World Workshop on Oral Medicine VI: Patient-reported outcome measures and oral mucosal disease: current status and future direction.

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Abstract

Objective: This systematic review aimed (i) to explore the Patient-Reported Outcome Measures (PROMs) currently used in the oral mucosal disease literature and to report on the type and context of the use of these instruments and (ii) to provide a future direction for PROMs in oral medicine practice and research.

Study Design: A systematic review of published English-language articles relating to the use of PROMs in the oral mucosal diseases literature was performed in November 2013.

Results: One hundred and thirty one articles met the inclusion criteria, which addressed the following oral mucosal conditions: 75 lichen planus; 30 recurrent aphthous stomatitis; 14 mucous membrane pemphigoid/pemphigus vulgaris; 1 orofacial granulomatosis and 11 articles addressed multiple oral mucosal diseases. The most commonly used instruments were Visual Analogue Scales (VAS) and the Oral Health Impact Profile (OHIP).

Conclusions: Limited progress has been achieved with use of PROMs in oral medicine in the last few decades in both clinical practice and a research setting. With the engagement of allied medical disciplines in PROM usage and the promotion of PROMs by national healthcare bodies globally, advancement of PROMs is imperative for oral medicine. Exposure through the World Workshop on Oral Medicine (WWOM), along with potential involvement in the Core Outcome Measures in Effectiveness Trials (COMET) or other such initiatives, will enable worldwide collaboration to promote the development and utilization of valid and reliable PROMs in oral medicine, and improve patient care.

Introduction

A patient-reported outcome measure (PROM) is an instrument for patients to assess their health, without external interpretation or extrapolation[1, 2]. The outcome may represent a measure of symptoms and signs that equate with the state of the disease, or it may represent a change from a previous measure. PROMs commonly include psychosocial changes, changes in health status, ability to function, and satisfaction with the care provided [3, 4]. The importance of evaluating the patients' perceptions of the impact of their health on daily living has been well established [5]. Patients can provide key information regarding the day to day impact of the chronic diseases they suffer from, which can prove helpful in their healthcare [6]. Studies have determined that PROM use in clinical practice can have a positive impact on communication between patients and clinicians, and can also have a positive impact on both diagnosis and treatment [7, 8]. Outcome measures are also increasingly important to establish patient reported benefits[9] in healthcare and evidence that PROMs improve patient care[10] in general medicine.

Some progress has been made in the use of PROMs in oral medicine from early studies reporting on anxiety and depression in population groups [11, 12], to the importance of valid and reliable instruments highlighted by Hegarty et al [13] and the use of PROMs as outcomes in clinical trials [14]. Due to the chronic nature of common oral medicine conditions such as orofacial pain, salivary dysfunction and oral mucosal lesions and an underestimation by clinicians of the impact of these conditions on the lives of patients [15, 16] , the use of

PROMs in assessing the treatment of patients with chronic oral mucosal diseases is of great importance.

Cochrane reviews of clinical trials of oral mucosal disease (i.e. management of both oral lichen planus (OLP) [17, 18], mucous membrane pemphigoid (MMP) [19], along with other reviews in the area of bullous diseases [20, 21]) provide limited information regarding PROMs. No overview of current PROMs usage in oral mucosal diseases literature has been reported. The purpose of this systematic review was (i) to explore the PROMs currently used in the oral mucosal disease literature and to report on the type and context of the use of these instruments and (ii) to provide future direction for PROMs in oral medicine practice and research.

Materials and Method

Search Strategy

Search strategies for this review were designed to retrieve references relating to the use of PROMs in the oral mucosal diseases literature. An initial search was conducted using the following key terms: ‘patient centered’, ‘outcome measurement’, ‘patient defined’, ‘patient reported outcome’, ‘patient reported outcome measure’, ‘subjective outcomes’, ‘scale’, ‘score’, ‘instrument’, ‘research instrument’, ‘questionnaire’, ‘inventory’ AND ‘oral lichen planus’, ‘recurrent aphthous stomatitis’, ‘recurrent oral ulcers’, ‘mouth ulcers’ ‘pemphigoid’, ‘pemphigus’, ‘orofacial granulomatosis’, ‘Melkersson Rosenthal Syndrome’, ‘cheilitis granulomatosa’, ‘granulomatous cheilitis’. This search, carried out in November 2013, was developed for MEDLINE (through

PubMed), and then adapted to the other databases, including EMBASE, CINDHL, Web of Science Citation Index and the Cochrane Database of Systematic Reviews.

Inclusion and Exclusion Criteria

Articles were included in the review if they fulfilled the following criteria:

Publication in the English language, published in a peer-reviewed journal, inclusion of a report on the use of a PROM in patients with a specific oral mucosal disease as identified in our search strategy.

Articles were excluded from this review if they were based solely on author opinion, or if they were editorials or letters. Articles concerning the etiology, management or narrative reviews of oral mucosal disease were also excluded.

Data extraction

A specific data extraction form was constructed for this review. Each reviewer was calibrated with three articles, which had completed gold standard data extraction forms. Data items recorded included study aims and objectives; study type (population-based studies; questionnaire properties, development and validation-based studies; treatment-based studies); patient reported outcome measures used and study outcome. Each article was evaluated independently by two reviewers, with disagreements resolved by the primary author (RNR).

Results

Search results

The initial literature search yielded a total of 986 citations, to include duplicates and unrelated references. Following a review of the titles and abstracts, 189 abstracts were selected with 131 deemed suitable for inclusion in this systematic review (Table 1). These papers were then catalogued as: OLP studies (n=75) (Table 2), recurrent aphthous stomatitis (RAS) studies (n=30) (Table 3), bullous (mucous membrane pemphigoid/pemphigus vulgaris (MMP/PV) disease studies (n=14) (Table 4), orofacial granulomatosis (OFG) studies (n=1) (Table 5) and multi-disease (multi) studies (n=11) (Table 6) with the PROMs used. The most commonly used instruments were Visual Analogue Scales (VAS) and the Oral Health Impact Profile (OHIP).

Of the 75 OLP articles, 47 concerned treatment interventions, 5 related to questionnaire validity, sensitivity and correlation to clinical scoring systems, and 23 studies were population based. The VAS was the most commonly used of the 33 various PROMs used in OLP studies.

Of the 30 RAS articles, 20 were concerned with treatment interventions, one was related to the development of a clinical scoring system for both RAS and Behçet's disease with the incorporation of patient input using a VAS to record pain, and nine studies were population-based measuring the psychological impact of the disease and the quality of life in patients with RAS. Eleven studies used VAS, with this instrument being the most commonly used PROM in RAS studies.

Of the 14 MMP/PV articles, four were concerned with treatment interventions, two were related to the development or validation of clinical scoring systems that included VAS, and eight studies were population based evaluating periodontal status, quality of life and mental health. Ten PROMs were used with clinical scoring systems incorporating VAS. This instrument being the most commonly used PROM in MMP/PV studies.

Paediatric Quality of Life Inventory (PaedsQL) was used in the single OFG article of a patient cohort attending paediatric oral medicine clinics.

Eleven articles incorporated multiple oral mucosal diseases, with one exploring the use of topical clobetasol propionate in the treatment of RAS and OLP, five were related to the development of new instruments, namely Chronic Oral Mucosal Diseases Questionnaire (COMDQ) and the Autoimmune Bullous Disease Quality of Life questionnaire (ABQOL), or the validation of existing PROMs, and five studies were population based. Ten various PROMs were used with OHIP, with this instrument being the most commonly used PROM in these studies.

Discussion

The importance of patient involvement in their own healthcare should not be underestimated [22]. The paradigm of the clinician as the single determinant of clinical care is shifting to a shared decision-making process [23]. A patient who

is actively involved in his/her individual healthcare is more likely to have improved treatment compliance and better outcomes [24, 25]. National health bodies such as the National Heath Service (NHS) in the United Kingdom (UK) are now promoting quantification and formal registration of the impact of disease via PROMs. In an initiative launched in 2009, PROMs are now being used to determine the impact of surgical intervention in the management of hernias, large joint arthritides and varicose veins [26]. Work is underway to extend PROM usage to chronic diseases such as diabetes, asthma and stroke [9]. The United States' Food and Drug Administration (FDA) recommended the inclusion of PROMs in US clinical trials [1] and a more recent development is the FDA Patient Focused Drug Development Initiative. A list of 20 diseases that are chronic, symptomatic and affect the activities of daily living of patients, such as heart failure, fibromyalgia and inflammatory bowel disease, have been designated in the initial process to be explored between 2013 and 2015, gaining direct patient input on the impact of these diseases on their lives. This information will then be used by the FDA to assess applications for new drugs for treatment of these diseases. The patient narrative from this process will also be used to develop or refine PROMs relevant to these disease areas. Based on the results of this review, there is limited usage of PROMs in the oral mucosal disease literature, with oral medicine slowly adopting this global initiative of patient engagement.

When considering levels of evidence and robustness of research, a clear goal is to produce high-quality randomised controlled trials, the outcomes of which would lend themselves to systematic review and meta-analysis for

comprehensive comparisons to be made between management interventions. Due to difficulties caused by heterogeneity of outcome measures in research, the COMET initiative was established in the UK in 2010 to promote the creation of a core outcome set for research topics. The goal of this group is to determine the minimum set of outcome measures that should be used in clinical trials, audit of clinical services and other forms of clinical research for a particular disease. A detailed methodology has been developed including a literature review to establish current outcomes used, engagement with patient groups to determine which outcomes they consider to be important, and then ultimately produce a list, ratified by both patients and clinicians, as the core outcome measurements for future research [27]. As demonstrated from the heterogeneity of outcomes delineated in this review, oral medicine has yet to fully engage in this process. The greatest advancement in this area has been made in rheumatology [28, 29] although other areas of healthcare are also employing this process with a core outcomes group registered for head and neck cancer and for recurrent aphthous ulcers. Now that the heterogeneity has been established in OLP, RAS, OFG, MMP and PV, a forum such as the World Workshop on Oral Medicine could mediate the progress of core outcomes research in oral medicine using the results of this review as a foundation for engagement of both clinicians and patients and hence, the creation of a definitive core outcome measurement list.

Although it is important to promote the use of PROMs in research and clinical practice, it remains essential that instruments used should be valid, reliable and appropriately administered. The Patient-Centered Outcomes Research

Institute (PCORI) is a research group authorized by the United States Congress to facilitate informed decision-making by patients with regard to their healthcare [30]. Central to the work of PCORI is the promotion of robust methodology in PROMs, thereby ensuring 'more valid, trustworthy and useful information' [31]. From the papers analysed in this review, a number of ad hoc instruments were used for recording burning pain [32], quality of life and symptom improvement, [33] while others circumvented the rigorous process of instrument development by changing the wording of an existing questionnaire for use without examining the impact of this change on the psychometrics of the instrument [34]. The process of questionnaire development ideally involves patients throughout each stage from item derivation to validity and reliability testing [35]. Using ad hoc questionnaires to record symptoms, as was done in a number of the studies included in this review, calls into question the usefulness of the information derived. The most commonly used PROM was VAS. Research has been conducted regarding the importance of using a paper version of the instrument [36], the horizontal aspect of the scale [37] and the caution required when photocopying the instrument [38]. Authors often fail to stipulate the method of usage of the VAS in studies and therefore call into question the validity of the instrument as a PROM. The work of PCORI is important to provide direction not only to patients in healthcare decision-making, but also in raising awareness of the importance of the appropriate use of valid and reliable PROMs.

PROMs are being used as discriminators in determining the progression of drug management in patients with chronic disease. Current National Institute

for Clinical Excellence (NICE) guidance in the UK on the use of biologics in psoriasis state that a patient with a Dermatology Life Quality Index (DLQI) score of greater than 10 are eligible for biologics such as adalimumab, enteracept or ustekinumab [39]. DLQI is one of many valid and reliable dermatology-specific quality of life instruments that was developed in the early 1990s by Finlay and Khan [40]. The list of PROMs generated in this review identifies only one oral medicine- specific quality of life instrument[41, 42] which demonstrates the limited development and utilization to date of PROMs in oral medicine practice.

In conclusion, the overall utility of PROMs is still limited, particularly in clinical trials. With engagement of allied medical disciplines in PROM usage and the promotion of PROMs by national healthcare bodies globally, advancement of PROMs is imperative for oral medicine. The World Workshop forum, along with the potential involvement in COMET or other such initiatives, will enable worldwide collaboration to promote the development and utilization of valid and reliable PROMs in oral medicine to improve patient care.

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Table 1.

Patient-reported outcome measure (PROMs) used, frequency of use and associated mucosal disease

PROM	Abbreviation	No. of times used	Disease
Autoimmune Bullous Disease Quality of Life questionnaire	ABQOL	1	Multi* (1) [43]
Ad hoc patient reported outcome measures	Ad hoc	9	OLP **(7) [32, 33, 44-48] RAS*** (1) [49] MMP/PV**** (1) [50]
Beck Depression Inventory	BDI	4	OLP (4) [51-54]
Covi Anxiety Screen	CAS	1	OLP (1) [53]
Cattell 16 Personality Factors	Cattell 16PF	2	OLP (2) [53, 55]
Cornell Medical Index Health Questionnaire	CMI	1	OLP (1) [47]
Chronic Oral Mucosal Diseases Questionnaire	COMDQ	3	Multi (3) [42, 56, 57]
Clinical Scoring System	CSS	9	OLP (3) [58-60] RAS (1) [61] MMP/PV (5) [62-66]
Dermatology Life Quality Index	DLQI	2	MMP/PV (2) [67, 68]
General Health Questionnaire	GHQ	5	OLP (2) [69, 70] MMP/PV (2) [67, 68] Multi (1) [71]
Hospital Anxiety and Depression	HAD	5	OLP (1) [55] RAS (1) [11] MMP/PV (1) [72] Multi (2) [73, 74]

Hamilton Anxiety Scale	HAS	1	OLP (1) [75]
Hassanyeh Rating of Anxiety-Depression-Vulnerability	Hassanyeh RADV	1	OLP (1) [53]
Insitute for Personality and Ability Testing	IPAT-CDQ	1	MMP/PV (1) [76]
Karolinska Scales of Personality	KSP	1	OLP (1) [77]
Lipp's Inventory of Stress and Symptoms	LISS	1	OLP (1) [51]
Montgomery-Asberg Depression Rating Scale	MADRS	1	OLP (1) [75]
Minnesota Multiphasic Personality Inventory	MMPI	1	OLP (1) [78]
McGill Pain Questionnaire	MPQ	2	OLP (2) [79, 80]
Numerical Rating Scale	NRS	5	OLP (3) [58, 81, 82] RAS (2) [83, 84]
Oral Health Impact Profile	OHIP	19	OLP (10) [14, 34, 79, 80, 85-90] RAS (3) [91-93] Multi (6) [13, 42, 71, 73, 94, 95]
Oral Health-Related Quality of Life	OHQoL	3	OLP (2) [80, 89] Multi (1) [13]
Oral Impacts on Daily Performance	OIDP	1	RAS (1) [96]
Paediatric Quality of Life Inventory	PaedsQL	1	OFG (1) [97]
Paykel's Inventory	PI	1	MMP/PV (1) [98]
Profile of Mood States	POMS	1	OLP (1) [99]

Patient Satisfaction Questionnaire	PSQ	1	OLP (1) [52]
Perceived Stress Scale	PSS	1	OLP (1) [70]
Quick Inventory of Depressive Symptomatology	QIDS	1	RAS (1) [100]
Raskin Depression Screen	RDS	1	OLP (1) [53]
Recent Life Changes Questionnaire	RLCQ	1	RAS (1) [101]
Self-rating Anxiety Scale	SAS	1	RAS (1) [102]
Medical Outcomes Study Short Form	SF	5	MMP/PV (2) [76, 103] Multi (3) [71, 94, 95]
State-Trait Anxiety Inventory	STAI	6	OLP (6) [12, 52-54, 104, 105]
Visual Analogue Scale	VAS	72	OLP (47) [14, 34, 58, 60, 79, 80, 85, 86, 90, 106-143] RAS (19) [91, 93, 144-161] MMP/PV (2) [162, 163] Multi (4) [13, 42, 73, 164]
Xerostomia Inventory	XI	1	OLP (1) [165]

*Multi: multiple mucosal diseases

**OLP: oral lichen planus

***RAS: recurrent aphthous stomatitis

****MMP/PV: mucous membrane pemphigoid/pemphigus vulgaris