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Original Research Article

Comparison of intermittent intravenous bolus of phenylephrine and noradrenaline in management of spinal anesthesia induced hypotension in elective cesarean section: A randomized controlled trial

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ABSTRACT

Background and Aims: Though Noradrenaline infusion is showing promising results for management of spinal anaesthesia-induced hypotension, there are very few studies that evaluated intermittent intravenous (i.v) bolus dose of inj. Noradrenaline. So, we aimed to compare intermittent i.v. bolus of phenylephrine and noradrenaline in management of spinal anaesthesia-induced hypotension in elective LSCS.

Materials and Methods: This randomized controlled study was conducted in obstetrics operation theatre from August 2022 to April 2023. Intermittent I.V. bolus dose of Phenylephrine (Group A) was compared with intermittent I.V. bolus dose of Noradrenaline (Group B). Data regarding baseline heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), hypotension, bradycardia, total number of bolus doses of study drugs required, intraoperative nausea and vomiting, neonatal Apgar score at one and 5minute, and umbilical cord blood gas analysis at birth were collected and analyzed using standard statistical tests.

Results: HR at 9 minute, 12 minutes, 15 minutes, and 20 minutes after spinal anaesthesia was significantly lower in group A than in group B. No statistically significant difference was found between the groups in terms of SBP, DBP, MAP, APGAR score at one and five minutes, UA pH, UA PO2, UA PCO2, UA HCO_3^-, UV pH, UV PO2, UV PCO2, UV HCO_3^-. Incidence of nausea and vomiting was higher in group A than in group B (P-value = 0.006).

Conclusion: Though intermittent I.V. bolus of both Phenylephrine and Noradrenaline are equally efficacious in management of spinal anaesthesia-induced hypotension during elective LSCS, inj. Noradrenaline is a better option with fewer adverse effects.

1. Introduction

Recently, phenylephrine, a pure alpha$_1$ agonist, has become the 1st line agent for treating spinal anaesthesia-induced hypotension in obstetrics.[1,2] The main drawback of using this agent is a dose-related decrease in heart rate (HR) and cardiac output (CO) which may adversely affect uteroplacental circulation.[1,3,4] Though it may not cause any serious problems with a normal foetus in elective lower segment caesarean section (LSCS), in case of emergency, where the foetus is already compromised, it can affect more.[2] In this context, a drug like noradrenaline (NA) is advantageous as it has both direct positive chronotropic and baroreceptor reflex-mediated negative chronotropic effects with the overall effect on HR considered to be approximately neutral, and contributes to an overall increase

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in CO and BP.[5–7]

Many studies have evaluated the efficacy of continuous infusion of inj. NA for management of spinal anaesthesia-induced hypotension during LSCS.[2,4,6] However, there are not many studies that have evaluated the intermittent intravenous bolus dose of inj. NA for management of spinal anaesthesia-induced hypotension. Most clinicians favour the use of intermittent boluses of vasopressors rather than infusions as infusion pumps are costly, not easily available (especially in resource-poor setups), and difficult to operate. For these reasons, though Noradrenaline infusion is showing promising results for prophylaxis and treatment of maternal hypotension, it is not gaining much popularity in day-to-day practice.

Because of the above observations, our study was planned to compare the intermittent intravenous bolus of phenylephrine and noradrenaline in the management of spinal anaesthesia-induced hypotension in elective LSCS. The foetal outcome was also compared.

2. Materials and Methods

After obtaining approval from the institutional ethical committee (CTRI/2022/08/044815), this prospective randomized double-blind study was conducted following the Helsinki Declaration-2013, in the obstetrics operation theatre of a tertiary care centre in eastern India from August 2022 to April 2023 in ASA II pregnant patients of age 18 years and above undergoing elective LSCS under spinal Anaesthesia. Patient's refusal to subarachnoid block, infection at the site of injection, height < 140cm and >180cm, patient in active labour, patient with any spine deformity, bleeding disorder, GDM, PIH, eclampsia, allergy to phenylephrine and norepinephrine, cardiac or neurological diseases, known allergy to the anaesthetic drugs used, systemic sepsis, failed/patchy block converted into general Anaesthesia were excluded from the study.

In this study, intermittent I.V. bolus dose of Phenylephrine was compared with intermittent I.V. bolus dose of Noradrenaline in the management of spinal anaesthesia-induced hypotension in elective LSCS. Two groups were compared in terms of the perioperative haemodynamic effects, side effect profiles, and foetal outcomes. When the MAP value falls 20% from the baseline, we define it as hypotension.[8,9] Heart Rate below 60 beats/minute (bpm) was defined as bradycardia.[8]

Patients were explained in detail about the procedure. After obtaining written informed consent, eligible study candidates were randomly allocated into two groups (Group A: Phenylephrine and Group B: Noradrenaline group), 51 in each group by closed envelope method. Anaesthesia machine, airway equipment, and drugs for resuscitation were kept ready before starting the procedure. Injection Phenylephrine was prepared with a concentration of 50 μg/ml and was labeled as 'DRUG A'. Inj. Noradrenaline was prepared as 4μg/ml and was labeled as 'DRUG B'. Study solutions were prepared by a senior Anaesthesiologist, who was given a written protocol for drug preparation. The Anaesthesiologist who administered the drug and recorded the data, and the study participants were unaware of the composition of the study drug administered. After the patient arrived in the operation theatre, I.V. access was secured with an 18G cannula, and ringer lactate was administered (15 ml/kg) in both groups. Monitoring included: SpO2, ECG, non-invasive blood pressure (NIBP), and HR. Baseline HR, mean arterial pressure (MAP), SPO2, and ECG were recorded. BP was recorded 3 times in 2-minute intervals before administering spinal anaesthesia. The mean of these three readings was taken as baseline MAP and HR. After antiseptic dressing and draping spinal anaesthesia was administered with 25μg (0.5ml) Fentanyl + 1.8ml Bupivacaine heavy (0.5%) @ 0.2 ml/sec rate with the patient in a sitting position with 27G Whitacre needle at L3-L4 intervertebral space after confirming free flow of CSF. Immediately after giving spinal anaesthesia patient was kept in a supine position with a wedge in the back as 15 degrees left lateral tilt. Mean arterial pressure was monitored at 3-minute intervals for 15 minutes, then at 5-minute intervals. After achieving a sensory block height up to T6 dermatome, LSCS was allowed. Patients were supplemented with oxygen @ 4-6lt/min through a face mask. Immediately after hypotension, 1 ml of DRUG A was administered to group A patients and 1 ml of DRUG B to the patients of group B. Nausea and vomiting were treated with inj. Ondansetron 4 mg intravenously. After delivery of the baby, blood from umbilical artery (UA) and umbilical vein (UV) was sent for arterial blood gas (ABG) analysis (pH, PO_2, PCO_2, HCO_3^-). Data regarding hypotension, bradycardia, the total number of bolus doses of Drug A and Drug B required, intraoperative nausea and vomiting, neonatal Apgar score at 1 min and 5 min, and umbilical cord blood gas analysis at birth were collected.

The sample size has been calculated with the help of Epi Info (TM) 3.5.3. The formula used for sample size calculation was:- $n = 4pq/(L^2)$; where, n = required sample size, p= 0.137 (as per the study by Singh P et al.),[10] q = 1 – p, L = Margin of error. Here p= 0.137, q=1-p = 1-0.137 =0.863, 4pq = 4 x 0.137x 0.863 = 0.4729, L^2 = 0.00462; $n = 4pq/(L^2) = 0.4729/0.00462 = 102.3 = 102$. So, the number of patients required for this study was 102 with 87% power. For statistical analysis, data were entered into a Microsoft Excel spreadsheet and then analyzed by SPSS (version 27, SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Data had been expressed as mean and standard deviation (SD) for numerical variables, and count and percentages for categorical variables. Independent samples or unpaired samples were compared by two-sample t-tests for a mean difference. The chi-square test or Fischer's exact test was used to compare Unpaired proportions, as appropriate. P-

value ≤ 0.05 was interpreted statistically significant.

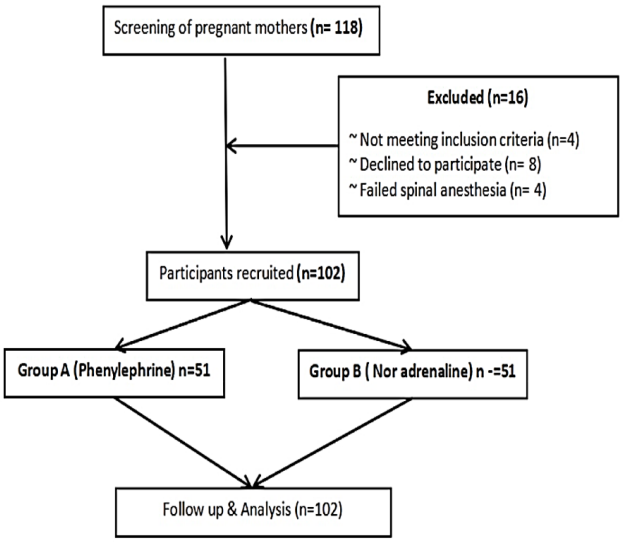

Figure 1: Consort diagram showing participants' recruitment and flow

3. Results

Data from 102 participants were analyzed. The two study groups (Group A and Group B) were comparable in terms of age, weight, height, and duration of pregnancy (Table 1).

From Figure 2, we can see that HR at 9 min, 12 min, 15 min, and 20 min after spinal Anaesthesia was significantly lower in group A than in group B with the HR of 51.05 ± 3.53 in group A and 88.76 ± 8.76 in group B (P-value: 0.00001), 51.21 ± 3.76 in group A and 86.13 ± 7.13 in group B (P-value: 0.0001), 51.94 ± 3.54 in group A and 84.8 ± 5.85 in group B (P-value: 0.0001), 68.58 ± 8.81 in group A and 83.25 ± 7.55 in group B (P-value: 0.003) at 9 minutes, 12 minutes, 15 minutes, and 20 minutes respectively. Even in some patients of group A, HR was as low as less than 50 bpm.

No statistically significant difference was found between the groups in terms of mean arterial pressure. (Figure 3)

No statistically significant difference was found between the two groups in terms of APGAR score at 1 minute and 5 minutes (Table 2). No statistically significant difference was found between the two groups concerning UA pH, UA PO_2, UA PCO_2, UA HCO_3^-, UV pH, UV PO_2, UV PCO_2, and UV HCO_3^- (Table 2). The incidence of nausea and vomiting in group A is 59% and in group B is 40% and the difference was statistically significant (P-value = 0.006). From Table 3, we can see that Group B patients received a greater number of bolus doses than Group A and the difference is statistically significant.

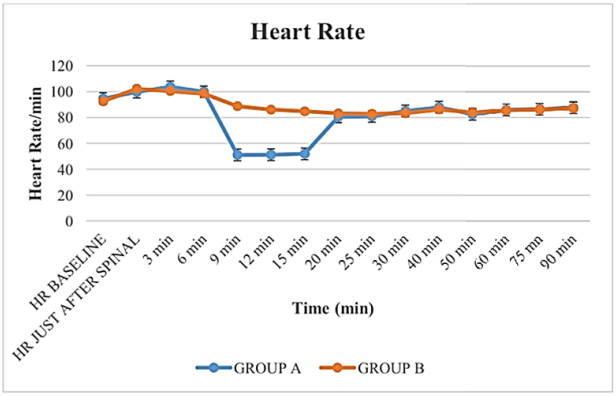

Figure 2: Graph demonstrating difference in HR at different time intervals

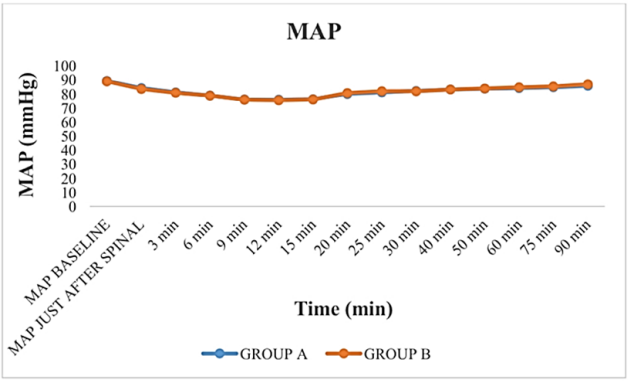

Figure 3: Graph demonstrating difference w.r.t MAP at different time intervals

4. Discussion

The present study shows that both inj. phenylephrine (50μg bolus) and inj. noradrenaline (4μg bolus) has similar efficacy for the management of hypotension during LSCS under spinal anaesthesia without causing any adverse neonatal outcome. However, patients who received phenylephrine bolus experienced more episodes of bradycardia (HR up to 37/min) than the patients who received noradrenaline. This finding corroborates our hypothesis that using $alpha_1$ agonists with $beta_1$ adrenergic action has similar efficacy in maintaining BP without causing a significant decrease in HR compared to pure $alpha_1$ agonists.

We have observed that patients of both groups maintained their BP throughout the whole duration of surgery. Differences in MAP were not statistically significant between the two groups. However, we have documented episodes of bradycardia in patients of group A after giving phenylephrine bolus without any increase in BP above the baseline. While comparing HR, differences in HR between both groups were statistically

Table 1: Distribution of maternal characteristic details

Parameters	Group	Mean (SD)	p-value
Age	A	24.88 (3.05)	0.85
	B	24.86 (3)	
Height(cm)	A	159.27 (4.87)	0.806
	B	159.96 (4.78)	
Weight (Kg)	A	59.98 (4.74)	0.999
	B	60.86 (5.09)	
Period of Gestation (week)	A	37.62 (0.68)	0.65
	B	37.57 (0.65)	

Table 2: Comparison between group A and group B concerning UA & UV blood gas analysis and mean APGAR score

Parameters	Group	Mean (SD)	p-value
UA pH	A	7.42 (0.24)	0.242
	B	7.38 (0.22)	
UA PO_2	A	14.563 (1.24)	0.18
	B	16.014 (0.92)	
UA PCO_2	A	45.987 (2.24)	0.47
	B	43.129 (1.82)	
UA HCO_3^-	A	23.987 (1.8238)	0.15
	B	24.68 (0.82)	
UV pH	A	7.389 (0.94)	0.44
	B	7.4 (0.82)	
UV PO_2	A	20.98 (2.89)	0.49
	B	21.35 (1.92)	
UV PCO_2	A	40.897 (1.94)	0.33
	B	41.67 (1.92)	
UV HCO_3^-	A	22.989 (1.82)	0.27
	B	23.67 (0.82)	
APGAR 1 min	A	8.49 (0.50)	0.84
	B	8.51 (0.51)	
APGAR 5 min	A	8.55 (0.50)	0.56
	B	8.49 (0.51)	

Table 3: Comparison between group A and group B concerning the number of bolus doses given

Parameter	Group	Mean (SD)	P-value
No. of bolus doses	Group A	4.16 (1.36)	<0.00001
	Group B	8.27 (1.51)	

significant at 9 minutes, 12 minutes, and 15 minutes after giving spinal anaesthesia. But BP never went above the baseline at those above-mentioned times. The incidence of bradycardia was 41 among 51 patients in group A (82%) and 2 in group B (4%). During LSCS under spinal anaesthesia, maternal bradycardia may occur due to the Bainbridge reflex, or from the blockade of cardiac accelerator sympathetic fibres (T_1-T_4).[8] Either mechanism would be counteracted by beta receptor-mediated agonistic activity.[2,6,7] Therefore, norepinephrine demonstrated a better HR maintenance profile and lower incidence of bradycardia than the patients who received phenylephrine.[5,7]

In the present study CO, SV, or SVR was not measured. But Xu S et al. in their meta-analysisfound that noradrenaline was associated with greater CO and lower SVR than phenylephrine.[2] Theoretically, this haemodynamic profile of noradrenaline may be potentially more favourable for maintaining perfusion in the uteroplacental bed and another peripheral vascular region.[2,7] The finding of our study is that group B patients had greater HR than group A. Due to more CO and lower SVR in patients receiving noradrenaline, there was a reflex increase in HR due to inhibition of the Bainbridge reflex and stimulation of the baroreceptor reflex. Singh J et al. found in their study that noradrenaline has less adverse effect on HR and greater CO compared to phenylephrine in preventing spinal anaesthesia-induced hypotension during LSCS.[11] M. Heesen et al. found that noradrenaline preserved better haemodynamic stability compared to phenylephrine.[12] Singh D et al. stated that phenylephrine causes serious bradycardia at the time of administration.[13] Aidan M

Sharkey et al. found that the haemodynamic profile offered by noradrenaline during caesarean delivery is superior to that of phenylephrine due to fewer fluctuations in HR and possibly CO.[14] Similar results were obtained in the present study.

In the present study, the incidence of nausea and vomiting is significantly lower in patients who received noradrenaline. Contributing factors may include opioids as an adjuvant for spinal anaesthesia, hypotension, or uterine exteriorization.[8,15,16] We used 25 μg of Fentanyl for every patient and uterine exteriorization was done in every case of our study population. Similar to the present study, Rai AV et al. have also observed a higher incidence of nausea and vomiting in the phenylephrine group than in the norepinephrine group.[4] Less incidence of nausea and vomiting in the noradrenaline group may be due to better gut and cerebral perfusion, followed by less serotonin release and less stimulation of the chemoreceptor trigger zone (CTZ).[17] This is an advantage of noradrenaline when compared to phenylephrine, as we have observed in the present study.

In our study, no significant difference in neonatal outcome was found between the two groups in terms of APGAR score (at 1min and 5 min), and UA and UV blood gas analysis at birth. Ngan Kee WD et al. also found in one of their studies that norepinephrine was non-inferior to phenylephrine for neonatal outcomes assessed by umbilical arterial pH and this result provided high-quality evidence supporting the foetal safety of norepinephrine in obstetric anaesthesia.[18]

We have used 50 μg of phenylephrine in group A and 4 μg of noradrenaline in group B. Warwick D. Ngan Kee et al. chose to study norepinephrine at a concentration of 6 μg/ml, which was estimated to be of equivalent potency to phenylephrine 100 μg/ml. This assumed a potency ratio for norepinephrine/phenylephrine of 16.7:1.[18] In another study of dose-response comparison of norepinephrine and phenylephrine, Ngan Kee et al. calculated a potency ratio of 13.1:1 (norepinephrine 7.6 μg equivalent to phenylephrine 100 μg).[19] Qian J et al.found that the estimated relative potency for norepinephrine: phenylephrine was about 6:1.[20] In the present study, the number of bolus doses used for phenylephrine was 4.16±1.36, and for noradrenaline, it was 8.27±1.51. and the difference is statistically significant. So, it can be concluded that the potency of phenylephrine is more than noradrenaline. The reasons for this difference in potency between the two study drugs may be due to the greater duration of action of phenylephrine (15-20 min) than that of noradrenaline (5-10 min) and the difference in the dose of the bolus injection used in the present study.

A concern of norepinephrine injection is vasoconstriction and skin necrosis, as peripheral veins have been used in our study for injection of the study drugs. Chen D et al. studied the skin colour in patients infused with normal saline or 5, 10, and 15μg/kg/h norepinephrine and they observed that the incidence of pale skin was similar among the groups (3.3% vs 3.4% vs 20% vs 10.7%, respectively P=.089).[5] Hasanin AM et al. and Nagan Kee WD et al. demonstrated the safety of norepinephrine for local tissue perfusion because noradrenaline was diluted before administration and was administered for a short duration.[7,18] An equally potent solution of norepinephrine infusion or bolus dose has a theoretically similar vasoconstrictive action as phenylephrine.[2,21] In the present study, no skin changes were found in either of the groups.

No study subject experienced reactive hypertension after administration of the vasopressor agents in the present study. However, in a study conducted by Yasmin S. Hassabelnaby et al., reactive hypertension occurred in 9% of the study population for both 6μg/ml and 10μg/ml bolus doses of noradrenaline.[22] Rai AV et al. used phenylephrine 100 μg/mL or norepinephrine 7.5 μg/mL in their study and reported reactive hypertension in 28.9% of patients who received phenylephrine and 4.4% of patients of Norepinephrine group.[4] These findings do not corroborate the findings of the present study. It may be because a lower dose of noradrenaline was used in the present study than in the reference studies.

While conducting the study and in clinical practice also, it was found that phenylephrine is not effective in some patients. In those instances, other vasopressors were chosen as rescue agents. Žunić M et al. also mentioned the same problem in their study.[23]

Limitations of the study include its single-center design, which may limit generalizability to broader populations. The exclusion of preeclamptic mothers also restricts applicability to this specific patient group. Additionally, we did not measure umbilical artery (UA) and umbilical vein (UV) levels of phenylephrine and noradrenaline, which could provide further insights into fetal exposure and effects during cesarean sections.

5. Conclusion

Our study demonstrates that both Phenylephrine and Noradrenaline are effective in managing spinal anesthesia-induced hypotension during elective LSCS when administered intermittently via IV bolus. However, Noradrenaline offers distinct advantages in preserving hemodynamic stability while exhibiting a reduced incidence of adverse effects compared to Phenylephrine. These findings highlight Noradrenaline as a preferred option in clinical practice for managing hypotension during LSCS under spinal anesthesia.

6. Source of Funding

None.

7. Conflict of Interest

None.

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