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Profile of Sexual and Genitourinary Treatment-Emergent Adverse Events Associated with Atomoxetine Treatment: A Pooled Analysis.

Camporeale A, Day KA, Ruff D, Arsenault J, Williams D, Kelsey DK.
Lilly Research Laboratories, Eli Lilly and Company, Indianapolis, IN, 46285, USA.

Drug Saf. 2013 Jun 18. [Epub ahead of print]

BACKGROUND:
Attention-deficit hyperactivity disorder (ADHD) is a neuropsychiatric disorder that begins in childhood. Atomoxetine is a selective inhibitor of the presynaptic norepinephrine transporter. Several studies have demonstrated the safety and efficacy of atomoxetine in the treatment of ADHD.

OBJECTIVE:
The objective of this analysis was to provide additional information on the frequency, time to onset and time to resolution of sexual and genitourinary (GU) treatment-emergent adverse events (TEAEs) reported during atomoxetine treatment in clinical trials.

METHODS:
Data from all adult atomoxetine placebo-controlled ADHD trials were pooled for this analysis, for a total of 3,314 patients (atomoxetine, n = 1,738; placebo, n = 1,576). Additionally, data from all adolescent patients (baseline age ≥13 to <18 years) within all ADHD placebo-controlled trials were pooled for analysis, for a total of 538 patients (atomoxetine, n = 329; placebo, n = 209). Rates of sexual and GU TEAEs were summarized by sex for each age group. Time to onset and resolution of sexual and GU TEAEs were summarized and compared using Kaplan-Meier methods.

RESULTS:
Overall, the baseline characteristics of randomized patients in the atomoxetine and placebo groups were similar. Profiles of sexual and GU TEAEs for atomoxetine appeared clinically similar to placebo in female patients and in adolescent male patients. Adult male patients reported relatively

more sexual and GU TEAEs when taking atomoxetine compared with placebo, with libido decreased (4.6 vs. 3.0 %), dysuria (3.7 vs. 1.5 %), urinary hesitation (6.9 vs. 2.4 %), urine flow decreased (2.5 vs. 0.6 %), ejaculation disorder (2.8 vs. 1.1 %) and erectile dysfunction (8.0 vs. 1.9 %) being the most common. The time to onset of the most common TEAEs in adult male patients tended to occur relatively early in dosing: within the first 2 weeks for GU TEAEs, and during the second and third week of dosing for erectile and ejaculation issues. The median time to resolution for these events ranged from around 3-8 weeks after event onset, depending on the event. While the common sexual and GU TEAEs showed numerically higher percentages of discontinuations in atomoxetine-treated patients compared with placebo, most incidences of the sexual and GU TEAEs were not considered severe.

CONCLUSIONS:
The sexual and GU TEAE profiles of patients taking atomoxetine were generally similar to those of patients taking placebo in the female and adolescent male populations, with greater frequency of TEAEs reported in adult males taking atomoxetine compared with placebo. The time to onset of the TEAEs tended to be shorter, and time to resolution tended to be longer in adult male patients treated with atomoxetine compared with those receiving placebo. The conclusions must be interpreted with caution because the TEAEs were likely underreported.