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Pratibha Jain Shah
Professor, Department of Anesthesiology and Pain Medicine, Pt. J.N.M. Medical College, Ayush University, Raipur, Chhattisgarh, India

Rashmi Naik Bhuaarya
Associate Professor, Department of Anesthesiology and Pain Medicine Pt. J.N.M. Medical College, Ayush University, Raipur, Chhattisgarh, India

Mohammed Firoz Sheikh
Resident Doctor, Department of Anesthesiology and Pain Medicine Pt. J.N.M. Medical College, Ayush University, Raipur, Chhattisgarh, India

Corresponding Author:
Mohammed Firoz Sheikh
Resident Doctor, Department of Anesthesiology and Pain Medicine Pt. J.N.M. Medical College, Ayush University, Raipur, Chhattisgarh, India

Block characteristics of hyperbaric bupivacaine versus hyperbaric ropivacaine in lower segment cesarean section: A randomized experimental study

Pratibha Jain Shah, Rashmi Naik Bhuaarya and Mohammed Firoz Sheikh

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Abstract
Introduction: Bupivacaine is used most commonly for spinal anesthesia, however the major concern is longer duration and cardiotoxicity, that led us to find safe alternative with shorter duration. Hence, we compared routinely used hyperbaric bupivacaine with recently available hyperbaric ropivacaine in terms of block characteristics in caesarean section (CS).
Objective: To compare the efficacy and safety of hyperbaric ropivacaine and bupivacaine in spinal anesthesia for elective CS with primary outcome as onset of sensory block at T 10 level & secondary outcomes as onset of motor block, grading & duration of sensory and motor block, duration of analgesia, hemodynamic changes & side effects.
Methodology: Eighty parturients with ASA grade II undergoing elective CS were allocated into two groups (n=40): group R (2 ml hyperbaric ropivacaine 0.75%) and group B (2 ml hyperbaric bupivacaine 0.5%).
Result: Though onset of sensory block (group B 3.40±0.63 min & in group R 4.13±0.79min) & motor block (group B 5.28±0.82 min & group R 7.10±0.84min) ($p<0.001$) were significantly shorter in group B, but duration of sensory & motor block and duration of analgesia was significantly shorter in group R ($p<0.001$). Incidence of side effects (i.e. hypotension, nausea & vomiting, shivering) was comparable in both the groups.
Conclusion: Ropivacaine can be preferred as an alternative to bupivacaine for spinal anesthesia in cesarean section because of early recovery & lesser side effects.

Keywords: Cesarean section, bupivacaine, ropivacaine, spinal anesthesia

Introduction

Caesarean section is growing at an "alarming" rate, accounting for 21% of births globally in 2015 up from 12% in 2000 [1]. In India as against 17.2% of C-section births (NFHS-4 2015-16), fifth round of NFHS survey now pegs the graph at 21.5% in 2020-2021 [2]. With the increasing number of cesarean section, the anaesthesiologist is trapped in a delicate web of decision making over the choice of anesthetic technique & drug to be employed which guarantee the safety of both the mother and fetus [3-5].

In the recent decades there has been a worldwide shift in obstetrics anaesthesia practice in favor of regional anaesthesia with spinal anaesthesia being the most popular among them [3-5]. Lignocaine a short acting amide local anaesthetic (LA) which is not used now for spinal anaesthesia in CS due to short duration of action and side effects like TNS. Bupivacaine, a long acting amide LA, is used most commonly for spinal anesthesia (SA). However, major concern about the longer duration &cardiotoxicity of bupivacaine led to development of ropivacaine. Ropivacaine, a pure S enantiomer, is less cardiotoxic, has shorter duration of action, and has lesser lipid solubility than bupivacaine. It also exhibits differential blockade property (sensory > motor), leading to early return of motor activity and postoperative ambulation [6-7].

Also, in the existing literature, there is gross variation in block characteristics between hyperbaric bupivacaine and hyperbaric ropivacaine. Hence, we proposed to conduct this study to shed some light on block characteristics of these two pharmacological agents. That would help us to choose these drugs for spinal anaesthesia according to patient's characteristic & surgical need for patient benefit.

Thus, the present study comparing anesthetic efficacy of intrathecal use of hyperbaric ropivacaine 0.75% and hyperbaric bupivacaine 0.5% was planned to conduct with the primary outcome to compare the onset of sensory block and secondary outcomes as onset of motor block, duration of sensory & motor block, grade of sensory & motor block & duration of analgesia in LSCS, if any of the above two study drugs.

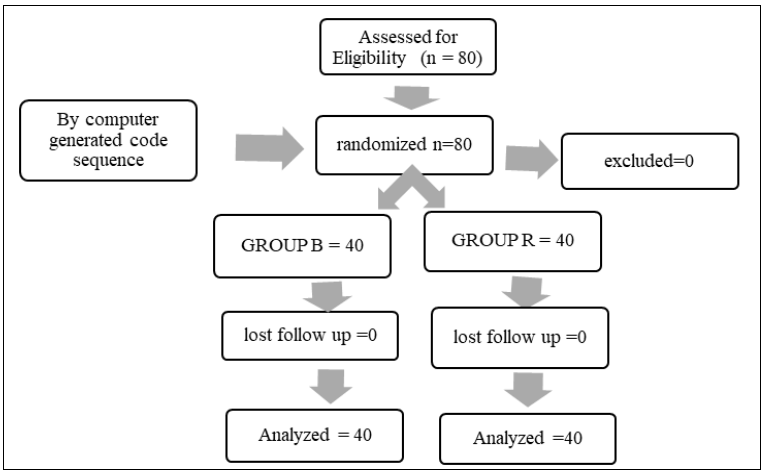
Material and Methods

This prospective, randomized, double blind study was conducted from May 2022 to December 2022 in the tertiary centre of Chhattisgarh, India after seeking the permission from the Institutional Scientific & Ethics Committee and CTRI registration (CTRI/2022/05/042898).

Sample Size calculation was done according to the previous data from the study of Dr. Chan - Jong Chung *et al*. (2001). Taking mean duration of onset of sensory block at the level of T_{10} into consideration and 95% consider interval,80% power, total sample size of 80 was calculated (n =40).'Group B' received 2 ml of hyperbaric 0.5% bupivacaine intrathecally & Group R' received 2 ml of hyperbaric 0.75% ropivacaine intrathecally. ASA grade II parturients of 18 to 40 years, height between 150 to 170 cm and weighing 50-75 kg who were planned for elective cesarean section under spinal anesthesia were included in the study. Exclusion criteria were patient refusal, any neurological condition (like demyelinating lesions, increased intracranial tension and head injuries), diabetes mellitus, hypertension, renal, hepatic, pulmonary or pre-existing severe cardiac (Severe aortic stenosis, severe mitral stenosis) disease, chronic pain medication, bleeding or coagulation disorders and those on anticoagulant therapy, history of allergy to study drugs, partial or failed spinal anaesthesia.

Methodology

Eighty parturients were randomly allocated into two groups either group B or group R, by computer generated code system. On parturients arrival to operating room review of PAC, recent lab values & consents were checked. As per the protocol of our institute, all parturients were kept nill per oral for 8 hrs prior to surgery. All parturients were informed and explained about procedure. Multipara monitor was attached and baseline BP, HR, RR and SpO_2 were recorded. An intravenous line was established with 18 G cannula and Ringer lactate solution @ 10 ml/kg was initiated. Premedication was done with iv ondansetron 4mg. Under all aseptic precautions subarachnoid block was given in the sitting position with 25-G Quincke's spinal needle through L3-L4 interspace &study drug was administered @ 0.2ml/sec as per group assigned. Sensory block was assessed & graded by pin prick method bilaterally along the midclavicular line every 1 minute during the first 10 minutes after the intrathecal injection, then every 5 min after the end of surgery till 2 segment regression of sensory block then every 10 min till complete regression of block. Onset of sensory block was considered as time from the intrathecal injection of local anaesthetics to sensory block at T10 level. Time between onset of sensory block and 2 dermatome regression of the sensory block after achievement of maximum sensory block was regarded as the duration of sensory block. Grade of sensory block was evaluated by using a Hollmen scale (Grade 1 - full sensation, Grade 2 - weak sensation, Grade 3 - recognized as light touch, Grade 4 - loss of sensation). Motor block was assessed & graded by using a modified Bromage scale (0 = no paralysis, 1= unable to raise extended leg, 2= unable to flex knee, 3 = unable to flex ankle) along with sensory block. Onset of motor block was considered as time from intrathecal injection of local anaesthetic till grade 3 modified Bromage scale was achieved. Time between grade 3 motor block (by modified Bromage scale) and complete regression of motor block to grade 0 (by modified Bromage scale) was considered as the duration of motor block. Surgery was commenced when the sensory block at or above the T6 dermatome were established. Time to first request for analgesia by parturients after intrathecal injection of local anaesthetic was considered as duration of analgesia. Vital parameters BP, HR, RR and SpO_2 were monitored continuously and recorded at baseline and every 2 min after subarachnoid block for first 20 minutes then every 5 min until the end of surgery. Side effects such as hypotension, bradycardia, nausea and vomiting, shivering and respiratory depression, were noted and adequately treated. Hypotension (fall in systolic blood pressure of more than 20% of baseline value or less than 100 mm Hg) was treated with volume expansion and by incremental doses of iv mephentermine 3-6 mg. Respiratory depression (Oxygen saturation of <94% on the pulse oximeter or respiratory rate <10 per minute) was treated with oxygen supplementation and assisted ventilation. Bradycardia (decrease in heart rate <55/min) was treated with 0.3 mg of intravenous atropine. Nausea and vomiting was treated with iv Ondansetron 4 mg.



Graph 1: Consort Diagram

Numerical data was summarized by mean ± SD & were compared by Student's t-test. Inter group comparison was done by unpaired t-test & intra group comparison was done by paired t-test &categorical data was summarized in terms of percentage & were compared by Chi-square test. p value > 0.05 was considered as not significant, p Value < 0.05 was considered as significant and $p<0.01$ was considered as highly significant. All the data were calculated with the help of graph-pad in stat software.

Result

The demographic profile (i.e. mean age, weight and height), duration of surgery, maximum sensory block level (T4-T5) were comparable in both the groups (p value >0.05). (Table - 1).

Table 1: Demographical profile, Duration of surgery, Maximum sensory block level

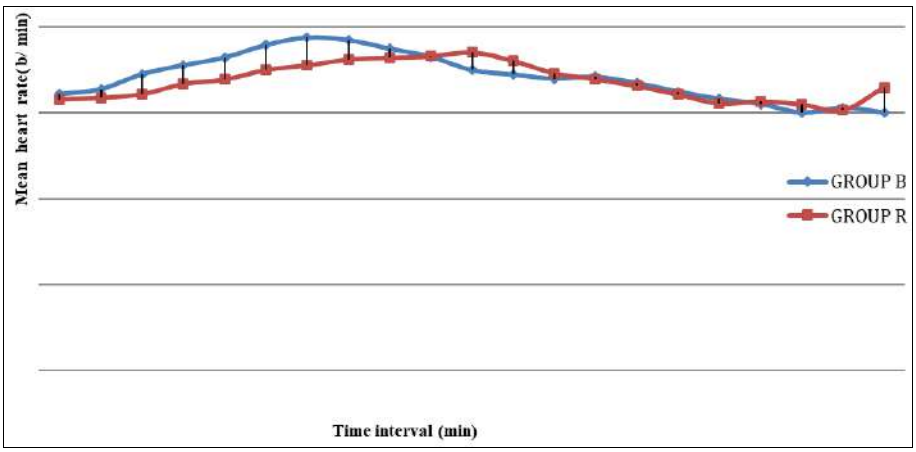
Parameters		Group B (Mean ±SD)	Group R (Mean ±SD)	p value
1	Demographic profile			
	Age (years)	25.15 ± 3.67	25.85±3.13	0.3613
	Weight (kg)	58.63± 5.08	58.76±4.47	0.8911
	Height (cm)	156.21±4.43	156.73±4.35	0.5976
2	Duration of surgery (min)	54.70 ± 5.72	52.80 ± 6.10	0.1547
3	Maximum sensory block level	T4- T5	T4-T5	1.000

Mean onset time of sensory block at T 10 level and motor block was slower with intrathecal ropivacaine than intrathecal bupivacaine ($p<$ 0.0001).The mean duration of sensory block, motor block and duration of analgesia was shorter with intrathecal ropivacaine than intrathecal bupivacaine and this difference was statistically significant (p value< 0.0001). All the parturients in both the groups achieved grade 4 sensory block by Hollmen scale at T10 level and at maximum level of block (T4-T6), (p=1.000). All the parturients in both the groups achieved grade 3 modified Bromage scale (p value=1.000). (Table - 2).

Table 2: Sensory and Motor blockade profile

Parameters (min)	Group B (Mean ± SD)	Group R (Mean ± SD)	p-Value
Onset of sensory block at T10 level	3.40± 0.63	4.13± 0.79	<0.0001
Onset of motor block	5.28 ± 0.82	7.10 ± 0.84	<0.0001
Duration of sensory block	87.75±10.25	70.50±10.85	<0.0001
Duration of motor block	164.50 ± 12.60	140.50 ± 11.18	<0.0001
Duration of analgesia	137.25±15.33	117.25±15.19	<0.0001

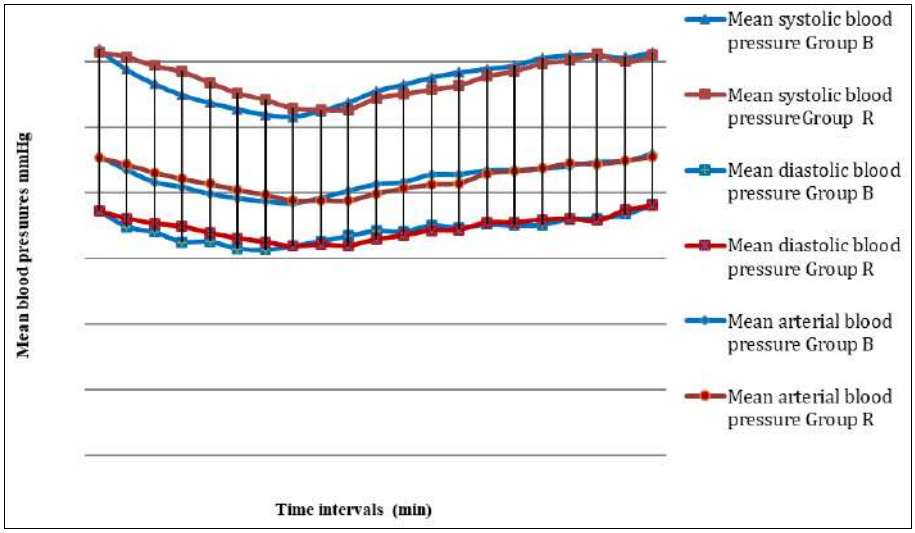
Mean heart rate during the initial 14 min was significant higher in intrathecal bupivacaine as compared to intrathecal ropivacaine (p value < 0.05). Thereafter, it was comparable between both the groups (p value > 0.05) (Graph - 2). Mean SBP during the initial 2 min to 12 min, mean DBP during the initial 4 min to 12 min & mean MAP during the initial 4 min to 8 min were significantly lower in intrathecal bupivacaine group as compared to intrathecal ropivacaine group (p value < 0.05). Thereafter all mean blood pressures were comparable between both the groups (p value >0.05) (Graph - 3). Mean respiratory rate & mean SpO_2were comparable between group B and group R at base line and at different time intervals after SAB. (p >0.05) APGAR score at 1st& 5th minute, in group-B was 8.05 ±0.50 & 9.28± 0.45 while in group-R was 8.10± 0.58 & 9.25 ± 0.54, respectively (p value > 0.05). Incidence of side effects (i. e, hypotension, bradycardia, nausea & vomiting, shivering & respiratory distress) were comparable in both the groups (p value > 0.05). In group B, 16 (40%) parturients received iv mephentermine while in group R, 11 (27.5%) parturients received iv mephentermine in various doses (3mg to 30mg) & this difference was statistically insignificant (p value > 0.05) (Table - 3).



Graph 2: Mean Heart Rate

Table 3: Incidence of side effects

Side effects	Group B	Group R	p value
Hypotension	16(40%)	11(27.5%)	0.2371
Bradycardia	0(0%)	0(0%)	-
Nausea & vomiting	6(15%)	5(12.5%)	0.7574
Shivering	3(7.5%)	2(5%)	0.6442
respiratory distress	0(0%)	0(0%)	-



Graph 3: Mean Blood Pressures

Discussion

The mean onset time of sensory block up to T10 level and motor block was significantly slower with intrathecal ropivacaine than intrathecal bupivacaine. The mean duration of sensory and motor block was significantly shorter with intrathecal ropivacaine than intrathecal bupivacaine. Intrathecal ropivacaine also had shorter duration of analgesia than intrathecal bupivacaine. All the parturients in both the groups achieved grade 4 sensory block by Hollmen scale at T_{10} level and at maximum level of block (T4-T6). All the parturients in both the groups achieved grade 3 modified Bromage scale & this difference considered statistically insignificant. Mean duration of surgery was comparable between group B & group R.

Similar to our study Singhal R K *et al*. [5], Chung C J *et al*. [6], Olapour A *et al*. [9], Chandra K *et al*. [10], Srivastava U *et al*. [7] & Feroz Ahmad D *et al*. [11] that observed onset of sensory and motor block was slower in ropivacaine group as compared to bupivacaine group. Chung C J *et al*. [6] observed faster onset of sensory block at T10 level and motor block (ropivacaine group 3.2 ± 1.2 min and 6.3 ± 2.2 min vs bupivacaine group 2.5 ± 1.0 min and 6.0 ± 1.9 min) which might be due to the use of 12 mg 0.5% hyperbaric bupivacaine and 18 mg of 0.5% hyperbaric ropivacaine which was made by mixing of 4 ml of 0.75% ropivacaine with 2 ml of 20% dextrose (which might have different specific gravity than drug which we used in our study) and block was administered in lateral position whereas we preformed block in sitting and used 10 mg of hyperbaric 0.5% bupivacaine & 15 mg of hyperbaric 0.75% ropivacaine. Olapour A *et al*[9]observed faster onset of sensory and motor block {in ropivacaine group 2.32±0.9 min and 2.86± 0.82 min vs in bupivacaine group 1.28± 0.4 min and 1.63±0.38 min, p value (< 0.001)} because they used different volume, dose & concentration of drug {hyperbaric 15 mg ropivacaine 1% (manufactured by L. olteni & C Dei Fratelli Societa Di Eserciozio SpA, Italy) & hyperbaric 10 mg bupivacaine 0.5% (manufactured by AstraZeneca Sweden)} than our study drug. Srivastava U *et al*. [7] (ropivacaine group 5.73+/- 0.45 min vs bupivacaine group 5.19+/-0.40min (p<0.05) &Subba S, *et al*. [8] (ropivacaine group 4.87 ± 1.72 min and bupivacaine group 4.87± 1.46 min) p-value< 0.05) reported slower onset of sensory block as compared to our study in both the groups. This may be attributable to the fact that Srivastava U *et al*. [7] used 15 mg of 0.5% hyperbaric ropivacaine in 8.3% dextrose and 10 mg of 0.5% hyperbaric bupivacaine and also assessment of block was done at different time intervals &Subba S, *et al*. [8] used 3 ml of 0.5% hyperbaric Ropivacaine (which was prepared by mixing of 1 ml of 25% dextrose with 2 ml 0.75% plain ropivacaine) & 2.5 ml of 0.5% hyperbaric bupivacaine intrathecally for LSCS and onset of sensory block was considered at T4 level while we observed onset of sensory block at T10 level. Chandra K *et al*. (2015) [10] & Feroz Ahmad D *et al*. (2015) [11] observed slower onset of motor block in both the groups this finding is contrary to our study (6.16 ± 1.25 min in bupivacaine group vs 9.04 ± 1.20 min in ropivacaine group &9 ± 1.3 min bupivacaine group vs 13 ± 1.6 min ropivacaine group (p< 0.001) respectively). This may be attributable to the fact that Chandra K, *et al*. [10] used elective gynecological surgeries patient & administer 3 ml of 0.5% hyperbaric ropivacaine (15 mg) and 3 ml of 0.5% hyperbaric bupivacaine (15 mg) intrathecally & Feroz Ahmad D, *et al*. [11] used lower limb and hip surgery patients & administered an intrathecal injection of 3 ml of hyperbaric 0.5% ropivacaine (prepared aseptically by mixing 5 ml of 0.75% isobaric ropivacaine (Ropin ®, Neon, India) with 2 ml of 25% dextrose and 0.5 ml sterile water at room temperature. This gave a total volume of 7.5 ml resulting in a final glucose concentration of 6.6% in hyperbaric ropivacaine solution with specific gravity of 1.0245 at room temperature.) or 3 ml of

hyperbaric 0.5% bupivacaine while we performed the block with already available drugs which has different concentration and specific gravity.

Srivastava U *et al.* [7] observed duration of sensory and motor block was longer in bupivacaine group (135 ± 26.8 min and 182.9 ± 30.83 min) compared to ropivacaine group (110.6 ± 12.0 min and 127±20.42min) (p<0.05). Duration of sensory block was longer in both the groups than our study result this may be attributable to fact that they considered regression of sensory block to T10 level as duration of sensory block while in our study we considered 2 dermatomal regression block level from the maximum level of sensory block achieved as duration of sensory block and also assessment of block was done at different time intervals and used 15 mg of 0.5% hyperbaric ropivacaine (in 8.3% dextrose) and 10 mg of 0.5% hyperbaric bupivacaine intrathecally for spinal anaesthesia. Feroz Ahmad D, *et al.* [11] observed shorter duration of motor block with ropivacaine i.e. 126 ± 9.2 min vs 174 ± 12.6 min (p< 0.001) in bupivacaine group. They used either intrathecal injection of 3 ml of hyperbaric ropivacaine 0.5% or 3 ml of hyperbaric bupivacaine 0.5% to patients who planned for lower limb and hip surgery while we used 2 ml 0.75% ropivacaine and 2 ml of 0.5% bupivacaine intrathecally for LSCS. Chung CJ, *et al.* [6] reported time to first request of analgesics (min) in bupivacaine group 143.2 ± 20.3 & in ropivacaine group 129.2 ± 28.5 (p< 0.05). Result of this study show slight longer duration of analgesia than our study in both the groups, this may be attributable to fact that they used 12 mg of 0.5% hyperbaric bupivacaine and 18 mg of 0.5% hyperbaric ropivacaine in the right lateral position at the L2-3 or L3-4 interspace & also they made hyperbaric ropivacaine solutions by mixing of 4 ml of 0.75% ropivacaine with 2 ml of 20% dextrose, which had different specific gravity to drug which we used in our study. Similar to our study Olapour A, *et al.* [9] also observed that the HR, SBP and DBP changed significantly during time, and also the trend of changes is almost similar in both ropivacaine and bupivacaine groups. Ingale L, *et al.* [12] and Tarkase AS, *et al.* [13] also observed comparable mean respiratory rate and mean SpO_2 throughout the study period similar to our study. Chung CJ, *et al.* [6] observed dyspnea in 6.7% patients in bupivacaine group & 10% in ropivacaine group and hypotension was the most common side effect in both groups. Result of this study were higher than our study result in both the groups, this may be attributable to the fact that they used higher drug volume (2.5 ml of 0.5% hyperbaric bupivacaine and 3.5 ml of 0.5% hyperbaric ropivacaine) & maximum level of block was T3 which is higher than our study result.

Limitations

- This study has been conducted in only one hospital and the study population were pregnant women undergoing elective cesarean section.
- Study drug dose was not equal between both the groups this might have impact on the result of the study.
- Besides Apgar score, umbilical blood analysis can be done to know the effect of drugs on neonates.
- Limited availability of similar studies for comparison.

Future scope

- Comparative study of the same drugs can be done among non-parturients patients undergoing surgery under spinal anaesthesia
- Besides Apgar score, umbilical blood analysis can be done to know the effect of drugs on neonates.

Conclusion

From above observations & results, it is observed that intrathecal bupivacaine has significant faster onset of sensory & motor block, prolonged duration of sensory & motor block, prolonged analgesia, with comparable grades of sensory & motor blocks & incidence of complications as compared with intrathecal ropivacaine. Thus we concluded that both are equal effective for LSCS in terms of grade & incidence of side effects. Ropivacaine can be preferred in LSCS because of significantly faster recovery & stable haemodynamics.

Conflict of Interest

Not available

Financial Support

Not available

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