

Comparison of Bolus Ephedrine, Mephentermine and Phenylephrine for the Management of Hypotension during Spinal Anaesthesia for Caesarean Section: A Clinical Study

D.V. Ravi Kumar¹, Suryasnata Sahoo², Anija Pattnaik³, Udaynath Behera⁴, Parimita Goud⁵

¹Assistant Professor, Department of Anaesthesiology & Critical Care, S.C.B. Medical College, Cuttack, Odisha, India.

²Assistant Professor, Department of Anaesthesiology & Critical Care, S.C.B. Medical College, Cuttack, Odisha, India.

³Assistant Professor, Department of Anaesthesiology & Critical Care, S.C.B. Medical College, Cuttack, Odisha, India.

⁴Assistant Professor, Department of Anaesthesiology & Critical Care, S.C.B. Medical College, Cuttack, Odisha, India.

⁵Senior Resident, Department of Anaesthesiology & Critical Care, S.C.B. Medical College, Cuttack, Odisha, India.

Received: 25-11-2022 / Revised: 25-12-2022 / Accepted: 15-01-2023

Corresponding author: Dr. Udaynath Behera

Conflict of interest: Nil

Abstract

Background: In this study, we wanted to compare the efficacy of ephedrine, mephentermine and phenylephrine in treating the hypotension for caesarean section and their undesirable side effects.

Methods: This was a hospital based prospective double blind randomized manner study conducted among 90 patients who underwent elective and emergency lower segment caesarean section (LSCS) in the Department of Obstetrics, S.C.B. Medical College & Hospital, Cuttack from June 2021 to July 2022, after obtaining clearance from Institutional Ethics Committee and written informed consent from the study participants.

Results: The mean value of heart rate was generally the highest in Group II followed by Group I and Group III. The mean variation of heart rate values between the three groups was statistically significant at 2 mts. Pair wise comparison of groups showed that the differences in mean values were statistically significant between Group II and III and between Group I and III at 2-mts. The mean value of diastolic BP was greater in Group III than Group I or Group II values at 2nd and 4th minute. The variation in the mean values of diastolic BP between the three groups was statistically significant at 2-mts ($p = 0.01$) and between 20 and 30 minutes. Pair wise comparison of groups revealed that the mean differences were statistically significant between Group I and Group II at 8-mts ($p = 0.02$). The mean differences in MAP values between the three groups were statistically significant at 2-mts ($p = 0.003$), 4 mts ($p < 0.001$) and 25-mts ($p = 0.04$). The pairwise comparisons between Group I and Group II were statistically significant at 25-mts ($p = 0.02$) and between Group I and Group III at 30-mts ($p = 0.03$).

Conclusion: All the three vasopressors namely ephedrine, mephentermine and phenylephrine are effective in IV bolus form in maintenance of maternal arterial pressure within 20 % limit of base line values, though phenylephrine has quicker peak effect, in comparison to ephedrine and mephentermine and it causes reduction in heart rate, which may be advantageous in

patients in whom tachycardia is undesirable. All the three vasopressors had no significant adverse effects on neonatal outcome.

Keywords: Bolus Ephedrine, Mephentermine, Phenylephrine, Hypotension, Spinal Anaesthesia, Caesarean

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Introduction

Anaesthesia to a parturient is not only unique but also requires highest degree of care because the anaesthesiologist has to look after two individuals, the mother and foetus. In elective caesarean section under spinal anaesthesia, hypotension has been reported in as many as 85 % of patients.[1] Hypotension during spinal anaesthesia for caesarean delivery can have detrimental effects on both mother and neonate. These effects include decreased uteroplacental blood flow, impaired foetal oxygenation with asphyxial stress and foetal acidosis and maternal symptoms of low cardiac output such as nausea, vomiting, dizziness and decreased consciousness. Therefore, there has been much attention in the literature to methods of preventing and treating hypotension in obstetric anaesthesia. Careful positioning with left uterine displacement and volume preloading with crystalloids or colloids has been used to prevent it, but these are not complete measures [2,3] and vasopressor is required to correct hypotension quickly. Vasopressor like ephedrine, mephentermine, phenylephrine, metaraminol and methoxamine are used for treating the hypotension. In this study, we compare the efficacy of ephedrine, mephentermine and phenylephrine in treating the hypotension for caesarean section and their undesirable side effects.

Aims and Objectives

To compare the effects of ephedrine, mephentermine and phenylephrine in the management of hypotension during spinal anaesthesia for caesarean section based on the following parameters.

1. Efficacy of vasopressor in treating hypotension,
2. Incidence of undesirable side effects,
3. Effect on neonatal outcome.

Methods

This was a hospital based prospective double blind randomized manner study conducted among 90 patients who underwent elective and emergency lower segment caesarean section (LSCS) in the Department of Obstetrics, S.C.B. Medical College & Hospital, Cuttack from June 2021 to July 2022, after obtaining clearance from Institutional Ethics Committee and written informed consent from the study participants.

Inclusion Criteria

1. Patients in age group of 18 – 35 years of age,
2. Healthy
3. ASA I & II patients with singleton full term pregnancy
4. Undergoing elective and emergency LSCS

Exclusion Criteria

1. Patients > 35 years of age
2. Known hypertensive patients, patients on anti-hypertensive drugs
3. Uncontrolled PIH
4. ASA III, IV patients
5. Multiple gestation
6. Obese (> 90 kg)
7. Short stature (< 140 cm)

Statistical Methods

The descriptive statistics of the variables studied were represented as two-way tables. The categorical factors were represented by the number and frequency

(%) of cases. The continuous variables were represented by measures of central frequency (like mean, median & mode) and deviation (say, standard deviation and range). The differences in the proportions of are tested for statistical significance using non-parametric Chi-square test for variables measured on nominal scale. When testing for two factors, the Mann-Whitney “U” test or Wilcoxon two sample test (by Kruskal-Wallis “H” test which is equivalent to Chi-square) was used. Fisher’s exact probability test was used

wherever indicated. For variables measured on a continuous scale, one-way analysis of variance (ANOVA) was employed to elicit the statistical significance of variation when three variables were taken together. When testing for two groups (pair wise), student “t” test is used to test for statistical significance in the differences of the two means.

Results

Table 1: Mean Distribution of Cases by Groups and HR

HR	Group I (n = 30)	Group II (n = 30)	Group III (n = 30)	P - Value
Base line Mean SD	86.4 12.25	83.9 10.39	90.1 13.62	0.14
HP (VP given) Mean SD	0.7 25.52	90.9 18.47	87.6 17.93	0.24
2 mts after VP Mean SD	93.1 21.21	93.8 18.3	83.2 17.8	0.04*
4-mts Mean SD	3.7 19.49	3.8 20.50	91.3 12.64	0.83
6-mts Mean SD	96.2 17.58	99.0 18.16	94.6 13.10	0.58
8-mts Mean SD	96.5 17.24	98.6 15.31	94.0 12.76	0.51
10-mts Mean SD	97.2 15.36	97.2 15.51	92.7 13.07	0.40
15-mts Mean SD	96.6 16.31	96.1 15.42	92.1 12.53	0.43
20-mts Mean SD	95.6 15.96	96.7 15.88	93.8 12.17	0.74
25-mts Mean SD	N = 29 96.3 15.31	N = 30 95.8 14.41	N = 30 93.1 11.98	0.63
30-mts Mean SD	N = 28 95.5 12.38	N = 30 96.1 14.67	N = 29 91.9 11.94	0.42

*Statistically Significant

The mean value of heart rate was generally the highest in Group II followed by Group I and Group III. The mean variation of heart rate values between the three groups was statistically significant at 2mts. Pair

wise comparison of groups showed that the differences in mean values were statistically significant between Group II and III and between Group I and III at 2-mts.

Table 2: Mean Distribution of Cases by Groups and Diastolic BP

Diastolic BP	Group I (n = 30)	Group II (n = 30)	Group III (n = 30)	P - Value
Baseline Mean SD	74.0 6.38	78.8 7.58	76.7 7.43	0.07
HP (VP given) Mean SD	50.6 9.95	51.8 9.22	49.3 9.82	0.62
2 mts after VP Mean SD	59.6 12.56	66.0 11.83	69.0 12.03	0.01*
4-mts MeanSD	64.6 13.79	66.4 8.63	68.0 14.29	0.54
6-mts MeanSD	64.5 10.33	68.6 10.10	66.2 13.62	0.39
8-mts MeanSD	64.8 9.32	70.2 8.03	66.5 13.73	0.15
10-mts MeanSD	65.8 9.03	70.5 9.66	69.0 11.2	0.19
15-mts MeanSD	65.4 9.54	69.8 9.50	68.5 9.94	0.20
20-mts MeanSD	64.9 8.15	70.5 7.97	69.7 9.65	0.03*
25-mts MeanSD	N = 2964.4 8.65	N = 3072.2 10.39	N = 3068.5 9.22	0.009*
30-mts MeanSD	N = 2865.3 9.45	N = 3071.8 9.93	N = 2971.9 8.97	0.01*

*Statistically Significant

The mean value of diastolic BP was greater in Group III than Group I or Group II values at 2nd and 4th mt. The variation in the mean values of diastolic BP between the three groups was statistically significant at 2-mts (p = 0.01) and between

20 and 30 minutes. Pair wise comparison of groups revealed that the mean differences were statistically significant between Group I and Group II at 8-mts (p = 0.02).

Table 3: Mean Distribution of Cases by Groups and MAP

MAP	Group I (n = 30)	Group II (n = 30)	Group III (n = 30)	p-Value
Baseline Mean SD	89.2 5.57	92.3 7.11	90.3 6.93	0.19
HP (VP given) Mean SD	62.2 7.69	62.1 7.47	61.4 7.33	0.89
2mts after VP Mean SD	74.6 13.38	83.7 7.60	83.3 11.7	0.003*
4-mts Mean SD	81.0 13.28	71.8 5.95	82.8 13.31	<0.001*
6-mts Mean SD	80.6 10.11	80.9 8.47	82.1 10.74	0.83
8-mts Mean SD	80.2 8.11	83.1 6.79	82.5 12.50	0.46
10-mts Mean SD	81.2	84.4	84.2	0.35

	8.43	9.46	10.11	
15-mts Mean SD	80.8 8.42	84.2 9.09	83.9 9.00	0.26
20-mts Mean SD	80.5 6.82	84.8 8.13	84.9 9.07	0.054
25-mts Mean SD	N = 2979.6 7.68	N = 3085.3 9.65	N = 3083.9 8.66	0.04*
30-mts Mean SD	N = 2882.0 7.03	N = 3085.4 9.16	N = 2986.6 8.40	0.10

*Statistically Significant

The mean differences in MAP values between the three groups were statistically significant at 2-mts ($p = 0.003$), 4 mts ($p < 0.001$) and 25-mts ($p = 0.04$). The pair wise comparisons between Group I and Group II were statistically significant at 25-mts ($p = 0.02$) and between Group I and Group III at 30-mts ($p = 0.03$).

Discussion

Haemodynamic Variables

Heart Rate

In our study, the mean value of heart rate was generally highest in Mephentermine Group followed by Ephedrine and Phenylephrine Groups. Also, the mean variation of heart rate between the three groups was statistically significant at 2 mts. Pair wise comparison between the three groups were also statistically significant between the three groups at 2 minutes after administration of the vasopressor. In spinal anaesthesia, since there is decreased venous return, decreased venous pressure and a decreased right heart pressure thus slowing of the heart rate is expected on the basis of the brain bridge reflex. Bradycardia is also expected in high spinal, probably due to some paralysis of the cardio-accelerator nerves. We found that the maternal heart rate was slower with phenylephrine than with ephedrine and mephentermine. This is consistent with the mechanism of action of these drugs that the decrease in heart rate found in phenylephrine group was due to pure α receptor activity compared with ephedrine and mephentermine as they had

got a mixed action directly as well as indirectly on α and β receptors. Similar results were seen in many studies which was consistent with our study.

In the study, done by Dinesh Sahu et al. [4] Phenylephrine was found to cause significant reduction in heart rate after the bolus dose. In the quantitative systematic review done by Anna Lee et al. [5] they found that maternal bradycardia was more likely to occur with phenylephrine than with ephedrine. Also, Thomas DG et al. [6] on comparing the efficacy of bolus ephedrine and phenylephrine, they found that mean maximum percentage change in maternal HR was larger in phenylephrine group than in the ephedrine group. As a consequence, atropine was required in eleven out of eighteen women in the phenylephrine group compared with two out of eighteen women in the ephedrine group.

In the systematic review by Ngan Kee et al. [7] he concluded that phenylephrine may decrease maternal heart rate and cardiac output. In David Cooper et al.'s [8] study on comparing the effects of ephedrine and phenylephrine when administered alone and in combinations they found that mean heart rate was higher in ephedrine group than in the phenylephrine group or the combination. In the study done by Lauckner W et al. [9] the efficacy of IV mephentermine in treating hypotension was studied in 10 late pregnant women undergoing elective LSCS under SAB and they found that heart rate and total peripheral vascular

resistance remain constant.

Kansai A et al. [10] on comparing the effects of IV infusions of ephedrine and mephentermine for maintenance of maternal arterial pressure they found that the baseline haemodynamic parameters, and haemodynamic changes subsequent to the start of vasopressor infusion, were statistically similar in both groups. In Ngan Kee WD et al. [11] study on comparing the effects of prophylactic infusion and bolus phenylephrine they found that heart rate was significantly slower over time in the infusion group compared with the control group.

On comparing the haemodynamic effects of ephedrine alone with ephedrine and colloid for the treatment of hypotension produced by subarachnoid anaesthesia in 30 patients aged 60 – 90 year with fractures of the neck of femur. Critchley LAH et al. [12] they found that in patients receiving ephedrine only, SVRI, CVP and SI decreased, and HR increased and in patients receiving ephedrine and colloid solution, SVRI decreased, and CI, SI and HR increased. They finally concluded that ephedrine was not a potent arterial vasoconstrictor and SAP was maintained mainly by increases in SI and HR.

In the study done by Brooker R F et al. [13] they found that phenylephrine was associated with a decrease in heart rate and in cardiac output. In the study done by Critchley LA et al. [14] Ephedrine was accompanied by increase in HR in 12 % of cases. Yap J C et al. [15] on comparing the efficacy of fluid preloading with IV ephedrine, IM depot ephedrine and metaraminol infusion for maintaining blood pressure they found that heart rate increased by 7% in group receiving IV bolus ephedrine and IM depot ephedrine was effective but was associated with an increase in heart rate.

Blood Pressure

The systolic, diastolic and mean arterial pressure were decreased statistically

significant at the onset of hypotension and increased after the bolus dose of drug in all the three groups. The pressures generally remained high in Mephentermine and Phenylephrine groups when compared with Ephedrine group. Systolic blood pressure was generally highest in Phenylephrine group immediately after the administration. The diastolic blood pressure was also greater in Phenylephrine group when compared with ephedrine and Mephentermine groups, especially after 2nd and 4th minute, after administration of the drug. In ephedrine group, the diastolic blood pressure was generally less throughout the study period, when compared with other two drugs. MAP was also less in ephedrine group when compared with mephentermine and phenylephrine groups. The mean differences in MAP between the three groups were statistically significant at 2nd, 4th and 25th minute after the administration of vasopressor. This finding is consistent with the onset of action and efficacy of the drug that phenylephrine has quicker onset of action and better maintenance of arterial pressures when compared with the other two drugs.

Dinesh Sahu et al. [4] studied the effects of bolus ephedrine, mephentermine, phenylephrine for the maintenance of arterial pressure during spinal anaesthesia for LSCS. In their study, all the three vasopressors effectively maintained arterial pressure within 20 % of baseline value though phenylephrine maintained better in first 6 minutes of bolus dose as compared with ephedrine and mephentermine and phenylephrine has a quicker peak effect. This finding is consistent with our study.

Laporta et al. [16] compared maternal and neonatal catecholamine concentrations, following the use of either bolus phenylephrine or ephedrine to treat a drop in maternal blood pressure after spinal anaesthesia for caesarean section. They found that phenylephrine appears to be

safe and effective as ephedrine in treatment of drop in blood pressure in healthy non-laboring parturient undergoing LSCS Anna Lee et al. [5] in their quantitative systematic review, they found that for the management (prevention and treatment) of hypotension, there was no difference between phenylephrine and ephedrine and both effectively maintained the systolic BP within 20 % of baseline values. Thomas D G et al. [6] in their study compared the efficacy of bolus ephedrine and phenylephrine for maintenance of arterial pressure during spinal anaesthesia for caesarean section and found that maternal systolic BP and cardiac output changes are similar in both groups.

Cyna AM et al. [17] studied the randomized controlled trials comparing the interventions to prevent hypotension during spinal anaesthesia for caesarean section. From 75 trials, they found that ephedrine was significantly more effective than control or crystalloid in preventing hypotension. There were no significant differences between ephedrine and phenylephrine in treating hypotension. Similar results were obtained from our study also. RamNathan et al. [18] assessed the maternal hemodynamic changes and neonatal acid-base status in 127 healthy patients undergoing elective caesarean under epidural anaesthesia and concluded that both ephedrine and phenylephrine increase cardiac pre-load and effectively maintained the systolic blood pressure within 20 % of baseline values.

David Cooper et al. [8] compared phenylephrine 100 µg, ephedrine 3 mg/ml and phenylephrine 50 µg/ml & ephedrine 1.5 mg/ml in combination given by infusion to maintain maternal systemic arterial pressure at baseline during spinal anaesthesia for LSCS and found that the mean systolic arterial pressure was similar in three groups. Lauckner W et al. [9] studied the effects of IV mephentermine in 10 late pregnant women with hypotension

after SAB and found that systolic and diastolic blood pressure increased significantly. The cause of this rise in arterial blood pressure is due to increase in stroke volume exclusively and no significant changes occurred in heart rate. They finally concluded that mephentermine is suitable for the treatment of hypotension during pregnancy.

Kansai A et al. [10] compared the effects of IV infusions of ephedrine and mephentermine for maintenance of maternal arterial pressure receiving subarachnoid block for LSCS and found that baseline hemodynamic parameters, hemodynamic changes subsequent to the start of vasopressor infusion, were statistically similar in both groups. Smith N et al. [19] investigated circulatory effects of single intravenous injections of 0.75 mg/kg mephentermine in five healthy volunteer subjects. They found that first injection of mephentermine increased mean arterial pressure, systemic vascular resistance, and left ventricular minute work, with no change in the other variables.

In the review done by Warwick D et al. [20] they discussed about various measures to prevent and treat hypotension. Recent studies support use of α -agonists such as phenylephrine. Phenylephrine is more effective and can be titrated more easily than ephedrine it may be given as boluses (50 – 100 µg) or by infusion (50 – 100 µg/min). Brooker R F et al. [13] studied sequential infusion of phenylephrine to manage hypotension. In their study also, phenylephrine was effective at restoring systolic blood pressure after spinal anaesthesia. YapJC et al. [15] on comparing the efficacy of fluid preloading with two fluid-vasopressor regimens IV ephedrine boluses was more effective in maintaining systolic blood pressure.

Alahutta S et al. [21] studied the effects of

ephedrine and phenylephrine to maintain the systolic arterial pressure 20 % above the baseline values during spinal anaesthesia for caesarean section. In this study also, both the vasopressors restored maternal arterial pressure effectively.

Side Effects

The heart rate remained generally low in phenylephrine group when compared with ephedrine and mephentermine group. Seven patients developed bradycardia in phenylephrine group compared with five and three patients in ephedrine and mephentermine groups and they were subsequently treated with Inj. atropine 0.3 mg IV bolus. Out of seven patients who developed bradycardia in phenylephrine group, five of them developed bradycardia after the administration of the drug. One patient in ephedrine and mephentermine group developed tachycardia and two patients in ephedrine group developed hypertension. The incidence of tachycardia is more in ephedrine and mephentermine groups than in phenylephrine group. This is due to both direct and indirect action of ephedrine and mephentermine compared with phenylephrine which has only direct α action. This direct action of phenylephrine is also responsible for the increased incidence of bradycardia as seen in our study.

In the quantitative systematic review of seven clinical trials, Anna Lee et al.[5] they found that maternal bradycardia was more likely to occur with phenylephrine than with ephedrine. In a review article by Ngan Kee et al. they found that ephedrine causes maternal tachycardia when compared with phenylephrine which causes decrease maternal heart rate. Cyna AM et al. in their review of 75 clinical trials found that high rates or doses of ephedrine may increase tachycardia incidence.

David Cooper et al. on comparing compared phenylephrine and ephedrine they found that the mean heart rate was

higher in ephedrine group than in the phenylephrine group or the combination group. Lauckner W et al. [22] found that when mephentermine was used to treat hypotension during SAB for LSCS, systolic and diastolic blood pressure increased significantly without changes in heart rate. Smith N et al. investigated circulatory effects of single intravenous injections of 0.75 mg/kg mephentermine in five healthy volunteer subjects. They found that the first injection of mephentermine increased mean arterial pressure, systemic vascular resistance, and left ventricular minute work, with no change in the other variables including heart rate. They finally concluded that for a given increase in arterial pressure, it produces much less drastic changes in other cardiovascular variables.

Mercier FJ et al. [22] in their review concluded that ephedrine has been the vasopressor of choice for long but has a weak prophylactic efficacy and also it can induce maternal cardiovascular adverse effects like tachycardia and hypertension. Also, prophylactic phenylephrine, with or without ephedrine according to maternal heart rate, is at least as effective as ephedrine, with less adverse effects.

Emmett RS et al. [23] also on reviewing 27 trials found that ephedrine is associated with dose-related maternal hypertension and tachycardia. When comparing the hemodynamic effects of ephedrine alone with ephedrine and colloid for the treatment of hypotension Critchley LAH et al. (1995) found that ephedrine was not a potent arterial vasoconstrictor and SAP was maintained mainly by increase in stroke index and heart rate.

On comparing three methods (preloading, infusion of ephedrine and metaraminol) in preventing hypotension during subarachnoid anaesthesia, Critchley LA et al. found that HR was increased in 12 % of patients receiving ephedrine. Yap JC et al. [15] on comparing the efficacy of fluid

preloading with IV ephedrine, IM ephedrine and metaraminol infusion found that heart rate increased by 7 % group receiving IV ephedrine and also in group receiving intramuscular ephedrine.

In our study, 5 % in group - 1, 6 % in group - 11, 3 % in group -1,11 developed nausea and vomiting. There was no significant difference among the three groups in the development of nausea and vomiting.

In Dinesh Sahu et al.'s study, 10 % patients in ephedrine and phenylephrine group and 15 % patients in mephentermine group developed nausea and vomiting. Moran DH et al. [24] also found that there were no significant differences between the ephedrine, phenylephrine groups in the frequency of maternal nausea and vomiting. In Turkoz A et al. study, nausea was observed in one patient (6 %) in the ephedrine infusion group and nausea and vomiting were observed in 10 patients (66 %) in the ephedrine bolus group.

Neonatal Outcome

Casey et al. [24] on their retrospective analysis found that APGAR (activity, pulse, grimace, appearance, respiration) score is comparable to umbilical artery pH in predicting the neonatal outcome. On assessing the APGAR score in our study, two neonates had APGAR of 6 in group – I and II and one neonate in group - III. At 5 mt, no neonate had an APGAR score of less than 7 in all three groups. Moran et al. reported in their study with one neonate with an APGAR of less than 7 in ephedrine group compared with no neonate in the phenylephrine group. However, at 5 mts, no neonate in the ephedrine or phenylephrine groups had an APGAR of less than 7. In the studies done by Thomas et al. Hall PA et al. [25] Alahutta et al. Laporta et al. Ayorinde et al. [26] also same results were obtained. All the neonates had an APGAR of more than 7 at 5 mts in both ephedrine and phenylephrine group. In the study done by

Dinesh Sahu et al. on comparing ephedrine, mephentermine and phenylephrine; they found no untoward effects on fetal outcome. In all the three groups the entire neonate had an APGAR of 7 and more than 7 at 1st and 5th minute. Kansai et al. on comparing the effects of IV infusion of ephedrine and mephentermine found that neonatal APGAR scores are comparable in both the groups.

Dosage Requirements

In Group - I: 70 % of patients required one, 27 % of patients required two and 3 % of patients required three bolus doses to maintain systolic pressure within 20 % limit of basal value. In Group - II: 77 % of patients required one and 23 % of patients required two bolus doses to maintain systolic pressure within 20 % limit of basal value. In Group - III: 90 % of patients required one and 10 % of patients required two doses to maintain systolic pressure within 20 % limit of basal value. Phenylephrine was most effective in treating hypotension followed by mephentermine and then by ephedrine.

Similar results were seen in the study done by Dinesh Sahu et al. with phenylephrine being most effective in treating hypotension on comparing with mephentermine and ephedrine. Thomas D G et al. concluded that in ephedrine and phenylephrine groups median (range) number of boluses of ephedrine and phenylephrine was similar. Kansai A et al. compared the effects of IV infusions of ephedrine and mephentermine and found that the amount of vasopressor required were statistically similar in both groups.

Thus, all the vasopressors effectively maintained the pressures within 25 % of baseline values; Phenylephrine maintained it effectively with fewer doses followed by mephentermine and ephedrine.

Conclusion

All the three vasopressors namely

ephedrine, mephentermine and phenylephrine are effective in IV bolus form in maintenance of maternal arterial pressure within 20 % limit of base line values, though phenylephrine has quicker peak effect, in comparison to ephedrine and mephentermine and it causes reduction in heart rate, which may be advantageous in patients in whom tachycardia is undesirable. All the three vasopressors had no significant adverse effects on neonatal outcome.

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