Human milk banking

JH Kim, S Unger; Canadian Paediatric Society, Nutrition and Gastroenterology Committee

Canadian Paediatric Society

Français en page 599

JH Kim, S Unger; Canadian Paediatric Society, Nutrition and Gastroenterology Committee. Human milk banking. Paediatr Child Health 2010;15(9):595-598.

It is universally accepted that breast milk is the optimum exclusive source of nutrition for the first six months of life, and may remain part of the healthy infant diet for the first two years of life and beyond. Despite advances in infant formulas, human breast milk provides a bioactive matrix of benefits that cannot be replicated by any other source of nutrition. When the mother's own milk is unavailable for the sick, hospitalized newborn, pasteurized human donor breast milk should be made available as an alternative feeding choice followed by commercial formula. There is a limited supply of donor breast milk in Canada and it should be prioritized to sick, hospitalized neonates who are the most vulnerable and most likely to benefit from exclusive human milk feeding.

Key Words: *Breast milk; Human donor breast milk; Human milk banking; Preterm infant*

JH Kim, S Unger; Société canadienne de pédiatrie, comité de nutrition et de gastroentérologie. Les banques de lait humain

Universellement, il est accepté que le lait humain constitue la source d'alimentation exclusive optimale pendant les six premiers mois de vie et qu'il peut continuer à faire partie du régime alimentaire d'un nourrisson en santé jusqu'à deux ans, et même après. Malgré les progrès des préparations lactées, le lait humain procure une matrice bioactive de bienfaits qui ne peuvent être reproduits par aucune autre source d'alimentation. Lorsque le lait de la mère n'est pas accessible au nouveau-né malade et hospitalisé, le lait humain pasteurisé de donneuses devrait être offert comme possibilité d'alimentation, suivi des préparations lactées. L'approvisionnement de lait de donneuses est limité au Canada et devrait être prioritairement attribué aux nouveau-nés malades et hospitalisés, qui sont les plus vulnérables et les plus susceptibles de profiter de l'alimentation exclusive de lait humain.

It is universally accepted that breast milk is the optimum exclusive source of nutrition for the first six months of life and may remain part of the healthy infant diet for the first two years of life and beyond (1). Human milk is species specific and is, thus, markedly superior to all alternatives for newborn feeding. Although bovine- and plant-based formulas approach the fat, protein and carbohydrate composition of human milk, they are not able to replicate the complexity or functionality of other bioactive factors found in human breast milk. The benefits of human breast milk include optimum growth (2,3), immune function (4-6) and development (7,8) at minimal cost to the family. The unique benefits of human breast milk feeding are seen both in the short and long term, with improved health and development of the child as well as the health of the mother (9,10). This is a great example of how a single nutritional measure can lead to broad health and health cost benefits to society as a whole (11,12). The goal of the present report is to review the benefits of human breast milk in the preterm population as well as the benefits of human donor breast milk when the mother's own milk is inadequate in supply. The benefits of breast milk for healthy term neonates have been extensively reviewed elsewhere.

Benefits of human breast milk for the preterm infant

For ethical reasons, it is not possible to study breast milk versus formula in a randomized fashion. Nevertheless, it has been shown that human breast milk-fed infants in the neonatal intensive care unit (NICU) have fewer severe infections (13-15), less necrotizing enterocolitis (NEC) (16) and a reduction in colonization by pathogenic organisms (17,18).

There is research supporting a decreased length of hospital stay for babies fed expressed human breast milk (19). Importantly, there are also data documenting an improved neurodevelopmental outcome for preterm infants fed breast milk; however, it can be difficult to control for the many risk factors for a poor outcome associated with preterm birth (7,20-22).

DONOR MILK

History of donor milk banking in Canada

The first human milk bank opened in Vienna, Austria, in 1909 (23). Milk banking in North America began in 1919 in Boston, USA. This continued until the 1980s when many banks closed because of the fear of HIV transmission. In Canada, only the Vancouver, British Columbia, milk bank remains and is operational today. This milk bank is not able to meet the needs of all preterm neonates in Canada. With current screening protocols and serological testing, the safety of human milk can again be assured. As such, further milk banking in Canada should be encouraged and promoted. There are currently 11 human donor milk banks in the Human Milk Banking Association of North America (HMBANA) that process more than one million

Correspondence: Canadian Paediatric Society, 2305 St Laurent Boulevard, Ottawa, Ontario K1G 4J8. Telephone 613-526-9397, fax 613-526-3332, websites www.cps.ca, www.caringforkids.cps.ca

ounces of milk every year (24). When new milk banks open, there is significant support from the community, and donor milk has been well received in NICUs (25).

The demand for human donor breast milk

The most critical demand for human donor breast milk is for the most vulnerable neonates who are either preterm or require gastrointestinal surgery as a newborn. There are approximately 350,000 children born in Canada annually, of whom approximately 7% (26) are born preterm. Most of the children's parents wish for their newborns to receive human milk as their nutritional source (26). When a child is born preterm, however, there may be many barriers to these children receiving their mother's milk. There may be physical barriers, with babies transported to hospitals far removed from their mother's location. The mother may not be able to produce an adequate milk supply for her newborn if she is ill herself or under tremendous stress due to having a newborn in an intensive care unit (27). It has been well established that donor breast milk is not only acceptable for these families, but it provides a tremendous relief knowing that their infant can still receive human breast milk (28). It does not remove the incentive for mothers to express their own breast milk. Donor breast milk is increasingly becoming available throughout the world including in the United States, Europe, South America and Australia.

Use of donor breast milk in preterm infants

A systematic review (29,30) comparing donor breast milk with infant formula has recently been published. There were only eight studies that met the criteria for inclusion in the Cochrane review, and only one study (31) compared nutrient-fortified breast milk. There was a reduction in NEC in donor breast milk-fed neonates. The authors concluded, however, that further research was required because most studies did not follow current feeding practices, which may account for the slower growth that was seen in donor breast milk-fed babies. The use of exclusive human breast milk intake that included the mother's breast milk and/or donor human breast milk plus a novel human-based human milk fortifier has been shown to reduce NEC by 63% and surgical NEC by 92% compared with an intake of the mother's milk and a standard bovine fortifier in extremely preterm infants weighing less than 1250 g (32).

Donor breast milk considerations

Donor breast milk must be considered and handled as a human body substance (28). All donors must undergo a rigorous screening process similar to that used for donating blood, which includes an interview, serological screening and physician consent. Serology includes testing for hepatitis B and C as well as HIV and the human T cell leukemia virus. All milk must be properly collected, stored, pasteurized and cultured in accordance with food preparation guidelines as set out by the Canadian Food Inspection Agency.

Using all of the aforementioned safety controls, there has never been a reported case of disease transmission through the use of pasteurized donor breast milk; however, this can never be absolutely assured. Written parental consent must be obtained before prescribing or administering human donor breast milk.

Although there may be a risk of allergic reaction to human donor breast milk, human breast milk is species specific and, thus, the risk is not higher than the alternative – formula feeding.

Milk banking process

Milk processing in North America follows guidelines set out by the HMBANA (28). Processing of human breast milk in Canada must also adhere to Health Canada regulations for food substances and must be inspected regularly by the Canadian Food Inspection Agency.

All member banks of the HMBANA are not for profit and supply milk to NICUs on a cost-recovery basis. Each free-standing milk bank must have a medical director and a governing board that includes physicians, dieticians, lactation consultants, nursing and infection control representatives. This board must meet regularly to review milk banking processes and policies. The daily operation of the milk bank is under the governance of lactation consultants. They may also employ dietary technicians and clerical support staff.

All donor mothers donate their milk for altruistic reasons. All mothers must undergo rigorous screening before donation including an interview, medical approval and serology, which must be repeated every six months. Mothers are not accepted if they are taking medications, smoke or drink. They are temporarily excluded during periods of over-the-counter medication use. Once accepted as a donor, a mother is taught the techniques for safe collection and storage of her milk. She may express one extra feeding or multiple feeds per day, as in the case of a bereaved mother, to donate to the milk bank. This milk is then frozen, stored and transported to the milk bank.

At the milk bank, the milk is batched from up to four different mothers to blend constituent variations. The milk is then thawed, and a bacterial culture is taken. The milk then undergoes Holder pasteurization (62.5°C for 30 min) in an industrial grade pasteurizer, and is recultured. Any milk that is culture positive for any pathogen or for greater than 10^4 colony-forming units/mL of skin flora before pasteurization or any positive culture after pasteurization is discarded. The milk is again frozen while awaiting final culture results. When an order for human milk is received at the milk bank, the milk is transported, thawed and dispensed as required.

According to the HMBANA guidelines, pasteurized human donor breast milk should only be dispensed following written informed consent from a parent or guardian, and a written prescription from the medical provider. It may be prescribed for a variety of medical conditions such as preterm birth, gastrointestinal surgery, malabsorption or feeding intolerance, and immunodeficiency.

Effects of pasteurization on human breast milk

The process of pasteurizing human breast milk inactivates bacterial and viral contaminants such as cytomegalovirus (33-35).

Spore-forming *Bacillus* species are known to survive routine Holder pasteurization but, unlike cow's milk, this is a rare contaminant of human breast milk and is detectable from the surveillance cultures performed before and after pasteurization (36). Despite viral inactivation, women are only accepted as donors if they are seronegative for hepatitis B and C, human T cell leukemia virus and HIV.

Many of the nutritional components are not altered or only minimally reduced in content through the process of pasteurization (37). Carbohydrates, fats and salts are unchanged. Thirteen per cent of the protein content is denatured. Fat-soluble vitamins are unchanged. While not all of the water-soluble vitamins have been studied, some have been shown to degrade following pasteurization (38,39).

There are effects on immunological factors (40). Along with inactivation of all viruses and most bacteria through pasteurization, all beneficial immune cells are also inactivated. Secretory immunoglobulin (Ig) A, which binds microbes within the digestive tract, is found at 67% to 100% of its original activity. Targeted IgG antibodies are reduced at 66% to 70%. IgM antibodies are completely removed. Lactoferrin, which binds iron required by many bacteria, thus reducing their growth, is reduced to 20% (41) of its original level. Lysozyme enzyme, which attacks bacterial cell walls, drops to 75% activity. A reduction in certain cytokines by pasteurization permits an expanded function of epidermal growth factor, which may lead to increased growth of intestinal epithelial cells exposed to pasteurized human donor breast milk (42).

Cost effectiveness

The full financial impact of promoting breastfeeding and using human donor breast milk in the NICU is difficult to measure. There have been no Canadian studies or data published on the economic evaluation of donor breast milk, and this is an area in which research is required. The processing cost of donor breast milk is modest in comparison with the cost of managing a single case of NEC or short bowel syndrome secondary to NEC. Therefore, even a small reduction in gastrointestinal complications with increased human breast milk use could recover operation costs of milk banking (43). There is evidence supporting the cost effectiveness of using donor human breast milk by reducing the length of stay, sepsis and NEC in sick hospitalized neonates (44).

A collateral benefit could be that donor milk banks may heighten breastfeeding awareness in the community at large, thus, conferring wider benefits to the population as a whole.

PARENTAL CHOICE

In this era of informed consent, it is of utmost importance for parents to be fully informed of all treatment options available for their children. Parents must thus be made aware of the possibility for their children to receive human donor breast milk along with all of the perceived benefits and potential risks. They must also be made aware of the health advantages of human breast milk compared with bovine milk. They may then make an informed decision as to the best feeding plan for their baby. Written informed consent from parents/guardians must always be obtained before the administration of human donor breast milk.

FUTURE CONSIDERATIONS

Human breast milk must remain an important area of research for the benefit of our most vulnerable NICU patients. Active areas of research include benefits to the preterm population, effects of pasteurization, nutritional analysis and economic impact.

RECOMMENDATIONS

- The preferred nutrition for the newborn is his/her own mother's milk. When this is not available or is limited, pasteurized human donor breast milk is a recommended alternative for hospitalized neonates.
- The use of pasteurized human donor breast milk should be prioritized to compromised preterm infants and selected ill term newborns.
- Pasteurized human donor breast milk should only be prescribed following written informed consent from a parent or guardian.
- Education of parents about the benefits of human breast milk or pasteurized human donor breast milk is essential to parental choice and informed decision making in prescribing an optimal feeding plan for hospitalized neonates.
- Milk banking should be adopted as a cost-effective nutritional source for hospitalized neonates because it reduces disease incidence and severity, thus reducing resource use during the hospitalization.
- Recognized functions of the human milk bank should include the promotion of breastfeeding and ongoing human milk research.
- There is a need for prospective studies to evaluate the benefits of banked human breast milk in preterm infants in the NICU.
- The Canadian Paediatric Society does not endorse the sharing of unprocessed human milk.

ACKNOWLEDGEMENTS: The authors thank Ms Debbie Stone RN IBCLC, Department of Clinical Dietetics, The Hospital for Sick Children (Toronto, Ontario), for her assistance in researching and editing the present article. The Canadian Paediatric Society's following committees reviewed this position statement: Bioethics, Fetus and Newborn, Infectious Diseases and Immunization.

REFERENCES

1. Boland MC, Canadian Paediatric Society, Nutrition Committee. Exclusive breastfeeding should continue to six months. Paediatr Child Health 2005;10:148.
2. O'Connor DL, Jacobs J, Hall R, et al. Growth and development of premature infants fed predominantly human milk, predominantly premature infant formula, or a combination of human milk and premature formula. J Pediatr Gastroenterol Nutr 2003;37:437-46.

3. The WHO Child Growth Standards. World Health Organization. <http://www.who.int/childgrowth/en/> (Accessed on September 14, 2010).
4. Beaudry M, Dufour R, Marcoux S. Relation between infant feeding and infections during the first six months of life. J Pediatr 1995;126:191-7.
5. Bhandari N, Bahl R, Mazumdar S, Martines J, Black RE, Bhan MK. Effect of community-based promotion of exclusive breastfeeding on diarrhoeal illness and growth: A cluster randomised controlled trial. Lancet 2003;361:1418-23.
6. Oddy WH, Sly PD, de Klerk NH, et al. Breast feeding and respiratory morbidity in infancy: A birth cohort study. Arch Dis Child 2003;88:224-8.
7. Lucas A, Morley R, Cole TJ, Lister G, Leeson-Payne C. Breast milk and subsequent intelligence quotient in children born preterm. Lancet 1992;339:261-4.
8. Mortensen EL, Michaelsen KF, Sanders SA, Reinisch JM. The association between duration of breastfeeding and adult intelligence. JAMA 2002;287:2365-71.
9. Newcomb PA, Storer BE, Longnecker MP, et al. Lactation and a reduced risk of premenopausal breast cancer. N Engl J Med 1994;330:81-7.
10. Rosenblatt KA, Thomas DB. Lactation and the risk of epithelial ovarian cancer. The WHO Collaborative Study of Neoplasia and Steroid Contraceptives. Int J Epidemiol 1993;22:192-7.
11. Riordan JM. The cost of not breastfeeding: A commentary. J Hum Lact 1997;13:93-7.
12. Ball TM, Wright AL. Health care costs of formula-feeding in the first year of life. Pediatrics 1999;103:870-6.
13. Hylander MA, Strobino DM, Dhanireddy R. Human milk feedings and infection among very low birth weight infants. Pediatrics 1998;102:E38.
14. el-Mohandes AE, Picard MB, Simmens SJ, Keiser JF. Use of human milk in the intensive care nursery decreases the incidence of nosocomial sepsis. J Perinatol 1997;17:130-4.
15. Narayanan I, Prakash K, Bala S, Verma RK, Gujral VV. Partial supplementation with expressed breast-milk for prevention of infection in low-birth-weight infants. Lancet 1980;2:561-3.
16. Lucas A, Cole TJ. Breast milk and neonatal necrotising enterocolitis. Lancet 1990;336:1519-23.
17. Yoshioka H, Iseki K, Fujita K. Development and differences of intestinal flora in the neonatal period in breast-fed and bottle-fed infants. Pediatrics 1983;72:317-21.
18. Claud EC, Walker WA. Hypothesis: Inappropriate colonization of the premature intestine can cause neonatal necrotizing enterocolitis. Faseb J 2001;15:1398-403.
19. Schanler RJ, Shulman RJ, Lau C. Feeding strategies for premature infants: Beneficial outcomes of feeding fortified human milk versus preterm formula. Pediatrics 1999;103:1150-7.
20. Vohr BR, Poindexter BB, Dusick AM, et al. Persistent beneficial effects of breast milk ingested in the neonatal intensive care unit on outcomes of extremely low birth weight infants at 30 months of age. Pediatrics 2007;120:e953-e959.
21. Furman L, Wilson-Costello D, Friedman H, Taylor HG, Minich N, Hack M. The effect of neonatal maternal milk feeding on the neurodevelopmental outcome of very low birth weight infants. J Dev Behav Pediatr 2004;25:247-53.
22. Lucas A, Morley R, Cole TJ. Randomised trial of early diet in preterm babies and later intelligence quotient. BMJ 1998;317:1481-7.
23. Jones F. History of North American donor milk banking: One hundred years of progress. J Hum Lact 2003;19:313-8.
24. Human Milk Banking Association of North America. <www.hmbana.org> (Accessed on September 14, 2010).
25. Simmer K, Hartmann B. The knowns and unknowns of human milk banking. Early Hum Dev 2009;85:701-4.
26. Canadian Perinatal Health Report. In: Public Health Agency of Canada, 2003.
27. Henderson JJ, Hartmann PE, Newnham JP, Simmer K. Effect of preterm birth and antenatal corticosteroid treatment on lactogenesis II in women. Pediatrics 2008;121:e92-e100.
28. 2007 Guidelines for the Establishment and Operation of a Donor Human Milk Bank. Raleigh, 2007.
29. Boyd CA, Quigley MA, Brocklehurst P. Donor breast milk versus infant formula for preterm infants: Systematic review and meta-analysis. Arch Dis Child Fetal Neonatal Ed 2007;92:F169-75.
30. Quigley MA, Henderson G, Anthony MY, McGuire W. Formula milk versus donor breast milk for feeding preterm or low birth weight infants. Cochrane Database Syst Rev 2007:CD002971.
31. Schanler RJ, Lau C, Hurst NM, Smith EO. Randomized trial of donor human milk versus preterm formula as substitutes for mothers' own milk in the feeding of extremely premature infants. Pediatrics 2005;116:400-6.
32. Sullivan S, Schanler RJ, Kim JH, et al. An exclusively human milk-based diet is associated with a lower rate of necrotizing enterocolitis than a diet of human milk and bovine milk-based products. J Pediatr 2010;156:562-7.e1.
33. Friis H, Andersen HK. Rate of inactivation of cytomegalovirus in raw banked milk during storage at –20 degrees C and pasteurisation. BMJ 1982;285:1604-5.
34. Yamato K, Taguchi H, Yoshimoto S, et al. Inactivation of lymphocyte-transforming activity of human T-cell leukemia virus type I by heat. Jpn J Cancer Res 1986;77:13-5.
35. Orloff SL, Wallingford JC, McDougal JS. Inactivation of human immunodeficiency virus type I in human milk: Effects of intrinsic factors in human milk and of pasteurization. J Hum Lact 1993;9:13-7.
36. Crielly EM, Logan NA, Anderton A. Studies on the *Bacillus* flora of milk and milk products. J Appl Bacteriol 1994;77:256-63.
37. Tully DB, Jones F, Tully MR. Donor milk: What's in it and what's not. J Hum Lact 2001;17:152-5.
38. Donnelly V, O'Connor DL, Shoukri M. Impact of pasteurization and procedures commonly used to rethermalize stored human milk on folate content. Nutr Res 1994;14:1305-16.
39. Van Zoeren-Grobben D, Schrijver J, Van den Berg H, Berger HM. Human milk vitamin content after pasteurisation, storage, or tube feeding. Arch Dis Child 1987;62:161-5.
40. Lawrence RA. Milk banking: The influence of storage procedures and subsequent processing on immunologic components of human milk. Adv Nutr Res 2001;10:389-404.
41. Czank C, Prime DK, Hartmann B, Simmer K, Hartmenn PE. Retention of the immunological proteins of pasteurized human milk in relation to pasteurizer design and practice. Pediatr Res 2009;66:374-9.
42. McPherson RJ, Wagner CL. The effect of pasteurization on transforming growth factor alpha and transforming growth factor beta 2 concentrations in human milk. Adv Exp Med Biol 2001;501:559-66.
43. Bisquera JA, Cooper TR, Berseth CL. Impact of necrotizing enterocolitis on length of stay and hospital charges in very low birth weight infants. Pediatrics 2002;109:423-8.
44. Wight NE. Donor human milk for preterm infants. J Perinatol 2001;21:249-54.

NUTRITION AND GASTROENTEROLOGY COMMITTEE

Members: *Drs Jeffrey Critch, St John's, Newfoundland and Labrador; Manjula Gowrishankar, Edmonton, Alberta; Jae Hong Kim, San Diego, California; Valerie Marchand, Montreal, Quebec (chair); Sharon Unger, Toronto, Ontario; Robin C Williams, Thorold, Ontario (board representative)*

Liaisons : *Ms Genevieve Courant, Sudbury, Ontario (Breast Feeding Committee for Canada); Dr A George F Davidson, Vancouver, British Columbia (Human Milk Banking Association); Ms Tanis Fenton, Calgary, Alberta (Dietitians of Canada); Dr Frank R Greer, Madison, Wisconsin (American Academy of Pediatrics); Ms Jennifer McCrea, Ottawa, Ontario (Health Canada); Ms Eunice Misskey, Regina, Saskatchewan (Dieticians of Canada); Ms Christina Zehaluk, Ottawa, Ontario (Bureau of Nutritional Sciences, Health Canada)*

Principal Authors: *Drs Jae Hong Kim, San Diego, California; Sharon Unger, Toronto, Ontario*