Clinical Therapeutics/Volume ▮, Number ▮, 2016

Physicians' Perception of Teratogenic Risk and Confidence in Prescribing Drugs in Pregnancy—Influence of Norwegian Drug Information Centers

Tina Bakkebø, PharmD[1]; Sofia Frost Widnes, PharmD, PhD[1,2]; Synnøve Stubmo Aamlid, PharmD[2,*]; and Jan Schjøtt, MD, PhD[1,2,3]

[1]Regional Medicines and Pharmacovigilance Centre (RELIS Vest), Haukeland University Hospital, Bergen, Norway; [2]Department of Clinical Science, Faculty of Medicine and Dentistry, University of Bergen, Bergen, Norway; and [3]Section of Clinical Pharmacology, Laboratory of Clinical Biochemistry, Haukeland University Hospital, Bergen, Norway

ABSTRACT

Purpose: Clinical decision support provided by drug information centers is an intervention that can ensure rational drug therapy for pregnant women. We have examined whether physicians' teratogenic risk perceptions and confidence in prescribing drugs to pregnant women is altered after advice from the Norwegian drug information centers, Regional Medicines and Pharmacovigilance Centres i Norway (RELIS).

Methods: Physicians who consulted RELIS for advice on patient-specific drug use in pregnancy from November 2013 to April 2014 completed questionnaires before and after receiving the advice. A scale from 1 to 7 was used to rate confidence in prescribing and perception of teratogenic risk. The lower part of the scale represented a low perception of teratogenic risk and a high confidence in prescribing a drug in pregnancy. The data were analyzed using a mixed linear model.

Findings: A total of 45 physicians participated in the study and they assessed 64 drugs or categories of drugs. Advice from RELIS increased confidence in prescribing, with a statistically significant mean change on the scale from 4.1 to 2.9. The assessment of teratogenic risk was reduced after advice from RELIS, with a mean change from 3.2 to 2.5, though this was not significant. A subgroup of 26 physicians completed questionnaires both before and after advice from RELIS and assessed a total of 32 drugs or categories of drugs. In 94% of these assessments, advice from RELIS altered the physician's confidence in prescribing. Perception of teratogenic risk was altered in 78% of the assessments.

Implications: Our results show that physicians' perception of teratogenic risk and confidence in prescribing drugs to pregnant women is influenced by advice from Norwegian drug information centers. (*Clin Ther.* 2016;▮:▮▮▮–▮▮▮) © 2016 Elsevier HS Journals, Inc. All rights reserved.

Key words: attitude of health personnel, drug information services, pregnancy, prescription drugs, risk perception, teratogenic drugs.

INTRODUCTION

Pregnant women, like women in general, may need to use drugs in order to manage acute and chronic disease or pregnancy-induced symptoms.[1] A multinational study found that >80% of pregnant women use a drug at some point during their pregnancy.[2] Before deciding on drug use in pregnancy, physicians need to assess whether the potential benefits for the mother outweigh the risks to the fetus.[3]

The baseline risk for major birth defects is 2%–4%, but <1% of these defects can be attributed to maternal use of drugs.[3,4] However, pregnant women generally attribute unrealistically high teratogenic risks to the use of drugs.[5] Several studies have shown that this overestimation of risk also applies to

*Current affiliation: Apotek 1 Galleriet, Bergen, Norway.

Accepted for publication February 17, 2016.
http://dx.doi.org/10.1016/j.clinthera.2016.02.018
0149-2918/$ - see front matter

physicians.[6–10] Some theories about what may influence teratogenic risk perception among physicians have been suggested. Only a few drugs are known human teratogens and, for most drugs, the knowledge of their teratogenic potential is not well established.[4] This scientific uncertainty may act to increase the physicians' perception of teratogenic risk.[11] Furthermore, the way teratogenic information is presented has also been shown to influence the risk perception among physicians.[6,10] Underuse of specialized information sources regarding teratogenicity of drugs may also contribute to the overestimation of risk.[8]

Teratogen information services and drug information centers (DIC) are among the specialized information sources that provide patient-specific advice to physicians seeking guidance for counseling pregnant women. Such decision support provided by DIC is found to influence both therapeutic decisions in general,[12,13] and those regarding pregnancy.[14] Importantly, prevention of unnecessary abortion has been reported.[14] Nevertheless, we do not know if this influence regarding drug use in pregnancy concerns altered risk perception and confidence in prescribing. To the best of our knowledge, this has not been reported. The aim of this study was therefore to examine whether physicians' teratogenic risk perception and confidence in prescribing drugs to pregnant patients is altered by the Norwegian DIC, Regional Medicines and Pharmacovigilance Centres i Norway (RELIS). The term *advice* is used throughout to include both information and advice provided by RELIS to obtain clinical decision support. The null hypothesis was that advice from RELIS did not change the physicians' assessment of teratogenic risk and confidence in prescribing drugs to pregnant women.

METHODS

RELIS is a network of 4 Norwegian DIC. The centers are localized at university hospitals, where pharmacists and clinical pharmacologists answer inquiries from health care professionals. The inquiries are typically patient related and concern clinical problems for which physicians' own experience and use of drug information sources fail to provide a sufficient solution. The majority of inquiries are submitted electronically, either through a web-based question form or via e-mail, but some inquiries are also communicated via telephone. In 2014, 16% of 3,070 inquiries to RELIS concerned drug use during pregnancy and breastfeeding.

All physicians who consulted RELIS for information on patient-specific drug use in pregnancy from November 2013 to April 2014 (a total of 145 days) were asked to complete two questionnaires. Questionnaire 1 (Q1) was to be completed before the physician's inquiry was answered by RELIS, and questionnaire 2 (Q2) was answered after the physician received the answer from RELIS. Electronic questionnaires (www.easyquest.com) were sent by e-mail for written inquiries (e-mail or web-based question form), together with an information letter. For telephone inquiries, the information and questionnaires were presented orally and completed by an employee at RELIS. For written answers to telephone inquiries, Q1 was filled in during the telephone consultation, while Q2 was sent by e-mail.

For each drug (such as citalopram), or category of drugs (such as selective serotonin reuptake inhibitors), for which the physician requested information on, the following 2 questions were repeated before and after the physicians received advice from RELIS: (1) How teratogenic do you consider this drug or category of drugs to be? (scale from 1: never teratogenic to 7: always teratogenic). (2) How confident are you in prescribing this drug or category of drugs to a pregnant woman? (scale from 1: very confident to 7: not at all confident).

Only the end points of the scale were defined and it was only possible to choose whole numbers. The physicians were also asked to provide information on their sex, workplace, and work experience.

The questionnaires were anonymous, but the physicians were asked to provide their e-mail address in order to pair Q1 and Q2 individually. A reminder was sent by e-mail if Q2 was not submitted after 3 working days. To increase the response rate, a lottery of a gift voucher worth €57, with 5 winners among participants filling in both questionnaires, was announced in the information letter. Due to confidentiality, there was no record of responders, and a physician could therefore participate more than once.

The study was presented to the Regional Committee for Medical Research Ethics, but because patient data were not included in the study, approval was not required. The study was approved by the representative for The Norwegian Data Protection Authority at Haukeland University Hospital.