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Predicting and Detecting Arm Motor Gains in a Trial of Robotic Therapy

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Introduction: Optimal patient selection and patient assessment can maximize the likelihood that a clinical trial of a restorative therapy will detect treatment-induced behavioral gains when present. The current analysis compared multiple arm motor assessments for ability to predict, and to detect, clinically meaningful behavioral gains from robotic therapy. **Methods:** Enrollees were combined across 3 studies that provided 23-24 hours of standardized arm motor robotic therapy, which consisted of repeated grasp-release affected hand movements. Entry criteria included age >18 yr, stroke >3 mo prior, >5 deg range of motion in affected index finger MCP, >25% prolongation to complete 9-hole pegboard (9HP), and no severe apraxia/sensory loss/aphasia/depression. Prior to and at end of therapy, patients were assessed on 8 different measures of arm motor status: Fugl-Meyer Arm Motor Scale (FM-total), Fugl-Meyer Arm Motor Scale-Hand Subsection (FM-Hand), Action Research Arm Test, Box/Blocks Test, time to complete 9HP, hand motor subscale of SIS-2, force of grasping, and force of pinching. Analyses used non-parametric statistics to (1) examine prediction of treatment gains; for each measure, baseline score was correlated with change in that score. (2) examine responsiveness of each scale, defined as percentage of subjects in whom the change in score exceeded 10% of that score's maximum value. **Results:** The 37 patients had a wide range of arm motor deficits at baseline, e.g., baseline FM scores ranged from 14-60 (38 +/- 15, mean +/- SD), with 38% having some aphasia and a wide range of generally moderate sensory deficits. Baseline scores were normally distributed for none of the 8 measures, instead showing tails at one or both ends. In terms of predictors, no single scale showed a significant and meaningful prediction across all subjects. However, among weaker patients (i.e., excluding patients in top quartile, as defined for each scale), FM-hand and FM-total (r=0.5, P<0.02 for both) were each significant predictors; among stronger patients (remove bottom quartile), Box/Blocks emerged as a significant predictor (r=0.57, P<0.04). In terms of responsiveness, SIS performed best (49% of subjects improved by 10% maximum score), followed by pinch and FM-hand. When analyzing only the 19 strongest or the 18 weakest patients, SIS remained the best performer. **Conclusions:** In a clinical trial setting, choice of test instrument is important for optimizing patient selection and for detecting treatment-induced gains when present. In the setting of arm motor therapy for chronic stroke, best prediction of treatment gains was achieved by using one test for weaker patients and a different test for stronger patients–no one test covered all. In terms of responsiveness, the self-rated SIS performed best. These results may be useful for guiding entry criteria and outcome measures in clinical trials of restorative agents.