Adverse event profiles of drug-induced liver injury caused by antidepressant drugs: a disproportionality analysis

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Abstract

Purpose: To evaluate the drug-induced liver injury (DILI) adverse events related to antidepressants. Method: Post-marketing cases were obtained from the United States Food and Drug Administration Adverse Events Reporting System (FAERS). Disproportionality analyses were conducted by estimating the reporting odds ratio (ROR) and the information component (IC). Result: There were a total of 10,355 reported cases of DILI out of a total of 324,588 cases reported from January 2004 to December 2021. Among the 42 antidepressants assessed, nefazodone (n = 47, ROR = 7.79, IC=2.91), fluvoxamine (n = 29, ROR = 4.69, IC=2.20), and clomipramine (n = 24, ROR = 3.97, IC=1.96), were the top three compounds ranked with the highest reporting odds of cholestatic injury. Mianserin (n = 3, ROR = 21.46, IC=3.99), nefazodone (n = 264, ROR = 18.67, IC=3.84), and maprotiline (n = 15, ROR = 5.65, IC=2.39), were the top three compounds ranked with the highest reporting odds of hepatocellular injury. Nefazodone (n = 187, ROR = 12.71, IC=0.48), clomipramine (n = 35, ROR = 2.07, IC=0.26), and mirtazapine (n = 483, ROR = 1.96, IC=0.94) were the top three on drug related severe hepatic disorders. Only nefazodone detected the signals (n = 48, ROR = 18.64, IC=4.16) in the study of hepatic faliure. Conclusion: The data mining of FAERS suggested significant association between DILI and nefazodone. Duloxetine and clomipramine detected the signals on three categories of DILI besaides hepatic failure. Moreover, DILI risk on the new generation of antidepressants should also be taken into consideration.

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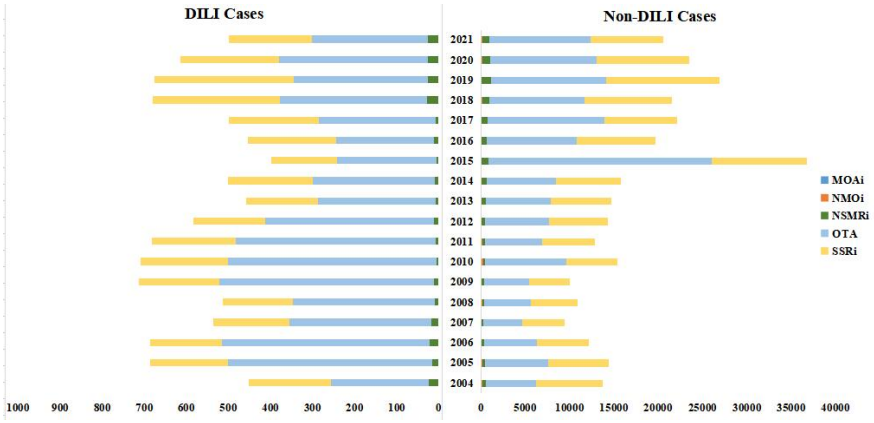

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