

**COMPLEMENTARY AND ALTERNATIVE THERAPIES: SUPPORTING THE
WOMAN WITH INADEQUATE MILK PRODUCTION**

by

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Abstract

While the benefits of breastfeeding are well established, and high initiation rates indicate that women recognize these benefits and wish to provide their infants with the healthiest beginnings, duration rates indicate that women are having difficulty overcoming challenges in the early weeks of breastfeeding. Studies indicate that early breastfeeding cessation is correlated with perceived or actual inadequate milk supply (Lewallen et al., 2006). While the traditional management of insufficient supply during breastfeeding has involved breastfeeding support with particular attention to effectiveness of maternal and infant position, milk transfer, and frequency of feeds, some women may not see improvement in supply from traditional measures. Breastfeeding websites, parenting books, and review articles by breastfeeding professionals suggest the use of complementary and alternative therapies such as acupuncture, herbal medicines, relaxation therapy, aromatherapy, and homeopathy to increase milk supply, however little clinical evidence exists to support the use of such therapies. This literature review summarizes the available data in research and grey literature regarding the use of acupuncture and herbal medicine in managing insufficient milk supply. The majority of evidence supporting the use of acupuncture and herbal medicine in the breastfeeding woman is qualitative and quasi-experimental, with few randomized controlled trials supporting the safety and efficacy of these treatments for increasing milk production in the lactating woman. The role of the nurse practitioner in supporting patients using complementary and alternative therapies is discussed.

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Glossary

Acupuncture

A treatment used in Traditional Chinese Medicine involving the insertion of needles at specific points to regulate the flow of energy (referred to as chi) in the body (Keegan, 2001).

Allopathic medicine

Allopathic medicine refers to the system of medicine practiced by holders of a medical degree or professionals such as nurse practitioners, nurses, physiotherapists, and psychologists. The term is used synonymously with Western medicine or conventional medicine (National Center for Complementary and Alternative Medicine, 2011).

Alternative therapy

An unconventional treatment used in place of conventional treatments recommended by the dominant system of medicine (Keegan, 2001; National Center for Complementary and Alternative Medicine, 2011).

Artificial baby milk

A term used to describe alternate substances for feeding infants when supplementation is required or if breastfeeding is not practiced. The term avoids the connotation that infant formula is scientifically developed and provides an equal form of nutrition when compared to breast milk (Wiessinger, 1996).

Complementary therapy

Refers to an alternative therapy used in conjunction with conventional medical therapies (Keegan, 2001; National Center for Complementary and Alternative Medicine, 2011).

Exclusive breastfeeding

Exclusive breastfeeding refers to feeding an infant with no substance other than breastfeeding or expressed breast milk from birth. Vitamins, minerals, and medications can be included in the definition of exclusive breastfeeding (Breastfeeding Committee for Canada, 2004)

Exclusive Pumping

The practice of pumping and bottle feeding breast milk to an infant who does not breastfeed directly from the breast (Mohrbacher, 2007)

Galactagogue

Drugs, botanical substances, foods, or beverages consumed for the purpose of increasing milk production (ABM, 2011).

Herbal Medicine

The practice of herbal medicine includes the use of herbs, supplements, and other botanical substances to treat illness and to preserve health (National Center for Complementary and Alternative Medicine, 2011).

Holistic Healing

Holistic care recognizes that health comes from a balance of physical, emotional, spiritual, and environmental factors. Healing requires personal responsibility and participation in health care. Lifestyle patterns that support balance are combined with all safe modalities for diagnosis and treatment (Keegan, 2001).

CHAPTER ONE

Introduction

Many women experience insufficient milk production or believe they experience low milk production during the course of breastfeeding. While the leading cause of insufficient production is infrequent breastfeeding and ineffective breast emptying by the infant, some women continue to experience insufficient milk production or perceived low milk supply even when breastfeeding management is corrected. When breastfeeding management is not effective in improving milk production, or is not improving it to a sufficient degree, it has become common practice for primary care providers to prescribe galactagogues, such as domperidone, to increase milk production. In clinical practice, some women express interest in or preference for complementary and alternative treatment modalities, while preferring to avoid prescription medication. This project will examine the use of complementary and alternative therapies to increase breast milk production in women with insufficient milk production. Literature describing the use of acupuncture and herbal medicines will be examined related to efficacy in increasing milk production in lactating women. The role of nurse practitioners as primary care providers in providing breastfeeding support to women with milk supply challenges will be discussed. The nurse practitioner (NP) roles and responsibilities regarding the use of complementary and alternative therapies in clinical practice will be described.

The Challenge of Early Weaning

Breastfeeding confers numerous health benefits on both the mother and infant (American Academy of Pediatrics [AAP], 2005). In order to receive the optimum benefits from breastfeeding, a period of exclusive breastfeeding for six months, with continued breastfeeding for two years or longer is recommended by public health authorities in Canada (World Health

Organization, 2003). In spite of the best efforts of health care professionals to protect, promote and support breastfeeding, the number of women who continue to breastfeed for the recommended duration is less than desired (Adams & Hewell, 1997). Canadian statistics for the initiation of breastfeeding indicate that 87.9% of women initiated breastfeeding in the 2007-2008 statistic collection period ("Breastfeeding Initiation in Canada," 2010). However, duration rates remain low at each period of measurement, with approximately 17% reaching the goal of exclusive breastfeeding for six months and fewer than 10% continuing to breastfeed beyond six months ("Duration of Exclusive Breastfeeding in Canada," 2010).

High breastfeeding initiation rates indicate that breastfeeding is the desired method of feeding for many women, yet rapid discontinuation of breastfeeding in the early postpartum period indicates that women experience challenges leading to ambivalence and loss of confidence in their ability to meet their infant's requirements for breast milk (Wilhelm, Stepan, Hertzog, Rodehorst, & Gardner, 2006). Studies evaluating the reasons for early weaning and early introduction of artificial baby milk have elicited a number of reasons that women are unable to continue breastfeeding. These include nipple pain and trauma, lack of effective support by health care providers, illness of mother or infant, or early return to work (Do Espirito Santo, De Oliveira, & Guigliani, 2007; Li, Fein, Chen, & Grummer-Strawn, 2008; McCarter-Spaulding & Kearney, 2001; Meedya, Fahy, & Kable, 2010).

The nutritional and immunological components of breast milk are associated with optimal infant health, including prevention of infectious diseases, such as diarrhea, otitis media, and respiratory tract infection; prevention of chronic diseases such as diabetes and obesity; and improved neuro-developmental outcomes (AAP, 2005). Since consumption of artificial baby milk is associated with increased morbidity and mortality among infants, low breastfeeding

initiation and duration rates are of significant concern (International Lactation Consultant Association [ILCA], 2005).

The most common cause of early weaning is actual or perceived insufficient milk production (Kent, Prime, & Garbin, 2012; Lewallen et al., 2006). Studies have indicated that as many as 34% of women believe their milk supply is inadequate for their baby's needs ("Breastfeeding Initiation in Canada," 2010). Up to 80 % of women who discontinue breastfeeding within six months of delivery have done so due to insufficient milk production (Hill, 1992). In addition, many women who continue to breastfeed beyond the early days postpartum are providing supplemental formula to their infants due to the belief their milk supply is inadequate. The practice of supplemental feeding can exacerbate the problem of inadequate milk production, leading to an increasing gap between breast milk production and the quantity of breast milk required by the infant.

Challenges and Barriers in the Establishment of Breastfeeding

While the benefits of breastfeeding for mother and baby have been clearly documented and widely publicized, it appears that having this knowledge is not sufficient to assist women to breastfeed exclusively for the recommended duration (Rowley & Dixon, 1997; Thulier & Mercer, 2009). In order to support women effectively in reaching recommended targets for breastfeeding duration it is important to understand the barriers and challenges that prevent women from reaching their breastfeeding goals. For several decades, it has been apparent that North American women who choose to breastfeed tend to be of higher socio-economic status compared to those who choose to bottle feed their infants. Research indicates that most women who choose to breastfeed have some post-secondary education, are over 25 years of age, and are

in a stable relationship. Breastfeeding initiation and duration correlate to social, economic, and cultural determinants of health in addition to personal characteristics (Callen & Pinelli, 2004).

Crisis of Maternal Confidence and Early Breastfeeding Cessation

Surveys indicate that most women who plan to breastfeed expect the breastfeeding experience to be enjoyable, convenient, natural, and emotionally satisfying. Women often assume that the ability to breastfeed is innate and are surprised by the challenges presented early in the breastfeeding experience (Purdy & Flaskerud, 2010; Thulier & Mercer, 2009). Expression of ambivalence about breastfeeding during the pregnancy and early postpartum period is associated with earlier breastfeeding cessation. Mothers' perception of infant behavior is an important influence on the duration of breastfeeding. Mothers who believe their baby is irritable, struggling to feed, hungry all the time, or crying too much are at risk of early breastfeeding cessation, particularly if the infant behavior is seen as an indication that the mothers' anatomy is abnormal or that her milk production is inadequate (Rowley & Dixon, 1997).

Maternal doubt about the ability to parent effectively has been associated with both the perception that milk production is inadequate as well as with early breastfeeding cessation (Kent et al., 2012; McCarter-Spaulding & Kearney, 2001). Mothers who believe that they have the necessary competence to parent and feed an infant are more likely to persist in the face of breastfeeding challenges. Believing that milk production is inadequate is associated with early introduction of supplemental feeding, which ultimately leads to less frequent breastfeeding and to a decrease in milk production over time. Research has provided little information describing the incidence of actual insufficient milk production compared to perceived low supply (Geddes, 2007), however the incidence of perceived insufficient milk production occurs far more frequently than actual insufficient milk supply (Thulier & Mercer, 2009).

Primary Care Support for Breastfeeding

Best practice standards indicate that management of insufficient milk production should consist of increased frequency of feeds, improved positioning of the infant at the breast, improved infant latch and milk transfer, along with professional support and encouragement (Jackson, 2010; Kent et al., 2012). These measures are known to increase milk production in many cases, while increasing maternal confidence, enabling the mother to continue breastfeeding (Walker, 2006). However, for some mothers, despite improvements in breastfeeding technique, milk production may remain inadequate, resulting in poor infant weight gain. One estimate indicates that up to 15% of women experiencing insufficient milk production fail to respond to intensive breastfeeding interventions (Neifert & Seacat, 1987). When this occurs, the mother, who may already feel like a failure because of her difficulties with breastfeeding, may blame herself for her inability to correct the problem with standard advice (Sakha & Behbahan, 2008).

The primary care provider is the first line responder to maternal concerns about the adequacy of milk production, evidenced by poor weight gain or infant crying, which may indicate a problem with milk production or maternal confidence. Support from the primary care provider has been shown to be one factor predicting increased breastfeeding initiation and duration (American Academy of Family Practice [AAFP], 2008). Primary care providers practicing in urban areas may have access to lactation specialists, and can refer patients experiencing breastfeeding challenges. NPs working in rural, isolated, or northern communities are less likely to have access to local specialists for referral, requiring patients who need specialist assistance to travel long distances. It benefits both NP and patient when the NP has clinical skills to provide information and support to women experiencing breastfeeding difficulties.

Nurse practitioners require a toolbox of breastfeeding management strategies in order to assist women to meet their breastfeeding goals. While many of these tools must reflect basic breastfeeding management, it is important to recognize that in some cases, basic breastfeeding management will not resolve milk supply issues. The use of prescription galactagogues has been well established in Canada for the treatment of low milk supply. In clinical practice, NPs will meet women who would prefer to avoid prescription medication or women for whom prescription medication is not working as well as expected. Increasing numbers of women are expressing a preference for natural or alternative methods of resolving problems in lactation (Ayers, 2000).

Complementary and Alternative Therapies in the Lactating Woman

Complementary and alternative medicine (CAM) therapies are one method of treating or correcting mild or chronic health conditions (Gossler, 2010). In cases where no therapy for a medical condition exists, or when a condition does not respond to conventional therapies, patients are likely to seek out some form of complementary or alternative therapy. Many systems of complementary and alternative therapy hold health promotion and lifestyle improvement as core values. Seeking to restore energy, balance, and vitality to the patient before disease develops is often the goal of therapy. The philosophy of CAM supports self-determination, personal choice, informed consent, and holistic healing, which are consistent with the philosophy of care in women's health and healing (Belew, 1999). CAM therapies integrate psychological, spiritual, and environmental approaches to healing along with physical treatments. The holistic approach to treatment is thought to be particularly effective for chronic conditions such as anxiety, for example, a condition for which traditional medicine offers little hope of cure (White, 2000).

Traditional providers of women's reproductive care, such as midwives, have long been proponents of complementary therapies (Allaire, Moos, & Wells, 2000). Women are leaders in the consumption of complementary and alternative therapies, therefore the use of such therapies for pregnancy related discomforts, childbirth, and breastfeeding are common. Such alternative approaches are widely described in the grey literature (Ayers, 2000). The use of herbs, foods, and drinks are examples of traditional practices used in the postpartum period to assist the new mother in the transition to motherhood, enhance recovery from childbirth, and to encourage breastfeeding (The Academy of Breastfeeding Medicine Protocol Committee [ABM], 2011).

The use of complementary and alternative therapies has been growing in popularity for at least two decades. Several Canadian and US studies carried out since 1990 have indicated a growing trend in the use of alternative remedies (Eisenberg et al., 1998; Esmail, 2007). Women are the largest consumers of health care, and the use of complementary and alternative medicine in women parallels the rate of health care use (Low Dog, 2009). In pregnancy and lactation, women are cautioned to avoid some medications, activities, and foods which would be considered safe at other times, leaving some women reluctant to use traditional medical treatment due to safety concerns. Many people perceive CAM as being a safer and healthier alternative to traditional medical treatments. With added concern about the safety of the infant during lactation, women may be reluctant to expose the infant to medications through breast milk (Ayers, 2000). Women are more likely to choose to use CAM therapies if the use of therapies is congruent with their cultural heritage and their personal health beliefs (Hall, McKenna, & Griffiths, 2010).

Evidentiary Support for Complementary and Alternative Medicine

Citing a lack of evidence, medical research has taken a cautionary tone toward the use of CAM in pregnant and breastfeeding women, indicating that the safety and efficacy for many therapies has not been established (Ernst, 2002). Guidelines developed by the World Health Organization (WHO) indicate that a prolonged history of safe and effective use of herbal therapies must be taken into account along with any research evidence that may exist when establishing recommendations for the use of traditional herbal therapies ("WHO Guidelines," 1993). Humphrey (2007) argues that high levels of proof of efficacy are required when herbs or medications are used to treat serious and acute conditions, however, in the science of lactation, few conditions are serious or acute, and so a lower level of proof can be used to justify the complementary role of herbal therapies. Some proponents of CAM argue that long term use of CAM therapies have provided sufficient data, although anecdotal in nature, establishing the safety and efficacy of established therapies.

The use of CAM is widely described on internet websites offering breastfeeding information to women experiencing breastfeeding challenges. Lay evidence is widespread in the grey literature, and describes the use of many alternative therapies to increase milk production. Well-respected clinicians, such as breastfeeding expert Dr. Jack Newman, recommend herbal preparations and other CAM therapies to women for insufficient milk production, in spite of the fact that some of these treatments are not researched to a standard that would be expected for conventional drugs or therapies (Newman & Kernerman, 2008). In some cases, the existing evidence is scant, while in other cases, the existing evidence may be contradictory. Much of the evidence present in the grey literature is entirely anecdotal in nature and describes personal experience rather than taking a scientific approach (Bryson, 2008). Although lactation research

is an emerging field, clinical practice has suffered from a lack of evidence-based practice (Bartick, Stuebe, Shealy, Walker, & Grummer-Strawn, 2009). When women approach a primary care provider for information on improving their milk production by using natural remedies, it is challenging to access high quality evidence on which to base recommendations for treatment.

Complementary and Alternative Medicine in Primary Care

Natural methods of healing have been practiced since the beginning of human history. Although plants and plant extracts have been used for their medicinal qualities for thousands of years, modern medical science provided cures for diseases that had previously been incurable (Keegan, 2001). The technology explosion of the 20th century produced a scientific approach to disease management, resulting in increased reliance on pharmaceutical treatments, while the use of traditional healing practices and remedies fell out of favor. As modern health care professionals began to recognize that science does not provide all the answers for health and wellbeing, the importance of understanding and treating the whole patient is once again gaining favor. Integrative medicine programs are attached to many medical and nursing schools, with the purpose of preparing health care professionals to advise clients about the use of CAM and in some cases, to prepare health care professionals to prescribe or deliver various types of CAM treatments (Marcus & McCullough, 2009). For example, the University of Portland offers nurse practitioner education with a focus in integrative health ("University of Portland," 2012).

As a discipline, nursing has long embraced the concept of the person as a holistic being, consisting not only of the physical body, but combining emotional, social, psychological, and spiritual facets as well. The College of Nurses of British Columbia (College of Registered Nurses of British Columbia [CRNBC], 2011) developed core competencies for nurse practitioner (NP) practice in the province of British Columbia. NP practice incorporates health promotion

and supportive care, as well as curative forms of treatment. Responsibility for recognizing the person as a holistic being is implied in the competencies, which require the NP to consider client perspectives in therapeutic decision-making. Measures for promotion of health, lifestyle improvement, and enhancement of patient self-efficacy are required in NP practice. At the same time, the core competencies for NP practice regarding CAM state that the NP must use an "evidence-informed approach in the selection or consideration of complementary and alternative therapies and consider[s] the benefits and risks to clients' health and safety" (CRNBC, 2011, p. 14). The use of CAM is often not part of the core curriculum of nursing and medical programs, therefore physicians, NPs and nurses may be unprepared to assist their patients in decision making regarding such therapies (Keegan, 2001).

Patient and Provider Communication

Of concern to primary health care providers such as physicians, midwives and NPs, is the indication that many users of CAM do not discuss this with their primary care provider. A large survey conducted to evaluate the use of CAM in Canada, indicated that 73% of Canadians had used an alternative therapy at sometime in their lives (Esmail, 2007). Among British Columbians, 84% of the population "admitted" to having used some method of alternative therapy during their lifetime. One study indicated that up to 96% of Canadian women use some form of herbal remedy during pregnancy or in the postpartum period (Holst, Wright, Haavik, & Nordeng, 2009). However, only 53% of respondents indicated they had told their primary care provider about their use of CAM (Esmail, 2007), while the majority rely on the advice of family and friends, personnel in health food stores, and the internet as sources of information (Holst et al., 2009).

Among those who did not disclose the use of CAM to their primary care provider, respondents gave numerous reasons. For example, patients indicated when the physician did not ask about the use of CAM, they did not need to tell, or even that the use of CAM was none of the physician's business. Some patients were concerned their doctor would not approve or understand their choice to use CAM therapies, while others were afraid their doctor would discourage them from continuing to use the therapy. Other patients indicated concern their doctor would not continue as their primary care provider if the use of CAM was disclosed (Esmail, 2007).

Many women using CAM during pregnancy and the postpartum period do not discuss the use of CAM with their primary care provider because CAM therapies are not perceived as medicine, and are believed to be innocuous (Moore, 2002). Patient safety is a potential concern when the primary care provider is not aware of the use of CAM by patients. Thus, physicians, nurse practitioners and other health care professionals working with pregnant and breastfeeding women need to cultivate an open and respectful relationship that invites disclosure of the use of CAM. At the same time, it is essential that primary care providers develop awareness of the effective and safe use of CAM therapies in the context of patient care. The therapeutic partnership between patient and primary care provider requires open communication as part of the decision making process (Kaegi, 1998). The onus for establishing and maintaining the therapeutic partnership rests with the care provider. Therapeutic communication within the partnership has been shown to enhance both physical and emotional health outcomes (Stewart, 1995).

CHAPTER TWO

Background and Context

In order to understand the role of CAM therapies including herbal galactagogues and acupuncture in the breastfeeding woman, it is essential for the NP to understand the causes of insufficient milk production. Understanding breastfeeding physiology is necessary to create a framework for understanding the role of herbal galactagogues, acupuncture, and effective lactation management (Anderson & Valdes, 2007). In order to incorporate galactagogues successfully in clinical practice, the process of milk production and infant feeding must be understood by the nurse practitioner or other primary care provider.

Causes of Low Milk Production

The breastfeeding relationship is a dynamic and reciprocal relationship between the mother and infant. When challenges arise in the establishment of breastfeeding, both maternal and infant factors must be evaluated and managed in order to resolve breastfeeding difficulties. While the interaction of maternal hormones in the production of adequate milk is not completely understood, a number of physiological causes related to hormonal imbalances are known to impact milk production (Mohrbacher, 2010). Hormones such as oxytocin, prolactin, insulin and cortisol have been identified as critical to breast milk production.

Maternal Factors Related to Milk Production

Placental insufficiency in pregnancy is associated with inhibited development of functional breast tissue (Mohrbacher, 2010). Postpartum hemorrhage is associated with inhibition of pituitary function and decreased prolactin levels, leading to decreased milk production. A stressful or prolonged labor and birth experience results in high levels of cortisol and can delay the onset of milk production. Cesarean delivery has been strongly associated with

delayed or insufficient milk supply (Dewey, Nommsen-Rivers, Heinig, & Cohen, 2003).

Anxiety has been widely reputed to decrease milk production, and studies have demonstrated that maternal anxiety has been inversely related to breast milk intake by infants (Sisk, Lovelady, Dillard, & Gruber, 2006). Hypertension, obesity, hypothyroidism, and anemia are all maternal conditions that may lead to decreased milk production. Both polycystic ovarian syndrome (PCOS) and diabetes are associated with insufficient milk production, although the role of abnormal insulin levels in the establishment of adequate milk production is not understood at this time (Czank, Henderson, Kent, Lai, & Hartmann, 2007; Dewey et al., 2003). Cigarette smoking has been associated with decreased breastfeeding duration (Thulier & Mercer, 2009). Smoking more than fifteen cigarettes per day may decrease milk production (Amir, 2006).

Infant Factors Related to Milk Production

Milk production, by its nature, is not static, but is meant to increase or decrease each day in response to the needs of the infant (Mohrbacher, 2010). Since the infant drives the production of milk, infant health issues can affect the establishment of adequate milk production. Ill or preterm infants may be unable to regulate milk production through effective suckling and milk removal from the breast. If the infant is not effectively latched to the breast, milk removal will be ineffective, leading to decreased rate of milk production. The hormone referred to as the feedback inhibitor of lactation (FIL) appears in breast milk when women have increased volumes of milk stored in the ductal system of the breast. If feeds are delayed by the mother, or if the baby is unable to drain the breast effectively, FIL decreases milk production from the breasts, apparently by interfering with protein synthesis. It has been shown to take 6 to 12 hours of effective breast emptying to reverse the effects of FIL and increase production again. Milk production is particularly sensitive to the effects of FIL during the first four weeks of

breastfeeding (Anderson & Valdes, 2007; Czank, Henderson, Kent, Lai, & Hartmann, 2007; Wagner, 2009).

Physiology of Breast Milk Production

In order for infants to feed at the breast, an adequate milk supply must be present. Milk production depends on the presence of mammary tissue, a cascade of hormonal influences, and breast stimulation through infant suckling. The breast is one of the most complicated endocrine organs and lactation is a process modulated by pituitary, ovarian, thyroid, adrenal, and pancreatic hormones. The influence of these hormones on milk production is not yet completely understood (Lawrence & Lawrence, 2011).

The presence of placental progesterone and estrogen prevents the production of a full milk supply during pregnancy, however, with the delivery of the placenta, the volume of milk production rises in the breast in response to hormonal changes and infant suckling. Increased blood flow to the breast occurs, resulting in increased uptake of oxygen and glucose (Lawrence & Lawrence, 2011). Milk composition changes, as lactose content and water content increase rapidly, resulting in increased milk secretion (Hurst, 2007). By the fifth postpartum day, milk production may be as high as 750 mLs/ day, then increasing to as much as 1000 mLs/ day by the second week of lactation (Anderson & Valdes, 2007). A delay in onset of full milk production has been observed in women with diabetes, following prolonged labor or stressful birth experiences, cesarean section delivery, or presence of retained placental fragments (Lawrence & Lawrence, 2011).

Hormonal Regulation of Milk Supply

Many hormones contribute to lactation and the regulation of milk supply (Lawrence & Lawrence, 2011). While prolactin and oxytocin are essential hormones, they work in

conjunction with thyroid hormone, parathyroid hormone, and insulin to support milk production. Oxytocin is produced in the posterior pituitary in response to tactile stimulation of the nipple, which occurs during suckling or skin-to-skin contact with the infant. It is responsible for the milk ejection reflex, which occurs during contractions of the smooth muscle cells surrounding the alveoli, forcing milk from the lumen of the alveoli, into the milk ducts, and out through the nipple pores (Mohrbacher, 2010; Schanler & Potak, 2009). Oxytocin release generally occurs within a minute of the onset of suckling. Research indicates that acute stress, anger or fright may blunt the release of oxytocin, however chronic stress does not appear to affect oxytocin release (Czank et al., 2007). Oxytocin acts as an anxiolytic and is thought to be responsible for bonding between mother and infant (Prime, Geddes & Hartmann, 2007).

Prolactin is released from the pituitary in response to skin-to-skin contact with the infant and suckling stimulation of the breast. It attaches to proteins on the epithelial layer of the alveolar cells of the breast enabling alveolar cells to produce milk. The prolactin receptor theory of breastfeeding involves a calibration period where prolactin activates receptors on the alveolar cells of the breast, enabling milk production from each cell during that lactation (Mohrbacher, 2010). The first 2-3 weeks postpartum is considered a critical period when prolactin receptors are open and responsive to the action of prolactin. If prolactin is not regularly stimulated in this critical period through skin-to-skin contact between mother and infant, and through frequent, effective, and exclusive breastfeeding, it is believed fewer receptors are activated and milk production for the entire duration of lactation will be decreased.

Role of Prolactin in Milk Production

The effect prolactin has on milk production is thought to be minor, outside of the critical period when receptors are activated (Mohrbacher, 2010). Prolactin levels peak after

breastfeeding, breast stimulation, or skin-to-skin contact between mother and infant. However, during the course of a normal lactation, prolactin levels continuously decrease, although they remain elevated from pre-pregnant levels as long as breastfeeding continues. It is now known that there is no direct correlation between prolactin levels and volume of milk produced (ABM, 2011; Anderson & Valdes, 2007; Hale, 2007; Hill et al., 2009). Milk production continues to occur as long as levels remain above the pre-pregnant baseline. Current research on pharmaceutical galactagogues, which work by antagonizing dopamine, thereby increasing prolactin levels, indicates that medication may be effective in women whose initial levels of prolactin are low, but is unlikely to have a significant impact on production when prolactin levels are above the non-pregnant, non-lactating range.

Breast Milk Production and Supply Problems

Most women are capable of producing more milk than their infants require, in fact, most women are capable of producing milk to feed twins, triplets, and even higher order multiples (Mohrbacher, 2010). Peak breast milk production generally occurs between one and six months postpartum, and decreases when solid foods are introduced. Many women require reassurance that they are capable of producing adequate amounts of milk for their infant, since women are apt to misinterpret cues such as changes in breast fullness or infant crying as indicating insufficient milk supply (Kent et al., 2012). If women are encouraged to allow their baby to feed as often as desired, they are less likely to encounter problems with milk production (Mohrbacher, 2010).

Indicators of Low Milk Production

While many mothers believe their milk supply is not adequate for their infants' needs, the rate of physiological inadequate milk production is very low, estimated at a range between 5-

15% (Hurst, 2007). In clinical practice, it is essential for the primary care provider to recognize and address indications that an infant is not feeding well or taking in sufficient milk. With early discharge from acute care after delivery, women may receive less breastfeeding support during the early days of breastfeeding, and infants may be at risk because of poor feeding (Dewey, Nommsen-Rivers, Heinig, & Cohen, 2003). Although the adequacy of milk production cannot easily be measured, a number of objective criteria have been developed to assist the clinician in assessing the adequacy of milk intake by the infant.

Signs of low milk intake by the infant include initial weight loss after birth of greater than seven to ten percent of birth weight; weight loss occurring after postpartum day three; infrequent swallowing by the infant; maternal sore nipples; fewer than six wet diapers per day after day four; or fewer than three stools per day (Hurst, 2007). Infant behavior indicating low milk intake may be demonstrated by irritability; or by sleepiness, lethargy, and a weak cry. The presence of dry skin, dry mucous membranes, poor skin turgor, and low muscle tone may also indicate a lack of sufficient milk intake (Carstens, 2009). Elevated serum sodium levels and hyperbilirubinemia may accompany dehydration due to inadequate milk intake (Wagner, 2009). Expected infant weight gain is also an indicator of adequate feeding. By the fifth day after birth, infants should be gaining between 20-35 gm per day and should return to birth weight by the tenth day of life (International Lactation Consultants Association, 2005). By four to five months of age, most infants should have doubled their birth weight, and weight gain should follow the same percentile on a growth chart during infancy (Wagner, 2009). When a mother's milk supply is inadequate, or the infant is feeding poorly and not transferring milk effectively from the breast, an effective management plan that meets the mothers' needs must be developed by the primary care provider in collaboration with the lactating woman.

CHAPTER THREE

Method

The aim of the literature review was to explore the existing evidence regarding the use of CAM to increase milk production in lactating women. The population includes postpartum women who choose to initiate breastfeeding their babies after birth, but excludes women who chose to induce lactation or relactate after a period without breastfeeding. The majority of postpartum women are between the ages of 18 and 40, and for the most part, make up a healthy population. Among these women, some experience physical causes for insufficient milk production, including a history of breast surgery, hormone disorders such as polycystic ovarian syndrome or hypoplastic breasts (Walker, 2011).

The treatments considered CAM therapies are widely varied and extensive. In order to limit the project to a realistic undertaking, the therapies to be considered are acupuncture and herbal medicine. These therapies are widely recommended in lay breastfeeding literature found on the internet, and are easily accessed, even in small, rural communities. Herbs to be reviewed include fenugreek, blessed thistle, milk thistle, goat's rue, wild asparagus, raspberry leaf, fennel, and chaste tree. Since nettles and alfalfa are thought to have lactogenic properties and comprise ingredients in commercially prepared herbal galactagogue formulations, their use will also be described. The effect of beer and other forms of alcohol on the establishment of milk supply are considered, since this is a common folk remedy for enhancement of milk production. The outcomes to be considered are the efficacy of the treatment and the safety of use in the lactating mother and infant. In order to provide a basis for comparison, conventional advice regarding the management of low milk production in nursing women will be evaluated. The role of nurse practitioners in evaluation and management of low milk supply will be described.

Question of Inquiry

The following research questions are addressed by this literature review: a) are CAM therapies such as herbal medicine and acupuncture safe and effective in increasing milk supply in breastfeeding women with perceived or actual low milk supply when compared with standard breastfeeding management? and b) what is the role of the nurse practitioner in support of the breastfeeding woman who wishes to use CAM therapies to increase milk supply?

Literature Review Method

In order to find sources of reliable published information on the use of CAM by lactating women, electronic databases related to health care were searched using key terms. Databases used for this literature review included MEDLINE, CINAHL, PubMed, Joanna Briggs Institute, Trip Database, Up to Date, NLM Databases, and the Cochrane Library. Search terms used to elicit information were complementary and alternative medicine, acupuncture, lactation, breastfeeding, hypogalactia, low milk supply, fenugreek, raspberry leaf, fennel, blessed thistle, wild asparagus, chaste berry, milk thistle, galactagogues, herbal galactagogues, and insufficient lactation. Boolean operators AND/ OR were used to combine search terms.

Research articles related to adoptive breastfeeding were excluded, since the focus of the project was not induced lactation. Animal studies on the use of herbs to increase milk production were not included, however if animal research was described within the context of a human study, such information was incorporated. In order to ensure the information included in this review is as current as possible, the date of publication of research articles was restricted to the years 2000-2012. Seminal articles on breast milk production by Neifert and Seacat (1987), Hill and Humenick (1989) and Hill (1992) were included despite their age.

While a substantial proportion of studies on the use of acupuncture in breastfeeding are published in Chinese, a small number of studies were available in English language journals. Although there are several studies on the use of herbs as galactagogues published in languages other than English, the incorporation of studies for the purposes of this paper was limited to those published in English. Since much of the published literature on the use of CAM is found in midwifery journals published in Australia and the UK, these sources have been included. For balance, medical literature is included to provide evidence from the allopathic point of view.

Hand searching of relevant journals such as the *Journal of Human Lactation*, *International Breastfeeding Journal*, *Neonatal Network*, *JOGNN*, and *BIRTH*, was done using the key search terms. In order to evaluate the prevalence and quality of breastfeeding literature available to NPs, a hand search of the journals *Nurse Practitioner* (2001-2011), *American Journal for Nurse Practitioners* (2009-2012), and *Patient Care for the Nurse Practitioner* (2000-2006) was completed. Fewer than twenty research and review articles describing some aspect of breastfeeding were available through journals referring to nurse practitioner practice, with a single article describing breastfeeding management for the NP being available. Few articles describing the relationship between the NP role and the use of CAM were located.

Monographs, such as textbooks on lactation and herbal medicine, have been included both to provide background information on management of breastfeeding and breastfeeding physiology, and to provide another source of information on the safety and efficacy of acupuncture and herbal medicine in lactation. Several popular works on breastfeeding, written by breastfeeding experts, and directed at parents were consulted. These books included works by Diana West, Lisa Marasco, Sheila Humphrey, and Hilary Jacobsen. These works were hand

searched and primary sources used in the preparation of the monograph were retrieved when available.

An internet search using Google and Google Scholar was completed, using the above search terms. A large variety of literature is available on the internet, directed at pregnant women and new mothers, providing information and advice on the use of CAM to support breastfeeding. In order to stay focused on the clinical evidence and avoid the inclusion of unsubstantiated health claims for products, lay websites have been excluded from this review unless an article written by a recognized breastfeeding expert addressing the use of CAM to increase milk supply was available. See Table 1.

Table 1 Website Search

Organization	URL
American Botanical Council	http://abc.herbalgram.org/site/PageServer
Breastfeeding Inc.	http://www.breastfeedinginc.ca/content.php?pagename=doc-HRMS
Chinese Medicine Gateway	www.accupuncture.com
Fraser Institute	www.fraserinstitute.org
Health Canada: Natural Health Products	http://www.hc-sc.gc.ca/dhp-mps/pubs/natur/index-eng.php
Kellymom Breastfeeding	http://kellymom.com/bf/can-i-breastfeed/herbs/herbal_galactagogue/
Lactmed Database	http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT
Mother Risk	www.motherisk.ca
National Center for Complementary and Alternative Medicine	http://nccam.nih.gov/
Toxicology Data Network	http://toxnet.nlm.nih.gov/cgi-bin/sis/search
U.S. Department of Health and Human Services: Women's Health	www.womenshealth.gov
World Health Organization	www.who.int

CHAPTER FOUR

Findings

Both alternative and conventional pharmaceutical galactagogues are commonly used to enhance milk production in breastfeeding mothers. This review will focus on the use of herbal galactagogues and acupuncture as strategies to increase breast milk production. The safety and efficacy of a number of herbal medicines and acupuncture will be evaluated.

Herbal Galactagogues

Historically, women in all cultures have used foods and herbs to support and increase milk supply. Early writings regarding the use of herbal medications to enhance lactation include the Ebers Papyrus, dating from about 1550 BC and the *Materia Medica* of Dioscorides, dating from about 70 AD (Osbaldeston, 2000). Dioscorides recommends a number of foods and herbs to support the production of milk. Drinking water that was used for boiling wheat or other grains, was considered to produce a copious milk supply, as was eating lentils boiled in seawater. Other remedies recommended by Dioscorides include common mallow, wild lettuce, anemone taken with barley water, and chaste tree. While Dioscorides mentions fenugreek as a remedy for skin problems and as a general tonic after childbirth, he does not describe its use as a galactagogue.

In the modern era, herbal galactagogues and lactogenic foods are widely recommended by lactation specialists, midwives, and by websites providing breastfeeding information and support. Current research indicates approximately 15% of breastfeeding women use herbal galactagogues at some point during lactation (Abascal & Yarnell, 2008). Fenugreek is the most widely recognized galactagogue, while other common herbal galactagogues include wild asparagus, blessed thistle, fennel, hops, anise, licorice, goat's rue, milk thistle, marshmallow,

borage, beer, and garlic (ABM, 2011; Ayers, 2000). Remarkably few studies on the use of herbal treatments during lactation exist, despite the fact that the use of herbs during lactation is common (Humphrey, 2007). While fenugreek is the most widely recommended herb used as a galactagogue, many other herbal products are used by breastfeeding women to increase milk supply. In many cases, combinations of herbs are used for their lactogenic effects, making it particularly difficult to ascertain the effects of an individual herb on milk production.

Fenugreek

Fenugreek (*Trigonella foenum-graecum*) is an herb from the pea family, which is indigenous to the Mediterranean, India, Africa, and the United Kingdom. Its use as a galactagogue is described in ancient Ayurvedic and Middle Eastern medical texts (Humphrey, 2007). Fenugreek is commonly used in cooking, where it comprises a component of curry powder. Fenugreek is used in the production of artificial maple flavoring due to its distinctive maple-like scent (Betzold, 2004). The greens can be eaten in salad and provide a good source of iron ("All about Fenugreek," 2011). Fenugreek is generally recognized as safe (GRAS) by the US Food and Drug Administration (LactMed Database, 2011). Fenugreek is used as a remedy for a variety of symptoms including menopausal symptoms, digestive symptoms, and loss of appetite (National Center for Complementary and Alternative Medicine [NCCAM], 2010). Fenugreek has been recommended for lowering blood sugar and decreasing serum cholesterol levels ("Fenugreek," 2011). It has been reported to increase the anticoagulant effect of warfarin (Conover & Buehler, 2004) and may decrease calcium oxalate deposition in the kidneys, preventing development of calcium oxalate stones (Mills, Duguoia, Perri, & Koren, 2006).

The Role of Fenugreek in Lactation. Fenugreek contains a number of active compounds including diosgenin, which may be the primary active compound in fenugreek related to lactation (Hale 2010). Animal studies have indicated that diosgenin induces mammary tissue growth (Humphrey, 2007). The active compounds in fenugreek are thought to act as hormone precursors, allowing an increase in milk supply. Fenugreek increases the body's ability to sweat, and this may be linked to its effects, as the breasts are thought to function in a similar fashion to sweat glands ("All About Fenugreek," 2011; Betzold, Hoover, & Snyder, 2004). It may increase the release of thyroid stimulating hormone and prolactin. Fenugreek has been shown to have an antidepressant and anxiolytic effect. Since anxiety can be part of the problem of insufficient milk supply, these properties may have some effect on its use as a galactagogue (Abascal & Yarnell, 2008).

Fenugreek Dosage. Fenugreek is usually taken as ground seeds in capsule form, however, it can be taken as tea, which is described as being unpleasant in taste. The effective dosage is not well established, with different sources describing dosages between one to four capsules taken three to four times daily. If tea is used, $\frac{1}{4}$ teaspoon of seed is steeped in a cup of water for ten minutes and taken three times daily (ABM, 2011). Humphrey (2007) indicates the effective dosage is between 3 and 6 gm of seed per day. Since there are no standardized concentrations for herbal preparations, it is difficult to ascertain how much of the herb is required to have a therapeutic effect.

Considerations and Complications. In order to evaluate the effectiveness of fenugreek, one author suggests that when the dosage is adequate, the milk will take on a maple scent, and sometimes the mother's skin and perspiration will smell like maple (Ayers, 2000). The infant can begin to smell like maple syrup as well, which could lead to a mistaken diagnosis of maple

syrup urine disease, although the maple scent is harmless (Laurence, 1996). Other concerns are the frequency of allergic reactions in individuals with legume sensitivity, potential exacerbation of asthma symptoms, diarrhea, and hypoglycemia (Hale, 2010). Fenugreek may have anti-platelet properties and may decrease the absorption of other medications (Tiran, 2003). Use in pregnancy is not recommended as fenugreek has been shown to have uterine stimulant effects in animal studies (ABM, 2011). However, fenugreek is widely used as a culinary ingredient in the Middle East and Asia, yet restriction of dietary use has not been observed in cultural practices related to pregnancy (Humphrey, 2007).

Fenugreek Research Summary. Much of the evidence supporting the use of fenugreek as a galactagogue is anecdotal. One frequently cited study on the use of fenugreek describes the use of fenugreek by approximately 1200 women in one lactation consultant's clinical practice (Huggins, n.d.). The author indicates that most women who take fenugreek will notice an increase in milk supply within 24-72 hours of treatment initiation. In most cases, the consumption of fenugreek was accompanied by the use of a hospital grade electric breast pump and increased frequency of pumping. Huggins indicates that most mothers can discontinue taking fenugreek when milk supply reaches the necessary level, provided they continue added breast stimulation and milk removal. Because of the absence of control groups, randomization, or blinding, it is impossible to ascertain if the noted effects are related to the use of the herb or the result of improved breast stimulation and drainage.

Another frequently cited study describing the use of fenugreek as a galactagogue is the work of Swafford and Berens (2000). The observational study involved ten women who were exclusively pumping over a two-week period (Swafford & Berens, 2000). The women kept a diary of production during the first week, in order to establish a baseline and allow each woman

to act as her own control. During the second week, three capsules of fenugreek were taken three times daily. The authors report that average daily milk production increased from 207 mLs/day to 464 mLs/day. The authors report that the range of production in the first week was 57-1057 mLs/day, while the range of production in the second week was 63-1140 mLs/day. The average increase in production appears to be significant with an average daily increase in milk volume of 257 mLs/day, the improvements in the range are less impressive with an increase of between 6 and 83 mLs/day. The reporting of data as a range without describing the effects on individual women, has obscured the potential value of the treatment in women with very low production (e.g. 57 mLs/day). Although the increase in production is reported as having a P-value of 0.004, indicating the treatment is likely to be the cause of increased milk supply, most women have an increase in supply as lactation progresses, leaving it difficult to determine if the increase was related to the use of fenugreek or to the duration of lactation.

It is not known what percentage of women using fenugreek experience an increase in milk supply. Westfall (2003) surveyed breastfeeding women living in Vancouver and Victoria British Columbia. Twenty-three women volunteered to answer a survey describing their experiences with herbal galactagogues and their overall breastfeeding experience. Of these, four women had used fenugreek to increase milk supply. All the women indicated they had some success with the use of fenugreek, however all of the women indicated that they had no objective means of measuring its effectiveness. Huggins (n.d.) indicates that nearly all women who have participated in her survey have indicated positive effects from the use of fenugreek. It is possible that women who have positive experiences with herbs are more likely to volunteer for surveys than those who have not experienced benefits from the use of herbal products.

Since prolactin is an essential hormone in early milk production, recent studies have evaluated the role of fenugreek in stimulating prolactin levels. One study used a convenience sample of mothers of preterm infants to evaluate the effect of fenugreek on prolactin levels in maternal serum (Reeder, Legrand, & O'Conner-Von, 2011). The treatment and control groups were instructed to pump and record pump frequency and milk volumes. Prolactin levels were drawn weekly during the 21-day study. No difference was seen between the treatment and placebo group in either prolactin levels or milk volumes.

Another study compared infant weight loss and pumped milk volume in the first three days after birth as well as time for infants to regain birth weight (Turkyilmaz et al., 2011). Participants were randomized to a control group, a placebo group, and a treatment group. The treatment group was provided with a tea containing fenugreek, goat's rue, fennel, raspberry leaf, rooibos, vervain, and hibiscus. All groups received education and support from a lactation consultant regarding positioning, latch, and breastfeeding technique. Groups were consistent in characteristics such as parity, gender of infant, type of birth, use of labor analgesia, birth weight of the infant, and gestational age of the infant. Average percentage of birth weight lost after birth was lower in the treatment group (5.7% of birth weight) compared to the control (8.3%) and placebo groups (6.6%). Average volume of pumped breast milk on the third day postpartum was 73 mLs compared to the placebo group, which produced an average of 38.8 mLs, and the control group, which produced an average of 31.1 mLs. Days for the infant to regain birth weight were 6.7 for the treatment group, 7.3 days for the placebo group and 9.9 days for the control group. It should be noted that expected weight loss after delivery is between 7 and 10% and the expected time to regain birth weight is 10 days. All the groups fell within expected outcomes for healthy breastfeeding infants (International Lactation Consultant Association, 2005).

Blessed Thistle

Blessed thistle (*Cnicus Benedictine*) is a weed which grows commonly in the Mediterranean region (Westfall, 2003). The flowers, leaves, and stems are used for medicinal purposes. Blessed thistle was used in the Middle Ages to treat bubonic plague and for use as a general tonic. It is believed to prevent hemorrhage after childbirth, and to act as an antidepressant. Modern use includes stimulation of appetite and treatment of dyspepsia through the stimulation of stomach acid ("Blessed thistle," 2011). It has been used topically as a poultice for boils, wounds, and skin ulcers. It contains tannins, which may have an anti-inflammatory effect. Hale (2010) indicates that it contains steroids, terpenoids, and volatile oils, which may account for its antibacterial and antiseptic properties. It stimulates blood flow to the breasts, leading to increased milk production; however, no studies have supported its use as a galactagogue (Conover & Buehler, 2004; Hale, 2010; Jackson, 2010). It is non-toxic and has GRAS status with the US Food and Drug Administration (Humphrey, 2007). It is a member of the ragweed family and related to chrysanthemums, marigolds, and daisies. Individuals with ragweed allergies may develop an allergic reaction to blessed thistle.

Westfall (2004) indicates that two participants in her survey used blessed thistle as a galactagogue in combination with other herbs. Neither of the women were able to describe with certainty that blessed thistle was effective as a galactagogue. Breastfeeding expert Dr. Jack Newman indicates that blessed thistle and fenugreek are most effective in combination, and appear to be most effective in the first week following delivery (Newman & Kernerman, 2008). The recommended dose is three capsules taken three times daily. Newman and Kernerman do not include references for their recommendations, therefore this article provides only an expert opinion regarding the effectiveness and dosing of these galactagogues.

Milk Thistle

Milk thistle (*Silybum marianum*) is botanically unrelated to blessed thistle. Its use as a liver tonic dates from the 4th century BC (Erlach, 2011). Its active ingredient is the flavinoid silymarin, which is thought to protect the liver from toxins such as liver damaging drugs, alcohol and some poisons. It may affect drug metabolism through alteration of the cytochrome P450 pathways for enzymes CYP2C9 and CYP3A4 (Mills et al., 2006). Silymarin is believed to have properties as an antioxidant, anti-inflammatory, and antihyperglycemic agent (O'Hara, Kiefer, Farrell, & Kemper, 1998). Silymarin is produced commercially in a micronized form referred to as BIO-C (Di Pierro, Callegari, Carotenuto, & Tapia, 2008). The galactagogue effect of silymarin has been demonstrated in dairy cows as well as in rats. Animal studies indicate that silymarin inhibits dopamine, allowing an increase in prolactin production, which encourages synthesis of milk in the breast tissue.

Dosing Considerations. When milk thistle is used as an herbal therapy, the seeds or young leaves are typically used. The seeds are crushed and 5 gm of seeds are steeped in a cup of boiling water for ten minutes. Two to three cups of tea per day are recommended (Dog, 2009). Milk thistle has been reported to cause mild diarrhea or intestinal upset in the first few days of use.

Milk Thistle Research Summary. A single human study conducted in Peru has attempted to demonstrate the galactagogue properties of silymarin. Di Pierro, Callegari, Carotenuto, and Tapia (2008) conducted a study on 50 women that demonstrated an 85% increase in milk production in the treatment group compared to a 39% increase in the control group. The authors hypothesize that the effect of silymarin in lactating women is due to antiestrogenic effects, as an increase in prolactin was not demonstrated. The study used

volunteer patients, and was controlled with a placebo treatment, however the study was not randomized and appears to have used matched controls based on maternal age, parity, age of last born, and number of sons (Di Pierro et al., 2008). The authors describe the study as being blinded from the patient perspective but do not discuss whether the investigators were blinded. Competing interests were not disclosed, so it is unknown if the study was sponsored by the company producing BIO-C.

Mothers in the treatment group were provided with 420 mg of a standardized extract of silymarin (Di Pierro et al., 2008). Milk production was measured by test weighing the infants before and after feeds, and measuring the pumped volume of milk obtained. The study results showed that the control group produced an average of 530 gm/day of breast milk at the beginning of the study, while the treatment group produced an average of 601 gm/day of breast milk at the beginning of the study. On day 30, the milk production of the control group was 649 gm/day, while the milk production of the treatment group was 989 gm/day. On the final day of the study (day 63), the milk production in the control group was 700 gm/day compared to 1119 gm/day in the treatment group.

While this is a large increase in average production in the treatment, both the placebo and treatment groups experienced increased production during the course of the study. The authors do not explain if any alterations were made to breastfeeding practices, influencing milk production in the control group. It is also interesting to note that the gestational ages and weights of infants in each group were not disclosed. Since breast milk production is largely dependent on infant demand, larger infants and full term infants would need higher calorie intake in order to gain weight, resulting in a larger demand for milk volume. If larger infants were assigned to the

treatment group, milk production would be higher than in the control group, and the effectiveness of the intervention would not be established.

Goat's Rue

The use of goat's rue (*Galega officinalis*) dates back to the Middle Ages, when it was used as an anti-infective and as a cure for the plague. It was first described as a galactagogue in 1873 when it was demonstrated to increase milk production in dairy cows by up to 50% (Humphrey, 2007; Low Dog, 2009). The seed, leaf, and flower are considered to contain active ingredients, including guanidine, galegine, coumarin, and flavonoids (Humphrey, 2007). Traditional uses for goat's rue include internal use for treatment of gout and topical use for healing of sores, ulcers, and sprains. It has been shown to have anti-platelet, antihyperglycemic, and antibacterial properties. Metformin, used as an oral hypoglycemic medication, is a synthetic chemical based on the galegine component of Goat's rue (Abascal & Yarnell, 2008). Goat's rue may increase the development of breast tissue and increase milk production. The mechanism of increased production is unknown, but may be related to its ability to cause sweating (Humphrey, 2007).

Dosing Considerations. If used as a galactagogue, goat's rue can be taken as a tea or tincture. One teaspoon of dried leaves can be steeped in a cup of water and taken twice daily as a tea (Abascal & Yarnell, 2008). Goat's rue has an unpleasant and bitter taste (Humphrey, 2007).

Goat's Rue Research Summary. Several controlled studies have indicated goat's rue combined with minerals resulted in increased milk production in lactating women of up to 60% greater than placebo. These studies by Heiss (1968) are published in German and were not available, but are cited by Humphrey (2007) and the National Library of Medicine LactMed

Database ("Goat's Rue," 2011). One randomized controlled study describes the use of a tea containing 100 mg of goat's rue in combination with a number of other herbs including fenugreek, raspberry leaves, and fennel in lactating women. Mothers receiving the tea produced more breast milk on the third day post-partum as measured by breast pumping, and their infants had a lower maximum weight loss compared to the placebo group that received an apple tea (Turkyilmaz et al., 2011). The authors attributed the galactagogue effect of the tea to the fenugreek content, not to the effect of the other herbs in the mixture.

Goat's rue is a noxious weed in the United States (Humphrey, 2007). There are cases of toxic and fatal effects of consumption of large quantities of goat's rue in animals. There is a single case report of toxic symptoms in two newborn infants of women drinking more than two litres per day of an herbal tea containing goat's rue in combination with licorice, anise, and fennel. The infants presented with hypotonia, lethargy, emesis, and poor suck. A history of poor feeding was identified prior to evaluation. Discontinuation of the tea resulted in resolution of the symptoms, however the use of the tea as the sole cause of the symptoms was not established (Rosti, Nardini, Bettinelli, & Rosti, 1994). Although the authors attributed the effects on the infant to be the chemical compound anethole, found in anise and fennel, no measurement was made in either the breast milk or infant serum to establish this. Maternal side effects may include headache, nausea, and dizziness.

Wild Asparagus

Wild asparagus (*Asparagus racemosus*) is a different species from the asparagus commonly used as food ("Wild asparagus," 2011). Wild asparagus, referred to as Shatavari in Ayurvedic medicine, has a long history of use as a female tonic and as a galactagogue (Humphrey, 2007). It improves gastric emptying at a rate comparable to metoclopramide, which

is a dopamine antagonist used off-label as a galactagogue in the United States (Goyal, Singh, & Lal, 2003). It acts as a protectant of gastric mucosa and decreases symptoms of duodenal ulcers. In animal studies, it inhibits uterine contractions by blocking oxytocin. Some animal research has indicated wild asparagus may act as a teratogen when used during pregnancy ("Asparagus Racemosus," n.d.)

Dosing Considerations. If taken as a galactagogue, the recommended dosage is 1 gm/day of powdered root (Low Dog, 2009). Low Dog does not discuss how this dosage recommendation was established. The trials conducted on the effectiveness of wild asparagus used varying dosages. For example, Sharma, Ramji, Kumari and Bapna (1996) provided participants with a dose of 15 gm daily of wild asparagus combined with other herbs, while Gupta and Shaw (2011) provided participants with a dose of 60 mg/kg/day of wild asparagus during their trial.

Wild Asparagus Research Summary. Several commercial preparations of wild asparagus are widely available in Asia. Ricalex contains a combination of wild asparagus and dicalcium phosphate. Lactare contains wild asparagus combined with ashwagandha, fenugreek, licorice, and garlic. Ricalex was studied in 15 women, of whom 11 described an increase in milk supply, evidenced by breast sensation, infant weight gain and hydration status. The study was not done with control groups, randomization, or blinding, and was intended as a preliminary screen prior to a controlled clinical trial (Joglekar, Ahuja, & Balwani, 1967).

A randomized controlled trial using wild asparagus was conducted on women who presented with infants with inadequate weight gain or frequent supplementation (Sharma, Ramji, Kumari, & Bapna, 1996). While the primary variable investigated in this trial was prolactin level, the researchers considered frequency of supplementation and infant weight gain as

secondary outcomes. Women in the treatment group experienced an average of a 33% increase in prolactin levels compared to those in the control group who averaged a 10% increase serum prolactin during the course of the study. Both the placebo and treatment groups demonstrated improved infant weight gain at the close of the trial, as well as decreased volumes of supplement required for the infant. These results led the authors to conclude that the herbal product was ineffective and that improvement in infant weight gain was due to improved breastfeeding practices.

The use of *Asparagus racemosus* was evaluated in a double blind, randomized, clinical trial in Kolkata, India (Gupta & Shaw, 2011). Sixty mothers were selected from an outpatient department after being evaluated for breastfeeding difficulties including inadequate lactation, infant crying, painful breasts, anxiety, or loss of appetite in the mother. The women were randomized into the treatment or control group, based on computer generated random numbers.

The treatment group was provided with 60 mg/kg/day of dried powdered asparagus root capsules, while the control group was provided with rice powder capsules. Neither group was provided with breastfeeding assistance, however all women were instructed not to take oral contraceptives, to feed their babies with their usual practices, to burp the babies after all feeds, and to avoid situations which would provoke anxiety or tension in the mother. Outcomes were measured based on measurement of serum prolactin levels and infant weight gain, as well as subjective indicators such as the happiness of the baby and the satisfaction of the mother. Ten patients dropped out of the study and their results were excluded from the study. The treatment group demonstrated higher prolactin levels, increased infant weight, improved maternal satisfaction, and higher infant happiness when compared to the control group. The P-value was 0.05, thus the results were considered to be statistically significant. The authors attributed the

study effects to the estrogenic like effects of asparagus racemosus resulting in increased breast tissue and increased milk production.

The results of the trials are contradictory, with the Sharma et al. (1996) study suggesting that the herbal medicine contributed little to improved breastfeeding; yet improved breastfeeding practices were able to produce a substantive increase in milk supply. The study by Gupta and Shaw (2011) indicates that a ten out of the sixty women recruited into the study dropped out before completion. Since dropouts from scientific studies are more likely to occur in patients who are not experiencing positive results from the study, it is possible that patients who did not experience improvement were eliminated from this study, biasing the results toward an appearance of greater effectiveness than is warranted.

Fennel

Fennel (*Foeniculum vulgare*) is one of a group of botanically related aromatic herbs, commonly used in cooking. These herbs include anise (*pimpinella anisum*), caraway (*Carum carvi*), cumin (*Cuminum cyminum*) and dill (*Anethum graveolens*), all of which are reputed to have lactogenic properties (Low Dog, 2009). Medicinally, fennel is used as a digestive aid and for treatment of dyspepsia (Westfall, 2003). Fennel tea is used to treat infants with colic (Westfall, n.d.). Fennel may thin secretions and increase ciliary activity in the upper respiratory tract (Mills et al., 2006). It is considered to promote menstruation, facilitate birth, and increase libido (Hale, 2010), however animal studies indicate that it blocks prostaglandin E2 leading to decreased intensity and rate of uterine contractions (Mills et al., 2006). Fennel and anise contain the compound anethole, which has properties as a weak estrogen, however, no mechanism for the purported lactogenic effect has been described (Humphrey, 2007). When taken as a galactagogue, the recommended dose is 5-7 gm of seed per day (Abascal & Yarnell, 2008).

Although fennel was used in combination with other purportedly lactogenic herbs in the study by Turkyilmaz et al. (2011), no clinical trials were found evaluating the use of fennel as a single herb.

Red Raspberry Leaf

Red raspberry leaf (*Rubus idaeus*) grows both as a wild plant and as a cultivar in temperate countries. It has been widely used for centuries as an aid to childbirth, and is widely promoted as a galactagogue (Wesson, 2007). Raspberry leaves are rich in tannins, which have antioxidant, antiseptic, and anti-inflammatory properties (Libster, 2002). The leaves are rich in minerals such as iron, calcium, and selenium, as well as Vitamins A, C, and K. Raspberry leaves were used as a component in the galactagogue tea tested by Turkyilmaz et al. (2011). Since numerous ingredients reported to be galactagogues were contained in the tea, it is impossible to ascertain if the effect of the tea was related to the raspberry component. Westfall (2003) describes three women who used raspberry leaf tea as a galactagogue. One woman noted that she had a sudden increase in milk volume when she began drinking the tea. Another woman described the benefit of raspberry leaf tea as providing relaxation and nurturing for mothers. If raspberry leaves are used, the recommended dose is between 2-8 gm of leaves, steeped in boiling water and taken three times daily (Wesson, 2007). No adverse effects have been identified.

Chaste Berry

Chaste berry or chaste tree (*Vitex agnus castus*) is native to Europe and Asia, and grows in the southern United States (Roemheld-Hamm, 2005). Chaste berry has been used since ancient times for a variety of gynecological conditions. It was used to decrease libido among celibate monks, leading to the common name chaste berry. It is used in Europe to treat PMS, fibrocystic breast pain, and dysfunctional uterine bleeding, and has undergone systematic

research to examine its usefulness for these conditions. While it has been used to prevent first trimester miscarriage (American College of Health Care Sciences, 2011), some sources indicate it may increase the risk of miscarriage (Ernst, 2002). The active ingredients are generally found in the berries, and include flavinoids, glycosides, and essential oils (Hardy, 2000). The leaves contain progesterones, testosterone, and androstenedione in very small quantities. It has been shown to have dopaminergic effects and to inhibit the release of both prolactin and thyrotrophic releasing hormone. Some animal studies have shown that its effect may be to balance the effects of prolactin, decreasing abnormally elevated levels, while increasing deficient levels (Abascal & Yarnell, 2008). Although its traditional use has been as a galactagogue, it is unclear whether its properties would lead to increasing or decreasing milk production. No randomized controlled trials evaluating the use of chaste berry as a galactagogue were located. If taken as a galactagogue, one teaspoon of dried berries steeped in a cup of water and taken three times daily is the recommended dosage (Walker, 2011).

Other Herbal Galactagogues

Other herbal remedies believed to have lactogenic effects include nettle (*urtica dioica*), licorice, marshmallow (*althaea officinalis*), alfalfa (*meicago sativa*), borage, and grains such as oats, brown rice, and barley (Humphrey, 2007). Nettles were used by the aboriginal people of North America as a pregnancy tonic and to increase the production of breast milk (Scott & Jacobson, 2005). Nettles are believed to support lactation through the provision of essential nutrients (Belew, 1999). It does not appear to have direct effect as a galactagogue. Animal studies have shown that nettles boost milk production in dairy cattle (Westfall, 2003). Nettles are a rich source of carotene, vitamin C, vitamin K, potassium, calcium, phosphorus, magnesium and chlorophyll (Westfall, 2003, Mills et al., 2006).

Alfalfa contains genistein, phytoestrogens, and flavinoids, as well as being a rich source of vitamins A, C, E, and K. It is reputed to have hypoglycemic properties. Animal studies have shown alfalfa contributes to increased breast tissue development, however it has not been systematically studied as a galactagogue in humans. Borage has been recommended as a galactagogue, it has been found to contain hepatotoxic alkaloids and is not recommended for use during lactation (Hale, 2010).

Beer and Breastfeeding

Beer has been traditionally recommended as a galactagogue, particularly in Northern European cultures. In the early 20th century, beer was marketed to postpartum women as an appetite stimulant, a tonic for restoring strength after childbirth, and as a method of enhancing milk production (Koletzko & Lehner, 2002). Some proponents have theorized that the relaxing effect of alcohol may facilitate lactation, others have hypothesized that beer may increase prolactin levels. Hops (*Humulus lupulus*) have traditionally been used in pregnancy as a relaxant and antispasmodic, and have been viewed as having lactogenic properties (Libster, 2002). Hops are a component of beer, although Libster indicates that there is no evidence that the active ingredients in hops survive the brewing process. A review by Koletzko and Lehner (2002), describes a number of studies where the effects of beer intake on prolactin levels have been studied. Both beer and non-alcoholic beer were shown to increase prolactin levels in men and non-lactating women. Animal studies have shown that beer ingestion increases prolactin levels; however, neither the ingestion of other forms of alcohol nor the ingestion of hops had the same effect. Barley extracts and malt extracts in animal appear to increase prolactin levels in animal studies. Koletzko and Lehner (2002) hypothesize that a polysaccharide contained in barley is responsible for the prolactin response.

Human studies on the use of alcohol by breastfeeding women present several contradictions. There are indications that infants consume less breast milk in the three to four hours following alcohol intake by their mothers than they do at other times (Menella, 2001). Alcohol may block the release of oxytocin from the pituitary, resulting in decreased milk ejection reflex for approximately two hours after alcohol ingestion (Bowen & Tumback, 2010). However, Menella (2001) notes that mothers who had ingested alcohol perceived that their breasts were fuller, and believed that their infants consumed more milk than they did when the mother ingested non-alcoholic beverages. At the same time, women who consume more than two drinks per day are more likely to wean prematurely than those who drink fewer than six drinks per week (Bowen & Tumback, 2010).

Ethical considerations make it impossible to conduct randomized controlled trials on the use of alcohol by lactating women, so the existing research relies on observational studies and animal research. With the widespread awareness of negative effects of alcohol on fetal development, concern exists regarding potential harm to the infant with regular ingestion of alcohol by the mother. Infants exposed on a daily basis to alcohol in breast milk have slight decreases in gross motor development, but not in mental development. Less than daily exposure to alcohol was not associated with developmental delay (Menella, 2001). In order to minimize the potentially damaging effects of maternal alcohol consumption on the infant, a nursing mother should wait several hours before breastfeeding after consuming alcohol. There is no need to pump and discard the milk, as the alcohol is metabolized from the milk at the same rate as it is metabolized from the blood (Lawrence & Lawrence, 2011).

The Use of Acupuncture to Increase Milk Supply in the Lactating Woman

Although acupuncture has been used to increase milk production in lactating women for approximately 2000 years, few English language studies exist describing the efficacy and safety of acupuncture in lactation (West & Marasco, 2009). Several clinical trials describing the use of acupuncture and electro-acupuncture to treat low milk supply have been published in recent years, however many of these studies suffer from structural flaws, including small sample sizes, lack of randomization and lack of blinding, resulting in difficulty ascertaining the value of acupuncture in clinical practice.

Acupuncture as a Treatment Modality

Acupuncture is believed to regulate the flow of vital energy or chi within the body (Ahn, 2011; Jackson, 1998). Acupuncture points are located near the surface of the body, allowing the flow of chi to be stimulated or regulated. The body has twelve meridians, or channels along which chi flows. Obstructions in the flow of energy can lead to pain or organ dysfunction. The body has 361 points along the meridians where it is possible to correct imbalances in the flow of energy through the application of needles, pressure (acupressure), or heat (moxibustion). Electrical wires may be attached to the needles to provide electrical stimulation. Breastfeeding expert Marsha Walker (2011) indicates that acupuncture treatments are most likely to be effective early in the postpartum period; however, milk supply problems are frequently not identified in the first two to three weeks postpartum, making effective clinical use of acupuncture less likely.

Few adverse effects are associated with the use of acupuncture. Most common events were bleeding or bruising at the site of needle insertion (Chung, Bui, & Mills, 2003). However, a small number of patients will experience an initial aggravation of symptoms, which usually

subsides without complication. Some patients will experience fainting, syncope, nausea, or vomiting during treatments. Several reports have described infections such as hepatitis B or sepsis resulting from acupuncture with inadequately sterilized equipment. Isolated cases of organ puncture have occurred with deep penetration of acupuncture needles including one fatality from a punctured heart and several cases of pneumothorax. Experts recommend that practitioners not practice deep puncture over the thorax or over the abdomen of a pregnant woman.

Challenges in Acupuncture Research

The inability or failure to blind studies has been a common challenge for acupuncture research (Smith & Cochrane, 2009). It is not possible to blind the researcher, since the acupuncturist will always know what treatment is given. Nor is it possible to completely blind participants, as they will obviously know that acupuncture is taking place. Some studies have attempted to partially blind participants by using sham acupuncture points for treatment of control group participants. However, some practitioners claim that treatment effects can occur even when sham points are used, either through the placebo effect or through the adjustment of the patient's chi by stimulation of a non-traditional acupuncture point.

Traditional Chinese Medicine Approach to Insufficient Lactation

Traditional Chinese Medicine (TCM) views lactation as requiring a balance between chi and blood for adequate milk production (Tureanu & Tureanu, 1994). If the production of breast milk is inadequate, the problem is due to a deficiency of blood and chi, or a stagnation of chi in the liver. A deficiency of blood and chi may be caused by poor general health of the mother, poor nutrition during pregnancy, and postpartum blood loss. Symptoms of deficiency of chi and blood in the mother include soft breasts, absence of milk, weakness, fatigue, pallor, poor

appetite, and a thready pulse. If the inadequate milk production is related to liver stagnation, the cause is thought to be depression or anxiety, which is seen as damaging to the liver. Symptoms of chi stagnation in the mother include breast engorgement and pain, absence of milk, depression, anxiety, loss of appetite, and a bounding pulse.

Acupuncture Research Summary

One study describes the use of acupuncture to treat insufficient milk supply among twenty-seven women (Tureanu & Tureanu, 1994). Patients were diagnosed using the TCM diagnoses of blood and chi deficiency or chi stagnation in the liver and acupuncture treatments used up to ten acupuncture points. The authors indicate that test weights were used to measure milk intake in the newborn, as well as monitoring newborn weight. The mothers were asked for subjective descriptions of breast fullness and pain to determine effectiveness of treatment. According to the authors, 70% of women had very good results, while 15% had satisfactory results and 15% had no response to acupuncture. The criteria used to determine whether results were rated good, satisfactory, or poor was not described. Acupuncture was effective for a greater percentage of multiparous women than primiparous women; however, the multiparous women required more treatments to achieve results. The women were not randomized, nor was there a control or placebo group. The authors hypothesize that acupuncture stimulates the release of serotonin, which is a precursor for the release of prolactin from the pituitary.

Another study described the effect of acupuncture on 90 women with insufficient milk supply (Neri et al., 2011). Inclusion criteria included singleton pregnancy, birth weight >2500 gm, and neonatal health. Women with complications during pregnancy such as diabetes or gestational hypertension were excluded from the study. The women were randomized to a treatment (acupuncture) group or to a control group based on a computer-generated program.

The treatment group received acupuncture treatments twice a week for three weeks, while a midwife provided breastfeeding support for both groups. The groups are reported as being consistent in demographic features such as average maternal age, socio-economic status, rate of caesarean section, and rate of postpartum hemorrhage. Three women withdrew from the study when they were randomized to the control group, and one woman withdrew from the treatment group due to noncompliance with acupuncture treatments. The women were evaluated for deficiency of chi and blood or for stagnation of liver chi, and the acupuncture points stimulated during treatments were based on this diagnosis.

The authors did not measure milk production in order to compare between the two groups. The treatment was considered successful since the rate of continued breastfeeding at three months postpartum was 35% compared to 15% in the control group. The authors point out that normal milk production varies widely between women, and state “the mother’s anxiety was often the most relevant problem” (Neri et al., 2011, p. 136). While the authors provide a lengthy description of the physiological effects of acupuncture, it is impossible to prove the treatment effects were due to the provision of acupuncture rather than to the increased attention received by the women in the treatment group, which may have been as effective at reducing anxiety related to breastfeeding as acupuncture treatments.

A case report describing an increase in milk production among thirty women treated for low milk production in Hebei, China, indicated that after one session of acupuncture 90% had increased milk production, while after 3-5 sessions the treatment effect was greater (Yan & Hui, 2006). This report relies on subjective perception of milk supply and provides no data describing how initial low supply was determined or how improvements were measured. There was no

control group for comparison purposes, so the effect of acupuncture to increase breast milk production cannot be established through this study.

A study of low milk supply in post-caesarean mothers at a hospital in Wuhan, China indicated that 89% of patients had a positive response to ear lobe acupuncture, resulting in increased milk supply (Zhou et al., 2009). Patients were randomized to either a treatment or control group. The control group and the treatment group were both given breastfeeding encouragement including recommendations for frequent breastfeeding. Patients were diagnosed according to TCM designation for causes of insufficient milk production and acupuncture points were chosen accordingly. Breast milk production was measured by hand expression. Serum prolactin levels were measured before and after treatments, which took place daily for five days. Milk production increased in both groups, as would be expected in the immediate postpartum period; however, supplementary feedings were markedly decreased in the treatment group, indicating that the infants of treated mothers were more satisfied with the quantity of milk obtained during feeding. Prolactin levels were higher in the treatment group after treatments than in the control group. Since the treatment group was not blinded, it is difficult to ascertain if the effects seen were due to treatment or placebo effect rather than to the effect of acupuncture.

One randomized control study describes the effects of electro-acupuncture for the treatment of low milk supply in postpartum women (Wei, Wang, Han, & Li, 2008). The patients were treated based on TCM designation of deficient chi and blood or stagnation of liver chi. Prolactin levels were measured before and after treatment once each day. Treatments were provided for ten days and follow up was continued for one month following completion of treatments. Milk production was measured by hand expression eight or more times daily. All participants in the treatment group experienced improvement or marked improvement in milk

supply, while approximately half of the patients in the control group experienced some improvement in milk supply. However, only 6% of patients in the control group experienced marked improvements in milk production. Thirty percent of patients in the control group experienced no improvement in milk supply during the duration of the study. Prolactin levels were higher for the duration of the study in patients in the treatment group, while prolactin levels declined in the control group. The study was not blinded, so it is difficult to ascertain if the results are related to the treatment or to frequent breast stimulation through hand expression.

Two cases of inadvertent galactorrhea following acupuncture in women who were not lactating have been described. One patient was receiving acupuncture treatment for post-surgical pain following a right mastectomy for breast cancer (Jenner & Filshie, 2002). Six days after acupuncture treatment, the patient began to leak milk from the left breast. The authors hypothesize that increased prolactin and oxytocin levels were triggered by acupuncture, although serum prolactin and oxytocin levels were not measured. Another case study describes the development of galactorrhea in an acupuncture trainee who received acupuncture for pain in a bunion in the left foot (Campbell & Macglashan, 2005). Leakage of milk from the left breast occurred within a few hours of treatment and recurred once during the course of acupuncture treatments. It is important to note that the quantity of milk produced in these patients was not described in these case reports. In the absence of frequent breast stimulation and breast emptying, it is unlikely that acupuncture would trigger the production of milk adequate to nourish an infant.

Galactagogues and Breastfeeding Management

Several studies describe the use of structured breastfeeding support programs to increase milk supply in women with breast feeding difficulties. One case study describes the use of

frequent hand expression between feeds and provision of a supplement by a tube device for supplementation at breast during feeds to increase breast stimulation, improve infant sucking, and improve infant fluid intake (De Melo & Murta, 2009). The authors use the term *translactation* to refer to the practice of providing supplemental feeds to the infant during breastfeeding with tube device at the breast. The mother hand expressed her milk between feeds every two hours and used the milk to supplement the infant during breast feeds. While the mother was only able to express five mLs of milk per session during the first day, by the end of two weeks she was able to express 30 mLs of milk every two hours. The authors indicate that this method of increasing production requires a great deal of maternal and professional effort and determination, however this study does point out that simple methods, requiring little in the way of equipment or medication can be successful.

Another study compared the effectiveness of improved breastfeeding management with the administration of a prescription galactagogue, metoclopramide (Sakha & Behbahan, 2008). The study enrolled primiparous women who had requested a prescription for artificial baby milk at a hospital in Tabriz, Iran. Women with preterm or ill infants, working mothers, and mothers with anatomical abnormalities of the breast were excluded from the study. The women were randomized into a control group, which received extensive breastfeeding education and support and the treatment group, which received metoclopramide in addition to extensive breastfeeding support. Women in both groups were assisted to attain a comfortable and effective latch, to avoid the use of supplements, and to provide unrestricted breastfeeds on infant cues. Although the weight gain of infants in the treatment group was slightly higher over the course of the fifteen-day study, the difference between the two groups was not statistically significant.

Galactagogues, either pharmaceutical or herbal, may be effective as adjunctive therapy for women who are following a plan to increase breast milk supply. However, galactagogues are not thought to be effective in isolation from effective breastfeeding management. Galactagogues should only be introduced when appropriate changes in breastfeeding practices have been implemented (The Royal Women's Hospital, 2006).

Clinical Practice Guidelines

There are few clinical guidelines addressing the management of insufficient milk production, particularly guidelines addressing herbal galactagogues as part of the approach to treatment. The Academy of Breastfeeding Medicine (ABM, 2011) Protocol #9: Use of Galactagogues in Initiating or Augmenting Maternal Milk Supply was first published in 2004 and later updated in 2011. The 2004 version of the guideline discusses the use of several herbal galactagogues including fenugreek, goat's rue, and milk thistle. The guideline acknowledges the anecdotal nature of the information available to the reviewers and suggests that preliminary reports support the efficacy of these common herbal remedies. The guideline cautions that composition of herbal supplements may be questionable and that a lack of standardization in preparation of herbal galactagogues makes dosing considerations challenging (Academy of Breastfeeding Medicine, 2004).

The 2011 revision of the protocol involves a number of changes from the previous version. First, the protocol indicates that while prolactin is essential for breast milk production, there is no direct correlation between serum prolactin levels and the volume of breast milk produced. The information provided on herbal remedies acknowledges that historical data supports the usefulness of herbs, foods, and beverages to strengthen the post-partum woman and enhance lactation, however scientific evidence for these remedies is lacking. Since prolactin is

now thought to have a smaller role in breast milk production than was previously believed, and since there is a lack of evidence supporting efficacy of both herbal and pharmaceutical galactagogues, the ABM urges caution in prescribing or recommending such remedies, particularly in the absence of intensive breastfeeding management (ABM, 2011). The deficiencies of the current studies are acknowledged and include lack of randomization, lack of blinding, lack of standardized breastfeeding advice in the control groups, and small study sizes. The guideline provides practice recommendations including suggestions for medical evaluation of potential causes of low milk production and evidence based interventions for breastfeeding management.

Neither guideline addresses the use of acupuncture in breastfeeding, nor was it possible to locate an example of such a guideline. The Board of Directors of Drugless Therapy: Naturopathy (2009) has provided a clinical practice guideline focusing on standards of practice for acceptable acupuncture technique; however, methods of addressing clinical conditions were not described. Although the National Center for Complementary and Alternative Medicine (<http://nccam.nih.gov/health/acupuncture>) provides examples of numerous clinical guidelines for the use of acupuncture in conditions such as chronic pain, fibromyalgia, and low back pain, no examples of guidelines for use of acupuncture in breastfeeding could be located.

Limitations of Existing Research

Although the majority of the existing evidence for the use of herbal remedies in breastfeeding is anecdotal or historical in nature, women still express an interest in using natural methods of increasing milk supply. In order to justify the use of CAM therapies such as acupuncture and herbal medicine for breastfeeding women with inadequate milk production, researchers have turned to clinical trials, attempting to explain the effect of these therapies on the

physiology of nursing women. Small sample sizes, lack of randomization, short study duration, and lack of blinding characterize many of the studies attempting to provide evidence that supports the use of CAM in management of inadequate milk production. At the same time, several studies have relied on subjective methods of measuring the success of interventions, including maternal perception of breast fullness and perception of increased infant satiety. Other problems demonstrated in these studies include lack of standardization of herbal preparations and failure to account for the treatment effect produced through encounters with researchers.

Objective Measurement of Milk Supply

A number of studies on acupuncture and herbal medicine have indicated that increased milk volume was achieved because of treatment; however, adequate and objective methods of evaluating the adequacy of milk production have yet to be developed. While some studies attempted to evaluate milk production by hand expression or pumping (Huggins, n.d.; Turkyilmaz et al., 2011; Wei et al., 2008; Zhou et al., 2009), this is not considered a reliable method of measurement, since milk expression by hand or pump is a learned skill that takes time and repetition to master (Mohrbacher, 2010). Even mothers with a full supply and thriving infants may have difficulty pumping or expressing milk. Test weighing, a method of measuring milk intake by the infant through weighing the infant before and after feeds, was used in some studies to evaluate milk production (Tureanu & Tureanu, 1994). However, test weighing is a strategy that may measure a baby's appetite or ability to transfer milk from the breast, but does not provide a direct measure of a mother's capacity to produce milk. Several studies relied on maternal perceptions of breast fullness and infant satisfaction to determine improvements in production (Gupta & Shaw, 2011; Westfall, 2003).

Since inadequate milk production is often a perceived problem reflecting maternal anxiety rather than physiological processes, relying on subjective methods of measurement such as maternal perceptions may fail to establish the existence of inadequate milk supply or effectively measure improvements produced by research interventions. Among the studies on the use of herbal remedies and acupuncture, there has been no consistent benchmark for establishment of efficacy of intervention. The research has presented a wide variety of standards for measuring improvement including clinical measurements such as prolactin levels and expressed or pumped milk volumes; infant weights pre and post feeding; infant weight gain; and maternal perceptions of breast fullness and infant satiety.

Since early breastfeeding cessation is been associated with a mismatch between maternal expectations and infant behavior, maternal perception may be misleading as a determinant of improvement (Kent et al., 2012; McCarter-Spaulding & Kearney, 2001). Many factors influence the duration of breastfeeding, including presence of social support, return to work, and presence of nipple pain. Perceived milk supply is an important factor, but is not the sole determining factor related to breastfeeding duration. Increased breastfeeding duration rates are the ultimate health promotion goal, and a single study demonstrated that acupuncture contributed to increased breastfeeding duration (Neri et al., 2011), while none of the studies reviewed were able to link the use of CAM therapies to increased breastfeeding duration (Swafford & Berens, 2000; Reeder, Legrand, & O'Conner-Von, 2011; Turkyilmaz et al., 2011). Since much of the current evidence for the use of CAM therapies is anecdotal or historical in nature, the need for clinical trials to identify the efficacy of CAM therapies has been identified as an important step in validating the usefulness of such therapies as an adjunct to breastfeeding management of low milk supply (ABM, 2011). In order to achieve high level evidence regarding the use of CAM

therapies to increase milk supply, a consistent and objective method of measurement of treatment effects must be determined.

Standardization of Herbal Preparations and Dosing

The lack of standardization in production of herbal preparations and doses used in studies has made it difficult to reconcile apparently contradictory research results. The methods used to extract active ingredients from herbs vary between producers and over time resulting in inconsistent concentrations of active ingredients ("About Dietary Supplements," n.d.). A number of studies have evaluated the use of combination products available commercially in different part of the world (Joglekar, Ahuja, & Balwani, 1967; Turkylimaz et al., 2011) The type and proportions of herbs present in such combination products can vary considerably over time, making it difficult to draw conclusions about efficacy of herbal products and appropriate dosing. In combination products, it is difficult to determine which ingredients are responsible for treatment effects, and which are responsible for adverse effects, if any occur. At the same time, concerns regarding the presence of contaminants, poisons, and toxins in herbal products result in fears on the part of health care providers that patients may consume an unsafe product resulting in harm or death (Youngkin & Israel, 1996).

The Holistic Approach to Perceived Insufficient Milk Supply

Although the problem of insufficient milk production is acknowledged to be physiological in a small percentage of cases, few studies identified the psychological, social, or emotional factors that impact a woman's ability to believe her body can produce milk following birth as biology has determined it will do. The work of Westfall (2003) identified the emotional and spiritual aspects of the woman's need for nurturance and support, which some women believed were being met by herbal remedies. Although CAM therapies may have dubious

efficacy in clinical trials, the belief that alternative remedies provide treatment effects may be enough to assist the woman in problem solving through breastfeeding challenges and enable her to experience a longer and more satisfying breastfeeding relationship with her infant.

In a holistic view of nursing care, health problems do not exist solely in the body. The body, mind, spirit, and environment interact to maintain health or resolve problems. Thus, another aspect of CAM therapy that may be significant in determining the apparent efficacy of alternative and complementary remedies is the therapeutic relationship between the CAM provider and the mother. While a visit with an allopathic primary care provider often takes less than 20 minutes, a visit with a naturopath, TCM physician, acupuncturist, or other complementary provider can take more than an hour (Lee, 2011). Significant reductions in anxiety and distress are experienced when people are able to tell stories about significant events to an interested listener. Not only does this process help the patient make sense out of the experience and to see solutions on their own, but it enables the practitioner to identify thought patterns, belief, and environmental factors that may be affecting the patient's ability to recuperate (Lee, 2011; Mehl-Madrona, 2007).

A number of studies cited in this paper describe significant relational support between the research group and the participants. The support provided to the breastfeeding mothers during the course of the trials may have contributed to the results showing improved milk production or perceived changes in infant satiety. Huggins (n.d.) is a lactation consultant in private practice in the United States. Her study provides an anecdotal account of the use of herbal galactagogues in more than a thousand clients. As a provider of lactation support, much of her clinical effectiveness is related to the therapeutic relationship and effectiveness of breastfeeding support strategies provided during her sessions with patients. It is significant that provision of

breastfeeding support was the factor that led to improved breast milk production in some cases, although the lack of data makes it impossible to establish whether the supportive relationship between the lactation consultant and patients, improved breastfeeding practices, or the use of galactagogues was the critical factor, leading to an increase in milk supply. In the studies by Turkyilmaz et al. (2011), Neri et al. (2011), and Sharma, Ramji, Kumari, and Bapna (1996) breastfeeding instruction was provided to both the treatment and control groups, implying a source of information and support for the mothers involved in the study. In the trial by Sharma et al., both the control and treatment groups experienced increases in milk production, leading the researchers to believe that the breastfeeding intervention, consisting of breastfeeding instruction and support, was the factor that led to increased milk production. Neri et al., suggest that the breastfeeding support was more significant in prolonging the duration of breastfeeding than the acupuncture treatments provided to the treatment group.

CHAPTER FIVE

Discussion

Nurse practitioners place a high value on health promotion and teaching in their practices. Since breastfeeding is acknowledged as the best source of nutrition for the human infant, and formula feeding is known to be a risk factor in the development of acute and chronic illness in infant and children, breastfeeding support and education may be among the most effective health promotion measures nurse practitioners can engage in (Hellings & Howe, 2000). Breastfeeding promotion should be a priority for any health care provider working with pregnant women (AAP, 2005; Henry, 2005).

Implications for Nurse Practitioner Practice

The literature on the role of the NP in breastfeeding support is scarce; however, the responsibilities of the role can be extrapolated from the literature on primary care physicians and midwives, which have been more extensively studied. As a supporter of breastfeeding women, the NP has a responsibility to facilitate breastfeeding through anticipatory guidance, assessment, and provision of support to the woman struggling to establish effective breastfeeding.

Challenges facing the NP supporting the woman who wishes to use CAM therapies include a lack of educational preparation regarding both breastfeeding support and the use of CAM treatments. In working with patients interested in a holistic approach, it is essential to keep the lines of communication open, allowing discussion of risks, benefits, and efficacy of CAM therapies in a culturally sensitive and appropriate manner.

The Role of Nurse Practitioners in Facilitating Breastfeeding

Primary care providers such as physicians and nurse practitioners are in a strong position to support women as they breastfeed their babies. Nurse practitioners provide prenatal care,

postnatal care, and well baby visits within their scope of practice. An ongoing relationship with the woman and her family results in the primary care provider having multiple opportunities to inform and support the woman, her partner, and other family members during the transition to parenthood. Studies have shown that primary care providers play a crucial role in the protection, promotion, and support of breastfeeding (AAFP, 2008). During the course of pregnancy and postpartum care, an NP is in an ideal position to educate clients about the benefits of breastfeeding and to provide anticipatory guidance regarding effective management of feeding problems (Sakha & Behbahan, 2008).

Early identification of risk factors during antenatal care visits will help primary care providers identify women with high risk for postpartum breastfeeding difficulties. Antenatal history taking should identify women with a history of breast surgery, history of inadequate milk supply in a previous lactation experience, or the presence of breast hypoplasia. Any of these conditions could result in low milk supply following delivery and require additional support and education (Hurst, 2007). A thorough antepartum assessment will allow the NP to identify risk factors for early breastfeeding cessation, ensuring that those at highest risk can be provided with the most support (Thulier & Mercer, 2009).

Regular and frequent post-partum visits with the maternal infant dyad are necessary to prevent poor outcomes associated with ineffective feeding. Treatment plans should include a visit at 24-48 hours after birth, with re-evaluation of breastfeeding, infant weight and hydration again at about 72 hours after birth. Further breastfeeding evaluation, accompanied by examination of the infant for jaundice, hydration, and appropriate elimination patterns should occur at 5-7 days after birth (Wagner, 2009). Emotional support, anticipatory guidance, and assistance with position and latch are necessary for mothers as they learn to breastfeed (Bear &

Tigges, 1993). Professional hands-on help with positioning and latch is one component of support women have identified as being essential to success in the early days of breastfeeding (Graffy & Taylor, 2005).

Although the primary care provider can be a significant source of support for breastfeeding women in the early days of lactation, it is important that women access as many sources of support as are available in the local community. As part of a collaborative team environment, NPs can work with lactation consultants, public health nurses, and grass-roots breastfeeding support programs. Social support for breastfeeding through mother-to-mother support programs is one of the most effective sources of breastfeeding support for new mothers (Dennis, 2002). Plans for postpartum lactation support should aim for a seamless transition between acute care and community services. According to the Ten Steps of the Baby Friendly Initiative, health care providers should foster the development of peer support programs and refer patients to peer support upon discharge from hospital (Breastfeeding Committee for Canada, 2012). While the NP will likely not be involved directly in the provision of peer support for breastfeeding mothers, it is important for the NP to be familiar with local peer support resources in order to refer women to reputable organizations.

Therapeutic Interventions for Lactating Women and Infants

Since hormonal conditions affecting the mother may be underlying causes of insufficient milk production, it is important for the primary care provider to address any underlying imbalance. NPs, as primary care providers have the capacity to order diagnostic tests and prescribe medications. When a mother presents with low supply, accompanied by poor infant intake, the primary care provider should consider blood tests to rule out maternal anemia and hypothyroidism (Amir, 2006). In addition, elevated levels of b-HCG may indicate retained

placenta or the early stages of a subsequent pregnancy. Testing for prolactin levels may establish whether pharmaceutical galactagogues are likely to improve milk production (Mohrbacher, 2010). Urinary tract infections and early sepsis may be asymptomatic in young infants, with the exception of feeding difficulties. If the infant demonstrates symptoms of dehydration or illness, the plan of care may involve referral to a pediatrician. In addition, urinalysis, blood counts, serum electrolytes, serum bilirubin and blood cultures may be indicated to rule out illnesses affecting feeding such as sepsis or hyperbilirubinemia (Amir, 2006). While cardiac problems in the infant are associated with poor weight gain in the infant, there is no direct correlation between cardiac defects and low milk supply and poor feeding (Mohrbacher, 2010). Breastfeeding management for the ill infant is beyond the scope of this paper.

Challenges Facing Nurse Practitioners Working with Lactating Women

Many health care professionals receive a minimal amount of breastfeeding education in pre-service education programs, resulting in entry to practice by health care professionals ill prepared to provide breastfeeding support (Hellings & Howe, 2000). The World Health Organization recommends that health care professionals receive a minimum of 20 hours of breastfeeding education in order to have baseline knowledge to provide breastfeeding support (World Health Organization, 2009). While it is tempting for NPs and other primary care providers to rely on acute care nurses, public health nurses, lactation specialists, and peer counseling programs to provide breastfeeding support, primary care providers are particularly well positioned to provide education and anticipatory guidance. When providing prenatal care, it is the responsibility of the primary care provider to discuss the benefits of breastfeeding, labor and birth options and their impact on breastfeeding, and potential challenges that arise and their management (Academy of Breastfeeding Medicine Protocol Committee, 2008; Battersby, 2011).

Mothers who use both prescription and herbal therapies could be at risk for drug-herb interactions. Although little is known about the interactions between many herbs and prescription medications, some herbs have been identified as decreasing the efficacy of prescription medications. Examples of this are St. John's Wort, which has been shown to decrease the effectiveness of oral contraceptives (Murphy, Kern, Stanczyk, & Westhoff, 2005), and fenugreek, which may potentiate the effects of warfarin (Jackson, 2010). In order to identify potential drug-herb interactions or to identify the incidence of adverse effects related to the use of herbal remedies, the NP must keep open lines of communication regarding the use of herbs, supplements, and CAM therapies. A critical component of history taking during client visits includes ascertaining which alternative therapies are in use, what purpose the woman is using the therapy for and what results she is experiencing (Conover & Buehler, 2004; Hall et al., 2010).

Dosing considerations are particularly challenging for primary health care providers wishing to support a mother considering the use of herbal medicines. Coupled with the fact that there are few standardized preparations of many herbal medicines, research has not yet provided clinical data regarding safe and efficacious doses of herbal galactagogues. Although many of these remedies are used as food, it is unlikely that herbs used as flavorings in culinary preparation of food would be consumed in sufficient quantity to have therapeutic or adverse effects. Insufficient evidence exists to guide the NP in recommending dosages of many herbal medicines. In addition, the potential for contamination of herbal remedies with toxins, poisons, chemicals, or extraneous herbs that are not a component of the medication, must be taken into consideration and discussed with women interested in the use of herbal medicine. Health Canada provides advisories when unsafe products are identified, but in some circumstances, products may be sold which have not been evaluated by Health Canada. Products having labels

containing a natural product number (NPM) or homeopathic medicine number (HMN) have been evaluated by Health Canada and are considered safe products (Health Canada, 2010). The NP can advise the patient of the importance of choosing products that have been evaluated by Health Canada.

Adams et al. (2002) suggest that a primary care provider may be distinctly uncomfortable offering counseling and education when a patient chooses CAM therapies for which there is little evidentiary support. The authors suggest that a risk benefit framework is used to analyze each situation on an individual basis. The primary care provider must consider the patients' capacity for decision -making, along with factors such as the severity of the illness; the invasiveness or toxicity of conventional treatments; evidence for the safety and efficacy for the CAM therapy; acceptance of risk by the patient; and the determination of the patient to use CAM therapy. In this way, the choices of the patient are supported, while ensuring that the patient makes treatment decisions based on all the available information. If existing evidence supports both safety and efficacy of the therapy, the primary care provider may choose to recommend therapy accompanied by ongoing monitoring. If only safety or efficacy is supported through research, the primary care provider may suggest a cautious approach to treatment accompanied by informational support for maternal decision making. If there is little evidence for either efficacy or safety, the primary care provider may be justified in discouraging the patient from pursuing the therapy.

Competencies Required for Support of Breastfeeding Women

According to CRNBC (2011), nurse practitioners have the responsibility to demonstrate "awareness of health products, medical devices, medications, alternative therapies and health programs, and [are] mindful of the power dynamics and marketing strategies used to promote

them (p. 14). Canada is a multi-cultural society, and as such, nurse practitioners will see clients who have immigrated from other cultures where traditional beliefs about healing may conflict with the beliefs of Western health care providers. Understanding the use of therapies such as herbal therapies and acupuncture will assist the NP to provide culturally sensitive care to clients with a variety of cultural backgrounds. Although the evidence supporting some types of complementary and alternative therapies fails to meet the gold standard of the randomized controlled clinical trial, the practice of herbal therapies and acupuncture have occurred for centuries. Traditional Chinese Medicine and Ayurvedic medicine are considered by many to be well established as systems of health care (Jackson, 1999).

Health promotion is one of the key competencies required in nurse practitioner practice (College of Registered Nurses of British Columbia, 2011). NPs must identify trends in population health, develop strategies to promote preventative health measures for individuals and populations, and collaborate with other professionals in health promotion strategies. Breastfeeding is a primary health strategy for prevention of acute infections in young infants. It is recognized as a strategy to decrease the burden of chronic diseases and enhance family food security, particularly in emergencies or conditions of social and economic hardship (World Health Organization, 2003). Promotion of breastfeeding at a societal level, and protection of breastfeeding at the individual level are activities that NPs can take to engage in health promotion for women, infants, and young children.

Recommendations for Practice

Nurse practitioners support women during both pregnancy and the post-partum period. For some women, the transition to motherhood involves anxiety that is expressed as uncertainty regarding infant feeding. Nurse practitioners are particularly well-placed to provide support in

the context of the primary care relationship due to the duration of the relationship and the frequency and length of visits. Interpersonal support, encouragement, and accurate information regarding breastfeeding establishment and infant feeding behavior are key strategies to decrease maternal anxiety. A successful breastfeeding experience contributes to the maternal perception of parenting self-efficacy, further decreasing maternal anxiety (McCarter-Spaulding & Kearney, 2001).

NPs are responsible to provide and recommend evidence informed treatments, requiring familiarity with both breastfeeding best practice and familiarity with alternative therapies and treatments used in the treatment of breastfeeding problems. The Baby Friendly Initiative (Breastfeeding Committee for Canada, 2012) provides primary care providers, acute care providers, and community care providers with a roadmap to best practices in breastfeeding, with ten steps that have been shown to increase breastfeeding initiation and duration in multiple studies (Chung, Raman, Trikalinos, Lau, & Ip, 2008). Current breastfeeding guidelines indicate that once breastfeeding management has been optimized, it may be necessary to consider the use of a galactagogue to increase breast milk production. For some mothers, CAM therapies may be preferred over pharmaceutical galactagogues.

Insufficient milk production is a complex problem that requires a multitude of strategies to manage effectively. NPs providing antenatal and post-partum support must develop an evidence based and effective approach to assessment and intervention for breastfeeding difficulties. These strategies include antenatal and post-partum education, assessment of risk factors, hands-on help with position and latch, accompanied by support and encouragement for the breastfeeding mother.

Anticipatory Guidance

- Anticipatory guidance for breastfeeding should take place during prenatal visits. Women should be educated on the benefits of breastfeeding, the risks of formula feeding, and the impact of birth processes on infant feeding.
- The importance of skin to skin contact, early and frequent breastfeeding, and avoidance of the use of pacifiers and supplements should be emphasized during antenatal education.
- Normal infant feeding behavior, crying, and sleep should be reviewed during the antepartum and post-partum period.
- Assessment of risk factors for low milk supply such as previous breast surgery, gestational diabetes, anemia, and hypothyroidism should take place during antepartum care and be communicated to acute care providers upon transfer of care.
- NPs should encourage pregnant women and their partners to participate in available prenatal preparation classes to increase their knowledge of the birth process, interventions, post-partum adjustments, and feeding choices.

Therapeutic Interventions

- The NP should ensure the mother/ infant dyad has regular and frequent post-partum visits until breastfeeding is going well.
- At each visit, the infant should be evaluated for weight gain and signs of hydration status. The mother should be given an opportunity to discuss any concerns or questions that may arise.
- Warning signs of ineffective feeding include use of supplemental feeds, infant weight loss $>10\%$, continued infant weight loss after the fifth day post-partum, failure to regain birth weight by the 14th day of life.

- The NP must evaluate feeding to establish effectiveness of position, latch and milk transfer if feeding difficulties are evident, and provide help with position and latch
- The NP must recommend frequent and effective infant feeding as a primary strategy for increasing milk supply. Hand expression or use of a breast pump to increase breast stimulation may be considered. Feedings should take place at intervals of no longer than 2-3 hours.
- Differential diagnoses for low milk supply include hypothyroidism, anemia, gestational diabetes, retained placental products, infrequent feeding, or ineffective milk transfer.
- Based on history and physical assessment, the NP may choose to perform diagnostic tests to rule out organic causes of low milk production.
- Women considering the use of galactagogues should be informed of the data describing efficacy and safety of medications or alternative therapies. Both pharmaceutical and alternative galactagogues may be considered as adjunct treatments to accompany a breastfeeding management plan.
- The nurse practitioner may consider prescribing a pharmaceutical galactagogue when non-pharmacological methods of increasing milk supply have been ineffective (ABM, 2011). Women who may benefit the most from pharmaceutical galactagogues are those who are pumping or expressing milk to feed an infant who is not breastfeeding, and those who have experienced complications such as maternal-infant separation, birth complications, or illness in the early days after birth. Domperidone and metoclopramide are the most commonly used pharmaceutical products, used on an “off-label” basis as galactagogues.

- For women choosing to use herbal remedies as an adjunct to lactation management, the use of fenugreek and wild asparagus, is supported by a more robust body of evidence than the use of many other lactogenic herbs or foods. Expert opinion suggests combining fenugreek with other lactogenic herbs such as blessed thistle may be more effective than the use of fenugreek alone (Newman & Kernerman, 2008).
- While there is little evidence that any of the purported lactogenic herbs may be harmful, there is anecdotal evidence suggesting that the use of Goat's Rue and borage have the potential to cause harm to the infant.
- There is low- level evidence suggesting the potential for benefit from the use of acupuncture, during the first few weeks of lactation. Women desiring to use acupuncture as an adjunctive therapy to lactation management should be referred to a reputable local practitioner for treatment after discussion of potential benefits, risks, and alternative treatments.
- The NP must encourage the mother to access appropriate community supports such as peer support groups, public health nursing, and lactation consultant services when available.

Considerations for Further Research

While it is important not to overlook the spiritual and emotional aspects of holistic treatments for low milk production, there is room for further research substantiating the safety and efficacy of acupuncture and herbal galactagogue use in breastfeeding management. Considerations for further research should include an emphasis on well-structured clinical trials with larger population samples. Standardized dosages and preparations of herbal products need to be incorporated to allow replication of research and comparison between study outcomes.

Until the efficacy of acupuncture in increasing milk production, and the safety and efficacy of commonly used galactagogues has been evaluated through well-structured research, breastfeeding management is considered the first line treatment for inadequate milk production.

Many of the recent randomized controlled trials, have focused on the role of acupuncture and herbal remedies to increase prolactin levels (Di Pierro, Callegari, Carotenuto, & Tapia, 2008; Gupta & Shaw, 2011; Reeder, Legrand, & O'Conner-Von, 2011; Sharma, Ramji, Kumari, & Bapna, 1996; Wei, Wang, Han & Li, 2008; Zhou et al., 2009) in spite of the evidence that prolactin levels are less significant in the establishment of milk production than had been previously thought (ABM, 2011). The role of insulin and the relationship between serum glucose regulation and milk production are little understood factors in the development of milk production; however, many of the identified herbal galactagogues have been studied for their role in moderation of blood insulin and glucose levels. This raises an intriguing prospect that further therapies for insufficient milk production may be developed after investigation of the physiology and treatment of metabolic disorders of glucose regulation in pregnant and breastfeeding women. Preliminary studies on women with PCOS have shown some success with the use of metformin, which increases insulin production and decreases insulin resistance, for increasing milk supply (Mohrbacher, 2010).

Conclusion

Many women who experience breastfeeding difficulties are facing a crisis of confidence stemming from a lack of self-efficacy as they adapt to the mothering role. Since many cases of inadequate milk supply are believed to be the result of maternal perception of inadequate supply rather than the result of a physiological condition, it is difficult to evaluate validity of studies based on maternal perceptions regarding the efficacy of treatment. Maternal beliefs are a key

component of breastfeeding self-efficacy, leading to improved breastfeeding duration and satisfaction. Breastfeeding support, including anticipatory guidance, hands-on help, and referral to peer support are first-line interventions in cases of inadequate milk supply. Since there is no good research evidence to support the use of complementary and alternative therapies as treatment for inadequate milk supply, these measures should be used as adjuncts following intensive breastfeeding management.

The body of research evidence describing the safety and efficacy of many CAM therapies to increase milk production is small. However, some preliminary studies suggest that the practice of acupuncture and a number of herbal remedies may offer some assistance in increasing milk production without risk to the mother or infant. Fenugreek, goat's rue, milk thistle, blessed thistle, wild asparagus, and fennel show some potential of benefit to the user with minimal presence of risk. Other purported galactagogues such as chaste berry, beer, and raspberry leaf appear to have a little likelihood of providing any benefit to the mother.

The NP must develop knowledge of alternative therapies and cultivate a strategy of open communication in order to ensure that patients are willing to disclose their personal preferences and practices regarding these health measures. It is essential that NPs are prepared to discuss the potential benefits, risks, and interactions with patients who choose to use CAM, ensuring that informed consent is obtained after discussing the available evidence. Since the popularity of CAM therapies is growing, it is likely that primary care providers will be called upon to cultivate a far wider knowledge of alternative practices than is currently included in many conventional nursing and medical programs.

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