

Disease specific global clinical rating scales for Lewy-body dementia: early concept identification

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Introduction/Overview

The 2015 JPND report on harmonizing clinical and biomarker protocols for studies in Lewy-body dementia (LBD) recognized use of the Clinical Dementia Rating (CDR) and Clinical Global Impression (CGI) as global clinician rated outcome (ClinRO) assessments but noted neither is disease specific. It was suggested that modifications to these assessments should address other relevant domains including cognition, attention/wakefulness, psychiatric symptoms, motor function, and functioning in daily life.

For example, in frontotemporal lobar degeneration (FTLD) a disease specific global ClinRO was developed by the use of a combination of the CDR (with items assessing memory, orientation, judgment and problem solving, community affairs, home and hobbies, and personal care) and the behavior and language domains from the Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC), to create the "The CDR plus NACC FTLD" assessment.

Literature reviews to identify clinical outcome assessments (COAs) and measurement concepts are one early component of concept identification to support COA instrument modification and development. We report here initial findings from a review of COA use in clinical trials and published clinical research.

Methods

Two data sources were used to explore use of COAs in clinical trials and clinical research in LBD. The first was clinicaltrials.gov (CT.gov). The second was a targeted literature review using terms related to COAs and Lewy body disease and dementia, including Parkinson's disease dementia.

Conclusions

Detailed evaluation of measurement concepts within COAs can be used to identify potential concepts and items as a basis for iterative development of global ClinROs such as the CDR and CGI, and in order to support the creation of disease specific instruments.

The use of concept elicitation via qualitative research with clinicians, patients and caregivers is critical to establishing content validity and prior to psychometric evaluation.

Development and validation of fit-for-purpose COAs is being given increasingly greater focus in the light of emerging FDA guidance and good practice as developed by ISPOR and other groups; and the Alzheimer's Association (ISTAART) Lewy Body Dementias Professional Interest Area (PIA) group continues to explore outcome measure development as a part of the trial methods working group.

Results

- The search of CT.gov identified 149 clinical trials in dementia with Lewy bodies or Parkinson's disease dementia.
- The most frequently used COAs were CDR (global; N=12), NPI (behavior/neuropsychiatric; N=27), and MMSE (cognition; N=26) - Figure 1.
- The most frequently assessed domain was cognition (N=58) – Figure 2.
- The literature review identified 20,695 results from peer reviewed journals of which the first 100 were selected and sorted by relevance. Further filtering left 24 results for detailed evaluation.
- Again, the CDR (N=4), NPI (N=7), and MMSE (N=13) were prominent in this sample.

Figure 1: Upset Plot of Frequency of COA Use in Industry Sponsored Clinical Trials

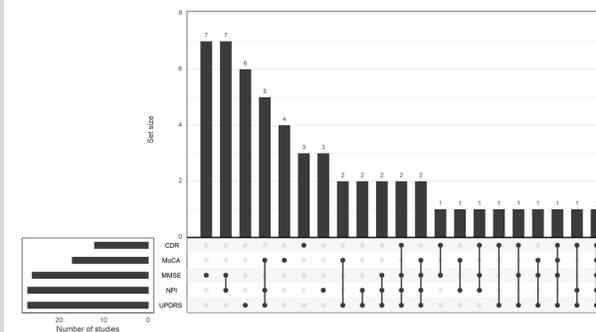
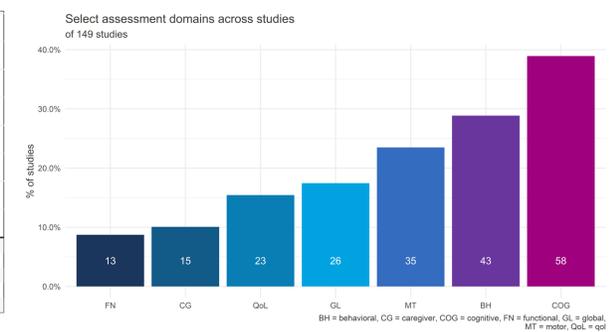


Figure 2: Prominence of Each Conceptual Domain of Assessment



Attendees are recommended to also attend or access the following:

- ADVANCES IN PD AND LBD DRUG DEVELOPMENT 2, Sun, 20.03.2022, 11:35 AM - 01:35 PM, Room 114; EFFECTS ON COGNITION AND FUNCTION ASSESSED BY CDR-SB OF THE ORAL P38A KINASE INHIBITOR NEFLAMAPIMOD IN PATIENTS WITH MILD-TO-MODERATE DEMENTIA WITH LEWY BODIES (DLB)
- Oral On-Demand 00171; VALIDITY AND RELIABILITY OF A COMPOSITE COGNITIVE OUTCOME MEASURE FOR CLINICAL TRIALS IN DEMENTIA WITH LEWY BODIES

P637; DISEASE SPECIFIC GLOBAL CLINICAL RATING SCALES FOR LEWY-BODY DEMENTIA: LITERATURE REVIEW AND CONCEPT IDENTIFICATION

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