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Efficacy and safety of clobazam in a pediatric refractory epilepsy population less than two years of age

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Rationale: To describe our experience with the efficacy and safety of clobazam in refractory epilepsy in a large population of children less than two years of age.

Methods: We retrospectively reviewed all patients between 0 and 2 years of age at Boston Children's Hospital from October 2011 to December 2016. We included patients who were treated with clobazam for refractory epilepsy, and who had a follow-up visit at least one month after starting clobazam. Response to clobazam was defined as >50% reduction in seizure frequency at the time of last follow-up visit as compared to baseline.

Results: One-hundred-and-fifty-five patients received clobazam, of which 116 (median age 12 months, IQR (p25-p75) 8-16 months) had full follow-up data ≥ 1 month after starting clobazam. Median follow-up age was 14 months (IQR (p25-p75) 9-18 months). At the time of clobazam initiation, 31/116 (27%) patients were on one antiepileptic drug (AED), 52/116 (45%) patients were on two AEDs, and 26/116 (22%) patients were on 3 or more AEDs. 7/116 (6%) patients received clobazam monotherapy. Overall response rate was 33% (38/116) with a median seizure reduction of 75%. 18 (16%) patients had $\leq 50\%$ reduction, 14 (12%) had no change and 16 (14%) had worsening of seizure frequency. 30 (26%) patients became seizure free. 8 (7%) patients discontinued clobazam.

Conclusions: Clobazam is both well tolerated and effective in reducing seizure frequency in pediatric patients less than two years of age with refractory epilepsy.

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