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Research Article

ROLE OF GANDUSHA IN *PITTAJA MUKHAPAKA* (APHTHOUS ULCER) –A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: *Pittaja Mukhapaka* or the Aphthous ulcer is a painful and often recurrent inflammatory process of the oral mucosa that can appear secondary to various well-defined disease processes. Idiopathic recurrent aphthous stomatitis is referred to as recurrent aphthous stomatitis.

Objectives: To evaluate the effect of *Patoladi kashaya gandusha* in *Toda*, *Daha, Asyavairasyata* and the pH of *Pittaja mukhapaka* (Aphthous ulcer) and to standardize the frequency of *Gandusha* (An Ayurvedic intervention).

Design: This was a randomized controlled study with thirty patients divided into two groups, 15 in each. In Group A, *Patoladi kashaya gandusha* (gargling) was given once a day for 7 days and in Group B, *Patoladi kashaya gandusha* (gargling) was carried out twice a day for 7 days. After the completion of treatment, follow up was done once in fifteen days for a period of 2 months.

Results: Statistically significant results were seen in reduction of *Toda* with $p<0.001$, Group A (61.53%) compared to Group B (81.81%), *Daha* with $p<0.001$ Group A (73.07%) compared to Group B (81.81%), *Asyavairasyata* with $p<0.001$ Group A (73.91%) compared to Group B (100%) and also in relieving the pH of saliva with $p<0.001$ and Group A (100%) compared to Group B (100%).

Conclusions: Group B (*Patoladi kashaya gandusha* given twice a day) showed statistically significant results compared to Group A (*Patoladi kashaya gandusha* given once a day) in reduction of *Toda, Daha, Asya vairasyata* and the pH of *Pittaja Mukhapaka* (Aphthous ulcer).

KEYWORDS: *Pittaja Mukhapaka, Gandusha, Patoladi kashaya*, Aphthous ulcer.

INTRODUCTION

Poor oral health may have a profound effect on general health and several oral diseases are related to chronic diseases (e.g. diabetes). WHO recently published a global review of oral health which emphasized that despite great improvements in the oral health of populations in several countries, global problems still persist. This is particularly so among underprivileged groups in both developing and developed countries. Oral diseases such as dental caries, periodontal disease, tooth loss, oral mucosal lesions and oropharyngeal cancers, human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) -related oral disease and orodental trauma are major public health problems worldwide. [1]

Recurrent Aphthous Stomatitis (RAS) is a condition in which ulcers repeatedly occur in the oral cavity.[2] Aphthous ulcers arise in the oral cavity at least four times a year.[3] It is prevalent in developed countries, occurring in all ages, geographic regions and races. [2,4] About 80% of people have one episode of oral aphthous ulcers before the age of 30 years.[2] Predisposing factors like trauma, deficiency of B-complex vitamins and folate, microbial factors, stress, hormonal changes and immunologic factors may contribute to the formation of ulcers. [5, 6]

Ulcers shows painful, shallow, round ulcers which have a pseudomembranous centre surrounded by an erythematous margin. Burning sensation is present for about 2 to 48 hours before the appearance of the ulcer.[5] Intense pain is present at the ulcer site and as healing occurs, the pain gradually recedes.[2] Most ulcers occur on the non-keratinizing epithelial surface of the mouth like the buccal and labial mucosa and the tongue in three

forms such as are minor, major and herpetiform recurrent aphthous stomatitis. [2,5]

Sixty five kinds of diseases affecting seven different sites of the oral cavity i.e. lips, the gums of the teeth, the teeth proper, the tongue, the palate, the throat and entire cavity has been described by Sushrutha, an Ayurvedic Surgeon. The one that occurs in the mucus membrane of the mouth is called as *Mukhapaka* or the *Sarvasara mukharoga* which can be compared to ulcerative stomatitis or Aphthous ulcers as per the modern medicine among which *Pittaja mukhapaka* is the most common.

The fundamental goals of treatment are to shorten the duration of ulcer, provide relief from pain, and increase disease-free periods while the secondary goals would be to lessen the frequency and severity of recurrences. [7,8] Additionally, since recurrent aphthous stomatitis can significantly affect a person's quality of life, efforts need to be made to bring forth a drug that can prevent recurrences as well. The same treatment regimen cannot be used in all patients as certain drugs appear to be effective in some, while others might have limited responses. [2] Topical therapy may be sufficient for occasional episodes of minor ulcers while systemic interventions are used in patients who are unresponsive to topical agents or have severe disease. [2,5,7]

Corticosteroids are widely used to control aphthous lesions; however, even their topical application may be associated with some side effects.[9] 1% to 4% alum solution is used as mouthwash or gargle in the treatment of stomatitis and pharyngitis.[10] It has astringent and hemostatic properties when applied topically.[11,12] This causes contraction of tissues and enhances wound healing by decreasing the inflammation in the mucosal membrane.[13] Although numerous treatment modalities have been recommended, very few studies have aimed to find an effective treatment for RAS as a distinct clinical entity. Recently, herbal medications have been suggested for treatment of these lesions due to having minimal or no side effects. [14]

Ayurveda, considered as one of the complementary and alternative medicine describes *Kavala, Gandusha* and *Pratisarana* etc local therapies for *Pittaja mukhapaka* or the Aphthous ulcer, among which *Gandusha* (gargling) is the most effective mode of local treatment for *Mukhapaka*. Though various works have been carried concerning the *Pittaja mukapaka, Patoladi kashaya* that is being described in Yogarathnakara samhitha[15] of Ayurveda was not studied. Considering the effectiveness, cost, easy and routine applicability, the present study was conducted to assess the efficacy of *Patoladi kashaya* in Aphthous ulcer or the *Pittaja mukhapaka*.

MATERIALS AND METHODS

The data were collected from the OPD and IPD of Shalakya Tantra, S.D.M college of Ayurveda and hospital Hassan. Patients with the features of *Pittaja mukha paka* (recurrent oral ulcers) with chronicity of less than 1 year and both males and females aged between 15 to 60yrs were included for the study. Patients with the features of other *Doshaja* and *Agantuja mukha paka* and also suffering from Grave's diseases, AIDS, Oral cancer and diabetes mellitus were excluded from the study.

Ethical clearance and consent

The study was approved by the institutional ethical committee and signed informed consent was obtained from all patients.

Design: In this randomized control study, 30 subjects who satisfied the study criteria were divided into two groups, Group A and Group B using a computer generated randomizer table (www.randomizer.org) with 15 patients in each group. Group A received *Patoladi Kashaya Gandusha* once a day for 7 days continuously and Group B received *Patoladi Kashaya Gandusha* twice a day for the same duration i.e., for 7 days. Both the groups were followed once in fifteen days for a period of 2 months. Outcome variables were recorded before the treatment on 1st day and on 15th day, 30th day 45th and 60th day after the treatment.

Outcome measures

Subjective parameters: *Toda, Daha* and *Asya vairasyata* were assessed before and after the treatment.

Objective parameter: pH value of saliva was assessed by litmus paper before and after treatment.

Table 1: Gradation Index

Subjective Symptoms	
Toda	
No *Toda*	0
Mild-*Toda* during churning of food	1
Moderate-*Toda* during talking and gets relief by topical anaesthetics	2
Severe- *Toda* even during rest, No relief by topical anaesthetics	3

Daha	
No *Daha*	0
Mild-tolerable, no need of cooling agents Like glycerine or cold juice	1
Moderate-intolerable, Gets relief by cooling agents	2
Severe-intolerable, no relief by cooling agents	3
Aasya Vairasyata	
Proper taste perception, enjoys taste of the food	0
Often complains regarding the taste of food	1
Shows disinterest towards food	2
Often skips meal	3
Objective Symptoms	
pH of Saliva	
7.0-7.5 Normal	0
>7.5 Slightly Alkali	1
<6.9-6.5 Slightly acidic	1
>6.5 Strongly acidic	2

INTERVENTION

Group A

The whole procedure was explained to the patient and was advised to complete his *Pratah karmas* (early morning chores) like *Malavisarjana, Dantadhavana* (brushing teeth) and *Jihva Nirlekhana* (tongue scraping) and to consume light food. Patient was made to sit in the most comfortable position and with calm mind. The freshly prepared warm *Patoladi kvatha* was given and asked to hold it in the mouth or the oral cavity (*Mukha kuhara*) to its full capacity with head slightly tilted upwards till the secretions were observed in *Nasa* (nose) and *Netra* (eyes) and the patient was asked to spit out the liquid and again fresh *Kvatha* was given for the second time to retain in the mouth. The same procedure was followed for 7 days in this group. After the completion of procedure, the patient was asked to wash his mouth with *Sukoshna jala* (warm water) and observations were made for *Samyaka, Hina* and *Atiyoga lakshanas*. Patient was also advised to avoid excessive exposure to wind and sun.

Group B

In this group, the same procedure of the intervention was followed but twice a day for 7 days.

Follow up

After the completion of treatment, all patients were advised to attend once in 15 days up to 2 months.

RESULTS

Thirty patients with features of *Pittaja mukhapaka* were registered for the study. In the present study, the incidence of *Pittaja mukhapaka* was more in 15-30 years (40%) age group, (57%) males, (80%) in Hindus, 57% in rural habitat, 43% in manual workers, 64% in *Pittavataja prakruti*, 73% with mixed dietary habits, 40% in people having the habit of consuming tea. *Pittaja mukhapaka* showed maximum of 44% incidence in anemic patients, 90% had no family history, 56% were having the duration of *Mukhapaka* between 6-12 months, 64% had taken medical treatment, 34 % of them had *Vrana* in *Jihwa*, *Gala* and *Ostha*.

Table 2: Demographic data

S.No	Demographic parameters	Group A	Group B	Total
1.	**Age**			
	15-30 yrs	6	6	12
	31-45 yrs	4	6	10
	46-60 yrs	5	3	08
2.	**Sex**			
	Males	10	07	17
	Females	05	08	13
3.	**Religion**			

	Hindu	12	12	24
	Muslim	02	02	04
	Christian	01	01	02
4.	**Occupation**			
	Sedentary	2	2	4
	Manual	8	5	13
	Labour	4	5	9
	Student	1	3	4
8.	***Prakruthi***			
	Pittavataja	10	9	19
	Pittakaphaja	2	4	6
	Kaphavataja	3	2	5
10.	**Habits**			
	Smoking	4	2	6
	Alcohol	0	1	1
	Tobacco chewing	5	3	8
	Tea/coffee	4	8	12
	No habits	2	1	3
11.	**Chronicity**			
	1 month-6 month	9	4	13
	6 months-12 months	6	11	17
12.	**Family history**			
	Present	2	1	3
	Absent	13	14	27
13.	**Hygienic status**			
	Poor	3	1	4
	Moderate	2	1	3
	Good	10	13	23
14.	***Manasika bhavas*** **(Psychological factors)**			
	Chinta	4	1	5
	Kroda	1	1	2
	Chinta Krodha	7	5	12
	Chinta Krodha Shoka	3	8	11
15.	**Capacity of *Kvatha***			
	80-40 ml	8	8	16
	41-50 ml	3	2	5
	51-60 ml	2	3	5
	61-70 ml	2	2	4
16.	**Time duration**			
	3-4 min	3	6	9
	4-5 min	7	5	12
	5-6 min	3	1	4
	6-7 min	2	3	5

Table 3: Incidence of Symptoms

		Group A	Group B	Total
1.	**Associated Symptoms**			
	Jwara	3	2	5
	Shirashoola	2	1	3
	Amlapitta	2	3	5
	Malabadhata	3	1	4
	Anaemia	5	8	13
2.	**Site of *Vrana***			
	Ostha Jihva	6	3	9
	Dantamoola	2	1	3
	Jihva Gala	4	1	5
	Jihva Ostha Gala	1	9	10
	Taalu	2	1	3
3.	**pH of Saliva**			
	Normal 7.0-7.5	4	1	5
	Slightly Alkali>7.5	7	5	12
	Slightly Acidic 6.5-6.9	4	9	13
	Strongly Acidic<6.5	0	0	0

Table 4: Severity of the Symptoms

1.	**Severity of *Toda***	Group A	Group B	Total
	Mild	2	1	3
	Moderate	8	6	14
	Severe	5	8	13
2.	**Severity of *Daha***			
	Mild	3	2	5
	Moderate	7	6	13
	Severe	5	7	12
3.	**Severity of *Asyavairasyata***			
	Mild	4	2	6
	Moderate	2	5	7
	Severe	9	8	17

Within Group Results (GROUP A)

Toda

In Group A, before the treatment, the initial mean score of *Toda* was 2.2 and reduced to 0.4 after 7 days of the treatment with 81.81% of relief and statistical significance ($p<0.001$).

Daha

In Group A, before the treatment, the initial mean score of *Daha* was 2.2 and reduced to 0.4 after 7 days of the treatment with 81.81% of relief and statistical significance ($p<0.001$).

Asyavairasyata

In Group A, before the treatment, the initial mean score of *Asyavairasya* was 1.4 and reduced to 0.0 after 7 days of the treatment with 100% of relief and statistical significance ($p<0.001$).

pH

In Group A, before the treatment, the initial mean score of *Asyavairasya* was 0.7 and reduced to 0.0 after 7 days of the treatment with 100% of relief and statistical significance ($p<0.001$).

Within Group Results (GROUP B)

Toda

In Group B, before the treatment, the initial mean score of *Toda* was 2.6 and reduced to 1.0 after 7 days of the treatment with 61.53% of relief and statistical significance (p<0.001).

Daha

In Group B, before the treatment, the initial mean score of *Daha* was 2.6 and reduced to 0.7 after 7 days of the treatment with 73.07% of relief and statistical significance (p<0.001).

Asyavairasyata

In Group B, before the treatment, the initial mean score of *Asyavairasya* was 2.3 and reduced to 0.6 after 7 days of the treatment with 73.91% of relief and statistical significance (p<0.001).

pH

In Group B, before the treatment, the initial mean score of *Asyavairasya* was 0.9 and reduced to 0.0 after 7 days of the treatment with 100% of relief and statistical significance (p<0.001).

Table 5: Within Group Results (Group B)

		Mean Score		Reduction in mean score	% of reduction in mean score	S.D of mean	S.E of mean	Df	't' Value	'p' Value
		BT	AT							
Toda										
P K A	AT	2.2	0.4	1.8	81.81	0.77	0.18	14	10.00	<0.001
	FU 1	2.2	1.6	0.6	27.27	0.50	0.12	14	5.00	<0.001
	FU 2	2.2	1.2	0.9	40.90	0.59	0.15	14	6.00	<0.001
	FU 3	2.2	1.6	0.6	22.72	0.63	0.16	14	3.12	<0.001
	FU 4	2.2	1.6	0.6	22.72	0.63	0.16	14	3.12	<0.001
Daha										
P K A	AT	2.2	0.4	1.8	81.81	0.67	0.17	14	10.58	<0.001
	FU 1	2.2	1.6	0.6	27.27	0.50	0.12	14	5.00	<0.001
	FU 2	2.2	1.2	0.9	40.91	0.59	0.15	14	6.00	<0.001
	FU 3	2.2	1.4	0.8	31.81	0.45	0.11	14	6.36	<0.001
	FU 4	2.2	1.4	0.8	36.30	0.45	0.11	14	6.36	<0.001
Asyavairasya										
	AT	1.4	0.0	1.4	100	0.50	0.12	14	11.6	<0.001
	FU 1	1.4	0.7	0.7	50.00	2.59	0.66	14	0.90	<0.10
	FU 2	1.4	0.2	1.1	7.85	0.83	0.21	14	5.23	<0.001
	FU 3	1.4	0.1	1.2	85.71	0.70	0.18	14	6.66	<0.001
	FU 4	1.4	0.4	1.0	71.40	0.37	0.09	14	11.1	<0.001
pH of Saliva										
P K A	AT	0.7	0.0	0.7	100	0.45	0.11	14	6.36	<0.001
	FU 1	0.7	0.0	0.7	100	0.45	0.11	14	6.36	<0.001
	FU 2	0.7	0.0	0.7	100	0.45	0.11	14	6.36	<0.001
	FU 3	0.7	0.0	0.7	100	0.45	0.11	14	6.36	<0.001
	FU 4	0.7	0.0	0.7	100	0.45	0.11	14	6.36	<0.001

Table 6: Within Group Results (Group A)

		Mean Score		Reduction in mean score	% of reduction in mean score	S.D of mean	S.E of mean	Df	't' Value	'p' Value
		BT	AT							
Toda										
P K	AT	2.6	1.0	1.6	61.53	0.48	0.12	14	13.3	<0.001
	FU 1	2.6	1.9	0.7	26.92	0.45	0.11	14	6.36	<0.001

B	FU 2	2.6	2.5	0.2	7.69	0.56	0.14	14	1.42	<0.10
	FU 3	2.6	1.8	0.8	30.76	0.56	0.14	14	5.71	<0.001
	FU 4	2.6	1.6	1.0	6.66	0.53	0.13	14	7.69	<0.001
Daha										
P K B	AT	2.6	0.7	1.9	73.07	0.25	0.06	14	31.6	<0.001
	FU 1	2.6	1.4	1.2	46.25	0.88	0.22	14	5.45	<0.001
	FU 2	2.6	2.5	0.2	7.69	0.56	0.14	14	1.42	<0.10
	FU 3	2.6	1.8	0.8	30.76	0.56	0.14	14	5.71	<0.001
	FU 4	2.6	1.6	1.0	38.46	0.53	0.13	14	7.69	<0.001
Asyavairasya										
P K B	AT	2.3	0.6	1.7	73.91	0.59	0.15	14	11.3	<0.001
	FU 1	2.3	0.4	1.9	82.60	1.22	0.31	14	6.12	<0.001
	FU 2	2.3	0.9	1.4	60.86	0.82	0.21	14	6.66	<0.001
	FU 3	2.3	0.7	1.5	65.21	0.74	0.19	14	7.89	<0.001
	FU 4	2.3	1.7	0.6	26.08	0.50	0.12	14	5.00	<0.001
pH of Saliva										
P K B	AT	0.9	0.0	0.9	100	0.25	0.06	14	15.0	<0.001
	FU 1	0.9	0.0	0.9	100	0.25	0.06	14	15.0	<0.001
	FU 2	0.9	0.0	0.9	100	0.25	0.06	14	15.0	<0.001
	FU 3	0.9	0.0	0.9	100	0.25	0.06	14	15.0	<0.001
	FU 4	0.9	0.0	0.9	100	0.25	0.06	14	15.0	<0.001

Table 7: Results between groups

Overall Improvement / Relief (in %)	**Group A**		**Group B**	
	Pts	**%**	**Pts**	**%**
Complete Remission	01	07	05	33
Marked Relief	00	00	00	00
Moderate Relief	09	60	02	13
Mild Relief	03	20	08	54
No Relief	02	13	00	00

Follow Up

Toda

In Group A, follow up was done on 15th day, 30th day, 45th day and 60th day at an interval of 15 days and showed the changes with mild variation (27.27%, 40.90%, 22.72%, and 22.72%). Whereas in Group B, follow up that was done on 15th day, 30th day, 45th day and 60th day at an interval of 15 days showed the changes with mild variation (26.92%, 07.69%, 30.76%, and 06.66%).

Daha

In Group A, follow up that was done on 15th day, 30th day, 45th day and 60th day at an interval of 15 days showed the changes with mild variation (27.27%, 40.91%, 31.81%, and 36.30%). Whereas in Group B, Follow up that was done on 15th day, 30th day, 45th day and 60th day at an interval of 15 days showed the changes with mild variation (46.25%, 7.69%, 30.76%, and 38.46%).

Asyavairasyata

In Group A, follow up that was done on 15th day, 30th day, 45th day and 60th day at an interval of 15 days showed the changes with mild variation (50%, 7.85%, 85.71%, and 71.40%). Whereas in Group B, Follow up that was done on 15th day, 30th day, 45th day and 60th day at an interval of 15 days showed the changes with mild variation (82.60%, 60.86%, 65.21%, and 26.08%).

pH

In Group A, follow up that was done on 15th day, 30th day, 45th day and 60th day at an interval of 15 days showed the changes with mild variation (100%, 100%, 100%, and 100%).

In Group B, follow up that was done on 15th day, 30th day, 45th day and 60th day at an interval of 15 days showed the changes with mild variation (100%, 100%, 100%, and 100%).

Overall

In Group A, follow up that was done on 15th day, 30th day, 45th day and 60th day at an interval of 15 days showed the changes with mild variation (71.42%, 28.57%, 42.85%, and 57.14%).

In Group B, follow up that was done on 15th day, 30th day, 45th day and 60th day at an interval of 15 days showed the changes with mild variation (100%, 100%, 100%, and 100%).

Table 8: Results after the treatment and Follow up (Group A & Group B)

Percentage Improvement/ Relief (in %)	Group A		Group B	
	AT	FU	AT	FU
Toda	81.81	22.72	61.53	6.66
Daha	81.81	36.30	73.07	38.40
Asyavairasyata	100	71.40	73.91	26.08
pH of saliva	100	100	100	100

Group A showed statistically significant results (81.81%) compared to Group B (61.53) in relieving the severity of *Toda* with p<0.001, Group A (81.81%) compared to Group B (73.07%) in *Daha* with p<0.001, Group A (100%) compared to Group B (73.91%) in *Asyavairasyata* with p<0.001 and Group A (100.00%) compared to Group B (100.00%) in relieving the severity of pH of saliva with p<0.001.

DISCUSSION

Mukhapaka is a condition characterized by *Vedana Yukta Vrana* (*Shopha*) in the *Mukha Kuhara Pratyangas* like *Kapola, Oshta, Jiwha, Danta, Mamsa* and *Talu*. The *Lakshanas* of *Mukhapaka* can be correlated to a clinical entity "Aphthous Ulcer" (recurrent ulcerative stomatitis) explained in the contemporary medical science, which is also characterized by painful superficial ulcers in the movable mucosa of the mouth with recurrent episodes. *Mukhapaka* is neither a serious disorder nor one that can be dismissed as cursory. It is not life threatening, but at the same time it can be crippling by grossly disturbing the individual's life style. It is a disorder of such kind, which gravely upset s the work output of the country's labor force, and has a disabling effect on the national economy. [16]

In this study 30 patients of *Pittaja mukhapaka* were treated in two groups each comprising of 15 patients. *Gandusha* was done with *Patoladi kashaya* once in a day in PKA group while twice in day in PKB group to ascertain whether the increase in the frequency of *Gandusha* provides better relief. 40% patients were in the age group of 15-30 years, followed by 34% in the group of 31-45 years. In Ayurveda, 15-40 years age is considered as *Yauvana kala* (youth) where Pitta is at its peak level. In *Pittaja mukhapaka* the same *Pitta* acts as *Rogarambhaka dosha* (causative factor). Male patients were 57% compared to females 43% showing that the females have inherent resistance due to the periodical menstrual bleeding that prevents the *Rakta dushti*, the major cause of *Pittaja mukhapaka. Pitta* disorders are found more in *Pitta prakruti* persons and in the present study, 64% patients were of *Vata pitta prakruti* with 20% *Pitta kaphaja* and 16% of *Kapha vataja*.

Regarding the diet pattern in the present study, maximum numbers of patients were having the habit of mixed diet with addictions of consuming excess tea/coffee-40%, tobacco chewing-26%, smoking-20% and alcohol-04% and 44% patients were having anemic. Maximum of 40% patients were afflicted with *Chinta* (stress) and *Kroda* (anger) which are said to be the strong influencing factors for the causation of *Pittaja mukhapaka*. As per the Ayurvedic science, *Tikta* (bitter) and *Madhura* (sweet) *Rasa* (tastes) influences *Kapha dosha* and *Amla* (sour) and *Katu* (pungent) *Rasa* vitiates *Pitta dosha* and therefore *Kapha* and *Pitta dosha* becomes the causative factor of the disease. In the present study, *Ahara rasa* preferred by the patients were *Tikta*-36%, *Madhura*-23%, *Amla*-17%, *Katu*-10% and *Lavana*-04%.

In the present study, 43% of patients had their saliva slightly acidic, 40% of patients had slightly alkaline saliva and remaining 17% patients had normal pH of their saliva. 56% of patients were suffering for 6 months to 1 year and 44% of patients were suffering for 1 month to 6 month, which forms the most important factor as usually this is neglected up to 6 months to 1 year. In 34% of patients, *Vrana* was seen in *Jihva, Ostha* and *Gala* 30% in *Ostha* and *Jihva*, 16% in *Jihva* and Gala and equal in *Taalu* and *Dantamoola* (10%).

This study also aimed to ascertain the maximum quantity of the liquid a person can hold in the mouth and for which, the quantity held by each patient was measured. It was found that 53% patients had the capacity of holding the liquid in their

mouth upto 30 to 40 ml, 17% patients with 41-60ml, 16% patients with 51-60ml and 16% patients with 61-70ml. Thus the average quantity of liquid filled in mouth (in 70% of patients) was ranging from 80-120 ml depending upon the size of mouth. 40% patients had the commencement of *Srava* in *Mukha* within 4-5 min, 30% patients showed secretion within 3-4 min, and 17% patients in 6-7 min and 13% patients in 5-6 min. Based on this observation it was inferred from the present study that the average time (in 70% of patients of initiation of *Srava* ranges from 4 minute to 5 minutes. With respect to the appearance of *Srava* in *Mukha, Nasa* and *Netra***,** 40% of the patients showed secretion only in *Mukha*, 26% patients in *Mukha* and *Nasa*, 20% patients in *Mukha* and *Netra*, 14% patients showed secretion in all the three i.e., *Mukha*, *Nasa* and *Netra* which is also found in the *Shastra* as the liquid should be retained in the mouth till the secretions are observed in *Mukha, Nasa*, and *Netra*.

RAS is classified into 3 types according to the diameter of the lesion, namely, the minor, major, and herpetiform aphthous ulcerations. The most common form of RAS is minor aphthous ulcerations, and the minor form is, respectively, followed by major and herpetiform ulcerations.[17] The etiology of RAS still remains unknown. These ulcerations may be indicative of underlying systemic diseases ranging from vitamin deficiency to autoimmunity.[18]

Recurrent Aphthous Stomatitis has been described as presenting in three forms including minor aphthae, major aphthae and herpetiform aphthae. [19] Minor aphthae account for 75-85 percent of all RAS cases and can involve any non-keratinized mucosa of the oral cavity. The characteristic lesions are smaller than 10 millimeters and heal within 7-14 days without scarring. Major aphthae, comprising 10-15 percent of RAS cases, are larger, of longer duration, are more intense than minor aphthae, and tend to leave scars after healing. The herpetiform ulcers represent only 5-10 percent of RAS cases and consist of multiple 1-3 mm painful ulcers resembling herpes simplex, but involving non-keratinized mucosa.[20] Other topical approaches for the management of RAS have been studied. Topical steroids such as triamcinolone acetonide in carboxymethylcellulose paste have been used for years.[21]

Topical betamethasone [22] and fluocinonide [23] are also suggested for management of RAS. Transient relief of pain was reported with benzydamine hydrochloride mouthwash, but it was not more effective than placebo on ulcer healing.[24] Hunter et al[25] reported that chlorhexidine gluconate mouthwash was not better than placebo and no significant difference in pain was recorded. Similar results were also reported by others.[26,24] The use of Listerine mouth rinse for RAS [27] did not show benefit compared to the control. Topical sucralfate was effective in managing discomfort associated with RAS [28] A trial of chlortetracycline mouthwashes on RAS [29] reported significant reduction in duration of the ulcers with no side effects; however, pain was not assessed in this study.

Whereas in the present study, Group B (*Patoladi kashaya gandusha* given twice a day) showed statistically significant results compared to Group A (*Patoladi kashaya gandusha* given once a day) in reduction of *Toda, Daha, Asya vairasyata* and the pH of *Pittaja Mukhapaka* (Aphthous ulcer).

Effect of *Patoladi Kashaya Gandusha* (Group A)

7 days *Gandusha* done with *Patoladi Kashaya* done twice a day provided significant relief in Toda by 07%, in *Daha* by 27%, in *Asyavairasya* by 40% and in pH of Saliva by 100%. In this group complete relief was found in 33% patients, moderate relief in 13% patients and mild improvement 54% patients.

Effect of *Patoladi Kashaya Gandusha* (Group B)

7 days *Gandusha* done with *Patoladi Kashaya* once in a day provided significant relief in *Toda* by 67%, in *Daha* by 67%, in *Asyavairasya* by 100%, and in pH of Saliva by 100%. In this group complete relief was found in 07% patients, moderate improvement in 60% patients, mild improvement in 20% patients and no relief in 13% patients. On the basis of above results it can be inferred that as PKB *Gandusha* provided better relief in all the symptoms of *Pittaja Mukhapaka* in comparison to PKA *Gandusha*.

Patoladi Kashaya drug is effective in both the groups. But the complete improvement, mild improvement is marked in the individual groups where as 100% response is observed in PKB i.e. *Patoladi Kashaya Gandusha* twice in a day. That is why PKB is more effective than the PKA group.

Mechanism of Gandusha

The action of Gandusha exerts increased mechanical pressure inside the oral cavity. So this increased pressure stimulates pressoreceptor (stretch reflex) that are present in the mouth. Once the pressoreceptor is stimulated, they send signals to salivary nuclei in the brain stem (pons and medulla). As a result, Parasympathetic nervous system activity increases and motor fibres in facial (VII) and glossopharyngeal (IX) nerve trigger dramatically increasing the output of saliva. Chemical constituent present in the drug also stimulate chemoreceptors present in the mouth, which in turn increases salivary secretions. An enzyme called lysozyme present in saliva is bacteriostatic in action. It prevents the growth of pathogenic microorganisms

in the oral cavity. Antibody IgA present in saliva also provide protection against microorganisms. Thus *Gandusha* increases local defence mechanism and promotes oral hygiene. Mucosal layer inferior to the tongue (sublingual) is thin and highly vascular enough to permit the rapid absorption of the lipid soluble drugs into systemic circulation. Some of the drugs irritates the oral mucosa (by their chemical nature) and increases vascular permeability. Thus an active principle of *Dravya* is absorbed into systemic circulation. Most of the *Dravas* given for *Gandusha* are *Sukhoshna* (warm) so raised temperature causes the increased vascular permeability thereby enhancing systemic absorption of drugs. [30]

Kavala and *Gandusha* are the two main oral cleansing procedures explained in the classics. These are not only the cleansing techniques, but also the treatment procedures for oral diseases as well as preventive measures. Daily practice of *Gandusha* helps in preventing the conditions like *Mukhavairasya, Durgandha* (bad odour), *Shopha* (swelling), *Jadya*, and strengthens the teeth. One who practices *Thaila* (oil) *Gandusha* regularly will not suffer from *Kantashosha* (dryness of mouth), *Oshtasputana* (cracking lips), *Dantakshaya* (loss of teeth), *Dantashula* (dental pain) and *Dantaharsha* (sensitivity).

Gandusha is other form of drug administration into the oral cavity in which the active ingredients and chemical constituents of the drugs are absorbed through the buccal mucosa and reach the blood stream. It is having both in local and systemic action but generally more in local effect. *Gandusha* stimulates the salivary glands to secrete more saliva. Saliva contains a variety of host defence factors. The IgA, IgM antibodies and lysozyme (a bactericidal enzyme that inhibits bacterial growth in the mouth) present in the saliva provide protection against micro-organisms by acting as local antibiotic. Saliva also contains coagulation factors (factors VIII, IX&X) which protect wounds from bacterial invasion. Hence, *Gandusha* increases the local defence mechanism of the oral cavity and helps to regain oral hygiene. *Gandusha* increases the vascular permeability in the oral cavity. It creates pressure over the oral mucosa. The active ingredients and chemical constituents of the warm medicated liquid irritate the oral mucosa and increase the vascular permeability. Therefore, the drugs get rapidly absorbed both locally and systemically. This can help to reduce inflammation and enhance the healing process of disease and thus cures the disease of oral cavity. The main function of salivary buffer is to maintain pH at the mucosal epithelial cell surface and the tooth surface. Healthy mouth is a non-acidic or neutral. Unhealthy mouth is acidic and increases the risk of oral diseases. *Gandusha* is an immediate solution for mouth acidity and change the oral pH quickly into a safe zone. The active ingredients and chemical constituents of the medicated liquid of *Gandusha* regulate and balance the pH of the oral cavity and help to reduce bacterial growth in the mouth. Thus *Gandusha* cures the disease and helps to regain oral hygiene by maintaining a good pH balance in the mouth. [31]

Duration of *Gandusha*

In a study of Nagatake T. et al, The subjects included a total of 23 adult patients, both males and females, with chronic respiratory diseases showing repeated infections. Patients were asked to gargle more than 4 times/day with povidone-iodine gargle over extended periods of time, i.e., from several months up to over 2 years. The incidence of episodes of acute exacerbation of chronic respiratory infections decreased significantly when compared with that before use of povidone-iodine gargle. [32]

In the observational study of Tatsuya Noda et al, the children were enrolled from 145 nursery schools in Fukuoka City, Japan and were instructed to gargle at least once a day. The endpoints of this study were incidence of fever during the daytime and incidence of sickness absence. Differences among gargling agents for each endpoint were also analyzed, where another explanation was suggested by a randomized clinical trial showing that oral rinsing with chlorhexidine gluconate for 30 seconds twice a day reduced the total nosocomial respiratory infection rate among patients in a cardiovascular intensive care unit. [33]

Regarding gargling agents, we found that gargling with green tea had a greater impact on febrile disease. The results of a prospective cohort study of the effect of gargling with green tea suggested that such gargling lowers the risk of influenza infection, although the effect was not significant in that study. [34]

Tea catechin is a type of flavonoid in green tea and has antiviral and bacteriocidal effects. [35-38] In a previous clinical study, gargling with a catechin extract of green tea inhibited influenza infection, and application of green tea extract to the oral or nasal cavities suppressed various pathogenic bacteria. [39, 40]

CONCLUSIONS

Patoladi kashaya gandusha given twice a day showed statistically significant results compared to *Patoladi kashaya gandusha* given once a day in reduction of *Toda, Daha, Asya vairasyata* and the pH of *Pittaja Mukhapaka* (Aphthous ulcer).

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