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Comparison Of Bolus Mephentermine, Ephedrine And Phenylephrine For The Treatment of Hypotension In Lower Segment Caesarean Section Under Spinal Anaesthesia: A Double Blinded Randomized Study

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Abstract

Background: Spinal anaesthesia has been a respected and valued option of anaesthesia for caesarean section since a long time. Hypotension after spinal anaesthesia in caesarean delivery can have delirious effects on mother as well as foetus. Various methods have been used to prevent it, but that may not be adequate and vasopressors are required to mitigate hypotension. This study planned to assess the efficacy of Mephentermine, Ephedrine, and Phenylephrine in treatment of the hypotension under spinal anasesthesia for caesarean section.
Methods: The study was conducted on 120 parturient who were scheduled for elective caesarean section under spinal anaesthesia. They were allocated into 3 groups of 40 each randomly to receive Group M-Mephentermine 6 mg, Group E- Ephedrine 6 mg, and Group P-Phenylephrine 100 microgram**.** The Vitals were recorded at interval of every minute till the onset of hypotension and then monitored for every two minutes interval for ten minutes and thereafter at every 5 minutes interval till the end of surgery. The study drug was given as IV bolus after development of hypotension which was defined as fall in Blood Pressure greater than twenty percent from baseline value.
Results: No significant differences were observed in mean heart rates and MAP among the groups. However, significant differences emerged at 2, 6, 8, 10, 15, 20, 25 and 30 minutes, with respective p-values of 0.003, 0.011, 0.02, 0.004, 0.0003, <.0001, 0.0009 and 0.0006 in mean heart rates. Specific pairwise comparisons revealed significant differences at 4, 6, 8, 10, 15, 20, 25 and 30 minutes, with respective p-values of 0.016, 0.016, 0.004, 0.011, 0.002, 0.002, <.0001 and 0.001 in MAP. Post-hoc analyses further revealed specific group pairs with significant differences in mean heart rate and MAP at specific time points.
Conclusions: Three vasopressor namely Mephentermine, Ephedrine, and Phenylephrine are effective in maintaining the blood pressure within twenty percent of baseline vitals. Phenylephrine has faster onset of effect as compare to Mephentermine and Ephedrine. Phenylephrine group also shows decrease in heart rate, which may render better option where tachycardia is undesirable in pregnant parturient

Keywords: LSCS, Spinal Anaesthesia, Hypotension, ArterialPpressure, Vasopress

Introduction

Globally, there has been an increase in the incidence of lower segment caesarean section (LSCS) due to multi-factorial reasons. One of the reasons is the safety of anaesthetics for caesarean section. Spinal

anaesthesia has been a respected and valued option of anaesthesia for caesarean section since a long time. 0.5 % Hyperbaric Bupivacaine is the commonest intrathecal local anaesthetic used in India for caesarean section. However, it has its own complications like hypotension and inadequate analgesia. Anaesthesia to pregnant women requires the highest degree of care because of the involvement of both mother as well as foetus.

In elective caesarean section under spinal anaesthesia, hypotension has been reported in as many as 85% of patients. Hypotension during spinal anaesthesia for caesarean delivery can have detrimental effects on mother as well as foetus which include impairement of foetal oxygenation with asphyxia stress, reduced utero placental blood flow, foetal acidosis, signs and symptoms of low cardiac output in mother such as nausea, vomiting, dizziness and altered consciousness. Therefore, there has been much attention in the literature to methods of preventing and treating hypotension during anaesthesia. Positioning with left uterine displacement and preloading with crystalloids or colloids has been used to prevent it which may not be adequate, requiring a vasopressor to correct hypotension quickly. Vasopressors like Mephentermine, Ephedrine, Phenylephrine, Metaraminol and Methoxamine are used for treating the hypotension [1-4].

The present study aims to compare the efficacy of Mephentermine, Ephedrine, and Phenylephrine in treating the hypotension under spinal anaesthesia for caesarean section and its side effects.

This article has been previously presented as E-Poster during the 11th Eastern Zonal Critical Care Conference (EZCCCON), 2023 held at Maniram Dewan Trade Centre, Guwahati on 4-5th November 2023.

Materials and methods

This prospective, randomized, double blind study was done in the Department of Anaesthesiology, TRIHMS, Medical College, Arunachal Pradesh, India from December 2022 to April 2024. This study approved by Institutional Scientific Research Committee (Ref. No.TRIHMS/Research/2019-Part-ll Dated 20-09-2022) and Institutional Ethical Committee (Ref. No.TRIHMS/ETHICS/O1/2019-20148, Dated 01/11/2022). Clinical Trials Registry-India (Reg. No. CTRI/2023/08/056070) was registered before enrolling the patients.

Inclusion criteria

Full term pregnant patient who are undergoing elective LSCS in age group of 18–35 years after giving informed written consent were included.

Exclusion criteria

known case of hypertensive patients, patients on anti-hypertensive drugs or uncontrolled PIH, Multiple Gestations, Obese (> 90kg) or BMI >30kg/m2, Short stature (< 140cm), Hemoglobin < 9gm/dl, Patients with spinal deformity or puncture site infection, Known hypersensitivity to any of the 3 drugs, Patients with bleeding diathesis or coagulopathy were excluded.

After pre-anaesthetic check-up, 150 patient meeting inclusion criteria were selected. A computer-generated randomisation was utilized to screen 120 patientsfor the study. Thereafter, all the 120 patients were categorized into three groups of 40 each, namely, Group M, Group E and Group P by using sequentially numbered opaque envelope method.

An informed consent was obtained from the entire pregnant patient after explaining the standard procedure and effect of drugs. Injection Pantoprazole 40 mg was given in the morning of surgery. An emergency crash cart trolley which contained airway management devices and emergency drugs were checked and kept ready. The patients were place in supine position in OT table and attached pulse oximetry, temperature, NIBP and ECG monitor. Intravenous access was obtained with 18G IV cannula in either of the arm. All patients were preloaded with Ringer lactate (15ml/Kg) rapidly and Heart rate, MAP and SPO2 was recorded and taken as baseline value.

Patients were placed in left lateral position. Skin around lumbar area was clean with chlorhexidine solution and draped with sterile towel. The L3-L4 interspace was identified and 25G Quincke-Babcock needle was introduced in this space through a midline approach. Once the needle pierced the dura and was in the subarachnoid space, stylet was removed and free flow of CSF was verified and 1.7ml of 0.5% Hyperbaric bupivacaine with 0.5ml of Fentanyl was administered intrathecally. Then the patients were turned supine. Oxygen was administered at a rate of

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5litre/min by a face mask to all the patients. Inj. Oxytocin 20U in Normal Saline (NS) was given after clamping the cord [4].

One who performed the subarachnoid block and recorded the observations was unaware of the study drug. The vitals were recorded at interval of every minute till the onset of hypotension and then monitored for every two minutes interval for ten minutes and thereafter at every 5 minutes interval till the end of surgery. The study drug was given as IV bolus upon occurrence of hypotension which was defined as fall in Blood Pressure greater than twenty percent from baseline value.

Statistical method:

Sample size calculations:

With the level of significance at 5% and the power of the study at 80%, and an SD from a previous study and error of 5% the sample size (N) was calculated to be 34.01 using the formula as given below:

$N = 2sd^2 (Z_\alpha/2 + Z_\beta)^2/d^2$

$= 34.01$

Taking into considerations of 10% attrition, we took the sample of 40 in each study arm.

The data was entered into Microsoft EXCEL and analysis was done using Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, version 25.0.

The statistical tests that was used for analysis of the results:

1. The quantitative data were entered as the means ± SD and as median with 25^{th} to 75^{th} percentiles (Interquartile range). The categorical variables were entered in the form of number and percentage (%). Shapiro-Wilk test was used to verify the data normality and when the data were not normal, non parametric tests was used.

2. The comparison of the variables which were quantitative and not normally distributed in nature were analyzed using Kruskal Wallis test and variables which were quantitative and normally distributed in nature were analyzed using ANOVA. A post-hoc test (Bonferroni correction) was applied after ANOVA for all normally distributed data. A post-hoc analysis by Dunn's multiple pair wise comparison tests was carried out for all not normally distributed data.

3. Chi-square test was used for the comparison of the variables which were qualitative in nature. If any cell had an expected value of less than 5, then Fisher's exact test was used.

4. P value of less than 0.05 was considered statistically significant.

Results

The study was conducted in the Department of Anaesthesiology, TRIHMS, Arunachal Pradesh. 120 patients of age group 18-35 years with full term pregnancy who underwent elective LSCS under spinal anaesthesia were included.

Baseline demographic and clinical characteristics of the three groups are comparable and summarized in **Table 1, 2, 3.**

Figure 1: Heart rate (bpm) was assessed at various time points in three groups: Group M, Group E, and Group P. At baseline, the mean heart rates were 92.7 ± 15.74 bpm for Group M, 91.9 ± 13.83 bpm for Group E, and 88.32 ± 14.06 bpm for Group P, with a non-significant overall p-value of 0.363. No significant differences were observed in mean heart rates between specific pairs of groups.

At different time intervals, including study drug administration, 2, 4, 6, 8, 10, 15, 20, 25 and 30 minutes, mean heart rates were compared among the three groups. Overall, no significant differences were found at baseline, during study drug administration and at 4 minutes. However, significant differences emerged at 2, 6, 8, 10, 15, 20, 25 and 30 minutes, with respective p-values of 0.003, 0.011, 0.02, 0.004, 0.0003, <.0001, 0.0009 and 0.0006. Post-hoc analyses revealed specific group pairs with significant differences in mean heart rate at these time points. At 2, 6, 8 and 30 minutes: Group E has a significantly higher mean heart rate compared to Group P and no significant difference was seen between other post-hoc comparison. At 10, 15, 20 and 25 minutes: Group P demonstrates a significantly lower mean heart rate compared to both Group M and Group Eand no significant difference was seen between group M and E. **(Figure 1)**

Figure 2: Mean arterial pressure (MAP) was assessed at various time points in three groups: Group M, Group E, and Group P. At baseline, no significant differences were observed in mean MAP among the

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groups (p-value = 0.458). This pattern remained consistent during the administration of the study drug and at 2 minutes, with no statistically significant variations detected (p = 0.479, p=0.121 respectively). However, at subsequent time intervals (4, 6, 8, 10, 15, 20, 25 and 30 minutes), significant differences in mean arterial pressure emerged. Specific pairwise comparisons revealed significant differences at 4, 6, 8, 10, 15, 20, 25 and 30 minutes, with respective p-values of 0.016, 0.016, 0.004, 0.011, 0.002, 0.002, <.0001 and 0.001. Post-hoc analyses further identified the specific pairs of groups contributing to these differences. At 4, 6, 8, 10, 20 minutes: Group P has a significantly higher mean arterial pressure compared to Group M and no significant difference was seen between other post-hoc comparison. At 15, 25 minutes: Group P has a significantly higher mean arterial pressure compared to Group E and M and no significant difference was seen between group E and M. At 30 minutes: Group M has a significantly lower mean arterial pressure compared to both Group P and Group E and no significant difference was seen between group P and E.

Discussion

Caesarean section is one of the most common obstetric surgeries that are performed. Over time, regional anaesthesia especially spinal anaesthesia proved to be the most preferred technique for Caesarean section [5-6].

The safety of spinal anaesthesia is of dual nature; pharmacological as well as physiologic with a low degree of physiologic disturbance along with profound degrees of sensory denervation and muscle relaxation. However, one main hurdle with this technique is the troublesome and persistent incidence of hypotension especially in gravid parturient. Dinesh Sahu et al found that maternal hypotension during spinal anaesthesia for caesarean delivery was a persistent problem in approximately 85% of cases [7].

Use of IV fluid as preload, avoidance of aortocaval compression and judicious use of various vasopressor agents can be used to treat hypotension under spinal anaesthesia. Three drugs Ephedrine, Mephentermine and phenylephrine having its own pharmacological properties were evaluated. Both Mephentermine and Ephedrine are synthetic non-catecholamine that acts directly as well as indirectly by stimulating α- and β-adrenergic receptors. Phenylephrine which is a synthetic non-catecholamine primarily stimulates alpha1-adrenergic receptors by a direct action [4]. Thomas and Colleagues reported that bolus phenylephrine 100 mcg is as effective as Ephedrine 5 mg restoring maternal arterial pressure above 100mmHg [8].

In present study, Phenylephrine Groups showed lower mean value of heart rate as compare to Mephentermine group and Ephedrine group. The mean heart rate varied significantly among the groups at specific time intervals. The frequency of tachycardia episode was analyzed in all the three groups and there were statistically significant lower in Phenylephrine group than the both Mephentermine and Ephedrine group. There is decreased venous return after the onset of spinal anaesthesia which in turn decreased venous pressure as well as right atrial pressure. Therefore decrease in heart rate is explained on the basis of the Bain bridge reflex. In high spinal anaesthesia, Bradycardia occurs due to paralysis of some of the cardio-accelerator nerves. In this study, the maternal heart rate was slower with Phenylephrine than with Mephentermine and Ephedrine. This is consistent with the mechanism of action of the particular drugs. Phenylephrine group was due to pure α receptor activity compared with Mephentermine and Ephedrine which has got a mixed action directly as well as indirectly on α and ß receptors [4].

In study of Dua et al [9], there were no incidence of bradycardia in ephedrine group and Mephentermine group. They conclude that bradycardia was due to reflex decrease in heart rate associated with increase in blood pressure after administration of Phenylephrine. However, bradycardia was responsive to atropine treatment without any adverse consequences. They found that maternal heart rate was slower with phenylephrine than with ephedrine and Mephentermine because Phenylephrine lacks action on beta receptors. This may be better in pregnant patients in whom tachycardia is undesirable [4]. Dinesh Sahu et al [7] observed that there was significant decrease in heart rate after the bolus dose by Phenylephrine.

Thomas DG et al [8], they also found that mean maximum percentage change in maternal heart rate was larger in Phenylephrine group as compare to

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Ephedrine group where atropine was required in eleven out of eighteen women in the Phenylephrine group compared with two out of eighteen women in the Ephedrine group. They reported a high (58%) incidence of bradycardia (heart rate less than 60 beats /min) when Phenylephrine was given as IV bolus after induction of spinal anaesthesia. Decrease in maternal heart rate and cardiac output by Phenylephrine was also observed in the systematic review by Ngan Kee et al [10]. In contrast, there was no episode of bradycardia requiring atropine in present study. Selection of patients and different criteria of treating hypotension could have caused the difference.

Dinesh Sahu et al [7] studied the effects of bolus Ephedrine, Mephentermine, Phenylephrine for the maintenance of arterial pressure during spinal anaesthesia for LSCS. In their study all the vasopressors effectively maintained arterial pressure within 20% of baseline value but Phenylephrine maintained better in first 6 minutes of bolus dose as compared with Ephedrine and Mephentermine which is consistent with finding of the present study [4]. Anna Lee et al [11] found that for the management of hypotension, there was no difference between phenylephrine and ephedrine and both effectively maintained the systolic BP within 20% of baseline values in their quantitative systematic review which is consistent with our study [4]. Similarly, Cyna AM et al [12] studied the randomized controlled trials comparing the interventions to prevent hypotension during spinal anaesthesia for cesarean section. From 75 trials they found that ephedrine was significantly more effective than control or crystalloid in preventing hypotension. There were no significant differences between ephedrine and phenylephrine in treating hypotension [4]. Similar to this study, David Cooper et al [13] compared phenylephrine 100 µg, ephedrine 3mg/ml and phenylephrine 50 µg/ml and ephedrine 1.5mg/ml in combination given by infusion to maintain maternal systemic arterial pressure at baseline during spinal anesthesia for LSCS and found that the mean systolic arterial pressure was similar in three groups [4]. Kansai A et al [14] compared the effects of IV infusions of ephedrine and mephentermine for maintenance of maternal arterial pressure receiving subarachnoid block for LSCS and found that baseline hemodynamic parameters and hemodynamic changes subsequent to the start of vasopressor infusion, were statistically similar in both groups [4]. Yap JC et al [15] on comparing the efficacy of fluid preloading with two fluid vasopressor regimens IV ephedrine boluses was more effective in maintaining systolic blood pressure [4]. Alahutta S et al [16] studied the effects of Ephedrine and Phenylephrine to maintain the systolic arterial pressure 20% above the baseline values during spinal anesthesia for cesarean section . In this study also both the vasopressors restored maternal arterial pressure effectively.

Nausea and vomiting was observed in 7.5% in Mephentermine group, 2.5 % in Ephedrine group, none in Phenylephrine group and there was no significant difference among the three groups in present study. Similar to this study, Moran DH et al [17] did not found any significant differences in maternal nausea and vomiting in the Ephedrine and Phenylephrine group in their study.

Conclusion

The study concluded that three vasopressor namely Mephentermine, Ephedrine and Phenylephrine are effective in maintaining the heart rate and blood pressure within twenty percent of baseline values. Phenylephrine has faster onset of effect as compare to Mephentermine and Ephedrine. Phenylephrine group also shows decrease in heart rate, which may render better option where tachycardia is undesirable in pregnant parturient.

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Table 1: Comparison of age (years) between Group M, E and P.

Age(years)	Group M(n=40)	Group E(n=40)	Group P(n=40)	P value
18 to 20 years	1 (2.50%)	2 (5%)	6 (15%)	0.083*
21 to 25 years	9 (22.50%)	15 (37.50%)	6 (15%)	M vs E:0.414*
26 to 30 years	16 (40%)	14 (35%)	20 (50%)	M vs P:0.109*
31 to 35 years	14 (35%)	9 (22.50%)	8 (20%)	E vs P:0.073*
Mean ± SD	28.42 ± 4.08	26.5 ± 4.37	27.15 ± 4.52	0.134+
Median(25th-75thpercentile)	28(25.75-32)	27(23-30)	28(24.5-30)	M vs E:0.147 M vs P:0.571

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Range	20-34	20-34	18-34	E vs P:1

* **Fisher's exact test,** ‡ **ANOVA**

Table 2: Comparison of ASA grade between Group M, E and P.

ASA grade	Group M(n=40)	Group E(n=40)	Group P(n=40)	P value
II	40 (100%)	40 (100%)	40 (100%)	NA
Total	40 (100%)	40 (100%)	40 (100%)	

Table 3: Comparison of obstetric history between Group M, E and P.

Obstetric history	Group M(n=40)	Group E(n=40)	Group P(n=40)	P value
Gravida				
G1	13 (32.50%)	12 (30%)	12 (30%)	0.974* M vs E:1* M vs P:0.839* E vs P:0.841*
G2	15 (37.50%)	15 (37.50%)	18 (45%)	
G3	8 (20%)	7 (17.50%)	5 (12.50%)	
G4	2 (5%)	3 (7.50%)	3 (7.50%)	
G5	2 (5%)	3 (7.50%)	1 (2.50%)	
G6	0 (0%)	0 (0%)	1 (2.50%)	
Parity				
P0	15 (37.50%)	14 (35%)	13 (32.50%)	0.858* M vs E:0.961* M vs P:0.443* E vs P:0.77*
P1	14 (35%)	16 (40%)	20 (50%)	
P2	8 (20%)	6 (15%)	3 (7.50%)	
P3	2 (5%)	2 (5%)	2 (5%)	
P4	1 (2.50%)	2 (5%)	1 (2.50%)	
P5	0 (0%)	0 (0%)	1 (2.50%)	
Live				
L0	15 (37.50%)	14 (35%)	15 (37.50%)	0.829* M vs E:1* M vs P:0.472* E vs P:0.657*
L1	15 (37.50%)	16 (40%)	19 (47.50%)	
L2	7 (17.50%)	6 (15%)	2 (5%)	
L3	2 (5%)	2 (5%)	3 (7.50%)	
L4	1 (2.50%)	2 (5%)	1 (2.50%)	
Abortion				
A0	36 (90%)	36 (90%)	33 (82.50%)	0.392* M vs E:0.581* M vs P:0.286* E vs P:0.484*
A1	3 (7.50%)	1 (2.50%)	4 (10%)	
A2	0 (0%)	2 (5%)	3 (7.50%)	
A3	1 (2.50%)	1 (2.50%)	0 (0%)	

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Figure 1: Comparison of trend of heart rate (BPM) at different time intervals between Group M, E and P.

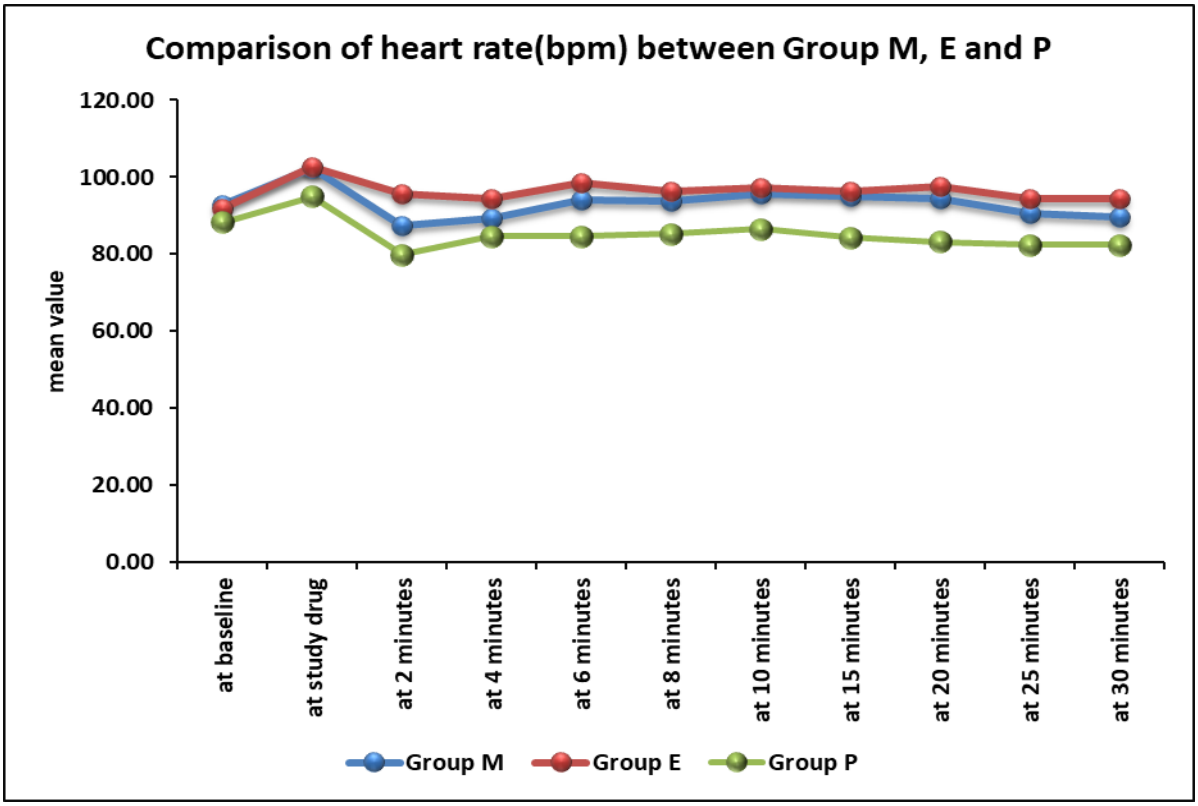
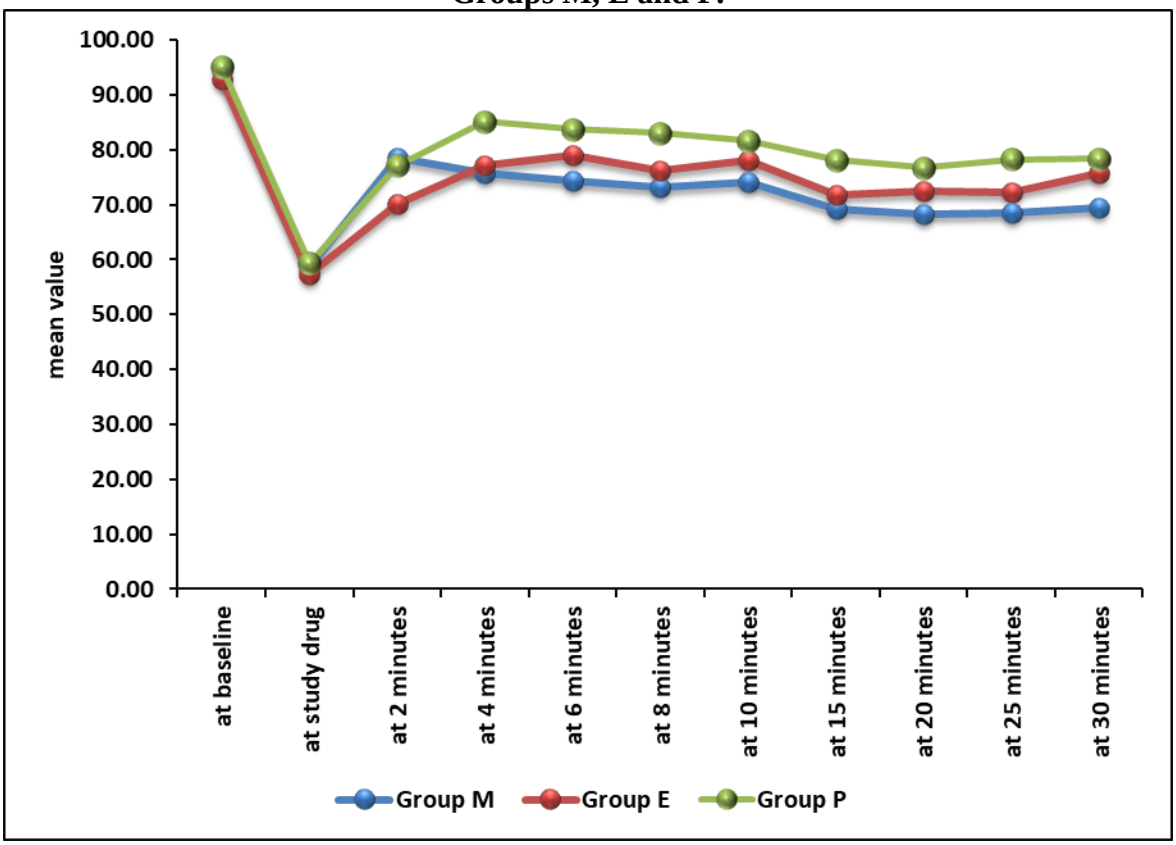


Figure 2: Comparison of trend of mean arterial pressure (mmHg) at different time intervals between Groups M, E and P.



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