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Importance of walking speed assessment as an indicator of functional improvement in adults with spastic hemiparesis after repeated administrations of abobotulinum toxin A

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Background: Walking speed (WS) has been established as an important predictor of walking capability along a continuum from limited household ambulation to unlimited community ambulation. It is considered a valid and objective measure. Walking ability has important health implications in providing protective effects against secondary complications common after a stroke or traumatic brain injury and is associated with improvements in quality of life.

Objective: To discuss the importance of the 10 meter walking speed test (10MWT) as an indicator of functional improvement in patients with spastic hemiparesis using data from a large phase-3 study examining the effects of repeated administrations of abobotulinum toxin A (aboBoNT-A, Dysport®).

Design/Methods: This was a phas- 3, multicenter, prospective, double-blind, randomized, placebo-controlled, single-treatment-cycle study that compared aboBoNT-A to placebo in adults with chronic hemiparesis (NCT01249404), followed by an open-label multiple-cycle extension study (NCT01251367). Muscle tone was the primary endpoint; unassisted Comfortable Barefoot Walking Speed (CBWS) was the secondary endpoint.

Results: In the double-blind study, mean change in CBWS from baseline assessed by the 10MWT showed no significant difference between placebo and aboBoNT-A groups at Week 4 (W4) of the treatment cycle. Improvements in CBWS were evident and sustained across the open-label treatment cycles with mean change from double-blind baseline [mean(SD)] reaching 0.07(0.12), 0.08(0.13), 0.08(0.13) and 0.09(0.14) m/s at W4 across Cycles 1-4, respectively. This progressive and sustained improvement is clinically relevant (0.06 m/s improvement considered a clinically meaningful change, impacting functional ambulation). AboBoNT-A exhibited a safety profile consistent with prior clinical experience.

Conclusions: The 10MWT is a validated measure of WS which relates to overall function. This is the first large phase-3 study of botulinum toxin type A assessing WS over repeated administrations (up to 5 injection cycles) of aboBoNT-A using the 10MWT and demonstrating sustained and clinically relevant WS improvement with functional implications.

Biography

Alberto Esquenazi is a member of American Academy of Physical Medicine and Rehabilitation, American Society of Biomechanics Gait and Clinical Movement Analysis Society and the International Society for Prosthetics and Orthotics. He is a professor of rehabilitation at Temple University School of Medicine, Thomas Jefferson University – Jefferson Medical College and Drexel University College of Medicine. He serves as director of the Annual Inter-City Gait and Orthotics course sponsored by the Temple/MossRehab physical medicine and rehabilitation residency training program. He was a member of the Task Force on Medical Rehabilitation Research for the U.S. Department of Health and Human Services. He is a fellow of the American Academy of Cerebral Palsy and Developmental Medicine and AAPM&R. Dr. Esquenazi has been recognized several times by Philadelphia magazine as one of the region's "Top Docs" and received the Distinguished clinician award from AAM&R and Pennsylvania Association of Rehabilitation Facilities. He has published many original papers, book chapters and has presented nationally and internationally on amputation, rehabilitation, orthosis, gait analysis and spasticity management. He's an active researcher in technology and rehabilitation.

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