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A comparative Clinical Study of Subarachnoid Block With 0.75% Isobaric Ropivacaine 15 mg & 0.5% Hyperbaric Bupivacaine 8 mg Patients for Caesarean Section

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Abstract

Background: Ropivacaine is a local anaesthetic agent which is a long acting amide, a pure S (-) enantiomer of propivacaine. It has reduced potential for neuro and cardiotoxicity and safer than bupivacaine. This drug is less lipid soluble and blocks sensory neurones to greater extent than motor nerves. Mother undergoing caesarean section will be mobile early, so that breastfeeding and other things will be easy for mother. We have designed present study to evaluate the sensory and motor characteristic and the advice effect of spinal 0.75% isobaric ropivacaine 15 mg compared to 0.5% bupivacaine 8 mg for caesarean section. *Material and Method:* Based on exclusion and inclusion criteria 80 parturients were enrolled for this study. The parturients were randomly allocated into two groups. We have used computer generated randomization table for randomization. Each group consists of forty parturients. Parturients who have received Bupivacaine were allocated in Group B and parturients who have received Ropivacaine were allocated in Group R. *Result:* Motor block characterisation in two groups, the mean time for onset of grade III block was 7.54 + 1.2 min in Group R and 3.34 + 2.86 min in Group B, This difference was statistically significant. Total duration of block in Group R was 98.67 + 12.38 and 121.74 + 17.38 min in Group B. This finding is significant statistically. Mean of total duration of analgesia was 164.66 + 19.68 min in Group R and 149.86 + 21.72 min in Group B. The value p value was 0.001. *Conclusion:* Based on our observation we can conclude that onset of sensory block was faster with bupivacaine, time to repression of sensory block was shorter with ropivacaine. The total duration of sensory block was little higher in bupivacaine but duration of analgesia were compared in two groups. Onset of motor block was late and duration of motor block was significant early in ropivacaine group. Haemodynamic parameter was comparison in both groups.

Keyword: Isobaric ropivacaine; Hyperbaric bupivacaine; Spinal anaesthesia; Caesarean section.

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Introduction

The first successful spinal blockade was performed by August Bier in Kile Germany in August 1898. In year 1902 Hopkins described its use for caesarean section [1]. For this purpose three things become essential injection, local anaesthetic agents and the introduction of lumber puncture. Cocaine was the first local anaesthetic

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agent who was used till first decade of 20th century. Because of various advantage like easy, low dose of local anaesthetic required, rapid onset of block and better quality of block, sub arachnoid block has become gold standard for caesarean section [2]. The incidence of caesarean section has increased in last two to three decade. The quality of anaesthesia and its effect on mother and foetus has become major concern. This depends upon the volume, concentration and doses of drug used for anaesthesia [3,4], Bupivacaine hydrochloride is a long acting amide local anaesthetic agent. It was synthesized by Ekenstam in Sweden in 1957 [5]. Since then bupivacaine become the most commonly used anaesthetic agent for spinal anaesthesia. It is available in two forms isobaric and hyperbaric which affects its distribution and diffusion pattern and both forms are used for spinal anaesthesia in caesarean section. Major limitation with the use of bupivacaine is its neurotoxicity, cardio toxicity and prolongation of motor block [6]. This has led to search for safe and effective alternative anaesthetic agent.

Ropivacaine is another local anaesthetic agent which is a long acting amide, a pure S (-) enantiomer of propivacaine. It has reduced potential for neuro and cardiotoxicity and safer than bupivacaine. This drug is less lipid soluble and blocks sensory neurones to greater extent than motor nerves. Mother undergoing caesarean section will be mobile early, so that breastfeeding and other things will be easy for mother [7,8].

Various studies have been conducted regarding safety and efficacy of ropivacaine in caesarean section. Khaw KS et al. has reported that anaesthesia with ropivacaine was successful in 8 to 25 mg group. The ED50 and ED95 was calculated to be 16.7 mg and 26.8 mg respectively [9]. Wenk M.J.S et al. has reported that 12.5 mg of ropivacaine produces sufficient block at T6 level and 15 mg of ropivacaine produces sensory block up to T4 level which is required for caesarean secretion [10]. The concept of minimum local anaesthetic concentration has suggested that in concentration used for labour analgesia ropivacaine is 40% less potent than bupivacaine. We have used for 0.5% bupivacaine to be ideal to compare with 0.75% ropivacaine. As hyperbaric ropivacaine is associated with hypotension we used isobaric ropivacaine.

We have designed present study to evaluate the sensory and motor characteristic and the advice effect of spinal 0.75% isobaric ropivacaine 15 mg compared to 0.5% bupivacaine 8 mg for caesarean section.

Material and method

This is a randomized prospective comparative study conducted in the department of anaesthesia Rangaraya Medical College, Kakinada, Andhra Pradesh from December 2017 to January 2019.

Subject: parturients admitted for elective caesarean section were enrolled for this study based on inclusion and exclusion criteria.

Inclusion criteria	*Exclusion criteria*
-Age 20 to 40 yrs -ASA scare I/II -Full term parturients undergoing elective Caesarea section	-Any contraindication for subarachnoid block. -Cardiac vascular and CNS disorder -Twin pregnancy, Knownf et al. anomaly et el.,

Sample size: For calculation sample size we have used clicalc. Com sample size calculator. The calculation was based on the result of previous studies, α- error was taken to be 0.05 and the power to be 80%. Based on all these parameter sample size was calculated to be 40 [10,11].

Method: Based on exclusion and inclusion criteria 80 parturients were enrolled for this study. The parturients were randomly allocated into two groups. We have used computer generated randomization table for randomization. Each group consists of forty parturients. Parturients who have received Bupivacaine were allocated in group B and parturients who have received Ropivacaine were allocated in group R.

Pre anaesthetic examination was done to all parturients before surgery. Procedure of anaesthesia was explained to parturients, all patients were evaluated for systemic diseases, and basic lab investigation was done. Base line recording of blood pressure, heart rate, arterial oxygen saturation was done.

Intravenous line was secured with 18 needles. All the parturients were received same preanaesthetic medications. Parturients were preload with an intravenous infusion of ringer lactate solution 10 mg/kg over 15 min.

Group B: 40 parturients s in Group B received 0.5% hyperbaric bupivacaine 8 mg (1.6 ml diluted up to 2 ml).

Group R: 40 parturients received 0.75% isobaric ropivacaine 15 mg (2 ml).

After shifting to the operation theatre patients were monitored for blood pressure (non – invasive)

heart rate (HR), and peripheral oxygen saturation (SpO_2). Spinal anaesthesia was performed with the patient in the right lateral position using a 23- gauge Quincke needle at L3-4 interspaces. The drug under study (2 ml) was injected over 30 sec. Patients was gently turned and placed in supine position.

After the spinal block HR, respiratory rate (RR), BP and Spo2 was measured immediately after subarachnoid block, then every 2 min for 10 min, every 5 min till completion of surgery and there every 15 min in post-operative period. Hypotension was defined as 20% decrease in blood pressure from base line value. Decrease in heart rate below 60 per min was taken as bradycardia and is treated appropriate. Various parameters like, time of onset of sensory analgesia at T10, highest level of sensory analgesia, time taken to achieve highest level of sensory analgesia, Highest level of dermatome achieved, time taken to achieve highest level of dermatomes, time taken for two segment regression and time for complete sensory recovery, was recorded.

Motors parameters like time of onset of grade 3, Motor block and its duration, was recorded. Duration on of analgesia, various side effects, like, hypotension, bradycardia, headache, and vomiting were recorded. APGAR score of neonate also were recorded.

The level of sensory block was determined bilaterally using a short bevelled 27 – gauge needle at mid-clavicular level. It was measured every min until it reached T10 level and then every 10 min during surgery. For accessing motor block we used modified Bromage scale [12].

- No motor block able to lift extend leg at lip= 0
- Able to flex the knee but not lift leg and extend=1
- Able to move feet = 2
- Complete motor block = 3

Time required for complete motor block and for complete recovery was also recorded.Parturients were monitored in post anaesthesia care unit for any other side effect.

Ethics: This study is approved by institutional ethics committee. Before enrolment of parturients for this study a written informed consent was obtained from all parturients.

Statistical analysis: In this study data were collected and tabulated into the excel sheet. For analysis of data SPPS version 16 software was used. Results were expressed as mean and percentage. The groups were compared by using unpaired t test and chi-square test. For all the tests a P value less or equal to 0.05 was considered significant.

Results

Present study has been designed to study the anaesthetic effect of 0.75% isobaric ropivacaine and 0.5% hyperbaric bupivacaine in parturients who were scheduled for caesarean section under spinal anaesthesia.

As per table 1 mean age of the patient in group B was 28.13 ± 6.66 yrs and in group R it was 27.63 ± 5.99 yrs, having P value 0.3824. Weight of the patient in group B was 58.40 ± 5.370 kg and in group R was 56.69 ± 6.31 kg having p value 0.1279. ASA score was I in 38 patient and II in 2 patients, in group B. In group R ratio of ASAI/II was 36/4. p value was 0.64417.

The mean gestational week of patients in group B was 38.58 ± 1.75 months and in group R it was 38.16 ± 3.99 yrs with P value 0.19850. The duration of surgery in Group B was 64.28 ± 5.06 min and in Group R it was 65.43 ± 4.379 min. the P value was 0.1626.

As per table 2 mean time for onset of sensory block was 1.92 ± 0.18 in group R and 1.74 ± 0.32 min in group B. The p value was 0.042. This difference is significant statistically. Mean time required reaching T10 level was 3.372 ± 0.63min in group R and 2.14 ± 0.42min group B the P value was < 0.05 and is significant statistically.Mean time required to reach at T4 was 5.42 ± 0.96 min in group R and 4.592 ± 1.72 min in Group B, the p value was 0.0812 which is not significant statistically. Mean time

Table 1: Demographic profile of parturient in two groups.

Variables	Group B (n=40) mean+SD	Group R (n=40) mean+SD	p value
Age (yrs)	28.13 + 6.66	27.63 + 5.99	0.3824
Weight (kg)	58.40 + 5.370	56.69 + 6.31	0.1279
ASA I/II	38/2	36/4	0.64417
Gestation weeks	38.58 + 1.75	38.16 + 3.99	.19850
Duration of surgery (in min)	64.28 + 5.06	65.13 + 4.379	0.1626

required in two dermatomal repressions was 76.42 ± 11.26 min in Group R and 88.28 ± 12.14 min in Group B, this difference is statistically significant. The total duration of block in Group R was 148.32 ± 26.43 min and Group B it was 164.432 ± 12.32 min which is significant from statistically.

Regarding motor block characterisation in two groups, the mean time for onset of grade III block was 7.54 ± 1.2 min in Group R and 3.34 ± 2.86 min in Group B, This difference was statistically significant. Total duration of block in Group R was 98.67 ± 12.38 and 121.74 ± 17.38 min in group B. This finding is significant statistically. Mean of total duration of analgesia was 164.66 ± 19.68 min in Group R and 149.86 ± 21.72 min in Group B. The value p value was 0.001.

As per table 3, 7.5% parturientsin group B and 2.5% parturients in Group R developed bradycardia. 45% patients in Group B and 40% patients in Group R developed hypotension. 2.5% parturients in Group B and 5% parturients have developed headache, vomiting and respiratory depression are usually distributed in both group.

There is no significant difference between APGAR scare at 1 min and 5 minte in two groups.

The heart rate and mean arterial pressure of parturients were measured in both groups. There is no significant difference in both these haemodynamic parameters in two groups.

Table 2: Characteristic of Anaesthesia.

Characters	variables	Group R(n=40) mean+SD(min)	Group B(n=40) mean+SD(min)	p value
Sensory	Onset of sensory block	1.92 + 0.18	1.74 + 0.32	0.042
	Time to reach T10	3.372 + 0.63	2.14 + 0.48	<0.05
	Time to reach T4	5.42 + 0.96	4.92 + 1.72	0.0812
	Time for two dermatome regression	76.42 + 11.26	88.28 + 12.14	0.1248
	Total duration of block	148.32 + 26.43	164.432 + 12.32	0.042
Motor	Onset of grade III block	7.54 + 1.2	3.34 + 2.86	0.0246
	Total duration of gr III block	98.67 + 12.38	121.74 + 17.38	0.0001
Analgesia	Duration of analgesia	149.86 + 21.72	164.66 + 19.68	0.0001

Table 3: Comparison of side effect in two groups,

Charters	Group B (n=40)	Group R
Bradycardia	3 (7.5%)	1 (2.5%)
Hypotension	18 (45%)	16 (40%)
Headache	1 (2.5%)	2 (5%)
Vomiting	1 (2.5%)	1 (2.5%)
Respiratory depression	0	0

Table 4: APGAR score of neonate in two groups

Characters	Variables	Group B (n=40) mean+SD	Group R (n=40) mean+SD	p value
APGAR Score	1 min	8.28 + 0.38	8.46 + 0.4	0.245
	5 min	9.60 + 0.52	9.48 + 0.4	0.224

Table 5: Comparison of and MAP mean pulse rate between the group

Time	Mean arterial presser			Mean Heart rate		
	Gr B	Gr l	P value	Gr B	Gr l	p value
Basel	89.58 + 13.59	88.4 + 4.73	0.2198	88.53 + 2.79	89.1 + 4.158	0.271
2 min	87.34 + 11.54	88.12 + 6.43	0.143	87.83 + 3.53	89.34 + 3.79	0.211
10 min	38.56 + 10.34	86.23 + 10.23	0.276	88.33 + 4.67	88.78 + 4.88	0.512
30 min	84.42 + 12.47	88.13 + 11.48	0.226	91.23 + 10.12	40.37 + 9.82	0.612
60 min	86.42 + 16.32	88.44 + 10.33	0.313	89.76 + 11.37	88.56 + 11.42	0.112
90 min	90.96 + 10.12	91.62 + 9.2	0.651	86.46 + 10.12	86.56 + 9.52	0.12

Discussion

Sub-arachnoid block is very safe anaesthesia technique with high success rate. But the selection of good local anaesthetic agent is always a limiting factor for this technique, drug which will be short acting, have good analgesia effect, early mobilisation and recovery is essential. Hence in present study we have compared the effects of low dose intrathecal isobaric ropivacaine 15 mg with hyperbaric bupivacaine 8 mg for caesarean section on the sensory and motor blocked characteristics haemodynamic parameter and safety.

In present study both the group were comparable to each other with regard to age, body weight, ASA score, gestation weeks, and duration of surgery. The P value was more than 0.05. This finding is similar to the work of Goyat A et al. and Layek A et al. [11,12]

Regarding sensory block characteristic between two group, time of onset of sensory block was significantly early in bupivacaine group then ropivacaine (1.74 ± 0.32 min vs 1.92 ± 0.18 min) (p=0.04). This finding is supported by the work of Kulkarni KR et al. [13]. Time required to reach at T4 level was higher in ropivacaine group then bupivacaine group (5.42 ± 0.96 vs 4.92 + 1.72) but is not significant statistically (p=0.0812). This is again supported by the work of Goyat A et al. and whiteside JB et al. [14,15]. The mean of total duration of sensory block was shorter in ropivacaine in comparison to bupivacaine.Which is significant statistically this finding corroborates with the study of Bhat SN et al. [15]

The onset of grade 3 motor block was significantly early in Bupivacaine then in Ropivacaine (3.34 ± 2.86 vs 7.54 ± 1.2). This finding is supported by the work of Goyal A et al. and Kulkarni KR et al. [11,13] The duration of motor block was significantly less in ropivacaine then bupivacaine (98.67 ± 12.38 min vs 121.74 ± 17.38 min). This finding is supported by the work of Ramana et al and Gupta R et al. [16,17].

There was significant difference between duration of analgesia in two groups, The duration of analgesia was less in group R than group B.(149.86 ± 21.72 vs 164.60 ± 19.08). This finding is supported by the work of Goyal A et al. Kulkarni KR et al. and SULE, Prasad M et al. [11,13,18]

We have observed that Bradycardia and hypotension was more common in bupivacaine then in ropivacaine other side effects are equally present in both groups. This finding is supported by the work of chari VRR et al. [19]. We have not found any significant difference in mean arterial pressure and mean heart rate between two groups. This finding is support by the work of Boztug N et al. and Eryilmaz NC et al. [20,21] The APGAR score of neonate in two group are comparable to each other, there was not significant literalness between two group. This is supported by the work of Goyal A et al. and Erylimaz NC et al. [11,21]

Conclusion

Based on our observation we can conclude that onset of sensory block was faster with bupivacaine, time to repression of sensory block was shorter with ropivacaine. The total duration of sensory block was little higher in bupivacaine but duration of analgesia were compared in two groups. Onset of motor block was late and duration of motor block was significant early in ropivacaine group. Haemodynamic parameter was comparison in both groups.

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