

A COMPARATIVE STUDY OF PROPHYLACTIC INTRAVENOUS BOLUS NOREPINEPHRINE, PHENYLEPHRINE AND MEPHENTERMINE FOR MAINTENANCE OF BLOOD PRESSURE DURING SPINAL ANAESTHESIA FOR CAESAREAN SECTION

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ABSTRACT

Background: Caesarean section delivery has seen a significant rise globally. Regional anaesthesia in the form of spinal anaesthesia is considered the first choice of anaesthesia in uncomplicated c-section cases for safe maternal and neonatal outcomes. Although SA is generally well tolerated, it is still associated with considerable side effects, the most common of which is maternal hypotension, which occur in about 80–90% of cases. Hypotension during SA for Caesarean delivery can have detrimental effects on both mother and neonate. The administration of vasopressors is a crucial method for preventing and treating hypotension. However, the best agent to use in any particular situation is unknown given the diversity of agents that are available globally. The objectives of the study were to compare the effectiveness of norepinephrine, mephentermine and phenylephrine on maintenance of arterial blood pressure during SA in CS and also to estimate the incidence of adverse effects and unwanted complications in both mother and baby. **Materials and Methods:** A double-blinded, randomized controlled study was conducted in the Department of Anaesthesiology, JNIMS, Porompat, Manipur during the period June 2023–June 2024. The study included 120 willing patients aged 18–40 years, categorized as ASA II who underwent elective Lower Segment CS (LSCS) under SA. They were categorized into 03 groups: Group A, Group B, and Group C using restricted block randomization with a block size of 38. Patients received the assigned study drug based on their allocated group as (1) Group A received 4 µg of norepinephrine (2) Group B received 50 µg of phenylephrine and (3) Group C received 3 mg of mephentermine. On arrival at the operating theatre, baseline vital signs were recorded after applying standard monitors. Preloading and premedication were done as per the institutional guidelines. Then, as per the group allocation, the assigned study drug was administered intravenously immediately after SA. All patients were monitored continuously, and parameters were recorded every 2 minutes until delivery and then every 5 minutes until the end of surgery. Whenever hypotension occurred, the assigned study drug was administered intravenously. The number of boluses required and the time taken to recover from hypotension were documented. **Result:** Regarding hemodynamic parameters, the SBP values showed variations across groups, but no significant differences were observed at most time points of observation. At baseline, the mean DBP was 78.68 ± 5.404 mmHg in Group A, 79.08 ± 5.151 mmHg in Group B, and 74.98 ± 7.813 mmHg in Group C, with a statistically significant difference ($p = 0.007$). Throughout the recorded intervals, significant differences in DBP were observed. Significant differences in MAP were observed at multiple time points: 2, 6, 8, 10, 35, 40 and 45 minutes. Also, significant differences in PR were observed at multiple time points except at 45 minutes. Hypotension was encountered in all the three groups (Group A=09, Group B=06 and Group C=12) and the difference was found to be

statistically significant ($p=0.001$). **Conclusion:** This study compared the effects of different vasopressors on maternal hemodynamics during SA for CS. The findings align with existing literature, confirming that both phenylephrine and norepinephrine are effective in maintaining blood pressure, though they exhibit different hemodynamic profiles. Phenylephrine demonstrated superior blood pressure stability but was associated with a higher incidence of bradycardia, requiring atropine in some cases.

INTRODUCTION

Caesarean section (C-section) delivery has seen a significant rise globally, and India is no exception to this trend. According to the latest National Family Health Survey (NFHS-5), the national C-section rate in India has risen to 21.5%, surpassing the World Health Organization's recommended range of 10-15%.^[1]

Globally, regional anaesthesia (RA) in the form of spinal anaesthesia (SA) is considered the first choice of anaesthesia in uncomplicated c-section cases for safe maternal and neonatal outcomes.^[2]

There are obvious advantages of regional anaesthesia over general anaesthesia, including avoiding the problem of a difficult airway, avoidance of multiple drugs required for general anaesthesia as well as allowing the parturient to be awake to witness the delivery of her baby thus enabling her to participate and enjoy the birthing experience.^[3]

Although SA is generally well tolerated, it is still associated with considerable side effects, the most common of which is maternal hypotension, which occur in about 80–90% of cases.^[4] Hypotension during SA for Caesarean delivery can have detrimental effects on both mother and neonate; these effects include decreased uteroplacental blood flow, impaired fetal oxygenation with asphyxial stress and fetal acidosis, depressed APGAR score and maternal symptoms of low cardiac output, such as nausea, vomiting, dizziness, and decreased consciousness.^[5]

It is stated by the Cochrane review published in 2017 that no single drug or technique is ideal or gold standard in preventing subarachnoid block (SAB) induced maternal hypotension.^[6] Studies have proved that preload or coload has limited efficacy in preventing maternal hypotension.^[5]

The administration of vasopressors is a crucial method for preventing and treating hypotension. However, the best agent to use in any particular situation is unknown given the diversity of agents that are available globally. Therefore, convenience, institutional availability, or clinical dogma are still factors that determine the choice of a vasopressor.^[7] Mephentermine (a mixed sympathomimetic with mainly indirect stimulation) is one of the most used drugs in our institute and India. It is a mixed sympathomimetic amine that acts both directly and indirectly via an action on α and β -adrenergic receptors. It has both cardiac and peripheral actions.^[8] It has a prominent β -receptor and a weak α -receptor stimulant effect and increases the blood pressure mainly by augmenting the cardiac output.^[9]

Norepinephrine, a potent α -agonist and a weak β -agonist, commonly used in septic shock has been showing promising results in many studies for spinal anaesthesia-induced hypotension (SAIH) with respect to maternal haemodynamic stability.^[10] It is a naturally occurring catecholamine. It stimulates the α and β receptors in the sympathetic nervous system. It may be a more suitable option for maintaining blood pressure with less negative effects on heart rate (HR).^[11]

Phenylephrine is a directly-acting sympathomimetic drug and a selective α -1 adrenergic agonist.^[12] This increases systolic blood pressure by peripheral vasoconstriction and causes baroreceptor-mediated reflex bradycardia in a dose dependent manner.^[13]

Aim & Objectives

The study was conducted to compare the efficacy and safety of prophylactic intravenous bolus norepinephrine, phenylephrine, and mephentermine in maintaining arterial blood pressure during Spinal Anaesthesia for Caesarean Section, while also assessing their associated maternal and neonatal outcomes. The specific objectives were to compare the effectiveness of norepinephrine, mephentermine and phenylephrine on maintenance of arterial blood pressure during SA in CS and also to estimate the incidence of adverse effects and unwanted complications in both mother and baby.

MATERIALS AND METHODS

A double-blinded, randomized controlled study was conducted in the Department of Anaesthesiology, Jawaharlal Nehru Institute of Medical Sciences, Porompat, Manipur during the period June 2023-June 2024. The study included willing patients aged 18-40 years, categorized as ASA II who underwent elective Lower Segment CS (LSCS) under SA. Patients with complicated obstetric conditions, including pregnancy-induced hypertension (PIH), pre-eclampsia, antepartum hemorrhage, and placenta previa, co-existing cardiac conditions, spinal deformities or local infection near the injection site, history of allergy to any of the study drugs, abnormal coagulation profile or any condition that is a contraindication to SA were excluded.

Based on a reference study with systolic blood pressure values of 103.87 ± 8.90 and 98.63 ± 7.30 , the estimated effect size was calculated. At a power of 80% and a significance level (p -value) of 0.05, the required sample size was determined to be 38 per group. To ensure adequacy, we selected a sample size of 40 per group. All eligible patients were

consecutively recruited until the calculated sample size was achieved.

The study population was categorized into three groups: Group A, Group B, and Group C using restricted block randomization with a block size of 38. Patients received the assigned study drug based on their allocated group as (1) Group A received 4 µg of norepinephrine as an IV bolus in a 2 mL syringe, (2) Group B received 50 µg of phenylephrine as an IV bolus in a 2 mL syringe and (3) Group C received 3 mg of mephentermine as an IV bolus in a 2 mL syringe.

Procedure and data collection

A detailed pre-anaesthetic check-up was performed for all participants, including a comprehensive history, physical examination, and required laboratory investigations. All patients were advised overnight fasting before the procedure.

On arrival at the operating theatre, baseline vital signs were recorded after applying standard monitors such as non-invasive blood pressure, pulse oximeter, and electrocardiogram. Preloading was done with Ringer's lactate (15 mL/kg) 20 minutes prior to the spinal block. Premedication was administered with an intravenous injection of Ondansetron (4 mg) before the spinal block.

SA was performed with the patient in the lateral position, under strict aseptic conditions, using a 25G Quincke needle at the L3-L4 or L2-L3 interspace. A total of 2.0 mL of local anaesthetic solution was administered, consisting of 1.7 mL of 0.5% hyperbaric bupivacaine and 0.3 mL (15 mcg) of fentanyl. After the block, the patient was positioned supine with a wedge under the right buttock. Supplemental oxygen was provided via face mask at a flow rate of 5 L/min.

The highest level of sensory blockade achieved was assessed. As per the group allocation, the assigned study drug was administered intravenously immediately after SA.

All patients were monitored continuously, and parameters were recorded every 2 minutes until delivery and then every 5 minutes until the end of surgery. Whenever hypotension occurred, the assigned study drug was administered intravenously. The number of boluses required and the time taken to recover from hypotension were documented.

The study variables were systolic and diastolic blood pressures, mean arterial pressure, heart rate, peripheral oxygen saturation (SpO₂), Apgar score and maternal adverse effect (nausea and vomiting). Hypotension after SA was defined as fall in systolic BP > 20% from the baseline value or a value < 90 mmHg. And significant bradycardia was defined as heart rate < 50 BPM.

Bradycardia was treated with an IV injection of atropine (0.6 mg). Any maternal side effects, including nausea, vomiting, or other adverse effects, were recorded and managed accordingly.

Neonatal outcomes were assessed using the Apgar score at the 1st and 5th minutes after birth.

Data collected were entered into an MS Excel sheet and later on transported to SPSSv23 for analysis. Descriptive data are presented using mean (SD) and proportions. To determine whether the difference between the findings of any two tests was statistically significant, Paired t-test and Chi-square (χ^2) test wherever appropriate. A p value of less than 0.05 was considered as statistically significant. Ethical clearance for the study was obtained from the Institutional Ethical Committee (IEC), JNIMS, Imphal.

RESULTS

Completed data sets could be collected from 120 study participants (40 each in the three groups). There were no statistically significant differences regarding age ($p=0.171$) and sex ($p=0.006$) among the three arms of intervention. All participants in Groups A, B, and C had a spinal block at the T4 level.

Hemodynamic parameters: At baseline, the mean SBP was 125.15 ± 9.203 mmHg in Group A, 122.85 ± 8.83 mmHg in Group B, and 122.25 ± 8.114 mmHg in Group C. The difference among the groups was not statistically significant ($p = 0.296$).

Throughout the recorded intervals, the SBP values showed variations across groups, but no significant differences were observed at most time points. [Figure 1]

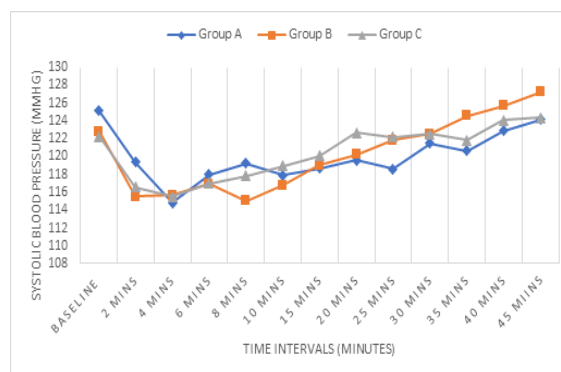


Figure 1: Trend of Systolic Blood Pressure Over Time Across Study Groups

At baseline, the mean DBP was 78.68 ± 5.404 mmHg in Group A, 79.08 ± 5.151 mmHg in Group B, and 74.98 ± 7.813 mmHg in Group C, with a statistically significant difference ($p = 0.007$). Throughout the recorded intervals, significant differences in DBP were observed at several time points and at these intervals, the p-values were below 0.05, indicating a statistically significant difference in DBP among the groups. However, at other time points at 4, 20, 25 and 30 minutes, the differences were not statistically significant ($p > 0.05$). [Figure 2]

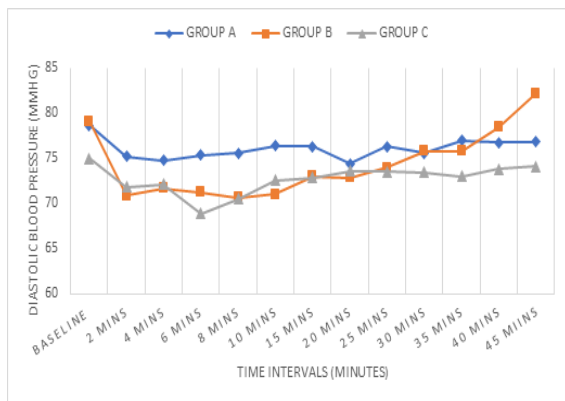


Figure 2: Trend of Diastolic Blood Pressure over Time Across Study Groups.

Table 1: Mean Arterial Pressure (MAP) Over Time

MAP	Group A	Group B	Group C	p value
baseline MAP	94.17 ± 4.79	93.67 ± 4.856	90.73 ± 5.865	0.008
2 mins	89.97 ± 7.205	85.78 ± 6.047	86.75 ± 7.839	0.024
4 mins	88.12 ± 7.461	86.57 ± 8.522	86.61 ± 8.534	0.629
6 mins	89.57 ± 7.011	86.5 ± 4.317	84.92 ± 10.138	0.022
8 mins	90.13 ± 6.149	85.48 ± 4.628	86.29 ± 7.762	0.003
10 mins	90.22 ± 6.857	86.28 ± 4.407	88.02 ± 6.523	0.016
15 mins	90.46 ± 6.024	88.34 ± 3.761	88.62 ± 8.155	0.261
20 mins	89.47 ± 6.216	88.65 ± 4.356	89.96 ± 5.341	0.546
25 mins	90.42 ± 6.138	89.95 ± 3.744	89.76 ± 5.862	0.852
30 mins	90.87 ± 5.406	91.38 ± 4.439	89.81 ± 5.488	0.381
35 mins	91.51 ± 4.776	92.06 ± 4.272	89.29 ± 5.656	0.033
40 mins	92.14 ± 4.518	94.22 ± 3.435	90.59 ± 4.412	0.001
45 mins	92.6 ± 5.643	97.19 ± 3.58	90.9 ± 6.162	<0.001

At baseline, the mean MAP was 94.17 ± 4.79 mmHg in Group A, 93.67 ± 4.856 mmHg in Group B, and 90.73 ± 5.865 mmHg in Group C, with a statistically significant difference ($p = 0.008$). Throughout the recorded intervals, significant differences in MAP were observed at multiple time points: 2, 6, 8, 10, 35, 40 and 45 minutes. At these time points, the p-values were below 0.05, indicating statistically significant differences in MAP among the groups. [Table 1] At baseline, the mean PR was in the three groups was comparable ($p = 0.878$). However, significant differences in PR were observed at multiple time points except at 45 minutes. [Figure 3]

Adverse effects: Regarding occurrence of adverse effects, 02 patients in Group A and 06 in Group C developed nausea. Further, 02 patients in Group C

had vomiting. Two patients in Group B developed bradycardia. [Table 2]

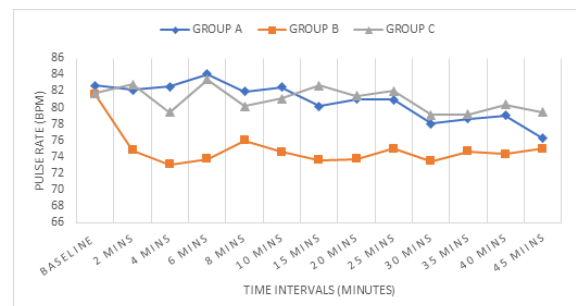


Figure 3: Trend of Pulse Rate Over Time Across Study Groups.

Table 2: Incidence of Hypotension among Study Participants

Incidence of hypotension	GROUPS			Total	P Value
	A	B	C		
Yes	9	6	12	27	0.001
No	31	34	28	93	

The optimal time for rescue bolus administration of assigned study drug in hypotension following SA was analysed at different time intervals (2, 4, 6, 8, 10, and 15 minutes). There was statistically significant difference among the three groups ($p=0.393$). Atropine injection was needed for 02 patients in Group B but none in Group A or C.

Regarding fetal outcome, the mean APGAR score at 1min and 5 min remained comparable in all the groups. It was 9 in all the three groups.

DISCUSSION

The literature extensively compares norepinephrine, phenylephrine, and mephentermine in managing hypotension during SA for CSs. These vasopressors

are widely used to stabilize blood pressure and heart rate, but their specific hemodynamic effects vary. Our study aimed to evaluate and compare these effects across different groups.

Several studies have demonstrated that norepinephrine, phenylephrine, and mephentermine influence systolic and diastolic blood pressure differently. Singh et al., Shah et al, and Xu et al reported that variations in systolic and diastolic BP between norepinephrine and mephentermine, as well as between phenylephrine and other vasopressors, were comparable, with no major differences noted.^[14-16]

In our study, SBP variations were observed across Groups A, B, and C at different time intervals. However, no significant differences were found at most time points, except at SBP 35 ($p = 0.050$), indicating borderline statistical significance. This suggests that while all vasopressors effectively maintain SBP, minor fluctuations may occur, potentially impacting patient stability during surgery. Regarding DBP, Mohta et al and Ngan Kee et al reported significant differences between norepinephrine and phenylephrine.^[10,17] On the other hand, Sharkey AM et al and Magalhaes et al observed more stability in DBP with norepinephrine use.^[18,19] Our study supports these findings, as significant DBP differences were noted at multiple time points ($p < 0.05$), emphasizing the distinct hemodynamic responses of each vasopressor.

Phenylephrine has been shown to maintain blood pressure more effectively than mephentermine. Studies by Lakshmi Mahajan et al, Preet M Singh et al, and Neerja Bhardwaj et al confirm this,^[20-22] and our study corroborates their findings. Significant MAP differences were observed at multiple time points, specifically at 2, 6, 8, 10, 35, 40, and 45 minutes ($p < 0.05$), highlighting the superior efficacy of phenylephrine in stabilizing MAP. This is crucial for maintaining uteroplacental perfusion during CSs. Heart rate variability among vasopressors has been widely studied. Modak A et al, Renu W et al, and Thomas D.G. et al found that phenylephrine induces significant bradycardia, whereas mephentermine increases HR due to its β -agonist properties.^[23-25] Our study supports these conclusions, as significant differences in pulse rate (PR) were observed at multiple time points, except at PR 45 ($p = 0.070$).

Additionally, reflex bradycardia has been reported as a dose-dependent effect of phenylephrine by Sharkey AM et al and Lee HM et al,^[18,26] our study found two cases of bradycardia in Group B ($p < 0.001$), aligning with these previous reports.

The incidence of intraoperative nausea and vomiting (IONV) is a critical concern in CS anaesthesia. Balki M et al found that phenylephrine significantly reduces IONV compared to mephentermine.^[27] Our study mirrors these findings, as nausea incidence was highest in Group C (15%), compared to Group A (5%) and Group B (0%) ($p < 0.001$). These results suggest that the vasopressor used in Group C may not be as effective in preventing IONV.

Regarding vomiting, our study identified two cases (5%) in Group C, which is consistent with the findings of Ronald B. George et al.^[28] Their study concluded that phenylephrine infusion is more effective in reducing IONV than bolus administration, supporting the benefits of continuous vasopressor infusion strategies.

Hypotension remains a significant concern during SA. In our study, hypotension was most frequent in Group C (30%), followed by Group A (22.5%) and least in Group B (15%) ($p < 0.001$). These results align with findings from Sarika Sudhir Lonkar et al and Xian Wang et al, who concluded that norepinephrine and phenylephrine provide better hypotension control than mephentermine.^[29,30]

Interestingly, no significant differences were observed in injection timing across the three groups ($p = 0.393$), suggesting that the onset of hypotension was similar regardless of the vasopressor used. This is consistent with reports from Ngan Kee et al and Mohta et al, who noted comparable onset times for hypotension with different vasopressors.^[7,10]

Atropine was required in two cases in Group B ($p < 0.001$). Our finding supports studies by Lee HM et al and Kamalakannan M et al, which reported that phenylephrine-related bradycardia occasionally necessitates atropine administration.^[26-31]

In our study, all three groups had identical APGAR scores of 9 at both 1 minute and 5 minutes, with no significant difference. This indicates that norepinephrine, phenylephrine, and mephentermine had no adverse effects on neonatal well-being immediately after birth. These findings align with previous research suggesting that all three vasopressors are safe for fetal health when used for maternal blood pressure management during CSs.

CONCLUSION

This study compared the effects of different vasopressors on maternal hemodynamics during SA for CS. The findings align with existing literature, confirming that both phenylephrine and norepinephrine are effective in maintaining blood pressure, though they exhibit different hemodynamic profiles. Phenylephrine demonstrated superior blood pressure stability but was associated with a higher incidence of bradycardia, requiring atropine in some cases. Mephentermine resulted in higher incidences of nausea, vomiting, and hypotension, suggesting it may be less effective in preventing maternal hypotension compared to phenylephrine and norepinephrine. Overall, phenylephrine and norepinephrine emerge as preferred choices for maintaining maternal hemodynamic stability, with norepinephrine offering the advantage of fewer heart rate fluctuations compared to phenylephrine. The results reinforce the shift in clinical preference toward norepinephrine as an effective alternative to phenylephrine, balancing blood pressure control with minimal heart rate disturbances. APGAR scores were

identical across all groups at both 1 and 5 minutes, indicating that none of the vasopressors negatively impacted neonatal health.

Further research with larger sample sizes and comparative studies between phenylephrine and norepinephrine will help refine the optimal choice for vasopressor management in CSs under SA.

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