Author's response to reviews

Title: Fear for external cephalic version and depression: predictors of successful external cephalic version for breech presentation at term?

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Version: 4 Date: 2 October 2013

Author's response to reviews: see over
September 30, 2013

Editor-in-Chief

BMC Pregnancy & Childbirth

Dear Editor,

Please find enclosed a reversed version of our Manuscript ID: 4621741910095644, entitled:

**Fear for external cephalic version and depression: predictors of successful external cephalic version for breech presentation at term?**

We have incorporated most of the comments of the reviewers and we feel that the quality of the paper has increased substantially. Description of the revisions and answers to the reviewers can be found in this document.

We hope that this reversed version is now suitable for publication in the Journal.

On behalf of all authors,

Simone M Kuppens, MD, PhD.


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Reviewer's report 1 with answers

Title: Fear for external cephalic version and depression: predictors of successful external cephalic version for breech presentation at term?

Version: 1 Date: 29 August 2013

Reviewer: Jorge Burgos

Reviewer's report:

To the authors:

My congratulations for this original paper about ECV. Some suggestions.

To the reviewer: we thank you for the compliment en for your reviewer’s report.

1. Background: In my opinion, the risk of vaginal breech delivery has not been increasing in the last 10 years. In the last 10 years there has been evidence that vaginal breech delivery is as safe as caesarean delivery without its consequences (PREMODA Study). ACOG, RCOG, SCGO… has guidelines to improve the selection of the patients for vaginal breech delivery. In contrast, in the last 10 years, there has been evidence of the consequences of Term Breech Trial in the rate of vaginal breech delivery. The rise of caesareans in breech delivery is one of the most important reasons for the popularity of ECV.

Answer: We agree with the reviewer and deleted the passage: “due to increasing evidence of vaginal breech delivery risks”

2. Material and method: Who has performed the questionnaires? Who and How has evaluated the questionnaires? How has evaluated the abdominal muscles tone? And the engagement of the fetal breech? And the palpability of the fetal head? Subjectively? Why have you analysed AFI as categorical variable instead of continuous variable? There is any explanation in discussion. Better in method??

Answer: The questionnaires were written by the authors. The EDS-Questionnaire (Edinburgh Depression Scale) is a validated questionnaire. The patients read the questionnaires themselves and fulfilled this questionnaire. There was a research nurse available for the patients to assist them when questions were unclear. We mentioned that in the discussion in the following sentence: “EDS-scores were carefully obtained under supervision of an unbiased research nurse who accompanied the women when completing the EDS-survey.”

The evaluation has been done by two authors (SK, VP). The EDS questionnaires are multiple choice (4 choices in each question). There is a standardized calculation formula for calculation the results.

The abdominal muscles, engagement of the fetal breech and palpability of the head were evaluated before the ECV by the obstetric gynecologist and the midwife who performed the ECV. They evaluated the uterine and the abdominal muscle tone with their hands. Both parameters were subjective assessments.

We added the following sentence on page 8 (assessments): “Abdominal muscle tone, uterine tone and engagement of the fetal breech were subjective assessments measured by the obstetric gynecologist and the midwife who performed the ECV.”
We have analysed AFI categorically because from the literature these are relevant cut-off values for the success.

3. Material and method: Which is the p Value to include the variable in multiple regression analysis?

Answer: \( P < 0.1 \)

Success ECV is the dependent outcome variable, degree of fear and depression are two independent variables. These were entered into the multiple logistic regression analysis regression.
Of the confounders we only entered those that were significant at a single level \( (P < 0.1) \) into the multiple logistic regression model.

4. Results: In methods you have described two categories of type of breech (frank vs non-frank) but in table 2 are frank vs complete. Please explain.

Answer: we agree with the reviewer. Different nomenclature can confuse the reader. Therefore we changed the text in table 2, additional file 1 and additional file 2 from frank vs complete into frank vs non-frank.

5. Results: Variables as tonus has three categories but the analysis was performed by merging two of them. Why the merged? The analysis can be made with the three categories.

Answer: because the size of some groups were too small to do statistical analysis, we merged them according to clinical important categories.

6. Results: Why “head palpable” was not included in multiple regression analysis?

Answer: We agree with the reviewer. We repeated the analysis and the p-value of “head palpable” in simple logistic regression was 0.058. We included this variable in the multiple regression \( (p = 0.875) \). Therefore we added the results to table 2.

7. I’m agree with the authors that engagement of the breech is one of the most important predictor (better than the most). But the ECV before 37 weeks is not the solution. The results of Early-ECV increase the success rate but not the caesarean rate, the main objective of ECV. The ECV before 37 weeks may increase the preterm delivery.

Answer: We agree with the reviewer. Therefore we added a sentence on page 10 in the discussion.

“However, the number of CS did not decrease despite higher ECV success rate”

8. The main objective of the study is original but the discussion about it is limited.
Most of the discussion is about other factors associated to ECV success.

\textit{We added a limitation to the discussion on page 12: “Unfortunately we only looked at fear in an one-dimensional way and we did not distinguish between women’s fear for pain, fear for adverse outcome for the baby or fear for adverse outcome for herself. It is arguable that different causes for fear of ECV might have different effects on a woman’s willingness to accept ECV and ability to relax during the procedure.”}

9. Which was the information previous to ECV during pregnancy?
\textit{Answer: We do not completely understand this question. Do you mean ‘which information was given to the pregnant women before ECV?’
Patients were counselled by their own midwife or obstetrician. Furthermore, we advice all our patients to watch our movie on the internet which explains and shows the ECV procedure \url{http://www.youtube.com/watch?v=qp_uil2RTOY}
Furthermore, we also give them our brochure: ‘een stuitligging’ (see link \url{http://www.catharinaziekenhuis.nl/files/Patient/Patientenfolders/_ScreensPages/Behandelingen/GYN-006-Een_stuitligging.pdf}).}

10. Conclusion: I suggest add to the first sentence “in women who undergo to ECV”. The last sentence is not a conclusion of the study data. I suggest conclusions without it. The “engagement of the fetal breech” is one factor associated with the success of ECV. It is not the same that it is a reason of ECV failure. You did not analyse the reason of ECV failure.
\textit{Answer: We agree with the reviewer and therefore added the passage: “in women who undergo ECV” in the first sentence of the conclusion. It is true that the last sentence is not a conclusion of our study data. We therefore decided to delete this sentence from the conclusion. We changed the sentence (see page 3) into “Main reason for ECV failure was engagement of the fetal breech” into: Engagement of the fetal breech was the most important factor associated with a successful ECV.
And on page 13: “Psychological factors (fear for ECV and depression EDS-scores) were not related with ECV success rate in this study. Parity, BMI, placental location and engagement of the fetal breech were significantly related with the outcome of ECV. With engagement of the fetal breech being the most important factor associated with a successful ECV”}

\textbf{Level of interest:} An article whose findings are important to those with closely related research interests
\textbf{Quality of written English:} Acceptable
\textbf{Statistical review:} No, the manuscript does not need to be seen by a statistician.
\textbf{Declaration of competing interests:}
I declare that I have no competing interests

\textbf{References:}
Reviewer's report 2 with answers

Title: Fear for external cephalic version and depression: predictors of successful external cephalic version for breech presentation at term?
Version: 1 Date: 2 September 2013
Reviewer: Marlies Rijnders

Reviewer's report:
This article addresses an interesting and so far unknown issue in obstetric healthcare namely whether a woman's fear has any effect on the success of External Cephalic Version.
To the reviewer: we thank you for the compliment en for your reviewer's report.

Minor Essential Revisions
method section: it remains unclear how abdominal muscle tone and uterine tone is measured. This should be described as abdominal muscle tone is interpreted by the researcher as an important factor in the pathway fear-succes of ECV.

Answer: We agree with the reviewer that abdominal muscle tone and uterine tone are important factors for prediction of ECV success rate and we should describe how these variables were measured. Both factors were measured by the obstetric gynecologist and the midwife who performed the ECV. They evaluated the uterine and the abdominal muscle tone with their hands. Both parameters were subjective assessments.
We added the following sentence on page 8 (assessments): “Abdominal muscle tone, uterine tone and engagement of the fetal breech were subjective assessments measured by the obstetric gynecologist and the midwife who performed the ECV.”

Discretionary Revisions
Although the study is carried out properly it is a bit disappointing that the researchers only looked at fear in a unidimensional way, and did not distinguish between women's fear for pain, adverse outcome for the baby or herself, effect of ECV on mode of birth etc. Different causes of fear are brought forward by women as possible barriers to undergo an ECV (Rosman et al Midwifery 2013). It is arguable that the cause for fear of an ECV might have a different effect on a woman's willingness to accept ECV and ability to relax during the procedure. This is a noteworthy limitation in the study that can be mentioned in the discussion section.

Answer: we agree with the reviewer that it would be very interesting to distinguish between women’s fear for pain, fear for adverse outcome and fear for effects of ECV on mode of birth. Unfortunately we did not include these options in the questionnaires and we have no information about the different causes of fear these patients had.
We added this limitation to the discussion on page 12: “Unfortunately we only looked at fear in an one-dimensional way and we did not distinguish between women’s fear for pain, fear for adverse outcome for the baby or fear for adverse outcome for herself. It is arguable that different causes for fear of ECV might have different effects on a woman’s willingness to accept ECV and ability to relax during the procedure.”

Thus, although this study shows no relation between a woman's fear and successrate of ECV I do hope the researcher will continue to study psychological factors related to the uptake and success of ECV on a more extended level.
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.
Declaration of competing interests: I declare that I have no competing interests
Reviewer's report 3 with answers
Title: Fear for external cephalic version and depression: predictors of successful external cephalic version for breech presentation at term?
Version: 1 Date: 22 August 2013
Reviewer: Hen Y Sela
Reviewer's report:

Minor Essential Revisions
The article is well written and the study was performed well, and it should be published as it bares information relevant to providers who care for women that might need ECV. The study question posed is well defined an deserve an answer.

To the reviewer: we thank you for the compliment en for your reviewer's report.

The methods are appropriate and well described though the abdominal muscles tone and uterine tone were both assessed, as these are subjective measures, were there any attempt to systemize the grading system used, and if so was it validated?

Answer: in all patients an obstetric gynecologist and a midwife assessed the abdominal muscle tone and the uterine tone with their hands. Both parameters were subjective assessments. Both factors (uterine and abdominal muscle tone) were assessed by the obstetric gynecologist and the midwife who performed the ECV. They evaluated the uterine and the abdominal muscle tone with their hands. Both parameters were subjective assessments. We systemize them both into 3 grades: strong, normal or weak abdominal muscles and intense, normal or relaxed uterine tone. These gradings were not validated. We added the following sentence on page 8 (assessments): “Abdominal muscle tone, uterine tone and engagement of the fetal breech were subjective assessments measured by the obstetric gynecologist and the midwife who performed the ECV.”

The data appear to be solid still a more detailed description of the gestational age would be important. In the results section the mean gestational age and the SD were reported, as in today’s world we are trying to reduce delivered in the both the late preterm period and early term period, it would be interesting to report on these 2 gestational age ranges and not just the mean and SD. Furthermore in regard to the data, rate of epidural use is not reported as well as repeat ECV. The authors attempted to assess the effects of fear on ECV success, and they even mentioned that the fear from ECV might even be driven by fear of pain, yet they do not describe the use of Epidural in this population even though epidural use had been shown to increase success rate of ECV and there is no doubt that it reduce the pain during the procedure. (Goetzinger KR, Harper LM, Tuuli MG, Maclones GA, Colditz GA. Effect of regional anesthesia on the success rate of external cephalic version: a systematic review and meta-analysis Obstet Gynecol. 2011 Nov;118(5):1137-44)

Answer: regarding gestational age, we analysed this variable in two ways; as a continuous variable and as a dichotomous variable (gestational age <37 weeks and ≥37 weeks) We added the new dichotomous variable to table one (patient characteristics). We repeated multiple logistic regression with this variable instead of gestational age as a continuous variable. For the complete group group there was no significant relation between AD (<37/>37) and success rate. The group of women who underwent ECV >37 weeks of
gestational age was very small; 27 women (16 nulliparous women and 11 multiparous women). For multiparous women there was no significant relation between AD (<37/>37 weeks) and ECV success rate. For nulliparous women the AD (<37/>37 weeks) was only univariate significant and not in multiple regression analysis. Because of the small size of the group who underwent ECV >37 weeks, we chose to use the AD as a continue variable in the tables.

We agree with the reviewer that the use of epidural anesthesia is proven effective and safe in ECV. Unfortunately, at the time of our study the use of epidural anesthesia during ECV in our clinic was not yet well introduced.

In our experience most women don’t want a repeat ECV. So we have no data on this.

The discussion is well balanced, still in the conclusions section the last sentence states: Main reason for ECV failure was engagement of the fetal breech. This might be modified by initiating ECV earlier in pregnancy. This should be modified as:
a. The aim of the study was to assess the relation between psychological factors and ECV success rate.
b. This study did not prove that early ECV reduce the rate of engaged breech.
c. Early ECV in this study, within the entire population and in both subset of population was not found on multiple LR to effect success rate of ECV, and ECV does carry a risk of CD that though small 0.8%, still if done early exposes the neonate to effects of early delivery.
d. Even in a much larger study (ref 13) that aimed to assess the outcome of early vs. late ECV the authors concluded that :”ECV at 34–35 weeks versus 37 or more weeks of gestation increases the likelihood of cephalic presentation at birth but does not reduce the rate of caesarean section and may increase the rate of preterm birth.”

Answer: we agree with the reviewer and changed the conclusion into the following (see page 13):

Psychological factors (fear for ECV and depression EDS-scores) were not related with ECV success rate in this study. Parity, BMI, placental location and engagement of the fetal breech were significantly related with the outcome of ECV. With engagement of the fetal breech being the most important factor associated with a successful ECV.

Level of interest: An article of limited interest
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:
'I declare that I have no competing interests'
Reviewers report 4 with answers
Title: Fear for external cephalic version and depression: predictors of successful external cephalic version for breech presentation at term?
Version: 1 Date: 26 August 2013
Reviewer: Peng Chiong Tan
Reviewer's report:
This is an original report but there are a number of basic weaknesses in the enterprise leading to an unsurprising negative finding.

To the reviewer: we thank you for your reviewer's report.

1. The premise that a measure of depression caseness using the EDS may influence a technical issue like the immediate success rate at ECV is verging on the implausible as a hypothesis. The authors justified this with a rather vague “antepartum depression may have deleterious effects on peripartum maternal and neonatal outcomes”. It is illuminating in the discussion that the authors mentioned “intervention strategies to reduce anxiety, such as hypnosis or pain relief…” It would be somewhat more plausible amongst psychological parameters to suggest anxiety rather than depression as a potential factor affecting ECV success.

Answer: we agree with the reviewer that the hypothesis about anxiety is more plausible and better explained than the hypothesis about depression/mood status. We would like to explain this more extensively.

The EDS-score consists of three subscores: anxiety, depression and anhedonia. If a women scores higher in one of the subscales the total score will automatically be higher too. Our hypothesis is that women who are more depressed or have a high anhedonia score, tend to have more negative expectations towards ECV. This may lead to less cooperation and unintended increase of abdominal muscle tension. Therefore we added the following sentence to our background: Our hypothesis is that women who are more depressed tend to have more negative expectations towards ECV. This may lead to less cooperation and unintended increase of abdominal muscle tension and thereby to a lower success rate.

2. Fear of pain resulting in tensing of abdominal muscles hence affecting ECV is plausible. However, it is not at all clear that the VAS for fear of the procedure actually deals with fear of pain rather than a generalized concern of ECV including that of safety. So the VAS used is possibly flawed for testing this hypothesis. In any case, study women by committing themselves to ECV had already effectively overcome “fear” and invested in ECV success.

Answer: we agree with the reviewer that it is not all clear that the VAS for fear of the procedure actually deals with fear for pain. We only looked at fear in an one-dimensional way and we did not distinguish between women’s fear for pain, fear for adverse outcome for the baby or fear for adverse outcome for herself. It is arguable that different causes for fear of ECV might have different effects on a woman’s willingness to accept ECV and ability to relax during the procedure.

We added this to the discussion as one of the limitations of the study.

3. Immediate ECV success is dictated in the main by technical issues like accessibility to the fetal head, mobility afforded by a lax uterus and the non-engaged breech (Lau TK et al Br J Obstet Gynaecol. 1997 Jul;104(7):798-802). Tocolysis and regional anaesthesia are proven effective and safe aids in ECV. The issue of intolerable pain hindering ECV is easily surmounted in current practice, making the issue somewhat peripheral.
Answer: we agree that the issue of intolerable pain is easily surmounted by using regional anaesthesia. However epidural anesthesia has some side effects, therefore not all women want this method of pain relief. In our clinic the use of epidural anesthesia during ECV is not yet well introduced. We will certainly try to introduce it now.

Level of interest: An article of limited interest
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:
I declare that I have no competing interests