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Research Article

An open-label pilot study evaluating the effectiveness of *Nava uppu mezhugu* (Internal) and *Peenisa thailam* (External) for the management of *Peenisam* (Sinusitis)

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Abstract

Background: *Peenisam* (Sinusitis) is a common nasal disorder described in Siddha literature, primarily due to derangement of *kabam* (Mucus accumulation). Objective: The study was designed to evaluate the clinical effectiveness of Siddha classic herbo-mineral formulation *Nava Uppu Mezhugu* (Internal) and *Peenisa thailam* (External-Oil Bath) for the management of *Peenisam* (Sinusitis). Methods: The study was conducted in patients diagnosed with *Peenisam* (Sinusitis) at Ayothidas Pandithar Hospital, National Institute of Siddha (IEC No. NIS/26/IEC/2024/M.P/9, CTRI/2024/06/068796) involving 15 patients within age limit of 18 to 60 years based on inclusion and exclusion criteria. Before starting the trial, Informed consent was obtained from each patient. Internal medicine *Nava Uppu Mezhugu* was given at a dose of 56 mg with *Panai vellam* (Palm jaggery), twice a day and External medicine *Peenisa Thailam* was given to take oil bath weekly once for the period of 28 days. The clinical improvement by using Adelaide Disease Severity Score was documented before and after treatment. The treatment was well tolerated and no adverse drug reaction was found during this trial. Results: Biostatistical report of Adelaide Disease Severity Score (ADSS) before and after treatment were statistically analysed using Wilcoxon Signed Rank Test that showed significant P value of 0.00064. Statistical analysis revealed that there is a significant (p value<0.001) difference before and after treatment. Conclusion: The study has concluded that the interventional drug is therapeutically effective and safe for the management of *Peenisam* (Sinusitis).

Keywords: *Peenisam, Sinusitis, Nava Uppu Mezhugu, Peenisa thailam, Siddha medicine, ADSS*

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Introduction

Siddha medicine offers a time-tested, holistic, and personalized approach to health and wellness. By focusing on balance, prevention, and natural healing, it serves not just as a medical system, but as a way of life. The main objective of Siddha treatment is to restore balance through natural and holistic methods. Siddha medicine includes a wide range of therapeutic approaches, such as Internal and External treatments and believed that disease could be avoided by following a disciplined lifestyle, proper food habits, seasonal regimens and ethical living. As described by Siddha literature *Yugi vaithiya chinthamani*, the diseases of nasal origin are 86, one such disease is ***Peenisam*** otherwise known as *Mookadaippu* or *Neerkovai*. The signs and symptoms include headache, lacrimation, sneezing, nasal block, nasal itching, clogged ears, itchy ears, running nose, postnasal drip, absence of taste, which may correlate with sinusitis in modern medicine. *Peenisam*(Sinusitis) arises due to derangement of *Kabam* (Mucus accumulation) along with involvement of *Vatham* (Dysregulation or obstruction of sinus discharge) and *Pitham* (Inflammation), leading to obstruction of nasal channels(1). The paranasal sinuses are aerated cavities in the bones of the face that develop as outpouches of the nasal cavity. Sinuses are lined with respiratory epithelium that includes mucus producing goblet cells and ciliated cells, the mucus blanket is carried towards the sinus openings (ostia). Obstruction of the ostia may lead to retained secretions and sinusitis(2).

Sinusitis is affecting people of all ages worldwide. It significantly impacts quality of life and healthcare systems due to its high

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prevalence and recurrence. Acute sinusitis affects approximately 1 in 8 adults annually. Chronic sinusitis affects around 10–12% of the global population. Studies show that 15–20% of the Indian population experiences some form of sinusitis. Women are slightly more affected than men, and incidence increases with age. Higher prevalence is noted in urban populations due to pollution and allergens.

Conventional management of sinusitis includes antibiotics, antihistamines, nasal decongestants, and corticosteroids. Although these modalities provide symptomatic relief, their long-term use is often associated with recurrence, drug resistance, adverse effects, and incomplete resolution of the disease. Hence, there is a growing need for alternative therapeutic approaches that offer sustained relief with minimal side effects. Siddha management emphasizes restoring humoral balance through internal medications and external therapies, thereby addressing the root cause rather than providing temporary symptomatic relief.

Nava Uppu Mezhugu is a classical herbo-mineral Siddha formulation known for its anti-inflammatory, expectorant and immunomodulatory properties. The unique combination of salts and mineral components facilitates deep tissue penetration and correction of metabolic disturbances, making it particularly effective in chronic inflammatory conditions involving the respiratory tract. A classical Siddha text, *Siddha Vaidhya Thirattu* indicate *Nava Uppu Mezhugu* for treating *Peenisam* (Sinusitis). *Peenisa Thailam*, an external therapeutic oil, is used for nasal application in treating *Peenisam* (Sinusitis) (3). Its local anti-inflammatory and decongestant actions help in clearing nasal passages, improving sinus drainage, and enhancing the bioavailability of the internal medicine. The combined use of internal and external therapies represents a holistic Siddha approach to disease management.

Despite the long-standing use of *Nava Uppu Mezhugu* and *Peenisa Thailam* in *Peenisam*, there is limited clinical evidence validating their efficacy and safety. Therefore, the present study was undertaken to clinically evaluate the therapeutic effectiveness of *Nava Uppu Mezhugu* and *Peenisa Thailam* in the management of *Peenisam* (Sinusitis)

Objective

To evaluate the clinical effectiveness of *Nava Uppu Mezhugu* (Internal) and *Peenisa thailam* (External-Oil Bath) in the management of *Peenisam* (Sinusitis) by evaluating the reduction in clinical symptoms following treatment using Adelaide Disease Severity Score.

Materials and Methods

An Open-label Pilot study was conducted after getting approval from the Institutional Research Review Board and Institutional Ethical Committee clearance (IEC No. NIS/26/IEC/2024/M.P/9) and the trial was registered in Clinical Trial Registry of India (CTRI/2024/06/068796). The Subject selection was made through patients reporting at the OPD with the clinical symptoms of sinusitis and examined clinically for enrolling in the study based on the inclusion and exclusion criteria.

The inclusion criteria include age limit between 18 to 60 years, participants who had Adelaide Disease Severity Score above 12 and with radiological evidence of X-Ray PNS. Patients with a baseline ADSS score exceeding 12, corresponding to the mean value of the total possible score of 25, were considered eligible for inclusion in the study to ensure the recruitment of individuals with moderate to severe disease activity. This inclusion criterion allowed for a meaningful assessment of therapeutic effectiveness and minimized the influence of spontaneous remission commonly seen in mild cases. The exclusion criteria include participants suffering from migraine, diabetes, acid peptic disease, dental Carries and Pregnant Women.

A total of 21 patients with clinically diagnosed cases were screened at the Outpatient Department (OPD) of Ayothidoss Pandithar Hospital, National Institute of Siddha, during the six-month study period. Among them, 15 patients who fulfilled the predefined inclusion and exclusion criteria were enrolled in the study, while six patients were excluded. Written informed consent was obtained from all participants prior to the commencement of the trial.

The treatment protocol commenced with the administration of *Peenisa Thailam* (70 ml) as an oil bath on Day 1. On Day 2, purgation therapy was administered with *Agasthiyar Kuzhambu* (130 mg) along with 10 mL of ginger juice, early in the morning on an empty stomach, followed by a day of rest. This therapeutic sequence was adopted to regulate the deranged humours, facilitate detoxification, and enhance the responsiveness to subsequent medications. From Day 4 onwards, the internal medicine *Nava Uppu Mezhugu* was administered at a dose of 56 mg twice daily after meals, with *Panai Vellam* (palm jaggery) as an adjuvant. Concurrently, *Peenisa Thailam* was prescribed externally at a dose of 70 ml for weekly oil bath application. The treatment regimen was continued for a duration of 28 days.

The treatment was well tolerated, with no major adverse events reported during the study period. Wilcoxon Signed Rank Test was employed to compare the pre- treatment and post- treatment Adelaide Disease Severity Scores.

Drug Profile (3) (4) (6) (7)

I. Internal medicine (*Nava Uppu Mezhugu)* Ingredients

S.No.	Vernacular names	Botanical names	Quantity
1	*Kariuppu*	Table salt	10g
2	*Intuppu*	Rock salt	10g
3	*Pottiluppu*	Petre salt	10g
4	*Kalluppu*	Black salt	10g
5	*Navaccaram*	Ammonium salt	10g
6	*Munkiluppu*	Bamboo salt	10g
7	*Puniru*	Fullers earth	10g
8	*Valaiyaluppu*	Glass gale	10g
9	*Paraiyuppu*	Rock salt	10g
10	*Viram*	*Hydrargyrum percholride*	40g
11	*Karpuram*	*Cinnamomum camphora*	20 g
12	*Milaku*	*Piper nigrum Linn.*	12 g
13	*Cukku*	*Zingiber officinale Mill.*	12 g
14	*Tippili*	*Piper longum Linn.*	12 g
15	*Nervalam*	*Croton tiglium L.*	10 g
16	*Tutti ver*	*Abutilon indicum L.*	Sufficient quantity
17	*Arruttummattic caru*	*Citrullus colocynthis Linn.*	Sufficient quantity
18	*Pacuvin pal*	Cow's Milk	Sufficient quantity

19	*Thiripalaik kiyalam*	Thiriphala Decoction	Sufficient quantity
20	*Taypal*	Mother's Milk	Sufficient quantity

Dosage and duration

56 mg (*Milagalavu*) with *Panai vellam* (Palm jaggery) twice a day for 28 days

II. External medicine (*Peenisa thailam)* Ingredients

S.No.	Vernacular names	Botanical names	Quantity
1	*Notchi charu*	*Vitex negundo Linn.*	2.6l
2	*Karisalai charu*	*Eclipta prostrata L.mant.*	2.6l
3	*Induppu*	Rock salt	20g
4	*Chitrathai*	*Alpinia officinarum Hance.*	20g
5	*Thippili*	*Piper longum Linn.*	20g
6	*Amanakku ver*	*Ricinus communis Linn.*	20g
7	*Kudasapalai ver*	*Holarrhena antidysenterica Wall.*	20g
8	*Kiranthi thagaram*	*Valeriana wallichii L.*	20g
9	*Chukku*	*Zingiber officinale Rosc.*	20g
10	*Kottam*	*Sausserea lappa C.B.Clarke.*	20g
11	*Thetran kottai*	*Strychnus potatorum L.*	20g
12	*Sathakuppai*	*Anethum graveolens Linn.*	20g
13	*Vaividangam*	*Embelica ribes Burm.*	20g
14	*Athimathuram*	*Glycyrrhiza glabra Linn.*	20g
15	Gingelly Oil	*Sesamum indicum L.*	2.6l
16	*Vellattu pal*	Goats milk	Sufficient quantity

Dosage and duration

70 ml, Weekly once oil bath for 28 days.

Procedure for oil bath application

Peenisa thailam was administered externally in the form of an oil bath. 70ml of medicated oil was gently warmed to a lukewarm temperature and applied uniformly over the scalp and body with mild massage. The oil was allowed to remain for approximately 30mins to facilitate absorption and advised to take bath using lukewarm water and herbal bath powder. The oil bath was performed in the morning on empty stomach as per siddha principles and exposure to cold, heavy physical exertion, day sleep to be avoided following the procedure.

Trial drug administration

The investigational drugs, *Nava Uppu Mezhugu* (Internal) and *Peenisa Thailam* (External) were stored in clean, dry, air tight containers to ensure their quality and stability. The drugs were dispensed from the hospital pharmacy to the participants at 7 days interval for a period of 28 days. Internal medicine was packed at a dose of 784mg and external medicine was packed at a dose of 70ml which was replenished at each follow up visit.

Adelaide Disease Severity Score

In the present study, the Adelaide Disease Severity Score (ADSS) was employed as a standardized and validated clinical assessment tool to objectively evaluate the severity of *Peenisam* (sinusitis) and to monitor therapeutic response. ADSS incorporates multiple symptom parameters including nasal obstruction, rhinorrhoea, postnasal drip, headache or facial pain, loss of sense of smell, and overall disease burden, thereby providing a comprehensive measure of disease severity (5). The score is used to assess the severity of sinusitis based on the score of each clinical symptom which an individual response. It provides a total score of 25 and is calculated by summing the score of each clinical symptom.

Symptoms	No symptoms	Mild	Moderate	Severe	Extreme
Nasal obstruction	1	2	3	4	5
Rhinorrhoea	1	2	3	4	5
Postnasal drip	1	2	3	4	5
Headache or facial pain	1	2	3	4	5
Loss of Sense of smell	1	2	3	4	5

The severity of the sinusitis is classified according to the following score:

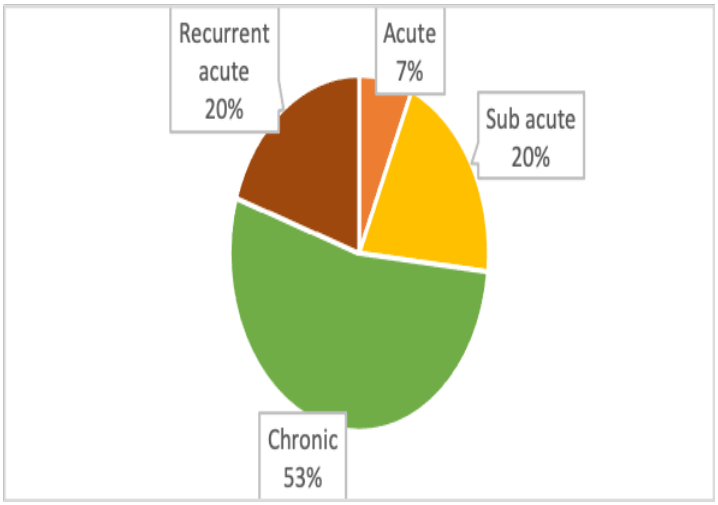
- 0-5: No symptoms
- 6-10: Mild
- 11-15: Moderate
- 16-20: Severe
- 21-25: Extreme

Statistical analysis

Statistical analysis was conducted using the Wilcoxon Signed Rank Test to evaluate the changes in the Adelaide Disease Severity Score before and after treatment.

Results

Figure 1: Duration of Illness



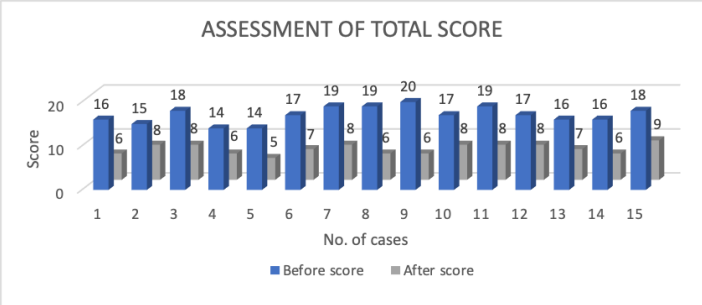
Among 15 cases, 1 case (7%) had Acute sinusitis, 3 cases (20%) had Subacute sinusitis, 8 cases (53%) had Chronic sinusitis, 3 cases (20%) had Recurrent sinusitis suggests that the Siddha formulation has potential efficacy even in long standing sinusitis (Fig 1).

Table 1: Assessment of total score

Number of cases	Before Treatment						After Treatment					
	A	B	C	D	E	T.S	A	B	C	D	E	T.S
1	4	4	2	4	2	16	1	1	1	2	1	6
2	4	4	2	4	1	15	2	1	1	3	1	8
3	5	4	3	4	2	18	2	2	1	2	1	8
4	3	5	3	1	2	14	1	2	1	1	1	6
5	5	5	2	1	1	14	1	1	1	1	1	5
6	4	4	4	3	2	17	2	1	1	2	1	7
7	5	5	3	4	2	19	2	2	1	2	1	8
8	4	5	4	4	2	19	1	2	1	1	1	6
9	4	5	4	5	2	20	1	1	1	2	1	6
10	4	3	4	4	2	17	2	1	2	2	1	8
11	3	5	4	4	3	19	1	1	2	2	2	8
12	4	4	4	3	2	17	2	2	1	2	1	8
13	4	3	3	4	2	16	1	2	1	2	1	7
14	4	4	2	4	2	16	1	1	1	2	1	6
15	5	4	4	4	1	18	2	2	2	2	1	9

***A- Nasal obstruction, B- Rhinorrhoea, C- Postnasal drip, D- Headache or facial pain, E- Loss of sense of smell, T.S- Total Score**

Figure 2: Assessment of total score



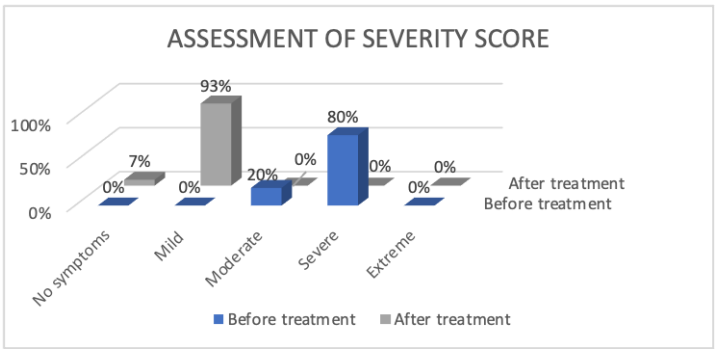
A total of 21 patients were screened; 15 were enrolled and completed the study. No dropouts occurred. The total score for 15 patients was calculated by summing the score of each clinical symptom for each participant through Adelaide Disease Severity Score before and after treatment.

Following the administration of *Nava Uppu Mezhugu* and *Peenisa Thailam*, a marked reduction in ADSS was observed in the majority of patients, with post-treatment scores falling below 9 and ranging between 9 and 5 (Tab 1 & Fig 2). This reduction indicates a significant improvement in clinical symptoms and reflects effective alleviation of disease severity. No adverse drug reactions were reported.

Table 2: Assessment of the severity score

	Before treatment		After Treatment	
	Number of cases	Percentage	Number of cases	Percentage
No Symptoms	0	0%	1	7%
Mild	0	0%	14	93%
Moderate	3	20%	0	0%
Severe	12	80%	0	0%
Extreme	0	0%	0	0%
Total	15	100%	15	100%

Figure 3: Assessment of severity score



Among the 15 patients enrolled, 12 (80%) presented with severe disease and 3 (20%) with moderate disease at baseline. Following treatment, all 12 patients (80%) with severe disease exhibited a reduction in symptom severity and were categorized as having mild disease. Among the three patients (20%) with moderate disease, two patients (13.3%) improved to the mild category, while one patient (6.7%) achieved complete remission of symptoms (Tab 2 and Fig 3). The observed shift from moderate-to-severe disease categories to mild disease or complete remission highlights the clinical significance and therapeutic efficacy of the Siddha intervention.

Table 3: Assessment of the Wilcoxon Signed Rank Test

Variable	Rank	N	Mean	Mean difference	Z value	P value	Inference
Adelaide Disease Severity Score	Negative Rank	15	120	-7.93	-3.4078	0.00064	Significant
	Positive Rank	0	0				
	Ties	0	0				
	Total	15					

Statistical analysis of Adelaide Disease Severity Score was done (Tab 3) with the Wilcoxon Signed Rank Test, that showed significant P value of 0.00064 (<0.05).

Discussion

The present clinical study demonstrated that the Siddha therapeutic regimen consisting of *Nava Uppu Mezhugu* and *Peenisa Thailam* produced significant symptomatic improvement in patients with sinusitis and was well tolerated throughout the study period. Notable reductions in nasal obstruction, rhinorrhoea, post-nasal drip, headache or facial pain, and olfactory disturbances indicate a potential role of the intervention in alleviating mucosal inflammation and promoting sinus drainage. The majority of cases were observed in the 18–30 years age group, particularly among private sector employees, suggesting the influence of occupational and environmental factors such as exposure to pollutants, air-conditioned settings, and recurrent upper respiratory tract infections. Furthermore, the predominance

of chronic sinusitis over acute, subacute, and recurrent forms emphasizes the persistent and recurrent nature of the disease.

According to *Uyir Thathukkal* (Physiological principles) as per *Vatham* (mobility), majority of the cases were affected with *Kirukaran* (restless) due to recurrent sneezing, followed by *Pranan*(vital force for respiration) due to nasal congestion, *Samanan* (equilibrium of body) due to derangement of other *Vadham* and few were affected by *Abanan* (excretory vital function) due to constipation and irregular bowel habits. As per *Pitham* (Metabolism), majority of the cases were affected with *Ranjagam* (blood forming) due to decrease in hemoglobin content. As per *Kabam* (Lubrication), majority of the cases were affected with *Avalambagam* (stability and endurance) due to upper respiratory issues and few were affected with *Santhigam* (joint stability) due to joint pain. According to *Udal Thathukkal* (bodily constituents), majority of the cases were affected with *Saram* (body fluid) due to general body tiredness and few cases were affected with *Seneer* (blood) due to decrease in hemoglobin content. According to the aspect of *Envagai Thervu* (diagnostic principle), most of the cases were observed with *Vadhapitha naadi* (pulse diagnosis) and were belonging to *Kaba neer* in *Neerkuri* (phlegmatic urine in examination). Few of them were affected with *Vizhi* (vision) due to burning sensation of the eyes and also *Malam* (faeces) due to constipation and irregular bowel habits before treatment, where most of them were completely relieved of affected derangements after treatment.

A Dissertation on Preclinical safety evaluation of *Nava Uppu Mezhugu* which was done in 2019 on acute toxicity study showed that the medicine doesn't produce any notable abnormalities observed in animal and the medicine with dose of 56mg twice a day is a safer therapeutic dose for human (8). Moreover, most of the components of this Siddha formulation have anti-inflammatory, anti-oxidant, immunomodulatory, analgesic and anti-microbial action as mentioned in Siddha texts and various research articles (9-16). These pharmacological actions correlate with the clinical outcomes noted in this study. Patients receiving the Siddha regimen exhibited faster reduction in nasal congestion and sinus tenderness compared to baseline, and many reported improved quality of breathing. The therapeutic response observed aligns with earlier Siddha literature that conceptualizes *Mookadaippu / Peenisam* (sinusitis) as a derangement of *Kabam* (mucus accumulation) with secondary involvement of *Pitham* (inflammation). The medicines used here appear to effectively restore humoral balance by reducing excessive mucous production (*Kabam*) and pacifying inflammatory processes (*Pitham*) (17). This traditional explanatory model parallels modern pathophysiological understanding of sinusitis involving mucosal oedema, impaired mucociliary clearance, and inflammatory mediator release.

The Adelaide Disease Severity Score was used to objectively assess disease severity and treatment response. Patients with baseline scores above 12, indicating moderate to severe sinusitis, were included in the study. Post-treatment assessment showed a reduction of scores to below 9, ranging from 9 to 5, reflecting a marked improvement in disease severity and symptom burden. This shift underscores the clinical effectiveness of the Siddha intervention. There was a recurrence observed in two patients possibly due to underlying anatomical variations, altered host immune response on continuous exposure to dust and pollutants or non-adherence to advised dietary and lifestyle modifications. So, the recurrence does not undermine the therapeutic potential but highlights the multifactorial etiology of sinusitis. Compared with conventional treatments such as antihistamines, decongestants, and intranasal corticosteroids; the Siddha regimen in this study offered a non-steroidal, multi-targeted approach. Importantly, no major adverse reactions were reported, indicating its safety and tolerability. This highlights the potential value of Siddha therapy as an adjunct or alternative which is economical for patients who cannot tolerate long-term allopathic medications. The study also supports the relevance of external therapies, which play a key role in Siddha medicine. Nasal fomentation, medicated steam inhalation, nasal drops and oil bath appeared to facilitate sinus drainage and symptom relief (18). Combining internal and external therapies likely contributed to the overall effectiveness observed.

Conclusion

The present pilot study demonstrated that the combined administration of *Nava Uppu Mezhugu* and *Peenisa Thailam* significantly reduced disease severity in patients with *Peenisam* (sinusitis), as evidenced by improvements in the Adelaide Disease Severity Score. Marked alleviation of major symptoms, including nasal obstruction, nasal discharge, facial pain, and headache, was observed following treatment. Statistical analysis using the Wilcoxon signed-rank test revealed a significant difference between pre-treatment and post-treatment scores, supporting the clinical effectiveness of the Siddha intervention. The treatment regimen was well tolerated, with no major adverse events reported during the study period, indicating a favourable safety profile. The combination of internal and external therapies may contribute to enhanced mucociliary clearance, reduction of inflammation, improved sinus drainage, and restoration of the deranged *Kabam* and *Pitham*, consistent with classical Siddha principles and contemporary understanding of sinus pathophysiology. These findings suggest that both the drugs constitute a safe, cost-effective, and clinically beneficial therapeutic approach, particularly in chronic and recurrent cases. Further studies with larger sample sizes and extended follow-up periods are warranted to validate these preliminary findings and establish their role in the integrative management of sinusitis.

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