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Utility of two oral health-related quality-of-life measures in patients with xerostomia

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Abstract – *Objectives:* The study compared the validity of the short form of the Oral Health Impact Profile (OHIP) and Oral Impacts on Daily Performance (OIDP) as measures of oral health-related quality of life in patients with xerostomia in the UK. *Methods:* A cross-sectional comparison of OHIP14 and OIDP with measures of clinical indicators, xerostomia symptom status, speech function, global oral health ratings and psychological well-being, in 85 patients attending outpatient clinics. *Results:* Both OHIP14 and OIDP had excellent internal reliability, and good criterion and construct validity when used in this population of xerostomia patients. In regression analyses, salivary gland condition and xerostomia symptom status significantly predicted oral health-related quality of life (OHRQoL), accounting for 29% and 14% of the variance in OHIP and OIDP scores respectively. In turn, OHRQoL predicted global ratings of oral health (26% of variance) and psychological well-being (depression) scores (15%). Sex, ethnicity and age were associated with clinical presentation and patient-reported symptoms. Clinical presentation, OHRQoL (as measured by the OIDP) and speech function were related to duration of symptoms. *Conclusion:* Both OHIP14 and OIDP have good psychometric properties and appear useful measures of OHRQoL in xerostomia. Overall, the OHIP14 performed better than did OIDP. For both measures, the additive scoring method may be more relevant for this population that the number of impacts.

Key words: oral health; quality of life; validity; well-being; xerostomia

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Xerostomia, or dry mouth, is a common chronic condition affecting one-quarter of adults and 40% of elderly people (1). The commonest cause of xerostomia, in developed countries, is the side effects of therapeutic drugs. Over 400 prescribed drugs cause xerostomia, particularly antidepressants, antihypertensives and antihistamines. Few appropriate alternative drugs are available, and many of these have other side effects. Xerostomia and hyposalivation are also seen as sequelae of damage to salivary glands in autoimmune (rheumatoid arthritis, Sjögren's syndrome, systemic lupus erythematosis) and other systemic diseases (multiple sclerosis and Alzheimer's disease) (2); and as a consequence of radiation for treatment of head and neck cancer. Symptoms of dryness include cracked lips and unquenchable thirst. Severe cases can present with soreness and a burning sensation, and reduced ability to speak, chew, swallow, taste and sleep (3, 4). Persistent dryness can lead to oral candidiasis, and an increased risk for caries and gingivitis (5).

In the absence of a curative treatment for xerostomia, the overriding therapeutic goal is long-term management. For such conditions, where treatment is not about cure but increasing patient comfort, there is a strong case for understanding the impact of the conditions on patients' everyday lives (6). To date, a number of oral health-related quality-of-life measures (OHRQoL) have been developed which explore the impact of oral health and disease on daily functioning (7). These

measures are predominately generic; that is, they are intended to assess OHRQoL across a range of different oral health conditions. Consequently, when such measures are employed to assess outcomes of a particular condition or disease, their reliability and validity may be reduced (8, 9). Yet, to date, there has been minimal research utilising OHRQoL measures in clinical settings with particular patient populations; instead, such measures have largely been employed in general or primary care population surveys.

Previous research in xerostomia has been predominately clinical in nature, focussed on the aetiology and management of the condition (4). Only a handful of studies have supplemented such clinical data with patient-reported measures of quality of life (10–12). The results indicated that, compared with healthy volunteers, patients with xerostomia had a reduced quality of life. However, all studies focussed on xerostomia in only one specific patient group – those with chronic autoimmune disorders, primary and secondary Sjögren's syndrome – and utilised generic as opposed to OHRQoL measures. The impact of primary and secondary Sjögren's syndrome is likely to be mediated by the extraglandular manifestations of the autoimmune disorder, e.g. arthritis, mylagia rather than oral symptoms, thus generalisation from this patient group to a wider xerostomia population including those with drug-induced xerostomia may be problematic. The one study to employ a specific oral health-related measure (OHIP49), again with a population of (southern Chinese) Sjögren's syndrome patients, found that their OHIP summary scores did not differ significantly from that of a control group. Given that the study did find group differences on the disease-specific dry mouth measure, the authors questioned the sensitivity of OHRQoL measures such as OHIP for this population (13).

The aim of the present study was to assess the performance of two OHRQoL measures: the abbreviated 14-item Oral Health Impact Profile (OHIP14) (14) and Oral Impacts on Daily Performance (OIDP) (15) in a sample of patients exhibiting xerostomia in the UK. These measures were chosen as both are theoretically derived (16), and both have been validated in the UK; OHIP14 (9, 17) and OIDP (15, 17). In addition, the OHIP is the most comprehensively used and well-known OHRQoL measure, and was used in the one previous study of OHRQoL in xerostomia. We compared the internal consistency, and criterion and construct validity of the OHIP14 and OIDP by assessing their relationships with relevant clinical variables, as well as patients' perceptions of their symptom status, global oral health ratings and psychological well-being.

Methods

Participants

The data were collected as baseline measures in a randomized control trial of reservoir bite-guards in the management of xerostomia (18). Inclusion criteria for participation were: (i) one or more symptoms of xerostomia from the European screening questionnaire (19), and (ii) whole unstimulated salivary flow <0.2 ml/min, which encompassed those with symptomatic xerostomia and secondary Sjögren's syndrome. Participants meeting the above criteria but who had: (i) clinical evidence of candidiasis on visual examination or *Candida* spp. colony counts >1000 cfu/ml from initial microbiology tests on saliva, or (ii) had taken antifungals in the previous month, were excluded from the study.

Patients attending outpatient rheumatology, liver, pain management, oral medicine, speech and language and Sjögren's syndrome clinics at two London teaching hospitals who met the study criteria were invited to participate. Patients who required hospital transport or were unable to understand and complete the questionnaires were excluded. After obtaining informed consent, demographic and clinical data were collected. Following this, whole-mouth saliva tests (unstimulated flow rates) were taken. Participants were then given the measures of symptom status, OHIP14, global oral health, and psychological well-being to take away with them. They returned approximately 1-week later to the clinic with the completed questionnaires, at which time they completed OIDP. Participants then completed the two speech tests. The project was approved by the Research Ethics Committee of King's College Hospital, and written consent was obtained from all participants.

Measures

Demographics and medical histories

Participant's provided information on age, sex, current or most recent employment status, self-classified ethnic group, and duration of dry mouth symptoms. Data on the underlying diagnosis and medication were collected from participants' medical records.

Clinical indicators

The three clinical variables – salivary flow, clinical signs, and salivary gland condition – were measured during the initial examination by a single clinician. Unstimulated whole-mouth salivary flow rates were measured by asking patients to dribble saliva into a pre-weighed glass vial for 5 min, the cut-off point for inclusion in the study being >0.2 ml/min. A second timed whole-mouth unstimulated salivary sample was collected for *Candida* spp. count estimation expressed as colony-forming units per millilitre in order to confirm the clinical diagnosis before entry into the trial.

Following this, the clinician recorded whether or not each of 10 clinical signs were present: lips dry, lips cracked, nose dry, skin dry, tongue coated, tongue fissured, mucous dry, thin, atrophied, or erythematous. If a sign was present, it was coded as 1; these were then summed together to give a total clinical sign score (range 0–10), a higher score indicating a worse clinical condition. The clinician then recorded the condition of the salivary glands; salivary glands that were infected, tender, or enlarged were recorded as 1, and those normal were coded as 0.

Symptom status

Xerostomia Inventory (XI) (20) is an 11-item scale which was derived to measure the range of the xerostomia experience. Respondents are asked to indicate the frequency with which they experienced each symptom on a scale of 0 (never) to 4 (very often) (e.g. 'I sip to aid in swallowing food'). Two summary measures were calculated; additive and number of impacts. The additive measure was the unweighted sum of all item codes (XI-additive; range 0–44), with higher scores indicating a greater severity of xerostomia symptoms. The impact measure is the number of items rated as 3 (often) or 4 (very often) (XI-impacts; range 0–11). This threshold was chosen on the basis of the sample as the number of impacts for xerostomia was high. The reliability and validity of the scale have been reported as good (20).

Oral health-related quality of life

Oral Health Impact Profile (OHIP14; 13) is a 14-item questionnaire designed to measure the frequency of problems associated with the mouth, teeth, or dentures over the previous month on seven dimensions: functional limitation, pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. Participants are asked to rate each of the items on a five-point scale from 0 (never) to 4 (very often). Two summary measures were created; additive and number of impacts. The additive measure is the unweighted sum of all items (0–56) (OHIP-additive), with higher scores indicating poorer OHRQoL. The impact measure is the number of items rated as 2 or above (i.e. 'occasionally', 'often', 'very often') (range 0–14) (OHIP-impacts), with higher scores indicating a greater number of impacts. In addition, separate scores can be obtained for each of the seven dimensions by summing the codes for the two items per dimension.

Oral Impacts of Daily Performance (OIDP; 14) measures the disabling and handicapping impacts of oral disease on the person's ability to perform eight daily activities: eating and enjoying food, speaking and pronouncing, cleaning teeth, sleeping and relaxing, smiling, laughing and showing your teeth without embarrassment, maintaining one's usual emotional status, carrying out one's major work or social role, and enjoying contact with people. A modified version of OIDP was used in which participants are asked to rate the impact on each of the eight daily activities in the previous 4 weeks ('yes', 'no'), and the severity of these impacts on a five-point scale from 0 (no effect) to 5 (very severe effect). In line with the OHIP data, additive and number of impacts summary measures were created. The impact measure was the total of items answered 'yes' (range 0–8) (OIDP-impacts), and the additive measure the sum of the unweighted items (range 0–32) (OIDP-additive).

Speech function

Assessment of Intelligibility of Dysarthric Speech (AIDS; 21) and the Robertson Dysarthria Profile (RDP; 22) were used to measure speech function. The AIDS assessment battery is currently recognized as the most objective assessment of speech intelligibility. In the present study, we used the single-word assessment, which requires patients to read aloud a list of 50 written words. Each word is selected at random from a choice of nine single words, which share similar articulatory features. The listener is blind to the target word. The score obtained is how many words out of 50 the participant speaks correctly.

Five subtests and one adapted subtest from the RDP were used to assess speed of speech (diadochokinetic articulation). The five subtests require the patient to say either one sound or two

alternating sounds as many times as possible in 5 s. These sounds are: 1 – 'oo–ee'; 2 – 'pa–pa–pa', 3 – 'ta–ta–ta', 4 – 'ka–ka–ka' and 5 – 'ka-la'. The sixth sound was adapted so that the production of the sequence of sounds 'p–t–k' was extended from 5 (as in the RDP) to 20 s. Separate scores are obtained for each of the six sounds, which represent how many times each is repeated in the time available. The six scores were summed to give an overall measure of speed of speech. All of the speech data were recorded onto a minidisc (Sony MZ-R37: Sony Corporation, Tokyo, Japan) and later scored by a speech and language therapist. A hand-held manual counter was used to score the number of repetitions achieved in the RPD tasks.

Global oral health rating

Participants were asked to rate the health of their mouth on a scale of 0 (poor) and 4 (excellent). Such single-item global ratings have been used extensively in the literature (9, 17), and have been found to be related to functional impairment (23), and well-being indicators (24).

Psychological well-being

Hospital Anxiety and Depression Scale (HADS; 25) is a 14-item measure designed to detect anxiety and depression in general medical outpatient populations. Participants rated each of the items on how they had felt in the last few days on a scale of 0 (not at all) to 3 (most of the time). Sample items include 'I feel tense or wound up' and 'I have lost interest in my appearance'. Responses for the seven anxiety items were summed so that the higher the score, the more anxiety reported by the participants (HADS-A; range 0–21). Similarly, the seven depression items were summed to give a depression score (HADS-D; range 0–21). On the basis of their scores, individuals can be assessed in four score ranges which indicate the severity of the states; 'normal' (0–7), 'mild' (8–10), 'moderate' (11–14), and 'severe' (15–21). The HADS has been used extensively in patient populations, and has good reliability and validity (25).

Data analysis

The internal consistency of each OHRQoL measure was used to assess the extent to which the items related to a particular dimension and was calculated using Cronbach's alpha and the split-half reliability. Given that OIDP has only eight items, each relating to a different domain, the split-half reliability of this measure could not be calculated.

Criterion validity was assessed by correlating the total score derived from each of the two instruments and the number of impacts with the two measures of speech function (AIDS, RDP) and the global oral health rating, and by calculating the correlation between the OHIP14 and OIDP scores. Convergent validity, an aspect of construct validity, was assessed by correlating each of the measures (OHIP14 and OIDP) with the clinical variables (salivary flow, clinical signs, condition of the salivary glands), patient reported symptoms of dry mouth (XI), and the measure of psychological well-being (HADS-A and HADS-D), using Spearman's rank or Pearson's product-moment correlations, as appropriate. To further explore the construct validity of the two OHRQoL measures in relation to patients' experience of xerostomia, a series of regression analyses were used to identify predictors and outcomes of the number of impacts and total scores for both measures. Wilson and Cleary's (26) conceptual model of patient outcomes was used to guide the statistical analysis.

The measure of the number of impacts for both OHIP14 and OIDP, as well as the measure of salivary flow were not normally distributed, and all were square root-transformed. No suitable transformations of the AIDS score could be found and this variable was dichotomized as 'high' or 'low' around the mean.

Results

Participant characteristics

Of 136 people who were invited to participate, 92 were recruited but six declined because of work commitments, ill health, lack of interest or childcare commitments. For one participant, the majority of clinical data were missing, leaving a total of 85 participants. Of these 85 (20 men, 65 women), the mean age was 59.8 (SD = 11.5) and they had had xerostomia for on average 6.3 years (SD = 6.3). Seventy-four participants (87%) were identified as white, with eight (9%) describing themselves as Black African, Black Caribbean, or Black other. Most of the sample was retired (58%).

On clinical examination, the primary diagnoses were rheumatoid arthritis ($n = 36$) and osteoarthritis ($n = 20$) with additional diagnoses of primary biliary cirrhosis ($n = 13$) and systemic lupus erythematosis ($n = 3$), insulin or non-insulin diabetes ($n = 9$), diet ($n = 4$), and scleroderma ($n = 1$). Medication use was high, predominately

Table 1. Mean (SDs), range, and sample sizes of study variables

	Mean (SD)	Range	*n*
Clinical indicators			
Flow rate (ml/min)	0.13 (0.14)	0–0.64	70
Number of clinical signs	6.03 (1.49)	2–9	79
Symptom status			
XI-additive	29.77 (7.83)	6–42	85
XI-impacts	6.98 (2.65)	0–11	85
Oral quality of life			
OHIP-additive	22.47 (12.97)	0–54	85
OHIP-impacts	7.35 (4.17)	0–14	85
OIDP-additive	12.51 (9.05)	0–40	85
OIDP-impacts	4.22 (2.39)	0–8	85
Speech function			
AIDS	43.90 (7.11)	18–50	73
RDP	110.35 (29.84)	13–180	80
Global oral health	0.91 (0.88)	0–4	85
Psychological well-being			
HADS–Anxiety	8.08 (4.80)	0–21	85
HADS–depression	6.49 (3.77)	0–19	85

Note: XI = Xerostomia Inventory; OHIP = Oral Health Impact Profile; OIDP = Oral Impacts on Daily Performance; HADS = Hospital Anxiety and Depression Scale; AIDS = Assessment of Intelligibility of Dysarthric Speech; RDP = Robertson Dysarthria Profile.

antidepressants (31%), non-steroid anti-inflammatories (35%), diuretics (24%), allergy (41%) and steroids (46%).

The clinical indicators and measures of OHRQoL, speech, global oral health, and psychological well-being were similar in both sexes. The only exception was a positive relationship between sex and clinical signs ($r = 0.23$, $P < 0.05$), such that women were reported as having a greater number of clinical signs than men. Women also reported greater xerostomia symptom status ($r = 0.22$, $P < 0.05$) and number of impacts ($r = 0.22$, $P < 0.05$), compared with men. Participants who were white British reported a worse xerostomia symptom status ($r = -0.23$, $P < 0.05$), a greater impact of symptoms ($r = -0.26$, $P < 0.05$), and were more likely to have infected, tender, or enlarged salivary glands ($r = -0.23$, $P < 0.05$) than those who were non-white. There were no significant relationships between age and study variables, with the exception that participants who were younger reported worse xerostomia symptom status ($r = -0.22$, $P < 0.05$). Finally, participants who reported symptoms of dry mouth for longer (8+ years) had a greater impact on daily functioning as measured by OIDP ($r = 0.23$, $P < 0.05$), were more likely to have infected, tender, or enlarged salivary glands ($r = 0.39$, $P < 0.001$), and had slower speech as measured by the RDP ($r = 0.25$, $P < 0.05$), compared with those with symptoms for a shorter duration (0–7 years).

Descriptive statistics

For measures (OHIP14, OIDP, XI) where data were missing for between 1 and 3 items for a participant, the items were mean-substituted. For measures where more than one participant's data were missing, the presented results are for those for whom data were available. Sample sizes for each measure are given alongside the descriptive statistics in Table 1, which presents the mean, standard deviations and ranges for all study variables. Given the inclusion criteria for participation in the study, clinical indicators of dry mouth, subjective measures of symptom status and of OHRQoL would be expected to be severe. Indeed, as can be seen from Table 1, salivary flow rate was minimal, and common clinical signs extensive, with 39% (33/85) of participants having infected, tender or enlarged salivary glands. The mean xerostomia symptom score was high (29.77) compared with the two previous studies utilizing this scale in a general population; $X = 19.95$ (20) and 20.19 (27). With regard to OHRQoL, the mean values for both measures were higher than those reported for a general primary care population; OHIP-additive (18.9), OHIP-impacts (6.2), and OIDP-impacts (3.5) (17). Of the participants, 5.9% did not report an impact on the OHIP14, compared with 2.4% on the OIDP. In addition, 8.2% (OHIP)

Table 2. Criterion and construct validity (*r*-values) of total scores and number of impacts using OHIP14 and OIDP

	OIDP-impacts	OHIP-additive	OHIP-impacts	OIDP-additive
Speech				
AIDS	−0.25*	−0.23*	−0.29**	−0.21
RDP	−0.06	−0.13	0.01	0.05
Global oral health	−0.51***	−0.45***	−0.53***	−0.45***
Clinical Indicators				
Salivary flow rate	−0.08	−0.03	−0.13	−0.03
Clinical signs	0.17	0.20	0.11	0.18
Salivary gland condition	0.29**	0.28**	0.21	0.28**
Symptom status				
XI-additive	0.46***	0.47***	0.34***	0.35***
XI-impacts	0.37***	0.39***	0.28**	0.32**
Psychological well-being				
HADS-Anxiety	0.21	0.15	0.14	0.09
HADS-Depression	0.40***	0.32**	0.34**	0.21

For abbreviations see Table 1.
All r_s = Pearson product-moment correlations, with the exception of global oral health, AIDS, and salivary gland condition, which were assessed with Spearman's rank coefficients. OHIP-impacts, OIDP-impacts, salivary flow rate √transformed.
*$P < .05$, **$P \leq .01$, ***$P \leq .001$.

and 11.8% (OIDP) of participants reported the maximum number of impacts for that scale. Of the OHIP14 dimensions, the mean scores were higher for functional limitations ($X = 4.07$) and psychological discomfort (4.01) compared with physical pain (3.64), psychological disability (3.41), physical disability (2.73), handicap (2.51) and social disability (2.11). No impacts were reported by 11.8% of participants for functional limitations or physical pain, 12.9% for psychological discomfort, 15.3%, 31.8% and 34.1% for psychological, physical and social disability, respectively, and 28.2% for handicap. Overall oral health perceptions of the sample, as indicated by the global rating, were low; 37.6% reported a rating of 'poor' and 38.8% 'fair', compared with ratings of 'good' (20%), 'very good' (2.4%) and 'excellent' (1.2%).

Using the clinical classification criteria for the psychological well-being measure, whereby a score of ≥8 indicates clinically significant levels of anxiety or depression (25), 48.2% of participants would be categorized as clinically anxious, with 27.1% of these defined as moderate or severe. One-third (34.1%) would be categorized as clinically depressed, with 12.9% moderately or severely so.

Internal consistency

The internal consistency for both OHRQoL scales was excellent, with Cronbach's alpha values for additive OHIP14 and OIDP being 0.92 and 0.83 respectively. Similarly, the split-half reliability for the additive OHIP14 scores was high, 0.91.

Criterion validity

The criterion validity of both measures when compared with speech function scores and global oral health ratings are presented in Table 2 (rows 1–3). Neither measure was associated with speed of speech (RPS). The additive scoring method for both OHIP14 and OIDP, and the number of impacts on OHIP14, were weakly and negatively related to the measure of speech intelligibility (AIDS). Both measures of OHRQoL showed highly significant negative relationships with the global oral health rating, indicating that individuals with poorer functioning reported their overall oral health to be lower. Although the relationships were highly significant for both scoring methods, the strength of the correlations was slightly lower with the number of impacts compared with the additive method. The correlation between OHIP14 and OIDP additive scores was 0.72 ($P < 0.001$).

Construct validity

Neither OHIP nor OIDP were associated with whole-mouth salivary flow rate or number of clinical signs (see Table 2). Both OHIP14 (additive and impacts) and OIDP (impacts) were related to major salivary gland symptoms such that those individuals whose major salivary glands (parotid and /or submandibular glands) were infected, tender or enlarged were more likely to report poorer oral health functioning. The correlation for OIDP-additive approached significance ($P = 0.05$).

Table 3. Hierarchical regressions predicting the impacts and additive scores for OHIP14 and OIDP

	Additive			Impacts		
Predictors	β	F-value	Adj. R^2	β	F	Adj. R^2
OHIP						
Step 1: Clinical variables						
Salivary gland condition	0.28**	6.79**	0.07	0.27**	6.30**	0.06
Step 2: Symptom status						
XI-additive	0.43***	12.77***	0.23	0.43***	12.64***	0.22
OIDP						
Step 1: Clinical variables						
Salivary gland condition	0.18	2.71	0.02	0.25*	5.50*	0.05
Step 2: Symptom status						
XI-additive	0.34**	6.18**	0.11	0.33**	7.59**	0.14

Note: See footnotes of Tables 1 and 2. All beta coefficients are standardized.

The correlations between both measures and xerostomia symptom status were all highly significant, with participants who reported greater severity of symptoms and more impacts having poorer oral health functioning. Regardless of the scoring method used, the associations for OHIP14 were consistently stronger than those for OIDP.

As can be seen in Table 2, both OHIP14 (additive and impacts) and OIDP (additive) were significantly related to depression but not anxiety scores; those individuals who reported poorer oral health functioning had greater depressive symptoms, with the relationship being strongest for OHIP14 using the additive scoring method.

Regression analyses

In the first set of regressions we assessed clinical variables and symptom status as predictors of the two OHRQoL measures. Only those clinical and symptoms measures for which significant correlations had been identified for OHIP14 and/or OIDP were entered in to the model (major salivary gland symptoms, XI). Salivary gland symptom scores were entered as the first step followed by the additive xerostomia score simultaneously in the second step (see Table 3). The final models were significant for both OHIP14 and OIDP regardless of scoring method. However, more variance was accounted in the additive and impact models of OHIP14 (23% and 22% respectively) than for OIDP (11% and 14%). While the clinical indicator – major salivary gland symptoms – was significant in the first step of the model for OHIP (additive and impacts) and OIDP (impacts), when the symptom status measure was entered, it was no longer a significant predictor. The xerostomia symptom score was a significant predictor in all models.

Table 4. Regression analyses predicting global health and psychological well being from OHIP14 and OIDP additive scores

Outcome variable	OHIP β	OIDP β	F-value	Adj. R
Global oral health	−0.30*	−0.27*	15.91***	0.26
HADS-D	0.33*	0.10	8.14***	0.15
HADS-A	0.21	−0.01	1.82	0.02

Note: See Table 3 footnote.

These regression analyses were repeated with number of xerostomia impacts as predictors instead of the additive scores. Interestingly, the clinical variable remained significant even after symptom status had been entered for both OHIP measures – additive ($\beta = 0.22$, $P < 0.05$) and impacts ($\beta = 0.21$, $P < 0.05$) – and approached significance for OIDP (impacts) ($\beta = 0.20$, $P = 0.06$). For all the models, the amount of variance accounted for was reduced compared with the equivalent additive models, OHIP (additive 16%, impacts 18%) and OIDP (additive 7%, impacts 12%).

In the final set of analyses, we assessed whether OHIP14 and OIDP were predictive of global oral health ratings and psychological well-being. Hierarchical regression analyses were carried out entering both OHIP and OIDP additive scores simultaneously (see Table 4). As can be seen, the models for global oral health ratings and depression scores were significant, accounting for 26% and 15% of the variance respectively. Both OHIP14 and OIDP were significant predictors of overall oral health, while for depression scores only OHIP14 reached significance.

Again, these analyses were repeated utilizing the number of impacts on OHIP14 and OIDP, instead

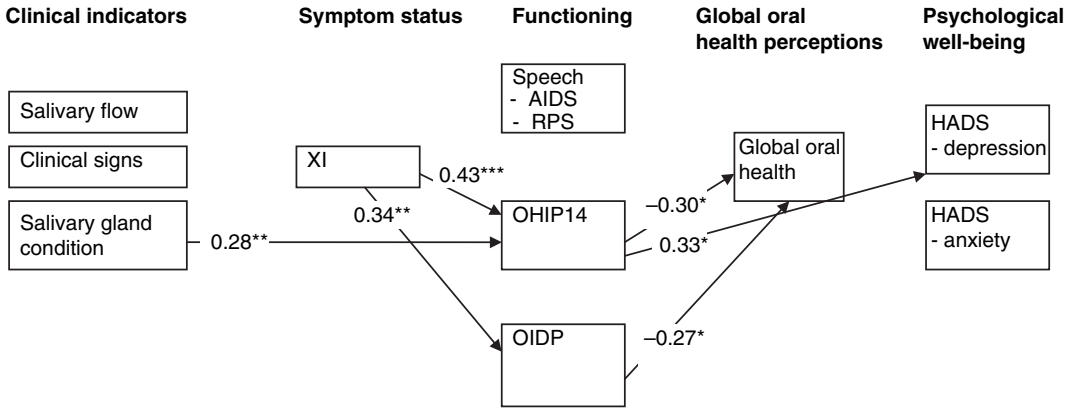

Fig. 1. Conceptual model of patient outcomes in xerostomia. Adapted from Wilson and Cleary [(26); p. 60. Copyright 1995, American Medical Association].

of the additive scores. The relationships were similar; with the exception that only the impacts for OHIP predicted global oral health. In addition, the amount of variance accounted for was reduced compared with the additive models; 8% (HADS-depression) and 23% (global health). The findings of the regression analyses are summarized in Fig. 1, using the conceptual model of patient outcomes as a framework (26). The results shown are those for the additive scoring method only for all measures, and include only coefficients that were significant in the regression models ($P < 0.05$) in order to ease interpretation.

Discussion

This study aimed to evaluate the validity of two OHRQoL measures in a specific clinical context: patients with xerostomia. As such, this was the first study to examine the predictors and correlates of OHRQoL in this population. The findings suggest that both OHIP14 and OIDP have good psychometric properties and are useful measures of OHRQoL in xerostomia. Overall, however, the OHIP14 performed better than did OIDP. The data also indicate that the additive scores – the total burden on patients – may be more important in this population than impacts – the number of areas of life affected.

The internal consistency of both measures was excellent. The value for Cronbach's alpha was similar to previous studies in relation to a UK primary care population with acute dental problems; OHIP14 (0.91) and OIDP (0.88) (17), far exceeded Nunally's standard of 0.70 appropriate for clinical trials and other studies involving group comparisons (28).

As would be expected in a population with a chronic oral health condition, both measures detected a high degree of impact on everyday functioning. Using the same 'occasional' threshold on the OHIP14, both the prevalence (94.1%) and the mean number of impacts (7.35) were higher than in the study reported above (88.2% and 6.2 respectively) (17). In contrast to this previous study, the present data indicated that the prevalence of impact was higher for OIDP than OHIP (97.6% versus 94.1%). Similarly, the number of participants reporting the maximum number of impacts was highest for OIDP (11.8%) than OHIP (8.2%). This may simply be due to the OIDP having fewer items. Alternatively, it may be related to the scale content; while OHIP and OIDP are theoretically and conceptually similar, differences in item content may influence their sensitivity to specific impacts in particular clinical conditions. Xerostomia is characterized by physical discomfort and/or pain relating to dryness of the mouth and skin, soreness, and burning sensation, together with difficulties in chewing, swallowing, speaking, tasting and sleeping. Indeed, on the OHIP, the prevalence of impacts was greatest for dimensions representing functional limitations (speech, taste), psychological discomfort (self-conscious, tense) and physical pain (aching, eating) and, to a lesser extent, psychological disability (difficulty relaxing, embarrassed). Approximately one-third of the sample reported no impacts on the six questions relating to physical disability, social disability, or handicap. In comparison, the OIDP gives less weight (2/8 items) to social disability and handicap (unable to carry out work/social role, difficulty in contact with people), which may be of little relevance in xerostomia. On this basis, more impacts would be expected on OIDP compared with OHIP. One implication being

that the face and content validity of OHRQoL measures should be assessed carefully before they are used in specific clinical conditions. Alternatively, large item measures could be used as a source of relevant items for disease-specific measures (29).

Both measures had significant and equally good criterion validity when compared against global oral health ratings. Again, this is contrary to a previous study (17), which found that the correlation between OIDP and global ratings of oral health were lower than that for OHIP, which may be related to the relative ill-health in the present sample. Here, for both measures, the additive scoring system correlated more highly than did the number of impacts.

Both OHIP and OIDP were only weakly related to one of the two measures of speech function, the assessment of speech intelligibility. While difficulty in speaking can be a symptom of xerostomia, it constitutes only one question on the OHIP and OIDP and, on this basis, it is perhaps not surprising that the OHRQoL measures were not related to speech function. Additionally, it is important to note that for the majority of the present patient sample, speech was not significantly disrupted; for example, 83.6% of participants scored ≥41 (of 50) on the measure of speech intelligibility.

Neither OHIP nor OIDP were related to two of the three clinical characteristics of xerostomia (salivary flow, number of clinical signs). The presence of salivary gland signs was associated with both OHRQoL instruments. Interestingly, while the number of impacts on OIDP was significant, the severity score was not. This may suggest that in this population, patients had a high number of impacts that were relatively minor in severity. Overall, these data are in accordance with previous research, which indicates only weak associations between clinical measures and subjective ratings of oral health (30).

In contrast to the clinical presentation, both OHIP and OIDP correlated highly with patients' perceptions of their dry mouth symptoms. These relationships were greater for OHIP14 compared with OIDP, regardless of the scoring method used. Furthermore, in the regression models, patient-rated symptom severity and number of impacts accounted for greater variance in OHIP (16%) compared with OIDP scores (9%). A similar pattern was evident in relation to psychological well-being; OHIP (additive and impacts) but not OIDP predicted patients' depression scores. Cumulatively, these findings support the construct validity of both OHRQoL measures when used in this clinical context but indicate that OHIP may perform better overall. Furthermore, in all regression models, both for predictors and outcomes of OHRQoL, the variance accounted for was lower when using the number of impacts scoring system, compared with the additive method. Given that the techniques used should be as simple as possible if OHRQoL measures are to gain widespread acceptance and can be used in clinical settings in patient assessment and treatment planning, the simplicity of the additive method of calculating total OHIP or OIDP scores is an advantage.

Here, using pre-validated cut-offs for the psychological well-being measure (HADS), a substantial proportion of the sample were found to be clinically anxious (48.2%) and/or depressed (34.1%). As previously noted (31), given the high incidence of co-existing conditions with xerostomia, high levels of psychological distress cannot be attributed exclusively to xerostomia *per se*. Certainly, in the present sample, a high number of participants had a variety of chronic health conditions (e.g. secondary Sjögren's syndrome associated with rheumatoid arthritis, osteoarthritis, primary bilary cirrhosis). Psychiatric disorders including depression and anxiety with frontal lobe abnormalities, memory loss and subtle changes in cognitive function have been described in many patients with Sjögren's syndrome and are considered as a component of the disease rather than a response to living with an autoimmune disorder (2). Furthermore, over a third of the patients were prescribed anti-depressants. While causality cannot be attributed to the present cross-sectional data, the findings support research which suggests that xerostomia symptoms can be severe and disabling, with a range of impacts on everyday functioning and subjective well-being (31, 32).

There was some indication that patient background is implicated in the experience of xerostomia. Sex and ethnicity were related both to clinical presentation and subjective ratings of symptoms. In the clinical examination, women had more clinical signs than men. Furthermore, in concordance with previous studies (20, 31, 32), women reported greater severity and number of xerostomia impacts. Symptom ratings were also greater in younger participants and in those who self-identified as white. The latter group were also more likely, in the clinical examination, to be rated as having infected, enlarged, or tender salivary

glands. Interestingly, while these demographic variables were associated with objective and/or subjective assessments of symptoms, they did not correlate with OHRQoL measures. There has been some suggestion in the literature, for example, of greater levels of impact on OHRQoL in younger people (17, 23). In the present study, duration of symptoms was the only background variable to be related to OHRQoL (specifically OIDP). This relationship was not confounded by age, as further analysis indicated that symptom duration and age were unrelated. It may be that the relationship was due, at least in part, to severity of clinical presentation; those participants who had had the condition for longer were more likely to have more severe symptoms which, in turn, may lead to poorer OHRQoL. There is some evidence for this in that greater symptom duration was related to worse salivary gland condition.

Using Wilson and Cleary's (26) conceptual model to guide the analysis, helped clarify the relationships between OHRQoL and both the clinical and non-clinical variables that may be of importance in xerostomia. As these authors note, in order to adequately assess HRQoL in relation to patient outcomes, it is necessary to examine the relationships between clinical variables, patient-reported symptoms, role, social and psychological functioning, health perceptions and subjective well-being and furthermore, to explore the intervening variables that may mediate these relationships. Explicit conceptualization of these (inter) relationships will facilitate our understanding of patient's experiences of their health condition and, most importantly, inform the development of effective intervention strategies. As applied to xerostomia, OHRQoL was found to be important in patient experiences of xerostomia, in particular, as to how the condition was related to functional limitations, psychological discomfort and disability, and physical pain, in addition to levels of depression. As predicted by the model, the severity of xerostomia symptoms – as measured both by patient reports and, to a lesser extent, clinical assessment – was related to OHRQoL. The finding that OHRQoL was only weakly associated with clinical indicators, supports Wilson and Cleary's contention that such variables should not be used as a 'gold standard', but rather that both clinical and subjective reports should be utilized in the same study (26).

Given this importance of patient-reported symptoms, it is vital that future studies are conducted on the factor structure, reliability and validity of the XI (20). To date, only a handful of studies have utilized the XI, while the majority have employed a single-item approach (How often does your mouth feel dry?) (33). This may, to a certain extent, have hampered our understanding of patients' experiences of xerostomia. Xerostomia is a complex multi-symptom condition; previous research has highlighted the poor correlation between traditional clinical assessment tools (salivary flow) and xerostomia symptoms such that patients can report symptoms of dry mouth when they have adequate salivary flow and vice versa (27). Future longitudinal research utilizing the XI, alongside clinical measures, would be beneficial in order to assess patients' awareness of xerostomia, and the consequences of symptoms on OHRQoL and well-being.

If OHIP14 is to be used in clinical settings, further validation of the short form needs to be carried out. The selection of items from the full OHIP was derived with a pre-determination to use the seven dimensions of Locker's model (16). Yet, as the author of OHIP14 notes (14), findings from the original factor analysis indicate that the shortened scale may measure one underlying dimension, rather than the seven separate domains. Moreover, as highlighted previously, other subsets of items from the OHIP49 may be better predictors in specific populations or contexts (9, 29). Here, for example, there was some evidence that domains of physical and social disability, as well as handicap, may not be as relevant to patients with xerostomia.

Future studies are required to further test and extend the findings reported here. First, given the cross-sectional nature of the data, the present findings address only the descriptive and discriminative potential of the two OHRQoL measures in relation to xerostomia. Longitudinal studies need to be conducted which assess the evaluative properties of these OHRQoL measures, for example, in relation to significant changes in patients over time as a result of clinical management. Secondly, given the small sample size, it was not possible to utilize more formal path analytic techniques, most notably structural equation modelling. Further research is needed that incorporates such techniques in order to explore more fully the direct and indirect relationships between OHRQoL and both clinical and non-clinical variables as measured here. Thirdly, the role of background variables in xerostomia needs to be explored in greater detail. The present data indicate that individual characteristics and symptom duration may influence the

relationship between clinical indicators and symptom reporting. Such information is important for treatment planning and the design of intervention strategies tailored towards 'high-risk' patients. Fourthly, the role of psychological factors needs to be considered. Previous research indicates that such factors play an important role in xerostomia (31), yet their interacting effects have not been assessed. There is a wealth of evidence from the psychology literature which details the direct and mediating influence of key psychological factors such as, dispositional optimism, coping strategies, and positive and negative mood on global health perceptions and symptom reporting (34, 35), as well as longer-term anxiety and depression (36). Finally, given that there are marked individual differences in the perception, recollection, or reporting of physical symptoms (37), future studies need to account for such influences. In particular, the influence of negative affectivity; that is, the disposition to experience chronic negative emotions, which leads to systematic biases in participants' ratings of health status and physical symptoms (34, 38) and OHRQoL (39).

Conclusion and implications

Both OHIP and OIDP measures had good psychometric properties as measured in this study. The present data have added to our knowledge of the validity of OHRQoL measures in clinical settings, and provided evidence for their potential use with this patient group. There was some evidence that the two measures may perform differently when applied in specific clinical settings. The choice of measure will depend on which domains are likely to be more important to the population under study (9). In relation to xerostomia, OHIP may prove more useful for future research and clinical assessment.

The recent WHO recommendation for improving the health of older people (40), highlights the need for socio-behavioural research examining well-being, oral functioning and quality of life in high-risk groups in order to help facilitate treatment planning and the development of effective programmes to improve OHRQoL. Given the high percentage of older people who experience xerostomia (1), and the impact such a chronic and sometimes debilitating condition can have on everyday functioning, in addition to psychological well-being, future research which explores further the model identified here is vital.

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