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Efficacy of *Jatyadi Kwatha Gandusha* in Management of *Pittaja Mukhapaka* with special reference to Aphthous Ulcer: A Randomized Controlled Clinical Trial

Research Article

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Abstract

The condition known as *Pittaja Mukhapaka* is frequently encountered by patients seeking treatment at the outpatient department of the Ears, Nose, and Throat department. This condition is characterized by inflammation, ulceration, and a burning sensation in the oral mucosa, and is often associated with Aphthous ulcers (*Pittaja Mukhapaka*). Although modern medicine has several treatment options, including anti-inflammatory drugs, topical corticosteroids, and topical tetracyclines, these treatments have limitations. In contrast, *Jatyadi Kwath Churna* is a traditional polyherbal composition in ayurvedic medicine that has been used to treat oral problems for centuries. This herbal preparation contains *Jati Patra, Guduchi, Draksha, Daru Haridra, Yavasa, Haritaki, Vibhitaki, Madhu, and Amlaki,* and is indicated for oral problems in the texts *Yogaratnakara* and *Bhaishajya Ratnavali*. Material and Methods: This study aims to evaluate the efficacy of *Jatyadi Kwatha Gandusha* for *Mukha Rogas*, a study was conducted with 30 subjects randomly allocated to either Group A (receiving *Gandusha* of *Jatyadi Kwatha* and *Madhu*) or Group B (receiving *Triphala Kwatha*). Result: Both groups experienced complete relief from discomfort, burning sensations, and excessive salivation, on analysis between the groups with a statistically significant p-value results are equally effective in both groups. Conclusion: The study successfully demonstrated the effectiveness of *Jatyadi Kwatha Gandusha* and *Triphala Kwatha* in managing *Pittaja Mukhapaka.*

Keywords: Ayurvedic polyherbal Drug, *Gandusha, Jatyadi Kwatha, Pittaja Mukhapaka, Triphala Kwatha*.

Introduction

According to the diagnostic feature outlined in *Astanga Hrudaya*, there appears to be a correlation between the manifestation of Aphthous ulcers (*Pittaja Mukhapaka*). Clinically observed symptoms of *Pittaja Mukhapaka* include a burning sensation and the presence of multiple, recurring oral ulcers with a yellowish base and surrounding redness of the skin (1). Aphthous ulcers (*Pittaja Mukhapaka*) have been reported to afflict a significant proportion of the global population, with prevalence rates ranging from 2% to 66%. Notably, India has a lifetime prevalence rate of 50.3% (2). According to Ayurvedic principles, *Agni* represents the power of growth, and the consumption of appropriate foods can lead to healthy development, complexion, and immunity (3). However, irregular functioning of *dosha, dhatu,* and *mala* can lead to psychological degradation, resulting in stress-inducing conditions like *Pittaja Mukhapaka*. The causes of this mouth ulcer are not fully understood, but they have been linked to factors such as hormonal abnormalities, injuries, toxic medicines, dietary irritants, vitamin deficiencies, and stress (4). Although modern science has approved drugs such as anti-inflammatories, topical corticosteroids, and topical tetracycline for the treatment of aphthous ulcers (*Pittaja Mukhapaka*), they have limitations (4). Ayurvedic texts suggest various therapies, including *Kavala(*gargling*), Gandusha* (holding of liquid inside the oral cavity*), Dhumapana (*medicated smoking*), Raktamokshana* (bloodletting*), Ksara (*alkalies*), and Agni karma (*cauterization), to effectively control *Pittaja Mukhapaka* (5). *Gandusha* is classified into four types: *Snehana (*internal oleation*), Shaman(*pacificatory*), Sodhana (*purifying*), and Ropana(*healing*)* with *Ropana Gandusha* and wound healing medicines being the preferred treatments for ulcers (6). Because the predominant clinical aspect of the symptom is an ulcer, wound healing medicines, and *Ropana Gandusha* were chosen. *Gandusha* (holding of liquid inside the oral cavity*)* and *Kavala(*gargling*)* are the most utilized therapies for *Mukhapaka*. Therefore, a randomized clinical study was conducted to evaluate the efficacy of *Jatyadi kwatha Gandusha* in treating *Pittaja Mukhapaka*, a condition characterized by pain and burning sensation ulcers in the oral cavity. *Pittaja*

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mukhapaka is, therefore, a disorder characterized by pain and burning sensation in the *Mukha pratyanga (oral parts)* such as *oshta (lips), dantamula (gums), danta (teeth), jihwa (toungue), talu (palate),* and *kantha(throat)*. The clinical symptoms of *Pittaja Mukhapaka* are similar to those of Aphthous ulcer, a highly prevalent condition causing recurring bouts (5).

The *Yogaratnakara* and *Bhaishajya Ratnavali* glorify *Jatyadi Kwath Churna,* a polyherbal concoction from the Ayurvedic tradition. Its potency in curing *Mukhapaka* has been recognized since ancient times. Hence, there arose a need to scrutinize *Jatyadi kwatha Churna* and authenticate its unadulterated quality. (7) *Jatyadi* is a blend of Jati Patra (*Jasminum grandiflorum* L), Guduchi (*Tinospora cordifolia* (Thunb) Miers), Draksha (*Vitis vinifera* L), Daru Haridra (*Berberis aristata* DC), Yavasa (*Alhagi Camelorum* Fisch), Madhu (*Apis mellifera Linn)*. *Triphala* is an equal blend of *Haritaki* (*Terminalia chebula* Retz.), *Vibhitaki*, (*Terminalia bellirica* (Gaertn*)* Roxb.), and *Amlaki* (*Emblica Officinalis* Gaertn.). The mixtures should be boiled with water, filtered, and mixed with honey and *Gandusha* (keeping liquid inside the oral cavity) as specified in *Yogaratnakara* and *Bhaishajya Ratnavalli* (7).

Jatyadi kwatha Churna was tested for quality, purity, macroscopic, and physicochemical standards. The purpose of this study is to provide an overview of the physicochemical properties identified in crude extracts of dried powdered (*Jatyadi kwatha churna*), with a focus on their pharmacological effects. Color, odor, and taste were all measured, as well as total Ash value, water-soluble ash, acid-insoluble ash, water-soluble extractive, and alcohol-soluble extractive. These pharmaceutical or proprietary medication values can be compared to the traditional values of Indian pharmacopeia to determine identity. This study aims to evaluate the effect and efficacy of *Jatyadi Kwatha Gandusha* in the management of *Pittaja Mukhapaka* and to compare the efficacy of *Jatyadi Kwatha Gandusha* over *Triphala Kwatha Gandusha* in the management of *Pittaja Mukhapaka.*

Materials and Methods

Selection of patients: Patients who met the clinical criteria for Pittaja Mukhapaka from the out-patient department of the Department of Shalakya Tantra, KAHER's Shri B.M.K Ayurveda Mahavidyalaya and Hospital, Karnataka, were chosen, regardless of gender, religion, occupation, social-economic status, or other factors.

Ethical clearance and trial registration number (if clinical trial):: The Institutional Ethics Committee cleared the study (Protocol no.: BMK/19/PG/SKT/5) and this study is registered at http://ctri.nic.in (Registration No. CTRI/2020/11/028998).

Patient Consent: Before beginning the trial, each patient willing to participate is provided with written consent.

Diagnostic criteria: Single or smaller round or oval lesions grow in the oral mucosa, creating a painful sore, burning sensation, inflammation, chew, and swallowing difficulties.

Inclusion criteria

1. The patients present with *Pittaja Mukhapaka's* symptoms were considered.
2. Age range 18-60 years old, regardless of gender, religion, or profession.

Exclusion criteria

1. Diabetes, tuberculosis, herpes, AIDS, lichen planus, an auto-immune illness, or any systemic ailment that interferes with therapy duration causes chronic ulcers.
2. A disorder contraindicated for *Gandusha* and traumatic mouth ulcer.

Drug preparation

KLE Ayurveda Pharmacy, Khasbag, Belagavi, provided the raw material. The Ayush recognised ASU Drug Testing Central Research Facility of KAHER's Shri. B.M.K. Ayurveda Mahavidyalaya, Belagavi was used to identify and authenticate *Jatyadi Kwath Churna* (Ref No. CRF/FG/258/2020-21) and *Triphala Kwatha Churna* (Ref No. CRF/FG/256/2020-21) The Drug was studied in the AYUSH-approved Central Research Facility of K.L.E U's Shri B.M.K Ayurveda Mahavidyalaya, Belagavi, Karnataka, 590003. The Drug was prepared and packaged in the GMP Certified KLE Ayurveda Pharmacy in Belagavi, Karnataka, and stored in the Medical Research Center of B.M.K. Ayurveda Mahavidyalaya in Belagavi, Karnataka. These drugs were made under the Shalakya Tantra department's standard operating procedure at KAHERS BMK Ayurveda Mahavidyalaya Belagavi.

Table 1: *Rasa panchaka* of *Jatyadi Kwatha Churna*

Sanskrit name	***Rasa***	***Guna***	***Veerya***	***Vipaka***	***Karma***	**Indication**
Jati patra	*Tikta, kashaya*	*Laghu, snigdha*	*Ushna*	*Katu*	*Tridosha hara*	*Mukharoga,danta roga, puti karna*
Guduchi	*Tikta, kashaya*	*Guru,snigdha*	*Ushna*	*Madhura*	*Tridosha hara*	*Amahara,Dahahara*
Draksha	*Madhura*	*Guru, snigdha, mrudu*	*Sheeta*	*Madhura*	*Vatapittahara*	*Sramahara, Kasahara virechanopaga*
Yavasa	*Madhura, tikta, kashaya*	*Laghu,*	*Sheeta*	*Katu*	*Kaphapittahara*	*Raktasthambana*

Daru haridra	*Kashaya, tikta*	*Laghu Ruksa*	*Ushna*	*Katu*	*Kapha pitta doshahara*	*Vranajit, karnanetramukharoga*
Amlaki	*Madhura, amla, katu, tikta, kashaya*	*Laghu,ruksa*	*Sheeta*	*Madhura*	*Tridoshahara*	*Chakshushya, kanthya, vrushya*
Haritaki	*Kashaya, madhura, amla katu, tikta*	*Laghu ruksa*	*Ushna*	*Madhura*	*Tridoshahara*	*Keshya,medhya dipana, pachana*
Vibhitaki	*Kashaya*	*Ruksha, laghu*	*Ushna*	*Madhura*	*Kaphapittahara*	*Kruminashana, Jwarahara ,kasahara*
***Madhu* (*Apis mellifera*)**	*Madhura, kashaya anurasa*	*Ruksha, laghu Yogavahi*	*Sheeta*	*Madhura*	*Tridoshagna*	*Ropana,sandhana lekhana*

Table 2: Botanical Name, Family, and parts used of a drug

Sanskrit Name	Latin Name	Family	Part Used
Jati Patra	*Jasminum Grandiflorum* L	Oleaceae	Leaves
Guduchi	*Tinospora cordifolia*	Menispermaceae	Stem
Yavasa	*Alhagi Camelorum*	Fabaceae	Stem
Daru Haridra	*Berberis aristata* DC	Berberidaceae	Fruits
Draksha	*Vitis Vinifera* L	Vitidaceae	Fruits
Amlaki	*Emblica Officinalis* Gaertn	Chyllanthaceae	Fruits
Haritaki	*Terminalia chebula* (Retz)	Combretaceae	Fruits
Vibhitaki	*Terminalia bellirica*(Gaertn Roxb)	Combretaceae	Fruits
Madhu	*Apis Mellifera*	Apidae	Liquid

Grouping and treatment schedule

The study was carried out at KLE Shri. B.M.K Ayurveda Hospital and 41 patients attending OPD were screened with 30 patients included in a randomized controlled clinical trial. Using the online software random number generator, the patients were randomly separated into two groups: trial drug and controlled Drug. Each group has 15 patients from the *Jatyadi Kwatha Gandusha* and *Triphala Kwatha Gandusha.* Group A patients were given *Jatyadi kwatha gandusha* and *Madhu,* four times a day for seven days. Patients in Group B were given *Triphala Kwatha gandusha* four times a day for seven days.

Follow-up

Patients were requested to come to the OPD on the 8th and 15th days, and assessments were performed after therapy completion based on the fundamental point of improvement in the following subjective and objective parameters.

Table 3: Group treatment intervention of the *Jatyadi kwatha Gandusha* and *Triphala kwatha Gandusha*

Groups	Sample Size	Intervention	Dose	Duration	Follow up
Group A Trial group	15	*Jatyadi kwatha Gandusha*	Quantum sufficient four times a day	7 days	8th and 15th day
Group B Control group	15	*Triphala kwatha Gandusha*	Quantum sufficient four times a day	7 days	8th and 15th day

Assessment criteria (Subjective Parameters)

Table 4. Grading of subjective parameters of the enrolled patients

Serial No.	Symptoms	0	1	2	3
1	Pain in the affected area	No Pain	Mild pain on touch	Moderate pain without touch	Pain causing difficulty in opening mouth
2	Burning sensation	No complaint	Mild with hot beverages	Moderate felt on taking spicy and acidic, salty food	Throughout the day without any aggravating factor
3	Difficulty in chewing/ ingestion	Can eat easily	Mild can eat solid food	Moderate-can eat liquid food only	Severe- cannot eat liquid as well as solid food
4	Excessive salivation	No complaint	Complaining of salivation	Must spit saliva	Dribbling of saliva

Assessment criteria (Objective Parameters)

Table 5: Grading of objective symptom parameters of the enrolled patients

Serial	Symptoms	0	1	2	3
1	Inflammation	No hyperemia	On ulcer margin only	Floor of ulcer	Centre of ulcer necrosed/ slough seen
2	Size (degree) of ulceration	No ulceration	<3 mm	3 mm - <1 cm	>1 cm
3	No. of ulceration	No ulceration	<1	2-10	>10

Photography of oral mucosa

According to photography standard operating procedures, it is followed for all subjects.

Statistical analysis

Statistical analysis was done by using the Chi-squared test, Mann-Whitney U test, Wilcoxon matched pairs test, and independent t-test. The significant *p*-value was considered at $p<0.05$.

Results

A total of 41 individuals were screened for this trial, 30 subjects were enrolled, and 29 patients completed the study. Patients were divided into two groups, *Jatyadi Kwatha Gandusha,* and *Triphala Kwatha Gandusha,* and analyzed the results with 15 in the A group and 14 in the B group. The observational data of 29 registered patients were collected and analyzed based on age, gender, occupation, habit, food habits, educational status, and other factors, as shown in Tables 6, 7 and 8. The following is the distribution of patients among several factors:

Age Groups

The age distributions of 30 patients are shown. The analysis of Group A found that 60% were between the ages of 18–30 years, and 40% were between the ages of 31–60 years, with a mean age of 32.47±9.22%. The survey found that 80% of those in Group B were between the ages of 18–30 years old, while 20% were between the ages of 31–60 years old, with a mean age of 28.60±11.21%. A total of 70% of patients were discovered to be between the ages of 18–30, and 30% were between the ages of 31–60, with a mean age of 30.53±10.27%. The following Table 6 provides more information:

Table 6: Shows the age-wise distribution of subjects in the study

Profile	Group A	%	Group B	%	Total	%	c^2	*p*-value
18-30 yrs	9	60.00	12	80.00	21	70.00	0.635	0.4260
31-60 yrs	6	40.00	3	20.00	9	30.00		
Mean age	32.47 yrs		28.60 yrs		30.53 yrs			
SD age	9.22		11.21		10.27			

Gender distribution

Gender distributions suggest that male individuals make up 33.33% of Group A and female subjects makeup 66.67% of Group B. Male participants makeup 53.33% of the 30 patients in Groups A and B, while female individuals make up 46.67%. A total of male subjects accounts for 43.33%, while the total of female subjects accounts for 56.67%. Most patients in this series are female, as shown in Table 7. Due to increased obligations and hormonal changes during menstruation, and pregnancy, which result in increased stress and mental disturbance, ultimately leading to metabolic alterations.

Religion

Religion-wise distributions are shown in groups A (Hindu is 93.33% and Muslim is 6.67%) and groups B (Hindu is 80%, Christian is 13.33%, and Muslim is 6.67%), for a total of 86.67% Hindu, 6.67% Christian, and 6.67% Muslim.

Socio-Economic Status (SES)

The socio-economic status distributions shown in Group A (Middle SES is 86.67%, and Upper SES is 13.33%). In Group B, (the middle SES is 80.00%, and the upper SES is 20.00%). Hence, 83.33% in the middle SES and 16.67% in the upper SES. Most of the patients registered belong to the middle economic class.

Occupation

The distribution of occupations as shown in groups A (sedentary is 33.33%, moderate is 66.67%, and labor is 0%) and Group B (sedentary is 40.00%, moderate is 53.33%, and labour is 6.67%). Hence, the total difference between Sedentary is 36.67%, moderate is 60.00%, and labor is 3.33%.

Table 7: Observations of subjects in the study

Observations	Profile	Group A	%	Group B	%	Total	%	c^2	p-value
Gender wise distribution	Male	5	33.33	8	53.33	13	43.33	1.222	0.2690
	Female	10	66.67	7	46.67	17	56.67		
Religion wise distribution	Hindu	14	93.33	12	80.00	26	86.67	0.288	0.5910
	Christian	0	0.00	2	13.33	2	6.67		
	Muslim	1	6.67	1	6.67	2	6.67		

Socio-economic status-wise distribution	Middle SES	13	86.67	12	80.00	25	83.33	0.0000	1.0000
	Upper SES	2	13.33	3	20.00	5	16.67		
Occupation wise distribution	Sedentary	5	33.33	6	40.00	11	36.67	0.144	0.7050
	Moderate	10	66.67	8	53.33	18	60.00		
	Labor	0	0.00	1	6.67	1	3.33		
	Total	15	100.00	15	100.00	30	100.00		

Personal history

The personal history data of the subjects are indicated in Table 8.

- **Ahara**: Among the 30 subjects, 40.00% were on a vegetarian diet, and 60.00% had a mixed food intake.
- **Ahara Time**: Most of the patients registered are those with an irregular food intake (53.33%) and those with a regular diet (46.67%).
- **Rasa**: Group A (*Madhura* is 33.33%, *Amla* is 13.33%, *Lavana* is 0%, and *Katu* is 53.33%) and Group B (Katu is 53.33%) (*Madhura* is 20%, *Amla* is 26.67%, *Lavana* is 6.67%, and *katu* is 46.67%). As a result, *Madhura* accounts for 26.67% of the total subjects, *Amla* accounts for 20.00%, *Lavana* accounts for 3.33%, *Katu* accounts for 50.00%, and *tikta* and *kashaya* account for 0%. The bulk of the patients in this series have *katu rasa*.
- **Nidra:** Nidra reveals that in Group A, sound sleep accounts for 40.00% of subjects, while disturbed sleep accounts for 60.00%, and in Group B, good sleep accounts for 46.67% of subjects, while disturbed sleep accounts for 53.33% of subjects. Because most patients use mobile phones, their circadian cycles and metabolic processes are disrupted, resulting in *mukhapaka*. As a result, most patients have disturbed sleep during the night.
- **Agni:** *Agni* shows in Group A (Samagni is 26.67 %, Mandagni is 66.67 %, Vishamagni is 6.67 %, and *Tikshnagni* is 0%) and Group B (Vishamagni is 6.67 %, and Tikshnagni is 0%). (Samagni is 20%, Mandagni is 60%, Vishamagni is 13.33%, and Tikshnagni is 3.33%). As a result, Samagni has 23.33% of the subjects, Mandagni has 63.33 %, Vishamagni has 10.00 %, and Tikshnagnis has 6.67 %. However, *Mandagni* is present in most of the patients included.
- **Koshta**: *Koshta* appears in Group A (*Mrudu* is 26.67 %, *Madhyama* is 13.33 %, and *Krura* is 60.00 %) and Group B. (*Mrudu* is 6.67%, *Madhyama* is 33.33%, *Krura* is 60.00 %). As a result, the total subjects of *Mrudu* are 16.67%, *Madhyama* is 23.33%, and *Krura* is 60.00%. However, *Krura Koshta* is present in most patients.
- **Vyasana**: Vyasana shows up in group A (alcohol is 20.00%, smoking is 13.33 %, tobacco is 20%, no addiction is 33.33%, and other addictions are 13.33%). Group B shows that alcohol is 20%, tobacco is 6.67%, no addiction is 60.00%, and other addictions are 13.33%. As a result, the overall number of subjects with alcoholism is 20.00%, smoking is 6.67%, tobacco is 13.33%, no addiction is 46.67%, and other addictions are 13.33%.
- **Vyayama:** In Group A, normal is 13.33%, less is 60.00%, moderate is 26.67%, and excess is 0%; and in Group B, normal is 0%, less is 66.67%, moderate is 20.00%, and excess is 13.33%. Hence, the total number of normal subjects is 6.67%, less than normal is 63.33%, moderate is 23.33%, and excess is 6.67%.

Table 8: Personal history of subjects in the study

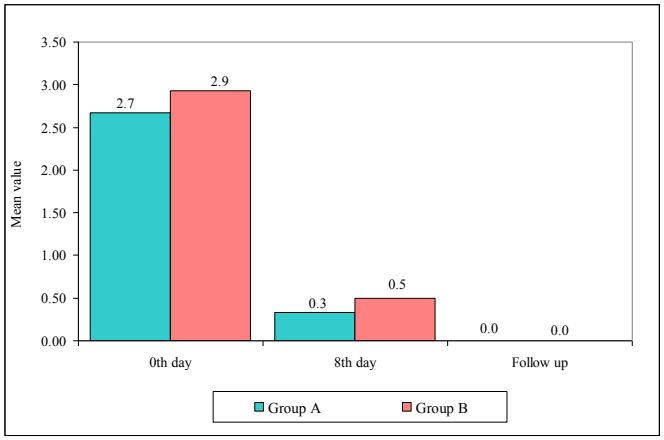
Personal history	Profile	Group A	%	Group B	%	Total subjects	%	c^2	p-value
Ahaara	Veg	8	53.33	4	26.67	12	40.00	2.2220	0.1360
	Mixed	7	46.67	11	73.33	18	60.00		
Ahara time	Regular	7	46.67	7	46.67	14	46.67	0.0000	1.0000
	Irregular	8	53.33	8	53.33	16	53.33		
Rasa	Madhura	5	33.33	3	20.00	8	26.67	2.2330	0.5250
	Amla	2	13.33	4	26.67	6	20.00		
	Lavana	0	0.00	1	6.67	1	3.33		
	Katu	8	53.33	7	46.67	15	50.00		
Nidra	Sound	6	40.00	7	46.67	13	43.33	0.1360	0.7130
	Disturbed	9	60.00	8	53.33	17	56.67		
Agni	Samagni	4	26.67	3	20.00	7	23.33	1.5290	0.6760
	Mandagni	10	66.67	9	60.00	19	63.33		
	Vishamagni	1	6.67	2	13.33	3	10.00		
	Tikshnagni	0	0.00	1	6.67	1	3.33		
Koshta	Mrudu	4	26.67	1	6.67	5	16.67	3.0860	0.2140
	Madhyama	2	13.33	5	33.33	7	23.33		
	Krura	9	60.00	9	60.00	18	60.00		

Vyasana	Alcohol	3	20.00	3	20.00	6	20.00	4.1430	0.3870
	Smoking	2	13.33	0	0.00	2	6.67		
	Tobacco	3	20.00	1	6.67	4	13.33		
	Others	2	13.33	2	13.33	4	13.33		
	No habit	5	33.33	9	60.00	14	46.67		
Vyayama	Normal	2	13.33	0	0.00	2	6.67	4.1950	0.2410
	Less	9	60.00	10	66.67	19	63.33		
	Moderate	4	26.67	3	20.00	7	23.33		
	Excess	0	0.00	2	13.33	2	6.67		
	Total	15	100.00	15	100.00	30	100.00		

Subjective parameters: Assessment of parameters in group A and group B treatment.

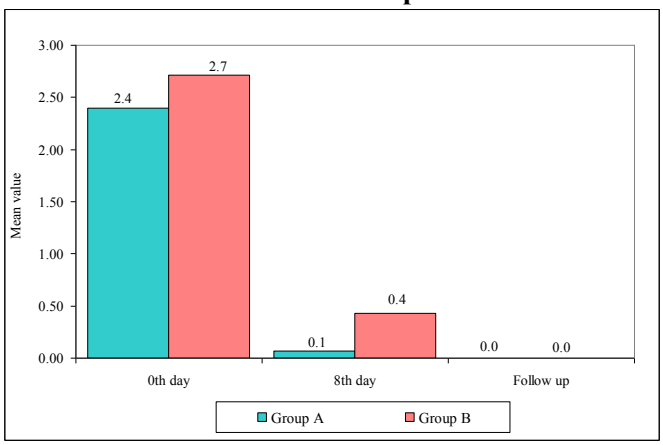
Pain: In this current study, we found the mean result of pain for Group A on the 0th day was 2.67±0.90 decreased significantly to 0.33±0.49 on the 8th day with a *p*-value of 0.0010* and on the follow-up and from 8th day to the follow-up with a *p*-value of 0.0431*. In Group B, we found the mean result of pain on the 0th day was 2.93±0.27, which decreased significantly on the 8th day to 0.52±0.50 with a p-value of 0.0010* and on the follow-up and from the 8th day to the follow-up with a *p*-value of 0.0180*. When the statistical significance of the groupings was examined, Group A outperformed Group B, shown in Figure 1.

Figure 1: Comparison of Groups A and B with Pain in the affected area on the 0th day, 8th day, and follow-up



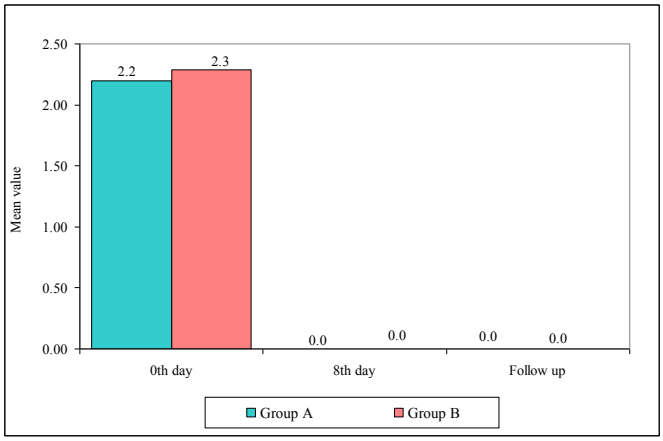
Burning Sensation: The mean score of burning sensation in Group A was 2.40±0.99 on the first visit (0th day) and decreased significantly to 0.07±0.26 on the eighth day with a p-value of 0.0010* and on the follow-up. The mean score of burning sensation in group B was 2.71±0.61 on the first visit (0th day), but it decreased significantly to 0.43±0.51 on the second visit (8th day) with a *p*-value of 0.0010* and from 0th day to follow-up with a *p*-value of 0.0010* and from the 8th day to follow-up with a *p*-value of 0.0277*. On analysis, there is a statistically significant difference between the groups, but Group A outperformed Group B, as shown in Figure 2.

Figure 2: Comparison of Group A and Group B with a status of burning sensation on the 0th day, 8th day, and follow-up



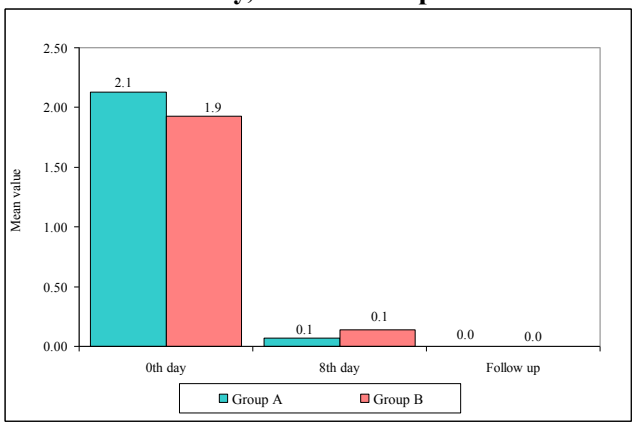
Difficulty in chewing: The mean chewing difficulty score in Group A was 2.20±0.94 on the first visit (day 0th) to the eighth day with a p-value of 0.0010* and from the 0th day to the follow-up with a p-value of 0.0010*. There was no difficulty chewing from the 8th day until the follow-up. Group B includes patients whose chewing problem was 2.29±2.00 on the first visit and decreased significantly with a p-value of 0.0010* from the first to the eighth day and from the first to the follow-up. Statistical significance exists inside the Group, and both results are the same, as shown in Figure 3.

Figure 3: Comparison of Group A and Group B with a status of difficulty in chewing & ingestion on the 0th day, 8th day, and follow-up



Excessive Salivation: The mean score of excessive salivation in Group A was 2.13±1.13 on the first visit (day 0th) and decreased significantly to 0.07±0.26 on the eighth day with a p-value of 0.0015* and from the 0th day to follow-up with a p-value of 00.0015*. The mean score of excessive salivation in group B was 1.93±1.27 on the first visit (day 0th) and decreased significantly to 0.14±0.36 on the eighth day with a p-value of 0.0033* and from the 0th day to the follow-up with a p-value of 00.0033*. Statistical significance exists between the groups, although the results are the same compared to Group B and Group A, as shown in Figure 4.

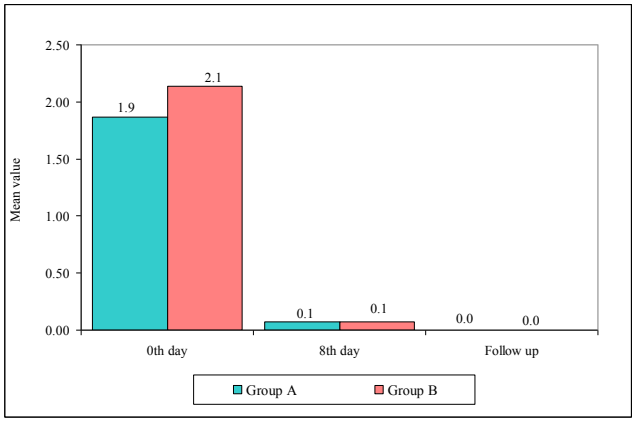
Figure 4: Comparison of Group A and Group B with a status of excessive salivation on the 0th day, 8th day, and follow-up



Objective parameters: Assessment of parameters in group A and group B treatment

Inflammation: The mean inflammation score in Group A was 1.87±0.64 on the first visit (day 0th), which decreased significantly to 0.07±0.26 on the eighth day with a p-value of 0.0007* and from the first visit to follow-up with a p-value of 0.0007*. The mean inflammatory score in group B was 2.14±0.86, which decreased significantly to 0.07±0.26 on the eighth day with a p-value of 0.0010* and from the first visit (day 0th) through follow-up with a p-value of 0.0010*. There is no statistical significance when comparing the groups shown in Figure 5.

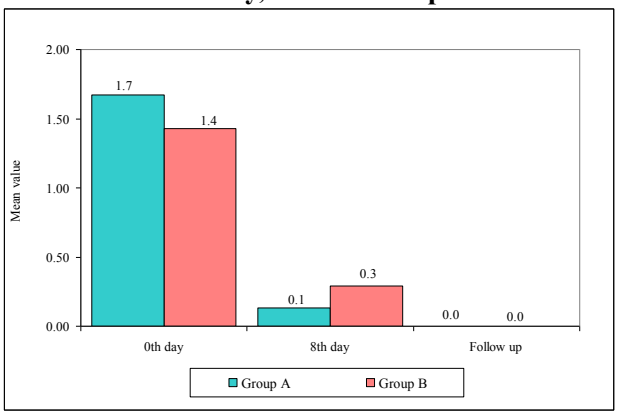
Figure 5: Comparison of Group A and Group B with a status of inflammation on the 0th day, 8th day, and follow-up



Size (Degree) of Ulceration

The mean score of the size (degree) of ulceration in Group A was 1.67±0.49 on the first visit (day 0th). Decreased significantly to 0.13±0.35 from the 0th to the 8th day with a p-value of 0.0007* and from the 0th to follow-up with a p-value of 0.0007*. The mean score of the size (degree) of ulceration on the first visit in group B was 1.43±0.51, and it decreased significantly on the eighth day to 0.29±0.47 with a p-value of 0.0015* and from the 0th day to follow-up with a p-value of 00.0010*. Statistical significance exists between the groups; however, the results in Group B are more significant than those in Group which is shown in Figure 6.

Figure 6: Comparison of Group A and Group B with a status of size (degree) of ulceration on the 0th day, 8th day, and follow up



Number of Ulcerations: The mean number of ulcerations during the first visit in Group A was 1.27±0.59, which reduced dramatically. There was no ulceration from the 8th day until the follow-up, with a p-value of 0.007*. In group B, the mean number of ulcerations at the first visit was 1.07±0.27, and there was no ulceration from the 8th day to follow-up with a p-value of 0.0010* and from the first visit to follow-up with a p-value of 00.0010*. Statistical significance exists inside the Group, and both results are the same, as shown in Figure 7.

Figure 7: Comparison of Group A and Group B with no. of ulceration on the 0th day, 8th day, and follow-up

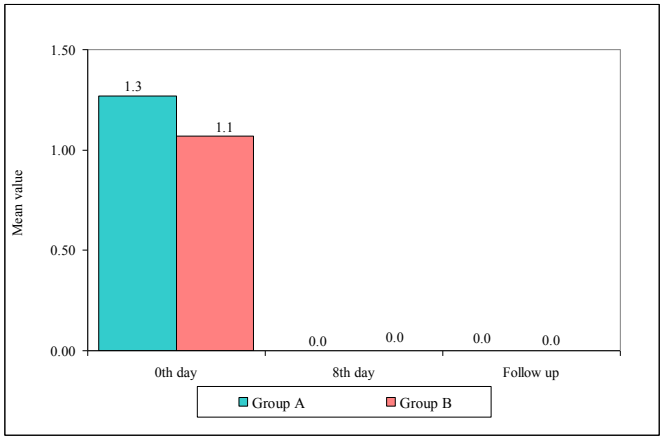


Table 9: Comparison of Group A and Group B with subjective parameters on the 0th day, 8th day, and follow-up by Mann-Whitney U test

Subjective/ Objective parameters	Time points	Group A				Group B				U-value	Z-value	p-value
		Mean	SD	Median	IQR	Mean	SD	Median	IQR			
Pain in the affected area	0th day	2.67	0.90	3.00	0.00	2.93	0.27	3.00	0.00	97.50	-0.305	0.7600
	8th day	0.33	0.49	0.00	0.50	0.50	0.52	0.50	0.50	87.50	-0.741	0.4581
	Follow ...	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	105.00	0.0218	0.9826
Status of burning sensation	0th day	2.40	0.99	3.00	0.50	2.71	0.61	3.00	0.13	90.00	-0.6328	0.5268
	8th day	0.07	0.26	0.00	0.00	0.43	0.51	0.00	0.50	67.00	-1.6366	0.1017
	Follow ...	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	105.00	0.0218	0.9826
Status of difficulty in chewing & ingestion	0th day	2.20	0.94	2.00	0.50	2.29	0.73	2.00	0.50	104.00	-0.0218	0.9826
	8th day	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	105.00	0.0218	0.9826
	Follow ...	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	105.00	0.0218	0.9826
Status of excessive salivation	0th day	2.13	1.13	3.00	1.00	1.93	1.27	2.50	1.13	97.00	0.3273	0.7434
	8th day	0.07	0.26	0.00	0.00	0.14	0.36	0.00	0.00	97.00	-0.3273	0.7434
	Follow ...	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	105.00	0.0218	0.9826
Status of inflammation	0th day	1.87	0.64	2.00	0.50	2.14	0.86	2.00	1.00	84.00	-0.8947	0.3710
	8th day	0.07	0.26	0.00	0.00	0.07	0.27	0.00	0.00	104.50	0.0000	1.0000
	Follow ...	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	105.00	0.0218	0.9826
Status of Size (degree) of ulceration	0th day	1.67	0.49	2.00	0.50	1.43	0.51	1.00	0.50	80.00	1.0693	0.2849
	8th day	0.13	0.35	0.00	0.00	0.29	0.47	0.00	0.50	89.00	-0.6765	0.4987
	Follow ...	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	105.00	0.0218	0.9826
No. of ulceration	0th day	1.27	0.59	1.00	0.00	1.07	0.27	1.00	0.00	91.00	0.5892	0.5557
	8th day	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	105.00	-0.0218	0.9826
	Follow ...	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	105.00	-0.0218	0.9826

Table 10: Comparison of 0th day, 8th day, and follow-up with subjective parameters in Group A and Group B by Wilcoxon matched pairs test

Subjective/ Objective parameters	Groups	Changes from	% of change	Z-value	*p*-value
Pain in the affected area	Group A	0th day to 8th day	87.50	3.2958	0.0010*
		0th day to follow-up	100.00	3.2958	0.0010*
		8th day to follow up	100.00	2.0226	0.0431*
	Group B	0th day to 8th day	82.93	3.2958	0.0010*
		0th day to follow-up	100.00	3.2958	0.0010*
		8th day to follow up	100.00	2.3664	0.0180*
Status of burning sensation	Group A	0th day to 8th day	97.22	3.2958	0.0010*
		0th day to follow-up	100.00	3.2958	0.0010*
		8th day to follow up	100.00	-	-
	Group B	0th day to 8th day	84.21	3.2958	0.0010*
		0th day to follow-up	100.00	3.2958	0.0010*
		8th day to follow up	100.00	2.2014	0.0277*
Status of difficulty in chewing & ingestion	Group A	0th day to 8th day	100.00	3.2958	0.0010*
		0th day to follow-up	100.00	3.2958	0.0010*
		8th day to follow up	--	--	--
	Group B	0th day to 8th day	100.00	3.2958	0.0010*
		0th day to follow-up	100.00	3.2958	0.0010*
		8th day to follow up	--	--	--

Status of excessive salivation	Group A	0th day to 8th day	96.88	3.1798	0.0015*
		0th day to follow-up	100.00	3.1798	0.0015*
		8th day to follow up	100.00	--	--
	Group B	0th day to 8th day	92.59	2.9341	0.0033*
		0th day to follow-up	100.00	2.9341	0.0033*
		8th day to follow up	100.00	-	-
Status of inflammation	Group A	0th day to 8th day	96.43	3.4078	0.0007*
		0th day to follow-up	100.00	3.4078	0.0007*
		8th day to follow up	100.00	-	-
	Group B	0th day to 8th day	96.67	3.2958	0.0010*
		0th day to follow-up	100.00	3.2958	0.0010*
		8th day to follow up	100.00	-	-
Status of Size (degree) of ulceration	Group A	0th day to 8th day	92.00	3.4078	0.0007*
		0th day to follow-up	100.00	3.4078	0.0007*
		8th day to follow up	100.00	-	-
	Group B	0th day to 8th day	80.00	3.1798	0.0015*
		0th day to follow-up	100.00	3.2958	0.0010*
		8th day to follow up	100.00	1.8257	0.0679
No. of ulceration	Group A	0th day to 8th day	100.00	3.4078	0.0007*
		0th day to follow-up	100.00	3.4078	0.0007*
		8th day to follow up	-	-	-
	Group B	0th day to 8th day	100.00	3.2958	0.0010*
		0th day to follow-up	100.00	3.2958	0.0010*
		8th day to follow up	-	-	-

The significant p-value was taken at *p<0.05.

Photography: The mean centimetre visible in mucosa photography in Group A was 0.31±0.24, which fell dramatically to 00±0.01 on the eighth day. The mean centimetre was observed in mucosa photography, as indicated in Figure 10. The mean centimetre seen in mucosa photography at the first visit in group B was 0.38±0.23, which decreased to 0.00±0.01 on the eighth day, indicating non-significant changes. In contrast, group B's p-value is 0.0001*, and group A's p-value is 0.0002*, meaning that there are changes and clinical significance between the groups but not within the groups, which can be observed in Table 11, Table 12, and Figure 8.

Table 11: Comparison of Group A and Group B with mean Photography of oral mucosa scores on the 0th day and 8th day of treatment by independent t-test

Time points	Group A		Group B		Mean Difference	t-value	p-value
	Mean	SD	Mean	SD			
0th day	0.31	0.24	0.38	0.23	-0.08	-0.8810	0.3861
8th day	0.00	0.01	0.00	0.01	0.00	-0.7086	0.4846

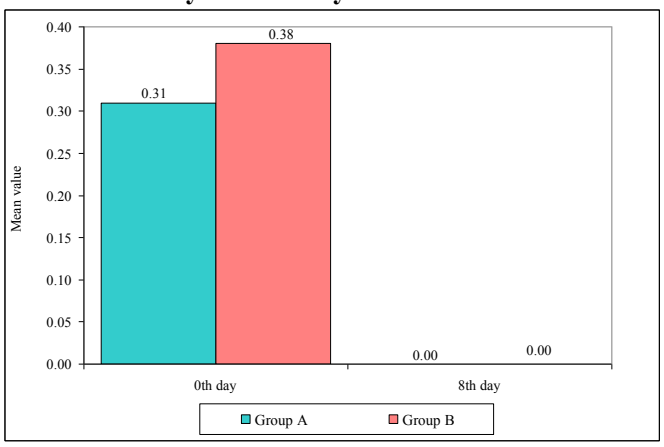
Table 12: Comparison of 0th day and 8th day of treatment with mean Photography of oral mucosa (cm) scores in Group A and Group B by dependent t-test

Groups	Time points	Mean	SD	Mean Diff.	SD diff.	% of change	t-value	p-value
Group A	0th day	0.31	0.24					
	8th day	0.00	0.01	0.30	0.24	99.35	4.8680	0.0002*
Group B	0th day	0.38	0.23					
	8th day	0.00	0.01	0.38	0.23	99.07	6.2989	0.0001*

*p<0.05 was chosen as the significant p-value.

Figure 8: Comparison of Group A and Group B with mean Photography of oral mucosa scores on the 0th

day and 8th day of treatment



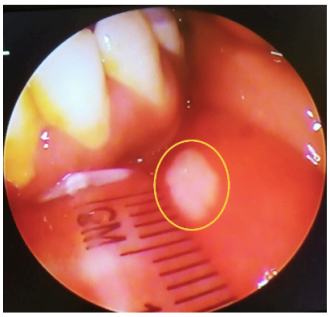


Figure 9: Before Treatment

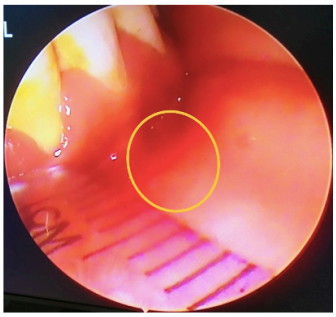


Figure 10: After Treatment

Discussion

The total count of listed patients was 41 with 30 patients enrolled and 29 patients completed treatment properly, and one dropped out. The reasons for dropping outpatients were not taking follow-up regularly. In this clinical study, the maximum number of patients, i.e.,70.00%, belong to the 18-30 age group. According to *Ayurveda,* it can be considered the peak level of *pitta* at this age (8) 56.67% were female, and 43.33% were male. Hormonal changes during menstruation and pregnancy cause more stress and mental disruption, eventually leading to metabolic abnormalities (9) In the case of religion, most of the patients were Hindu 86.67%, Christian 6.67%, and Muslim 6.67%. The registered patients' were majority is Hindu. Socio-economic status mostly belonged to middle socio-economic status, with 83.33% and 16.67% in the upper socio-economic class. Occupations of most of the patients in these distributions were sedentary (36.67%), moderate (60.00%), and labor (3.33%). The reason behind this is stress, outside food, improper timing of diet, and sleep leads to the derangement of circadian rhythm, ultimately affecting the metabolism. These essential factors contribute to recurrent oral ulcers, which are highly common in these people.

In this current study, *Ahara* of the patients suffered were most from being mixed diet (60.00%) and vegetarian (40.00%). Hence, the patients are primarily non-veg eaters. In *Ahara's* time, the registered patients were those with an irregular intake of food (53.33%) and those with a regular diet (46.67%). In *Rasa* study, most of the patients are having *Katu rasa* (50.00%), *Madhura* (26.67%), *Amla* (20.00%), *Lavana* (3.33%), *tikta* (0%), and *kashaya* (0%). In this series, most patients have *katu rasa*, which aggravated *Pitta dosha*. Most of the patients were having disturbed sleep (56.67%), and sound sleep (43.33%) as most of the patients were using mobile phones, which may cause a deranged circadian rhythm and metabolic changes leading to *Mukhapaka.* Most of the patients (*Agni*) enrolled had *Mandagni* (63.33%), Samagni (23.33%), Vishamagni (10.00%), Tikshnagnis (6.67%) as it has caused the metabolic disturbance, ultimately having less absorption may cause *Mukhapaka.* The impaired digestive status may have an indirect impact on disease production in the long run by causing deficiency status and affecting tissue metabolism (*Dhatukshaya*) and thus aggravating the disease condition in *Koshta pravrutti* (60.00 %), *Madhyama* (23.33 %), and *Mrudu* (16.67 %). Out of 30 patients of *Mukhapaka*, the patients practiced *Vyasan* such as alcohol (20.00%), smoking (6.67%), tobacco (13.33%), and other addictions (13.33%) like tea, coffee, etc. Majority of patients are less exercised (63.33%), Moderate (23.33%), Normal (6.67%), and excessively exercised (6.67%). *Vyayama Shakti* may be reflecting on the earlier seen *Dhatu Sarata* and *Samhanana.*

When the pain levels of the group, Group A outperforms Group B statistically compared. Group A showed better results, with the patient having relief, the *gandoosha kwatha* having *tikta,* and the *kashaya rasa* was considered as *Shoolahara (*reduces pain*) Vedanasthapana (*pain relieving*) Vranapachana (*wound healing*)* and *Pittashamaka* (pacify heat). *Kashaya Rasa's* action aids in the loss of pain perception, which then reduces *Ruja*. It may also have a soothing effect by reducing external trauma. After *Gandoosha, Daha* (Burning Sensation) showed an improvement in group A that was statistically significant compared to Group B. On the 8th and 15th days, the results were compared before and after the *Gandoosha t*reatment; patients were relieved of burning symptoms. The efficacy is perhaps due to *tikta(bitter), Madhura(sweet), kashaya rasa(*astringent taste*), pittahara(*reduces pitta*), daha prashamana (*pacify burning sensation*)* of *Jatyadi kwath gandusha,* and *Triphala kwatha gandusha. Tikta rasa* acts on the nociceptors (inactivates pain perception), lessening the burning feeling. On analysis between the groups, statistical significance is there on the difficulty in chewing compared to Group B and Group A results are the same because in both the Group's difficulty in chewing reduced significantly from day 0th day to the 8th day with a p-value of 0.0010*. Excessive salivation in Group A from the 0th day to follow-up with a 100% change decreased significantly with a p-value of 00.0015*. Group B significantly reduced from the 0th day to follow-up with 100%. Still, between the Groups, there is no statistically significant. On analysis between the groups, inflammation was statistically significant within the Group compared to group B, and group A was equally effective.

The efficacy is perhaps due to *Tikta, Madhura, Kashaya Rasa Pradhanata, Pitta Shamaka,* and *Vranaghna* properties of *Jatyadi* and *Triphala kwath*

Gandusha. The magnitude (degree) of ulceration demonstrates statistical significance in both groups, with a p-value of 0.0007* in Group A and 0.0015* in Group B. Still, between the groups, it is equally effective. The efficacy is possibly due to the *Vranashodhan, Vranaropana* property of *Triphala kwath gandoosha*. On analysis within the groups, the number of vrana having a p-value of 0.0007* in Group A and a p-value of 0.0010* in Group B, comparing the groups, is equally compelling. The efficacy is perhaps due to the *Pitta shamaka, Sheeta virya*, *Vranapachana*, and *Vranaghna* properties of *Jatyadi Kwath Gandoosha*. In group A, the mean cm seen in Photography of mucosa at the first visit was 0.31±0.24, which decreased to 00±0.01 on the 8th day. In group B, the mean cm seen in Photography of mucosa at first visits was 0.38±0.23, which is reduced to 0.00±0.01 on the 8th day showing non-significant changes. However, the a significant difference between the two groups, with p-values of 0.0001* in group B and 0.0002* in group A.

In the local mode of action of *Gandusha* it increases the local defense mechanism, enhances both mechanical and chemical digestion of food, removes metabolic wastes, produces a soothing effect on lesions like ulcers, and strengthens muscles of the oral cavity (10). In the systemic mode of action, because the sublingual region is tiny and highly vascular, lipid-soluble drugs can enter systemic circulation quickly. Most of the *Dravyas* given for *Gandusha* are *Sukoshna (lukewarm),* so raised temperature causes an increase in vascular permeability, thereby enhancing systemic absorption of drugs. The drug used in *Gandusha* stimulates the parasympathetic fibers of the salivary gland and causes the secretion of saliva. The parasympathetic fibers stimulate acinar cells and widen salivary gland blood vessels. Further, saliva stops bacterial growth by separating the materials, which work as culture media to develop the microbes. The Proline-rich proteins present in saliva have antimicrobial effects; in saliva, immunoglobulin (Ig) is said to have anti-bacterial & anti-viral action (11).

The Probable Mechanism of Action of *Jatyadi Kwatha Gandusha*

1. *Jati* (*Jasminum grandiflorm* L) is having *tikta(*bitter*) Kashaya rasa (*astringent taste*) laghu (*light*) sheeta* (cold*) guna, ushna virya(*hot potency*),* and *katu vipaka* (light to digest) *Acharya Vagbhata* while explaining the functions of rasa, mentioned tikta rasa act as *lekhana, dhatunashana*, Shoshana of *meda, vasa, majja,* and *lasika* i.e., it acts as *shothahara.* It may help increase Vrana's tensile strength and remove slough tissue; maybe the drug acts as *lekhana, shoshana of meda, vasa, majja,* and *lasika,* i.e., it acts as *shothahara (*anti-inflammatory*), vrana shodhana*(wound purify*),* and *vrana ropana(*wound healing*)* (12). *Kashaya rasa* act as both *Vrana shodhana* and *Vrana ropana*. It forms a protective covering over the wound area and helps contract wounds. *Katu vipaka* decreases the doshas with the above-said *guna karmas* of *Jati* and enhances the *Vrana ropana*. According to pharmacology, *Jati* mainly contains tannins. The leaf extract of *Jasminum grandiflorum* forms the protective covering on the wound's surface, which helps in wound healing activity (13). The anti-ulcer activity of leaves possibly has the soothing property of essential oils or protein precipitating property of tannins which combine tissue protein and act as mild antiseptics(14).

2. *Guduchi* (*Tinospora cordifolia*) has beneficial effects on the immune system and has been tested successfully for its anti-allergic, anti-oxidant, immunomodulatory, and anti-ulcer activity (15,16). *Guduchi* assembles important anti-inflammatory activity (17). *Guduchi* has *Rasayana* effect as well as anti-bacterial (18).

3. *Yavasa (Alhagi camelorum* Fisch*)* is a medicinal plant in folklore. Traditionally, it treats metabolic, Gastrointestinal, and liver disorders, wound healing, diuretics, rheumatic conditions, migraines, fever, warts, and rash. The watery extract of *Yavasa* showed significant protective and anti-secretory effects (19). It is considered a medicinal plant with prospective potent flavonoids. Other biological activities, such as anti-oxidant, antidiarrheal, antinociceptive, and ureteral stone expulsion are also been reported from this plant (19).

4. *Daruharidra (Berberis aristate* DC*)* are *Kashaya rasa, Laghu, Ruksha guna, Ushna virya, Katu vipaka* are *Shothahara* and *Vedanastapana*. Berberine's chemical constituents are believed to have various pharmacological effects, such as anti-bacterial, anti-neoplastic, ophthalmic, antipyretic, anti-diabetic, cardiotonic, and hepatoprotective activities (20). *Berberis aristata* contains protoberberine and bis isoquinoline type of alkaloid. Berberine, with a yield of 2.23 %, is the most abundant alkaloid found in *B. aristata,* followed by palmatine (21).

5. *Draksha (Vitis vinifera* L*)* The Drug *Draksha* is *Madhura* in *Rasa, Snigdha, Guru, Mrudu guna, Sheeta, Veerya*, and *Madhuravipaka*. It is *Vatapittashamaka*. The drug acts on Dushita pitta and is effective in restoring pitta to normalcy. Draksha reduces the number of ulcers, maybe due to a higher polyphenol content or a powerful anti-oxidant, which may contribute to their action. (22). *Draksha* fruit is rich in sugars, organic acids, and bioflavonoids. Raisins contain calcium, magnesium, potassium, and ascorbic acid, i.e., the oxidized form of ascorbic acid, which helps absorb the available iron (23,24).

6. Madhu (*Apis mellifera Linn)* stimulates tissue regeneration, angiogenesis, and fibroblast activity. Studies found that madhu helps in anti-bacterial and lesion-healing effects without manifesting any adverse effects (25,26). Madhu may have a direct nutrient effect on regenerating tissue because it contains a broad scale of amino acids and vitamins. Vitamin C in *Madhu* is essential in collagen synthesis. *Madhu* may increase the oxygenation of tissues to speed healing (27,28). Honey is a natural compound shown efficacy in wound care,

which helps in healing the growth of common pathogenic organisms that grow in the area of soreness (26). It is believed to be due to fructose, besides vitamins and minerals (28,29).

The Probable mechanism of action of *Triphala Kwatha Gandusha* (Controlled Drug)

1. *Haritaki* (*Terminalia chebula Retz*) is having *Pancha rasa, Laghu, Ruksha guna Ushna veerya, Madhura vipaka* are *Shothahara, Vedanastapana, Vranaropana.* (30) *Haritaki* is the solitary ingredient in *Triphala*. This medicine was used in wound healing, fungal infections, inflammations of the mucous membrane of the buccal cavity, and internally as a rejuvenating, astringent, purgative, stomachic, and laxative (30).

2. *Vibhitaki (Terminalia bellirica* Roxb.) found that the plant has multiple principal phytoconstituents. These compounds were said to be responsible for antimicrobial, antioxidant, analgesic, immunomodulatory, etc. (31,32).

3. *Amalaki* (*Emblica Officinalis Gaertn*.) is *Amla rasa pradhana* which increases the quality and quantity of *Rakta dhatu.* Regarding *Durbalata*, the result may be attributed to the *shamana* of *Pitta Dosha* by *Amalaki churna* greater extent and due to *Rasayana Vayasthapana*, *Virechanopaga*, *Deepana*, *Pachana*, *Tridoshahara* especially *Pittashamaka dravya* acts on *Dhatu Shithilata* properties that are necessary for *Dhatukshayaja vikaras* which removes *Dhatu Shaithilya*. (33).

4. *Triphala* is combined with all three of them and which are reported to have vitamin C, ellagic acid, gallic acid, tannins, flavonoids, etc., which are anti-inflammatory, analgesic, anti-cancer, and many activities (34). The safety profiles of *Jatyadi kwatha Gandusha* and *Triphala Kwatha Gandusha* were good, with no adverse drug reactions observed.

Conclusion

In all criteria, the trial drug (*Jatyadi kwatha Gandusha*) and the Control drug, (*Triphala Kvatha Gandusha*) are comparable. Between the groups *Jatyadi Kwatha Gandusha* and *Triphala, Kwatha Gandusha* is equivalent and exhibits good results in treating *Pittaja Mukhapaka,* particularly Aphthous ulcer. *Jatyadi Kwatha Gandusha* and *Triphala Kwatha Gandusha* performed well and demonstrated statistically significant favorable outcomes within the Group in terms of discomfort, burning sensation, difficulty chewing and ingesting, excessive salivation, inflammation, size of ulceration, and number of ulcerations. Even though there is a limitation due to fewer sample size of the sample but recommendation for the further scope of the study are necessary for the clinical trials as all types of *Mukhapaka* can be considered and a comparative study is to be done on the effect of *Bahya chikitsa* with *Abhyantara chikitsa.*

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