An evaluation of domperidone use for increased milk production in the immediate postpartum in breastfeeding women



Yolanda Lin, B.Sc.(Pharm.); Vanessa Paquette, B.Sc.(Pharm.), ACPR, Pharm.D; Roxane Carr, B.Sc.(Pharm.), ACPR, Pharm.D, BCPS, FCSHP

BACKGROUND

- Approximately 7000 deliveries occur at BC Women's Hospital (BCWH) each year.
- 26% of breastfeeding women in Canada stop due to low milk supply¹.
- Despite not being approved by Health Canada, domperidone is commonly used to stimulate milk production.
- 2011 BC study²:
- 32% and 19% of women with premature and term deliveries respectively were prescribed domperidone within 6 months postpartum.
- median dose of 80 mg per day
- Health Canada issued two safety warnings about domperidone^{3,4}
- 2012:
 - risk of cardiac adverse events e.g., serious ventricular arrhythmias and sudden cardiac death
 - recommended a maximum dose of 30 mg per day
- 2015:
- reiterated 2012 warning
- added contraindications including cardiac disease, and concomitant QTc-prolonging drugs, and CYP3A4 inhibitors
- It is unclear how the safety warnings impacted prescribing of domperidone for lactation.

OBJECTIVES

 To describe domperidone usage before and after the warnings from Health Canada in postpartum women at BCWH

Secondary objectives:

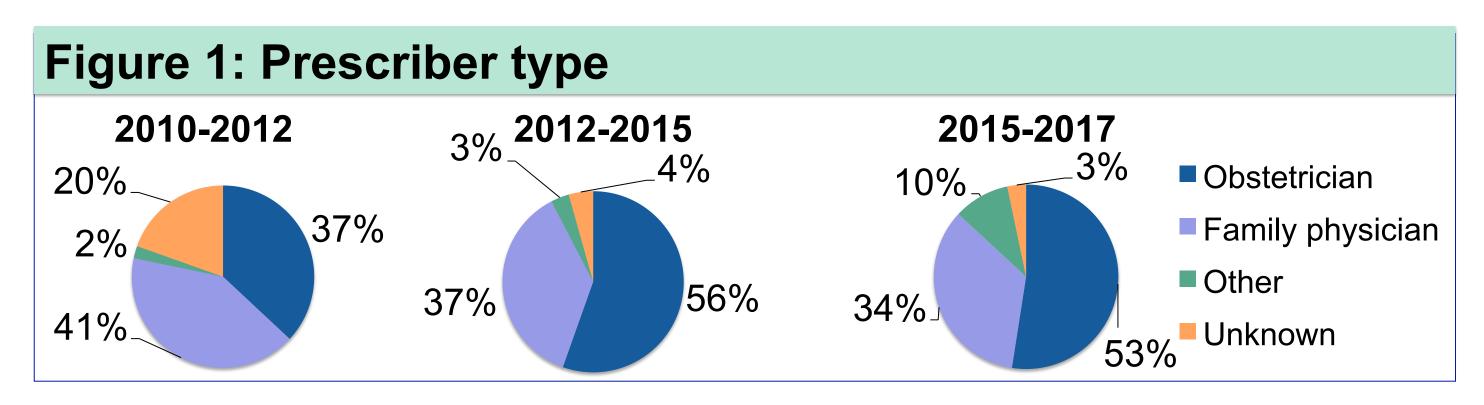
- Describe effectiveness and safety of domperidone for lactation
- Describe timing of domperidone initiation postpartum, type of prescriber, cardiac monitoring, and interventions by pharmacists

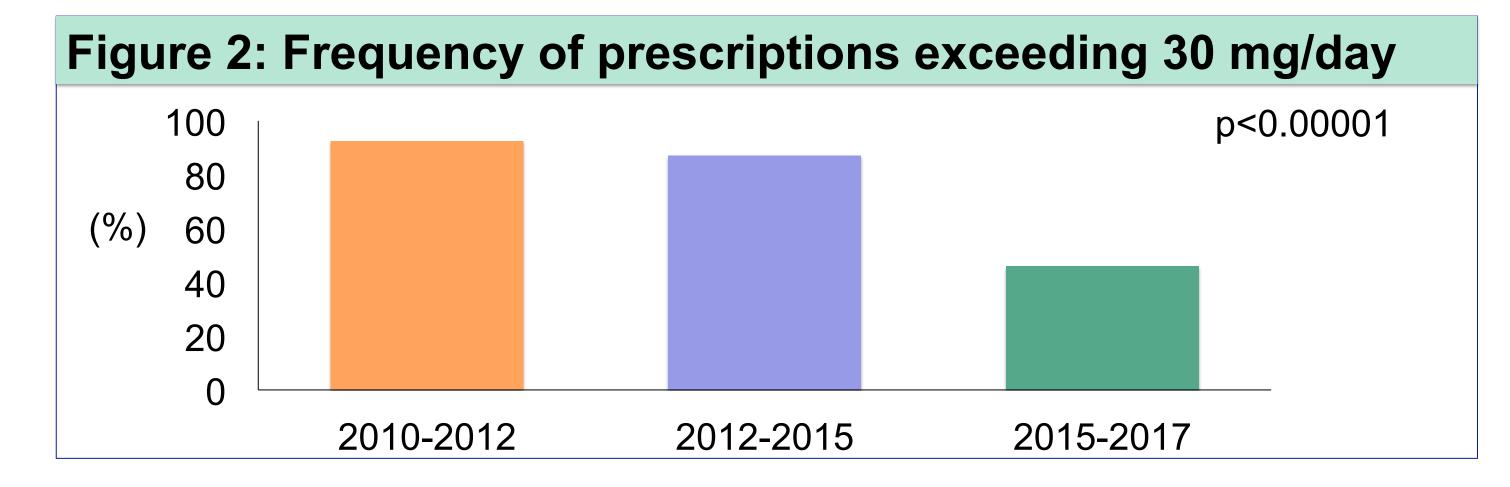
METHODS

- Design: Retrospective cohort health record review
- Inclusion: Postpartum women admitted to BCWH, prescribed domperidone for lactation, January 2010 to July 2017
- Frequency of prescribing: Number of domperidone prescriptions divided by admissions for the same time periods
 - Randomly sampled for each time period
- Adverse effect: Evaluated using the Naranjo Scale (scores ≥3 (possible) were included)
- Statistics: ANOVA, chi squared test, descriptive statistics
- Comparisons were made between the 1st and 3rd period and the 2nd and 3rd period
- Sample size: N=245 to detect a difference of 20%, significance level of 0.05 and power of 80%

RESULTS Table 1: Frequency of prescribing 2010-2012 2012-2015 2015-2017 P Frequency of prescribing (%) 1.4 1.0 0.4 < 0.00001</th> Number of prescriptions 204 191 61

Table 2: Characteristics					
	2010-2012 N=92	2012-2015 N=92	2015-2017 N=61		
Mean age, years (±SD)	34±5	34±5	34±5		
Primiparous, n (%)	24 (26)	26 (28)	17 (28)		
Preterm birth, n (%)	24 (26)	36 (39)	22 (36)		
Vaginal delivery, n (%)	43 (47)	40 (43)	24 (39)		
Single gestation, n (%)	78 (85)	78 (85)	54 (89)		
Median time postpartum domperidone was initiated, days (IQR)	2 (1-4.25)	2.5 (1-5.25)	2 (1-6)		
Lactation consultant (LC), n (%)	33 (36)	29 (32)	23 (38)		
Domperidone initiated pre LC, n (%)	14 (42)	8 (28)	10 (43)		
Pumping, n (%)	82 (89)	73 (79)	56 (92)		
Pharmacist intervention, n (%)	0	1 (2)	9 (15)		





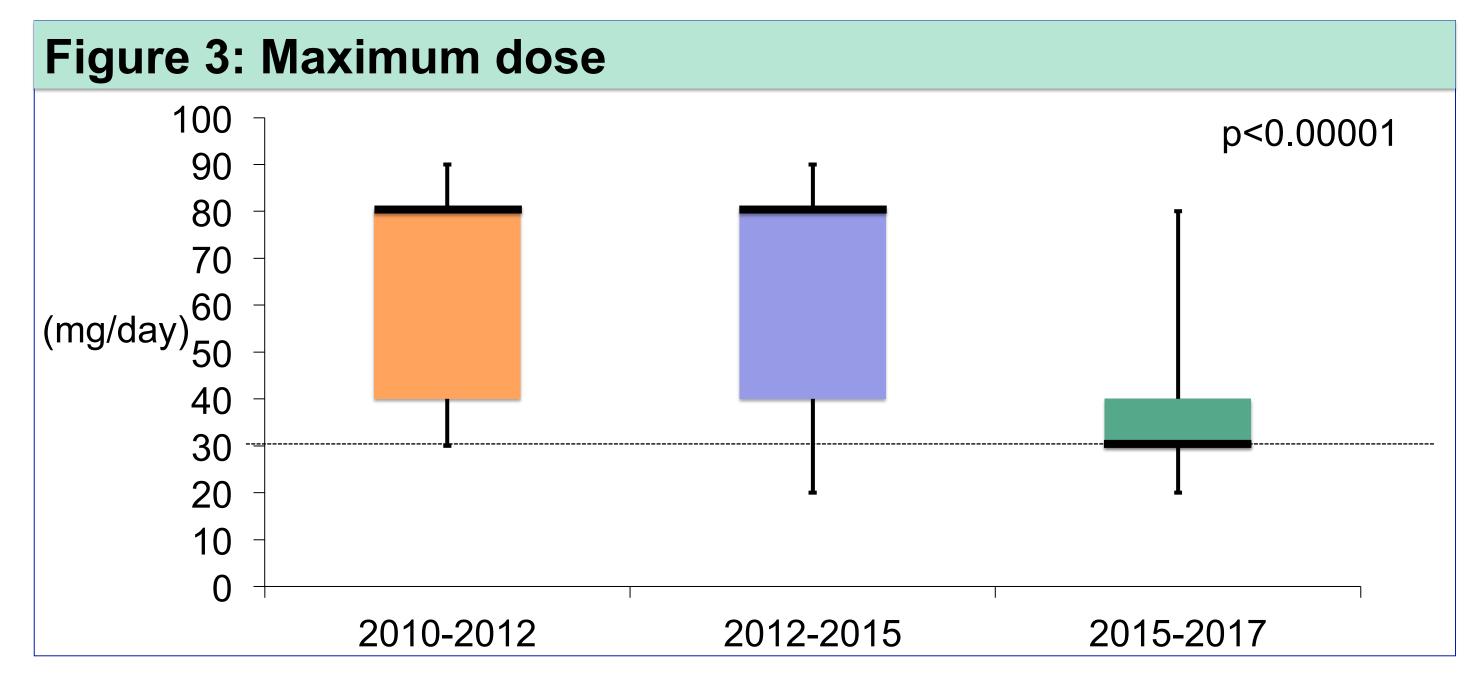


Table 3: Effectiveness 2010-2012 2012-2015 2015-2017 N=8 N=16 N=11 Increase in measured milk volume, n (%) (if reported) 8 (100) 10 (63) 11 (100)

	N=92	N=61
1 (1)	2 (2)	0
0	1 (1)	1(2)
16 (17) 9 (10) 4 (4) 4 (4)	16 (17) 11 (12) 2 (2) 4 (4)	6 (10) 3 (5) 0 4 (7)
	0 16 (17) 9 (10) 4 (4)	0 1 (1) 16 (17) 16 (17) 9 (10) 11 (12) 4 (4) 2 (2) 4 (4) 4 (4)

Table 5: Safety monitoring				
	2010-2012 N=92	2012-2015 N=92	2015-2017 N=61	
ECG, n (%)	2 (2)	6 (7)	7 (11)	
Adverse effect, n (%)	0	4 (4)	0	
- Chest pain, n (%)		1 (1)		
- Lightheadedness, n (%)		1 (1)		
- Dizziness, n (%)		1 (1)		
- Diarrhea, n (%)		1 (1)		

LIMITATIONS

- Retrospective chart review
- Increase in milk volume is in correlation with the time period of natural increase in milk production
- In the immediate postpartum period only

CONCLUSION

- Frequency of prescribing domperidone for lactation and dosage prescribed have decreased since the Health Canada warnings.
 However, there was a lag between the warnings and change in practice.
- The initiation of domperidone often occurred prior to the natural increase in milk production.
- Unable to assess the effectiveness and safety of domperidone for lactation.
- Further studies needed to assess the long-term effectiveness and safety of domperidone for lactation.

REFERENCES

- 1. Gionet L. Breastfeeding Trends in Canada [Internet]. Statistics Canada; 2015 [cited 2017 Jul 25]. Available from: http://www.statcan.gc.ca/pub/
- 82-624-x/2013001/article/11879-eng.htm
- Smolina K, Morgan SG, Hanley GE, Oberlander TF, Mintzes B. Postpartum domperidone use in British Columbia: a retrospective cohort study CMAJ Open [Internet]. 2016 [cited 2017 Jul 25];4(1):E13–9. Available from: http://cmajopen.ca/cgi/doi/10.9778/cmajo.2015006716
- 3. Health Canada, Summary Safety Review DOMPERIDONE Serious abnormal heart rhythms and sudden death (cardiac arrest) [Internet]
 Ottawa: Health Canada; 2015 [cited 2017 Jul 25]. Available from: http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2015/43423a-
- 4. Health Canada, Domperidone Maleate Association with Serious Abnormal Heart Rhythms and Sudden Death (Cardiac Arrest) For Health Professionals Recalls and safety alerts [Internet]. Ottawa: Health Canada; 2012 [cited 2017 Sep 7]. Available from: http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2012/15857a-eng.php







