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Comparing the effect of volume preload versus ephedrine infusion for the prevention of hypotension due to spinal anesthesia for lower abdominal and lower limb vascular surgery

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Abstract

Objective
To evaluate the efficacy of ephedrine infusion without preblock crystalloid administration in reducing the incidence of hypotension during spinal anesthesia.

Patients and methods
Fifty patients presented for lower abdominal and lower limb surgery under spinal anesthesia who were divided into equal groups (group F and group E), each group had 25 patients each.

Results
As regards demographic data there was no statistical significance between both groups. As regards blood pressure there is statistical significance between both groups except at 4 and 22 min postspinal; regarding heart rate there was no statistical significance between both groups; and regarding the incidence of complication, there is statistical significance between both groups.

Conclusion
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.

Keywords: Ephedrine, spinal anesthesia, vascular surgery, volume preload

Introduction

Spinal anesthesia provides a fast, profound, and symmetrical sensory and motor block of high quality in patients undergoing lower abdominal and lower limbs surgeries [1]. Spinal anesthesia has fewer side effects and risks than general anesthesia (asleep and pain-free). Patients usually recover much faster and can be discharged early.

Successful regional anesthesia effectively suppresses many of the pain-mediated stress responses to surgery such as rise in blood pressure, heart rate, and increase in plasma concentrations of catecholamines, cortisol, and glucose. A spinal block is also associated with a lesser amount of surgical hemorrhage [2]. Spinal anesthesia produces few adverse effects on the respiratory system as long as unduly high blocks are avoided [3]. Control of the airway is not compromised; there is a reduced risk of airway obstruction or the aspiration of gastric contents. Spinal anesthesia provides excellent muscle relaxation for

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lower abdominal and lower limb surgery [4]. Postoperative deep vein thrombosis and pulmonary emboli are less common following spinal anesthesia [5]. Hypotension is the most common complication of spinal anesthesia for lower abdominal and lower limb surgery [6]. Hypotension during spinal anesthesia can cause significant morbidity and mortality [7], which is due to sympathetic nervous system blockade. As a result, decreased systemic vascular resistance and peripheral pooling of blood occurs, which decreases the cardiac output [8]. Various attempts have been made to reduce the incidence and severity of hypotension by including the expansion of intravascular volume with up to 2 l of fluids [9]. Fluid loading has been shown to reduce the risk of hypotension but does not eliminate it. It also takes time to achieve, and many patients still need vasopressor treatment to correct hypotension. An infusion of ephedrine may be an effective alternative. Ephedrine is a noncatecholamine sympathomimetic agent that stimulates alpha-adrenergic and beta-adrenergic receptors directly and predominantly indirectly, producing its effects by releasing norepinephrine from nerve endings in the autonomous nervous system. Traditionally, it is the vasopressor of choice in spinal anesthesia despite the lack of confirmation of its superiority over other vasopressors [10].

Patients and methods

In all, 50 patients presented to lower abdominal or lower limb surgery were enrolled into this study.

Inclusion criteria

(1) The patient was selected according to American Society of Anesthesiologists (ASA) status (ASA I and ASA II).
(2) Normal coagulation profile.
(3) Age range between 20 and 60 years old.

The patients were divided into two equal groups of 25 patients each: group E and group F.

Exclusion criteria

The exclusion criteria for this result include:
(1) Patient refusal.
(2) Infection at the site of injection.
(3) Patients having any coagulopathy disorder or receiving any anticoagulant drugs.
(4) Any preexisting neurological disease.
(5) Patients with signs suggesting cardiac or respiratory system failure.
(6) Patients with a known history of allergy to local anesthetic drugs.

Methodology

Preoperative investigations were done (e.g., CBC, PT, PTT, INR, liver function tests, kidney function tests, and fasting blood sugar) for evaluation of the patient's medical status and no premedication was given. Patients were fasting for 6–8 h before the procedure. Consent was taken from the patients for a spinal block, and the procedure was explained to the patients.

Intraoperative period

On arrival to the operating room, continuous monitoring with ECG, noninvasive blood pressure, and pulse oximetry were started. Baseline systolic blood pressure (SBP), heart rate, and arterial oxygen saturation were recorded. A suitable peripheral vein was cannulated with an 18 G peripheral catheter.

Patients were randomly divided into two groups of 25 patients each (by the closed envelope method). Group F: those who received a crystalloid preloading of 15 ml/kg (Ringer's lactate) over 10 min before the procedure. Group E*:* those who received prophylactic ephedrine intravenously (25 mg in 50 ml saline), 5 mg at first and second minute and 1 mg at every minute after that for 15 min after the block (ephedrine ampoule 1 ml = 25 mg ephedrine hydrochloride).

Patient positioning

The patient was put in the sitting position with leaning forward sterilization by povidone iodine in a circular manner with covering the back by sterilized towels just exposing the spinal segments to be injected. Dural puncture was performed at L4–L5 interspace or L3–L4 with a 22-G spinal needle after infiltration of the skin at the site of lumbar puncture with 2 cm of lidocaine 1%. The blocks were performed with the patient in the sitting position. All the patients received the same amount of local anesthetic 2.4 ml of 0.5% heavy bupivacaine + fentanyl (25 μg). Then the patient was placed in the supine position with the elevation of the head by a pillow, and an oxygen mask was used at the rate of 5 l/min.

Intraoperative monitoring

The level of sensory block was assessed by loss of pinprick sensation (all patients included in the study had sensory level T4–T5). Heart rate and SBP were measured noninvasively at 1 min after spinal anesthesia and then every 3 min for the first 30 min and every 5 min for 30 min; after 30 min O_2 saturation was recorded by pulse oximetry continuously and recorded every 30 min. Nausea, vomiting, and chest symptoms (dyspnea and tachypnea) were also recorded. An infusion of Ringer's lactate at a rate of 2 ml/kg/h was given during the whole surgical procedure. Hypotension (20% decrease in SBP from the baseline) was treated immediately by 5 mg bolus intravenous ephedrine every 2 min until SBP returned to the normal value in all groups. Nausea and vomiting were treated immediately with 10 mg metoclopramide whether unrelated to hypotension or not corrected by ephedrine boluses alone.

Postoperative period

All patients in the two groups were assessed postoperatively for heart rate, blood pressure noninvasively, and oxygen saturation were recorded postoperatively after 30 min. Complications were hypotension, nausea and vomiting, and chest symptoms (dyspnea or tachypnea).

Statistical analysis

A prospective power study showed that a sample size of 25 per study group would have 80% power at the 5% significance level to detect a difference of 50% in the incidence of

hypotension in the E group compared with F group assuming a baseline incidence of 80% as reported by a published study of a similar patient group. Statistical analysis will be done with mixed analysis of variance design to compare intergroup and intragroup results. The obtained data will be presented as mean ± SD or median, interquartile range, or count and percentage as appropriate. Comparisons will be performed using Student's *t* test, χ^2 test, or analysis of variance according to the type of variance. Data will be analyzed using computer (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.) and Microsoft Excel 2013 value less than or equal to 0.05 will be considered statistically significant.

Results

Fifty patients were recruited for this study and were randomly allocated into two groups, F group (fluid) and E group (ephedrine).

Demographic data

They showed no significant differences as regards age, BMI, height, and sex (Table 1).

Blood pressure

SBP was generally higher in the E group when compared with the F group. However, the results were not statistically significant except at 4 and 22 min postspinal (Table 2).

Heart rate

Heart rate was generally in the E group when compared with the F group. However, it was not statistically significant (Table 3).

Incidence of complication

Regarding incidence of complications, the incidence of hypotension was significantly higher in the F group when compared with the E group; the incidence of nausea and vomiting was higher in the F group when compared with the E group, but it was not statistically significant, and there were no chest symptoms in both groups (Table 4).

Number of ephedrine boluses

The number of boluses of ephedrine required to correct hypotension was significantly lower in the ephedrine group when compared with the fluid group (Table 5).

Oxygen saturation

Regarding oxygen saturation, there were no significant differences between the two groups (Table 6).

Table 1: Demographic data of patients included in the study

	F group	E group	*P*
Age	27 (20-39)	27 (20-40)	0.21
BMI	35.2±1.7	35.3±1.7	0.40
Height	162.7±2.9	163.3±3.7	0.24
Male sex	29 (72.5)	21 (52.5)	0.65

Data represented as mean±SD or median (range).

Table 2: Systolic blood pressure

	F group	E group	*P*
Baseline	122.6±7.8	119±9.9	0.09
1 min	116.3±12.3	116.4±12.3	0.48
4 min	103.9±8.8	110.2±15.5	0.04*
7 min	110.6±12.8	111.7±13.7	0.4
10 min	111.7±10.1	112.4±13.2	0.4
13 min	108.7±6.6	110.4±12.0	0.3
16 min	111.4±10.2	115.6±10.9	0.08
19 min	111.9±10.9	113.7±13.5	0.3
22 min	112.1±11.8	117.8±10.8	0.04*
25 min	113.3±8.6	116.4±9.7	0.1
28 min	113.3±12.5	117.5±11.9	0.08
31 min	114.3±8.3	118.1±9.7	0.0
36 min	112.4±9.7	116±9	0.0
41 min	115.1±6.1	116.2±6.0	0.3
46 min	113.4±6.8	116.4±9.8	0.1
51 min	117.0±5.4	118±6.7	0.3
56 min	119.1±9	119.7±6.2	0.4
61 min	122.5±6.2	122.9±5.2	0.4
90 min	120.5±6.5	121.4±7.59	0.3

Data represented as mean±SD. **P* value less than or equal to 0.05.

Discussion

In this study, we compared the efficacy of fluid preloading with 15 ml/kg lactated Ringer's (F group) versus prophylactic intravenous ephedrine infusion without fluid preload (E group) for the prevention of hypotension after spinal anesthesia for lower abdominal and lower limb surgery. Our findings showed that the incidence of hypotension was significantly lower in the E group 6/25 (24%) when compared with the F group 12/25 (12%), *P* value of 0.03. Also, the incidence of nausea and vomiting was lower in the E group when compared with the F group; however, this was not statistically significant. In our study, the number of boluses of ephedrine required to correct hypotension was significantly lower in the E group (0.6 ± 0.8) when compared with the F group (0.3 ± 0.54), *P* value of 0.046. Our findings showed that SBP was generally higher in the ephedrine group when compared with the fluid group and it was statistically significant at 4 and 21 min postspinal, and the heart rate was generally higher in the E group when compared with the F group, In the F group the mean pulse rate changed from baseline of 90.1 ± 8.5 to a maximum of 92.6 ± 11.7 at 28 min. In the E group, the mean pulse rate increased from a baseline of 92.5 ± 5 to a maximum of 95.6 ± 8 at 7 min after spinal block. There was no significant difference in the heart rate between the two groups. This could be explained both by the effect of rescue ephedrine and by baroreceptor-mediated reflex increases in heart rate in patients who became hypotensive. In consistence with our results, Gajraj [11] compared the efficacy of an ephedrine infusion with crystalloid administration for reducing the incidence of hypotension during spinal anesthesia for patients scheduled lower abdominal and lower limb surgery under spinal anesthesia. He found that the incidence of hypotension was

Table 3: Heart rate trends

	F group	E group	*P*
Baseline	90.1±8.5	92.5±5	0.1
1 min	92.7±13.4	93.9±7.4	0.35
4 min	90.5±16.5	92.2±9.1	0.32
7 min	91.9±13	95.6±8	0.11
10 min	92±10.6	94.7±9.5	0.17
13 min	91.5±11.3	94.7±10.6	0.15
16 min	91.6±8.8	95±10.4	0.11
19 min	90±10.5	93.2±8.4	0.11
22 min	87.9±13.6	91.6±7.5	0.11
25 min	90.6±14.2	92.6±9.2	0.27
28 min	92.6±11.7	94.2±9.6	0.3
31 min	91.2±9.4	94.5±8.9	0.10
36 min	91±10.9	93.4±8.4	0.2
41 min	90.7±12	91.2±6.5	0.42
46 min	88.7±10.9	91.4±7.2	0.10
51 min	88.4±9.4	91.4±7.2	0.10
56 min	87.9±8.7	90.5±5.6	0.10
61 min	88.3±9	91±5.9	0.10
90 min	85.6±9.5	87.7±6.3	0.17

Data represented as mean±SD.

Table 4: Incidence of complications

	F group	E group	*P*
Hypotension	12/25 (48)	6/25 (24)	0.03*
Nausea and vomiting	5/25 (20)	3/25 (12)	0.23
Chest symptoms	0/25	0/25	0

Data represented as the number of positive cases/total number of patients (%). **P* value less than or equal to 0.05.

Table 5: Number of ephedrine boluses required to correct hypotension

	F group	E group	*P*
Number of boluses	0.6±0.8	0.3±0.54	0.046*

Data represented as mean±SD. **P* value less than or equal to 0.05.

Table 6: Oxygen saturation

	F group	E group	*P*
Baseline	98.5±0.8	98.3±0.7	0.23
30 min	99.7±0.5	99.8±0.4	0.26
60 min	99.8±0.4	99.8±0.4	0.5
90 min (post)	98.9±0.5	98.7±0.6	0.11

Data represented as mean±SD.

significantly higher in the crystalloid group compared with the infusion group ($P < 0.05$). There was no significant difference between the groups in relation to the level of anesthesia or maximal heart rate, and hypertension did not occur in either group, which is similar to our results. However, there was no difference in the incidence of nausea and vomiting in contrast to our study. Madhusoodana and Bhovi [12] studied the efficacy of ephedrine for preventing hypotension in patients undergoing cesarean section under spinal anesthesia. The study revealed that the incidence of hypotension was significantly higher in the patient group who received fluid preload (60%) compared with 12% the patients' group who received ephedrine infusion. The incidence of hypotension in the ephedrine group in this study was 12%; in comparison with our study the incidence of hypotension in the ephedrine group was 24%. This difference may be due to the different doses of ephedrine used and the different volume of infusion.

In contrast to our study, Thiangtham and Asampinwat [13] found that there was no statistically significant difference in the incidence of hypotension between the two groups. The incidence of hypotension was 93.8% in the control group and 85.4% in the study group, this may be due to the small dose of ephedrine used and different infusion rate. In contrast to this study, Kol *et al*. [14] designed a randomized, double-blinded study to determine the efficacy and safety of 0.5 mg/kg intravenous ephedrine for the prevention of hypotension during spinal anesthesia for cesarean delivery, and its effect on the neonatal outcome and umbilical artery pH. Patients were randomly allocated into two groups: ephedrine group and control group. All patients received preloading with 15 ml/kg lactated ringer before the spinal block, patients of the ephedrine group were injected with 0.5 mg/kg ephedrine intravenously over 60 s while patients of the control group were injected with saline. He found that there were significantly lower incidences of hypotension and nausea and vomiting in the ephedrine group compared with the control group. Regarding the same aspect, Simin *et al.* [15] studied the effect of ephedrine and phenylephrine in the treatment of hypotension after spinal anesthesia.

Conclusion

We conclude that prophylactic intravenous ephedrine infusion is more effective than fluid preload prevention of hypotension due to spinal anesthesia for lower abdominal and lower limb surgery.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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