

episode, because of the presence of tremor and family reports of marked functional decline (from being independent for daily life activities to being bound to a wheelchair and with worsening cognitive symptoms), the psychiatrist opted for a gradual switch from valproate to carbamazepine. During our interview, her husband pointed to the complete dose of 100 mg of carbamazepine 3 weeks ago as the onset of her current symptoms. The patient demonstrated clear psychomotor inhibition, with an absence of spontaneous movement and sporadic, almost monosyllabic, responses to only the simplest questions. Although aware that she was in a hospital, she could not recall its name and was completely disoriented in regards to time. Barely capable of emoting with her facial muscles, she denied feeling depressed and only acknowledged a stomachache. After spending the night in observation, and the suspension of carbamazepine, the patient experienced an improvement of her cognitive functions: although still not fully oriented in space and time, she could now speak in sentences and answer most of our questions. Even though she still maintained not being depressed, when pressed about any weird sensations she admitted to the feeling of being dead inside. The decision was made to transfer her to the psychogeriatric hospitalization unit.

Discussion. The initial assessment of the patient was complicated due to a variety of factors. Beyond the physical comorbidities, the psychomotor inhibition impeded a thorough examination of her emotional state. Only the suppression of her evening dose of carbamazepine allowed for the diagnosis of Cotard-like major depressive symptoms. Even though the cognitive impairment was apparent before, the state of the patient was markedly improved with just the removal of carbamazepine and was confirmed by her family to be a lot closer to her base state of more than a month ago.

Conclusion. The use of anticonvulsant therapy in elderly bipolar patients with cognitive impairment can have important side effects. Further evidence of the prevalence and specific nature and frequency of its side effects is needed.

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Pure Verbal Autopalinacousis

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Abstract

Introduction. Palinacousis, the phenomenon in which sounds are internally perseverated or repeated has not heretofore been reported occurring exclusively to an individual's own voice.

Methods. A 52-year-old woman started to experience auditory hallucinations of her voice at 3 years old when she began talking out loud. The auditory hallucinations of her own voice, yclept autopalinacousis, consisting of one to three words, were affectively neutral, rarely disruptive, and unchanged by psychiatric medications. During these palinacoustic phenomena, she would hear the last few words she had spoken out loud repeat inside her head in both ears. When the autopalinacousis occurred, the words were repeated just once. Sound quality was an exact replication of how it was originally spoken. She only experienced the palinacousis to her own voice and never to any other sounds. For the palinacousis to occur, she had to verbally state the words loud

enough for her to hear. If she spoke out loud but could not hear her own voice, via occlusion of her external auditory canal or presence of loud noise, the internal auditory repetition would not occur. However, after the auditory stimulus was sensed, nothing could reduce the palinacousis. The palinacousis could occur if she read out loud, but not if she read silently. The frequency of the autopalinacousis ranged from a few times a week to several times a day and was associated with reduced sleep, but unaffected by mood, psychiatric medications, or headaches. Five months prior to her psychiatric hospitalization, she began to experience paranoid delusions, decreased sleep, increased activity, rapid speech, and auditory hallucinations of one male and two female voices. In contrast to autopalinacousis, these auditory hallucinations consisted of full phrases or sentences, were affectively charged, intrusive, and diminished by psychiatric medications. No palinacousis occurred with the hallucinated voices.

Results. Abnormalities: Mental Status Examination: Speech: pressured. Oriented x2. Memory: ability to remember 5 digits forwards and 2 digits backwards. She is not able to spell with word "world." Calculation ability: poor. MRI of brain with and without contrast: normal.

Discussion. In cases where patients with psychotic illness experience palinacousis, the palinacousis always appear after the psychotic illness has already manifested, anywhere from less than a year to 15 years later. Our patient's palinacousis presented almost 5 decades before the onset of her auditory hallucinations and paranoid delusions. Furthermore, her palinacousis only occurred to her own spoken voice and never to any other voices. In those who present with auditory hallucinations, query as to the presence and characteristics of palinacousis is warranted.

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STARS Adjunct Trial: Evidence for the Effectiveness of a Digital Therapeutic as Adjunct to Treatment With Medication in Pediatric ADHD

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Abstract

Background. Treatment of attention deficit hyperactivity disorder (ADHD) includes pharmacological and non-pharmacological interventions, both of which have demonstrated short-term efficacy. While efficacious, there are limitations to both modalities of treatment. Due partly to these limitations, there has been considerable interest in additional approaches to augmenting ADHD management. Digital therapeutics may offer improved access, minimal side effects, and low potential for abuse, while providing targeted treatment options for improving cognitive functions such as attention. AKL-T01 (EndeavorRx®) is the first and only FDA-cleared

nonpharmacological prescription digital therapeutic delivered through a video game interface for the treatment of ADHD.

Objective. The objective is to summarize the data from a clinical trial in support of FDA clearance using AKL-T01 adjunctively in children currently taking stimulant medication for ADHD.

Methods. The STARS-Adjunct Trial was a multicenter, 12-week, open-label study of AKL-T01 in 206 children aged 8 to 14 years with a confirmed diagnosis of primarily inattentive or combined-type ADHD. The study included two cohorts: (1) subjects currently treated with ADHD medication (n=130) and (2) subjects not on any ADHD medication (n=76). Subjects had an ADHD Impairment Rating Scale (IRS) score ≥ 3 at baseline, and both cohorts used AKL-T01 for approximately 25 minutes per day, 5 days per week, over two 4-week treatment periods separated by a 4-week treatment pause.

Results. AKL-T01 significantly improved (lowered) ADHD-related impairment as measured with the IRS (clinician rated) after the first 4-week treatment in both cohorts ($P < 0.001$). Results show that effects persist during a 4-week treatment pause and further improve with a second 4-week treatment period. A majority of parents and children indicated a perceived improvement in ability to pay attention after the trial. Most common device-related adverse events were decreased frustration tolerance, headache, and irritability which ranged from mild to moderate. No serious adverse events were reported.

Conclusions. This study adds to and extends the clinical evidence base for AKL-T01, a video game-based treatment for improving attentional functioning in 8–12-year-old children with ADHD. Continued evaluation of the effects of AKL-T01 on other important aspects of functioning, like academic and social functioning, health utilization, and health outcomes, would continue to add to the evidence base that the effects observed in this and previous studies have substantial clinical and functional impact.

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Impact of Cariprazine on Weight and Blood Pressure in Bipolar I Depression: A Real-World Study Using Electronic Medical Records

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Abstract

Introduction. Patients with a severe mental illness such as bipolar I disorder (BP-I) have a higher prevalence of obesity and related metabolic comorbidities than the general population. This study

evaluated the impact of cariprazine on weight and blood pressure in patients with BP-I depression using electronic medical records (EMRs) from a nationally representative database.

Methods. Analyses were based on data from EMRs in the Symphony Health's Integrated Dataverse[®] from March 2015 to October 2018. Patients ≥ 18 years of age with ≥ 2 cariprazine fills (first dispensing=index date) and clinical activity for ≥ 12 months pre-index (baseline) and ≥ 1 month post-index were included. Patients also had a diagnosis of BP-I depression at their most recent episode prior to cariprazine initiation. The on-treatment period spanned from the index date to the earliest of cariprazine discontinuation, a switch to another atypical or long-acting injectable antipsychotic, end of clinical activity, or end of data. Metabolic outcomes of interest were weight and blood pressure (systolic and diastolic). For each outcome, patients were required to have ≥ 1 measurement in both the baseline and on-treatment periods. Linear trajectories during those periods were estimated using mixed-effects models; 95% confidence intervals (CIs) were calculated using non-parametric bootstrap procedures.

Results. In total, 1702 patients who met study eligibility criteria had ≥ 1 weight measurement recorded in the baseline and on-treatment periods; of these patients, 178 had bipolar I depression as their most recent episode. Patients gained an average of 2.43 kg/year during the baseline period and 0.60 (95% CI: -1.97, 3.70) kg/year during the on-treatment period. Analyses of blood pressure change (n=179) showed that cariprazine had neutral effects over the on-treatment period. Patients' systolic blood pressure increased at 1.12 mmHg/year during baseline and decreased at -0.63 (95% CI: -3.59, 2.25) mmHg/year during the on-treatment period. For diastolic blood pressure, increases of 0.25 mmHg/year during baseline and 0.44 (95% CI: -1.65, 2.16) mmHg/year during the on-treatment period were observed.

Conclusions. Although patient weight was increasing prior to cariprazine initiation, a neutral weight trajectory was seen with long-term cariprazine treatment among those with a most recent BP-I depression episode. Cariprazine also had minimal impact on systolic or diastolic blood pressure. Overall, these findings are consistent with prior short- and long-term studies showing that cariprazine has a neutral weight and metabolic profile.

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Treatment Success and Psychiatric Stability in Adults With Tardive Dyskinesia: Post Hoc Analyses of Two Long-Term Valbenazine Studies

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