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Wet-cupping in the treatment of recalcitrant oral and genital ulceration of Behçet disease: A randomized controlled trial

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The recalcitrant oral ulceration (OU) and genital ulceration (GU) of Behçet disease (BD) can be very distressing and no standard therapy has been established yet. To determine the efficacy of Wet-cupping (W-C) as adjuvant treatment of oral and genital ulceration of BD, 24 patients were included in this prospective and comparative study. All patients included in the study had a recalcitrant oral and/or genital ulceration BD to conventional drug treatment. Treatment with W-C decreased significantly the number of episodes per month, number of ulcers per episode and duration of the episode after 06 months of conventional treatment associated with the W-C of OU and GU compared with the group treated only with conventional treatment. In patients with OU and GU, the difference in improvement ratings between therapy with W-C group and the group treated only with conventional treatment was statistically significant, 91,7% of patients in intervention group had a complete response to oral aphtose, versus 25% of control group. For aphtosis genital response was complete in 100% cases in Intervention group, versus 25% in control group. Our results showed that combining W-C plus conventional treatment shows great promise as an effective treatment for oral and genital ulceration in patients with Behçet disease.

Keywords: Vascularitis, Dermatology involvement, Cupping, Traditional treatment

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Behçet disease (BD) is a chronic relapsing disease characterized by multiple signs and symptoms such as recurrent orogenital ulceration, eye involvement, skin manifestations, and other system involvement; it is currently classified as Vasculitis[1]. Although the etiopathogenesis of the disease remains unknown[2]. Treatment of BD is still not well established although many drugs have been used to control the signs and symptoms of the disease; these drugs include colchicine, levamisole hydrochloride, corticosteroids, acyclovir, chloram-bucil, cyclophosphamide, cyclosporine, azathioprine, and thalidomide, with varying success; none of them result in cure of the disease, and they are associated with a variety of side effects[3]. Oral and genital ulceration are the most common manifestation of mucocutaneous lesions in BD, and can be very distressing, but no standard therapy has been established yet. The agents, such as topical or intralesional corticosteroids and local anesthetics, are used only for palliative therapy[4].

Wet-cupping therapy is being practiced nowadays in many parts of the globe such Asia, the Middle East and Europe[5]. By description, a glass cup is applied to the skin, and a partial vacuum created inside the cup. After a few minutes, superficial incisions are made to the skin, and bloodletting induced through replacement of the cup with vacuum. This process is repeated a few times[6].

From literature, it is found any clinical trial reports on wet cupping therapy for BD. Therefore, this study aims to evaluate the beneficial and harmful effects of wet cupping therapy for treatment of recurrent oral and genital ulceration of behçet disease.

Materials and methods

Patient selection

Twenty-four patients with BD, diagnosed according to the criteria of International Study Group for Behcet's disease, 50% was male and 50% female, aged 27–50 yrs. The mean duration of the disease was 97,75 month with an average of 59,93. All patients included in the study had a recalcitrant oral and/or genital ulceration BD to conventional drug treatment, principally colchine. Patients were excluded who have contraindications to the Wet-cupping (Infants, Pregnant women, menstruating women, cancer

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(metastatic), patients with bone fractures, muscle spasms, patients who have ulcers, arteries[7], the choice of the group that will own each patient was done according to a draw. This study was designed as a prospective and comparative study. All study participants gave their informed consent. The study protocol was reviewed and approved by the Ethics Committee of the Medical Faculty University of Cadi Ayyad of Marrakech.

Therapies

The patients were observed for 6 months before the study and they were divided into a treatment group (12 cases) treated by wet-cupping and conventional treatment or Intervention group (IG) (colchicine, corticoticosteroids, imurel); and a control group (CG) (12 cases) treated with only conventional treatment.

Wet-cupping was performed using vacuum cups with plastic vessels. The site for wet-cupping used in our study was between the two scapulas.

1 Disinfection of the skin at the shoulder triangle (over the M. trapezius),
2 Primary sucking: The cup is placed on the selected site and the air inside the cup is rarified via manual suction, for a period of 5 minutes.
3 Scarification: Superficial incisions are made on the skin.
4 Bloodletting: The cup is placed back on the skin, using the same manner described above, until it is filled with blood from the capillary vessels.
5 Removal: The cup is removed after 3 min, and the process is repeated 3 times.
6 Dressing.

Criteria for therapeutic effect

The primary endpoint is represented by the OU, and the accessory criteria are GU. The evaluation of these criteria is made sixth month after the treatment. For aphthosis: a complete response is defined by the disappearance of ulceration, partial response is defined by a lower number of episodes per month, and or number of ulcers per episode, and/or duration of the episode. The lack of response is defined as no improvement.

Statistical analysis

SPSS 17.0 software was used for statistical analysis. Differences in improvement ratings (overall responses) between groups were tested using the Pearson's X^2 test. $P<0.05$ was accepted as significant.

Results

In all patients, medications uses were well tolerated, and no patients were withdrawn from the study because of adverse events. The demographic data of these patients are shown in Table 1. Number of episodes per month, number of ulcers per episode and duration of the episode of OU and GU for both treatment groups and statistical results are summarized in Table 2. The groups were not significantly different in measured disease parameters at the beginning of the study. Treatment with Wet-cupping decreased significantly the Number of episodes per month, number of ulcers per episode and duration of the episode after 06 months of conventional treatment associated with the Wet-cupping of OU and GU compared with the group treated only with conventional treatment. Full results

Table 1—The demographic and Ulceration characteristics of intervention and control group

Group Parameters	Intervention group	Control group
M/F	6/6	6/6
Mean ± SD age	36.08 +/-8,27	38.33+/-8,85
Oral ulceration at the beginning of therapy	12	12
Mean ± SD duration of number of episodes per month in OU/ month	2	2.5
Mean ± SD duration of number of ulcers per episode in OU/ month	3.5	3.5
Mean ± SD duration of duration of the episode in OU/ day	7.33	7.75
Genital ulceration at the beginning of therapy	09	09
Mean ± SD duration of Number of episodes per month in GU/ month	1.5	2
Mean ± SD duration of number of ulcers per episode in GU/ month	1.7	1.33
Mean ± SD duration of duration of the episode in GU/day	9.6	9

M/F: Male/Female
SD: Standard Deviation
OU : Oral Ulceration
GU: Genital Ulceration

Table 2—Number of episodes per month, number of ulcers per episode and duration of the episode after 06 months of the study

	Oral Ulceration			Genital Ulceration		
	IG	CG	P	IG	CG	P
Number of episodes per month (Mean ± SD)	0,08+/-0,289	1,83+/-1,403	0,018	0	0,50+/-0,522	0,005
number of ulcers per episode (Mean ± SD)	0,08+/-0,289	2,42+/-1,975	0,028	0	0,58+/-0,669	0,018
duration of the episode (Mean ± SD)	0,25+/-0,866	5,58+/-3,630	0,006	0	4,50+/-4,815	0,018

Pearson's x^2 test was used to test the differences.
Intervention group: IG
Control group: CG

Table 3—Overall Response of Ulceration in Patients With Behcet Disease

	Oral Ulceration			Genital Ulceration		
Effect	IG	CG	X_2P	IG	CG	X_2P
Complete response	11	3	0,001	12	3	0,0001
Partial response or No response	1	9	0,001	0	9	0,0001

Pearson's x^2 test was used to test the differences.
Intervention group: IG
Control group: CG

are represented in Table 2. In patients with OU and GU, the difference in improvement ratings between therapy with Wet-cupping group and the group treated only with conventional treatment was statistically significant. 91,7% of patients in IG had a complete response to oral aphtose, versus 25% of CG. For aphtosis genital response was complete in 100% cases in IG, versus 25% in CG. Full results are represented in Table 3.

Discussion

Oral ulcers and GUs, the most common of mucocutaneous lesions in patients with BD, are characterized by recurrent and painful ulcerations of the oral and genital mucosa, respectively. Oral ulcers and GUs are a required feature for the diagnosis of BD and often are the initial presenting sign[3].

Many treatment modalities of OUs and GUs in BD have been used, with varying degrees of success. Topical antiseptic and anti-inflammatory mouthwash preparations, topical corticosteroids, topical anaesthetics or tetracycline mouthwash are generally considered first-line treatment for OUs in BD[8]. Recently, topical sucralfate suspension was found to be effective for oral and genital ulceration treatment[8]. Our pilot study used Bloodletting with cupping, also known as "wet cupping"; cupping therapy is one of the oldest ways of healing. Presently it is getting re-attention in many parts of the globe such as Asia, America and Europe[9], currently the cupping therapy is classified as a complementary and an alternative medicine[9].

The principle of cupping is a sucking method. The cupping glass is applied to the skin, mostly to parts of the back of the patient. Because of the vacuum, the skin is sucked into the cupping glass, becomes red and warm, and shows, when the vacuum is strong, signs of sub- and/or intracutaneous bleeding (petechiae). Furthermore, moisture is sucked out of the skin and, in case of wet-cupping, blood is collected in the cupping glass[10].

Various theories have been put forward to explain its workings. In one of these theories, it was reasoned that cupping increases the circulation around the area being treated and enables toxins trapped deep in the soft-tissue layers to be brought to the body surface When combined with a technique called ''wet cupping'', which involves piercing the skin, cupping has the effect of drawing out the toxins together with blood[11]. Wet-cupping is a commonly used with a wide application all around the world for various conditions: pain[5], hypertension[12]; stroke rehabilitation[13], infection disease like herpes zoster[14].

Our study suggest favorable effects when the wet-cupping is used as an adjunct to conventional drug treatment compared with conventional treatment only in treatment of oral and genital ulceration of Behçet disease. But, we were not able to locate any controlled clinical trial on wet cupping which uses

in treatment of OU and GU in Behcet's disease, therefore we cannot compare our results to others. Therefore, to our knowledge, this study represents the first controlled empirical test of its efficacy.

Furthermore, our data suggest that patients in both the experimental and control groups reported improvement, but the patients in the wet-cupping group scored significantly lower on Number of episodes per month, number of ulcers per episode and duration of OU and GU in Behçet's disease. Moreover, our study had certain limitations; the main limitation was the relatively small sample size, which increases the possibility of biases and might have influenced our results; consequently, future investigations of this topic should adopt rigorous trial methodology in order to minimize bias. They should also have sufficiently large sample sizes.

In this study, patients with recalcitrant oral and genital ulceration of Behçet disease who were treated with wet cupping experienced a highly significant decrease in the number of episodes per month, number of ulcers per episode and duration of the episode. The observed improvements are most likely attributable to this traditional therapeutic intervention.

Conclusion

Our results showed the favorable effect of combining wet-cupping plus conventional treatment in treatment of oral and genital ulceration of Behçet disease, but we suggest future trials to comply with international standards in the evaluation of treatment effect.

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