duration, limited scientific evidence establishes the duration of psychiatric hospitalization in patients with BD. The objective of this study is to assess the clinical characteristics and factors influencing the duration of hospital stay in patients with BD.

This is a retrospective observational and descriptive study. The protocol was approved by the ethics and research committee of the Hospital Universitario "Dr. José Eleuterio Gonzalez" in Monterrey, Nuevo León, México under the name "Factores predictores del tiempo de hospitalización psiquiátrica en pacientes con trastorno bipolar". Retrospective investigation was carried out of patients admitted between July 2015 and May 2022. Clinical and sociodemographic characteristics of 276 patients diagnosed with BD type 1 and type 2 were collected. Descriptive analyses were conducted for all variables using frequencies and percentages for categorical variables. Typical dispersion measures were applied to quantitative variables. Mann-Whitney U test was used to compare means between groups for dichotomous variables, and the Kruskal-Wallis test for variables with more than two categories. Spearman's correlation coefficient was used for quantitative variables. Statistically significant values were considered at $p < 0.05$.

Factors associated with longer hospital stay included younger age ($p < 0.001$), being separated or divorced ($p = 0.002$), unemployment (x=27.94 vs. x=23.77; p=0.12), absence of medical comorbidity (x=27.21 vs. x=20.73; p=0.11), previous hospitalization history (x=28.50 vs. x=23.26; p=0.005), history of substance abuse (x=28.55 vs. 24.68; p=0.26), use of pharmacological restraint (p=0.28), and non-use of mood stabilizers during hospitalization (x=27.54 vs. x=24.11; p=0.27).

Overall, this study highlights the significance of comprehensive and personalized treatment approaches for patients with bipolar disorder. By addressing specific risk factors and optimizing therapeutic strategies, healthcare professionals can potentially reduce the length of hospital stays, leading to improved patient well-being and resource utilization within psychiatric care facilities. However, further research and intervention studies are warranted to validate and implement these findings in clinical practice.

Funding. No Funding

Sex Differences in Attention Improvements Across Two Clinical Trials of AKL-T01, A Novel Digital Therapeutic for Inattentive Symptoms in Children and Adolescents with ADHD

Antonia Savarese, PhD[1], Amanda M. Maple, PhD[1], Caitlin A. Stamatis, PhD[1], Catherine Mercaldi, MPH[1], Stephen Hinshaw, PhD[2] and Scott H. Kollins, PhD[1]

[1]Akili Interactive, Boston, MA and [2]University of California, Berkeley, Berkeley, CA

Objectives. Attention-deficit/hyperactivity disorder (ADHD) remains underdiagnosed and undertreated in girls. One important contributor is the predominance of inattentive symptoms in girls relative to boys. Though less "visible," inattentive symptoms represent a key driver of impairment, often persisting into adulthood. EndeavorRx (AKL-T01) is a game-based, FDA-authorized digital therapeutic directly targeting inattention. This analysis sought to examine potential sex differences in the efficacy of AKL-T01.

Methods. We conducted a secondary analysis of clinical outcomes by sex in 326 children and adolescents from two trials of AKL-T01 ($n1$ = 180 children; 30.6% female, M age = 9.71; $n2$ = 146 adolescents; 41.1% female, M age = 14.34). All participants had high inattention per a baseline score ≤ -1.8 on the Test of Variables of Attention (TOVA), a computerized, FDA-cleared continuous performance task objectively measuring attention. Participants used AKL-T01 for 25 minutes/day over 4 weeks. Primary outcomes included change in attention on the TOVA Attention Comparison Score (ACS) and sub-metrics, and change in symptoms on clinician-rated ADHD Rating Scale (ADHD-RS). To evaluate study hypotheses, we conducted a series of t-tests of TOVA and ADHD-RS change scores by sex.

Results. Across the pooled sample, girls using AKL-T01 demonstrated significantly greater improvements in attention on the TOVA ACS ($M\Delta = 2.44$) compared to boys ($M\Delta = 1.32$; $t[211.77] = 2.62$, $d = .31$, $p = .009$), as well as TOVA reaction time standard score (girls' $M\Delta = 13.22$; boys' $M\Delta = 3.54$; $t[229.12] = 3.93$, $d = .46$, $p < .001$). We did not observe sex differences in the 2 other TOVA sub-metrics, nor in ADHD-RS ($ps > .05$). There were sex differences in compliance ($t[207.99] = 2.17$, $d = .26$, $p = .031$), with girls completing more sessions on average ($M = 90.22$) compared to boys ($M = 80.19$).

Conclusions. Results suggest that AKL-T01 may be associated with particularly strong improvements to attentional functioning in girls relative to boys. That there were no significant sex differences in ADHD symptom change over the course of treatment in either sex underscores the specificity of these effects to inattention processes rather than broad ADHD symptoms. Limitations include categorization based on binary sex, which may not capture nuances of gender identity.

Funding. Akili Interactive

A Single-Arm Pivotal Trial to Assess the Efficacy of AKL-T01, a Novel Digital Intervention for Attention, in Adults Diagnosed with Attention Deficit Hyperactivity Disorder

Amanda M. Maple, PhD, Antonia Savarese, PhD, Caitlin A. Stamatis, PhD, Catherine Mercaldi, MPH and Scott H. Kollins, PhD

Akili Interactive, Boston, MA

Objectives. Rates of attention deficit hyperactivity disorder (ADHD) have increased among adults, and barriers to treatment (e.g., medication shortages; inaccessibility of behavioral treatments) underscore need for novel, scalable interventions. There is a

https://doi.org/10.1017/S1092852924001214 Published online by Cambridge University Press

particular need for treatments for inattentive symptoms, which are the most frequently endorsed ADHD symptoms in adults. AKL-T01 (EndeavorRx®) is an FDA-authorized digital therapeutic, currently approved for attention in children ages 8-12 with inattentive or combined-type ADHD and a demonstrated attention issue. This study evaluated the efficacy and safety of AKL-T01 in adults.

Methods. STARS-ADHD-Adults (NCT05183919) was a multicenter, single-arm trial at 14 US sites. Enrolled patients were 18 or older, had a diagnosis of ADHD (combined or inattentive), and demonstrated attentional impairment with a Test of Variables of Attention (TOVA) Attention Comparison Score (ACS) ≤ -1.8. Treatment involved using AKL-T01 at home 25 minutes/day, 5 days/week, for 6 weeks. The primary endpoint was change in TOVA-ACS. Secondary endpoints were changes in the ADHD Rating Scale-IV (ADHD-RS-IV) inattention subscale and total score, and Adult ADHD Quality of Life (AAQoL) total score. Safety, tolerability, and compliance were assessed.

Results. Of 440 participants screened, 221 were enrolled, and 153 (*M* age = 39.9, 70% female; 39% current stimulant use) had sufficient data for analysis. TOVA-ACS significantly improved from baseline to study day 42, *M* change = 6.46, *SD* = 6.95, $t(152) = 11.49$, $p < .0001$. There was significant improvement across all secondary endpoints (*p*s <.0001). In exploratory responder analyses, 36.6% moved into the normative range on TOVA (ACS>0), and 27.1% had ADHD-RS-IV improvement ≥ 30%. The treatment was well-tolerated (5% reported ADEs; none serious), and compliance was high (*M* = 81.1%).

Conclusions. Results support the efficacy of AKL-T01 in adults, and the magnitude of TOVA change in adults was nearly 7x the change reported in pediatric trials. Given the increasing rates of ADHD in adults, the barriers to accessing evidence-based treatments, and the centrality of inattentive symptoms as ADHD patients develop into adulthood, AKL-T01 holds promise as a scalable, targeted treatment for attention in adult ADHD with impacts to real-world symptoms.

Funding. Akili Interactive

Evaluation of the Efficacy of Viloxazine ER in Children and Adolescents with ADHD Inattentive and Combined Presentations

Robert L Findling[1], Jeffrey H. Newcorn[2,3], Andrew J Cutler[4], Ann Childress[5], Peibing Qin[6], Jennifer Koch[6], Christian Teter[6], Jami Earnest[6] and Jonathan Rubin[6]

[1]Department of Psychiatry Virginia Commonwealth University, Richmond, VA, USA; [2]Department of Psychiatry, Division of ADHD, Learning Disabilities, and Related Disorders, Icahn School of Medicine at Mount Sinai, New York, NY, USA; [3]Department of Pediatrics Division of ADHD, Learning Disabilities, and Related Disorders, Icahn School of Medicine at Mount Sinai, New York, NY, USA; [4]Department of Psychiatry, SUNY Upstate Medical University, Syracuse, NY, USA; [5]Center for Psychiatry and Behavioral Medicine, Inc., Las Vegas, NV, USA and [6]Supernus Pharmaceuticals, Inc., Rockville, MD, USA

Introduction. Studies show stimulant medications are effective for different ADHD presentations (predominantly inattentive [IA], predominantly hyperactive-impulsive [HI] or combined [C]); however, few studies have evaluated nonstimulant efficacy in different ADHD presentations. Viloxazine ER [VLX ER] is a nonstimulant, FDA-approved medication for pediatric (≥6 yrs) and adult ADHD. This post-hoc analysis of 4 double-blind (DB), Phase 3, clinical trials (2 in adolescents [NCT03247517 and NCT03247556], 2 in children [NCT03247530 and NCT03247543]), evaluates VLX ER efficacy by ADHD presentation as derived from ADHD Rating Scale, 5th Edition (ADHD-RS-5) assessments at Baseline.

Methods. Children and adolescents with ADHD and an ADHD-RS-5 Total score ≥ 28 were eligible for enrollment. ADHD presentation was defined as a rating of ≥2 on at least 6 of 9 ADHD-RS-5 inattention items, or hyperactive-impulsive items or both. For each ADHD presentation, the change from Baseline (CFB) in ADHD-RS-5 Total score (primary outcome in each study) was assessed using mixed models for repeated measures (MMRM). Responder rate (secondary outcome), ≥50% reduction from baseline in ADHD-RS-5 Total score, was analyzed using generalized estimating equations (GEE).

Results. Of 1354 subjects [placebo N = 452, VLX ER N = 902], ADHD presentation was assigned as 288 (21.3%) [IA], 1010 (74.5%) [C], 40 (3.0%) [HI], 16 (1.2%) [none of these]. Due to the small sample size of [HI], only the [IA] and [C] results are presented. At Week 6 (pooled data endpoint), ADHD-RS-5 Total scores were significantly improved for VLX ER relative to placebo for both the [IA] and [C] ADHD presentations. LS mean (SE) treatment differences, p-values were: [IA] -3.1 (1.35), p = 0.0219, and [C] 5.8 (0.97), p < 0.0001. Responder rates were also significantly higher for VLX ER: 43.0% [IA] and 42.7% [C] relative to placebo 29.5% [IA] and 25.5 % [C] (p=.0311 and p<.0001).

Conclusions. Viloxazine ER significantly reduced ADHD symptoms in individuals meeting criteria for ADHD [IA] or [C] presentations at Baseline. Limitations include post-hoc methodology, smaller sample sizes of [IA] and [HI] groups, and the ADHD-RS-5 ≥ 28 eligibility requirement, that may favor enrollment of individuals with ADHD [C] over ADHD [IA] or [HI] presentations. Consistency of response during long-term use should be evaluated.

Funding. Supernus Pharmaceuticals, Inc.

Centanafadine Sustained Release Is Efficacious in the Treatment of Adult ADHD Across Disease Severities

Andrew J Cutler[1,2], Alan Zhang[3], Caroline Ward[3], Jessica McDonough[3] and Greg W Mattingly[4]

[1]SUNY Upstate Medical University, Syracuse, NY; [2]Neuroscience Education Institute, Lakewood Ranch, FL; [3]Otsuka Pharmaceutical Development & Commercialization, Inc., Princeton, NJ and [4]Washington University School of Medicine, Midwest Research Group, St. Louis, MO

https://doi.org/10.1017/S1092852924001214 Published online by Cambridge University Press