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Choice of a patient-reported outcome measure for patients with anal cancer for use in cancer clinical trials and routine clinical practice: a mixed methods approach

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Abstract

Background

In the USA, more than 7200 new cases of anal cancer were diagnosed in 2014 with incidence rising. Concurrent chemoradiotherapy improves cancer-related outcomes but has led to an increase in acute and late adverse events. Patient-reported outcomes (PRO) are increasingly included in trials as a surrogate measure for reporting of late adverse events. This study aimed to select the most effective PRO to use in clinical research and practice for anal cancer since no questionnaire specific for anal cancer has been developed.

Methods

A mixed methods approach was used. A systematic review estimated the frequency of use of PROs and clinician reporting instruments used in anal cancer trials including radiation treatment. Health professional semi-structured interviews explored preferred questionnaires and revealed missing items; analysis was done using the framework approach. Two symptom-based, validated questionnaires were selected and assessed by means of inductive content analysis to highlight discrepancies relevant to anal cancer.

Findings

34 relevant studies reported on radiotherapy adverse events. For PROs, EORTC QLQ-C30 (n=5) and EORTC QLQ-CR38 (n=3) were used most frequently. RTOG/EORTC (n=17) and CTCAE (n=15) criteria were most commonly used for clinician reporting. EORTC QLQ-C30 and EORTC QLQ-CR38, and National Cancer Institute's (NCI) PRO-CTCAE were selected for further analysis. No consensus for questionnaire content or design was found through health professional interviews (n=8). Domains and codes relevant to anal cancer treatment were selected from interviews to inform questionnaire analysis. 27 domains and 60 codes were found in EORTC questionnaires, and 21 domains and 44 codes in NCI PRO-CTCAE. Four domains and 16 codes were not covered by EORTC systems including radiation skin reaction. Six domains and 45 codes were not covered by NCI PRO-CTCAE including vaginal stenosis and bowel urgency.

Interpretation

This study shows that there are gaps in the questionnaires commonly used to record adverse events using PROs for anal cancer. Expert opinion is valuable in highlighting relevant missing items but

provides no consensus on design and wording preferences. For use in longitudinal follow-up of patients with anal cancer treated with (chemo)radiation, the EORTC-QLQ system has the fewest missing symptom items for use as a validated PRO in clinical research and practice.

AG – design, conception, analysis of project and first author of abstract

EOF – design and analysis of content analysis of validated questionnaires and approval of abstract

JB – conception of design for content analysis of validated questionnaires and approval of abstract

SD, DSM, GV – design, conception and analysis of project and approval of abstract.