Medication for Gravid and Nursing Dental Patients

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KEYWORDS

• Dentistry • Pregnancy • Nursing • Drugs • Medications • Lactating • Risk

KEY POINTS

- There is a new labeling system for the safety of medications in pregnant and lactating patients.
- Available data related to the safe use of medications in pregnant and lactating patients are constantly changing.
- The benefits of using a medication must always be weighed against its risks for that patient.

The topics the authors address in this article are in many ways both broad and narrow. The broadness of this topic is clear when one considers the intersection of 2 of the more complex areas in medicine: pharmacology and obstetrics. At the same time when considered in the format of a review article, one can only hope to provide a snapshot of information, which will inevitably change over time. The information provided here is for reference only and the authors suggest consultation with the patients' obstetrician (or pediatrician for breastfeeding patients) for up-to-date and patient-specific information on a case-by-case basis.

The effect of a medication on a developing fetus depends on many factors. One medication may have a variety of different adverse effects depending on fetal development at the time it is administered. Other considerations include molecular weight of a drug and whether it is lipid or water soluble. Maternal factors, such as altered gastric absorption, may also play a roll.

There are very few known teratogenic medications, and most contraindications to the use of medicaments in gravid patients are relative contraindications only. In other words, rarely is it necessary to prescribe an alternative medication for pregnant patients. The establishment of teratogenicity depends on the meeting of several criteria. Review of these criteria is irrelevant for this article. The reader may refer to Buhimschi and Weiner[1] "Medications in Pregnancy and Lactation: Part 1" for more information. It

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is important to realize, however, that one of the reasons that there are so few established teratogens is that it is difficult to prove for a particular drug that all criteria have been met for teratogenicity.

The publication of this article coincides with a new labeling system recently instituted by the Food and Drug Administration (FDA). Doctors *and patients* are both familiar with the grading system instituted by the FDA in 1979 for indicating drug safety in pregnant patients (**Table 1**).

There are several problems with this labeling scheme (**Box 1**). Firstly it oversimplifies the decision-making process for prescribing medications to pregnant patients. By narrowly defining medications within the framework of this system, many practitioners feel limited to prescribing medications in the A and B categories only. Indication for use of a category C drugs often triggers a medical clearance request to the obstetrician often delaying care of patients.

Secondly, when viewed through a medical-legal lens, this system provides easy fodder for plaintiff's attorneys to clearly present to a jury supposed evidence of a dentist's deviation from the standard of care.

Finally, assignment of a medication to a category often becomes a lifetime sentence, as said assignment is seldom updated when new evidence becomes available. This point becomes clear when considering the X designation assigned to triazolam, which has been considered safe for use during pregnancy since the 1990s.

Fortunately, the FDA has recently set forth new guidelines for pregnancy and lactation labeling of medications.[2,3] This new labeling scheme went into effect on June 30, 2015 and includes sections for both pregnancy and lactation as well as the new

Table 1
Previous FDA drug labeling for pregnancy

Category	Description
A	Adequate, well-controlled studies in pregnant women have not shown an increased risk of fetal abnormalities to the fetus in any trimester of pregnancy.
B	Animal studies have revealed no evidence of harm to the fetus; however, there are no adequate and well-controlled studies in pregnant women. *OR* Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester.
C	Animal studies have shown an adverse effect, and there are no adequate and well-controlled studies in pregnant women. *OR* No animal studies have been conducted, and there are no adequate and well-controlled studies in pregnant women.
D	Adequate well-controlled or observational studies in pregnant women have demonstrated a risk to the fetus. However, the benefits of therapy may outweigh the potential risk. For example, the drug may be acceptable if needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective.
X	Adequate well-controlled or observational studies in animals or pregnant women have demonstrated positive evidence of fetal abnormalities or risks. The use of the product is contraindicated in women who are or may become pregnant.

From FDA use-in-pregnancy ratings. Available at: http://www.perinatology.com/exposures/Drugs/FDACategories.htm. Accessed July 29, 2015; with permission.