

PROPHYLACTIC ADMINISTRATION OF DOPAMINE FOR PREVENTING SPINAL HYPOTENSION: A RANDOMISED CONTROL STUDY

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ABSTRACT

BACKGROUND

Hypotension is the most common complication during spinal anaesthesia. This study is aimed to investigate the effects of dopamine on the intraoperative haemodynamics in patients undergoing surgeries under spinal anaesthesia.

MATERIAL/METHODS

This is a randomised control study including 120 patients undergoing elective surgeries under spinal anaesthesia. Patients were randomly assigned into 4 groups (n=30 per group): Group A, Group B, Group C and Group D to receive intravenous dopamine infusion @ 0, 3, 5, and 7 mcg/kg/minute respectively. Pulse rate, blood pressure, mean arterial pressure, ECG, SpO₂ were recorded at varying intervals [T1 (1st minute), T2 (2nd minute), T3, T4, T5] then every 5 minutes up to 30 minutes, then every 10 minutes till the end of the surgery. Urine output was measured every 60 minutes.

RESULTS

When systolic blood pressure was compared between group A and the other 3 groups, there was significant statistical difference between group A and C, A and D, from T2 to T90 minutes. Mean arterial pressure of the three groups B,C and D, compared with control group A, there was statistically significant difference seen between the groups A and C (T2-T100), A and D (T3, T10-T40). Diastolic blood pressure of the control group was compared with the other three groups B, C and D, there was no significant difference statistically. The heart rate of group A is compared with other three groups, there was no consistent statistical difference till T30 in group A vs. C, A vs. D, but after T30 minutes, there was significant fall in the heart rate in group A when compared to other 3 groups. There was a significant difference in urine output noted between the control group A and groups which received dopamine infusion. The average volume of urine in control group is 73.9 mL at the end of 60 minutes, but it was around 10 times more in group B, C and D.

CONCLUSIONS

Continuous intravenous infusion of 5 µg/kg/min. dopamine is safe and effective in maintaining hemodynamic stability in patients undergoing surgeries under spinal anaesthesia.

KEYWORDS

Anesthesia, Spinal, Haemodynamics, Dopamine.

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INTRODUCTION: Spinal anaesthesia is one of the most popular and widely used anaesthetic procedures. It is a simple, cost effective and efficient technique that provides complete sensory and motor block, as well as postoperative analgesia with a high success rate. Several advantages of spinal anaesthesia include a decreased incidence of deep vein thrombosis, reduced intraoperative blood loss, as well as the prevention of pulmonary aspiration in case of emergency, especially in patients with potential airway problems and known respiratory diseases.

Although subarachnoid block provides excellent anaesthesia for many surgeries, it is frequently accompanied by hypotension.^{1,2} This is largely due to the result of sympathetic nerve blockade. Excessive hypotension may potentially produce myocardial, cerebral and renal ischaemia.^{3,4} Methods to prevent and treat this hypotension has been the subject of much investigation and controversy. One of the mainstays of management is the use of vasopressor agents and those currently available are not perfect.^{5,6,7} In this study, the role of dopamine as a vasopressor in spinal hypotension is being studied. Ephedrine was the first agent used for this purpose and it has withstood the test of time, it is the agent against which all others are compared.^{8,9} It remains the first-line agent in spinal anaesthesia induced hypotension, but it cannot be relied upon to be 100% successful and other agents must be considered when it is inadequate.^{10,11}

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Hence in this study, the effects of various doses of dopamine continuous intravenous infusion on the intraoperative haemodynamics in patients undergoing elective surgeries under spinal anaesthesia were studied to decide about the appropriate dose of dopamine needed to prevent hypotension in patients undergoing surgeries under spinal anaesthesia.

Primary Objective: To compare the various parameters observed during infusion of various doses of dopamine like,

- Heart Rate.
- Systolic Blood Pressure.
- Diastolic Blood Pressure.
- Mean Arterial Pressure.

Secondary Objective: To compare the Urine output in all 4 groups.

MATERIALS AND METHODS:

Patient Selection: After getting approval from the ethical committee of our institution and getting written informed consent from patients/relatives, 120 patients of ASA I & II who underwent elective surgeries under spinal anaesthesia at Government Kilpauk Medical College Hospital were enrolled in this study group.

Inclusion Criteria:

- Patients of age between 25 to 65 years.
- Height >150 cm and <170 cm.
- Weight 40-75 kg.
- Patients undergoing elective surgeries under spinal anaesthesia requiring sensory blockade level of T6 and below.
- ASA I & ASA II.
- Consent from patient.

Exclusion Criteria:

- ASA III & ASA IV.
- Patients who are known allergic to study drugs.
- Patients having contraindications for spinal anaesthesia.
- Emergency surgeries.
- Valvular heart disease.
- Ischaemic heart disease.
- Hypertension.
- Metabolic disorders.
- Anaemic patients.
- Prolonged surgeries for more than 2 hours.
- Surgeries requiring sensory blockade above T6.
- Surgeries causing major fluid shifts/blood loss >10% of blood volume.
- Surgeries requiring other than supine position.
- Severe liver or kidney insufficiency.
- History of hyperthyroidism/hypothyroidism.
- Recent administration of tricyclic antidepressants or monoamine oxidase inhibitors.
- History of type 2 DM >5 yrs.
- Patients not willing to take part in study.

GROUPS:

- a. Group A: 30 patients who do not receive dopamine infusion during surgery.
- b. Group B: 30 patients who receive continuous intravenous Dopamine infusion @3 mcg/kg/minute.
- c. Group C: 30 patients who receive continuous intravenous Dopamine infusion @5 mcg/kg/minute.
- d. Group D: 30 patients who receive continuous intravenous Dopamine infusion @7 mcg/kg/minute.

METHODOLOGY: This study was designed as a randomised control study. Patients were preoperatively evaluated, clinically examined and proper investigations were done prior to assessment. Procedure was explained in detail and written consent was obtained. After ascertaining the inclusion criteria, preoperative investigations were recorded.

Anaesthesia Procedure: The procedure was carried out in the theatre where facilities for resuscitation were available. All patients were deprived of food for overnight before surgery. Patients were randomly selected and divided into Group A, Group B, Group C and Group D to receive intravenous dopamine infusion @ 0, 3, 5, and 7 mcg/kg/minute respectively. Intravenous cannulation was carried out with 18G Venflon. All patients in four groups received inj. midazolam 2 mg and inj. ondansetron 4 mg intramuscularly half an hour prior to shifting to operating room. All the patients were preloaded with 15 mL/kg of Ringer lactate solution half an hour prior to subjecting to spinal anaesthesia. Vitals such as BP, Pulse, Respiratory rate, SPO2 were measured before the patient is being shifted to operating room. After shifting to operating room all the patients were subjected to spinal anaesthesia in lateral decubitus position, under sterile aseptic precautions using 25G Quincke needle at L3-L4 space and 3.5 mL of 0.5% bupivacaine [Heavy] was given.

Intraoperatively group A, B, C and D patients received dopamine infusion @ 0, 3, 5, 7 mcg/kg/minute respectively soon after positioning the patient. Level of sensory blockade checked at 5 minutes after subarachnoid block. All the 4 group patients received crystalloid infusion intraoperatively @ 10 mL/kg/hr. If any patients in group A, B, C, D had Hypotension (Defined as a decrease in systolic arterial pressure (SAP) more than 20% below baseline and to below 100 mmHg) intraoperatively, they received incremental doses of ephedrine (6 mg) IV bolus as required.

Anaesthesia Monitoring: Pulse rate, blood pressure, mean arterial pressure, ECG, SpO2 were recorded at varying intervals [T1 (1st minute), T2 (2nd minute), T3, T4, T5] then every 5 minutes up to 30 minutes, then every 10 minutes till the end of the surgery. Urine output was measured every 60 minutes. Then, the data were collected and analysed.

The parameters studied are:

1. Systolic pressure.
2. Diastolic pressure.
3. Mean arterial pressure.

4. Heart rate.
5. Urine output.

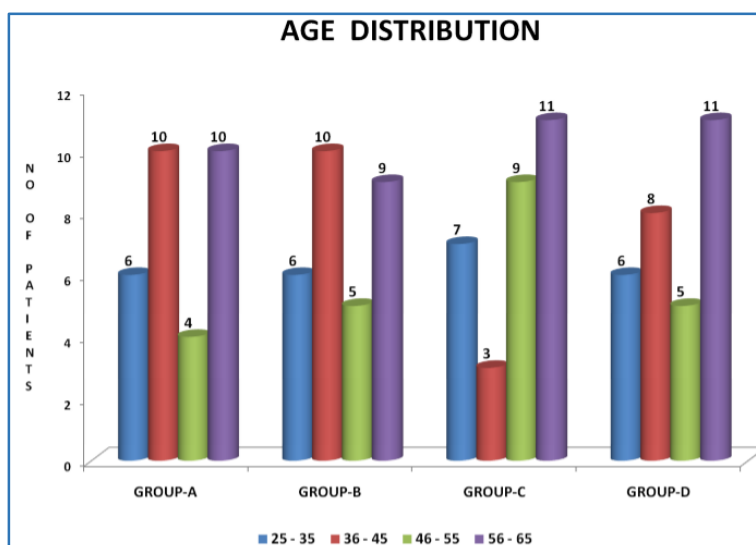
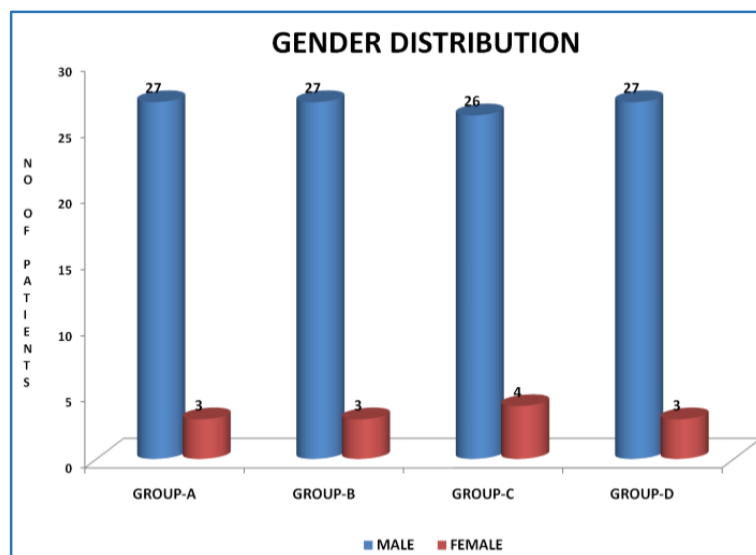
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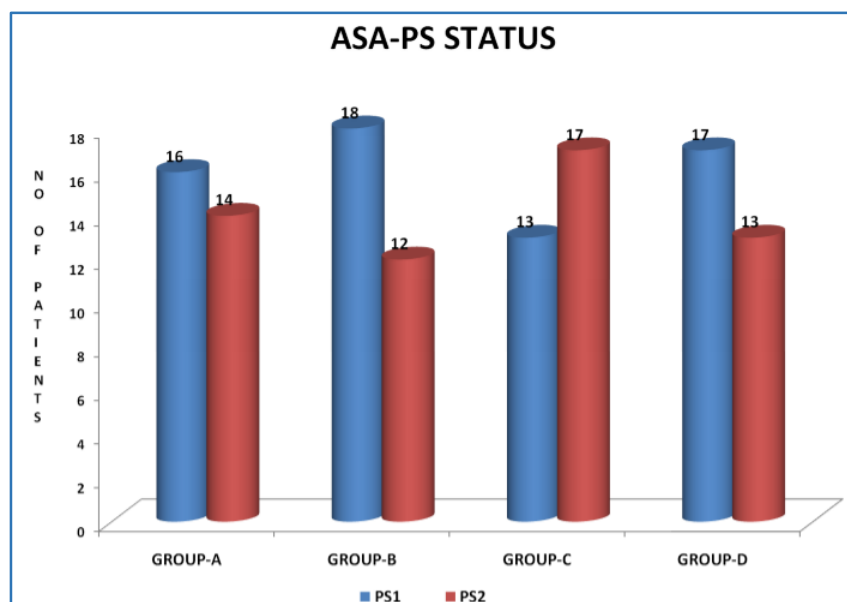
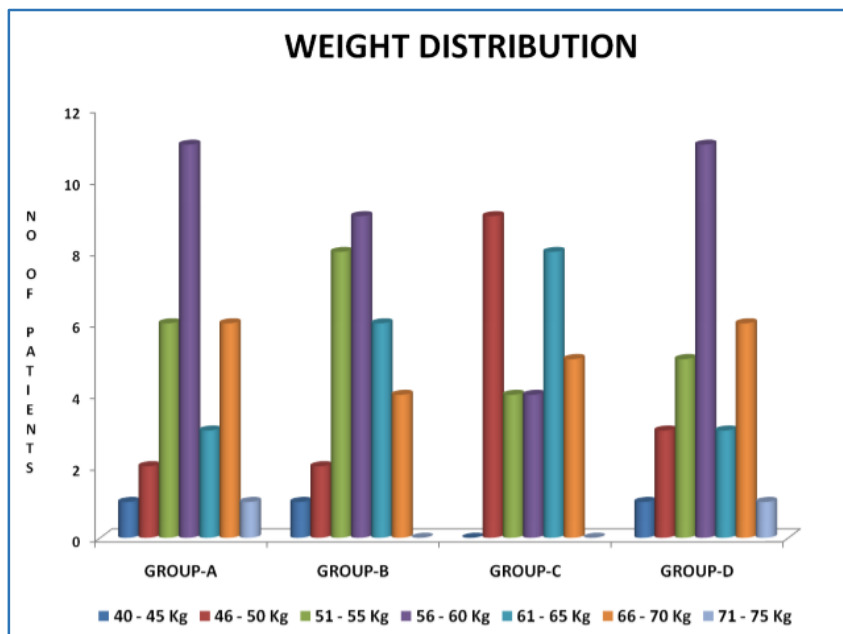
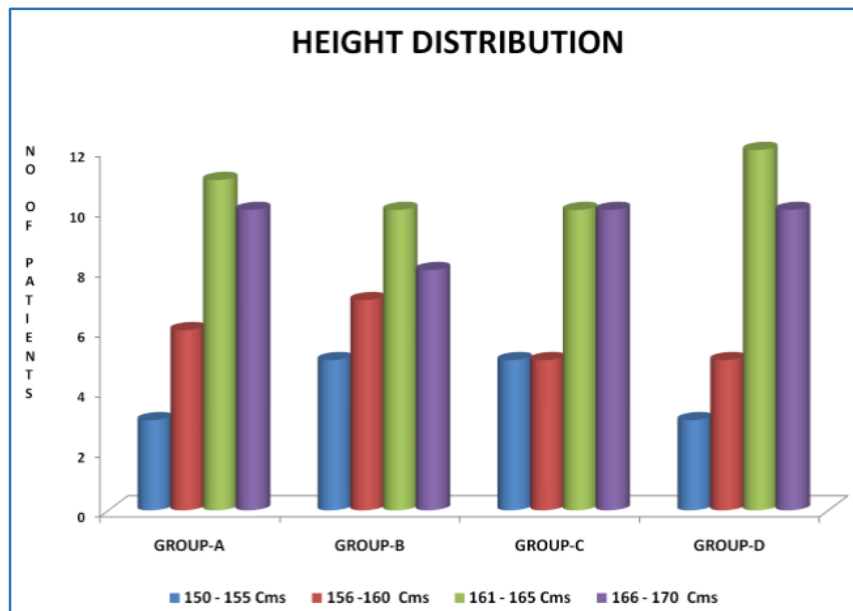
- Pulse Oximetry.
- NIBP (Arterial Blood Pressure was measured by Oscillometric Method).
- ECG (3 Lead ECG).

Data Analysis: Statistical analyses were performed using SPSS 23.0 (SPSS Inc., IBM, Chicago, IL, USA). Sample size estimation was determined by power analysis with one-way analysis of variance (ANOVA). Sample size of 120 subjects (n=30 per group) was determined to be sufficient to detect differences in the means among the 4 groups, with a statistical power greater than 90%. All numerical values are presented as the mean and standard deviation (SD). Repeated-measures ANOVA was used to compare differences within the same group. One-way ANOVA was used to compare differences among groups. Categorical data were compared by the chi-squared test. Differences with $p < 0.05$ were considered to be statistically significant.

OBSERVATION AND RESULTS:

- A total of 120 patients of ASA- PS1/PS2 were studied in this study.
- Thirty patients were enrolled into each of the four groups (A, B, C and D).
- There was no statistical significance between the four groups when the demographic parameters like age distribution, sex distribution, weight and height of the patients and ASA status classification were compared.
- The comparison of parameters like preoperative systolic blood pressure, diastolic blood pressure, mean arterial pressure, and heart rate was also found to be statistically insignificant between the four groups.
- Sensory blockade level was also comparable between all groups and statistically insignificant.
- All the 120 patients underwent similar procedures which lasted for less than 120 minutes with insignificant blood loss.





Systolic Blood Pressure:

	Group - A	Group - B	Group - C	Group - D	Significance (p value)		
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	A vs B	A vs C	A vs D
Pre op	126.27±13.92	128.30±06.94	125.10±11.03	126.13±11.41	*0.48	*0.72	*0.96
T1	126.90±15.01	122.33±05.90	127.27±10.68	116.57±16.48	*0.13	*0.91	0.01
T2	114.60±19.82	114.50±10.47	129.17±11.56	114.00±17.17	*0.98	0.0001	*0.90
T3	109.57±18.81	111.47±12.36	133.33±15.43	119.87±19.56	*0.65	0.0001	0.04
T4	109.57±18.81	111.47±12.36	133.33±15.43	119.87±19.56	*0.62	0.0001	0.02
T5	108.20±15.12	105.20±14.92	128.77±12.76	123.20±23.15	*0.44	0.0001	0.004
T10	109.73±15.59	103.90±16.12	127.30±13.61	124.77±20.84	*0.16	0.0001	0.002
T15	108.67±14.26	109.03±11.60	123.67±12.06	124.60±19.91	*0.91	0.0001	0.001
T20	109.70±12.69	110.27±12.86	124.87±11.11	126.70±22.47	*0.86	0.0001	0.001
T25	107.80±13.79	109.70±12.52	125.37±14.28	136.50±25.97	*0.58	0.0001	0.0001
T30	108.97±13.83	112.87±11.46	121.43±14.09	133.23±21.34	*0.24	0.001	0.0001
T40	108.13±14.35	114.70±11.11	124.47±12.13	128.23±15.01	0.05	0.0001	0.0001
T50	110.90±14.31	115.40±10.10	126.90±13.17	127.80±13.69	*0.17	0.0001	0.0001
T60	112.40±14.24	114.23±9.22	127.33±12.08	125.73±6.57	*0.56	0.0001	0.0001
T70	105.26±22.70	117.90±11.91	124.93±14.51	120.50±5.13	0.01	0.0001	0.001
T80	112.80±13.03	119.73±9.04	124.77±13.72	123.10±3.48	0.02	0.002	0.0001
T90	111.05±12.52	119.47±8.36	124.96±9.09	120.13±2.16	0.01	0.0001	0.0001
T100	115.53±13.06	121.37±4.44	122.29±8.31	119.63±4.86	*0.08	*0.08	*0.13

Table 1

*** Not Significant**

- When systolic blood pressure was compared between group A and the other 3 groups, there was significant statistical difference between group A and C, A and D, from T2 to T90 minutes.

Diastolic Blood Pressure:

	Group - A	Group - B	Group - C	Group - D	Significance		
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	A vs B	A vs C	A vs D
Pre op	84.63±9.07	82.53±2.43	83.07±4.46	81.76±8.40	*0.23	*0.40	*0.21
T1	79.70±9.52	78.13±2.89	81.13±10.58	74.43±16.58	*0.39	*0.58	*0.14
T2	72.37±12.45	72.23±7.20	77.83±9.25	71.33±16.85	*0.96	*0.06	*0.79
T3	69.43±10.48	68.67±8.97	79.97±9.74	74.93±14.76	*0.76	0.0001	*0.10
T4	70.67±11.80	67.50±10.20	76.23±9.80	75.83±14.77	*0.27	0.05	*0.14
T5	69.47±10.49	65.20±12.66	74.60±10.99	69.73±16.27	*0.16	*0.07	*0.94
T10	69.00±10.69	65.57±11.06	74.53±9.73	71.27±14.55	*0.23	0.04	*0.49
T15	68.33±11.45	70.63±12.61	72.87±8.59	71.47±15.04	*0.46	*0.09	*0.37
T20	69.73±10.73	69.23±10.26	73.90±8.16	71.90±14.61	*0.85	*0.10	*0.52
T25	68.03±10.80	67.57±6.68	73.57±11.02	73.40±14.33	*0.84	0.05	*0.11
T30	69.00±10.58	68.00±7.46	71.97±11.20	73.67±14.50	*0.67	*0.30	*0.16
T40	67.37±10.36	70.17±7.23	71.60±11.34	70.83±9.82	*0.23	*0.14	*0.19
T50	69.30±11.38	71.83±6.81	72.17±8.65	70.30±11.52	*0.30	*0.28	*0.74
T60	71.57±11.29	71.23±7.20	73.03±9.21	74.20±10.64	*0.89	*0.58	*0.36
T70	73.37±11.10	69.03±11.26	70.20±7.99	71.10±7.78	*0.15	*0.22	*0.37
T80	71.84±10.69	72.53±6.24	76.37±6.45	73.73±8.09	*0.77	*0.06	*0.46
T90	70.95±9.61	73.93±4.79	75.35±4.69	70.90±6.74	*0.15	0.05	*0.98
T100	72.94±10.67	78.79±7.74	78.35±4.17	73.43±4.69	*0.07	*0.06	*0.83

Table 2

*** Not Significant**

- When diastolic blood pressure of the control group was compared with the other three groups B, C and D, there was no significant difference statistically.

Mean Arterial Pressure:

	Group - A	Group - B	Group - C	Group - D	Significant		
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	A vs B	A vs C	A vs D
Pre op	102.33±9.22	101.40±5.65	101.27±8.46	102.37±8.07	*0.64	*0.64	*0.99
T1	94.50±9.08	92.13±4.09	94.90±9.44	86.70±16.17	*0.20	*0.87	0.03
T2	85.60±14.02	84.80±8.43	93.67±7.50	88.43±15.93	*0.79	0.01	*0.47
T3	82.67±12.51	82.13±10.53	96.67±8.25	91.40±16.26	*0.86	0.0001	0.02
T4	82.13±12.88	81.17±11.29	95.87±7.32	89.20±16.61	*0.76	0.0001	*0.07
T5	81.03±11.28	77.47±14.02	93.80±7.00	85.87±18.87	*0.28	0.0001	*0.23
T10	81.03±10.16	77.23±13.71	93.63±9.26	88.27±16.11	*0.23	0.0001	0.04
T15	80.87±10.47	83.87±14.53	89.90±8.13	89.70±17.89	*0.36	0.0001	0.02
T20	80.63±10.16	82.50±11.22	89.07±7.83	91.20±21.30	*0.50	0.001	0.02
T25	79.83±10.78	81.27±8.84	92.13±10.05	94.70±19.18	*0.58	0.0001	0.0001
T30	80.80±10.12	82.27±8.67	87.80±8.70	94.80±17.81	*0.55	0.01	0.0001
T40	80.00±10.54	83.97±8.43	89.43±7.33	86.93±13.78	*0.11	0.0001	0.03
T50	81.63±10.79	84.70±7.63	90.23±7.20	88.40±13.35	*0.21	0.001	*0.34
T60	84.20±10.44	84.10±7.94	92.30±6.95	88.23±8.86	*0.97	0.001	*0.11
T70	80.89±12.86	84.57±10.57	88.23±6.69	85.17±5.84	*0.24	0.01	*0.11
T80	84.60±9.86	85.77±8.10	91.77±7.65	88.57±5.71	*0.63	0.01	*0.07
T90	85.10±10.39	86.90±7.14	94.46±7.81	85.10±1.42	*0.47	0.001	*1.00
T100	87.59±11.53	90.68±8.08	95.53±8.66	86.47±1.14	*0.35	0.03	*0.60

Table 3

*** Not Significant**

- When mean arterial pressure of the three groups B, C and D, compared with control group A, there was statistically significant difference seen between the groups A and C (T2-T100), A and D (T3, T10-T40).

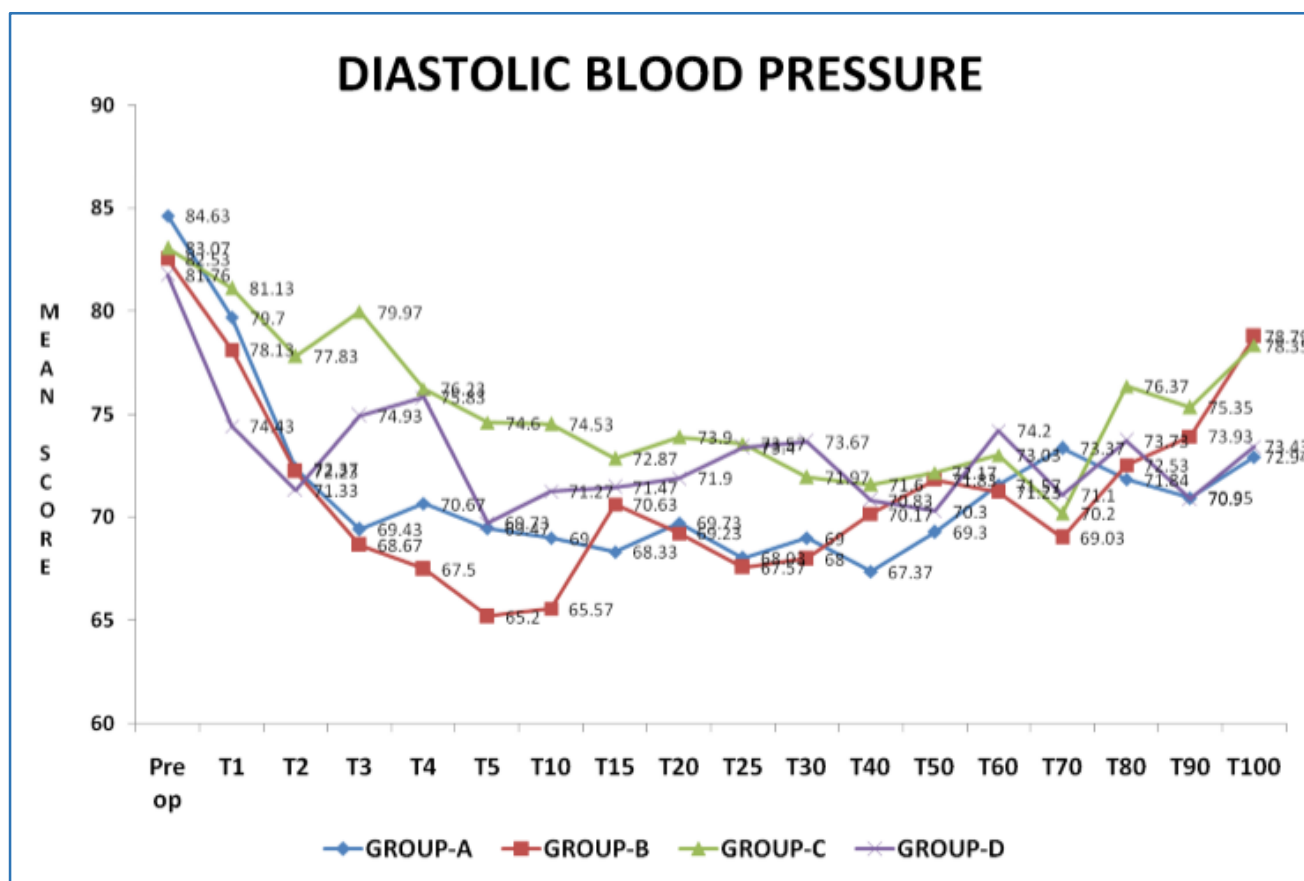
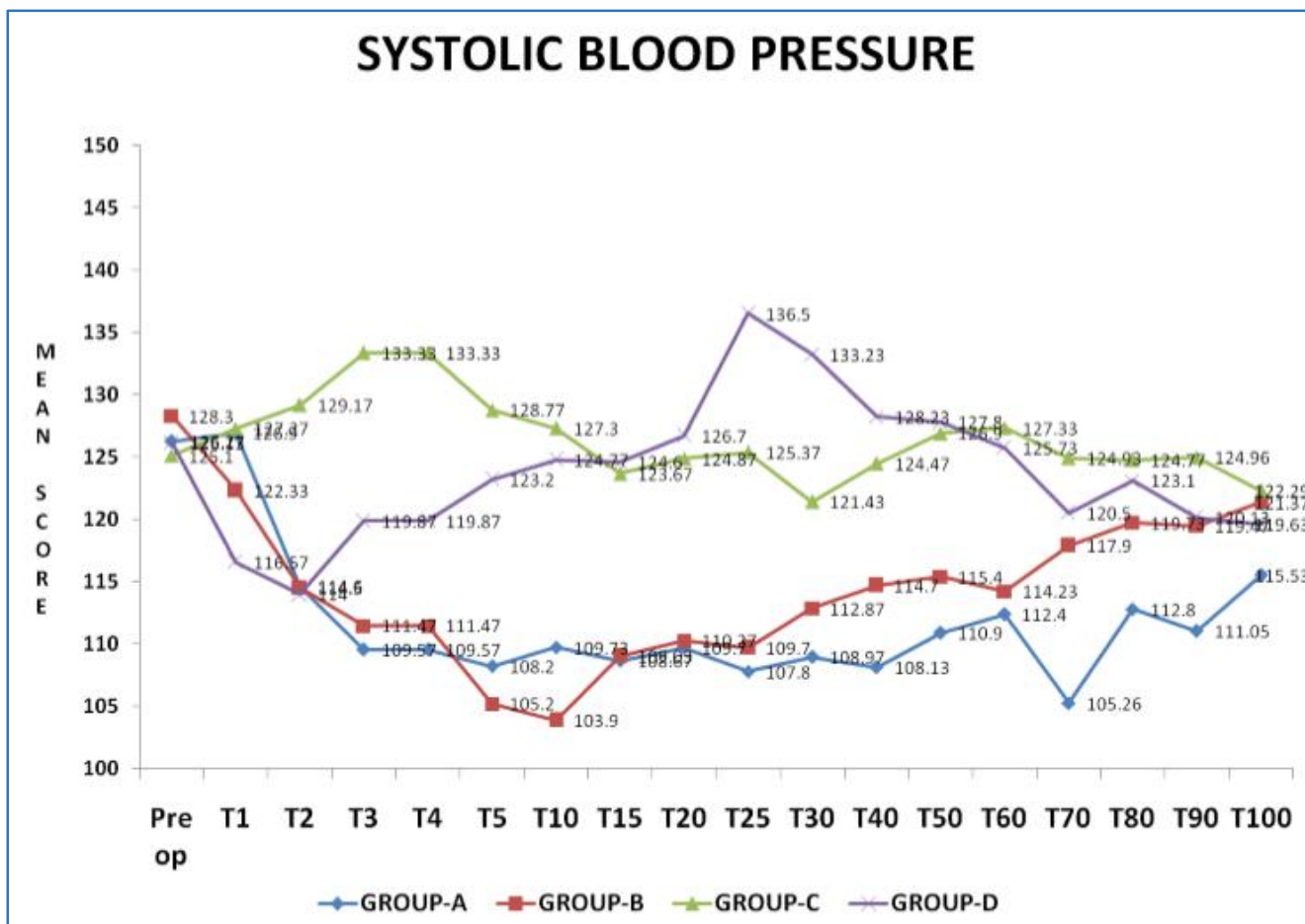
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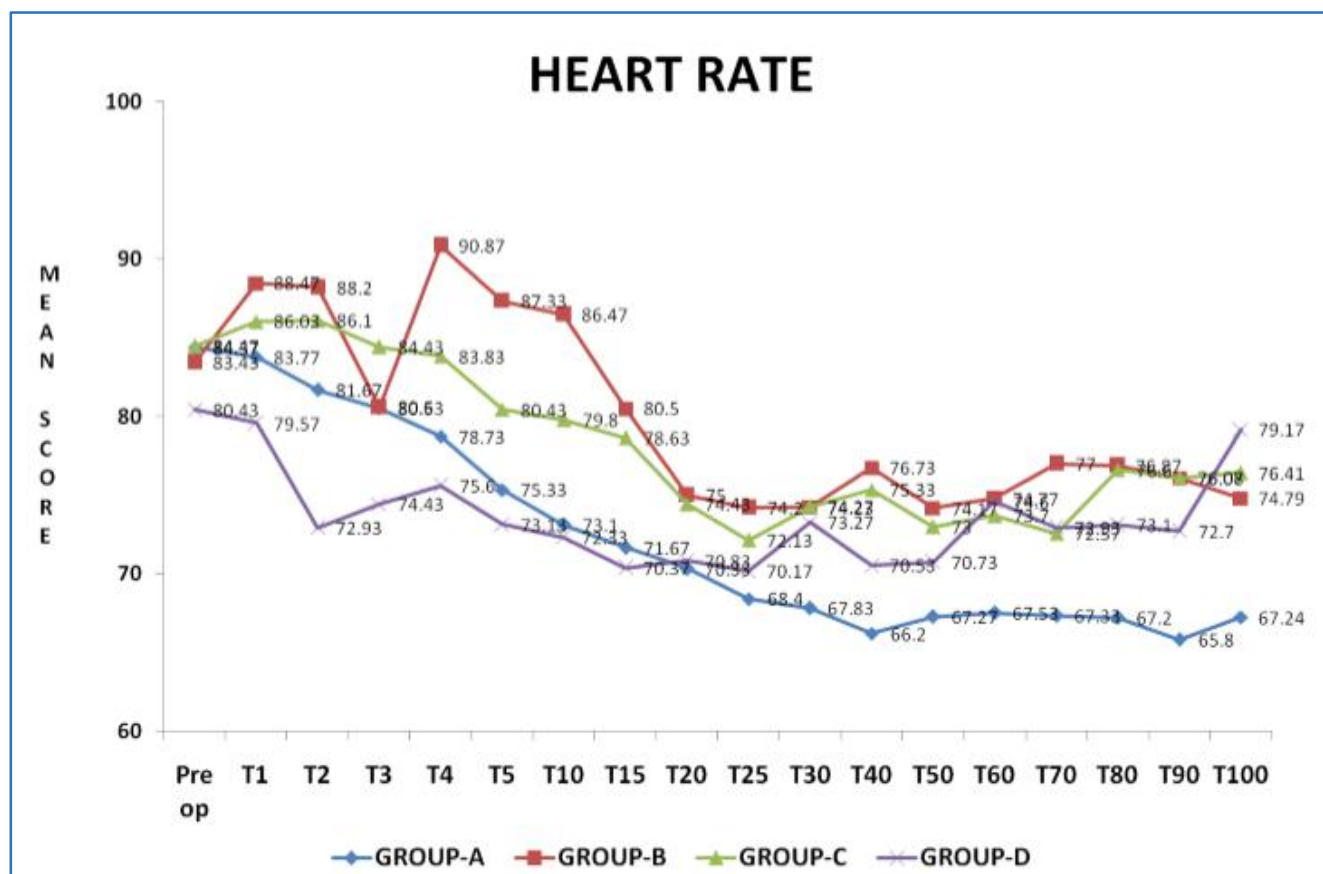
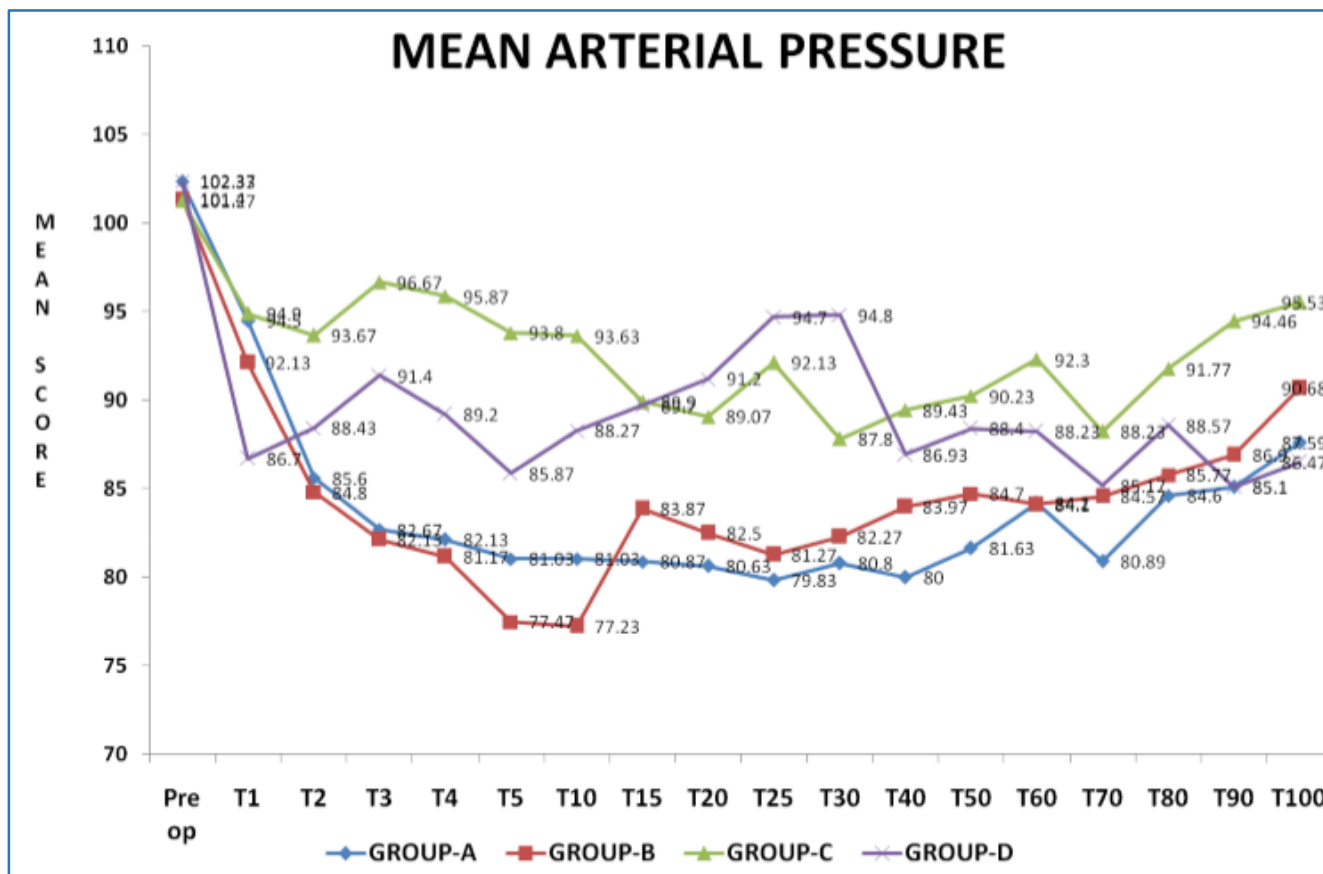
	Group - A	Group - B	Group - C	Group - D	Significant		
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	A vs B	A vs C	A vs D
Pre op	84.37±12.36	83.43±10.01	84.47±8.22	80.43±11.39	*0.74	*0.97	*0.20
T1	83.77±14.21	88.47±9.02	86.03±8.77	79.57±14.04	*0.13	*0.46	*0.25
T2	81.67±15.89	88.20±6.55	86.10±8.22	72.93±8.66	0.04	*0.18	0.01
T3	80.53±15.96	80.60±6.44	84.43±10.99	74.43±8.42	*0.06	*0.28	*0.07
T4	78.73±16.05	90.87±7.79	83.83±13.22	75.60±10.01	0.0001	*0.18	*0.37
T5	75.33±14.43	87.33±8.78	80.43±8.92	73.13±8.63	0.0001	*0.11	*0.48
T10	73.10±13.62	86.47±10.52	79.80±12.91	72.33±10.23	0.0001	*0.06	*0.81
T15	71.67±12.63	80.50±10.33	78.63±9.55	70.37±11.40	0.004	0.02	*0.68
T20	70.33±12.23	75.00±12.87	74.43±12.41	70.83±9.65	*0.16	*0.20	*0.86
T25	68.40±10.44	74.20±13.28	72.13±7.53	70.17±8.89	*0.07	*0.12	*0.48
T30	67.83±9.82	74.23±14.11	74.27±9.17	73.27±8.54	0.05	0.01	0.03
T40	66.20±9.56	76.73±15.16	75.33±7.99	70.53±8.51	0.002	0.0001	*0.07
T50	67.27±9.63	74.17±12.40	73.00±7.41	70.73±9.90	0.02	0.01	*0.18
T60	67.53±10.21	74.77±13.41	73.70±8.00	74.60±8.91	0.02	0.01	0.01
T70	67.33±18.82	77.00±13.29	72.57±4.97	72.93±9.98	0.03	*0.15	*0.16
T80	67.20±10.34	76.87±14.18	76.60±5.64	73.10±11.74	0.01	0.0001	*0.06
T90	65.80±10.21	76.07±11.06	76.08±5.54	72.70±2.93	0.002	0.0001	0.001
T100	67.24±10.42	74.79±15.24	76.41±6.51	79.17±9.25	*0.10	0.004	0.0001

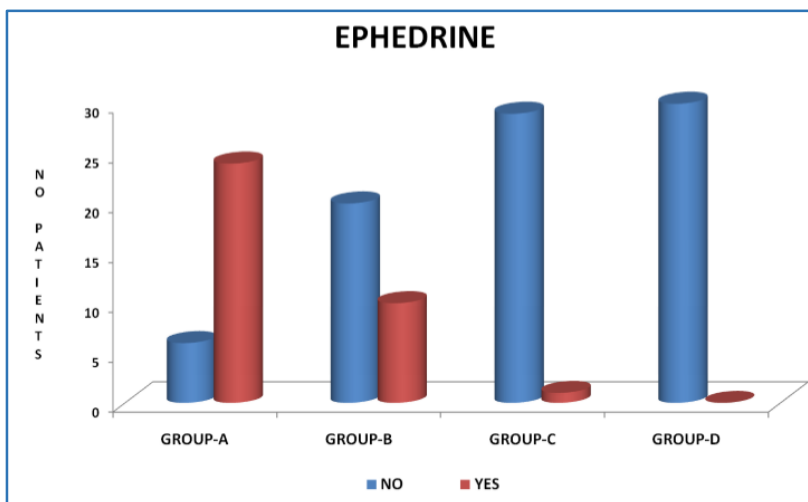
Table 4

*** Not Significant**

- When the heart rate of group A is compared with other three groups there was no consistent statistical difference till T30 in group A vs. C, A vs. D. But after T30 minutes there was significant fall in the heart rate in group A when compared to other 3 groups.



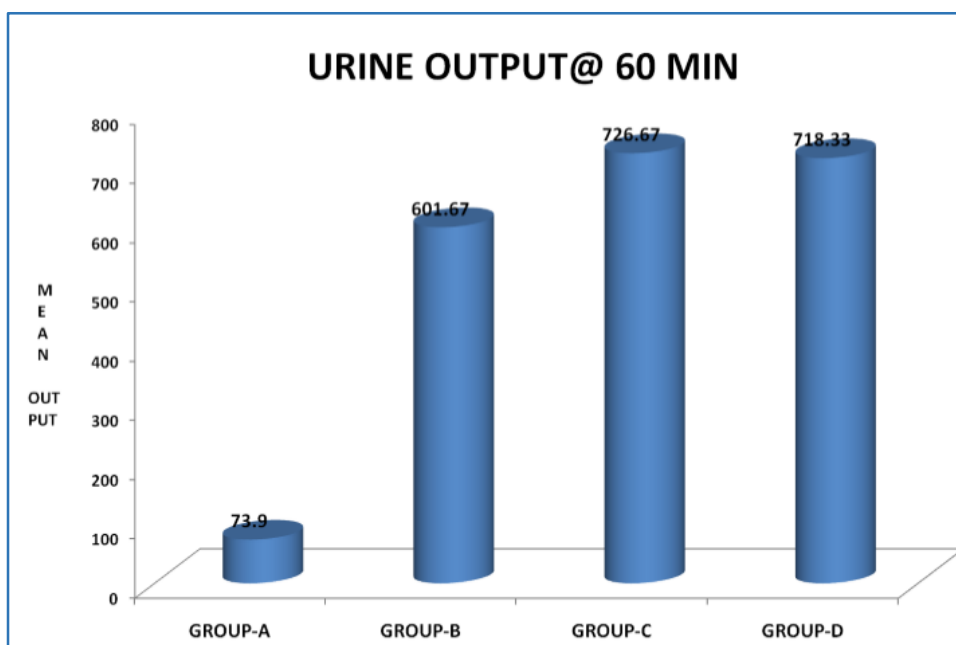




Ephedrine	Group - A		Group - B		Group - C		Group - D	
	N	%	N	%	N	%	N	%
No	6	20.00	20	66.66	29	96.66	30	100
Yes	24	80.00	10	33.33	1	3.33	0	0
Total	30	100	30	100	30	100	30	100

Table 5

- In group A, 24 patients required ephedrine intravenous boluses.
- In group B, 10 patients required ephedrine intravenous boluses.
- In group C, 1 patient and in group D none required ephedrine respectively.



- There was a significant difference in urine output noted between the control group A and groups which received dopamine infusion.
- The average volume of urine in control group is 73.9 mL at the end of 60 minutes, but it was around 10 times more in group B, C and D.

DISCUSSION: With very few exceptions, the effects of spinal anaesthesia on the cardiovascular system are almost entirely because of block of the preganglionic sympathetic fibres by the local anaesthetic injected in the subarachnoid space.¹²

Physiologic trespass is directly related to the intrathecal level of sympathetic denervation. The degree to which the spinal anaesthetic alters the normal hemodynamic status; however, varies considerably. Differences may be due to many factors, including the general state of health, age,

intravascular fluid status, and concurrent medications. In general, more extensive sympathetic block produces more profound haemodynamic changes. The effects of sympathetic denervation are extensive, both on the arterial and venous vessels. Hence sympathomimetics are the mainstay in the management of central neuraxial blockade induced hypotension.^{13,14,15} In our study, dopamine was used preemptively.^{16,17,18} as vasopressor in three different doses 3, 5, 7 mcg per kg per minute, to compare the intraoperative haemodynamics of various doses of dopamine infusion.

Dopamine at a dose of 5 mcg/kg/min. increases the BP without obviously affecting the HR. Thus, it can be used to control haemodynamics during spinal anaesthesia, without increasing myocardial consumption. We investigated the effects of continuous intravenous infusion of dopamine at 3, 5, and 7 µg/kg/min. on the hemodynamic parameters of patients undergoing surgeries under spinal anaesthesia. Systolic BP and MAP were higher in Groups C and D compared to Group A suggesting that continuous intravenous infusion of dopamine at 5 or 7 µg/kg/min. is effective in maintaining haemodynamic stability during surgery. HR was not increased in Group B, C or D when compared with Group A, suggesting that dopamine does not cause tachycardia even at a dose of 7 mcg/kg/min.

However, the hypertension incidence was higher in Group D than in any other group. Therefore, even though it maintains the haemodynamic stability, continuous intravenous infusion of 7 µg/kg/min. dopamine may not be safe for patients. Overall, our findings indicate that continuous intravenous infusion of 5 µg/ kg/min. dopamine may be safe and effective in controlling haemodynamic stability for patients undergoing surgeries under spinal anaesthesia. The effects of dopamine on haemodynamic parameters were examined at several time points before and during surgery. In the control group, systolic BP, MAP was lower at T2–T100 compared to T1, suggesting that spinal anaesthesia induced hypotension in these patients was not well managed by intermittent ephedrine intravenous boluses. In Group B, systolic BP, MAP were low and not different from those in Group A, suggesting that continuous intravenous infusion of 3 µg/kg/min. dopamine did not effectively control haemodynamic stability. In our study, we found that dopamine infusion at a dose of 5 mcg/kg/min. can be used as a safe alternative to ephedrine IV boluses for spinal anaesthesia induced hypotension and dopamine infusion had a better cardiovascular stability when compared to ephedrine group and there was no tachycardia reported even at the dose of 7 mcg/kg/min.

In our study, even after preloading with crystalloids @15 mL/kg, group A patients had hypotension necessitating ephedrine intravenous boluses.¹⁹ But in group B, 10 patients required ephedrine bolus; in group C, only one patient needed ephedrine bolus; and in group D, patients did not require ephedrine bolus. Moreover patients in group B, C & D had an average urine output of >700 mL at the end of 60 minutes, indicating that patients who received dopamine had better haemodynamics.

SUMMARY:

In this study:

- We observed that dopamine continuous infusion @ 5 mcg/kg/min. prevented spinal anaesthesia induced hypotension effectively without causing significant tachycardia.
- We observed that dopamine infusion @ 3 mcg/kg/min. was not able to maintain stable haemodynamics in patients undergoing surgeries under spinal anaesthesia.
- We observed that dopamine infusion @ 7 mcg/kg/min. was even though able to prevent spinal anaesthesia induced hypotension, it produced hypertension in significant number of patients.
- We observed that intermittent intravenous ephedrine boluses failed to prevent the spinal anaesthesia induced hypotension.
- We also observed that patients who received dopamine infusion had a higher urine output in all 3 doses when compared to control group.

CONCLUSION: With this study, we conclude that preemptive dopamine continuous intravenous infusion at a dose of 5 mcg/kg/min. effectively prevented spinal anaesthesia induced hypotension without any significant adverse effects. Hence, with this study, we recommend that dopamine @ 5 mcg/kg/min. infusion can be used as a safe alternative vasopressor for preventing spinal anaesthesia induced hypotension.

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