Response to Letter Regarding Article, “Patient-Reported Measures Provide Unique Insights Into Motor Function After Stroke”

We thank Drs Stinear and Byblow for their kind words. These authors identified a compelling message regarding patient stratification from Figure 2 of our prior report: specific ranges of upper extremity (UE) Fugl-Meyer (FM) scores correspond to distinct UE functional states (see below). This approach provides a Rosetta Stone, whereby examination assessments are expressed in terms that are clinically meaningful and elegantly simple.

Drs Stinear and Byblow consider use of this approach in the setting of clinical care delivery, but its value might also extend to clinical trial design, including end points. In some studies, a continuous variable used to measure behavior is collapsed into a categorical variable. Although doing so can decrease statistical power and reduce granularity of the measure, this approach can be advantageous in certain settings, 2 of which are considered below: (1) when the levels of the categorical variable are defined in a manner that has strong clinical validity, and (2) when conversion to a categorical variable enables use of a sliding dichotomous outcome analysis.

Gait velocity is one example where investigators sometimes reduce a continuous measure to a categorical variable, with levels that are clinically valid and meaningful. A key rationale for doing so is a study by Perry et al, who found that self-selected gait velocity among ambulatory patients with chronic stroke fell into 3 categories, each of which is associated with a particular level of ambulation:

1. gait velocity <0.4 m/s, which is associated with ambulation only in home;
2. gait velocity 0.4 to 0.8 m/s, which is associated with limited community ambulation;
3. gait velocity >0.8 m/s, which is associated with unlimited community ambulation.

These 3 descriptions of ambulation are simple and compelling for patients and practitioners. The idea provided by Drs Stinear and Byblow can be rephrased as a suggestion to use this same approach for UE (ie, classify UE movement into 1 of 3 simple categories according to cutoffs in an examination measure). The examination measure for the lower extremity is gait velocity, whereas for the UE it is the arm motor FM score, as follows:

1. FM score 0 to 25, which is associated with UE is not used.
2. FM score 26 to 55, which is associated with UE is used, but at best this is very difficult and very rare.
3. FM score 56 to 66, which is associated with UE is used, and generally functional levels.

A second potential implication of this issue for clinical trial design relates to sliding dichotomous outcome analysis. This type of analysis classifies treatment response dichotomously (ie, as successful or not). Importantly, the criteria used to classify treatment response as successful or not differ according to the severity of stroke. The utility provided a sliding dichotomous outcome approach that has been reviewed for acute stroke trials, which aim to increase the amount of brain tissue that survives and generally use global outcome measures, and for restorative stroke trials, which aim to promote plasticity in surviving brain tissue and increasingly use modality-specific outcome measures.

These ideas require further study. Limitations might be present when Stroke Impact Scale and Motor Activity Log measure UE usage in patients with more severe impairments. For example, the Stroke Impact Scale and Motor Activity Log generally focus on unimanual tasks; however, motor rehabilitation with severe motor impairments may focus on bimanual task training or on use of the paretic UE as an active assist to the less impaired (nonparetic) hand; examples include using the nonparetic hand to stabilize writing paper or holding a box with the paretic UE to open the box using the nonparetic UE. Therefore, measurement of amount and difficulty of UE use in such patients could conceivably benefit from addition of measures that attend to this issue. Such measures would include tasks that are bimanual as well as tasks that have the paretic hand used as an active assist.

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References
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