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Review

Assessment of oral health-related quality of life instruments for oral submucous fibrosis: A systematic review using the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist

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ABSTRACT

Quality of life (QoL) instruments are becoming increasingly important in research and often used in clinical practice. Various QoL instruments have been developed/ validated for assessment of oral health-related QoL (OHRQoL) in patients with oral submucous fibrosis (OSF). Selection of an adequate instrument is challenging in routine practice due to lack of information on psychometric quality of measurement instruments. This systematic review gives an extensive overview of quality of all the currently available measurement instruments for use in OSF patients. PubMed, Scopus, Web of Science and CINAHL were searched for relevant literature until December 2018 and the information was extracted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The quality of the identified studies was assessed per measurement property according to the COnsensus-based Standards for the selection of health Measurements Instruments (COSMIN) checklist. Four studies that met the inclusion criteria were included. Three generic and one disease-specific QoL instruments were identified. Information regarding important measurement properties was often incomplete. The evidence for the quality of measurement instruments was found to be variable, none of the instruments performed sufficient on all measurement properties. Based on the available information, OHRQoL-OSF appeared to have adequate COSMIN measurement properties. As recently published, newer QoL instruments have not yet been evaluated in an adequate manner for use in OSF. We suggest future studies should implement OSF-specific OHRQoL-OSF to better understand OSF patients' perspectives and help inform clinicians to propose treatment strategies as per patients' needs.

Introduction

Oral submucous fibrosis (OSF) is a potentially malignant disorder of the oral mucosa [1] with malignant transformation rate of 7%–30% [2]. The prevalence of OSF has exponentially grown from 0.03 to 6.42 over the last four decades with five million cases reported in India alone [3–5]. OSF manifests as burning sensation in the mouth, frequent oral ulcerations, blanching and stiffening of the oral mucosa and oropharynx resulting in progressive limited mouth opening. Past literature demonstrated significant health-related (HR) impacts of OSF including functional limitations and psycho-social impairment resulting in worsened quality of life (QoL) in advanced stages of the disease [6–8]. Although variety of therapeutic options has been tried in the past, no promising treatment modality is available for complete relief of OSF symptoms [9]. Moreover, with its considerably high malignant potential and recent evidence of increasing trend of OSF-associated oral cancer [10], OSF is considered a disorder with significant mortality rate.

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Historically, outcome assessment of OSF patients focused mainly on the clinical assessment. In routine practice, clinicians do not always take into consideration the patient's feelings, opinions or well-being, which actually patients feels more important for them [11]. In recent years, outcome assessment has been increasingly shifting towards patients' perspectives. This patient-centred approach assesses the outcome as per patient's opinions. For this, QoL instruments that are sensitive enough to measure changes in QoL are required. Past literature exhibited a positive contribution of QoL instruments to research and clinical practice in monitoring benefits and response to treatment [12,13]. In addition, aggregate level of QoL instruments data can be helpful to identify health inequalities as well as different determinants of QoL in patients [14].

At present, variety of QoL instruments (generic and condition-specific) are available and have been used to assess the patient reported outcomes and experiences in OSF [13,15–17]. Furthermore, researchers are continuously in the process of developing new questionnaires, making it difficult for researchers and clinicians in selecting an adequate QoL instrument for use in this population. One could not obtain an optimal informative HRQoL data if an inappropriate QoL instruments are used for these patients or else the data reported may be misleading. Evidently, a QoL instrument is considered as good as the methodological quality of the studies. To date, no comprehensive review has been undertaken to systematically establish the methodological quality of the validation studies of the QoL instruments used in OSF. Here, we attempted a systematic review aimed at (i) identifying QoL instruments used in validation studies involving OSF patients and (ii) to determine their measurement properties. We hope that outcomes of this study might be helpful to provide evidence based guidance to clinicians and researchers in selecting a comprehensive QoL instrument for OSF patients.

Materials and methods

The present review was conducted by using the following guidelines: (i) the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [18] guidance (Supplementary material 1), (ii) COnsensus based Standards for the selection of health Measurement INstruments (COSMIN) guidance [19].

Search strategy

A literature search was performed from 10th to 15th December 2018 to identify all the studies on instruments to assess OHRQoL in patients with OSF.A search strategy (Supplementary material 2&3) was developed to find relevant papers. Non-validation studies were excluded. A systematic search was conducted on electronic databases including Medline through PubMed, Scopus, Web of Science and CINAHL. Initially, the search string was developed in PubMed and later adapted for other databases. Additionally, the reference lists of all relevant articles were also hand-searched.

Eligibility criteria

Eligible publications were full text articles(i) about the development or validation of a self-administered measurement instrument to assess oral health-related QoL (OHRQoL); (ii) study participants were adult OSF patients ($\geq$18 years old); (iii) studies that determined at least one measurement property of the instrument. No restriction was applied on sample size, gender of the participants, country of origin of the study, date and language of the publication. According to search protocol of Terwee et al. [20], publications including editorials and case reports were excluded.

Selection of studies

Two reviewers (SG and RB) independently screened titles and abstracts of the relevant studies for their eligibility. Full texts of all potentially eligible papers were then retrieved and assessed again independently by the same reviewers (SG and RB). Any discrepancies were resolved by discussion with third reviewer (AG/SS) and a list of the articles to be included in this review was finalized.

Data extraction

Full text articles were screened by two reviewers (SG and RB) again independently and the following predefined data were extracted from each article: measurement instrument, country and language, study population, number of patients, mode of administration, number of domains, scoring methods and recall periods used. In addition, data required to complete the COSMIN checklist assessment were also extracted.

Quality assessment

The COSMIN checklist was used to evaluate the methodological quality of the included validation studies. Two reviewers (SG and RB) independently completed the COSMIN checklist and any disagreements were resolved by discussion with the third reviewer (AG/SS). The checklist covers nine measurement properties: internal consistency, reliability, measurement error, content validity, construct validity, criterion validity, hypothesis testing, structural validity and responsiveness. Interpretability is not a measurement property but is a meaningful requisite for the applicability of instruments in research. Each measurement property was scored as per the quality of reporting by the studies and rated as 'excellent', 'good', 'fair' or 'poor'. An overall score of each study is then determined by the 'worst score counts' method.

For each measurement instrument, the psychometric results was determined as per the criteria proposed by Terwee et al. [21] and ranked as '+' positive, '?' indeterminate or '−' negative.

Results

Study selection

Sixty seven articles were retrieved from the electronic databases (PubMed/Medline: 28, Scopus: 26, CINAHL: 10 and Web of Science: 3) and no results were found from manual searching. Subsequent to elimination of duplicates only 10 titles remained for screening. The titles and abstracts of these articles were reviewed in depth for their eligibility by two researchers (SG and RB). Consequently, seven articles were suitable for full text assessment, of which, three articles were excluded because of non-validation study and review articles. Finally, four papers [12,16,17,22] that met the selection criteria were included in the present systematic review (Fig. 1). Assessment of references of these four articles did not provide any extra applicable studies.

Study characteristics

The studies presented in this review had between 100 and 362 participants (a total of 776 participants) and all the patients were adults. All the studies included OSF patients only except for one by Tadakmadla et al. who had included patients with OSF along with patients with oral leukoplakia, oral lichen planus and healthy individuals (n = 150). Across studies, the mean age of the participants reported was between 31.51 ± 7.4 and 37.8 ± 10.2 years. These studies included a proportion of males ranged from 62% to 87.2%. Among four, only one study by Gondivkar et al. had categorized OSF participants into grade I to grade IV disease severity. Sansare et al. used

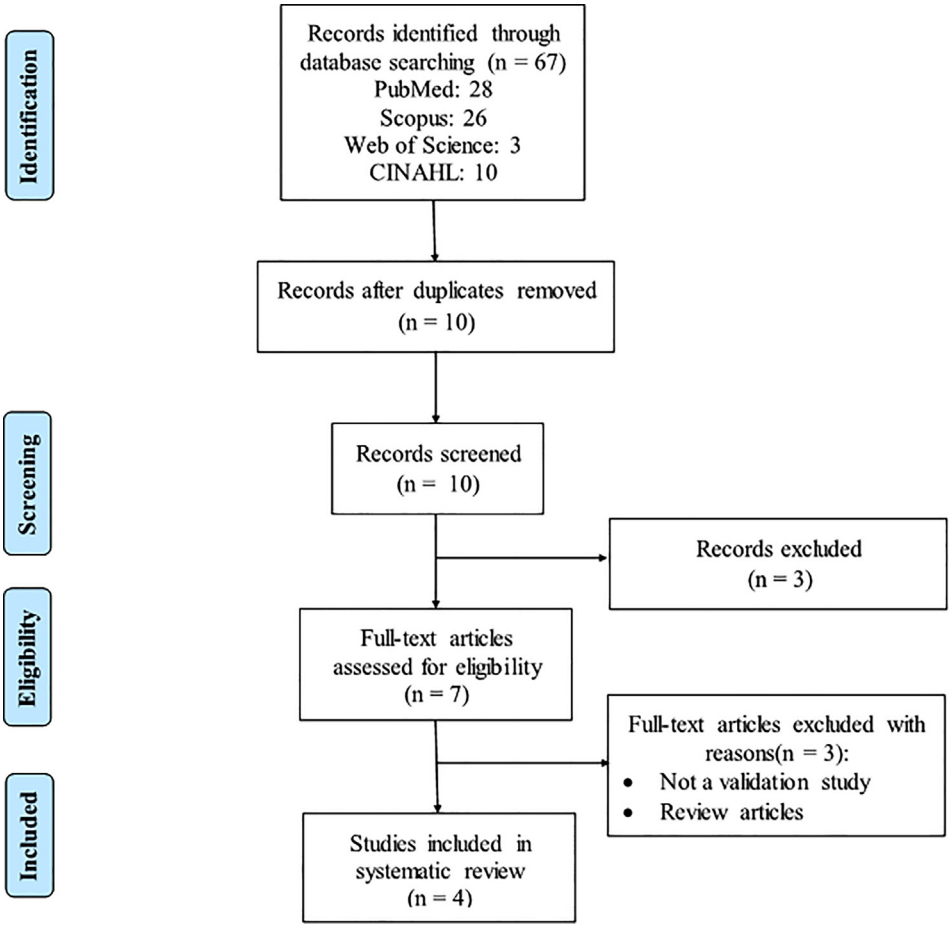

Figure 1. PRISMA flowchart showing flow of information.

inter-incisal mouth opening measurement for discriminant analysis.

OHRQoL measurement instruments

An overview of the characteristics of all the included measurement instruments is presented in Table 1. We identified four measurement instruments which were originally developed/validated in OSF patients between 2015 (Nepalese OHIP-14) and 2018 (OHRQoL-OSF and COMDQ). Across 4 measurement instruments, three were generic instruments (Nepalese OHIP-14, OPMDQoL and COMDQ) and only one was OSF-specific (OHRQoL-OSF). The measurement instruments contained 14 (OHIP-14) to 26 (COMDQ) items and 4 (OHRQoL-OSF) to 7 (OHIP-14) HRQoL domains. All four measurement instruments used the scoring method in the form of total scores and subscale scores. The target population of the three measurement instruments were patients with OSF in specific whereas one instrument focused on the patients with oral submucous fibrosis, oral leukoplakia and oral lichen planus. The measurement instruments presented in this review had varying recall periods ranging from four weeks (OPMDQoL) to 1 year (OHIP-14). The completion time of only OHIP-14 was reported (15–20 min).

Measurement properties/psychometric properties

Table 2 presents an overview of the measurement properties for all the measurement instruments. All studies reported clear information about the content validity of the instruments. Among 4, two of the instruments (OHRQoL-OSF and OPMDQoL) undertaken a mix of previous available literature, clinical experts in the concerned field and patients, and cognitive or pilot testing of items for content validity. Thus, content validity was rated positive for OHRQoL-OSF because of an extensive development process that started with patient interviews and focus group discussions. As OPMDQoL involved patients with OSF, oral leukoplakia and oral lichen planus, the content validity was rated as indeterminate. Other two instruments (Nepalese OHIP-14 and COMDQ) assessed content validity using forward and backward translation technique by experts and pilot testing. As both these studies were validation studies and not enough information provided regarding comprehensiveness of the instruments, content validity was rated indeterminate. Majority of the studies reported information about construct validity but relatively inadequate than other measurement properties. Exploratory or confirmatory factor analysis was performed to assess structural validity. All the studies reported correlation of studied instrument with other previously validated instrument (convergent validity) measuring the same construct except for one study in which Rimal et al. assessed construct validity of Nepalese OHIP-14 by comparing scores with self-perceived oral health status, self-perceived dental treatment need and satisfaction with oral health status. Additionally, sample size was inadequate and thus rated indeterminate. None of the study has performed Rasch analysis.

Internal consistency of the measurement instrument was usually presented as Cronbach's α. Three of the four studies reported acceptable Cronbach's α for the overall scales and domains (subscales) and rated positive. However, Rimal et al. did not report Cronbach's α for the domains and therefore, rated indeterminate. Two of the four included studies reported test-retest reliability with excellent intra-class correlation coefficient [17,22]. Both these studies administered measurement instruments twice separately at 15 days interval. Therefore, reliability for the instruments were rated positive. However, Rimal et al. [12] and Sansare et al. [16] did not present test-retest reliability and thus rated indeterminate.

Table 1
Overview of the included studies.

Sr. no.	Questionnaire	Acronym	Mode of administration	Country/ language	Purpose of the measurement	HRQoL domains	Year of development/ validation	Target population	Number of items	Scoring method	Recall period	Completion time
1.	Oral Health Impact Profile- 14 (Nepalese version)	OHIP-14	Self-administered	Nepal/ Nepalese	Oral Health Related Quality of Life	FL PP PSD PD PSD SD H	2015	Patients with OSF	14	Subscale and total scores	1 year	15–20 min
2.	Oral Potentially Malignant Disorders Quality of Life	OPMDQoL	Self-administered	India/Telugu	Oral Health Related Quality of Life	DD PFL PSB TRE	2017	Patients with OL, OSF, OLP and healthy individuals	19	Subscale and total scores	4 weeks	NR
3.	Oral Health Related Quality of Life-Oral Submucous Fibrosis	OHRQoL-OSF	Self-administered	India/ Marathi	Oral Health Related Quality of Life	DFI PSCW SW PW	2018	Patients with OSF	17	Subscale and total scores	6 months	NR
4.	Chronic Oral Mucosal Disorders Questionnaire	COMDQ	Self-administered	India/ Marathi & Hindi	Oral Health Related Quality of Life	PF MT SE PS	2018	Patients with OSF	26	Subscale and total scores	NR	NR

OHIP-14: FL: Functional limitation, PP: Physical pain, PSD: Psychological discomfort, PD: Physical disability, PSD: Psychological disability, SH: Social handicap, H: Handicap.
OPMDQoL: DD: Difficulties with diagnosis, PFL: Physical and functional limitation, PSB: Psychological and social wellbeing, TRE: Effect of treatment on daily life.
OHRQoL-OSF: DFI: Discomfort and functional impairment, PSCW: Psychological wellness, SW: Social wellness, PW: Physical wellness.
COMDQ: PF: Pain and function limitation, MT: Medication and treatment, SE: Social and emotional, PS: Patient support.
HRQoL: Health-related quality of life; OSF: Oral submucous fibrosis; NR: Not reported.

Table 2
Rating of measurement properties of the instruments.

Sr. no.	Author	Measurement instrument	Measurement instrument	Population	Sample size	Content validity	Construct validity	Internal consistency	Reliability	Absolute measurement error	Responsiveness	Interpretability
	Rimal J & Shrestha A	OHIP-14	OHIP-14	Patients with OSF	124	?	?	?	?	NR	+	+
	Tadakmadla J et al.	OPMDQoL	OPMDQoL	Patients with OL, OSF, OLP and healthy individuals	362	?	?	+	+	NR	NR	+
	Gondivkar SM et al.	OHRQoL-OSF	OHRQoL-OSF	Patients with OSF	190	+	+	+	+	NR	NR	+
	Sansare K et al.	COMDQ	COMDQ	Patients with OSF	100	?	+	+	?	NR	NR	+

NR: Not reported.

Responsiveness was reported only in one study with evidence for positive responsiveness for Nepalese OHIP-14 scale. But the authors did not report pre-treatment and post-treatment subscale scores. Furthermore, none of the studies reported information about the measurement error. Considering the available information, OHRQoL-OSF showed good content and construct validity and the instrument is reliable. The OPMDQoL also appeared to have adequate psychometric properties because of its good internal consistency and reliability. Other instruments had reasonable measurement properties.

Discussion

Over last decades, scientific community has increasingly recognized the importance of HRQoL using QoL measures [23]. Although our previous literature identified numerous instruments studied in OSF population [15], the information on their measurement properties was lacking. Thus, there was an urgent need of evaluating measurement properties of available instruments to help inform the most suitable tool in future research and clinical practice.

The present systematic review identified 3 generic and 1 disease-specific self-administered OHRQoL measurement instruments for use in OSF population. None of the included studies reported adequate information on all the measurement properties of the instruments studied as per the COSMIN criteria. Notably, two among the included studies did not even evaluate the basic measurement properties including construct validity and reliability. Majority of the studies have not assessed responsiveness; even though it is of great help to monitor treatment responses as well as patients' opinions over time. Considering the results of this review, OHRQoL-OSF could currently be a promising tool for use in OSF population. Although OPMDQoL appears to be suitable for OSF patients, this generic instrument is bit extensive and was developed by considering oral potentially malignant disorders including OSF, oral leukoplakia and oral lichen planus.

The development of OHRQoL-OSF and OPMDQoL involved patients and subject experts in the concerned field. Moreover, these instruments were pilot tested for the comprehensiveness and intelligibility in patients' native language, assuring completeness and inclusion of relevant items for OSF patients, particularly in OHRQoL-OSF. As the instrument was intended for use in patients with oral potentially malignant disorders, OPMDQoL included additional items, many of which are not related to OSF. Both these studies have performed factor analysis, provided subscale structures and reported outcomes per subscale. Therefore, the evidence for internal consistency was rated as strong in both these studies. In addition, correlation with other available relevant OHRQoL instruments was performed by incorporating adequate sample size. Thus, utilization of the good methodological quality in the study resulted in moderate evidence for content and construct validity of OHRQoL-OSF, and limited for OPMDQoL.

Since accurate and reproducible measurements are pre-requisites for an adequate instrument, an acceptable reliability is essential. The present review noticed that reliability was determined for OHRQoL-OSF and OPMDQoL and not for other instruments. For OHRQoL-OSF, there is moderate evidence supporting good reliability. The present study demonstrated that 75% of the included studies intended to quantify the disease burden and its impact using constructs such as HRQoL and severity of symptoms. Only one study evaluated efficacy of treatment provided. The Nepalese OHIP-14 showed moderate evidence for good responsiveness. As responsiveness was never assessed in other studies, there is lack in evidence. We believe that this is worrisome finding of the present review because QoL tools are frequently used in clinical practice and therapeutic researches as an indicator of quality of care. Thus, these studies should be further validated to strengthen these findings. The observations of the present study do not mean that these QoL instruments presented herein have poor measurement properties and thus are of poor quality. Other medical fields also showed lack of adequate assessment of all measurement properties in good

methodological studies [24–26].

It is always helpful to use QoL instrument as an outcome measure along with traditional methods for better understanding of patients' needs and care. Selecting an instrument among currently available generic and disease-specific measures depends on choice of the clinician/researcher. It has been recommended that psychometric properties of the measure should be considered while selection [27]. The present review exhibited that generic instruments such as OHIP-14 and COMDQ are used even though these tools are not formally validated in OSF population. Both these generic measures are established internationally with numerous non-OSF researches and accepted as being valid, reliable and applicable to a variety of oral health disparities. Although these instruments may be useful to measure burden of OSF, they may lack sensitivity in identifying OSF-specific problems; resulting in misleading outcomes. The use of disease-specific OHRQoL-OSF will provide more detailed assessment of OSF-associated symptoms such as limited mouth opening, burning sensation, frequent oral ulcerations, dryness of mouth etc., and their impacts on QoL of patients. Furthermore, OHRQoL-OSF will be better tool to identify disease severity and may inform management protocol and patient support in OSF [28]. Since OSF-specific OHRQoL-OSF have been recently developed, it have not been used in research. The present review found more support for OHRQoL-OSF as it has scored more favourably using COSMIN.

Strengths and limitations

The present study has certain strengths and limitations. To the best of our knowledge, this is the first of its kind study that has used the PRISMA and COSMIN guidelines to assess the methodological quality of the validation studies of the QoL instruments for OSF. As recommended by COSMIN group, two independent reviewers have assessed the quality of each study with the help of third reviewer in cases of disagreement. Furthermore, this review included studies in which the target population of the instrument was focused at OSF population. The relevant articles were searched in multiple electronic databases without any restrictions of time and language; minimizing chances of missing any relevant papers. Although we have used broad search strategy, we could find only four relevant studies, demonstrating a lack of literature on this topic. There is a possibility of publication bias as in all systematic reviews. The validation studies with negative results may have never been published. It may be possible that some validation studies have been conducted properly but are not described well enough as per COSMIN criteria, affecting their quality ratings. As few included studies are very recently published, the instruments have not been used in research for evaluation of measurement properties across various cultural and language contexts.

Conclusion

The present study identified three generic and one disease-specific validated QoL instruments that quantify OHRQoL in OSF patients. Considering the results of this study and being disease-specific, OHRQoL-OSF appeared to be a promising new instrument for OHRQoL assessment in this population. The OPMDQoL also come into consideration to measure the disease burden as like other generic instruments. However, further validation studies are required to fill the evidence gaps of the measurement properties of these instruments. The present study provided improved clarity about the quality of currently available OHRQoL instruments. As recently published newer QoL instruments for use in OSF may not be perceived adequately by the scientific community, we recommend that future research should implement OSF-specific OHRQoL-OSF for detailed assessment of patients' perspectives in order to gain comprehensive information. We strongly believe that selecting an adequate and comprehensive QoL instrument will definitely help inform health care professionals for upgrading the clinical outcomes, care and support that OSF patients expects.

Conflict of interest statement

All authors declare that they do not have any conflicts of interest.

Source of funding

None.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.oraloncology.2019.04.009.

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