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ORIGINAL ARTICLE

COMPARATIVE EVALUATION OF PROPHYLACTIC INTRAMUSCULAR PHENYLEPHRINE AND EPHEDRINE ON SPINAL ANAESTHESIA INDUCED HYPOTENSION DURING CAESAREAN SECTION AND THEIR EFFECTS ON APGAR SCORE AND NEONATAL OUTCOMES

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ABSTRACT: The incidence of hypotension during spinal anaesthesia for caesarean section is reported to be as high as 80% and effects neonatal outcome. Ephedrine, unlike phenylephrine, has a dose-related propensity to depress fetal pH during spinal anesthesia during cesarean section. A low arterial umbilical cord pH has a strong association with neonatal mortality and morbidity. Randomized prospective clinical trial was done to evaluate the efficacy of intramuscular ephedrine and phenylephrine administered 10 minutes before the induction of spinal anaesthesia in preventing hypotension following spinal anaesthesia for caesarean section. We evaluated the impact of vasopressor change on Apgar scores (1 and 5 min), incidence of Apgar score <7(1 and 5 min) in low-risk elective cesarean sections Patients and methods: Two hundred ASA Grade I and Grade II parturients scheduled for undergoing elective caesarean section under spinal anaesthesia were divided into four groups to receive intramuscular ephedrine or phenylephrine or equal volume of saline, 10 minutes before induction of spinal anaesthesia. Results: Incidence of hypotension was significantly less in phenylephrine 4mg group (32%) and ephedrine 45mg group (42%) compared to phenylephrine 2mg group (70%) and control group (86%). They also had a lower total dose of rescue IV ephedrine i.e 20 doses and 25 doses compared with phenylephrine 2mg group i.e 61 doses and controls i.e 80 doses. Conclusion: prophylactic intramuscular bolus of phenylephrine 4mg and ephedrine 45mg reduced the severity and incidence of hypotension and the total dose rescue IV ephedrine during spinal anaesthesia for caesarean section and have no impact on neonatal venous pH & outcome.

KEYWORDS: Spinal anaesthesia, Hypotension, Phenylephrine, Ephedrine, Apgar score.

INTRODUCTION: Spinal anaesthesia provides optimum operative conditions in women undergoing caesarean section. However, the incidence of hypotension during spinal anaesthesia is reported to be as high as 80% despite fluid preload lateral uterine displacement and use of vasopressors.(1) Maternal hypotension is associated with the distressing symptoms of dizziness, nausea and vomiting and may also interfere with the surgical procedure.(2) Maternal hypotension ultimately affects the foetal wellbeing and neonatal outcome.(3) Fetal acidosis identified by umbilical artery pH in spinal anesthesia for cesarean section is mainly the result of metabolic acidosis with low BE.(4,5,6,7) It is postulated that the metabolic component of acidosis could contribute to the increased risk of adverse outcomes instead of the respiratory component.(4,5,6,7)

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Although fluid preloading is still widely used, its place in the management of hypotension induced by spinal anaesthesia has been questioned.[8] The management of choice of this common problem is the use of IV vasopressors as required. The usual approach to the use of vasopressors is reactive rather than proactive; spinal anaesthesia induced maternal hypotension is allowed to develop and is then treated accordingly given the frequency with which it occurs, a more logical approach to its prevention may be the administration of prophylactic vasopressors. Therefore, this study was designed to evaluate phenylephrine 4mg and 2mg intramuscular in comparison with ephedrine 45 mg intramuscular and saline, given 10 minutes before induction of spinal anaesthesia, in terms of hemodynamic stability, requirement for rescue IV vasopressors therapy and neonatal umbilical cord pH values.

MATERIALS AND METHODS: After obtaining approval from the hospital ethics committee and written informed consent two hundred women ASA status I or II, who had a maternal age between 20 and 42years, full term pregnancy (≥37 week's gestation), and infants weighing ≥2,500 g without any known fetal anomalies. We excluded cesarean sections cases which were converted to general anaesthesia, patients who received sedatives prior to delivery of newborn, twin pregnancy, intrauterine growth retardation, oligohydroamnios, and placenta previa. Mothers with hypertension (Including pregnancy-induced hypertension), diabetes mellitus (Including gestational diabetes mellitus), cardiovascular, cerebrovascular, respiratory, or renal disease or those who were American Society of Anesthesiologists physical status III or greater were also excluded.

Patients were randomly allocated to four groups of fifty patients each; Group I received phenylephrine 4mg im (P4), Group II received phenylephrine 2mg im (P2), Group III received ephedrine 45mg im (E45), while Group IV, the control Group, received saline 0.9%. All study medications was made up-to 2ml with 0.95 saline and administered intramuscularly 10 minutes before induction of spinal anaesthesia.

After the patients were brought into the operative room, a good IV line with 16G IV cannula was established and infusion of Ringer's lactate solution started. Multichannel monitor was attached and vital parameters like baseline heart rate, noninvasive blood pressure (Systolic, diastolic and mean arterial pressures), electrocardiogram (ECG) and oxygen saturation (SPO2) were recorded. The lowest NIBP (Systolic, diastolic, mean arterial pressures) recorded in the 10 minute before receiving a study medication was taken as base line valve to minimize the influence of anxiety in patients. The base line heart rate was taken as the highest recorded heart rate before administration of the study drug. The study medication was injected intramuscularly into left vast us lateralis muscle 10min. before induction of spinal anaesthesia. Under all aseptic precaution and with the patient in a sitting position 2.5ml (12.5mg) 0.5% hyperbaric bupivacaine was administered in the subarachnoid space with a 25G Quince's needle at L3-L4 intervertebral space.

The patient was then placed in the spine position with a 15^0 left lateral tilt. Vital parameters like NIBP (Systolic, diastolic and mean arterial pressures), HR, ECG, an oxygen saturation were recorded every minute starting from im administration of study medication till induction of spinal anaesthesia i.e first 10min., then every 2min. after the induction of spinal anaesthesia for 20min. and there after at every 5min. interval till completion if caesarean section. Rescue IV bolus doses of ephedrine (6mg) were given whenever hypotension occurred. Hypotension was taken as a 20% or more decrease in mean arterial pressure or a systolic pressure from the baseline value. The timing

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and doses of rescue ephedrine given were recorded. Bradycardia (Heat rate<50bpm) was recorded and treated with 0.3mg bolus of atropine IV.

Dermatomal levels of anaesthesia (Block height) were recorded at 5 and 15 minutes. Neonatal APGAR scores at 1 and 5 minutes and umbilical cord venous blood pH at delivery were recorded. We compared the Apgar scores and neonatal outcomes in both groups during the two time periods (Demographic data were analyzed using Student's t-test, Apgar scores were analyzed with Mann Whitney U test.

RESULTS: Physical characteristics, basal line hemodynamic data and dermatomal sensory levels are given in table 1. No difference could be demonstrated among the four groups in terms of age, weight, baseline hemodynamic data and dermatomal sensory levels. All the patients had adequate surgical anaesthesia.

TABLE 1: Patient characteristics, hemodynamic data and dermatomal sensory levels. Age, Weight, Duration of surgery, Heart rate, SAP, DAP and MAP are expressed as mean±(SD).SAP= systolic arterial pressure, DAP=diastolic arterial pressure, MAP= mean arterial pressure. P4= phenylephrine 4mg, P2= phenylephrine 2mg, E45=ephedrine 45mg.

Parameter	Group I (P4) n=50	Group II (P2) n=50	Group III (E45) n=50	Group IV (control) n=50
Age (yrs)	25.75±(2.13)	25.64±(2.132)	25.16±(2.13)	26.28±(2.23)
Weight (kg)	56.08±(5.45)	56.18±(5.26)	55.52±(5.25)	39.10±(3.54)
Duration of procedure (min)	38.90±(3.545)	38.80±(3.545)	38.80±(35.45)	39.10±(3.54)
Baseline heart rate	99.82±(3.82)	98.72±(5.45)	97.42±(5.38)	98.10±(3.95)
Baseline SAP(mmHg)	118.80±(2.58)	119.50±(3.17)	120.04±(3.64)	119.62±(2.42)
Baseline DAP (mmHg)	74.44 (3.13)	75.64(3.98)	75.98±(5.42)	76.12±(3.39)
Baseline MAP (mmHg)	89.16±(2.44)	90.04±(3.39)	90.78±(4.46)	90.66±(2.60)
Block height (5 min.)	T9(T8-T10)	T9(T8-T10)	T9(T7-T10)	T9(T8-T10)
Block height (15 min.)	T7(T6-T8)	T7(T6-T8)	T7(T6-T8)	T7(T6-T8)

Table 1

Changes in systolic, diastolic and mean arterial pressures and heart rate from administration of study medication till induction of spinal anaesthesia and then from induction of spinal anaesthesia till completion of surgery among all the four groups are demonstrated in Table 2 and Table 3 respectively. The incidence of hypotension is shown in Table 4. The incidence of hypotension was 32% in phenylephrine 4mg group, 42% in ephedrine 45mg group, 70% in the phenylephrine 2mg group and 86% in the control group. The incidence of hypotension was significantly lower in the

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phenylephrine 4mg group compared with controls (p=0.001).patients who received phenylephrine 4mg i.m and ephedrine 45mg i.m had a significantly lower percentage reduction in MAP compared with phenylephrine 2mg i.m and controls (p=0.003). These two groups also required significantly lower doses of rescue IV ephedrine i.e 20 doses and 25 doses respectively (p<0.001). The time to first requirement for rescue IV ephedrine therapy is significantly delayed in P4 and E45 groups compared to controls (p=0.0003) Table 4. There was no significant difference between the groups with respect umbilical venous blood pH and APGAR scores (Table 5). The heart rate shows significant difference between the groups with ephedrine 45 mg group having higher mean heart rate (p=0.0001), both from administration of study medication till induction of spinal anaesthesia as well from spinal anaesthesia till completion of surgery (Table 2 and 3). Bradycardia was noticed in 18, 15 and 29 Cases in group I, II and IV (control) respectively while as tachycardia was common in group III.

Parameters	Group I (P4) n=50	Group II (P2) n=50	Group III (E45) n=50	Group IV (Control) n=50
Heart rate(bpm)	94.97±(3.86)	95.24±(4.92)	101.69±(4.91)	94.30±(3.72)
SAP(mmHg)	126.34±(2.93)	125.12±(4.42)	125.12±(4.42)	125.34±(2.02)
DAP(mmHg)	79.67±(5.27)	79.70±(5.67)	80.45±(4.78)	78.58±(3.65)
MAP(mmHg)	94.70±(3.09)	94.64±(5.00)	95.72±(4.06)	94.32±(2.55)

Table 2

Haemodynamic data from administration of study medication till induction of spinal anaesthesia.

Table 3: Haemodynamic data from induction of spinal anaesthesia till completion of surgery Parameters Group I (P4).

Parameters	Group I(P4) n=50	Group II(P2) n=50	Group III(E45) n=50	Group IV (control) n=50
Heart rate(bpm)	91.59±(3.10)	92.81±(3.63)	94.89±(4.16)	93.44±(3.40)
SAP(mmHg)	122.05±(2.37)	117.41±(4.31)	120.33±(3.22)	115.35±(2.47)
DAP(mmHg)	68.25±(4.31)	65.52±(4.96)	67.62±(4.12)	65.43±(4.39)
MAP(mmHg)	84.31±(3.39)	82.17±(4.35)	83.50±(3.04)	82.11±(3.44)

Table 3

Table 4: Incidence of hypotension requirement for rescue ephedrine with time to first administration. Incidence of hypotension and bradycardia are expressed as number (%age) and time to first rescue ephedrine is expressed as mean (S.D)

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Parameters	Group I (P4) n=50	Group II (P2) n=50	Group III (E45) n=50	Group IV (control) n=50
Incidence of hypotension	16(32%)	35(70%)	21(42%)	43(86%)
Doses of rescue IV ephedrine required	20	61	25	80
Time to first ephedrine(min.)	14.38	12.91	12.38	3.65
Incidence of bradycardia	18(36%)	15(30%)	nil	12(24%)

Table 4

Table 5: Neonatal data. Cord pH is expressed as mean and APGAR scores as median (range). Parameters Group I (P4).

Parameters	Group I(P4) n=50	Group II (P2) n=50	Group III (E45) n=50	Group IV (Control) n=50
APGAR score (1 min.	7(7–8)	7(7–8)	7(7–8)	7(7–8)
APGAR score (5 min.)	10(9-10	10(9-10)	10(9-10)	10(9-10)
Cord pH	7.29	7.29	7.29	7.29

Table 5

There was no significant difference between the groups. P4=phenylephrine 4mg, P2=phenylephrine 2mg, E45=ephedrine 45mg

DISCUSSION: The current study has shown that phenylephrine 4mg i.m and ephedrine 45mg i.m given 10 min. before induction of spinal anaesthesia for caesarean section, reduce the severity of hypotension and the total dose of rescue IV ephedrine required compared with controls and phenylephrine 2mg i.m. Hypotension is defined arbitrarily in most studies with values ranging from a 20-30% reduction from baseline systolic arterial pressures 1.[8,9] The incidence of hypotension clearly depends on this definition. We choose the lowest MAP value in the 10min. stabilization period to allow anxiety patients to settle and avoid spuriously high MAP values.

In this study, we investigated the effect of i.m vasopressors given before the onset of hypotension and found a therapeutically useful effect. Phenylephrine effectively restores SAP, MAP and DAP but decreases heart rate and cardiac output when given by infusion to patients undergoing elective surgery under spinal anaesthesia.[10] Another study found a 58% incidence of bradycardia (HR<60bpm) when phenylephrine as an IV bolus after the induction of spinal anaesthesia.[11] In consensus the present study showed the incidence of bradycardia (HR<60bpm) 36% and 30% in phenylephrine 4mg and phenylephrine 2mg groups respectively.

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Ephedrine is not a potent arterial vasoconstrictor; it maintains SAP mainly by increasing cardiac output and heart rate.[12] Similarly in our study ephedrine 45mg group showed an increase in heart rate, which can be explained by its beta1 adrenoreceptor activity. The place of IV vasopressors for treatment of hypotension during caesarean section is well established.,[11,13,14] However, giving i.m vasopressors before a spinal anaesthesia is controversial.[15] A study comparing 37.5mg i.m with placebo showed improved cardio vascular stability in the ephedrine group but with a persistent 50% incidence of hypotension.[9] Sternlo and colleagues found ephedrine 0.6mg/kg i.m was effective in reducing the incidence of hypotension in patients undergoing hip arthroplasty under spinal anaesthesia.[16]

`Pharmacokinetic studies have suggested that the peak effect of i.m phenylephrine or ephedrine is 10–15min. after administration.[17] This pharmacokinetic profile suggested the use of i.m vasopressors 10min. before the intrathecal injection to achieve a beneficial effect. We have demonstrated a reduction in the severity and incidence of hypotension and requirement of rescue Iv ephedrine by giving relatively higher dose of vasopressors giving them before induction of spinal anaesthesia. In addition, no hypertension was observed in any group because time to peak vasopressor effect was influenced by spinal anaesthesia. A systematic review that analyzed 481,753 infants demonstrated that a low pH of the umbilical artery had a strong association with neonatal mortality and morbidity (Hypoxic ischemic encephalopathy, seizures, intraventricular hemorrhage, periventricular leucomalacia, and cerebral palsy.[18]

For newborn evaluation, Apgar scoring system was developed by Virginia Apgar, the Apgar score remains an important method for the early detection of infants at risk for serious and fatal conditions.[19,20] There were no differences in Apgar scores and the risk of low Apgar scores between the phenylephrine and ephedrine groups.[21,22,23,24,25,26,27,28] However, the sample sizes of these studies may be too small to detect differences in Apgar scores.

The correlation of umbilical artery pH and Apgar score is unclear. An Apgar scores less than 7 at 5 min neonatal intensive care unit admission and assisted neonatal ventilation had significant inverse relationships with both umbilical artery pH and BE ($P<0.0001$) in a study of term singleton births with no major abnormalities.[29]

Known risk factors for low Apgar scores include preterm birth, post term birth, low birth weight, small for gestational age, congenital malformation, and maternal smoking during pregnancy.[30,31,32] We excluded most risk factors in our study.

Median values of 5min Apgar scores and the incidence of low 5min Apgar scores were similar in all groups. Richardson et al.,[33] reported a small drop in umbilical artery pH, and BE was generally well tolerated, with no difference in incidence of 5 min Apgar scores <7.

There was no impact of vasopressors therapy on the foetus with respect to umbilical cord venous blood pH and Apgar scores.

CONCLUSION: Phenylephrine 4mg i.m and ephedrine 45mg i.m given 10 min. before intrathecal injection reduce the severity and incidence of hypotension, the total dose of rescue IV ephedrine and delay the time to first rescue IV ephedrine therapy during spinal anaesthesia for caesarean section. Besides they have no impact on the foetus in terms of umbilical cord venous blood pH an APGAR scores.

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