

A CLINICAL EVALUATION OF VIDANGADI VATIKA GUGGULU ANDKHADIRADI VATIKA IN THE MANAGEMENT OF SARAVASARA ROGA (MUKHPAKA) W.S.R. TO APHTHOUS ULCER

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ABSTRACT

The concept of mouth ulcer has been dealt in *Ayurveda* under the heading of *Savasara or Mukhpaka Roga*^[1]. The word *Mukhpaka* is formed by two words – *Mukha* and *Paka*. *Mukha* includes *Osthaadi* seven parts i.e. *ostha*, *Danta*, *Dantamoola*, *Jihwa*, *Taalu*, *Kantha* and *Sarvasara*, *Paka* indicates *Pachana* and *Kledana*. An Aphthous ulcer is a type of mouth ulcer or canker sore which presents as painful open sore, inside the mouth caused by a break in the mucous membrane. As per *Ayurveda* the line of treatment for *Mukhpaka* should be *pittashamaka*, *shothahara*, *vedanasthapana*, *vranaropana*, *raktaprasadaka* and keeping in mind the pathogenesis *Vidangadi Vatika Guggulu* as oral drug and *Khadiradi Vatika* for local use has been elected for present study. The present study was done on 30 patients of *Mukhpaka*, who were grouped into 3 groups with 10 patients in each group. Group A was treated with *Vidangadi Vatika Guggulu* as oral drug, Group B with *Khadiradi Vatika* for local effect and Group C with combination of both. The signs and symptoms were studied before and after treatment. Results of study showed, 10% patients were cured, 30% were markedly improved, 40% patients had moderate improvement, 20% showed mild improvement. There were no patients who were unimproved.

KEYWORDS: *Mukhpaka*, Aphthous ulcer, *sarvasara roga*, *Vidangadi guggulu*, *KhadiradiVatika*.

INTRODUCTION

Sarvasara Roga (Mukhpaka) or the Aphthous ulcer is painful and often recurrent inflammatory process of the oral mucosa that can appear secondary to various well-defined disease processes. Idiopathic aphthous stomatitis is referred to as recurrent aphthous stomatitis. Recurrent aphthous stomatitis (RAS) is a condition in which ulcers repeatedly occur in the oral cavity at least four times a year.^[2] It is prevalent in developed countries. Occurring in all ages, geographic regions and races.^[3] Predisposing factors like trauma, deficiency of B-complex vitamins and folate, microbial factors, stress, hormonal changes and immunological factors may contribute to the formation of ulcers.^[4,5] Immune mechanism appears at play in persons with a genetic predisposition to oral ulceration. Histopathologically, aphthae contains a mononuclear infiltrate with a fibrin coating. Patients with recurrent aphthae may have alteration of local cell mediated immunity or autoimmune disorders; (over reaction by body's own immune system). Systemic T and B cell responses have been also reported altered in patients with recurrent aphthae.^[6] Ulcers shows painful, round ulcers which have a pseudomembranous centre surrounded by an erythematous margin. Burning sensation is present for

about 2 to 48 hours before the appearance of ulcer.^[4] Most ulcers occur on the non-keratinising epithelial surface of the mouth like the buccal and labial mucosa and the tongue in three forms such as minor, major and herpetiform recurrent aphthous stomatitis. The fundamental goals of treatment are to shorten the duration of ulcer, provide relief from pain and increase disease free periods while the secondary goals would be to lessen the frequency and severity of recurrences.^[7,8]

Ayurveda, considered as one of the complementary and alternative medicine describes several formulations in the form of *Vatika*, *Guggulu*, *Churna*, *Kwath* etc. oral therapies for treatment of *Sarvasara Roga (Mukhpaka)* among which *Vidangadi Vatika Guggulu* and *Khadiradi Vatika* was selected to assess their efficacy under the topic entitled "A Clinical evaluation of *Vidangadi Vatika Guggulu* and *Khadiradi Vatika* in the management of *Sarvasara Roga (Mukhpaka)* w.s.r. to Aphthous Ulcer."

AIMS & OBJECTIVES

- To study the *Mukhpaka Roga* according to the *Ayurvedic* concept.
- To study the Aphthous Ulcer in the light of

modern concepts and to avail the latest information related to research as possible.

- To study the efficacy of the formulation *Vidangadi Vatika Guggulu* and *Khadiradi Vatika* in the context of Aphthous Ulcer.
- To promote complete ulcer healing within a short period of time.
- To avoid its complication or sequel and to study any side effects of the therapy.

MATERIALS AND METHODS

Group, Dose & Duration-Single group

Study design:

Open uncontrolled study Number of patients -10

Drug Schedule

❖ *Vidangadi Vatika Guggulu* as oral drug
Dose 500mg TID

❖ *Khadiradi Vatika* for Chewing
Dose 250mg QID

Duration of treatment 15 days

Follow up after 15 days

Selection Criteria

Uncomplicated patients with signs and symptoms of aphthous ulcer, attending OPD of R.G.G.P.G. *Ayurvedic* Hospital Paprola were selected above 12 years age, after obtaining their consent. Case selection was regardless of sex, occupation, socio-economic consideration & religion etc. All the patients were followed up after 15 days.

Inclusion Criteria

- Patients having ulcers in the oral cavity.
- Patient presenting with signs and symptoms of Aphthous ulcer.
- Age above 12 years irrespective of sex.

Exclusion Criteria

- Ulcer formed due to malignancy, seropositive patients.
- Patients below 12 years of age.
- Associated symptoms i.e. fever, malaise and tender lymphadenopathy.
- Associated with complex autoimmune disorder including Bechet's syndrome, Reiter syndrome, IBS, SLE etc.
- Cardiac, diabetic and hypertensive patients.

Plan of work

The study was planned in different steps as mentioned below:

1. Proforma: A special proforma will be prepared for the evaluation of etiopathogenesis and assessment of treatment efficacy. A detailed history will be taken and

simultaneously general and systemic examination of the patients was done having signs and symptoms suggesting of aphthous ulcer.

2. Investigations

Complete haemogram- (Hb%, TLC, DLC, ESR)
Biochemistry- FBS/PP/R
VDRL
HIV-I & II (if required)

Clinical assessment

Assessment of the effect of treatment has been done on the basis of relief of sign and symptoms of aphthous ulcers on the basis of grading and scoring system.

a) Pain in the effected area

- No Pain
- pain on touch
- pain without touch
- Pain causing difficulty in opening mouth

b) Burning sensation

- No complaint
- with hot beverages
- felt on taking spicy and acidic salty food
- Severe throughout the day without any aggravating factor

c) Difficulty in chewing/ingestion

- Can eat easily
- can eat solid food
- can eat liquid food only
- cannot eat liquid as well as solid food

d) Excessive salivation

- No complaint
- Complaining of salivation
- Has to spit saliva
- Dribbling of saliva

e) Inflammation

- No hyperemia
- At ulcer margin only
- Centre of ulcer necrosed / slough seen

f) Size (degree) of ulceration

- No ulceration
- <3mm
- 3mm -<1cm
- >1cm

g) No. of ulceration

- No ulceration
- <1
- 2-10
- >10

Criteria For Over All Assessment

| | |
|-------------------|---|
| Cured | 100% relief in signs and symptoms and no recurrence during follow-up study have been considered as cured. |
| Markedly improved | 75% - <99% improvement in signs and symptoms has been considered as marked improvement. |
| Moderate improved | 50% - <74% improvement in signs and symptoms has been recorded as moderate improvement. |
| Mild improved | 25% - <49% improvement in signs and symptoms has been considered a mild improvement. |
| Unimproved | Up to 25% reduction in signs and symptoms was noted as unchanged. |

Drug Review**Ingredients of Vidangadi Vatika Guggulu^[9]**

| Sr. no | Name of plant | Botanical name | Dosha karma | Family | Part used | Quantity |
|--------|---------------|-----------------------------------|-------------------|---------------|----------------|----------|
| 1. | Vaya Vidanga | <i>Embelia ribes</i> Burm.f | Vatakaphahara | Myrsinaceae | Fruit | 1 part |
| 2. | Haritaki | <i>Terminalia chebula</i> Retz. | Tridosahara | Combretaceae | Fruit Pericarp | 1 part |
| 3. | Vibheetaki | <i>Terminalia bellirica</i> Roxb. | Tridoshanashaka | Combretaceae | Fruit Pericarp | 1 part |
| 4. | Amalaki | <i>Emblia officinalis</i> Gaertn. | Tridosahara | Euphorbiaceae | Fruit Pericarp | 1 part |
| 5. | Shunthi | <i>Zingiber officinale</i> Roxb. | Vata Kaphahara | Zingiberaceae | Rhizome | 1 part |
| 6. | Maricha | <i>Piper nigrum</i> Linn. | Vata Kaphashamaka | Piperaceae | Fruit | 1 part |
| 7. | Pippali | <i>Piper longum</i> | Vata kaphahra | Piperaceae | Fruit | 1 part |
| 8. | Guggulu | Linn. <i>Commiphora mukul</i> | Tridosahara | Byrseraceae | Exudate | 7 parts |

Rasa Panchaka of Vidangadi Vatika Guggulu

Vidangadi Vatika Guggulu have *Katu Ras*, *Laghu Guna*, *Ushna Virya*, *Madhura Vipaka* and *Kapha Vata Shamaka* properties.

Amalaki, *Shunthi*, *Maricha* and *Pippali* are powdered in mini pulveriser and dried. Now, *Shudh Guggulu* is added in it on the fire and stirred thoroughly. After that tablets of 500 mg are prepared.

Method of preparation of Vidangadi Vatika Guggulu

The contents *Vaya Vidanga*, *Haritaki*, *Vibheetaki*,

Ingredients of Khadiradi Vatika^[10]

| Sr. no. | Name of plant | Botanical name | Dosha karma | Family | Part used | Quantity |
|---------|---------------|--|-----------------------|---------------|--------------------|----------|
| 1. | Khadir Saar | <i>Accacia catechu</i> (Linn.f.) Wild. | Kaphapitta shamaka | Fabaceae | Ht. Wood (Saar) | 1 Part |
| 2 | Javitri | <i>Myristica fragrans</i> Houtt. | Kapha Vata Shamak | Myristicaceae | Aril Sub. | ¼ Part. |
| 3. | Karpur | <i>Cinnamomum camphora</i> (L.) J. Presl. | Tridosahara | Lauraceae | Ext. | ¼ Part |
| 4. | Pugiphala | <i>Areca catechu</i> Linn. | Kaphapittajit | Arecaceae | Fruit | ¼ Part |
| 5 | Kankol | <i>Piper cubeba</i> Linn.f. | Kaphavatahara | Piperaceae | Fruit | ¼ Part |

Rasa Panchaka of Khadiradi Vatika

Khadiradi Vatika have *Tikta Ras*, *Laghu Guna*, *Sheeta Virya*, *Katu Vipaka* and *Kapha Vata Shamaka* properties.

The results were considered significant or insignificant depending upon value of 'p'.

- Highly significant - $p < 0.001$
- Significant - $p < 0.01$ and $p < 0.05$.
- Insignificant - $p > 0.05$.

Method of preparation of Khadiradi Vatika

The contents *Khadir saar*, *Kapoor*, *Javitri*, *Pugiphala* and *Kankol* are powdered in mini pulveriser. After that tablets of 250 mg are prepared.

Consent of patient

All the patients selected for trial were explained the nature of the study and their written consent was obtained on the proforma before including them in the clinical study.

Statistical Analysis

The information gathered regarding demographic data is shown in percentage. The score of criteria of assessment were analysed statistically in form of mean score B.T. (Before Treatment), A.T. (After Treatment), (B.T.-A.T.) difference of mean, S.D. (Standard deviation), S.E. (Standard error), Student paired 't' test was carried out at $p > 0.05$, $p < 0.05$ and $p < 0.001$.

OBSERVATIONS

Among 10 patients 36.67% were of age group 31-40 yrs, 80% were females, 86.67% unmarried, 83.33% residents

of rural area, Hindu 100%, Housewives 56.67%, 33.33% Educated upto graduation, 83.33% belonged to middle class, 56.67% had positive family history, 66.67% were having mixed diet, 53.33% were addiction to tea, 50% had poor appetite, 60% had disturbed sleep, 56.67% had affinity towards *MadhuraRasa*. 46.67% of patients had *KaphapittajaPrakriti*, 76.67% had *RajasikaPrakriti*, 53.33% *Madhyama Sara*, 63.33% had *Madhamsamhanana*, 66.67% *Madhyama Pramana*, 80% had *MahyamaSatva*, 80% had *AvaraVyayam Shakti*. 70% of patients had *Mandagni*, 73.33% had non-satisfactory Bowel habits, 73.33% *KruraKostha*. 76.67% of patients were taking *Guru ahara*, 46.67% were taking *Virudhahara* and 46.67% were practising *Adyashana*. 53.33% of patients were suffering from *Krodha* and 36.67% were from *Chinta*. 56.67% of patients 56.67% had *AvaraJaran Shakti*. Most common symptoms were pain in affected area along with burning sensation, difficulty in chewing and inflammation which is found in 100% of patients.

Effect of Therapy

1. Pain in affected area

The initial score of pain in affected was 1.6 which was reduced to 0.1 after the treatment. The %age of relief was 93.75% which is highly significant statistically at the level of $p < 0.001$ ($t = 9.000$).

2. Burning Sensation

The initial score of burning sensation was 1.9 which was reduced to 0.7 after the treatment. The %age of relief was 63.15% which is highly significant statistically at the level of $p < 0.001$ ($t = 6.000$).

3. Difficulty in Chewing / swallowing

The initial score of difficulty in chewing / swallowing was 1.1 which was reduced to 0.4 after the treatment. The %age of relief was 63.63% which is significant statistically at the level of $p = 0.001$ ($t = 4.583$).

4. Excessive Salivation

The initial score of excessive salivation was 0.6 which was reduced to 0.1 after the treatment. The %age of relief was 83.33% which is significant statistically at the level of $p = 0.015$ ($t = 3.000$).

5. Inflammation

The initial score of inflammation was 1.4 which was reduced to 0.3 after the treatment. The %age of relief was 78.57% which is highly significant statistically at the level of $p < 0.001$ ($t = 6.128$).

6. Degree (size) of ulceration

The initial score of pain in affected was 1.4 which was reduced to 0.5 after the treatment. The %age of relief was 64.28% which is highly significant statistically at the level of $p < 0.001$ ($t = 5.014$).

7. No. of ulceration

The initial score of size of ulceration was 1.8 which was

reduced to 0.6 after the treatment. The %age of relief was 66.67% which is highly significant statistically at the level of $p < 0.001$ ($t = 6.000$).

Overall effect of the drugs

Overall effect showed moderate improvement in 14 patients (46.67%), mild improvement in 9 patients (30%), 5 patients (16.67%) were markedly improved, 2 patients (6.67%) were cured and there was no patient who was unimproved.

DISCUSSION

To treat the disease in a proper way, it is necessary to know the causative factor and the disease process. According to modern concept, the exact Etiology is unknown but recent studies suggest that an altered cellular immune response is a predisposing factor. In *Ayurveda* looking at the *Samprapti* of *Mukhapaka* the main vitiated *Doshas* are *Kapha* and *Pitta*. These vitiated *Doshas* again interact with vitiated *Vatadosha*, which further vitiated *Rakta*. The aetiological factors or the *Hetus* by the specific pathogenesis of the *Samprapti* lead to *Paka* and *Vrana* in the mouth. So *Vidangadi Vatika Guggulu* was chosen as the trial drug, which is having *Kaphavata Shamaka* properties (55.55%), *VatapittaShamaka* properties (11.11%) and *TridoshaShamaka* properties (33.33%). The Trial drug *Vidangadi Vatika Guggulu* is having dominance of *Katu Rasa* (77.77%), *Laghu Guna* (77.77%), *Ushana Veerya* (66.66%), *Madhura Vipaka* (77.77%), *Kapha-VataShamaka* (55.55%) and *TridoshaShamaka* (33.33%) properties which counteract the *Samprapti* of *Mukhpaka*. The *Rasa Katu* has *Shodhana*, *Krimihara*, *Kanduhara*, *Kledahara*, *Vrana Avsaadaka*, *Pitta Shleshma Upshoshaka* and *Lekhana* properties as per *Ch.Su.26/42-5*^[11] which act against the symptomatology of *Mukhpaka*.

In this formulation '*Guggulu*'^[12] which is the main ingredient is having *Lekhna* (*PuranaGuggulu*) *Tridosahara* properties along with *Deepanam* in nature which helps in management of *Mukhpaka*. And also indicated in *Vrana*, *Granthi*, *Shotha*, *Kushta*. It has anti-inflammatory properties also. '*VayaVidanga*'^[13] which is *Vatakaphahara* contains *Krimighna*, *Dipana*, *Pachana*, *Sothahara*, *Kusthaghna*, *Raktashodhak* properties. '*Haritaki*'^[14] which is *Tridosahara* in nature and has *Raktastambhaka*, *Shothahara*, *Shonitsthapana*, *Vedanasthapana*, *Vranaropana* properties. '*Vibheetaki*'^[15] has *Tridoshanashamka* (Mainly *Kaphanashamka*) and *Chedana* properties along with Anti-inflammatory, analgesic action. '*Amalaki*'^[16] is *Tridosahara* (Mainly *Pittashamaka*) along with Antibacterial, anti-inflammation, antitumor, antifungal, immunomodulator and antioxidant properties. '*Shunthi*'^[17] is *VataKaphahara* along with *Shothahara*, *Amapachana*, *Shoolaprashamana* in action. '*Maricha*'^[18] is *VataKaphashamaka* and has *Deepana*, *Pachana*, *Krimighna*, *Kusthaghna* properties. '*Pippali*'^[19] is *Vatakaphahra* in nature and has

Deepaniya, Shoolprashmana (Ch.), *Urdhavabhadra*, *Shirovirechan* (Su.) properties.

In this formulation '*Khadir saar*'^[20] which is the main ingredient is having *Kaphapittashamaka*, *Raktashodhaka* properties along with *Kushthaghana*, *Kandughana*, *Vranaropaka*. in nature which helps in management of *Mukhpaka*. It is regarded as best astringent, haemostatic, cooling and digestive. Externally it is employed for ulcers (bed sores), boils and eruption of skin. It is reported to be an antileprotic drug. '*Javitri*'^[21] which is *KaphaVatashamaka* contains astringent, analgesic, aphrodisiac, digestive, anti-inflammatory, antiseptic properties. '*Kapoor*'^[22] which is *Tridosahara* in nature and the essential oil from plant possesses potent anti-fungal activity against many fungi such as *aspergillus fumigatus*, *candida albicans* etc. '*Pugiphala*'^[23] has *Kaphapittajit* property along with *Deepana*, *Kledanasanashana*, *Mukhshodana*, *Vikasi*, *Mukhavikaranashak* action. '*Kankol*'^[24] is *Kaphvatahara* along with *Deepana*, *Pachana*, *Ruchya*, *Mukhadargandhyahara*, *Mukharogahar*, *Shoolaghan* properties.

CONCLUSION

Recurrent Aphthous ulceration is one of the most common oral conditions with a prevalence of upto 25% in the general population and three month recurrence in upto 50% or in other words these are estimated to affect one-fourth of the population world wide. The younger age group is most commonly affected. The symptomatology of *Mukhpaka* and Aphthous ulcer was found to be same. Hence there is correlation between *Mukhpaka* and Aphthous ulcer. All the patients with *Mukhpaka* who received proposed formulation, tolerated well and no untoward effect were reported by the patients registered for the current trial.

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