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Original Research Article

A Comparative Study on Efficacy of Intrathecal Ropivacaine Heavy with Fentanyl and Intrathecal Bupivacaine Heavy with Fentanyl for Surgeries below Umblicus

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Conflict of interest: Nil

Abstract:

Introduction: Limited literature and controversy regarding the studies for the assessment of efficacy of intrathecal Ropivacaine Heavy with fentanyl and intrathecal Bupivacaine Heavy with fentanyl for infraumbilical surgeries provided the need for a study to be conducted in a well-designed manner.

Aim and Objectives: To study and compare the Onset and Duration of Sensory and Motor blockade in Intrathecal Ropivacaine Heavy with Fentanyl and Intrathecal Bupivacaine Heavy with Fentanyl. To study and compare haemodynamic changes and postoperative analgesia along with side effects (if any) between these two groups.

Material and Methods: Present prospective study was conducted at Department of Anesthesiology and critical care, Saraswathi Institute of Medical Sciences, Hapur among 100 patients posted for infraumbilical surgeries. Patients were divided in two groups. Group RF received 3ml intrathecal Roipvacaine Heavy 0.75% with 25mcg (0.5ml) fentanyl. Group BF received 3ml intrathecal Bupivacaine Heavy 0.5% with 25mcg (0.5ml) fentanyl. Total Volume 3.5ml in each group. Mann-Whitney U test, independent t test and Chi-Square test was applied. 'p' value<0.05 indicated a statistically significant association.

Results: The mean onset times for Sensory and Motor Block were comparable between the two groups. The mean duration of Sensory block was significantly higher in BF Group (220.50±18.49 min) compared to RF group (160.62±15.39 min). The mean duration of Motor Block was significantly higher in BF Group (194.88±17.96 min) compared to RF group (126.74±19.81 min). Time to rescue analgesia was significantly higher in BF group (365.64±59.44) compared to RF group (293.56±80.69). Hemodynamic parameters were comparable between the two groups. No significant adverse effects were observed.

Conclusion: Intrathecal Bupivacaine Heavy with Fentanyl provides a longer duration of sensory and motor block, prolonged postoperative analgesia and also overall less analgesic drug requirement as compared to Intrathecal Ropivacaine Heavy with Fentanyl.

Keywords: Bupivacaine; Fentanyl; Intrathecal; Motor Block; Ropivacaine.

Introduction

The best gift that can be offered to patients is most likely a painless surgery and a smooth postoperative period. Patient satisfaction is increased when post-operative pain is managed well [1].Additionally, it lowers hospital expenses, shortens hospital stay and results in faster mobilization. Also minimizing LA drug doses by using adjuvants (like opioids) aids in reducing incidence of side effects without compromising quality of anaesthesia and postoperative analgesia. Earlier studies have shown that additives, if combined with Bupivacaine can effectively increase the duration of analgesia and reduce the requirement of post-operative analgesics [2, 3, 4, 5]. Ropivacaine is considered as a newer alternative to Bupivacaine due to its lower cardiovascular toxicity [6]. It is a pure S-enantiomer of bupivacaine, which is expected to have a better clinical profile, but the studies for the same are yet limited. Some studies suggest equivalent action of

Ropivacaine and Bupivacaine, whereas others report Ropivacaine producing less motor blockade. Furthermore, there are various studies of isobaric ropivacaine in peripheral nerve blocks. However, the use of intrathecal hyperbaric ropivacaine is not much studied. Recently, ropivacaine 0.75% has been made hyperbaric by the addition of dextrose to it for intrathecal use and is now commercially available. With this background, we decided to study the efficacy of intrathecal Ropivacaine heavy 0.75% with fentanyl against intrathecal Bupivacaine heavy 0.5% with fentanyl for infraumbilical surgeries.

Aim and Objectives

1. To Study block characteristics (Onset and Duration of Sensory and Motor blockade) in Intrathecal Ropivacaine Heavy with Fentanyl group.
2. To Study block characteristics (Onset and Duration of Sensory and Motor blockade) in Intrathecal Bupivacaine Heavy with Fentanyl group.
3. To Compare block characteristics (Onset and Duration of Sensory and Motor blockade) between two study groups.
4. To Study and Compare Hemodynamic parameters between the two Study Groups.
5. To Compare Post-Operative Analgesia using Visual Analogue Scale between the two Study Groups.
6. To Compare the Side Effects (if any) between the two Study Groups.

Material and Methods

This prospective study was conducted at Department of Anaesthesiology and Critical Care, Saraswathi Institute of Medical Sciences, Hapur over a period of 2 years from July 2022 to June 2024 after obtaining approval from the Institutional Ethical Committee (IEC Letter no.: SIMS/ FMT/ETHI/21/2022 dated 15/09/2022)with the aim to compare the Efficacy of Intrathecal Ropivacaine Heavy with Fentanyl and Intrathecal Bupivacaine Heavy with Fentanyl for surgeries below umbilicus. 100 patients listed for infraumbilical surgeries and belonging to ASA 1 & 2 were selected.

Inclusion Criteria:

- Patients who are scheduled to undergo elective surgeries below umbilicus under spinal anaesthesia.
- Patients age between 18 to 60 years.
- Patients belonging to American Society of Anaesthesiologists (ASA) Physical status 1 or 2.
- Patients of either gender.

Exclusion Criteria:

- Patients with contraindication to spinal anaesthesia.
- Patients with heart rate less than 60 beats per minute pre operatively.
- Patients with systolic blood pressure less than 100mm of Hg preoperatively.
- Patient having allergy to Bupivacaine/Ropivacaine/Fentanyl
- Patients not willing to participate in the study.

Patients were randomly assigned into two groups of 50 patients each, using a slip in the box technique

Group RF = patients received 3ml Intrathecal Ropivacaine heavy 0.75% with 0.5ml Fentanyl 25mcg (total volume 3.5ml)

Group BF = patients received 3ml Intrathecal Bupivacaine heavy 0.5% with 0.5ml Fentanyl 25mcg (total volume 3.5ml)

A pre-anaesthetic assessment was done on the day before surgery. The study and the anesthetic technique were explained to them in understandable language. Every patient was acquainted with visual analogue scale (VAS) a day prior to surgery and its use for measuring the postoperative pain. They were advised for fasting for 8 hours and received alprazolam 0.5 mg as premedication a night before surgery. After receiving the patient in operation theatre, electrocardiogram, non-invasive blood pressure and pulse oximeter were attached, and baseline parameters were noted. An intravenous access with 18G intravenous cannula in large peripheral vein of hand was secured and patients were preloaded with ringer lactate (RL) solution 10ml/kg body weight which was administered over 15 minutes. Anaesthesia machine, air-way equipment was checked and drugs for resuscitation and general anaesthesia made ready before starting the procedure. The study drug to be administered was prepared by a trained anesthesia resident not involved in data collection or further study to ensure blinding. Under strict aseptic precautions, spinal anesthesia was administered by trained anesthesia resident using a 25G Quincke's spinal needle in sitting position using midline approach into L3-L4 interspace and after confirming good flow of clear cerebrospinal fluid, study drug was injected over 20 seconds with cephalic orientation of the spinal needle bevel. After drug administration spinal needle removed and a small sterile dressing applied at the injection site, and patients were placed supine with a pillow under the head and neck. The patients as well as anesthesiologist who performed spinal anesthesia and collected data were blind about group allocation. Verbal communication with the patient was maintained after spinal anesthesia. Heart rate, blood pressure (SBP, DBP), oxygen saturation

(SPo2) and respiratory rate were continuously monitored and recorded. Adverse effects including shivering, nausea, vomiting, pruritus, respiratory depression, bradycardia and hypotension were noted and managed according to clinical protocol in the intra and post-operative periods. Spinal injection time was noted as time zero.

Bradycardia was defined as >20% decrease in heart rate from baseline or fall below 50 beats/min and was treated with atropine 0.6mg IV stat. Hypotension was defined as >20% decrease in SBP from the baseline and was treated with intravenous mephentermine 6mg IV stat. Respiratory Depression was defined as bradypnea (respiratory rate less than 10). Supplemental oxygen was planned with Hudson mask if sPO_2 goes below 90%.

Sensory Block: The level of sensory blockade was evaluated at 2,4,6,8,10 and 15 mins and thereafter at 15 min interval till complete resolution of sensory block with sterile pin prick test and the Onset of sensory block was defined as the time between intrathecal drug injection to the absence of sensations at T10 level. Duration of sensory block was taken as interval between intrathecal study drug injection and return of sensations to L1 dermatome.

Motor Block: This was evaluated with the modified Bromage scale (0 – no motor block, 1 – inability to raise extended leg, able to bend knee, 2 – inability to bend the knee, can flex ankle; 3 – no movement).Time of onset of motor block was defined as time taken to achieve Bromage scale-3, further recovery from motor block was defined with Bromage score of zero. The duration of motor block was taken as the total time interval between intrathecal drug injection and the complete recovery of motor function (bromage scale-zero).

Analgesia: The Duration of analgesia was defined as the period from intrathecal drug injection to the first rescue analgesia given in the postoperative period which was given with VAS >4. In the postoperative period, Pain score was recorded initially every 30 minutes for 6 hours then every 4 hourly till 24 hours.

The rescue analgesia was given in the form of injection Paracetamol (1gm) IV infusion at VAS >4 and the time of administration noted.

Results

Data were collected and expressed as mean with standard deviation.

Statistical analysis was done using IBM SPSS version 25.0 Software. Mann-Whitney U test, independent t test and Chi-Square test was applied. 'p' value<0.05 indicated a statistically significant association. Sample size calculated using the formula:

$$\mathbf{n}=\left(\mathbf{s_1^2}+\mathbf{s_2^2}\right)*\frac{\left(\frac{\mathbf{Z_{\alpha}}+\mathbf{Z_{1-\beta}}}{2}\right)^2}{(\mu_1-\mu_2)^2}=\left(\mathbf{s_1^2}+\mathbf{s_2^2}\right)*\frac{\left(\frac{\mathbf{Z_{\alpha}}+\mathbf{Z_{1-\beta}}}{2}\right)^2}{(\mathbf{d})^2}$$

In our study, a total of 100 patients who underwent infra-umbilical surgeries were randomized into two groups of 50 each. In both groups, demographic parameters such as age, height, weight and sex were comparable (Table 1). Duration of surgery was comparable in both groups.

Sensory and Motor Block characteristics

The mean Onset of Sensory Block and Motor Block was earlier in Group RF compared to Group BF though the difference was not statistically significant (p>0.05). Duration of Sensory Block and Motor Block was significantly higher in BF group compared to RF group.

Hemodynamic parameters

Intraoperative hemodynamic parameters such as Heart rate, SBP, DBP, MAP, Respiratory rate, oxygen saturation were comparable between the two groups. In Group RF 3 patients (6%) developed bradycardia whereas in Group BF 4 patients (8%) developed bradycardia and were treated with atropine 0.6 mg IV. In Group RF 5 patients (10%) and in Group BF 7 patients (14%) developed hypotension which responded well to inj Mephentermine. None of the patients developed any respiratory depression requiring oxygen supplementation in either group.

Duration of postoperative analgesia

Time to First Rescue Analgesia was prolonged in group BF compared to group RF and this difference was statistically significant (p<0.05)

Adverse events: No noteworthy adverse effects were detected in the groups. Hypotension and bradycardia were observed higher in number in group BF though the difference was statistically insignificant.

Table 1: Demographic parameters in the two groups

Demographic/ Anthropometric Data	Group RF (Mean ±SD)	Group BF (Mean ±SD)	t Value	P value	Remark
Age (years)	34.88±13.14	33.48±11.11	0.575	0.566	NS
Height (cm)	163.28±6.17	163.84±6.13	-0.567	0.572	NS
Weight (kg)	60.28±12.18	61.76±13.86	-0.455	0.650	NS
Sex (F/M)	18/32(36%/64%)	22/28(44%/56%)	-	0.414	NS

Table 2: Block characteristics (onset and duration of sensory and motor block)

Onset of Sensory Block (in min)	Group RF (Mean ±SD)	Group BF (Mean ±SD)	t Value	P value	Remark
	6.40±1.03	6.76±0.93	-1.84	0.068	NS
Onset of Motor Block (in min)	7.16±1.17	7.59±1.13	-1.84	0.068	NS
Duration of Sensory block (in min)	160.62±15.39	220.50±18.49	-17.59	0.000	S
Duration of Motor block(in min)	126.74±19.81	194.88±17.96	-18.02	0.000	S

Table 3: Time for rescue analgesia (in min)

Time for rescue analgesia (in min)	Group RF (Mean ±SD)	Group BF (Mean ±SD)	t Value	P value	Remark
	293.56±80.69	365.64±59.44	-5.09	0.000	S

Discussion

Present study observed no significant differences in the demographic characteristics of the patients such as Age, Weight, and Gender distribution, thus both groups could be matched demographically. Studies conducted by Arish Sadaf (2020)[7], Lee YY, et al. (2005)[8], Koltka K et al. (2009)[9], Layek A, et al. (2015)[10] also did not find any significant differences in demographic parameters such as age, weight, or gender between the study groups, similar to our study. In the present study, the patients who received 3ml Intrathecal Ropivacaine heavy 0.75% with 0.5ml Fentanyl and patients who received 3ml Intrathecal Bupivacaine heavy 0.5% with 0.5ml Fentanyl were analysed.

The literature suggested that the dose of fentanyl given in a range of dose (10-25 mcg) was safe and provided prolonged analgesia, so this study used 25 microgram of fentanyl as adjuvant with bupivacaine and ropivacaine. In this study, we used equimilligram dose (25 mcg) of the opioid (fentanyl), while Luck et al [11] used 15 mcg. Fentanyl, an opioid adjuvant that prolongs and improves sensory analgesia without worsening motor blockade or delaying recovery from spinal anaesthesia, was found to improve the intraoperative duration of anaesthesia.

In this study, it was found that Group BF had a mean onset of sensory block that was delayed (6.76±0.93min) in comparison to Group RF (6.40±1.03min), however, the mean duration of Sensory block was significantly prolonged in BF Group (220.50±18.49 min) as compared with the RF group (160.62±15.39 min). Arish Sadaf (2020) [7] also reported that the duration of the sensory block was statistically significantly longer in Group BF (217.71±20.59 minutes) as compared to Group RF (137.43±19.26 minutes). Koltka K et al. (2009) [9] observed that the mean onset of sensory blockade was 10±4.5 minutes in Group BF and 9±4.0 minutes in Group RF while the duration of the sensory block was 185±40 minutes and 160±40 minutes in Group BF and Group RF respectively. In the present study, the mean time to achieve motor block was shorter in Group RF (7.16±1.17 min) in comparison to Group BF (7.59±1.13 min) though the difference was not statistically significant ($p>0.05$). Arish Sadaf (2020) [7] also found that the mean time to onset of motor block was shorter in Group RF (5.86±0.69 minutes) as compared to Group BF (7.91±0.70 mins) similar to our study. Jagtap S et al. (2014)[12] observed that the mean onset time of motor blockade was 6.02±2.1 minutes in Group RF and 6±3.6 minutes in Group BF. Study conducted by McNamee et al. (2002)[13] is concordant with the present study, in their study, the total duration of motor block was significantly lesser in the ropivacaine + Fentanyl group (2.1 hrs) as compared to the bupivacaine+ Fentanyl group (3.9 hrs). Chung et al. (2001) [14] reported that the time of regression of block to S1 was longer (188.56±28.2 mins) in the intrathecal bupivacaine + Fentany group when compared to ropivacaine + Fentanyl group (162.56±20.2 mins). Few other studies also reported similar findings as our study such as Koltka K et al. (2009) [9] observed the duration of motor block was 182±46 minutes in group BF and was significantly prolonged in comparison to Group RF (139±39.10). Jagtap S et al. (2014) [12] observed that the mean duration of the motor block was 242.8±47.06 minutes and 268±49.9 minutes in Group RF and Group BF respectively. Arish Sadaf (2020) [7] observed that the mean duration of the motor block was greater in Group BF (193.71±18.48 minutes) compared to Group RF (121.71±15.81 minutes). Kuthiala G (2011) [15] described that In comparison to bupivacaine, ropivacaine exhibited lower lipophilicity, making it less likely to permeate large myelinated motor fibres. As a result, it 81 selectively affected A-delta and C nerves responsible for pain transmission, rather than Aβ fibres involved in motor function. Ravikumar M et. al. (2023) [16] studied the patients who received intrathecal 2.5ml of 0.75% Ropivacaine + 0.5ml fentanyl (25mcg) and observed that the duration of the motor block was 294.83±6.29 and the duration of analgesia was 282.43±13.74.

In current study, the mean duration of analgesia was prolonged in Group BF as compared with RF which is also supported by Jatap S et al. (2014) [12] who reported that analgesia duration was

prolonged in Group BF (263.33±63 min) in comparison to Group RF (234.44 ± 58.76 min), P = 0.021. Padmanabhan K. R (2016) [17] also found prolonged 80 mean duration of analgesia in study Group BF (289.2±16.38) than RF (242.27±12.81) for elective operations involving lower limb. A similar result was found by Arish Sadaf (2020) [7] who found the duration of analgesia in Group BF was higher (427.43±44.28 minutes) as compared to Group RF (305.43±28.63 minutes).

In the present study there was no statistically significant change in haemodynamic variables in both groups intraoperatively and postoperatively ($p>0.05$). There was no significant hemodynamic instability in the two groups after spinal anaesthesia. This finding was in concordance with the studies conducted by Jagtap S et al. (2014)[12], Layek A et al. (2015) [10], Padmanabhan K. R. et al. (2016)[17], Arish Sadaf (2020)[7], and Kumar RA (2020)[18] who also reported stable hemodynamic profiles.

Conclusion

Based on our study, we conclude that Intrathecal Bupivacaine Heavy with Fentanyl provides an extended period of sensory block, motor block and prolonged postoperative analgesia with overall less analgesic drug requirement in first 24 hours as compared to Intrathecal Ropivacaine Heavy with Fentanyl. Although both Ropivacaine heavy and Bupivacaine heavy with Fentanyl as an adjuvant provide an adequate anaesthetic environment with hemodynamic stability and minimal side effects, intrathecal bupivacaine heavy with fentanyl combination can be preferred for operations requiring longer duration of sensory block and motor block.

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