

## Research design is important in comparing the analgesic efficacy of different regional blocks following modified radical mastectomy

Dear Editor,

With great interest, we read the recent article by Sharma *et al.*<sup>[1]</sup> comparing the postoperative analgesic efficacy of continuous erector spinae plane block (ESPB) and thoracic paravertebral block (TPVB) in patients undergoing modified radical mastectomy. We highlight concerns related to the methods and results of this study.

Firstly, this is a randomised controlled non-inferiority trial, and the primary end-point was the visual analogue scale (VAS) pain score. In statistical analysis, the authors described that a 2-point VAS pain score was defined as the non-inferiority margin according to the critical appraisal of the published literature on the TPVB.<sup>[2]</sup> However, this published literature is a meta-analysis of randomised controlled trials comparing post-operative analgesic efficacy and safety between the TPVB and non-block interventions and does not provide an average pain score during post-operative 24 h in patients receiving the TPVB. In a randomised controlled non-inferiority trial, a non-inferiority margin should be determined based on the minimal clinically important difference or clinically meaningful differences of the primary end-point<sup>[3]</sup> such as the VAS score of acute post-operative pain. It has been shown that a change of about 1 point on an 11-point VAS produced by analgesic interventions signifies a clinically important improvement or deterioration.<sup>[4]</sup> Thus, a non-inferiority margin of 1.0 points is often selected in randomised controlled non-inferiority trials comparing the postoperative analgesic efficacy of different regional blocks.<sup>[5,6]</sup>

Secondly, in sample size evaluation, the authors stated that the assumed true mean difference between the two interventions, that is, effect size, was zero. It was unclear why an effect size of 0 was selected. In designing a randomised controlled non-inferiority trial, the non-inferiority margin is actually the effect size and is used for sample size evaluation<sup>[3]</sup> as performed in other works.<sup>[5,6]</sup>

Thirdly, during the 24-h post-operative period, 0.2% ropivacaine with fentanyl 2 µg/mL was infused in both groups. We were very interested in knowing whether a bolus injection of local anaesthetic–fentanyl solution was allowed if the post-operative VAS pain score was 4 or more.

Finally, regarding post-operative analgesic strategies, round-the-clock analgesia was not provided. The reported regime does not meet the requirements of an opioid-sparing multi-modal analgesia strategy in the current enhanced recovery after surgery practices for radical mastectomy.<sup>[7]</sup> As the conversion factor for equivalent dose conversion of morphine to tramadol is 0.1,<sup>[8]</sup> 2 mg/kg of tramadol is equivalent to 0.2 mg/kg of morphine, which is significantly larger than the recommended opioid dose of rescue analgesia.<sup>[7]</sup>

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### Conflicts of interest

There are no conflicts of interest.

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### REFERENCES

- Sharma L, Bhatia P, Mohammed S, Sethi P, Chhabra S, Kumar M. Comparison of continuous erector spinae plane block and thoracic paravertebral block for postoperative analgesia in patients undergoing modified radical mastectomy: A randomised controlled non-inferiority trial. *Indian J Anaesth* 2023;67:357-63.
- Schnabel A, Reichl SU, Kranke P, Pogatzki-Zahn EM, Zahn PK. Efficacy and safety of paravertebral blocks in breast surgery: A metaanalysis of randomized controlled trials. *Br J Anaesth* 2010;105:84252.

3. Angeli F, Verdecchia P, Vaudo G, Masnaghetti S, Reboldi G. Optimal use of the non-inferiority trial design. *Pharmaceut Med* 2020;34:159-65.
4. Myles PS, Myles DB, Galagher W, Boyd D, Chew C, MacDonald N, *et al.* Measuring acute postoperative pain using the visual analog scale: The minimal clinically important difference and patient acceptable symptom state. *Br J Anaesth* 2017;118:424-9.
5. Fan Q, Liu H, Li Y, Dai H, Wang Y. Comparison of ultrasound-guided erector spinae plane block and thoracic paravertebral block for postoperative analgesia after laparoscopic nephrectomy: A randomized controlled non-inferiority clinical trial. *Minerva Anesthesiol* 2023;89:520-8.
6. Andrade Filho PH, Pereira VE, da Escossia Melo Sousa D, da Gama Costa L, Nunes YP, Taglialegna G. Analgesic efficacy of erector spinae plane block versus paravertebral block in lung surgeries-A non-inferiority randomised controlled trial. *Acta Anaesthesiol Scand* 2023. doi: 10.1111/aas. 14325.
7. Liu S, Shen Y, Xiang J, Zhou F, Liu J, Zhou N, Cai L. Accelerated perioperative rehabilitation for breast cancer patients undergoing radical mastectomy: A systematic review. *J Perianesth Nurs* 2023;38:339-48.
8. Duthie DJ. Remifentanyl and tramadol. *Br J Anaesth* 1998;81:51-7.

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