



Research Article

AN OPEN LABEL SINGLE ARM CLINICAL STUDY TO EVALUATE THE EFFICACY OF *TUMBURU* (*ZANTHOXYLUM ARMATUM* DC.) IN TOBACCO CHEWING ADDICTION

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ABSTRACT


India is the second largest tobacco producing nation and the second largest consumer of tobacco worldwide. The World Health Organization classifies tobacco addiction as a chronic condition driven by nicotine dependence, which creates a complex cycle of physical and psychological dependence. **Aim and Objectives:** To evaluate the clinical efficacy of *Tumburu* (*Zanthoxylum armatum* DC.) in tobacco chewing addiction. The objectives were to develop an *ayurvedic* remedy for reduction in the harmful effects of nicotine and to introduce an alternative replacement drug therapy. **Methods:** Based on inclusion and exclusion criteria, total 40 tobacco addicted individuals were selected irrespective of their gender, caste or creed. It was an Open Label Single Arm Clinical Trial which was conducted for 2 months. Fruit pericarp of *Tumburu* was given 4-5 times a day when there was an urge to chew tobacco. It was kept in the oral cavity. The data was recorded and evaluated through the subjective and objective parameters. **Statistical analysis:** Wilcoxon signed ranked test was applied for subjective parameters and Paired t-test was applied for objective parameters. **Result:** The overall response to the treatment with *Tumburu* in addicted individuals were statistically significant. 20% had marked improvement, 14.29% had moderate improvement, 37.14% had mild improvement and 28.57% had no improvement. **Conclusion:** This study provides the clinical validation for the effectiveness of *Zanthoxylum armatum* in tobacco chewing addiction and contributed and provided support to quit tobacco's use for better health outcomes.

INTRODUCTION

Tobacco, being one of the *Sthavara Vanaspatika visha* when accumulated into the body for over a long period of time even in low doses may cause harm when the concentration in different tissues reaches a high level due to their cumulative effect. It acts as a *Dushi Visha* (slow poison) in the body^[1]. Repeated and continued use of tobacco results in addiction. Tobacco's nicotine content makes it a potent and highly addictive substance. Once an individual becomes hooked on nicotine, breaking free becomes a challenge due to the relentless grip of withdrawal

symptoms and insatiable cravings. For some, tobacco becomes a coping mechanism helping them to navigate the stress, anxiety and emotional turmoil of life. This reliance births a psychological dependence that's hard to escape.

Nicotine is cardiotoxic in nature which stimulates the release of dopamine in the brain's mesolimbic reward system which is responsible for pleasure and makes an individual feel good^[2]. This creates a feeling of pleasure and relaxation, reinforcing the cycle of dependence. Over time, a person develops tolerance, requiring higher doses to achieve the same effect. Withdrawal symptoms such as irritability, anxiety, cravings and insomnia further entrench the habit, making quitting challenging. Nicotine addiction involves the brain's nerve cells and neurotransmitters like acetylcholine. Nicotinic receptors are activated by nicotine and activate the nicotinic acetylcholine receptors (nAChRs) in the central nervous system,

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leading to increased activity which then can affect the mood, appetite, memory, learning etc. Later on, it affects the normal functioning of the central nervous system.

In Ayurveda, addiction is not mentioned directly but some texts do mention terms like *Vyasana*, *Mada*, *Madakari* etc. *Vyasana* implies a strong, harmful attachment or craving that is often tied with the consumption of drugs/substances. In the 17th century, an ayurvedic text *Yogratnakara* was the first to describe tobacco as *Tamakhu*^[3]. Tobacco is mentioned to be *Madapittabhramakaram* (that causes *Mada*, *Pitta* and *Bhrama*) and *Drishtimandhyakaram* (which diminishes eyesight) in the text. Another text, *Shaligram Nighantu* has also commented it to be *Madak*, *Bhramak* and *Dhrishtimadhyakara*^[4]. Chewing tobacco contains nicotine, carcinogens (TSNAs, PAHs) and other harmful substances (mostly heavy metals such as cadmium, uranium and polonium) that impacts the different systems of the body^[5]. One of the features of tobacco related mortality in India is the high incidence of oral cancers. Chewing tobacco contains, about more than 28 cancer causing agents including benzopyrene^[5]. Efforts to combat this global threat is essential to save lives and improve public health.

Prevalence: India is the second largest tobacco producing nation^[6] and the second largest consumer of tobacco worldwide^[7]. The World Health Organization (WHO) classifies tobacco addiction as a chronic condition driven by nicotine dependence, which creates a complex cycle of physical and psychological dependence. According to the GATS 2 (Global Adult Tobacco Survey Second) which was carried out during August 2016 - February 2017 revealed that 28.6% (266.8 million) of adults in India aged 15 and above use tobacco in some form or another. About 24.9% of adults (232.4 million) are daily users and 3.7% (34.4 million) are occasional users of whom 42.4% are men and 14.2% are women. Every tenth adult in India (10.7%) currently smokes tobacco, and every fifth adult (21.4%) in India uses smokeless tobacco. Prevalence among men is 29.6% and 12.8% in women for smokeless tobacco^[8]. Smokeless tobacco usage poses serious health risks, and there is no safe level of exposure to tobacco. Thus, the clinical study entitled "Clinical evaluation of the effect of *Tumburu* (*Zanthoxylum armatum* DC.) in tobacco chewing addiction" was planned to see the efficacy of *Tumburu* in tobacco chewing addiction.

Duration of treatment – 2 months (60 days)

Group	Addicted individuals	Drug	Dose & Duration
Single	40	<i>Tumburu</i>	2 fruit pericarp, four to five times a day for 2 months.

AIM AND OBJECTIVES

1. To evaluate the clinical efficacy of *Tumburu* (*Zanthoxylum armatum* DC.) in tobacco chewing addiction.
2. To conduct a clinical study regarding *Tumburu* in tobacco chewing addiction.
3. To develop an Ayurvedic remedy for reduction in the harmful effects by nicotine consumption.
4. To introduce an alternative replacement drug therapy for the tobacco chewing addiction.
5. To establish a reliable, safe and cost-effective Ayurvedic remedy for tobacco chewing de-addiction.

MATERIALS AND METHODS

The study was approved and ethical clearance was obtained from Institutional committee of Uttarakhand Ayurved university, Rishikul campus, Haridwar (UAU/RC/IEC/2024/PG/187). The trial was registered with the Central trial registry of India (CTRI/2024/09/074194). The drug *Tumburu* was collected from Munsyari region of Pithoragarh district, Uttarakhand in the month of October 2024.

Plan of Study

Detailed study of tobacco and tobacco addiction was studied from different authentic sources of ayurveda and modern science, previous and ongoing research works, journals and publications. The study was conducted on 40 addicted individuals in a single group depending on the detailed clinical history, addiction history, physical examination and other necessary investigations irrespective of their gender, caste or creed. Based on inclusion and exclusion criteria total 40 tobacco addicted patients were selected from OPD no. 2 of PG Department of Agad Tantra, Rishikul campus, Haridwar.

Study Design

- ❖ Type of the study – Open Label Single Arm Clinical Trial
- ❖ Method of treatment
 - Selected drug – *Tumburu*
 - Form of drug – Pericarp of fruit (raw dry form without seed)
 - Dose of medicine – 2 fruit pericarp (dry raw form) 4-5 times a day when there was an urge to chew tobacco.
 - Route of administration – the drug *Tumburu* was administered orally. It was kept in the oral cavity.

Follow up: There were a total of 4 assessments, each at an interval of 15 days and a subsequent follow up at the 30th day after completion of the study trial.

Inclusion criteria

- Patients willing for trial.
- Age ≥18 and ≤ 60 years.
- Patients of either sex.
- Patients having tobacco addiction taking *Jarda, Gutka, Khaini, Pan masala* etc.
- Patients having history of tobacco chewing for at least 2 years.

Exclusion criteria

- Patient not willing for trial.
- Individual with age < 18 and > 60 years.
- Patients having history of tobacco chewing for < 2 yrs.
- Addicted patients suffering from any psychosomatic disorders.
- Addicted patients suffering from diagnosed case of oral cancer, sub mucosal fibrosis or any other malignancy.
- Patients suffering from any major systemic illness like cardiac, renal, diabetes etc.
- Patients who are involved in some other ongoing medical research.

Criteria for withdrawal

- Personal matters.
- Intercurrent illness.
- Aggravation of symptoms.
- Leave against medical advice (LAMA).

Assessment Criteria

The assessment was done on the basis of subjective and objective parameters and scoring was done before and after the treatment.

Subjective Assessment

1. Subjective assessment [9,10,11,12]

Assessment was done before, during (every 15th day) and after the treatment on the basis of following symptoms -

- Craving/Desire
- Irritability/Anger
- Anxiety
- Lack of concentration
- Depression/sadness
- Sleep pattern
- Headache
- Constipation
- Appetite

Craving/ Desire		
Grade score	Intensity	Features
0	None	No craving /no intake of tobacco.
1	Mild	Thinking about chewing tobacco and taking tobacco once/twice a day.
2	Moderate	Wanting to chew tobacco and takes tobacco four to five times a day
3	Severe	Having strong urges to chew, Unable to control and takes more than five times a day.

Irritability/ Anger		
Grade score	Intensity	Features
0	None	Normal
1	Mild	Feeling little irritated/ angered about minor things.
2	Moderate	Having trouble sitting still/Over- thinking about things.
3	Severe	Been easily irritable / angered over a person or things.

Anxiety		
Grade score	Intensity	Features
0	None	No anxiety
1	Mild	Feeling nervous, tense, anxious.
2	Moderate	Feeling impatient about things in life or work, worrying about minor problems, muscle tightens.
3	Severe	Feeling panic, fatigue, agitated, trembling, shortness of breath.

Lack of Concentration		
Grade score	Intensity	Features
0	None	Proper concentration
1	Mild	Having trouble paying attention, easily distracted, not paying attention to details, prone to make careless mistakes.
2	Moderate	Hard paying attention to things, inability to listen or follow a conversation, hard to focus on what someone is saying and following directions.
3	Severe	Confusion, forgetful and misplaces the necessary things and have trouble in organizing and completing task/activities.

Depression / Sadness		
Grade score	Intensity	Features
0	None	Being optimistic
1	Mild	Feeling little hopeless or discouraged in life.
2	Moderate	Feeling depressed, lonely and extremely upset about things.
3	Severe	Feeling stressed/ in grief, Negative feelings, Lacks motivation.

Sleep Pattern		
Grade score	Intensity	Features
0	None	Sound sleep No difficulty in falling asleep (feels fresh when wakes up).
1	Mild	Occasional difficulty in falling asleep (takes more than half an hour to sleep) feels fresh when wakes up
2	Moderate	Waking up frequently during night (1-2 times), being restless and disturbed, feels unrefreshed on waking up.
3	Severe	Difficulty falling asleep/waking up frequently in between sleep and hampers daily day to day activities, no fixed sleep wake pattern.

Headache		
Grade score	Intensity	Features
0	None	Absent
1	Mild	Occasionally at a particular time, heaviness.
2	Moderate	Frequent headache after work/at rest, sensation of tightness, Pressure across forehead or on the sides and back of the head.
3	Severe	Constant headache throughout the day with heaviness and discomfort, throbbing pain, sensitive to light & sound.

Constipation		
Grade score	Intensity	Features
0	None	Daily normal evacuation
1	Mild	Incomplete defecation (2-3 times a day). Normal evacuation of stool with the help of some laxatives (once a week).
2	Moderate	Difficulty in defecation, No evacuation without laxatives daily or enema.
3	Severe	Hard stool, Defecation with manual evacuation.

Appetite		
Grade score	Intensity	Features
0	None	Normal usual diet as always
1	Mild	Occasionally less desire to intake food and takes normal diet as usual.
2	Moderate	Skips a meal in a day / stomach feels full. and frequently less desire to intake food.
3	Severe	Feels bloated, uncomfortable, weak, physically sick, sleepy No desire to intake food.

Objective Assessment

Fagerstrom tolerance questionnaire – Smokeless Tobacco (FTQ-ST)¹³ was used for objective assessment. It was done Before and after the treatment.

Fagerström Tolerance Questionnaire for Smokeless Tobacco (FTQ-ST)

Questions	Response	Points
1. After a normal sleeping period, do you use smokeless tobacco within 30 minutes of waking?	Yes	1
	No	0
2. Is it difficult for you not to use smokeless tobacco where its use would be unsuitable or restricted?	Yes	1
	No	0
3. Do you use smokeless tobacco when you are sick or have mouth sores?	Yes	1
	No	0
4. Nicotine content	Low	1
	Medium	2
	High	3
5. How many days does a tin/can last you?	6 to 7	1
	3 to 5	2
	<3	3
6. On average how, many minutes do you keep a fresh dip or chew in your mouth?	10 to 19	1
	20 to 30	2
	>30	3
7. How often do you swallow tobacco juices?	Never	0
	Sometimes	1
	Always	2
8. Do you keep a dip or chew in your mouth almost all the time?	Yes	1
	No	0
9. Do you experience strong cravings for a dip/chew when you go for more than 2 hours without one?	Yes	1
	No	0
10. On average how many dips or chews do you take each day?	1 to 9	1
	10 to 15	2
	>15	3

*The total score for the FTQ-ST was calculated as the sum of the 10 items. Possible scores range from 4 to 19.

Score ≤ 4 - very low dependence

Score 5 to 8 - low dependence

Score 9 to 11 - moderate dependence
 Score 12 to 15 - high dependence
 Score 16 to 19 - very high dependence

Investigations

Following Investigations was done before and after the treatment-

- Hb %
- Fasting blood sugar
- Random blood sugar
- LFT profile
- KFT profile

Statistical Analysis

All information on various parameters was gathered and statistical study was carried out in terms of mean, standard deviation (S.D.), standard error (SE). Wilcoxon signed rank test was used on the subjective parameters before and after treatment while Paired t-test was applied on the objective parameters before and after treatment in the intra group. The data gathered based on observations was examined to determine the significances at various levels, i.e., at 0.05, 0.01 and 0.001 levels. Finally, results were incorporated in terms of probability (P) as:

P > 0.05 - Insignificant/ Not significant (NS)

P < 0.05 and P < 0.01 - Significant (S)

P < 0.001 - Highly Significant (HS)

Clinical Assessment

Assessment was done in the clinical improvement of following symptoms

- Craving / Desire
- Irritability/ Anger
- Anxiety
- Lack of Concentration
- Depression / sadness
- Sleep Pattern
- Headache
- Constipation
- Appetite

Assessment of Overall Effect of the Therapy

Overall percentage improvement of each patient was calculated by the following formula:

$$\text{Total BT} - \text{Total AT} / \text{Total BT} * 100$$

The result thus obtained from individual patient was categorized according to the following percentile -

Marked improvement: ≥ 75% to 100%

Moderate improvement: ≥ 51% to 74%

Mild improvement: ≥ 26% to 50%

No improvement: ≤ 25%

RESULTS

The clinical trial was conducted on a single group consisting of 40 individuals who were addicted to tobacco chewing. Out of the 40 patients who enrolled in the study, 35 patients successfully completed the trial while 5 patients discontinued the treatment. The data collected from the study trial was subjected to statistical analysis.

Table 1: Effect Based on Subjective Parameters

Subjective Parameters	Mean		Median		SD		Wilcoxon W	P-Value	% Effect	Result
	BT	AT	BT	AT	BT	AT				
Craving/desire	2.80	1.89	3.00	2.00	0.41	1.08	-3.895	<0.001	32.65	HS
Irritability/anger	1.20	0.74	1.00	1.00	0.63	0.74	-4.000	<0.001	38.10	HS
Anxiety	1.34	0.71	1.00	1.00	0.80	0.67	-4.300	<0.001	46.81	HS
Lack of concentration	0.83	0.57	1.00	1.00	0.89	0.61	-2.460	0.014	31.03	S
Depression/sadness	0.80	0.54	1.00	0.00	0.72	0.61	-3.000	0.003	32.14	S
Sleep pattern	0.77	0.46	0.00	0.00	0.97	0.61	-3.051	0.002	40.74	S
Headache	1.06	0.74	1.00	1.00	0.42	0.44	-3.051	0.002	29.73	S
Constipation	0.74	0.23	1.00	0.00	0.82	0.43	-3.491	<0.001	69.23	HS
Appetite	0.49	0.17	0.00	0.00	0.82	0.45	-2.636	0.008	64.71	S

Since observations of subjective parameters are on ordinal scale, Wilcoxon Signed Rank Test was used to test efficacy. From the above table no. 1, it was observed that P-Value for parameters craving/desire, irritability/anger, anxiety and constipation is less than 0.001 which shows statistically highly significant results. Lack of concentration, depression/sadness, sleep pattern and appetite is less than 0.05 which shows statistically significant results. Hence, it is concluded that effect of *Tumburu* was observed in all the parameters.

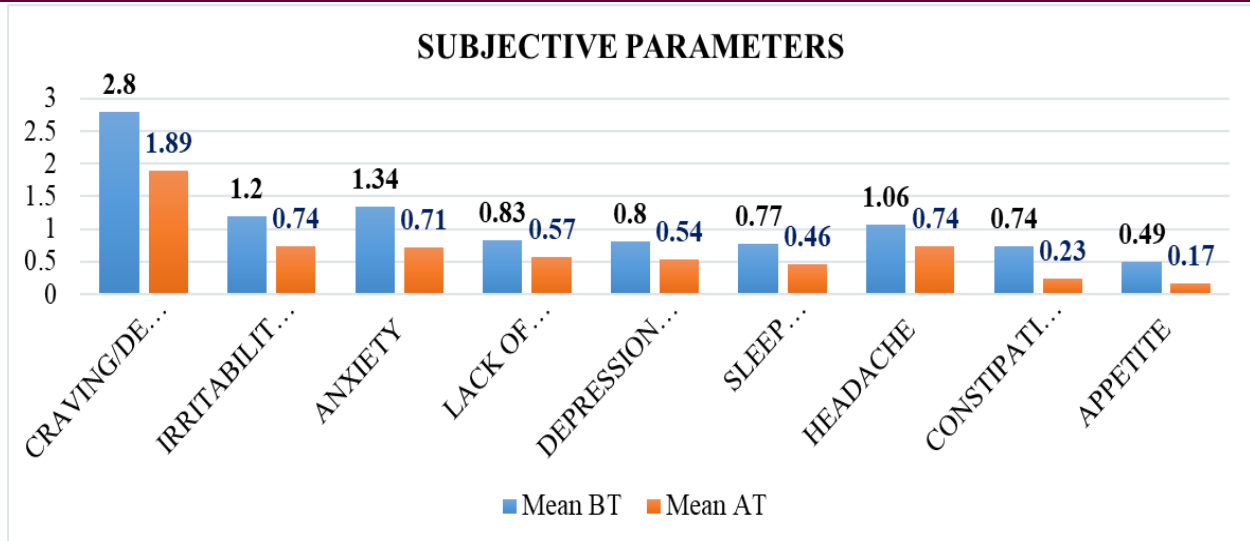


Table 2: Effect Based on Objective Parameter

FTQ-ST	Mean	N	SD	SE	t-Value	P-Value	% Change	Result
BT	13.94	35	2.91	0.49	6.448	< 0.001	31.15	HS
AT	9.60	35	3.83	0.65				

Since observations of objective parameter is quantitative, Paired t- Test was used to test the efficacy. From the above table no. 2, it is observed that P-Value for FTQ-ST parameter is less than 0.001. Hence, it can be concluded that the effect observed in FTQ-ST shows statistically highly significant results.

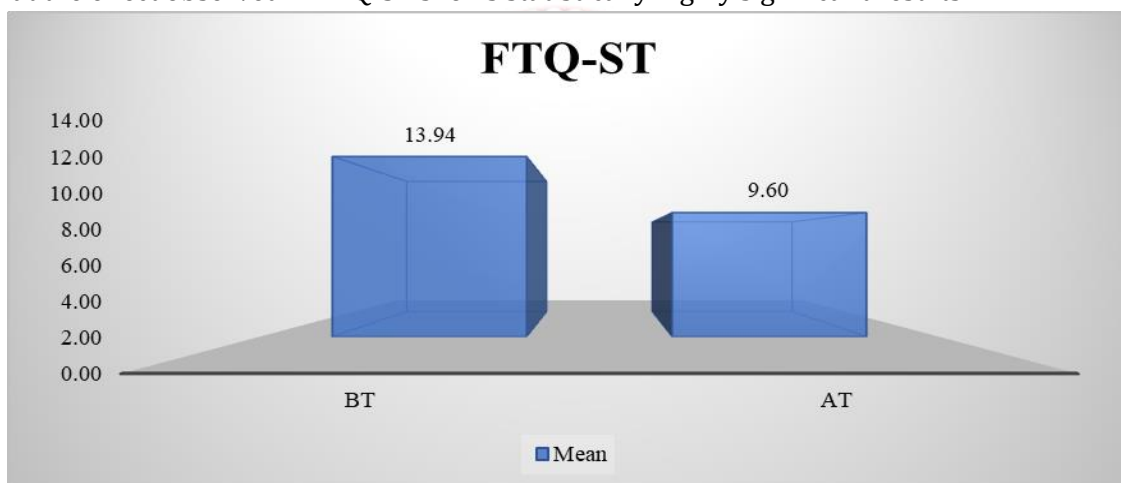
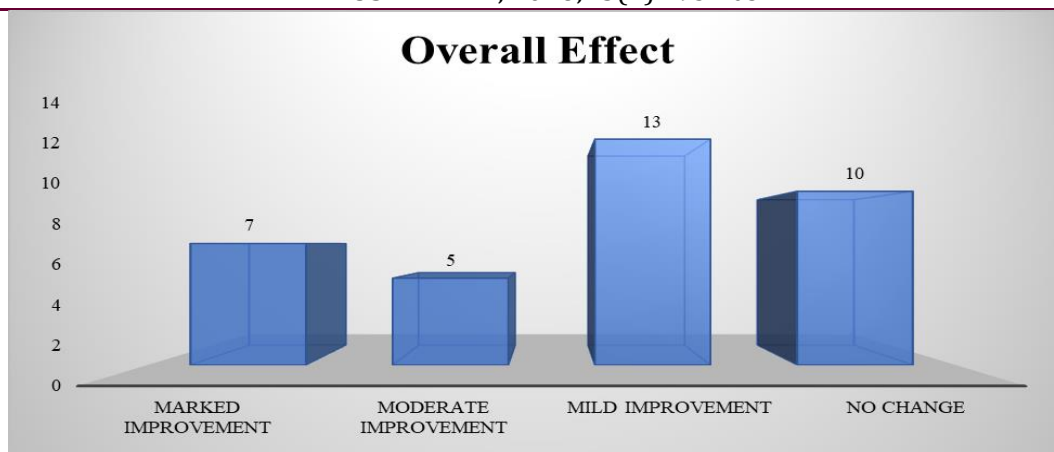


Table 3: Overall Effect of Treatment

Overall Effect	No. of Patients	Percentage
Marked Improvement	7	20%
Moderate Improvement	5	14.29%
Mild Improvement	13	37.14%
No Change	10	28.57%
Total	35	100%

In the above table no.3, among the 35 individuals, 7 addicted individuals (20%) had marked improvement, 5 individuals (14.29%) had moderate improvement, 13 individuals (37.14%) had mild improvement and 10 individuals (28.57%) had no change/improvement.



DISCUSSION

Subjective Outcomes: Constipation (69.23%), appetite (64.71%), anxiety (46.81%), sleep (40.74%), irritability/anger (38.10%), craving/desire (32.65%), depression/sadness (32.14%), lack of concentration (31.03%) and headache (29.73%) had improved significantly as the intake of tobacco got reduced from daily lifestyle.

Objective Outcome: FTQ-ST %effect was 31.15%. **Nidana Parivarjana (habit breaking)** was the key to this outcome.

Overall outcome: The treatment effectiveness of *Tumburu* on various symptoms showed significant improvement. The variations for the effect may be due to the differences in the *Satva Bala*, *Prakriti* and *Satmya* of the addicted individuals.

Tumburu pacifies both the *Kapha* and *Vata Dosh*. It helps to clear the *Srotas* and prevents the oral and throat infections. It also helps to calm the restlessness and improves nerve function, thereby easing both physiological and psychological withdrawal symptoms. *Katu Rasa* (pungent) stimulates saliva and oral mucosa, creating a tingling/numbing sensation that mimics the sensory stimulation of tobacco, helping to reduce cravings. *Tikta Rasa* (bitter) detoxifies tissues, cleanses the oral cavity and reduces dependency-forming tendencies by tobacco chewing. *Madhura Rasa* (sweet) provides nourishing and stabilizing effect counteracting irritability, fatigue and tissue depletion caused by chronic tobacco use. *Laghu Guna* improves digestion and metabolism countering loss of appetite caused by tobacco. *Tikshna Guna* (sharpness) penetrates deeper tissues, breaking down accumulated toxins (*Ama*) and stubborn cravings. *Ruksha Guna* (dryness) reduces excess *Kapha*, phlegm and stickiness in oral cavity caused by chronic chewing. *Vidahi Guna* produces a local burning/tingling effect replacing the oral stimulation of chewing tobacco. *Ushna Virya* stimulates *Agni* (digestive fire), which removes sluggishness and clears toxins from *Srotas* (channels). It helps to overcome

Kapha conditions in the oral cavity and respiratory tract, reducing infection risk common in tobacco users. *Katu Vipaka* enhances metabolism, clears toxins and prevents fat/mucus accumulation. *Deepana-Pachana* property stimulates the *Agni* which removes *Ama* and clears toxins from *Srotas*. Together, all these properties combined makes it a strong Ayurvedic drug for tobacco chewing cessation. No side effects were observed during the study. It combats the chewing habit and provided support to quit its use for better health outcomes.

CONCLUSION

On the basis of the clinical study, observation, results and discussion it can be concluded that in the clinical trial of 60 days, tobacco addicted individuals given *Tumburu* for tobacco cessation showed statistically significant results. *Tamakhu* (tobacco) is viewed as a cardio toxic substance that disrupts the balance of *Doshas*, damages *Dhatu*s and leads to severe health concerns over time. Overcoming nicotine addiction is crucial for preventing long-term health consequences and complications and improving overall health. The therapeutic potential of *Zanthoxylum armatum* proves as a multitarget herbal remedy that interrupts the psychological habit loop of tobacco use. The diverse pharmacological profile of *Tumburu* positions it as a valuable phytomedicine that alleviates both the physical consequences and psychological withdrawal symptoms associated with cessation. It offers a holistic approach which can significantly help to decrease the craving intensity and improve symptoms as irritability, anxiety, lack of concentration, depression, appetite, headache etc. Thus, this study provides the clinical validation for the effectiveness of *Tumburu* in tobacco chewing addiction which is safe and cost-effective.

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