Development and Validation of Oral Cancer Health Literacy Tool

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Abstract

Introduction: Oral health literacy is vital to the decision making process for screening, prevention and treatment of oral diseases. Although there are several tools available for assessing oral health literacy, there is none to assess oral cancer health literacy. **Aim:** To develop and validate an Oral Cancer Health Literacy Tool (OCHLT).

Materials & Methods: The study was conducted in two phases- tool development and validation among the population. The Delphi method was adopted for content development of the tool. Fifteen experts were selected based on their expertise in the field, years of experience, number of specialties etc. The categories included in the tool were 'word recognition', 'functional health literacy' and 'information methods'. A convenient sample of 140 reporting to the OPD at the Faculty of Dental Sciences, MS. Ramaiah University of Applied Sciences, Bangalore, India were selected. The data thus obtained was assessed for the for reliability, criterion validity and construct validity.

Results: There were positive correlation between OCHLT scores and proxy measures number of years of education, satisfaction with oral health status and absence of tobacco related habits (p=0.001). The intra-class correlation coefficient of OCHLT was 0.849 and the Cronbach's a was 0.79. This resulted in a tool consisting of 32 items.

Conclusion: The final tool accounts for the multi- dimensionality of oral cancer health literacy showing acceptable psychometric properties.

Key-words: *Health literacy, Delphi, Oral cancer*

Introduction

Diseases and pathological conditions related to the oral cavity are among the most prevalent health problems witnessed in populations across the globe. Apart from being the target site for a range of highly prevalent oral diseases, the oral cavity also plays a vital role in an individual's general health, being the primary gateway through which foreign matter can enter the human body. Consequentially, maintaining the health of the oral cavity becomes a crucial need that, in turn, is dependent on the degree of the individual's awareness about oral health. Oral health literacy (OHL) can hence be defined as the 'degree of an individual's capacity to obtain, process and understand basic oral health information and services needed to make appropriate health decisions' [1–3]. This ability to access and leverage oral health-related information and services serves as the most reliable indicator of oral health levels, since a high degree of OHL would correspond to a higher likelihood of good oral health being maintained. Being able to measure such an important indicator, therefore, would

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prove to be extremely valuable in assessing overall oral health levels of a given population.

There have been several methods and techniques proposed to measure the OHL levels of individuals as well as that of populations. The most reliable of them, till date, are oral health instruments/tools, which attribute quantitative values to oral health awareness levels of the respondents. A number of such tools, after conducting several studies on various populations, have been developed so far. The most widely used of them all is the Rapid Estimate of Adult Literacy in Dentistry (REALD-99) [4]; of which several variants have been subsequently developed. Other popular tools such as the Test of Functional Health Literacy in Dentistry (ToFHLiD) [5]; the Comprehensive Measure of Oral Health Knowledge (CMOHK) [6] and the Health Literacy in Dentistry (HeLD) scale [7] have also been greatly successful.

Arriving at an estimate of the respondents' OHL levels using these tools, however, depends upon testing their word recognition abilities and reading skills. In this regard, only a few tools have been developed till date that provide a comprehensive and comparable view of the respondents' overall level of oral health awareness.

Furthermore, there is a dire need for disease-specific oral health literacy assessment tools, as incorporating parameters that are based on disease-specific salient features in to a tool improves the level of its accuracy and provides better insights regarding the population.

Oral cancer is a substantial component of the global burden of cancer [8]. It affects 300,000 people worldwide annually, who constitute 2.1% of the total world population, with two-thirds of the occurrence being seen in men [9]. In India, it ranks amongst the three most common cancers and accounts for almost 40% of total cancer deaths in some areas. In most regions of the country, oral cancer is the second most common malignancy diagnosed in men and the fourth most common in women [10]. As a lack of health literacy is a potentially significant factor contributing to oral cancer among these people, it needs to be further explored. The present study, hence, was conducted to develop and validate an oral cancer literacy tool that detects and assesses poor health literacy.

Methods

Instrument Development

The Delphi method, consisting of three rounds, was used to develop the tool. The expert panel consisted of 15 members: four oral surgeons, three oral medicine specialists, four oral pathologists, two oncologists and two public health dentists. The selection of the members of the expert panel was based on their knowledge and expertise with respect to the study subject, i.e., oral cancer.

The first round began with a thorough literature search to evaluate existing data about oral cancer. An open-ended questionnaire was designed to solicit the experts for specific information related to oral cancer. Along with their responses, various oral cancer health educational materials and text types were used for generating the items. Following the first round, the tool was developed in three levels and the number of items in each level was:

1. Word recognition- 27 items

2. Functional health literacy- 6 items

3. Information methods- 5 items

The next two rounds constituted the quantitative phase, where the experts rated each item on a Likert scale to assess the level of agreement on them. In the third round, all items obtained an agreement mean value of more than 3 and the final tool thus developed, consisting of 37 items, was assessed for psychometric properties.

Participant Selection

The tool was tested on a convenience sample population reporting to the OPD at the institute. The study was conducted between May 2016 and August 2017, and was approved by the Institute's Ethics Committee. The participants included those who were aged 18 years or older and could read and write in English. A total of 140 participants took part in the study. The participants were asked to provide following details their demographic details, including sex, age, years of education, contact details, satisfaction with oral health status, tobacco-related habit and filled OCHLT. The duration for filling the tool ranged from 20 to 25 minutes. Two weeks later, 15 of the participants were contacted for a retest.

Assessment of Psychometric Properties

Content validity. The panel of experts responded to the following question for each item: "Is the skill or knowledge measured by this item 'essential', 'useful, but not essential,' or 'not necessary' to the performance of the construct?", following which the Content Validity Ratio was evaluated as proposed by Lawshe [11–13]. Five of the items had a value less than 0.49, and were hence eliminated. Upon completion of the content validation, the final OCHLT included 32 items.

Construct validity. Principal factor analysis was used to evaluate the construct validity. The Kaiser-Meyer-Olkin Measure of Sampling Adequacy determined that the patterns of the correlations are relatively compact and so factor analysis will extract distinct and reliable factors. The value of greater than 0.5 is considered as good [14]. Bartlett's Test of Sphericity tests that null hypothesis that original correlation matrix is an identity matrix. Here, it demonstrated that the correlation matrix ($p<0.001$). An Eigen value greater than 1 was used as the criterion for factor inclusion, representing the variance accounted for by each underlying factor. As for the rotation, the method used was Direct oblimin [15–17].

Criterion validity. It pertains to the evidence of a relationship between the attributes in a measurement tool with respect to its performance on some other variable that accurately measures the same phenomenon of interest [13]. Due to the lack of a gold standard for measuring oral cancer health literacy, subjective proxy measures were used to measure the criterion validity.

Data for subjective proxy measures on the years of education, satisfaction with oral health status and tobacco-related habit status were obtained.

Reliability. Cronbach's α (alpha) was used to measure the internal consistency (reliability) of the tool. Test-retest reliability was evaluated by means of intra-class correlation coefficient, using the data collected from the 15 participants.

Data were coded and analyzed using the Statistical Program for Social Sciences (SPSS) version 20.0 software.

Results

Content validity of OCHLT using Lawshe's method

According to the content validity ratio (Lawshe's method 1975); the minimum value of 0.49 was considered for the 15 panellists. Another five items from Level 1 — items numbered 1.5, 1.22, 1.23, 1.24 and 1.25 — had value less than 0.49 and, hence, were eliminated. Consequently, the final OCHLT comprised 32 items. Care was taken to include positively and negatively worded questions in the OCHLT to discourage respondent acquiescence.

Internal reliability and Test retest reliability of OCHLT

The Cronbach's alpha value of the OCHLT was 0.849. The Cronbach's alpha did not depict a significant increase upon deleting any of the items. All items were therefore retained.

Test-retest reliability was assessed using intra-class coefficient (ranged from 0.4 to 1.0), which resulted in an overall correlation of 0.79.

Criterion validity

There were statistically significant associations between the OCHLT scores and three of the proxy measures, with the former being directly associated with the number of years of education ($p=0.001$), satisfaction with oral health status ($p=0.001$) and absence of tobacco-related habits ($p=0.001$). The proxy measures with respect to the predictor and criterion variables were correlated and the strength of this positive correlation substantially supports the extent to which the instrument accurately estimates performance on each criterion.

Table 1: Pearson's correlation of OCHLT with years of education, satisfaction with oral health status and absence of tobacco related habits

Proxy measure	**r**	**P value**
Years of education	0.262	0.001
Satisfaction with oral health status	0.399	0.001
Absence of tobacco related habits	0.516	0.001
Note: Pearson Correlation was used (p<0.05- significant)		

Construct validity

Construct validity was evaluated using Principal Component Analysis. Assumptions in the correlation matrix were confirmed prior to the analysis. Table 2 demonstrates that Factor analysis of the 32 items yielded nine factors with Eigen values greater than 1 (9.151, 2.236, 2.048, 1.602, 1.394, 1.335, 1.230, 1.208 and 1.005), which explained 66.273% of the variance (28.596%, 6.987%, 6.399%, 5.005%, 4.357%, 4.172%, 3.842%, 3.775% and 3.141%, respectively). A rotated solution was then arrived at to simplify their interpretation, for which only those loading factors higher than 0.4 were considered as significant, based on the requirements of sample size.

Table 2: Item factor analysis results

Rotated loadings from the seven factor solution									
	1	2	3	4	5	6	7	8	9
Level 1.1	.872								
Level 1.2	.800								
Level 1.3	.889								
Level 1.4	.772								
Level 1.5		.527							
Level 1.6	.831								
Level 1.7		.832							
Level 1.8				.839					
Level 1.9	.598								
Level 1.10				.637					
Level 1.11								.680	
Level 1.12	.678								
Level 1.13		.413						.374	
Level 1.14	.595								
Level 1.15	.613								
Level 1.16	.853								
Level 1.17								.531	
Level 1.18								.806	
Level 1.19		.443						.516	
Level 1.20	.837								
Level 1.21						.502			

***Cont.*. Table 2: Item factor analysis results**

Level 2.1					-.804				
Level 2.2			.666						
Level 2.3			.733						
Level 2.4			.530						
Level 2.5				-.388					
Level 2.6					.452		-.414		
Level 3.1						.757			
Level 3.2		.421							.522
Level 3.3						.601			
Level 3.4							-.815		
Level 3.5									.828

Note: Kaiser-Meyer-Olkin Measure of Sampling Adequacy- 0.858
Bartlett's Test of Sphericity tests- 0.001
Rotation Method: Oblimin

Annexure- Oral Cancer Health Literacy Tool (OCHLT)

	Level 1- Word recognition		
	If you are able to read and understand the following given words, kindly tick 'Yes' in front of each word or else tick 'No'.		
	1. Smoking	Yes ☐	No ☐
	2. Habit	Yes ☐	No ☐
	3. Cigarette	Yes ☐	No ☐
	4. Beedi	Yes ☐	No ☐
	5. Betel nut	Yes ☐	No ☐
	6. Tobacco	Yes ☐	No ☐
	7. Betel quid	Yes ☐	No ☐
	8. Spicy food	Yes ☐	No ☐
	9. Alcohol	Yes ☐	No ☐
	10. Sharp teeth	Yes ☐	No ☐
	11. ill- fitting denture	Yes ☐	No ☐
	12. Risk factors	Yes ☐	No ☐
	13. Palate	Yes ☐	No ☐
	14. Mouth	Yes ☐	No ☐
	15. Ulcer	Yes ☐	No ☐
	16. Swelling	Yes ☐	No ☐
	17. Lump	Yes ☐	No ☐
	18. Hoarse voice	Yes ☐	No ☐
	19. Lymph nodes	Yes ☐	No ☐
	20. Surgery	Yes ☐	No ☐
	21. Chemotherapy	Yes ☐	No ☐

	Level 2- Functional health literacy Kindly read the following questions and tick the correct option given.
1.	"Green leafy vegetables and fruits are good for preventing oral cancer." After reading the above sentence, answer the following question. Which one of the following is the best food to prevent oral cancer? 1. Greens and apple ☐ 2. Chocolate and ice cream ☐ 3. Spicy curry ☐
2.	If you observe an ulcer in your mouth that **does not** heal for more than 2 weeks, what you should do? 1. Wait for it to heal ☐ 2. Immediately consult the Dentist ☐ 3. Buy over- the- counter medication and take it ☐

3.	Blood report The normal range for haemoglobin for a female is 12.0 to 15.5 g/dl. Jaya's haemoglobin is 9.7 g/dl. Is Jaya within the normal range? 1. Yes ☐ 2. No ☐
4.	**Patient's name:** Ramesh **Age/Sex:** 35/M **Date:** 20/09/2017 **R_x** Tab. Lycopene (anti-oxidant) for 3 weeks (0-0-1) × 20 days Doctor Ramesh has to take medicine at what time of the day? 1. Morning ☐ 2. Afternoon ☐ 3. Night ☐
5.	A tumour biopsy is done to: 1. Diagnose it ☐ 2. Treat it ☐ 3. Both ☐
6.	Chemotherapy is given to oral cancer patients to 1. Remove it ☐ 2. Diagnose it ☐ 3. Treat it ☐

	Level 3- Information methods Kindly read the following questions and tick the correct option given.
1.	Do you think TV, radio, newspapers are giving enough information about the effects of tobacco on oral health? 1. Yes ☐ 2. No ☐
2.	Do you face any difficulty in understanding the information about oral cancer provided by Doctors in hospitals/ clinics? 1. Yes ☐ 2. No ☐
3.	Do you think there are sufficient oral- cancer related patient education materials in regional languages in hospitals that you have been visiting? 1. Yes ☐ 2. No ☐
4.	Do you fill your medical forms on your own? 1. Yes ☐ 2. No ☐
5.	Do you take help from others to understand your medical prescriptions? 1. Yes ☐ 2. No ☐

Discussion

The objective of this study was to develop and validate a new instrument to measure oral cancer health literacy for adults, and to complement other functional oral health literacy instruments that are currently available. In the OCHLT, items appropriate for studying oral cancer were generated using the Delphi method [18]. One of the major advantages of the Delphi method is that all the experts had the same degree of impact on the consensus process and helped to ensure the validity of the study. The expert panel in the present study, although comprising participants with different fields of expertise, were treated as a homogenous group. In this respect, expert knowledge representing a variety of viewpoints can provide relevant inputs in the Delphi process, this can also help in minimising bias.

The OCHLT was modelled on a previously validated medical instrument which was developed to measure cancer health literacy among patients.[19] The study also used a Delphi Panel to discuss domains of health literacy to develop a psychometrically sound instrument designed to measure cancer health literacy along a continuum (CHLT-30). In China, Chinese-specific tool for paediatric nurses to assess risk of infection in oncology patients was developed using Delphi method. The authors in the study mention that the high response rate could be due to the authors' ongoing communication regarding the importance of each participant's contribution, continual reminders and a limit set at three rounds. It also reflects the experts' understanding of the importance of the study [20].

OCHLT displayed high internal consistency with a value of 0.849 indicating how well the items on a tool fit together conceptually. A coefficient alpha of 0.70 is acceptable for new scales[13]. Test retest reliability was evaluated after 2 weeks as it is the generally accepted time interval for retesting with intra class correlation value of 0.79. Similarly CHLT-30 also showed Cronbach's alpha internal consistency reliability of 0.88 and 2-week test–retest reliability of 0.90, and 6-month test–retest reliability of 0.92, all of which are indicative of a highly consistent measure of cancer health literacy[19].

In recognition of the importance of oral health literacy, the measurement of health literacy has been an area of growing research. Various types of instruments have been developed to measure oral health literacy to direct test individual's oral health literacy abilities and self-report of oral health literacy abilities. But there are no oral disease specific tools.

Considering, oral cancer as a threat, it is estimated that around 43% of cancer deaths. Low-income and disadvantaged groups are generally more exposed to avoidable risk factors such as environmental carcinogens, alcohol, infectious agents, and tobacco use. [8] Another factor that possibly contributes to oral cancer may be low levels of health literacy. This study was an attempt to develop first tool on oral cancer to assess oral cancer health literacy in adult population.

One of the limitations of the study was the convenience sampling methods that may alter the psychometric properties of the instrument in a larger, more representative sample. Secondly, this tool was designed in English language and thus limiting its applicability on rural population of India where different regional languages are used.

Conclusion

OCHLT developed using Delphi method containing 32 items shows acceptable psychometric properties. The tool accounts for the multi- dimensionality of oral cancer health literacy by encompassing the domains of Word recognition, Functional health literacy and Information methods. It appears promising in planning appropriate strategic intervention for oral cancer by all stakeholders to address this emerging public health problem.

Future Recommendations

We would like to give few recommendations, based on the results of this study. The validity of the tool should be tested on other diverse populations, different age groups and environment. The tool should be considered for cross cultural validation.

Ethical Clearance- Taken from M.S Ramaiah University of Applied Sciences Ethics committee

Source of Funding- Self

Conflict of Interest - Nil

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