BELIEVE MIDWIFERY SERVICES

TITLE: GALACTOGOGUES FOR INITIATING OR AUGMENTING MATERNAL MILK SUPPLY
EFFECTIVE DATE: November 7th, 2013

POLICY STATEMENT
Galactogogues (or lactogogues) are medications or other substances believed to assist initiation, maintenance, or augmentation of maternal milk production. However, use of galactogogues for faltering milk supply should generally be reserved for situations after both a thorough evaluation for treatable causes and increased frequency of breastfeeding or pumping or expression has not been successful.

BLOOD BORNE PATHOGEN
EXPOSURE CATEGORY: II (Involves no exposure to blood, body fluids, or tissues)

FUNCTION: Care of Clients

POINTS OF EMPHASIS:
Worldwide, maternal perception of insufficient milk production is the most common reason reported by mothers for early cessation of breastfeeding. For those mothers, the use of galactogogues is often considered. In the United States, it is estimated that 15% of breastfeeding women use herbal galactogogues, whereas in a Norwegian study, this estimate is 43%.

Common indications for galactogogues are adoptive nursing, relactation, and increasing a faltering milk supply, and increasing a faltering milk supply because of maternal or infant illness or separation. Mothers who are not directly breastfeeding but are expressing milk by hand or with a pump often experience a decline in milk production after several weeks. One of the most common indications for galactogogues is to augment a declining milk supply in mothers of preterm or ill infants in the neonatal intensive care unit.

PROCEDURE:
1. Before using any substance to try to increase milk supply, a full evaluation of current maternal milk supply and effectiveness of milk transfer is imperative. Attention must be directed to the evaluation and augmentation of frequency and thoroughness of milk removal. This can be accomplished through increased frequency and duration of breastfeeding (if the infant has been shown to be effective at emptying the breasts) or pumping.
   a. A full-size, cycling breast pump, capable of draining both breasts at the same time is recommended, if available.
   b. Problems such as inappropriate timing and duration of feedings, inappropriate supplementation, mother-infant separation, ineffective latch, and inadequate milk transfer should be corrected.
2. Women should be informed of any data (or lack thereof) regarding the efficacy, safety, and timing of use of galactogogues.
3. Mothers should be screened for contraindications to the chosen medication or substance and informed as to possible side effects.
4. The prescribing CNM must follow the client, to ensure appropriate follow-up is provided regarding appropriate milk supply and medication side effects.
5. Although short-term use (1-3 weeks) has been evaluated for some of these substances, long-term use has not been studied. Anecdotal reports suggest no increase in side effects with the most commonly used medications (metoclopramide, domperidone, fenugreek), but long term effects on both mother and infant are unknown.

Specific Galactogogues
Many medications, foods, and herbal therapies have been recommended as galactogogues. The medications used often exert their effects through antagonism of dopamine receptors, resulting in increased prolactin. In many cases, the mechanism of actions are unknown.

Metoclopramide (Reglan)
1. Reglan is the most well studied and most commonly used medication for inducing or augmenting lactation in the United States.
2. It promotes lactation by antagonizing the release of dopamine in the central nervous system, thereby increasing prolactin levels.
3. It is an antiemetic and also commonly used for gastroesophageal reflux in infants.
4. Although levels found in breastmilk have been measured higher than maternal serum levels, levels in infants have been undetectable or well below infant therapeutic levels with no reported side effects.
5. Maternal restlessness, drowsiness, fatigue, and diarrhea may occur but usually do not require stopping the medication. The drug should be discontinued if any of the rare extrapyramidal side effects of sleeplessness, headache, confusion, dizziness, mental depression, or feelings of anxiety or agitation occur. Acute dystonic reactions are very rare (<0.05%) and may require Benadryl treatment.
6. Reglan should not be used if clients have epilepsy or are on antiseizure medications, have a history of significant depression or are on antidepressant drugs, have a pheochromocytoma or uncontrolled hypertension, have intestinal bleeding or obstruction, or have a known allergy or prior reaction to metoclopramide.
7. The usual dose is 30 to 45 mg/day in three or four divided doses, with a dose-response effect up to 45 mg daily. It is usually given for 7 to 14 days at full dose with a taper off over 5 to 7 days. Longer periods of use may be associated with an increased incidence of depression.
8. Occasionally a mother’s milk supply will falter as the dose is reduced; the lowest effective dose has been continued for longer periods of time successfully.
9. Some experts also advise a gradual increase when beginning the dose.

**Domperidone (Motilium)**

1. Domperidone is also a dopamine antagonist available outside the United States for the treatment of gastroesophageal reflux and emesis. Because of its drug characteristics it is less likely to cross the maternal blood-brain barrier, resulting in less extrapyramidal side effects than metoclopramide. It is also less likely to cross into the breastmilk.
2. Administration of domperidone 10 mg TID for 7-14 days results in significant increases in mean serum prolactin levels in normal women.
3. Domperidone is metabolized by CYP3A4, which is inhibited by a number of substances, such as grapefruit juice, fluconazole, erythromycin, clarithromycin and others. These agents increase maternal serum domperidone concentrations from 3- to 5-fold, which adds to the risk of prolonged QT interval and cardiac arrhythmia (Anderson, 2013).
4. Domperidone is the only galactogogue evaluated in a randomized controlled trial and shown to be safe and effective in increasing breastmilk production.
5. Side effects are very uncommon and include dry mouth, headache (resolved with decreased dosage), and abdominal cramps.
6. Domperidone is contraindicated in clients with known sensitivity to the drug and in situations in which gastrointestinal stimulation might be dangerous.
7. Despite the fact that domperidone is approved for use in most of the developed world and has been used for many years with an excellent safety record, the U.S.Food and Drug Administration (FDA) issued a warning against its use in the United States based on safety concerns with IV use and risks associated with drug importation. There is no evidence that oral administration is associated with toxicity in either mother or infant.
   a. The Canadian governmental agency charged with drug regulation released a warning to health professionals on March 2nd, 2012 concerning an increased risk of arrhythmias and sudden cardiac death caused by prolonged QT interval in patients receiving daily domperidone dosages greater than 30 mg.
   b. The warning states that domperidone should be initiated at the lowest possible dosage and that “patients should be advised to stop taking domperidone and seek immediate medical attention if they experience signs or symptoms of an abnormal heart rate or rhythm while taking domperidone. These include dizziness, palpitations, syncope or seizures.”

**Herbal Galactagogues**

Throughout world history women have used certain herbs or foods to enhance their milk supply. Most of these substances have not been scientifically evaluated but traditional use suggests safety and some efficacy. The
mechanisms of action for all are unknown. Herbs commonly mentioned as galactogogues include fenugreek, goat’s rue, milk thistle, anise, basil, blessed thistle, fennel seeds, marshmallow, and others. Beer is commonly used in some cultures, but alcohol may actually reduce milk production and there is no evidence to support that the yeasts in beer are effective galactogogues.

It is of note that herbs and dietary supplements were removed by the Federal 1994 Dietary Supplement Act from undergoing the rigorous evaluation by the U.S. Food and Drug Administration that is required for drugs. The composition of herbal and dietary supplements are unknown and have been known to contain toxic substances. This is especially true for herbs from mainland China. There is no standard dosing, preparation, or composition, and fraudulent preparations may be at risk.

**Fenugreek**

1. Fenugreek is the most commonly recommended herbal galactogogue, treasured as a spice and medicine throughout India and the Middle East for thousands of years. It is a member of the pea family listed as “generally regarded as safe” by the U.S. Food and Drug Administration.
2. Usual dose is one to four capsules (580-610 mg) three to four times per day, although as with most herbal remedies there is no standard dosing. The higher of these doses may be required in relactating or adoptive mothers.
3. Alternatively, it can be taken as one cup of strained tea three times per day (1/4 tsp seeds steeped in 8 oz water for 10 minutes).
4. Anecdotally, fenugreek increases milk supply within 24 to 72 hours.
5. Reported side effects are rare: maple like odor to sweat, milk and urine; diarrhea; and increased asthmatic symptoms.
6. Use during pregnancy is not recommended because of its uterine stimulant effects.
7. Fenugreek is known to lower blood glucose, so caution is advised.

**Goat’s Rue**

1. Goat’s Rue is a traditional galactogogue, widely recommended in Europe, based on observations of increased milk supply when fed to cows in the 1990s. No controlled human trials have been done, and no adverse effects have been reported with the following possible exception: Maternal ingestion of a lactation tea containing extracts of licorice, fennel, anise, and goat’s rue was linked to drowsiness, hypotonia, lethargy, emesis, and poor sucking in two breastfed neonates. An infection work-up was negative, and symptoms and signs resolved on discontinuation of the tea and a 2-day break from breastfeeding. The tea was not tested for contaminants or adulterants, and there have been no other adverse events reported in Europe or South America, where the herb is also used as a hypoglycemic agent.
2. It is usually used as a tea (1 tsp dried leaves steeped in 8 oz water for 10 minutes) with 1 cup taken three times a day.

**Milk Thistle**

1. Milk thistle has been used historically throughout Europe, but there are no randomized controlled trials to validate its use. The plant is still commonly known as St. Mary’s thistle in honor of the Virgin Mary. Early Christians believed that the white colored veins in the leaves were symbolic of her breastmilk.
2. The American Herbal Products Association gives it a rating of 1, meaning that the herb may be safely consumed when used appropriately and does not contraindicate its use during lactation.
3. It is used as a strained tea (simmer 1 tsp crushed seeds in 8 oz water for 10 minutes) taking two to three cups per day.

REFERENCES:


**Originated:** June, 2009

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<th>Penny Lane MSN, CNM, IBCLC</th>
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<td>Holly Hopkins MSN, CNM</td>
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