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COMPARISON OF NOREPINEPHRINE AND PHENYLEPHRINE BOLUSES FOR THE TREATMENT OF HYPOTENSION DURING SPINAL ANESTHESIA FOR CESAREAN SECTION: A DOUBLE-BLIND RANDOMIZED CLINICAL STUDY.

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ABSTRACT.

Introduction:
Phenylephrine in small boluses of 50 to 100µgm or infusion is commonly used to treat hypotension following spinal anesthesia in addition to fluids transfusion and compression stockings in lower limbs. Noradrenaline, the preferred drug for the management of hypotension in shock is now being tried to treat hypotension following spinal anesthesia in small increments. The present study was carried out to compare the efficacy of noradrenalin over phenylephrine in treating hypotension following spinal anesthesia.

Materials and Methods:
A hundred patients undergoing cesarean section were randomly divided into two groups. One group received phenylephrine 50µgm intravenous bolus and the other group received noradrenalin 4µgm intravenous bolus to treat hypotension following spinal anesthesia. The doses of phenylephrine and noradrenaline required to treat spinal hypotension, the incidence of bradycardia, hypotension, nausea, and vomiting in the mother and fetal outcome were recorded.

Observation:
The number of boluses of vasopressors required to treat hypotension was significantly lower in the noradrenaline group (Group NE=1.36±0.563, Group PE=2.00±0.699, p-value=0.000). The frequency of bradycardia was higher in the phenylephrine group and was statistically significant (Group NE=2 (4%), Group PE=11 (22%) p-value=0.015). Maternal complications such as nausea vomiting and shivering were comparable between the groups. The fetal parameters were also comparable between the two groups.

Conclusion:
Noradrenaline boluses are equally effective to phenylephrine in treating spinal anesthesia-induced hypotension and can be considered an alternative to phenylephrine. The incidence of side effects is comparable between the groups.

Recommendations:
Based on the study findings, it is recommended to consider noradrenaline boluses as a viable alternative to phenylephrine for treating hypotension following spinal anesthesia in patients undergoing cesarean section. Noradrenaline demonstrates similar efficacy in addressing spinal anesthesia-induced hypotension while maintaining comparable rates of side effects.

Keywords: *Spinal anesthesia, Hypotension, Phenylephrine, Noradrenaline*
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INTRODUCTION.

The subarachnoid block is a widely used anesthesia technique for cesarean section due to its quick onset of action, excellent surgical anesthesia, patient comfort, and lesser incidence of complications[1]. However, it is frequently associated with maternal hypotension, which causes nausea and vomiting, decreased uteroplacental blood flow, and an increased risk of fetal acidosis[2]. Various methods are

employed to decrease the incidence of hypotension like preventing aorto-caval compression by left uterine displacement, transfusion of crystalloids and colloids, and use of vasopressor[3,4]. Phenylephrine is currently the drug of choice in preventing and treating spinal anesthesia-induced hypotension as it is a potent vasopressor with rapid onset and short duration of action[5]. However, it causes reflex bradycardia which decreases cardiac output and adverse fetal and maternal outcomes. Noradrenaline, another potent vasopressor with alpha -1 and beta -1 agonistic action causes reflex negative chronotropic action due to its potent alpha agonist effect which is balanced by the weak beta agonist-mediated positive chronotropic effect.[6] Hence it has a lesser tendency to cause bradycardia as compared to phenylephrine. This study was carried out to find the safety, efficacy, adverse effects, and fetal and neonatal outcomes in cesarean-section patients treated with phenylephrine or noradrenaline for hypotension.

MATERIALS AND METHODS.

Study setting.

The study was conducted at Saheed Laxman Nayak Medical College and Hospital (SLN MCH) Koraput, India, for a duration of one year (2021-2022)

Study design.

This was a double-blind randomized clinical study carried out on 100 patients undergoing elective cesarean section under spinal anesthesia.

Inclusion criteria.

Term parturients of 37 to 42 weeks of gestation, age 21 and 35 years, singleton pregnancy, American Society of Anesthesiologists (ASA) physical class I and II, and elective cesarean section under spinal anesthesia were included in the study.

Exclusion criteria.

Participant refusal, allergy or hypersensitivity to the drugs to be used, hypertensive disorders of pregnancy, and parturients with cardiovascular or cerebrovascular disease and with fetal abnormalities were excluded from the study.

Ethical considerations.

Informed consent was taken from all the participants.

Procedure.

The parturients were randomized into group P and group N by a computer-generated random sequence of numbers and concealed by closed envelope technique.

In the theatre, an 18-gaFuge intravenous cannula was inserted and standard monitoring with non-invasive arterial pressure, electrocardiography, and pulse oximetry was done. The baseline vitals were noted. They were preloaded with 15 mL/kg of lactated Ringer's solution. Subarachnoid block was done with 25-G quincke's spinal needle in the left lateral position at L3–L4 or L4–L5 level using a standard technique with 2.0 mL of 0.5% hyperbaric bupivacaine. The patients were turned supine with a wedge for left uterine displacement to prevent aorto-caval compression.

The highest level of sensory blockade was assessed with ice cubes 5 min after intrathecal injection. Norepinephrine and phenylephrine were diluted and loaded in an identical coded 10-mL syringe to give norepinephrine 4 µgm/mL (Noracare, Arvincare) and phenylephrine 50 µg/mL (Phenpres LS, Neon). An anesthetist posted in the theatre blinded to the study used a vasopressor-labeled syringe to treat hypotension and collected the data for analysis. The patient and the investigator were blinded to the vasopressor used. Blood pressure and HR were monitored every 2 min till 10 min and thereafter every 5 min till the end of surgery. Patients received phenylephrine 50µg or 4µg of norepinephrine intravenous bolus whenever the systolic arterial pressure dropped below 20% of baseline. After the delivery of the baby, 10 U of oxytocin was given as a slow infusion. Incidence of hypotension, bradycardia, and the total dose of vasopressor used intraoperatively were noted. Bradycardia was defined as an HR of less than 50 beats/min (bpm) and was treated with intravenous atropine 0.6 mg. A pediatrician who was not aware of the vasopressor used noted Apgar score at 1 and 5 min. An umbilical vein sample at the time of birth for blood gas analysis was collected and pH, PCO2, bicarbonate, and base excess were analyzed. The total duration of surgery, incidences of nausea and vomiting, and shivering were also noted.

Quantitative variables.

Hemodynamic parameters like heart rate, systolic blood pressure, diastolic blood pressure, and bradycardia were noted. Fetal parameters like APGAR at 1 min, 5 min, and cord blood analysis were recorded.

Statistical analysis.

Data was collected in the preformed data sheet and was recorded in Microsoft Excel. Data was analyzed in SPSS ver.23. P value <0.05 was taken as statistically significant.

OBSERVATION.

Table 1. Comparison of demographic profile.

Demography	Group NE (n=50)	Group PE (n=50)	P Value
Age (years)	26.08±3.288	25.94±3.616	0.840 (NS)
Weight (kg)	71.98±6.046	73.14±6.389	0.353 (NS)
Height (cm)	149.30±4.249	147.96±4.257	0.118 (NS)

The mean age, weight, and height were comparable between the groups as the P value is not significant in any case.

Table 2. Comparison of Duration of surgery and block height.

	Group NE (n=50)	Group PE(n=50)	P Value
Duration (min)	58.86±3.891	60.2±4.136	0.098(NS)
Block Height			
T3	2	0	0.304(NS)
T4	26	30	
T5	22	20	

The two Groups were comparable in terms of duration of surgery (Group NE = 58.86±3.891 m in and Group PE = 60.2±4.136 min with a p-value of 0.098, using Chi-square test) and height of block (p-value 0.34).

Table 3. Comparison of Haemodynamic variables.

	Group NE (n=50)	Group PE (n=50)	p-value
No. of boluses of vasopressors	1.36±0.563	2.00±0.699	0.000(S)
Incidence of bradycardia	2 (4%)	11 (22%)	0.015(S)

The number of boluses of vasopressors required to treat hypotension was significantly lower in group NE patients. (Group NE=1.36±0.563, Group PE=2.00±0.699, p-value=0.000). The frequency of bradycardia was high in group PE, and the difference was statistically significant [Group NE=2 (4%), Group PE=11 (22%) p-value=0.015].

Table 4. Comparison of Maternal and Fetal parameters.

	Group NE (n=50)	Group PE (n=50)	p-value
Maternal shivering	6 (12%)	6 (12%)	1.000
Maternal nausea and vomiting	4 (8%)	4 (8%)	1.000
pH of cord blood	7.327±0.312	7.323±0.310	0.533
pO2	34.96±7.753	35.74±5.915	0.578
pCO2	43.50±2.643	42.88±2.666	0.246
Lactates	1.986±0.140	1.982±0.1034	0.860
APGAR SCORE APGAR at 1 min			
7	8 (16%)	11 (22%)	0.724
8	14 (28%)	12 (24%)	
9	28 (56%)	27 (54%)	
APGAR at 5 min			
8	2 (4%)	0 (0%)	0.353
9	24 (48%)	24 (48%)	
10	24 (48%)	26 (52%)	

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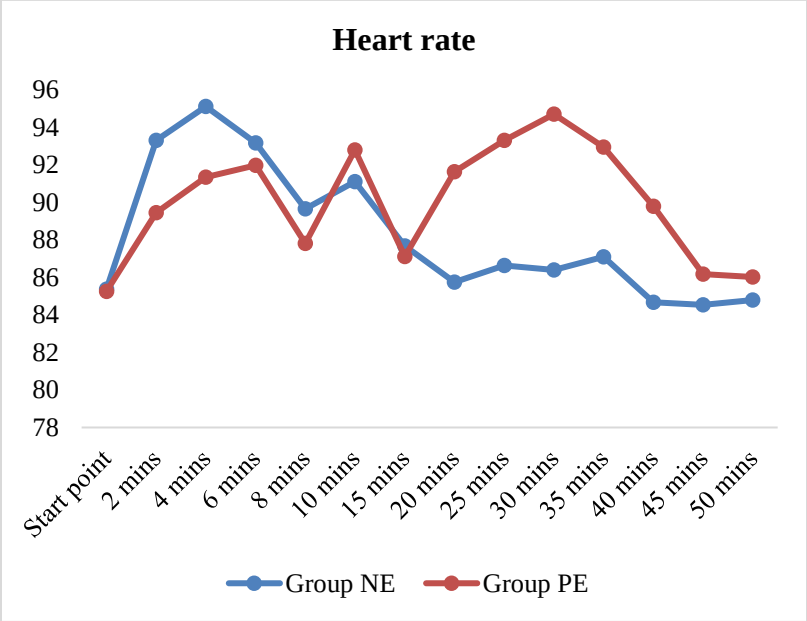
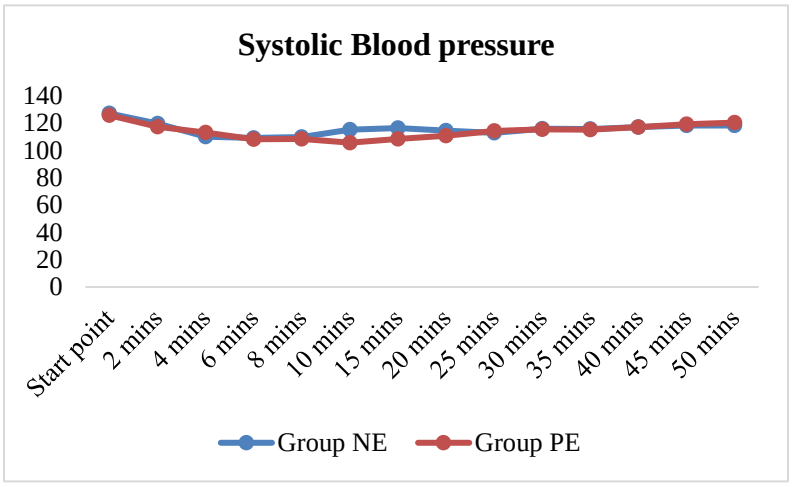
Maternal complications such as nausea, vomiting, and shivering were comparable between the groups. The fetal parameters were comparable between the two groups, and no statistical difference was noted.

Graph 1. Heart rate trends.



The heart rate of the parturients was comparable between the group NE and PE throughout the LSCS except in the 20th min, 25th min, 30th min, 35th min, and 40th min which is statistically significant (p-value <0.05). The heart rate in this phase is higher in Group PE than in Group NE. This may be attributed to the use of Inj. Atropine boluses in group PE to treat bradycardia ultimately causing an increase in heart rate compared to Group NE where Inj Atropine is used less commonly because of the lesser incidence of bradycardia in this group.

Graph 2. Systolic Blood Pressure Trend.



The systolic blood pressure (SBP) is also comparable in both groups except at 10 minutes and 15 minutes where the SBP of group PE is less than group NE.

DISCUSSION.

In this study, hypotension was defined as systolic blood pressure less than 80% of the baseline and bradycardia as less than 50 beats per minute. Several methods have been adapted to prevent and treat spinal anesthesia-induced hypotension which include change of maternal posture, pre-loading with fluids, use of compression stockings of lower limbs, and use of vasopressors, etc. Hypotension is the major adverse effect after spinal anesthesia for cesarean section with an incidence up to 71%.2 Hypotension develops due to aortocaval compression by the gravid uterus in pregnant patients and higher levels of sympathetic blockade causing the pooling of blood in the venous capacitance vessels. Hypotension is detrimental to both mother and fetus and should be prevented rather than treated. Hypotension is defined as the reduction in arterial pressure 20% below baseline.

In this study, 100 participants were allocated into 2 groups which were group NE (norepinephrine) and group PE (phenylephrine). Patients belonging to the norepinephrine group received an i.v. a bolus of norepinephrine (4 mcg/ml) and those in the phenylephrine group received an i.v. bolus of phenylephrine (50mcg/ml) based on the results of the study by Ngan Kee et al.[7] as 4 µg of norepinephrine was found to be equipotent to 50 µg of phenyleph.
In this study, it was found that the number of boluses of vasopressors required to treat hypotension was significantly lower in group NE patients. (Group NE=1.36±0.563, Group PE=2.00±0.699, p-value=0.000) and the frequency of bradycardia was higher in group PE and the difference was statistically significant [Group NE=2 (4%), Group PE=11 (22%) p-value=0.015].
In a trial conducted by Hasanin et al[8] in 140 mothers compared the efficacy and safety of phenylephrine and norepinephrine during cesarean delivery and were given prophylactic vasopressors after spinal anesthesia at a rate of 0.05 microgram/kilogram/minute and 0.75 microgram/kg/minute respectively. The incidence of bradycardia was half in the NE group compared to the PE group but did not reach statistical significance (12% in the NE group versus 24% in the PE group with a P =value of 0.1). In a double-blind randomized controlled trial by M Mohta et al[9], 90 women received 100mcgm phenylephrine (n=58) and 5mcgm noradrenaline (n=61) as boluses. The incidence of bradycardia was 37.8% with phenylephrine as compared to 22.2% with the noradrenaline group (p-value was 0.167) which was not statistically significant.

A randomized double-blind study conducted by Goel et al.[10] on 200 parturients undergoing cesarean section under the subarachnoid block (SAB) received variable rate, manually controlled infusions of phenylephrine and norepinephrine targeting maintenance of SBP to 100% of the baseline value. Bradycardia was higher in the phenylephrine group than in the noradrenaline group and was statistically significant (16% versus 1% respectively; P value- 0.001). The higher incidence of bradycardia was due to α-adrenergic agonist property which leads to decreased heart rate (HR) and cardiac output (CO) even when BP is maintained at baseline. The Norepinephrine group had a lesser reduction of heart rate due to its direct positive chronotropic along the reflex negative chronotropic actions.
Ngan Kee et al.[11] enrolled 668 subjects for elective and non-elective cesarean delivery under spinal or combined spinal-epidural anesthesia in a randomized double-blind two-arm parallel non-inferiority clinical trial received norepinephrine 6mcg/ml and phenylephrine 100mcg/ml either prophylactically, as an infusion or bolus. Incidence of bradycardia was lower in the norepinephrine group (26%) as compared to the phenylephrine group (42%) (RR=0.61; 95% CI, 0.49-0.77). Kunpeng et al.[12] included 238 term parturients who underwent cesarean delivery and compared the effects of phenylephrine and norepinephrine administered as a continuous infusion on maternal hemodynamic parameters and maternal and fetal outcomes. Heart rates in the Phenylephrine group were significantly lower than the control group at the 3rd, 4th, 5th, 6th, 7th, and 8th minute, and also lower than the norepinephrine group at the 5th, 6th, 7th, 8th, and 9th minute. However, in this study, the heart rate of the parturients was comparable in both the group NE and PE throughout the LSCS except in the 20th min, 25th min, 30th min, 35th min, and 40th min which is statistically significant (p-value < 0.05). This may be attributed to the use of Inj. Atropine 0.6 mg IV boluses in group PE to treat bradycardia ultimately causing an increase in heart rate compared to Group NE where Inj Atropine 0.6 mg IV is used less commonly because of lesser incidence of bradycardia in this group.

In a study conducted by Puthenveettil et al., [13] fifty patients undergoing elective cesarean section under spinal anesthesia received phenylephrine 50 micrograms of as an IV bolus or 4 micrograms of norepinephrine as an IV bolus to treat post-spinal hypotension. The number of boluses of vasopressors required to treat hypotension was significantly lower in group N patients compared to the P group (1.40 ± 0.577 vs. 2.28 ± 1.061, P = 0.001). The frequency of bradycardia was high in group P, but the difference was not statistically significant (4% vs. 20% P = 0.192).
The pH of cord blood in group NE was 7.327±0.312 and group PE was 7.323±0.310 with a mean difference of 0.004 and a non-significant p-value of 0.533. This suggested that both the drugs were safe and their use didn't lead to fetal acidosis (pH<7). In a study by Ngan Kee et al.[11], the umbilical artery mean pH was 7.289 (95% CI, 7.284-7.294) in the norepinephrine group and 7.287 (95% CI, 7.281-7.292) in the phenylephrine group. The mean difference in

umbilical artery pH between groups was 0.002 (95% CI, 0.005 to 0.009).
It was found that both APGAR at 1 minute and 5 minutes are statistically comparable (p-value 0.724 and 0.353 respectively). In a study conducted by Goel et al.[10] a comparable and favorable neonatal outcome was found which was reflected clinically by overall good APGAR scores with no score less than 8. In a similar study conducted by Hassanin et al[14] blood gas analyses between the Group NE and PE were comparable and statistically non-significant (P value of 0.2 for the pH of cord blood gas analysis) comparable to the study (p-value of 0.533). Mohta et al[9] conducted blood gas analysis between Group NE and Group PE and found comparable and statistically non-significant results [P value of 0.85 for the pH of cord blood gas analysis].

In this study, the incidence of nausea and vomiting was 8% in both Group NE and Group PE and was comparable. In the study by Hasanin et al., [15] the incidence of nausea was 15% in the NE group and 6% in the PE group, and the incidence of vomiting was 5% in the NE group and 3% in the PE group and was statistically insignificant which was similar to the study. Goel et al.10 compared the incidence of nausea (11% of patients in group A- Phenylephrine and 7% of patients in group B- Norepinephrine) (P=0.323). Ngan et al.[11] in a closed-loop feedback computer-controlled infusion of phenylephrine or norepinephrine for maintaining blood pressure in 53 patients having spinal anesthesia for elective cesarean section observed that none of the patients had nausea or vomiting. (RR=1.14; 95% CI, 0.88-1.50).
There are controversies regarding the use of norepinephrine through peripheral veins, but we did not encounter side effects with its use in any of the patients.

CONCLUSION.

Intermittent boluses of norepinephrine were effective in maintaining the hemodynamic parameters better as compared to boluses of phenylephrine following spinal anesthesia during cesarean section. There were no significant differences in complications among both groups. The neonatal arterial blood gases and Apgar scores were also comparable with phenylephrine. Thus, to conclude norepinephrine boluses can be considered a better alternative to phenylephrine boluses for the management of spinal-induced hypotension during cesarean section.

LIMITATIONS.

The major limitation of the present study was that vasopressor was used to maintain the systolic pressure without monitoring the cardiac output. Non-invasive cardiac output monitor could have been used. Furthermore, a larger sample size could have provided a wider perspective on maternal and fetal effects. The study could be extended to a larger number of patients with intermittent or continuous infusions of norepinephrine.

RECOMMENDATIONS.

Based on the study findings, it is recommended to consider noradrenaline boluses as a viable alternative to phenylephrine for treating hypotension following spinal anesthesia in patients undergoing cesarean section. Noradrenaline demonstrates similar efficacy in addressing spinal anesthesia-induced hypotension while maintaining comparable rates of side effects.

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LIST OF ABBREVIATIONS.

ASA:	American Society of Anesthesiologist
SBP:	Systolic Blood Pressure
NE:	Norepinephrine
PE:	Phenylephrine
CO:	Cardiac Output
HR:	Heart Rate

SOURCE OF FUNDING.

The study had no funding

CONFLICT OF INTEREST.

The authors report no conflicts of interest in this work.

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