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COMPARISON OF EFFECTS OF PROPHYLACTIC INFUSION OF PHENYLEPHRINE VERSUS EPHEDRINE ON MATERNAL HEMODYNAMICS IN ELECTIVE CAESAREAN SECTION UNDER SPINAL ANAESTHESIA

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ABSTRACT

BACKGROUND

The most common complication after spinal Anesthesia is hypotension. In order to help and treat this complication different styles have been used. But , hypotension remains the most common problem , in spite of preloading the patient with Crystalloid and colloid . Among utmost of the cases, to treat spinal Anesthesia convinced hypotension, vasopressors are needed. Studies involving both administration of phenylephrine and ephedrine are multitudinous . But , studies regarding precautionary infusion of these medicines and their comparison on motherly hemodynamics and are rare.

METHODOLOGY

This is a randomized control study conducted on 60 cases aged between 18-35years with normal singleton gestation beyond 36 weeks of gravidity and belonging to ASAII posted for caesarean sections under spinal anesthesia are aimlessly named and distributed to either Group A- Phenylephrine and Group B- Ephedrine. (By lottery method)

RESULTS

Maternal blood pressure was maintained in both the groups and was not statistically significant. Bradycardia was seen in 23% of group A and nausea of 20% was seen in group A, where as there was no prevalence of any complications in group B. Neonatal assessment

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was done using APGAR scoring and umbilical vein ABG and was plant statistically insignificant.

CONCLUSION

It was observed that maternal blood pressure was maintained well with both ephedrine as well as phenylephrine, but there was prevalence of bradycardia and nausea with phenylephrine. There was no major effects APGAR score , fetal umbilical vein ABG in both groups.

KEY WORDS: alpha adrenergic, maternal hypotension, foetal distress, APGAR

INTRODUCTION

Maternal hypotension results in dizziness, nausea, vomiting, may also interfere with surgical procedure and can also induce fetal bradycardia (1-4) and acidosis (4-6). Many trials comparing phenylephrine and ephedrine for management of hypotension during spinal Anesthesia for Caesarean section have shown favourable results. Some of the measures taken to drop the prevalence of maternal hypotension are preloading, left uterine relegation ,. Administration of precautionary vasopressors, leg contraction , trendelenberg position etc.(7-9) The vasopressor of choice in pregnant women has been ephedrine. The use of alpha agonists has been avoided because of their adverse effects on uterine blood flow. However, in a quantitative, systematic review of randomized controlled trials of ephedrine versus phenylephrine for the management of hypotension during spinal anaesthesia for cesarean delivery, Lee and colleagues showed that there was no difference between ephedrine and phenylephrine in efficacy. They did find, however, that women given phenylephrine had neonates with higher umbilical cord blood pH values than women given ephedrine, although the risk of true fetal acidosis (umbilical pH value of 7.20) was similar in both groups.Because acidotic changes in the umbilical arterial pH are sensitive indicators of reduced uteroplacental perfusion, the authors concluded that their finding was indirect evidence that uterine blood flow may in fact be better with phenylephrine compared with ephedrine. Utmost of the studies are grounded on the effects of preloading (10-12) or vasopressors.(13,14) Ephedrine which has both alpha and beta agonistic activity , increases cardiac output and heart rate and therefore maintains the blood pressure. Where as phenylephrine which is an alpha agonist , rectifies the drop in systemic vascular resistance convinced by spinal Anesthesia. Rather of treating the hypotension as done generally , it is better to help the hypotension induced by spinal Anesthesia. Therefore , we have studied the effects of precautionary infusion of phenylephrine versus ephedrine on maternal hemodynamics in elective Caesarean section under spinal Anesthesia.

METHODS AND MATERIALS

This is a randomized control study conducted at hospitals attached to Bangalore Medical College and Research Institute , Bangalore. A total of sixty cases aged between 18-35 years with normal singleton gestation beyond 36 weeks of gravidity and belonging to ASA II posted for caesarean sections under spinal anesthesia. They were randomly allocated to two groups: A received Phenylephrine and B received Ephedrine.Cases are explained about the procedure and informed / spoken concurrence attained. Two intravenous lines are established. Cases are pre-loaded with 500ml Ringer lactate and Pre- medicated with Inj-Pantoprazole 40mg I.V and Inj-Metaclopromide 10mg I.V 15 minutes after pre-medication, baseline parameters –Heart rate, saturation, blood pressure and ECG, monitored using pulse-oximetry, Noninvasive blood pressure and ECG monitor.

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Under strict aseptic precautions, using 27G quincke needle, inj. Bupivacaine heavy (0.5%) of 2 ml was injected intrathecally. Following this injection, patient was repositioned with the conservation of left uterine relegation . Cases were randomized based on computer generated randomized sequence into group A and group B.

Group A – phenylephrine of infusion after giving spinal anesthesia of 500 microgram in 500 ml NS at the rate of 1000 ml/h until cord clamping

Group B – ephedrine infusion after giving spinal anesthesia of 50mg in 500ml NS at the rate of 1000 ml/h until cord clamping.

Each group received a titrated IV infusion of a solution containing one of the two drugs soon after spinal Anesthesia . Monitoring of heart rate, blood pressure, saturation done at every minute till 10 minutes, after that for every 3mins till the end of surgery. Fall in BP > 20% of the rudimentary is treated with a bolus of ephedrine 6mg only if pulse rate is <100 per minute, if >100per minute 40microgram of phenylephrine was given. Fall in heart rate < 60 per minute for > 30sec treated by atropine 0.6mg I.v . In order to maintain maternal BP at near-baseline levels, a predefined algorithm was used: (a) rate of infusion was maintained (1000ml/h) if BP remained within 90-110% of the baseline; (b) rate of infusion was halved (500ml/h) if BP increased to 110-120% of the baseline; (c) infusion was stopped if BP increased to more than 120% of the baseline. Hypotension was defined as SBP <90% of the baseline reading and hypertension was defined as SBP >110% of the baseline. The infusion was discontinued following delivery of the baby.Fall in Spo2 < 95% is managed by oxygen supplementation via clear (Hudson's) face mask at 4 liters per min. Neonatal status is assessed by Apgar scoring and umbilical vein ABG after cord clamping Post operative monitoring of the patient is continued in the post anesthesia care unit for 1 hour.

Fall in Spo2 < 95% is managed by oxygen supplementation via clear (Hudson's) face mask at 4 liters per min. Neonatal status is assessed by Apgar scoring and umbilical vein ABG.

EFFICACY PARAMETERS :

- Time of spinal block
- Time taken to achieve maximum level of sensory block
- Time of start of infusion of the study drug
- Skin incision time
- Uterine incision time
- Maternal hemodynamics heart rate , blood pressure, spo2 respiratory rate
- Baby delivery time
- Neonatal APAGAR score at one and five minutes
- Umbilical vein

ABG SAFETY PARAMETERS: Adverse effects any will be noted.

STATISTICAL ANALYSIS: the data was entered into an MS Excel spreadsheet and analysed using SPSS v21. Results attained will be anatomized by descriptive statistics. Chi-square study, Fisher exact test, student t-test. P value < 0.05 was considered statistically significant.

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RESULTS

Table :1

Basic Variable	Group A	Group B	Pvalue
Age	25.10±3.98	27.07±4.354	0.254
Height	157.70±6.51	157.13±4.89	0.832
Weight	70.20±7.672	73.0±7.83	0.902

The age of the patients ranged from 18-35 years.

The age, height and weight were comparable in both the groups, hence deemed not statistically significant.

The time taken to reach maximum sensory blockade in both groups is similar and average tme taken to reach maximum blockade in both groups is 3 minutes with a p value of 0.443 which is insignificant.

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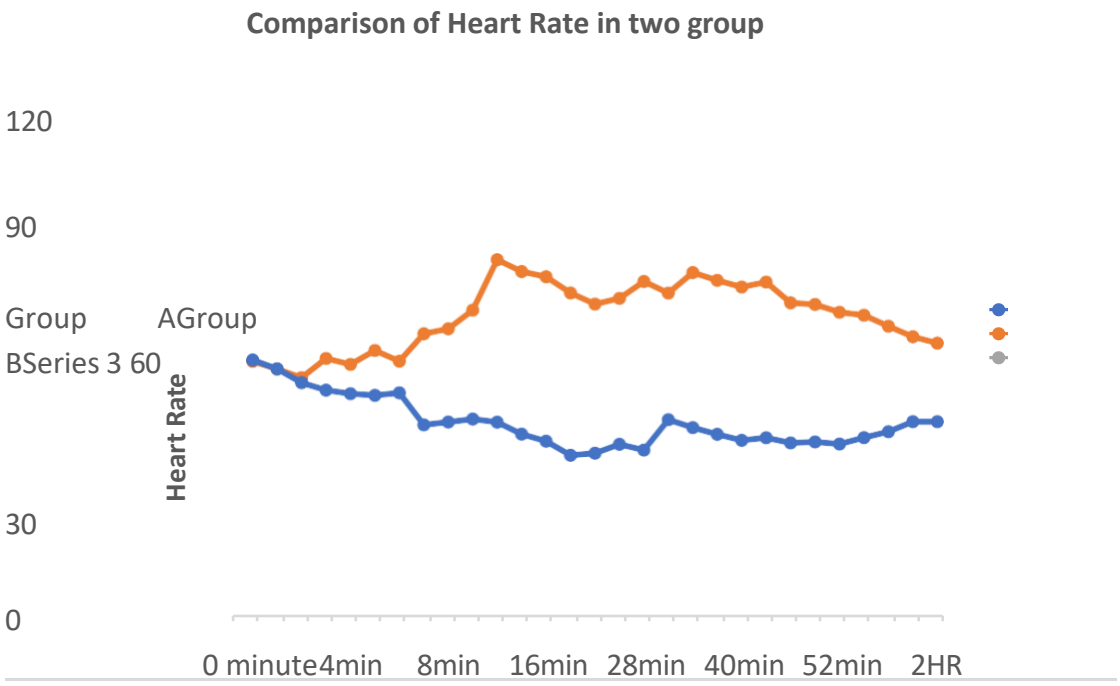

Figure:1

GROUP B had persistent increase in the heart rate upto 16 minutes and later on, it maintained at a higher level; whereas group A had persistant fall in heartrate upto 28 minute and later on it maintained at a lower level . And the difference between the twogroups was found to be statistically significant at 2,6,7,8,9,10,13,16,22 minutes.

SBP in group B showed initial fall at 3,4,5,6,55th minute and stabilised from 7th minute stabilised towards baseline. Group A had stable SBP throughout. And the difference between the twogroups was found to be statistically significant at 6,19,25,28,31,34,37,40,43,46,49,55,60,90,120 minutes.

DBP showed a fall at 60th minute in group A and at 55th minute in group B whichlater on stablised towards baseline in bot the groups.

The MAP was maintained in group A throughout but in group B there was initial fallupto 5 minute and stabilised towards baseline later on.

Oxygen saturation was well maintained between the two groups and was not statistically significant.

APGAR SCORE:

The mean value of APGAR score at 1 min in group A and Group B were 8.53 and 8.6 respectively and showed no significant difference between the two groups.

The mean value of APGAR score at 5 min in group I and Group II were 9.68 and 9.80 respectively and showed no significant difference between the two groups

In Group A only 20% patients had nausea, 23.3% patients had bradycardia who needed treatment and had no vomiting and hypotensionIn GroupB had no incidence of nausea ,vomiting ,hypotension and bradycardia.

DISCUSSION

Amidst the acceptable anaesthetic techniques, regional anaesthesia especially spinal anaesthesia proved to be the most preferred technique for Caesarean section. (15) The reason being the unique potential of spinal technique to give anaesthesia with a blend of low degree of physiologic trespass and with profound degrees of sensory denervation and

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muscle relaxation. Thus, the safety of spinal anaesthesia is of dual nature; pharmacological as well as physiologic.

The only flaw with this technique Is the risk of hypotension especially in gravid patients. Dinesh Sahu et al38 found that maternal hypotension during spinal anaesthesia for Caesarean delivery was a persistent problem in approximately 85% of cases. Other studies quote an incidence of 50-80%. Differing definitions of "significant" hypotension are partly responsible for the wide variation in incidence of hypotension reported in literature. (15(Careful positioning and volume preloading with intravenous crystalloid solution or colloid solution have been standard practice for prevention of hypotension, but these are not complete measures [35] .

Heart rate:

In this study phenylephrine group had significant fall in heart rate (23% of study group) which needed treatment with atropine. Heart rate increased more than basal values with ephedrine upto 16 minutes which may be due to beta agonistic action of ephedrine. Possible bradycardia associated with spinal anaesthesia may have been annulled by ephedrine due to increased chronotropic action by stimulation of beta receptors. Result correlates with the study by **Dinesh Sahu et al (16)** , the heart rate values significantly reduced upto 28minutes after infusion of phenylephrine where as in ephedrine group heart rate stayed higher till 13 minutes after infusion of ephedrine .. Incidence of bradycardia was 23% of the phenylephrine group and none in ephedrine group. Bradycardia that passed with phenylephrine was not associated with hypotension. Bradycardia in phenylephrine group is due to baroreceotor intermediated reflex mechanism, which was transient and corrected by atropine.

P.A.Hall and colleages [(17)] studied prophylactic bolus followed by infusion of ephedrine(6mg iv bolus followed by 1mg/min infusion) and phenylephrine (20µg iv bolus followed by 10 µg infusion), showed 20% incidence of bradycardia taking treatment with atropine .This result correlate with our study.

Systolic Blood Pressure:

In the present study both the vasopressors, effectively maintained arterial pressure within 20% limit of baseline value though phenylephrine maintained better as compared to ephedrine .which may be due to, phenylephrine having faster onset of action by one minute, compared to ephedrine having 2-5 mins. The result is similar to study done by **Dinesh Sahu et al** comparing the IV bolus dose of 100mg phenylephrine and ephedrine 6 mg, showed the rise in systolic blood pressure with phenylephrine incontinently after administration, where as in ephedrine this rise was 6mins after the drug administration. (16)

In the present study after terminating the infusion of study drug, stabilisation of systolic blood pressure to basal values was gradual in both ephedrine as well as phenylephrine .

Diastolic Blood Pressure:

In the present study diastolic blood pressure values with phenylephrine was higher than ephedrine values immediately after bolus drug administration this may be due to early onset of action of phenylephrine than ephedrine.Throughout the intraoperative period diastolic blood pressure values of phenylephrine stayed higher than ephedrine which may be due to increase in systemic vascular resistance by phenylephrine. This results correlates with the

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study done by **Dinesh Sahu et al** [16] , in their study DBP values in phenyleprine group was maintained higher than ephedrine, immediatelyafter bolus administrations.

In the present study the diastolic blood pressure in both the groups was maintainedand the diastolic blood pressure values were slightly lower than basal at 1hour in group A and at 55 minutes in group Bnot more than 20% the baseline). And duration of action of ephedrine infusion is 50 -55 minutes resulting in fall in DBP at 55 minute.

Mean Arterial Pressures:

In the present study, there was an initial fall in mean arterial pressure in ephedrine group upto 5 minutes later the values were maintained stable and comparable betweenthe two groups. This result correlates with the study done by **Dinesh sahu** [16] who administered IV bolus doses of phenylepherine 100mg and compared with 6mg IV bolus, in their study they had similar trend of fall in mean arterial pressure initial 2and 4 mins in ephedrine the groups, later values stayed higher in phenylephrine group compared to ephedrine group.

In the present study after termination of the infusion of study drugs, mean arterial pressure reduced to values lower than basal values earlier in ephedrine group than compared to phenylephrine group.

On Neonatal outcome

In the study neonatal assessment which done by APGAR scoring at 1 st and 5th min was more than 8 in both the study groups , fetal umbilical vein blood gas analysis wasdone and was not significant in both the groups.. This result identified well with study done by **Alahuhta et al (18)** with ephedrine 5mg or phenylephrine 100µg followed by 50mg/hr ephedrine and 1000 µg/hr phenylepherine , showed no change in APGAR scoring.

Adverse Effects

NAUSEA AND VOMITING

In the present study there was 20% incidence of nausea in phenylephrine group compared to ephedrine group. Nausea was not associated with hypotension and was treated with Inj.ondenstrone 4mg IV. . None of the patients had vomiting in both the groups. The incidence of complications were less when compared to study done by **P.A.Hall et al** (17) who showed nausea was 30% in ephedrine group and 40% in phenyl ephedrine group , these episodes were associated with hypotension .

Dinesh sahu et al (16) study with bolus IV ephedrine and phenylephrine showed 10% incidence of nausea in both ephedrine and phenyl ephedrine group. These episodes of nausea was not associated with hypotension.

CONCLUSION

A precautionary infusion of study drugs i,e; Phenylephrine, Ephedrine can be safely used during spinal anaesthesia for caesarean section for forestalment of hypotension. Phenylephrine would better preferred in caseswith, hyperthyroidism, PIH, Mitral stenosis , aortic stenosis and other cardiac diseases,where strict and titrable control of haemodynamics is needed.

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