Author’s response to reviews

Title: Preprocedural Ultrasound versus Landmark Techniques for Spinal Anesthesia Performed by Novice Residents in Elderly: A Randomized Controlled Trial

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Author’s response to reviews:

We are grateful for considering for publication our manuscript, pending an adequate response to the reviewers’ recommendations. All comments were examined, and we responded in detail to each of the points raised. Also, modifications were incorporated and highlighted as required in the revised manuscript. The comments are addressed as follows:

Editor Comments

We would like to thank the Editor for his valuable comments.

Line 87: The sentence suggests a study of superiority. I rather suggest "In this prospective, randomized, controlled study, we hypothesized that both pre-procedural US-guided techniques would result in different spinal anesthesia success rates at first attempt when compared with the conventional landmark-guided midline technique in elderly patients".

As suggested by the Editor, the following sentence “We hypothesized that both pre-procedural US-guided techniques would improve spinal anesthesia success rates at first attempt when compared with the conventional landmark-guided midline technique in elderly patients” was modified in the Introduction section of the revised manuscript to read:
"In this prospective, randomized, controlled study, we hypothesized that both pre-procedural US-guided techniques would result in different spinal anesthesia success rates at first attempt when compared with the conventional landmark-guided midline technique in elderly patients”.

Please do not compare the baseline patients’ parameters (not recommended in a randomized study). Thank you for adding the standardized difference on the table.

As recommended by the Editor, P values for the baseline patients’ parameters were deleted from Table 1 of the revised manuscript.

We would like to thank the Editor for his recommendation; however, it will be too confusing to compare all three groups using the standardized difference. Please advise whether to add it to Table 1 or not.

I also suggest keeping the same order for the description of the statistical tests, namely, describe the test used to compare the primary outcome and how that result is expressed, and similarly for the secondary ones.

The following paragraph (Continuous data…….. Mann-Whitney U-test) was modified in Methods section of the revised manuscript to read:

The primary outcome (successful dural puncture on first attempt) was expressed as numbers and percentages and was analyzed using Chi square or Fisher’s exact test as appropriate.

For secondary outcomes, categorical data (gender, type of surgery, ease of landmark palpation, grading by US, successful dural puncture, successful dural puncture on first pass, patient satisfaction, verbal attending assistance, and complications) were reported as numbers and percentages and were analyzed using Chi square or Fisher’s exact test as appropriate. Non-parametric data (number of attempts, number of passes, and pain scores) were reported as medians and interquartile ranges and were analyzed using Mann-Whitney U-test. Continuous data (age, height, weight, BMI, and time taken to perform spinal anesthesia) were reported as means ± standard deviations and were analyzed using ANOVA test using Tukey. P<0.05 was considered significant. We used SPSS version 23 (SPSS Inc, Chicago, IL) for our statistical analysis.

Table 1. Please remove the statistical comparison test and the p value. Just add the standardized difference.

P values for demographic data were deleted from the Table 1 of the revised manuscript.

Table 2 and 3 could be merged, adequately identifying the primary outcome of the secondary ones.

As suggested by the Editor, tables 2 and 3 are merged, and both primary and secondary outcomes are adequately identified in the table 2 in the revised manuscript.
The figure is not necessary, its results will be on the main table.

Figure 2 is deleted from the revised manuscript as its results are in table 2.

Reviewer 1

1. The design of the study have not eliminated two main sources of bias: 1) Patient bias: the anticipated degree of difficulty of obtaining a successful spinal anesthetic in the study population has not been standardized as an inclusion criterion for the study. For example, one group may have included more patients without features indicating a 'difficult spinal' than other groups and 2) Operator bias: residents who performed the spinal were junior resident who performed less than five spinal anesthetics. This is problematic because usually these residents with very limited experience can be at very different stages on their learning curve. It is assumed that about twenty repetitions of a certain procedure may produce a more even group of operators who have close levels of experience. This issue of sampling bias has to be addressed clearly in the discussion. The reader should be more confident that sampling bias has not been a factor in the observed results.

We agree with the reviewer that the design of the study did not eliminate two main sources of bias: 1) patient bias and 2) operator bias.

The following paragraph was added to the Discussion section of the revised manuscript to read: “the design of the study did not completely eliminate both patient and operator bias. However, we assumed that computer-generated randomization would equally distribute patients of different levels of spinal anesthesia difficulty and thus would decrease patient bias. Anyhow, results showed that none of our patients had scoliosis or previous spine operations, both of which are common features that would further increase the difficulty of spinal anesthesia. In addition, the ease of landmark palpation was not different among the three groups.

Although operator bias cannot be ruled out completely, we believe that our operator group is a homogenous one consisting of junior residents with less than 5 spinal anesthesia experience and at the lower end of the learning spectrum”.

2. Page 4 line 71: Define 'regular patient'.

“Regular patient” was replaced by “patients with normal back” in the Introduction section of the revised manuscript.

3. Page 5 line 97: Why the definition of an elderly patient was assumed to be patients above 60 years? It is always assumed from a chronological viewpoint, that medical treatment of the elderly starts from the age of 65 years old.
We agree with the reviewer that “it is assumed from a chronological viewpoint, that medical treatment of the elderly starts from the age of 65 years old”. However, the UN agreed cutoff is 60+ years to refer to the older or elderly persons. (http://www.searo.who.int/entity/health_situation_trends/data/chi/elderly-population/en/)

In the three groups, the mean age varied between 71 and 73 years.

4. Page 5 line 109: Was the presence of spinal abnormalities detected by imaging studies?

The presence of spinal abnormalities was detected only by physical exam and not by imaging studies.

The following sentence “Baseline patients characteristics recorded were: age, gender, body mass index, and presence of any spinal abnormalities (including scoliosis and previous spine operations with instrumentation)” was modified in the Methods section of the revised manuscript to read:

“Baseline patients characteristics recorded were: age, gender, body mass index, and presence of any spinal abnormalities (including significant scoliosis on physical exam and previous spine operations with instrumentation”).

5. Page 8 lines 162-168: Define clearly the primary outcome and highlight the difference between such outcome and the secondary outcome 'number of needle insertion attempts and number of needles passes.

As suggested by the reviewer, the primary outcome was clearly defined, and the difference between such outcome and the secondary outcome “number of needle insertion attempts and number of needles passes” were highlighted in the Methods section of the revised manuscript to read:

“The primary outcome measure was the rate of successful dural puncture on the first needle insertion attempt. Any additional needle attempt is defined as a complete withdrawal of the introducer needle from the skin and subsequent reinsertion. This differs from a needle redirection which is defined as an incomplete withdrawal of the needle from the patient’s skin and change in its insertion path. The secondary outcomes included the following: the number of needle insertion attempts required for successful dural puncture, number of needle passes (insertion + redirection attempts required for successful dural puncture),…”

6. Page 9 line 179-183: Name the statistical test used to calculate the sample size.

Sample size was calculated using the test of proportion.
7. Page 11 lines 233-246: The manuscript should not compare the results of other reports to the current results because the operators in this manuscript are first year residents and not senior residents or staff anesthesiologists.

The following sentence “Our findings contradict results reported in metanalyses suggesting that preprocedural US leads to reduction of the risk of failure and a lower number of needle passes compared to conventional palpation approach [10, 11, 12]” was modified in the Discussion section of the revised manuscript to read:

“Metanalyses suggest that preprocedural US leads to reduction of the risk of failure and a lower number of needle passes compared to conventional palpation approach [10, 11, 12].”

The following sentence “In fact, the first success rate in the LM and UM groups (77% and 73% respectively) were higher than that reported in a previous study conducted by Chin et al. in a nonobstetric patient population with difficult anatomic landmarks (32% in landmark group and 65% in US group) was modified in the Discussion section of the revised manuscript to read:

“In fact, the first success rate in the LM and UM groups (77% and 73% respectively) were higher than that reported in a previous study conducted by Chin et al. in a nonobstetric patient population with difficult anatomic landmarks (32% in landmark group and 65% in US group), even though operator in all cases in the aforementioned study was a clinical fellow in regional anesthesia or consultant with more than 5 yr clinical experience [1]”

Reviewer 2:

L118. Substitute "lumbar flexion" for "an arched back".

As suggested by the reviewer, the following sentence “All patients were requested to maintain an arched back posture” was replaced in the Methods section of the revised manuscript to read: “All patients were requested to maintain a lumbar flexion posture”.

L122. The description of the block allocation and the number of residents doing each procedure in each block is confusing. Please clarify how residents were selected to perform the study intervention when a subject was enrolled...presumably not all residents were available at all times, did they each do six in a row (as in the blocks you describe)?

It was easy to select junior residents to perform the study intervention when a subject was enrolled, since junior residents are available in operating room almost every day; and each resident did six spinal blocks in a row (added to the Methods section of the revised manuscript).

The statement that "the resident had to complete two to three blocks" is also confusing...a reader might interpret "blocks" as neuraxial procedures. Suggest renaming it "subject allocation blocks" or something similar.
The following sentence “… and had to complete two to three blocks” was modified in the Methods section of the revised manuscript to read: “… and had to complete two to three subject allocation blocks”.

L127. Was there any evidence of a learning effect over the course of the study? Please comment on this possibility and, if present, how was it mitigated

Potential learning effect over the course of the study could be present; however, it was mitigated by performing all spinal blocks in a row and minimizing the number of procedures done outside study. Yet, it must be noted that as per Kopacz et al., notable improvement in the spinal anesthesia technique among novice residents require at least 20 procedures to be performed (Reg Anesth. 1996 May-Jun;21(3):182-90). In our study, 12 residents performed each 12 spinal blocks and only 2 residents performed each 18 spinal blocks, all of which are below minimal required number (added to the Discussion section of the revised manuscript).

L133. What anatomic range was selected...between L1 and S1? Or more narrow? Earlier language seems to just say lumbar.

The following sentence was added to the Methods section of the revised manuscript to read:

“Lumbar interspaces selected were presumably between L2 and L5”.

The following sentence “The interspace that appeared widest was chosen for the first attempt,…” was modified in the Methods section of the revised manuscript to read: “The lumbar interspace that appeared widest was chosen for the first attempt, …”.

The following sentence “In group UM, the transducer was applied in the parasagittal plane, and after identification of the intervertebral levels, …” was modified in the Methods section of the revised manuscript to read: “In group UM, the transducer was applied in the parasagittal plane, and after identification of the intervertebral levels as described above, …”.

L149. Please describe explicitly where the skin mark was made...both sides of probe? towards midline?

The following sentence “… in the middle of the US probe” was modified in the Methods section of the revised manuscript to read:

“…at the intersection point of 2 lines joining the midpoints of long and short borders of the probe”.

L274-283...suggest summarizing/shortening this paragraph

The following paragraph was deleted from the Discussion section of the revised manuscript: “Turkestra et al. found that the time to perform the spinal procedure and its rate of completion by an attending anesthesiologist were 75 s and 10% via and mark technique versus 92 s and 15% via
the preprocedural US technique. These results are comparable to our findings (87 s and 12% in the landmark group vs 116 s and 20% in the US midline group, respectively).