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Comparative study between the safety and efficacy of Phenylephrine and Mephentermine in management of spinal anaesthesia induced hypotension

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Abstract

Background and objectives: Spinal anaesthesia induced hypotension is the commonest side effect with the prevalence of 16-33%. Occurrence of hypotension is primarily due to preganglionic sympathetic blockade resulting in vasodilation and pooling of blood in the lower limbs. This reduces the cardiac preload and output. Elevation of the Patient leg, head down tilt and use of pressure stockings augment venous return and increase cardiac output and may be sufficient to restore blood pressure to an acceptable level.

Ephedrine/Norepinephrine was the first agent to be used successfully to treat hypotension induced by spinal anaesthesia. Mephentermine is the most commonly used drug for this purpose. But it is known to cause tachycardia. Phenylephrine is a potent alpha agonist

having α1 mediated vasoconstrictor action, thus causes elevation in blood pressure. Phenylephrine being selective α-agonist, does not have much cardiac side effects and hence better drug in patients with cardiovascular comorbid conditions.

Objectives: Present study was conducted to compare the efficacy and safety of Phenylephrine and Mephentermine in spinal anaesthesia induced hypotension.

Methodology: Present study was conducted at Hassan Institute of Medical Sciences, Hassan, Karnataka. After Institutional Ethics Committee clearance, we recruited 100 patients who were posted for operation from the department of Surgery, Orthopaedics, Gynaecology and developed hypotension followed by spinal anaesthesia were recruited for the study based on the inclusion criteria. Patients were divided into Phenylephrine and Mephentermine groups by simple randomization having 50 patients in each group. One group had received 100 mcg i.v bolus dose of Phenylephrine and the other group had received 6 mg/i.v. bolus dose of Mephentermine. Demographic profile of the patients were statistically insignificant. Average duration of the procedure, Baseline heart rate, Baseline systolic blood pressure, Baseline diastolic blood pressure and Mean arterial pressure were almost similar in both groups.

Results: Comparison of the blood pressure fall and recovery time had showed moderate significance between both the groups. Least recovery time was in Phenylephrine group (6.08±3.53) and whereas 7.42±4.00 for Mephentermine group. Statistically significant variation in heart rate was seen after administration of Mephentermine but was insignificant clinically. Variation in the systolic, Diastolic and Mean arterial pressure were not significant.

Conclusion: After analyzing the findings, we conclude that Phenylephrine and Mephentermine are equally efficacious in controlling the hypotension due to spinal anaesthesia. Phenylephrine comparatively needs lesser time to show recovery from the hypotension requiring lesser number of bolus doses. Mephentermine causes more variation in heart rate than the Phenylephrine group hence Phenylephrine is better drug in patients who are prone to develop tachycardia.

Keywords: Mephentermine; Phenylephrine; Spinal anaesthesia induced hypotension

Introduction

Spinal anaesthesia follows the injection of local anaesthetic into the CSF in the lumbar space, usually between the lumbar spaces L2-L3 or L3-L4.[1] Spinal anaesthesia induced hypotension caused due to these reflexes remains one of the commonest side effects with the accounting for about 16-33%.[2,3] Primarily due to preganglionic sympathetic blockade resulting in vasodilation and pooling of blood in the lower limbs which will reduce the cardiac preload and output. [2,3]

Elevation of Patient's leg, head down tilt and use of pressure stockings augment venous return and increase cardiac output and may be sufficient to restore blood pressure to an acceptable level.[4,5] Volume expansion can be done with crystalloid or colloid infusion.[6]

Various vasopressors have been tried for the prevention as well as the treatment of spinal block induced hypotension. However, the prophylactic administration of Ephedrine in spinal blockade is no longer advocated due the major adverse effects. Mephentermine is associated with reduction in hypotensive episodes, lesser vasopressor doses and a shorter time of recovery from hypotension without any major side effects.[7]

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Phenylephrine is a potent alpha agonist having α1 mediated vasoconstrictor action, thus causes elevation in blood pressure. Phenylephrine being selective α agonist, does not have much cardiac side effects and hence better drug in patients with cardiovascular comorbid conditions.[7,8]

Many studies have been done to compare the efficacy and safety of multiple vasopressors and also the intramuscular or iv infusion of phenylephrine. Majority of the articles had conducted on pregnant females. There are very few studies which have particularly compared the efficacy and safety of Mephentermine and phenylephrine.

So, we conducted a study to compare the efficacy and safety of intravenous bolus doses of Mephentermine and Phenylephrine and also to observe the adverse events caused by these drugs.

Objectives

- To compare the safety and efficacy of Mephentermine versus Phenylephrine in spinal anaesthesia induced hypotension.
- To observe the adverse events of Mephentermine and Phenylephrine.

Methodology

After obtaining the Ethical committee clearance (IEC/HIMS/RR6/2-11-2018), Patients Posted for lower abdomen surgery from the department of Surgery, Gynaecology and lower limb surgeries from department of orthopaedics at Sri Chama Rajendra Hospital, HIMS, Hassan were recruited for the study. A Prospective, Open labelled, randomized interventional study. Total 100 patients who developed hypotension induced by spinal anaesthesia were included in the study after fulfilling the inclusion criteria.

Sample size estimation

$$\frac{(Z_\alpha + Z_\beta)^2 \text{ X } SD^2 \text{ X } 2}{d^2}$$

$$\frac{(1.96 + 1.282)^2 \text{ x } (4)^2 \text{ x } 2}{3^2}$$

37.71, Approximately 38 samples in each group

Minimum suggested sample size was 38. So, we took 50 cases in each group.

Inclusion Criteria

- Patients belonging to American Society of Anaesthesiologists Classification[9] (ASA) 1 and ASA 2 were recruited.
- 18–60-year-old patients, both genders were included in the study.
- Patients posted for infra-umbilical and lower limb surgeries, who developed hypotension were recruited.
- Written and Informed consent.

Exclusion Criteria

- Patients with known history of ischemic heart disease or other cardiac abnormalities are excluded from the study.
- Patients allergic to either of the drugs were not included.
- Patients falling under scale ASA grade 3 and above.
- Patients not willing for written informed consent.

Patients were kept over-night fasting. Patients were shifted to Operation theatre, were explained about the study. Written -informed consent was taken. Test dose of

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the drug was given. Patients were started with pre loading of intravenous (i.v) fluid with 500 ml Normal Saline (NS). 2.5 cc of 0.5% Bupivacaine (H) was administered at the level between L3-4 using 25G spinal needle. Simple randomisation was done. Patients developing hypotension followed by Spinal anaesthesia were designated alternatively to Mephentermine and Phenylephrine group.

Preparation of required dosage

Phenylephrine: Available as 10mg/ml ampoule. This 1 ml of the drug was mixed in 99 ml NS to make it 100mcg/ml (10,000mg in 100ml =100mcg/ml).

Mephentermine: Available as 30mg/ml of 5 ml vial. 1 ml in 4 ml of NS is taken to make it 6mg/ml. Number of bolus given to for the correction of blood pressure and time duration taken by the bolus to increase in blood pressure is noted.

Baseline systolic Blood pressure (SBP), Diastolic blood pressure (DBP), Mean arterial pressure (MAP), Heart rate (HR), Electrocardiography (ECG), Oxygen saturation (SpO_2) were recorded before Spinal anaesthesia as baseline. Then the above parameters have been recorded every 10 minutes after the administration of spinal anaesthesia for 30 minutes and there after every 15 min till the end of the surgery.

If fall in SBP < 20% or an absolute value of < 100 mm Hg, then the drug was administered. And monitoring is done every 5 min till the end of the procedure. The number of boluses given and the time taken for recovery was noted. BP and HR were also monitored every 5 minutes till the end of the procedure. Adverse events were assessed according to the Naranjo's and World Health Organisation Adverse Drug Reaction (WHO ADR) Causality Assessment Scale.

Statistical analysis

Statistical Methods: Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5% level of significance.

Statistical software: The Statistical software namely SPSS 22.0, and R environment ver. 3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc**.**

Results

Hundred patients were included in the study. 17 from department of surgery, 17 from department of Orthopaedics and 16 from Gynaecology each in both the groups. Out of 100 patients, 50 patients received Phenylephrine 100mcg iv bolus dose and the other 50 patients received Mephentermine 6 mg iv bolus.

Table 1: Demographic details and Baseline parameters.

Baseline parameters	Phenylephrine	Mephentermine	P value
Mean age ± SD	44.78 ±9.08	45.08 ±9.04	0.869
Male: Female	19(38%)/31(62 %)	21(42%)/29(58 %)	0.670
Comorbidities DM HTN BOTH	21 2 14 5	19 1 12 6	0.838
ASA1/ASA2	29/21	31/19	0.667
Average duration of surgery	53.50 ±12.42	52.20 ±11.43	0.587
Average Fall in blood pressure	27.80±9.74	27.70±9.70	0.595
Average baseline HR	81.36±8.59	82.94±6.38	0.579
Average	127±13.71	127.58±13.71	0.869

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baseline SBP			
Average baseline DBP	75.24±9.19	76.16±8.45	0.604
Average baseline MAP	92.46±10.01	93.26±8.95	0.674

Table 2 shows the demographic details and baseline parameters of the patients included in the study. There was no significant difference in the baseline parameters.

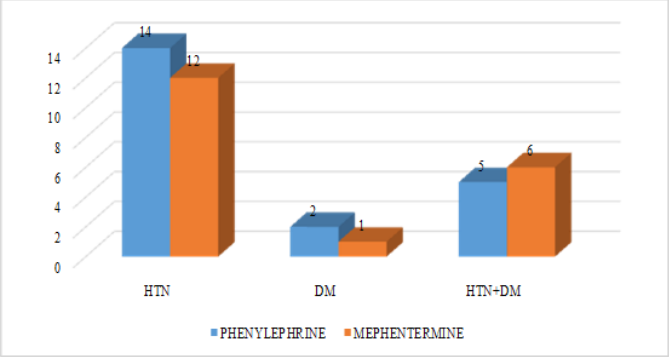

Figure 1: Distribution of comorbidities in two groups of patients studied

Figure 1 represents the distribution of comorbid condition in ASA2 patients between Phenylephrine and Mephentermine. Among the 21 patients who fell under ASA2 in the Phenylephrine group, 14 of them had Hypertension (HTN), 2 of them suffering from Diabetes mellitus (DM) and 5 were on treatment for both HTN and DM. In the Mephentermine group 31(62%) classified under ASA1 and 19(38%) under ASA2.

Table 2: Distribution of duration of the procedure in two groups of patients

Duration	Phenylephrine group	Mephentermine group
<40	2(4%)	1(2%)
40-50	25(50%)	26(52%)
51-60	15(30%)	16(32%)
>60	8(16%)	7(14%)
Mean ± SD	53.50 ±12.42	52.20 ±11.43

p 0.587, Not Significant, Student t Test

Distribution of the duration of procedure has been tabulated in Table 2. Which did not have significant difference between the two groups.

Average fall in blood pressure took at 27.80±9.74 minutes in Phenylephrine group and at 27.70±9.70 minutes in Mephentermine group.

Table 3: Distribution of number of bolus doses required in two groups of patients

Dose	Phenylephrine group	Mephentermine group
1	41(82%)	30(60%)
2	8(16%)	13(26%)
3	1(2%)	7(14%)
Mean ± SD	1.20±0.45	2.1±0.57

P 0.05, Significant, Fisher Exact Test

The average number of bolus doses required for the correction of intraoperative blood pressure was significantly higher in Mephentermine group.

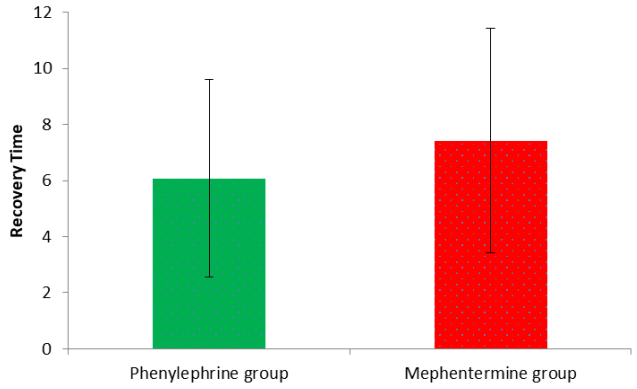

Figure 2: Comparison of Recovery time in minutes between Phenylephrine and Mephentermine

The mean recovery time taken to rise in blood pressure was 6.08±3.53 and 7.42±4.00 for Phenylephrine and Mephentermine group respectively. This is represented in Figure 2.

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Table 4: A Comparison of fall time and recovery time in two groups of patients studied

Variable	Phenylephrine group	Mephentermine group	Total	P Value
Fall Time in min	27.80±9.74	27.70±9.70	27.75±9.67	0.959
Recovery Time in min	6.08±3.53	7.42±4.00	6.75±3.81	0.05

Comparison of the time taken to fall in blood pressure and the recovery time for Phenylephrine group was suggestively significant with the p value 0.05.

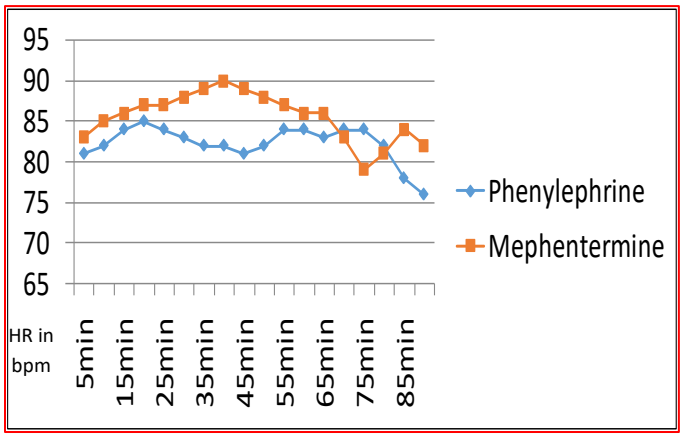

Figure 3: Comparison of Intraoperative variation in heart rate

Baseline heart rate of 81.36±8.59 and 83.94±6.38 respectively for the Phenylephrine and Mephentermine. Intraoperative variation in the heart rate after the administration was not having significant change in both groups. Variation in heart rate between the groups indicated statistically significant increase in Mephentermine group at 35, 40, 45 and 50th minute.

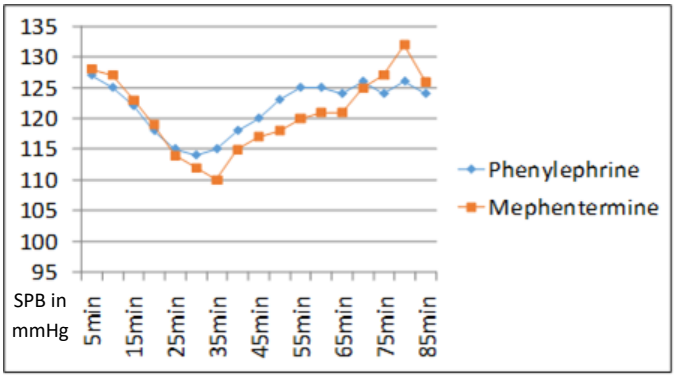

Figure 4: Comparison of intraoperative variation of systolic blood pressure

Intraoperative variation in the systolic blood pressure was more in Mephentermine group than Phenylephrine. Which was clinically significant at 40, 45 and 50th minutes but was not statistically significant.

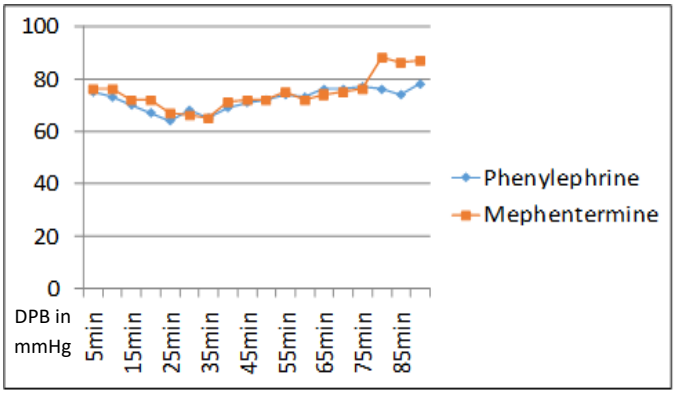

Figure 5: Comparison of intraoperative variation of the diastolic blood pressure

The comparison of intraoperative variation of diastolic blood pressure between Phenylephrine and Mephentermine group showed that the mean baseline diastolic blood pressure 75.24±9.19 and 76.16±8.45 mmHg respectively and the variations was neither clinically significant nor statistically.

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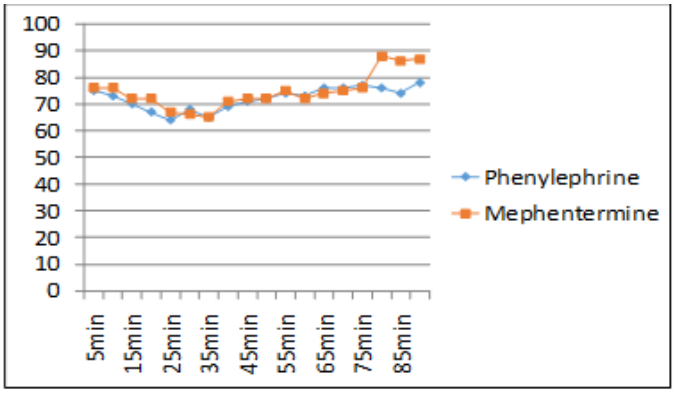

Figure 6: Comparison of intraoperative variation of the Mean arterial pressure

Comparison of baseline and intraoperative variation in mean arterial pressure also did not show any statistical or clinical significance throughout the procedure.

Table 5: Comparison of BP Fall time and recovery time according to ASA grading – phenylephrine group

Variable in min	ASA – phenylephrine group		Total	p Value
	Grade 1	Grade 2		
Fall Time	32.94±12.38	24.15±6.90	27.80±9.74	0.006**
Recovery Time	6.23±3.97	6.00±3.34	6.08±3.53	0.826

According to Table 5 which describes the intra group comparison in Phenylephrine group among ASA1 and ASA2 patients. Though there is significant fall time, the recovery time between these group was insignificant.

Discussion

Spinal anaesthesia induced hypotension is one of the most common complications during surgeries. Many vasopressor agents are being tried to overcome the hypotension.[10,11] Ephedrine was proven to increase the blood pressure but the side effects like tachycardia made it outdated. Mephentermine, indirectly acting vasopressor agent has the good prognosis with minimal adverse effect of tachycardia. But Phenylephrine being a directly acting alpha 1 agonist drug has less cardiac side effects. [12,13]

Out of hundred patients recruited in the study, fifty had received 100mcg of Phenylephrine and the other 50 patients received 6 mg of Mephentermine bolus dose. There was no statistically significant difference in the baseline values between both groups.

Among the patients who received Phenylephrine, 29(58%) fell under ASA1 classification with normal physiological condition and 21(42%) came under ASA2 grading. 14 of them had Hypertension (HTN), 2(4%) Diabetes mellitus (DM) and 5 were on treatment for both HTN and DM. In the Mephentermine group 31(62%) were classified under ASA1 and 19(38%) under ASA2.

Average fall in blood pressure took at 27.80±9.74 minutes in Phenylephrine group and at 27.70±9.70 minutes in Mephentermine group. 41(82%) Patients in Phenylephrine group and 30(60%) of the Mephentermine group patients had required one bolus dose to recover from the fall in blood pressure, which was comparatively higher in the study conducted by Ramesh et al[14] in which, 20% of the patients received one dose of 100mcg of Phenylephrine and 24% in Mephentermine received 6mg of one bolus dose.

In our study, 8(16%) in Phenylephrine and 13(26%) in Mephentermine group had received two bolus doses. The finding was similar in Ramesh et al[14] where 14% and 8% of the patient in Phenylephrine and Mephentermine group respectively required two doses.

1(2%) and 7 (14%) of the patients had required three bolus doses to overcome the fall in blood pressure in our study. But none of the patients in the comparative study had required three bolus doses.

According to the present study Phenylephrine group required significantly lesser number of average bolus

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dose for the correction of blood pressure. This is contrary to the finding of Kaur et al.[15] in which number of bolus doses required by Phenylephrine group was higher.

The mean recovery time taken to rise in blood pressure in our study was 6.08±3.53 and 7.42±4 min for Phenylephrine and Mephentermine group respectively. The value is almost similar with the work done by Dua D et al.,[16] in their study, recovery time for Phenylephrine was 6 min. Comparison of the time taken for fall in blood pressure and the recovery time for Phenylephrine group was faster with significant the p value 0.05.

This finding was partially similar with the results of Ganeshanavar A et al.,[17] and Raja Nalini et al.,[18] Ganeshanavar had compared bolus of Phenylephrine, ephedrine and Mephentermine for maintenance of arterial pressure during spinal anaesthesia and obtained that phenylephrine group had quicker control of blood pressure compared to the other two groups.[17] And also similar effect was seen with Raja Nalini et al.[18] However, as the time elapsed all drugs achieved comparable control of blood pressure. This finding is also comparable with our study. But their observation of Phenylephrine causing significant reduction in heart rate is contradictory to our study.

According to our study, Baseline heart rate was 81.36±8.59 and 83.94±6.38bpm respectively for Phenylephrine and Mephentermine. Intraoperative variation in the heart rate after the administration was not having clinically significant change in both the groups. This outcome was contradictory to the findings obtained by Kaur D et al[15] and Bhattarai et al.[19] They found that, Phenylephrine was causing significant bradycardia. But in another study by Raja Nalini et al[18] showed that Phenylephrine was causing bradycardia but it was neither clinically significant nor statistically. In turn it was desirable effect in patients who were having cardiac disease.

Another study (Kamala Kannan et al)[20] also had increased heart rate in Mephentermine group and no much variation in Phenylephrine group, which is similar to our study.

Mean baseline systolic blood pressure of Phenylephrine and Mephentermine were 127±13.71 and 128±11.5mmHg intraoperative variation in the systolic blood pressure was more in Mephentermine group than Phenylephrine, which was clinically significant at 40, 45 and 50th minutes but was not statistically significant. This is similar with the results of Anil Ganeshanavar et al.[17]

Though the correction of SBP was clinically significant with one bolus dose of Phenylephrine, it was not statistically significant in our study. This observation coincides with the study conducted by Ramesh et al.[14]

The comparison of intraoperative variation of diastolic blood pressure between Phenylephrine and Mephentermine group showed that the mean baseline diastolic blood pressure 75.24 ± 9.19 and 76.16 ±8 .45 mmHg respectively. And the variations was neither clinically significant nor statistically.

The results of our study is similar with finding of Sharma R et al.,[21] they found that Mephentermine was causing undesirable increased heart rate. But the efficacy of both drugs was same with respect to maintenance of blood pressure intraoperatively. Whereas in our study, comparative variation in heart rate between the groups were statistically significant at 35, 40, 45 and 50th minute. This variation was because of the increase in heart rate caused by Mephentermine.

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Intra group comparison of blood pressure fall time and recovery time according to ASA grading showed that there was significant fall in blood pressure among ASA2 patients in Phenylephrine group but the recovery time taken by both the groups was almost same with no statistically significant changes.

We observed that there was no statistically significant intra operative variation of systolic blood pressure, diastolic blood pressure, mean arterial pressure and heart rate between ASA1 and ASA2 patients in both the groups. In a study, Hypertension and Anaesthesia conducted by Hanada et al,[22] also mentioned that mild and moderate hypertensive patients had no significant intraoperative variation in blood pressure or heart rate.

Conclusion

- Efficacy of Phenylephrine and Mephentermine in controlling the hypotension due to spinal anaesthesia is almost same.
- Recovery time required by the Phenylephrine is comparatively lesser than the Mephentermine group.
- Number of bolus doses required by the Phenylephrine is comparatively less than Mephentermine.
- Phenylephrine is comparatively faster acting than the Mephentermine.
- Change in heart rate followed by the Mephentermine bolus dose is more than the Phenylephrine group.
- Phenylephrine is a better drug in patients who are prone to develop increased heart rate.

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