

Promising results for dexamethasome ointment for treatment of recurrent aphthae

Abstracted from

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Question: Is dexamethasone ointment safe and effective for the treatment of recurrent aphthous ulceration?

Design Randomised controlled trial.

Intervention Patients were randomised to receive either a 5g tube of dexamethasone ointment (containing 5 mg dexamethasone) [n=120] or placebo ointment [n=120]. Participants were instructed to apply the given agents to the ulcer three times a day (after meals) for five days. The initial application of the medication was performed under observation for >30 minutes for any signs of adverse effects. Patients kept a daily log and were reviewed clinically on day 6 ± 2 .

Outcome measure The size, pain level, healing ratio, average duration of ulcers and the safety of the agents were evaluated. The serum concentration of dexamethasone was monitored.

Results After 6 ± 2 days of treatment, there was significant difference in the ulcer size between the treatment group (7.167± 6.3415 mm²) and the control group (4.346 ± 7.0666 mm²; P=.000), and in the variation of pain level between the treatment group (5.623± 1.9570) and the control group (4.940± 2.2449; P=.001). The healing ratio was 83.33% in the treatment group and 54.70% in the control group (P=.000). No severe adverse reactions were observed. No serum dexamethasone was detected before or after the use of the agents (<0.502 ng/mL). **Conclusions** The current study revealed that dexamethasone ointment was safe and efficient in reducing ulcer size, alleviating ulcer pain and hastening ulcer healing in patients with recurrent aphthous ulceration. In addition, the patients had a good overall assessment of the agents. We could not detect dexamethasone in the serum of patients, which illustrated further the safety of dexamethasone ointment.

Commentary

The prevalence and severity of recurrent aphthous ulcers varies, and several factors and risks are attributed to the condition. It has been estimated that 20% of the general population will suffer from recurrent aphthous ulcers at some time in their lives.¹ The minor type can heal within 10-14 days without treatment and scarring, however for many people pain and discomfort are associated and quality of life is affected. Since frequency and recurrence varies, many products are marketed worldwide to reduce the symptoms and the duration.

A systematic review from 2008 compiled data from questionable quality studies and found that most of the treatment provided with corticosteroid compared to placebo showed a reduction of the healing time and an improvement of pain.² The present study seems to appropriately answer the question with a properly constructed short research design with regard to the effectiveness of a therapy for a common oral lesion seen in clinical practice. Several features are presented to attempt to minimise the risk of bias. The sample size necessary for the study was calculated by a statistical analysis.

The blinded randomisation was done by a computerised system. The drop out rate was minimal. Blinding was done for the patients and treatment, and control groups were treated equally. Monitoring of the sites was done during and after the collection of data. Even though it is mentioned that clinicians and research assistants received training, and that each participant was measured and recorded by the same researcher, it is unclear about the blinding of the evaluator and calibration of them, and it is reported that a possible source of bias could happen in one of the centres.

The authors provided all of the data including confidence intervals, to calculate the true estimate and the magnitude of the treatment effect. Pain reduction was similar for all of the groups. However the variation and the reduction in size seem more clinically relevant in the treatment group than in the control group. At baseline, the treatment group had a mean size of the lesions that was larger than the control group. That difference in the lesion seems more relevant post treatment, which supports the effectiveness of the dexamethasone ointment. Overall, the short trial results seem to positively favour the use of simple application of a short-term steroid for the treatment of recurrent aphthous ulcers. The size of the lesion can be reduced with no immediate side effects. Cost, availability and acceptance are something that needs to be evaluated for the immediate use.

Practice points

- A short study showed promising results for local dexamethasone ointment as an effective and safe treatment for recurrent aphthous ulcers.
- Evidence shows that healing time seems to be reduced with dexamethasone but there is not any evidence for variation in pain relief against placebo.

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