Introduction

Although gait impairment is a disabling symptom in MS leading to reduced mobility and improved quality of life, interventions (eg, rehabilitation therapy and pharmacological management) only marginally improve gait function. Transcranial magnetic stimulation (TMS) delivered by the portable handheld stimulator system (Helius PoNS® Therapy) has demonstrated improvements in gait in MS in randomized controlled trials (RCTs). However, no published research has examined the real-world impact of PoNS® Therapy in people with MS. The aim of this study was to assess the impact of PoNS® Therapy on gait in people with MS in an unselected routine clinical care setting (real-world environment [RWE]).

Objectives

The primary objective of the RWE was to determine if PoNS® Therapy, in combination with a supervised exercise programme, can improve gait deficits in people with MS based on real-world evidence (RWE). RWE data were collected on a clinical care setting and pooled with available data from RCTs to further understand the impact of PoNS® Therapy on gait in people with MS.

Methods

RWE Data Collection

• Gait performance assessment was determined using the Functional Gait Assessment (FGA), a 10-item clinical gait test for assessing lower limb function.
• The previous RCTs used a mixed model for repeated measures (MMMR). "Truth to account for missing data over time in the RWE analysis, and the parameter estimates of the FGA were extracted using SAS Proc Mixed." - PoNS® Therapy was associated with a broader range of FGA score improvements, with values over time and changes from baseline being summarized by least square means from random effects model for repeated measures (LSM). The LSM assumed an unstructured covariance matrix that allows for the correlation of the values over time and the changes from baseline.

Results

Demographic and Baseline Characteristics

The RWE analysis included 42 patients with a mean age of 45.5 years, median age of 45.5 years, and median age of 45.5 years in the primary analysis. The mean change in FGA total score from baseline to Week 14 was -3.61 (95% CI: -5.65 to -1.57), indicating greater improvement in gait function.

Conclusions

In this evaluation of a real-world dataset of patients with MS with generally long duration of disease, transcranial neurostimulation (PoNS Therapy) combined with a therapeutic exercise program significantly improved gait function at Week 2. The earliest evaluated time point was at every subsequent time point. At Week 14, 58.3% of patients had an FGA improvement of 24 points, surpassing the MRC for older adults, stroke patients, and persons with other neurological disease.

Analysis of real-world data pooled with the 2 randomized clinical trials demonstrated, consistent with the RCT data, that transcranial neurostimulation (PoNS Therapy) combined with a therapeutic exercise program is safe and effective for improving gait deficits in individuals with mild and moderate symptoms of MS.