Author’s response to reviews

Title: Perioperative Effects of Caudal Block on Pediatric Patients in Laparoscopic Upper Urinary Tract Surgery: A Randomized Controlled Trial

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Version: 1 Date: 25 Jul 2019

Author’s response to reviews:

Manuscript number: BPED-D-19-00308

MS Type: Article
Title: "Perioperative Effects of Caudal Block on Pediatric Patients in Laparoscopic Upper Urinary Tract Surgery"
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Dear Dr. Uchida,

Thank you very much for your attention and the reviewer’s evaluation and comments on our paper “Perioperative Effects of Caudal Block on Pediatric Patients in Laparoscopic Upper Urinary Tract Surgery”. The valuable comments helped us improve the manuscript a lot.

We have revised the manuscript according to your kind advices and reviewer’s detailed suggestions. Enclosed please find the responses to the reviewers. We sincerely hope this manuscript will be finally acceptable to be published on BMC pediatrics.

Thank you again for all your help and looking forward to hearing from you soon.

Best regards
Please find the following Response to the comments of referees:

Response to the comments of Dr. Kendigelen

1. Have you registered the study in website such as clinicaltrials? Reply: Yes, we registered this study at Chinese Clinical Trial Registry (http://www.chictr.org.cn), the register number is ChiCTR1800015549. At the beginning, we tried to register our study at clinical trials, but the administrator suggested us to register our study at Chinese Clinical Trial Registry.

2. Why did you choose fentanyl as a caudal additive for supraumblical or laporoscopic surgery? Reply: Nowadays, there are several additives used for neuraxial block such as morphine, fentanyl, sufentanil and Alpha 2 adrenoreceptor antagonists like clonidine and dexmedetomidine. In our department, we have used fentanyl as additive for caudal block for more than twenty years. We have experiences of using fentanyl as an additive to enhance the analgesic effect of local anesthetics and keep pediatric patients safe, so in this study, we choose fentanyl.

3. Why did you prefer etomidate and succinylcholine? The unwanted side effects of succinylcholine are well known. More important, viable alternatives to succinylcholine now exist for intermediate or long surgical procedures. With short-acting non-depolarizing relaxants available, succinylcholine is obsolete for routine anesthesia care. Reply: As we know, propofol and etomidate are the most common drugs used for anesthesia induction. Since propofol will cause injection pain to most of the patients, while etomidate will not, so we chose etomidate as our induction drug in this study.

Thank you for your kind advice of choose right muscle relaxant. As you mentioned succinylcholine do have many side effects, we still use it because of its rapid onset, providing complete muscle relax and short duration. Also our department have used succinylcholine as anesthesia induction drug for many years, no server side effects were founded, based on our experiences, we used succinylcholine in our study.

4- I did not understand that how did you calculate sample size? Which did you use the mean of? (The pilot data showed that the mean ± SD of the non-block group, the ROP1.0 group and the ROP 1.3 group were 1.87±0.35 µg/kg, 1.57±0.32 µg/kg and 1.29±0.29 µg/kg respectively.) Reply: Sorry for our misunderstanding expression, we corrected this from “The pilot data showed that the mean ± SD of the non-block group,” to “The pilot data showed that the
perioperative fentanyl use (the primary outcome variable of this study) of the non-block group,” (Method section, line 6, page 9).

First we calculated the sample size based on multiple groups comparison, the sample size was 8 per group, then we calculated the sample size based on two groups comparison (the non-block group vs. the ROP 1.0 group, sample size was 24; the ROP 1.0 group vs. the ROP 1.3 group, sample size was 27). An online sample size calculation website helped us to calculate the sample size (cnstat.org).

5- How long do you observe patient in PACU? (minimum time) Is this safe that less than 30 minutes stay in PACU especially children with caudal block? Which criteria do you use to discharge patients from PACU?

Reply: The observe time of the patients was about 30-40 minutes, while the minimum time in PACU was 20 minutes. Since in PACU, caudal block has been performed for about two hours, there is a low incidence of severe side effects (such as subarachnoid injection by mistake) caused by caudal block may happen.

The criteria of discharge patients from PACU were listed below:

1. the patient is awake, alert, and oriented.
2. No nausea and/or vomiting.
3. Stable vital signs.
4. The SPO2 is more than 95% when breathing air.
5. Recovery of muscle strength (raise their head from bed and hold for more than 2 seconds, deep breath and cough)

Response to the comments of Dr. Gong

1. I am assuming that the anesthesiologist who managed the patient intra-operatively was blinded to what the patient was randomized to. I believe that this is stated on Page 7, line 12, but could be made more definitive. Reply: Thank you for giving us this kind suggestion. According to your suggestion, we corrected this part to “After the procedure of caudal block, the anesthesiologist who performed caudal block left the operating room, another anesthesiologist, who was blind to the grouping information, enter the operating room and managed the patients intraoperatively.” (Method Section, line 21, page 6).
2. Page 7, line 36, all patients were given ondansetron prior to case completion, this may have an effect on differences in post-operative nausea and vomiting, including this as part of the discussion in comparison to previous studies could be beneficial.

Reply: As you mentioned that giving ondansetron prior to case completion may affect the differences in post-operative nausea and vomiting, however if we do not give antiemetic to the patients, the incidence of post-operative nausea and vomiting will be very high, which is not allowed by our ethics committee.

3. It does not appear that scheduled post-operative ketorolac or other NSAIDs were utilized, allowing this study to better address the differences in need for post-operative pain medications between groups. This could be added to the discussion on Page 13, Line 48.

Reply: Thank you Dr. Gong for your kind advice. We addressed post-operative pain medications between groups in the discussion section. (Discussion Section, page 13, Line 48, highlighted with yellow).

4. Line 19, Page 12: Citation 14 investigated the effect of caudal block on upper urinary tract robot assisted laparoscopic surgery. It seems inaccurate to say this is the first to investigate this question.

Reply: Sorry for our incorrect statement. The study performed by Faasse et al was a retrospective study comparing the perioperative effects of caudal block and transversus abdominis plane block, while our study was a prospective study comparing different volume of caudal block and non-block. We have corrected this sentence to “our study was the first perspective study…” (Discussion section, page 12, line19)

5. Line 38-39, Page 13: (Faasse's study or previous studies?) This needs to be clarified. Similar in line 50-51.

Reply: Thank you Dr. Gong for pointing out this mistake. It should be Faasse’s study. We have corrected it. (Discussion section, page 13, line 49)

6. Line 34, Page 15: I am unclear what this line means: "Caudal block with 1.3 mL/kg of 0.15% ropivacaine is optional."

Reply: We have rewritten this part to “Caudal block with 1.3 mL/kg of 0.15% ropivacaine reduced perioperative fentanyl use during laparoscopic upper urinary tract surgery on pediatric patients and produced good postoperative analgesia when compared with no caudal block and caudal block with 1.0 mL/kg of 0.15% ropivacaine.”