

NUTRITION Conceptual paper

The Operation and Data of the First Human Milk Bank in Mainland China

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Abstract

Background: Human milk banks have been in existence for over 100 years, based on guidelines for operation established in North America and Europe. In mainland China, the first nonprofit human milk bank was established in 2013.

Objective: To describe and review the operation of the first human milk bank in mainland China, based on a survey of attitudes and an assessment of the collection, use, and benefits of donor milk for the nourishment of ill and hospitalized children.

Methods: In 2012, prior to the opening of the milk bank, a questionnaire was administered to 360 pregnant and postpartum women to obtain information about attitudes towards human milk donation; human milk bank was operated according to the guidelines of the Human Milk Banking Association of North America and the European Milk Bank Association, modified to meet needs and circumstances in China.

Results: Results of the questionnaire indicated a low level of willingness among women in China to donate breast milk (25% positive response) or to accept donor milk for a critically ill child in need (8% positive response). During one and half year of operation, we collected a total of 422 L passed breast milk from 396 eligible donors, and administered the milk to 103 sick inpatient children including preterm infants and malnourished children.

Conclusions: The lactation women in China should be educated to know the benefits of human milk donation and use. The development and sustainability of human milk banks in mainland China require proper management, establishment of national guidelines, support of appropriate authorities, and financial investment by the government.

Keywords: Human milk banking; Breast milk; Donor milk; Breast feeding

Background

The first human milk bank (HMB) was established in Austria over a century ago. Today, there are 203 active milk banks and 13 planned milk banks in the USA and Europe proving donor milk for ill and preterm infants. This growth has been stimulated by evidence showing the clinical benefits of donor human milk (DHM) for preterm infants. Guidelines for the operation of milk banks were created by the Human Milk Banking Association of North America (HMBANA) and the European Milk Bank Association (EMBA). The Committee on Nutrition of the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) recommends the use of DHM in preterm babies in neonatal intensive care units (NICUs). However, HMBs was a novel concept in China when the first opened in March, 2013. This article is a description of our milk banking practices and experiences with donor screening and processing, as well as difficulties encountered. Questionnaire survey on milk donation, current situation and misunderstanding of breast feeding in China

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During November and December 2012, we conducted a survey about milk donation among 360 pregnant and postpartum women at the Departments of Obstetrics and Neonatology and at the outpatient clinic of our medical center. The first question was: Do you want to donate extra milk? The second question was: Are you willing to accept donor milk if your baby is critically ill and you have not enough breast milk yourself? Only 91 (25.28%) and 29 (8.06%) said yes to these questions, respectively.

Why the result was so frustrating? Maybe we should speculate on the reasons for this trepidation. First, the breastfeeding rate is comparatively low in China. China experienced a rapid decline in the prevalence of breastfeeding in the late 1970s when infant formula became readily available. Since the early 1990s, the Chinese Government has introduced the 'Baby Friendly Hospital Initiative' together with regulations on the marketing of infant formula. As a result, the breastfeeding rate appears to be increasing, with several studies reporting greater than 90% breast feeding at hospital discharge [1-3]. Unfortunately, the rate of exclusive breastfeeding declines rapidly thereafter. For example, a study from rural western China reported exclusive breastfeeding rates of only 16.0% at 4 months and 2.5% at 6 months [4]. Furthermore, an earlier study from Sinkiang found that the mean duration of 'any breastfeeding' was only 5 months and a more recent estimate of the average exclusive breastfeeding duration was less than 3 months [5,6]. These studies indicate that the breastfeeding rate in China was far below the target of 80% "exclusive breastfeeding to 4 months" proposed by the Chinese Children's Development Plan [7] and below the goal recommended by the World Health Organization (WHO) of "exclusive breastfeeding for 6 months" [8]. Multiple factors affect breastfeeding rates, including demographics, attitudes and social support, socioeconomic status, parents' educational backgrounds, and high cesarean section rates.

Second, there are still many misconceptions about the benefits of breastfeeding both in the general population and among healthcare professionals. In China, the one-child policy, the increasing rate of infertility, the rising costs of childcare, and the Chinese cultural norm of caring for grandparents, may result in "overprotection" and consequent suspicion of HMB safety. Grandparents from rural areas with low education may believe the superstition that the baby will inherit the physical, mental, and emotional traits of the donor through the donor milk, and/or may doubt whether the donor milk is clean. On the other hand, potential donors may worry that there would not be enough milk left for their own baby after donation.

The state of knowledge among health-care professionals was also less than satisfactory even in the neonatology department or NICU. A multi-center study of preterm infant nutritional status in China involving 974 cases showed that the median time to initial enteral feeding was 2.0 days, with 77.0% of premature infants fed special formulae for low birth weight, while only 13.6% were fed human milk mixed with formula, and very few received breast milk exclusively. In this cohort, 60.0% had extra uterine growth retardation (EUGR) of weight, 58.9% of length, and 29.5% of head circumference at the time of discharge, while the rates of intrauterine growth retardation (IUGR) at birth were only 27.3%, 28% and 19.3%, respectively [9]. These data from the 10 best tertiary NICUs in China suggested that the general nutritional status of preterm infants in NICUs throughout China was not optimal and that there were great variations in clinical practice. Most neonatologists were aware that improvements in early life nutritional practices for premature infants could enhance growth and nutritional status during hospitalization [10,11], but the majority of pediatricians paid closer attention to respiratory treatment, rescue measures, and total parenteral nutrition while ignoring the importance of enteral nutrition [12]. Some even thought that formula was much better than human milk, a possible result of infant formula advertisements ubiquitous in China.

Operation of our human milk bank

The first human milk bank in mainland China was operated in Guangzhou in 2013, according to the guidelines of the Human Milk Banking Association of North America(HMBANA) and the European Milk Bank Association(EMBA) as below, modified to meet needs and circumstances in China.

Basic facilities: The milk bank consists of 4 functional areas: a reception room, donor milk expression room, pasteurization room, and milk storage rooms. The following equipment was installed: a hospital-level Medela Electric Breast Pump, water bath (Thermo), a milk

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composition analyzer (Miris), refrigerators, and One-Day Pump Sets for each donor. One senior nurse works all day collecting and processing donor milk.

Donor screening: All donors are screened verbally for health history and sign an informed consent form stating that they are donating their breast milk voluntarily and without compensation and promise not to interfere in the use and distribution of the donor milk. The donor inclusion criteria are (1) in good physical and psychological health, (2) no tobacco, illegal drug, or excessive alcohol use, (3) not regularly using medication or herbal supplements, (4) have not received organ or tissue transplant or blood transfusion in the past 12 months, (5) negative for HIV, hepatitis B and C, CMV, and syphilis, (6) mother of a healthy growing infant without any congenital diseases or genetic diseases, (7) promising not to deprive her infant nutritionally and only to donate extra breast milk, and (8) willing to donate at least 100 ml of milk per day at least 3 times.

The beneficiaries of DHM were hospitalized with the following conditions: (1) premature delivery or low birth weight, (2) cow's milk protein allergy (CMPA) with malnutrition or nutritional risk, (3) feeding/formula intolerance, (4) immunologic deficiency post-transplantation, post-radiotherapy, or during chemotherapy for various malignancies, (5) requiring nutritional support after a major operation (e.g., for congenital heart disease, necrotizing enterocolitis, intestinal atresia), (6) serious infectious diseases such as sepsis or severe pneumonia, and (7) inborn errors of metabolism.

Basic operating procedures

Collection and processing

- a. Cleaning the donor's breast by the trained nurse working in the milk bank.
- b. Collecting the donor milk by the nurse with the One-Day Pump Set through the electric breast pump in the milk expression room.
- c. Labeling each bottle of milk after collection, including the donor's serial number and name, date of collection, and milk volume (ml).
- d. Bacteriologic screening by microbiology laboratory twice: pre-pasteurization and post-pasteurization.
- e. Pasteurizing the milk soon after collection (Holder method, 30 min at 62.5°C).
- f. Re-labeling the bottles to include date of pasteurization, heat treatment, and time.
- g. Rapidly cooling the milk to 4°C or lower within 10 minutes after pasteurization.
- h. Storage of milk at -20°C for no longer than 6 months from date of expression.

Donor milk use procedure

- a. Nutritional assessments and consultation: The clinical specialist completes the primary nutritional assessment of the inpatient child, and then plans ongoing nutrition consultation.
- b. Re-assessment by the clinical nutritionist to ensure that the patient meets the recipient conditions.
- c. Signing of an informed consent form for use of donor milk at no cost by the patient's parent or other caretaker.
- d. Thawing of milk: Milk is usually thawed in a refrigerator or using warm water (less than 37°C) under sterile conditions.
- e. Sent to the ward by nutritionist and refrigerated at 4-8°C.
- f. Inform the parent or caretaker how to use the milk and the ward nurse how to store and manage the milk
- g. Daily monitoring by the specialist and nutritionist.
- h. Completing records including the recipient name, sex, age, hospital number, diagnosis, date of milk use, feeding options, amount used, feeding tolerance, and the batch number of donor milk.

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Administration

- a. Standards of practice: refer to the guidelines of HMBANA and EMBA
- b. Management team: The team is made up of one director of the hospital, one obstetrician, two neonatologists, and three nutrition ists, one director of the microbiology laboratory, two senior nurses, and one chief member of the infection control office.
- c. All milk must be expressed and collected by an experienced nurse at the HMB (milk collected at home and frozen is refused).
- d. Regular monitoring of freezer temperatures, pasteurization processes, and stock control.
- e. All the containers used are disposable aseptic packaging.
- f. Free donation and free use: totally nonprofit and hospital-based.
- g. Financial support: most comes from the hospital, including the donor blood tests, bacteriologic screening of milk, HMB nurse's salary and the related equipments.
- h. Milk bank fund: donated by community members and only used to buy the containers.

Data of this one and half year from the first human milk in mainland China

From March 2013 to December 2014, a total of 396 eligible donors from 428 lactating women passed the questionnaire screen and blood tests (Table 1 below). They donated a total of 422 L of passed milk out of 494 L (mean 1.15 L/donor). One third of the donors came to donate only once, the rest of them donated twice or more. During this period, one woman donated as often as 326 times with 136 L in total. Some women could easily donate 650 ml in one sitting. During this period, 103 critically ill inpatient children became the recipients including preterm infants or low birth weight (42 cases, 40.8%), postoperative malnutrition of intestinal congenital malformation (23 cases, 22.3%), serious infections including severe pneumonia and sepsis (16 cases, 15.5%), post-chemotherapy complications of hematological malignancies (12 cases, 11.7%), and severe malnutrition caused by other diseases such as cleft palate and congenital heart disease (10 cases, 9.7%). Most recipients received donor milk from the HMB for short durations (2-3 weeks). The minimum age of the recipients was 24 hours and the maximum age was 10 years.

Discussion

The benefits of breast milk are well known, optimal nutrition, easy digestibility, and immunologic protection for infants, as well as improved nutritional, psychological, and cardiovascular health and cognitive abilities in later life. In addition, human milk contains growth factors that can protect immature tissues, promote maturation, particularly of the gastrointestinal tract, and promote healing of damaged tissues. Since the introduction of donor milk, many studies have demonstrated the clinical efficacy for preterm infants. The guidelines for milk banks were created by the AAP, HMBANA, and EMBA (Arnold, 2000; Tully, 2001). Our milk bank, the first in mainland China, follows the guidelines of other successfully operated HMBs in North America and Europe, with many modifications for China as discussed below.

Milk expressed at home is refused

All donors must come to our milk bank and their milk must be collected by the trained full-time nurse using the One-time & One-Day Pump Set. We refuse all frozen milk collected at home. Therefore, the amount of donor milk is limited and we can collect only 500-700 ml per day on average, which cannot possibly satisfy the needs of 80-100 preterm infants in the 3 NICUs of our medical centre. However, we must refuse milk collected at home due to the bad medical environment in China. Medical disputes have increased in recent years, with growing tensions between doctors and patients that have even resulted in attempts to hurt or kill doctors by patients dissatisfied with curative effects [13,14]. As a result, the basic trust between doctor and patient has been damaged. Consequently, medical staff must protect themselves from liability as much as possible (for example by studious application of informed consent) [15]. When the medical situation in China normalizes, we expect to collect as much donor milk as in North America and Europe using a mobile community collection facility.

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General Information	n	%
Donors		
Total donors	428	
Eligible donors	396	92.5
Times of donation		
Total	2340	
Only once	136 donors	
More than twice	160 donors	
Max times by a donor	326	
Amount of donor milk		
Total	494 L	
Passed milk	422 L	85.4
Max amount by one donor	136L	
Minimum per time	80 ml	
Maximum per time	670 ml	
Recipients		
Total	103	
Preterm infants/low birth weight	42	40.8
Postoperative malnutrition	23	22.3
Serious infections	16	15.5
Post-chemotherapy complications	12	11.7
Other severe malnutrition	10	9.7

Table 1: One and half years' data of the first HMB in main land China.

Donor milk is not pooled

We pasteurize and store each donor's milk separately, then try to give the same donor's milk to the same recipient with regular monitoring of feeding tolerance, nutritional status, and prognosis by the doctor specializing in clinical nutrition. Why? First, the onechild policy has made mother and baby the center of the family. New mothers are pressured to eat and drink products believed to enhance milk secretion and maintain milk quality, especially during the traditional month-long postpartum convalescence. On the other hand, China is composed of 56 nationalities with unique diets, cooking methods, eating habits, and lifestyles. One result of these dietary differences is variable milk composition (manuscript in preparation). Therefore, we attempt to match donor milk with recipient by considering donor age, the month postpartum, and the ideal milk composition for that recipient.

Participation of the media

Before the opening of our donor milk bank, we conducted a questionnaire to assess the willingness of expectant and new mothers to donate milk or use donated milk, with discouraging results. Fortunately, the first donor was a famous radio host in Guangdong province who was trying to promote breastfeeding in China after she became a mother. This led to coverage from local television stations, radio stations, network media, newspapers, and magazines, which brought our donor milk bank to the attention of many mothers wishing to donate, including mothers from areas far from our medical centre. Meanwhile, we raised a special fund called 'Breast Milk Loving Fund' with money given by local people, and organized a group of volunteers from among the donors and some media workers. The stature of the first milk bank in mainland China was further expanded by public lectures, photograph exhibitions, and charity sales. Now, many

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many people know about milk banking in mainland China and its benefits. In brief, our current success depended on the active participation of the media and the publicity it provided.

Remaining challenges and future questions

The HMB in mainland China has run more smoothly than expected given the results of the questionnaire survey, but there are still many challenges.

- a. The number of donors and the amount of donor milk are still limited.
- b. More people need to be made aware of the benefits of breastfeeding and the value of donor human milk in China.
- c. Financial shortages: The cost of operating our HMB is high, mostly because of charges by our medical center for serological screening, but also from the purchase of electric breast pumps, milk processing fees, bacteriological testing, and the nurse's salary. The Breast Milk Loving Fund was limited to 380,000 RMB, which could only be used to buy the expensive One-time & One-Day Pump Sets. Moreover, the donor milk is totally free for all recipients in our hospital, so we worry how long our HMB can continue operation without strong financial support.
- d. There was an urgent need for national guidelines from an accredited national academic society. The Chinese Association of Milk Banking was formed to ensure that the donor milk bank operates according to the best standards of practice. There are many blood banks, cord blood banks, and sperm banks in China, each with strict and standard regulations from state and local governments. Human milk banks are new to China and there are currently only two on the mainland. We plan to prepare preliminary Chinese guidelines similar to those in the US and Europe to optimize the functioning of the existing HMBs and to list the essential requirements in order to unify organization, management, and procedures, as we expect to see the establishment of more HMBs in the future.
- e. The benefits of human milk for nourishing preterm infants have been demonstrated unequivocally over the years. Occasionally, donor human milk has also been used to treat illnesses in older children or even in adults, such as cystic fibrosis, failure to thrive, congenital anomalies, necrotizing enterocolitis, immune deficiency, cardiac postoperative therapy, and cancer [16,17]. Similarly, we have seen substantial short-term clinical and lifesaving effects of donor milk in infants and children, especially in children with postoperative intestinal problems, results not easily explained by traditional nutritional knowledge. Obviously, future studies should address the mechanisms for these benefits.

Conclusion

The lactation women in China should be educated to know the benefits of human milk donation and use. The first human donor milk bank was set up one and half year ago in China following the guidelines of the HMBANA and EMBA, but adapted to the Chinese context. The donated milk is pumped only in the milk bank with assistance by a trained nurse and we refuse to accept donations expressed outside the HMB. We pasteurize and store each donor's milk separately and give the recipient milk from the same donor as often as possible. At the same time, we provide each recipient an individualized feeding strategy through milk composition analysis. The recipients use the donor milk totally free of charge, although the cost of operating the milk bank is very high. Donor human milk could provide the best food for the preterm infants and other seriously sick children. The development and sustainability of human milk bank in mainland China needs national guideline, proper management and financial support by the government and authorities or academic societies.

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