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# Treatment Outcomes with Lisdexamfetamine Dimesylate in Children Who Have Attention-Deficit/Hyperactivity Disorder with Emotional Control Impairments

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**Objective:** The purpose of this study was to assess lisdexamfetamine dimesylate (LDX) treatment effects based on baseline emotional control dysfunction in children with attention-deficit/hyperactivity disorder (ADHD) categorized with or without impairments of executive function (EF) emotional control.

**Methods:** Post-hoc analyses of a 7 week, open-label LDX study in children with ADHD (American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders, 4th ed., Text Revision [DSM-IV-TR] defined) and impairments in EF control of emotional response. At baseline, participants were dichotomized by Behavior Rating Inventory of EF (BRIEF) emotional control domain T-scores of  $\geq 65$  (with impairment) or  $< 65$  (without impairment). ADHD Rating Scale-IV (ADHD-RS-IV), BRIEF Global Executive Composite and emotional control domain, Expression and Emotion Scale for Children (EESC) scores, Pearson correlations for BRIEF versus ADHD-RS-IV and EESC, and Clinical Global Impressions scores were assessed at baseline and end of study (week 7)/early termination (EOS/ET) by baseline category of BRIEF emotional control impairment. Safety assessments included treatment-emergent adverse events (TEAEs).

**Results:** At baseline and EOS/ET, respectively, 53.0% and 20.7% met criteria for emotional control impairment. Participants with and without emotional control impairments had similar ADHD-RS-IV change scores. Mean (SD) change from baseline for those with and without emotional control impairments were  $-20.8$  (12.89) and  $-14.6$  (11.25) for BRIEF global scores and  $-16.0$  (13.19) and  $-5.0$  (9.48) for BRIEF emotional control domain scores. Participants with emotional control impairments had greater mean EESC total score changes. BRIEF emotional control domain and all

ADHD-RS-IV scores indicated moderate correlations between change scores (all  $p < 0.0001$ ). Overall, 84.9% of participants had TEAEs (mostly mild-to-moderate in severity); 3.8% discontinued because of TEAEs.

Conclusions: The proportion of children with behavioral impairments in EF control of emotional response decreased during LDX treatment. ADHD symptoms improved in both groups. The moderate correlations between EF behaviors and ADHD symptoms suggest there may be utility in evaluating behavioral domains beyond core ADHD symptoms.