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CLINICAL EVALUATION OF VISHMUSTHYADI VATI AND KALYANK CHURNA IN THE WITHDRAWAL MANAGEMENT OF TOBACCO CHEWING ADDICTION

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I. Abstract

A. Background

The global prevalence of tobacco use remains a critical public health challenge, with smokeless tobacco (SLT) consumption, predominantly chewing forms, representing a major public health burden in India. Ayurveda classifies tobacco (*Nicotiana tabacum*) as a *Sthavara Patra Visha* (plant-origin poison) , whose properties (*Ushna, Vyavayi*) induce *Vata-Kapha* vitiation, leading to neurological and metabolic disturbances analogous to *Madatyaya* (alcohol-related disorder) and chronic *Dushi Visha* toxicity. Nicotine dependence is characterized by intense cravings, loss of control, and debilitating physical and psychological withdrawal symptoms. The objective of this study was to assess the clinical efficacy of a novel dual-formulation Ayurvedic regimen *Vishmusthyadi Vati* (a formulation for systemic detoxification and nerve strengthening) and *Kalyank Churna* (a polyherbal powder used for internal administration and oral substitution) in mitigating the physical and psychological withdrawal syndrome in patients with tobacco chewing addiction.[i]

B. Methods

This investigation employed a prospective, single-arm, open-label, interventional clinical trial design. The study protocol was granted ethical clearance (IEC No.- DSRRAU/PGIAS/IEC/22-23/702) and registered with the Clinical Trials Registry-India (CTRI/2024/07/069867). A cohort of 30 patients (N=30, age range 18–50 years, 96.66% male) diagnosed with chewing tobacco addiction (e.g., *khaini, gutka, zarda*) completed the 21-day therapeutic intervention. The regimen consisted of combined therapy: *Vishmusthyadi Vati* (2 *vati*, 250 mg total, twice daily after meals with lukewarm water) and *Kalyank Churna* (3g, four times daily, chewed as per need for psychological substitution). The primary outcome measure was the reduction in the severity of withdrawal symptoms, quantified using the Nicotine Withdrawal Scale (NWS) for Tobacco

Chewing. Secondary outcomes included systemic biomarkers such as Hemoglobin (Hb), Lipid Profile (HDL, LDL), and Pulse Rate, assessed before and after treatment. Statistical analysis utilized the Wilcoxon matched signed-ranks test for non-parametric data and the Paired *t*-test for parametric data, with a significance threshold set at $P<0.05$.

C. Results

The 21-day intervention resulted in a highly significant reduction in all measured withdrawal symptoms. The mean total NWS score decreased dramatically from 18.7±3.32 at baseline (categorized as moderate/severe withdrawal) to 6.26±1.08 post-treatment (categorized as mild withdrawal). The overall therapeutic relief achieved was **66.47%**, statistically highly significant ($P<0.0001$). Specific symptoms showing the highest percentage of relief included Constipation (95.88%) and Insomnia (95.14%). Objective analysis demonstrated systemic benefits, including a highly significant increase in Hemoglobin ($P<0.0001$) and HDL cholesterol ($P<0.0001$), alongside a significant reduction in LDL cholesterol ($P=0.028$). No Adverse Drug Reactions (ADR) were reported during the trial duration.

D. Conclusion

The combined Ayurvedic regimen of *Vishmusthyadi Vati* and *Kalyank Churna* proved safe, well-tolerated, and highly efficacious in the acute management and withdrawal of tobacco chewing addiction. This dual approach successfully addresses both the neurophysiological withdrawal symptoms (*Nadibalya* action) and the behavioral compulsion (*Manasika* substitution) , further supported by objective evidence of systemic detoxification (*Visha Shamana*). The results accept the alternate hypothesis ($H1$) that the regimen is effective in the withdrawal of tobacco chewing addiction.

II. Introduction

A. Global and Indian Epidemiology of Tobacco Dependence

Tobacco use represents a leading preventable cause of death globally, with its consumption sustained by nicotine, a highly addictive alkaloid. Global strategies have resulted in a gradual decline in the adult prevalence of tobacco use, dropping from 32.7% in 2000 to 19.8% in 2022, with the total number of users decreasing from 1.36 billion to 1.25 billion. However, this global progress masks the concentrated burden found in regions like India.[ii]

In India, 28.6% of the adult population uses tobacco in some form. The demographic profile of use is notably skewed, with higher prevalence observed among men (42.4%) compared to women (14.2%) and significantly higher rates in rural areas (32.5%) versus urban areas (21.2%). The vast scale of addiction is evident in the estimated 266.8 million adult users. Crucially, the Indian scenario is dominated by smokeless tobacco (SLT) use, affecting 21.4% of adults, nearly double the proportion who smoke (10.7%). Products like *khaini* (11.2%), *gutka* (6.8%), and betel quid with tobacco (6%) contribute to a total of 199.4 million smokeless tobacco users. The sheer volume of users, most of whom are daily consumers (85% of smokeless users), establishes SLT addiction as a primary national health concern.[iii]

The entrenched nature of tobacco use is also economic; India ranks as the second-largest global producer, with 86% of its domestic production dedicated to traditional smokeless and hand-rolled forms. Chronic SLT exposure introduces approximately 4,000 toxic substances, including potent carcinogens like tobacco-specific nitrosamines (TSNAs), leading inevitably to severe oral pathology, gum disease, leukoplakia, and oral cancer. This highlights the necessity for effective cessation strategies tailored specifically to the unique delivery mechanisms of chewing tobacco.

B. Neurobiological Basis of Nicotine Dependence and Withdrawal

Nicotine drives addiction through its rapid interaction with the central nervous system, binding specifically to nicotinic acetylcholine receptors (nAChRs), notably the α4β2 subunits. This

binding triggers an exaggerated release of dopamine within the mesolimbic pathway (the brain's reward circuit, involving the ventral tegmental area and the nucleus accumbens). This surge produces intense feelings of pleasure and reinforcement, generating a persistent desire or "wanting" that sustains substance use a concept termed incentive salience.[iv]

The progression to addiction is recognized in three neurobiological stages, corresponding to the DSM-5 and ICD-10 criteria for Substance Use Disorder. The first stage, Binge/Intoxication, involves the pleasurable effects driven by the basal ganglia. The second, Withdrawal/Negative Affect, is characterized by the emergence of distress (anxiety, stress, dysphoria) when nicotine is absent, driven by heightened activation in the extended amygdala stress circuits. The final stage, Preoccupation/Anticipation, represents the compulsive drug-seeking behavior, where executive functions located in the prefrontal cortex (PFC) responsible for decision-making and impulse control are impaired.[v]

C. The Ayurvedic Conceptualization: *Visha*, *Mada*, and *Manas* Pathology

The classical texts of Ayurveda address pathological substance use through several concepts within *Agadtantra* (Toxicology) and *Manasika Roga* (Psychiatric Disorders).

1. Tobacco as *Visha* and *Madatyaya*

Tobacco, categorized as *Sthavara Patra Visha* , possesses a severe profile of *Gunas* (qualities): *Tikshna* (sharp), *Ushna* (hot), *Vyavayi* (rapidly diffusible), and *Vikashi* (tissue-disintegrating). These characteristics enable rapid absorption and dissemination throughout the body, vitiating the *Doshas* (especially *Vata* and *Pitta*) and contaminating the *Dhatus* (tissues), particularly *Rasa* and *Rakta*. Chronic, low-dose exposure leads to progressive systemic damage, correlating with the concept of *Dushi Visha* (chronic latent poison). Furthermore, the disease state resulting from continuous, excessive use of intoxicants is described as *Madatyaya*.[vi]

2. The Role of *Vyasana* and *Rajas-Tamas*

Addiction is also framed under the concept of *Vyasana*, denoting habitual indulgence that leads to the physical, mental, and moral degradation of the individual. The process of acquired tolerance is described by *Okasatmya*, where the body adapts to a substance, and its absence causes discomfort. The pathogenesis of tobacco dependence involves the disruption of the mental faculties (*Manasika Doshas*). When *Pragyapradh* (intellectual error) and weak spiritual strength (*Avara Satva*) are present, the mind is overpowered by *Rajas* (passion, restlessness) and *Tamas* (inertia, delusion). This disturbance impairs judgment (*Buddhi Vikara*) and willpower (*Sattva Vikara*), leading to a compulsive, self-destructive cycle.[vii]

The strong clinical prevalence of the *Rajasika Manasika Prakriti* (66.66%) and *Vata-Pittaja Sharirika Prakriti* (60%) within the study cohort establishes a crucial link between constitutional vulnerability and addictive behavior. The *Vata-Pittaja* individual tends towards hyperactive neurological and metabolic states, manifesting clinically as anxiety, irritability, and restlessness—all universally reported withdrawal symptoms. This profile confirms that the core pathology is one of *Manovaha Srotas Dushti* driven by excessive *Rajas*, necessitating therapeutic intervention focused on stabilizing *Vata* and promoting *Satva Bala* (mental strength). [viii]

D. Rationale and Objectives of the Study[ix]

Despite the high burden of SLT addiction, safe and effective non-pharmacological interventions are urgently needed. Ayurvedic management offers a holistic approach combining detoxification (*Visha Shamana*) and mental strengthening (*Manasika Balya Chikitsa*). This study investigates a novel dual regimen strategically selected to address the core pathological components

1. ***Vishmusthyadi Vati***: A classical preparation, its chief ingredient, purified *Kuchla* (*Strychnos nux-vomica*), is a renowned *Nadibalya* (nervine tonic) and *Vishaghna* , chosen to counter the acute neuro-withdrawal symptoms and systemic toxicity associated with tobacco cessation.[x]

2. ***Kalyank Churna***: Cited in *Apasmara Chikitsa* , this polyherbal *churna* is rich in *Deepana-Pachana* and *Medhya* (intellect-promoting) herbs. The therapeutic strategy utilizes the *churna* for chewing, which provides necessary sensory substitution to manage the intense oral craving habit of chewing tobacco.

The primary aim of this research was to assess the clinical efficacy of this combined regimen in achieving the withdrawal of tobacco chewing addiction. The primary objective was the statistical quantification of the reduction in withdrawal symptoms using a standardized scale, while secondary objectives included evaluating the systemic effects on chronic toxicity markers and providing effective de-addiction counseling.

III. Materials and Methods

A. Study Design and Ethical Compliance

The research was executed as a prospective, single-arm, open-label, interventional clinical trial spanning 21 days. The trial was initiated only after receiving approval from the Institutional Ethics Committee (IEC No.- DSRRAU/PGIAS/IEC/22-23/702). Furthermore, the study was mandatorily registered with the Clinical Trials Registry-India (CTRI/2024/07/069867) to ensure transparency and accountability. All participants were thoroughly counseled regarding the study purpose, procedure, and potential effects, and written informed consent was secured in their native language. The total sample size was 30 patients who completed the trial (N=30).

B. Patient Selection Criteria and Enrollment

Patients were recruited from the outpatient department (OPD) of the affiliated Ayurved University hospital and organized health camps in surrounding villages.

1. Inclusion and Exclusion Criteria

Inclusion was restricted to patients aged 18–50 years, clinically diagnosed with addiction to chewing tobacco or similar smokeless products (*khaini, zarda, pan masala, gutka*), and actively exhibiting clinical manifestations of withdrawal (e.g., anxiety, depression, restlessness) upon cessation. Exclusion criteria were strictly enforced to eliminate systemic confounders, including patients with malignancies (oral cavity, lung, esophagus), major systemic illnesses (diabetes, hypertension, ischemic heart disease), or severe major psychiatric disorders (schizophrenia, mania).

2. Patient Profile and Enrollment

The final cohort consisted of 30 patients. The study cohort exhibited a strong male predominance (96.66%). Analysis of lifestyle and constitutional factors revealed key vulnerabilities: 60% of patients had *Vata-Pittaja Sharirika Prakriti*, and 66.66% were classified as *Rajasika Manasika Prakriti*. The majority of users were moderate consumers, with 56.66% using tobacco 6–10 times per day. The baseline mean Nicotine Withdrawal Scale (NWS) score was 18.7±3.32, confirming that the enrolled population suffered from moderate-to-severe withdrawal symptoms.

C. Drug Standardization and Posology

The raw drugs for both formulations were authenticated by experts from the relevant departments (*Dravya Guna* and *Rasa Shastra*) at the institutional pharmacy before preparation.

1. *Vishmusthyadi Vati* Preparation and Dosage[xi]

The key constituent of *Vishmusthyadi Vati* is *Kuchla* (*Strychnos nux-vomica*). Prior to formulation, the seeds of *Kuchla* underwent mandatory *Shodhana* (purification) involving frying in *Erand Taila* (Castor oil) until the outer coat turned lead color, followed by decoating and immediate pulverization. This process is essential to minimize the acute neurotoxic potential of Strychnine, ensuring the safety of the medicine when administered internally. The purified *Kuchla* powder was

mixed with *Maricha* (*Piper nigrum*) and triturated with *Indravaruni* (*Citrullus colocynthis*) fruit juice to form a homogenous mass, which was then rolled into 125mg pills (*Vati*).

- **Posology:** 2 *vati* (250 mg total) administered orally twice daily (morning and evening) after meals, with lukewarm water (*Anupana*).

2. *Kalyank Churna* Preparation and Dosage

Kalyank Churna is a polyherbal formulation containing 16 ingredients, including *Pippali, Pippali Mool, Shunthi, Maricha, Chitrak Mool, Triphala (Amalaki, Haritaki, Bibhitaki), Vidanga, Yavani, Dhanyaka, Jeerak*, and salts (*Vida Lavana, Saindhava*). All ingredients were dried in the shade, pulverized coarsely, and mixed homogeneously.

- **Posology:** 3g administered orally four times a day, specifically advised to be chewed as needed by the patient.

The methodology mandated the use of *Kalyank Churna* for chewing, which provides a critical therapeutic function. The *Katu* (pungent) and *Lavana* (salty) taste profile, primarily derived from *Trikatu* and the mineral salts , delivers a strong sensory and mucosal stimulation. This deliberate technique of sensory substitution directly addresses the behavioral and psychological dependence associated with oral gratification in smokeless tobacco users, actively replacing the physical habit and mitigating the intense behavioral compulsion that drives craving.[xii]

D. Assessment and Statistical Analysis

The treatment duration was 21 days, with weekly follow-ups.

1. Criteria of Assessment

Subjective Parameters: Clinical efficacy in managing withdrawal symptoms was assessed using the **Nicotine Withdrawal Scale (NWS) for Tobacco Chewing**. The total score was 30, and based on this score, the severity of withdrawal was categorized into mild, moderate, or severe.

Objective Parameters: Systemic effects were monitored through laboratory investigations (CBC, ESR, Lipid Profile, Pulse Rate, BP) before and after treatment.

2. Statistical Analysis

The Wilcoxon matched signed-ranks test was applied for non-parametric data, and the Paired *t*-test was used for parametric data. Statistical significance was defined as $P<0.05$, with $P<0.001$ indicating a highly significant result.

IV. Results

The therapeutic intervention resulted in significant improvement across all subjective and several objective parameters within the 21-day period.

A. Baseline Characteristics and Withdrawal Symptom Profile

The demographic profile indicated that the majority of patients exhibited constitutional vulnerabilities conducive to addiction, characterized by *Vata-Pittaja Prakriti* (60%) and *Rajasika Manasika Prakriti* (66.66%). Clinically, these imbalances manifested as acute withdrawal distress. At baseline, 100% of patients reported Craving, Anxiety, Irritability, Anger, Constipation, and Difficulty in Concentration, confirming a complex psychoneurological and visceral involvement. The collective distress was classified as moderate-to-severe, with a total mean NWS score of 18.7±3.32.

B. Primary Outcome: Efficacy on Nicotine Withdrawal Scale (NWS)

The primary objective was successfully achieved, demonstrating substantial reduction in the overall severity of withdrawal symptoms. The total mean NWS score decreased by 66.47%, a change found to be statistically highly significant ($P<0.0001$).

Table 1: Effect of Combined Ayurvedic Therapy on Nicotine Withdrawal Symptoms (NWS)

Symptom	**BT Mean ± SD**	**AT Mean ± SD**	**Mean Difference (MD)**	**% Relief**	**P-value**	**Result**
Craving	2.56±0.50	0.96±0.18	1.600	62.50	<0.0001	Significant
Headache	1.5±0.57	0.26±0.44	1.233	82.20	<0.0001	Significant
Insomnia	0.7±0.65	0.033±0.182	0.666	95.14	<0.0001	Significant
Difficulty in Concentration	2.36±0.49	0.96±0.18	1.400	59.32	<0.0001	Significant
Anxiety	2.36±0.49	1.06±0.25	1.300	55.08	<0.0001	Significant
Irritability	2.56±0.50	1.00±0.00	1.567	61.21	<0.0001	Significant
Depression	1.7±0.65	0.66±0.54	1.033	60.76	<0.0001	Significant
Anger	2.06±0.44	0.93±0.25	1.133	55.00	<0.0001	Significant
Constipation	1.53±0.50	0.06±0.25	1.467	95.88	<0.0001	Significant
Appetite	1.33±0.84	0.3±0.46	1.033	77.67	<0.0001	Significant
Total NWS Score	**18.7±3.32**	**6.26±1.08**	**12.430**	**66.47**	**<0.0001**	**Significant**

Physical symptoms showed the most dramatic response, with Constipation improving by 95.88% and Insomnia by 95.14%. Craving showed an encouraging reduction of 62.50%. All affective and psychological symptoms, including Anxiety, Irritability, and Depression, demonstrated improvements exceeding 55%, all determined to be statistically highly significant.

C. Secondary Outcomes: Objective Parameters and Systemic Effects

Assessment of objective biomarkers, traditionally considered secondary in addiction trials, revealed critical evidence of systemic healing.

Table 2: Changes in Key Hematological and Lipid Parameters Post-Intervention

Parameter	**BT Mean ± SD**	**AT Mean ± SD**	**% Change**	**P-value**	**Significance**
Hemoglobin (g/dL)	13.91±2.09	14.38±1.92	+3.38	<0.0001	Highly Significant
HDL Cholesterol (mg/dL)	45.99±8.11	48.67±6.90	+5.81	<0.0001	Highly Significant
LDL Cholesterol (mg/dL)	79.37±23.22	72.52±18.39	−8.63	0.028	Significant
Pulse Rate (beats/min)	73.33±3.64	74.13±3.10	+1.09	0.002	Significant
ESR (mm/hr)	13.1±10.11	11.33±3.88	−13.49	0.101	Non-Significant

The statistically highly significant increase in Hemoglobin (P<0.0001) and the favorable shift in the lipid profile—specifically the significant elevation of cardioprotective HDL (P<0.0001) and reduction in atherogenic LDL (P=0.028)—provides objective proof of the therapeutic regimen's ability to reverse systemic toxicity rapidly. Parameters related to chronic inflammation (ESR, P=0.101) and general blood pressure (P=0.719) did not show significant changes, a result consistent with the brief 21-day duration of the study.

V. Discussion

A. Mechanistic Elucidation of Efficacy

The clinical success, marked by 66.47% overall relief and complete absence of ADRs, is rooted in the synergistic dual action of the *Vati* and *Churna* on the *Sharira* (body) and *Manas* (mind). The rapid and profound resolution of withdrawal symptoms demonstrates that the regimen effectively interrupted the complex *Samprapti* (pathogenesis) of tobacco addiction.

1. Targeting Neuro-Visceral Instability

The near-complete resolution of Constipation and Insomnia, both cardinal manifestations of acute *Vata* vitiation during withdrawal, is a triumph of *Vata-Anulomana* therapy. The *Deepana-Pachana* and *Vatanulomana* properties of *Kalyank Churna*'s *Trikatu* and salt components effectively normalized *Apana Vata*, relieving visceral distress.

Furthermore, the management of emotional instability (Anxiety, Irritability) directly addresses the *Rajasika* nature of the affected population. The *Nadibalya* (nervine tonic) and *Satvavardhaka* action of the formulation, particularly from the purified *Kuchla* in *Vishmusthyadi Vati*, stabilizes the hyperactive *Vata* and *Rajas Gunas*. This correlation demonstrates that therapeutic success in this population requires specific pharmacologic tools designed to stabilize the *Manovaha Srotas* and fortify *Satva Bala* against the stress and dysphoria of nicotine withdrawal.[xiii]

2. Psychological and Behavioral Substitution

The strategic administration of *Kalyank Churna* for chewing proved essential in managing the 100% prevalent symptom of Craving. Tobacco chewing creates an *Okasatmya*—an acquired, ritualistic dependence involving oral engagement. The sharp (*Katu*) and salty (*Lavana*) taste of the *Churna* provides strong sensory feedback, fulfilling the compulsive need for oral stimulation better than inert or mildly flavored substitutes. This therapeutic strategy validates the conceptual link between physical sensation and behavioral management, showing that Ayurvedic *Dravya Guna* can be intelligently adapted to function as an effective psychological antidote, reducing craving by 62.50%.

B. Evidence of Systemic Detoxification (*Visha Shamana*)

The rapid and significant improvements in Hemoglobin, HDL, and LDL within 21 days provide objective confirmation that the regimen initiated active systemic healing, far exceeding mere symptom control. Chronic tobacco exposure establishes a state of *Dushi Visha*, slowly degrading *Dhatus* and predisposing the individual to diseases like dyslipidemia and anemia.

The highly significant increase in Hemoglobin suggests a swift reversal of *Rakta Dhatu Dushthi*. Similarly, the favorable modulation of the lipid profile (increased HDL, decreased LDL) points to potent *Medonasha* (metabolic correction) properties. Ingredients like *Chitrak* and *Vidanga* are well-known *Lekhana* (scraping) agents that facilitate the clearance of accumulated *Ama* and correct disturbed *Medo Dhatu Agni*. This physiological reversal demonstrates the holistic detoxification capacity of the combined *Ayurvedic* therapy, actively minimizing future cardiovascular risk associated with prior tobacco use. The speed of this objective improvement, achieved within three weeks, strongly underscores the biophysiological potency of the formulations.

VI. Conclusion

The 21-day interventional study utilizing the combined Ayurvedic therapy of *Vishmusthyadi Vati* and *Kalyank Churna* achieved an overall therapeutic relief rate of 66.47% in managing the acute withdrawal symptoms of tobacco chewing addiction, demonstrating highly significant clinical efficacy ($P<0.0001$).

The intervention successfully reduced all ten measured symptoms, including Craving, Anxiety, and Depression, while achieving near-complete resolution of key physical markers (Constipation and Insomnia). Objective data further supported the systemic antitoxic action of the regimen, evidenced

by significant improvements in Hemoglobin and a favorable shift in the cardiovascular risk markers (HDL and LDL). The integrated dual therapy provides a potent, safe, and holistic method for breaking the addiction cycle by simultaneously addressing *Vata-Kapha* deregulation, neurobiological instability, and the physical act of oral compulsion.

Consequently, the null hypothesis (H0), which posited that the regimen is ineffective in tobacco withdrawal, is conclusively rejected, and the alternate hypothesis (*H*1) is accepted. This Ayurvedic regimen represents a highly promising and patient-friendly therapeutic option for smokeless tobacco cessation.

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