Author’s response to reviews

Title: Anal incontinence, urinary incontinence and sexual problems in primiparous women - a comparison between women with episiotomy only and women with episiotomy and obstetric anal sphincter injury.

Authors:

Mona Stedenfeldt (mona.stedenfeldt@gmail.com)
Jouko Pirhonen (tj.pirhonen@gmail.com)
Ellen Blix (ellen.blix@unn.no)
Tom Wilsgaard (tom.wilsgaard@uit.no)
Barthold Vonen (tom.wilsgaard@uit.no)
Pål Øian (pal.oian@unn.no)

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Author’s response to reviews: see over
Dear Dr Palacios

Please find enclosed our revised manuscript entitled:

**Anal incontinence, urinary incontinence and sexual problems in primiparous women – a comparison between women with episiotomy only and women with episiotomy and obstetric anal sphincter injury.**

We are grateful to the editor and both reviewers for all important and helpful comments on this manuscript. We greatly appreciate the input. Please find our enclosed revised version that will hopefully address the concern in the reviews and our detailed responses below.

Thank you for further consideration.

Sincerely,

Mona Stedenfeldt

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**To Referee #1, many thanks for your detailed review of the tutorial’s example. We have addressed these issues and your broader structural comments as follows:**

**Major Compulsory Revisions**

1. Title - The title is misleading as it implies a comparison of episiotomies with OASIs - this study compares women with episiotomies only and those who have both episiotomies and OASIs.

   **Answer:** Thank you for pointing that out. We agree and have changed the title to: **Anal incontinence, urinary incontinence and sexual problems in primiparous women – a comparison between women with episiotomy only and women with episiotomy and obstetric anal sphincter injury.**

2. Is the question posed original, important and well defined? - The aims of this study as written in last paragraph of the Background:
Primary aim - assess if there was a difference in prevalence of AI, UI and sexual problems in women with episiotomy and OASIS compared to women with episiotomy only.

Second aim - assess if episiotomy characteristics were associated with AI, UI and sexual problems.

These are clear, however confusion arises on p5 lines 116-118 where another aim is mentioned regarding assessing associations between episiotomy characteristics and OASI - authors then report this has been published. This section needs to be moved to the background. This paper does not investigate this aspect, and it is confusing to have it in the methods section. Ensuing sections of the paper refer to such association, and it would be clearer if the authors briefly reported these findings at the outset in the background.

**Answer:** Thank you for the clarification. We agree and have followed your advise. The previous findings in the background section are now removed from the method section. We have changed the wording in the method section to: *This was the second part of a matched case-control study carried out at the University Hospital of North Norway and Nordland Hospital [18], to make sure we are referring correctly to previous published material.*

Are the data sound and well controlled?

Are the methods appropriate and well described, and are sufficient details provided to allow others to evaluate and/or replicate the work?

3. The authors refer to this study as a retrospective cohort, however it is actually a matched cohort.

**Answers:** We have changed how we refer to the study from “a retrospective cohort” to “a matched cohort”.

4. Although the authors report the definition and collection of certain variables in quite a bit of detail, more detail is required for selection of women into the study. The authors do not report the number of women with OASI and episiotomy who were identified through birth logs, nor those with episiotomy alone. The decision to match on instrumental delivery has obviously influenced selection of participants, however there is no detail regarding why such matching was considered necessary and needs to be justified. Once women had been identified as potential participants, there needs to be reporting of how women were then recruited into the study, with reporting of participation rates. Without more detail, there is major concern regarding selection bias. A major confounder which has not been discussed in the methods or results sections is parity, although it is mentioned in the paper title, title of Table 5 and in the conclusion implying that the cohort did consist of primiparous women.

**Answer:** The method section is now rewritten to include details about
a) number of women with OASI and episiotomy who were identified through birth logs,
b) number of women with episiotomy alone
c) why the decision to match on instrumental delivery was made
d) how many identified as potential participants were then recruited into the study, with reporting of participation rates
e) parity

Results

5. Table 1 – Demographics. The authors presented conditional logistic regression results, but I am unsure why they then did not actually report the ORs and confidence intervals rather than just the p values. I assume these results are univariate associations although this is not stated. Was regression undertaken because the variables were continuous – otherwise McNemar’s test may have been more appropriate. Was the assumption of log linearity tested?

Answer: Table 1 is a description of demographic differences between groups. And since it is a matched case-control study a conditional –logistic analysis is the appropriate test to use. In this analysis OR and CI has less interest since we are not assessing the odds for risk of being a case. The conditional – logistic analysis is appropriate for both categorical and continuous variables. Since the groups are matched the analysis is adjusted for instrumental delivery, but no extra adjustments are made. Log linearity is tested by for all predictor variables that are continuous (Mothers Age, Birth Weight, Head Circumference and Time since birth). The test is performed by including both a linear and a quadratic term for the continuous predictor variable in the model. The p-value for the quadratic term was non significant for all variables except Time since birth. This indicates a log-linear relationship for all variables except Time since birth.

We categorized time according to 33.33 percentile and found following relationship:

<table>
<thead>
<tr>
<th>Year since birth</th>
<th>Women with OASIS (n=37)</th>
<th>Women without OASIS (n=37)</th>
<th>p value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>0- 1.37</td>
<td>12 (32)</td>
<td>13 (35)</td>
<td>0.80</td>
</tr>
<tr>
<td>1.33 – 3-15</td>
<td>7 (20)</td>
<td>18 (49)</td>
<td>0.02</td>
</tr>
<tr>
<td>3.16- 6.51</td>
<td>18 (48)</td>
<td>6 (16)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

This relationship is inverse between the groups at 1.33 -3.15 years after birth compared to 3.16-6.51 years after birth and not linear.
Table 2:

6. There needs to be detail of whether any adjustment was undertaken in these models.

**Answer:** The purpose of matching the case and control group on instrumental delivery was to control for what is considered to be important covariate. We used conditional logistic regression in order to adjust for the matched design of our study. Further adjustment for other covariates was not performed.

7. Has the assumption of log linearity been assessed?

It is not reported, and from the distribution of these variables when categorised, it looks questionable.

**Answer:** The logistic regression model does not assume any distribution for the independent variables. These variables may be normal or skewed, or they may be categorical. A log linear relationship between a categorical variable and odds for being a case is not meaningful. However, such a relationship is assumed for continuous variables. Non-linear relationships may be assessed by including both a linear and a quadratic term for the continuous variable in the model. A non-significant p-value for the quadratic term may be used as evidence against a non-linear relationship. Log-linear relationship has been assessed for the following predictor variables, that are continuous: Sexual pain, Sexual orgasm, Sexual desire and found not significant. We have removed the analysis for continuous predictor variable AI and UI.

I would consider whether reporting of per unit increase is actually a clinically relevant score, as categorisation results are more easily interpreted.

**Answer:** Thank you for this comment. We agree that the first analysis and the seventh analysis (uncategorical) are not as clinically important as the report on categorized data. Thus, we have removed these analyses.

Although the odds ratios are presented in the table, it is of note that they are not discussed in the text.

**Answer:** Thank you for pointing that out. We have now included OR and CI for these findings in the result section.

It may be less confusing for the reader to undertake this analysis using McNemar test (assuming no adjustment was undertaken).

**Answer:** The conditional logistic regression test and the McNemar test would result in approximately similar p-values when we use variables that are binary. However, since conditional logistic regression models are more flexible
and may include continuous and polytomous variables we prefer to use the latter method throughout the paper.

8. The sexual responses are generated from likert scales - and thus the data is ordinal, and analysis should be restricted to categorical approaches (not means).

**Answer:** That is an important point. We agree and have edited the table to report median and IQR.

I am also concerned about the validity of creating an overall sexual problem score and scoring system for frequency of complaints by adding up likert scales. Has this approach been previously validated for this questionnaire?

**Answer:** Thank you for raising this important concern. We have questioned the authors of the origin to the questionnaire and this approach has not been validated for this questionnaire. We have therefore removed the overall sexual problem score in Table 2 and rewritten accordingly.

Table 3 & Table 4

9. Were the distributions of the episiotomy characteristics normally distributed? From the apparent distributions in Table 3, it would appear they were skewed – as such medians (not means) should be presented in Table 3. I would however debate the necessity of Table 3 as length and depth can be reported in the text, and information regarding incision point and angle is also presented in table 4 – the median values for these values could be added to this table.

**Answer:** Yes the distribution of all the episiotomy characteristic are tested and normal. We agree that Table 3 is not necessary. We have reported episiotomy length and depth in the text, and removed Table 3.

10. Table 5 The methods section states that Spearman coefficient was used to estimate correlation between episiotomy characteristics and AI, UI and sexual problems in the two groups separately, however Table 5 does not report the separate results, nor are they mentioned in the text.

**Answer:** Thank you for detecting this error. The correct description of using the Spearman coefficient is: “Spearman’s correlation coefficient was used to estimate correlation between episiotomy characteristics and AI, UI and sexual problems for the groups combined.” The text is corrected accordingly.

Is the interpretation (discussion and conclusion) well balanced and supported by the data?

11. The authors refer to episiotomies without associated OASIs as 'protective'. I feel they would be better described just as episiotomies without OASIs - the use of the word protective becomes confused with characteristics of the episiotomy that
the authors have stated as protective features of an episiotomy such as length and depth (p10 line 216). The results state that there was a moderate correlation for sexual problems with episiotomy length and depth - however this is contradicted in the discussion with the statement "there were no associations..." (p11 lines 242-244). I find this aspect poorly described and confusing, and distracting from the main message as I was often unsure if the authors were referring to protective features of an episiotomy or not.

**Answer:** We do understand that the terminology and way we have referred to the test of association between protective characteristics and dysfunctions can be confusing.

“Protective” are episiotomies that have specific characteristics that are associated with decreased risk of OASIS (Stedenfeldt et al 2012). In this cohort there are both women with episiotomies with “protective” characteristics with OASIS, and women with “not protective” characteristics without OASIS. What we and other studies have found is that some specific characteristics reduce the risk of OASIS, thus they are called to be protective.

To describe protective characteristics and association more clearly we have changed the wording in:

- **line 55:** “Episiotomy with protective characteristics was not associated with increased dysfunctions.”
- **line 114:** “... found that a lateral episiotomy with correct angle, sufficient length and depth was exceedingly reducing the risk of sustaining OASIS compared to mediolateral episiotomy [18].”
- **line 274:** “The correlation is positive, meaning that the episiotomies with protective characteristics of length and depth were associated with fewer problems.”
- **line 338:** “We did not find any association between episiotomy with protective characteristics and postpartum AI, UI and increased sexual problems.”

12. Statements such as "thus it is important to prevent OASIS" (p12 line 279) are unnecessary as this is self evident. If the authors are truly arguing that an appropriately performed episiotomy may help to prevent OASI and that this study highlights that the sequelae of episiotomy are not as bad as for OASI then they should state it as such.

**Answer:** Thank you for this valid point. We have revised the wording in the conclusion.

Minor Essential Revisions
1. Table 5 - Needs notation that this table is reporting Spearmans coefficient.
Answer: Notation is added.

2. I find the discussion around "association between episiotomy characteristics with dysfunctions" (p9 line 201) confusing, as Table 4 which is mentioned immediately after this statement does not reflect this but just reports the range.

Answer: The classification is stated in the method section. To make it more clear the sentence is revised and classification for medial and lateral incision point is stated in parenthesis.

3. p4 line 79 Refs 1-3 do not actually report anal incontinence of 30%-50% as stated in the first paragraph of the paper (eg Roos reports 20%, de Leeuw reports 31% with fecal incontinence and 10% with fecal soiling – not necessarily mutually exclusive, and Marsh reports 4% fecal incontinence with 24% poor-variable control of flatus)

Answer: Thank you for this observation. Unfortunately one of the references was left out. Norderval et al. report an incidence of 59% AI amongst Norwegian women 25 months after birth. This reference is now included and the reference list updated.

Discretionary revisions

1. It would be informative to have more information regarding ‘birth logs’ – for example, are they the complete clinical record or an administrative dataset?
   
   Answer: The birth logs are electronic patient journal system. We have now stated this in the manuscript.

2. p4 line 90 "and continue" should be "and continues"
   
   Answer: Thank you. It is corrected.

3. p4 lines 96 when highlighting that mediolateral episiotomies are rarely performed properly, it would add more meaning if you stated what the research has found that clinicians do that is improper
   
   Answer: Thank you for the suggestion. We agree and have revised the sentence.

4. p5 lines 121-122 "women with OASIS that had episiotomy" should be written as "women ...who had"
   
   Answer: Thank you. It is corrected.

5. p6 line 144 suggest "assessed" instead of "registered"
   
   Answer: Thank you. It is corrected.
6. p8 line 181 add the word OASIS "women with compared.." should be "women with OASIS compared..."

**Answer:** Thank you. It is corrected.

7. p8 line 182 Table 2 reports 22% not 21%, and 16% not 14%

**Answer:** Thank you. It is corrected.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**To Referee #2, many thanks for your time and input. In response to your specific comments:**

**Reviewer's report:**

1. Abstract is too long the aim of the study must be briefly written as objective not the background.

**Answer:** Unfortunately, we cannot find the guidelines that state that the word count has a limit less than ours. We have followed the template which states the following headings for the abstract: **Background, Methods, Results, Conclusions.** Therefore we do feel it is most appropriate to have the aim of the study in the background section.

line 38. mean time should be presented in the results.

**Answer:** Thank you. We have revised, and mean time is now stated in the result section.

line 41-44 statistical methods should not be presented in the abstract. line 46 p valu should be presented.

**Answer:** Thank you. We have revised and removed the statistical method. Fourteen vs. three is number of women. We have rewritten the sentence to make it clear.

2. 111 pg5 the primary outcome and the secondar outcome should be briefly defined. The primary outcome of this study is an expected matter as AI is mostly expecte in patients with OASIS than only episiotomy. The interesting part of this manuscript is the clasification of the episitomies and OASIS ans the secondary outcome might be the primary outcome?
Answer: Thank you for an interesting question. It is true that greater dysfunction was expected among the women with OASIS. However, viewed chronologically we think this must be investigated, thus also stated, as a primary outcome to further investigate the secondary outcome.

3. pg8 line 181-182 significantly more frequent and p=0.05 is it significant or not?

Answer: The result is significant and is now stated with OR and CI.

4. Although it is presented in tables; Double incontinence OR 3.3 is not presented in the results. OR=3.3 and p value 0.07 not significant? may be consider giving only OR or P value

Answer: That is correct. The results did not reach significant. However, as we state, this is a small study and results should be interpreted with caution. We revised the results section and reported the results.

Level of interest: An article of importance in its field
Quality of written English: Needs some language corrections before being published
Statistical review: Yes, and I have assessed the statistics in my report. Declaration of competing interests:
I have no conflict of interest on this manuscript

Thank you again for your time and effort, and for helping to improve the manuscript. We hope that these changes have made it more appropriate for publication, and we look forward to your response.

Reference: