Effects of three methods of breast milk expression on breastfeeding initiation, breast milk extraction and proportion of exclusive breastfeeding—an open label, randomized controlled trial

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Research

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Abstract

Background Direct breastfeeding has multiple health benefits. Some mothers need to express their breasts when directly breast feeding is unavailable immediately after delivery. However, there is insufficient evidence regarding an effective method of breast milk expression in the absence of an infant's suction. This trial was designed to investigate the effects of different methods of breast milk expression on breastfeeding initiation, efficacy of breast milk extraction, and on the rate of exclusive breastfeeding at 6 months.

Methods The participants of mother-infant dyads separated immediately after birth for at least 6 hrs were recruited and randomly assigned (1:1:1) into three groups: (1) hand expression of breast milk; (2) sequential and (3) simultaneous electrical breast pumping. The two primary outcome measures were the time required for initiation of breastfeeding and the milk volume expressed in a 10-minute session (direct breastfeeding in hand expression group) at 3 days and at 6 weeks; a secondary outcome was the proportion of exclusive breastfeeding at 4 and 6 months. Intention-to-treat data set was used in this analysis.

Results Between 2018 and 2019, we recruited 226 participants, of whom 154 were randomized. The median time (in hour) of breastfeeding initiation of sequential (46.5, 95% CI 36.1-50.5) and simultaneous (45.6, 95% CI 34.2-53.0) breast pumping groups did not differ from those of hand expression (46.7, 95% CI 40.8-50.0) ($p=1.000$). At 3 days the breast volume through simultaneous pumping (13.1 ± 10.9 ml), but not sequential pumping (16.7 ± 11.6 ml) ($p=0.560$), was significantly less than hand expression (23.8 ± 26.2 ml through direct sucking) ($p=0.007$). At 6 weeks the breast volume through sequential pumping (64.7 ± 51.0 ml), but not simultaneous pumping (71.6 ± 50.8 ml) ($p=0.670$), was significantly less than hand expression (89.8 ± 67.3 ml through direct sucking) ($p=0.035$). The breast milk volume through sequential breast pumping (10 min per breast) was 37.9 ml less than those of simultaneous pumping ($p=0.000$). The rate of exclusive breastfeeding at 4 months was 21.0%, and at 6 months 10.6%, and did not differ between the three methods of breast milk expression.

Conclusions Hand expression, sequential breast pumping, or simultaneous breast pumping in absence of immediate infant suction after birth did not show differences on the time required to initiate breastfeeding, or on the rate of exclusive breastfeeding at 4 and 6 months.

Trial registration This trial was registered with www.chictr.org.cn (ChiCTR1800018193) on 4 September 2018.

Background

Breastfeeding provides natural, and is considered unequivocally to be the optimal nutrition for infants.^{1,2} Indeed, the World Health Organization (WHO) recommends exclusive breastfeeding for at least the first six months of life and continued with appropriate introduced supplement food for up to two years and beyond.³ The health benefits of breastfeeding include prevention of infant death,⁴⁻⁶ of diseases such as

otitis media, atopic eczema, and possibly allergic rhinitis in early life,^{1,7} and of non-communicable diseases such as obesity, diabetes and heart diseases in later life;⁸⁻¹⁰ enhancement of early childhood development, especially neurodevelopment, as reflected by increased IQ scores and better school performance;¹¹ and reduction of maternal risks of postpartum hemorrhage, breast and ovarian cancer, and some cardiovascular diseases.^{1,12-16} In addition, breastfeeding is considered to be a socioeconomic lever to mitigate inequities in provision of health service resources.¹⁷

There are a number of circumstances in which initiating breastfeeding soon after birth (<1 hr) and sustaining exclusive breastfeeding are not possible. First, premature infants have difficulties in latching-on, sucking and digestion,^{18,19} yet provision to these infants with their own mothers' milk is important². Compared with full-term mothers, mothers of preterm infants find it more difficult to establish and sustain lactation,²⁰ it has been reported that only about 50% of them are able to express sufficient milk for their infants.²¹ Unless within 1 hr of delivery, the breast pumping in mothers of premature birth would not shorten the time lag of stage II lactogenesis.²²⁻²⁴ Second, mothers who deliver by cesarean section are usually prevented from putting their infants to breast <1 hr after birth, and hence have a delay in lactation initiation and reduced lactation duration.²⁵⁻³³ The Cesarean delivery rates raised from 28.8% in 2008 to 34.9% in 2014 in China,³⁴ together with the short period (14 weeks) of paid maternal leave,³⁵ the actual prevalence of breast pumping was quite possible higher than the Cesarean delivery rate. Mothers of established breastfeeding believe that the excessive breast milk after direct breastfeeding should be squeeze out and the breast milk should be expressed regularly in absence of infant's sucking, in order to maintain the breast milk production. As a result, the breast expressing, manual or with pump, was common practice in nursing mother.^{19,27,36-38} As a result, the breast expressing was recommended to nursing mothers in absence of infant suction after birth or after established lactation in context-specific manner.

Survey data indicated that the rate of breast milk expressing could reach 85% before 4 months in Australia women³⁹. Apart from scenarios that necessitate expression of breast milk, there is evidence that many women with full-term, healthy infants also express breast milk regularly. Among Australian women with healthy term infants 60% had a breast pump within two days postpartum and 40% of them expressed several times a day in the following two weeks.⁴⁰ Among Chinese women with healthy term infants 64% used a breast pump and 22% expressed exclusively at 6 weeks postpartum⁴¹. The undeserved prominence of breast milk expressing prevalence even drove the evolution of the definition of exclusive breastfeeding by including both at the breast and with exclusively pumped milk, though its potential consequence is unknown.^{42,43} On the other hand, bottle-feeding the full-term, healthy infants with expressed milk (exclusively pumped in this case) did not contribute to the rate and duration of exclusive breastfeeding.^{23,41,44,45} Breast pumping should not be used in full-term, healthy birth as stated in the fourth step of the revised "Ten steps to successful breastfeeding" guidance that "*Facilitate immediate and uninterrupted skin-to-skin contact and support mothers to initiate breastfeeding as soon as possible after birth*" [<https://www.who.int/nutrition/bfhi/ten-steps/en/>]. With regard to methods of

breast expression, a systematic review concluded that, depending on the purpose of milk expression, hand expressing may be as effective as electric pumping but there was considerable heterogeneity between studies and potential bias arising from commercial involvement in about half of the included studies.⁴⁶ Thus, the effectiveness of different methods of breast pumping remains unclear.

We therefore undertook a randomized controlled trial of the effect of alternative methods of breast pumping on time required to initiate lactation, volume of milk production and rate of direct breastfeeding in otherwise healthy mother-infant pairs in which the neonates had been separated from their mothers immediately after birth for at least 6 hrs to undergo medical observation or examination. Three typical methods in breast milk expressing were included in this trial, namely hand expressing

(different from vacuum sucking, usually positive pressure without any extra gadget), sequential and simultaneous suction (electronic pump).

Methods

The aim

To investigate the effects of different methods of breast milk expression on breastfeeding initiation, efficacy of breast milk extraction, and as a consequence, on the rate of exclusive breastfeeding at 6 months.

Design and setting of the study

In this open-label, randomized controlled trial, the participants were recruited at Xinhua Hospital affiliated to Shanghai Jiaotong University, a hospital certified as a Baby Friendly Hospital. This is a tertiary general hospital with a 75-bed obstetrics unit and approximately 3300-3500 deliveries annually. Being the Shanghai Critical Maternal Transfer Center, Shanghai Prenatal Diagnosis Center, and Shanghai Premature Birth Center, it is also a referral centre for high-risk pregnancies from other hospitals in Shanghai City and surrounding provinces.

Participants

The participants were recruited from 2018 to Sept. 2019 through posters at an Obstetrics unit and in a delivery room of the hospital. Mother-neonate dyads were potentially eligible if the mother was aged 20-40 years, had attended antenatal education course in the hospital, committed to direct breastfeeding for at least 4 months in her maternity leave and were willing to express breast milk if required. The neonates had to have been delivered at gestational age ≥ 34 weeks and body weight ≥ 2000 gram with 1-minute Apgar score ≥ 7 . Dyads in which the woman had a history of smoking or regular alcohol drinking, or contraindications (such as human immunodeficiency virus infectious diseases) to direct breastfeeding, or the infant had congenital anomalies or was unsuitable for direct breastfeeding, were excluded. Ethical approval of this trial was obtained from the Institutional Review Board of Shanghai Jiaotong University

School of Medicine. All participants provided written informed consent before any trial-related procedures, first during antenatal preparation classes in the 30th-37th weeks of gestation, and then if the mother-infant dyads matched the eligibility criteria, just before delivery or within 2 hours after delivery, depending on the clinical situation of the baby. Since participants recruitment the principles of quality control were followed. This trial is registered with Chinese Clinical Trial Registry (<http://www.chictr.org.cn>), code ChiCTR1800018193. The reporting of the trial is guided by the extension to the CONSORT statement for multi-arm parallel-group randomized trials.⁴⁷

Randomization and masking

Participants were randomly assigned into three groups (1:1:1) through a simple “lottery drawing” process without replacement. The lottery of grouping information, pre-sealed in 155 opaque envelopes, was opened in the face of two investigators. The three groups were defined according to the methods of breast milk expression in the absence of infant sucking, namely hand expression, sequential pumping (Avent SCF902/11 single electric breast pump, Philips Invest, China) and simultaneous pumping (Avent SCF303/01 bilateral electric breast pumps, Philips Invest, China) in the first 6 months after birth.

Avent SCF902/11 single electric breast pump provided five-gear vacuum pressure (5 to 1) labeled from -250 to -130 mmHg. Avent SCF 303/01 provide two mode of suction: Stimulation and Expression, both in four-gear mode. Vacuum pressure in Stimulation mode was from -150 to -80 mmHg, and from -250 to -170 mmHg in Expression mode. The suction frequency was 1.0-2.5 Hz in Stimulation mode and 0.71-1.05 Hz in Expression mode accordingly, while the single electric breast pump only provided constant vacuum pressure.

This was an open-label trial. The diary check, coding, questionnaire information collection were conducted by two nurses who did not know the allocation. The groups were coded that would not suggest any clue for electric breast pump usage and statistician could not know the information of grouping in prior.

Procedures

Participants were interviewed face-to-face during antenatal preparation classes before recruitment. Actual recruitment and simple randomization occurred immediately (<30 min) after birth at bedside of delivery/recovery room that the decision was made based on whether the neonates should be separated from their mothers for ≥ 6 hours. The common causes of mother and infant separation include preterm birth, neonatal asphyxia, maternal or neonatal suspicious infections (such as maternal fever before delivery, meconium-stained amniotic fluid) and complications of delivery. Physical examination and laboratory tests in pregnancy were carried out and demographic data were obtained.

All participants were trained in manual expression of breast milk during mother-baby separation according to guidelines for initiating milk supply in the absence of infant suction.⁴⁸ Women were asked to begin breast milk expression at 2 hours after birth and continue with an interval of 2-3 hours between

subsequent sessions (each comprising 10 min of pumping per breast per session) until initiation of direct breastfeeding. After the infants were able to suck, the usage of breast pump was restricted to remove excessive breast milk, to alleviate the fullness of breast milk, to donate breast milk, or to discard breast milk likely to be contaminated with medications. The number of sessions of breast pumping per day was expected to decrease gradually as lactation became established in healthy mother-infant dyads.

The 10-minute expression volume of breast milk per breast at 3 days and at 6 weeks postpartum were recorded, and the mother-infant dyads were followed up at 4 and 6 months after birth (Figure 1).

All women in this study would be at hospital more than 48 hrs after delivery and discharge at the 3rd day. At the 3rd day, the two breasts were sequentially or simultaneously pumped for 10 minutes per breast. This was repeated 2-3 hours later, using the same type of pumping (Figure 1).

On a follow-up about day 6 weeks postpartum, the mothers were asked to breastfeed directly first, and one hour later each breast was pumped for 10 minutes per breast. After a clinical review, the mothers were asked to breastfeed their infants directly again, and then have milk pumped with the type of breast pump crossed over one hour after second direct breastfeeding.

The participants also joined an online trial member group through WeChat (Tencent, China), a mobile phone App that facilitates instant communication between participants and investigators. One investigator was assigned to answer questions from the trial group and provide professional advice. The information on breastfeeding at 4 and 6 months were collected through online questionnaire.

Outcomes and data collection

The two primary outcomes were (1) Time for lactation initiation: also known as time for breastfeeding initiation, defined as the time of the infant was provided successfully direct breastfeeding or with expressed breast milk between delivery and hospital discharge and (2) Volume or weight of expressed breast milk in 20 min (10 min per breast) at three days or six weeks postpartum. To assess the effects of manual breast expression, milk transfer was measured at 3 days and at 6 weeks postpartum. The infants were weighed just before and after breastfeeding to determine milk transfer to the infant in the obstetrician ward. This method had been validated and was used in lactogenesis research^{23,49}. Test weights of infants in cradle were obtained in duplicate using an electronic scale (accuracy=0.1 g). Each weight was recorded when the measurement was stable for 10 seconds. A density factor of 1.03 g/ml was used in conversion between weight and volume of breast milk.

The secondary outcomes were the rates of exclusive breastfeeding at 4 and 6 months. The mode of feeding divided into seven categories: direct breastfeeding, direct breastfeeding plus expressed breast milk, direct breastfeeding plus expressed breast milk and formula milk powder, direct breastfeeding plus formula milk powder, merely expressed breast milk, expressed breast milk plus formula milk powder, total formula milk powder. The data of self-reported mode of feeding were collected online.

The reported adverse events during breast pumping include those from mothers and from device. General adverse events are those, which patients or trial participants have complained about or clinicians have observed.

Statistical analysis

According to unpublished data from a pilot comparison between two groups of lactation-established women that each applied one of the two types of breast pumps, there was a difference in breast milk volume of around 15 ml with a standard deviation of 40 ml. The sample size was then estimated to be 90 participants in each group with statistical power of 0.8 and significant level of 0.05. Considering the limit of eligible participants, the sample size was adjusted to 50 participants in each group, and a cross over design of breast pump types was used at 6 weeks.

The data were analysed according to intention-to-treat (ITT). The continuous data were presented with mean $\pm$ SD and the categorical data were presented as count and percentage. To compare baseline characteristics, two-tailed one-way ANOVA was conducted for variables with a normal distribution or the Wilcoxon signed rank (Mann-Whitney U) test for those not. Among three trial groups, nonparametric Kruskal-Wallis rank sum test and chi-squared test were applied for continuous and categorical data, respectively. Tukey honest significant differences were calculated in multiple comparison adjusted with p value. Paired student's t test was applied to compare the milk volume between left and right breast or between two breast pumps. The log-rank test was applied to compare the time required for breastfeeding initiation (event=1). Linear mixed-effect modelling (lme4 package) was used to analyze the association between the expressed milk volume and co-variates. $p < 0.05$ was considered statistically significant. Statistical analyses were done with R(version 3.3.3).⁵⁰

Results

Study participants

Following prenatal examination 226 participants returned written informed consent. After delivery 2/3 of them ($n=154$) were randomized into three groups of breast expression. Six participants withdrew between hospital discharge and review at 6 weeks. Meanwhile 2 participants stopped breastfeeding prematurely due to maternal health problems. Afterwards over 20% participants declined feedback at 4 months though they remained in contact. At 6 months less than half of participants in total remained in contact. More participants lost in follow-up during the last 2 months than in previous 4 months, especially in group of sequential breast expression (Figure 1). The three groups were well balanced at baseline (Table 1).

Table 1. Basic Characteristics

	Hand (n=51)	Sequential (n=52)	Simultaneous (n=51)	pooled (n=154)	p value
Maternal factors					
Maternal age at giving birth, yr	31.7(3.6)	31.0(3.3)	31.9(3.6)	31.5(3.5)	0.358
Gestational age at enrollment, wk	30.8(2.6)	30.7(2.3)	32.1(3.9)	31.2(3.1)	0.125
Gestational age at delivery, wk	39.0(1.0)	39.1(1.3)	38.7(0.8)	38.9(1.1)	0.070
Prepregnancy BMI, kg/m ²	21.7(3.3)	21.2(3.1)	22.6(4.0)	21.8(3.5)	0.103
Education level college or higher, %(n)	94.1(48)	90.4(47)	84.3(43)	89.6(138)	0.267
Monthly income ≥5000 RMB, %(n)	80.4(41)	82.7(43)	74.5(38)	79.2(122)	0.594
Social insurance, %(n)	90.0(45)	90.0(45)	84.0(42)	88.0(132)	0.698
Natural implant, %(n)	94.1(48)	92.3(48)	92.2(47)	92.9(143)	1.000
Nullipara, %(n)	88.2(45)	82.7(43)	74.5(38)	81.8(126)	0.208
Family support of direct breastfeeding, %(n)	41.2(21)	63.5(33)	56.0(28)	53.6(82)	0.072
Know benefit of direct breastfeeding, %(n)	41.2(21)	63.5(33)	56.0(28)	53.6(82)	0.069
Feel confident in direct breastfeeding, %(n)	39.2(20)	61.5(32)	54.0(27)	51.6(79)	0.064
Prepared formula milk before delivery, %(n)	70.6(36)	71.2(37)	72.5(37)	71.4(110)	1.000
Prepared breast pump before delivery, %(n)	39.2(20)	42.3(22)	33.3(16)	38.4(58)	0.638
Self-reported risk factors, %(n)					0.996
Age >35yr	24.4(11)	10.4(5)	25.0(11)	19.7(27)	
Gestational diabetes	24.4(11)	14.6(7)	34.1(15)	24.1(33)	
C-section indication	2.2(1)	0(0)	4.5(2)	2.2(3)	
Other risk factors	0(0)	0(0)	2.3(1)	0.7(1)	
Delivery mode, %(n)					0.896
Vaginal delivery (including anesthesia)	45.1(23)	48.1(25)	43.1(22)	45.5(70)	
C-section (including emergency)	54.9(28)	51.9(27)	56.9(29)	54.5(84)	
Planned maternal leave, m	4.4(1.4)	5.4(2.8)	5.0(2.7)	5.0(2.4)	0.145
Times of breast expression in first day postpartum	2.5(2.2)	3.6(2.7)	4.1(2.7)	3.5(2.6)	0.0345
Time interval of breast expression in first day postpartum, hr	3.8(6.8)	3.9(2.9)	4.9(5.1)	4.2(5.1)	0.004
Breast milk production increased significantly, day	7.5(7.4)	6.0(4.7)	7.4(6.8)	7.0(6.4)	0.323
Neonatal factors					
Male, %(n)	40.0(20)	49.0(25)	51.0(26)	46.7(71)	0.509
Body weight, g	3308.7(371.5)	3332.2(383.2)	3330.9(475.7)	3323.9(410.2)	0.943
Body length, cm	49.6(1.3)	49.5(1.6)	49.6(1.6)	49.6(1.5)	0.944
Apgar score (1 min)	9.9(0.5)	9.9(0.3)	9.9(0.1)	9.9(0.3)	0.555
First breast suckling by neonate, hr	18.5(14.4)	18.6(16.1)	17.0(12.3)	18.0(14.3)	0.858
Infant body weight at 6 weeks, g	5120.0(640.3)	5113.4(602.5)	5189.9(608.6)	5141.3(614.5)	0.789
Infant body length at 6 weeks, cm	56.7(2.2)	57.2(2.3)	57.3(2.1)	57.1(2.2)	0.401
Times of breastfeeding (directly or indirectly) in 24 hs at 6 wks	6.3(2.9)	5.5(3.6)	5.4(3.4)	5.7(3.3)	0.485
Time of breastfeeding per session at 6 weeks, min	23.5(11.7)	23.0(12.7)	20.1(12.4)	22.3(12.3)	0.280
Plan to breastfeed, month	10.2(3.5)	10.0(2.4)	9.8(3.3)	10.0(3.1)	0.480
Plan to supplement food, month	6.5(1.6)	6.2(0.9)	5.9(1.3)	6.2(1.3)	0.141

Notes: summary statistics for continuous variables presented as mean (SD), categorical as %(n); BMI:

body mass index;

Primary outcomes

The method of breast milk expression on the time required for breastfeeding initiation was a primary outcome measure. The estimated median time that was required for breastfeeding initiation of hand expression, sequential breast pumping, and simultaneous breast pumping were 46.7 (95% CI 40.8-50.0), 46.5 (95% CI 36.1-50.5) and 45.6 (95% CI 34.2-53.0) hours, respectively. Each of 3 groups had around 10% participants that initiated breastfeeding after 3 days (>72 hr). Compared with hand expression,

sequential and simultaneous breast pumping did not promote earlier initiation of breastfeeding (log-rank test, $p=1.000$) (Figure 2A). For dyads with vaginal delivery, the median time to breastfeeding initiation with simultaneous breast pumping was 34.2 (95% CI 26.9-53.0) hours, with sequential pumping is 45.3 (95% CI 20.3-49.0) hours, and with hand expression 45.7 (95% CI 31.4-51.8) hours. For dyads in which cesarean section had been used, the median times to initiation with breast pumps were somewhat longer - 49.3 (95% CI 38.9-66.8, $p=0.096$) hours for simultaneous pumping and 50.5 (95% CI 40.2-67.1, $p=0.086$) hours for sequential pumping. However, the differences were not statistically significant (Figure 2B). Comparing the time between two delivery modes, the time required for breastfeeding initiation in women with vaginal delivery was significantly earlier (median 45.1 (95% CI 31.4-48.0) hours) than in women who had cesarean section (median 48.2 (95% CI 43.5-53.0) hours; $p=0.002$). Comparing with vaginal delivery, the median times of breastfeeding initiation were longer in mothers with cesarean section in two breast pump groups, 50.5 hrs (95% CI 40.2-67.1) versus 45.3 hrs (95% CI 20.3-49.0) in sequential breast pump group and 49.3 hrs (95% CI 38.9-66.8) versus 34.2 hrs (95% CI 26.9-53.0) in simultaneous breast pump group (Figure 2C).

The efficacy of breast expression in early and mature stages of lactation was measured through expressed breast milk volume. The breast milk volume was estimated from weight, either of test weighing in hand expressing group at 3 days or 6 weeks, or of weights in two breast pump groups at 3 days when the milk volume was <10 ml. At 3 days after birth the infants in hand expression group were breastfed directly and weighed right before and after feeding. Averaged breast milk volumes were 23.8 ± 26.2 ml for hand expression, 16.7 ± 11.6 ml for sequential pumping and 13.1 ± 10.9 ml for simultaneous pumping. Averaged breast milk volume in simultaneous pumping was less than that in hand expression group through direct breastfeeding ($p=0.007$). However, it was not different from that for sequential pumping ($p=0.560$). There was no difference between two delivery modes (vaginal delivery vs cesarean section) and no difference in subgroups of delivery mode in three groups (Figure 3A).

At 6 weeks the averaged breast milk volumes were 89.8 ± 67.3 ml of hand expression, 64.7 ± 51.0 ml of sequential pumping and 71.6 ± 50.8 ml of simultaneous pumping in a 10-minute session. The average breast milk volume of sequential pumping was statistically less than that of hand expression ($p=0.035$) but was not different from that of simultaneous pumping ($p=0.670$). The averaged breast milk volume in participants with different delivery modes was not different ($p=0.834$), with 72.8 ± 55.1 ml in vaginal delivery and 71.8 ± 55.0 ml in cesarean section group. Further subgroup analysis of breast milk volume of delivery modes in three groups did not show any statistical difference (Figure 3B). The average milk volume from left breast was about 2 ml less than those from right breast ($p=0.012$).

To minimize random effect from individual woman, the design of two breast pump types by two periods (2×2) cross over was applied at 6 weeks. In 1st period (before breast pump cross over) the average breast milk volumes of sequential and simultaneous pumping groups were 40.4 ± 25.3 ml and 76.5 ± 52.5 ml ($p=0.001$), respectively. In 2nd period (after breast pump cross over) the averaged breast milk volumes of sequential and simultaneous pumping groups were 88.6 ± 58.3 ml and 67.0 ± 49.7 ml ($p=0.167$), respectively. Total breast milk volume pumped in 1st period (59.3 ± 45.0 ml) was less than that in 2nd

period (79.0±55.1 ml) (p=0.009). The breast milk volume increased from sequential to simultaneous pumping transition was statistically significant (p<0.001), while the converse simultaneous to sequential transition was not (Figure 4). Next, a linear mixed effects model was fitted for this cross over design by using breast milk volume at 6 weeks as the dependent variable. The predictive value of breast milk volume at 3 days was negligible by using a backward elimination for linear mixed models (lmerTest package). After restricted likelihood ratio tests on simulated values (RLRsim package), the estimated model coefficients indicated that the breastfeeding initiation time would affect the breast milk volume inversely and sequential pumping was inferior to simultaneous pumping in efficacy of breast milk expression (Table 2).

Table 2 The estimated coefficients in fitted linear mixed effects model for breast milk volume at 6 weeks

	Estimate	Std Error	t value	df	p value
Intercept	93.36	10.587	8.818	112	<0.0001
Breastfeeding initiation	-0.380	0.181	2.105	90	0.038
Groups/sequential	-37.94	9.717	3.905	144	0.000
Period/2nd period	-9.672	7.167	1.349	91	0.181
Sequential:2nd period	58.41	9.946	5.873	90	<0.0001

Note: Group/sequential stands for sequential pumping compared with simultaneous pumping;
Period/2nd period stands for the period 2 in cross-over (2x2) compared with the first period;
Sequential:2nd period stands for the effect of sequential pumping (1st period) change into simultaneous pumping (2nd period)

Secondary outcomes

At 4 months the median count of self-reported direct breastfeeding was 5.5 (interquartile range, IQR 2-8) sessions each day, median of count of using breast pump was 2 (IQR 2-4) sessions per day, and the averaged breast milk volume expressed each session was 172.4±95.7 ml in responsive women. In the following two months the body weight increased by about 800 grams (p<0.0001) and body length increased by 3 cm (p=0.030) on average. The baby's body weights differed between the three groups at six months (p=0.016) while their body lengths differed between the three groups at four months (p=0.033). Except that there was no difference in three groups in recorded feedbacks. In two breast pumping groups, 80% of mothers used breast pumps frequently. The paired student t test on expressed milk volume of mothers showed no difference (p=0.787) between their response at 4 and at 6 months (pairs=41). The expressed breast milk volume in mothers who responded only once (at 4 months, n=35) was less than that responded twice (at 4 and 6 months, n=41), with 136.8 ml vs 202.6 ml, p=0.002. Among participants who responded, 80.0% used breast pumps at 4 months and 71.9% at 6 months. The proportions were not different among three groups at 4 and 6 months (p=0.079, p=0.436), or by delivery modes (p=0.737). At 4 months, the maternity leave of 50.4% nursing mothers had ended, and this rose to 80.0% at 6 months (p=0.000). About 90% mothers supplemented food for their infants at 6 months.

Absence of milk, milk insufficiency, or return-to-work might explain why the rate of introduction of formula milk was 40%- at 4 and 50% at 6 months. In terms of breastfeeding mode, the proportion of exclusive breastfeeding dropped from 21% at 4 months to 10% at 6 months, the exclusive breastfeeding rates among three groups were not different at 4 months ($p=0.109$) or at 6 months ($p=0.459$). (Table 3).

Table 3 Breastfeeding mode at 4 and 6 months

	Time point	Hand	Sequential	Simultaneous	pooled
EBF, %(n)	4m	32.4 (12/37)	12.8 (5/39)	18.6 (8/42)	21.0 (25/118)
	6m	8.7 (2/23)	20.0 (3/15)	7.1 (2/28)	10.6 (7/66)
	p value	0.072	0.812	0.296	0.103
BF+, %(n)	4m	67.6 (25/37)	59.0 (23/39)	58.1 (24/42)	61.3 (73/118)
	6m	52.2 (12/23)	40.0 (6/15)	39.3 (11/28)	43.9 (29/66)
	p value	0.358	0.342	0.222	0.021
+milk powder, %(n)	4m	40.5 (15/37)	41.0 (16/39)	39.5 (17/42)	40.3 (48/118)
	6m	47.8 (11/23)	33.3 (5/15)	57.1 (16/28)	50.0 (33/66)
	p value	0.775	0.835	0.224	0.278
solely milk powder, %(n)	4m	2.7 (1/37)	7.7 (3/39)	7.0 (3/42)	5.9 (7/118)
	6m	0 (0/23)	0 (0/15)	3.6 (1/28)	1.5 (1/66)
	p value	1.0	0.658	0.645	0.262

Note: EBF, exclusive direct breastfeeding; BF+, breastfeeding directly or with sucked milk plus other food including milk powder; +milk powder, supplemented with milk powder; p value, of Fisher's exact test;

Adverse events

No serious or severe adverse events episodes were reported in follow-up to six months. The proportion of all types of local breast adverse events was 11.5% and of all types of systemic adverse events of mild to moderate severity was 2.9%. Eleven participants (one from hand expressing group, two from sequential breast pump and eight from simultaneous pump group) reported 12 local (breast) adverse events with mild to moderate severity, however, these local adverse events resolved without treatment. These local adverse events included breast skin rash, breast pain, breast lump or swelling, nipple broken and areola slightly peeling. Three cases (one from control and two from sequential breast pump group) reported fever, mastitis and antibiotics for high fever with moderate severity and resolved after medical treatment.

Discussion

In this open-label, randomized control trial, we studied different methods of breast expression immediately after birth in the absence of infant sucking. The time required for breastfeeding initiation in the three groups - hand expression, sequential electric pumping, and simultaneous electrical pumping was not statistically different. The 10-minute breast milk volume extracted through breast pumps was less than that of direct breastfeeding. Compared with participants with vaginal delivery, the time required for breastfeeding initiation was delayed in those with cesarean section, however, there was no significant difference in breast milk volume at 3 days and 6 weeks. Further analysis indicated that the time required for breastfeeding initiation may inversely predict expressed breast milk volume at 6 weeks. The effectiveness of breast pump for different women (e.g. with premature birth or full-term birth) was different. The effectiveness of breast pump for different starting time (e.g. <1 hr or >2 hrs after birth) for same women was also different. Based upon these inconsistent results, if we suppose the suction of breast pump could stimulate the production of breast milk, this stimulating effect would be very weak. The efficacy of sequential pumping was inferior to that of simultaneous pumping in the 10 min per breast test. The rates of exclusive breastfeeding at 4 and 6 months were not different in three groups.

Comparison with other studies

Breastfeeding initiation within 1 hr after birth may facilitate the appearance of copious breast milk volume^{22-24,51} and reduce risk of infant death in first 28 days.⁵² Early skin-to-skin contact, mode of delivery, and maternal illness were associated with early breastfeeding initiation.^{53,54} For participants of immediate mother-and-infant separation after birth, they also had other conditions that require medical care. That made introduction of breast expression within 1 hr not always practical. We introduced breast expression as soon as possible after birth. This was intended to promote an early breastfeeding initiation for the dyads who were separated more than 6 hrs,²² as breast expression at 24-72 hrs after cesarean section would not improve milk transfer.²³ Alternatively, antenatal breast expressing (twice daily at convenient time) after 37 weeks of gestational age was recommended⁵⁵⁻⁵⁸ and trial was taken recently in women with diabetes in pregnancy.⁵⁹ In the present trial, the time for breastfeeding initiation ranged from 17 hrs before delivery to 95 hrs after delivery, with median time greater than 45 hrs in all six subgroups of expression methods and delivery mode. This suggests some common underlying causes had influence on both the mother-infant separation after birth and timing of lactation initiation. In line with this delayed breastfeeding initiation, the median time between delivery and sudden copious breast milk (self-reported data to indicate start of lactogenesis stage II) ranged from 4.0 to 7.5 days. Usually, the lactogenesis stage II would start at 30-48 hrs, and delayed lactogenesis stage II (>72 hrs) would happen in 22%-31% of mothers.^{60,61}

Clinical relevance

Breast milk transfer in the hand expression group under specified conditions, such as maternal-baby separation by delivery complications, could be viewed as comparable to that in healthy infants of direct breastfeeding in general population. At 3 days, the averaged breast milk volume through pumping was less than those from hand expressing though only those in simultaneous pumping group was significant.

At 6 weeks the breast milk volume pumped simultaneously in the 10-minute period was much closer to that obtained through direct breastfeeding than to that pumped sequentially. Nevertheless, the average milk volume pumped was 18 ml less than that of direct breastfeeding in the same period. Therefore, direct breastfeeding is undoubtedly the optimal option of breast milk extraction. Compared with sequential pumping, simultaneous breast pumping had an extra stimulation step (with 1.0-2.5 Hz and 80-150 mmHg vacuum) before expression. Compared with sequential pumping, the simultaneous breast pump introduced cyclic expressing mode accompanied with different vacuum pressure and an extra stimulation mode before expression. However, we have no data to support whether this design improved the total breast milk production in mothers of established lactation. The inconsistency of breast pumps in different study populations and timing indicated that the role of feedback control of breast milk extraction, if any, was limited.^{22,25,45,62,63} The electric breast pumps should be viewed as a tool solely for breast milk expression when other methods are not available and should not interfere with breastfeeding practice.

Comparison among the three method of breast expression

The reasons for inadequate rate and duration of exclusive breastfeeding often result from factors including planned cesarean section delivery,⁶⁴ gestational age at delivery, breast refusal, sore nipple, lack of access to breast pumps, use of free formula milk,^{37,41,63,65} insufficient support for breastfeeding, self-perceived inadequacy of milk supply, having to leave infants to go to work or school^{19,39,40,66,67} and medical conditions⁴⁵. Among participants who responded, 80.0% used breast pumps at 4 months and 71.9% at 6 months. The proportions were not different among three groups at 4 and 6 months ($p=0.079$, $p=0.436$), or by delivery modes ($p=0.737$). At 4 months, the maternity leave of 50.4% nursing mothers had ended, and this rose to 80.0% at 6 months ($p=0.000$). However, the proportion of breast pump usage in maternity leave was not different from those out of maternity leave at 4 months ($p=1.000$), or at 6 months ($p=0.691$). We do not know the reasons for application of breast pumps before 6 months, however, the high rate of breast pump usage could match the proportion of exclusive breastfeeding quite well inversely.

Limitations of the study

This trial was conducted in nearly healthy mother and infants, considering the mandatory mother-infant separation immediately after birth, the extrapolation to general population should be cautious. Women in trial groups with sufficient breast milk supply would be more likely to respond at 4 and 6 months. The high rate of breast pumping among nursing women, instead of laborious hand expressing, would lead to biased estimation of breast milk volume as the effect of breast pump on breast milk production yet to be justified.

Conclusions

Introducing breast expression (hand expressing, sequential and simultaneous pumping) in the period of mother-infant-separation since 2 hrs postpartum did not display different effects on time for breastfeeding initiation. Simultaneous breast pumping (in this case) was more effective than sequential pumping in breastfeeding established women both in volume and time while the direct breastfeeding was optimal in breast milk extraction at 3 days and 6 weeks. The time for breastfeeding initiation could predict the volume of pumped breast milk at 6 weeks inversely. Three methods of breast expression did not affect the rates of exclusive breastfeeding at 4 and 6 months.

List Of Abbreviations

WHO: World Health Organization; CONSORT statement; ITT: Intention-to-treat; one-way ANOVA: One-factor Analysis of Variance; IQR: Interquartile range; BMI: Body mass index; EBF: Exclusive direct breastfeeding; BF+: Breastfeeding directly or with sucked milk plus other food including milk powder.

Declarations

Ethics approval and consent to participate

All participants in this study provided written informed consent before recruitment, and the Institutional Review Board of Xinhua hospital approved this project (XHEC-C2017-108-2).

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' Contributors

LZ and JYN designed the study. LZ coordinated the study. YZ and JYN enrolled the participants and arranged informed consent from the participants and drafted of the manuscript. LJW and CCZ provided care for participants and checked the questionnaires. YC and CCZ conducted the test weighing and checked the breast milk volume and conducted the breast pump types cross over. LZ and YZ did the data analyses including statistical analyses. All authors critically reviewed the report. LZ had full access to all of the data in this study and take responsibility for the integrity of the data and accuracy of the data analyses.

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Figures

Figure 1

Participants flowchart Hand stands for hand expression if required and the infants were breastfed directly; sequent stands for sequential breast pumping; simult stands for simultaneous breast pumping; an inset graph for detailed cross over of breast pumps was also provided.

Figure 2

Time for breastfeeding initiation in survival analysis Breastfeeding initiation, also known as colostrum appearance in this study, was viewed as an event; successful breastfeeding initiation defined as events=1; VD, vaginal delivery; C-sect, cesarean section; (A) breastfeeding initiation in hand expression, sequential and simultaneous pumping; (B) breastfeeding initiation in subgroups of delivery mode (VD vs C-sect) of three groups; (C) comparison between two delivery mode across all three groups;

Figure 3

Breast milk volume expressed at 3 days and 6 weeks Breast milk volume in hand expression group was estimated through test weighing of transferred milk through infants' sucking, strictly speaking it was not expressed; the mere difference in three groups were the methods of breast expression without infant sucking, the infant should be direct breastfed or indicated otherwise;

Figure 4

Breast pumps cross over at 6 weeks. The upper panel displayed the breast milk volume in two periods of pumping in individual in two different pattern of shift, namely from sequential to simultaneous pumping or vice versa; the green dots represented the sequential pumping, the orange dots for simultaneous pumping; the lower panel provided the averaged levels of each groups in each period; sim, simultaneous pumping; seq, sequential pumping;

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