Jessica Anderson

Patient-centered care and persons with multiple sclerosis (MS) perspective on treatment efficacy for gait impairments: a review of current evidence

The goal of this capstone project is to provide understanding on what persons with multiple sclerosis (PwMS) perceive to be effective physical therapy treatment and to identify if clinicians are taking patient perspectives into consideration when evaluating treatment efficacy. By understanding the decision-making clinicians employ to select and assess treatment benefit, as well as determining how patients perceive if and how they have benefited from treatment, patient-centered measures of treatment effect can be used to assess how the patient has responded to treatment. Patient-centered care is generally known as the transition from "treating the disease" to "treating the patient" by incorporating a patient's values, preferences, and needs into decision-making concerning treatment[1]. This form of care has been associated with better adherence to treatment and improved outcomes in PwMS[1]. While patient-centered care and its benefits are not a novel concept, it is important to assess clinician and patient perspectives on what is considered effective or meaningful treatment outcomes to ensure the patient's needs are being met. In current pharmacological research on dalfampridine extended-release (D-ER, Ampyra®), a disconnect has been identified between what researcher's consider a treatment "responder" (>20% improvement in gait speed) and what the subject considers to be "clinically meaningful improvement"[2,3]. This treatment "responder" definition lacks patient-centeredness and narrows the scope of assessing treatment efficacy to gait speed. Gait speed is not the sole parameter of gait-ability, and walking faster does not always translate to walking "better". It is important for the patient to define what "clinically meaningful improvement" is regarding their walking to not only inform treatment strategies and assessment of those strategies but also to practice patient-centered care.

The need for a better understanding of what patients perceive to be meaningful outcomes concerning walking impairment treatment is evident in the increased use of patient-reported outcomes (PROs), alone or in conjunction with objectives walking measures, to determine the impact of pharmacological management on PwMS with walking impairment[4,5]. In Macdonell et al, researchers used the objective Timed 25-Foot Walk Test (T25FWT) along with the 12-item MS Walking Scale (MSWS-12) and the 36-item Short-Form Health Survey (SF-36) physical component summary score to assess whether there was a patient-perceived health impact in PwMS with walking impairment while taking D-ER for an extended period of time (48 weeks)[4]. In Crayton et al, researchers implemented a patient feedback program to assess patient perceived-improvements while on D-ER by administering a survey at baseline prior to initiating medication, at 30 days after initiation, and at 60 days after initiation[5]. This survey included modified versions of the MSWS-12 to assess walking ability and the Sheehan Disability Scale (mSDS) to assess functional impairment. It also included the following patient satisfaction questions: "Overall, how satisfied are you so far with dalfampridine-ER?" and "How satisfied have you been with how dalfampridine-ER has helped with your walking?"[5]. An interesting finding to note from this study, was that participants

identified D-ER-use improved not only their mMSWS-12 scores but also their mSDS score from baseline, demonstrating improvement in walking and functional domains (ie. work, social and daily activity)[5]. The addition of patient-reported outcome measures provided context outside of a clinical setting for the researchers testing the efficacy of D-ER, and it broadened the assessment scope of the drug in a way that accounted for PwMS perspectives.

Just as researchers use gait speed to define a treatment "responder", physical therapists also use gait speed and objective walking measures to capture intervention effects[6,7]. Therapists will use the minimal clinically important difference (MCID), or the smallest difference in an outcome measure that is perceived as beneficial by patients, for an outcome measure to determine the effectiveness of treatment[8,9]. Meaningful change for PwMS may or may not be captured by an outcome measure's MCID because improvement captured by an MCID is based on the outcome measure the therapist chose to use. If the therapist chose to use an outcome measure that captured what they perceived to be important change in their treatment (ie. gait speed or distance walked), but did not take into account what the patient perceives to be important in treatment and treatment outcomes (ie. quality of life), then the treatment may not be meaningful for the patient. If a therapist does not know what the patient deems to be "clinically meaningful improvement", then how can they know if their treatment is effective? In a study by Bloom et al, 27 patients with MS were asked to rank 55 possible rehabilitation goals and identify their five most important individual goals during an inpatient rehabilitation stay[10]. They ranked the 55 goals based on importance using a 5-point scale, with 0 being "not important" and 4 being "extremely important"[9]. These goals fell into five broad categories: health/medical issues, daily activities, mobility, community life, and personal well-being[10]. Members of the participants' rehabilitation team were also asked to rank 55 possible rehabilitation goals using the same 5-point scale and identify their five most important rehabilitation goals for each participant[10]. The rehabilitation team consisted of a physiatrist, physical therapist, occupational therapist, nurse and a social worker[10]. The rehabilitation team and the patients with MS agreed on 1.7 out of 5 of the patient's top-rated goals, and the patient's ranked the health/medical, mobility and daily activities domain goals with higher importance than the rehabilitation team[10]. While this study was relatively small, and cannot be generalized to other settings; it indicates the possibility of a gap that can exist between clinicians and PwMS concerning their treatment expectations and goal-setting. This study also highlights the importance of shared-decision making and mutually defining desired rehabilitation outcomes.

While brief, this literature review has identified the need for additional research concerning clinician and patient perspectives on what constitutes a meaningful treatment outcome as well as the need for additional research on how best to capture what is considered a meaningful treatment outcome. The use of objective walking-related outcome measures and patient-reported quality of life outcome measures, as seen in the pharmacological studies cited and in physical therapy practice in general, may be a way to bridge the gap between clinician and PwMS perspectives as well as more effectively assess treatment efficacy.

References:

1. Golan D, Staun-Ram E, Miller A. Shifting paradigms in multiple sclerosis: from disease-specific, through population-specific toward patient-specific. Curr. Opin. Neurol. 2016;29(3):354-361. doi:10.1097/WCO.0000000000000324.
2. Goodman AD, Brown TR, Edwards KR, et al. A phase 3 trial of extended release oral dalfampridine in multiple sclerosis. Ann. Neurol. 2010;68(4):494-502. doi:10.1002/ana.22240.
3. Goodman AD, Brown TR, Krupp LB, et al. Sustained-release oral fampridine in multiple sclerosis: a randomised, double-blind, controlled trial. The Lancet 2009;373(9665):732-738. doi:10.1016/S0140-6736(09)60442-6.
4. Macdonell R, Nagels G, Laplaud D-A, et al. Improved patient-reported health impact of multiple sclerosis: The ENABLE study of PR-fampridine. Mult. Scler. 2016;22(7):944-954. doi:10.1177/1352458515606809.
5. Crayton H, Sidovar M, Wulf S, Guo A. Patient perspectives and experience with dalfampridine treatment in multiple sclerosis-related walking impairment: the step together program. Patient 2015;8(3):283-291. doi:10.1007/s40271-014-0102-z.
6. Baert I, Freeman J, Smedal T, et al. Responsiveness and clinically meaningful improvement, according to disability level, of five walking measures after rehabilitation in multiple sclerosis: a European multicenter study. Neurorehabil. Neural Repair 2014;28(7):621-631. doi:10.1177/1545968314521010.
7. Motl RW, Cohen JA, Benedict R, et al. Validity of the timed 25-foot walk as an ambulatory performance outcome measure for multiple sclerosis. Mult. Scler. 2017;23(5):704-710. doi:10.1177/1352458517690823.
8. Coleman, CI, Sobieraj, DM, Marinucci, LN. Minimally important clinical difference of the Timed 25-Foot Walk Test: Results from a randomized controlled trial in patients with multiple sclerosis. Curr Med Res Opin 2012; 28: 49–56.
9. Miller D, Rudick RA, Hutchinson M. Patient-centered outcomes: translating clinical efficacy into benefits on health-related quality of life. Neurology 2010;74 Suppl 3:S24-35. doi:10.1212/WNL.0b013e3181dbb884.
10. Bloom LF, Lapierre NM, Wilson KG, Curran D, DeForge DA, Blackmer J. Concordance in goal setting between patients with multiple sclerosis and their rehabilitation team. Am. J. Phys. Med. Rehabil. 2006;85(10):807-813. doi:10.1097/01.phm.0000237871.91829.30.