Development of the EORTC QLQ-CAX24, a questionnaire for cancer patients with cachexia

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Cancer cachexia is...

...a multidimensional syndrome characterised by

- involuntary weight loss
- muscle atrophy
- physiological changes

Adversely effects

- performance status & QOL
- response to & tolerance of therapy
- survival

Why do we need a HRQOL tool?

1. Patient reported outcomes important endpoints for clinical trials

2. Provide evidence of patient perceived benefit

3. Communication aid

Inadequacy of current tools

- Most relevant & important HRQOL issues not covered by EORTC QLQ-C30 or FACT-G

- FAACT – methodological flaws in development & fails to address social impact

European Organisation for Research and Treatment of Cancer

Quality of Life Group

Core questionnaire = QLQ-C30

EORTC QLG Methodology

Phase 1: Issue generation (1 yr)

Phase 2: Create provisional questionnaire (6m)

Phase 3: Pilot testing (1 yr)

Phase 4: International validation (2 yrs)
Phase 1: Issue generation
- Systematic literature review
- Semi-structured interviews
  a. Data saturation for issues (patients)
  b. Review whole issue list (patients & HCPs)

Phase 2: Item creation
- Issues → items
- Translated into relevant languages for Phase 3

Phase 3: Pilot testing
- QLQ C30 + cachexia questionnaire
  Rate relevance & importance
  Additional comments?

Results: Patient participants
<table>
<thead>
<tr>
<th></th>
<th>Pure</th>
<th>Mixed (secondary)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syndrome</td>
<td>54</td>
<td>51</td>
</tr>
<tr>
<td>Refractory</td>
<td>21</td>
<td>22</td>
</tr>
</tbody>
</table>
- N=149 patients (84 male)
- Mean age 62 yrs (SD=13 yrs), range: 20-93 yrs

Primary diagnosis
- Lung
- Upper GI
- Head & neck
- Colorectal
- Breast
- Lymphoma
- Gynaecological
- Male cancer
- Melanoma
- Kidney
- Unknown origin
- Thyroid
- Brain

Phase 1
- Literature review
  68 issues
- Semi-structured patient interviews (n=21)
  64 issues (22 new)
- 90 issues rationalised to 50
  Reviewed by 18 patients and 12 HCPs
Phase 2: Provisional questionnaire created

50 issues → 44 items

7 additional issues
2 new issues
4 issues separated into 9 items

13 issues deleted
Participant feedback: 9
Issue valence ambiguity: 2
Moved to case report form: 2

Translated into 7 languages

During the past week:

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>A little</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you felt your weight loss was out of control?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Phase 3: Pilot testing in 110 patients

44 items → 24 items

7 items deleted
Failed item retention criteria: 15
Patient comments: 4
Scoring ambiguity: 1

Relevance & importance scores
Prevalence
Floor & ceiling effects

CONCEPTUAL SCALE

<table>
<thead>
<tr>
<th>ISSUES</th>
<th>ISSUES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eating and weight-loss worry</td>
<td>Worried about weight loss. Worried not eating enough. Worried about ultimate result of weight loss.</td>
</tr>
<tr>
<td>Eating difficulties</td>
<td>Willing but not able to eat. Difficulty drinking. Difficulties swallowing.</td>
</tr>
<tr>
<td>Physical decline</td>
<td>Weight loss preventing usual activities. Too tired to eat. Unable to eat because in pain.</td>
</tr>
<tr>
<td>4 single items</td>
<td>Dry mouth. Indigestion/heartburn. Forcing self to eat. Inadequate information.</td>
</tr>
</tbody>
</table>

Scale

<table>
<thead>
<tr>
<th>Convergent Validity with scale (range)</th>
<th>Internal Consistency</th>
<th>Cronbach’s alpha</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food aversion</td>
<td>0.41 to 0.53</td>
<td>0.72</td>
</tr>
<tr>
<td>Eating and weight-loss worry</td>
<td>0.52 to 0.60</td>
<td>0.74</td>
</tr>
<tr>
<td>Eating difficulties</td>
<td>0.32 to 0.49</td>
<td>0.62</td>
</tr>
<tr>
<td>Loss of control</td>
<td>0.43 to 0.66</td>
<td>0.79</td>
</tr>
<tr>
<td>Physical decline</td>
<td>0.39 to 0.52</td>
<td>0.62</td>
</tr>
</tbody>
</table>

Summary

Conclusion
The QLQ-CAX24 is relevant, acceptable & applicable to patients with cancer cachexia. It may be used for research & in clinical practice.
Acknowledgements

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