Assessment of immediate pain relief with laser treatment in recurrent aphthous stomatitis

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Objectives. To compare immediate pain relief, healing time between minor recurrent aphthous ulcers treated with a single session of carbon dioxide (CO₂) laser and a placebo.

Study Design. A prospective clinical study was performed on 25 patients with minor recurrent aphthous stomatitis. Pretreatment pain levels were recorded using a numerical rating scale. Ulcers were randomized to either receive treatment or placebo. Pain levels were assessed immediately after treatment and after 24 h. Healing was assessed on days 3 and 4, and once every 2 days thereafter for 2 weeks.

Results. Mean pain scores in the laser group were significantly reduced immediately after treatment (0.68 ± 0.6) compared with pretreatment $(8.48 \pm 0.71; P < .001)$. In contrast, the placebo group showed little difference in pain scores between pretreatment (8.08 ± 0.70) and immediately after treatment (7.96 ± 0.84) . In the laser group, significant improvements in healing times were observed $(4.08 \pm 0.81 \text{ vs. } 7.84 \pm 0.90 \text{ days; } P < .001)$.

Conclusion. CO₂ laser therapy in recurrent aphthous stomatitis (RAS) provides immediate pain relief sustained over 24 h, along with accelerated healing time. (Oral Surg Oral Med Oral Pathol Oral Radiol 2013;116:189-193)

Recurrent aphthous ulceration (RAU), commonly known as canker sores¹ is a common oral mucosal disorder characterized by recurring ulcers in patients without the presence of any other systemic disease.² It affects 5%-25% of the general population, predominantly in the age groups between 10 and 30 years.³ Despite detailed investigations by researchers, the etiology and pathogenesis of this condition have largely remained unknown.⁴ The challenges faced in determining RAU have been its non-specific histological features and a lack of reproducibility of identifiable endogenous and exogenous causes.³ The condition is routinely diagnosed based on recording a detailed patient history and comprehensive clinical examination.⁴

Several etiological factors such as local trauma, immunological factors, genetic background, allergic agents, nutrition deficiency, hormonal changes in women, physical or psychic stress, chemical irritants and infective agents have been suspected, but no definitive etiology has been established conclusively.^{1,2,5}

Minor RAU (miRAU) is the most common subtype of this condition and it occurs on non-keratinized mucosa as recurrent, round, clearly defined, small painful ulcers with shallow necrotic centers, raised margins, and erythematous halo.^{4,6} The ulcers tend to be painful with the pain usually subsiding after 4-5

days. During their course, they can significantly interfere with eating and speaking affecting quality of life.⁶

Different treatment options for miRAU include systemic medications, topical applications, acupuncture, corticosteroids, psychotherapy, and combination therapy. In addition, accumulating evidence provides support of laser therapy in the treatment of oral mucosal lesions and aphthous ulcers. Recently, a study revealed that 75% of the patients experienced relief of pain immediately after low-level laser treatment and a total regression of the ulcer in 4 days when compared with a group treated with corticoid agent, where the regression was observed between 5 and 7 days. In particular, there have been reports of carbon dioxide (CO₂) lasers being used to treat aphthous ulcers with considerable success with regard to pain relief. A study by Colvard and Kuo⁹ have reported the use of CO₂ laser for ablation of aphthous ulcers while 3 other studies have also reported beneficial effects of CO2 lasers with regard to pain resolution in aphthous ulcers and host versus graft disease cases.^{6,8,10} With the presence of such preliminary evidences, lasers have emerged as one of the treatment modalities for this common, painful mucosal lesion. Unlike pharmacological interventions, it has no known side effects or deleterious interactions.⁶

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Statement of Clinical Relevance

A single session CO_2 laser operated at 0.7w power with a de-focused hand piece 5-7 mm from the mucosal surface for 5-8 seconds in a non-ablative manner can be a promising treatment modality for RAS.

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The present study was designed and undertaken to assess the efficacy of a single session CO₂ laser treatment, at 10.6 nm wavelength, in a non-ablative manner to provide immediate pain relief in patients presenting with miRAU.

MATERIALS AND METHODS

The study sample was composed of a total of 25 adults, with history of miRAU, selected from a pool of patients visiting the Department of Oral Medicine and Radiology at the Oxford Dental College in Bangalore, between July 2010 and May 2012. Local privately practicing physicians were requested to screen patients for history of recurrent oral ulcers and refer them to our institution out-patient clinic. The sample size was limited to 25 among the total of 42 patients who fulfilled the inclusion criteria as only those 25 were available for the complete duration of the study. The 25 subjects were selected based on the predetermined inclusion and exclusion criteria listed below. All subjects signed an informed consent to participate in the study. The clinical protocol was reviewed and approved by the ethics committee of the Oxford Dental College.

Prior to enrollment into the study, all subjects underwent routine clinical examination from a qualified physician and necessary laboratory investigations were conducted. Those patients with authentic history of miRAU, with the presence of at least 2 discrete painful minor aphthous ulcers at the same time presenting to the hospital within 3 days of appearance of such ulcers were included in the study. Exclusion criteria were pregnancy, history of systemic disease or condition that could predispose the patient to develop oral ulcers, presence of any major herpetiform aphthae, traumatic ulcers, ulcers caused due to topical or systemic medications, and, ulcers currently under treatment. The enrolled patients agreed not to take analgesics before, during and 3 days after the procedure.

STUDY DESIGN

In each of these patients, 2 ulcers as measured by the investigator, of dimension approximately 1 cm or less were selected in different locations in the oral cavity. One of them was randomly allocated to be treated with CO₂ laser (Union Medical Engineering Co., UM-L25 special edition, Korea), and the other served as a placebo. It was a single-blind study designed in a manner such that the patients were unaware as to which of the lesions was going to be treated with laser and which one would be selected as a placebo. Pain scores recorded prior to commencement of treatment were compared with those recorded immediately after the treatment and at 24 h following completion of treatment. Healing period of the laser treated ulcer was

compared with the placebo ulcer on a follow-up visit conducted 3-4 days subsequent to treatment.

STUDY PROCEDURE

Patients were requested to sip water before commencement of the treatment to keep the mucosa wet. Subsequently, a high water gel, devoid of any anesthetic properties, and composed of a combination of 90% water and 10% carboxymethyl cellulose (Shristi Pharmaceuticals, Bangalore) was applied on both the ulcers using a sterile cotton. The CO2 laser was operated at 0.7 W power, with a de-focused hand piece in a continuous mode for 5-8 s, at a distance of 5-7 mm away from the mucosal surface in spiral motion. The placebo lesion was irradiated with the same instrument, but with an inactive probe. The patients were requested to grade the pain of their ulcers on a numerical rating scale of 1-10, [score '0' indicated no pain and score '10' indicated maximum pain] before and immediately after the procedure. Scores were also recorded postoperatively after 24 h. In patients with more than 2 ulcers, Lignocaine gel (Lignox gel, Warren Pharmaceuticals, India) was prescribed to be applied 24 h postlaser treatment to manage pain in those ulcers that were neither part of laser group nor placebo.

Healing time of the laser-irradiated ulcer was compared with the placebo in a recall clinical visit 3-4 days following completion of the treatment. The patients were evaluated every 2 days for the next 2 weeks. Total reduction of erythema and the absence of an ulcer clinically was considered as healed. Regular telephone calls were made once in an every 2 weeks for a period of 6 months to evaluate the recurrence rates of the ulcers. The findings of the recurrence rates of laser-irradiated ulcers are not reported here.

STATISTICAL ANALYSIS

Data were analyzed using SPSS software version 13 (SPSS Inc., Chicago, IL, USA). Mann—Whitney test was used to statistically analyze and compare mean pain scores between the 2 groups. Wilcoxon-signed ranks test was used to compare the change in mean pain scores from baseline to other time intervals within each group. A *P* value of <.05 was considered statistically significant.

RESULTS

Twenty-five subjects ranging in age from 18 to 40 years composed the study cohort. The overall mean age of the patients was 27.48 ± 6.82 with no significant differences between the mean ages of men and women $(28.20 \pm 6.11$ and 26.40 ± 7.99 respectively). The mean pretreatment pain scores in the laser and placebo groups were observed to be 8.48 ± 0.71 and 8.08 ± 0.70 respectively (Table I). Immediately after

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