European Journal of Oncology Nursing 22 (2016) 63–70

Contents lists available at ScienceDirect

European Journal of Oncology Nursing

journal homepage: www.elsevier.com/locate/ejon

Preliminary evaluation of reliability and validity of head and neck external lymphedema and fibrosis assessment criteria

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ARTICLE INFO

Article history:
Received 5 August 2015
Received in revised form
23 January 2016
Accepted 1 February 2016

Keywords:
Head and neck cancer
Radiation
Lymphedema
Fibrosis
Measurement
Assessment criteria
Ultrasonography
Reliability
Validation
Clinician-reported outcome measure

ABSTRACT

Purpose: Measurement of head and neck external lymphedema and fibrosis (LEF) is challenging. To address this gap, we developed the Head and Neck External Lymphedema and Fibrosis (HN-LEF) Assessment Criteria. This article aimed to report preliminary data on reliability and validity of the HN-LEF Assessment Criteria.

Methods: Sixty head and neck cancer (HNC) patients who were ≥3-month post cancer therapy were recruited. Study measures included 1) demographic/medical data; 2) LEF physical examination completed independently by two staff members for interrater reliability (intrarater reliability completed by one of them); and 3) grayscale ultrasound examination of the head and neck skin. Reliability estimates used percent agreement and Kappa statistic. Validity was assessed via Spearman correlations of physical examination findings with ultrasound measurements.

Results: Fifty-one out of 60 HNC patients completed both physical examination and ultrasound assessments. *Interrater reliability*: 91.0% agreement (Kappa = 0.81, $p < 0.001$) on the presence of types of LEF; 84.9% agreement regarding the grade of LEF (Kappa = 0.70, $p < 0.001$) across all anatomic sites. *Intrarater reliability:* 96.1% agreement for type of LEF; and 91.4% agreement for grade across all sites. *Ultrasound examination* demonstrates characteristics and patterns for different types of LEF (particularly in the cheek, submental, and neck regions).

Conclusions: The study provided initial reliability and validity data for a clinician-reported tool evaluating external LEF in the HNC population. These preliminary findings demonstrate that the tool had good reliability. Associations with the ultrasound examination results demonstrate that the tool validly captures soft tissue changes at select sites. Further validation of the tool is warranted.

1. Introduction

Although the incidence of head and neck cancer (HNC) has slightly decreased over the past two decades, the number of HNC survivors in the United States has increased due to early identification of disease, aggressive multi-modality cancer therapy, and improved management of side-effects (Murphy et al., 2007; Murphy and Deng, 2015; Ringash, 2015). There are over a half million HNC survivors alive in the United States (Swierzewski, 2014). Currently, head and neck cancer is the sixth most common cancer worldwide (Holland et al., 2015). Clearly, supportive care needs for the HNC population is substantial. Thus, it is critically important for healthcare professionals to address the late effects and long-term survivorship issues facing HNC survivors, including secondary lymphedema and fibrosis (LEF) (Deng et al., 2012; Jeffs and Huit, 2015; McGarvey et al., 2014; Smith and Lewin, 2010). Recent data support that a high percentage of HNC survivors treated with radiation therapy experience secondary LEF (Deng et al., 2012). LEF may be located externally (e.g., located at the face and neck) or internally (e.g., involving the pharynx and larynx) (Bruns et al., 2003; Deng et al., 2011, 2012; Micke et al., 2003; Zimmermann et al., 2005). A cross-sectional study reported that the severity of LEF was significantly associated with symptom burden, functional impairments, and decreased quality of life (QOL)

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http://dx.doi.org/10.1016/j.ejon.2016.02.001
1462-3889/

(Deng et al., 2013a). Because LEF can progress over time, it is important for clinicians to identify this process early and refer patients in a timely manner to certified therapists for management (Földi et al., 2006; Stubblefield and O'Dell, 2009; Lee et al., 2011). Thus, reliable and validated tools are critically needed for diagnosis, assessment, and monitoring of LEF.

Measurement of HNC related LEF is challenging (Deng et al., 2015a; Purcell et al., 2016) and validated tools based on a clinically relevant conceptual framework are needed (Deng et al., 2013b). To address this need, we developed the Head and Neck External Lymphedema and Fibrosis (HN-LEF) Assessment Criteria and conducted initial testing in 30 patients (Deng et al., 2015b). The purpose of this study was to further test the HN-LEF Assessment Criteria for interrater and intrarater reliability. In addition, preliminary validity assessment was undertaken.

During the course of selecting imaging modalities for validating the tool, we found that computerized tomography (CT scan), magnetic resonance imaging (MRI), and ultrasonography have been investigated as modalities for evaluation of soft tissue changes related to extremity lymphedema (Shin et al., 2013; Sagen et al., 2009; Tassenoy et al., 2009; International Society of Lymphology (2013); Tassenoy et al., 2011). Data from one study with small sample size (N = 30) provided preliminary evidence that CT scans have the potential to be effective tools for assessment of face/neck lymphedema (Chen et al., 2010); however, valid protocols and grading criteria for CT scans have yet to be established. Although MRI has been shown to provide details of soft tissue changes related to extremity lymphedema (Warren et al., 2007), similar studies in the HNC population are lacking. Compared with CT and MRI, ultrasonography is a noninvasive and inexpensive technique to visualize the dermal and subcutaneous tissue (International Society of Lymphology (2013); Tassenoy et al., 2011). Two small studies (N = 11; N = 20 respectively) used gray scale ultrasound to measure skin and soft tissue width in patients with severe face and neck edema (Piso et al., 2001, 2002). They showed that ultrasonography was able to measure asymmetry between the lymphedema-affected and unaffected anatomical sites (Piso et al., 2001, 2002). In this study, we used ultrasonography as a technique to evaluate soft tissue changes of LEF in HNC patients and to help validate the HN-LEF Assessment Criteria.

2. Methods

2.1. Samples and setting

The study was approved by the Institutional Review Board and the Scientific Review Committee at the study site. A cross-sectional, correlational design was used. Written informed consent was obtained. Individuals were enrolled into the study if they met the following eligibility criteria for participation: (1) >21 years of age; (2) >3 months after HNC treatment; (3) no evidence of cancer; (4) able to provide informed consent; and (5) external edema or fibrotic changes based on physical examination. From May 31, 2012 to August 30, 2013, 70 HNC survivors were approached and 60 patients signed informed consent. Six patients did not complete any study-related activities due to 1) time restrains (3 patients); and 2) new onset of complications (i.e., one patient with dental infection; the other two patients with skin infection). Another 3 patients did not complete both ultrasound and physical examination resulting in an analysis sample size of 51.

2.2. Procedures

Participants completed a demographic survey. Then, using the HN-LEF Assessment Criteria, two trained research nurses scored independently the participants' LEF status for testing interrater reliability. On the same day, the study sonographer with over 20 years' experience conducted a high resolution ultrasound examination to obtain imaging data of the head and neck region per study protocol. After the ultrasound examination, one of the above study nurses re-scored the patients' LEF status to establish intrarater reliability.

2.3. Study measures and methods

2.3.1. Demographic and medical data

Self-report demographic data were obtained from participants, including gender, age, ethnicity, educational level, marital status, current employment status, residence area, annual household income, and alcohol and tobacco use. Medical data were collected from the chart review, including date of diagnosis of HNC, primary tumor site, histology, tumor stage, and treatment type and dates.

2.3.2. Physical examination of the head and neck skin

Two licensed research nurses completed physical examinations using a standard procedure to ensure consistency in LEF assessment. Prior to initiation of study assessments raters underwent rigorous training.

2.3.3. Head and neck external lymphedema and fibrosis (HN-LEF) assessment criteria

The tool development was previously reported (Deng et al., 2015b). The tool includes four types of the soft tissue abnormalities as seen on physical examinations, including type A, B, C and D. Type A is defined as “palpable thickening and/or tightness of dermis without visible soft tissue swelling”; type B is defined as “visible soft tissue swelling; involved tissues are soft to touch; tissue swelling is reducible and fluctuates in severity”; type C is defined as “visible soft tissue swelling; involved tissues are firm to touch; tissue swelling is non-reducible and persistent”; and type D is described as “firm skin with increased density and decreased compliance in the absence of swelling”. Under each type (except for type A), a grade is used to describe the severity of the soft tissue abnormalities, ranging from mild to severe. For instance, within the type B, mild is defined as “visible soft tissue swelling on close inspection”; moderate is described as “easily visible swelling that significantly alters normal tissue contours”; and severe is defined as “extreme or massive tissue swelling”. Patients may have different types of skin/soft tissue abnormalities at different anatomical sites; thus, the tool includes a table that allows documentation of the type and grade of soft tissue abnormalities at various anatomical sites (left/right peri-orbital region, left/right cheek, submental, left/right neck, left/right supraclavicular fossa, and other sites) (see Appendix 1).

2.3.4. Ultrasound examination

2.3.4.1. Protocol development. An interdisciplinary team of experts developed a protocol for ultrasound measurement based on literature review, our previous work, and expert opinion. The team includes two head and neck oncologists, one ultrasound professor, two senior sonographers, two lymphedema researchers, and one lymphedema therapist. The protocol delineates the following parameters: type and frequency of transducer; measurement pressure; participants' position; anatomical sites; measurement distances (from external skin surface to internal boundary) for each anatomical site; and procedures.

2.3.4.2. Measurement parameters and procedure. (1) Transducer: ultrasound evaluation of the head and neck skin was performed using a 17-MHz linear transducer attached to an IU22 Philips