Author's response to reviews

Title: Sciatic lateral popliteal block with clonidine alone or clonidine plus 0.2% ropivacaine: effect on the intra- and postoperative analgesia for lower extremity surgery in children. A randomized prospective controlled study

Authors:

Kalliopi Petroheilou (kpetrohilou@yahoo.com)
Stavros Livanios (st_livanios@yahoo.gr)
Nick Zavras (nikzav2000@yahoo.com)
John Hager (Knomikos_1@hotmail.com)
Argyro Fassoulaki (afassoul@otenet.gr)

Version: 3 Date: 22 September 2011

Author's response to reviews: see over
Dear Editors,

Thank you and the reviewers for the constructive comments of research article, MS: 1324466156509649, entitled: Sciatic lateral popliteal block with clonidine alone or clonidine plus 0.2% ropivacaine: effect on the intra- and postoperative analgesia for lower extremity surgery in children. A randomized prospective controlled study.

We respond to reviewer Arjunan Ganesh as follows:

According to the usefulness of the femoral block in the tourniquet pain, it has been reported in the discussion pages 12, 13:

It has been suggested that an effective block by a large dose of long acting local anaesthetic may reduce the incidence of tourniquet pain by blocking C and Aδ fibres [30]. However, in our study the limited duration of the foot surgery and the added clonidine in the femoral block demonstrate the absence of the incidence of tourniquet pain [30] in clonidine group and clonidine plus ropivacaine group, while all the patients in the control group complained of mild tourniquet pain with CAS score: 30mm-35mm in the area of its application. The tourniquet pain was differentiated by the more intense surgical pain with CAS score> 35mm-55mm.

About the motor block, it was not found in our patients, confirming previous studies that demonstrate that 0.2% ropivacaine and clonidine in small dose provide preservation of motor function [6, 23].

By failed sciatic block has been corrected as follows: failure to localize the sciatic nerve with stimulator guidance.

We respond to reviewer Jean-Marc Malinovsky as follows:

We didn’t compare perineural clonidine to a group receiving only local anesthetic or to a group with intravenous clonidine alone. We report the following text in the discussion page 13.
One could be claimed to the role of 0.2% ropivacaine alone or to the intravenous use of clonidine alone. However, our results demonstrated the superior analgesic effect when clonidine administered as adjuvant for 0.2% ropivacaine in comparison to previous studies using 0.2% ropivacaine alone in the popliteal fossa block for similar painful foot procedures [31] or in the axillary brachial plexus block [12].

Regarding to methods, the section about patients, randomization, and blindness has been rewritten as follows:

*Patients, Randomization and Blindness*

Between January 2009 to May 2010, children, ASA physical status I and II, aged 5-14 years were scheduled for elective mild to moderate painful foot and ankle surgery. It should be studied 66 children according to the power analysis. During the study, eleven children with neurologic or neuromuscular disease, problems in communication, skin infection at the site of needle insertion, or children’s parents refusal were excluded. We used a computer generated table program to produce random numbers. We made a choice of twenty one (n=21) random numbers from 1 till 66 in order to be in the control group, twenty three (n=23) random numbers remained from the first choice to be in the clonidine group, and the rest twenty two (n=22) numbers to be in the clonidine plus 0.2% ropivacaine group. The investigators were blind to the group assignment. The placebo or the treatment solutions were prepared by the pharmacy and supplied to the Department of Anesthesia in syringes labeled with predetermined code for each solution. There were two syringes for the SLPB and the femoral block respectively. In the SLPB, the syringes contained a) for the control group isotonic saline 10 ml plus 0.25 ml/kg and saline 0.13 ml/kg, b) for the clonidine group isotonic saline 10 ml plus 0.25 ml/kg, and clonidine 2 μg/kg (0.13 ml/kg) respectively. c) finally in the clonidine plus 0.2% ropivacaine group the syringes contained 0.2% ropivacaine 10 ml plus 0.25 ml/kg (maximum 25 ml) and clonidine 2 μg/kg (0.13 ml/kg) respectively. Similarly in the femoral block the syringes contained a) for the control group isotonic saline: 0.4 ml/kg and 0.065 ml/kg respectively, b) for the clonidine group isotonic saline 0.4 ml/kg and
clonidine 1µg/kg (0.065 ml/kg) respectively, and c) for clonidine plus 0.2% ropivacaine group
0.2% ropivacaine 0.4 ml/kg and clonidine 1µg/kg (0.065 ml/kg) respectively. The maximum
dose of 0.2% ropivacaine was decided to be 3.5 mg/kg and for clonidine 3 µg/kg.
The children were enrolled in the study after approval of The Scientific Ethics Committee
(General Children’s Hospital, Penteli, Athens). Preoperatively, we explained to parents our
intervention treatment. After understanding and accepting the alternative treatments by
randomization, without coercion or manipulation, written informed consent was obtained in
the card anesthesia.
The results of table 3 were inserted in the text of manuscript as follows:
Particularly, the patients in the clonidine plus ropivacaine group had a
significantly longer time to first analgesic request compared to clonidine group
(Figure 2), [mean time: 21.5 hours S.E.M: 1.26, S.D:5.90, 95% CI:19.0-23.9
versus 11.6 hours S.E.M:1.74  S.D: 8.33,  95% CI: 8.2-15.1, median time: 24
hours range:0-24, 95% CI :21.6-26.4 versus 6 hours range:6-24, 95% CI :5.6-
6.4], (p=0.001). On the contrary to the control group that all patients required
rescue nalbuphine in the recovery room (time:0), the patients in the clonidine
group had a longer mean time to first rescue nalbuphine (p<0.0005) ( Figure 2).
It is not necessary to have the table 2, but we report to the discussion, (page 10)
the following text: Our results also show that in most children eliciting plantar
flexion or strong inversion the foot had better quality of analgesia requiring
fewer rescue doses of nalbuphine. This is ought to the better spread of local
anesthetic solution, when the injecting needle tip presumably lies between the
common peroneal nerve laterally and the tibial nerve medially (plantar flexion of
the foot), or very close to the trunk of the sciatic nerve before its division (strong
inversion of the foot). (Results: Chi-Square=18.66, p=0.003, page 9).
Clinical acceptable analgesia of clonidine was not a correct term. We corrected the discussion
manuscript, page 10 as follows: In our study, clonidine alone seems promising with regard to
analgesic action at the peripheral distal nerve fibers: intraoperatively maintaining the hemodynamic parameters SAP, DAP, HR to the lower normal values so that no patient needed nalbuphine under 0.6 MAC sevoflurane anesthesia, and postoperatively without analgesic request for a median time of 6 hours. Moreover, clonidine administered as adjuvant enhances ropivacaine’s analgesic effect for the first postoperative day (p=0.001).

Clonidine is proposed as premedication to decrease agitation and nausea during the postoperative period in children even under regional analgesia. In the discussion section page 11 we respond as follows:

In this study a systemic effect of clonidine cannot be excluded, indicating the calmness without postoperative delirium, as well as without incidence of shivering and PONV, that could be ought to the use of sevoflurane, in the patients of both SLPB. These effects could make clonidine a useful oral premedication medicine in children (21, 22).