Author’s response to reviews

Title: A novel approach to neuraxial anesthesia: application of an automated ultrasound spinal landmark identification

Authors:

Ting Ting Oh (oh.ting.ting@singhealth.com.sg)
Mohammad Ikhsan (mohammad.ikhsan@u.nus.edu.sg)
Kok Kiong Tan (eletankk@nus.edu.sg)
Sultana Rehena (rehena.sultana@duke-nus.edu.sg)
Nian-Lin Reena Han (han.nianlin@kkh.com.sg)
Alex Tiong Heng Sia (alex.sia.t.h@singhealth.com.sg)
Ban Leong SNG (sng.ban.leong@singhealth.com.sg)

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Author’s response to reviews:

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To: Dr Guangde Tu
The Editor
BMC Anesthesiology

Dear Dr Tu,

RE: “A novel approach to neuraxial anesthesia: application of an automated ultrasound spinal landmark identification” (Submission ID: BANE-D-18-00450)
Thank you very much for the review of our manuscript entitled "A Novel Approach Using an Automated Ultrasound Spinal Landmark Identification for Neuraxial Anesthesia" (Submission ID: BANE-D-18-00450).

We appreciate your comments and kind help to improve on the manuscript.

Please find below point-by-point responses to each of the comments (in Italic red font). Amendments to the text are tracked-change in the revised manuscript.

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Reviewer reports

Vincent Chan (Reviewer 1):

The authors have revised the manuscript. I have remaining questions and comments.

Again I respectfully disagree with your primary aim "to evaluate the first attempt success rate of spinal anesthesia using landmarks obtained from the automated spinal landmark identification technique." I strongly believe that your primary aim should be to evaluate the correlation between spinal landmark identification by the automated machine and identification by an expert anesthesiologist skilled in spine imaging." Your image processing system does not improve operator error in needle insertion technique. This should be clearly addressed in the Discussion section.

------ Thank you very much for your time and effort to review our manuscript.

We chose our primary aim to evaluate the clinical relevance of the automated ultrasound guided system as we had previously evaluated the correlation between spinal landmark identified by the automated machine and identified by an expert anesthesiologist skilled in spine imaging in our preliminary study, which had showed a 93% correlation (reference number 13). We agree that the image processing system does not improve operator error in needle insertion technique, but we are evaluating how the automated ultrasound guided technique can improve first pass attempts despite variations in operator errors in needle insertion technique.
We have added the above statements in Discussion, Limitation, page 15

The text says, "The transverse scan consisted of horizontal movements of the ultrasound probe along the previously marked line at the level of L3/4 by the investigator with minimal rotational movements to obtain the best view." Who decides on the best view? Does the software program help the operator to get the best view? What signal does the machine provide if a good view is not obtained?

------ Yes, the software program assists the operator in finding the best view - the appearance of a green tick on the screen indicates the achievement of a good view. The green tick would not appear if no good view can be obtained. We have added the above statement in Methods, page 9.

Can the machine make faulty assumption and give wrong information when the ultrasound image is not optimal?

------ The program will only give instructions when ALL the anatomical landmarks are identified. Hence, having faulty assumption is less likely. We have added this statement in Methods, page 9

It seems that identification of the L3/4 interspinous space is important as a reference point. Can the machine software program be fooled to misinterpret the interspinous spaces e.g., L2/3 for L3/4? If yes, how does this happen?

------ The software program requires first identifying the sacrum and then counting the spinal level till L3/4. The abnormal anatomy such as fusion or reduced interspinous distance could increase the risk of misinterpretation.

We have added the above statements in Discussion, Limitation, page 15

How much can the software program pick up human error especially with regard to poor or suboptimal scanning skill and poor image acquisition?

------ When there is poor or suboptimal scans and poor image acquisition, the spinous level will not be detected and no green tick with the appropriate spinous level will appear.
Also, would ultrasound artifact fool the image processing system?

----- The parameters in the image processing systems have undergone the offline training based on anatomical landmark images from patient’s database, hence the artefacts are less likely to affect the image processing system. All the identified images landmarks have been validated by the clinician investigatorst during the study.

The above sentences have been added in Methods, page 9

How does the imaging system identify the ligamentum flavum and distinguish it from the dura in the transverse view? Most of the time, we cannot separate the ligamentum flavum from the dura and we call the 2 structures the posterior complex.

----- Thank you for your comments. We use the term “posterior complex”. We have changed the term “ligamentum flavum” to “posterior complex”.

Can the machine misinterpret the anterior complex as the posterior complex in some instance? The posterior complex may not be seen universally at a given interspace.

----- We have not had this problem. However, in abnormal or complex cases, we would need to validate in future trials.

The text says, "Even in normal surgical patients, the neuraxial anesthesia needle insertion first attempt success rate is only about 50 to 60% when the palpation technique is used."

----- This was not found in our study but in our referenced studies (references 10 and 11).

While ultrasound visualization of the interspace helps to identify the site of needle access, it may not improve successful needle insertion with the first attempt. Failure can be due to suboptimal needle insertion since this is NOT a real time ultrasound guided technique. We encounter this issue all the time with pre-procedure ultrasound scan during neuraxial needle insertion.

----- We are evaluating if identification of the site of needle insertion will improve successful needle insertion with the first attempt. Often, especially with junior trainees or in patients with more challenging anatomy, the wrong identification of site of needle insertion is a significant contribution to the inability to obtain a successful needle insertion with the first attempt. The utility of this automated spinal landmark identification is to circumvent errors in identifying site of needle insertion and henceforth, improve successful needle insertion with the first attempt.
The text says, "the primary hypothesis of the study was that automated spinal landmark identification algorithm using image processing system would achieve a mean 90% first attempt success rate of spinal anesthesia." It is important to state clearly who did the ultrasound scan and spinal needle insertion in this study. Were junior trainees recruited to participate in this study? Surely, as an experienced anesthesiologist, the success of first needle spinal attempt must be > 90% in normal sized young patients with normal spine anatomy. Please clearly state who performed the scan and needle insertion and their level of training in this study.

------ The scans were done by only the principal investigator and co-investigator who are anesthesiology specialists. However, the needle insertions were done mostly by anesthesiology trainees who were assigned to the operating theatre as our center is a teaching hospital in obstetric anesthesia.

The above sentences have been added in Methods, page 10.

Please write a full paragraph on the limitations of your imaging processing system. What can fool the machine? What errors can the machine make? What is the margin of error with this system? Has the accuracy been validated against expert evaluation or any other well established imaging tools?

------ The limitation of the proposed image processing program is the high sensitivity required of quality of ultrasound images. However, it is crucial to achieve a high accuracy (less false positives) at the sacrifice of non-optimal recall rate. This may lead to possible additional attempts in scanning as the algorithm is highly specific to only accept given information when all landmarks are detected. The system is validated by our study population (young obstetric women with BMI below 10kg/m2) and it is not designed or/validated by complex spinal anatomy, obesity patients, paediatric patients and/geriatric populations.

We have added the above statements in Discussion, Limitation, page 15.
Does this image processing system work for individuals of any age? Have you tested in children and infants?

What does this software show when a scan is performed in an elderly 50 kg person with severe spinal stenosis? While it is easy to identify the spinous processes, the interspinous spaces may be too narrow to be imaged. Can the software still identify the levels properly?

-----The limitations of our study involves the study population being mostly obstetric and thus, lacking in heterogeneity. The program has not been tested in the paediatric and geriatric population in our study.

In the Results section, please report the following:

1) Skin to spinous process and ligamentum flavum distance in successful and failed first needle attempt.

------ Thank you for your feedback. We have done the analysis as requested. The 1st attempt distance is 44.7 (6.3) mm and non 1st attempt is 39.6 (6.7) mm. Hence the distance measured would not provide sufficient reason for why these patients had more than 1 attempt at insertion.

The results have been added in Table 1. We have changed the term “ligamentum flavum” to “posterior complex”.

2) Detailed information on patient characteristics (e.g., height, weight, BMI), level of operator training, imaging processing result and needle insertion for failed first needle insertion. In other words, what are the common reasons for failure?

------We have provided the detailed information on patient characteristics (Height, weight, BMI) in Table 1. The level of scanning operator is performed at investigators who are consultants. The imaging processing information is provided on being able to identify the landmarks and the number of needle attempts are provided in the manuscript.

There are no obvious reasons from our study from the information that could suggest failure. Thank you for your feedback and we have included some of the limitations of the study in the discussion.
3) The text says, "Primary inaccuracy was mainly due to the poor identification of the L5/S1 interspace." Please elaborate on this point. Was this due to poor operator scanning skill, spine anatomy or both?

-----We are uncertain of the exact reasons on review the spinal anatomy seem uncomplicated.

I still believe figure 2 shows laminae and not spinous processes.

-----Sorry for the error. We agree that figure 1 shows laminae. Correction done.
We have changed the term “spinous process” to “lamina”.

Rakhee K. Goyal (Reviewer 2):

-----Thank you for your time and effort to review our manuscript.

Berrin Günaydin (Reviewer 3): Acceptable.

-----Thank you for your time and effort to review our manuscript.