

The Creation and Validation of a New Rib Fracture-Specific Patient-Reported Outcome Measure: The Outcomes After Chest Trauma Study

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Purpose: Chest wall injury is a common cause of morbidity after blunt-force trauma. The use of patient reported outcome measures (PROMs) in these patients is inconsistent in the current literature, with limited validation of the currently used PROMs in a rib fracture population. No rib fracture-specific PROM existed. This study reports on the generation and subsequent validation of the first disease-specific PROM for chest wall trauma.

Methods: A three-phase multicenter study was performed across 20 hospitals to produce and validate a new PROM, the Chest Trauma Score (CTS). The COSMIN criteria were used throughout to guide the development and the validation of the score. Phase one consisted of a series of focus groups in which the experiences of rib fracture patients were used to generate items for the new PROM. A constructivist grounded theory method was applied to the data and a new conceptual model for rib fracture recovery was created. Phase two involved formal cognitive interviews and focus groups with both rib fracture patients and the health-care professionals involved in delivering chest trauma care. Content validity and readability scores were used to judge the overall content validity of the new PROM against two comparative instruments, the Short Form-12 (SF-12) and the EuroQol 5 Dimensions 5-Level (EQ-5D-5L). Phase three was a prospective longitudinal validation of the PROMs at baseline, post-injury, and 90 and 104 days post-injury. The CTS was further refined by a mixture of classic test theory and Rasch analysis. A "global rating of change" score was used as the anchor to calculate the minimum clinically important difference (MCID). Test-retest reliability, internal consistency, the standard error of measurement (SEM), and the smallest detectable change (SDC) were calculated to assess the suitability of the CTS as a potential research outcome measure.

Results: 22 patients attended focus groups to generate items (phase one). 12 patients and 16 health-care professionals underwent cognitive interviews to establish content validity (phase two). 311 patients completed the instrument in phase three. The CTS consists of 32 items assessing pain, mobility, activities, independence, respiratory and psychological health. The CTS obtained greater content validity scores than the EQ-5D and SF-12, which lack questions on respiratory health. The CTS fit the Rasch model well (RMSE = 0.01, IMSNQ 1.05, ZSTD 0.2). Test-retest reliability was excellent (intraclass correlation coefficient = 0.98). Internal consistency was equally high (Cronbach's $\alpha = 0.94$). The MCID for the CTS was 9; this change was above the SDC (SDC = 6) and so could be detected by the instrument. The total scores for the CTS correlated well with the EQ-5D.

Conclusion: This study provides the first condition-specific and validated PROM for use in chest trauma. Important measurement properties of the CTS have been defined and validated, allowing the CTS to be used in both research and clinical practice.