

# No effect seen for multivitamin therapy on recurrent aphthous stomatitis patients

## Abstracted from

**Lalla RV, Choquette LE, Feinn RS et al.**

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## Question: Does a daily multi-vitamin supplement have a positive effect on the number and duration of recurrent aphthous stomatitis (RAS) episodes?

**Design** Randomised controlled trial.

**Intervention** Patients with a validated history of at least three episodes of idiopathic recurrent aphthous stomatitis were randomised to either a once-daily multivitamin containing 100% of the U.S. reference daily intake (RDI) of essential vitamins or a placebo for at least one year.

**Outcome measure** Number of new RAS episodes, mouth pain, normalcy of diet and medication compliance.

**Results** There were no significant differences in mean number of new RAS episodes between the multivitamin (4.19 episodes) and placebo (4.60 episodes) groups. Mean duration of new episodes was similar for the two groups at 8.66 days for multivitamin group and 8.99 days for placebo ( $P = .60$ ). There were no differences with other measures.

**Conclusions** Daily multivitamin supplementation, with the RDI of essential vitamins, did not result in a reduction in the number or duration of RAS episodes.

## Commentary

This randomised controlled trial investigated the effect of a daily multivitamin tablet on the number and severity of recurrent aphthous stomatitis (RAS) episodes in patients that experienced at least three RAS events in the previous year.

The study was designed with the intention of possibly identifying a low-cost, non-toxic product to prevent RAS that does not even require invasive baseline testing.

As the authors explained, the aetiology of RAS is not completely understood. As a result there are many therapeutic approaches with a larger number of topical options and less numerous systemic therapies. Most topical treatments are used to provide symptom relief while systemic therapies are being studied to prevent or limit the number and duration of recurrences, with less success.

Of the possible factors associated with RAS, the authors concentrated on vitamin deficiencies, specifically B complex. The supplement used in the research follows the US daily-recommended dosage for A, B complex, C, D and E vitamins.

The primary outcome evaluated was the number and duration of RAS episodes over a period of one year, and secondary pain and normalcy of diet.

Power calculation was used for determining sample size. Patients were enrolled based on self-report history of RAS and clear exclusion criteria. Patients were then randomised using a stratified block separated into two groups according to the frequency of RAS, (high and low). Study investigators and patients were masked of the treatment allocation. Baseline vitamin B<sub>12</sub> and foliate levels were assessed. There was no correlation between frequency of recurrences and vitamin B<sub>12</sub> baseline levels.

Patients were requested to keep a record of medication intake and in the case of a RAS episode, its duration, pain and normalcy of diet. Patients were evaluated at six and twelve months and they were requested to come during RAS episodes. Of the 575 episodes that underwent a clinical examination 13% were not RAS.

No differences between groups were observed in any of the studied outcomes over the duration of the study.

The investigators faced issues with patient compliance. Compliance could play a role in the lack of observed effect.

Volkov and colleagues in 2009<sup>1</sup> reported 74% success in preventing episodes over a six-month period by using a much higher concentration of a sublingual vitamin B<sub>12</sub> tablet available over the counter.

Besides the dosage, we may need to consider that the delivery system could have an effect on the treatment success.

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1. Volkov I, Rudoy I, Freud T, et al. Effectiveness of vitamin B12 in treating recurrent aphthous stomatitis: a randomized, double-blind, placebo-controlled trial. *J Am Board Fam Med* 2009; **22**: 9–16.

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