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Review

Structured review of the patient-reported outcome instruments used in clinical trials in head and neck surgery

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Abstract

The number of clinical trials that relate to patients with cancer of the head and neck is growing. Patient-reported outcomes, which are rarely the primary outcome, are now an important component, and in this structured review to identify and report the characteristics of the questionnaires that have been used in these trials, we summarise the findings reported. We searched several online databases using the key terms: head and neck oncology, head and neck surgery, reconstruction, clinical trials patient-reported outcomes, questionnaires, quality of life (QoL), validated instruments, and patients' satisfaction. We screened 1342 papers to collect information about the topic of the paper, sample size, selection criteria, main advantages and disadvantages of the patient-reported outcome used, and if it was used in conjunction with another measure. A total of 54 were eligible, and from them we identified 22 questionnaires. The primary reason for using a questionnaire was its relevance to the focus of the paper, such as xerostomia, pain, or swallowing. To allow the experience of patients to be the focus of the primary outcome in a clinical trial, we recommend that the measures used should be appropriate, reliable, valid, responsive, precise, interpretable, acceptable, and feasible. The trials used validated questionnaires, but the patient-reported outcome measures tended not to be the focus. There is merit in such measures being the primary outcomes in future trials and these should be designed around an explicit hypothesis.

Keywords: Patient-reported outcomes; health-related quality of life; oral cancer; head and neck cancer; randomised controlled trials

Introduction

The measurement of quality of life (QoL) is essential, as the increasing incidence of head and neck cancer in the UK[1] means that the associated debilitating physiological and psychological morbidities will become more prevalent.[2] Randomised controlled trials in head and neck cancer have tended to focus on treatment, with many comparing the toxicity of different types, or providing ideal interventions for side effects such as xerostomia. However, we know of no universal instrument that is sufficiently robust to compare QoL and morbidity in patients after initial operation, chemotherapy, and radiotherapy.[3]

It is difficult to establish precisely the degree to which patients are affected by their initial treatment, but it affects adherence and compliance, as well as morbidity and

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mortality.[4] Patient-related outcomes are therefore important, and this review aims to summarise those used in clinical trials, the focus of the research, and the key clinical findings.

Material and methods

We devised a search strategy using the key terms: head and neck oncology, head and neck surgery, reconstruction, clinical trials, patient-reported outcomes, questionnaires, QoL, validated instruments, and patient satisfaction. The following databases were examined: HaNDLE-on-QoL (Faculty of Health and Social Care, Edge Hill University); Medline; Embase (Excerpta Medica); HaPI (Health and Psychosocial Instruments, Behavioral Measurement Database Sevices); Science Citation Index and Social Sciences Citation Index; Ovid evidence-based medicine databases; and PsychINFO® (American Psychological Association).

Only manuscripts written in English were included. They all involved the use of patient-reported outcomes that measured QoL or satisfaction, or both, which had been developed and validated for use by patients with cancer of the head and neck. The search and presentation of the results followed PRISMA (preferred reporting items for systematic reviews and meta-analyses) guidance.[5] A total of 2072 papers described QoL measures, and after evaluation of the abstracts and available full text, we closely examined 54 (Fig. 1).[6–59] To appraise the psychometric and operational performance of the instruments, we looked for evidence of the criteria shown in Table 1.[60]

Results

From the 54 papers[6–59] we found 22 questionnaires that satisfied our inclusion criteria (Fig. 1). Many studies included

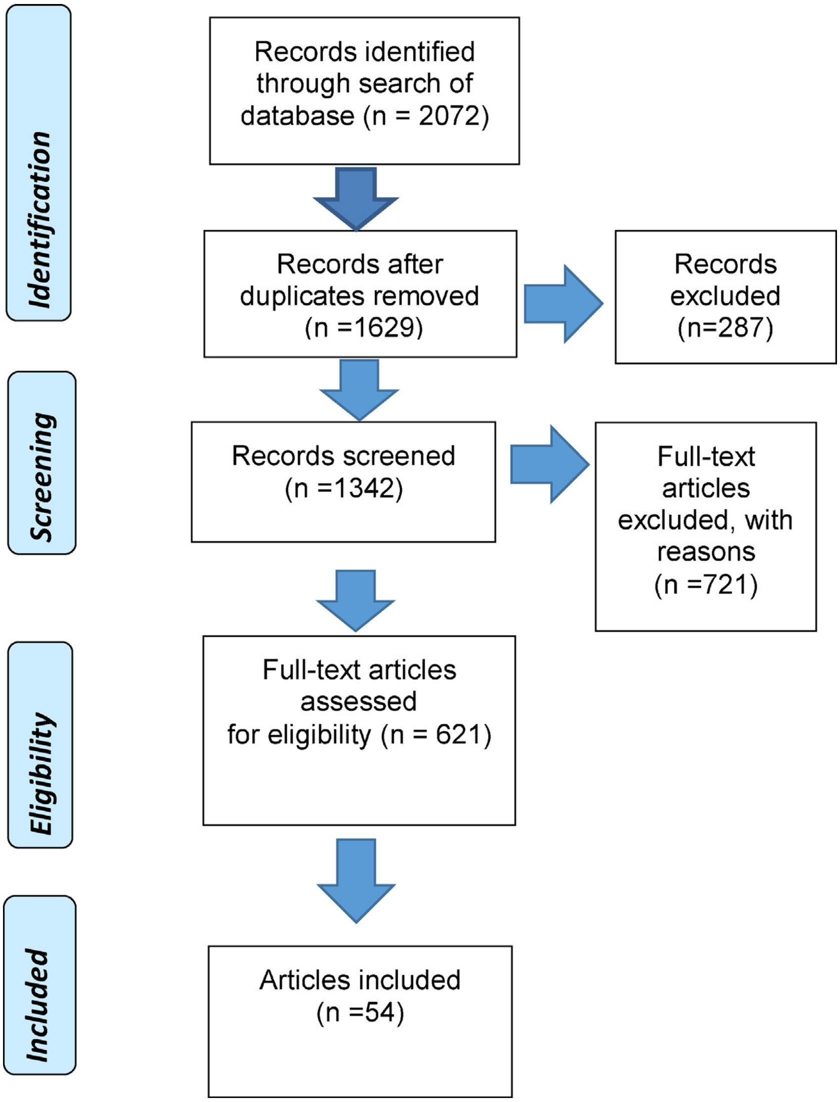

Fig. 1. Search results.

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