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Clinical Study To Compare The Effect Of Bolus Inj Mephentermine And Inj Phenylephrine For Management Of Hypotension During Caesarean Section Performed Under Subarachnoid Block

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ABSTRACT

Background: Hypotension is a common complication during caesarean sections performed under subarachnoid block, posing risks to both mother and fetus. Vasopressors like phenylephrine and mephentermine are commonly used to manage this condition. This study compares the efficacy and side-effect profiles of intravenous bolus doses of phenylephrine and mephentermine in treating intraoperative hypotension.

Methods: This randomized, parallel-group clinical trial included 80 parturients undergoing caesarean section under spinal anaesthesia. Participants were allocated into two groups: Group M received 6 mg mephentermine IV bolus; Group P received 100 µg phenylephrine IV bolus. Hemodynamic parameters, need for rescue vasopressor doses, and adverse effects were recorded and statistically analyzed.

Results: Both vasopressors effectively maintained systolic and diastolic blood pressure, mean arterial pressure, and heart rate with no statistically significant differences in most parameters. However, Group P required significantly fewer rescue doses (25% vs. 62.5%; $p < 0.001$). Tachycardia was significantly more common in Group M (25% vs. 0%; $p = 0.001$), while bradycardia and nausea/vomiting occurred at similar rates in both groups.

Conclusion: Both phenylephrine and mephentermine are effective in managing spinal-induced hypotension during caesarean sections. Phenylephrine showed a better hemodynamic stability profile with fewer rescue doses and lower incidence of tachycardia, making it a potentially preferable choice in clinical practice.

Keywords: *APH, Maternal outcomes, Fetal outcomes*

1. INTRODUCTION

Caesarean section is one of the most common surgical procedures performed in the field of Obstetrics across the Globe.[1]

The obstetric patients undergoing caesarean section poses more challenges to anaesthesiologists as compared to other patients as the anaesthesiologists have to provide highest possible care to not only the mother but also the foetus.[2,3] Thus, to ensure safety of both mother and foetus, the anaesthesiologists have to decide the type of anaesthetic technique to be used. Various regional anaesthetic techniques have been used Globally in Obstetric and surgical Anaesthesia practice such as spinal anaesthesia, epidural anaesthesia, combined spinal - epidural block .[4] Subarachnoid block have also been found to be highly efficient technique of anaesthesia with few drug dose requirements. Though it is associated with certain adverse effects, particularly hypotension, which can be seen in as high as 70 to 80% of the cases in absence of pharmacological prophylaxis.[5-7]

The hypotension resulting from Subarachnoid block (SAB) have been attributed to aortocaval compression, which exacerbates already decreased venous return and sympathetic blockade leading to hemodynamic sequelae. Systolic hypotension (>20%) from the baseline blood pressure of patients is associated with low maternal perfusion pressure, which

manifest as nausea, dizziness, vomiting, low consciousness level, uteroplacental hypoperfusion etc. These factors may have adverse effect on the foetus in the form of fetal bradycardia and acid base imbalance, which if prolonged may later cause neurodevelopmental changes.[8,9]

Various strategies have been used to minimize or prevent the development of hypotension. These include infusion of intravenous fluids (crystalloids/ colloids) to increase effective blood volume, proper positioning of mother so as to displace off the uterus away from vena-cava, leg wrapping to minimize venous pooling of the blood in the legs and improve venous return, periodic monitoring of blood pressure throughout the procedure and use of vasopressor agents.[9,10]

Common vasopressor agents used in practice are sympathomimetic drugs such as Phenylephrine, Ephedrine, Mephentermine, Methoxamine, Metaraminol etc. These drugs acts either directly or indirectly on adrenergic receptors and induce the release of noradrenaline.[11]

Phenylephrine primarily is a selective alpha 1-adrenergic receptor agonist with minimal to nil beta adrenergic activity. This agent is used as a vasopressor agent, as decongestant and as mydriatic agent.

Mephentermine is another sympathomimetic amine which acts on both alpha and beta adrenergic receptors. It has effects on cardiovascular as well as peripheral vascular system. This agent increases the blood pressure primarily by increasing the cardiac output and to a lesser extent by selective constrictive effect on peripheral vascular bed.[12,13,14]

Both these drugs may cross the placenta and thus may have implications on not only the mother but also the fetus.[15,16] Some studies found no significant difference in the efficacy of phenylephrine as compared to mephentermine in managing perioperative hypotension in obstetric cases[17-23], whereas others have shown phenylephrine to be superior in counteracting hypotension as compared to other drugs.[24-26]

With the above background, we conducted this study at tertiary care centre to compare the use of bolus Phenylephrine and Mephentermine for management of hypotension during subarachnoid block in Caesarean section and to assess and compare their effect on haemodynamic variables and adverse effects.

2. MATERIALS AND METHODS

The was conducted as a Randomized Parallel Group Trial on 80 patients undergoing Caesarean section under subarachnoid block at Department of Anaesthesiology, People's Hospital associated with People's College of Medical Sciences& Research Institute .

80 patients were divided into two groups :

Group 1 (n=40): Inj Bolus i.v Mephentermine 6 mg

Group 2 (n=40): Inj Bolus i.v Phenylephrine 100 mcg

Patients were assigned to the two study groups by computer generated randomization.

The inclusion criteria for the study were patients with Full-term parturient age group of 20–35 years , Physical status American Society of Anaesthesiologists (ASA) classes I and Scheduled for caesarean section under Subarachnoid block during the study period . Patient refusal, age Below 20 years and above 35 years ,History of hypertension, preeclampsia/eclampsia, hyperthyroidism, history of any coexisting neurological, cerebrovascular, cardiovascular, renal, metabolic, psychiatric disorder, glaucoma, occlusive vascular disorder & having known fetal abnormalities and fetal distress were included in the exclusion criteria.

After obtaining ethical clearance from Institute's ethical committee, all the patients fulfilling the inclusion criteria were enrolled and written consent was obtained from them.

On the day of surgery, fasting status of the patients was confirmed and they were taken inside operation theatre (OT). Monitors (pulse oximeter, sphygmomanometer, ECG leads) was attached. Baseline parameters i.e., heart rate, systolic and diastolic BP was noted. Intravenous access was secured using 18G IV cannula and preloading with crystalloids at the rate of 10 ml/kg was done rapidly over 15 minutes.

Parturients were placed in the supine position inside the operation theater, oxygenation through face mask at 4 L/min was initiated and continued till delivery of the baby. Under all aseptic precautions, with parturients in sitting position, skin infiltration was done with lignocaine 2%. Lumbar puncture was performed at L3-L4 vertebral interspace using a 25 G Quincke needle, and hyperbaric 0.5% bupivacaine 2 ml was injected intrathecally. Parturients were then immediately placed in supine position with left uterine displacement with the help of a 15 degree wedge. SBP, DBP, MAP, HR, and SPO2 were measured at 1 min interval beginning after subarachnoid block till 3 minutes, thereafter every 3 minutes till 15 minutes, then every 5 minutes till 30 minutes and thereafter every 10 minutes till 60 minutes.

Hypotension was defined as fall in MAP of >20% of baseline. Bradycardia was defined as fall in HR of < 20% of baseline. Tachycardia was defined as increase in HR >20% of baseline. Immediately at the onset of hypotension, patients in Group P were given phenylephrine 100 mcg i.v bolus, whereas for parturients in the Group M received Mephentermine 6mg i.v bolus. Rescue dose of i.v Mephentermine 3 mg and i.v Phenylephrine 50 mcg was given after 5 mins of first dose if MAP does not increase or falls further . Any incidences of nausea (reported by parturients) or vomiting (observed by investigators) was recorded.

3. STATISTICAL ANALYSIS

Data was compiled using MsExcel and analysis was done using IBM SPSS software version 20 (Chicago, Illinois). The data in both the groups was presented as frequency and percentage for categorical variables and mean and standard deviation for continuous variables. Two groups were compared using chi square test and independent t test for categorical and continuous variables respectively. P value of less than 0.05 was considered statistically significant.

4. RESULTS

The table presents the age distribution of study participants across two groups, M and P.

Group M: The mean age of participants in group M is 27.075 years, with a standard deviation (SD) of 4.8059 years. The median age is 27.0 years, with ages ranging from a minimum of 19.0 years to a maximum of 35.0 years. Group P: The mean age of participants in group P is slightly higher at 27.125 years, with a standard deviation of 4.5018 years. The median age is also 27.0 years, with the same age range of 19.0 to 35.0 years. The p-value for the age distribution between the two groups is 0.962, indicating no statistically significant difference in age between groups M and P. This suggests that the age distribution is similar across both groups.

Group	Mean	SD	Median	Minimum	Maximum	p-value
M	27.075	4.805	27	19	35	0.962
P	27.125	4.501	27	19	35	
Total	27.1	4.626	27	19	35	

The table presents the weight distribution of study participants across two groups, M and P.

Group	Mean	SD	Median	Minimum	Maximum	p-value
M	49.95	8.0796	47	45	88	0.777
P	49.5	5.9009	47.5	45	78	
Total	49.725	7.0333	47	45	88	

Group M: The mean weight of participants in group M is 49.950 kg, with a standard deviation (SD) of 8.0796 kg. The median weight is 47.0 kg, and the weights range from a minimum of 45.0 kg to a maximum of 88.0 kg. Group P: The mean weight of participants in group P is slightly lower at 49.500 kg, with a standard deviation of 5.9009 kg. The median weight is 47.5 kg, with weights ranging from 45.0 kg to 78.0 kg. The p-value for the weight distribution between the two groups is 0.777, indicating no statistically significant difference in weight between groups M and P. This suggests that the weight distribution is similar across both groups.

The table compares systolic blood pressure (SBP) at various time intervals between groups M and P. Overall, the data indicate that while there insignificant differences in SBP between groups M and P at each time interval.

Time	**M**		**P**		**p-value**
	Mean	SD	Mean	SD	
Baseline	115.8	21.024	116.75	12.3802	0.951
1 min	100.775	13.55	105.125	9.5359	0.302
2 min	98.215	14.9555	100.475	11.1148	0.601
3 min	96.415	11.8256	94.95	17.7243	0.412
5 min	125.9	13.2158	128.7	9.6853	0.487
10 min	122.775	11.6806	124.15	6.8108	0.148
20 min	113.6	8.3291	118.625	7.9314	0.106
30 min	112.1	8.7202	114.525	7.5786	0.391
45 min	109.25	8.4056	113.35	7.1774	0.531
60 min	108.15	8.126	110.231	7.452	0.685

The table compares diastolic blood pressure (DBP) at various time intervals between groups M and P. Overall, the data indicate that while there insignificant differences in DBP between groups M and P at each time interval.

Time	M		P		p-value
	Mean	SD	Mean	SD	
Baseline	73.05	14.062	74.25	7.6418	0.937
1 min	71.23	9.2048	70.32	8.4453	0.701
2 min	68.87	9.8046	66.62	7.2402	0.691
3 min	66.4	11.5377	62.265	6.6425	0.821
5 min	79.075	10.8377	80.575	5.0934	0.671
10 min	76.225	8.807	77.2	7.783	0.438
20 min	73.25	8.6551	74.425	7.7753	0.129
30 min	72.1	8.938	72.7	6.9585	0.473
45 min	70.1	8.289	72.45	7.0491	0.176
60 min	74.83	16.596	71.65	6.652	0.273

The table comparing Mean Arterial Pressure (MAP) at different time intervals between groups M and P: Overall, the data suggest that insignificant differences in MAP between groups M and P are observed at each interval.

Time	M		P		p-value
	Mean	SD	Mean	SD	
Baseline	87.03	15.8017	88.416	6.3065	0.83
1 min	80.82	12.5779	81.92	10.1473	0.553
2 min	78.65	11.9486	77.903	9.6216	0.55

3 min	76.403	14.62	73.156	8.153	0.341
5 min	94.413	15.491	96.616	7.86	0.256
10 min	91.736	13.027	92.85	7.489	0.286
20 min	86.701	9.636	89.158	10.785	0.551
30 min	85.433	11.15	86.641	7.872	0.692
45 min	83.15	7.98	86.083	7.887	0.764
60 min	85.936	8.253	84.51	8.08	0.865

The table comparing Heart Rate (HR) at different time intervals between groups M and P: Overall, the data indicate that Group M shows higher HR compared to Group P post- intervention but is statistically insignificant.

Time	**M**		**P**		**p-value**
	Mean	SD	Mean	SD	
Baseline	78.85	13.0395	80.3	3.345	0.498
1 min	68.8	7.3107	74.3	8.261	0.104
2 min	67.975	5.5815	65.142	7.654	0.782
3 min	62.075	4.5595	68.541	7.704	0.565
5 min	89.625	8.699	72.575	6.13	0.345
10 min	90.6	8.923	71.125	5.42	0.642

20 min	88.9	8.341	74.245	4.312	0.427
30 min	85	6.882	74.65	5.741	0.685
45 min	81.475	6.633	76.541	5.674	0.54
60 min	79	6.351	72.76	6.119	0.219

This table presents the comparison of rescue dose administration between the two study groups, designated as M and P. The data shows that in the M group, 25 participants (62.5%) received rescue doses, while in the P group, 10 participants (25.0%) received rescue doses. The p-value of 0.001 indicates that the difference in the proportion of participants receiving rescue doses between the two groups is statistically significant.

Rescue doses	**M**		**P**		**p-value**
	Count	%	Count	%	
Yes	25	62.50%	10	25.00%	0.0001
No	15	37.5	30	75.00%	
Total	40	100.00%	40	100.00%	

The table compares the occurrence of different side effects between groups M and P. In group M, 5.0% of participants experienced bradycardia, whereas in group P, this side effect was observed in 12.5% of participants. The difference in incidence between the two groups was not statistically significant . Only 25.0% of participants in group M experienced tachycardia, while no cases were reported in group P. The difference was statistically significant (p = 0.001). Among participants in group M, 7.5% reported nausea and vomiting, compared to 5.0% in group P. This difference was also not statistically significant (p = 0.644).

Side effects	**M**		**P**		**p-value**
	Count	%	Count	%	
Bradycardia	2	5.00%	5	12.50%	0.194
Tachycardia	10	25.00%	0	0	0.001

Nausea and vomiting	3	7.50%	2	5.00%	0.644

5. DISCUSSION

Hypotension during Caesarean sections performed under subarachnoid block is a common and significant clinical challenge. Effective management of this condition is crucial for the safety and well-being of both the mother and the infant. Subarachnoid block, while providing excellent analgesia, can lead to a reduction in systemic vascular resistance and venous return, resulting in hypotension. Various pharmacological agents, such as vasopressors, are used to manage this condition. Phenylephrine and Mephentermine are among the commonly used vasopressors for this purpose. Phenylephrine, a selective alpha-1 adrenergic receptor agonist, increases blood pressure primarily through vasoconstriction. Mephentermine, on the other hand, is a sympathomimetic agent with both direct and indirect actions, increasing blood pressure by stimulating the release of norepinephrine and directly acting on adrenergic receptors.

The present study found no statistically significant difference in the age distribution between the Phenylephrine group (Group P) and the Mephentermine group (Group M). The mean age of the participants in Group P was 27.125 years, while in Group M, it was 27.075 years. These findings are consistent with the results reported in various studies included in the comparison.

Sahu et al. [27], Mohta et al. [28], Nazir et al. [19], Das et al. [17], Modak et al. [29], and Kamalkannan et al. [5] did not report any statistically significant differences in the age distribution between the study groups in their respective investigations.

The present study evaluated the hemodynamic parameters, including systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR), and mean arterial pressure (MAP), between the Phenylephrine group (Group P) and the Mephentermine group (Group M) during the caesarean section procedures.

The results showed no statistically significant differences in these hemodynamic parameters between the two groups at the various time intervals measured except in HR. Incidence of tachycardia was observed to be higher in M group. These findings are consistent with the observations made in several of the studies included in the comparison.

Sahu et al.[27] and Mohta et al. [28] reported that both Phenylephrine and Mephentermine were effective in maintaining maternal arterial pressure within 20% of the baseline values, with no significant differences between the two vasopressor agents.

Similarly, Nazir et al. [19], Das et al. [17], and Kamalkannan et al. [5] found no significant differences in the hemodynamic parameters, including SBP, DBP, and HR, between the Phenylephrine and Mephentermine (or Ephedrine) groups.

The present study evaluated the need for rescue doses of the vasopressor agents and the total number of doses administered during the Caesarean section procedures in the Phenylephrine group (Group P) and the Mephentermine group (Group M).

The results showed a statistically significant difference in the need for rescue doses between the two groups. In Group M (Mephentermine), 62.5% of the participants required rescue doses, whereas in Group P (Phenylephrine), only 25% required rescue doses. These findings suggest that the Phenylephrine group required fewer rescue doses compared to the Mephentermine group.

The findings of the present study are partially consistent with the results reported in the other studies included in the comparison.

Choudhury et al. [30] and Manhas et al. [6] also found that Phenylephrine required fewer rescue doses compared to Mephentermine for the management of hypotension during Caesarean section procedures. However, Kaur et al. [4] reported that Mephentermine and Ephedrine had lower recurring hypotensive events and required fewer total doses compared to Phenylephrine.

The results showed that the incidence of bradycardia was higher in the Phenylephrine group (12.5%) compared to the Mephentermine group (5.0%), although this difference was not statistically significant. In contrast, the incidence of tachycardia was significantly higher in the Mephentermine group (25.0%) compared to the Phenylephrine group (0%). The incidence of nausea and vomiting was similar between the two groups, with no statistically significant differen Sahu et al. [27], Das et al. [17], and Manhas et al. [6] reported that Phenylephrine was associated with a reduction in heart rate, which can be advantageous in patients where tachycardia is undesirable, such as those with cardiovascular comorbidities.

Nazir et al. [19] and Kaur et al. [4] also found a higher incidence of bradycardia in the Phenylephrine group compared to the Ephedrine or Mephentermine groups. The increased incidence of tachycardia with Mephentermine is also in line with the results reported by Choudhury et al. [30]. The similar incidence of nausea and vomiting between the Phenylephrine and

Mephentermine groups observed in the present study is consistent with the findings reported by Nazir et al. [19], Kamalkannan et al. [3], and Manhas et al. [6].

6. CONCLUSION

The present study compared the use of bolus intravenous inj. Phenylephrine and inj. Mephentermine for the management of hypotension during Caesarean section performed under spinal anaesthesia. There were no statistically significant differences in the hemodynamic parameters, including systolic blood pressure, diastolic blood pressure, mean arterial pressure, HR between the Phenylephrine and Mephentermine groups. The requirement of rescue doses was significantly lesser in Phenylephrine group as compared to mephentermine group. The incidence of tachycardia was significantly higher in the Mephentermine group as compared to Phenylephrine group. The occurrence of nausea and vomiting was similar between the groups.

Based on the above findings we can conclude that both Phenylephrine and Mephentermine are effective in the management of hypotension during Caesarean section under spinal anaesthesia, with distinct side effect profiles that may guide the selection of the appropriate vasopressor agent based on the individual patient's clinical needs and treatment goals.

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