

CLINICAL STUDY ON EFFICACY OF *MADHUYASHTYADI PRATISARAN* IN THE MANAGEMENT OF ORAL TOBACCO TOXICITY DUE TO TOBACCO ADDICTION

Sanjay B. Nandedkar¹, Nilesh K. Nemade², Mamta Narvekar³

¹Professor and HOD, ³Assistant Professor

Dept. of Agadtantra & Vyavahar Ayurved Vidhi Vaidyaka,

Y.M.T. Ayurvedic Medical College & Hospital, Kharghar, Navi Mumbai, Maharashtra, India

²Associate Professor & HOD, Dept. of Agadtantra & Vyavahar Ayurved Vidhi Vaidyaka,
Smt. K.G. Mittal P Ayurveda College & Hospital, Mumbai, Maharashtra, India – 400002.

Email: sanjaybnandedkar@gmail.com

ABSTRACT

The habit of chewing or smoking of tobacco has become common in India. The 40% of total patients who take tobacco die of tobacco consumption. In *Ashtangrhridayasutrasthana Acharya* has mentioned different *mukhagatavishalakshnas* when poisons administered in mouth. These *lakshanas* (symptoms) can be compared with oral tobacco toxicity. These seven *lakshanas* are taken for the study. Tobacco is *laghu*, *tikshna*, *vyavayi*, *vikasi* and *madakari* in *guna* which are similar to *vishaguna*. When tobacco is chewed habitually parts of mouth like *Oshtha*, *Danta*, *Dantamula*, *Jivha*, *Talu* and *Kantha* repeatedly comes in contact with tobacco which causes *Raktadushti* and *tridoshaprakopa* and produces *mukhagatavishalakshana* in the oral cavity. *Madhuyashtyadi pratisarana* has properties like *kaphanashak*, *vatanashaka* *Tridoshaprashamanam*, *Sthavarvishanashak*, by these properties *pratisarana* of *Madhuyashtyadi* powder reduce signs and symptoms of tobacco toxicity.

Keywords: Oral tobacco toxicity, *Mukhagatavishalakshnas*, *Madhuyashtyadi pratisarana*.

INTRODUCTION

Tobacco is one of the most widely abused substances in the world. It is highly addictive. The Centers for Disease Control and Prevention estimates that tobacco causes 6 million deaths per year. This makes tobacco the leading cause of preventable death.¹

The habit of chewing or smoking of tobacco has become common in India. The

40% of total patients who take tobacco die of tobacco consumption.² Addiction of tobacco is more because of its easy availability in the market. Severe use of tobacco is responsible for different types of malignancies. Most of this type of cancer can be attributed to the use of chewing tobacco considering more Indians chew tobacco than smoke it.³ During chewing

of tobacco tissues of oral cavity get exposed which can cause sub mucous fibrosis, gingivitis, leukoplakia, erythroplakia etc. If these diseases are not treated in their initial stages they can turn in to malignant stages. Ayurveda has described effective treatment like- *Kaval*, *Gandush*, *Pratisaran*, *Pralepa* etc. *inmukha-gatavishachikitsa* (Oral toxicity treatment). Application or gentle massage of drug on the teeth, tongue, and buccal cavity with tip of the finger for the short duration is called *pratisarana Madhuyashtyadi pratisaran* was prepared with *Madhuyashti*, *Pippali*, *Tankan* in *Madhu*(Honey)

Madhuyashti (Liquorice, botanically: *Glycyrrhiza Glabra*, also known as *Mulethi* in Hindi and *Yashtimadhu* in Ayurveda) is an important herb used in *Ayurveda*, Indian medicines, home remedies and folk medicines. The health benefits of Liquorice include its use in hyperacidity, ulcer, general debility, joint pains and some other diseases. It is beneficial in these diseases due to its medicinal properties. It is a good anti-inflammatory and analgesic agent.⁴

Pippali-Long Pepper (Botanical Name- *Piper Longum* Linn.) is a very diverse essential in the world of *Ayurvedic* medicine. The name itself means “to drink and digest” revealing one of its main benefits of increasing the digestion and burning toxins. Long pepper is known to contain the chemical compound piperlongumine.⁵ Piperlongumine may have anti-cancer properties. In *in vitro* experiments, it selectively kills some type of

cancer cells over normal cells.⁶ Some piperlongumine derivatives were potent anti-inflammatory agents.⁷

Tankan or Borax has wide variety of uses. It has wound healing property. It also reduces *dahashothadilakshanas* of *mukhapaka*. It acts as sedative and antiseptic in wound. As *tankan* is mentioned as *sthavar Vishanashaka* which is easily available cost effective and also effective for oral toxicity induced by tobacco chewing.⁸

Hence this intended study has been taken. So here the clinical study has been planned to find out the efficacy *Madhuyashtyadi pratisarana* in the management oral tobacco toxicity due to tobacco chewing and spread awareness of the hazards of tobacco chewing.

AIMS AND OBJECTIVES:

1. To study the efficacy of *Madhuyashtyadi pratisaran* on oral tobacco toxicity due to tobacco addiction.
2. To assess the effect of *Madhuyashtyadi pratisaran* in oral tobacco toxicity due to tobacco addiction.
3. To create awareness on health hazards of tobacco chewing.

MATERIALS AND METHODS:

Materials:

Madhuyashtyadi pratisaran was prepared with *Madhuyashti*, *Pippali*, *Tankan* in *Madhu*(Honey) with following proportion: -

Table 1: Contains of *Madhuyashtyadi pratisaran*

Sr. No.	Sanskrit Name of Drug	Botanical/Latin Name	Quantity
1	<i>Madhuyashti</i>	<i>Glycyrrhiza Glabra</i>	2 part
2	<i>Pippali</i>	<i>Piper Longum</i> Linn.	1 part
3	<i>Tankan</i>	Borax	1 part
4	<i>Madhu</i> (Honey)	Melli	1 part

Collection of Material

- Identification, authentication and standardization had done from approved laboratory.
- Agmark standard Honey and Cow Ghee was purchased from a GMP Approved company.

Standardization:

- The drug sample is studied exomorphically and microscopically standardized from respected pharmacy.
- Analytical study report obtained from laboratory on demand for research work.

Patient Selection Criteria:

- 1) Patient presenting with one or group of symptoms of Oral tobacco toxicity with or without development of lesion.
- 2) **Symptoms of Oral toxicity** (*Mukhagatavishalakshanas*) described in *Ash-tanghridayamsutrasthana*⁹
 - *LalaStrava* (Salivation)
 - *Jivhaoshthajadata* (affected speech due to heaviness on tongue & lips)
 - *Daha* (Burning sensation)
 - *Chimchimayan* (Tingling numbness)
 - *Dantaharsha* (Sensibility of teeth)
 - *Rasa adnyatva* (loss of sensation of taste)
 - *Hanustambha* (Lock jaw)

Inclusive Criteria:

- 1) Individuals between 20-60 years' age group have been included.
- 2) Both male & female patients have been included
- 3) Patients fulfilling above patient's selection criteria.

Exclusive Criteria:

- 1) Patients having sub mucous fibrosis
- 2) Leukoplakia or Erythroplakia showing malignant changes.
- 3) Patients other than tobacco chewers.
- 4) Patients having systemic disease.
- 5) Patients of oral candidiasis, diabetes and HIV positive.

Methods:

Sampling: Random sampling method was adopted for the selection of the patients.

1. Grouping:

A total number of 70 patients were registered for the present clinical study; out of them 60 patients completed the treatment. 4 patients from group A and 6 patients from group B have dropped out during study for some unknown reason. Therefore, the data of remaining 60 patients were divided into 2 groups.

Group A (Trial Group):

30 patients of this group were treated by *Madhuyashtyadi mukhagat pratisaran* with *madhu* (honey) for 30 days.

Group B (Control Group):

30 patients of this group were treated by Cow-Ghee (*Goghrita*) for *mukhagatpratisaran* for 30 days.

Method of Administration of Drug:

Madhuyashti powder is mixed with *Pippali* powder and *tankan lahi* in honey. It is taken on tip of index finger of the patients and advised to apply on the teeth, gums, tongue and buccal cavity for 15 min. and told to gargle with lukewarm water. The same procedure has been applied for the control group with *ghrita* (cow-ghee) cessations of tobacco chewing have been advised. All subjective and objective parameters have been recorded systematically on each follow up. In the time span of study other medications have been stopped.

Dose:

Group A (Trial Group): 4gms of *Madhuyashtyadi* powder with 1gms of honey for *pratisaran* twice a day.

Group B (Control Group): 4 gms of *Goghrita* (cow-ghee) for *pratisaran* twice a day.

Follow up:

Patients were observed before, during and after treatment.

1st follow up 10th day.

2nd follow up 20th day.

3rd follow up 30th day.

Subjective parameters: -

Patients presenting with *mukhagatavishalaksanas* and addiction of tobacco chewing Gradation from 0 to 3 will be done on the basis of severity of complaints.

1) *LalaStrava* (Salivation):

0= No complaints

1= Patient is complaining of salivation while chewing tobacco.

2= patient has to be spit saliva.

3= dribbling of saliva at sleep.

2) *Jivhaoshthajadata* (affected speech due to heaviness on tongue & lips):

0= Clear speech

1= slightly affected speech only *Talavya* alphabets.

2= Affected speech only *Dantya* and *Talavya* alphabets.

3= Slurred speech of alphabets.

3) *Daha* (Burning sensation):

0= No complaints of burning sensation.

1= No complaints of burning sensation felt on touch with hot beverage.

2= Burning sensation felt on taking spicy and salty food.

3= Burning sensation felt throughout day without any aggravating factor.

4) *Chimchimaya* (Tingling numbness):

0= Not seen

1= On any one lip.

2= Any one lip with anyone *mukhaparshva*.

3= Both lips with one or both *mukhaparshva*.

5) *Dantaharsha*:

0= No pain with minimal discomfort on eating /drinking *amlapadarhta*.

1= Mild pain with minimal discomfort on eating /drinking *amlapadarhta*.

2= Moderate pain with difficulty to eat / drink *sheetapadartha*.

3= Sever pain in teeth with unable to chew/ even touch.

6) *Rasa adnyatva*(loss of sensation of taste):

0= Good sensation of all six *rasas*.

1= No sensation of one of the six *rasas*. (Most probably *lavanrasa*)

2= No sensation of two of the six *rasas*.

3= No sensation of more than three of six *rasas*.

7) *Hanustambha* (Lock jaw):

0= No *Hanustambha*

1= Mild *Hanustambha*

2= Moderate *Hanustambha*

3= Sever *Hanustambha*

Assessment of Clinical Result:

The total effect of therapy will be assessed as below:

A] Excellent- relief from sign and symptoms above 75%.

B] Good- relief from sign and symptoms between 51% to 75%.

C] Moderate- relief from sign and symptoms between 26 % to 50%

D] Poor / Mild- relief from sign and symptoms below 25%.

RESULTS:

Table 2: Incidence Rate of *Lakshanas*:

<i>Lakshanas</i>	Group- A	Group-B	Total	Percentage
<i>LalaStrava</i>	26	24	50	83.33%
<i>Jivhaoshthajadata</i>	10	13	23	38.30%
<i>Daha</i>	29	29	58	96.70%
<i>Chimchimayan</i>	19	22	41	68.34%
<i>Dantaharsha</i>	19	16	35	58.30%
<i>Rasa adnyatva</i>	16	14	30	50.00%
<i>Hanustambha</i>	05	05	10	16.70%

Graph 1: Incidence Rate of Lakshanas in both groups.

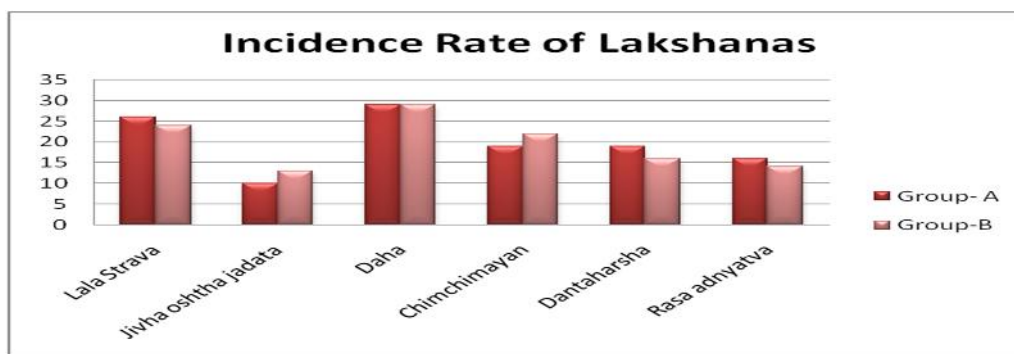


Table 3: Comparative analysis for Group A and B

Lakshanas	Group-A				Group-B			
	Mean Score		SE	Calculated 't'	Mean Score		SE	Calculated 't'
	BT	AT			BT	AT		
<i>LalaStrava</i>	1.567	0.100	0.164	8.930	1.333	0.83	0.093	5.385
<i>Jivhaoshthajadata</i>	0.433	0.133	0.085	3.525	0.533	0.40	0.085	2.112
<i>Daha</i>	1.367	0.000	0.112	12.173	1.667	0.80	0.093	9.355
<i>Chimchimayan</i>	1.100	0.133	0.162	5.950	1.267	0.87	0.091	4.397
<i>Dantaharsha</i>	1.067	0.333	0.126	5.809	0.900	0.57	0.088	3.808
<i>Rasa adnyatva</i>	0.767	0.333	0.092	4.709	0.633	0.40	0.079	2.971
<i>Hanustambha</i>	0.167	0.033	0.063	2.112	0.172	0.10	0.046	1.439

Table 4: Overall improvement in Subjective Criteria:

Grade	No. of Patients in Grp. -A	%	No. of Patients in Grp. -B	%
Excellent (>75%)	23	76.67	00	00
Good (51% to 75%)	07	23.33	07	23.33%
Moderate (26 % to 50%)	00	00	15	50%
Poor / Mild (<25%)	00	00	08	26.67%

A-Group shows excellent relief in subjective criteria in 23 patients (76.67%) and good relief in 7 patients (23.33%).

No excellent relief is found in B-Group which is treated with *Ghrta* (Cow-ghee), good relief is found in 07 patients (23.33%), moderate relief in 15 patients (50%) and poor relief in 8 patients (26.67%)

DISCUSSION

The comparative statistical analysis of groups for *LalaStrava* where t-score shows the difference is significant at 30thday(p<0.041) i.e. at the end of study. It means that the said therapy used for *LalaStrava* is effective as compare to control group.

Jivhaoshthajadata is seen due to vitiated *vatadosha* which is reduced by the property of *ushnavirya* of *tankana*. The comparative statistical analysis of groups for *Jivha-*

oshthajadata shows that the difference is not significant at $t=1.573(p>0.05)$.

The comparative statistical analysis of groups for *Daha* where t-score shows the difference is significant after treatment ($p=0.0005$ or $p=0.055\%$) It means that *Madhuyashtyadi* powder used for *Daha* is effective as compared to control group.

Incidence rate of *Chimchimayan* 68.34%. It occurs due to *Vatakaphaprakopa*. The comparative statistical analysis of groups for *Chimchimayan* shows that the difference is significant at $t=3.043(p<0.01)$. It means that the *Madhuyashtyadi* powder is used for *Chimchimayan* is effective as compare to control group.

The comparative statistical analysis of group A & B for *Dantaharsha* where t-score shows the difference is significant after treatment ($p=0.005842$ or $p=0.5842\%$) at the end of the study group-A shows better result.

The comparative statistical analysis of groups for *Rasa adnyatva* shows that the difference is not significant at $t=1.653(p>0.05)$ so Group -A did not show better result as compare to Group-B

Incidence rate of *Hanustambha* is only 16.70% which is very less. This *lakshana* is seen due to *Vatadosha*. *Vatadosha* is responsible for *chalaguna*. We can correlate *Hanustambha* with difficulty in opening of mouth which is mostly seen in oral *submucous* fibrosis that we have not taken in study.

CONCLUSION

Tobacco has toxic effect on oral cavity. *Mukhagatavishalakshanas* can be correlated with toxicity developed due to tobacco chewing. *Daha* and *LalaStrava* have high incidence rate whereas *Chimchimayan*, *Dantaharsha*

and *Rasa Adnyatva* has moderate incidence rate and *Hanustambha* has low incidence rate.

If we compare the therapy of Group-A & Group-B, *Madhuyashtyadi*pratisaran (Group-A) shows significant reduction in *Daha*, *Chimchimayan*, *Dantaharsha*, *LalaStrava* and no significant reduction in *Rasa adnyatva*, *Jivhaoshthajadata* and *Hanustambha*as compare to *Ghrita* (Cow-ghee) *Pratisarana*. *Madhuyashtyadi*pratisaran shows significant reduction in some symptoms.

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