doi:10.5737/1181912x143168174

Assessing the reliability and validity of the revised WCCNR Stomatitis Staging System for cancer therapy-induced stomatitis

By Karin Olson, John Hanson, Joan Hamilton, Dawn Stacey, Margaret Eades, Deborah Gue, Harry Plummer, Karen Janes, Margaret Fitch, Debra Bakker, Pamela Baker, and Catherine Oliver

Abstract

Before developing interventions for stomatitis, nurses require a simple, valid and reliable approach to staging severity. The eight-item WCCNR was previously validated for chemotherapy-induced stomatitis. In this study, the validity and reliability of the WCCNR[R], a shorter three-item tool for staging stomatitis caused by chemotherapy, radiotherapy, or both, was assessed. Pairs of data collectors evaluated 207 patients from 10 Canadian cancer centres. The WCCNR[R] correlated well with the MacDibbs Mouth Assessment (r=0.44, p=0.0002 to r=0.54, p<0.0001), a standardized tool for staging radiotherapy-induced stomatitis. Agreement between data collectors at five sites was acceptable (kappa=0.75); three additional sites were close to this target. Findings indicate that the WCCNR[R] is a valid and reasonably reliable tool for staging stomatitis due to cancer therapy.

Stomatitis is one of the most common oral complications of cancer therapy. Incidence levels range from 10% to 52% in individuals receiving stomatotoxic chemotherapy (Bennett et al., 1988; Fountzilas et al., 1988; Fountzilas et al., 1989; Kin et al., 1988; Levi et al., 1990), and from 30% to 90% in individuals receiving radiotherapy to the head and neck (Epstein & Spektor, 1993; National Institutes of Health, 1990; Rothwell & Spektor, 1990). The health consequences of stomatitis (pain, weight loss, difficulty talking, infections, emotional distress) are significant (Dodd et al., 2001).

The oral mucosa is made up of epithelial cells, basal cells, and squamous cells. Normally, the epithelial cells divide to produce a daughter cell or a basal cell. The daughter cells push upward becoming squamous cells, replacing the surface cells that are old or damaged. These squamous cells provide a protective layer in the mouth. The new basal cells replace damaged or old basal cells. Cancer treatment causes stomatitis in several different ways. First, stomatotoxic chemotherapeutic agents, such as antimetabolites and antitumour antibiotics, directly interfere with the replication of rapidly dividing cells, regardless of whether they are healthy or cancerous (Sonis, 1993). This process slows the production of new basal cells. The inflammation that defines stomatitis (Madeya, 1996) is an early sign of the tissue damage associated with declining basal cell production.[1] In the case of severe stomatitis, the production of new basal cells is sufficiently suppressed so that large areas of the mouth become ulcerated with the underlying connective tissue exposed, leaving these individuals at risk for infection. Cancer treatments that cause myelosuppression, leading to thrombocytopenia and neutropenia, may further increase the negative health consequences associated with stomatitis, such as hemorrhage and infection. Greenberg (1990) reported that 30% of infections leading to morbidity and death in leukemic patients stemmed from oral complications. Stomatitis also results from irradiation of the mouth and throat. As with chemotherapy, irradiation triggers inflammation by altering epithelial cell regeneration. In addition, however, it increases the risk for further damage to the thinning oral epithelium by decreasing saliva production and altering oral circulation (Cox, 1994).

A number of factors are known to increase the severity of stomatitis in cancer patients. These factors include the type and extent of the treatment, the duration and degree of myelosuppression, poor nutritional status, poor oral hygiene, dental caries, gingival disease, younger (<20) or older (>60) age, exposure to alcohol or cigarette smoke, chronic low-grade oral infections, and administration of immunosuppressants or oxygen (Browman et al., 1988; Dose, 1995; Hortobagyi et al., 1989; Thatcher et al., 1989).

Assessing the severity of stomatitis

As with pain and other symptoms, the development and evaluation of evidence-based interventions for stomatitis depend on the availability of a valid and reliable assessment tool. Table One outlines the most common assessment tools, a few of which have undergone psychometric testing. Three tools (indicated by * in

Karin Olson, RN, PhD[1, 12] is an Associate Professor, Faculty of Nursing, University of Alberta. John Hanson, MSc,[2], is a Biostatistician, Division of Epidemiology and Screening, Alberta Cancer Board, Edmonton, Alberta. Joan Hamilton, RN, MSc (A), [3] Queen Elizabeth II Health Sciences, Halifax, Nova Scotia. Dawn Stacey, RN, MScN, PhD(c),[4, 13] Population Health, University of Ottawa, Ottawa, Ontario. Margaret Eades, RN, MSc(A),[5] McGill University Health Centre, Montreal, Quebec. Deborah Gue, RN, MSN[6, 14] is a Clinical Nurse Specialist, Palliative Care Program, Providence Health Care, Vancouver, British Columbia. Harry Plummer, RN, PhD[7, 15], is an Assistant Professor, Faculty of Nursing, University of Calgary, Calgary, Alberta. Karen Janes, RN, MSN[8], is a Regional Professional Practice/Academic Leader, Nursing, British Columbia Cancer Agency, Vancouver Centre, Vancouver, British Columbia. Margaret Fitch, RN, PhD[9], Toronto-Sunnybrook Regional Cancer Centre, Toronto, Ontario. Debra Bakker, RN, PhD[10, 16], Professor, School of Nursing, Laurentian University, Sudbury, Ontario. Pamela Baker, RN, MN[11, 17], St. John's, Newfoundland. Catherine Oliver, RN, MSc(A)[5], Clinical Nurse Specialist, Palliative Care, McGill University Health Centre, Montreal, Quebec.

Departmental affiliations of all authors at the time of the study: [1] Nursing, Cross Cancer Institute, Edmonton, AB; [2] Epidemiology, Alberta Cancer Board, Edmonton, AB; [3] Nursing, Queen Elizabeth II Health Sciences Centre, Halifax, NS; [4] Nursing, Ottawa Regional Cancer Centre, Ottawa, ON; [5] Nursing, Montreal General Hospital, Montreal, PQ; [6] Nursing, Vancouver Hospital and Health Sciences Centre, Vancouver, BC; [7] Nursing, Tom Baker Cancer Centre, Calgary; AB; [8] Nursing, British Columbia Cancer Agency, Vancouver, BC; [9] Nursing, Toronto Sunnybrook Regional Cancer Centre, Toronto, ON; [10] Northeastern Ontario Regional Cancer Centre, Sudbury, ON; [11] Nursing, Dr. H. Bliss Murphy Cancer Centre, St. John's, NF.

Changes of affiliation: [12] Associate Professor, Faculty of Nursing at the University of Alberta, Edmonton, AB; [13] Population Health, University of Ottawa, Ottawa, ON; [14] Providence Health Care, c/o St. Paul's Hospital, Vancouver, BC; [15] Faculty of Nursing, University of Calgary, Calgary, AB; [16] School of Nursing at Laurentian University, Sudbury, ON; [17] retired.

Table One), the Oral Assessment Guide (OAG) (Eilers, Berger, & Peterson, 1988), the MacDibbs Mouth Assessment (Dibble, Shiha, MacPhail, & Dodd, 1996), and the World Health Organization (WHO) Grading Scale for Mucositis (Miller, Hoogstraten, Staquet, & Winkler, 1981) have been used extensively with cancer patients. Both the OAG and the MacDibbs Mouth Assessment have been used in nursing intervention studies for stomatitis prevention and/or treatment.

The OAG is an eight-item tool which requires assessment of the lips, tongue, mucous membranes, gingiva, teeth/dentures, voice, swallow, and saliva. All items are rated from one (normal) to three (most severe) (Eilers et al., 1988). This tool has been used to assess stomatitis attributable to both radiotherapy and chemotherapy (Zerbe, Parkerson, Ortlieb, & Spitzer, 1992). Correlation between paired assessments by nurses' scores was excellent (r=0.92) and per cent agreement ranged from 85% for mucous membrane assessments to

Table One: Characteristics of mucositis assessment tools

Source (year) and and name of tool	Assessment items	Measurement scale	Population	Validity/ reliability
1. Passos & Brand (1966) Guide numerical rating of the condition of mouth	8 items: saliva, tongue, palates, membranes, gums, odour, lips, nares	1 (normal) to 3 (severe)	Intensive care	Not reported
2. VanDrimmelen & Rollins (1969)	11 items: Palates and membranes for moisture and debris, the tongue for coating and moisture, gingiva, teeth, lips for moisture, general condition, odour	1 (normal) to 3 (worst possible condition	Nursing home (n=179)	Not reported
3. Bruya & Madeira (1975)	17 items: Physical state of the patient [level of consciousness, breathing habits, nutritional status, chewing ability, self-care ability]; lips and tongue [texture, colour, and moisture]; mucous membranes; gingival tissue; teeth; saliva; taste; voice	1 (worst possible to 3 (normal)	Chemotherapy	Not assessed
4. Beck (1979) Beck's Oral Exam Guide	15 items: Lips, tongue, mucous membranes, gingiva, teeth/dentures, saliva, voice, ability to swallow	1 (normal) to 4 (most severe)	Chemo	Not reported
*5. Eilers et al. (1988); Zerbe et al. (1992) Oral Assessment Guide (OAG)	8 items: Lips, tongue, mucous membranes, gingiva, teeth/dentures, voice, swallow, saliva	1 (normal) to 3 (most severe	Radiation & chemo (bone marrow transplant) N=20	Correlation r= 0.92 agreement 85-100%
6. Kolbinson, Schubert, Flournoy, & Truelove (1988); McGuire et al. (1993) Oral Mucositis Index	37 items: Lips, labial mucosa, buccal mucosa, hard palate, soft palate, dorsal tongue, ventral tongue, and gingiva each assessed for colour changes, atrophy, vascularity, ulceration; angular stomatitis, bleeding/crusting, saliva viscosity, xerostomia, pain, fungal, viral cultures	Anatomical regions rated 0 (normal) to 3 (severe change); dryness and pain rated 0 (no dryness or pain) to 10 (worst possible dryness or pain); also recorded results of fungal and viral cultures and medication use.	Bone marrow transplant (n=23+18)	Not provided: extensive missing data
*7. Dibble et al. (1996) MacDibbs Mouth Assessment	14 items: Patient information (pain, dryness, eating, talking, swallowing, tasting, and saliva production); examination results (number of ulcers, size of largest ulcer in millimetres, presence of vesicles, red areas, or white patches); potassium hydroxide smear (to check for fungal growth); herpes simplex virus culture	0 (no problem) to 3 (severe)	Radiation therapy	Agreement 85-100%
*8. Miller et al. (1981) WHO Grading Scale for Mucositis	1 item	0 (no side effects) to 4 (unable to eat or drink)	Oncology	Not reported

* indicates tools used extensively with cancer patients

100% for swallow assessments. The clinical utility and validity of this tool was evaluated with 20 patients (10 women, 10 men) undergoing bone marrow transplantation. Patients' scores on the OAG increased as the condition of the mouth declined, and decreased as the condition of the mouth improved. Staff compliance with use of the tool was high. The OAG has been used to evaluate stomatitis prevention protocols (Graham, Pecoraro, Bentura, & Meyer, 1993; Verdi, Garewal, Koenig, Vaughn, & Burkhead, 1995) and to identify factors associated with changes in oral cavity status (Berger & Eilers, 1998; Dodd, Miaskowski et al., 2000).

The MacDibbs Mouth Assessment was developed to evaluate stomatitis in patients receiving radiation therapy (Dibble et al., 1996). This 14-item tool comprises four sections: patient information (pain, dryness, eating, talking, swallowing, tasting, and saliva production), examination (number of ulcers, size of largest ulcer in millimetres, presence of vesicles, red areas, or white patches), potassium hydroxide smear (to check for fungal growth) and herpes simplex virus culture. Patient information items were rated from zero (no problem) to three (severe problem). The content validity of the tool was established through consultation with an expert panel consisting of dentists, nurses, and radiation therapists. The per cent agreement between raters was excellent, at 100% for 13 items. The ulcer size item had an agreement level of 85%. A strength of this tool is its ability to distinguish patients who have radiotherapy-induced stomatitis from those who have other serious oral health problems (*candida* infections and herpetic lesions). The MacDibbs Mouth Assessment and the OAG have been incorporated in a nursing intervention designed to reduce stomatitis (Larson et al., 1998; Dodd, Dibble et al., 2000).

In the 1970s, the World Health Organization convened two meetings with representatives from a number of international groups for the purpose of developing a standardized assessment and reporting method for symptoms, such as mucositis, that could be used worldwide. The results of these meetings was the WHO Grading Scale for Mucositis, which ranges from zero (no side effects) to four (unable to eat or drink) (Miller et al., 1981). The WHO scale differed significantly from the oral health assessment tools in that it did not require the assessment of different parts of the oral cavity. Rather, health care providers were required to stage severity along a single dimension with fixed endpoints from zero (no side effects) to four (unable to eat or drink). No evidence of testing for validity or reliability for this tool was found, but the WHO scale is considered to be the "gold standard" for assessment and staging of stomatitis in both clinical trials and in general cancer care.

The tools outlined in Table One are problematic for four reasons. First, a patient could obtain a given score, 10 for example, in many different ways, depending on the scores a nurse assigned following the assessment of each part of the oral cavity. Thus, the clinical meaning of a given score may change. A second closely related problem is that a patient's score could stay the same from one day to the next even though the key aspects of his/her mouth changed [two items in the assessment tool received increased scores (from two to three) while two other items in the assessment tool received scores that decreased by the same amount (from four to three)]. As a result of these two problems, the above tools are unable to provide a score with a consistent clinical meaning. This is problematic since changes that warrant an alteration in intervention may remain undetected.

Third, the above tools require the separate assessment on average, of 14 items (eight to 37). In a busy oncology nursing practice, length or complexity may limit the systematic use of stomatitis rating tools. A tool that is simple and yet valid and reliable would be easier to incorporate into a routine nursing assessment.

Finally, these tools all require the evaluation of at least one item (level of consciousness breathing habits, nutritional status, chewing ability, self-care ability, teeth, taste, and voice) that is not directly related to the effect of cancer treatment on oral mucosa. While some of these factors correlate with stomatitis severity, it is incorrect to increase the severity score simply because these factors are present. Rather, in order to ascertain stomatitis severity, only the mucosa

Table Two: Age and gender by treatment group (n=207)

	Gender	Mean age
Chemotherapy (n=87)	Male: 48% (n=42) Female: 51% (n=45)	50 years
Radiotherapy (n=71)	Male: 76% (n=54) Female: 24% (n=17)	63 years
Combined Chemotherapy and Radiotherapy (n=46)	Male: 57% (n=26) Female: 43% (n=20)	43 years

Note: Demographic information missing for three participants

Table Three: Recruitment by treatment, stage, and site

	Chemotherapy				Radiotherapy				Combined chemotherapy and radiotherapy				Total
	Stage				Stage				Stage				
Site	Stg0	Stg1	Stg2	Stg3	Stg0	Stg1	Stg2	Stg3	Stg0	Stg1	Stg2	Stg3	
1		1	2	1						3	1		8
2		3				11	2	1		1	1		19
3	4	9	7	1	5	1	1	2	4	8	4	3	49
4		5	2	1		4	2	1	1				16
5	5	7	1	1	5	14	8	3	2	2	1	1	50
6*						4	5	1					10
7	7	5	4	1						4	4	2	27
8	3	3								1			7
9	2	3	1						1				7
10		6	2	1		1		1		1		1	13
Total	21	42	19	6	10	35	18	9	8	20	11	7	206

* One missing case due to lack of treatment information.

doi:10.5737/1181912x143168174

should be assessed. In our view, inclusion of these items changes the clinical meaning of the resulting score from stomatitis severity to oral health. This is a serious matter since stomatitis severity (not oral health) is a dose-limiting toxicity in many cancer treatment protocols.

Development of the WCCNR stomatitis staging system

In the mid 1980s, the Western Consortium for Cancer Nursing Research (WCCNR) conducted a survey of Canadian cancer nurses to establish national research priorities. The development of nursing interventions for stomatitis was identified as one of the most pressing concerns (WCCNR, 1987). The objective of the WCCNR was to create an assessment tool that measured only stomatitis (not oral health), and that was reliable, valid, and easy to use. Clinically significant indicators were identified by interviewing dentists, physicians, and nurses in the four western Canadian provinces who had extensive experience with cancer patients. The eight descriptors arising from this qualitative study (lesions, colour, bleeding, moisture, edema, infection, ability to eat and drink, and pain) formed the original version of the WCCNR stomatitis staging system. In a study involving cancer patients recruited from the four western provinces, WCCNR scores correlated well with the OAG ($r=0.76$, $p<0.01$) and the WHO mucositis grading scale ($r=0.69$, $p<0.01$) (WCCNR, 1991). A supplementary project showed that three of the original descriptors (lesions, colour, and bleeding) could accurately predict stage 96.4% of the time (WCCNR, 1998). The following year, the Mucositis Study Group (MSG) published a modification of the OAG that requires the assessment of ulceration and erythema only, making it very similar to the revised WCCNR stomatitis staging system (WCCNR^R) (Sonis et al., 1999).

Study objectives

The objectives of the current study were to determine the validity of the revised WCCNR (WCCNR^R) for assessing stomatitis in two additional cancer populations (radiotherapy, combined radiotherapy-chemotherapy), and to determine the reliability of the WCCNR^R for patients receiving chemotherapy, radiotherapy, and combined radiotherapy-chemotherapy at 12 centres providing cancer treatment in Canada from British Columbia to Newfoundland.

Methods

Sample

Eligibility criteria included having a diagnosis of cancer, being at least 18 years old, currently receiving chemotherapy, radiotherapy, or combined chemotherapy and radiotherapy, and being able to read and understand English. Pairs of nurse data collectors evaluated 207 participants from 10 sites over a period of three years (see Table Two for age and gender by treatment group and Table Three for recruitment by treatment and site).

Data collection and analysis

Following receipt of ethical clearance from all data collection sites, a standardized training program was developed for all data collectors. Following training, data collectors began identifying eligible patients during the course of their routine nursing care. Upon identification of an eligible individual, the data collectors explained the study, obtained written consent, assessed participants' mouths using the WCCNR^R, and documented their severity rating (see Table Four). Total scores ranged from zero for normal mucosa to nine for severe stomatitis.

Because the validity of the tool had not yet been established for stomatitis due to radiotherapy, patients with radiotherapy-induced stomatitis were also assessed using a modified version of the MacDibbs Mouth Assessment (patient information and examination sections only), a tool that had been validated for assessing radiotherapy-induced stomatitis. The data collector who completed the first assessment then contacted the second data collector who independently assessed the patient within 12 hours. The validity of the WCCNR^R for patients with stomatitis related to radiotherapy was determined by calculating the correlation between the WCCNR^R and the MacDibbs Mouth Assessment. Reliability was determined by calculating Cohen's weighted Kappa for each pair of raters of each treatment group (chemotherapy, radiotherapy, combined chemotherapy and radiotherapy) at each of the 10 data collection sites.

Table Four: Revised WCCNR Stomatitis Staging System (WCCNR^R)

Score	Lesions	Erythema	Bleeding
0	None	50% or more pink	None
1	1-4	50% or more slightly red	
2	>4	50% or more moderately red	With eating or mouth care
3	More than 50% denuded	50% or more very red	Spontaneous

Assessment and Scoring Instructions

Using gloves, a penlight flashlight, (tongue blade as necessary):

- Inspect all oral surfaces. Lesions related to the tumour or to the surgical site, or cracks in the lips are <u>not</u> counted as ulcerated areas. Spontaneous bleeding may include finding dried blood on the pillow.
- Add scores for lesions, erythema, and bleeding.
- Rate as follows: 0=Normal Mucosa; 1-4=Mild Stomatitis; 5-7=Moderate Stomatitis; 8-9=Severe Stomatitis.

Examples:

1) A patient with two lesions (score=1), 50% or more pink mucosa (score=0), and no bleeding (score=0) would receive a total score of 1 (stage=mild).

2) A patient with more than four lesions (score=2), 50% or more very red mucosa (score=3), and bleeding with mouth care (score=2) would receive a total score of 7 (stage=moderate).

3) A patient with more than four lesions (score=2), 50% or more very red (score=3), and spontaneous bleeding (score=3) would receive a total score of 8 (stage=severe).

Findings

Table Five shows the WCCNR^R scores assigned by both data collectors across all 10 sites for all three treatment groups (n=207). The Pearson Product-Moment correlation between the WCCNR^R scores and the MacDibbs Mouth Assessment for patients who received radiotherapy only ranged from 0.44 ($p=0.0002$) to 0.54 ($p<0001$, $n=71$). As can be seen in Table Six, the weighted kappas for all three treatment groups at sites one, two, five, nine, and 10 remained above the target of 0.75 originally set during the training session. The weighted kappas at sites three and eight were close to the target. Site seven reported results for two treatment groups; in one group the weighted kappa was above the target and in the second group it was slightly below the target. The weighted kappas for sites four and six were considerably below the levels obtained at the other eight sites.

In order to further investigate the validity of our scoring system, we received ethical clearance to conduct a secondary analysis of a data set from a previous WCCNR study (WCCNR, 1998). The data set for the secondary analysis included scores for 56 chemotherapy patients on all eight descriptors from the original version of the WCCNR stomatitis

staging system. Using the scoring formula and data for lesions, colour, and bleeding, 79% of the cases were correctly classified. Using the formula and the data for lesions, colour, and moisture, however, 88% of the cases were correctly classified.

Discussion

Studies of this nature require sample size calculations. Since we were studying reliability and validity, our primary interest was in ensuring that our sample was large enough to detect true differences between scores assigned by pairs of data collectors, but we also wanted to detect differences in scores due to the treatment received and to setting. We expected the variation between nurses' scores to be small (effect size=0.1) as we had developed a standardized training program. We thought the variation between treatment groups would be moderate (effect size=0.25) because the WCCNR^R no longer included an assessment of moisture, an important element of stomatitis attributable to radiotherapy. We expected the variation between hospitals to be large (effect size=0.40) as the organization of cancer care varies considerably across Canada. These estimates were used to calculate the sample size using the approach developed by Cohen (1977). It is customary to base the calculations on the smallest effect size which, in this case, was expected to be the nurses' scores. Setting α to 0.05 and β to 0.06, our calculations showed that a sample of 1,320 would be required to detect a true difference between the nurse data collectors' scores, if one existed, 94% of the time. We hoped to have one pair of nurse data collectors at each site and to recruit five patients at each stage (zero to three) across three treatment groups (chemotherapy, radiotherapy, combined chemotherapy-radiotherapy) for a total sample size of 60 patients per site. This approach would have provided a total sample of 720 patients (1,440 observations) across 12 sites, leaving some cases for expected attrition, and would have allowed us to determine the variation in assessment scores attributable to the nurse data collectors, the treatment group, and the site.

Several challenges prevented the study team from carrying out this study as planned. We designed this study to run within the context of the usual work roles of the investigative team and the data collectors. No one was hired to collect data for this project. The only personnel cost was related to coverage of one to two shifts per data collector at each site during their training. We made this decision because we wanted to ascertain reliability and validity of the WCCNR^R under "usual work" conditions. Thus, this study was particularly vulnerable to changes in staff responsibility and broader organizational issues.

Changes in health care delivery also affected data collection. During the course of the study, stage three stomatitis became less common with the increasing use of colony stimulating factors at some sites. In addition, an increase in the management of chemotherapy patients at home meant that stomatitis occurred and was managed outside the clinic environment, thus reducing the number of individuals available for recruitment. Recruitment was also influenced by the fact that nurses at some centres were unfamiliar with both the research process and formal assessment of stomatitis. Thus, recruitment of study participants required a change in practice. Last, since the data collectors from a given site often worked various shifts and were usually not from the same unit, significant effort was required to coordinate the timing of their assessments. The lengthy recruitment period required the training of new data collectors at most centres.

Despite these challenges, this study showed that the WCCNR^R is a valid tool for staging stomatitis due to radiotherapy. Although the agreement between nurses was not as high as anticipated, this study also showed that the WCCNR^R is reasonably reliable. The agreement for eight sites (one, two, three, five, eight, nine, and 10) out of 10 suggests that the variation between nurses is indeed small, and that the variation between hospitals may be smaller than expected. The low kappas at sites four and six suggest data collection training issues at those locations. Our ability to detect these low scores suggests that our sample size, although not ideal, was sufficiently large to identify important differences that warrant further attention. The most noticeable variation between these eight sites is across treatment groups. This pattern is also reflected in the data from site seven where participants from two treatment groups were recruited; the kappa for combined chemotherapy and radiotherapy was higher than the target, but the kappa for chemotherapy alone was slightly below the target.

Table Five: WCCNR^R scores by rater

Rater 1	Normal (0)	Mild (1-4)	Moderate (5-7)	Severe (8-9)	Total
Rater 2: Chemotherapy only					
Normal (0)	19	2	0	0	21
Mild (1-4)	5	32	4	1	42
Moderate (5-7)	0	4	13	2	19
Severe (8-9)	0	0	1	5	6
Total	24	38	18	8	88
Rater 2: Radiotherapy only					
Normal (0)	10	0	0	0	10
Mild (1-4)	1	30	3	0	34
Moderate (5-7)	0	3	12	3	18
Severe (8-9)	0	0	2	6	8
Total	11	33	17	9	70
Rater 2: Chemotherapy and Radiotherapy					
Normal (0)	8	0	0	0	8
Mild (1-4)	3	15	2	0	20
Moderate (5-7)	0	0	7	4	11
Severe (8-9)	0	0	1	6	7
Total	11	15	10	10	46

Two missing cases

Table Six: Weighted kappa for each treatment group by site

	Combined Chemotherapy and Radiotherapy	Chemotherapy	Radiotherapy	Total
Site 1	1.0 (n=4)	1.0 (n=4)	n=0	8
Site 2	1.0 (n=2)	1.0 (n=3)	0.86 (n=14)	19
Site 3	0.71 (n=19)	0.68 (n=21)	0.96 (n=9)	49
Site 4	1.0 (n=1)	0.27 (n=8)	0.17 (n=7)	16
Site 5	1.0 (n=6)	1.0 (n=14)	0.89 (n=30)	50
Site 6*	n=0	n=0	0.37 (n=10)	10
Site 7	0.88 (n=10)	0.67 (n=17)	n=0	27
Site 8	1.0 (n=1)	0.67 (n=6)	(n=0)	7
Site 9	1.0 (n=1)	1.0 (n=6)	(n=0)	7
Site 10	1.0 (n=2)	0.84 (n=9)	1.0 (n=2)	13
Total	46	88	72	206

* missing treatment information in one case

doi:10.5737/1181912x143168174

The results of the secondary analysis were surprising. The scoring system, based on lesions, colour, and bleeding, was developed to stage stomatitis across three treatment groups (chemotherapy, radiotherapy, and combined chemotherapy and radiotherapy). The availability of all eight of the original descriptors (lesions, colour, bleeding, moisture, edema, infection, ability to eat/drink, discomfort) in the data set from a study previously conducted by our group provided the opportunity to examine the extent to which the scoring system could correctly stage the patients from our previous study. When scores for moisture replaced bleeding scores in the scoring system, the proportion of cases correctly staged increased by 9%. Unfortunately, patients in the previous data set were only assessed by one nurse so the reliability of assessments of moisture is unknown. In our next study, we had planned to test the reliability of the WCCNR^R in French. Given the results of the secondary analysis, however, we will revise the WCCNR^R Stomatitis Staging System slightly in the French study by adding moisture to the current three descriptors. Data collectors will also be asked to complete the WHO Mucositis Toxicity Grading Scale for each participant. The objective will be to determine a set of predictors that correlates well with the WHO Mucositis Toxicity Grading Scale, and that correctly stages at least 90% of cases.

Our study group continues to discuss the extent to which factors that did not appear to be important in the accurate staging of stomatitis severity, such as pain, may require assessment in order to develop nursing interventions. In our previous study (WCCNR, 1998), the addition of pain in the discriminant analysis did not increase our ability to correctly stage the severity of stomatitis. Similarly, in their study of patients undergoing bone marrow transplantation, McGuire, Yeager, Peterson, Owen, and Wingard (1998) found that although stomatitis appeared to be relatively mild, pain scores, on the other hand, were in the "mild" to "moderate" range (56 on a 0 to 100 scale and 2.62 on a 0 to 5 scale) and that, consistent with the work of others (Chapko, Syrjala, Schilter, Cummings, & Sullivan, 1989; McGuire et al., 1993), the availability of medication and other kinds of interventions did not result in complete pain relief. The solution to this problem will rest with the decisions we make regarding the outcome variables in our intervention studies. Will the outcome of interest be only visible tissue damage (lesions, colour, and bleeding)? To what extent might the pain be related to factors unrelated to the stomatitis?

Implications for research and practice

Given the problems associated with other assessment tools identified above, the initial intent of the WCCNR was to use the toxicity grading format for our tool and to refrain from the development of a scoring system. Data collectors, however, found this approach unworkable. Our future studies will confirm whether the scoring system that is now part of the tool has resulted in the identification of boundaries between significant clinical changes that will warrant different nursing interventions.

The WCCNR^R has several advantages over other valid and reliable tools for assessing stomatitis due to chemotherapy, radiotherapy, or both. In addition to assessing and staging only stomatitis, the symptom of interest when evaluating treatment-related toxicity, it is quick and easy to incorporate into a busy clinical practice. The tool is a hybrid, composed of the stomatitis indicators from the oral health assessment tools and the toxicity grading scale format used in the WHO tool. Individuals or groups wishing to use the WCCNR^R stomatitis staging system in clinical practice are invited to visit http://www.ualberta.ca/ ~kolson/stomatitis/stomatitis.htm and to complete the training material provided. The website also provides an opportunity for those who have completed the training to indicate an interest in participating in intervention studies and to assist with the development of an on-line colour atlas of stomatitis severity.

Clinical Coordinator

Oversee the day-to-day operations of patient care, Cancer Care Program

NANAIMO (VANCOUVER ISLAND), BC

Vancouver Island Health Authority (VIHA) provides a full range of dynamic and progressive healthcare services to residents of Vancouver Island.

You will be responsible for: • coordinating daily clinical activities while leading a multi-disciplinary team • assisting staff with professional development and achieving unit/service goals • taking a long-range view of operations and patient service delivery and following through on issues that impact on the overall quality of care • developing policies and procedures to optimize patient care at unit/service levels • contributing to the operating plan.

You have a Bachelor's degree in Nursing (preferably at the Master's level), as well as current RNABC registration and 5 – 7 years' related experience including 2 years' relevant clinical experience and 2 years at the supervisory level. An equivalent combination of education and experience may be considered.

Please send a résumé, citing reference #8316/CI-CONJ, to: Vancouver Island Health Authority, Central/North Island, 300 - 6475 Metral Drive, Nanaimo, BC V9T 2L9. Tel: 250.755.7615; fax: 250.740.6920; email: jobs@cvihr.bc.ca.

VANCOUVER ISLAND health authority

M33261

For more details visit www.viha.ca

Acknowledgements

The authors gratefully acknowledge funding for this study from AMGEN. They wish to acknowledge the following individuals who assisted with planning the study: Nancy Runzer, British Columbia Cancer Agency, Vancouver, BC; and Colleen Johnson and Janice Wright, Ontario Cancer Institute/Princess Margaret Hospital, Toronto, ON.

They also wish to acknowledge the following nurses who assisted with data collection: British Columbia Cancer Agency, Vancouver, BC: Barbara Brisebois, Sue Snelgrove, Kikine Capier; Vancouver Hospital and Health Sciences Centre, Vancouver BC: Anne Vlahadamis, and Carla Geekie; Tom Baker Cancer Centre and the Foothills Hospital, Calgary, AB: Cindy Railton; Cross Cancer Institute, Edmonton, AB: Brenda Macklem and Evelyn Sansregret; Northeastern Ontario Regional Cancer Centre, Sudbury, ON: Maria Laamanen; Ottawa Regional Cancer Centre, Ottawa, ON: Annette Beriault and Denise Connors; Toronto Sunnybrook Regional Cancer Centre, Toronto, ON: Sherrol Palmer-Wickham, Marg Cutrara, Anita McGowan, Angela Boudreau, Macey Farhadian, and Carmen Gosselin; McGill University Health Centre, Montreal, PQ: Carol Burnett, Marika Swidzinski, Liz O'Hagan, Joyce Constantin, Louise Duguay, and Samar Assousa; Queen Elizabeth II Health Sciences Centre, Halifax, NS: Cathy Murphy, Cindy Hyson, Lorrie Bambury, and Diane Nilsen; and the data collectors from Ontario Cancer Institute/Princess Margaret Hospital, Toronto, ON and Dr. H. Bliss Murphy Cancer Centre, St. John's, NF.

We also sincerely appreciate the assistance of Dr. Suzanne Dibble who provided consultation with regard to the use of the MacDibbs Mouth Assessment, Paul Beaulne who provided statistical consultation, and Luc Therrien who assisted with data management.

References are found on page 174.

Note: For the purposes of this study, stomatitis is defined as inflammation of the mucous membranes in the mouth. As such, it is a special case of mucositis (inflammation of mucous membranes) throughout the body (Thomas, 1997).

References

Beck, S. (1979). Impact of a systematic oral care protocol on stomatitis after chemotherapy. **Cancer Nursing, 2**(3), 185-199.

Bennett, J., Muss, H., Droshow, J., Wolff, S., Krementz, E., Cartwright, K., et al. (1988). A randomized multi-center trial comparing mitoxantrone, cyclophosphamide, and fluorouracil with doxorubicin, cyclophosphamide, and fluorouracil in the therapy of metastatic breast carcinoma. **Journal of Clinical Oncology, 6**, 1611-20.

Berger, A., & Eilers, J. (1998). Factors influencing oral cavity status during high-dose antineoplastic therapy: A secondary data analysis. **Oncology Nursing Forum, 25**(9), 1623-1626.

Browman, G., Levine, M., Goodyear, M., Russell, R., Archibald, S., Jackson, B., et al. (1988). Methotrexate/fluorouracil scheduling influences normal tissue toxicity but not antitumour effects in patients with squamous cell head and neck cancer: Results from a randomized trial. **Journal of Clinical Oncology, 6**, 963-8.

Bruya, M., & Madeira, N. (1975). Stomatitis after chemotherapy. **American Journal of Nursing, 75**(8), 1349-1352.

Chapko, M., Syrjala, K., Schilter, L., Cummings, L., & Sullivan, K. (1989). Chemoradiaotherapy toxicity during bone marrow transplantation: Time course and variation in pain and nausea. **Bone Marrow Transplant, 4**, 181-6.

Cohen, J. (1977). **Statistical power analysis for the behavioural science** (rev.). New York: Academic Press.

Cox, J. (Ed.). (1994). **Moss' radiation oncology** (7th ed.). St. Louis: Mosby.

Dibble, S., Shiha, G., MacPhail, L., & Dodd, M. (1996). MacDibbs Mouth Assessment: A new tool to evaluate mucositis in the radiation therapy patient. **Cancer Nursing, 4**(3), 135-139.

Dodd, M., Dibble, S., Miaskowski, C., MacPhail, L., Greenspan, D., Paul, S., & Larson, P. (2000). Randomized clinical trial of the effectiveness of three commonly used mouthwashes to treat chemotherapy-induced mucositis. **Oral Surgery, Oral Medicine, Oral Pathology, 90**(1), 39-47.

Dodd, M., Dibble, S., Miaskowski, C., Paul, S., Cho., M., MacPhail, L., et al. (2001). A comparison of the affective state and quality of life of chemotherapy patients who do and do not develop chemotherapy-induced oral mucositis. **Journal of Pain and Symptom Management, 21**(6), 498-505.

Dodd, M., Miaskowski, C., Dibble, S., Paul, S., MacPhail, L., & Greenspan, L. (2000). Factors influencing oral mucositis in patients receiving chemotherapy. **Cancer Practice, 8**(6), 291-297.

Dose, M. (1995). The symptom experience of mucositis, stomatitis, and xerostomia. **Seminars in Oncology Nursing, 11**(4), 248-255.

Eilers, J., Berger, A., & Petersen, M. (1988). Development, testing, and application of the oral assessment guide. **Oncology Nursing Forum, 15**(3), 325-330.

Epstein, J., & Spektor, W. (1993). Radiation therapy and pain in patients with head and neck cancer. **Oral Oncology, European Journal of Cancer, 2**(9B), 191-199.

Fountzilas, G., Daniilidis, J., Kalogera-Fountzilas, A., Apostolidis, T., Vritsios, A., & Tourkantonis, A. (1988). Combined therapy of locally advanced squamous epithelial cancers in the area of the head and neck [German]. **Laryngologie, Rhinologie, Otologie, 67**(4), 165-70.

Fountzilas, G., Nicolaou, A., Sridhar, K., Sideras, T., Haritanti, A., & Anastasakis, C., et al., (1989). Induction chemotherapy with cisplatinum, 5-fluorouracil, bleomycin, mitamycin-C, and hydroxyurea for previously untreated locally advanced squamous cell carcinomas of the head and neck. **Archives Oto-Rhino-Laryngology, 246**, 373-7.

Graham, K., Pecoraro, D., Bentura, M., & Meyer, C. (1993). Reducing the incidence of stomatitis using a quality assessment approach. **Cancer Nursing, 16**(2), 117-122.

Greenberg, M. (1990). Pre-chemotherapy dental treatment to prevent bacteremia. **National Cancer Institute Monographs, 9**, 49-50.

Hortobagyi, G., Frye, D., Busdar, A., Ewer, M., Fraschini, G., Hug, B., et al. (1989). Decreased cardiac toxicity of doxorubicin administered by continuous intravenous infusion in combination chemotherapy for metastatic breast carcinoma. **Cancer, 63,** 37-45.

Kin, R., Iwamori , S., Saeki, S., Nishimawari, K., Akiyama, H., Nagusa, Y., et al. (1988). Clinical observations of hepatic artery infusion therapy combined with hepatic artery ligation in metastatic liver cancers. **Gan To Kagaku Ryoho, 15**, 661-5.

Kolbinson, D., Schubert, M., Flournoy, N., & Truelove, E. (1988). Early oral changes following bone marrow transplantation. **Oral Surgery, 66**(1), 130-138.

Larson, P., Miaskowski, C., MacPhail, L., Dodd, M., Greenspan, D., Dibble, S., et al. (1998). The PRO-SELF (C) Mouth Aware program: An effective approach for reducing chemotherapy-induced mucositis. **Cancer Nursing, 21**(4), 263-268.

Levi, J., Thomson, D., Harvey, V., Gill, G., Raghavean, D., Tattersall, M., et al. (1990). Effective salvage chemotherapy with etoposide, dactinomycin, and methotrexate in refractory germ cell cancer. **Journal of Clinical Oncology, 8**, 27-32.

Madeya, M. (1996). Oral complications from cancer therapy: Part 1—pathophysiology and secondary complications. **Oncology Nursing Forum, 23**(5), 801-807.

McGuire, D., Altomonte, V., Peterson, D., Wingard, J., Jones, R., & Grochow, L. (1993). Patterns of mucositis and pain in patients receiving preparative chemotherapy and bone marrow transplantation. **Oncology Nursing Forum, 20**(10), 1493-1502.

McGuire, D., Yeager, K., Peterson, D., Owen, D., & Wingard. J. (1998). Acute oral pain and mucositis in bone marrow transplant and leukemia patients: Data from a pilot study. **Cancer Nursing, 21**(6), 385-393.

Miller, A., Hoogstraten, B., Staquet, M., & Winkler, A. (1981). Reporting results of cancer treatment. **Cancer, 47**(1), 207-214.

National Institutes of Health. (1990). National Institutes of Health Consensus Development Conference on oral complications of cancer therapies: Diagnosis, prevention, and treatment. **National Cancer Institute Monographs, 7**(7), 1-25, Bethesda, MD.

Passos, J., & Brand, L. (1966). Effects of agents used for oral hygiene. **Nursing Research, 15**(3), 196-202.

Rothwell, B., & Spektor, W. (1990). Palliation of radiation related mucositis. **Special Care in Dentistry, 10**(1), 21-25.

Sonis, S. (1993). Oral complications of cancer therapy. In V. DeVita, S. Hellman, & S. Rosenberg (Eds.), **Cancer: Principles and practice of oncology** (2nd ed.). Philadelphia: J.B. Lippincott.

Sonis, S., Eilers, J., Epstein, J., LeVeque , F., Liggett, W., Mulagha, M., et al. (1999). Validation of a new scoring system for the assessment of clinical trial research of oral mucositis induced by radiation or chemotherapy. **Cancer, 85**(10), 2103-2113.

Thatcher, D., Lind, M., Morgenstern, G., Carr, T., Chadwich, G., & Jones, R., et al. (1989). **Cancer, 63**, 1296-302.

Thomas, C. (1997). **Taber's cyclopedic medical dictionary** (18th ed.). Philadelphia: F.A. Davis.

Van Drimmelen, J., & Rollins, H.F. (1969). Evaluation of a commonly used oral hygiene agent. **Nursing Research, 18**(4), 327-332.

Verdi, C., Garewal, H., Koenig, M., Vaughn, B., & Burkhead, T. (1995). A double-blind, randomized, placebo-controlled, crossover trial of pentoxifylline for the prevention of chemotherapy-induced oral mucositis. **Oral Surgery, Oral Medicine, Oral Pathology, 80**(1), 35-42.

Western Consortium for Cancer Nursing Research (WCCNR). (1987). Priorities for cancer nursing research. **Cancer Nursing, 10**(6), 319-326.

Western Consortium for Cancer Nursing Research (WCCNR). (1991). Development of a staging system for chemotherapy-induced stomatitis. **Cancer Nursing, 14**(1), 6-12.

Western Consortium for Cancer Nursing Research (WCCNR). (1998). Assessing stomatitis: Refinement of the Western Consortium for Cancer Nursing Research (WCCNR) stomatitis staging system. **Canadian Oncology Nursing Journal, 8**(3),160-162.

Zerbe, M., Parkerson, S., Ortlieb, M., & Spitzer, T. (1992). Relationships between oral mucositis and treatment variables in bone marrow transplant patients. **Cancer Nursing, 15**(3), 196-205.