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Efficacy of Druva Siddha Ghrita Gandusha in Management of Pittaja Mukhapaka with Special reference to Aphthous Ulcer: A Randomized Controlled Clinical Trial

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ABSTRACT

Pittaja Mukhapaka is a common condition observed among patients visiting the Ear, Nose, and Throat (ENT) outpatient department. It presents with symptoms such as oral mucosal inflammation, ulceration, and a burning sensation, often linked to Aphthous ulcers (Pittaja Mukhapaka). While modern medicine offers treatments like anti-inflammatory drugs, topical corticosteroids, and tetracyclines, these options have certain limitations. In Ayurveda, Druva Siddha Ghrita is a well-known polyherbal formulation traditionally used for oral disorders. Composed of ingredients like Jati Patra, Guduchi, Draksha, Daru Haridra, Yavasa, Haritaki, Vibhitaki, Madhu, and Amalaki, this remedy is referenced in classical texts such as
Yogaratnakara and Bhaishajya Ratnavali for managing oral health issues. Materials and Methods: To assess the efficacy of Druva Siddha Ghrita in treating Mukha Rogas, a study was conducted involving 30 participants. They were randomly divided into two groups: Group A received Gandusha (oil pulling therapy) with Druva Siddha Ghrita and Madhu (honey). Group B was administered Triphala Siddha Ghrita along with Madhu. Results: Both groups showed complete relief from discomfort, burning sensations, and excessive salivation. Statistical analysis revealed a significant p-value, indicating that both treatments were equally effective. Conclusion: The study confirmed that Druva Siddha Ghrita Gandusha and Triphala Siddha Ghrita are effective in managing Pittaja Mukhapaka, providing a viable Ayurvedic alternative to conventional therapies.

Keywords: Ayurvedic Polyherbal Drug, Gandusha, Druva Siddha Ghrita, Pittaja Mukhapaka, Triphala Siddha Ghrita

1. INTRODUCTION

In the realm of *Ashtanga Hridaya*, the clinical description of *Pittaja Mukhapaka* appears to echo the modern understanding of aphthous ulcers. Hallmark symptoms observed include a pronounced burning sensation, multiple recurrent oral ulcers with a characteristic yellowish base, and inflamed, reddened mucosa (1). Globally, aphthous ulcers (analogous to *Pittaja Mukhapaka*) impact a substantial proportion of the population, with prevalence rates spanning from 2% to a staggering 66%. In India alone, the lifetime prevalence is notably high at 50.3% (2).According to Ayurveda's timeless wisdom, *Agni* — the metaphorical inner fire — fuels growth, radiance, and immunity when nurtured through proper diet (3). However, imbalance

among *Dosha*, *Dhatu*, and *Mala* can derail psychological well-being, precipitating conditions such as *Pittaja Mukhapaka*. The exact causative factors remain elusive but have been associated with hormonal imbalances, oral trauma, toxicity from certain medications, irritating foods, nutritional deficiencies, and stress-induced disturbances (4). While modern medicine recommends interventions like anti-inflammatory agents, topical corticosteroids, and antibiotics such as tetracycline for managing aphthous ulcers (*Pittaja Mukhapaka*), these treatments often fall short of delivering sustained relief (4). In contrast, classical Ayurvedic texts advocate therapies such as *Kavala* (gargling), *Gandusha* (retention of medicated liquids in the mouth), *Dhumapana* (medicated smoking), *Raktamokshana* (bloodletting), application of *Ksara* (alkaline preparations), and *Agnikarma* (therapeutic cauterization) to manage *Pittaja Mukhapaka* effectively (5). Among these, *Gandusha* stands out and is classified into four distinct types — *Snehana* (oleation), *Shamana* (pacification), *Shodhana* (cleansing), and *Ropana* (healing). Given the ulcerative nature of the disorder, *Ropana Gandusha* combined with wound-healing formulations is particularly indicated (6). *Gandusha* and *Kavala* thus become front-line therapies for managing inflammatory oral conditions like *Mukhapaka*. Driven by this traditional knowledge, a randomized clinical trial was undertaken to evaluate the therapeutic potential of *Druva Siddha Ghrita Gandusha* in treating *Pittaja Mukhapaka* — a condition defined by painful, burning ulcers affecting oral structures such as the lips (*Oshta*), gums (*Dantamula*), teeth (*Danta*), tongue (*Jihva*), palate (*Talu*), and throat (*Kantha*).Notably, both *Yogaratnakara* and *Bhaishajya Ratnavali* extol the virtues of *Druva Siddha Ghrita*, a venerable medicated ghee preparation, in alleviating *Mukhapaka*. Its historic acclaim sparked a need to scientifically validate and authenticate this formulation's traditional merit.The primary ingredients of *Druva Siddha Ghrita* include: *Durva* (*Cynodon dactylon* — Bermuda grass), revered for wound-healing and anti-inflammatory prowess; *Jati Patra* (*Jasminum grandiflorum* — Jasmine leaves), known for soothing inflamed tissues; *Guduchi* (*Tinospora cordifolia* — Giloy), an immunomodulatory and rejuvenating herb; *Haridra* (*Curcuma longa* — Turmeric) and *Daruharidra* (*Berberis aristata* — Indian Barberry), both potent anti-inflammatories and Pitta-balancing agents; *Triphala* (a blend of *Haritaki*, *Vibhitaki*, and *Amalaki*), recognized for detoxification and tissue rejuvenation; and *Ghrita* (clarified butter), which acts as a bio-enhancer for delivering active compounds. Supportive ingredients mentioned in classical references include *Yashtimadhu* (*Glycyrrhiza glabra* — Licorice) for its soothing effects, *Madhu* (Honey) for promoting wound healing, and *Sariva* (*Hemidesmus indicus*) for its cooling, blood-purifying qualities. Quality assessment was carried out through rigorous testing of macroscopic and physicochemical parameters — including color, odor, taste, total ash content, acid-insoluble ash, water- and alcohol-soluble extractives — ensuring compliance with standards outlined in the Indian Pharmacopoeia. The primary aim of this study was to evaluate the efficacy of *Druva Siddha Ghrita Gandusha* in managing *Pittaja Mukhapaka* and to compare its therapeutic outcomes against *Triphala Siddha Ghrita Gandusha*, thereby illuminating the superior treatment pathway for this distressing oral condition.

2. 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, Bharati Vidyapeeth (Deemed to be University) College of Ayurved & Hospital, Pune, Maharashtra 411043, were chosen, regardless of gender, religion, occupation, social-economic status, or other factors, and were treated in the OPD of the Department of Swastha Vritta and Yoga." Bharati Vidyapeeth (Deemed to be University) College of Ayurved & Hospital, Pune, Maharashtra 411043.
Ethical clearance and trial registration number (if clinical trial):: The Institutional Ethics Committee cleared the study (Project No.BVDUCOA/EC/M.D./SWT/2023-24) and this study is registered at http://ctri.nic.in (Registration No. CTRI/2024/03/064602).
Patient Consent: Prior to the initiation of the trial, every patient who agrees to participate is given a written consent form.
Diagnostic criteria: One or more small, round or oval lesions develop on the oral mucosa, leading to painful sores, a burning sensation, inflammation, and difficulties with chewing and swallowing.

Inclusion criteria:

- Patients exhibiting symptoms of *Pittaja Mukhapaka* were included in the study.
- Individuals aged between 18 and 60 years, irrespective of their gender, religion, or occupation, were considered.

Exclusion criteria:

- Patients suffering from conditions such as diabetes, tuberculosis, herpes, AIDS, lichen planus, autoimmune diseases, or any systemic disorder that prolongs ulcer healing were excluded.
- Additionally, disorders where *Gandusha* is contraindicated or cases of traumatic oral ulcers were also excluded.

3. DRUG PREPARATION:

The Raw materials were purchased from local Vendor. Sheetal Analytical Laboratory was used to identify and authenticate *Druva Siddha Ghrita* and *Triphala Siddha Ghrita*. *Druva Siddha Ghrita was prepared according to Sneha Kalpana vidhi.* The Drug was standardized, prepared and packed and stored at In House Quality Control Laboratory, Department of Rasashastra Bhaishajya Kalpana Vigyan, Bharati Vidyapeeth (Deemed to be University) College of Ayurved & Hospital, Pune, Maharashtra 411043.

Table 1: Rasa Panchaka of Druva Siddha Ghrita

Ingredient (English/Sanskrit)	Rasa	Guna	Veerya	Vipaka	Karma (Actions)	Indications
Bermuda Grass (Druva / Dūrvā)	Madhura, Tikta	Laghu, Snigdha	Sheeta	Madhura	Sandhāniya (healing), Stambhana (hemostatic), Shothahara (anti-inflammatory)	Wounds, bleeding disorders, Pitta conditions, ulcers
Indian Barberry (Daru Haridra / Dāruharidrā)	Tikta, Kashaya	Laghu, Ruksha	Ushna	Katu	Pittahara, Krimighna (antimicrobial), Raktashodhana	Liver disorders, eye infections, Pittaja ulcers
Turmeric (Haridra / Haridrā)	Tikta, Katu	Laghu, Ruksha	Ushna	Katu	Shothahara, Raktashodhana, Vranaropana (wound healing)	Inflammation, skin disorders, infections
Giloy (Guduchi / Guḍūchī)	Tikta, Kashaya	Laghu, Snigdha	Ushna	Madhura	Jvaraghna (antipyretic), Rasayana (rejuvenating), Pittahara (Pitta-balancing)	Fever, immunity boost, chronic ulcers
Jasmine Leaves (Jati Patra / Jātīpatra)	Tikta, Kashaya	Laghu, Ruksha	Sheeta	Katu	Shothahara (anti-inflammatory), Raktashodhana (blood-purifying), Vedanasthapana (analgesic)	Oral ulcers, skin inflammation, bleeding gums
Haritaki (Haritakī)	Madhura, Amla, Katu, Tikta, Kashaya	Laghu, Ruksha	Ushna	Madhura	Anulomana (laxative), Rasayana, Deepana (digestive)	Constipation, detoxification, oral health
Vibhitaki (Vibhītaka)	Kashaya	Laghu, Ruksha	Ushna	Madhura	Keshya (hair health), Shothahara, Medhya (brain tonic)	Respiratory issues, cholesterol balance
Amlaki (Āmalakī)	Amla, Madhura, Tikta, Kashaya, Katu	Laghu, Ruksha	Sheeta	Madhura	Rasayana, Vrishya (aphrodisiac), Chakshushya (eye health)	Rejuvenation, diabetes, hyperacidity
Clarified Butter (Ghṛita)	Madhura	Snigdha, Guru	Sheeta	Madhura	Vata-Pitta Shamaka, Brimhana (nourishing), Ojovardhaka (immunity)	Ulcers, burns, nervous disorders
Licorice (Yashtimadhu / Yaṣṭimadhu)	Madhura, Tikta	Guru, Snigdha	Sheeta	Madhura	Shothahara, Vedanasthapana, Rasayana	Cough, throat inflammation, peptic ulcers
Honey (Madhu / Madhu)	Madhura, Kashaya	Laghu, Ruksha	Sheeta	Katu	Sandhāniya, Shramahara (fatigue relief), Krimighna	Wound healing, infections, Kapha balance
Indian Sarsaparilla (Sariva / Śārivā)	Madhura, Tikta	Guru, Snigdha	Sheeta	Madhura	Raktashodhana, Dahaprashamana (burning relief), Vrishya	Skin diseases, fever, blood disorders

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

No.	Ingredient (English/Sanskrit)	Latin Name	Family	Parts used
1.	Bermuda Grass (Druva)	*Cynodon dactylon (L.) Pers.*	Poaceae	Whole plant
2.	Indian Barberry (Daru Haridra)	*Berberis aristata DC.*	Berberidaceae	Root bark
3.	Turmeric (Haridra)	*Curcuma longa L.*	Zingiberaceae	Rhizome
4.	Giloy (Guduchi)	*Tinospora cordifolia (Thunb.) Miers*	Menispermaceae	Stem
5.	Jasmine Leaves (Jati Patra)	*Jasminum grandiflorum L.*	Oleaceae	Leaves
6.	Triphala (Haritaki)	*Terminalia chebula Retz.*	Combretaceae	Fruit
7.	Triphala (Vibhitaki)	*Terminalia bellirica (Gaertn.) Roxb.*	Combretaceae	Fruit
8.	Triphala (Amlaki)	*Emblica officinalis Gaertn.*	Phyllanthaceae	Fruit

9.	Clarified Butter (Ghrita)	-	- (Animal source: Cow)	Milk fat
	Optional/Supportive Ingredients			
10.	Licorice (Yashtimadhu)	*Glycyrrhiza glabra* L.	Fabaceae	Root
11.	Honey (Madhu)	*Apis mellifera* Linn.	Apidae (Bee product)	Processed nectar
12.	Indian Sarsaparilla (Sariva)	*Hemidesmus indicus* L.	Apocynaceae	Root

- ***Triphala*** is a blend of ***Haritaki, Vibhitaki, and Amalaki*** (all fruits).
- ***Ghrita*** is derived from **cow's milk** (no botanical family; classified as *animal product*).

Grouping and Treatment Schedule

This study was conducted at Bharati Vidyapeeth (Deemed to be University) College of Ayurved & Hospital, Pune, Maharashtra-411043. Out of 41 patients screened from the OPD, 30 patients were selected to participate in a randomized controlled clinical trial. Random allocation into two groups was done using an online random number generator. Each group, consisting of 15 patients, was assigned to either *Druva Siddha Ghrita Gandusha* or *Triphala Siddha Ghrita Gandusha* therapy. Group A participants received *Druva Siddha Ghrita Gandusha* along with *Madhu*, administered four times daily for a period of seven days. Group B participants were treated with *Triphala Siddha Ghrita Gandusha*, also four times a day for seven days.

Follow up

Patients were advised to report to the OPD on the 8th and 15th days for follow-up, where evaluations were conducted post-treatment, focusing on improvements observed in both subjective and objective parameters.

Table 3: Group treatment intervention of the *Druva siddha Ghrita* and *Triphala Siddha ghrita* .

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

4. PHOTOGRAPHY OF ORAL MUCOSA

Photography standard operating procedures were adhered to for all subjects throughout the study.

Statistical Analysis

Statistical analysis was performed utilizing the Chi-squared test, Mann-Whitney U test, Wilcoxon matched-pairs test, and independent t-test, with a p-value of less than 0.05 considered statistically significant.

Results

A total of 41 individuals were screened for participation in the trial, with 30 subjects enrolled and 29 completing the study. The participants were assigned to two groups: *Druva Siddha Ghrita Gandusha* (Group A) and *Triphala Siddha Ghrita Gandusha* (Group B), consisting of 15 patients in Group A and 14 in Group B. Observational data from the 29 registered patients were collected and analyzed based on factors such as age, gender, occupation, habits, dietary patterns, educational background, and others, as presented in Tables 6, 7, and 8. The distribution of patients across these various factors is outlined below.

Age Groups

The age distribution of the 30 patients is presented. In Group A, 60% of patients were aged between 18 and 30 years, while 40% were between 31 and 60 years, with a mean age of 32.47 ± 9.22 years. For Group B, 80% were in the 18–30 year age range, and 20% were between 31 and 60 years, with a mean age of 28.60 ± 11.21 years. Overall, 70% of the patients were aged 18–30 years, and 30% were aged 31–60 years, with a mean age of 30.53 ± 10.27 years. Further details are provided in Table 6.

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:

The gender distribution revealed that males constituted 33.33% of Group A, while females represented 66.67% of Group B. Among the total 30 patients from both groups, 53.33% were male and 46.67% were female. Overall, 43.33% of the subjects were male, whereas 56.67% were female. The majority of patients in this study were female, as detailed in Table 7. This trend may be attributed to heightened responsibilities and hormonal fluctuations during menstruation and pregnancy, which can increase stress and mental disturbances, eventually causing metabolic changes.

Religion:

Religion-wise distribution revealed that in Group A, 93.33% of patients were Hindu and 6.67% were Muslim. In Group B, 80% were Hindu, 13.33% were Christian, and 6.67% were Muslim. Overall, 86.67% of the patients identified as Hindu, while 6.67% each were Christian and Muslim.

Seconomic Status (SES)

The distribution of socio-economic status indicated that in Group A, 86.67% of patients belonged to the middle socio-economic class and 13.33% to the upper class. In Group B, 80.00% were from the middle socio-economic class and 20.00% from the upper class. Overall, 83.33% of patients were categorized under the middle socio-economic status, while 16.67% belonged to the upper class. The majority of registered patients were from the middle-income group.

Occupation:

The occupational distribution revealed that in Group A, 33.33% had sedentary work, 66.67% had moderate activity occupations, and none were engaged in labor-intensive jobs. In Group B, 40.00% had sedentary occupations, 53.33% had moderately active work, and 6.67% were involved in labor work. Overall, 36.67% of patients were engaged in sedentary jobs, 60.00% in moderately active occupations, and 3.33% in labor-intensive professions.

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 of the study participants is detailed in Table 8.

- **Ahara (Dietary habits):** Among the 30 subjects, 40.00% followed a purely vegetarian diet, while 60.00% consumed a mixed diet.
- **Ahara Time (Meal timings):** A majority of patients (53.33%) reported irregular meal timings, while 46.67% maintained a regular eating schedule.
- **Rasa (Taste preference):** In Group A, 33.33% favored Madhura (sweet), 13.33% preferred Amla (sour), none preferred Lavana (salty), and 53.33% leaned towards Katu (pungent) taste. In Group B, 20% favored Madhura, 26.67% Amla, 6.67% Lavana, and 46.67% Katu. Overall, among all subjects, Madhura was preferred by 26.67%, Amla by 20.00%, Lavana by 3.33%, and Katu by 50.00%. Preferences for Tikta (bitter) and Kashaya (astringent) tastes were not observed. The predominant taste inclination among patients was towards Katu Rasa.
- **Nidra (Sleep patterns):** Sleep history revealed that in Group A, 40.00% of subjects enjoyed sound sleep, while 60.00% experienced disturbed sleep. In Group B, 46.67% had sound sleep, whereas 53.33% suffered from disturbed sleep. A major contributing factor appeared to be excessive mobile phone usage, leading to disruption of circadian rhythms and metabolic processes, ultimately resulting in Mukhapaka. Consequently, a significant proportion of patients reported disturbed sleep during night time.
- **Agni:** In Group A, 26.67% exhibited Samagni (balanced digestion), 66.67% had Mandagni (slow digestion), 6.67% had Vishamagni (irregular digestion), and none exhibited Tikshnagni (sharp digestion). In Group B, 20% had Samagni, 60% showed Mandagni, 13.33% had Vishamagni, and 6.67% had Tikshnagni. Overall, Samagni was found in 23.33% of the patients, Mandagni in 63.33%, Vishamagni in 10%, and Tikshnagni in 6.67%. Thus, Mandagni was the most prevalent type of Agni among the subjects.
- **Koshta:** In Group A, Mrudu Koshta (soft bowel habit) was present in 26.67% of patients, Madhyama Koshta (moderate bowel habit) in 13.33%, and Krura Koshta (hard bowel habit) in 60.00%. Similarly, in Group B, Mrudu Koshta was found in 6.67%, Madhyama Koshta in 33.33%, and Krura Koshta in 60.00%. Overall, 16.67% had Mrudu Koshta, 23.33% had Madhyama Koshta, and 60.00% had Krura Koshta. Krura Koshta was the most dominant pattern observed.
- **Vyasana:** Group A showed 20.00% of individuals consuming alcohol, 13.33% smoking, 20.00% using tobacco, 33.33% with no addiction, and 13.33% with other addictions. Group B showed 20.00% with alcohol use, 6.67% with tobacco use, 60.00% with no addictions, and 13.33% with other forms of addiction. Overall, 20.00% consumed alcohol, 6.67% smoked, 13.33% used tobacco, 46.67% had no addictions, and 13.33% had other addictions.
- **Vyayama**: Analysis revealed that in Group A, 13.33% of participants reported normal exercise habits, 60.00% exercised less than normal, 26.67% had moderate exercise levels, and none engaged in excessive exercise. In Group B, none reported normal exercise habits, 66.67% had low physical activity, 20.00% maintained moderate exercise routines, and 13.33% engaged in excessive exercise. Overall, 6.67% had normal exercise habits, 63.33% exercised less than required, 23.33% had moderate activity levels, and 6.67% exercised excessively.

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

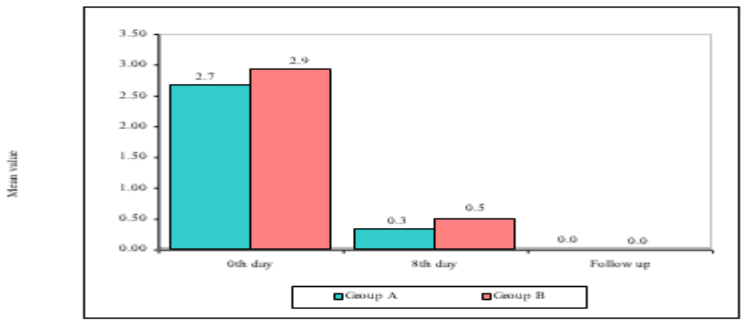
Table 8: Personal history of subjects in the study

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		

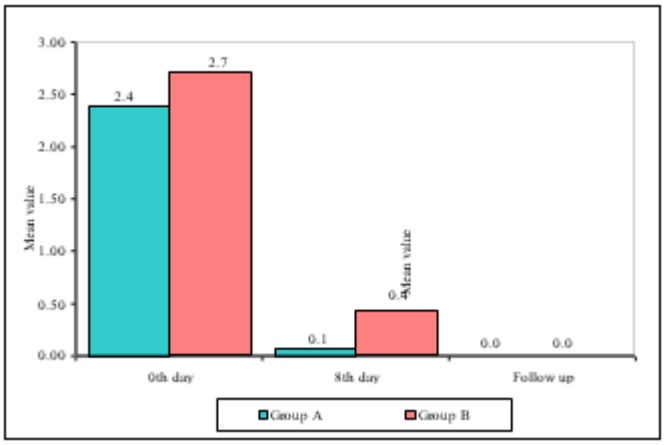
In the present investigation, the mean pain score in Group A was observed to be 2.67±0.90 on the 0th day, which showed a significant reduction to 0.33±0.49 by the 8th day, with a highly significant p-value of 0.0010. Additionally, further improvement was noted from the 8th day to the follow-up period, with a p-value of 0.0431.Similarly, in Group B, the mean pain score recorded on the 0th day was 2.93±0.27, which markedly decreased to 0.52±0.50 by the 8th day, with a significant p-value of 0.0010*. From the 8th day to the follow-up, continued improvement was observed with a p-value of 0.0180*.Upon comparative statistical analysis between the groups, Group A demonstrated superior outcomes over Group B, as illustrated 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



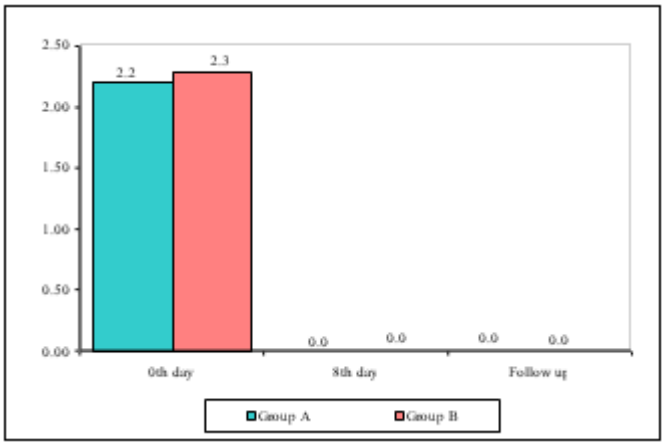
Burning Sensation: *In Group A, the mean burning sensation score recorded at the initial visit (0th day) was 2.40±0.99, which significantly declined to 0.07±0.26 by the 8th day, with a highly significant p-value of 0.0010*, and continued to show improvement at follow-up.In Group B, the mean burning sensation score on the 0th day was 2.71±0.61, which also reduced notably to 0.43±0.51 by the 8th day (p=0.0010*), with further significant improvement noted from the 0th day to follow-up (p=0.0010*) and from the 8th day to follow-up (p=0.0277*).Comparative statistical evaluation highlighted a significant difference between the two groups, with Group A exhibiting superior results over Group B, as illustrated 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



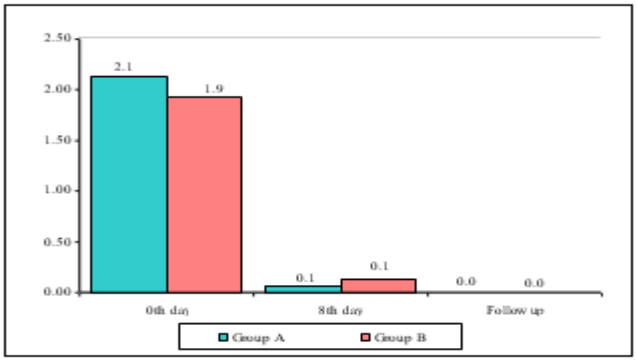
Difficulty in chewing: In Group A, the mean score for chewing difficulty was 2.20±0.94 on the initial visit (Day 0), which significantly decreased by the 8th day (p=0.0010) and continued to show marked improvement through the follow-up period (p=0.0010). No chewing difficulties were reported from the 8th day onwards until the follow-up.In Group B, patients exhibited a mean chewing difficulty score of 2.29±2.00 at baseline, which also declined significantly from Day 0 to Day 8 and from Day 0 to the follow-up (p=0.0010* for both comparisons).Statistical analysis revealed significant improvements within both groups individually, with outcomes being comparable between Group A and Group B, as depicted in Figure 3.

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



Excessive Salivation: In Group A, the mean excessive salivation score recorded at the initial visit (Day 0) was 2.13±1.13, which significantly reduced to 0.07±0.26 by the 8th day (p=0.0015) and continued to improve at follow-up (p=0.0015).In Group B, the mean score for excessive salivation was 1.93±1.27 on Day 0, which also showed a significant decline to 0.14±0.36 by the 8th day (p=0.0033*) and maintained improvement through the follow-up period (p=0.0033*).Although both groups demonstrated statistically significant reductions in symptoms, the comparative analysis revealed similar outcomes between Group A and Group B, as illustrated in Figure 4.

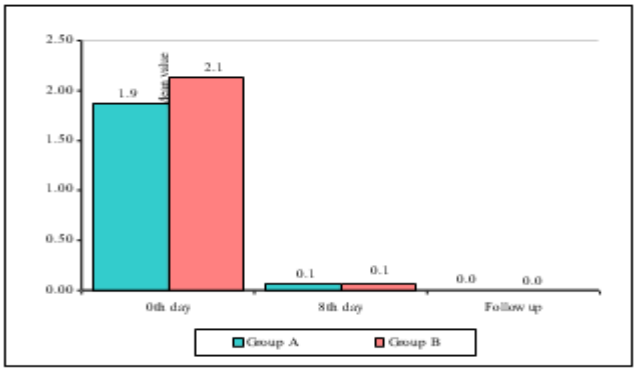
Figure 4: Comparison of Group A and Group B with a status of excessive salivation on the 0th day, 8th day, and follow-up



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

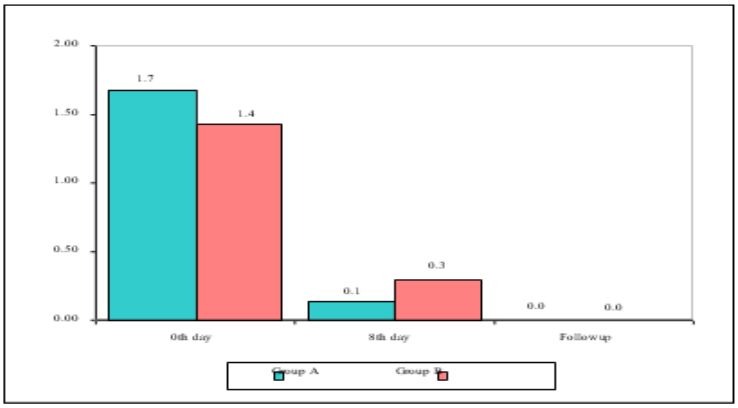
Inflammation: In Group A, the mean inflammation score at the initial visit (Day 0) was 1.87±0.64, which significantly decreased to 0.07±0.26 by the 8th day (p=0.0007) and remained consistent through follow-up (p=0.0007).In Group B, the mean inflammation score on Day 0 was 2.14±0.86, which also showed a significant reduction to 0.07±0.26 on the 8th day (p=0.0010*) and remained low through follow-up (p=0.0010*).When comparing the two groups, no statistically significant difference was observed, as demonstrated 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: In Group A, the mean score for ulcer size (degree) at the first visit (Day 0) was 1.67±0.49, which significantly reduced to 0.13±0.35 by the 8th day (p=0.0007) and continued to show improvement at follow-up (p=0.0007).In Group B, the mean ulcer size score at baseline was 1.43±0.51, which decreased significantly to 0.29±0.47 on the 8th day (p=0.0015*) and showed further improvement through follow-up (p=0.0010*).Although both groups showed statistically significant reductions in ulcer size, Group B demonstrated a more pronounced effect compared to Group A, as 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: In Group A, the mean number of ulcerations at the first visit was 1.27±0.59, which significantly decreased. No ulcerations were observed from the 8th day through follow-up, with a p-value of 0.007.In Group B, the mean number of ulcerations at the initial visit was 1.07±0.27, and no ulcerations were noted from the 8th day to follow-up (p=0.0010*) and from the first visit to follow-up (p=0.0010*).Statistical significance was observed within both groups, with the outcomes being similar in each, 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

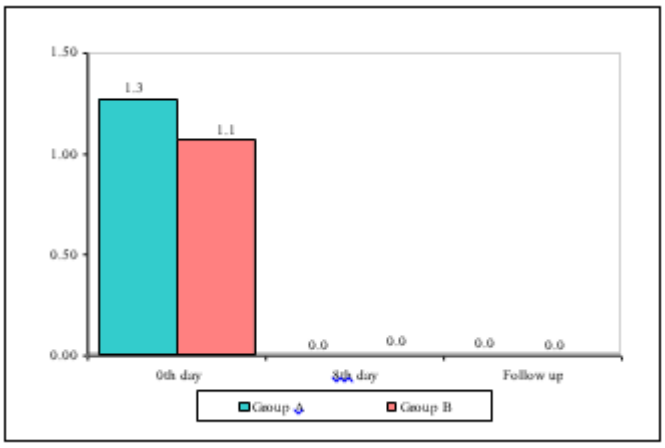


Table 9: Comparison of Group A and Group B with subjective parameters on the 0th day, 8th day, and follow-up by Mann-Whitney U test

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	96.43	3.4078	0.0007*

		day			
		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: In Group A, the mean visible ulcer size in mucosa photography at the first visit was 0.31±0.24 cm, which drastically decreased to 0.00±0.01 cm on the 8th day. This change is depicted in Figure 10.

In Group B, the mean visible ulcer size at the first visit was 0.38±0.23 cm, which reduced to 0.00±0.01 cm by the 8th day, showing minimal change.

However, statistical analysis revealed a p-value of 0.0001 for Group B and 0.0002 for Group A, indicating clinically significant changes between the groups, though not within the groups themselves. These results are shown 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

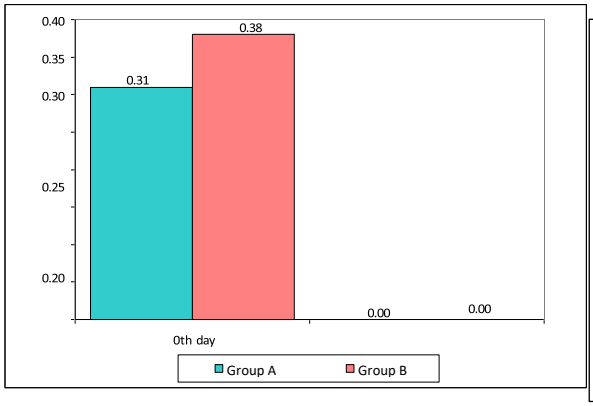


Fig. 9: Before treatment

Fig. 9: After treatment

5. DISCUSSION

The total number of patients listed for the study was 41, with 30 patients enrolled, and 29 completing the treatment as per protocol, while one patient dropped out. The primary reason for the dropout was irregular follow-up visits. In this clinical trial, the largest proportion of patients, 70%, were in the 18-30 age group, which is considered the peak stage of pitta according to Ayurveda (8). Of the participants, 56.67% were female and 43.33% were male. Hormonal fluctuations during menstruation and pregnancy often lead to increased stress and mental disturbances, which in turn can cause metabolic irregularities (9). Regarding religion, the majority of patients were Hindu (86.67%), followed by Christian (6.67%) and Muslim (6.67%). In terms of socio-economic status, most patients (83.33%) belonged to the middle class, with 16.67% from the upper socio-economic class. Occupation-wise, most patients had sedentary jobs (36.67%), followed by moderate activity (60.00%) and manual labor (3.33%). Stress, consumption of outside food, irregular meal timings, and poor sleep patterns are all contributing factors that disrupt the circadian rhythm, ultimately impacting metabolism. These factors play a significant role in the frequent occurrence of oral ulcers, which are commonly seen in this demographic.

In this study, the majority of patients reported consuming a mixed diet (60.00%), with 40.00% following a vegetarian diet, indicating that most patients were non-vegetarian. Regarding their dietary habits, a greater portion of patients (53.33%) had irregular eating patterns, while 46.67% followed a more consistent diet. In terms of taste preferences (Rasa), most patients favored Katu rasa (50.00%), followed by Madhura (26.67%), Amla (20.00%), and a small proportion chose Lavana (3.33%). No patients preferred Tikta or Kashaya. The dominance of Katu rasa suggests a potential aggravation of Pitta Dosha. When analyzing sleep patterns, a majority of patients (56.67%) reported disturbed sleep, while 43.33% experienced sound sleep. This disturbance could be linked to mobile phone usage, which may disrupt circadian rhythms and contribute to metabolic changes, possibly leading to conditions like Mukhapaka. Regarding digestive fire (Agni), a significant number of patients (63.33%) exhibited Mandagni, while fewer had Samagni (23.33%), Vishamagni (10.00%), and Tikshnagnis (6.67%). The presence of Mandagni likely caused metabolic disruptions, impacting nutrient absorption and potentially contributing to Mukhapaka. Such digestive imbalances could indirectly affect disease progression by causing deficiencies and altering tissue metabolism (Dhatukshaya), thereby worsening the clinical condition. In terms of gastrointestinal constitution (Koshta pravrutti), most patients were of the Madhyama type (60.00%), with some categorized as Mrudu (16.67%) and the remaining as Prakrita (23.33%). Regarding lifestyle habits, a percentage of patients (20.00%) consumed alcohol, 6.67% smoked, 13.33% used tobacco, and 13.33% were addicted to other substances like tea and coffee. Physical activity levels revealed that a large proportion of patients (63.33%) had low levels of exercise, while 23.33% exercised moderately. A smaller percentage (6.67%) exercised normally, and another 6.67% engaged in excessive exercise. These variations in physical activity may have an impact on Dhatu Sarata and Samhanana, as reflected in the patients' overall health.

Upon comparing pain levels across groups, Group A statistically outperformed Group B. Participants in Group A experienced greater relief, which can be attributed to the properties of the Gandusha Ghrita, rich in Tikta (bitter) and Kashaya (astringent) Rasas. These Rasas are traditionally acknowledged for their Shoolahara (pain-alleviating), Vedanasthapana (pain-stabilizing), Vranapachana (wound-maturing), and Pittashamaka (Pitta-pacifying) effects. The action of Kashaya Rasa, by diminishing pain perception, contributed to the reduction of Ruja (pain). Furthermore, it may exert a calming influence by mitigating external irritation. Following Gandusha therapy, a statistically significant improvement in Daha (burning sensation) was observed in Group A compared to Group B. Outcomes assessed on the 8th and 15th days post-treatment revealed marked relief from burning discomfort. This therapeutic success may be credited to the Tikta, Madhura (sweet), and Kashaya Rasas, along with the Pittahara (Pitta-pacifying) and Daha Prashamana (burning alleviating) properties of Druva Siddha Ghrita Gandusha and Triphala Siddha Ghrita Gandusha. Tikta Rasa, known for its action on nociceptors, likely plays a role in reducing pain perception, thus decreasing the burning sensations experienced by the patients. When analyzing difficulty in chewing between the groups, both showed significant improvement from the 0th day to the 8th day, with a p-value of 0.0010*. Although each group improved significantly within itself, there was no substantial difference between the two groups. Similarly, excessive salivation showed a 100% decrease within Group A from baseline to follow-up, with a p-value of 0.0015*. Group B demonstrated an equivalent within-group improvement, but comparison between groups did not reveal statistical significance.On evaluating inflammation, statistical significance was observed within Group A compared to Group B, though the overall effectiveness between the groups remained similar. This therapeutic action may be linked to the Tikta, Madhura, Kashaya Rasa dominance, and the Pitta Shamaka and Vranaghna (wound-healing) properties inherent in Druva Siddha and Triphala Siddha Ghrita Gandusha.The extent of ulceration showed statistically significant improvement within both groups, with a p-value of 0.0007* for Group A and 0.0015* for Group B. However, comparative analysis between groups indicated equal effectiveness. This outcome is possibly due to the Vranashodhana (wound-cleansing) and Vranaropana (wound-healing) activities of Triphala Siddha Ghrita Gandusha. Analysis of the number of ulcers revealed significant reductions within both groups ($p = 0.0007$* for Group A and $p = 0.0010$* for Group B), and, again, between-group comparisons showed similar efficacy. These results are likely influenced by the Pitta Shamaka, Sheeta Virya (cold potency), Vranapachana, and Vranaghna attributes of Druva Siddha Ghrita Gandusha.Photographic evaluation of mucosal lesions showed that in Group A, the mean lesion size decreased from 0.31±0.24 cm at the first visit to nearly 0.00±0.01 cm by the 8th day. In Group B, a similar reduction from 0.38±0.23 cm to 0.00±0.01 cm was noted. Although within-group improvements were statistically significant ($p = 0.0001$* in Group B and $p = 0.0002$* in Group A), intergroup comparison revealed no major differences in outcomes.

In its local action, Gandusha fortifies the oral cavity's defense mechanisms, improves both mechanical and chemical aspects of digestion, assists in the elimination of metabolic waste products, soothes lesions such as ulcers, and contributes to the strengthening of oral musculature (10).

In its systemic action, Gandusha leverages the highly vascular and compact nature of the sublingual region, allowing lipid-soluble constituents to swiftly enter the systemic circulation. Most of the Dravyas used in Gandusha are administered Sukoshna (lukewarm), and this mild warmth enhances vascular permeability, facilitating more efficient systemic absorption of the medicinal substances. The act of Gandusha also stimulates the parasympathetic fibers associated with the salivary glands, promoting increased saliva production by activating the acinar cells and dilating the blood vessels supplying these glands. Moreover, the surge in saliva production plays a defensive role by diluting and removing substances that could serve as growth media for microbes, thereby inhibiting bacterial proliferation. Notably, Proline-rich proteins in saliva contribute potent antimicrobial properties, while immunoglobulins (Ig) present in saliva offer additional antibacterial and antiviral defenses (11).

Probable Mechanism of Action of Druva Siddha Ghrita Gandusha:

Jati (Jasminum grandiflorum L.) is characterized by its Tikta (bitter) and Kashaya (astringent) rasa, along with Laghu (light) and Sheeta (cool) gunas, Ushna Virya (hot potency), and Katu Vipaka (pungent post-digestive effect). Acharya Vagbhata, while elaborating on the actions of various rasas, states that Tikta Rasa exhibits Lekhana (scraping), Dhatunashana (depletion of tissues), and Shoshana (drying) effects on Meda (fat), Vasa (muscle fat), Majja (marrow), and Lasika (lymphatic fluid), thereby contributing to Shothahara (anti-inflammatory) action. In the context of wound healing, these properties may contribute to enhancing the tensile strength of Vranas (wounds) and aid in the debridement of slough tissue. Thus, Jati, by virtue of its Lekhana (scraping), Shoshana (absorbing), Shothahara (inflammation-reducing), Vrana Shodhana (cleansing wounds), and Vrana Ropana (wound healing) attributes, likely supports the overall therapeutic efficacy of Druva Siddha Ghrita Gandusha (12). Kashaya Rasa serves a dual purpose, acting as both a Vrana Shodhana (wound cleanser) and Vrana Ropana (wound healer). It aids in forming a protective layer over the wound site, promoting wound contraction and facilitating recovery. Katu Vipaka, through its property of dosha pacification, further supports and amplifies the healing process initiated by the Guna Karmas of Jati. From a pharmacological standpoint, Jati (Jasminum grandiflorum) is rich in tannins. The leaf extracts of this plant are known to create a protective film over wounds, thereby assisting in the natural wound-healing mechanism (13). Additionally, the leaves exhibit notable anti-ulcer activity, possibly attributed to the soothing nature of their essential oils or the protein-precipitating action of tannins. These tannins bind to tissue proteins and act as gentle antiseptics, further encouraging tissue repair and defense (14).

Guduchi (Tinospora cordifolia) has been recognized for its positive influence on the immune system, demonstrating notable anti-allergic, antioxidant, immunomodulatory, and anti-ulcer activities through various studies (15,16). It also

exhibits significant anti-inflammatory properties (17). Beyond these, Guduchi is esteemed in Ayurveda for its Rasayana (rejuvenative) effects and has been documented for its antibacterial activity as well (18). Yavasa (Alhagi camelorum Fisch), a revered herb in traditional medicine, has been utilized to address a variety of conditions, including metabolic disorders, gastrointestinal issues, liver ailments, wound healing, rheumatic diseases, migraines, fevers, warts, and skin rashes. The aqueous extract of Yavasa has demonstrated remarkable protective and antisecretory properties in experimental studies (19). Furthermore, this plant is a promising source of potent flavonoids, and has been associated with various biological activities such as antioxidant, antidiarrheal, antinociceptive (pain-relieving), and ureteral stone expulsion effects (19).

Daruharidra (Berberis aristata DC) possesses Kashaya Rasa (astringent taste), along with Laghu (light) and Ruksha (dry) gunas, Ushna Virya (hot potency), and Katu Vipaka (pungent post-digestive effect). It is traditionally known for its Shothahara (anti-inflammatory) and Vedanastapana (pain-relieving) actions.

The principal chemical constituent, Berberine, is attributed with a wide range of pharmacological activities, including antibacterial, anticancer, ophthalmic, antipyretic, antidiabetic, cardiotonic, and hepatoprotective effects (20). Phytochemical analysis reveals that Berberis aristata predominantly contains alkaloids of the protoberberine and bis-isoquinoline types. Among these, Berberine is the most abundant, yielding approximately 2.23%, followed by Palmatine as another significant alkaloid (21).

Draksha (Vitis vinifera L.) is characterized by its Madhura Rasa (sweet taste), along with Snigdha (unctuous), Guru (heavy), and Mridu (soft) gunas. It exhibits Sheeta Virya (cool potency) and Madhura Vipaka (sweet post-digestive effect). Draksha is particularly effective in pacifying Vata and Pitta doshas. It is believed to act on vitiated Pitta, helping to restore it to a balanced state. The ulcer-reducing potential of Draksha may be attributed to its high polyphenol content and potent antioxidant properties (22). Nutritionally, Draksha fruits are rich in natural sugars, organic acids, and bioflavonoids. Additionally, raisins (dried Draksha) provide essential minerals such as calcium, magnesium, potassium, and ascorbic acid (vitamin C), which is known to enhance the absorption of dietary iron (23,24).

Madhu (Apis mellifera Linn), commonly known as honey, is recognized for its ability to stimulate tissue regeneration, angiogenesis (formation of new blood vessels), and the activation of fibroblast activity. Research indicates that honey possesses antibacterial and lesion-healing properties without showing significant adverse effects (25,26). Honey may support tissue regeneration directly by providing a rich supply of amino acids and vitamins. Vitamin C in honey plays a critical role in collagen synthesis, essential for wound healing. Additionally, honey may promote increased oxygenation of tissues, accelerating the healing process (27,28). As a natural substance, honey has proven effective in wound care, aiding in the healing process and inhibiting the growth of common pathogenic organisms in affected areas (26). This is likely due to its content of fructose, along with a variety of vitamins and minerals (28,29).

Probable Mechanism of Action of Triphala Siddha Ghrita Gandusha (Controlled Drug).

1. Haritaki (Terminalia chebula Retz) exhibits Pancha Rasa (five tastes), with Laghu (light), Ruksha (dry) gunas, and Ushna Veerya (hot potency), along with a Madhura Vipaka (sweet post-digestive effect). It is recognized for its Shothahara (anti-inflammatory), Vedanastapana (pain-relieving), and Vranaropana (wound healing) actions (30). Haritaki is the primary ingredient in Triphala and has been traditionally used for wound healing, addressing fungal infections, treating inflammations of the mucous membranes in the buccal cavity, and taken internally as a rejuvenative, astringent, purgative, stomachic, and laxative (30).
2. Vibhitaki (Terminalia bellirica Roxb.) contains several key phytoconstituents believed to contribute to its antimicrobial, antioxidant, analgesic, and immunomodulatory properties (31,32).
3. Amalaki (Emblica officinalis Gaertn.) is primarily Amla Rasa (sour taste), known for improving both the quality and quantity of Rakta Dhatu (blood tissue). Its role in addressing Durbalata (weakness) may be attributed to its Pitta-shamaka (Pitta-balancing) effect, which is enhanced by its Rasayana (rejuvenating), Vayasthapana (anti-aging), Virechanopaga (aids in purgation), Deepana (digestive stimulant), and Pachana (digestion-promoting) qualities. Additionally, Amalaki helps alleviate Tridoshaja vikaras (diseases caused by imbalance of the three doshas) and restores Dhatu Shithilata (tissue weakness), making it beneficial for conditions caused by Dhatu Kshayaja (tissue depletion) (33).
4. Triphala, being a combination of these three potent herbs, is rich in bioactive compounds such as vitamin C, ellagic acid, gallic acid, tannins, and flavonoids, which are known for their anti-inflammatory, analgesic, anti-cancer, and antioxidant activities (34).

Both Druva Siddha Ghrita Gandusha and Triphala Siddha Ghrita Gandusha are considered safe, with no observed adverse drug reactions, supporting their favorable safety profiles.

6. CONCLUSION

Both the trial drug (Druva Siddha Ghrita Gandusha) and the control drug (Triphala Siddha Ghrita Gandusha) are found to be comparable across all criteria assessed. The two treatments—Druva Siddha Ghrita Gandusha and Triphala Siddha Ghrita Gandusha—demonstrate equivalent efficacy in managing Pittaja Mukhapaka, especially in the treatment of aphthous ulcers. Both formulations have shown remarkable outcomes, with statistically significant improvements in symptoms such as discomfort, burning sensation, difficulty in chewing and swallowing, excessive salivation, inflammation, ulcer size, and the number of ulcerations. While the study is constrained by a small sample size, further

investigation is warranted. It is recommended that future clinical trials expand to include all types of Mukhapaka and incorporate a comparative evaluation of the effects of Bahya Chikitsa versus Abhyantara Chikitsa.

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