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.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-031766
Article Type:	Research
Date Submitted by the Author:	17-May-2019
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Keywords:	Maternal medicine < OBSTETRICS, Caesarean section, Vaginal Birth after Caesarean, Birth Preference after Caesarean, Randomised Trial on Mode of Birth

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

Running Title: Survey of Women's Views after a first Caesarean

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Abstract

Objective:

To assess the views of women after a first caesarean section on their birth experience, preference for future mode of delivery and willingness to participate in a randomised controlled trial on mode of birth in a future pregnancy.

Design:

Questionnaire survey.

Setting:

Two tertiary maternity centres in Ireland, Galway University Hospital, Galway and the National Maternity Hospital, Dublin.

Participants:

Women with one previous caesarean section.

Methods:

Eligible women were consented to participate, and postal surveys forwarded. Results were collected and analysed. Results were compared between women who had elective and emergency operations.

Primary Outcome Measures:

The satisfaction levels of women after a first caesarean, their preference for mode of birth in a future pregnancy and their willingness to participate in a randomised trial on mode of birth.

Results:

There were 347 completed surveys of 633 women consented (54.8%), of whom 285 and 62 had emergency and elective caesarean deliveries respectively. In general, satisfaction ratings with the delivery were greater than 90%, with similar levels of satisfaction with the care received from doctors and midwives. Women who an emergency procedure expressed lower satisfaction levels with the information about the caesarean and the debriefing received afterwards than women who had a planned operation (P<0.05). For future mode of delivery 39.5% expressed a preference for vaginal birth after caesarean in a subsequent pregnancy and 80% said they would consider involvement in a randomised trial in a future pregnancy.

Conclusion:

Debriefing and counselling women after a caesarean section is an important part of pregnancy care and can significantly impact on a woman's overall birth experience. A significant proportion of this cohort considered vaginal birth after caesarean as a future birth option. These data indicate that a randomised trial on mode of birth after caesarean would be viewed positively by women in our population.

Strengths and Limitations of this Study

- This study assesses the satisfactions levels of women having a first caesarean sections on various aspects of care and investigates whether the type of

caesarean delivery influences preference for future mode of delivery and willingness to participate in a randomised trial on mode of birth in a future pregnancy.

- The strengths of this study include the large number of women recruited across two different geographical sites.
- The evaluation of future birth preferences and willingness to participate in a randomised controlled trial on mode of delivery is a topic on which there are minimal data in a European obstetric population.
- This analysis gives an overview of preference for future mode of birth and willingness to be involved in a trial on mode of birth, but we are unable to assess how this preference may change over time.

Disclosure of interests

None declared.

Funding Statement

This research received no specific funding from any funding agency in the public, commercial or not-for-profit sectors.

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

Introduction

Women who have had one previous caesarean section (CS) represent a significant proportion of all women presenting for antenatal care in pregnancy [1,2]. For the majority of such women, the option of having either a vaginal birth after caesarean (VBAC) or a repeat elective caesarean section (ELSCS) is a focus of major discussion in a subsequent pregnancy. Many factors influence this decision including the reason for the original CS, other obstetric variables, views of the attending obstetrician, and finally, and most importantly, the views of the mother and her partner [1,3]. This discussion includes attention to the risks and benefits of VBAC versus repeat ELSCS [3-8]. Apart from these clinical issues, there are many geographical [1,9-11], institutional

[12], epidemiological and legal factors [13] that influence VBAC rates worldwide. What is clear however is that VBAC attempt rates [1], and VBAC rates [1], have been declining significantly in recent years in developed countries [1,7]. Apart from the clinical importance of this topic, and the associated morbidity, increasing CS rates also place a significant burden on healthcare resources [14,15].

Notwithstanding the issues outlined above, the evidence available for counselling the woman who has had one CS regarding her birth options in a future pregnancy is limited. Currently, the only data from randomised controlled trials (RCT) of VBAC versus repeat ELSCS emanates from two trials [16,17], totalling 320 women. Only one of these provided results on maternal and fetal outcomes [17], and the numbers were too small to generate strong recommendations that might inform women's decision on mode of birth. A Cochrane review concluded that both options of VBAC and repeat ELSCS are associated with benefits and harms, however evidence for the magnitude of these outcomes was drawn from non-randomised studies, associated with potential bias, and hence must be interpreted with caution [4]. The need for further RCTs was emphasized. However, there remains a doubt concerning the feasibility of such a trial, and whether or not women would agree to randomisation [4,14]. There are minimal data regarding women's views on this topic, and none to our knowledge pertaining to a European population of expectant mothers. The aims of this study were to evaluate the views of women who had one previous CS regarding their experience of delivery, their preference for birth options in a future pregnancy, and finally their willingness, or otherwise, to participate in a potential future RCT of VBAC versus repeat ELSCS.

Methods

This study used a written questionnaire survey of women who had their first CS 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. Institutional review board approval was obtained at both sites (Galway University Hospital Reference No. 1804 and National Maternity Hospital Reference No. EC 37.2017). Eligible participants were identified using hospital maintained computerised databases. Women were contacted by telephone or post for consent, and postal surveys forwarded subsequently. Surveys were distributed over a 9-month period (September 2017-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. Exclusion criteria included women under 18 years of age and women identified as having had a perinatal loss (information received from the hospital databases).

The following factors were included in the survey instrument: 1. The reason for CS; 2. Whether it was planned or unplanned/emergency; 3. Women's satisfaction regarding; (a) the statement that a caesarean section was the best option for them at the time; (b) the care received from the obstetric team; (c) the care received from the midwifery team; (d) the information received prior to delivery regarding the CS; (e) the information / debriefing received after delivery regarding the CS; 4. Women's preference for mode of delivery in a future pregnancy; and 5. Women's willingness or otherwise, to participate in a future RCT of VBAC versus repeat ELSCS. Satisfaction scores obtained (1-5) were grouped into those from women who described themselves as satisfied (satisfaction rating 1-2) with their experience or those that were not

satisfied (satisfaction rating 3-5). A copy of the survey form is in Supplementary File 1 and has been forwarded to the editorial board.

Demographic details including maternal age, BMI, gestation at delivery, parity and ethnicity were ascertained from the hospital databases. Statistical analyses were performed using Chi-Square test and T-Test as appropriate (IBM SPSS Version 24). A P value of <0.05 was accepted as being statistically significant. A subgroup analysis was also performed between women who had a planned / ELSCS and women who had an unplanned/ emergency CS (EMCS).

Results

A total number of 734 women were identified from the hospital databases as being eligible to participate in the survey and 633/734 (86.2%) consented to participate and were sent postal questionnaire surveys. There were 347/633 (54.8%%) completed survey forms returned for analysis; 154/242 (63%) at Galway University Hospital and 193/391 (49.4%) at the National Maternity Hospital, Dublin. Of these, 285/347(82.1%%) had an EMCS, and 62/347 (17.9%) had an ELSCS. The main reasons for CS were failure to progress in labour or failed induction of labour 121/347 (34.9%); abnormal fetal heart rate pattern 108/347 (31.1%); malposition (including breech presentation) 50/347 (14.4%); other (including previous third-degree tear, maternal anxiety, previous shoulder dystocia, urinary incontinence) 35/347 (10.1%), maternal medical reason 24/347 (6.9%), failed instrumental delivery 8/347 (2.3%) and one where the woman was unsure of the indication for CS 1/347 (0.3%). There were 261 women who had the CS in their first pregnancy (Para 1) and 86 women had the CS in a second or subsequent pregnancy (parity >1). The demographics of the group are presented in Table 1. The average

maternal age was 34.9 years and the average BMI was 25.9 kg/m^2. The mean gestation at time of birth was higher in the EMCS group than in the ELSCS group (39^{+6} weeks vs 38^{+5} weeks respectively, P=0.01). There were no other significant differences in the demographics of both groups of women.

A comparison of the results of the survey questions by women in EMCS and ELSCS groups are presented in Table 2. The vast majority of women in both groups (95-96%) were satisfied in general that CS was the most appropriate delivery option for them given their clinical circumstances. Replies to the question pertaining to the medical care provided revealed satisfaction levels of 92-98%. Regarding midwifery care, satisfaction levels were 90-93%. However, women in the EMCS group were less satisfied with the information received regarding the CS, both prior to delivery (P<0.05) and postnatally (P<0.01) (Table 2). The lowest rates of satisfaction overall (54%) were experienced by women in the EMCS group regarding their views on the debriefing information they received postnatally. No difference was observed between hospital sites in relation to these levels of satisfaction.

In the overall cohort, 39.5% of women expressed a preference for VBAC in a subsequent pregnancy, and this was similar for women in the EMCS and ELSCS groups (Table 3). The preference rate for repeat ELSCS overall was 31.7%. The proportion of women who were undecided was 28.8%. Approximately 80% of women in both groups said they would consider randomisation in a future pregnancy (Table 3). These findings were similar among women across both hospital sites.

Conclusion

Management of delivery for the woman who has had one previous CS is a controversial area of obstetric practice, with many factors influencing the decision to pursue either VBAC or ERCS [1, 3,13,18], as outlined above. However, it is well established that the view of the woman is paramount in arriving at a decision regarding mode of delivery in these circumstances [19], and hence the focus of this study was that of the satisfaction levels of women who had one CS regarding their past delivery, and their plans or deliberations for a future birth. There are minimal data to our knowledge on this topic in a European obstetric population. The strengths of this study include the large number of women recruited across two different geographical sites, specific evaluation of future birth preferences and willingness to participate in a randomised controlled trial on mode of delivery, and finally, the level of concordance of the results across both sites. The limitations of this study are discussed below.

In this study, satisfaction with the delivery, i.e. having had a CS, was in the region of 95% and was similar for both EMCS and ELSCS groups. This is in contrast to other studies which have reported lower satisfaction rates for women who had unplanned caesarean sections compared with women who had planned caesarean

sections [20,21]. We similarly observed high satisfaction rates, i.e. greater than 90% with care providers. This study also assessed the level of satisfaction women experienced related to information received at the time of CS and the postnatal debriefing provided. Unsurprisingly, women who had an EMCS reported a significantly lower satisfaction level with information received at the time of delivery than their counterparts who had an ELSCS. This factor may well be related to the fact that the majority of these operations were performed intrapartum, and in many cases done as an emergency procedure. It is disappointing that only 54% of women in the EMCS group were satisfied with postnatal counselling and debriefing. Specific comments from women included 'I found the aftercare disappointing', 'there was no counselling or information given about what happened or what to expect', 'my experience was very frightening, and the reason discussed only briefly' and 'I still have unanswered questions about my delivery'. The NICE guideline on CS states that women after a CS should be given the opportunity to discuss the reasons for the CS and be provided with both verbal and printed information about future birth options [22]. Despite this recommendation there remains a paucity of guidelines surrounding the best practice for postnatal debriefing, and similarly there is a lack of guidance regarding postnatal follow up for women who may have had more difficult or traumatic childbirth experiences.

Regarding future mode of birth, 39.5% of the overall group expressed a preference for VBAC, while 31.7% had a preference for repeat ELSCS and 28.8% were undecided. The statistic of approximately 40% of women expressing a preference for VBAC is remarkably consistent from the studies that are available. A recent US study on this topic reported that at 12 months postpartum, 45% of women who delivered by caesarean in their first birth wanted to have their

next delivery vaginally [23]. An Australian survey by Dodd et al explored the views of women in the first 6 months after delivery and found a similar preference with regards to VBAC at 41%, while only 23% expressed an interest in a repeat ELSCS and 35% described themselves as being unsure [14]. However, when it comes to willingness to be recruited to a future RCT of VBAC versus repeat ELSCS, the data from our study are markedly in contrast to the findings from the one other study that examined this [14]. 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 [14]. 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.

We recognise that there are certain limitations to our study. This analysis gives an overview of women's satisfaction with their CS and their preference for future mode of birth but was not able to assess the strength of this preference. Similarly, the birth preference may change over time and the data presented may not truly reflect the proportion who ultimately pursue their stated preference in a subsequent pregnancy. It is encouraging for a future RCT that 80% of our population expressed an interest in being recruited but that statistic, as alluded to above, may change during the course of a subsequent pregnancy. It was not possible to assess the strength of

the views expressed, particularly as randomly assigning mode of birth would remove the element of clinician preference and patient choice, though one could argue that agreeing to randomisation is in fact a birth preference in itself.

In conclusion, a significant proportion of women in this cohort considered VBAC as an option for a future birth, and a majority of women stated they would consider randomisation in a potential RCT on the topic. These data indicate that randomised trial of VBAC versus repeat ELSCS would be viewed positively by women with one previous CS.

Contribution to authorship

Study concept and design GR, JM, FM. Data acquisition and analysis GR, KOD. Drafting and critical revision of the manuscript GR, JM, DD, FM.

Details of ethics approval

Ethical approval was received from both Galway University Hospital and the National Maternity Hospital for this study (Galway University Hospital Reference No. 1804, 13th October 2017 and National Maternity Hospital Reference No. EC 37.2017, 8th January 2018).

Acknowledgements

We are grateful to all the women who participated in this study and all involved in collecting and analysing the data at both hospital sites.

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	Overall group (n=347)	EMCS (n=285)	ELSCS (n=62)	P Value
Para>1	86	56	30	
Para=1	261	229	32	
Average age (Years)	34.9	34.99	34.89	ns
Average BMI (kg/m²)	25.9	25.95	25.43	ns
Gestation at Delivery (weeks + days) Mean	39^{+5}	39^{+6}	38^{+5}	P<0.01
Nationality: Irish	276 (79.5%)	227 (79.6%)	49 (79.04%)	
Other	71 (20.5%)	58 (20.35%)	13 (20.96%)	

Table 1: Demographic Features of the Groups.

Table 1 Legend. Patient demographic features comparing the emergency caesarean delivery group with elective caesarean delivery group.
Statistical significance was taken as P<0.05. ns=Not significant.
EMCS = emergency caesarean section. ELSCS= elective caesarean section.
Para1=Women after their first pregnancy. Para>1 =Women in a second or subsequent pregnancy.

Table 2. Patients Level of Satisfaction by Emergency Caesarean Delivery versus Elective Caesarean Delivery

	EMCS (n=285)	ELSCS**(n=62)**	**P Value**
Satisfied with Mode of Delivery	272 (95.5%)	60 (96.8%%)	ns
Satisfied with Medical Care Provided	263 (92.3%)	61 (98.4%)	ns
Satisfied with Midwifery Care Provided	259 (90.9%)	58 (93.5%)	ns
Satisfied with information at time of delivery	250 (87.8%)	61 (98.4%)	P<0.05
Satisfied with Postnatal Counselling & Information about Caesarean	154 (54%)	51 (82.3%)	P<0.001

Table 2 Legend. Patient satisfaction levels comparing emergency caesarean delivery group with elective caesarean delivery group.
Statistical significance was taken as P<0.05. ns=Not significant.
EMCS = emergency caesarean delivery. ELSCS= elective caesarean delivery

	Overall Group (n=347)	EMCS (n=285)	ELSCS (n=62)	P Value
Preference for Future Mode of Delivery:				
VBAC	137 (39.5%)	114 (40%)	23 (37.1%)	ns
Repeat ELSCS	110 (31.7%)	83 (29.1%)	27 (43.5%)	ns
Undecided	100 (28.8%)	88 (30.9%)	12 (19.4%)	ns
Would consider involvement in an RCT of VBAC vs Repeat ELSCS?				
Yes	281 (81%)	230 (80.7%)	51 (82.3%)	ns
No	66 (19%)	55 (19.3%)	11(17.7%)	ns

Table 3. Preferences for Future Delivery.

Table 3 Legend. Patient preferences for future mode of delivery and willingness to be involved in a future randomised trial of vaginal birth after caesarean or elective repeat caesarean delivery. Statistical significance was taken a P<0.05. ns=Not significant.
VBAC= vaginal birth after caesarean. RCT= randomised controlled trial.
EMCS = emergency caesarean section. ELSCS= elective caesarean section.

Supplementary File 1. The questionnaire survey completed by patients.

Questionnaire

1. **What reason below best fits with the reason you had the caesarean section? (Please tick beside most appropriate answer)**

    1. Fetal Distress i.e. there was concern about the baby in labour
    2. Failure to Progress/Failed induction of labour/Very slow or poor progress in labour
    3. Maternal medical reason (e.g. diabetes, low lying placenta)
    4. Baby in the wrong position (e.g. breech, transverse)
    5. No success with delivery of the baby with forceps or vacuum
    6. Other
    7. Don't know

2. **Was it a planned procedure in advance (called elective) or what was it an emergency?** _____

3. **Are you satisfied that the caesarean section was the best option, for you in those circumstances, for the delivery of the baby?**

    1. Very satisfied
    2. Satisfied
    3. Not sure
    4. Not satisfied
    5. Very unsatisfied

4. **Do you feel the care you received was professional and supportive from the doctors?**

    1. Very satisfied
    2. Satisfied
    3. Not sure
    4. Not satisfied
    5. Very unsatisfied

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5. **Do you feel the care you received was professional and supportive from the midwifery team?**

    1. Very satisfied
    2. Satisfied
    3. Not sure
    4. Not satisfied
    5. Very unsatisfied

6. **Are you satisfied that you received adequate information about the reason for caesarean section at the time of your delivery?**

    1. Very satisfied
    2. Satisfied
    3. Not sure
    4. Not satisfied
    5. Very unsatisfied

7. **Are you satisfied that you received adequate information and counselling in the postnatal period (i.e. after delivery)?**

    1. Very satisfied
    2. Satisfied
    3. Not sure
    4. Not satisfied
    5. Very unsatisfied

8. **What would be your preferred option for a future delivery?**

    1. Normal labour and delivery
    2. Repeat planned caesarean section
    3. Undecided

9. **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?**

    1. Yes
    2. No

(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 in any way.)

Standards for Reporting Qualitative Research (SRQR)*

http://www.equator-network.org/reporting-guidelines/srqr/

	Page/line no(s).
Title and abstract	
Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	Yes
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	Yes
Introduction	
Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	Yes
Purpose or research question - Purpose of the study and specific objectives or questions	Yes
Methods	
Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	Yes
Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	Yes
Context - Setting/site and salient contextual factors; rationale**	Yes
Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	Yes
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	YES
Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	Yes

Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	Yes
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	Yes
Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	Yes
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	Yes
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	Yes

Results/findings

Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	Yes
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	Yes
Limitations - Trustworthiness and limitations of findings	Yes

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	Yes
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	Yes

*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

**The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

Reference:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014
DOI: 10.1097/ACM.0000000000000388

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-031766.R1
Article Type:	Original research
Date Submitted by the Author:	15-Aug-2019
Complete List of Authors:	Ryan, Gillian; NUI Galway, Department of Obstetrics and Gynaecology; Galway University Hospitals, Department of Obstetrics and Gynaecology O Doherty, Kate; National Maternity Hospital, Obstetrics and Gynaecology Devane, Declan; National University Of Ireland, Galway, School of Nursing & Midwifery McAuliffe, Fionnuala; University College Dublin, UCD Perinatal Research Centre; National Maternity Hospital, Obstetrics and Gynaecology Morrison, John; National University of Ireland Galway, Obstetrics and Gynaecology
Primary Subject Heading:	Obstetrics and gynaecology
Secondary Subject Heading:	Obstetrics and gynaecology
Keywords:	Maternal medicine < OBSTETRICS, Caesarean section, Vaginal Birth after Caesarean, Birth Preference after Caesarean, Randomised Trial on Mode of Birth

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.

Running Title: Survey of Women's Views after a first Caesarean

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Abstract

Objective:

To assess the views of women after a first caesarean section on their birth experience, preference for future mode of birth and willingness to participate in a randomised controlled trial on mode of birth in a future pregnancy.

Design:

Questionnaire survey.

Setting:

Two tertiary maternity centres in Ireland, Galway University Hospital, Galway and the National Maternity Hospital, Dublin.

Participants:

Women with one previous caesarean section.

Methods:

Eligible women were consented to participate, and postal surveys forwarded. Results were collected and analysed. Results were compared between women who had elective and emergency operations.

Primary Outcome Measures:

The satisfaction levels of women after a first caesarean, their preference for mode of birth in a future pregnancy and their willingness to participate in a randomised trial on mode of birth.

Results:

There were 347 completed surveys of 633 women consented (54.8%), of whom 285 and 62 had emergency and elective caesarean deliveries respectively. In general, satisfaction ratings with the delivery were greater than 90%, with similar levels of satisfaction with the care received from doctors and midwives. Women who an emergency procedure expressed lower satisfaction levels with the information about the caesarean and the debriefing received afterwards than women who had a planned operation (P<0.05). For future mode of birth 39.5% expressed a preference for vaginal birth after caesarean in a subsequent pregnancy and 80% said they would consider involvement in a randomised trial in a future pregnancy.

Conclusion:

Debriefing and counselling women after a caesarean section is an important part of pregnancy care and can significantly impact on a woman's overall birth experience. A significant proportion of this cohort considered vaginal birth after caesarean as a future birth option. These data indicate that a randomised trial on mode of birth after caesarean would be viewed positively by women in our population.

Strengths and Limitations of this Study

- This study assesses the satisfactions levels of women having a first caesarean section on various aspects of care and investigates whether the type of caesarean delivery influences their preference for future

mode of birth and their willingness to participate in a randomised trial on mode of birth in a future pregnancy.

- The strengths of this study include the large number of women recruited across two different geographical sites.
- The evaluation of future birth preferences and willingness to participate in a randomised controlled trial on mode of birth is a topic on which there are minimal data in a European obstetric population.
- This analysis gives an overview of preference for future mode of birth and willingness to be involved in a trial on mode of birth, but we are unable to assess how this preference may change over time.

Disclosure of interests

None declared.

Funding Statement

This research received no specific funding from any funding agency in the public, commercial or not-for-profit sectors.

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.

Introduction

Women who have had one previous caesarean section (CS) represent a significant proportion of all women presenting for antenatal care in pregnancy [1,2]. For the majority of such women, the option of having either a vaginal birth after caesarean (VBAC) or a repeat elective caesarean section (ELSCS) is a focus of major discussion in a subsequent pregnancy. Many factors influence this decision including the reason for the original CS, other obstetric variables, views of the attending obstetrician, and finally, and most importantly, the views of the mother and her partner [1,3]. This discussion includes attention to the risks and benefits of VBAC versus repeat ELSCS [3-8]. Apart from these clinical issues, there are many geographical [1,9-11], institutional [12], epidemiological and legal factors [13] that influence VBAC rates worldwide. What is clear however is that VBAC attempt rates [1], and VBAC rates [1], have been declining significantly in recent years in developed countries [1,7]. Apart from the clinical importance of this topic, and the associated morbidity, increasing CS rates also place a significant burden on healthcare resources [14,15].

Notwithstanding the issues outlined above, the evidence available for counselling the woman who has had one CS regarding her birth options in a future pregnancy is limited. Currently, the only data from randomised controlled trials (RCT) of VBAC versus repeat ELSCS emanates from two trials [16,17], totalling 320 women. Only one of these provided results on maternal and fetal outcomes [17], and the numbers were too small to generate any strong recommendations that might inform women's decision on mode of birth. A Cochrane review concluded that both options of VBAC and repeat ELSCS are associated with benefits and harms, however the evidence for the magnitude of these outcomes was drawn from non-randomised studies, and associated with potential bias, and therefore must be interpreted with caution [4]. The need for further RCTs was emphasized. However, there remains a doubt concerning the feasibility of such a trial, and whether or not women would agree to randomisation [4,14]. There are minimal data regarding women's views on this topic, and none to our knowledge pertaining to a European population of expectant mothers. The aims of this study were to evaluate the views of women who had one previous CS regarding their experience of delivery, their preference for birth options in a future pregnancy, and finally their willingness, or otherwise, to participate in a potential future RCT of VBAC versus repeat ELSCS.

Methods

This study used a written questionnaire survey of women who had their first CS between January and August 2017 in two tertiary teaching hospitals in the Republic of Ireland, Galway University Hospital, Galway on the west coast, and the National Maternity Hospital, Dublin on the east coast. Institutional review board approval was obtained at both sites (Galway University Hospital

Reference No. 1804 and National Maternity Hospital Reference No. EC 37.2017). Eligible participants were identified using hospital maintained computerised databases. Women were contacted by telephone or post for consent, and postal surveys subsequently forwarded. 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. Exclusion criteria included women under 18 years of age and any women who had a perinatal loss (information received from the hospital databases). A patient interaction focus group was organised prior to the study with a number (n=10) of women who 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.

The following factors were included in the survey instrument: 1. The reason for the CS; 2. Whether it was a planned or unplanned/emergency procedure; 3. Women's satisfaction regarding; (a) the statement that a CS was the best option for them at the time; (b) the care received from the obstetric team; (c) the care received from the midwifery team; (d) the information received prior to delivery regarding the CS; (e) the information / debriefing received after delivery regarding the CS; 4. Women's preference for mode of birth in a future pregnancy; and 5. Women's willingness or otherwise, to participate in a future RCT of VBAC versus repeat ELSCS. Satisfaction scores obtained (1-5) were grouped into those from women who described themselves as satisfied (satisfaction rating 1-2) with their experience or those that were not satisfied (satisfaction rating 3-5). A copy of the survey form is in Supplementary File 1 and has been forwarded to the editorial board.

Demographic details including maternal age, BMI, gestation at delivery, parity and ethnicity were ascertained from the hospital databases. Statistical analyses were performed using Chi-Square test and T-Test as appropriate (IBM SPSS Version 24). A P value of <0.05 was accepted as being statistically significant. A subgroup analysis was also performed between women who had a planned / ELSCS and women who had an unplanned/ emergency CS (EMCS).

Patient and Public Involvement

During the development of this questionnaire survey women after a first CS were invited to take part in a focus group to share their experience surrounding their care at the time of CS and their preferences for future mode of birth. They were also invited to give their opinion on what information they felt was important to be collected for the survey. During the initial phase of the survey responses were selected at random and patients were contacted to discuss their responses to the survey to ensure they had no comments on how to improve it. Once published, the data will be made available on both hospital sites, for antenatal clinic visits, and for formal prenatal education classes.

Results

A total of n=734 women were identified from the hospital databases as being eligible to participate in the survey and 633/734 (86.2%) consented to participate and were sent postal questionnaire surveys. There were 347/633 (54.8%%) completed survey forms returned for analysis; 154/242 (63%) at Galway University Hospital and 193/391 (49.4%) at the National

Maternity Hospital, Dublin. Of these, 285/347(82.1%%) had an EMCS, and 62/347 (17.9%) had an ELSCS. The main reasons for CS were failure to progress in labour or failed induction of labour 121/347 (34.9%); abnormal fetal heart rate pattern 108/347 (31.1%); malposition (including breech presentation) 50/347 (14.4%); other (including previous third-degree tear, maternal anxiety, previous shoulder dystocia, urinary incontinence) 35/347 (10.1%), maternal medical reason 24/347 (6.9%), failed instrumental delivery 8/347 (2.3%) and one where the woman was unsure of the indication for CS 1/347 (0.3%). There were 261 women who had the CS in their first pregnancy (Para 1) and 86 women had their first CS in a second or subsequent pregnancy (Para >1). The demographic features of the groups are presented in Table 1. The average maternal age was 34.9 years and the average BMI was 25.9 kg/m^2. The mean gestation at the time of birth was higher in the EMCS group than in the ELSCS group (39^{+6} weeks vs 38^{+5} weeks respectively, p=0.01). There were no other significant differences between the demographics of the groups.

A comparison of the results of the survey questions divided by women in the EMCS and ELSCS groups are presented in Table 2. The vast majority of women in both groups (95-96%) were satisfied in general that CS was the most appropriate delivery option for them given their clinical circumstances. Replies to the question pertaining to the medical care provided revealed satisfaction levels of 92-98%. Regarding midwifery care, satisfaction levels were 90-93%. However, women in the EMCS group were less satisfied with the information received regarding the CS, both prior to delivery ($p<0.05$) and postnatally ($p<0.01$) (Table 2). The lowest rates of satisfaction overall (54%) were experienced by women in the EMCS group regarding their views

on the debriefing information they received postnatally. No difference was observed between hospital sites in relation to these levels of satisfaction.

In the overall cohort, 39.5% of women expressed a preference for VBAC in a subsequent pregnancy, and this was similar for women in the EMCS and ELSCS groups (Table 3). The preference rate for repeat ELSCS overall was 31.7%. The proportion of women who were undecided was 28.8%. Approximately 80% of women in both groups said they would consider randomisation in a future pregnancy (Table 3). These findings were similar among women across both hospital sites.

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 expressing 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, Para 1=82.4% and Para >1= 76.7% ($p=0.25$).

Discussion

Management of delivery for the woman who has had one previous CS is a controversial area of obstetric practice, with many factors influencing the decision to pursue either VBAC or ERCS

[1, 3,13,18], as outlined above. However, it is well established that the view of the woman is paramount in arriving at a decision regarding mode of birth in these circumstances [19], and hence the focus of this study was on the satisfaction levels of women who had one CS regarding their past birth, and their plans or deliberations for a future birth. There are minimal data to our knowledge on this topic in a European obstetric population. The strengths of this study include the large number of women recruited across two different geographical sites, specific evaluation of future birth preferences and willingness to participate in a randomised controlled trial on mode of birth, and finally, the level of concordance of the results across both sites. The limitations of this study are discussed below.

In this study, satisfaction with the delivery, i.e. having had a CS, was in the region of 95% and was similar for both EMCS and ELSCS groups. This is in contrast to other studies which have reported lower satisfaction rates for women who had unplanned caesarean sections compared with women who had planned caesarean sections [20,21]. We similarly observed high satisfaction rates, i.e. greater than 90% with care providers. This study also assessed the level of satisfaction the women experienced in relation to information received at the time of CS and the postnatal debriefing provided. Unsurprisingly, women who had an EMCS reported a significantly lower satisfaction level with the information received at the time of delivery than women who had an ELSCS. This factor may well be related to the fact that the majority of these operations were performed intrapartum, as an emergency procedure. It is disappointing that only 54% of women in the EMCS group were satisfied with postnatal counselling and debriefing. Specific comments from women included ‘I found the aftercare disappointing’, ‘there was no counselling or information given about what happened or what to expect’, ‘my experience was

very frightening, and the reason discussed only briefly' and 'I still have unanswered questions about my delivery'. The usual practice at both hospital sites for counselling women after their first CS 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. The NICE guideline on CS states that women after a CS should be given the opportunity to discuss the reasons for the CS and be provided with both verbal and printed information about future birth options [22]. Despite this recommendation there remains a paucity of guidelines surrounding the best practice for postnatal debriefing, and similarly there is a lack of guidance regarding postnatal follow up for women who may have had more difficult or traumatic childbirth experiences.

Regarding future mode of birth, 39.5% of the overall group expressed a preference for VBAC, while 31.7% had a preference for repeat ELSCS and 28.8% were undecided. The statistic of approximately 40% of women expressing a preference for VBAC is remarkably consistent from the studies that are available. A recent US study on this topic reported that at 12 months postpartum, 45% of women who delivered by caesarean in their first birth wanted to have their next delivery vaginally [23]. An Australian survey by Dodd et al explored the views of women in the first 6 months after delivery and found a similar preference with regards to VBAC at 41%, while only 23% expressed an interest in a repeat ELSCS and 35% described themselves as being unsure [14]. However, when it comes to willingness to be recruited to a future RCT of VBAC versus repeat ELSCS, the data from our study are markedly in contrast to the findings from the one other study that examined this [14]. 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 [14]. 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.

We recognise that there are certain limitations to our study. This analysis gives an overview of women's satisfaction with their CS and their preference for future mode of birth but was not able to assess the strength of this preference. Similarly, the birth preference may change over time and the data presented may not truly reflect the proportion who ultimately pursue their stated preference in a subsequent pregnancy. It is encouraging for a future RCT that 80% of our population expressed an interest in being recruited but that statistic, as alluded to above, may change during the course of a subsequent pregnancy. It was not possible to assess the strength of the views expressed, particularly as randomly assigning mode of birth would remove the element of clinician preference and patient choice, though one could argue that agreeing to randomisation is in fact a birth preference in itself. A further limitation is that these results reflect the opinions of those who responded to the study. We are aware that the 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 this nature.

In conclusion, a significant proportion of women in this cohort considered VBAC as an option for a future birth, and a majority of women stated they would consider randomisation in a potential RCT on the topic. These data indicate that randomised trial of VBAC versus repeat ELSCS would be viewed positively by women with one previous CS.

Contribution to authorship

Study concept and design GR, JM, FM. Data acquisition and analysis GR, KOD. Drafting and critical revision of the manuscript GR, JM, DD, FM.

Details of ethics approval

Ethical approval was received from both Galway University Hospital and the National Maternity Hospital for this study (Galway University Hospital Reference No. 1804, 13th October 2017 and National Maternity Hospital Reference No. EC 37.2017, 8th January 2018).

Acknowledgements

We are grateful to all the women who participated in this study and all involved in collecting and analysing the data at both hospital sites.

Data Sharing Statement

All data have been included in the manuscript. A copy of the survey form is in Supplementary File 1 and has been forwarded to the editorial board.

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	Overall group (n=347)	EMCS (n=285)	ELSCS (n=62)	P Value
Para>1	86	56	30	
Para=1	261	229	32	
Average age (Years)	34.9	34.99	34.89	ns
Average BMI (kg/m^2)	25.9	25.95	25.43	ns
Gestation at Delivery (weeks $^{+ \text{days}}$) Mean	39^{+5}	39^{+6}	38^{+5}	P<0.01
Nationality: Irish	276 (79.5%)	227 (79.6%)	49 (79.04%)	
Other	71 (20.5%)	58 (20.35%)	13 (20.96%)	

Table 1:

Demographic Features of the Groups.

	EMCS (n=285)	ELSCS(n=62)	P Value
Satisfied with Mode of Delivery	272 (95.5%)	60 (96.8%%)	ns
Satisfied with Medical Care Provided	263 (92.3%)	61 (98.4%)	ns
Satisfied with Midwifery Care Provided	259 (90.9%)	58 (93.5%)	ns

Table 1 Legend. Patient demographic features comparing the emergency caesarean delivery group with elective caesarean delivery group.
Statistical significance was taken as p<0.05. ns=Not significant.
EMCS = emergency caesarean section. ELSCS= elective caesarean section.
Para 1=Women after their first pregnancy. Para >1 =Women in a second or subsequent pregnancy.

Table 2. Patients Level of Satisfaction by Emergency Caesarean Delivery versus Elective Caesarean Delivery

Satisfied with information at time of delivery	250 (81.8%)	61 (98.4%)		P<0.05
	Overall Group (n=345)	**EMCS (n=285)**	**ELSCS (n=62)**	**P Value**
Satisfied with Postnatal Counselling & Information about Caesarean	174 (54%)	151 (82.3%)		P<0.001
Preference for Future Mode of Delivery:				
VBAC	137 (39.5%)	114 (40%)	23 (37.1%)	ns
Repeat ELSCS	110 (31.7%)	83 (29.1%)	27 (43.5%)	ns
Undecided	100 (28.8%)	88 (30.9%)	12 (19.4%)	ns

Table 2 Legend. Patient satisfaction levels comparing emergency caesarean delivery group with elective caesarean delivery group.
Statistical significance was taken as p<0.05. ns=Not significant.
EMCS = emergency caesarean delivery. ELSCS= elective caesarean delivery

Table 3. Preferences for Future Delivery

Would consider involvement in an RCT of VBAC vs Repeat ELSCS?				
Yes	281 (81%)	230 (80.7%)	51 (82.3%)	ns
No	66 (19%)	55 (19.3%)	11(17.7%)	ns

Table 3 Legend. Patient preferences for future mode of delivery and willingness to be involved in a future randomised trial of vaginal birth after caesarean or elective repeat caesarean delivery. Statistical significance was taken as p<0.05. ns=Not significant.
VBAC= vaginal birth after caesarean. RCT= randomised controlled trial.
EMCS = emergency caesarean section. ELSCS= elective caesarean section.

Supplementary File 1. The questionnaire survey completed by patients.

Questionnaire

1. **What reason below best fits with the reason you had the caesarean section? (Please tick beside most appropriate answer)**

    1. Fetal Distress i.e. there was concern about the baby in labour
    2. Failure to Progress/Failed induction of labour/Very slow or poor progress in labour
    3. Maternal medical reason (e.g. diabetes, low lying placenta)
    4. Baby in the wrong position (e.g. breech, transverse)
    5. No success with delivery of the baby with forceps or vacuum
    6. Other
    7. Don't know

2. **Was it a planned procedure in advance (called elective) or what was it an emergency?** _____

3. **Are you satisfied that the caesarean section was the best option, for you in those circumstances, for the delivery of the baby?**

    1. Very satisfied
    2. Satisfied
    3. Not sure
    4. Not satisfied
    5. Very unsatisfied

4. **Do you feel the care you received was professional and supportive from the doctors?**

    1. Very satisfied
    2. Satisfied
    3. Not sure
    4. Not satisfied
    5. Very unsatisfied

PTO

5. **Do you feel the care you received was professional and supportive from the midwifery team?**

    1. Very satisfied
    2. Satisfied
    3. Not sure
    4. Not satisfied
    5. Very unsatisfied

6. **Are you satisfied that you received adequate information about the reason for caesarean section at the time of your delivery?**

    1. Very satisfied
    2. Satisfied
    3. Not sure
    4. Not satisfied
    5. Very unsatisfied

7. **Are you satisfied that you received adequate information and counselling in the postnatal period (i.e. after delivery)?**

    1. Very satisfied
    2. Satisfied
    3. Not sure
    4. Not satisfied
    5. Very unsatisfied

8. **What would be your preferred option for a future delivery?**

    1. Normal labour and delivery
    2. Repeat planned caesarean section
    3. Undecided

9. **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?**

    1. Yes
    2. No

(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 in any way.)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract Done - P1 (Title) and P2 (Abstract)
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found Included P2
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported P5
Objectives	3	State specific objectives, including any prespecified hypotheses P6
Methods		
Study design	4	Present key elements of study design early in the paper Included P6 and 7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection Included P6 and 7
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Included in P6 and 7 *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable Included P7 and P8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group Included P7 and P8
Bias	9	Describe any efforts to address potential sources of bias NA
Study size	10	Explain how the study size was arrived at P6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why P7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding

		P7 and 8
		(*b*) Describe any methods used to examine subgroups and interactions P7 and P8
		(*c*) Explain how missing data were addressed P13
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed NA *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses

Continued on next page

Results

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed P8
		(b) Give reasons for non-participation at each stage NA
		(c) Consider use of a flow diagram NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders P9
		(b) Indicate number of participants with missing data for each variable of interest NA
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount) P9
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time P9 and P10
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included Main results presented P9 and 10 and Tables 1,2 and 3 (P18-20)
		(*b*) Report category boundaries when continuous variables were categorized Main results presented P9 and 10 and Tables 1,2 and 3 (P18-20)
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses P10

Discussion

Key results	18	Summarise key results with reference to study objectives P10 and P11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias P11 and P12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence P11 and 12
Generalisability	21	Discuss the generalisability (external validity) of the study results P11 and P12
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based NA

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

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.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-031766.R2
Article Type:	Original research
Date Submitted by the Author:	05-Sep-2019
Complete List of Authors:	Ryan, Gillian; NUI Galway, Department of Obstetrics and Gynaecology; Galway University Hospitals, Department of Obstetrics and Gynaecology O Doherty, Kate; National Maternity Hospital, Obstetrics and Gynaecology Devane, Declan; National University Of Ireland, Galway, School of Nursing & Midwifery McAuliffe, Fionnuala; University College Dublin, UCD Perinatal Research Centre; National Maternity Hospital, Obstetrics and Gynaecology Morrison, John; National University of Ireland Galway, Obstetrics and Gynaecology
Primary Subject Heading:	Obstetrics and gynaecology
Secondary Subject Heading:	Obstetrics and gynaecology
Keywords:	Maternal medicine < OBSTETRICS, Caesarean section, Vaginal Birth after Caesarean, Birth Preference after Caesarean, Randomised Trial on Mode of Birth

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.

Running Title: Survey of Women's Views after a first Caesarean

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Abstract

Objective:

To assess the views of women after a first caesarean section on their birth experience, preference for future mode of birth and willingness to participate in a randomised controlled trial on mode of birth in a future pregnancy.

Design:

Questionnaire survey.

Setting:

Two tertiary maternity centres in Ireland, Galway University Hospital, Galway and the National Maternity Hospital, Dublin.

Participants:

Women with one previous caesarean section.

Methods:

Eligible women were consented to participate, and postal surveys forwarded. Results were collected and analysed. Results were compared between women who had elective and emergency operations.

Primary Outcome Measures:

The satisfaction levels of women after a first caesarean, their preference for mode of birth in a future pregnancy and their willingness to participate in a randomised trial on mode of birth.

Results:

There were 347 completed surveys of 633 women consented (54.8%), of whom 285 and 62 had emergency and elective caesarean deliveries respectively. In general, satisfaction ratings with the delivery were greater than 90%, with similar levels of satisfaction with the care received from doctors and midwives. Women who an emergency procedure expressed lower satisfaction levels with the information about the caesarean and the debriefing received afterwards than women who had a planned operation (P<0.05). For future mode of birth 39.5% expressed a preference for vaginal birth after caesarean in a subsequent pregnancy and 80% said they would consider involvement in a randomised trial in a future pregnancy.

Conclusion:

Debriefing and counselling women after a caesarean section is an important part of pregnancy care and can significantly impact on a woman's overall birth experience. A significant proportion of this cohort considered vaginal birth after caesarean as a future birth option. These data indicate that a randomised trial on mode of birth after caesarean would be viewed positively by women in our population.

Strengths and Limitations of this Study

- This study assesses the satisfactions levels of women having a first caesarean section on various aspects of care and investigates whether the type of caesarean delivery influences their preference for future

mode of birth and their willingness to participate in a randomised trial on mode of birth in a future pregnancy.

- The strengths of this study include the large number of women recruited across two different geographical sites.
- The evaluation of future birth preferences and willingness to participate in a randomised controlled trial on mode of birth is a topic on which there are minimal data in a European obstetric population.
- This analysis gives an overview of preference for future mode of birth and willingness to be involved in a trial on mode of birth, but we are unable to assess how this preference may change over time.

Disclosure of interests

None declared.

Funding Statement

This research received no specific funding from any funding agency in the public, commercial or not-for-profit sectors.

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.

Introduction

Women who have had one previous caesarean section (CS) represent a significant proportion of all women presenting for antenatal care in pregnancy [1,2]. For the majority of such women, the option of having either a vaginal birth after caesarean (VBAC) or a repeat elective caesarean section (ELSCS) is a focus of major discussion in a subsequent pregnancy. Many factors influence this decision including the reason for the original CS, other obstetric variables, views of the attending obstetrician, and finally, and most importantly, the views of the mother and her partner [1,3]. This discussion includes attention to the risks and benefits of VBAC versus repeat ELSCS [3-8]. Apart from these clinical issues, there are many geographical [1,9-11], institutional [12], epidemiological and legal factors [13] that influence VBAC rates worldwide. What is clear however is that VBAC attempt rates [1], and VBAC rates [1], have been declining significantly in recent years in developed countries [1,7]. Apart from the clinical importance of this topic, and the associated morbidity, increasing CS rates also place a significant burden on healthcare resources [14,15].

Notwithstanding the issues outlined above, the evidence available for counselling the woman who has had one CS regarding her birth options in a future pregnancy is limited. Currently, the only data from randomised controlled trials (RCT) of VBAC versus repeat ELSCS emanates from two trials [16,17], totalling 320 women. Only one of these provided results on maternal and fetal outcomes [17], and the numbers were too small to generate any strong recommendations that might inform women's decision on mode of birth. A Cochrane review concluded that both options of VBAC and repeat ELSCS are associated with benefits and harms, however the evidence for the magnitude of these outcomes was drawn from non-randomised studies, and associated with potential bias, and therefore must be interpreted with caution [4]. The need for further RCTs was emphasized. However, there remains a doubt concerning the feasibility of such a trial, and whether or not women would agree to randomisation [4,14]. There are minimal data regarding women's views on this topic, and none to our knowledge pertaining to a European population of expectant mothers. The aims of this study were to evaluate the views of women who had one previous CS regarding their experience of delivery, their preference for birth options in a future pregnancy, and finally their willingness, or otherwise, to participate in a potential future RCT of VBAC versus repeat ELSCS.

Methods

This study used a written questionnaire survey of women who had their first CS between January and August 2017 in two tertiary teaching hospitals in the Republic of Ireland, Galway University Hospital, Galway on the west coast, and the National Maternity Hospital, Dublin on the east coast. Institutional review board approval was obtained at both sites (Galway University Hospital

Reference No. 1804 and National Maternity Hospital Reference No. EC 37.2017). Eligible participants were identified using hospital maintained computerised databases. Women were contacted by telephone or post for consent, and postal surveys subsequently forwarded. 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 birth within the first year after the index pregnancy. Exclusion criteria included women under 18 years of age and any women who had a perinatal loss (information received from the hospital databases). A patient interaction focus group was organised prior to the study with a number (n=10) of women who 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.

The following factors were included in the survey instrument: 1. The reason for the CS; 2. Whether it was a planned or unplanned/emergency procedure; 3. Women's satisfaction regarding; (a) the statement that a CS was the best option for them at the time; (b) the care received from the obstetric team; (c) the care received from the midwifery team; (d) the information received prior to delivery regarding the CS; (e) the information / debriefing received after delivery regarding the CS; 4. Women's preference for mode of birth in a future pregnancy; and 5. Women's willingness or otherwise, to participate in a future RCT of VBAC versus repeat ELSCS. Satisfaction scores obtained (1-5) were grouped into those from women who described themselves as satisfied (satisfaction rating 1-2) with their experience or those that were not satisfied (satisfaction rating 3-5). A copy of the survey form is in Supplementary File 1 and has been forwarded to the editorial board.

Demographic details including maternal age, BMI, gestation at delivery, parity and ethnicity were ascertained from the hospital databases. Statistical analyses were performed using Chi-Square test and T-Test as appropriate (IBM SPSS Version 24). A P value of <0.05 was accepted as being statistically significant. A subgroup analysis was also performed between women who had a planned / ELSCS and women who had an unplanned/ emergency CS (EMCS).

Patient and Public Involvement

During the development of this questionnaire survey women after a first CS were invited to take part in a focus group to share their experience surrounding their care at the time of CS and their preferences for future mode of birth. They were also invited to give their opinion on what information they felt was important to be collected for the survey. During the initial phase of the survey responses were selected at random and patients were contacted to discuss their responses to the survey to ensure they had no comments on how to improve it. Once published, the data will be made available on both hospital sites, for antenatal clinic visits, and for formal prenatal education classes.

Results

A total of n=734 women were identified from the hospital databases as being eligible to participate in the survey and 633/734 (86.2%) consented to participate and were sent postal questionnaire surveys. There were 347/633 (54.8%%) completed survey forms returned for analysis; 154/242 (63%) at Galway University Hospital and 193/391 (49.4%) at the National

Maternity Hospital, Dublin. Of these, 285/347(82.1%%) had an EMCS, and 62/347 (17.9%) had an ELSCS. The main reasons for CS were failure to progress in labour or failed induction of labour 121/347 (34.9%); abnormal fetal heart rate pattern 108/347 (31.1%); malposition (including breech presentation) 50/347 (14.4%); other (including previous third-degree tear, maternal anxiety, previous shoulder dystocia, urinary incontinence) 35/347 (10.1%), maternal medical reason 24/347 (6.9%), failed instrumental delivery 8/347 (2.3%) and one where the woman was unsure of the indication for CS 1/347 (0.3%). There were 261 women who had the CS in their first pregnancy (Para 1) and 86 women had their first CS in a second or subsequent pregnancy (Para >1). The demographic features of the groups are presented in Table 1. The average maternal age was 34.9 years and the average BMI was 25.9 kg/m^2. The mean gestation at the time of birth was higher in the EMCS group than in the ELSCS group (39^{+6} weeks vs 38^{+5} weeks respectively, p=0.01). There were no other significant differences between the demographics of the groups.

A comparison of the results of the survey questions divided by women in the EMCS and ELSCS groups are presented in Table 2. The vast majority of women in both groups (95-96%) were satisfied in general that CS was the most appropriate delivery option for them given their clinical circumstances. Replies to the question pertaining to the medical care provided revealed satisfaction levels of 92-98%. Regarding midwifery care, satisfaction levels were 90-93%. However, women in the EMCS group were less satisfied with the information received regarding the CS, both prior to delivery ($p<0.05$) and postnatally ($p<0.01$) (Table 2). The lowest rates of satisfaction overall (54%) were experienced by women in the EMCS group regarding their views

on the debriefing information they received postnatally. No difference was observed between hospital sites in relation to these levels of satisfaction.

In the overall cohort, 39.5% of women expressed a preference for VBAC in a subsequent pregnancy, and this was similar for women in the EMCS and ELSCS groups (Table 3). The preference rate for repeat ELSCS overall was 31.7%. The proportion of women who were undecided was 28.8%. Approximately 80% of women in both groups said they would consider randomisation in a future pregnancy (Table 3). These findings were similar among women across both hospital sites.

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 birth, with 35.6% in the Para 1 group expressing 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, Para 1=82.4% and Para >1= 76.7% ($p=0.25$).

Discussion

Management of delivery for the woman who has had one previous CS is a controversial area of obstetric practice, with many factors influencing the decision to pursue either VBAC or ERCS

[1, 3,13,18], as outlined above. However, it is well established that the view of the woman is paramount in arriving at a decision regarding mode of birth in these circumstances [19], and hence the focus of this study was on the satisfaction levels of women who had one CS regarding their past birth, and their plans or deliberations for a future birth. There are minimal data to our knowledge on this topic in a European obstetric population. The strengths of this study include the large number of women recruited across two different geographical sites, specific evaluation of future birth preferences and willingness to participate in a randomised controlled trial on mode of birth, and finally, the level of concordance of the results across both sites. The limitations of this study are discussed below.

In this study, satisfaction with the delivery, i.e. having had a CS, was in the region of 95% and was similar for both EMCS and ELSCS groups. This is in contrast to other studies which have reported lower satisfaction rates for women who had unplanned caesarean sections compared with women who had planned caesarean sections [20,21]. We similarly observed high satisfaction rates, i.e. greater than 90% with care providers. This study also assessed the level of satisfaction the women experienced in relation to information received at the time of CS and the postnatal debriefing provided. Unsurprisingly, women who had an EMCS reported a significantly lower satisfaction level with the information received at the time of delivery than women who had an ELSCS. This factor may well be related to the fact that the majority of these operations were performed intrapartum, as an emergency procedure. It is disappointing that only 54% of women in the EMCS group were satisfied with postnatal counselling and debriefing. Specific comments from women included ‘I found the aftercare disappointing’, ‘there was no counselling or information given about what happened or what to expect’, ‘my experience was

very frightening, and the reason discussed only briefly' and 'I still have unanswered questions about my delivery'. The usual practice at both hospital sites for counselling women after their first CS 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. The NICE guideline on CS states that women after a CS should be given the opportunity to discuss the reasons for the CS and be provided with both verbal and printed information about future birth options [22]. Despite this recommendation there remains a paucity of guidelines surrounding the best practice for postnatal debriefing, and similarly there is a lack of guidance regarding postnatal follow up for women who may have had more difficult or traumatic childbirth experiences.

Regarding future mode of birth, 39.5% of the overall group expressed a preference for VBAC, while 31.7% had a preference for repeat ELSCS and 28.8% were undecided. The statistic of approximately 40% of women expressing a preference for VBAC is remarkably consistent from the studies that are available. A recent US study on this topic reported that at 12 months postpartum, 45% of women who delivered by caesarean in their first birth wanted to have their next delivery vaginally [23]. An Australian survey by Dodd et al explored the views of women in the first 6 months after delivery and found a similar preference with regards to VBAC at 41%, while only 23% expressed an interest in a repeat ELSCS and 35% described themselves as being unsure [14]. However, when it comes to willingness to be recruited to a future RCT of VBAC versus repeat ELSCS, the data from our study are markedly in contrast to the findings from the one other study that examined this [14]. In our study, 80% of the women expressed a

willingness to being involved in a future RCT in which their mode of birtth 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 [14]. 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.

We recognise that there are certain limitations to our study. This analysis gives an overview of women's satisfaction with their CS and their preference for future mode of birth but was not able to assess the strength of this preference. Similarly, the birth preference may change over time and the data presented may not truly reflect the proportion who ultimately pursue their stated preference in a subsequent pregnancy. It is encouraging for a future RCT that 80% of our population expressed an interest in being recruited but that statistic, as alluded to above, may change during the course of a subsequent pregnancy. It was not possible to assess the strength of the views expressed, particularly as randomly assigning mode of birth would remove the element of clinician preference and patient choice, though one could argue that agreeing to randomisation is in fact a birth preference in itself. A further limitation is that these results reflect the opinions of those who responded to the study. We are aware that the 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 this nature. 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 responses and are therefore unable to comment if this would have influenced their views in any way.

In conclusion, a significant proportion of women in this cohort considered VBAC as an option for a future birth, and a majority of women stated they would consider randomisation in a potential RCT on the topic. These data indicate that randomised trial of VBAC versus repeat ELSCS would be viewed positively by women with one previous CS.

Contribution to authorship

Study concept and design GR, JM, FM. Data acquisition and analysis GR, KOD. Drafting and critical revision of the manuscript GR, JM, DD, FM.

Details of ethics approval

Ethical approval was received from both Galway University Hospital and the National Maternity Hospital for this study (Galway University Hospital Reference No. 1804, 13th October 2017 and National Maternity Hospital Reference No. EC 37.2017, 8th January 2018).

Acknowledgements

We are grateful to all the women who participated in this study and all involved in collecting and analysing the data at both hospital sites.

Data Sharing Statement

All data have been included in the manuscript. A copy of the survey form is in Supplementary File 1 and has been forwarded to the editorial board.

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	Overall group (n=347)	EMCS (n=285)	ELSCS (n=62)	P Value
Para>1	86	56	30	
Para=1	261	229	32	
Average age (Years)	34.9	34.99	34.89	ns
Average BMI (kg/m^2)	25.9	25.95	25.43	ns
Gestation at Delivery (weeks $^{+ \text{days}}$) Mean	39^{+5}	39^{+6}	38^{+5}	P<0.01
Nationality: Irish	276 (79.5%)	227 (79.6%)	49 (79.04%)	
Other	71 (20.5%)	58 (20.35%)	13 (20.96%)	

Table 1: Demographic Features of the Groups.

	EMCS (n=285)	ELSCS(n=62)	P Value
Satisfied with Mode of Delivery	272	60	ns

Table 1 Legend. Patient demographic features comparing the emergency caesarean delivery group with elective caesarean delivery group.
Statistical significance was taken as p<0.05. ns=Not significant.
EMCS = emergency caesarean section. ELSCS= elective caesarean section.
Para 1=Women after their first pregnancy. Para >1 =Women in a second or subsequent pregnancy.

Table 2. Patients Level of Satisfaction by Emergency Caesarean Delivery versus Elective Caesarean Delivery

	(95.5%)	(96.8%%)		
Satisfied with Medical Care Provided	**Overall Group (n=347)**	**EMCS (n=285)**	**ELSCS (n=62)**	**P Value**
	(97.3%)	(98.4%)	ns	
Satisfied with Midwifery Care Provided	259 (90.9%)	58 (93.5%)	ns	
Satisfied with information at time of delivery	250 (87.8%)	61 (98.4%)	P<0.05	
Satisfied with Postnatal Counselling & Information about Caesarean	154 (54%)	51 (82.3%)	P<0.001	

Table 2 Legend. Patient satisfaction levels comparing emergency caesarean delivery group with elective caesarean delivery group.
Statistical significance was taken as p<0.05. ns=Not significant.
EMCS = emergency caesarean delivery. ELSCS= elective caesarean delivery

Table 3. Preferences for Future Delivery

Preference for Future Mode of Delivery:				
VBAC	137 (39.5%)	114 (40%)	23 (37.1%)	ns
Repeat ELSCS	110 (31.7%)	83 (29.1%)	27 (43.5%)	ns
Undecided	100 (28.8%)	88 (30.9%)	12 (19.4%)	ns
Would consider involvement in an RCT of VBAC vs Repeat ELSCS?				
Yes	281 (81%)	230 (80.7%)	51 (82.3%)	ns
No	66 (19%)	55 (19.3%)	11(17.7%)	ns

Table 3 Legend. Patient preferences for future mode of delivery and willingness to be involved in a future randomised trial of vaginal birth after caesarean or elective repeat caesarean delivery. Statistical significance was taken as p<0.05. ns=Not significant.
VBAC= vaginal birth after caesarean. RCT= randomised controlled trial.
EMCS = emergency caesarean section. ELSCS= elective caesarean section.

Supplementary File 1. The questionnaire survey completed by patients.

Questionnaire

1. **What reason below best fits with the reason you had the caesarean section? (Please tick beside most appropriate answer)**

    1. Fetal Distress i.e. there was concern about the baby in labour
    2. Failure to Progress/Failed induction of labour/Very slow or poor progress in labour
    3. Maternal medical reason (e.g. diabetes, low lying placenta)
    4. Baby in the wrong position (e.g. breech, transverse)
    5. No success with delivery of the baby with forceps or vacuum
    6. Other
    7. Don't know

2. **Was it a planned procedure in advance (called elective) or what was it an emergency?** _____

3. **Are you satisfied that the caesarean section was the best option, for you in those circumstances, for the delivery of the baby?**

    1. Very satisfied
    2. Satisfied
    3. Not sure
    4. Not satisfied
    5. Very unsatisfied

4. **Do you feel the care you received was professional and supportive from the doctors?**

    1. Very satisfied
    2. Satisfied
    3. Not sure
    4. Not satisfied
    5. Very unsatisfied

PTO

5. **Do you feel the care you received was professional and supportive from the midwifery team?**

    1. Very satisfied
    2. Satisfied
    3. Not sure
    4. Not satisfied
    5. Very unsatisfied

6. **Are you satisfied that you received adequate information about the reason for caesarean section at the time of your delivery?**

    1. Very satisfied
    2. Satisfied
    3. Not sure
    4. Not satisfied
    5. Very unsatisfied

7. **Are you satisfied that you received adequate information and counselling in the postnatal period (i.e. after delivery)?**

    1. Very satisfied
    2. Satisfied
    3. Not sure
    4. Not satisfied
    5. Very unsatisfied

8. **What would be your preferred option for a future delivery?**

    1. Normal labour and delivery
    2. Repeat planned caesarean section
    3. Undecided

9. **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?**

    1. Yes
    2. No

(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 in any way.)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract Done - P1 (Title) and P2 (Abstract)
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found Included P2
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported P5
Objectives	3	State specific objectives, including any prespecified hypotheses P6
Methods		
Study design	4	Present key elements of study design early in the paper Included P6 and 7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection Included P6 and 7
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Included in P6 and 7 *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable Included P7 and P8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group Included P7 and P8
Bias	9	Describe any efforts to address potential sources of bias NA
Study size	10	Explain how the study size was arrived at P6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why P7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding

		P7 and 8
		(*b*) Describe any methods used to examine subgroups and interactions P7 and P8
		(*c*) Explain how missing data were addressed P13
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed NA *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses

Continued on next page

Results

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed P8
		(b) Give reasons for non-participation at each stage NA
		(c) Consider use of a flow diagram NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders P9
		(b) Indicate number of participants with missing data for each variable of interest NA
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount) P9
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time P9 and P10
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included Main results presented P9 and 10 and Tables 1,2 and 3 (P18-20)
		(*b*) Report category boundaries when continuous variables were categorized Main results presented P9 and 10 and Tables 1,2 and 3 (P18-20)
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses P10

Discussion

Key results	18	Summarise key results with reference to study objectives P10 and P11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias P11 and P12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence P11 and 12
Generalisability	21	Discuss the generalisability (external validity) of the study results P11 and P12
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based NA

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.