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ORIGINAL ARTICLE

Validity, reliability and optimisation of the TOPICOP questionnaire for oral lichen planus

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ABSTRACT

Objectives: Due to their anti-inflammatory and immunosuppressive effects, topical corticosteroids (TCs) are commonly used for the treatment of patients with oral lichen planus (OLP) with an erosive or ulcerative component. It has been suggested that many of these patients may suffer from fear or anxiety as a result of prolonged treatment with TCs. The objective of this study was twofold: (1) to optimise a patient reported outcome measure (PROM) in order to explore this feature, and (2) to evaluate this PROM in the treatment of OLP patients.

Methods: A group of qualitative researchers adapted the TOPICOP questionnaire in order for it to be used as a PROM for OLP *via* structural equation modelling (SEM) and internal consistency (IC) analysis. Consequently, 34 patients with symptomatic OLP who were undergoing treatment with TCs completed a questionnaire and underwent a clinical assessment.

Results: SEM presented an adequate fit (RMSA = 0.07, CFI = 0.94 and WRMR = 1.18), as well as a high IC ($\alpha = 0.81$). A total of 16 patients (47.1%) reported TCs phobia. The receiver operating characteristic analysis (ROC) revealed that a TOPICOP value $\geq$50% predicted the presence of TCs phobia with a sensitivity of 93% and a specificity of 100%.

Conclusions: The optimised TOPICOP scale proved valuable as a PROM in OLP. TCs phobia can be a real consideration in OLP, nonetheless, it does not appear to be an impediment to treatment adherence.

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Oral lichen planus; patient reported outcome measures; steroid phobia; topical corticosteroid; TOPICOP

Introduction

A phobia is a type of anxiety disorder which has been defined in the Diagnostic and Statistical Manual of Mental Disorders Fifth Edition [1] as a persistent and excessive fear of an object or situation. Functional brain imaging studies have demonstrated that amygdala and insula hyper-reactivity are common findings among phobic subjects. In this line, and from a neurobiological perspective, limbic dysfunction and hypothalamo-pituitary-adrenocortical axis dysregulation represent the key neural networks in the understanding of this psychological disorder [2].

The American Psychiatric Association classifies phobias into three main categories: specific phobias, agoraphobia and social phobias. A specific phobia is considered as an unreasonable or irrational fear which is related to exposure to specific objects or situations [2]. This subcategory of anxiety disorder affects up to 12% of people at some point in their life [3]. Pharmacophobia or medication phobia is a type of specific phobia, defined as the fear of using pharmacological treatments. Many patients lack the sufficient health literacy skills in order to be involved in shared decision-making and this ultimately contributes towards the onset of this anxiety disorder [4]. In addition, different cognitive patterns can lead *per se* to the refusal or non-adherence to necessary pharmacological interventions, therefore emphasising the need to inform and educate patients [5].

Corticosteroids are commonly highlighted among the described drugs that represent a significant risk of pharmacophobia [6]. This kind of specific phobia has been named as corticophobia and since it was first described by Tuft et al. back in 1979 [7] it has been presented as a relevant and ubiquitous phenomenon in several medical specialties. Topically delivered formulations of these steroids are considered as the gold standard therapeutic option for the management of many mucosal and skin diseases. In this line, topical corticosteroids (TCs) are widely used in dermatology and oral medicine as symptomatic but not curative therapies for many disorders [8]. TCs are frequently used for unpredictable and often prolonged periods [9]. Therefore, the detection of corticophobia and related non-adherence to TCs may play a pivotal role in the search for treatment efficiency [5].

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Supplemental data for this article can be accessed here.

Recently, dermatological literature has placed special emphasis on the effects of TCs phobia in atopic dermatitis (AD) patients [10–12]. According to a recent systematic review, the prevalence of TCs phobia among AD-affected patients and patients' caregivers ranges from 21.0% to 83.7%, and it is understood that this may be associated with a high rate of non-adherence. Nonetheless, the authors highlighted that the nomenclature and assessment methods for TCs phobia lack standardisation and validation as a patient-reported outcome measure (PROM) [13]. Two of the main scales which are used to evaluate TCs phobia among AD patients are the TOPICOP scale and the 10-point visual analogue scale (VAS) [11].

To the best of our knowledge, no previous study has focussed on identifying TCs phobia and its possible related outcomes in an oral mucosa disorder. Nonetheless, oral medicine specialists and general dental practitioners frequently use TCs for the treatment of several oral diseases [14]. In this vein, oral lichen planus (OLP) occasionally produces severe erosive or ulcerative lesions that can have an impact on the patient's quality of life and on their psychosocial interaction [8]. Our group has recently evidenced, by means of a case-control study, the presence of a marked somatisation among affected individuals [15]. The symptoms of OLP frequently require the use of high-potency TCs [16]. According to a recent review, the PROMs currently used for patients with OLP focus predominantly on their symptoms, psychosocial status and quality of life, however, no specific PROM is available to detect TCs phobia [17].

Prompted by the discussed literature, the objective of the present study was twofold: (i) to optimise a patient reported outcome measure (PROM) to explore this feature, and (ii) to evaluate the effects of this PROM in the treatment of OLP-affected patients.

Methods

Before commencing this study, approval was received from the local ethics committee (Ref. 1023/17), and from the Galician Committee for Medicinal Products for Human Use (Ref. 2019/355).

All of the participants gave their written informed consent. The research was conducted in accordance with the ethical principles stated in the World Medical Association Declaration of Helsinki.

Study design and participants

A single-centre, questionnaire-based, cross-sectional study of patients attending the Oral Medicine Unit of the University of Santiago de Compostela, Spain, was conducted between September 2018 and February 2019. The following inclusion criteria were applied; (i) patients with a histological diagnosis of OLP according to the World Health Organisation criteria [18]; (ii) patients with painful lesions which were being treated with a 0.3% or 0.5% triamcinolone acetonide (TA) mouth rinse; (iii) patients with a follow-up period of more than four months. The following exclusion criteria were applied; (i) patients being treated with other doses or formulations of TA, or patients being treated with other TCs; (ii) patients with contraindications for TCs use (immunodeficiency, severe haematological alterations, pregnancy or lactation); (iii) the presence of candidiasis prior to treatment; (iv) patients who were unable to read/speak Spanish and (v) patients undergoing co-treatment with TCs for oral lesions.

The patients were assessed by means of a detailed recollection of anamnestic data and oral symptoms, followed by a conventional oral examination and photographic documentation of the observed lesions by a single oral medicine specialist (MPS). The following data was collected; age; sex; reason for consultation; smoking habits; lesion location; lesion shape and the characteristics of the lesion according to the Thongprasom Index [19]; treatment received; and the incidence of fungal over-infection. According to Thongprasom et al. the clinical presentation of OLP can be scored from 0 to 5 according to the following findings: (0) no lesion; (1) mild white lesions without erythematous areas; (2) white striae with atrophic lesions $\leq$ 1 cm; (3) white striae with atrophic lesions $>$ 1 cm; (4) white lesions with ulcerative areas $\leq$ 1 cm; and (5) white lesions with ulcerative areas $\geq$ 1 cm [19]. Fungal over-infection was identified by means of a clinical examination and it was tested by conventional culture (>50 colony-forming units per square mm) using the API ID 32 C yeast identification kit (bioMédrieux, Marcy l'Etoile, France) [20].

All of the patients were prescribed an aqueous solution containing TA at 0.3% or 0.5%. Patients were instructed to rinse their mouth three times daily with 10 ml of the solution for five minutes until resolution. In the first month after remission, this treatment regimen was changed to two minute rinses with 10 ml of the solution and this was subsequently reduced to one minute rinses in the second month after remission followed by a six-month maintenance (i.e. treatment reduction phase). Patients were included in the study at any point of this protocol. This protocol was previously described by our group [20]. In order to check the level of adherence, the TCs containers were weighed at all of the scheduled appointments from the moment in which these were given out.

Instrument optimisation and validation

A survey was provided to all participants after anamnestic collection by the participating researchers. In order to obtain more reliable PROM measures, participation in the study was completely anonymous. The participants were given a paper copy of the questionnaires at the end of consultation, in accordance with the blinding assessment protocol and bearing in mind the subjective nature of this specific PROM.

The questionnaire included two initial questions: (1) 'Do you have concerns about using a steroid mouth rinse prescribed by your dentist?', and (2) 'Have you ever not used the steroid creams as prescribed due to your concerns about using them?'. There were only two possible answers (yes or no) for the first part of this questionnaire. These questions made it possible to divide patients in relation to their TCs

phobia (TCs phobia + vs. TCs phobia –) and treatment adherence (adherent vs. non-adherent).

PROM validation was constructed by confronting it to a gold-standard checklist, the COnsensus based Standards for the selection of health Measurement INstruments (COSMIN) [21]. The COSMIN taxonomy is organised in nine measurement properties which are clustered within three domains (i.e. reliability, validity, and responsiveness); in particular, a variation described by Terwee et al. [22] was used to establish a rating system (Table 1).

Thereafter, a 0–10 Visual Analogue Scale (VAS) and a modification of the TOPICOP scale were used [10,11] to assess the intensity of the patients' concerns when using TCs. According to the VAS scale, 1 represented the least intense fear and 10 represented the most intense fear; this scale has been extensively used as a PROM for OLP so it was not subjected to any further analysis [17].

On the other hand, TOPICOP is a scale ranging from 0–36, in which the global results are expressed as a percentage. The TOPICOP questionnaire was comprised of 12 items, covering two dimensions relative to 'worries' (WOR) and 'beliefs' (BEL), where scores of 0–3 points were attributed (four sections). This scale was originally designed by a qualitative research approach by means of focus-groups and it was validated using Jöreskog's linear structural–relationships method [10]. The TOPICOP scale is the only available method for quantitatively measuring TCs phobia and several articles have highlighted its potential use as a PROM, especially in the case of AD patients [10–12]. In order to extrapolate the data, a Delphi-like approach was applied [23]. In this vein, the original TOPICOP questionnaire and an information sheet including the study objectives were sent by email to ten experts in the field: two psychologists, two psychiatrists, two dermatologists, and four specialists in Oral Medicine. Each of them evaluated two dimensions per item (reliability and validity) using a 5-point Likert scale. The statistical median at the end of the first round of this procedure and the participants' feedback was collected. In this line, all of the questions, except three (4, 8, and 9) were deemed appropriate by all participants. Subsequently the participant researcher, with extensive expertise in social research proposed three modifications to these items before sending them to the experts for a second time. Original BEL 4 item: 'TCs damage your skin' was modified to 'TCs damage your mouth'; WOR 2 item 'I'm afraid of applying too much cream' was modified to 'I'm afraid of applying too much rinse'; WOR 3 item 'I'm afraid of putting cream on certain zones like eyelids, where the skin is thinner' was modified to 'I'm afraid of swallowing rinse'. The second round was executed and a median of 4 was attained for all of the items on both dimensions, and likewise positive feedback was received. As a result, the Delphi-like approach ended at this second round.

Readability

In order to ensure the patients' comprehension of the final construct in both selected languages, two readability formulas were applied. The Fernández-Huerta Index (FHI) was used for the Spanish text, and the Flesch reading-ease formula (FRES) was used for the English text. These were calculated as follows; FHI = 206.84 [0.60 (total words/total sentences)] − [1.02 (total syllables/total words)], and FRES = 206.835(1.015 × average number of words per sentence) − (84.6 × average number of syllables per word). This was performed using automatised calculations available at https://legible.es/ and https://www.readability-score.com/. Both versions reached acceptable legibility levels for lay-persons according to standardised cut-off points described elsewhere (FHI = 65.5; FRES = 57.8) [24].

Reliability

Internal consistency was assessed using Cronbach's α-coefficient independently and jointly for WOR and BEL items. The obtained values ascertained a high internal consistency for WOR ($\alpha = 0.78$) and BEL ($\alpha = 0.84$). The weighted Cronbach's α-coefficient for both dimensions was $\alpha = 0.81$.

Confirmatory factor analysis

Structural Equation Modelling (SEM) by means of confirmatory factor analysis (CFA) was carried out to ratify the two dimensions of TOPICOP. Prior to this, Bartlett's sphericity test and the Kaiser-Meyer-Olkin test were performed to ensure the adequacy of the SEM. In the SEM, the adjustment of the model was measured with the following indicators: RMSA, Comparative Fit Index (CFI), and Weighted Root Mean Square Residual (WRMR). The suitability of performing the factorial analysis was determined by using Bartlett's sphericity test (approximation $\chi 2 = 156.57$ [$p < .001$]) and the Kaiser-Meyer-Olkin test for sampling adequacy (KMO = 0.61). The final model presented a moderately adequate fit: RMSA = 0.07, CFI = 0.94, and WRMR = 1.18. Figure 1 shows the model with the standardised SEM values. Given that none showed saturations of less than 0.4, no items were eliminated nor was the covariance performed. AMOS 21.0 software was used to build the SEM analyses.

The overall rating according to the aforementioned COSMIN scale variation is also presented in Table 1 according to the predefined criteria [22].

Translation process

The original TOPICOP scale has been validated in 10 languages (Danish, English, French, Hungarian, Japanese, Polish, Portuguese, Spanish, Swedish and Ukrainian) [12]. For this present study, the Spanish version was used. The text was translated into English by an ad hoc team using a forward and backward translation approach. This team was comprised of three bilingual researchers in accordance with a methodology explained in detail elsewhere [25]. Final versions of the present TOPICOP adaptation can be found as Supplementary Material with the first version in English and the second in Spanish.

Table 1. Compliance of the final construct with Consensus based Standards for the selection of health Measurement Instruments with the variation proposed by Terwee et al. [22].

COSMIN checklist	Rating matrix	Criteria	TOPICOP ratings
Reliability			
Internal consistency	+	(Sub)scale unidimensional AND Crohnbach's alpha(s) $\geq$ 0.70	+
"the interrelatedness among instruments"	?	Dimensionally not known OR Crohnbach's alpha(s) not determined	
	–	(Sub)scale not unidimensional OR Crohnbach's alpha(s) $<$ 0.07	
Measurement error	+	MIC $>$ SDC OR MIC outside the LOA	?
"the systematic and random error of a patient's score that is not attributed to true changes in the construct to be measured"	?	MIC not defined	
	–	MIC $\leq$ SDC OR MIC equals or inside LO	
Reliability	+	ICC/weighted kappa $\geq$ 0.70 OR Pearson's R $\geq$ 0.80	+
"the proportion of total variance in the measurements, which is due to true differences between patients"	?	Neither ICC/weighted kappa nor Pearson's R determined	
	–	ICC/weighted Kappa $<$ 0.70 OR Person's R $<$ 0.80	
Validity			
Content validity	+	The target population considers all items in the questionnaire to be relevant AND considers the questionnaire to be complete	+
"the degree to which the content of a questionnaire is an adequate reflection of the construct to be measured"	?	No target population involvement	
	–	The target population considers items in the questionnaire to be irrelevant OR considers the questionnaire to be incomplete	
Construct validity			
Structural validity	+	Factors should explain at least 50% of the variance	+
"the degree to which the scores of an instrument are an adequate reflection of the dimensionality of the construct to be measured"	?	Explained variance not mentioned	
	–	Factors explain $<$ 50% of the variance	
Hypothesis testing	+	(Correlation with an instrument measuring the same construct $\geq$ 0.50 OR at least 75% of the results are in accordance with the hypotheses) AND correlation with the related constructs is higher than with unrelated constructs	+
"the degree to which a particular measure relates to other measures in a way one would expect if it is validly measuring the supposed construct, i.e. in accordance with predefined hypotheses about the correlation or differences between the measures"	?	Solely correlations determined with unrelated constructs	
	–	Correlation with an instrument measuring the same construct $<$ 0.50 OR at $<$ 75% of the results are in accordance with the hypotheses OR correlation with the related constructs is lower than with unrelated constructs	
Responsiveness			
Responsiveness	+	(Correlation with an instrument measuring the same construct $\geq$ 0.50 OR at least 75% of the results are in accordance with the hypotheses OR AUC $\geq$ 0.70) AND correlation with the related constructs is higher than with unrelated constructs	+
"the instrument's ability to detect change over time"	?	Solely correlations determined with unrelated construct	
	–	Correlation with an instrument measuring the same construct $<$ 0.50 OR $<$ 75% of the results are in accordance with the hypotheses OR AUC $<$ 0.70 OR correlation with the related constructs is lower than with unrelated constructs	

MIC: minimal important change; SDC: smallest detectable change; LOA: limits of agreement; ICC: interclass correlation coefficient; AUC: area under the curve; +: positive rating; ?: indeterminate rating; –: negative rating.

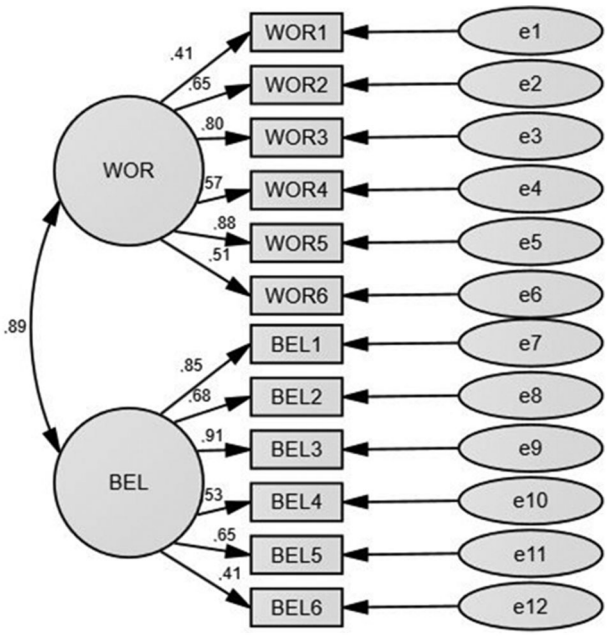

Figure 1. Path analysis with standardised bootstrapped estimates of the conceptual model involving latent (WOR and BEL) and observed variables of TOPICOP by means of structural equation modelling. WOR: worries; BEL: beliefs.

Statistical analysis

Up to now, no studies have evaluated this PROM in OLP patients. Therefore, it was not possible to calculate a minimally required sample size and, as such, a sample of 30 OLP patients was deemed appropriate for this cross-sectional pilot study.

The patients were considered as the basic statistical unit. Analyses were performed using IBM SPSS Statistics 20.0 software for Mac. Continuous variables were reported as mean ± standard deviation and these were analysed by using the Shapiro-Wilks test in order to distinguish between Gaussian and non-Gaussian distributions. Frequency analysis was performed for the categorical variables. The TOPICOP scale was collapsed into dichotomous variables: affirmative (almost agree and totally agree), and negative (totally disagree and don't really agree). Chi-square tests were used to examine the differences between distributions. In order to calculate the best discriminant cut-off point for the TOPICOP scale for identifying TCs phobia, a receiver operating characteristic (ROC) analysis was carried out. The bootstrap resampling method ($k = 1{,}000$) was used for this analysis. Pearson correlation coefficients were calculated to examine the relationship between the VAS and TOPICOP scale answers. The significance level considered in all statistical analyses was 5%.

Results

Participants' data

After the described criteria were applied and having verified the availability of the completed questionnaires, a total of 34 patients were included in the present study. The sample was made up predominantly of women (76.5%) and the median age of patients was 64.18 ± 10.46. The distribution of the clinical presentation according to Thongprasom Index was as follows: stage 2 = 10 (29.4%), stage 3 = 2 (5.9%), stage 4 = 19 (55.9%), stage 5 = 3 (8.8%). The distribution of patients according to lesion localisation were as follows: 3 tongue (8.8%); 15 buccal mucosae (44.1%); 5 gingivae, tongue and buccal mucosae (14.7%); 4 buccal mucosae and gingivae (11.8%); 7 buccal mucosae and tongue (20.6%). 3 of the patients were smokers (8.8%). The most common systemic comorbidities found were rheumatoid arthritis which affected 3 patients (8.8%) and Hepatitis C which affected a single patient (2.9%). The consumption of Anxiolytics or antidepressants was a common finding within the present cohort (41.2%). The most common reasons for consultation were: scheduled medical examinations (32.4%) and concerted examination due to the outbreak of a disease (67.6%). Mean follow-up was 7.4 ± 5.1 months. Fungal over-infection was outlined in 14 OLP patients (41.2%). Moreover, treatment adherence in all participants was validated by weighing the preparations as previously described.

Distribution of the intensity of the concerns according to the TOPICOP and VAS scales

The two initial questions that served as state variables for the ROC analysis were answered as follows. The first question identified 18 TCs phobia + (52.9%) and 16 TCs phobia – (47.1%) patients. With regards to the second question, none of the patients declared non-adherence to treatment. The results from the TOPICOP scale are displayed in Figure 2. In the case of the VAS results, the median score was 4.4 ± 1.5. Table 2 shows a frequency analysis of the TOPICOP scale collapsed into dichotomous variables as indicated above and the results have been stratified according to TCs phobia + vs. TCs phobia –. It also shows the results of a bivariate analysis. With regards to the qualitative dimension of TOPICOP, a great heterogeneity in the results obtained was identified and this has been indicated in Table 2. All of the TOPICOP items reached statistical significance with two exceptions (items 1 and 12).

Given that none of the patients declared non-adherence to treatment, the option to execute a ROC analysis according to this variable was withdrawn and the diagnostic accuracy analysis performed was based on TCs phobia as state variable. The optimal cut-off value for TOPICOP was identified as 50%. ROC analysis showed an area under the curve (AUC) of 0.969 (95% CI: 0.898–1.000, $p < .0001$) with a sensitivity of 93% and a specificity of 100%. A strong positive correlation was obtained between the VAS and TOPICOP answers ($R = 0.89$, $p < .0001$).

Discussion

Modern medicine can reduce pain and related symptomatology and it can even prevent long-term complications, but ultimately it cannot provide complete remission from any chronic disease. OLP treatment requires high levels of adherence and in order to attain correct disease management, this treatment must be pursued with a strict daily schedule for

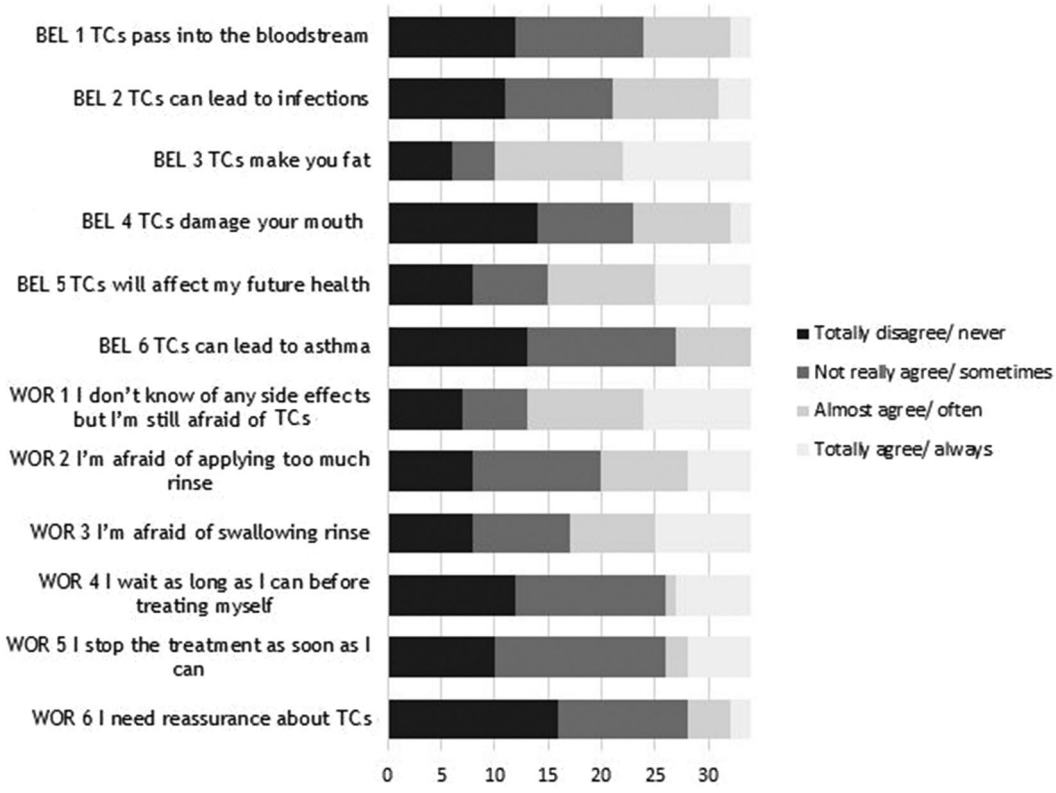

Figure 2. Frequency of responses for each TOPICOP item. WOR: worries; BEL: beliefs; TCs: topical corticosteroids.

Table 2. Answers to the TOPICOP scale grouped by initial focus question.

		TCs phobia −		TCs phobia +		Total	
Item	Thresholds	n	%	n	%	N	%
BEL 1 TCs pass into the bloodstream	Affirmative	3	16.7	7	43.8	10	29.4
	Negative	15	83.3	9	56.3	24	70.6
p Value = .88	Total	18	100	16	100	34	100
BEL 2 TCs can lead to infections	Affirmative	3	16.7	10	62.	13	61.8
	Negative	15	83.3	6	37.5	21	38.2
p Value < .001	Total	18	100	16	100	34	100
BEL 3 TCs make you fat	Affirmative	8	44.4	16	100	24	70.6
	Negative	10	55.6	0	0	10	29.4
p Value < .001	Total	18	100	16	100	34	100
BEL 4 TCs damage your mouth	Affirmative	2	11.1	9	56.3	11	32.4
	Negative	16	88.9	7	43.8	23	67.6
p Value = .006	Total	18	100	16	100	34	100
BEL 5 TCs will affect my future health	Affirmative	4	22.2	15	93.8	19	55.9
	Negative	14	77.8	1	6.3	15	44.1
p Value < .001	Total	18	100	16	100	34	100
BEL 6 TCs can lead to asthma	Affirmative	1	5.6	6	37.5	7	20.6
	Negative	17	94.4	10	62.5	27	79.4
p Value = .023	Total	18	100	16	100	34	100
WOR 1 I don't know of any side effects but I'm still afraid of TCs	Affirmative	7	38.9	14	87.5	21	61.8
	Negative	11	61.1	2	12.5	13	38.2
p Value = .004	Total	18	100	16	100	34	100
WOR 2 I'm afraid of applying too much rinse	Affirmative	3	83.3	11	68.8	14	41.2
	Negative	15	16.7	5	31.2	20	58.8
p Value = .002	Total	18	100	16	100	34	100
WOR 3 I'm afraid of swallowing rinse	Affirmative	3	16.7	14	87.5	17	50.0
	Negative	15	83.3	2	12.5	17	50.0
p Value < .001	Total	18	100	16	100	34	100
WOR 4 I wait as long as I can before treating myself	Affirmative	1	5.6	7	43.8	8	23.5
	Negative	17	94.4	9	56.3	26	76.5
p value = .010	Total	18	100	16	100	34	100
WOR 5 I stop the treatment as soon as I can	Affirmative	0	0	8	50.0	8	23.5
	Negative	18	100	8	50.0	26	76.5
p value = .001	All	18	100	16	100	34	100
WOR 6 I need reassurance about TCs	Affirmative	3	16.7	3	18.8	6	17.6
	Negative	15	83.3	13	81.2	28	82.4
p value = .875	All	18	100	16	100	34	100

WOR: worries; BEL: beliefs; TCs: topical corticosteroids.

weeks, if not months. Such a demanding task can be perceived by some patients as an overwhelming responsibility and this can lead to the development of concerns and fears. Oral physicians must help these patients overcome said legitimate worries by fully informing them of risks, benefits and modalities of treatment [14]. All prescribed treatments impose daily routines on the patients and it is the patients themselves who are responsible for adhering to these routines and this can cause concern or even fear amongst said individuals, nonetheless, medical professionals also share a part of this responsibility [26]. The use of PROMs in this setting represents a landmark initiative in current medical practice [27].

Wiriyakijja et al. recently performed a review that dealt with the use of PROMs in OLP. In this study, a total of 41 were detected, of which VAS was the most commonly used. These measures demonstrated great variability in terms of the concepts that they were made for, although in general three subcategories were identified and catalogued as follows: oral symptoms, psychosocial status, and quality of life. Authors have also found great heterogeneity in terms of psychometric properties across selected studies [17]. To the best of our knowledge, the possibility of the existence of TCs phobia among patients affected by any chronic oral mucosa disorders, and its possible impact on treatment responsiveness, and the idea of constructing or optimising a PROM to address this hypothesis have never been the subject of a study.

Due to the importance of generating robust PROMs in the field of oral medicine, the authors comprehensively evaluated the properties of this PROM adaptation against the COSMIN checklist [21]. In the authors' opinion, two domains of this checklist; reliability and validity were satisfactory addressed with the current qualitative-based methodology *via* SEM, IC and patients' appropriateness. In fact, one of the major strengths of the present study is the use of SEM to confirm the preservation of the initially proposed theoretical latent variables (i.e. WOR and BEL) containing observed items after the Delphi-like approach had been used to optimise this PROM [23]. It is interesting to note that, as represented in Figure 1, the items that reached the poorest saturation were WOR1 and BEL6, and these in turn were not modified during the Delphi-like approach. The Cronbach's α of 0.81 for TOPICOP achieved for this cohort of patients with OLP can be considered as very good, and no significant modification could be achieved by removing any item [28].

Nonetheless, due to the cross-sectional nature of this present report and due to the lack of a gold standard measure for this PROM, an alternative method to establish a ROC curve analysis was developed by means of an adapted VAS scale and by the use of two questions in the line of previous research; for example, Mueller et al. used the same methodology to optimise TOPICOP in AD-affected patients, reporting that the key to correctly implementing this methodology was the use of blinding in order to empower patients autonomy [11]. This ROC curve analysis elucidated the valuable diagnostic accuracy of the present construct with an AUC of 0.969 (95% CI: 0.898–1.000, $p < .0001$; sensitivity = 93%; specificity = 100%), confirming the strong relationship between VAS and TOPICOP ($R = 0.89$, $p < .0001$). It is worth mentioning that, according to the canonical rules delineated by DeVellis [28] in the assessment of responsiveness, an indispensable prerequisite for attaining gold standard PROMs is the existence of a stable disease and this is not the case in OLP [14]. According to Ni Riordain et al. the validity of these transition judgements may be coupled to the cohort effect, a patient's opinion of their current state rather than an actual change over time [27].

In addition, the present pilot study ascertained that almost half of the participants (47.1%) were affected by TCs phobia. The authors consider this preliminary finding to be very relevant for general dental professionals and oral medicine specialists, despite the fact that this somatisation does not seem to result in non-adherence to treatment. Due to the novel nature of this report, it is difficult to compare presented results. Nonetheless, Li et al. recently performed a meta-analysis of prevalence in order to quantify the presence of TCs phobia among AD patients, falling within wide limits 21.0% (95% CI, 15.8%−26.2%) to 83.7% (95% CI, 81.9%−85.5%) and in line with our results [13].

Finally, the authors are aware that the sample size in this pilot study was quite low for ROC and SEM analysis. In addition, a prospective approach and a comprehensive follow-up may help to establish a stronger validation. According to the described methodology, patients showed good treatment adherence; nonetheless, weighing the prepared solutions does not fully serve as a safeguard against possible uncontrolled biases. Likewise, elaborating other language versions in order to determine if values are impacted by cross-cultural differences would be desirable. When considered together, these factors may hinder the generalisation of the results obtained and further studies are necessary in order to better characterise this PROM and its implications for treatment adherence.

Conclusions

The present TOPICOP extrapolation appears to be useful as a PROM for OLP-affected individuals. OLP patients may sometimes present with TCs phobia although this somatisation does not seem to affect adherence to treatment. Future studies with larger samples are warranted in order to verify the present findings. Clinicians should explore patients' attitudes towards TCs prescription in order to personalise patient management and to instruct them on health literacy.

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