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Comparison of two methods for cleaning breast pump milk collection kits in human milk banks

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SUMMARY

Background: Appropriate decontamination of breast pump milk collection kits (BPKs) is critical to obtain safe milk for infants and to avoid discarding donor human milk (DHM).
Aim: To evaluate two strategies for BPK decontamination by assessing microbial cultures and the proportion of discarded DHM, according to the criteria of the National Institute for Health and Care Excellence for pre-pasteurization cultures.
Methods: Prospective comparative study, allocation ratio 1:1, microbiologist-blind.
Participants: 47 new donors in a human milk bank in Madrid.
Interventions: Study group (N=21): BPKs washed with water and detergent after each use and further steam decontamination within a microwavable bag. Control group (N=26): washing, rinsing and drying only. Five samples: first sample by hand expression and four samples (one per week) collected using the same pump and method.
Outcomes: Primary: proportion of DHM discarded due to contamination. Secondary: comparison of the microbiota between samples obtained by hand expression and breast pump in both groups.
Findings: In total, 217 milk samples were collected: 47 by hand expression and 170 by pump expression (78 from study group). Steam decontamination of BPKs using a microwavable bag after washing resulted in a lower proportion of discarded DHM samples (1.3% vs 18.5%, P<0.001) and samples contaminated with Enterobacteriaceae (1.3% vs 22.8%, P<0.001) and *Candida* spp. (1.3% vs 14.1%, P<0.05) compared with samples collected with BPKs that were washed but not steam decontaminated. There were no differences in bacterial contamination between samples obtained using steam decontaminated BPKs and those obtained by hand expression.
Conclusions: Steam decontamination of BPKs using a microwavable bag after washing decreases the amount of discarded DHM and the number of samples with potentially pathogenic bacteria.
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Introduction

The use of breast pumps is very common in neonatal intensive care units and human milk banks. However, breast pumps may be a potential route for the transmission of infectious diseases. As such, breast pump milk collection kits (BPKs) should be cleaned carefully before each use [1–3]. Most human milk banks include a pre-pasteurization milk culture in their methods. If donor human milk (DHM) is highly contaminated, it is discarded. The National Institute for Health and Care Excellence (NICE) guidelines recommend discarding milk if the pre-pasteurization sample has a total microbial count exceeding 10^5 colony-forming units (cfu)/mL, or 10^4 cfu/mL for Enterobacteriaceae or *Staphylococcus aureus* [4].

Therefore, it is essential for BPKs to be decontaminated appropriately. Benefits and drawbacks of each decontamination method have been published [5]. However, there is a lack of scientific evidence to determine which method is most effective. Most guidelines recommend washing with detergent followed by thorough rinsing and drying after each use [2,6,7]. The US Centers for Disease Control and Prevention (CDC) has recently issued updated guidelines following an unfortunate case of a preterm infant who suffered from meningitis by *Cronobacter sakazakii*, transmitted from expressed breast milk (EBM) obtained with a contaminated breast pump [3]. CDC now recommends using an additional decontamination method, particularly for highly susceptible infants such as premature babies, children under 3 months of age or those with immunodeficiency [7].

In order to collect relevant information, which may allow the establishment of evidence-based recommendations, and to facilitate the expression process for donors as much as possible, a prospective comparative study was conducted in human milk donors. The objective was to evaluate two different BPK cleaning strategies (washing, rinsing and drying vs washing and steam decontamination) according to the results of milk microbial cultures and the proportion of discarded DHM. DHM was discarded according to the criteria defined in the NICE guideline for pre-pasteurization cultures.

Methods

Following a pilot study in 2015, a prospective randomized comparative study was conducted in the human milk bank in Madrid from February 2016 to June 2017.

Participants

Women who were starting a new episode of human milk donation.

Inclusion criteria

- Using or willing to use their own breast pump, without sharing it with any other woman. If the donor did not carry her own breast pump, or if it had been borrowed, the human milk bank would lend her a pump and a sterilized collection kit.
- Willing to provide a sample of breast milk by hand expression.
- Able to understand verbal and written instructions in Spanish.

Exclusion criteria

- An episode of mastitis any time before or during the study period.
- Receipt of antibiotic treatment during the study period or during the preceding three months.
- Did not meet inclusion criteria.

Intervention

Once informed consent was signed, new donors were assigned at random to one of the following groups:

- Study group: milk collection kit washed in water with detergent, rinsed and dried thoroughly after each use, followed by an additional steam decontamination step in a microwaveable bag once per day.
- Control group: milk collection kit washed in water with detergent, rinsed and dried thoroughly after each use.

All donors were individually instructed by the same nurse, during a face-to-face interview, ensuring good understanding. The instructions provided were the same for all donors, except for the additional intervention in the study group. Additionally, each milk donor was given an information leaflet containing written instructions (Table SI, see online supplementary material).

The first sample of breast milk (5 mL) was collected by hand expression from both breasts. Another four samples (10 mL each) were collected from each donor with a breast pump at an interval of at least seven days. Donors had to express milk directly into a sterile container, which was frozen immediately after expression. Together with each sample obtained for the study, they had to complete a form indicating the place in which the milk was expressed, the date, the collection method, the storage conditions of the breast pump, and the time spent travelling to the human milk bank.

Donors had to use the same breast pump and the same cleaning method throughout the study.

Milk samples were stored and then thawed at room temperature. Inoculation of samples into the culture media was performed in a laminar air flow cabinet within 10 min of thawing completely. Ten-microlitre samples were inoculated on to blood agar, chocolate agar, MacConkey agar and Sabouraud chloramphenicol agar plates.

After 48 h of incubating the plates, micro-organisms were identified using matrix-assisted laser desorption-ionization time of flight mass spectrometry (Bruker Daltonics, Billerica, MA, USA).

Micro-organisms considered as potential pathogens were Gram-negative bacilli, group B streptococci, *S. aureus*, enterococci and *Bacillus cereus* [8].

Outcomes

The primary outcome was comparison of the proportions of discarded DHM in the study and control groups. The secondary outcomes were comparison of breast milk bacterial contamination in the study and control groups, and comparison of breast milk bacterial contamination following hand expression vs pump expression.

Table I
Baseline maternal and infant characteristics

Data	Study group: Steam decontamination (*N*=21)	Control group: Washing alone (*N*=26)	*P*-value
Maternal data			
Mean age in years (SD)	35.8 (3.7)	33.7 (3.5)	0.05
Primigravida (%)	13 (61.9)	15 (57.7)	0.77
Second donation (%)	3 (14.3)	2 (7.7)	0.64
Breast pump borrowed from the human milk bank (%)	7 (33.3)	8 (30.8)	0.85
Infant data			
Preterm (%)	1 (4.8)	1 (3.8)	1
Mean age in months (SD)	4.7 (3.9)	3.3 (2.7)	0.15
Admission to NICU (%)	1 (4.8)	3 (11.5)	0.62

SD, standard deviation; NICU, neonatal intensive care unit.

Sample size

In the previous pilot study, the difference in the proportion of contaminated samples between the two cleaning methods was 5%. Accepting an alpha risk of 0.05 and a beta risk of <0.2 in a bilateral contrast, 152 samples were needed in each group. The sample was overestimated by 20% to allow for possible losses, for which the sample size was 184 samples in each group.

Follow-up of adverse events

To prevent excessive loss of DHM due to bacterial contamination, and to ensure that there were no adverse events in children, a planned interim analysis was performed when half of the donors were enrolled.

Randomization method

Random allocation was designed in a 1:1 ratio by an independent statistician (JD-B) and implemented using serially numbered opaque, sealed envelopes. One of the human milk bank nurses (MAM-S) was responsible for the participants' enrolment and intervention assignment.

Sample analysis was blinded to the microbiologist.

Statistical analysis

The analyses were based on an intention-to-treat principle. A descriptive analysis was conducted using data from donors and cultures. Comparison analysis between the two intervention groups was performed using Chi-squared test or Fisher's test, as appropriate. Statistical analysis was undertaken using SPSS Statistics v.15.0 (IBM Corp., Armonk, NY, USA). Statistical significance was set at $P \leq 0.05$.

The trial protocol was approved by the Institutional Review Board of Hospital 12 de Octubre. All participants gave written informed consent.

Results

When the planned interim analysis was performed, 48 donors had been enrolled and randomized: 22 in the study group (washed plus steam decontamination) and 26 in the control group (washed, rinsed and dried). One donor in the study group was excluded because she only provided one sample (obtained by hand expression). The data showed that the study outcomes had been achieved and recruitment was stopped. No significant differences in the baseline clinical characteristics were found between the two intervention groups (Table I).

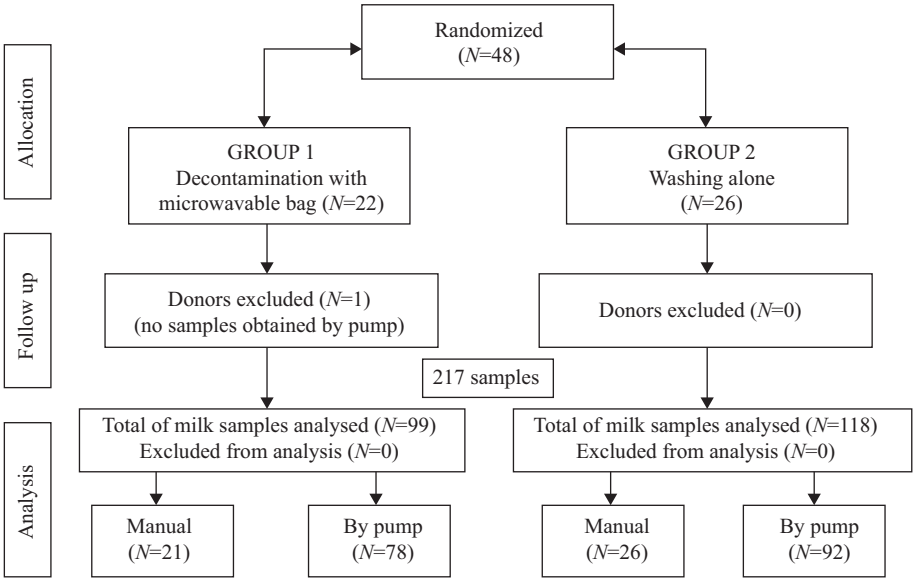

Figure 1. Flow diagram of donors and milk samples through the study.

Table II
Comparison of microbiological culture results between milk samples from study and control groups

	Samples obtained by pump (study group)[a] (*N*=78) Number of samples (%)	Samples obtained by pump (control group)[a] (*N*=92) Number of samples (%)	*P*-value
Samples containing skin flora[b] (>10^4 cfu/mL)	11 (14.1%)	8 (8.7%)	0.27
Samples containing *Bacillus* spp. (any quantity)	0 (0)	7 (7.6%)	0.016[d]
Samples containing *Staphylococcus aureus* (any quantity)	4 (5.1%)	2 (2.2%)	0.41
Samples containing *Enterococcus* spp. (any quantity)	0 (0)	0 (0)	-
Samples containing Gram-negative bacteria (any quantity)	4 (5.1%)	34 (37%)	<0.001[d]
Samples containing non-fermenting Gram-negative bacilli (any quantity)	3 (3.8%)	32 (34.8%)	<0.001[d]
Samples containing Enterobacteriaceae (any quantity)	1 (1.3%)	21 (22.8%)	<0.001[d]
Samples containing *Candida* spp. (any quantity)	1 (1.3%)	13 (14.1%)	0.002[d]
Samples discarded according to NICE criteria	1 (1.3%)	17 (18.5%)	<0.001[d]
Samples contaminated with potentially pathogenic bacteria[c] (any quantity)	7 (9%)	43 (46.7%)	<0.001[d]

NICE, National Institute for Health and Care Excellence; cfu, colony-forming units.
[a] Study group, washed and rinsed followed by steam decontamination (microwave); control group, washed, rinsed and dried.
[b] In 95.3% (162/170) of milk samples obtained by breast pumps, normal skin flora was identified (coagulase-negative staphylococci, such as *S. epidermidis*, *S. hominis*, *S. lugdunensis*, *S. warneri*, *S. pasteuri*, *S. capitis* and *S. pettenkoferi; Streptococcus viridans*; and other Gram-positive cocci: *Rothia, Micrococcus, Kokuria, Granulicatella* and *Dermacoccus* spp.).
[c] Micro-organisms considered potentially pathogenic bacteria were Gram-negative bacilli, group B streptococci, *Staphylococcus aureus*, enterococci and *Bacillus cereus*.
[d] Significant differences.

Fifteen out of 47 (31.9%) donors used a breast pump that had been lent to them by the human milk bank. Most donors (76.6%, 36/47) used the same model of a simple electric breast pump.

All but one of the hand expression samples were collected at the milk bank at the time of inclusion in the study. All pump expression samples were collected at home.

The mean transport time to the human milk bank was 25.6 min (standard deviation 10.3 min, range 15–60 min), with no differences between groups.

In total, 217 milk samples were analysed, 47 of which were obtained by hand expression (one per participant), and the remaining 170 were obtained by breast pump expression (Figure 1). According to the NICE criteria, the number of milk samples that were discarded was significantly lower in the study group: 1.3% (1/78) vs 18.5% (17/92) in the control group ($P<0.001$). Other comparisons of samples collected by pump expression are shown in Table II. The number of donors whose milk samples were contaminated with potentially pathogenic bacteria was significantly lower in the study group: 14.3% (3/21) vs 50% (13/26) in the control group ($P<0.05$).

Comparisons of samples collected by pump vs manual expression are shown in Tables S2 and S3 (see online supplementary material). There were no differences in bacterial contamination between samples obtained by steam decontaminated kits and those obtained by hand expression.

Discussion

This study shows that using steam decontamination after washing BPKs (compared with washing, rinsing and drying alone) decreases the proportion of DHM that would have to be discarded because of bacterial contamination (according to the NICE criteria) by 17.2%.

To the authors' knowledge, this is the first study involving milk donors conducted to determine the best way to clean BPKs and, consequently, to prevent DHM wastage.

Most human milk bank guidelines emphasize the importance of appropriate BPK cleaning, but do not specify the method of choice [4,9,10]; instead, they recommend the use of detergent wash rinse [11,12] or additional sodium hypochlorite [13]. Following the manufacturer's instructions is an option, although the lack of strong scientific evidence is most probably the reason for their contrasting recommendations.

As stated above, when the interim analysis was performed, important differences in microbial contamination of milk were found depending on the cleaning method. Thus, in order to prevent the human milk bank from continuing to receive contaminated milk, the study had to be stopped. Since then, BPK cleaning standards in the human milk bank have included steam decontamination after regular washing. Although this may interfere with the donation process, it is necessary to ensure that the smallest amount of DHM is discarded.

Hand expression is the method recommended by the study human milk bank, in common with many others [4], but most donors collect their milk using a pump. The Cochrane review found no significant differences between milk obtained by hand expression, a manual pump or an electric pump [14]. This study results suggest that milk samples obtained by expression with a properly washed and steam decontaminated BPK present a microbiota which is similar to that observed in samples collected by hand expression; however, the same is not true for milk obtained by pumps which are only washed in water with detergent. Similarly, other authors found no differences in the rate of bacterial contamination among milk samples obtained by hand expression or any type of pump using a new and sterile pump collection kit or a BPK cleaned with boiling water [15,16].

In this study, EBM samples obtained using a pump were collected in donors' home. In this respect, some authors have found contamination of EBM to be more common when expression is done at home than in the hospital [16–18], although Borges *et al*. confirmed that there were no differences in the quality of breast milk wherever it was expressed, provided that hygiene, conservation and transport standards were met [19].

External validity may be limited by the fact that most donors used the same type of breast pump, although some authors have stated that bacterial contamination rates of EBM specimens obtained from different pumps are not different [16].

Another limitation is that this study was not double-blinded, although the professional who provided the information about bacterial growth ignored how the milk sample had been obtained. Notwithstanding these limitations, the results provide evidence-based data to be added to current recommendations already given by certain guidelines [20].

Given the common use of breast pumps, well-designed clinical trials are needed to further compare the aforementioned strategies as well as other cleaning approaches for different types of breast pumps and within different settings (neonatal unit, home, etc.), in order to appropriately identify the best cleaning method in each particular case.

In conclusion, the use of steam decontamination after washing BPKs decreased the amount of DHM that had to be discarded due to bacterial contamination (compared with recommended washing, rinsing and drying methods). There were no significant differences in bacterial contamination between samples obtained by manual expression and samples obtained using steam-decontaminated BPKs.

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Conflict of interest statement
None declared.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jhin.2019.07.007.

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