

Contents lists available at ScienceDirect

Midwifery



journal homepage: www.elsevier.com/midw

Diabetes and antenatal milk expressing: a pilot project to inform the development of a randomised controlled trial

Della A. Forster, Dip.App.Sci.(Nurs), BHealth.Sci.(Nurs), MMid, PhD (Senior Research Fellow and Midwifery Consultant)^{a,b,*}, Kerri McEgan, RN, RM (Unit Manager)^c, Rachael Ford, BNurs (Clinical Midwife and Research Scholarship Fellow)^b, Anita Moorhead, RN, RM (Clinical Midwifery Consultant)^b, Gillian Opie, MBBS (Neonatal Paediatrician)^c, Susan Walker, MBBS, MD (Associate Professor, Director of Perinatal Medicine)^c, Cath McNamara, BA, Grad Cert Diab Ed (Diabetic Educator)^c

^a Mother and Child Health Research, La Trobe University, Melbourne, Australia

^b Royal Women's Hospital, Parkville, Australia

^c Mercy Hospital for Women, Heidelberg, Australia

ARTICLE INFO

Article history: Received 24 November 2008 Received in revised form 30 April 2009 Accepted 20 May 2009

Keywords: Diabetes Breast feeding Expressed breast milk Women's views Pregnancy care

ABSTRACT

Objective: infants of women with diabetes in pregnancy are at increased risk of hypoglycaemia. If the infant's blood glucose is low and the mother is unable to breast feed/provide sufficient expressed breast milk, infants are often given formula. Some hospitals encourage women with diabetes to express breast milk before birth. However, there is limited evidence for this practice, including its impact on labour and birth, e.g. causing premature birth may be a concern. A pilot study was undertaken to establish the feasibility of conducting an adequately powered randomised controlled trial to evaluate this practice. *Design:* consecutive eligible women with pre-existing or gestational diabetes (requiring insulin), planning to breast feed and attending the study hospital were offered participation. *Inclusion criteria*: 34–36 weeks of gestation; singleton pregnancy; cephalic presentation; and able to speak, read and write in English. *Exclusion criteria:* history of spontaneous preterm birth, antepartum haemorrhage, placenta praevia and suspected fetal compromise. Women were encouraged to express colostrum twice a day from 36 weeks of gestation, and advised how to store the colostrum, which was frozen for their infant's use after birth. They were asked to keep a diary documenting their expressing. *Data:* demographic questionnaire, telephone interview at six and 12 weeks postpartum and medical record data.

Setting: a public, tertiary, women's hospital in Melbourne, Australia.

Participants: 43 women with diabetes in pregnancy (requiring insulin).

Findings: cardiotocographs were undertaken after the first expressing episode and none of the infants showed any sign of fetal compromise. Forty per cent of infants received formula in the 24 hours postpartum. The proportion of infants receiving any breast milk at six weeks was 90%, and this decreased to 75% at 12 weeks. No women showed evidence of hypoglycaemia post expressing. The intervention was positively received by most women; 95% said that they would express antenatally again if the practice proved to be beneficial. The amount of colostrum varied according to the number of expressions, the length of time in the study and the time spent expressing, with a median of 14 days expressing and 39.6 ml of colostrum obtained.

Key conclusions: the small number of women in this pilot was not an adequate number to examine safety or efficacy, but this study does provide evidence that it would be feasible and desirable to conduct a randomised controlled trial of antenatal milk expressing for women with diabetes requiring insulin in pregnancy.

Implications for practice: it is important that this widespread practice undergoes rigorous evaluation to assess both efficacy and safety. Until such evidence is available, the authors suggest that the routine encouragement of antenatal milk expressing in women with diabetes in pregnancy should cease.

© 2009 Elsevier Ltd. All rights reserved.

^{*} Corresponding author at: Mother and Child Health Research, La Trobe University, 324–328 Little Lonsdale St, Melbourne 3000, Australia. *E-mail address:* d.forster@latrobe.edu.au (D.A. Forster).

Background

The importance of exclusive breast feeding, i.e. giving the infant no other food/drink apart from breast milk, is being increasingly recognised (World Health Organization, 2003; Coovadia et al., 2007; Fewtrell et al., 2007). The World Health Organization (WHO) recommends exclusive breast feeding for the first six months of life, followed by continued breast feeding into the second year and beyond (World Health Organization, 2003). Breast milk is the normal food for infants; there are risks associated with the use of formula (Berry and Gribble, 2008; Cattaneo, 2008). The neonatal bowel is immature, especially in preterm infants, and macromolecules of the diet can cross the bowel wall leading to future ill health (Newburg and Walker, 2007). At a time when the newborn gut is vulnerable to pathogens and the risk of mucosal damage, colostrum has high levels of immunosuppressive factors that reduce pro-inflammatory processes and inhibit specific pathogens (Newburg and Walker, 2007). Unlike formula, breast milk accelerates maturation of the gut barrier function (Newburg and Walker, 2007).

Risks for infants of women with diabetes

Infants of women with diabetes in pregnancy are at increased risk of hypoglycaemia and other morbidities in the early neonatal period (Hanson and Persson, 1993). These infants are often admitted to special care nurseries (SCNs) for routine blood glucose monitoring and may need supplementation with formula or intravenous glucose if their blood glucose is low, and the mother is unable to breast feed or provide adequate amounts of expressed breast milk. Mothers are also more likely to be separated from their infants following caesarean births or admission to an SCN.

Infants of women with diabetes in pregnancy are also at higher risk of not being exclusively breast fed in the immediate postpartum period due to hypoglycaemia, risk of hypoglycaemia, prematurity, maternal obesity and other co-morbidities. However, exclusive breast feeding is strongly encouraged because children of diabetic women have a higher than average risk of developing diabetes themselves (Phillip et al., 2001).

The use, value and availability of colostrum to treat infant hypoglycaemia

Many Australian parents are keen to avoid the use of formula, in accordance with step six of the WHO/UNICEF Ten Steps to Successful Breast feeding, i.e. Give newborn infants no food or drink other than breast milk, unless medically indicated (WHO/ UNICEF, 1989). Additionally, lactation consultants are concerned about the potential harm in 'just one bottle' (Walker, undated) and the issue that the use of *any* formula may be detrimental to an infant's health.

Given the fact that many infants of women with diabetes require complementary feeding, colostrum is the preferred supplement. If the volume of colostrum is not sufficient, pasteurised donor milk is the preferred alternative (Cordes et al., 2002). However, in Victoria, Australia, there is currently no donor human milk bank so formula is used, most of which is cow's milk based. 'Standard' care involves liberal formula supplementation ... to prevent hypoglycaemic episodes (Cordero et al., 1998, p. 250). Cow's-milk-based formula is suboptimal as it is less well tolerated by infants than breast milk, particularly for those infants who are premature (Ewer et al., 1994). There is evidence that early exposure to cow's milk proteins may increase the incidence of type 1 (juvenile-onset) diabetes (Mayer et al., 1988; Virtanen et al., 1991) and later-onset type II diabetes (Owen et al., 2006; Horta et al., 2007). Although women may express dissatisfaction and concern with giving of formula to their infants (to complement breast feeding if required), they are otherwise faced with the invasive procedure of intravenous glucose administration.

Women with diabetes are also at risk of delay in lactogenesis II (the onset of copious milk secretion between 30 and 40 hours following the birth) of up to 24 hours compared with women without diabetes, which puts their infants at further risk of receiving formula (Bitman et al., 1989; Miyake et al., 1989; Arthur et al., 1994; Murtaugh et al., 1998). Women with diabetes are at risk of other co-morbidities, the most common of which is obesity (Hawkins and Casey, 2007). In turn, women who are overweight or obese are less likely to be successful at breast feeding in general (Amir and Donath, 2007), as are obese women with diabetes (Schaefer-Graf et al., 2006).

Colostrum is produced from the second trimester of pregnancy and some women will spontaneously leak colostrum, particularly during the third trimester. Colostrum contains high levels of lactose that readily breaks down to glucose and galactose, and in turn is readily bioavailable to the infant (Cordero et al., 1998, p. 254). It is also rich in immunoglobulins. Colostrum contains higher levels of protein and lower fat than breast milk in established lactation (Saint et al., 1984; Lawrence and Lawrence, 1999a, b, p. 103). The mean amount of colostrum normally produced in the first 24 hours has been estimated to be 37.1 g (range 7–122.5) (Saint et al., 1984).

Expressing colostrum antenatally

In light of the fact that many infants of women with diabetes are at increased risk of receiving formula, midwives and lactation consultants are suggesting that these women should express colostrum antenatally for use in the postpartum period (Cox, 2006). This is based on the idea that establishing a supply of colostrum pre-birth might help to overcome many of the issues described above: the increased risk of hypoglycaemia in infants of women with diabetes, the delayed lactogenesis in women with diabetes, the number of infants of women with diabetes who are required to receive either formula or intravenous glucose, and the number of infants of women with diabetes who require SCN admission. A number of maternity providers in Victoria offer women with diabetes the opportunity to express and store breast milk in the last weeks prior to their expected birth date (particularly when the date is known due to a planned caesarean section)

A practice such as expressing breast milk antenatally should not be undertaken without good evidence of its efficacy and safety; however, the authors were unable to identify any evidence to support this practice. To the authors' knowledge, there has only been one retrospective cohort study including 94 diabetic women which has made any attempt to explore whether the practice is (a) beneficial or (b) causes harm (Soltani, 2008). Potential risks include the possibility that nipple stimulation may provoke preterm contractions or elicit fetal compromise. However, there is no current advice to pregnant women to avoid sexual activity in late pregnancy (and some clinicians suggest sexual activity as a means to get women into labour when post term). In the past, women were encouraged to express colostrum antenatally; e.g. in 1972, Llewellyn-Jones recommended daily expressing from the 32nd week ... to keep the ducts open (Llewellyn-Jones, 1972, p. 156). In Soltani et al.'s cohort study, infants of women who expressed were born one week earlier, on average, and were more likely to be admitted to the SCN than the infants of mothers who did not express (Soltani et al., 2008).

With the aim of investigating antenatal expression of colostrum in a randomised controlled trial (RCT), the authors conducted a pilot study in 2007 to determine feasibility and begin to assess safety and efficacy. This paper reports on the pilot findings.

Methods

This study was conducted at the Mercy Hospital for Women (MHW), a public tertiary hospital in metropolitan Melbourne.

Participants

Consecutive eligible women with pre-existing or gestational diabetes (requiring insulin), planning to breast feed and attending the study hospital were offered participation. To be eligible for the study, women needed to be at 34–36 weeks of gestation with a singleton pregnancy in a cephalic presentation, and be able to speak, read and write in English. Exclusion criteria included: a history of spontaneous preterm birth, antepartum haemorrhage or placenta praevia in the current pregnancy, and any suspicion of fetal compromise. Study participation was offered to women during a visit with the diabetic educator. Once written consent was obtained, women's details were given to one of the research team (KMc), who contacted the women and made an appointment to meet with them at a mutually convenient time.

Pilot intervention

Women in the study received routine advice regarding the benefits of breast feeding, and were given instructions on antenatal expressing. Each woman was taught how to hand express colostrum and encouraged to do this twice daily for approximately 10 minutes until she was admitted to hospital to have her baby. Women were provided with written and verbal instructions on the safe storage and transportation of colostrum (again, as per the existing MHW SCN guideline). The expressed colostrum was labelled with the woman's hospital medical record number and kept in syringes in her home freezer. Women were asked to bring the frozen colostrum with them when they were admitted for the birth, at which time the expressed colostrum was to be stored in a suitable hospital freezer. Women were provided with the equipment they required, e.g. syringes (2 and 5 ml), specimen bags, a portable cold storage container and a diary to document each episode of expressing.

Women were advised of precautions related to expressing in pregnancy. In particular, they were advised to ensure normal fetal activity prior to expressing and to report any excessive uterine activity, vaginal blood loss or decreased fetal movements during or after expressing. In addition, fetal monitoring with cardiotocography was performed before, during and after the first expressing episode. Prior to commencing expressing, the cardiotocograph had to be reactive, meeting all the criteria for a healthy antenatal cardiotocograph, and expressing was to be discontinued if there was any change in baseline, decelerations or evidence of uterine hyperstimulation. Women were also instructed to measure their blood glucose levels after the first three episodes of expressing, to ensure that the expressing was not causing hypoglycaemia (which has been described with breast feeding) (Lawrence and Lawrence, 1999a, b; McElduff et al., 2005). Women were informed that if they had concerns regarding any of these issues, they should cease expressing and contact the diabetic educator (or the emergency department after hours) for further advice.

Following birth, if complementary feeding was indicated, infants of women in the study received 5–10 ml/kg of expressed colostrum if available (fresh or defrosted) instead of the usual formula. The clinical areas involved with the postnatal care of women and infants were informed to use the colostrum that had been collected in pregnancy.

Data collection and analysis

As this was a pilot study, it was estimated that a sample of 40 women and their infants would be sufficient to provide baseline data from which to plan a trial. Women completed a questionnaire on study enrolment to collect demographic information and infant-feeding intentions. Women were also asked to keep a diary document their expressing practices. This was provided as a preformatted A5 booklet, which women were asked to return when they came to the hospital for the birth. Medical and obstetric outcome data were collected from the medical record, and other outcome data were collected at six and 12 weeks postpartum by structured telephone interviews.

Quantitative data were analysed in STATA Version 8.0 (Stata Corporation, College Station, TX, USA) using descriptive statistics such as frequencies. Where appropriate, χ^2 tests were undertaken to compare categorical data. Open-ended comments were analysed using simple thematic analysis (Ezzy, 2002).

In addition to the pilot study, audits were conducted at MHW and the Royal Women's Hospital (RWH) to identify the prevalence of key outcomes for infants of women who were not in the pilot, e.g. the proportion of infants of mothers with diabetes in pregnancy (requiring insulin) who received formula in the first 24 hours of life. The audits were conducted using the medical records of infants who were born between May 2007 and May 2008, and the authors aimed to audit 50 records from each site, i.e. 100 in total. A template was developed to guide data abstraction to be congruent with the pilot data collection. These outcomes were required as a comparison group to assist with future trial sample size calculations. Data from the pilot as well as the audits (where applicable) are presented below.

Ethical approval for the study was obtained from the Mercy Health and Aged Care Research Ethics Committee.

Findings

Recruitment to the pilot study took place from May 2007 to March 2008. In total, 43 women agreed to participate; an uptake of 35%. Background characteristics of participants are presented in Table 1. The average gestation at recruitment was 36 weeks (range 33–39). Just under half of the participants were having their first baby. All infants were born at or after 37 weeks of gestation. One infant died in the neonatal period prior to the six-week interview (unrelated to the study); therefore, data were available for only 42 women for the latter time points. Data were available for 95% of women (40/42) at six weeks postpartum and 86% (36/42) at 12 weeks. Eighty-six per cent (19/22) of women having their second or subsequent infant had previously breast fed.

Infant feeding

The primary outcome of the study was the use of formula in the 24 hours postpartum (Table 2). Forty per cent of infants in the pilot received any formula in the first 24 hours, compared with 56% of the audit 'control' infants [relative risk (RR) 0.72; 95% confidence interval (CI) 0.48–1.09]. Similarly, 63% of infants in the pilot received artificial milk during their hospital stay compared

Table 1

| Background characteristics of participan | ts $(n = 43)$. |
|--|-----------------|
|--|-----------------|

| Age in years (median, range) 32.8 $(25-44)$ Marital status Married 34 79.1 Living with partner 8 18.6 Has partner, not cohabiting 0 - Single 1 2.3 Separated or divorced/widowed 0 - Secondary schooling Completed secondary school to final year (12) 38 88.4 Did not complete secondary school 5 11.6 Higher education Degree or higher 19 44.2 No degree 34 55.8 Taxable income for the household for last year, AUD (n = 42) $<$ $$40,000$ 4 9.5 \$40,000 4 9.5 $$40,000$ 11 26.2 $$60,000$ 11 26.2 $$$80,000$ 16 38.1 Country of birth A 9.5 $$14.4$ 16.3 37.7 $17aq$ 12.3 2.3 Lebanon 1 2.3 51.44 12.3 31.44 12.3 31.44 12.3 31.44 12.3 31.44 12 | Characteristic | n | % |
|--|---|------|---------|
| Married 34 79.1 Living with partner 8 18.6 Has partner, not cohabiting 0 - Single 1 2.3 Separated or divorced/widowed 0 - Secondary schooling 2 38 88.4 Did not complete secondary school 5 11.6 16 Higher education 2 34 55.8 Taxable income for the household for last year, AUD (n = 42) <\$40,000 | Age in years (median, range) | 32.8 | (25-44) |
| Living with partner 8 18.6 Has partner, not cohabiting 0 - Single 1 2.3 Separated or divorced/widowed 0 - Secondary schooling Completed secondary school to final year (12) 38 88.4 Did not complete secondary school 5 11.6 Higher education Degree or higher 19 44.2 No degree 34 55.8 Taxable income for the household for last year, AUD (n = 42) 44.2 55.8 <\$40,000 | Marital status | | |
| Has partner, not cohabiting 0 - Single 1 2.3 Separated or divorced/widowed 0 - Secondary schooling 0 - Completed secondary school to final year (12) 38 88.4 Did not complete secondary school 5 11.6 Higher education 19 44.2 No degree 34 55.8 Taxable income for the household for last year, AUD (n = 42) 44.2 <\$40,000 | Married | 34 | |
| Single 1 2.3 Separated or divorced/widowed 0 - Secondary schooling 38 88.4 Did not complete secondary school 5 11.6 Higher education 9 44.2 No degree 34 55.8 Taxable income for the household for last year, 34 9.5 $AUD (n = 42)$ <\$40,000 | | 8 | 18.6 |
| Separated or divorced/widowed 0 - Secondary schooling Completed secondary school 38 88.4 Did not complete secondary school 5 11.6 Higher education Degree or higher 19 44.2 No degree 34 55.8 Taxable income for the household for last year, AUD (n = 42) 4 9.5 <\$40,000 | | | |
| Secondary schooling Completed secondary school to final year (12) 38 88.4 Did not complete secondary school 5 11.6 Higher education 9 44.2 No degree 34 55.8 Taxable income for the household for last year, AUD (n = 42) 4 9.5 <\$40,000 | 0 | - | 2.3 |
| Completed secondary school to final year (12) 38 88.4 Did not complete secondary school 5 11.6 Higher education 9 44.2 No degree 34 55.8 Taxable income for the household for last year, AUD $(n = 42)$ < | Separated or divorced/widowed | 0 | - |
| Did not complete secondary school511.6Higher education Degree or higher1944.2No degree3455.8Taxable income for the household for last year, AUD (n = 42) <\$40,000 | | | |
| Higher eduction 19 44.2 No degree 34 55.8 Taxable income for the household for last year, 4UD (n = 42) $<$ <40,000 | | | |
| Degree or higher1944.2No degree3455.8Taxable income for the household for last year, AUD (n = 42) < \$40,000 | Did not complete secondary school | 5 | 11.6 |
| No degree 34 55.8 Taxable income for the household for last year, AUD (n = 42) <\$40,000 | | | |
| Taxable income for the household for last year, AUD (n = 42) <\$40,000 | | 19 | 44.2 |
| AUD (n = 42) $<$ \$40,000 4 9.5 \$40,000 to < 60,000 | No degree | 34 | 55.8 |
| $\begin{array}{c cccc} \$40,000 \ {\rm to} < 60,000 & 11 & 26.2 \\ \$60,000 \ {\rm to} < 80,000 & 11 & 26.2 \\ > \$80,000 & 16 & 38.1 \\ \hline \\ \hline \\ \ \\ \ \\ \ \\ \ \\ \ \\ \ \\ \ \\ \$ | | | |
| \$60,000 to < 80,000 | | 4 | 9.5 |
| > \$80,000 16 38.1 Country of birth 35 81.4 Australia 35 81.4 India 3 7 Iraq 1 2.3 Lebanon 1 2.3 Singapore 1 2.3 Sri Lanka 1 2.3 English first language 39 90.7 Religion 2 4.6 Hindu 2 4.6 Hindu 2 4.6 Buddhist 1 2.3 Other 4 9.3 None 13 30.2 Current smoker 1 2.3 Gestation at recruitment (median, range) 36 (33–39) First infant 21 48.8 Used insulin in previous pregnancy (n = 22) ^a 5 22.7 Breast fed previously (n = 22) ^a 19 86.4 | \$40,000 to <60,000 | 11 | 26.2 |
| Country of birth Australia 35 81.4 India 3 7 Iraq 1 2.3 Lebanon 1 2.3 Malta 1 2.3 Singapore 1 2.3 Sri Lanka 1 2.3 English first language 39 90.7 Religion 21 48.8 Muslim 2 4.6 Hindu 2 4.6 Buddhist 1 2.3 Other 4 9.3 None 13 30.2 Current smoker 1 2.3 Gestation at recruitment (median, range) 36 (33-39) First infant 21 48.8 Used insulin in previous pregnancy (n = 22) ^a 5 22.7 Breast fed previously (n = 22) ^a 19 86.4 | \$60,000 to <80,000 | 11 | 26.2 |
| Australia3581.4India37Iraq12.3Lebanon12.3Malta12.3Singapore12.3Sri Lanka12.3English first language3990.7Religion24.6Hindu24.6Hindu24.6Buddhist12.3Other49.3None1330.2Current smoker12.3Gestation at recruitment (median, range)36(33-39)First infant2148.8Used insulin in previous pregnancy (n = 22) ^a 522.7Breast fed previously (n = 22) ^a 1986.4 | >\$80,000 | 16 | 38.1 |
| Australia3581.4India37Iraq12.3Lebanon12.3Malta12.3Singapore12.3Sri Lanka12.3English first language3990.7Religion24.6Hindu24.6Hindu24.6Buddhist12.3Other49.3None1330.2Current smoker12.3Gestation at recruitment (median, range)36(33-39)First infant2148.8Used insulin in previous pregnancy (n = 22) ^a 522.7Breast fed previously (n = 22) ^a 1986.4 | Country of birth | | |
| Iraq12.3Lebanon12.3Malta12.3Singapore12.3Sri Lanka12.3English first language3990.7Religion24.6Hindu24.6Hindu24.6Buddhist12.3Other49.3None1330.2Current smoker12.3Gestation at recruitment (median, range)36(33-39)First infant2148.8Used insulin in previous pregnancy (n = 22) ^a 522.7Breast fed previously (n = 22) ^a 1986.4 | Australia | 35 | 81.4 |
| Lebanon12.3Malta12.3Singapore12.3Sri Lanka12.3English first language3990.7Religion24.6Christian24.6Hindu24.6Buddhist12.3Other49.3None1330.2Current smoker12.3Gestation at recruitment (median, range)36(33-39)First infant2148.8Used insulin in previous pregnancy (n = 22) ^a 522.7Breast fed previously (n = 22) ^a 1986.4 | India | 3 | 7 |
| Malta 1 2.3 Singapore 1 2.3 Sri Lanka 1 2.3 English first language 39 90.7 Religion 21 48.8 Muslim 2 4.6 Hindu 2 4.6 Buddhist 1 2.3 Other 4 9.3 None 13 30.2 Current smoker 1 2.3 Gestation at recruitment (median, range) 36 (33-39) First infant 21 48.8 Used insulin in previous pregnancy (n = 22) ^a 5 22.7 Breast fed previously (n = 22) ^a 19 86.4 | Iraq | 1 | 2.3 |
| Singapore 1 2.3 Sri Lanka 1 2.3 English first language 39 90.7 Religion 2 4.6 Muslim 2 4.6 Hindu 2 4.6 Buddhist 1 2.3 Other 4 9.3 None 13 30.2 Current smoker 1 2.3 Gestation at recruitment (median, range) 36 (33-39) First infant 21 48.8 Used insulin in previous pregnancy (n = 22) ^a 5 22.7 Breast fed previously (n = 22) ^a 19 86.4 | Lebanon | 1 | 2.3 |
| Sri Lanka12.3English first language3990.7Religion2148.8Muslim24.6Hindu24.6Buddhist12.3Other49.3None1330.2Current smoker12.3Gestation at recruitment (median, range)36 $(33-39)$ First infant2148.8Used insulin in previous pregnancy (n = 22) ^a 522.7Breast fed previously (n = 22) ^a 1986.4 | Malta | 1 | 2.3 |
| English first language 39 90.7 Religion 21 48.8 Muslim 2 4.6 Hindu 2 4.6 Buddhist 1 2.3 Other 4 9.3 None 13 30.2 Current smoker 1 2.3 Gestation at recruitment (median, range) 36 (33–39) First infant 21 48.8 Used insulin in previous pregnancy (n = 22) ^a 5 22.7 Breast fed previously (n = 22) ^a 19 86.4 | Singapore | 1 | 2.3 |
| Religion 21 48.8 Christian 2 4.6 Muslim 2 4.6 Hindu 2 4.6 Buddhist 1 2.3 Other 4 9.3 None 13 30.2 Current smoker 1 2.3 Gestation at recruitment (median, range) 36 (33-39) First infant 21 48.8 Used insulin in previous pregnancy (n = 22) ^a 5 22.7 Breast fed previously (n = 22) ^a 19 86.4 | Sri Lanka | 1 | 2.3 |
| $ \begin{array}{c} {\rm Christian} & 21 & 48.8 \\ {\rm Muslim} & 2 & 4.6 \\ {\rm Hindu} & 2 & 4.6 \\ {\rm Buddhist} & 1 & 2.3 \\ {\rm Other} & 4 & 9.3 \\ {\rm None} & 13 & 30.2 \\ {\rm Current\ smoker} & 1 & 2.3 \\ {\rm Gestation\ at\ recruitment\ (median,\ range)} & 36 & (33-39) \\ {\rm First\ infant} & 21 & 48.8 \\ {\rm Used\ insulin\ in\ previous\ pregnancy\ (n=22)^a} & 5 & 22.7 \\ {\rm Breast\ fed\ previously\ (n=22)^a} & 19 & 86.4 \\ \end{array} $ | English first language | 39 | 90.7 |
| $ \begin{array}{c} {\rm Christian} & 21 & 48.8 \\ {\rm Muslim} & 2 & 4.6 \\ {\rm Hindu} & 2 & 4.6 \\ {\rm Buddhist} & 1 & 2.3 \\ {\rm Other} & 4 & 9.3 \\ {\rm None} & 13 & 30.2 \\ {\rm Current\ smoker} & 1 & 2.3 \\ {\rm Gestation\ at\ recruitment\ (median,\ range)} & 36 & (33-39) \\ {\rm First\ infant} & 21 & 48.8 \\ {\rm Used\ insulin\ in\ previous\ pregnancy\ (n=22)^a} & 5 & 22.7 \\ {\rm Breast\ fed\ previously\ (n=22)^a} & 19 & 86.4 \\ \end{array} $ | Religion | | |
| Muslim24.6Hindu24.6Buddhist12.3Other49.3None1330.2Current smoker12.3Gestation at recruitment (median, range)36 $(33-39)$ First infant2148.8Used insulin in previous pregnancy $(n = 22)^a$ 522.7Breast fed previously $(n = 22)^a$ 1986.4 | • | 21 | 48.8 |
| Buddhist 1 2.3 Other 4 9.3 None 13 30.2 Current smoker 1 2.3 Gestation at recruitment (median, range) 36 $(33-39)$ First infant 21 48.8 Used insulin in previous pregnancy $(n = 22)^a$ 5 22.7 Breast fed previously $(n = 22)^a$ 19 86.4 | | | |
| Other 4 9.3 None 13 30.2 Current smoker 1 2.3 Gestation at recruitment (median, range) 36 $(33-39)$ First infant 21 48.8 Used insulin in previous pregnancy $(n = 22)^a$ 5 22.7 Breast fed previously $(n = 22)^a$ 19 86.4 | Hindu | 2 | 4.6 |
| None 13 30.2 Current smoker 1 2.3 Gestation at recruitment (median, range) 36 $(33-39)$ First infant 21 48.8 Used insulin in previous pregnancy $(n = 22)^a$ 5 22.7 Breast fed previously $(n = 22)^a$ 19 86.4 | Buddhist | 1 | 2.3 |
| Current smoker12.3Current smoker36 $(33-39)$ First infant2148.8Used insulin in previous pregnancy $(n = 22)^a$ 522.7Breast fed previously $(n = 22)^a$ 1986.4 | Other | 4 | 9.3 |
| Gestation at recruitment (median, range) 36 $(33-39)$ First infant 21 48.8 Used insulin in previous pregnancy $(n = 22)^a$ 5 22.7 Breast fed previously $(n = 22)^a$ 19 86.4 | None | 13 | 30.2 |
| Gestation at recruitment (median, range) 36 $(33-39)$ First infant 21 48.8 Used insulin in previous pregnancy $(n = 22)^a$ 5 22.7 Breast fed previously $(n = 22)^a$ 19 86.4 | Current smoker | 1 | 2.3 |
| First infant2148.8Used insulin in previous pregnancy $(n = 22)^a$ 522.7Breast fed previously $(n = 22)^a$ 1986.4 | | | |
| Used insulin in previous pregnancy $(n = 22)^a$ 5 22.7 Breast fed previously $(n = 22)^a$ 19 86.4 | | | |
| Breast fed previously $(n = 22)^a$ 19 86.4 | | | |
| | | | |
| | Expressed antenatally previously $(n = 22)^{a}$ | 0 | - |

^a Not applicable if having first infant.

Table 2

Infant outcomes: a comparison of pilot and audit data.

with 73% of the audited infants (RR 0.86; 95% CI 0.66–1.12). Feeding at discharge is usually considered as the feeding method in the preceding 24 hours, and 60% of pilot infants received only breast milk during this period compared with 44% of controls (RR 1.36; 95% CI 0.96–1.92). None of these differences were statistically significant. Of those pilot infants who received artificial milk, the reasons (which could be more than one) included: low true blood glucose (TBG) (18/27; 66%), insufficient colostrum (5/27; 18%), mother's preference (3/27; 11%), and feeding issues (4/27; 15%). At six weeks postpartum 90%, of infants were receiving at least some breast milk, as were 75% of infants at 12 weeks.

Infant well-being

Cardiotocographs were undertaken before, during and after the first expressing episode and in no case was there any sign of fetal compromise. Special care admissions were higher in the pilot infants (30%) than for those audited (17%) (RR 1.79; 95% CI 0.94–3.33) (Table 3). This finding could be by chance given the small numbers, or it may be that mothers of these infants were more reluctant to give formula. Of the 13 admissions to the SCN in the pilot, nine (64%) were for hypoglycaemia. Other reasons were respiratory support (n = 2) and hypothermia (n = 1). In the audit data, 8/15 (53%) admissions to the SCN were for hypoglycaemia, two for respiratory support and the others for a range of reasons. Intravenous glucose use was 14% for pilot infants and 8% for audit infants; a non-significant difference (RR 1.77; 95% CI 0.63–4.96).

Neonatal hypoglycaemia is defined as a TBG < 2.6 mmol/l. Standard management of these infants involves serial blood glucose levels prior to feeds until there are three measurements of 2.6 mmol/l or higher. In practice, these may be undertaken using one of two methods; a blood 'sugar' level (BSL) is measured by a blood glucose monitor using reagent strips (inaccurate for lower levels of blood glucose), whereas the more accurate 'gold-standard' method (TBG) is performed using a blood gas analyser or in a pathology laboratory. In the pilot, the mean number of neonatal blood glucose measurements was 3.70 [standard deviation (SD) 1.21] and the range was 1–7. Only two infants had a BSL measured at the first assessment—the rest had a TBG. Of the first three measurements taken, 35% (15/43), 81% (34/42) and 77% (30/39), respectively, were performed *prior* to a feed. For those

| Outcome | F | ilot | | Audit | |
|---|----------------------------------|------------------------------|--|----------------------|--|
| | n | % | n | % | |
| Infant received any formula in the 24 hours post partum | 17/42 | 40.1 | MHW 25/41 RWH 21/41 Combined 46/82 | 61.0 51.2 56.1 | |
| Infant received any formula during hospital stay | 27/43 | 62.8 | MHW 34/45 RWH 31/44 Combined 65/89 | 75.6 70.4 73.0 | |
| Received only breast milk in 24 hours prior to postnatal discharge | 25/42 | 59.5 | MHW 20/41 RWH 16/41 Combined 36/82 | 48.8 39.0 43.9 | |
| Received any breast milk in 24 hours prior to postnatal discharge | 40/41 | 97.6 | MHW 35/41 RWH 38/42 Combined 73/83 | 85.4 90.5 89.0 | |
| Received any breast milk at six weeks post partum Received only breast milk at six weeks post partum Received any breast milk at 12 weeks post partum Received only breast milk at 12 weeks postpartum | 35/39 26/39 27/36 19/36 | 89.7 66.7 75.0 52.8 | n/a n/a n/a n/a | - - - | |

MHW, Mercy Hospital for Women; RWH, Royal Women's Hospital; n/a, not applicable.

Table 3

Infant well-being: a comparison of pilot and audit data.

| Outcome | Pilot | | Audit | |
|---|-------|---------|--|----------------------|
| | n | % | n | % |
| Infant received intravenous glucose (n, %) | 6/43 | 14.0 | MHW 4/45 RWH 3/44 Combined 7/89 | 8.9 6.8 7.9 |
| Infant admitted to special care nursery $(n, \%)$ | 13/43 | 30.2 | MHW 8/45 RWH 7/44 Combined 15/89 | 17.8 15.9 16.9 |
| Number of blood glucose measurements (mean, SD) $(n = 43)$ | 3.70 | 1.21 | 3.2 (n = 46) | 1.39 |
| First blood glucose measurement (mmol/l, if TBG) (median, range) $(n = 41)$ | 2.66 | 0.1-4 | 2.5 (n = 47) | 0.7–5.6 |
| Second blood glucose measurement (mmol/l, TBG/BSL) (median, range) $(n = 42)$ | 3.0 | 0.9-4.7 | 3.7 (n = 43) | 1.04–5.8 |
| Third blood glucose measurement (mmol/l, TBG/BSL) (median, range) $(n = 39)$ | 2.8 | 1.2-4.3 | 3.8 (n = 39) | 2.0-6.6 |
| Time to first blood glucose measurement (hours) (median, range) $(n = 43)$ | 1.7 | 0.2–5 | Combined 1.8 (n = 93) | 0.2–6.7 |

MHW, Mercy Hospital for Women; RWH, Royal Women's Hospital.

who had their first measurement as a TBG (n = 41), the median was 2.6 mmol/l (range 0.1–4) and the mean was 2.53 (SD 0.84). The median time that this was performed after the birth was 1.7 hours (range 0.2–5). It was not possible to determine if subsequent measurements were BSLs or TBGs; however, the median second BSL/TBG was 3 mmol/l (range 0.9–4.7) and the third was 2.8 mmol/l (range 1.2–4.3). The audited (non-pilot) infants had very similar outcomes for these measures (Table 3).

Expressing outcomes

Women were asked to keep a diary documenting their expressing; these were received from 26/43 (60%) women. The total amount of colostrum varied according to the number of expressions, the length of time in the study and the time spent expressing, with a median of 14 days expressing (range 4–30) and 39.6 ml (range 5–310 ml) of colostrum obtained (Table 4). Women were asked to record blood glucose levels following their first three expressing episodes. Although the median blood glucose levels were normal and suggested no evidence of hypoglycaemia at the group level, 10% (2/20) of women had a blood glucose < 3.5 mmol/l after the first expressing episode.

Women were asked for comments on the intervention at their six-week telephone interview as well as in the expressing diaries. The intervention was positively received by the majority of women in the study, and 95% (38/40) said that they would express antenatally again if the practice proved to be beneficial, mainly to have a supply of breast milk for the infant if it was needed. Around two-thirds (20/34; 59%) of women found the staff on the postnatal ward to be supportive of the practice and 95% (37/39) felt that there were benefits to expressing and storing breast milk, including decreasing the need for either artificial milk supplementation or intravenous cannulation postnatally. Positive reflections on antenatal expressing included: increased confidence and preparedness for breast feeding (7/23; 30%), doing something for the baby (7/23; 30%), having a supply of colostrum (6/23; 26%), and learning how to express (6/23; 26%). Negative reflections included: anxiety about not getting 'enough' colostrum (6/23; 26%), difficulty finding time to express (6/23; 26%), discomfort or pain with expressing (4/23; 17%), and the time it took (2/23; 9%). One woman was concerned that the expressing might start labour.

Women were asked if they experienced any symptoms as a result of expressing. Some found it difficult generally (8/26; 31%) (Table 5) and five (19%) reported that they experienced

Table 4

Outcomes related to maternal expressing.

| Outcome | Median | Range |
|--|--------|-------------|
| Volume of colostrum obtained antenatally (ml) (n = 26) | 39.6 | (5-310) |
| Total days expressing (median, range) (n = 26) | 14 | (4-30) |
| Volume of colostrum/episode of expressing $(ml) (n = 26)$ | 1.67 | (0.21–14.1) |
| Total expressing episodes $(n = 26)$ | 24 | (7-56) |
| Maternal blood glucose level after first expressing (mmol/l) ($n = 20$) | 5.25 | (3.1–9.5) |
| Maternal blood glucose level after second expressing $(mmol/l)$ $(n = 20)$ | 5.85 | (3.8–7.7) |
| Maternal blood glucose level after third expressing (mmol/l) $(n = 20)$ | 5.9 | (3.9–11.9) |

Table 5

Reported symptoms during or following expressing.

| Symptom | n | % ^a |
|--|----------|----------------|
| | (n = 26) | |
| Difficult to do/awkward | 8 | 30.8 |
| Slight lower tightening/Braxton Hicks contractions/cramping | 7 | 26.9 |
| Sore breasts/nipples | 5 | 19.2 |
| Increased fetal activity | 4 | 15.4 |
| Fatigue | 3 | 11.5 |
| Nausea | 1 | 3.8 |
| Back pain | 1 | 3.8 |
| Hypoglycaemia | 1 | 3.8 |
| Back and shoulder strain | 1 | 3.8 |
| Dizziness | 1 | 3.8 |
| Frustrating | 1 | 3.8 |

^a May add to > 100% as women could report more than one symptom.

tightenings or Braxton Hicks contractions as a result. One of this group ceased the intervention for this reason. A range of other symptoms were also reported (Table 5).

Discussion

The practice of encouraging women with diabetes in pregnancy to express colostrum in the late antenatal period is apparently widespread and being encouraged in the literature (Cox, 2006). It is being 'rolled out' across Victoria, nationally (personal communication with a number of lactation consultants at scientific meetings in the last two years) and internationally (Soltani, 2008). Although intuitively attractive, there is no highlevel evidence to support the safety or efficacy of this practice. It is important that a rigorous evaluation be undertaken.

This pilot was designed to assess the feasibility of undertaking this practice in an RCT—with a focus on whether it was acceptable to women, and whether there were any apparent signs that the intervention might cause harm. The pilot also explored whether the practice has measurable positive outcomes, such as the volumes of colostrum expressed, infant outcomes and women's views. The small number of women in this pilot was not an adequate number to examine these issues in a meaningful way, but the study does provide evidence that it would be feasible and desirable to go on and conduct an RCT of antenatal milk expressing for women with diabetes requiring insulin in pregnancy.

The authors recommend that an adequately powered RCT should be conducted, and that until this time, clinicians should not recommend this practice to women. This small pilot showed no obvious evidence of harm; however, there were more pilot infants admitted to the SCN than very similar infants that were audited. This finding is similar to that reported by Soltani et al. (2008). Their retrospective cohort study also showed that women who expressed laboured spontaneously 1 week earlier, on average than similar women in their study who did not express (Soltani, 2008). It is important that this intervention is subject to further evaluation prior to being 'rolled out'.

The authors recommend that other ways forward should also be explored; for example, the use of donor human milk for use when an infant's mother's milk is unavailable. It is also important, wherever possible, that a consistent approach to the management of neonatal hypoglycaemia that promotes breast feeding is in place.

Acknowledgements

We would like to thank all the women who took part in this study as well as our colleagues who supported us with the study. In particular, thanks to Gemma Wills who helped set up the study, obtain ethics approval and design the questionnaires, and to Deb Boyce who helped to recruit the women. We also acknowledge Novo Nordisk for the small grant obtained to assist in undertaking the study.

References

- Amir, L.H., Donath, S., 2007. A systematic review of maternal obesity and breastfeeding intention, initiation and duration. BMC Pregnancy Childbirth 7.
- Arthur, P., Kent, J., et al., 1994. Metabolites of lactose synthesis in milk from diabetic and nondiabetic women during lactogenesis II. J. Pediatr. Gastroenterol. Nutr. 19, 100–108.
- Berry, N.J., Gribble, K.D., 2008. Breast is no longer best: promoting normal infant feeding. Maternal 4, 74–79.
- Bitman, J., Hamosh, M., Hamosh, P., et al., 1989. Milk composition and volume during the onset of lactation in a diabetic mother. The American Journal of Clinical Nutrition 50, 1364–1369.
- Cattaneo, A., 2008. The benefits of breastfeeding or the harm of formula feeding? Journal of Paediatrics and Child Health 44, 1–2.

- Coovadia, H.M., Rollins, N.C., Bland, R.M., et al., 2007. Mother-to-child transmission of HIV-1 infection during exclusive breastfeeding in the first 6 months of life: an intervention cohort study. Lancet 369, 1107–1116.
- Cordero, L., Treuer, S.H., Landon, M.B., et al., 1998. Management of infants of diabetic mothers. Archives of Pediatrics and Adolescent Medicine 152, 249–254.
- Cordes, R., Howard, C.R., Wight, N.E., et al., 2002. Protocol #3: hospital guidelines for the Use of Supplementary Feedings in the Healthy Term Breastfed Infant <http://www.bfmed.org/ace-images/ProtocolSuppl3rev.pdf>.
- Cox, S.G., 2006. Expressing and storing colostrum antenatally for use in the newborn period. Breastfeeding Review 14, 11–16.
- Ewer, A.K., Durbin, G.M., Morgan, M.E., et al., 1994. Gastric emptying in preterm infants. Archives of Disease in Childhood. Fetal and Neonatal Edition 71, F24–F27.
- Ezzy, D., 2002. Qualitative Analysis: Practice and Innovation. Allen and Unwin, Sydney.
- Fewtrell, M.S., Morgan, J.B., Duggan, C., et al., 2007. Optimal duration of exclusive breastfeeding: what is the evidence to support current recommendations. The American Journal of Clinical Nutrition 85, 6355–638S.
- Hanson, U., Persson, B., 1993. Outcome of pregnancies complicated by type 1 insulin-dependent diabetes in Sweden: acute pregnancy complications, neonatal mortality and morbidity. American Journal of Perinatology 10, 330–333.
- Hawkins, J.S., Casey, BM., 2007. Labor and delivery management for women with diabetes. Obstetrics and Gynecology Clinics of North America 34, 323–334.
- Horta, B.L., Bahl, R., Martines, J.C., et al., 2007. Evidence on the Long-term Effects of Breastfeeding: Systematic Reviews and Meta-analyses. World Health Organization, Geneva.
- Lawrence, R.A., Lawrence, R.M., 1999a. Colostrum. In: Breastfeeding: a Guide for the Medical Profession, vols. 99–103. Mosby, St. Louis, pp. 737–739.
- Lawrence, R.A., Lawrence, R.M., 1999b. Diabetes mellitus. In: Breastfeeding: a Guide for the Medical Profession. Mosby, St. Louis, pp. 515–521.
- Llewellyn-Jones, D., 1972. Everywoman. Faber, London.
- Mayer, E., Hamman, R., Gay, E.C., et al., 1988. Reduced risk of IDDM among breastfed children. Colo. IDDM Regist. Diabetes 37, 1625–1632.
- McElduff, A., Cheung, N.W., McIntyre, H.D., et al., 2005. The Australasian Diabetes in Pregnancy Society consensus guidelines for the management of type 1 and type 2 diabetes in relation to pregnancy. Medical Journal of Australia 183, 373–377.
- Miyake, A., Tahara, M., Koike, K., et al., 1989. Decrease in neonatal suckled milk volume in diabetic women. European Journal of Obstetrics, Gynecology, and Reproductive Biology 33, 49–53.
- Murtaugh, M., Ferris, A., Capacchione, C.M., et al., 1998. Energy intake and glycemia in lactating women with type 1 diabetes. Journal of the American Dietetic Association 98, 642–648.
- Newburg, D.S., Walker, W.A., 2007. Protection of the neonate by the innate immune system of developing gut and of human milk. Pediatric Research 61, 2–8.
- Owen, C.G., Martin, R.M., Whincup, P.H., et al., 2006. Does breastfeeding influence risk of type 2 diabetes in later life? A quantitative analysis of published evidence. The American Journal of Clinical Nutrition 85, 1043–1054.
- Phillip, B., Merewood, A., Miller, L.W., et al., 2001. Baby-friendly Hospital Initiative improves breastfeeding initiation rates in a US hospital setting. Pediatrics 108, 677–681.
- Saint, L., Smith, M., Hartmann, P.E., 1984. The yield and nutrient content of colostrum and milk of women from giving birth to 1 month post-partum. The British Journal of Nutrition 52, 87–95.
- Schaefer-Graf, U.M., Hartmann, R., Pawliczak, J., et al., 2006. Association of breastfeeding and early childhood overweight in children from mothers with gestational diabetes mellitus. Diabetes Care 29, 1105–1107.
- Soltani, H., 2008. Breastfeeding practices and views among diabetic women: a retrospective cohort study. Midwifery 24, 471–479.
- Soltani, H., Lakl, J., Kalk, J., et al., 2008. Antenatal breast expression and the risk of labour induction—from a baby friendly perspective and promotion of breastfeeding in diabetic women. In: International Confederation of Midwives 28th Triennial Congress, Glasgow.
- Virtanen, S., Rasanen, L., Aro, A., et al., 1991. Infant feeding in Finnish children less than 7 yr of age with newly diagnosed IDDM. Child. Diabetes Finl. Study Group. Diabetes Care 14, 415–417.
- Walker, M. Supplementation of the Breastfed Baby: 'Just One Bottle Won't Hurt'—or will it? http://www.naba-breastfeeding.org/images/Just%20one. pdf > (last accessed 20 November 2008).
- WHO/UNICEF J.S., 1989. Protecting, Promoting and Supporting Breast-feeding: the Special Role of Maternity Services. WHO, Geneva.
- World Health Organization, 2003. Global Strategy for Infant and Young Child Feeding. http://www.who.int/child-adolescent-health/NUTRITION/global_strategy.htm).