period followed by a 10-week, randomized, double-blind, placebo-controlled period. A total of 170 patients were randomized to receive a physician-determined dose of botulinium toxin type A (BoNT-A) or placebo. Functional disability was measured by patients and physicians using a scale from 0 (no functional disability) to 4 (very severe disability). Functional disability was measured at study visits at weeks 2, 4, 6, 8, and 10 of the randomized, double-blind period of the study. **RESULTS:** The baseline mean physician-assessed functional disability scores were 1.87 for botulinium toxin and 1.88 for placebo. The mean change in physician-assessed functional disability showed a greater reduction in the BoNT-A group compared with the placebo group at all timepoints, with the difference being significant at weeks 4, 6, and 8 (P ≤ 0.029). A higher proportion of patients had a decrease of one grade or more in physician-assessed functional disability in the BoNT-A group at all time periods. The baseline mean patient-assessed functional disability scores were 1.95 in the BoNT-A group and 1.78 in the placebo group. A greater reduction in the mean change of patient-assessed functional disability was seen with BoNT-A compared with placebo at all timepoints. The patient-assessed functional disability between the two groups was significantly different at weeks 2, 6, 8, and 10 (P ≤ 0.008). A one grade or greater reduction in patient-assessed functional disability was experienced by a higher proportion of botulinium toxin patients at all timepoints compared with placebo. Rates of adverse events were nearly equivalent between groups (59.1% BoNT-A vs. 58.5% placebo group). **CONCLUSION:** Treatment with BoNT-A showed significant and sustained improvements in functional disability when assessed by both the physician and the patient.

PHYSICAL AND PATIENT REPORTED OUTCOMES IN MULTIPLE SCLEROSIS

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OBJECTIVE: Most Multiple Sclerosis (MS) clinical trials focus on relapses and MRI measures of disease activity. Disease outcome measures in clinical trials and practice focus on physical outcomes and, in particular, the ambulation oriented Expanded Disability Severity Scale (EDSS). This study evaluated the relationships between various physical and patient reported outcomes (PROs) in MS patients. **METHODS:** Charts were abstracted for 98 MS patients in a single MS center that captured both physician-evaluated outcomes and PROs. This study reports the last available evaluation. Spearman rank correlations and a recursive partitioning algorithm were used to evaluate relationships between five physical (box/blocks, 9-hole peg, timed walk, Tinetti balance, and EDSS) and 3 PRO (modified fatigue impact scale, Beck depression inventory, and Espworth sleepiness scale) measures in addition to standard demographic and disease characterizing variables. **RESULTS:** The rank correlation between the box/blocks and nine-hole peg tests (standard tests for fine motor control) was 0.9 (p < 0.001) while the rank correlation between box/blocks and timed walk was 0.71 (p < 0.001). Moderate correlations were observed for the PROs: fatigue and depression was 0.57 (p < 0.001); fatigue and sleepiness was 0.52 (p < 0.001); and depression and sleepiness was 0.39 (p < 0.001). No significant correlations were observed between either depression or sleepiness and any physical outcome measure. Fatigue was correlated with 9-hole peg (0.41, p = 0.023), timed walk (0.44, p = 0.014), and EDSS (0.34, p = 0.013). The recursive partitioning algorithm found the strongest physical outcome associated with fatigue to be EDSS and the best split was at EDSS <= ("minimal" versus "mild" disability). **CONCLUSION:** Moderate correlations were found within the physical outcome measures and within PROs; but the relationship between physical outcomes and PROs was weak. Because most clinical trials and evaluating neurologists focus on physical measures in MS, it is likely that much of the disease impact is being missed.

PHYSICIAN AND PATIENT REPORTED OUTCOMES REVEAL RAPID ONSET OF IMPROVEMENT AND OVERALL CONVENIENCE, TOLERABILITY AND EASE-OF-USE WITH RASAGILINE IN PARKINSON'S DISEASE (PD) IN LEGATO

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OBJECTIVE: To evaluate investigator and patient-reported satisfaction and ease-of-use of Azilect(r) (rasagiline tablets) in community neurological practices. Rasagiline is a potent, once daily, novel, irreversible MAO-B inhibitor approved for PD as initial monotherapy or adjunct therapy. Pivotal trials showed improvement in the Unified Parkinson's Disease Rating Scale for monotherapy and reduced OFF time for adjunct therapy. Other measures of patient- and investigator-reported outcomes may be important such as ease-of-use and patient satisfaction. **METHODS:** LEGATO is an open-label study of once-daily rasagiline 0.5 mg and 1 mg in PD patients at 38 community-based centers. Baseline treatment determined patients' stratification to adjunct or monotherapy. Evaluations were at weeks 1, 2, 4, and 12. Endpoints included: patient and investigator reported Clinical Global Improvement(CGI) score; investigator-and patient-reported change from baseline in Schwab & England Activities of Daily (ADL) score; and investigator-and patient-reported satisfaction/ease-of-use ratings. **RESULTS:** A total of 272 patients were enrolled: 123 monotherapy patients and 149 adjunct patients with 245 completers. At all visits, investigator reported CGI was significantly improved for both mono and adjunct therapy (p < 0.001). At all visits, patient reported CGI was also significantly improved for both mono and adjunct therapy (p < 0.001). Patient-reported CGI was similar to Investigators', although maximal improvement occurred later for patients. Median satisfaction/ease-of-use scores were 9 for monotherapy (range 6 to 30 with 6 being best) and 10 for adjunct therapy (range of 8 to 40 with 8 being best) for both patients and investigators. Investigators noted statistically significant improvement in ADL of 3 points at the end of 12 weeks, whereas patients did not note changes from baseline. **CONCLUSION:** Both investigators and patients noted significant effectiveness beginning at week one as measured by CGI, found rasagiline convenient and easy to use, and were satisfied with the dosing frequency and tolerability of once-daily rasagiline.

THE DEVELOPMENT OF A PATIENT SATISFACTION INSTRUMENT FOR INSOMNIA: A PSYCHOMETRIC APPROACH

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OBJECTIVE: The purpose of this study was to develop an instrument to assess treatment satisfaction for patients with insomnia. **METHODS:** Specific patient satisfaction items were identified from the existing literature by an expert panel of physicians,