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Development and preliminary testing of head and neck cancer related external lymphedema and fibrosis assessment criteria☆

Jie Deng*, Sheila H. Ridner, Nancy Wells, Mary S. Dietrich, Barbara A. Murphy

School of Nursing, Vanderbilt-Ingram Cancer Center, and Department of Biostatistics, School of Medicine, Vanderbilt University, Nashville TN, USA

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A B S T R A C T

Purpose: To develop assessment criteria for evaluating and documenting status of external lymphedema and fibrosis in patients with head and neck cancer (HNC).

Methods: This was a two-phase instrument development study. In Phase I, initial assessment criteria for head and neck external lymphedema and fibrosis were generated based on a conceptual framework developed to describe the continuum of lymphedema – fibrosis in HNC patients. The initial Head and Neck External Lymphedema and Fibrosis (HN-ELAF) Assessment Criteria with three components were revised based on expert feedback. In Phase II, a pilot study was conducted to evaluate the revised assessment criteria through direct physical examination of 30 HNC patients with facial swelling and/or scar-like tissue >3 months post-treatment. The following statistical methods were used to evaluate interrater reliability in Phase II: simple percent agreement, the Kappa statistic, and the concordance correlation coefficient. Then, a post-test revision was made to further modify the tool based on the results of the pilot test.

Results: In Phase I, the initial HN-ELAF was revised including deleting Grade 0 (subclinical disease) and two components (i.e., symptoms and functional impairments). The revised HN-ELAF Assessment Criteria demonstrated good content/face validity. In Phase II, the assessment criteria had an acceptable interrater reliability, e.g., 83% exact agreement on grading lymphedema and fibrosis severity; and kappa = 0.75 ($p < .001$). The assessment criteria were further modified including three dimensions: type, severity, and anatomical sites of lymphedema and fibrosis.

Conclusions: Validation of the modified HN-ELAF Assessment Criteria in larger sample sizes is ongoing.

Introduction

It was estimated that 52,610 Americans developed head and neck cancer (HNC) and 11,500 deaths from oral cavity, pharynx, and larynx cancers occurred in 2012 (American Cancer Society, 2012). There have been several paradigm shifts over the past two decades in the treatment of patients with HNC. First, aggressive multimodality therapy has led to improvement in function preservation, local control and survival in HNC patients with locally advanced disease, thus it is now a mainstay of treatment (Hanna et al., 2013; Posner, 2010). In addition, there has been an epidemic of human papillomavirus-related cancers that are associated with improved survival (Dayyani et al., 2010; Fakhry et al., 2008; Oral Cancer Foundation, 2012; United States Department of Health and Human Services, National Institutes of Health and National Cancer Institute, 2012). Together, these trends would support an anticipated rapid growth in the number of HNC survivors over the next decade. Furthermore, individual patients will live longer with the late effects from their cancer and/or cancer treatment (Bentzen et al., 2003; Berger, Oncology Nursing Society and ONS Foundation Endowment, 2009). Aggressive identification and treatment of late effects thus becomes a critical issue. Cancer, surgery, radiation, or chemotherapy may disrupt lymphatic structures, damage surrounding soft tissue leading to fibrotic tissue formation, and further limit lymphatic function; therefore, HNC survivors are at high risk for developing secondary lymphedema and/or fibrosis (Deng et al., 2011; Deng et al., 2012; Deng et al., 2013a,b; Dennert and Horneber, 2006; Földi et al., 2007; Lymphoedema Framework, 2006; Murphy et al., 2007; Ridner, 2008; Smith and Lewin, 2010). Due to use of different treatment regimens, some HNC patients may have fibrosis only and some

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* Corresponding author. Vanderbilt University School of Nursing, 461 21st Ave. South, 516 Godchaux Hall, Nashville, TN 37240, USA.
E-mail address: jie.deng@vanderbilt.edu (J. Deng).

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patients may have typical lymphedema only. We have also found that many patients have both fibrosis and lymphedema simultaneously. That is, fibrosis and lymphedema may be found at different anatomical sites in the head and neck region (such as neck fibrosis and cheek lymphedema). Current state of science indicates that fibrosis and lymphedema each may have different underlying mechanisms (Avraham et al., 2009; Avraham et al., 2012). They may also share common inflammatory components (Avraham et al., 2009, 2012). Clearly, soft tissue fibrosis could damage the lymphatic system, which contributes to lymphedema; chronic lymphedema may progress to fibrosis in affected areas. Therefore, it is clinically important to evaluate both types of soft tissue abnormalities simultaneously. In addition, given overlaps of symptoms and functional impacts from fibrosis and lymphedema, it is critical to document both lymphedema and fibrosis in clinical settings. However, measurement for head and neck lymphedema and fibrosis is challenging.

We previously compared four assessment criteria for lymphedema and fibrosis in a cohort of 103 HNC patients >3 months post treatment (Deng et al., 2013a,b). Two of them were specific to HNC patients: CTCAE Lymphedema Grading Criteria – Head & Neck *v* 3.0 and ACS Lymphedema of the Head and Neck Grading Criteria (American Cancer Society and Donaldson, 2006; United States Department of Health and Human Services, National Institutes of Health and National Cancer Institute, 2006). The other two grading criteria were developed for lymphedema and fibrosis in general without reference to the specific patient population: Stages of Lymphedema (Földi et al., 2007) and CTCAE Lymphedema-related Fibrosis Grading Criteria (United States Department of Health and Human Services et al., 2006). Numerous issues related to the function of these assessment criteria were identified and reported in the previous study (Deng et al., 2013a,b). The CTCAE Lymphedema Grading Criteria (v3.0) and ACS Lymphedema Grading Criteria only measured edema/swelling of the skin and soft tissues but lack assessment of lymphedema-related fibrotic changes. For instance, although both scales evaluate functional impairment (e.g., difficulty in turning neck or opening mouth) that may be the significant late effects due to lymphedema or fibrotic change of subcutaneous tissue, they fail to directly evaluate skin/soft tissue changes related to fibrotic changes.

The CTCAE Fibrosis Grading Criteria (v3.0) center on lymphedema-related fibrotic changes without consideration of soft tissue changes related to lymphedema. The Stages of Lymphedema is the only one that captured the continuum of soft tissue abnormalities from swelling to fibrotic changes (Deng et al., 2013b); however, several issues were identified when the Stages of Lymphedema was used to assess HNC associated lymphedema and fibrosis. First, visible, non-pitting lymphedema of the head and neck is not included in the Stages of Lymphedema. Second, stage III lymphedema ("elephantiasis" with "invalidism") is a rare manifestation of head and neck lymphedema, thus it needs to be modified (Deng et al., 2013b). Clearly, a need exists to develop and/or validate assessment criteria for evaluating and documenting unique characteristics of head and neck lymphedema and fibrosis. Herein we report the development and initial testing of such a tool.

Methods

Two-phase design

The HNC Related External Lymphedema and Fibrosis (HN-ELAF) Assessment Criteria were developed using a two-phase process described below. Approval was obtained from the Institutional Review Board at the study site prior to recruitment. Written informed consent was obtained from all participants prior to initiating any study-related activities.

Phase I: Instrument development

Initial assessment criteria. Our initial proposed assessment criteria for head and neck external lymphedema and fibrosis were based on a conceptual framework established via an extensive literature review, findings from our previous and current studies of lymphedema and fibrosis in HNC patients, and clinical experience. First, it has been recognized that lymphedema and fibrosis exist on a continuum (Földi et al., 2007; Lymphoedema Framework, 2006); thus, a measure of lymphedema and fibrosis should incorporate assessment of both swelling/edema and fibrotic change. Second, the severity and extent of lymphedema and fibrosis varies dramatically, therefore, a tool should capture these characteristics of soft tissue change (Deng et al., 2013b). Finally, lymphedema and fibrosis may be associated with symptoms or functional impairment (Deng et al., 2013a,b; Smith and Lewin, 2010); thus, assessment of symptom burden and functional deficits is an important construct. We used these key conceptual components to guide the development of initial grading criteria. The initial assessment criteria included evaluation of lymphedema and fibrosis, symptom burden and functional impairments.

Revised assessment criteria. The initial assessment criteria were reviewed by an expert panel comprised of an interdisciplinary group of ten healthcare professionals with expertise in HNC including: a medical oncologist, a radiation oncologist, two surgical oncologists, two lymphedema therapists, an oncology nurse practitioner, two oncology nursing researchers, and a speech and language pathologist. Based on the feedback from the expert panel, the components of the initial assessment criteria were revised.

Phase II: Pilot testing and post-test revision

The revised assessment criteria were tested via direct physical examination of 30 HNC patients with swelling and/or scar-like tissue in the head and neck region. The following recruitment method was used. Patients who were seen at the study site for follow-up after completion of HNC treatment were approached to evaluate interest in participation in the study. For those who expressed interest, the study staff gave them a consent form. After they signed the consent form, they were screened via a screening sheet for eligibility for the study. Inclusion criteria for participation included (1) >21years of age, (2) >3 months after completion of HNC treatment (no cancer treatment related acute edema), (3) no current evidence of cancer, (4) external swelling and/or scar-like tissue based on physical examination, and (5) ability to provide the informed consent. Exclusion criteria included actively undergoing chemotherapy or radiation therapy, metastatic cancer or any other active cancer, and unable to provide informed consent. All patients were asked to complete a demographic survey. Tumor and treatment-related data were obtained through electronic medical record review. Each patient's external lymphedema and fibrosis was examined and rated independently by two trained study staff (licensed RN and MD) using the revised assessment criteria developed in Phase I. This allowed assessment of interrater reliability. Based on the results of the pilot testing, the revised assessment criteria were further modified (post-test revision).

Data analysis

Data collected from this study were entered into the statistical software package SPSS version 19.0. Descriptive statistics were used to describe the sample, including demographic information, HNC disease and treatment information, and lymphedema disease