Drugs and devices for increasing milk supply

What's the evidence?

Cathy Fetherston PhD

Methods for increasing supply

Involve:
- Frequent removal of milk
- Facilitating the normal hormonal milieu
- Always advise normal physiological strategies BEFORE interventions

Where there is low supply

Always investigate if:
- A co-existing aetiology is known or suspected
- Inadequate milk supply persists
- There is severe insufficiency or outright failure

Conditions to consider:
- Anaemia (Hx and FBP) - hypopituitarism
- Hypothyroidism (TSH)
- Retained placenta (HCG)
- PCOS (androgens, glucose metabolism TSH, prolactin, etc)
- Gestational ovarian theca cysts (testosterone)
- Delayed lactogenesis II: SSRIs, stress, birth interventions

Mechanisms of action - usually related to prolactin secretion

Galactagogues

FlaUM 4-7 Hormone levels during pregnancy and lactation. Adapted from Lowe, S. Dr Susan Lowe's Breast Book, Addison-Wesley, Boston, 1990, p. 54.
Mechanisms of action

Complex, may be achieved by:
- Direct stimulation of prolactin production
- Stimulation of prolactin releasing hormone (TSH e.g. sulpiride)
- Suppression of prolactin inhibitory factor (dopamine)
  - Inhibiting dopamine-producing neurons
  - Blocking hypothalamic dopaminergic receptors (e.g. maxalon)
  - Blocking peripheral dopamine receptors (e.g. metoclopramide)

Pharmaceutical galactagogues

- Antiemetics (dopamine antagonists)
  - domperidone (Motilium)
  - metoclopramide (Maxalon)
- Neuroleptics
  - chlorpromazine
  - sulpiride
- Hormones
  - Oxytocin
  - Growth hormone (GH, somatotrophin)
  - Thyrotrophin releasing hormone (TRH)

Lactation Risk Categories

- L5: contraindicated
- L4: possibly hazardous
- L3: moderately safe
- L2: safer
- L1: safest

Drug queries see Dr Tom Hale’s website:
http://neonatal.ttuhs.edu/lactindex.html or
KEMH Obstetric Drug Information Service 9340 2723

Pharmaceuticals

Metoclopramide, LRC:L2

- Antagonizes the release of dopamine in the CNS
- Commonly used for GORD in infants
- Dose 10 mg tds (up to 45mg/day) for 10-14 days and taper off over 5-7 days
- Side effects: restlessness, anxiety, drowsiness and fatigue (10%) diarrhoea, headache, insomnia and caution with extrapyramidal effects (1%)
- Contraindications: epilepsy, depression, hypertension, intestinal bleeding, pheochromocytoma

Herbal and natural preparations

- Fenugreek
- Silmarin (Milk Thistle, Bio-C)
- Galega (Goat’s rue)
- alfalfa, mulanggay, blessed thistle, shatavari, anise, basil, fennel, mauve, verbena, grape and coffee

Domperidone (LRC: L1)

- Peripheral and D2 dopamine receptor antagonist
- Gastrokinetic and antiemetic effects
- Milk volume increases 79% (Petaglia et al. 1985); 175% (da Silva et al., 2001); 215 - 367% (Wan et al., 2008)
- Approved for use in 80 countries but not the USA
- Dose 10-20 mg tds to qid
- Side effects very rare, oral dryness, abdominal cramping & headache
- Special precautions - interaction with ketoconazole, mothers with arrhythmias

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Domperidone Studies (Wan et al., 2008)
- Pre-term mothers with low supply <300ml/day (n=7, mean of 53 days post partum)
- Double blind, 3 phase randomised crossover trial, no ITT (n=6)
- Phase 1: no drug; Phase 2: 10 mg tds; Phase 3: 20 mg tds
- Volume increased 215% (30mg) to 367% (60mg) in the responders

Domperidone studies (da Silva)
- Randomised, double blinded, drug (11); placebo (9)
- Similar baseline prolactins, although not consistent sampling.
- 36% drop out in intervention group (n=4), no intention to treat.
- No follow up after 7 days.
- Such a huge difference in outcome is concerning in a small sample.

The domperidone controversy
- FDA banned the compounding of domperidone citing significant side effects where pts were receiving high doses of IV domperidone during cancer therapy (1985 studies)
- 2004 FDA issues a warning on its use, despite the AAP recommendation that it is “usually compatible with breastfeeding”
- Domperidone is only 13-17% bioavailable orally due to significant first pass hepatic and intestinal metabolism.
- Domperidone has been used in more than 33 countries world-wide for more than 30 years including England, Australia, Canada and is available over-the-counter in many countries.

The neuroleptics
- Never the first line of choice due to CNS effects and possible risk for extra pyramidal side effects.
- Risk – benefit ratio is unclear.
Oxytocin

- Stimulates the MER
- Dose – 1 spray (3 drops) nostril (40U/ml sol'n) before expression or feeding
- Fewtrell et al., Randomised double trial of oxytocin nasal spray in mothers expressing breastmilk for pre-term infants Arch Dis Child Fetal Neonatal Ed, 2005
- MacDonald et al., A review of safety, side-effects and subjective reactions to intranasal oxytocin in human research Psychoneuroendocrinology, 2011
- Does not significantly improve outcomes in lactation, nor produce detectable subjective changes in recipients

Herbs and Natural Remedies

While there is some regulation of herbs, quality/potency varies:
- Standardized vs non-standardized products
- Part of plant used or % of parts in mix used
(Different parts can have different effects)
- Freshness of the herb
- Shelf life
- Exposure to light
- Interactions and potentiating effects

Best reference aid

Safety Ratings

A- no safety issues identified; generally considered safe when used appropriately
B- May not be appropriate for self-use by some individuals, or may cause side-effects if misused. Seek reliable safety and dose info.
C- Moderate potential for toxicity, mainly dose related
D- Use only with supervision of knowledgeable physician
E- Avoid. Toxic plant with no justifiable medical use.

Fenugreek

- From the pea family
- Used to flavour curries, chutneys, artificial maple syrup
- Used to alleviate coughs, bronchitis, sore throat and dysmenorrhea
- Mechanism of action. ?R/T stimulates sweat production, ?growth hormone
- GRAS

An herb is a plant or plant part used for its scent, flavour or therapeutic properties.
- Sold as tablets, capsules, powders, teas, extracts and fresh or dried plants.
- However, some cause health problems, some are not effective and some may interact with other drugs.

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Fenugreek

- A standard dose has not been defined
- 1 - 4 caps (580-610mg) tds to qid, or
- *One cup of strained tea tds (1/4 tsp seeds steeped in 8 oz water for 10 mins)
- Transfer of fenugreek into milk is unknown
- Hale Risk = L3, herbal safety rating = B

Fenugreek – side effects

- Maple syrup smell to urine and sweat
- Possible side effects: diarrhea (mother or baby), stomach upset, hypoglycemia, allergy. Could worsen asthma.
- Allergies (from the peanut family)
- Care in diabetics? Potentiates the actions hypoglycaemics
- Contraindicated in pregnancy

Evidence for the use of fenugreek

- Documented anecdotal evidence since 1945
- Reeder et al. (ILCA 2010 conference poster)
- N=26, preterm mothers <31weeks, randomised double blind, fenugreek for 21 days from Day 5, pumping 8-10 times/day
- Prolactin levels measured every 5 - 7 days

Turkyilmaz et al., 2011. The Effect of Galactagogue Herbal Tea on Breast Milk Production and Short-Term Catch-Up of Birth Weight in the First Week of Life

66 exclusively BF healthy mothers of healthy term neonates randomised into 3 groups
- Group 1 – 3 cups of herbal tea/day containing fenugreek; Group 2 - a placebo; Group - no intervention
- Group 1 had lower maximum weight loss, regained their BW quicker and had higher mean expressed breastmilk volume expressed on Day 3

| Table 2. Prevalence, Nutritional Status, Loss, Gain on CEE/ or BF Rate, and Nutritional Status in the Control Group |
|---------------------------------------------------------------|---------------------------------------------------------------|---------------------------------------------------------------|---------------------------------------------------------------|
| Group 1 15 mothers   | Group 2 15 mothers   | Group 3 15 mothers   | p-value |
| Prevalence of BF mothers (%) | Prevalence of BF mothers (%) | Prevalence of BF mothers (%) | p-value |
| Birth weight (SD) | Birth weight (SD) | Birth weight (SD) | p-value |
| Newborn weight (SD) | Newborn weight (SD) | Newborn weight (SD) | p-value |
| Infant weight (SD) | Infant weight (SD) | Infant weight (SD) | p-value |

- Similar education received by the same LC for both groups
- No significant difference in demographics between groups
- A Choice of 2 different herbal teas recommended by a paediatric for the intervention group and an apple tea for the placebo group
- Blinding details unclear
- Breastmilk was expressed (consecutively) for 16 mins on the 2nd day using the same pump
For more information refer to:

- Commonly used herbal galactagogues by Lisa Marasco
  http://www.ilca.org/files/resources/HealthCareProviders/Galactogogue%20Dosage%20&%20Reference%20Table%20V2.pdf
- ABM Protocol 6 (revised Jan 2011)
  http://www.bfmed.org/Resources/Protocols.aspx

Evidence Based Practice

([Diagram showing the process of evidence-based practice])