Clinical importance of accelerometer output in multiple sclerosis

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Introduction

There has been increased interest in the objective monitoring of community ambulation (i.e., walking in the real world) using accelerometers in clinical research and practice involving MS. This is based on performance measures of ambulation having limited ecological validity (i.e., reflecting walking in daily life).

Accelerometers are typically worn on an elastic belt around a person’s waist and capture the displacement of the body’s center of mass during ambulation. This is important as there is a smooth vertical acceleration and deceleration of the body’s center of mass during ambulation. The magnitude of the vertical displacement of the center of mass is dependent upon gait and ambulatory function. This further limits noise from non-walking leg movements.

There is research on the association between accelerometer output and markers of walking impairment in MS. Total movement counts in the vertical axis per day over a 7-day period have been associated with clinical (e.g., EDSS), performance (e.g., T25FW & GMS), physiological (e.g., O2 cost of walking), kinematic (e.g., gait speed), and patient-reported (e.g., MSWS-12) measures of ambulation.

To date, there are no published data on the clinical importance (i.e., minimal clinically important difference [MCID] or effect size) of accelerometer output in persons with MS since the clinical importance of accelerometer output in persons with MS should be based on IMPACT: Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials recommendations. Those recommendations were generated as part of a consensus meeting with the goal of providing a framework for determining clinically important changes for measures of pain. These same recommendations have been applied for identifying the clinical importance of Multiple Sclerosis Impact Scale-29 (MSIS-29) and MSWS-12 scores.

Method

Sample

The analyses included samples from two longitudinal non-drug investigations. The first sample included complete accelerometer, MSIS-29, employment status, assistive device use, and PDSS scale data from 252 subjects with MS collected at two time points separated by 6 months. The second sample included complete accelerometer, MSIS-29, MSWS-12, employment status, assistive device use, and PDSS scale data from 216 subjects with MS collected at two time points separated by 6 months. Overall, the combined sample included 465 subjects demographic and clinical characteristics are provided in the Table.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean (SD)</th>
</tr>
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<tbody>
<tr>
<td>Age (years)</td>
<td>47.3 (19.1)</td>
</tr>
<tr>
<td>Sex (% female)</td>
<td>38.8%</td>
</tr>
<tr>
<td>Employment (% employed)</td>
<td>25.8%</td>
</tr>
<tr>
<td>MS Type (% RRMS)</td>
<td>42.0%</td>
</tr>
<tr>
<td>Disease duration (years)</td>
<td>9.6 (7.5)</td>
</tr>
<tr>
<td>PDSS (median)</td>
<td>2 (0-6)</td>
</tr>
<tr>
<td>Device (% using cane)</td>
<td>118.50</td>
</tr>
</tbody>
</table>
| Stage of cane use (% early cane) | 60.79%

Measures

Accelerometer: The ActiGraph, model 7164, accelerometer recorded minute-by-minute movement counts that were summed across each of the 7 days and then the total daily movement counts were averaged across the 7 days. This yielded accelerometer data in total daily movement counts in the vertical axis per day over a 7-day period.

MSIS-29: The MSIS-29 is a 29-item patient-reported measure of the physical and psychological impact of MS during the past 2 weeks. The MCID for the MSIS-29 physical domain is estimated to be 8 points.

MSWS-12: The MSWS-12 is a 12-item patient-rated measure of the impact of MS on walking-related activities including walking, running, standing, and climbing stairs. The MCID for the MSWS-12 is estimated to be 4 and 6 points.

Employment: Employment status was recorded as part of a demographic scale and coded as employed or unemployed.

Assistive Device Use: Assistive device use was recorded as part of a demographic scale and coded as with or without an aid.

Stage of Cane Use: Cane use was categorized by stage of cane use into early and late cane use based on PDSS scale scores of 4 and 5, respectively.

Method (cont.)

Data analysis

Based on the IMPACT recommendations, the primary analyses were conducted as follows:

1. Anchor-based method for between-subjects analysis: ANOVA’s on total daily movement counts in the vertical axis from the accelerometer using the three anchor-based estimates of the MCID from the MSIS-29 physical and MSWS-12 instruments.

2. Distribution-based method for within-subject analysis: SEM was measured for total daily movement counts in the vertical axis from the accelerometer for baseline and follow-up.

3. Anchor-based method for between-subjects analysis: Cohen’s d was estimated as the difference in means between groups divided by the pooled baseline standard deviation.

Results

Anchor-based method for within-subjects analysis:

1. Based on an 8-point change in MSIS-29 physical scores, the mean (SD) for those who were stable on MSIS-29 was 220.057 (103.098) counts/day, whereas the mean (SD) for those who worsened was 191,630 (82,021) counts/day. The mean difference between groups was 28,427 counts/day.

2. Using a 4-point change in MSWS-12 scores, the mean (SD) for those who were stable on MSWS-12 was 225,157 (58,651) counts/day, whereas the mean (SD) for those who worsened was 193,081 (70,377) counts/day. The mean difference between groups was 32,076 counts/day.

3. Using a 6-point change in MSWS-12 scores, the mean (SD) for those who were stable on MSWS-12 was 214,793 (56,246) counts/day, whereas the mean (SD) for those who worsened was 192,368 (70,008) counts/day. The mean difference between groups was 22,404 counts/day.

Distribution-based method for within-subjects analysis:

1. The SEM estimates for baseline and follow-up accelerometer data were 35,683 counts/day and 27,788 counts/day, respectively.

Conclusions

The change in accelerometer output of -28,000 counts/day or -4 SDs, based on averages across analyses, represents a clinically meaningful change for therapeutic interventions in persons with MS who have mild disability. This MCID translates to a change of ~1,400 steps/day based on our prior data.

Acknowledgments/Disclosures

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