Author's response to reviews

Title: Musculoskeletal sequelae in patients with obstetric fistula - a case-control study

Authors:

Merete K Tennfjord (merete.kolberg@gmail.com)
Mulu Muleta (m.muleta@yahoo.com)
Torvid Kiserud (torvid.kiserud@kk.uib.no)

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Author's response to reviews: see over
Dear editor of BMC Women’s Health

Thank you for your valuable suggestions to our manuscript “Musculoskeletal sequelae in patients with obstetric fistula - a case-control study” and for the positive and constructive review. Below we have provided itemized answers and made the amendments in the text visible using the change-tracking application. We have also submitted a clean copy of the revised manuscript.

Editor's Comments:

"Minor essential revision - The authors need to add details of the ethics committee who approved the study.
Answer: Additional information has been provided on page 5, line 90: “The study was approved by the Regional Committee for Medical and Health Research Ethics, Western-Norway (REK Vest 2010/503), and the ethics committee of Gondar University, Ethiopia (RCS/05/540/2010), and carried out in agreement with the Helsinki declaration.

Minor revision - the footers of the table should read 'statistical significance' rather than 'statistically significance'
Answer: The text is amended accordingly.

Minor revision - please also clarify the # footers. The median, range and 95% CI appear to be presented, rather than the stated median with p values."
Answer: 95% CI is substituted by p-value in table 1

Editorial Requirements:

1. STROBE guidelines

In accordance with BioMed Central editorial policies (http://www.biomedcentral.com/about/editorialpolicies#StandardsofReporting), could you please ensure your manuscript reporting adheres to STROBE guidelines(http://www.strobe-statement.org/) for reporting observational research. This is so your methodology can be fully evaluated and utilised. Can
you please include a completed STROBE checklist as an additional file when submitting your revised manuscript.

Answer: A checklist has been uploaded with the revised version of the manuscript including references to page numbers. Page 9, line 191: New sentence: “Incomplete or missing data were included in the analysis and is listed in the tables were appropriate”.

2. Acknowledgement:

Please also include the source(s) of funding for each author, and for the manuscript preparation. Authors must describe the role of the funding body, if any, in design, in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication.

Answer: Page 17, line 395: “The project received economical support for data collection and publishing from University of Bergen and the Norwegian Physiotherapy Association. MM was employed by Women and Health Alliance International and TK by University of Bergen during the study period. These sources have had no involvement in designing the study or how data were collected, analysed or interpreted, or whether to publish the results”.

Referee 1:

Minor Essential Revisions:
- Information is needed in the methods as to who performed the examinations, and how they were trained and standardized.

Answer: New information added on page 6, line 121 “A protocol was prepared and the test procedures were conducted twice with a few days in between in each volunteer to ensure reproducibility. The preparatory period was conducted in Norway by the main investigator and in Gondar by the second investigator. It was not possible for the investigators to do simultaneous testing on the same women. Due to time constrains a walking test and sensory testing were not carried out.

On page 7, line 139 information was already provided related to standardisation of the measurements.

- Please present the results on weight, height and BMI in the results.

Answer: New sentence added on page 9, line 199: “There was a significant difference between cases and controls for weight, 44.9 Kg, (SD 6.8) versus 48.7 (SD 8.2) (95%C I: 0.9, 5.5) and for height, 151.6 cm
(SD 7.4) versus 156.7 (SD 5.6) (95%CI: -7.1,-3.0), respectively, but no difference in BMI, 19 (SD 2.4) versus 19.31 (SD 3.3) (95%CI: -1.2, 0.6), respectively.”

- The results were not adjusted for age, and so the difference between cases and controls may have been due to confounding (though the age distribution was similar between these groups). It would be important to either adjust for age, or else to explain the potential impact of not having adjusted in the limitations section of the discussion.
Answer: Age was not different for the study group and controls. We have not found any plausible reason to believe that age in this study should impact the groups differently. Since the reviewer suggests a possible confounding effect we explored the possibility by stratifying by age ≤20 and >20 years and found no indication that age could have influenced our results e.g. the results were still significant in the age group >20 years. In the age group ≤20 some of the variables were no longer significant different between groups, but the results were hampered by the reduced statistical power. We have not included this in the manuscript but are willing to do so if the editor advises so.

Discretionary Revisions
- Page 5, line 109. This sentence is not clear to me.
Answer: We have changed the sentence to (Page 6, line 113): “The controls were recruited if they came from a rural area and were matched for age (±5 years) and years since delivery (±5 years)”.

- It would be helpful to explain how the cases were recruited to the hospital, if this is known. Was this through screening camps, or did the women present themselves?
Answer: New sentence added on page 5, line 103: “The fistula patients presented themselves to the hospital in Gondar or were invited through information campaigns”.

- In the methods it states that the controls were matched to the cases on age and years since delivery, yet there were many more controls than cases and so this does not seem coherent to me.
Answer: The study aimed at recruiting 100 cases and 100 matched controls, but due to time constrains only 70 cases were recruited. This information is already provided in the results section page 9, line 197.

- Did the live born neonates of any of the controls die in the first week of life (page 9, lines 202)?
Answer: The control group had three stillborn, but none of their live born died within the first week of life. This information is inserted on page 10, line 218: “...and none in the control group”.

- In the tables - I would suggest reporting result to one decimal place throughout (it varies a bit) P values should be presented to 2 significant figures.
Answer: This has now been taken into account.

Referee 2:

Minor essential revisions
1. Within the Results, Socio-demographic characteristics you note a statistically significant difference between the fistula and control groups in relation to parity, so I feel this should be discussed.
Answer: New sentence has been added in the discussion on page 11, line 260: “The high number of primiparous women in the study group (one of the factors thought to increase the risk of developing neurological and musculoskeletal deficits [7]) may have skewed the result towards a larger difference.”

2. Title (and elsewhere in text). I think it would be more accurate to use the term sequelae rather than sequel as there are several impairments/changes reported
Answer: This is now changed.

3. Pain is mentioned under methods in the abstract and throughout the submission. How was this assessed/measured? Were the women only questioned about leg pain specifically?
Answer: The women were asked about body pain and were asked to mark this pain location on a figure. The information related to lower extremities were reported if the pain was from pelvis and down.
New sentence added in methods. Page 6, line 135: “The latter was drawn from a figure in which the women were asked to mark if they had pain somewhere in the body.”

4. Throughout, there is mention of activities of daily living (ADL) sometimes referred to in the text as daily life activities. Could the terminology be standardised?
Answer: This has now been changed.
5. How were the women questioned about ADL? Were they asked about particular, relevant ADLs e.g. lifting?
Answer: The women were asked about ADL such as cooking, cleaning, carrying the children, bringing water to the household etc and registered as a problem if it was related to walking.
New sentence added on page 6, line 130: “Difficulties with activities of daily living (ADL) were noted if it was related to walking when taking care of the house and the children, cooking, cleaning etc”.

6. Under Methods, Joint range of movement, there is no mention of ankle inversion and eversion but this is reported in the results table
Answer: Ankle inversion and eversion were only tested for strength, not range of motion.

7. How were the women questioned about their walking? It would be interesting to know the line of questioning. Were distances involved?
Answer: The women were only asked whether they had difficulties in walking, yes or no, but not distance, or other information that could have detailed this issue. We planned on including a walking test “timed up and go”, but due to the restricted examination space and time constrains this was left out:
New sentence added on page 6, line 125: “Due to time constrains a walk test and sensory testing was not carried out.”
New sentence is added in the methods section, page 6 line 131: “The information on walking and ADL was registered as yes or no”.
New sentence added in the discussion section, page 15 line 355: “A more complete representation of the musculoskeletal deficits would have been achieved by including sensory and walk tests. However, due to time constrains these tests were not carried out.”

8. The results under Musculoskeletal findings are confusing when considered alongside Table 2. The table indicates that 20 women had walking difficulties after delivery, and 19 at the present time. In the text, it says 4 women reported spontaneous recovery, and 2 had recently developed difficulty, which would make a total of 18. I think this needs to be amended or explained differently if I am misunderstanding the figures.
Answer: a new sentence is added in the results section to clarify the issue, page 10 line 224: “One fistula case (1.4%) with walking difficulties before the index pregnancy had these difficulties at present and four (4%) of the controls”.

Discretionary revisions

9. Under Methods, Outcomes, there is brief mention of a preparatory period using the tests on 12 women. Could this be expanded on a bit? Did this lead to any changes in the study protocol? 
Answer: The preparatory period did not lead to changes in the protocol. New information added on page 6, line 121. “A protocol was prepared and the test procedures were conducted twice with a few days in between in each volunteer to ensure reproducibility. The preparatory period was conducted in Norway by the main investigator and in Gondar by the second investigator. It was not possible for the investigators to do simultaneous testing on the same women. Due to time constraints a walking test and sensory testing were not carried out”. This question was also elaborated under point 7.

10. Although the number of women with foot drop was low, might there be some discussion about the fact that they were all right sided? 
Answer: We have referred to two studies that describe this finding, one among women with obstetric fistula and another study on women with obstructed labour and no fistula. Both studies found drop foot on the right side to be more common but with no plausible explanation for this result. We have slightly expanded the text correspondingly, page 13, line 286: “Foot drop was found on the right side, a finding seen in previous studies [5, 13].”

11. Could there be some discussion about why there might be diminished reflexes within the control group? 
Answer: New information added on page 12, line 265. “On the other hand side, the reduced Achilles reflex in the control group could possibly reflect their reasons for seeking medical help”.

We have tried our best to respond to the reviewers’ comments and we believe the manuscript has improved hopefully to a publishable level.

With kind regards
Merete Kolberg Tennfjord
Mulu Muleta
Torvid Kiserud