PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Obstetric perineal tears, sexual function and dyspareunia among primiparous women 12 months postpartum: a prospective cohort study
AUTHORS	Gommesen, Ditte; Nøhr, Ellen; Qvist, Niels; Rasch, Vibeke

VERSION 1 – REVIEW

REVIEWER	Gin-Den Chen Department of Obstetrics and Gynecology, Chung Shan Medical University Hospital, Taiwan
REVIEW RETURNED	02-Jul-2019

GENERAL COMMENTS	Authors assessed the correlations of sexual function and sequelae of perineal ruptures using used PISQ-12, length of perineal body, squeeze pressure of the vagina and demographic characteristics. They found that impairment of sexual health is common among primiparous women after vaginal delivery and more than half of the women with an anal sphincter rupture experiences dyspareunia at 12 months postpartum. Authors have highlighted the strengths and potential limitations of this manuscript. This is a well-designed study and well-written manuscript. It would provide interesting issues for the readers of the BMJ open.

REVIEWER	Özkan Özdamar Istanbul Medeniyet University, Faculty of Medicine, Department of Obstetrics and Gynecology, Istanbul, Turkey.
REVIEW RETURNED	03-Jul-2019

GENERAL COMMENTS	I have read the article entitled 'Obstetric perineal ruptures, sexual function and dyspareunia among primiparous women 12 months postpartum: a prospective cohort study' with great interest. Sexuality is a very important component of human physiology and sociality and pregnancy, parturition and related processes, such as episiotomy, might potentially contribute to the female sexuality. Thus, I consider this article to be of importance. I have some contributions listed below; 1. Episiotomy may be a potential confounder, which might have significant effects on dyspareunia scores or postpartum sexual dysfunction.This issue might be addressed in the discussion section. 2. Recall bias cannot be ignored in cohort studies employing questionnaires to determine the pre- and post- procedure differences. Thus, this issue should be expressed in the discussion section.

REVIEWER	Guillaume DUCARME

	Centre Hospitalier Departemental La Roche sur Yon, France
REVIEW RETURNED	18-Jul-2019

GENERAL COMMENTS	The authors reported a prospective cohort study including 554 primiparous women in 4 Danish hospitals and aimed to examine the association between degree of perineal tears and sexual function 12 months partum. The subject is very interesting and the manuscript is very-well written. But, some problems in the article decrease the interest and necessitate some modifications: • All along the manuscript, "perineal rupture" should be modified in "perineal tears" • Abstract needs to be completely rewritten. Results only contain some data about dyspareunia and no data about PISQ-12 and multivariable analysis which are well-detailed in the text and are the most interesting results of the study • Data about mode of delivery (spontaneous vaginal delivery, operative vaginal delivery), rate of episiotomy … should be added in the abstract to increase the interest for lecturer • All along the article, details and data about 3D HRAM should be deleted in the article; the article is very interesting with clinical examination and questionnaire at 12 months postpartum which is a strength of the study, and this data should be deleted • The paragraph about the degrees of perineal tears should be deleted because that's not increased the interest and the authors did not respect the reported classification in their analysis (grade 3a, 3b, 3c…). • The authors should explain and justify why they have decided to define the baseline at 16 days postpartum. Why not before pregnancy or during the third trimester? • The results showed a significative association between 2nd spontaneous degree perineal tears and dyspareunia (as 3rd and 4th degree perineal tears) although 2nd (mediolateral episiotomy) degree perineal tears were not associated with dyspareunia. The conclusion should be mediolateral episiotomy should be done to prevent dyspareunia?? That should address some discussions and explanations • In the discussion, the authors should discuss the rate of dyspareunia which is noted as "pre-pregnancy dyspareunia" (19.3%). These data should be also discussed because the data were obtained at 16 days postpartum and are then retrospective and probably contain some recall bias, as noted by the authors (a great limitation of the study!) • Page 13, line 210: "At 12 months postpartum…" should be added to clarify the results

REVIEWER	Deirdre O'Malley Trinity College Dublin Ireland
REVIEW RETURNED	30-Jul-2019

GENERAL COMMENTS	Thank you for submitting a very interesting study. The subject is introduced, however I find it somewhat confusing as the author frequently alternates between discussing sexual dysfunction and sexual function. It might be useful to define or explain what is meant by sexual dysfunction. Also when referring to sexual dysfunction are the authors referring to the DSM 5 classification and does the PISQ-12 used the new classification

	system? Are there particular cut-off points that indicate sexual dysfunction on this scale? I would be cautious about referring to delayed resumption of sexual intercourse as a sexual dysfunction, e.g. what is considered a delay? Initial consent to email is not addressed in the manuscript presented. Presenting sampling in a flow diagram would illustrate the final numbers included in the analysis in a more reader friendly way. It needs to be made explicate that the clinical assessment carried out at 12 months was identical to that carried out at 16=/- 5 days. Where did this examination take place, was there any cost to the women, could they bring their baby? The use of the PISQ-12 measurement tool could be discussed in more detail, particularly its biophysical focus and the lack of relational and psychological issues that impact on postpartum sexual health. The clinical implication is not new, counsel women at risk of postpartum sexual dysfunction. However the opportunity to support and counsel women with dyspareunia prior to pregnancy is not addressed in any way. This is the one time in a woman's life when they are in contact with the health services, an opportunity is being lost help these women. That they are at risk of persistent sexual health problems 12 months after birth is significant. Wishing you every success with this interesting manuscript.

VERSION 1 – AUTHOR RESPONSE

REVIEWER 2, POINT 1:
A. Comment:
Episiotomy may be a potential confounder, which might have significant effects on dyspareunia scores or postpartum sexual dysfunction. This issue might be addressed in the discussion section.
B. Response:
Thank you for pointing this interesting issue out. We agree and in our primary adjusted analyses we included episiotomy to adjust for any potential confounding effect. However, excluding episiotomy only changed the adjusted estimates marginally and thus episiotomy did not seem to be a potential confounder. We decided to leave episiotomy out in effort to make the analyses more robust. We have addressed this in the discussion.
C. Changes:
Page 21, line 285-289
D. Textual change:
"In accordance with the results from a large Irish cohort study, we did not find episiotomies to be associated with sexual health problems 12 months postpartum. In our primary adjusted analyses, we included episiotomy to adjust for any potential confounding effect. Excluding episiotomy from the analyses only changed the adjusted estimates marginally and thus episiotomy did not seem to be a confounder in this study."
REVIEWER 2, POINT 2:
A. Comment:
Recall bias cannot be ignored in cohort studies employing questionnaires to determine the pre- and post- procedure differences. Thus, this issue should be expressed in the discussion section.
B. Response:
We agree and have addressed this in the discussion section.
C. Changes:
Page 21, line 290-294
D. Textual change:

“We found 19.3% to report pre-pregnancy dyspareunia. However, the study had a risk of recall bias as we asked the women to recall pre-pregnancy information 2 weeks postpartum, which might be influenced by the degree of perineal tear experienced. Ideally, sexual function should have been established before pregnancy but this would require another study design.”

Comments and responses
REVIEWER 3, POINT 1:
A. Comment:
All along the manuscript, “perineal rupture” should be modified in “perineal tears”
B. Response:
We have added corrections all along the manuscript and consequently changed “rupture” to “tear”.

REVIEWER 3, POINT 2:
A. Comment, Abstract:
Abstract needs to be completely rewritten.
• Results only contain some data about dyspareunia and no data about PISQ-12 and multivariable analysis which are well-detailed in the text and are the most interesting results of the study
• Data about mode of delivery (spontaneous vaginal delivery, operative vaginal delivery), rate of episiotomy … should be added in the abstract to increase the interest for lecturer
B. Response:
Thank you for pointing this out. We have added results about PISQ-12 score and information about mode of delivery. We hope these changes meet your requests.
C. Changes:
Abstract, page 3, line 51-57
D. Textual change:
“Results: Episiotomy was performed in 54 cases and 95 women had an operative vaginal delivery. The proportion of women with dyspareunia was: 25%, 38% and 53% of women with no/labia/first-degree, second-degree or third-/fourth-degree tears, respectively.
Compared to women with no/labia/first-degree tears, women with second degree or third-/fourth-degree tears had higher risk of dyspareunia (aRR 2.05; 95% CI 1.51-2.78 and aRR 2.09; 95% CI 1.55-2.81, respectively). Women with third- or fourth-degree tears had a higher mean PISQ-12 score (12.2) than women with no/labia/first-degree tears (10.4) “

REVIEWER 3, POINT 3:
A. Comment:
• All along the article, details and data about 3D HRAM should be deleted in the article; the article is very interesting with clinical examination and questionnaire at 12 months postpartum which is a strength of the study, and this data should be deleted
B. Response:
Thank you for the comment, which we find relevant. Accordingly we have deleted the text on the 3D HRAM and perineal strength.
C. Changes:
Throughout the manuscript including Table 4

REVIEWER 3, POINT 4:
A. Comment:
The paragraph about the degrees of perineal tears should be deleted because that’s not increased the interest and the authors did not respect the reported classification in their analysis (grade 3a, 3b, 3c…).

B. Response:
We agree and have modified the paragraph. However, we have not deleted it completely as the paragraph describes the definition of the main exposure variable.
C. Changes:
Page 7, line134-145
D. Textual change:
“The degree of perineal tear was defined according to the Green-top Guideline No. 29. First-degree tears were defined as injury to perineal skin and/or vaginal mucosa. Second-degree tears were defined as injury to perineum involving perineal muscles but not the anal sphincter. Third- and fourth-degree tears were defined as injury to perineum involving the anal sphincter complex. Episiotomies were lateral or mediolateral. Episiotomies equivalent to a second-degree tear were analysed independently while episiotomies extending to the anal sphincter muscles were classified as a third- or fourth-degree tear.”
REVIEWER 3, POINT 5:
A. Comment:
The authors should explain and justify why they have decided to define the baseline at 16 days postpartum. Why not before pregnancy or during the third trimester?
B. Response:
This is a very relevant question. This was a matter of logistics and study design. As our primary aim was to investigate the association between degree of tears and sexual function, we aimed to include 200 women in all three groups of tears including 200 women with anal sphincter ruptures. By inclusion before pregnancy or in the third trimester, we would have needed to include much more women into the study before reaching 200 women with anal sphincter ruptures. Due to the time limit and resources in the study, this was not possible.

REVIEWER 3, POINT 6:
A. Comment:
The results showed a significative association between 2nd spontaneous degree perineal tears and dyspareunia (as 3rd and 4th degree perineal tears) although 2nd (mediolateral episiotomy) degree perineal tears were not associated with dyspareunia. The conclusion should be mediolateral episiotomy should be done to prevent dyspareunia?? That should address some discussions and explanations
B. Response:
We agree and have added this to the clinical impact paragraph.
C. Changes:
Page 22, line 304-308
D. Textual change:
“Spontaneous second-degree tears seemed to increase the risk of dyspareunia. This association was not found between mediolateral or lateral episiotomies and dyspareunia. Thus, episiotomy might be considered to prevent dyspareunia in some cases. However, this needs to be investigated further in larger datasets with more episiotomies and perhaps also accounting for methods of repair which may vary across clinical settings.”

REVIEWER 3, POINT 7:
A. Comment:
In the discussion, the authors should discuss the rate of dyspareunia which is noted as “pre-pregnancy dyspareunia” (19.3%). These data should be also discussed because the data were obtained at 16 days postpartum and are then retrospective and probably contain some recall bias, as noted by the authors (a great limitation of the study!)
B. Response:
We agree to this comment and have added this issue to the discussion.
C. Changes:

Page 21, line 290-294
D. Textual change:
“We found 19.3% to report pre-pregnancy dyspareunia. However, the study had a risk of recall bias as we asked the women to recall pre-pregnancy information 2 weeks postpartum, which might be influenced by the degree of perineal tear experienced. Ideally, sexual function should have been established before pregnancy but this would require another study design.”

REVIEWER 3, POINT 8:
A. Comment:
Page 13, line 210: “At 12 months postpartum…” should be added to clarify the results
B. Response:
We have added this suggestion to the text.
C. Changes:
Page 14, line 214
D. Textual change:
“At 12 months postpartum the mean PISQ-12 score was higher among women…”

REVIEWER 4, POINT 1:
A. Comment:
The subject is introduced, however I find it somewhat confusing as the author frequently alternates between discussing sexual dysfunction and sexual function. It might be useful to define or explain what is meant by sexual dysfunction. Also when referring to sexual dysfunction are the authors referring to the DSM 5 classification and does the PISQ-12 used the new classification system? Are there particular cut-off points that indicate sexual dysfunction on this scale?
B. Response:
We agree and have come to the conclusion, that the term “dysfunction” should not be used in this paper, as our use of the term is not referring to any definitions. Thus we have changed the wording throughout the paper, using “sexual function” or “sexual health problems”. We hope this will meet your request.

REVIEWER 4, POINT 2:
A. Comment:
I would be cautious about referring to delayed resumption of sexual intercourse as a sexual dysfunction, e.g. what is considered a delay?
B. Response:
This is referring to the study by Radestad et al., 2008. They defined a delayed resumption of sexual intercourse to be more than 3 months after giving birth.
C. Changes:
Page 5, line 84-86
D. Textual change:
“A large cohort study from Sweden found vaginal or perineal tears, regardless of degree, to be associated with a delay in women’s resumption of sexual intercourse defined as more than 3 months after giving birth…”

REVIEWER 4, POINT 3:
A. Comment:
Initial consent to email is not addressed in the manuscript presented.
Presenting sampling in a flow diagram would illustrate the final numbers
included in the analysis in a more reader friendly way.
B. Response:

We have added a flow-chart of inclusion as Figure 1.

REVIEWER 4, POINT 4:
A. Comment:
It needs to be made explicate that the clinical assessment carried out at 12 months was identical to that carried out at 16=/- 5 days. Where did this examination take place, was there any cost to the women, could they bring their baby?
B. Response:
The clinical examinations at 16+-5 days and at 12 months were not identical. At 12 months, a gynaecological examination was performed, whereas only a perineal inspection and careful palpation was performed at 16+-5 days due to more pain and soreness in the perineal area in the initial postpartum period. The examinations took place at the hospital and some transport costs applied to the women. They could all bring their baby.
C. Changes:
Page 6, line 110-116
D. Textual change:
"Further information was sent by e-mail and the women were invited by phone to participate in a face-to-face interview including baseline questionnaires and a clinical examination comprised of a perineal inspection at 16±5 days postpartum. Written informed consent was obtained at baseline. At 12 months postpartum, all participants received the same questionnaires electronically and were invited to a gynaecological examination. All examinations took place at the hospital and participants could bring their baby."

REVIEWER 4, POINT 5:
A. Comment:
The use of the PISQ-12 measurement tool could be discussed in more detail, particularly its biophysical focus and the lack of relational and psychological issues that impact on postpartum sexual health.
B. Response:
A more thorough discussion of the tool has been added.
C. Changes:
Page 21, line 277-280
D. Textual change:
"The PISQ-12 score has biophysical focus in general and lacks the relational and psychological issues that may have an impact on postpartum sexual health. Thus, this study does not address these issues, which are highly relevant in the context of sexual health in a vulnerable period of life."

REVIEWER 4, POINT 6:
A. Comment:
The clinical implication is not new, counsel women at risk of postpartum sexual dysfunction. However the opportunity to support and counsel women with dyspareunia prior to pregnancy is not addressed in any way. This is the one time in a woman's life when they are in contact with the health services, an opportunity is being lost help these women. That they are at risk of persistent sexual health problems 12 months after birth is significant.
B. Response:
We agree and have included this in the discussion section.
C. Changes:
Page 22, line 302-304
D. Textual change:

"Further, pregnancy is a time in women's life when they are in contact with the health services. This leaves an opportunity to identify and counsel women with dyspareunia as they are at risk of persistent sexual health problems 12 months postpartum."

VERSION 2 – REVIEW

REVIEWER	Ducarme, G Central Hospital Les Oudaires
REVIEW RETURNED	16-Sep-2019

GENERAL COMMENTS	The authors have answered to all reviewers 'comments and have significantly improved the manuscript by clarifying several issues suggested by the reviewer.

REVIEWER	Deirdre O'Malley Trinity College Dublin Ireland
REVIEW RETURNED	09-Sep-2019

GENERAL COMMENTS	Thank you for the re submission of this manuscript. Changes made greatly improve the readability and clarified the purpose of the presented research. The changes to the discussion add to the discussion on sexual health, both before and after pregnancy. The last paragraph on page 21 needs to be looked at, there is repetition present and I am unsure if it is true to day that women's recall of pre-pregnancy dyspareunia would be influenced by there perineal trauma 16 days post birth Line 282 suggest change 'leaves an opportunity' to 'provides an opportunity' Suggesting that episiotomy may be protective of sexual function as a clinical implication needs to be reconsidered, as you identify the numbers with an episiotomy in this sample was small - therefore can this non significant result lead to a clinical implication? Is there other studies to support this? This discussion might be better placed in the discussion section. A clinical implication might be how to protect the perineum from spontaneous 2nd degree tears in labour e.g. upright positions, avoidance of epidural analgesia, perineal massage etc Good luck with your submission