Author's response to reviews

Title: Hemodynamic impact of isobaric levobupivacaine versus hyperbaric bupivacaine for subarachnoid anesthesia in patients aged 65 and older undergoing hip surgery

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Cover Letter

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BMC Anesthesiology

Re (Title of Manuscript)

Hemodynamic impact of isobaric levobupivacaine versus hyperbaric bupivacaine for spinal anesthesia in patients aged and older undergoing hip surgery.

On behalf of my co-authors, I am submitting the enclosed material for possible publication in BMC Anesthesiology. It has not been submitted for publication nor has it been published in whole or in part elsewhere. I attest to the fact that all authors listed on the title page have read the manuscript, attest to the validity and legitimacy of the data and its interpretation, and agree to its submission to BMC Anesthesiology.

Description of the changes made

1. ACKNOWLEDGEMENTS: We sincerely thank Elena García and Davinia Oltra for their contribution to the design of the statistical study and the various negotiations with the Spanish Drug Agency.

2. RESPONSE TO THE REVIEWER’ S REPORT (Guniz Meyanci Koskal)
   a. This study is not a clinical trial but a descriptive, observational pilot study to assess the hemodynamic impact of subarachnoid anesthesia with isobaric levobupivacaine versus hyperbaric bupivacaine for hip fracture surgery.
b. Material-method: mean arterial pressure (MAP) was not evaluated because PAM values are not recorded in the anesthesia graph, just systolic blood pressure (SBP) and dyastolic blood pressure (DBP) values, heart rate (HR) and hemoglobin (Hb) and partial oxygen saturation (SpO₂%) values.

c. Conclusion: this descriptive, observational study suggests that subarachnoid administration of low-dose 0.5% levobupivacaine plus fentanyl in elderly patients undergoing hip fracture surgery is as safe as the administration of low-dose hyperbaric bupivacaine plus fentanyl. Our results, especially regarding intra- and postoperative events, suggest that subarachnoid low-dose isobaric levobupivacaine was safer and should be used instead of hyperbaric bupivacaine in elderly patients undergoing surgical hip fracture repair. We will compare these results in the near future with those obtained in the clinical trial completed (low-dose 0.5% levobupivacaine and bupivacaine plus fentanyl in elderly patients undergoing hip fracture surgery and invasive monitoring of hemodynamics and metabolism) and awaiting publication.

3. RESPONSE TO THE REVIEWER’ S REPORT (Koh Shingu)

a. Major Compulsory revisions:

• We don’t describe the levels of analgesia, first because is not a clinical trial but a descriptive, observational pilot study. Data were collected from the patients’ hospital records in the CHGUV archive and the level of analgesia and anesthesia is normally not recorded in the graph of anesthesia; second because it would require a large sample size.

• Factors related with postoperative congestive heart failure as hypotension, fluid therapy, use of vasopressors and anemia were not recorded correctly in all anesthesia graphs. Collection of data in the anesthetic sheet was not accurate, especially because SBP and DBP values were not collected invasively and because readings of these values could have been influenced subjectively by the investigators.

• “Which factors affected the results?” Depends on both the agent and the baricity as anesthetic volume. Subarachnoid block was undertaken using a mean local anesthetic volume of 1.3 ± 0.23 mL (range 2.40-1) and a mean dose of 10.75 ± 2.64 µg fentanyl (range 5-20). A higher
volume of bupivacaine was used (1.43 mL) compared to levobupivacaine (1.16 mL). Significant differences were found in the volume of the anesthetic solution but not in the dose of fentanyl.

b. Minor Essential Revisions:

- P2, L17: “at the end of anesthesia” mean “at the time when the patient may be transferred to the post surgical recovery unit”.

- P2, L 18-19: “1.43 mg” and “1.16 mg”

- P4, L28: “at 30 min into surgery” mean “30 min after anesthesia”; “at the end of anesthesia” mean when the patient could be transferred to the post surgical recovery unit.

- P7, L15-21. The levels of sensory and motor block were not generally recorded by the anesthesiologist on the graph of anesthesia.

- P12, L9-10. The vasoactive properties of local anaesthetics may determine the duration of their therapeutic activity. Thus, the difference may be also explained by the greater vasoconstrictive properties of levobupivacaine than bupivacaine in the subaracnoid space.

Dra. Rosa Herrera

Date

Valencia, June 20th, 2014