Original Research Paper

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INTRATHECAL HYPERBARIC ROPIVACAINE VERSUS HYPERBARIC BUPIVACAINE IN OVARIAN CYSTECTOMY : COMPARISON OF INTRAOPERATIVE FLUCTUATION OF HAEMODYNAMICS.

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ABSTRACT **Background and aim :** Less lipid solubility of ropivacaine than bupivacaine leads to fewer penetration of drug to the myelinated nerve fibre causing less motor blockade with greater sensory block. Aim: To compare change in haemodynamics between Intrathecal hyperbaric Ropivacaine and hyperbaric bupivacaine. **Methods :** 60 patients with age 18-59 year with ASA physical status I and II undergoing cystectomy under spinal anaesthesia were selected for the study and randomly divided in to two groups of 30 participants each. Group R received 3 ml 0.75% hyperbaric ropivacaine and group B received 3 ml 0.5% hyperbaric bupivacaine. SBP,DBP,HR,SPO2 were recorded at 0,1,3,5,10,15,30,60 minutes after administration of spinal anesthesia. Total intravenous Mephentermine used during the intraoperative period also recorded. Appropriate statistical tools were used to compare the parameter. **Results :** Change in intraoperative SBP, DBP, HR, were observed in both the group however Compared to ropivacaine group, bupivacaine group showed greater change in intraoperative haemodynamics at 1,3,5,10,15 minutes after administration of spinal anestehsia($p<0.05$). At 30 and 60 minute significant change in haemodynamic were not observed. No significant change in SPO2 was observed in both the groups. Total intraoperative mephentermine required in group R (2.8±2.9mg) was significantly less than group B (7.86±2.77mg) $p<0.0001$. **Conclusion:** When 3 ml of hyperbaric ropivacaine administerd intrathecaly, offers safe haemodynamic profile compared to 3 ml hyperbaric bupivacaine in respect to less incidence of hypotension and less mephentermine requirement.

KEYWORDS : Hyperbaric, Isobaric, Ropivacaine, Bupivacaine, Haemodynamics

INTRODUCTION

Currently the most popular drug used in spinal anesthesia is 0.5% hyperbaric bupivacaine which has cardiotxic propensity and prolonged motor blockade duration. When compared to intrathecal Bupivacaine, the more recent medication Ropivacaine provides less motor blockage and lasts for a shorter period of time, which lessens the psychological stress of being immobile for a longer period of time following surgery [1,2].

Ropivacaine a pure S- enantiomer of propivacaine is a long acting amide local anaesthetic with less potential cardiac and neurotoxicity. Lipid solubility is less than recaemic mixture and bupivacaine which leads to fewer penetration of drug to the myelinated nerve fibre causing less motor blockade with greater sensory block3. Previous studies evaluated the safety and efficacy of intrathecal isobaric ropivacaine4 and found to be safe with shorter duration of action than bupivacaine and lesser incidence of transient neurological symptom than intrathecal lignocaine5. With the availability of commercial preparation of hyperbaric ropivacaine, the problems associated with preparation of hyperbaric ropivacaine is stand off and pharmacological stability of the drug is maintained6. The aim of this study was to compare the maximum height of sensory block, haemodynamic parameter and associated complication between hyperbaric ropivacaine and hyperbaric bupivacaine.

Subject and Methods

A prospective, comparative, hospital based, single blinded clinical trial was conducted under the Department of anesthesiology and critical care, Fakhruddin Ali Ahmed Medical college and hospital, Barpeta with due permission and approval from the institutional ethics committee.

Sixty patients with age 18-59 year with ASA physical status I and II undergoing cystectomy under spinal anaesthesia were selected for the study. Patients with coagulopathy, hypovolaemia, body mass index greater than 35 kg/m2, spinal abnormalities, lumbar spine infection, or a history of allergy to amide local anaesthetics were excluded.

Using a computer-generated random number sequence, subjects were randomly assigned to two groups of 30 participants each to the intervention groups. Subjects belonging to group R received 3 ml (22.5 mg) 0.75% hyperbaric Ropivacaine(Ropin Heavy, Neon pharma) and group B received 3 ml (15mg) .5% hyperbaric Bupivacaine(Anawin heavy, Neon pharma). The Serially Numbered Opaque Sealed Envelope (SNOSE) method was used for allocation concealment. The study included two observers. Observer 1 performed a thorough preoperative evaluation the day before surgery, reviewed laboratory investigations, explained the procedure, recorded intraoperative timings, and assessed the outcome.The subarachnoid block was performed by Observer 2. The person evaluating the outcomes was not aware of the intervention.

On arrival in the anesthetic room IV line was accessed and Intravenous (IV) infusion was given with ringer lactate , continuous monitoring with electrocardiogram, noninvasive arterial blood pressure and pulse oximetry were started. Pre-medication in the form of (IV) midazolam 0.05 mg/kg and anti-aspiration prophylaxis with 10 mg metoclopramide and 50 mg ranitidine IV was given. Patients were placed in the left lateral position for lumbar puncture and SA was performed using a midline approach at the L3-4 or L4-5 intervertebral space. With the distal port oriented laterally, a 25-gauge Quincke needle was introduced, and the necessary LA medication was administered over a period of 10-15 seconds.

After injection, patients were immediately laid down supine. A researcher who was oblivious to the nature and type of drug that was injected observed the block's development. The level of sensory block (analgesia to pinprick), degree of lower limb motor block (using the James modified Bromage Scale 0 = full movement; 1 = inability to raise extended leg, can bend knee; 2 = inability to bend knee, can flex ankle; 3 = no movement). Systolic blood pressure ,diastolic blood pressure, heart rate ,SPO2 were recorded at 0,1,3,5,10,15,30,60 minutes.

Hypotension was treated with an IV bolus of 5 ml/kg ringers lactate and, if necessary, 6 mg of Mephentermine was administered. Hypotension was defined as a reduction in systolic pressure of more than 20% from baseline. In order to replenish intraoperative losses, fluids were given.

Bradycardia was defined as reduction of heart rate less than 60 bpm and therapeutic intervention was taken in the from of IV atropine if heart rate <50 bpm. At the end of the surgery, patients were shifted to recovery room.

RESULTS:

The demographic characteristics of the patients of the study group in terms of age, weight, height, ASA status, duration of the surgery were analysed between both the groups and statistical tool did not show any significance variation.

The mean ± SD duration of the surgery was similar in both the groups and completed within 1 hour in both the group.

The mean ± SD systolic BP was 121.6±10.88, 116.9±9.88, 114.03±9.18, 115.8±8.56, 118.8±8.40 mmHg at 0,1,3,5,10,15,30,60 minutes respectively in group R and 120.2±9.14, 109.13±7.28, 103.77±5.13, 105.37±4.68, 109.5±4.07, 112.4±4.07, 113.9±18.98 mmHg at 0,1,3,5,10,15,30,60 minutes respectively in group B. Intraoperative systolic blood pressure in both the group were compared and studied with unpaired t test and p values were .591, .0008, .0001, .0002, .0071, .054, .201 at 0,1,3,5,10,15,30,60 minutes respectively.

The mean ± SD diastolic BP was 75±5.83, 71.9±5.09, 69.5±4.12, 70.4±3.54, 71.9±3.91, 72.8±3.36 mmHg at 0,1,3,5,10,15,30,60 minutes respectively in group R and 75.4±5.76, 66.4±4.60, 62.3±3.62, 64.07±3.18, 67.16±2.94, 70±2.19, 74.13±2.21 mmHg at 0,1,3,5,10,15,30,60 minutes respectively in group B with P value .894, .0001, .0001, .0002, .0003, .0238, .075 respectively.

The mean ± SD heart rate was 77.8±6.93, 81.57±6.43, 83.8±6.07, 83.8±6.54, 81.6±5.98, 80.2±4.03, 79.9±2.99 beat per minute at 0,1,3,5,10,15,30,60 minutes respectively in group R and 81.5±8.39, 92.7±8.02, 100.2±8.44, 94.8±7.44, 89.4±6.58, 82.1±4.93, 80.1±4.20 beat per minute at 0,1,3,5,10,15,30,60 minutes respectively in group B with p value .06, .0001, .0001, .0001, .0001, .027, .832 respectively.

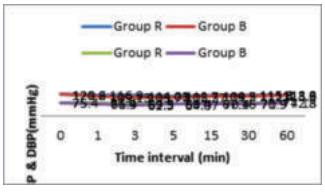

Fig 1 : Line diagram showing comparison of intraoperative systolic & diastolic blood pressure between the groups.

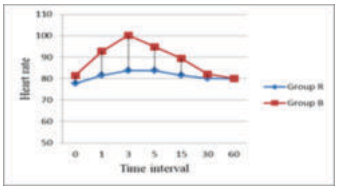

Fig 2 : Line diagram showing comparison of intraoperative heart rate between the groups.

Total intraoperative mephentermine required in group R was 2.8±2.9 mg and in group B was 7.86±2.77 mg. Statistical analysis was done by unpaired t test and p value was <0.0001.

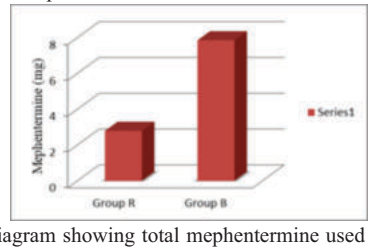

Fig 3: Bar diagram showing total mephentermine used between the groups.

DISCUSSION :

Intraoperative systolic blood pressure in both the group were compared and studied with unpaired t test and found to be significant with p value <0.05 from 1 minutes onward after spinal anesthesia till 15 minutes. Compared to intrathecal bupivacaine, ropivacaine provide better stable intraoperative systolic blood pressure. After 15 minutes till the end of the surgery statistical tool didn't show any significant change in the systolic blood pressure between the groups. Intraoperative diastolic blood pressure in both the group were compared and studied with unpaired t test and found to be significant with p value <0.05 from 1 minutes onward after spinal anesthesia till 30 minutes. Intrathecal bupivacaine group showed more reduction in intraoperative diastolic BP compared to ropivacaine group. Intraoperative heart rates in both the group were compared and found to be significant with p value <0.05 from 1 minutes onward after spinal anesthesia till 30 minutes. Intraoperative stable heart rate was observed with ropivacaine group compared to bupivacaine group. In A study conducted by Naren CK et al7 stated that ropivacaine provides safe intraoperative haemodynamic profile as few number of patients had hypotension and gross haemodynamic fluctuation in comparasion with bupivacaine in elective gynaecological surgeries. In an another study conducted by Dar FA et al8 stated that there was a significant difference in the incidence of hypotension between the group. Ropivacaine group showed better stable haemodynamics in lower limb and hip surgery compared to bupivacaine. Study conducted by Kulkarni KR et al9 found no significant change in haemodynamic between the groups. They made hyperbaric ropivacaine by adding dextrose to isobaric ropivacaine which may reduce the drug potency. With the availability of commercial preparation of hyperbaric ropivacaine, the problems associated with preparation of hyperbaric ropivacaine is stand off and pharmacological stability of the drug is maintained.

Total intraoperative mephentermine required in group R was 2.8±2.9 mg and in group B was 7.86±2.77 mg. Statistical analysis was done by unpaired t test and p value was <0.0001. in the ropivacaine group less amount of intraoperative mephentermine is needed to maintain desired blood pressure. This indicate ropivacaine maintain stable haemodynamics during the operation compared to bupivacaine.

CONCLUSION:

Administration of 3 ml of hyperbaric ropivacaine intrathecally offers safe haemodynamic profile as compared to 3 ml hyperbaric bupivacaine with respect to less incidence of hypotension and less mephentermine requirement. Due to its potential for cardiostability, ropivacaine can be ideal for high risk patients.

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