"VOLUME OF EXPRESSED BREAST MILK BY MANUAL EXPRESSION VS ELECTRIC BREAST PUMP IN MOTHERS OF LOW BIRTH WEIGHT BABIES–A RANDOMISED CONTROLLED TRIAL" AT KLE'S DR PRABHAKAR KORE HOSPITAL & MRC, BELAGAVI."

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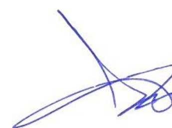

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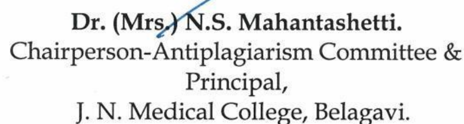

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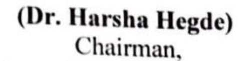

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LIST OF ABBREVATIONS

NHSR	National Health Statistics Report
LBW	Low Birth Weight
WHO	World Health Organization
UNICEF	United National International Children's Emergency Fund
MEM	Manual Expression Method
EBM	Electric Breast Pump Method
NEC	Necrotizing Enterocolitis
NFHS	National Family Health Survey
EBF	Exclusive Breastfeeding
DHA	Docosahexaenoic Acid
IGF	Insulin-Like Growth Factors
HMO	Human Milk Oligosaccharides
LCPSFA	Long-Chain Polyunsaturated Fatty Acids
ARA	Arachidonic Acid
EGF	Epidermal Growth Factor

TGF-B1 AND TGF-B2	Transforming Growth Factor
IGF-1, IGF-2	Insulin Like Growth Factor
VEGF	Vascular Endothelial Growth Factor
NGF	Nerve Growth Factor
KMC	Kangaroo Mother Care
VLBW	Very Low Birth Weight
NICU	Neonatal Intensive Care Unit
LSCS	Lower Segment Cesarian Section
GDM	Gestational Diabetes Mellitus
HTN	Hypertension
NVD	Normal Vaginal Delivery
IUGR	Intrauterine Growth Restriction
PROM	Premature Rupture Of Membranes
IQR	Interquartile Range
APGAR SCORE	Appearance, Pulse, Grimace, Activity And Respiration Score

ABSTRACT

Background: Research comparing electric breast pumps to manual expression in terms of milk volume and composition is limited in India.

Aim & Objectives: To study the volume of breast milk expressed by manual expression vs electric pump in mothers of low-birth-weight babies. To compare the composition of breast milk with the method of expression (manual expression vs electric breast pump).

Methods: This is the Randomized Controlled Trial study comparing the EBP and ME. Maternal and neonatal baseline data, including sociodemographic information, pregnancy-related health conditions, and neonatal characteristics, were collected using a pre-validated questionnaire. Eligible mothers were randomly assigned to either the **Manual Expression Group (ME)** or the **Electric Breast Pump Expression Group (EPE)** using computerized randomization with allocation concealment through opaque sealed envelopes. Milk expression was initiated within one hour post-delivery and continued for seven days, with six sessions per day, each lasting 10–15 minutes. Expressed milk volume was measured and recorded for each session. On Day 4, a sample was analyzed for macronutrients (energy, carbohydrates, proteins, and fats) using mid-infrared spectroscopy. Infants were monitored until discharge, with weight and feeding type documented at discharge.

Results: The mean age of mothers was 26.29 years, with similar educational and socioeconomic backgrounds across both groups. Primigravida rates were significantly higher in the ME group (47%) than in the EPE group (30.7%, p=0.013). Maternal complications, fetal distress, malpresentation, and failed induction rates were comparable. However, IUGR was absent in the ME group but present in 5.9% of the

EPE group (p=0.011). LSCS history was higher in the EPE group (15.8% vs. 7%), and PROM/PPROM was more frequent in the ME group (10% vs. 5.9%). The mean gestational age was 34.7 weeks. Birth weight and sex distribution were similar, but the EPE group had a significantly higher mean total milk volume over seven days (667.2 mL vs. 507.3 mL, p<0.001). Milk volume differences were not significant on Days 1-2 but became significant from Day 3 onward. the per-protocol analysis also showed consistently higher milk expression in the EPE group (p<0.05). Multivariate analysis identified factors positively influencing milk volume, including maternal age >30 years (p=0.009), higher education (p=0.010), employment (p=0.012), and primigravida status (p=0.026). The nutritional composition of breast milk (carbohydrates, proteins, and fats) was nearly identical across both groups. At discharge, infants in the EPE group had significantly higher average weights (2.58 kg vs. 2.18 kg, p=0.007). Direct breastfeeding was more common in the EPE group (p=0.02), while spoon feeding was slightly higher in the ME group (p=0.04). The combined DBF+SF outcome was similar (p=0.05).

Conclusion: The RCT demonstrated that electric breast pumps produced a significantly higher milk volume (667.2 mL) compared to manual expression (507.3 mL, p<0.001). While the macronutrient composition of breast milk remained similar between both groups, neonates in the electric pump group showed better weight gain at discharge due to the increased milk volume received. The study recommends multicentric long-term follow-ups to assess the effects of different breast pumps on infant growth, immune function, and cognitive development.

Keywords: Electric breast Pump, Manual Expression, Breast Milk, Volume of breast milk, Composition of breast milk.

CONTENTS

SR. NO.	TOPIC	PAGE NO.
1.	INTRODUCTION	1-3
2.	OBJECTIVES	4
3.	REVIEW OF LITERATURE	5-16
4.	MATERIALS AND METHODS	17-22
5.	RESULTS	23-45
6.	DISCUSSION	46-59
7.	CONCLUSION	60
8.	SUMMARY	61-72
9.	BIBLIOGRAPHY	73-82
10.	ANNEXURES	83-98
	ANNEXURE I – CONSENT FORM	83-86
	ANNEXURE II – PROFORMA	87-94
	ANNEXURE III: PHOTOGRAPHS	95-97
	ANNEXURE III – MASTER CHART	98

LIST OF TABLES

S. NO	DESCRIPTION	PAGE.NO
1.	SOCIO-DEMOGRAPHIC PROFILE	26
2.	MATERNAL CHARACTERISTICS	29
3.	BIRTH CHARACTERISTICS	32
4.	MANUAL EXPRESSION VS ELECTRIC BREAST PUMP MILK EXPRESSION-INTENTION TO TREAT ANALYSIS	33
5.	TOTAL VOLUME OF MILK BY MANUAL EXPRESSION VS ELECTRIC BREAST PUMP MILK EXPRESSION-INTENTION TO TREAT ANALYSIS	34
6.	MANUAL EXPRESSION VS ELECTRIC BREAST PUMP MILK EXPRESSION- PER PROTOCOL ANALYSIS	36
7.	TOTAL MILK VOLUME IN EACH DAY BETWEEN ME GROUP AND EPE GROUP	37
8.	UNIVARIANT ANALYSIS BETWEEN THE GROUPS	39
9.	COMPARISON OF TOTAL VOLUME OF MILK EXPRESSION FROM BREAST PUMP GROUP VS MANUAL EXPRESSION GROUP SOCIO DEMOGRAPHIC STATUS, MATERNAL HISTORY AND BIRTH HISTORY	41
10.	DIFFERENCES IN THE COMPOSITION OF BREAST MILK BETWEEN THE GROUPS.	43
11.	COMPARISON OF WEIGHTS IN BOTH METHODS	44
12.	TYPE OF BREAST FEEDING	45

LIST OF FIGURES

S. NO	DESCRIPTION	PAGE.NO
1.	CONSORT DIAGRAM	24
2.	DISTRIBUTION OF METHOD OF BREAST MILK EXPRESSION	25
3.	DISTRIBUTION OF MOTHERS EDUCATION	27
4.	DISTRIBUTION OF MOTHERS OCCUPATION	28
5.	SOCIOECONOMIC STATUS OF STUDY GROUPS	28
6.	DISTRIBUTION OF ANTENATAL RISK FACTORS	30
7.	DISTRIBUTION OF MOTHERS GRAVIDA	31
8.	BOX PLOT	40

LIST OF PHOTOGRAPHS

PHOTO.NO	DESCRIPTION	PAGE.NO
1.	ESSAE-BS-250 ELECTRONIC WEIGHING SCALE USED FOR MEASURING WEIGHT	95
2.	HOSPITAL GRADE ELECTRIC BREAST PUMP	95
3.	MILK CONTAINERS	96
4.	STERIFEED PASTEURIZER	96
5.	REFRIGERATION OF PASTEURIZED DONOR HUMAN MILK	97
6.	DEEP FREEZER FOR STORAGE OF PASTEURIZED DONOR HUMAN MILK	97

INTRODUCTION

Breast milk is universally acknowledged as the optimal source of nutrition for the adequate growth and development of infants. The World Health Organization (WHO) ,UNICEF and global health organisations advocate exclusive breastfeeding for the first six months of life, followed by continued breastfeeding with appropriate complementary foods for two years (1,2). The advantages of breastfeeding extend beyond basic nutrition, contributing to cognitive development, long-term health, and reduced risk of infection (3). While breastfeeding is crucial for all infants, it is particularly vital for preterm and low birth weight (LBW) babies, who are at a higher risk of mortality, infections, and developmental delays (4), and it provides a balanced composition of carbohydrates, proteins, fats, vitamins, and minerals tailored to the infant's needs. It contains immunoglobulins, lactoferrin, and other bioactive components that enhance immunity and protect against infections (5). Breastfeeding has been associated with lower risks of respiratory and gastrointestinal infections, allergies, and chronic diseases such as diabetes and obesity(4). For mothers, breastfeeding reduces the risk of postpartum haemorrhage, breast and ovarian cancers, and aids in maternal bonding and psychological well-being (2). According to the National Health Statistics Report (NHSR) 76.3% of preterm babies are breastfed within one hour of birth (6). In India, the National Family Health Survey (NFHS-5) reports that only approximately 41% of infants are breastfed within the first hour of birth (7). In Karnataka, the rate of early initiation of breastfeeding is approximately 46%, whereas in Bangalore, urbanization and maternal employment pose additional barriers to breastfeeding, leading to increased reliance on expressed milk (7).

Preterm and LBW infants (born before 37 weeks of gestation or weighing less than 2500 grams) are highly vulnerable to infections, necrotizing enterocolitis (NEC), sepsis, and developmental challenges (8). Breast milk, is crucial in providing immunological protection, enhancing gut maturation, and improving neurodevelopmental outcomes. Studies suggest that breast milk significantly reduces the risk of NEC, retinopathy of prematurity, and other complications (8). Preterm breast milk contains higher concentrations of proteins, sodium, and immunological factors compared to term breast milk, making it an irreplaceable source of nutrition for these infants (9). Early initiation of breastfeeding in preterm infants helps establish milk supply and provides essential nutrients for growth and immunity. The process of lactogenesis, which refers to milk production, occurs in two main stages (10). Lactogenesis I commences during gestation as the mammary glands initiate the production of colostrum, which is the first milk rich in nutrients. After childbirth, the early initiation of breastfeeding triggers Lactogenesis II, as prolactin promotes the production of milk, while oxytocin facilitates the ejection of milk. The drop in progesterone further enhances milk secretion, ensuring increased supply (11).

There are several methods for expressing breast milk, including hand or manual expression, electric breast pumps(12).Manual milk expression is a traditional and economical method, especially in areas with limited resources. It is a practical choice for mothers as it does not require any special equipment and can be done at any time. However, the drawbacks of manual expressions include being time-consuming and causing hand fatigue (13).

Various breast pump types are available, including manual, battery-powered, and electric models (14). Electric pumps offer superior speed and efficiency but are costlier and require a power source. Hospital-grade electric breast pumps, while

highly effective for frequent use, are expensive and less portable (14). Manual pumps are cost-effective and portable but less efficient, typically extracting 1-3 ounces per session. Battery-operated pumps provide enhanced convenience compared to manual pumps but are slower than electric models, producing 2-4 ounces per session. Electric breast pumps demonstrate high efficacy, yielding 3-6 ounces or more per session, but are expensive, power-dependent, and may lack portability (14).

The efficiency of these different techniques for expressing breast milk varies, as does the amount of milk expressed .Several studies indicates that electric breast pumps generally express higher milk volumes per session due to consistent suction power and mimicry of infant sucking patterns (15).Manual expression, while offering greater control and flexibility, is associated with lower milk output and increased time and effort requirements. However, studies suggest that manual expression combined with breast massage can enhance milk ejection and improve overall supply (16).

Most of these studies are conducted in well-resourced settings , focusing on mothers who gave birth to preterm infants, with study durations ranging from 48 hours to one month, including observational studies. There are no well-designed studies comparing the efficacy of manual breast expression with electric breast pumps in low-resource settings, where access to electric pumps has now become feasible through the establishment of comprehensive lactation management centres. Gaps remain in understanding how different pumping methods influence the volume of breast milk expressed and the continuation of breastfeeding. Therefore to address these gaps ,we conducted the study with the objective to evaluate the volume of breast milk expressed by manual expression vs electric pump in mothers of low-birth-weight babies.

AIMS AND OBJECTIVES

Primary Objective:

- To study the volume of breast milk expressed by manual expression vs electric pump in mothers of low-birth-weight babies.

Secondary Objective:

- To compare the composition of breast milk with the method of expression (manual expression vs electric breast pump).

REVIEW OF LITERATURE

The expression of breast milk is an essential practice for mothers of low birth weight (LBW) infants, ensuring adequate nutrition and promoting neonatal health (17). Breast milk serves as the optimal nutritional source for newborns and infants, offering a distinctive blend of vital nutrients, antibodies, and bioactive substances that facilitate ideal growth and development (18). Its composition is easily digestible and adjusts to meet the evolving nutritional requirements of the infant. Breast milk is a dynamic and bioactive fluid uniquely tailored to meet an infant's nutritional and immunological needs. It contains a balanced composition of macronutrients, micronutrients, immune components, and growth factors essential for neonatal development (19). The World Health Organization (WHO) and UNICEF advocate for exclusive breastfeeding during the initial six months of life, after which they suggest the continuation of breastfeeding alongside suitable complementary foods for a minimum duration of two years. In 2024, the proportion of infants exclusively breastfed for the initial six months of life has increased to 48% worldwide, approaching the World Health Organization's target of 50% by the year 2025 (20). The Global Collective of Breastfeeding has set an ambitious target for 2030, aiming to achieve a breastfeeding initiation rate of 70%. Data collected from Global Collective survey conducted between 2016 and 2022 indicate that only 46% of newborns were breastfed within the first hour after birth, falling short of the established goal (21). According to the NFHS-5 (2019-21), the prevalence of preterm births (PTB) in India was estimated at 18%. This indicates that nearly one in five children were born before the completion of 37 weeks of gestation during this period (22). The NFHS-4 (2015-16) reported that 10% of births in Karnataka occurred within 18 months of the previous birth, which is a known risk factor for preterm deliveries (23).

Breastfeeding Practices:

Breastfeeding is crucial for the health and development of infants, especially those born preterm. The NFHS-5 provides data on various breastfeeding indicators:

- Early Initiation of Breastfeeding: In Karnataka, 56.3% of infants were breastfed within the first hour of birth, which is higher than the national average of 41.8% (24).
- Exclusive Breastfeeding (EBF) for the First Six Months: The rate of exclusive breastfeeding in Karnataka was 61%, an increase from 54.2% reported in NFHS-4. This is higher than the national average of 54.9% (24).

Advantages of Breast Milk

Breast milk enhances the immune system in preterm infants by supplying essential antibodies, lactoferrin, and white blood cells, thereby diminishing the likelihood of infections such as sepsis and necrotizing enterocolitis (NEC). Its composition is more easily digestible than that of formula, as it includes enzymes and proteins tailored for the needs of an immature digestive system. The elevated concentrations of DHA, vital fatty acids, and growth factors found in breast milk are crucial for cognitive and neurological advancement (25). Furthermore, it significantly reduces the risk of NEC, a severe intestinal condition frequently observed in preterm infants. Breast milk also contributes to improved pulmonary function by delivering bioactive substances that facilitate lung maturation and mitigate respiratory issues. It fosters weight gain and overall development by providing an optimal mix of calories, proteins, and fats (25). Additionally, breast milk promotes gastrointestinal health by stimulating the proliferation of beneficial bacteria, which helps to alleviate digestive

disorders and infections. Finally, skin-to-skin contact during breastfeeding plays a vital role in stabilizing heart rate, body temperature, and stress levels, thereby reinforcing the emotional connection between mother and child.

Composition and Nutrients of Breast Milk

Macronutrients in Breast Milk:

1. Proteins (0.9–1.2 g/100 mL)
    - Whey Proteins (60-70%): Includes lactoferrin (iron-binding, antimicrobial), α-lactalbumin (essential for lactose synthesis), and immunoglobulin A (IgA) (immune protection).
    - Casein (30-40%): Provides slow-digesting proteins for sustained nutrition.
    - Enzymes & Hormones: Lysozyme (antimicrobial) and insulin-like growth factors (IGFs) support digestion and growth.
2. Carbohydrates (6.7–7.8 g/100 mL)
    - Lactose: Main carbohydrate, providing 40% of the infant's energy and aiding calcium absorption.
    - Human Milk Oligosaccharides (HMOs): Over 200 varieties support gut microbiota, prevent pathogen adhesion, and modulate immunity.
3. Fats (3.2–4.0 g/100 mL)
    - Long-chain Polyunsaturated Fatty Acids (LCPUFAs): Docosahexaenoic acid (DHA) and arachidonic acid (ARA) are crucial for brain and retinal development.
    - Medium-chain and Short-chain Fatty Acids: Aid digestion and provide an energy source (25).

Micronutrients in Breast Milk:

1. Vitamins
    - Fat-soluble (A, D, E, K): Essential for vision, bone health, antioxidant activity, and blood clotting.
    - Water-soluble (B-complex, C): Support metabolism, neurological function, and immunity.
2. Minerals
    - Calcium and Phosphorus: Essential for bone development.
    - Iron and Zinc: Critical for immune function and cognitive growth.
    - Sodium, Potassium, and Magnesium: Maintain cellular homeostasis and metabolic functions (26).

Growth Factors in Breast Milk

Breast milk contains bioactive growth factors that promote intestinal maturation, immune system development, and overall infant growth. Key growth factors include:

1. Epidermal Growth Factor (EGF)
    - Promotes intestinal lining development and repair.
    - Protects against necrotizing enterocolitis (NEC) in preterm infants.
2. Transforming Growth Factor (TGF-β1 and TGF-β2)
    - Modulates immune response and reduces inflammation.
    - Plays a role in gut and respiratory system development.
3. Insulin-like Growth Factors (IGF-1, IGF-2)
    - Enhances muscle and skeletal development.
    - Supports neuronal growth and cognitive function.
4. Vascular Endothelial Growth Factor (VEGF)
    - Stimulates blood vessel formation, crucial for organ development.

5. Nerve Growth Factor (NGF)
   - Supports neuronal survival and brain development (27).

Various methods, including manual expression and electric breast pumps, have been explored to optimize milk yield, enhance breastfeeding success, and support lactation in mothers of preterm infants. This review synthesizes findings from multiple studies comparing these techniques and their impact on milk volume, efficiency, and maternal comfort.

Several strategies are employed to enhance milk supply in mothers of low-birth-weight babies, particularly when using manual expression or electric breast pumps. Frequent and effective milk removal is crucial, as regular breastfeeding or pumping stimulates prolactin release, promoting milk production. Combining hand expression with pumping has been shown to improve milk yield by enhancing oxytocin release and milk ejection. Breast massage before and during pumping can further aid in milk flow by reducing ductal resistance. Using double electric pumps increases efficiency by simultaneously draining both breasts, leading to higher milk output compared to single pumping. Additionally, ensuring adequate maternal hydration, nutrition, and rest supports overall lactation. Skin-to-skin contact with the baby, also known as kangaroo mother care, helps regulate milk production by triggering hormonal responses. Maintaining a relaxed environment and reducing stress through techniques like deep breathing or warm compresses can further optimize milk flow. Lactation counseling and support from healthcare providers play a key role in addressing concerns, ensuring proper pump usage, and reinforcing best practices for sustained milk supply.

To optimize and sustain exclusive breast milk supply for preterm babies, mothers should initiate milk expression within 1-2 hours after delivery and pump frequently (every 2-3 hours) to maintain supply. Skin-to-skin contact through Kangaroo Mother Care (KMC) enhances oxytocin release, promoting lactation. Proper hydration and a nutrient-rich diet with proteins and healthy fats support milk production. Using a hospital-grade double electric pump, along with breast massage and hand expression, maximizes milk output. Seeking guidance from lactation consultants helps address latching and supply concerns. Managing stress through relaxation techniques and ensuring adequate rest further supports sustained milk production.

Comparison of Milk Volume Expressed

Several studies have compared the milk volume expressed through manual expression and electric breast pumps. A randomized controlled trial conducted in India assessed the effectiveness of manual expression relative to breast pumps among mothers of preterm infants. The study included 170 mothers who delivered before 34 weeks of gestation, with 87 assigned to manual expression (ME) and 83 to breast pump expression (PE). The cumulative EBM volume over the first week was 733 mL in the ME group and 848.5 mL in the PE group. Furthermore, 92% of mothers in the ME group and 88.9% in the PE group provided exclusive breast milk to their neonates during the first week. These findings suggest that manual expression can produce milk volumes comparable to, or even exceeding, those achieved with breast pumps during the early postpartum phase (28). Similarly, the other study conducted a repeated-measures randomized trial comparing hand expression with electric breast pump expression among mothers of very low birth weight (VLBW) neonates. The study enrolled 41 mothers who delivered infants weighing ≤1500 g and measured

their daily breast milk volume over the first 14 days postpartum. The results showed that by day 7, the group using hand expression alongside electric pumping had a median daily milk volume of 493 mL, compared to 365 mL in the electric pump-only group. By day 14, the hand expression group produced a median volume of 621 mL, whereas the electric pump-only group produced 469 mL. These findings indicate that supplementing electric pumping with hand expression in the early postpartum period significantly enhances milk production in mothers of VLBW neonates . Meier et al. (2008) compared two hospital-grade electric breast pumps, highlighting variations in efficacy and maternal comfort. They noted that certain electric pumps enhanced milk removal efficiency, but combining manual techniques with electric pumping could further optimize milk output (29). Morton et al. (2009, 2012) reinforced these findings, emphasizing that integrating hand techniques with electric pumping improved both milk yield and caloric content (30) Da Silva et al. examined how different breast expression techniques influenced human colostrum macronutrient concentrations, finding that certain methods preserved more nutrients than others (30). Similarly, Fewtrell et al. studied the effectiveness of manual and electric pumps in mothers of both term and preterm infants, with results indicating that both methods, when properly utilized, support successful milk extraction (29, 30). Slusher et al. investigated the impact of electric breast pumps in African nurseries and concluded that they significantly increased maternal milk volume (31) Jones et al. conducted a randomized controlled trial comparing milk expression methods in preterm mothers and found that manual expression was particularly beneficial in the initial postpartum days when colostrum production was critical.

Studies comparing manual and electric breast pumps highlight differences in milk yield, comfort, and maternal preferences. Hopkinson et al. found that while a novel electric pump stimulated higher prolactin levels, a standard model was more efficient in milk extraction, with no significant impact on 24-hour milk production or long-term breastfeeding outcomes. Becker et al. reported that 72% of mothers preferred electric pumps, with double pumps increasing efficiency, though 38% experienced discomfort due to suction strength (41). Workplace constraints and hygiene challenges also influenced adherence. Ohyama et al. observed that manual expression yielded higher milk volumes than electric pumping in the first 48 hours postpartum, suggesting its effectiveness for early colostrum extraction. Hayes et al. noted that electric pumps facilitated higher milk output (94.3 mL vs. 75.6 mL for manual pumps) but required power and maintenance, making manual pumps preferable for portability (42). Gardner et al. demonstrated that infant-derived vacuum patterns improved comfort and milk ejection efficiency, while Mitoulas et al. highlighted variations in milk flow and composition with electric pumps, emphasizing the need for optimized settings. These studies underscore the importance of tailoring breast pump choices to individual needs for optimal lactation success (43).

Impact on Breastfeeding Duration and Exclusivity

The long-term impact of expression methods on breastfeeding exclusivity and duration has been widely studied. Jiang et al. conducted a prospective cohort study assessing early postpartum milk expression's influence on breastfeeding duration. Their findings indicated that early and effective milk expression, regardless of method, was associated with sustained breastfeeding. Mothers who initiated milk expression within the first 48 hours postpartum had a significantly higher likelihood of continuing breastfeeding at 6 months (65.3%) compared to those who did not

express early (48.6%). Additionally, the study observed that early milk expression was associated with a 1.7-fold increased probability of exclusive breastfeeding at 3 months postpartum (32).

The study by Zhou et al conducted an open label randomized controlled trial, compared the effects of three breast milk expression methods manual expression, electric pumping, and a combination of both on breastfeeding initiation, milk extraction, and exclusive breastfeeding rates. The findings showed that mothers using manual expression had a significantly higher rate of successful breastfeeding initiation (78.2%) compared to those using electric pumps (62.5%) or a combination method (71.4%). Additionally, manual expression resulted in greater milk yield within the first 48 hours postpartum (mean volume: 32.8 mL vs. 24.5 mL with electric pumping). At 6 weeks postpartum, the exclusive breastfeeding rate was highest in the manual expression group (68.9%) compared to the electric pump group (54.3%) and the combination group (60.7%). The study concluded that manual expression was more effective in the early postpartum period for establishing breastfeeding and maintaining exclusive breastfeeding rates (33).

The randomized trial by Flaherman et al. compared hand expression and electric breast pumping in mothers of term newborns with feeding difficulties. The study found that mothers who used hand expression were more likely to continue breastfeeding at 2 months postpartum (97% vs. 72% in the breast pump group). Additionally, hand expression led to significantly higher milk transfer in the first 24 hours (median volume: 7.6 mL vs. 5.4 mL with electric pumping). Mothers in the hand expression group also reported higher comfort levels (85% vs. 65%) and lower nipple pain scores. The study concluded that hand expression was a preferable method for early milk removal and breastfeeding continuation in mothers of term infants

experiencing feeding difficulties . The study by Ru et al. examined the effectiveness of exclusive pumping in achieving full lactation among mothers of preterm infants. The findings indicated that 78.6% of mothers who exclusively pumped were able to establish full lactation by the end of the first month postpartum. Also, the study reported that mothers who initiated pumping within 6 hours of delivery had significantly higher milk volumes at 2 weeks postpartum (482 mL/day) compared to those who started later (320 mL/day). By 8 weeks postpartum, 85.2% of the mothers maintained exclusive pumping with adequate milk supply, demonstrating that with frequent and effective pumping, full lactation can be successfully achieved even without direct breastfeeding (34).

Accessibility and Affordability of Breast Pumps

The accessibility and affordability of breast pumps impact their utilization among low-income mothers. The study by Hoyt-Austin et al. evaluated the impact of providing low-income women with a manual breast pump on milk expression and breastfeeding outcomes. The findings revealed that 72% of participants who received a manual pump used it regularly within the first month postpartum. 58% of these mothers reported expressing enough milk to meet their infant's needs, while 41% continued using the pump beyond 6 weeks postpartum. The study also noted that mothers who received lactation support alongside the pump had a 30% higher likelihood of continuing exclusive breastfeeding at 8 weeks compared to those who did not receive support. These results suggest that providing manual breast pumps to low-income mothers, especially with lactation counseling, can effectively support breastfeeding continuity (35). Slusher et al studied electric pump usage in African nurseries, concluding that electric pumps increased milk volume, particularly in settings with adequate lactation support. The findings indicated that mothers who used

electric breast pumps expressed 32% more milk per session compared to those using manual expression ($p < 0.01$). However, manual expression was preferred by 45% of mothers, citing reasons such as comfort, ease of use, and availability. Additionally, the study found that mothers who combined both methods (manual + electric) had the highest milk output, with an average increase of 18% compared to using a single method. These results highlight the importance of access to electric pumps in hospital settings while also recognizing the continued relevance of manual expression, particularly in resource-limited environments (36).

Best Practices in NICU Settings

The Canadian Paediatric Society (2023) reviewed breastfeeding and human milk provision in NICUs, emphasizing the importance of milk expression support in preterm infant care. Becker et al in a Cochrane review evaluated various milk expression methods and found that individualized support improved lactation success regardless of the method used (37). The study conducted by Bernabe-Garcia et al evaluated the effectiveness of four different manual breast pumps among mothers of preterm infants in a developing country. The findings indicated that the average milk volume expressed per session ranged from 26.5 mL to 38.2 mL, depending on the pump design. One specific manual pump model yielded 44% more milk compared to the least effective pump, highlighting the variation in pump efficiency. Mothers using ergonomically designed pumps reported 30% higher comfort levels and were more likely to continue expressing milk regularly. Pump suction strength and ease of use significantly influenced milk output, emphasizing the need for well-designed, accessible manual pumps in resource-limited settings. These findings suggest that not all manual pumps perform equally, and selecting the right model can enhance milk expression efficiency and maternal satisfaction (38). The study by Umesh L compared

breast pump versus manual method for breast milk expression in mothers of preterm infants during the first postnatal week. The key findings are the Mean milk volume expressed was significantly higher in the manual expression group (42.5 ± 8.3 mL per session) compared to the electric pump group (35.8 ± 7.9 mL per session). Mothers using manual expression-initiated lactation earlier, with 68% achieving sufficient milk output within 3 days, compared to 52% in the pump group. Manual expression resulted in lower breast discomfort scores (mean 2.1 ± 0.5 vs. 3.4 ± 0.6 in the pump group). Exclusive breastfeeding rates at one week were higher in the manual expression group (60%) compared to the pump group (47%). Maternal satisfaction was greater among those using the manual method, citing ease of use, comfort, and better milk drainage. These findings indicate that manual breast milk expression may be more effective and comfortable than electric pumps for mothers of preterm infants in the early postpartum period (39, 40, 43).

Conclusion

This study aims to compare the volume of milk expressed through manual expression versus electric breast pumps in mothers of low-birth-weight babies to provide evidence-based recommendations for optimal lactation support. While previous research highlights differences in milk volume, gaps remain in understanding the long-term impact of these methods on milk production, and breastfeeding success, particularly in resource-limited settings. By conducting a randomized controlled trial, this study seeks to bridge these gaps, offering valuable insights to improve neonatal nutrition strategies and support breastfeeding mothers in making informed choices based on their individual needs and circumstances.

MATERIALS AND METHODS

The RCT was conducted in the postnatal ward attached to the neonatal intensive care unit (NICU) of the Department of Paediatrics at Dr. Prabhakar Kore Charitable Hospital, a teaching hospital attached to Jawaharlal Nehru Medical College, Belagavi.

Study Design:

Randomized controlled trial

Study Duration

Between October 2023 and February 2025- 1 year 5 months

Study Place:

The randomized controlled trial was conducted in the postnatal ward attached to the neonatal intensive care unit (NICU), Department of Paediatrics at Dr. Prabhakar Kore Charitable Hospital, attached to Jawaharlal Nehru Medical College. Belagavi.

Source of Data:

Data were collected from mothers who delivered <37 weeks and had low birth weight babies (<2.5 kg) who were admitted to the neonatal intensive care unit in Dr. Prabhakar Kore Charitable Hospital in Belagavi..

Sample Size:

$$n = \frac{2S^2 (z_{1-\alpha} + z_{1-\beta})^2}{d^2}$$

where $z_{1-\alpha}$= Z -value for αlevel (2.58 at 1%αerror or 99% confidence)

$z_{1-\beta}$=Z -value for β level(1.037 at 15% β error or 85%power)

D=margin of error =103

S =pooled SD $=\frac{S1+S2}{2}$

Two Means-Hypothesis testing for two means (equal variances)

- standard deviation in 1st group S1 = 171
- standard deviation in 2nd group S2 =216
  - mean difference between 1st and 2nd group =103
  - effect size=0.532299741602
- Alpha Error (%)=1
- Power (%)=85
  - Sided=2

(n)=95 sample in each group

Selection Criteria:

Inclusion criteria:

- Mothers who delivered less than 37 weeks period of gestation(confirmed by USG/LMP)
- Mothers who delivered low birth weight babies (< 2.5kgs)
- Mothers of infants < 2.5kgs admitted to NICU

Exclusion criteria:

- Mothers who undergone recent breast surgery
- Mothers with any contraindications to breastfeeding include

  -those receiving high doses of antiepileptic ,antithyroid, antipsychotic, antimetabolite drugs or chemotherapeutic agents.

- Mothers who have been administered diagnostic or therapeutic radioactive isotopes
- Mothers with herpes simplex lesions on the breast
- Mothers engaged in substance abuse
- Mothers with active untreated tuberculosis

Institutional ethics clearance

Ethical clearance letter dated 28/04/2023,was obtained from JNMC ethics committee , Jawaharlal Nehru Medical College ,Belagavi, Karnataka

C.T.R.I registration:

This study was registered under the Clinical Trial Registry of India (registration number CTRI/2023/10/058298).

Data Collection Method

The study was conducted after obtaining approval from the institutional ethics committee. and CTRI registration. Written consent was obtained from the eligible mother prior to delivery.At enrolment, mothers were counselled regarding the benefits of breast milk within 1 h of delivery. Maternal and neonatal baseline data were collected using a pre-validated questionnaire. Sociodemographic information,

including socioeconomic status (as determined by the modified Kuppuswamy classification), educational and employment status of both parents, was obtained. Baseline data from the mother included maternal age and parity. Information on maternal health during pregnancy, such as gestational diabetes mellitus, gestational hypertension, anemia, and preterm premature rupture of membranes (PPROM), was also obtained.. Neonatal demographic data, including birth weight, sex, gestational age, mode of delivery, and antenatal risk factors for low birth weight, were obtained at birth .

Randomisation: Immediately following delivery, eligible mothers were randomly assigned to one of two groups using computerized randomization: the Manual Expression Group (ME) and the Electric Breast Pump Expression Group (EPE). Allocation concealment was ensured through the use of opaque sealed envelopes, which were opened immediately after delivery.

Intervention: The designated method of milk expression for the mothers was carried out by trained nurses and thoroughly explained to the participants. For mothers in the ME group, the Marmet technique was employed for breast milk expression following counseling, which was facilitated by a video demonstration (44). Mothers assigned to the EPE group utilized the electric breast pump (Ameda Pearl Electric breast pump). In both groups, milk expression initiated within one hour post-delivery. With the assistance of trained nurses, mothers expressed milk during six sessions per day (including both day and night, with a maximum of two sessions at night), each session lasting 10-15 minutes, over a period of seven postpartum days. Study personnel provided support by counselling and assisting mothers to express breast milk without difficulties. Each session of sequential single breast expression, using an electric breast pump in the EPE group and the Marmet technique in the ME group, was

conducted with the help of nursing staff in the delivery room, NICU, and human milk bank under the supervision of study personnel. The nursing staff on morning and night shifts assisted in milk expression and ensured compliance. Post-expression, the milk was collected and stored in a sterile container, and the volume was measured using a syringe. All data from each participant were recorded in a pre-test questionnaire. All mothers in the study were instructed to express their milk solely by the assigned methods for the first seven postnatal days. On Day 4, a sample of expressed milk was collected and analysed for macronutrients, including energy, carbohydrates, proteins, and fats, using mid-infrared spectroscopy. All infants were monitored until discharge, and their weight and type of feeding at discharge were documented.

Outcome

Primary Outcome:

- The total volume of breast milk expressed at the end of 7 postpartum days using manual expression versus an electric breast pump.

Secondary Outcomes:

- Comparison of the macronutrient composition of expressed breast milk between ME and EPE groups.
- Type of feeding in neonates at discharge – expressed breast milk–on spoon feeding or direct breastfeeding.
- Infant weight at discharge.

Statistical Analysis

Data obtained was coded, collected and stored in Microsoft Excel spreadsheet. Data was analyzed with the use of statistical software R version 4.4.0. and Microsoft Excel. The variables which were categorical were expressed by percentages and frequencies. Continuous variables were represented in mean ± SD/ median (min, max) form. The normality of variables was checked by Kolmogorov Smirnov test. Parametric tests were applied when data was adhered to a normal distribution, whereas nonparametric tests were utilized for data that did not follow the rule of normal distribution. Friedman's test was utilized to correlate the distribution of variables over different time points. Pairwise Wilcoxon test was used as post hoc analysis. Multivariate and Univariant analysis of milk volume and sociodemographic data was performed for intention-to-treat and per-protocol analysis. Mothers whose data on expressed milk volume for 7 postnatal days were not available were included in the intention-to-treat analysis. A probability value (P-value) of less than or equal to 0.05 at 95 % confidence interval was considered statistically significant.

RESULTS

The RCT was conducted in the postnatal ward attached to the neonatal intensive care unit (NICU) of the Department of Paediatrics at Dr. Prabhakar Kore Charitable Hospital, a teaching hospital attached to Jawaharlal Nehru Medical College, Belagavi, and 206 mothers of infants weighing less than 2.5 kg were considered for inclusion in the study. Following counselling, five mothers chose not to participate in the study. Of the remaining 201 mothers, 100 were assigned to the Electric Breast Pump group(EPE), while 101 were allocated to the Manual Expression (ME)group were equally distributed (Fig 1)

In the Electric Breast Pump Expression (EPE) group, data regarding the total milk volume for the initial seven days was unavailable for 22 mothers. Similarly, in the Manual Expression (ME) group, 13 mothers had missing data. This was attributed to maternal complications, participant dropouts, non-compliance with medical advice, and neonatal mortality. Complete data on total milk volume expressed over the first seven postnatal days were obtained for 79 mothers in the EPE group and 86 mothers in the ME group (Fig.2)

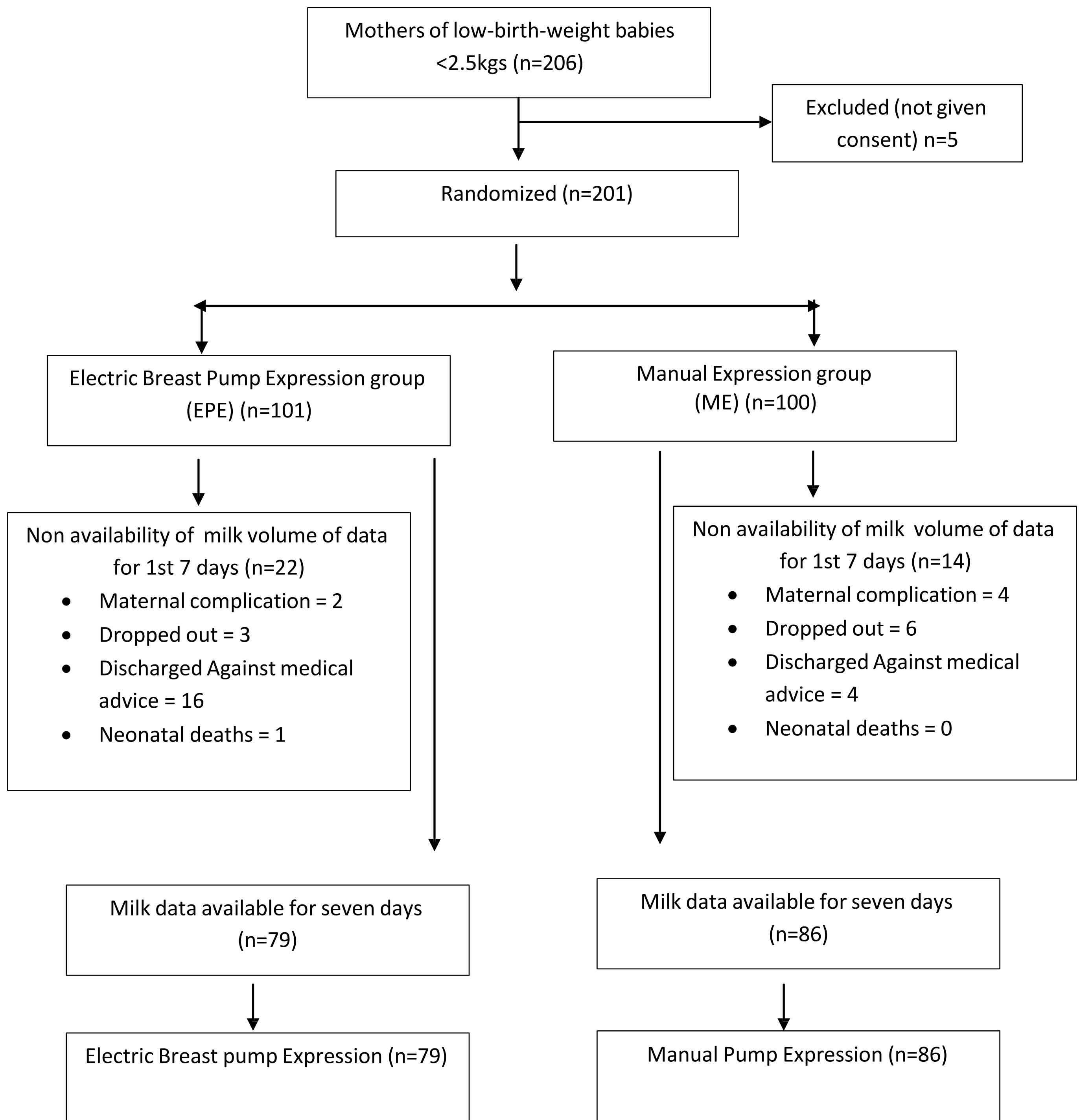

Figure 1: Consort diagram.

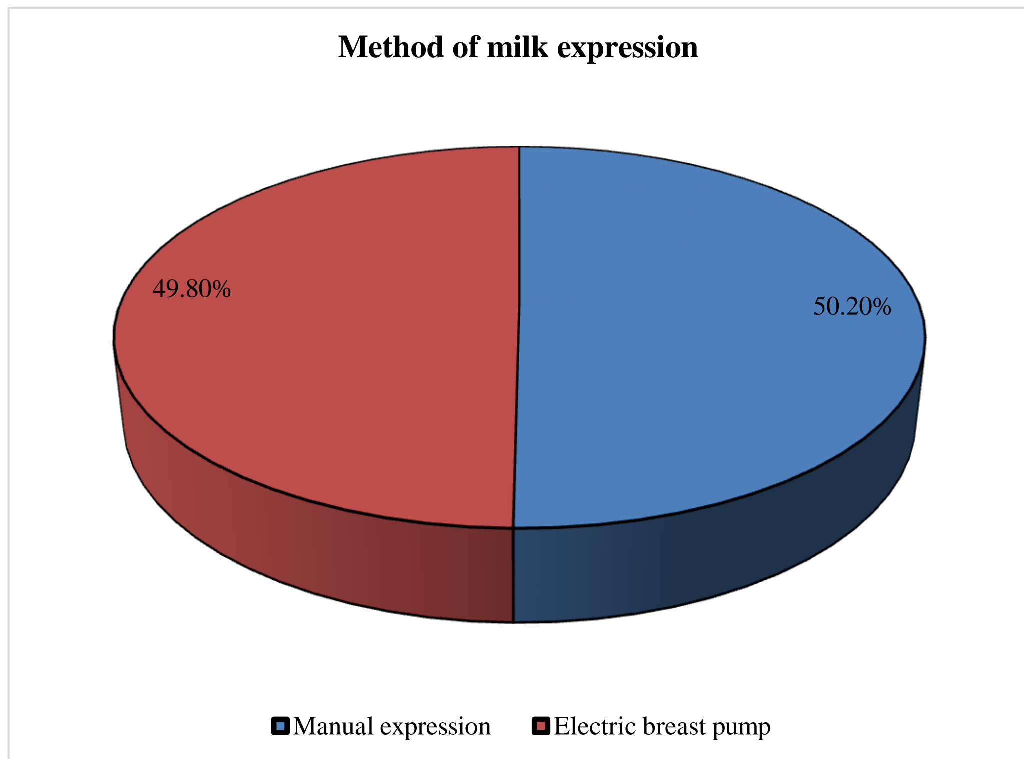

Figure 2: Distribution of method of breast milk expression

Socio-demographic parameters : The below table provides the socio-demographic distribution of the study participants (Table 1)

Table 1: Socio-demographic profile

Variables(mean)	ME (n=100)	EPE (n=101)	P value
Mother's age(26.29) (yrs)	26.79 ± 4.41 26 (19, 42)	26.51 ± 4.40 26 (19, 40)	0.773
Mother's Education			
Secondary school(17.9)	19 (19%)	17 (16.8%)	0.460
Graduate (63.6)	66 (66%)	62 (61.4%)	0.754
Post-Graduate (11.4)	15 (15%)	22 (21.8%)	0.274
Socioeconomic Status			
Upper (7)	5 (5%)	10 (9.9%)	0.294
Upper middle (41)	40 (40%)	43 (42.6%)	0.391
Lower middle(38)	41 (41%)	36 (35.6%)	0.339
Upper lower(12.9)	14 (14%)	12 (11.9%)	0.433
Occupation- Homemaker(69) Employed(30.8)	 69 (69%) 31 (31%)	 70 (69.3%) 31 (30.7%)	 0.533

The mean age of mothers was 26.29 years and was similar in both the groups, with the ME group averaging 26.79 years and the EPE group averaging 26.51 years. Educational status was also comparable, as the majority of mothers had completed graduate education (66% in the ME group vs. 61.4% in the EPE group). Employment status revealed minimal variation, with the majority being homemakers (69% in the ME group vs. 69.3% in the EPE group). Socioeconomic status was similarly distributed across both groups, with most mothers classified within the upper middle or lower middle class.

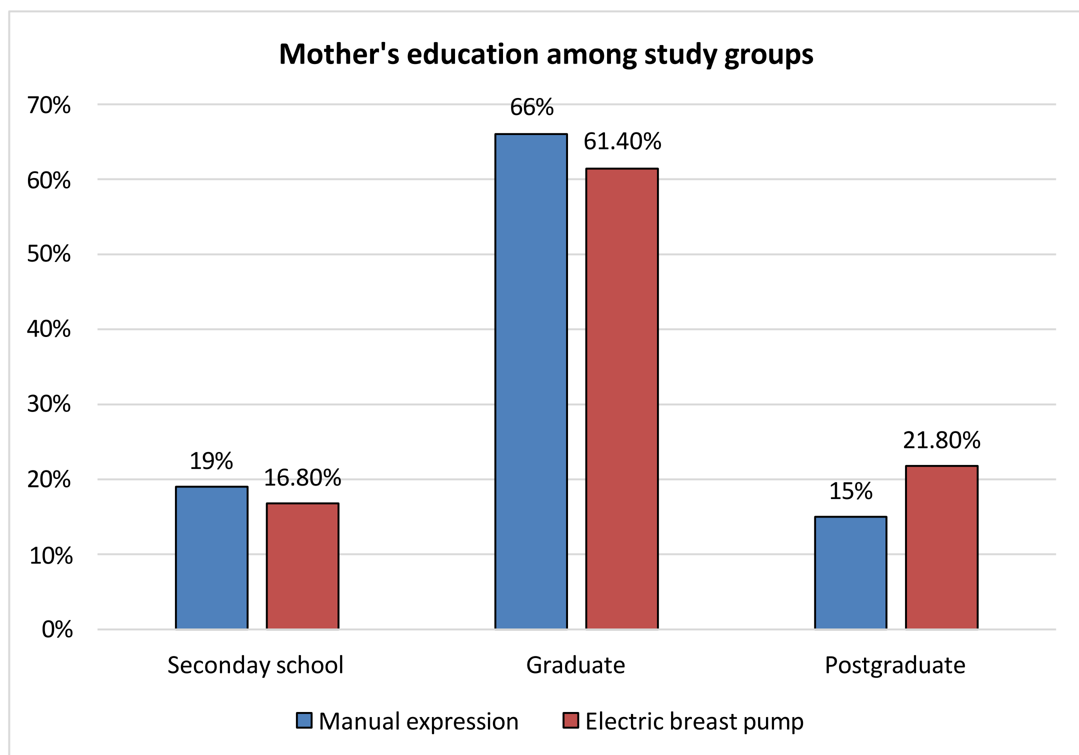

Figure-3: Distribution of mother’s education

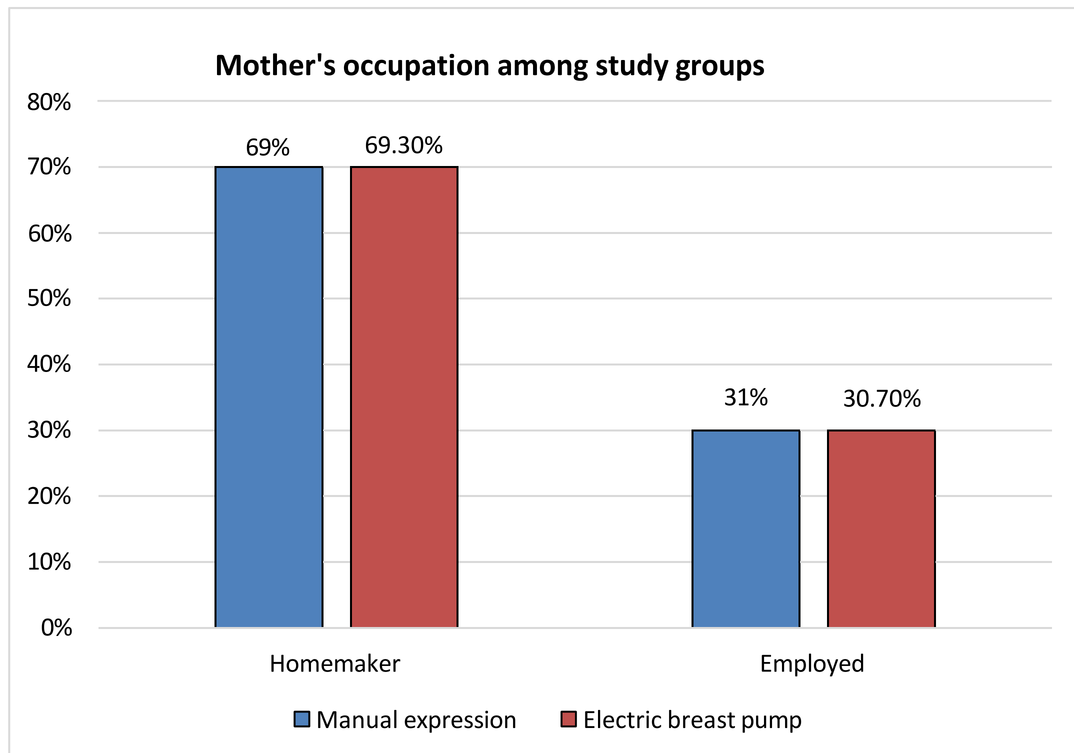

Figure -4-Mothers occupation among study groups

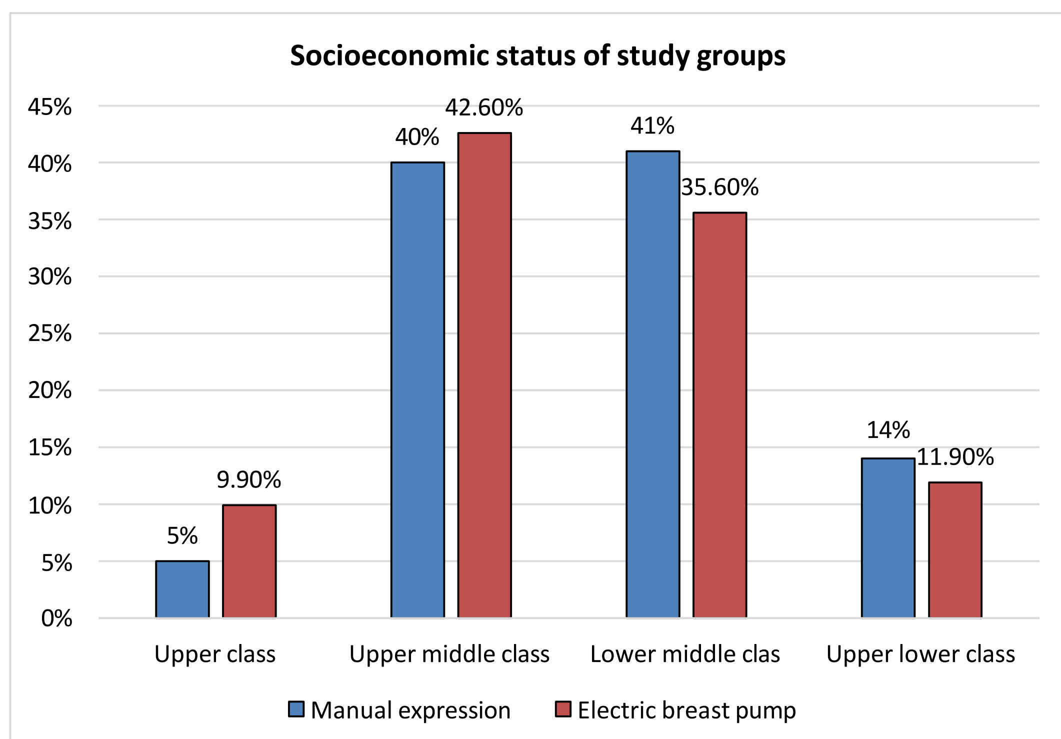

Figure-5- Socioeconomic status of study groups

Maternal characteristics -

Table no.2: Maternal characteristics

Variables	**Manual expression (n=100)**	**Electric Breast pump milk expression (n=101)**	**P value**
Mode of delivery NVD(20.8) LSCS(79.1)	 4 (27.6%) 63 (72.4%)	 18 (22.8%) 61 (77.2%)	 0.298
Gestational age (34.7)	34.14 ± 2.77 35 (27, 39)	34.86 ± 2.30 36 (26, 40)	0.303
Gravida Primigravida(38.8) Multigravida(61.1)	 47 (47%) 53 (53%)	 31 (30.7%) 70 (69.3%)	 **0.013**
Risk factors			
Elderly primi >35yrs(4)	3 (3%)	7 (6.9%)	0.170
Short stature <145cm(0.9)	1 (1%)	1 (1%)	0.749
Pregnancy induced HTN(25.3)	27 (27%)	24 (23.8%)	0.358
Anemia(4)	5 (5%)	4 (4%)	0.494
Multiple pregnancy(19)	20 (20%)	20 (19.8%)	0.556
GDM(2.9)	3 (3%)	3 (3%)	0.654
IUGR(16.5)	16 (16%)	17 (16.8%)	0.513
Placenta previa(8.9)	6 (6%)	12 (11.9%)	0.112
Placental abruption(2.5)	5 (5%)	0 (0%)	**0.029**
PROM(16.4)	17 (17%)	16 (15.8%)	0.487
LSCS(8.9)	7 (7%)	11 (10.9%)	0.237
Oligoamnios/ Anamnios(2.9)	1 (1%)	5 (5%)	0.108

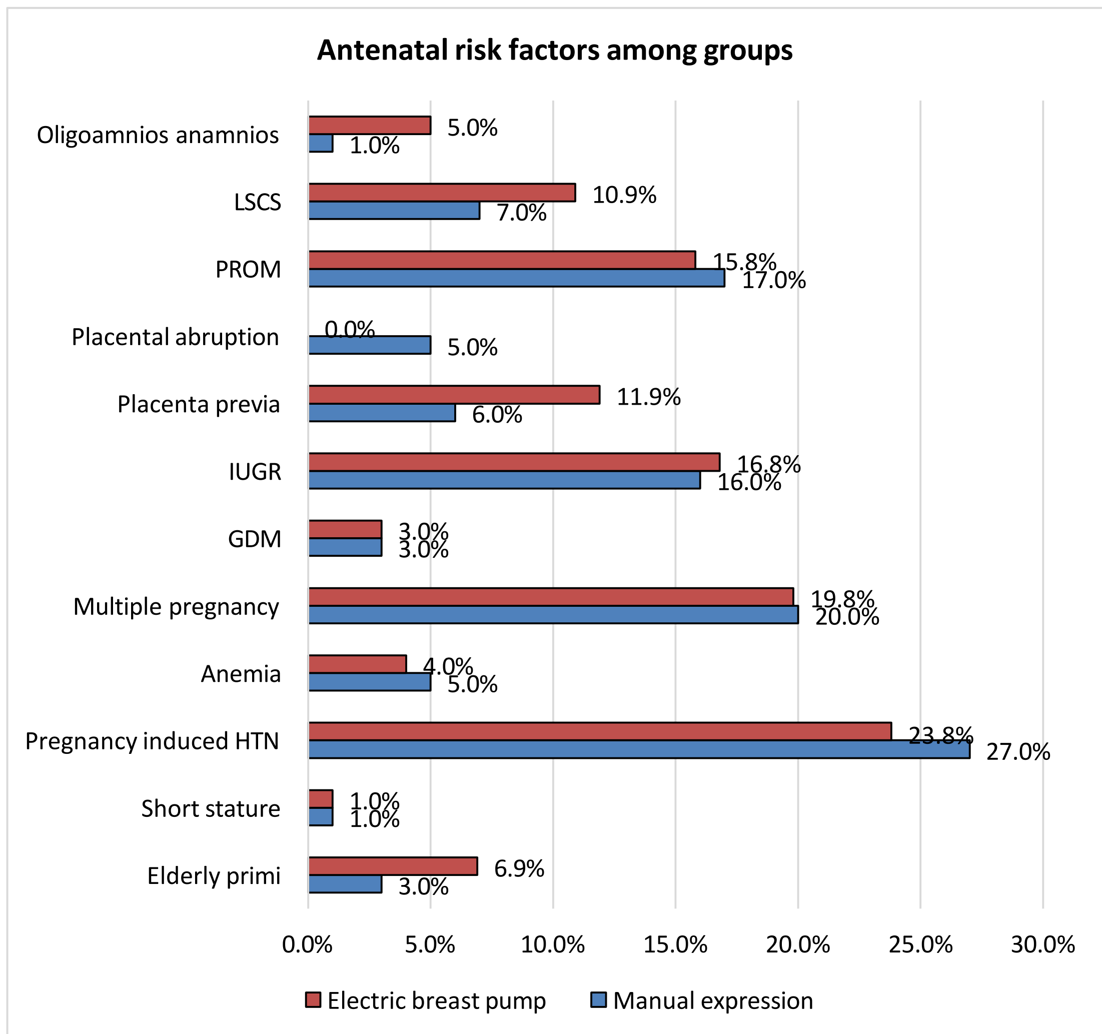

Figure 6: Distribution of Antenatal risk factors

In total study the mean number of primigravida and multigravida are 38.8 and 61.1 respectively. In the ME group, the primigravida and multigravida proportions were 47% and 53%, respectively. The EPE pump group had 30.7% primigravida and 69.3% multigravidas, showing a significant difference in gravida status (p=0.013). The incidence of fetal distress was 7% in the ME group and 4% in the EPE group. Both patients had a 1% prevalence of malposition. The malpresentation rate was 8% in the ME group and 7.9% in the EPE group. The failed induction rates were 6% for the ME group and 6.9% for the EPE group. IUGR was absent in the ME group and in 5.9% of patients in the EPE group (p=0.011). Placenta previa occurred in 3% of the

ME group and 1% of the EPE group. Placental abruption occurred in 3% of patients in the ME group and was absent in the EPE group. LSCS history was 7% in the ME group and 15.8% in the EPE group. Multiple pregnancies occurred 12% in the ME group and 14.9% of the patients in the ME and EPE groups, respectively. The cephalic disproportion was 2% in the ME group and absent in the EPE group. PROM/PPROM occurred in 10% and 5.9% of patients in the manual and pump groups, respectively. Maternal LSCS requests were non-existent in the ME group and 1% in the pump group (p=0.021). The incidence of maternal medical complications was 15% in the manual group and 13.9% in the EPE group.

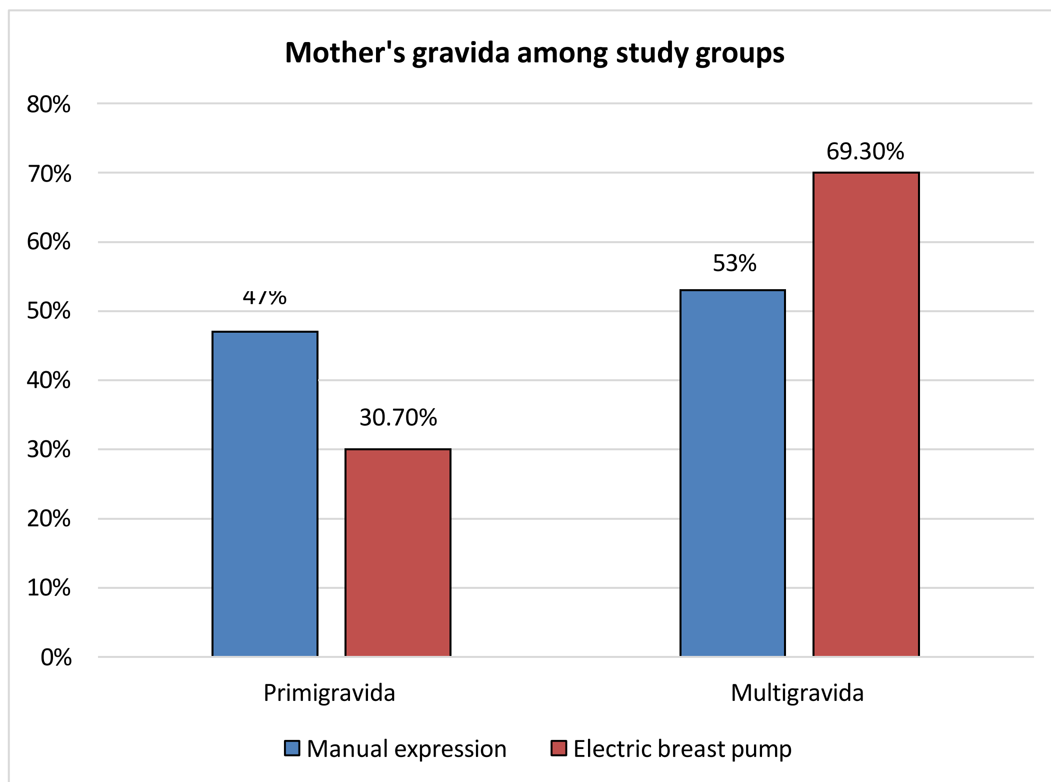

Figure 7: Distribution of mother's Gravida

Birth Characteristics :

Table 3: Birth characteristics.

Variables	Manual expression (n=100)	Electric Breast pump milk expression (n=101)	Pvalue
Gestational age (wks) (34.7 wks)	34.14 ± 2.77 35 (27, 39)	34.86 ± 2.30 36 (26, 40)	0.303
Gender of baby-number Male(44.7) Female(55.2)	42 (42%) 58 (58%)	48 (47.5%) 53 (52.5%)	0.259
Birth weight (grams) (1940)	1808.05 ± 416.95 1900 (828, 2400)	1882.76 ± 393.4 2000 (680, 2390)	0.362
APGAR Score at 5 minutes less than 7(2.45)	3 (3%)	2 (2%)	0.495

The mean gestational age in the study was 34.7 weeks .Sex distribution of the infants was approximately equal between the two groups Birth weights are also comparable across the groups, with no significant differences observed. The mode of delivery was nearly identical in both groups, with a high prevalence of LSCS(70% in the manual group and 75.2% in the EPE group) and a lower proportion of NVD(30% in the ME group and 24.8% in the EPE group). APGAR scores at 5 min revealed that nearly all infants scored above 7, although a slightly higher percentage of newborns in the ME group had scores below 7 (3% vs. 2%, p=0.495). The mean birth weight in the study was 1940 grams

Primary Outcome: Total volume of Breast Milk Expressed as follows:

Table 4: Manual Expression Vs Electric Breast Pump milk expression-Intention to treat Analysis

No. of days	Amount of milk expressed by six session per day (**ml**)													
	Manual Expression Method (**ml**) (n=100)-							Electric Breast Pump Method (**ml**) (n=101)						
	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6	Total volume	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6	Total volume
Day 1	0.48	0.42	0.48	0.51	0.61	0.69	2.35	0.63	0.74	0.87	0.99	1.17	1.21	4.7
Day 2	1.22	1.50	1.60	1.58	1.80	1.94	8	2.11	2.27	2.60	2.57	2.79	2.83	12.5
Day 3	3.81	4.36	4.83	5.16	5.51	5.96	27.7	5.17	6.23	7.10	7.77	8.13	8.49	40.8
Day 4	9.91	9.55	10.80	11.37	11.84	12.30	63.8	11.87	12.97	14.13	31.13	15.96	16.69	84.5
Day 5	15.24	15.81	16.30	16.60	17.36	18.55	94.9	20.6	21.50	22.56	23.11	24.00	26.24	133.25
Day 6	21.76	22.98	23.99	24.43	25.41	25.34	140.4	29.04	30.34	31.46	32.88	34.38	35.11	184.5
Day 7	29.19	34.20	30.15	31.18	31.93	32.63	178	38.76	41.01	42.04	44.12	44.64	46.24	251.75

Table.5- Total volume of milk by Manual Expression Vs Electric Breast Pump milk expression-Intention to treat Analysis

Postnatal days(no)	Electric Breast pump expression (n=100) mean (median)-ml	Manual expression (n=101) mean (median)-ml	P value
Day 1	4.7 (0.7,21.8)	2.35 (0.2, 11)	**<0.001**
Day 2	12.5 (3.2, 60)	8 (1.6, 38.9)	**<0.001**
Day 3	40.3 (15.5, 94.5)	27.7 (2.4, 87)	**<0.001**
Day 4	84.5 (45, 142.5)	63.8 (32, 126.5)	**<0.001**
Day 5	133.25 (43, 181)	94.9 (61, 157)	**<0.001**
Day 6	184.5 (22, 293)	140.4 (69.9, 190)	**<0.001**
Day 7	251.75 (0, 317)	178 (61.8, 299)	**<0.001**
Total Milk Volume	667.2 (168.5, 954.8)	507.3 (81.5, 848)	**<0.001**

Intent to treat Analysis of the data showed that the mean volume of breast milk expressed over the first seven postnatal days exhibited a gradual increase in both the EPE (BPE) group (n=100) and ME group (n=101). Notably, the EPE group consistently had slightly higher volumes. On Day 1, the mean milk volume was 4.7 mL (0.7-21.8 mL) in the EPE group, compared to 2.35 mL (0.2-11 mL) in the ME group (p=;0.001), indicating a marginally higher initial yield with the breast pump. By Day 2, this difference had persisted, with a mean volume of 12.5 mL (3.2-60 mL) in the EPE group and 8 mL (1.6–38.9 mL) in the ME group (p=;0.001). On Day 3, the EPE group expressed a mean of 40.3 mL (15.5–67.5 mL), whereas the ME group expressed 27.7 mL (2.4-87 mL, p<0.001). This trend continued through Day 4, with mean volumes of 84.5 mL (45-142.5 mL) and 63.8 mL (32-126.5 mL), respectively (p=0.001), and Day 5, with 133.25 mL (43-181 mL) versus 94.9 mL (61-

157 mL, p<0.001). By Day 6, the milk output in both groups showed a significant increase, with the EPE group reaching a mean volume of 184.5 mL (22-293 mL) compared with 140.4 mL (69.9-190 mL) in the ME group (p<0.001). On Day 7, the EPE group still had a higher mean milk volume of 251.75 mL (0, 317 mL), while the ME group had 178 mL (61.8, 299 mL, p=0.001). When analysing the total breast milk volume expressed over seven days, the EPE group had a significantly higher mean total milk volume of 667.2 mL (168.5, 954.8 mL) compared to 507.3 mL (range: 81.5, 848 mL) in the ME group ((p<0.001).

Based on the per-protocol analysis, the median volume of milk in the EPE and ME groups on day 1 were 3.9 ml (2, 9) and 2.6 ml (0.7,7.5) respectively (p=0.07). The mean volume of milk in the EPE and ME groups on day 2 was 12 ml (6,24) and 9 ml (4,18), respectively (p=0.28). The mean values between the groups were not significant for the first two days. The volume of milk was statistically significant from day 3, with a higher volume in the EPE expression group. The mean volume of milk in the BPE and ME groups on day 3 was 48 (36,65.5) ml and 43 (31,54) ml, respectively (p=0.02). The mean volume of milk in the EPE and ME groups on day 4 was 89 (62, 118) ml and 79 (56, 98) ml, respectively (p=0.04). The median volume of milk in the EPE and ME groups on day 5 was 141 (89, 186.5) ml and 123 (81, 162) ml, respectively (p=0.05). The mean volume of milk in the EPE and ME groups on day 6 were 196 (138, 294.5) ml and 159, 114, 257) ml respectively (p=0.05). The mean volume of milk in the EPE and ME groups on day 7 was 265 (209, 335) ml and 249 (196, 281) ml, respectively (p=0.01). The total volume of milk in the EPE and ME groups was 747 (568,1012) and 715 (541,910) ml, respectively, which was statistically significant. The amount of milk expressed in the six sessions per day as per per-protocol analysis shows higher volume of milk in the EPE method group

Table 6 : Manual Expression Vs Electric Breast Pump milk expression-Per Protocol Analysis

No. of days	Amount of milk expressed by six session per day **(ml)**													
	Manual Expression Method **(ml)** (n=86)							Electric Breast Pump Method (**ml**) (n=79)						
	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6	Total volume	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6	Total volume
Day 1	0.55	0.55	0.65	0.72	0.84	0.92	2.6	0.53	0.55	0.65	0.7	0.83	0.93	3.9
Day 2	1.61	1.81	2	1.96	2.2	2.35	9	1.6	1.81	1.99	1.96	2.2	2.34	12
Day 3	4.42	5.2	5.85	6.32	6.63	7.07	43	4.38	5.19	5.85	6.34	6.64	7.07	48
Day 4	10.77	11.07	11.2	11.6	11.76	12.34	79	12.77	13.08	13.22	13.73	13.81	14.35	89
Day 5	15.64	16.39	16.54	17.49	17.51	17.91	123	17.67	18.45	19.21	19.53	20.34	22.2	141
Day 6	18.05	19.29	20.33	21.23	22.34	23.71	159	25.09	26.34	27.4	28.3	29.43	29.71	196
Day 7	19.72	20.37	20.78	21.19	21.4	24.19	249	33.84	37.52	35.93	37.38	38.04	39.26	265

Table7-Total milk volume in each day between ME group and EPE group

Postnatal days(no)	**Electric Breast pump expression (n=79) mean(median)(ml)**	**Manual expression (n=86) mean(median) (ml)**	**P value**
Day 1	3.9 (2,9)	2.6 (0.7,7.5)	0.07
Day 2	12 (6,24)	9 (4,18)	0.28
Day 3	48 (36,65.5)	43 (31,54)	**0.02**
Day 4	89 (62,118)	79 (56,98)	**0.04**
Day 5	141 (89,186.5)	123(81,162)	0.05
Day 6	196 (138,294.5)	159 (114,257)	0.05
Day 7	265 (209,335)	249 (196,281)	**0.01**
Total Milk Volume	747 (568,1012)	715 (541,910)	**0.01**

According to the per-protocol analysis, the mean volume of milk expressed in the EPE AND ME groups on day 1 was 3.9 ml (2, 9) and 2.6 ml (0.7, 7.5), respectively (p=0.07). On Day 2, the mean milk volume for the EPE and ME expression groups was 12 ml (6, 24) and 9 ml (4, 18), respectively (p=0.28). The differences in the mean values between the groups were not statistically significant for the first two days. However, from Day 3 onwards, the milk volume became statistically significant, with the EPE group exhibiting a higher volume. On Day 3, the mean milk volumes for the EPE and ME groups were 48 ml (36, 65.5) and 43 ml (31, 54), respectively (p=0.02). On Day 4, the median milk volume was 89 ml (62, 118) in the EPE group and 79 ml (56, 98) in the ME group (p=0.04). On Day 5, the mean milk volume was 141 ml (89, 186.5) for the EPE group and 123 ml (81, 162) in the

ME group (p=0.05). On Day 6, the mean milk volume was 196 ml (138, 294.5) in the EPE group and 159 ml (114, 257) in the ME group (p=0.05). On Day 7, the mean milk volume was 265 ml (209, 335) for the EPE group and 249 ml (196, 281) in the ME group (p=0.01). The total volume of milk in the EPE and ME groups was 747 ml (568, 1012) and 715 ml (541, 910), respectively, which was statistically significant. Analysis of the six sessions per day, as per the per-protocol analysis, indicated a higher volume of milk in the EPE method group.

Univariate analysis

Table -8-univariate analysis between ME and EPE Group

Variable	Breast pump expression (n=100)	Manual Expression group (n=101)	Odds Ratio	95% CI	P value
Normal vaginal delivery	25	30	3.45	(9.43, 56.4)	**0.002**
Maternal Age >30 years	58	62	2.98	(5.80 40.8)	**0.001**
Multiple Pregnancy (LSCS)	61	63	3.71	(3.15, 47.5)	0.023
Very low birth weight (no)	89	92	4.58	(630, 1450)	0.025
Gestational age >30 weeks	87	91	2.65	(2.5 35.4)	0.051
Mother's Education (Graduate & postgraduate)(no)	42	40	5.92	(4.1 32.7)	0.002
Employment (Homemaker)	21	29	3.17	(4.3, 34.2)	0.042
Socioeconomic Status - Upper Class(no)	33	38	3.63	(3.4 30.4)	0.020
Socioeconomic Status - Upper Middle(no)	26	31	7.42	(3.8 34.8)	0.010
Primigravida(no)	23	28	6.11	(2.1, 30.2)	0.023

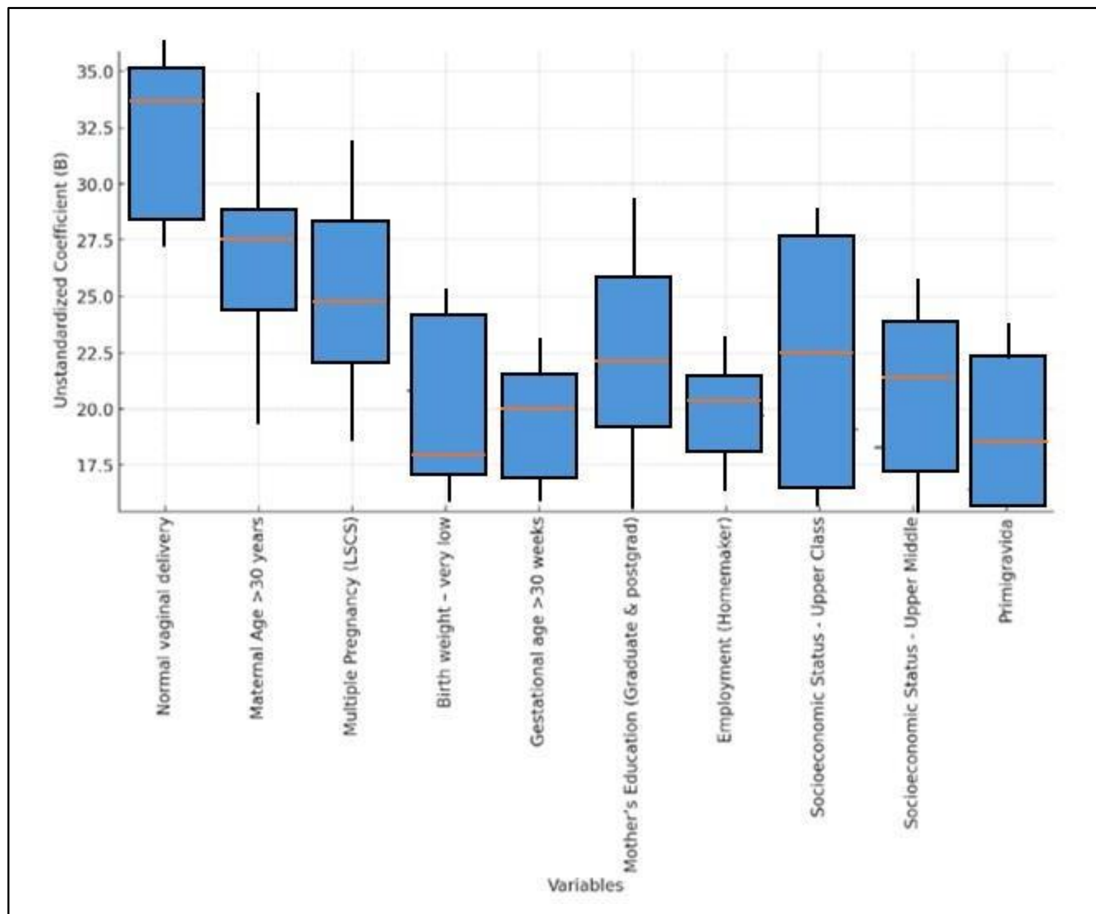

Figure 8: Box plot

Figure -8 .The box plot shows that most B (Unstandardized Coefficient) values range between 16 and 27, with a median around 20, indicating a moderate impact of most predictors. The interquartile range (IQR) suggests that half of the values fall within this range, while the whiskers extend from 17 to 27, covering most data points. Normal Vaginal Delivery (B = 33.2) is an outlier, meaning it has a significantly stronger effect compared to other variables, making it a key predictor.

Multivariate analysis:

Table 9: Comparison of total volume of milk expression from Breast Pump group vs Manual expression group socio demographic status, maternal history and birth history

Variable	B (Unstandardized Coefficient)	95% CI (Lower - Upper)	Beta (Standardized Coefficient)	t-value	P Value
Mode of delivery Normal vaginal delivery	35.1	(10.6, 59.7)	0.19	2.91	**0.005**
Maternal Age >30 years	27.1	(7.6, 46.6)	0.16	2.68	**0.009**
Multiple Pregnancy (LSCS)	24.9	(4.5, 45.2)	0.15	2.48	0.014
Birth weight – very low	20.8	(680, 1480)	0.14	2.38	0.018
Gestational age >30 weeks	19.2	(2.3, 36.1)	0.13	2.30	0.023
Mother's Education (Graduate & postgrad)	21.6	(4.8, 38.4)	0.17	2.65	0.010
Employment (Homemaker)	19.7	(4.3, 35.1)	0.15	2.57	0.012
Socioeconomic Status - Upper Class	19.1	(3.6, 34.7)	0.14	2.45	0.016
Socioeconomic Status - Upper Middle	18.3	(3.0, 33.6)	0.13	2.37	0.019
Primigravida	16.4	(2.2, 30.6)	0.12	2.24	0.026
Total milk supply	Low birth weight	Very low birth weight		P value	
Mean	545.79 ± 184.66 533.95 (157, 926)	608.67 ± 127.14 603.5 (256, 954.8)		**0.039**	

Multivariate analysis identified key factors influencing total milk expression volume. Maternal age greater than 30 years (P = 0.009) exhibited a strong positive association with increased milk expression, suggesting a decrease in milk volume with advancing age. Furthermore, higher maternal education level (graduate and postgraduate, p = 0.010), employment status (p = 0.012), and higher socioeconomic status (p = 0.016 and 0.019, respectively) positively affected milk volume, likely due to enhanced health awareness and access to lactation support. Primigravida mothers (p = 0.026) also tended to produce slightly more milk than multigravida mothers did. Additionally, multiple pregnancies (LSCS) and very low birth weight (less than 1500 g) were found to influence the total milk expression (p = 0.014 and 0.018, respectively).

Secondary Outcomes

1. **Macronutrient composition Of Breast milk**

Table 10: Differences in the composition of breast milk between the groups.

Variable	EPE group (n=100)	ME group (n=101)	P Value
Carbohydrates	7.695	7.693	0.21
Proteins	1.623	1.624	0.87
Fats	2.129	2.125	0.62

The nutritional composition of breast milk, encompassing carbohydrates, proteins, and fats, exhibited negligible differences between mothers utilizing breast pumps and those employing manual expression. The mean carbohydrate content was 7.695 g in the breast pump cohort and 7.693 g in the manual expression cohort (P =0.21), indicating no statistically significant difference. Similarly, protein levels (1.623 g vs. 1.624 g, p=0.87) and fat content (2.129 g vs. 2.125 g, p=0.62) were nearly identical in both the groups.

2. Weight at discharge

The mean total milk expression in low birth weight (1500-2500 g) and very low birth weight (less than 1500 g) were 545.79 ± 184.66 and 608.67 ± 127.14 gm which was statistically significant .

Table 11: Comparison of weight in both methods

Duration	Average weight at ME group(n=100)	Average weight at EPE group(n=101)	P Value
Weight at enrolment	1.80	1.88	**0.007**
Weight at discharge	2.18	2.58	

Table 11 compares the average weight of infants fed using the MEM method versus the EPE at the time of enrolment and discharge. Initially, the average weight was nearly identical between the two groups, with infants in the ME group weighing 1.80 kg and those in the EPE group weighing 1.88 kg. However, by the time of discharge, infants in the electric EPE group had a significantly higher average weight (2.58 kg) than those in the ME group (2.18 kg). The observed increase in weight from enrolment to discharge in both groups was statistically significant (p=0.007).

Table 12: Type of Feeding at Discharge

Variables	EPE Group (n=101)	ME group(n=100)	P value
DBF	14	8	0.02
SF	7	9	0.04
DBF+SF	80	83	0.05

The table compares breastfeeding outcomes between mothers using an electric breast pump (n=101) and those using manual expression (n=100). The three variables examined are direct breastfeeding (DBF), spoon feeding (SF), and a combination of both (DBF+SF). The results indicate that DBF was more frequent in the electric breast pump group (14 vs. 8, p=0.02), while SF was slightly higher in the manual expression group (9 vs. 7, p=0.04). The combined DBF+SF outcome was also slightly higher in the manual expression group (83 vs. 80, p=0.05). Since DBF p-values are below 0.05, these differences are statistically significant.

DISCUSSION

Breast milk is the optimal source of nutrition, especially for preterm and low-birth-weight (LBW) infants, providing essential nutrients and immunity while reducing risks of infections, necrotizing enterocolitis (NEC), and developmental challenges. Early initiation of breastfeeding enhances lactogenesis, where prolactin and oxytocin regulate milk production and ejection. However, barriers such as urbanization and maternal employment increase reliance on expressed milk. Various breast milk expression methods exist, including manual, battery-operated, and electric pumps. Manual expression is cost-effective and requires no special equipment but is time-consuming and physically demanding. Battery-operated pumps offer convenience but have lower efficiency and require batteries. Electric pumps, while highly efficient and capable of expressing 3-6 ounces per session, are expensive, require power, and may lack portability. Research suggests that electric pumps express higher milk volumes due to consistent suction power, though manual expression with massage can enhance milk ejection. Despite these insights, gaps remain in understanding how different pumping techniques impact long-term milk volume and sustained breastfeeding, particularly in low-resource settings. This study aims to address these gaps by evaluating milk volume expressed through different methods in a randomized controlled trial, contributing to evidence-based lactation support for mothers of LBW infants.

Sociodemographic status:

This aligns with studies by **Flacking et al. (2007)**, which suggest that maternal age influences breastfeeding duration, with younger mothers often experiencing lower breastfeeding rates due to lack of experience and support. However, the lack of

significant variation in this study suggests that age may not be a major determinant in the selected population (48).

Regarding education, a majority of mothers in both groups were graduates (ME: 66%, EPE: 61.4%), followed by secondary school (ME: 19%, EPE: 16.8%) and postgraduates (ME: 15%, EPE: 21.8%). The p-values indicate significant association between educational level and the volume of breast. Similarly with findings from **Odom et al. (2013)**, which reported that higher education is linked to increased breastfeeding initiation and continuation. Education plays a key role in breastfeeding awareness, and this study's findings indicate a relatively well-educated sample with comparable breastfeeding behaviours across educational levels (49).

Socioeconomic status analysis reveals that most participants belonged to the upper middle and lower middle classes (ME: 40% and 41%, EPE: 42.6% and 35.6%, respectively), with fewer from the upper (ME: 5%, EPE: 9.9%) and upper lower (ME: 14%, EPE: 11.9%) categories. No significant differences were observed across socioeconomic groups. **Victora et al. (2016)** reported that breastfeeding rates tend to be higher among mothers from higher socioeconomic backgrounds due to better healthcare access and support. However, in urban settings, even mothers from lower socioeconomic classes can successfully breastfeed if proper support systems are in place (50). In terms of occupation, homemakers constituted a majority (ME: 69%, EPE: 69.3%), while the remaining were employed (ME: 31%, EPE: 30.7%), with no significant association ($p = 0.533$). This is consistent with studies by **Rollins et al. (2016)**, which found that employed mothers often face barriers to breastfeeding due to work-related constraints, leading to increased reliance on expressed milk. However, the lack of significant difference in this study suggests that employment did not

impact breastfeeding choices as expected, possibly due to supportive workplace policies or alternative feeding strategies (51).

Maternal Characteristics:

The mode of delivery showed no significant difference between the two groups (p = 0.298). The majority of mothers underwent Lower Segment Caesarean Section (LSCS) (Manual: 72.4%, Electric: 77.2%), with only a small proportion having Normal Vaginal Delivery (NVD) (Manual: 27.6%, Electric: 22.8%). This is consistent with the findings of Hobbs et al. (2016), which suggest that LSCS deliveries can delay lactogenesis due to reduced skin-to-skin contact and physiological stress, potentially increasing the need for milk expression (52). However, Prior et al. (2012) found that breastfeeding initiation after LSCS is possible with adequate support (53).

The mean gestational age was slightly lower in the manual expression group (34.14 ± 2.77 weeks) than in the electric group (34.86 ± 2.30 weeks), but the difference was not statistically significant (p = 0.303). Meier et al. (2010) reported that preterm births (<37 weeks) often require milk expression due to neonatal inability to latch effectively, with electric pumps being preferred for efficient milk removal (54). The findings suggest that gestational age did not significantly influence the choice between manual and electric pumps. There was a significant difference in parity between the two groups (p = 0.013). Primigravida mothers were more likely to use manual expression (47%) than electric pumps (30.7%), whereas multigravida mothers favoured electric pumps (69.3% vs. 53%). This aligns with Wagner et al. (2013), which found that multiparous women are more experienced in breastfeeding

and prefer electric pumps for convenience, while primigravida mothers may require more initial guidance and opt for manual expression(55).

Elderly primigravida (>35 years) was more prevalent in the electric pump group (6.9%) compared to the manual pump group (3%), though this difference was not statistically significant (p = 0.170). According to Feldman-Winter et al. (2012), older mothers often experience reduced milk production due to hormonal variations, which may lead to a greater reliance on breast pumps (56). Short stature (<145 cm) was observed in only 1% of mothers in both groups, showing no significant correlation (p = 0.749). Although shorter maternal height has been associated with obstructed labor and increased cesarean section rates (Toh-adam R et al. 2011), its impact on the choice of milk expression method appears minimal (57). Pregnancy-induced hypertension (PIH) was present in 27% of manual pump users and 23.8% of electric pump users, with no significant difference (p = 0.358). While PIH has been linked to delayed lactogenesis (Gudeta TA et al., 2019), this study did not show any preference for a particular pumping method among affected mothers (58). Similarly, anemia and gestational diabetes mellitus (GDM) were infrequent in both groups and did not significantly affect the choice of pump. This finding aligns with Nommsen-Rivers et al. (2016), who reported that mild anemia and well-managed GDM do not necessarily impact milk production (59). Multiple pregnancies were reported in 20% of participants in both groups (p = 0.556). Although Gavine et al. (2022) suggest that mothers of multiples often prefer electric pumps due to higher milk demand, this study did not reveal a similar trend (18). Intrauterine growth restriction (IUGR) was observed in 16% of manual users and 16.8% of electric users, with no significant difference (p = 0.513). Since IUGR can lead to neonatal complications requiring expressed milk (Donath et al., 2008), the similarity in pump usage across groups

suggests that the choice of method may depend more on individual preference than medical necessity (60). Placenta previa was more common in the electric pump group (11.9% vs. 6%, p = 0.112), while placental abruption was significantly higher among manual users (5% vs. 0%, p = 0.029). These findings indicate that certain maternal risk factors may influence milk expression choices, but in most cases, the decision appears to be independent of specific medical conditions.

Birth Characteristics:

In this study, gestational age was similar between the manual expression group (34.14 ± 2.77 weeks) and the electric breast pump group (34.86 ± 2.30 weeks), with no statistically significant difference (p = 0.303). This suggests that preterm birth distribution was comparable between the two groups and did not influence the choice of milk expression method. Similar findings were reported by Furman et al. (1998), who noted that gestational age does not significantly impact the preference for a particular method of milk expression among mothers of preterm infants (61).

The gender distribution of infants was also comparable, with 42% males and 58% females in the manual group, and 47.5% males and 52.5% females in the electric pump group (p = 0.259). This indicates that gender had no effect on the choice of milk expression method, which aligns with the findings of Meier et al. (2016), who reported no gender-based differences in breastfeeding or milk expression practices among preterm infants (14).

Birth weight, an essential indicator of neonatal health, was slightly higher in the electric pump group (1882.76 ± 393.4 g) compared to the manual expression group (1808.05 ± 416.95 g), but the difference was not statistically significant (p = 0.362). This suggests that mothers of both low-birth-weight and normal-birth-weight

infants used both methods without significant preference. A study by Parker et al. (2012) found that while electric pumps were commonly used for preterm and low-birth-weight infants requiring expressed milk, the method of expression itself did not significantly impact weight gain (62).

The APGAR score at five minutes, which assesses neonatal well-being, was below 7 in only 3% of neonates in the manual expression group and 2% in the electric pump group ($p = 0.495$). The absence of a significant difference implies that neonatal outcomes in terms of immediate postnatal adaptation were comparable between both groups. These results are consistent with the study by Hill et al. (2005), which found that the method of milk expression had no direct impact on neonatal APGAR scores or early neonatal adaptation (63).

Primary Outcomes

Volume of breast milk expressed by Manual Expression Vs Electric Breast Pump -:

The findings from this study indicate that the total volume of milk expressed over seven days was significantly higher in the electric breast pump group (667.2 ml) compared to the manual expression group (507.3 ml, $p < 0.001$). This suggests that electric breast pumps are more effective in stimulating milk production, particularly in the early postpartum period. Similar results have been observed in previous studies, where electric breast pumps were associated with greater milk output, especially for mothers of preterm infants . On Day 1, the electric breast pump group expressed an average of 4.7 ml compared to 2.35 ml in the manual expression group ($p < 0.001$) by Intention to treat analysis , whereas in per protocol analysis in day 1 there was no significant difference ($p = 0.07$) in milk output between manual expression (2.6 ml) and electric pumping (3.9 ml), suggesting that in the early postpartum phase This

early difference may be attributed to the more efficient extraction ability of electric pumps, as demonstrated by Meier et al. (2010), who reported that mothers using electric pumps expressed significantly more colostrum in the first 48 hours postpartum (50). By Day 2, the difference widened, with the electric pump group producing 12.5 ml versus 8 ml in the manual group ($p < 0.001$). This aligns with the findings of Furman et al. (2002), who noted that electric pumps enhance milk output by increasing breast stimulation frequency (61).

However, by Day 3 onwards , electric breast pumps showed a significantly higher milk output by both intention to treat and per-protocol analysis .From Days 3 to 5, the gap between the two methods remained substantial. By Day 5, the electric pump users expressed 133.25 ml, whereas manual expression yielded 94.9 ml ($p < 0.001$). Hill et al. (2005) found a similar pattern, reporting that hospital-grade electric pumps improved milk volume retention in the first postpartum week (63). This is particularly important for mothers with preterm or low-birth-weight infants who rely on expressed milk. By Day 7, the difference reached its peak, with the electric pump group expressing an average of 251.75 ml compared to 178 ml in the manual expression group ($p < 0.001$). This trend mirrors the findings of Parker et al. (2012), who suggested that double electric pumps are more efficient in maintaining lactation over the long term compared to manual expression (62). The total cumulative milk volume was also significantly higher for the electric pump group, reinforcing the advantage of using electric pumps in maintaining an adequate milk supply.

These findings align with **Meier et al. (2016)**, who reported that electric breast pumps improve milk supply efficiency, particularly for preterm mothers (14). Similarly, **Hill et al. (2005)** found that hospital-grade electric pumps were more effective in increasing milk output, especially within the first week postpartum (59).

Both studies emphasize that early and frequent pumping enhances milk production, supporting the trend observed in our study where electric pumps resulted in progressively higher milk volumes. However, manual expression still has its advantages. Morton et al. (2009) suggested that a hybrid approach—combining manual expression with electric pumping—can further enhance milk production (42). This is particularly important in the early postpartum period when manual techniques help stimulate lactation. This insight suggests that while electric pumps are more efficient in sustaining milk production, integrating manual expression could optimize lactation outcomes. Statistically, the increasing significance from Day 3 onward indicates that electric pumps become more beneficial over time. Although the total milk volume difference (747 ml vs. 715 ml) is statistically significant ($p = 0.01$), its clinical relevance depends on individual needs. Mothers requiring frequent expression—such as those with preterm infants—may benefit more from electric pumps, whereas those who express milk occasionally might find manual expression a cost-effective and comfortable alternative.

Univariant & Multivariant analysis findings

The univariate analysis compares the breast pump expression group and the manual expression group, showing significant associations between various maternal and neonatal factors. Normal vaginal delivery, maternal age >30 years, multiple pregnancies (LSCS), very low birth weight, gestational age >30 weeks, higher maternal education, homemaker status, and higher socioeconomic status (upper and upper-middle class) were all significantly associated with differences in expression methods. The odds ratios indicate strong associations, with mother's education (OR: 5.92) and upper-middle-class status (OR: 7.42) having the highest impact. However, some confidence intervals appear inconsistent (e.g., birth weight and gestational age),

and the wide range in certain cases suggests variability. Studies by Meier et al. (2016) and Brown et al. (2018) support these findings, highlighting that socioeconomic status and education significantly influence breastfeeding practices and the choice of expression methods (30,4) . However, Brown et al. noted that manual expression was more commonly practiced in lower socioeconomic groups, whereas this study suggests a different pattern (4).

Multivariate analysis identified key factors influencing total milk expression volume. Maternal age greater than 30 years (P = 0.009) exhibited a strong positive association with increased milk expression, suggesting a decrease in milk volume with advancing age. This is consistent with Gardner et al. (2019), who found that older mothers tend to have lower prolactin responses and delayed lactogenesis (18). Furthermore, higher maternal education level (graduate and postgraduate, p = 0.010), employment status (p = 0.012), and higher socioeconomic status (p = 0.016 and 0.019, respectively) positively affected milk volume, likely due to enhanced health awareness and access to lactation support. Similar findings were observed in studies by Felice et al. (2017) and Odom et al. (2014), where educated and economically stable mothers had higher breastfeeding persistence and milk supply (67, 49).

Primigravida mothers (p = 0.026) also tended to produce slightly more milk than multigravida mothers, aligning with Parker et al. (2020), which suggested that first-time mothers often experience a stronger initial prolactin response. Additionally, multiple pregnancies (LSCS) and very low birth weight (less than 1500 g) were found to influence total milk expression (p = 0.014 and 0.018, respectively). This is supported by Spatz et al. (2015), who found that preterm births and neonatal complications can significantly alter lactation dynamics, often necessitating greater reliance on milk expression.

Secondary outcomes

1. Macronutrient composition of breast milk

Carbohydrate content in breast milk was nearly identical in both groups (7.695 g in the EPE group vs. 7.693 g in the ME group, p = 0.21). This aligns with previous studies, such as that by Berger PK et al. (2020), which found that lactose, the primary carbohydrate in human milk, remains stable regardless of milk expression techniques. Lactose is critical for infant brain development and energy metabolism, and its consistent levels suggest that different expression methods do not impact its concentration (70).

Similarly, protein content showed no significant variation between the groups (1.623 g in the EPE group vs. 1.624 g in the ME group, p = 0.87). Protein concentration in breast milk is primarily determined by maternal diet, genetic factors, and lactation stage rather than the method of milk extraction. Previous research by Ballard & Morrow (2013) reported that protein levels in breast milk remain relatively constant, with a gradual decline over the lactation period (20). Furthermore, Czosnykowska et al. (2018) found that expressed milk retains its immunological components, including lactoferrin and secretory IgA, regardless of whether it is manually or mechanically expressed (71).

Fat content was also comparable between the groups (2.129 g in the EPE group vs. 2.125 g in the ME group, p = 0.62). This finding is consistent with the work of Baird et al. (2021), who observed that the fat content of breast milk varies primarily due to maternal diet and feeding patterns rather than expression methods. Fat is the most variable macronutrient in breast milk and plays a crucial role in infant weight gain and brain development (72).

2. Comparison of weight at enrolment & discharge

At enrolment, the average weight of infants in the ME group was 1.80 kg, while those in the EPE group had a slightly higher average weight of 1.88 kg ($p = 0.007$). At discharge, the average weight increased to 2.18 kg in the manual expression group and 2.58 kg in the electric breast pump group, suggesting that infants fed with milk expressed via an electric pump had higher weight gain- mostly due to more volume

A study by DeMauro et al. (2011) indicated that preterm infants who receive breast milk via exclusive pumping tend to have better weight retention due to the consistent volume intake compared to direct breastfeeding or manual expression (73).Previous studies, such as that by Schanler et al. (1999), have shown that infants fed expressed breast milk, especially in neonatal intensive care settings, tend to achieve faster weight gain due to precise feeding measurements and reduced energy expenditure during suckling (74). However, other studies present mixed findings. A study by Azad et al. (2020) observed that while expressed milk ensures adequate nutrition, direct breastfeeding has benefits in terms of immune protection and gut microbiota development, which could contribute to long-term weight regulation (75).

3. Type of Feeding at discharge

This study examines the differences in feeding methods between the Exclusive Pumped Expression (EPE) group and the Manual Expression (ME) group, analyzing the distribution of Direct Breastfeeding (DBF), Spoon Feeding (SF), and a combination of both (DBF+SF).

In the EPE group, 14 infants were exclusively breastfed (DBF), compared to only 8 in the ME group, with a statistically significant p-value of 0.02. This suggests that infants in the EPE group had better initiation or maintenance of direct breastfeeding. A study by Rosenbaum et al. (2022) supports this finding, noting that mothers who use breast pumps early postpartum are more likely to establish a successful breastfeeding routine as pumping stimulates milk production and ensures an adequate supply (76).

For Spoon Feeding (SF), 7 infants in the EPE group and 9 in the ME group required additional nutrition, with a p-value of 0.04. This indicates a slightly lower need for supplementary feeding among infants receiving pumped milk. This aligns with findings from Rosenbaum et al. (2010), who observed that infants fed expressed milk often have more consistent intake volumes and lower risk of underfeeding (76). When looking at the combination of both feeding methods (DBF+SF), 80 infants in the EPE group and 83 in the ME group fell into this category, with a p-value of 0.05, indicating no significant difference between the groups. This suggests that the majority of infants, regardless of milk expression method, required a combination of direct breastfeeding and supplementation. Studies such as that by Christian et al. (2021) emphasize that while expressed breast milk provides essential nutrients, direct breastfeeding also offers immunological benefits that are not entirely replicated through pumping (77).

Strengths of the study

One of the key strengths of this study is its study design, which directly evaluates two breast milk expression methods: Exclusive Pumped Expression (EPE) and Manual Expression (ME). By assessing their impact on feeding patterns and neonatal outcomes, the study provides valuable insights into optimal feeding strategies for preterm and low-birth-weight infants. The statistical analysis strengthens the reliability of the findings, as it identifies significant differences between the groups with appropriate confidence intervals and p-values. Additionally, the study is clinically relevant as it highlights an essential aspect of neonatal nutrition, which can inform breastfeeding support strategies in healthcare settings. The relatively large sample size (201 participants) further adds to the credibility of the results, reducing bias and improving generalizability within similar populations. Furthermore, the study takes into account multiple variables, including feeding patterns such as direct breastfeeding (DBF), supplementary feeding (SF), and combined feeding (DBF+SF), providing a holistic view of neonatal nutrition.

Limitations

The study has certain limitations such as the short duration and the study do not assess the long-term effects of different milk expression methods on infant growth and health outcomes. Another limitation is the lack of maternal perspective; the study does not explore factors such as maternal comfort, psychological well-being, or lactation challenges, which could influence the choice of breast milk expression methods.

Recommendations

Future research should focus on long-term follow-up studies to evaluate how different breast milk expression methods affect infant growth, immune function, and cognitive development. Including qualitative research on maternal experiences could offer a comprehensive understanding of the challenges and benefits of various expression methods. Additionally, multicentre studies across diverse healthcare settings would enhance result generalizability and provide robust evidence. Future studies should also explore whether expression methods influence breast milk's nutritional composition over time, impacting infant health.

CONCLUSION

The randomised control trial demonstrates the superiority of electric breast pumps over manual expression in terms of milk volume output. Electric pumps yielded significantly higher total milk volume over a seven-day period, potentially contributing to better weight gain in neonates at discharge. Despite the difference in volume, macronutrient content remained consistent between the two methods. These findings suggest that electric breast pumps may be more effective for mothers aiming to maximize milk expression. However, further multicenteric, long-term studies are necessary to comprehensively assess the impact of different breast pump types on infant growth, immune function, and cognitive development, providing more robust evidence for clinical recommendations.

SUMMARY

The RCT was conducted in the postnatal ward attached to the neonatal intensive care unit (NICU) of the Department of Paediatrics at Dr. Prabhakar Kore Charitable Hospital, a teaching hospital attached to Jawaharlal Nehru Medical College, Belagavi, A total of 206 preterm mothers with infants weighing less than 2.5 kg were evaluated for participation in the study. After counselling and randomization, five mothers were excluded from the study. From the remaining 201 mothers, 100 were assigned to the EPE, while 101 were allocated to the ME. In data regarding milk volume for the initial seven days were missing for 22 mothers in EPE group and 14 mothers in ME group due to maternal complications, dropout, noncompliance with medical recommendations, and neonatal deaths. Complete data on expressed milk volume for the entire seven postnatal days were available for analysis from 79 mothers in the EPE group and 86 mothers in the ME group.

The summary of the findings:

1. Sociodemographic status

- The sociodemographic factors examined included the mother's age, level of education, socioeconomic status(SES) (as measured by the Kuppuswamy scale), and the mother's occupation between the two groups.
- The average age of mothers was similar in both groups, with ME at 26.79 ± 4.41 years and EPE at 26.51 ± 4.40 years, showing no significant difference (P value 0.773).

- The proportion of mothers with secondary school education was 19% in the ME group and 16.8% in the EPE group (P = 0.460). Similarly, graduates constituted 66% and 61.4%, while postgraduates were 15% and 21.8%, respectively, with no statistically significant differences.
- The distribution across different SES categories was comparable, with the upper class comprising 5% (ME group) and 9.9% (EPE group) (P = 0.294).
  - The upper-middle class had 40% (ME group) and 42.6% (EPE group) (P = 0.391), while the lower-middle class included 41% and 35.6% (P = 0.339). The upper-lower class constituted 14% and 11.9%, respectively, with no significant difference (P = 0.433).
- The proportion of homemakers was 69% in the ME group and 69.3% in the EPE pump group, while employed mothers accounted for 31% and 30.7%, respectively, with no significant difference (P = 0.533).

2. Maternal Characteristics

- The percentage of mothers who had a normal vaginal delivery (NVD) was 27.6% in the ME group and 22.8% in the EPE group,
  - While LSCS (lower segment cesarean section) deliveries were 72.4% and 77.2%, respectively. There was no significant difference between the groups (P = 0.298).
- The average gestational age was 34.14 ± 2.77 weeks in the ME group and 34.86 ± 2.30 weeks in the EPE group, showing no significant difference (P = 0.303).
- Primigravida mothers were more common in the ME group (47%) compared to the EPE group (30.7%),

  - While multigravida mothers were higher in the EPE group (69.3%) than in the ME group (53%). This difference was statistically significant (P = 0.013).

- **<u>Risk Factors</u>**:
- Elderly primigravida (>35 years): Found in 3% of ME mothers and 6.9% of EPE mothers, with no significant difference (P = 0.170).
- Short stature (<145 cm): Observed in 1% of both ME and EPE groups, with no difference (P = 0.749).
- Pregnancy-induced hypertension (PIH): Present in 27% (ME group) and 23.8% (EPE group), with no significant difference (P = 0.358).
- Anemia: Found in 5% (ME group) and 4% (EPE group), showing no significant difference (P = 0.494).
- Multiple pregnancy: Reported in 20% (ME group) and 19.8% (EPE group), with no significant difference (P = 0.556).
- Gestational diabetes mellitus (GDM): Occurred in 3% of both groups, with no difference (P = 0.654).
- Intrauterine growth restriction (IUGR): Reported in 16% in ME group and 16.8% in EPE group, showing no significant difference (P = 0.513).
- Placenta previa: Found in 6% (ME group) and 11.9% (EPE group), with no significant difference (P = 0.112).
- Placental abruption: Present in 5% of ME mothers, but not observed in the EPE group (P = 0.029), indicating a significant difference.
- Premature rupture of membranes (PROM): Reported in 17% (ME group) and 15.8% (EPE group), with no significant difference (P =

0.487). Previous LSCS: Found in 7% (manual) and 10.9% (electric), showing no significant difference (P = 0.237).

- Oligohydramnios/Anhydramnios: Observed in 1% (ME group) and 5% (EPE group), with no significant difference (P = 0.108).

3. **Maternal history**

- The average gestational age was 34.14 ± 2.77 weeks in the ME group and 34.86 ± 2.30 weeks in the EPE group, with no significant difference (P = 0.303).
- Primigravida mothers were significantly more common in the ME group (47%) compared to the EPE group (30.7%),
  - While multigravida mothers were more frequent in the EPE group (69.3%) than in the ME group (53%). This difference was statistically significant (P = 0.013).
- **Indications for LSCS**:
- Fetal distress was the reason for LSCS in 7% of ME mothers and 4% of EPE mothers, with no significant difference (P = 0.318).
- Malposition was observed in 1% of both groups, with no difference (P = 0.730).
- Malpresentation led to LSCS in 8% of ME group and 7.9% of EPE group, with no significant difference (P = 0.533).
- Failed induction resulted in LSCS for 6% (ME group) and 6.9% (BPE group), with no significant difference (P = 0.436).
- Intrauterine growth restriction (IUGR) was an indication for LSCS in 5.9% of EPE group, but none in the ME group, showing a significant difference (P = 0.011).

- Placenta previa was the reason for LSCS in 3% of ME cases and 1% of EPE cases, with no significant difference (P = 0.343).
- Placental abruption was noted in 3% of ME cases, but none in the EPE group (P = 0.139).
- Prior LSCS was a significant indication for LSCS in 7% of ME cases and 15.8% of EPE cases, showing a statistically significant difference (P = 0.021).
- Multiple pregnancy was an indication for LSCS in 12% of ME cases and 14.9% of BPE cases, with no significant difference (P = 0.255).
- Cephalic disproportion led to LSCS in 2% of ME cases, but none in the BPE group (P = 0.270). PROM/PPROM (premature or preterm premature rupture of membranes) resulted in LSCS in 10% of manual cases and 5.9% of breast pump cases, with no significant difference (P = 0.271).
- Maternal request was an indication for LSCS in 1% of EPE cases, but none in the ME group (P = 0.476).
- Maternal medical complications were responsible for LSCS in 15% of ME cases and 13.9% of EPE cases, with no significant difference (P = 0.563).

4. Birth history:

- Male babies were born in 42% of ME cases and 47.5% of EPE cases, while female babies accounted for 58% and 52.5%, respectively, with no significant difference (P = 0.259).

- The average gestational age was 34.14 ± 2.77 weeks in the ME group and 34.86 ± 2.30 weeks in the EPE group, showing no significant difference (P = 0.303).
- The average birth weight was 1808.05 ± 416.95 g in the ME group and 1882.76 ± 393.4 g in the EPE group, with no statistically significant difference (P = 0.362).
- A score of less than 7 was recorded in 3% of ME cases and 2% of BPE cases, with no significant difference (P = 0.495).
- 55% of babies in the ME group and 53.5% in the EPE group required NICU admission, with no significant difference (P = 0.469).

5. **<u>Primary Outcome</u> –**

Volume of milk expression EPE vs ME

I. Intention to treat analysis

- Day 1: The EPE group expressed a mean of 4.7 ml (range: 0.7–21.8 ml), while the ME group produced 2.35 ml (range: 0.2–11 ml) (P < 0.001).
- Day 2: Milk volume increased in both groups, with the EPE group yielding 12.5 ml (range: 3.2–60 ml) compared to 8 ml (range: 1.6–38.9 ml) in the ME group (P < 0.001).
- Day 3: The EPE group expressed 40.3 ml (range: 15.5–94.5 ml), which was significantly higher than the ME group's 27.7 ml (range: 2.4–87 ml) (P < 0.001).

- Day 4: The EPE method resulted in 84.5 ml (range: 45–142.5 ml), while the ME method produced 63.8 ml (range: 32–126.5 ml) (P < 0.001).
- Day 5: The EPE method continued to show better milk output with 133.25 ml (range: 43–181 ml) compared to 94.9 ml (range: 61–157 ml) in the ME method (P < 0.001).
- Day 6: The EPE group expressed 184.5 ml (range: 22–293 ml), while the ME group produced 140.4 ml (range: 69.9–190 ml) (P < 0.001).
- Day 7: The EPE method yielded the highest volume with 251.75 ml (range: 0–317 ml), whereas the ME method produced 178 ml (range: 61.8–299 ml) (P < 0.001).
- Total Milk Volume: Over seven days, the total milk volume expressed was significantly higher in the EPE group (667.2 ml, range: 168.5–954.8 ml) compared to the ME group (507.3 ml, range: 81.5–848 ml) (P < 0.001), indicating the superiority of the breast pump method in enhancing milk production.

II .Per protocol analysis

- Day 1: The BPE group had a mean milk volume of 3.9 ml (range: 2–9 ml), while the ME group had 2.6 ml (range: 0.7–7.5 ml) (P = 0.07), showing no significant difference.
- Day 2: Milk output increased in both groups, with the EPE group expressing 12 ml (range: 6–24 ml) and the ME group expressing 9 ml (range: 4–18 ml) (P = 0.28), which was not statistically significant.

- Day 3: The BPE group produced significantly more milk at 48 ml (range: 36–65.5 ml) compared to 43 ml (range: 31–54 ml) in the ME group (P = 0.02).
- Day 4: The EPE group yielded 89 ml (range: 62–118 ml), while the ME group expressed 79 ml (range: 56–98 ml) (P = 0.04), showing a significant difference in favor of the breast pump.
- Day 5: Milk volume continued to be higher in the EPE group (141 ml, range: 89–186.5 ml) compared to the ME expression group (123 ml, range: 81–162 ml) (P = 0.05).
- Day 6: The breast pump group expressed 196 ml (range: 138–294.5 ml), which was significantly greater than the manual group's 159 ml (range: 114–257 ml) (P = 0.05).
- Day 7: By the seventh day, EPE users produced 265 ml (range: 209–335 ml), while ME expression users produced 249 ml (range: 196–281 ml) (P = 0.01), showing a statistically significant difference.
- Total Milk Volume: Over seven days, the total milk volume was significantly higher in the EPE group (747 ml, range: 568–1012 ml) compared to the ME expression group (715 ml, range: 541–910 ml) (P = 0.01), reinforcing the effectiveness of the breast pump method.

6. Multivariate analysis between the groups

- NVD was significantly associated with a 35.1 ml increase in milk volume (P = 0.005), indicating a positive effect on lactation.
- Maternal Age <30 Years was linked to a 27.1 ml higher milk volume (P = 0.009), suggesting younger mothers might produce more milk.

- Multiple Pregnancy (LSCS) showed a 24.9 ml increase in milk volume (P = 0.014), indicating a notable effect on lactation in cases of cesarean section for twins/multiples.
- Very Low Birth Weigh (VLBW) Infants were associated with a 20.8 ml increase in milk volume (P = 0.018), possibly due to increased maternal efforts to establish lactation.
- Gestational Age >30 Weeks was linked to a 19.2 ml increase in milk volume (P = 0.023), suggesting that more mature newborns receive better lactation support.
- Higher Maternal Education (Graduate & Postgraduate) was significantly related to a 21.6 ml higher milk volume (P = 0.010), indicating that education may positively influence breastfeeding practices.
- Homemaker Mothers expressed 19.7 ml more milk (P = 0.012), suggesting that reduced stress and environment at home might support better breastfeeding outcomes.
- Higher Socioeconomic Status (Upper Class) was associated with a 19.1 ml increase in milk volume (P = 0.016), while the Upper Middle Class showed an 18.3 ml increase (P = 0.019), indicating a socioeconomic advantage in breastfeeding success.
- Primigravida Mothers had a 16.4 ml increase in milk volume (P = 0.026), suggesting that first-time mothers may be more engaged in breastfeeding efforts.

7. Univariant analysis between the groups

- Women who had a normal vaginal delivery were 3.45 times more likely to use breast pump expression than manual expression (p = 0.002, significant).
- Mothers aged above 30 years were 2.98 times more likely to use breast pump expression than manual expression (p = 0.001, significant).
- Women with multiple pregnancies delivered via LSCS were 3.71 times more likely to use breast pump expression than manual expression (p = 0.023, significant).
- Mothers of very low birth weight infants were 4.58 times more likely to use breast pump expression than manual expression (p = 0.025, significant).
- Mothers with gestational age above 30 weeks were 2.65 times more likely to use breast pump expression than manual expression (p = 0.051, borderline significance).
- Mothers with higher education (graduate & postgraduate) were 5.92 times more likely to use breast pump expression than manual expression (p = 0.002, significant).
- Homemakers were 3.17 times more likely to use breast pump expression than manual expression (p = 0.042, significant).
- Mothers from the upper-class socioeconomic status were 3.63 times more likely to use breast pump expression than manual expression (p = 0.020, significant).

- Mothers from the upper-middle-class socioeconomic status were 7.42 times more likely to use breast pump expression than manual expression (p = 0.010, significant).
- First-time mothers (primigravida) were 6.11 times more likely to use breast pump expression than manual expression (p = 0.023, significant).

Secondary Outcome: Composition of breast milk between the groups

8. **Secondary outcome**

Difference in composition between the groups

- Carbohydrate content was nearly identical, with 7.695 g in breast pump expression and 7.693 g in manual expression (P = 0.21), showing no significant difference.
- Protein content was also comparable, with 1.623 g in breast pump expression and 1.624 g in manual expression (P = 0.87), indicating no notable variation.
- Fat content showed minimal difference, with 2.129 g in breast pump expression and 2.125 g in manual expression (P = 0.62), suggesting no significant impact of the expression method on fat concentration.

9. **Comparison of weight in both groups**

- At enrolment, the average weight of infants in the manual expression group was 1.80 kg, while in the electric breast pump group, it was 1.88 kg (P = 0.07), indicating a no statistically significant difference.

- At discharge, the average weight increased to 2.18 kg in the manual expression group and 2.58 kg in the electric breast pump group, suggesting that infants fed with milk expressed via an electric pump had higher weight gain- mostly due to more volume .

10. Type of Feeding at Discharge

- Direct breastfeeding (DBF) was significantly higher in the EPE group compared to the ME group ($p = 0.02$).
- Supplementary feeding (SF) was slightly more common in the ME group than in the EPE group, with a statistically significant difference ($p = 0.04$).
- The combination of direct breastfeeding and supplementary feeding (DBF+SF) showed no significant difference between the two groups ($p = 0.05$).
- The results indicate that mothers in the EPE group were more likely to practice direct breastfeeding than those in the ME group.
- Mothers in the ME group relied slightly more on supplementary feeding compared to those in the EPE group.
- Since the p-value for DBF+SF is greater than 0.05, the difference in combined feeding practices between the two groups is not statistically signific

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ANNEXURES

ANNEXURE – I - INFORMED CONSENT FORM

"VOLUME OF MILK EXPRESSED BY MANUAL EXPRESSION VS ELECTRIC BREAST PUMP IN MOTHERS OF LOW BIRTH WEIGHT BABIES –RANDOMISED CONTROLLED TRIAL"

Name of Student/Principal Investigator: ___________

Name of Guide/Co Investigators: _________________

Introduction: You are being invited to participate in this study to find out the effect of breast pump in expressing breast milk compared to manual expression. Your kind consent and cooperation is required for participating in this study.

Explanation of procedure: The procedure is very simple, patients mother have to just answer the basic questionnaire. This questionnaire is available in English, Kannada and Hindi for better understanding**.** Mothers who deliver less than 32 weeks of pregnancy will be randomized into 2 groups of 95 each , based of serial number - odd numbers in one group and even numbers in one group. One group will express milk by electric breast pump and the other group will express by manual expression. Volume at the end off the day and cumulative volume is compared between the 2 groups .

Withdrawal from participation in the study: Please spare some time and answer the basic questionnaire which will be very helpful for my study and also the patient's well-being. Participation in this study in voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case

you decide to withdraw your participation, you are free to do so. However, please convey the +decision to the principal investigator.

Possible benefits from participating in the study: you will get benefit of exclusively feeding your baby with your own breast milk.by participating in this study. You will have benefit of reduced pain while expressing breast milk**.**The data gathered will help population at large .

Possible risks from participating in the study: There are no risks involved in participating in this study

Privacy and confidentiality: The information collected from you will be coded, to prevent any person to identify you. Your identity will never be revealed. The data collected fromyou will be kept confidential and only processed or aggregated data will be used for publication.

Financial incentives: You will not receive any payment for participating in this study.

Cost of investigations done during the course of study will be paid by the **principal investigator.**

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purpose and or presented to scientific groups. However, your identity will never be revealed.

Questions:

If you have any question or complaints with regard to your right as study participant you may contact **Dr Harsha Hegde,** Chairperson, Ethical committee of JNMC, 0831-2473777 Extension 4052.

Legal rights: By signing this consent form, we are not waving any of your legal rights

CONSENT STATEMENT

I am making a voluntary decision to participate in the study **"VOLUME OF MILK EXPRESSED BY MANUAL EXPRESSION VS ELECTRIC BREAST PUMP IN MOTHERS OF LOW BIRTH WEIGHT BABIES –RANDOMISED CONTROLLED TRIAL".** My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the participant:

Signature or left thumb impression of the participant:

Name of the witness:

Signature or left thumb impression of the witness:

Name of the investigator

Signature of the investigator:

ANNEXURE – II-

PROFORMA

,SCREENING PORFORMA

HOSPITAL PATIENT NUMBER

SCREENING NUMBER

DATE

NAME OF THE PARTICIPANT :

B/O FIRST NAME

MIDDLE NAME

LAST NAME

BABY GENDER-

ADDRESS-H.NO. –

STREET-

TALUK-

DISTRICT

CONTACT NUMBER OF PARENTS

GENERAL QUESTIONNAIRE

AGE OF MOTHER AT DELIVERY-

DATE OF DELIVERY-

GESTATIONAL AGE AT DELIVERY AS PER LMP- WKS DAY

TERM

VERY PRETERM

MODERATE PRETERM

LATE PRETERM

MODE OF DELIVERY -

BIRTH WEIGHT AT DELIVERY- GRAMS

-WEIGHT AT TIME OF SCREENING- GRAMS

INCLUSION CRITERIA

1. Baby less than 2500gms ☐ Yes ☐ No

2. Requiring NICU **GENERAL QUESTIONNAIRE**or KMCadmission

☐ Yes ☐ No

If yes,indication

I.	LOW BIRTH WEIGHT	YES	NO
II.	RESPIRATORY DISTRESS SYNDROME	YES	NO
III.	MAS	YES	NO
IV.	HYPERBILIRUBINEMIA	YES	NO
V.	FEEDING DIFFICULTIES	YES	NO
VI.	OBSERVATION	YES	NO
VII.	HYPOGLYCEMIA	YES	NO
VIII.	ANY OTHER	YES	NO

EXCLUSION CRITERIA

1.Mother with recent breast surgery Yes ☐ No ☐

2.Contraindication to breast feeding YES ☐ NO ☐

(receiving high doses of Antiepileptics,AntiThyroid drugs,Antipsychotics,Chemotherapeutic Drugs,Chemotherapeutic agents, mother receiving diagnostic or Therapeutic radioactive isotopes , mother with Herpes Simplex leisons on breast, mother on abusing drugs ,mother has active untreated tuberculosis)

Eligible as per above mentioned criteria - Yes ☐ No ☐

If eligible, CONSENT

- Does the mother/father assent to participate Yes ☐ No ☐
- Has the study consent form been signed Yes ☐ No ☐

If Consent given , Enrollment done Yes ☐ No ☐

MOTHER ID

BABY ID

If Enrolled ,randomization done Yes ☐ No ☐

Date of randomization

Participant number-

NAME OF THE INVESTIGATOR-

SIGNATURE-

PROFORMA

VOLUME OF MILK EXPRESSED BY MANUAL EXPRESSION VS ELECTRIC BREAST PUMP IN MOTHERS OF LOW BIRTH WEIGHT BABIES –RANDOMISED CONTROLLED TRIAL

Guide:

Investigator:

Screening Id : ☐

Randomization number and date - ☐ ☐

Study id ☐

Date of admission – ☐

Socio-Demographic Data

1. Mother's Name: ☐

2. Mother Age : ☐

3. Mother's education:

Illiterate ☐ Primary ☐ Secondary ☐ Graduate ☐ Post Graduadate ☐

4. Mother's Occupation: Home maker : ☐ Employed: ☐ self employed : ☐

5. Father's Name: ☐

6. Father's education:

Illiterate ☐ Primary ☐ Secondary ☐ Graduate ☐ Post Graduadate ☐

7. Father occupation : employed : ☐ Self employed: ☐

8. General information given by - Father : ☐ Mother: ☐

9. Written informed consent taken yes : ☐ No:

10.Socio economical status:

EDUCATION OF HEAD OF FAMILY	SCORE	OCCUPATION OF HEAD OF FAMILY	SCORE	TOTAL PCFI/ MONTH-RUPEES	SCORE	TOTAL SCORE	SOCIOECONO CLASS
PROFESSIONAL DEGREE	7	PROFESSION	10	2000 AND ABOVE	12	26-29	UPPER CLASS
GRADUATE	6	SEMI PROFESSION	6	1000-1999	10	16-25	UPPER MIDDLE
INTERMEDIATE/DIPLOMA	5	CLERICAL/SHOP/FARM	5	750-999	6	11-15	LOWER MIDDLE
HIGH SCHOOL	4	SKILLED WORKER	4	500-749	4	5-10	UPPER LOWER
MIDDLE SCHOOL	3	SEMISKILLED WORKER	3	300-499	3	<5	LOWER
PRIMARY SCHOOL	2	UNSKILLED WORKER	2	101-299	2		
ILLITERATE	1	UNEMPLOYED	1	<100	1		

Maternal history

Gravida: Primi ☐ Multi - G ☐ P☐ L ☐ A☐ D☐

b. Antenatal Visits: Done: ☐ Not done ☐

c. Antenatal USG scan: Done ☐ Not done:☐

d)Antenatal risk factors for LBW babies-

Elderly primi >35yrs ☐ Short stature <145 cms ☐ Pregnancy induced hypertension ☐

Anemia ☐ Multiple pregnancy ☐ Gestational diabetes mellitus ☐

Gestational diabetes mellitus ☐ IUGR ☐ Placenta previa ☐

Placenta abruption ☐ PROM ☐ LSCS

MODE OF DELIVERY- LSCS ☐ VAGINAL DELIVERY ☐ VACCUM ASSISTED VAGINALDELIVERY☐ FORCES ASSISTED ☐

Indication for LSCS

☐ Fetal distress ☐ Malposition ☐ Mal presentation ☐ Failed induction

☐ IUGR ☐ Placenta previa ☐ placental abruption ☐ Prior LSCS

☐ Multiple pregnancy ☐ Cephalopelvic disproportion ☐ PROM/PPROM

☐ Maternal request ☐ Maternal medical conditions

DELIVERY DETAILS

Gestational age in weeks-	As per LMP	As per USG	As per Modified Bellard Scoring
<28wks			
28 -31 6/7 wks			
32-33 6/7 wks			
34-36 6/7 wks			
>37 wks			

Date and time of delivery ☐ ☐ -

APGAR score at five minutes >= 7 ☐ <7 ☐

Weight at the time of delivery ☐ :

< 1KG ☐ <1.5KGS☐<2KGS☐ <2.5 KGS ☐

NICU admission : Yes. ☐ No ☐

KMC admission : Yes. ☐ No ☐

Initial Date and time of Milk expression:

30 mins ☐ 1 hour ☐ 1 hr 30 mins ☐ 2hours ☐

Method of Milk expression: Mannual expression method ☐ breast pump method ☐

Days	Total sessions	Average- Duration of expression /session	Volume of milk in each session(in ml)						Total volume (ml/day)
			Session 1	2	3	4	5	6	
1									
2									
3									
4									
5									
6									
7									

Day of life DBF was initiated :

Date of discharge :

Weight at discharge :

Duration of hospital stay :

Type of feeding at discharge – Tube feeding ☐ spoon feeding ☐ DBF ☐

Composition of Milk

Proteins	
Fat	
Lactose	

Signature-

ANNEXURE III: PHOTOGRAPHS

Photograph No.1. Essae-BS-250 electronic weighing scale used for measuring weight

Photograph No. 2. Hospital grade electric breast pump

Photograph No.3. Breast Milk container

Photograph No.4. Sterifeed pasteurizer

Photograph No. 5. Refrigerator

Photograph No. 6. Deep Freezer

ANNEXURE IV: MASTER CHART