PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Questionnaire Survey on Women's Views after a first Caesarean Delivery in Two Tertiary Centres in Ireland and their Preference for Involvement in a Future Randomised Trial on Mode of Birth.
AUTHORS	Ryan, Gillian; O Doherty, Kate; Devane, Declan; McAuliffe, Fionnuala; Morrison, John

VERSION 1 - REVIEW

REVIEWER	Professor David Ellwood Griffith University School of Medicine, Queensland, Australia
REVIEW RETURNED	21-Jun-2019

GENERAL COMMENTS	Thank you for allowing me to review your interesting manuscript. I agree that this is an important area to research as the absence of adequately powered PCTs on VBAC limits our ability to provide evidence-based information to women after a first caesarean section. I have several comments and questions; 1. In your paper you note that the views of women about their satisfaction with their delivery outcome, and presumably also their willingness to consider either option for their next birth, may vary over time but no clear information is given as to when these surveys were administered. Were they all done immediately post-partum or did the time of administering the survey vary. Can you please provide this information? 2. The response that 80% of women would agree to be randomised is very high and this is surprising given the contrasting results from the only previous study like this. The survey question does not clearly state to women that they might be randomised to a type of birth and have no ability to choose. Can you respond to this concern? As this result is the most important one from this study it is critical to try to explain the reasons behind this high response rate. 3. I am concerned that this study combines data from both women having a c/section after their first birth and others who may have been in a subsequent pregnancy. Presumably some of these women may have had vaginal births the first time, whilst some may have had a previous c/section. Can you provide some further information about the women who were not in their first pregnancy.

	If the index c/section was not their first then this will impact significantly on their likelihood to consider VBAC 4. Can you provide some further information about the usual practice at both hospitals with respect to the counselling or debriefing after EMCS? The level of satisfaction with what was provided to women may or may not reflect this but knowing what is usual practice would help to understand these data. 5. I also have some concerns about the use of a 5-step scale to measure complicated matters such as satisfaction with care, and then combining steps 1,2 (satisfied), and 3, 4 & 5 (unsatisfied) to give a binary 'yes' or 'no' response. Have you attempted to validate this approach at all? Finally, the main message in this paper is that 80% of women might agree to be randomised which suggest that a RCT based on VBAC versus ELCS might be feasible. Do you have any plans to do this, what would your sample size need to be, and how long would this study take you to perform?

REVIEWER	Hannah Dahlen Western Sydney University Australia We are undertaking a large survey on VBAC in Australia that has just concluded
REVIEW RETURNED	18-Jul-2019

GENERAL COMMENTS	Review for BMJ Open : Questionnaire Survey on Women's Views after a first Caesarean Delivery and Preference for Involvement in a Future Randomised Trial on Mode of Birth. Thank you for the opportunity to review this paper. The topic is important and relevant in an era of less and less VBAC options for women. I have some comments: The paper needs a good edit as there are quite a few grammatical and sentence structure issues. I am not going to go through all of them but someone needs to do a good edit. In fact, the font changes all the way through so I wonder if the final version was the one submitted. You also use mode of birth and mode of delivery interchangeably. Women prefer mode of birth The strengths and weaknesses are all strengths and need to be redone as quite basic and non-informative. Put in some limitations One of the major factors that you need to address is the difference in women saying they will consent to an RCT and actually consenting. Other studies have encountered just this problem. A pilot study will be essential before a full trial proceeds. Also are Irish women more compliant with medical recommendations than other women as seen in the differences in willingness to participate in an RCTL? Also if you are targeting the women who don't really care either way what happens and agree to be randomised you will suffer the same issue the recent ARRIVE trial did where you have a non-representative population. These are serious considerations and more discussion is needed. Can you also look at response difference in desire to be included in a RCT between those who had a EMCS and ELSCS?

	Can you discuss the limitations and ethics of proposing a RCT on what is a complex intervention like this? What would your primary outcome measure be and you would need to do a feasibility and pilot study first. What is the current VBAC rate in Ireland and if different from the 40% in this study then what happens that means many women don't get their choice? While the surveys were sent out in a nine months period have you looked at differences in what women say early (before three months) and later on as this may impact on responses and also be interesting to know. For example, the undecided rate may be influenced by when the survey was done. The decision to agree to be randomised would likewise be affected by this. Can we get some ranges etc? Likewise looking at the difference between primips and multips would be important as they have different contexts and reasons for the caesarean section i.e much higher percentage of elective caesarean sections proportionally in multips. Have any of the scales used been validated? This is a very simple survey and no open for open text response. Was the survey translated for non-English speaking women? Can you comment as to why there was such a difference in the return rate between the two different organisations? Can you separate out failure to progress in labour from failed induction? This would be important to know as it is your number one reason for C/S. You have a results section and then a section called conclusion but it is really the discussion You need to make note in your limitations that non-responders may have been less satisfied and given different response. Another limitation is you gave no scope for open text responses which may have provided you even more valuable data.

VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 1

Reviewer Name: Professor David Ellwood

Institution and Country: Griffith University School of Medicine, Queensland, Australia

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

Thank you for allowing me to review your interesting manuscript. I agree that this is an important area to research as the absence of adequately powered PCTs on VBAC limits our ability to provide evidence-based information to women after a first caesarean section.

I have several comments and questions;

1. In your paper you note that the views of women about their satisfaction with their delivery outcome, and presumably also their willingness to consider either option for their next birth, may vary over time but no clear information is given as to when these surveys were administered. Were they all done immediately post-partum or did the time of administering the survey vary. Can you please provide this information?

Response:

This information has already been provided in the Methods section of the original manuscript, as per the text outlined below.

'This study was distributed to women who had their first caesarean birth between January and August 2017 in two tertiary teaching hospitals in the Republic of Ireland, Galway University Hospital on the west coast, and the National Maternity Hospital, Dublin on the east coast. The surveys were distributed over a 9-month period from September 2017 to March 2018 in an effort to capture the woman's views on a subsequent mode of delivery within the first year after the index pregnancy'.

This has now been highlighted in the Methods sections of the paper.

2. The response that 80% of women would agree to be randomised is very high and this is surprising given the contrasting results from the only previous study like this. The survey question does not clearly state to women that they might be randomised to a type of birth and have no ability to choose. Can you respond to this concern? As this result is the most important one from this study it is critical to try to explain the reasons behind this high response rate.

The survey question read as follows:

If you have a future pregnancy, discussion will take place between you and your doctor about the best method of delivery again, i.e. a normal labour and delivery or a repeat caesarean section. Sometimes the answer is not always clear. If there is a research study on this topic, which assigns you to one or the other option, would you agree to participate?

(If you did opt into a research study you would have the power to opt out at any time if you changed your mind. This question is for research purposes only and will not affect your future care.)

1. Yes

2. No

We are of the view that the survey question is well explained. We organised a focus group prior to the study with a number of women who had one previous caesarean section, in order to help validate the survey questions. In addition, a random selection of women (a sample of n=20) were contacted after receipt of the survey to discuss their understanding and ease of use of the survey. The feedback we received indicated that the participants had a good understanding of the issue addressed in this question. We have now inserted text in the Methods section of the paper outlining details of the above. The text reads as follows:

'A patient interaction focus group was organised prior to the study with a number (n=10) of women who had recently had their first caesarean section. Validation of the survey questions was a component of this meeting. In addition, telephone contact was made with a small number of participants (n=20) after receipt of the survey, to assess their understanding of the information included.'

Notwithstanding all of this, we agree that 80% was surprisingly high, and we have modified the text with inclusion of the need for a pilot study. The text reads as follows:

'In our study, 80% of the women expressed a willingness to being involved in a future RCT in which their mode of delivery would be determined by a process of randomisation. In the Australian study, only 29 women (10%) indicated a willingness to take part in such a trial. While we acknowledge it is unlikely that women with a clear preference for ELSCS will opt in to such a study, we are of the opinion that women who are undecided (28.8%) and those with an interest in having a VBAC (39.5%) may remain open to being involved in such a trial, but it is difficult to estimate, with any accuracy, those that would eventually agree to randomisation in a future pregnancy. This is an important finding from our study as it supports the concept of feasibility of such an RCT in an Irish population. It is our view that prior to any future RCT on this topic it would still be wise to perform a pilot study'.

3. I am concerned that this study combines data from both women having a c/section after their first birth and others who may have been in a subsequent pregnancy. Presumably some of these women may have had vaginal births the first time, whilst some may have had a previous c/section. Can you provide some further information about the women who were not in their first pregnancy? If the index c/section was not their first then this will impact significantly on their likelihood to consider VBAC

Women who had a previous vaginal delivery did have a higher preference for VBAC in a subsequent pregnancy than women after CS only in a first pregnancy. More women after their first pregnancy described themselves as being undecided. These data have all been outlined in the text. There was however no significant difference between primiparous women and multiparous women with regards to potential involvement in a future randomized trial on the topic. We have now inserted additional text

based on these comments analysing the rates of emergency caesarean section in both groups, and the effect this had on satisfaction rates. Interestingly these factors had no bearing on willingness to be involved in a future randomized controlled trial. This has been clarified in the text as follows:

'Women in the Para 1 group had an EMCS rate of 87.7% compared to 65.1% in the Para >1 group (P<0.01). The women in the Para 1 group were also less satisfied with the postnatal counselling received than those in the Para >1 group (55.6% vs 72.1%, p<0.01). There was also a difference observed in the preference for future mode of delivery, with 35.6% in the Para 1 group having had a preference for VBAC compared to 52.3% of women in the Para >1 (p<0.01). Despite this there was no difference observed in the proportions who would consider involvement in a future randomised trial on mode of birth, P1=82.4% and P>1= 76.7% (P=0.25).'

4. Can you provide some further information about the usual practice at both hospitals with respect to the counselling or debriefing after EMCS? The level of satisfaction with what was provided to women may or may not reflect this but knowing what is usual practice would help to understand these data.

The usual practice at both hospital sites for counselling women after their first caesarean section includes a number of approaches. The women and their partners are debriefed in the first 24 hours by the medical obstetric team involved. Depending on circumstances, and if it reflects patient preference, a hospital postnatal visit is arranged for 6 weeks after the delivery. This has now been inserted in the Discussion section of the paper as follows:

'The usual practice at both hospital sites for counselling women after their first caesarean section includes a number of approaches. The women and their partners are debriefed in the first 24 hours by the medical obstetric team involved. Depending on circumstances, and if it reflects patient preference, a hospital postnatal visit is arranged for 6 weeks after the delivery.'

5. I also have some concerns about the use of a 5-step scale to measure complicated matters such as satisfaction with care, and then combining steps 1,2 (satisfied), and 3, 4 & 5 (unsatisfied) to give a binary 'yes' or 'no' response. Have you attempted to validate this approach at all?

This approach was used after discussion with our statistician. We appreciate that objective measurement of the subjective perception of satisfaction is not ideal no matter how performed. We are of the view that this method is reasonably satisfactory.

Finally, the main message in this paper is that 80% of women might agree to be randomised which suggest that a RCT based on VBAC versus ELCS might be feasible. Do you have any plans to do this, what would your sample size need to be, and how long would this study take you to perform?

An RCT on this topic is a major undertaking, and in the past has proven rather challenging, hence the paucity of data. This group have a planned approach to this topic, starting with a pilot feasibility study. We are happy to share these plans with the reviewer as requested, but they are separate to the current paper/ study under review. The aim is to perform a pilot feasibility study on mode of delivery after a first caesarean section. Ethical committee approval has been obtained for a feasibility study to be performed. The number of patients required for recruitment in the initial phase of study is 200.

The aims of this study would be to:

1. To perform feasibility study to examine the willingness of participants to be randomised to a VBAC versus ERCS trial and to determine parameters for outcome measures and follow up

2. To simultaneously conduct this feasibility study as a pilot RCT to test design and processes for a future definitive study

3. To perform a study within a trial (SWAT) pertaining to timing of recruitment during pregnancy in relation to compliance and completion

4. To investigate the factors that influence women's' decisions to accept or reject randomization using survey and interview methodology

5. To assess maternal satisfaction regarding MOD and the pilot study. These objectives are designed as a prerequisite to a future definitive RCT.

Primary Study Endpoints:

1. The primary research objectives are:

- To ascertain the proportion of eligible women who would agree to participate in the pilot study of this two-arm randomized controlled trial – assessed by number recruited over number of eligible approached for study participation.

- To assess the acceptability of women to participate in such a RCT as assessed by questionnaire

- To assess the proportion of women that complied with the study protocol.

2. Secondary analysis of the following maternal and fetal data will also be performed:

- Maternal outcomes include: vaginal birth, caesarean section (emergency vs elective), death, uterine rupture, haemorrhage or need for transfusion, endometritis, hysterectomy, wound infection,

venous thromboembolism, wound infection, wound dehiscence, vulval or perineal haematoma, surgical complications (bowel or bladder damage intra operatively, significant uterine extension).

- Fetal outcomes include: Perinatal death, Apgar Score <7 at 5 mins, birthweight, neonatal intensive care unit admission, birth trauma, seizures, neonatal encephalopathy, severe respiratory distress syndrome, systemic infection.

A further patient satisfaction survey will be performed at 6 weeks follow up to determine if they were satisfied with the randomisation process and outcome of delivery.

Reviewer: 2

Reviewer Name: Hannah Dahlen

Institution and Country: Western Sydney University, Australia

Please state any competing interests or state 'None declared': We are undertaking a large survey on VBAC in Australia that has just concluded

Please leave your comments for the authors below

Review for BMJ Open : Questionnaire Survey on Women's Views after a first Caesarean Delivery and Preference for Involvement in a Future Randomised Trial on Mode of Birth.

Thank you for the opportunity to review this paper. The topic is important and relevant in an era of less and less VBAC options for women.

I have some comments:

The paper needs a good edit as there are quite a few grammatical and sentence structure issues. I am not going to go through all of them but someone needs to do a good edit. In fact, the font changes all the way through so I wonder if the final version was the one submitted.

Thank you for this comment. The text has been rechecked in detail prior to re-submission and any errors corrected.

You also use mode of birth and mode of delivery interchangeably. Women prefer mode of birth

This has been amended throughout the text to mode of birth

The strengths and weaknesses are all strengths and need to be redone as quite basic and non-informative. Put in some limitations

Thank you for this comment. There were in fact some limitations highlighted in the paragraph in the original manuscript, i.e. the fact that women's view might change over time or in a subsequent pregnancy and that it was not possible to assess the strength of the views expressed. However, we have added further limitations on the back of this comment, and particularly speculating in relation to the possible views of the non-responders. Further limitations were included in the text as follows:

'A further limitation is that these results reflect the opinions of the women who responded to the study. We are aware that the 45.2% of women who did not respond may have a different preference on mode of birth and may not be willing to participate in a trial of his nature.'

One of the major factors that you need to address is the difference in women saying they will consent to an RCT and actually consenting. Other studies have encountered just this problem. A pilot study will be essential before a full trial proceeds. Also are Irish women more compliant with medical recommendations than other women as seen in the differences in willingness to participate in an RCTL? Also if you are targeting the women who don't really care either way what happens and agree to be randomised you will suffer the same issue the recent ARRIVE trial did where you have a non-representative population. These are serious considerations and more discussion is needed. Can you also look at response difference in desire to be included in a RCT between those who had a EMCS and ELSCS?

Thank you for this comment. We agree that determining the actual number of women who would ultimately agree to randomization is a difficult to estimate with any accuracy, and moreover it is impossible to determine the actual number who would comply with the study protocol. We have highlighted this clearly in the Discussion section of the manuscript. We also agree that a pilot feasibility study needs to be implemented initially to determine if in fact our population would be willing to be involved in such a trial. An RCT on this topic remains a challenging undertaking.

With regards to the response difference in desire to be included in a RCT between those who had a EMCS and ELSCS, this information is provided in Table 3 of the original manuscript.

Can you discuss the limitations and ethics of proposing a RCT on what is a complex intervention like this? What would your primary outcome measure be and you would need to do a feasibility and pilot study first. What is the current VBAC rate in Ireland and if different from the 40% in this study then what happens that means many women don't get their choice?

The reply to this query regarding a pilot feasibility study is included above in response to reviewer 1 (Point 5.b).

The VBAC rate in Ireland varies significantly from one hospital to another as frequently occurs, and in the hospital sites of the study ranges between 30-40% at this time.

While the surveys were sent out in a nine months period have you looked at differences in what women say early (before three months) and later on as this may impact on responses and also be interesting to know. For example, the undecided rate may be influenced by when the survey was done. The decision to agree to be randomised would likewise be affected by this. Can we get some ranges etc? Likewise looking at the difference between primips and multips would be important as they have different contexts and reasons for the caesarean section i.e much higher percentage of elective caesarean sections proportionally in multips.

Unfortunately, we have no details on the exact time within the first year after the index caesarean that these women received and responded to the survey. The study was designed to get replies within the first year.

Regarding the difference between primips and mutips we have reviewed the data and included a further paragraph in the results sections as follows. This is detailed in the response above to Reviewer one (Point 3.).

Have any of the scales used been validated? This is a very simple survey and no open for open text response.

Prior to commencing the survey these questions were trialled on a small focus group of 10 women in the immediate postnatal period (4-6 weeks postnatally) to determine if there were any concerns understanding the survey questions. Initial surveys responders (approx. 25) were randomly selected also phoned to confirm some answers and ensure they had understood the questions accurately in an effort to validate the survey.

Was the survey translated for non-English speaking women?

The survey was available in English only and not translated into other languages. However, women were contacted by telephone to consent to the survey prior in advance, and it was established that they were happy with the English language.

Can you comment as to why there was such a difference in the return rate between the two different organisations?

The return rate in Galway was 54.8% and in Dublin was 49.4%. We are unable to comment on this difference.

Can you separate out failure to progress in labour from failed induction? This would be important to know as it is your number one reason for C/S.

Failure to progress in labour can occur in women who are induced or who go into spontaneous labour. What does one call failure to progress at 8cm, for example, in a woman who has been induced? The concept of induction of labour was however not intrinsic to the study and we simply categorized the reason for delivery on this basis.

You have a results section and then a section called conclusion, but it is really the discussion

This has been changed Discussion section.

You need to make note in your limitations that non-responders may have been less satisfied and given different response.

This has been added to the limitations as documented above.

Another limitation is you gave no scope for open text responses which may have provided you even more valuable data.

Thank you for this comment. While there was no specific comments section when patients were telephoned for consent to participate, they were encouraged to add additional comments and as a result we received both positive and negative feedback surrounding the delivery. Some of these comments have been included in the discussion section of the manuscript.

VERSION 2 – REVIEW

REVIEWER	David Ellwood, Dean of Medicine and Professor of Obstetrics & Gynaecology. Griffith University School of Medicne, Queensland, Australia
REVIEW RETURNED	18-Aug-2019

GENERAL COMMENTS	Thanks for your responses to my questions and the modifications to your manuscript. My questions about the timing of the survey in the first 12 months post-caesarean section, and the approach to debriefing after the birth were to help me to understand if the very positive responses you had could be explained by the timing after birth and the impact of the care given in the first few days or weeks after the birth. The responses may well change over time and in particular may be different early in the next pregnancy. However, I am encouraged by your plans for the pilot study before embarking on a major RCT and wish you every success with what would be a very important and landmark study if you can complete it.

REVIEWER	Hannah Dahlen Western Sydney University Australia We have undertaken a survey on VBAC but with diferent questions and aims
REVIEW RETURNED	26-Aug-2019

GENERAL COMMENTS	Thanks for these responses I feel this query has not been adequately answered. If you don't have any data on what the average time frame was in months that the survey was answered and what the range was please add this in your limitations 1. In your paper you note that the views of women about their satisfaction with their delivery outcome, and presumably also their willingness to consider either option for their next birth, may vary over time but no clear information is given as to when these surveys were administered. Were they all done immediately post-partum or did the time of administering the survey vary. Can you please provide this information Can you change the term delivery on page 38 line 31 to birth. You have changed most of these, thanks

VERSION 2 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 1

Reviewer Name: David Ellwood, Dean of Medicine and Professor of Obstetrics & Gynaecology.

Institution and Country: Griffith University School of Medicne, Queensland, Australia

Please state any competing interests or state ‘None declared’: None declared

Please leave your comments for the authors below

Thanks for your responses to my questions and the modifications to your manuscript. My questions about the timing of the survey in the first 12 months post-caesarean section, and the approach to debriefing after the birth were to help me to understand if the very positive responses you had could be explained by the timing after birth and the impact of the care given in the first few days or weeks after the birth. The responses may well change over time and in particular may be different early in the next pregnancy. However, I am encouraged by your plans for the pilot study before embarking on a major RCT and wish you every success with what would be a very important and landmark study if you can complete it.

Reviewer: 2

Reviewer Name: Hannah Dahlen

Institution and Country: Western Sydney University

Australia

Please state any competing interests or state ‘None declared’: We have undertaken a survey on VBAC but with different questions and aims

Please leave your comments for the authors below

Thanks for these responses

I feel this query has not been adequately answered. If you don’t have any data on what the average time frame was in months that the survey was answered and what the range was please add this in your limitations

1. In your paper you note that the views of women about their satisfaction with their delivery outcome, and presumably also their willingness to consider either option for their next birth, may vary over time but no clear information is given as to when these surveys were administered. Were they all done immediately post-partum or did the time of administering the survey vary. Can you please provide this information

The aim of this survey was to capture women's views on a first caesarean delivery within one year of the index birth. Unfortunately, we do not have data on the average time frame that these women responded. We have amended the text to include this as a further limitation as requested as follows:

"The aim of this study was to capture the views of women within one year after their first CS. A further limitation of the study is that we do not have data on the average time frame and the range of their response and are therefore unable to comment if this would have influenced their responses in any way".

Can you change the term delivery on page 38 line 31 to birth. You have changed most of these, thanks

These changes have been made.