Minimally Clinically Important Difference (MCID) and Effect Sizes (ES) for Patient-Reported Outcomes Measurement Information System (PROMIS) in Lower Extremity Trauma

Amir Human Hoveidaei, Henry Tout Shu, Anthony R Carlini, Katherine Frey, Robert V O'Toole, Paul Tornetta, George V Russell, David C Teague, Susan Catherine Jane Collins, Michael John Weaver, Thomas F Higgins, Michael J Bosse, Lauren Allen, William T. Obremskey, Conor P Kleweno, Saam Morshed, Babar Shafiq, Paul Tornetta, Renan C Castillo

INTRODUCTION: The interpretability of Patient-Reported Outcomes Measurement Information System (PROMIS) surveys in the orthopaedic trauma population is severely limited as the distributions and minimally clinically important differences (MCIDs) of these measures are unknown. Therefore, the purpose of this study was to establish a range of MCIDs for 10 PROMIS measures, including 3 physical health domains, 3 social health domains, and 4 mental health domains, in patients with lower extremity trauma. Additionally, we sought to define if those MCIDs were broadly applicable across sex, age, and follow-up timepoints.

METHODS: We included 1000 patients with lower extremity fractures from 7 prospective multicenter trials from an orthopaedic trauma consortium. Computerized adaptive testing PROMIS scores were collected at 3 months, 6 months, and 12 months. Physical health domain measures included Physical Function (PF), Pain Interference (PI), and Sleep Disturbance (SLD). Mental health domains included Anxiety, Depression, Psychosocial Illness Impact (PII), and Applied Cognition (AC). Social health domains included Ability to Participate in Social Roles and Activities (APSRA), Satisfaction with Social Roles and Activities (SSRA), and Emotional Support (EMS). MCIDs were calculated by 1) one-half standard deviation, 2) twice the standard error of measurement, and 3) the minimum detectable change (MDC). Additionally, small (0.2), medium (0.5), and large (0.8) Cohen's d effect sizes were calculated.

RESULTS: Patients completed 2546 PF surveys, 2541 PI surveys, 1776 SLD surveys, 2536 Anxiety surveys, 2532 depression surveys, 2515 PSII surveys, 1783 AC surveys, 2529 APSRA surveys, 1780 SSRA surveys, and 1774 EMS surveys. The mean±SD age was 42±13 years and most patients were male (69%). Physical health MCIDs were between 3.61 to 8.34 T-score points, Mental health MCIDs were between 5.22 to 9.12 T-score points, and social health MCIDs were between 4.53 to 7.75 T-score points (**Figure 1**). Across all domains, small ES were between 1.45 to 2.24, medium ES were between 3.61 to 5.61, and large ES were between 5.78 to 8.97 T-score points. Across all surveys, the MDC consistently provided the highest MCID estimates. For all measures, there were generally little MCID differences between sex, age, and follow-up timepoints for each survey (**Table 1**).

DISCUSSION AND CONCLUSION:

In lower extremity trauma patients, MCIDs were between 3.51 to 9.23 T-score points. The MDC provided the greatest estimates, consistent with prior studies. As MCIDs varied little across sex, age, and follow-up, these MCIDs can be applied broadly to lower extremity trauma patients. These results allow for clinical interpretation of these survey scores in lower extremity trauma patients and can be used to guide planning and interpretation of future orthopaedic trauma clinical trials.