Original Article

A comparative study of different doses of intrathecal ropivacaine (I) with respect to anaesthetic parameters in caesarean section

Umesh U Deshmush[1*], Shrinivas L Sangnor[2]

[1]Assistant Professor, Department of Anesthesia, Government Medical College, Latur, Maharashtra, INDIA.
[2]Ex Resident, Department of Anesthesia, Mahatma Gandhi Medical College, Aurangabad, Maharashtra, INDIA.
Email: apexbeat32@yahoo.co.in

Abstract

Introduction: Spinal anaesthesia is preferred for caesarean section as it offers a few advantages over general anaesthesia. **Aims and Objectives:** To study of different doses of intrathecal ropivacaine (I) with respect to anaesthetic parameters in caesarean section**. Material and methods:** The study was carried out in 60 patients of age group 20-40 years coming for elective caesarean section in the time period from august 2010 to April 2012.Patients were divided in two equal groups, and received intrathecal ropivacaine [I] (0.5%) 3ml or 4ml marketed by neon laboratory as ropivacaine 0.5%(I) USP [united states pharmacopeia] in L3-L4 interspace in left lateral position by spinal needle no. 23G.Statistical analysis done by unpaired t-test. **Results**: Mean age group-A was 25.83±3.15 years. In group A, mean time for onset of sensory block was 8.33±2min. in group B, mean time for onset of sensory block was 8.40±2.94min (not statistically significant, p=0.93)In group A mean time for duration of sensory block was 152±14.8min. in group B mean time for duration of sensory block was 130±17.4min. (Statistically significant. p=0.0001). The mean time for onset of motor block was 11.00±3.23 min in group A and 9.79±3.45min in group B (with no significant difference among two groups, p=0.19). All patients in ropivacaine 20mg group developed complete motor block of Bromage grade III while 25 patients in ropivacaine 15mg group developed complete motor block of Bromage grade III. Five patients in ropivacaine 15mg group developed motor block of Bromage grade II, (The difference in two groups is statistically significant p=0.010). In group A mean time of duration of motor block was 158±15.9min in group B mean time for duration of motor block was 126±16.2min. he difference in two groups is statistically significant.[p=0.001]. The mean time for supplementation of first analgesic was longer in group A (320±42min) than group B (206±30min). The difference was statistically significant (p=0.0005). **Conclusion:** We conclude that 20mg isobaric ropivacaine had better efficacy and safety profile as shown by absence of unduly high cephalad spread and absence of severe hypotension and bradycardia.

Key Words: Ropivacaine (I), Caesarean section, Bromage grading**.**

[*]**Address for Correspondence:**
Dr. Umesh U. Deshmush, Assistant Professor, Department of Anesthesia, Government Medical College, Latur, Maharashtra, INDIA.
Email: apexbeat32@yahoo.co.in
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INTRODUCTION

Spinal anaesthesia is preferred for caesarean section as it offers a few advantage over general anaesthesia. There is no risk of aspiration and maternal bonding with child is early the other advantage are ease of administration and cost effectiveness. This is of importance in peripheral health centres in India. It offers high level of post operative analgesia and patients satisfaction. The local anaesthetics used in India today are bupivacaine [H] and lignocaine [H]. Lignocaine [H] is almost loosing ground, the reason being transient neurological symptoms [TNS] which is seen in the post operative period. This leaves the patient dissatisfied. [1] bupivacaine [H] is widely used for caesarean section. Duration of the block obtained by the commonly used dose of 10mg bupivacaine is around 2hrs.[2] this far exceeds the duration of surgery (caesarean section) in our setup (40-60min). Ropivacaine has been in clinical use since 1996 and was approved for spinal block

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by European union in Feb 2004.[3] Ropivacaine[1] has short duration of sensory and motor block as compared to bupivacaine H[4] therefore it seems a better drug for caesarean section, where 2hrs bupivacaine block is not needed. Further ropivacaine[1] being less lipid soluble has lesser penetration in the thicker my line A fibres which are motor. This results in a less degree of motor block. In cases of caesarean section, less degree of moto block in lower intercostals gives less breathing difficulties to patients who depends less on diaphragm and more on thoracic respiration[5] Isobaric ropivacaine spreads less than hyperbaric ropivacaine. Hence it gives less degree of hypotension. Hypotension is deleterious to baby and gives discomfort to patients causing nausea and vomiting.[6] Hence these advantage of less hypotension, less respiratory difficulty and prolonged post operative analgesia may prove isobaric ropivacaine more suitable for caesarean section. We decide to explore on this. Isobaric ropivacaine has been used for caesarean section by various workers in varied doses from 14.22mg to 25mg.[7,8,10] We have been using bupivacaine [H] 10 mg for caesarean section. The equipotent dose of ropivacaine is 15mg as per potency ratio of 3:2 [8] or 20mg as per potency ratio of 2:1[9] We therefore decided to study and compare the clinical profile of subarachnoid block in caesarean section using these two doses in two groups.

MATERIAL AND METHODS

The study was carried out in 60 patients of age group 20-40 years coming for elective caesarean section in the time period from august 2010 to April 2012, based on following inclusion and exclusion criteria, Parturient of ASA grade I and II, Normal pregnancy and normal fatal heart rate, Caesarean delivery >37 wks. were included into the study while Coagulation defect, Pregnancy induced hypertension, Multiple pregnancy, suspected fetal abnormality, Placenta previa, Patients with heart disease were excluded from the study. A detailed explanation about the procedure was given to patients including the methods of testing of the neural blockade and consent was taken. Parameter like age. Height, weight was noted. Patients were divided in two equal groups of 30 patients each according to dose of ropivacaine (I) received. Group A received intrathecal ropivacaine(I)0.5% 20mg and Group B received intrathecal ropivacaine (I) 0.5% 15mg marketed by neon laboratory as ropivacaine 0.5%(I) USP [united states pharmacopeia] in L3-L4 interspace in left lateral position by spinal needle no. 23G.After intrathecal injection, sensory level was assessed using loss of pinprick sensation on each side at midclavicular level. Sensory block was measured every 2 min till T6 and subsequently at 5 min intervals for the first 30 min and every 10 min intervals till completion of surgery. Thereafter every 15 min intervals until sensation at the L1 dermatome. The maximum cephalad spread of sensory block was determined. Surgery was allowed after upper dermatome level of loss of pin prick at a above T6 in midline and motor block of grade III. Failure to achieve required sensory and motor block at 30 minutes was noted as inadequate block.[6] number of such cases were noted. These cases were given general anaesthesia for surgery. Statistical analysis done by chi-square test for non-parametric data and student t test for parametric data.

RESULTS

Table 1: Age wise distribution of patients

Age(years)	No of patients in group A	No. of patients in group B
18-22	06(20%)	05(17%)
23-37	13(43%)	16(53%)
28-32	11(37%)	09(30%)
Total	30(100)	30(100%)
Mean±SD	25.83±3.15	25.23±2.74
T-value	1.01	
T-value	P=0.32 NS	

The minimum age was 20 years and maximum age was 30 years. Mean age group-A was 25.83±3.15 years. In group-B was 25.23±2.74 years. The difference was not statistically significant. [p=0.32]. the mean age was comparable in two groups.

Table 2: Time of onset of sensory blockade

Mean±SD	Group A	Group B
T-value	8.33±2.63min	8.40±2.94min
P-value	0.088	
	P=0.93 ns	

In group A, mean time for onset of sensory block was 8.33±2min. in group B, mean time for onset of sensory block was 8.40±2.94min. in two group the mean time of onset of sensory block to T6 was comparable as difference was not statistically significant. (p=0.93)

Table 3: Duration of sensory blockade

	Group A	Group B
Mean±SD	152±14.8 min	130±17.4 min
T-value	5.18	
P-value	P=0.0001 S	

In group A mean time for duration of sensory block was 152±14.8min. in group B mean time for duration of sensory block was 130±17.4min. The difference in two groups is statistically significant. [p=0.0001] the duration of sensory block was longer with ropivacaine 4ml than ropivacaine 3mml group.

Table 4: Time of onset of motor blockade

	Group	Group
Mean± SD	11.0±3.27 min	9.79±3.45 min
T-value	1.33	
P-value	P=0.19 NS	

The mean time for onset of motor block was 11.00±3.23 min in group A and 9.79±3.45min in group B with no significant difference among two groups. (p=0.19)

Table 5: Grade of motor block

Grade of motor Block	Group A	Group B		
0	0(00%)	0(00%)	Chi square	P- value
I	0(00%)	0(00%)	value	p=0.010
II	0(00%)	5(17%)	6.60	S
III	30(100%)	25(83%)		
Total	**30**	**30**		

All patients in ropivacaine 20mg group developed complete motor block of Bromage grade III while 25 patients in ropivacaine 15mg group developed complete motor block of Bromage grade III. Five patients in ropivacaine 15mg group developed motor block of Bromage grade II. These were the patients with sensory with sensory block height of T 10and L1.The difference in two groups is statistically significant. [p=0.010]

Table 6: Duration of motor blockade

	Group A	Group B
Mean±SD	158±15.9min	126±16.2Min
T-value	1.03	
P-value	P=0.001 S	

In group A mean time of duration of motor block was 158±15.9min in group B mean time for duration of motor block was 126±16.2min. The difference in two groups is statistically significant.[p=0.001]

Table 7: Showing distribution of time of need of first analgesic

Time for analgesic from onset of block(min)	No. of patients in Group A	No. of Patient in Group B
0-90	00(00%)	00(00%)
91-180	00(00%)	02(07%)
181-270	04(13%)	12(40%)
271-360	18(60%)	03(10%)
361-450	07(24%)	01(03%)
451-540	01(03%)	00(00%)
Total	**30(100%)**	**18(60%)**

In group A 13% of patients required first analgesic request between 181-27min. 60% of patients required between 271-360min, 24% of patients required between 361-450min and 3% of patients between 451-540min.In group B 7% of patients required first analgesic request between 91-180min, 40% of patients required between 181-270min. 10% of patients required between 271-360min and 3% of patients required between 361-450min.

Table 8: Showing the mean time of analgesic supplementation

	Group-A	Group-B
Mean	320±42min	206±30min
P-value		
T-value	0.0005 S	

The mean time for supplementation of first analgesic was longer in group A (320±42min) than group B (206±30min).The difference was statistically significant (p=0.0005

DISCUSSION

Spinal anaesthesiais the most commonly used technique[13,14] for lower abdominal and lower limb surgeries. The main advantage being its simplicity, ease of technique and reliability 15[,16]. Till recently bupivacaine was the only drug used after discontinuation of intrathecal lidocaineuse[17]. The sensory and motor block characteristics of intrathecalRopivacaine are found to be inconsistent in various studies [18,19.] For any drug to be accepted in clinical practice, two criteria need to be fulfilled. One, it has to effective in more than 95% cases. Second, it should not pose the patients for any serious complication. In case of intrathecal drug this could be getting more cephalad segment block than needed which puts the patients at risk for severs bradycardia, hypotension and respiratory inadequacy. Keeping this in mind we studied effectiveness and safety of roplvacaine 15mg and 20mg for caesarean section. The sensory motor differention of ropivacaine over bupivacaine would give an earlier motor recovery with prolonged analgesic period.[11] this was the point behind our hypothesis that ropivacaine would provide a shorter block over bupivacaine with added advantage of less degree of hypotension due to less motor block. The parameters studied to efficiency were, sensory block (onset, duration, degree and highest level) motor block(onset, duration, degree) and post-operative analgesic period. In the present study, the mean time for onset of sensory block in group A was 8.33±2.63 min and in group B was 8.40±2.94 min. The mean time for onset of sensory blockade in two groups was comparable as difference was not statistically significant. (p=0.93) showing that onset is not related to dose. The onset period observed is acceptable for caesarean section and is comparable to currently used drug that is bupivacaine 10 mg. [11] Similar observation have been made by P.O.W. fettes of at (2004), who used ropivacaine (1) 15 mg (3ml) for perineal surgery. The mean time for onset of sensory block was 10 min. In 2000 jean marc *et al* studied intrathecal ropivacaine (1) 15mg (5ml) for urological surgery block was 10 min. In the study by H kallio *et al* (2004), they found the mean onset of sensory block was 10 min with ropivacaine (I) 0.75% 2ml for lower limb surgery. All the above-mentioned studies had different volume of injected drug and dilution. This did not influence the onset time. The observation in caesarean section studies regarding onset time are as follows. In the present study, the mean time for duration of sensory

block in group A and in group B was 152±14.8min. and 130±17min. Respectively. The difference in two groups is statistically significant. [p=0.001] in 2001 Kim khaw *et al* studied in doses finding study ropivacaine (I) 15mg 3ml and 20mg 3ml in patients for caesarean section. The duration of sensory block was 173min and 180 min respectively. This was comparable. This differs from our observation. Kim khaw took regression to L1 as duration of sensory block where as we took two segment regression as duration of sensory block. They also show that two segment regression was faster with smaller doses but duration of sensory block at L1 and S1 was greater with increasing dose. In the present study the mean time of motor block was 11.00±3.27min and 9.79±3.45 min for ropivacaine 20 mg and ropivacaine 15mg respectively, showing that onset is not related to dose. The mean time for onset of motor block was comparable as difference was not statistically significant. (p=0.95) Similar observation has been made by Kim Khaw *et al* (2001)[6], who used ropivacaine (i) 20mg 3ml and 15mg 3ml in a patients for caesarean section. The mean time for onset of motor block was similar in two groups. In the study by Kim khaw *et al* (2002)[6] who studied ropivacaine (i) 25mg and ropivacaine (H) 25mg in patients for caesarean section. Comparing the hyperbaric and isobaric ropivacaine 25mg the onset seen was 10min and 14min. In the present study all patients in ropivacaine (i) 20mg group developed complete motor block of grade III, in ropivacaine (i) 15mg group 25 patients developed motor block of grade III. Five patients in ropivacaine (I) 15mg group developed motor block of grade II. In the present study, the highest median extent of sensory block to ropivacaine 20mg was T3 (T2-T6) and with ropivacaine 15 mg was also T3(T3-T10) with no difference in between two groups showing that number of segment blocked is not related to dosage of drug. Similar observation is found in study by Kim khaw *et al* [6] who studied ropivacaine 20mg and 15mg in patients for caesarean section. The median maximum height of block in ropivacaine 20 mg group was T3 (T11-C2) and in ropivacaine 15mg group was also T3 (T11-C7) with no difference in two groups. In the study by Kim khaw *et al* (2002)[6] who studied ropivacaine (i) 25mg and (H) 25mg in a patients for caesarean section. 25% of patients in ropivacaine (i) 25mg group required intraoperative analgesia and in ropivacaine (H) 25 mg group 10% of patient required intraoperative analgesia. We also observed that In group A 13% of patients required first analgesic request between 181-27min. 60% of patients required between 271-360min, 24% of patients required between 361-450min and 3% of patients between 451-540min.In group B 7% of patients required first analgesic request between 91-180min, 40% of patients required between 181-270min. 10% of patients required between 271-360min and 3% of patients required between 361-450min.The mean time for supplementation of first analgesic was longer in group A (320±42min) than group B (206±30min). The difference was statistically significant (p=0.0005).

CONCLUSION

We conclude that 20mg isobaric ropivacaine had better efficacy and safety profile as shown by absence of unduly high cephalad spread and absence of severe hypotension and bradycardia.

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