

# A Comparison of Efficacy of Domperidone and Placebo among Postnatal Women with Inadequate Breast Milk Production

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## ABSTRACT

**Aim:** To compare the efficacy of domperidone and placebo among postnatal women with inadequate breast milk production.

**Study design:** It was a randomized clinical trial.

**Duration of study:** From March 2012 to September 2012.

**Material and method:** Women delivered at term with inadequate milk production from the Department of Obstetrics & Gynaecology, Jinnah Hospital, Lahore.

**Result:** We recorded most of the patients in both groups between 20-25 years i.e., 24(48%) in Treatment Group and 21(42%) in Control Group, mean and sd was calculated as 25.76±2.21 in Treatment Group and 26.59±2.88 years in Control Group. Comparison of efficacy of Domperidone and placebo among postnatal women with inadequate breast milk production was done which reveals 36(72%) in Treatment Group and 11(22%) in Control Group, chi square test was applied which shows 0.002 as p value which shows significant milk production in treatment group.

**Conclusion:** Domperidone is found to be significantly higher effective than the placebo among postnatal women with inadequate breast milk production

**Keywords:** Inadequate breast milk production, postnatal women, efficacy, domperidone

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## INTRODUCTION

The best first food for a baby is breast milk. Exclusive breastfeeding is very important for health and development of babies<sup>1</sup>. Exclusive breast feeding for complete 6 months is not routinely practiced by most of mothers therefore newborns are deprived of this right in majority of societies. Socioeconomic status, literacy level, and gender bias are the factors affecting breastfeeding<sup>2</sup>.

Counseling nursing mothers for proper lactation before delivery and their continued training thereafter are the main clinical pathways towards successful and sustained breastfeeding<sup>3</sup>. One of the most common complaints of nursing mothers in a few days after delivery is insufficient lactation. This often results in the beginning of bottle feeding, which finally diminishes or ceases their breastfeeding<sup>3</sup>. Among the women who fail to exclusively breast feed their new ones, about 71% do so due to inadequate milk production<sup>4</sup>. Poor production of breast milk is, thus, the most frequent cause of lactation failure. Often, physicians prescribe medications or other substances to solve this problem<sup>5</sup>.

Galactogogues are medications that aid in initiating and maintaining adequate milk production. Most exert their pharmacologic effects through interactions with dopamine receptors, resulting in

increased prolactin levels and thereby augmenting milk supply. Metoclopramide and Domperidone remain the galactogogues of choice due to their documented record of efficacy and safety in women and infants. Traditional antipsychotics, sulpiride, chlorpromazine, Human growth hormone, thyrotrophin-releasing hormone, oxytocin, medroxyprogesterone and natural products fenugreek, galega, and milk thistle are other galactogogues<sup>6</sup>.

The use of galactogogues should be limited to those situations in which reduced milk production from treatable causes has been excluded<sup>5</sup>. Studies show that Domperidone increases the volume of breast milk of mothers experiencing lactation failure without substantially altering the nutrient composition. Breast milk volumes increased in a study in the domperidone-treated group as compared to placebo group. In another study<sup>3</sup> of women with inadequate milk production developed adequate milk production without any treatment and those women were only properly trained for proper breast feeding techniques<sup>3</sup>.

Although seem ideal for mothers with inadequate breast milk, some studies prove galactogogues to be of little value with no statistical difference in milk production between those who used and those who didn't use any galactogogue<sup>3</sup>.

However, this study is to compare the efficacy of domperidone and placebo among postnatal women

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presenting with in adequate milk production. This study is designed to find the best choice in our local population as the variability in literature regarding galactogogues and placebos for milk production. Also most of the previous studies done on the similar context have used in adequate sample size and the results were not conclusive. In our study if we find the role of domperidone to be more effective than the placebo group we will share the results of this study with other obstetricians and pediatricians and will recommend the routine use of domperidone for women with in adequate milk production.

## MATERIAL & METHODS

A total of 100 cases (50 in each group) who delivered at term at Jinnah Hospital Lahore during March 2012 to September 2012 and having inadequate breast milk production ( $\leq 10$ ml breast milk per single expression (both breasts) at 6<sup>th</sup> postnatal day) were included in the study while women with medical diseases like chronic renal diseases or tuberculosis possibly decreasing milk output. Malnutrition with BMI  $< 18$ kg/m, women with some breast diseases like abscess, mastitis, or malignancy on clinical examination and medical records and women with known allergy or prior reaction to Domperidone were excluded from the study. All women were subjected to detailed history and clinical examination relevant obstetrical and past medical records were carefully scrutinized. All women were randomly allocated in two groups by lottery method, women in treatment group was subjected to domperidone 10mg three times a day and women in control group were subjected to placebo i.e., trained and explained for proper breast feeding technique and practices including good diet and proper positioning. All women were followed up on 7<sup>th</sup> day to detect the efficacy of drug/placebo in terms of adequacy of milk production.

The data was analyzed in SPSS version 16. Mean $\pm$ SD was calculated for numerical variables like age. Frequencies and percentages were calculated for categorical variables like efficacy ( $\geq 50$ ml breast milk expressed per single expression (both breasts) after 7 days use of domperidone or placebo). Chi square test was used to compare efficacy in both the groups, P value of  $\leq 0.05$  as significant. Efficacy in both groups was stratified among age and post natal day to see the effect modifications.

## RESULTS

Age distribution of the patients was done in Table 1, where we recorded most of the patients in both groups between 20-25 years i.e., 24(48%) in Treatment Group and 21(42%) in Control Group,

17(34%) in Treatment Group and 15(30%) in Control Group were between 26-30 years while only 9(18%) in Treatment Group and 14(28%) in Control Group, mean and sd was calculated as 25.76 $\pm$ 2.21 in Treatment Group and 26.59 $\pm$ 2.88 years in Control Group (Table 1).

Comparison of efficacy of Domperidone and placebo among postnatal women with inadequate breast milk production was done which reveals 36(72%) in Treatment Group and 11(22%) in Control Group while remaining 14(28%) in Treatment and 39(78%) in Control Group had no adequate improvement, chi square test was applied which shows 0.002 as p value which shows significant milk production in treatment group (Table 2).

Table 1: Age distribution of the subjects

Age in years	Treatment Group (n=50)	Control Group (n=50)
20-25	24(48%)	21(42%)
26-30	17(34%)	15(30%)
31-35	9(18%)	14(28%)
Mean $\pm$ sd	25.76 $\pm$ 2.21	26.59 $\pm$ 2.88

Table 2: Comparison of efficacy in both groups

Efficacy	Treatment Group (n=50)	Control Group (n=50)
Yes	36(72%)	11(22%)
No	14(28%)	39(78%)

P value=0.002

## DISCUSSION

Domperidone, a peripheral dopamine receptor antagonist, is believed to enhance breast milk production by increasing prolactin secretion<sup>7</sup>. It has a favorable safety profile when compared to metoclopramide, another dopamine receptor antagonist, with only rare extra-pyramidal side effects owing likely to poor blood-brain barrier penetration of domperidone<sup>8,9,10</sup>.

We compared the efficacy of domperidone and placebo among postnatal women presenting with in adequate milk production, however, the best choice in our local population as the variability in literature regarding galactogogues and placebos for milk production may be determined.

In our study, efficacy of Domperidone and placebo among postnatal women with inadequate breast milk production was compared which reveals 36(72%) in Treatment Group and 11(22%) in Control Group while remaining 14(28%) in Treatment and 39(78%) in Control Group had no adequate improvement, chi square test was applied which shows 0.002 as p value which shows significant milk production in treatment group.

The findings of the study are in agreement with Campbell ML<sup>11</sup> who recorded serum prolactin increased by 97% in the domperidone group and by 17% in the placebo group ( $P = 0.07$ )<sup>11</sup>. While another study, 85.7%<sup>3</sup> of women with inadequate milk production developed adequate milk production without any treatment but those women were only properly trained for proper breast feeding techniques<sup>3</sup>.

Da Silva et al reported that after 7-day treatment, the mean daily milk volume had increased by 49.5 (SD=29.4) mL/day in the domperidone group compared to 8.0 (SD=39.5)mL/day in the placebo group<sup>7</sup>. Similarly, Petraglia et al. demonstrated that, following 10-day treatment, daily milk yield was significantly higher in a small group of domperidone-treated mothers than that of the placebo-treated group<sup>12</sup>. The mean increase in daily milk yield was 326 (imputed SD=21.4)mL/day after domperidone versus 63 (imputed SD=23.7)mL/day after placebo treatment.

Finally, a significant increase in daily breast milk production was found in Campbell-Yeo et al<sup>11</sup> mean increase of 195.8 (imputed SD=98.1)mL/day after a 14-day course of domperidone compared to 33.1 (imputed SD=83.2)mL/day in a placebo-treated group<sup>13</sup>.

Overall, in absolute values, all three studies had shown a statistically significant increase from baseline in breast milk production following treatment with domperidone.

However, findings of the current study in agreement with other international studies justify the hypothesis of the study that "Domperidone is more effective than placebo for inadequate breast milk production."

The result of the study may be shared with other obstetricians and pediatricians and recommend the routine use of domperidone for women with inadequate milk production.

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