Author’s response to reviews

Title: The MOVE-trial: Monocryl® vs. Vicryl Rapide™ for skin repair in mediolateral Episiotomies: a randomized controlled trial.

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Author’s response to reviews:

Concerning the second re-submission of the manuscript PRCH-D-16-00466

“The MOVE-trial: Monocryl® vs. Vicryl Rapide™ for skin repair in mediolateral Episiotomies: a randomized controlled trial.”

Dear Madam/Sir,

We would like to re-submit the manuscript and we would like to thank the editors and reviewers for the re-assessment of the manuscript and for the suggestions made to improve the manuscript. You will find our response to each comment of the reviewers below, itemised one by one.

All line numbers indicated in this cover letter correspond with the line numbers in the second revised version of the manuscript. This means the line numbers in the comments also have been changed to match the revised manuscript.
Reviewer 1.

Thank you for the possibility to re-review the manuscript of Odijk et al. The authors have made significant changes to the manuscript based on the comments from both reviewers. The quality of the manuscript was improved considerably. I recommend the article for publication without further comments.

Response

We would kindly like to thank the reviewer for the work in re-assessing our manuscript and are happy with the reviewers’ recommendation to publish the manuscript.

Reviewer 2

The authors made significant improvements to their manuscript reporting the results of their randomized controlled trial of suture types (Monocryl® vs Vicryl Rapide™) for repair of uncomplicated episiotomy after vaginal delivery in primiparous patients. They addressed the reviewer comments, however there are a few outstanding points that could be clarified.

Comment 1. While the authors met their goal enrollment of 250 patients to achieve a 90% power to detect a 1cm difference in VAS scores at 10 days, the significant loss to follow up results in comparison groups that are underpowered to detect their primary difference. Although the authors address the loss to follow up as a limitation to the study, they should use caution in assuming that their results are not biased. Especially since VAS scores did not correlate with analgesic use in this cohort, it may be inaccurate to assume that those who did not complete the questionnaires are similar to those who did (or have less pain than those that did).

Response: We fully agree with the argument made by the reviewer. We did indeed not assume that the responders and non-responders were similar. As stated in line 291-293 the group of non-responders was significantly younger and contained significantly more non-Caucasians. There definitely is a possibility of bias with the non-responders being different on primary or secondary outcomes compared to the in the group responders

However, when corrected for age and Caucasian background there was no difference between the two materials in VAS scores at day 10. The loss to follow up was also similar in the Monocryl® and Vicryl Rapide™ groups. So although it cannot be ruled out it seems unlikely that this bias has been in favor of one of the materials.
Background:

Comment 1. Line 59: Please replace 'has' with 'have'
Response: The suggested replacement has been made.

Results:

Comment 1. Line 195-196: The decision to remove this section from table 4 and discuss in text adds to the clarity of the table. However, these differences are small and not clinically or statistically significant. These 4 lines could be replaced with a statement that there is no difference in intercourse at 10 days postpartum or in analgesic use at 6 weeks or 3 months postpartum.
Response: The suggested change has been made. We agree that this adds to clarity in this segment of the article.

Comment 2. Line 200-206: The thorough discussion of VAS scores in the ventouse vs spontaneous groups may be unnecessary. As this study did not aim to address differences in pain with ventouse deliveries, but this was a notable difference in the groups after randomization, the statement beginning with "after correction for the difference" (line 206-210) is sufficient for this discussion. Lines 200-206 can likely be eliminated.
Response: We do agree that the conclusion of the paragraph is the relevant part and that the first part of the discussion is of less relevance. We removed the suggested section.

Comment 3. Line 215: Please replace 'then' with 'than'
Response: The suggested replacement has been made.

Comment 4. Line 223-227: Please include corresponding p-values to correlation coefficients.
Response: p values were included in the article. The p value for 24 hours was 0.22. This means that there was not even a significant correlation between VAS score and analgesic use. After 10 days the correlation was significant (p=0.01) but at 0.22 was still very weak.
Discussion:

Comment 1. Line 244: it seems this sentence is missing the word 'pain' after 'interrupted sutures may cause…'

Response: The sentence indeed was somewhat confusing. The sentence was rewritten and now is “Due to external knots on the perineal skin, interrupted sutures may cause the painful so-called “barbed wire effect”.

Comment 2. Lines 268-270: The addition of the statement regarding the benefit of resuturing episiotomies deserves further discussion in this paragraph. The statement seems out of place as the concluding thought of the paragraph.

Response: To our knowledge common clinical practice is to treat dehiscence of episiotomies expectatively. We considered the recent finding that resuturing of the episiotomies does decrease complaints relevant for anyone interested in dehiscence of episiotomies. This led us to believe bringing this article to the attention of the reader was a useful addition to the discussion on this topic. What the clinical significance was of the self-reported dehiscence in our trial is unclear. The statement was indeed somewhat out of place as the concluding sentence in the paragraph. We therefore moved it to be the introductory statement of the paragraph.

Comment 3. Lines 273-274: The statement 'depending on the suture material' is confusing. The percentages refer to the follow-up time, not the suture material group, and there was no difference between suture materials as stated in the subsequent sentence. That statement can be removed.

Response: The statement can indeed be confusing and the statement was removed.

Comment 4. Line 281: Please replace 'lost' with 'loss'.

Response: The suggested replacement of “lost” with “loss” was made throughout the article wherever appropriate.

Comment 5. Line 284-285: The authors state in line 284 that patients were contacted with text messages but go one in 285 to say 'despite phone calls'. Did patients receive both text messages and phone calls? Please clarify.
Response: All patients received text messages at 10 days, 6 weeks and 3 months. Only when the questionnaires were not received in the weeks to months after the 3-month post partum questionnaire phone calls were made. Unfortunately a significant portion of women did not answer repeatedly or did not sent back the questionnaires after the telephone calls.

We hope we addressed all comments of the reviewers appropriately and think we have improved the quality of our manuscript. We would like to thank the reviewers for re-reading the manuscript and providing additional feedback.

We hope the manuscript is suitable for publication in your journal in its current form.

We look forward to your response.

Yours Sincerely,

On behalf of the research group,

Roeland Odijk