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Original Research Article

A comparative study of intrathecal isobaric ropivacaine and hyperbaric bupivacaine for elective lower segment caesarean section

M. Ramarao[1], K. Laxman Rao[1], M. Santhi Sree[2]*, M. Raghuvardhan[1]

[1]Department of Anaesthesia, Govt. Medical Collage, Rajamahendravaram, Andhra Pradesh, India
[2]Department of Anaesthesia, ACSR Medical Collage, Nellore, Andhra Pradesh, India

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***Correspondence:**
Dr. M. Santhi Sree,
Email: santhisreemulam@gmail.com

ABSTRACT

Background: The study was to compare intrathecal isobaric ropivacaine and hyperbaric bupivacaine in terms of onset of sensory block, maximum height of sensory block, total sensory duration, onset of motor block, degree of motor block and duration of motor block, quality of anesthesia.
Methods: The 100 cases of ASA II undergoing elective lower segment caesarean section were taken for the study and divided into two groups. Group B patients received 2 ml of hyperbaric bupivacaine intrathecally. Group R patients received 2ml of isobaric ropivacaine intrathecally. Patients were evaluated for onset and duration of sensory block, onset and duration of motor block, maximum height of sensory block, quality of anaesthesia, time to request for analgesia, hemodynamic parameters and side effects if any were studied.
Results: There were no significant differences between the two groups in mean time to onset of sensoryblock. Maximum sensory height attained in group B ranged between T4 and T6, where as in group R, it ranged between T2 and T6 which was clinically and statistically highly significant ($p<0.001$). Total duration of sensory block in group B and in group R, which is not significant ($p=0.068$). Mean time onset of motor block was 4min in group B and 8 min in group R, ($p<0.001$). Duration of motor block was 155.20±14.95 min in group B and 94.10±8.31 min group R, which is clinically and statistically significant ($p<0.001$).
Conclusions: Ropivacaine 15 mg (2 ml of 0.75% isobaric ropivacaine) provides comparable quality of sensoryblock but has slower onset and significantly shorter duration of motor block compared to bupivacaine.

Keywords: Bupivacaine, Ropivacaine, Intrathecal, Caesarean section

INTRODUCTION

Regional anaesthesia is preferred now over general anaesthesia as it provides immediate and better pain relief which results in good patient satisfaction. There is no airway manipulation and no need of skeletal muscle relaxation, less incidence of postoperative nausea and vomiting, speedy recovery and early discharge following surgery.[1]

Even though modern general anaesthesia is more certain safer, faster and acceptable, more commonly used regional anaesthesia has been proved to be safe, effective as well. It offers less interference with normal metabolic process and vital functions of body as compared to general anaesthesia. Regional anesthesia is also preferred for surgery on patients who are less suitable for general anaesthesia like patients with full stomach, cardiopulmonary disease, metabolic and endocrine diseases etc.[2]

August Bier performed 1st spinal anaesthesia more than a century ago by injecting cocaineinto CSF of a patient.[3]

Subarachnoid block is the anaesthetic technique of the choice and gold standard for caesarean section compared to general and epidural anaesthesia, as there is chance of gastric acid aspirationwith general anaesthesia and lack of reliability with epidural anaesthesia.[4,5]

Lidocaine has been most widely used local anaesthetic for spinal anaesthesia in caesarean section because of its faster onset and short duration of action but it is associated very highincidence of transient neurological symptoms.[6]

Bupivacaine 0.5% produces motor blockade of prolonged duration, but cardiotoxic, if accidentally injected into blood.

Ropivacaine is relatively new amino amide long acting enantiomerically pure (S-enantiomer) local anaesthetic with high pKa and low lipid solubility, and it is considered to block sensory nerves to greater degree than motor nerves and having similar local anaesthetic properties and chemical structure to that of bupivacaine.

Newer drug ropivacaine being comparatively less cardiotoxic, it also produces minimal motorblockade of shorter duration, which relives psychological distress of being immobile for longer period of time after C-section.

Hence purpose of this study is to assess duration of sensory, motor blockade and toxicside effects if any of ropivacaine compared to intrathecal bupivacaine during C- section.

Aim and objectives

Aim and objectives were to compare effects of 2 ml of intrathecal isobaric ropivacaine 0.75% and 2 ml hyperbaric bupivacaine 0.5%, compared onset and duration of sensory block, onset and duration of motor block, maximum height of sensory block and quality of anaesthesia.

METHODS

Study type

A prospective double blinded randomized controlled study type was used.

Study location

Study conducted at department of anaesthesiology, government district general hospital, Rajamahendravaram, East Godavari, Andhra Pradesh.

Study period

Study carried out from June 2021 to May 2022.

Study population

Patients between 18-40 years, ASA grade II, full term parturient undergoing elective lower segment caesarean section for singleton pregnancy after taking ethics committee approval.

Study sample size

Total number of patients to be studied are 100 and undergoing elective lower segment caesarean section, of which 50 patients are in isobaric ropivacaine groupand 50 patients in hyperbaric bupivacaine group. R-Ropivacaine(isobaric) group (n=50) and B-bupivacaine (hyperbaric) group (n=50).

According to statistical analysis, $n=4PQ/L^2$

P=Prevalence; Q=100-P; L=Allowable error between 10-20% of P.

Sample technique

Systemic random sampling technique was used.

Statistical methods

All descriptive statistical data will be presented mean ± standard deviation and percentages. Data also tabulated and graphically represented. Chi square test will be used to assess the association among various categorical variables. Student t test will be used to compare the means of various continuous variables or groups. Mann Whitney U-test was used to compare the two non-parametric variables or groups. For all statistical analysis $p<0.05$ will be considered as statistically significant. Moderately significance ($p=0.01<p<0.05$), strongly significance ($p<0.01$).

Statistical software

All statistical analysis will be performed by using SPSS software versionand MS excel 2007.

Inclusion criteria

Patients with ASA physical status II, full term parturient undergoing elective caesarean section for singleton pregnancy and valid informed/explained consent were included in the study.

Exclusion criteria

Patients with cardiac disease, hematological disease, diabetes, eclampsia, bleeding excluded from the study.

Pre-anaesthetic examination and preparation

The study was approved by hospital ethics committee and ethical clearance was obtained from the institution for the study. Pre-anesthetic check-up was done one day prior to the surgery. Basicdemographic data like age, sex, height, weight was recorded.

Patients were evaluated for any systemic disease and laboratory investigations recorded. The procedure of spinal anaesthesia was explained to the patients and an attempt was made to alleviate the anxiety of the patient. A meticulous airway assessment was also carried out.

During pre-anaesthetic checkup the visual analogue scale was explained to all patients using 10 cm scale. Informed and written was obtained from all the patients after detailed explanation of procedure to be performed. After getting clearance from the preoperative assessment (PAC), all patients included in the study were advised 8 hours nil by mouth and surgical site was prepared prior to the procedure. Intravenous access was obtained with 18G cannula and premedicated with injection ondansetron 4 mg and injection pantoprazole 40 mg in preoperative holding. Patient was preloaded with an intravenous fluid infusion of 1 liter of ringer lactate solution.

The 100 patients were randomly divided into 2 groups of 50 each.

Group 1:50 patients received 2 ml of injection 0.5% hyperbaric bupivacaine intrathecally. Group 2: 50 patients received 2 ml of injection 0.75% isobaric ropivacaine intrathecally.

Preparation of operative room

Boyle's anaesthesia machine was checked. Appropriate size of endotracheal tubes, working laryngoscope with medium and large size blades, stylet and working suction apparatus were keptready before the procedure.

After shifting to the operating theatre, IV access was obtained on the forearm with 18G IV cannula and IV infusion started with ringer lactate.

Patients were monitored for HR (heart rate) NIBP (Non-invasive blood pressure) SpO_2 (Peripheral oxygen saturation). Spinal anaesthesia was performed with the patient in the lateralposition using a 25G Quincke needle at level of L3-L4 or L4-L5 interspace. Study solution (2 ml) was administered over 30 seconds. Patient was turned gently and placed supinewith left uterine displacement.

After the spinal block, HR, RR, SpO_2, and NIBP were measured every 5 minutes until delivery and then every 15 minutes in the post operative period. Hypotension was defined as 20% decrease inblood pressure from baseline values, and was treated with incremental IV boluses of ephedrine 5-10 mg. Bradycardia was defined the heart rate less than 60 bpm and treated with IV atropine 0.6 mg. Supplementary oxygen was given through a facemask. The level of sensory anaesthesia, defined as the loss of temperature sensation with ice in test tube at midclavicular level, and was measured every minute until it reached the T8 dermatome level and then every 10minutes during surgery. The following variable were recorded. Time for onset of block at T8, maximum block height, time for regression to L1, total duration of analgesia (at S1) time to request for analgesia, time of onset of motor block, degree of motor block, total duration of bloc, quality of anaesthesia, and analgesic supplements given, if any.

Time to motor block was assessed every minute using the Bromage scale (0=no motor block, 3=complete motor block of lower limbs) until complete motor block and then every 30 minutes until the return of normal motor function. The time to complete motor block and complete recovery were recorded. Time to first complaint of pain and request for rescue analgesiawas recorded. Quality of anaesthesia, the quality of muscle relaxation (judged by surgeon) and the degree of intraoperative patient comfort (judged by patient) were recorded as excellent, good, and poor.

RESULTS

All demographic data like age, sex, height and weight are comparable among two groups.

Table 1: Onset of sensory block (n=50).

Time (seconds)	Group B	Group R
60-120	19	14
121-180	26	29
181-240	4	5
241-300	1	2

Onset of sensory blockade at T8 was achieved by 180 seconds in 52% of patients in group B and 58% of patients in group R (Table 1). This was not clinically and statistically significant. By end of 240 seconds 98% of patients in group B and 96% of patients in group R had reached level of T8. Mean time needed for sensory blockade at T8 was 158.40±41.89 seconds in group B and 174.0±44.12 seconds in group R and clinically and statistically not significant. All the patients attained a level of T8 sensory block in both the groups (Table 2).

Table 2: Maximum height of sensory blockade (n=50).

Level of block	Group B, N (%)	Group R, N (%)
T2	0	21 (42)
T3	0	14 (28)
T4	16 (32)	10 (20)
T5	9 (18)	4 (8)
T6	25 (50)	1 (2)

All patients except 1 in each group achieved sensory blockade at T8 for surgery. One patient each in group received supplemental analgesia. Median height of block attained is T5 in group B, whereas T4 in group R, highest level of block reached in group B was T4 in 32% of patients compared toT2 in 42% of patients in group R. These findings were both clinically and statistically highly significant ($p<0.001$).

Table 3: Time to request for analgesia (n=50).

Time (minutes)	Group B	Group R
60-120	1	0
121-180	46	49
181-240	3	1

The 92% of patients in group B and 98% of patients in group R demand analgesia by 3 hours which was comparable, 3 patients in group B and patient in group R had analgesia for more than 3 hours (Table 3). However, this was neither clinically nor statistically significant. Mean duration of analgesia 158.80±15.31 minutes in group B and 157.50±13.22 minutes in group R and was comparable

Table 4: Regression of sensory block to L1 (n=50).

Time (minutes)	Group B	Group R
60-120	0	1
121-180	42	43
181-240	8	6

Sensory block persisted above level of L1 for 2 hours in all patients of group B and 98% of patients in group R. At 3 hours, 84% of patients in group B and 86% of patients in group R showed regression of sensory block to L1. Mean duration for regression of sensory block to L1 was 172.30±14.17 minutes in group B compared to 163±17.29 minutes in group R, this was statistically highly significant (p=0.004) (Table 4).

Table 5: Total duration of sensory block (Regression to S1) (n=50).

Time (minutes)	Group B	Group R
60-120	0	0
121-180	13	6
181 -240	37	43
241-300	0	1

Sensory block persisted for 2 hours in both groups. At 3 hours 26% of patients in group band 12% of patients in group R had recovered from sensory block. By 4 hours all patients in group B and 98% of patients in group R had complete regression of sensory blockade (Table 5). The mean duration of sensory block was 193.10±15.65 minutes and 199.60±18.88 minutes. This was not significant clinically or statistically with a p=0.068 (Table 5).

Table 6: Onset of motor blockade (n=50).

Time (seconds)	Group B	Group R
120-240	21	1
241-360	27	6
361-480	2	23
>480	0	20

In group B, onset of motor block ranged between 2 minutes and 8 minutes, where as in group R it ranged from 2 minutes and 16 minutes, 96% of patients in group B had onset of motor blockade by 6 minutes, whereas only 14% of patients in group R had onset of motor block by 6 minutes. All patients (100%) in group B had attained motor blockade by 8 minutes, whereas only 40% of patients in group R attained motor blockade by 8 minutes. The mean time for onset of motor blockade was 275.70±67.42 seconds in group B and 492.80±123.87 seconds in group R respectively. This was clinically and statistically highly significant (p<0.001) (Table 6).

Table 7: Degree of motor blockade (n=50).

Variables	Criteria	Degree of block
Grades		
0	Free movements of legs and feet	Nil (0%)
1	Just able to flex knees with Free movements of feet	Partial (33%)
2	Unable to flex knees, but with free movements of feet	Almost complete (66%)
3	Unable to move legs or feet	Complete (100%)
Degree of motor block	**Group B**	**Group R**
1	0	0
2	0	0
3	50 (100%)	50 (100%)

Complete motor blockade was observed in all patients in both groups. This was clinically and statistically not significant (Table 7).

Table 8: Duration of motor blockade (n=50).

Time (seconds)	Group B	Group R
60-120	1	50
121-180	48	0
181-240	1	0

Duration of motor blockade ranged from 120-190 minutes in group B, whereas it ranged from 75-120 minutes in group R (Table 8). At 100th minute none of the patients were recovered from motor block ingroup B while 90% of patients in group R recovered from motor blockade. Only 2% of the patients recovered from motor block at 120 minutes in group B compared to 100% of patients ingroup R. Maximum duration of motor blockade noted in group B was 190 minutes in 1 patient, whereas in group R itwas120 minutes in 1 patient. The mean duration of motor blockade was 155.20±14.95 min group B compared to 94.10±8.31 minutes in group R. This was clinically and statistically highly significant.

Table 9: Quality of anaesthesia (n=50).

Quality of anaesthesia	Group B, N (%)	Group R, N (%)
Poor	2 (4)	1 (2)
Good	47 (94)	49 (98)
Excellent	1 (2)	0

Quality of anaesthesia was opined to be good to excellent in 96% and 98% of patients in group B and group R respectively (Table 9).

The fall in the systolic blood pressure was observed in the both groups following institution of spinal anaesthesia. The maximum fall was observed during 10th and 50th in the groups. The magnitude of fall varied between 1 mmHg to 60 mmHg in group B, while it ranged between 1 mmHg and 54 mmHg in group R. The mean fall in systolic blood pressure was 29.7±25.4 mmHg in group B, whereas in group R, it was 29.04±22.78 mmHg. This was not clinically or statistically significant.

There was fall in diastolic blood pressure following spinal anaesthesia in both groups. The magnitude of fall was similar in both groups and it was not clinically and statistically significant.

In concurrence with fall in the systolic and diastolic blood pressure, there was fall in the mean arterial pressure also, following spinal anaesthesia. The median fall in mean arterial pressure was 24 mmHg (range 1-49 mmHg) in the group B, compared with 31 mmHg (range 4-50 mmHg) in the group R. This was clinically and statistically not significant.

There were no significant changes in heart rate following spinal anaesthesia in both groups. The heart rates were comparable in both groups without any clinical or statistical significance.

Table 10: Side effects (n=50).

Side effects	Group B, N (%)	Group R, N (%)
Hypotension	38 (76)	37 (74)
Bradycardia	6 (12)	0
Nausea and vomiting	4 (8)	3 (6)
Urinary retention	0	0

Hypotension was noted in 38 (76%) of patients in group B and 37 (74%) of patients in group R. Bradycardia was noted in 6 (12%) of patients in group B, no bradycardia was noted in group R. Nausea and vomiting was noted in 4 (8%) and 3 (6%) of patients in group B and group R respectively. As all patients were catheterized, urinary retention could not be monitored. There was no clinical or statistical significance in the incidence of side effects in both groups (Table 10).

DISCUSSION

Subarachnoid block is commonly employed anaesthetic technique for performing caesarean section. It is a safe, in expensive and easy to administer technique which also offers a high level of post anaesthesia satisfaction for patients. The technique is simple, has rapid onset and is reliable. The risk of general anaesthesia, including mishaps due to airway management in a parturient are avoided by this technique. Bupivacaine is the local anaesthetic used routinely for caesarean section because of its high potency and minimal neurological symptoms. Though cardiotoxicity is not a concern in subarachnoid block, the quality of sensory blockade, motor blockade, hemodynamic changes and side effects profile are some considerations in selecting a drug for spinal anaesthesia.

Ropivacaine, a 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 are shorter duration of motor block with similar sensory block properties compared to bupivacaine. Thus, it minimizes the psychological discomfort of being immobile for long time. Also, its major advantage is lesser cardiotoxic property compared to bupivacaine hence this study was conducted to assess the sensory and motor block characteristicsof ropivacaine for spinal anaesthesia in parturient coming for C-section.

A prospective randomized controlled double-blind study was done at government district general hospital, Rajamandravaram, East Godavari, Andhra Pradesh, involving 100 ASA II parturient who underwent caesarean section under subarachnoid block.

Previous studies showed that equipotent ratio between Ropivacaine and Bupivacaine was considered to be 3:2 or 2:1. Hyperbaric bupivacaine 10 mg is the commonly used dose in our institution for C-section. Hence an equipotent dose of 15 mg of ropivacaine was used for the study.

Sensory block at T8

All patients receiving either drug achieved adequate level of anaesthesia except one patient in each group who required intraoperative opioid supplementation. Various authors have considered a block upto T10 for onset of sensory blockade, however we considered T8 for onset as was more appropriate for caesarean section. Chung and colleagues used 18 mg of hyperbaric ropivacaine for caesarean section and found that onset time of block to T10 was 3.2 minutes.[7] In our study, we noted that mean time for onset at T8 was 158 seconds (2.5 min) with 15 mg ropivacaine, this difference in onset time could be because of isobaric solution used in our study. Kallio and colleagues used 3.5 ml of 5 mg/ml (17.5 mg) isobaric ropivacaine for totalhip arthroplasty and found to have a median onset time of minutes (2.5 min).[8]

Maximum level of sensory block

Whiteside and colleagues in their study, noted that the maximum level of sensory block attained was T7 with ropivacaine and T5 with bupivacaine when 15 mg of hyperbaric ropivacaine and bupivacaine were used for lower abdominal and lower limb surgeries.[9] However, higher level of sensory blockade was noticed in ropivacaine group (T2-T6) compared to bupivacaine group (T4-T6) in our study. This may be attributed to use of isobaric solution of ropivacaine in our study.

Regression of sensory block to L1

Boztug and others noted that time of regression of block to L1 was faster with ropivacaine (116±31 minutes in ropivacaine group vs 152.2±64.5 minutes in bupivacaine group) when used for outpatient arthroscopic surgeries.[10] We also observed that regression to L1 with ropivacaine was faster compared to bupivacaine and this auger well with results of above-mentioned study.

Regression of sensory block to S1

However,we observed that regression of nerve block to S1 was comparable in both the groups in our study and concurs with observations of Khaw et al who also noted of regression to S1 was comparable when either intrathecal isobaric bupivacaine or ropivacaine was used for caesarean delivery.[11]

Request for rescue analgesia

Time to request for first rescue analgesia with ropivacaine group in our study was 157.50±13.22 minutes, and 158.80±15.31 minutes in bupivacaine group. Mean duration for request was comparable in both groups in our study concurs with study of Gautier colleagues who compared the effects of intrathecal ropivacaine, levobupivacaine and bupivacaine for caesarean section.[12]

Time for onset of motor block

Gautier et al compared of the effects of the intrathecal bupivacaine (8 mg), levobupivacaine (8 mg), ropivacaine (12 mg), for caesarean section and found that the mean time for onset of grade 3 Bromage motor block was 9 minutes and 14 minutes for bupivacaine and ropivacaine respectively.[12] We noticed that the mean time for onset of motor blockade was 4.5 minutes with bupivacaine and 9.25 minutes with ropivacaine. Rapid onset of block in our study can be attributed to higher doses of local anaesthetics used. In our study, patients receiving ropivacaine had delayed onset of grade 3 motor blockade compared to bupivacaine, this is in agreement with above-mentioned study and also study conducted by Ogun and others.[13]

Duration of motor block

In our study, duration of motor blockade was 95 minutes (80-120 minutes). We observed a shorter duration of motor blockade with ropivacaine compared to bupivacaine. Our findings are in affirmation with that of Chung et al and Kallio and others who also found shorter duration (120 minutes) of motor blockade with ropivacaine when compared to bupivacaine.[7,8]

Degree of motor blockade

Boztu and others observed complete motor blockade in 88 percentages of patients receiving ropivacaine and 100 percentages patients receiving bupivacaine when administered for knee arthroscopy.[10] All patients in our study receiving either ropivacaine or bupivacaine developed complete motor block and is in agreement with the above mentioned study.

Quality of anaesthesia

Anaesthesia was well accepted by all patients belonging to both groups. Majority of patients opined that the quality of anaesthesia is good to excellent with both the drugs.

Hemodynamic parameters

In our study hypotension occurred in 38% of patients in group B and 37% of patients in group R, bradycardia was noticed in 8% of bupivacaine group and no bradycardia in ropivacaine group.

Mean fall in mean arterial pressure was 24 mmHg with ropivacaine compared to 31 mmHg in bupivacaine. Incidence of hypotension was comparable in both groups, which was easily managed by ephedrine boluses. This auger well with results of Ogun and others also observed comparable hemodynamics in their study.[13]

All the babies delivered in either-groups were healthy. None of the babies had APGAR score lessthan 7. Incidence of nausea and vomiting were comparable between groups in our study. Urinary retention could not be observed as all the patients were catheterized for 24 hours. No other side effects were noted in the study.

Quality of muscle relaxation

The anaesthesia was well accepted by all patients belonging to both groups. Quality of muscle relaxation was judged by surgeon intraoperatively. Most of the patients opined that quality of anaesthesia is good to excellent with both drugs.

Intraoperative patient comfort

In our study the anaesthesia was well accepted by all patient belonging to both groups. Degree of intraoperative patient comfort was judged by patient.

Majority of the patients opined that degreeof intraoperative comfort is good to excellent with both drugs.

CONCLUSION

Our study reveals that 15 mg of isobaric ropivacaine (2 ml of 0.75%) when administered intrathecally provide adequate anaesthesia for caesarean section. Onset of sensory blockade is similar to that of bupivacaine, with level of sensory block was slightly higher and duration of analgesia at L1 (L1 regression) was significantly shorter with ropivacaine. But there is delayed onset of motor block and shorter duration of motor block with ropivacaine compared to bupivacaine. Hence, ropivacaine can be used successfully for caesarean section whereearly recovery is well appreciated by mother.

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