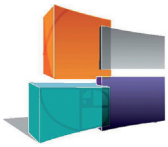
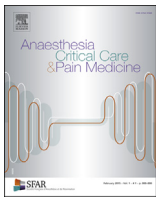
Anaesth Crit Care Pain Med 35 (2016) 37–43



SFAR
Société Française d'Anesthésie et de Réanimation



Original Article

Impact of preoperative continuous femoral blockades on morphine consumption and morphine side effects in hip-fracture patients: A randomized, placebo-controlled study☆

Aurélie Chaudet [a], Guillaume Bouhours [a], Emmanuel Rineau [a], Jean-François Hamel [b], Damien Leblanc [a], Vincent Steiger [c], Sigismond Lasocki [a,*]

[a] Département d'anesthésie-réanimation, LUNAM université, université d'Angers, CHU d'Angers, 49000 Angers, France
[b] Centre de recherche clinique, LUNAM université, université d'Angers, CHU d'Angers, 49000 Angers, France
[c] Département de chirurgie osseuse, LUNAM université, université d'Angers, CHU d'Angers, 49000 Angers, France

ARTICLE INFO

Article history:
Available online 10 November 2015

Keywords:
Hip fracture
Opioid
Femoral blockade
Side effects
Pain

ABSTRACT

Background: Upon arrival at the emergency department, hip-fracture pain relief is usually carried out via systemic opioids. Continuous nerve blocks are efficient in the postoperative period, but have not been evaluated preoperatively. This study compared the reduction in morphine consumption and related side effects of a continuous femoral block with a single shot block in hip-fracture patients.
Methods: Hip-fracture patients admitted to the emergency department received a femoral nerve catheter, with a single lidocaine injection. They were then randomized to ropivacaine (group R) or saline continuous infusion (placebo, group P) in a double-blind manner. Morphine consumption and side effects were prospectively collected until the 24th postoperative hour.
Results: Sixty patients were included and 55 analyzed. There were no significant differences between the 2 groups regarding fracture types, delay before surgery (median [Q1–Q3]: 21.3 [14.5–29.4] versus 20.8 [15.7–36.2] hours for groups R and P, respectively; $P = 0.87$) and catheter duration (47.5 [39.8–52.4] versus 42.5 [32.1–50.5] hours, $P = 0.29$). Total morphine consumption was not significantly decreased in group R (5 [0–14] versus 8 [4.5–11] mg, $P = 0.3$) and pain scores were similar (mean ± SD; VAS 29 ± 15/100 versus 33 ± 13, $P = 0.3$). We observed a significant reduction in morphine adverse effects (31% versus 69% for groups R and P, respectively; $P < 0.01$), mainly nausea (31% versus 59%, $P = 0.03$). One morphine side effect could be avoided for every 5 patients treated.
Conclusion: Preoperative continuous femoral blockades using ropivacaine reduce morphine side effects (mainly nausea) in hip-fracture patients without reducing morphine consumption.

1. Introduction

Hip fractures are very common, with an incidence of around 1.6 million cases/year worldwide [1]. This high incidence is expected to rapidly increase in the coming decades, driven by population aging [2,3]. Hip-fracture patients are in severe pain upon arrival at the emergency department (ED) [4,5]. Effective pain management is thus a primary goal and should be continued throughout the perioperative period [5]. Indeed, patients who experience greater pain are at a higher risk for delirium, prolonged hospital stays and poorer health-related quality of life [6]. Pain management is usually based on systemic opioids that have many side effects [7], particularly among frail, elderly populations [8,9]. A possible alternative for the latter is regional analgesia [6,10].

Femoral nerve blocks have been proposed for acute pain control in hip surgery [5]. The literature concerning this block is limited to a few descriptive studies and fewer randomized studies, where it is used as a single shot analgesia in the preoperative period [6,11,12] or as a single shot and/or continuous blockade in the postoperative period [13–15]. In these studies, femoral blockades appear to reduce morphine consumption and/or side effects. However, the delay for surgery may be prolonged in hip-fracture patients [16]

☆ KTcol study, www.clinicaltrials.gov: NCT01052974.

* Corresponding author. Pôle d'anesthésie-réanimation chirurgicale, CHU d'Angers, 4, rue Larrey, 49933 Angers cedex 9, France. Tel.: +33 2 41 35 36 35; fax: +33 2 41 35 39 67.
E-mail address: sigismond@lasocki.com (S. Lasocki).

http://dx.doi.org/10.1016/j.accpm.2015.07.004
2352-5568/

and a single shot block (which lasts for only a few hours) may be insufficient for patients who must wait more than 24 hours for their surgery. The use of a continuous femoral blockade on ED admission and prolonged to the postoperative period may thus reduce morphine consumption and side effects in these patients.

This randomized, double-blind, placebo-controlled study was performed in hip-fracture patients to compare morphine consumption and adverse event rates (from ED admission to 24 hours postoperatively) associated with continuous femoral blockades with those of a single shot femoral block.

2. Methods

We conducted this prospective, randomized, double-blinded, placebo-controlled study in a single centre, the Angers University Hospital (a tertiary university hospital), in France. The study was approved by the local ethics committee ("Comité de protection des personnes Ouest II") and was conducted in accordance with the Declaration of Helsinki. All patients gave and signed an informed consent form. The study was registered at www.clinicaltrials.gov (NCT01052974).

2.1. Patients

Between March 2009 and April 2010, all patients admitted to the ED of the Angers University Hospital with a clinical suspicion of hip fracture (before the X-ray) were eligible and screened, provided one of the study investigators was available. The inclusion criteria were the ability to provide a written informed consent and a mini-mental test score (MMS) [17] higher than 16/30, as required by the local ethics committee for obtaining a valid "informed consent". Exclusion criteria were: patient refusal, any contraindications for regional analgesia (i.e., treatment with clopidogrel or anticoagulation therapy, local infection at the puncture site, history of homolateral vascular surgery), known allergy to local anaesthetic medications, severe renal or hepatic failure, regular narcotic use and use of class III antiarrhythmic drugs.

2.2. Study design

Patients were screened and included in the ED just after their admission. They were then transferred to the emergency theatre recovery room, which is located inside the ED. A femoral perineural catheter was inserted by one of the study investigators under sonographic guidance and/or neurostimulation (using a final current intensity of less than 0.8 mA) under aseptic conditions. Thirty minutes after the injection of 20 mL of lidocaine 20 mg/mL with adrenaline 0.0125 mg/mL, the catheter position was verified by a cold test before performing a hip X-ray. Regional analgesia was expected to reduce the pain linked to patient mobilization for the X-ray, justifying the insertion of a perinervous catheter in the placebo group.

Patients were then randomized in two parallel groups (the ropivacaine group [R] or the placebo group [P]) with a 1:1 allocation ratio, using a randomization list electronically generated by the independent statistician. The randomization list was kept in the possession of the independent research pharmacy that prepared the study medications. Patients were secondarily excluded in case of absence of hip fracture when X-rayed.

The perineural catheters for patients in the R group were perfused with ropivacaine 2 mg/mL (Naropeine®, AstraZeneca Polybag®, France) at a constant rate of 8 mL/h, using an elastomeric pump of 400 mL capacity (Easypum®, B. Braun, France). In the P group, catheters were similarly perfused, using a saline solution. These perfusions were prepared and initiated by a research nurse who was not involved in patient care following the lidocaine bolus. The patient and all the staff involved in his/her care or in data collection were blinded to the solution used. Treatment was administered for a maximum of 4 days preoperatively and for 24 hours postoperatively.

The study drug was stopped and catheters removed in case of perioperative complications related to femoral catheters (i.e. signs of overdose of local anaesthetic drugs, ineffective analgesia after a cold test, catheter displacement, catheter puncture site inflammation), a delay of more than 4 days before surgery or hospitalization in intensive care.

2.3. Anaesthesia and analgesia protocols

Surgery was performed under standardized general anaesthesia. For induction, 0.15 mg/kg of sufentanil, 1 mg/kg of propofol (or 0.2 mg/kg of etomidate for patients $>$ 70 years old) and atracurium as necessary were used. Anaesthesia maintenance and sufentanil reinjections were left at the discretion of the anaesthetist in charge. Paracetamol was administered before the end of surgery and intravenous morphine titration was performed in the postoperative period according to a written protocol (i.e., a 2 mg bolus every 5 min for patients aged $<$ 80 and 1 mg every 5 min for patients $\geq$ 80 years old, until Visual Analog Scales [VASs] for pain were $\leq$ 30/100).

In addition, patients received a standardized analgesia protocol (preoperatively and later in the ward) consisting of the systematic administration of 15 mg/kg intravenous paracetamol every 6 hours and 0.1 mg/kg of subcutaneous morphine if VASs were $>$ 30/100.

2.4. Study parameters

Demographic, clinical and biological characteristics were recorded. The type of fracture (extra or intracapsular), surgery information (type, delay and duration) and the doses of anaesthetic drugs were recorded. Pain evaluation assessed via VASs, morphine consumption and the presence of morphine-related adverse effects (nausea, vomiting, pruritus, respiratory depression, urine retention) were prospectively collected every 6 hours and after each patient's mobilization (i.e. standing up, X-ray, physiotherapy...). Nausea and/or vomiting were treated using intravenous ondansetron (Zophren®, GlaxoSmithkline, France). Respiratory depression was defined as a respiratory rate of less than 10/min, and was treated by close surveillance together with naloxone (Narcan®, SERB, France), if necessary. Urine retention was recorded only in case of bladder catheterization. We recorded these adverse events when they required treatment, and, for analysis, pooled all these "clinically relevant" events together.

Finally, mortality was assessed at 1 and 6 months.

2.5. Statistical analysis

Data were analysed using Stata version 12.1 (StataCorp LP, Texas, USA). Data are presented as medians [Q1–Q3] or means (SD) as appropriate for continuous variables, and as percentages for categorical variables.

We hypothesized that continuous femoral blockades using ropivacaine would reduce morphine consumption and morphine side effects during the pre- and postoperative periods (i.e. until the 24th postoperative hour). The primary endpoints were total morphine consumption from ED admission until 24 hours post-surgery and the prevalence of morphine side effects during the same period, because lowering the rate of side effects is the primary goal of reducing morphine consumption. Secondary endpoints were median pain scores during this period, as well as mortality during hospitalization and at 1 and 6 months.