

cost effectiveness^{3,4}. Nonetheless regional anaesthesia is not without hazard. Morbidity and mortality are mainly associated to unwarranted high regional block and harmfulness of local anaesthetic solution. Lessening in dose, concentration and perfection in technique to evade higher block levels and intensified alertness to the toxicity of local anesthetics, subsidized to the decline of complications associated with regional anaesthesia⁵.

Bupivacaine, an amide form of local anaesthetic, a highly potent, and sluggish in onset but has extended duration of action. For spinal anaesthesia it is frequently used drug in Pakistan. It is existing in two diverse formulae hyperbaric 0.75% and isobaric 0.5% bupivacaine. The major determinants of spread of intrathecally administered solutions are their dose, volume, concentration and baricity⁶.

Baricity variances amongst spinal anaesthetic solutions are alleged to produce alterations in the distribution of the anaesthetics inside subarchnoid space and expected to affect the onset, degree and length of sensory block, as well as side effects and post-operative analgesia⁷. Caesarean section requires a T4 sensory level block for optimum condition for surgery.

Hyperbaric 0.75% bupivacaine has long duration of sensory blockade with delayed recovery of motor function, prolongs post anaesthesia care unit stay after delivery⁸. Intrathecal anaesthesia with isobaric solution is considered by abundant discrepancy in the cephalad distribution of the block, even total spinal anaesthesia and associated hypotension⁹. Pregnancy enhances the cardiovascular toxicity of bupivacaine¹. Haemodynamic complications are associated with spinal anaesthesia and in obstetric patients; hypotension is perhaps the most frequent complication⁹. Increased venous capacitance, pooling of a larger share of blood volume in lower extremities and splanchnic bed and reduced systemic vascular resistance are the reasons behind it^{1,10}.

A reduction in systolic blood pressure of at least 25% or any systolic blood pressure less than 100 mmHg is a definition of hypotension in

obstetric population^{1,10}. It presents with disturbing symptoms of vertigo, nausea and vomiting but also prejudices placental perfusion and complicates fetal outcome¹¹. Pregnant women require less dose of bupivacaine to achieve a given level of anaesthesia than do non pregnant women¹².

So it was decided to carry out this study to compare the clinical characteristics of the intrathecal anaesthesia intraoperatively in Caesarean section in terms of onset of sensory block and haemodynamic changes after intrathecal injection of isobaric 0.5% versus hyperbaric bupivacaine 0.75% in same dose (12mg) to reduce the haemodynamic instability in the patients underwent caesarean section so that the better of two techniques may be followed.

MATERIAL AND METHODS:

It was randomized controlled trial conducted in the Department of Anaesthesiology, Surgical Intensive Care Unit and Pain Management and Department of Obstetrics and Gynaecology, Peoples University of Medical and Health Sciences for Women Nawabshah, from March 2015 to September 2015. A total of 140 pregnant women were included in this study, who were divided into two groups (IB & HB) each group contained 70 patients. The sampling technique was non probability purposive.

Sample Selection:

Inclusion criteria:

- * Age between 18 to 35 years.
- * ASA physical status I and II.
- * Weight range (50 kg to 70 kg).
- * Pregnant woman having singleton pregnancy.
- * Pregnant women of 37 to 42 weeks of gestation (assessed by ultrasound).
- * Pregnant woman undergoing caesarean section.

Exclusion criteria:

- * Refusal of patient for spinal anaesthesia.
- * Uncooperative patients.
- * Patients with hemodynamic instability.
- * Coagulopathy.
- * Infection at the site of lumbar puncture.
- * Anatomical abnormality of vertebral column.
- * Severe hypovolemia.
- * Ante partum haemorrhage.

* Allergy to bupivacaine.

* Failed or partial intrathecal anaesthesia assessed by sensory or motor blockade.

Data Collection Procedure: Pregnant mothers from obstetric department of this hospital were included in this study meeting the inclusion standards after taking informed and written consent. They were divided into two groups and randomly allocated by envelope method.

Group IB: Included parturient mothers underwent spinal anaesthesia for caesarean section was received 12mg (2.4 ml) of isobaric 0.5% bupivacaine hydrochloride intrathecally.

Group HB: Included parturient mothers underwent spinal anaesthesia for caesarean section was received 12mg (1.6ml) of hyperbaric 0.75% bupivacaine hydrochloride intrathecally.

All patients received aspiration prophylaxis and after application of monitors, baseline blood pressure and heart rate was recorded preoperatively. After maintaining two intravenous lines with 18 G I/V cannulae, lactated Ringer's solution over 10 minutes at a rate of 15ml/kg was given for preloading and then patient positioned in sitting posture. Patient was anaesthetized by using a 25 gauge Quincke Babcock needle introduced at L 3-4 or L4-5 intervertebral space in sitting position via midline approach. Patients were positioned immediately supine with 15 degree left lateral tilt after the injection of bupivacaine, supplemental oxygen started and continued throughout surgery and verbal contact maintained at all time during surgery. Patient's data was collected including the age, weight, height, ASA Status, duration of surgery (skin incision to closure) and indication of surgery. Time of onset of sensory block up to T6 dermatomal level after injection of bupivacaine intrathecally was assessed after 02 minutes by blunt pin prick. Systolic blood pressure (normal range 90-120 mmHg) and heart rate (normal range 60-100 beats per minute) was recorded every minute for first five minutes then every five minutes up to the end of surgery in both groups in the proforma by on duty anaesthetist. The final outcome was measured as mean systolic blood pressure & mean heart rate at the end of the procedure.

Data Analysis Procedure: Statistical packages for social science (SPSS version 10.0), was used for data analysis. Numerical variables like age, weight, height, onset of sensory block, mean systolic blood pressure, mean heart rate and duration of surgery of both groups was computed by Mean \pm SD. The data was analyzed by using student t-test for both groups. A p- value $<$ 0.05 with 95% confidence interval was considered significant.

RESULTS:

In this study 140 pregnant women underwent caesarean section were included. Seventy patients were given 12 mg (2.4ml) of isobaric 0.5% bupivacaine hydrochloride intrathecally while the remaining 70 patients were treated with 12 mg (1.4ml) of hyperbaric 0.75% bupivacaine hydrochloride intrathecally.

Maximum no. of the patients was 21 to 30 years of age in both groups. 26.71 ± 4.63 years (95%CI: 25.93 to 27.48) was the mean age of the women while the mean duration of surgery and time of onset of sensory block are 53.57 ± 7.59 min (95%CI: 52.30 to 54.84) and 4.505 ± 0.86 min (95%CI: 4.360 to 4.65), similarly average weight, height, base line systolic and heart rate are also presented in table 01. Average age, height, duration of surgery, baseline systolic blood pressure and heart rate were not significant between groups while average weight was significantly high in group IB than group HB as shown in table 02.

Out of 140 pregnant women, elective caesarean section was performed in 90(64.3%) while emergency caesarean section in 50(35.7%) women. Regarding ASA status, ratio of ASA I and ASA II are approximated equal in both groups. In group IB ASA-I status found in 42(60%) while 40(57.1%) in HB group total 82(58.6%). ASA-II 28(40%) in IB group and 30(42.9%) in HB group total 58(41.4%).

Most common indication of caesarean section was previous caesarean section that was observed in 50(35.7%). In group IB was 42.9% and in group HB was 28.6%. Followed by breech 12(16.4%), fetal distress 16(11.4%) similarly

indications of caesarean section likes BOH, CPD, fail trial of labor, non-progress of labor, leaking, precious pregnancy, primi breech, term pregnancy and transverse lie.

In group IB 4.60 ± 0.86 minutes was the mean time of onset of sensory block as compared to 4.407 ± 0.85 minutes in group HB significant difference was not observed between groups ($p=0.183$) as presented in figure 01. The mean systolic blood pressure recorded in group IB was 117.07 ± 16.97 mmHg and 116.19 ± 4.89 mmHg in group HB. Significant difference was not observed between groups in mean systolic blood pressure (0.87 ± 0.211 (95%CI of difference: -3.29 to 5.05) as presented in figure 02. Similarly difference in mean heart rate was also not significant between groups (0.316 ± 1.45 (95%CI of difference: -2.55 to 3.18) as shown in figure 03. Hypotension was observed in 04(5.71%) patients in isobaric group while 03(4.28%) patients in hyperbaric group.

DISUCCION:

General anaesthesia can be anaesthetic technique for caesarean section in emergency situations or when regional anaesthesia is contraindicated. Because of the less chance of complications compared to general anaesthesia, spinal anaesthesia is a preferred choice for caesarean section¹³. Spinal anaesthesia for caesarean section has gained widespread and overwhelming popularity in developing countries as a result of associated decrease risk of maternal mortality^{14,15}.

For spinal anaesthesia; in our country Bupivacaine hydrochloride is the most frequently used drug. Two dissimilar concentrations i.e. 0.5% isobaric and 0.75% hyperbaric are existing. The density of CSF at 37° C is 1.0003 g/ml while density of 0.5% isobaric bupivacaine is 0.9993 g/ml and 0.75% hyperbaric bupivacaine is 1.0241 g/ml.

Age, height, anatomy of the vertebral column, injection site, volume of drug, concentration, baracity of the drug, position of the patient, barbotage, speed of injection and addition of vasoconstrictor are the factors that have been demonstrated to effect the distribution of local anaesthetic solutions in CSF^{16,17}.

In this study all patients were full term, young, mostly age between 21-30 years. ASA I and II, weighing between 50-70 kg and height between 126-156cm. Age, height, gestational age, ASA status and duration of surgery, was not observed significant statistically between means amongst the groups.

The mean difference for weight was observed statistically significant among groups ($P<0.01$). For surgery the time for attaining satisfactory sensory level escalates linearly with height and declines with increasing weight. Weight and height are substantial variables in predicting the final level of the block recognized by clinical observations¹⁸.

In determining the extent of local anaesthetic solution in CSF, total dose of bupivacaine is more essential than volume or concentration of anaesthetic solution¹⁷. To observe the impact of only baricity of bupivacaine on mean onset of sensory block and mean haemodynamic changes, all other factors that are known to affect the outcome like spinal needle, intervertebral space, speed of injection and patient position, were tried to keep constant in the present study. We used the two dissimilar baricities of bupivacaine at similar dose but as dose, volume and concentration of a drug has a close association so the dose was kept constant 12mg in both the groups.

In our study, both 0.75% hyperbaric bupivacaine and 0.5% isobaric bupivacaine produce adequate spinal anaesthesia for caesarean section, though some trials have claimed that the spreading of both solutions within the cerebrospinal fluid appears to be inadequate. Hence the reason for using generous doses (12.5-15mg) to guarantee desirable surgical anaesthesia¹⁹. There is considerable risk of inadequate block, necessitating supplementary analgesia when doses less than 10mg is used during Caesarean section^{20,21}.

The time to sensory/highest sensory analgesia level, insufficient block, period of analgesia and complications are believed to be the effects of local anaesthetic existing in the subarachnoid space²².

Table-01: Descriptive Statistics of Study Characteristics of the Patients (n=140)

Variables	Mean±SD	95%CI	Median (IQR)	Max-Min
Age (Years)	26.71±4.63	25.93 to 27.48	25.50 (6)	40-18
Weight (kg)	61.08±7.21	59.87 to 62.28	62(8)	70-50
Height (cm)	140.19±6.79	139.06 to 141.33	140(10)	156-126
Duration of surgery (minutes)	53.57±7.59	52.30 to 54.84	52.5(10)	70-40
Time of onset of sensory block (min)	4.505±0.86	4.360 to 4.65	4.4 (1.1)	6.3-3
Baseline SBP (mmHg)	123.46±9.35	121.90 to 125.02	124 (15)	139-101
Baseline Heart Rate (mmHg)	95.31±15.16	92.77 to 97.84	95.5(27)	125-65

Table-02: Descriptive Statics with Respect to Groups

Variables	Group IB n=70	Group HB n=70	Total n=140 p value
Age (Years)	27.39±5.11	26.03±4.01	0.08
Weight (kg)	62.30±5.08	59.86±8.72	0.04
Height (cm)	140.61±6.52	139.77±7.07	0.46
Duration of surgery (minutes)	51.37±0.48	53.29±8.20	0.65
Baseline SBP (mmHg)	122.84±9.13	124.07±9.58	0.43
Baseline Heart Rate (mmHg)	94.71±16.08	95.9±14.27	0.64

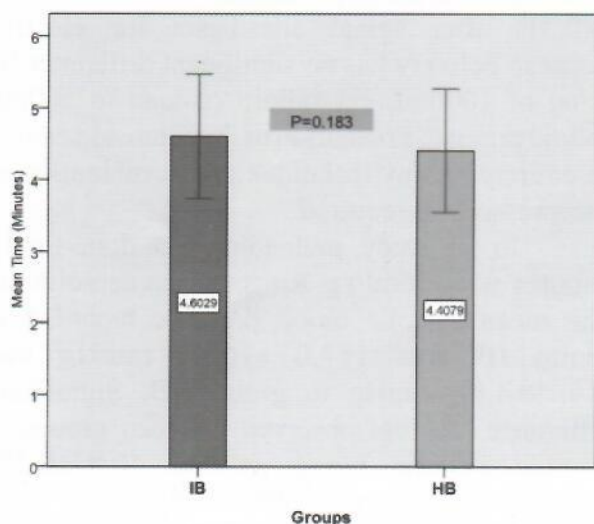


Fig-1: Comparison of Time of Onset of Sensory Block between Groups

Mean difference= 0.19±0.146 (95%CI of difference: -0.093 to 0.48)

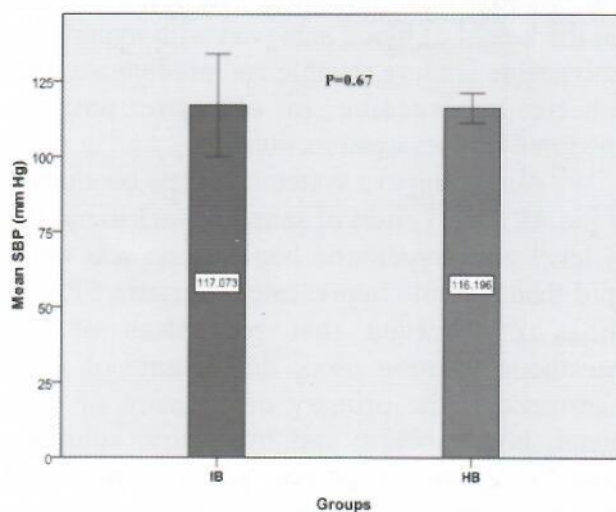


Fig-2: Comparison of Systolic Blood Pressure between Groups

Mean difference= 0.87±0.211 (95%CI of difference: -3.29 to 5.05)

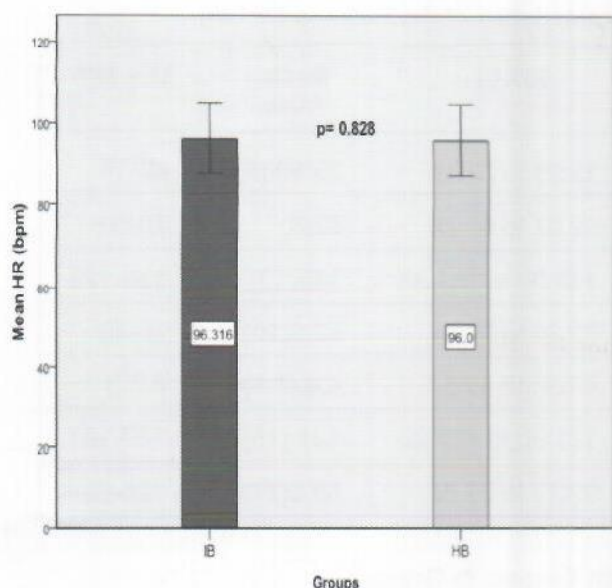


Fig-3: Comparison of Heart Rate between Groups

Mean difference = 0.316 ± 1.45
(95%CI of difference: -2.55 to 3.18)

Time of onset of T6 sensory block in group IB was 4.60 ± 0.86 minutes as compared to 4.407 ± 0.85 minutes in group HB, in our study. In a study by Aftab S and colleagues observed that, time to T4 analgesia in 0.5% isobaric group was 6 ± 0.64 and 6.93 ± 0.78 minutes in 0.75% hyperbaric group⁴.

Martin et al²³ concluded that the onset of spinal block was more quick with isobaric than with hyperbaric bupivacaine. Nasir KK²⁴ found that the height of block achieved with hyperbaric bupivacaine is more reliable and predictable than isobaric bupivacaine in obstetric patients scheduled for caesarean section.

According to a systemic review conducted by Sia AT et al;²⁵ onset of sensory blockade at the T4 level with hyperbaric bupivacaine was more rapid than isobaric bupivacaine. Hussain SR and Abbas Z²⁶ observed that regardless of the anaesthetic solution used, the volume of local anaesthetic is the primary determinant of drug spread, both isobaric and hyperbaric solutions given in 2.5ml, in lateral position produced adequate analgesic level, but the onset of sensory block was quicker and statistically significant with isobaric solution.

Russel and Holmquist²⁷ did not found any difference in the rate of onset of sensory block

when they compared the isobaric with hyperbaric 0.5% solutions given for caesarean section. A study by Runza M et al²⁸ found no difference in time to onset and maximal height of blockade, when two different concentrations; 0.75% and 1% hyperbaric bupivacaine was used.

The most common complication of spinal anaesthesia for caesarean section is hypotension. The value of volume preloading have questioned by Vercauteran et al²⁹. The use of colloids rather than crystalloids has been focused as they reduce volume requirement and maintain oncotic pressure of plasma, as incidence of hypotension during spinal anaesthesia may be reduce to 10% by using 6% hydroxyethyl starch (HES).

Rusell and Holmquist²⁷ noticed hypotension in more than 50% of the patients despite of the baricity used, crystalloid preloading and ephedrine 20mg given prophylactically by intramuscular route.

Edward Riley and colleagues³⁰ compared six percent hetastarch with lactated Ringer's solution for prevention of hypotension after spinal anaesthesia for caesarean section and found 6% hetastarch plus Ringer's lactate solution more effective than the Ringer's lactate solution alone.

Tawfik MM³¹ noted in a study that the incidence of hypotension (52.4% vs. 42.2%; P=0.18) or severe hypotension (15.5% vs. 9.8%; P=0.31) after spinal anesthesia for elective cesarean delivery has no significant difference by using of 1000mL crystalloid co-load to 500mL colloid preload. Prevention of hypotension cannot be entirely by any technique and combination of vasopressor was required.

In our study, preloading was done for 10 minutes with 15ml/kg Ringer's lactate solution. The mean systolic blood pressure recorded in group IB was 117.07 ± 16.97 mmHg and 116.19 ± 4.89 mmHg in group HB. Significant difference was not observed between groups in average systolic blood pressure (0.87 ± 0.211 (95%CI of difference: -3.29 to 5.05).

Similarly difference in average heart rate was also not significant between groups 94.71 ± 16.08 and 95.9 ± 14.27 (0.316 ± 1.45 (95%CI of difference: -2.55 to 3.18).

The mean systolic blood pressure recorded in Aftab S and colleagues⁴ study in 0.5% isobaric group was 83.27 ± 12.69 mmHg while 114.33 ± 13.83 mmHg minutes in 0.75% hyperbaric group, which was statistically significant. While difference in average heart rate, was not significant between the groups 94.71 ± 16.08 and 95.9 ± 14.27 .

In the present study, hypotension was observed in 04 (5.71%) patients in isobaric group while 03 (4.28%) patients in hyperbaric group. Phelan and Mac Evilly⁷, on the other hand noted a greater incidence of hypotension in pregnant patients with hyperbaric bupivacaine. Hypotension after spinal anaesthesia for caesarean section is common regardless of the use of uterine displacement and volume preloading, and can lead to grave complications.³²

Hussain SR and Abbas Z²⁶ observed that blood pressure drop was more in hyperbaric group as compared to isobaric group, but statistically not significant. Maximum heart rate change was similar in both groups. Srivastava et al,³³ also found that risk of hypotension was marginally higher in hyperbaric group, when they compared the effects of 2 mg (2ml) hyperbaric and isobaric bupivacaine combined with 25 mg preservative free fentanyl for spinal anaesthesia during caesarean section.

Sikander IR et al³⁴ performed a comparative study between 0.75% and 0.5% hyperbaric bupivacaine and found no statistically significant difference in haemodynamics of both groups but the prevalence of hypotension was significantly low in 0.5% hyperbaric bupivacaine. Runza M et al²⁸ observed no statistically significant change in the amount of ephedrine given to treat hypotension, both 0.75% and 1% hyperbaric bupivacaine concentrations made comparable changes in blood pressure and heart rate.

Punshi G D & Afshan G³⁵ concluded that in caesarean section both plain and hyperbaric bupivacaine 10mg, with fentanyl produced satisfactory anaesthesia without any variations in the time of onset, extent of the block and haemodynamic constraints. However, in the plain group sensory level reversion was late, which may

have caused extended period of block.

In expecting the outcome of spinal anaesthesia, there are several variables. Alteration in dose of the drug, concentration or baricity along with discrete patient factors may create variable consequences, depending on availability in any particular institution without much improvement or harm at patients end²⁶. All these variables should be considered by every anaesthetist to make spinal anaesthesia an effective and harmless technique.

CONCLUSION:

Both isobaric and hyperbaric bupivacaine offers satisfactory surgical anaesthesia for caesarean section in the present study. This study was unable to identify, significant benefits and superiority of one preparation over the other.

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