World Workshop on Oral Medicine VIII: Development of a core outcome set for oral lichen planus: a systematic review of outcome domains

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Objective. There is a lack of consensus regarding clinician- and patient-reported oral lichen planus (OLP) outcomes. The World Workshop on Oral Medicine Outcomes Initiative for the Direction of Research (WONDER) Project aims to develop a core outcome set (COS) for OLP, which would inform the design of clinical trials and, importantly, facilitate meta-analysis, leading to the establishment of more robust evidence for the management of this condition and hence improved patient care.

Study Design. Ovid MEDLINE, Embase, CINAHL, CENTRAL, and Clinicaltrials.gov were searched for interventional studies (randomized controlled trials, controlled clinical trials, and case series including ≥5 participants) on OLP and oral lichenoid reactions published between January 2001 and March 2022 without language restriction. All reported primary and secondary outcomes were extracted.

Results. The searches yielded 9,135 records, and 291 studies were included after applying the inclusion criteria. A total of 422 outcomes were identified. These were then grouped based on semantic similarity, condensing the list to 69 outcomes. The most frequently measured outcomes were pain (51.9%), clinical grading of the lesions (29.6%), lesion size/extension/area (27.5%), and adverse events (17.5%).

Conclusion. As a first step in developing a COS for OLP, we summarized the outcomes that have been used in interventional studies over the past 2 decades, which are numerous and heterogeneous. (Oral Surg Oral Med Oral Pathol Oral Radiol 2023;135:772−780)

Oral lichen planus (OLP) is a common, immune-mediated condition that affects nearly 1% of the global population.[1] Although the exact etiology remains unknown, the development of OLP is hypothesized to result from an interplay between the immunologic system, environmental factors, and genetic

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Statement of Clinical Relevance

As a first step in developing a core outcome set for oral lichen planus, this systematic review summarizes the outcomes that have been used in interventional studies for this condition over the past 2 decades.

predispositions.[2] Oral lichen planus typically presents with bilaterally symmetric white reticular striations involving the oral mucosa. Variable degrees of severity and extent of erythema, erosions, and ulcerations may also be present.[3,4] These features are characterized by pain, burning sensation, and discomfort, which decrease the patient's quality of life.[5] Given this condition's chronic nature, the primary goal of treatment is to alleviate patient discomfort. In many individuals, achieving long-term complete resolution of symptoms and lesions is not feasible or realistic.

In addition to measuring the impact of therapeutics on symptoms, interventional studies on OLP have used a wide variety of outcome measures, both clinician and patient-reported, rendering meta-analysis of data across these studies difficult. A recent Cochrane review on interventions for treating OLP highlighted the lack of standardization in the primary outcome measures evaluated and methods used to measure them.[6] Outcome measures used in trials were traditionally selected by investigators alone. Initiatives such as Outcome Measures in Rheumatology have served a critical role over the past 20 years in developing core outcome sets (COS) and validating clinical and radiographic outcome measures in several rheumatic diseases.[7] A COS is an agreed standardized set of outcomes that should be measured and reported, as a minimum, in all clinical trials of a specific condition.[8] They do not imply that outcomes in a particular study should be restricted to those in the COS. Instead, there is an expectation that the core outcomes will be collected and reported to allow the results of trials and other studies to be compared, contrasted, and combined as appropriate and that researchers will continue to collect and explore other outcomes. Notably, COS must be developed with the input of different stakeholders, including clinicians, researchers, and patients.

Currently, the use of COS in oral mucosal disease research is practically non-existent. The World Workshop on Oral Medicine Outcomes Initiative for the Direction of Research (WONDER) Project was launched in January 2020 to develop COS for different oral conditions such as OLP. Developing a COS for OLP would standardize the results to be reported, reduce investigator bias, and facilitate meta-analysis, leading to more robust evidence for the management of OLP and hence improved patient care. Once the need to develop a COS has been established, the process's first step consists of identifying outcomes used in previous interventional studies. For this purpose, we conducted a systematic review to identify all primary and secondary outcomes reported in interventional studies on OLP over the past 2 decades.

MATERIALS AND METHODS

The protocol was registered in the International Prospective Registry of Systematic Reviews (PROSPERO) (Registration number: CRD42021266357) and the Core Outcome Measures in Effectiveness Trials (COMET) Database (https://www.comet-initiative.org/Studies/Details/1558). This systematic review was conducted following the Core Outcome Measures in Effectiveness Trials Handbook,[8] and was reported based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols statement.[9]

Eligibility criteria

Inclusion criteria. We included all interventional studies (e.g., randomized controlled trials [RCTs], controlled clinical trials [CCTs], and case series including 5 or more participants) published in any language between January 1st, 2001 and March 8th, 2022 investigating any active treatment (preventive, palliative, or curative, either pharmacologic or non-pharmacologic) administered topically or systemically in patients with OLP or oral lichenoid reactions (OLRs). The latter group of oral mucosal diseases was included as their associated symptoms and clinical and histopathologic features resemble those of OLP. Only the outcomes related to the oral lesions were extracted for interventional studies of mucocutaneous disease. The patients must have been diagnosed clinically with or without histopathologic confirmation. All comparators/controls were included: usual treatment, alternative treatment, placebo, or no treatment to assess the effectiveness of the investigated intervention.

Exclusion criteria. We excluded non-interventional studies and studies involving patients with malignant comorbidity (e.g., graft-vs-host disease and paraneoplastic autoimmune multiorgan syndrome) or histopathologically diagnosed with oral epithelial dysplasia. Also, studies investigating treatments for extraoral involvement only were excluded.

Information sources and search strategy

An exhaustive search was performed by a librarian on July 15th, 2021, and March 8th, 2022, in the following electronic databases: Ovid MEDLINE, Embase, CINAHL, CENTRAL, and Clinicaltrials.gov. The

search strategy used on each electronic database is shown in Table I.

Selection process

The search records were exported into EndNote 20 (Clarivate, PLC, London, UK). After removing the duplicates, R.M.L-P., S.S.K.R., J.A.V., H.D., C.B., C.H., R.N.R., J.T., and J.R-S. screened full titles and abstracts independently using Microsoft Excel for Mac (Microsoft, Corp, Redmond, WA, USA) to identify the studies that met the inclusion criteria. Then, R.M.L-P., M.D-F., S.S.K.R., J.A.V., H.D., and C.B. independently read the identified studies in full text. One investigator screened each reference. Any disagreements were resolved by discussion with J.R-S. and J.T.

Data collection process and data items

R.M.L-P., M.D-F., S.S.K.R., J.A.V., H.D., and C.B. independently extracted the data from the selected studies using a tool designed in Google Forms (Google, LLC, Mountain View, CA, USA) specifically for this purpose (Supplemental Table S1). One investigator extracted the following data from each study: reference number, title, names of the authors, journal, year of publication, country of origin, study design (RCT, CCT, or case series), language, the primary outcome, and the secondary outcome(s). All studies not written in English were translated to extract the study design and the primary and secondary outcomes. Any doubts were resolved with J.T. and J.R-S. Finally, the collected data were exported into Microsoft Excel for Mac (Microsoft, Corp).

Table I. Search strategy used on each electronic database

Source	*Interface*	*Search strategy*	*Retrieved records*
MEDLINE	OvidSP	1 Lichen Planus, Oral/ (2604) 2 ("lichen planus" and (mouth or oral)).tw. (3984) 3 (OLP and (oral or mouth)).tw. (1623) 4 or/1-3 (4476) 5 (lichenoid and reaction* and (oral or mouth)).tw. (360) 6 (OLR and (oral or mouth)).tw. (48) 7 or/5-6 (369) 8 4 or 7 (4624)	3391
EMBASE	OvidSP	1 ("lichen planus" and (mouth or oral)).tw. (5086) 2 (OLP and (oral or mouth)).tw. (1872) 3 or/1-2 (5125) 4 (lichenoid and reaction* and (oral or mouth)).tw. (525) 5 (OLR and (oral or mouth)).tw. (54) 6 or/4-5 (538) 7 3 or 6 (5419)	3993
CINAHL	EBSCOhost	S1 (MH "Lichen Planus, Oral") (980) S2 TI ((("lichen planus") and (mouth or oral))) OR AB ((("lichen planus") and (mouth or oral))) (1,051) S3 TI ((OLP and (oral or mouth))) OR AB ((OLP and (oral or mouth)))(497) S4 S1 OR S2 OR S3 (1,283) S5 TI (((lichenoid and reaction*) and (oral or mouth))) OR AB (((lichenoid and reaction*) and (oral or mouth))) (97) S6 TI ((OLR and (oral or mouth))) OR AB ((OLR and (oral or mouth))) (19) S7 S5 OR S6 (100) S8 S4 OR S7 (1,315)	1245
CENTRAL	Cochrane Library/Wiley Interscience	#1 MeSH descriptor: [Lichen Planus, Oral] explode all trees (186) #2 (("lichen planus") and (mouth or oral)):ti,ab (457) #3 (OLP and (oral or mouth)):ti,ab (228) #4 {or #1-#3} (483) #5 ((lichenoid and reaction*) and (oral or mouth)):ti,ab (13) #6 (OLR and (oral or mouth)):ti,ab (3) #7 {or #5-#6} (15)	430
Clinicaltrials.gov	https://clinicaltrials.gov/	Condition or disease: Oral Lichen Planus or Oral Lichenoid Reaction	76

Study quality assessment

Because all interventional studies reporting outcome measures were included and their results were not considered, the studies were not assessed regarding their risk of bias or graded.

Statistical analysis

The descriptive analyses (frequency distribution) were performed using IBM SPSS Statistics for Windows, Version 27.0 (IBM SPSS, Inc, Armonk, NY, USA).

RESULTS

The database searches yielded 9,135 records, of which 3,045 were duplicates (Figure 1). After screening 6,090 references by title and abstract, 5,405 were excluded for not meeting the inclusion criteria. Of the remaining 685 studies, 18 could not be retrieved, and 667 were evaluated in full text. Of these, 374 did not meet the inclusion criteria, and 2 were duplicated. Therefore, 291 studies were included in this systematic review (Supplemental Table S2).

One hundred and two studies (35%) were published between 2001 and 2010, 158 (54.3%) between 2011 and 2020, and 31 (10.7%) between 2021 and March 8th, 2022. The studies were published in 135 journals in various fields, such as dentistry, maxillofacial surgery, medicine, dermatology, otorhinolaryngology, and laser therapy. Most studies were conducted in Asia (47%), followed by Europe (34.3%), America (11.3%), Africa (6.8%), and Australia (0.6%) (Figure 2). Only 2 studies had a multicenter approach, of which 1 was conducted across different continents (Europe and North America). Regarding the study design, 155 (53.3%) were RCTs, 39 (13.4%) CCTs, 90 (30.9%) case series, and 7 (2.4%) were retrospective studies of clinical records. Finally, 270 (92.8%) were published in English, 13 (4.5%) in Mandarin Chinese, 4 (1.4%) in Persian, 2 (0.7%) in Russian, 1 (0.3%) in French, and 1 (0.3%) in German.

After removing the duplicates, 422 outcomes were identified (Supplemental Table S3). Three investigators (R.M.L-P., M.D-F., J.R-S.) grouped the synonyms or semantically related outcomes, obtaining a final list of 69 items (Table II). "Pain" was the most frequent outcome, measured in 51.9% of the studies. Other types of symptoms such as burning sensation (12.4%), discomfort (4.1%), xerostomia (1.4%), itching (1%), taste disorders (1%), pruritus (0.7%), irritation (0.3%), and soreness (0.3%) were also identified. Forty-three studies (14.8%) measured symptoms without specifying the type. Other commonly measured outcomes included "clinical grading of the lesions" (29.6%), "lesion size/extension/area" (27.5%), "adverse events/side effects" (17.5%), "clinical response to treatment" (14.1%), "type of lesion" (13.4%), "recurrence" (11.7%), "disease severity" (10%), and quality of life (8.6%).

Outcomes such as complete blood count, glucose, and coagulation tests were grouped into the "biochemical analyses" category. Outcomes such as bleeding on probing, plaque index, and probing depth were grouped into the "clinical periodontal parameters" category.

DISCUSSION

The development of a COS is a multi-stage process aimed at standardizing the selection, measuring, and reporting of treatment outcomes to facilitate study comparison and data pooling in systematic reviews and meta-analyses, thus leading to more robust evidence-based interventions.[8] The first step in developing a COS involves identifying the outcomes used in previous interventional studies for a specific condition (Figure 3). Then, focus groups of patients with this condition are incorporated to identify other relevant outcomes through synergistic discussions between individuals with different disease experiences.[10] Thereafter, various working groups gather the individual outcomes identified through these 2 processes into outcome domains. Finally, various voting procedures have achieved a consensus among the stakeholders (i.e., clinicians, researchers, and patients) on the domains to be included in the COS.[11-13] Thus, as the first step in developing a COS for OLP, this study summarizes the outcomes used in interventional studies for this disease over the past 2 decades.

Through a comprehensive scientific literature search, we identified 422 unique terms used as treatment outcomes for OLP. This finding highlights the lack of standardized terminology and the wide variety of outcomes used in interventional studies to measure the efficacy of OLP treatments. As many of these outcomes were synonyms or semantically related, we grouped these terms into a condensed list of 69 outcomes, which was central for constructing the outcome domains in the later stages of the process. As the primary goal of treating OLP is to alleviate symptoms, patient-reported outcomes (PROs) are critical to assessing whether clinicians are improving patients' health.[14] In this systematic review, "pain" was the most frequently used outcome, but other PROs, such as "burning sensation," "discomfort," "xerostomia," "itching/pruritus," "taste disorders," "irritation," and "soreness," were also identified. Altogether, symptoms were used as an outcome in 253 studies.

Clinician-reported outcomes related to the appearance and severity of the lesions were also frequently used and included "clinical grading of the lesions," "lesion size/extension/area," "type of lesion," "disease severity," "clinical signs," "clinical characteristics of

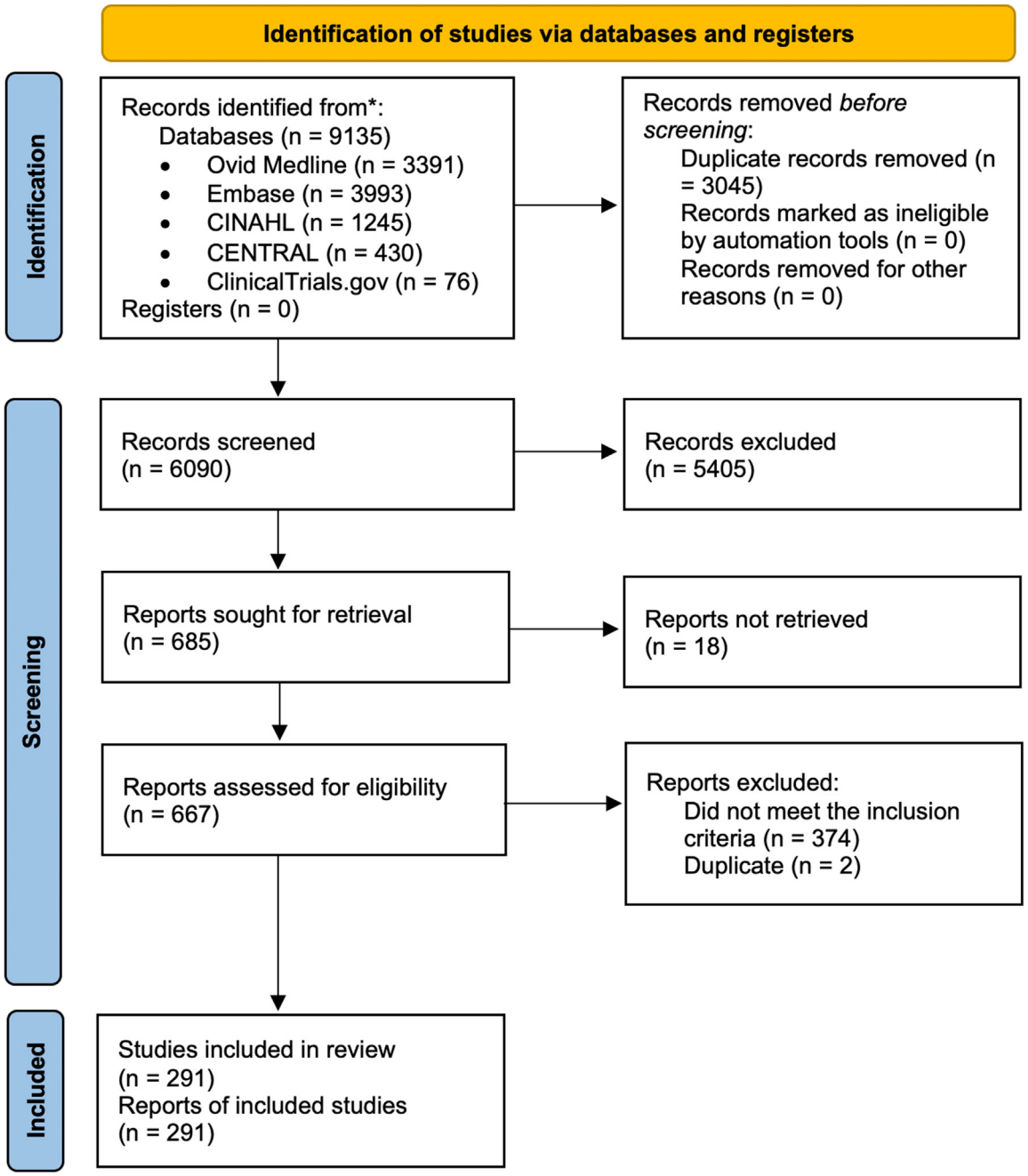

Fig. 1. Flow diagram of the literature search according to the Preferred Reporting Items for Systematic Review and Meta-Analyses.

the lesions," "the number of erosions," "the number of lesions," "color," "erythema size," and "surface texture." Altogether, these outcomes were used in 296 studies.

Exacerbations and remissions characterize the clinical course of OLP.[15] Furthermore, the treatment response between patients is highly variable. Therefore, it is essential for a clinical trial to measure the behavior of lesions and symptoms over time. A cumulative of 108 studies used timeline-related outcomes, such as "clinical response to treatment," "recurrence of lesions/relapse," "resolution of lesions," "period between the start of treatment and remission," "complete healing time," "stability of the result/effect," and "lesion-free period."

In contrast, some PROs and clinician-reported outcomes were reported in a remarkably low number of studies. For example, adverse events were only

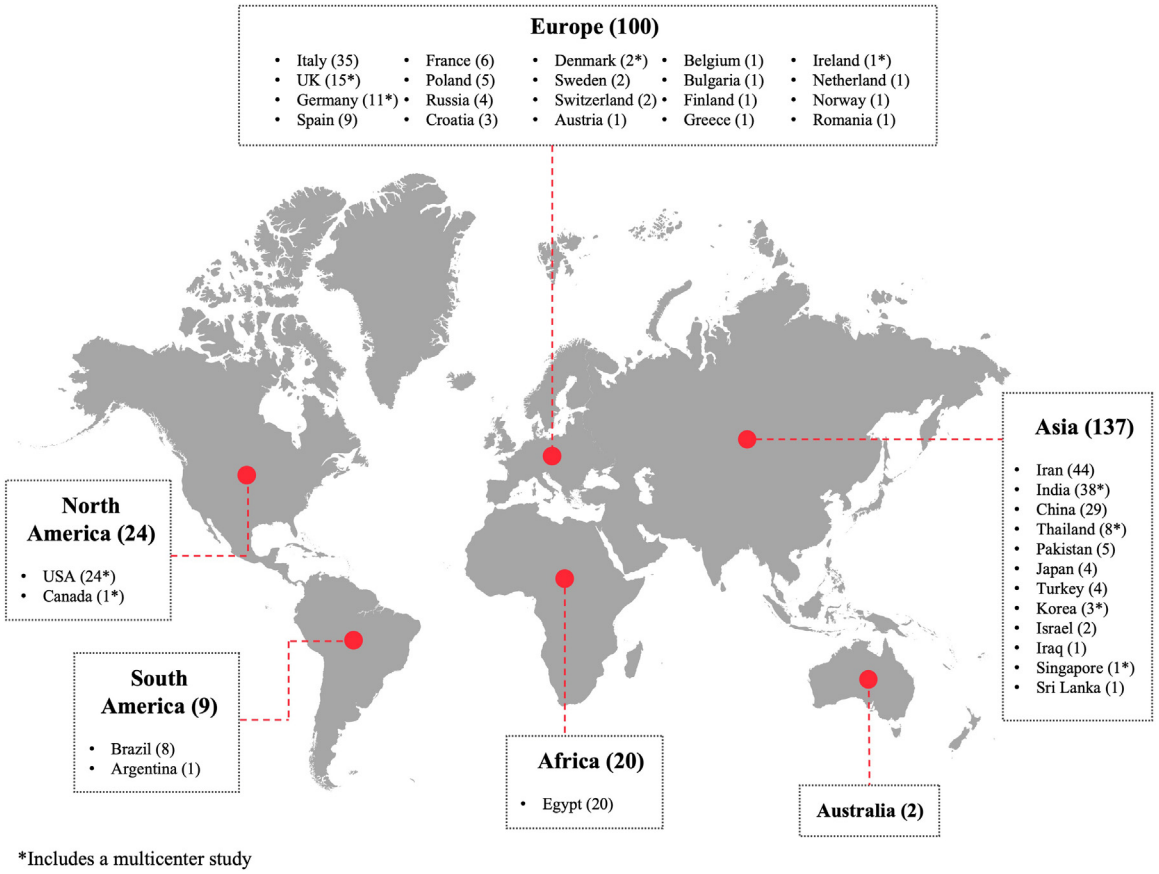

Fig. 2. Number of studies included by country and continent.

measured in a cumulative of 58 studies. Of these, 9 reported "clinical diagnosis of candidiasis" and "malignant transformation" as adverse events of topical corticosteroids, although little is known about the role of these medications in the promotion of carcinogenesis. Other outcomes related to the psychosocial impact, such as "quality of life," "oral function," "anxiety and depression," "interference with daily activities," "maximum mouth opening," "breath odor and oral freshness," and "psychological recovery," were used in 46 studies. Also, only 1 study used the "need for rescue medication" as a secondary outcome.

Interestingly, 59 studies measured crevicular fluid, cytologic, salivary, serologic, or histopathologic biomarkers in patients with OLP before and after treatment. Currently, no biomarker or biochemical analysis has been shown to accurately assess the patient's symptoms, the clinical or histopathologic changes of the lesions, or the malignant progression.[16] Furthermore, many of these investigations are invasive and expensive. Therefore, these outcomes are unlikely to be included in the COS.

A recent review of the outcome measures used in RCTs on OLP since 2004 showed diversities in outcome selection, high heterogeneity of outcome measures, low degree of consensus on measurement methods, inadequate reporting of adverse effects, and little focus on oral health-related quality of life.[17] The methodological limitation of many trials is the lack of standardized outcome measures, which has been emphasized since the early 2000s.[18] Our systematic review aimed to collect information on the reported outcomes and not on the measurement instruments or timing of measurements, as this is a future stage of COS development.[19]

The strength of this systematic review is the comprehensive screening of all interventional studies published on OLP and OLRs in the past 21 years. Firstly, the search was not limited to RCTs but included all other types of interventional studies, such as CCTs and case series (including $\geq$5 participants), investigating any active treatment administered topically or systemically in patients with OLP and OLRs. Secondly, we included all interventional studies on OLRs (e.g., oral lichenoid contact reactions, oral lichenoid drug reactions, and oral lichenoid lesions of graft-vs-host-disease) because these conditions may occasionally represent a diagnostic challenge for their clinical and histopathologic similarity to OLP. Furthermore, the symptoms associated with OLRs are indistinguishable

Table II. Summary of the outcomes used in interventional studies on oral lichen planus

Outcome	*No. of studies*	*%*
Pain	151	51.9
Clinical grading of the lesions/clinical score/clinical index	86	29.6
Lesion size/extension/area	80	27.5
Adverse events/side effects	51	17.5
Symptoms	43	14.8
Clinical/treatment response	41	14.1
Type of the lesion	39	13.4
Burning	36	12.4
Recurrence of lesions/relapse	34	11.7
Disease severity	29	10.0
Quality of life	25	8.6
Treatment efficacy	24	8.2
Clinical improvement	23	7.9
Serological biomarkers	20	6.9
Clinical signs	18	6.2
Clinical assessment of the disease (e.g., site, severity, activity)	17	5.8
Resolution of lesions	16	5.5
Extension of lesions	15	5.2
Assessment of the clinical presentation of the lesions	14	4.8
Remaining disease	13	4.5
Clinical characteristics of the lesions	12	4.1
Discomfort	12	4.1
Biochemical analyses (e.g., CBC, glucose, fibrinogen, SGOT, SGPT, PT, PTT, TT)	11	3.8
Safety	10	3.4
Clinical evaluation	9	3.1
No. of erosions	9	3.1
Salivary biomarkers	9	3.1
Period between the start of treatment and remission	8	2.7
Histological biomarkers	8	2.7
Periodontal parameters (plaque index, bleeding on probing)	8	2.7
Color	7	2.4
No. of lesions	7	2.4
Oral function	7	2.4
Histopathologic features	7	2.4
Erythema size	6	2.1
Anxiety and depression	6	2.1
Complete healing time	6	2.1
Interference with daily activities	5	1.7
Clinical diagnosis of candidiasis	5	1.7
Xerostomia	4	1.4
Compliance	4	1.4
Treatment satisfaction	4	1.4
Malignant transformation	4	1.4
Resolution of symptoms	4	1.4
Lesion location	3	1.0
Surface texture	3	1.0
Itching	3	1.0
Taste disorders	3	1.0
Tolerance to treatment	3	1.0
Candida carriage	3	1.0
Pruritus	2	0.7
Treatment success	2	0.7
Toxicity	2	0.7
Stability of the result/effect	2	0.7
Cytological biomarkers	2	0.7
Salivary flow rate	2	0.7
Detection of salivary bacteria	2	0.7
Irritation	1	0.3
Soreness	1	0.3
Maximum mouth opening	1	0.3
Breath odor and oral freshness	1	0.3
Psychological recovery	1	0.3
Cost	1	0.3
Cost-effectiveness/benefit	1	0.3
Lesion-free period	1	0.3
Use of rescue medication for pain management	1	0.3
Crevicular fluid biomarkers	1	0.3
Total volume of gingival crevicular fluid	1	0.3
Salivary consistency	1	0.3

CBC, complete blood count; *SGOT*, serum glutamic-oxaloacetic transaminase; *SGPT*, serum glutamic pyruvic transaminase; *PT*, prothrombin time; *PTT*, partial thromboplastin time; *TT*, thrombin time.

from those of OLP. Therefore, by increasing the number of studies, we ensured that all potential outcomes were included. Thirdly, the search included all studies involving patients without a histopathologically confirmed diagnosis, not to limit the number of studies. In many trials, the diagnosis of OLP or OLRs was made based on the clinical features of the lesions only. Finally, no language restriction was applied.

The first limitation of this review is related to the year limit applied to the searches. We decided not to include articles published before 2001 because a preliminary PubMed search of RCTs and clinical trials

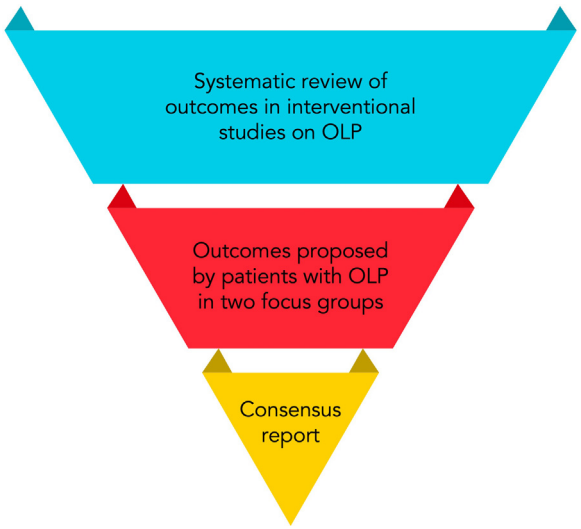

Fig. 3. Three-stage approach for developing a core outcome set for oral lichen planus (Adapted from Taylor et al., 2017).

on OLP showed that >70% were published after 2001. In addition, due to the large number of studies elicited (9,135), each abstract was screened only by a single investigator, which could have resulted in selection bias.

In summary, this systematic review presents a list of 69 outcomes used in interventional studies over the past 2 decades and highlights the lack of standardized terminology and the wide variety of outcomes used to measure the efficacy of OLP treatments. These outcomes will be discussed in focus groups of patients with OLP[20] and other working groups, including oral medicine experts (clinicians and researchers) at the 2022 American Academy of Oral Medicine Annual Conference[21] in Memphis, TN, USA, to achieve a consensus on the domains to be included in the COS for OLP.

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DECLARATION OF INTEREST

None.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.oooo.2023.01.014.

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