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Drugs and dilated cardiomyopathies: a case/noncase study in the French Pharmacovigilance Database; Montastruc G., Favreliere S., Sommet A., Pathak A., Lapeyre-Mestre M., Perault-Pochat M.C., Montastruc J.L., French Association of Regional Pharmacovigilance Centres; British Journal of Clinical Pharmacology 69 (3), 287-94 (Mar 2010)

WHAT IS ALREADY KNOWN ABOUT THIS SUBJECT * Dilated cardiomyopathy is a frequent disease, responsible for 40-50% of cases of heart failure. * Several aetiologies have been reported: idiopathic, familial/genetic, viral and/or immune but also toxic agents (alcohol, cobalt, carbon monoxide, lead, cocaine, mercury or drugs). * Among drugs, anthracyclines are well known to induce such an adverse drug reaction. WHAT THIS STUDY ADDS * This study describes an association with already suspected drugs (anthracyclines, antiretrovirals). * It also found a signal with other drugs (antipsychotics, lithium, antidepressants, retinoids). * This pharmacovigilance signal should be confirmed by further prospective studies. AIMS To evaluate putative associations between drugs and dilated cardiomyopathy. METHODS We used the case/noncase method in the French Pharmacovigilance Database (FPVD). Cases were all the observations with dilated cardiomyopathy registered into the FPVD between 1 January 1990 and 30 June 2007. Noncases were all other reports other than those studied. Anthracyclines were used as positive controls. Data were expressed as reporting odds ratio (ROR) with their 95% confidence intervals. RESULTS Out of the 258 729 adverse drug reaction (ADR) reports recorded in the FPVD between 1 January 1990 and 30 June 2007, 47 (22 men, mean age 49 years) were defined as dilated cardiomyopathy. In these 47 patients, 67 drugs were 'suspect'. A significant ROR was found with cytotoxic (epirubicin, mitoxantrone, cyclophosphamide, gemcitabine, fluorouracil) and antiretroviral (lamivudine, zidovudine, abacavir) but also with isotretinoin, prednisone, appetite suppressant (clobenzorex) and psychotropic [antipsychotic (clozapine, olanzapine), lithium, antidepressant (clomipramine, amitriptyline, fluvoxamine)] drugs. CONCLUSIONS The present study describes an association between some drugs and reports of dilated cardiomyopathies. This relationship involves not only some already suspected drugs (anthracyclines, antiretrovirals), but also other drugs (antipsychotics, lithium, antidepressants, retinoids) less known to induce such an ADR. Despite the mandatory limits of this kind of study (underreporting, confounding factors ...), these data represent a pharmacovigilance signal and could contribute to establish further prospective studies in order to confirm such signals.