Original Article

Cross-Cultural Adaptation and Validation of European Organization for Research and Treatment of Cancer Quality of Life Questionnaire – Oral Health 15 into Hindi Version for Cancer Patients

Neha Agrawal[1], Narinder Dev Gupta[1], Shahid Ali Siddiqui[2]

[1]Department of Periodontia and Community Dentistry, Dr. Z. A. Dental College, Aligarh Muslim University, Aligarh, Uttar Pradesh, [2]Department of Radiation Oncology, Mahatma Gandhi Medical College and Hospital, Jaipur, Rajasthan, India.

ABSTRACT

Objectives: The multidimensional concept of quality of life (QoL) has become vital in cancer care, and research and is crucial for epidemiological investigations. The primary objective of the research was to translate and culturally adapt the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – Oral Health15 (EORTC QLQ OH15) questionnaire into Hindi, assessing its reliability and validity for implementation among cancer patients of Aligarh.

Materials and Methods: This study was carried out from June 2019 to May 2021. Permissions were obtained from the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ) group for cross-cultural adaptation and translation of the Quality of Life Questionnaire-Oral Health15 (QLQ-OH15) and ethical clearance was secured from the Institutional Ethical Review Board at Aligarh Muslim University. Informed consent was provided by participating patients. The translation and cultural adaptation of the QLQ-OH15 followed an eight-phase procedure in compliance with the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire translation manual, ensuring consistency. Psychometric properties were evaluated using the Statistical Program for the Social Sciences 20, assessing content validity, convergent and discriminant validity, criterion validity, construct validity, reliability and test-retest reproducibility.

Results: The content validity ratio exceeded 0.75, with Cronbach's alpha values above 0.70 for each scale, confirming reliability. Factor analysis identified five factors: 'Pain and discomfort,' 'Information,' 'Soreness,' 'Denture' and 'Xerostomia.' Every item in every scale had its item convergent validity validated; all values were over 0.4 and there were no scaling mistakes observed. All of the items' correlation coefficients for the other scales were lower than their scales, indicating discriminant validity. There were statistically significant associations between Hindi EORTC QLQ-OH15 scores and three proxy measures: Perceived oral health ($P = 0.000$), perceived satisfaction with the mouth ($P = 0.000$) and perceived dental treatment need ($P = 0.001$).

Conclusion: The Hindi version of the QLQ-OH15 is a valid and reliable tool for assessing oral health-related quality of life in Indian cancer patients. This adaptation facilitates better symptom management and improved QoL in this population, emphasising the importance of oral health in comprehensive cancer care.

Keywords: Cancer, Oral health quality of life, Quality of life questionnaire oral health15, Validation

INTRODUCTION

As a leading cause of death globally, cancer presents a significant challenge to increasing life expectancy worldwide.[1] In 2018, the World Health Organization estimated that cancer was responsible for 9.6 million deaths, accounting for approximately 1 in 6 deaths globally. Low- and middle-income countries, like India, face greater challenges due to limited healthcare access and low health insurance coverage.[2] The GLOBOCAN 2022 data indicated 20 million new cases of cancer alongside 9.7 million deaths, with projections of 35 million new cases of cancer by 2050.[3]

Cancer patients often experience numerous and severe oral health issues, including xerostomia, altered salivary flow, taste abnormalities, caries, infections, jaw pain, mucosal

inflammation, ulceration, candidiasis and bleeding.[4,5] These complications significantly affect their quality of life (QoL), with oral complications expected in 40–70% of cancer patients due to the disease or its treatment.[6] Although well-researched in head and neck cancer patients, oral health issues are often underreported in patients with other malignancies, leading to insufficient symptom management and reduced QoL.[7]

The multifaceted concept of QoL is increasingly crucial in cancer treatment and research, encompassing the physical, mental and social impacts of cancer therapy.[8] Patient-reported QoL outcomes are essential in cancer care due to the various symptoms and functional limitations patients experience, such as activity restrictions, dietary changes and altered relationships.[9] The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ)-C30 is a widely used, valid and comprehensive QoL measure for cancer patients, developed by the European Organisation for Research and Treatment of Cancer (EORTC).[9-11] The quality of life questionnaire oral health15 (QLQ-OH15) module, used alongside the core QLQ-C30, focuses on oral health issues affecting QoL in cancer patients.[12]

Adapting existing tools culturally, rather than creating new ones, offers numerous advantages, such as standardsed measures and cross-cultural comparability.[10] In India, the cross-cultural adaptation of the EORTC QLQ-OH-15 has not yet been undertaken, highlighting the need for this research to translate and adapt the questionnaire into Hindi, ensuring its reliability and validity for Indian cancer patients.

MATERIALS AND METHODS

The cross-cultural adaptation and validation of the EORTC QLQ-OH-15 questionnaire were conducted among patients with heterogeneous cancer at the Radiotherapy Department, J Awaharlal Nehru Medical College, Faculty of Medicine, Aligarh Muslim University, Aligarh, India, from June 2019 to May 2021. Permission for adaptation and translation was obtained from the EORTC QLQ group, and ethical clearance was obtained from the Institutional Ethical Review Board, Faculty of Medicine, Aligarh Muslim University, Aligarh. Permission was obtained from the respective authorities of the Department of Radiotherapy, Aligarh. Patients who agreed to participate in the research provided informed consent.

Inclusion criteria

Patients with a diagnosed heterogeneous sample of malignancy, patients having different types of cancer, for example, breast cancer, lung cancer, oral cancer, prostate cancer and each with unique characteristics who gave written informed consent, were either receiving radiotherapy therapy or within 3 years of finishing treatment, comprehended, were able to read and communicate in the Hindi language and were at least 18 years of age.

Exclusion criteria

Patients who are elderly (65 years of age or older) and frail, experiencing cognitive decline, individuals with psychiatric conditions, those diagnosed with cancer who have limited literacy and are unable to read or individuals unable to complete the questionnaires due to disease-related deterioration, enrolled in an oral health intervention or clinical research were excluded from the study.

Translation, adaptation process and psychometric evaluation

The study consisted
1. The translation and cross-cultural adaptation of the EORTC QLQ-OH-15 questionnaire in Hindi language.
2. Validity and reliability and psychometric evaluation.

The translation and modification procedure comprised eight phases and was carried out in compliance with the EORTC translation manual.[13]

• Step 1: Translation preparation

The EORTC translation unit (TU) authorised the translation of the form into Hindi before the commencement of the translation process. The translation documents included earlier EORTC translations from the EORTC Item Library, an English version of the EORTC QLQ-OH15 survey form and a translation review report alongside the original English version.

• Step 2: Forward translations

The English form of the EORTC QLQ-OH15 was separately translated into Hindi by two native Hindi-speaking individuals with an excellent knowledge of English. Before translation, the EORTC QLQ-OH15 questionnaire in English and a file containing a few previous translations from the EORTC Item Library were sent to them.

• Step 3: Reconciled translation

The two forward translations were merged into one by the translation coordinator. Choosing or creating the ideal translation for each item from the two forward translations is the aim of the reconciliation.

• Step 4: Back translations

The resolved translated form was separately translated into English by two people who speak English by birth. Only the reconciled translation and the back translation guidelines were sent to the two translators.

• Step 5: Back translation report

The five translation files–two forward, one reconciling and two back translations–as well as the remarks of the translation coordinator were forwarded to the EORTC TU for a thorough examination. An agreement was established with the EORTC TU following multiple cycles of conversation. The EORTC TU then produced an early version of the translation for proofreading.

• Step 6: Proofreading

A qualified proofreader received the preliminary translation

of the EORTC QLQ-OH15 from the EORTC TU for assessment. The proofreader evaluated the first translation with the original English questionnaire and then created a report outlining all the modifications and recommendations along with justifications for their necessity.

The TU produced a preliminary translation for pilot testing following a discussion of all the issues and a consensus between the proofreader and the translation coordinator.

- Step 7: Pilot testing

Native Hindi speakers undergoing active cancer therapy and meeting histological diagnosis criteria were included in the study. To ensure diverse representation, ten patients of varying ages, genders, educational backgrounds and incomes were selected using the EORTC translation manual.[13] After completing the Hindi version of the EORTC QLQ-OH15 questionnaire, each patient underwent an informal interview guided by an EORTC template. The interviewer sought feedback on question clarity and adjusted phrasing as needed. A report summarising pilot test findings and recommendations was submitted to the EORTC TU. These patients were not included in the main validation study.

- Step 8: Completion

The translation coordinator and the EORTC TU came to an agreement after multiple rounds of deliberation. After approving the finalised translation, the TU concluded the assignment.

Cultural adaptation

The cultural adaptations were conducted to prevent inconsistent translations. A pilot test involving at least five patients showed no significant comprehension issues with the current translation, leading to the retention of the final translated version.

Evaluation of psychometric properties

It is vital to test the psychometric qualities of a scale each time that it is used with a different demographic group or in a new situation. A psychometric parameter assessment of the Hindi EORTC QLQ OH-15 was conducted. Content validity, convergent and discriminant validity, criterion, construct validity and reliability, in words of consistency (internal reliability) and test-retest reproducibility (external reliability) were among the psychometric features that were studied. Three extra questions were also added to the instrument to check the criteria validity as self-perceived oral health status, satisfaction with oral health status and self-perceived oral treatment need.

Data analysis was carried out utilising the Statistical Program for the Social Sciences 20. Data normality was tested using Kolmogorov–Smirnov and Shapiro–Wilk tests. Content validity was assessed with Lawshe's Content Validity Ratio. Criteria validity was evaluated using Spearman's rank correlation coefficient. Convergent and discriminant validity were assessed by multi-trait scaling analysis. Inter-

item correlation and internal reliability were measured with Spearman's rank correlation and Cronbach's alpha, respectively. Test-retest reliability was determined using the intra-class correlation coefficient (ICC). Construct validity was analysed through exploratory factor analysis (EFA) with oblimin rotation.

RESULTS

Initially, 161 cancer patients were evaluated to see if they qualified for the trial. A total of 147 patients who fulfilled the eligibility requirements were extended an invitation to take part, and 140 of them were accepted, yielding a 95.23% response rate. Only two patients marked samvedansheelata (sensitivity) as confusing or difficult to answer. Therefore, the final version of the questionnaire was left unchanged. The raw data obtained from the study were compiled, tabulated and subjected to statistical analysis.

The data were not normally distributed, as indicated by statistically significant findings ($P < 0.01$) from the Kolmogorov–Smirnov and Shapiro–Wilk tests. As per Lawshe's 1975 study on content validity ratio, the initial items of the measure yielded agreement ratings higher than the suggested threshold of 0.75. Satisfactory internal consistency was indicated by the overall scale score of 0.75, which varied from 0.71 for soreness to 0.86 for pain and discomfort. The ICC estimates varied from 0.731 for soreness to 0.959 for pain and discomfort indicating high reliability. Details of reliability statistics are provided in Table 1.

An additional assessment of construct validity was conducted using EFA. Details of factor analysis are provided in Table 2. The sample size used for the validation was sufficient (140), as indicated by the Kayser–Meyer–Olkin measure of sampling adequacy (0.717), and Bartlett's test of sphericity showed that the correlation matrix differed from an identity matrix ($P < 0.001$), indicating the factorability of the correlation matrix. The majority of the values in the correlation matrix were more than 0.3, indicating that factor analysis was appropriate. Five factors outperformed Eigenvalue by more than one, according to the results, and 74.86% of the variation was explained collectively. To make their interpretation easier, a rotational solution was then produced, and only

Table 1: EORTC QLQ-OH15 reliability statistics.

Measures	No. of items	Cronbach's alpha	ICC (95% CI)
Pain and discomfort	6	0.86	0.959 (0.932–0.964)
Information	2	0.76	0.867 (0.821–873)
Soreness	2	0.71	0.731 (0.711–0.752)
Xerostomia	3	0.75	0.937 (0.916–0.946)

EORTC QLQ-OH15: European organization for research and treatment of cancer quality of life questionnaire-oral health15, ICC: Intraclass correlation coefficient, CI: Confidence interval

Table 2: Factor analysis.

KMO and Bartlett's test		
Kaiser–Meyer–Olkin measure of sampling adequacy		0.717
Bartlett's test of Sphericity	Approx. Chi-Square	1237.202
	Df	105
	Sig.	0.000

Entire variance elucidated							
Component	**Initial eigenvalues**			**Extraction sums of squared loadings**			**Rotation sums of squared loadings[a]**
	Total	**% of Variance**	**Cumulative %**	**Total**	**% of Variance**	**Cumulative %**	**Total**
1	5.115	34.102	34.102	5.115	34.102	34.102	4.205
2	2.132	14.214	48.316	2.132	14.214	48.316	2.601
3	1.465	9.766	58.082	1.465	9.766	58.082	2.632
4	1.274	8.496	66.578	1.274	8.496	66.578	1.308
5	1.243	8.288	74.866	1.243	8.288	74.866	3.001
6	0.840	5.600	80.467				
7	0.767	5.112	85.579				
8	0.581	3.874	89.453				
9	0.479	3.195	92.648				
10	0.303	2.019	94.667				
11	0.281	1.874	96.541				
12	0.178	1.185	97.727				
13	0.159	1.062	98.788				
14	0.122	0.811	99.599				
15	0.060	0.401	100.000				

Extraction Method: Principal Component Analysis. [a]When components are correlated, sums of squared loadings cannot be added to obtain a total variance

Pattern matrix					
EORTC QLQ-OH15	**Component**				
	1	**2**	**3**	**4**	**5**
	Pain and discomfort	**Information**	**Soreness**	**Denture**	**Xerostomia**
31EORTCQLQOH15	0.770				
32EORTCQLQOH15	0.773				
33EORTCQLQOH15			0.933		
34EORTCQLQOH15	0.820				
35EORTCQLQOH15	0.853				
36EORTCQLQOH15			0.911		
37EORTCQLQOH15					0.817
38EORTCQLQOH15					0.878
39EORTCQLQOH15	0.756				
40EORTCQLQOH15	0.768				
41EORTCQLQOH15					0.702
42EORTCQLQOH15				0.821	
43EORTCQLQOH15				0.764	
44EORTCQLQOH15		0.942			
45EORTCQLQOH15		0.954			

Extraction Method: Principal Component Analysis. Rotation Method: Oblimin with Kaiser Normalization. [a]Rotation converged in 7 iterations, KMO: Kaiser–Meyer–Olkin measure of sampling adequacy, Df: Degrees of freedom, Sig.: Significance

loading factors >0.40 were deemed significant in accordance with sample size requirements. The parameters had loaded to five factors with substantial coefficients when looking at the component matrix. Since all six items were substantially correlated with the first factor – pain and discomfort – the scale has been called the 'Pain and discomfort' scale. The 'Information' scale comprised two items entered into the second component, while the 'Soreness' scale comprised two items loaded into the third element. The 'Denture' scale comprised two components that were loaded into the fourth factor. Three parameters loaded to the fifth factor named 'Xerostomia'. The EORTC committee recommended a linear transformation for symptom scales and items, which was applied to the scores to convert them to a 0–100 scale. Greater ratings demonstrated a greater number of problems or symptoms.

All of the scaling predictions have been verified by multi-trait scaling analysis. Details of the same are provided in Table 3. Every item in every scale had its item convergent validity validated; all values were over 0.4 and there were no scaling mistakes observed. Queries Have you had gum pain? Have you experienced gum bleeding? Have you experienced dental issues? Have you experienced oral soreness? Has food and drink caused any sensitivity in your mouth? Have you had unusual tastes for food or drink? All these were connected with the subscale of pain and discomfort.

The queries have you heard anything concerning potential oral or dental issues? And how satisfied were you with the quantity of information you were given on potential oral or dental issues? Had a correlation with the subscale of information. Queries did you ever get lip sores? And do you have any history of mouth sores in the corners? Were associated with the subscale of soreness. Queries have you ever worn dentures? Do you have any history of denture fitting issues? Were associated with the subscale for dentures. Queries Has your mouth felt dry? Did you ever have sticky saliva? and Do you have any trouble consuming solid food? Had a correlation with the subscale of xerostomia. They were all statistically significant correlations.

All of the items' correlation coefficients for the other scales were lower than their own scales, indicating discriminant validity.

There were statistically significant associations between Hindi EORTC QLQ-OH15 scores and three proxy measures: Perceived oral health ($P = 0.000$), perceived satisfaction with the mouth ($P = 0.000$) and perceived dental treatment need ($P = 0.001$).

Details of criteria validity are provided in Table 4. The findings showed that oral health-related quality of life (OHRQoL) was considerably higher in patients who reported better oral well-being and were satisfied with their mouth than in patients who reported poor oral health and mouth dissatisfaction ($P < 0.01$). Individuals who felt they needed dental care had significantly lower overall OHRQoL contrasted to others who did not feel they needed any care ($P < 0.01$).

Table 3: Multi-trait scaling analysis of Hindi EORTC QLQ-OH15 subscales.

	Pain and discomfort	Information	Soreness	Denture	Xerostomia
Have you had pain in your gums?	**0.559****	0.002	0.254**	0.145	0.284**
Have you had problems with bleeding gums?	**0.505****	0.035	0.340**	0.130	0.168*
Have you had lip sores?	0.130	0.264**	0.714**	0.046	0.090
Have you had problems with your teeth?	**0.708****	0.337**	0.014	0.313**	0.145
Have you had soreness in your mouth?	**0.762****	0.268**	0.051	0.050	0.323**
Have you had sores in the corners of your mouth?	0.092	0.283**	0.800**	0.143	0.123
Have you had a dry mouth?	0.332**	0.222**	0.145	0.062	**0.816****
Have you had sticky saliva?	0.092	0.260**	0.063	0.151	**0.860****
Has eating or drinking anything caused any sensitivity in your mouth?	**0.747****	0.232**	0.160	0.082	0.230**
Have you had unusual tastes for food or beverage?	**0.761****	0.458**	0.515**	0.147	0.476**
Do you have difficulty consuming solid a meal?	0.219**	0.245**	0.257**	0.323**	**0.797****
Are you a denture user?	0.220**	0.157	0.171*	**0.353****	0.108
Have you experienced issues with a denture that is not properly-fitting?	0.242**	0.247**	0.031	**0.761****	0.108
Have you heard anything concerning potential oral or dental issues?	0.114	0.797**	0.180*	0.079	0.375**
Have you felt satisfied with the quantity of information you have been given on potential oral or dental issues?	0.164	**0.923****	0.244**	0.122	0.373**

*Correlation is significant at the 0.05 level (two-tailed). **Correlation is significant at the 0.01 level (two-tailed). EORTC QLQ-OH15: European organization for research and treatment of cancer quality of life questionnaire-oral health15. If a p-value is less than 0.05, it is flagged with one star (*). If a $P < 0.01$, it is flagged with 2 stars (**). Bold values indicate: Item own scale correlation higher than item correlation with the other scales of the area

Table 4: Evaluation of criteria validity.

	EORTC QLQ-OH15	Perceived oral health	Perceived satisfaction with mouth	Perceived dental treatment need
Correlations				
Spearman's rho				
EORTC QLQ-OH15				
Correlation coefficient	1.000	0.482**	0.369**	−0.287**
Sig. (two-tailed)	.	0.000	0.000	0.001
N	140	140	140	140
Perceived oral health				
Correlation coefficient	0.482**	1.000	0.635**	−0.351**
Sig. (two-tailed)	0.000	.	0.000	0.000
N	140	140	140	140
Perceived satisfaction with mouth				
Correlation coefficient	0.369**	0.635**	1.000	−0.407**
Sig. (two-tailed)	0.000	0.000	.	0.000
N	140	140	140	140
Perceived dental treatment need				
Correlation coefficient	−0.287**	−0.351**	−0.407**	1.000
Sig. (two-tailed)	0.001	0.000	0.000	.
N	140	140	140	140

**Correlation is significant at the 0.01 level (2-tailed). EORTC QLQ-OH15: European organization for research and treatment of cancer quality of life questionnaire-oral health15. N: Number, Sig.: Significance

DISCUSSION

Cancer prognosis traditionally relies on survival rates and disease-free life expectancy, but assessing health-related quality of life (HRQOL) is increasingly crucial, impacting work, psychological well-being and social interactions.[14,15] Cancer treatments often detrimentally affect oral health, with 40–70% of patients experiencing issues such as mucositis, dental problems and pain, which significantly affect QoL.[16,17]

In developing countries like India, HRQOL research is sparse due to literacy and poverty challenges, complicating QoL assessment. Most QoL questionnaires are not culturally adapted for India's diverse population. The EORTC QLQ-OH15 module was translated into Hindi to assess its feasibility and psychometric properties for Indian cancer patients, representing its first validation in this context. Successful validation would facilitate nationwide multicentric research, enhancing the evaluation of OHRQOL in Indian cancer patients.

Translating the validated EORTC QLQ-OH15 into Hindi was efficient and aligned with EORTC guidelines, benefiting from widespread English proficiency in India. A pilot test involving 15 patients confirmed the acceptability of the translated version, which was approved by the EORTC QoL group's translation office.[13]

Acceptance

The EORTC-QLQ-OH-15 Indian Hindi version was well-accepted and easy to comprehend, taking an average of 10 min to complete, which is longer compared to some studies (<5 min) but shorter than others.[18,19] The absence of missing data indicated that cancer patients generally accepted and understood the questionnaire.

Content validity

The EORTC QLQ-OH17 was developed to address oral health and associated QoL issues in cancer patients.[20] The QLQ-OH15, a 15-item questionnaire, demonstrated strong content validity during international field testing and in this study, with all items exceeding the content validity ratio threshold of 0.75.[12,19] Patients' positive feedback confirmed the tool's relevance and comprehensibility.

Reliability

Reliability, assessed through test-retest reliability and internal consistency (Cronbach's α), showed high reproducibility and consistency. Cronbach's alpha values ranged from 0.731 to 0.959, which is comparable to other studies.[18-20] These findings indicate the high reliability of the QLQ-OH15 subscales in the Indian cancer patient sample, supporting its use alongside EORTC QLQ-C30 for a comprehensive assessment of OHRQoL.[20]

Factor analysis

Factor analysis, particularly EFA, was employed to identify the fundamental constructs within the OHRQoL domain due to its suitability in early-scale development phases.[21,22] EFA was preferred over confirmatory factor analysis to ensure factorial integrity before formal testing. The PCA findings showed that elements loaded into the model aligned with the original instrument's design. Parameters distributed into five factors were named: 'Pain and Discomfort' (six items), 'Information' (two items), 'Soreness' (two items), 'Denture' (two items) and 'Xerostomia' (three items). This was consistent with previous research but required adapting for the specific context of Indian cancer patients.[18-20]

Scale structure and items

Initially, four scales were proposed for EORTC QLQ-OH17: Pain/discomfort, xerostomia, eating and information.[20] However, variations in factor structure were observed in studies from Persia and Sri Lanka.[19,23] In this study, one item related to dentures was excluded due to its irrelevance among participants, possibly due to socioeconomic status or distress from oral malignancy. PCA revealed substantial correlations for items within their respective factors, demonstrating a well-defined structure.[21,22]

Convergent and discriminant validity

Multi-trait scaling analysis confirmed the QLQ-OH15's convergent and discriminant validity with no scaling errors, achieving 100% item convergence and discriminance across all scales.[18-20,23] These results were consistent with previous findings, supporting the reliability of the QLQ-OH15 in the Indian context.

Correlations and independence

All correlations between QLQ-OH15 and QLQ-C30 were below 0.4, indicating their autonomy and supporting the EORTC's recommendation for their combined use to comprehensively assess OHRQoL in cancer patients.[20] This contrasted with another study that found significant correlations between QLQ-OH17 subscales and QLQ-C30 core scales.[23]

Validity of criteria

The Indian QLQ-OH15 showed excellent criteria validity, similar to Persian studies. It effectively differentiated patients based on their oral health perceptions, with those reporting healthy mouths and satisfaction displaying better OHRQoL. Previous trials did not assess criteria validity.[18-20,23]

The study is constrained by the fact that, since there is no universally accepted OHRQoL tool for cancer patients, the assessment of the concurrent validity was done using the personal perspectives of the patients.

Strengths of the study

1. The cross-cultural adaptation and validation were conducted based on well-known EORTC recommendations
2. Factorial consistency has been evaluated alongside standard psychometric validity and reliability assessments
3. The apparent clinical validity and the good feedback from the patient.

CONCLUSION

The Hindi version of the QLQ-OH15 questionnaire, adapted for use in Indian cancer patients, proves to be a valid and reliable tool for evaluating OHRQoL. It effectively captures differences in QoL among various demographic and clinical groups, highlighting its utility in clinical practice and research. The study underscores the importance of integrating QoL assessments into multidisciplinary patient care to improve therapeutic outcomes and mitigate oral side effects associated with cancer treatments. This validated tool now supports future clinical investigations and multicentric research endeavours aimed at enhancing cancer patient care in India.

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