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ORIGINAL ARTICLE

Donor human milk use in neonatal units: practice and opinions in the Republic of Ireland

Bronwyn Dervyla Power[1] · Mary Isabel O'Dea[1] · Michael Joseph O'Grady[1,2]

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Abstract

Background Over the past decade, where mother's own milk (MOM) is unavailable, the use of donor human milk has become increasingly common in preterm and very low birth weight (VLBW) neonates. Limited literature exists regarding donor human milk practices in neonatal units.

Aims To examine practices and opinions regarding use of donor human milk in neonatal units in the Republic of Ireland.

Methods Cross-sectional postal survey of all neonatologists and paediatricians working in each of the 19 neonatal units in the Republic of Ireland.

Main results Eighty-eight paediatricians and neonatologists were surveyed and 44 (50%) replied. Responses were received from 20 (95%) neonatal units, of whom 15 (75%) reported using donor milk. Sixty percent of units had a written donor milk policy however significant variation existed in birth weight and gestational age thresholds for its use. Thirty-eight (86%) of respondents were opposed to the use of donor milk for supplementation of otherwise healthy term neonates. Ten (23%) of respondents believed that supplementation with donor milk compared to formula improves long-term breastfeeding rates. Twenty-two (56%) agreed that the majority of studies supporting the use of donor milk to prevent necrotising enterocolitis in preterm infants were undertaken in the past 15 years.

Conclusion This is the first study to evaluate current practices and opinions regarding donor milk use in the Republic of Ireland and highlights the necessity to develop a national guideline of evidence-based best practice.

Keywords Donor breast milk · Preterm · Very low birth weight

Introduction

Maternal breast milk is the optimal source of enteral nutrition for preterm and very low birth weight (VLBW) neonates in whom it has been associated with reduced rates of necrotizing enterocolitis (NEC) [1], late-onset sepsis [2], bronchopulmonary dysplasia and also improved neurodevelopmental outcomes [3] when compared with formula feeding.

Use of pasteurised donor human milk (DHM) has been endorsed by The European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN), and the World Health Organisation (WHO) [4] for preterm and low birth weight (LBW) infants respectively where mothers own milk (MOM) is unavailable. This is despite limited comparative data regarding nutritional properties and health outcomes. The need to fortify DHM with exogenous bovine-based protein and other macronutrients has been highlighted in numerous studies [5–7]. Similarly, limited research has been conducted comparing feeding with formula versus nutrient-fortified DHM. Some evidence exists outlining the efficacy of DHM in reducing the incidence and severity of NEC in infants compared to formula [5, 8, 9]. However, studies investigating the use of DHM have not demonstrated a reduction in sepsis, chronic lung disease or indeed a positive impact on neurodevelopmental outcome in VLBW infants [5, 6, 9, 10].

Literature regarding DHM practices in neonatal units is sparse and to date has been limited to the United Kingdom (UK) [11] and USA [12, 13]. In the UK, 60.7% of neonatal units initiated DHM in 2013. In the USA, between 2007 and 2011, there was an 80% increase in DHM use in Neonatal

✉ Michael Joseph O'Grady
michaelogrady@physicians.ie

[1] Department of Paediatrics, Regional Hospital Mullingar, Co. Westmeath, Ireland

[2] Women's and Children's Health, School of Medicine, University College Dublin, Belfield, Dublin 4, Ireland

Intensive Care Units (NICU) (25 to 45%) [14], and this has recently increased further to 59% [12].

The Irish *National Infant Feeding Policy for Maternity and Neonatal Services* [15] states that infants should be fed human milk exclusively for the first 6 months of life, including DHM if MOM is unavailable. It also states that DHM should be available in neonatal units at all times; however, there are no more explicit national or international guidelines governing its use, other than the broad endorsement from WHO, AAP and ESPGHAN. The British Association of Perinatal Medicine (BAPM) has concluded that there is currently inadequate evidence to make firm recommendations regarding DHM use.

The Western Trust Milk Bank, based in Irvinestown, Co. Fermanagh is solely responsible for supplying DHM to neonatal units in Northern Ireland where it is based, but also to the Republic of Ireland. Concerns now exist that following the decision of the UK to leave the European Union that the existing agreement to supply DHM to the Republic of Ireland may be rescinded. Furthermore, data from the milk bank demonstrates that usage of DHM varies significantly between two of the largest tertiary NICUs who cater for very similar numbers of VLBW infants. The Rotunda Hospital and the Coombe Womens and Infants University Hospital were collectively responsible for 47% of DHM use nationally over the past decade, whereas the National Maternity Hospital (NMH), Holles St. which is of similar size and activity accounted for a mere 2%. DHM usage was lower in NMH than in several regional units with lower VLBW infant numbers (Limerick (8.9%), Galway (8.4%) and Waterford (6.4%)). In addition, the volume of DHM used nationally has increased by 315% in the decade from 2006 to 2017. In the context of this variation, we aimed to examine in greater detail the practices and opinions regarding DHM use in neonatal units in the Republic of Ireland.

Materials and methods

Between September and November 2016, we conducted an anonymous cross-sectional postal survey of paediatricians and neonatologists working in each of the 19 neonatal units in the Republic of Ireland (four level 3 (tertiary NICU), four level 2 (regional NICU) and 11 level 1 (Special Care Baby Unit (SCBU)). Eighty-eight eligible participants (25 neonatologists and 63 paediatricians) were identified from the 2016–2017 edition of the *Irish Medical Directory*. As this was an anonymous clinical practice audit of DHM use in Ireland which did not collect personal information, Research Ethics Committee (REC) approval was not required [16], similar to other research studies on this subject [11–13]. Each participant provided expressed consent for participation at the time of survey submission. The proforma consisted of ten items and sought respondent demographics, indications for DHM use, factors limiting its use, presence of a written guideline and the consent process. In addition, respondents were provided with three statements regarding current practice and knowledge of the evidence base for DHM indicating the level of agreement on a Likert scale from one (strongly disagree) to six (strongly agree). These were as follows:

1. In an otherwise healthy, breastfed term infant on the postnatal ward, DHM should be provided in lieu of cow's milk-based formula, in infants requiring supplementation. [True (opinion); *10 Steps to Successful Breastfeeding*]
2. Compared to using formula, provision of DHM to infants requiring supplementation increases long-term breastfeeding rates [False].
3. The majority of the trials supporting the use of DHM to lower NEC risk in preterm VLBW infants have been performed in the past 15 years. [False]

Data were entered on a Microsoft Excel (Microsoft Corp., Redmond, WA) spreadsheet and analysed using descriptive statistics. Comparisons between categorical variables were undertaken using $\chi 2$ and Fishers exact test. Analyses were undertaken using StatsDirect™ (version 2.7.8). A p value < 0.05 was considered statistically significant.

Results

Responses were received from 20 (95%) neonatal units of whom 15 (75%) used DHM. Forty-four (50%) consultants with a median of 22 (11–35) years of experience responded; this included 19 (76%) neonatologists and 25 (36%) paediatricians. Thirty-three (75%) reported using DHM. For units not using DHM, the neonatal population cared for, followed by access to DHM were the main reported barriers to its use. Indications for DHM use are outlined in Table 1.

Nine (60%) units had a written DHM policy. Thirteen units (86%) reported obtaining informed consent prior to the commencement of DHM; however, only four units (26%) obtain written consent. Eighteen units (90%) routinely use breast milk fortifier, eight (44%) of whom obtain informed consent for same.

Regarding the knowledge and opinion statements, 38 (86%) consultants were opposed to the use of DHM for supplementation of otherwise healthy term neonates, including 21 (48%) who strongly disagreed with this practice. Ten (23%) respondents believed that supplementation with DHM compared to formula improves long-term breastfeeding rates. Twenty-two (56%) agreed that the majority of studies supporting the use of DHM to prevent NEC in preterm infants were performed in the past 15 years. There were no significant differences in responses obtained from neonatologists and paediatricians to the knowledge items (questions 2 and 3). Combining responses

Table 1 Absolute and Relative indications for DHM use

	Absolute indications *n* (%)	Relative indications *n* (%)
Gestation		
32–40 weeks	0 (0)	3 (9)
< 32 weeks	8 (24)	9 (27)
< 30 weeks	2 (6)	3 (9)
< 28 weeks	6 (18)	3 (9)
None	17 (48)	15 (45)
Birth weight		
< 1500 g	5 (15)	13 (39)
< 1250 g	5 (15)	1 (3)
< 1000 g	11 (33)	7 (21)
None	12 (36)	12 (36)
Infant co-morbidities		
IUGR	9 (27)	15 (45)
Absent/reversed end diastolic flow	13 (33)	13 (39)
Post-surgical NEC	13 (33)	16 (48)
None	16 (48)	11 (33)
	*2 co-morbidities DHM indicated—*n* = 6	*2 co-morbidities DHM indicated *n* = 6
	*3 co-morbidities DHM indicated—*n* = 6	*3 co-morbidities DHM indicated—*n* = 8
Maternal co-morbidities		
Unwilling to breast feed	1 (3)	5 (15)
Medical co-morbidity	6 (18)	10 (30)
Inadequate supply—18% (*n* = 6)	6 (18)	0 (0)
None	24 (72)	21 (63)
	*2 co-morbidities indicated—*n* = 3	* 2 co-morbidities indicated *n* = 3
	*3 co-morbidities indicated—*n* = 1	

from both questions, there was a trend towards neonatologists being more likely to provide a correct answer to either question that approached significance ($p = 0.07$).

Discussion

This is the first study examining DHM use in Irish neonatal units and with responses from 95% of units and 50% of consultants, provides an accurate representation of current practice. The current practice regarding average duration of feeding with donor milk, recommended volumes of donor milk or indeed methods of weaning to formula or maternal milk if required were not explored in this study.

Our study revealed that 75% of neonatal units and all level 3 NICUs initiated DHM. Zipitis and colleagues reported that 60.7% of UK neonatal units overall and 75% of UK NICUs initiated DHM [11]. In the USA, 59% of level 3 and 4 NICUs recently reported providing DHM [12]. In the US study, participation in the Vermont-Oxford Network (VON) was associated with provision of DHM; all 19 units in our study are VON participants, which may account for the higher proportion of donor milk provision compared to the UK and US cohorts.

In contrast to our study, cost was reported to be the major limiting factor for centres not using DHM in both the UK and USA. Actual donor milk costs are similar in the USA and Ireland (€100 per litre in Ireland, $133/€109 per litre in the USA). While there are studies outlining the cost-effectiveness of DHM on the basis that it reduces medical and surgical NEC and their associated costs [17, 18], the two most recent randomised trials [2, 19] suggest DHM does not reduce NEC rates, which would clearly impact cost-effectiveness.

DHM policies were in place in 96.7% of UK neonatal units and 79% of US NICUs in contrast to just 60% of Irish neonatal units. All Irish level 3 centres had a written policy, compared to just 40% of level 1 or 2 units. Our study highlighted that informed consent prior to commencement of DHM is obtained in 86% of units, similar to the USA, which contrasts with universal consent in UK units. The majority of units in our study use breast milk fortifier in contrast to just 18% of US NICUs. The reasons for this disparity are unclear. Breast milk fortification appears necessary to support growth of preterm

infants and its use does not appear to increase the incidence of NEC [20].

Regarding indications for commencement of DHM, a wide variation in gestational age and birth weight thresholds were noted, as in previous studies. In our study, the majority suggested a gestational age threshold of 32 weeks as an absolute indication for DHM. While multiple studies have examined the benefits of DHM in 'preterm' infants [21, 22], the gestational age at which maximum benefit occurs is often not clearly defined. This variability in practice is consistent with implementation of general recommendations as a result of insufficient evidence to define specific indications. The AAP and the WHO suggest that, if MOM is not available, then DHM should be provided to all preterm LBW infants.

Despite a lack of evidence supporting the use of DHM rather than formula in term infants requiring supplementation on the postnatal ward, 14% of our respondents favoured its use in this scenario, compared to 6% of UK units. A trend towards increasing DHM use in healthy term newborns has also been observed in the USA with rates in one academic centre increasing more than 100-fold (0.04 to 4.7%) over the past 4 years [23]. In the northeast USA, between 29 and 43% of all birth hospitals currently use DHM in healthy newborns [24]. This may reflect its inclusion in the *'10 Steps to Successful Breastfeeding'* [25] and accordingly, US hospitals using DHM in term infants reported higher exclusive breastfeeding rates. This higher rate is however likely to be multifactorial. In our cohort, 23% agreed that DHM use, when compared to formula, improves long-term breastfeeding rates. The study by Belfort et al. [24] found that 83% of respondents agreed or strongly agreed that supplementation with DHM, when indicated, was an effective method of increasing the rate of exclusive breastfeeding. Conversely, a systematic review [26], demonstrated that use of DHM did not significantly alter the rate of exclusive breast milk feeding at discharge or the exclusive provision of MOM in the first month of life. In recent years, the Western Trust Milk Bank has at times, struggled to meet demand. More research needed to understand the repercussions of the practice of DHM supplementation in term infants on resource utilisation as well as short- and long-term breastfeeding and health outcomes.

Over half of consultants surveyed strongly agreed that the majority of the trials supporting the use of DHM to lower NEC risk in preterm VLBW infants have been performed in the past 15 years. Conversely, the majority of the nine trials included in the Cochrane systematic review, which concluded that DHM reduced the risk of NEC in preterm LBW infants were undertaken more than 30 years ago, when practices in neonatal units were very different [5] and survival odds of infants differed significantly. Following results from two more recent randomised trials [2, 19] and a more recent review excluding the older studies [27], the benefits of DHM in preventing NEC are less clear. Most DHM studies included some MOM feedings within a larger human milk pool, with no information about the relative proportions of MOM and DHM received before the onset of NEC. Furthermore, there are a number of observational and retrospective studies suggesting that donor milk use remains protective against NEC development [28–30], but it is important to consider the place of such studies in the hierarchy of evidence compared to randomised controlled trials. There is an excellent recent review regarding DHM outlining the evidence for DHM use and what practices are and are not supported by evidence [31].

There remain many unanswered questions regarding DHM; our results have highlighted a gap in awareness of the current literature among consultants suggesting that enthusiasm for its use may exceed evidence for its benefits and cost-effectiveness.

Conclusion

This is the first study to evaluate current practices and opinions regarding DHM use in the Republic of Ireland, which highlights the necessity to develop a national guideline of evidence-based best practice and supports the need for further high-quality randomised trials to further explore potential benefits of DHM. Many neonatologists and paediatricians appear unaware of the limitations of research supporting the use of donor milk for prevention of necrotising enterocolitis in preterm infants and the vast majority do not agree with donor milk supplementation of term infants as proposed in the 'Ten Steps to Successful Breastfeeding'.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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