Clinical Evaluation of *Vishmusthyadi vati* and *kalyank churna* in the withdrawal of tobacco chewing addiction: a case study



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I. Abstract

Background

Smokeless tobacco (ST) chewing addiction represents a substantial public health burden, particularly in India, necessitating effective withdrawal strategies. In Ayurveda, tobacco (*Tamraparna* or *Nicotiana tabacum*) is classified as a *Sthavara Vanaspatij Visha* (immobile plant poison). Chronic use and subsequent withdrawal induce a neurobehavioral syndrome characterized by the vitiation of *Vata* and *Kapha Doshas* and disturbance of the *Manovaha Srotas*. This report details the outcome of an Ayurvedic combined therapeutic regimen targeting this withdrawal pathology.ⁱ,

Case Presentation

A 25-year-old male labourer, presented with a 5-to-6-year history of daily smokeless tobacco (*Zarda*) addiction. Initial assessment using the Nicotine Withdrawal Scale for Tobacco Chewing Addiction yielded a total score of 24, classifying the patient as suffering from Severe Withdrawal. Primary complaints included severe craving, anxiety, irritability, and difficulty in concentration.

Intervention

The patient was administered a combined regimen for a continuous period of 21 days as per the research protocol. The intervention comprised *Vishmusthyadi Vati* (1–2 Vati, orally, twice daily with lukewarm water after meals) and *Kalyank Churna* (3g, four times daily, administered specifically for chewing).

Results

Subjective clinical efficacy was highly significant. The total Nicotine Withdrawal Score decreased substantially from 24 (Severe) at baseline to 7 (Mild) at the end of the 21-day intervention, representing a 70.83% improvement in symptomatic relief. The primary end point patient unwillingness to consume tobacco was achieved. Objective assessments revealed metabolic shifts typical of the acute cessation phase, including increases in Total Cholesterol (120.9 to 152.2) and Triglycerides (111.6 to 131.2). Hematological markers (ESR, TLC) showed favorable minor reductions.

Conclusion

The synergistic application of the nervine tonic and antitoxic *Vishmusthyadi Vati* alongside the *Deepana-Pachana* and behavioral substitution agent *Kalyank Churna* proved highly effective in managing acute tobacco withdrawal symptoms. The regimen addresses both the *Visha* effects and the associated *Vata-Kapha* pathology. The results indicate a successful cessation strategy, though they mandate continued metabolic monitoring in the post-cessation phase.

Keywords Tobacco Chewing Addiction, Nicotine Withdrawal, *Vishmusthyadi Vati, Kalyank Churna, Agad Tantra, Sthavara Visha, Strychnos nux-vomica*.

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II. Introduction

2.1. Global Burden and Health Implications of Smokeless Tobacco Use

Tobacco consumption, in both smoking and smokeless forms, constitutes a severe global health crisis. Specifically in India, the prevalence of smokeless tobacco (ST) use (21.38%) exceeds that of smoking tobacco use (10.38%), according to the Global Adult Tobacco Survey (GATS) 2016–17. In Rajasthan, where this study originates, 14.1% of adults are smokeless tobacco users. This widespread consumption is directly correlated with catastrophic health outcomes, notably oral cancer, leukoplakia, erythroplakia, oral sub-mucous fibrosis, and cardiovascular diseases. ii

The unique nature of smokeless tobacco addiction, often involving products like *gutka*, *jarda*, and *pan masala*, is characterized not only by pharmacological nicotine dependence but also by a strong behavioral component, specifically the oral fixation associated with the act of chewing and holding the product in the mouth. Effective cessation programs must therefore address both the chemical withdrawal symptoms (craving, anxiety) and the habitual need for oral engagement, which supports the rationale for using therapeutic substances designed for chewing.¹

2.2. Modern Neuropharmacology and Withdrawal Syndrome

Nicotine, the primary active constituent, exerts its highly addictive effects by mimicking the neurotransmitter acetylcholine, thereby increasing its functional presence in the brain. Prolonged exposure leads to complex neurochemical adaptations, whereby the brain requires nicotine input to maintain normal function.Cessation interrupts this delicate balance, resulting in the Nicotine Withdrawal Syndrome. **Symptom** manifestations include severe psychological disturbances (anxiety, depression, irritability) and somatic complaints (headache, insomnia. constipation, and intense craving). iii, iv

Contemporary cessation strategies often rely on nicotine replacement therapies (NRTs) or pharmacological agents that modulate nicotinic acetylcholine receptors. However, these approaches may not adequately address the comprehensive psychosomatic distress experienced during withdrawal, particularly when complicated by the behavioral dependence inherent in chewing habits.

2.3. Ayurvedic Toxicology (*Agad Tantra*): Tobacco as *Sthayara Vanaspatii Visha*

In Ayurvedic literature, tobacco (*Nicotiana Tobaccum*), often referred to as *Tamraparna*, is not mentioned in the classical *Samhitas* but is classified in later texts under the category of *Sthavara*

Vanaspatij Visha (immobile plant poison). The plant is known for its toxic principles, which include nicotine, tar, and carbon monoxide. The inherent properties of Tamraparna Katu (pungent) Rasa, Ushna (hot) and Tikshna (sharp) Guna, and Ushna Virya (hot potency) are conducive to rapid and potent action, which aligns with its classification as a Visha. Chronic ingestion leads to a complex Samprapti (pathogenesis). The Ushna and Tikshna qualities initially disturb the Pitta Dosha but the dominant pathology is driven by the vitiation of *Vata* and Kapha. Vata is characterized by its Ruksha (dry) and Chala (mobile) qualities, manifesting as restlessness, anxiety, difficulty concentrating, insomnia, and intense craving. Simultaneously, *Kapha* vitiation contributes to lethargy, jaw stiffness, and depression. The psychotropic and toxic effects ultimately disrupt the Manovaha Srotas (channels related to the mind) and Jatharāgni (digestive fire), necessitating a therapy that simultaneously pacifies Vata and Kapha while supporting neurological function. v , vi

2.4. Rationale for the Combined Therapeutic Regimen

The selection of *Vishmusthyadi Vati* and *Kalyank Churna* is rooted in the principle of *Samprapti Vighatana* (interruption of pathogenesis) by addressing both the systemic *Visha* effects and the associated psycho-physical symptoms.^{vii}

- Vishmusthyadi Vati: The core ingredient, Kuchla (Shodhita Strychnos nux-vomica), is itself a potent rigorous but, following purification (Shodhana), is employed in Agad Tantra as a powerful nervine tonic and stimulant. This action is intended to counteract the neurological depression and instability caused by long-term nicotine exposure and acute withdrawal, providing symptomatic relief for the *Vata* component.
- Kalyank Churna: Referenced in Yogratnakar for treating conditions related to the Manovaha Srotas (mind), this formulation possesses Deepana (appetizer), Pachana (digestive), Medhya (intellect promoter), and Balya (strength promoter) properties. It corrects the underlying Agni disturbance, manages mental anguish, and crucially, serves as a non-addictive therapeutic substitute administered specifically for chewing. This dual approach targets both the chemical dependence and the crucial behavioral addiction component.

III. Materials and Methods

3.1. Study Design and Ethical Clearance

This clinical evaluation is presented as a single-case report derived from a formal interventional study conducted at the Outpatient Department (OPD) of Sanjeevani Ayurveda Hospital, PGIA, Jodhpur. The study was designed to assess the clinical efficacy of

the combined drug regimen over a 21-day period. The patient provided informed written consent for participation, adhering to institutional ethical standards.

3.2. Patient Selection and Profile

A Patient 25-year-old male labourer of middle socioeconomic status residing in a rural habitat, was clinically diagnosed with Tobacco Chewing Addiction. He met all inclusion criteria, including being between 18 and 50 years of age and actively exhibiting clinical manifestations of withdrawal such as anxiety, insomnia, and restlessness. Exclusion criteria were confirmed, noting no major systemic illnesses (such as cancer, diabetes, or hypertension) or psychiatric disorders. The patient reported an addiction duration of 5-6 years, consuming Zarda 10-12 times per day, estimated at 1 to 3 grams per sitting. Ayurvedic examination revealed a history of Vishamaashana (irregular dietary timing), Tikshna Agni (sharp digestion), and ongoing psychological complaints of Anxiety and Insomnia.

3.3. Interventions: Formulation and Posology

The selected formulations were prepared in the pharmacy of Nagarjuna Pharmacy, Dr. Sarvepalli Radhakrishnan Rajasthan Ayurved University using classical methods.

Vishmusthyadi Vati

The reference for this formulation is *Siddha Bhasajya Manimala*. It consists of *Shodhita Kuchla (Strychnos nux-vomica)* and *Maricha (Piper nigrum)*, taken in equal quantity, and processed with the *Swarasa* (juice) of *Indravaruni (Citrullus colocynthis*). Tablets of 125 mg each were prepared.

Kalyank Churna

The reference for this powder formulation is *Yogratnakar*. It is a polyherbal compound containing sixteen ingredients in equal parts, including *Panchakola* (Pippali, Pippali Mool, Chavya, Chitrak Mool, Shunthi), *Triphala* (Amalki, Haritaki, Bibhitaki), Maricha, Vidanga, Karanja, Ajmoda, Dhanyaka, Jeerak (Sukla), Vida Lavana, and Saindhav.

The treatment regimen was:

Table 1: Drug Formulations, Administration, and Posologyviii, ix

Medicine	Dose	Mode of	Anupana	Timing
		Administration		
Vishmusthyadi Vati	1-2 Vati (125 mg each)	Oral	Lukewarm water	Twice daily, after meal
Kalyank Churna	3 gm	Chewing	N/A	Four times a day

The mode of administration for *Kalyank Churna* (for chewing) is designed as a direct physical and psychological replacement for the act of chewing tobacco. This approach addresses the underlying behavioral fixation, supporting compliance during the critical 21-day withdrawal period.

3.4. Assessment Criteria

Assessment relied on both subjective and objective parameters.

Subjective Parameters

The clinical assessment was quantified using the Nicotine Withdrawal Scale for Tobacco Chewing. This scale grades 10 withdrawal symptoms (e.g., Craving, Anxiety, Insomnia, Depression, Constipation) from 0 (None) to 3 (Severe), yielding a total possible score of 30. Severity was categorized as Mild (1–10), Moderate (11–20), and Severe (21–30). Follow-up assessments were scheduled weekly.

Objective Parameters

Standard laboratory investigations were conducted before and after the 21-day trial, including Routine Blood Tests (CBC, ESR) and Lipid Profile (Total Cholesterol, Triglycerides, HDL cholesterol).¹ Vital

signs, specifically Pulse Rate and Blood Pressure, were also monitored.

IV. Case Narrative and Clinical Data

4.1. Detailed Patient History and Baseline Assessment

The patient, XXX, presented with chronic tobacco chewing (Zarda) and concurrent psychological distress, noted as Anxiety and Insomnia. Key complaints included constant craving, headache, lethargy, and jaw stiffness. His physical examination noted a moderate build, an anxious general appearance, and dirty, yellow-stained teeth, indicative of chronic smokeless tobacco use.

Initial Ayurvedic findings highlighted a disturbed homeostasis. The history of irregular dietary intake (*Vishamaashana*) coupled with a report of *Tikshna Agni* suggested a deeply rooted metabolic irregularity (*Ama* generation), which, when mobilized by aggravated *Vata*, creates the psychosomatic instability observed in withdrawal. The involvement of *Vata* was clearly evidenced by the symptoms of Insomnia, Anxiety, and Irregular Defecation.

4.2. Treatment Progression and Symptom Profile

The patient completed the full 21-day protocol. Treatment progression demonstrated a rapid and

steady reduction in withdrawal severity, achieving the primary end point (patient not willing to consume tobacco).

Table 2: Nicotine Withdrawal Scale Score Comparison (Pre- and Post-Treatment)

Withdrawal Symptom	Baseline Score (BT)	Post-Treatment Score (AT)	Improvement (%)	Severity Shift
Craving	3 (Within 1 hr)	0 (No craving)	100%	Severe None
Headache	2 (Usually)	1 (Rarely)	50.0%	Moderate Mild
Insomnia	1 (Occasional difficulty)	0 (No difficulty)	100%	Mild None
Difficulty in concentration	3 (Unable to concentrate)	1 (Occasional lapse)	66.7%	Severe Mild
Anxiety	3 (Nearly every day)	1 (Most days)	66.7%	Severe Mild
Irritability	3 (Persistent irritability)	1 (Slight increase occasionally)	66.7%	Severe Mild
Depression	2 (More than 50% days)	0 (Never)	100%	Moderate None
Anger	2 (Frequent outbursts)	1 (Occasionally feels short-tempered)	50.0%	Moderate Mild
Constipation	2 (Usually)	0 (None)	100%	Moderate None
Appetite (Change)	3 (Marked overeating)	1 (Slight increase in appetite)	66.7%	Severe Mild
Total Score	24 (Severe Withdrawal)	7 (Mild Withdrawal)	70.83%	Severe Mild

4.3. Objective Data Assessment

Objective parameters monitored before and after the 21-day intervention are presented below.

Table 3: Pre- and Post-Treatment Objective Laboratory and Vital Parameters (21 Days)

Test Parameter	Unit	Day 1 (Before Treatment)	Day 21 (After Treatment)	Change
Pulse Rate	/min	72	72	Stable
Blood Pressure	mmHg	110/70	120/80	10/10 mmHg
Hb gm%	g/dL	16.1	16.6	(0.5 g/dL)
TLC WBC	10^3/\mu	7.12	6.61	(0.51 10^3/\mu L)
ESR	mm/Hr	11	10	(1 mm/Hr)
Total Cholesterol	-	120.9	152.2	(25.9%)
Triglyceride - serum	mg/dL	111.6	131.2	(17.6%)
HDL cholesterol - serum	mg/dL	49.9	48.4	(Minor 3.0%)

V. Results

5.1. Primary Outcome: Symptomatic Efficacy

The clinical trial successfully demonstrated that the combined administration of *Vishmusthyadi Vati* and *Kalyank Churna* resulted in a profound reduction in tobacco withdrawal severity. The total score on the Nicotine Withdrawal Scale decreased from 24 (Severe Withdrawal) at baseline to 7 (Mild Withdrawal) by Day 21, translating to a 70.83% symptomatic improvement.

Highly impactful results were observed in key psychological and somatic symptoms. Craving, the primary driver of relapse, resolved completely (Grade 3). Furthermore, Depression (Grade 2), Insomnia (Grade 1), and Constipation (Grade 2)

were fully mitigated, showcasing the potent *Medhya* and *Vata Shamaka* properties of the regimen. Other core symptoms, such as Anxiety and Irritability, decreased substantially from Severe (Grade 3) to Mild (Grade 1).

5.2. Secondary Outcome: Objective Parameter Changes

Inflammatory and Hematological Markers

The objective markers showed favorable trends consistent with the reversal of chronic *Visha* effects. Chronic nicotine exposure is known to increase white blood cell counts, a reflection of systemic inflammatory stress.⁹ The patient exhibited a reduction in Total Leukocyte Count (TLC) from 7.12

times 10^3/\mu L to 6.61 times 10^3 mu L, and a minor decrease in Erythrocyte Sedimentation Rate (ESR) from 11 to 10 mm/Hr. These subtle improvements suggest the initiation of systemic detoxification and anti-inflammatory action, mitigating the chronic inflammatory load induced by long-term tobacco use.

Cardiovascular and Metabolic Parameters

Assessment of cardiovascular parameters revealed a stable pulse rate (72/min) but a slight increase in Blood Pressure from 110/70 mmHg to 120/80 mmHg.More notably, significant changes were observed in the lipid profile. Total Cholesterol increased by 25.9 (120.9 to 152.2), and Triglycerides increased by 7.6 (111.6 to 131.2). High-Density Lipoprotein (HDL) cholesterol exhibited a minor decrease (49.9 to 48.4). This metabolic shift requires detailed interpretation within the context of nicotine cessation physiology.

VI. Discussion

6.1. Samprapti Vighatana (Interruption of Pathogenesis) through Dual Action

The success of this 21-day trial is directly attributable to the strategic application of two complementary Ayurvedic formulations, targeting both the core toxicity (*Visha*) and the psychosomatic pathology (*Vata-Kapha* imbalance).

Systemic Agad Action: Vishmusthyadi Vati

The withdrawal symptoms, characterized by profound neurobehavioral instability (Anxiety, Irritability, Craving), are direct manifestations of the nervous system's acute response to the absence of nicotine, which is classified as *Tamraparna Visha*. *Vishmusthyadi Vati*, containing purified *Kuchla* (*Strychnos nux-vomica*), applies the sophisticated principle of *Agad Tantra* the controlled administration of a purified *Visha* to manage the effects of chronic toxicity.

Kuchla, post-Shodhana, is utilized as a potent nervine tonic and stimulant, known to increase reflex excitability. By providing controlled, stabilizing stimulation to the nervous system, the Vati effectively counteracts the Vata-driven neurobehavioral depression, lethargy, and neuro-

instability. This mechanism explains the rapid mitigation of severe psychological symptoms, such as Anxiety, Irritability and Anger.

Holistic and Behavioral Management: *Kalyank Churna*

Kalyank Churna provides a comprehensive therapeutic layer. Its indication in Yogratnakar for Apasmara (epilepsy) and other neurological conditions supports its classification as a Medhya drug, which helps stabilize the Manovaha Srotas. The resolution of Depression and Insomnia suggests a powerful psycho-stabilizing effect.

Moreover, the extensive list of ingredients, including the Panchakola group and Chitrak Mool, confers strong Deepana and Pachana properties. This function is critical for correcting the patient's underlying Vishama Agni and removing Ama, which essential for systemic detoxification and preventing the recurrence of Visha-related symptoms. Crucially, the prescribed mode of administration chewing the Churna four times a day is a highly targeted behavioral intervention. This strategy leverages the known psychological need for oral fixation in smokeless tobacco users, effectively replacing the harmful ritual of Zarda consumption with a therapeutic, non-addictive substitute, thus reinforcing patient compliance and supporting the primary goal of cessation.

VII. Conclusion

This case study demonstrates the robust clinical efficacy of the combined Ayurvedic regimen of Vishmusthyadi Vati and Kalyank Churna in achieving the withdrawal of chronic tobacco chewing addiction. The 21-day intervention resulted in a reduction in withdrawal severity, achieving abstinence by addressing the complex pathogenesis through sophisticated dual a mechanism. Vishmusthyadi Vati successfully stabilized the Vatadriven neurological effects of Tamraparna Visha, while Kalyank Churna provided critical metabolic support (Deepana-Pachana) and a successful behavioral substitution therapy.

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