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# A clinical study to evaluate the efficacy of *Triphala Kwatha* with *Madhu Mukha Dhavana* in the management of *Mukhapaka* w.s.r. to Stomatitis

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## ABSTRACT

**Background:** The *Mukha* (Oral cavity) is considered to be one of important part of the *Urdhwajatru* because it work as the reflector of the body health by acting as gateway of the alimentary canal. *Sarvasara Mukha Rogas* are named as "*Mukha Paka*" occur by spreading completely in the *Mukha* so only named as *Sarvasara Mukha Rogas*. *Mukhapaka* can be correlated to Stomatitis. **Methodology:** This is a single-arm clinical trial where 20 patients fulfilling the inclusion criteria of *Mukhapaka* were selected and evaluated to see the efficacy of *Triphala Kwatha* with *Madhu Mukha Dhavana*. Source of patients was O.P.D and I.P.D of Shalakya Tantra, SMVVS RKM Ayurvedic Medical College, Vijayapura. **Results:** Signs and symptoms were given with suitable scores according to their severity based on relief after treatment. The results having P value less than  $< 0.001$  were considered as statistically significant in this study. *Triphala Kwatha* with *Madhu Mukha Dhavana* was effective and significant on parameters of *Mukhapaka*. **Discussion:** *Triphala Kwatha* with *Madhu* has very significant effect in the management of *Mukhapaka*. Marked reduction in clinical symptom was well appreciated within 7 days of treatment. *Triphala Kwatha* with *Madhu* is proved to be cost effective, adoptive, safe and better drug of choice in the management of *Mukhapaka*.

**Key words:** *Mukhapaka*, Stomatitis, *Triphala Kwatha*, *Madhu*, Honey

## INTRODUCTION

Ayurveda is goldmine of traditional medicine. It is the holy ocean of *Amrutha* that can never be exploited and utilized fully, even with the strenuous and constant effort and research of any generation. Ayurveda is a gift of nature, which guides us to perfect living and its

root can be searched in Vedic period are even early year it is rational and scientific. It is formulated after centuries of experiments and experiences. Ayurveda has its own concepts of Health and ill health. Ayurveda does not need any validation as it was already done very carefully long ago, our problem is not validation but the standardization of drugs traditional practices should be modified to suit the changed Lifestyle. Ayurveda is so wide and it considers that each and every particle in the universe has some medicinal value.

*Sarvasara Mukha Rogas* are named as *Mukhapaka* as it occurs by spreading completely in the present Era word is looking at Ayurveda with the hope that it is going to provide good asset to the treatment of ailing humanity.

Stomatitis is diffused inflammation of oral mucosa nearly 20% of population is suffering with this

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problem.<sup>[1]</sup> It is characterized by superficial ulcers in the movable mucosa of the mouth with recurrent episodes which occur due to various causes like simple cut to the mouth eating very hot food items in proper cleaning of teeth, vitamin deficiencies general weaknesses, tobacco chewing, smoking etc. and complaints are inflammation of oral mucosa ulceration the mouth, Altered taste, pain, burning sensation, itching sensation, difficulty in mastication and discomfort.

According to Acharya Charaka, *Mukhapaka* is mentioned under 40 *Pittaja Nanatmaja Vikara*.<sup>[2]</sup> *Dalhana* in his commentary on *Sushruta Samhita*, mentions *Mukhapaka* as a *Pittaja Vikara* but Acharya *Sushruta* has classified *Sarvasara Mukharogas (Mukhapaka)* into 4 types, i.e., *Vataja, Pittaja, Kaphaja* and *Raktaja*.<sup>[3]</sup> The deteriorated *Vatadi Doshas* reaches the *Mukha* to produce *Paka* and *Vrana*.

Even through lot of research on the condition with different treatment modalities is undergoing in biomedical world considerable number of world population is suffering from this disease without satisfactory relief. This arises the need to explore and effective line of management for this disorder.

Ayurveda *Acharyas* mentioned various drugs which are effective as well as affordable for the patients. Among these *Triphala Kwatha* with *Madhu*<sup>[4]</sup> were selected for *Mukhadhavan* in the management of *Mukhapaka*.

## OBJECTIVES OF THE STUDY

To evaluate the efficacy of *Triphala Kwatha* with *Madhu Mukha Dhavana* in the management of *Mukhapaka*.

## MATERIALS AND METHODS

### Source of data

The patients attending the OPD & IPD and patients from various medical camps conducted by Smt. Rajeshwari Karpurmath Ayurveda Medical College, Hospital & P.G. Research Centre, Vijayapura, Karnataka, India.

## Criteria for selection of patients

### Inclusion Criteria

1. The patients presenting with classical features of *Mukhapaka* will be selected irrespective of Gender, occupation, religion etc.
2. Patients who are willing to enroll for clinical trial.
3. Patients in the age between 16-70 years.

### Exclusion Criteria

1. Patients suffering from any other systemic illness which interfere the duration of course of treatment.
2. Patients suffering from Non-healing ulcers of mouth, malignancy, syphilis, AIDS etc., will be excluded.

## Research Design

This is a single-arm clinical trial where 20 patients fulfilling the inclusion criteria of *Mukhapaka* were selected and evaluated to see the efficacy of *Triphala Kwatha* with *Madhu Mukha Dhavana*.

## Composition of drug formulation

### Collection of drugs

All the raw materials required for the preparation of *Triphala Kwatha* were purchased from the department of Dravya Guna, R K M Ayurveda Medical College and Hospital, Vijayapura.

### Preparation of medicine

All drugs were identified and collected. Preparation of medicine was done as per classical methods in the Dept of Rasa Shashtra and Bhaishajya Kalpana of SMVVS's R.K.M. Ayurvedic Medical College, Hospital and PG Research Centre, Vijayapura, Karnataka.

**Table 1: Triphala Kwatha with Madhu**

SN	Drugs	Quantity
1.	<i>Triphala Churna</i>	1 part
2.	Water	8 parts
3.	<i>Madhu</i>	1/8 of <i>Kwatha</i>

*Kwatha* will be prepared by adding 8 parts of water to 1 part of *Triphala Kwatha Churna* and reducing to 1/4<sup>th</sup> by heating on *Mandagni*.

**Posology:** As required

#### Subjective Parameters

- Pain
- Burning sensation

#### Objective Parameters

- Number of ulcers
- Size of ulcer
- Redness.

#### Gradation Index

#### Gradation of symptoms

**Table 2: Ruja (pain)**

No pain	0
Mild pain during churning of food	1
Moderate pain during talking and gets relief by topical anesthetics	2
Several pain even during rest, No relief by topical anesthetics	3

**Table 3: Daha (burning sensation)**

No Daha	0
Mild tolerable, no need of cooling agents Like glycerin or cold juice	1
Moderate intolerable, Gets relief by cooling agents	2
Severe intolerable, no relief by cooling agents	3

**Table 4: Number of Vrana**

No Vrana	0
1-5 Vrana	1
6-10 Vrana	2

More than 10	3
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**Table 5: Size of the Vrana**

Absence of the Vrana	0
Size of the Vrana between 0-5 mm	1
Size of the Vrana between 6-10 mm	2
Size of the Vrana greater than 10mm	3

**Table 6: Rakta Varnata (Redness)**

No redness	0
Dull red or pink red	1
Colour of magenta	2
Bright red	3

#### Follow up study

After completion of 7 days of course of *Mukhadhavan* the patient was asked to report for the follow-up once in 7 days for one month period.

#### Statistical Analysis

On the basis of scoring given to them, the data obtained was subjected to bio-statistical analysis using students 't' test and final inferences were drawn.

#### OBSERVATIONS AND RESULTS

In the present clinical study, it was observed that 10 (50%) patients of *Mukhapaka* were in the age group of 16-30 years followed by 9 (45%) patients in the age group of 31-45 years and 1 (5%) patient in the age group of 45-60 years. In the present clinical study, it was observed that the 15 subjects (75%) were male and 5 subjects (25%) were female. In the present clinical study, it was observed that 18 (90%) of married patients were suffering from *Mukhapaka* and 2 (10%) of unmarried were also sufferers. In the present clinical study, it was observed that 17 (85%) of the patients were from the rural area and 3 (15%) of patients were from urban area. In the present clinical study, it was

observed that patients belonging to lower class were 12 (60%), middle class were 5 (25%), and upper class were 3 (15%). In the present clinical study, it was observed that Labour and were affected more than other class with 15 (75%) patients.

In present study 14 (70%) patients were taking *Ushna*, *Tikshna* and *Vidahi Ahara* and *Dugdha Sevana* regularly as well as consuming excessive chilies and spices with about 14 (70%) of patients followed by 9 (45%) patients were taking *Alpa*, *Pramita* and *Ruksha Ahara*. In this series 9 patients i.e. (45%) had chewing habit of arecanut, tobacco and its related products while along with these 02 (10%) of patients had smoking habit. Maximum 16 (80%) patients had fewer intakes of fruits and green leafy vegetables in their diet as well as taking curd regularly in their diet. 5 (25%) patients were consuming *Ikshuvikara*, 2 (10%) were having *Amamulaka* as well as 2 (10%) *Masha supa*, while 1 (5%) patient was doing *Matsya Sevana*.

In 5 (25%) patient *Danta Dhavana Dwesha* was found. It was observed that 02 patients (7.5%) had the habit of smoking tobacco as shown in the below table. Maximum number of patients was addicted to Tea 17 (85%) patients, followed by addiction to Tobacco 8 (40%) patients & Chewing pan each in 01 (5%) of cases. 70% of the patients had bad oral hygiene. 95% of the patients were vegetarian. 65% patients had reported emotional stress.

Sleep wise distribution shows, maximum 12 (60%) patients were having disturbed sleep whereas 8 (40%) patients had sound sleep. Maximum 15 (75%) patients had regular bowel habit while 5 (25%) patients were having irregular bowel habit. Maximum 9 (45%) patients were having *Mandagni*, followed by 7 (35%) of patients having *Vishamagni* and 4 (20%) were having *Samagni*. Maximum patients had *Mrudu Koshta* with an incidence of 50% in the present study. Maximum patients i.e., 17 (85%) had *Sama Jihva* was noted and in rest there was *Nirama Jihva*.

It was observed in the clinical trial that 9 patients (45%) were *Vata Pittaja Prakruthi* and 8 patients (40%) were *Kapha-Pitta Prakruthi*.

**Effect of therapy on Subjective Parameters of Mukhapaka**

**Table 7: Effect of Triphala Kwatha and Madhu Dhavana on Pain**

SN	Data	Mean		%	S.D	S.E	T	P
		BT	AT					
1.	AT	1.95	0.5	74.35	0.3657	0.1352	10.7214	<0.001
2.	AFU1	1.95	0.5	74.35	0.3657	0.1352	10.7214	<0.001
3	AFU2	1.95	0.6	69.23	0.3447	0.1312	10.2823	<0.001
4	AFU3	1.95	0.6	69.23	0.3447	0.1312	10.2823	<0.001
5	AFU4	1.95	0.6	69.23	0.3447	0.1312	10.2823	<0.001

On analyzing the data it was found that the treatment provided 74.35% and 69.23% of relief after treatment (AT) and AFU respectively on the parameter Pain

On statistical analysis *Triphala Kwatha* and *Madhu Dhavana* proved to be highly significant (< 0.001) after treatment (AT) and AFU respectively on the parameter Pain

**Table 8: Effect of Triphala Kwatha and Madhu Dhavana on Daha**

SN	Data	Mean		%	S.D	S.E	T	P
		BT	AT					
1.	AT	1.85	0.4	78.37	0.3657	0.1352	10.7214	<0.001
2.	AFU1	1.85	0.4	78.37	0.3657	0.1352	10.7214	<0.001
3	AFU2	1.85	0.45	75.67	0.3578	0.1337	10.4653	<0.001
4	AFU3	1.85	0.5	72.97	0.3447	0.1312	10.2823	<0.001
5	AFU4	1.85	0.5	72.97	0.3447	0.1312	10.2823	<0.001



On analyzing the data it was found that treatment provided 78.37% and 72.97% of relief after treatment (AT) and AFU respectively on the parameter *Daha*.

On statistical analysis *Triphala Kwatha* and *Madhu Dhavana* proved to be highly significant (< 0.001) after treatment (AT) and AFU on the parameter *Daha*.

**Table 9: Effect of Triphala Kwatha and Madhu Dhavana on number of ulceration**

S N	Data	Mean		%	S.D	S.E	T	P
		BT	AT					
1.	AT	1.85	0.35	81.08	0.4736	0.1539	9.7464	< 0.001
2.	AFU1	1.85	0.4	78.37	0.4710	0.1534	9.4478	< 0.001
3.	AFU2	1.85	0.45	75.67	0.4631	0.1521	9.1995	< 0.001
4.	AFU3	1.85	0.45	75.67	0.4631	0.1521	9.1995	< 0.001
5.	AFU4	1.85	0.45	75.67	0.4631	0.1521	9.1995	< 0.001

On analyzing the data it was found that treatment provided 81.08% and 75.67% of relief after treatment (AT) and AFU respectively on the parameter Number of ulceration.

On statistical analysis *Triphala Kwatha* and *Madhu Dhavana* proved to be highly significant (< 0.001) after treatment (AT) and AFU on the parameter Number of ulceration.

**Table 10: Effect of Triphala Kwatha and Madhu Dhavana on Size of ulceration**

SN	Data	Mean		%	S.D	S.E	T	P
		BT	AT					
1.	AT	1.85	0.35	80.55	0.4710	0.1534	9.4478	< 0.001
2.	AFU1	1.85	0.4	77.7	0.5684	0.1685	8.3041	< 0.001
3.	AFU2	1.85	0.45	75	0.45	0.1500	8.9997	< 0.001

4.	AFU3	1.85	0.45	75	0.45	0.1500	8.9997	< 0.001
5.	AFU4	1.85	0.45	75	0.45	0.1500	8.9997	< 0.001

On analyzing the data, it was found that treatment provided 80.55% and 75% of relief after treatment (AT) and AFU respectively on the parameter Size of ulceration.

On statistical analysis *Triphala Kwatha* and *Madhu Dhavana* proved to be highly significant (< 0.001) after treatment (AT) and AFU on the parameter Size of ulceration.

**Table 11: Effect of Triphala Kwatha and Madhu Dhavana on Colour of ulceration**

SN	Data	Mean		%	S.D	S.E	T	P
		BT	AT					
1.	AT	1.7	0.35	79.41	0.45	0.1500	8.9997	< 0.001
2.	AFU1	1.7	0.35	79.41	0.45	0.1500	8.9997	< 0.001
3.	AFU2	1.7	0.35	79.41	0.45	0.1500	8.9997	< 0.001
4.	AFU3	1.7	0.4	76.47	0.4315	0.1469	8.8494	< 0.001
5.	AFU4	1.7	0.4	76.47	0.4315	0.1469	8.8494	< 0.001

On analyzing the data, it was found that treatment provided 79.41% and 76.47% of relief after treatment (AT) and AFU respectively on the parameter Colour of ulceration.

On statistical analysis *Triphala Kwatha* and *Madhu Dhavana* proved to be highly significant (< 0.001) after treatment (AT) and AFU on the parameter Colour of ulceration.

**DISCUSSION**

The study was carried out in the patients of *Mukhapaka*. Sample size of the study was 20. Patients

were subjected to *Triphala Kwath* with *Madhu Mukhadhavana* for a duration of 7 days.

### Discussion on Drug

As per *Ashtanga Samgraha*, *Mukhapaka* is mentioned as *Pitta Dosha Roga* and *Susrutha Samhitha* is mentioned as *Pitta Kapha Dosha Vyadhi*. Here both *Triphala Kwatha* and *Madhu* and *Jati Patra Kwatha* are basic formulated as *Kwatha* base. The drugs used are *Vranahara* in action.

*Triphala Kwatha* and *Madhu* is a combination widely used in treatment of *Mukhapaka* and it is acts as *Tridoshaghna* and *Vrana Shodhana, Ropana*. These drugs are used as a *Shodhana* as well as *Shamana* actions. Honey is having the property of *Yogavahi* so it takes the goodness of the medicine to the desired target organ. *Jati Patra Kwatha* is a combination used in *Mukhapaka*. It is having *Tikta Kasaya Rasa, Kaphapitta Shamana, Vranahara* property.

### Discussion on observation

#### Data related to age incidence

In the present clinical study, it was observed that majority of the 10 patients of *Mukhapaka* were in the age group of 16-30 years with an incidence of 50% followed by 9 patients in the age group of 31-45 years with an incidence of 45%.

**Data related to Gender** present clinical study it was observed that the 15 subjects (75%) were male and 05 subjects (25%)

#### Data related to marital status

In the present clinical study it was observed that 90% of married patients were suffering from *Mukhapaka* and 10% of unmarried were also sufferers.

#### Data related to Habitat

In the present clinical study it was observed that 85% of the patients were from the rural area and 15% of patients were from urban area.

#### Data related to socio-economic status

In the present clinical study it was observed that patients belonging to lower class were 60%, middle class were 25% and upper class were 15%.

#### Data related to Occupation

In the present clinical study it was observed that Labour were affected more than other class with 75%

#### Incidence of Nidana

70% patients were taking *Ushna, Tikshna* and *Vidahi Ahara* and *Dugdha Sevana* regularly as well as consuming excessive chilies and spices with about 70% of patients followed by 45% was taking *Alpa, Pramita* and *Ruksha Ahara*.

In this series 45% patients had chewing habit of arecanut, tobacco and its related products while along with these 10% of patients had smoking habit.

Maximum 80% patient had fewer intakes of fruits and green leafy vegetables in their diet as well as taking curd regularly in their diet.

25% were having *Ikshuvikara*, 10% were having *Amamulaka* as well as 10% *Masha* supa while 5% were having *Matsya Sevana*. In 25% patient *Danta Dhavana Dwesha* was found.

#### Data related to Addiction

In the present clinical study it was observed that 02 patients (7.5%) had the habit of smoking tobacco. Maximum number of patients was addicted to Tea (85%), followed by addiction to Tobacco (40%) & Chewing pan each in 5% of cases.

#### Oral Hygiene

Oral hygiene distribution shows that in maximum i.e., 70% patients' oral hygiene was poor and in rest of the patients it was fair.

#### Data related to Diet

Regarding personal history it was observed that maximum patients were taking vegetarian diet i.e. 95%

#### Emotional stress wise

35% patient had no emotion stress while 65% patients had reported emotional stress.

#### Sleep wise

Maximum 60% patients were having disturbed sleep where as 40% patients had of sound sleep.

**Bowel habits**

Maximum 75 % patients had regular bowel habit while 25% patients were having irregular bowel habit

**Agni Bala**

Maximum 45% patients were having *Mandagni*, followed by 35% of patients having *Vishamagni* and 20% were having *Samagni*.

**Data related to Koshta**

It was observed in the clinical trial that maximum patients had *Mrudu Koshta* with an incidence of 50% in the present study.

**Jihva wise**

Maximum patients i.e., 85% *Sama Jihva* was noted and in rest there was *Nirama jihva*.

**Data related to Prakruthi**

It was observed in the clinical trial that 9 patients (45%) were *Vata Pittaja Prakruthi* and 8 patients (40%) were *Kapha-Pitta Prakruthi*.

**CONCLUSION**

*Triphala Kwatha* with *Madhu Mukhadhavana* shows decrease in the severity of symptoms of *Mukhapaka*. There might be fluctuation of results because of small sample size. *Mukhadhavan* is cost effective and can be

practiced at OPD basis. The study can be conducted for large sample size to get accurate result.

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