
Rhodus NL, Bereuter J.

ABSTRACT

OBJECTIVE: Recurrent aphthous stomatitis is a very common condition, currently treated with anti-inflammatory agents, which palliate the symptoms. The purpose of this clinical trial was to compare a medication commonly used to treat recurrent aphthous stomatitis, Kenalog-in-Orabase, and a newer agent, Debacterol.

METHOD AND MATERIALS: Sixty patients diagnosed with recurrent aphthous stomatitis were enrolled in the study. Twenty patients were assigned to each of the two treatment groups, and 20 age- and sex-matched patients were assigned to the control group, which received no treatment. After the diagnosis was made, clinical examinations and ulcer measurements were performed, and a subjective evaluation of symptoms (100-mm visual analog scale) was completed by each subject. The subjects did not use any other medications. Both agents were applied topically (the frequency varied depending on the group of subjects) at specified intervals. Ulcer measurements and subjective evaluations were made at days 0, 3, 6, and 10 for all subjects.

RESULTS: In both treatment groups, by day 10, 100% of the ulcers had clinically healed and were no longer causing pain. Patients in the Debacterol group reported a significantly greater decrease in pain at 3 days (> 70%) than did subjects in the other groups (< 20%), although the size of the ulcer did not differ significantly in any of the groups. After day 6, 80% of the ulcers in the Debacterol group had clinically disappeared and no longer caused symptoms, as compared to about 30% in the other groups.

CONCLUSION: Patients subjectively reported significantly greater relief from symptoms with Debacterol than with Kenalog-in-Orabase or no treatment. The relief of symptoms associated with recurrent aphthous stomatitis may or may not correspond to clinical improvement, and these two topical medications may affect signs and symptoms of the lesions differently.

SUMMARY: Rhodus and Bereuter (1998) compared the canker sore treatment Debacterol to a topical preparation containing both a steroid (Kenalog) and a numbing agent (Orabase containing Benzocaine, an anesthetic) and to no treatment. The study included 60 subjects and data was recorded on day one, three, six and 10 regarding the size of the ulcers and the pain experienced by subjects.

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The researchers report that Debacterol provided significant and substantially superior pain relief to subjects compared to Kenalog/Oragel and no treatment. Healing of ulcers was also expedited. They state:

“*The results indicate that immediate and significant relief of the pain accompanying RAS [recurrent aphthous stomatitis / canker sores] was achieved in a large majority of subjects with RAS through the use of Debacterolas compared to Kenalog-in-Orabase or no treatment. The clinical healing of the RAS ulcers was also expedited with the use of Debacterol . . . .”*