PEER REVIEW HISTORY

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This paper was submitted to the JECH but declined for publication following peer review. The authors addressed the reviewers' comments and submitted the revised paper to BMJ Open. The paper was subsequently accepted for publication at BMJ Open.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Sexual violence and neonatal outcomes: a Norwegian population-based cohort study
AUTHORS	Henriksen, Lena; Schei, Berit; Vangen, Siri; Lukasse, Mirjam

VERSION 1 - REVIEW

REVIEWER	Patricia O'Campo University of Toronto Canada
REVIEW RETURNED	19-Jul-2014

GENERAL COMMENTS	This study contributes to a growing body of research on the relationship between exposure to violence and pregnancy outcomes. While the strengths of the study include a large data set and validated outcomes, the study requires greater attention to a range of issues outlined below. The authors are missing key information from the Introduction. First, the authors do not talk about the theory behind their research question. Why would sexual violence, uniquely or in combination with other types of violence, be associated with adverse pregnancy outcomes? What is the mechanism? Is it a physiological or a psychological mechanism? This has been written about and should be included in the Introduction, in particular about why it is important to investigate sexual violence separately from other types of violence. Moreover, the authors have the ability to potentially examine the different pathways here since they have data on more psychological exposures (pressure to engage in sexual activities) vesus more physiologic pathways (e.g., rape). Information about the methodological challenges that arise when studying are mostly absent from the paper. Past studies have shown that few women experience only one type of violence making it almost impossible to differentiate the effects of sexual violence from other types of violence. While this is mentioned in the methods as a means of adjustment it might be highlighted further. The authors suggest in their Introduction that the role of behavioural or social factors in producing PTB or LBW are less understood than biologicial risk factors which is not necessarily the case as there is still much uncertainty around some biological risk factors. Moreover, how is ethnicity (exclusively) a biological factor when much recent

	research focuses on this variable as a social exposure (e.g., racism or cultural practices)? The rationale for excluding the 13000 repeat pregnancies should be discussed. It would appear that this group of women could contribute to the research question being posed. Which of the pregnancies was excluded and why? Some of the adjustment variables could be in the pathway between sexual violence and the outcome and are not confounders but mediators. Adjusting for mediators is a potential problem and should be commented upon. Mental distress is one such variable. Again this could be an opportunity to examine a unique pathway by separating a mediating variable such as mental distress from the other potential confounders. The authors note that the low response rate of 40% is a weakness of the study. Do the authors have evidence on just how the sample bias impacts upon the associations reported? For example, in past studies where there is a rich existing literature, have the associations reported been similar to that in the literature? If so, this would support the idea that this study to might demonstrate associations in an unbiased way. Other important methodological limitations are not mentioned such as the relationship of the perpetrator of sexual violence to the respondent, measures of severity according to frequency, perceived impact of the exposure (especially for mild sexual violence), whether the pregnancy was a consequence of the sexual violence among others. The authors should present more information on these potential limitations. The authors do not talk about limitations in their own operationalization of the variables of sexual violence. Is pressure to perform sexual acts sexual violence? What might the authors recommend for the future of this particular research agenda in terms of methodological improvements?

REVIEWER	Ines Keygnaert, PhD Ghent University, Belgium
REVIEW RETURNED	12-Aug-2014

GENERAL COMMENTS	First of all I would like to stress the importance of publishing results on the impact of sexual violence on health intergenerationally, yet I feel that this paper could be strenghtened if the following aspects are considered and dealt with better: page 5, exposure variable: it is unclear what you understand by "pressure to perform sexual acts": does it include penetration of any body opening or just physical contact without penetration or also harassment without contact, which definition is used? The same goes for "forced with violence": forced with violence to do what? and forced with what type of violence?. Also for rape: please provide a clear definition Furthermore, you do not mention what mild, moderate and severe SV entails. (probably the 3 you mentioned before but this is hypothetical). These are vital things, otherwise comparing results to other international studies becomes difficult. It might be helpful to add the questionnaire as an extra file.

	page 8 line 23-30: recent SV is grouped as during pregnancy or the last 6 or 12 months: what do you mean: the last 12 months, or last 6 months, or the last 6 to 12 months? In most recent research the last 12 months is used, and then when it regards pregnancy, gestational weeks are given. Given this, would it be possible to split up your analysis for the women who were pregnant when being exposed to SV and those who weren't? Please add this, or explain more on this in the discussion section. A main limitation in my opinion is the fact that SV is measured in the Q1 at 17 weeks, while several authors argue that the risk of SV raises with the length of pregnancy and that a lot of the results on recent SV & pregnancy can thus be questioned. This is not sufficiently discussed in the limitations section now, nor reflected in the rest of the paper. Finally, the paper posits that socio-demographic and behavioral factors made the links between a history of SV and poor neonatal outcome disappear. It is known that these factors are considered as consequences of SV and as risk factors for poor neonatal outcome. On page 10 the paper confirms that also in this study the women with a history of SV were significantly younger, more likely to have primary school education, were smoking, high BMI, mental distress. How certain can we be that these health indicators are not the result of their prior sexual victimisation and thus, indirectly contributed to poorer neonatal outcome? The role of mediators and confounders on this matter is not clear enough yet. So, please elaborate a little more on this when discussing the results and its relevance for health workers providing services to pregnant women and young mothers.

VERSION 1 – AUTHOR RESPONSE

Reviewer Patricia O'Campo

Comment 1: The authors are missing key information from the Introduction. First, the authors do not talk about the theory behind their research question. Why would sexual violence, uniquely or in combination with other types of violence, be associated with adverse pregnancy outcomes? What is the mechanism? Is it a physiological or a psychological mechanism? This has been written about and should be included in the Introduction, in particular about why it is important to investigate sexual violence separately from other types of violence. Moreover, the authors have the ability to potentially examine the different pathways here since they have data on more psychological exposures (pressure to engage in sexual activities) versus more physiologic pathways (e.g., rape).

Response: We thank the reviewer for this valuable comment. We have added suggested pathways between sexual violence and PTB/LBW in the introduction and further emphasised why it is important to investigate sexual violence separately from other type of abuse.

In the regression analysis, we did examine the effect of the different level of sexual violence, as the variable sexual violence was used as a categorical variable with: 0= no sexual 1= mild sexual violence, 2= moderate sexual violence and 3= severe sexual violence. Whether pressure to engage in sexual relations is a more psychological exposure and rape more physiological is unfortunately not possible to assess from the questions in MoBa-study.We have also adressed these issues in comments 1 from reviewer 2. We have made changes in the discussion section were we discuss these concerns.

Comment 2: Information about the methodological challenges that arise when studying are mostly absent from the paper. Past studies have shown that few women experience only one type of violence making it almost impossible to differentiate the effects of sexual violence from other types of violence. While this is mentioned in the methods as a means of adjustment it might be highlighted further.

Response: We have added information about the methodological challenges in the discussion section.

Comment 3: The authors suggest in their Introduction that the role of behavioural or social factors in producing PTB or LBW are less understood than biological risk factors, which is not necessarily the case as there is still much uncertainty around some biological risk factors. Moreover, how is ethnicity (exclusively) a biological factor when much recent research focuses on this variable as a social exposure (e.g., racism or cultural practices)?

Response: We agree with the reviewer view on this matter and we have changed the wording regarding the biological factors and other risk factors for PTB and LBW.

Comment 4: The rationale for excluding the 13000 repeat pregnancies should be discussed. It would appear that this group of women could contribute to the research question being posed. Which of the pregnancies was excluded and why?

Response: In the MoBa study a pregnancy is the observation unit. In our study we wanted the woman to be the observation unit, hence the initial removing of pregnancies of women participating more than once. It is the first pregnancy that the woman participated with that is included. Another important reason is that if we had kept the original observation unit we might have counted the exposure for the same women twice. We have clarified this concern in the methods section.

Comment 5: Some of the adjustment variables could be in the pathway between sexual violence and the outcome and are not confounders but mediators. Adjusting for mediators is a potential problem and should be commented upon. Mental distress is one such variable. Again this could be an opportunity to examine a unique pathway by separating a mediating variable such as mental distress from the other potential confounders.

Response: We understand the reviewer's concern about adjusting for mediators. We agree that mental distress can be on the causal pathway between sexual violence and we did discuss whether to adjust for mental distress or not. We ended up controlling for this because studies show that mental distress/depression may be caused by sexual violence but also that mental distress may be a risk factor for sexual violence. We have emphasized this in the methods section an added a reference regarding this issue.

Comment 6: The authors note that the low response rate of 40% is a weakness of the study. Do the authors have evidence on just how the sample bias impacts upon the associations reported? For example, in past studies where there is a rich existing literature, have the associations reported been similar to that in the literature? If so, this would support the idea that this study to might demonstrate associations in an unbiased way.

Response: We agree that this is an important issue and we have described two studies that support our findings more carefully. In addition, we have discussed whether the low response rate cause misclassification.

Comment 7:Other important methodological limitations are not mentioned such as the relationship of the perpetrator of sexual violence to the respondent, measures of severity according to frequency, perceived impact of the exposure (especially for mild sexual violence), whether the pregnancy was a consequence of the sexual violence among others. The authors should present more information on these potential limitations.

Response: We agree with the reviewer regarding this. Sadly we have no information on context or frequency in our study. Questions about perpetrator were removed in order to protect the participants. We have added more information about these potential limitations in the discussion.

Comment 8: The authors do not talk about limitations in their own operationalization of the variables of sexual violence. Is pressure to perform sexual acts sexual violence? What might the authors recommend for the future of this particular research agenda in terms of methodological improvements?

Response: We thank the reviewer for this valuable comment. We have also adressed these issues in comment 1 from reviewer two. We have added more information regarding the operationalization of the exposure variable in the methods section and also added more regarding methodological aspects in the discussion.

Reviewer Ines Keygnaert

Comment 1: page 5, exposure variable: it is unclear what you understand by "pressure to perform sexual acts": does it include penetration of any body opening or just physical contact without penetration or also harassment without contact, which definition is used?

The same goes for "forced with violence": forced with violence to do what? and forced with what type of violence?. Also for rape: please provide a clear definition Furthermore, you do not mention what mild, moderate and severe SV entails. (probably the 3 you mentioned before but this is hypothetical). These are vital things, otherwise comparing results to other international studies becomes difficult. It might be helpful to add the questionnaire as an extra file.

Response: We understand the reviewer's concern regarding the exposure variable and we see the problem with the instrument used to assess sexual violence in the MoBa study. We have added the questions used as a supplementary file. We have also added a link to the questionnaires in the paper. As to the classification mild, moderate and severe, we have used this terminology as it corresponds with other validated instruments that are used to study prevalences of violence. Women were not forced to choose between the three options in questionnaire 1 (pressured, forced with violence and raped) but could tick off any one or all of them. However, we re-coded them in such a way that each women was categorized according to the most serious level they had indicated. According to WHOs definition of sexual violence (Ref: Krug EG et al, World report on violence and health. WHO Geneva: 2002 page 149), all the different answer options is sexual violence. We have clarified the limitations regarding the exposure in the discussion.

In the English version of the questionnaires that can be viewed on MoBa's website, the wording regarding the exposure says “sexual intercourse”, but in the Norwegian version the term “omgang” is used. This is better translated into “sexual relations”. The majority of the respondents have used the Norwegian version of the questionnaires.

Comment 2: page 8 line 23-30: recent SV is grouped as during pregnancy or the last 6 or 12 months:

what do you mean: the last 12 months, or last 6 months, or the last 6 to 12 months? In most recent research the last 12 months is used, and then when it regards pregnancy, gestational weeks are given. Given this, would it be possible to split up your analysis for the women who were pregnant when being exposed to SV and those who weren't? Please add this, or explain more on this in the discussion section.

Response: The reason for using 6 and 12 month is that there have been different versions of the different questionnaires used in MoBa. In the first version of questionnaire 1, the question regarding the timing of the violence was a little different form the later versions.

We have clarified the rationale behind the timing variable. Few women were exposed to violence in pregnancy, hence we made the variable recent containing sexual violence during pregnancy or the last 6 and 12 month. We have added the questions regarding the exposure as suggested supplementary information and also added the web address were all the questionnaires that were used in MoBa can be found.

Comment 3: A main limitation in my opinion is the fact that SV is measured in the Q1 at 17 weeks, while several authors argue that the risk of SV raises with the length of pregnancy and that a lot of the results on recent SV & pregnancy can thus be questioned. This is not sufficiently discussed in the limitations section now, nor reflected in the rest of the paper.

Response: We agree with the reviewer comment and have added the fact that that the exposure is not measured after week 17 under limitations and we have also reflected more on this in the discussion section.

Comment 4: Finally, the paper posits that socio-demographic and behavioral factors made the links between a history of SV and poor neonatal outcome disappear. It is known that these factors are considered as consequences of SV and as risk factors for poor neonatal outcome. On page 10 the paper confirms that also in this study the women with a history of SV were significantly younger, more likely to have primary school education, were smoking, high BMI, mental distress. How certain can we be that these health indicators are not the result of their prior sexual victimisation and thus, indirectly contributed to poorer neonatal outcome? The role of mediators and confounders on this matter is not clear enough yet. So, please elaborate a little more on this when discussing the results and its relevance for health workers providing services to pregnant women and young mothers.

Response: We thank the reviewer for this valuable comment. Whether the mentioned health indicators are the result of prior sexual victimisation and an indirectly contributing to poorer neonatal outcome is difficult to assess. We have presented the crude and the adjusted OR in the paper and the crude OR may be a more accurate inference. Nevertheless, the covariates that we have chosen in our study are considered to be associated with the outcome, especially birth weight and therefore we chose to control for smoking, BMI and mental distress. We have discussed this further as suggested by both reviewers.

VERSION 2 – REVIEW

REVIEWER	Ines Keygnaert Ghent University, Belgium
REVIEW RETURNED	24-Sep-2014

GENERAL COMMENTS	My former remarks have been well addressed and the paper has overall been improved a lot, especially the discussion section. Just one minor thing: Q1 is mostly indicated to be taken at gestational week 17, yet when describing the outcome variables it is mentioned gestational week 18.