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A comparative study of post-operative hemodynamic stability in patients with intraperitoneal instillation of injection Ropivacaine 0.375% versus placebo on postoperative analgesia for laparoscopic abdominal surgery

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Abstract
Pain relief is an important aim of any surgery. Different methods have been proposed to relieve postoperative pain after laparoscopy. These include NSAIDS/opioids, intra peritoneal, and port site infiltration of local anaesthetics, intraperitoneal saline, and use of N20 in place of CO2. Intraperitoneal instillation of local anaesthetics at the end of laparoscopic procedures reduces post-operative pain and lengthens the period of first postoperative analgesia requirement. A comparative, Randomised study will be conducted on 60 adult patients ASA 1 and ASA 2 undergoing elective laparoscopic abdominal surgeries under general anaesthesia for 18 months in Basaveshwara Medical college and hospital, Chitradurga, divided into 2 groups of 30 each, Group S - Intraperitoneal instillation with 40 ml of 0.9% normal saline and Group R - with 40 ml of 0.375% Ropivacaine. The mean of duration of analgesia in Group S was 4.47+0.86 hours, in Group B 7.93+1.44 hours and in Group R 13.47+1.38 hours during the postoperative period. Thus, the mean duration of analgesia in Group R was almost double the duration of analgesia observed in Group B and three times the duration of analgesia observed in Group S. This difference was statistically as well as clinically significant.

Keywords: Hemodynamic stability, ropivacaine, postoperative analgesia

Introduction
Laparoscopic abdominal surgeries are one of the most commonly performed elective day care procedures. Providing adequate postoperative pain relief is of importance to enhance recovery. Although pain following Laparoscopic surgery is less intense than open surgery it can occur due to stretching of the abdominal wall from insufflation of gas and release of inflammatory mediators, local dissection and irritation of the peritoneum produced by blood, CO_2 used for pneumoperitoneum [1]. In laparoscopic abdominal surgeries the cause of pain are of somatic and visceral origin. Somatic pain is due to skin incision and the visceral pain is due to peritoneal distension and visceral irritation caused by creation of capnoperitoneum and surgical handling. Many patients complain of pain radiating to the right shoulder which is due to residual carbon dioxide post pneumoperitoneum irritating the diaphragm [2].
Pain relief is an important aim of any surgery. Different methods have been proposed to relieve postoperative pain after laparoscopy. These include NSAIDS/opioids, intra peritoneal, port site infiltration of local anaesthetics, intraperitoneal saline, use of N20 in place of CO_2. Intraperitoneal instillation of local anaesthetics at the end of laparoscopic procedures reduces post-operative pain and lengthens the period of first postoperative analgesia requirement. Intraperitoneal local anaesthesia is a simple, cheap and safest method of providing postoperative analgesia after laparoscopic abdominal surgeries. The main advantage of using local anaesthetics is that they do not have the adverse effects of opioids, which may delay recovery and discharge from hospital. These effects include postoperative nausea, vomiting, sedation, impairment of return of gastrointestinal motility and pruritus. Many local anaesthetics in various concentrations are used in practice including lignocaine, bupivacaine the latest being Ropivacaine. Ropivacaine has shown to be less toxic to cardiac and central nervous system as compared to other drugs.

Ropivacaine is an amino amide which is a member of the pipecoloxylidide group of local anaesthetics. S-ropivacaine is more potent and less cardiotoxic than R-ropivacaine [3]. The drug used in our study is racemic mixture ropivacaine.
Ropivacaine acts by reversible blockade of generation and propagation of action potential in nerves and other excitable tissues at the level of sodium channels. Ropivacaine is long acting amide when given intraperitoneally its action starts in 15-20 minutes and reduces postoperative visceral and shoulder pain following laparoscopic surgeries [4].

Materials and Methods

Study was conducted on 60 adult Patients scheduled for elective laparoscopic abdominal surgery at Basaveshwara Medical college and Hospital, Chitradurga for 18 months.
A comparative, Randomised study will be conducted on 60 adult patients ASA 1 and ASA 2 undergoing elective laparoscopic abdominal surgeries under general anaesthesia for 18 months in Basaveshwara Medical college and hospital, Chitradurga, divided into 2 groups of 30 each, Group S Intraperitoneal instillation with 40 ml of 0.9% normal saline and Group R with 40 ml of 0.375% Ropivacaine.

Stastical Analysis

Sample size was calculated using published data of a previous study based on the anticipated difference in the pain score between the bupivacaine and Ropivacaine groups.
The pain scores with use of 0.375% Ropivacaine was (mean ± standard deviation) 13.47±1.33. Assuming Type I error of 5% and Type II error of 20% (power of 80%), a decrease in the pain score by 25% (at least one point) is considered clinically significant.
This resulted in a sample size of 27 patients for each group calculated by using the formula.
The data was compiled using an excel sheet. Statistical analysis will be conducted using Statistical Package for Social Services (SPSS ver 20). The categorical variables will be presented as frequencies and percentages and chi square test will be used as test of Significance.
After the approval by the institutional Ethical committee, written informed consent was obtained from all the patients before being included in the study. The study population was subdivided randomly into 2 groups by the use of random number generator each consisting of 30 patients: Group S (N=30) and Group R (N=30).
The study is carried out as a randomised, prospective, double blind and controlled trial.
Patients undergoing laparoscopic abdominal surgery and who gave written informed consent to participate in the trial are allocated into two groups (S and R) of 30 patients each using computer generated random numbers.
Group S (N=30) - These patients receives intraperitoneal instillation with 40 ml of 0.9% normal saline
Group R (N=30) - These patients receives intraperitoneal instillation with 40 ml of 0.375% Ropivacaine.

Inclusion Criteria

- Patients willing to participate in the study.
- ASA 1 & 2 posted for elective laprotomy abdominal surgeries
- Age between 18 to 60 yrs.
- Patient weight between 50 to 80 kgs.

Exclusion criteria

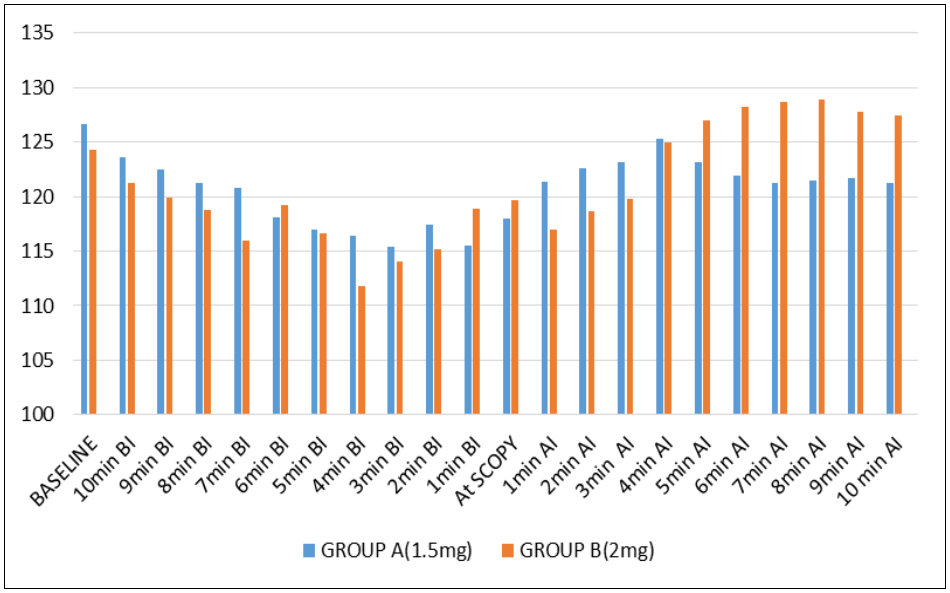
- Patient with severe systemic disease
- Patient with morbid obesity, heart block, hepatorenal disease.
- Surgeries converted to open,
- Patient on chronic use of analgesics
- Pregnancy
- Patient with hypersensitivity for local anaesthetics.

Anaesthetic Technique

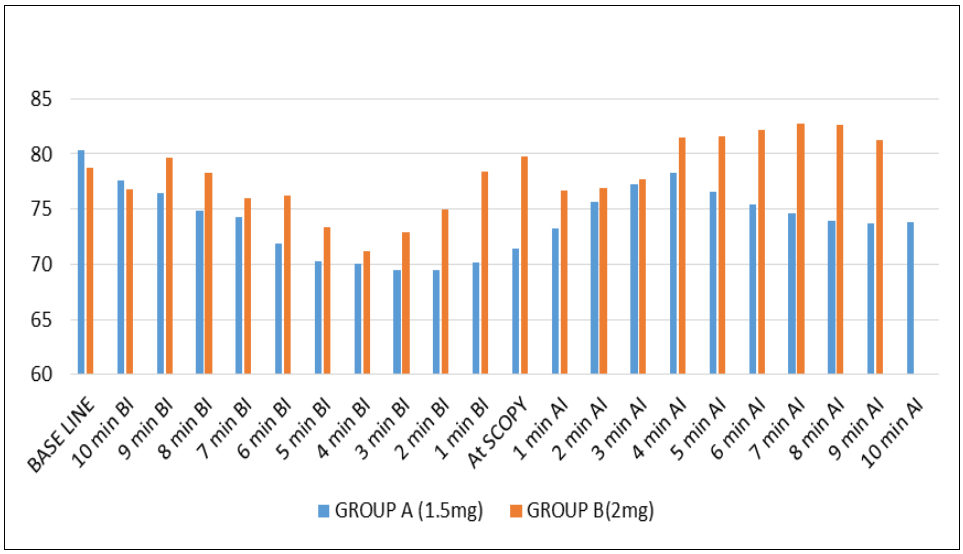
In the pre-op ward all the patients are explained about the proper use of Numerical Rating Scale (NRS) for assessing pain. The severity of pain is assessed with NRS with 0 = no pain and 10 = worst imaginable pain. Once Patient shifted on the OT table, intravenous line will be secured using 18G IV cannula, connected to ASA standard monitoring comprising heart rate, non-invasive measurements of systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), oxygen saturation (SpO2), end tidal carbon dioxide (EtCo2), temperature probe and continuous ECG monitoring.
Patients will be premedicated with IV Glycopyrrolate 0.2mg, IV Fentanyl 2mcg/kg and induced with IV Propofol 2 mg/kg followed by Suxamethonium 2 mg/kg. Intubated using a laryngoscope and endotracheal tube is fixed after confirmation of bilateral air entry. Anaesthesia was maintained with O_2, N20, Isoflurane and Vecuronium. Laparoscopic abdominal surgeries are performed according to the standard surgical and anaesthesia protocols. Standard 10 mm trocar umbilical port and epigastric ports are used. Pneumoperitoneum is achieved using non humidified and non-heated CO_2 with the intra-abdominal pressure maintained between 14 and 17 mmHg.
The required fluids were calculated according to the instructions for intra operative fluid infusion. All the patients receive 15 mg/kg of IV paracetamol 30 minutes prior to extubation.
The drug (40 ml) was injected intraperitoneally before removal of trochar at the end of the surgery, in Trendelenburg's position. It facilitates dispersion of drug solution in subhepatic region.
Parietal pain (it is superficial pain felt on touch) and visceral pain (deep, dull aching, not able to localize to specific point) are assessed with NRS at rest and on movement/cough. The incidence of shoulder pain are also recorded.
The intensity of pain is recorded for all patients using Numerical Rating Scale at 0.5, 1, 2, 4, 8, 12, 24 hours after surgery. Rescue analgesia requirement is recorded for 24 hours. If NRS is more than or equal to 5 patients are prescribed rescue analgesia in the form of IV tramadol 1 mg/kg it is repeated if necessary, to maintain NRS < 5.

Results

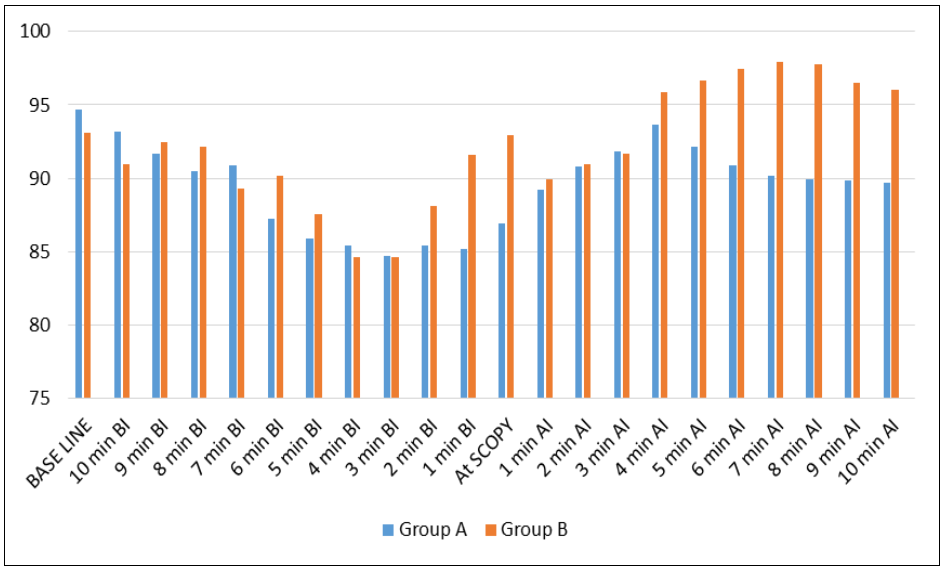
Demographic data between the groups being statistically insignificant Hemodynamic data between the grs being statistically insignificant.
The Mean NRS was < 5 till only for 4 hrs in groups, till 8 hrs in group B, 16 hrs in group.



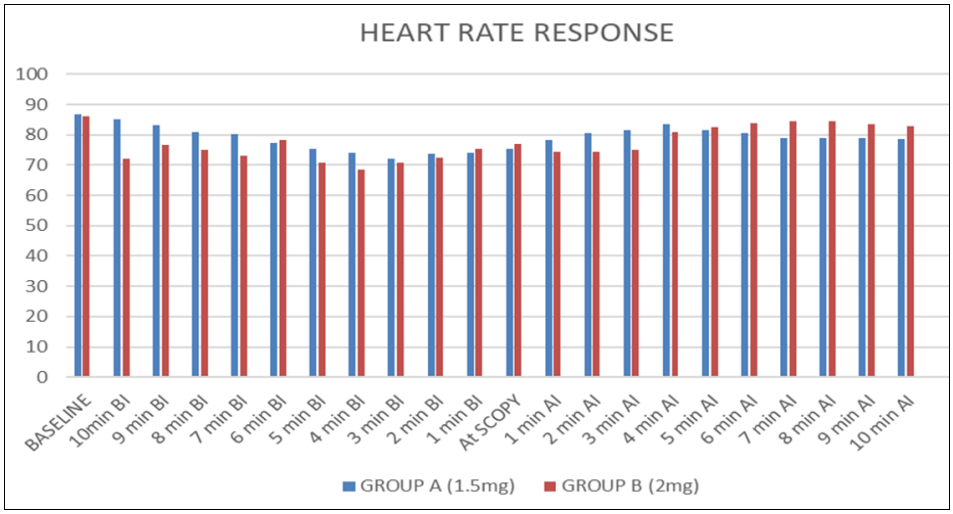
Graph 1: Systolic blood pressure



Graph 2: Diastolic blood pressure



Graph 3: Mean arterial pressure



Graph 4: Herat rate

Discussion

The duration of postoperative analgesia was counted from the first reading in PACU to the time of administration of rescue analgesia. Rescue analgesia was administered when the NRS score was > 5 in the form of IV tramadol (1 mg/kg).

The mean of duration of analgesia in Group S was 4.47+0.86 hours, in Group B 7.93+1.44 hours and in Group R 13.47+1.38 hours during the postoperative period. Thus, the mean duration of analgesia in Group R was almost double the duration of analgesia observed in Group B and three times the duration of analgesia observed in Group S. This difference was statistically as well as clinically significant.

This shows that the duration of analgesia was longer in the local anaesthesia groups where intraperitoneal local anaesthetic infiltration in the gallbladder fossa and suprahepatic surface was provided. Use of Ropivacaine significantly prolonged and improved the analgesia as assessed by NRS score. No patient from our study complained of shoulder pain. Intraperitoneal infiltration in gallbladder fossa and suprahepatic surface with bupivacaine and Ropivacaine also helped in maintaining better heamodynamics profile in the postoperative period. Ropivacaine had a more profound and longer duration of analgesia as compared to bupivacaine.

We observed for various complications like nausea, vomiting, bradycardia, respiratory depression, hypotension and sweating in all patients. No patient from the entire study population had any incident of any of these complications. This shows that intraperitoneal instillation of Ropivacaine and bupivacaine in the volume and dose used in our study is not associated with any adverse effects.

Conclusion

Trocar site infiltration and intraperitoneal instillation in the gallbladder fossa and sub diaphragmatic hepatic surface using Ropivacaine (35 ml of 0.375%) and bupivacaine (35 ml of 0.25%) at the end of surgery as a part of multimodal analgesia provide safe and effective somato-visceral analgesia in patients undergoing LC. Ropivacaine provides a more profound and prolonged analgesia as compared to bupivacaine. This technique of providing postoperative analgesia is simple, effective and will help in improving the postoperative recovery profile of the patient and help in making it a truly out-patient based surgery.

In the immediate post-operative period for up to 24 hrs, pts with intraperitoneal infiltration has better hemodynamic stability when compared to placebo.

Conflict of Interest: Not available

Financial Support: Not available

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