

Relative efficacy of fluocinolone acetonide compared with triamcinolone acetonide in treatment of oral lichen planus

K. Thongprasom¹,
L. Luangjarmekorn¹, T. Sererat¹ and
W. Taweasap²

Departments of ¹Oral Medicine,
²Pharmacology Faculty of Dentistry,
Chulalongkorn University, Thailand

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Twenty patients with oral lichen planus and topically treated with fluocinolone acetonide in orabase 0.1% (FAO) were compared with 20 treated with triamcinolone acetonide in orabase 0.1% (TAO). During 4 wk of treatment the lesions in 13 of 19 patients could be effectively cured with FAO whereas only 8 of 19 patients were cured with TAO. These differences were statistically significant. There were no differences in blood pressure, plasma cortisol or number of circulating lymphocytes after treatment with FAO, but the number of eosinophils was reduced in every case after treatment for 6 months. There was no permanent adrenal cortical suppression after treatment for 6 months. Acute pseudomembranous candidiasis during the treatment was common but could be cured with antifungal drug in every case. This study shows that FAO in a majority of cases is an effective treatment of oral lichen planus without any serious clinical side effects apart from treatable candidiasis.

Key words: fluocinolone acetonide; lichen planus, oral; mouth, diseases; triamcinolone acetonide.

Kobkan Thongprasom, Oral Medicine Department, Faculty of Dentistry, Chulalongkorn University, Bangkok 10330, Thailand.

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Lichen planus is a common chronic inflammatory disease of the skin and oral mucosa (1). The erosive type of oral lichen planus can be particularly painful and may interfere with eating, speaking and swallowing (2). Long-standing erosive and atrophic oral lichen planus can in a few instance be transformed into squamous cell carcinoma (3). Although the etiology of lichen planus is still unknown, there are indications that it may be associated with stress, some systemic diseases, drugs and immunologic disorders (4). Various new treatments have recently been tried but complete cure is difficult (5–9). Corticosteroids have been widely used for reducing inflammation and pain and remain the management of choice. Triamcinolone acetonide in orabase (TAO) is commonly used but is not always effective particularly in severe cases (10). In this study, we aimed to compare the topical steroid, fluocinolone acetonide in orabase (FAO) at the concentration of 0.1% for the treatment of oral lichen planus (OLP) with TAO 0.1%. We also investigated for possible systemic and local adverse effects by smear for *Candida albicans*, peripheral blood lymphocyte

and eosinophil counts, blood pressure, and plasma cortisol assay.

Patients and methods

Forty patients with erosive and atrophic oral lichen planus confirmed by tissue biopsy were studied. By oral examination of the lesions before and after treatment, scoring 0–5 were recorded according to the criteria set as the follows: Score 5 = white striae with erosive area more than 1 cm²
Score 4 = white striae with erosive area less than 1 cm²
Score 3 = white striae with atrophic area more than 1 cm²
Score 2 = white striae with atrophic area less than 1 cm²
Score 1 = mild white striae, no erythematous area
Score 0 = no lesion, normal mucosa

Oral examination of all lesions was performed by two clinicians double checking each other. The criteria for cured lesions were no inflammation or erythematous areas, no white striae or only very mild white striae and no other symptoms. Scores were either zero or one. Twenty cases were treated with

0.1% TAO in orabase and the other twenty cases with 0.1% FAO in orabase. Patients were advised to apply the FAO or TAO topically to the lesions four times a day for 1 month. When the lesions responded to the treatment (score 2), the patients should apply FAO or TAO three times a day and then gradually reduced to twice (score 1) and once (score 0) a day respectively. After a period of 6–8 months, the patients stopped using FAO or TAO completely. It was necessary that they not be treated with other medications for at least 2 wk before the study and have no serious systemic diseases. Because FAO at the concentration of 0.1% is a new preparation; smear and stain for *Candida*, blood pressure, complete blood examination and plasma cortisol levels were assayed before and 6 months after treatment. The comparisons of treatment between the FAO and TAO groups were evaluated after wk 2 and wk 4.

Results

The characteristics of the study groups are shown in Table 1. The number of women was greater than that of men

Table 1. Comparison of sex, age, type, site and duration of disease in OLP patients TAO & FAO group

Group	No. of patients	Cases (%)		Age in yrs mean (ranges)	Type of OLP (%)		Sites of OLP (%)					Duration range (months)	
		Men	Women		E	A	B	T	G	M	P		L
TAO	20	4 (10)	16 (40)	44.55 (20-74)	9 (22.5)	11 (27.5)	17 (42.5)	6 (15)	6 (15)	2 (5)	4 (10)	1 (2.5)	2-48
FAO	20	5 (12.5)	15 (37.5)	49.05 (30-79)	9 (22.5)	11 (27.5)	16 (40)	3 (7.5)	2 (5)	5 (12.5)	2 (5)	4 (10)	3-129
Total	40 (100)	22.5	77.5	46.8 (20.79)	18 (45)	22 (55)	33 (82.5)	9 (22.5)	8 (20)	7 (17.5)	6 (15)	5 (12.5)	2-129

E=erosive lichen planus. A=atrophic lichen planus. B=buccal mucosa. T=tongue. G=gingiva. M=mucobuccal fold. P=palate. L=lips.

in both groups. The mean age of the patients in both groups was in the forties. The duration of disease in the



Fig. 1. Patient with erosive lichen planus before treatment with FAO.

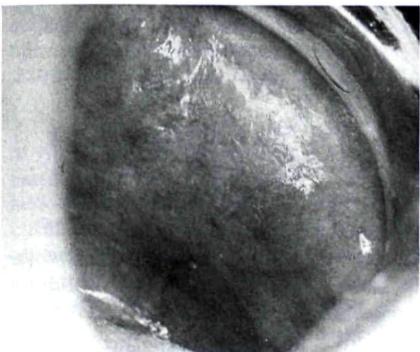


Fig. 2. Same patient, 1 month after start of treatment with FAO.



Fig. 3. Same patient, 1 yr after treatment with FAO, FAO stopped after 8 months.

group eventually treated with FAO was longer than that of the TAO group but the types of OLP were the same. Lesions were most commonly found in the buccal mucosa, followed by tongue, gingiva, mucobuccal fold, palate and lips respectively.

The comparison of OLP patients treated with the TAO and the FAO after wk 2 and wk 4 indicated that there was

no statistically significant clinical improvement between the two groups at 2 wk but, after 4 wk, the lesions in 13 of 19 cases in the FAO group were cured whereas the lesions in only 8 of 19 cases in the TAO were cured. One patient dropped out in each group. A patient with erosive lichen planus before treatment with the FAO was illustrated (Fig. 1). The clinical improvement was clear

Table 2. Comparison of OLP patients treated with TAO and FAO during 2 and 4 wk

Group	No. of patients					
	2 wk			4 wk		
	Cured	Uncured	Total	Cured	Uncured	Total
TAO	8	12	20	8	11	19
FAO	8	7	15	13	6	19
Total	16	19	35	21	17	38
Chi-square test	$\chi^2 = 1.2688$			$\chi^2 = 6.1141$		
Significance	NS			$P < 0.05$		

Table 3. Comparison of peripheral blood lymphocyte and eosinophil counts in OLP patients before and after treatment with FAO for 6 months

Treatment Cases	Blood 1 mm ³	
	Mean lymphocytes \pm SD (range)	Mean eosinophils \pm SD (range)
Before 16	39.6785 \pm 10.025 (21-62)	3.8124 \pm 3.103 (0-11)
After 16	38.5000 \pm 6.282 (27-48)	0.0625 \pm 0.025 (0-1)
Paired-samples t-tests	$P = 0.713$	$P = 0.000$
Significance	NS	$P < 0.05$

Table 4. Plasma cortisol level before and after treatment with FAO

Cases	Treatment	Plasma cortisol ($\mu\text{g}\%$)	
		Before injecting ACTH Mean \pm SD (range)	After injecting ACTH Mean \pm SD (range)
14	Before	9.2057 \pm 3.821 (3.65-14.8)	35.3857 \pm 8.44 (15.6-50.5)
14	After	9.6792 \pm 3.400 (4.05-16.25)	35.7779 \pm 9.996 (21.5-53.5)
Paired-samples t-tests		$P = 0.721$	$P = 0.895$
Significance		NS	NS

(Fig. 2) and the lesion almost completely healed (Fig. 3). There was a statistically significant difference after 4-wk treatment in the FAO and TAO groups (Table 2).

Table 3 is the comparison of peripheral blood lymphocyte and eosinophil counts in oral lichen planus patients before and after treatment with topical fluocinolone acetonide 0.1% for 6 months and shows no statistically significant changes in lymphocyte number after treatment. However, there was a statistically significant fall in eosinophil numbers during FAO treatment ($P < 0.05$).

The plasma cortisol level before and 6 months after treatment with FAO showed that there was no statistically significant difference: thus no adrenal suppression was found in this study (Table 4).

Moreover, in 15 patients there was no statistically significant difference in blood systolic and diastolic pressure between before and 6 months after treatment with FAO. With regard to acute pseudomembranous candidiasis during 2–6 months after the start of treatment, the number of cases of candidiasis found in the FAO group was 9 of 19 compared with 4 of 16 cases in the TAO group. However, candidiasis could be completely cured with topical antifungals (miconazole gel) in every case. No other clinical side-effects were found in this study.

Discussion

The sex, age and the site of the lesions in this study shows that the study group is similar to those in other reports (11, 12). The number of the patients with erosive and atrophic lichen planus was the same in both the TAO and FAO groups. The duration of prior disease in the FAO was longer than that of the TAO because all of the former had failed to respond to the TAO and other medications. However, after 4 wk treatment significantly more lesions in the FAO group were cured than in the TAO group. After follow-up for more than 1 yr, the lesions of only 2 FAO patients were cured completely whereas the others had some recurrence. FAO was not effective in 6 of 19 cases in this study. This might be due to the patients' lack of compliance with the prescription. A recent study showed that fluocinolone acetonide cream could also treat desquamative gingivitis without any significant differences in blood pres-

sure and Synacthen test between before and after treatment (13).

The present study showed that the mean plasma cortisol level in the FAO group still responded at 3–5 times the base line plasma cortisol before and after FAO treatment showing there is no permanent adrenal cortical suppression after treatment with the FAO for 6 months. Moreover, there were no significant differences between before and after treatment in blood pressure, as well as the peripheral blood lymphocyte counts in the patients with FAO. The number of eosinophils was reduced in every case after treatment with FAO for 6 months. A decrease in the number of circulating eosinophils has followed topical applications of synthetic steroids and fluocinolone acetonide in many reports (14–17). However, steroids used topically or by local injection are often more effective and safer than systemic steroids (18–19). Only one significant side effect could be found in this study; that was acute pseudomembranous candidiasis in 9 of 19 cases of the FAO group. Oral candidiasis is a common complication in patients treated with any topical steroids (20–21). However, candidiasis could readily be cured with topical antifungal drug in every case. In conclusion, FAO may be recommended as a drug of choice in the treatment of severe cases of OLP which have failed to other medications: it is effective, safe, practical, of low cost and presents no serious clinical side effects.

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