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A COMPARATIVE STUDY TO EVALUATE THE PRE-EMPTIVE ANALGESIA BY INTRA PERITONEAL INSTILLATION OF ROPIVACAINE WITH DEXAMETHASONE VERSUS ROPIVACAINE ALONE VERSUS NORMAL SALINE IN PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY – A RANDOMIZED CLINICAL TRIAL

Anaesthesiology

Dr. Samudyatha T J Assistant Professor, Department of Anaesthesiology, BMCRI, Bangalore, Karnataka, India.

Dr. Soumya Patted 3rd year Post Graduate student, Department of Anaesthesiology, BMCRI, Bangalore, Karnataka, India.

Dr Triveni M R Assistant Professor, Institute Of Gastroenterology And Oragan Transplant, Bangalore.

Dr Anurita K Senior Resident, BMCRI.

ABSTRACT

Pre- emptive analgesia is found to be more effective than a similar analgesic given after surgery as it reduces immediate postoperative pain and also prevents chronic pain by reducing the altered central sensory processing. Intraperitoneal local anesthetics provide the benefit of analgesia without systemic side effects that may arise from use of enterally and parenterally administered drugs. Ropivacaine has advantage of low toxicity and longer duration of action. When ropivacaine is given intraperitoneally it starts acting within 10–20 min, and duration of action lasts for 4–6 hours.Some studies have shown that better abdominal and shoulder tip pain control was observed when larger volume of local anesthetic solution was used for instillation rather than smaller volume.Hence the study is being done to compare the effectiveness of ropivacaine as a preemptive analgesic and also if it causes any significant hemodynamic effects. Patients were randomized to Group R(Ropivacaine),Group NS(Control-Normal Saline), Group RD(Ropivacaine + dexamethasone).After induction of General Anaesthesia, drug instilled intraperitoneally before creation of pneumoperitoneum using 3ml/kg body weight Ropivacaine in group R and RD along with 8 mg of Dexamethasone in group RD and drug was diluted to make total 100 ml ,100 ml of NS in control group was used. Hemodynamic parameters, VAS score of abdomen and shoulder pain, duration of analgesia and need of rescue analgesia (paracetamol) were assessed. Total analgesic requirements in 1st 24 hours was more in Group NS compared to Group R and Group RD.Time for first rescue analgesia was much earlier in Group C than Group R. Mean duration of analgesia was significantly higher in Group RD with stable haemodynamics & no adverse effects.

KEYWORDS

Preemptive analgesia , Postoperative pain, Ropivacaine , Dexamethasone

INTRODUCTION

Laparoscopic Cholecystectomy (LC) has revolutionized surgical practice and has replaced open surgical approach by offering minimal invasiveness, faster recovery, and shorter hospital stays. Although laparoscopic procedures generally cause less postoperative pain than open surgery, the pain can still be intese, thus , effective postoperative pain management remains essential to ensure patient comfort, promote early mobility, and reduce complications.

Multimodal analgesia that utilizes a combination of analgesic agents to target different pain pathways has been introduced to manage postoperative pain, including parenteral analgesics like nonsteroidal anti-inflammatory drugs (NSAIDs) and opioids, as well as nerve blocks (interpleural and intercostal), and intraperitoneal administration of local anesthetics (LA) and opioids.

Local anesthetics are commonly applied via skin infiltration or epidural administration in abdominal surgery.They can also be instilled into the peritoneal cavity to block visceral pain signals and potentially alter pain perception and associated physiological responses.Proposed mechanism for postoperative pain of LC is stretch of the subdiaphragmatic fibers by an increased concavity of diaphragm induced by pneumo-peritoneum with CO2 insufflated into the abdominal cavity.[1]

The preemptive analgesia with intraperitoneal instillation of local anasthetic before pneumoperitoneum will cause the inhibition of posttraumatic hyperalgesia resulting in less shoulder pain.[2]

Preemptive analgesia is found to be more effective than a similar analgesic given after surgery as it reduces immediate postoperative pain and also prevents chronic pain by reducing the altered central sensory processing.[3]Intraperitoneal local anesthetics provide the benefit of analgesia without systemic side effects that may arise from use of enterally and parenterally administered drugs. Studies have shown that the addition of dexamethasone prolongs the duration of analgesia in various regional anesthesia techniques like epidural, caudal, subarachnoid, and brachial plexus blocks.

Although bupivacaine is effective, it carries a risk of cardiotoxicity when used in high concentrations or if inadvertently injected into a blood vessel. Ropivacaine, a structurally related S(−) enantiomer, has a better safety profile with reduced toxicity. For this reason, our study selected ropivacaine over bupivacaine.

The study aimed to evaluate and compare the effectiveness of intraperitoneal instillation of normal saline versus ropivacaine alone versus ropivacaine combined with 8 mg dexamethasone in patients undergoing LC. The primary outcome was to assess pain severity using the Visual Analogue Scale (VAS), while secondary outcomes included the time to first rescue analgesia, total rescue analgesic dosage required within 24 hours , hemodynamic profile any adverse effects related to the intervention.

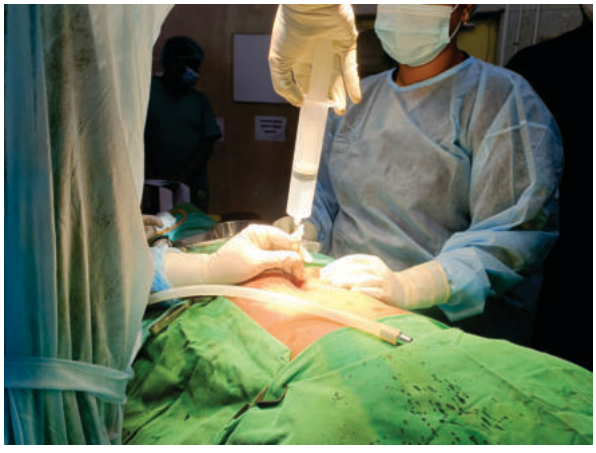


Figure 1: Instillation of study drug

METHODOLOGY

This prospective randomized study was conducted after obtaining approval from institutional research ethical committee . The clinical trial registration was done before the start of the study. Inclusion Criteria included patients who gave informed written consent, between 18 – 60 years scheduled for elective Laparoscopic cholecystectomy under general anaesthesia belonging to ASA I, II.The following patients were excluded : who refused to give informed written consent , ASA physical status III or more, emergency surgeries, history of alcohol or drug abuse, have allergy or

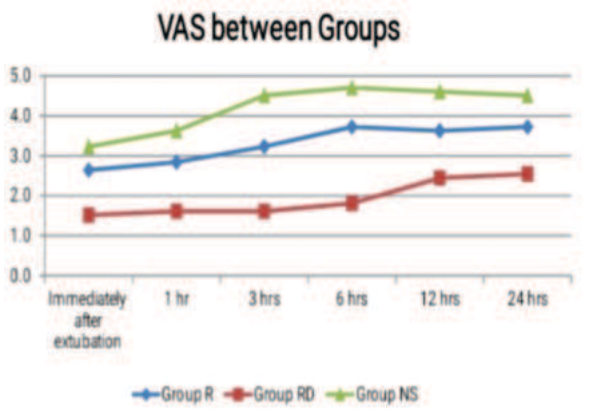
hypersensitivity to local anaesthetics, pregnant or breastfeeding women, with mental illness , renal , pulmonary, cardiovascular, hepatic, neurological, neuromuscular diseases , anticipated difficult intubation , acute cholecystitis , acute pancreatitis or peritonitis.

After obtaining informed written consent from patients during pre-operative visit, 60 patients were randomly grouped by computer generated numbers and assigned to one of the three groups.Blinding was ensured by preparing the study drugs in a ready to inject coded 50 ml syringe by the anaesthesiologist not involved with the study protocol and the postoperative follow-up of the study participant was done by one of the anaesthesiologist blinded to the study drug administration and not involved with intraoperative management of the case. Three groups were Group A (n=20): 100 ml Normal Saline (NS) Group B (n=20): 3 mg/ kg of Ropivacaine in 100 ml N and Group C (n=20): 3 mg/ kg of Ropivacaine with 8 mg dexamethasone in 100 ml NS .

All patients were fasted for 8 hours, Inj Rantidine 50mg and Inj Metaclopramide 10 mg were given intravenously half an hour preoperatively as pre-medication and explained about the study and visual analogue scale (VAS) to indicate their pain perception.All standard monitors like pulse oximetry(spO2), non-invasive blood pressure (NIBP), and electrocardiogram (ECG) were attached and baseline hemodynamic parameters recorded in preoperative room. Intra venous(IV) Ringer's lactate solution was administered as maintenance fluid (10ml/kg) through 18G peripheral venous cannula.

After preoxygenation with 100% oxygen via an anatomical face mask for 3 min, all patients were induced with 0.2mg glycopyrrolate, lignocaine 1.0 mg/kg, fentanyl 2 µg/kg and propofol 2–2.5 mg/kg. Succinylcholine 1.5 mg/kg was given to facilitate oral endotracheal intubation with appropriate size endotracheal tube.After checking and securing the endotracheal tube,anesthesia was maintained with intermittent positive pressure ventilation using closed circuit and 0.5%–2% isoflourane.Muscle relaxation was achieved with intermittent vecuronium bromide.Drug solution was administered using veress needle before creation of pneumoperitoneum by the surgeon who did not participate in the study. During surgery, all patients received an IV infusion of lactated ringers solution at a rate of 5–7 ml/kg/hour and placed in 15°–20° reverse trendelenbergh's position with left side downward tilt. During laparoscopy, intra-abdominal pressure will be limited to 10–12 mmHg nad also normocapnia was ensured. The CO2 was carefully evacuated at the end of surgery and residual neuromuscular blockade reversed using injection neostigmine 0.05mg/kg and injection glycopyrollate 0.01mg/kg body weight and patient was shifted to Post Anaesthesia Care Unit(PACU) where the anesthesiologist was unaware of study drug to which each patient is randomized. The patients with VAS score ≥4 or when they had pain were administered an infusion of 1g paracetamol (IV) as rescue analgesia.Patients were administered injection ondansetron 4 mg on complaint of nausea/vomiting. Any other adverse effects like hypotension , bradycardia were noted.All patients were assessed in terms of following parameters: Heart rate , Systolic Blood Pressure (SBP) , Diastolic Blood Pressure (DBP), respiratory rate(RR) was recorded at regular intervals, abdomen and shoulder tip pain (immediately after extubation.i.e.0 h, at 1, 3, 6, 12 and 24 h at rest), time for first rescue analgesic(duration of analgesia) and also the total rescue analgesia requirement in 24 hours.

VAS	Group R	Group RD	Group NS	p-value
Immediately after extubation	2.6 ± 1.3	1.6 ± 1	3.2 ± 1	0.005**
1 hr	2.7 ± 1.2	1.5 ± 1	3.6 ± 0.8	0.004*
3 hrs	3.2 ± 1	1.6 ± 1	4.5 ± 0.7	0.005 **
6 hrs	3.7 ± 0.9	1.8± 0.9	4.7 ± 0.8	0.005 **
12 hrs	3 .6 ± 0.8	2.4 ± 0.8	4.6 ± 0.6	0.005**
24 hrs	3.7 ± 0.7	2.5 ± 0.7	4.5 ± 0.6	0.005 **
** Highly Statistical Significant at p <0.01				



	Group R	Group RD	Group NS	p-value
Time for frst rescue analgesia (mins)	303 ± 65.1	410.5 ± 67.5	148.3 ± 46.4	0.0005 **
Rescue analgesia requirement (grams)	2.7 ± 1	1.6 ± 1.1	3.9 ± 0.9	0.0005 **
** Highly Significant at p <0.01				

Statistical Analysis And Results

The collected data were entered in the Microsoft Excel 2016 and analysed with IBM SPSS Statistics for Windows, Version 29.0.(Armonk, NY: IBM Corp).To describe about the data descriptive statistics frequency analysis, percentage analysis wereused for categorical variables and the mean & S.D were used for continuousvariables. To find the significant difference in the multivariate analysis the oneway ANOVA with Tukey's Post-Hoctest was used.To find the significance in qualitative categorical data Chi-Square test was used.In all the above statistical tools the probability value .05 is considered as significant level.

CONCLUSIONS

The addition of 8mg dexamethasone to intraperitoneal ropivacaine signifcantly prolongs the time of first rescue analgesic requirement and reduces the total consumption of rescue analgesic in 24h.

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