A comparative study of hyperbaric ropivacaine with fentanyl and hyperbaric bupivacaine with fentanyl in intrathecal block for perineal surgeries: A prospective randomized double blind clinical study

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Abstract

Introduction: To compare the clinical effects of intrathecal 2.5ml of Hyperbaric Ropivacaine with Fentanyl and 2.5ml of Hyperbaric Bupivacaine with Fentanyl in patients undergoing various perineal surgeries.

Materials and Methods: After meeting the inclusion criterias 120 patients belonging ASA physical status 1 & 2, were divided in to two groups of 60 each. Randomization was done by computer generated randomization table.

Group B patients received 2.5 ml solution, which was prepared from 3.5ml 0.5% hyperbaric Bupivacaine (5 mg/ ml) along with 0.5 ml Fentanyl (25µg/ml).

Group R patients received 2.5 ml solution, which was prepared from 2.5 ml of Ropivacaine (7.5 mg/ ml) along with 0.5 ml Fentanyl (25µg/ml). To make it hyperbaric 1 ml of 10% dextrose was added.

Both the groups were studied for duration of sensory and motor blocks and hemodynamic variations.

Results: Regression of sensory block to T 10 was statistically significant with group R (119±24 min) as compared to group B (153±21.3 min), P value being less than 0.001.Duration of regression of motor block to Bromage scale 0 was also statistically significant with group R (144.5±26.1 min) as compared to group B (181±21.3 min). P value being less than 0.001 degree of motor blockade was statistically significant with group R (80%) compared to group B (100%).

Conclusion: Hyperbaric Ropivacaine with Fentanyl is a more suitable alternative to hyperbaric Bupivacaine with Fentanyl in perineal surgeries.

Keywords: Intrathecal, Hyperbaric, Ropivacaine, Bupivacaine and fentanyl.

Introduction

Subarachnoid block is a popular anaesthesia procedure practiced worldwide. It is a standard of care for lower abdominal, lower limb and perineal surgeries.

Lidocaine has been the most widely used local anesthetic for subarachnoid block because of its faster onset and shorter duration of block. It is also less popular because of its association with transient neurologic symptoms and cauda equine condition.[1]

Newer local anesthetics for instance Ropivacaine was synthesized simultaneously with Bupivacaine by E Kenstam almost 50 years ago and was first launched in1996. It is the first pure S enantiomeric local anesthetic to be clinically introduced. Several clinical studies confirm that Ropivacaine has lower and different toxicity profile compared to Bupivacaine.[2]

Ropivacaine with high pka, low lipid solubility is considered to block sensory nerves to a greater degree than motor nerves and has similar local anesthetic properties and chemical structures compared to Bupivacaine. Because of sensorimotor dissociation Ropivacaine should be a favorable drug for day care surgeries and could be associated with early post-operative mobilization.[3]

Various adjutants like opioids, α agonists, neostigmine, midazolam and others have shown to improve the analgesic duration post spinal anesthesia. However opioids because of their motor sparing property are popular than others for the same thereby improving the quality and success of anaesthesia.

Hence we aimed to compare the effectiveness of Intrathecal hyperbaric Ropivacaine and hyperbaric Bupivacaine with fenltanyl[4-7] as an adjuvant in perineal surgeries.

Objectives

Primary: To assess the quality and duration of sensory and motor blocks in both the groups

Secondary: To study hemodynamic changes and complications.

Materials and Methods

This prospective randomized single blind study was conducted on 120 patients undergoing various perineal surgeries like anal fissure, fistula in ano, hemorrhoida, peri anal abscess etc under subarachnoid block in S. Nijalingappa medical college and H S K Hospital and research centre, Bagalkot between the time period of January 2012 to February 2013,conducted over a period of 14 months.

Inclusion Criteria

ASA I and II

Age group between 18 to 60 years

Patients posted for short duration surgeries of perianal region.

Exclusion Criteria

ASA III, IV, patients with a history of allergy to the study drug, contraindications for subarachnoid block and longer procedures of perianal region

After the clearance of institutional ethical committee and written informed consent, 120 selected patients were divided randomly into 2 groups of 60 each based on computer generated randomization table into 2 groups of 60 patients each.

Group R patients received 2.5 ml of Ropivacaine and fentanyl mixture{prepared from 2.5 ml of Ropivacaine plain 0.75% along with 1 ml of 10%dextrose to make it hyperbaric and 0.5 ml 25µg Fentanyl, total volume being 4 ml out of which only 2.5 ml was given.}[8-10] The specific gravity of the solution was assessed by urinometer (1.0227-1.0278) which was similar to hyperbaric Bupivacaine.

Group B patients received 2.5ml of Bupivacaine and fentanyl mixture {prepared from 3.5 ml of hyperbaric Bupivacaine and 0.5 ml 25µg/ml fentanyl, total volume being 4 ml out of which only 2.5 ml was given} Both the drug combinations were freshly prepared at the time of the procedure by the principle investigator.

On the day of surgery patients were shifted to operation theatre and intravenous access was obtained with 18G cannula. Premedication in the form of inj. Ranitidine 50mg and inj. Ondansetron 4mg were given. Preloading in the form of inj.Ringer lactate 10ml/kg was started. All the monitors including pulse oximeter, ECG and non-invasive blood pressure were attached, and baseline parameters were noted.

Based on the group patients belonged to, all patients were given subarachnoid anesthesia with 25G Quincke's needle at L2-L3 or L3-L4 spaces in sitting position and spinal drug injected over 10 to 15 seconds after negative aspiration for blood and CSF accordingly. Immediately after spinal block all the patients were placed supine.

Hemodynamic parameters, sensory, and motor blockade was assessed by blinded anesthesiologist at 0, 5, 10, 15, 30,45,60,90 and 120 mins following block. Thereafter observation was continued at 30 minutes interval until the complete regression of motor loss based on modified Bromage scale.

The following parameters were assessed in the following manner

Duration of Sensory Block: The time from intrathecal injection to regression of pin prick sensation to T10 level.

Degree of Motor Blockade: Modified Bromage scale.

Duration of Motor Block: The duration of intrathecal injection to regression of motor block to Bromage grade 0.

Sensory block was assessed and surgery allowed to begin once T-10 was reached. If sensory failed then the case was converted to general anesthesia and excluded from the study. Hypotension was defined as fall in blood pressure of >20%of the baseline and was treated by inj Mephentermine 6mg bolus along with crystalloids. Bradycardia was defined as fall in heart rate of <50bpm and treated with inj Atropine 0.6mg iv. The end of the study period was the time period when sensory block regressed below T-10 or at Bromage score 0 whichever occurred later. Time from intrathecal injection to first mitcuration was noted.

Statistical analysis was done using SPSS software16.0.Data obtained was tabulated in the form of mean±standard deviation and analysed with Chi-square test for proportion and t-test for Quantitative data and Block characteristics were compared using Mann –Whitney U test.

Results

We conducted a randomized study in S.N. Medical college Bagalkot during the period 2012 to 2013 of 120 patients divided into 2 groups of 60 each of which-

Group R patients received hyperbaric Ropivacaine 2.5ml along with Fentanyl 25µg.

Group B patients received hyperbaric Bupivacaine 2.5ml along with Fentanyl 25µg.

Data obtained were analyzed and final results were tabulated.

Table 1: Demographic data

Variables	Group R	Group B	p value
Age(Yrs)	40.8±11.7	39.79±10.98	0.85 NS
Weight(Kgs)	62.93±6.38	60.91±5.44	0.06 NS
Height(Cms)	163.91±6.01	162.87±5.98	0.34 NS
BMI	23.3±1.23	22.9±1.34	0.07 NS
ASA Status I/II	46/14	52/39	0.15 NS

Table 2: Types of surgeries

Types of Surgeries	Group R	Group B	p value
Fissure in ano	7	16	0.09 NS
Fistula in ano	16	19	
Hemorrhoids	23	17	
perineal abscess	14	8	

Graph 1: Comparison of duration of sensory and motor blockade in both the groups

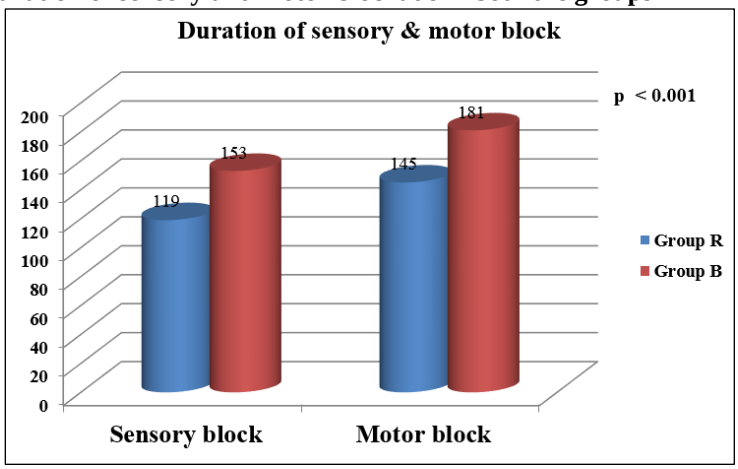
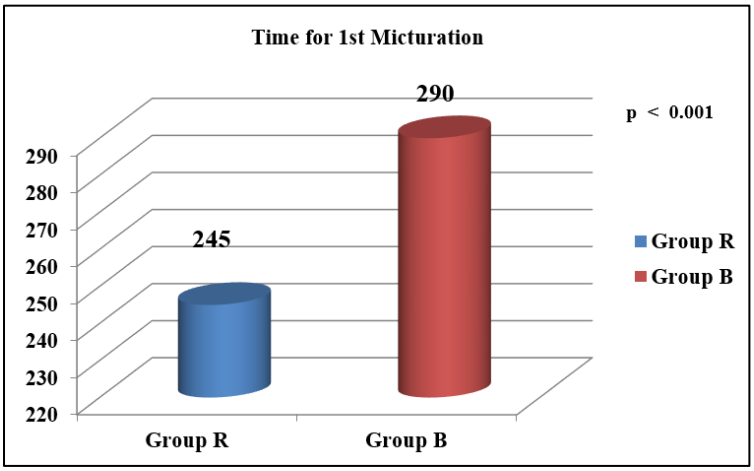


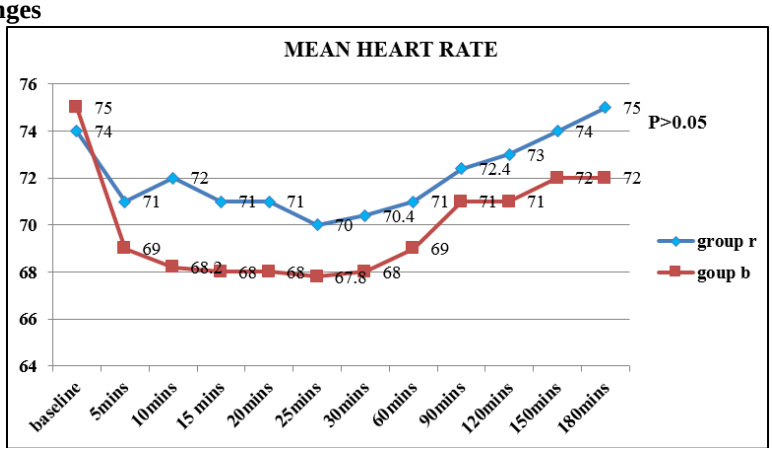
Table 3: Degree of motor blockade

Variable	Group R	Group B	p value
Degree of motor blockade (Grade 3)	80%	100%	< 0.001 HS

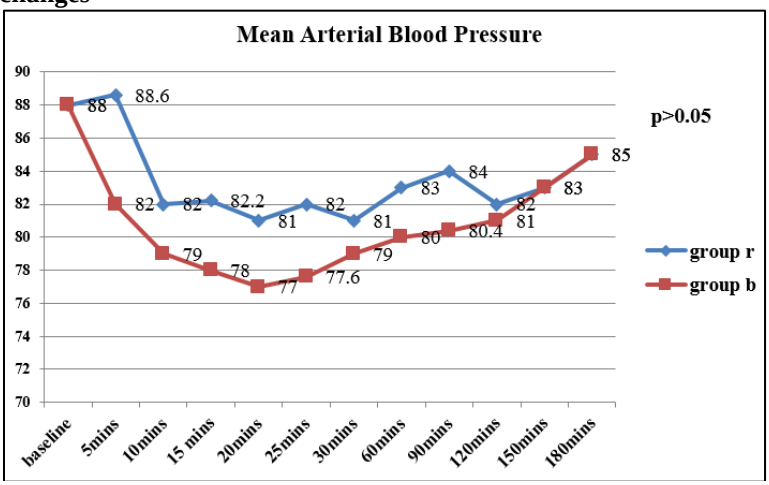
Graph 2: Time of onset of micturation reflex



Graph 3: Heart rate changes



Graph 4: Blood pressure changes



In our study we noted that there was statistically significant difference in the duration for regression of sensory block to T 10 with group R (119±24 min) compared to group B (153±20.4 min). p value being less than 0.001. Similarly we found a statistically significant difference in time for regression of motor block to Bromage score 0 with group R (144.5±26.1 min), as compared with group B (181±21.3 min) p value being less than 0.001.

Discussion

SAB is a commonly and popularly employed anaesthetic technique for performing perineal surgeries. It is a safe, inexpensive and easy to administer technique which also offers a high level of post anesthesia satisfaction for patients. The technique is simple, has rapid onset and is reliable. The risk of aspiration/mishaps of airway and polypharmacy associated with general anesthesia are avoided by this technique.

Bupivacaine is routinely used for perineal surgeries because of its high potency and minimal neurological symptoms. Profound motor blockade and longer duration of action are some considerations for selecting this durg for spinal anaesthesia.

Ropivacaine, an S-enantiomer of Bupivacaine is being increasingly used for spinal anaesthesia in caesarean section, lower abdominal and perineal surgeries including lower limb surgeries. Advantages claimed with Ropivacaine are shorter duration of motor block with similar sensory blockade properties compared to Bupivacaine (Mc Donald SB). Thus Ropivacaine minimizes the psychological discomfort of being immobile for long time. Also its major advantage is being less cardiotoxic as compared to Bupivacaine.

Current study was done to evaluate the quality and duration of sensory and motor blockade of both the local Anaesthetics.

Our results showed that both the groups are comparable with respect to Age, Gender, Height, weight, BMI, level of anesthesia and ASA score (P values >0.05).

Whiteside et al[10] found that there was significant reduction in median duration for regression of sensory block to T10 with hyperbaric Ropivacaine 56.5(28-145)min as compared with hyperbaric Bupivacaine 118(80-238)min when 3ml of 0.5% of hyperbaric Ropivacaine and 3ml of 0.5% of hyperbaric Bupivacaine was used in patients undergoing lower abdominal, perineal or lower limb surgeries. U Srivastava et al[11] in their study found that there was significant reduction in duration for regression of sensory block to T10 with hyperbaric Ropivacaine 110±12.0min as compared to hyperbaric Bupivacaine 135±26.8min when patients received 15mg of 0.5% hyperbaric Ropivacaine and 11mg of 0.5% hyperbaric Bupivacaine for caesarean delivery. In our study we noted that there was statistical significant difference in duration for regression of sensory block to T10 with Group R 119.0±24.0 min compared to group B 153±20.4min (P<0.001). However in comparison with previous studies, the duration of sensory block in both the groups is probably due to adjuvant effect of Intrathecal fentanyl which was used in our study.

U Srivastava et al[11] found that the time for regression of motor block as assessed with Bromage score 0 was significantly less with hyperbaric Ropivacaine 127±20.42min as compared with hyperbaric Bupivacaine 182±30.83min. In our study we also found a statistically significant difference in time for regression of motor block to Bromage score 0 with group R 144.5±26.1 min as compared with group B 181.0±21.3 min(P<0.001). Hence Ropivacaine provides lesser duration of motor block than Bupivacaine.

Whiteside et al found that degree of motor blockade assessed with Bromage score of 3 was achieved in 100% with hyperbaric Bupivacaine, while only in 70% with hyperbaric Ropivacaine. In our study we found that Bromage score of 3 was achieved in 100% of group B and in 80% of group R. Hence, Bupivacaine gives a better degree of motor blockade than Ropivacaine.

Micturation is affected vowing to SAB, inability to micturate along with regression of motor blockade are key considerations for ambulatory surgeries.

Whiteside et al found that there was significant reduction in median time to first Micturation with hyperbaric Ropivacaine 276(177-494) mins as compared to hyperbaric Bupivacaine 340.5(268-497) mins. In our study we noted that there was statistical significant difference in time to first Micturation with group R 245±40.9mins compared to group B 290±47.6mins. (P<0.001)

Hemodynamic parameters amongst the two groups were compared. HR, Systolic BP, Diastolic BP and MAP decreased after the block in both the groups but were comparatively lower in group B than in group R. Intergroup hemodynamic parameters were well within normal limits. Intergroup hemodynamic parameters at different time intervals though revealed a significant difference, no conclusion could be drawn due to many confounding factors viz volume status, coloading, positioning. No episodes of bradycardia or hypotension were reported in both the groups in our study.

Conclusion

Hyperbaric Ropivacaine achieves a lesser duration of sensory and motor blockade, lesser degree of motor blockade and time for first micutration as compared with Hyperbaric Bupivacaine. Hence, Hyperbaric Ropivacaine with fentanyl in Spinal Anesthesia is a better alternative for perineal day care surgeries.

Conflict of Interest: None.

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