Radiotherapy and Oncology xxx (2016) xxx–xxx

Contents lists available at ScienceDirect

Radiotherapy and Oncology

journal homepage: www.thegreenjournal.com

Original article

A controlled study of use of patient-reported outcomes to improve assessment of late effects after treatment for head-and-neck cancer

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ARTICLE INFO

Article history:
Received 4 January 2016
Received in revised form 25 April 2016
Accepted 25 April 2016
Available online xxxx
Trial registration: The Danish Data Protection Board (File number, 2013-41-1857) and clinicaltrials.gov (NCT01803061).

Keywords:
Head-and-neck cancer
Patient-reported outcomes
Late effects

ABSTRACT

Background and purpose: To test the effect of longitudinal feedback on late effects reported by survivors of head-and-neck cancer (HNC) to clinicians during regular follow-up.

Material and methods: A total of 266 participants were sequentially assigned to either control or intervention group and filled in electronic versions of the EORTC QLQ C-30, H&N35, HADS and a study-specific list of symptoms at up to two consecutive follow-up visits. Participants' symptoms displayed according to severity were provided to the clinician for the intervention group but not for the control group. Linear mixed-effects models were used to examine the number of symptoms assessed by clinicians (primary outcome). Multivariate linear regression models examined participants' long-term symptom control and QoL (secondary outcome).

Results: More symptoms were assessed by clinicians in the intervention group at all three visits ($P < 0.001$, <0.001, and $P = 0.04$). No effect was observed on most patient outcomes. When prompted by patient-reported outcomes at consultations, clinicians and patients were in better agreement about the occurrence of severe symptoms at all three visits.

Conclusion: Timely patient-reported outcomes to clinicians in routine follow-up of HNC survivors enhanced clinicians' rates of assessment of late symptoms. Giving reports of patient-reported outcome to clinicians had limited impact on participants' QoL or symptom burden.

Survivors of head-and-neck cancer (HNC) often have functional problems related to the disease and to the aggressive multimodal treatment [1]. Treatment may result in fibrosis and damage of vascular and neural structures, leading to sometimes irreversible late effects [2–5].

The many late adverse effects have led to intense research into finding ways of preventing acute and late effects without compromising the effect of treatment. Intensity modulated radiation therapy (IMRT), organ sparing concomitant chemotherapy, epidermal growth factors receptor inhibitor use and function-sparing surgery are all important therapeutic approaches that bring positive changes to long-term survivorship [4,6–8]. However, as it may not always be possible to spare organ function, researchers also concentrate on the evaluation and predictors of normal tissue toxicity and late effects in HNC patients so that high-risk and low-risk patients at an early stage during treatment can be identified [9–11].

Most studies on late effects in this patient population have been based on ratings by the clinicians treating patients, thereby combining clinical examination results with the clinicians' interpretation and rating of symptoms as expressed by patients [12,13]. Management of these symptoms could be improved by involving patients more actively, and a few reports support that patient-reported outcomes given in a timely manner to oncologists are valuable in clinical care [12,14–16].

Patient-reported outcomes have been shown to enhance communication about and assessment of symptoms and health-related quality of life (QoL) [17–20] and also raise awareness of these issues both among clinicians and patients [21,22]. However, the evidence is not consistent probably due to differences among studies in overall design, outcome measures applied and patient populations [17–19,21,23–29].

We report data from a controlled intervention study (WebCan), which developed and tested a computer-based patient-reported outcome assessment tool to examine whether longitudinal feedback of outcomes to oncologists during follow-up care would affect the number of symptoms assessed by the oncologists

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http://dx.doi.org/10.1016/j.radonc.2016.04.034
0167-8140/

(primary outcome) and improve patients' long-term symptom control and health-related QoL (secondary outcome). We further tested for congruence of symptoms reported by participants and oncologists.

Materials and methods

The study has been described in detail elsewhere [30,31]. Briefly, between August 1, 2011 and May 31, 2013, we invited 560 survivors of cancers in the oral cavity, pharynx, larynx, tongue or salivary glands, who were treated with radiotherapy alone or with chemotherapy or surgery to participate in the WebCan study. Patients were eligible if they were recurrence-free, had finished treatment at least 6 months before the invitation and were enrolled in the regular follow-up programme, with at least three planned visits to the outpatient clinic at the Department of Oncology, Herlev University Hospital, Copenhagen, Denmark.

Sample size

Power calculations were made to identify relevant end-points described in the literatureavailable at the time of the set-up of the study [32,33]. We hypothesised that the WebCan tool would enable oncologists to increase the assessment rates for HNC-specific symptoms by at least 25%. The sample size was determined with a power of 0.90 and an alpha of 0.05 for a sample size of 100 eligible survivors in each group. On the basis of previous findings of participant attrition in studies of HNC patients [34,35], we aimed at including 130 survivors in each group.

Ethics and data protection

Consenting patients who fulfilled the inclusion criteria signed the consent form and were subsequently telephoned by a research assistant, who provided oral information and obtained oral consent. In Denmark, participating clinical wards grant ethical approval of studies in which biological material is not collected, while approval of data handling from the Danish Data Protection Board is mandatory. The WebCan study was approved by this authority (File number, 2013–41-1857) and registered at www.clinicaltrials.gov (NCT01803061).

Design

We conducted a controlled intervention study with sequential assignment of patients first to a 'control' condition and subsequently to an intervention. Collection of data was completed in the control group first and thereafter in the intervention group. When all participants in the control group had completed up to three visits to the clinic, each 4–6 months apart, participants in the intervention group were included. This study design was chosen to avoid the risk of carry-over effect, which we feared would contaminate the data. If an oncologist was exposed to the outcomes reported by one patient, we anticipated that the oncologist would be sensitised to the value of such reports and accordingly change his or her consultation style with all subsequent patients [36], and patients in different groups might share information about the benefits of the reports, thereby diluting the effect of the intervention.

Intervention

Computers were accessible in the patient waiting area, which patients used to fill in a brief questionnaire (the WebCan symptom list), including an empirically derived symptom checklist and a standardised scale for measuring anxiety and depression. All participants completed the electronic questionnaire immediately before their regular follow-up visit.

Each time a participant in the intervention group completed the study questionnaire, the computer scored the response and generated a two-page report (the WebCan report), which displayed the predefined symptoms according to severity by colour and height on a bar graph. The report was printed and provided to the participant and the oncologist, so that the information was available for the subsequent regular follow-up visit. No directions were given to the oncologist on how to use the available information.

Control condition

Participants allocated to the control group also filled in the questionnaire including the WebCan symptom list immediately before the consultation, but no printed WebCan report was provided to oncologists or participants.

Patient-reported outcomes used

The WebCan symptom list comprises 23 symptoms relevant to long-term HNC survivors, chosen in cooperation with oncologists employed at the clinic. Participants were asked to indicate the prevalence and severity of each symptom on a 10-point rating scale, 1 being 'Not at all' and 10 being 'The worst you can imagine'. The cut-off points were none (1 point), mild (2–5), moderate (6–8) and severe (8–10). These cut-off points were chosen on the basis of other studies of assessment of the severity of symptoms in cancer patients at points of care [37]. The symptoms on the WebCan symptom list were summarised in the WebCan report provided to the oncologist and participants.

The WebCan symptom list also included measures of anxiety and depression, for which we used the Hospital Anxiety and Depression Scale (HADS). This questionnaire contains 14 questions divided into two subscales (anxiety and depression) with 7 questions each. The scores range from 0 to 21. The total scores on each subscale classify severity, scores of 0–7 being considered 'normal', 8–10 'mild', 11–14 'moderate' and 15–21 'severe', according to the guidelines [38].

Clinical information

Information on clinical variables was obtained from the DAHANCA clinical database, which was established in 1976 and has since prospectively collected clinical information on aetiological factors, TNM classifications, staging and treatment modalities [39]. Disease stages were defined according to the UICC TNM stage grouping system [40].

The burden of comorbidity was assessed on the basis of somatic disorders retrieved from the Danish National Patient Register [41], which includes somatic discharge diagnosis and information on all hospitalisations since 1977 and outpatient visits since 1995. Data were cumulated from 10 years before the cancer diagnosis through to the time of the WebCan baseline assessment. Diagnoses were coded into a modified Danish version of the International Classification of Diseases version 8 (ICD-8) until 1993 and thereafter into ICD-10.

The Charlson comorbidity index was calculated, covering 19 selected conditions scored from 1 to 6 by degree of severity [42]. The scores of the clinical conditions were summed and grouped as 0 (none), 1–2 and 3 or more.

Information on outcome measures

To obtain information on the number of symptoms that were assessed during consultations (primary outcome), two experienced

Please cite this article in press as: Kjaer T et al. A controlled study of use of patient-reported outcomes to improve assessment of late effects after treatment for head-and-neck cancer. Radiother Oncol (2016), http://dx.doi.org/10.1016/j.radonc.2016.04.034