Patients previously diagnosed, suffering from a psychotic disorder or unable to follow-up the study were excluded. Three visits were conducted per protocol (baseline, 6 and 12 months).

RESULTS: A total of 921 patients were included in the analysis. Mean (SD) age was 74.3 (6.8) years and 66.9% were women. First suspected diagnosis were: age related memory impairment (17.5% of patients), cognitive impairment (21.9%), dementia (29.2%), and psychopathological disorders (14.9%). Diagnostic methods used were: anamnesis (96.2% of patients); physical and neurological examination (87.5% and 85.6%), screening and laboratory test (85.9% and 89%). In all, 630 patients attended to at least one visit “out of protocol” to their PCP during the follow-up period. Mean (SD) number of visits was 4.28 (3.1). Percentile 25, 50, and 75 were 2, 3, and 6 visits respectively. The visits were previously appointed by physicians (54.7%) or were spontaneous consultations (39.7%). Main reason for “out of protocol” visits were to evaluate patient evolution. 45.1% of patients were never derived, 36.9% and 18% were derived to specialist once, or more than once, respectively. Main reason was diagnostic confirmation. CONCLUSION: Initial visit of patients with memory complaints or cognitive impairment to PCP, originate a careful follow-up of the patient. Different number of diagnostic methods and high time consumer procedures (as anamnesis, or screening test) have been applied. Derivations to specialist seem to be low.

NEUROLOGICAL DISORDERS (Migraine, Alzheimer’s, Dementia)

NEUROLOGICAL DISORDERS (Migraine, Alzheimer’s, Dementia)—Quality of Life/Utility/Preference

VALIDATING THE RESTLESS LEGS SYNDROME QUALITY OF LIFE QUESTIONNAIRE (RLSQOL) IN A TRIAL PATIENT POPULATION

OBJECTIVES: To determine the psychometric properties of the RLSQoL (V1.1) in a clinical trial setting. METHODS: Patient from two matching, placebo-controlled, multinational studies assessing the effectiveness and safety of ropinirole for treating moderate-to-severe RLS formed the basis of a psychometric assessment of the RLSQoL. Tests for validity and reliability were performed using baseline data. Responsiveness was determined using longitudinal, 12-week data. Tests were performed on blinded, individual trial data. RESULTS: A total of 547 subjects formed the baseline validation population, 519 were used for assessing responsiveness (n = 284/271 and 263/248 for both studies, respectively). Construct validity assessment confirmed an overall life-impact score could be calculated (accounting for 39% and 46% of the variance in the two studies, respectively). All items passed the test for item convergent validity (item-scale correlation 0.4), except items 1 “distress” (r = 0.36) and 5 “late for work/first appointments” (r = 0.35) in one study. There were no significant missing data, floor or ceiling effects for the RLSQoL overall life-impact score. Cronbach’s α were 0.82 and 0.87, confirming internal consistency reliability of the scale. Concurrent validity was determined by correlation with the International Restless Legs Scale, measuring similar health constructs (r = -0.68, -0.67, p = 0.0001); known groups validity by its ability to discriminate between subjects with different levels of sleep problems (p < 0.0001) and clinical validity by its ability to discriminate between levels of global health status determined by a Clinical Global Impression of severity (CGI-S) (p < 0.0001). Responsiveness was demonstrated by statistically significant differences in RLSQoL overall life-impact change scores between CGI improvement levels after 12 weeks of treatment (p < 0.0001; effect size range: 0.74–1.15 and 0.54–1.51 for improved groups). CONCLUSIONS: The RLSQoL is a valid, reliable and responsive measure of quality of life for patients with RLS when used in a clinical trial setting.

A SIMPLIFIED SEVERITY SCALE FOR THE ASSESSMENT OF RESTLESS LEGS SYNDROME: THE DESYR STUDY GROUP

OBJECTIVES: To develop a simple dichotomous scale for the assessment of RLS severity to be used for facilitating therapeutic decisions. METHODS: A prospective epidemiological study was conducted in primary healthcare in France. First, patients fulfilling the RLS diagnostic criteria from the International Restless Legs Study Group were identified. Secondly, severity of identified RLS subjects was assessed using the IRLS rating scale. This scale includes ten items, each rated on a five point Likert scale from zero to four (“non” to “very severe”) and summed in a global score from zero to 40 (0–20: non-severe; 21–40: severe). Using a segmentation analysis applied to the rating scale items and other measures of RLS impact, we attempted to find a small number of items able to distinguish severe from non-severe RLS patients as the rating scale would have done. RESULTS: A total of 537 patients were analyzed. Three items came up from the segmentation analysis, consolidated into “RS-3”. All three were part of the rating scale. They dealt with: overall RLS severity, overall sleep disturbance and mood disturbance. The decision rule was that an answer zero,one or two (ie. none, mild or moderate) to at least one of the three items assigned an RS-3 grade of “non-severe”. The sensitivity and specificity of RS-3 were 82% and 95% respectively. The positive and negative predictive values (PPV and NPV) were 92% and 88%. Sensitivity analyses with thresholds of 15, 25 and 30 were performed without improving sensitivity and specificity. The reproducibility of the RS-3 was assessed in another RLS population (731 subjects from the INSTANT Study) with sensitivity / specificity of 88% and 91% and PPV and NPV of 73% and 97%, respectively. CONCLUSIONS: The metrology of the RS-3 scale appears to be strong enough to be used in larger sample.