PSYCHOMETRIC PROPERTIES OF THE EORTC QLQ-PR25 ASSESSMENT INSTRUMENT IN PATIENTS WITH PROSTATE CANCER

Hypothesis / aims of study

Prostate cancer is the most common form of cancer among males in North America and Europe, and its incidence rate has increased rapidly in Asia during the past few years. Although the survival time for those patients with prostate cancer has increased due to early detection and improved treatments, the treatment-associated side effects and disease-related symptoms (e.g., urinary, sexual, and bowel dysfunction) have been shown to significantly impact their health-related quality of life (HRQOL). It is, therefore, important to collect and use reliable and valid HRQOL information from these patients to document responsiveness to any specific treatments or interventions and to facilitate and guide clinical decisions.

Patient-reported outcomes (PROs), including HRQOL, are becoming increasingly important in clinical research and practice, and therefore much effort has been directed toward the development of more objective methods of assessment [1]. The aim of this study was to evaluate the psychometric properties of the EORTC QLQ-PR25 for HRQOL assessment in patients with prostate cancer.

Study design, materials and methods

135 prostate cancer patients were recruited in the urology outpatient clinic of a university teaching hospital. Each patient completed the EORTC QLQ-PR25 at every visit between 2004 and 2008, totaling 633 assessments.

This study employed both classical test theory (confirmatory factor analysis; CFA) and Rasch model based approaches [2] to thoroughly examine and understand the psychometric properties of the EORTC QLQ-PR25 for examining the stability of item calibrations within each of the four domains across different time of assessment and evaluating whether the item coverage was adequate to reliably assess the person traits along the latent construct.

The EORTC QLQ-PR25 questionnaire, developed by the European Cancer Research and Treatment Organization (EORTC), is a 25-item prostate cancer specific HRQOL questionnaire and measures four domains: Urinary Symptoms (US; 9 items), Bowel Symptoms (BS; 4 items), Hormonal-treatment-related Symptoms (TS; 6 items) and Sexual Functioning (SX; 6 items). To facilitate ease of interpretation of the results from Rasch analysis, so that each item was scored in the same direction, from 1 (worst HRQOL) to 4 (best HRQOL), with higher scores indicating better HRQOL (less symptoms or better functioning). All confirmatory factor analysis were conducted with the LISREL program 8.72 (Scientific Software International, Inc.) and Rasch analyses were conducted with Winsteps software version 3.47.

Results

CFA and Rasch analysis supported the unidimensionality of the four EORTC QLQ-PR25 domains. Overall, there was steady item hierarchy and good item stability (item parameter invariance) across the assessment time periods in all four domains. The items in the urinary symptoms domain spread satisfactorily along the latent trait (coverage rate, 71.3%). Both BS and TS domains had a significant ceiling effect, while the SX domain showed a noticeable floor effect, which showed insufficient coverage of the construct at the lower end in these three domains.

The range of item thresholds and person measures of the EORTC QLQ-PR25

<table>
<thead>
<tr>
<th>Item threshold</th>
<th>US</th>
<th>BS</th>
<th>TS</th>
<th>SX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cover %</td>
<td>73.1</td>
<td>13.0</td>
<td>38.5</td>
<td>42.7</td>
</tr>
<tr>
<td>Floor effect (%)</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>56.9</td>
</tr>
<tr>
<td>Ceiling effect (%)</td>
<td>26.9</td>
<td>87.0</td>
<td>61.5</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Cover %: Item threshold range covered person measure percentage

Interpretation of results

Since patients with prostate cancer always exhibit multiple treatment modalities and long disease duration, our sample was a cohort representative of the prostate cancer population and therefore the results from this pooled sample can be more practical in reflecting the clinical implication.

Concluding message

Rasch analysis indicated that item stability across different time periods was demonstrated for each of the four EORTC QLQ-PR25 domains. Adding more clinical relevant and content appropriate items to each domain to fill the item gaps as well as to
eliminate the ceiling and floor effects would be desirable so that the content relevance and scale performance can be improved. Our systematic and thorough analysis steps provided a way to better understand the psychometric properties of the EORTC QLQ-PR25 and it may be used to identify what can and should be done for the future development of a more objective questionnaire.

References
2. Value Health 2004;7 Suppl 1:S22-26

Disclosures
Funding: None Clinical Trial: No Subjects: HUMAN Ethics Committee: Institutional Review Board of the China Medical University Hospital Helsinki: Yes Informed Consent: Yes