

A Prospective Study on Efficacy of Rebamipide in Recurrent Aphthous Stomatitis.

Dr .K .Kesavalingham¹, *Dr.V.Sivakumar², Dr.S.S Meera³, Dr.T.Karthikeyan⁴,
Dr.Vijayanand⁵, Dr.R.Venkateshwar⁶,

¹M.S, Associate Professor

²M.S, Senior Assistant Professor

³M.S, Senior Assistant Professor

⁴M.S, Assistant Professor

⁵M.S, Assistant Professor

Junior Resident

Surgical unit 3, Department of General Surgery, Government Mohan Kumaramangalam medical college hospital, Salem -1

Corresponding author: Dr.V.Sivakumar

Abstract: Recurrent aphthous ulcers have been estimated to affect more than 10 million people per year in India. Though it is a much common condition which presents as recurrent small, ovoid oral ulcers with circumscribed margins, erythematous halos and yellow floors, still etiology remains a debatable one. Recurrent aphthous ulcers may be a manifestation of a disorder rather than a separate entity⁽¹⁾. So a better drug with maximal efficacy and minimal side effect is the need of the hour and so we conducted a prospective study on efficacy of Rebamipide in recurrent oral aphthous stomatitis. Rebamipide is already marketed as a gastro protective agent. Our study conducted in a tertiary care centre has approved the efficacy of Rebamipide in recurrent aphthous stomatitis, which can be marketed as a promising drug for the same.

Keywords: Recurrent aphthous stomatitis, Rebamipide

Date of Submission: 22-09-2017

Date of acceptance: 05-10-2017

I. Introduction

Recurrent aphthous stomatitis is a much common condition, which affects more than 10 million people per year in India. It presents as recurrent small, ovoid oral ulcers with circumscribed margins, erythematous halos and yellow floors. Though many etiological factors have been hypothesized, still the proven etiological factor is a debatable one. Multiple drugs have been targeted to cure this condition, but a perfect choice is still lacking. So we tried a novel therapeutic gastro protective agent Rebamipide in treatment of recurrent aphthous stomatitis in our Medical college hospital.

Aims & Objectives:

To assess the efficacy of Rebamipide in recurrent aphthous stomatitis in GMK Medical college hospital, Salem.

II. Methods & Materials:

1. **Study type** :- Interventional
2. **Study design** :- Non randomized prospective study.
3. **Study group**:- Over 6 months, 100 patients with history of recurrent aphthous ulcers attending the General surgery department of GMK medical college hospital, Salem were considered as data source. Patients who fulfilled the inclusive and exclusive criteria were enrolled in this study.
4. **Inclusion criteria:**
Age: - 15 to 55 years
Sex: - both males and females
Symptoms :- Recurrent oral ulcers.
5. **Exclusion criteria:**
Malignancy
Immunocompromised state
Not willing to give consent.

6. Study method instituted :-

Patients of age group 15 to 55 years presenting to general surgery OP with complaints of recurrent oral ulcers were included in this study. Malignancy and immunocompromised state were excluded first by clinical assessment and in some cases radiological and histological assessment. Rebamipide 100mgs oral tablet was given as thrice daily for 2 weeks to all patients enrolled in the study. All patients were followed up for a period of 6 months and recurrence if any was documented. Intake of tablets and self-reporting were documented as compliance. Pain and clinical assessment at initial visit at initial visit and subsequent visits were documented using visual analog scale using a VAS ruler. VAS ruler is a linear analogue 10 point scale with markings from 0 to 10, in which 0 denotes absence of ulcer and pain and 10 denotes most severe pain and macroscopically large and multiple ulcers. Results were documented as per clinical examination and visual analog scale.

7. Follow up:-

Bimonthly follow up was done in all patients for a period of 6 months and each time, results documented.

III. Results

Out of 100 patients studied, 64 patients had history of recurrent oral painful ulcers for more than 3 times. A VAS score of 10 was recorded by 42% patients and other patients recorded VAS score of 4 to 9. The number of aphthous ulcers clinically ranged from 1 to 6 and size of ulcers ranged from a pin head to 0.5*0.5cms. A very good response was noted in 90% patients with significant decrease in VAS scoring from 10 to 3 in one week and total absence of lesion at the end 2nd week was documented. In 6% patients there was recurrence within the study period of 6 months. 4% patients discontinued the follow up. No adverse reactions of drug was noted in any patient.

IV. Discussion

Recurrent aphthous stomatitis management has always been elusive for general practitioners, physicians, surgeons and a magic drug for perfect management of this condition is a great expectation for both treating authorities and affected patients. The exact cause of recurrent oral ulcers is still idiopathic, though many cause like viral, autoimmunity, vitamin deficiencies, drug induced and stress have been postulated. Till date many treatment strategies have been tried including vitamin supplements, topical and oral steroids, antiviral etc. But a perfect drug with maximal efficacy and minimal side effects is the need of the hour. So we have conducted this prospective study in a tertiary care teaching institution with a gastro protective drug Rebamipide. Rebamipide is an aminoacid analog of 2(1H) – quinolone⁽²⁾, which acts as a gastro protective agent by being a free radical scavenger and also by production of prostaglandins in gastric ulcer mucosa and by increase of vascularity in gastric mucosa through enhanced nitric oxide synthase activity and by down regulation of 15 hydroxy prostaglandin dehydrogenase⁽³⁾.

Till date no other drug has been proved to be so much effective as Rebamipide. Also there is no proven cross reaction of this drug with other drugs. Also, there were no demonstrable side effects of this drug during our study. Pain score has been dramatically reduced and this drug is also very safe and well tolerated.

V. Conclusion

Rebamipide is proved to be much effective in treatment of recurrent aphthous stomatitis, which can be marketed as a promising drug for the same. Rebamipide is very safe and well tolerated with maximal efficacy in recurrent aphthous stomatitis.

References

- [1]. Preeti L. et al, recurrent aphthous stomatitis. J oral maxillofacillary pathology, 2011 september 15 (3):252-6 (medicine)
- [2]. Mohan H Kudur et al; Rebamipide: A novel agent in the treatment of recurrent aphthous ulcer and Behcet's syndrome, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC 3778773/> Indian journal of Dermatology.
- [3]. Tangawa T et al, Rebamipide, a mucoprotective drug, inhibits NSAIDs – induced gastric mucosal injury, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC 3045688/>.

*Dr.V.Sivakumar. "A Prospective Study on Efficacy of Rebamipide in Recurrentaphthous Stomatitis." IOSR Journal of Dental and Medical Sciences (IOSR-JDMS) 16.10 (2017): 44-45