

Association Between Mothers' Milk Supply and Subsequent Direct Breastfeeding
Success Among Preterm Infants: A Pilot Study

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Abstract

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Background

For mothers of preterm infants, an established breastmilk supply is essential for reaching the goal of successful transition to direct breastfeeding after the infants' discharge from the neonatal intensive care unit (NICU). The purpose of this study was to evaluate the association between maternal breastmilk supply at 7 and 14 days post-birth and subsequent direct breastfeeding at 42 weeks gestational age of preterm infants.

Methods

A prospective cohort design was utilized. The independent variable was pumped breastmilk supply of ≥ 500 ml/24 hours. The dependent variable was transition to direct breastfeeding ($>80\%$ of daily feeds by direct breastfeeding) measured at 42 weeks gestational age. Subjects were mothers of infants born <34 weeks gestation, admitted to the NICU between November 2013-April 2014. The initial phase included collection of demographic information and 24-hour pumped milk volumes and pumping frequencies at days 7 and 14 and on infant's day of

discharge. Subsequent data were obtained through phone interviews at approximately 42 weeks gestation to evaluate direct breastfeeding status post discharge from the NICU.

Results

Breastmilk volumes and frequency data were collected from 47 women. Follow-up interviews were conducted for 31 women. By day 7, 22 of the mothers (47%) had attained the breastmilk volume goal of 500ml/day. By day 14, 31 (66%) of the mothers had achieved this goal. At follow-up interviews at approximately 42 weeks gestational age, three (10%) of women reported full transition to direct breastfeeding (>80% feeds at breast). Thirteen (42%) reported that all feedings were provided by bottle alone and they had stopped providing any direct breastfeeding to their infants. The remaining 15 women (48%) reported feeding by combination of bottle and breast. Of the women with < 500 ml/day breastmilk volume at day 14, none reported any direct breastfeeding at the follow-up interview. In contrast, of the women with ≥ 500 ml/day at day 14, 13 (43%) reported providing some direct breastfeeding, either alone or in combination with bottle supplementation ($p = .032$).

Conclusion

The results of this study indicate that maternal breastmilk volume ≥ 500 ml/day at day 14 post-birth is associated with significantly higher likelihood of any direct breastfeeding and of direct breastfeeding for $\geq 50\%$ of feedings following discharge from the NICU. The findings of this study provide valuable information regarding the challenges to breastfeeding faced by mothers of premature infants following discharge from the NICU. More research is needed in the area of post discharge nutritional needs for preterm infants, as well as effective feeding methods for provision of necessary additional fortification, to support mothers in their efforts to transition to direct breastfeeding for preterm infants.

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INTRODUCTION

Breastfeeding and breastmilk feedings are defined as optimal nutrition for both full term and preterm infants by the American Academy of Pediatrics. (AAP 2012) One in every nine babies born in the United States is preterm (less than 37 weeks gestation). (CDC 2014) Breastmilk provides short and long-term protective benefits for this vulnerable population, usually admitted to a neonatal intensive care unit (NICU). (Meier 2013)

Breastfeeding may be defined as either direct feeding at the breast, or feeding of breastmilk by an alternative method, such as bottle or cup. (WHO 2014; Parker 2013) Breastmilk production, as well as transition to direct breastfeeding, is often challenging for the mothers of preterm infants. The preterm infant, lacking developmental feeding maturity, is unable to stimulate an adequate breastmilk supply. The mother becomes dependent on use of an electric breast pump in order to establish an adequate milk supply. (Meier 2010) The past decade has seen a dramatic increase in the use of breastmilk and donor breastmilk for preterm infants. (Meier 2013; Parker 2013) More research is needed to support mothers of preterm infants in establishing milk production, as well as the transition to direct breastfeeding.

Background

For decades, NICU nurses, maternity nurses, and lactation staff have encouraged mothers of preterm infants to begin frequent breast pumping as soon as possible in the first 24 hours after delivery, knowing that the establishment of an abundant breastmilk supply in the first week post-delivery is critical to successful transition to full breastfeeding. (Meier 1993; Renfrew 2009) The current standard of care in many NICUs in the United States includes recent advances promoting

breastmilk feedings and breastmilk production. Most prominent are: early and frequent milk expression both by hand and electric breast pump, skin-to-skin holding, the use of lactation peer counselors, advances in technology surrounding milk expression, and education of families and staff related to the benefits of breastmilk feedings for the NICU population. (Meier 2010; Meier 2013; Merewood 2006)

Benefits of Breastfeeding

The benefits of breastfeeding and breastmilk feedings are numerous and well publicized. The American Academy of Pediatrics (AAP), in its 2012 position statement, *"Breastfeeding and the Use of Human Milk"*, states: "Breastfeeding and human milk are the normative standards for infant feeding and nutrition. Given the documented short and long-term medical and neurodevelopmental advantages of breastfeeding, infant nutrition should be considered a public health issue and not only a lifestyle choice." (AAP 2012) The AAP recommends "exclusive breastfeeding for about 6 months, followed by continued breastfeeding as complementary solid foods are introduced, with continuation of breastfeeding for one year or longer as is mutually desired by mother and infant". (AAP 2012)

The benefits of breastmilk feedings for preterm infants have been well documented. (Meier 2010) The protective aspects of breastmilk in decreasing necrotizing enterocolitis and nosocomial infections are crucial for preterm infants with immature immune systems. (Meier 2013) Barrier protection in the intestines creates an environment hostile to pathogenic bacteria, which is especially important for the very low birth weight infant. Breastmilk is found to be

easily digestible for the immature gut, and preterm infants receiving breastmilk attain full enteral feeds sooner than formula fed counterparts. (Rodriguez 2005)

There are many benefits of at-breast or direct breast feedings (versus provision of breastmilk by alternative method). One is the time savings benefit of directly feeding from the breast versus pumping and then providing breastmilk by an alternative method. (Buckley 2006) Chen and colleagues noted improved oxygenation and temperature regulation during breastfeeding versus bottle-feeding in preterm infants. (Chen 2000) Direct breastfeeding ensures optimal nutritional and immunological benefits of breastmilk that are otherwise potentially lost or decreased due to freezing, thawing and warming of stored breastmilk. (Buckley 2006) Maternal benefits include enhanced bonding and connection with infant, decreased anxiety, increased skin-to-skin holding experience, as well as increased motivation to continue the often exhausting and time consuming routine of pumping to maintain milk supply. (Hurst 2013)

Lactogenesis

Lactogenesis (the onset of lactation) in a woman is a two-stage event. Lactogenesis I begins in pregnancy as the mammary glands prepare to secrete milk. Colostrum, containing high levels of immunoglobulins and lactoferrin, is produced during this stage. Lactogenesis II occurs 30-40 hours post-delivery in full term infants, as milk production increases dramatically. (Neville 2001) The complete removal of the placenta after birth produces a 10-fold decrease in progesterone, thus allowing the mother's breasts to begin producing milk. Early and frequent suckling or breast emptying allows the establishment of an adequate milk supply. (Hurst 2007)

Although the hormonal changes produced by removal of the placenta also occur in mothers delivering prematurely, these mothers remain at high risk for delayed lactogenesis II due to the lack of sufficient breast stimulation/breast emptying from a nursing infant. (Hurst 2007) Parker and colleagues found that initiation of milk expression at 1 hour post-delivery decreased the time to lactogenesis stage II in mothers of very low birth weight infants. (Parker 2012) Skin-to-skin holding (kangaroo holding) has also been found to be advantageous in promoting the onset of stage II lactogenesis. (Hake-Brooks 2008)

Breastmilk volume by day 10-14 post delivery of preterm infants has been categorized as:

- Ideal milk volume: >750 ml/day
- Borderline milk volume: 350-500 ml/day
- Low milk volume: <350 ml/day. (Meier 2010)

Approximate breastmilk volume requirement for a 2.5 kg infant at typical time of discharge (36-37 weeks gestation) is 400 ml/day (160ml/kg). (Groh-Wargo 2009)

Hill and colleagues studied weekly milk output of mothers of preterm and term infants for 6 weeks post-delivery. Preterm mothers were 2.8 times more likely to produce inadequate amounts of milk at 6 weeks, and milk output at day 7 was predictive of milk adequacy at week 6 in preterm mothers (Hill 2005). Term mothers' output increased as the weeks progressed, while preterm mothers' supply remained flat or declined over time while using the breast pump for stimulation. The study definition used for adequate milk supply was defined as ≥ 500 ml/24 hours. (Hill 2005)

Developmental Maturity

Successful transition to oral feeds is one of the milestones necessary for discharge from the NICU. For preterm infants, the ability to take sufficient amounts of milk for adequate nutrition does not imply full maturity of the "suck swallow breathe" coordination or the suck mechanism. (Amaizu 2008) The sucking pattern of a term infant is characterized by a rhythmic alternation of suction and expression/compression. Suction creates the negative intraoral pressure generated as the infant draws milk into his mouth. The preterm infant suck is often characterized by the expression/compression component without a mature suction component. (Lau 2000) This allows for adequate feeding from a bottle at time of discharge from the NICU. Infants are often not taking full amounts from the breast at discharge due to their immature suck and lack of the suction component. As infants approach full term gestation, most will acquire a mature sucking pattern. (Wolf 1992; Amaizu 2008) Wooldridge, et al, studied preterm infants in the 4-week period post-NICU discharge (approximately 36-40 weeks gestational age) and noted an increase in ability to take adequate volumes at breast by week 4 post-NICU discharge, with 50% of infants taking 80% or more of total feeds directly from breast. An adequately established milk supply while the infant was in the hospital was a key factor in successful transition to breastfeeding post discharge. (Wooldridge 2003) Thus, at approximately 40 weeks corrected gestational age, many preterm infants may have the ability to take most, if not all feeds, directly from the breast.

Post-discharge Nutritional Needs

Nutritional strategies for the preterm infant both prior to and post discharge seek to mimic in-utero growth. Non-supplemented breastmilk often cannot meet caloric, protein, calcium and

phosphorus needs of the preterm infant and thus additional supplements are necessary. Limited stores of iron as well as other minerals require additional additives to breastmilk. (Lapillone 2013; Conrad 2013) The balance between the nutritional needs of the post-discharge preterm infant and the goal of attaining maximum direct breastfeeding presents challenges. More research is needed to provide consistent guidelines in this area.

Research Aims

The aims of this study were:

1. To assess the association between maternal supply of breastmilk at 7 and 14 days post-birth and subsequent direct breastfeeding success at 42 weeks gestational age of a preterm infant.
2. To gain an understanding of factors that support direct breastfeeding for the preterm infant following discharge.

The research hypothesis for this study was:

Establishment of an adequate breastmilk supply by mothers of preterm infants at 7 and 14 days after birth will be associated with higher rate of direct breastfeeding post-discharge from the NICU at 42 weeks gestational age.

METHODS

Study Design

A prospective cohort study design was used to study the proposed hypothesis.

The independent variable was:

Pumped breastmilk supply of ≥ 500 ml/24 hours versus < 500 ml /24 hours at day 7 and day 14 post-delivery.

The dependent variable was:

Transition to direct breastfeeding ($>80\%$ of daily feeds by direct breastfeeding) measured at 42 weeks gestational age.

Milk volume data was measured using a continuous scale (ml breastmilk/ 24 hours).

Study Setting

The study took place in the 60-bed level III NICU located in Portland, Oregon, at Providence St Vincent's Medical Center. Enrollment occurred during the 5-month period beginning November 2013 and ending April 2014. The 523-bed hospital had 5,046 newborn deliveries in 2013. Average daily NICU census during this time period was 40. The unit had a team of international board certified lactation consultants (IBCLC) providing coverage in the NICU 6 hours/day, 7 days/week. The research study was approved by both the University of Washington Institutional Review Board and the Providence St. Vincent's Medical Center Institutional Review Board prior to initiation of data collection.

Study Subjects

Subjects were mothers of infants born < 34 weeks gestation who had a stated breastfeeding goal of at least 3 months. All mothers of infants, born at less than 34 weeks gestation, admitted (inborn or transport) to the NICU, during the period of November 2013 to April 2014, were eligible for enrollment if inclusion criteria were met.

Inclusion criteria:

- Mothers with infants born at less than 34 weeks gestation and admitted to the NICU
- Mothers with a stated breastfeeding goal of greater than 3 months after term age (asked at time of consent).
- Mother had signed consent for study.
- If twins, first born twin was enrolled in study.

Exclusion criteria:

- Mothers of higher order multiple infants (triplets, quadruplets, etc.)
- Mothers with known history of breast reduction surgery
- Mothers unable to breastfeed due to contraindicated medications
- Mothers with significant social history (e.g., drug abuse, foster care, DHS involvement, adoption, surrogacy)
- Non-English speaking mothers
- Infants with congenital or chromosomal anomalies

Mothers were approached for enrollment at least 24 hours after delivery of their preterm infant and prior to their discharge from the hospital. All participants were enrolled by day 6 post delivery. Written consent was obtained from all participants prior to enrollment. Mothers of

infants discharged on tube feedings, G-tube, or any other feeding difficulties affecting the ability to breastfeed were later excluded from the study prior to phone interviews.

Definition of Breastfeeding

The Index of BreastFeeding Status (IBS), developed in 1990 by the Interagency Group for Action on Breastfeeding, has standardized definitions for breastfeeding status. (Labbok 1990) These definitions were used for this study. (See Figure 1) Full breastfeeding is defined as exclusive or almost exclusive feeding at the breast. In this category, all liquids are given via direct breastfeeding with the exception of vitamins/minerals or infrequently given ritualistic feeds. Partial breastfeeding is divided into 3 categories: Partial High is defined as >80% feeds at breast, Partial Medium is 20-80% at breast, and Partial Low is < 20% at breast. For the purpose of this study, successful transition to direct breastfeeding was defined as mothers providing feeds for their infants as described in the Full or Partial High categories at follow-up. (See Figure 1)

Data Collection

Collection of data occurred in two phases. The initial phase included collection of demographic information (gestational age, maternal age, race, parity), followed by collection of 24-hour pumped milk volumes and pumping frequency at day 7, 14 and on infant's day of discharge. The second phase consisted of a phone interview at approximately 42 weeks gestation, after infant's discharge from NICU, to evaluate direct breastfeeding status.

After written consent was obtained, the primary investigator verified that the mother had received the standardized NICU admission packet (contains written guidelines for collection and

storage of breastmilk, information on breastfeeding and breastmilk establishment for the NICU infant, and pump log), as well as a 30-minute lactation consultation in mother's room with board certified lactation staff within the first 24 hours post delivery. The primary investigator also verified mother's knowledge and accuracy of milk storage bottle volume measurements to demonstrate the validity of volume measurement. Demographic information was collected during this visit as well as mother's email/telephone contact information.

All participants were provided with a written pump log. It was determined that some participants preferred logging milk volumes and times on smart phones. This became an accepted reporting method in addition to, or in place of, the written log. Pump logs were examined and milk volume and pumping frequency data were collected and recorded. Milk volumes for days 7 and 14 post-delivery were obtained from participants' logs by the primary investigator.

All mothers of NICU infants received standardized verbal and written breastmilk collection and storage guidelines from lactation staff, as well as from postpartum and NICU nursing staff. Instruction emphasized frequent, complete breast emptying (8x/day) using a hospital grade electric breast pump with no more than one 5-hour stretch between pumpings at night. "Hands on" pumping was encouraged, using massage prior to pump use, massage/compression during pumping, and hand expression after pump use.

NICU lactation staff provided two consultation visits prior to mother's discharge from hospital. Subsequently, they provided continued ongoing support for as long as the infant was hospitalized. A final consultation occurred approximately 24 hours prior to infant's discharge. Lactation staff

reviewed the pump log and documented 24-hour milk volume and frequency of pumping in the electronic medical record (EMR) as part of the standard assessment and documentation. For this study, milk volume and frequency data for the day of discharge was obtained by the primary investigator from the EMR.

Follow-up phone interviews occurred in the week after the infant reached 42 weeks gestation. Participants received an email prior to the phone interview alerting them of the upcoming interview and type of information to be requested. Participants were asked a general question about the health and weight of the infant, followed by specific questions related to number of feeds: 1) at breast alone, 2) a combination of breast and bottle, and 3) by bottle alone. (See Appendix A for list of questions asked during interview). Type of milk (breastmilk versus formula) was not investigated during the interview. Due to difficulty in reaching some families, 5 interviews occurred up to one month later than 42 weeks gestation and one interview occurred four months after the 42 week target date due to out an of state location of the family.

Data Analysis

After collection of phone interview data, all study information was de-identified prior to data analysis. Descriptive statistics were utilized to analyze demographic and breastmilk volume data. Spearman rank correlation was used to assess the relationship between breastmilk volumes on day 7, day 14 and on discharge. Breastmilk volume at day 7 and day 14 was dichotomized as $<500\text{ml/day}$ and $\geq 500\text{ ml/day}$ to assess the association between breastmilk volumes and transition to direct breastfeeding. Given that only three mothers successfully transitioned to direct breastfeeding ($>80\%$ of daily feeds by direct breastfeeding), frequency of direct

breastfeeding was analyzed as none or any ($>0\%$), as well as none, $>0\%$ to $<50\%$, and $\geq 50\%$ of daily feeds. Fisher's exact test and linear-by-linear trend test were used to assess for an association between breastmilk volume at 7 and 14 days and frequency of breastfeeding at 42 weeks gestation. SPSS version 19.0 was used for all data analysis.

RESULTS

Subjects

Seventy-seven infants less than 34 weeks gestational age were admitted to the NICU during the study period. Of those, one mother decline study enrollment and 25 mother/infant dyads were deemed ineligible. Reasons for ineligibility included congenital/chromosomal anomalies (5), positive drug screen and/or DHS involvement (4), adoption/surrogacy (2), desire to bottle feed only (2), non-English speaking (4), infant and/or mother in critical condition (4), history of breast surgery (3), and triplet pregnancy (1). Subsequently, 51 mothers were enrolled. Prior to initial milk volume data collection (day 7), one infant died, two infants were discharged, and one mother could not keep a pump log. Milk volumes and frequencies data were collected from 47 mothers. (Table 1)

Demographic data of participants is summarized in Table 2. The majority of mothers were Caucasian (70%) or Hispanic (23%). Sixty percent were first time mothers, and 81% had single births (versus twins). Maternal age ranged from 16-44 years with a mean of 30 years. Gestational age of the infants ranged from 24 6/7 weeks to 33 6/7 weeks at birth, with a mean of 30.8 weeks. Of note, 43% of infants ranged from 32 – 33 6/7 weeks gestational age at birth, while only 6% were less than 28 weeks gestational age. Length of hospital stay ranged from 11 days to 103 days, with a mean of 40 days.

Breastmilk Production

Breastmilk volumes and pumping frequency data for enrolled mothers are summarized in Table 3. By day 7, only 22 (47%) of mothers had attained 500ml/day breastmilk volume goal volume. By day 14, 31 (66%) of mothers had achieved the goal of at least 500ml/day. Twenty-seven mothers (57%) had attained milk volumes of at least 500ml/day on both day 7 and day 14.

There were strong positive correlations between day 7 and day 14 volumes ($r = 0.917$, $p < .001$), between day 7 and day of discharge volumes ($r = 0.602$, $p < .001$), and between day 14 and day of discharge volumes ($r = 0.720$, $p < .001$). Correlations between breastmilk volumes and length of stay or direct breastfeeding frequency were not significant (r 's < 0.3 , $p > .05$). (Table 3)

Mean pumping frequency for day 7 and 14 was approximately 7 times/day. At day 7, only 5 women reported pumping frequencies less than 6 times/day. By day 14, only four women reported frequencies under 6 times/day, which included two women with frequencies less than 6 times/day at day 7. Of note, 79% ($n=39$) of all women had pumping frequencies of 7, 8 or 9 times/day.

Transition to Breastfeeding

Follow-up phone interviews were completed for 31 mothers of the 47 mothers with milk volume data collection. Six mothers had stopped pumping at time of discharge from the NICU, one infant died between the 14th day and day of discharge, one infant received a gastrostomy tube for feedings prior to discharge, and one mother requested to withdraw from the study due to anxiety

related to pumping. Seven mothers were not interviewed due to loss to follow-up despite multiple attempts to contact them by phone and email.

The phone interview results are summarized in Table 5 and Figure 2. Of those receiving follow-up interviews (n=31), only two women reported a full transition to 100% of feeds by direct breastfeeding; one mother reported 88% feeds in a 24-hour period by breast alone, two mothers reported 75% of feeds by breast alone. Twenty-one mothers (68%) reported that no feedings during the day were provided by direct breastfeeding alone (without bottle supplementation). Ten women reported offering direct breastfeeding, followed by bottle supplementation. Thirteen (42%) of the women interviewed reported that all feedings provided were by bottle and they had stopped providing any direct breastfeeding to their infants. Mothers delivering twins comprised 19% (n=9) of those enrolled. Of the nine mothers enrolled, six received follow-up interviews. Only one mother reported any direct breastfeeding of her infants.

Of the five mothers providing greater than or equal to 75% of feedings by breastfeeding alone, four of the five were multipara and had successfully breastfed other children. Interestingly, the two multipara mothers who reported providing 100% of feeds by breast had day 7 milk volumes <500ml/day (216ml, 473ml) but had day 14 volumes \geq 500ml (510ml, 650ml).

The relationship between milk volumes at day 7 and 14 and direct breastfeeding frequency at 42 weeks gestational age is presented in Table 6. Of the women who had less than 500ml/day breastmilk volume on day 7, 20% reported some direct breastfeeding at 42 weeks gestation, compared to 44% of the women with more than 500ml/d on day 7 (p = .25). Of the women who

had less than 500 ml/day at day 14, none reported any direct breastfeeding at the follow-up interview compared to 43% of women who had ≥ 500 ml/day at day 14 who reported providing some direct breastfeeding, either alone or in combination with bottle supplementation, in the follow-up period ($p = .032$). Secondary analysis compared milk volumes and frequency of direct breastfeeding in the breastfeeding categories of $>0\%$ to $<50\%$, and $\geq 50\%$ of daily feeds. Among mothers with breastmilk volumes <500 ml/day at day 7, 20% were direct breastfeeding $\geq 50\%$ of the time as compared to 19% of mothers with breastmilk volumes ≥ 500 ml/day. In contrast, no mothers with breastmilk volumes <500 ml/day at day 14 were direct breastfeeding $\geq 50\%$ of time, as compared to 26% of mothers with breastmilk volumes ≥ 500 ml/day. (Table 6)

The mothers' reported reasons for not providing direct breastfeeding were varied but some common themes were present. The most common reasons were related to the ease and preference by baby or mother for bottle feeding (7). Some mothers stated their infant would not latch or would fall asleep prior to taking sufficient volume. One mother reported she wanted to give her own breastmilk by bottle instead of by breast so she could know the exact volume taken, as she was concerned about her infant's growth. The need for continued fortification of feedings (6), as well as decreasing milk supply (4) were other reasons given. The experience of returning to work was cited by three mothers as presenting challenges in continued breastfeeding and milk supply. Frustration with reflux/colic was mentioned by three mothers. Many of the mothers reported they were still providing partial or full feedings of breastmilk (versus formula) to their infants by bottle, but this was not specifically researched in this study.

DISCUSSION

This pilot study provides valuable insights and implications for further research in the area of breastmilk production and breastfeeding of the preterm infant. While only three mothers (10%) met the study definition of successful transition to direct breastfeeding (full or partial high: >80%), these study results do demonstrate a significantly higher likelihood of any direct breastfeeding and of breastfeeding $\geq 50\%$ of feedings, if breastmilk volumes are $\geq 500\text{ml/day}$ at day 14. This positive association can be used in the counseling and support of these mothers in the feeding of their infants. The day 14 milk volume assessment (as opposed to day 7) is key to the determination of potential direct breastfeeding success post discharge from the NICU. Also of note was that no woman with less than 500ml/day at day 14 reported any direct breastfeeding in the follow-up interview.

Both mean breastmilk volume at day 7 and 14 and mean pumping frequencies found in this study were higher than those reported by Hill and colleagues. (Hill, Aldag 2005) Improved electric pumping technology, as well as use of hands on pumping, could possibly account for the increase in volumes. Bishara et al reported 3-week volumes of 525ml/day , which is below the mean 14-day volume reported in the present study. (Bishara 2009) It is difficult to compare the present study's findings with other previous research findings due to the inclusion of breastmilk feedings given by alternative method other than direct breastfeeding (i.e., bottle) in the definition of full exclusive breastfeeding in some of the previous studies. (Lessen 2006; Dowling 2012; Ahmed 2010)

Breastmilk volume and frequency results demonstrate the ability of many mothers to successfully establish an adequate supply of breastmilk for their preterm infants. Of interest was the improving milk supply of many of the women, with adequate pumping frequency between day 7 and 14 and continuing to increase for some until the day of discharge. Hill and colleagues had noted an increasing supply in the first 6 weeks for mothers of term infants only. Mothers of preterm infants had milk supplies that remained flat or decreased over the 6-week period of time. The findings of the present study have practice implications in the support of mothers who have not reached the goal volume of 500ml/d at day 7.

Also important to note is the high pumping frequency (>6 times/day) in the mothers with successful milk supply establishment. Of the five women pumping less than 6 times/day at day 7, only one woman (multipara) successfully established a milk supply over 500 ml/day at day 14 or at her infant's day of discharge. Four women at day 14 were pumping less than 6 times/day and, of these, only one reported a milk volume >500ml/day. This woman was the only one of the four that reported any direct breastfeeding during follow-up interviews.

Of the mothers of twins who were enrolled in the study (9), only one mother reported any direct breastfeeding of her twin at the time of follow-up interview. The other mothers of twins described limitations of time, the need for family assistance, as well as supply challenges as reasons for providing all feeds by bottle. As many NICUs care for mothers delivering multiples, there is an increasing need to support these families in the many challenges, including breastfeeding, they face during and after their NICU stay.

The direct breastfeeding results, although disappointingly low, provide valuable information regarding the challenges faced by mothers of premature infants following discharge from the NICU. Reasons provided by mothers during the interviews for not feeding directly at breast were consistent with those reported by Hill and colleagues. (Hill 1997) The most common reason given, that of ease and preference for bottle over breast, may be understandable in light of the Ten Steps to Successful Breastfeeding, the foundational guidelines set forth by the WHO/Unicef launched Baby Friendly Hospital Initiative. Bottle feeding, while being an efficient method of feeding adequate volumes to developmentally immature preterm infants, may in fact be hindering these infants from transition to full direct breastfeeding. Step #9 of the 10 Steps to Successful Breastfeeding recommends no artificial nipples be given to breastfeeding infants (non-NICU) as this has been found to interfere with infants learning to suckle at breast. (WHO 1998;Benoit 2014) Canadian J Callen and colleagues conducted a qualitative study investigating the barriers of breastfeeding in very low birth weight infants in the hospital and post discharge. Low milk volume and the mother being physically compromised, as well as need for complementary feeds given by bottle post NICU discharge, were reported as barriers to successful maintenance of breastfeeding post discharge. (Callen 2005) A national survey of Danish NICUs reported a well-established practice in their hospitals of restricting use of bottle feedings in preterm infants. Tube feeding was primarily used in the transition to exclusive breastfeeding. (Maastrup 2014) In the present study, it is not known whether the actual use of the bottle feeding method impeded the transition to direct breastfeeding, as the infants may have possibly grown accustomed to the ease and flow of the bottle.

In the present study, an additional reason for not breastfeeding directly voiced by women was the need for continued fortification of feedings. Meeting the pre- and post-discharge nutritional needs of preterm infants continues to be a challenging balancing act while supporting the transition to direct breastfeeding. Fortified feedings are generally provided most conveniently by bottle in the first weeks, and sometimes months, following discharge from the NICU, thus requiring these infants to have a breast and bottle combination of feeding methods. (Zachariassen 2011) More research and consistent guidelines are needed in this area.

Study Limitations

One limitation of this study, consistent with the prospective cohort study design, was loss to follow-up. The primary investigator was unable to contact seven mothers for follow-up interview despite multiple attempts. Mothers with unsuccessful breastfeeding experiences may have been reluctant to provide follow-up interview information. Also lost to follow-up were the six mothers who stopped pumping by the time of infant's hospital discharge.

Another potential limitation of the present study is the accuracy of pump log data. Log data was provided by the mothers without ongoing verification of accuracy due to the self-reporting nature of the log. During enrollment, efforts were made to ensure that all mothers could accurately measure and record breastmilk volumes. Inaccuracy in reporting by mothers during follow-up interviews was possible as there was no method to verify the interview reports of feeding status.

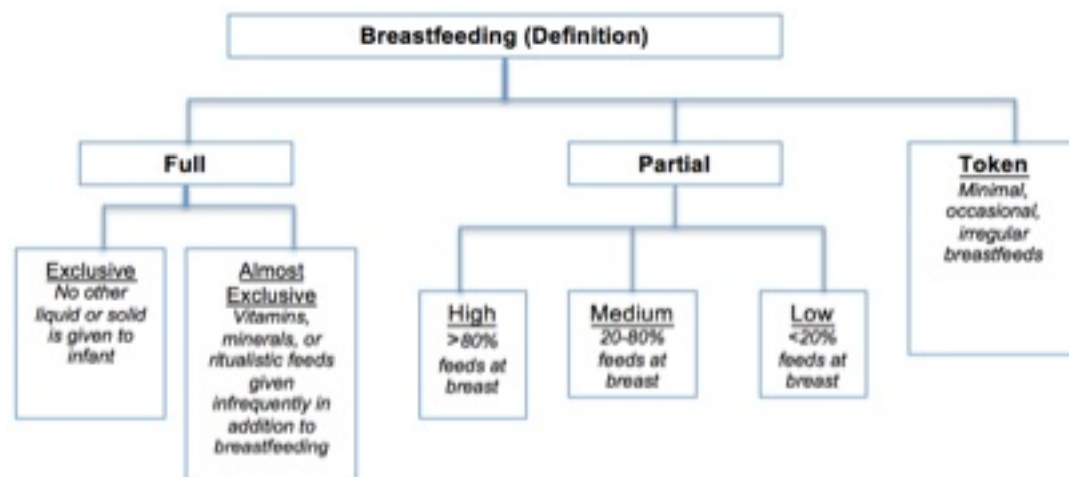
An additional limitation of the study was lack of information on the type of milk (breastmilk versus formula) given by bottle. Information regarding the type of feeding provided by bottle

was not obtained during the follow-up interviews. It could not be determined how many mothers were providing breastmilk via bottle (versus formula) to their infants.

Implications for Future Research

This study provides valuable insights for all professionals providing care for mothers and preterm infants in the NICU setting, as well as following infant's hospital discharge. The need for successful establishment of an adequate milk supply is indicated by the findings of this study. The study results demonstrate the ability of many mothers, with early consistent support and motivation, to successfully establish and maintain an adequate milk supply. More research is needed in the area of post discharge nutritional needs for preterm infants, as well as effective feeding methods for provision of necessary additional fortification to infants, and support to mothers, in order to achieve the goal of transition to full direct breastfeeding for these vulnerable infants.

Figure 1



Labbok, 1990

Table 1
Flow Table of Study Participants

Assessed for eligibility	n=77	
		<p>Ineligible or declined enrollment (n=26)</p> <ul style="list-style-type: none"> • Congenital/chromosomal anomalies (n=5) • Positive drug screen/DHS involvement (n=4) • Desire to bottle feed only (n=2) • Non-English speaking (n=4) • Infant or mother in critical condition (n=4) • History of breast surgery (n=3) • Triplet pregnancy (n=1) • Adoption/surrogacy (n=2) • Declined enrollment (n=1)
Enrolled	n=51	
		<p>Lost to milk volume data collection (n=4)</p> <ul style="list-style-type: none"> • Infant died (n=1) • Infant discharged prior to Day 7 (n=2) • Pump log not kept (n=1)
Milk volume data collected	n=47	
		<p>Lost to follow-up (n=16)</p> <ul style="list-style-type: none"> • Stopped pumping at time of discharge (n=6) • Infant died before discharge (n=1) • Received gastrostomy tube for feeding (n=1) • Withdrew due to pumping anxiety (n=1) • Unable to contact (n=7)
Follow-up interview & analyzed	n=31	

Table 2
Demographic Information

CHARACTERISTIC	MOTHERS (n=47) n (%)
GESTATIONAL AGE AT BIRTH (wks)	
mean (SD), range	30.8 (2.5) 24.7 – 33.9
<28 weeks	6 (13)
28 – 31 6/7 weeks	21 (44)
32 – 33 6/7 weeks	20 (43)
PARITY	
Primipara	28 (60)
Multipara	19 (40)
RACE	
Caucasian	33 (70)
Hispanic	11 (23)
Pacific Islander	1 (2)
American Indian	1 (2)
African American	1 (2)
MATERNAL AGE (yrs)	
mean (SD), range	30.1 (6.6) 16-44
<18 years	1 (2)
18-25 years	12 (25)
26-34 years	23 (49)
35-40 years	9 (20)
>40 years	2 (4)
Single birth (vs twin)	
Single	38 (81)
Twin	9 (19)
Length of Stay (days)	
mean (SD)	40.4 (25.1)
Range	11*-103

*Infant discharged on day 11, prior to day 14. Day 11 (DOD) milk volume used as 14 day milk volume

Table 3
Breastmilk Volume/Pumping Frequency
(n=47)

Variables	Day 7	Day 14	Day of Discharge
Breast milk volume (ml/day)			
mean (SD)	512 (344.1)	678 (405.6)	668 (417.9)
range	18-1595	40-1690	0-1600
Breast Milk volume n (%)			
<500ml	25 (53)	16 (34)	15 (33)
≥ 500 ml	22 (47)	31 (66)	30 (67)
Pumping Frequency (times/day)			
mean (SD)	7.1 (1.4)	7.0 (1.5)	6.0 (2.5)
range	2-8	2-9	0-8

Table 4
Spearman's rank correlations between breastmilk volume at Day 7, Day 14 and day of discharge, breastfeeding frequency and length of hospital stay (n=31)

	Breastmilk volume, day 14	Breastmilk volume at discharge	Breastfeeding frequency	Length of stay
Breastmilk volume, Day 7	.94***	.70***	.27	.01
Breastmilk volume, Day 14		.75***	.22	-.02
Breastmilk volume, discharge			.24	.14
Breastfeeding frequency				.17

*P < .05; **P < .01; ***P < .001

Table 5
Breast and Bottle Feeding Frequency at 42 weeks Gestation
Mothers Interviewed n=31

Reported Frequency	Breast Alone n(%)	Breast/Bottle Combination n(%)	Bottle Alone n(%)
100% of Feeds	2(6.4)	0(0)	13(41.9)
50-99% of Feeds	4(12.9)	5(16.1)	10(32.3)
1-50% of Feeds	4(12.9)	5(16.1)	5(16.1)
0% of Feeds	21(67.8)	21(67.8)	3(9.7)

Figure 2

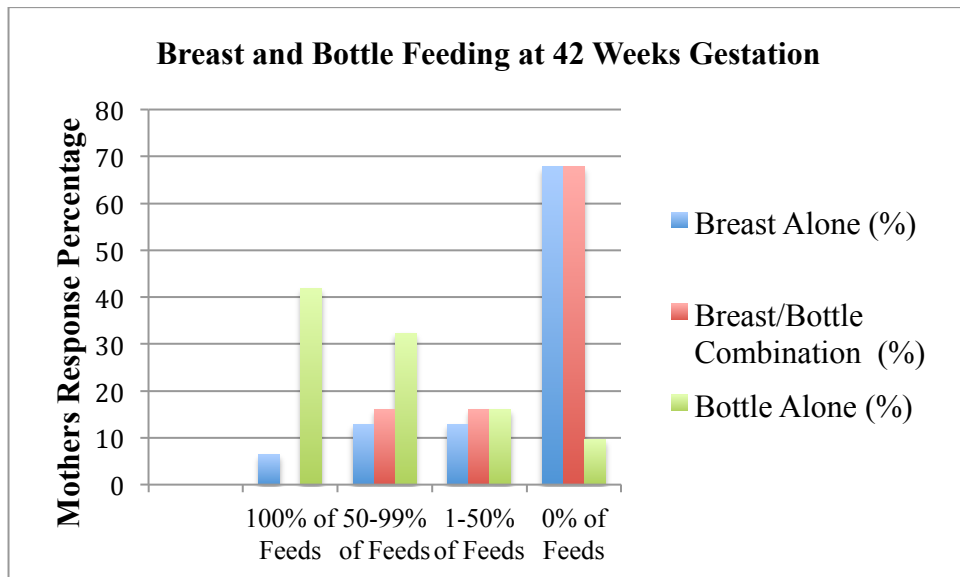


Table 6
Breastfeeding Frequency at 42 weeks Gestation by Breastmilk Volume at
Day 7 and Day 14

Breastmilk Volume	N(%)	Any Breastfeeding		Breastfeeding frequency			P²
		>0%	P¹	0%	>0% to <50%	≥50%	
		n (%)		n (%)	n (%)	n (%)	
Day 7			.25				.44
<500 ml	15 (48)	3 (20)		12 (80)	0 (0)	3 (20)	
≥500 ml	16 (52)	7 (44)		9 (56)	4 (25)	3 (19)	
Day 14			.032				.037
<500 ml	8 (26)	0 (0)		8 (100)	0 (0)	0 (0)	
≥500 ml	23 (74)	10 (43)		13 (57)	4 (17)	6 (26)	

¹P = Fisher's exact test p-value; ²P = Trend test p-value

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APPENDIX A

Research Phone Interview Intake Form

Phone interview begins with:

- (a) a check to make sure that the person answering the phone is the right person, followed by,
 - (b) a reminder identifying the caller and the study, and her departmental and University of Washington affiliation, and
 - (c) a statement or question that allows the prospective subject to opt out of the telephone interview, or set a more convenient time ("Are you still willing to participate in this interview? Is this a good time to talk?").
1. How is your baby doing? Are there any medical concerns or problems?
 2. How are you (the mother) doing?
 3. Do you have any concerns about your baby's growth?
 4. Are you putting your baby directly to the breast for feedings? (Yes/No)
 - a. If "No", what are the reasons?
 5. (If yes in # 4) How many feedings in the last 24 hours were done solely at the breast, with no bottle supplementation?
 6. (If yes in # 4) How many feeds in the last 24 hours consisted of a combination of direct breastfeeding and bottle feeding?
 7. How many bottle feedings (without breastfeeding) were provided in the past 24 hours?
 8. How many feedings total feedings were provided to your baby in the last 24-hour period?
 9. What is the most recent weight of your baby?

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INFORMED CONSENT FOR A RESEARCH STUDY

Title: Association Between Mothers' Milk Supply and Subsequent Direct Breastfeeding Success Among Preterm Infants: A Pilot Study (PH&S IRB # 13-033B)

**Principal Investigator: Cynthia C Jackson RNC, IBCLC
Staff RN, NICU, Providence St Vincent's Medical Center, Portland, OR
University of Washington, School of Public Health, Department of Health Services**

Introduction and Purpose

You are invited to take part in a research study conducted by Cynthia C. Jackson, RNC, IBCLC (study investigator), graduate student at the University of Washington and nurse at Providence St. Vincent Medical Center, as part of the requirements of her degree in Master of Public Health. You are being asked to take part in this research study because you are the mother of a preterm baby and you plan to breastfeed. This consent form will explain this study to you, and what you need to do if you take part. Make sure you understand what is written; ask as many questions as needed before you decide whether to take part. After this study is explained to you, and if you choose to take part, you will be asked to sign this consent form.

The purpose of this study is to see if there is a relationship between the amount of breast milk pumped by mothers of preterm babies in the first weeks of life and their ability to directly breastfeed by the time babies reach full term (around 42 weeks gestational age). "Full term" is defined as 38 to 42 weeks gestational age. Your due date is set at 40 weeks gestational age.

This study involves collecting information from you. This study does not involve any treatment or procedures. Your medical care and your baby's medical care will not be affected by you taking part in this study.

About 50 women will take part in this study.

Study Procedures

After signing the consent form, you will be enrolled in this study. We will ask you for specific information (your age, race, gestational age of your baby, and the number of babies you have had.) We will also collect contact information from you (phone number, home address and email address).

Like all mothers of preterm babies in the NICU (Neonatal Intensive Care Unit), you will be given a pump log to record your breast pumping. You will be asked to keep an accurate record of the times that you pump and the amount of milk pumped.

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We will collect information from you about the total amount of milk pumped in a 24-hour period on days 7 and 14 after the birth of your baby and on the day your baby is discharged. This is information that our Lactation staff is accustomed to obtaining as they support you while your infant is in the NICU

Follow-up

After your baby is discharged from the hospital, we will call you by phone when your baby is approximately 42 weeks gestational age. We will ask you questions regarding your baby's breastfeeding and bottle feeding patterns in the past 48 hours as well as your baby's weight. This phone call will take about 10 minutes. You don't have to answer any questions you do not wish to answer. You will receive an email and/or letter 2-3 days prior to the phone call. Included will be a document to keep track of your baby's feeding for the next 2 -3 days.

Your enrollment in the study will end at the completion of the phone interview.

Possible Risks

There is a risk of loss of privacy or confidentiality of your personal information that is collected for this study. However, steps have been taken to keep your personal information confidential, and the risk of this happening is very small. (See below under "privacy".)

Possible Benefits

There are no guaranteed benefits to you for taking part in this study. However, information learned from this study may help mothers of preterm babies who plan to breastfeed in the future.

Alternatives

You may choose not to take part in this study.

General Information

Your taking part in this study is voluntary. Your refusal to take part will not affect your regular medical care, including support by the Lactation staff, or your health care benefits. If you decide to take part, you are free to stop at any time without any effect on your medical care or your relationship with Providence Health & Services.

While in this study, any important new information that may affect your plan to continue taking part will be given to you.

You do not give up any of your legal rights by signing this consent form and taking part in this study.

Costs

You will not be paid to take part in this study; nor will it cost you anything to take part.

You are responsible and must pay for the costs of you routine medical care and medications; however, these costs may be covered, at least in part, by most major insurance companies or Medicare.

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Patient Initials _____

My initials indicate I have read this page

Privacy

Your personal information regarding your pumped milk supply at 7 and 14 days after delivery and at discharge, will be collected and stored on paper and electronically in a secure location in the NICU as well as on a laptop computer encrypted by Providence. (No one can have access to the data unless they are authorized to do so.) Also collected will be your contact information as well as demographic information (your age, race, gestational age of your baby, and the number of babies you have birthed). Your contact information is needed to be able to phone you after your baby is discharged. After your phone interview is complete, all of your personal information will be “de-identified”, so that no one can match you with the information collected.

Your medical and study records are personal and private and only the study investigator, yourself and anyone you allow have the right to look at your records. It is important for the Providence Health & Services Institutional Review Board (IRB – a committee that reviews research to protect your rights), and representatives of Providence to be able to look at your medical and study records. When you sign this consent form, you agree to allow this. If results of this study are reported in journals or at meetings, your identity will remain secret.

The signed consent form will be provided to Providence to document your authorization and will be a part of your medical record.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) gives you certain rights to protect the privacy of your study information and records. Under HIPAA, you must give your permission before anyone uses or shares your information. This information is also called protected health information (PHI). Your rights, as well as the reasons for using your PHI, are described below.

The study investigator will need to use your PHI for this study. This includes your name, address, and telephone number. This information will be kept in a secure location and will only be used until the phone interview is complete and will then be destroyed.

By signing this consent form, you agree to allow the study investigator to use and share your PHI for the following reasons:

- Evaluate the results of this study
- Make conclusions about the study results
- Provide study results to other researchers
- Re-evaluate study results in the future, as needed
- Include your study information with results from other similar studies
- Send study information to representatives of the study investigator
- Any other purposes as described in this consent form.

If you are not willing to allow your PHI information to be shared, you will not be able to take part in this study.

The study investigator and her representatives, the IRB and any regulatory agencies may review your medical records and make copies. The reasons this might happen is to make sure this study

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is being done properly, study information is being collected correctly, and for other purposes allowed by law.

Your permission to use to use and share your PHI will end after your phone interview is completed and your information provided is "de-identified". The link between your identity and the data is destroyed at this point.

You may cancel your permission at any time by sending a written notice to the study investigator. Your PHI for this study will no longer be used or shared. If you cancel your permission, you will no longer be able to take part in this study. The study investigator will still use any PHI received before you cancel your permission.

If you have questions about your privacy rights, please call the Providence Health & Services HIPAA Privacy Officer at (503) 574-9123.

Questions:

Any questions you have about this research study can be answered by:

***Study Investigator: Cynthia Jackson RNC, IBCLC
503-348-7659, cynthia.jackson@providence.org***

Any questions you have about your rights as a research subject will be answered by the Providence Health & Services Institutional Review Board at (503)215-2046.

You may also contact the University of Washington Human Subjects Division at 206-543-0098 or hsdinfo@uw.edu.

You are free to ask questions about this study at any time.

Consent:

I have read all of the above, and received satisfactory answers about what I did not understand. I agree to take part in this research study. I have been given a copy of this consent form for my records.

Name of Patient (Please Print)

Signature of Patient

Date

Name of Person Obtaining Consent (Please Print)

Signature of Person Obtaining Consent

Date

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My initials indicate I have read this page