PART – 2

SYNOPSIS

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TITLE

“GALLBLADDER BED IRRIGATION WITH ROPIVACAINE IMPROVES PULMONARY FUNCTIONS AFTER LAPAROSCOPIC CHOLECYSTECTOMY”

INTRODUCTION

Laparoscopic cholecystectomy has become the gold standard for the surgical treatment of symptomatic cholelithiasis and replaced conventional open cholecystectomy. [1] It is characterized by a short hospital stay and an early return to regular activity. [2,3] Strategies to handle the different intraabdominal surgical pathologies with a laparoscopic approach offer a significant benefit compared with the conventional technique. [4]

patients who undergo major surgical procedures often develop postoperative respiratory complications including atelectasis and infection. for upper abdominal surgery, the morbidity and mortality range from 20%-25% [5,6]

Impaired diaphragmatic function, type of skin incision, postoperative pain, muscle paralysis, and decreased functional residual capacity have all been found to contribute to postoperative pulmonary dysfunction. Some investigators consider pain to be an important determinant of postoperative pulmonary dysfunction [7]. However, even with good pain relief, lung function as measured by FVC and FEV, decreased to approximately 50%-60% of the preoperative value after abdominal surgery [8]. Several studies indicated that epidural analgesia results in an average improvement of lung function of 15% compared with systemic analgesia [9, 10].

Many researchers determined that a reduction in pulmonary function occurred within the first 6 h after laparoscopic cholecystectomy [11,12]. Reflex inhibition of the diaphragm by afferent stimulus arising from the gallbladder and its bed may be formed in the early phase of the postoperative period.

Studies have shown patients receiving bupivacaine intrapleural have an increase in FEV1 and FVC. The results indicated that bupivacaine provides sustained pain relief and as a result has an effect on pulmonary function. [13]. The advantage of analgesia

has been reported as lack of respiratory depression or hypotension, high quality of pain relief, and simplicity of technique.

Various studies have suggested that diaphragmatic dysfunction possibly results from reflex inhibition of efferent phrenic nerve activity secondary to irritation of splanchnic afferents [14,15]. Diaphragmatic reflex inhibition may happen from the gallbladder bed due to afferent stimulus [16]. It has been proposed that pulmonary functions will improve following laparoscopic cholecystectomy by suppressing this stimulation.

REVIEW OF LITERATURE

Iqbal A et al (2022)[17] studied that the Gallstones in western countries are primarily composed of cholesterol. However, mixed or pigment stones, which contain a higher proportion of bilirubin, are more frequently seen in developing nations and Asia than in western countries. Abdominal and shoulder tip pains (STPs) are common complaints following the standard laparoscopic cholecystectomy procedure. To date, all pain management modalities have proven variable outcomes.

They conducted that prospective randomized study included 82 patients who underwent elective laparoscopic cholecystectomy.

They found that the control group received 20 mL of normal saline, whereas the study group received a 20-mL instillation of 0.5% bupivacaine at the gallbladder bed after surgical resection. The Visual Analog Scale (VAS) was used to analyze abdominal pain and STP. The mean age ranged from 20 to 80 years. Abdominal VAS at 6, 12, 18, 24, 30, 36, and 48 hours were statistically insignificant. The majority were discharged on postoperative day 1 (32 studies, 37 control). Follow-up VAS after 1 week for STP VAS and abdominal pain VAS in both groups were statistically insignificant.

They concluded that even with small numbers of a well-conducted randomized trial, we demonstrated that bupivacaine irrigation at the gallbladder bedpost laparoscopic cholecystectomy does not affect pain relief.[17]

Ahmed T et al (2022)[18] studied that Laparoscopic cholecystectomy is the most commonly done procedure for gallstone diseases and is characterized by a short hospital stay. However, pain is one of the most important reasons for overnight stay following laparoscopic cholecystectomy. This study aims to evaluate the effect of infiltration of bupivacaine at the laparoscopic port sites and intraperitoneal wash of gallbladder bed with bupivacaine on post-operative pain after laparoscopic cholecystectomy.

They conducted a This study included 60 patients undergoing elective laparoscopic cholecystectomy who were prospectively randomized into 2 groups. The placebo group (n = 30) received a saline wash without bupivacaine installed into the gallbladder bed. The bupivacaine group (n = 30) received an intraperitoneal wash of the gallbladder bed with 30 cc of 0.5% bupivacaine and another 20 cc of 0.5% bupivacaine was infiltrated into the port sites.

They found that Pain was assessed at 1, 2, 6, 12, and 24 h post-surgery using a visual analogue scale (VAS). Rescue analgesics used and duration of hospital stay were also recorded. The visual analog

score was significantly lower immediately after laparoscopic cholecystectomy for the bupivacaine group. Patients in the bupivacaine group also required a lower total amount of rescue analgesics during their hospital stay. They also had a shorter hospital stay after laparoscopic cholecystectomy compared to the patients in the placebo group.

They concluded Combined port site infiltration and intraperitoneal irrigation of gallbladder bed with bupivacaine after laparoscopic cholecystectomy significantly decreased early post operative pain and may explain the reduced use of rescue analgesics and earlier discharge of the patients in our study.[18]

Sandhya S et al (2021)[19] studied that aimed to assess the efficacy of intraperitoneal nebulization of local anesthetic in alleviating postoperative pain in patients undergoing laparoscopic cholecystectomy.

They conducted a randomized control double-blinded study was conducted after obtaining approval from the hospital ethics committee and informed consent from patients undergoing laparoscopic cholecystectomy under general anesthesia. Patients recruited were divided into two equal groups of 20 each. Group B received intraperitoneal nebulization with 4 ml of 0.75% ropivacaine and Group C received intraperitoneal nebulization with 4ml of saline before surgical dissection. Postoperative pain score using a numeric rating scale was monitored until 24 h, the need for rescue analgesics and associated complications were noted. Chi-square test, Student's test, and Mann–Whitney U test was used for statistical analysis.

They found that the pain score was significantly less in Group B during rest and deep breathing up to 24 h with a P value <0.05. The pain score on movement was also less in Group B and this difference was statistically significant at 6 and 24 h (P = 0.004 and 0.005, respectively). Tramadol consumption was less in Group B and was statistically significant at 24 h with P value of 0.044. No adverse events were noted.

They concluded that Intraperitoneal nebulization of ropivacaine is effective and safe in providing postoperative analgesia in patients undergoing laparoscopic cholecystectomy.[19]

Akter B et al (2021)[20] studied that to see the analgesic efficacy of port-site infiltration of bupivacaine in laparoscopic cholecystectomy**.**

They conducted a randomized controlled clinical trial was conducted in the Department of Surgery, Sylhet MAG Osmani Medical College Hospital, Sylhet from September 2017 to March 2018. Sixty patients underwent laparoscopic cholecystectomy were randomized into the experimental group and control group by odd and even numbers respectively. Infiltration of 0.5% bupivacaine was at port sites subcutaneously in the experimental group and none in the control group. Postoperative pain intensity was measured using the Numeric Rating Scale (NRS) at 6, 12, 24 and 48 hours.

They found that the Pain score was lesser in the experimental group compared to the control group at 6, 12, 24, and 48 hours ($p< 0.001$). The amount of opioid analgesic needed ($p=0.006$) and hospital stay ($p=0.048$) were significantly lesser in the experimental group. Less frequent nausea/vomiting ($p=0.034$) and bladder dysfunction ($p=0.012$) were in the experimental group.

They concluded that Port-site infiltration of bupivacaine is effective in the reduction of postoperative pain in laparoscopic cholecystectomy.[20]

Paliwal P et al (2020)[21] studied that Laparoscopic cholecystectomy is a well-established procedure for gallbladder disease. Pain in laparoscopic cholecystectomy is associated with multiple factors: somatic, visceral, and phrenic nerve irritation. Effective analgesic support should, therefore, be a multimodal approach following laparoscopic surgery for better patient compliance.

They used A prospective, randomized observational study was undertaken at a tertiary research center for a period of two years (2018-2020). 160 patients undergoing laparoscopic cholecystectomy were chosen and randomized using a computer program into 2 groups. No infiltration was given in the control population. The study group was irrigated with a 0.5% bupivacaine solution (20cc in 30 ml normal saline).

They found that the bupivacaine group required fewer analgesics in comparison to the control faction, with less pain at 6 hrs. The timing of oral intake and ambulation were comparable in both factions.

They concluded that Combined bupivacaine use led to a considerable decrease in postoperative pain thereby leading to decreased analgesic use. [21]

Ravishankar N et al (2018)[22] studied that Laparoscopy involves insufflation of the abdomen by gas, so that the scope (usually 6-10 mm in diameter) can view the intra-abdominal contents without being in direct contact with the viscera or tissues. Surgical procedures can be carried out by instruments produced through one or more additional ports.

They were conducted in 60 patients aged 30-50 years. The patients were divided into two Groups A: 0.5 Bupivacaine, B: Saline intraperitoneal instillation; 30 patients in each group undergoing elective surgery.

They found that the post-operative analgesic effect of 20 mL 0.5% Bupivacaine given intraperitoneally at the end of laparoscopic surgery with control 0.9% saline 20 mL at Bupivacaine group had better postoperative pain relief in the first six hours with no complications.

They concluded 0.5% Bupivacaine irrigation at the surgical bed is effective for cholecystectomy.[22]

Toleska M et al (2018)[23] They evaluated the effect of intraperitoneal infiltration of local anaesthetic (bupivacaine) for pain relief after laparoscopic cholecystectomy.

They conducted a prospective, controlled, and randomized study were included 50 patients aged 25-60 years (35 female and 15 male), scheduled to laparoscopic cholecystectomy with ASA classification 1 and 2. Patients were classified randomly into two groups: group A, which included 25 patients who received intraperitoneal instillation of bupivacaine 0.5% 20 ml; and group B, which included 25 patients who didn't receive any intraperitoneal instillation. Postoperative pain was recorded using the visual analog scale (VAS) for 24 hours after laparoscopic cholecystectomy.

They found that There was no significant difference with respect to age, weight, sex; duration of surgery; or anaesthesia time. VAS scores at different time intervals were statistically significantly lower at all times in group A compared to group B. There were statistically significant differences in VAS scores between group A and group B at all postoperative time points - 1hr,4 hr,8 hr,12hr, and 24hr ($p < 0.00001$).

They concluded that Intraperitoneal instillation of bupivacaine provides good analgesia in the postoperative laparoscopic cholecystectomy.[23]

Bhatia N et al (2018)[24] studied that Intraperitoneal local anaesthetic nebulization is a new and novel technique for providing pain relief following laparoscopic cholecystectomy. We compared the analgesic efficacy of intraperitoneal ropivacaine-fentanyl nebulization with ropivacaine nebulization alone for providing pain relief following laparoscopic cholecystectomy.

They conducted a prospective, randomized, double-blind, placebo-controlled trial included 75 American Society of Anaesthesiologists I/II patients, 18–60 years old, scheduled to undergo laparoscopic cholecystectomy under general anaesthesia. Patients were randomly allocated to one of the three groups of 25 patients each to receive intraperitoneal nebulization using normal saline (group I), 30 mg of 0.75% ropivacaine (group II), or 30 mg of 0.75% ropivacaine with 100 μg fentanyl (group III). Visual analogue scale (VAS) scores for pain during rest and movement, shoulder pain, nausea or vomiting, and sedation were recorded for 48 hours postoperatively. Time to providing first rescue analgesia and 48-hour tramadol consumption were also noted.

They found that significantly greater number of patients in the placebo group had overall VAS >30 both at rest and during movement. Greater number of these patients also complained of postoperative shoulder pain and had significantly more tramadol consumption in the postoperative period. Furthermore, patients in the ropivacaine-fentanyl group demanded first dose of rescue analgesic significantly later than the other two groups.

They concluded that Nebulization results in better and uniform dispersion of analgesic drug intraperitoneally. Following laparoscopic cholecystectomy surgeries, ropivacaine nebulization of intraperitoneal cavity, with or without fentanyl, provides highly effective postoperative analgesia,

with decreased incidence of shoulder pain. Furthermore, addition of fentanyl to ropivacaine prolongs the duration of analgesia. [24]

Geun Joo Choi et al (2015)[25] To systematically evaluate the effect of intraperitoneal local anesthetic on pain characteristics after laparoscopic cholecystectomy. searched MEDLINE, EMBASE, and

the Cochrane Library. Randomized controlled trials in English that compared the effect of intraperitoneal administration of local anesthetics on pain with that of placebo or nothing after elective LC under general anesthesia were included. included 39 studies of 3045 patients in total. The administration of intraperitoneal local anesthetic reduced pain intensity in a resting state after laparoscopic cholecystectomy: abdominal [standardized mean difference (SMD) = -0.741; 95%CI: -1.001 to -0.48, P < 0.001]; visceral (SMD = -0.249; 95%CI: -0.493 to -0.006, P = 0.774); and shoulder (SMD = -0.273; 95%CI: -0.464 to -0.082, P = 0.097). Application of intraperitoneal local anesthetic significantly reduced the incidence of shoulder pain (RR = 0.437; 95%CI: 0.299 to 0.639, P < 0.001). There was no favorable effect on resting parietal or dynamic abdominal pain. Intraperitoneal local anesthetic as an analgesic adjuvant in patients undergoing laparoscopic cholecystectomy exhibited beneficial effects on postoperative abdominal, visceral, and shoulder pain in a resting state. [(25)]

Bablekos GD et al (2014) To present and integrate findings of studies investigating the effects of laparoscopic cholecystectomy on various aspects of lung function. They extensively reviewed literature of the past 24 years concerning the effects of laparoscopic cholecystectomy in comparison to the open procedure on many aspects of lung function including spirometry values, arterial blood gases, respiratory muscle performance, and aspects of breathing control, by critically analyzing physiopathologic interpretations and clinically important conclusions. A total of thirty-four articles were used to extract information for the meta-analysis concerning the impact of the laparoscopic procedure on lung function and respiratory physiopathology. Most of the relevant studies have investigated and compared changes in spirometry parameters. The median percentage and interquartile range (IQR) of preoperative values in forced vital capacity (FVC), forced expiratory volume in 1 s, and forced expiratory flow (FEF) at 25%-75% of FVC (FEF25%-75%) expressed as a percentage of their preoperative values 24 h after LC and OC were respectively as follows: [77.6 (73.0, 80.0) L vs 55.4 (50.0, 64.0) L, P < 0.001; 76.0 (72.3, 81.0) L vs 52.5 (50.0, 56.7) L, P < 0.001; and 78.8 (68.8, 80.9) L/s vs 60.0 (36.1, 66.1) L/s, P = 0.005]. Concerning arterial blood gases, partial pressure of oxygen [PaO2 (kPa)] at 24 or 48 h after surgical treatment showed reductions that were significantly greater in OC compared with LC [LC median 1.0, IQR (0.6, 1.3); OC median 2.4, IQR

(1.2, 2.6), P = 0.019]. Laparoscopic cholecystectomy seems to be associated with less postoperative derangement of lung function compared to the open procedure. [26]

Castillo-Garza G et al (2012) evaluate the effect of bupivacaine irrigated at the surgical bed on postoperative pain relief in laparoscopic cholecystectomy patients. This study included 60 patients undergoing elective laparoscopic cholecystectomy who were prospectively randomized into 2 groups. The placebo group (n=30) received 20cc saline, installed into the gallbladder bed without bupivacaine. The bupivacaine group (n=30) received 20cc of 0.5% bupivacaine at the same surgical site. Pain was assessed at 0, 6, 12, and 24 hours by using a visual analog scale (VAS). A significant difference (P=.018) was observed in pain levels between both groups at 6 hours postoperatively. The average analgesic requirement was lower in the bupivacaine group, but this did not reach statistical significance. The use of bupivacaine irrigated over the surgical bed was an effective method for reducing pain during the first postoperative hours after laparoscopic cholecystectomy. [27]

Cha SM et al (2011) evaluate the effect of perifocal, intraperitoneal, or combined perifocal-intraperitoneal ropivacaine on the parietal, visceral, and shoulder tip pain after laparoscopic cholecystectomy. Eighty patients were randomly assigned to four groups. Group A received perifocal and intraperitoneal saline. Group B received perirectal saline and intraperitoneal ropivacaine. Group C received perifocal ropivacaine and intraperitoneal saline. Group D received perifocal and intraperitoneal ropivacaine. In visceral pain, significantly lower VAS scores were observed in Group B from 2 to 4 h and in Group D from 2 to 8 h. In parietal pain, significantly lower VAS scores were observed in Group C from 4 to 24 h and in Group D from 2 to 12 h. In shoulder tip pain, significantly lower VAS scores were observed in Group B from 4 to 48 h and in Group D from 2 to 12 h. The fentanyl use and the frequency of pushing the button of the PCA were the highest in Group A and the lowest in Group D at every time point. They conclude that perirectal infiltration of ropivacaine significantly decreases parietal pain and intraperitoneal instillation of ropivacaine decreases the visceral and shoulder tip pain. Their effects are additive concerning the total pain. [28]

Mario Bucciero et al (2011) randomized, double-blind study assessed the effects of intraperitoneal local anesthetic nebulization on pain relief after laparoscopic cholecystectomy. Patients undergoing elective laparoscopic cholecystectomy were randomly assigned to receive either instillation of ropivacaine 0.5%, 20 mL after induction of the pneumoperitoneum, or nebulization of ropivacaine 1%, 3 mL before and after surgery. Anaesthetic and surgical techniques were standardized. 60

patients were included; 3 exclusions occurred for conversion to open surgery. There were no differences between groups in pain scores or morphine consumption. No patients in the nebulization group presented significant shoulder pain in comparison with 83% of patients in the instillation group (absolute risk reduction -83, 95% CI -97 to -70, P<0.001). 60 patients were included; 3 exclusions occurred for conversion to open surgery. There were no differences between groups in pain scores or morphine consumption. No patients in the nebulization group presented significant shoulder pain in comparison with 83% of patients in the instillation group (absolute risk reduction -83, 95% CI -97 to -70, P<0.001). [29]

Ige OA et al (2011) to enhance patient comfort with improved analgesia and reduced opioid requirements. a prospective, randomized, placebo-controlled study, 46 patients (23 per group) scheduled for elective gynecological surgery under general anesthesia had subcutaneous and intravesical wound infiltration of 40 ml, 0.25% bupivacaine (study patients) or 40 ml 0.9% saline (control) just before the end of surgery. PEFR, FVC, and FEV1 were reduced in both the control and study groups but the reduction was greater in the control group. Bupivacaine wound infiltration produced statistically significant elevations in pulmonary function test results at all assessment periods. [30]

Alptekin H et al (2010) A randomized prospective study evaluated this hypothesis in patients who underwent laparoscopic cholecystectomy. During the study period, 30 patients who underwent laparoscopic cholecystectomy were randomly divided into three groups. Group I: Laparoscopic cholecystectomy; Group II: Laparoscopic cholecystectomy + irrigation of gallbladder bed with 20 mL 0.5% bupivacaine solution; Group III: Laparoscopic cholecystectomy + irrigation of gallbladder bed with bupivacaine + 10 mL 0.5% bupivacaine solution was given via a catheter every 6 h. Pulmonary function tests were performed on the day before the operation and the morning of the first postoperative day. Forced vital capacity (FVC), forced expiratory volume at 1 s (FEV-1), and forced expiratory flow at 25% to 75% (FEF 25-75%) were obtained. postoperative FVC measured 53.3 +/- 4.5% of preoperative function for group I, 70.8 +/- 5.7% for group II, and 68.8 +/- 4.7% for group III ($p < 0.05$). Postoperative FEV-1 measured 52.8 +/- 5.3% of preoperative function for group I, 69.7 +/- 4.9% for group II, and 70.5 +/- 5% for group III ($p < 0.05$). The results from this study indicated that considerable improvement in pulmonary function was acquired by gallbladder bed irrigation with bupivacaine after laparoscopic cholecystectomy. [31]

Research Question-

Is there any improvement in pulmonary functions after Gallbladder bed irrigation with ropivacaine, when used as an adjunctive technique during laparoscopic cholecystectomy?

Hypothesis

H0 - Gallbladder bed irrigation with ropivacaine, when used as an adjunctive technique during laparoscopic cholecystectomy, will result in no improvement in pulmonary functions compared to standard laparoscopic cholecystectomy without ropivacaine irrigation.

H1 –Gallbladder bed irrigation with ropivacaine, when used as an adjunctive technique during laparoscopic cholecystectomy, will result in improved pulmonary functions compared to standard laparoscopic cholecystectomy without ropivacaine irrigation.

AIM: -

To investigate the impact of gallbladder bed irrigation with ropivacaine on postoperative pulmonary functions in patients undergoing laparoscopic cholecystectomy.

1. Primary Objective:

1. To assess whether ropivacaine irrigation in the gallbladder bed reduces postoperative pain and opioid consumption following laparoscopic cholecystectomy.
2. To compare the postoperative pulmonary function parameters, including forced vital capacity (FVC) and forced expiratory volume in one second (FEV1), between patients who receive gallbladder bed irrigation with ropivacaine and those who do not.

2. Secondary Objectives:

1. To measure and compare postoperative pain scores (using standardized pain scales, e.g., Visual Analog Scale) between the ropivacaine irrigation group and the control group.
2. To evaluate the safety and feasibility of gallbladder bed irrigation with ropivacaine as an adjunctive technique in laparoscopic cholecystectomy.

RESEARCH METHODOLOGY

1) **STUDY DESIGN:** Prospective Randomised Controlled Trial.
2) **STUDY SITE:** The study will be conducted at a tertiary care hospital in the anaesthesia department.
3) **STUDY DURATION:** The study will be conducted over a period of 2years

Finalization of broad thesis topic with guide	1 month
Review of literature	2 months
IEC Approval	1 month
Data collection	14 months
Data Analysis	3 months
Report writing	2 months
Submission of the dissertation to the university	Aug 2024/July 2025

4) **STUDY SIZE:** About 60 patients are estimated to be included in the study.

Two-sided significance level(1-alpha): 95

Power (1-beta, % chance of detecting): 80

The ratio of sample size, $n_1 : n_2 = 1:1$

Percent of Unexposed with Outcome: 5

Percent of Exposed with Outcome: 25

Odds Ratio: 6.3

Risk/Prevalence Ratio: 5

Risk/Prevalence difference: 20

Sample Size – n_1 49

Sample Size - n_2 49

For our convenience sample size taken 50-50 for each group.

Sample size: - **100** (50 – Group 1; 50-Group 2.)

5. SELECTION CRITERIA:

Inclusion Criteria:

1. Surgical Procedure:
   Patients who are scheduled to undergo laparoscopic cholecystectomy (gallbladder removal) for gallstone disease or other appropriate indications.
2. Age Range:
   Adult patients are typically between the ages of 18 and 75 years.
3. Medical Fitness:
   Patients who are medically fit for surgery, as determined by preoperative assessments, including cardiopulmonary evaluations.
4. Informed Consent:
   Patients who provide informed consent to participate in the study and comply with study requirements. [1]

Exclusion Criteria:

1) Contraindications to Ropivacaine:
   Patients with known allergies or contraindications to ropivacaine, the agent used for gallbladder bed irrigation.
2) Pregnancy or Lactation:
   Pregnant or lactating patients, as the safety of ropivacaine use during pregnancy and lactation, may not be established.
3) Chronic Respiratory Conditions; Severe Cardiovascular Disease; Severe Liver or kidney disease.
4) History of Allergic Reactions; Current Medications; Patients currently taking medications that may interact with ropivacaine or affect pulmonary function, particularly medications that influence neuromuscular function or respiratory depression.

5) Patients who are not willing to participate in the study; and participated in other clinical trials. [1]

4. PRETREATMENT PROTOCOLS:

Group 1: - Laparoscopic cholecystectomy;

Group 2: - Laparoscopic cholecystectomy + Irrigation of gallbladder bed with 20 mL 0.5% ropivacaine solution; [1,]

5. OUTCOME MEASURES:

Primary Outcome: Assess and compare the incidence and severity of pain during propofol injection using a validated pain scale (e.g., Visual Analog Scale).

Secondary Outcomes: Include factors such as heart rate, blood pressure, adverse events, and patient satisfaction.

ETHICAL CONSIDERATION:

The study will be conducted after obtaining permission from the Institutional Ethical Committee and the Department of Anaesthesia of Grant Government Medical College and Sir J.J. Group of Hospital, Mumbai.

All the data collected will be strictly confidential and used for the purpose of this study as described below. Written informed consent (in English/ Hindi/ Marathi) will be taken from the subjects and/or their attendants before the recruitment of the subjects in the study. Any deviations from the below-given methods/ procedure will be informed to the Institutional Ethics Committee and only after its approval, any changes will be made. The proforma for the written informed consent is given herewith.

STUDY PROCEDURE:

Patient characteristics: -

During the study period, 30 patients who underwent laparoscopic cholecystectomy were randomly divided into two groups.

During the study period, 30 female patients suffering from symptomatic cholelithiasis were enrolled in this study at the Department of General Surgery, tertiary care hospital, Mumbai.

By using selection criteria (Inclusion and exclusion) 30 patients were included in the study after their consent form. Exclusion criteria were acute cholecystitis, choledocholithiasis, age more than 45, and obesity (defined as body mass index more than 29). Patients who had previous cardiopulmonary disease, smoking history, and upper abdominal operations were also excluded. In addition, the patients were excluded who had iatrogenic gallbladder perforation during the operation.

All patients accepted and signed the informed consent form allowing attendance at the study. (All patients had ASA I and ASA II physical status.

Group I: Laparoscopic cholecystectomy;

Group II: Laparoscopic cholecystectomy + Irrigation of gallbladder bed with 20 mL 0.5% ropivacaine solution; (1,2)

Pulmonary function tests were performed on the day before the operation and in the morning of the first postoperative day. Forced vital capacity (FVC), forced expiratory volume at 1 s (FEV-1), and forced expiratory flow at 25% to 75% (FEF 25–75%) was obtained.

We decided that 15 patients in each group would be suitable for this study. [1]

Pulmonary function studies: -

1. Pulmonary function testing was performed on the day before the operation and the morning of the first postoperative day.

2. Spirometry studies were performed using the MIR Spirolab II® spirometer by the same physician who was unaware of the nature of the study. Forced vital capacity (FVC), forced expiratory volume at 1 s (FEV-1), and forced expiratory flow at 25% to 75% (FEF 25–75%) was obtained.

3. Bronchodilator drugs were not administered during the testing. A fraction of the baseline pulmonary function was calculated by dividing the postoperative value by the preoperative value and multiplying by 100%. Data are presented as mean ± SD. [1]

Treatment protocol and surgical procedure: -

1. Suitable patients were divided into three groups consisting of 15 patients by simple randomization sampling. Laparoscopic cholecystectomy was performed alone in group I. For the patients in group II, after laparoscopic cholecystectomy and removal of the gallbladder, its bed was irrigated with 20 ml 0.5% ropivacaine solution.

2. Laparoscopic cholecystectomy was performed using a four-trocar technique. During laparoscopy, intra-abdominal pressure was maintained automatically at 12 mmHg by carbon dioxide insufflator. During the first 24 hours after operation, methimazole 1 g was given every 6 hours as necessary. [1]

DATA COLLECTION AND ANALYSIS:

After obtaining IEC Approval, data collection will be started. The patients selected under the study approved all the criteria for selection, case record form will be filled out. All data collected from patients will be compiled in a Microsoft Office Excel sheet and will be analyzed. Results will be displayed in a tabular and graphical format. Appropriate statistical tests will be applied wherever necessary.

PROCEDURE/ ENROLLMENT

After obtaining approval from the ethical committee and written informed consent from participant's parents this study will be started including patients with inclusion criteria for surgery.

Preanesthetic evaluation will be done. Patients will be randomly allotted in two groups. Routine investigations like blood grouping, haemoglobin, blood urea, blood sugar, platelet count and ECG will be assessed. Patients will be randomly divided into two groups of 24 patients each: Group I and Group II.

Patients will be kept nil oral for 6 hours before the surgery. Patients will be shifted to the operation theatre and Pulse oximeter; non-invasive blood pressure and ECG monitors will be connected.

Anaesthesia was induced and maintained using intravenous propofol, together with opioids. Neuromuscular monitoring was performed with VAS scale.

RANDOMIZATION (Allocation)

GROUP-I	**GROUP-II**
Patients undergoing Laparoscopic cholecystectomy. (15 patients).	Patients undergoing (15) Laparoscopic cholecystectomy + Irrigation of gallbladder bed with 20 mL 0.5% ropivacaine solution.

FOLLOW-UP

Pulmonary function studies: -

1. Pulmonary function testing was performed on the day before the operation and in the morning of the first postoperative day.

Treatment protocol and surgical procedure: -

1. Suitable patients were divided into three groups consisting of 15 patients by simple randomization sampling. Laparoscopic cholecystectomy was performed alone in group 2. For the patients in group II, after laparoscopic cholecystectomy and removal of the gallbladder, its bed was irrigated with 20 ml 0.5% ropivacaine solution.

ANALYSIS

Outcome Measures: -

a) Assess and compare the incidence and severity of pain during propofol injection using a validated pain scale (e.g., Visual Analog Scale)..
b) Include factors such as heart rate, blood pressure, adverse events, and patient satisfaction.

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Annexure A

"GALLBLADDER BED IRRIGATION WITH ROPIVACAINE IMPROVES PULMONARY FUNCTIONS AFTER LAPAROSCOPIC CHOLECYSTECTOMY"

Group: ASA: Date:

Patient's initials: Reg. No:

Age: years Sex: Weight: Kg

Height: BMI: kg/m^2

Diagnosis: Posted for:

HISTORY

H/o medical or surgical illness:

H/o drug intake:

H/o neuromuscular blockade, abnormal LFT/ RFT.

H/o Allergy:

H/o cardiovascular, respiratory, CNS problems:

Birth history:

Family history:

Personal history:

GENERAL EXAMINATION:

General condition:

Pulse: /minute

B.P:

Respiratory Rate:

Pallor:	Lymphadenopathy:
Icterus:	Oedema:
Clubbing:	Cyanosis:

SYSTEMIC EXAMINATION:

Respiratory system:

Cardiovascular system:

Per Abdomen:

Central nervous system:

Local examination of the spine:

AIRWAY ASSESSMENT:

Mouth Opening:

MPC Grade:

Teeth:

Oral Cavity:

INVESTIGATIONS:

Hb, TC, Platelets:

Liver Function Tests:

Kidney Function tests:

Bleeding time, Clotting time:

Blood Sugar Level:

Electrocardiogram (ECG):

Chest X-ray:

MONITORING

- NAME: MRD NO: UNIT:
- AGE: SEX: MPC:
- WEIGHT: HEIGHT: BMI: Kg/m
- DIAGNOSIS
- SURGERY:
- DURATION OF SURGERY:

INTRAOPERATIVE:

TIME	HR	SBP	RR	Spo2
0min				
3min				
6min				
10min				
20min				
30min				
40min				
50min				
60min				
70min				
80min				
90min				
100min				

110min				
120min				
130min				
140min				
150min				
160min				
170min				
180min				

- **RHYTHM CHANGES IN ECG: PRESENT ABSENT**

➢ The ASA score[32]: -

I. The patient is a completely healthy fit patient.

II. The patient has mild systemic disease.

III. The patient has a severe systemic disease that is not incapacitating.

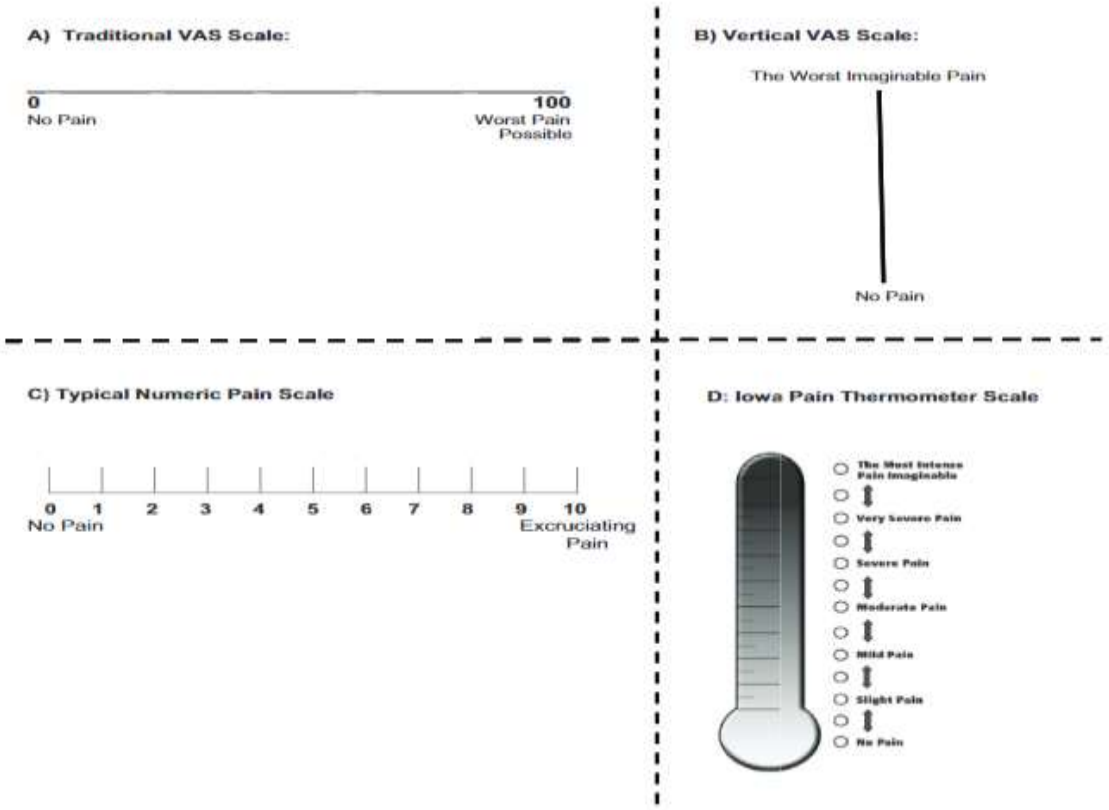
IV. The patient has an incapacitating disease that is a constant threat to life.

V. A moribund patient who is not expected to live 24 hours with or without surgery.

POSTOPERATIVE:

	15mins	**30mins**	**1hr**	**2hrs**	**4hrs**	**6hrs**	**12hrs**	**24hrs**
HR								
SBP								
RR								

VAS – visual analog scale [34]



ANNEXURE 2

INFORMED CONSENT

I Mr/Mrs……age ……Years hereby give my consent to participate in the

"GALLBLADDER BED IRRIGATION WITH ROPIVACAINE IMPROVES PULMONARY FUNCTIONS AFTER LAPAROSCOPIC CHOLECYSTECTOMY"

1. There is no compulsion on me to participate in this project and I am giving my free consent for it.
2. I am ready and willing to undergo all tests and treatments in the present project.
3. I have read and I have been explained the general information and purpose of the present project.
4. I have been informed / I have read the probable complications while participating in the presentproject.
5. I know that I can withdraw from the present project at any time.
6. Any data or analysis of this project will be purely used for scientific purposes and my name will bekept confidential except when required for any legal purpose.
7. I can read English / I can understand data read out to me in English.

Date:

Name and Signature of the study participant: Thumbprint:

Name and Signature of the investigator:

ANNEXURE 2

सूचित सहमति प्रपत्र

मैं, श्रीमान/श्रीमती

,_____आयु_____ वर्ष

एतद्द्वारा "में भाग लेने के लिए मेरी सूचित सहमति देता हूँ"

पूर्ण शीर्षक : **"रोपिवैकेन लेप्रोस्कोपिक से पित्ताशय की सिंचाई के बाद फेफड़ा के कार्यों में सुधार होता है"**

1. इस परियोजना में भाग लेने के लिए मुझ पर कोई बाध्यता नहीं है और मैं इसके लिए अपनी स्वतंत्र सहमति दे रहा हूं।
2. मैं वर्तमान परियोजना में सभी परीक्षणों और उपचारों से गुजरने के लिए तैयार और तैयार हूं।
3. मैंने पढ़ा है और मुझे वर्तमान परियोजना की सामान्य जानकारी और उद्देश्य के बारे में बताया गया है।
4. मुझे सूचित किया गया है / मैंने वर्तमान परियोजना में भाग लेने के दौरान संभावित जटिलताओं को पढ़ा है।
5. मुझे पता है कि मैं किसी भी समय वर्तमान परियोजना से हट सकता हूं।
6. इस परियोजना के किसी भी डेटा या विश्लेषण का उपयोग विशुद्ध रूप से वैज्ञानिक उद्देश्य के लिए किया जाएगा और मेरा नाम गोपनीय रखा जाएगा जब तक कि किसी कानूनी उद्देश्य के लिए आवश्यक न हो।
7. मैं हिन्दी पढ़ सकता/सकती हूं / मैं हिन्दी में पढ़े गए डेटा को समझ सकता हूं।

दिनांक :

अध्ययन प्रतिभागी का नाम और हस्ताक्षर

अंगूठे का निशान

अन्वेषक का नाम और हस्ताक्षर

ANNEXURE 2

सूचित संमती फॉर्म

मी, श्री/श्रीमती,

_____

____वय,_ ____ वर्षे

याद्वारे सहभागी होण्यासाठी माझी सूचित संमती द्याया प्रकल्पात सहभागी होण्यासाठी माझ्यावर कोणतीही सक्ती नाही आणि मी त्यासाठी माझी विनामूल्य संमती देत आहे.

. शीर्षक: **''रोपीव्हाकेन सिंचन लॅपरोस्कोपिक स्वादुपिंडाचा दाह: सिंचन प्रक्रियानंतर पित्ताशयातील पलंगाचे आणि फुफ्फुसाचा कार्ये सुधारते.''**

1. या प्रकल्पात सहभागी होण्यासाठी माझ्यावर कोणतीही सक्ती नाही आणि मी त्यासाठी माझी विनामूल्य संमती देत आहे.

2. मी सध्याच्या प्रकल्पातील सर्व चाचण्या आणि उपचारांना सामोरे जाण्यास तयार आणि तयार आहे.

3.मी वाचले आहे आणि मला सामान्य माहिती समजावून सांगितली आहे
आणि सध्याच्या प्रकल्पाचा उद्देश.

4. मला माहिती देण्यात आली आहे / मी सध्याच्या प्रकल्पात भाग घेत असताना संभाव्य गुंतागुंत वाचल्या आहेत.

5.मला माहित आहे की मी सध्याच्या प्रकल्पातून कधीही माघार घेऊ शकतो.

6.या प्रकल्पाचा कोणताही डेटा किंवा विश्लेषण पूर्णपणे वैज्ञानिक हेतूसाठी वापरला जाईल आणि कोणत्याही कायदेशीर कारणासाठी आवश्यक असल्याशिवाय माझे नाव गोपनीय ठेवले जाईल.

7.मी मराठी वाचू शकतो / मला मराठी वाचलेला डेटा समजू शकतो

तारीख:

अभ्यासात सहभागी झालेल्या व्यक्तीचे नाव आणि स्वाक्षरी अंगठ्याची छाप

अन्वेषकाचे नाव आणि स्वाक्षरी

FINANCIAL DISCLOSURE

I, **DR**. **XXXX YYYY**, HAVE A DISSERTATION STUDY ENTITLED **"GALLBLADDER BED IRRIGATION WITH ROPIVACAINE IMPROVES PULMONARY FUNCTIONS AFTER LAPAROSCOPIC CHOLECYSTECTOMY"** THIS IS A PURELY RESEARCH-ORIENTED STUDY. NO HARM WILL BE CAUSED TO THE ENROLLED SUBJECTS/PATIENTS BY ANY MEANS. ANY EXPENSES RELATED TO THE STUDY WILL BE BORNE BY ME. NO EXPENSES WILL BE BORNE BY SUBJECTS/PATIENTS OTHER THAN TREATMENT AND/OR INVESTIGATIONS WHICH HE HAS TO DO NORMALLY FOR HIS ROUTINE TREATMENT.

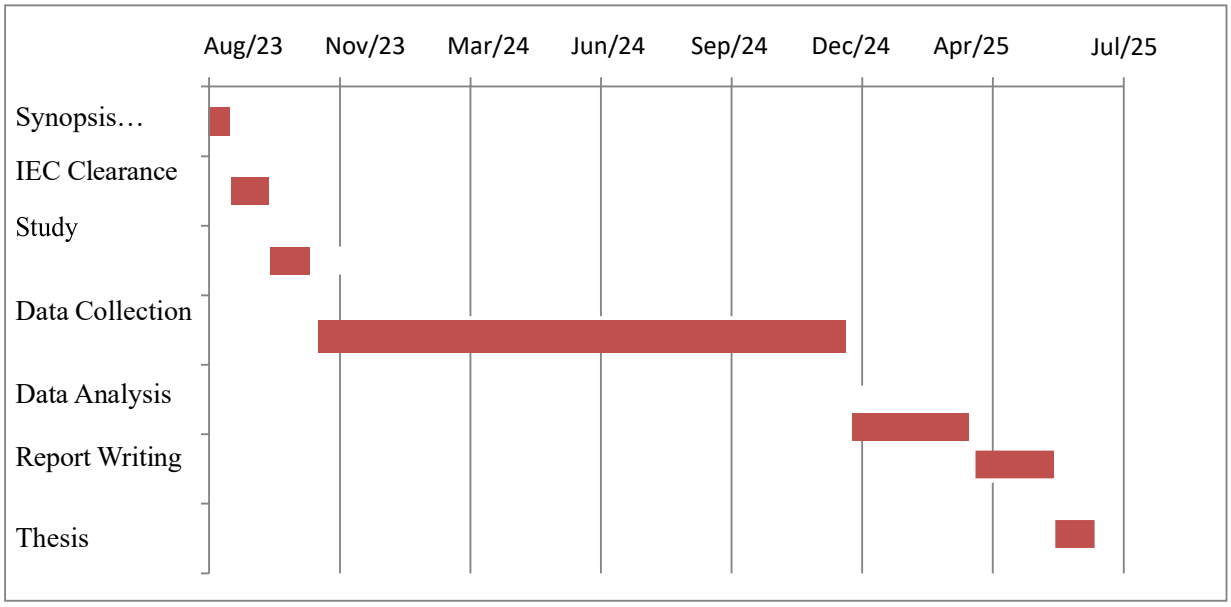
DR. XXXX YYYY

SIGN

DR. XXXX YYYY

PG GUIDE SIGN

GANTT CHART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Synopsis…
IEC Clearance
Study
Data Collection
Data Analysis
Report Writing
Thesis