

RE-KINECT: Real-World Dyskinesia Screening Study

ANDREW CUTLER: I'm Dr. Andrew Cutler, executive vice president and chief medical officer of Meridian Research in Bradenton, Florida. Over the next few minutes, I'll be reviewing data from the RE-KINECT study. RE-KINECT is a prospective, real world dyskinesia screening study in patients taking antipsychotic agents.

As an introduction, tardive dyskinesia, or TD, is a persistent movement disorder associated with prolonged exposure to antipsychotics. In fact, any patient treated with any antipsychotic for a few months is at risk for developing TD, and therefore all patients treated with these medications should be screened for TD. Despite this, an analyses the demonstrated TD prevalence of approximately 25% in patients taking first or second generation antipsychotics, recent surveys indicate that screening for TD is not of high priority for clinicians.

Having said this, understanding the impact of TD is important. RE-KINECT is a prospective study conducted at 37 US outpatient psychiatry practices. The patients included in this study were adults with a psychiatric condition and exposure to at least one antipsychotic for at least three months.

The study included a two tiered symptom screen of possible TD. Tier 1 was a visual observation during intake at a usual care visit by a staff member familiar with detection procedures for involuntary movements, that is possible TD, in any of four main body regions. That is head or face, neck or trunk, upper extremities, lower extremities.

Tier 2 was a clinician assessment of involuntary movements and confirmation of whether movements could be considered possible TD. Patients were assigned to one of two cohorts based on clinician assessment. Cohort 1 comprised outpatients without visible signs of involuntary movements or with movements not deemed consistent with TD and cohort 2 comprised outpatients with visible signs of involuntary movements, that is clinician confirmed possible TD.

Remember, these are possible TD cases, as formal diagnoses were not made. A simplified clinician assessment was developed to identify the presence, location, and severity of involuntary movements and confirm possible TD for cohort assignment. Health-related quality of life, or HRQoL questionnaires completed by patients in both cohorts included the EuroQoL or EQ 5D 5L questionnaire, which ranges from 1, meaning no problems, to 5, meaning unable to perform.

And the Sheehan Disability Scale, or SDS, which ranges from 0, meaning no or none, to 10, meaning extreme. Of the 739 patients that were clinically evaluated, 72.4% were assigned to cohort 1. That is, without possible TD, and 27.6% in cohort 2, that is with possible TD.

Interestingly, bipolar disorder and major depressive disorder were the most common antipsychotic treated disorders in cohort 1. Anxiety disorder was a frequent comorbidity in both cohorts. While sex, age, and race were similar between the two cohorts, there were some differences between cohorts in marital status, current domestic situation, and employment status.

Now, we'll review the symptom burden assessment results from RE-KINECT. Based on clinician assessment at visit 1 of the 200 patients with possible TD that is in cohort 2, all body regions were

affected, defined as some or a lot by uncontrollable or involuntary movements. 47.1% of patients with possible TD were impacted in one body region and 52.9% were impacted in two or more regions.

The maximum severity score across the four body regions was 1, defined as some, in 66.7% of patients, and two, defined as a lot, in 33.3%. A higher percentage of patients with possible TD versus those without possible TD reported at least slight problems in all EQ 5D 5L domains, including mobility, self care, usual activities, pain or discomfort, and anxiety or depression.

In addition, compared with cohort 1, a higher proportion of patients in cohort 2 that is with possible TD reported moderate or marked or extreme disruption in the SDS domains of work or school and social life. To summarize, in this naturalistic, real world sample of patients who were treated with an antipsychotic, 27.6%, or 204 patients, had possible TD confirmed by clinician assessment. Over half, or 52.9%, of patients with possible TD were impacted by their uncontrollable or involuntary movement in two or more body regions.

A higher proportion of patients in cohort 2 versus cohort 1 had problems in all five EQ 5D 5L domains and moderate or marked or extreme disruptions in two of three SDS domains. Results were likely associated with other variables affecting functioning, such as age, sex, diagnosis. The burden of TD should be considered when treating patients exposed to antipsychotic medication.