Author’s response to reviews

Title: Comparison of lumbar plexus block using the axis in-plane method at the plane of the transverse process and at the articular process: A randomized controlled trial

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Author’s response to reviews:

Dear Editor:

We are very pleased to learn from your letter about revision for our manuscript entitled “Comparison of double guided lumbar plexus block using beach chair or short axis in-plane method: A randomized controlled trial” (Manuscript number: BANE-D-17-00216). Thank you for your attention and the helpful comments and advices. We have revised the manuscript according to the comments, and highlighted the modifications in the new manuscript compared with the original manuscript.

We would like to express our great appreciation to you and reviewers for comments on our paper. Looking forward to hearing from you.

Thank you and best regards.

Yours sincerely,

Rui Lv

Corresponding author: Kai-Zhi Lu
Responds to the reviewer’s comments:

Vishal Uppal (Reviewer 1): Thanks for the opportunity to review this trial. The authors are describing an interesting approach to lumbar plexus block (LPB).

Major strengths: The technique of ultrasound-guidance for lumbar plexus block is evolving, so the topic is important. Figures 1 and 2 are excellent in describing the technique.

Major weaknesses:

The description of the methodology and written explanation of the technique is not very clear. Please revise the methodology and results section in a way that allows the trial to be repeated if needed. The described technique resembles the shamrock approach, given the manner of ultrasound image acquisition, as described by Sauter et al. However, here the needle insertion approach is adjacent to the probe as opposed to para-median. The control group uses a technique as described by Doi et al, though this technique has not gained widespread popularity because of various logistical reasons.

Answer: Thanks very much for reviewer’s attention. It’s a very good advice. We have revised the methodology and results section to make them clearer.

The title is misleading: To compare "beach chair", an ultrasound image description, with "short axis in-plane method" which means a needle insertion approach is misleading. Please revise.

Answer: Thanks very much for reviewer’s comment. It’s a very good advice. We have revised it.

Feasibility of the technique: The authors have presented a mean BMI of 22 for their population. The height and weight information of the population is missing. I suspect their technique would be difficult to perform in the general population as the needle may not reach the lumbar plexus when inserted that far laterally. Furthermore, identification of structures may be difficult when you start with lateral above the iliac crest.

Answer: Thanks very much for reviewer’s attention. It’s a very good comment. In this study, we did not encounter a particular obese patient and the BMI of the most obese patient is 29. The biggest advantage of puncturing from the lateral abdominal wall is that there is no bony structure at the lateral side of the nerve root thus it could not obscure the image of lumbar plexus nerve root. Additionally, we adopted a low-frequency probe in the operation which can develop the image within 15 cm. Moreover, the tissue of lateral abdominal are very soft and the operator can press the probe to shorten the distance between the probe and the nerve root. Although the depth would be increase by doing that, the appearance of the bony structure in the image can help us locating. Although the probe is located on the iliac crest, the probe can be skewed to develop the nerve root imaging which is located below the iliac crest level. This can also show that when we encounter obese patients, we will take such action to find a clear image and avoid poor imaging
due to the depth increasing and fat scattering. Undoubtedly, we also consider that the subsequent multi-center study which has a larger sample should be done to further confirm our method.

The description of outcomes: The description of outcomes as used by the authors is confusing throughout: "image positioning time"; "puncture time"; and "number of puncture times". It is suggested these should be replaced by "imaging time," "needling time" and "number of needle punctures or attempts."

Answer: Thanks very much for reviewer’s attention. It’s a very good advice. We have revised it.

The rationale for the study is not convincing: On Page 4, line 55: "could not achieve the requirement of continuous visualization during the entire puncture process." The authors do not provide any reference or evidence to support this claim.

Answer: Thanks very much for reviewer’s comment. It’s a very good advice. We did not express clearly about this part. In the control method, the puncture site is close to the bony structure which located on the middle line of the back and the puncture angle could be limited by the obscuration of articular process. On account of this reason, the length of ultrasound image of lumbar plexus nerve root could be very short (only a part of image is developed) which would increase the difficulty of operation. We have revised it in the revised manuscript.

Page 5, line 5: The claim that the Doi technique reveals that "target is often located in this anechoic region" is incorrect. The Doi technique visualizes the plexus in the inter-transverse process area. As well, the authors refer to "rainbow shaped ultrasound signal" multiple times without any description or figure showing it. Please explain clearly.

Answer: Thanks very much for reviewer’s attention. Similar to the previous question, the part of target (lumbar plexus nerve root) could be developed in the screen but the image could not be displayed entirely due to the obscuration of articular process. This part discussed the same problem which has been illustrated previously; therefore, we have deleted this part in the revised manuscript. As for the "rainbow shaped ultrasound signal", it is the ultrasound signal of lumbar plexus root which has a certain range and is similar to the “rainbow” and we have added this explanation in the revised manuscript.

Methodology poorly described: The trial registry is in the Chinese language, therefore, I was unable to extract any information. The initials of the performers need to be provided e.g. RLV, CS, CY. The level of experience and the explanation of the training of the performers are missing. The method of performing the sciatic block needs to be described. Also, the length of needle used for the lumbar plexus block is not given.

Answer: Thanks very much for reviewer’s attention. We have added this information in the revised manuscript. The length of needle used for the LPB is 11 cm.

Statistical analysis: The primary outcome is not stated. The minimal clinically important difference is not given. Delta for sample size calculation is not described. I get an impression that a delta of 33% reduction in epidural spread was used (40%−6.67%).
Answer: Thanks very much for reviewer`s comment. It`s a very good advice. We have added this information in the revised manuscript.

Effect size:

Page 12: "The image positioning time [34.2 sec; 95% CI, (28.2-40.2) vs. 48.9 sec; 95% CI, (42.9-54.9), P = 0.001], the puncture time [85.0 sec; 95% CI, (68.8-101.2) vs. 131.4 sec; 95% CI, (99.8-162.9), P = 0.013]"

Instead of using CI of each value it would be more useful if the authors presented the mean difference (MD) of each outcome with 95% CI.

Page 13 "The incidence of epidural anesthesia in the beach chair group was significantly lower than that in the short axis in-plane group [1 case (3.3%) vs. 9 (30.0%), P = 0.006"

Please clarify if the authors have used chi-squared test for low expected counts.

Answer: Thanks very much for reviewer`s comment. We have added this information in the revised manuscript. We also adopted the standard deviation (SD) instead of using CI, which is a better indicator that could reflect the discretization of data.

Minor points:

The manuscript needs major language and grammatical editing.

Page 4: "L1-3 anterior branch, and L4 anterior branch." Could have been L1-4 anterior branches. "posterior quarter quadrant of the psoas major muscle" is usually described at posterior 1/3 of psoas. "so that it make the front, medial" should be "innervates the front, medial."

Answer: Thanks very much for reviewer`s attention. It`s a very good advice. We have revised it.

Page 8: Did the authors have any patients with failure to elicit nerve stimulation?

Answer: There are no patients with failure to elicit nerve stimulation. Because this is an objective indicator and we can locate the drug injection site suitably after the motion was elicited at the current of 0.3 mA.

Table 1: Please provide height and weight of population, remove column of p-values. For an RCT that is not needed.

Answer: Thanks very much for reviewer`s attention. It`s a very good advice. We have revised it.

Table 3 can be deleted as all the values are non-significant. This can be simply stated in the text. The first row, the third column says 9.3% instead of 93%
Table 2 and Table 4 should be merged

Answer: Thanks very much for reviewer’s attention. It’s a very good advice. We have revised it and deleted the Table 3.

Figures 1 and 2: Please provide labels for the structures.

Answer: Thanks very much for reviewer’s attention. It’s a very good advice. We have revised it.

Gianluca Cappelleri (Reviewer 2):

Specific comments

Abstract:

- What does maneuverability mean? The authors should provide a more clear definition for primary endpoint

Answer: Thanks very much for reviewer’s comment. We have revised it.

- P2L13: "High rate of epidural anesthesia". I think that the authors should use "epidural spread" rather than "epidural anesthesia".

Answer: Thanks very much for reviewer’s comment. It’s a very good advice. We have revised it.

P2L27 Methods. Please provide information about type and dose of the used LA.

Answer: Thanks very much for reviewer’s attention. It’s a very good advice. We have added the information of type and dose of the used LA.

P2L38 results: Numeric value of the results should be reported extensively; the pValue alone is not sufficient.

Answer: Thanks very much for reviewer’s comment. It’s a very good advice. We have revised it.

Background:

- The first sentence is not clear. LP originates from T12 to L5. The anterior branch from L2-L4 supply the obturator nerve, the posterior branch from L2-L4 supply the femoral nerve. The anatomy description should be more accurate. Please revise.

Answer: Thanks very much for reviewer’s comment. We have revised it.
- **P4L27:** The main advantage of LPB over spinal anesthesia is that LPB is a peripheral nerve block, therefore without or with few hemodynamic effects.

Answer: Thanks very much for reviewer’s comment. We have revised it.

- **P4L38:** references #8-10 report complications after LPB achieved with a pure landmarks technique. You can use just the same but you need to correct your sentence in the text.

Answer: Thanks very much for reviewer’s comment. We have revised it.

- **P4L60:** Background should be ended here. The following paragraphs must be moved to the methods (the new technique description) and to discussion.

Answer: Thanks very much for reviewer’s comment. It’s a very good advice. We have revised it.

Methods:

Presentation is confused. Both techniques have to be clearly described separately with all passages, avoiding the first paragraph (block details…) that is confounding and not useful.

- **P7L36:** ASA V or VI? Please correct to ASA IV or V

Answer: Thanks very much for reviewer’s comment. It’s a very good advice. We have revised it.

- **P7L55:** how randomization was performed? Description is confused. It seems that number of enrollment was not consecutive.

Answer: Thanks very much for reviewer’s attention. We get sixty random numbers which is generated by a computer-generated randomization code. These random numbers range from 1 to 60 and each number does not repeat with others. We put each of these random numbers in a sealed envelope according to their order in the number matrix and patients will acquiring it according to their order of visiting in anesthesia outpatient clinics; for example the first enrolled patient acquire the first envelope and we defined odd-numbered patients were incorporated into the beach chair group and even-numbered patients were incorporated into the control group.

- **P8L51** By writing simply "in a sterile manner" authors can better synthetize all the procedure.

Answer: Thanks very much for reviewer’s comment. It’s a very good advice. We have revised it.

- By considering the LA volume used for LPB (30 ml ropivacaine 0.5%) the authors should also provide the LA dose used for sciatic block.

Answer: Thanks very much for reviewer’s comment. We have added this information in the revised manuscript.
Short axis and beach chair description: These descriptions are very difficult to follow. The beach chair technique could be a logical consequence of the quadratus muscle approach recently described by Bendtsen (anesth analg 2017). You should mention it. A more accurate "English" description focusing on the structures visualize is needs.

Answer: Thanks very much for reviewer’s comment. It’s a very good advice. We have revised this part.

- P10L30: what's motion? May be you mean "motor" block

Answer: Thanks very much for reviewer’s comment. It’s a very good advice. We have revised it.

- How sensory assessment was made? By ice application? pinprick test? both? Yet, The Lateral-cutaneous nerve is a pure sensory nerve while the obturator is a motor nerve with a sensory distribution variable. How did you assess both? Please clarify.

Answer: Thanks very much for reviewer’s comment. It’s a good question. The sensory was assessed by both ice application and pinprick test. The ice application was used for assessing temperature sensory and pinprick test was used for assessing pain. In order to evaluate the effect of obturator block more accurately in this study, we also evaluated the adduction of the thigh. The obturator block would be considered successful when both the sensory and thigh adduction was blocked. Therefore we combined the sensory assessment with motor assessment of obturator nerve together in our study. We have added this information in the revised manuscript.

- In block assessment, after the description of the score, the authors have to provide a definition of success and how long they have considered to reach all criteria.

Answer: Thanks very much for reviewer’s comment. It’s a very good advice. The score which is less than or equal to 2 levels was considered as successful motor block. The patient was instructed to do the corresponding action to evaluate their motor block degree and it would take roughly 15 sec to do this assessment. We have added this information in the revised manuscript.

- How the epidural anesthesia was assessed? This fundamental point is lacking.

Answer: Thanks very much for reviewer’s comment. It would be considered that an epidural anesthesia has occurred when the sensory block occurred on the both side of leg. We have added this clarify in the revised manuscript.

- Statistical analysis: The authors cited an epidural incidence for both techniques but they did not provide a reference.

Answer: Thanks very much for reviewer’s comment. The epidural incidence for both techniques where we described in the statistical analysis section is the result of our preliminary experiment for this study and this is what we used to calculate the sample size in this study. Therefore, this data is not come from the other published research.
Results

- P12 from L22 to L38: This paragraph is superfluous. Data reported in table or figure have not to be reported also in the text. Please remove.

Answer: Thanks very much for reviewer’s comment. It’s a very good advice. We have revised it.

- P12 L58: The authors state that all patients had a successful LPB, but they did not report a definition of success.

Answer: Thanks very much for reviewer’s comment. It’s a very good advice. When the quadriceps twitches was triggered at the current of 0.3-0.5 mA and local anesthetic was injected successfully, it would be considered that we have carried out a successful LPB. We have added this information in the Assessment after block section.

Discussion:

The first sentences are not useful with the purpose of the article. A more logical structure is needed. The following is an example of brief outline:

- Presentation of results.
- The main differences with these results and literature,
- A possible explanation of the reasons for these differences
- Limitations of the study
- Conclusions

Overall the discussion is very difficult to follow and should be entirely revised.

Answer: Thanks very much for reviewer’s comment. It’s a very good advice. We have rewritten this part.