Chapter 11
PHYTORELIEF™-CC: A PILOT REGISTRY IN APHTHAE AND APHTHOUS STOMATITIS

HU S., DUGALL M.
IRVINE3 LABS, DEPT SC MED OR BIOTEC, CH-PE, UNIVERSITY

Mucosal mouth aphthae are minute, painful ulcers often covered by a gray or white exudate. Aphthous stomatitis (AS) and recurrent AS (RAS) are very common. This study evaluated the effects of PhytoRelief™-CC on AS and RAS.
RAS had been defined by the occurrence of at least 3 aphthous episodes in the previous 6 months.
There are 3 types of aphthae:
a) a minor, superficial aphthous ulceration,
b) a major aphthous ulceration,
c) herpetiform ulceration.

Minor aphthous ulcerations are the most common type; they are a cluster of 1–6 small (2-4 mm in diameter), round/oval ulcers with a yellow-grey color and an erythematous (reddish) "halo". The ulcers heal without scarring in some 7-10 days.
Many ulcers tend to reoccur at intervals of about 1-4 months.
Major aphthous ulcerations are less common and produce more important symptoms and severe lesions.
Major aphthous ulcerations include larger (>1 cm diameter) ulcers that take longer to heal (10-40 days) and may leave some scarring. The minor and major subtypes of aphthous stomatitis produce lesions on the non-keratinized oral mucosa (inside of the cheeks, lips, underneath the tongue and the floor of the mouth); rarely major aphthous ulcers may occur in other parts of the mouth or on keratinized mucosal surfaces.
The least common type is defined herpetiform ulceration, so named because the condition resembles primary herpetic gingivostomatitis.
Herpetiform ulcers begin as small blisters (vesicles) which break down into 2-3 mm ulcers. Herpetiform ulcers appear in "clusters" sometimes hundreds in number, which can coalesce to form larger areas of ulceration. This subtype may cause severe pain, heals with scarring and may reoccur frequently.

THE PHYTORELIEF™-CC GROUP EXPERIENCE. A group of 18 otherwise healthy subjects with AS (6) or RAS (12) were included (age 34.8;2.2) as the **control group.** Another group of 14 comparable subjects used the supplement **PhytoRelief™-CC** (4-6 gummy tablets/day for at least 8 days); details of this group are shown in the Table 11.1.

Table 11.1. Details of the two groups.

	AS	*RAS*	*Total*
Controls (c)			
Number	6	12	18
Females	4	7	11
PhytoRelief™-CC	4	10	14
Females	2	6	
Days with Symptoms PhytoRelief™-CC			c 8.9;2 4.1;1
Ulcers visible (Days) PhytoRelief™-CC			c 6.5;1.1 3.2;0.6

PhytoRelief™-CC includes dantabija (Punica granatum), 20 mg, haridra (Curcuma longa) 50 mg, Zingiber officinalis 5 mg in gummy tablets to dissolve slowly in the mouth.

PRELIMINARY RESULTS

The use of PhytoRelief™-CC did not cause any safety or tolerability problems. The days with symptoms were significantly decreased with PhytoRelief™-CC ($P<0.05$).
Also, ulcers were visible in average of 6.5;1.1 days in controls vs only 3.2;0.6 in the PhytoRelief™-CC group ($p<0.05$). Only 3 out of 14 subjects (21.4%) in the PhytoRelief™-CC group could feel the ulcer at 8 days vs 8 out of 18 (44.44%) in the control group. This corresponds to a very important 23.04% reduction even in a small sample and in a short period.

Conclusion. This is the first study that shows efficacy of a supplement in a very common problem. Another study is evaluating whether low-dose (1-2 tablets/day) for a long period of time could stop recurrence.

DISCUSSION

The exact cause of aphthous stomatitis is unknown, but there may be a genetic predisposition in some people. Other possible causes include hematinic deficiency (folate, vitamin B, iron), stress, menstruation, trauma, some food allergies or hypersensitivity to sodium lauryl sulphate (found in many brands of toothpaste).
Aphthous stomatitis has no clinically detectable signs or symptoms outside the mouth: the recurrent ulceration can cause much discomfort to sufferers. Treatment is aimed at reducing the pain and swelling and speeding healing; treatments may involve systemic or topical steroids, analgesics (pain-killers), local antiseptics, anti-inflammatories or barrier pastes/ointments to protect the raw area(s).
The vast majority of people with aphthous stomatitis have minor symptoms and do not require any specific therapy. The pain is often tolerable with simple dietary modification during an episode of ulceration such as avoiding spicy and acidic foods and beverages. Many different topical and systemic medications have been proposed, sometimes showing little or no evidence of efficacy when formally investigated. No therapy is curative. Most treatments tend to relieve pain, promote healing and reduce the frequency of episodes of ulceration.

In conclusion PhytoRelief™-CC may be a significant option in the management of aphthae to be explored in larger, prospective studies.

References

1. Scully, Crispian (2008). "Chapter 14: Soreness and ulcers". Oral and maxillofacial medicine: the basis of diagnosis and treatment (2nd ed.). Edinburgh: Churchill Livingstone. pp. 131-139. ISBN 978-0-443-06818-8.