Improving Delayed Lactogenesis and Suppressed Lactation in At-Risk Mothers

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High breastfeeding initiation rates show that most mothers in the U.S. want to breastfeed and are trying to do so. However, low breastfeeding rates among infants who are six and 12 months of age indicate that many mothers do not continue breastfeeding as recommended. These rates suggest that mothers, in part, may not be getting the support they need, such as from healthcare providers, family members, and employers.... The early postpartum period is a critical time for establishing and supporting breastfeeding.

CDC 2016 Breastfeeding Report Card [1]

WHITE PAPER

EXECUTIVE SUMMARY

Although breastfeeding initiation is at an all-time high of 81%, rates of breastfeeding exclusivity and duration lag behind national goals. Women who stop breastfeeding before meeting their goals often report they did not have enough milk.

The ability to initiate, build and maintain breast milk volumes sufficient to meet an infant's needs are dependent on complex interwoven factors. Additionally, there are multiple maternal risk factors for delayed milk production and suppressed lactation:

- Primiparity
- Cesarean sections
- Maternal age > 30
- Elevated BMI
- Glucose resistance

Demographic trends in the United States indicate all these risk factors have increased, some quite dramatically, in the last 20 years. Additionally, many women have multiple risk factors and are at significant risk for lactation problems.

New evidence suggests babies' feeding behaviors have an important role in determining lactation success. These unique infant sucking patterns in the first few days of life appear to program mothers' breasts for optimal milk production. New breast pump initiation technology that mimics early newborn sucking is a potentially viable and safe intervention to provide at-risk mothers with additional breast stimulation for optimal milk production outcomes.

In many lactation situations, interventions aren't started until a mother reports problems. By identifying mothers who are at risk for delayed or suppressed milk production, especially those mothers with multiple risk factors, clinicians can increase surveillance of infant feeding progress and intervene proactively with breast pump initiation technology.

INTRODUCTION

National efforts to promote breastfeeding have led to substantial gains in breastfeeding initiation rates, now at an all-time high of 81%. However, lactation duration rates continue to be less than optimal. For example, only 52% of mothers are fully or partially breastfeeding at six months postpartum.[1] Human-milk feeding is critical to US public health as it has multiple short and long-term health benefits for infants and young children, which are conferred in a dose-response manner.[2-6] Human milk feeding is endorsed internationally as the gold standard of infant nutrition and is proven to reduce risks of infant respiratory, ear and gastrointestinal infections, SIDS, leukemia, diabetes in all infants and life-threatening morbidities in preterm babies.[2,7,8] For parous women, lactation reduces risks of later-life cardiac disease, stroke, breast and reproductive cancers and metabolic disorders related to insulin resistance.[9-12]

The ability to initiate, build and maintain breast milk volumes sufficient to meet an infant's needs are dependent on complex interwoven factors. Hormonal shifts in the childbearing cycle drive pro-lactation breast changes during pregnancy and release barriers to lactogenesis after birth (defined here as the process of milk "coming in," also known as lactogenesis II or secretory activation). Hormonal changes post-birth are necessary but not sufficient for optimal milk production. New evidence suggests babies feeding behaviors have an important role in determining lactation success.

During the first few days of life, infant feeding behavior consists of short sucking bursts of varying intensities interspersed with long pauses. This early sucking behavior appears to program mothers' breasts for later milk production and may play a greater role than milk removal in the initial stage of lactation.[13-15] After the first two weeks, the key factor in maintaining breast milk production is frequent and sufficient removal of milk by breastfeeding or milk expression.[16,17]

Many breastfeeding mothers are concerned they don't produce enough milk for their babies. Insufficient milk supply is a primary reason women give for discontinuing lactation, both in the early weeks and later months.[18,19] Historically, some of these concerns were attributed to delayed or insufficient breastfeeding, unrealistic maternal expectations of early milk production, and infant formula marketing encouraging the use of feeding supplements. In the last 10 years, nationwide breastfeeding advocacy programs within the federal government and by major health professional organizations joined forces to promote comprehensive breastfeeding enhancement strategies, many of which are based on the World Health Organization and UNICEF's Ten Steps to Successful Breastfeeding. During this time, the percentage of U.S. births in Baby-Friendly facilities has risen from 2.7% to 21.3%.[20] Increases in the percentage of US hospitals implementing a majority of the Ten Steps, without receiving Baby-Friendly designation, increased from about 29% in 2007, to nearly 54% in 2013.[21] Even with these recent improvements in perinatal practices, it has not resolved the continued problem of sub-par lactation duration rates and mothers' continuing reports of "not having enough milk for my baby."

Market Drivers

All benefits of breastfeeding for infants and mothers are expressed in a dose-response relationship. That is, the more human milk a baby gets, the better the benefit. Likewise, the more a woman lactates – the more exclusive it is and the longer she produces milk, the better her chances are of reducing her risks

of heart disease, stroke, cancer, glucose intolerance and diabetes and other diseases.[7] If we could improve milk production in women who are known to be at risk, we could more effectively support exclusive breastfeeding and longer durations, impacting both infant and women's health outcomes.

In-depth analyses by Bartick and associates have estimated a combined cost saving to US society of over $30 billion annually if 90% of US mothers were able to exclusively breastfeed for six months. This calculation includes an annual cost savings of $13 billion attributed to improved infant outcomes[22] and $17.4 billion related to women's health outcomes.[23] On a micro level, each incidence of avoided illness or disease translates into healthcare savings, a more productive society and a higher quality of life for mothers and their infants.

CONDITIONS CAUSING SUPPRESSED LACTATION

Mothers who are unable to breastfeed

Mothers with hospitalized and/or preterm infants are at risk for delayed lactogenesis and suppressed lactation. They are more likely to have medical complications and operative deliveries and even if they did not plan to breastfeed, they are strongly encouraged to produce milk for their babies. These moms face several challenges; thus, numerous clinical protocols, best practices and national health policies specify strategies to support them to provide milk for their infants.[24-26]

General maternal risk factors

Of the multiple maternal risk factors associated with breast milk production, primiparity, maternal age ≥ 30, surgical delivery and BMI > 27 are the most consistent and significant.[27-29] Trend lines show increases in all of these variables compared to 20 years ago. Indeed, demographic data suggests childbearing women are at higher risk today for sub-par lactation than at any other time in recent history. According to the Department of Health and Human Services,[30] 38%, or more than one-third, of U.S. births in 2015 were to first-time mothers. The average age of women giving birth is at an all-time high of 26.4 years with 44% of all births attributed to women ≥ 30. Additionally, U.S. cesarean section rates have been over 30% since 2005, and although declining slightly, they are still 32%.[30]

Primiparity and maternal age

A complete review of the literature on lactation risk factors exceeds the scope of this paper; however, discussion of several key findings will underscore the impact of selected variables. Of these, primiparity has one of the strongest associations with delayed lactogenesis (>72 hours postpartum).[27-29,31] For example, in a study of primiparous and multiparous women with term healthy newborns, Dewey et al. found 22% of mothers had delayed lactogenesis. Multiple regression analysis revealed primiparity was the most significant risk factor for delayed lactogenesis and suboptimal breastfeeding. When milk production was delayed, infants had a seven-fold risk of greater than 10% weight loss by day three.[28] Early infant weight loss may lead to dehydration (and early introduction of supplements), delayed meconi-

um passage, higher bilirubin levels, and higher rates of readmission within the first two weeks. Mothers with delayed lactogenesis or sub-par breastfeeding whose infants have significant early weight loss are at high risk for short breastfeeding duration.[29]

Exploring further the concept of parity as a lactation risk factor, Nommsen-Rivers et al.[29] examined 431 first-time mothers with term babies. A remarkable 44% of these mothers reported delayed lactogenesis. These authors found first-time mothers were at highest risk if they were 30 or older, were overweight and/or had an infant over 3600 grams. An important early clinical predictor of delayed lactogenesis in this population was infant breastfeeding no more than once in the first 24 hours.

Cesarean section

Several studies of mothers with term infants confirm unplanned surgical delivery is a significant risk factor for delayed lactogenesis and/or suboptimal breastfeeding.[27,28,32,33] Chapman and Perez-Escamilla found a 5.6 odds ratio (95% CI:1.8-16.8) of delayed lactogenesis in women with unscheduled cesareans compared to a 1.4 odds ratio (95% CI: 0.5-4.4) in women with scheduled cesareans. Dewey et al.[28] also reported increased lactation risks with operative deliveries, especially urgent cesareans.

Maternal BMI and insulin resistance

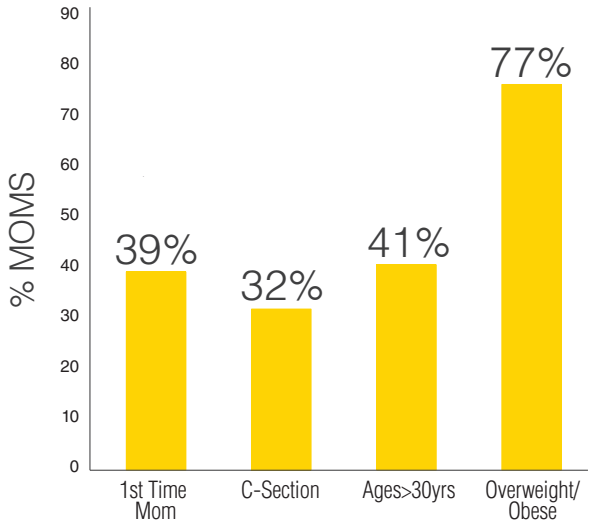
Of all variables associated with delayed lactogenesis and suppressed lactation, perhaps the most daunting is the influence of elevated maternal BMI. This astoundingly pervasive factor is highly correlated with poor maternal-child health outcomes like premature delivery, operative delivery and glucose intolerance, all of which compound a mother's risk for lactation failure.

Without a doubt, the incidence of overweight and obesity in the US population is a national crisis that impacts all aspects of public health. In 2016, the CDC reported nearly half of women are overweight or obese before they become pregnant, and nearly half of women gained too much weight during pregnancy.[34]

According to Nommsen-Rivers,[35] Dewey et al.[28] and others,[36] multiple national and international cohort studies indicate a statistically significant, dose-response relationship between elevated maternal BMI, delayed onset of lactogenesis and shortened duration of lactation. Furthermore, elevated BMI and obesity are known risk factors for glucose intolerance in pregnancy. Indeed, Riddle and Nommsen-Rivers[35,36] report any diabetes and/or insulin resistance in pregnancy is associated with a 2.6 fold risk of low milk supply within the first three months postpartum.

The onset of lactogenesis is attributed to withdrawal of progesterone at delivery and the actions of several hormones, most notably prolactin, on milk secreting cells in the breast. The role of insulin in lactogenesis was not well understood until 2009 when research by Berlato and Doppler[37] and others[38] demonstrated insulin receptors are dramatically upgraded during early lactogenesis, enhancing mammary tissue sensitivity to insulin. The interaction of insulin to changing insulin receptors is now recognized as fundamental to milk synthesis. In instances of insulin resistance and lower levels of insulin as seen in diabetic mothers, reduced insulin levels and/or reduced effectiveness impedes milk synthesis both early on and throughout lactation.[35,37,39] Thus women with impaired glucose tolerance are at risk for delayed lactogenesis and suppressed lactation. Collectively, documented risk factors for suboptimal milk production – separation of mother and infant, primaparity, higher maternal age, cesarean section, increased BMI and insulin resistance – present a daunting healthcare challenge.

KNOWN MOM LACTATION RISK FACTORS[1, 25, 40]



SOLUTIONS

Initiation Technology™

Traditionally, mothers most vulnerable for delayed lactogenesis or suppressed lactation were those unable to breastfeed because their babies were premature or sick. Even with consistent standard breast pumping programs, average milk production in pump-dependent women was often lower than that of women breastfeeding healthy term infants. However, new breast pump initiation technology -- designed to mimic normal newborn sucking patterns in the first few days of life -- is able to mitigate this disparity.

The Symphony® PLUS™ breast pump with the Initiation Technology pattern, which imitates irregular newborn sucking, decreases the time to lactogenesis in pumping mothers by an average of more than 24 hours.[14] When paired with a second pattern to maintain milk production once milk comes in, average milk levels exceed breast milk volumes of mothers using a standard pump pattern and approximate average milk volumes of breastfeeding mothers.[13-15]

Three clinical trials to evaluate the effectiveness of the Symphony PLUS Initiation Technology pattern varied in methodology and populations but had similar outcomes. Meier et al. conducted a randomized control trial of women whose infants were born ≤ 34 weeks, while Torowicz et al. evaluated mothers whose term infants were admitted to coronary intensive care. Lastly, Post et al. studied pumping mothers of term, late-preterm and preterm babies. None of the studies excluded mothers for medical conditions, prenatal complications or lactation-related risk factors.

Although populations and methods were different, these studies yielded consistent results related to breast milk production: when compared to mothers who used (or in previous studies had used) a standard breast pump program, mothers who used the Symphony PLUS breast pump with the Initiation Technology pattern had:

- A normal onset of lactogenesis
- Sustained milk production gains for at least two weeks (or until infant was discharged, usually two to four weeks)

More specifically, Meier et al. reported the Symphony PLUS group achieved 67% more milk than the control group by day seven, with more than twice the number of mothers obtaining milk output goals of 500 mL/day by the end of two weeks.[13] Post et al. reported daily milk production was significantly higher in the initiation program group at each time

point from days three through 14. At two weeks postpartum, mothers in this group produced on average ~ 67% more milk (~750 mL/day compared to ~ 500/day in the standard program group). Post et al. also noted women using the Initiation Technology achieved lactogenesis on average by 3.3 days compared to 4.5 days for those who used a standard pump pattern.[14] Torowicz et al. report mothers who used this technology attained average daily milk volumes above 600 mL by the end of the second week, levels that were maintained or increased in the next two weeks.[15]

If exposure to a pumping pattern that imitates normal newborn sucking behavior can positively influence lactation in women who can't breastfeed immediately and consistently after delivery (pump-dependent mothers), use of the Symphony PLUS Initiation Technology pattern might help other mothers who are breastfeeding but are at risk for delayed lactogenesis or suppressed lactation. First time mothers, mothers who have had cesarean sections, and/or those over age 30 might benefit from Symphony PLUS Initiation Technology supplementation of breastfeeding. Likewise, women who are overweight, obese or have glucose intolerance could perhaps offset some of their risks by additional appropriate breast stimulation.

Timing of breast stimulation

World Health Organization recommends new mothers initiate breastfeeding within 30 minutes to one hour of birth.[41] For some women, this is not always possible. Research related to timing of initial breast stimulation has focused on mothers of preterm infants. In 2012, Parker et al.[42] conducted a randomized study of mothers of very low birth weight infants that suggested pumping within the first hour produces more milk and leads to an earlier onset of lactogenesis than pumping one to six hours after delivery. Mothers who pumped within the first hour produced double the average daily milk volumes at one, three and six weeks. A later study by Parker and associates validated the importance of pumping within the first hour.[43] Both early breastfeeding and pumping when infant is not available provide essential breast and nipple stimulation, contributing to the cascade of physiologic and hormonal events that stimulate milk production.

Challenges

In many lactation situations, interventions aren't started until a mother reports problems. By identifying mothers who are at risk for suppressed lactation or milk production, especially those mothers with multiple risk factors, clinicians can increase surveillance of infant feeding progress and intervene proactively. Some of these moms may just need short-term assistance with breast pump initiation technology. Challenges to such interventions include timely introduction of breast pumping without interfering with new family development and the breastfeeding relationship. Additionally, thoughtful recommendations for use must consider mothers' risk factors, preferences, maternal physical condition and abilities of the baby to adequately breastfeed.

Closing Comments

Suboptimal breastfeeding continues to be a major public health challenge despite recent intense efforts to promote and support breastfeeding within the early postpartum period. While new evidence suggests several prominent physical and demographic factors negatively influence lactation initiation and maintenance, little has been done to address these problems.

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