

Comparison Of Effects Of Isobaric Levobupivacaine Versus Hyperbaric Bupivacaine In Elective Caesarean Sections In Spinal Anaesthesia : A Randomized Prospective Study

Poonam Kalra¹, Akansha Ladla², Priyanka Jain^{3*}

¹Senior Professor, Department of Anesthesia, SMS medical college Jaipur, Rajasthan, India

²Post graduate, Department of Anesthesia, SMS medical college Jaipur, Rajasthan, India

³Associate Professor, Department of Anesthesia, SMS medical college Jaipur, Rajasthan, India

Received: 03-06-2021 / Revised: 18-07-2021 / Accepted: 09-08-2021

Abstract

Background and Aim: The aim of this study was to compare the sensory, motor and hemodynamic effects of Isobaric levobupivacaine with fentanyl versus hyperbaric bupivacaine with fentanyl in elective caesarean sections in spinal anaesthesia and to compare the difference in time to first rescue analgesic requirement in both the groups. **Methods:** 126 patients of ASA grade I and grade II included in this prospective, randomized, interventional study were randomly allocated into 2 groups- Group I (n=63) received Isobaric levobupivacaine 0.5% (10 mg) 2ml + fentanyl 0.5 ml (25 mcg) and Group II (n=63) received 0.5% Hyperbaric bupivacaine (10 mg) 2ml + fentanyl 0.5 ml (25 mcg). The onset of sensory block was defined as the time taken for sensory block to reach T10 and the motor block was assessed using Bromage score and time taken to reach Bromage score 1 was defined as onset of motor block. Total duration of analgesia was assessed using VAS Scale and rescue analgesic was given at VAS score of 3 or more. **Results:** The demographic variables were comparable in both the groups. The onset of sensory and motor block and time taken to achieve maximum level of sensory and motor block was significantly delayed in levobupivacaine group as compared to bupivacaine group (p value < 0.001). The sensory and motor block duration was however longer in bupivacaine group as compared to levobupivacaine group (p value < 0.001). The total duration of analgesia in patients of levobupivacaine group was 157.3±7.13 (minutes) and shorter than in patients of bupivacaine group (165.32±7.35 (minutes)). The side effects like hypotension and bradycardia occurred significantly more in patients of bupivacaine group as compared to levobupivacaine group. **Conclusion:** Intrathecal combination of levobupivacaine and fentanyl can be a good and safe option for caesarean section with shorter motor block and less hemodynamic side effects but with shorter duration of postoperative analgesia as compared to combination of intrathecal bupivacaine and fentanyl.

Keywords: levobupivacaine, bupivacaine, caesarean

This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.

Introduction

General anaesthesia (GA) is associated with greater maternal risk in caesarean section than the widely used spinal anaesthesia. Hyperbaric bupivacaine is the most frequently used local anaesthetic in spinal anaesthesia however hyperbaric solutions may cause hypotension or bradycardia after mobilization, so isobaric solutions are preferred as they are less sensitive to position change [1]. Recently, levobupivacaine, the pure S (-) enantiomer of bupivacaine, is preferred during spinal anaesthesia due to its lower cardiovascular and central nervous related side effects [2]. The plain levobupivacaine has also been shown to be truly isobaric with respect to cerebrospinal fluid (CSF) of pregnant women [3,4]. Its use in spinal anaesthesia may offer special advantages because this property may translate to a more predictable spread [5-8]. The purpose of this study was to compare the anaesthetic effects of hyperbaric bupivacaine with fentanyl vs Isobaric levobupivacaine with fentanyl in elective caesarean sections in spinal anaesthesia with the primary objectives being to determine the difference of onset, time to achieve maximum level of sensory and motor block and total duration of motor and sensory block in both the groups and to determine the difference in time to first rescue analgesic requirement in both groups. The hemodynamic variations at different time

intervals and the differences in side effects (if any) in both the groups were also compared in our study.

Materials and Methods

This prospective, randomized, double blind, comparative, interventional study was conducted after the approval of institutional ethics committee and obtaining written and informed consent from all patients before participation. All patients were between 20-35 years of age, weighing less than 100 kg, scheduled to undergo elective lower segment caesarean section. Patients refusing regional anaesthesia, having any contraindications to spinal anaesthesia, or expectant mothers with fetal anomaly, placenta previa, abruptio placenta were excluded from the study. Sample size was calculated as 63 in each group at 95% confidence interval and 80% power to verify the expected minimum difference of 33.08±4.9 minutes for total duration of motor block in both groups based on previous study [9]. 126 patients of ASA grade I and grade II were randomly allocated into 2 groups- Group I (n=63) received Isobaric levobupivacaine 0.5% (10 mg) 2ml + fentanyl 0.5 ml (25 mcg) and Group II (n=63) received 0.5% Hyperbaric bupivacaine (10 mg) 2ml + fentanyl 0.5 ml (25 mcg). In the operation room standard ASA monitoring (heart rate (HR), noninvasive blood pressure (NIBP), electrocardiogram (ECG) and oxygen saturation (SpO₂)) was established. Baseline vital parameters like HR, BP and SpO₂ were recorded. Under all aseptic precautions spinal anaesthesia was performed at L₃ - L₄ interspace, with the patient in the left lateral position and the study drug was injected over 10 to 15 seconds through a 25-gauge Quincke spinal needle. Patient was placed in supine position with a 15° head down tilt immediately after spinal injection to achieve T5-T6 level. The sensory level of spinal anaesthesia was assessed bilaterally in the

*Correspondence

Dr. Priyanka Jain

Associate Professor, Department of Anesthesia, SMS medical college Jaipur, Rajasthan, India

E-mail: aiims.priyanka@gmail.com

midclavicular line by pinprick, using a short beveled 25-gauge needle and cotton swab. Considering the time of intrathecal injection as zero, the level of sensory block was checked every minute till highest level of sensory block was achieved. Onset of sensory block was defined as the time taken for sensory block to reach T10 and the time taken to achieve highest level of sensory block was taken as time taken to reach maximum level of sensory block. Motor block was assessed using Bromage score and time taken to reach Bromage score 1 was defined as onset of motor block. Hemodynamic parameters were noted every minute till 5 minutes and then at an interval of 5 minutes till the end of surgery. Hypotension and bradycardia were noted and treated. Postoperatively level of sensory and motor block was assessed and the time taken to reach sensory level S1 from the highest level was noted as total duration of sensory block and time taken to reach Bromage score 0 from Bromage score 3 was noted as total duration of motor block. Total duration of analgesia was assessed using VAS Scale and rescue analgesia was given at VAS score of 3 or more. Time from intra-thecal drug

administration to patient's first demand of rescue analgesia was defined as total duration of analgesia. Intravenous infusion Inj. Diclofenac 75 mg was given as rescue analgesic. The side effects were also noted and compared in the two groups.

Statistical Analysis: Results on continuous measurements were presented on Mean \pm SD and results on categorical measurements were presented in Number (%). Significance was assessed at 5 % level of significance. Student t test (two tailed, independent) was used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Chi-square/ Fisher Exact test was used to find the significance of study parameters on categorical scale between two groups.

Results

There was no statistically significant difference in the demographic data in both the groups. Mean age, height, weight, gestation period and ASA grading of the patients as well as duration of surgery, in group I and group II hence excluding any bias.

Table 1: Comparative results between the groups

Parameters	Group I (Mean \pm SD)	Group II (Mean \pm SD)	P value
Age (Years)	26.46 \pm 3.63	27.95 \pm 5.19	0.114(NS)
Weight (Kgs)	64.92 \pm 6.32	64.62 \pm 10.76	0.848(NS)
Height(cms)	156.25 \pm 4.93	155.3 \pm 4.46	0.258(NS)
Gestation period (weeks)	37.7 \pm 0.80	38.1 \pm 0.62	0.241(NS)
ASA Grade (I: II)	43:20	44:19	0.847(NS)
Total duration of surgery (minutes)	51.19 \pm 5.51	51.9 \pm 5.42	0.572(NS)
Onset of sensory block(minutes)	4.7 \pm 1.94	4.3 \pm 1.25	<0.001(S)
Onset of motor block(minutes)	7.61 \pm 1.08	5.52 \pm 1.2	<0.001(S)
Time to reach maximum level of sensory block (minutes)	5.86 \pm 0.98	4.73 \pm 0.99	<0.001(S)
Time to reach maximum level of motor block(minutes)	9.3 \pm 0.78	6.89 \pm 0.7	<0.001(S)
Total duration of sensory block (minutes)	188.25 \pm 8.14	192.67 \pm 10.78	<0.001(S)
Total duration of motor block (minutes)	97.94 \pm 7.44	134.44 \pm 8.57	<0.001(S)
Total duration of analgesia (minutes)	157.3 \pm 7.13	165.32 \pm 7.35	<0.001(S)

Table 2:Side Effects

Side effects	Group I(n=63)	Group II(n=63)	P value
Hypotension	13(20.6%)	29(46.03%)	0.002**
Bradycardia	8(12.69%)	15(23.8%)	0.006**
Headache	6(9.5%)	5(7.93%)	0.752
Respiratory depression	3(4.76%)	4(6.34%)	1.000
Nausea	10(15.87%)	13(20.63%)	0.489
Vomiting	10(15.87%)	11(17.46 %)	0.811
Shivering	2(3.17%)	4(6.34 %)	0.680

Table 1 shows the mean time of onset of sensory block in patients of group I was 4.7 \pm 1.94 (minutes) and the mean time to sensory onset in patients of group II was 4.3 \pm 1.25 (minutes) (p value <0.001). This indicates onset of sensory block was significantly delayed in group I as compared to group II. Difference in mean time of onset of motor block was statistically significant (p value < 0.001) i.e. motor onset was delayed in group I as compared to group II. Time taken to achieve maximum level of sensory and motor block was delayed in group I as compared to group II (p value < 0.001). The sensory and motor block duration was longer in group II as compared to group I. (p value <0.001). The total duration of analgesia in patients of group

I was 157.3 \pm 7.13 (minutes) and in patients of group II was 165.32 \pm 7.35 (minutes). Difference was statistically significant (p value < 0.001). As shown in Table 2, when comparing side effects, hypotension and bradycardia occurred significantly more in patients of Group II as compared to Group I. The mean heart rate in group II was more than group I and the difference was statistically significant in both groups up to 30 mins (fig.1). Intra-operative mean BP was lower in group II as compared to group I and difference was statistically significant up to 15 minutes between both groups (p value < 0.05) (fig.2). Mean VAS score was lower in group II as compared to group I (Fig. 3).

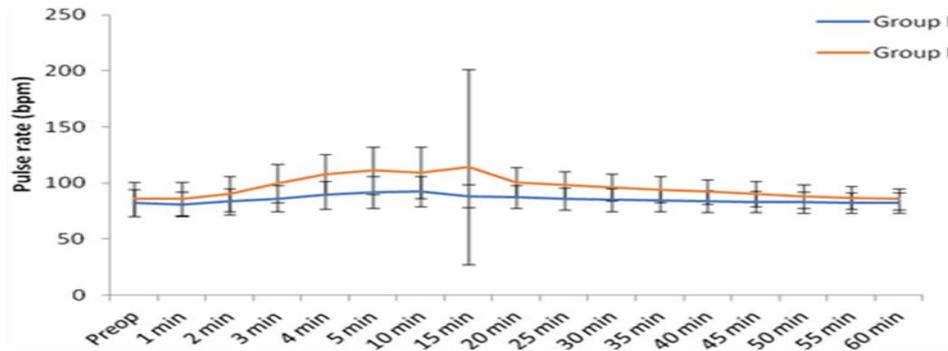


Fig 1: Mean Heart Rate

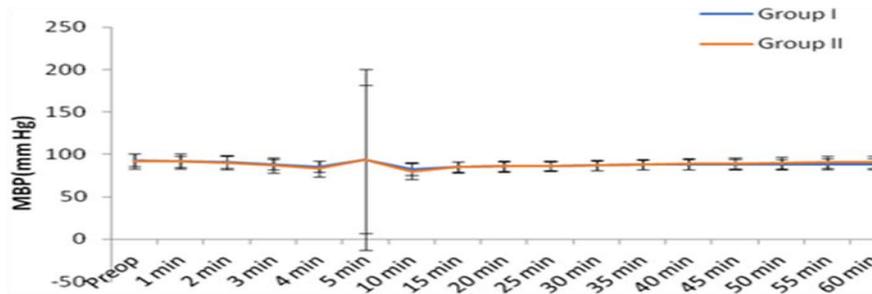


Fig 2: Mean Blood Pressure

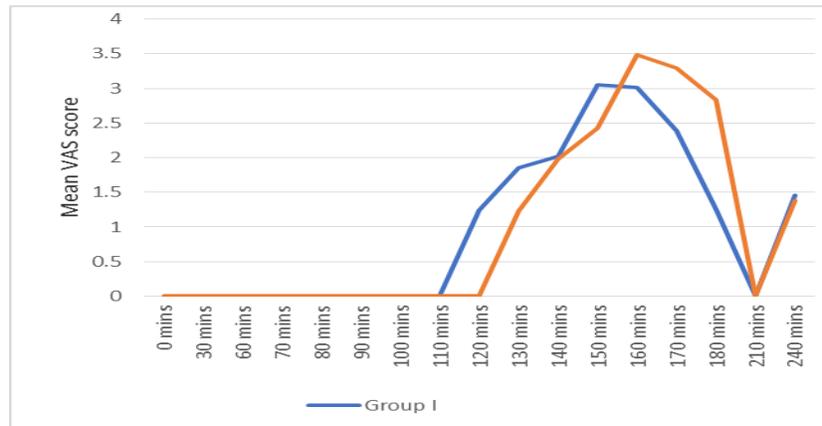


Fig 3: Mean VAS score

Discussion

Spinal anaesthesia is the preferred method for elective caesarean section and it is associated with short duration of analgesia post operatively which can be supplemented by analgesics once patient experiences pain and demands for its relief. Intrathecal opioids cause segmental analgesia by binding to opioid receptors in the dorsal horn of the spinal cord. They prolong the duration of analgesia without affecting motor or autonomic nervous function. The combination of intrathecal opioids with intrathecal local anaesthetic limits the regression of the sensory block seen with local anaesthetic alone. The present study was conducted to compare anaesthetic effects of intrathecal hyperbaric bupivacaine with fentanyl and intrathecal isobaric levobupivacaine with fentanyl in elective lower segment caesarean section wherein we found that the onset and time taken to

reach maximum level of sensory and motor block was delayed in levobupivacaine+ fentanyl group as compared to bupivacaine+ fentanyl group with p value <0.001 (statistically significant). The duration of sensory and motor block was longer in bupivacaine+ fentanyl group as compared to levobupivacaine+ fentanyl group (p value < 0.001). Similarly previous studies by Choudhary et al[10] and Gadkari et al[11] have also documented delayed onset of sensory and motor block with levobupivacaine as compared to bupivacaine in spinal anaesthesia. However difference in the onset time of sensory and motor block onset time and also shorter duration of sensory block in the study by Chaudhary et al as compared to ours can be attributed to difference in dose of study drug i.e 7.5 mg as compared to 10 mg used in our study.

Gadkari et al[11] in their study also found that mean time of onset of sensory block in patients of levobupivacaine + fentanyl group was 2.50 ± 0.51 mins and in patients with bupivacaine + fentanyl group was 1.67 ± 0.37 minutes. Difference in their sensory onset time as compared to our study can be explained by difference in sensory onset criteria, they defined sensory block onset as time taken for the block to reach L1 sensory level. They also reported that that time taken to reach maximum level of sensory block in Group I was 8.49 ± 0.59 minutes and in Group II was 7.53 ± 0.35 minutes. Difference was statistically significant. Delay in their time taken to reach maximum level of sensory block and shorter duration as compared to our study can be explained as they used less dose of study drug i.e. 5 mg. In our study, duration of motor block (time to reach Bromage score 0 from score 3) was 97.94 ± 7.44 minutes in levobupivacaine while in group bupivacaine the mean duration of motor block was 134.44 ± 8.57 minutes (p value < 0.001). The results of present study were in agreement to the study by Guler et al[12]. In their study, they also found that total duration of motor block was more in bupivacaine group than levobupivacaine group and the difference was statistically significant.

Total duration of analgesia was longer in bupivacaine+ fentanyl group than levobupivacaine + fentanyl group and the difference was statistically significant. (p < 0.001) in the present study.

Goyal et al. in their study found that the mean duration of analgesia was 157.3 ± 7.13 minutes in levobupivacaine group and in bupivacaine group was 165.32 ± 7.35 minutes and the difference was significant between the groups.

Guler et al. in their study found that the total duration of analgesia in levobupivacaine+ fentanyl group was 145.5 ± 11 minutes and in bupivacaine+fentanyl group was 161.3 ± 12.5 minutes, which were similar to our study.

In our study we found that intra- operative NIBP was lower in bupivacaine group as compared to levobupivacaine with significantly more episodes of hypotension and bradycardia in bupivacaine than levobupivacaine. Hypotension was reported in 20.6% patients of levobupivacaine group and in 46.03% patients of bupivacaine group. Bradycardia occurred in 12.69% patients of levobupivacaine group and 23.8% patients of bupivacaine group. Hence levobupivacaine proved to be more hemodynamically safe than bupivacaine in this study. Previous authors[13-18] have also reported that hemodynamic parameters were more stable in levobupivacaine+ fentanyl group as compared to bupivacaine+ fentanyl group.

In this study, there was no significant difference with respect to shivering, respiratory depression, nausea and vomiting in both groups.

Conclusion

We concluded from our study that the combination of levobupivacaine and fentanyl can be a good and safe alternative to hyperbaric bupivacaine and fentanyl in spinal anesthesia for cesarean sections owing to shorter duration of motor block with adequate sensory block and better hemodynamic stability but at the cost of lesser total duration of analgesia requiring early rescue analgesic in the postoperative period.

References

1. McLeod GA. Density of spinal anaesthetic solutions of bupivacaine, levobupivacaine, and ropivacaine with and without dextrose. *Br J Anaesth.* 2004;92(4):547-51.
2. Foster RH, Markham A. Levobupivacaine: A review of its pharmacology and use as a local anaesthetic. *Drugs.* 2000;59(3):551-79.

3. McLeod GA, Burke D. Levobupivacaine. *Anaesthesia.* 2001; 56(4):331-41.
4. Morrison SG, Dominguez JJ, Frascarolo P, Reiz S. A comparison of the electrocardiographic cardiotoxic effects of racemic bupivacaine, levobupivacaine, and ropivacaine in anesthetized swine. *Anesth Analg.* 2000;90(6):1308-14.
5. Vanna O, Chumsang L, Thongmee S. Levobupivacaine and bupivacaine in spinal anesthesia for transurethral endoscopic surgery. *J Med Assoc Thai.* 2006; 89:1133-9.
6. Glaser C, Marhofer P, Zimpfer G, Heinz MT, Sitzwohl C, Kapral S *et al.* Levobupivacaine versus racemic bupivacaine for spinal anesthesia. *Anesth Analg.* 2002;94:194-8.
7. Lee YY, Muchhal K, Chan CK. Levobupivacaine versus racemic bupivacaine in spinal anaesthesia for urological surgery. *Anaesth Intensive Care.* 2003;31:637-41.
8. Fattorini F, Ricci Z, Rocco A, Romano R, Pascarella MA, Pinto G. Levobupivacaine versus racemic bupivacaine for spinal anaesthesia in orthopaedic major surgery. *Minerva Anesthesiol.* 2006;72:637-44.
9. Goyal A, Shankaranarayan P, Ganapathi P. A randomized clinical study comparing spinal anesthesia with isobaric levobupivacaine with fentanyl and hyperbaric bupivacaine with fentanyl in elective cesarean sections. *Anesth Essays Res.* 2015; 9:57-62.
10. Choudhary D, Sethi P, Chouhan DS *et al.* Comparison between racemic bupivacaine and levobupivacaine; both combined with low dose fentanyl, through intrathecal route for transurethral resection of prostate. *Int. j. clin. biomed. res.* 2018; 4(3):10-13.
11. Charuta Gadkari, Rishihesh Jirapure, Anjali Bhure. Comparison of efficacy of Interathecal 0.5% Isobaric Levobupivacaine With Fentanyl Versus 0.5% Isobaric Bupivacaine with Fentanyl for Inguinal Hernia Repair. *International Journal of Contemporary Medical Research.* 2019; 6(1):A12-A17.
12. Guler G, Cakir G, Ulgey A, Ugur F, Bicer C, Gunes *I et al.* A comparison of spinal anesthesia with levobupivacaine and hyperbaric bupivacaine for cesarean sections: A randomized trial. *Open J Anesthesiol.* 2012;2:84-9.
13. Attri JP, Kaur G, Kaur S, Kaur R, Mohan B, Kashyap K. Comparison of levobupivacaine and levobupivacaine with fentanyl in infraumbilical surgeries under spinal anaesthesia. *Anesth Essays Res.* 2015;9:178-84
14. Brahmabhatt NP, Prajapati AI, Upadhyay MR. Combination of low dose isobaric levobupivacaine 0.5% and fentanyl compared with isobaric levobupivacaine 0.5% in spinal anaesthesia for lower abdominal and perineal surgeries. *Int J Res Med.* 2015; 4:55-60.
15. Mohan S, Saran J, Kashyap M. Comparative Study of 0.5% Levobupivacaine and 0.5% Levobupivacaine with Fentanyl in Transurethral Resection of Prostate. *Int J Sci Stud.* 2017;4(10):67-72
16. Bidikar M, Mudakanagoudar MS, Santhosh MC. Comparison of intrathecal levobupivacaine and levobupivacaine plus fentanyl for cesarean section. *Anesth Essays Res.* 2017;11:495-8
17. Singh G, Mukherjee A. Intrathecal block in caesarean section-comparison between levobupivacaine-fentanyl and levobupivacaine. *Ann Int Med Den Res.* 2017;3(4):AN09-AN12
18. Chandra, Kumar Brahma, Subir. Comparison between racemic bupivacaine and levobupivacaine; both combined with low dose fentanyl, through intrathecal route for transurethral resection of prostate. *Int. J. Clin Biomed Res.* 2018; 4(3):10-13.

Conflict of Interest: Nil Source of support: Nil