

DSEN ABSTRACT

Use of Domperidone and Risk of Serious Cardiac Events in Postpartum Women

A study conducted by the Canadian Network for Observational Drug Effect Studies (CNODES)

Summary

- The incidence of cardiac death and ventricular tachyarrhythmia is very low in postpartum women.
- Although this potential increased risk is low and could not be confirmed in this large study, it should be discussed when considering treatment options for individual patients.

Key messages

- Domperidone use among postpartum women increased substantially between 2004 and 2017.
- Domperidone users had a higher frequency of cardiac death or ventricular tachyarrhythmia than non-users. Due to the rarity of these events and lack of statistical adjustment, these results should be interpreted with caution.

Project Lead & Team

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Link to publication

- Moriello et al. CMAJ Open 2021. doi: [10.9778/cmajo.20200084](https://doi.org/10.9778/cmajo.20200084)

What is the issue?

- Domperidone, an antiemetic and prokinetic drug, is often used off-label to promote lactation among postpartum women with insufficient breast milk supply.
- Safety concerns have been raised that domperidone could potentially increase the risk of sudden cardiac death (SCD) and ventricular tachyarrhythmia (VT), with Health Canada advisories in 2012 and 2015.

What was the aim of the study?

- This study, conducted by CNODES, evaluated the impact of the Health Canada advisories on the use of domperidone and assessed its safety in postpartum women.

How was the study conducted?

- CNODES conducted a retrospective cohort study using administrative health databases from five Canadian provinces with records of close to 1.2 million postpartum women.
- Domperidone utilization postpartum, rates of initiation, and average dose and duration were estimated. The impacts of the 2012 and 2015 advisories were assessed via interrupted time-series analysis.
- Crude rate ratios and differences were estimated for the composite endpoint (VT or SCD) and secondary outcomes (VT, SCD, and all-cause mortality) for use versus non-use of domperidone, postpartum.

What did the study find?

- The cohort included 1,190,987 pregnancies, with 11.5% exposed to domperidone.
- Domperidone use increased among postpartum women between 2004 and 2017, although variations existed across provinces.
- The 2012 Health Canada safety advisory was followed by a reduction in prescribing across provinces, whereas the 2015 advisory had a more modest impact on prescribing practices, despite its stronger content.
- A crude analysis suggests that domperidone may increase the risk of the composite endpoint of VT or SCD (rate ratio: 2.01; 95% CI: 0.47, 8.60; rate difference per 100,000 person-years: 3.7; 95% CI: -6.7, 14.1). A safety analysis with statistical adjustment was not feasible due to the rarity of these adverse events.

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