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ABSTRACT: Background: Repetitive deep transcranial magnetic stimulation (dTMS) is efficacious for treatment resistant major depressive disorder (TRD) with the H1 coil by stimulating the prefrontal cortex, left more than right, at high frequency. Theoretically, the efficacy of dTMS could be optimized by simultaneously stimulating the right and left lateral prefrontal cortices (PFC) with different frequencies. This study tested the efficacy of a novel dual-channel dTMS stimulator with dual dTMS coils, in patients with TRD.

METHODS: This study recruited forty-seven outpatients diagnosed with TRD, age 18-65, Hamilton Depression Rating Scale (HDRS-21) score ≥ 25. Each patient received 20 open label treatment sessions, five days a week for 4 consecutive weeks. Treatments were administered with the dual-channel stimulator (Brainsway Multiway dTMS device) using two channels: a. 10 Hz over the left PFC. b. 1 Hz over the right PFC. Primary and secondary efficacy outcome measures were the change in HDRS-21 score and response/remission rates at week 5, respectively.

RESULTS: The HDRS-21 score decreased from an average of 25.94 to 14.69 ($P < 0.001$). Thirty-six patients completed four weeks of treatment. Of them, seventeen (47%) responded (HDRS-21 score decrease of ≥ 50% from their initial score) and eight (22%) remitted (HDRS-21 score of < 10 at the end of the study).

DISCUSSION: This open study shows promising results for multichannel simultaneous dTMS treatment of TRD using the Brainsway Multiway Device. Further randomized controlled studies are necessary to aid the high number of patients with TRD.

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Healthcare Utilization and Costs for Patients With Tardive Dyskinesia

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ABSTRACT: Introduction: Tardive dyskinesia (TD) is an often-irreversible movement disorder that usually results from prolonged use of antipsychotics. Although the burden of TD on patients' quality of life has been reported, there is limited evidence of its impact on the healthcare system.

OBJECTIVE: To assess healthcare utilization and costs between TD and non-TD patients in a sample of patients from the commercially insured and Medicare Supplemental US populations.

METHODS: A retrospective cohort analysis was conducted using Truven MarketScan Commercial/Medicare claims data. For each patient included in the analysis, the index date was set as the first TD diagnosis between 1/1/2008 and 9/30/2014. Patients with TD were then matched to similar patients without TD to compare resource utilization andcosts. Descriptive statistics on the incidence of resource utilization and costs of healthcare were reported.

RESULTS: A total of 1020 patients were included in this analysis. TD patients had significantly greater annual all-cause (TD: $54,656; non-TD: $28,777) and mental health-related (TD: $10,199; non-TD: $2,605) healthcare costs compared with non-TD patients ($P < 0.01$). This was primarily because a higher proportion of the TD patientsexperienced hospitalizations (all-cause 56%; mental health 17%) and emergency room visits (all-cause 62%; mental health 27%) compared with non-TD patients(hospitalizations: all-cause 26%, mental health 5%; emergency room visits: all-cause 41%; mental health 13%) (all $P < 0.001$).

CONCLUSIONS: Patients identified as being diagnosed with TD demonstrate significantly higher healthcare utilization and costs in the 12 months after diagnosis than do similar patients without TD.

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Dasotraline for the Treatment of Moderate to Severe Binge Eating Disorder in Adults: Results From a Randomized, Double-Blind, Placebo-Controlled Study

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ABSTRACT: Objectives: Binge eating disorder (BED) is the most common eating disorder in the US, with a lifetime prevalence of 2.8%. Disturbances in reward circuitry have been implicated in its pathogenesis. Dasotraline is a novel and potent dopamine and norepinephrine reuptake inhibitor with slow absorption and a long half-life resulting in stable plasma concentrations over 24 hours with once-daily dosing. This study evaluated the efficacy and safety of flexibly-dosed dasotraline (4, 6, and 8 mg/day) vs placebo in adults with moderate to severe BED over a 12-week period (NCT02564588).

METHODS: Key inclusion criteria included moderate to severe BED based on a history of ≥2 binge eating days/week for ≥6 months prior to screening, and ≥3 binge eating days for each of2 weeks prior to randomization, as documented in participant's binge eating diary. Patients were randomized 1:1 to flexibly-dosed dasotraline (4, 6, 8 mg/day) or placebo. Theprimary endpoint was change from baseline (CFB) in the number of binge eating days per week at Week 12. Key secondary endpoints were: CFB in Clinical Global Impression–Severity (CGI-S) Scale at Week 12; CFB in Yale-Brown Obsessive Compulsive Scale Modified for Binge Eating (YBOCS-BE) at Week 12; and the percentage ofsubjects with a 4-week cessation from binge eating prior to Week 12 or end of treatment (EOT). Except for 4-week cessation, the other three variables were analyzed using amixed model for repeated measures (MMRM).

RESULTS: 317 subjects (84% female) received ≥1 dose of study medication (mean age was 38.2 years; mean number of binge eating days per week, 4.25; mean CGI-S score, 4.5; mean BMI, 34.7). The MMRM analysis of CFB at Week 12 in the number of binge days/week yielded a significant mean difference of –0.99 (95% CI: –0.65 to –1.33; $p < 0.001$) infavour of dasotraline (–3.74 in the dasotraline group vs –2.75 in the placebo group). All three key secondary endpoints were met at Week 12 or EOT: 46.5% of subjects in thedasotraline group achieved at least 4 consecutive weeks' cessation from binge eating vs 20.6% in the placebo group ($p < 0.001$); CFB in CGI-S and YBOCS-BE scores were also statistically significant in favour of dasotraline ($p < 0.001$). The treatment-emergent adverse events (TEAEs) that occurred more frequently with dasotraline vs placebo at >2% incidence included: insomnia (44.6% vs 8.1%), dry mouth (27.4% vs 5.0%), decreased appetite (19.7% vs 6.9%), anxiety (17.8% vs 2.5%), nausea (12.7% vs 6.9%) and decreased body weight (12.1% vs 0%). Discontinuation due to AEs occurred in 11.5% of patients taking dasotraline vs 2.5% taking placebo.

CONCLUSIONS: In adults with moderate to severe BED, there were highly significant and clinically meaningful reductions with dasotraline vs placebo in the frequency of binge eating, global severity of illness, and obsessive-compulsive symptoms related to binge eating. These results suggest dasotraline may offer a novel, well-tolerated and efficacious treatmentfor BED.

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Retrospective Analysis of Clozapine Augmentation in Treatment-Resistant Schizophrenia in an Outpatient Setting

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ABSTRACT: Study Objectives: This retrospective analysis hopes to add to the literature about Treatment Resistant Schizophrenia (TRS), augmentation strategies with antipsychotics used in our patient population with the hopes of clarifying what possibilities should be further studied. In addition, we aim to emphasize the need for focusing on individualized treatment and multidisciplinary efforts to ensure compliance and appropriate disposition options.

METHOD: We reviewed retrospectively 3025 charts of patients between January 2017 to March 2017 in our outpatient department establishing which antipsychotic clozapineaugmentation strategies were being used. We also did a literature review to establish what augmentation strategies are recommended. These patients will then be compared to a random sample of patients in the clinic who were not prescribed clozapine and compared for readmission rate, side effect profile, length of stay while admitted, frequency of clinic attendance and compliance with outpatient appointments.

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