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THE EFFICACY OF TOPICAL COCONUT CREAM VERSUS TOPICAL TRIAMCINOLONE IN THE MANAGEMENT OF ORAL LICHEN PLANUS

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ABSTRACT

Background: Oral lichen planus (OLP) is a chronic mucocutaneous disease. The cause of oral lichen planus is not well known and the successful management of OLP is still difficult to achieve.

Aim: The aim of this randomized clinical trial was to compare the therapeutic effects of triamcinolone acetonide (TA) preparation versus topical 50% coconut cream preparation in the management of atrophic OLP.

Methods: 20 patients who had atrophic OLP were selected and randomly divided into two equal groups. (Group I) received topical 50% coconut cream, and (Group II) received topical 0.1% triamcinolone for a period of 4 weeks. Patients were evaluated at baseline before treatment and on days 14, 21 and 28. The following parameters were evaluated; visual analogue scale (VAS) score, degree of erythema and size of erosive area.

Results: Our results showed a statistically significant reduction in both groups with a 64.1% reduction in VAS score and 68.5% reduction is the lesion size in the coconut group compared to 74.7% and 77% in the VAS and lesion size in the 0.1% TA group respectively. After 28 days follow up period there was a statistically significant difference between both groups.

Conclusion: 50% coconut cream showed a significant reduction in the VAS, degree of erythema and lesion size with no signs of toxicity nor side effects informed during the treatment or follow-up period, thus proving to be a safe and promising medication for OLP.

KEY WORDS: Oral lichen planus(OLP), coconut, corticosteroids, pain,

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INTRODUCTION

Lichen planus is a widespread chronic mucocutaneous diseases and it has been documented that oral lichen planus (OLP) involved 0.1-4% of the population worldwide which can be detected mostly in the fifth and sixth decades of life with a twice prevalence in females in comparison to males and characterized by periods of remission and exacerbation [1-3].

The etiology of the OLP remains unclear but it is most likely caused by immunological progression initiated by an antigen that changes the basal keratinocytes of the oral mucosa making them susceptible to cell immune response[4-6].

Different therapies are described for OLP but some of their clinical values remain controversial. Corticosteroid therapy is usually considered the first line of treatment due to its profound anti-inflammatory properties but on the other hand, it has various side effects including oral candidiasis, burning sensation, mucosal atrophy, bad taste, nausea, sore throat, and dry mouth.[7,8]

Systemic absorption and adrenal suppression from super potent topical and systemic steroids have also been reported specially when used for the long term management of diseases that are chronic in nature such as OLP.[9]

In the last decades, the use of natural products for the treatment of human disorders has gained new interest in the scientific community especially after the discovery of novel natural drugs and their utilization as new therapies for the treatment of human diseases.[10]

Coconut (*Cocos nucifera Linn*) is a plant from the Palmae family [11]. known for centuries for its medicinal, anti-inflammatory, antioxidant, and immunomodulatory properties. The anti-inflammatory, antioxidant and immunomodulatory effects are due to lauric acid, palmitic acid and capric acid respectively. Coconut oil has no known adverse effects, easily available, cost-effective and simply extracted [12]. Hence the aim of the present study was to compare the efficacy of topical coconut cream versus triamcinolone in the management of atrophic OLP.

SUBJECTS AND METHODS

Ethical approval

The current trial was conducted in accordance with the World Medical Association guidelines of ethics (Declaration of Helsinki, 1978, as revised in 2008) for studies including human contributors. The contemplate protocol was accepted by the Research Ethics Committee of the Future University in Egypt (FUE.REC) and was registered in code no **(33)/11-2022.** In advance to starting the study all the participants signed an informed consent afterward full explanation of the study steps.

Sample size calculation

Sample size calculation of this randomized controlled trial was calculated based on **Youssef et al., 2019 [1],** If the true difference in the experimental and control means is 1, we will need to study 20 subjects (10 in each group) to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05.

Selection of patients:

This study included a total number of 20 patients with atrophic OLP, who attended the oral medicine, diagnosis and periodontology department, Faculty of Dentistry, Future University in Egypt. According to the modified WHO criteria the diagnosis of OLP was carried out subsequent to clinical examination using the unit led light and the diagnostic examination instruments[13].

Inclusion and exclusion criteria

The study inclusion criteria were patients of both sexes, ranging from 45 to 60 years old with atrophic type OLP, while the exclusion criteria included pregnant or lactating women, smokers, patients consuming lichenoid reaction-inducing drugs, patients with hepatitis C virus (HCV), systemic diseases that may participate in the existence of OLP such as uncontrolled diabetes and hypertension.

Steps of coconut cream preparation

The topical coconut cream was prepared by using 100% pure coconut oil that was warmed to 600°C. Surfactant Span 60 of 2.5 ml was added and dissolved. The mixture was then blended with surfactant tween 20 of 2.5 ml in a homogenizer for 10 min. Carbopol 940 about 1 g solution was dissolved in warm distilled water (25 ml) and then added to the coconut oil. This mixture was kept in a homogenizer for 15 seconds. Vanillin and triethanolamine (0.2 g) were added and triturated. The cream was then dispensed in airtight sterile plastic containers and stored at 4°C in a refrigerator. Lastly, the composition per 100 g of 50% coconut cream contained coconut oil (50 ml), span 60 (surfactant-2.5 g), tween 20 (surfactant-2.5 g), Carbopol 940 (gelling agent-1 g), triethanolamine (viscous organic compound-0.2 g) and vanillin (0.001 g).

Study design

The involved 20 patients were randomly allocated by means of preoperative envelope drawing, to be managed in the diverse study groups. The patients were divided equally into two groups. In **Group I**: ten patients received 50% coconut cream. **Group II**: ten patients received topical triamcinolone acetonide 0.1% (Kenacort-A Orabase®, Turkey).

All patients were instructed to use the prescribed topical treatment four times per day for four weeks. Patients were not allowed to eat or drink for at least 1 hour following treatment application. The patients were instructed to halt the treatment immediately if any unwanted side effects occurred. The patients were instructed not to use any treatment for the lesions other than the prescribed one.

Clinical examination

Patients were evaluated at baseline before treatment and on days 14, 21 and 28 days. The severity of pain was assessed using the visual analog scale (VAS), and patients were asked to rate their pain on a scale of 0-10, where 0 indicated no pain and 10 indicated the most intense pain [14]. The intensity score for erythema was measured using the modified oral mucositis index (MOMI) (0-3) as (0 normal, 1 mild erythema, 2 moderate erythema, 3 severe erythema) [15]. Based on the ulceration area, ulceration score was applied as follows (0 no ulcerations, 1 between 0-0.25 cm2, 2 between 0.25-1 cm2, 3 1 cm2 or greater). In case of various ulcers at a site, their surface area was totaled to obtain the entire surface area [15]. In addition, the size of an ulcer or erosive area was measured in millimeters using a periodontal probe.

Statistical analysis

All data were tabulated and analyzed using SPSS version 17.0. The results are presented as mean ± standard deviation. Comparison between the groups was done by Mann-Whitney *U* test. Follow up scores were done by paired *t* test. Statistical significance was set at $P \leq 0.05$.

RESULTS

A total of 20 patients consented to take part in the study. All the patients complied with follow up periods and the results were recorded.

Group I included 2 male and 8 female patients whereas group II had 3 male and 7 female patients. The average age of the participants was 52.53 years for group I and 53.74 for group II and there was no significant difference noted between the two groups regarding age and sex distribution.

All scores reduced considerably in all patients and showed a constant decrease in every follow-up appointment. However, a highly statistically significant difference was only seen between the two groups in the VAS and size scores at the end of day 28 but for the remainder of the days, there was no significant difference between the two groups. **Table (1)**

Regarding the change by time in each group, there was a significant decrease in all three parameters in all time intervals in both groups. **Table (2).**

TABLE (1): Comparison between the VAS, MOMI and size scores in the two studied groups:

Day	Parameter	Group I		Group II		*P.value*
		Mean	SD	Mean	SD	
Baseline	VAS	7.81	±0.65	7.73	±0.87	0.8197
	MOMI	2.50	±0.53	2.60	±0.52	0.6733
	SIZE	8.1	±0.87	8.05	±0.95	0.904
Day 14	VAS	6.95	±0.64	6.85	±0.91	0.7813
	MOMI	1.80	±0.42	1.80	±0.79	1.000
	SIZE	6.35	±1.08	6.95	±1.09	0.232
Day 21	VAS	5.05	±0.72	4.50	±0.88	0.1449
	MOMI	1.20	±0.63	1.00	±0.67	0.5001
	SIZE	4.95	±1.14	4.40	±0.69	0.2102
Day 28	VAS	2.80	±0.97	1.95	±0.64	0.0338*
	MOMI	0.40	±0.52	0.30	±0.48	0.6601
	SIZE	2.55	±0.72	1.85	±0.41	0.0161*

: Significant at P ≤ 0.05

TABLE (2) Effect of post-treatment duration time on the mean change in VAS, MOMI and size within each group

Score	BL-14 days	14 -21 days	21 -28 days	BL-28 days
VAS (Group I)	0.860 ±0.05	1.90 ±0.22	2.250 ±0.2	5.010 ±0.25
	*P= <0.0001**	*P= <0.0001**	*P= <0.0001**	*P= <0.0001**
VAS (Group II)	0.880 ±0.05	2.35 ±0.22	2.550 ±0.15	5.780 ±0.19
	*P= <0.0001**	*P= <0.0001**	*P= <0.0001**	*P= <0.0001**
MOMI (Group I)	0.70 ±0.15	0.60 ±0.16	0.80 ±0.13	2.10 ±0.18
	*P= <0.0013**	*P= <0.0051**	*P= <0.0002**	*P= <0.0001**
MOMI (Group I)	0.80 ±0.2	0.80 ±0.2	0.70 ±0.26	2.30 ±0.21
	*P= <0.0224**	*P= <0.0031**	*P= <0.0248**	*P= <0.0001**
Size (Group I)	1.750 ±0.27	1.40 ±0.14	2.40 ±0.22	5.55 ±0.21
	*P= <0.0001**	*P= <0.0001**	*P= <0.0001**	*P= <0.0001**
Size (Group I)	1.100 ±0.14	2.550 ±0.25	2.55 ±0.17	6.20 ± 0.27
	*P= <0.0001**	*P= <0.0001**	*P= <0.0001**	*P= <0.0001**

: Significant at P ≤ 0.05

DISCUSSION

The management of OLP is a very challengeable due to its chronic nature which requires a long term treatment, but generally OLP treatment is only necessary when it is symptomatic [16]. Corticosteroid is the first choice in OLP management owing to its inflammatory and immunological characters, however it is associated with numerous adverse effects, such as oral mucosa atrophy, tachyphylaxis, and candidiasis [17]. In protracted treatment with local corticosteroids, endocrine, metabolic, and ocular systemic adverse effects may occur [18]. Therefore various studies have been performed to find alternative natural treatments such as Aloe vera, curcumin, Glycyrrhiza glabra, Purslane, Raspberry leaf extract and Lycopene [19].

Coconut oil is mostly composed of medium chain fatty acids; therefore, it is considered unique when compared to other dietary oils, which are mainly made up of long chain fatty acids. Nearly 50% of these medium-chain fatty acids are lauric acid. Human breast milk is the only other naturally occurring substance with such a high concentration of lauric acid which is known for its anti-inflammatory and antimicrobial benefits [20, 21].

Natural origin drugs represent a safe and effective replacement therapy for many oral disorders; therefore, the current study was conducted to assess the effectiveness of pharmaceutically prepared topical coconut cream compared to commercially available topical steroid gel in the management of atrophic OLP.

Up to our knowledge, only one study assessed and compared the use of topical Coconut 50% cream and 0.05% for the management of OLP. In their study, Mamadapur et al., 2022 showed after 60 days follow up period a 85% regression in the size of OLP lesions when using coconut cream compared to 95% size regression with 0.05% Clobetasol propionate ointment[12]. In our study there was a 68.5% size regression in the coconut cream group and a 77% size regression in the triamcinolone group after 28 days follow up period. The percentage difference in the lesion size between the two studies can be due to the difference in the follow up periods but the percentage difference between the two groups in both studies is almost the same in the favor of the corticosteroid group.

In addition, Mamadapur et al., 2022 evaluated the Numeric Pain Rating scale (NPS) in their study that showed a 100% reduction in the coconut cream group and a 95% reduction in the steroid group with no significant difference between the two groups [12]. Although in our study we assessed the severity of pain using the visual analog scale (VAS) instead of the NPS, there was a significant difference between the two groups by the 28th day in favor of the steroid group that showed a 74.7 % pain severity reduction compared to 64.1 % reduction in the coconut cream group.

In all time intervals, there was a significant reduction in the VAS, MOMI and size scores in both groups, with no significant difference between both groups except at day 28 there was a significant difference in the VAS and size scores in favor of the steroid group.

Regarding the results of the present study topical coconut cream was found to have a significant effect on the healing of atrophic OLP lesions which may be explained by its pleiotropic effects mainly its anti-inflammatory and anti-microbial properties [20]. In a recent systematic review and meta-analysis, coconut oil was found to have a very effective anti-microbial action as it attaches to the tooth surface even after being washed out and cleared from saliva [25]. In addition, coconut oil demonstrated a decrease in mean gingival indices, plaque scores, and S. mutans count within few days of usage [26,27].

The significant reduction in pain scores in the coconut cream group may be explained by three recognized mechanisms which are its capability to accelerate re-epithelization, improve antioxidant enzymes activities and stimulation of higher collagen cross-linking within the repaired tissues [28]. The activity of monolaurin, the monoglycerides of Lauric acid in virgin coconut oil (VCO) has anti-inflammatory property that inhibits the prostaglandin biosynthesis and reduces the sensitivity of the blood vessels to bradykin and histamine, in addition to its analgesic property that acts by blocking the synthesis or release of the endogenous substance responsible for pain production [28].

Halim et al., 2014 compared the effectiveness of virgin coconut oil (VCO) compared to 0.1% triamcinolone acetonide in treating recurrent aphthous stomatitis (RAS) and concluded that both treatments had comparable effectiveness as both of them relieved pain and reduced the ulcer size [29]. Also, coconut is known for prompt wound healing property due to proteolytic enzymes expression, which in sequence affects the host tissue remodeling process and the active synthesis and deposition of matrix proteins in the granulation tissues. This is obvious from the higher turnover and cross-linking of collagen, in wounds treated with VCO [28].

Unlike corticosteroids which are considered a common risk factor for oral candidiasis the results of the present study recorded the absence of fungal infection by candida albicans in coconut cream group and these results were in accordance with a recent study which approved the antifungal effect of VCO against oral candida albicans with exposure time of two days [30].

CONCLUSION

Topical coconut cream may be used as a novel, profound, cost- effective and safe treatment modality for atrophic OLP management.

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