Risk of Suicidal Events With Atomoxetine Compared to Stimulant Treatment: A Cohort Study.

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Abstract

BACKGROUND:
Antidepressant effects on increased suicidality in children have raised public concern in recent years. Approved in 2002 for attention-deficit/hyperactivity disorder treatment, the selective noradrenalin-reuptake-inhibitor atomoxetine was initially investigated for the treatment of depression. In post-hoc analyses of clinical trial data, atomoxetine has been associated with an increased risk of suicidal ideation in children and adolescents. We analyzed whether the observed increased risk of suicidal ideation in clinical trials translates into an increased risk of suicidal events in pediatric patients treated with atomoxetine compared with stimulants in 26 Medicaid programs.

METHODS:
Employing a retrospective cohort design, we used propensity score-adjusted Cox proportional hazard models to evaluate the risk of suicide and suicide attempt in pediatric patients initiating treatment with atomoxetine compared with stimulants from 2002 to 2006.

RESULTS:
The first-line treatment cohort included 279 315 patients. During the first year of follow-up, the adjusted hazard ratio for current atomoxetine use compared with current stimulant use was 0.95 (95% CI 0.47-1.92, P = .88). The second-line treatment cohort included 220 215 patients. During the first year of follow-up, the adjusted hazard ratio for current atomoxetine use compared with current stimulant use was 0.71 (95% CI 0.30-1.67, P = .43).

CONCLUSIONS:
First- and second-line treatment of youths age 5 to 18 with atomoxetine compared with stimulants was not significantly associated with an increased risk of suicidal events. The low incidence of suicide and suicide attempt resulted in wide confidence intervals and did not allow stratified analysis of high-risk groups or assessment of suicidal risk associated with long-term use of atomoxetine.