

Superiority of the Hyperbaric Bupivacaine 0.50% Over 0.75% Hyperbaric Bupivacaine in patients Undergoing Elective cesarean Section: A Uni-Center Double Blind Randomized Control Trial

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ABSTRACT

Objective: The objective of this study was to compare 0.75% and 0.50% hyperbaric bupivacaine in terms of hemodynamic stability in elective cesarean section.

Study Design: Randomized Controlled Trial.

Place and duration: Department of Anesthesiology, Intensive care and pain management, Combined Military Hospital, Mardan from September 2021 to March 2022.

Methodology: Total 104 women were randomly divided into Group-A (0.50% drug concentration) and Group-B (0.75% drug concentration) hyperbaric bupivacaine. Base line systolic blood pressure was noted. Lumber puncture was done in L3/L4 or L4/L5 space. Reading were taken at 1-min, 3-min, 5-min and 30-min. Drop in SBP<20% from baseline was taken as hemodynamic stability. Stability in SBP systolic blood pressure among the two groups A and B were compared.

Results: The mean systolic blood pressure of group A was 123.77±8.43 mmHg while in group B it was 123.66±9.14 mmHg. In group A more than 20% decrease in SBP were noted in 42.3% while in group B it was observed in 63.5% patients. Hemodynamic stability was noted in 57.7% patients and 36.5% patient respectively in study group A and B and difference was significant (p=0.031).

Conclusions: The Hyperbaric Bupivacaine 0.50% is found superior than 0.75% interms of hemodynamic stability in patients undergoing elective Cesarean Section.

Keywords: Hyperbaric Bupivacaine, Hemodynamic Stability, Elective Cesarean Section

INTRODUCTION

According to a survey conducted across Asia, the prevalence of caesarean sections is 27.3 %, with rates ranging from 15 % in Thailand to 48 % in Sweden.^{1,2} General anaesthesia is typically not chosen for non-emergency caesareans compared to regional anaesthesia. Patients having spinal anaesthetic without sedatives may experience a decline in consciousness, according to one study, whereas spinal anaesthesia with sedatives may have an impact on a patient's degree of consciousness.³

A lot of caesarean sections are performed under spinal anaesthetic. The use of regional anaesthesia techniques has a number of benefits, including as a reduced chance of unsuccessful intubation and stomach aspiration, the avoidance of depressive medications, and the possibility for the mother to stay awake and take pleasure in the delivery process. Additionally, it has been hypothesised that regional anaesthetic for caesarean birth reduces blood loss. It has been discovered that spinal anaesthetic is quicker, more affordable, and offers a superior block.⁴ Patients undergoing With spinal anaesthesia, a caesarean delivery demonstrated a lower level of consciousness.^{5,6}

Compared to general anaesthesia, regional anaesthesia is associated with lower maternal mortality and morbidity.⁷ Most often occurring side effects of sympathetic inhibition are hypotension and bradycardia, which are made worse by aortocaval compression brought on by a gravid uterus. Up to 90% of people have bradycardia and hypotension.⁸

MATERIAL AND METHODS

This double blind randomized controlled trial was conducted at Department of Anesthesiology, Intensive care and pain management, Combined Military Hospital, Mardan from September 2021 to March 2022. Sample size was calculated on WHO calculator with 5% Significance level, Power of the test 80% while considering the incidence of the hypotension i.e. instability in 0.75% Hyperbaric Bupivacaine Group as 57% and the incidence of hypotension in 0.50% hyperbaric Bupivacaine Group as 30% which was a total of 104 patients which were equally divided in two groups Group A and Group B of 52 patients each randomly by the lottery method. An inclusion and exclusion criteria for the sample

collection was devised and all the female patients of reproductive age who need elective Cesarean Section under Spinal anaesthesia with Gestational age 37 to 42 weeks and ASA grade I & II and not suffering from Placenta previa III & IV or Placenta accreta were included in the study. Emergency Cesarean Section, Twin pregnancy and patients having absolute contraindication for neuraxial anaesthesia e.g. infection at the site of injection, increased intracranial pressure, severe systolic stenosis, severe mitral stenosis and the coagulopathy were all excluded from this study .All patients who fulfilled the inclusion criteria were included through non-probability consecutive sampling technique.

Drugs were prepared by a person not involved in the research and the patients were also unaware of the groups. The baseline characteristics of both groups are comparable and are shown in the Table 1. Group A were treated by 0.50% while Group B were treated with 0.75% hyperbaric Bupivacaine and the hypotheses narrates that there is a difference between 0.50% and 0.75% hyperbaric bupivacaine in terms of hemodynamic stability in elective cesarean section. Syringes were containing 12 mg of drugs either 1.6ml of 0.75% or 2.4ml of 0.50% hyperbaric bupivacaine. Two large bore (18G) I/V lines were passed. Patients were preloaded with 1 liter R/L (Hartmann's solution) and base line systolic blood pressure was noted. Under aseptic measures lumber puncture was done in L3/L4 or L4/L5 space using 25 g Quincke Babcock cutting needle in sitting position by the consultant Anesthetist having more than 2 years post fellowship experience. Baseline systolic blood pressure was recorded before giving spinal anaesthesia and the readings were taken at 1 min, 3 min, then at 5 minute and at the 30 minute intervals and shown in the Table 2. Drop in SBP < 20% from baseline during any reading was taken as hemodynamic stability. In case of drop in SBP ≥ 20% from baseline injection vasopressure was given I/V. This information along with age, parity and weight was recorded, entered and analyzed through SPSS version 17.

RESULTS

Total 104 women with age between 18 to 40 years were included in the study to compare 0.50% and 0.75% hyperbaric bupivacaine in terms of hemodynamic stability in elective cesarean section. The mean age of study subjects in Treatment Group A was 28.36±4.24

years while mean age in Treatment Group B was 28.01±4.56 years.

In study group A, Systolic Blood Pressure at base line, at 1 minute, at 3 minutes, at 5 minutes and at 30 minutes was 135.10 ±10.18, 125.66 ±12.66, 116.73 ±12.67, 120.47 ±16.54 and 120.63 ±10.14 respectively. In study group B, Systolic Blood Pressure at base line, at 1 minute, at 3 minutes, at 5 minutes and at 30 minutes was 132.77 ±15.05, 126.28 ±9.85, 119.01 ±14.73, 118.86 ±11.91 and 121.38 ±9.02 respectively. Table 1

Haemodynamic Stability was noted in 30 (57.69%) patients of A while in 19 (36.54%) patients of study group B. Difference of Haemodynamic Stability between study group A and B was statistically significant (P = 0.049). (Table 2)

Age group Age group ≤ 25 years and age group Age group >25 years created. Total 16 (30.77%) patients of study group A and 15 (28.85%) patients of study group B belonged to age group ≤ 25 years. Haemodynamic Stability was noted in 7 (43.75%) patients and 6 (40%) patients respectively in study group A and B. Difference was not significant (P = 1.000). In Age group >25 years, 36 (69.23%) patients belonged to study group A and 37 (71.15%) patients belonged to study group B. Difference of Haemodynamic Stability between the both groups was significant (P = 0.019). (Table 3)

Total 7 (13.46%) patients of study group A while 3 (5.77%) patients of study group B had BMI ≤ 25. Haemodynamic Stability was noted in 5 (71.43%) patients of study group A and 1 (33.34%) patient of study group B. Difference was not significant (P 5.000). Total 45 (86.54%) patients of study group A and 49 (94.23%) patients of study group B had BMI >25. Haemodynamic Stability was noted in 25 (55.56%) patients and 18 (36.73%) patients respectively in study group A and B. But difference was not significant (P = 0.097). (Table 4)

Table 1: Mean systolic blood pressure at different time interval

Measured (SBP) Systolic Blood Pressure (n=104)	Group A (n=52)	Group B (n=52)
Base Line SBP (Mean ±SD)	135.10 ±10.18	132.77 ±15.05
At 1 Minute (Mean ±SD)	125.66 ±12.66	126.28 ±9.85
At 3 Minute (Mean ±SD)	116.73 ±12.67	119.01 ±14.73
At 5 Minute (Mean ±SD)	120.47 ±16.54	118.86 ±11.91
At 30 Minute (Mean ±SD)	120.63 ±10.14	121.38 ±9.02

Table 2: Comparison of Haemodynamic Stability between the groups

Group	Haemodynamic Stability		Total	P value
	Yes	No		
A	30 (57.69%)	22 (42.31%)	52	0.049
B	19 (36.54%)	33 (63.46%)	52	

Table 3: Association of hemodynamics stability with age groups

Group	Haemodynamic Stability		Total	P value
	Yes	No		
Age group ≤ 25 years				
A	7 (43.75%)	9 (56.25%)	16 (30.77%)	1.000
B	6 (40%)	9 (60%)	15 (28.85%)	
Age group >25 years				
A	23 (63.89%)	13 (36.11%)	36 (69.23%)	0.019
B	13 (35.14%)	24 (64.86%)	37 (71.15%)	

Table 4: Association of hemodynamics stability with age groups

Group	Haemodynamic Stability		Total	P value
	Yes	No		
BMI ≤ 25				
A	5 (71.43%)	2 (28.57%)	7 (13.46%)	0.500
B	1 (33.34%)	2 (66.66%)	3 (5.77%)	
BMI >25				
A	25 (55.56%)	20 (44.44%)	45 (86.54%)	0.097
B	18 (36.73%)	31 (63.27%)	49 (94.23%)	

Total 33 (63.46%) patients of study group A and 25 (48.08%) patients of study group B had ≤ 2 Childs. Haemodynamic Stability

was noted in 18 (54.55%) patients and 9 (36%) patients respectively in study group A and B. Difference was not significant (P = 0.191). Total 19 (36.54%) patients of study group A while 27 (51.92%) patients of study group B had >2 Childs. Haemodynamic Stability was noted in 12 (63.16%) patients of study group A and in 10 (37.04%) patients of study group B. Difference of Haemodynamic Stability was not significant (P = 0.133). (Table 5)

Table 5: Association of hemodynamics stability with age groups

Group	Haemodynamic Stability		Total	P value
	Yes	No		
≤ 2 Childs				
A	18 (54.55%)	15 (45.45%)	33 (63.46%)	0.191
B	9 (36%)	16 (64)	25 (48.08%)	
>2 Childs				
A	12 (63.16%)	7 (36.84%)	19 (36.54%)	0.133
B	10 (37.04%)	17 (62.96%)	27 (51.92%)	

DISCUSSION

General anesthesia used for caesarian section resulted in higher maternal and fetal mortality and morbidity. With the introduction of spinal anesthesia for caesarian section fetal outcome dramatically improved. But specific complications are linked with local anesthesia, the most troublesome spinal hypotension. Different strategies are in use to tackle these complications; to use minimal effective dose of a local anesthetic, judicious use of crystalloids and using same dose of a local anesthetic with different strengths⁹. In our study we tried hyperbaric bupivacain with different strength and found that the lower strength (0.5 vs 0.75%) was well tolerated with good efficacy. Like our study, similar strategy has been applied in other set up also with almost similar results. Hina Iftekhhar et al. studied the same drug with similar strength in their patients. They recorded the effect of bupivacain 0.5 vs 0.75% on blood pressure and heart rate. Statistically significant difference was observed in blood pressure and heart rate with different strengths (0.5% well tolerated as compared to 0.75%). Total number of patients in their study was 830 while in our study the number of patients was 104. We only noted the effect of bupivacain on blood pressure, however, they also recoded heart rate with blood pressure¹⁰.

Amjad et al. also studied the effect of both drugs on systolic blood pressure and heart rate. They also noted other unpleasant effect like nausea, vomiting and discomfort. Like our study both group of patients were comparable in age. However, in contrast to our study no significant difference was observed in term of systolic blood pressure in both groups. Patients with 0.5% bupivacanie experienced less nausea and vomiting and effective anesthetic effect¹¹. similar finding were reported by Rai et al. also. They recruited 200 patients with age group between 20 years to 40 years. They administer about 10 mg of bupivacain to all patients. They recorded changes in systolic blood pressure at 5 min and 10 min. they also noted changes in heart rate and reported significant changes in heart rate after 10 min of drugs administration. However, changes in systolic blood pressure after 5 min recoding were significant but no significant changes in blood pressure were appreciated after 10 min of drug administration¹². Unlike their study, we didn't recorded changes in heart rate and significant changes in blood pressure were observed in our patients at 1, 3, 5 and 10 min.

In a study by Sikander et al. patients who were given 0.50% hyperbaric Bupivacaine experienced higher level of block as compared to those who received 0.75% hyperbaric Bupivacaine without adding to the complications (P=0.001).¹³ Although they didn't find statistically significant difference between the haemodynamics of two groups but those who were given 0.75% hyperbaric Bupivacaine required more rescue ephedrine. Moreover there was statistically less incidence of nausea/vomiting and pain/uneasiness during C Section in parturients receiving 0.5% hyperbaric Bupivacaine (P=0.05 and 0.005) Duration of surgery

was also comparable as it is known to affect the pain or comfort during spinal anaesthesia.¹³

A study data indicated that subarachnoid injection of 0.50% hyperbaric bupivacaine is safe and effective in establishing anesthesia for cesarean section. Other studies^{14, 15} also indicate that with the use of 0.50% hyperbaric bupivacaine for spinal anesthesia, increasing the dose increases the duration of sensory and the profundity of motor blockade. The incidence of hypotension in their patients given 7.5-10mg bupivacaine (24%) was greater than the 9% previously reported by them.¹⁴ The latter study included a significant number of patients in labor. The tendency for hypotension to develop after regional anesthesia is less in laboring mothers undergoing cesarean section than it is in those having elective sections.¹⁶ Similarly, we used 12 mg bupivacaine alone with different strength. Different trials have been carried out with lesser dose of the same drug and with different combination with other drugs.^{9, 17, 18}

Study limitation: The main limitation of the present study includes a single-center experience. One of the limitations of this study is that it was conducted with small sample size and in urban environment therefore, the results might not be representative of larger populations. This fact highlights the need of further studies in this regard in a more handsome sample size which may or may not be multicenter based.

CONCLUSION

The difference was found statistically significant between two strengths 0.50% and 0.75% of Hyperbaric Bupivacaine. It was concluded that the Hyperbaric Bupivacaine 0.50% is superior to 0.75% in terms of hemodynamic stability, by low incidence of hypotension, unconsciousness and also provides comfort to patients during elective cesarean section.

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