

Pyridoxine-doxylamine drug safety data lacking

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(Medical Xpress)—The most commonly prescribed drug for pregnant women suffering from morning sickness in their first trimester does not prevent birth defects even though drug safety data says it does, according to research out of St. Michael's Hospital

The [drug](#) pyridoxine-doxylamine is so popular that it has been prescribed in 33 million women worldwide. It's used in half of Canadian pregnancies that result in live births. The Society of Obstetricians and Gynecologists of Canada lists it as the standard of care for women with nausea and vomiting "since it has the greatest evidence to support its efficacy and safety."

"When prescribing the drug to one of my patients she had a lot of questions," said Dr. Nav Persaud, a family and community medicine physician at St. Michael's Hospital. "I found myself making strong statements about its safety and realized that I should know more."

He went back and looked at all of the data that led to pyridoxine-doxylamine's top safety ranking. Dr. Persaud found that the number of patients that were part of the original studies wasn't more than 200,000, as previously stated, but was closer to 130,000. The drug's safety data – numbers that are still cited and used by clinicians today – said that the use of the drug decreased the risk of [birth defects](#) such as limb malformation or [congenital heart defects](#).

"The numbers didn't add up," said Dr. Persaud, who is also a scientist in

the hospital's Li Ka Shing Knowledge Institute . "Despite claims that it reduced the risks of birth defects, data was much closer to natural average of birth defects – between three and five per cent of all pregnancies."

The commentary, published today in *Journal of Obstetrics and Gynaecology Canada*, examines the primary studies that formed the basis of the Canadian guideline recommendations for pyridoxine-doxylamine.

After reviewing the reports and studies, Dr. Persaud said he found the evidence lacking.

"The guidelines should change," said Dr. Persaud.

Anti-nausea alternatives exist and are already used more frequently in other parts of the world. Pyridoxine, without doxylamine, has stronger safety data supporting it, but is prescribed less often.

Dr. Persaud said he was concerned that some patients may still prefer taking pyridoxine-doxylamine because they used it in previous pregnancies or because they've read about its [safety](#) and know the drug is considered standard of care.

"Vitamin B6 is similarly effective at treating nausea and vomiting in pregnancy," said Dr. Persaud. "I've changed my practice and now recommend alternatives to pyridoxine-doxylamine that have been demonstrated to be safe."

Provided by St. Michael's Hospital

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