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Breast feeding after caesarean delivery on maternal request: protocol of a systematic review and meta-analysis

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ABSTRACT

Introduction Caesarean delivery under maternal request (CDMR) is a major factor contributing to the rising global rates of caesarean section (CS) procedure. The choice of CDMR without medical indications could provide a sense of assured safety by avoiding the experiences and complications of vaginal birth, and the risks related to an emergency CS. However, it might adversely influence women's breast feeding patterns and produce a long-lasting impact on maternal and neonatal health. This study aims to systematically review the current evidence relating to the effects of intentions of performing CDMR on breast feeding.

Methods and analysis A comprehensive literature search will be performed in three English-language electronic databases, major clinical study registries and other sources for original studies reporting the breast feeding outcomes after a planned CDMR or vaginal delivery. The three databases Medline, Embase and the Cochrane Central Register of Controlled Trials will be searched via Ovid from inception to February 2020. Randomised controlled trials (RCTs), pseudo-RCTs, cohort studies and case–control studies on this topic will be included. Participants in the experimental or case group should meet the Robson criteria of classes 2B or 4B and have experienced planned CS undertaken for no maternal or foetal indication, whereas participants in the control group have undergone scheduled vaginal delivery. All kinds of breast feeding outcomes will be included. Meta-analyses will be attempted to provide an estimate of the pooled effect and will be stratified by different study designs. A qualitative description will be provided if quantitative synthesis proves to be fruitless.

Ethics and dissemination This study is a secondary literature review that does not need ethical approval. No primary data will be collected from the participants. Findings of this study will be presented at scientific conferences and be published in scientific journals.

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INTRODUCTION

Caesarean delivery under maternal request (CDMR) is defined as a primary prelabour caesarean delivery on maternal request without obvious or generally accepted medical or obstetric indication.[1] In industrialised countries, the proportion of delivery

Strengths and limitations of this study

► This study will use intention-to-treat analysis, a strategy that mimics randomised controlled trials.
► Robson criteria will be used to enhance the definition of caesarean delivery under maternal request.
► This systematic review and meta-analysis will include both observational studies and clinical trials, which may cause difficulties in the interpretation of the results.

by caesarean section (CS) varied between 16.1% and 50%.[2] The growing rate of CDMR is a major driving force behind the rising CS trends worldwide.[3] It is reported that CDMR accounts for about 7.6% of caesarean deliveries in the USA in 2009[4] and about 40% in China in 2010.[5]

The reasons behind women's preference for CDMR have been investigated in systematic reviews of quantitative or qualitative studies.[6–11] Decisions for CDMR were typically driven by women's emotional experiences of fear and unknown, personal experiences of previous births or clinician guidance and social norms that recognise CS as a modern and autonomous way that offers guaranteed safety for both the mother and the foetus.[6 7] Similarly, patient surveys and narratives often suggest that CS is a less risky[8] and painless[9] medical procedure that avoids multiple harms from vaginal delivery.[10 11] The drawbacks of attempting a CDMR in the absence of a medical indication such as causing avoidable maternal complications and added risks in subsequent pregnancies as well as increased infant morbidity have not been highlighted until recently.[12–14]

The importance of breast feeding is well recognised for its positive physical health, psychosocial, economic and environmental effects, both in the short term and in the long run.[15–17] Compared with vaginal delivery, CDMR may have consequences on breast

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feeding outcomes such as decreasing breast feeding initiation and duration, which may, in turn, put infants at excess risks of severe respiratory infections, subsequent hospitalisations and sudden death syndrome.[15] It could also affect breast feeding by introducing later and lower rates of mother–infant skin-to-skin contact than after an uncomplicated vaginal delivery.[18 19] Moreover, it can continue to influence infants' psychopathological development until preschool age.[20] On the contrary, a greater degree of and longer durations spent on breast feeding are generally indicative of better maternal and infant health outcomes.[17] It is crucial to investigate the influence of planned/intended CDMR on breast feeding patterns to inform practice and policy-making.

This topic has been investigated in a few clinical studies. A prospective cohort study of 357 healthy primiparas reported 79% women who had planned CDMR continued breast feeding 3 months post partum compared with 93% women who had planned vaginal delivery (p<0.01) but observed no difference in the women's experiences with the initiation of breast feeding 2 days after birth.[21] In 2019, a birth cohort study in China with 3319 mother–child pairs reported that the rate of exclusive breast feeding during 4–6 postnatal months does not differ significantly between the two modes of delivery (21.7% in the vaginal delivery group vs 20.8% in the CDMR group).[20]

Our team has also identified systematic reviews addressing similar clinical questions. In Visco and his colleagues' systematic review of a series of maternal and neonatal outcomes following CDMR, weak evidence from one study suggests no difference in breast feeding durations between women with planned CDMR and those who underwent vaginal delivery.[22] A 2012 Cochrane review intends to include only randomised controlled trials (RCTs) of planned CS versus planned vaginal birth for non-medical reasons at term and found no study which met the inclusion criteria.[23] Breast feeding failure is among the many outcomes under investigation.

Previous systematic reviews have contributed little to the current body of evidence on CDMR for breast feeding outcomes. They are limited due to their unclear definitions of CDMR (ie, they failed to use an accepted classification system), failure to adopt an intention-to-treat approach (ie, they compared outcomes of actual rather than planned routes of delivery) or negligence of the breast feeding outcomes.

In this study, we plan to summarise current evidence of the impact of intention for CDMR on breastfeeding through a systematic review and meta-analysis, in the hope of informing novel strategies for making the best of CSs.

METHODS AND ANALYSIS
This protocol is developed following the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols 2015 statement.[24]

Table 1 The Robson criteria: categories 2 and 4

Group	Description
2	Nullipara, singleton, cephalic, ≥37 weeks' gestation A: induced labour B: caesarean section before labour
4	Multiparous without a previous uterine scar, with singleton, cephalic pregnancy, ≥37 weeks' gestation A: induced labour B: caesarean section before labour

Inclusion criteria
Types of study
We plan to include studies that meet the following criteria: (1) RCTs, pseudo-RCTs, cohort studies or case–control studies; (2) provided data on breast feeding outcomes after a planned CDMR or planned vaginal birth.

We decided to include both randomised and non-randomised evidence because this will generate a complete picture[25] and also because it is expected that few RCTs will be available,[23] in which case findings from non-RCTs would represent the best available evidence to answer the research question.[26]

Studies will be excluded if they failed to provide a detailed description of the study population, which meant that our research team could not classify study participants into planned CDMR versus planned vaginal birth.

Types of participants
The participants are healthy pregnant women undergoing a planned caesarean delivery or vaginal delivery. They are at term (≥37 weeks' gestation) with a singleton foetus in cephalic presentation and have no medical indication for CS.

Interventions and comparisons
Intervention (or case/exposure) is planned CDMR undertaken for no maternal or foetal indication. We defined a CS performed on women with Robson criteria of classes 2B or 4B (see table 1) as CDMR.[27 28] Comparison is planned vaginal delivery.

The Robson criteria is a system designed to classify all deliveries into ten categories based on their obstetric characteristics of parity, the number of foetuses, previous CS, the onset of labour, gestational age and foetal presentation.[28] The Robson classification is an internationally applicable and verified tool for standardised identification of the CS population.[27 29]

Outcome measures
We will assess all measures of breast feeding including, but not limited to: intention for breast feeding, initiation of breast feeding, exclusive breast feeding, breast feeding duration, continued breast feeding rates and feeding or breast feeding problems including pain, difficulty to

breastfeed and straining and emotions towards breast feeding.

Search strategy

Relevant studies will be identified by searching for reports in three English-language electronic databases, major international clinical study registries and the reference list of pertinent review articles and included studies.

Electronic searches

A librarian helped develop the search strategies for each database. Two reviewers (WM and YHH) will perform a comprehensive search of Medline, Embase and the Cochrane Central Register of Controlled Trials via Ovid from inception to February 2020 to identify potentially eligible studies. Bridging searches will be performed to identify literature published from February 2020 until the final review publication.

An example of our search strategy developed for Medline is provided in online supplementary appendix 1.

Searching other resources

The reference lists of relevant review and clinical studies will be screened for the possible inclusion of additional literature. Major international clinical registries such as ClinicalTrials.gov, the Chinese Clinical Trial Registry and the WHO International Clinical Trials Registry Platform will be searched to identify ongoing or unpublished studies. We will use Google Scholar searches to identify grey literature further.

Data collection and analysis

Study selection

The EndNote software will be used for citation management. Two reviewers (WM and YHH) will independently select publications against the inclusion criteria and assess them for eligibility, first by looking through the title and abstract of studies retrieved from literature searches, and then by retrieving and reviewing the full text of potentially eligible studies. Permission will be asked prior to the use of unpublished data. Discrepancies between reviewers will be resolved by consensus or discussion with a third reviewer (SWW). The study selection process will be demonstrated in a Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart[30] (figure 1).

Data extraction and management

Two reviewers (WM and AC) will independently extract data and fill in a standard data extraction form. The following information will be retrieved:

1. Publication details: title, authors, publication year, funding and country.
2. Study details: aim, design, setting, study year, inclusion and exclusion criteria, and methodological features.
3. Participant characteristics: Robson classification, sample size and the number of women included in the analysis.
4. Comparisons: the experimental and control interventions in RCTs and pseudo-RCTs, case and control in

case–control studies or exposure and control in cohort studies.
5. Breast feeding outcomes: tools for outcome assessment, effect sizes (unadjusted and adjusted) and the adjustments.

For non-available study data, a reviewer (AC or IL) will contact the corresponding author to obtain missing data. If no response is received after two requests of the corresponding author, or the author is unable to provide the information required, or the data received does not match those in the published results, the study will be excluded.

Assessment of risk of bias in included studies

Two authors (WM and AC) will independently assess the methodological quality of each included study using the Cochrane Risk of Bias Tool[31] for RCT and pseudo-RCT and using the Newcastle-Ottawa Scale[32] for case–control and cohort studies.

An RCT or pseudo-RCT will be assessed in seven respects: random sequence generation (selection bias); allocation concealment (selection bias); blinding of participants and personnel (performance bias); blinding of outcome assessment (detection bias); incomplete outcome data (attrition bias); selective outcome reporting (reporting bias); and other biases. Two reviewers will independently evaluate each study for the above aspects and rate them to be of low, unclear or high risk. The ratings and corresponding explanations will be presented in a 'Risk of Bias Table'.

The Newcastle-Ottawa Scale is a validated tool for evaluating the quality of case–control and cohort studies. A case–control study will be judged from three perspectives, including the selection of case and controls, comparability of case and controls and ascertainment of exposure.[32] Similarly, a cohort study will be assessed by possible risk of bias present in the selection of cohorts, comparability of cohorts and assessment of outcome.[28] Each study will be allocated a star rating score out of a maximum of nine on all three domains. A study will be graded as of good, fair or poor quality according to the total score obtained and the domain that obtains a score.[32]

The results of the methodological assessment will be cross-checked between reviewers. Any disagreement will be resolved through discussion with a third reviewer (SWW).

Measures of breastfeeding outcomes

The effect on breast feeding will be summarised using pooled OR or risk ratio with 95% CI for the dichotomous outcome and using mean difference or standardised mean difference with 95% CI for continuous outcomes.

For cohort studies and case–controlled studies, pooling of the adjusted effect sizes will be preferred,[33] if available, as they have been adjusted for known confounding factors.

Assessment of heterogeneity

Heterogeneity among included studies reporting a common outcome will be assessed using the χ^2 test and
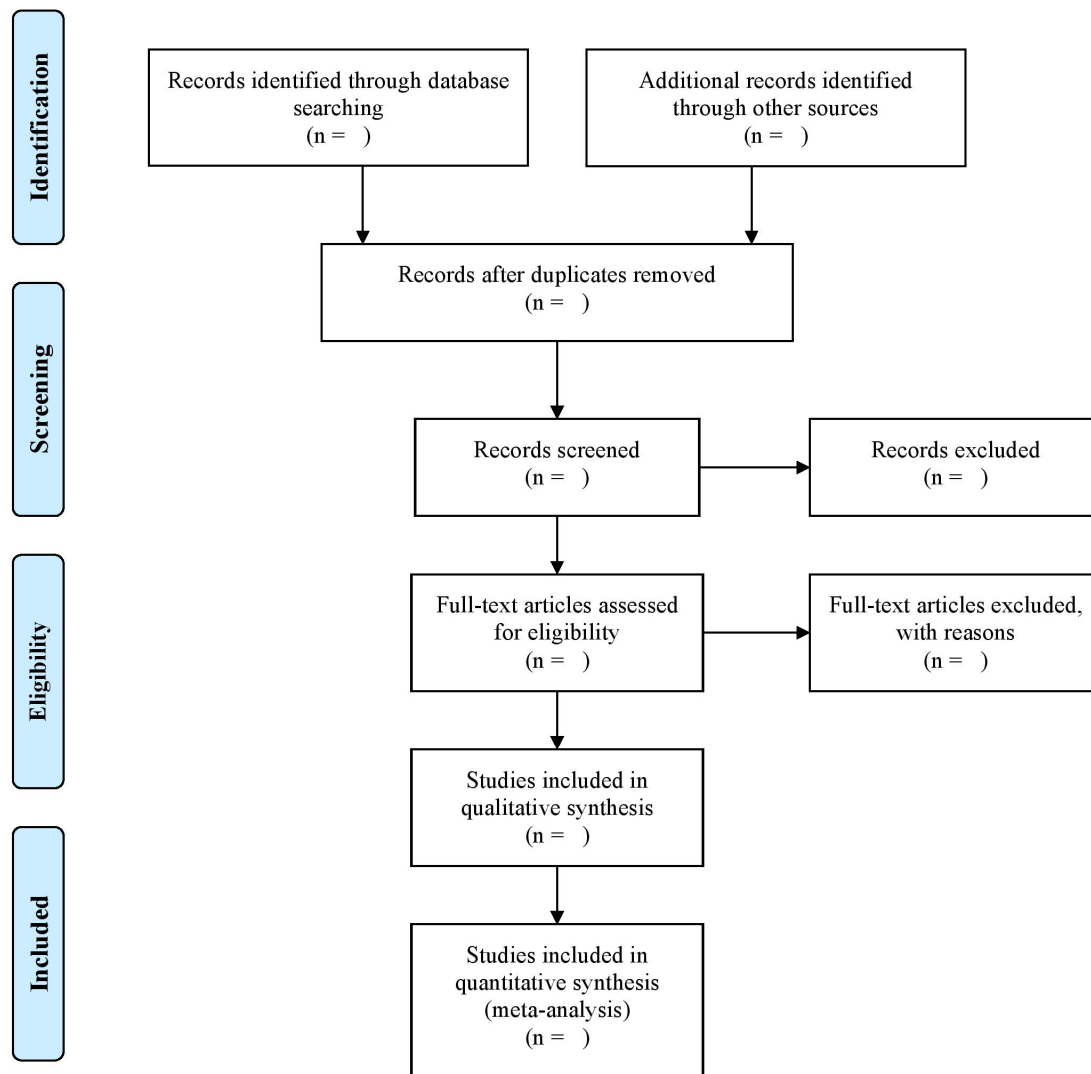
Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram.

I^2 test. Existence of statistically significant variation is assumed if the p value of the χ^2 test does not exceed 0.1 or the I^2 value is above 50%. Subgroup analysis or sensitivity analysis will be attempted in search of the source of clinical or methodological heterogeneity.

Assessment of reporting biases
A funnel plot will be drawn to examine publication bias if there are ten or more studies included for one common outcome.[34]

Data synthesis
Meta-analyses will be conducted using the Review Manager V.5.3 software. We will approach the pooling of results in a way that highlights the contribution of the study design to heterogeneity in effect estimates.[35] Generally, meta-analysis will be stratified by study design. Data of RCTs and pseudo-RCTs will be pooled in one meta-analysis, and data of cohort studies and case–control studies will be pooled separately.[25 36] However, a combination of the results will be considered if they are very similar, and

there is evidence that study design has little impact on major study characteristics.[37 38]

The inverse variance method will be used for the pooling of the continuous outcome and the Mantel-Haenszel method for the dichotomous outcome.[39] The choice between a fixed-effect and a random-effect model typically depends on the degree of statistical heterogeneity as evidenced by the I^2 value relative to 50%. A random-effect model will be adopted if I^2 is greater than 50% or in the case of the pooling of data from cohort studies or case–control studies.[40]

A qualitative description will be provided for each individual study included if quantitative synthesis is fruitless in the case of the collection of insufficient or heterogeneous data for a specific outcome.

Subgroup analysis and investigation of heterogeneity
The following subgroup analyses are planned to assess possible heterogeneity (if sufficient data are available) according to:

1. Different study designs (eg, RCTs and pseudo-RCTs vs cohort studies vs case–control studies).
2. Durations of observation (eg, less than 3 months vs 3–6 months vs 6 months and above).
3. Participant characteristics (eg, primiparity).
4. Risk factors for breast feeding (eg, type of hospital, skin-to-skin contact at birth and type of feeding in previous children).

The χ^2 test will be used in analysing the intervention effect. A p value of less than 0.05 indicates a statistically significant difference between subgroups.

Sensitivity analysis

A sensitivity analysis will be attempted to assess the reliability of the pooled results by excluding studies with extremely large effect sizes or by switching between fixed or random effect models.

Summary of findings table and quality of evidence

The web-based GRADEpro Guideline Development Tool (GDT)[41] will be adopted to create a summary of findings table for each outcome. Two reviewers (WM and YHH) will assess the quality of evidence in five respects: study limitations, inconsistency, imprecision, indirectness and publication bias. The quality of evidence for each outcome will fall into one of four ratings (very low, low, moderate and high). Disagreements will be resolved by discussion with a third review author (SWW).

Patient and public involvement

Patient or public participation was not sought while drafting the protocol. We will not involve the patient or the public in the conduct of this systematic review and meta-analysis.

Amendments

We will include the date, the rationale and a clear description of the changes to the original protocol in any amendment.

ETHICS AND DISSEMINATION

This study does not require ethical approval because no primary data are collected. This review will provide a systematic evaluation of the effect of CDMR versus vaginal delivery on a variety of breast feeding outcomes. Findings of this meta-analysis will be presented at scientific conferences and be published in scientific journals.

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