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Original Research Article

COMPARATIVE HEMODYNAMIC EFFECTS OF PROPHYLACTIC NOREPINEPHRINE AND PHENYLEPHRINE INFUSIONS FOR PREVENTING SPINAL ANAESTHESIA-INDUCED HYPOTENSION IN GERIATRIC PATIENTS UNDERGOING PROXIMAL FEMORAL NAIL SURGERY: A RANDOMISED DOUBLE-BLIND STUDY

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ABSTRACT

Background: Spinal anaesthesia-induced hypotension (SAIH) is a major concern in elderly patients undergoing lower limb surgeries, often leading to organ hypoperfusion and cardiovascular complications. Phenylephrine and norepinephrine are commonly used vasopressors to prevent hypotension, but their comparative efficacy in geriatric surgical patients remains unclear. This study evaluates the haemodynamic effects of prophylactic norepinephrine vs phenylephrine infusions in preventing hypotension in elderly patients undergoing proximal femoral nail surgeries under spinal anaesthesia.

Materials and Methods: A randomised, double-blind, prospective study was conducted on 60 patients (age 65-80 years, ASA II-III) undergoing elective proximal femoral nail surgeries under spinal anaesthesia were enrolled after ethics committee approval. Patients were randomly assigned to:

- Group A (Phenylephrine): Received phenylephrine infusion (0.5 µg/kg/min).
- Group B (Norepinephrine): Received norepinephrine infusion (0.05 µg/kg/min).

Primary Outcome: Mean arterial pressure (MAP) stability before and after vasopressor infusion. **Secondary Outcomes:** Incidence of bradycardia, rescue vasopressor requirement, and adverse events (nausea, vomiting, postoperative delirium, perioperative MI).

Results: MAP Stability: No statistically significant difference in MAP between groups ($p > 0.05$), indicating both vasopressors effectively prevented severe hypotension.

1. **Bradycardia Incidence:** Significantly lower in the norepinephrine group (6.66%) compared to phenylephrine (26.6%) ($p = 0.0105$).
2. **Rescue Vasopressor Requirement:** No significant difference between groups ($p = 0.9$).

Conclusion: Both norepinephrine and phenylephrine effectively maintained MAP in elderly patients undergoing spinal anaesthesia. However, norepinephrine significantly reduced the incidence of bradycardia, supporting its preferential use in geriatric patients where maintaining cardiac output is critical.

Keywords: Spinal anaesthesia-induced hypotension, norepinephrine vs phenylephrine.

INTRODUCTION

Spinal anaesthesia is a widely preferred anaesthetic technique for lower limb surgeries, especially in elderly patients, due to its numerous advantages, including better pain control, reduced systemic side effects, and lower rates of postoperative pulmonary complications.[1] However, spinal anaesthesia-induced hypotension (SAIH) remains a significant challenge, particularly in geriatric patients who have age-related physiological alterations, including impaired baroreceptor reflexes, reduced vascular compliance, and diminished cardiac output reserves.[2]

The incidence of spinal anaesthesia-induced hypotension in elderly surgical patients is reported to be as high as 36–75%.[3] Hypotension after spinal anaesthesia primarily occurs due to sympathetic blockade, leading to venodilation, reduced venous return, and subsequent decreases in cardiac output and systemic vascular resistance (SVR).[4] In elderly patients, this hypotension can result in cerebral hypo perfusion, myocardial ischemia, renal dysfunction, and increased postoperative morbidity.[5]

Vasopressor Selection in the Management of Spinal Hypotension

To counteract spinal anaesthesia-induced hypotension (SAIH), vasopressors are routinely administered to restore hemodynamic stability by counteracting venodilation, reducing venous return, and maintaining adequate cardiac output. Among the available vasopressors, phenylephrine and norepinephrine are the most commonly used in clinical practice. However, their pharmacologic profiles differ significantly, influencing their effects on blood pressure, cardiac output, and heart rate.

Phenylephrine

Pharmacology and Mechanism of Action

- Phenylephrine is a pure α1-adrenergic receptor agonist, meaning it exclusively stimulates α1 receptors, leading to peripheral vasoconstriction and increased systemic vascular resistance (SVR).[6]
- This vasoconstrictive effect rapidly restores blood pressure by increasing mean arterial pressure (MAP), making it a potent agent for treating spinal anaesthesia-induced hypotension.[7]
- However, phenylephrine lacks β1-adrenergic activity, which means it does not exert any direct cardiac stimulation. This results in:
  - Baroreceptor-mediated reflex bradycardia, which may be problematic in patients with pre-existing low cardiac output or advanced age.[8]
  - Decreased stroke volume and cardiac output (CO), which could potentially impair end-organ perfusion, especially in elderly patients.[9]

Clinical Implications: While phenylephrine is effective in restoring blood pressure, its bradycardia-inducing effects could be detrimental in elderly, hypovolemic, or cardiac-compromised patients.[10] Studies suggest that phenylephrine is highly effective in obstetric anaesthesia but may not be the optimal choice for geriatric populations undergoing lower limb surgeries.[11]

Norepinephrine

Pharmacology and Mechanism of Action

- Norepinephrine is a mixed α1- and weak β1-adrenergic agonist, meaning it:
  - Increases SVR and MAP (via α1 receptor stimulation, similar to phenylephrine).
  - Has mild β1 activity, helping maintain heart rate and cardiac output.[12]
- Due to this dual mechanism, norepinephrine effectively restores blood pressure while reducing the incidence of reflex bradycardia.[13]
- Compared to phenylephrine, norepinephrine has been found to be 6.03 times more potent, meaning it can achieve the same MAP stability at lower doses.[14]

Clinical Implications

- The addition of β1 stimulation helps prevent bradycardia, making norepinephrine a preferable choice for elderly patients with compromised cardiac function.[15]
- Norepinephrine is increasingly recommended in non-obstetric populations, particularly geriatric surgical patients and high-risk cardiac patients undergoing lower limb surgeries.[16]

Phenylephrine is a highly effective vasopressor for preventing hypotension in obstetric anaesthesia but is associated with increased bradycardia and reduced cardiac output, making it less suitable for elderly surgical patients. Norepinephrine provides a more balanced hemodynamic profile, maintaining MAP and CO with fewer bradycardia episodes, making it a preferred choice for elderly patients undergoing orthopedic surgeries. Given that norepinephrine is 6.03 times more potent than phenylephrine, lower doses can be used, potentially reducing the risk of excessive vasoconstriction and ischemia. These findings suggest that norepinephrine should be considered as a first-line agent in elderly patients undergoing lower limb surgeries under spinal anaesthesia to optimise hemodynamic stability while minimising cardiac depression and reflex bradycardia.

Several studies have compared phenylephrine and norepinephrine in the context of spinal anaesthesia-induced hypotension. Meta-Analysis by Kang et al. (2023): Compared norepinephrine vs. phenylephrine in cesarean sections and found no significant difference in MAP maintenance. However, norepinephrine was associated with fewer bradycardia episodes.[12] Randomised Controlled Trial by Wakhloo et al. (2022): Demonstrated that norepinephrine provided better hemodynamic stability than phenylephrine in spinal anaesthesia patients undergoing cesarean section. Norepinephrine maintained heart rate and cardiac output better than phenylephrine.[10] Potency Study by Qian et al. (2022): Norepinephrine was found to

be 6.03 times more potent than phenylephrine in preventing spinal anaesthesia-induced hypotension.[14] Prothrombotic Effects Study by Tao et al. (2023): Investigated whether norepinephrine increases the risk of thrombotic events compared to phenylephrine. This is particularly relevant in elderly patients, who already have an increased risk of thrombosis due to aging-related hypercoagulability.[15]

Table 1: Comparison of Key Studies on Vasopressor Use in Spinal Anaesthesia

Study & Year	Study Type	Findings on MAP Maintenance	Effect on Heart Rate	Potency Comparison	Special Considerations
Kang et al. (2023)	Meta-analysis of multiple RCTs (Cesarean section)	No significant difference between norepinephrine and phenylephrine	Norepinephrine was associated with fewer bradycardia episodes	Not assessed	Large dataset, confirming norepinephrine's advantage in heart rate stability.[12]
Wakhloo et al. (2022)	Randomized Controlled Trial (RCT) (Cesarean section)	Norepinephrine provided better hemodynamic stability	Better maintenance of heart rate and cardiac output compared to phenylephrine	Not assessed	Supports the preference of norepinephrine for maintaining cardiac output.[13]
Qian et al. (2022)	Potency Determination Study	Not assessed	Not assessed	Norepinephrine is 6.03 times more potent than phenylephrine	Suggests lower norepinephrine doses can achieve comparable effects with fewer side effects [14] .
Tao et al. (2023)	Prothrombotic Effects Study	Not assessed	Not assessed	Not assessed	Investigated whether norepinephrine increases thrombotic risk, relevant for elderly patients with pre-existing hypercoagulability [15] .

MAP Maintenance: Both norepinephrine and phenylephrine effectively maintain blood pressure, with no major differences in MAP stability. Bradycardia: Norepinephrine is superior in reducing baroreceptor-mediated reflex bradycardia, making it a better option for elderly patients. Potency: Norepinephrine is 6.03 times more potent than phenylephrine, allowing for lower doses while achieving similar hemodynamic stability. Thrombotic Risk: Further studies (e.g., Tao et al., 2023) are needed to clarify potential thrombotic risks associated with norepinephrine infusion in elderly and high-risk patients. These studies provide strong clinical evidence favouring norepinephrine as a more balanced vasopressor, particularly for elderly patients or those at risk of bradycardia during spinal anaesthesia-induced hypotension. Future studies should further explore its long-term safety and prothrombotic effects.

Aims & Objectives

Although there is ample evidence supporting norepinephrine's advantages over phenylephrine in obstetric anaesthesia, data on their use in elderly surgical patients undergoing orthopedic procedures remains limited. Since geriatric patients have higher risks of hypotension-related complications, this study aims to:

1. Compare the prophylactic use of norepinephrine and phenylephrine infusions in elderly patients undergoing proximal femoral nail surgeries under spinal anaesthesia.
2. Evaluate hemodynamic parameters, including mean arterial pressure (MAP) stability and heart rate maintenance.
3. Assess rescue vasopressor requirements and incidence of adverse effects, such as bradycardia, nausea, vomiting, and postoperative delirium.

By addressing these objectives, this study aims to provide clinically relevant data that could guide the choice of vasopressor therapy for elderly patients undergoing lower limb surgeries under spinal anaesthesia.

MATERIALS AND METHODS

Study Design & Period

Study Design: A randomised, double-blind, prospective study.

Study Setting: Conducted at tertiary-care hospital following institutional ethical approval (IEC ApplicationNo. 006-ACAD./E3B/2023-2024 dated 27-10-2023) and registration with the Clinical Trials Registry-India (CTRI/2024/03/064165).

Study Period: Conducted over 10 months, from March 2024 to January 2025.

Sample Size: 60 patients were recruited and randomly assigned into two groups (n=30 per group) using a computer-generated randomisation sequence. Written informed consent was obtained from all the patients.

Anaesthetic Protocol

- Patients were preloaded with 6% hydroxyethyl starch.
- Intrathecal anaesthesia: 0.5% bupivacaine heavy (2 ml) + 25 mcg fentanyl.
- Group A: Phenylephrine infusion at 0.5 mcg/kg/min.

- Group B: Norepinephrine infusion at 0.05 mcg/kg/min.
- Monitoring: MAP, HR, need for rescue vasopressors, and incidence of bradycardia, nausea, vomiting, and postoperative delirium.

Inclusion & Exclusion Criteria

Inclusion Criteria

- Age 65-80 years.
- Patients classified as ASA (American Society of Anaesthesiologists) physical status I or II.
- Scheduled for elective proximal femoral nail surgery under spinal anaesthesia.
- No history of severe cardiovascular, neurological, or endocrine disorders.

Exclusion Criteria

- Patients with pre-existing cardiac abnormalities (e.g., heart failure, arrhythmias, valvular disease).
- Uncontrolled hypertension (SBP > 180 mmHg, DBP > 110 mmHg).
- Patients with hyperthyroidism or untreated endocrine disorders.
- Known coagulation disorders or anticoagulant therapy.
- Patients with renal dysfunction (eGFR < 30 mL/min/1.73m²).
- Allergy or contraindication to the study drugs (norepinephrine or phenylephrine).

Statistical Analysis

- Sample size calculation: Based on previous studies, with a mean HR of 68 ± 9 bpm in the phenylephrine group, detecting a 10 bpm difference required 28 patients per group (power 80%, α=0.05).
- Data analysis: Mean ± standard deviation (SD) and analysed using the unpaired Student's t-test.
- Statistical significance: $p<0.05$.

RESULTS

The study compares the haemodynamic effects of prophylactic norepinephrine (Noradrenaline) and phenylephrine infusions in preventing hypotension in geriatric patients undergoing proximal femoral nail surgeries under spinal anaesthesia.

Demographic Data

Table 2: The demographic characteristics of both groups were comparable

Parameter	Group A (Phenylephrine, n=30)	Group B (Noradrenaline, n=30)	P-value
Age (years)	71 ± 5.8	71 ± 6.4	0.869
BMI (kg/m²)	24.9 ± 4.8	26.7 ± 5.2	0.259
ASA (I/II)	22/8	20/10	0.71
Duration of Surgery (min)	60	70	0.665

No significant difference in age, BMI, ASA status, or surgery duration between groups ($p > 0.05$). This suggests that both groups were comparable at baseline, making the results valid for comparison.

Basal and Follow-Up Values of Mean Arterial Pressure (MAP)

The study analysed **baseline MAP values** and their variations post-infusion in both groups.

Table 3: Basal and Follow-Up Values of Mean Arterial Pressure (MAP)

Timepoint	Group A (Phenylephrine)	Group B (Noradrenaline)	P-value
Baseline MAP (mmHg)	92.3 ± 7.5	91.8 ± 6.9	0.821
After Spinal Anaesthesia	81.5 ± 5.8	83.2 ± 6.1	0.357
After Vasopressor Infusion	89.1 ± 4.6	90.3 ± 5.1	0.425

No statistically significant difference in mean arterial pressure (MAP) between the two groups during drug infusion ($p > 0.05$). Both norepinephrine and phenylephrine effectively maintained MAP, preventing severe hypotension.

Bradycardia Incidence

Table 4: Bradycardia Incidence

Bradycardia Incidence	Group A (Phenylephrine)	Group B (Noradrenaline)	P-value
Patients affected (%)	26.6%	6.66%	**0.0105**

Significantly lower bradycardia incidence in Group B (Noradrenaline) compared to Group A (Phenylephrine) ($p = 0.0105$). Noradrenaline maintained better heart rate stability, which is an important consideration for elderly patients.

Rescue Vasopressor Requirement

Table 5: Rescue Vasopressor Use

Rescue Vasopressor Use	Group A (Phenylephrine)	Group B (Noradrenaline)	P-value
Patients requiring rescue doses	1	1	0.9

No statistically significant difference (p = 0.9) in rescue vasopressor requirement between groups. Both drugs were equally effective in preventing the need for additional vasopressors.

Adverse Events

Table 6: Adverse Event

Adverse Event	Group A (Phenylephrine, n=30)	Group B (Noradrenaline, n=30)	P-value
Nausea & Vomiting (%)	2 (6.6%)	1 (3.3%)	0.55
Postoperative Delirium	0	0	-
Perioperative MI	0	0	-

Interpretation: No significant difference in nausea, vomiting, or other adverse effects between groups (p > 0.05). No cases of postoperative delirium or perioperative myocardial infarction (MI) in either group.

Baseline MAP: Similar for both groups (~92 mmHg). After Spinal Anaesthesia: Both groups experienced a drop in MAP, but Group B (Noradrenaline) had a slightly lesser drop. After Vasopressor Infusion: MAP restored to near baseline in both groups, with no significant difference. Both drugs effectively maintained MAP and prevented severe hypotension. Noradrenaline had significantly lower bradycardia incidence compared to phenylephrine. No major differences in adverse events or rescue vasopressor use.

DISCUSSION

Spinal anaesthesia-induced hypotension is a significant concern, especially in elderly surgical patients and parturients undergoing cesarean sections. Vasopressors such as norepinephrine (noradrenaline) and phenylephrine play a pivotal role in counteracting this effect. The current study compares prophylactic norepinephrine and phenylephrine infusions in maintaining hemodynamic stability in elderly patients undergoing proximal femoral nail surgeries under spinal anaesthesia. Our findings are discussed in the context of previous literature.

Hemodynamic Stability and Mean Arterial Pressure (MAP)

Our study observed no statistically significant difference in MAP between norepinephrine and phenylephrine groups at various intraoperative time points (p > 0.05). This aligns with previous findings in obstetric anaesthesia. Kang et al. (2023) conducted a meta-analysis comparing umbilical artery (UA) and umbilical vein (UV) pH and base excess (BE) in parturients receiving norepinephrine vs. phenylephrine. Their results showed no significant difference in neonatal acid-base status, suggesting both vasopressors maintain effective perfusion without metabolic compromise.[9] Similarly, Wakhloo et al. (2022) found that norepinephrine provided comparable hypotension prevention as phenylephrine in cesarean patients.[10] Qian et al. (2022) determined the relative potency of these agents when given as infusions and found that norepinephrine is 6.03 times more potent than phenylephrine, allowing for lower doses.[14]

Both norepinephrine and phenylephrine act primarily through α1-adrenergic receptor activation, leading to arterial and venous vasoconstriction, which increases systemic vascular resistance (SVR) and venous return, stabilising cardiac output (CO) and MAP. Phenylephrine is a pure α1 agonist with no β-adrenergic effects, leading to increased SVR but a reflex decrease in heart rate due to baroreceptor activation.[3] Norepinephrine is a mixed α1 and weak β1 agonist, meaning it increases BP while maintaining CO and reducing the reflex bradycardia.[3] Thus, our study's comparable MAP results confirm that both vasopressors effectively prevent hypotension in elderly patients under spinal anaesthesia.

Bradycardia Incidence

Our study found a significantly lower incidence of bradycardia in the norepinephrine group (6.66%) compared to the phenylephrine group (26.6%) (p = 0.0105), confirming its superior heart rate maintenance. This finding is consistent with the meta-analysis by Kang et al. (2023), where no significant difference in neonatal outcomes was observed, but norepinephrine showed better heart rate preservation.[9] Wakhloo et al. (2022) also reported that phenylephrine led to more bradycardia episodes than norepinephrine in parturients.[10] Qian et al. (2022) confirmed that norepinephrine's β1 agonism counteracts reflex bradycardia, unlike phenylephrine, which lacks β-adrenergic effects.[14] Phenylephrine, being a pure α1 agonist, increases SVR significantly, which triggers baroreceptor-mediated reflex bradycardia. Norepinephrine, due to its β1 adrenergic activity, modestly increases heart rate while maintaining CO. This supports the preferential use of norepinephrine in elderly patients, where bradycardia and reduced CO could be detrimental.

Rescue Vasopressor Requirement

Both groups had an equal and statistically insignificant need for rescue vasopressors (p = 0.9). Tao et al. (2023) studied prophylactic norepinephrine vs. phenylephrine in cesarean sections and observed similar hemodynamic effects, without significant differences in rescue vasopressor requirements.[15] This suggests that both agents adequately prevent hypotension, reducing the need for additional vasopressor intervention.

Prothrombotic Response and Safety Concerns

The potential impact of vasopressors on coagulation status is an emerging concern. Tao et al. (2023) hypothesised that norepinephrine might be associated with increased prothrombotic activity due to its endogenous release effects in a hypercoagulable state.[15] While our study did not assess coagulation parameters, future trials should evaluate whether norepinephrine poses a thrombotic risk in elderly patients with pre-existing cardiovascular comorbidities.

Relative Potency of Norepinephrine vs. Phenylephrine

Qian et al. (2022) determined that norepinephrine is 6.03 times more potent than phenylephrine, requiring lower doses to maintain blood pressure.[14] This suggests that lower norepinephrine doses may achieve comparable MAP stability while reducing the risks of excessive vasoconstriction and ischemia.

Clinical Implications

Our study contributes to the growing evidence supporting norepinephrine as a superior alternative to phenylephrine in elderly surgical patients by demonstrating:

1. Comparable MAP control between norepinephrine and phenylephrine.
2. Significantly lower bradycardia incidence with norepinephrine ($p = 0.0105$).
3. No significant difference in rescue vasopressor requirements ($p = 0.9$).
4. Potential for lower doses of norepinephrine, reducing excessive vasoconstriction risks.

Given these findings, norepinephrine should be considered the preferred vasopressor in elderly patients undergoing spinal anaesthesia, particularly in those at risk of bradycardia and low cardiac output.

CONCLUSION

This randomised, double-blind study confirms that both norepinephrine and phenylephrine effectively prevent spinal anaesthesia-induced hypotension in elderly patients undergoing proximal femoral nail surgeries. However, norepinephrine is associated with significantly lower bradycardia incidence, making it a preferable alternative for this patient population.

Future research should focus on

- Expanding the sample size to strengthen statistical power.
- Evaluating long-term cardiovascular outcomes in elderly patients receiving different vasopressors.
- Assessing the potential prothrombotic risks of norepinephrine infusion.

Our study reinforces norepinephrine's role as a safe and effective vasopressor, particularly for patients at risk of bradycardia and cardiac output reduction.

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