

Evaluating Construct Validity of the Patient-Reported Outcomes Measurement Information System 16-Item Profile in Total Laryngectomy Patients

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Background

The Patient-Reported Outcomes Measurement Information System® (PROMIS®)-16 Profile assesses eight health-related quality of life domains using two items per domain. The PROMIS-16 was developed using data from a sample of 5775 general population respondents and demonstrated strong psychometric properties in a second cohort of general population respondents.

Objective

Evaluate the construct validity of the PROMIS-16 domain and summary scores among total laryngectomy patients.

Methods

- 253 laryngectomy patients were recruited between July 2023 and March 2024 from Massachusetts Eye and Ear Hospital, International Association of Laryngectomees, and two online laryngectomy support groups.
- The PROMIS-16, EQ-5D-5L, and University of Washington Quality of Life Questionnaire (UW-QoL) were administered.
- We evaluated 130 evidence-based a priori construct validity hypotheses** concerning the magnitude and direction of Pearson product moment correlations reflecting associations of PROMIS-16 scores with UW-QoL and EQ-5D scores. We applied standard thresholds to classify effect sizes as low ($r < .30$), moderate ($.30 \leq r < .70$), or high ($r \geq .70$).

KEY TAKEAWAY

Construct validity of the PROMIS-16 domain and summary scores was demonstrated in patients who underwent total laryngectomy providing support for the usefulness of the PROMIS-16 in clinical samples.

Results

Over half (65%) of patients were male, median age was 69 years (IQR: 62 – 74), most were White (93%), non-Hispanic (98%), and residing in the United States (88%).

Domain scores ranged from 46.6 (SD=11.8) for cognitive function to 53.8 (SD=7.1) for social roles. The physical and mental health summary scores were 49.7 (SD=7.8) and 51.6 (SD=7.8), respectively.

Eighty-seven percent of associations conformed with our hypotheses, well exceeding the 75% COSMIN criteria, with more alignment for EQ-5D (93%) than UW-QoL (81%). Except for cognitive function, which was not associated with any UW-QoL or EQ-5D scores, the PROMIS-16 domain scores were significantly associated with those of UW-QoL and EQ-5D, with absolute correlations ranging from 0.23 to 0.69 and 0.29 to 0.74, respectively. The physical and mental health summary scores were significantly associated with all UW-QoL and EQ-5D scores (range: 0.31 to 0.62 and 0.40 to 0.71, respectively).

Table 1. Absolute Correlations of PROMIS-16 Domain and Summary Scores with UW-QoL and EQ-5D Scores among Laryngectomy Patients (N=253)

| COMPARISON MEASURES | | PROMIS-16 | | | | | | | | | |
|---------------------|--------------------|-------------|------|-------------|-------------|-------------|------|-------------|-------------|-------------|-------------|
| | | CF | SOC | ANX | DEP | FTG | SLP | PI | PF | PHY_SUM | MEN_SUM |
| UW-QoL | Activity | 0.06 | 0.50 | 0.42 | 0.45 | 0.56 | 0.47 | 0.41 | 0.57 | 0.61 | 0.61 |
| | Appearance | 0.07 | 0.34 | 0.29 | 0.37 | 0.29 | 0.31 | 0.32 | 0.26 | 0.31 | 0.40 |
| | Pain | 0.15 | 0.36 | 0.23 | 0.29 | 0.35 | 0.30 | 0.65 | 0.29 | 0.37 | 0.47 |
| | Mood | 0.14 | 0.52 | 0.57 | 0.69 | 0.50 | 0.45 | 0.32 | 0.38 | 0.43 | 0.62 |
| | Anxiety | 0.03 | 0.38 | 0.55 | 0.58 | 0.41 | 0.37 | 0.30 | 0.29 | 0.33 | 0.51 |
| | General HRQoL | 0.09 | 0.50 | 0.40 | 0.44 | 0.51 | 0.42 | 0.44 | 0.51 | 0.56 | 0.58 |
| | Overall QoL | 0.18 | 0.49 | 0.43 | 0.53 | 0.47 | 0.40 | 0.44 | 0.40 | 0.46 | 0.60 |
| EQ-5D | Mobility | 0.03 | 0.38 | 0.31 | 0.29 | 0.38 | 0.31 | 0.48 | 0.68 | 0.71 | 0.46 |
| | Self care | 0.03 | 0.39 | 0.32 | 0.30 | 0.32 | 0.30 | 0.42 | 0.42 | 0.46 | 0.44 |
| | Usual activities | 0.07 | 0.57 | 0.48 | 0.52 | 0.55 | 0.47 | 0.49 | 0.57 | 0.62 | 0.65 |
| | Pain/discomfort | 0.12 | 0.34 | 0.30 | 0.31 | 0.41 | 0.33 | 0.72 | 0.38 | 0.45 | 0.51 |
| | Anxiety/depression | 0.10 | 0.49 | 0.62 | 0.74 | 0.51 | 0.44 | 0.38 | 0.33 | 0.40 | 0.65 |
| | Total EQ-5D | 0.13 | 0.54 | 0.55 | 0.61 | 0.57 | 0.46 | 0.68 | 0.55 | 0.62 | 0.71 |

Note: Shading tracks magnitude of correlations from dark green (lowest) to dark red (highest); bold italic entries did not conform with hypotheses; Cognitive Function – Abilities (CF); Ability to Participate in Social Roles and Activities (SOC); Anxiety (ANX); Depression (DEP); Fatigue (FTG); Sleep Disturbance (SLP); Pain Interference (PI); Physical Function (PF); PHY_SUM: Physical Health Summary Score; MEN_SUM: Mental Health Summary Score UW-QoL: University of Washington Quality of Life Scale; EQ-5D: EQ-5D Health Questionnaire; HRQoL: Health Related Quality of Life; QoL: Quality of Life

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