Development of a Health-related Quality of Life Questionnaire specifically for people
with Anal Cancer treated with Chemoradiotherapy: The EORTC QLQ-ANL27

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Introduction

Anal carcinoma is an uncommon malignancy accounting for 2% of gastrointestinal malignancies with higher incidence seen in women and increasing prevalence over the past 25 years [1]. Chemoradiotherapy (CRT) is the standard of care for non-metastatic cases and achieves good loco-regional control and sphincter preservation [2]. However this approach to treatment is associated with significant morbidity compromising health-related quality of life (HRQoL) with clinician-reported acute grade 3/4 toxicities (e.g., skin, bowel, urinary) as high as 80% and severe late effects (e.g., bowel and sexual function) recorded in about 10% patients [3]. However these treatment-related effects are poorly quantified not least because there has previously been no anal cancer specific HRQoL measure.

Objective

Develop a questionnaire to supplement the core EORTC Quality of Life Questionnaire (EORTC QLQ-C30) to measure all specific and relevant HRQoL issues facing anal cancer patients treated with CRT including late effects of treatment.

Methods

The methodology was informed by the rigorous EORTC QLG Module Development Guidelines [4] and included three phases:

- 1. a) **Generation of a list of HRQoL issues** through a systematic review of the literature and semi-structured interviews with anal cancer patients treated with CRT recruited from different countries across Europe and Canada; b) **Review of the issues** by Health Care Professionals (HCPs) with expertise in anal cancer and patients
- 2. **Operationalisation of the list of issues into questions** using the EORTC Item Library.
- 3. **Pilot testing the draft questionnaire** with a larger group of patients to examine the performance of the questions and their relevance and importance to patients.

The following a priori decision rules for the exclusion of questions in the final version of the questionnaire were applied:

- ❖ <60% patients rated the item as relevant and important (quite a bit or very much);
- ❖ <70% patients reported the issue applies a little bit, quite a bit or very much;
- ❖ Floor or ceiling effects (<10% patient endorsing response options 1/2 and 3/4);
- ❖ Patient comments and clinical judgement

Results

Phase 1

- ❖ 152 publications reporting HRQoL issues of anal cancer patients treated with CRT were reviewed and only 11 studies used patient-reported outcome measures. In the absence of an anal cancer specific tool, generic (e.g., EORTC QLQ-C30) or colorectal cancer specific measures (e.g., EORTC QLQ-CR29) were used. Bowel function, particularly diarrhoea, and sexual problems were the most commonly reported QoL concerns [5].
- ❖ 43 patients from 5 countries (Canada, Cyprus, Germany, Poland, and UK) across the disease / treatment spectrum were interviewed. The sample included 30 females, 13 males, mean age 62.9 years, 47% on treatment or within 6 months of starting treatment and 7 patients with a stoma.
- ❖ 197 HRQoL issues were generated.
- ❖ A refined list of **134 issues** was reviewed for relevance and importance by 34 HCPs and 10 patients.

Phase 2

A draft **65 item** questionnaire was created with a 4 point Likert-type scale (1 “not at all” to 4 “very much”).

Phase 3

- ❖ 100 patients from 8 counties (Canada, Cyprus, Germany, Greece, Italy, Norway, Poland, and UK) completed the pilot questionnaire and took part in a debrief interview. The sample included 64 females, 36 males, mean age 62.3 years, 41% on treatment or within 6 months of starting treatment and 11 patients with a stoma.
- ❖ After application of the decision rules, questions were removed, combined or modified resulting in a **27 item** measure– the **EORTC QLQ-ANL27**
- ❖ The following multi-item subscales were hypothesised
 - ❖ **Bowel function** (6 questions)
 - ❖ **Pain or discomfort** (6 questions)
 - ❖ **Sexual function** (7 questions separate male and female questions)
 - ❖ **Stoma-related** (3 questions)
- ❖ **Single items** (frequent urination, keeping clean, proximity to toilet, lower limb oedema, planning activities)
- ❖ Stoma and sexual activity screening questions

Conclusions

The EORTC QLQ-ANL27 is the first anal cancer-specific HRQoL measure capturing acute and chronic effects of anal cancer treated with CRT and is suitable for use in clinical trials and clinical practice.
International validation of the EORTC QLQ-ANL27 is now underway to test its psychometric properties and confirm the hypothesised subscales.

References

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PHASE 1

Literature review & interviews (134 issues)

PHASE 2

Create preliminary questionnaire (65-items)

PHASE 3

Pilot testing