A COMPARATIVE STUDY OF TWO DIFFERENT DOSES OF 0.75% HYPERBARIC BUPIVACAINE FOR SPINAL ANAESTHESIA IN ELECTIVE CAESAREAN SECTION

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ABSTRACT

Objective: To compare the effect of 7.5mg versus 10mg of 0.75% hyperbaric bupivacaine in spinal anaesthesia for caesarean section.

Study Design: Randomized controlled trial.

Place and Duration of Study: Department of Anesthesia, Combined Military Hospital Rawalpindi, from Sep 2014 to Mar 2015.

Material and Methods: One hundred and thirty patients fulfilling the inclusion/exclusion criteria were included in this study and they were divided into two groups. Group A was given 7.5mg and group B was given 10mg of 0.75% Bupivacaine. Blood pressure was recorded before and 03 minutes after administration of spinal anesthesia. Findings were recorded in the proforma. All the data collected through proforma was entered in the Statistical Package for Social Sciences (SPSS) Version 13.0 and analyzed using its statistical package.

Results: The mean age in group A was 30.58 ± 3.12 years and in group B was 28.32 ± 2.53 years. The mean weight in group A was 64.45 ± 3.99 kg and in group B was 65.00 ± 5.38 kg. In group A, 5 (7.7%) patients developed hypotension while in group B there were 20 (30.8%) that developed it. Majority of the patients were between 31-35 years old in both groups. Mean systolic blood pressure after spinal anaesthesia was 80.23 ± 7.41 and 83.00 ± 7.43 in group-A and B respectively. The difference between two groups was statistically significant (p=0.001).

Conclusion: In conclusion we can say that dose of local anesthetic is a significant factor that indirectly affects the maternal blood pressure and use of low dose bupivacaine is associated with decreased frequency of hypotension.

Keywords: Anesthesia, Bupivacaine, Caesarean section, Hypotension, Maternal blood pressure, Spinal.

INTRODUCTION

Neuraxial anesthesia has a great impact in obstetrics. Nowadays more and more caesarean sections are being performed under regional anesthesia as compared to general anesthesia[1]. Spinal anesthesia is safest technique for cesarean section because general anesthesia is associated with higher maternal morbidity and mortality[2]. Neuraxial anesthesia has become the anaesthetic technique of choice in caesarean section deliveries with increasing popularity because of its safety, low failure rate, prevention of aspiration pneumonia, drug induced neonatal depression and reduction in maternal mortality[3-5].

It provides a fast rapid, profound and symmetrical sensory and motor block of high quality in patients undergoing cesarean section[6].

Common complications of spinal anesthesia are hypotension, postdural puncture headache, nausea, vomiting, backache, hypoventilation, paresthesias and inadequate analgesia[7].

Hypotension during spinal block is secondary to the sympathetic block. Maternal hypotension may have harmful effects on uterine blood flow, fetal well-being and ultimately neonatal outcome[8]. It can result in maternal morbidity and can directly influence the neonate well-being by reducing uteroplacental blood flow[9]. While effective surgical anesthesia is the primary objective of the spinal technique, it must be accomplished while minimizing maternal and neonatal side-effects[10]. Though there is no definite method to prevent the sympathetic block and resultant hypotension after spinal anesthesia however different methods are used for the prevention of hypotension associated with spinal

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anesthesia like colloid/crystalloid preloading, prophylactic administration of vasopressors, spinal opioids in combination with local anaesthetics, leg bandage, positioning of patient or using low dose spinal local anesthetics[11-15].

Dose of local anesthetic is a useful determinant of spinal block characteristics. Increasing the dose of local anesthetic increases the risk of associated complications. The toxicity of the local anesthetic agent is another complication of regional anesthesia in addition to the high sympathetic blockage[11]. Thus it is time and again emphasized in literature that the lowest effective dose should be administered. Studies also that show that reducing the spinal dose has a favorable effect on maternal hemodynamic stability[16-18].

Bupivacaine is the commonly used local anesthetic in caesarean deliveries. Lowest effective dose of bupivacaine for these procedures has not been determined[9].

We hypothesized that a lowered intrathecal dose of this drug could be used safely, satisfactorily but with fewer side effects.

Obstetric anesthesia is generally considered to be one of the higher-risk areas of anaesthetic practice. Changes in maternal physiology during pregnancy and the care of both mother and fetus present unique challenges to the obstetric anesthetists. Although new systems and technologies are developing to provide consistent and safe anaesthetic care to pregnant mothers, the modern-day obstetric anesthetist has to also grapple with issues related to changing population characteristics, including maternal obesity, advanced maternal age and an increased complexity of medical diseases (including cardiac diseases), which may affect women with a reproductive potential[20].

Regional anaesthesia is considered to be safe and better tolerated as compared to general anaesthesia for caesarean section. However, the incidence of hypotension is more commonly observed during spinal anesthesia, which may impair placental circulation as well as circulation to vital organs, hypotension occurs due to vasodilatation secondary to blockage of sympathetic outflow from the spinal cord[21,22].

The rationale of study was to find out if administration of low dose bupivacaine is better in reducing the frequency of hypotension in spinal anesthesia during cesarean section. Based on statistics it will enable us to prevent significant hypotension in patients undergoing elective caesarean section under spinal anesthesia.

MATERIAL AND METHODS

This randomized controlled trial was carried out department of Anesthesia, Combined Military Hospital Rawalpindi over a duration of six months from 15 September 2014 to 15 March 2015. The sample size has been calculated by using WHO sample size calculator. Level of significance 5%, Power of the test 80%, Anticipated population proportion1 (P1) is 41.6%. Anticipated population proportion 2 (P2) is 91.6%[19]. The sample size is 65 in each group. The total sample size of study is 130.

One hundred and thirty patients fulfilling the inclusion/exclusion criteria were included in this study and they were divided into two groups of 65 each by consecutive sampling. American society of Anesthesiology (ASA) status of all patients undergoing caesarean sections was assessed. All aged between 25-35 years and undergoing elective caesarean section were included in the study.

All patients undergoing emergency caesarean section, with multiple pregnancies, which have cardiovascular, pulmonary, renal or liver disease, have history of drug allergy or are unwilling for the study, were excluded from the study.

After seeking permission from the hospital ethical committee, the purpose and procedure of the study and risk benefit ratio was explained to the patients and an informed written consent was obtained.

Those who were willing and eligible for the study were randomly divided into two groups (A

and B), based on lottery method. Group A was given 7.5mg and group B was given 10mg of 0.75% Bupivacaine.

Both groups were preloaded with Hartmann's solution 15ml/kg body weight. Spinal anesthesia was achieved by 0.75% hyper-baric bupivacaine L3-L4 interspace level with 25 gauge Quincke spinal needle.

Blood pressure was recorded before and 03 minutes after administration of spinal anesthesia by trainee Researcher. Findings were recorded in the proforma. All the data collected through proforma was entered in the Statistical Package for Social Sciences (SPSS) Version 20 and analyzed using its statistical package. The study variables were age, height, weight, blood pressure before the administration of spinal anesthesia, blood pressure 3 minutes after the administration of spinal anesthesia and hypotension.

Hypotension was defined as a greater than 20% decrease in the patient's baseline blood pressure, or a systolic blood pressure less than 100 mm Hg recorded at 3 min.

Descriptive statistics was calculated. Mean and standard deviation was calculated for quantitative data age, height, and weight, blood pressure before the administration of spinal anesthesia and blood pressure 3 minutes after the administration of spinal anesthesia. Independent sample t-test was applied for the comparison of quantitative variable among groups. Frequencies and percentages were calculated for qualitative variables (hypotension, and no hypotension). Chi Square test was applied to determine the difference in hypotension in two groups.

Level of significance was taken as $p<0.05$. Effect modifiers like age and ASA status was controlled by stratification. Post stratification chi square test was applied keeping p-value <0.05 as significant.

Table-I: Distribution of patients by demographics.

	Group A (n=65) Mean ± SD	Group B (n=65) Mean ± SD	*p*-value
Age	30.35 ± 3.08	28.32 ± 2.53	0.00
Height	157.22 ± 5.34	158.68 ± 5.89	0.14
Weight	64.45 ± 3.99	65.00 ± 3.88	0.42

SD = Standard deviation

Table-II: Distribution of patients by blood pressure.

Group		SBP before SA	DBP before SA	SBP after SA	DBP after SA
A	Mean ± SD	124.92 ± 10.21	80.23 ± 7.41	113.46 ± 11.55	69.69 ± 7.59
B		124.23 ± 10.12	83.00 ± 7.43	107.15 ± 14.73	69.85 ± 10.93
p-value		0.69	0.04	0.01	0.93

SBP = Systolic Blood Pressure, DBP = Diastolic Blood Pressure, SA = Spinal Anesthesia, SD = Standard deviation

Table-III: Distribution of patients by hypotension.

Hypotension	Group A (n=65)	Group B (n=65)
	Frequency (%)	Frequency (%)
Yes	5 (7.7)	20 (30.8)
No	60 (92.3)	45 (69.2)
Total	65 (100.0)	65 (100.0)

p-value=0.001

RESULTS

One hundred and thirty patients were selected for this study and they were divided into two equal groups.

The mean age in group A was 30.58 ± 3.06 years while the mean age in group B was 28.34 ± 2.94 years. The mean height in group A was 158.34 ± 3.12 cm while the mean height in group B was 158.66 ± 4.83 cm. The mean weight in group A was 64.45 ± 3.99 kg while the mean weight in group B was 65.00 ± 5.38 kg (table-I).

The mean systolic blood pressure before spinal anaesthesia in group A was 124.92 ± 10.21 mmHg while the mean systolic blood pressure before spinal anaesthesia in group B was 124.23 ± 10.12 mmHg. The mean diastolic blood pressure before spinal anaesthesia in group A was 80.23 ± 7.41 mmHg while the mean diastolic blood pressure before spinal anaesthesia in group B was 83.00 ± 7.43 mmHg. The mean systolic blood pressure after spinal anaesthesia in group A was 113.46 ± 11.55 mmHg while the mean systolic blood pressure after spinal anaesthesia in group B was 107.15 ± 14.73 mmHg. The mean diastolic blood pressure after spinal anaesthesia in group A was 69.69 ± 7.59 mmHg while the mean diastolic blood pressure after spinal anaesthesia in group B was 69.85 ± 10.93 mmHg (table-II).

In group A, there were 5 (7.7%) patients of hypotension while in group B there were 20 (30.8%) patients of hypotension. In group A, there were 60 (92.3%) patients with no hypotension while in group B there were 45 (69.2%) patients with no hypotension (table-III).

DISCUSSION

Various local anesthetics commonly used for spinal anesthesia are lignocaine, bupivacaine, levobupivacaine, and ropivacaine[23].

Effect of spinal anesthesia on the cardiovascular system is primarily indirect and occurs through blockade of sympathetic nervous system and includes a reflex response to the primary cardiovascular effects[20]. Most significant easily measurable effects of spinal anesthesia are changed blood pressure and pulse. The aim of all anesthesiologists is to perform the spinal anesthesia with the least deviation in blood pressure and pulse rate. Reducing the dose of local anaesthetic can reduce the incidence of hypotension. Many studies have been undertaken in this regard.

Results obtained in our study showed changes in terms of reduction of basic hemodynamic variables during anesthesia compared with values before anesthesia in terms of lowering blood pressure. Changes in high dose group were significantly higher than in low dose group with all measured parameters deviating significantly more in high dose group than in low dose group.

In our study we hypothesized that using low dose bupivacaine was beneficial in terms of reducing the incidences of hypotension in spinal anesthesia during caesarian sections.

This topic is under research abroad and in our country especially in low resource settings where hypotension can lead to hazardous complications. Many of these studies agree with our findings in terms of reduced dose and hypotensive episodes.

A study was done in Japanese parturients to compare 2 doses of bupivacaine in caesarian section. The analgesic efficacy and incidence of hypotension were noted. Patients were divided into 2 groups, with total number of thirty-six patients in both groups. One group received 8mg of hyperbaric bupivacaine while the other received 10mg. results showed incidence of hypotension was lower in 8mg group (37%) than in 10mg group (71%). And no differences were seen in neonatal outcome[24].

Another study done on forty patients showed the incidence of hypotension was less when using low dose bupivacaine in spinal anesthesia. Patients were divided into two groups of twenty each. One group was administered 10mg of hyperbaric bupivacaine while the other group received 7.5mg. Second group was also administered 25 micrograms of fentanyl. Results showed that episodes of hypotension were significantly less (80% vs. 40%) in low dose group. Therefore, it was concluded that lowering the dose of bupivacaine in caesarian section would significantly reduce the incidence of hypotension[25].

A meta-analysis shows that low dose bupivacaine is beneficial in preventing hypotension in patients undergoing caesarian section. Systemic review of randomized control trials was done, 35 were identified for eligibility assessment and 15 were selected for data extraction. Results

revealed that although there was no difference in neonatal outcome or clinical quality variables but incidence of hypotension was less in low dose group[10].

Another study done on fifty patients showed that using low dose bupivacaine was better than conventional dose. Patients were divided into two groups of 25 each. One group received conventional dose of 10mg of hyperbaric bupivacaine whereas the second group received low dose bupivacaine of 7.5mg along with twenty-five micrograms of fentanyl. The result showed that there was a significant decrease in incidence of hypotensive episodes in patients receiving low dose bupivacaine and is thus recommended for use in patients of caesarian section[26].

A few limitations to our study that could affect the results included a low sample size, age restrictions, inclusions of only healthy parturients, singleton deliveries. If these limitations are addressed to we would be able to more efficiently see the effects of low dose bupivacaine in the patients. For future research it is suggested that the sample size be increased with the sampling age of patients and inclusion of parturients with minimal comorbities.

CONCLUSION

In conclusion we can say that dose of bupivacaine is an important determinant of maternal hemodynamic variables. In our study it showed that using low dose bupivacaine showed less incidence of hypotension than high dose bupivacaine. In our study in group A, no hypotension occurred in 10% patients while in group B no hypotension occurred in 46%.

CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any author.

REFERENCES

1. Solakovic N. Comparison of hemodynamic effects of hyperbaric and isobaric bupivacaine in spinal anesthesia. Med Arh 2010; 64: 11-4.
2. Naz F, Khan S. Complications of spinal anaesthesia in caesarean section. Pak J Med Health Sci 2010; 4: 277-80.
3. Khan F, Sabbar S, Ahmad J, Sattar A. Comparison of haemodynamic changes in unilateral and conventional spinal anaesthesia. Pak J Surg 2010; 26: 130-3.
4. Abdallah FW, Halpern SH, Margarido CB. Transversus abdominis plane block for postoperative analgesia after Caesarean delivery performed under spinal anaesthesia? A systematic review and meta-analysis. Br J Anaesth 2012; 109(5): 679-87.
5. Shrestha SK, Bhattarai B, Shah R. Comparative Study of Hyperbaric Bupivacaine Plus Ketamine Vs Bupivacaine Plus Fentanyl for Spinal Anaesthesia During Caesarean Section. Kathmandu Univ Med J 2013; 44(4): 287-91.
6. Saygı Aİ, Özdamar Ö, Gün İ, Emirkadı H, Müngen E, Akpak YK. Comparison of maternal and fetal outcomes among patients undergoing cesarean section under general and spinal anesthesia: A randomized clinical trial. Sao Paulo Med J 2015; 133(3): 227-34.
7. Husain RS, Abbas Z. Spinal anaesthesia for Caesarean Section: A comparative study of isobaric and hyperbaric solutions of 0.5% Bupivacaine. J Surg Pakistan 2003; 08: 26-9.
8. Bhardwaj N, Jain K, Arora S, Bharti N. A comparison of three vasopressors for tight control of maternal blood pressure during cesarean section under spinal anesthesia: Effect on maternal and fetal outcome. J Anaesthesiol Clin Pharmacol 2013; 29: 26-31.
9. Mebazaa MS, Ouerghi S, Ben Meftah R, Ben Cheikh M, Mestiri T, Ben Ammar MS. Reduction of bupivacaine dose in spinal anaesthesia for caesarean section may improve maternal satisfaction by reducing incidence of low blood pressure episodes. Middle East J Anesthesiol 2010; 20: 673-8.
10. Arzola C, Wieczorek PM. Efficacy of low-dose bupivacaine in spinal anaesthesia for caesarean delivery: systematic review and meta-analysis. Br J Anaesth 2011; 107: 308-18.
11. Gulec H, Degerli S, Ozayar E, Bercin F, Sahin S. The effects of 7 mg levobupivacaine on maternal hemodynamics with side effects in combined spinal-epidural anaesthesia for cesarean section. Anaesth Pain Intens Care 2012; 16: 127-30.
12. Akhtar MN, Tariq S, Abbas N, Murtaza G, Naqvi SMN. Comparison of haemodynamic changes in patients undergoing unilateral and bilateral spinal anaesthesia. J Coll Physicians Surg Pak 2012; 22: 747-50.
13. Doherty A, Ohashi Y, Downey K, Carvalho JC. Phenylephrine infusion versus bolus regimens during cesarean delivery under spinal anesthesia: A double-blind randomized clinical trial to assess hemodynamic changes. Anesth Analg 2012; 115: 1343-50.
14. Jabalameli M, Soltani HA, Hashemi J, Behdad S, Soleimani B. A randomized comparative trial of combinational methods for preventing post-spinal hypotension at elective cesarean delivery. J Res Med Sci 2011; 16: 1129-38.
15. McDonald S, Fernando R, Ashpole K, Columb M. Maternal cardiac output changes after crystalloid or colloid coload following spinal anesthesia for elective cesarean delivery: A randomized controlled trial. Anesth Analg 2011; 113: 803-10.
16. Magalhães E, Govêia CS, de Araújo Ladeira LC, Nascimento BG, Kluthcouski SM. Ephedrine versus phenylephrine: Prevention of hypotension during spinal block for cesarean section and effects on the fetus. Rev Bras Anestesiol 2009; 59: 11-20.
17. Leo S, Sng BL, Lim Y, Sia AT. A randomized comparison of low doses of hyperbaric bupivacaine in combined spinal-epidural anesthesia for cesarean delivery. Anesth Analg 2009; 109: 1600-5.
18. Roofthooft E, Van de Velde M. Low-dose spinal anaesthesia for Caesarean section to prevent spinal-induced hypotension. Curr Opin Anaesthesiol 2008; 21: 259-62.
19. Jain K, Makkar JK, Anbarasan I, Yadanappudi S, Gander S. A randomized double-blind comparison of low-dose and high-dose bupivacaine for caesarean section in severely preeclamptic

women using invasive blood pressure monitoring. J Obstet Anaesth Crit Care 2013; 3: 84-90.
20. Jadon A. Complications of regional and general anaesthesia in obstetric practice. Indian J Anaesth 2010; 54(5): 415-20.
21. Butterworth IV JF, Mackey DC. Morgan and Mikhail's Clinical Anesthesiology. 5th ed. USA: McGraw-Hill; 2013. 945p.
22. Herrera R, De Andrés J, Estañ L, Olivas FJ, Martínez-Mir I, Steinfeldt T. Hemodynamic impact of isobaric levobupivacaine versus hyperbaric bupivacaine for subarachnoid anesthesia in patients aged 65 and older undergoing hip surgery. BMC Anesthesiol 2014; 14: 97.
23. Miller RD, Cohen NH, Eriksson LI, Fleisher LA, Wiener-kronish JP, Young WL. Miller's Anesthesia. 8th ed. Pennsylvania: Churchil Livingstone; 2015.
24. Nagata E, Yoshimine K, Minoda Y, Kawaguchi Y, Sakamoto M, Takehara A. Comparison of 8 mg and 10 mg hyperbaric bupivacaine during spinal anesthesia for cesarean section in Japanese parturients. Masui 2004; 53(2): 131-6.
25. Farouk G, El-Sokkary M. Comparative Study Between Low Dose Bupivacaine With Fentanyl & Bupivacaine Alone For Cesarean Section. JNSCI 2011; 9(6): 14-17.002.
26. Venkata HG, Pasupuleti S, Pabba UG, Porika S, Talari G. A randomized controlled prospective study comparing a low dose bupivacaine and fentanyl mixture to a conventional dose of hyperbaric bupivacaine for cesarean section. Saudi J Anaesth 2015; 9: 122-7.