

## A CLINICAL EVALUATION OF VIDANGADI VATIKA GUGGULU 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 *Sarvasara or Mukhpaka Roga*<sup>[1]</sup> The word *Mukhpaka* is formed by two words – *Mukha* and *Paka*. *Mukha* includes *Osthaadi* seven parts i.e. *ostha*, *Danta*, *Dantamoola*, *Jihwa*, *Taal*, *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 has been elected for present study. So present study was done on 10 patients of *Mukhpaka and Vidangadi Vatika Guggulu* is given to them to evaluate the local effect of drug. The signs and symptoms were studied before and after treatment. Results of study showed, 10% were markedly improved, 40% patients had moderate improvement and 50% had mild improvement.

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

### INTRODUCTION

*Mukhpaka* is disease mentioned by Acharya Sushruta under *Nidana sthana* in the chapter named *Mukhrognanam nidana*.<sup>[2]</sup> *Mukhpakaroga* is mentioned under 40 *Nanatmaja pitta Roga* according to *Charaka*. *Dalhana* on his commentary on *Sushruta Samhita* mentioned *Mukhpaka* as basically and purely as *Pittaja Vyadhi* but Acharya Sushruta has classified *Mukhroga* as *Vataja*, *Pittaja*, *Kaphaja* and *Raktaja*, the aggravated *Vatadi doshas* afflict the mouth to produce *Paka* and *Vrana*.

In recent years, there has been significant change in life-style, dieting pattern. Due to growing affluence, rapid industrialization and socio-economic development there is increase in stress and strain<sup>[3]</sup> These factors have led to increases prevalence of the disease; Aphthous Ulcer i.e. upto 25% in general population. Autoimmune mechanism is believed to be the root cause of Aphthous ulcers.<sup>[4]</sup>

In general, *Mukhpaka* is a *Sadhya Roga*. If the aetiological factors exists, there chronicity and thereby it

becomes *Krichasadhya*. The *Kapha*, *Pitta Prakriti* of patients, *Balya* and *Yuvana*, *Varsha* and *Sheeta Kala*, excessive usage of *Kapha Pitta* predominant *Aharas* makes the condition worst and lead to chronicity and recurrence. The general measure which are adopted in the management of *Mukhpaka* irrespective of *Doshaja Bhedas* and stage of diseases are included under *Samanya Chikitsa Sidhant*. The three basic measures included under this modality of *Chikitsa* include *Nidana*, *Parvarjana*, *Shodhana* and *Sanshamna*.

Therefore keeping in the view the need of time and gravity of the disease, present study was undertaken with the topic entitled “A Clinical evaluation of *Vidangadi Vatika Guggulu* 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 *Vidangaadi 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

**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

0 No Pain

1 pain on touch

2 pain without touch

3 Pain causing difficulty in opening mouth

#### b) Burning sensation

0 No complaint

1 with hot beverages

2 felt on taking spicy and acidic salty food

3 Severe throughout the day without any aggravating factor

#### c) Difficulty in chewing/ingestion

0 Can eat easily

1 Can eat solid food

2 Can eat liquid food only

3 Cannot eat liquid as well as solid food

#### d) Excessive salivation

0 No complaint

1 Complaining of salivation

2 Has to spit saliva

3 Dribbling of saliva

#### e) Inflammation

0 No hyperemia

1 At ulcer margin only

2 Floor of ulcer

3 Centre of ulcer necrosed / slough seen

#### f) Size (degree) of ulceration

0 No ulceration

1 <3mm

2 3mm -<1cm

3 >1cm

#### g) No. of ulceration

0 No ulceration

1 <1

2 2-10

3 >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*<sup>[5]</sup>

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

#### Rasa Panchaka of *Vidangadi Vatika Guggulu*

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

#### Method of preparation of *Vidangadi Vatika Guggulu*

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

#### 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  $p<0.001$ .

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-  $p>0.05$ .

#### 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.

#### 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 *Kaphapittaja Prakriti*, 76.67% had *RajasikaPrakriti*, 53.33% *Madhyama Sara*, 63.33% had *Madhamsamhanana*, 66.67% *MadhyamaPramana*, 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 0.7 after the treatment. The %age of relief was 56.25% which is highly significant statistically at the level of  $p<0.001$  ( $t=5.014$ ).

##### 2. Burning Sensation

The initial score of burning sensation was 1.9 which was reduced to 1.2 after the treatment. The %age of relief was 36.84% which is significant statistically at the level of  $p=0.001$  ( $t=4.583$ ).

##### 3. Difficulty in Chewing / swallowing

The initial score of difficulty in chewing / swallowing was 1.2 which was reduced to 0.7 after the treatment. The %age of relief was 41.67% which is significant statistically at the level of  $p=0.015$  ( $t=3.000$ ).

#### 4. Excessive Salivation

The initial score of excessive salivation was 0.8 which was reduced to 0.3 after the treatment. The %age of relief was 62.5% which is significant statistically at the level of  $p=0.037$  ( $t=2.449$ ).

#### 5. Inflammation

The initial score of inflammation was 1.7 which was reduced to 0.8 after the treatment. The %age of relief was 52.94% which is highly significant statistically at the level of  $p<0.001$  ( $t=9.000$ ).

#### 6. Degree (size) of ulceration

The initial score of pain in affected was 1.6 which was reduced to 1.1 after the treatment. The %age of relief was 31.25% which is significant statistically at the level of  $p=0.015$  ( $t=3.000$ ).

#### 7. No. of ulceration

The initial score of size of ulceration was 1.9 which was reduced to 1.1 after the treatment. The %age of relief was 42.10% which is significant statistically at the level of  $p=0.003$  ( $t=4.000$ ).

#### Overall effect of the drugs

Among 10 Patients 1 patient was markedly improved, 4 patients had moderate improvement, 5 had mild improvement. There was no patient, who was unimproved or cured.

#### 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<sup>[6]</sup> In Ayurveda, looking at the *Samprapti* of *Mukhpaka* 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 *KaphavataShamakaproperties* (55.55%), *Vatapitta Shamaka 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 *Tridosha Shamaka* (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*<sup>[7]</sup> which act against the symptomatology of *Mukhpaka*.

In this formulation '*Guggulu*'<sup>[8]</sup> which is the main ingredient is having *Lekhna (PuranaGuggulu)* *Tridoshahara* 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*'<sup>[9]</sup> which is *Vatakaphahara* contains *Krimighna, Dipana, Pachana, Sothahara, Kusthaghna, Raktashodhak* properties. '*Haritaki*'<sup>[10]</sup> which is *Tridoshahara* in nature and has *Raktastambhaka, Shothahara, Shonitsthapana, Vedanasthapana Vranaropana* properties. '*Vibheetaki*'<sup>[11]</sup> has *Tridoshanashamka* (Mainly *Kaphanashamka*) and *Chedana* properties along with Anti-inflammatory, analgesic action. '*Amalaki*'<sup>[12]</sup> is *Tridoshahara* (Mainly *Pittashamaka*) along with Antibacterial, anti-inflammation, antitumor, antifungal, immunomodulator and antioxidant properties. '*Shunthi*'<sup>[13]</sup> is *VataKaphahara* along with *Shothahara, Amapachana, Shoolaprashamana* in action. '*Maricha*'<sup>[14]</sup> is *VataKaphashamaka* and has *Deepana, Pachana, Krimighna, Kusthaghna* properties. '*Pippali*'<sup>[15]</sup> is *Vatakaphahra* in nature and has *Deepaniya, Shoolprashmana* (Ch.), *Urdhavabhadhar, Shirovirechan* (Su.) 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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