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Anesthesia

Efficacy of Noradrenaline and Ephedrine for the Treatment of Intra Operative Hypotension in Elective Cesarean Section Following Subarachnoid Block- A Comparative Study

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Abstract | **Original Research Article**

Background: Spinal hypotension during cesarean section is a common complication which must be adequately managed to ensure maternal and fetal safety. Vasopressor drugs like ephedrine and norepinephrine are used to augment maternal blood pressure, but their comparative effects on maternal hemodynamics and fetal outcome are yet to be completely assessed. ***Objective:*** To assess the effectiveness and safety of ephedrine and norepinephrine in augmenting maternal blood pressure and fetal status during elective cesarean section under spinal anesthesia. ***Method:*** A six-month (February 2 to August 1, 2017) double-blind comparative study was carried out at the Department of Anaesthesiology and ICU, Dhaka Medical College Hospital (DMCH), Dhaka. A total of 120 ASA I–II parturients scheduled for elective cesarean section under spinal anesthesia were randomly allocated to receive intermittent intravenous bolus of norepinephrine or ephedrine for hypotension. Maternal hemodynamics and neonatal Apgar scores were obtained and compared. ***Result:*** Norepinephrine sustained maternal blood pressure with less frequent tachycardia than with ephedrine. Although in the norepinephrine group fewer vasopressor boluses were given, such a difference was not statistically significant. No significant group difference in neonatal Apgar scores was observed. ***Conclusion:*** Norepinephrine is an effective and safe alternative to ephedrine for control of spinal anesthesia-induced hypotension during cesarean delivery without compromising neonatal outcome while offering superior maternal heart rate control.

Keywords: Spinal hypotension, cesarean section, vasopressors, ephedrine, norepinephrine, maternal hemodynamics, neonatal outcomes, spinal anesthesia, blood pressure management, tachycardia, elective cesarean delivery, maternal safety, fetal safety.

INTRODUCTION

Spinal anesthesia has become the anesthetic technique of choice for the elective cesarean section, displacing general anesthesia due to pregnancy-induced physiologic changes that compromise airway management [1]. The reason spinal anesthesia is so well-liked is because it has quick onset, is easy, is cost-effective, has great muscle relaxation, and reduces exposure to drugs of the mother and neonate [2]. It also leaves the mother conscious during labor and greatly reduces the risk of aspiration [3]. But despite all these advantages, spinal anesthesia has some drawbacks, the most significant of which is maternal hypotension that may occur in up to 95% of the patients [4]. Postsubarachnoid block hypotension results from sympathetic blockade and consequent decreased systemic vascular resistance and venous return [5]. This hemodynamic disturbance jeopardizes uteroplacental perfusion and results in fetal bradycardia, acidosis, and later neurobehavioral changes [6]. For the mother, hypotension for an extended period leads to nausea, vomiting, and dizziness, as well as decreased cerebral perfusion—side effects that detract from patient satisfaction and safety for one of a woman's most significant life experiences [7]. Contributory physiological mechanisms include a mix of sympathetic denervation, compression of the vena cava and aorta, and

venodilatation—more specifically of the splanchnic circulation (T5-T11)—resulting in a substantial reduction in venous return and sometimes triggering the Bezold–Jarisch Reflex, an action on the heart that further intensifies bradycardia and hypotension [8]. Numerous prophylactic and therapeutic strategies have been proposed to manage spinal-induced hypotension (SIH) including maternal positioning, intravenous fluid loading, and mechanical modalities [9]. Nevertheless, among all the interventions discussed above, vasopressor therapy remains the cornerstone of effective management [10]. Vasopressors restore blood pressure by vasoconstriction and/or enhancing cardiac output through stimulation of adrenergic receptors. Of these, ephedrine and noradrenaline (norepinephrine) are two agents most controversially debated [11]. Ephedrine, α and β-adrenergic agonist, never has been the drug of choice as a vasopressor due to its dual action [12]. Its β1-agonist action increases the maternal heart rate and myocardial oxygen consumption, and hence the patients are liable to tachycardia and arrhythmias [13]. Additionally, ephedrine readily crosses the placental barrier and has resulted in fetal acidosis, elevated fetal catecholamine levels, and lowered umbilical pH [14]. On the other hand, noradrenaline, with predominantly α-adrenergic action but slight β1 effect, causes intense vasoconstriction with minimal effect on chronotropic activity [15]. It possesses a good hemodynamic profile with maintenance of maternal heart rate and cardiac output with no increased frequency of fetal acidosis [16]. Its efficacy in the prevention of spinal hypotension was found to have quick onset, brief duration, and minimal risk of tachyphylaxis, a known drawback with ephedrine. With the new evidence, greater interest is now observed as to whether and how it can be determined whether noradrenaline would be more effective and safer than ephedrine in management of intraoperative hypotension during cesarean section under spinal anesthesia [17]. This study has been designed to provide a head-to-head comparative evaluation of intravenous bolus ephedrine (5000 µg) and noradrenaline (5 µg) in terms of efficacy for the management of hypotension during subarachnoid block in parturients undergoing elective cesarean section. Through this, it aims to guide anesthetic practice towards evidence-based, safer, and better vasopressor use to attain optimum hemodynamic maternal stability and fetal outcome.

METHODOLOGY

This prospective, randomized, double-blind, comparative study was conducted over six months, from February 2 to August 1, 2017, at the Department of Anaesthesiology and ICU of Dhaka Medical College Hospital (DMCH), Dhaka. A total of 120 parturients undergoing elective cesarean section under spinal anesthesia were selected based on specific inclusion and exclusion criteria. Eligible subjects were ASA physical status I or II and provided written, informed consent once they had been fully informed of the purpose of the research, procedures, benefits, and risks in their native language. Patients who were ASA grade III or IV, had known contraindications to spinal anesthetic block, pregnancy complicated by hypertensive disorders, or hypersensitivity to study drug were excluded. The participants were randomly divided into two equal-sized groups, Group A and Group B, by a straightforward technique of sampling of cards so that there would be an equal number of cards in both groups to make them equal-sized. 60 in group size was derived using the formula for standard hypothesis test for two proportions from the evidence at hand of response of 64.8% in Group A (to which 5 µg noradrenaline had been administered) and 40% in Group B (to which 5000 µg ephedrine had been administered) at a significance of 5% and the test being 80% powered. All the patients received a pre-anaesthetic check-up in the form of history, physical examination, and recording the baseline NIBP and HR. Preloading with crystalloid fluid (Hartmann's solution) at 20 ml/kg was administered over 30 minutes prior to anaesthesia, and routine premedications such as IV ranitidine were employed. In the theatre, spinal anaesthesia was done in sitting position at interspace L3-L4 using 25G Quincke spinal needle and intrathecal bolus injection of 2.5 ml hyperbaric bupivacaine 0.5% on noticing movement of cerebrospinal fluid. Postoperative patients were positioned in supine with 15-degree left lateral tilt with a wedge placed under right hip to prevent compression of the aorta. Supplemental oxygen was given at 5 liters/min via face mask during anesthesia. Sensory level was checked with cold and surgery was started after confirming the sensory blockade up to the T4 dermatome. Monitoring and intraoperative care were managed by an independent blinded anesthesiologist. Sequential observation of HR, SBP, DBP, MAP, and SpO2 was carried out after administration of spinal anesthesia and then every 2 minutes for the first 10 minutes, and then every 5 minutes until the procedure was completed. Postoperative observation was done at 15-minute intervals for an hour in the postoperative recovery unit. Hypotension was a fall in MAP of greater than 25% from baseline and was managed by intravenous bolus injections of 5 µg noradrenaline in Group A or 5000 µg ephedrine in Group B. Bradycardia, HR <60 bpm, was managed by 0.6 mg IV atropine. Nausea and vomiting were managed by 8 mg IV ondansetron, and shivering was managed with 25 mg IV pethidine. Neonatal status in terms of APGAR score at 5 minutes and 1 minute post-delivery was quantified. Patient information that was relevant was duly recorded on standard data collection forms with preoperative, intraoperative, and postoperative outcomes. Accuracy and quality information validity were ensured through pretesting of the questionnaire and employment of a pre-established data collection protocol. Following collection, data was taken through registration, manual checking, computerized data entry, and SPSS version 19 analysis. Continuous data were analyzed using student's t-test or Mann–Whitney U test depending on distribution while categorical data were analyzed using Chi-square

test or Fisher's exact test where applicable. Statistical significance was assessed using a p-value of < 0.05. Ethical clearance was obtained from Dhaka Medical College Hospital Ethical Review Committee prior to the study. Confidentiality, informed consent, voluntariness, and right of withdrawal were assured during the study process. No audio tapes and patient identifiers were collected in order to maintain utmost privacy. This systematic review sought to compare the efficacy and safety of noradrenaline and ephedrine in the management of spinal anesthesia-induced hypotension during elective cesarean section. With careful planning, rigorous methodology, and ethical awareness, this study aspired to make an important contribution to improved anesthetic management and maternal-fetal outcome.

RESULTS

120 patients were recruited for the study and equally distributed in Group A and Group B. The age of the patient ranged from 20 to 40 years. 55.84% of the patients were in the age group of 26–30 years, followed by 19.2% in the age group of 20–25 years, 17.5% in the age group of 31–35 years, and 7.5% in the age group of 36–40 years. The mean age in Group A was 28.45 ± 4.24 years and that of Group B was 28.78 ± 4.05 years, and there was no statistically significant difference between the groups (p = 0.635). Based on ASA classification, two groups were evenly distributed. Group A included 42 patients (70%) who were ASA I and 18 patients (30%) who were ASA II. Group B included 45 patients (75%) who were ASA I and 15 patients (25%) who were ASA II. Statistically, there was no difference between the two groups for distribution (p = 0.540). Heart rate between the two groups was the same at baseline (86.90 ± 4.63 bpm for Group A, and 87.87 ± 5.28 bpm for Group B, p = 0.266) and 2 minutes (89.07 ± 4.49 vs. 89.95 ± 4.66 bpm, p = 0.248). At 4 minutes too, it was statistically not significant. But starting from the 6th minute, there was a statistically significant difference. Group A had a mean heart rate of 91.88 ± 4.64 bpm, while that of Group B rose to 102.00 ± 4.53 bpm (p < 0.001). This pattern was maintained at: at 8 minutes, Group A heart rate at 93.02 ± 5.00 bpm versus 106.12 ± 4.85 bpm for Group B (p < 0.001), and at 10 minutes, 93.80 ± 5.52 bpm for Group A versus 110.15 ± 5.50 bpm for Group B (p < 0.001). Max mean heart rate for Group B was at 20 minutes (116.35 ± 5.39 bpm) and was significantly different from Group A at 94.73 ± 5.37 bpm (p < 0.001). Although both groups' heart rates decreased progressively from the peak, Group B remained higher than during the observation time until 60 minutes. The systolic blood pressure (SBP) of the two groups was not significantly different at any of the points in time. Baseline SBP in Group A was 121.93 ± 5.43 mmHg, and in Group B, it was 122.35 ± 5.00 mmHg (p = 0.657). SBP reduced from both groups at 6 minutes' post-anesthetic induction to around 93 mmHg and at 8 minutes Group A measured a mean SBP of 91.27 ± 4.81 mmHg and Group B 90.73 ± 5.59 mmHg (p = 0.576). SBP was marginally lower in Group B at later intervals but the differences were statistically irrelevant. Diastolic blood pressure (DBP) was also trending on the same lines. Baseline DBP was 80.03 ± 5.58 mmHg in Group A and 80.77 ± 5.14 mmHg in Group B (p = 0.446). At 4 minutes, was reduced to 69.45 ± 4.47 mmHg in Group A and 70.08 ± 4.36 mmHg in Group B (p = 0.377) with no significant difference. Group A's minimum nadir DBP of 65.50 ± 3.86 mmHg at 10 minutes was lower but Group B was not significantly different by 63.95 ± 4.50 mmHg (p = 0.058). Although there were a few times when the difference was nearly significant, DBP trends between groups were statistically similar overall.

Table 1: Age Distribution of Patients (N=120)

Age Group (years)	Number of Patients	Percentage (%)
20 – 25 Yrs.	23	19.2
26 – 30 Yrs.	67	55.84
31 – 35 Yrs.	21	17.5
36 – 40 Yrs.	9	7.5
Total	120	100

Table 2: Mean Age by Group (N=120)

Group	Mean Age (years)	Standard Deviation	p-value
Group A	28.45	4.24	
Group B	28.78	4.05	0.635

Table 3: ASA Classification Distribution (N=120)

ASA Class	Group A (n=60)	Percentage (%)	Group B (n=60)	Percentage (%)	p-value
ASA I	42	70	45	75	
ASA II	18	30	15	25	0.540

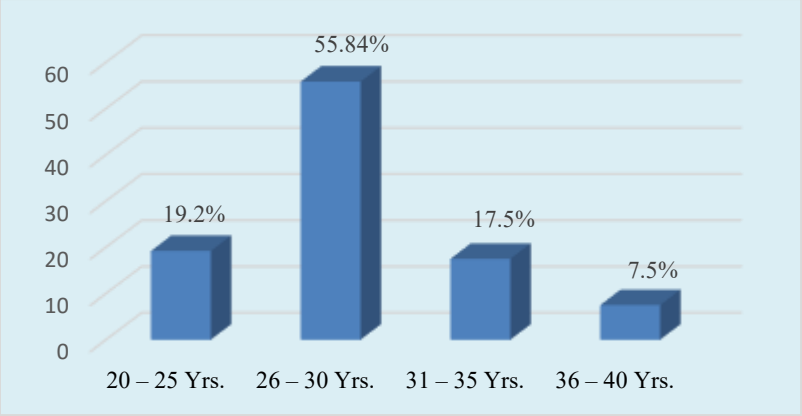

Figure 1: Column chart showed age distribution of the participants (N=120)

Table 4: Heart Rate (bpm) Over Time by Group (N=120)

Time (minutes)	Group A Mean ± SD	Group B Mean ± SD	p-value
Baseline	86.90 ± 4.63	87.87 ± 5.28	0.266
2	89.07 ± 4.49	89.95 ± 4.66	0.248
4	Not specified	Not specified	NS
6	91.88 ± 4.64	102.00 ± 4.53	< 0.001
8	93.02 ± 5.00	106.12 ± 4.85	< 0.001
10	93.80 ± 5.52	110.15 ± 5.50	< 0.001
20	94.73 ± 5.37	116.35 ± 5.39	< 0.001
60	Higher in Group B	Higher in Group B	< 0.001

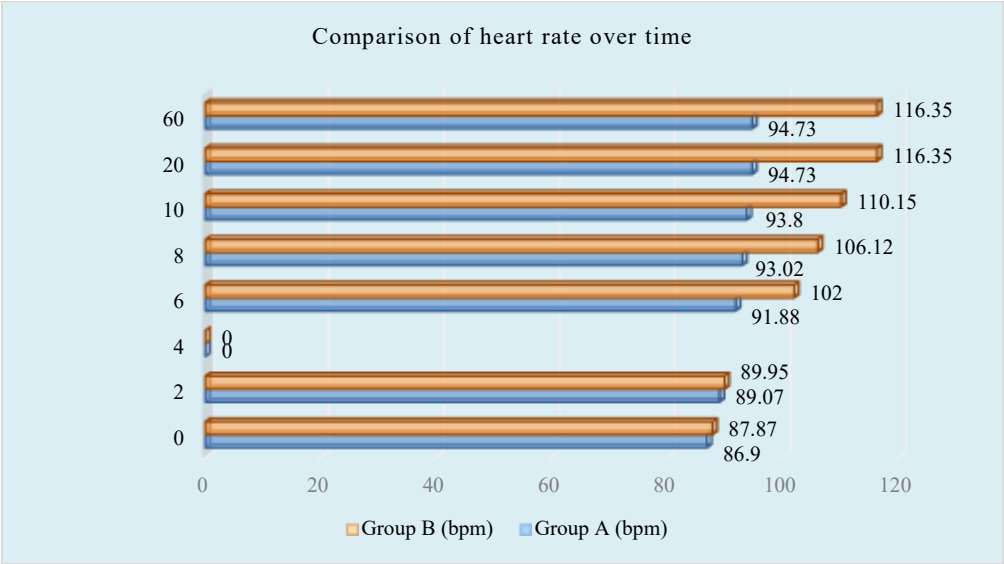

Figure 2: Bar chart showed a comparison of heart rate over time (N=120)

Table 5: Systolic Blood Pressure (mmHg) Over Time by Group (N=120)

Time (minutes)	Group A Mean ± SD	Group B Mean ± SD	p-value
Baseline	121.93 ± 5.43	122.35 ± 5.00	0.657
6	~93	~93	NS
8	91.27 ± 4.81	90.73 ± 5.59	0.576

Table 6: Diastolic Blood Pressure (mmHg) Over Time by Group (N=120)

Time (minutes)	Group A Mean ± SD	Group B Mean ± SD	p-value
Baseline	80.03 ± 5.58	80.77 ± 5.14	0.446
4	69.45 ± 4.47	70.08 ± 4.36	0.377
10	65.50 ± 3.86	63.95 ± 4.50	0.058

DISCUSSION

The current research illustrated that norepinephrine, as compared to ephedrine, preserved mothers' blood pressure and uterine artery blood flow under cesarean section in spinal anesthesia in an ideal manner. Norepinephrine was also associated with less incidence of tachycardia in mothers and required fewer bolus vasopressors, although the difference between them was not statistically significant. Hypotension caused by spinal anesthesia is still a major issue in obstetric anesthesia. The ideal vasopressor would be cheap, readily available, have a rapid onset of action, be reliable, have minimal adverse effect on maternal heart rate, and preserve fetal and placental perfusion [18]. Phenylephrine and ephedrine have been the traditional first-line vasopressors for prophylaxis and treatment of spinal hypotension. Both are effective at preventing hypotension and subsequent maternal discomfort [19]. However, clinical practice and literature reveal that phenylephrine is prone to cause reflex bradycardia requiring atropine treatment, while ephedrine can cause tachycardia and tachyphylaxis with repeated doses [20]. Also, phenylephrine may not be available everywhere, e.g., Bangladesh, so search for other alternatives like norepinephrine has come into the picture. Maternal hypotension induced by spinal anesthesia is a potentially serious threat to neonatal outcomes via its effect on uteroplacental blood flow, which in turn is directly linked to maternal blood pressure. Neonatal condition, as measured by Apgar scores, in our study did not differ significantly between the ephedrine and norepinephrine groups and showed both vasopressors to be effective in preserving fetal well-being. Nevertheless, the beta-adrenergic action of ephedrine to elevate fetal sympathetic tone and produce fetal tachycardia can result in fetal acidosis when there is compromised oxygen availability. In comparison, the norepinephrine combined alpha and weak beta agonist action appears to maintain maternal cardiac output and blood pressure more effectively with fewer unwanted fetal effects. Norepinephrine's pharmacological action as an agonist at both alpha-1 and beta-1 receptors allows it to increase peripheral vascular resistance and cardiac output and thus reverse sympathetic blockade of spinal anesthesia. Although precaution is taken against reflex bradycardia as a result of increased vagal tone, it can be easily managed with anticholinergic agents such as atropine or glycopyrrolate. This was confirmed again from our findings with none of the patients experiencing significant bradycardia, nor any significant side effects. Supporting evidence in the current literature confirms our results. Ngan Kee *et al*., [21] for example, demonstrated the superiority of norepinephrine over phenylephrine in preserving cardiac output and mother's heart rate. Although in our study intermittent bolus rather than continuous infusion was administered, the same hemodynamic benefits of norepinephrine over ephedrine were observed. Vallejo *et al*. [22] and Onwochei *et al*. [23] also reported the efficacy and safety of norepinephrine in maintaining the mother's blood pressure during cesarean section. Our findings are also corroborated by El Shafei *et al*., [24] who proved the superiority of norepinephrine to achieve systolic blood pressure with less occurrence of tachycardia in coronary artery disease patients, in favor of the drug's cardiovascular profile in different patient populations. Additionally, Ali Mohamed *et al*. [25] proved less hypotensive and hypertensive episodes and reduced incidences of bradycardia and tachycardia with norepinephrine compared to ephedrine, which is also in concurrence with our findings. From this cumulative evidence, norepinephrine is a valuable vasopressor in the obstetric anesthesia armamentarium that allows good hemodynamic control with an excellent safety profile for mother and fetus. Ease of titration and availability and fewer maternal heart rate changes make it an appealing alternative when phenylephrine is not available or not ideal. Large-scale sample studies as well as continuous infusion regimens can also determine the role of norepinephrine and also tailor dosing regimens in this clinical context.

CONCLUSION

Norepinephrine maintains maternal blood pressure and uterine perfusion effectively during cesarean section with fewer side effects like tachycardia compared to ephedrine. Norepinephrine is infant- and mother-safe and therefore a safe alternative vasopressor for hypotension caused by spinal anesthesia.

LIMITATION OF THE STUDY

This study included a small sample of subjects, and this might have possibly limited the generalizability of the findings. Furthermore, intermittent bolus dosing versus continuous infusion may have changed the hemodynamic effects. Large studies must confirm these results as well as measure long-term neonatal and maternal outcomes.

ABBREVIATIONS

- ASA: American Society of Anesthesiologists
- bpm: Beats per minute
- CS: Cesarean section
- DBP: Diastolic blood pressure
- DMCH: Dhaka Medical College Hospital
- HR: Heart rate
- IV: Intravenous
- MAP: Mean arterial pressure
- NIBP: Non-invasive blood pressure
- NS: Not significant
- SBP: Systolic blood pressure
- SIH: Spinal-induced hypotension
- SpO2: Peripheral capillary oxygen saturation
- T: Thoracic dermatome level

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this article.

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