Abstract 1275

Validation of the FeetMe® System versus GAITRite® to Assess Gait Characteristics in Patients with Multiple Sclerosis: Subpopulation analysis

Type: Poster Presentation

Keyword: Clinical Outcome Measures

Authors: A. Granja Domínguez[1], A. Hochsprung[1], S. Palao[1], C. Páramo[1], A. Alemán Rodríguez[1], C. Durán[1], G. Navarro[1], A. Venegas[1], R. Romero Sevilla[2], M.J. Moreno Jiménez[2], G. Izquierdo[1]; [1]Fundación para el desarrollo de la Investigación y asistencia de enfermedades Neurológicas y Afines Crónicas (DINAC)/Castilleja De La Cuesta, Sevilla/Spain, [2]Novartis Farmacéutica, S.A./Barcelona/Spain

Background

The complete and objective gait assessment in multiple sclerosis (MS) patients is an unmet need, with important biases in the usual way of assessing gait (neurological examination/EDSS). GAITRite® measures different visuospatial gait parameters; however, its use is limited to a few centres due to its high price, physical space and the need of trained personnel for use and interpretation.

Objectives

To determine the statistical agreement and precision of gait velocity in MS patients, measured by a shoe insole device with integrated motion and pressure sensors (FeetMe®) vs reference system (GAITRite®), in 25-Foot Walk Test (25FWT).

Methods

This was an observational, cross-sectional, prospective, single-centre study. Patients 18-55 years, with MS (McDonald-2010), EDSS 0–6.5 and relapse free ≥30 days were included. GAITRite®/FeetMe® devices used. Primary endpoint was gait velocity (cm/second) (velocity-1/velocity-2 formulas). Secondary endpoints: ambulation time (seconds), gait cadence (steps/min) and stride length (cm), among others. Results of the 25FWT-both devices patient group with valid data (25PG+VD) analysis are presented, corresponding to the subpopulation who met all the selection criteria and performed 25FWT with both devices, having valid and evaluable data, at least for velocity.

Results

127 patients included. At baseline, mean (SD) age was 40.7 (8.2) years, 67.7% women, 83.5% RRMS, EDSS 2.8 (1.9). Mean (SD) velocity-1 was 104.5 (31.6) for GAITRite®, 107.6 (30.3) FeetMe® with 0.88 intraclass coefficient correlation (ICC) and 0.89 Pearson correlation, while for velocity-2 were 104.5 (31.6) and 108.9 (31.0), respectively, with 0.90 ICC and 0.91 Pearson correlation. These results indicate a very strong agreement between devices on the same subjects. Mean (SD) ambulation time difference between devices was -0.01 (0.3). Cadence-1 and cadence-2 differences between devices were -0.3 (2.7) and -2.5 (2.7), respectively. Mean (SD) stride length difference was -2.6 (19.8). A stronger association was observed between EDSS and velocity, cadence and stride length, these parameters correlation decreased with higher EDSS scores. The analysis suggested that precision of FeetMe® device could be affected by level of disability of MS patients.

Conclusions

Agreement between devices was almost perfect (ICC≥0.8). FeetMe® assesses the gait of MS patients completely and objectively, with results correlated with significant clinical variables.

Print