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Original Article

EFFECTIVENESS OF PHENYLEPHRINE IN THE TREATMENT OF SUBARACHNOID BLOCK INDUCED HYPOTENSION DURING ELECTIVE CAESAREAN SECTION- A COMPARATIVE STUDY WITH EPHEDRINE

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Abstract:

Background: *Maternal hypotension is one of the common complications after spinal anesthesia for cesarean delivery, resulting in adverse maternal and fetal outcomes. The selection of the most efficient treatment is one of the main challenges in obstetric cases. Prompt treatment of hypotension with intravenous vasopressor is necessary to avoid these maternal and fetal effects. This study will set to compare phenylephrine's effectiveness in treating subarachnoid block induced hypotension in relation to ephedrine during elective lower uterine cesarean section (LUCS) under the subarachnoid block (SAB).*

Objectives: *The study objective is to compare the effects of a bolus dose of ephedrine versus phenylephrine in treating subarachnoid block-induced hypotension during elective lower uterine cesarean section.*

Study of Place: *Department of Anesthesiology & Intensive Care Unit (ICU), East West Medical College, Dhaka, Bangladesh.*

Study period: *From September 2023 to February 2024.*

Study design: *Prospective, randomized, double-blinded trial Method: The study population was women undergoing lower uterine cesarean section (LUCS) who fulfilled the selection criteria. The study sample was selected by prospective, randomized, double-blinded trial. Ninety patients were enrolled in this study and allocated equally into Group A (Ephedrine administered group) and Group B (Phenylephrine administered group). All relevant data were collected and analyzed with a statistical package of social science (SPSS) version 23 software, and all the statistical tests were considered significant when p value <0.05.*

Results: *The study results showed that after using a vasopressor and its response in mean arterial pressure of the patient at 2nd, 4th, and 6th minutes were greater in the phenylephrine group in comparison to the ephedrine group, and it was statistically significant (p value 0.043, 0.038, and 0.049, respectively). Vasopressor response to mean heart rate of the patient at 2nd, 4th, 6th and 8th minutes was lesser in the phenylephrine group than the ephedrine group, and it was also statistically significant (0.036, 0.028, 0.018, and 0.048, respectively). However, the study results comparing two groups revealed no significance concerning demographic variables, i.e., Mean age ± SD, Body mass index (BMI) Mean ± SD (p value 0.523 and 0.567, respectively). The fetal response measured as APGAR scores at 1st and 5th minutes, between two groups, were not significant (p value 0.096 and 0.427, respectively). The comparison between the two groups to determine the maternal respiratory rate and percentage saturation of oxygen (SpO2) were not significant.*

Conclusion: *The study concluded that the uses of phenylephrine compared to ephedrine were relatively better to raise the mean arterial pressure for subarachnoid block-induced hypotension in lower uterine cesarean section (LUCS).*

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Phenylephrine, subarachnoid block, spinal anesthesia, hypotension, elective caesarean section, obstetric anesthesia, vasopressor therapy, haemodynamic stability, blood pressure management.

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Introduction

Maternal hypotension is one of the most common complications following spinal anesthesia for caesarean delivery and remains a significant concern due to its potential to produce adverse maternal and fetal outcomes. Subarachnoid block (SAB) is widely accepted as the anesthetic technique of choice for lower uterine caesarean section (LUCS) because of its rapid onset, dense sensory blockade, minimal drug transfer to the fetus, and favorable safety profile. However, SAB-induced hypotension continues to pose an important clinical challenge. The incidence of hypotension after spinal anesthesia in obstetric patients can be as high as 60–70%, particularly in otherwise healthy term parturients who are physiologically more susceptible to sympathetic blockade.[1,2]The physiological basis of SAB-induced hypotension lies mainly in arterial and venous vasodilatation caused by sympathetic nervous system blockade. This leads to a reduction in systemic vascular resistance, pooling of blood in the lower extremities, decreased venous return, and subsequent fall in cardiac output. Pregnant women are especially vulnerable as the gravid uterus further impedes venous return by compressing the inferior vena cava. If left untreated, maternal hypotension may result in nausea, vomiting, dizziness, loss of consciousness, and pulmonary aspiration. More importantly, reduced uteroplacental perfusion may cause fetal acidosis, bradycardia, and neonatal depression at birth.[1,2,3] Multiple strategies have been investigated to prevent and manage hypotension during spinal anesthesia for LUCS. These include non-pharmacological interventions such as fluid loading (preload or co-load with crystalloids or colloids), lateral uterine displacement, limb wrapping, and proper patient positioning. Among these, fluid therapy remains the cornerstone of preventive management; however, its effects are often transient because vasodilatation persists as long as the sympathetic block remains. Therefore, pharmacological intervention is frequently required to maintain adequate blood pressure.[3] Vasopressors are the mainstay of treatment, and several agents have been evaluated for obstetric use. Commonly used vasopressors include ephedrine, phenylephrine, metaraminol, methoxamine, and epinephrine. Ephedrine has historically been considered the drug of choice because of its mixed α- and β-adrenergic activity, which maintains maternal blood pressure by increasing cardiac output. However, concerns have been raised regarding its association with fetal acidosis due to placental transfer.3 Phenylephrine, a selective á1-adrenergic agonist, has gained popularity in recent years as it effectively increases systemic vascular resistance and restores blood pressure without significant adverse fetal effects. It has also been associated with improved maternal hemodynamic stability, fewer episodes of nausea and vomiting, and better fetal acid–base status compared to ephedrine.[1,2] Despite the wide use of vasopressors, the optimal agent and dosing strategy in obstetric anesthesia continue to be debated. The selection of the most effective treatment option is one of the major challenges in clinical practice. Prompt treatment of hypotension with intravenous vasopressors is essential to prevent maternal discomfort and avoid deleterious effects on the fetus. Considering the evolving evidence base, the present study is designed to compare the effectiveness of phenylephrine versus ephedrine in the management of subarachnoid block-induced hypotension during elective LUCS under spinal anesthesia.[1,2,3]

Materials and Methods

This study was designed as a prospective, randomized, double-blinded clinical trial. The study was conducted in the Department of Anaesthesiology, East West Medical College, Dhaka, Bangladesh from September 2023 to February 2024. The study population consisted of full-term pregnant mothers undergoing lower uterine caesarean section (LUCS) under subarachnoid block (SAB) who subsequently developed hypotension. All patients were managed in the operating theatre of BMCH.

Sample Size: The sample size was estimated using the standard formula:

$n = Z^2 \times p \times q / d^2$

Where:

Z = 1.96 at 95% confidence level

p = prevalence of hypotension following SAB = 0.75

$q = 1 - p = 0.25$

d = allowable error = 0.10

Thus,

$n = (1.96)^2 \times 0.75 \times 0.25 / (0.10)^2$

$n = 129$

Given the six-month study duration, the expected sample size could not be achieved; therefore, 90 patients were finally included, with 45 in each group.

Sampling Technique

Purposive sampling was used to identify eligible patients who developed hypotension after SAB. Random allocation to study groups was performed afterward.

Selection Criteria

Inclusion Criteria:

- Age 18–45 years
- Full-term parturients undergoing LUCS under SAB
- Developed hypotension following SAB
- ASA physical status I or II

Exclusion Criteria:

- Age <18 or >45 years
- Known hypersensitivity to ephedrine or phenylephrine
- Patients taking antihypertensive medications
- ASA III or IV physical status

Variables

The primary variables assessed included:

- Maternal mean arterial pressure
- Maternal heart rate
- Respiratory rate
- Oxygen saturation (SpO,)
- Maternal demographic parameters
- Neonatal APGAR scores at 1 and 5 minutes

Operational Definitions

Spinal Hypotension: A fall in mean arterial pressure below 80% of baseline, or systolic arterial pressure ≤100 mmHg, or ≤80% of baseline.

APGAR Score: A clinical scoring system assessing newborn status at 1 and 5 minutes based on activity, pulse, grimace, appearance, and respiration (0–10 scale).\

Study Procedure

Pre-anesthetic Evaluation

Eligible patients were assessed one day before surgery. A detailed clinical examination and routine investigations were performed, and informed written consent was taken. Patients were kept fasting for six hours before surgery.

Premedication

All patients received intravenous ondansetron 0.15 mg/kg.

Randomization and Blinding

After developing hypotension following SAB, patients were randomly assigned using a computer-generated schedule into two equal groups (n=45 each). Sequentially numbered opaque sealed envelopes were used to maintain blinding for investigators, anesthetists, and data collectors.

• Group A: Ephedrine 6 mg IV bolus

• Group B: Phenylephrine 50 µg IV bolus

Study drugs were prepared in identical syringes (5 mL) by an independent anesthetist to ensure blinding.

Anesthetic Technique

Standard monitors (ECG, NIBP, SpO,) were applied. Baseline vital parameters were recorded. Preloading was done with Ringer's lactate 15 mL/kg. SAB was performed in the sitting position using a 25G or 27G Quincke needle at L3–4 or L4–5, administering 2.5 mL of 0.5% hyperbaric bupivacaine, targeting a T4 sensory level.

Vital signs (heart rate, blood pressure, SpO, , respiratory rate) were recorded every 2 minutes for the first 10 minutes, then every 5 minutes until completion of surgery, and continued for 30 minutes postoperatively.

When hypotension occurred, patients received the allocated vasopressor bolus. Additional doses were given if hypotension persisted. Atropine 0.5 mg was administered for heart rate <60 bpm. Supplemental oxygen at 3–4 L/min was delivered via face mask. Oxytocin 10 IU IV followed by an infusion of 10 IU in 500 mL crystalloid was given after delivery.

APGAR scores at 1 and 5 minutes were recorded using the standard scoring system.

Data Collection and Analysis

Data were collected by a trained research assistant using a structured proforma. The study continued through the postoperative period, and any hypotension in recovery was managed with additional vasopressor and fluids. Data were analyzed with the help of a statistician.

Ethical Considerations

Ethical approval was obtained from the Institutional Ethical Review Board of EWMCH. The study objectives

and procedures were explained to all participants, confidentiality was ensured, and informed written consent was obtained.

Results:

Table-I

Distribution of the demographic variable between the groups

Demographic Variable	Group A	Group B	*p* value
Age Mean ± SD	30.5±6.43	31.4±8.02	0.523[ns]
BMI Mean ± SD	23.69 ± 2.71	24.23 ± 3.37	0.567 [ns]

ns= not significant, p value reached from Student t test, Group A= patients with SAB induced hypotension were treated with bolus dose of ephedrine 6mg, Group B= patients with SAB induced hypotension were treated with bolus dose of phenylephrine 50µg

Table I Shows distribution of demographic variables i.e., Age and BMI, between the groups. Mean age of the patients in Group A was 30.5±6.43 and in Group B was 31.4±8.02, and comparison between the group was not significant (*p* 0.523). Mean BMI of the patients in Group A was 23.69± 2.71 and in Group B was 24.23 ± 3.37, and comparison between the group was not significant (*p* 0.567).

Table-II

Distribution of the study patients according to Induction to delivery time (n=90)

	Comparison of drug		P value
	Group A	Group B	
Induction to delivery time In minute	15.17± 3.04	16.37± 2.69	0.615 ns

ns= not significant, p- value reached from students t test

Table II Shows induction to delivery time is slightly larger in group B, but no statistically significance was found when correlated. (p>0.05)

Table-III

Distribution of the study patients according to changes in mean arterial blood pressure following application of vasopressor (mmHg) (n=90)

Time	Group A Mean ± SD	Group B Mean ± SD	P value
Baseline	72.68 ± 9.21	73.17 ± 5.32	0.363
At Hypotension	61.56 ± 2.98	60.3 ± 3.91	0.641
2 min after V.P.	110.43 ± 2.58	118.68 ± 4.21	0.043[s]
4 min after V.P.	111.43 ± 4.21	120.58 ± 2.81	0.038[s]
6 min after V.P.	109.34 ± 2.54	119.38 ± 1.73	0.049[s]
8 min after V.P.	118.71 ± 2.34	120.30 ± 4.75	0.194
10 min after V.P.	118.32 ± 4.23	122.73 ± 6.32	0.235
15 min after V.P.	118.32 ± 1.54	119.72 ± 3.73	0.421
20 min after V.P.	116.34 ± 1.21	118.21 ± 5.21	0.512
25 min after V.P.	117.43 ± 4.23	123.49 ± 2.85	0.563
30 min after V.P.	119.45 ± 3.65	121.30 ± 8.12	0.351

V.P.= Vasopressor
ns= not significant, n= significant
p value reached from students t test

Table-IV

Distribution of the study patients according to changes in mean heart rate after application of vasopressor (beat/min) (n=90)

Time	Group A Mean ± SD	Group B Mean ± SD	P value
Baseline	85.64 ± 4.76	88.17 ± 2.87	0.241
At Hypotension	98.34 ± 2.98	99.34 ± 3.91	0.386
2 min after V.P.	108.43 ± 2.58	71.68 ± 4.21	0.036[s]
4 min after V.P.	109.43 ± 4.21	74.58 ± 2.81	0.028[s]
6 min after V.P.	107.34 ± 2.54	78.38 ± 1.73	0.018[s]
8 min after V.P.	110.71 ± 2.34	78.30 ± 4.75	0.048[s]
10 min after V.P.	115.32 ± 4.23	110.73 ± 6.32	0.734
15 min after V.P.	111.32 ± 1.54	105.72 ± 3.73	0.187
20 min after V.P.	112.34 ± 1.21	107.21 ± 5.21	0.290
25 min after V.P.	111.43 ± 4.23	109.49 ± 2.85	0.531
30 min after V.P.	117.45 ± 3.65	110.30 ± 8.12	0.583

V.P.= Vasopressor
ns= not significant, n= significant
P value reached from students t test

Table-V

Distribution of the study patients according to changes in mean oxygen saturation (%) (n=90)

Time	Group A Mean ± SD	Group B Mean ± SD	P value
Baseline	99.65 ± 4.76	99.53 ± 2.87	0.241
2 min	99.43 ± 2.58	98.68 ± 4.21	0.736
4 min	99.43 ± 4.21	98.58 ± 2.81	0.528
6 min	99.34 ± 2.54	99.38 ± 1.73	0.418
8 min	98.71 ± 2.34	98.30 ± 4.75	0.748
10 min	99.32 ± 4.23	99.73 ± 6.32	0.734
15 min	99.32 ± 1.54	99.72 ± 3.73	0.187
20 min	99.34 ± 1.21	99.21 ± 5.21	0.290
25 min	99.43 ± 4.23	99.49 ± 2.85	0.531
30 min	99.45 ± 3.65	99.30 ± 8.12	0.583

ns= not significant, n= significant
p value reached from students t test

Table-VI

Distribution of the study patients according to changes in mean resp rate (rate/min) (n=90)

Time	Group A Mean ± SD	Group B Mean ± SD	P value
Baseline	12.65 ± 4.76	12.53 ± 2.87	0.928
2 min	12.43 ± 2.58	13.68 ± 4.21	0.318
4 min	12.43 ± 4.21	13.58 ± 2.81	0.541
6 min	12.34 ± 2.54	12.38 ± 1.73	0.636
8 min	13.71 ± 2.34	13.30 ± 4.75	0.387
10 min	12.32 ± 4.23	12.73 ± 6.32	0.790
15 min	12.32 ± 1.54	12.72 ± 3.73	0.648
20 min	12.34 ± 1.21	12.21 ± 5.21	0.434
25 min	12.43 ± 4.23	12.49 ± 2.85	0.512
30 min	12.45 ± 3.65	12.30 ± 8.12	0.573

Table-VII

Distribution of the study patients according to APGAR score of new born in 1st minute and 5th minute

	Time	Comparison of drug		P value
		Group A	Group B	
APGAR score	1st minute	9.7± 3.04	9.5± 2.69	0.096 ns
	5th minute	9.8± 1.76	9.8± 1.34	0.427 ns

Table III Shows mean arterial blood pressure was statistically significant($p<0.05$) at 2nd, 4th and 6th minute after I/V administration of vasopressor and mean pressure of phenylephrine group was great when compared to ephedrine group, and the rest were statistically not significant up to 30 minutes after application of vasopressor.

Table IV Shows mean heart rate was statistically significant($p<0.05$) at 2,4,6 and 8 minutes after application of vasopressor and mean heart rate of phenylephrine group was less when compared to ephedrine group, and the rest were statistically not significant up to 30 minutes after application of vasopressor.

Table V Shows mean oxygen saturation were statistically not significant up to 30 minutes counting from induction.

Table VI Shows mean respiratory rate were statistically not significant up to 30 minutes counting from induction.

Table VII Shows APGAR score were slightly higher in Group A when compared to Group B in 1st minute and almost equal at 5th minute and that was not statistically significant($p>0.05$).

Discussion

This prospective, randomized, double-blinded study was conducted in Department of Anaesthesiology & ICU, East West Medical College & Hospital, Dhaka from September 2023 to February 2024. Total of 90 patients fulfilling inclusion/exclusion criteria were studied to compare effectiveness of phenylephrine in the treatment of subarachnoid block induced hypotension during elective caesarean section with ephedrine. In this study observed that the mean age was found 30.5±6.43 years in group A and 31.4±8.02 years in group B & was not statistically significant ($p>0.05$) between two groups. Similar observation was found Maqsood Ahmad et al. [4] they showed the mean age for Group A was 26.3±4.4 years and in Group B was 26.2±4.3 years. The difference was not statistically significant ($p>0.05$) between two groups. Nitu Puthenveettil et al.[5]they showed the mean age for group N was 29.96±4.046 years and in group P was 29.04±4.748 years. The difference was not statistically significant ($p>0.05$) between two groups.In this study observed that the mean BMI was found 23.6877 ± 2.70563 $kg.m^{-2}$ in group A and 24.2342 ± 3.36568 $kg.m^{-2}$ in group B & was not statistically significant ($p>0.05$) between two groups. In this study observed that the incision to delivery time was 15.17± 3.04 minute for Group A and was 16.37± 2.69 min in Group B and that was not statistically significant. In this study observed that the mean arterial blood pressure following application of vasopressor was 110.43 ± 2.58 mmHg at 2 min, 111.43 ± 4.21 mmHg at 4 min, 109.34 ± 2.54 mmHg at 6 min for Group A and was 118.68 ± 4.21 mmHg at 2 min, 120.58 ± 2.81 mmHg at 4 min and 119.38 ± 1.73 mmHg at 6 min for Group B and they were statistically significant. Rest data up to 30 minutes were not statistically significant. Devender Dua et al.[6] did a similar study and found that mean systolic blood pressure following application of vasopressor was 118.53±6.72 mmHg at 2 min, 120.8±7.62 mmHg at 4 min, 120.67±10.68 mmHg at 6 min for Group P and was 110.33±6.87 mmHg at 2 min, 113±6.12 mmHg at 4 min and 113.47±7.86 mmHg at 6 min for Group E and they were statistically significant. Rest was not statistically significant. In this study observed that the mean heart rate following application of vasopressor was 108.43 ± 2.58 beat/min at 2 min, 109.43 ± 4.21 beat/min at 4 min, 107.34 ± 2.54 beat/min at 6 min, 110.71 ± 2.34 beat/min at 8 min for Group A and was 71.68 ± 4.21 beat/min at 2 min, 74.58 ± 2.81 beat/min at 4 min and 78.38 ± 1.73 beat/min at 6 min, 78.30 ± 4.75 beat/min at 8 min for Group B and they were statistically significant. Rest data up to 30 minutes were not statistically significant. Devender Dua et al.[6] did a similar study and found that mean heart rate following application of vasopressor were all statistically significant between Group P and Group E. Mean oxygen saturation were statistically not significant up to 30 minutes counting from induction between two groups. Mean respiratory rate were statistically not significant up to 30 minutes counting from induction between two groups.[7,8,9,10] Side effect following administration of drug were slightly higher in Group A when compared to Group B in vomiting and dizziness but that was not statistically

significant(p>0.05). Nitu Puthenveettil et al.5 they showed that incidence of bradycardia were 1(4%) in group N and were 4(20%) in group P and that was not statistically significant, incidence of nausea/ vomiting were 2(8%) in group N and were 2(8%) in group P and that was not statistically significant, incidence of shivering were 4(16%) in group N and were 1(4%) in group P and that was not statistically significant.

Conclusion

Present study demonstrates that statistically significant difference was noted in the mean arterial blood pressure at 2nd, 4th and 6th minute after administration of vasopressor and mean pressure for phenylephrine were greater compared to ephedrine. Present study also demonstrates that mean heart rate at 2nd, 4th, 6th and 8th minute were also statistically significant mean heart rate for phenylephrine were lesser compared to ephedrine. Results of our study suggest that all two vasopressors effectively maintained arterial pressure within 20% limit of baseline value though phenylephrine maintained better in first 6 minute of bolus dose as compared to ephedrine.

Limitations of the study

- In terms of limitations, the study did not investigate the side effects of drugs.
- The study population was selected from one selected hospital in Dhaka city, so that the results of the study may not reflect the exact picture of the country.
- Small sample size was also a limitation of the present study. Therefore, in future further study may be under taken with large sample size.

Recommendations

- As the study was conducted in a single center, a multicenter study is recommended before making any final recommendation that could have policy-implication. Further studies can be undertaken by including large number of patients in multiple tertiary level hospitals

Conflict of interest:

None to declare

Ethical approval:

Approved by IRB, East West Medical College.

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