Adverse effects of gender-affirming hormonal therapy in transgender persons: assessing reports in the French Pharmacovigilance Database

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Abstract

Objective: Limited data are available on adverse drug reactions (ADRs) of gender-affirming hormone therapy (HT), mainly due to the lack of population-based studies with adequate controls, thus making spontaneous reporting systems a valuable tool to detect potential side reactions. In this nationwide retrospective study, we aimed to analyze ADRs related to gender-affirming HT reported in the French pharmacovigilance database (FPVD). Design: We requested all the individual case safety reports related to gender-affirming HT recorded in the FPVD before the 27th of May 2020. We excluded previously published cases and those for which gender-affirming hormone therapy was not the suspected drug. Results: A total of 28 reports of ADRs were identified. Six concerned transgender men (age range 21-40 years) and 22 transgender women (age range 22-68 years). In transgender men taking testosterone enanthate, all reported adverse effects were cardiovascular events with pulmonary embolism in 50% of cases. In transgender women, antiandrogens, mainly cyproterone acetate, were involved in 68% of cases. Estrogens were involved in 77% of cases, mostly in association with progestin or cyproterone acetate. Meningioma was the principal ADR, followed by cardiovascular events. Conclusions: Our data show a previously unreported and non-negligible proportion of cases indicating cardiovascular ADRs in transgender men younger than 40 years, taking testosterone enanthate. In transgender women, cardiovascular events were the second most frequently reported ADR. Further research is necessary to identify risk factors that might help to the individualization of treatment strategies. There is a necessity to increase awareness and implement preventive and education measures.

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