Assessment of External Lymphedema in Patients With Head and Neck Cancer: A Comparison of Four Scales

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Purpose/Objectives: To compare available grading and staging scales that measure external lymphedema in patients with head and neck cancer (HNC) and to assess problems and gaps related to these tools.

Design: Cross-sectional.

Setting: A comprehensive cancer center in Tennessee.

Sample: 103 participants post-HNC treatment.

Methods: Four scales were used to evaluate study participant external lymphedema status, including the Common Terminology Criteria for Adverse Events (CTCAE) Lymphedema Scale (version 3.0), American Cancer Society Lymphedema Scale, Stages of Lymphedema (Földi's Scale), and the CTCAE Fibrosis Scale (version 3.0).

Main Research Variables: Occurrence rate, severity of lymphedema, and components and descriptors of each scale.

Findings: The prevalence and severity of external lymphedema differed based on the tools. Each tool had an identified limitation. Current theory postulates a continuum between lymphedema and fibrosis, but only the Földi's Scale adequately reflected that concept.

Conclusions: None of the available scales clearly captured all the important characteristics of external lymphedema in patients with HNC. A need exists to develop a clearly defined and validated scale of external lymphedema in the HNC population.

Implications for Nursing: Oncology nurses should take an active role in addressing issues related to lymphedema assessment in patients post-HNC treatment; however, new assessment tools need to be developed for clinical use.

Knowledge Translation: Early identification and accurate documentation of head and neck lymphedema are critically important to prevent lymphedema progress. However, existing grading criteria failed to capture important characteristics of external head and neck lymphedema. More research efforts need to be made to address this under-recognized issue.

Damage to or removal of regional lymph nodes and vessels from cancer or its treatment are among the most common conditions that lead to secondary lymphedema in the United States (Holcomb, 2006; Rockson & Rivera, 2008). Although lymphedema is an acknowledged problem in the breast cancer population, the problem is only now being recognized in patients with head and neck cancer (HNC) (Bruns et al., 2004; Deng et al., 2012; Deng, Ridner, & Murphy, 2011; Lewin, Hutcheson, Barringer, & Smith, 2010; Micke et al., 2003; Smith & Lewin, 2010). Aggressive multimodality treatment has improved survival rates for patients with HNC, leaving them at risk for the development of late treatment effects. Patients with HNC are at high risk for the development of secondary lymphedema because of treatment-related lymphatic system damage from surgery, radiation, and tumor infiltration of soft tissues (Deng et al., 2012; Smith & Lewin, 2010). These patients may develop secondary lymphedema externally (e.g., face, neck) and internally (e.g., larynx, pharynx). The current study's authors reported the results of a cross-sectional analysis of lymphedema in 103 patients with HNC post-treatment. Those results indicated that lymphedema is a frequent complication of HNC treatment associated with substantial symptom burden, functional deficits, and decreased quality of life (QOL) (Deng et al., 2013). Although the data clearly indicated that lymphedema is a clinically meaningful problem in the HNC population, confirmatory data are lacking, in part because of a lack of validated tools for lymphedema assessment in this population.

To date, little attention has been given to methodologic approaches specific to secondary lymphedema in patients with HNC (Deng et al., 2011; Földi, Földi, Strössenreuther, & Kubik, 2007; Lymphoedema Framework, 2006). Prior to selecting the assessment tools for their preliminary study, the current authors developed a comprehensive literature review to select the most suitable tools to measure lymphedema in their cross-sectional study. Based on that review, they identified four scales that evaluated secondary lymphedema. Some tools were specific to patients with HNC, whereas others were developed for lymphedema in general without reference to the cause. Specifically, two scales were developed for grading head and neck lymphedema: the Common Terminology Criteria for Adverse Events (CTCAE) Lymphedema Scale

Head and Neck (version 3.0) (CTCAE Lymphedema Scale) (National Cancer Institute [NCI], 2006) and the American Cancer Society (ACS) Lymphedema of the Head and Neck Scale (ACS Lymphedema Scale) (ACS & Donaldson, 2006). The other two scales were developed to grade general lymphedema: the Stages of Lymphedema (Földi's Scale) (Földi, Földi, & Kubik, 2003; Földi et al., 2007) and CTCAE Lymphedema-Related Fibrosis Scale (version 3.0) (CTCAE Fibrosis Scale) (NCI, 2006). Each of the scales uses different descriptors and diverse components.

Studies describing the psychometric characteristics of any of these scales have not been published. In particular, data on validity (construct, convergent, and divergent validity) and reliability (inter- or intrarater) are lacking. No comparative data exist to support the use of one of these scales over another in the HNC population. Finally, no data are available to support that these scales have adequately captured important characteristics of head and neck lymphedema or fibrosis. To address that knowledge gap, a secondary aim to the parent study was to assess the strengths and weaknesses of currently available measurement tools for evaluating external lymphedema in patients with HNC. Therefore, the purpose of the current analysis was to simultaneously compare these four scales in patients with HNC who were three months or more post-treatment, examining differences in findings based on each scale, and identifying the gaps in assessment of external lymphedema in the HNC population.

Methods

Permission to conduct this study was obtained from the institutional review board at Vanderbilt University and the scientific review committee at Vanderbilt-Ingram Cancer Center. Written informed consent was obtained from all participants. A descriptive, cross-sectional design was used. Of the 114 patients with HNC approached at the Vanderbilt-Ingram Cancer Center Head and Neck Cancer Clinic, 103 patients consented and were recruited into the study. The eligibility criteria for participation included being (a) aged 18 years or older, (b) more than three months post-HNC treatment, (c) currently free of evidence of cancer, and (d) able to provide informed consent. Four available measures were used to evaluate participants' lymphedema status.

Procedure

Prior to data collection, the first author was trained by two coauthors regarding evaluation of external lymphedema and fibrosis of skin and soft tissues. During data collection, demographic information and a medical history were taken and a physical examination of the head and neck areas of all participants was conducted using visual inspection and palpation (Földi et al., 2007). The first author then documented participant lymphedema stage using each of the four scales. In addition, neck range of motion was measured using the cervical range of motion device and symptom burden was measured using the Vanderbilt Head and Neck Symptom Survey. Those results were reported elsewhere (Deng et al., 2012).

Measures

The **CTCAE Lymphedema Scale** (version 3.0) and **Fibrosis Scale** (version 3.0) were developed and published by the NCI (2006). The lymphedema scale was developed to evaluate head and neck edema as an adverse event related to damage of the lymphatic system in patients undergoing cancer treatment. It grades lymphedema on a scale ranging from 1–5 (higher grade indicates more severe lymphedema) and includes the affected areas or sites (from local or general) and functional impairment from lymphedema (from none to severe). The CTCAE Fibrosis Scale grades fibrosis on a scale ranging from 1–3 (higher grade indicates more severe fibrosis), assessing tissue texture changes (minimal or moderate increase, marked increase, or very marked increase in tissue texture). The fibrosis scale only focuses on lymphedema-related skin or soft tissue fibrosis after cancer treatment, not swelling or edema. In addition, the scales both are general and not specific to patients with HNC.

The **ACS Lymphedema Scale** provides a staging scale (0–III, with higher stage indicating more severe lymphedema) for grading the severity of swelling related to lymphedema in the head and neck region (ACS & Donaldson, 2006). It assesses edema only and includes an assessment of the affected sites (from local or general) and functional impairment (from none to severe).

The **Földi's Scale** was developed to grade general lymphedema (Földi et al., 2003, 2007). The authors developed the scale based on their experience treating more than 100,000 patients with various types of lymphedema. Földi's Scale stages tissue changes from 0–III, with higher stage indicating more severe lymphedema. It includes clinical descriptors ranging from pitting edema to hard swelling, thus incorporating both lymphedema and fibrosis. It also includes pathology, signs and symptoms, and diagnostic recommendation.

Data were double entered into SPSS®, version 19.0, and cleaned prior to analysis. Descriptive statistics were used to summarize the distribution of the lymphedema severity. Cross-tabulation was used to compare the agreement of lymphedema severity across the scales.

Findings

Sample Characteristics

A convenience sample of 103 participants completed the study from December 2009 to May 2010 at Vanderbilt-Ingram Cancer Center. Most participants were men (69%)

and Caucasian (89%), with a median age of 60.2 years. The histologic type of most participant tumors was squamous cell carcinoma (93%). Advanced stage disease (III/IV) was present in about 81% of all participants. About 90% of participants had received at least two modalities of HNC treatment (e.g., concurrent chemoradiation), and the time since HNC treatment had ended ranged from 3.1–156.4 months (median = 19.9 months).

Assessing Lymphedema

Thirty-seven participants (36%) had external lymphedema according to the CTCAE Lymphedema Scale and ACS Lymphedema Scale; 48 (47%) of the patients had external lymphedema using the Földi's Scale, and 23 (22%) had external lymphedema-related fibrosis based on the CTCAE Fibrosis Scale (see Table 1).

The external lymphedema severities scored by the CTCAE Lymphedema Scale and ACS Lymphedema Scale were well matched because of the identical constructs and components measured by the two scales (see Table 2). Because the CTCAE Lymphedema Scale and the ACS Lymphedema Scale capture identical patients, Table 3 presents the comparison between the CTCAE Lymphedema Scale and the Földi's Scale as an example. The external lymphedema severities scored by the CTCAE Lymphedema Scale and Földi's Scale were not compatible because of the different constructs and components measured by the two scales. For instance, 11 participants scored by the Földi's Scale (three in stage I and eight in stage II) were not captured and graded using the CTCAE Lymphedema Scale (or ACS Lymphedema Scale). The patients captured on the Földi's Scale but not on the CTCAE or ACS Lymphedema Scales had fibrosis only.

As expected, the severities scores reported by the CTCAE Lymphedema Scale and CTCAE Fibrosis Scale were not comparable because of the different constructs measured by the two scales (see Table 4). Of note, 12 patients had both edema and lymphedema-related fibrosis.

The external lymphedema severities scored by the Földi's Scale and CTCAE Fibrosis Scale were not comparable because of the different constructs measured by the two scales (see Table 5). For example, 25 (24%) participants with external swelling or edema only scored by the Földi's Scale were not captured using the CTCAE Fibrosis Scale. Patients captured on the Földi's Scale but not on the CTCAE Fibrosis Scale had edema only.

Table 1. External Lymphedema Data From Four Lymphedema Scales (N = 103)

Scale Grade or Stage	n	%
CTCAE Lymphedema Scale		
None	66	64
1	22	21
2	12	12
3	3	3
4	–	–
5	–	–
American Cancer Society Lymphedema Scale		
None	66	64
0	22	21
I	12	12
II	3	3
III	–	–
Földi's Scale		
0	55	53
I	21	20
II	27	26
III	–	–
CTCAE Fibrosis Scale		
None	80	78
1	16	16
2	7	7
3	–	–

CTCAE—Common Terminology Criteria for Adverse Events
Note. Because of rounding, not all percentages total 100.

Discussion

The authors examined the occurrence rates of lymphedema in the sample and identified that the four scales resulted in inconsistent findings. The highest occurrence rate of lymphedema was reported using Földi's Scale, followed by the ACS Lymphedema and CTCAE Lymphedema Scales. That was expected because Földi's Scale incorporates a range of soft tissue damage, from edema to fibrosis. The lowest rate of soft tissue damage was reported by the CTCAE Fibrosis Scale because isolated fibrosis was the least common soft tissue change. Because of the lack of a fibrosis component in the scales, the CTCAE Lymphedema and ACS Lymphedema Scales identified only patients with edema or swelling, excluding participants with fibrosis only (n = 11, 11%). Conversely, the CTCAE Fibrosis Scale does not identify patients with edema or swelling; therefore, it only captured patients with fibrosis (n = 25, 24%). The current understanding of pathobiologic mechanisms indicates that edema and fibrosis exist on a continuum. Some patients experience swelling (edema) that resolves spontaneously over time, whereas others may develop fibrosis without a previous history of edema. However, most patients develop edema and fibrosis. In addition, fibrosis appears to be the end stage of lymphedema for most patients. Taking that into consideration, Földi's Scale is the only scale that captured the continuum of soft-tissue abnormalities, ranging from reducible pitting edema to brawny hard edema that does not recede with elevation. Földi's Scale reported the highest occurrence rate of soft tissue abnormalities.

Scale Strengths and Weaknesses

In addition to the clinical description of soft tissue damage, each scale has the following strengths and weaknesses regarding other descriptive components.

Table 2. Comparison of Lymphedema Severity Between the CTCAE Lymphedema and ACS Lymphedema Scales (N = 103)

ACS Lymphedema Scale	CTCAE Lymphedema Scale			
	No Indication	Grade 1	Grade 2	Grade 3
	n	n	n	n
No indication	66	–	–	–
Stage 0	–	22	–	–
Stage I	–	–	12	–
Stage II	–	–	–	3

ACS—American Cancer Society; CTCAE—Common Terminology Criteria for Adverse Events

Note. No participants scored in stage III of the ACS Lymphedema Scale or grades 4 or 5 of the CTCAE Lymphedema Scale.

Common Terminology Criteria of Adverse Events Lymphedema Scale and the American Cancer Society Lymphedema Scale: Although these two scales include critical descriptive components (i.e., severity of edema or swelling, range and scope of lymphedema-affected areas, and functional impairment) (ACS & Donaldson, 2006; NCI, 2006), three issues were identified using these scales to evaluate lymphedema in the sample. Both scales lack a fibrosis component, a late stage of lymphedema. Second, the components of lymphedema-affected areas and sites were not clearly defined or described within the scale. Both scales used two levels to describe the areas affected by lymphedema (local and general); nevertheless, the scales did not provide a precise definition or description regarding the meaning of those terms, which may cause issues with inter- and intrarater reliability and agreement. Similarly, according to the criteria in the two scales, participants with lymphedema severity at or above grade 2 (CTCAE Lymphedema Scale) or at or above stage I (ACS Lymphedema Scale) must have some levels of functional impairments (i.e., difficulty in turning neck or opening mouth when compared to baseline). However, neither scale provided a detailed description regarding functional impairments, so those must be obtained based on participant self-report or raters' inquiry. Again, that may cause inconsistency among different participants and raters. The problem is complicated by the varied sites affected by lymphedema in the head and neck region, resulting in a wide range of functional impairments that could be experienced by individuals with head and neck lymphedema. Without a clearly defined checklist including all possible functional impairments in the two scales, a possible inter- or intrarater reliability issue may exist among different raters and assessment points.

Common Terminology Criteria of Adverse Events Fibrosis Scale: The CTCAE Fibrosis Scale focuses on the severity and areas of soft tissues affected by lymphedema-related fibrotic changes (NCI, 2006). Two issues were found using this scale in the sample. First, because of a lack of an edema or swelling component, the scale is inappropriate to capture the early stage of lymphedema when patients may manifest with swelling without fibrotic changes post-HNC treatment. Second, the scale includes the component "fibrosis affected-areas/sites;" however, that was not well described. For instance, detailed explanations for "minimal-to-moderate" and "marked-to-very marked" fibrosis are lacking in the scale, which likely causes an inter- or intrarater reliability issue using this scale among different raters or times.

Földi's Scale: Although the Földi's Scale is the only one that captured the continuum of edema and fibrosis (Földi et al., 2003, 2007), four issues were identified when using it to grade lymphedema severity among the study participants. First, the descriptor of stage I in the Földi's Scale, "pitting edema," was infrequently seen in the study sample (only 3 of 21 participants with pitting edema in the stage I lymphedema, or 14%). In other words, 18 participants met the criteria for stage I using other criteria for the Földi's Scale (i.e., reversible edema). That finding confirms the authors' clinical experience that nonpitting edema is frequent in patients with HNC post-treatment, which suggests that stage I of the Földi's Scale needs to be modified to be more relevant to the clinical findings noted in patients with head and neck lymphedema. Second, the descriptor of stage III in the Földi's Scale, "elephantiasis" with "invalidism," was not seen in any study participants with head and neck lymphedema. Again, the authors' clinical experience concurs with the study findings that elephantiasis with invalidism is

Table 3. Comparison of Lymphedema Severity Between the CTCAE Lymphedema and Földi's Scales (N = 103)

CTCAE Lymphedema Scale	Földi's Scale		
	Stage 0	Stage I	Stage II
	n	n	n
No indication	55	–	–
Grade 1	–	12	10
Grade 2	–	4	8
Grade 3	–	2	1
No indication	–	**3**	**8**

CTCAE—Common Terminology Criteria for Adverse Events

Note. No participants scored in the stage III of Földi's Scale or grades 4 or 5 of the CTCAE Lymphedema Scale.

Note. The cells that do not match in grades (bolded) indicate discrepancies in grading. For example, 11 participants scored by Földi's Scale (3 in stage I and 8 in stage II) were not captured and graded using the CTCAE Lymphedema Scale.

Table 4. Comparison of Lymphedema Severity Between the CTCAE Lymphedema and CTCAE Fibrosis Scales (N = 103)

CTCAE Lymphedema Scale	CTCAE Fibrosis Scale: No Indication n	Grade 1 n	Grade 2 n
No indication	55	–	–
Grade 1	**17**	4	1
Grade 2	**6**	5	1
Grade 3	**2**	–	1
No indication	–	**7**	**4**

CTCAE—Common Terminology Criteria for Adverse Events

Note. No participants scored in grade 3 of the CTCAE Fibrosis Scale or grades 4 or 5 of the CTCAE Lymphedema Scale.

Note. The cells that do not match in grades (bolded) indicate discrepancies in grading. For example, 25 participants with external swelling or edema only scored by the CTCAE Lymphedema Scale were not captured and graded using the CTCAE Fibrosis Scale. Eleven participants with fibrosis only scored by the CTCAE Fibrosis Scale were not identified using the CTCAE Lymphedema Scale.

infrequently seen in HNC treatment–associated lymphedema. Third, the scale fails to distinguish component parts of the edema and fibrosis that coexist in some patients. A tool that allows independent description of both components at differing sites within the head and neck would allow a more complete assessment. Finally, the diagnosis component of the scale is of little clinical use and could be deleted.

Through a comparison of the four scales, the authors recognized the strengths and deficiencies of the available scales for the assessment of head and neck lymphedema. Clearly, no single scale comprehensively captured the important characteristics of head and neck lymphedema, based on the findings from the current study. Although CTCAE version 4.03 was published in 2010 (NCI, 2010), it includes lymphedema as an adverse event but is not specific for evaluation of head and neck lymphedema. In other words, it has not covered the important and critical components of head and neck lymphedema. Only one study has attempted to address that issue. Smith and Lewin (2010) developed the MD Anderson Cancer Center Head and Neck Lymphedema Rating Scale; however, the validity and reliability data of the scale have not been reported. A need exists to develop and validate a scale of head and neck external lymphedema to be consistently used among researchers and clinicians.

Limitations

The study had a few limitations. The study was cross-sectional, with its associated limitations. A prospective, longitudinal study with a baseline assessment followed by repeated measures during acute and late recovery would provide a better understanding of the needs and gaps in measurement of secondary lymphedema in the HNC population. In addition, lymphedema severity in the sample was determined based on physical examination. In future studies, other modalities (e.g., imaging) should be used to confirm lymphedema severity when developing and validating a new scale for assessing head and neck external lymphedema.

Implications for Clinical Practice

Oncology nurses should take an active role to address issues related to lymphedema assessment in patients post-HNC treatment; however, new tools need to be developed for clinical use. A clearly defined and validated tool could have significant clinical use because of its ease of use by oncology nurses and other healthcare professionals (e.g., head and neck oncologists, lymphedema therapists) during each office or clinic visit to evaluate head and neck external lymphedema during routine collection of vital signs and weight. Oncology nurses and other healthcare professionals could clearly document and follow patient lymphedema status over time, inform patients of critical knowledge about lymphedema (e.g., early signs and symptoms), and refer them for lymphedema treatment. Successful management of lymphedema will make a significant contribution to decreasing lymphedema-related symptom burden, functional impairments, and improving QOL in patients with HNC.

Conclusions

External lymphedema was evaluated in patients with HNC through physical examination and by using the currently available scales, capturing the basic characteristics of head and neck external lymphedema. The study identified the similarities and differences among

Table 5. Comparison of Lymphedema Severity Between Földi's Scale and the CTCAE Fibrosis Scales (N = 103)

Földi's Scale	CTCAE Fibrosis Scale: No Indication n	Grade 1 n	Grade 2 n
Stage 0	55	–	–
Stage I	**15**	6	–
Stage II	**10**	10	7

CTCAE—Common Terminology Criteria for Adverse Events

Note. No participants scored in grade 3 of the CTCAE Fibrosis Scale or stage III of Földi's Scale.

Note. The cells that do not match in grades (bolded) indicate discrepancies in grading. For example, 25 participants with external swelling or edema only scored by Földi's Scale were not captured using the CTCAE Fibrosis Scale.

these scales. Key components and issues related to each of the four scales in assessing head and neck external lymphedema were identified. The comparisons among the scales have provided insight into understanding head and neck external lymphedema and helped to establish a conceptual framework for future studies regarding development of a lymphedema tool in patients with HNC.

The scales currently available are insufficient to capture the important characteristics of external lymphedema in patients with HNC. A need exists to develop a validated scale of soft tissue abnormality in the HNC population based on current understanding of pathobiologic and clinical manifestations. Such a tool could provide clinicians with a method for assessing damage of soft tissue caused by lymphedema. Only when such a tool is available can the frequency, severity, and impact of this devastating late effect be understood in the HNC population.

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