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Efficacy and Safety of Prophylactic Ephedrine in Preventing Hypotension during Subarachnoid Block

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Abstract

Background: Hypotension frequently occurs with subarachnoid block (SAB) due to sympathetic blockade. Ephedrine is used to maintain blood pressure, but requires caution due to possible adverse effects. This study aims to evaluate the efficacy and safety of prophylactic intravenous ephedrine in preventing hypotension in patients undergoing surgery under SAB. **Methods:** This prospective, randomized controlled trial was conducted at the Department of Anesthesiology, Gazi Medical College and Hospital, Khulna, Bangladesh. A total of 200 patients undergoing elective surgeries under SAB were randomly assigned to one of two groups using an odd-even method to either the prophylactic Ephedrine Group (n=100) or the Control Group (n=100). Hemodynamic parameters were monitored at multiple intervals. Primary and secondary outcomes included hypotension incidence, additional vasopressor use, and adverse effects. Statistical analyses were performed using SPSS version 26, with $p<0.05$ considered significant. **Results:** Baseline characteristics, including age, BMI, and ASA grade, were comparable between groups. The Ephedrine group demonstrated significantly higher SBP and DBP at 5, 10, and 15 minutes post-SAB ($p<0.001$). MAP was significantly better maintained in the Ephedrine group at all measured intervals ($p<0.001$ at 5–15 minutes). The incidence of hypotension was significantly lower in the Ephedrine group (9%) compared to the Control (44%, $p<0.001$). Fewer patients in the Ephedrine group required additional vasoconstrictors (5% vs. 15%, p=0.021). There was no significant difference in HR or SpO_2 between groups. The Ephedrine group had a shorter mean discharge time (48.6 ± 10.5 vs. 53.2 ± 12.3 min, p=0.038). No significant adverse events related to ephedrine were observed. **Conclusion:** Prophylactic ephedrine prevents hypotension during subarachnoid block, ensuring hemodynamic stability with minimal side effects. Patients receiving prophylactic ephedrine required fewer additional vasoconstrictors and had shorter shifting times.

Keywords: Prophylactic vasoconstrictors, Ephedrine, Subarachnoid block, Hypotension, Hemodynamic stability.

Introduction

Hypotension is a prevalent and significant complication during subarachnoid block (SAB), with reported incidences ranging from 55% to 90%.[1] This decrease in blood pressure can lead to adverse patient outcomes, including nausea, vomiting, and decreased uteroplacental perfusion.[2] The pathophysiology of SAB-induced hypotension primarily involves sympathetic blockade, resulting in vasodilation and reduced systemic vascular resistance.[3] Prophylactic administration of vasoconstrictors has been explored as a strategy to mitigate this hypotensive response. Among the vasopressors, ephedrine has been widely studied for its efficacy in maintaining hemodynamic stability during SAB.[4]

Ephedrine, which has both α- and β-adrenergic activity, maintains blood pressure by increasing heart rate and cardiac output.[5] It is one of the most commonly used vasopressors in clinical practice.[6] The advantages of using ephedrine include its ability to restore diastolic blood pressure and mean arterial pressure more effectively than other agents like epinephrine following

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SAB-induced hypotension.[7] Additionally, prophylactic intravenous (IV) infusion of ephedrine is more effective than fluid preload alone in preventing hypotension associated with spinal anesthesia.[8] For intramuscular (IM) administration, a dose of 30 mg given 10 minutes before SAB is recommended as it maintains systolic arterial pressure effectively without significant side effects.[9] Intravenous (IV) doses typically range from 5 mg to 25 mg, with studies indicating that even small doses like 5 mg can significantly reduce the incidence and severity of hypotension.[10] Unlike pure α-agonists, ephedrine stimulates both α- and β-receptors, leading not only to vasoconstriction but also to enhanced cardiac contractility and increased heart rate, thereby preventing the reduction in cardiac output that is often seen with other vasopressors.[6]

Ephedrine also acts indirectly by promoting the release of endogenous norepinephrine from sympathetic nerve endings, which contributes to its longer duration of action compared to direct-acting agents.[11] Due to these combined mechanisms, ephedrine is particularly useful in cases where hypotension is accompanied by bradycardia or when maintaining cardiac output is critical.[12] However, ephedrine may be associated with fetal side effects due to increased placental transfer.[5] Despite its benefits, the use of prophylactic vasoconstrictors must be balanced against potential adverse effects. Excessive vasoconstriction can lead to hypertension, reflex bradycardia, and decreased cardiac output.[13] Moreover, the impact on uteroplacental blood flow is a concern, as it may increase uterine vascular resistance.[14] Therefore, careful titration and monitoring are essential to optimize maternal and fetal outcomes.[15]

The selection of the appropriate agent, dosing, and administration technique should be individualized, considering the patient's clinical status and potential side effects.[14] Further research is needed to establish optimal protocols that maximize efficacy while minimizing risks. This study aims to evaluate the efficacy and safety of prophylactic intravenous ephedrine in preventing hypotension in patients undergoing surgery under subarachnoid block (SAB).

Materials and methods

This prospective, randomized controlled trial was conducted in the Department of Anesthesiology at Gazi Medical College and Hospital, Khulna, Bangladesh, from July to December 2024. The study enrolled 200 adults (18–60 years) scheduled for elective surgery under subarachnoid block (SAB), after obtaining informed consent and ethical approval. Eligible participants were ASA Grade I–III. Exclusion criteria included hypersensitivity to bupivacaine or vasoconstrictors, cardiovascular diseases, severe hypotension, coagulopathy, raised intracranial pressure, and spinal deformities. Patients were randomly assigned using an odd–even method into two groups. The Prophylactic Ephedrine group (n = 100) received 10 mg intravenous ephedrine before SAB. The Control Group (n = 100) received no vasoconstrictor.

All patients received a 15 mL/kg crystalloid preload 15–20 minutes before SAB. The block was performed at the L3–L4 or L4–L5 interspace using a 25G Quincke-Babcock needle. Between 2.5–3.5 mL of 0.5% hyperbaric bupivacaine was administered slowly under aseptic precautions. Patients were positioned supine immediately afterward. Continuous monitoring included systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), heart rate (HR), and oxygen saturation (SpO_2) using a G3L Patient Monitor (Shenzhen General Meditech Inc.). Hemodynamic data were recorded at baseline and at 5, 10, 15, 30, and 60 minutes post-SAB. The primary outcome was the incidence of hypotension. Hypotension was defined as a ≥20% fall in SBP from baseline or MAP < 65 mmHg. Secondary outcomes included variations in DBP, MAP, HR, SpO_2, vasoconstrictor requirements, adverse events, and time to hospital discharge. Hypotension was treated with fluid boluses and vasopressors. Bradycardia (HR < 60 bpm) was managed with atropine. Operative parameters, including surgical duration, type of procedure, and drug dosage, were recorded.

Data were collected using a structured proforma and analyzed in SPSS version 26. Continuous variables were expressed as mean ± standard deviation (SD) and compared with the independent t-test. Categorical data were analyzed using the chi-square or Fisher's exact test as appropriate. A p-value < 0.05 was considered statistically significant.

Results

The mean age in the Ephedrine group was 31.73±15.33 years, compared to 28.63±9.91 years in the Control group, with no significant difference. Mean BMI was similar between groups (27.21±3.76 kg/m² vs 27.40±3.75 kg/m²). ASA grading distribution was also comparable, with Grade I being the most common (60% vs. 65%) (Table 01).

The ephedrine group experienced a significantly longer surgery duration (61.26±22.72 min) in comparison to the control group (56.45±14.78 min, p=0.039). The ephedrine group maintained significantly higher SBP over time, with a smaller drop at 5 minutes (117.42±15.38 mmHg) compared to the control (99.35±11.07 mmHg, p<0.001), and this trend remained significant at 10, 15, 30, and 60 minutes (p<0.05) (Table 02). The ephedrine group maintained significantly higher DBP at 5 minutes (70.91±10.79 mmHg) than the control (56.86±9.58 mmHg, p<0.001), with this trend continuing at 10 and 15 minutes (p<0.001) but diminishing by 30 and 60 minutes (p=0.063, p=0.69) (Table 03).

At baseline, MAP was similar between the Ephedrine group (96.0±11.8 mmHg) and the Control group (95.1±8.8 mmHg). However, at 5 minutes, the Ephedrine group showed a significantly higher MAP (86.4±12.2 mmHg) compared to the Control group (71.0±10.4 mmHg; p<0.001). This trend continued at 10, 15, 30, and 60 minutes (Table 04). Heart rate (Table 05) and oxygen saturation (SpO_2) (Table 06) remained comparable between the groups at all time points, with no significant differences (p>0.05), ranging from 98.12% to 98.37% in the ephedrine group and 98.33% to 98.90% in the control group.

In Ephedrine Group, the most common type of surgery was cesarean section (C/S), accounting for 60% of cases. Other surgeries in the ephedrine group included hysterectomy (11%), appendectomy (6%), ORIF (6%), and smaller percentages of TURP, myomectomy, PCNL, and others (1-4%) (Table 07). In the Control Group, the most common surgeries were cesarean section (75%), followed by hysterectomy (11%), appendectomy (4%), and smaller percentages of incisional hernia, incision and drainage, TURP, URS, Longo, ORIF, herniotomy, myomectomy, and endometrial polyp removal (1-4%) (Table 08).

Regarding additional medications, 74% and 60% of the control and ephedrine group did not receive any, respectively (Table 09). The incidence of hypotension (MAP < 65 mmHg) was significantly lower in the Ephedrine group (9.0%) than in the Control group (44.0%; p<0.001). Fewer patients in the Ephedrine group required additional vasoconstrictors (5.0% vs. 15.0%; p=0.021). Additionally, the Ephedrine group had a shorter mean discharge time (48.6 ± 10.5 min) compared to the Control group (53.2 ± 12.3 min; p=0.038) (Table 10). The overall effectiveness was high in the ephedrine group, with 85% reporting it as effective (Figure 01).

Table 01: Patients' Characteristics and Surgery duration of the groups

Traits	Ephedrine Group (n=100)		Control Group (n=100)		P-value
	n	%	n	%	
	Mean±SD		Mean±SD		
Age (in years)	31.73±15.33		28.63±9.91		0.702
BMI (kg/m2)	27.21±3.76		27.40±3.75		0.553
ASA Grading					
Grade I	60	60.00	65	65.00	0.195
Grade II	30	30.00	28	28.00	
Grade III	10	10.00	7	7.00	
Duration of Surgery (min)	61.26±22.72		56.45±14.78		0.039

Table 02: Changes of Systolic Blood Pressure (SBP) Over Time

Systolic BP	Ephedrine Group (n=100)	Control Group (n=100)	P-value
	Mean±SD	Mean±SD	
Baseline	128.10±15	123.75±9.44	0.26
At 5 min	117.42±15.38	99.35±11.07	< 0.001
At 10 min	118.33±15.2	99.60±10.27	<0.001
At 15 min	119.23±13.40	105.96±10.12	<0.001
At 30 min	119.67±12.01	111.71±7.59	<0.001
At 60 min	126.94±12.14	115.38±9.67	0.016

Table 03: Changes of Diastolic Blood Pressure (DBP) Over Time

Diastolic BP	Ephedrine Group (n=100)	Control Group (n=100)	P-value
	Mean±SD	Mean±SD	
Baseline	80.00±10.22	80.78±7.64	0.314
At 5 min	70.91±10.79	56.86±9.58	<0.001
At 10 min	69.49±9.75	59.56±8.51	<0.001
At 15 min	70.10±9.47	63.18±7.57	<0.001
At 30 min	70.93±7.83	67.74±6.86	0.063
At 60 min	70.56±9.38	71.15±9.82	0.69

Table 04: MAP Variation across Time in Ephedrine and Control Groups under SAB

MAP	Ephedrine Group (n=100)	Control Group (n=100)	p-value
Baseline	96.0 ± 11.8	95.1 ± 8.8	0.7019
At 5 min	86.4 ± 12.2	71.0 ± 10.4	<0.001
At 10 min	85.8 ± 11.6	72.9 ± 9.8	<0.001
At 15 min	86.5 ± 10.9	77.4 ± 8.7	<0.001
At 30 min	87.2 ± 9.4	82.4 ± 7.3	<0.001
At 60 min	89.4 ± 10.3	85.9 ± 9.6	0.0048

Table 05: Changes in Heart Rate Over Time

Heart Rate	Ephedrine Group (n=100)	Control Group (n=100)	P-value
	Mean±SD	Mean±SD	
Baseline	86.71±13.10	86.43±13.73	0.488
At 5 min	88.03±13.94	90.63±16.28	0.442
At 10 min	87.77±16.07	92.89±16.84	0.239
At 15 min	84.56±10.98	87.09±14.01	0.096
At 30 min	83.17±12.04	84.55±9.59	0.071
At 60 min	87.45±9.48	85.22±9.31	0.175

Table 06: Oxygen Saturation (SpO_2) Over Time

SpO_2%	Ephedrine Group (n=100)	Control Group (n=100)	P-value
	Mean±SD	Mean±SD	
Baseline	98.20±1.02	98.33±0.70	0.283
At 5 min	98.12±1.01	98.40±0.65	0.227
At 10 min	98.27±1.29	98.90±1.10	0.107
At 15 min	98.28±0.92	98.58±0.63	0.216
At 30 min	98.37±0.96	98.53±0.59	0.577
At 60 min	98.26±1.02	98.39±0.61	0.528

Table 07: Type of Surgery in Ephedrine Group (n=100)

Type of surgery (Ephedrine Group)	Frequency (n)	Percentage (%)
C/S	60	60.0
Hysterectomy	11	11.0
Appendectomy	6	6.0
Incision and Drainage	1	1.0
TURP	3	3.0
Longo	1	1.0
ORIF	6	6.0
Myomectomy	4	4.0
PCNL	3	3.0
TURBT	1	1.0
Plate Screw Removal	1	1.0
Laser	1	1.0
CRIF	2	2.0

Table 08: Type of Surgery in Control Group (n=100)

Type of surgery (Control Group)	Frequency (n)	Percentage (%)
C/S	76	76.0
Hysterectomy	11	11.0
Appendectomy	4	4.0
Incisional Hernia	1	1.0
Incision and Drainage	1	1.0
TURP	1	1.0
URS	1	1.0
Longo	1	1.0
ORIF	1	1.0
Herniotomy	1	1.0
Myomectomy	1	1.0
Endometrial Polyp Removal	1	1.0

Table 09: Additional Medications Used

Additional Medication used	Ephedrine Group (n=100)		Control Group (n=100)		P-value
	n	%	n	%	
No	60	60.0	74	74.0	0.035
Fentanyl	40	40.0	26	26.0	

Table 10: Adverse Events and Complications

Variables	Ephedrine Group (n=100)		Control Group (n=100)		P-value
	n	%	n	%	
Hypotension (MAP < 65 mmHg)	9	9.00	44	44.00	<0.001
Additional Vasopressors	5	5.00	15	15.00	0.021
Nausea/Vomiting	12	12.00	20	20.00	0.078
Bradycardia	8	8.00	14	14.00	0.115
Tachycardia	10	10.00	18	18.00	0.067
Other adverse events	6	6.00	14	14.00	0.045
Complications	5	5.00	12	12.00	0.041
Time of discharge (min), Mean±SD	48.6 ± 10.5		53.2 ± 12.3		0.038

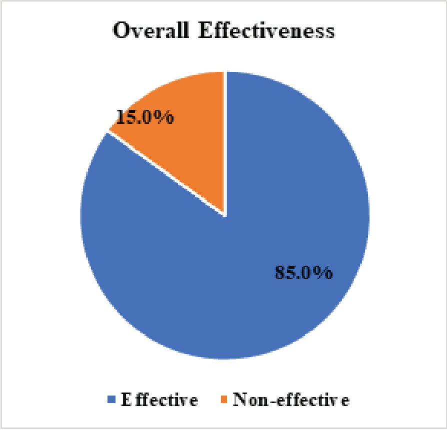

Figure 01: Overall Effectiveness of Ephedrine Group (n=100)

Discussion

Subarachnoid block (SAB) is commonly used for surgical anesthesia but often leads to hypotension, which can cause serious complications. Prophylactic vasoconstrictors are used, such as ephedrine, to prevent this drop in blood pressure, yet their efficacy and safety remain subjects of debate.16 The baseline characteristics of participants were comparable between the ephedrine and control groups, with no statistically significant differences observed. The mean age of

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participants in the ephedrine group was 31.73±15.33 years, while in the control group, it was 28.63±9.91 years (p=0.702). The mean BMI was also similar between groups (27.21±3.76 kg/m² vs. 27.40±3.75 kg/m², p=0.553). The findings of our study are comparable with the studies of Rahman et al and Oparanozie et al.[7,17]

The distribution of ASA grading was similar between the ephedrine and control groups, with Grade I observed in 60% and 65% of patients, Grade II in 30% and 28%, and Grade III in 10% and 7%, respectively (p=0.195). Our study demonstrated a significant increase in both systolic, diastolic blood pressure and MAP in the ephedrine group at 5, 10, 15, and 30 minutes following spinal anesthesia (p<0.05). Morgan et al.[14] reported that reactive hypertension occurred in 10% of patients receiving phenylephrine and 3.4% of those treated with ephedrine. Additionally, findings from Oparanozie et al. indicated that phenylephrine more effectively maintained systolic, diastolic, and mean arterial blood pressure closer to baseline levels compared to ephedrine.[17]

Regarding heart rate (HR) variations, our findings reveal no significant differences between the groups across various time points, except for a slight, albeit non-significant, increase observed in the control group at 5 and 10 minutes. Previous research has demonstrated that ephedrine leads to a progressive increase in both cardiac output and heart rate, whereas phenylephrine is associated with a decline in these parameters.[18] Additionally, no significant differences in oxygen saturation (SpO_2) were observed between the groups, indicating that ephedrine does not impair oxygenation. These results are consistent with the findings of Sternlo et al., who reported stable SpO_2 levels in patients administered ephedrine prophylactically during spinal anesthesia.[19]

A study conducted by Kol et al. evaluated the effectiveness of administering a 0.5 mg/kg intravenous bolus of ephedrine immediately after spinal anesthesia induction, following a crystalloid fluid preload, in preventing hypotension during cesarean delivery.[20] Their findings demonstrated a significant reduction in the incidence of hypotension, indicating the efficacy of this approach in maintaining hemodynamic stability. Moreover, neonatal outcomes, including Apgar scores and umbilical artery blood gas parameters, showed no significant differences between the ephedrine and control groups. These results suggest that maternal oxygen saturation (SpO_2) levels remained stable throughout the procedure, indicating the safety of ephedrine in this clinical setting.

Our study found, surgical outcomes and medication parameters revealed that the ephedrine group experienced a slightly longer surgery duration (P=0.039). These findings are consistent with the study by Aragão et al., which reported that prophylactic ephedrine administration in prolonged surgeries may necessitate increased cumulative doses to maintain hemodynamic stability.[21] Despite the higher dosage, our results indicate that ephedrine was well-tolerated, with no significant increase in adverse events. Notably, the incidence of additional vasopressor requirements was significantly lower in the ephedrine group (P=0.021), suggesting that prophylactic administration contributes to better hemodynamic control. This observation aligns with previous studies demonstrating that early vasopressor intervention minimizes the need for rescue medications and enhances overall hemodynamic stability.[22,23]

Moreover, the overall complication rate was significantly lower in the ephedrine group (P=0.041), and time to discharge was shorter (P=0.038), reinforcing the clinical benefits of maintaining perioperative hemodynamic stability. These findings contrast with those of Kol et al., who found that ephedrine use was associated with a higher incidence of nausea and vomiting, possibly due to its beta-adrenergic effects.[20] However, our study did not observe a statistically significant difference in nausea and vomiting rates between groups (P=0.078), suggesting that ephedrine's emetogenic potential may be dose-dependent.

Limitations of the study

The study's limitations include a modest sample size that may not detect rare adverse events and potential selection bias from the odd-even allocation method. Only ephedrine was evaluated, without comparison to other vasopressors, and long-term outcomes were not assessed. Additionally, confounding factors like fluid management and comorbidities were not analyzed in detail.

Conclusion

Prophylactic ephedrine effectively prevents hypotension during subarachnoid block, maintaining higher hemodynamic stability compared to controls, without significant changes in heart rate or oxygen saturation. It reduces the need for additional vasoconstrictors, lowers complication rates, and shortens discharge time, demonstrating both efficacy and safety in perioperative hemodynamic management. Further large-scale studies are recommended to refine dosing and compare its efficacy with other agents.

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