



ORIGINAL ARTICLE

Drugs use in pregnancy in the Valencia Region and the risk of congenital anomalies^{☆☆☆}



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KEYWORDS

Congenital abnormalities;
Pharmaceutical preparations;
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Abstract

Background: Despite the potential risks of drug use during pregnancy, consumption has increased in recent decades.

Objective: To identify the risk of congenital anomalies (CA) associated with the use of drugs in primary care in pregnant women resident in the Valencia Region.

Methods: A case-control study, considering a case as a less than one year old live birth in 2009–2010, diagnosed with a CA and resident in the Valencia Region, obtained from the CA population-based registry. Controls were selected from the Metabolic Disease Registry, and the drugs prescribed and dispensed from the Integral Management of Pharmaceutical Services. Crude odds ratio (OR) was calculated with its 95% confidence intervals and adjusted OR was calculated using logistic regression.

Results: A total of 1.913 cases and 3.826 controls were identified. The most frequently used drug groups were those acting on the musculoskeletal, nervous and respiratory systems, on the blood and blood forming organs, and anti-infection drugs. The most common drugs used were ibuprofen, dexketoprofen, paracetamol, amoxicillin, ferrous sulphate, and a combination of folic acid. A significantly increased risk of CA was identified for drugs acting on the musculoskeletal system (adjusted OR 1.14 [95% confidence interval 1.02–1.28]). A significantly decreased risk was observed for drugs acting on the blood and blood forming organs (adjusted OR 0.87 [95% confidence interval 0.78–0.98]).

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PALABRAS CLAVE

Anomalías congénitas; Preparación farmacéutica; Embarazo; Factores de riesgo; Comunitat Valenciana

Conclusions: Associations between drugs and CA in pregnant women resident in the Valencia Region have been identified for drugs that act as risk factors of CA, and for drugs that act as protective factors of CA.

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Consumo de medicamentos en el embarazo y riesgo de anomalías congénitas en la Comunitat Valenciana

Resumen

Antecedentes: El consumo de medicamentos durante el embarazo se ha incrementado en las últimas décadas.

Objetivo: Identificar el riesgo de anomalías congénitas (AC) asociado a la utilización de medicamentos en atención ambulatoria en embarazadas residentes en la Comunitat Valenciana.

Métodos: Estudio de casos-controles, considerando caso a menores de un año nacidos vivos en 2009-2010 diagnosticados de AC y residentes en la Comunitat Valenciana, obtenidos del registro poblacional de AC. Los controles se seleccionaron del Registro de Metabolopatías y la medicación prescrita y dispensada se obtuvo del módulo Gestión Integral de Prestación Farmacéutica. Se calcularon las odds ratio (OR) y los intervalos de confianza al 95% y las OR ajustadas mediante regresión logística.

Resultados: Se identificaron 1.913 casos y 3.826 controles. Los grupos de medicamentos más frecuentemente prescritos y dispensados fueron: los que actúan sobre los sistemas musculoesquelético, nervioso, respiratorio, sobre la sangre y órganos hematopoyéticos, y antiinflamatorios. Los medicamentos más habituales fueron: ibuprofeno, dexketoprofeno, paracetamol, amoxicilina, sulfato de hierro y una combinación de ácido fólico. Se identificó un aumento del riesgo de anomalías congénitas significativo para los fármacos de acción sobre el sistema musculoesquelético (OR ajustada de 1,14 [intervalo de confianza al 95% 1,02-1,28]). Se observó una disminución del riesgo significativa en el grupo que actúa sobre la sangre y los órganos hematopoyéticos (OR ajustada de 0,87 [intervalo de confianza al 95% 0,78-0,98]).

Conclusiones: Se han identificado asociaciones de medicamentos con AC en mujeres embarazadas residentes en la Comunitat Valenciana, tanto para fármacos que actúan como factores de riesgo de AC como para fármacos que actúan como factores protectores de AC.

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Introduction

The term congenital anomaly (CA) comprehends any type of defect in physical, psychological, functional, sensory or motor development that occurs during intrauterine life and is detected during pregnancy, labour or later in life. It may even include genetic disorders and inborn errors of metabolism.¹

Congenital anomalies are an important public health problem on account of their impact on the quality of life of affected patients and families, their contribution to foetal and infant mortality, emotional costs to the family, and the financial cost of medical, social and educational services to improve quality of life of affected individuals and their families.²

The aetiology of CAs is unknown; it is believed that they result from interactions between genetic and environmental factors, although their specific interactions and relative importance have not yet been established.^{3,4}

Since the teratogenic effect of thalidomide was first discovered,⁵ there have been advances in the investigation

of the teratogenic effects that specific drugs may have on the foetus through a variety of mechanisms, especially when used in the first trimester of pregnancy. However, the results obtained by these studies have not always been conclusive.⁶ Thus, drugs used for the treatment of hyperthyroidism, such as carbimazole or thiamazole, have been associated with CAs like choanal atresia and omphalocele,⁷ although this association has not been observed in every study.⁸

Antibiotic drugs have been studied extensively and shown to have different effects. Penicillins, erythromycin and cephalosporins have not been associated to CAs. Cleft lip and palate have been associated with the use of amoxicillin in the early months of pregnancy. Sulfamides and nitrofurantoin have been associated with severe CAs such as anencephaly and cardiac CAs, as well as choanal atresia, lip and cleft palate and diaphragmatic hernia.^{9,10}

Findings for other drug classes such as antiepileptic drugs have been contradictory^{11,12} or the evidence of their association with CAs was inconclusive.¹³ In other instances, it was difficult to differentiate between potential

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