Author's response to reviews

Title: Postnatal quality of life in women after normal vaginal delivery and caesarean section

Authors:

 Behnaz Torkan (torkan@khuisf.ac.ir)
 Ali Montazeri (montazeri@acecr.ac.ir)
 Sousan Parsay (Suepar_nut@sbmu.ac.ir)
 Minoor Lamyian (lamyianm@modares.ac.ir)
 Anoshirvan Kazemnejad (kazem_an@modares.ac.ir)

Version: 2 Date: 5 November 2008

Author's response to reviews: see over
Dear Dr. Koutsos,

Thank you for your kind e-mail. I have found the reviewers’ comments very helpful. The manuscript was revised based on their suggestions. Please see below the point-by-point responses as requested.

**Reviewer: Professor Soo Downe**

1. Is the question posed by the authors well defined?
   The question is reasonably clear.
   Thank you.

2. Are the methods appropriate and well described?
   **Design**
   p12 states that this is a case control study, but it actually appears to be a cohort study - the authors do not demonstrate that the 'controls' were matched to the 'cases' in any specific way, either individually, or as a population.
   The sentence was deleted to avoid confusion.
   **Sample and power**
   The authors need to clarify how the sample was selected (and on what criteria).
   How did the authors ensure that the sample was representative of the population? For example, were the 130 women selected consecutively?
   I'm not sure why the exclusions were applied, or how many were excluded after entering the study. This matters because of the risk of bias in excluding people after entry to the study.
   This was clarified as requested (please see the two next comments and responses).
   The authors need to discuss the implications of including both emergency and elective CS in the CS group, as previous evidence would suggest that women in these groups may experience rather different quality of life postnatally.
   The following sentences were added to the Discussion:
   However, since in our study mothers in the caesarean section group consisted of both emergency and elective caesarean section, therefore one might argue the findings were influenced by the fact that women with elective or emergency caesarean may experience rather different quality of life during postnatal period [13,14].
   It is interesting that, although the exclusions are numerous, both groups ended up with 50 women each. Was study entry stopped at this stage, and were any balancing criteria applied (ie, if one group reached 50 first, was recruitment stopped in that group until the other group reached 50?)
   This was re-written as follows:
   **Design**
   This was a prospective study of quality of life of women living in Isfahan (a famous and historical city in the central part of Iran), and admitted for delivery in Isfahan health centers, affiliated to Isfahan university of Medical Sciences. In all a consecutive sample of 130 women were approached during their antenatal care and agreed to take part in the study after childbirth. Applying
inclusion and exclusion criteria 100 women (50 with normal delivery and 50 with caesarean section) made up the study sample and no one were excluded after entering the study. The recruitment was not based on the power calculation, and it was done post-hoc. Inclusion criteria were: being in the age range of 20-40 at the time of delivery, having one or two children, experience of just one type of delivery method, having a maximum of one abortion in the medical history and receiving prenatal care. Exclusion criteria were: having history of dystocia or instrumental delivery, still birth, having diseased or handicapped child, giving birth to a child with a weight of less than 2500 grams, history of general medical conditions, disabilities, depression, drug intake, major psychological problems, having stress inducing experiences such as lose of a family member, divorce, or family problems. Also, those with medical conditions such as low back pain, chronic constipation, urination problems, and breast problems before pregnancy were excluded from the study. Quality of life was measured at two points in time: time 1 (six to eight weeks after delivery), time 2 (12 to 14 weeks postpartum). Normal delivery was defined as unassisted vaginal delivery and the type of caesarean section included both emergency and elective caesareans. A trained female nurse collected the data in face-to-face interviews at two points in time: 6 to 8 weeks and 12 to 14 weeks after delivery.

Was the recruitment based on the power calculation, or was this done post-hoc?
The recruitment was not based on the power calculation, and it was done post-hoc.

Is a 10% difference in the (overall?) SF36 the standard difference for clinical significance?
To be honest we do not know.

Instrument
I'm not clear why the SF36 was chosen over the MGI and MAPP-QOL. It would be helpful if the authors could explain this.

This was clarified in the Methods under Measures subtitle:
Since at the time of this study the Iranian versions of postnatal quality of life measures such as the MGI or the MAPP-QOL were not available, quality of life was measured using the Iranian version of Short Form Health Survey (SF-36).

Data collection
The authors talk about interviews at two postnatal time points - but it appears that at least some data collection (such as demographics) may have been collected antenatally - can the authors please clarify this?

This was clarified in the Methods.

In addition, demographic data were collected using a short questionnaire during antenatal period and included recording of age, educational level, employment status, and number of children as a proxy of childbirth experiences.

Tables
Table one: significance tests are not needed or appropriate for comparing sample data (See the CONSORT statement: Standard errors and confidence intervals are not appropriate for describing variability -- they are inferential rather than descriptive statistics).
To our best knowledge the CONSERT statements applies to clinical trials. However, just we kept the significant test to show that the both groups were very similar.

ALL THE ABOVE ARE ESSENTIAL REVISIONS

Table 2: would it be possible to give confidence intervals for these data
95% CI for the mean differences both for Table 2 and Table 3 were provided.

DISCRETIONARY REVISION

3. Are the data sound?
If the questions above can be answered, then the data are probably sound.
Please see the above responses. Hope you find it satisfactory.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?
Again, this depends on the answers given to question 2 above
Please see the above responses. Hope you find it satisfactory.

5. Are the discussion and conclusions well balanced and adequately supported by the data?
The authors are right in saying that this is a small-scale study and therefore can't be generalised, but some of the statements in the discussion section are rather sweeping, and imply generalisibility beyond this population. The authors need to review the discussion section, and make reference only to this sample, and/or to any hypotheses arising from the study that could be tested in larger samples selected with minimum bias.

Done. The Discussion was tidied-up.

MAJOR ESSENTIAL REVISION

6. Are limitations of the work clearly stated?
See the response to point 5 above.

Limitations were revised.

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?
I would like to know how the studies using the MGI and MAPP-QOL might add to or detract from the conclusions drawn by the authors of this study.
These are very new instruments and we should wait for up-coming results from studies that are using these measures. We could not find studies of postnatal quality of life in women after normal vaginal delivery and caesarean section.

MINOR ESSENTIAL REVISION

8. Do the title and abstract accurately convey what has been found?
Not at present - some of the issues raised above about the body of the text are also relevant for the abstract.

Abstract was revised.

MAJOR ESSENTIAL REVISION

9. Is the writing acceptable?
Yes, with a few grammatical and spelling errors

Thank you. To our best knowledge we have tried to tidy-up the manuscript.

MINOR ESSENTIAL REVISIONS

Conclusions
It is unusual to see a study on this topic from the Middle East, and the authors are to be congratulated for embarking on this work. However, the issues above need to be addressed before the paper can be considered for
publication. I hope the authors are able to respond to these comments, and to resubmit their paper for further consideration in future.

Thank you. All comments were considered.

Reviewer: Dr. Marie Hatem

(1) General comments
The authors address a very important issue in the maternity care: the impact of Caesarean section on women’s postnatal quality of life. In fact, there is an epidemic even more a pandemic of planned Caesarean sections as if the women are no longer able to deliver naturally. Addressing the question is a very good choice to contribute to the development of knowledge of the decision makers in the field, at the different levels of the health system, starting from the stakeholders, the health institution administrators, the physicians and of course the women and their families.

The authors designed a prospective study and considered a sample of 100 women who delivered normally (50) or by caesarean (50). They measured the quality of life of these women at two points in time (time 1: 6 to 8 weeks after delivery; time 2: 12 to 14 weeks after delivery). Data were analyzed to compare quality of life in the two study groups.

(2) Specific comments
2.1. Is the question posed by the authors well defined?
The question is well defined: the authors sought to measure the health-related quality of life of women after normal delivery and caesarean section.

Thank you.

2.2. Are the methods appropriate and well described?
The methods are appropriate: the authors constituted a sample of 50 women who delivered normally and 50 women who had a caesarean section and questioned them about their health-related quality of life in the postpartum period, using a validated questionnaire. Criteria for inclusion and exclusion have been considered. A trained female nurse collected the data in face-to-face interviews. But the calculation of the sample size is not clear. Please see the study Design. This was revised to clarify sampling method.

2.3. Are the data sound?
The instrument used for the data collection has been already validated. Nevertheless, it assesses the general health-related quality of life and not that related to the postpartum period while the literature announces the existence of instruments that covers such issue. One can wonder why the generic instrument has been chosen.

This was clarified in the Methods under Measures subtitle:
Since at the time of this study the Iranian versions of postnatal quality of life measures such as the MGI or the MAPP-QOL were not available, quality of life was measured using the Iranian version of Short Form Health Survey (SF-36).

Regarding the analysis, it would have been interesting to have a comparison of the difference of the means of the two times (X1nd-X2nd) vs (X1cs-X2cs): are these differences significant within the groups and between the groups. In fact, the tables show a higher positive difference in the means for the caesarean section group vs vaginal delivery (role physical 17% vs 7%; vitality 10% vs -2%; role emotional 22% vs 11%; mental health 6% vs -1%; social functioning 8% vs -2%). It would have been important to discuss these issues;
one can consider that Caesarean section is better than vaginal delivery on the long run!!

This was considered and the following table (Table 4) was added to the manuscript. Accordingly a paragraph was added to the Results, and the abstract and the conclusion also was revised. A few sentences also added to the Discussion.

A. Table

Table 4: The mean score differences within each group (time 2 scores minus time 1 scores)*

<table>
<thead>
<tr>
<th></th>
<th>Normal delivery (n = 50)</th>
<th>Caesarean section (n = 50)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean Difference (SD)</td>
<td>Mean Difference (SD)</td>
<td></td>
</tr>
<tr>
<td>Physical functioning</td>
<td>8.9 (24.2)</td>
<td>4.3 (24.2)</td>
<td>0.34</td>
</tr>
<tr>
<td>Role physical</td>
<td>17.0 (40.8)</td>
<td>17.0 (40-8)</td>
<td>1.0</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>9.0 (22.9)</td>
<td>8.6 (21.5)</td>
<td>0.92</td>
</tr>
<tr>
<td>General health</td>
<td>2.5 (17.4)</td>
<td>-4.0 (16.0)</td>
<td>0.05</td>
</tr>
<tr>
<td>Vitality</td>
<td>-1.8 (22.1)</td>
<td>9.9 (16.3)</td>
<td>0.003</td>
</tr>
<tr>
<td>Mental Health</td>
<td>-0.4 (15.1)</td>
<td>5.6 (16.5)</td>
<td>0.06</td>
</tr>
<tr>
<td>Role emotional</td>
<td>11.3 (46.9)</td>
<td>22.6 (50.5)</td>
<td>0.24</td>
</tr>
<tr>
<td>Social functioning</td>
<td>2.3 (22.9)</td>
<td>8.3 (25.0)</td>
<td>0.21</td>
</tr>
</tbody>
</table>

* Positive values indicate improvements and negative values indicate deteriorations. Higher positive values indicate more improvements and higher negative values indicate more deteriorations.

B. Results

To compare the findings within each group the analysis showed that the normal vaginal delivery group showed more improvements on physical health related quality of life while the caesarean section group showed more improvements on mental health related quality of life. These were just significant for the general health subscale in favor of the normal delivery group (P = 0.05) and highly significant for the vitality subscale in favor of the caesarean section group. The results are shown in Table 4.

C. Abstract

1. Results: However, comparing the findings within each group the analysis showed that the normal vaginal delivery group showed more improvements on physical health related quality of life while the caesarean section group showed more improvements on mental health related quality of life.
2. Conclusion: …….the findings suggest that normal vaginal delivery might lead to a better quality of life especially resulting in a superior physical health.

D. Discussion

However, since in our study mothers in the caesarean section group consisted of both emergency and elective caesarean section, therefore one might argue the findings were influenced by the fact that women with elective or emergency caesarean may experience rather different quality of life during postnatal period [13,14]. Even this might explain the observed within group differences (Table 4).

2.4. Does the manuscript adhere to the relevant standards for reporting and data deposition?
Globally yes, it seems that the manuscript respects the relevant standards for reporting and data deposition. My unique comment goes to the references to the Iranian studies on page 6. I think that it is important to mention the year of the references 8 and 9.

These were mentioned.

2.5. Are the discussion and conclusions well balanced and adequately supported by the data?
Considering the analysis, the discussion is well written. Nevertheless, the conclusion may differ if the authors have to consider the comment in 2.3.

This is true. Thus we changed conclusion to: .......the findings suggest that normal vaginal delivery might lead to a better quality of life especially resulting in a superior physical health. [mental health was deleted from this sentence].

2.6. Are limitations of the work clearly stated?
The discussion covered mostly the sample size and the generalisability. It did not cover the choice of the instrument.

This also was added:
In addition we recommend the future studies include both general and specific measures in assessing postnatal quality of life among women. Unfortunately we only used a general instrument and this might be considered as a limitation.

2.7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?

Yes. Thank you.

2.8. Do the title and abstract accurately convey what has been found?
The title is fine.

In the abstract, it is mentioned in the methods that “a sample of women with normal delivery and matched cases with caesarean section... were entered into the study”. If the matching was really done, it is not obvious from the paper: there is no mention of such method in the text of the manuscript.

This was corrected.

2.10. Is the writing acceptable?

Globally yes. As I am not perfect in English, it would be preferable if an English speaking person does the assessment.

I can mention a few obvious error:
P. 7. “The aim of the study was to examine whether postnatal health-related quality of life was differed among...” eliminate was, or consider: was different

P. 10. “The primary physical health... of new mothers are also equally important” (use also or equally!)

P. 10. “Although these differences were disappeared in the second assessment...”

P. 11. “and child related factors (for example the condition of the baby)” maybe specify what you mean by condition.

P. 11. “It is argued postpartum mothers...” please add “argued that”.

P. 11. “This is consistencet with recent findings...”

P. 11. In two three areas, women after caesarean section scored... and vitality and social functioning at second evaluation (Table 2 and Table 3)” (even if it is not too high for social functioning, it is higher!).
A review of the literature showed a small numbers of women would request a caesarean section and these this request is influenced by a range of...

It seems that still there is a need to carry...” (or make some other changes in the phrase...)

Indeed in the absence of medical indications, normal vaginal (add delivery) might be better...

AK contributed (please add to) the statistical analysis...

All were corrected as requested (Thank you).

Reviewer: Dr. Pamela D Hill

In the concluding comments (Conclusion section) this reviewer strongly suggests that ‘elective termination of pregnancy’ is not appropriate as this research focused on vaginal vs. C/S in women who intended to deliver a term infant. It would seem that the authors have gone beyond the scope of the data with this concluding remark.

Elective termination of pregnancy was changed to term pregnancy.

I hope you find the corrections satisfactory. I also thanks the referees for reviewing this manuscript.
I wish you all the best.
Kind regards
Ali Montazeri