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A comparison between self-formulation dexamethasone and compounded formulation dexamethasone mouth rinse for oral lichen planus: A pilot randomized cross-over trial

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Abstract

Aim: There is a lack of appropriate commercially available topical corticosteroid formulations for use in oral lichen planus (OLP) and oral lichenoid reaction (OLR). Current therapy includes crushing a dexamethasone tablet and mixing it with water for use as a mouth rinse. This formulation is aesthetically not pleasing and unpleasant to use in the mouth as it is a bitter and gritty suspension, resulting in poor compliance. Thus, the present study was designed to formulate and pilot an effective, aesthetically pleasing formulation.

Methods: A single-blinded, crossover trial was designed, with two treatment arms. Patients were monitored for seven weeks. Quantitative and qualitative data was assessed using VAS, numeric pain scales, TSQM-9, and thematic analysis to determine primary patient reported outcomes including satisfaction, compliance, quality of life and symptom relief.

Results: Nine patients completed the pilot trial. Data analysis revealed the new compounded formulation to be superior to existing therapy due to its convenience, positive contribution to compliance, patient perceived faster onset of action and improved symptom relief.

Conclusion: Topical dexamethasone is useful in the treatment of OLP. When carefully formulated into a compounded mouth rinse, it improves patient outcomes.

Key Words: Oral Lichen Planus; Oral Lichenoid Reaction; Dexamethasone; Pain; Quality of Life

Introduction

Oral lichen planus (OLP) and oral lichenoid reaction (OLR) are oral mucosal diseases affecting the general population with a reported prevalence between 0.5 and 2.2%.[1,2] Women aged 40 years and older are more frequently affected than men of the same age with a ratio of approximately 3:1.[3] OLP is a chronic immunologically-mediated disease that may present as white reticular striae, white papular or plaque-like lesions, erythema, erosions and ulcerated lesions.[4] OLR is a term used to denote lichenoid lesions due to a systemically administered medication or the local presence of dental restorative materials.[4] OLP is often accompanied by pain and discomfort that interfere with daily activities such as eating, speaking, and sleeping; significantly impacting upon the patient's quality of life (QoL).[5]

OLP involves an established immune-mediated pathogenesis in which auto-cytotoxic CD8 T-lymphocytes trigger apoptosis of epithelial cells resulting in inflammation.[4,6] Lesions may typically occur on the buccal mucosa, tongue and gingivae.[7,8] There have been reports on the potential malignant transformation of OLP.[5,9–12]

Symptomatic OLP is an ongoing issue for clinicians due to the immunologic complexity and refractory nature of the disease. Treatment presents as a challenge, often leaving palliation as the primary goal of therapy.[13] Therapeutic agents currently used for the treatment of OLP include corticosteroids, immunomodulators, and retinoids.[5,14] Despite the multitude of documented interventions, topical corticosteroids such as dexamethasone are considered first line therapy and are effective in the management of symptomatic OLP.[13] This is due to their anti-inflammatory effects and anti-immunologic properties of suppressing T lymphocyte function.[13] Although corticosteroids can be administered intra-lesionally or systemically, topical therapy remains the treatment of choice as it can be applied to lesions with minimal systemic absorption and potential for side effects.[4,15] Systemic therapy should be reserved for severe, widespread OLP and cases involving other mucocutaneous sites.[4,14] There are few corticosteroid formulations available for oral application as most have been developed for the management of external, dermatological conditions and are not designed to be used in the mouth.[15] Numerous obstacles are faced when administering preparations to this area namely the presence of saliva, taste, limited surface area, poor tissue penetration, enzymatic degradation, and accidental swallowing leading to unwanted systemic absorption.[16] This is particularly challenging when treating OLP as there are further difficulties to overcome; such as possible systemic absorption of medicament through the breach in the oral epithelium especially in ulcerative type, the importance to minimize the potential for direct physical irritation, chemical trauma caused by acidic, spicy, or strongly flavored substances which may exacerbate symptoms.[17,18] Therefore, when considering a formulation for use in conditions such as OLP and OLR, excipients with the potential to exacerbate symptoms such as flavoring, coloring, and alcohol should be excluded.[4] On the contrary excipients that are unlikely to exacerbate the condition and overcome obstacles faced in drug delivery to the oral mucosa should be investigated.

There is evidence[6,19] to support the use of mouth rinses in patients with widespread symptomatic OLP as lesions are not easily accessible for the placement of creams, ointments or gels. As of April 2016, there are no commercially available steroid-containing oral rinses in Australia. Those documented[20–22] abroad are designed for systemic use and contain excipients such as isopropyl alcohol, flavoring, and acidic buffers which may exacerbate OLP if used topically.[23] Despite the lack of commercially available products, a myriad of formulations or modes of delivery for topical corticosteroids are available through compounding pharmacies such as pastes, sprays, adhesive bandages, and mouth rinses.[24]

Compounding pharmacists are therefore able to overcome the need of an appropriate therapy for those with OLP. Current OLP therapy at the research site involves the use of crushed 0.5 mg dexamethasone tablets (Dexmethsone, Aspen Pharmacare, Australia) mixed with water to be used as a mouth rinse. Patients report an improvement in their condition when using this therapy however, the bitter taste of dexamethasone and the presence of excipients in tablets result in a gritty and unpleasant formulation. Also of concern is the difficulty in preparation of the rinse, being inconvenient to prepare in the workplace and alike. This could result in compromising the therapeutic dosage and reluctance to continue treatment, leading to poor compliance.[19]

This pilot trial compared the efficacy of the current therapy, self-formulation (crushed tablet) dexamethasone rinse (0.5mg dexamethasone tablet crushed, mixed with up to 20 mL water, and then used as a rinse) with 2 mL of a compounded mouth rinse of dexamethasone (0.5 mg/2 mL) in patients with clinically diagnosed symptomatic OLP, with respect to improving the patient outcomes of satisfaction, compliance, quality of life and symptom relief. All participants received a total of 0.5 mg of dexamethasone per dose.

Materials and methods

The research protocol was approved by the Griffith University Human Research Ethics Committee (EC00162). Witnessed written consent was obtained from all patients before eligibility to participate was granted by JH and the dental nurse on duty. Thorough clinical examination, medical and OLP or OLR disease progression histories were documented during the initial visit by an oral medicine specialist (RGN). Participants were randomised

into two groups using unbiased randomiser software (Research Randomizer V.3.0) by JH to determine which therapy they received first. The details of each participant were put into concealed envelopes for un-blinding if any adverse event was to occur. All patients were clinically and/or histopathologically diagnosed with OLP or OLR requiring treatment at the Oral Medicine Clinic, Griffith Health Clinics, Gold Coast, Australia.

The inclusion criteria were:

- diagnosis of OLP requiring treatment
- otherwise healthy, passing medical assessment
- 18 years of age or older

Patients on prescribed medication for OLP (those using oral or topical medications for OLP such as corticosteroids, immunomodulators, analgesics, anti-inflammatories or mouth rinses) were entered into the trial after an ample washout period calculated by the study pharmacist.

Exclusion criteria included:

- pregnancy, lactation or intended pregnancy
- prescribed significant medications with potential for drug interactions
- significant medical conditions
- highly dependent on medical care
- currently taking (and unable to cease) medications with documented potential to cause OLR
- allergy to, or experience of adverse effects from topical corticosteroids or excipients in either formulation

The study was a single blinded, cross-over pilot trial. It consisted of a seven week protocol where participants were divided into two groups, “A” or “B”. Each participant had three weeks of self-formulation rinse as a ‘control’, a one week washout period, and three weeks of treatment with the compounded mouth rinse (Figure 1). If any adverse event was reported or suspected the clinician (RGN) was un-blinded and the participant referred for appropriate care and treatment discontinued. As the study was a preliminary, small-scale pilot it was not registered as a full-scale randomized controlled trial and no power calculation was required.[25]

Intervention

Participants were instructed to use 2 mL of the dexamethasone 0.5 mg/2 mL compounded mouth rinse or one 0.5 mg tablet crushed and mixed with 20 mL of water three times per day, for three weeks. All were instructed to rinse and hold the product in their mouths for a minimum of 2-3 minutes and then expectorate along with any saliva produced for the following minute, and not to swallow. Participants were also advised to avoid consuming food, drinks and cleaning their mouth or teeth for 30 minutes after use.

A team of compounding pharmacists provided patients with both dexamethasone tablets for crushing and the compounded mouth rinse which contained unionised, micronized, dexamethasone, sweetening and thickening agents, and preserved water. Participants were directed to store the compounded mouth rinse protected from light, between 2-8°C and a 28 day expiry was applied.[26] The compounded mouth rinse and tablets for the self-formulation rinse were provided free of charge for the duration of the study.

Clinical Assessment and Analysis

Participants were evaluated at weeks 0, 3, 4 and 7 during the treatment period. Assessments included an objective numerical score for symptoms, a 100 mm Visual Analogue Scale (VAS)[27]; the Treatment Satisfaction Questionnaire for Medication (TSQM-9)[28]; comparisons of clinical photographs; and self-assessment *via* Patient Daily Diary entries to record compliance with each dose and comment on Quality of Life (QoL).

The severity of pain was measured by a VAS; a 0 to 10 horizontally marked line where 0 represented no pain and 100 represented worst pain experienced. Analysis of data gathered from the TSQM-9 questionnaire was utilised to identify common trends. The scoring system for the TSQM-9 was ranked using a 5 point scale (1 = very dissatisfied, 2 = not satisfied, 3 = neutral, 4 = satisfied, 5 = very satisfied). The assessment of symptom relief, compliance, and QoL occurred daily. Participants recorded a numeric value of perceived symptom severity on a scale of 1 (best symptom relief) to 10 (no symptom relief), used a tick-box tool to record compliance with each dose, and provided comments on their QoL. Compliance was calculated using a percentage of total doses taken over 63 days. Due to the small sample size, statistical analysis was not feasible. Thematic and narrative analysis was undertaken to report findings.

Results

Nine participants, two men and seven women, with a mean age of 62.3 years (range 27-78 years) were enrolled in the trial for a period of six months. Recruitment ceased to allow appropriate time for data analysis. All nine patients completed the study; however one patient (patient 3) did not return his diary. A summary of the characteristics and clinical outcomes of the nine patients is presented in Table 1.

When participants used the compounded mouth rinse, their mean compliance with the prescribed dose regimen was 90.06% over 21 days and 63 doses, compared to 77.37% when using the self-formulation rinse. Analysis of clinical data from the TSQM-9 revealed the compounded mouth rinse more favourable than self-formulation rinse with mean improvement in convenience of therapy (22.25%); onset of action (8.48%) and attained symptom relief (4.18%). Clinical photographs (Figures 2 and 3) show a reduction in the size of ulcerative lesions after compounded rinse therapy. Patient diaries supported these objective findings which related to compliance and convenience, onset of action, QoL, and a preference for the compounded mouth rinse over the self-formulation rinse. It was shown that a therapy convenient for patients to use resulted in improved compliance where improved adherence to therapy resulted in better treatment outcomes. Patients reported instantaneous cooling and improved relief from the compounded mouth rinse compared to the self-formulation rinse. Improving a patient's QoL is one of the main goals of therapy and an indication for effective symptom relief. In one instance a patient was extremely satisfied due to being able to consume spicy foods after therapy with the compounded mouth rinse. Patient specific comments on factors pertaining to aesthetics were also an emerging theme that impacted upon therapy. It was often reported that taste and texture as well as the absence of stinging in the mouth while using the compounded formulation made it a preferential dosage form compared to the self-formulation mouth rinse.

Safety Analysis

No patients experienced or reported systemic or topical adverse reactions. All patients tolerated both treatments and completed the seven week protocol.

Discussion

There are many unique challenges in an oral medicine (oral physician) practice when it comes to topical medication delivery in chronic oral diseases. This is primarily due to the lack of availability of commercial formulations designed for the oral cavity because of the small market size. A compounding pharmacist is able to use their specialized formulation knowledge to contribute to the care of oral medicine patients.[29,30] Working collaboratively with oral medicine clinicians and their patients enables pharmacists to develop formulations tailored to individual therapeutic requirements.[29,30] This contributes to a holistic approach of patient care where common treatment outcomes are desired such as patient satisfaction, QoL, symptom relief and increased compliance.[31]

Though not designed for oral environment, products made for systemic, cutaneous and nasal preparations such as topical dexamethasone in the form of a crushed tablet mouth rinse, aerosols, suspensions, and ointments have shown to be clinically effective in the treatment of OLP and OLR.[32,33] There is extensive documentation of the use of dexamethasone in OLP and other mucocutaneous inflammatory conditions.[32,33,34] Evidence is suggestive of dexamethasone in the form of a mouth rinse can significantly decrease the production of locally produced pro-inflammatory cytokines to give satisfactory clinical outcomes in OLP.[6,19] The use of a mouth rinse as topical therapy for OLP is thought to be more beneficial than other forms as it is a more efficient means for targeting larger areas, easily applied to posterior areas of the mouth and extensile surfaces, and most importantly lowering systemic absorption rates compared with oral ingestion.[31,35]

An *in vivo* study has demonstrated the ability of the buccal mucosa to retain a reservoir of long acting glucocorticoids such as dexamethasone after topical application[36]. Other recent studies have also demonstrated a reservoir function of the buccal mucosa using *in vitro* models.[37,38] It was found that only 1% of dexamethasone is delivered across the mucosa, significantly decreasing the potential for systemic absorption after topical application.[37,38] This permeability profile is ideal for the use of dexamethasone in topical treatment of OLP as penetration and retention of the medication at the site of action is optimal for therapeutic outcomes.

Although the percentage improvements shown in Table 1 do not necessarily translate into clinically significant improvements, this pilot trial showed that the use of a specialized formulation developed by compounding pharmacists may contribute to better clinical outcomes for OLP and OLR patients. Participants experienced improvements in satisfaction, compliance, QoL and symptom relief from the compounded mouth rinse compared with the self-formulation rinse. The cost of the compounded mouth rinse was only slightly more expensive than purchasing the tablets to self-formulate, making it a feasible therapeutic option. When given the opportunity, participants unanimously selected the compounded mouth rinse as their preferred treatment.

A mouth rinse containing unionized, micronized, dexamethasone for optimal mucosal absorption, minimal excipients that may cause irritation such as alcohol, and inclusion of beneficial excipients to increase retention time at the site of action shows promising evidence in OLP therapy. Oral Medicine clinicians should therefore be aware of the benefits a compounding pharmacist can contribute to patient outcomes.

Due to the small sample size, single-blinding, short duration of intervention and follow-up, this pilot study was unable to evaluate long term safety and efficacy. A full-scale, double blinded randomized controlled trial with a larger sample size, a longer duration and follow-up up and multiple sites is necessary to confirm our findings. The use of a dexamethasone compounded mouth rinse could be considered as a treatment for those with OLP and OLR.

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Table 1. Outcome of topical dexamethasone therapies

				Crushed Tablet Rinse (CTR)				Compounded Mouth Rinse (CMR)			
Patient	**Age (years)**	**Sex**	**Group**	**Compliance (%) Mean**	**Convenience (not convenient=1, convenient=5)**	**Onset of Action (1=slow, 5=fast)**	**Symptom Relief (1=no relief, 5=relief)**	**Compliance (%) Mean**	**Convenience (not convenient=1, convenient=5)**	**Onset of Action (1=slow, 5=fast)**	**Symptom Relief (1=no relief, 5=relief)**
1	56	F	A	80.97	5	5	5	80.93	5	5	5
2	27	F	A	23.81	1	3	3	63.39	5	4	4
3	55	M	B	-	3	4	4	-	5	4	4
4	58	F	B	95.23	2	3	4	100	5	4	4
5	68	F	A	93.65	3	4	4	100	4	5	4
6	70	F	A	60.3	4	4	4	87.30	5	4	5
7	76	F	A	95.20	5	5	5	98.40	5	5	5
8	73	F	B	79.34	1	3	3	95.24	5	5	4
9	78	M	B	90.47	4	1	2	95.20	5	2	2
Mean of all pts	62.3			77.37 (618.97)	3.11 (28)	3.56 (32)	3.78 (34)	90.06 (720.46)	4.89 (44)	4.22 (38)	4.11 (37)
								↑12.69%	↑22.25%	↑8.48%	↑4.18%