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LETTER

Letter to the Editor Regarding "The Effect of Ultrasound-Guided Erector Spinae Plane Block Combined with Dexmedetomidine on Postoperative Analgesia in Patients Undergoing Modified Radical Mastectomy: A Randomized Controlled Trial"

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Key Summary Points

This letter was written in response to the article "The Effect of Ultrasound-Guided Erector Spinae Plane Block Combined with Dexmedetomidine on Postoperative Analgesia in Patients Undergoing Modified Radical Mastectomy: A Randomized Controlled Trial," in which the addition of dexmedetomidine to ropivacaine solution was demonstrated to significantly improve the postoperative analgesic efficacy of erector spinae plane block.

This letter pointed out severe issues in the design of this randomized controlled trial; for example, there was no sample size evaluation, flow diagram of the included and excluded patients, or assessment regarding patients' satisfaction with postoperative analgesia.

This letter questioned the clinical significance of study results that the postoperative analgesic efficacy of erector spinae plane block was significantly improved by combining dexmedetomidine with ropivacaine.

This letter recommended a reasonable method to report rescue analgesic consumption after surgery.

The authors believe that clarification of these issues would improve the transparency and interpretation of this study.

To the Editor,

Wang et al. [1] reported a randomized double-blind trial including 60 female patients who underwent a modified radical mastectomy, showing that the addition of dexmedetomidine to ropivacaine solution significantly improved the efficacy of ultrasound-guided erector spinae plane block for postoperative analgesia. As the use of non-opioid or opioid-sparing strategies to improve postoperative analgesia is being emphasized in current practice [2], the authors should be congratulated for their important work to find new options for postoperative acute pain control. However, we noted several issues in the methods and results of this study that needed further clarification.

First, this was a randomized controlled trial with a small sample of only 30 patients in each arm, and the authors did not provide information on sample size calculation in the methods. It must be emphasized that sample size calculation is an important part of the randomized controlled trial design for avoidance of type 1 and type 2 statistical errors. As a basic principle, sample size calculation should be carried out based only on the primary endpoint. Before sample size calculation, moreover, the minimal clinically important difference of primary endpoint between the groups must be evaluated to demonstrate a power that is required to achieve clinically important significance [3]. Due to the lack of a flow diagram of the included and excluded patients, it was also unclear how many patients were preoperatively screened of the 60 study subjects included in the final analysis.

Second, in the methods, the authors described that propofol 4–6 mg/kg and remifentanil 0.1–1 μg/kg were given for anesthesia maintenance. Furthermore, sufentanil 0.2 μg/kg was administered intravenously when intraoperative hemodynamic changes exceeded 20% of the baselines. We would like to know why the authors did not apply intravenous infusion of drugs to maintain stable anesthesia. In Table 1 of this article, it was unclear why the dosage of remifentanil in the dexmedetomidine plus ropivacaine group was zero. The bispectral index was measured in all patients, but the results of bispectral index monitoring during surgery were not provided and compared between the groups. In fact, the bispectral index is a common method for monitoring anesthesia depth and is a well-accepted variable for adjusting doses and concentrations of anesthetic and analgesic drugs during anesthesia and surgery [4].

Third, the severity of postoperative pain in the resting and movement states was assessed by a visual analog scale (VAS) on a scale of 0 (no pain)

to 10 (worst pain imaginable) at 1, 6, 12, 24 and 48 h after surgery. Furthermore, the VAS scores of postoperative pain in the resting and movement states at some time points were significantly lower in the dexmedetomidine plus ropivacaine group than in the ropivacaine group. However, we noted that the medians of postoperative pain VAS scores in the movement state at all time points were 3 or less, with 95% confidence intervals of 1–3. These results indicate that a high proportion of patients had a clinically acceptable pain level in the early postoperative period [2]. Furthermore, the between-group net differences in median VAS scores at most time points after surgery were only 0–1. In addition, the authors did not provide and compare the proportion of patients with a VAS score of > 4 who needed rescue analgesia using intravenous flurbiprofen 50 mg. Thus, it is difficult for the readers to determine whether the improved postoperative analgesic efficacy of erector spinae plane block by combining dexmedetomidine with ropivacaine in this study should be considered as clinically important.

Fourth, the dosage of flurbiprofen for rescue analgesia within 48 h after surgery was designed as the primary outcome of this study, and median postoperative flurbiprofen consumption was significantly lower in the dexmedetomidine plus ropivacaine group than in the ropivacaine group. According to clinical practice, however, total postoperative flurbiprofen consumption is best calculated based on the body weight of the patient or per unit time (i.e., mg/24 h) and then compared between the groups, as performed in previous studies [5, 6]. We are very interested in knowing whether a combination of dexmedetomidine with ropivacaine for erector spinae plane block also significantly decreased postoperative flurbiprofen consumption dose per kilogram body weight or per 24 h.

Finally, this study did not observe patients' satisfaction with postoperative analgesia. In fact, patients' satisfaction is very important for determining the clinical feasibility of an intervention and is very easily measured using a five-point Likert scale (5 = completely satisfied, 4 = quite satisfied, 3 = slightly dissatisfied, 2 = dissatisfied, 1 = very dissatisfied) [7]. We believe that this study would have provided more useful data about clinical value of erector spinae plane block with dexmedetomidine plus ropivacaine for postoperative pain control after modified radical mastectomy, if the design had included the assessment of patients' satisfaction with postoperative analgesia.

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

Disclosures. Nong He, Fu-Shan Xue and Cheng-Wen Li 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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