Author’s response to reviews

Title: Obstetric fistulae in Southern Mozambique: Incidence, obstetric characteristics and treatment

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Version: 1 Date: 13 Oct 2017

Author’s response to reviews:

Overview:

…The authors did not use any statistical analysis to analysis the data. Therefore, I did not see the relevant of this paper. It is better to publish it as a case report rather than research.

Thank you for the comment. We aimed to estimate the incidence of obstetric fistula and, to this end, over 4000 participants were interviewed to identify incidences of fistula. Therefore, this cannot be considered a case report. The very few numbers of confirmed fistulae that we found did not permit further in-depth epidemiological analysis. We were aware, from anecdotal evidence, that some cases of fistulae still occur, particularly in poor rural areas, but there was no scientific evidence to support this occurrence, nor was there any quantification of the problem. This paper fills the gap in the literature regarding the sparsity of fistula incidence and prevalence data in Mozambique.
Abstract:

…on the methodology part the authors did not explain about how they select the study participants as well as what type of software used to analysis the data.

Thank you for the comment. We acknowledge that the explanation given may not have been sufficiently clear. A cohort of women of reproductive age (12–49 years) was formed from a baseline census covering households in rural areas of Maputo and Gaza provinces, Southern Mozambique, as part of an ongoing intervention trial (the Community Level Interventions for Pre-eclampsia trial or CLIP trial). We identified from this cohort all women who had delivered during the 12 months before the start of the study (June, 1st 2016). From this group, we interviewed all those who we were able to join after a maximum of two attempts and who had agreed to participate in our study.

We have made changes in the text to clarify how we selected the study participants as well as the type of software used to analyse the data.

Page 2 and 3

Ln 44-50: We selected women who had delivered up to 12 months before the start of the study (June, 1st 2016). They were part of a cohort of women of reproductive age (12–49 years) recruited from selected clusters in rural areas of Maputo and Gaza provinces, Southern Mozambique, who were participating in an intervention trial (the Community Level Interventions for Pre-eclampsia trial or CLIP trial). Case identification was completed by self-reported constant urine leakage and was confirmed by clinical assessment. Women who had confirmed obstetric fistulae were referred for surgical repair. Data were entered into a REDCap database and analysed using R software.

Background:

…In this section, the authors should describe about the magnitude of obstetric fistula in worldwide and the magnitude of obstetric fistula in developing countries as well as in Mozambique.

Thank you for this important comment. We agree that estimates on the magnitude were missing in our previous version of the manuscript. We have revised the text accordingly.

Page 4, Ln 84-92: Obstetric fistula is one of the most devastating consequences of unmet needs in obstetric services. The World Health Organization (WHO) defines a fistula as an abnormal
opening between the woman’s vagina and bladder and/or rectum, through which her urine and/or faeces continually leak [1]. Estimates indicate that two million women suffer from undetected or untreated fistulae globally, and that 50,000 to 100,000 new cases occur each year, mainly in low- and middle-income countries (LMICs) in sub-Saharan Africa and South Asia [2], where maternal mortality is high [3, 4]. While the most common cause of fistula is prolonged or obstructed labour [5, 6], recent studies suggest that an increasing proportion of urogenital fistulae in LMICs may be iatrogenic, mainly resulting from caesarean section [5].

Page 4-5, Ln 93-97: Reported rates of obstetric fistula in LMICs vary widely, from 0 to 4.09 obstetric fistula cases per 1000 deliveries, and reliable data on the prevalence and incidence are sparse [7]. Most estimates are based on self-reporting, personal communication with surgeons, studies conducted by advocacy groups, and the review of hospital services. In all of these reports, the relevant denominators, such as the source population and number of births, are unknown or unreported [8-10].

We also added the comment that very few data exist in relation to Mozambique.

Page 5, Ln 116-119: In 2015, it was estimated that 100,000 women suffer from obstetric fistula in Mozambique [22], and only 556 were identified and underwent surgery for the condition during the campaigns for fistula treatment [Melo, A.; Unpublished data from the Mozambican National Programme for fistula prevention and treatment, 2015].

…Moreover, what interventions have been done to alleviate the existing problem? What was the outcome of the intervention? What is the gap still not addressed by the implemented strategies.

Thank you for raising this point. The aim of this article is not to describe the existing interventions, but instead to estimate the incidence of obstetric fistulae in recently delivered mothers, and to describe the clinical characteristics and care, as well as the outcome after surgical repair. We report here on existing interventions, but in relation to the gaps that still need to be addressed. We highlight the on-going Mozambican National Programme for fistula prevention and treatment and their campaigns for performing fistula surgery in all provinces, and we stress the lack of adequate epidemiological data for better strategic planning.

Page 5, Ln 113-116: In Mozambique there is an on-going programme for fistula prevention and treatment which consists of raising awareness, early detection and surgery campaigns in all provinces, however exact data on the prevalence and incidence are not available [22], thus limiting the effectiveness of programme planning [23].

…Generally, the paper needs extensive grammatical edition thought-out the document.
We thank you very much for this important comment. We acknowledge that English is not our first language and have had the manuscript edited by a professional language editor before submitting the revised version.

Methods:

…The authors mentioned about the sample size calculation, but they did not show us anything how they calculated it.

Thank you for the comment. We have addressed this point and rephrased our explanation about the sample size calculation: Page 7, Ln 151-152. The sample size calculation was based on the prevalence of 0.15% reported by Adler et al. [25]. A sample of 3700 births was deemed appropriate to estimate the prevalence with a 0.05 significance level.

…The authors did not report anything about the quality assurance of the data

Thank you for the comment. In relation to the quality assurance of the data, we previously stated that (Lines 162-163) the questionnaire was pre-tested and piloted before its application. Details relating to the process of ensuring the quality of the data have been added. Page 8

Ln 181-187: Data collectors were monitored by the field supervisor to ensure their compliance with the study protocol. The supervisors performed random second interviews with 1% of the women to test the quality of the data and to determine whether the data collectors needed re-training. Once a week, the PI and the data management team reviewed both the completed questionnaire and the database to check for missing answers, duplications and inconsistencies, and, if needed, the data collector was sent back to the field to gather data where corrections and clarifications were necessary.

…The authors did not talk about either the training was given to the data collectors or not

We have improved the description of the data collectors to make the training process more clear.Page 8, Ln 177-181:

Data were collected by means of structured interviews at household level between June 1st, 2016 and October 28th, 2016 by 13 experienced female data collectors who had been trained on the protocol, the data collection forms, and the administration of informed consent. Special focus was placed on the appropriate approaches to take when asking sensitive questions and on when to communicate the Portuguese questions in the local language (Changana).
…On the analysis part, the authors used R software but they did not assess any factors which affect the incidence of Fistulæ why

Thank you for the comment. We agree that it would have been helpful to assess the factors that affect the incidence of fistula, however, our sample size and the fact that we only identified 5 cases precluded such an analysis.

…Page 5, line 117, on method, the authors said that they interviewed recently delivered women. What does recent mean? If it includes immediately after delivery, the complication might be due to other cause which may result during Labour cell contraction. And also, how did you relate pre-eclampsia with obstetric fistula?

Thank you for this comment. By recently delivered women we mean women who delivered during the 12 months before the start of the study. As described in the literature, fistula usually occurs between one and 10 days after delivery. That is why we did not include women who had delivered during the 15 days before the start of the study. We have improved the phrasing of this description. Page 6, Ln 126-129: We interviewed recently delivered women (mothers), defined as those having given birth during the 12 months before the start of the study (June, 1st 2016). We did not, however, include those who had delivered in the two weeks preceding this time, as fistula usually occurs between one and 10 days after delivery.

We did not intend to relate obstetric fistula with pre-eclampsia. The cohort of women of reproductive age was established by the census conducted as part of the CLIP study for the purpose of the trial. We used that database to identify and then interview those women who had already delivered without relating to the occurrence of pre-eclampsia during their pregnancies. Page 6, Ln 132-133: The CLIP database was only used to facilitate the identification of the women and their households.

…What type of intervention was taken for women confirmed with fistula? All mothers with fistula were referred to Maputo Central Hospital for surgical fistula repair. We have clarified this point by providing further information. Page 9, line 199-200: All mothers identified as having a fistula were referred to Maputo Central Hospital for surgical fistula repair. The study team provided transport and support throughout the process.
Results:

…IIn this section, the researchers reported about the characteristics of five cases with detail description as a result this is a case report rather than research finding. Therefore, for researchers I recommended to do reanalysis to see the determinants of fistulae among these women's otherwise this finding is simply reporting the number of cases. As a result, this might have no any implication for implementation.

Thank you for this important comment. We acknowledge the reviewer’s point and agree that it would have been helpful to identify determinants of fistulae using regression analysis. However, the fact that we only identified 5 cases precludes such an analysis. In fact, the aim of our household survey was to estimate the incidence of fistulae. We believe this is an important research question in view of the scarcity of evidence, as highlighted in the review by Adler et al (2013) and the recommendations from Tunçalp et al. (2014). We therefore chose to present a detailed description of the clinical assessments, as presented in Table 2, as they related to the occurrence of fistulae and indicate possible aetiology. We believe that by showing that delays occurred at the health facilities we have raised the issue of the need to improve the quality of care and to explore the possibility of including iatrogenic fistula in future research.

…As observed on page 10, line 216, table1, Characteristics of the mothers with obstetric fistula, women found in the reproductive age group, that means 15-49, but nothing has been said on the ethical issues of women age less than 18 years old in the method sections. Therefore, how did you managed the ethical issues of these women, since they did not give consent for their self??

Thank you for rising this important issue. According to our study protocol, mothers aged less than 18 years (although according to the Mozambican law women are allowed to get married from age 16 and are considered emancipated) were asked about their willingness to participate and informed consent was first provided by their parents or legal tutors and additional agreement was then obtained from the participants. We added a sentence in the Declaration section, in the Ethical approval and consent to participate sub-section, to clarify this point. Page 18,

Ln 400-402: Those aged less than 18 years were asked about their willingness to participate. Thereafter, informed consent was obtained from their parents or legal guardians, and additional assent was then obtained from the participants.

Discussion:

…This section of the research did not give any meaning to the finding. The authors simply put the result but they should interpret the result and compare this finding with other previous research output studied either in the country or other countries, WHO or country guideline.
Moreover, they should come up with possible justifications. Their finding has no possible justification for the discrepancy. The discussion is really weak and does not explain the importance of the study as well.

Thank you for your comment. Our result is compared, on page 14, Ln 307, with the figures reported in the few community-based studies where the diagnostic of fistula was confirmed by clinical examination.

We have addressed the possible justifications for the findings and have rephrased our discussion section.

Page 14-15, Ln 314-329: The fistula incidence of 1.1 per 1000 recently pregnant women that we found is higher than Adler’s [11] pooled incidence estimates in LMICs of 0.09 and 0.66 per 1000 recently pregnant women in community-based and hospital-based studies, respectively. It is recognized in the literature that reported rates of obstetric fistula vary widely. Taking into account that our survey was followed by gold-standard gynaecological exams, the variation could represent true differences in incidence. We emphasize the importance of the clinical examination and confirmation of all women who reported fistula symptoms: 78% of the mothers who reported fistula-like symptoms had conditions other than fistula. Similar to our study, a community-based screening for fistulae in Nigeria, using the fistula module questionnaire, found that 53% of the women who reported symptoms did not have a fistula [38].

Our estimate is close to the fistula incidence of 1.2 per 1000 births found in the only prospective population-based study, which was undertaken in rural West Africa in 1999 [12]. That incidence was, similar to our study, observed in rural areas where women are at higher risk of labour complications. However, the study from West Africa was undertaken in an area with a much lower proportion of births attended by skilled health personnel (39.6% vs 85%) and lower caesarean section rates (0.7% vs 3.8%)

The study also collects data which will be expressed using narrating qualitatively. But, there is no information stated as corrected said by the respondents. Where is cot, individual response?

We did not intend to report any qualitative data in this manuscript. The analysis of the qualitative data collected though in-depth interviews is currently under way and the results will be published in a separate paper.

Conclusion:

…This section is relatively good and stated well. But, what is your base or reference to say the incidence of obstetric fistulae in an area with high facility births?
Thank you for your comment. We consider that the 85% facility delivery rate is high, when compared to the data from the Mozambican Ministry of Health, which reported a national birth facility coverage of 75.4% with a range 47.0%–87.7% in 2015. We observed that, in a rural setting with 85% coverage of facility delivery, the incidence was very close to the incidence observed in a similar setting with a much lower facility delivery, at 39.6%. It was expected that the increase in facility deliveries will lead to an improvement in health outcomes, including reduced occurrence of obstetric fistula, which was not the case. These women with obstetric fistula are used as indicators of failure of the health system to deliver accessible, timely and appropriate intrapartum care. No women should have fistula, and the incidence we found is higher than previously reported.

…Where is your operational definitions incorporated at the method section?

Thank you for this important question. We agree that the definitions of obstetric fistula and fistula incidence were missing in our previous version of the manuscript. We have revised the text accordingly. Page 6, Ln 135-137:

An obstetric fistula was defined as an abnormal opening between the woman’s vagina and bladder and/or rectum, through which her urine and/or faeces continually leak. The fistula incidence was calculated using the total number of women who delivered as the denominator.

…What was the normal or standard and also the cut-off point to say high or low?

Compared to the only meta-analysis that we found, we considered those higher than 0.09 per 1000 recently pregnant women to be high, and those below that proportion to be low.

…And also the authors stated that the quality of care as cause/concern for high incidence of obstetric fistulae. But, how did they know the quality of care since they did not assess it?

We agree that we did not assess the quality of care, but we consider that it is well recognized that the occurrence of obstetric fistula is used as a measure to determine the quality of the healthcare system in a given area. So, the occurrence of obstetric fistula, which is preventable, is related to the quality of care provided. In addition, we said before, one important finding in our study was the delays in appropriate care that occurred inside the health facilities.

…Page 10, line 216, table 1: Incomplete title. A title of a table must answer at least three basic questions of the reader. But, this table title did not fulfil the required one
Thank you for this valuable and justified comment. We changed the title of the table according to the suggestion of the reviewer and have also rephrased the title of Table 2.

Page 11, Ln 242: Table 1. Background, perinatal characteristics and outcome of the five mothers diagnosed with obstetric fistula in Maputo and Gaza provinces, Mozambique 2016

Page 23, Ln 569: Table 2. Labour, outcome, fistula characteristics and repair of the 5 mothers diagnosed with vesico-vaginal fistulae in Maputo and Gaza provinces, Mozambique 2016

...On the same page, 10, table. The value or figure of each variable described in the table contains only frequency. But, rather more illustrative is describe percentage together with frequency

Thank you for this justified comment. We are not sure whether calculating the percentage for the low numbers of fistulas will add any further information, but we would be happy to provide this should the editor wish us to.