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Comparative study of intrathecal isobaric and hyperbaric ropivacaine in cesarean delivery

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***Abstract*---**Introduction: Spinal Anesthesia is a common safe, economical, easy to perform and effective technique which provides rapid and reliable anesthesia with muscle relaxation for pts undergoing lower abdominal surgery. Aim: To compare isobaric and hyperbaric ropivacaine in patients undergoing cesarean delivery Materials and Methods: Prospective Observational Clinical Study patients admitted for elective cesearan Delivery. The Duration of study is one year. 80 patients , aged 21 years to 30 years , belongs to ASA physical status 1 & 2, posted for elective Caesarean delivery under spinal Anaesthesia. These patients are divided into two groups of 40 patients Each. Group I : patients received 2ml of 0.75% Isobaric Ropivacaine (isobaric group), Group H: patients received 2 ml of 0.75% hyperbaric Ropivacaine in dextrose 50mg/ml (Hyperbaric group).Results: There was no significant difference in the onset of sensory block. Time from injection to highest sensory block is significantly higher in isobaric group [Group-I], when compared to hyperbaric group [Group-H]. Time for onset of modified bromage grade 3 is longer in isobaric group than hyperbaric group. Time for motor regression is faster in hyperbaric group than in isobaric group so that early mobilization in hyperbaric group patients than isobaric

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group patients is possible. no much significant difference hemodynamic variable and side effects during intraoperative period between both groups. Conclusion: Hyperbaric ropivacaine produced more consistent, reliable and good quality of motor block with faster onset and early mobilization and rehabilitation than an Isobaric Ropivacaine, which is required for day care surgery in which prolong immobilization is undesirable .

***Keywords*---**hyperbaric ropivacaine, caesarean delivery, prolong immobilization.

Introduction

Spinal Anesthesia is a common safe, economical, easy to perform and effective technique which provides rapid and reliable anesthesia with muscle relaxation for pts undergoing lower abdominal surgery. Various local anesthetic commonly used for spinal anesthesia are Lignocaine, Bupivacaine, Levobupivacaine, and Ropivacaine. The versatility of spinal anesthesia is afforded by a wide range of local anesthetics And additives that allow control over the level, The time of onset and the duration of Spinal anesthesia. The distribution of local anesthetic solutions with in the sub arachnoid space determines the extent of the neural blockade produced by spinal anesthesia.[1] Nowadays ropivacaine gaining popularity because of reduced risk of central nervous System and cardiac toxicity, early ambulation and discharge with good quality of post-operative analgesia. Isobaric Ropivacaine is the pure S (-) enantiomer of Ropivacaine, which is a new long acting amino amide with lipid solubility, produces variable sensory and motor block when it is given in isobaric form. Hyperbaric ropivacaine produced more reliable sensory and motor block, with faster onset, better quality of muscle relaxation than isobaric ropivacaine. [2] we aim to compare isobaric and hyperbaric ropivacaine in patients undergoing cesarean delivery and onset of sensory and motor blockade, duration of sensory and motor blockade hemodynamic changes and any adverse effects.

Materials and Methods

Prospective Observational clinical study conducted at Gandhi Medical College And Hospital, Secunderabad on patients admitted for elective caesarean delivery for duration of study is one year. Following institutional ethical and scientific committee approval, patients were thoroughly explained Regarding the nature of the study. The study was conducted after informed and written consent is taken From patients in both groups under consultant Anaesthesiologist guidance in the hospital. 80 patients , aged 21 years to 30 years , belongs to ASA physical status 1 & 2, posted for elective Caesarean delivery under spinal Anaesthesia. These patients are divided into two groups of 40 patients Each.

Group I:This group of patients received 2ml of 0.75% Isobaric Ropivacaine (isobaric group)
Group H: This group of patients received 2 ml of 0.75% hyperbaric Ropivacaine in dextrose 50mg/ml (Hyperbaric group).

Inclusion Criteria: Patients belongs to ASA physical status 1&2 aged 21 to 30 years posted for elective caesarean delivery.
Exclusion Criteria: Patients with severe systemic disease, metabolic disorder, neurological, congenital or cardiovascular disease, coagulation disorders, Local sepsis at site of spinal injection, allergic to local anaesthetics.

Pre anesthetic checkup was carried out with a detailed examination including history, clinical examination, systemic examination of cardiovascular, respiratory and central nervous systems and examination of spine for deformity, infection was carried out. Airway assessment done. The basic laboratory examinations were done. An informed written consent was obtained from patient and her relatives. patients were kept fasting for 6 hours to solids and 2 hours to clear fluids preoperatively. the procedure of spinal anesthesia was explained and the patient was informed to communicate to the Anesthesiologist about perception of any pain or discomfort during surgery. In the operation theatre, an intravenous line was secured. Baseline heartrate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), respiratory rate (RR), Arterial oxygen saturation (spo2) were for all subjects. All patients received 10ml/kg of ringer lactate solution as preload within 20-30 mins. Subarachnoid block was performed under strict aseptic conditions in the sitting position at the level of L3-4 intervertebral space by using 25G quincke's spinal needle. The midline approach was used to perform the spinal blocks after infiltrating the skin with 1ml of 2% lignocaine. the test drug was injected over 15secs. Following the subarachnoid block, the patient was put in supine position. Intraoperatively HR, SBP, DBP, RR, and SPO2 were recorded 3 minutes (min) intervals for the first 30mins from the time of injection of spinal solution and there after every 5min till 60 min there after every 15min for the complete period of surgery. Hypotension (MAP<60mm of Hg) was treated with fluid boluses and 6mg intravenous bolus of Mephenteramine, Bradycardia was treated with 0.6mg of Atropine. Respiratory rate <8breaths/min or SPO2 of <90% on room air. All patients were given supplemental oxygen via facemask at 6l/min if the SPO2 decreased below 90%.

Statistical Analysis : Raw data was entered into a Microsoft excel spreadsheet. Appropriate statistical tests were done using SPSS 17A and openepi.com to compare between qualitative data and quantitative data. The qualitative data were presented in the form of number and percentage and the quantitative data were presented in the form of mean and standard deviation. T-tests were used to analyze differences between two groups . Chi square test used to analyze hypotension, bradycardia, pruritis, nausea, vomiting and urinary retention. Consideration of p values: <0.05 = significant and >0.05 = Not significant.

Results

Table-1: Age and ASA grade distribution in both groups

Age group	Isobaric group	Percentage	Hyperbaric group	Percentage
20-24 years	18	45%	18	45%
25-29 years	20	50%	19	47.5%
>30 years	2	5%	3	7.5%

Total	40	100%	40	100%
Mean and SD	25.1±2.71		24.825±2.72	
ASA grade				
I	35	87.5%	30	75%
II	5	12.5%	10	25%

There is no significance between 2 groups on demographic data.

Table-2: Variables distribution in both groups

Parameters	Isobaric group	Hyperbaric group
Height	159.7±2.78	159.7±2.78
Weight	71.35±9.58	71.35±9.58
Duration of surgery	71.8±9.02	72.2±9.35

There is no significance between 2 groups on height, weight and duration of surgery .

Table-3: Level of highest sensory block in both groups

Level of highest sensory block	Isobaric group	Percentage	Hyperbaric group	Percentage	P value
T4	10	25%	20	50%	0.06
T6	27	67.5%	18	45%	
T8	3	7.5%	2	5%	
Total	40	100%	40	100%	

Level of highest sensory block is highest at T6 followed by T4 and T8 levels.

Table-4: Block characteristics in both groups

Parameters	Isobaric group	Hyperbaric group	P value
Time of onset of sensory block	4.22±1.32	4.625 ±1.004	0.12
Time from injection to reach the highest level	12.52±2.23	10.175±1.059	<0.0000001
Time of 2 segment regression from highest sensory level	98.72±5.87	79.025 ± 5.42	<0.0000001
Time for sensory regression	149.55±2.06	154.025±7.95	0.0009
Time for onset of modified bromage	12.275±1.01	7.925±0.655	<0.0000001
Time to reach modified bromage	3.275±0.98	2.5±0.506	0.00002

There is significant difference in both groups at time from injection to reach highest level, sensory regression, Time for onset of modified bromage and modified bromage.

Table-4: Comparision of systolic and diastolic blood pressure in both groups

TIME	Isobaric group	Hyperbaric group	P Value
Systolic blood pressure			
0 min	124±5.78	125±7.53	0.5
3 min	117.15±9.94	120.55±8.32	0.1
6 min	116.7±7.75	118.9±7.33	0.19

9 min	113.625±12.59	117.47±10.43	0.14
12 min	117.675±7.50	118.925±7.32	0.45
15 min	117.375±6.57	120.4±6.82	0.04**
18 min	118.625±6.09	120.225±6.90	0.2
21 min	118.25±7.02	121.025±6.55	0.07
24 min	119.375±7.17	121.525±6.32	0.15
27 min	119.075±7.80	120.825±6.25	0.27
30 min	119.45±7.24	120.8±6.08	0.36
35 min	118.95 ± 6.675	120.975±6.082	0.16
40 min	119.4±6.34	121.45±6.45	0.17
45 min	118.975±7.10	121.55±7.22	0.11
50 min	119.25±7.55	121.775±6.806	0.12
55 min	118.65±7.49	122.2±6.70	0.02**
60 min	119±7.65	122.325±6.30	0.03**
65 min	118.875±6.93	121.275±6.27	0.1
70 min	119.2±6.8	121.15±6.56	.0.1
75 min	120.15±6.58	121.775±6.212	0.25
90 min	120.625 ± 6.355	120.3±6.14	.0.81
105 min	121.2±6.85	120.2±5.86	.0.48
120 min	121.175±6.67	120.6±6.23	0.69
Diastolic Blood pressure			
0 min	77.1±5.66	77.45±5.83	0.78
3 min	72.675±8.069	75.05±5.45	0.12
6 min	72.9±5.744	73.85±5.70	0.46
9 min	70.275±8.459	71.35±9.22	0.58
12 min	72.95±5.76	72.55±4.83	0.73
15 min	72.9±5.23	73.625±3.89	.0.48
18 min	73.4±4.29	74.15±4.39	0.44
21 min	74.025±4.69	75.075±4.60	0.31
24 min	74.85±5.72	75.9±4.61	0.36
27 min	74.85±5.95	75.75±5.45	0.48
30 min	74.8±5.8	75.55±5.38	0.55
35 min	73.675±4.46	75.6±4.77	0.06
40 min	73.775±5.46	76.35±5.17	0.03**
45 min	74.4±5.62	75.875±5.65	0.24
50 min	74.2±6.022	76.3±5.57	0.1
55 min	74.15±6.074	76.6±5.15	0.05
60 min	73.97±5.88	76.025±5.126	0.09
65 min	73.8±5.25	75.7±4.92	0.09
70 min	74.35±5.48	75.75±4.39	0.211
75 min	74.225±5.70	76.3±5.20	0.09
90 min	75.52±5.74	75.475±4.72	0.96
105 min	76.625±5.62	75.75±4.98	0.46

120 min	75.875±5.56	76.05±5.72	0.89

Figure-3: Comparision of heart rate in both groups

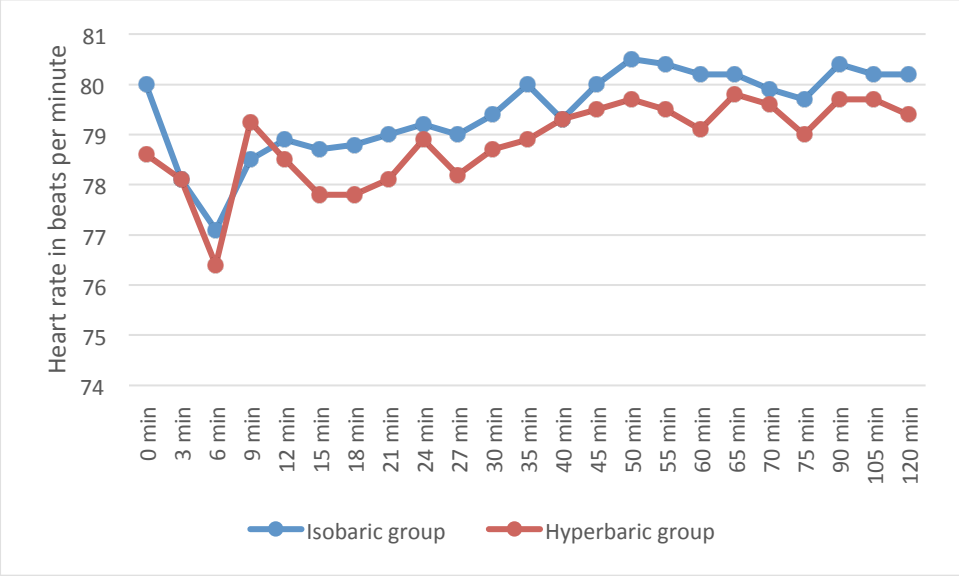
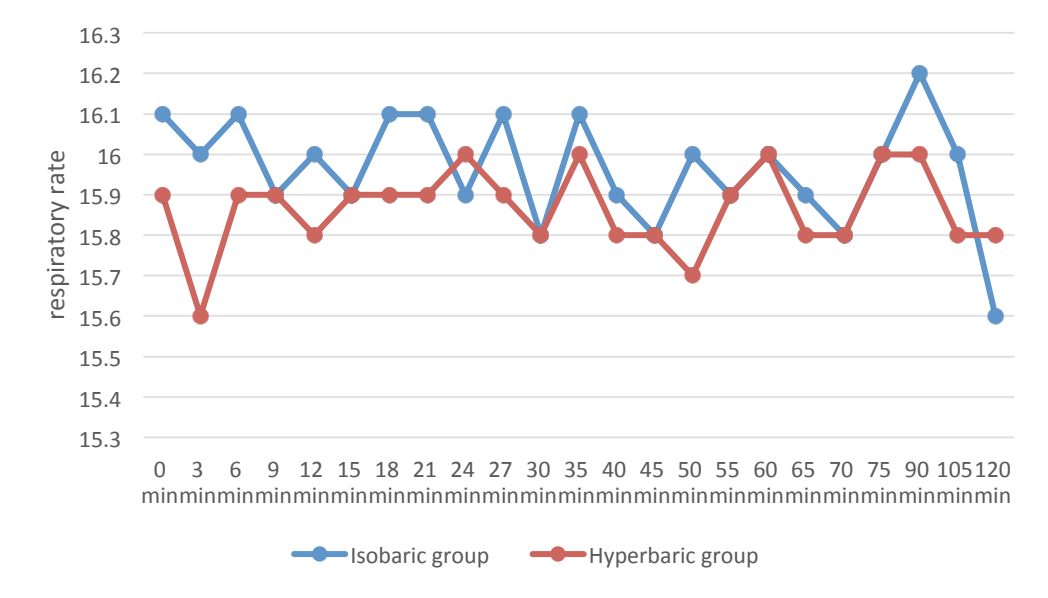


Figure-4: Comparision of spo2 in both groups



Mean systolic blood pressure recordings when compared to isobaric group were high in hyperbaric group at 15 min ,55min,60 min after subarachnoid block Mean diastolic blood pressure recording when compared to Isobaric group was high in hyperbaric group at 40min after subarachnoid block. Mean arterial

pressure recordings when compared to isobaric group were high in hyperbaric group at 35min,40 min, 55 min,60 min, 65 min after subarachnoid block. And there is no significant difference in remaining intraoperative period. There is no significant difference in heart rate, respiratory rate, oxygen saturation during intra operative period between both groups.

Discussion

Spinal anaesthesia is a common safe, economical, easy to perform and effective technique which provides rapid and reliable anaesthesia with muscle relaxation for patients undergoing lower abdominal surgery.[3] Various local anaesthetic commonly used for spinal anaesthesia are lignocaine, bupivacaine, levobupivacaine, and ropivacaine.[3]Nowadays, ropivacaine is gaining increasing popularity because of reduced risk of central nervous system and cardiac toxicity, early ambulation and discharge with good quality of post-operative analgesia. Isobaric Ropivacaine is the pure S (□) enantiomer of ropivacaine, new long-acting amino amide with lower lipid solubility, produces variable sensory and motor block when it is given in isobaric form while hypothetically, hyperbaric ropivacaine produced more reliable sensory and motor block, with faster onset, better quality of muscles relaxation than isobaric ropivacaine. Therefore, this study was designed to compare isobaric with hyperbaric ropivacaine for spinal anaesthesia in patients undergoing lower abdominal surgery. The aim of the current study is to compare the intra operative characteristics and recovery profile of isobaric and hyperbaric solution of ropivacaine in cesarean delivery.

Comparative study conducted between isobaric and hyperbaric ropivacaine has shown that hyperbaric solution of ropivacaine produces a more consistent block with a greater success rate and less frequent incidence of intraoperative pain than a isobaric solution. addition of glucose 50 mg/ml[1] led to a more rapid spread to a higher median dermatomal level and with less variation in maximum height of sensory block. We chose a dextrose concentration of 50mg/ml in the hyperbaric solution for two reasons. first, a previous study by whiteside et al[4] has demonstrated the clinical efficacy of a solution of ropivacaine containing glucose 50 mg/ ml. in the absence of a commercially available glucose preparation, this solution can be easily prepared before spinal anesthesia using readily available solutions, and provides a solution that is sufficiently hyperbaric for its purpose. Second, previous works by Bannister et al[5] with bupivacaine have suggested that lower concentrations of glucose then are present in the commercially available hyperbaric solution (8.3%) may be sufficient to provide the previously stated benefits over plain solutions.

When a hyperbaric solution is injected in the left lateral position, the tendency for it would be to spread in the cephalad direction, gravity presumably encouraging spread of the bolus of drug down the slopes of the lumbar curve when the patient is placed supine after injection resulting in a more even distribution of the local anesthetic solution. in contrast, a isobaric solution would not have such gravity-assisted spread and thus would concentrate in the lower lumbar segments. This would explain the less reliability of the block for abdominal surgery but prolonged sensory and motor block in the lower limbs due to dense blockade of the lumbar and sacral segments.

In agreement with previous work, in our study, the sensory block with the isobaric solution of local anesthetic spread unpredictably; 3 patients (7.5%) in Isobaric group attained sensory block till T8 dermatome and the highest extent of sensory block varied widely. this is also in accordance with the results of Khaw et al[6], who reported that all patients in the hyperbaric group had sufficient analgesia for Caesarean section. The cephalic spread of sensory block was significantly greater with hyperbaric ropivacaine T4 than in isobaric group and this trend, is similar to earlier study by Kallio et al[7], with (15mg) ropivacaine having a median cephalad spread of T4 and T9 in the hyperbaric and plain groups, respectively. Whiteside et al[4] studied hyperbaric ropivacaine 15 mg and reported a median maximum cephalic spread of sensory block at T7 dermatome, which is somewhat lower but comparable to our study with hyperbaric ropivacaine 15mg T4 .

In our study time of onset of sensory blockade in Isobaric group is 4.22+1.32min where as in Hyperbaric group 4.625+1.004min shows that not much difference in both groups similar results in Rajini Gupta et al[8] study. Time to reach highest level of sensory blockade in isobaric group 12.52+2.23min and in hyperbaric group 10.17+1.059min same like in Rajini Gupta et al[8] study. Time of two segment regression time in our study, the 98.72 min regression of the sensory block to the T10 level was comparable with that (115.8 min) in an earlier study by Chung et al [9] with a slightly lower dose of hyperbaric ropivacaine (18 mg). The median time to 2 segment regression of sensory block was faster with hyperbaric ropivacaine (79.025 min) in comparison to plain ropivacaine (98.72 min). These findings were in accordance with Kallio et al[7] who found median time to 2 segment regression of sensory block with 15mg ropivacaine to be 90 min and 60 min in the plain and hyperbaric ropivacaine group, respectively. Faster recovery from both sensory and motor block with an increase in the useful duration of sensory block translated into faster mobilization in the patients of hyperbaric group. Similar findings were also seen in two previous studies by Kallio et al[7] stated that spinal anesthesia with hyperbaric ropivacaine was associated with early mobilization and faster discharge times.

Mean systolic blood pressure recordings when compared to isobaric group were high in hyperbaric group at 15 min ,55min,60 min after subarachnoid block Mean diastolic blood pressure recording when compared to Isobaric group was high in hyperbaric group at 40min after subarachnoid block. Mean arterial pressure recordings when compared to isobaric group were high in hyperbaric group at 35min, 40 min, 55 min, 60 min, 65 min after subarachnoid block. And there is no significant difference in remaining intraoperative period. There is no significant difference in heart rate, respiratory rate, oxygen saturation during intra operative period between both groups. In the study conducted by Puneeth Dwivedi et al[1] the both groups did not differ in hemodynamics in the operative room and the recovery room.in group A (Isobaric Ropivacaine), only 4 patients out of 40 developed hypotension and 2 patients developed bradycardia. In group B (hyperbaric ropivacaine), only 5 out of 40 patients developed hypotension and 3 patients developed bradycardia. Patients in both groups were administered sympathomimetics or anticholinergics in the operating room as per protocol.

Conclusion

Hyperbaric ropivacaine produced more consistent, reliable and good quality of motor block with faster onset and early mobilization and rehabilitation than an Isobaric Ropivacaine, which is required for day care surgery in which prolong immobilization is undesirable . The present study concludes that there was no significant difference in the onset of sensory block. Time from injection to highest sensory block is significantly higher in isobaric group [Group-I], when compared to hyperbaric group [Group-H]. Hyper baric ropivacaine produced more rapid onset of more extensive, but less variable than isobaric ropivacaine. Time of two segment sensory regression from highest sensory level is more in isobaric group than hyperbaric group. Time for onset of modified bromage grade 3 is longer in isobaric group than hyperbaric group. Time for motor regression is faster in hyperbaric group than in isobaric group so that early mobilization in hyperbaric group patients than isobaric group patients is possible. There is no much significant difference in systolic blood pressure, diastolic blood pressure, mean arterial pressure, heart rate, respiratory rate, peripheral oxygen saturation during intraoperative period between both groups.

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