Reviewer's report

Title: COMPARISON OF THE EFFICACY OF ERECTOR SPINAE PLANE BLOCK PERFORMED WITH DIFFERENT CONCENTRATIONS OF BUPIVACAINE ON POSTOPERATIVE ANALGESIA AFTER MASTECTOMY SURGERY: RANDOMIZED, PROSPECTIVE, DOUBLE BLINDED TRIAL

Version: 0 Date: 27 Nov 2018

Reviewer: Edward C. Nemergut

Reviewer's report:

Altiparmak et al.: Evaluation of efficacy of erector spinal plane block performed with two different bupivacaine concentrations on postoperative analgesia of adult female patients after mastectomy surgery.

The manuscript by Altiparmak et al. describes a randomized, double-blinded, prospective "efficacy" study where ASA I-II patients undergoing unilateral radical mastectomy with axillary lymph node dissection were randomly assigned to receive high dose 0.375% (n=21) or 0.25% (n=21) bupivacaine ultrasound guided erector spinal plane (ESP) blocks.

The primary outcome measure of the study was total postoperative tramadol consumption in the first 24 hours. Their secondary endpoints were pain scores, and intra-operative fentanyl need. All patients received 0.05 mg/kg IV midazolam for preoperative sedation followed by general anesthesia with desflurane and N2O titrated to a Bi-spectral index between 40-60. All patients received IV ondansetron 4 mg, dexamethasone 8 mg, and dexketoprofen trometamol 75 mg for prophylaxis of post-operative nausea-vomiting and analgesia. Intraoperative IV fentanyl 0.5 mcg/kg was administered to patients when their hemodynamic parameters of heart rate and blood pressure increased 20% above their base-line measurements. All patients received a patient-controlled analgesia (PCA) device in the recovery room that administered 10 mg IV tramadol with a 20 minute lock-out and no basal infusion. Patients pain scores were recorded using an 11-point scale (0-10) at 15 and 30 minutes in the recovery room and 1, 2, 6, 12, and 24 hours on the surgical ward. When patients pain scores were >4, they received 4 mg IV morphine as rescue analgesia while on the surgical ward.

The authors found a statistically significant (p=0.001) decrease tramadol consumption in the High ESP block group vs the Low ESP block group (149.52+/−25.39 mg vs 199.52+/−32.78 mg). The also reported overall lower pain scores in the High ESP group for the first 12 hours. The authors did not find a difference in mean intraoperative fentanyl need between the two groups.

Major Points:

Page 10 states: postoperative rescue analgesic requirement in the surgical ward was significantly higher in the Low ESP group (p=0.030). However, Table 2 shows post operative rescue analgesia on the surgical ward is higher in the High ESP group. Also, this table is difficult to
interpret as there are no units indicated for the rescue analgesic rows. Furthermore, we do not know when the patients required the rescue analgesic other than to say they required it on the surgical ward. As I understand the study, the patients moved to the surgical ward after 30 minutes in the recovery room. This would suggest that patients in the High group received less tramadol but required more rescue morphine on the surgical ward. This fact must be addressed in a revision.

IT appears that the authors used the t-test to compare total consumption over the first 24 hours. This is not clear from Methodology described on Page 9. (Indeed, if this is incorrect, the Methods should be revised such that this is more clear by directly writing something like "the primary endpoint, difference in tramadol consumption over 24 hours, was assessed by XXX". Regardless, a RMANOVA would be more appropriate.

Minor points:

The manuscript contains multiple grammatical and syntactical errors that must be addressed prior to publication.

Page 4: In the Methods section, study is described as efficiency study. My understanding is that this is an efficacy study.

Page 9: For the reported value of tramadol consumption in the control group, units should be reported. Units of milligrams were reported appropriately in the High ESP group.

The information in Table 3 seems redundant and to contain the same information as Figure 2. If this is not true, I am unclear what differences are.

In summary, with regards to the authors primary endpoint, the overall reduction in tramadol consumption, while statistically significant, is not likely to be clinically significant. Furthermore, it is unclear to this reader whether the reduction in tramadol consumption was influenced by IV morphine rescue analgesia.

Statistical issues above must be addressed.

With regards to the authors secondary endpoints, there again is a statistically significant difference between the High ESP vs. Low ESP block groups with respect to post-operative pain ratings. However, the difference of approximately 1 point on the numerical rating scale is also of questionable clinical significance.

Respectfully submitted,
Edward C. Nemergut and Kenneth Mullen
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
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No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
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