Two Different Solicitation Methods for Obtaining Information on Adverse Events Associated with Methylphenidate in Adolescents: A 12-Week Multicenter, Open-Label Study.

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Abstract Objective: We explored two different methods of determining adverse events (AEs) among methylphenidate (MPH)-treated adolescents with attention-deficit/hyperactivity disorder (ADHD).

Methods: We performed a 12-week open label study of osmotic-release oral system (OROS) MPH in adolescents with ADHD who were recruited from four child and adolescent psychiatric outpatient clinics. The AEs were evaluated via a two-step procedure at weeks 1, 3, 6, and 12. The first step was to ask a general question to subjects and their parents regarding AEs. The second step included an AE evaluation process by the investigators, which was performed using a drug-specific checklist. One-way repeated measures ANOVA were used to compare the number of AEs reported by patients and their parents compared with the number reported by clinicians. This statistical technique was also used to compare the number of AEs reported by various sources (i.e., patients, parents, and clinicians) at weeks 1, 3, 6, and 12.

Results: Of the 55 participants (43 males, 12 females) between the ages of 12 and 18 enrolled in this study, 47 participants completed the trial. When the number of AEs reported by patients, parents and clinicians were compared, there were no statistically significant differences. When the numbers of AEs obtained from the three different information sources at each study visit were compared, we noted differences. At week 6, the number of AEs evaluated by clinical investigators was higher than those reported by patients and their parents ($p=0.003$). Although the results did not reach statistical significance, the number of AEs reported by clinical investigators appeared to be greater than those obtained from patients or parents at weeks 3 and 12. The number of AEs reported by patients and their parents were similar at every visit. There were some differences in the pattern of AEs reported between patients and their parents.

Conclusions: Clinicians should supplement the subjective report on AEs from patients or their parents with a more drug-specific checklist to obtain drug side effects more effectively. As there are some differences in the pattern of AEs reported by patients and their parents, it is generally recommended that clinicians obtain information from both parties when possible.