Drug use during pregnancy: report from the Regional Pharmacovigilance Centre of Catania

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Approximately 50% of pregnant women take at least one medication other than a vitamin or mineral supplement during pregnancy (Mitchell et al., 2011). Physicians caring for pregnant women have often little information to help them decide whether the potential benefits outweigh the risks to the fetus (Koren et al., 1998). The decision to use any potentially harmful drug in pregnancy should be made on a case-by-case basis. (Shehata et al., 2000). Women can consult a teratogen-information service in order to receive updated and evidence-based information on drug safety during pregnancy. In this line, Catania Pharmacovigilance Centre provides counseling about the risk associated to drugs, dietary supplements and herbal medicines during pregnancy and lactation. The Centre offers support to physicians or other health professionals and ordinary citizens through a call centre. For each request, the staff, based on literature data, defines the risk class of drugs according to the Food and Drug Administration (FDA) classification and the need for any further investigation, recommending suspension or continuation of treatment. In reply to physicians the Centre sends a written report by fax or electronic mail. Three months after the expected date of delivery, the patient is called in order to get follow-up information, such as pregnancy outcome and neonatal data that are recorded into a database for statistical and epidemiological assessments. During the period 2010-2012, 34% of the counseling was requested by health professionals and 66% from women or their family members. 67% of consultations focused on prospective questions, while 33% focused on preventive questions. In 2012 there was an increased number of consultations compared to the 2010-2011 period. According to the ATC classification, the most represented category was N (31%), followed by J (16%) and A (13%). Within the N category, the drugs most represented were Psychoanaleptics (N06), in particular antidepressants (N06A), and psycholeptics (N05), in particular anxiolytic drugs (N05B) and antipsychotics (N05A). Antidepressant drugs for which it was carried out the largest number of consultations were SSRI. Within J category, the drugs for which it has been required a greater number of consultations were Antibacterial agents for systemic use (J01), followed by Vaccines (J07). Within J01 category the most represented drugs were beta-lactam antibacterials-penicillins (J01C), followed by tetracyclines (J01A) and quinolone (J01M). In the category A, a greater number of consultations were asked for Drugs for disorders related to acid secretion (A02), followed by Drugs for functional gastrointestinal disorders (A03). The analysis of the recorded data showed that the most represented risk class was C (35%), followed by the class B (22%), D (17%), X (4%) and A (1%). In 21% of cases it was not possible to determine the risk class. The follow-up information collected did not show evidence of significant health problems for newborn baby exposed to drugs during pregnancy or lactation. Recognition of the teratogenic effect of a drug is a complex process that must take into account experimental animal data and experience in humans (De Santis et al., 2004). The risks of exposure to drugs must be weighed against the risks of untreated illness (Yonkers et al., 2009). Thus, it is important to analyze single cases in order to establish the necessity of a treatment and the associated risk.

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