International Journal of Research in Medical Sciences
Kumari P et al. Int J Res Med Sci. 2019 May;7(5):1479-1485
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: http://dx.doi.org/10.18203/2320-6012.ijrms20191546

Original Research Article

Comparison of commonly used vasopressors for treating hypotension after spinal anaesthesia in elective lower abdominal surgery: a randomized, observational, case-control study

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Received: 22 March 2019
Accepted: 15 April 2019

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ABSTRACT

Background: During caesarean section hypotension due to spinal block is secondary to the sympathetic blockade and aorto-caval compression by the uterus. It can have important consequences for the mother and may affect neonatal outcome. The present study was aimed to compare intravenous bolus doses of phenylephrine and ephedrine to treat maternal hypotension during spinal block for elective caesarean section.
Methods: After fulfilling the inclusion criteria, 100 parturient were randomly allocated into two groups of fifty each. For spinal anesthesia lumber puncture was done and 12.5mg, 0.5% hyperbaric bupivacaine was given intra-thecally. In this observational study, patients who developed hypotension under spinal anesthesia were selected for the study. According to their group, patients received either ephedrine 6mg (Group E) or phenylephrine 75µg (Group P) as vasopressor. During the study, number of vasopressor boluses, hemodynamic response and time taken to recover from hypotension was noted.
Results: Ephedrine and phenylephrine were used in the mean doses of 6.72±1.97mg and 91.5±31.38µg respectively. In 88% parturient single bolus dose of ephedrine was effective in treating hypotension while phenylephrine was effective in 78% parturient. There was no significant difference observed in total number of boluses used. No significant difference was seen in mean systolic blood pressure, mean diastolic blood pressure and mean arterial pressure over a given period of time in Group E and Group P. Mean systolic BP was less than 20% when compared to baseline in both the groups at different time intervals. In Group P the mean heart rate was significantly lower as compared to the Group E ($p<0.05$).
Conclusions: Intravenous phenylephrine and ephedrine are both similar in performance in treating hypotension after spinal anesthesia for elective caesarean section and the hypotensive control offered is comparable.

Keywords: Caesarean section, Ephedrine, Elective lower abdominal surgery, Phenylephrine, Postspinal hypotension

INTRODUCTION

Maternal hypotension after regional anesthesia for caesarean section is secondary to the sympathetic blockade. Hypotension associated with spinal anesthesia may be defined as a systolic blood pressure (SBP) less than 90mmHg or 100mmHg or in relative, termed as a percentage (20%) fall from baseline.[1] The incidence of hypotension can be as high as 70%-80% when pharmacological prophylaxis is not used.[2,3] Among the

deleterious effect, one can mention important consequences like nausea, vomiting, dizziness, disruption of fetal oxygenation and fetal acidosis etc.[4]

Numerous attempts have been used to restrict hypotension like prior hydration, vasopressor drugs and lower leg compression. Despite numerous attempts to restrict it, many parturient become hypotensive after spinal anesthesia and require intervention.[5] To prevent or reduce this serious complication several drugs and methods have been used. But no single drug or method completely prevents hypotension without any adverse effects.[6-7] Numerous vasopressors are commonly used at present to counteract the hypotensive effect by vasoconstriction and also by increasing the cardiac output. Most commonly drugs used are the sympathomimetic agents which act through the adrenergic receptors.

Phenylephrine is a direct acting pure α1-adrenergic agonist. It promotes dose-dependent vasoconstriction, which is more pronounced in the venous than in the arterial bed. It, therefore, causes a rapid increase in systemic vascular resistance and blood pressure.[8] Ephedrine is a non-catecholamine sympathomimetic agent that stimulates alpha and beta adrenergic receptors directly and predominantly indirectly, producing its effects by releasing norepinephrine from nerve endings in the autonomous nervous system. Despite lack of confirmation of its superiority over other vasopressors, phenylephrine is traditionally the vasopressor of choice in the obstetric anesthesia. Studies have shown that the phenylephrine maintain uterine and placental blood flow and higher umbilical cord pH than ephedrine, having similar efficacy in controlling hypotension but with a lower risk of fetal acidosis.[9-11]

The present study was aimed to compare the use of bolus phenylephrine and ephedrine for maintenance of arterial pressure during caesarean section surgeries under spinal anesthesia. Primary objective of this study was to compare the arterial pressure during spinal anesthesia in elective caesarean section with the use of phenylephrine or ephedrine and the secondary objective was to evaluate and compare the time taken for recovery from hypotension using different drugs being compared.

METHODS

After obtaining approval from Institutional Ethical Committee, the present observational study was conducted at a Maternity Hospital which is one of the associated hospitals of a Government Medical College. Prior to this study, all patients signed an informed consent. The present study was carried out on 100 ASA physical status II females with singleton pregnancies undergoing elective caesarean section and developed hypotension after spinal anaesthesia. The study subjects were in the age range of 24 to 35 years, height 152-167cm, weight 63-85kg and gestational age 36-39 weeks and were a candidate of elective lower abdominal surgery. Patients with classic contraindications to subarachnoid block, pre-existing systemic disease, known fetal abnormalities, pre-eclampsia and known allergy to test drugs were excluded from the study. A total of 100 patients were enrolled in this study. These patients were allocated into two groups of 50 each as follows:

- Group E: Ephedrine 6mg in 1ml as intravenous (IV) bolus,
- Group P: Phenylephrine 75µg in 1ml as IV bolus.

Patients in the operative rooms were placed supine with left uterine displacement and standard monitors for noninvasive blood pressure (NIBP), pulse oximetry and cardiovascular monitoring were applied. Base line heart rate (HR), SBP and DBP were calculated. An 18 gauge IV line was taken in a peripheral vein for fluid preload. Each patient received 10ml/kg of ringers lactate solution, which was infused over 10min as preload then infusion rate was reduced to keep vein open. After preloading, change in maternal blood pressure and heart rate was recorded before spinal block.

With careful antiseptic preparation and patients in the sitting position, subarachnoid block was performed by 25 gauges Quinke needle. In every patient after confirming the free flow of CSF, 2.5ml of 0.5% hyperbaric bupivacaine is injected intrathecally through a lumbar puncture at L3-L4 interspaces for both groups. Patients were then immediately placed in supine position with 15 degree left lateral tilt position using wedge under right hip.

All patients were given supplemental oxygen at 5 liter min^{-1} via facemask. After spinal anesthesia HR, SBP, DBP and MAP was recorded immediately and every three min (minutes) interval after spinal block until delivery of the baby. Oxygen was administered to all patients until the umbilical cord is clamped. Injection of oxytocin (10 units in 5% dextrose) was given after clamping the cord.

The highest level of sensory block was assessed by pin prick method 5min after the subarachnoid block. Patients were given the drug under study, if there is >20% decrease in systolic blood pressure from the baseline value or if it is <90mmHg.The ephedrine group patients (Group E) received 6mg of ephedrine as an IV bolus and the phenylephrine group patients (Group P) received 75µg of phenylephrine as an IV bolus.

In cases, where hypotension did not improve additional boluses of same vasopressor was given to keep systolic BP ≥90mmHg. If heart rate was less than 50beats/minute Atropine 0.6mg was given intravenously to patients. All procedures were carried out by one team of obstetric surgeons and anesthetists; premedication and anesthesia was standardized in all patients.

Statistical analysis

All analyses were performed using SPSS version 16.0 (SPSS Ltd, Chicago, IL, USA). Categorical data were analyzed with Chi-square test. Mean and standard deviation were computed for age, weight, height, BMI and gestational age and analyzed by independent sample *t*-test, while primary outcome that is correcting hypotension was measured in proportion and percentage and analyzed by Chi-square tests between the groups. A *p*-value <0.05 was accepted as statistically significant.

RESULTS

After fulfilling the inclusion and exclusion criteria, a total of 100 parturient ASA grade II patients undergoing elective caesarean section under spinal anesthesia were included in this study. Hypotension developed in all the parturient and the study population was divided into two groups of 50 patients in each group. The two groups were comparable with respect to demographic, clinical and physical status and did not show statistically significant differences (Table 1). The mean age of patients in Group E was 28.4±2.61 years and 27.7±2.45 years in Group P. The mean weight in Group E and Group P respectively was 75.08±5.72kg and 73.40±5.79kg.

Table 1: Patient demographic characteristics.

General characteristics	Group E (n=50)	Group P (n=50)	*p*
Age (years)	28.4±2.61	27.7±2.45	0.12
Range	24-35	24-34	
Weight (kg)	75.08±5.72	73.40±5.79	0.14
Range	65-86	63-85	
Height (cm)	160.2±3.11	159.7±4.14	0.446
Range	155-167	152-167	
Gestational age			
36-37 (Weeks)			0.536
n	24	25	
(%)	48	50	
38-39 (Weeks)			
n	26	25	
(%)	52	50	
Mean±SD	37.6±1.14	37.4±1.11	

Values expressed as Mean±SD, *p<0.05 is significant

Table 2: Anesthetic and intraoperative variables in three groups.

Parameters	Group E (n = 30)	Group P (n = 30)	*P* value
Sensitive level at T4 (%)	4 (8%)	3 (6%)	0.287
Sensitive level at T5 (%)	26 (52%)	21 (42%)	
Sensitive level at T6 (%)	20 (40%)	26 (52%)	
Time from spinal block to delivery (min)	16.3±1.04	16.6±1.05	0.129
Range	15-18	15-18	
Time from skin incision to delivery time (min)	10.48±1.31	10.76±1.36	0.298
Range	8-13	8-13	
Vasopressor dose (mg)	6.72±1.97mg	91.5±31.38µg	
Range	6-12	75-150	

Values expressed as Mean±SD, *p<0.05 is significant

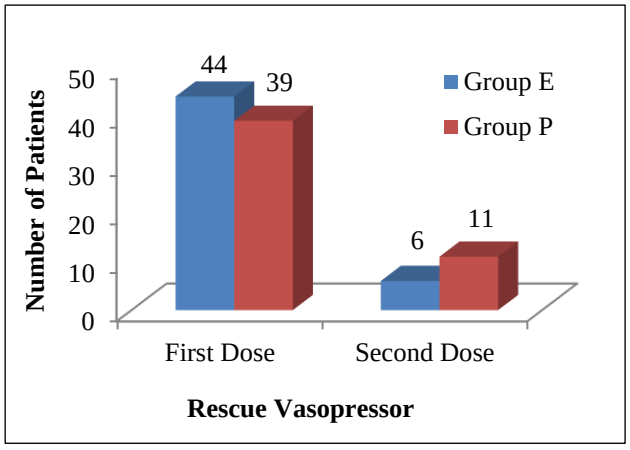


Figure 1: Comparison of IV bolus doses of vasopressors required to treat hypotension.

As for the Sensory level of block it was achieved upto T4 or above in all patients that was comparable in both groups (Table 2).

In Group P 78 percent parturient required a single dose of 75µg of phenylephrine while 22 percent patients needed second dose of vasopressor to maintain systolic blood pressure as shown in Figure 1. This use of vasopressor ephedrine at a dose of 6mg was respectively 88 percent and 12 percent in Group E.

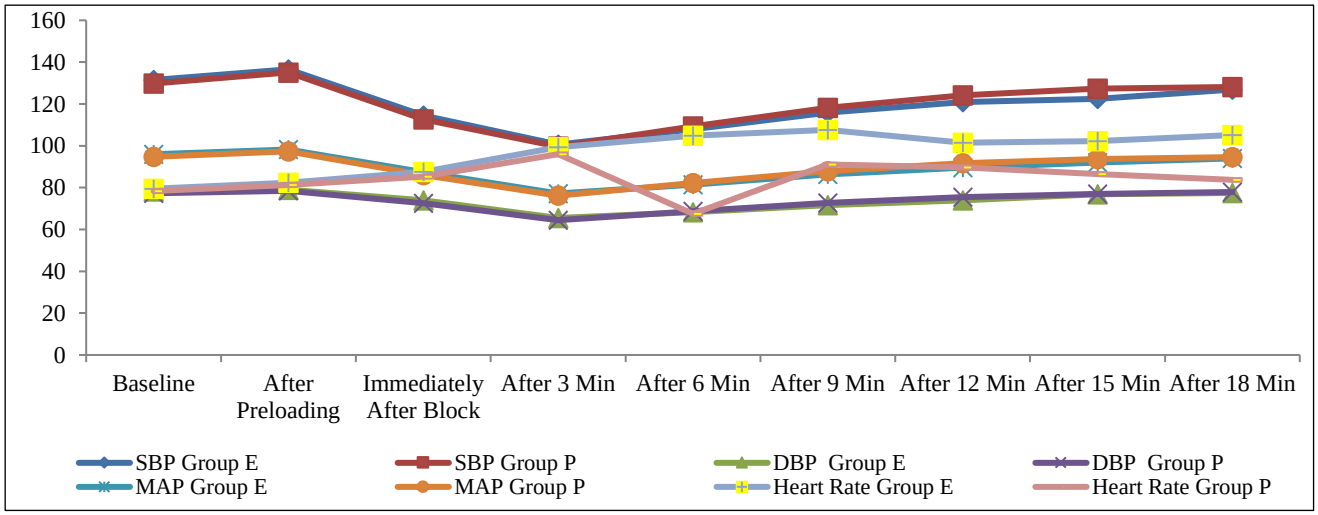
The number of rescue doses required in both the groups was statistically insignificant (*P*<0.05, significant). The difference observed in baseline HR, systolic, diastolic, and mean BP between two groups was statistically insignificant (Table 3).

Table 3: Comparison of baseline HR, systolic, diastolic and mean BP in all groups.

Group parameter	Group E Mean±SD	Group P Mean±SD	*P* value
Heart rate	79.50±4.83	78.40±4.14	0.224
Systolic blood pressure	131.54±5.48	129.80±5.41	0.113
Diastolic blood pressure	78.16±3.63	77.26±3.63	0.218
Mean blood pressure	95.95±3.78	94.77±3.72	0.117

The difference in SBP, DBP, and MAP between two groups (E and P) at baseline, after preloading and till 18 minutes of block was not statistically significant(P>0.05) (Figure 2).

Statistically, there was insignificant difference observed in baseline HR, after preloading and at 3 mins after block. At 6, 9, 12, 15 and 18 mins of block, the difference observed in HR was statistically significant between two studied groups (p<0.05). There was a decrease in HR in Group P as compared to Group E, thus reflecting reflex bradycardia of phenylephrine.



*SBP (systolic blood pressure), DBP (diastolic blood pressure), MAP (Mean Blood Pressure), HR (heart rate)

Figure 2: Trend of SBP, DBP, MAP, and HR during the intervention between two groups.

Table 4: Intragroup comparison of changes in systolic BP (mmHg) at different time intervals.

Time Interval	Group E				Group P			P-value
	Mean	Diff. from BL	%age	P-value	Mean	Diff. from BL	%age	
Baseline	131.54	-	-	-	129.80	-	-	-
After preloading	136.56	5.02	3.8	<0.001*	135.08	5.28	4.1	<0.001*
Immediately after block	114.54	-17.00	-12.9	<0.001*	112.68	-17.12	-13.2	<0.001*
After 3 Min	100.60	-30.94	-23.5	<0.001*	99.64	-30.16	-23.2	<0.001*
After 6 Min	107.92	-23.62	-18.0	<0.001*	109.34	-20.46	-15.8	<0.001*
After 9 Min	115.80	-15.74	-12.0	<0.001*	118.15	-11.65	-9.0	<0.001*
After 12 Min	120.92	-10.62	-8.1	<0.001*	124.18	-5.62	-4.3	<0.001*
After 15 Min	122.48	-9.06	-6.9	<0.001*	127.30	-2.50	-1.9	0.0003*
After 18 Min	126.86	-4.68	-3.6	<0.001*	128.16	-1.64	-1.3	0.016*

The mean SBP showed a fall by 23.5% (>20%) in Group E and 23.2% (>20%) in Group P at 3 minutes after spinal block (Table 4). After administration of drug, ephedrine in Group E and phenylephrine in Group P, it showed a rising trend in both the groups. In both the groups the difference in mean SBP was less than 20% when compared to baseline SBP after the administration of the respective sympathomimetic drug at 3mins after block. However, mean SBP never reached to baseline till 18 mins after spinal block and the difference was statistically significant (p<0.05). Similar trend was shown by mean DBP (Table 5) and MAP (Table 6). The difference in HR from baseline at different time intervals was statistically significant in both groups (Table 7), and the difference was more in Group E (25.72) as compared to Group P (5.34).

Table 5: Intragroup comparison of changes in diastolic BP (mmHg) at different time intervals.

Time Interval	Group E				Group P			P-value
	Mean	Diff. from BL	%age	P-value	Mean	Diff. from BL	%age	
Baseline	78.16	-	-	-	77.26	-	-	-
After preloading	79.04	0.88	1.1	0.152	78.48	1.22	1.6	0.095
Immediately after block	73.90	-4.26	-5.5	<0.001*	72.58	-4.68	-6.1	<0.001*
After 3 Min	65.50	-12.66	-16.2	<0.001*	64.44	-12.82	-16.6	<0.001*
After 6 Min	68.28	-9.88	-12.6	<0.001*	68.74	-8.52	-11.0	<0.001*
After 9 Min	71.60	-6.56	-8.4	<0.001*	72.78	-4.48	-5.8	<0.001*
After 12 Min	73.90	-4.26	-5.5	<0.001*	75.54	-1.72	-2.2	0.042*
After 15 Min	76.82	-1.34	-1.7	0.091	76.92	-0.34	-0.4	0.335
After 18 Min	77.50	-0.66	-0.8	0.185	77.84	0.58	0.8	0.053

Table 6: Intragroup comparison of changes in mean arterial pressure (mmHg) at different time intervals.

Time Interval	Group E				Group P			P-value
	Mean	Diff. from BL	%age	P-value	Mean	Diff. from BL	%age	
Baseline	95.95	-	-	-	94.77	-	-	-
After preloading	98.21	2.27	2.4	<0.001*	97.35	2.58	2.7	<0.001*
Immediately after block	87.45	-8.49	-8.9	<0.001*	85.95	-8.82	-9.3	<0.001*
After 3 Min	77.20	-18.74	-19.5	<0.001*	76.17	-18.60	-19.6	<0.001*
After 6 Min	81.49	-14.45	-15.1	<0.001*	82.27	-12.50	-13.2	<0.001*
After 9 Min	86.33	-9.61	-10.0	<0.001*	87.90	-6.87	-7.2	<0.001*
After 12 Min	89.57	-6.37	-6.6	<0.001*	91.75	-3.02	-3.2	<0.001*
After 15 Min	92.04	-3.90	-4.1	<0.001*	93.71	-1.06	-1.1	0.002*
After 18 Min	93.96	-1.98	-2.1	<0.001*	94.61	-0.16	-0.2	0.608

Table 7: Intragroup comparison of changes in heart rate (beats/min) at different time intervals.

Time Interval	Group E				Group P			P-value
	Mean	Diff. from BL	%age	P-value	Mean	Diff. from BL	%age	
Baseline	79.50	-	-	-	78.40	-	-	-
After prelosading	82.42	2.92	3.7	<0.001*	81.22	2.82	3.6	<0.001*
Immediately after block	87.50	8.00	10.1	<0.001*	85.24	6.84	8.7	<0.001*
After 3 Min	99.28	19.78	24.9	<0.001*	96.00	17.60	22.4	<0.001*
After 6 Min	104.88	25.38	31.9	<0.001*	67.50	-10.90	-13.9	<0.001*
After 9 Min	107.62	28.12	35.4	<0.001*	91.12	12.72	16.2	<0.001*
After 12 Min	101.46	21.96	27.6	<0.001*	89.66	11.26	14.4	<0.001*
After 15 Min	102.28	22.78	28.7	<0.001*	86.54	8.14	10.4	<0.001*
After 18 Min	105.22	25.72	32.4	<0.001*	83.74	5.34	6.8	<0.001*

DISCUSSION

Due to the reduction in maternal and fetal morbidity and mortality, regional anesthesia has gained acceptance in obstetrics.[12] However, due to preganglionic sympathetic block, maternal hypotension is the most common and important physiological result of spinal anesthesia. Despite numerous attempts to restrict, it continues to be a cause of concern to the anesthetist with an incidence of about 80%.[13] Limited efficacy has been seen by traditional non-pharmacological interventions such as leg elevation, compressive leg devices, left uterine displacement and IV fluid loading.[14] As a result, vasopressors are often necessary.[15] In many studies ephedrine and phenylephrine have been used for the treatment of intra-operative hypotension. During caesarean section, ephedrine is effective in the treatment of spinal anesthesia induced hypotension, but it can cause fetal acidosis.[16-17] Ephedrine being a mixed α and β agonist, causes increase in cardiac output and heart rate. Phenylephrine is a pure α_1-adrenergic agonist which increases systemic vascular resistance and causes reflex bradycardia.[18] The present study was aimed to compare the use of bolus phenylephrine and ephedrine for

maintenance of arterial pressure during spinal anesthesia in lower abdominal surgeries.

In this study, all patients in the two groups were comparable with respect to age, gender, body weight, operation duration and ASA status. The difference observed in baseline parameters between the groups was statistically insignificant. We confirmed in this study that there was no significant difference between ephedrine and phenylephrinein their efficacy for prevention of hypotension following spinal anesthesia in patients undergoing lower abdominal surgeries. The difference in number of vasopressor doses required between ephedrine and phenylephrine groups for treatment of hypotension was not statistically significant. Both the studied groups shared a rising trend in mean systolic blood pressure after administration of respective sympathomimetic drugs. However, the mean systolic blood pressure never reached the baseline level during the observation period. The difference in mean systolic blood pressure from baseline systolic blood pressure was always less than 20% at different time intervals after the administration of the respective drug. The difference in systolic blood pressure immediately after block and after administration of vasopressor between two groups (ephedrine and phenylephrine) was not significant statistically at different time intervals. Although the increase in systolic blood pressure after administration of vasopressor was slightly more in phenylephrine group than ephedrine group in our study. This is in accordance with study done by Abdalla EM et al in which they noticed the increase in systolic blood pressure was less in the ephedrine group compared with the phenylephrine group.[19] There was statistically insignificant difference in mean arterial pressure between two studied groups at different time intervals till 18mins of block after administration of vasopressors. This is in accordance with the study by Thomas et al who reported that bolus phenylephrine 100µg is as effective as ephedrine 5mg in restoring maternal arterial pressure above 100mmHg.[20]

In this study, there was a higher incidence of bradycardia in patients receiving phenylephrine than those receiving ephedrine. There was statistically no significant difference in heart rate immediately after block until the administration of vasopressors. After administration of vasopressors statistically significant difference was observed in heart rate at 6, 9, 12, 15 and 18mins of block. Increase in blood pressure with an α-agonist may lead to reactive bradycardia (baroreceptor reflex). The rise in HR in Group E was more as compared to Group P. The results of this study were in accordance with the study of other investigators. They also reported higher incidence of bradycardia in patients receiving phenylephrine as compared with patients receiving ephedrine for prevention of hypotension during spinal anesthesia for caesarean section (21-23). On contrary to the results of the present study, Adigun et al found bolus IV phenylephrine 100µg to be as effective as ephedrine 5mg with no significant difference in HR between two groups and an equivalent hypotensive control.[24] This may be attributed to the lower dose of ephedrine used in their study. The limitations of this study are that only uncomplicated and elective caesarean deliveries were included. In complicated and emergency cases response of vasopressors may be different.

CONCLUSION

On the basis of the above results it can be concluded that intravenous bolus doses of phenylephrine 75µg and ephedrine 6mg were both effective in treating hypotension after spinal anesthesia for elective caesarean section. There was no difference between the two studied groups for the treatment of hypotension. Both sympathomimetic drugs ephedrine and phenylephrine effectively restored the systolic, diastolic and mean arterial pressures. In both the groups the mean SBP was less than 20% when compared to baseline SBP at different time intervals. There was significant difference in HR between the two groups with higher incidence of bradycardia in phenylephrine group.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Kumari P, Tahir S, Kumari H, Mir AA. Comparison of commonly used vasopressors for treating hypotension after spinal anaesthesia in elective lower abdominal surgery: a randomized, observational, case-control study. Int J Res Med Sci 2019;7:1479-85.