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Comparison of different doses of hyperbaric ropivacaine in the cesarean section under spinal anesthesia
Short title: Ropivacaine in cesarean section.

Dr. Kante Sugatri C, Dr. Dr Kante, Dr. Vijaya C kante, Dr. RG Pathak , Dr. Tanmay C Kante , Dr. Shashikanth Rasakatla D.Ortho,

MD Anaesthesia,IDCCM, Assistant professor in Prathima institute of medical sciences. 7780560622, sugatri1@gmail.com, House,no 4-8/22,KR colony, road no 2, behind Kodand Ramalayam, after railway crossing, Theegalguttapally, Karimnagar
C.A, MD General Medicine, Associate professor in Ulhasrao patil medical college, Jalgaon, Maharastra.
MBBS, Medical officer at regional mental hospital , Pune.
MD Anesthesia retierd professor and HOD of department of Anesthesiology at Dr. S.C.G.M.C Nanded.
MBBS, CMO at Ulhasrao patil medical college.
DNB Ortho, Assistant professor at Prathima institute of medical sciences.

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ABSTRACT
The hyperbaric solution of ropivacaine for spinal anesthesia was studied, it produces a predictable and reliable spread of anesthesia for surgery. Data from non-obstetric cases can't be applied to obstetric cases because of the lower dose requirement. Ropivacaine has no side effects on the fetus, doesn't have neurological complications, and produces a shorter duration of motor block, so can be safely used in obstetrics. In pregnancy low doses of the intrathecal drug are preferred to avoid maternal hypotension and effect on the fetus and helps in rapid recovery from motor block aiding early ambulation. Three different concentrations of drug ropivacaine were prepared as 10mg,12.5mg, and 15mg after mixing with 25% dextrose.Each 50 patients out of total 150 patients. divided in R1,R2,R3 group received 10mg,12.5mg,15mg respectively.Parameters sensory blockade, motor blockade, highest quality of analgesia, hemodynamics, and complications studied. Statistical analysis was done by (ANOVA) test. 'P-value was significant in the onset of analgesia at T10, the onset of analgesia at T7, regression to T10 level, time of motor onset. In group R1, R2, and R3, 56%,88%, and 98% of the patients had an excellent quality of the block respectively. In group R1 none of the patients had hypotension. In group R2 8% of the patients had hypotension. In group R3 40% of the patients had hypotension. Thus we conclude that 12.5 mg hyperbaric ropivacaine provides effective spinal anesthesia as well as good hemodynamics than 15 mg and 10 mg hyperbaric ropivacaine.

Keywords: Apgar score, cesarean section, hemodynamics, ropivacaine. spinal anesthesia.

I. INTRODUCTION

Data from non-obstetric cases can't be directly applied to obstetric cases because of the lower dose requirements. Isobaric (plain) and hyperbaric solutions of spinal ropivacaine were compared for cesarean section,[1]. Plain ropivacaine resulted in the lesser cephalic spread, slower onset of analgesia, and lower maximal extent of sensory and motor block in comparison with hyperbaric solutions,[1] Increasing the dose of ropivacaine increases the proportion of patients developing full motor block,[2] ED50 and ED95 of spinal hyperbaric ropivacaine for cesarean delivery were 10.37 mg and 15.39 mg, respectively,[3]. There are few studies of different doses of hyperbaric ropivacaine in cesarean section. Hence the present study is to compare the effects of different doses of hyperbaric ropivacaine in cesarean section in respect of onset of analgesia at T10 level, the onset of analgesia at the T7 level, the maximum cephalic spread of analgesia, regression to T10 and S2 level onset and degree of motor block, duration of sensory and motor block, complications and any postoperative complications, seen for up to 24 hrs.

II. METHODS:

After approval of the ethical committee of the institution and informed consent obtained from patients, this prospective and double-blind study was carried out to " compare different doses of hyperbaric ropivacaine in the cesarean section under spinal anesthesia." tertiary care center between Jan2011-Dec2012. Data collected from a total of 150 patients belonging to ASA grade I and II posted for the cesarean section. The parturients

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having a history of allergy or sensitivity to amide-type local anesthetics, multiple pregnancies,)suspected fetal abnormality, complicated pregnancy, short stature were excluded from the study. Inside operation theatre patients were accepted for study after pre-anesthetic evaluation. I.V access was secured, and ringer lactate 10ml/kg preloaded before spinal anesthesia. Baseline vital parameters (BP, pulse, respiratory rate, SPO2)were measured. Under all aseptic precautions, spinal anesthesia was given in a sitting position in L3-L4 interspace with 25 GZ quincke spinal needle using hyperbaric ropivacaine as a drug. After aspirating C.S.F drug was injected and time was defined as zero. The patient was slowly positioned into a supine horizontal position with a left lateral tilt. The patient was again evaluated every 2 minutes till 15 minutes then every 5 minutes till 30 minutes and then every 15 minutes till operation and every 2 hrs in the postoperative period. Intraoperative vital parameters are monitored and if BP falls <30% of baseline value or <90mmhg.vasopressor injection mephentermine in 6 mg incremental doses given. If bradycardia occurs injection atropine was given.

Dosages of drugs prepared as follows:

Group R1 : Ropivacaine (10 mg) 0.5% 2 ml + 1 ml 25% dextrose.

Group R2: Ropivacaine (5mg) 0.5% 1 ml + Ropivacaine (7.5mg (0.75% 1 ml)+1 ml 25% dextrose.

Group R3: Ropivacaine (15mg) 0.75% 2 ml + 1 ml 25% dextrose.

Statistical analysis:

All data are presented as mean ± SD. Analysis was performed with the use of spss software for the windows statistical package. Data were assessed by one-way analysis of variance (ANOVA) test and incidence data were analyzed by Fisher exact test,[4]. Statistical significance was defined as 'P'< 0.001 with a confidence interval of 99%.

III. RESULTS :

P-value is significant in the onset of analgesia at T10, the onset of analgesia at T7, regression to T10 level, regression to T7 level, time of motor onset, total duration of motor block. mean and standard deviation (SD) of each of the above parameters studied and compared in 10 mg,12.5mg, and 15mg group. Tables and graphs are attached after the manuscript.

In R1, R2, and R3group 56%,88%, and 98% of the patients had an excellent quality of the block respectively. In R1, R2, and R3 group 16%,8%, and 2% of the patients had a good quality of block. In group R1 28% of the patients had the fair quality of block, and in a group, R2,4% of the patients had the fair quality of block. None of the patients had poor quality of the block. Quality of block compared in all three groups by 'ANOVA' test and 'P' value was <0.001 and it is significant.

In group R1 none of the patients had hypotension, in group R2 8% of the patients had hypotension, in group R3 40% of the patients had hypotension.2% of the patient in group R3 had bradycardia. None of the patients in group R1 and R2 had bradycardia. None of the patients in groups R1, R2, and R3 had nausea and any neurological complication.

APGAR Score in all three groups was incomparable by 'ANOVA'test.

In group R1 28% of the patients required supplementation anesthesia in the form of injection ketamine, 4% of the patients in group R2 required supplementation.

anesthesia and none of the patients in group R3 required supplementation anesthesia.

IV. DISCUSSION

The time of onset of sensory block at T10 suggests the duration of onset of sensory block, i.e. the time taken from administration of the drug intrathecally to the loss of pinprick sensation at T10 dermatome level bilaterally. In Chen, Xz., et al.,[3] they studied sixty parturients undergoing cesarean section and were randomized to receive 10.5mg,12mg,13.5mg,and15mg dose of hyperbaric ropivacaine. In their double-blind study mean time of onset to T10 for the 15 mg group was 2.59+-1.29 minutes. In our study mean time of onset to T10 was 1.90-+0.47minutes. Their study was done in the right lateral position whereas ours was done in the supine position. In their study onset to T10 in the 10.5mg group was 2.54±1.12 minutes, and in our study onset to T10 in the 10mg group was 4.32±0.40 minutes. In their study onset to T 10 in the 12mg group was 3.30±2.03 minutes, and in our study onset to T10 in the 12.5mg group was 3.14±0.60minutes. In perspective, double-blind, randomized study of Al-Abdulhadi O, et al.,[5] for elective cesarean section were studied where sixty-six parturients were randomized to receive 15 mg of hyperbaric ropivacaine and 11.25 mg of hyperbaric bupivacaine. Which mean onset of time to T10 was 1.88±0.89 minutes which is comparable to our study where the mean onset of time to T10 was 1.9±0.47 minutes in the 15mg hyperbaric ropivacaine group. In India A, et al, [6]15mg of hyperbaric ropivacaine was compared with 11mg

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hyperbaric bupivacaine. In this study, Spinal anesthesia was given in the left lateral position. In the 15 mg, hyperbaric ropivacaine group means the onset of time to T10 was 5.37±0.45 minutes. In our study mean onset of time to T10 in the 15 mg group was 1.90±0.47 minutes, the reason being different positions used left lateral position in their study and sitting position in our study.

In Chen, Xz., et al.,[3]they studied 10.5mg,12mg,13.5mg,and15mg dose of hyperbaric ropivacaine. In their study mean time of onset to T7 in 10.5mg was 7.38±2.67minutes, meantime of onset to T7 in 12 mg was 8.13±2.07minutes, in 15mg group mean time of onset to T7 was 6.53±3.07 minutes. In our study, in the 10 mg group mean time of onset to T7 was 7.74±0.59 minutes. In group, 12.5 mg mean time of onset to T7was 5.84±0.42 minutes. In the 15mg group mean time of onset to T7was 5.37±0.81 minutes.' P' value is <0.001 and which is statistically significant.

In Chen XZ, et al,[3] maximal level of analgesia in 10.5mg,12 mg, and 15mg groups were T6, T5, and T5 respectively. In Al-Abdulhadi O, et al.,[5] in 15 mg group maximal level of analgesia was T3. In India A, et al, [6] double-blind, randomized, prospective study,80(Eighty) parturients were randomized into two groups and one group received 15mg hyperbaric ropivacaine. In the 15mg group, the maximal level of analgesia was T2 which is comparable to our study. In Wenk MJ, et al, [7] Forty women undergoing elective cesarean section received the following doses of spinal ropivacaine: 10 mg + 0.1 mg morphine, 12.5 + 0.1 mg morphine, 12.5 mg or 15 mg of spinal ropivacaine, In this study 15 mg of spinal ropivacaine produced sensory block at T3/4 level; 12.5 mg produced sufficient sensory block at T6 and T7. In our study group. In group 12.5mg 72% of the patients achieved a maximal level of analgesia at the T5 level. In group 15mg, 70% of the patients had achieved a maximal level of analgesia at T4 and it is comparable to our study.

Time for regression to T10 suggests the time from maximum sensory attainment of sensory block to regression to T10 level. In Chen, Xz., et al.,[3] taken for regression to T10 in 10.5mg group was 46.00 ± 12.05 minutes, In 12 mg group mean of time taken for regression to T10 was 52.33± 13.60 minutes, in 15 mg mean of time taken for regression to T10 was 73.40 ± 18.59 minutes. In our study in the 15mg group mean of time taken for regression to T10 was 71.12 ± 2.70 minutes. 'P' value was < 0.001 and it is significant, which is comparable to our study. In Al-Abdulhadi O, et al.,[5] in the 15mg group mean of time taken for regression to T10 was 50±10 minutes. In a randomized study, India A, et al,[6] in 15mg group mean of time taken for regression to T10 was 110.6±12.0 minutes.

In Al-Abdulhadi O, et al., [5] in 15 mg group mean of time taken for regression to S2 was 173.6±8.6 minutes. In Wenk MJ et al.,[7] in 12.5 mg group time taken for regression to S2 was 72 ± 7 minutes. In Qian XW, et al.,[8]80 (Eighty) ASA grade I and II parturients undergoing elective cesarean delivery under combined spinal-epidural anesthesia randomized in two groups each of 15 mg hyperbaric ropivacaine and 10mg of hyperbaric ropivacaine. In the 10 mg group time taken for regression to S2 was 65.9 ± 15.1 minutes. In 15 mg group time taken for regression to S2 was 125.4 ± 26.4 minutes.' P' value is < 0.005 and it is significant. In our study, the in-group 'P-value was <0.001 and it is significant, which is comparable to our study.

In Chen, Xz., et al.,[3] study time taken for the onset of motor block in 10.5mg,12mg, and 15 mg group is 2.87±0.35 minutes,2.80±0.41 minutes,2.93±0.260 minutes respectively. In Al-Abdulhadi O, et al.,[5] study time taken for onset of motor block in 15 mg group was 6.6±0.6 minutes. In India A, et al., [6] in 15 mg group, time is taken for onset of motor block was 6.97 ± 2.36 minutes. In X.W. Qian, et al.,[8] study in the 10 mg group, the onset of motor block was 4.6 ± 2.5 min and in the 15 mg group the onset of motor block was in 2.9 ± 1.1 minutes and it is comparable to our study.

In Chen, Xz., et al.,[3] study time taken for the total duration of motor block in 10.5mg,12mg, and 15 mg group is 58.67± 21.38 minutes,64.67±19.45 minutes,94.20±17.95 minutes respectively.' P' value is < 0.0001 and it was significant. In our study, the 'P' value was <0.001 and is significant, which is also comparable to our study. In Al-Abdulhadi O, et al.,[5] study time taken for a total duration of motor block in the 15 mg group was 85±7.7 minutes. In the study, India A, et al.,[6] in 15 mg group time taken for a total duration of motor block was 127 ± 20.42 minutes.

In Al-Abdulhadi O, et al.,[5]study in 15mg group 70% of the patients had hypotension.,and 1 patient had a history of bradycardia. In our study in the 15mg group, 40% of the patients had hypotension and 2% of the patient had bradycardia, which is comparable to our study. None of the

patients in the 10mg,12.5mg 15mg groups had nausea and any neurological complication. In study India A, et al, [6] in the 15 mg group 57% of the patients had hypotension and 4% of patients had bradycardia, which is also compared to our study. In Qian XW, et al.,[8] study in the 10 mg group there are fewer chances of hypotension than in the 15 mg group, which is also compared to our study.

In our study, none of the patients had an APGAR score of less than 7. In Chen, Xz., et al., [3] study also all the patients in 10.5mg,12mg,15mg group APGAR score were more than 10 and which is comparable to our study. In India A, et al.,[6] study mean of APGAR score at 1 minute is 7.10 ± 1.34, and the mean of APGAR score at 5 minutes is 9.35± 0.68 and which is comparable to our study. In Al-Abdulhadi O, et al.,[5] study conditions of neonates were good and no maternal or fetal sequelae, with normal APGAR scores.

There was no perioperative complication within 24 hrs of spinal anesthesia.

Our study explored new horizons for the safest anesthesia not only for the mother but also for the fetus and that too without any neurologic complications. This research was carried out in a single center and was limited to one region but in the future, there is always scope to apply the same findings to parturients of different races, regions, nationalities and see the effects which will be helpful to mankind. This study determined an adequate dose of hyperbaric ropivacaine in the cesarean section under spinal anesthesia which adds to the available evidence, good for patient care, no neurological complications, and is an effective health policy. Possible mechanisms for a good outcome are the proper selection of parturients who were ASA grade I and II, slowly positioning of the patient from sitting to supine after giving spinal anesthesia with a left lateral tilt of 15 degrees by applying wedge on the right side, using all precautions and correct technique, proper co-loading of fluids and strict monitoring of the patient.

V. CONCLUSION

Thus we conclude that 12.5mg dose of hyperbaric ropivacaine provides effective spinal anesthesia and good hemodynamic stability and excellent quality of block, whereas 10mg requires more amount of supplementation and in 15 mg there are more chances of hypotension.

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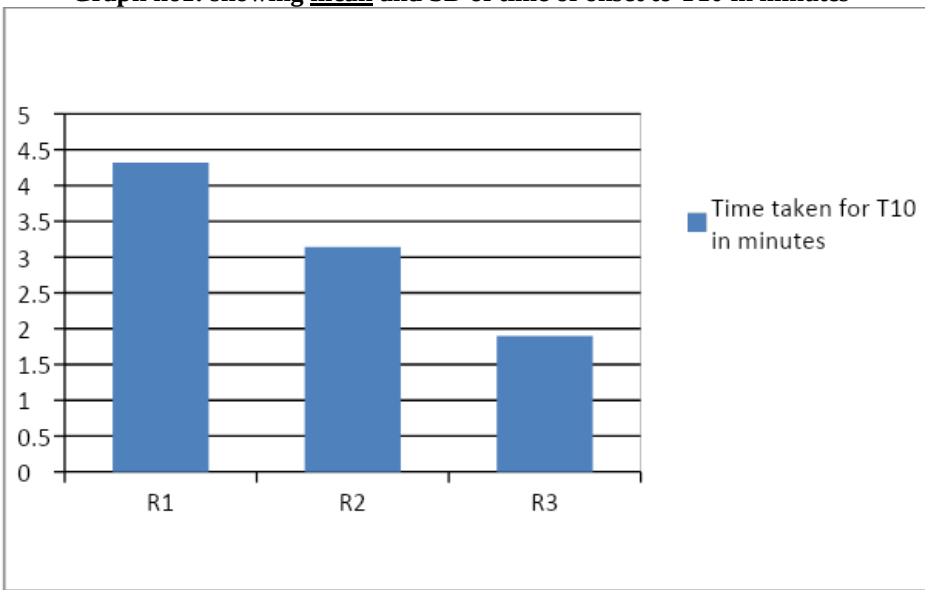
Tables and Graphs

Graph no1: showing mean and SD of time of onset to T10 in minutes



R1=1Omg ,R2=12.5mg,R3=15mg,SD-standard deviation

In the R1 group mean time of onset to T10 was 4.32±0.40 minutes. In the group, R2's meantime of onset to T10 was 3.14±0.60 minutes. In the group, R3's meantime of onset to T10 was 1.90±0.47 minutes. Time of onset to T10 in group R1, R2, and R3 were compared by the 'ANOVA' test and
'P' value was <0.001 and which is statistically significant.

Table no 1: showing mean and SD of time of onset to T7 in minutes

Groups	No	Mean Time of Onset to T6(minutes)	SD	P-Value
R1	50	7.74	0.59	<0.001 S
R2	50	5.84	0.42	
R3	50	5.37	0.81	

In the R1 group mean time of onset to T7 was 7.74±0.59 minutes. In the group, the R2 mean time of onset to T7was 5.84±0.42 minutes. In the group, R3 mean time of onset to T7was 5.37±0.81 minutes. The three groups R1, R2, and R3 were compared and the 'P' value was <0.001 and which is
statistically significant.

Table no 2: Mean and SD of time taken for regression to T10 (minutes)

Groups	No	Mean of time taken for regression to T10(minutes) and SD	'P' Value
R1	50	51.46 ± 2.8799	<0.001 S
R2	50	60.02 ± 2.10	
R3	50	71.12 ± 2.70	

In group R1 mean time taken for regression to T10 was 51.46 ± 2.8799 minutes, In group R2 mean time taken for regression to T10 was 60.02 ± 2.10 minutes, in group R3 mean time taken for regression to T10 was 71.12 ± 2.70 minutes. Meantime taken for regression to T10 were compared in R1, R2, and R3 group by

'ANOVA' test and'P' value was < 0.001 and it is significant.

Table no 3: Mean and SD of time taken for regression to S2 (minutes)

Groups	No	Mean of time taken for regression to S2(minutes)	SD	'P' Value
R1	50	79.14	4.3846	<0.001 S
R2	50	118	5.0400	
R3	50	147.82	3.1800	

In group, R1 means time taken for regression to S2 was 79.14 ± 4.3846 minutes. In group, R2 mean time taken for regression to S2 was 118 ± 5.04 minutes. In group, R3 means time taken for regression to S2 was 147.82± 3.18 minutes. The three groups R1, R2, and R3 compared by 'ANOVA'test and P-value were <0.001 and it is significant.

Table no 4: Showing mean and SD for the time of motor onset (minutes)

Groups	No	Mean of motor onset in minutes	SD	P-Value
R1	50	3.24	0.43	<0.001 S
R2	50	2.42	0.53	
R3	50	2.04	0.40	

The mean and SD of time of motor onset in groups R1, R2, and R3 are 3.24±0.43 minutes, 2.42±0.53 minutes, and 2.04±0.4 minutes respectively. Time of motor onset was compared by the
The 'ANOVA' test and 'P' value were <0.001 and it is statistically significant.

Table no 5: showing mean and SD of a total duration of motor block (minutes)

Groups	No	Mean of a total duration of motor block in minutes	SD	'P' Value
R1	50	60.48	2.149	<0.001 S
R2	50	79	2.72	
R3	50	101.78	5.20	

In group, R1 mean total duration of motor block is 60.48 ± 2.149 minutes. In group, R2's mean total duration of motor block is 79 ± 2.72 minutes. In group, R3's mean total duration of motor block is 101.78 ± 5.20 minutes. The total duration of the motor block was compared in three groups
by 'ANOVA' test and the P-value is <0.001 and is significant.