



Original contribution

Prophylactic phenylephrine infusion for the prevention of hypotension after spinal anesthesia in the elderly: a randomized controlled clinical trial ☆,☆☆,★



Fabrice Ferré MD^a,*, Philippe Marty MD^a, Laura Bruneteau MD^a, Virgine Merlet MD^a, Benoît Bataille MD^b, Anne Ferrier MD^a, Claude Gris MD^a, Matt Kurrek MD^c, Olivier Fourcade MD, PhD^a, Vincent Minville MD, PhD^a

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Abstract

Study objective: Hypotension frequently occurs during spinal anesthesia (SA), especially in the elderly. Phenylephrine is effective to prevent SA-induced hypotension during cesarean delivery. The objective of this study was to evaluate the efficacy and safety of prophylactic infusion of phenylephrine after SA for orthopedic surgery in the elderly.

Design: This prospective, randomized, double-blind, and placebo-controlled study included 54 patients older than 60 years undergoing elective lower limb surgery under SA (injection of 10 mg of isobaric bupivacaine with 5 μ g of sufentanyl).

Intervention: Patients were randomized to group $P(100-\mu g/mL)$ solution of phenylephrine solution at 1 mL/min after placement of SA) or the control group C(0.9%) isotonic sodium chloride solution). The flow of the infusion was stopped if the mean arterial blood pressure (MAP) was higher than the baseline MAP and maintained or restarted at 1 mL/min if MAP was equal to or lower than the baseline MAP. Heart rate and MAP were collected throughout the case.

Measurements: *Hypotension* was defined by a 20% decrease and *hypertension* as a 20% increase from baseline MAP. *Bradycardia* was defined as a heart rate lower than 50 beats per minute.

E-mail address: Fabriceferre31@gmail.com (F. Ferré).

^aDepartment of Anesthesiology and Critical Care Medicine, Purpan University Hospital, Toulouse, France

^bDepartment of Critical Care Medicine, Narbonne Hospital, Narbonne, France

^cDepartment of Anesthesia, University of Toronto, 150 College St, Room 121, Fitzgerald Bldg, Toronto, Ontario, M5S 3E2, Canada

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^{*} Corresponding author at: Department of Anesthesiology and Critical Care Medicine, Purpan University Hospital, Hôpital Purpan, Place du Dr Baylac, TSA 40 031, 31059 Toulouse CEDEX 9, France. Tel.: +33 0 5 61 77 99 88.

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Main results: Twenty-eight patients were randomized to group P and 26 patients to group C. MAP was higher in group P than in group C (92 ± 2 vs 82 ± 2 mm Hg, mean \pm SD, P< .001). The number of hypotensive episodes per patient was higher in group C compared with group P (9 [0-39] vs 1 [0-10], median [extremes], P< .01), but the number of hypotensive patients was similar between groups (19 [73%] vs 20 [71%], P= 1). The time to onset of the first hypotension was shorter in group C (3 [1-13] vs 15 [1-95] minutes, P= .004). The proportion of patients without hypotension (cumulative survival) was better in group P (P= .04). The number of hypertensive episodes per patient and the number of bradycardic episodes per patient were similar between groups (P= not significant).

Conclusion: Prophylactic phenylephrine infusion is an effective method of reducing SA-induced hypotension in the elderly. Compared with a control group, it delays the time to onset of hypotension and decreases the number of hypotensive episodes per patient. More data are needed to evaluate clinical outcomes of such a strategy.

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1. Introduction

Orthopedic surgery is the most common operation among patients older than 60 years [1], and lower extremities surgery represents 24% of all interventions among patients older than 75 years [2,3]. Spinal anesthesia (SA) is frequently chosen by anesthesiologists [4,5] but often associated with arterial hypotension [6]. This phenomenon is caused by the block of preganglionic sympathetic nerve fibers and is due to a decrease of both the systemic vascular resistance [7] as well as the cardiac output (stemming from a lower preload due to diminished venous return) [8-10]. Contrary to SA-induced hypotension for cesarean deliveries (where the effects of uteroplacental hypoperfusion can be directly assessed by the degree of fetal acidosis through umbilical cord pH) [11], the clinical effects and significance of mild hypotension after SA for other procedures are more difficult to evaluate and continue to be a matter of debate. 1 Nevertheless, the high incidence of hypotension after SA in the elderly represents a significant anesthetic concern because this patient population frequently suffers from various comorbid conditions and is at high risk for hypoperfusion of organs with already decreased functional reserve [12-17].

The prevention of arterial hypotension after SA presents a challenging task, and the routine bolus administration of crystalloid fluids is not always effective and can quickly lead to volume overload and signs of congestive heart failure when the effects of SA dissipate [18,19]. For that reason, a number of authors have instead proposed the use of vasopressors, but agents such as ephedrine, a direct and indirect alpha adrenergic agent, increase heart rate and myocardial oxygen consumption, which can lead to adverse cardiovascular effects in elderly patients [7,20]. Phenylephrine, on the other hand, is a pure direct alpha-1 receptor agonist without a direct effect on heart rate, and its beneficial effect during SA for cesarean delivery has been well demonstrated [11,21-23]. Nishikawa et al [24] demonstrated that a prophylactic intramuscular injection of

phenylephrine in elderly patients undergoing surgical repair of hip fracture under SA could reduce the incidence of hypotension. However, the effects of intramuscular vasopressors are often more difficult to predict, and such a route of administration is generally not the first choice of most clinicians who usually favor repeated small doses of intravenous (IV) agents. The principal goal of our study was to evaluate the effectiveness of prophylactic IV phenylephrine infusion on the prevention of hypotension following SA in patients older than 60 years undergoing elective orthopedic surgery. We also intended to measure safety by evaluating the incidence of adverse events (hypertension and bradycardia) of the study medication. Cardiac and neurologic complications that can be associated with arterial hypotension were also recorded.

2. Methods

This prospective, randomized, double-blind, and placebocontrolled study was approved by the local research ethics board (protocol number 09.001.03, favorable opinion of the CPP Sud-Ouest et Outre-Mer 1 dated January 19, 2011) and carried out between September 2011 and January 2013. This trial was registered at ClinicalTrials.gov (NCT01533662). All study subjects gave informed consent. Patients older than 60 years undergoing SA for elective orthopedic surgery on the lower extremities at the local university department (Centre Hospitalier Universitaire Rangueil de Toulouse, France) were eligible for inclusion. Exclusion criteria included uncontrolled hypertension, hyperthyroidism, dementia, symptomatic coronary artery disease, anemia with a hemoglobin <10 g/dL, or any contraindications to SA or administration of vasoconstrictors. The subjects were randomized to either treatment with IV phenylephrine (group P) or control (group C).

According to routine practice at our institution, antihypertensive medications were discontinued the day before surgery except β -blockers. The usual criteria of fasting (6 hours for solids and 2 hours for nonparticulate liquids) were observed. Patients received no premedication before arrival in the operating room.

Neal JM. Hypotension and bradycardia during spinal anesthesia: significance, prevention, and treatment. *Techniques in Regional Anesthesia & Pain Management* 2000;4(4):148-54.

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