RESULTS: 281 patients were enrolled; 277 (mean age, 41.4 years) received ≥1 dose of study drug, and 183 (66.1%) completed the extension study. The most common reasons for discontinuation were withdrawal by patient (15.5%), loss to follow-up (6.9%), and AEs (5.8%). AEs were reported in 136 (49.1%) patients; most were mild in severity. The most common AEs were increased weight (13.4%), somnolence (8.3%), nasopharyngitis (4.0%), and headache (4.0%). Mean weight increase from baseline in patients completing 52 weeks of treatment was 1.86 kg, a 2.79% increase. No clinically significant changes in mean laboratory parameters were observed. Mean (SD) changes from baseline to week 52 in PANSS total score and CGI-S score were –16.2 (15.41) and –0.9 (0.92), respectively (both P<0.001).

DISCUSSION: OLZ/SAM was generally well tolerated with a safety profile that supports long-term treatment. During this 52-week extension study, there were improvements in schizophrenia symptoms.

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It Smells Fishy: A Case Report and Discussion of Olfactory Reference Syndrome

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ABSTRACT: Background: Olfactory reference syndrome (ORS) is a psychiatric condition characterized by the belief that one is emitting a foul body odor. The earliest cases of this disorder were often labeled as variants of schizophrenia. There remains significant controversy over whether this condition represents a manifestation of other psychiatric conditions or if it is a unique disorder in its own right. Through various revisions of the DSM, the disorder has been categorized at times as an atypical somatoform disorder (DSM-III), a delusional disorder (DSM-IV-TR), and an Other Specified Obsessive-Compulsive Disorder (DSM-5).

CASE HISTORY: We present the case of a 51 year old African American female who initially presented to an emergency room with chief complaint of vaginal odor. She stated that if the odor was not treated, she would commit suicide. Medical workup in the emergency room was unremarkable and no odor was detected. The patient was placed on a psychiatric hold and transferred to the Psychiatric Emergency Room. In the PES, the patient reported that she was afraid of eviction from her apartment due to the "horrible" smell that she was emitting. The patient had presented to multiple emergency departments over the preceding year complaining of vaginal odor. The patient persisted in her belief about this smell despite multiple medical providers informing her that they could detect no abnormal smell. Unconvinced, the patient went to great lengths to treat this odor. When normal showering did not cause the odor to cease, the patient began manually inserting pieces of deodorant into her vaginal canal. This was extracted at an outside hospital after the patient presented for treatment after developing an infection. After discharge, the patient began mixing a household cleaning product containing benzalkonium chloride with bleach and used this mixture for vaginal douching. When even this did not eliminate the perceived odor, she presented to our emergency room stating that if the odor was not treated, she would attempt suicide.

DISCUSSION: Although ORS has been described since the 1800's, the first systematic description in the literature was a case series in 1971 by Pryse-Phillips. While ORS has been increasingly reported in the scientific literature, the DSM-5 does not consider it to be a unique clinical entity.

CONCLUSION/TEACHING POINT: This case highlights the importance of clinicians being aware of clinical entities which exist outside the DSM-5. As shown in this case, ORS may lead to severe impairment and even suicidal ideation Despite this, there is a scarcity of literature on evidence based treatments for ORS. It has typically been treated with either a moderate dose SSRI or a low dose antipsychotic, with or without CBT. Given the high level of distress and disability caused by the condition, greater awareness of its existence and greater research on its treatment is certainly warranted.

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Catatonia Complicated by Encephalopathy-Diagnostic and Treatment Challenges

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ABSTRACT: The term Catatonia was coined by Kraepelin in 1893 and was categorized as a subtype of dementia praecox. Bleuler in 1906 redefined it as catatonic Schizophrenia. Over the period of time by accumulating evidence of various case reports and studies its apparent that catatonia is not only seen in Schizophrenia, Affective disorders but is also seen secondary to various medical problems. There is very limited literature describing catatonia in the presence of neurological problems like Encephalopathy. The pathophysiology of Catatonia remains unclear. Given the involvement of common substrates like GABA, Dopamine and glutamate that are altered in many neurological problems and catatonia the differentiation and treatment become complicated.

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METHOD: We present the case of a 32-year-old male with bipolar II disorder, who was initially went through elective cholecystectomy complicated by bowel perforation and septic shock. Patient had to be intubated and had complicated ICU stay. Various consultation services including Neurology, Infectious disease, psychiatry, Intensivist got involved to address the multiple medical comorbidities like sepsis, encephalopathy and apathy. In spite of improving EEG showing resolving encephalopathy patient remained mute, immobile, not following any instructions, with no oral intake. All imaging including CT scan and MRI repeated 3 times over the period of time were negative. Patient's psychiatric medications that includes Wellbutrin was held to minimize the risk of seizures. Patient's neuro exam had positive Babinski and pupils dilated. He also had autonomic dysfunction. There were no clear-cut symptoms to enable us differentiating hypoxic brain injury and Malignant catatonia. We considered the differential diagnosis of Catatonia and initiated Ativan IV challenge.

RESULTS: The patient was reassessed one hour after administration of lorazepam. He displayed slight response to Ativan by moving his fingers in the first 24 hrs. We had to continue to titrate the Ativan to very high doses in the period of 3 weeks with a very slow but good response.

CONCLUSION: This case reflects the intricacy in diagnosing Catatonia complicated by Encephalopathy and the challenges in its treatment. We want to add on to the current literature on Catatonia masked by multiple medical comorbidities and the challenges of treatment

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Determining Meaningful Change in Depression Symptoms Assessed with PHQ-9 and SDS in Treatment-resistant Depression Trials of Esketamine Nasal Spray

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ABSTRACT: Introduction: Major depressive disorder (MDD) has been ranked among the top causes worldwide of years lived with disability. In this study we assessed meaningful change for the PHQ-9 and the SDS and determined the meaningful change threshold (MCT) using anchor-based methods, which could be used to compare meaningful differences in patients within different treatment arms.

METHODS: TRANSFORM-1 (NCT02417064) and -2 (NCT0241858) were Phase 3 trials that evaluated the efficacy and safety of fixed and flexible doses of esketamine nasal spray (56 mg or 84 mg) in combination with newly initiated oral antidepressant (ESK+AD) vs oral antidepressant + placebo nasal spray (AD+PBO) in TRD patients. Patient Reported Outcomes (PROs) were integrated into these trials to evaluate the patient perspective of treatment using instruments capturing concepts of importance to patients. The 9-item Patient Health Questionnaire (PHQ-9) is a PRO instrument used to assess self-reported depression symptoms and the Sheehan Disability Scale (SDS) is a PRO for self-reported function and disability. Blinded trial data (combined treatment groups) from TRANSFORM-1 was used for the anchor-based analysis. The Clinical Global Impression - Severity (CGI-S) was used as an anchor and patients were classified into response groups depending on their level of change over the course of the study. Patients were classified among all possible change categories (15 levels, ranging from -7 to 7 where negative change scores indicate improvement). Cumulative Distribution Function (CDF) curves of change from baseline to day 28 were generated using unblinded data from TRANSFORM-2 to visualize the range of responses demonstrated in the respective treatment groups for the PHQ-9 and SDS. MCT values were used to as thresholds to evaluate percentage of responders in each treatment group.

RESULTS: In anchor-based analyses using TRANSFORM-1 combined treatment groups, the correlation between change on the CGI-S and change on the PHQ-9 at Day 28 was high (> 0.60) with anchor-based MCTs ranging from 5 to 8 points. The magnitude of change (standardized effect size estimate within-subject change) for patients improving was exceptionally high (> 0.80). Similar results were observed on the SDS: high correlation of

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