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ORIGINAL PAPER

Homeopathic treatment of minor aphthous ulcer: a randomized, placebo-controlled clinical trial

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Objective: **The objectives of this study were to clinically determine the efficacy of individualised homeopathy in the treatment of minor recurrent aphthous ulceration (MiRAU).**
Design & intervention: **A randomized, single blind, placebo-controlled clinical trial of individualised homeopathy. One hundred patients with minor aphthous ulcer were treated with individualised homeopathic medicines or placebo and followed up for 6 days. Patients received two doses of individualised homeopathic medicines in the 6C potency as oral liquid at baseline and 12 h later. Pain intensity and ulcer size were recorded at baseline during and at the end of the trial (mornings of days 4 and 6).**
Result: **All 100 patients completed treatment. Between group differences for pain intensity and ulcer size were statistically significant at day 4 and at day 6 ($P < 0.05$). No adverse effects were reported.**
Conclusion: **The results suggest that homeopathic treatment is an effective and safe method in the treatment of MiRAU.** *Homeopathy* (2009) **98**, 137–141.

Keywords: Homeopathy; aphthous ulcer; randomized; control clinical trial

Introduction

Recurrent aphthous ulcer (RAU) is a common oral condition, affecting around 20% of the population.[1] It is usually involves the nonkeratinized oral mucosa, such as the buccal and labial mucosa, and causing painful ulcers. Based on the size, number, and duration of the ulcers, RAU is classified into 3 classes: minor, major, and herpetiform. Minor recurrent aphthous ulceration (MiRAU) is the most common form, comprising 70–87% of the population with RAU.[2] MiRAU usually manifests with 1–5 ulcers per episode, with each ulcer less than 1 cm in diameter. These ulcers are self-limiting and can resolve in 4–14 days without scarring,[3] most episodes last for 7–10 days.[1] The minor aphthous ulcer is typically shallow and less than 1 cm in diameter with a necrotic centre covered by a grey or yellow pseudomembrane. A major aphthous lesion is typically larger, deeper, and persists longer than its minor counterpart (up to four weeks). It is also more painful and heals with scarring, a clinical finding used to distinguish between the 'minor' and 'major' subtypes.[4]

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The aetiology of aphthosis is not clear. One third of patients give a positive family history, and there is an association with certain HLA types. In addition, the occurrence of recurrent aphthosis could be due to an underlying disease, such as anaemia due to folic acid or iron deficiency or familial selective vitamin B12 absorption deficiency, or cyclical neutropenia. Other aetiological factors may be stress, trauma, cessation of tobacco smoking or celiac disease.[5]

Treatment of RAU is symptomatic and mainly empirical. It is mainly directed at relieving pain and diminishing functional disability, inhibition of the acute inflammatory reaction as well as the frequency and the degree of severity of the recurrences.[6]

We did not find any documented study on the effect of homeopathic treatment on aphthous ulcers. In order to clinically determine the efficacy of homeopathy for the treatment of MiRAU, a randomized, controlled clinical trial was performed.

Patients and methods

Patients

An experimental, prospective, single blind (patient blind), randomized controlled clinical trial was implemented. One hundred patients with minor aphthous ulcer referred to Oral Medicine Clinic of Tehran University from

March 2002 to March 2004, were enrolled in this study and each patient signed a detailed informed consent form.

Patients between 18 and 65 years old were included if they presented with 1–5 aphthous ulcers of less than 24 h duration and had a RAU (more than 5 episodes in the preceding year). The ulcers diameter was not greater than 6 mm and they did not suffer from acute or chronic diseases of the oral mucosa.

Patients were excluded from the study if they had concurrent clinical conditions including serious liver, kidney, and heart dysfunctions or if they had ulcers as a manifestation of a systemic disease process such as ulcerative colitis, Crohn's disease, Behçet's syndrome, or serious anaemia. To minimize the effect of confounding variables in the psycho-physiological component of the study, the patients could not have a history of alcohol or drug abuse nor could they be taking any narcotic analgesics. Patients were excluded if they had a history of systemic immunosuppressive therapy.

Methods

Patients were assigned randomly (by computer-generated random number list), to receive homeopathic medicines or identical sucrose placebo globules. After enrolment, the size of ulcers was measured by the investigator, and pain was evaluated by the subjects based on visual analogue scale (VAS) before drug application (day 1) then their case histories were taken. Next patients took a single dose of the selected homeopathic medicine in 6C dilution, in liquid form, diluted in 100 ml of water. The same dose was repeated after 12 h. In placebo group, patients took a single placebo globule diluted in 100 ml of water and it repeated after 12 h. The placebo globules were not impregnated with alcohol.

The index ulcer's size was measured on day 1 (before intervention) and on treatment days 4 and 6. To determine the size of the ulcers, the investigators measured the distance between 2 opposite outside edges of the white border, using a calibrated dental probe with millimetre markings. 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 ulcer.

To evaluate pain, a 100 mm VAS was used, a horizontal line, 100 mm in length, anchored by word descriptors at each end. The VAS score is determined by measuring in millimetres from the left-hand end of the line to the point that the patient marks.[7]

The efficacy indices (EI) of the ulcer size and pain were calculated as a percentage of the baseline value and evaluated on a 4-rank scale:

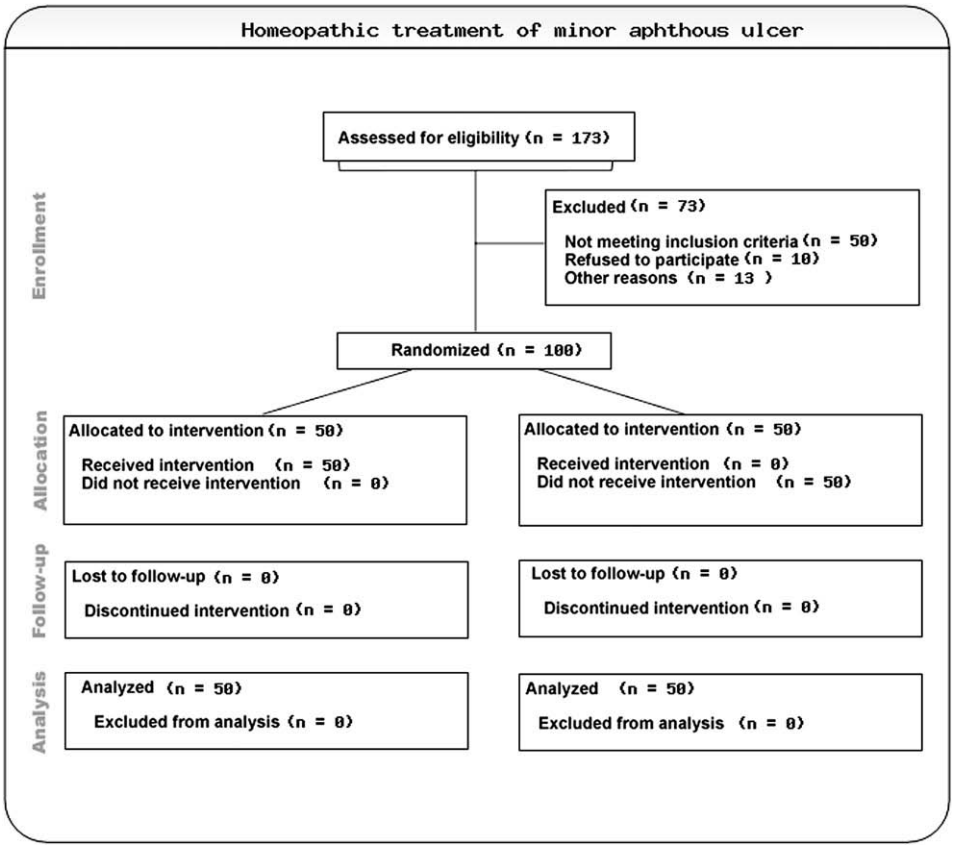

Figure 1 Patient flowchart.

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