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The Use of Newly Marketed Drugs During Pregnancy and Lactation: The FARVIGRAL Project

Georgios Eleftheriou[1], Anna Sangiovanni[1], Fabiola Petrocelli[1], Mariapina Gallo[1], Andrea Giampreti[1], Lorella Faraoni[1], Marco Cirronis[1], Maria Gioia Contessa[1], Andrea Missanelli[2], Giorgio Tabasso[3], Alessandra Pistelli[2], Giuseppe Bacis[1]

[1]*Poison Control Center and Teratology Information Center, Bergamo, Italy*
[2]*Poison Control Center and Teratology Information Center, Florence, Italy*
[3]*University of Florence, Florence, Italy*

Introduction

There is a recognized need to strengthen the evidence concerning the use of newly marketed medicines (primary aim) and other drugs with limited available data during pregnancy and lactation (secondary aim), as well as to support the early identification of potential safety signals. To address this, a collaborative initiative - named the FARVIGRAL Project - was launched, involving the Teratology Information Services of Bergamo and Florence.

Methods

Between November 2021 and March 2024, telephone follow-up was conducted with all patients who met the inclusion criteria relevant to the project's primary and secondary objectives. The primary objective focused on the following pharmaceutical classes: taxane antineoplastics, monoclonal IgG4 antibodies, anti-C5 antibodies, CFTR protein modulators, B-cell depleting anti-CD20 agents, hepatitis C virus NS3/4A serine protease inhibitors, sphingosine-1-phosphate receptor modulators, and PD-1 inhibitors. The secondary objective considered relatively new antiepileptics, antidiabetics, antivirals, antihistamines, and the combination doxylamine/pyridoxine.

Results

A total of 1,043 patients were enrolled during pregnancy and 1,622 during lactation. Regarding newly marketed drugs, 68 cases were identified: 1 paclitaxel, 30 dupilumab, 7 fingolimod, 1 ivacaftor, 18 rituximab, 5 ivacaftor/tezacaftor/elexacaftor, 3 nivolumab, 1 glecaprevir/pibrentasvir, and 2 eculizumab. The secondary aim of the project involved 2,590 patients; of these, 697 (29.2%) were lost to follow-up, while in 1,128 (43.5%) an alternative treatment was proposed. In terms of pregnancy outcomes, the following events were observed: in rituximab group one neonate with a cleft lip and one with neonatal apnoea, in doxylamine/pyridoxine one spontaneous abortion and one case of intrauterine growth restriction (IUGR), in ivacaftor/tezacaftor/elexacaftor, one neonate with inguinal hernia, in eculizumab one pregnancy with IUGR, in lacosamide/brivaracetam one hypospadias (no severity grade is reported). One case of spontaneous abortion was also reported for zonisamide and for liraglutide, respectively. No adverse drug reactions (ADRs) were reported in breastfed infants.

Conclusions

The project findings suggest that there is currently no indication of an increased incidence of reported adverse events associated both with the use of newly marketed drugs and other drugs with limited available data during pregnancy and lactation. However, the number of cases for each specific medication remains too limited to draw definitive conclusions. These preliminary findings need to be confirmed through large-scale, multicenter pharmacoepidemiological studies, even in the absence of specific maternal toxicities or recurrent patterns of congenital anomalies.

The FARVIGRAL project: Malformations and adverse effects observed

	N° of cases	Adverse effects		N° of cases	Adverse effects
Rituximab	3	1 case cleft lip	Doxylamine/pyridoxine	15	2 cases AS 1 case IUGR
Eculizumab	1	1 case IUGR	Ivacaftor/tezacaftor/elexacaftor	3	1 case inguinal hernia
Zonisamide	4	1 case AS	Lacosamide	13	1 case inguinal hernia 1 case hypospadias
Liraglutide	1	1 case AS	Rupatadine	27	6 cases AS
Semaglutide	3	1 case AS	Ebastine	38	4 AS 1 case facial angioma
Bilastine	29	3 cases AS			

AS Spontaneous abortion
IUGR Intrauterine Growth Restriction