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An evidence-based approach to dermatological medication risk counseling in pregnancy

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Abstract

Introduction & Objectives: As many as 40-80% of women receive at least one prescription drug during pregnancy. It is, therefore, crucial that pregnant women are offered appropriate counseling regarding the potential teratogenicity of medications. In this review, a new evidence-based medicine approach to evaluating medication risk is compared to international pregnancy classifications, providing clinicians with a powerful counseling tool.

Material & Methods: A search of Medline database of articles pertaining to pregnancy classifications for medication risk was conducted.

Results: Three of the most widely accepted international pregnancy classifications are the FASS (Swedish Catalogue of Approved Drugs), the US FDA (Food and Drug Administration), and the Australian system. One study compared the US and European systems, interviewing 934 physicians and pharmacists, and revealed that the European system was favored largely over the FDA system because: (1) The US focuses too much on animal data. (2) There is a readiness of the US system to label medications new to the market as class B (safe in pregnancy). Besides the FASS and FDA, there are alternative references to guide clinicians in choosing appropriate drug therapy in pregnancy. In the book, "Drugs During Pregnancy and Lactation: Treatment Options and Risk Assessment," a consortium of physicians active in teratological societies in the US and Europe, created a highly regarded system focused on an "Evidence-Based Medicine" (EBM) approach to counseling and advising patients. The EBM system divides pregnancy into three time intervals: the embryonic period (first trimester), fetal period (second and majority of third trimester), and peripartum (last month of pregnancy). There are five categories for assessment at each pregnancy time frame: 1 (drug of first choice), 2 (drug of second choice), S (single dose/low dosages are tolerable), T (potentially teratogenic/toxic), and C (contraindicated).

Conclusions: This new EBM system is a preferable counseling tool for three reasons. First, it highlights differences of use/concern within a pregnancy. Second, it takes into consideration how long a medication has been used and what are available supporting data regarding safety. Third, it tends to be more reasonable and coincide with common sense. For example, most consider hydrocortisone to be a safer option than infliximab for psoriasis, but the FDA system indicates infliximab is a safer choice than hydrocortisone, likely due to paucity of animal studies. We hope that access to this comparison of safety classifications will provide clinicians with a powerful tool to use when counseling women of childbearing age who are pregnant or considering pregnancy in the future.