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Original Research Article

A COMPARATIVE STUDY OF TWO DIFFERENT PROPHYLACTIC DOSES OF PHENYLEPHRINE INFUSION TO PREVENT HYPOTENSION IN ELECTIVE CESAREAN DELIVERY

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ABSTRACT

Background: Spinal hypotension in a parturient can occur precipitously and may contribute significantly to regional anesthesia-related maternal mortality. The primary research within the field of obstetric anesthesia has been about the prevention of spinal hypotension. The objective of the present study is to compare the patients not receiving phenylephrine infusion and those receiving prophylactic phenylephrine infusion of 50 µg/min, and those of 100 µg/min.

Material and Methods: This prospective randomized comparative study done on 75 ASA I and II patients, undergoing elective cesarean section under spinal anesthesia, randomly divided into three groups of 25 each, control group (Group-A), phenylephrine-50mcg group (Group-B), and phenylephrine-100mcg group (Group-C). All the patients were preloaded with 500ml of ringer lactate. According to the group, phenylephrine infusion of 50 µg/min or 100 µg/min was started immediately after spinal anesthesia and continued till baseline vitals were achieved. All the vitals are monitored and studied.

Results: Demographic variables are comparable among the groups. There was a statistically significant difference in mean heart rates between three groups at 5, 10, and 20 minutes point of time for heart rate. There was a statistically significant difference in systolic, diastolic and mean blood pressure between the three groups from 3 minutes to 25 minutes. Hypotension and nausea were more in the control group than in the phenylephrine-50 and phenylephrine-100 groups. Bradycardia and maternal hypertension were more in the phenylephrine-100 group compared to the other two groups. No significant adverse effects in the both the groups.

Conclusion: Prophylactic phenylephrine infusion is an effective and simple method of reducing the incidence and magnitude of spinal hypotension for cesarean delivery compared to the control group. Phenylephrine 50 mcg/min group had comparatively fewer adverse events like hypertension, bradycardia than the phenylephrine 100 mcg/min group.

Keywords: Spinal anaesthesia, hypotension, prophylactic vasopressors, phenylephrine, obstetric anaesthesia,

INTRODUCTION

One of the first exciting and rewarding eras in medicine is the birth of a baby to a conscious and painless mother. Now, the delivery of a baby by a cesarean section has become more and more popular.[1] Owing to low failure rates, minor side effects, and the circumvention of life- threatening risks, spinal anesthesia has become common technique for cesarean section. While spinal anesthesia provides many benefits, such as sensory block, profound muscle relaxation, reduced possibility of aspiration, and a well-awake patient to determine the clinical situation, significant adverse

effects such as hypotension are also associated with it. Hypotension, being the most common intraoperatively, is defined as systolic blood pressure < 90 mm of Hg or mean arterial pressure < 65 mm of Hg or systolic blood pressure < 20% of the patient's baseline value, with a prevalence of up to 71% in women undergoing spinal anesthesia for cesarean delivery. Hypotension is secondary to sympathetic blockade and aortocaval compression of the uterus after the caesarean section due to spinal block. If severe, it can lead to substantial adverse perinatal effects, such as maternal nausea and vomiting, placental blood flow disruption,[2] and fetal acidosis,[3] and may significantly affect neonatal outcomes, and may contribute significantly to regional anesthesia-related maternal mortality. Our understanding of the multiple pathophysiological pathways involved has been enhanced by recent studies, including the use of noninvasive & minimally invasive cardiac output testing.

Steps to minimize maternal hypotension include left uterine displacement, fluid preload, prophylactic vasoconstrictors, Trendelenburg position, etc with varying degree of success. The primary research within the field of obstetric anesthesia has been about the prevention of spinal hypotension. One of the leading methods includes prophylactic administration of intravenous fluids before implementation of subarachnoid block to offset the hypotensive effects of sympathetic blockade by maintaining intravascular volume which is commonly called as pre-loading. The conflicting literary evidence & unequivocal results of the technique of pre-loading has made co-loading, a method of administration of intravenous fluid bolus immediately after the subarachnoid block a preferred choice.[5]

However for both the prevention and control of spinal hypotension, vasopressors are the mainstay of care. Many studies have been focused on the effects of preloading,[6,7] or vasopressors.[8] Phenylephrine, an alpha-1 adrenergic agonist whose action is to counteract a decrease in systemic vascular resistance induced by spinal anaesthesia has been found to be safe and effective when given in IV infusion doses to patients undergoing caesarean section. The present study aims to compare the two different doses of prophylactic phenylephrine infusion with crystalloid preload to prevent hypotension in elective cesarean delivery.

Aims and Objectives of the Study

The aim of the present study is to compare the three groups of patients divided as those not receiving phenylephrine infusion and those receiving prophylactic phenylephrine infusion of 50 µg/min, and those with prophylactic phenylephrine infusion of 100 µg/min.

MATERIAL AND METHODS

The present study was a prospective randomized comparative study conducted on 75 patients coming for elective cesarean sections at Government General Hospital, Ongole, Andhra Pradesh from July 2022 to July 2023 in the Department of Anaesthesiology in Government Medical College, Ongole. An anaesthesiologist performed a pre-anesthetic evaluation of all the patients. Written informed consent was taken from all the patients/guardians of the patients for participation in the study. These were collected and recorded in the proforma prepared for this study purpose.

Patients having normal pregnancy, gestational age beyond 36 weeks, between 18 and 35 years of age, American Society of Anesthesiologists Class I, II status, Weight between 50 and 120 kg, height ranging from 150-180 cm were only included in the study. Patients having contraindications for spinal anaesthesia, complications of pregnancy, pregnancy-induced hypertension, multiple gestations, chronic hypertension, fetal abnormalities, prematurity, clinical evidence of fetal distress, signs of onset of labor, failed spinal anesthesia are excluded from the study. Patients fulfilling the above criteria, undergoing elective cesarean section requiring spinal anesthesia were randomly divided into three groups. Namely,

Study Group-A (Control Group): No prophylactic phenylephrine was given.

Study Group-B: Prophylactic Phenylephrine infusion 50 µg/min.

Study Group-C: Prophylactic Phenylephrine infusion 100 µg/min.

After shifting the patient inside the operation theatre, the following hemodynamic variables were recorded and documented as baseline parameters, such as blood pressure by NIBP (SBP, DBP, MAP) HR, SPO2 on room air, RR and ECG. These parameters were monitored throughout the procedure. An 18-gauge Intravenous (IV) catheter was secured. They were pre-medicated with Inj. Ranitidine 50 mg and Inj. Ondansetron 4 mg intravenously. Preloading with Ringer lactate (500 ml) was done over 15 min, prior to spinal anesthesia for all the patients. The patient was positioned in the left lateral position, and after identification of the appropriate site of injection, the area was painted with povidone-iodine and spirit, and under strict aseptic precautions, the injection area was infiltrated with 2% lidocaine. Using a 25 gauge Quincke's spinal needle, 2 ml of 0.5% hyperbaric bupivacaine was injected in the L3-L4 interspace after ensuring the free flow of cerebrospinal fluid. The patients were immediately turned to the supine position with a wedge of 10 cm below the right buttock. The level of spinal anesthesia was maintained up to T4 to T6.

According to the group, patients received the study drug of either 50 µg/min or 100 µg/min which was infused immediately after the spinal anesthesia and was continued till baseline values were achieved. In the control group, phenylephrine 50-100 µg bolus was given whenever the systolic blood pressure decreased to 20 % of the baseline value and depending on the response of the patient.

The following parameters were recorded and noted. Heart rate and blood pressure at 0 minutes, 3 minutes, and every five minutes after that, the time interval between subarachnoid block to skin incision, skin incision to uterine incision, and uterine incision to deliver the baby, APGAR scores at 1 minute to initiate neonatal resuscitation and at 5 minutes to assess neonatal outcome, the total dose of the phenylephrine used in both groups, total episodes of the hypotension in the control group, the upper level of sensory anesthesia after 5 minutes, incidence of nausea and vomiting, supplemental oxygen requirement, the total duration of surgery, incidence of adverse hemodynamic effects were noted.

After delivery of the baby, blood pressure and heart rate were maintained by infusing fluids and vasopressors, and the umbilical cord was clamped at two ends. Bradycardia was treated with injection atropine 0.6 mg IV if the heart rate was below 50 per minute and persisted for more than 15 minutes duration and symptomatic. Oxygen was supplemented if the oxygen saturation dropped below 95%.

Phenylephrine infusion was made by diluting inj. phenylephrine 10 mg (1ml) to 50 ml of Normal Saline (NS) such that each ml contains 200 µg/ml. Whenever the systolic blood pressure decreased to less than 20% from the baseline, it was considered hypotension, and the infusion was restarted. Infusions were stopped when two subsequent readings were normal. Heart rate greater than 100 beats/min was considered as tachycardia. Episodes of hypotension, hypertension (SBP >20-30% of the baseline value), tachycardia, bradycardia, need for rescue doses of vasopressors, infusion discontinuation, atropine administration and episodes of nausea and vomiting were recorded until the end of caesarean section and if nausea and vomiting occurred, they were treated with ondansetron 4 mg IV. Immediately after the surgery, pulse rate and blood pressure were recorded. Patients were moved to the recovery room, and vitals were recorded at regular intervals of 10 mins for 30 mins. Once the patient is recovered, and the vital functions are stable, patients were transferred to the post-operative ward. In the post-operative ward, the vital parameters were monitored as per hospital protocol. Patients were followed up till discharge.

Statistical Analysis

The data has been entered into MS-Excel, and statistical analysis was done by using IBM SPSS version 25.0. For categorical variables, the data values were expressed as numbers and percentages. To test the association between the groups, the chi-square test was used. For continuous variables, the data values were represented as mean and standard deviation. To test the mean difference between the three or more groups, the ANOVA test was used. All the p-values were having less than 0.05 are considered statistically significant.

RESULTS

Demographic characteristics are comparable between the groups.

Table-1 showed the comparison of mean heart rate (HR) between the groups at different intervals (say, baseline to 30 minutes). It was inferred that there was a statistically significant difference in the heart rate between the three groups at 5 minutes, 10 minutes, and 20 minutes point of time ($P<0.05$), and at other points of time, there was no statistically significant difference ($P>0.05$). [Table 1]

There was a statistically significant difference in SBP,DBP, and MAP between the three groups from 3 minutes to 25 minutes ($P<0.05$), and at other points of time, there was no clinically significant difference ($P>0.05$).No significant changes in the APGAR score at 1 and 5 minutes, respiratory rate and saturation is seen between the groups. [Table 4]

Table-5 showed that adverse events between the groups, In the control group, five patients had nausea, one patient had bradycardia, and five patients had hypotension, one patient had tachycardia. In Group B, four patients had nausea, two patients had bradycardia, and one patient had tachycardia, and 2 patients had hypotension. In the Group C, three patients had nausea, four patients had bradycardia, and eight patients had hypertension. [Table 5]

Table 1: Comparison of mean Heart rate (HR) between the groups

Heart Rate	Control Group (A)	Phenylephrine 50 Group (B)	Phenylephrine- 100 Group (C)
Baseline	81.88 ± 7.87	83.00 ± 7.56	82.92 ± 7.51
0 min	82.92 ± 8.88	82.28 ± 7.74	81.76 ± 8.23
3 min	82.96 ± 9.38	81.08 ± 7.64	81.84 ± 8.47
5 min	88.96 ± 5.84	83.28 ± 9.17	80.60 ± 7.66
10 min	85.52 ± 6.89	83.84 ± 7.10	80.16 ± 6.52
15 min	84.84 ± 9.20	82.12 ± 9.09	78.96 ± 9.46
20 min	85.08 ± 9.17	81.80 ± 9.46	78.00 ± 8.49
25 min	84.64 ± 9.44	78.92 ± 7.85	82.08 ± 9.11
30 min	84.48 ± 7.42	79.84 ± 6.95	82.36 ± 8.95

Table 2: Comparison of mean Systolic blood pressure (SBP) between the groups

SBP	Control Group (A)	Phenylephrine- 50 Group (B)	Phenylephrine- 100 Group (C)
Baseline	111.44 ± 4.76	111.56 ± 4.62	113.64 ± 5.92
0 min	118.72 ± 8.04	123.2 ± 12.82	126.00 ± 11.90
3 min	110.96 ± 4.54	125.04 ± 8.10	142.08 ± 14.99
5 min	108.64 ± 4.35	112.36 ± 8.22	136.40 ± 12.87

10 min	110.40 ± 3.35	108.04 ± 5.65	130.08 ± 11.65
15 min	109.04 ± 3.69	111.56 ± 5.59	124.56 ± 12.71
20 min	109.40 ± 4.10	112.08 ± 5.04	120.88 ± 10.89
25 min	110.28 ± 4.25	112.28 ± 6.19	116.60 ± 7.73
30 min	110.32 ± 3.57	110.28 ± 6.35	112.36 ± 6.86

Table 3: Comparison of mean diastolic blood pressure (DBP) between the groups

DBP	Control Group (A)	Phenylephrine- 50 Group (B)	Phenylephrine- 100 Group (C)
Baseline	69.44 ± 6.42	72.12 ± 4.77	73.20 ± 6.93
0 min	70.24 ± 6.89	74.20 ± 7.61	74.84 ± 8.06
3 min	67.16 ± 6.03	75.84 ± 5.67	80.64 ± 5.91
5 min	67.44 ± 4.20	74.72 ± 8.05	83.56 ± 4.66
10 min	66.96 ± 4.13	72.16 ± 4.88	78.48 ± 6.84
15 min	63.48 ± 5.16	68.20 ± 4.01	74.16 ± 5.39
20 min	64.92 ± 5.76	70.24 ± 6.19	71.92 ± 5.75
25 min	65.16 ± 4.77	71.04 ± 5.86	71.88 ± 5.70
30 min	66.20 ± 6.06	69.64 ± 7.73	71.16 ± 8.47

Table 4: Comparison of Mean Arterial Pressure (MAP) between the groups

MAP	Control Group (A)	Phenylephrine- 50 Group (B)	Phenylephrine- 100 Group (C)
Baseline	83.52 ± 4.83	85.40 ± 3.80	86.64 ± 5.35
0 min	86.40 ± 5.38	88.32 ± 6.00	89.84 ± 3.58
3 min	81.72 ± 4.04	92.12 ± 5.04	101.08 ± 5.15
5 min	81.12 ± 2.98	87.28 ± 6.24	101.12 ± 4.75
10 min	81.52 ± 3.02	84.08 ± 3.66	95.68 ± 6.34
15 min	78.68 ± 3.12	82.72 ± 3.86	91.00 ± 5.49
20 min	79.80 ± 3.76	84.12 ± 3.76	88.28 ± 4.48
25 min	80.20 ± 3.82	84.80 ± 4.21	86.24 ± 5.19
30 min	80.88 ± 4.19	82.64 ± 5.86	84.44 ± 6.21

Table 5: Adverse events between the groups

Adverse events	Control Group (A)	Phenylephrine-50 Group (B)	Phenylephrine-100 Group (C)
Nausea	5 (20.0%)	4 (16.0%)	3 (12.0%)
Vomiting	0 (0.0%)	0 (0.0%)	0 (0.0%)
Bradycardia	1(4.0%)	2(8.0%)	4 (16.0%)
Tachycardia	1 (4.0%)	1 (4.0%)	0 (0.0%)
Maternal Hypotension	5(20.0%)	2 (8.0%)	0 (0.0%)
Hypertension	0(0.0%)	0(0%)	8(32.0%)

DISCUSSION

Spinal Hypotension is associated with a near fall in uterine blood flow and placental perfusion leading to fetal hypoxemia and acidosis if not promptly treated. Prophylaxis against rather than treatment of spinal anesthesia-induced hypotension is essential not only in the interests of fetal well-being but also of the mother.

Demographic variables are comparable between the groups. In this study, the mean heart rate was highest in the control group, followed by the phenylephrine-50 group followed by the phenylephrine-100 group. The mean variation of heart rate between the three groups and pair-wise comparison between the three groups were statistically significant at 5 and 10, and 20 minutes and at other points of time, there was no statistical significance. Bradycardia was seen more with the phenylephrine 100 group than the other two groups in our study. 4(16%) patients in the phenylephrine 100 group had bradycardia, whereas 2(8%) patients in the phenylephrine 50 group and 1(4%) in the control group had bradycardia. 1(4%) patient in each of phenylephrine 50 group and control group had tachycardia.

In a study of Ngan Kee et al. (2004a),[9] by comparing the effects of prophylactic infusion & bolus phenylephrine, they found that heart rate was significantly slower overtime in the infusion compared with the control group. Moreover, HR increased after the phenylephrine infusion was stopped, and no patient required treatment with atropine. Our study correlated with this study regarding decreases in heart rate in phenylephrine infusion groups compared to the control group. No treatment was given in our study for bradycardia with phenylephrine infusion as the heart rate increased after the infusion was stopped.

In a study of Stewart et al. (2010),[10] HR decreased significantly with time in all groups (P=0.001). Compared with baseline values, the reductions in HR at 20 minutes were 8, 12, and 22 bpm in groups 25, 50, and 100 respectively. There were significant concentration- dependent reductions in HR. At all-time points from the start of the phenylephrine infusion, the HR was the most rapid in group-25 and lowest in group-100. Hence, dose- dependent drop in HR was associated with continuous infusion of phenylephrine during spinal anesthesia for cesarean delivery. Whereas in our study, heart rate reductions were more significant with the phenylephrine 100 group than in other groups. In this way, our study correlated with this study.

In a study of Jaitawat et al. (2019),[11] the mean heart rate was significantly lower in the phenylephrine-100 group than the phenylephrine-75 group and the control group. Our study correlated with this study in respect of lower heart rate in the phenylephrine 100 group. Hence, the findings in our study are following the study.

In our study, blood pressure was significantly higher in the Group C, followed by the Group B and Group A from 3-minutes to 25-minutes after the administration of phenylephrine. At 5-minutes, the blood pressure of the Group B reached the baseline, and infusion was stopped, and restarted in two (8.0%) cases where hypotensive episodes occurred at ten and 15-minutes of time, respectively, and was continued till baseline values were reached. In Group C, at 3-minutes, baseline values were reached, and the infusion was stopped. And in eight (32.0%) cases, hypertensive episodes were noted at 3-minutes. Blood pressure returned to baseline in 10 minutes in 5 patients,15 minutes in 2 patients, 20 minutes in 1 patient. In the control group, 5 (20.0%) patients had hypotension after spinal anesthesia for which rescue bolus doses of phenylephrine-100 mcg was given. Baseline values were attained within 2 to 5 minutes after bolus dose.

Ngan Kee et al. (2004a),[9] found that the prophylactic phenylephrine infusion is a simple, safe, & effective method of maintaining arterial blood pressure during spinal anesthesia for cesarean delivery. Serial analysis of hemodynamic changes showed that blood pressure was significantly greater overtime in the infusion group than in the control group and the hypotension was delayed & occurred after the initial infusion was stopped whereas the control group had more incidence and more episodes of hypotension, which were corrected following phenylephrine 100 µg bolus injection.

In a study of Ngan Kee et al. (2004b),[12] blood pressure was higher in Group 100 compared with Group 80 (P<0.001) and Group 90 (P=0.009). The incidence of reactive hypertension was similar among groups. They concluded that the phenylephrine should be titrated to maintain maternal BP at near-baseline values for optimal management. Our study also got higher blood pressure values with the phenylephrine 100 group compared to other groups.

In a study by Stewart et al. (2010),[10] the 100, 75, 50, 25 µg of phenylephrine are compared and found that even though statistically significant, the difference among groups at any time point was <15 mmHg and therefore less than the clinically significant minimum difference of 20% as demanded by the protocol. Overall, blood pressure was 6% higher (P=0.049) in group 100 compared with group 25. There were no significant clinical deviations of blood pressure among the groups (P<0.05). The number of minutes blood pressure was recorded as an above baseline was significantly higher in group 100 (P=0.01).

In a study of Jaitawat et al. (2019),[11] the mean of SBP was significantly higher in the phenylephrine-100 group, the phenylephrine-75 group, and the control group.

In the present study, all three groups were compared to APGAR score at 1 and 5 minute. There was no clinical and statistically significant difference between the groups for the APGAR scores similar to the studies done by Ngan Kee et al. (2004a),[9] Das et al. (2011),[13] Vakili et al. (2017),[14] and Jaitawat et al. (2019),[11] No clinically and statistically significant differences seen between the groups in respiratory rate and saturations similar to all the previous studies.[9,13,14,11]

Four patients (16%) developed bradycardia in the phenylephrine-100 group compared with two (8%) and one (4%) patients in the phenylephrine-50 group and control group, respectively, for which phenylephrine infusion was stopped and monitored. One patient (4%) in the control and phenylephrine-50 group respectively developed tachycardia, which is statistically not significant which might have occurred due to various factors like anxiety. One patient (4%) in the control group, two patients (8%) in the phenylephrine- 50 group, and four patients (16%) in the phenylephrine-100 group had bradycardia after spinal anesthesia. In control group inj. atropine 0.6 mg IV was given, whereas, in phenylephrine-50 and 100 groups, heart rate returned to baseline after stopping the infusion.

Eight (32%) patients in the phenylephrine-100 group developed hypertension after initiation of infusion, which returned to baseline 15-20 minutes after discontinuation of the infusion. Hypertension was not recorded in the other two groups. In this study, 5 (20%) patients in the control group, 4 (16%) patients in the phenylephrine-50 group, and 3 (12%) patients in the phenylephrine-100 group developed nausea. There was no major difference among the three groups in the development of nausea. No patient experienced vomiting in all three groups. The above shows that the adverse events occurred low in the phenylephrine- 50 compared to the control and phenylephrine-100 groups in the present study. In a study of Ngan Kee et al. (2004a) 9, the difference in the incidence of nausea & vomiting between groups was not statistically significant (P>0.05).

In a study of Ngan Kee et al. (2004b),[12] in phenylephrine group-100, 4% patients had nausea or vomiting than 16% in the phenylephrine group-90 and 40% in the phenylephrine group-80. Our study is comparable to this study as nausea was comparatively less in the phenylephrine 100 group than in other groups. Inj. Ondansetron 4 mg i.v was given in our study to alleviate nausea.

Allen TK et al. (2010) 15 compared the four different infusion rates of phenylephrine: 25, 50, 75, 100 µg/min, and a control group. A higher incidence of predelivery hypotension was observed in the control group (80%) compared with patients receiving phenylephrine infusions of 50 (15%), 75 (11%), and 100 µg/min (0%). The frequencies of hypertensive episodes reported were more significant for patients receiving 75 and 100 µg/min than those receiving

lower infusion rates. There were no major differences among groups concerning the incidence of intraoperative nausea, vomiting, and the need for rescue antiemetics. However, phenylephrine at a dose of 100µg/min significantly reduced the incidence of hypotension-induced nausea when compared with the control group. Our study correlates with this study, given a lower incidence of nausea with phenylephrine 100 group than other groups.

In a study of Jaitawat et al. (2019),[11] there was no statistically significant difference in the incidence of nausea, vomiting, headache, and patients with bradycardia were higher in the phenylephrine-100 group than the phenylephrine-75 group and the control group.

This study confirmed the clinical impression that starting a prophylactic infusion of phenylephrine immediately after the initiation of spinal anesthesia for cesarean delivery would be effective at reducing the incidence, frequency, and severity of hypotension without significant adverse events.

The study was designed to be as simple as possible, with one criterion for starting and stopping the infusion & one set infusion rate. Of note, in the infusion group with one or more hypotension episodes, the hypotension happened after the initial infusion was stopped. In these cases, even though the infusion was restarted when blood pressure decreased to less than baseline because phenylephrine has latency for effect, transient hypotension occurred.

Limitations of the study

It is difficult to appeal a decision from this small number of subjects and extrapolate it on the entire population because many patient factors, surgical factors, and fetal factors affect this change. Many more studies need to be conducted comparing the two different doses of phenylephrine infusion to prevent hypotension in elective cesarean delivery. Researches are to be conducted further to throw light on other alternatives of prevention of hypotension.

CONCLUSION

In conclusion, these data suggest that a prophylactic phenylephrine infusion is an effective and simple method of reducing the incidence and magnitude of hypotension during spinal anesthesia for cesarean delivery compared to the control group.

Phenylephrine 50 mcg/min group had comparatively fewer adverse events like hypertension, bradycardia than the phenylephrine 100 mcg/min group. Baseline values of systolic blood pressure, diastolic blood pressure, mean arterial pressure, and heart rate was achieved earlier in the phenylephrine 100 mcg/min group when compared to the other two groups.

Conflicts of interest: Nil

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