RE-KINECT: A Prospective Real-World Dyskinesia Screening Study and Registry in Patients Taking Antipsychotic Agents: Caregiver Burden Results

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ABSTRACT

Background: Tardive dyskinesia (TD) is a persistent and potentially debilitating movement disorder that is associated with prolonged exposure to antipsychotics. Caregivers are often instrumental in identifying and managing TD, and this disorder can negatively affect their own lives. However, the impact/burden on caregivers has not been well-defined or researched. RE-KINECT (NCT03062033) is an ongoing registry study that is being conducted in a real-world population of patients exposed to antipsychotics. One of the goals of this study is to characterize the social, emotional, and functional impacts of TD on caregivers.

Methods: RE-KINECT is designed to enroll patients from up to 70 US psychiatric practices. Adults with ≥3 months lifetime exposure to antipsychotic(s) and ≥1 psychiatric disorder(s) are eligible for screening, which involves a clinician looking for abnormal involuntary movements in general body regions (head/face, neck/trunk, upper/lower limbs) and assessment of possible TD. Based on clinician evaluation, patients are assigned to Cohort 1 (without visible signs of involuntary movements) or Cohort 2 (with visible signs and clinician assessment of possible TD). For Cohort 2, caregiver-reported outcomes included: employment status, relationship to patient, burden of patient's health on caregiver's life. Caregivers who reported seeing uncontrollable movements responded to questions about how those movements in the patient affect the caregiver's ability to continue usual activities, be productive, take care of themselves, and socialize. Questions regarding caregiver embarrassment and anger/frustration due to the patient's uncontrollable movements were also asked.

Results: Interim data are currently available from 15 caregivers, 11 (73%) of whom reported seeing uncontrollable movements in the person to whom care was provided. Nine of these 11 caregivers (82%) reported that ≥2 body regions were affected, and >50% reported that the movements had some or a lot of impact on their own ability to continue usual activities (55%), be productive (64%), take care of themselves (73%), or socialize (73%). A fraction of these 11 caregivers expressed some or a lot of embarrassment (27%) or anger/frustration (18%) as a result of the patient's visible, uncontrollable movements. The majority of all 15 caregivers were related to the patient (73%). Caregivers were either employed full-time (40%) or retired (33%), but some (13%) were not working due to their own disability. The health conditions they helped patients to manage were mental health (60%), chronic disease(s) (33%), and physical activity/nutrition (33%).

Conclusion: Current results from this novel registry study suggest that TD can be a substantial burden for caregivers. Further analyses that explore the impacts of this disorder on caregivers will be presented at the meeting.

Updated results are presented in this poster.

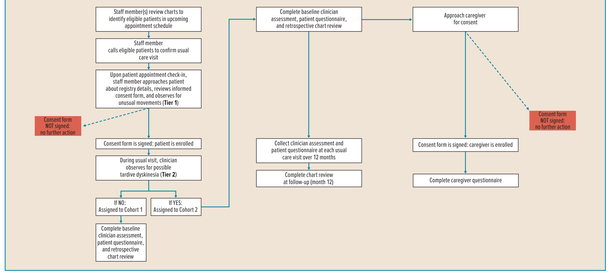
INTRODUCTION

- All patients with exposure to antipsychotics are at risk of developing tardive dyskinesia (TD), an involuntary movement disorder that can affect the face, mouth, trunk, limbs, and/or extremities[1-4]
- In a recent meta-analysis of clinical trials, a TD prevalence of 25.3% was found in patients taking a first- or second-generation antipsychotic medication[5]
- While TD has been reported to negatively impact treatment outcomes and the daily functioning of patients with psychiatric disorders (i.e., schizophrenia or mood disorder),[6-8] less is known about the impact on individuals who care for patients with TD
- The RE-KINECT (NCT03062033) study, which documents the presence and impact of TD in psychiatric outpatients, included a caregiver questionnaire; results from this questionnaire are presented below

METHODS

- RE-KINECT is a prospective registry that included 37 outpatient psychiatry practices from across the United States
- Key eligibility criteria:
  - Age 18 years or older with at least 3 months of cumulative lifetime exposure to ≥1 antipsychotic medication(s)
  - At least 1 clinician-confirmed psychiatric disorder meeting DSM-5 criteria
  - Willingness and ability to provide informed consent for study participation
- The study included a 2-tiered symptom screen of possible TD (**Figure 1**)
  - *Tier 1*: visual observation during intake at usual care visit by a staff member familiar with detection procedures for involuntary movements (i.e., possible TD) in any of 4 main body regions (i.e., head/face, neck/trunk, upper extremities, lower extremities)
  - *Tier 2*: clinician assessment of involuntary movements and confirmation whether movements can be considered possible TD
- Patients were assigned to 1 of 2 cohorts based on clinician assessment
  - *Cohort 1*: outpatients without visible signs of involuntary movements or with movements not deemed consistent with TD
  - *Cohort 2*: outpatients with visible signs of involuntary movements (clinician-confirmed possible TD)
- This presentation focuses on the caregivers of cohort 2 patients; caregivers who gave consent were invited to complete a questionnaire at the baseline visit
- Caregiver-reported outcomes included: demographic characteristics, relationship to patient, rating of patient's overall health, presence and severity of patient's involuntary movements, and aspects of caregiver burden

Figure 1. Overview of Two-Tier Symptom Screen and Cohort Assignment



RESULTS

- Of 204 cohort 2 patients, 41 had a caregiver who consented to enrollment
- Baseline characteristics of the caregivers are presented in **Table 1**

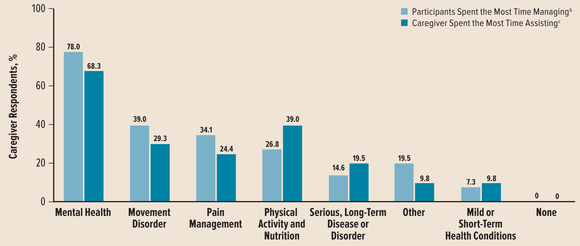
Table 1. Baseline Characteristics[a]

Characteristic	Cohort 2 Caregivers (N=41)
Race, n (%)	
White	27 (65.9)
Black	7 (17.1)
Asian	7 (17.1)
Marital status, n (%)	
Single	5 (12.2)
Married	28 (68.3)
Divorced	6 (14.6)
Other[b]	2 (4.9)
Current living/domestic situation, n (%)	
Living alone	3 (7.3)
Living with a partner, spouse, family, or friends	35 (85.4)
Other	3 (7.3)
Employment status, n (%)	
Employed, full-time	16 (39.0)
Employed, part-time	4 (9.8)
Unemployed	4 (9.8)
Retired	11 (26.8)
Disabled	5 (12.2)
Other	1 (2.4)
Relationship to patient, n (%)	
Family member	29 (70.7)
Friend	4 (9.8)
Someone the patient lives with	1 (2.4)
Other	7 (17.1)

[a]Caregivers of patients with clinician-confirmed possible TD.
[b]Includes widowed or other (not specified).

- A majority of cohort 2 caregivers and patients spent the most time managing the patient's mental health or a movement disorder (**Figure 2**)

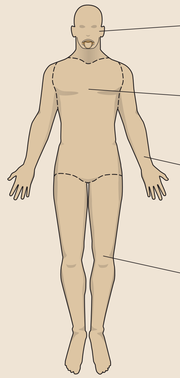
Figure 2. Health Conditions Requiring the Most Time by Cohort 2 Patients and Caregivers[a]



[a]Conditions are not mutually exclusive.
[b]Per caregiver responses, health condition(s) that the Cohort 2 patient spent the most time managing.
[c]Per caregiver responses, health condition(s) that the Cohort 2 caregiver spent the most time assisting.

- Based on caregiver ratings (range, 0=no problem/impact to 10=as bad as you can imagine), mean (SD) scores were 5.3 (2.4) for the patient's overall health status and 5.2 (3.3) for the impact of patient's health on caregiver's life
- Of the 41 enrolled caregivers, 36 (87.8%) noticed uncontrollable movements in their patient
  - Affected regions included head/face, neck/trunk, upper extremities, and lower extremities (**Figure 3**)
  - 26 (72.2%) of the 36 caregivers reported that their patient experienced involuntary movements in ≥2 body regions

Figure 3. Location and Severity of Uncontrollable/Involuntary Movements in Cohort 2 Patients[a]



Head/face: facial muscles, lips, tongue, or jaw
- None: 25.0%
- Some: 36.1%
- A lot: 25.0%

Neck/trunk: neck, shoulders, chest, or hips
- None: 58.3%
- Some: 13.9%
- A lot: 11.1%

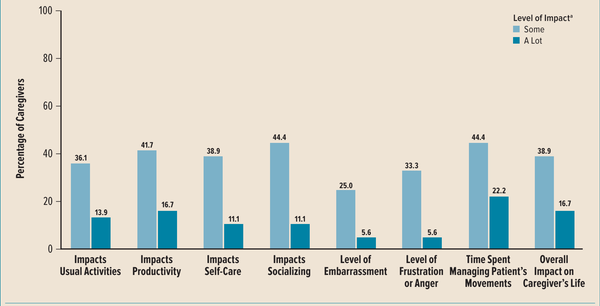
Upper extremities: arms, hands, or fingers
- None: 30.6%
- Some: 44.4%
- A lot: 19.4%

Lower extremities: legs, feet, or toes
- None: 30.6%
- Some: 47.2%
- A lot: 16.7%

[a]Any visible uncontrollable movements as reported by the caregiver (n=36).
Some missing caregiver data were observed (5 for head, 2 for upper and lower extremities; 6 for trunk).

- Many caregivers reported that uncontrollable movements in their patients had social, emotional, or functional impacts on their lives "some" or "a lot" of the time (**Figure 4**)

Figure 4. Effects of Cohort 2 Patients' Uncontrollable Movements[a] on Caregivers' Lives



Some missing caregiver data were observed (1 for self-care and socializing; 2 for usual activities and productivity).
[a]Based on caregivers' ratings ("none", "some", "a lot") of how the patient's uncontrollable movements affected their own daily activities, level of emotional distress, and overall impact on life.

CONCLUSIONS

- Most caregivers were family members and assisted patients with multiple health conditions, including movement disorders
- Based on caregiver reports, >70% of cohort 2 patients (with clinician-confirmed possible TD) had uncontrollable movements in 2 or more body regions
- This study identified aspects of caregiver burden, with possible TD having considerable impact on several areas of caregivers' lives
- The burden of TD on the caregiver should be considered when treating patients exposed to antipsychotic medications
- More research is needed to evaluate the effects of approved TD treatments on both patients' and caregivers' quality of life

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