Original Article/นิพนธ์ต้นฉบับ

Effectiveness of Domperidone in Augmenting Breastmilk Production Measured by Manual Expression in Postpartum Women at Charoenkrung Pracharak Hospital

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Abstract

Background: Breastmilk is the ideal food for infants. Domperidone was found to increase breastmilk production but its use is still controversial. Most of the studies used electric breast pump to collect breastmilk. However, manual expression of breastmilk has some advantages over electric breast pump.

Objective: To study effectiveness of domperidone in increasing breastmilk production among postpartum women by using manual expression to collect breastmilk.

Methods: This study recruited 50 postpartum women who had term spontaneous normal vaginal delivery in Charoenkrung Pracharak Hospital from September 1, 2015 to November 30, 2015. The participants were randomly assigned to receive domperidone or placebo, 25 women in each group. Drugs were first given to postpartum women at 24 hours after delivery. Breastmilk was collected by manually expression at 24 hours after delivery before receiving drugs, then at 48 hours, 72 hours and 96 hours after delivery. Chi-square test and Mann-Whitney U test were used for hypothesis testing and the statistical significance was set at $P < 0.05$.

Results: The median volume of breastmilk in both groups at 24 hours after delivery and before receiving drugs were 2 milliliters in domperidone group and 1 milliliter in placebo group. Breastmilk median volume increased in both groups afterwards. At 48 hours after delivery, the volumes were 8 and 3 milliliters in domperidone and placebo group respectively. At 72 hours, the volumes were 15 and 10 milliliters, at 96 hours, the volumes were 35 and 15 milliliters in groups respectively. The differences were statistically significant ($P < 0.05$). There was no side effect of domperidone among the postpartum women in the domperidone group.

Conclusions: Domperidone effectively increased more breastmilk production measured by manual expression than placebo.

Keywords: Domperidone, Breastfeeding

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Introduction

Human milk is the ideal food for infants in the first few months of life as it provides most appropriate nutrition[1] as well as unique advantages such as reduced morbidity,[2] increased immunity and protection against infections,[3] improved retinal function,[4] enhanced cognitive development,[5,6] lowered prevalence of diabetes[7] and possibly with a reduction in some cardio respiratory risk factors in later life.[8] The benefits of breastfeeding are well recognized for both the mother and baby. Efforts have been made to promote initiation, duration, and exclusivity of breastfeeding.[9]

Study among Canadian women showed that breastfeeding intention and initiating rates were fairly high, 90% and 90.3%, respectively. However, reported exclusive breastfeeding rates at three and six months fell substantially to 51.7% and 14.4%, respectively.[10] In Thailand, the reported rate of 6 months exclusive breastfeeding was 15%.[11] The early recognition and timely management of modifiable risk factors is warranted to improve lactation performance.[12] Various nonpharmacological interventions have been shown to be effective. Among them are individual and group breastfeeding education provided by lactation specialists, peer counseling, in-person, or telephone support.[13] Pharmacological interventions to improve lactation, mainly dopamine antagonists, are usually recommended only after nonpharmacological modalities have failed, and this is largely due to scarcity of available evidence and potential safety issues with pharmaceutical galactagogues.[14, 15] Many researches on breastfeeding found that domperidone significantly increased breastmilk production compared to placebo without serious side effects to either mother or baby.[16-21]

Domperidone, a peripheral dopamine receptor antagonist, is believed to enhance breastmilk production by increasing prolactin secretion. It has a favorable safety profile when compared to metoclopramide, another dopamine receptor antagonist, with only rare extra-pyramidal side effects due to poor blood-brain barrier penetration of domperidone. The drug is well tolerated with relatively few side effects reported including headache, dry mouth, and abdominal cramps. While domperidone is not available for any indication in the United States due to arrhythmia concerns, it is approved in Canada and other countries as a prokinetic agent. Moreover, there is a worldwide experience with domperidone in treating nausea and vomiting. The use of domperidone as a galactagogue represents an "off-label" indication.[18]

Charoenkrung Pracharak Hospital is a one of the Baby Friendly Initiatives Hospital and has a policy and campaign of promoting postpartum women to breastfeed correctly and successfully. Domperidone is frequently use in the Charoenkrung Pracharak Hospital without any systematic evaluation. Studies in Thailand on the effectiveness of the drug for augmenting breastmilk production had different results.

This study aimed to evaluate the effectiveness of domperidone among postpartum women in Charoenkrung Pracharak Hospital by measuring breastmilk volume expressed manually. Comparison of breastmilk volume between postpartum women who received domperidone and women who received placebo was done.

Methods

The study was approved by the Ethics Committee, Faculty of Medicine Ramathibodi Hospital, Mahidol University, No. MURA2014/713 on February 6, 2015, and the Ethics Committee on Human Research of Bangkok Metropolitan Administration No. U015h/58 on August 20, 2015.

This randomized double-blinded placebo-controlled clinical trial collected breastmilk from postpartum women by manual expression. The population of this study was the postpartum women who had normal vaginal delivery of normal term infants at Charoenkrung Pracharak Hospital from September to November 2015, and agreed to participate in this study. Inclusion criteria were maternal age between 20 - 34 years, primipara, singleton pregnancy, gestation age 37 - 42 weeks at delivery, no complication during pregnancy

and delivery, no serious diseases or taking any drugs or any other galactogogues, no history of breast surgery, normal electrocardiogram (EKG), newborn is healthy without asphyxia and congenital anomaly, newborn's suckling well and stayed with mothers 24 hours (rooming in) and mother's willing to cooperate. Exclusion criteria were maternal mastitis and not complete follow-up. Sample size was calculated on the basis of data from previous study.[20] Twenty-four participants were required in each group to achieve statistical significance using type I error of 0.05 and a power of 80%. An additional 10% were included to cover potential withdrawal during the trial. Categorical data analysis between groups was done by chi-square test (X^2). Breastmilk volume was analyzed by Mann-Whitney U test for nonparametric data.

After vaginal delivery, postpartum women were admitted to postpartum wards. Study information was explained to postpartum women and they signed consent form in order to participate in the study. Randomization was done by simple randomization. The study group received domperidone treatment and the control group received placebo. The domperidone dosage was one tablet (10 mg) orally three times after meals for four days starting at 24 hours after delivery. The prescription was under the supervision of a medical doctor at Charoenkrung Pracharak Hospital. Evaluation of breastmilk product was done by manual expression.

The steps of collecting breastmilk were as follows:[22]

1) Mother washed her hands well before the expression to prevent contamination and infection.

2) Mother sat in a comfortable position and gently massage her breasts with both hands and fingers.

3) Mother placed little finger under her breasts, against ribs, and spread other fingers slightly, to support breast. Thumb needs to be on top, about 3 cm (1.2 in) or 4 cm (1.6 in) back from the base of nipple. Adjust fingers, if mothers need to, so that their first finger and thumb are opposite each other, making a big C-shape around your breast.

4) Mother pushed her breasts against the chest wall.

5) The pressure should be gentle and firm. Avoid over tightening or over stretching skin over the areola because this will make it more difficult to express breastmilk. Press thumb and index finger directly back into the breast tissue, against chest wall.

6) Use a rolling motion away from their body with their thumbs and fingers. Press and then relax was done alternatively.

7) This process usually takes about 15 minutes for each breast.

8) Breastmilk was collected in a container or a cup and was measured in milliliters.

Every postpartum women were taught about manual expression of breastmilk and were instructed to collect breastmilk by manual expression at 24 hours after delivery before receiving drugs or placebo, then at 48, 72 and 96 hours after delivery. The process of manual expression of breastmilk was supervised and monitored by researchers and nurses to assure that every postpartum women could do it correctly. They were also asked to record side effects during treatment such as dry mouth, headache, insomnia, abdominal cramps, diarrhea, nausea and urinary retention.

Profile of clinical trial was shown in Figure 1 Fifty-four postpartum women were recruited and randomly assigned to either the domperidone group or the placebo group. In each group, 2 women withdrew from study because of incomplete collection of breastmilk. The final analysis, therefore, included 25 postpartum women in each group.

Results

Characteristics of postpartum women and newborn included age, education, occupation, body weight, height, gestational age, number of antenatal visits, attended antenatal class of breastfeeding, volume of drinking water after delivery, rest and stress during postpartum period, newborn gender, birth weight and Apgar score (5 minutes). There was no statistically

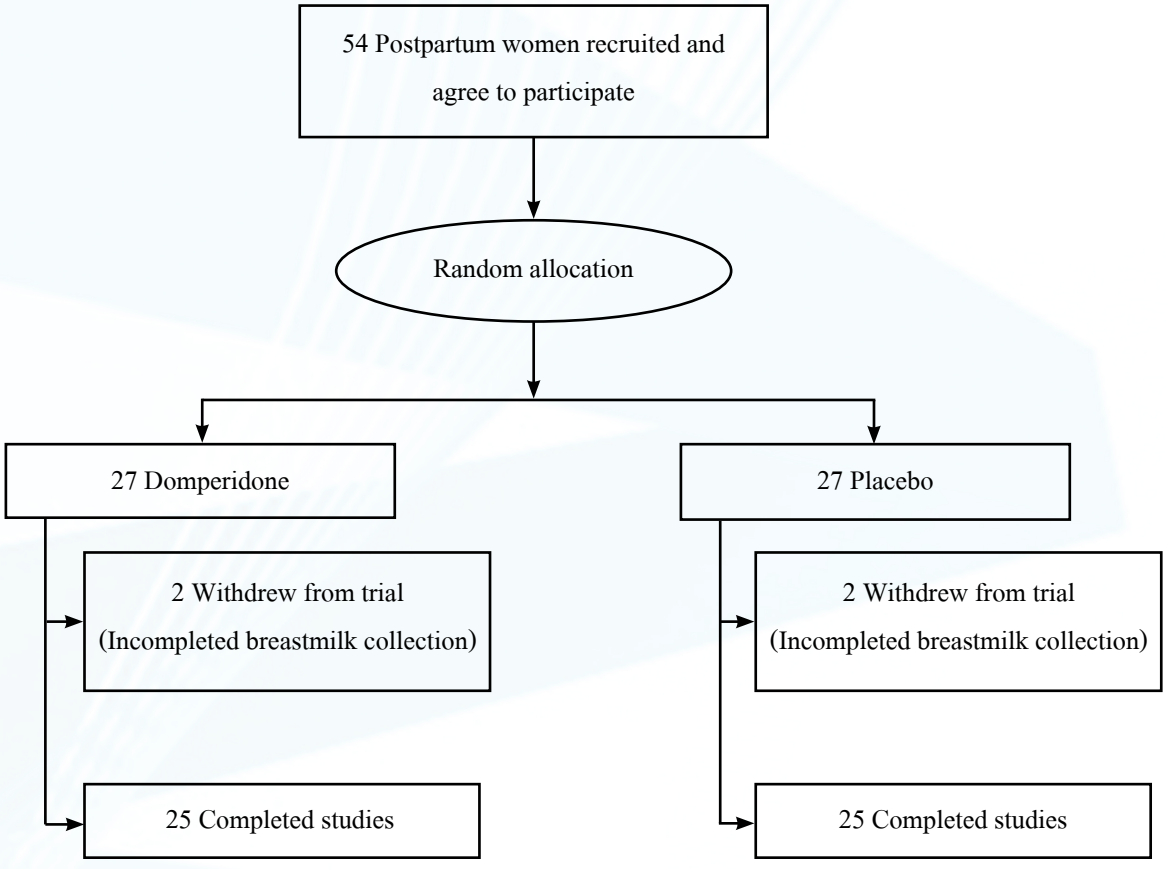


Figure 1 *Clinical Trail Flow*

significant difference in characteristics of women in both groups (Table 1).

Most of newborns in both groups were female (56%). The mean birth-weight of newborns in domperidone group was 3006.40 grams (SD = 233.75) compared to 3138.56 grams (SD = 289.33) in placebo group. All newborns in both groups had Apgar score 10 at 5 minutes after birth. There was no statistical difference between characteristics of newborns in both groups (Table 1).

The median breastmilk volume at 24 hours after delivery before receiving drugs was 2 milliliters in the domperidone group and 1 milliliter in the placebo group. The difference was not statistically significant ($P = 0.22$). At 48 hours after delivery, the volumes were 8 and 3 milliliters in domperidone and placebo group respectively. At 72 hours, the volumes were 15 and 10 milliliters and at 96 hours, the volumes were 35 and 15 milliliters in groups, respectively. The differences between breastmilk volume at 48 hours and afterwards were statistically significant ($P < 0.001$) (Table 2 and Figure 2).

No adverse effect of domperidone was recorded among postpartum women who received domperidone.

Table 1 Characteristics of Postpartum Women and Newborn

Characteristic	No. (%)			X^2	*df*	*P* Value
	Domperidone (n = 25)	Placebo (n = 25)	Total (n = 50)			
Age, y						
20 - 22	8 (32.0)	7 (28.0)	15 (30.0)			
23 - 25	6 (24.0)	9 (36.0)	15 (30.0)			
26 - 33	11 (44.0)	9 (36.0)	20 (40.0)	0.87	2	0.65
Mean ± SD	24.72 ± 3.35	24.36 ± 3.24	24.54 ± 3.27			
Education						
Primary School or less	12 (48.0)	7 (28.0)	19 (38.0)			
High school or higher	13 (52.0)	18 (72.0)	31 (62.0)	2.12	1	0.15
Occupation						
Housewife	5 (20.0)	10 (40.0)	15 (30.0)			
Other	20 (80.0)	15 (60.0)	35 (70.0)	2.38	1	0.12
Body weight, kg						
45 - 58	7 (28.0)	8 (32.0)	15 (30.0)			
59 - 65	11 (44.0)	7 (28.0)	18 (36.0)			
66 - 88	7 (28.0)	10 (40.0)	17 (34.0)	1.49	2	0.48
Mean ± SD	61.60 ± 6.25	63.88 ± 10.86	62.74 ± 8.85			
Height, cm						
147 - 154	7 (28.0)	8 (32.0)	15 (30.0)			
155 - 159	4 (16.0)	7 (28.0)	11 (22.0)			
160 - 172	14 (56.0)	10 (40.0)	24 (48.0)	1.55	2	0.46
Mean ± SD	158.44 ± 5.39	157.68 ± 6.41	158.06 ± 5.88			
Gestational age, wk						
37 - 38	10 (40.0)	13 (52.0)	23 (46.0)			
39 - 41	15 (60.0)	12 (48.0)	27 (54.0)	0.73	1	0.40
Mean ± SD	38.88 ± 1.27	38.60 ± 1.29	38.74 ± 1.28			
Number of antenatal visits						
≤ 7	8 (32.0)	8 (32.0)	16 (32.0)			
8 - 9	5 (20.0)	7 (28.0)	12 (24.0)			
≥ 10	12 (48.0)	10 (40.0)	22 (44.0)	0.52	2	0.77
Mean ± SD	8.76 ± 2.89	8.44 ± 2.89	8.60 ± 2.86			
Attending antenatal class of breast						
Yes	13 (52.0)	8 (32.0)	21 (42.0)			
No	12 (48.0)	17 (68.0)	29 (58.0)	2.05	1	0.15

Abbreviation: *df* , degree of freedom; SD, standard deviation; X^2, chi-square test.

[a] Fisher's exact test.

Table 1 Characteristics of Postpartum Women and Newborn (Continued)

Characteristic	No. (%)			X^2	*df*	*P* Value
	Domperidone (n = 25)	Placebo (n = 25)	Total (n = 50)			
Drinking water (postpartum) (mL/d)						
≤ 2000	3 (12.0)	4 (16.0)	7 (14.0)			
> 2000	22 (88.0)	21 (84.0)	43 (86.0)			1.00[a]
Rest during postpartum						
Adequate	10 (40.0)	11 (44.0)	21 (42.0)			
Inadequate	15 (60.0)	14 (56.0)	29 (58.0)			1.00[a]
Stress during postpartum						
Mild	22 (88.0)	22 (88.0)	44 (88.0)			
Moderate	3 (12.0)	3 (12.0)	6 (12.0)			1.00[a]
Newborn gender						
Male	11 (44.0)	11 (44.0)	22 (44.0)			
Female	14 (56.0)	14 (56.0)	28 (56.0)			1.00[a]
Birth weight, g						
2500 - 2900	8 (32.0)	4 (16.0)	12 (24.0)			
2901 - 3200	14 (56.0)	11 (44.0)	25 (50.0)			
3201 - 3700	3 (12.0)	10 (40.0)	13 (26.0)	5.46	2	0.07
Mean ± SD	3006.4 ± 233.7	3138.4 ± 289.3	3072.4 ± 268.7			

Abbreviation: *df* , degree of freedom; SD, standard deviation; X^2, chi-square test.

[a] Fisher's exact test.

Table 2 Median Volume of Breastmilk by Manual Expression of Postpartum Women in Domperidone and Placebo Groups

Time After Delivery	Median of Breastmilk Volume (mL) (min-max)		
	Domperidone (n = 25)	Placebo (n = 25)	*P* Value[a]
24-h (before receiving drugs)	2 (0-3)	1 (0-5)	0.22
48-h	8 (5-15)	3 (2-10)	< 0.05
72-h	15 (10-30)	10 (5-15)	< 0.05
96-h	35 (15-50)	15 (8-30)	< 0.05

[a] Mann-Whitney U test.

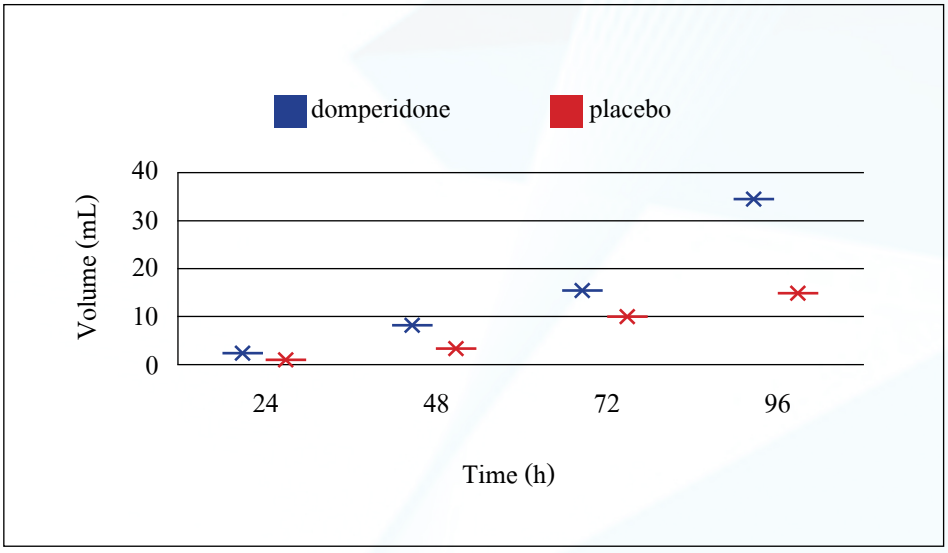


Figure 2 *Median Volume of Breastmilk in Domperidone and Placebo Group*

Discussion

In this study of randomized controlled trial, there were no significant differences in the characteristics of postpartum women and newborns between the two groups. This study found that the median volume of breastmilk of postpartum women in domperidone group significantly increased more than placebo group. This study was concordance with da Silva et al[16] who studied the efficacy of domperidone in augmenting milk production in mothers of premature newborns, they found that women in the domperidone group had more breastmilk volume and a significantly greater rised in the serum prolactin levels than in the placebo group. Wan et al[17] studied the efficacy of domperidone as a galactogogue in preterm mothers with insufficient milk supply, and its transfer into milk in Nedlands in 2008. They also found a significant increase in milk production in domperidone group.[17] In Thailand, Rachuso[19] studied the effectiveness of domperidone in augmentation of breastmilk production among mothers at term after cesarean deliveries in Nong Khai in 2009, and found that the median volume of collected breastmilk in domperidone group were significantly higher than in placebo group without any side effects. Jantarasaengaram et al[20] studied the effects of domperidone on augmentation of breastmilk production following caesarean delivery among full term postpartum women in Bangkok in 2012. They also found that there was significant increase in breastmilk production in the domperidone group compared to the placebo group.

Osadchy et al[18] published a systematic review and meta-analysis of the available data assessing the effect of domperidone on breastmilk production in women. They found that all studies showed statistically significant increase in breastmilk production following treatment with domperidone. No maternal or neonatal adverse events were observed in any of the trials.

The strengths of this study were a randomized double blinded controlled design. Outcomes were measured objectively. The other strength of this study was the collection of breastmilk with manual expression.

Compare to all other studies which used electric pump to collect breastmilk. This may be due to the fact that electric breast pump is more convenient, more powerful and can collect more breastmilk.[23] But electric breast pump is not natural with high pressure and cannot be afforded by most mothers. Collection of breastmilk by manual expression is more gentle, cheaper and more convenient. It may take a little practice to learn this skill, but it is worth the effort.

If women had master the skill, they can express milk at any time. In Uganda, although electric breast pumps provided the highest mean maternal milk volumes, many mothers obtained adequate feeding volumes for their infants' daily nutritional needs with the single non-electric manual breast pump and hand breastmilk expression.[24]

Contamination of breastmilk by methods of expression in another issue of interest. The study of Boo et al[25] is showed that when breastmilk was expressed in the hospital, there was no significant difference in contamination rates between breast pump and manual expression. When breastmilk was expressed at home, the rates of bacterial contamination by staphylococci ($P = 0.003$) and gram-negative bacilli ($P = 0.002$) were significantly higher in the breast pump group than the manual group. The rate of bacterial contamination of expressed breastmilk of mothers of very low birthweight infants was high, especially when expressed breastmilk was obtained by the breast pump especially when expression was carried out at home.

The weakness of this study was the lack of long term follow-up. Whether the significant increase in breastmilk production during the first four days after delivery may not be significant in terms of the success of breastfeeding in the long run if other nonpharmacological interactions were applied. But it is evident that domperidone can enhance breastmilk product in during the early stage of breastfeeding.

It is recommended that postpartum women who had delay or insufficient breast milk during the first few days can take domperidone to enhance breastmilk production. Long term follow-up of breastfeeding among mothers who took domperidone or placebo should be done. The appropriate duration of domperidone administration should also be studied.

In conclusion, domperidone effectively increased breastmilk production in the early stage of breastfeeding.

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Original Article/นิพนธ์ต้นฉบับ

ประสิทธิผลของยาดอมเพอริโดนต่อการเพิ่มน้ำนมในสตรีหลังคลอดโดยการบีบน้ำนมด้วยมือ ณ โรงพยาบาลเจริญกรุงประชารักษ์

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บทคัดย่อ

บทนำ: น้ำนมแม่เป็นอาหารที่ดีที่สุดของทารก และยาดอมเพอริโดนสามารถเพิ่มปริมาณน้ำนมแม่ได้ แต่การนำไปใช้ยังมีข้อถกเถียงกัน การศึกษาวิจัยในอดีตส่วนใหญ่นิยมใช้เครื่องปั๊มน้ำนมไฟฟ้าในการเก็บน้ำนมแม่ แต่การบีบน้ำนมด้วยมือมีข้อดีกว่าเครื่องปั๊มน้ำนมไฟฟ้าบางประการ

วัตถุประสงค์: เพื่อเปรียบเทียบประสิทธิผลของยาดอมเพอริโดนต่อการเพิ่มปริมาณน้ำนมในสตรีหลังคลอดโดยการประเมินด้วยการบีบน้ำนมด้วยมือ

วิธีการศึกษา: การศึกษาแบบทดลองโดยผู้เข้าร่วมวิจัยไม่ทราบชนิดของยา กลุ่มตัวอย่างได้แก่ สตรีหลังคลอดครรภ์ครบกำหนดที่คลอดปกติ ณ โรงพยาบาลเจริญกรุงประชารักษ์ ระหว่างวันที่ 1 กันยายน ถึง 30 พฤศจิกายน พ.ศ. 2558 จำนวน 50 คน ผู้เข้าร่วมวิจัยถูกสุ่มโดยวิธีจับสลากเข้าสู่กลุ่มที่ได้รับยาดอมเพอริโดนและยาหลอก กลุ่มละ 25 คน ทั้งสองกลุ่มได้รับยาครั้งแรกเมื่อครบ 24 ชั่วโมงหลังคลอด เก็บปริมาณน้ำนมโดยวิธีใช้มือบีบ การทดสอบสมมติฐานโดยใช้สถิติ Chi-square test และ Mann-Whitney U test โดยกำหนดค่านัยสำคัญทางสถิติที่ 0.05

ผลการศึกษา: ค่ามัธยฐานปริมาณน้ำนมแม่ที่บีบได้จากสตรีหลังคลอดกลุ่มที่ได้รับยาดอมเพอริโดนและกลุ่มยาหลอกเมื่อเวลา 24 ชั่วโมงหลังคลอด ก่อนได้รับยาเท่ากับ 2 และ 1 มิลลิลิตร ตามลำดับ และไม่มีความแตกต่างอย่างมีนัยสำคัญทางสถิติ หลังจากนั้นน้ำนมแม่เพิ่มขึ้นทั้งสองกลุ่มเมื่อเวลา 48 ชั่วโมงหลังคลอดปริมาณน้ำนมแม่เท่ากับ 8 และ 3 มิลลิลิตร เมื่อเวลา 72 ชั่วโมงหลังคลอด ปริมาณน้ำนมแม่เท่ากับ 15 และ 10 มิลลิลิตร และเมื่อเวลา 96 ชั่วโมงหลังคลอด ปริมาณน้ำนมแม่เท่ากับ 35 และ 15 มิลลิลิตร ตามลำดับ ความแตกต่างของปริมาณน้ำนมแม่หลังได้รับยาแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($P < 0.05$) โดยไม่พบอาการข้างเคียงใดๆ ของยาดอมเพอริโดนในสตรีหลังคลอดที่รับประทานยาดอมเพอริโดน

สรุป: ยาดอมเพอริโดนมีประสิทธิผลดีในการกระตุ้นการสร้างน้ำนมแม่ในระยะ 4 วันแรกหลังคลอดได้ดีกว่ายาหลอกอย่างมีนัยสำคัญทางสถิติ เมื่อวัดปริมาณน้ำนมจากการใช้มือบีบเต้านม

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