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Classification System of Drugs' Risk during Pregnancy

Stephanie Viroga*

University of the Republic, Uruguay

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*Corresponding author: Stephanie Viroga, Gynecology Clinic B, University of the Republic, Montevideo, Uruguay, Email: stephyviroga@gmail.com

Abstract

The exposure to medicines during pregnancy have a potential risk of teratogenic effects, to facilitate prescription classifications have been created to advice prescribers. The most popular internationally used is the Food and Drugs Administration one. This classification was based in five categories based on evidence of risk, or no risk in pregnancy controlled and animal studies. Multiple limitations have been described for this classification so in 2015 the FDA stated that regulations for information on risks in pregnancy would be modified with narrative descriptions of drug usage during pregnancy and lactation, adding as a new section the potential reproductive risks for both men and women.

Keywords: Risk classification; Pregnancy

Introduction

During pregnancy there is a high exposure to medicines, although the prevalence is heterogeneous there are some countries with up to 90% usage [1]. This period in women's life is classically considered to be a risk for drugs due to the potential teratogenic effects, the drugs usage during pregnancy is causing 1% of teratogenesis [2].

To facilitate prescription during pregnancy, classifications have been created to advice the prescriber on possible risks and to facilitate the selection process. Even though there are different classifications, there are some inconsistencies among them. According to a study published in the Drug Safety 2000, only 1 in 4 drugs were classified with a similar risk, category three, classification systems. Differences were attributed to the disparity between definitions, as well as the disparity of literature and sources consulted to determine the risk of drugs [3].

Discussion

Among these classifications, the most popular internationally is the Food and Drug Administration (FDA), an American classification launched in 1979, in response to the tragedy caused by the usage of thalidomide in pregnant women [4]. Although it is an FDA regulation, it has a well known global impact. There are other risk classifications of drug usage in pregnancy that have attempted to correct some limitations of the FDA classification, such as the Australian classification [5], but with a lower global impact.

The FDA classification is based on 5 categories (A, B, C, D, X) and the designation for each category is based on evidence of risk, or no risk in pregnancy controlled and animal studies [4]. Multiple limitations have been described for this classification, for example the fact that it is a hierarchical classification, in increasing order of estimated risk where Category A drugs are considered to be safe in pregnancy, and those in category X are contraindicated, but this does not mean that a drug classified as C is safer than one classified as D. Other limitations described are the fact that it does not consider clinical experience of medication use, does not evaluate frequency, intensity or type of fetal effects, performs extrapolation of animal studies, is not specific and does not take into account the period of exposure on the drug or dose. To this 1979 classification, the FDA between 2006-2008 [6] regulates to add in the drug prospects a classification of narrative risk divided in three sections "pregnancy", "Labor and delivery," and "Nursing mothers", but maintaining the categorization of previous risk.

In 2015 the FDA stated that from that year, regulations for information on risks in pregnancy would be modified. The final regulation promotes the removal of pregnancy risk categories A, B, C, D and X and this should include a summary of the risks of using the drug during pregnancy and lactation, discussion of evidence supporting this data, and relevant information so that the prescriber can make a rational prescription in this population [7]. Regarding the removal of risk categories in pregnancy, the experience and the comments received have shown for some

time now that these categories are confusing and do not clearly show differences in fetal risk, is added the misinterpretation of the medical personnel since a prescription is usually made based on the categories instead of a correct compression of the information that granted that category to the medicine. In 2009, the FDA conducted a study (Mental Models Research study) [8] a type of study that through a structured interview evaluates the practices that are used to make decisions in order to understand the drug selection process at the time of prescribing at pregnancy and lactation during chronic pathologies and thus to evaluate how doctors used the classification of risk. The results were consistent with the comments the agency was already receiving. For example, research showed that pregnancy categories were invoked by many health professionals almost to the exclusion of other information found in the prospectus. It also showed that providers often relied on secondary sources to find the pregnancy category of a particular product instead of using the approval datasheet. The FDA then considers that a narrative structure is better than a categorical system, and that such classification is not consistent with the need to communicate fetal risks

The proposed new regulation [7] deals with the narrative description of drug usage during pregnancy and lactation, adding as a new section the potential reproductive risks for both men and women. The agency is specific in what should be included in each of these sections, in a descriptive way. In the pregnancy section should be included whether or not there is a register of exposure during pregnancy to this drug with contact information of said record, either to obtain information or as enrollment of patients; whether is demonstrated that the drug does not have systemic absorption in the section of risks should only be marked this fact, since if it is not detected in blood is not expected fetal exposure to the drug, and if it has systemic absorption should include all aspects relevant risk factors for adverse effects with information on potential maternal-fetal-neonatal risks as well as effects at birth and possible dose adjustments during pregnancy and postpartum. Whether, there is evidence at both the human and animal level the conclusions should be based on human information prior to

animal. During the lactation period, should be included (if the drug has systemic absorption): Information about the drug in breast milk, Effects on the quantity of milk production and its implications on infant feeding, possible effects on the infant with a risk-benefit assessment unless lactation is contraindicated in the drug administration and information to minimize infant exposure to the drug and interventions to monitor exposure. The section on potential risks on male and female should include relevant information on the need to rule out a pregnancy prior to the usage of a drug or ensure contraception for it, as well as information on side effects on fertility.

Conclusion

This non-categorical description of drug usage risk during pregnancy and lactation tries to solve limitations of categorical classification and the difficulty of its application, in order to analyze the risk-benefit balance that allows us to get a rational selection.

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