Assessing Quality of Life

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Disclosures

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2. Accuray and Erasmus MC have a research agreement in place

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Assessing Quality of Life

Outline

• What is Quality of Life (QoL)?
• Why measure QoL?
• How to assess QoL?
• Examples from trials of radiotherapy for prostate cancer
• Take home messages
What is Quality of Life?

• An individual’s perceptions of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns

• It is a broad ranging concept affected in a complex way by the persons’ physical health, psychological state, level of independence, social relationships and their relationship to salient features of their environment

WHO QoL Group, 1995. www.who.int
Health-Related Quality of Life (HRQOL)

- Symptoms of disease and treatment
- Physical health
- Psychological state
- Social relationships
- Spiritual functioning
- Environment
- Financial issues
- Independence level
- ...
Why Measure Quality of Life?

1. Collection of QoL data in clinical practice allows unique insight into the experiences of patients:
   - It provides unique information not captured by standard clinical or laboratory information
   - It facilitates clinical decision-making
   - It helps monitoring disease progression
   - It improves accuracy of prognosis
   - It helps improving physician-patient communication

2. Collection of data in clinical research:
   - It helps stratifying patients for cancer clinical trials
   - It helps better understanding trial results
   - It identifies sensitive scales for a specific population
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Feedback to Patient (and Clinician)

Your score for cognitive functioning: 65

- The green part represents all scores that are higher than the average.
- The yellow part represents all average scores.
- The red part represents all scores that are lower than the average.

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2. Collection of data in **clinical research**:
   - It helps stratifying patients for cancer clinical trials
   - It helps better understanding trial results
   - It identifies sensitive scales for a specific population
• Clinicians have the propensity to underestimate the incidence, severity and distress of symptoms experienced by cancer patients
• In addition, patients report symptom onsets earlier than clinicians do
• QoL data provide independent prognostic information for survival
• Major efforts are needed to implement such knowledge into routine care applications

Systematic review n=36 studies
Xiao C et al, Cancer Nurs 2013;36:E1-16
Reporting Symptoms: Patient vs. Clinician

n=200, genito-urinary cancers (94% prostate cancer)
Observable symptoms (vomiting) vs. subjective symptoms (fatigue)

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Is Quality of Life Predictive of Overall Survival?

n=137 studies with QoL data published over the last 5 yrs

Yes =118 (86%)
No=19 (14%)

IPSS: International Prognostic Scoring System

Efficace F et al, Lancet Oncology 2015;16:1506-14
Why Measure Quality of Life? (cont’d)

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Patient Reported Outcome (Measures)

PRO(Ms): Umbrella term for symptoms, functioning, quality of life (QoL), well-being:

- It is provided by the patient without interpretation or adjustment from clinician (or anybody else)
- Proxy ratings are only acceptable when individuals are unable to make their own judgements

FDA and EMA recognize PROMs as:

- Indicator for quality of care
- Guidelines for evaluation in clinical trials and effectiveness studies
How to Evaluate Quality of Life?

• Several measures:
  • EORTC QLQ-C30
  • FACT-G (Functional Assessment of Cancer Therapy)
  • EPIC-26 (Expanded Prostate Cancer Index Composite)
  • PROMIS (Patient-Reported Outcomes Measurement Information System)
  • (PRO)-CTCAE (Common Terminology Criteria for Adverse Events)
  • …

• CTCAE is the most widely used method for quantifying harm from treatment experienced by patients
• QoL is not (only) toxicity
• Think of patient’s burden
• Make a careful selection
• Use questionnaires that are meaningful also to patients
• Minimize overlap
• If possible, use computerized adaptive testing (CAT)
EORTC QLQ-C30

Five functional scales:
- Physical
- Role
- Cognitive
- Emotional
- Social

Three symptom scales:
- Fatigue
- Pain
- Nausea/vomiting

Global health and quality of life scale

Single items (dyspnoea, insomnia, appetite loss, constipation, diarrhoea, financial impact)

Several specific modules

Aaronson NK et al. J Natl Cancer Inst. 1993;85:365-76
**HYPRO Trial: Quality of Life**

EORTC QLQ-PR 25: Prostate (not radiotherapy) specific; 6 domains; scale score 0-100

<table>
<thead>
<tr>
<th>Domain</th>
<th>Symptoms/Impacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bowel</td>
<td>blood loss, bloated feeling, incontinency</td>
</tr>
<tr>
<td>Urinary</td>
<td>frequency, nocturia, urgency, dysuria, incontinence</td>
</tr>
<tr>
<td>Sexual function</td>
<td>erectile function, ejaculation, pleasure</td>
</tr>
<tr>
<td>Sexual activity</td>
<td>activity, interest</td>
</tr>
<tr>
<td>Hormone</td>
<td>flushes, swollen nipples, weight gain, masculinity</td>
</tr>
<tr>
<td>Incontinence</td>
<td>problems related to use of pads</td>
</tr>
</tbody>
</table>

HYPRO Trial: EORTC QLQ-PR 25

Association Between Moderate-Severe QoL Reduction and RTOG-EORTC Grade ≥2 Toxicity

<table>
<thead>
<tr>
<th>Genitourinary toxicity</th>
<th>Arm</th>
<th>Grade ≥ 2</th>
<th>Grade 0-1</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;10 points reduction in QoL over baseline</td>
<td>39 x 2 Gy</td>
<td>53.7 %</td>
<td>46.3 %</td>
</tr>
<tr>
<td></td>
<td>19 x 3.4 Gy</td>
<td>62.8%</td>
<td>37.2%</td>
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<tr>
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<td>19 x 3.4 Gy</td>
<td>42.1%</td>
<td>57.9%</td>
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</table>
Genitourinary, Gastrointestinal and Sexual Toxicity over Time

n=864 patients with QOL data; dose 36.25 Gy (84%); EPIC questionnaire

Baseline, 1,2,3 mos, then 3-6 mos intervals. Clinically significant is change of >½ SD of baseline value

EPIC (scale 0-100>better)

Take Home Messages

• Quality of Life (QoL) should be routinely assessed in clinical practice and in cancer trials
• QoL data improve decision-making, help monitoring treatment outcome, and improve physician-patient communication
• QoL data are prognostic for overall survival
• Several instruments are available, make the right choice!
• In hypofractionation trials of prostate cancer, QoL decreases but in the same way as in conventional schedules
Thank you