



Abstract

Development of a milk supply is a complex process that is not always understood by women who are breast-feeding. Galactagogues are substances commonly used by breastfeeding women who perceive that they have an insufficient milk supply. They can be herbal substances or pharmaceuticals. Herbal galactagogues are advertised and sold to women as capsules, cookies, milk shakes, and teas, as well as other forms of herbal supplements. Herbal galactagogues are classified as dietary supplements and not reviewed or regulated by the U.S. Food and Drug Administration. There are limited data on their safety and efficacy. Women experiencing problems with their milk supply should receive a thorough and thoughtful assessment of the situation. There are many factors that should be considered when counseling breastfeeding women about use of galactagogues. The physiology of lactation, process of milk supply development, and the evidence for use of galactagogues are reviewed to add to the knowledge of nurses and other health care providers working with women who are breastfeeding.

Key words: Breastfeeding; Counseling; Galactagogues; Herbal supplements; Lactation; Milk supply.

GALACTAGOGUES AND LACTATION: CONSIDERATIONS FOR COUNSELING BREASTFEEDING MOTHERS

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Exclusive breastfeeding until at least 6 months of age, with the addition of solid food supplements around 6 months of age, is recommended by the American Academy of Pediatrics and other experts in infant feeding practices (American Academy of Pediatrics, 2012; World Health Organization, 2021). More women than ever in the United States are choosing to breastfeed their babies. In 2017, breastfeeding was initiated by 84.1% of women after the birth of their baby (Centers for Disease Control and Prevention [CDC], 2020). However, by 2 days of age, infant formula supplementation was introduced to 19.2% of breastfed babies, and by 3 months of age, only 46.9% of babies continue to exclusively breastfeed (CDC). Early introduction of infant formula has the potential to lead to a decreased milk supply. Several studies have identified real or perceived lack of sufficient milk supply as one of the most important reasons women stop breastfeeding (Li et al., 2008; Schafer et al., 2017; Whipps & Demirci, 2021). Many women who wish to continue to breastfeed their babies, but are having issues with milk supply, turn to galactagogues to boost supply. Galactagogues are “either medications or other substances believed to assist with initiation, maintenance, or augmentation of maternal milk supply” (Brodribb & The Academy of Breastfeeding Medicine, 2018, p. 307). The purpose of this article is to discuss the issues that should be considered when advising new mothers about the use of galactagogues.

What are Galactagogues?

Various foods have been identified by cultures around the world (e.g., India, China, Iran) as important for women to consume when breastfeeding (Kim-Godwin, 2003; Sun et al., 2021). These traditional foods usually contain herbs that have been identified as possibly beneficial for breastfeeding women. Today, milk supply enhancing remedies may be sold in various forms including teas, milk shakes, cookies, capsules, and other herbal supplements. The products may contain fenugreek (*foenugraeci semen*), blessed thistle (*cnici benedicti herba*), fennel (*foeniculi fructus*), milk thistle (*Silybum marianum*) and goat's rue (*galegae officinalis herba*), or alfalfa, barley, oatmeal, dill, dandelion, and other substances alone or in various combinations (Table 1). These substances and others have been in use for centuries; the Greeks used fenugreek in 65 A.D. (Sun et al.). However, little is known about their mechanism of action and safety or efficacy (Brodribb & The Academy of Breastfeeding Medicine, 2018). It is thought that some of the



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Safety and Effectiveness of Galactagogues

There are several recent reviews of the safety and efficacy of galactagogues. The most recent is a Cochrane Systematic Review of the evidence relating to effect of oral galactagogues for increasing milk production in mothers with healthy term infants (Foong et al., 2020). Other reviews (Amer et al., 2015; Bazzano et al., 2016; Grzeskowiak et al., 2019) have also assessed the literature concerning galactagogues and milk supply. Two reviews (Bazzano et al.; Foong et al.) specified a methodology that included a search for randomized controlled trials or quasi-randomized controlled trials of the use of both herbal and pharmaceutical substances by mothers of healthy term infants. Grzeskowiak et al. only reviewed the use of pharmaceutical galactagogues. Substances reviewed differed somewhat in each article but included the herbals anise, blessed thistle, fennel, fenugreek, goat's rue, moringa, shatavari, silymarin, and malunggay, and the pharmaceuticals dom-

herbal galactagogues may influence prolactin secretion (Foong et al., 2020). Most herbal galactagogues fall into the U.S. Food & Drug Administration (FDA) "generally recognized as safe" category for herbal substances. However, side effects such as allergic reactions, gastrointestinal symptoms, and changes in blood glucose can occur. There is no standardization of dosage or guarantee of purity of these products. They are classified as dietary supplements and not reviewed or regulated by the U.S. FDA. The FDA can only remove these products from the market if they are unsafe or contain false or misleading information (U.S. Food and Drug Administration, n.d.).

peridone and metoclopramide.

Bazzano et al. (2016) found eight blinded placebo-controlled studies of common herbal galactagogues, but more than one study for only three of the popular herbs (shatavari, fenugreek, and malunggay). They found that the results were statistically significant in only one study for each herb and concluded small sample sizes and different methodologies for the studies make it difficult to make recommendations concerning efficacy of these substances.

In a very detailed review, Foong et al. (2020) evaluated 27 studies comparing herbal galactagogues to placebo or no treatment and eight studies where one galactagogue was compared with another. Although there was some

evidence that the galactagogues may show an increase in infant weight gain, the evidence was described as “low certainty” by the authors. Given that the eight studies comparing one galactagogue to another were small, it was not possible to determine if one galactagogue worked better than another. Lack of standardization in form of the herb used (leaves, seeds, capsules) and dosage make study comparisons difficult. Not all the studies reviewed reported on adverse events for mother or baby.

The pharmaceutical agents domperidone and metoclopramide have been identified as possibly beneficial in enhancing the development of milk supply for new mothers. Domperidone and metoclopramide are thought to enhance milk supply by increasing the levels of circulating prolactin, using their dopamine agonist mechanism. Increase in prolactin level is thought to lead to an increase in supply. However, as Brodribb and The Academy of Breastfeeding Medicine (2018) report, although prolactin is required for lactation, “once lactation is established, no direct correlation has been established between serum prolactin levels and the volume of milk produced in lactating women” (p. 307).

Domperidone is commonly used in Canada and Australia for lactation support. A review from Australia (Grzeskowiak et al., 2019) supports use of domperidone in treatment of lactation insufficiency, even though the studies reviewed showed only modest effects. Their conclusions may differ from Foong et al. (2020) because they included studies of use of domperidone in mothers of premature infants, including a meta-analysis of five studies, whereas Foong et al. included only studies involving healthy term infants. Grzeskowiak et al. (2019) discuss metoclopramide but identify it as less desirable to use with lactating mothers because of its more concerning adverse side effect profile including depression. It is important to note that domperidone does not have FDA approval for use as a galactagogue in the United States and can only be prescribed off-label. This means that the drug has been approved by the FDA for treatment of some medical condition, but not for treatment of insufficient lactation. The FDA has issued an advisory against use of domperidone in lactation because of some reports of heart arrhythmias, and a black box warning

TABLE 1. COMMON GALACTAGOGUES

Name	Mechanism of Action	Suggested Dose and Duration	Lactation Risk Categories and Efficacy ^b	Comment	Effect on Lactation
Pharmaceutical					
Domperidone	Dopamine agonist Increases serum prolactin	10 mg, orally, 3 times per day Maximum effect usually reached by 7–14 days ^a	L3 Probably Compatible	Should be avoided or used with caution in women with risk factors for QTc-prolongation ^c The U.S. FDA has issued an advisory against use of this drug ^a	Increased milk secretion ^b
Metoclopramide	Dopamine agonist Increases serum prolactin	10 mg, orally, 3 to 4 times daily 7 to 14 days ^a	L2 Probably Compatible	Increased risk of depression makes this less desirable choice ^c The U.S. FDA has issued a black box warning against use of this drug ^a	Increased milk secretion ^b
Herbal					
Blessed Thistle	May stimulate flow of blood to mammary gland ^f	1.5–3 g as a tea up to 3 times daily ^b	L3 No Data Probably Compatible	No data found supporting use as galactagogue ^b	Unknown
Fennel	May stimulate prolactin. May assist milk ejection reflex ^f	0.1 mL–0.6 mL oil ^e	Not categorized	Usually used with in combination with other herbs No peer-reviewed publications found ^d	Unknown
Fenugreek	Possibly acts on sweat glands The breast is a modified sweat gland ^d	Herbal tea (200 mL 3 times per day) 570–600 mg orally 3 times daily 1–3 weeks ^a	L3 Probably Compatible Insufficient evidence of efficacy ^a	Maple syrup odor of urine and sweat of mother and baby can occur ^b	Increased milk secretion

(Continues)

TABLE 1. COMMON GALACTAGOGUES (CONTINUED)

Name	Mechanism of Action	Suggested Dose and Duration	Lactation Risk Categories and Efficacy ^b	Comment	Effect on Lactation
Goat's Rue (<i>Galega officinalis herba</i>)	May stimulate mammary growth ^f	1 mL to 2 mL of tincture, 2–3 times daily ^e	Not categorized	May lower blood glucose	Unknown
Milk Thistle (<i>Silybum Marianum</i> , <i>Silymarin</i>)	May stimulate prolactin ^f	200–400 mg per day via extracts ^b	L3-no data Probably compatible Little evidence ^b	Possible gastrointestinal symptoms and allergic reactions ^b	Inconclusive ^a
Anise (Anisi fructus)	Unknown	3.5 grams to 7 grams as tincture or tea 5 to 6 times a day ^e	Not categorized	May cause allergic reaction ^e	Unknown
Moringa oleifera (malunggay)	May increase prolactin ^f	250 mg to 350 mg capsules twice a day ^d	Not categorized	Very little available information	2 small studies, results merit more investigation ^d
Shatavari (<i>asparagus racemosus</i>)	May stimulate prolactin ^f	Root extract 60 mg/kg body weight per day ^d	Not categorized	Very little available information	2 small studies with different findings ^d

Note. Key: The categories in column four refer to the lactation risk categories identified by Hale, T.W. (2021). *Hale's medications and mothers' milk* (19th ed.). Springer Publishing. L1 Compatible: Drug which has been taken by many breastfeeding mothers without any observed increase in adverse effects in the infant. L2 Probably Compatible: Drug which has been studied in a limited number of breastfeeding women without an increase in adverse effects in the infant. And/or the evidence of a demonstrated risk which is likely to follow use of this medication in breastfeeding woman is remote. L3 Probably Compatible: There are no controlled studies in breastfeeding women; however, the risk of untoward effects to a breastfeeding infant is possible, or controlled studies show only minimal nonthreatening adverse effects. Drugs should only be given if the potential benefit justifies the potential risk to the infant. L4 Potentially Hazardous: There is positive evidence of risk to a breastfed infant or to breastmilk production. L5 Hazardous: Studies in breastfeeding mothers have demonstrated that there is significant and documented risk to the infant based on human experience, or it is a medication that has a high risk of causing significant damage to an infant.

Table References

- ^aBrodribb, W., & The Academy of Breastfeeding Medicine. (2018). ABM clinical protocol #9: Use of galactagogues in initiating or augmenting maternal milk production, second revision 2018. *Breastfeeding Medicine*, 13(5), 307–314. <https://doi.org/10.1089/bfm.2018.29092.wjb>
- ^bHale, T.W. (2021). *Hale's medications and mothers' milk* (19th ed.). Springer Publishing.
- ^cGrzeskowiak, L. E., Wlodek, M. E., & Geddes, D. T. (2019). What evidence do we have for pharmaceutical galactagogues in the treatment of lactation insufficiency?—A narrative review. *Nutrients*, 11(5), 974. <https://doi.org/10.3390/nu11050974>
- ^dBazzano, A. N., Hofer, R., Thibaut, S., Gillispie, V., Jacobs, M., & Theall, K. P. (2016). A review of herbal and pharmaceutical galactagogues for breastfeeding. *The Ochsner Journal*, 16(4), 511–524. PMID: 27999511; PMCID: PMC5158159
- ^eNice, E. J. (2011). *Nonprescription drugs for the breastfeeding mother* (2nd ed.). Hale Publishing.
- ^fFoong, S. C., Tan, M. L., Foong, W. C., Marasco, L. A., Ho, J. J., & Ong, J. H. (2020). Oral galactagogues (natural therapies or drugs) for increasing breast milk production in mothers of non hospitalised term infants. *The Cochrane Database of Systematic Reviews*, 5(5), CD011505. <https://doi.org/10.1002/14651858.CD011505.pub2>

concerning the use of metoclopramide because of the potential for central nervous system effects (Brodribb & The Academy of Breastfeeding Medicine, 2018), so the benefits and risks of use must be weighed carefully. Grzeskowiak et al. (p. 9) note that a large study of Canadian women taking domperidone showed no cases of ventricular arrhythmia unless the woman had a prior history of ventricular arrhythmia. The Cochrane systematic review of studies of pharmacological galactagogues reported “low certainty evidence” that they may increase milk volume (Foong et al., 2020, p. 2). Although Grzeskowiak et al. believe that there is evidence supporting use of domperidone in treatment of lactation insufficiency, Brodribb and The Academy of Breastfeeding Medicine (2018, p. 312) concluded that “existing studies about galactagogues cannot be considered conclusive.” The variation in advice concerning galactagogues makes it

difficult for health team members to develop clinical practice guidelines. There are several excellent references available concerning the use of galactagogues and medications during breastfeeding (Hale, 2021; LactMed@NIH, 2006; Nice, 2011a) that provide in-depth discussions of the benefits and risks of both herbal and pharmaceutical galactagogues. See Table 1 for a summary of information concerning selected galactagogues.

How Does Milk Production Occur?

Development of human milk production or lactogenesis is a process that begins during pregnancy and continues throughout the period that an infant is breastfed directly, or milk is expressed by hand or with the aid of a breast pump. Some combination of direct breastfeeding and milk expression may also be used. It is important to understand the lactogenesis process when working with



New mothers need assistance in understanding how the body makes milk and how to grow and maintain a milk supply.

mothers who are breastfeeding, especially when they have questions about milk supply.

The mammary gland completes its development during pregnancy, primarily under the influence of the hormones estrogen and progesterone (Wagner et al., 2018). The body must also have adequate levels of prolactin, placental lactogen, and epidermal growth factor for this development to occur (Wagner et al.). This first stage in the development of a milk supply is called secretory differentiation (Pang & Hartmann, 2007). After the infant's birth and expulsion of the placenta, levels of circulating hormones estrogen and progesterone decrease in the mother's body, allowing an increase in the hormones prolactin and oxytocin, which are critical in human milk production and excretion. Adequate levels of the hormones insulin, growth factor-1, and the thyroxines are also important for effective mammary gland functioning (Wagner et al.). Wagner et al. (2018, p. 7) describe "a synchrony of hormonal signals" that must be in place for the mammary gland to go from preparing to produce human milk to producing enough milk to support the infant. This second stage in the development of a milk supply is known as secretory activation (Pang & Hartmann, 2007).

Transition from the stage of beginning milk production to production of copious amounts of milk, or secretory activation, should occur during the first 3 days after the birth of the infant (Pang & Hartmann, 2007). During this time, the infant must learn to latch on to the mother's breast and suckle effectively enough to initiate the flow of milk. A variety of hormonal signals must occur to facilitate this transition. This can be a stressful time for the new mother. A mother can have adequate levels of prolactin to produce milk, but if she is not able to letdown the milk and empty her breasts on a regular basis, then milk production can be compromised (Wagner et al., 2018). Ideally, analysis of levels of circulating hormones in new mothers would help to clarify prob-

lems with the development of milk supply. However, as discussed by Wagner et al. (2018) when and how milk or blood samples are collected can cause variations in what constitutes a normal hormonal level and cloud the clinical picture. Whether or not hormonal analysis is conducted, the new mother's stress level and any pain she may be experiencing should be considered when evaluating the development of her milk supply.

Frequent and effective milk drainage from the breasts is the primary means of increasing milk synthesis after the first week post birth (Brodribb & The Academy of Breastfeeding Medicine, 2018). New mothers need to understand how often a breastfeeding newborn will feed, variations in normal feeding patterns, and how to tell that the breasts are emptying, and the baby is transferring milk to correctly evaluate their milk supply. Measures such as monitoring urine and stool output and test weighing of the infant can be used to follow this transition. Guidelines are available for normal intake and stooling patterns (Westerfield et al., 2018).

Maternal Perception of Milk Supply Sufficiency

New mothers do not always understand how the body produces milk and what constitutes an adequate milk supply. If they are told that they do not have enough milk for the baby in the first week, when rapid changes are taking place, and the body is transitioning from producing small quantities of milk to a more copious supply, they may find it difficult to recognize an adequate supply when it develops. Several researchers have identified, "perceived insufficient milk supply" as the most common reason for early weaning from breastfeeding (Li et al, 2008; Schafer et al., 2017; Whipps & Demirci, 2021; Wood et al., 2021). True physiological insufficiency of milk supply does occur, although its prevalence is unknown. However, according to Whipps and Demirci (2021, p. 935) "the consensus of the field remains that many more women perceive inadequacy than actually have an inadequacy of supply due to physiological issues." Unrealistic expectations and comparisons with amounts being reported by others, can fuel doubts in a new mother's mind. The health care team's fixation on infant weight gain adds to the stress for new mothers, if adequate explanations and counseling concerning milk supply development are not offered.

New mothers need to be assisted in understanding the process that occurs during the development of their milk supply, and in assessing the progress of this process, especially during the early weeks after birth. If supplementation is medically indicated during the first week after birth, it is important to explain both the medical indication for the supplementation, and how to assess the further development of the supply. If supplementation is indicated because of a temporary situation (i.e., jaundice or latch problems) or a more permanent situation (insufficient glandular tissue, hormonal/endocrine problems, or surgical removal of breast tissue), this should be

explained to the mother in a way that helps her understand how this will impact the development of her supply. She should also be assisted in using manual expression or a breast pump, when needed, to support development of her supply to the maximum degree possible if there are early problems that impede the baby's ability to nurse at the breast.

The infant plays an important role in development of the mother's milk supply because the frequency of milk removal, and how completely the breasts are emptied, impact supply. An infant who has a medical condition that makes it difficult for them to suckle effectively, producing an intraoral vacuum sufficient to extract milk, or is having difficulty learning to latch on to their mother's breast, can be unable to empty the mother's breast adequately and stimulate the development of the mother's milk supply (Geddes et al., 2008). This can result in an insufficient milk supply and early weaning. New mothers, especially first-time mothers, need assistance in assessing milk transfer when infants are suckling. Mothers whose babies are not suckling well enough to transfer milk, need assistance in correcting the problems that can be corrected, such as poor latch from incorrect positioning, and guidance in supporting the development of their milk supply while an infant issue, such as tongue-tie, is diagnosed and treated.

Considerations when Counseling New Mothers about Milk Supply Issues

Nurses working with new mothers and babies on issues of milk supply adequacy need to carefully consider the needs of each new mother–baby pair before making any recommendations. A mother may have started taking a galactagogue thinking it will solve her real or perceived milk supply issues, when overlooked, but correctable issues, are inhibiting her supply. Nurses who are not familiar with assessment of milk supply in nursing mothers should consult with a lactation specialist or refer the mother–baby pair to the lactation specialist. An adequate milk supply is one that meets the baby's needs for nutrition and supports their growth and development. Factors such as size and gestational age of the infant can have an impact on their nutritional needs. In general, if an infant is latching on and suckling well enough to transfer milk, the infant is latched on whenever they demonstrate feeding cues, and the mother's body is anatomically and physiologically prepared to produce milk, the body should produce a sufficient supply for the baby.

In the first week postpartum, history concerning the changes that occurred in the mother's breasts during pregnancy should be obtained as part of the assessment. The breasts should enlarge by about one bra cup size during pregnancy. There should also be evidence of an increase in diameter of the areola, enlargement of the sebaceous gland around the areola, changes in pigmentation and vascularity of the areola, and erectile activity of the nipple as the pregnancy progresses (Wagner et al., 2018). Lack of changes in the breast during pregnancy would be

concerning. It is essential to note any surgical procedures to the breasts that could interfere with lactation or expression of milk. How often the baby is latching on to the breast, and whether there is evidence of milk transfer during the feedings are important determinations.

If an infant is not latching on and suckling well enough to transfer milk, a new mother needs specific guidance on how to empty her breasts, how often to express milk, and an understanding that milk expression will stimulate milk production. In the early days, she needs to know that milk expression will result in small amounts of milk at each expression session initially, but that her supply should build as she expresses over the course of the first week. Helping the mother to have realistic expectations about the amount of milk yield per expression session is important. Manual expression can be helpful in the first few days when amounts are small. Nurses who work with breastfeeding mothers, and need to update their knowledge, should take additional continuing education in the areas of breastfeeding and human lactation so that they can provide evidence-based advice.

If the mother has been instructed to express her milk, her expression routine should be discussed in detail. Any routine that has been started in the hospital after birth may be continued by the mother whether or not conditions have changed. Her own milk supply may have increased to adequately meet her baby's needs, but she may continue to perceive that supplementation is necessary. Her baby may be latching and suckling more effectively, but the new mother lacks confidence in direct feeding, so continues to search for something to improve her supply. Observation of a breastfeeding session and test weighing the baby before and after a feeding are helpful components of the assessment.

A mother whose milk supply developed well in the early days of breastfeeding may develop questions about supply as her baby moves through various developmental stages, and she returns to work. The more distracted behavior at the breast of an older infant can be confusing for the new mother. A day care provider may ask for more milk than her baby takes at home. Differences in yield of milk during milk expression sessions can be distressing. Any of these issues can make a mother doubt her supply and wonder if galactagogues might be the answer. A new mother needs anticipatory guidance concerning these issues throughout the time she is providing her milk for her baby.

Are Galactagogues Useful for Selected Breastfeeding Mothers?

Assessment of the milk supply may lead to the conclusion that the milk supply is not sufficient to meet the needs of the infant. If so, the most important questions are what factors are causing the low supply and can they be modified? If the breasts are not being emptied often enough, "down-regulation" or inhibition of further milk production occurs, decreasing the supply (Wagner et al., 2018). Galactagogues will not be helpful if the glandular tissue has

SUGGESTED CLINICAL IMPLICATIONS

- Milk supply issues are common problems for new mothers, resulting in a search for solutions such as galactagogues.
- Breastfeeding women need anticipatory guidance concerning how their body develops a milk supply and how to maintain that supply through various stages of infant development.
- Nurses advising new mothers should be prepared to evaluate milk supply adequacy and advise women concerning the use of galactagogues.
- Breastfeeding women should be advised concerning techniques for maintaining their milk supply when they return to work.
- If a new mother decides to take galactagogues to enhance milk supply, provide evidence-based information concerning the limitations of scientific understanding of the efficacy and purity of these substances as well as their safety.

not developed or has been surgically altered. Mothers who have endocrine conditions such as diabetes or hypothyroidism require medical treatment for those conditions to improve milk supply. New mothers need to know that even if they are not able to produce a milk supply that fully meets their baby's needs, the milk they are able to produce has many qualities that are beneficial for the baby's health, growth, and development. This helps them to determine if it is "worth it" to continue to breastfeed and/or express milk for their baby even if supplementation is necessary.

Return to work can be a stressful time for new mothers. If their employer has not made provisions for them to have the break time and private place to express milk to which they are entitled, they can find it difficult to empty their breasts often enough to maintain milk supply. Galactagogues are an appealing choice to increase supply but will not be helpful in the face of inadequate emptying of the breasts. Balkam et al. (2011) found that specific counseling concerning how to maintain the milk supply while separated from the baby at work can lead to a longer duration of any breastfeeding at 6 months post birth of the infant. New mothers need information on what type of breast pump to choose, how often to pump, and the most effective pumping strategies. Make sure that the new mother is aware of her rights under the 2010 Affordable Care Act to break time and a private place to express milk (U.S. Department of Labor, 2018).

Advice on Galactagogues for Breastfeeding Mothers

For cultural or personal preference reasons, a mother may decide to take galactagogues. She may have learned about them online or from family or friends. Unless the mother has a chronic health condition or takes medications that might be affected by the herbs, in general, use of galactagogues should not be problematic, although they may not

be effective. Health care providers may decide to prescribe domperidone, off label, in situations where it has been found to be effective, such as with mothers of premature infants. The nurse should support the mother's choice, help her correct any milk supply problems that are correctable, and provide information concerning the limitations in scientific evidence about galactagogues. Some types of galactagogues can be costly. Mothers should be aware that there are minimal safety and efficacy data for most herbal galactagogues and of their status as dietary supplements, thus not reviewed or regulated by the FDA. This knowledge will help the mother make an informed decision about their use and temper their expectations of solving a milk supply issue. ✚

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