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CONTENTS

DITORIAL	
Indian needs stricter implementation	
Pankaj Chaturvedi	129
RIGINAL ARTICLES	
Point of sale tobacco advertisements in India	
Chaudhry S, Chaudhry S, Chaudhry K	13
Activity and toxicity of 2-CDA in Langerhans cell histiocytosis: A single institutional Biswas G, Khadwal A, Arora B, Bhagwat R, Banavali SD, Nair CN, Pai SK, Kurkure P	l experience 2A, Parikh PM 133
In vitro chemosensitivity profile of oral squamous cell cancer and its correlation w response to chemotherapy	ith clinical
Pathak KA, Juvekar AS, Radhakrishnan DK, Deshpande MS, Pai VR, Chaturvedi P, Pa Chaukar DA, D'Cruz AK, Parikh PM	ai PS, 142
Validation of the University of Washington quality of life questionnaires for head a patients in India	nd neck cancer
D'cruz AK, Yueh B, Das AK, Mcdowell JA, Chaukar DA, Ernest AW	147
ASE REPORT	
Penile metastasis from rectal carcinoma	
Murhekar KM, Majhi U, Mahajan V, Satheesan B	155
Radiotherapy-induced depigmentation in a patient with breast cancer	
Anusheel Munshi, Sandeep Jain, Ashwini Budrukkar, Rakesh Jalali, Rajiv Sarin	157
UTHOR INDEX - 2007	159
ITLE INDEX - 2007	16 ⁻

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Original Article

Validation of the University of Washington quality of life questionnaires for head and neck cancer patients in India

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Abstract

Quality of life (QOL) is a multidimensional construct capturing the subjective wellbeing of patients in physical, emotional, functional and social domains. Available work on post treatment QOL have only been made in western literature and less in Indian literature. **AIMS:** To translate the UWQOL into both Hindi and Marathi and psychometrically validate the translation in HandN cancer patients in Indian population. **SETTINGS AND DESIGN:** A prospective study was done at the Tata Memorial Hospital for patients who were treated for H and N cancers. **MATERIALS AND METHODS:** 147 patients were enrolled from January to April 2005. The study was carried out in two phases. Patients were given translated versions of the UWQOL and EORTC QOL questionnaires preoperatively, 15 days postoperatively and then three months postoperatively. **RESULTS:** Both the Hindi and Marathi translations had strong internal consistency (Cronbach's alpha=0.7971 and 0.7839). UWQOL composite scores correlated well with the global questions on overall QOL in both the Hindi (r=0.69) and Marathi (r=0.66) translations and also with Tstage. QOL scores were worse three months postoperatively than preoperatively and for patients undergoing surgery that violated the mucosa. A strong correlations was observed (r>0.50) between all similar domains on the UWQOL and EORTC HandN35 except the saliva item on the Marathi translation, where r<0.50, but Pvalues were significant. **CONCLUSIONS:** The Marathi and Hindi versions of the UWQOL appear to be valid and reliable instruments for assessing the QOL in Indian population and will be a vital tool for achieving greater insight into the short and the long term QOL.

Key words: Head and neck cancer, quality of life, questionnaires, validity

Introduction

Increasing attention has been given in recent years to the importance of quality of life (QOL) in assessing outcomes of patients treated for head and neck (H and N) cancers. QOL is a multidimensional construct capturing the subjective wellbeing of patients in physical, emotional, functional and social domains. Although therapeutic options may provide similar survival rates, QOL outcomes between treatment modalities may vary significantly. It is therefore ideal for pre-therapy discussions to include consideration of optimal post-therapy QOL outcomes.

Although substantial efforts have been made in the western literature to document posttherapy QOL, less has been documented in the Indian literature, despite the prevalence of H and N cancer in the Indian population.^[1-5] A variety of scales have been developed, with the most widely used and accepted scales being the European Organization for Research and Treatment of Cancer's Quality of Life Questionnaire (EORTCH and N35), the Functional Assessment of Cancer Therapy (FACT H and N) scale and the University of

Washington Quality of Life questionnaire (UWQOL).

An instrument suitable for routine clinical use should be brief and impose minimal patient burden. The EORTC QOL questionnaire is the most widely used instrument and has been validated in various languages. We were the first to validate the same in Hindi and Marathi^[6] the two vernacular languages most widely spoken by our patients. Our findings did suggest that this instrument was suitable in our patient population; however these scales are lengthy, complex and time consuming consisting of 35 (H and N specific) and 30 (Global) questions, respectively. The UWQOL is brief, consisting of 12 questions and is commonly used by many centers globally. The aim of this project was to translate the UWQOL into both Hindi and Marathi and psychometrically validate the translation in head and neck cancer patients in India and compare the same with the previously validated EORTC questionnaire.

Materials and Methods

This study was carried out in two phases. We performed a linguistic and cultural translation of the UWQOL from English to the Indian languages in Phase 1 and then prospectively validated the translated scales at Tata Memorial Hospital (Parel, India) in Phase 2.

Translation process

The translation process began with a forward translation of the original US English questionnaire into both Hindi and Marathi [Figures 1-2]. Two native Hindi and Marathi speakers with bicultural expertise (US and Indian) were used for each forward translation. After translation, a bilingual coordinator performed a review of each of the translations and, along with the translators, reached an iterative consensus. The consensus version of both the Hindi and Marathi translations were sent to new translators who performed a back translation from each of the Indian languages to English. The coordinator finally amalgamated the two English back translations into a final questionnaire that was then compared to the original English version to ensure concordance with not only the translation but also nuances in meaning.

Psychometric validation of the translated questionnaires

Study Population. We enrolled patients from the Tata Memorial Hospital who had received treatment for cancers of the head and neck. The Tata Memorial Hospital is a tertiary cancer site with the largest volume of H and N cancer in India. All participants were adult patients with thyroid and H and N squamous cell carcinoma who were presenting for preoperative

Figure 1. Hindi translation कृपण तब प्रश्नों का सड़ी प्रसर बॉक्स में दिस करके थे। यह प्ररत्मानी जायके स्वास्थ्य और क्वालिटी ऑफ लक्षप के बारे में है। हम जानना वाहते हैं कि फिल्ले ताल दिन में उतपकी लवियत केली रही। 1, 12 मुझे सिल्कुल भी वर्ष नहीं है। जल्का सा वर्ष हे पर वयाई की जलवत मही है। मुझे सोका नहें हे - निवमित सामई की प्राप्तरत हे (कोडीम का अन्य वर्ष निवारक) मुझे बहुत तेज यहे है जो किये नारकोटिक से कंट्रोज में आता है। मुझे बहुत तेज वर्द हे जो जिसी मारखोटिक से कंट्रोज में नहीं आता है। 1.22 मेरे प्राप्ती तथा में खोई प्रचलाय नहीं है। मेरे बलनी रूप का बदलाव बहुत ही जांतिक है। गुझे अपना बाहरी रूप का बगलांग परेशान करता है पर मैं जाता रहता है। मुझे अपना साथ खडित लगता है और इससिर में आपना काम करत सीमित साथ से कलाग है। में अपने बांहरी जम के कारण लोगों के साम नहीं रह रजसा। एहिलपिटी/कार्यसीलवा में जलना ही एक्टिक हैं, जिलना पहले था। कभी ऐसा जोता है जब में प्रवयं पीचे पहिल्क गहीं होता. पर ऐसा कम होता है। में अजसन थया जाता हूँ और अपनी कार्यलेंजी को सम करता हूँ पर फिन भी में बाहर जाता है। में। बाहर नहीं जाता क्योंकि मुझमें ताबना नहीं है। में अवसर सेतल हूँ या कुली पर बेवला हूँ और घर के बाहर नहीं जाता। मनोरालन चार या साहर मुझे मनोरंपान के हर हाथ में गणा आता है। कुछ भीजें ऐसी है जो में कर नहीं सकता पर बिर भी बाहर जाकर जीवन में मजा लेता अकार में पालता हूँ कि में अधिक साहर का रुद्धे पर में कर नहीं पाला। मेरे हर बाम में मुझे अनेक बाध आदी है तो मैं अक्सर घर में स्ट्रकर टीवी देखता हूँ। में कुछ भी ऐसा नहीं कर पाला जिसमें मुझे माला आये। 1. States : में पहले पीसे निगल सकता है। में कुछ लोलिक खाना नहीं का पता। में सिर्फ तपाल बाने के प्रदार्थ निगल लकता है। में बिलकुल गिगल नहीं सकता वयोंकि यो माला तर चला जाता है और मैं चोक हो जाता है। 0. 114771 में पहले जेतो मधा लावला हूँ। में सॉफ्ट सोशिक खाना तबा सकता हूँ पर हर तरह का खाना नहीं तथा सकता । में लॉपर सेलिव व्यमा भी नहीं बच्च सकता हूँ। दीलवास : गेरी बोठासाठा महत्वे की तरब है। मुझे कुछ शब्द कहने में तकलीक होती है पर लोग मुझे फोन पर समझ लेते हैं। तिकं मेरे महिवार और मित्र मेरी बाल्वील तमझते हैं। मुझे कोई भी फिल्कुल नहीं समझ पाला। 8. 東町 गुझे उसने करों में कोई तकलीश नहीं है। मेरा कथा बोवा कवा है पर इससे मेरे वाम जाव या शकित में बोर्ड प्रके नहीं घटा है। कये में नर्ग वा समजोरी के सारण मुझे उपना काम बनलमा पढा है। में क्रमें की लकानीय के कारण कोई काल नहीं कर पता । साव मुझे खाने का त्यात नार्मल उरला है। ण्यादालर खाने की चीजों का त्याद नामेंस आत है। में कुछ भीजे का त्याद पाला हूँ। मुझे व्याने का स्वाद नहीं प्रता चलता । 10. 118 गेरे युक्त का राखायन नामेल है। मेरे मुँह में कम शुक है पर वी मामेल है। गेरे गुँह ने बहुत कम मूक है। गेरा मुँह एकश्म सुखा है। 11. HPL Rafft मेरी मन्द्र लिपछि उत्तम लया मेरे केंत्रल से तप्रभावित है।

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evaluation. Subjects were required to speak and read Hindi or Marathi. Patients were recruited between January and April 2005.

Data Collection. Enrollees (n=147) were given a packet of self-administered questionnaires during a routine preoperative consultation. The packet included translated versions of the UWQOL and EORTC H and N35. Patients were asked to complete this packet preoperatively, 15 days postoperatively and then three months postoperatively. An additional cohort of patients (n=35) were asked to return a second UW-QOL within 710 days, which was returned by mail, in order to evaluate the test-retest reliability of the scale. This interval was chosen because enough time had elapsed to prevent patients from remembering their जनन महय नतेवाईबोन व मिक-वींग्लीन में बेलतेते माजले.
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Figure 2: Marathi translation

responses to the first administration of the scale, but not enough time to allow clinically meaningful change to have occurred in the interim. Patients did not receive remuneration. The medical records of these patients were abstracted to obtain data on demographics, cancer site, stage and treatment.

Scoring of UWQOL and EORTC H and N35

Each item (question) on the UWQOL (version 4) is scored from 0 to 100. A higher score is indicative of better quality of life. A 'composite' score is obtained by calculating the mean of the 12 items. There are also 3 'global' questions which are analyzed separately.

Individual items on the EORTC H and N35 module were also scored from 0 to 100. A higher score on functional scale indicates higher QOL while a higher score on symptom scale indicates worst QOL.

Data analysis

Reliability was established by measuring both internal consistency (Cronbach's alpha) and test-retest reliability (intraclass correlation coefficient). Internal consistency is considered good if alpha approximates 0.70 but does not exceed 0.90, because values over 0.90 imply the presence of redundant items.^[7] Test-retest reliability was measured with the intraclass correlation coefficient (ICC), which is more rigorous than Pearson's correlation coefficient r because it considers not just the strength of the correlation but also systematic variations.^[8]

The 'validity' of a scale depends on whether the scale truly measures what it purports to measure. Three forms of validity-content, criterion and construct-are typically sought. Content validity has been ensured by the translation process, as the authors have made sure that the translated scale touches on issues relevant to an Indian H and N population. Criterion validity asks whether the scale compares favorably to a gold standard, but this is typically less relevant in quality of life research since there is no "gold standard" measure of QOL. Construct validity therefore receives the bulk of attention. One popular method for establishing construct validity is to compare the scale's scores against other variables ('concurrent validity'). For example, one might theorize that scores should be worse in patients with advanced stage disease. In this study, we evaluated the relationship of UWQOL composite scores with: Tstage, global UWQOL scores and relevant EORTC H and NQ35 subscales.

Finally, we evaluated the transition scores (difference between preoperative and postoperative) scores, theorizing that patients with operations involving the mucosa (as opposed to neck and thyroid procedures) experience the greatest diminishments in QOL. We also calculated sought to evaluate the magnitude of transition scores, to evaluate the sensitivity of the translated scales to clinically important change.^[9] All statistical analyses were performed using with Stata for Windows (Version 8.2, College Station, Texas, USA).

Results

The UWQOL was successfully translated into both Hindi and Marathi [Figures 1, 2]. Of the 147 patients who participated in the validation phase, 86 completed the Hindi version and 61 completed the Marathi version. The mean age of participants was 50.5, with the majority of patients being male (74.5%). Other baseline characteristics of our cohort are summarized in Table 1. We note that a greater percentage of patients completing the Hindi questionnaires were male and had tumors of the oral tongue and pyriform sinus.

Table 1: Patient	characteristics	(validity phase)
Variable	Marathi n=61	Hindi n=86
Age		
<50	28	42
50–60	14	32
61–70	15	9
>70	4	3
Gender		
Male	39	70
Female	22	16
T Stage		
1	7	10
2	20	31
3	16	26
4	16	16
Unknown	2	0
Site		
Squamous cell		
Buccal mucosa	18	18
Alveolar ridge	15	13
Oral tongue	8	21
Pyriform sinus	3	10
Glottis	2	2
Supraglottis	2	2
Retromolar trigone	1	5
Soft palate	1	1
Lip	0	1
Other	3	3
Thyroid	6	8
Salivary gland	2	2

Both the Hindi and Marathi translations had strong internal consistency (Cronbach's alpha=0.7971 and 0.7839, respectively, using data collected before surgery). Test-retest reliability was also excellent (ICC=0.9069 for Marathi; 0.8964 for Hindi); the raw data are shown in Figure 3.

There was also strong evidence of construct validity. UWQOL composite scores correlated very well with the global question on overall QOL in both the Hindi (r=0.69) and Marathi (r=0.66) translations. There was strong relationship between the composite and global scores, with better composite scores associated with better global scores, as expected [Figures 4, 5]. UW-QOL composite scores also correlated with T-stage, with patients with early stage disease having better composite scores both preoperatively and postoperatively [Figures 6-9]. As expected, QOL scores are worse three months



Figure 3: Test-retest data for both Marathi and Hindi patients. Composite scores from the first administration of the UW-QOL are plotted along the y-axis; composite scores from the second administration are plotted along the x-axis. Scores along the y=x line would suggest perfect correlation



Figure 4: Graphic representation of the association 3 months after surgery between the Marathi composite score and the global question on overall QOL (r=0.6630, *P*<0.0000)



Figure 5: Graphic representation of the association 3 months after surgery between the Hindi composite score and the global question on overall QOL (r=0.6921, *P*<0.0000)



Figure 6: Graphic representation of the association between the Marathi composite score at baseline before surgery and T stage (Prob > |t| = 0.1026)



Figure 7: Graphic representation of the association between the Marathi composite score 3 months after surgery and T stage (Prob > |t| = 0.0024)



Figure 8: Graphic representation of the association between the Hindi composite score at baseline before surgery and T stage (Prob > |t| = 0.0393)



Figure 9: Graphic representation of the association between the Hindi composite score 3 months after surgery and T stage (Prob > |t| = 0.0063)

after surgery than preoperatively, since the recovery time for surgical patients usually requires one year.^[10]

Because no composite score from the EORTC H and N35 is calculated, only comparisons between relevant domains between the UWQOL and the H and N35 are relevant [Table 2]. In general, strong correlations were observed (r>0.50) between all similar domains, including pain, swallowing, speech and saliva items on the UWQOL. The only exception was with the saliva item on the Marathi translation, where r<0.50, but *P* values were still statistically significant.

Both translated versions were also sensitive to clinically important change, such as an operation in the head and neck region. The effect size of the change score was 0.68 in the Marathi population and 0.70 with the Hindi population. For reference, an effect size of 0.5

Table 2	: Correlations	between	item	specific	University	of	Washington	quality	of li	fe scores	and	EORTC
HNQ35	subscales 3	months a	fter s	urgery.								

EORTC subscales						
UWQOL Item	Pain	Swallowing	Speech	Sticky	Dry mouth	
Pain	-0.6400					
	<i>P</i> <0.0001					
Swallowing		-0.7094				
		<i>P</i> <0.0001				
Speech			-0.6768			
			<i>P</i> <0.0001			
Saliva				-0.2434	-0.4112	
				<i>P</i> <0.05	<i>P</i> <0.001	
		Marat	hi data			
		EORTC :	subscales			
UWQOL	Pain	Swallowing	Speech	Sticky	Dry mouth	
Item				Saliva		
Pain	0.6172					
	<i>P</i> <0.0001					
Swallowing		0.7294				
		<i>P</i> <0.0001				
Speech			0.5832			
			<i>P</i> <0.0001			
Saliva				0.5086	0.5470	
				<i>P</i> <0.0001	<i>P</i> <0.0001	
Hindi data						

is considered representative of moderate change and an effect size of 0.8 is considered large.^[11] By excluding thyroid and salivary tumors (since the UWQOL is aimed at patients with squamous carcinoma of the H and N), the effect sizes are even larger (0.81 and 0.73, for Marathi and Hindi patients, respectively). We also found that greater decrements were observed for patients undergoing surgery that violated the mucosa, as expected [Table 3].

Discussion

Disease specific health status scales not only an important tool that help to monitor an individual patient's health status after treatment, but also are

 Table 3: Effect size of change in composite
 scores (difference between scores before

 surgery and 3 months after surgery), by type
 of surgery

Type of surgery	Marathi	Hindi
All patients	0.68	0.70
Violation of mucosa	0.87	0.76
No violation	0.31	0.36

useful to elucidate important differences in QOL for within and between diverse populations. In this study, we have successfully translated the UWQOL into Hindi and Marathi and have separately validated these scales in Indian head and neck patients.

The resulting scales maintain the brevity of the original UWQOL scale. The design of the scale enabled easy administration and resulted in little burden on our patients. We are also encouraged by the scale's performance, since it not only appears to appropriately measure QOL in our patient population, but also seems to be sensitive to clinically meaningful change.

Limitations

We have tested the translated scales on patients seen exclusively at the Tata Memorial Hospital in Parel, India. Although we do not anticipate that responses from patients in the rest of India would vary systematically from ours, we do note that generalizing the rest of the Indian population requires further study. It is also important to note the small sample size used in the test-retest phase of the validation. Finally, it is also important to recognize that more data are required in order to achieve greater understanding of benchmark values for H and N patients.

Conclusions

Nonetheless, the Marathi and Hindi versions of the UWQOL appear to be valid and reliable instruments. Because of its brevity and ease of administration, we believe it can be rapidly implemented into general routine clinical practice to monitor a patient's H and N cancerspecific QOL and will be a vital tool for achieving greater insight into the short and long term QOL of our individual and collective patients. Furthermore, emerging translations of this scale into Brazilian, Portuguese,^[12] Swahili, Spanish and several Asian languages will facilitate greater understanding of how QOL differs in developing countries around the world.

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