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Comparison of prophylactic and therapeutic intermittent intravenous bolus doses of phenylephrine to treat spinal-induced hypotension in patient undergoing elective cesarean delivery at Shree Birendra Hospital, Chhauni

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Abstract

Introduction: Spinal anesthesia is the preferred technique for elective cesarean delivery due to favorable maternal and fetal outcomes. However, spinal-induced hypotension is common and may cause maternal nausea, vomiting, and reduced uteroplacental perfusion, potentially affecting the fetus. Phenylephrine is widely used to prevent or treat this, but the optimal timing remains debated. This study compared prophylactic versus therapeutic intermittent intravenous bolus phenylephrine for maintaining maternal hemodynamic stability and evaluated maternal side effects and neonatal APGAR scores.

Method: This interventional study was conducted in the Department of Anaesthesiology Shree Birendra Hospital, Chhauni. Forty ASA II, non-laboring parturients over 18 years undergoing elective cesarean under spinal anesthesia were included. Patients were assigned to two groups (Group P and Group T) of 20 based on surgery day. All received spinal anesthesia with 10 mg of 0.5% hyperbaric bupivacaine at L3–L4 and Ringer's lactate co-loading 10 ml/kg. Group P received phenylephrine 100 µg IV immediately after spinal block, while Group T received it only after hypotension (MAP <65 mmHg or >20% decrease). Maternal hemodynamics, side effects, and neonatal APGAR scores at 1 and 5 minutes were recorded. Rescue phenylephrine boluses were given as needed.

Result: Prophylactic phenylephrine maintained more stable maternal blood pressure, reduced hypotensive episodes, and required fewer rescue boluses. Nausea and vomiting were less frequent in the prophylactic group. Bradycardia, hypertension, and neonatal APGAR scores were comparable between groups.

Conclusion: Prophylactic intermittent IV phenylephrine is more effective than therapeutic dosing in preventing spinal-induced hypotension during elective cesarean delivery without affecting neonatal outcomes.

Keywords: Cesarean section; Phenylephrine; Spinal anesthesia; Spinal-induced hypotension

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Introduction

Cesarean delivery is one of the most frequently performed obstetric procedures worldwide. Spinal anesthesia is the preferred technique for elective cesarean section due to its safety, technical simplicity, high success rate, minimal maternal–fetal drug exposure, and reduced risk of aspiration, while allowing an awake, cooperative parturient.[1–3] Globally, spinal anesthesia is associated with maternal hypotension in 60–80% of cases, which may lead to nausea, vomiting, dizziness, cardiovascular instability, and decreased uteroplacental perfusion, potentially causing fetal hypoxia and acidosis.[4–7]

In Nepal and similar settings, spinal hypotension remains a significant clinical challenge due to pregnancy – related physiologic changes including aortocaval compression, decreased systemic vascular resistance (SVR), and increased baroreceptor sensitivity.[8-10] Various interventions, including fluid loading, lateral positioning, and vasopressors, have been employed to mitigate hypotension, but controversy exists regarding the most effective strategy.[11–13]

Phenylephrine, a selective α_1 adrenergic agonist, is widely used to prevent or treat spinal-induced hypotension.[14] It increases SVR and venous return (VR) through arterial and venous vasoconstriction, with minimal β-adrenergic effects and fetal impact.[15] Reflex bradycardia may occur, but therapeutic doses effectively maintain maternal blood pressure without compromising neonatal outcomes.[16] Its rapid onset and short duration make it suitable for intermittent intravenous bolus administration.[17]

This study compares the efficacy of prophylactic versus therapeutic intermittent intravenous bolus doses of phenylephrine for maintaining hemodynamic stability during elective cesarean delivery, assessing maternal side effects and neonatal outcomes including APGAR scores, to guide local obstetric anesthesia practice.

Method

This interventional study was conducted at the Department of Anaesthesiology, Shree Birendra Hospital, Chhauni, Nepal, over a period of 18 months (from August 2022- October 2023) following institutional approval and up until the required sample size was achieved. Ethical approval was obtained from the Department of Anesthesiology, Shree Birendra Hospital, Institutional Review Committee of Nepalese Army Institute of Health Sciences (NAIHS) and the Nepal Health Research Council (NHRC) (Ref. 261/ 2022 MT), and written informed consent was obtained from all participants. The study population included American Society of Anesthesiologists (ASA) physical status II, non-laboring parturients aged over 18 years with singleton pregnancies beyond 36 weeks undergoing elective cesarean section under spinal anesthesia. Women with pre-existing or pregnancy-induced hypertension, diabetes, cardiovascular or cerebrovascular disease, fetal abnormalities, known allergy to phenylephrine, or who refused participation were excluded.

A total of 40 patients were recruited using convenience sampling, with parturients scheduled on odd dates allocated to the prophylactic group (Group P) and those on even dates to the therapeutic group (Group T). Sample size was calculated based on the study by das Neves et al., with 16 patients per group, where the study showed the difference in hypotension incidence by 52.5% among prophylactic and therapeutic group; at 80% power and 5% type I error, adjusted to 20 per group to account for potential dropouts.[18]

All patients underwent standard pre-anesthetic evaluation, including demographic data, vital signs, and routine investigations. On the day of surgery, patients were nil per oral for eight hours, positioned supine with left lateral tilt, and monitored with ECG, non-invasive BP, and pulse oximetry. Spinal anesthesia was administered at L3–L4 with 10 mg of 0.5% hyperbaric bupivacaine. Group P received prophylactic phenylephrine 100 µg IV immediately after the block, while Group T received the same dose only after hypotension, defined as MAP <65 mmHg or >20% decrease from baseline. Rescue doses were administered as needed. Sensory and motor blockade was assessed using pinprick testing and the Modified Bromage scale. Maternal hemodynamics, side effects, and neonatal APGAR scores at 1 and 5 minutes were recorded.

Data were compiled and analyzed using MS Excel, GraphPad Prism 8.4.2, and SPSS Version 16. Descriptive statistics were presented as mean ± SD or percentages. Normally distributed continuous variables (eg: age, weight, height BMI, systolic BP, diastolic BP and MAP) were analyzed using the unpaired Student's t-test and are presented as mean ± SD. Repeated hemodynamic measurements over time were analyzed using RM ANOVA. Categorical variables were compared using Chi-square or Fisher's Exact Test. A p-value <0.05 was considered statistically significant. Participants' safety, privacy, and ethical considerations were maintained throughout the study

Result

Forty parturients undergoing elective cesarean section under spinal anesthesia were included in the analysis, with 20(50%) patients in the prophylactic phenylephrine group and 20 (50%) in the therapeutic phenylephrine group. Baseline demographic and obstetric characteristics were comparable between

the two groups, with no statistically significant differences observed. Table 1.

Table 1. Demographic factors (N = 40)

Demographic parameters	Group P Mean ± SD	Group T Mean ± SD	P Value*
Age(years)	29.5 ± 4.9	29.0 ± 5.4	0.737
Weight(kg)	71.4 ± 5.0	72.1 ± 6.9	0.696
Height(cm)	158.9 ± 5.1	161.1 ± 6.5	0.255
BMI(kg/m^2)	28.5 ± 1.9	27.8 ± 2.5	0.325

* Unpaired t-test applied

It was seen that most of the patients across both the groups had history of previous caesarean section (70% in prophylactic group and 55% in therapeutic group), Table 2. The p-value was 0.327 suggestive of no statistically significant difference.

Table 2. Previous caesarean section (CS) in two interventional groups (N = 40)

Previous CS	Group P (N=20) n (%)	Group T (N=20 n (%)	P Value⁺
Yes	14(70%)	11(55%)	0.327
No	6(30%)	9(45%)	

⁺ Chi-square test applied

Systolic blood pressure was better maintained in the prophylactic group during the early post-spinal period, with statistically significant differences observed at 10 minutes and 15 minutes following spinal anesthesia, Figure 1.

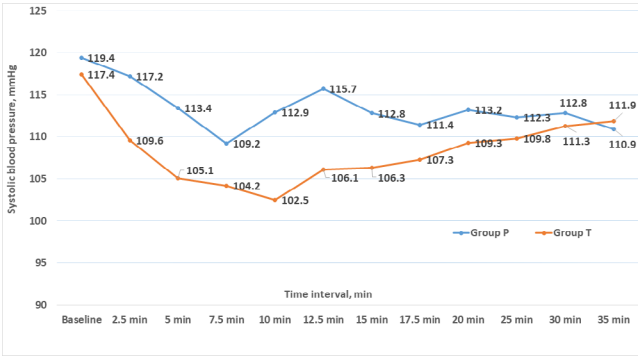

Figure 1. Systolic blood pressure trends in two interventional group

Diastolic blood pressure was significantly lower in the therapeutic group at multiple early time points, particularly at 2.5, 5, 10, 12.5, and 17.5 minutes after spinal anesthesia, Figure 2.

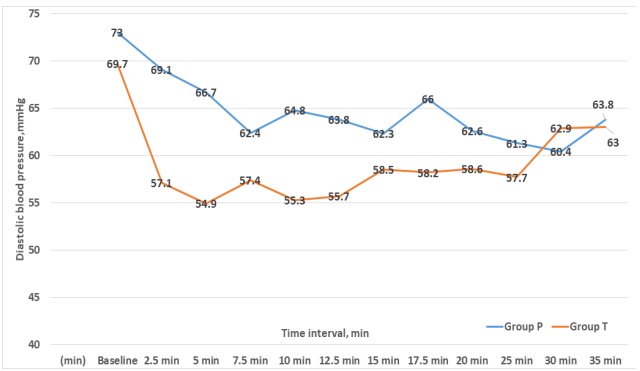

Figure 2. Diastolic blood pressure trends in two interventional groups

Mean arterial pressure remained significantly higher in the prophylactic group during the early intraoperative period, with statistically significant differences noted at 2.5, 5, and 10 minutes following spinal anesthesia, Figure 3.

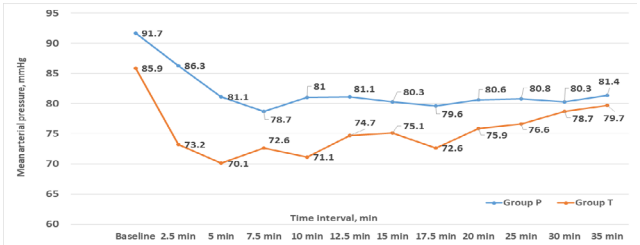

Figure 3. Mean arterial pressure trends in two interventional groups

The requirement for rescue phenylephrine boluses and the cumulative phenylephrine dose were higher in the therapeutic group compared with the prophylactic group (Table 3, Table 4).

Table 3. Rescue bolus dose requirement in two interventional groups (N = 40)

Time interval (min)	Group P (N=20) n (%)	Group T (N=20) n (%)	P Value
2.5 min	0(0%)	9(45%)	0.001[3]
5 min	5(25%)	7(35%)	0.49⁺
7.5 min	2(10%)	5(25%)	0.405[3]
10 min	2(10%)	10(50%)	0.004[3]
12.5 min	3(15%)	4(20%)	1⁺
15 min	2(10%)	4(20%)	0.658⁺
17.5 min	4(20%)	5(25%)	1[3]
20 min	1(5%)	5(25%)	0.184⁺
25 min	2(10%)	5(25%)	0.405⁺
30 min	0(0%)	2(10%)	0.487⁺
35 min	0(0%)	1(5%)	1⁺

[3] Fisher exact test applied; ⁺Chi-square test applied

Table 4. Cumulative dose of bolus phenylephrine required in two interventional groups

Cumulative Bolus dose of Phenylephrine	Group P (N=20) n (%)	Group T (N=20) n (%)	P value[3]
None	5(25%)	0(0%)	<0.001
100mcg	9(45%)	1(5%)	
200mcg	6(30%)	9(45%)	
300mcg	0(0%)	4(20%)	
400mcg	0(0%)	4(20%)	
500mcg	0(0%)	2(10%)	

[3]Fischer exact test applied

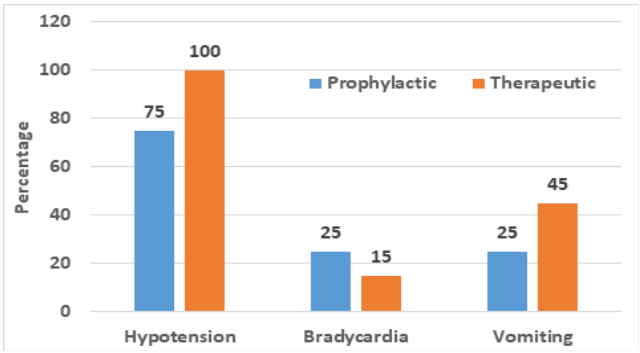

Figure 4. Incidence of adverse effects in two interventional groups

The incidence of hypotension was higher in the therapeutic group, whereas the incidence of bradycardia was comparable between the two groups (Figure 4) and there was no hypertension reported between both groups.

The other adverse effect of phenylephrine vomiting, occurred more frequently in the therapeutic group, while the incidence of high spinal block was low and comparable between groups (Figure 4)

Neonatal outcomes were similar between groups, with no statistically significant differences in APGAR scores at 1 minute and 5 minutes (Figure 5).

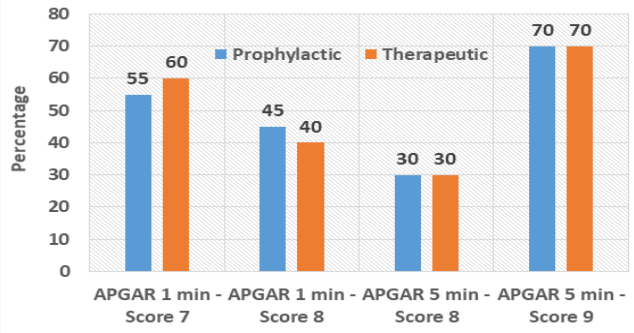

Figure 5. APGAR score at 1 min and 5 min

Discussion

This study demonstrates that prophylactic intermittent intravenous bolus of phenylephrine provides better maternal hemodynamic stability than therapeutic dosing in elective cesarean deliveries under spinal anesthesia. Systolic, diastolic, and mean arterial pressures were consistently higher in the prophylactic group during the first 20 minutes after spinal block, with fewer episodes of hypotension and reduced need for rescue boluses. Heart rate, incidence of bradycardia and hypertension, and neonatal APGAR scores at 1 and 5 minutes were comparable between the groups, indicating that prophylactic administration does not compromise maternal or fetal safety.

These results align with previous research. A study from Brazil[18] reported a lower incidence of hypotension with prophylactic phenylephrine compared to therapeutic dosing. Similarly, another randomized study[19] and an international consensus statement[20] emphasized the effectiveness of prophylactic alpha-adrenergic vasopressors in maintaining maternal blood pressure and minimizing maternal symptoms without affecting neonatal outcomes. The improved stability observed with prophylactic dosing may be attributed to early vasoconstriction mediated by alpha-adrenergic stimulation, preserving venous return and cardiac output immediately after spinal anesthesia. Variations in outcomes compared with some studies, such as this Randomized double blinded study[21], may be related to differences in dosing, patient characteristics, or monitoring protocols.

Adverse effect were comparable between the two groups, with no significant differences in the incidence of bradycardia or hypertension. However, hypotension was significantly more frequent in the therapeutic group, which was also associated with a higher incidence of nausea and vomiting. No serious drug-related adverse effect were observed in either group, and neonatal outcomes were similar. A Randomized study [19] reported that prophylactic phenylephrine 100 µg significantly reduced hypotension compared to 50 µg ($p = 0.04$), without increasing adverse effects. No differences were observed in bradycardia, hypertension, nausea, vomiting, or neonatal APGAR scores. These findings are consistent with the present study.

Overall, these findings support prophylactic intermittent IV phenylephrine as a safe and effective approach to prevent spinal-induced hypotension during elective cesarean delivery.

However, the study was powered enough to detect the difference in incidence of hypotension only as the sample size was based on it. Further studies with larger cohorts and additional neonatal parameters, such as umbilical cord blood gases, could strengthen and expand these observations.

Conclusion

Prophylactic intermittent intravenous phenylephrine (100 µg) provided superior hemodynamic stability compared to therapeutic dosing during elective cesarean delivery under spinal anesthesia. It significantly reduced hypotension (75% vs. 100%), lowered rescue bolus requirements, and decreased the incidence of vomiting, while bradycardia, hypertension, and neonatal APGAR scores at 1 and 5 minutes were similar between groups. These findings support prophylactic phenylephrine as the preferred strategy for spinal-induced hypotension in this setting, though larger studies incorporating umbilical cord blood gas analysis are warranted to confirm its neonatal safety profile.

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Conflict of Interest

None

Funding

None

Author Contribution

Concept, design, planning: TA, NKC, PT, KD, GK; Literature review: TA, KD, GK; Data collection: TA, GK Data analysis: TA, GK; Draft manuscript: TA, NKC, PT; Revision of draft: NKC, PT, KD; Final manuscript: TA, NKC, PT, KD, GK; Accountability of the work: TA, NKC, PT, KD, GK.

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