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Exploratory Factor Analysis of NRG Oncology's University of Washington Quality of Life Questionnaire – RTOG Modification

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Abstract

Context—The 15-item University of Washington Quality of Life questionnaire – Radiation Therapy Oncology Group (RTOG) modification (UW-QOL-RTOG modification) has been used in several trials of head and neck cancer conducted by NRG Oncology such as RTOG 9709, RTOG 9901, RTOG 0244, and RTOG 0537.

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Objectives—This study is an exploratory factor analysis (EFA) to establish validity and reliability of the instrument subscales.

Methods—EFA on the UW-QOL - RTOG modification was conducted using baseline data from NRG Oncology's RTOG 0537, a trial of acupuncture-like transcutaneous electrical nerve stimulation in treating radiation-induced xerostomia. Cronbach's α coefficient was calculated to measure reliability; correlation with the University of Michigan Xerostomia Related Quality of Life Scale (XeQOLS) was used to evaluate concurrent validity; and correlations between consecutive time points were used to assess test-retest reliability.

Results—The 15-item EFA of the modified tool resulted in 11 items split into 4 factors: mucus, eating, pain, and activities. Cronbach's α ranged from 0.71 to 0.93 for the factors and total score, consisting of all 11 items. There were strong correlations ($\rho \geq 0.60$) between consecutive time points and between total score and the XeQOLS total score ($\rho > 0.65$).

Conclusion—The UW-QOL-RTOG modification is a valid tool that can be used to assess symptom burden of head and neck cancer patients receiving radiation therapy or those who have recently completed radiation. The modified tool has acceptable reliability, concurrent validity, and test-retest reliability in this patient population, as well as the advantage of having being shortened from 15 to 11 items.

Keywords

quality of life; factor analysis; xerostomia

Introduction

Patients with head and neck cancer experience a multitude of symptoms that affect their health-related quality of life (HR-QOL).[1] Common side effects of radiation therapy (RT) for head and neck cancer include xerostomia or dry mouth, pain in the mouth and throat, mucositis, changes in taste, difficulty chewing, altered speech, dysphagia (i.e., difficulty swallowing), interference with daily and social activities, and mood complaints.[2-8] RT is also a key cause of mucositis, with the severity and onset being directly related to the RT dose, fraction size, and frequency.[3,4,8] Radiation damage to the salivary glands changes saliva from thin to thick secretions.[3] During RT, pain and mouth and throat soreness tend to increase in severity, require analgesics, and decrease HR-QOL, which can last well after the completion of therapy.[3,4,9] This multitude of symptoms is highly distressing and must be continuously assessed by providers. In order to do this effectively, accurate symptom measurement is critical.

Since HR-QOL is directly affected by symptom burden, the gold standard for symptom measurement must be used. That standard consists of patient-reported outcomes (PRO). Patient perceptions are subjective and patient self-assessments can differ from physician assessments.[10] Moreover, studies have shown that physicians under-report the incidence or severity of symptoms experienced by cancer patients, particularly for subjective toxicities such as pain.[9,11-13] Xiao et al.[12] also found that patients tended to report frequency and severity of symptoms earlier than physicians and advocated for the use of PROs in routine clinical practice.

While various HR-QOL PRO tools are used with head and neck cancer patients, none were found that adequately covered the key issues of RT patients. The closest match to the needs of RT head and neck patients is the University of Washington-Health Related Quality of Life tool (UW-QOL).[14] Since the UW-QOL tool does not have a copyright agreement, it was selected to fill this gap in available measurement. RTOG modified the UW-QOL tool to more accurately reflect symptoms unique to patients receiving RT for head and neck cancer. The UW-QOL – RTOG modification (see Supplemental Table 1) was first created for use in NRG Oncology's RTOG 9709 trial, a phase III trial examining the effect of pilocarpine during RT in head and neck cancer patients.[15-17] Several additional NRG Oncology studies have since used this RTOG-modified tool.[18-22] While the modified measure is reliable in single-factor analyses, the purpose of this secondary analysis was to validate this modified tool as a reliable measure for use with head and neck cancer patients receiving RT. The research aims were to conduct an exploratory factor analysis and assess reliability, concurrent validity using correlation with another HR-QOL tool, and test-retest reliability of the modified tool.

Methods

Sample

The UW-QOL – RTOG modification was completed by 137 patients at baseline on NRG Oncology RTOG 0537, a phase III trial of acupuncture-like transcutaneous electrical nerve stimulation in treating early radiation-induced xerostomia.[21,22] The majority of the sample was male, approximately 58 years of age, functioning normally with respect to daily activities, with a history of prior chemotherapy but no prior pilocarpine (Table 1). All patients were required to have completed RT with or without chemotherapy at least 3 months before enrolling on the study and had not had surgery.

Instruments

The UW-QOL questionnaire was designed to broadly address problems incurred by head and neck cancer patients, rather than those specifically receiving RT. Hassan and Weymuller[14] first validated this tool. Since then, there have been several published versions and corresponding validations.[23,24] The most recent is version 4; it has been extensively validated, is commonly used, has been translated into over 40 languages, and is in world-wide use.[14,23-28] In addition to questions specific to head and neck cancer patients, version 4 also includes three global quality of life questions and a rating scale asking patients to choose three issues that were the most important in the last seven days.

The UW-QOL – RTOG modification consists of 15 items with response options ranging from 10-50, in multiples of 10. That is, the lowest symptom burden is rated as 10, while the highest symptom burden is rated as 50. The individual item scores are totaled and then averaged to obtain the final score. This scoring results in a lower score indicating greater HR-QOL; and conversely, higher scores indicating lower HR-QOL. Modifications involved three conceptual areas including pain, mucus and shoulder disability. Questions differentiating between pain in general versus either mouth or throat pain were added. Pain tends to intensify during RT and can last well after the end of treatment.[7] Given the

frequency and severity of mucositis in this patient population, two items on mucus were added: one on amount and the other on consistency. To reduce the total number of items, the less relevant question for a non-surgical patient population on shoulder disability was removed. The focus of this modified tool was to assess RT-related symptoms and some studies have found that patients do not always view shoulder disability as important.[29,30] Specifically, Rogers et al.[29] found that the UW-QOL (v4) shoulder domain was significantly reduced post-operatively; however an increase in its importance rating among patients was not found. The language in the questions and responses remained as consistent as possible with the original UW-QOL. Specifically for the additional questions, the question stems, which are the part of the question that presents the issue, were worded to parallel the question stems for the UW-QOL. Also as mentioned earlier, following the pattern of the original measure, the minimum score was kept at 10 corresponding to no dysfunction while the maximum score was 50 corresponding to total dysfunction.

The University of Michigan Xerostomia Related Quality of Life Scale (XeQOLS) measures xerostomia, the primary endpoint of NRG Oncology RTOG 0537, and was used to assess concurrent validity of the UW-QOL – RTOG modification. The 15-item XeQOLS measures the impact of salivary gland dysfunction and xerostomia on four domains of oral health related quality of life: 1) physical functioning; 2) personal/psychological functioning; 3) social functioning; and 4) pain/discomfort issues.[31] The focus of this tool is different from the UW-QOL since all items address only dryness within their respective domains. The tool employs a Likert-type scale with five options ranging from “not at all” to “very much,” without a numerical rating for each choice. The internal validity coefficients for the four domains are statistically significant at $p<0.001$ with a range from $r=0.36$ to 0.73.

Analyses

In order to appropriately analyze results from the UW-QOL - RTOG modification tool, an exploratory factor analysis was conducted using baseline data from NRG Oncology RTOG 0537. The standardized Cronbach's α coefficient was used to determine reliability. Principal axis factoring with oblique rotation, specifically PROMAX, was used as the factor model with squared multiple correlation used to estimate communalities. The number of factors was determined by examination of the scree plot and using total percent variance explained, specifically to retain factors with eigenvalues greater than the average eigenvalue. Factor loading > 0.30 was used to identify significant factors.[32]

Additionally, to ensure that all items were useful in discriminating responses, each item was examined to determine if rates of either extreme (i.e., “I have no pain” and “I have severe pain not controlled by narcotics” are the extremes for the questions on pain) exceeded a 95% response rate. Correlation of the total score with the total score from the XeQOLS was conducted to assess concurrent validity.[21,31] Correlations at consecutive follow-up time points in NRG Oncology RTOG 0537 for the total score were conducted to assess test-retest reliability.

Results

Aim 1: Conduct an exploratory factor analysis

The standardized Cronbach's α coefficient for all 15 items was 0.88, suggesting acceptable reliability of the UW-QOL – RTOG modification. The eigenvalues of the correlation matrix are found in Figure 1. By retaining the factors that were greater than the average eigenvalue (0.44), four factors were kept with factor loadings > 0.3 (Table 2). The scree plot, depicted in Figure 1, also shows a break after four factors further suggesting retention of four factors.[32] Calculation of Cronbach's α coefficient, inter-factor correlations, and the rotated factor pattern were repeated after the removal of any item until all items had one significant factor loading. Four iterations occurred; each removed a single question. Question 8, chewing, was the first question removed. Its highest factor loading was 0.279 on Factor 2. The next iteration removed question 7 on employment. Its highest factor loading was 0.265 on Factor 4. Question 13, speech, was the next question removed, with its highest factor loading being 0.298 on Factor 2. Question 4, disfigurement, was the last question removed with its highest factor loading on Factor 1 of 0.285. Eleven questions were retained across four factors (Table 3).

The remaining factors were mucus (amount and consistency of mucus), eating (swallowing, amount and consistency of saliva, and taste), pain (general, mouth, and throat pain), and activity (activity, recreation/entertainment). The resulting Cronbach's α coefficient for all of the remaining questions was 0.79; although slightly smaller as compared to that of all questions, it still suggested acceptable reliability. Cronbach's α coefficient for the four subscales ranged from 0.71 for eating and pain factors to 0.93 for mucus factor. The activity factor had a coefficient of 0.84. The resulting factors are located in Table 3.

Aim 2: Analyze each item individually for concurrent validity and test-retest reliability

Examination of the distribution of responses to each item did not reveal any extreme distributions. Correlations were strong ($\rho > 0.67$) between the UW-QOL – RTOG modification total score and the XeQOLS total score suggesting satisfactory concurrent validity (Table 4). The highest correlations occurred at 9 months and the lowest at 6 months (ρ=0.82 and 0.67, respectively). The correlations at consecutive follow-up time points for the UW-QOL – RTOG modification total score and factor scores are shown in Table 5. Correlations for total score, eating, pain, and activities factors were strong with $\rho \geq 0.70$, suggesting adequate test-retest reliability.[33] Mucus factor had the weakest correlations but represent a large effect ($\rho \geq 0.60$).[34]

Discussion

According to Elting et al.[4], virtually all patients who are undergoing RT with or without chemotherapy for head and neck cancer develop symptoms severe enough to reduce their HR-QOL. The goal of this analysis was to create a scale that focused on the side effects of RT. The factor analyses, specifically the item reduction process, eliminated those items with poor responsiveness to RT. The current analysis advances measurement science for head and

neck cancer patient symptom assessment by creating a succinct tool with four substantial factors.

Of the four resulting factors (subscales), the Eating subscale based on this analysis consists of swallowing and taste and two items added by the RTOG on amount of saliva and consistency of saliva. The second factor modified was pain. The pain items were adapted to not only assess overall pain, but to discriminate between the pain location (general vs. mouth vs. throat) and measure effects on eating. These additional questions on pain and saliva strengthen this measure for RT patients by placing more emphasis on symptoms affecting oral quality of life. Head and neck RT patients need emphasis on such symptoms that are linked to saliva and pain issues of the mouth as it is a common site of acute and chronic complications in these patients.[35-37]

Results of the analysis of the UW-QOL – RTOG modification have been previously published.[22] Although patients receiving ALTENS consistently had lower score, no significant treatment differences were found. Statistical modeling showed a significant time effect through 15 months of data collection, specifically radiation-induced xerostomia improved across time for all patients. These conditions do not provide an ideal setting to assess test-retest reliability. Even in light of these conditions, this analysis still showed strong correlations for the total score and factor scores between consecutive time points.

While the correlations were strong ($\rho > 0.67$) between the UW-QOL – RTOG modification total score and the XeQOLS total score, the UW-QOL – RTOG modification has several advantages. As mentioned with the factor analysis above, the UW-QOL-RTOG modification captures more detail on key symptoms. Further, it addresses much more than dryness across various domains, which would be equivalent to amount of saliva. The UW-QOL-RTOG modification provides a comprehensive evaluation of oral symptoms and HR-QOL.

These analyses also produced an additional advantage by reducing the instrument burden from 15 items to 11. This is always a goal in instrument refinement and has been successfully achieved with this newly minimized measure. However, in reducing the number of items, the relevant patient population was also reduced. Specifically, this tool does not address symptoms experienced by post-operative patients, such as shoulder dysfunction.

Validation of the utility of the measure with broader samples is still needed since the current sample was dominated by white, non-Hispanic men treated with chemo-RT 3 months to 2 years previously and able to function normally with respect to activities of daily life as measured by Zubrod performance status.[38] Race, ethnicity, and gender can affect a patient's quality of life.[39-41] For example, Cleeland et al.[42] showed that minorities and patients with better performance status were more likely to receive inadequate pain control.

Therefore, the four subscales found for UW- QOL - RTOG-modification as a result of reliability testing with NRG Oncology RTOG 0537 indicate major areas of possible symptom burden that affect daily living function and thus are crucial when treating types of head and neck cancer patients with RT. This modified measure also moves the science from a single scale measure to a four-subscale tool which better informs the underlying constructs. Given the need to assess oral symptoms that are experienced by head and neck

cancer patients receiving RT, the UW-QOL - RTOG modification captures symptoms suffered by these patients in a concise yet comprehensive tool.

The revised 11-item UW-QOL - RTOG modification tool revealed four factors with acceptable reliability, concurrent validity, and test-retest reliability. Such testing is needed to refine new and modified tools to provide the least burden to patients and the greatest accuracy in measurement of constructs of interest.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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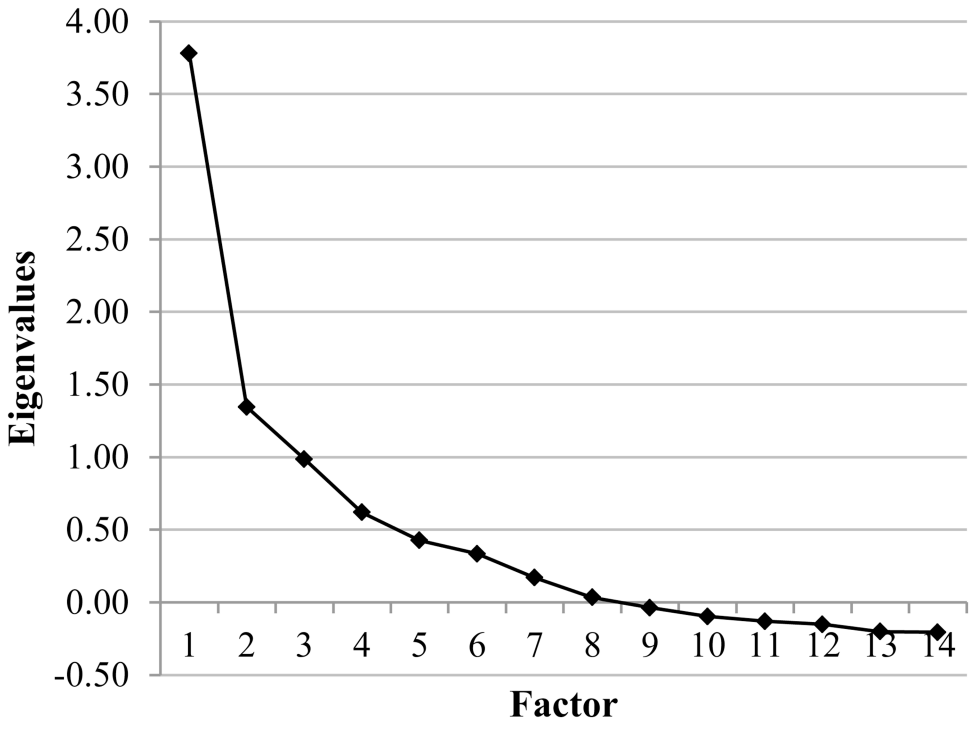

Figure 1.
Scree Plot. Total eigenvalue = 6.575, average eigenvalue = 0.4384.

Table 1

Pretreatment Characteristics (n=137)

Age (years)	
Mean	58.2
Std. Dev.	8.6
Gender	
Male	118 (86.1%)
Female	19 (13.9%)
Race	
American Indian or Alaska Native	3 (2.2%)
Asian	7 (5.1%)
Black or African American	7 (5.1%)
White	120 (87.6%)
Ethnicity	
Hispanic or Latino	6 (4.4%)
Not Hispanic or Latino	125 (91.2%)
Unknown	6 (4.4%)
Zubrod Performance Status	
0	111 (81.0%)
1	25 (18.2%)
2	1 (0.7%)
Country of Residence	
United States	101 (73.7%)
Canada	36 (26.3%)
Prior Chemotherapy	
No	25 (18.2%)
Yes	112 (81.8%)
Time since RT +/- Chemotherapy	
3-6 months ago	36 (26.3%)
More than 6 months to 1 year ago	53 (38.7%)
1-2 years ago	48 (35.0%)
Prior Use of Pilocarpine	
No	116 (84.7%)
Yes	21 (15.3%)

Table 2

Final Factor Loadings

Item	Factor1	Factor2	Factor3	Factor4	Final Communality
Pain-General	-0.084	-0.037	0.680	0.022	0.456
Pain-Mouth	0.098	-0.040	0.797	-0.049	0.633
Pain-Throat	-0.047	0.138	0.465	0.106	0.302
Activity	0.052	-0.012	0.077	0.784	0.692
Recreation/Entertainment	0.024	0.038	-0.030	0.796	0.661
Eating-Swallowing	-0.109	0.583	0.028	0.196	0.438
Salvia-Amount	-0.004	0.648	-0.041	0.002	0.413
Salvia-Consistency	0.168	0.627	0.030	-0.123	0.439
Taste	0.040	0.326	0.008	0.232	0.252
Mucus-Amount	0.894	-0.037	-0.048	0.063	0.803
Mucus-Consistency	0.877	0.068	0.027	0.000	0.831
Variance explained	1.290	0.922	1.126	0.890	

Underlined factor loadings indicates significant loading (>0.30)

Table 3

Resulting Factors

Factor 1 - Mucus	Factor 2 - Eating	Factor 3 - Pain	Factor 4 - Activities	Removed items
Amount of mucus Consistency of mucus	Swallowing Amount of saliva Consistency of saliva Taste	General pain Mouth pain Throat pain	Activity Recreation/entertainment	Disfigurement Employment Chewing Speech

11 item Cronbach's α coefficient = 0.79

Table 4

Correlations between UW-QOL – RTOG modification total score and XeQOLS total score at specified time points

	n	ρ*	p-value
Baseline	118	0.73	<0.01
4 Months	92	0.80	<0.01
6 Months	88	0.67	<0.01
9 Months	93	0.82	<0.01
15 Months	87	0.75	<0.01

*Pearson correlation coefficient

Table 5

Correlations of UW-QOL – RTOG modification total score and factor scores at consecutive time points

		n	ρ*	p-value
UW-QOL – RTOG modification				
Total score	4 & 6 months	84	0.84	<0.01
	6 & 9 months	84	0.88	<0.01
	9 & 15 months	89	0.86	<0.01
Mucus factor score	4 & 6 months	86	0.60	<0.01
	6 & 9 months	89	0.69	<0.01
	9 & 15 months	91	0.62	<0.01
Eating factor score	4 & 6 months	87	0.87	<0.01
	6 & 9 months	88	0.88	<0.01
	9 & 15 months	89	0.80	<0.01
Pain factor score	4 & 6 months	85	0.78	<0.01
	6 & 9 months	87	0.70	<0.01
	9 & 15 months	91	0.62	<0.01
Activities score	4 & 6 months	86	0.82	<0.01
	6 & 9 months	88	0.73	<0.01
	9 & 15 months	90	0.74	<0.01

*Pearson correlation coefficient