

EFFECTS OF INTRATHECAL HYPERBARIC VERSUS ISOBARIC BUPIVACAINE IN ELECTIVE CAESAREAN SECTION

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ABSTRACT:

OBJECTIVE: The aim of this study was to choose a better drug as far as effects are regarded such as rapid onset, a block that is adequate (in both extent and degree) for proposed surgery but without producing undesirable effects such as hypotension and a high block.

STUDY DESIGN: A randomized control study was carried out for comparison.

SETTING & DURATION: This study was conducted at department of anaesthesia and intensive care, Punjab medical college and affiliated hospitals, Faisalabad from September 2009 to June 2010.

SAMPLE SIZE: The group under study consisted of 146 females aged 19 to 36 years, ASA status I & II undergoing elective cesarean section under spinal anaesthesia.

METHODS: The patients were randomly allocated to receive spinal anaesthesia either by using isobaric or hyperbaric bupivacaine. Patients were monitored throughout the procedure.

RESULTS: Compared with hyperbaric group haemodynamic instability was significant in isobaric group. In our study frequency of hypotension was 24.7% in isobaric group (group A) as compared to 9.6% in hyperbaric group (group B). Extra fluids and vasopressors were required more frequently in isobaric group.

While assessing the quality of block, the onset of block was more rapid in hyperbaric group, however both drugs offered adequate anaesthesia for proposed surgery.

CONCLUSION: It is suggested that hyperbaric bupivacaine is associated with adequate Intrathecal block with greater haemodynamic stability in patients undergoing elective caesarean section.

KEY WORDS: Bupivacaine, Intrathecal, Spinal Anaesthesia, Caesarean Section.

INTRODUCTION:

Intrathecal anaesthesia is very popular for caesarean section because it offers a profound & symmetrical sensory & motor block of high quality. It has many advantages including simplicity of technique, rapid onset, dense blockade & cost effectiveness. There is a low risk of the drug toxicity as the volume of local anaesthetic required to perform the block is very small. Intrathecal anaesthesia is presumed to reduce dorsal horn nervous excitability and postoperative pain. Intrathecal anaesthesia is being practiced since 1898. Since then several drugs have

been used. But Bupivacaine is one of the most widely used drugs. Unfortunately, in 1947 after grave spinal cord paralysis in Wolley & Roe, the two patients having spinal block on the same day, spinal block remained unpopular for several years¹. However in 1954, a reassuring study of 10,098 spinal anaesthetics conducted with

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only 71 minor neuropathies, spinal anaesthesia reemerged as a safe anaesthesia method.

Today intrathecal anaesthesia is used for almost any procedure below umbilicus².

Historically intrathecal anaesthesia has been in intermittent use in obstetrics since 1900³. Intrathecal anaesthesia has been shown to block stress response to surgery, decrease intraoperative blood loss, lower incidence of postoperative thromboembolism and decrease mortality & morbidity in high risk patients however intrathecal block is associated with certain intraoperative and postoperative complications which limits its use.

The most important problems include haemodynamic changes such as hypotension⁴ & bradycardia⁵, failure of block or inadequate block. Several other problems are either directly or indirectly related to haemodynamic instability such as nausea, vomiting, feeling of feeling sick & dyspnea. Among postoperative complications the most distressing are backache & post-dural puncture headache (PDPH)⁶.

A successful intrathecal block should be adequate in both extent and duration for proposed surgery without producing undesirable effects such as hypotension and a high block⁷.

Both the haemodynamic changes and adequacy of block are directly related to height of block which is determined by cephalad spread of local anaesthetic within subarachnoid space.

Posture and baricity are the two most important determinants of the spread of local anaesthetic within subarachnoid space^{8,9}.

Baricity of local anaesthetic can be more, equal or less than that of Cerebrospinal fluid (CSF) i.e. they may be isobaric, hyperbaric or hypobaric.

In our setup more than 90% of caesarean sections are performed in intrathecal block. Bupivacaine is most widely used local anaesthetic in Pakistan. No study had ever been carried out in our setup regarding comparison of hyperbaric and isobaric bupivacaine, so this study was worth performing in our setup.

MATERIAL AND METHODS:

SETTING: Study was conducted at Department of Anaesthesia, Punjab Medical College and affiliated hospitals.

DURATION OF STUDY:

The study was conducted from September 2009 to June 2010.

SAMPLE SIZE:

By using WHO calculator for sample size estimation, sample size was calculated as 73 (seventy three) patients in each group. After fulfilling the inclusion criteria 146 patients were taken, in which 73 were placed in group A and 73 in group B. In group A spinal anaesthesia was administered by using Isobaric Bupivacaine and in group B spinal anaesthesia was administered by Hyperbaric Bupivacaine.

SAMPLING TECHNIQUE:

Consecutive (Non Probability) sampling technique was used.

SAMPLE SELECTION:

INCLUSION CRITERIA:

- Patients between 18 to 40 years
- Singleton pregnancy
- American society of anesthetist (ASA) grade I and II patients

EXCLUSION CRITERIA:

- Raised intracranial pressure
- Coagulopathy
- Skin or soft tissue infection in lumbar region
- Pre-existing neurological disease, like eclampsia, paraplegia, multiple sclerosis etc.
- Previous history of surgery in lumbar region
- H/O allergy to bupivacaine

STUDY DESIGN

Randomized control trial

DATA COLLECTION PROCEDURE

After ethical approval and written, informed consent, 146 patients prepared in labour room for elective caesarean section were selected according to inclusion criteria. Exclusion

criteria were strictly followed to control confounding variables.

Using lottery method, patients were randomly allocated to receive isobaric or hyperbaric bupivacaine solutions. This created 2 distinct groups A & B respectively.

Detailed data of the patients was collected including age, height, weight, ASA status baseline blood pressure and heart rate

Senior anaesthesiologist was responsible for patient randomization and a resident doctor performed the spinal block and collected preoperative and intraoperative data. Both the resident doctor and the patients were unaware of group allocation.

Patients were preloaded with 1000 ml of lactated ringer solution prior to spinal anaesthesia. After all aseptic measures and skin infiltration with 2% xylocaine solution. LP was performed in midline at 90 degree to skin between L2-L3 or L3-L4 space in sitting position. 2.5 ml of 0.5% isobaric bupivacaine was injected intrathecally to group A while 2.5 ml of 0.5% hyperbaric bupivacaine was given to group B. Patient were given supine position with 10 degree head tilt and left lateral tilt. All patients and resident doctor were blinded to the drug used. Motor Block was assessed by using a modified bromage scale.

Complete loss to cold sensation to T6 on both sides was regarded as sufficient for surgery. Detailed data of patients was collected including time of onset of block, highest sensory analgesia level, degree of motor block, cardio-respiratory status and duration of surgery (skin incision to closure), B.P., heart rate, respiratory rate, oxygen saturation was recorded every 3 minutes for 30 minutes, and then every 5 minutes till the end of surgery. Special note was made of any hypotension, use of ephedrine and extra

fluids. Hypotension was defined as the systolic blood pressure less than 90 mmHg or a 20% decrease from baseline values, bradycardia as heart rate less than 60/min and desaturation as SpO₂ less than 93%. Hypotension was treated with IV boluses of ephedrine and bradycardia with 0.5mg of IV atropine. Patients were discharged from recovery room after meeting the following criteria:

- Oriented
- Stable vital signs
- No surgical complications
- Adequate pain control
- Resolution of motor and sensory block at or below S3

DATA ANALYSIS PLAN

Data was analyzed using SPSS (version 10)

- Mean and standard deviation was calculated for quantitative variables i.e. Time of onset of block, age, weight and height.
- Frequency and percentages were presented for qualitative variables, i.e. hypotension, sensory block, motor block, use of ephedrine, oxygen saturation and respiratory rate.
- Independent sample t-test was used to compare time of onset of block in both groups.
- Chi square test was applied to compare hypotension, sensory block, motor block, use of ephedrine oxygen saturation and respiratory rate.
- P value <0.05 was considered significant.

RESULTS:

Both the groups were comparable with regard to weight, height, age and duration of surgery. [Table 1]

Table 1: Demographic Data

Group	N	Weight (Kgs)	Height (Inches)	Age (Years)	Duration of Surgery (min)	ASA Physical Status [I/II]
Group A	73	70.70±3.99	62.41±2.07	26.78±3.42	39.32±7.37	54/19
Group B	73	69.66±3.97	62.27±1.70	26.51±3.66	38.08±5.50	43/30

Despite randomization ASA status differed significantly between the two groups (p=0.025). Comparing with hyperbaric group the frequency of hypotension was significantly higher (p=0.008) in isobaric group. Heart rate dropped in both groups but significant bradycardia was not seen in any group. No change was seen in respiratory rate and SpO₂ in both groups. [Table 2]

Table 2: Physiological Changes

Variable	Group A (n=73)		Group B (n=73)		P
	No of Pts.	%age	No of Pts.	%age	
Bradycardia	6	8.2%	4	5.4%	0.256
Hypotension	18	24.6%	7	9.5%	0.008
Changes in Respiratory Rate	0	0%	0	0%	
Changes in Oxygen Saturation	0	0%	0	0%	

Extra fluids were used in 30% of patients in Group A and in 18% of patients in Group B ($p = 0.0405$). Ephedrine requirement was 8.2% in Group A as compare to 5.5 % in Group B ($p = 0.256$). [Table 3]

Table 3: Management of Hypotension

Variable	Group A (n=73)		Group B (n=73)		P
	No of Pts.	%age	No of Pts.	%age	
Extra IV Fluids	22	30%	13	18%	0.0405
Ephedrine	6	8.2%	4	4%	0.256

Mean time of onset of block was short in group B being 3.51 minutes as compared to 5.77 minutes in group A which is statistically significant ($p = 0.0005$). [Table 4]

Table 4: Block Characteristics

Variable	Group A (n=73)	Group B (n=73)	P
Time of Onset of Block (Min)	5.77±0.77	3.51±0.67	0.0005
Height of Sensory Block Reaching T6 Dermatome [Y/N]	73/0	73/0	*N/A
Motor Block (Bromage Scale) [1/2/3/4]	0/0/15/58	0/0/10/63	0.136

* No statistics are computed because Height of Sensory Block (Y/N) is a constant.

However final levels achieved were same in both groups. All patients had adequate sensory and motor block.

DISCUSSION:

This study was performed to assess the effects i.e. haemodynamic changes & quality of block while comparing solutions of differing baricities for intrathecal block in elective caesarean section. The technique was standardized with respect to volume of drug, needle size, patient position and lumbar interspace. Patients were standardized regarding age, weight, type of surgery & ASA status.

Hypotension is the most common cardiovascular response to spinal block. More than 30% of the patients undergoing spinal block develop intraoperative hypotension¹⁰. In my study systolic, diastolic and mean arterial blood pressure dropped in both groups

but the drop was significantly higher in isobaric group (Group A) as compared to hyperbaric group (Group B). Frequency of hypotension was 24.7% in group A while it was 9.6% in group B which is statistically significant ($p = 0.008$). Extra fluids were used in 30% of patients in Group A and in 18% of patients in Group B ($p = 0.0405$). Ephedrine requirement was 8.2% in Group A as compare to 5.5 % in Group B ($p = 0.256$).

A study carried out by Hallworth SP et al supports my study. The study shows increasing incidence of hypotension & concomitant ephedrine use with decreasing baricity of bupivacaine¹¹. The results are further supported by the study carried out by Aftab S et al in which systolic blood pressure

dropped significantly in isobaric group as compared to hyperbaric group ¹².

Another study conducted by Nasir KK et al concludes that haemodynamic stability is greater with hyperbaric bupivacaine than isobaric bupivacaine in obstetric patients ¹³. While D'Souza et al concluded that hyperbaric bupivacaine produces adequate sensory and motor block at the cost of haemodynamic stability as compared to isobaric bupivacaine ¹⁴.

A randomized double blind study conducted by Sia AT et al is in contradiction to my study. The study shows higher haemodynamic changes & subjective feeling of feeling sick in hyperbaric group as compared to isobaric group ¹⁵.

Study conducted by Herrera R et al is in contradiction to my results and indicates higher incidence of feeling of felling sick, nausea, vomiting & hypotension with hyperbaric bupivacaine ¹⁶.

In our study while assessing the quality of block, the onset was more rapid in hyperbaric group, mean time of onset being 3.51 minutes as compared to 5.77 minutes in isobaric group which is statistically significant ($p = 0.0005$). However final level achieved with both drugs was adequate for surgery. Motor block was complete in both groups.

Study carried out by Narejo S.A. et al shows no significant differences between two groups regarding the quality of block but the onset was rapid with hyperbaric bupivacaine ¹⁷.

Raushan R et al observed a delayed sensory and motor block as well as quicker recovery with isobaric bupivacaine as compared to hyperbaric drug. ¹⁸.

Punshi GD and Afshan G concluded that both plain and hyperbaric bupivacaine produce adequate block for caesarean section without any difference in time of onset and haemodynamics. However sensory level regression was delayed in isobaric group ¹⁹.

Study by Xu et al ²⁰ and Sarvela PJ ²¹ shows no difference in onset of block between two groups and the block was adequate for proposed surgery.

In contrast to non-pregnant patients when a parturient is turned from lateral to supine position height of block is influenced by displacement of CSF and local anaesthetic.

Isobaric solutions mix well with CSF free from anatomy of spine. However because of gravity, hyperbaric solutions will pool down to the lowest point of thoracic hollow around T4-5. So cephalad spread is less important with hyperbaric than isobaric solutions. Thus the lower risk of hypotension in the hyperbaric group might be explained by a more reliable block without excessive rostral spread of local anaesthetic.

Regarding recovery, the block regression was quicker in hyperbaric group as compared to isobaric group.

CONCLUSION:

We conclude that the use of isobaric bupivacaine in subarachnoid block for elective caesarean section is associated with an increased incidence of hypotension. Extra fluids and vasopressors are required more frequently with isobaric bupivacaine.

A profound sensory and motor block is achieved more rapidly with hyperbaric bupivacaine however both drugs offer adequate block for caesarean section.

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