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Author(s)	Mcmillan, AS; Leung, KCM; Leung, WK; Wong, MCM; Lau, CS; Mok, TMY
Citation	Journal Of Oral Rehabilitation, 2004, v. 31 n. 7, p. 653-659
Issued Date	2004
URL	http://hdl.handle.net/10722/55452
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Impact of Sjögren's syndrome on oral health-related quality of life in southern Chinese

Running title: Sjögren's syndrome and oral health-related quality of life

Anne S. McMillan¹, Katherine C.M. Leung², W. Keung Leung³, May C.M. Wong⁴, Chak S. Lau⁵, Temy M.Y. Mok⁶

^{1,2}Oral Rehabilitation,

³Periodontology,

⁴Dental Public Health,

Faculty of Dentistry,

University of Hong Kong,

Hong Kong SAR

^{5,6}Division of Rheumatology &

Clinical Immunology,

Dept. of Medicine,

Faculty of Medicine.

University of Hong Kong,

Hong Kong SAR

Address all correspondence to:

Professor Anne McMillan

Oral Rehabilitation, Faculty of Dentistry, University of Hong Kong

34 Hospital Road, Hong Kong SAR

FAX +852 2856 6114

e-mail: annemcmillan@hku.hk

SUMMARY

The effect of oral symptoms of Sjögren's syndrome (SS) on health-related quality of life is presently uncertain. This study aimed to investigate oral health-related quality of life (OHRQOL) among southern Chinese people with SS. 26 primary SS cases, 25 secondary cases and 29 matched controls took part in this cross-sectional study. Each participant completed a SF-36 questionnaire, the Oral Health Impact Profile (OHIP-49) and a dry mouth measure, assisted by a trained interviewer. Data on socio-demographic variables were also collected. The dry mouth measure revealed that people with primary and secondary SS had significant problems associated with subjective symptoms of dry mouth generally, and dry mouth when eating and speaking ($p < 0.01$). Sticky saliva and coughing were also problems in some primary SS cases. OHIP summary and sub-scale scores did not reveal differences in negative impacts between groups. Mean SF-36 sub-scale scores were significantly different between groups ($p < 0.05$). In physical function, role-physical and general health domains, primary and secondary SS sufferers had lower scores indicating poorer health. Oral symptoms of SS, notably xerostomia, had a negative effect on OHRQOL. Health-related quality of life in general was also impaired in SS sufferers. The OHIP did not appear to discriminate oral problems of concern to SS sufferers.

KEY WORDS: Sjögren's syndrome, quality of life, oral health, health status measures, complications, xerostomia.

INTRODUCTION

Sjogren's syndrome (SS) is an autoimmune disease of the exocrine glands that particularly involves the salivary and lacrimal glands (1, 2). It affects 3-4 % of the adult population, mainly middle age or older women. The condition may present in isolation (primary SS) or be associated with various systemic autoimmune disorders and connective tissue diseases (secondary SS). The major pathological changes involve infiltration of the lacrimal, salivary and other exocrine glands by lymphocytes and plasma cells and progressive destruction of gland acini (2). The clinical presentation is characterized by dryness of all mucosa. Symptoms may range from local consequences of exocrine dysfunction to major systemic complications such as vasculitis (3,4).

Oral symptoms of SS are caused predominantly by reduced salivary flow (5). Dryness of the mouth can be severe (xerostomia) and leads to discomfort and difficulty speaking, eating and swallowing, altered taste, difficulty wearing dentures, oral candidal infections and dental caries (6). Oral symptoms are generally thought to be more severe in primary SS cases. Oral symptoms of SS may be assessed clinically using objective measures. However, problems involving the mouth and teeth have been shown to have a key effect on many aspects of daily living and are not adequately captured by clinical assessment alone (7). Sjögren's syndrome can have a profound impact on health-related quality of life in general (2, 8, 9). However, the effect of oral symptoms of SS on health-related quality of life is presently unclear, although given that end organ damage is a notable feature in the mouth a negative impact is likely (10).

Health status measures are increasingly being used to assess the impact of oral disorders (11-13). A comprehensive approach to the measurement of oral health-related quality of

life (OHRQOL) combines the use of generic, oral specific and condition specific measures (12, 14). The Medical Outcomes Short-Form Health Survey Questionnaire 36 (SF-36) is a measure of the impact of general health condition on quality of life and has been used in many different populations and disease conditions including SS (2, 9, 15). Among oral-specific measures, the oral health impact profile (OHIP) is presently one of the most comprehensive measures of the impact of oral condition on health-related quality of life (16, 17). In the measurement of xerostomia, single item and multi-dimensional approaches have been used (18, 19). A disease-specific SS questionnaire has also been developed that seeks to determine oral conditions of direct concern to patients (20).

The aim of the study was to investigate OHRQOL among patients with Sjogren's syndrome. We tested the hypothesis that oral symptoms of SS, namely xerostomia and its sequelae, have a major impact on health-related quality of life.

METHOD

A cross-sectional study design was used and involved three experimental groups:

1. Patients with primary SS.
2. Patients with secondary SS.
3. Patients attending for review at the Prince Philip Dental Hospital, Hong Kong were recruited as controls.

Subjects with SS were recruited at the Rheumatology Clinic, Department of Medicine, Queen Mary Hospital, Hong Kong. Sjögren's syndrome patients had been diagnosed as primary or secondary cases based on the European Community Diagnostic Criteria (3, 4).

Primary cases had oral and eye symptoms only whereas secondary cases had systemic autoimmune connective tissue disease and oral/ocular symptoms. All participants had been diagnosed at least six months previously. None of the SS patients were taking medication for dry mouth symptoms. A number (29%) were taking hydroxychloroquine as part of the management of concurrent rheumatoid arthritis and systemic lupus erythematosus. None of the patients were on therapeutic agents with anticholinergic effects. The control group comprised medically healthy patients attending the Prince Philip Dental Hospital for periodic review of their dental condition and were not receiving treatment at the time of study. Potential controls with a history of systemic autoimmune connective tissue disease, who had received radiotherapy in the head and neck region, or any concurrent condition involving altered saliva flow were excluded from the study. Participants in the control group were selected for similar age and gender using the age/gender characteristics of the first 29 SS subjects recruited. All subjects in the study were southern Hong Kong Chinese. The Faculty of Dentistry Ethics Committee, The University of Hong Kong, approved the study.

Questionnaires

The SF-36 consists of 35 statements divided into eight sub-scales: physical functioning, social functioning, role limitation-physical, role limitation-emotional, mental health, vitality, pain and general health perception; and one health transition statement (15). For each sub-scale, raw data are transformed and summed on a 0-100 scale with a higher score indicating better health state. The SF-36 scale has been translated and validated for use in Hong Kong (21, 22).

The OHIP, developed by Slade and Spencer (17), is a multidimensional measure that is based on Locker's conceptual model of measuring oral health (23). The OHIP-49 measure contains 49 statements divided into seven domains: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. The question format is 'how often have you... because of problems with your teeth, mouth or dentures?'. Responses were recorded using a five-point Likert scale (i.e., 0 = never, 1 = hardly ever, 2 = occasionally, 3 = fairly often, and 4 = very often). The Chinese (Cantonese) version of the OHIP has been validated previously (24). The simple counts method of scoring was used to compute the number of negative impacts for individual OHIP statements. This involved data being reduced to a dichotomy with "very often" and "fairly often" indicating a negative impact (25). Sub-scale scores were computed by summing responses within each of the seven domains. Summary scores were calculated by summing scores across the 49 statements (OHIP-ADD) and summing the negative impacts (OHIP-SC).

The dry mouth measure comprised seven questions based on subjective symptoms associated with dry mouth. The questions were abstracted from the Workshop on Diagnostic Criteria for Sjögren's Syndrome and also based on dry mouth related questions in the EORTC QLQ-H&N35 scale (20, 26). The measure had a Likert format that ranged from 1 to 4 ("not at all" to "very often" respectively). The variables assessed were: painful throat, dry mouth generally, dry mouth when eating or speaking, sticky saliva, coughing, hoarseness and altered taste. For example, "During the past four weeks, has your mouth felt dry when eating or speaking?" Data for individual questions were reduced to a dichotomy, the responses "very often" and "sometimes" indicated a negative impact.

The three questionnaires and four socio-demographic questions (age, gender, educational level, and employment status) were completed by all participants, assisted by a trained interviewer. The interviewer was not involved in any aspect of the medical or dental care of the participants.

Data analysis

The demographic background and data from the SF-36, OHIP and the dry mouth measure of the three groups were compared. Differences in categorical variables among the three groups were tested by Chi-squared tests or Chi-squared exact tests whichever appropriate. 1-way ANOVA tests were used to compare differences in the continuous variables among the three groups. The level of significance of the above tests was set at 0.05. Multiple comparisons for the individual OHIP statements were made and p values were adjusted using Bonferroni's correction method. All data were analyzed using SPSS for Windows 11.0.

RESULTS

Eighty subjects aged 27 to 75 years participated in the study. Twenty six had primary SS, 25 had secondary SS, and 29 were controls. Socio-demographic data are displayed in Table 1. Almost all the participants in each group were female. The mean age of the primary SS group was slightly higher than the other two groups ($p=0.05$). There was no statistically significant difference in gender, educational level or work status between groups. For primary SS cases, the mean time since diagnosis of the condition was 6.7 (SD, 7.1) years and for secondary SS cases it was 4.8 (SD, 4.5) years. For secondary SS cases, the underlying systemic conditions were systemic lupus erythematosus (20 cases),

three patients had rheumatoid arthritis, three had sicca symptoms, and one had autoimmune hepatitis.

SF-36

Data for the SF-36 subscales are described in Table 2. Normative data for the population of Hong Kong were incorporated for comparison. Data from the control group were consistent with Hong Kong population data (22). There was a significant difference between groups in the physical functioning ($p<0.01$), role-physical ($p<0.05$) and general health ($p<0.01$) domains with lower scores for the primary and secondary SS groups indicating a poorer condition. The scores for primary and secondary SS cases were similar in all domains. Assessment of the health transition statement data revealed no differences between groups (Table 3).

OHIP

There was no difference in the reporting of negative impacts between groups for any of the 49 statements. When OHIP sub-scale data and summary scores (OHIP-ADD, OHIP-SC) were compared, there were no differences between groups (Table 4).

Dry mouth measure

More primary and secondary SS patients had negative impacts associated with subjective symptoms of dry mouth generally, and dry mouth when eating and speaking ($p<0.01$) [Table 5]. Primary SS patients also had a negative impact associated with sticky saliva ($p<0.01$) and marginally more problems with coughing ($p=0.06$). More than 75 % of SS patients experienced dry mouth symptoms sometimes or very often. There were no

differences in painful throat, coughing, hoarse voice and altered taste symptoms between groups.

DISCUSSION

The prevalence of chronic health conditions is increasing world wide, and therapeutic goals are increasingly being weighted towards long-term management of patients rather than curing diseases and are focused on reducing the progression of diseases and the impact on quality of life (27). This is particularly the case in SS where there is presently no curative treatment but considerable advances have been made in symptomatic relief using local and systemic treatments (8).

The signs, symptoms and clinical course of health problems are complex. In SS, the symptoms may vary widely (2). The present data suggest that SS has a negative impact on perceived health and well being in southern Chinese living in Hong Kong. SF-36 scores in physical function, role-physical and general health domains were lower in SS patients reflecting directly the impact of the condition on health related quality of life generally as a consequence of systemic conditions related to SS. In a previous study on the impact of SS, Thomas et al. (2) described low scores in all SF-36 domains for a group of 13 SS sufferers. Caution should be exercised when interpreting small group data particularly in this case where there was an indication of co-existing conditions including fibromyalgia and chronic fatigue syndrome that may have contributed to low scores in domains such as social functioning and emotional role limitation. Likewise, Strömbeck et al. (9) showed that all SF-36 sub-scale scores were reduced in primary SS patients. However, again there was the complication of co-morbidity notably fibromyalgia. None of the SS patients in our study had co-existing fibromyalgia or chronic fatigue syndrome

although it is not possible to eliminate the potential additional effects of underlying connective tissue disorders on health related quality of life in patients with secondary SS. It is, however, possible that our cohort of southern Chinese SS patients did not have such a severe manifestation of the condition and their perceived health and well being although impaired was not as adversely affected as SS sufferers in the studies by Thomas et al. (2) and Strömbeck et al. (9). Moreover, there were no differences in SF-36 subscale scores between primary and secondary SS cases indicating a similar negative impact on general health. The similarity in general impact may be accounted for, at least in part, by the fact that primary cases often have major systemic conditions such as vasculitis and pulmonary involvement and in secondary cases systemic autoimmune conditions such as rheumatoid arthritis are ubiquitous. The SF-36 health transition statement revealed no difference between groups and underpinned the chronicity of the SS condition in a patient group with established disease that is relatively stable over time.

The impact of prevailing oral conditions were greater in SS sufferers compared with controls. The conditions of concern to SS patients related to symptoms associated with xerostomia. The dry mouth measure revealed that most SS patients had problems associated with a subjective feeling of dry mouth particularly when eating and speaking. Sticky saliva and coughing were also features in more than half of the primary cases. Such frequent problems associated with common and basic daily living activities indicate a significant disability and negative impact on OHRQOL.

Overall, the impact of SS on oral condition generally as revealed by OHIP summary scores did not differ significantly from controls. This observation suggested that OHIP as a summary measure had less power than the domain specific dry mouth measure. The

apparent lack of differences in OHIP summary scores between groups did not appear to be due to sample size. To explore the possible lack of sensitivity of the measure in SS patients, data from the three groups were used to calculate the sample size necessary to meet appropriate statistical criteria ($\alpha = 0.05$, $\beta = 0.8$). Based on our results, a sample size of 500-1000 subjects would be required in order to show a significant difference in the OHIP summary score (OHIP-ADD). OHIP is acknowledged as a measure of "ultimate impact" in that it is a comprehensive measure of dysfunction, discomfort and disability attributed to oral conditions generally (17, 28). However, it did not appear to discriminate the oral problems of particular concern to southern Chinese patients with SS possibly because the dry mouth was not severe enough to cause general oral problems described by the OHIP. This contrasts with our findings in southern Chinese after head and neck radiotherapy for nasopharyngeal carcinoma where OHIP sub-scale and summary scores were much higher than controls (29). After radiotherapy, dry mouth symptoms were profound and other debilitating conditions including mucositis and trismus also contributed to the impairment of OHRQOL.

The measurement of xerostomia is complex as it comprises symptoms that are best assessed by subjective questioning in contradistinction to salivary gland hypofunction that can be measured by clinical techniques such as sialometry (30, 31). The present multi-item dry mouth measure sought to discern the magnitude of impact of different known symptoms of xerostomia rather than use previous single item approaches involving a global question such as "How often does your mouth feel dry?". The subjective feelings of dry mouth in SS patients revealed by the measure were consistent with objective measures. In this same group of SS sufferers, stimulated whole saliva flow

was significantly less in both primary and secondary cases compared with controls (32). However, it is still not clear precisely what gives rise to the condition a patient describes as dry mouth as subjective symptoms of dry mouth can occur in the presence of apparently adequate saliva flow and the converse has also been described (30, 33). Recent developments in the measurement of xerostomia, notably the 11-item Xerostomia Inventory that has the capacity to measure xerostomia severity as a continuous variable suggests that this multidimensional measure may be the most appropriate instrument for use as an outcome measure in future clinical studies involving medications for the treatment of dry mouth in SS (19, 31).

ACKNOWLEDGEMENT

This study was funded by a CRCG grant from the University of Hong Kong.

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TABLE 1. Socio-demographic features and treatment seeking, by group.

	1° SS (n=26)	2° SS (n=25)	Controls (n=29)	<i>p</i> †
<i>Age (years) [mean, SD]</i>	50.1 (14.2)	43.3 (11.0)	44.3 (10.6)	0.05
<i>Gender (%)</i>				
Male	7.4	4.0	6.9	0.86
Female	92.6	96.0	93.1	
<i>Education level</i>				
No formal education	18.5	0	3.4	0.17
Primary	22.2	28.0	17.3	
Secondary	37.0	48.0	58.6	
Post-secondary	22.3	24.0	20.7	
<i>Working status</i>				
Full time working	37.0	52.0	48.3	0.99
Part time working	7.4	12.0	10.3	
Not working	0	16.0	6.9	
Housewife	33.4	20.0	27.6	
Retired	22.2	0	6.9	

† Independent 1-way ANOVA for testing means; Independent Chi-square tests or Chi-square exact tests for testing proportions whichever appropriate. * p=0.05

TABLE 2. SF-36 scale scores, by group.

Scale (mean, SD)	1° SS (n=26)	2° SS (n=25)	Controls (n=29)	Hong Kong 41-64-yr-old* (n=695)	P†
Physical functioning	80.0 (14.8)	81.0 (12.7)	90.3 (12.5)	93.0 (10.8)	0.01*
Role-physical	57.4 (37.8)	59.0 (41.3)	79.3 (34.1)	86.1 (27.5)	0.05*
Bodily pain	68.0 (26.9)	65.4 (23.9)	75.2 (21.9)	86.5 (20.3)	0.30
General health	41.8 (21.8)	41.0 (15.5)	58.3 (18.4)	56.4 (19.7)	0.01*
Vitality	51.6 (22.3)	51.0 (20.0)	60.3 (17.2)	62.6 (17.0)	0.15
Social functioning	83.7 (23.4)	79.5 (19.3)	88.3 (17.0)	93.6 (14.2)	0.27
Role-emotional	69.1 (40.2)	65.3 (36.6)	80.4 (35.0)	79.3 (33.5)	0.30
Mental health	77.4 (18.0)	68.3 (16.4)	74.4 (14.7)	73.8 (16.8)	0.13

† Independent 1-way ANOVA for comparing the means between the three groups. *= $p < 0.05$

* Lam *et al.* (1999)

TABLE 3. SF-36 health transition statement.

	1° SS (n=26)	2° SS (n=25)	Controls (n=29)
<i>Health compared with 1 year ago (%)</i>			
Better	22.2	16.0	10.3
About the same	48.2	44.0	65.5
Worse	29.6	40.0	24.2

Chi-square test, p=0.45

TABLE 4. OHIP sub-scale and summary scores, by group

SUB-SCALE (<i>mean, SEM</i>)	1° SS	2° SS	Controls	<i>p</i> †
Functional limitation	11.9(1.3)	11.6(1.0)	10.2(1.2)	ns
Physical pain	8.9(1.4)	9.0(0.8)	8.8(1.1)	ns
Psychol discomfort	4.4(0.9)	5.4(0.9)	4.9(0.8)	ns
Physical disability	7.0(1.2)	4.8(0.7)	4.7(1.0)	ns
Psychol disability	3.3(0.9)	3.0(0.7)	3.3(0.8)	ns
Social disability	1.0(0.4)	0.9(0.3)	1.0(0.4)	ns
Handicap	3.0(0.8)	2.4(0.4)	2.2(0.6)	ns
OHIP-ADD	39.4(5.9)	37.0(3.7)	35.1(5.2)	ns
OHIP-SC	5.3(1.3)	4.5(0.7)	4.0(1.1)	ns

†Independent 1-way ANOVA tests

TABLE 5. Dry mouth measure: Subjects (%) with negative impacts.

Questions	1° SS (n=26)	2° SS (n=25)	Controls (n=29)	p†
Painful throat	25.9	40.0	31.0	0.55
General dry mouth	77.8	84.0	37.9	<0.01*
Dry eating/speaking	74.1	72.0	34.5	0.01*
Sticky saliva	54.2	26.1	17.2	<0.01*
Cough	51.9	24.0	27.2	0.06
Hoarse voice	33.3	28.0	24.1	0.75
Altered taste	7.4	4.0	0	0.40

†Independent Chi-square tests or Chi-square exact tests. *=p<0.05