

A Pilot Study of an Over-the-Counter Mouthwash in the Treatment of HIV-associated Oral Candidiasis

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Background: Oral candidiasis (OC) has been a common cause of significant morbidity among persons living with HIV/AIDS. HIV-infection has been associated with abnormalities of salivary flow and composition, including a deficiency of salivary lactoferrin, an iron-binding protein which has been shown to be fungicidal to *Candida*. Lysozyme, another constituent of normal saliva has also been demonstrated to have activity against *Candida* species. We describe here the results of a pilot study to evaluate the effectiveness of biotène, a mouthwash which contains lactoferrin and lysozyme in the treatment of HIV-related OC.

Methods: 12 subjects were enrolled and evaluated at two weeks. Subjects were monitored for CD4+ lymphocyte count, viral load, concomitant medications, symptoms, diet and weight changes. Enrolled subjects must have been treated with antifungal agents for over 30 days or untreated for OC for at least 30 days and have developed new or worsening OC. No other changes were made to the subjects' treatment. They were instructed to swish and spit a teaspoonful of the mouthwash for 30 seconds four times daily—after meals and at bedtime.

Results: 7/12 subjects were taking antiretroviral therapy during the study. 3/12 had been receiving antifungal therapy for more than 30 days prior to study entry. 10/12 had CD4+ lymphocyte counts below 200/mm³. All available *Candida* isolates (6/12) were *Candida albicans*. All subjects had a decrease in the extent of their OC and symptoms (where relevant) after 2 weeks treatment. Average decrease in OC lesions was 73%. 6/12 had complete resolution of OC. 2/3 subjects failing antifungal therapy had a complete response at week 2. 1/3 had a 55% decrease in OC prior to leaving the study due to severe concomitant illness. 5 subjects gained between 2-5% of baseline body weight during the study. No subject lost weight. No treatment-related adverse events were reported.

Conclusion: HIV-infected patients with OC demonstrated, on average, a 73% response to a two week course of treatment with a lactoferrin and lysozyme-containing mouthwash. We conclude that lactoferrin, lysozyme or both possess significant anticandidal activity *in vivo*. Further studies are needed.