Comparison of Efficacy of Domperidone and Placebo among Postnatal Women with Inadequate Breastmilk Production

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Abstract

Objectives: To compare the efficacy of domperidone and placebo among postnatal women with insufficient production of breast milks.

Methods: This Randomized controlled trial was conducted at Khyber Teaching Hospital Peshawar, from January 2011 to July 2011 and comprised of women with inadequate breast milk production till 6th postnatal day who have delivered term babies. All participants were divided in two groups. One group was given Domperidone and another placebo. All were followed on 7th day for the efficacy of breast milk production.

Results: off the total 174 participants, 72.41% (n=63) in Domperidone group and 21.84% (n=19) in placebo group shows a significant breast milk production.

Conclusion: Comparison of the study reveals that domperidone is significantly higher effective than the placebo among postnatal women who present with inadequate production of breast milk.

Key words: Inadequate breast milk production, postnatal women, efficacy, domperidone

INTRODUCTION

The best first food for a baby is breast milk. Exclusive breastfeeding is very important for health and development of babies[1]. 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[2]. Counselling of breast-feeding mothers for proper lactation before delivery and after delivery are the main clinical pathways for successful and sustained breastfeeding[3]. Among the women who fail to exclusively breast feed their new ones, about 71% do so due to inadequate milk production[4]. Less production of milk in breast is, the most common cause of lactation failure.

Often, physicians prescribe medications or other substances to solve this problem[5].Galactogogues are medicines that help in first starting and then maintaining adequate production of breast milk. They have pharmacologic action via interactions with dopamine receptors. Metoclopramide and Domperidone remain the galactagogues of choice because of their proven efficacy and because they are safe in breastfeeding women and infants. Traditional antipsychotics, sulpiride, chlorpromazine, Human growth hormone, TRH, oxytocin, medroxyprogesterone; and natural products fenugreek, galega, and milk thistle are other galactogogues[6].

The use of galactagogues should be limited to those situations in which reduced milk production from treatable causes has been excluded[5]. Studies show that Domperidone increases the amount of breast milk of those mothers who have inadequate lactation but does not change the nutrient composition of breast milk. The volume of breast milk increased in a study by 67% in the group who was treated with domperidone and by eighteen percent in the placebo group (P 0 .005). Level of prolactin in blood increased by ninety-seven percent in the group treated with domperidone and by seventeen percent in the placebo group (P 0 .07)[7]. In another study, 85.7%[3] 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[3].Although seem ideal for mothers with inadequate breast milk, some studies prove galactagogues to be of little value with no statistical difference in milk production between those who used and those who didn't use any galactogogue[3].

The rationale behind doing this study is to

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compare the efficacy of domperidone and placebo in women after delivery who present with in adequate lactation. This study is designed to find the best choice in our local population as the variability in literature regarding galactagogues and placebos for milk production.

OBJECTIVE

To compare the efficacy of domperidone and placebo among postnatal women with insufficient production of breast milk.

MATERIAL AND METHODS

The current study was a Randomized controlled trial conducted at obstetrics & gynecology department of Khyber Teaching Hospital, Peshawar. The duration of study was six months from, Jan 2011 to July 2011. Consecutive (non-probability) sampling technique was used to select the participants. Women presenting with inadequate milk production till 6th postnatal day were invited to participate in the study through OPD. All women with inadequate breast milk production who have delivered term babies were included. Women with medical diseases like chronic renal diseases or tuberculosis possibly decreasing milk output, with malnutrition with BMI < 18kg/m^2 and with some breastdiseases like abscess, mastitis, or malignancy on clinical examination and medical records were excluded. Similarly, women with known allergy or prior reaction to Domperidone were also excluded. Ethical approval for this study was taken from ethical and research committee of the hospital. Written informed consent was obtained from those who agree to participate in the study. 174 women were studied in total, 87 in each arm of the study. Detailed history was taken from all women and clinical examination done along with review of relevant obstetrical and past medical records. Random allocation of all women were done by lottery method, in two groups. Women in group A were subjected to domperidone 10mg three times a day and women in group B 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 7th day to detect the efficacy of the drug/placebo in terms of adequacy of milk production. All these information was recorded in a pre-designed proforma.

DATA ANALYSIS:

Data was stored and analysis done in SPSS version 10. Mean $\pm$ SD was calculated for numerical variables like age. Frequencies and %ages were calculated for categorical variables like efficacy. Chi square test was used for comparison of efficacy in both groups while keeping a P value of $\leq$ 0.05 as significant. Efficacy in both groups A&B was stratified among age and postnatal day to see the effect modifications. All results were presented in the form of graphs and tables.

RESULTS

Total of 87 subjects (in each group) fulfilling the inclusion/exclusion criteria were enrolled. Table No. 1 shows age distribution of the patients, where we recorded most of the patients between 20-25 years i.e. 47.13%(n=41) in Group-A and 41.38%(n=36) in Group-B. Mean and SD was calculated as 27.32+4.36 in Group-A and 24.67+3.87 years in Group-B. (Table 1). The efficacy of Domperidone and placebo was compared among postnatal women with inadequate production of breast milk, which reveals 72.41%(n=63) in Group-A and 21.84%(n=19) in Group-B had adequate improvement, while 27.59%(n=24) in Group-A and 78.16%(n=68) in Group-B had no adequate improvement. Chi square test was applied which shows a p value of 0.02 which is highly significant in Group- A (Table 1). Stratification of efficacy for age of the patients was done in both groups (Table 3).

Table 1: Age of the subjects (N=174)

Age (years)	Group-A (n=87)		Group-B(n=87)	
	No. of patients	%	No. of patients	%
20-25	41	47.13	36	41.38
26-30	29	33.33	27	31.03
31-35	17	19.54	24	27.59
Total	87	100	87	100
Mean and SD	27.32±4.36		24.67±3.87	

Table 2: Comparison of efficacy of domperidone and placebo amongpostnatal women presenting withinsufficient breast milk production (n=174)

Efficacy	Group-A(n=87)		Group-B(n=87)	
	No. of patients	%	No. of patients	%
Yes	63	72.41	19	21.84
No	24	27.59	68	78.16
Total	87	100	87	100

P value=0.002

Table 3: Stratification of efficacy forage of the patients (N=174)

Age (years)	Group-A(n=87)		Group-B(n=87)	
	No. of patients	(n=63) Efficacy(%)	No. of patients	(n=19) Efficacy(%)
20-25	41	31(75.61 %)	36	9(25%)
26-30	29	19(65.52 %)	27	6(22.22 %)
31-35	17	13(76.47 %)	24	4(16.67 %)
Total	87	63	87	19

DISCUSSION

The benefits of breastfeeding are wellknown both for the mother and baby; thus, every effort should be done to promote initiation of breastfeeding, giving it for theproper duration, andexclusive breastfeeding for six months.[8] Exclusive breastfeeding rates at 3 months and 6 months has fallen substantially 51.7%and 14.4%. There are multiple factors which affect success

of breastfeeding, some can be modified some are nonmodifiable. The early recognition of modifiable risk factors and their management on time is needed to improve lactation performance.[9]The effectiveness of various non-pharmacological have been shown and currently are clinically recommended for promoting breastfeeding.[8] Among them are breastfeeding education which is provided by lactation specialists to individuals and in groups, peer counseling, in-person counseling, or support given telephonically. Pharmacological interventions for lactation improvement, mainly dopamine antagonists, are usuallyrecommended only when non-pharmacological interventions have failed, and this is mainly because the available evidence is scarce and safety issues with pharmaceutical interventions.[10-11]

Domperidone is believed to increase breast milk production by increasing prolactin secretion.[12-14] It is more safe when compared to metoclopramide, another dopamine receptor antagonist, with only rare extra- pyramidal side effects because it poorly penetrate the blood brain barrier.[15-17]

We planned this study to compare the efficacy of domperidone and placebo among women after delivery who present with inadequate production of breast milk, however, the best choice in our local population as the variability in literature regarding galactagogues and placebos for milk production may be determined.The findings of the study are in agreement with Campbell ML[7] who recorded prolactin level in the serum increased by ninety-seven percent in the domperidone group and by seventeen percent in the placebo group (P = 0 .07)[7]. While another study, 85.7%[3] 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[3]. Da Silva et al reported the increase in mean daily milk volume 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, after seven days treatment .[14] Similarly, Petraglia et al. demonstrated that the daily milk yield was significantly higher in asmall group of mothers who were treated domperidone for 10 days than that of the placebo-treated group.[18] The mean increase in daily milk yield was 326 (imputed SD = 21.4) mL/day when treated with domperidone as compared to 63 (imputed SD = 23.7) mL/day when treated with placebos.

Finally, a significant improvement in daily production of breast milk was found in Campbell-Yeo et al[19]. Mean increase of 195.8 (imputed SD = 98.1) mL/day when treatment with domperidone was done for 14-days as compared to 33.1 (imputed SD = 83.2) mL/day in a group treated with placebo.[19] Overall, in absolute values, all the 3 studies had shown that there is statistically significant increase in production of breast milk, from baseline, when treated 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 withinadequate milk production.

CONCLUSION

Comparison of the study reveals that domperidone is significantly higher effective than the placebo among postnatalwomen who present with inadequate production of breast milk.

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