Original Research Article

Comparison between prophylactic intravenous ephedrine and crystalloid preloading for prevention of post spinal hypotension

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Abstract

Background: Hypotension is the most common complication of spinal anesthesia for lower abdominal and lower limb surgery, can cause significant morbidity and mortality. In present study we aimed to compare between prophylactic intravenous ephedrine and crystalloid preloading for prevention of post spinal hypotension at a tertiary hospital. **Material and Methods:** Present study was hospital based, comparative study, conducted in patients of age between 19 - 60 years old, with body mass index (BMI) between 19- 30, American Society of Anesthesiologist (ASA) physical status class I or II, posted for elective lower abdomen or lower limb surgeries. 60 Patients were randomly divided (by computer generated randomisation table) into two equal groups of 30 patients each as Group F: received crystalloid preloading 15 ml/kg (Ringer lactate) before the procedure and Group E: received prophylactic ephedrine intravenously 25 mg in 50 ml saline as follow, 5 mg at 1st and 2nd minute and then infusion of 1 mg/min over 15 minutes after block. **Results:** After spinal anaesthesia, we noted significant fall in systolic blood pressure (in mmHg) at 3, 6, 9 and 12 minutes in Group F (received crystalloid preloading of RL @ 15 ml/kg) as compared to Group E (received prophylactic iv ephedrine) and difference was statistically significant ($p < 0.05$). We observed increased complications (Hypotension, Nausea and vomiting and Chest symptoms) as well as increased number of ephedrine boluses required in Group F (received crystalloid preloading of RL @ 15 ml/kg) as compared to Group E (received prophylactic iv ephedrine) and difference was statistically significant ($p < 0.05$). **Conclusion:** For elective lower abdomen or lower limb surgeries, prophylactic intra-venous ephedrine immediately after spinal anesthesia is a quick, simple, safe and effective technique in preventing hypotension without unwanted side effects.
Keywords: prophylactic crystalloid preloading, ephedrine, spinal anaesthesia, post spinal hypotension

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INTRODUCTION

Spinal anaesthesia is frequently used for lower abdominal and lower extremity surgeries due to features such as simple to perform, economical, requires comparatively less time than epidural anaesthesia to produce more rapid onset of good quality sensory and motor blockade. Hypotension is the most common complication of spinal anesthesia for lower abdominal and lower limb surgery, can cause significant morbidity and mortality.[1] As a result, decreased systemic vascular resistance and peripheral pooling of blood occurs, which decreases the cardiac output.[2] Prophylactic methods to counter the spinal induced hypotension like preloading with colloid/crystalloids, leg elevation with compression bandages, stockings or inflatable boots, premedication with IVAtropine0.6mg, IM Glycopyrrolate, Ondansetron, Vasopressors.[3] Fluid co-loading appears to be more physiological and rational approach as the maximal effect can be achieved at the time of onset of the block.[4]

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Ephedrine is proven to be more effective for increasing arterial blood pressure with better preservation of utero-placental blood flow as compared to other vasopressors. It has a predominant β-effect that causes increase in arterial blood pressure by increasing cardiac output rather than by vasoconstriction.[5] In present study we aimed to compare between prophylactic intravenous ephedrine and crystalloid preloading for prevention of post spinal hypotension at a tertiary hospital.

MATERIAL AND METHODS

Present study was hospital based, comparative study, conducted in patients posted for lower abdomen or lower limb surgeries. Study was conducted in operation theaters under Department of Anaesthesia, Kamineni Institute of Medical Sciences, Sreepuram Narketpally, India. Study was conducted during January 2020 to December 2020 (1 year). Study was approved by institutional ethical committee.

Inclusion criteria: Patients of age between 19 - 60 years old, with body mass index (BMI) between 19- 30, American Society of Anesthesiologist (ASA) physical status class I or II, posted for elective lower abdomen or lower limb surgeries.

Exclusion criteria: Pregnant women. patients who refused spinal anaesthesia, patients with a history of allergic reactions to local anaesthetics and opioids, patients with coagulopathy (due to blood disease, liver diseases or on anticoagulants), patients with severe cardiac, respiratory, hepatic or renal disease.

Study was explained to patients and informed written consent from each patient was obtained. After enrolment, patients were assessed by detailed history taking, physical examination and routine preoperative investigations (e.g., CBC, PT, PTT, INR, liver function tests, kidney function tests and fasting blood sugar) for evaluation of the pre-anaesthetic fitness.

60 Patients were randomly divided (by computer generated randomisation table) into two equal groups of 30 patients each as,

Group F: received crystalloid preloading 15 ml/kg (Ringer lactate) before the procedure.

Group E: received prophylactic ephedrine intravenously 25 mg in 50 ml saline as follow, 5 mg at 1st and 2nd minute and then infusion of 1 mg/min over 15 minutes after block.

On arrival to the operating room, continuous monitoring with electrocardiography, non-invasive blood pressure, and pulse oximetry was started. Baseline systolic blood pressure, heart rate, and arterial oxygen saturation were recorded. Intravenous access secured with 18G peripheral cannula. Spinal anaesthesia was given in sitting position, at interspace L3-L4 with a 22 gauge spinal needle, 2.5 ml of 0.5% heavy Bupivacaine + fentanyl (25 µg) under all aseptic precautions. Then the patient was placed with slight elevation of the head; oxygen nasal cannula was used 4 litres/minute. Heart rate and systolic blood pressure were measured noninvasively at 1min after spinal anaesthesia, and then every 3 minutes for the first 30 minutes then every 5 minutes for 30 minutes then after 30 minutes. O2 saturation was recorded by pulse oximetry continuously and recorded every 30 minutes. An infusion of Ringer lactate at a rate of 2 ml/Kg/hr was given during the whole surgical procedure. Hypotension (20% decrease in SBP from the baseline) was treated immediately by 5 mg bolus IV ephedrine every 3 minutes until SBP returned to normal value in all groups. Nausea, vomiting and chest symptoms (dyspnoea and tachypnoea) were also recorded. Nausea and vomiting treated with 10 mg metoclopramide. The primary outcome was to detect the incidence of hypotension after spinal anaesthesia, after prophylactic fluid infusion or ephedrine infusion, while secondary outcome was to detect other complications like nausea and vomiting, chest symptoms and number of ephedrine doses to treat hypotension. Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Frequency, percentage, means and standard deviations (SD) was calculated for the continuous variables, while ratios and proportions were calculated for the categorical variables. Difference of proportions between qualitative variables were tested using chi- square test or Fisher exact test as applicable. P value less than 0.5 was considered as statistically significant.

RESULTS

In present study, general characteristics such as age (years), weight (Kg), BMI (Kg/m2), gender, ASA status grade and duration of surgery (min) were comparable between two groups and difference was not statistically significant (p>0.05).

Table 1: General characteristics

General characteristics	Group E (Mean±SD /percentage)	Group F (Mean±SD /percentage)	P-value
Age (years)	47.9 ± 9.3	46.3 ± 11.6	0.84
Weight (Kg)	67.1 ± 10.5	66.9 ± 10.7	0.47
BMI (Kg/m2)	23.9 ± 2.1	24.1 ± 1.9	0.19
Gender (M/F)			0.64
Male	13	14	
Female	17	16	

ASA status grade			0.41
I	22	23	
II	8	7	
Duration of surgery (min)	68.1 ± 43.2	72.5 ± 44.2	0.67

After spinal anaesthesia, we noted significant fall in systolic blood pressure (in mmHg) at 3, 6, 9 and 12 minutes in Group F (received crystalloid preloading of RL @ 15 ml/kg) as compared to Group E (received prophylactic iv ephedrine) and difference was statistically significant ($p < 0.05$).

Table 2: Comparison of systolic blood pressure (in mmHg) in the two groups

Time intervals (min)	Group E (Mean±SD)	Group F (Mean±SD)	P value
Baseline	119.28 ± 11.45	121.25±7.68	0.72
0	120.34 ± 6.45	119.51 ± 7.68	0.55
3	118.80 ± 14.61	108.44 ± 18.36	0.026
6	116.36 ± 21.29	98.12 ± 24.23	0.018
9	119.28 ± 11.45	96.2 ± 8.90	0.001
12	116.64 ± 6.67	110.01 ± 7.70	0.049
15	109.44±3.98	108.80 ± 3.31	0.06
18	110.20±5.09	112.00 ± 7.63	0.30
21	110.40±5.38	111.00 ± 6.45	0.90
24	111.28±5.99	110.40±6.11	1
27	111.44±5.33	110.40±6.11	0.96
30	110.40±5.38	111.20±7.81	0.40
35	114.80±7.70	113.20±9.00	1
40	114.20±8.71	110.4±6.11	0.71
45	115.20±8.71	113.64±6.67	0.37
50	109.84±3.73	113.20±6.90	0.92
55	108.80±3.31	115.40±6.11	0.54
60	112.00±7.63	108.80±3.31	0.06

We observed increased complications (Hypotension, Nausea and vomiting and Chest symptoms) as well as increased number of ephedrine boluses required in Group F (received crystalloid preloading of RL @ 15 ml/kg) as compared to Group E (received prophylactic iv ephedrine) and difference was statistically significant ($p < 0.05$).

Table 3: Secondary outcome

Secondary outcome	Group E (Mean±SD /percentage)	Group F (Mean±SD /percentage)	P value
Complications			0.039
Hypotension	3	7	
Nausea and vomiting	5	9	
Chest symptoms	0	1	
Number of ephedrine boluses required			
Number of boluses	0.2 ± 0.4	0.6 ± 0.4	0.046

DISCUSSION

The high incidence of post spinal hypotension (PSH) with different pharmacological and nonpharmacological methods necessitates for combination of different methods for prevention and management of this problem. Treatment of spinal-induced hypotension is best achieved by reversing the underlying physiologic changes like decreased systemic vascular resistance (SVR), preload, and cardiac output. Traditional teaching is that hypotension can be minimized or prevented by intravenous (IV) fluid preloading, positioning of the patient using left uterine displacement, and by the prophylactic and therapeutic use of vasopressors.[6] Even though the sensory and motor onset of SA starts around after 5 min, its autonomic effect is expected to start immediately after SA which is evidenced by significant hypotension in those without ephedrine prophylaxis at earlier times after spinal anesthetic injection.[7] In study by Hegde BK,[8] patients were allocated to group I (crystalloid preload) and group II (crystalloid with ephedrine before spinal block). Incidence of hypotension was 70% in the crystalloid group and 5% in the crystalloid with ephedrine group, difference was statistically significant ($P < 0.001$). The number of patients receiving rescue bolus of ephedrine was higher in the crystalloid group (40% before delivery and 30% after delivery) compared to crystalloid with ephedrine group (5% before delivery and none after delivery); the difference was statistically significant ($P < 0.001$). 40% in the crystalloid group experienced nausea compared to 15% in the crystalloid with ephedrine group; the difference was

statistically significant with a (P - 0.012). Jabalameli M *et al.*,[9] studied 150 candidates of elective cesarean delivery under spinal anesthesia were randomly allocated to three treatment groups; 1---Ringer's Lactate (RL) solution (15 ml/kg) plus Hemaxel (7 ml/kg) preload, 2---RL solution (15 ml/kg) preload plus ephedrine (15 mg, IV, bolus), 3---Hemaxel (7 ml/kg) preload plus ephedrine (15 mg, IV, bolus) and cumulative incidence of hypotension was 44%, 40%, and 46% in groups 1 to 3, respectively. Combination of preventive methods decreased the occurrence of hypotension following spinal anesthesia to an acceptable level. Overall, the most effective method was a combination of crystalloid preload with ephedrine. In study by Ahmed, H.O *et al.*,[10] patients were randomly allocating to group F (preloading with 15 ml/kg Ringer lactate before induction of spinal anesthesia) and group E (IV ephedrine -5 mg in 1st minute after spinal anesthesia and 5 mg in the 2nd minute and 1 mg every minute after that for 15 minutes). A statistically significant difference in the incidence of hypotension between group F (48%) and group E (24%) was seen, (p-value 0.03). Regarding side effects, the incidence of nausea and vomiting was higher in the group F (20%) when compared to group E (12%), (p-value 0.23). Mahmoud S *et al.*,[11] noted that for blood pressure there is statistical significance between both groups except at 4- and 22-min post spinal; regarding heart rate there was no statistical significance between both groups; and regarding the incidence of complication, there is statistical significance between both groups. Prophylactic intravenous ephedrine infusion is more effective than fluid preload in the prevention of hypotension due to spinal anesthesia for lower abdominal and lower limb vascular surgery.

Limitations of present study were small sample size, single center study, with only elective surgeries. Also hypotension may be due to blood loss of significant amount which was not measured in present study. We recommend that larger studies are required to confirm present study findings.

CONCLUSION

For elective lower abdomen or lower limb surgeries, prophylactic intra-venous ephedrine immediately after spinal anesthesia is a quick, simple, safe and effective technique in preventing hypotension without unwanted side effects.

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