may be a prodromal syndrome which may act as a biological marker of dietary vitamin deficiency.
BMS is highly prevalent in postmenopausal women, wherein trigeminal nerve sensitivity may amplify and worsen pain, given a decrease in estrogen and progesterone [Martin 2007], indirectly influencing her BMS pain. Salivary output and composition can alter due to a drop in estrogen and progesterone as well, allowing baseline reduction of proprioceptive input on the tongue. Ergo, acting through Melzack and Wall's Gate Control Theory of Pain to disinhibit small C-fibers, it may be perceived as burning pain [Melzack 1965]. Given this case, in those who undergo abdominal surgery or hyperalimentation, query regarding BMS symptoms is warranted.

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The Effects of Valbenazine on Tardive Dyskinesia: Subgroup Analyses of 3 Randomized, Double-Blind, Placebo-Controlled Trials

Jonathan Meyer, MD[1]; Gary Remington, MD[2]; Ali Norbash[3]; Joshua Burke[4]; Scott Siegert[5]; and Grace S. Liang, MD[6]

[1] Psychiatrist and Assistant Clinical Professor of Psychiatry at the University of California, San Diego; San Diego, CA
[2] Senior Scientist in the Campbell Family Mental Health Research Institute and Chief of the Schizophrenia Division at the Centre for Addiction and Mental Health; Toronto, Ontario, Canada
[3] Senior Medical Science Liaison, Neurocrine Biosciences, Inc., San Diego, CA
[4] Biostats, Neurocrine Biosciences, Inc.; San Diego, CA
[5] Executive Director, Head of Medical Affairs, Neurocrine Biosciences, Inc., San Diego, CA
[6] Medical Director, Clinical, Neurocrine Biosciences, Inc.; San Diego, CA

ABSTRACT: Study Objectives: The approval of valbenazine (INGREZZA; VBZ) for the treatment of tardive dyskinesia (TD) in adults was based on results from double-blind, placebo (PBO)-controlled trials. These studies demonstrated the efficacy of once-daily VBZ based on intent-to-treat analyses. However, because many different types ofpatients can develop TD, subgroup analyses describing treatment outcomes by various patient factors were also conducted.

METHODS: Data were pooled from three 6-week trials: KINECT (NCT01688037), KINECT 2 (NCT01733121), KINECT 3 (NCT02274558), with outcomes analyzed by VBZ dose (80 mg, 40 mg) and PBO. Descriptive analyses conducted using the Abnormal Involuntary Movement Scale (AIMS) total score included: mean change from baseline to Week 6; and AIMS response, defined as 50% improvement from baseline to Week 6. Subgroups were defined as follows: age (<55 years, ≥ 55 years), sex (male, female), psychiatric diagnosis (schizophrenia/schizoaffective disorder, mood disorder), CYP2D6 genotype (poor metabolizer [PM], non-PM), body mass index (BMI) (<18.5, 18.5 to <25, 25 to <30, ≥30 kg/m2), concomitant antipsychotic (yes, no); type of antipsychotic (atypical, typical/both); lifetime history of suicidality (yes, no); concomitant anticholinergic (yes, no); TD duration (<7 years, ≥7 years).

RESULTS: The pooled population included 373 participants (VBZ 80 mg, n = 101; VBZ 40 mg, n = 114; PBO, n = 158). Mean improvements from baseline to Week 6 in AIMS total score were greater overall with VBZ compared to PBO. Within subgroup categories, AIMS score improvement with VBZ 80 mg (recommended dose) was greater in CYP2D6 PMs (n = 17; 80 mg, -6.8; 40 mg, 2.4; PBO, 0.5), participants taking no concomitant antipsychotics (n = 64; 80 mg, -4.9; 40 mg, -3.0; PBO, 0.0), and overweight participants (BMI 25 to <30 kg/m2, n = 115; 80 mg, -4.2; 40 mg, 2.7; PBO, -0.7). Overweight participants also had the highest AIMS response rates at Week 6 (80 mg, 57.7%; 40 mg, 31.6%; PBO, 11.8%), followed by participants taking typical/both antipsychotics (n = 67; 80 mg, 57.1%; 40 mg, 20.0%; PBO, 25.0%), and those taking anticholinergics (n = 126; 80 mg, 52.9%; 40 mg, 22.7%; PBO, 6.3%).

CONCLUSION: These preliminary analyses indicate that TD improvements were generally greater with VBZ than PBO across most subgroups. However, the small sizes of some subgroups may need to be considered when interpreting results. Additional analyses within subgroup categories are ongoing and will be presented at the meeting.

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The Burden of Tardive Dyskinesia Secondary to Antipsychotic Medication Use Among Patients With Mental Disorders

Joseph McEvoy, MD[1]; Tyson Park, PharmD[2]; Traci Schilling, MD[2]; Emi Terasawa, PhD[3]; Rajeev Ayyagari, PhD[4]; and Benjamin Carroll, PharmD[2]

[1] Medical College of Georgia, Augusta, Georgia, USA
[2] Teva Pharmaceutical Industries, Frazer, Pennsylvania, USA
[3] Analysis Group, Inc., New York, New York, USA
[4] Analysis Group, Inc., Boston, Massachusetts, USA

ABSTRACT: Introduction: Extrapyramidal symptoms (EPS), including tardive dyskinesia (TD), may result

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from exposure to antipsychotics. TD is often irreversible, may be debilitating, and cause additional burden to patients with underlying psychiatric conditions.

OBJECTIVE: To assess the impact of developing TD, both with and without other EPS, on healthcare resource utilization (HRU).

METHODS: Data on patients receiving antipsychotics who had schizophrenia, major depressive disorder, or bipolar disorder were extracted from a Medicaid claims database. Patients from the TD cohorts (TD+EPS and TD non-EPS) were matched to those in the non-TD/EPS cohort at ~1:5 ratio. HRU outcomes associated with TD were assessed.

RESULTS: TD+EPS (n = 289) and TD non-EPS (n = 394) cohorts were matched with 1398 and 1922 control patients, respectively. The percentage of patients with all-cause and mental disorder-related inpatient admissions increased from baseline to follow-up in the TD+EPS (12.8% and 12.5%, respectively) and TD non-EPS (16.0% and 13.5%) cohorts, in contrast with slight decreases (~3%) in matched controls. A higher percentage of patients in the TD cohorts had medical admissions/visits and claims for drugs that might be used to address TD or EPS than their matched controls at baseline and follow-up. The within-cohort change from baseline to follow-up in the use of potential drugs for TD or EPS was similar between the TD cohorts and their matched controls; however, both TD cohorts exhibited a larger increase in crisis–non-specific psychotherapy services versus matched controls.

CONCLUSIONS: Results demonstrated increased HRU in TD patients with or without other pre-existing EPS, compared with matched controls.

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Effect of Tardive Dyskinesia on Quality of Life: Patient-Reported Symptom Severity Is Associated With Deficits in Physical, Mental, and Social Functioning

Joseph McEvoy, MD[1]; Benjamin Carroll, PharmD[2]; Sanjay Gandhi, PhD[2]; Avery Rizio, PhD[3]; Stephen Maher, PhD[3]; Mark Kosinski, MA[3]; and Jakob Bjorner, MD, PhD[3]

[1] Medical College of Georgia, Augusta, Georgia, USA
[2] Teva Pharmaceutical Industries, Frazer, Pennsylvania, USA
[3] Optum, Johnston, Rhode Island, USA

ABSTRACT: Introduction: Tardive dyskinesia (TD), an often-irreversible movement disorder typically caused by exposure to antipsychotics, most commonly affects the face, mouth, and tongue and may be debilitating

OBJECTIVE: To investigate TD burden on patients' quality of life and functionality

METHODS: Adults with clinician-confirmed schizophrenia, bipolar disorder, or major depressive disorder participated in an observational study. Approximately half (47%) ofparticipants had a clinician-confirmed TD diagnosis. Participants completed the SF-12v2 Health Survey® (SF-12v2), Quality of Life Enjoyment and Satisfaction Questionnaire Short Form (Q-LES-Q-SF), social withdrawal subscale of the Internalized Stigma of Mental Illness scale (SW-ISMI), and rated the severity of their TD symptoms. Group differences in SF-12v2 physical and mental component summaries (PCS and MCS), Q-LES-Q-SF, and SW-ISMI scores were analyzed.

RESULTS: TD (n = 79) and non-TD (n = 90) groups were similar in age, gender, and number of patients with schizophrenia, bipolar disorder, and major depressive disorder. TD patients reported significantly worse scores on PCS ($P = 0.003$), Q-LES-Q-SF ($P < 0.001$) and SW-ISMI ($P < 0.001$) than non-TD patients. The difference in PCS exceeded the established minimal clinically important difference (MCID) of 3 points. When stratified by TD severity, those with more severe symptoms had significantly worse Q-LES-Q-SF ($P < 0.001$) and SW-ISMI ($P = 0.006$) scores than those with less severe symptoms. Differences in PCS ($P = 0.12$) and MCS ($P = 0.89$) were in the expected direction and exceeded the MCID.

CONCLUSIONS: Among patients with psychiatric disorders, TD is associated with significant physical health burden and incremental mental health burden. TD severity is also associated with lower overall quality of life and greater social withdrawal.

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A Clinical Practice Assessment In Tardive Dyskinesia: Are Physicians Up-to-Date?

Jovana Lubarda, PhD[1]; Stacey Hughes[1]; and Christoph U. Correll, MD[2]

[1] Medscape Education, New York, NY

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