

Manual Method vs Breast Pump for Breast Milk Expression in Mothers of Preterm Babies During First Postnatal Week: *A Randomized Controlled Trial*

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Objectives: To compare breast milk volume between manual method and breast pump expression in mothers of preterm infants at different time point of first week.

Design: Randomized controlled trial.

Setting: Postpartum ward of Obstetrics department and tertiary level neonatal intensive care unit (NICU) in a single institution in Orissa between October, 2020 and May, 2021.

Participants: Mothers who delivered before 34 completed weeks of gestation.

Interventions: Manual breastmilk expression (ME) group using Marmet technique and breast pump milk expression (PE) group using pigeon manual breast pump, initiated milk expression within one hour of delivery.

Outcome measures: Expressed breast milk (EBM) volume in mothers of preterm infants at different time point of first week,

and cumulative milk volume.

Results: Out of 170 mothers (83 PE and 87 ME group), 7-days milk volume data was available for 137 (71 ME and 66 PE) mothers. In per protocol analysis for 126 mothers (63 in each group), the median (IQR) EBM volume on day 2 and day 7 of ME and PE groups were similar [10 (5,20) vs 12 (5,28), $P=0.10$] and [280 (220-356) vs 280 (220-360), $P=0.66$]. The median (IQR) cumulative EBM volume over first 7 days in ME group was not significantly different from PE group [733 (593-995) vs 848.5 (571-1009)] $P=0.55$. A similar number of mothers in the PE and ME group [56 (88.9%) vs 58 (92%); $P=0.14$] provided exclusive breast milk for their neonates during the first week. Similar results were found on intention to treat analysis.

Conclusion: EBM volume expressed was comparable between mothers expressing manually or with breast pump.

Key words: Lactation, Low birthweight, Nutrition, Volume.

Mothers own milk is always prioritized for enteral nutrition of preterm neonates [1]. However, premature delivery is associated with immature mammary gland, delayed onset of lactogenesis phase II, lack of physiologic breast suckling and presence of maternal stress, resulting in low milk yield in initial days [2]. Early initiation of milk expression within one hour of delivery is an important dimension for availability of breast milk [3,4]. Manual hand expression is a standard practice for milk availability, and breast pump is used as a rescue modality during lactation failure. Increased maternal comfortness during milk expression favors the use of breast pump [5,6].

The milk production in mothers of preterm babies is a complex physiological phenomenon, influenced by timing and type of milk expression. There is limited literature regarding utility of breast pump from early postpartum period for availability of colostrum and long term milk supply. Considering the need of mother's own milk for aggressive enteral nutrition, the objective of the present study was to determine the efficacy of exclusive pump expression in mothers of preterm babies compared to

manual expression for availability of expressed breast milk (EBM) volume when initiated within one hour of delivery.

METHODS

This was a non-blinded parallel group randomized control trial conducted in the postpartum ward of the obstetrics department and tertiary level neonatal intensive care unit (NICU) of our hospital between October, 2020 and May, 2021. All mothers delivering a live baby before 34 weeks of completed gestation, except mothers with recent breast surgery or any contraindications to breastfeeding, were eligible to participate in the study. The study was conducted after approval from the institutional ethics committee. Mothers with gestational age <34 week (as per last menstrual period or first trimester antenatal ultrasound), when planned for cesarean section or proceeding for vaginal delivery, were recruited in the study after taking written informed consent. All recruited mothers were re-counselled about advantages of breastmilk and need of breast milk expression within one hour of delivery, and then randomized into the two groups in the ratio 1:1 viz., Manual breastmilk expression (ME) group and Breast pump milk expression (PE) group.

Computer generated randomization was done and group assignment was placed in serial number for the calculated sample size; allocation concealment was done through opaque sealed envelope, that were opened prior to delivery. A non-electrical (pigeon) manual breast pump was provided to all mothers allocated to the PE group, immediately after delivery, which was free of charge for the first 7 days of postpartum period. Breast pump was autoclaved after each use. The Marmet technique was demonstrated to mothers allocated to the ME group. Mothers of both groups were assisted by delivery room nursing staffs and lactation educators for breast milk expression within one hour of delivery irrespective of the feeding status of their neonate. Each mother was explained the technique for milk expression through an educational video, verbal instruction, and hands-on support during initial three to four sessions of milk expression. Pumping every 2-3 hours with no more than a 5-hour break during the night (minimum 6 cycles a day for a minimum of 15 minutes each) was the scheduled frequency of the milk expression for mothers of both groups. The evening and night shift nursing staffs assisting in the study had ensured compliance with assigned milk expression method by monitoring mothers twice during their duty hours.

Each session comprised of sequential single breast milk expression with the manual pump (pigeon) in PE or Marmet technique in ME after maternal self or assisted breast massage. Milk was collected in a sterilized container and milk volume was measured with the help of syringe. A written log document 'milk diary' was maintained by all mothers that contained the time of expression, method of expression, and the milk volume obtained at each session throughout the initial seven postnatal days. Those mothers who failed to express at least three sessions per 12 hours, were counseled by a lactation nurse educator in a face-to-face session or telephonically under guidance of the principal investigator. During the non-availability of breast milk as per baby needs, pasteurized donor breast milk was used for enteral nutrition. Mothers were not given galactogogues during this period, irrespective of milk output. Participants were asked to exclusively use the assigned method of expression for the first 7 days after baby birth, and thereafter mothers of each group were free to choose any one or both of the methods for milk expression. Kangaroo mother care was provided to preterm neonates who were hemodynamically stable and not requiring intensive care management. The EBM volume on different postnatal days, cumulative EBM volume over first postnatal week of ME and PE were compared.

Maternal characteristics such as age, mode of conception, parity, educational qualification, working status, socioeconomic status (Kuppuswamy scale) were

documented in a structured form. Maternal health status during pregnancy including gestational diabetes, hypertension, thyroid disorders, premature rupture of membranes, antenatal steroids was collected from maternal case records. Mode of delivery, initial timing of milk expression, frequency of milk expression was strictly monitored by designated delivery room nursing staff and postnatal ward nurse educator. Neonatal demographic characters like birthweight, gender, gestational age and type of feeding were recorded. Enteral nutrition of preterm neonates including trophic feeding and feed advancement were guided by NICU preterm feeding protocol.

In a previous RCT, comparing expressed breast milk volume between breast pump vs hand expression, the mean (SD) breast milk volume over 6 days pumping in group were 631.7 (426) mL and 419.6 (290.4) mL, respectively [7]. The expected sample size with equal number of cases in both arms, with a power of 90% at 99% confidence interval, was calculated to be 176. We recruited 170 participants during the study period (time allowed for student dissertation). Total 126 (63 in ME and 63 in PE) participants remained after drop out beyond randomization, this sample size satisfies 90% power with 95% confidence interval for this study purpose.

Statistical analysis: Comparison of EBM between two groups has been performed using Mann Whitney U test. Fisher exact test/Chi-square test has been used for comparing categorical variables between the groups. Both intention to treat analysis and per protocol analysis were done. Mothers whose 7 postnatal days expressed milk volume in ME and PE group were available were included for intention to treat analysis. A P value <0.05 was considered as statistically significant, and data were analyzed by SPSS version 25.0.

RESULTS

During the study period, a total of 170 preterm mothers with gestational age <34 weeks were delivered. After antenatal counseling and randomization, 83 mothers were allocated to PE group and 87 mothers in ME group. The complete seven postnatal days expressed milk volume data available in 71 mothers in ME and 66 mothers in PE group were analyzed by intention to treat analysis. Data of 63 mothers in ME group and 63 in PE group were subjected to per protocol analysis (**Fig.1**).

Total 146 preterm neonates were delivered from 126 mothers (40 being twin pregnancy). The mean (SD) gestation age and birthweight of neonates were 31.3 (2.5) weeks and 1381.6 (314.4) grams, respectively. Among these, 78 (53.4%) were females, and 84 (57.5%) neonates were delivered vaginally. Maximum neonates delivered

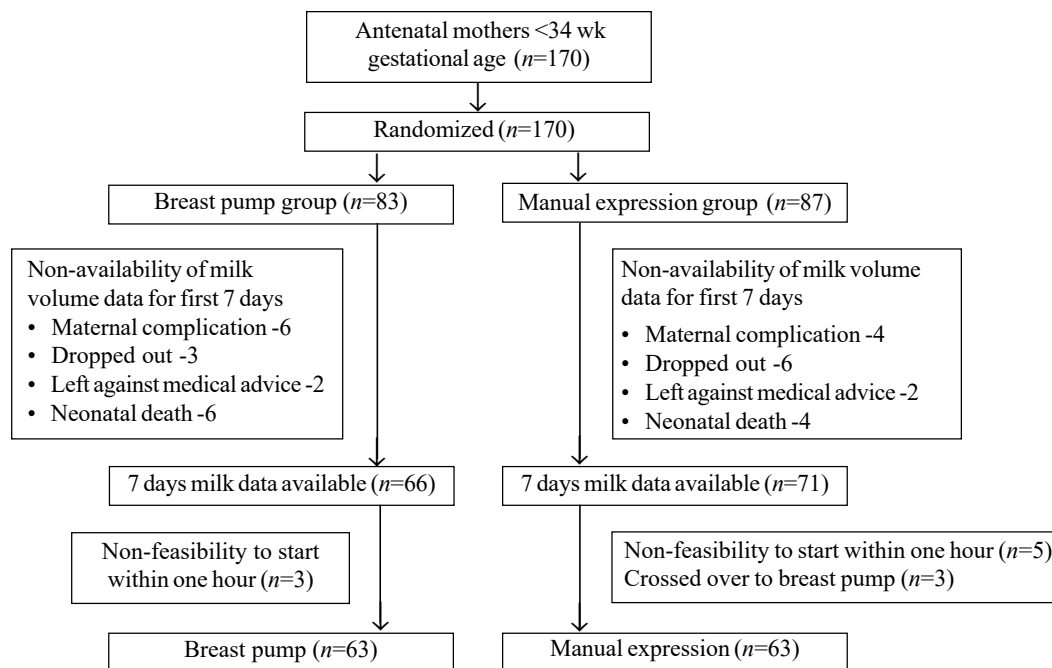


Fig. 1 Study flow diagram.

were between gestation age of 32-34 weeks (51.2%), followed by 28-32 weeks (33.7%).

The baseline maternal characteristics were comparable between the two groups (**Table I**). Both ME and PE groups were initiated with exclusively expressed breast milk on median (IQR) postnatal day 2 (1,2). The number of neonates receiving exclusive breast milk within first postnatal week in ME and PE groups were 56 (88.9%) and 58 (92%), respectively in per protocol analysis. The median EBM volume on different postnatal days and cumulative EBM of first postnatal week were comparable between ME and PE groups by both per protocol and intention to treat analysis (**Table II**).

DISCUSSION

In this study, with early initiation of milk expression using either manual or pump method, the availability of cumulative EBM volume over first postnatal week were similar. Majority of neonates (90%) in both groups were fed mother's own milk exclusively, and there were no significant difference in EBM volume on different postnatal days between the groups, for availability of colostrum and further enteral feed advancement.

The maternal demographic parameters, pregnancy related maternal morbidities, antenatal steroid exposure, frequency of milk expression per day and practice of KMC, which are known confounders towards milk production, were comparable between both groups [8,9].

Early milk expression behaves as a priming of breast tissue, increases hormonal production and influences lactogenesis [10]. The average EBM on day 2 as colostrum, day 7, and cumulative EBM during first postnatal week in this study is consistent with Parker, et al. [4] with initiation of milk expression within one hour of delivery. In comparison to a previous study from this center [11], the available EBM by seventh postnatal days was much higher, with introduction of earlier milk expression. Similarly, in a quality improvement study [12], the day 7 mothers' own milk volume in the intervention phase increased more than three-folds compared to observation period with prioritizing of early initiation of milk expression.

In a cross over study [13], higher volume of breastmilk was obtained through breast pump compared to manual expression and mothers preferred pump method in first postnatal week and manual method subsequently. Similarly, the EBM volumes in both electric and non-electric pump group were significantly higher than hand expression in a multicentric randomized controlled trial in Africa [7]. In another randomized controlled trial, where milk expression was initiated within six hours of birth, the cumulative EBM in first 7 postpartum days was significantly higher in electric pump group compared to manual expression among mothers of very low birth weight neonates [14]. However, in a randomized cross over study of preterm mothers, where milk expression was initiated after six hours of baby birth, more EBM volume was

Table I Maternal Characteristics in Manual Expression and Breast Pump Expression Groups

Maternal characteristics	Manual expression (n=87)	Breast pump (n=83)
Gestational age (wk) ^a	31.0 (2.57)	31.5 (2.45)
<i>Pregnancy</i>		
Singleton	67 (77)	57 (68.7)
Multiple	20 (23)	26 (31.3)
Primigravida	41 (47.1)	49 (59)
<i>Mode of delivery</i>		
Vaginal	57 (65.5)	50 (60.2)
Caesarean	30 (34.5)	33 (39.8)
<i>Education</i>		
Less than 10th grade	43 (49.4)	38 (45.8)
10th-12th grade	19 (21.9)	15 (18.1)
Graduate	14 (16.1)	20 (24.1)
Postgraduate	11 (12.6)	10 (12)
<i>Socioeconomic status (Kuppuswamy scale)</i>		
Upper	9 (10.3)	5 (6)
Upper Middle	28 (32.2)	35 (42.2)
Lower Middle	32 (36.8)	24 (28.9)
Upper Lower	17 (19.5)	14 (16.9)
Lower	1 (1.1)	5 (6)
<i>Occupation</i>		
Homemaker	72 (82.8)	69 (83.1)
Working	15 (17.2)	14 (16.9)
Gestational diabetes	17 (19.5)	16 (19.3)
Thyroid disorder	19 (21.8)	12 (14.5)
PIH	25 (28.7)	28 (33.7)
Cardio-respiratory disease	2 (2.2)	3 (3.6)
PPROM	26 (29.9)	24 (28.9)
Antenatal steroids	54 (62.1)	56 (67.5)
Kangaroo mother care	14 (16.1)	16 (19.2)

Values in no. (%) or ^amean (SD). PPROM: Preterm premature rupture of membrane; PIH: Pregnancy induced hypertension. All $P > 0.05$.

obtained using manual expression over electric breast pump during early postpartum period [15]. The discrepancy could be explained by timing of initiation of milk expression, type of breast pump used, and the preterm maternal population characteristics. The advantage of early expression could nullify the benefit of pump, and hence timing of expression should be more prioritized towards availability of EBM.

To the best of our knowledge, this is the first randomized control trial comparing breast pump and manual expression, where sample recruitment and randomization was done prior to delivery, and milk expression was initiated within one hour of birth. The expressed milk volume is influenced by types of pump such as single or simultaneous pumping, electric versus foot-operated or manual pump, bilateral or single electric pump [16]. In this study, manual breast pump was used, and hence results may not be generalizable to other pump types. The study was conducted during the COVID-19 pandemic, so there were many mothers who were counseled virtually rather than face-to-face.

The aggressive enteral nutrition practice for preterm neonates is crucial in early postnatal days. As hand expression is as good as expression by manual pump, we advocate to initiate milk expression, using either manual or pump method at the earliest period after delivery to maximize breast milk for preterm infants. The decision regarding method for preterm milk expression during initial days may be based on maternal choices. Antenatal breast milk counselling and provision of lactation support immediately after birth is the need of the hour.

Ethics clearance: IEC, KIMS Hospital; No. KIMS/KIIT/IEC/521/2020 dated Dec 08, 2020.

Table II Expressed Breast Milk Volume (in mL) in Manual Expression and Breast Pump Expression Groups of Mothers of Preterm (<34 week) Neonates in First Postnatal Week

Postnatal days	Intention to treat analysis			Per protocol analysis		
	Manual expression (n=71)	Breast pump expression (n=66)	P value	Manual expression (n=63)	Breast pump expression (n=63)	P value
Day-1	2 (0.5, 5)	3.5 (1, 8.5)	0.09	2 (1, 6)	4 (1, 9)	0.06
Day-2	10 (5, 18)	11 (5, 27.5)	0.32	10 (5, 20)	12 (5, 28)	0.10
Day-3	40 (30, 50)	46 (35, 64.5)	0.09	40 (34, 52)	47 (39, 65)	0.10
Day-4	80 (55, 110)	86.5 (60, 113.5)	0.28	85 (65, 110)	90 (65, 115)	0.20
Day-5	120 (86, 185)	137 (90, 185.25)	0.46	120 (90, 186)	140 (94, 186)	0.50
Day-6	185 (145, 255)	200 (141.5, 275)	0.59	190 (150, 256)	210 (150, 275)	0.70
Day-7	270 (205, 347)	275 (217.5, 352.5)	0.49	280 (220, 356)	280 (220, 360)	0.66
Milk volume ^a	703 (593, 935)	759 (571, 1002)	0.56	733 (593, 995)	848.5 (571, 1009)	0.55

Data in median (IQR). ^aCummulative milk volume.

WHAT IS ALREADY KNOWN?

- Breast pump is used as a rescue modality during lactation failure with manual expression in preterm mothers.

WHAT THIS STUDY ADDS?

- With early milk expression, manual method is comparable with pump expression for availability of breast milk in preterm mothers.

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REFERENCES

1. Cleminson JS, Zalewski SP, Embleton ND. Nutrition in the preterm infant: what's new? *Curr Opin Clin Nutr Metab Care.* 2016;19:220-5.
2. Cregan MD, De Mello TR, Kershaw D. Initiation of lactation in women after preterm delivery. *Acta Obstet Gynecol Scand.* 2002;81:870-7
3. Furman L, Minich N, Hack M. Correlates of lactation in mothers of very low birth weight infants. *Pediatrics.* 2002; 109:e57.
4. Parker LA, Sullivan S, Krueger C, Mueller M. Association of timing of initiation of breastmilk expression on milk volume and timing of lactogenesis stage II among mothers of very low-birth-weight infants. *Breastfeed Med.* 2015;10:84-91.
5. Hill PD, Aldag JC, Chatterton RT, Zinaman M. Comparison of milk output between mothers of preterm and term infants: the first 6 weeks after birth. *J Hum Lact.* 2005;21:22-30.
6. Clemons SN, Amir LH. Breastfeeding women's experience of expressing: a descriptive study. *J Hum Lact.* 2010;26: 258-65.
7. Slusher T, Slusher IL, Biomdo M, et al. Electric breast pump use increases maternal milk volume in African nurseries. *J Trop Pediatr.* 2007;53:125-30.
8. Suman RP, Udani R, Nanavati R. Kangaroo mother care for low birth weight infants: a randomized controlled trial. *Indian Pediatr.* 2008;45:17-23.
9. 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.
10. Pang WW, Hartmann PE. Initiation of human lactation: Secretory differentiation and secretory activation. *J Mammary Gland Biol Neoplasia.* 2007;12:211-21.
11. Panda SK, Sahoo K, Jena PK, et al. Availability of breast milk for preterm neonates by gestational age during NICU stay. *J Child Sci.* 2021;11:e227-e232.
12. Sethi A, Joshi M, Thukral A, et al. A quality improvement initiative: improving exclusive breastfeeding rates of preterm neonates. *Indian J Pediatr.* 2017;84:322-25.
13. Paul VK, Singh M, Deorari AK, et al. Manual and pump methods of expression of breast milk. *Indian J Pediatr.* 1996; 63:87-92.
14. Lussier MM, Brownell EA, Proulx TA, et al. Daily breastmilk volume in mothers of very low birth weight neonates: A repeated- measures randomized trial of hand expression versus electric breast pump expression. *Breastfeed Med.* 2015;10:312-7.
15. Ohyama M, Watabe H, Hayasaka Y. Manual expression and electric breast pumping in the first 48 h after delivery. *Pediatr Int.* 2010;52:39-43.
16. Becker GE, Smith HA, Cooney F. Methods of milk expression for lactating women. *Cochrane Database Syst Rev.* 2016;9:CD006170.