Effect of domperidone on insufficient lactation in puerperal women: a systematic review and meta-analysis of randomized controlled trials

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CRD summary
The review concluded that, for some women experiencing insufficient breast milk production, evidence from a few small randomised trials of moderate-to-high quality suggested that domperidone produced a greater increase in milk supply than placebo. The conclusions from this well-conducted review are likely to be reliable.

Authors' objectives
To assess the effect of domperidone on breast milk supply in women experiencing insufficient breast milk production.

Searching
MEDLINE, EMBASE and The Cochrane library were searched to May 2011 without language restrictions; search terms were reported. Reference lists of relevant articles were also examined to identify further studies.

Study selection
Randomised controlled trials (RCTs) were eligible for inclusion if they examined the effect of domperidone in puerperal women experiencing insufficient breast milk production. Any definition of insufficient lactation was eligible. Comparator treatments had to be placebo or no treatment. The main review outcome was percent change in daily breast milk volume after domperidone treatment.

All mothers were recruited a few weeks postpartum; only one study specifically mentioned providing extensive lactation counselling. All studies were placebo-controlled and used domperidone at a dose of 30mg/d (10mg orally, three times). Duration of treatment ranged from seven to 14 days. Studies assessed milk volume either by infant weight (when full-term infants were breast-fed directly) or by the amount of milk expressed (when a pump was used for pre-term infants). Studies were published between 1985 and 2010.

Two reviewers independently selected studies for inclusion, with disagreements resolved by discussion.

Assessment of study quality
Study quality was evaluated using both the Cochrane risk of bias and GRADE tools. One reviewer assessed study quality, with the results being checked by a second reviewer. Disagreements were resolved by discussion.

Data extraction
Data were extracted in order to calculate relative and absolute mean changes from baseline with 95% confidence intervals. Standard deviations were imputed when missing. One reviewer extracted data which were then checked by a second reviewer. Disagreements were resolved by discussion.

Methods of synthesis
Meta-analyses were performed to calculate pooled weighted mean differences in relative changes from baseline, with 95% confidence intervals. A random-effects model was used. Heterogeneity was assessed using $I^2$.

Results of the review
Three RCTs (78 participants) were included. Two studies had mostly low-risk of bias judgements and were classed as high-quality evidence; one study was not well-reported (with many "unclear risk" judgements) and was classed as moderate-quality evidence.

There was a statistically significant increase of 74.7% (95% CI 54.6 to 94.9; $I^2$=50%; three RCTs) in daily milk production following treatment with domperidone, when compared with placebo. No maternal or neonatal adverse events were observed.
Authors' conclusions
Evidence from a few small randomised trials of moderate-to-high quality suggested that domperidone produced a greater increase in breast milk supply than placebo in some puerperal women with insufficient milk production.

CRD commentary
The review addressed a clear question and was supported by reproducible eligibility criteria. Attempts to identify all relevant studies in any language were undertaken by searching electronic databases and checking references. Suitable methods (such as independent duplicate processes) were used to reduce the risk of reviewer error and bias throughout the review.

Study quality was assessed and was used to help interpret the results of the review, and to inform the recommendations for research and practice. Adequate primary study details were provided, and appropriate methods were used to pool data and to assess heterogeneity. The review was well-conducted and the authors’ conclusions are likely to be reliable.

Implications of the review for practice and research
Practice: The authors stated that their analysis supported consideration that domperidone might be an effective treatment option for selected women with inadequate lactation. It appears to be prudent though to try non-pharmacological interventions first (for example, maternal lactation education). They also noted that generalisable recommendations might be still premature, considering the very small trial populations.

Research: The authors stated that additional randomised clinical trials of adequate sample size were desirable.

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This is a systematic review that meets the criteria for inclusion on DARE.