

THE BREASTFEEDING ANSWER BOOK



GALACTOGOGUES

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Update

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Explore factors that impact milk production

When mothers ask about galactogogues in the context of insufficient milk production, it is essential to go back to the basics of milk production. ALL physiological factors (inadequate milk removal, supplementation, maternal and infant health conditions) and psychological factors (depression, anxiety, separation, exhaustion) that impact milk supply and production should be explored and addressed first.

Case for galactogogues weakening

The Academy of Breastfeeding Medicine aptly summed up galactogogues when it said, “As new evidence has emerged regarding various interventions to increase milk supply, the case for using pharmaceutical galactogogues has grown weaker” (ABM 2011).

Only use up-to-date resources

The next most important step to take when counseling a mother about medications is to use an up-to-date comprehensive reference, which includes specific breastfeeding information. Most pharmaceutical reference material does not provide adequate information about effects on the breastfeeding mother and infant.

Lactmed

A free online searchable database is available at the National Library of Medicine TOXNET website <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT>. The easiest way to access the database is to enter LACTMED in your browser’s search bar. The contents are peer reviewed and references are included. Free iPhone/Android applications are available.

Infant Risk Center

Another resource is the Infant Risk Center directed by Thomas W. Hale, RPh, PhD and accessible at www.infantrisk.com. Health care professionals (including LLLI Leaders) can submit questions by phone 1-806-352-2519, or on the web forum where you can expect responses from staff within 24-48 hours. The public can search and review posts. An iPhone/Android application containing regularly updated information from Dr Hale’s database is available for purchase for an annual fee.

The Breastfeeding Network

The Breastfeeding Network has Drug Info Factsheets available online at <http://www.breastfeedingnetwork.org.uk/drugs-in-breastmilk-information-and-factsheets.html>. Specific questions will be answered by phone at the Drugs In Breastmilk Helpline 0844 412 4665 or by email at drug-information-2011@breastfeedingnetwork.org.uk.

Books

For areas with limited or unreliable access to technology, the books *Medications and Mothers Milk* by Thomas Hale and *Drugs in Pregnancy and Lactation* by Gerald Briggs, Roger Freeman and Sumner Yaffe, are indispensable resources. Both books categorize medications by risk, discuss how the drug works, estimate infant exposure, and summarize available evidence. The *Drugs in Pregnancy and Lactation* text also has a mobile application and searchable updated online site. Always use the most recent edition available.

Avoid outdated resources

Avoid older resources that are not regularly updated and do not include the most recent information. Older references include *the Breastfeeding and Maternal Medication Recommendations for Drugs* from the WHO and UNICEF published in 2002 and the American Academy of Pediatrics (AAP) policy statement “The Transfer of Drugs and Other Chemicals into Human Milk” retired in 2010.

Use caution

The third most important step when discussing medications with a breastfeeding or pregnant mother is to use caution. Medications and the uses they are approved for vary from country to country. Medications might not be approved for any use, or only for specific uses, for example:

- Domperidone is not Food and Drug Administration (FDA) approved for any use in the United States.
- Metoclopramide is FDA approved for gastrointestinal uses but not breastfeeding uses in the United States.

When a legal medication is prescribed for an unapproved use it is referred to as being prescribed “off label”. Galactogogues have been associated with serious side effects and death.

Academy of Breastfeeding Medicine Protocol

The Academy of Breastfeeding Medicine (ABM) Clinical Protocol #9: “Use of Galactogogues in Initiating or Augmenting the Rate of Maternal Milk Secretion” is a must-read resource for anyone discussing galactogogues. It is available for free at the AMB website www.bfmed.org in the Protocols and Statements section.

Limited high quality data demonstrating effectiveness, except in select populations, and significant side effects have caused the ABM to change its position on the use of galactogogues in the last decade. The “ABM cannot recommend any specific pharmacologic or herbal galactogogues at this time” (ABM 2011). According to the current policy statement “we should exercise more caution in recommending these drugs to induce or increase the rate of milk secretion in lactating women, particularly in women without specific risk factors” (ABM 2011).

How galactogogues might work

Despite the current ABM recommendation, domperidone and metoclopramide continue to be used to try to increase milk production. Both are dopamine antagonists. Dopamine inhibits the release of prolactin by the pituitary in the brain. Medications that cause the opposite effect,

called dopamine antagonists, increase prolactin release and raise maternal prolactin levels in the blood (ABM 2011). In theory higher prolactin levels should lead to an increase in milk production. Prolactin levels are higher in women who take domperidone or metoclopramide (ABM 2011). However, there is no data linking prolactin levels with milk production (ABM 2011). While it is plausible that domperidone and metoclopramide increase milk production, it is also possible that some of the effect of prescription galactogogues is likely to be a placebo effect. Unfortunately the evidence does not definitively address all the questions surrounding galactogogues at this time.

Much of the data on both domperidone and metoclopramide is limited by a lack of blinded, randomized studies and by small numbers.

Domperidone after preterm birth and cesarean delivery

In select populations domperidone works; it has been shown to increase milk production for mothers of preterm infants expressing their milk (Campbell-Yeo 2010, Wan 2008, Toparre 1994). In one small study of women without milk supply issues, domperidone increased milk production after cesarean delivery (Jantarsaengram 2012). Whether this effect on milk production can be applied to other populations, for example a mother with a term infant who is not exclusively expressing milk, remains to be seen. Mothers are typically prescribed 10 mg of domperidone to be taken orally three times a day (ABM 2011). Serious side effects in the mother include cardiac arrhythmias, which can cause death (Anderson 2007). There are no known side effects for the infant (Lactmed).

Domperidone side effects

Domperidone is approved for use and available in some countries for the treatment of specific gastrointestinal problems. According to the FDA, domperidone is not approved for enhancing breast milk production in any country (www.fda.gov, query domperidone, FDA Warning) even if mothers have been able to obtain it off-label or off-list. Domperidone is not FDA approved for any use in the United States and it is no longer available from compounding pharmacies in the United States. In 2004 the FDA released a warning “not to use an unapproved drug, domperidone, to increase milk production” because of the “potential public health risks” (FDA Warning 2004). The FDA also notified several pharmacies and drug supply companies that compounding and importing domperidone are both illegal activities in the United States (FDA Talk Paper, June 7, 2004). Physicians who wish to prescribe domperidone in the United States for gastric motility problems must complete an Investigational New Drug application with the FDA.

Metoclopramide

The evidence-based data demonstrating a positive relationship between milk production and metoclopramide is even less convincing. None of the randomized controlled trials have demonstrated a positive effect on milk production when compared to a placebo. This is contrary to the findings on some older less well-designed studies (ABM 2011, Anderson 2007). The ABM has concluded that metoclopramide’s effect on milk production is not clear (ABM 2011). The typical dose is 10 mg orally three to four times a day for 7-14 days. Side effects can be significant and include depression and tardive dyskinesia or abnormal, involuntary movements, typically of the face muscles, which can be irreversible. The only reported adverse effects in infants are gas and intestinal discomfort (Lactmed).

Focus on optimal breastfeeding practices

Assisting mothers to achieve optimal breastfeeding practice is imperative. At least one study has shown maternal counseling about “perfect breastfeeding” to be as effective as metoclopramide (Sakha 2008). Focus your discussion with the mother on the importance of regular effective milk removal.

References

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