ORIGINAL ARTICLE

Effect of Three Different Prophylactic Bolus Doses of Phenylephrine on Hypotension Following Caesarean Section Under Combined Spinal-Epidural Anaesthesia

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ABSTRACT **Background:** Maternal hypotension is a frequent and potentially serious complication of spinal anaesthesia during Caesarean section. Phenylephrine is a commonly used vasopressor for prevention, but optimal dosing remains uncertain.

Objective: To evaluate the effectiveness of three prophylactic bolus doses of phenylephrine in preventing spinal-induced maternal hypotension during elective Caesarean section under combined spinal–epidural anaesthesia.

Methodology: A prospective comparative study at the University of Port Harcourt Teaching Hospital included 136 parturients scheduled for elective Caesarean section. All received an admixture of intrathecal 10 mg of 0.5% hyperbaric bupivacaine and 25 µg fentanyl. Participants were randomly assigned to four groups: a control group receiving normal saline and three intervention groups receiving 50 µg, 60 µg, or 80 µg of phenylephrine. Haemodynamic parameters were monitored every five minutes. Total phenylephrine used and neonatal Apgar scores were recorded.

Results: Demographic characteristics were comparable across groups. The incidence of hypotension was highest in the saline group (85.5%) and lowest in the 80µg group (10.0%). Differences in hypotension rates were statistically significant between the 80 µg and saline group ($p < 0.0001$), and between other dose comparisons. Bradycardia was more frequent in the 80µg group (20.6%) ($p = 0.030$). Apgar scores were similar across groups, though umbilical cord venous pH was significantly lower in the saline group ($p < 0.0001$).

Conclusion: Prophylactic bolus doses of phenylephrine, particularly 80 µg, are effective in preventing spinal-induced maternal hypotension but with a relatively higher incidence of bradycardia during Caesarean section without adverse neonatal outcomes.

Keywords: Caesarean section, Hypotension, Phenylephrine, Combined spinal–epidural block, Prophylactic.

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INTRODUCTION

Hypotension remains a prevailing challenge following spinal anaesthesia for abdominal delivery of the parturient. Combined-spinal epidural anaesthesia is being adopted as the standard technique because it is devoid of complications associated with general anaesthesia and provides extended analgesia in the post-operative period.[1] Hypotension is still a complication following combined spinal epidural anaesthesia during Caesarean section. Klohr et al.[2] reported an incidence of 7.4% to as high as 74.4% of hypotension following spinal anaesthesia. There is no agreed global definition of maternal induced spinal hypotension; however, the generally acceptable definition is a decrease in systolic blood pressure by 20% from the baseline value; systolic arterial pressure below 100 mmHg or a fall of systolic arterial pressure below 80% of baseline.[3] Poor neonatal outcome has been correlated with the severity and duration of hypotension.[4]

Various agents have been used to treat hypotension following a neuraxial block. Phenylephrine, a vasopressor with alpha-1 agonist activity has been extensively used due to its faster onset of action, minimal effect on foetal pH and better outcomes on maternal haemodynamics.[5, 6] Various doses of phenylephrine have been used, the traditional dose being 100µg.[7] Thus, the current study was designed to compare the effect of three different prophylactic bolus doses of phenylephrine on hypotension following Caesarean section under combined spinal-epidural anaesthesia.

METHODOLOGY

Following the approval of the University of Port Harcourt Teaching Hospital's Ethics and Research Committee with reference number UPTH/ADM/90/SII/VOL.XI/1050, this prospective, double-blind, randomized, comparative study was carried out on 136 parturients following a sample size calculation using *G*Power v3.1.9.4 (Erdfelder, 2007), suitable for studies involving more than two groups. *G*power is software used for this type of sample size calculation using chi-square test, effect of 0.3 as recommended a degree of freedom of 3 and a power of 80% for the study, allowing an attrition of 10%. Parturients who presented for elective Caesarean section under combined-spinal epidural anaesthesia and met the inclusion criteria, were randomly allocated into four groups of thirty-four each after giving informed consent, each group receiving either 50µg (1ml), 60µg (1.1mls), or 80µg (1.8mls) of intravenous bolus phenylephrine. The research drug was prepared in 50µg/ml. All consenting pregnant women 18-45years scheduled for elective Caesarean section at term under combined spinal-epidural anaesthesia were included while exclusion criteria included patient's refusal, contraindications to combined-spinal epidural anaesthesia, high risk pregnancies (multiple gestations, intrauterine growth retardation, preeclampsia, eclampsia or pregnancy induced hypertension, maternal cardiovascular or pulmonary diseases, ante partum haemorrhage), and ASA III and above patients.

Using simple random sampling, parturients were randomized into four groups (P0–P3) by picking a sheet from a non-transparent envelope supervised by a reception nurse. Each sheet (34 per group) indicates the assigned group: P0 (control), P1 (50 µg), P2 (60 µg), or P3 (80 µg) phenylephrine, with no replacement after picking. Patients received appropriate pre-anaesthetic review and care and informed consent obtained. Routine fasting guidelines and acid aspiration prophylaxis were instituted.

On arrival of the parturient in the induction room of the theatre, baseline vital signs such as pulse rate (PR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial blood pressure (MAP, electrocardiogram (ECG) and peripheral oxygen saturation (SPO_2) were measured and recorded using the DASH 4000, GE Medical systems information Technologies Inc. 8200W. Tower Ave Milwaukee, Wisconsin USA. While patient was in the left lateral position, two intravenous accesses were secured with a size 16 G cannula into each forearm. Co-loading with fluid was done with the infusion of 500mls of 0.9% normal saline. The maintenance fluid was given according to the needs of the parturient.

After positioning of the parturient in sitting position, under aseptic technique, the epidural space was identified through the L3/L4 interspace using the loss of resistance to saline technique. Passing the size 25 G Whitacre needle through the Tuohy needle, the subarachnoid block was instituted using 10mg 0.5% heavy bupivacaine and 25µg fentanyl admixture. At the withdrawal of the spinal needle, the epidural catheter was passed and secured, and puncture site dressed. The parturient was returned to supine position and maintained at 15-30° left lateral uterine tilt using an improvised Crawford wedge.

Phenylephrine was administered as a bolus at the doses for the different groups depending on parturients' group while the control group received placebo. A research assistant ensured preparation and administration of the dosages of phenylephrine for each group while ensuring the proper preservation of the constituted bank as per manufacturer's directives. This ensured blinding and excluded bias. The parturients' blood pressure, heart rate, SpO_2 and level of consciousness were monitored at 2-minute intervals for the first 10 minutes, then every 5 minutes until end of surgery. Sensory block was ascertained with loss of temperature discrimination to cold liquid. Motor block was assessed with the Bromage scoring system, as modified by Breen et al.[8] Parturients received oxygen supplementation via nasal prongs at a rate of 1-5 l/min. Intravenous Carbetocin 100 µg was administered at the delivery of the baby.

In this study, hypotension was defined as a systolic blood pressure <90mmHg or >20% decrease from base line, while bradycardia was considered as heart rate <50 beats/minute. Hypotension and bradycardia were managed with bolus doses of ephedrine 5 mg and atropine 0.6 mg, respectively for the control group. P_1, P_2 and P_3 groups and a repeat was given if necessary. However, if hypotension persisted at these doses, 100 µg of phenylephrine and/or intravenous saline was infused at a rate of 15 ml/kg was used until the normal blood pressure was restored. Newborn wellbeing was assessed with Apgar score at the first and fifth minutes. Two millilitres of umbilical venous blood was collected for pH measurements using the ISFET pH meter (Mini Lab) Model IQ 120, immediately after the umbilical cord was clamped and baby separated from the mother.

DATA ANALYSIS

Data generated from this study were analyzed using IBM® SPSS® statistics software version 25 (Armonk, New York). Data was collected and presented in tabular and chart forms as appropriate. Quantitative variables

were summarized using means and standard deviations while qualitative variables were expressed as proportions and frequencies. Differences in means were compared using statistical test of one-way ANOVA tables while differences in proportion were compared using Chi square and Fisher exact as appropriate. P value of < 0.05 was considered statistically significant. Primary outcome measure was the incidence of maternal hypotension. The secondary outcome measures include: nausea, vomiting and bradycardia, foetal Apgar score and foetal acidosis using umbilical cord pH.

RESULTS

Table I: Demographic, Obstetric, and Baseline Maternal Haemodynamic Characteristics of Study Participants

	P_0: Control (n=34)	**P_1: 50µg (n=34)**	**P_2: 60µg (n=34)**	**P_3: 80µg (n=34)**	**Total**	**FET**	**p**
Age Category							
≤ 25 yrs.	4 (11.8%)	0 (0%)	4 (11.8%)	1 (2.9%)	9 (6.6%)	12.885	0.332
26-30 yrs.	7 (20.6%)	10 (29.4%)	10 (29.4)	7 (20.6%)	34 (25%)		
31- 35 yrs.	12 (35.3%)	17 (50%)	8 (23.5%)	16 (47.1)	53 (39%)		
36 -40 yrs.	9 (26.5%)	6 (17.6%)	11 (32.4)	9 (26.5%)	35 (25.7%)		
>40 yrs.	2 (5.9%)	1 (2.9%)	1 (2.9%)	1 (2.9%)	5 (3.7%)		
BMI							
Underweight	0 (0%)	0 (0%)	1 (2.9%)	0 (0%)	1 (0.7%)	4.830	0.930
Normal	7 (20.6%)	8 (23.5%)	4 (11.8%)	8 (23.5%)	27 (19.9%)		
Overweight	12 (35.3%)	12 (35.3%)	13 (38.2)	12 (35.3)	49 (36%)		
Obese	15 (44.1%)	14 (41.2%)	16 (47.1)	14 (41.2)	59 (43.4%)		
Parity							
1	7 (20.6%)	13 (38.2%)	13 (38.2)	10 (29.4)	43 (31.6%)	11.243	0.253
2	10 (29.4%)	15 (44.1%)	7 (20.6%)	10 (29.4)	42 (30.9%)		
3	11 (32.4%)	4 (11.8%)	10 (29.4)	10 (29.4)	35 (25.7%)		
4	6 (17.6%)	2 (5.9%)	4 (11.8%)	4 (11.8%)	16 (11.8%)		
Gestational Week							
< 37 weeks	3 (8.8%)	3 (8.8%)	0 (0%)	0 (0%)	6 (4.4%)	5.574	0.082
≥ 37 weeks	31 (91.2%)	31 (91.2%)	34 (100%)	34 (100%)	130 (95%)		
			Mean ± SD			**†F**	
Age (yrs)	32.8 ± 5.4	33.4 ± 4.8	33.7 ± 4.7	33.2 ± 4.1	33.3 ± 7.0	0.089	0.966
Weight (kg)	82.9 ± 14.4	108.2 ± 15.6	80.8 ± 16.2	79.6 ± 16.1	87.7 ± 14.9	1.072	0.356
Height (cm)	166.2 ± 5.7	168.2 ± 6.2	163.8 ± 5.7	165.9 ± 6.9	164.9 ± 8.4	1.560	0.209
BMI (kg/m^2)	30.1 ± 5.4	30.3 ± 6.1	30.1 ± 6.2	28.4 ± 5.4	29.7 ± 5.8	0.831	0.479
SBP (mmHg)	133.9 ± 17.1	136.4 ± 15.1	136.5 ± 16.7	127.3 ± 17.4	133.5 ± 16.8	2.320	0.078
DBP (mmHg)	74.9 ± 9.9	78.5 ± 13.3	78.8 ± 10.3	73.1 ± 11.7	76.3 ± 11.5	2.053	0.110
MAP (mmHg)	93.4 ± 12.5	96.7 ± 13.7	94.7 ± 11.2	89.3 ± 11.8	93.5 ± 12.4	2.091	0.105
HR (bpm)	94.9 ± 13.5	97.8 ± 14.4	96.6 ± 13.5	96.4 ± 14.8	96.4 ± 13.9	0.250	0.857
			Median (IQR)			****χ^2**	
Gestational week	38.0 (37.8–39.0)	38.0 (37.4–38.3)	38.0 (38.0–39.9)	38.0 (38.0–39.0)	38.0 (38.0–39.0)	5.655	0.130
SpO_2(%)	98.5 (98–99)	98 (98–98)	99 (98–100)	98 (98–100)	98 (98–100)	7.127	0.068

FET = Fisher's Exact test, † = ANOVA test; ** = Kruskal-Wallis test

All the parturients participated throughout the study. The demographic and obstetric characteristics were comparable across the groups as shown in Table I. Also in Table I, there were no significant differences in the baseline maternal haemodynamic parameters of SBP (p=0.078), DBP (p=0.110), MAP (p= 0.105), HR (p=0.857) and SpO_2 (p=0.068).

Table II: Overall incidence of hypotension and bradycardia among the respondents

	P_0	**P_1**	**P_2**	**P_3**	**Total**	**Test**	**p-value**
Hypotension	29(85.3)	19(55.9)	17(50.0)	10(29.4)	75(55.1)	21.965[b]	<0.0001
Bradycardia	0(0)	4(11.8)	3(8.8)	7(20.6)	14(10.3)	8.348[a]	0.030*

a = Fisher's test. b=Chi square; *statistically significant

Table II indicates that there was statistically significant association between hypotension/bradycardia and the bolus dosage of phenylephrine in the number of patients who had hypotension/bradycardia within the time interval of 2 mins to 75 mins ($p < 0.0001$). The frequency was highest in the Control group (29; 85.3%) and was lowest in the 80µg group (10; 29.4%). There was also a significant difference in the incidence of bradycardia, which was 4 (11.8%); 3 (8.8%); 7 (20.6%) and 0 (0%) in the P_1, P_2, P_3 and P_0 groups respectively ($p = 0.030$). The occurrence of hypertension was also statistically significant across the groups at 2 mins (0.028) and in the overall frequency ($p = 0.011$).

Table III: P values for intergroup comparison for overall incidence of hypotension, bradycardia and hypertension and haemodynamic parameters (where significant differences were observed)

	Groups					
	P_1 vs P_2	P_1 vs P_3	P_1 vs P_0	P_2 vs P_3	P_2 vs P_0	P_3 vs P_0
Hypotension						
Overall	0.808	0.049*	0.015*	0.136	0.004*	<0.0001*
Bradycardia						
Overall	1.000	0.510	0.114	0.304	0.239	0.011*
Hypertension.						
2 min	0.808	0.136	0.080	0.049*	0.026*	1.000
Overall	0.294	0.145	0.224	0.006*	0.013*	1.000
Haemodynamic parameters						
SBP (mmHg)						
2 min	0.572	0.174	0.032*	0.426	0.112	0.426
4 min	0.019*	0.965	0.961	0.017*	0.017*	0.966
DBP (mmHg)						
2 min	0.016	0.856	0.540	0.009*	0.003*	0.666
10 min	0.142	0.155	0.298	0.004*	0.013*	0.701
MAP (mmHg)						
2 min	0.114	0.573	0.099	0.033*	0.001*	0.276
4 min	0.017*	0.719	0.769	0.042*	0.008*	0.514
10 min	0.324	0.176	0.114	0.020*	0.011*	0.816
HR (bpm)						
Overall	0.425	0.003*	0.007*	0.028*	0.047	0.923
SpO_2 (%)						
4 min	0.843	0.769	0.025*	0.934	0.011*	0.007*

Table III shows an intergroup comparison of the overall incidence of hypotension, bradycardia and hypertension. The table shows significant differences in overall incidence of hypotension between P_3 vs P_0 ($p < 0.0001$); P_2 vs P_0 ($p = 0.004$); P_1 vs P_0 ($p = 0.015$) and P_1 vs P_3 ($p = 0.049$); and a significant difference in the overall incidence of bradycardia between P_3 vs P_0 ($p = 0.011$). There were significant differences in the incidence of hypertension between P_2 vs P_3 ($p = 0.006$) and between P_2 vs P_0 ($p = 0.013$) in this study. The SBP (mmHg) at 2 min between P_1 vs P_0 ($p = 0.032$), and at 4 min between were P_1 vs P_2 ($p = 0.019$), P_2 vs P_3 ($p = 0.017$). For DBP (mmHg) there was significant difference at 2 min (P_2 vs P_3; $p = 0.033$ and P_2 vs P_0; $p = 0.003$) and 10 min (P_2 vs P_3; $p = 0.004$ and P_2 vs P_0; $p = 0.013$). For overall HR, there were significant differences between P_1 vs P_3 ($p = 0.003$), P_1 vs P_0 ($p = 0.007$), P_2 vs P_3 ($p = 0.028$) and between P_2 vs P_0 ($p = 0.047$).

Table IV: Neonatal Outcomes

	P_0	P_1	P_2	P_3	Overall	χ^2/F	p
†APGAR Score at 1 min	8 (8-9)	8 (7.8-8)	7.8 (7-7.9)	8 (7-8.3)	8 (7-9)	2.031[a]	0.362
†APGAR Score at 5 min	10 (9-10)	10 (9-10)	10 (9-10)	10 (10-10)	10 (10-10)	7.387[a]	0.061
Birth Weight (kg).	3.1 ± 0.5	3.2 ± 0.4	3.3 ± 0.4	3.2 ± 0.5	3.2 ± 0.5	1.397[b]	0.247
Foetal pH	7.3 ± 0.04	7.4 ± 0.02	7.4 ± 0.04	7.4 ± 0.03	7.4 ± 0.04	29.527[b]	<0.001*

†Presented in median (IQR); a=Kruskall Wallis test; b=One way ANOVA

Neonatal Outcomes: While there were no significant differences in the Apgar score at 1 minute (p = 0.362), Apgar score at 5 minutes (p = 0.061) as shown in Table IV, a significant difference in foetal pH was observed. The foetal pH in the 60µg group was statistically significantly higher than that observed in the controls (p <0.0001).

Figure I and II show the incidence of hypotension and bradycardia among the study participants across specific timeframes.

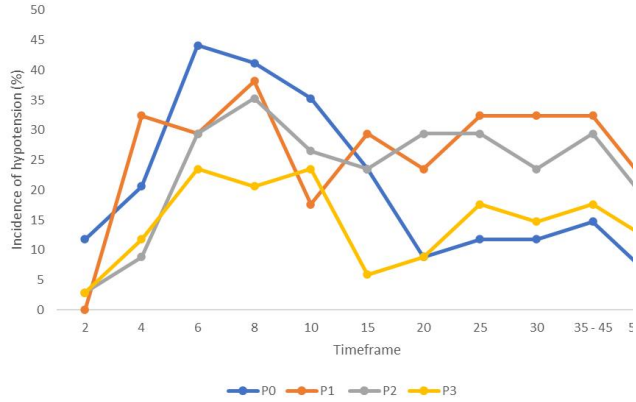

Figure I: Incidence of hypotension across timeframes among the study participants

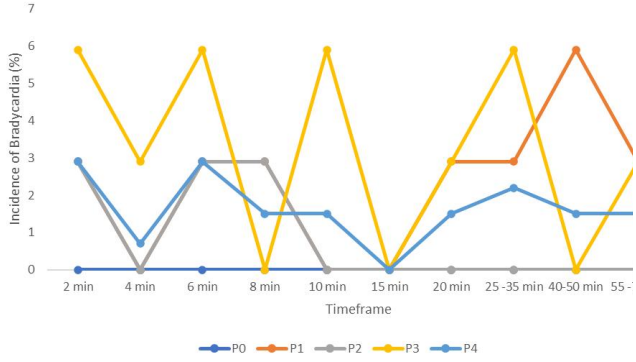

Figure II: Incidence of bradycardia across timeframes among the study participants

DISCUSSION

This study showed that prophylactic bolus doses of phenylephrine were effective in the prevention of maternal spinal hypotension. The frequency of hypotension and bradycardia was highest in the Control group (29; 85.3%) and was lowest in the 80µg group (10; 29.4%). There was also a significant difference in the incidence of bradycardia, which was 4 (11.8%); 3 (8.8%); 7 (20.6%) and 0 (0%) in the P_1, P_2, P_3 and P_0 groups respectively (p = 0.030). We also found that there were significant differences in the incidence of hypertension between P_2 vs P_3 (p = 0.006) and between P_2 vs P_0 (p = 0.013) in this study. The foetal outcome was essentially comparable between the groups.

This study showed that prophylactic bolus doses of phenylephrine were effective in the prevention of maternal spinal hypotension. There was statistically significant association between hypotension/bradycardia and the bolus dosage of phenylephrine in the number of patients who had hypotension/bradycardia within the time interval of 2 mins to 75 mins (p < 0.0001). The frequency of hypotension was highest in the Control group (29; 85.3%) and was lowest in the 80µg group (10; 29.4%). There was also a significant difference in the incidence of bradycardia, with a higher percentage (20%) seen in the parturients who received 80µg. The occurrence of hypertension was also statistically significant across the groups at 2 mins (0.028) and in the overall frequency (p = 0.011). The foetal outcome was essentially comparable between groups. Phenylephrine a vasopressor with alpha -1 agonist activity is the preferred pharmacological agent in the management of maternal spinal hypotension.[10] It is preferred due to its faster onset of action, minimal effect on foetal pH and better outcomes on maternal haemodynamics following its use.[7] It however causes hypertension and reflex bradycardia as its main side effects, although anaphylaxis has been reported amongst some patients.[11]

The incidence of hypotension amongst the study groups was lower than the findings by Lee et al[9], who evaluated the effects of prophylactic bolus phenylephrine on hypotension during low-dose spinal anaesthesia for Caesarean section using a weighted based dose for each group. The incidence of hypotension amongst patients who received phenylephrine was higher than what was observed but more in the group that received lower doses in our study. This may be due to a higher number of parturients used per group studied compared to the current study, as more patients may have hypotension and as such affect the incidence calculated comparatively. However, the incidence of hypotension in the control group in Lee et al[9] study was lower than that obtained in the control group of the current study and may be due to the dose of local anaesthetic agent used for spinal anaesthesia. Whilst 7 mg of bupivacaine with 10 µg of fentanyl was used in the Lee et al[9] study, we used 10 mg bupivacaine with 25 µg of fentanyl in our study, which is frequently associated with hypotension.[10]

The cause of hypotension during spinal anaesthesia could be multifactorial. Obasuyi et al[12] in evaluating the effect of spinal anaesthesia and positioning found that the incidence of hypotension was more in sitting position than in lateral position. This may explain the reason for higher incidence of hypotension reported in the current study as the combined-spinal epidural anaesthesia was performed with parturients in the sitting position.

Volume and type of fluid administered during spinal anaesthesia could also influence the incidence of hypotension. Ngan kee et al[13], observed a higher incidence of hypotension amongst the groups evaluated in their study; there were no use of a crystalloid preloading or co-loading before induction of anaesthesia in their study unlike in the current study. This may have accounted for the higher incidence of hypotension in their study when compared to that observed in ours. Although current trends in the prevention and

management of hypotension advocates for the use of vasopressor over administration of fluid bolus, preloading and co-loading have been established as effective methods of prevention and management of spinal induced hypotension.[14]

The addition of fentanyl to a lower dose of hyperbaric bupivacaine during spinal anaesthesia for Caesarean section could provide comparable anaesthesia with the lower risk of hypotension and longer postoperative analgesia. Ten milligrams of bupivacaine with 25µg fentanyl was used in our study and this probably contributed significantly to the lower incidence of hypotension observed across the groups that received phenylephrine.

The administration of high doses of phenylephrine either as an infusion or bolus doses has been found to cause a significant widespread vasoconstriction and decrease in cardiac output and a consequential decrease in in end-organ perfusion.[15] While one study reports that a continuous administration of an infusion of phenylephrine demonstrated a more stable haemodynamic parameters probably due to a steadier plasma level;[16] another prospective intervention study conducted by Buthelezi et al. reported that prophylactic phenylephrine infusion significantly reduces the incidence of maternal hypotension when compared with the phenylephrine bolus group ($p<0.011$).[17] Although our study did not compare the differences in outcome between infusions versus bolus doses of phenylephrine, it has been shown that a more stable plasma concentration of phenylephrine produces a better control over the haemodynamic variables. However, using doses less than 100 µg of phenylephrine has been advocated.[18] due to reflex bradycardia seen; the highest dose used in our study was 80 µg.

Bradycardia occurred more commonly in the 80µg group in the current study. The same finding was made by Jawatait et al[5], Lee et al[9] and Ngan kee[12], with reflex bradycardia occurring more in the group that received the highest dose of phenylephrine. Reflex bradycardia results from stimulation of the carotid baroreceptors due to elevated blood pressures that follow the systemic peripheral vasoconstriction produced by phenylephrine. Use of atropine or glycopyrrolate often abolishes this side effect, although clinically the bradycardia appears tolerable and often occurs with elevated blood pressure. This is contrary to the findings by Tanaka et al[19] who recorded no incidence of bradycardia despite use of high doses in their study. Although phenylephrine is the current drug of choice for maternal spinal hypotension, its use is limited in most obstetric anaesthesia units in the teaching hospitals across Nigeria. Ephedrine an indirect sympathomimetic with both alpha and beta-adrenergic properties is more commonly used mainly due to cost and ease of availability.

The clinical outcome of the neonates in this study was comparable as evidenced by the Apgar scores and the umbilical pH values. Although the umbilical venous pH was higher in the group that received the highest dose of phenylephrine as was also reported in other studies.[9] However, comparing a higher dose of Phenylephrine 100µg than what was used in our study, it was demonstrated that there was no statistically significant difference in the primary outcome measure of umbilical artery pH.[20]

Although we acknowledge that our study design was not ideal, limiting our study to only elective surgeries may have introduced logistical challenges. Being a referral centre, we often have more emergencies than elective Caesarean sections. We are doubtful if these results can be extended to elective and emergency Caesarean sections indicated for uteroplacental insufficiencies and other clinical situations of foeto-maternal compromise. Further studies are therefore encouraged to include more emergent surgeries.

CONCLUSION

This study shows that a higher prophylactic bolus dose of phenylephrine was effective in the prevention of maternal spinal hypotension and maintained maternal blood pressure during combined spinal anaesthesia for Caesarean section. Whilst the incidence of bradycardia was higher with a higher dose of phenylephrine, hypotension was more in the control group. The clinical outcome of the neonates in this study was also generally favourable.

Conflicts of interest: There are no conflicts of interest.

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