Author's response to reviews

Title: Vocal local versus pharmacological treatments for pain management in tubal ligation procedures in rural Kenya: a non-inferiority study

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Version: 3
Date: 2 January 2014

Author's response to reviews: see over
Dear Editor and Reviewers,

We thank the editor and the two reviewers for taking the time to read our manuscript carefully, and for their helpful comments, which have helped improve the paper overall. Below is a point-by-point response to each comment. We hope these adequately answer your questions. Do not hesitate to contact us for further clarifications.

**Editorial comments:**

The ethics aspects related to the study are not discussed: approval by the local Ethics Committee, collection of informed consent, possibility for the women not to take part in the study, etc. Please describe these aspects in the methods section.

*Thank you for your comments. We have added more details of the informed consent procedures on page 5.*

**Reviewer 1:**

1. Were the patients informed about no use of analgesia while taking an informed consent? What was their response?

   *Yes, the patients were informed about no use of analgesia. As mentioned in the article, pain management without use of analgesia is in fact the standard technique used in MSI mobile clinics, so they were not withheld any treatment, and were aware that this was the standard technique in MSI clinics. We have added a few sentences to clarify this on page 5-6.*

2. Were all cases at a center performed by same doctor? How does it impact the study?

   There were 4 teams in each arm equalling 4 teams in total. Each team was trained to provide VL+LA or VL+LA+analgesic. So all cases at a given centre were performed by the same team, but not all cases in each of the study groups (control or intervention) were performed by the same team. The only way this could lead to some bias is if the 2 teams in each study group were more similar to each other than to the 2 teams in the other study group. However, there is no reason to believe this was the case: all teams were trained equally, and having two teams (rather than one) in each arm ensured the differences between the control and intervention groups were not simply due to a particular team’s way of performing the procedure.

3. How were the assistants trained for VL? By whom?

   *Assistants followed standard MSI training for VL as part of their job training, since VL is part of standard MSI pain management techniques. In addition, a refresher training*
course for VL was conducted before the start of the study. We have added a sentence to this effect on page 5.

4. Does training of these assistants, keeping separate assistants for this job does not incur charges? Considering this fact, how to explain cost reduction?

The VL technique is standard practice in MSI mobile clinics, so there are no extra costs for this study compared to what is usually being done. The cost reduction is explained by cost savings from not providing additional analgesics, and shorter treatment times due to not having to administer analgesics (enabling a greater client turnover).

5. How can this technique be useful in Cesarean as mentioned by the author? Local anaesthesia is not recommended for Cesareans?

This technique can be useful in any procedure where anxiety reduction and distraction can help manage pain for the woman, including a Cesarean. VL is not limited to procedures involving local anaesthesia. Thus, VL can also be used in a Cesarean either as a complement to analgesics or as a substitute (if further research shows it to be as effective as analgesics for Cesareans).

6. Most painful moment should have also included the time of performing the procedure as most of the patients have maximum pain while holding the tubes.

The most painful moment did include the time of performing the procedure, it was up to each individual woman to decide when her most painful moment was, and in most cases this was indeed the moment the ligation was performed. An explanation of this outcome has been added on page 6.

Discretionary Revisions
7. Cases and controls were recruited from different centers. This could have led to many biases including the different personnel giving VL differently. What do the authors say about allocation of patients in two groups from each center?

The personnel performing the tubal ligations were the same across centers (see point 2 above) so there was no bias in the way the treatment was delivered. However, it is possible that clients from different centers exhibited differences in certain characteristics that could have affected the outcomes. To adjust for these potential differences between clients in different centers, we collected information on various personal characteristics that might differ between centers and that might affect the outcomes (potential confounders, listed in table 4), including for example socio-demographic characteristics and travel time to the clinic, and we controlled for these in the multivariate regressions.

Minor Essential Revisions
8. Brief description of VL technique would increase the value of this article.
The VL technique is described in paragraph 2 of the background (page 3). We have added a few more details to give the reader a better understanding on the technique.

Reviewer 2:

Thank you for the submission to this journal, please consider the following: in the Abstract, define VL/LA and in the body of the article initially, change opiate to opioid, background expand on VL AND LA on p3;

Thanks, these changes have been made, and we have expanded on the VL technique on page 3, and LA on page 4.

p 4 anesthetic define which one, analgesics define which one, later tramadol comes up with lidocaine/lignocaine.

We have defined which analgesic and which anesthetic on page 4.

As an aside consider the expectations of other patients in other countries where a broader plan of ob anesthesia/analgesia is expected, this deserves retrospective/prospective comments on patient expectation and how this unique method may be population specific.

Thank you, this is an important and interesting point. We have now added a paragraph to elaborate on this on page 11-12.