PREVENTION OF POST SPINAL HYPOTENSION;
COMPARISON BETWEEN PRELOADING WITH AND WITHOUT INTRAMUSCULAR EPHEDRINE IN ELDERLY PATIENTS UNDERGOING INGUINAL HERNIA SURGERY

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ABSTRACT... Objective: Objective of the study is to evaluate the efficacy of intramuscular ephedrine along with preloading in prevention of post spinal hypotension in elderly patients undergoing inguinal hernia surgery. **Study design:** This is a quasi experimental study. **Place and duration of study:** The study was conducted at the department of Anaesthesia and Intensive Care Combined Military Hospital, Peshawar over a period of one year. **Patients and Methods:** In a double-blind, randomized study, 80 elderly patients undergoing inguinal hernia surgery under spinal anaesthesia divided into two equal groups of A and B. Forty patients received i/m inj of ephedrine 45mg deep in the paravertebral muscles immediately after injection of bupivacaine, and 40 received an equal volume of saline. Patients in both groups were given the same volumes of fluid before anaesthesia. The incidence of hypotension (Systolic arterial pressure <90mmHg or <80 % of baseline) were recorded. and incidence of fall in the heart rate was recorded. Results: Systolic arterial pressure during the first 60 min after anaesthesia remained significantly more stable in the ephedrine-treated group, and there was also a significantly smaller number of patients in this group who had decreases in pressure of more than 30% of pre-block levels and fewer required rescue i.v. Ephedrine. An increase in heart rate or systolic pressure of > 20% from baseline was found in two patients in the ephedrine group and in one patient in the placebo group. **Conclusions:** We conclude that ephedrine 45mg administered in the paravertebral muscles immediately after plain bupivacaine spinal anaesthesia is a simple and effective means of reducing the incidence of hypotensive episodes in the elderly patient.

Key words: Anaesthetic techniques, subarachnoid, Sympathetic nervous system, ephedrine. Complications, hypotension.

INTRODUCTION

Spinal anaesthesia is one of the most popular techniques for the surgical procedures on lower abdomen and limbs including Cesarean section.

One of its most important and predicted physiological effects is hypotension[1]. Overall incidence of hypotension during spinal anaesthesia is reported to be 33%[2]. Even a mild drop in blood pressure must be avoided in high-risk patients such as elderly and in those with organ dysfunction in whom the auto regulatory mechanism may be abnormal[1]. Sympathetic blockade causes an exaggerated decrease in systemic vascular resistance in elderly as compared to younger patients.

The most important question that seeks attention is its prevention. Mechanical methods, volume loading and vasopressors have been tried with variable results. Most of the studies are centered on the effects of preloading and vasopressors[3]. Preloading may be achieved in different ways with different solutions, fluid volumes and infusion rates. These differences determine the clinical responses in terms of preventing hypotension[4].

Ephedrine is an alkaloid originally extracted from the Chinese plant Ma Huang, used in traditional Chinese medicine for centuries. In the late 1920s,

this sympathomimetic amine was introduced as a vasopressor into anaesthetic practice by Ockerblad and Dillon[5]. Its modern synthetic congener remains a drug of choice for treating hypotension induced by spinal or extradural anaesthesia[6]. The dose and timing of administration, however, have not been fully investigated, although the trend today seems to favour i.v. administration, either in titrated single doses or as a continuous infusion. The efficacy of prophylactic i.m. ephedrine has been questioned and there is concern

regarding the potential for causing harmful hypertension or tachycardia[6].

The aim of our study was to investigate the efficacy of ephedrine in maintaining haemodynamic stability in elderly patients when administered in a single i.m. dose and given at the same time as spinal anaesthesia.

PATIENTS AND METHODS

This double-blind, placebo-controlled, randomized study was approved by the Ethics Committee at the Combined Military Hospital Peshawar. We studied 80 consecutive patients undergoing Inguinal Hernia Repair under spinal anaesthesia with abocaine 0.5%(2.5ml). Premedication was given approximately 1 h before anaesthesia with i.v Maxalon 5-10 mg and i.v midazolam 3-5 mg according to age and body weight. Patients medicated with beta receptor or calcium channel blockers were given their ordinary morning doses. During the 20-min period before anaesthesia the patients received 6%HES(Hydroxy Ethyl Starch)7 ml per kg body weight. Systolic arterial pressure (SAP) was measured with a calibrated aneroid sphygmomanometer and radial pulse palpation. Heart rate (HR) was obtained from a three-lead ECG.

Spinal anaesthesia with 0.5 % bupivacaine 2.5 ml was performed in the L2-3 or L3-4 interspaces with the patient in the sitting position. Immediately after completion of the spinal injection, the needle was withdrawn and redirected laterally, and the trial solution was injected deep into the paravertebral muscles. The solution comprised either ephedrine 45mg or saline. The patient was then placed immediately in the lateral position towards the side of inguinal hernia surgery. After anaesthesia, a crystalloid lactated ringers solution was started and continued at a rate of 4 ml/ kg/h throughout surgery. A decrease in SAP of > 30 % from the baseline recording to less than 100 mm Hg was treated immediately with i.v. ephedrine in 5-mg increments until a stable SAP above this threshold level was established. Plasma volume maintenance with colloids and packed red cell transfusions to compensate for intra operative blood loss were based on a each individual patient, taking into account age, sex, body weight and height, preoperative haemoglobin (Hb) concentration and predetermined lowest acceptable postoperative Hb. In order to provide a comfortable state during surgery, midazolam was administered as required in doses of 1.25 mg. In a few patients small doses of i.v. Nalbuphine were given to alleviate pain from unanaesthetized areas. SAP and HR were recorded before anaesthesia, 2 and 5 min after anaesthesia, and every 5 min thereafter. All SAP measurements were obtained from the upper arm. A reduction in SAP > 30 % from the baseline level was considered a negative outcome in terms of efficacy, whereas increases in SAP > 20 % to a level >160 mm Hg, and in HR > 20 % to a level > 90 beat /min were considered adverse reactions. The groups were compared by $P < 0.05$ was considered significant.

RESULTS

There were no differences between the groups in patient characteristics, baseline haemodynamic state, time from anaesthesia to surgery, intraoperative volume replacement or bleeding (table I). There were no significant differences in the amount of midazolam or Nalbuphine given within 5, 10, 30 and 60 min after anaesthesia or in the total cumulated doses throughout the whole procedure (table II). Spinal anaesthesia was successful in all patients. The median values of the upper segmental sensory level of the spinal anaesthesia were T4 (range T3-10) and T5 (T2-10) for the ephedrine-treated and placebo groups, respectively.

The incidence of nausea and vomiting and the amounts of antiemetics administered during operation and within 12 h after operation did not differ significantly between the groups. SAP in the placebo group was significantly lower compared with the ephedrine group when assessed every 5 min after anaesthesia, and the reduction in SAP compared with the corresponding baseline value was significantly more pronounced in the placebo group 10 min after anaesthesia ($P < 0.001$) and throughout the first hour after anaesthesia. There were also statistically significant differences between the groups in the percentage of patients given rescue i.v. ephedrine aimed at maintaining SAP above the threshold level (fig. 2). These differences were apparent when the groups were compared during the first 60 min after anaesthesia, and also throughout the whole procedure. The number of patients with reductions in SAP of more than 30% from the baseline level were significantly lower

in the ephedrine group at 10, 25, 45, 50 and 55 min after anaesthesia (table III).

Table-I. Patient data, peroperative blood loss, and fluid and blood replacement

	Placebo group	Ephedrine group
n	40	40
Sex (M : F)	28:12	30:10
Age (yr)	69 (43-86)	70 (37-89)
ASA I:II:III:IV	18:20:2:0	11:20:8:1
b and/or Ca blockers (n)	6	9
Height (cm)	164 (7)	164 (6)
Weight (kg)	71 (12)	75 (14)
Haemoglobin (g dl)	12.7 (1.5)	12.7 (1.3)
SAP (mm Hg) (upper arm, lateral post.)	143 (22)	148 (26)
HR (beat min-1)	74 (10)	75 (10)
Duration of surgery (min)	79 (30)	75 (10)
6% HES (litre)	1.1 (0.3)	1.2 (0.2)
Crystalloid (litre)	1.3 (0.4)	1.2 (0.4)

(mean (SD or range) or number). No significant differences between groups

Three patients in the ephedrine group and 07 in the placebo group were receiving medication with beta adrenergic, calcium channel blockers, or both. In these patients the value of SAP was higher at all times after anaesthesia if prophylactic ephedrine had been given and this difference was statistically significant at 10 min, and between 35 and 60 min of anaesthesia. The need for rescue i.v. ephedrine in patients treated with beta adrenergic, calcium channel blockers, or both, was significantly less if prophylactic ephedrine had been given (table-IV).

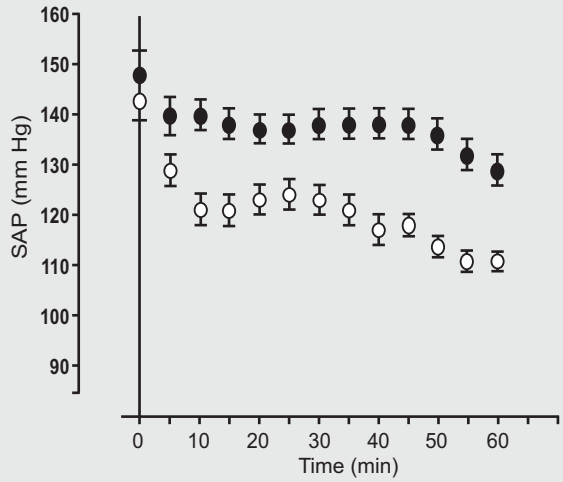
In the corresponding subgroup of patients not treated with beta adrenergic or calcium channel blockers, the significant differences in SAP between the two groups were consistent with the data for all of the patients studied, as indicated in figure 1.

Table-II. Cumulated doses of Midazolam and Nalbuphine

Midazolam (mg)	1.3 (1.3) [0-5]	1.2 (1.2) [0-3.75]
Nalbuphine (mg)	6.0 (10.0) [0-15]	1.0 (8.0) [0-10]

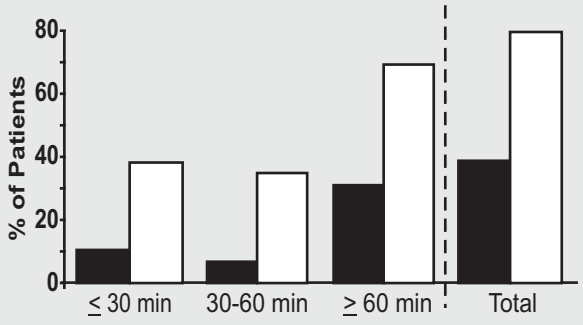
(mean (SD) [range]). Median = 0 for nalbuphine in both groups, and 1.25 mg for midazolam in both groups. No significant differences between groups

Figure-1. Systolic arterial pressure



mean, SEM) during the first 60 min after anaesthesia in the placebo (O) and ephedrine (#) groups. Except at time = 0, all differences were significant (P < 0.05).

Figure-2. Percentage of patients given i.v. rescue ephedrine according to study criteria with regard to time after anaesthesia in the ephedrine (o) and placebo (●) groups.



The difference obtained within 30 min was significant at P < 0.01 and the other comparisons at P < 0.001

Table-III. Number of patients with a reduction in systolic arterial pressure > 30 % of that before anaesthesia within the first hour after anaesthesia (mean reduction (Reduction %)). Group P = placebo, group E = ephedrine. * P < 0.05

Time after block (min)	Group	n	Reduction %
5	P	3	44
	E	-	
10	P	10*	34
	E	-	
15	P	6	38
	E	2	33
20	P	6	36
	E	2	37
25	P	6*	37
	E	1	33
30	P	7	34
	E	3	37
35	P	12	39
	E	9	33
40	P	16	39
	E	9	36
45	P	16*	35
	E	6	39
50	P	20*	38
	E	7	36
55	P	24*	37
	E	7	39
60	P	20	38
	E	11	36

However, as hypotension may develop rapidly after spinal anaesthesia, optimal SAP control with these techniques calls for very close monitoring by invasive or automated techniques, and these are not always feasible. On the other hand, i.m. prophylactic administration of ephedrine is generally not recommended because of the alleged unpredictable absorption from the injection site and the belief that a relative overdose may result in hypertension, tachycardia, or both, which may be detrimental[6-7]. Indeed, use of the i.m. route in obstetric spinal or extradural anaesthesia has been condemned. In a study by Rolbin and colleagues in which ephedrine was given i.m. 15-30 min before extradural anaesthesia for elective Caesarean section, ephedrine 25mg was ineffective in reducing the incidence of maternal hypotension, while a dose of 50 mg produced unacceptable hypertension which was associated with derangement in fetal acid-base status[8].

Rout and co-workers also recommended that prophylactic i.m. ephedrine not be used before obstetric spinal or extradural anaesthesia in case the block should fail and it became necessary to resort to general anaesthesia[9]. However, in non-obstetric cases, Hemmingsen, Poulsen and Risbo administered i.m. ephedrine 37.5 mg after an initial i.v. bolus of 12.5 mg. This was compared with placebo in 48 patients undergoing surgery of the lower abdomen or lower extremities during bupivacaine spinal anaesthesia. Greater stability of arterial pressure occurred in ephedrine-treated patients, especially in a subgroup of ASA III patients, where all eight patients in the placebo group had a decrease in mean arterial pressure exceeding 33% compared with none in the ephedrine-treated group. Tachycardia or hypertension was not observed[10].

The detailed part of this study was terminated 60 min after anaesthesia, as we expected that the effects of i.m. ephedrine would have terminated within this period and also we expected that any difference in haemodynamic state would be influenced or obscured by surgical blood loss. Nevertheless, the percentage of patients treated with i.v. ephedrine after the first 60 min was also significantly higher (70% vs 31%; P < 0.001) in the placebo group. The price paid for SAP stability in the ephedrine group may have been a 31 % increase in SAP in a patient suffering from heart failure, atrial fibrillation and diabetes who was haemodynamically unstable both before and during anaesthesia. Increases in HR occurred in one patient in each group. These results must be weighed against the significantly inferior haemodynamic stability in a substantial number of patients in the placebo group. The incidence of nausea and vomiting during and after operation was not affected by the use of ephedrine[11] and there was no effect on blood loss and need for intraoperative transfusion[12].

Finally, it should be emphasized that we used plain bupivacaine, which has a rather slow onset of action compared with other local anaesthetics[13].Our results cannot be indiscriminately applied therefore to all situations where spinal anaesthesia is used.

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