



Research Article

## EVALUATING THE EFFICACY OF *HARIDRADI LEPA* IN THE TREATMENT OF *SARVASARA MUKHAPAKA*: A CLINICAL STUDY WITH FOCUS ON INFLAMMATORY ORAL MUCOSAL CONDITIONS

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### ABSTRACT


*Mukhapaka* is one among diseases mentioned under *Mukha Rogas* (diseases of oral cavity) where vitiated *Vatadi Doshas* will give rise to *Shotha* (inflammation) or *Vrana* (ulcer) which are similar with inflammatory oral mucosal conditions. *Sthanika Chikitsa* as *Haridra Yashtimadhu Kumari Lepa* (topical paste) was selected as trial drug and its efficacy was compared with Triamcinolone Acetonide 0.1% oral gel which is a commonly used and previously researched drug. A forethought was given on the patient's quality of life, drug's literary pharmacological review, convenience of availability and usage, trends of effect on long term usage of control drug, preservative free drug preparation and compatibility to oral pH value. **Aims and Objectives:** To evaluate the role of *Haridra Yashtimadhu Kumari Lepa* in the management of *Mukhapaka*. The objective of the study was to evaluate and re-evaluate the efficacy of both the drugs and also to compare both. Secondary objectives were to assess improvement in quality of life based on subjective parameters International OHR QOL questionnaire and the objective parameters - size of *Mukhapaka* and colorimetry.

**Materials and methods:** Thirty subjects fulfilling the inclusion criteria were randomly divided and equally assigned to two groups A and B. Group A was given trial drug- *Haridra Yashtimadhu Kumari Lepa* and Group B was given control drug- Triamcinolone Acetonide 0.1% oral gel. Both the drugs were given to be used as topical application at the affected oral mucosal region, bed time for seven days. Statistical evaluation was done using Sigma stat version 3.1 and IBM SPSS Version 26. **Results:** Both the groups showed statistically significant improvement in the condition and no statistical difference in between the groups. There were clinically better results from group A in comparison with group B. **Conclusion:** Though null hypothesis is accepted, group A showed clinically better results.

### INTRODUCTION

Ayurveda has given unique concepts like *Tridosha*, *Dhatu* and *Mala* for the homeostasis of the body.<sup>[1]</sup> According to Ayurveda, the *Urdhwanga* (head and neck) includes the *Mukha* (oral cavity).<sup>[2]</sup>

It provides insight into the body's overall well-being. The alimentary canal starts at the *Mukha*. In *Ayurveda*, there is mentioning of daily regimens for *Swasthya* (health) and oral care like *Mukha Prakshalana* (rinsing), *Danta Dhavana* (brushing), *Jihwa Nirlekhana* (tongue cleaning), *Kavala* (squashing), *Gandusha* (retaining medication in mouth), *Tambula Sevana* (betel leaf chewing).<sup>[3]</sup> When these are not followed and unwholesome practices adopted along with stress factor various oral diseases get manifested.

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*Sarvasara Mukhapaka* is one such disease mentioned under *Mukha Roga*. Here, *Sarvasara* specifies 'Vyapakatva' or spread and *Saratva* or movement. The word 'Paka' is digestion or transformation due to heat. It also means ripening, inflammation. *Vedana Yukta Shopha* and *Vrana* in the *Mukha Pratyangas* (sub parts of oral cavity) are the characteristic features of *Mukhapaka*. *Acharya Lakshanas of Mukhapaka*

*Sushrutha* has classified *Mukhapaka* into three types - *Vataja*, *Pittaja* and *Kaphaja*. *Acharya Vagbhata* has classified *Mukhapaka* into five types *Vataja*, *Pittaja*, *Kaphaja*, *Raktaja* and *Sannipataja*. Characteristic features of different types of *Mukhapaka* are described in Table 1. [4,5,6] Whereas *Acharya Charaka* has described it under *Pittaja Nanatmaja Vyadhi*.

**Table 1: Showing Lakshanas of each type of Mukhapaka**

Names of diseases	S <sup>50</sup>	A.H./A.S <sup>51</sup>
<i>Vataja Mukhapaka</i>	<i>Sphota</i> <i>Toda</i>	<i>Antar Vrana</i> , <i>Aruna</i> , <i>Ruksha</i> , <i>Tamra Oshta</i> , <i>Chala Twacha</i> , <i>Jihwa- Sheeta asaha</i> , <i>Gurvi, Sputita, Kankachita, Kruchra Vivranata.</i>
<i>Pittaja Mukhapaka</i>	<i>Peeta</i> <i>Daaha</i> <i>Tanu</i>	<i>Daaha</i> , <i>Tikta vaktrata</i> , <i>Ksharokshita kshata sama vrana</i>
<i>Kaphaja Mukhapaka</i>	<i>Kandu</i> <i>Alpa Ruja</i> <i>Savarna</i>	<i>Madhurasyata</i> , <i>Kandu</i> <i>Pichila Vrana</i>
<i>Raktaja Mukhapaka</i>	<i>Pittodita</i> <i>Eka Eva</i>	<i>Daaha</i> , <i>Oosha</i> <i>Tikta vaktrata</i> , <i>Ksharokshita Kshata sama vrana</i>
<i>Sannipataja</i>	-	Characteristics of all the other types of <i>Mukhapaka</i>

In contemporary science, symptoms of *Mukhapaka* can be correlated to the inflammatory oral mucosal conditions which are caused by local and systemic causes. The prevalence of oral mucosal lesions was found to be 10.26% - 16.8%. [7] These range from acute to chronic conditions and are listed under the classification of red and white lesions of the oral mucosa, ulcerative, vesicular, and bullous lesions. Caused by infections like viral, bacterial and fungal; immune disorders, trauma: physical chemical, thermal injuries, skin disorders, systemic causes like Behcet's disease, Crohn's disease and miscellaneous like cancer chemotherapy.

The cardinal features of inflammation being rubor (redness), tumor (swelling), calor (heat), dolor (pain) and functio laesa (loss of function). [8] Stomatitis is a general term coined for diffuse inflammation of the oral cavity which can be associated with lesions. White lesion is a non-specific term used to describe any abnormal area of oral mucosa that on the clinical examination appears whiter than surrounding tissue and is usually slightly raised, roughened, or otherwise

of a different texture from normal tissue. Whereas red lesion refers to an area of reddened mucosa that may be smooth and "atrophic looking" or exhibits a granular, velvety texture.

The commonest treatment modalities include topical and systemic steroid but they have their own side effects on prolonged usage. [9] Triamcinolone Acetonide 0.1% oral gel [10] is one among them, which is proven to be effective in case of oral mucosal inflammations. Various conditions of oral inflammations are encountered daily in our Out Patient Department ranging from acute to chronic. This paves way for finding alternative treatments to minimize the ill effects caused by these conditions.

There are various treatments mentioned in Ayurvedic classics, *Lepana* is one among them. [11] It is a procedure in which medicated paste is applied in the mouth and retained for a certain period of time. Hence, here an attempt is made to compare the effect of *Haridra Yashtimadhu Kumari Lepa* which has anti-inflammatory properties with Triamcinolone

acetonide 0.1% oral gel in *Mukhapaka* w.s.r to Inflammatory oral mucosal conditions.

**AIM OF THE STUDY**

To evaluate the role of *Haridra Yashtimadhu Kumari Lepa* in the management of *Mukhapaka* (inflammatory oral mucosal conditions).

**MATERIAL AND METHODS**

It was a randomized open labelled comparative clinical study with pre and post-test design. Thirty subjects diagnosed with *Mukhapaka* with special reference to Inflammatory oral mucosal conditions, were taken randomly and were divided into two groups of fifteen subjects each. The study was started after approval from the Institutional Ethics Committee SSIEC/257/2022. The study was registered in CTRI with register No. CTRI/2022/12/048527.

The drugs were procured by the good manufacturing practice (GMP) certified pharmacy, Sri Sri Tattva. Raw drug *Kumari Patra* was procured from Nurserymen Co-operative Society Limited.

Patient information sheet was given to all thirty subjects and informed consent was taken.

**Diagnostic criteria**

**Subjective parameters-** *Ruja* (pain), *Daha* (burning sensation), *Kruchra Mukha Vivrunata* (difficulty in opening mouth).

**Objective Parameters-** Size of *Mukhapaka* (Measurement with calibrated periodontal probe), Colorimetric Scale, Laboratory Investigations like-Complete Hemogram and C-Reactive Protein.

**Inclusion criteria**

Subjects aged between 21 to 60 years irrespective of gender, occupation, religion, socio-economic status and fulfilling the diagnostic criteria were included. Also, the subjects willing to sign the informed consent and subjects under immunomodulatory medications were included. (None of the subjects enrolled for study were under existing Immunomodulatory medications).

**Exclusion criteria**

Subjects having *Mukhapaka* due to necrosis or sublingual abscess, other oral lesions due to systemic diseases and under any other treatments for *Mukhapaka* were excluded.

**Withdrawal criteria**

Subjects were free to withdraw from the study at any time by their own will. However, none of the subjects withdrew from the trial.

**Assessment criteria**

**Subjective parameters**

1. *Ruja* (pain) - Numeric Pain Rating Scale<sup>[12]</sup>
2. *Daha* (burning sensation) – VAS scale scoring<sup>[13]</sup>
3. *Kruchra Mukha Vivrunata* (difficulty in opening mouth)<sup>[14]</sup> as per [Table 2]
4. International OHR QOL questionnaire:<sup>[15]</sup>

**Objective Parameters: (Figure 1), (Table 3)**

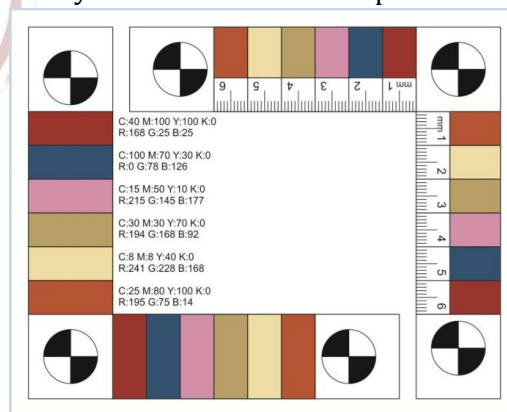
1. Size of *Mukhapaka* was measured with calibrated periodontal probe.<sup>[16]</sup>

Here sum total of size of *Mukhapaka* of different sites is taken in mm diameter.

Subjects diagnosed with Lichen planus were having overall size more than 3cm and are chronic in nature; so, they were omitted from this parameter.

2. Colorimetric Scales<sup>[17]</sup>

Colorimetry CMYK and RGB color specifications<sup>17</sup>:



**Table 2: Showing grading for *Kruchra Mukha Vivrunata* parameter<sup>14</sup>**

Score	Grade	Criteria
0	Nil	No discomfort, can open mouth completely
1	Mild	Mild- cannot open mouth completely, 3 fingers gap
2	Moderate	cannot open mouth completely, 2 fingers gap
3	Severe	cannot open mouth, gets pain by slight opening of mouth

**Table 3: Showing grading for Colorimetry<sup>17</sup>**

Score	Color	Color specification
0	Purple	C:15 M:50 Y:10 K:0; R:215 G:145; B:177
1	Bluish	C:100 M:70 Y:30 K:0; R:0 G:78; B: 126
2	Dark red	C:40 M:100 Y:100 K:0; R:168 G:25; B: 25

**Intervention**

**Table 4: Intervention given in Group A and B**

Group	Treatment	Dose	Duration	Assessment	Follow up	Study period
A (trial) 15 subjects	<i>Haridra</i> <i>Yashtimadhu</i> <i>Kumari Lepa</i>	QS (Overnight application from 10pm to 6am)	Continuously 7 days	-0 <sup>th</sup> , 3 <sup>rd</sup> , 7 <sup>th</sup> , 14 <sup>th</sup> , 21 <sup>st</sup> and 28 <sup>th</sup> day	14 <sup>th</sup> , 21 <sup>st</sup> and 28 <sup>th</sup> day	28 days
B (control) <sup>[21]</sup> 15 subjects	Triamcinolone Acetonide 0.1% Oral gel	QS (Overnight application from 10pm to 6am)	Continuously 7 days	-0 <sup>th</sup> , 3 <sup>rd</sup> , 7 <sup>th</sup> , 14 <sup>th</sup> , 21 <sup>st</sup> and 28 <sup>th</sup> day	14 <sup>th</sup> , 21 <sup>st</sup> and 28 <sup>th</sup> day	28 days

Group A (Trial Group) –fifteen subjects were treated with *Haridra Yashtimadhu Kumari Lepa* [18,19,20] for seven days.

**Preparation:** Equal quantity of finely powdered *Haridra Churna* and *Yashtimadhu Churna* were mixed with sufficient quantity of fresh *Kumari* pulp (washed and devoid of yellow latex) to prepare a homogenous mixture. This mixture is used for local application. **[Figure 3]**



**Showing trial drug *Haridra Yashtimadhu Kumari Lepa***

Group B (Control Group) –fifteen samples were treated with Triamcinolone Acetonide 0.1% Oral gel for seven days. For both the groups intervention was scheduled as below:

Route of administration: Topical administration

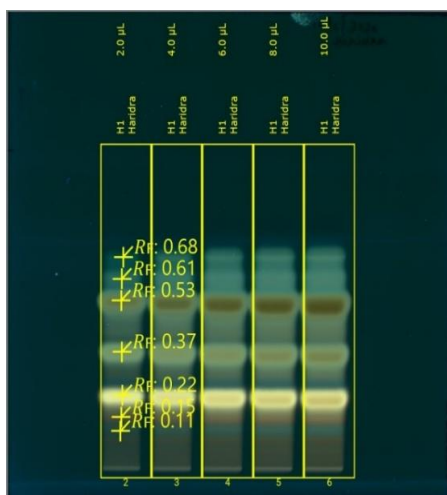
**Statistical analysis**

Statistical evaluation was done using Sigma stat version 3.1 and IBM SPSS Version 26. Within the group analysis was done using Friedman Repeated Measures Analysis of Variance on Rank. Between group analysis was done with Mann Whitney Rank Sum test. Interpretation was done based on the p value. Effect size difference (ESD) within the group was done with Friedman Test for repeated measures and effect size difference (ESD) between the group with Fisher exact test

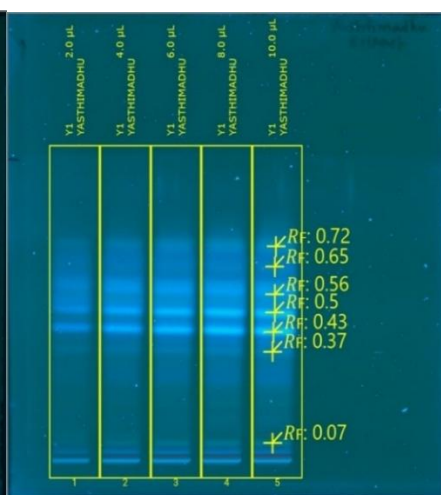
**OBSERVATION**

Drug Analysis of the Trial Drug was carried out for-

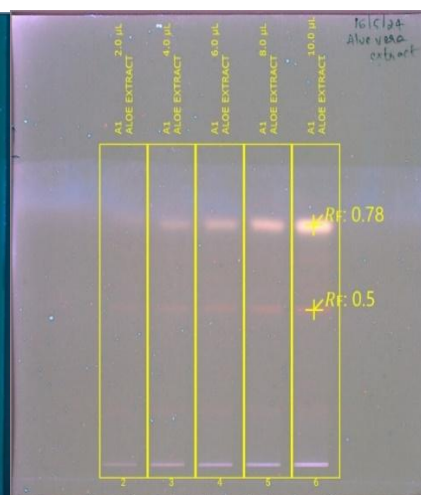
1. Organoleptic evaluation of *Lepa*- colour was yellowish brown. Texture was rough and Slimy. Odor- Characteristic odor. Taste was sweet and astringent.
2. Physicochemical analysis and
3. HPTLC (High-Performance Thin Layer Chromatography) Fingerprinting for each constituent of the *Lepa* was done - several significant peaks were observed across different tracks of HPTLC, indicating the presence of major active compounds. [Figure 4, 5, 6]



**Figure 4: Showing HPTLC plates at 366nm of *Haridra***



**Figure 5: Showing HPTLC plates at 366nm of *Yashtimadhu***



**Figure 6: Showing HPTLC plates at 366nm of *Kumari***

The clinical study was conducted on 30 subjects. In this study, 11 participants (36.66%), 8 participants (26.66%) were in the age group of 21-30 and 51-60 years, majority of subjects, i.e., 20 (66.66%) were females, maximum 11 (36.66%) subjects were home makers, maximum 26 (86.66%) subjects were from middle class and all had gradual onset of the disease. 19 (63.33%) had bilateral involvement and in 21 (43.75%) subjects affected site was buccal mucosa. Out of all 18 (60%) were acute cases and 12 (40%) were chronic cases.

14 (46.67%) had nil or irregular routine of exercising. 17 (56.66%) were vegetarians. 22 (25%) had one of the probable *Nidana* (cause) as curd intake, 20 (22.73%) as spicy food consumption among multiple *Nidanas*. Tea 29 (58%), coffee 18 (36%) and tobacco smoking 2 (2.27%) were important contributors among multiple habits. Base on the identified types of *Mukhapaka* according to classics *Pittaja Mukhapaka* was majorly seen among 17 (56.67%) subjects, *Sannipataja* was 12 (40%), *Vataja* was 1 (3.33%) while there was no *Kaphaja* category.

**RESULTS**

**Table 5: *Ruja* assessment at various intervals**

Group	<i>Ruja</i> assessment at different points of time (Data: Median, 25 <sup>th</sup> & 75 <sup>th</sup> Percentile)					
	Day 0 (D0)	Day 3 (D3)	Day 7 (D7)	Day 14 (D14)	Day 21 (D21)	Day 28 (D28)
Group A	2.50 (2.00-3.00)	1.00 (1.00-1.00)*	0.00 (0.00-1.00)*	0.00 (0.00-1.00)*	0.00 (0.00-1.00)*	0.00 (0.00-1.00)*
Group B	2.00 (1.00-2.00)	1.50 (1.00-2.00)	1.00 (0.00-1.00)*	1.00 (0.00-1.00)*	1.00 (0.00-1.00)*	1.00 (0.00-1.00)*
Comparison within the Group - * P = <0.05 in comparison to the D0 values (Friedman test) Comparison between the Groups- (Mann Whitney rank sum test)						

Group A showed significant decrease in *Ruja* on Day (D) 3, D7, D14, D21 and D28. P = <0.05. Group B showed significant decrease in *Ruja* D7, D14, D21 and D28. But not on D3. P = <0.05. Therapeutic effect was seen in both groups but statistically not significant with p value > 0.05.

**Table 6: *Daha* assessment at various intervals**

Group	<i>Daha</i> assessment at different points of time (Data: Median, 25 <sup>th</sup> & 75 <sup>th</sup> Percentile)					
	Day 0 (D0)	Day 3 (D3)	Day 7 (D7)	Day 14 (D14)	Day 21 (D21)	Day 28(D28)
Group A	2.00 (2.00-3.00)	1.00 (1.00-1.00)*	0.00 (0.00-1.00)*	0.00 (0.00-1.00)*	0.00 (0.00-1.00)*	0.00 (0.00-1.00)*
Group B	2.00 (2.00-2.75)	2.00 (1.25-2.00)@	0.00 (0.00-1.00)*	0.00 (0.00-1.00)*	0.00 (0.00-1.00)*	0.00 (0.00-1.00)*
Comparison within the Group - * P = <0.05 in comparison to the D0 values (Friedman test) Comparison between the Group- @ P= 0.013 (Mann Whitney rank sum test)						

Group A showed significant decrease in *Daha* on D3, D7, D14, D21 and D28. p value <0.05. Group B showed significant decrease in *Daha* was noticed on D7, D14, D21 and D28. But not on D3. P value <0.05. Therapeutic effect was seen in both groups statistically significant on day 3 but statistically not significant on other days with p value > 0.05.

**Table 7: QOL assessment at various intervals**

Group	QOL assessment at different points of time (Data: Median, 25 <sup>th</sup> & 75 <sup>th</sup> Percentile)	
	Day0 (D0)	Day 7 (D3)
Group A	2.00 (2.00-3.00)	2.00 (2.75-2.00)*
Group B	2.00 (2.00-2.75)	1.00 (0.00-1.00)*
Comparison within the Group - * P = <0.001 in comparison to the D0 values (Friedman test) Comparison between the Group- (Mann Whitney rank sum test)		

Group A showed significant decrease in QOL on D7. p value <0.001. Group B showed significant decrease in QOL was noticed on D7 with p value <0.001. Therapeutic effect improvement of QOL was seen in both groups but statistically not significant with p value > 0.05. In Group A subjects felt better reduction of discomfort in chewing food during the course of treatment.

**Table 8: Size assessment on different points of time**

Group	Size assessment at different points of time (Data: Median, 25 <sup>th</sup> & 75 <sup>th</sup> Percentile)					
	Day 0 (D0)	Day 3 (D3)	Day 7 (D7)	Day 14 (D14)	Day 21 (D21)	Day 28 (D28)
<b>Group A</b>	2.00 (1.00-2.25)	1.00 (0.00-1.00)**	0.00 (0.00-0.00) **Nil	0.00 (0.00-0.00) *Nil	0.00 (0.00-0.00) **Nil	0.00 (0.00-0.00) **Nil
<b>Group B</b>	2.000 (1.00-2.00)	1.00 (1.00-1.25)*@	0.00 (0.00-0.00) **Nil	0.00 (0.00-0.00) **Nil	0.00 (0.00-0.00) **Nil	0.00 (0.00-0.00) *Nil
Comparison within the Group - *P<0.05, **P = <0.001 in comparison to the D0 values, Nil- zero size score (Complete relief) (Friedman test)						
Comparison between the Group- @ P = 0.069 (Mann Whitney rank sum test)						

Group A showed highly significant decrease in Size on D3, D7, D14, D21 and D28. P = <0.001. Group B showed highly significant decrease in Size was noticed on D7, D14, D21, D28 and significant decrease on D3. P = <0.001. Therapeutic effect was seen in both groups but statistically not significant with p value > 0.05.

**Table 9: Colorimetry assessment on different points of time**

GROUP	Colorimetry assessment at different points of time (Data: Median, 25 <sup>th</sup> & 75 <sup>th</sup> Percentile)					
	Day 0 (D0)	Day 3 (D3)	Day 7 (D7)	Day 14 (D14)	Day 21 (D21)	Day 28 (D28)
<b>GROUP A</b>	2.00 (2.00-2.00)	1.00 (0.25-2.00)*	0.00 (0.00-1.00)**	0.00 (0.00-1.00)**	0.00 (0.00-1.00)**	0.00 (0.00-1.00)**
<b>GROUP B</b>	2.00 (2.00-2.00)	2.00 (1.00-2.00)	0.00 (0.00-1.00)*	0.00 (0.00-1.00)*	0.00 (0.0-1.00)**	0.00 (0.00-1.00)**
Comparison within the Group - * P = <0.05, **P = <0.001 in comparison to the D0 values (Friedman test)						
Comparison between the Group (Mann Whitney rank sum test)						

Group A highly significant decrease in Colorimetry was noticed on D7, D14, D21, D28 and significant decrease on D3. P = <0.001. Group A highly significant decrease in Size was noticed on D7, D14, D21, D28 and significant decrease on D3. P = <0.001. Therapeutic effect was seen in both groups but statistically not significant with p value > 0.05.

**Table 10: Showing effect size difference between the groups based on Fisher exact test for repeated measures**

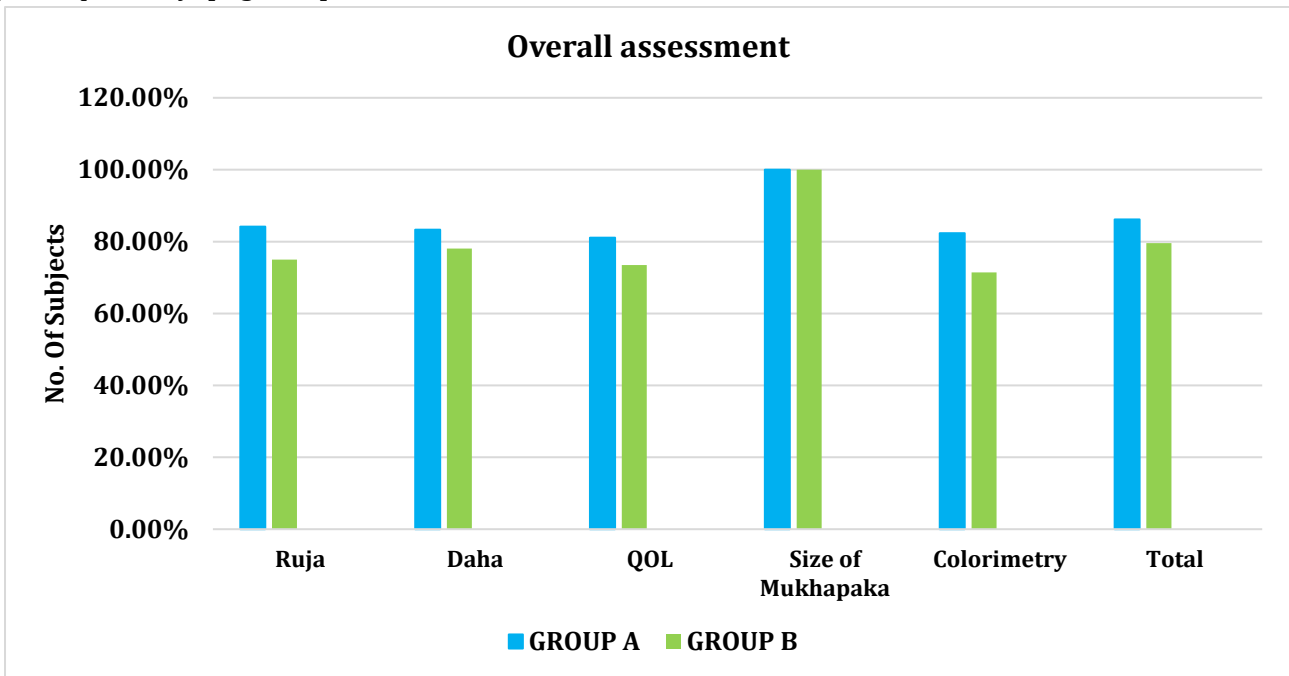
Parameters	Day 3	Day 7	Day 14	Day 21	Day 28
<i>Ruja</i>	0.000	0.126 Small	0.126 Small	0.126 Small	0.126 Small
<i>Daha</i>	0.000	0.000	0.0039 Very small	0.000	0.000
QOL	-	-	-	-	0.134 Small
Size of <i>Mukhapaka</i>	0.535 Medium	0.000	0.000	0.000	0.000
Colorimetry	0.167 Small	0.0692 Small	0.0692 Small	0.0692 Small	0.0692 Small

Effect size difference between the groups showed small difference of 0.126 in *Ruja*, 0.134 in QOL, 0.0692 in colorimetry on D7, very small difference 0.0039 in *Daha* on first follow-up.

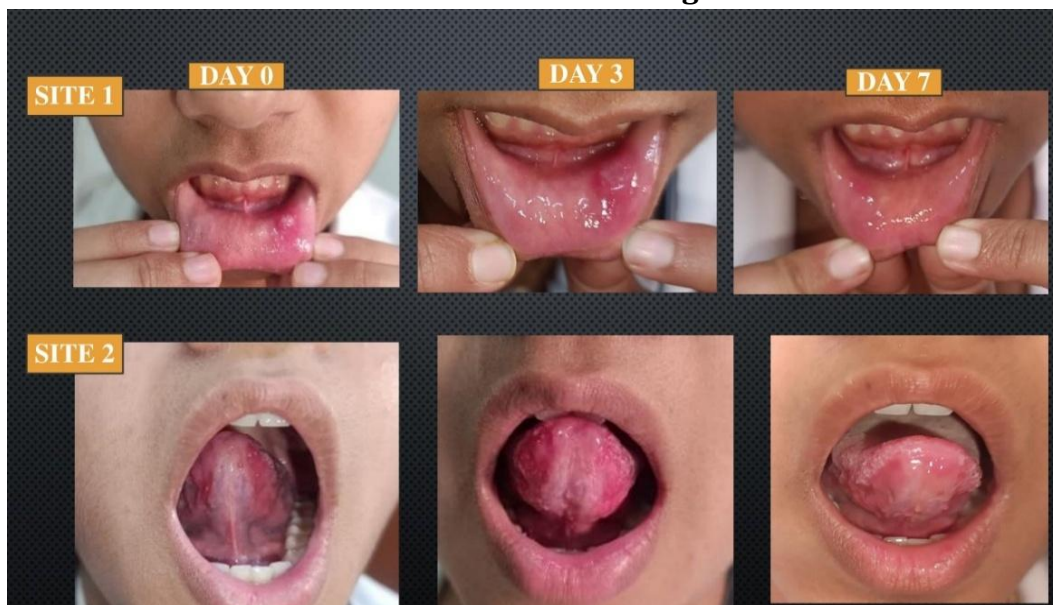
**Table 11: Mean score percentage**

Parameter	Parameter	Parameter
<i>Ruja</i>	84.17%	75%
<i>Daha</i>	83.33%	78.07%
QOL Assessment	81.07%	73.5%
Size of <i>Mukhapaka</i>	100%	100%
Colorimetry	82.32%	71.45%
<b>Total</b>	<b>86.17%</b>	<b>79.60%</b>

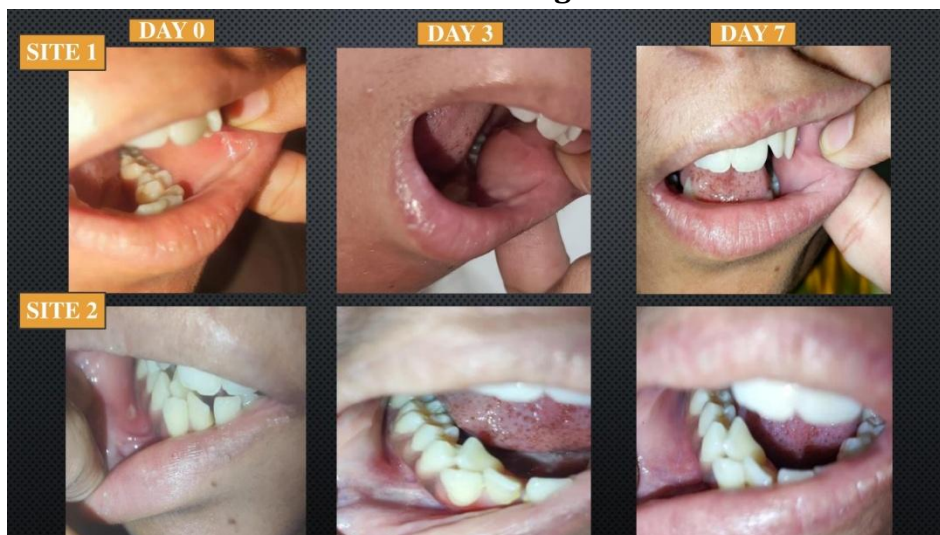
The overall assessment of parameters showed mean score percentage as 86.17% and 79.60% in Group A and Group B respectively. [Figure 7]



**Figure 8: Showing 0<sup>th</sup>, 3<sup>rd</sup>, 7<sup>th</sup> day images of a case on Aphthous Ulcers at 2 sites out of the 3 treated with trial drug**



**Figure 9: Showing 0<sup>th</sup>, 3<sup>rd</sup>, 7<sup>th</sup> day images of a case on Aphthous Ulcers at 2 sites treated with control drug**



**Figure 10: Showing 0<sup>th</sup>, 3<sup>rd</sup>, 7<sup>th</sup> day images of Lichen planus at 2 sites out of the 3 treated with trial drug**



**Figure 11: Showing 0<sup>th</sup>, 3<sup>rd</sup>, 7<sup>th</sup> day images of Lichen planus at 2 sites out of the 3 treated with trial drug**



## DISCUSSION

Ayurveda has emphasised importance of oral health right from its basics where *Dinacharya* (daily regimen) has been explained.<sup>[21]</sup> *Vedana Yukta Shopha* and *Vrana* in the *Mukha Pratyangas* is a characteristic of *Mukhapaka* caused by *Vatadi Doshas*.

After the study was completed, data collected throughout the study period was examined and sorted systematically. Age group 21-30 were majority; this age range is *Pitta Kaala*. The female predominance which could be due to hormonal influence during menstruation and pregnancy.<sup>[22,23]</sup> Majority of subjects ignored the importance of regular physical activity like exercise showing importance of life style change that is required. As exercise enhances metabolic activity. Also, reduces cortisol levels in the body which helps prevent stress induced *Mukhapaka*.

According to *Acharya Charaka Mukhapaka* is *Pittaja Nanatmaja Vyadhi*. Majority of the subjects indulged in *Pittakara Nidana* that shows the cause for *Pittaja Mukhapaka* to be prevalent.

Majority of the subjects had acute conditions like Aphthous ulcer and mucositis which is closely related with symptoms of *Pittaja Mukhapaka* having features like that of *Saraktha* (mucosal erythema), *Tanu* (thin), *Peeta* (Yellowish colour), *Ksharokshita Kshatasama Vrana* (resembling wound caused due to *Kshaara*) resembling floor of the ulcer and other signs and symptoms. This could have been caused due to *Pittakara Nidanas* adopted like those of *Katu Ahara* (spicy food), *Amla Rasa Pradhana Ahara* (sour food) and *Anarogyakara Dhooma Pana* (tobacco smoking).

The subjects who had *Vataja Mukhapaka* had signs like *Toda-* pain, *Shopha-* inflammation, *Kantakachita* resembling lingual papillitis, *Arunata-* redness, *Sputita-* cracks on the tongue and *Sheeta Asaha-* sensitivity to cold articles. This could have caused due to stress and other factors like *Vatakara Ahara Vihara*. Here the subject had a history of long journey which could have led to the *Mukhapaka*. This can be corelated to mucositis.

The other set of subjects encountered in the study had Lichen planus (LP), a chronic condition. This can be closely related with *Sannipataja Mukhapaka* with signs and symptoms such as *Daha* (generalized burning sensation), *Osha* (localized burning sensation), *Tanu* (thin), *Ksharokshita Kshatasama Vrana* (ulcer resembles alkali burn), *Alpa Ruja* (pain), *Antar Vrana* (ulcer) and *Krichrena Vivrunoti* (difficulty opening mouth). LP is an autoimmune disease having a strong association with anxiety and stress.<sup>[24]</sup> Subjects with *Sannipataja Mukhapaka* could have acquired it mainly due to lifestyle changes and stress.<sup>[25]</sup> Wickham's striae was a differentiating feature in most.

Here mainly *Lakshanas* mentioned by *Acharya Vagbhata's* are considered but as other authors also opine similar, their opinions are not omitted.

### Discussion on Probable mode of action of trial drug

The trial drug contains *Haridra* which has been mentioned under *Kushtagna Varga* and *Lekhaniya Varga*. It is *Vrana Ropaka, Shothahara Dravya* that could have reduced *Ruja* and *Daha, Kruchra Mukha Vivrunata*, reducing colorimetry scale, reducing size of *Mukhapaka, Kapha-Pitta Shamana* property might have helped in reducing *Manda Ruja/ Kinchit Doha. Ruksha, Lekhana* property of *Haridra* might have help in reducing *Kapha* and Wickham's striae in *Sannipataja Mukhapaka*.<sup>[26,27,28]</sup>

*Yashtimadhu* is *Vrana Ropana, Shothahara*. The *Madhura Rasa, Sheeta Veerya, Snigdha Guna*, of *Yashtimadhu* reduces *Pitta* and *Vata* which might have helped subside *Daha, Ruja*, reduce size of *Mukhapaka*, bringing about changes in colorimetry.<sup>[29,30,31]</sup>

*Madhura Rasa* of *Kumari* reduces both *Pitta* and *Vata*. *Kumari* has *Snigdha Picchila Guna* which forms a soothing layer over the *Mukhapaka* reducing *Vata* and sensitization to surrounding structures. *Kumari* with *Tiktarasa*, might have helped reduce *Kapha*. It has *Vrana Ropana, Shothahara* properties which might have helped subside *Daha, Ruja*, reduce size of *Mukhapaka*, bringing about changes in colorimetry.<sup>[32,33]</sup>

Chemical constituents present in the *Lepa* like Curcumin, Bisacumol, Glycyrrhizin, Genistein, Glycyrrhetic acid bond with the protein responsible for inflammation by ligand protein bonding thus might have helped reduce inflammation. Similarly, Bisacumol D-Glucuronic acid, Glycoproteins, lupeol C-glucosayl chromone by transmucosal absorption, exhibit ligand protein binding and might reduce pain.

Combined properties of the drugs are anti-inflammatory, anti-oxidant, analgesic, immunomodulatory and anti-ulcer might have acted on cellular and vascular level on vasoactive amines, arachidonic acid metabolites, lysosomal enzymes and others; preventing tissue damage.

Supporting this the molecular docking study showed good protein bonding (related to inflammatory and pain pathway) and probable interaction of the drug to the target. But this is only probable and more research is needed on this with more number of ligands.

*Lepana* is a topical treatment that bypasses gastric metabolism. As the oral mucosal tissues have no or little stratum corneum and high absorbability, there by showing lower impedance which could be a

reason for higher drug permeation through oral mucosa. Water can diffuse across keratinized and nonkeratinized oral tissues.<sup>[37]</sup> Transmucosal absorbability is significantly higher than that in skin.<sup>[38]</sup> As it is prepared fresh each time it is used, synthetic preservatives were not used, thus avoids any probable untoward effect of long-term use of synthetic preservatives like oral cancer. While the *Lepa* formulation can be used in *Mukhapaka* caused due to viral and fungal infections where the Triamcinolone gel is contraindicated.

### Discussion on Probable mode of action of control drug

Within corticosteroid medication class, triamcinolone is a glucocorticoid. It inhibits production of prostaglandins and leukotrienes by lowering expression of the enzymes cyclooxygenase (COX) and lipoxygenase (LOX). By blocking the phospholipase A2 enzyme on phospholipid layer of cell membrane, it has anti-inflammatory and also immunosuppressive properties by preventing the synthesis of arachidonic acid and impeding breakdown of the leukocyte lysosomal membranes. This might have helped in healing the *Mukhapaka*. It is a topical applicant and palatable by nature.

### Discussion on overall outcome

With respect to subjective parameters, within the group analysis, Group A is highly significant in 4/5 assessments and significant in 1/5 assessments. Group B is highly significant in 3/5 assessments, and statistically significant in 2/5 assessments of *Mukhapaka* after treatment.

There were 100% results in acute cases among both the groups and also major improvements were seen by day 3 during the treatment. The overall assessment of parameters as mean score percentage showed 86.17% and 79.60% results in Group A and Group B respectively. Both the groups showed statistically significant improvement in the condition and no statistical difference between groups. There were clinically better results from group A with small effect size difference between the groups.

### CONCLUSION

The classical signs and symptoms of *Mukhapaka* is closely related to inflammatory oral mucosal conditions mainly those of Aphthous stomatitis, mucositis and Lichen planus. The results of this study suggest that the *Sthanika Chikitsa* with *Haridra Yashtimadhu Kumari Lepa* for the treatment of *Mukhapaka* was effective and requires prolonged duration of treatment and follow ups in case of the chronic conditions like Lichen planus.

### Scope of the study

Local therapies proved to be satisfactory, gave complete results in acute conditions but could yield better results in chronic condition if combined with *Shodhana* and *Shamana Chikitsa*.

Histopathological study, microbiological study before and after treatment can be adopted to identify the changes happening in cellular level.

It is recommended to have prolonged duration of treatment and follow ups in case of the chronic conditions like Lichen planus.

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