BMJ Open

Maternal and newborn outcomes of antenatal breastmilk expression: a scoping review protocol

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To cite: Foudil-Bey I, Murphy MSQ, Keely EJ, *et al*. Maternal and newborn outcomes of antenatal breastmilk expression: a scoping review protocol. *BMJ Open* 2020;**10**:e033101. doi:10.1136/bmjopen-2019-033101

► Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2019-033101).

Received 19 July 2019
Revised 25 February 2020
Accepted 07 April 2020

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ABSTRACT

Introduction Mothers with diabetes face unique challenges associated with breastfeeding initiation and maintenance. Antenatal breastmilk expression (BME) may be suggested to mothers, including mothers with diabetes, to improve breastfeeding, maternal, and infant outcomes postpartum. However, there have been few evaluations of the potential harms and benefits of this practice. The objective of our scoping review will be to broadly examine the literature describing maternal and infant outcomes of antenatal BME.

Methods and analysis This scoping review will address the research question: 'Among women who engaged in antenatal BME, what maternal and infant outcomes have been evaluated?' A search of published and unpublished studies available in English will be conducted in February 2020 using the following databases: Medline (OVID), Embase (OVID), CINAHL (EBSCOHost), and Cochrane Database of Systematic Reviews (OVID). A search of the British Library E-Theses Online Services (EThOS) database and OpenGrey will be conducted to identify relevant grey literature. This scoping review will use a five-step framework to guide the selection, extraction, and analysis of eligible studies. Clinical consultation will be included as a sixth step to our methodology. Literature reporting on the effect of antenatal BME on maternal and infant outcomes, breastfeeding initiation and duration, and the experiences of women who have engaged in the practice will be considered. The data will be summarised with attention paid to high-risk obstetrical populations such as women with diabetes. Our results will be reported as outlined by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews.

Ethics and dissemination Research ethics board approval will not be required due to the nature of the study's methodology. The results of this review will be disseminated through peer-reviewed publication and presentation at relevant conferences.

Trail registration number Open Science Framework (osf.io/gfp2q).

Strengths and limitations of this study

- Primary studies included in this review will be critically appraised to offer new perspectives on the literature, to ensure that our conclusions are based on strong evidence, and to inform future work.
- A clinician expert will be consulted and engaged throughout the study to validate the interpretation of our findings.
- Reflecting resource constraints, only articles available in English will be included.

INTRODUCTION

Diabetes is a significant public health concern that is projected to affect 529 million people by 2035.[1] Hyperglycaemia in pregnancy affects approximately 16.9% of all women worldwide, and in Canada up to 20% of women will acquire gestational diabetes mellitus (GDM) in the course of pregnancy, depending on their risk factors.[2] The incidence of hyperglycaemia in pregnancy is increasing as a result of many factors, namely a shift towards higher maternal age, an increase in the prevalence of obesity, and new developments in screening and diagnostic criteria.[2] Women who develop GDM and their offspring have an increased risk of developing diabetes later in life.[1 3 4]

Evidence suggests that there are substantial benefits to breastfeeding for women with diabetes and their infants for mitigating long-term risks associated with the disease.[2 4] Indeed, clinical practice guidelines recommend that breastfeeding be initiated immediately after birth to prevent hypoglycaemia in the newborn[2 5] and maintained for a minimum of 4 months to prevent the development of obesity in childhood, and the development of diabetes in the mother and the newborn later in life.[2] Early initiation of breastfeeding after delivery ensures that colostrum, breastmilk produced in the second trimester of pregnancy,[6] is administered to the infant in the first few hours of life. Colostrum contains high levels of bioavailable glucose and galactose[4] which can prevent postpartum hypoglycaemia and has many benefits on newborn gut health[4 6] and immune function.[4 6 7]

Mothers with diabetes face many challenges that may interfere with the initiation and maintenance of breastfeeding.[9]

Euglycemia is said to influence the onset of lactogenesis II (milk let down postpartum),[7] and thus women with diabetes in pregnancy may experience delay or absence of this process.[1 7 8] Women with pre-existing or gestational diabetes are also more likely to experience complications warranting caesarian sections and neonate admission to intensive care that can prolong maternal-newborn separation f[1 9] and make it difficult to initiate early breastfeeding.[1 9] Moreover, newborns of mothers with diabetes are at risk of hypoglycaemia directly after birth and are often given formula milk or intravenous glucose to stabilise their blood glucose levels,[10] which may also interfere with breastfeeding initiation.[3] Lastly, mothers with type 1 diabetes may be reluctant to breastfeed due to fear of consequent maternal hypoglycaemia.[3] Although the majority of mothers express a desire to engage in breastfeeding,[3] unique challenges experienced by this population may deprive mothers and their infants from its many benefits.

Antenatal breastmilk expression (BME) emerged as a practice to improve milk flow postpartum, decrease breast engorgement, and increase exclusive breastfeeding 6 months postpartum.[11] Its popularity dwindled however as studies in the 1980s demonstrated increased rates of mastitis,[12] increased breast engorgement,[13] and no effect on breastfeeding success at 6 months postpartum.[11 13] Others also raised concern around the association between antenatal breast stimulation and oxytocin release, which can induce preterm labour or miscarriage.[6] More recently, women with diabetes have been encouraged to express colostrum antenatally to support newborn feeding immediately after birth.[3 6 11] The rationale for antenatal BME in this population is to support initiation of breastfeeding and avoid in-hospital formula or intravenous glucose replacement therapy in infants who become hypoglycaemic,[4 6 7] although few studies have investigated the safety, efficacy, and outcomes of this practice.

In 2013, Chapman and colleagues provided a critical review of literature related to nipple stimulation and antenatal BME.[11] The authors discussed historical and current purposes of antenatal BME and provided an appraisal of studies published up to 2011 and determined that evidence for the safety and efficacy of antenatal BME was inconclusive. A 2014 Cochrane Review sought to identify randomised controlled trials comparing outcomes for women with diabetes following expression and storage of breastmilk during late pregnancy, but identified no published or unpublished studies meeting the criteria for inclusion.[7] A recent search of the WHO's International Clinical Trials Registry Platform, which synthesises clinical trial registrations across 17 primary registries yielded three results. The Diabetes and Antenatal Milk Expressing randomised controlled trial (ACTRN12611000217909) evaluated the safety and efficacy of antenatal BME in women with diabetes in pregnancy.[10] A total of 635 women with pre-existing or gestational diabetes were randomised to either expressing breastmilk (from 36 weeks' gestation) or standard midwifery and obstetric care, supplemented by support from a diabetes educator. The trial found no evidence of harm from antenatal BME for the primary outcome of interest—newborn admission to NICU.[10] Two newer interventional trials are registered, but not yet actively recruiting. The PRenatal Video-Based Education and PostPARtum Effects trial (NCT04258709) will evaluate the impact of antenatal BME on breastfeeding outcomes among overweight and obese women using a video-based instructional tool.[14] The Antenatal Colostrum Expressing study (ACTRN12619000748112) will use two intervention arms to assess the effectiveness of video-based versus face-to-face instruction for antenatal colostrum expression compared with standard care on breastfeeding outcomes.[15] Given the growing interest in, and application of antenatal BME in clinical practice,[7 10 11 16 17] a current synthesis of the literature is warranted. Investigating the safety and efficacy of antenatal BME as well as analysing existing study designs, interventions, and reported outcomes would be particularly beneficial in providing guidance for future interventional studies.

The objective of this scoping review will be to broadly examine the literature describing maternal and infant outcomes of antenatal BME. Outcomes specific to higher risk populations including mothers with gestational or pre-existing diabetes will be of particular interest. Among maternal outcomes, the impact of antenatal BME on breastfeeding initiation and duration will be considered. The scoping review methodology was selected because it allows authors to include multiple study designs and to explore broad and multi-faceted clinical questions,[18] making it a suitable approach to address this topic.

METHODS AND ANALYSIS

In this scoping review we seek to consolidate the current state of evidence on maternal and infant outcomes associated with antenatal BME in pregnant women as well as identify gaps in the literature on this topic. A five step approach developed by the Johanna Briggs Institute, based on the seminal frameworks proposed by Arksey and O'Malley[19] and Levac *et al*,[20] will serve as the foundation for the methodology of our scoping review.[21] The five steps are outlined as follows: (1) identification of the research question, (2) identification of relevant studies, (3) selection of studies, (4) charting of data and (5) summary of results.[21] A critical appraisal, an optional but recommended evaluation component of a scoping review,[22] will be included in step four. Lastly, a sixth consultation step (EK) recommended by Levac *et al* will be included to add clinical value and perspective to the review.[20] Adherence to these six steps will ensure that all aspects of a scoping review are accounted for.

Step 1: Identifying the research question

The development of the research question was an iterative process driven by the authors' increasing familiarity with the literature. Our initial research question was:

What are the maternal and infant outcomes of antenatal BME in mothers with diabetes?

Initial review of the literature identified a paucity of primary studies reporting on maternal and infant outcomes in the specified population. Therefore, we expanded the scope of this review to include the general obstetrical population to more broadly review the evidence on outcomes associated with antenatal BME. This approach is optimal as it permits the authors to consider the potential outcomes of antenatal BME in all women and to consider unique factors affecting higher-risk populations including women with diabetes. In consultation with the research team, the primary research question was therefore modified to be purposefully broad and defined as:

Among women who engaged in antenatal BME, what maternal and infant outcomes have been evaluated?

The purpose of this review will be to extract key concepts and details of studies reporting on antenatal BME to provide direction for future studies. Specifically, we will map the literature in relation to time, location, source/origin, and approaches used to assess outcomes related to antenatal BME, along with the evaluated outcomes themselves. The extent to which the outcomes have been affected by, or are associated with, antenatal BME will not be the focus of this review.

Step 2: Identifying relevant studies

A search of published and unpublished studies available in English will be conducted in February 2020. We will include all studies made available before 1 January 2020. Due to the anticipated small number of eligible studies, the location and environment of published studies will not be limited. In June of 2019, an initial exploratory search was conducted of Medline (OVID) and Embase (OVID) to inform the optimum search strategy. This initial search strategy used the following keywords: diabetes, gestational diabetes, pregnancy, antenatal, colostrum, breastmilk expression, breastfeeding and antenatal breast expression. An iterative process was used to further refine the key search terms. To ensure that key terms and consequent studies are not missed, a medical librarian was consulted. The finalised search strategy for Medline (OVID) is provided in online supplementary appendix 1. Our search will be applied to the following databases: Medline (OVID), Embase (OVID), CINAHL (EBSCOHost), and Cochrane Database of Systematic Reviews (OVID). Further, a search of the British Library E-Theses Online Services (EThOS) database and OpenGrey will be conducted to identify relevant grey literature. Word text in the titles and abstracts of the identified articles, as well as the index terms used to describe the articles will be analysed. Only primary studies will be included.

Table 1 Population–Concept–Context

Population	All studies including pregnant women will be included.
Concepts	Literature reporting on the outcomes of pregnant women who engaged in antenatal BME will be reviewed. Literature reporting on infant outcomes; the collection, storage, and administration of colostrum to infants; and the effects of antenatal BME on breastfeeding initiation and duration will also be reviewed. We will also consider the experiences and perspectives of women who have engaged in antenatal BME.
Context	The context will be settings in which pregnant women are engaging in antenatal BME with or without storage of colostrum for later use. The location, timeframe, and environment will not be limited.

BME, breastmilk expression.

Step 3: Selecting the studies

All published literature identified from the search will be uploaded to Covidence[23] and duplicates will be removed. The titles and abstracts will be screened by two independent reviewers (IF-B and MSQM) using the Population–Concept–Context framework to determine which articles meet the minimum inclusion criteria (table 1).

Texts that meet the inclusion criteria based on title and abstract review will be retrieved in full and imported to Covidence.[23] When necessary, authors will be contacted to request full texts. Retrieved texts will then be reviewed by the two independent reviewers to assess if the full-text articles meet the study's inclusion criteria. The reference lists of included articles will be screened for primary studies that may have been missed by the search strategy. We will also examine the reference lists of literature reviews relevant to our research question to identify primary studies that may have been missed. Throughout the study selection, disagreements about study eligibility will be discussed by the two reviewers and if consensus is not reached, a third independent reviewer (DE-C) will be consulted. Studies that do not meet the inclusion criteria will be excluded and a narrative description of the search decision process will be provided. The study selection process will be reported using a Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram.[24]

Step 4: Charting the data

The two independent reviewers will individually extract key concepts and data from selected articles using Covidence.[23] A data collection form will be used to support extraction of study characteristics. Any modifications to the data extraction strategy will be reported in the results section of the final scoping review. The initial data-collection form will include the following elements: study title, authors, year of publication, study journal,

study citation details, type of study, country of origin, study objective(s), setting, study population(s)/sample size, outcome measure(s), methods, intervention type, comparator, outcome measure(s), duration of intervention, and results. A proposed data extraction chart is provided (see online supplementary appendix 2).

Due to the anticipated limited number of primary research articles available on antenatal BME, a critical appraisal of included studies will be conducted to offer new perspectives on the current literature, to ensure that recommendations being made are based on strong evidence, and to inform future studies.[20] The two independent reviewers will use the Mixed Methods Appraisal Tool—Version 2018 to appraise primary studies that are experimental, observational, or simulated in nature.[25]

Step 5: Collating, summarising and reporting the results

Results from the scoping review will be presented in a descriptive and tabular or diagrammatic format. The objectives of each of the selected studies, the concepts or approaches adopted in each article, and the results related to the study research question will be summarised and explained in the results. The results of individual critical appraisals will be presented in a tabular format followed by a narrative description, if necessary. Data gathered on maternal and infant outcomes of antenatal BME, with special attention to mothers with diabetes, will be summarised as the literature permits.

Step 6: Consultation

A clinical expert (EJK) will be consulted to provide insight beyond the literature such as determine additional sources of information, gain unique perspectives, and identify clinical applicability of the scoping review. Preliminary findings from step five of this protocol will be used to inform the nature of the clinical consultation and to validate the interpretation of our findings. As per Levac *et al*'s recommendations, this stage will also be used to support knowledge transfer of preliminary data and identification of appropriate dissemination strategies.[20]

Patient and public involvement

This protocol was developed without patient involvement. Patients were not invited to comment on the protocol design and were not consulted to synthesise outcomes or interpret the results. Patients were not invited to contribute to the writing or editing of this document for readability or accuracy. The results of this scoping review will inform the development and design of a research study for which patient and public partnership will be sought.

ETHICS AND DISSEMINATION

Since the scoping review methodology aims to synthesise information from publicly available literature, this study will not require research ethics board approval. The results of this review will be discussed with a clinical consultant prior to dissemination through peer-reviewed publication and presentation at relevant conferences.

Some women are encouraged to attempt antenatal BME to promote lactogenesis and support breastfeeding initiation and maintenance postpartum.[3 6 11] However, high-quality evidence on the potential risks and benefits of antenatal BME on maternal, infant, and breastfeeding outcomes is currently limited to one randomised controlled trial.[10] The proposed scoping review will provide valuable insight into the current state of evidence on maternal and infant outcomes of antenatal BME. Additionally, our findings will provide guidance for future interventional studies that aim to assess the safety and efficacy of antenatal BME.

Contributors DE-C conceptualised the study. IF-B and MSQM contributed to the scope and design of the review. IF-B, MSQM and DE-C created and reviewed the inclusion and exclusion criteria. IF-B developed the search strategy in consultation with a medical librarian. IF-B and MSQM designed the data extraction tool. IF-B prepared the manuscript for publication. DE-C, MSQM and EK provided feedback on the methodology, and all authors reviewed the manuscript and gave approval for publication of the protocol.

Funding This research is being supported by a Canadian Institutes for Health Research Foundation Grant (FDN 148438) and a University of Ottawa Faculty of Medicine Summer Studentship bursary.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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