Antenatal breast milk expression by women with diabetes for improving infant outcomes (Protocol)

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[Intervention Protocol]

Antenatal breast milk expression by women with diabetes for improving infant outcomes

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To evaluate the benefits and harms of the expression and storage of breast milk during pregnancy by women with diabetes.

BACKGROUND

Description of the condition

Numerous health benefits to both the mother and baby can be ascribed to breastfeeding, in addition to the substantial cost savings it affords to families and health services (Renfrew 2012). The World Health Organization (WHO) recommends that infants be exclusively breastfed, whether directly from the breast or as expressed breast milk, for the first six months, that is, without any supplements, artificial formula or solid food (WHO 2011).

Infants born to mothers who have diabetes in pregnancy (gestational or pre-existing) are at increased risk of neonatal hypoglycaemia (low blood sugar) compared to other infants (Hanson 1993). This can be explained by their exposure to higher glucose levels in utero than usual, with subsequent increased insulin secretion. These infants may then need to adjust their insulin secretion to deal with postnatal glucose intake levels. It is for this reason that, in the first few days of life, many of these infants become hypoglycaemic and will require additional glucose, provided by donor human milk, artificial formula or via an intravenous infusion, as well as the intake from breastfeeding or breast milk expressed after birth. Because euglycaemia (normal levels of glucose in the blood) appears to be an important influence on the onset of lactogenesis II (the copious flow of milk 30 to 40 hours after giving birth), women with diabetes in pregnancy with hypoglycaemia or hyperglycaemia may be at increased risk of delaying this progression (Arthur 1994; Neubauer 1993). Thus, the infant who is already at increased risk of morbidity related to his/her mother's diabetes, may also be exposed to artificial formula and separation from the mother if transferred to a nursery facility for intravenous fluid administration and glucose monitoring.

Further, avoidance of dietary exposure to some proteins found in cow's milk and the potential for a stronger immune system in exclusively breastfed infants may decrease the likelihood of these children subsequently developing B-cell autoimmunity and Type

1 diabetes (Ip 2007; Newburg 2005; Silverman 1995).

Description of the intervention

Antenatal breast milk expression has historically been proposed as a means of breast preparation (Chapman 2012a), although its popularity declined when the evidence emerged demonstrating no benefits in doing this (for example, Brown 1975). However, the practice has since been utilised as a means of building up a store of colostrum antenatally. The advantage of doing this is that, following birth, should additional nutrition be required, maternal colostrum can be given instead of artificial formula (Cox 2006). A survey of lactation consultants in Australia reported a growing awareness of antenatal breast milk expression, even when the practice was not promoted by the individual lactation consultants who responded to the survey (Chapman 2012b).

How the intervention might work

The storage of expressed colostrum to be given (if required) in addition to breast milk obtained directly from the breast or expressed after birth, may avert the need for artificial formula or intravenous fluid administration if correction of hypoglycaemia is required. Some clinical guidelines (e.g.NICE 2008) recommend close monitoring of the baby's blood sugar level in the postnatal period, with the mother and baby remaining together for care. Should the infant become hypoglycaemic (often defined as a true blood glucose (TBG) of < 2.6 mmol/L), a prescribed series of escalating interventions is followed, which may include separation of the baby from the mother through admission to a special or intensive care nursery if an additional feed of breast milk or formula does not result in euglycaemia within an hour, or by the time of the next feed (NETS 2009). Some hospitals mandate the infant's automatic admission to the special or intensive care nursery following birth, rather than mother and baby being cared for together, for example, for the infant of a woman with Type 1 diabetes, or an infant of a woman with gestational diabetes who required in excess of a specified number of units of insulin daily (e.g. Southern Health 2011). Moreover, there are substantial economic and social costs attributable to such admissions and to separation of the mother and her baby (Argus 2009; Figueiredo 2009). The limited expenses involved in educating women to express and the provision of sterile containers and freezer storage would be likely to be considerably less than the costs of specialised nursery admission and treatment.

Potential concerns arising from breast/nipple stimulation

Uterine contractions may result from the release of the hormone, oxytocin, that accompanies nipple stimulation (Christensson 1989). Therefore, the potential for this intervention to cause harm by bringing on labour early raises concern. Specifically, breast stimulation may be utilised as a means of inducing labour, as reported in a systematic review of six trials (719 women) comparing breast stimulation with no intervention in women from 37 weeks of gestation (Kavanagh 2005). The review reported a significant reduction in the proportion of women not in labour within 72 hours (62.7% versus 93.6%, risk ratio (RR) 0.67, 95% confidence interval (CI) 0.60 to 0.74). Although these findings were only significant in women who entered the study with a favourable cervix (that is, ready for labour), other randomised trials have demonstrated an improvement in the Bishop's score, which gauges cervical preparedness for labour (Damania 1992; Di Lieto 1989; Salmon 1986). To address this concern, Soltani 2012 reported a retrospective cohort study of 94 diabetic women. Infants of mothers who had expressed antenatally were more likely to be born a week earlier than infants whose mothers had not undertaken antenatal breast milk expression.

Further concerns include the potential for earlier birth to contribute to neonatal nursery admission and/or for hypoglycaemia to develop or persist despite being given the colostrum. The study by Soltani 2012 reported that more babies were admitted to the special care nursery in the group that expressed milk antenatally. Forster 2011 enrolled 43 women with diabetes in a prospective non-randomised study of antenatal breast milk expression twice a day for 10 minutes from 36 weeks' gestation. Outcomes for this group were compared with those from a retrospective audit of 89 women with diabetes who had not expressed during pregnancy. The study reported that five women experienced uterine tightening or Braxton Hicks contractions after expressing and did not continue this activity. Forty per cent of infants of women who had expressed milk received artificial formula within 24 hours of birth compared with 56% of the comparison group (RR 0.72, 95% CI 0.48 to 1.09). The finding of potentially increased rates of admission to the special care nursery in the expressing group were of concern even though they did not reach statistical significance (RR 1.79, 95% CI 0.94 to 3.33). The wide confidence interval suggests that more participants would be required to confirm or refute this concern.

Why it is important to do this review

Despite the concerns for the potential of earlier birth or neonatal nursery admissions for interventions to correct hypoglycaemia, antenatal breast milk expression and storage is emerging within clinical practice on the basis of its theoretical benefits to infants of women with diabetes in pregnancy (for example, Cox 2010; Ramsay Health Care 2011). The observational evidence that suggests the potential for an increased risk to the mother of premature labour and to the baby of premature birth and nursery admission following such practice (Forster 2011; Soltani 2012), needs to be followed through with a systematic review of randomised

controlled trial evidence to determine the benefits and harms of antenatal breast milk expression, to then inform clinical practice. When it is determined that this practice is, or is not, beneficial to infants, there will be implications for promoting successful breastfeeding in the mother to reduce her risk of diabetes later in life and for the child's potential for developing diabetes.

OBJECTIVES

To evaluate the benefits and harms of the expression and storage of breast milk during pregnancy by women with diabetes.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials, quasi-randomised trials and cluster-randomised trials. Cross-over trials are unlikely to be appropriate for this research question and will therefore be excluded. We will exclude studies that are only reported in abstract form.

Types of participants

Pregnant women with diabetes (pre-existing or gestational) with a singleton pregnancy.

Types of interventions

Randomised controlled trials that compare antenatal breast milk expressing compared with not expressing.

Types of outcome measures

Primary outcomes

Infant

1. Exclusive breastfeeding during the period of hospital-based care following birth.
2. Number of episodes of low blood glucose.
3. Duration of low blood glucose episode(s).
4. Administration of intravenous dextrose.

Secondary outcomes

Maternal

1. Uterine contractions during or after antenatal breast milk expression.
2. Onset of established labour prior to 37 weeks gestation.
3. Commenced breastfeeding or milk expression following birth.
4. Women's satisfaction with breastfeeding.

Infant

1. Gestational age at birth.
2. Admission to special care nursery or neonatal intensive care nursery.
3. Exclusive breastfeeding within 24 hours of discharge from hospital-based care.
4. Any breastfeeding within 24 hours of discharge from hospital-based care.
5. Exclusive breastfeeding at three and six months.
6. Any breastfeeding at three and six months.
7. Economic costs (as defined by trial author).

Other outcomes / considerations

We will also consider women's views on antenatal breast milk expression in the expressing group.

Search methods for identification of studies

Electronic searches

We will contact the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register.
The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. weekly searches of EMBASE;
4. handsearches of 30 journals and the proceedings of major conferences;
5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL, MEDLINE and EMBASE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section

within the editorial information about the Cochrane Pregnancy and Childbirth Group.
Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.
We will not apply any language restrictions.

Data collection and analysis

Selection of studies

At least two review authors will independently assess for inclusion all the potential studies we identify as a result of the search strategy. We will resolve any disagreement through discussion or, if required, we will consult a third person.

Data extraction and management

We will design a form to extract data. For eligible studies, at least two review authors will extract the data using the agreed form. We will resolve discrepancies through discussion or, if required, we will consult a third person. We will enter data into Review Manager software (RevMan 2011) and check for accuracy.
When information regarding any of the above is unclear, we will attempt to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors will independently assess risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will resolve any disagreement by discussion or by involving a third assessor.

(1) Random sequence generation (checking for possible selection bias)

We will describe for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.
We will assess the method as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
- unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias)

We will describe for each included study the method used to conceal allocation to interventions prior to assignment and will assess whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.
We will assess the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

(3.1) Blinding of participants and personnel (checking for possible performance bias)

We will describe for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We will consider that studies are at low risk of bias if they were blinded, or if we judge that the lack of blinding would be unlikely to affect results. We will assess blinding separately for different outcomes or classes of outcomes.
We will assess the methods as:

- low, high or unclear risk of bias for participants;
- low, high or unclear risk of bias for personnel.

(3.2) Blinding of outcome assessment (checking for possible detection bias)

We will describe for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We will assess blinding separately for different outcomes or classes of outcomes.
We will assess methods used to blind outcome assessment as:

- low, high or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)

We will describe for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We will state whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information is reported, or can be supplied by the trial authors, we will re-include missing data in the analyses which we undertake.
We will assess methods as:

- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation);
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias)

We will describe for each included study how we investigated the possibility of selective outcome reporting bias and what we found. We will assess the methods as:

- low risk of bias (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other bias (checking for bias due to problems not covered by (1) to (5) above)

We will describe for each included study any important concerns we have about other possible sources of bias.

We will assess whether each study was free of other problems that could put it at risk of bias:

- low risk of other bias;
- high risk of other bias;
- unclear whether there is risk of other bias.

(7) Overall risk of bias

We will make explicit judgements about whether studies are at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2011). With reference to (1) to (6) above, we will assess the likely magnitude and direction of the bias and whether we consider it is likely to impact on the findings. We will explore the impact of the level of bias through undertaking sensitivity analyses - *see* Sensitivity analysis.

Measures of treatment effect

Dichotomous data

For dichotomous data, we will present results as summary risk ratio with 95% confidence intervals.

Continuous data

For continuous data, we will use the mean difference if outcomes are measured in the same way between trials. We will use the standardised mean difference to combine trials that measure the same outcome, but use different methods.

Unit of analysis issues

Cluster-randomised trials

We will include cluster-randomised trials in the analyses along with individually-randomised trials. We will adjust their sample sizes using the methods described in the *Handbook* using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually-randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely.

We will also acknowledge heterogeneity in the randomisation unit and perform a subgroup analysis to investigate the effects of the randomisation unit.

Cross-over trials

As it unlikely that cross-over designs will be appropriate for this research question, we will exclude them.

Other unit of analysis issues

We will exclude multiple pregnancies in order to avoid the related issues with the unit of analysis.

Dealing with missing data

For included studies, we will note levels of attrition. We will explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

For all outcomes, we will carry out analyses, as far as possible, on an intention-to-treat basis, i.e. we will attempt to include all participants randomised to each group in the analyses, and all participants will be analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial will be the number randomised minus any participants whose outcomes are known to be missing.

Assessment of heterogeneity

We will assess statistical heterogeneity in each meta-analysis using the T^2, I^2 and Chi^2 statistics. We will regard heterogeneity as substantial if the I^2 is greater than 30% and either T^2 is greater than zero, or there is a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

If there are 10 or more studies in the meta-analysis we will investigate reporting biases (such as publication bias) using funnel plots. We will assess
funnel plot asymmetry visually. If asymmetry is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We will carry out statistical analysis using the Review Manager software (RevMan 2011). We will use fixed-effect meta-analysis for combining data where it is reasonable to assume that studies are estimating the same underlying treatment effect: i.e. where trials are examining the same intervention, and the trials' populations and methods are judged sufficiently similar. If there is clinical heterogeneity sufficient to expect that the underlying treatment effects differ between trials, or if substantial statistical heterogeneity is detected, we will use random-effects meta-analysis to produce an overall summary if an average treatment effect across trials is considered clinically meaningful. The random-effects summary will be treated as the average range of possible treatment effects and we will discuss the clinical implications of treatment effects differing between trials. If the average treatment effect is not clinically meaningful, we will not combine trials.

If we use random-effects analyses, the results will be presented as the average treatment effect with 95% confidence intervals, and the estimates of T^2 and I^2.

Subgroup analysis and investigation of heterogeneity

If we identify substantial heterogeneity, we will investigate it using subgroup analyses and sensitivity analyses. We will consider whether an overall summary is meaningful, and if it is, use random-effects analysis to produce it.
We plan to carry out the following subgroup analysis.

- Type of diabetes: gestational versus Type 1 versus Type 2.

The following outcome will be used in subgroup analysis.

- Exclusive breastfeeding during the period of hospital-based care following birth.

We will assess subgroup differences by interaction tests available within RevMan (RevMan 2011). We will report the results of subgroup analyses quoting the χ^2 statistic and P value, and the interaction test I^2 value.

Sensitivity analysis

We will carry out sensitivity analysis to explore the effects of trial quality assessed by allocation concealment and other risk of bias components, by omitting studies rated as 'high risk of bias' for these components. This will be restricted to the primary outcomes.

ACKNOWLEDGEMENTS

As part of the pre-publication editorial process, this review has been commented on by two peers (an editor and referee who is external to the editorial team), a member of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.

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* *Indicates the major publication for the study*

CONTRIBUTIONS OF AUTHORS

Christine East compiled the protocol and is the guarantor for the review.

Willie Dolan and Della Forster contributed to the protocol content and reviewed it prior to submission.

DECLARATIONS OF INTEREST

Willie J Dolan: none known.

Della Forster is the Principal Investigator and Christine East is a co-investigator on a study that directly addresses this issue and that, when completed, would be included in this systematic review. All decisions relating to inclusion of that trial (assessment for inclusion, trial quality and data extraction) will be carried out by Willie Dolan and potentially by an additional co-author (yet to be named) of this review who are not directly involved in the trial.

SOURCES OF SUPPORT

Internal sources

- Southern Health, Australia.

Women's and Children's Program

- Monash University, Australia.

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Mother and Child Health Research

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