

EVALUATION OF EFFECT OF AN AYURVEDIC FORMULATION IN THE MANAGEMENT OF SARVASAR ROGA (MUKHAPAKA) W.S.R. TO APHTHOUS ULCER

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ABSTRACT

Mukhapaka or Aphthous Ulcer is the inflammatory condition of mucous membrane of the oral mucosa with or without ulceration is referred to as stomatitis. There are many variety of oral ulceration but aphthous ulceration is an unfortunately common disease, having 25% prevalence, world wide. It is recurrent type of disease with female predominance. To study the efficacy of fomulation in the context of Aphthous ulcer, to promote complete ulcer healing within the short period of time and to avoid its complication or sequale or to study any side effect of the therapy. The efficacy of both the therapies i.e.

Soubhagya pravahi and *Kamdudha* rasa in combination was adjudged in 26 patients on various parameters and results were derived after execution of statistical methodology. Over all result of Treatment in 26 patients of *Mukhapaka* (Aphthous ulcer) under trial was Cured in 69%, Markedly improved in 15%, Moderately improved in 8% and Slightly improved in 8%.

KEYWORDS: Aphthous Ulcer, mukhapaka, Sarvasar.

INTRODUCTION

Shalakyta Tantra is one of the divisions of *Ashtang* Ayurveda in which study of “*UrdhwajatrugatVyadhi*” i.e. diseases regarding Ear, Nose, Throat and Eyes are mentioned.^[1]

Today's life style of Hurry, Worry, Curry and also bad habits of *Gutakha* and Tobacco chewing, irregular timing of food and sleep causes the disturbance of the normal physiology which makes them prone to many diseases. *Mukhapaka* is one of them.

As we see in Ayurveda, *Mukhapaka* reveals involvement of *Pitta*, *Rakta*, *Kapha* and *Vata dosha*.^[2] According to modern science, it is a benign painful condition of the oral cavity often referred to as canker sore.^[3] Stomatitis means inflammation of the mouth (including the lips, tongue and mucous membranes).^[4]

Aphthae typically are small, round or ovoid ulcers with a circumscribed margin, erythematous halo and a yellow or grey floor, each lasting from one to approximately four weeks before healing.^[5]

In *Mukhapaka*, patients suffer from difficulty to eat solid or liquid food, depending upon the severity of the disease. Food in any form is essential for growth of the body and for maintenance of health. So restriction of food by any reason causes the reduction of immunity and prone to many diseases. Our body mechanism always tries to maintain balance by the process of immunity. If we depend on this mechanism and do not treat the disease in early stage, the chances of severity and chronicity of the disease will increase. In our country, infection, trauma, skin and blood disorders, drug allergies, vitamin deficiency, new life style, fast food etc. are the common causes of stomatitis. It represents the most common non-traumatic form of ulceration with an incidence range between 20% and 40% of the population.^[6]

Mukhapaka/sarvasar vyadhi (stomatitis) is found in all age groups and both sex. Data indicating a greater prevalence among those in professional groups, those of higher socio-economic status and non-smokers.^[7]

Purpose of selection of topic

The symptoms of Stomatitis are very distressing to the patients and if left untreated often they can lead to complications.

In modern medicine stomatitis is treated by vitamins, steroid administrations, applications of some local anaesthetic etc.^[8] But the treatment is not satisfactory and also it has many side effects.

The entire world is focusing on alternative and traditional systems of medicine for the solution to the ever complicating, undiagnosed symptoms/syndromes and diseases occurring again and again. The international health regulatory bodies are eagerly looking forward to traditional systems of medicine, where *Ayurveda* holds a key position.

Ayurveda the life science renowned from time immemorial. The research work is integral part of the science dealing with health and disease. There are enumerable ailments but only few of them are most common in world population affecting the health scenario worldwide. The disease Recurrent Aphthous Ulcer is a common condition characterized by recurring episodes of ulcers, dating typically from childhood or adolescence.^[9]

So an attempt was made to find out very simple and easily available treatment from *Ayurved* to overcome stomatitis problem.

Present study is planned to evaluate the nature of the disease, its course and management with the help of some herbal drugs with the hope that these will prove to be more efficacious and less toxic. Thus the research work was planned for the evaluation of combined effect of two formulations named *Soubhagya pravahi* and *Kamdudha rasa* under the research project entitled **“Evaluation of Effect of an Ayurvedic Formulation in the Management of Sarvasar Roga (Mukhapaka) w.s.r. to Aphthous Ulcer.”**

In this present research work 30 patients of Aphthous ulcer were selected and taken into single group. The duration of treatment was 15 days with two follow ups at weekly intervals and 1 follow up in the last of the month.

The analysis of subjective and objective parameters proved that the combination of formulation is highly effective in relieving the symptoms and also preventing the recurrence of this disease.

This goes to show that this formulation when administered keeping in mind the authentic principles of *Ayurveda* can effectively combat the menacing symptoms of aphthous ulceration.

Drug Review

The concept of *Ayurvedic* Drugs represent one of the finest example of an “Advanced Technology Platform” described in our vast pool of traditional knowledge. Today the

penultimate aim of *Ayurvedic* research is the correct interpretation of the accretions of Ayurveda and their proper mobilization into faultless practice to the absolute satisfaction of every one including the modern man. Today, after experiencing the changing of behaviour and side effects of modern medicine, many people all over the world are shifting towards *Ayurvedic* Medicine.

Keeping in view these points the trial drug *Soubhagya pravahi (RasTantra Sara)* and *Kamdudha rasa (Ras Yoga Sagar)*, were chosen for the present clinical study in case of *Sarvasarroga (Mukhapaka)* w.s.r. to Aphthous ulcer.

Though the combination of formulation for the present clinical study is not mentioned in *Ayurvedic* texts; the fundamentals of *Ayurvedic* treatment i.e. '*Dosha Dushyavimarsha*' are deemed and respected in every sense. Apart from this aspect an endeavour has been made to coalesce proven drugs having potency against root cause and pathogenesis of Aphthous ulcer manifestation.

Anti inflammatory, analgesic, ulcer healing, effective soothing, are also featuring in these formulations.

I. Ingredients of Soubhagya Pravahi (RasTantraSar)^[10]

1. Sphatika - 1 part
2. Madhuyashti - 1 part
3. Tankan - 2 parts
4. *Mishri* - 20 parts

II. Ingredients of KamdudhaRas (RasYogSagar)^[11]

1. Satvagiloy - 4 parts
2. Swarngairika - 1 part
3. *Abhrak Bhasma* - 1 part

AIMS AND OBJECTIVES

1. To study the *Mukhapakaroga* according to *Ayurvedic* concept.
2. To study aphthous ulcer in the light of modern concept and to avail latest information related with research as possible.
3. To study the efficacy of formulation *Soubhagya pravahi* combined with *Kamdudha rasa* in the context of Aphthous ulcer.

4. To promote complete ulcer healing within the short period of time.
5. To avoid its complication or sequale and to study any side effect of the therapy.

Justification of selection of Disease

1. Aphthous ulcer is a fairly common ailment afflicting many people.
2. It hampers day to day activity due to pain and interference with eating.
3. It is a major source of worry to the patient.

MATERIALS AND METHODS

Plan of study

To meet the objective of present research work, the study was planned as under.

Clinical study

A total number of 30 patients were selected from *Shalakyatantra* OPD/IPD of hospital affiliated to R.G.G.P.G. Ayu. College, Paprola, after obtaining their consent. Case study was random and patients were selected irrespective of sex, caste, religion etc. History of all the patients was recorded according to the proforma. All the patients were followed up after commencement of trial.

Criteria for selection of patient

I Inclusion criteria

- i) Patients having ulcer in oral cavity (lasting less than 1 month)
- ii) Patients presenting with signs and symptoms of Aphthous ulcer.
- iii) Age above 5 years irrespective of sex.

II. Exclusion criteria

- i) Ulcer formed due to malignancy, seropositive patients.
- ii) Patients below 5 years of age.
- iii) Ulcer due to viral infection, secondary bacterial infection.
- iv) Associated symptoms i.e. fever, malaise and tender lymphadenopathy.
- v) Cardiac, diabetic and hypertensive patients.

Method of study

After careful examination, 30 patients were selected from the OPD of *Shalakyatantra* of R. G. G. P. G. Ayu. Hospital, Paprola and treated in single trial group.

Trial Group and Trial drug

In this group both *Soubhagya pravahi* and *Kamdudha rasa* were given to 30 patients as a trial drugs combination.

Mode of administration and dose of trial drug in trial group -

- *Soubhagyappravahi* – for local application twice a day.
- *Kamdudha rasa* per orally- 500 mg twice a day with water.

Duration of trial - 15 days

Follow up - 2 follow ups at weekly interval.

1 follow up in the last of the month.

Criteria for assessment of result

i) Subjective

ii) Objective

- i) Subjective - Grading and scoring system was adopted for assessing each symptom before the commencement of trial and after completion of trial. The overall score of each symptom was recorded as :

Table No. 1.

Sr. No.	Symptoms	0	1	2	3
1.	Pain in the affected area	No complaint	Mild- pain on touch	Moderate- pain without touch	Pain causing difficulty in opening mouth
2.	Burning sensation	No complaint	Mild- on touch with hot beverages	Moderate- felt on taking spicy and acidic, salty food	Severe- throughout the day without any aggravating factor
3.	Difficulty in chewing / ingestion	Can eat easily	Mild- can eat solid food	Moderate-can eat liquid food only	Severe-cannot eat liquid as well as solid food.
4.	Excessive salivation	No complaint	Complaining of salivation	Has to spit saliva	Dribbling of saliva in sleep
5.	Inflammation	No hyperemia	At ulcer margin only	Floor of ulcer	Centre of ulcer necrosed/slough seen
6.	Size (degree) of Ulceration (size)	No ulceration	< 3 mm	3 mm - < 1 cm	1 cm- 3 cm
7.	No. of Ulceration	No ulceration	<2	2-10	> 10
8.	Site of Ulceration	Nil	< 3	3- 5	>5

Statistical analysis

The information gathered regarding demographic data was given in percentage. The scoring of criteria's of assessment was analysed statistically in terms of B.T. (before treatment), A.T. (after treatment), X (B.T.- A.T.), S.D. (Standard deviation), S.E. (Standard Error), Paired 't' test was carried out at the level of $p < 0.05$ and $p < 0.001$.

Overall results were adjudged in terms of percentage relief obtained in symptoms.

Cured

100% relief in chief complaint and no recurrence during follow up study.

Markedly improved

>75% relief in chief complaints was recorded as markedly improved.

Moderately improved

> 50%, <75% relief in chief complaints was considered moderately improved.

Slightly improved

>25%, < 50% relief in chief complaints was considered slightly improved.

Unimproved

<25% relief in chief complaints was noticed as unchanged or unimproved.

Objective criteria

Haematological parameters - Hb%, TLC, DLC, ESR

OBSERVATION

The observations have been made in the present study on the demographic constitutional and clinical profile of 26 patients.

No. of patients registered

30

No. of patients completed trial

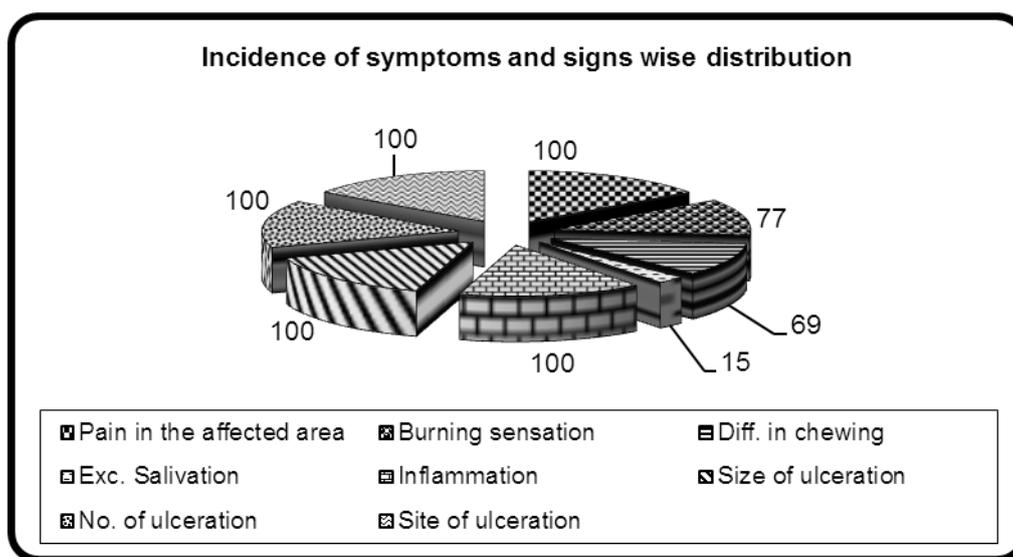
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Symptoms and Signs

Table No. 2: Incidence of Symptoms and Signs wise distribution of 26 patients of *Mukhapaka* under trial.

Sr. No.	Symptoms	No. of patients	% age
1.	Pain in the affected area	26	100 %
2.	Burning sensation	20	77 %
3.	Difficulty in chewing/ingestion	18	69 %
4.	Excessive salivation	4	15 %
5.	Inflammation	26	100 %
6.	Size (Degree) of ulceration	26	100 %
7.	No. of ulceration	26	100%
8.	Site of ulceration	26	100 %

In the group of 26 patients, pain in affected area, Inflammation, Size (degree) of ulceration, No. of ulceration, site of ulceration was observed in 100% of patients respectively, burning sensation was observed in 77% of patients, difficulty in chewing was observed in 69% patients, excessive salivation was observed in 15% patients.

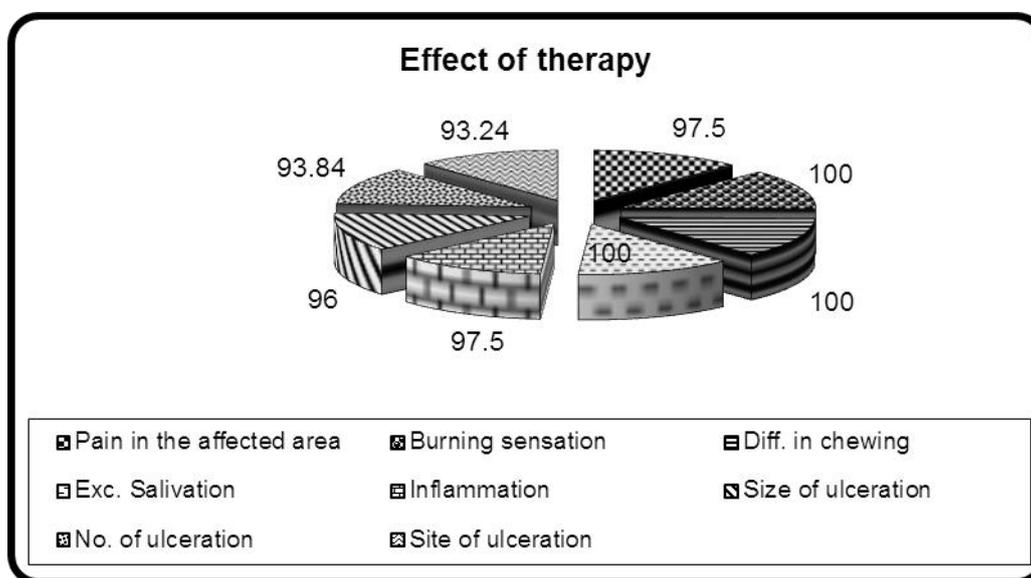


Effect of therapy

The efficacy of both the therapies i.e. *Soubhagya pravahi* and *Kamdudha rasa* in combination was adjudged in 26 patients on various parameters and results were derived after execution of statistical methodology.

Table No. 3.

Sr. No.	Symptoms	N	Mean		% relief	S.D. ±	S.E. ±	't'	P
			B.T.	A.T.					
1.	Pain in the affected area	26	2.07	1.07	48.3	0.63	0.12	8.07	<0.001
2.	Burning sensation	20	1.3	0.61	53	0.63	0.12	5.57	<0.001
3.	Difficulty in chewing/ ingestion	18	1.15	0.30	73	0.74	0.14	5.77	<0.001
4.	Excessive salivation	4	0.23	0.03	86	0.49	0.09	1.97	>0.05
5.	Inflammation	26	1.76	1	43	0.52	0.10	7.4	<0.001
6.	Degree (size) of ulceration	26	1.61	0.5	68	0.59	0.11	9.5	<0.001
7.	No. of ulceration	26	1.46	0.46	68	0.48	0.09	10.6	<0.001
8.	Site of ulceration	26	1.34	0.46	65	0.66	0.13	6.78	<0.001



1. Pain in affected area

The initial score of pain in affected area was 2.07 which was reduced to 1.07 after the treatment. The %age of relief was 48.3% which is highly significant statistically at the level of $p < 0.001$ ($t = 8.07$).

2. Burning sensation

The initial score of burning sensation was 1.3 which was reduced to 0.61 after the treatment. The percentage of relief was 53%, which is highly significant statistically at the level of $p < 0.001$ ($t = 5.57$).

3. *Difficulty in chewing/ingestion*

The initial mean score of difficulty in ingestion before the treatment was 1.15 which was reduced to 0.30 after the treatment. The percentage of relief was 73% which is highly significant at the level of $p < 0.001$ ($t = 5.77$).

4. *Excessive salivation*

The initial mean score of excessive salivation before the treatment was 0.23 which was reduced to 0.03 after the treatment. The percentage of relief was 86% which is insignificant at the level of $p > 0.05$ ($t = 1.97$).

5. *Inflammation*

The initial mean score of inflammation before the treatment was 1.76 which was reduced to 1 after the treatment. The percentage of relief was 43% which is highly significant at the level of $p < 0.001$ ($t = 7.4$).

6. *Degree (size) of ulceration*

The initial mean score of size of ulceration before the treatment was 1.61 which was reduced to 0.5 after the treatment. The percentage of relief was 68% which is highly significant at the level of $p < 0.001$ ($t = 9.5$).

7. *No. of ulceration*

The initial mean score of number of ulceration before the treatment was 1.46 which was reduced to 0.46 after the treatment. The percentage of relief was 68% which is highly significant at the level of $p < 0.001$ ($t = 10.6$).

8. *Site of ulceration*

The initial mean score of site of ulceration before the treatment was 1.34 which was reduced to 0.46 after the treatment. The percentage of relief was 65% which is highly significant at the level of $p < 0.001$ ($t = 6.78$).

Effect of *Soubhagyapravahi* and *Kamdudharasa* on Hematological parameters

Table no. 4.

Sr. No	Haematological test	Mean		% age	S.D. \pm	S.E. \pm	t'	P
		B.T.	A.T.					
1.	Hb %	11.34	11.58	2.1	0.23	0.04	6.25	<0.001
2.	TLC	6952	6908	0.63	76.3	15.26	2.8	<0.01
3.	ESR	10.84	9.84	9.2	0.70	0.14	7.14	<0.001

1. Hb %

The initial mean score of Haemoglobin percent before the treatment was 11.34 which was increased to 11.58 after the treatment. The percentage of change was 2.1% which is highly significant at the level of $p < 0.001$ ($t = 6.25$).

2. TLC

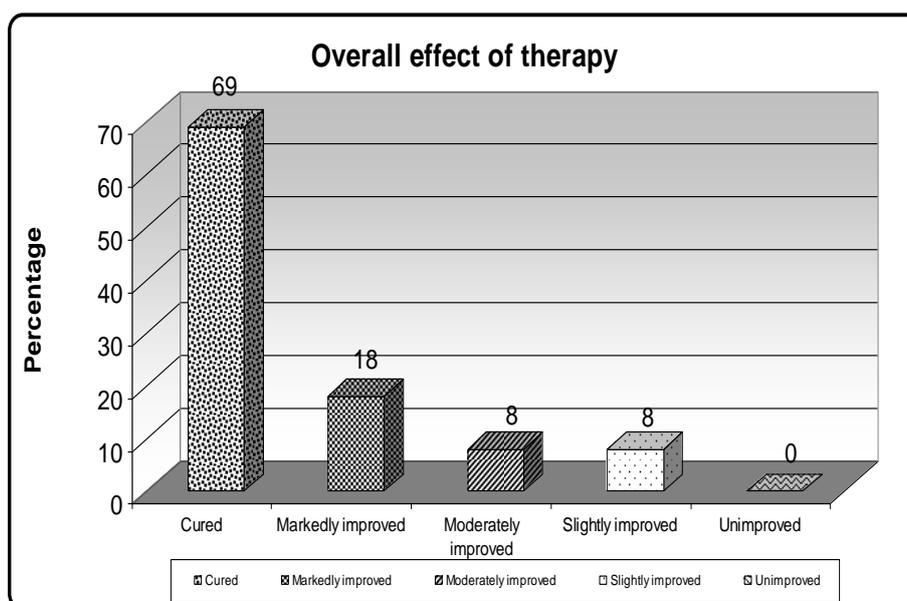
The initial mean score of total leukocyte count before the treatment was 6952 which was reduced to 6908 after the treatment. The percentage of change was 0.63% which is significant at the level of $p < 0.01$ ($t=2.8$).

3. ESR

The initial mean score of erythrocyte sedimentation rate before the treatment was 10.84 which were decreased to 9.84 after the treatment. The percentage of change was 1%, which is highly significant at the level of $p < 0.001$ ($t= 7.14$).

Over all result of Treatment in 26 patients of *Mukhapaka*(Apthous ulcer) under trial.

Sr. No.	Assessment	No. of patients	% age
1.	Cured	18	69%
2.	Markedly improved	4	15%
3.	Moderately improved	2	8%
4.	Slightly improved	2	8%
5.	Unimproved	0	0



Probable Mode of Action

The probable mode of action of drug can be attributed to the annexed effect of the pharmacotherapeutic properties of various constituents of the trial drugs. To sketch the mode of action of a drug it is imperative to look into the *Raspanchaka* as it is the fundamental of pharmacotherapeutics of *Ayurvedic* management.

As told by *Acharyas*, *Mukhapaka* is mainly due to vitiation of *Pitta dosha* in *Mukha Pradesh*. *Soubhagyapravahi* is having dominance of *Madhura rasa* (60%), *Snigdha guna* (42.9%), *Sheetaveerya* (66%), *Madhuravipaka* (100%) and *Pitta vatashamaka* (75%) properties respectively.

Whereas *Kamdudha rasa* is having dominance of *Kashaya rasa* (50%), *Snigdha guna* (75%), *Sheet veerya* (66%), *Madhuravipaka* (100%) and *Tridoshahara* (50%), *Pitta vatashamaka* properties.

Due to these properties vitiated *Pitta dosha* is pacified.

Apart from these facts the constituents of combinations also have potentially proven pharmacological actions like.

- | | | |
|------------------------------------|---|---|
| i) Anti inflammatory | - | <i>Madhuyashti</i> ^[12] , <i>Tankan</i> , <i>Guduchi</i> ^[13] |
| ii) Analgesic | - | <i>Madhuyashti</i> ^[14] , <i>Guduchi</i> |
| iii) Anti microbial | - | <i>Tankan</i> ^[15] |
| iv) Ulcer healing/vasoconstriction | - | <i>Sphatika</i> ^[16] |
| v) Astringent | - | <i>Sphatika</i> |
| vi) Haemostatic/cool effect | - | <i>Madhuyashti</i> ^[17] , <i>Tankan</i> , <i>Sphatika</i> |

All these properties by acting in a synergistic way may help in reducing signs and symptoms of Aphthous ulcer and create a favourable environment for fast recovery of Aphthous ulcer and prevent the recurrence of disease process. All these properties are thus helpful to counteract the various sequences of events responsible for the pathogenesis of Aphthous ulcer.

Scope for further research

Although the present trial gave satisfactory results but

- A large scale study i.e. large number of patients with longer follow up is needed.

- Further research work can be done if there is correlation between types of *Mukhapaka* and types of aphthous ulcers.
- The trial can be reviewed over excluded groups e.g. ulcers due to infection and trauma induced.

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