Subject: Ali et al. (2015). Persistent Sexual Dysfunction and Suicidal Ideation in Young Men Treated with...
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Abstract

Study Objective:
Finasteride, a 5?-reductase inhibitor, is marketed in a low dose (1 mg) as a popular therapy for androgenic alopecia in young men. As case reports and small surveys have suggested a link between persistent sexual dysfunction (SD) and suicidal ideation (SI) with low-dose finasteride, the aim of this study was to detect signals of SD and SI secondary to low-dose finasteride use in young men.

Design:
Retrospective pharmacovigilance disproportionality analysis.

Data Source:
United States Food and Drug Administration Adverse Event Reporting System (FAERS) database.

Measurements and Main Results:
Low-dose finasteride-related adverse event reports for men aged 1845 years that were submitted to the FAERS between 1998 and 2013 were retrieved. Multi-item Gamma Poisson Shrinker disproportionality analysis was applied to calculate the empirical Bayes geometric mean (EBGM) and corresponding 95% confidence interval (CI) as an association metric between low-dose finasteride and the events of interest. Signals were defined as associations with thresholds of a CI lower limit of 2.0 or greater. Medical Dictionary for Regulatory Activities Preferred Terms denoting to SD and SI were identified to reflect the outcome of interest. In total, of 4910 reports, 577 persistent SD and 39 SI adverse event reports (11.8% and 7.9%, respectively) were identified for young men using low-dose finasteride; 34 (87.2%) of the 39 men with SI also experienced SD. The majority of these events were serious (e.g., contributed to the patient's death, hospitalization, or disability). Low-dose finasteride was associated with more than expected reporting of SD in young men compared with reporting of these events with all other drugs within the database (EBGM 28.0, 95% CI 26.130.0). Disproportional reporting in SI events was noted, although it did not reach signal threshold (EBGM 1.72; 95% CI 1.312.23). Among serious SD events, 43% led to disability; 28% required medical intervention, including hospitalization; and 5% were life-threatening. Six fatal SD reports were identified.

Conclusion:
Persistent SD might be a potential risk of low-dose finasteride for androgenic alopecia therapy in young men, and this risk might contribute to SI. Our findings provide a strong hypothesis for pharmacoepidemiologic studies to further examine this association.