this regard. Activation of sympathoadrenal, and neuroendocrine axes may play a major impact on myocardial oxygen supply and demand.

Catecholamine induced tachycardia, enhanced contractility, rise in afterload and rise in preload from hypervolemia caused by enhanced release of arginine vasopressin and aldosterone, are well characterized determinants of increased oxygen demand. Increased oxygen demand, with hypervolemia, may induce ischemia and acute cardiac failure, especially in patients with poorly compensated coronary artery or valvular heart disease[45]. Myocardial oxygen supply may be diminished as a result

of pulmonary dysfunction, in particular, atelectasis secondary to pain-induced hypoventilation[46].

b. Pulmonary effects

Pulmonary function can be significantly altered by post surgical pain. The classical pulmonary response to upper abdominal surgery includes tachypnoea with decreased tidal volume, vital capacity, forced expiratory volume and functional residual capacity. Those pathophysiologic alterations are characteristic of acute restrictive pulmonary disease and, as such, may be associated with clinically significant hypoxia and hypercarbia[46].

Pain increases total body oxygen consumption and carbon dioxide production which necessitated an increase in the work of breathing. Patients with poor pain control (specially in upper abdominal and thoracic procedures) breath less deeply and have inadequate cough this leads to further reduction in the tidal volume and functional residual capacity which in turn can cause atelectasis, intrapulmonary shunting and hypoxemia[44].

c. Gastro intesinal effects

Pain induced Sympathetic hyperactivity increases tone of sphincters and decrease motility of intestine, causing ileus, pain also increases stress ulceration due to increase in gastric acid secretion[47].

d. Endocrinal effects

The dominant neuroendocrine responses to pain involve hypothalamico-pitutary-adrenocortical interactions. Those interactions results in increased catecholamine and catabolic hormone release. This in-turn causes sodium and water retention, and increased levels of blood glucose, free fatty acids and lactate. The negative nitrogen balance and protein catabolism may hamper patients

convalescence[48].

e. Haematological effects

The stress response causes decrease in the levels of natural anticoagulants, inhibition of fibrinolysis and increase in platelet reactivity which initiate a Post-operative hypercoagulable state[49].

f. Psychogenic effects

Intense anxiety, fear, and the loss of control that accompany severe tissue injury may have profound impact on the hypothalamic-pituitary axis. Behavioral responses associated with poorly controlled pain include sleep deprivation and reduced morale[43].

In many patients, uncontrolled postoperative pain can produce a series of long term emotional disturbances, which could impair the patient's mood, and cause undue fear and anxiety if subsequent surgery is required[43].

Lastly, optimizing treatment of acute postoperative pain can improve health related quality of life, while poor postoperative pain control may intervene with patients activities of daily living.

MEASUREMENT OF PAIN

As suggested, Pain can be measured by two methods;

Type I methods

These methods are objective, done by the physician as he assigns parameters about the patient condition. It includes the following:

Physiological indices

a. Endocrinal (increase in serum cortisol and catecholamine).
b. Cardiovascular (increase in blood pressure and heart rate)
c. Respiratory (increase in respiratory rate and decrease in tidal volume)

Neuro-pharmacological

a. Correlation with beta endorphin (decreased in acute painful conditions)

b. Thermography (hypo-emission in chronic pain)

Neurological

a. Nerve conduction velocity

b. Evoked potentials

c. Single positron emission tomography (SPET).

Behavioural

a. Sighing

b. Crying

c. Shouting,

d. Trembling.

Type II methods It includes either:

a. Single dimension methods

- Category scale (verbal rating scale)
- Numerical rating scale
- Graphic rating scale

b. Multi-dimensional methods

- Mc Gill pain Questionnaire, MPQ
- Dartmouth pain Questionnaire, DPQ
- West Haven-Yale pain Questionnaire, WHYPQ.[40]

Measurement of pain in clinical practice depends mainly on verbal dialogue between the patient and the doctor or nurse. A rating scale is mandatory in research projects and ideally when clinical data are being collected.

A number of individual differences between patients make comparisons of pain measurements more difficult. For example, the past history of surgery or hospitalisation of patients can influence their present perception of pain. Also, demographic factors such as gender, age, and ethnic background influence the individual's perception of pain. It has been observed that in patients who are clinically depressed and anxious, tend to report more pain intensity[33].

Although pain is a subjective experience, importance has been paid to the quantification of this experience. As pain is subjective experience, everyone has different perceptions of that experience. Differences are found in how individuals quantify pain. For example, some individuals would never say that their pain was a (10) on a scale from (0) to (10). On the other hand, other individuals report their pain as a constant (10) despite looking calm and relaxed. Also, all numeric scales used to measure pain have floor and ceiling effects. If the patients describe their pain to be a (10), there is no way to report an increase in pain intensity. VAS and VRS are the most commonly used scales in the single dimension method[33].

VISUAL ANALOGUE SCALE (VAS)

The visual analogue scale uses a straight line with extremities of pain intensity on either end. The line is typically 10 cm long with one end defined as "no pain" and the other end being excruciating unbearable pain". The line can be either vertical or horizontal. The patients are asked to place a mark on the line to describe the amount of pain that they are currently experiencing. The distance between the end labeled "no pain" and the mark placed by the patient is measured and rounded to the nearest centimeter. To assist in describing the intensity of pain, words can be placed along the scale (for example, mild, moderate, or severe). Such descriptors can help to orient the patient for the degree of pain; this particular variation of the VAS has been known as

a graphic rating scale. Explanation to the patient is needed by the clinician when using the VAS. Occasionally, the patient may be confused about the line, perceiving it to represent time of degree of relief rather than degree of pain intensity[33].

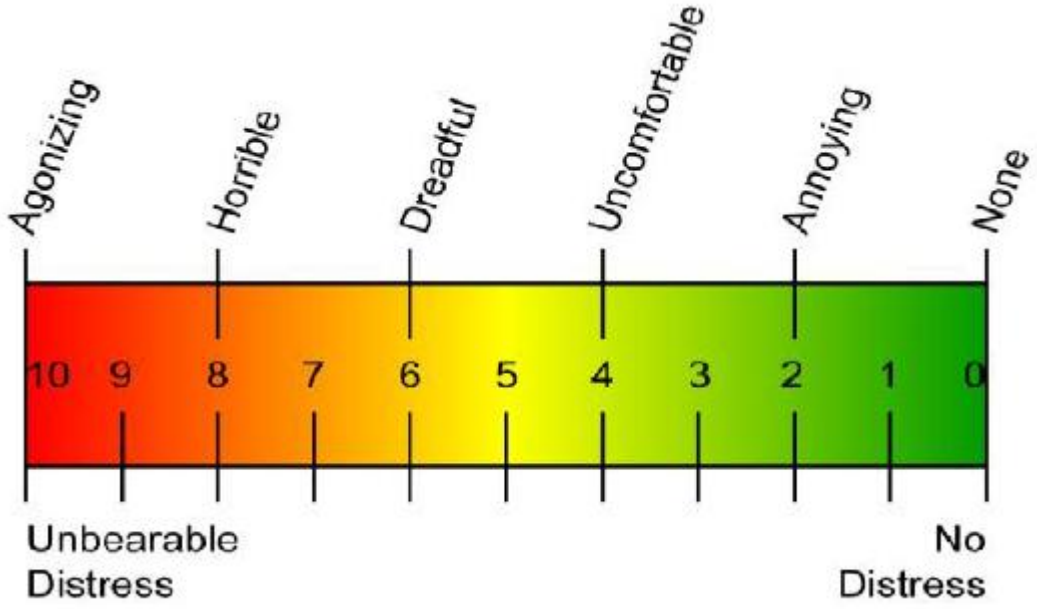


Illustration 5. Visual analogue scale[33]

METHODOLOGY

The present study was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, from January 2016 to December 2016 on 40 patients with posted for elective laparoscopic cholecystectomy.

Study design

The study design was a randomized controlled trial. Study period and duration The present study was carried out for a period of one year from January 2016 to December 2016

Place

This study was done under the Department of General Surgery of a tertiary care teaching hospital attached to KLE University's Jawaharlal Nehru Medical College, Belagavi.

Source of Data

Patients scheduled for elective laparoscopic cholecystectomy were included in the study.

Sample size

The study sample was comprised of 40 patients divided into two groups of 20 each.

$$n = \frac{2(Z\alpha+Z\beta)^2 S^2}{(x_1-x_2)^2} = 20$$

where, n = sample size

$Z\alpha = 1.96$

$Z\beta = 0.84$

S = Standard deviation

x_1-x_2 = effect size

Statistical analysis: Students 't' test.

Sampling procedure

Applying thumb rule, 40 cases of LC were taken up for study. They were divided into two groups of 20 each using computer generated random numbers.

Selection criteria

Inclusion criteria

- Patients aged 20 years and above.
- Patients of either sex.
- Patients with ASA grade I and II with symptomatic cholelithiasis requiring elective LC.

Exclusion criteria

- Uncooperative and unwilling patients.
- Patients with history of anaphylaxis to opioids.
- Patients with ASA grade III, IV and V.
- Immuno compromised patients
- Patients requiring conversion to OC.
- Empyema GB
- Emphysematouc cholecystitis
- GB carcinoma

Ethical clearance

The Ethical Clearance was obtained from the Institutional Ethics Committee, Jawaharlal Nehru Medical College, Belagavi prior to the commencement.

Informed Consent

Those patients who fulfilled selection criteria were briefed about the nature of study and a written informed consent was obtained (Annexure I) prior to the enrolment.

Method of collection of data

Patients satisfying selection criteria were interviewed and the demographic data such as age and sex, presenting complaints were noted. Further the patients were subjected to clinical and systemic examination and the findings were noted on a predesigned and pretested proforma (Annexure II).

Randomization

Patients were randomly assigned to one of the two groups using computer generated random numbers as below.

- Group A (n=20): Patients in this group, GB was retrieved via Epigastric port
- Group B (n=20): Patients in this group, GB was retrieved via Umbilical port

After randomization of the patient has been done and assigned to Group A or B, the same will be informed to the operating surgeon and is kept confidential from the patient post operatively.

Procedure of laparoscopic cholecystectomy

Position

Classical supine position with the patient in 30 degree reverse trendelenburg tilt. Nasogastric tube is used to ensure complete gastric deflation during the procedure, since a distended stomach and duodenal cap can obscure the operative field. The urinary bladder is emptied by a catheter prior to creation of pneumoperitoneum. If catheterization not done, it is important to percuss the suprapubic region to exclude a distended urinary bladder before inserting the Veress

needle. The nasogastric tube is removed at the end of the operation. Part preparation and draping done in the standard manner.

Access to peritoneal cavity

Open technique using the modified Hasson's cannula.

Closed technique using Veress needle.

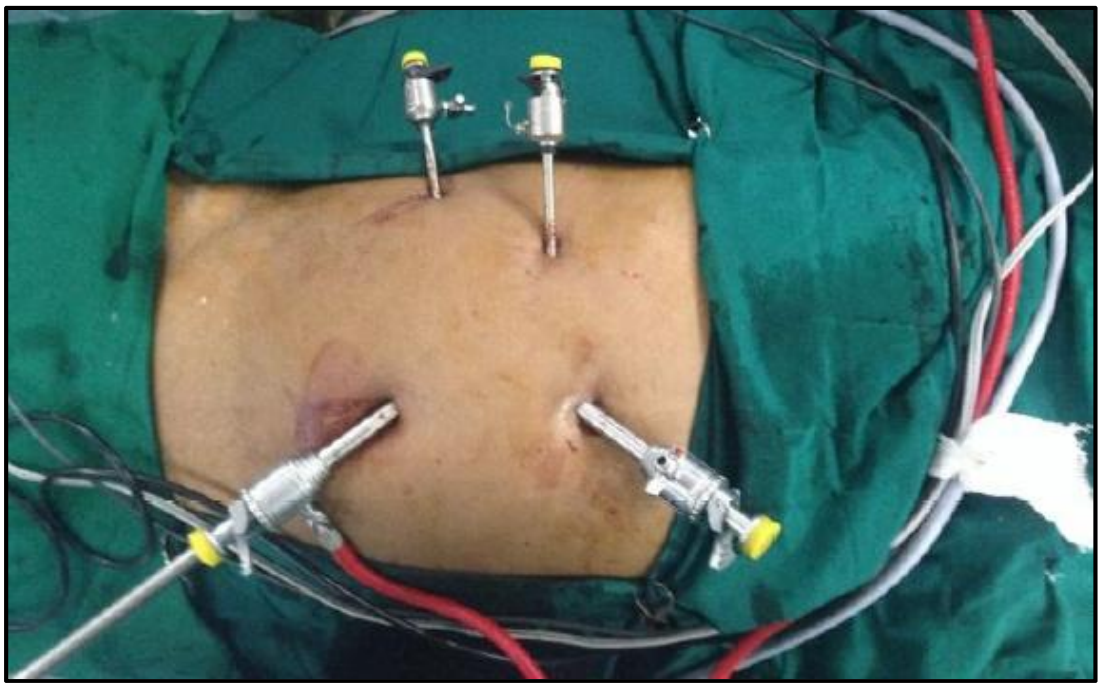


Illustration 6. Port Placement

Insufflation of the peritoneal cavity is done through the Supra umbilical/ Infra umbilical/transumbilical trocar if open technique is adopted, or following insertion of Veress needle if closed technique is adopted, at an initial inflow rate of about 1 L/min. If this process proceeds smoothly without significant change in the cardiovascular changes, the insufflators can be switched to high flow to allow complete filling of the peritoneal cavity to a pressure of approximately 10 to 15 mmHg. During the insufflation all quadrants of the abdomen are percussed to confirm uniform distension. Once pneumoperitoneum is established, a 10 mm port is inserted at the Trans-

umbilical/Supraumbilical/Infraumbilical region, through which the camera (30 degree) is introduced.

Following this the abdomen is inspected for the following;

a. To detect any injury to organs or vessels caused during insufflations and insertion of main trocar.

b. Exclusion of additional unsuspected intra abdominal pathology.

c. Assessment of the feasibility of LC. After inspection, three more ports inserted under vision. A 10mm Right upper paramedian (Epigastric port), placed 1cm lateral to linea alba and 3 cm below the left costal margin (to avoid the falciform ligament). Two 5mm ports placed below the right sub-costal margin in the midclavicular line and 5 cms below the right sub-costal margin in the anterior axillary line.

The cystic pedicle is exposed by grasping the GB fundus which is retracted laterally, superiorly and rolled backwards to expose the subhepatic pouch. A second atraumatic grasper is applied to the Hartmanns pouch which is retracted laterally and inferiorly. The cystic pedicle outlines the margins of the triangle of Calot and contains between it, superior and inferior leaves the cystic duct (usually anteriorly), the cystic artery (above and behind the duct) and the cystic lymph node of Lund.

The prominent anterior free edge of the cystic pedicle is formed as the peritoneum folds over the cystic duct. The dissection of the pedicle is carried out using scissors, or atraumatic graspers and the superior leaf of the pedicle is divided. Once the cystic duct and artery are well exposed, the cystic duct is clipped and cut between the two clippings, followed by the cystic artery which is similarly clipped and cut between the clippings. The dissection is carried out between the loose fibrous layer which separates the gallbladder from the subjacent fascia covering the liver bed.

INTERVENTION: Once separation of gallbladder is complete off the liver bed, it is parked in the Morrisons pouch and an endobag (Sterilized plastic bag of 15x8cm) is inserted via 10mm Epigastric port and was inserted into the peritoneal cavity. The GB along with its contents is inserted into the endobag and the same is then held with claw grasper and extracted via Epigastric port Or Umbilical port (10 mm port) as per randomization. Care is taken to avoid spillage of contents into the peritoneal cavity during the extraction. After this final inspection is done to look for any oozing, if present, heamostasis is achieved. All ports are removed under vision after decompressing the abdominal cavity to evacuate the carbon dioxide. Ports are closed using 1 no. Polyglactin (Vicryl) port closure for the rectus sheath and skin using 3-0 Nylon (Ethilon). Sterile dressing applied.

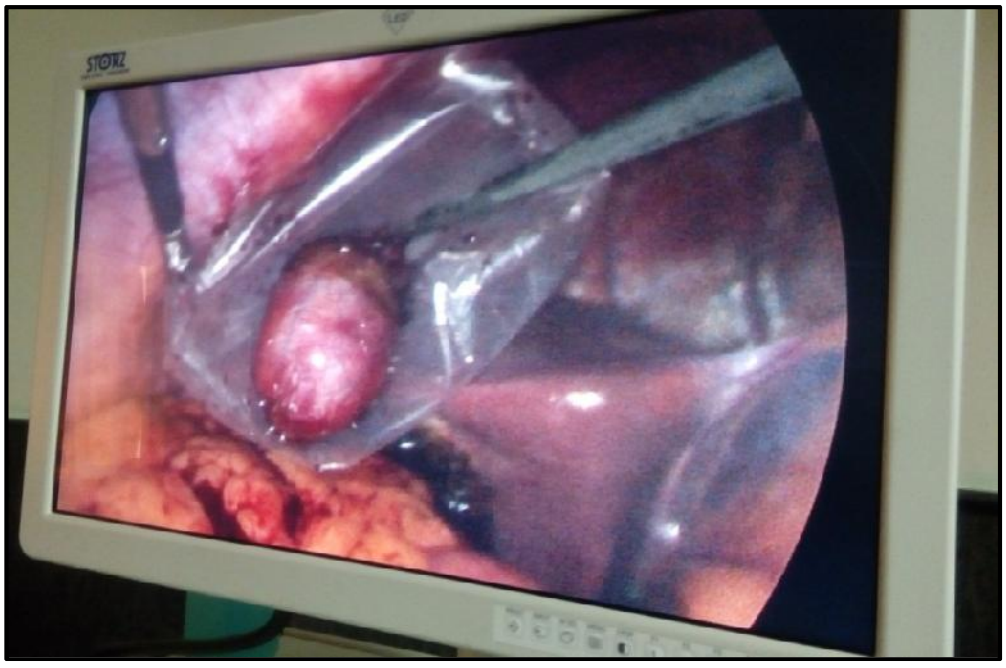


Illustration 7: Placement of GB in the Endobag

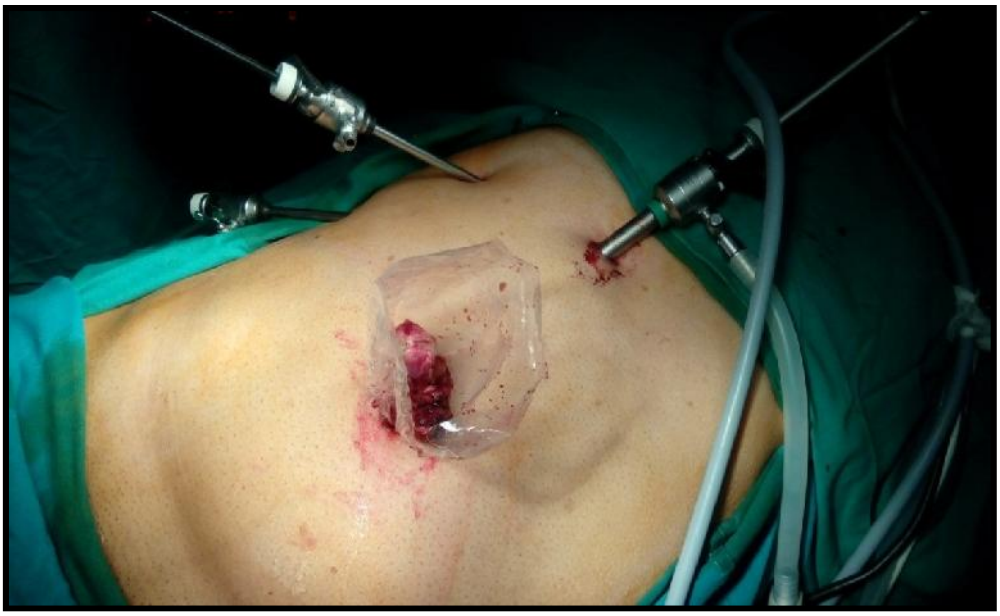


Illustration 8: Retrieval of GB from Umbilical port

Postoperatively patients were extubated and simultaneously Intravenous Paracetamol 20ml/Kg body weight was given as infusion and shifted to recovery room where the primary outcome of pain which was observed and recorded by the surgeon using the VAS at 0, 1, 6, 12 and 24 hours as per the study protocol. As duration of action of 1gm paractemaol is 6 hours, Intravenous Paracetamol 1gm was given every 6^{th} hourly post operatively till 24 hours.

ANALYSIS OF OUTCOMES

Demographics

Patients age, sex, Site of pain abdomen, Mean weight, vitals, Co- morbidities like hypertension and diabetes, mean duration of surgery**,** were assessed and compared between the two groups using Students 't' test**.**

Pain

Pain was assessed using Visual Analogue Score ranging from 0 to 10 considering 0 as no pain and 10 as maximum pain. Visual analogue scale of 0 to 10

was explained to patient during pre op visit, considering zero as no pain, 1 to 3 mild pain, 4 to 7 moderate pain and 7 to 10 severe pain. A score of below 4 out of ten was considered satisfactory. The assessment of pain was done immediate post operatively, 1 hour, 6 hours, 12 hours, and 24 hours post surgery. Patients with VAS greater than or equal to 4 were given inj. Tramadol 50mg iv as a rescue analgesic as onset of action is 15 mins.

Mean VAS scores at different time intervals (immediate post operatively, 1 hour, 6 hours, 12 hours, and 24 hours post surgery), Requirement of rescue analgesia and Severity of pain between the two groups were assessed and compared between the two groups using the students 't' test to ascertain statistical significance, if any.

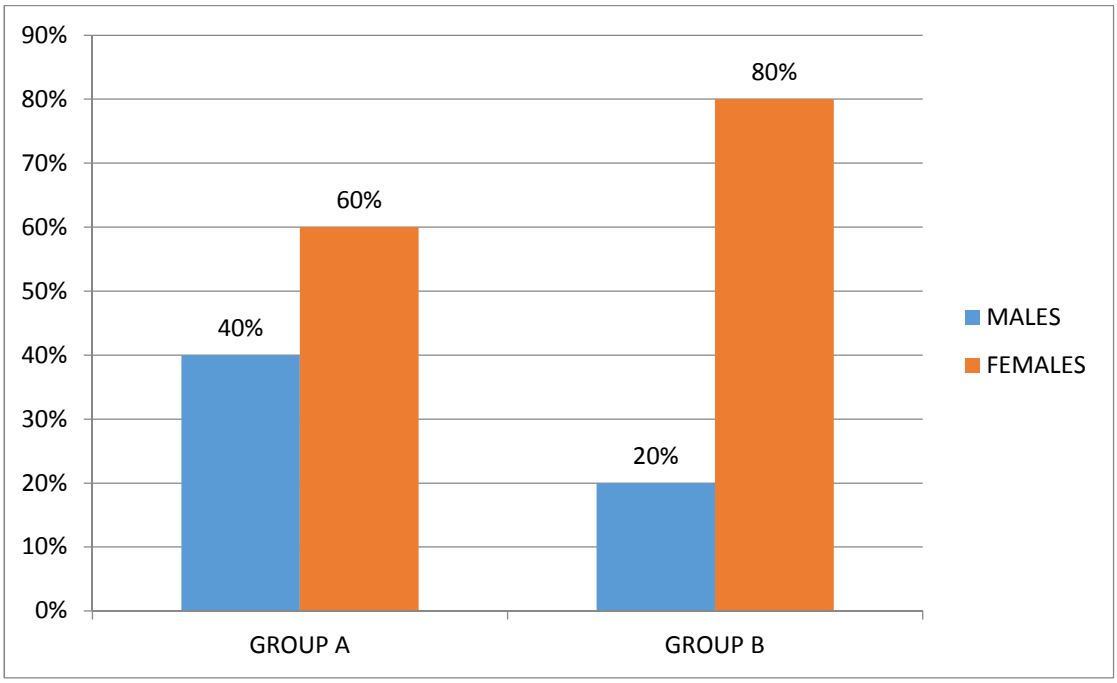
RESULT

The data obtained was tabulated and analysed using Students‘t’ test. The final results and observations were tabulated as below

TABLE 1: SEX DISTRIBUTION

SEX	GROUP A (n=20)		GROUP B (n=20)	
	FREQUENCY	PERCENTAGE	FREQUENCY	PERCENTAGE
MALE	8	40%	4	20%
FEMALE	12	60%	16	80%
TOTAL	20	100%	20	100%

GRAPH 1: SEX DISTRIBUTION

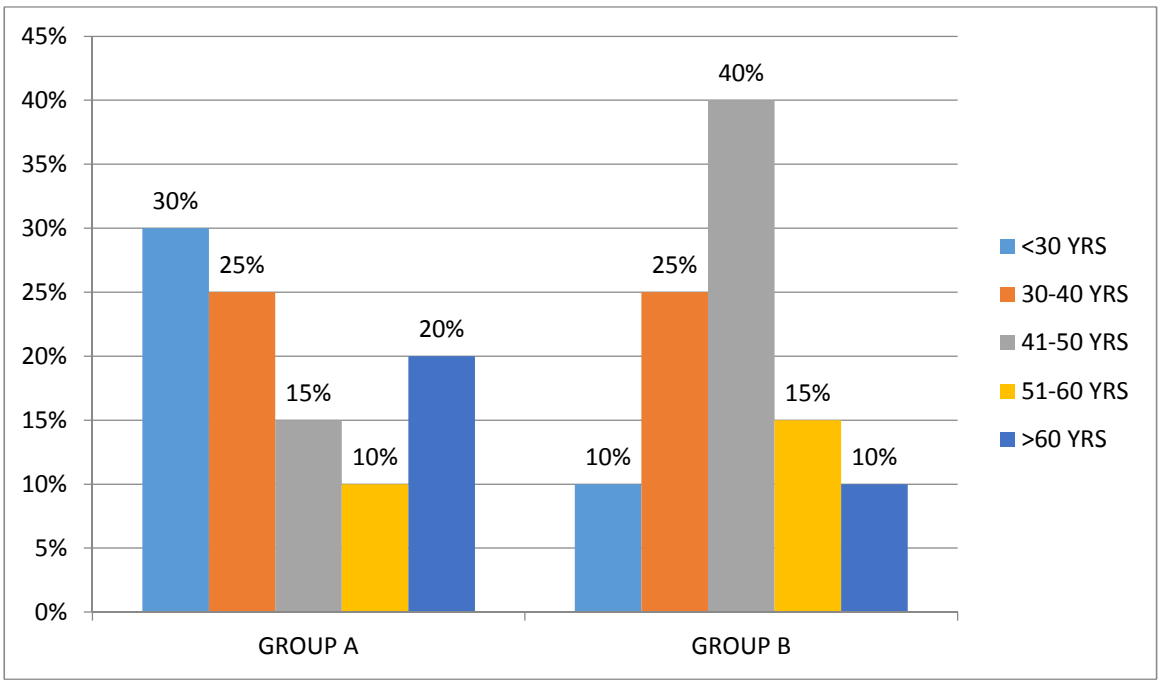


In the present study 30% of the patients were males and 70% were females. The male to female ratio was 1:1.5 in group A and 1:4 in group B. The sex distribution in group A and B was comparable

TABLE 2: AGE DISTRIBUTION

AGE GROUP (YEARS)	GROUP A (n=20)	GROUP B (n=20)
	FREQUENCY (%)	FREQUENCY (%)
<30 YRS	6 (30%)	2 (10%)
30-40 YRS	5 (25%)	5 (25%)
41-50 YRS	3 (15%)	8 (40%)
51-60 YRS	2 (10%)	3 (15%)
>60 YRS	4 (20%)	2 (10%)
TOTAL	20 (100%)	20 (100%)

GRAPH 2: AGE DISTRIBUTION



In this study the commonest age group in patients with group A was <30years (30%) compared to 41 to 50years in group B (40%). However the difference was statistically not significant.

TABLE 3: COMPARISON OF MEAN AGE

VARIABLES	GROUP A (n=20) (MEAN±S.D.)	GROUP B (n=20) (MEAN±S.D)	p value
AGE	42.5±15.00	43.75±10.00	0.7582

In this study the mean age in group A was 42.50 ± 15.00 compared to 43.75 ± 10.00 years. However the difference was statistically not significant (p=0.7582).

TABLE 4: COMPARISON OF OTHER COMORBID CONDITIONS

COMORBID CONDITIONS	FINDINGS	GROUP A (n=20) Number (%)	GROUP B (n=20) Number (%)	P value
Hypertension	Yes	2 (10%)	5 (25%)	0.4053
	No	18 (90%)	15 (75%)	
	Total	20 (100%)	20 (100%)	
Diabetes mellitus	Yes	4 (20%)	2 (10%)	0.6579
	No	16 (80%)	18 (90%)	
	Total	20 (100%)	20 (100%)	

In this study the comorbid conditions including hypertension and diabetes mellitus were comparable in both the groups (p=0.4053 and 0.6579).

TABLE 5: COMPARISON OF CLINICAL EXAMINATION FINDINGS

SIGNS	FINDINGS	GROUP A (n=20) Number (%)	GROUP B (n=20) Number (%)	P value
PAIN IN EPIGASTRIUM	Yes	5 (25%)	6 (30%)	0.7233
	No	15 (75%)	14 (70%)	
	Total	20 (100%)	20 (100%)	
PAIN IN RIGHT HYPOCHONDRIUM	Yes	17 (85%)	18 (90%)	0.6326
	No	3 (15%)	2 (10%)	
	Total	20 (100%)	20 (100%)	

The right hypochondrium pain was present in 87.5% of the patients and epigastric pain in 27.5% of the patients respectively. However these findings were comparable in group A and B ($p>0.050$).

TABLE 6: COMPARISON OF MEAN DURATION OF ABDOMINAL PAIN

VARIABLES	GROUP A (n=20) (MEAN±S.D.)	GROUP B (n=20) (MEAN±S.D)	p value
DURATION (WEEKS)	3.4±0.88	3.7±0.98	0.3148

In this study the mean duration of abdominal pain was comparable in group A and B (3.4 ± 0.88 vs 3.7 ± 0.98 weeks; $p=0.3148$).

TABLE 7: COMAPRISON OF MEANS OF WEIGHT AND VITALS

VARIABLES	GROUP A (n=20)	GROUP B (n=20)	P value
	MEAN±S.D.	MEAN±S.D.	
WEIGHT (KGS)	76.5±8.33	80.45±9.65	0.1739
PULSE RATE (/MINUTE)	81.3±8.71	83.5±4.3	0.3175
RESPIRATORY RATE (/MINUTE)	15.15±2.71	15.1±2.69	0.9536
SBP (mm Hg)	118.4±13.2	118.5±18.2	0.9842
DBP (mm Hg)	73.71±7.8	74.2±7.34	0.8390

Table 7 shows comparison of mean weight and vitals. It was observed that the weight, pulse rate, respiratory rate, systolic and diastolic blood pressure were comparable in both the groups (p>0.050).

TABLE 8: COMPARISON OF MEAN DURATION OF SURGERY

VARIABLES	GROUP A (n=20) (MEAN±S.D.)	GROUP B (n=20) (MEAN±S.D)	p value
DURATION (MINUTES)	73.55±10.6	68.9±10.3	0.1676

In the present study mean duration of surgery was 73.55 ± 10.6 minutes in group A and in group B it was 68.9 ± 10.3 minutes. However the difference was statistically not significant (p=0.1676).

TABLE 9: COMPARISON OF MEAN VAS SCORES AT DIFFERENT INTERVALS

INTERVALS	GROUP A (n=20)	GROUP B (n=20)	P value
	MEAN±S.D.	MEAN±S.D.	
IMMEDIATE POST-OP	2.05±0.6	0.4±0.5	**<0.0001**
1 HOUR	2.4±0.5	0.95±0.69	**<0.0001**
6 HOURS	2.95±0.69	0.9±0.55	**<0.0001**
12 HOURS	3.15±0.67	1.15±0.37	**<0.0001**
24 HOURS	3.65±0.67	1.5±0.61	**<0.0001**

GRAPH 3: COMPARISON OF MEAN VAS SCORES AT DIFFERENT INTERVALS

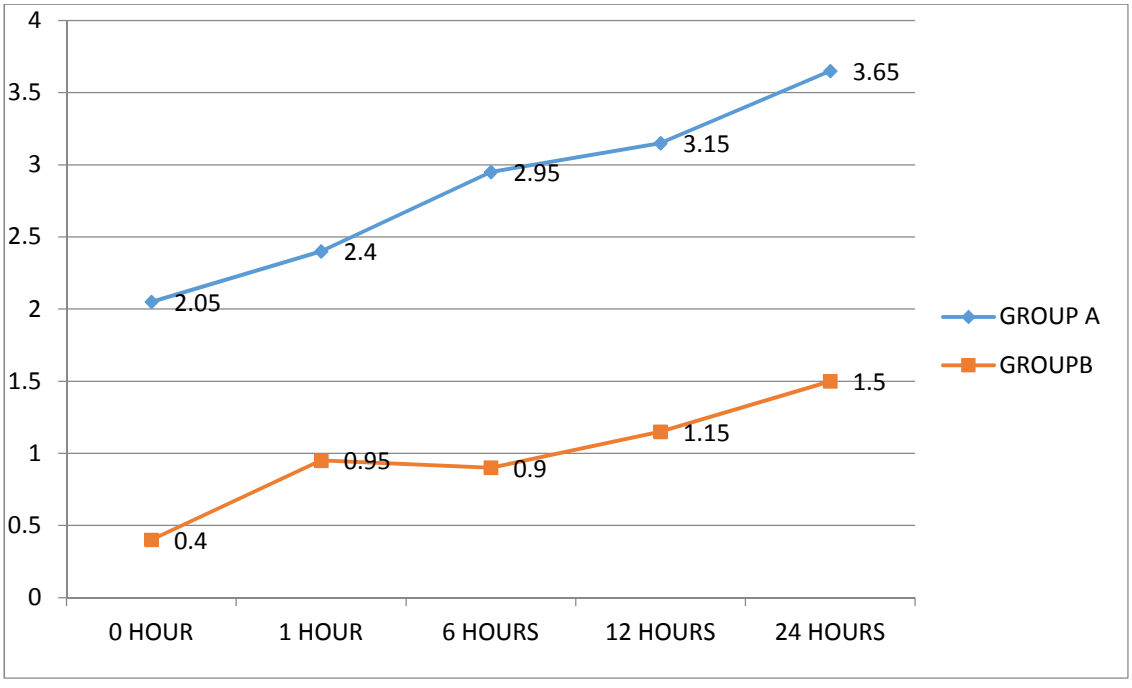


Table 9 and graph 3 shows the mean pain score at different intervals. It was observed that, in patients with group B, the mean pain scores at all the intervals were significantly low ($p<0.050$)

TABLE 10: COMPARISON OF REQUIREMENT OF RESCUE ANALGESIA

INTERVALS	GROUP A (n=20)	GROUP B (n=20)
	N (%)	N (%)
IMMEDIATE POST-OP	0 (0%)	**0 (0%)**
1 HOUR	0 (0%)	**0 (0%)**
6 HOURS	5 (25%)	**0 (0%)**
12 HOURS	5 (25%)	**0 (0%)**
24 HOURS	11 (55%)	**0 (100%)**

Table 10 shows that rescue analgesia was required in 25% of the patients in group A at the 6 hour and 12 hour intervals and 55% at the 24 hour interval. However, in group B, no requirement of rescue analgesia was required.

TABLE 11: COMPARISON OF SEVERITY OF POSTOPERATIVE PAIN

SEVERITY OF PAIN	GROUP A	GROUP B
NO PAIN	0 (%)	0 (0%)
MILD	9 (45%)	20 (100%)
MODERATE	11 (55%)	0 (0%)
SEVERE	0 (0%)	0 (0%)
TOTAL	20 (100%)	20 (100%)

Table 11 shows that in group A, 45% of the patients had mild pain, 55 % of the patients had moderate pin when compared to group B, where all the patients had mild pain only.

DISCUSSION

Despite many advances in laparoscopic cholecystectomy, postoperative pain is still a serious problem, and in most reports, up to 80% of patients ask for analgesics after laparoscopic cholecystectomy[55]. Pain reaches a peak within the first few hours following LC, but diminishes during the next 2 or 3 days. Some patients experience a rather painful early post-operative period, and some dynamic conditions such as coughing and mobilization can further aggravate the pain[52].

Retrieval of gall bladder through a particular port is also associated with further tissue trauma at the port site that contributes to post-operative port site pain. Therefore, we aimed to hypothesize which is a superior port to retrieve the GB which results in lesser post operative port site pain.

In our study, post-operative pain was assessed and the mean VAS score was 3.65±0.67 in Group-A while 1.5±0.61 in Group- B. The p-value was < 0.0001 suggesting that retrieval of GB by umbilical port was associated with lesser post operative port site pain.

A study conducted by Siddique et al, considered umbilical port to be the better port in terms of VAS. In their randomized control trial of 120 patients, patients were randomized to either group A (n = 60, GB retrieval through epigastric/sub xiphoid port) or group B (n = 60, GB retrieval through umbilical port).15 VAS for pain was assessed by a registered nurse at 1, 6, 12, 24 and 36 h after surgery. The VAS for pain at umbilical port was less than subxiphoid port at 6, 12, 24 and 36 h after surgery (5.9±1.1 versus 4.1±1.5, 4.6±0.94 versus 3.5±1.05, 3.9±0.85 versus 2.4±0.79, 3.05±0.87 versus 2.15±0.87, respectively) and the difference was statistically significant (p-value < 0.001)[50].

In a study conducted by Jugendra Pal Singh Shakya et al, post-operative pain, in terms of VAS was 3.67±1.42 in Group-A while 2.47±1.17 in Group-B with 10 being the worst pain. The p-value was calculated as 0.000048. The result is significant at $p<0.05$ with umbilical port being the better port for extraction[51].

A trial done by Nadeem Ahmed Siddiqui et al The VAS for pain at umbilical port was less than epigastric port at 1, 6, 12, 24 and 36 h after surgery (5.9 ± 1.1 vs. 4.1 ± 1.5, 4.6 ± 0.94 vs. 3.5 ± 1.05, 3.9 ± 0.85 vs. 2.4 ± 0.79, 3.05 ± 0.87 vs. 2.15 ± 0.87, respectively) and the difference was statistically significant (p-value < 0.001)[52].

A study conducted by Prem Chand et al concluded in their study that port site pain was significantly more at the epigastric port compared to umbilical port irrespective whether the gall bladder was retrieved via the epigastric port.[53]

Our result is contradictory to the results of the study by Bashir et al where post-operative pain score came out to be 3.54±1.034 in sub xiphoid group while 3.11±1.368 in umbilical group on visual analogue scale of 10 with 10 as worst pain. The difference in 24-hour postoperative pain score was statistically non-significant (p value = 0.089)[54].

Initially in LC, Epigastric port was used to retrieve the GB as covention and became standard practice as described in the books. As there was scarce literature regarding the same, and studies proving increased port site pain at the epigastric port, recent trials have been undertaken to assess other ports to retrieve GB in LC in terms of lesser post operative pain, port site infection. We hypothesized in our study that Umbilical port was a superior port compared to epigastric port in terms of lesser post operative port site pain when GB was retrieved through it in LC

Pain is a subjective phenomenon and is a difficult parameter to assess. Pain has motivational and affective components which might be related to cultural and

previous pain experiences. The difficulty in retrieval of GB from port site where in dilatation of incision by metallic dilators is an important determinant of post operative pain in LC. Other mechanisms of pain other than tissue trauma secondary to GB retrieval are: incision sites within the abdominal wall; the pneumoperitoneum in association with both local (peritoneal and diaphragmatic stretching, acidosis and ischemia) and systemic (hypercarbia causing sympathetic nervous system excitation with an amplification of local tissue inflammatory response) changes; and the ‘‘post cholecystectomy wound’’ within the liver.

Pre-emptive local anaesthesia at port sites is a standard of care at present, is a common measure aimed to reduce pain by one or more of the mechanisms of pain described above[56]. In our study a relatively new intervention was adopted where we assessed retrieval of GB from two ports ports would be associated with lesser post operative pain.

A trial conducted by Tsimoyiannis, E.C., et al. (1998) hypothesized Intraperitoneal Normal Saline Infusion would reduce post operative pain following LC as it causes evacuation of retained intra peritoneal CO2 which causes visceral pain[14]

A similar study conducted by Saadati K et al where intra peritoneal infusion of Soda Bicarbonate versus normal saline for post operative pain relief in LC showed reduction of the acidic milieu of the peritoneum which is one of the mechanisms of pain.[55]

A study done by Yadava A et al, where they compared intraperitoneal bupivacaine-tramadol with bupivacaine-magnesium sulphate for pain relief after laparoscopic cholecystectomy showed that MgSo4 bupivicaine combination reduces post operative pain as Magnesium reduces calcium influx to the cell, and also

antagonises N-methyl-D-aspartate (NMDA) receptors hence reducing both somatic as well as visceral pain[57.]

Limitations in this study were that ours was a single centric study with a sample size of 40. Difficulties in assessing pain, multi factorial causes of post operative pain is a hurdle in terms of coming to a conclusion as to which is the best intervention to reduce post operative pain after LC. Visceral pain and referred pain was not assessed in our study.

We suggest multi centric, larger sample size studies to support a similar hypothesis. Also, further studies should assess somatic pain, visceral pain and referred pain separately and interventions targeted to reduce the same based on their respective mechanisms. Other complications of LC that contribute to post operative pain like surgical site infection should be taken into account in future studies.

We hypothesize there is no single intervention that can reduce post operative pain in LC. Based on previous trials it is clear that there is scope for a multi modal approach to reduce the different types of post operative pain following LC resulting in less morbidity, shorter hospital stay.

CONCLUSION

Based on the findings of this study, it may be concluded that in laparoscopic cholecystectomy, gall bladder retrieval through the umbilical port could be a better alternative to gall bladder extraction via epigastric port in terms of lesser post-operative pain.

Multi centric studies with larger sample size are required to support this hypothesis

SUMMARY

The present study aimed to determine which is a superior port when the gall bladder was retrieved via the epigastric port versus umbilical port in terms of lesser post operative pain.

This one year randomized controlled trial was done with the Department of Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2016 to December 2016. A total of 40 patients posted for elective cholecystectomy were studied. The patients were divided into two groups of 20 each as Group A (Gall bladder retrieved via the Epigastric port) and Group B (Gall bladder retrieved via the Umbilical port)

In the present study mean duration of surgery was 73.55 ± 10.6 minutes in group A and in group B it was 68.9 ± 10.3 minutes. However the difference was statistically not significant (p=0.1676) in patients with group B.

The mean pain scores at all the intervals were significantly low (p<0.050) Rescue analgesia was required in 25% of the patients in group A at the 6 hour and 12 hour intervals and 55% at the 24 hour interval. However, in group B, no requirement of rescue analgesia was required.

In group A, 45% of the patients had mild pain, 55 % of the patients had moderate pain when compared to group B, where all the patients had mild pain only.

Overall, Umbilical port could be better port for retrieval of GB in laparoscopic cholecystectomy in terms of lesser post operative port site pain, lesser requirement of analgesia. In order to support this hypothesis, larger trials at multiple centres are required.

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ANNEXURE-I

Dear Mr/Mrs/Dr_____, you are kindly requested to enrol yourself in a research study titled " A COMPARISON OF POST OPERATIVE PORT SITE PAIN WHEN GALL BLADDER IS RETRIEVED FROM UMBILICAL PORT VERSUS EPIGASTRIC PORT FOLLOWING LAPAROSCOPIC CHOLECYSTECTOMY. A ONE YEAR RANDOMIZED CONTROL TRIAL : SINGLE CENTRIC HOSPITAL BASED STUDY" being conducted by Dr. _____, a post graduate student in M.S. General Surgery and study will be carried out under the direct supervision and guidance of Dr. _____ Professor, Department of General Surgery, Jawaharlal Nehru Medical College, Belagavi.

You have been requested to participate in this as you fit into the laid out criteria for a study 'subject'/ participant.

Your participation in study is voluntary. During the study you will be asked some questions and you are supposed to answer to the best of your knowledge. Your decision whether or not to participate in the study will not affect your treatment in any form during your hospital stay. If you decide to participate you are free to withdraw at any time.

TITLE OF THE STUDY:

"A COMPARISON OF POST OPERATIVE PORT SITE PAIN WHEN GALL BLADDER IS RETRIEVED FROM UMBILICAL PORT VERSUS EPIGASTRIC PORT FOLLOWING LAPAROSCOPIC CHOLECYSTECTOMY. A ONE YEAR RANDOMIZED CONTROL TRIAL: SINGLE CENTRIC HOSPITAL BASED STUDY"

PURPOSE OF THE STUDY:

To determine whether post-operative port site pain is lesser when gall bladder is retrieved via the epigastric port versus umbilical port following a four port elective laparoscopic cholecystectomy at a tertiary care hospital.

PROCEDURE/ INTERVENTION:

If you agree to enrol yourself in my study, you will be interviewed regarding your present, past and family history then you will be clinically examined in detail and investigated accordingly.

You will be randomly allocated using computer generated numbers into group A (GB retrieval from Epigastric port) and group B (GB retrieval from Umbilical port port)

Surgery will be done by a consultant general surgeon under general anesthesia with four ports technique. 10 mm ports were inserted by the open or closed technique as per surgeons choice at Infra umbilical/ Supra umbilical/ Trans umbilical and epigastric regions. Two 5mm ports were placed in the right sub costal region. After completion of dissection, GB was extracted via an Endobag (Sterilized Plastic bag of 15x8cms) either through epigastric or umbilical port as per randomization.

Postoperative analgesia was standardized in both the groups.

Analgesic used in both groups post operatively: Inj Paracetamol 1gm at the time of extubation and every 6^{th} hourly till 24 hours

Rescue analgesic - ; Inj Tramadol 50ml/kg

Outcome i.e. postoperative port site pain was assessed with Visual Analogue score ranging from zero to ten, considering zero as no pain and ten as maximum pain.

Patients were educated about the use of VAS preoperatively (either in clinic or in ward before surgery). Pain was assessed in every patient at both port sites at 0, 1, 6, 12, 24h postoperatively by the assessor (Surgeon).

SAMPLE SIZE= 20 in each group

Analgesic used in both groups post operatively: Inj Paracetamol 1gm at the time of extubation and every 6^{th} hourly till 24 hours

Rescue analgesic - ; Inj Tramadol 50ml/kg

Postoperative pain scores at 0 min, 1hr, 6 hours, 12 hours, 24 hours

RISKS AND BENEFITS:

There potential risks involved with the procedure is same as conventional laparoscopic cholecystectomy procedure and anaesthesia related risks.

Benefits of taking part in this research:

Lesser post operative pain

Lesser requirement of opoids and NSAIDS in post operative period.

Lesser duration of hospital stay.

VOLUNTARY PARTICIPATION / WITHDRAWAL FROM THE STUDY:

Taking part in the study is voluntary. You may choose not to enroll yourself in this study and may choose to leave the study anytime in between.

ALTERNATIVES:

Your decision regarding participation in study will not change present or future health care services offered to you at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. You would simply be excluded from the study

and all your details shall be kept confidential and you will get the routine line of management.

PRIVACY AND CONFIDENTIALITY:

All data collected or disclosed by you during the course of participation of study, will be kept fully confidential. If however during the course it becomes necessary for the progress of the course to disclose the identity, it would be done so only after your informed & written consent.

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

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

AUTHORIZATION TO PUBLISH RESULT:

The results of the study may be used to publish an article. When the results of research published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information obtained in connection with this study and that can be identified with you will remain confidential.

FINANCIAL INCENTIVES FOR PARTICIPATION:

No additional costs shall be incurred upon you for the purpose of this study. It is purely being done with the idea of research and all the cost of study will be borne by the investigator.

COMPENSATION:

In the event that you become injured as a result of taking part in this study, treatment will be offered to you at KLES Dr. Prabhakar Kore Hospital and Medical

Research Centre, Belgaum., or you will be given information about where to receive medical care in which case you/your insurance company will be responsible for the costs. However, no reimbursement, compensation or free medical care will be given.

QUESTIONS/CONTACT DETAILS:

WHOM SHOULD I CONTACT IF I NEED SOME CLARIFICATION OR HELP AT ANYTIME DURING THE STUDY PERIOD?

*You shall be free to contact the below mentioned name & addresses anytime during the study period for any clarification or help as you may desire for.

Dr. _____

M.B.B.S
(Post Graduate Student)
Department of Surgery
Jawaharlal Nehru Medical College
Nehru Nagar, KLE Hospital Road
Belgaum 590010
Mobile – _____

Dr. _____

M S GEN. SURGERY, Professor,
Dept. of General Surgery.
Jawaharlal Nehru Medical College
Nehru Nagar, KLE Hospital Road
Belgaum 590010
Mobile - _____

In case you need any further information regarding your rights as study participant you may contact:

Dr. _____

Chairman
College Ethical Dissertation
And Research Committee,
Jawaharlal Nehru Medical College
Nehru Nagar, KLE Hospital Road
Belgaum 590 010
Mobile – _____

CONSENT STATEMENT:

I the undersigned Mr/Mrs/Dr_____ do hereby give consent for my participation in this research study after being explained in-depth about the important elements of this study in own my vernacular language.

I give this consent voluntarily in my sound mind knowing very well the risks involved and been given enough time to clear my doubts and other queries to participate as a 'subject' in this study. I do hereby also give consent for publication of this article in any media / journal and have no objections whatsoever.

Signature or left thumb print of participant or legally authorized representative

Participant' name_____ Signature_____

Witness'/guardian name _____ Signature_____

Investigator – **Dr. MIHIR SHANKAR** Signature_____

GUIDE - **Dr. V.M. PATTANSHETTI**

Signature_____

Date___/___/____

Place _____

ANNEXURE II – PROFORMA

PROFORMA / QUESTIONNAIRE TO BE USED FOR DATA COLLECION

The proposed proforma / questionnaire to be used for data collection for the study titled "A COMPARISON OF POST OPERATIVE PORT SITE PAIN WHEN GALL BLADDER IS RETRIEVED FROM UMBILICAL PORT VERSUS EPIGASTRIC PORT FOLLOWING LAPAROSCOPIC CHOLECYSTECTOMY. A ONE YEAR RANDOMIZED CONTROL TRIAL: SINGLE CENTRIC HOSPITAL BASED STUDY" ***is as:***

PATIENT DETAILS:

I.P/ O.P.D NO.: ***D.O.A:***

NAME : ***D.O.S:***

SEX :

AGE:

ADDRESS :

Chief Complaints:

PAIN ABDOMEN:

	Yes / No	***Duration***

SITE OF PAIN :
Umbilical region/ right iliac fossa / left iliac fossa/ epigastrium/ left hypochondrium/ right hypochondrium.

TYPE OF PAIN:
Radiating / localized

Throbbing / Pricking / Dull aching
INTENSITY:
Mild / Moderate / Severe

ASSOCIATION WITH FOOD INTAKE: Yes / No
FEVER: Yes / No

DURATION -

DEGREE OF FEVER--
Mild / Moderate / Severe

TYPE OF FEVER----
Continuous / Intermittent / Spiking

VOMITING : Yes/no
Duration and frequency:
Content:

LOSS OF WEIGHT: Yes/No

HISTORY OF ANAPHYLAXIS TO PARACETAMOL/ TRAMADOL: YES / NO

GENERAL EXAMINATION:

Built and Nourishment :

Weight :

PULSE:

BP :

R/R :

TEMPERATURE:

PER ABDOMEN - TENDERNESS

Umbilical port

Epigastric port

Right hypochondrium

Epigastrium
Periumbilical

Left hypochondrium

Left iliac fossa

Hypogastrium

CVS ***NORMAL*** ***ABNORMAL FINDINGS***

RESPIRATORY-

CNS-

INVESTIGATIONS:

CBC :

RBS :

Blood Urea :

Sr. Creatinine:

Bleeding time:

Clotting time:

Urine :

Routine

Microscopy

USG ABDOMEN:-

GROUP : GROUP **A** GROUP **B**

OPERATION DETAILS: -

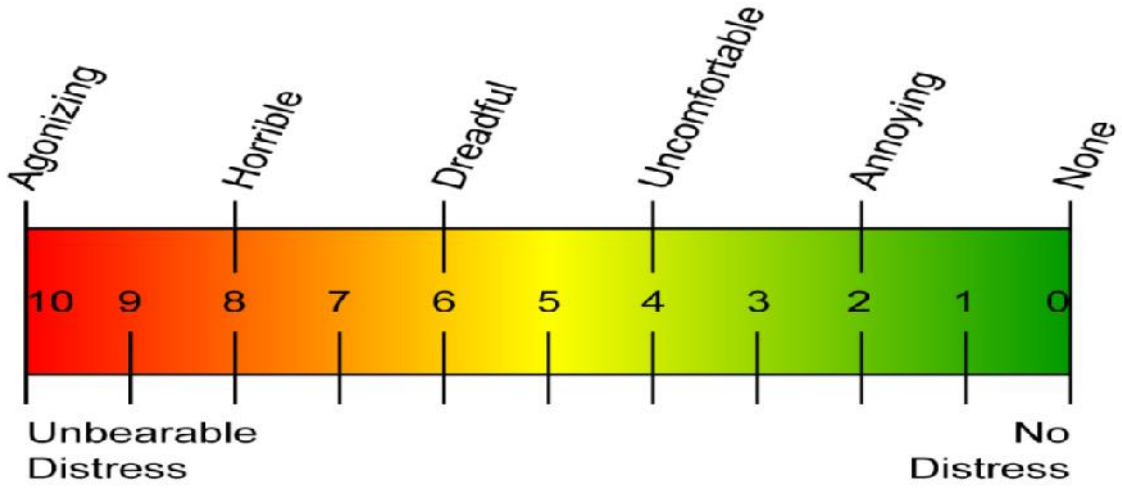
Date of Surgery:

Name of Surgery: LAPAROSCOPIC CHOLECYSTECTOMY

Anaesthesia: GENERAL ANAESTHESIA

Duration of surgery:

ASSESSMENT OF POST OPERATIVE PAIN - VISUAL ANALOGUE SCALE



Task _____

Date _____ *Start* _____ *End* _____

SEVERITY OF PAIN:

0 – NO PAIN

1-3 – MILD PAIN

4-7 – MODERATE PAIN

8-10 – SEVERE PAIN

HRS	**0**	**1**	**6**	**12**	**24**
EPIGASTRIC PORT SITE PAIN					
UMBILICAL PORT SITE PAIN					

KEY TO MASTERCHART

A	-	Group where GB was retrieved via epigastic port
B	-	Group where GB was retrieved via umbilical port
B.P	-	Blood pressure
E	-	Epigastrium
F	-	Female
I.P	-	In patient
M	-	Male
mm Hg	-	Millimetres of mercury
n	-	No
p	-	Present
RH	-	Right hypochondrium
VAS	-	Visual Analogue score
Y	-	Yes

Serial number	IP Number	Group	Sex	Age (Years)	History				Examination					Per abdomen		Duration of surgery (minutes)	Post operative assessment for severity of pain																Severity of pain			
												BP					Pain (VAS Scores at different intervals)									Rescue Analgesia										
					Hypertension	Diabetes	site of pain abdomen	Duration of pain abdomen(Weel	Weight (Kgs)	Pulse rate (/Minute)	Respiratory rate (/Minute)	Systolic (mm Hg)	Diastolic (mm Hg)	Tenderness	Bowel sounds		0 Hour(Epigastric port)	0 Hour(Umbilical port)	1 Hour(Epigastric port)	1 Hour(Umbilical port)	6 Hours(Epigastric port)	6 Hours(Umbilical port)	12 Hours(Epigastric port)	12 Hours(Umbilical port)	24 Hours(Epigastric port)	24 Hours(Umbilical port)	0 Hour	1 Hour	6 Hour	12 Hour	24 Hour	0- No Pain	1-3- Mild Pain	4-7- Moderate Pain	8-10-Severe Pain
1	74439	A	F	60	n	n	RH	3	68	88	11	118	68	n	p	87	2	0	3	0	3	0	3	1	3	2	0	0	0	0	0	n	y	n	n
2	745970	A	M	65	n	n	E	4	75	76	17	122	78	n	p	76	3	1	2	1	4	0	4	0	4	2	0	0	1	1	1	n	n	y	n
3	745854	A	F	43	n	n	RH	3	69	67	14	112	86	n	p	68	2	0	2	0	3	0	3	1	3	1	0	0	0	0	0	n	y	n	n
4	747160	A	M	36	n	n	RH	4	78	89	16	120	80	n	p	80	1	1	3	1	3	0	3	1	4	1	0	0	0	0	1	n	n	y	n
5	747597	A	F	46	n	n	RH	3	89	87	16	110	84	n	p	90	2	1	2	1	3	0	3	1	4	2	0	0	0	0	1	n	n	y	n
6	748527	A	M	28	n	n	RH	4	86	76	12	114	68	n	p	64	1	0	2	1	2	1	3	0	3	1	0	0	0	0	0	n	y	n	n
7	750397	A	F	45	n	n	RH	2	66	78	17	110	74	n	p	77	3	0	3	0	4	0	4	1	5	2	0	0	1	1	1	n	n	y	n
8	750891	A	M	60	n	n	RH	3	78	67	15	124	70	n	p	68	2	0	3	1	3	0	3	1	4	2	0	0	0	0	1	n	n	y	n
9	751545	A	F	62	n	n	RH	4	98	68	15	96	86	y	p	83	2	1	2	0	3	1	3	1	3	1	0	0	0	0	0	n	y	n	n
10	755484	A	F	29	n	n	E	3	78	74	11	112	84	n	p	58	2	0	2	1	2	1	3	0	4	1	0	0	0	0	1	n	n	y	n
11	756213	A	F	35	n	n	RH	4	67	83	13	98	90	n	p	76	2	0	2	1	3	0	3	0	3	2	0	0	0	0	0	n	y	n	n
12	756816	A	F	40	n	n	RH	2	85	91	16	128	62	n	p	70	2	0	2	0	2	0	2	0	3	2	0	0	0	0	0	n	y	n	n
13	756932	A	M	33	n	y	E	3	74	75	14	122	74	n	p	73	1	0	2	0	2	0	3	0	4	1	0	0	0	0	1	n	n	y	n
14	757137	A	F	65	n	n	RH	5	69	84	17	112	84	n	p	68	2	0	2	0	2	1	2	0	3	2	0	0	0	0	0	n	y	n	n
15	758025	A	M	65	y	n	RH	3	74	93	16	148	74	y	p	78	2	0	3	1	3	1	3	0	4	2	0	0	0	0	1	n	n	y	n
16	757905	A	M	28	n	n	RH	2	68	86	12	116	82	n	p	91	2	0	2	0	3	0	3	0	3	2	0	0	0	0	0	n	y	n	n
17	758843	A	M	32	n	y	RH	4	84	77	13	120	74	n	p	54	3	0	3	0	3	0	4	1	4	2	0	0	1	1	1	n	n	y	n
18	763257	A	F	22	n	n	RH	5	75	86	21	124	76	n	p	67	2	0	3	1	4	0	3	1	4	1	0	0	1	1	1	n	n	y	n
19	764922	A	F	28	n	y	RH	3	76	97	20	112	82	n	p	84	3	0	3	1	4	1	5	1	5	2	0	0	1	1	1	n	n	y	n
20	764617	A	F	28	y	n	RH	4	76	84	17	150	64	n	p	59	2	1	2	0	3	1	3	1	3	1	0	0	0	0	0	n	y	n	n
21	763977	B	F	62	y	n	RH	2	76	85	16	144	66	n	p	77	2	0	1	1	1	1	2	1	2	1	0	0	0	0	0	n	y	n	n
22	768147	B	F	38	n	n	E	4	79	87	14	118	88	n	p	65	0	0	1	1	1	2	1	1	1	2	0	0	0	0	0	n	y	n	n
23	775766	B	M	50	n	n	RH	5	98	94	19	108	62	y	p	70	0	0	0	1	1	1	2	2	1	2	0	0	0	0	0	n	y	n	n
24	775552	B	M	45	n	n	RH	3	85	75	18	110	74	n	p	51	0	0	1	1	1	1	2	1	1	2	0	0	0	0	0	n	y	n	n
25	774277	B	F	40	n	n	RH	4	83	84	18	104	76	n	p	66	1	0	0	0	1	0	1	2	2	1	0	0	0	0	0	n	y	n	n
26	776608	B	F	43	y	n	RH	5	75	82	16	154	80	n	p	75	0	0	0	0	1	1	1	1	1	2	0	0	0	0	0	n	y	n	n
27	779265	B	F	28	n	n	RH	3	68	86	17	100	74	n	p	47	0	1	1	1	1	1	1	1	1	1	0	0	0	0	0	n	y	n	n
28	785008	B	F	64	n	n	RH	2	88	84	14	98	64	n	p	89	0	0	0	1	2	1	1	1	1	1	0	0	0	0	0	n	y	n	n
29	786112	B	F	43	n	y	RH	4	85	75	14	122	66	n	p	70	1	1	0	2	0	1	1	1	2	1	0	0	0	0	0	n	y	n	n
30	786821	B	F	35	y	n	RH	5	89	84	12	148	74	n	p	83	0	0	1	1	1	1	1	1	1	2	0	0	0	0	0	n	y	n	n
31	788234	B	F	51	y	y	E	3	77	84	13	146	66	y	p	66	0	0	0	0	2	1	2	1	1	2	0	0	0	0	0	n	y	n	n
32	788865	B	M	45	n	n	RH	4	69	83	16	102	80	n	p	68	1	0	1	1	2	2	2	2	1	3	0	0	0	0	0	n	y	n	n
33	789123	B	F	43	n	n	RH	3	80	76	15	108	74	n	p	65	1	1	0	1	1	1	1	1	2	1	0	0	0	0	0	n	y	n	n
34	789012	B	F	37	n	n	RH	4	70	85	14	102	78	n	p	80	1	1	1	0	1	1	1	1	1	1	0	0	0	0	0	n	y	n	n
35	790167	B	F	42	n	n	RH	3	95	86	16	100	80	n	p	77	0	1	1	2	2	1	1	1	2	1	0	0	0	0	0	n	y	n	n
36	792612	B	M	34	n	n	RH	5	64	84	20	120	82	n	p	73	0	0	1	2	1	0	2	1	1	2	0	0	0	0	0	n	y	n	n
37	793723	B	F	53	n	n	RH	3	78	83	17	112	68	n	p	58	1	0	2	0	0	0	1	1	1	1	0	0	0	0	0	n	y	n	n
38	795672	B	F	23	y	n	RH	4	96	86	10	140	86	y	p	70	0	1	1	2	0	1	1	1	1	1	0	0	0	0	0	n	y	n	n
39	797821	B	F	45	n	n	RH	3	71	83	11	124	76	n	p	58	1	1	1	1	0	1	1	1	2	1	0	0	0	0	0	n	y	n	n
40	799453	B	F	54	n	n	RH	5	83	84	12	110	70	n	p	70	0	1	0	1	1	0	1	1	2	2	0	0	0	0	0	n	y	n	n