



# **Comparative Evaluation of Efficacy of *Jasminum grandiflorum* with Honey and Corticosteroids in Management of Recurrent Aphthous Stomatitis- A Study Protocol**

**Suwarna Dangore Khasbage<sup>1\*</sup>, Dhanashri R. Tijare<sup>1</sup>, Monika Khubchandani<sup>1</sup>  
and Surbhi Juneja<sup>1</sup>**

<sup>1</sup>Department of Oral Medicine and Radiology, Sharad Pawar Dental College and Hospital, Datta Meghe Institute of Medical Sciences, Deemed to be University, Sawangi (Meghe), Wardha – 442001, India.

## **Authors' contributions**

*This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.*

## **Article Information**

DOI: 10.9734/JPRI/2021/v33i49A33328

Editor(s):

(1) Dr. Mohamed Fawzy Ramadan Hassanien, Zagazig University, Egypt.

Reviewers:

(1) Florense Gabriela da Silva, Universidade Cruzeiro do Sul, Brazil.

(2) Iraida María Pino Román, Universidad de Ciencias Médicas, Cuba.

Complete Peer review History: <https://www.sdiarticle4.com/review-history/75456>

**Received 12 August 2021**

**Accepted 19 October 2021**

**Published 11 November 2021**

**Study Protocol**

## **ABSTRACT**

**Aim:** To determine the efficacy of *J grandiflorum* in the treatment of aphthous ulcer on the basis of reduction in size of the ulcer, erythema and pain.

**Study Design:** Prospective, Observational.

**Place and Duration:** Department of Oral Medicine and Radiology, Sharad Pawar Dental College and Hospital, Datta Meghe Institute of Medical Sciences, Deemed to be University, Sawangi (Meghe), Wardha.

**Duration:** One year.

**Methodology:** One Hundred and Twenty patients visiting to the dental OPD and diagnosed to have aphthous ulcer will be selected. The patients will be divided in three groups and the formulated gel will be prescribed to one group of patient and other will be given corticosteroid and monitoring will be done.

**Expected Results:** With all the studies performed till now it is expected that the *J. grandiflorum* and honey together will have good synergistic effect over aphthous ulcer and will help in reduction of size, pain and erythema level of aphthous ulcer.

**Conclusion:** *J. grandiflorum* and honey may be effective in management of recurrent aphthous stomatitis.

**Keywords:** *J. grandiflorum*; honey; aphthous ulcer; corticosteroids.

## 1. INTRODUCTION

Recurrent aphthous stomatitis (RAS) is one of the common mucosal diseases affecting about 10- 20% of the population. The etiology of RAS is still unknown, but several local, systemic, immunologic, genetic, allergic, nutritional, viral and bacterial infections, and immune or endocrine disturbances have been proposed as causative agents [1,2]. It is characterized by the periodic appearance of painful, small, round to oval crateriform ulceration on the mucosa of the vestibule, cheeks, lips, tongue, soft-palate, floor of mouth & pharynx with bright red circular inflammatory zone around the ulceration with gray to yellow pseudomembrane. Both the sexes are equally involved [2].

RAS is clinically divided into following three types [3, 4].

1. Minor RAS: Also called as Mikulicz's aphthae & it accounts for 75-85% of all aphthous lesions. These are round or oval lesions with gray-white pseudomembranes, erythematous halo. Lesion is <10mm and usually resolve in 4-14 days without scarring.
2. Major RAS: Also called as Periapical Mucosa Necrotica Recurrence (PMNR) and "Sutton's Disease" & it occurs in approximately 10% of RAS patients [5]. These are > 10mm and are commonly present on lips, soft palate, pharynx. These lesions persist >6 weeks and heal with scarring
3. Herpetiform aphthae: affects 5-10% of all RAS patients [6]. These are usually small, deep ulcers that commonly converge irregular contour. Lesions resolve in <30 days.

The management of RAS is largely directed towards symptomatic pain relief. Many therapeutic agents are there including topical steroids, tetracycline mouth rinses, antibiotics,

local anesthetic gel, etc for the treatment of the RAS [1,2]. The choice of treatment is based on the severity of condition as well as basic etiology for the same in a particular case. It is preferred to begin treatment with topical medication and advance to systemic medication with a goal of decreasing recurrence rate and severity of the outbreaks [2]. Amongst the topical agents, chlorhexidine 0.2% rinse, doxycycline or minocycline mouthwash are used to control secondary infection while local application of benzocaine 20%, Lidocaine 5% ointment or lidocaine 10% spray is effective to achieve temporary pain relief [3,7].

Amongst systemic drugs, oral antimicrobials, such as penicillin G, Clofazimine, corticosteroids, pentoxifylline, immunomodulators etc are helpful in decreasing the overall symptoms and aid in reducing severity of outbreaks. Certain steroid-sparing agents, such as colchicine, dapsone may also be effective. Thalidomide at a dose of 50 to 100mg/day is considered the most effective immunomodulator for RAS. But, the utility of all these medications is limited by their side-effect profile [3].

On the contrary, nature is the most important source for producing the new medicines and two natural products with medicinal property, '*Jasminum grandiflorum* Linn and honey will be used in the present study for management of RAS.

In Ayurveda, *Jasminum grandiflorum* is described as the flower of God. The leaves of *J. grandiflorum* possess the potential antiulcer activity, which may be attributed to its free radical scavenging activity which ultimately aids in healing of RAS [8]. Also, *J. grandiflorum* possess many medicinal properties like anti-inflammatory activities [9], antimicrobial activities [10], wound healing [11] & anti acne activities [12].

Similarly, honey has been described in ancient and modern medicine as being effective in the healing of various infected wounds, healing of burns, ulcers and open wound [13,14].

Nowadays honey and honey-based products are used as the source of energy and nutrition & also in the human health care and treatment. Honey is also one of the best natural ingredients for the treatment of RAS. Gupta, D.V et al reported about its utility in oral ulcers [13].

Even though the effectiveness of *Jasminum grandiflorum* as well as honey is reported in the literature, separately this study will assess the combine utilization of all the useful medicinal anti-ulcer properties of both J. grandiflorum and honey by comparing with one of the well documented medicine (0.1% triamcinolone acetamide) for RAS.

### 1.1 Aim

To compare the efficacy of *Jasminum grandiflorum* with honey and corticosteroids in management of recurrent aphthous stomatitis.

### 1.2 Objectives

- To evaluate & compare the effect of *Jasminum grandiflorum* with honey & corticosteroids to relieve pain of RAS.
- To evaluate & compare the effect of *Jasminum grandiflorum* with honey & corticosteroids on size of ulcer/ulceration.
- To evaluate & compare the effect of *Jasminum grandiflorum* with honey & corticosteroids on surrounding erythema on aphthous ulcer.
- To evaluate & compare the effect of *Jasminum grandiflorum* with honey & corticosteroids on healing duration of ulcer/ulceration.

## 2. METHODOLOGY

Written Informed consent will be obtained from each participant after briefing about the study.

### 2.1 Type of Study

Prospective

### 2.2 Study Design

Observational

### 2.3 Study Population

One hundred and twenty patients visiting to the outdoor patient department (OPD) of Oral

Medicine & Radiology with the complaint of recurrent oral ulcers

### 2.4 Sample Size

One hundred and twenty subjects by using purposive sampling will be selected for study and they will be divided in three equal groups as:

Group A: 40 patients- will be treated by topical application of combined gel. (*Jasminum grandiflorum* with honey)

Group B: 40 patients -will be treated by topical application of *Jasminum grandiflorum* only or without honey.

Group C: 40 patients -will be treated by topical application of corticosteroid.(0.1 % triamcinolone acetamide)

### 2.5 Inclusion Criteria

- Individuals in age group 10-60 years
- Subjects having one or more mouth ulcers
- Patients having duration of ulcer not more than 48 hours
- Patient should not be on any medication for oral ulcer

### 2.6 Exclusion Criteria

- Patients suffering from any systemic disorders which are known to cause oral ulceration
- Patients with chronic non-healing ulcers.
- Patient who are denture wearer.
- Patient suffering from oral submucous fibrosis.
- Patient having known history of serious drug hypersensitivities.
- Patient unable to attend multiple visits

### 2.7 Proposed Intervention

Patients of study group will be given ayurvedic drug that is *J. grandiflorum* with honey for topical application (40 subjects), or topical application of *Jasminum grandiflorum* only (40 subjects), while the control group will be treated by topical application of corticosteroid. (0.1 % triamcinolone acetamide). Patients will be observed for the parameters like pain score by Visual Analog Scale, degree of surrounding erythema and ulcer

size in millimeter. These three parameters will be recorded on the first visit, that is before the start of the treatment. Then on 3<sup>rd</sup>, 5<sup>th</sup> and 7<sup>th</sup> day findings will be recorded for evaluating the effectiveness of the drugs used.

## 2.8 Data Collection Procedure

Data will be collected from the patients visiting to the OPD of Oral Medicine & Radiology by recording detail history and the oral findings.

## 2.9 Material Used

Leaves of *J. Grandiflorum*

Honey Distilled Water

Chemicals: Carbopol, Triethylamine (TEM)

## 2.10 Formulation of the Gel

The oral gel will be prepared by using *j. grandiflorum L.* & honey by following S.O.P. that is Standard Operative Procedure of the gel formation [15].

## 2.11 Quality Control

Quality will be controlled by maintaining clean, sterilized working field for the gel preparation.

## 2.12 Confidentiality

The information obtained from the patient will be kept confidential.

## 2.13 Plan of analysis

The collected data will be recorded in tabular format and analysed by using following tests:

- a. Chi-Square Test
- b. Student-t Test

## 3. EXPECTED OUTCOME

Considering various properties of *j. grandiflorum* and honey, it is expected that if these two herbal preparations are used in combination, it will have good synergistic effect in management of aphthous ulcer with reference to reduction in size, pain and erythema level.

## 4. DISCUSSION

In the review given by P. Rajasri Bharathi, Shubashini K. Sripathi and A. Naga Lakshmi

named "*Jasminum grandiflorum* linn. – an update review" it is stated that the plants are essential to both human and animal life. When compared to manufactured chemicals, plants are a preferable alternative for medical uses, and nature has offered a variety of therapeutic plants. Linn's *Jasminum grandiflorum*. (family Oleaceae) is a flowering plant that blooms at night and is a major source of methyl jasmonates, which are used in plant defense, fruit ripening, plant growth senescence, and other physiological processes. *Jasminum grandiflorum* Linn is a fragrant shrub. Is a plant that is native to tropical and warm temperate regions, and it has been shown to have beneficial characteristics that can be utilized to treat a variety of disorders.

## 5. CONCLUSION

Considering the number of medicinal properties of *J grandiflorum* and honey, the herbal preparation comprised of these two drugs would be effective in management of RAS. Therefore, instead of using corticosteroids for such a common condition one can use natural herbal treatment which will have least side effects.

## 6. SCOPE OF STUDY

*Jasminum grandiflorum* is a herbal preparation that will be used for the management of aphthous ulcerations in oral cavity with an ayurvedic approach of treatment that will have least side effects and is an holistic remedy.

## DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

## NOTE

The study highlights the efficacy of "herbal treatment" which is an ancient tradition, used in some parts of India. This ancient concept should be carefully evaluated in the light of modern medical science and can be utilized partially if found suitable.

## CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

## ETHICAL APPROVAL

The study will be conducted after obtaining approval from Institutional Ethics Committee of Datta Meghe Institute of Medical Sciences University, Sawangi (M), Wardha.

## COMPETING INTERESTS

Authors have declared that no competing interests exist.

## REFERENCES

1. Akintoye SO, Greenberg MS. Recurrent aphthous stomatitis. *Dent Clin North Am.* 2014;58(2): 281-297.
2. Edgar NR, Saleh D, Miller RA. Recurrent Aphthous Stomatitis: A Review. *J Clin Aesthet Dermatol.* 2017;10(3):26-36.
3. Belenguer-Guallar I, Jiménez-Soriano Y, Claramunt-Lozano A. Treatment of recurrent aphthous stomatitis. A literature review. *J Clin Exp Dent.* 2014;6(2):e168–e174
4. Wallace A, Rogers HJ, Hughes SC, et al. Management of recurrent aphthous stomatitis in children. *Oral Medicine* 2015;42(6):564–572.
5. Burruano F, Tortorici S. Stomatite aftosa major (malattia di Sutton). Etiopatogenesi, quadri istologici ed aspetti clinici [Major aphthous stomatitis (Sutton's disease): etiopathogenesis, histological and clinical aspects]. *Minerva Stomatol.* 2000; 49(1-2):41-50.
6. Rogers RS III. Recurrent Aphthous Stomatitis: Clinical Characteristics and Associated Systemic Disorders. *Seminars in Cutaneous Medicine and Surgery.* 1997; 16:278-283.
7. Gomes CC, Gomez RS, Zina LG, Amaral FR. Recurrent aphthous stomatitis and Helicobacter pylori. *Med Oral Patol Oral Cir Bucal.* 2016;21(2):e187–19
8. Uma maheshwari M, Ashok kumar K, Rathidevi R, Sivashanmugam AT, Subbhadra devi V, Rati TK. Anti ulcer and in vitro antioxidant activities of *Jasminum grandiflorum* L. *J Ethano pharmacol.* 2007;110(3): 464-70.
9. Fulzele SV, Sattkrwar PM, Joshi SB, Dorle AK. Studies on anti-inflammatory activity of a polyherbal formulation – Jatya Dighrita. *Indian Drugs.* 2002;39(1):42-44.
10. Priya Joy, Patric RD. Anti-bacterial activity studies of *Jasminum grandiflorum* and *Jasminum sambac*. *Ethnobotanical Leaflets.* 2008;(12):481-483
11. Nayak BS, Krishna M. Influence of ethanolic extract of *Jasminum grandiflorum* Linn. flower on wound healing activity in rats. *Indian J Physiol Pharmacol.* 2007;51(2):189– 194.
12. . Kumar GS, Khanam S. Anti-acne activity of natural products. *Indian J Nat Prod.* 2004;30(4): 7-9.
13. Gupta DV, Lohe DK, Bhowate DR. Comparison of efficacy of Natural honey and Triamcinolone acetonide (0.1%) in the healing of oral ulcers- A clinical study. *J Apither.* 2018; 3(1): 1-8.
14. Mohamed SS, Al-Douri AS. The Effect of Honey on the Healing of Oral Ulcers (Clinical Study). *Al- Rafidain Dent J.* 2008;8(2):157–160.
15. Markov IA, Markova EA, Gaponyuk PP, Markova IN, Gaponyuk PYa, Zinatullin RM, Gizatullin TR, Kataev VA, Khunafin SN, Egorov PV: Gel formulation for wounds and burns of various etiologies enabling epithelization. *Russ.RU 2496478 C1.* 20131027, 2013.

© 2021 Khasbage et al.; This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Peer-review history:

The peer review history for this paper can be accessed here:  
<https://www.sdiarticle4.com/review-history/75456>