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Effects of Domperidone in Milk Production of Postpartum Mothers with Insufficient Lactation

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ABSTRACT--- *Breast milk is important for newborn nutrition. Impaired breast milk production in postpartum mothers can affect the growth of newborns.This study aims to investigate the effects of domperidone on newborn birth weight gain and the adverse events of this treatment in postpartum mothers with insufficient lactation.This study is randomized controlled trial was conducted on postpartum mothers with insufficient lactation in the primary health care. The birth weight measured on day 3 after delivery. Each mother was randomized to domperidone 10 mg + vitamin B12 50 mcg or placebo on the 3rd day of postpartum 3 times daily for 7 days. The birth weight is measured every day during the mothers treatment and the side effects on the mother during treatment also recorded.The Results of this study was conducted on 60 postpartum mothers with insufficient lactation. Thirty mothers received domperidone + placebo and 30 mothers received a placebo. The birth weight increased significantly after both domperidone and placebo treatment (p <0.05). Side effects observed in the domperidone group including tremble, palpitations and dry mouth whereas the placebo group experienced with palpitations, dry mouth, and diarrhea. Most of mothers (>80%) in both study groups did not experience any side effects.The study Concludes thet weight gain in newborns from postpartum mothers with insufficient lactation increased significantly after 7 days of domperidone administration with minimal adverse events*

Keywords--- *Domperidone, postpartum, insufficient lactation, breast milk*

I. INTRODUCTION

Lactation is the process of producing and secreting milk. This complex process involves physical, emotional and hormonal control factors including estrogen, progesterone, oxytocin, prolactin, growth hormone, glucocorticoids, and insulin. Physiologically, breast milk is stimulated to secretion after the placenta is born. This

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process due to a decrease in estrogen and progesterone levels and an increase in prolactin levels. Prolactin and oxytocin are the most important hormones during lactation (Wada Y et al, 2019). Although the two hormones act on different cellular receptors, the combination of these hormones is important for the success of lactation. Prolactin is involved in milk production through the central nervous system whereas oxytocin plays a role in the secretion of breast milk. (Henderson A, 2003; Chatterton RT et al, 2000)

Breastfeeding is the best way to provide the nutrition for newbors growth and development. Breast milk also participates in cognitive, sensory development and provides protection against infections and chronic diseases (Beck, 2010). In addition, breast milk also contains a substantial whey protein which easier to digest and accelerates gastric emptying, as a source of long-chain fatty acids for brain and red blood cell membrane, providing psychological benefits through maternal and newborn inner bonds, reducing risk of eczema and atopic disease, systemic infection and improve psychomotor development (Zuppa, 2010; Furman L, 2002; Gartner LM, 2005, Quigley MA,2011)

Mothers who intend to breastfeed their newborn can sometimes face difficulties with milk supply. Provision of breastfeeding drugs or galactogogue needs to be considered as the importance of breast milk for the health of infants. Domperidone is a potent dopamine D2 receptor antagonist that act as a galactogogue like metoclopramide may help to promote milk secretion. Domperidone is less permeable than metoclopramide and less soluble in water with a greater molecular weight so that its extrapyramidic effect is less frequent than metoclopramid. Due its characteristics, domperidone is preferable than metoclopramid to increase breast milk production (Henderson, 2003; Da Silva OP, 2001; Osadchy A 2012).The purpose of our study is to investigate the effect of domperidone on newborn weight gain and the adverse events of domperidone treatment in postpartum mothers with insufficient lactation.

II. METHODOLOGY

This randomized controlled trial was conducted on postpartum mothers with insufficient lactation in primary health care. Insufficient lactation is the inability to breastfeeding on demand so that it cannot produce an adequate amount of breast milk for newborn. Mothers aged 20-35 years old, normal delivery in 37-40 weeks of gestation, normsight and no history of taking galactogogue were included in this trial. Mothers with allergy to domperidone, already taking domperidone, underweight or obese, diabetes, mastitis and those with prior breast surgery were excluded. All mothers had taken lactation counseling prior to the study. We obtained written consent from all participants. The newborns birth weight measured on day 3 after delivery. Each mother was randomized for domperidone 10 mg + vitamin B12 50 mcg or placebo (vitamin B12 50 mcg) on the 3rd day postpartum 3 times daily for 7 days. The newborn weight is measured every day during mother's treatment. The adverse events on mothers during the treatment are recorded. Differences in newborns weight before and after treatment were analyzed using paired t test with a *p*-value <.05.

III. RESULTS

This study was conducted on 60 postpartum mothers with insufficient lactation. Thirty mothers were administered domperidone + vitamin B12 50 mcg and thirty mothers just received placebo (vitamin B12 50

mcg). The proportions of maternal age for the two study groups were comparable. Most of the mothers are multiparous in domperidone group. In contrast, primiparous mothers were more in the placebo group. 43% of mothers in the domperidone group with BMI ≤21-22 kg/m^2 whereas 53% of mothers in the placebo group have BMI ≤23-24.9 kg/m^2. The characteristics of the mothers are shown in table 1. The newborns weight gained significantly after treatment for both domperidone and placebo (table 2). Minimal adverse events in mothers from the domperidone group included tremble, palpitations and dry mouth whereas in the placebo group experienced with palpitations, dry mouth and diarrhea. Most of the mothers (> 80%) for both study groups did not experience any side effects (table 3).

In the present study, the increase in newborn weight from mothers who received domperidone + placebo group was 308.24 grams for 7 days or the average newborns weight gain 44.03 grams was greater than the increase in the placebo group 129.46 grams for 7 days or newborn weight gain on average 18.49 grams per day. This value exceeds the average value of newborn weight gain per day according to WHO which ranges from 14-21 gr/day. Our results shows that domperidone administration has been able to significantly increase milk production.

In previous studies reported administration of domperidone for 14 days can increase the volume of breast milk up to 267% compared with 18.5% in placebo. Serum prolactin also increased by 97% in the domperidone group compared with 17% in the placebo group (Campbell, 2010). A moderate increase in milk production after domperidone compared with placebo also reported in a study by Grzeskowiak (Grzeskowiak, 2013). In addition to increasing breast milk volume, domperidone also increases prolactin production with minimal side effects (Wada et al., 2019).

Tremble, palpitations, dry mouth, headaches, itching, and diarrhea were observed after administration of domperidone. Majority of the subjects experienced no side effects for both study groups. We observed minimal adverse events including tremble, palpitations, dry mouth and diarrhea. Previous study reported no significant differences with regard to maternal side effects and there were no reported cardiovascular cases or sudden cardiac death (Wada, 2019). Other study also reported that domperidone does not increase the risk of adverse events including headache, gastrointestinal, respiratory disorders, and neurological symptoms such as sleep disorders and dizziness in the mother (Grzeskowiak, 2013, Da Silva OP 2001). The minimal adverse events due to domperidone might caused by its higher molecular weight and 90% of its molecule binds to protein (Jones, 2011; Bunik M, 2011; Albright LM 2004)

Limitations in the study are not recalling the diet status of each subject, not calculating calorie requirements and nutritional intake of each subject, not fully supervising during the study of all food or anything consumed by the subject, and in this study also the newborn weight gain was not calculated by same person.

Table 1. Patient's characteristics

Characteristics	Domperidone		Plasebo		*P*
	n	%	n	%	
Age (years)					
≥20–<25	9	30	10	33.3	0.861

≥25–<30	11	36.7	9	30	
≥30–35	10	33.3	11	36.7	
Parity					
Primiparous	12	40	16	53.3	0.301
Multiparous	18	60	14	46.7	
Postpartum BMI (kg/m^2)					
≥18,5–≤20	6	20	4	13.3	0.424
≥21-22	13	43.3	10	33.3	
≥23-24.9	11	36.7	16	53.3	
Age of gestation (weeks)					
≥37–<38	7	23.3	9	30	0.843
≥38–<39	11	36.7	10	33.3	
≥39 –40	12	40	11	36.7	

Table 2. Birthweight before and after treatment

Treatment	Birth weight (mean±SD gr)	*P*
Domperidone+placebo (n=30)		
Before	3118.3±360.05	0.001
After	3426.6±360.47	
Placebo (n=30)		
Before	3091.7±337.86	0.043
After	3221.1±336.46	

Table 3. Treatment side effect

Side effects	Domperidone + placebo (n=30)	Placebo (n=30)
Tremble	1 (3.3%)	0
Palpitation	1 (3.3%)	2 (6.7%)
Dry mouth	4 (13.3%)	2 (6.7%)
Diarrhea	0	1 (3.3%)
No side effects	24 (80%)	25 (83.3%)

IV. CONCLUSION

Weight gain in newborns from postpartum mothers with insufficient lactation increased significantly after 7 days of domperidone administration with minimal adverse events.

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