Canada's Drug Agency
L'Agence des médicaments du Canada
Drugs. Health Technologies and Systems. Médicaments, technologies de la santé et systèmes.

CoLab Network

Summary Report

Utilization of Antidiabetic Drugs During Pregnancy

Report Authors

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This study was conducted by the Canadian Network for Observational Drug Effect Studies (CNODES) the through the Post-Market Drug Evaluation (PMDE) CoLab Network.

Executive Summary

Exposure to antidiabetic drugs (ADDs) during pregnancy is increasing. As the prevalence of diabetes and gestational diabetes mellitus (GDM) rise and treatment guidelines change, there is a need for current data on the use of ADDs during pregnancy in Canada.

We analyzed data from 249,063 unique live birth and stillbirth pregnancies (among 166,529 individuals) from 2012 to 2022 from Manitoba, Ontario, and Saskatchewan. Overall, 2.0% of individuals had pre-existing diabetes and 12.6% had GDM without pre-existing diabetes. Insulin was used in 3.8% of pregnancies, while metformin was used in 3.1% and sulfonylureas in 0.3% at some point during pregnancy. Notably, insulin use increased from the first trimester to the third trimester, and ADD use increased with maternal age and over the course of the study period.

Our findings indicate a continued increase in the percentage of pregnancies exposed to ADDs, including newer therapies for which there are limited safety data, emphasizing the need for ongoing safety monitoring and real-world studies on ADD use during pregnancy in Canada.

Background

The prevalence of diabetes and GDM have increased over the past 2 decades, leading to increasing exposure to ADDs during pregnancy. Insulin is the primary (first line) treatment for both pre-existing diabetes and GDM, whereas metformin or sulfonylureas, such as glyburide, are second-line treatments. Metformin is the only oral ADD recommended for use during pregnancy; glyburide is generally for patients who cannot take insulin and where metformin alone is not effective.

In January 2020, a study by the US FDA Sentinel Initiative examined ADD use during pregnancy from 2001 to 2013, showing trends in diabetes treatment among pregnant women with and without pre-existing diabetes. A Canadian study conducted in Alberta from 2009 to 2014 found that the percentage of pregnant women with GDM prescribed an ADD had increased from 25% to 31.4% by 2014.

There is a growing emphasis on monitoring the use and safety of ADDs in pregnancy, and the data from these studies are now outdated.

Policy Issue

As diabetes during pregnancy rises and treatment guidelines change, there is a need for current data on the use of ADDs during pregnancy in Canada.

Policy Question

1. What is the utilization of ADDs during pregnancy in Canada?

Objective

> This is 1 of several FDA Sentinel Common Data Model (CDM) demonstration projects. This project demonstrates the feasibility of replicating an FDA Sentinel analysis using Canadian administrative health data transformed into the Sentinel CDM.

Our objective was to conduct a cohort study to document the use of ADDs among pregnant persons in Canada.

Findings

We identified 249,063 unique pregnancies among 166,529 individuals across 3 provinces (Manitoba, Ontario, and Saskatchewan), from 2012 to 2022. In total, 3,308 individuals (2.0%) had pre-existing diabetes, and 21,031 individuals (12.6%) had GDM without pre-existing diabetes.

Overall, 3.8% of pregnancies were exposed to insulin, 3.1% to metformin, and 0.3% to a sulfonylurea. Insulin use increased during pregnancy, rising from 1.3% in the first trimester to 3.7% in the third trimester. As expected, ADD use increased with maternal age and during the study period.

Among the 4,058 pregnancies with pre-existing diabetes, 86.0% were exposed to insulin, 50.4% to metformin, and 15.4% to a sulfonylurea. Insulin use rose sharply throughout pregnancy, while the use of other ADDs remained stable. The number of people taking metformin and sulfonylureas increased with maternal age, but insulin use stayed high (85% to 88%) across all age groups.

Among the 24,448 pregnancies with GDM, 23.4% were exposed to insulin and 18.9% to metformin. The use of both medications increased sharply throughout pregnancy and over the study period but varied little with maternal age.

Strengths and Limitations

To our knowledge, this is the first multiprovincial, population-based study of ADD use during pregnancy in Canada, and the first Canadian project to use the FDA Sentinel CDM to study drug use during pregnancy.

Strengths of this study include its use of population-based data from multiple provinces and its inclusion of data from both publicly and privately insured residents. We also classified pregnancies according to whether there was pre-existing diabetes or GDM.

However, the study also has limitations. As in any study of administrative data, there is risk for misclassification, including the precise timing of when pregnancies began, the presence of diabetes and other conditions, and whether ADDs dispensed just before conception continued during pregnancy.

Implications for Policy-Making

We successfully demonstrated the feasibility of replicating the FDA Sentinel analysis using Canadian data transformed into the Sentinel CDM.

Our findings confirm that a growing percentage of pregnancies are being exposed to ADDs in Canada, including to newer therapies for which there are limited safety data. This highlights the importance of ongoing surveillance and targeted studies of the real-world use and safety of ADDs during pregnancy.

Considerations

Post-Market Drug Evaluation (PMDE) projects aim to produce health policy issue evidence and are not linked to a recommendation.

This work was intended to inform health policy. Clinical questions regarding the use of antidiabetic drugs should be directed to a health care professional.

For more information on CoLab and its work, visit the **CoLab website**.

For the full scientific report, visit:

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This work was conducted by the Canadian Network for Observational Drug Effect Studies (CNODES) through the Post-Market Drug Evaluation CoLab Network. It was supported by Canada's Drug Agency (CDA-AMC) and its Post-Market Drug Evaluation Program through funding provided by Health Canada.

CDA-AMC is a pan-Canadian health organization. Created and funded by Canada's federal, provincial, and territorial governments, we're responsible for driving better coordination, alignment, and public value within Canada's drug and health technology landscape. We provide Canada's health system leaders with independent evidence and advice so they can make informed drug, health technology, and health system decisions, and we collaborate with national and international partners to enhance our collective impact.

CoLab is a pan-Canadian network of experts in applied research, scientific methods, and data analysis. CoLab members work with the Post-Market Drug Evaluation Program to produce credible and timely evidence on postmarket drug safety and effectiveness.

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