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LETTER

# Letter to the Editor Regarding "Analgesia Effect of Ultrasound-Guided Transversus Abdominis Plane Block Combined with Intravenous Analgesia After Cesarean Section: A Double-Blind Controlled Trial"

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To the Editor,

In a single-center randomized controlled trial with a double-blind design and a total of 180 full-term puerperae undergoing cesarean section, Xue et al. [1] assessed postoperative analgesic efficacy of ultrasound-guided transversus abdominis plane block (UGTAPB) combined with patient-controlled intravenous analgesia (PCIA) by comparing to PCIA alone. They showed that PCIA or PCIA combined with UGTAPB could provide safe and effective analgesia, but PCIA combined with UGTAPB was better in analgesic effect with a lower incidence of side effects and reduced opioid consumption. As a multimodal analgesia protocol including local blocks is an important component of enhanced recovery after cesarean delivery (ERAC) and ERAC has been significantly associated with decreased length of stay, times to first mobilization and urinary catheter removal, risk of postoperative complications, and opioid consumption [2], this study has potentially clinical implications. However, there are several issues in this study that need further clarification. We wish to get the authors' reply.

First, in the method and results, the authors clearly described that a total of 180 full-term puerperae were enrolled into the study and the included puerperae were randomly divided into three groups with 60 cases in each group. However, in the CONSORT flow diagram of patient enrollment, we noted that only 120 full-term puerperae were enrolled and each group included 40 cases. Obviously, this is a mistake that needs correction.

Second, this study design included several primary outcomes, such as visual analogue scale (VAS) scores at static and dynamic states during 48 h postoperatively, time for first PCIA pump compression, and total number of compressions in 48 h postoperatively. According to the basic principle of designing a randomized controlled trial, however, only a primary outcome is allowed and sample size calculation should be performed on solely the primary outcome [3]. Furthermore, the authors calculated the sample size based on their pilot study including 15

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patients in each group, in which VAS scores at 12 h postoperatively were $2.75 \pm 0.35$, $2.73 \pm 0.31$, and $2.80 \pm 0.36$ in groups A, B, and C, respectively. However, it was unclear whether these values were static or dynamic pain scores. This was a randomized controlled trial with three arms to explore the optimal analgesic scheme after cesarean section, but the authors did not clearly state which between-group difference of mean VAS scores at 12 h postoperatively was used for sample calculation. Most importantly, the net differences in mean VAS scores at 12 h postoperatively among groups and their standard deviations were very small. We were very interested in knowing what the expected minimal clinically important difference of primary outcome for sample calculation in this study was. In available literature, the recommended minimal clinically important difference for acute postoperative pain control is 1.5 when pain was assessed by a 0–10 VAS [4].

Third, in the key summary points and introduction section, the authors described that this study was designed on the basis of the concepts of ERAC and multimodal analgesia. However, a single-mode postoperative analgesia strategy, i.e., PCIA with sufentanil, was used in the control patients (group A). In fact, the current ERAC protocols recommend the multimodal strategies of postoperative analgesia, in which a package of basic analgesics, such as paracetamol, NSAIDs or cyclooxygenase-2-specific inhibitors, and dexamethasone, is included [2]. Thus, we believe that different results about postoperative analgesic efficacy of UGTAPB would have been obtained if a package of basic analgesics had been included in the postoperative analgesia strategy of control patients in this study. Recently, there has been a call for special attention to this issue of randomized clinical trials assessing postoperative analgesic efficacy of local blocks [5].

Finally, this study showed that PCIA combined with UGTAPB improved postoperative analgesic efficacy and patient satisfaction, and decreased incidence of side effects and opioid consumption. However, this study did not evaluate other important outcome variables of the ERAC, such as the length of hospital stay, time to mobilization, time to urinary catheter removal, the occurrence of postoperative complications, readmission rates, and cost savings [6, 7]. Because of this design limitation, an important issue that this study cannot answer is whether improved postoperative pain control and decreased incidence of side effects by PCIA combined with UGTAPB can be translated into the early postoperative benefits of patients undergoing cesarean delivery.

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***Author Contributions.*** All authors carefully read the manuscript by Xue et al., and reviewed their methods and data. Rui-Ping Li suggested comment points and drafted the manuscript. Fu-Shan Xue and Yi Cheng revised the comment points and manuscript. All authors have read and approved the final manuscript.

***Disclosures.*** Rui-Ping Li, Fu-Shan Xue and Yi Cheng declare that they have no conflict of interest for this work.

***Compliance with Ethics Guidelines.*** This article is based on a previously conducted study and does not contain any study with human participants or animals performed by any of the authors.

***Data Availability.*** Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

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