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Pregnancy rates and outcomes for women using oral isotretinoin in Australia: A population-based study

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Abstract

Background and Aims: Isotretinoin is commonly used to treat acne, however it is highly teratogenic. Previous Australian studies have found isotretinoin-contraception co-prescribing rates are low. The aim of this study was to investigate the rate of isotretinoin-exposed pregnancies, and pregnancy outcomes.

Design and Methods: This was a population-based observational study using data from the Medicines Intelligence Data Platform. All women aged 18-50 years and residing in New South Wales, Australia between 2003 and 2020 were included. Pregnancies, pregnancy outcomes, and isotretinoin dispensings were established using linked hospital admissions, emergency department visits, Medicare, and pharmaceutical benefits scheme claims data. Isotretinoin-exposed pregnancies were defined as pregnancies with an isotretinoin dispensing in the month prior to conception, or between conception and the end of the pregnancy. Pregnancy outcomes were defined as miscarriage, termination of pregnancy, or birth. Rates and relative risk of pregnancy outcomes compared with non-exposed pregnancies were determined.

Results: Of women who used isotretinoin, 63 090 pregnancies occurred, with 596 exposed to isotretinoin, an average of 33 isotretinoin-exposed pregnancies per year. Of exposed pregnancies, approximately 80% of pregnancies ended in miscarriage or termination of pregnancy, and 20% ended in a birth. The risk of miscarriage (RR 1.46; 95% CI 1.36-1.57) and termination of pregnancy (RR 4.95; 95% CI 4.31-5.67) was

higher in isotretinoin-exposed pregnancies compared to non-exposed pregnancies, and the risk of birth was lower (RR 0.34; 95% CI 0.29-0.40).

Conclusions: Despite recommendations for pregnancy prevention when using isotretinoin, an average 33 isotretinoin-exposed pregnancies occur in NSW each year, with poor pregnancy outcomes.