

ORIGINAL PAPER

Ignatia in the treatment of oral lichen planus

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Objective: To evaluate the effectiveness of *Ignatia* homeopathic 30C in management of oral lichen planus (OLP).

Methods and materials: In this single blind randomized control clinical trial, 30 consecutive patients with oral lesions consistent clinically and histologically with erosive and/or atrophic OLP were recruited. The patients were randomly divided into two groups to receive *Ignatia* or placebo. They were treated for 4 months.

Results: Mean lesion sizes and mean pain measures differed between control and treatment groups favouring *Ignatia* ($p < 0.05$).

Conclusion: Our results suggest that *Ignatia* has a beneficial effect in treatment of OLP in selected patients. *Homeopathy* (2009) 98, 40–44.

Keywords: Oral lichen planus; *Ignatia*; Single blind randomized controlled trial; Oral disease; Homeopathy

Introduction

Oral lichen planus (OLP) is a T-cell-mediated autoimmune disease of unknown etiology.¹ It was first described by Erasmus Wilson in 1869.² Its true prevalence is unknown, but incidence is reported to be approximately 0.5–2%.^{3,4} The lesions in OLP are usually bilateral and most commonly affect the posterior buccal mucosa, gingiva, and tongue.⁴ OLP predominantly affects the middle-aged population (50–55 years old), although it may be seen in persons of any age;⁵ women are more susceptible.⁶ Clinically, OLP can manifest as reticular, papular, atrophic, erosive, or bullous subtypes. Atrophic and erosive subtypes are particularly resistant to therapy and have a low resolution rate.⁴ Because the etiology of OLP remains unknown, most therapies are only symptomatic.

Treatment of symptomatic OLP is challenging. Several drugs have been used with varying success. Specific treatment includes corticosteroids (topical, intraregional or systemic), retinoid, cyclosporin, psoralen plus ultraviolet A light (PUVA), griseofulvin, hydroxychloroquine and dapsone.⁶

Corticosteroids are beneficial in the management of OLP because of their anti-inflammatory effect and anti-immunologic properties of suppressing T-cell function. Although corticosteroids can be administered intralesionally or systemically, topical corticosteroid therapy remains the treatment of choice, because it can be applied on the lesions with minimal potential for systemic side effects.⁷ However, not all patients respond to corticosteroids.

Therefore various other treatment modalities including griseofulvin, retinoid and vitamin A analogues, dapsone, phenytoin, azathioprine, levamisole, immunomodulatory agents, photo chemotherapy, and surgical excision have been advocated.⁸

Several homeopathic medicines including *Antim crud.*, *Ars-alb.*, *Ars-iod.*, *Jugl-c.*, *Kali-bi.*, *Sul-iod.*, *Ign.*, *Sepia*, *Sulphur*, and *Thuja* may be indicated for the treatment of OLP.^{9,10}

Ignatia amara is not among the homeopathic medicines traditionally recommended in OLP, but stress and psycho-social condition have an important role in improvement or worsened lichen planus. As a result *Ignatia* could be so useful for treatment of this autoimmune disease. The purpose of this study was to compare the clinical efficacy of *Ignatia* in treating OLP with placebo.

Ignatia is especially suited to nervous temperament; women of a sensitive, easily excited nature; dark hair and skin but mild disposition, quick to perceive, rapid in execution.¹¹

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Patients and methods

Patients

An experimental, prospective, single blind, randomized clinical controlled trial included the following.

Thirty consecutive patients, with a current presentation of atrophic or erosive OLP confirmed by histology (hematoxylin and eosin and/or direct immunofluorescence), were recruited from the Oral Medicine Clinic at the School of Dental Medicine, Tehran University, between September 2006 and July 2007 (Figure 1). Informed consent was obtained from all patients entering the study.

Patients were included if they were between 18 and 65 years old, did not suffer from another acute or chronic diseases of the oral mucosa. The patients were required to have oral lesions of at least 10 mm in their longest dimension, and had the mind and general symptom of *Ignatia*.

Patients were excluded from the study if they had concurrent clinical conditions that could pose a health risk, including serious liver, kidney, and heart dysfunctions. Pregnant or nursing women and patients who had therapy for OLP within the 4 weeks before the study were excluded.

To minimize the effect of confounding variables in the psycho-physiological component of the study, the patients were excluded if they had a history of alcohol or drug abuse or were taking any narcotic analgesics. To prevent cross-actions from other homeopathic and medical therapies, patients were excluded if they had a history of systemic immunosuppressive therapy.

Methods

After enrolment, a complete history was taken and the head and neck examination performed on the screening day. The patients were then randomly assigned to one of two treatment groups (15 patients in each group) using verum *Ignatia* or placebo treatment. Randomization was performed using computer-generated random number tables.

During treatment, the patients were assessed at months 0, 1, 2, 3, 4. In all patients, the site of lesions was recorded and the most severe area was identified as the marker lesion. The size of ulcers was measured by the investigator, and pain was evaluated by the subjects by visual analogue scale (VAS) before starting treatment (baseline). Patients took a single dose of an *Ignatia* (*Ignatia amara* manufactured by Dolisos) in 30C dilution, in liquid form, diluted in 100 ml of water. In control group, patients took a single placebo globule diluted in 100 ml of water. Treatments were repeated at subsequent visits (at months 1, 2, 3, 4).

The index ulcer's size was measured on day 0 (before intervention) and at months 1, 2, 3, 4 for treatment evaluation. To determine the size of the ulcers, the lesion was measured by a transparent grid calibrated to 2 mm to confirm the scores. The investigators measured the distance between two opposite outside edges of the white border. Two measurements approximately 90° from each other were obtained; the largest distance was used as one of the measurements. The two measurements were then multiplied to represent the cross-sectional areas of the lesion.

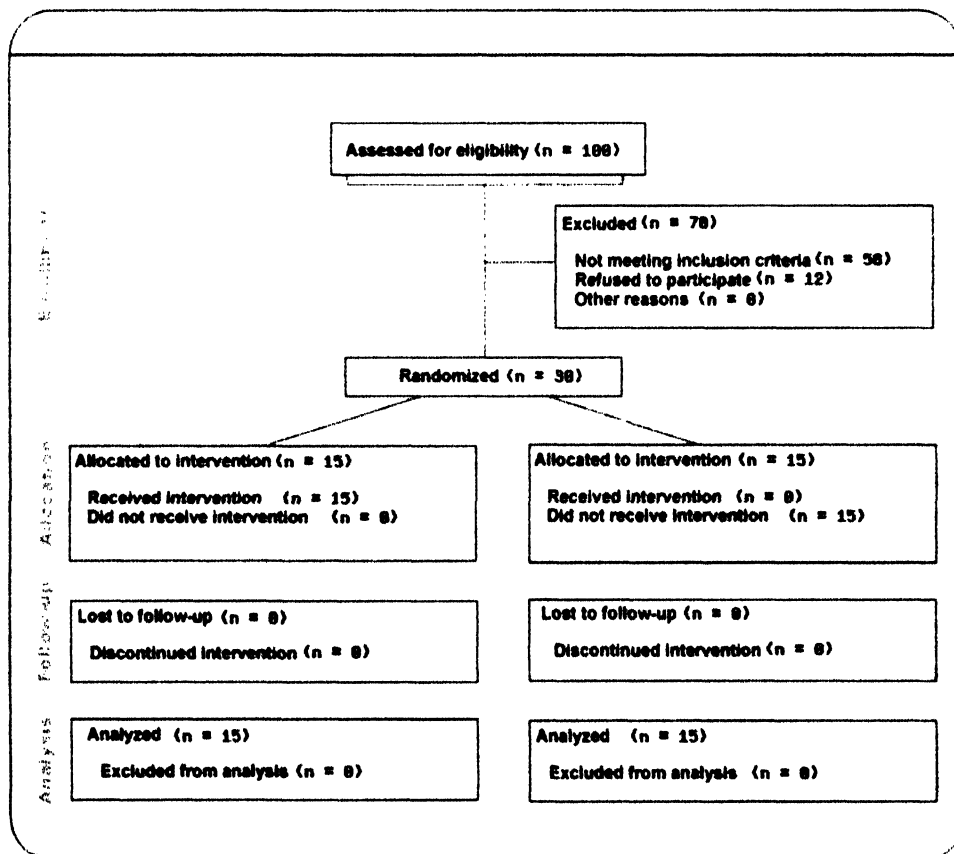


Figure 1 Consort flowchart.

Table 1 Patient characteristics

Patients (n = 30)	<i>Ignatia</i> (n = 15)	Control group (n = 15)
Female/male	10/15	10/15
Age (years), mean (range)	56.3 (30–65)	54.6 (32–65)
Duration of lesions (months), mean (range)	36 (1–120)	34 (1–120)

To evaluate pain, a 100 mm VAS was used. The VAS score was determined by measuring in millimeters from the left-hand end of the line to the point that the patient marks.¹²

Ethical consideration

The Joint Ethical Committee of Tehran University approved the study plan. Ethical considerations included requiring patients to sign the informed consent forms.

Statistical analysis

Group differences between the treatment group and the control group were evaluated for each visit. The Friedman test was used to compare pain and the size of ulcer between two groups. All data were analyzed using SPSS software (SPSS 12.0 for Windows; SPSS Inc.). The level of significance was established at a *p* value less than 0.05.

Results

Thirty patients with erosive or atrophic OLP were enrolled in the study. The mean age was 55.4 years. The female-to-male ratio was 2 (20:10). All patients were symptomatic, 25 patients had only oral lesions, and five patients (20%) had both oral and skin lesions. Durations of the lesions were from 1 month to 120 months with a mean of 35 months. Lesions were on buccal mucosa (24 patients), followed by attached gingiva (20 patients) and/or tongue (12 patients). The clinical characteristics of OLP patients are shown in Table 1.

The common complaints were described as discomfort, pain, or burning and tingling sensations. The common problematic foods were spicy foods, tomato and hot sauces, salad dressing, and toothpaste.

Table 2 shows the mean lesion size and VAS scores for each treatment or control group. According to these results, difference between treatment group (homeopathic treatment with *Ignatia*) and control group is statistically significant, not only compared to base line visit but also to

previous value, both in size of ulcer and reduction of pain based on VAS scores (*p* < 0.05). Reduction of pain and lesion size between visits was also significant (*p* < 0.05) (Figures 2 and 3).

Discussion

The findings demonstrate that homeopathic treatment (*Ign*) can reduce pain and size of lesions in patients with lichen planus. To our knowledge this is the first—albeit small—published study in which homeopathy has been used to treat lichen planus. It suggests that *Ignatia* as a homeopathic remedy is a potentially low-risk, option in an integrated package of care for the treatment of lichen planus. This is a control study and we compared the effect of *Ign* with placebo treatment.

According to materia medica,¹¹ all patients of study had the mind and general symptom of *Ignatia* as follows.

General symptoms

General symptoms of *Ignatia* include: a marked hyperesthesia of all the senses, and a tendency to clonic spasms. Mentally, the emotional element is uppermost and co-ordination of function interfered with. Hence, it is one of the chief remedies for hysteria. It is especially adapted to the nervous temperament – women of sensitive, easily excited nature, dark, mild disposition, quick to perceive, rapid in execution. Rapid change of mental and physical conditions is opposite to each other. Great contradictions. Alert, nervous, apprehensive, rigid, trembling patients who suffer acutely in mind or body, at the same time made worse by drinking coffee. The superficial and erratic character of its symptoms is most characteristic. Effects of grief and worry. Cannot bear tobacco. Pain is small, circumscribed spots. Hiccough and hysterical vomiting.

Mind

Mental symptoms include: 'changeable mood; introspective; silently brooding. Melancholic, sad, tearful. Not communicative. Sighing and sobbing. After shocks, grief, disappointment.¹¹

Lichen planus is an autoimmune disease that is known to worsen during periods of stress. Immunomodulatory responses to neural signals may play a significant role in affecting the natural history of this disease. On the other hand, the immune system was reinforced by homeopathic treatment. This may be reason why *Ignatia* effect was observed in this study.

Table 2 Within group comparisons (Friedman test) (**p* < 0.05)

Variable		Baseline	1st month	2nd month	3rd month	4th month	<i>p</i> Value
Active	Lesion (longest dimension) (cm)	3.9	3.45*	3*	2.45*	2.2*	<i>p</i> < 0.05
	VAS score (mm)	5	3.7*	2.5*	2.3*	1.3*	<i>p</i> < 0.05
Control	Lesion size (cm)	4.3	4	4.2	3.9	4.3	Not significant
	VAS score (mm)	4.8	4.5	4.4	4.5	4	Not significant

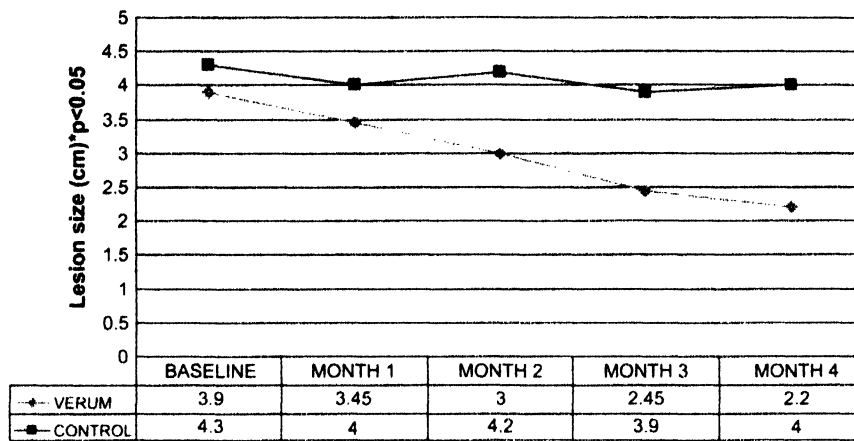


Figure 2 Change in mean size of lesion (the longest dimension) (* $p < 0.05$).

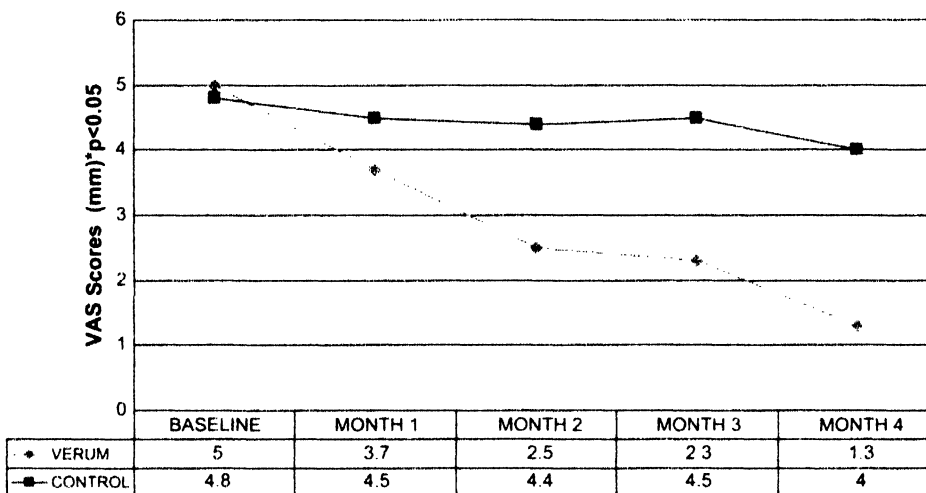


Figure 3 Change in mean VAS scores for pain (* $p < 0.05$).

Conclusion

We found *Ignatia amara* 30C monthly to be useful in the treatment of OLP in selected patients. The mean lesion size and VAS decreased, and the changes compared with control were statistically significant (Table 2).

After treatment, the patients were able to eat foods that previously they were unable to eat owing to pain and/or burning sensation. Most of the patients treated in this study expressed a significant improvement in quality of their life in terms of eating well and performing oral hygiene without discomfort.

A direct comparison between homeopathic treatment and medical therapy is difficult. There are strong differences in the types of treatments, the methods of description, the types of drugs, and the philosophy of cure. Due to the lack of homeopathic studies on the treatment of lichen planus, we cannot compare our results with similar studies.

Discussion

Our results suggest that the homeopathic medicine *Ignatia amara* 30C is effective in treatment of OLP in selected patients. It decreased the pain and discomfort of lesions

based on VAS scores and reduced the size of lesions. All of these findings were statistically significant in comparison with control group who were treated with placebo.

It is only the first step in understanding the potential of such treatment and should be seen as a starting point. More research with larger sample sizes and over longer time periods of time is warranted.

Conflict of interest

None declared.

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