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Comparative Evaluation of Triamcinolone Acetonide And CurcuminLozenges in Patients with Erosive Lichen Planus: A Pilot Clinical Study

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Abstract

Oral erosive lichen plan is autoimmune mediated mucocutaneous disorder that manifests as painful ulcerative lesion present bilaterally on buccal mucosa, tongue and lips. Till date there is no single definitive treatment for OLP. Corticosteroids have been the mainstay of treatment; however, their usage is associated with potential side effects. Curcumin a plant based herbal medicament can be a safer alternative to these synthetic drugs. Hence the aim of present study was to compare and evaluate the effect of curcumin lozenges and topical corticosteroids for the treatment of erosive lichen planus lesions. Twenty patients were included in the study and were randomly divided into two groups. Patients in Group 1 were given triamcinolone acetonide 0.1% for topical application along with multivitamin capsules and Group 2 were given turmeric lozenges (Turmnova) along with multivitamin capsules. Improvement in pain intensity was recorded on the Visual Analogue Scale at baseline and on subsequent visits after one week and two weeks and clinically healing was evaluated after two weeks. All the data collected were analysed using SPSS version 22 software using the Mann- Whitney Test where $P<0.05$ was considered statistically significant. In our study curcumin lozenges has shown similar improvement in severity of pain after one week and two weeks when compared with triamcinolone acetonide 0.1% paste. Curcumin has shown promising results by decreasing the lesion size, pain and burning sensation. Hence, can be a new ray of hope in

minimizing the sign and symptoms of OLP with minimal side effects.

Keywords: Oral Erosive Lichen Planus, Curcumin, Herbal, Corticosteroids, Anti-Inflammatory.

Introduction

Oral lichen planus (OLP) is one of the most common immune mediated chronic inflammatory mucocutaneous disorder that manifests as various forms of lesions i.e., keratotic (reticular or plaque like) to erythematous, ulcerative and erosive.[1]It was first described by Wilson in 1869and it affects between 0.5%-2% of world's population. In majority of patient's dermal lesions are associated with oral lesions. These lesions have higher incidence in middle- aged female patients; and rarely affect children and teenagers.[2]

Dermal lesions are distributed in a bilaterally symmetrical pattern most commonly on flexor surfaces of the wrist, forearm, trunk and inner aspects of knees and thighs. In oral cavity disease manifests as bilateral lesions most commonly present on buccal mucosa, tongue, lips, gingiva and to, lesser extent involves floor of the mouth and palate. The oral lesions are classically characterized as radiating greyish-white, velvety, thread like papules in a linear, annular or retiform arrangement forming typical lacy, reticular patches, rings and streaks over the buccal mucosa.[3]

Erosive lichen planus is an autoimmune damage mediated by CD8+T cytotoxic cells which trigger the apoptosis of oral epithelial cells.[4] Oral erosive lichen planus are painful ulcerative lesion that are commonly present bilaterally on buccal mucosa, tongue and lips. It undergoes period of remission followed by exacerbations due to anxiety, emotional changes, trauma, infection and malnutrition. These lesions are characterized by mucosal bleeding even on mild trauma due to tooth brushing or while having food which may lead to anorexia, weight loss, nutritional deficiencies and depression.[3]

There is no definite single recommended therapy for erosive oral lichen planus. The main aim of therapy is the prolongation of painless intervals, resolution of oral lesions and maintenance of good oral hygiene.

Corticosteroids, calcineurin inhibitors, retinoids, daps one, hydroxychloroquine, mycophenolatemofetil and enoxaparin, photodynamic therapy, co_2 laser are various treatment modalities for oral lichen planus.[5]Corticosteroids are the first line drug therapy because of their effectiveness in dampening the cell mediated immune activity. Other drugs are also effective but has high risk of toxicities and has shown resistance to treatment and recurrence of lesion.[1]Steroid can be used topically or systemically in such lesions, but it has many detrimental effects like thinning of the mucosa, the possibility of systemic absorption, irritation of the digestive system and adrenal suppression, opportunistic fungal infections and toxicity.[6]

Natural herbs have a long history of use and have minimal side effects. Curcumin is extracted from Curcuma plant and has antioxidant, anti-inflammatory, antimicrobial, and anti-carcinogenic activities.[7]

Hence the aim of present study was to compare and evaluate the effect of curcumin lozenges and topical corticosteroids for the treatment of erosive lichen planus lesions.

Material and methods

This prospective clinical trial included twenty patients with clinical signs of erosive oral lichen planus that were selected from outpatient department of department of dentistry, Indira Gandhi Institute of Medical science, Patna. Written and informed consent was taken from selected patients and were randomly divided into two groups. Patients in Group 1were given triamcinolone

acetonide 0.1% for topical application along with becadexamin capsule and Group 2 were given curcumin lozenges along with becadexamin capsule.

Inclusion criteria

1. Patients with clinical signs of oral erosive lichen planus.

Exclusion criteria

1. Patients allergic to corticosteroids and curcumin;
2. Pregnant and lactating mothers;
3. Patient with history of gastric or duodenal ulcer.

The interventions used in this pilot clinical study were corticosteroid topical paste (Triamcinolone acetonide 0.1% [Kenacort 0.1% paste]) to apply twice daily for two weeks on the lesion in group1along with becadexamin capsule once daily for two weeks. Patients in group 2 were given turmeric lozenges (Turmeric extract 100 mg, 6.4 mg Eucalyptus oil, Menthol oil 6.3 mg[Turmnova lozenges]) three times daily for two weeks and becadexamin capsule once daily for two weeks. Improvement in pain intensity was recorded on the Visual Analogue Scale at baseline and on subsequent visits after one week and two weeks.

In our study, clinically healing was evaluated after two weeks excellent response was defined as 100% reduction in signs and symptoms, very good response was defined as 50% or more reduction in signs and symptoms but still less than 100%. Good response was defined as less than 50% reduction in signs and symptoms.

Result

Clinical assessment of pain was done by VAS at baseline and was further assessed after 1 week and 2 weeks. All the data collected were analysed using SPSS version 22 software using the Mann- Whitney Test where $P<0.05$ was considered statistically significant.

Table.1 shows intergroup comparison in which no statistically significant difference was noted between the two groups.

Table.2 shows intragroup comparison with statistically highly significant reduction in severity of pain when compared at baseline vs 1 week, at baseline vs 2 week and at 1 week vs 2 week with p value <0.001.

At the end of the 2 weeks of treatment healing was assessed in both the groups. In the triamcinolone group out of ten patients four patients (40%) had excellent response, two patients (20%) had very good response and four patients (40%) had good response. In the curcumin group out of ten patients five patients (50%) had excellent response, three patients (30%) had very good response and two patients (20%) had good response.

In our study curcumin lozenges has shown similar improvement in severity of pain after one week and two weeks when compared with triamcinolone acetonide 0.1% paste.

Discussion

Oral lichen planus (OLP) is a chronic autoimmune disease that needs effective palliative treatment. Erosive and atrophic types of lichen planus cause burning to severe pain which highly effects the quality of life of the patients.[8]Malignant transformation is the of the most potential complications of OLP, but is still controversial.[9] However, most studies indicate that OLP patients may develop oral cancer, increasing the risk of incidence (10 times) compared to general population.[10,11]

The main goal of treatment of OLP is symptomatic relief to patient and elimination of potential triggers and irritants such as dental malocclusion or fractured carious teeth, ill-fitting dentures.

Topical treatment is preferred due to fewer side effects but in case of widespread lesions involving skin or other non-oral mucosa systemic therapy is advised.[12] Most published studies consider topical corticosteroids as the most useful drug for OLP treatment and positive response has been seen to medium-potency corticosteroid treatment, such as

acetate triamcinolone 0.1%.[13,14]Adrenal suppression is not found in the long term, even with oral application of topical corticosteroids such as triamcinolone acetonide, fluocinolone and clobetasol propionate.[15,16]

Corticosteroids have well-documented anti-inflammatory and anti-immune effects. Anti-inflammatory response is by inhibiting synthesis of the two main inflammatory products, prostaglandins and leukotrienes. It also suppresses the cell mediated immunity by inhibiting genes that code for the pro-inflammatory cytokines and tumor necrosis factor- α genes.[17]

Alternative treatments are retinoids, ultraviolet phototherapy, steroid sparing agents (hydroxyl chloroquine, azathioprine, mycophenolate mofetil) and pimecrolimus. These drugs have shown positive results in the treatment of OLP however, resistance to treatment recurrence of lesion and a high risk of toxicities limit their use. FDA issued a "black box" warning on the use of tacrolimus and pimecrolimus due to an increased theoretical risk of cancer (squamous cell carcinoma and lymphoma) in patients treated with tacrolimus/pimecrolimus for psoriasis.[18,19]

Pseudomembranous candidiasis, mucosal atrophy is the only common side-effect of treatment with topical corticosteroids.[20]Sosuitable alternatives to these synthetic drugs causing systemic toxicity and other side effects and also considering the chronic nature of OLP is needed.

In our study we have used an herbal medicament curcumin which is nontoxic and has diversified effects in various oral diseases. It exhibits anti-inflammatory, antioxidant, antimicrobial, anti-carcinogenic activities, anti-proliferative, anti-mutagenic, neuro-protective, and immune-system modulating properties which have been confirmed in many previous studies.[21,22]The reason for use of turmeric is in our study is that in patients with OLP there is destruction of basement membrane by the lymphocytes and apoptosis of inflammatory cells is also reduced or absent which is believed to contribute to the development of OLP.[23]Thus, turmeric can induce apoptosis, promote healing and help us reduce the severity of disease. Another mechanism of destruction is proteolytic degradation of the connective tissue matrix of the oral mucous membrane in such patients which can also be prevented by turmeric as it inhibits MMP-9 expression via inhibition of nuclear factor-kappa B assembly and can help in maintaining the integrity of oral mucous membrane.[24]

In most of the studies curcumin has been used in higher doses due to rapid metabolism and rapid systemic elimination which causes poor bioavailability due to first pass effect. Though curcumin is well tolerated at higher doses but can have fewer side effects abdominal discomfort, nausea and diarrhea. [25,26]In our study we have used turmnova lozenges that contains the purest form of whole turmeric extract, delivered in the form of a buccal dissolving lozenge. The Quick sorb Technology patented in this product helps dissolving with our saliva, thereby keeping its bioactive ingredients intact, with all its therapeutic activity delivered into the bloodstream instantly even at lowest doses of 100 milligram. Buccal absorption bypasses the hostile environment of the gastrointestinal tract.

In 2012, Chainani-Wu N et al conducted a study on 20 and patients where Curcuminoids at doses of 6000 mg/d in 3 divided doses were given for 12 days. He concluded that curcumin was well tolerated and may prove efficacious in controlling signs and symptoms of oral lichen planus.[27]

In 2015, Maryam Amirchaghmaghi et. al performed a randomized controlled- trial on patients with OLP. She concluded that curcumin can be a better alternative to steroids with minimal side effects.[28]

In our study the VAS scores decreased in both groups from base line to 1-week and 2 weeks follow-up session. Table.2 Mann- Whitney Test showed that the differences between the follow-up sessions were significant ($P < 0.05$). However, the differences between the group streated with curcumin and local corticosteroid were not significant ($P > 0.05$) table.1. Similar results were seen in study conducted by Deepika K et al.2015 where OLP patients was divided and was treated with triamcinolone acetonide 0.1%and the other group with commercially available topical Curcumin ointment each to be applied thrice daily for 2 weeks. They concluded that curcumin can be used as an alternative to steroid in the management of signs and symptoms of OLP with minimal side effects as compared to steroids with similar efficacy.[29]

Conclusion

In our study curcumin was found to safe and effective in controlling the signs and symptoms of OLP. Herbal medicines i.e., turmeric can be used as an alternative to corticosteroids. Turmeric is safe, non-toxic, effective and economical alternative with no side effects for many traditional drugs used. Turmeric can be a new ray of hope in minimizing the sign and symptoms of OLP with minimal side effects. Further studies with larger sample size are recommended to generalize the results.

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Legend Tables

Table.1: Intergroup comparison of Mean VAS Score at baseline, 1 week and 2 weeks.

Group	Baseline Score	At 1 Week	At 2 Week
Group 1 (n=10)	7.80± 1.02	5.40± 1.38	3.60± 1.19
Group 2 (n=10)	7.84± 1.05	5.30± 2.08	3.00± 2.02
p- value*	0.32	0.46	0.68

Table.2: Intragroup comparison of Mean VAS Score at baseline, 1 week and 2 weeks.

Groups	Baseline	At 1 week	At 2weeks	P value [Baseline vs at 1 week]	P value [Baseline vs at 2 weeks]	P value [At 1 week vs at 2 weeks]
Group 1	7.80±1.02	5.40±1.38	3.60 ± 1.19	<.001	<.001	<.001
Group 2	7.84±1.05	5.30± 2.08	3.00 ± 2.02	<.001	<.001	<.001