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Original Article

Comparative Evaluation of the Effect of Pharmacotherapy, Low-Level Laser Therapy, and Behavioral Counseling on Tobacco Cessation: A Parallel Randomized Clinical Trial

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Abstract

Background: Nicotine lozenges help reduce nicotine gradually. They are a discreet NRT alternative. This study compared nicotine dependence, cotinine levels, quit rates, and physical effects before and after one month of NRT lozenges, laser therapy, and counselling.

Methods: This randomised controlled trial tested nicotine lozenges, laser therapy, and counselling. This trial included 75 participants (25 per group) over one month. Seventy-five participants were divided into three groups of 25. The "Jus-Check™ Rapid Nicotine Test" was used. Laser therapy targeted both ears weekly for four weeks, with counselling provided weekly. Primary outcomes included nicotine dependence, cotinine levels (saliva/urine), and quit rates; whereas, secondary outcomes included physical effects before and after intervention.

Findings: The results showed a significant decrease in nicotine dependence and cotinine ($P<0.001$) in all groups. However, differences between groups and quit rates were not statistically significant.

Conclusion: Nicotine lozenges are as effective as laser therapy and counselling for quitting smokeless tobacco. This approach reduces dependence, lowers cotinine, increases quit rates, and improves physical effects.

Keywords: Tobacco use cessation, Nicotine, Cotinine, Counselling, Smokeless

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Introduction

Tobacco, derived from Nicotiana plants of the Solanaceae family, contains nicotine—an addictive compound that stimulates the dopaminergic system, increasing dopamine release, and reinforcing dependence.[1,2] The tobacco epidemic is a global public health crisis causing over 8 million deaths annually, including 1.2 million from second-hand smoke exposure. Tobacco use is a major preventable risk factor for cancers, cardiovascular diseases, and respiratory diseases. In India, 28.6% of the population uses tobacco, with 42.4% of men, 14.2% of women, and 4% of adolescents aged 15–17 years affected.[3]

Smokeless tobacco, associated with increased risk of oral cancer and periodontal disease, remains a major global health concern despite ongoing cessation initiatives. Tobacco addiction can be addressed through a range of cessation strategies, including behavioral counselling, pharmacological interventions such as Nicotine Replacement Therapy (NRT), and laser therapy.[4]

Although widely used, behavioral counselling alone shows limited success, with relapse rates approaching 20%.[5] Consequently, adjunctive pharmacotherapies such as Nicotine Replacement Therapies (NRTs), bupropion, and varenicline have been explored to enhance counselling effectiveness.[6]

Nicotine Replacement Therapy (NRT) is financially burdensome for individuals with lower socioeconomic status and may lead to dependence. Acupuncture, by promoting neurochemical release for analgesia and relaxation, offers a potential alternative for tobacco cessation.[7]

Acupuncture has been explored as a method to reduce tobacco cravings, and a novel, non-invasive approach, low-level laser therapy, is now employed to target acupoints related to tobacco cessation. The probe emits light at 660 nm and 880 nm, which is absorbed by mitochondria

and chromatophores, promoting enhanced cellular activity.[8] Although previous studies have investigated the effectiveness of lasers for smoking cessation, none have specifically addressed tobacco chewers, and few have utilised quantitative measures to assess outcomes. The lack of sufficient quantitative data and research on laser auricular acupuncture for smokeless tobacco cessation underscores the need for studies evaluating the combined impact of laser therapy and behavioural counselling in aiding cessation.[9]

There is a necessity for effective interventions, as 64% of smokeless tobacco users express a desire to cease using. Behavioural approaches effectively enhance ST abstinence rates. The nicotine lozenge (NRT) and laser auricular acupuncture represent the latest methods shown to enhance tobacco abstinence rates and alleviate withdrawal symptoms in cigarette users.[10]

While extensive research has investigated the combination of nicotine replacement therapy (NRT) and behavioural counselling, comparative studies involving NRT, laser auricular acupuncture, and counselling for smokeless tobacco cessation remain limited.[11] Although each therapy has demonstrated efficacy, robust comparisons, particularly regarding the long-term effects of NRT alongside alternative treatments, are scarce. Understanding NRT's comparative efficacy is essential for developing more effective, personalised cessation strategies.

The primary objective of the study was to evaluate and compare nicotine dependence, quit rates, and salivary and urine cotinine levels among smokeless tobacco users before and one month following NRT-lozenge, laser therapy, and behavioral counselling. The secondary purpose was to assess and compare the physiological effects of tobacco consumption before and one month following the administration of NRT lozenges, laser therapy, and behavioral counselling. The null hypothesis posited that 'there is no difference in the efficacy of NRT lozenge, laser auricular acupuncture (LLLT), and behavioral counselling' for nicotine cessation.

Methodology

Study Design

The present investigation employed a randomised controlled trial with a concurrent parallel design, in which participants were randomly allocated to three groups: the behavioral counselling group, the NRT group (Lozenges), and the Low-Level Laser group.

Study Setting

The research was conducted between March 2024 and June 2024 at the Unit of Public Health Dentistry, a unit within the dental institute.

Ethical Clearance

The study protocol received approval from the Institutional Ethical Committee. [Reference Number: Dean/2024/EC/6975, dated: 28/02/2024]. The protocol was registered in the Clinical Trial Registry India (CTRI/2024/07/071001).

Sample Size Determination

Sample size was calculated based on the results of the study done by Panos NG et al using the G Power software version 3.1.9.7 with an effect size of 0.933 being estimated from the mean scores of the previous study.[12] A minimum of 20 samples per group was needed at 80% power and 5% α error. Considering the length of follow-ups and a drop-out rate of 20%, the final sample size was increased to 25 per group. Sampling was done using a simple random sampling technique.

Inclusion and Exclusion Criteria

Participants aged 18-70 years old, current tobacco users with low to moderate nicotine dependence, and participants who are self-willing to quit tobacco were included in the study. Known patients with diabetes mellitus, cardiac problems, epilepsy, people lacking skin sensation, immunocompromised individuals, patients with autoimmune diseases, severe skin lesions people suffering from undiagnosed fever, infection at and around the acupuncture points, pregnant females and lactating mothers, people who were taking psychiatric medication and unable to comply with scheduled appointments, people using Roaccutane at any time within the last six months, and subjects who underwent TCC/NRT previously, were excluded.

Random Sequence Generation

Randomization was performed using the Clinical Trial Randomization Tool made available by the National Cancer Institute.[13] And for the allocation of concealment mechanism, the codes generated after randomisation were concealed in sequentially numbered, opaque, sealed envelopes by a third person who was not a part of the main study.

Blinding

The investigator remained blinded till the participants' enrollment in the group assignments, and the outcomes were evaluated by an independent assessor who was also unaware of the participants' group allocation.

Study methods

A total of 75 eligible participants were randomly divided into the following intervention groups. Enrolled subjects (n = 25) were assigned to either Nicotine replacement therapy (Nicotine lozenge; Group I) and Laser auricular acupuncture (laser therapy; Group II), and Behavioural Counselling (Group III) at a ratio of 1:1 (n = 25 for each

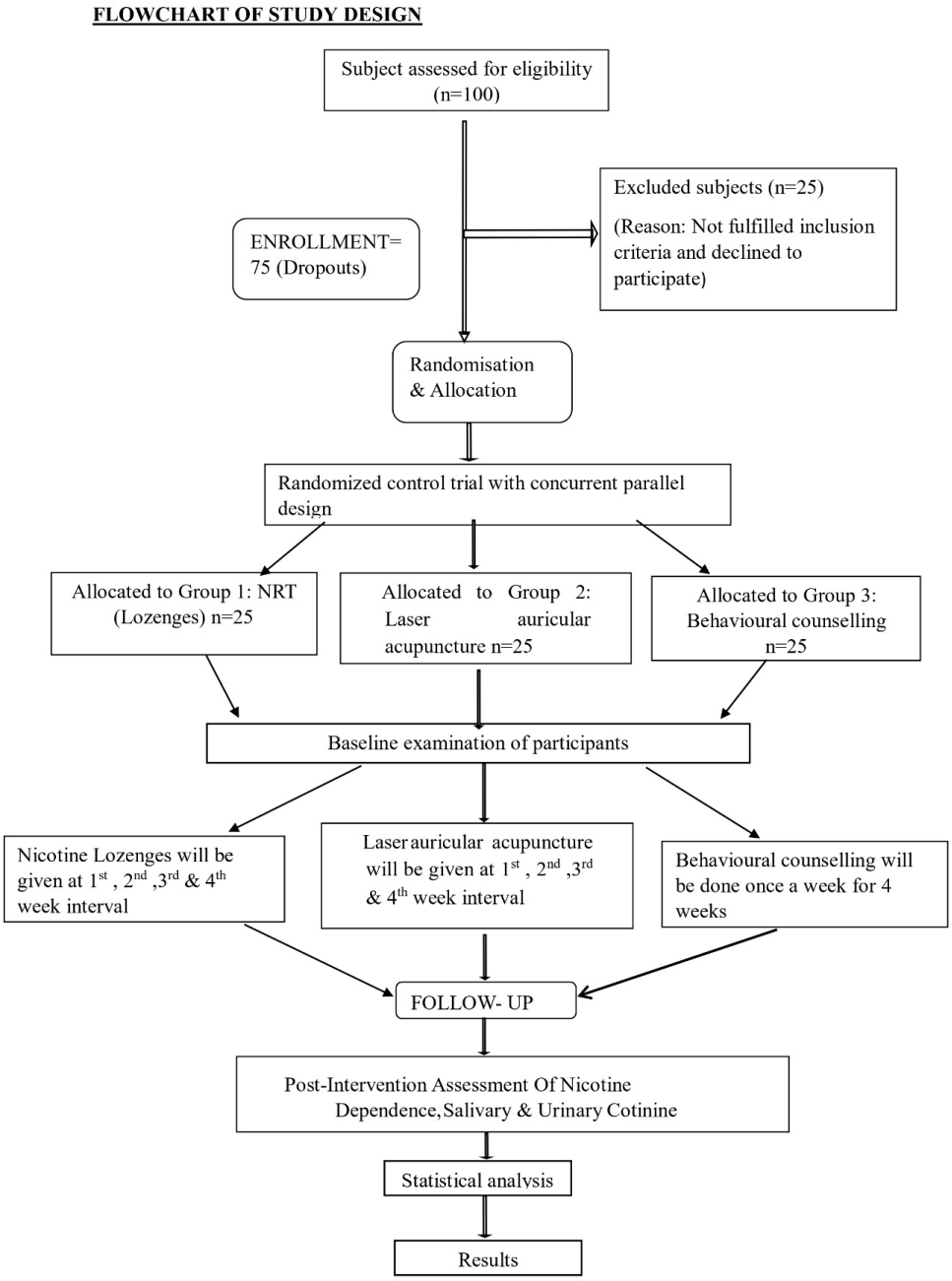

Figure 1. The CONSORT flowchart of the study design

group). [Figure 1]

Group 1 consisted of 25 participants who received Behavioral counselling. Participants underwent behavioral counselling as they showed a willingness to quit tobacco. Participants in the behavioral counselling group received organised cessation support rooted in the 5 A's (Ask, Advise, Assess, Assist, Arrange) and 5 R's (Relevance, Risks, Rewards, Roadblocks, Repetition) framework as recommended by the WHO and the U.S. Public Health Service. Sessions lasting between 45 and 60 minutes were held weekly for four weeks by a qualified dental public health professional. The counselling focused on enhancing motivation, establishing a quit date, managing cravings and withdrawal symptoms, preventing relapse, and providing reinforcement through tailored advice and educational materials. Documentation was maintained for each session to ensure consistency and adherence to follow-up.

Group 2 was Nicotine Replacement Therapy (NRT-lozenge): The NRT group of 25 participants received 2 mg nicotine lozenges named Nobacco based on their tobacco intake frequency. Subjects were instructed to suck the lozenge until a tingling sensation was felt, then place it in the cheek and repeat the process until the nicotine was mostly absorbed, retaining each lozenge for at least 45 minutes. Participants were asked to avoid citrus, beverages, or soft drinks one hour before and after using NRT. The daily lozenge count was reduced by two pieces

every week over four weeks. Cotinine levels in saliva and urine were assessed at the start and end using the JusChek Rapid Nicotine Test.

Group 3 consisted of 25 participants who received laser auricular acupuncture through a low-level diode laser once weekly for four weeks. The protocol adhered to the guidelines set by the National Acupuncture Detoxification Association (NADA) for selecting and applying acupoints.[14] A continuous-wave diode laser (with a power output of 100 mW, beam area measuring 0.62 cm^2, a wavelength of 660 nm, and an energy density of 7.2 J/cm^2 per point) was utilized in contact mode. The laser treatment was applied to four standardized auricular acupoints on each ear—Shenmen, Sympathetic, Lung, and Liver—which are typically associated with reducing cravings, promoting relaxation, and facilitating detoxification. Each acupoint received irradiation for 1 minute, resulting in a total of 8 minutes per session (4 points per ear × 1 minute each). The treatment sessions took place once a week for four weeks while maintaining aseptic procedures. Both the operator and the participant were required to wear protective eyewear throughout the treatment. Participants were comfortably positioned in a semi-reclined posture in a calm environment to reduce external distractions. The same operator conducted all treatments to maintain consistency. To enhance participant comfort and ensure standardization, verbal relaxation cues were provided before and after each session. No adverse effects were reported during or after the sessions.

Outcome Assessment

FTND for Smokeless Tobacco

The nicotine dependence was assessed using the Fagerström test for nicotine dependence as per the Fagerström Test for Nicotine Dependence-Smokeless Tobacco (FTND-ST) and was categorized as low, moderate, or high levels of dependence.[15] The FTND-ST format is provided in (Table 1).

Salivary and Urinary Cotinine Assessment

Saliva and urine samples were collected using the JusChek Rapid Nicotine Test strip. This test was conducted at baseline and at the end of a one-month study to detect cotinine. The strip provides a reliable qualitative measure of cotinine, indicating both active and passive tobacco exposure, with a cutoff concentration of 200 ng/ml.

Frequency of Consumption to Assess the Quit Rate

Patients were asked about the number of tobacco products consumed per day during the first week and one month of the intervention.

Physical Effects Determined by Visual Analogue Scale

Physical effects were evaluated before and after intervention in both groups on a scale of 0 to 10, i.e., irritability, calmness, tiredness, anxiety, unpleasant taste, headache, ability to concentrate, and appetite. The scores for physical effects were recorded through the Visual Analogue Scale. The participants were asked about each physical effect and to rate it from 0 to 10 according to the intensity felt by the participant (Figure 2).

Table 1. The FTND-ST format for recording questionnaire

Please select one answer for each question		
Questions	**Options**	**Score**
1. How soon after you wake up do you place your first dip?	Within 5 min	3
	5–30 min	2
	31–60 min	1
	After 60 min	0
2. How often do you intentionally swallow tobacco juice?	Always	2
	Sometimes	1
	Never	0
3. Which chew would you hate to give up most?	First in the morning	1
	Any other	0
4. How many cans/pouches per week do you use?	More than 3	2
	2–3	1
	1	0
5. Do you chew more frequently during the first hours after awakening than during the rest of the day?	Yes	1
	No	0
6. Do you chew if you are so ill that you are in bed most of the day?	Yes	1
	No	0

Score: 1-2 = Low dependence; 3-4 = Low to moderate dependence; 5-7 = Moderate dependence; 8 + = High dependence

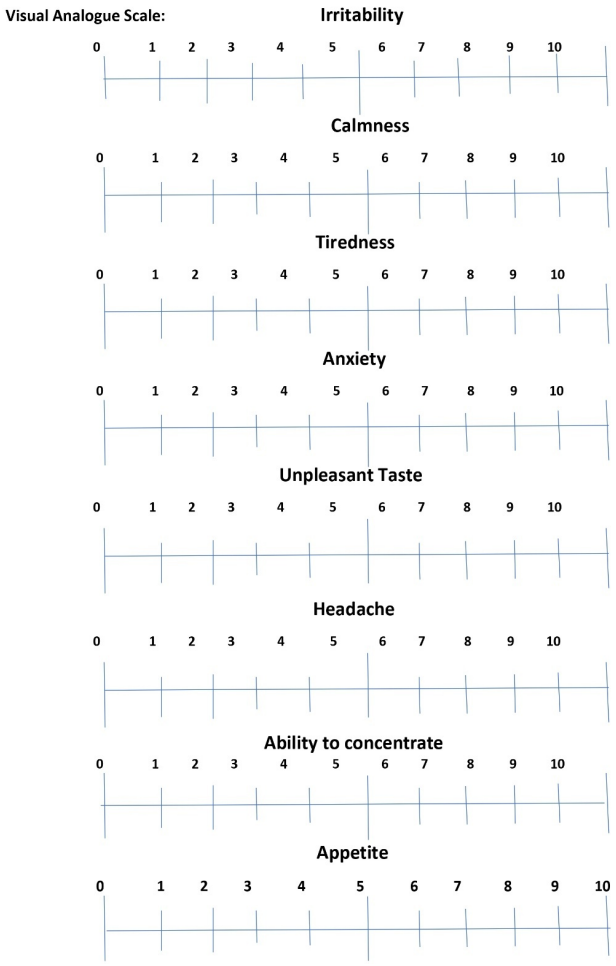

Figure 2. The Visual Analogue Scale (VAS) format to see the physical effects

Statistical Analysis

Statistical analyses were performed using IBM SPSS software (version 25), with the significance level set at 0.05. The Shapiro-Wilk test was applied to evaluate the normality of the data distribution, revealing that the data did not follow a normal distribution. Consequently, non-parametric tests were employed for subsequent analyses. The Wilcoxon signed-rank test and Kruskal-Wallis test were utilized to assess intra- and inter-group differences in nicotine dependence levels, as measured by the Fagerström Test for Nicotine Dependence, and in physical effects, assessed using the Visual Analogue Scale (VAS). Inter- and intra-group comparisons of quit rates and salivary and urinary cotinine levels were conducted using the Chi-square test, while the McNemar test was specifically applied to intra-group comparisons of salivary and urinary cotinine levels.

Results

Table 2 presents the comparison of Nicotine dependence through the Fagerström scale. The intra-group comparison across all three groups demonstrated a statistically significant reduction in Fagerström scores ($P<0.001$). However, no significant differences were observed in the inter-group comparison between the groups before the intervention (Cohen's effect size f = 0.14; $P=0.45$) as well as after the intervention (Cohen's effect size f = 0.09; $P=0.76$) (Table 2).

Table 3 presents the comparison of salivary and urinary cotinine levels. The intra-group analysis of salivary and

Table 2. Inter- and Intra-group comparison of Nicotine dependence through the Fagerstrom scale between three groups

Group	Pre-intervention Fagerstrom score		Post-intervention Fagerstrom score		Intragroup *P* value*
	Mean ± SD	95% CI	Mean ± SD	95% CI	
Counseling	3.60 ± 0.82	3.22-3.98	0.30 ± 0.47	0.08-0.52	<0.001
NRT	3.55 ± 0.82	3.16-3.94	0.20 ± 0.41	0.01-0.39	<0.001
Laser	3.35 ± 0.74	3.00-3.70	0.25 ± 0.44	0.04-0.46	<0.001
Intergroup *P* value**	0.45		0.76		

*Wilcoxon signed rank test, **Kruskal Wallis test (*P*-value ≤ 0.05 is considered significant).

Table 3. Inter- and intra-group comparison of Salivary and Urinary Cotinine between three groups

VARIABLES	GROUPS						
	COUNSELING		NRT		LASER		*P* value*
	Yes n (%)	No n (%)	Yes n (%)	No n (%)	Yes n (%)	No n (%)	
Pre-intervention Salivary Cotinine	20(100%)	0	20(100%)	0	20(100%)	0	-
Post-intervention Salivary Cotinine	14(70%)	6(30%)	16(80%)	4(20%)	15(80%)	5(25%)	**0.76**
P value**	**<0.001**		**<0.001**		**<0.001**		
Pre-intervention Urinary Cotinine	20	0	20	0	20	0	**-**
Post-intervention Urinary Cotinine	15(75%)	5(25%)	16(80%)	4(20%)	15(75%)	5(20%)	**0.91**
P value**	**<0.001**		**<0.001**		**<0.001**		

*Chi-square test, McNemar Test** (*P* value ≤ 0.05 is considered significant). Bold numers mean statistically significant.

urinary cotinine levels revealed a statistically significant reduction within the behavioral counselling, NRT lozenge, and low-level laser therapy groups ($P<0.001$). However, the inter-group comparison showed no statistically significant differences with a small effect size among the groups ($P=0.76$; Cramer's V = 0.09 and $P=0.91$; Cramer's V = 0.06, respectively) (Table 3).

Table 4 presents the results of the quit rate as self-reported by participants. In the NRT group, 16 participants (80%) reported quitting tobacco use, while 4 participants (20%) continued. Similarly, in the laser group, 15 participants (75%) reported quitting, and 5 participants (25%) continued. In contrast, 14 participants (70%) in the counseling group reported quitting, whereas 6 participants (30%) continued tobacco use. The difference in quit rates was found to be statistically non-significant ($P=0.766$) among the groups with a small effect size (Cramer's V = 0.09) (Table 4)

Table 5 presents the results of the physical effects. The Visual Analogue Scale was used to assess the physical effects, with an intergroup comparison of pre-intervention values revealing no statistically significant differences across all tested variables. Similarly, the intergroup comparison of post-intervention values demonstrated no significant differences for most variables, except for irritability, which showed a statistically significant result ($P<0.001$).

In the nicotine lozenge group, post-intervention

Table 4. Inter- and intra-group comparison of the Quit rate between the three groups

	Groups						
Variables	**Counseling**		**NRT**		**Laser**		***P* value***
	Yes n (%)	**No n (%)**	**Yes n (%)**	**No n (%)**	**Yes n (%)**	**No n (%)**	
Quit Rate	14(70%)	6(30%)	16(80%)	4(20%)	15(75%)	5(25%)	**0.76**

***Chi-square test** (*P*-value≤0.05 is considered significant). Bold numers mean statistically significant.

Table 5. Inter- and Intra-group comparison of nicotine dependence through the physical effects using the VAS scale between three groups

	Groups			
VARIABLES	**Counseling (Mean ± SD)**	**NRT (Mean ± SD)**	**Laser (Mean ± SD)**	***P* value****
Irritability Pre	5.05 ± 0.82	5.35 ± 0.67	5.00 ± 0.97	**0.26**
Irritability Post	3.90 ± 0.91	3.80 ± 0.76	2.65 ± 1.38	**<0.001**
P value*	**<0.001**	**<0.001**	**<0.001**	
Calmness Pre	4.00 ± 0.72	3.35 ± 0.67	3.55 ± 0.88	**0.37**
Calmness Post	4.65 ± 0.81	4.55 ± 0.82	4.35 ± 1.08	**0.66**
P value*	**0.004**	**<0.001**	**0.017**	
Tiredness Pre	4.95 ± 0.82	5.20 ± 0.89	4.90 ± 0.96	**0.46**
Tiredness Post	3.75 ± 0.91	3.80 ± 0.69	2.95 ± 1.31	**0.059**
P value*	**<0.001**	**<0.001**	**<0.001**	
Anxiety Pre	6.05 ± 0.94	5.10 ± 0.91	5.05 ± 0.88	**0.77**
Anxiety Post	3.90 ± 0.78	4.10 ± 0.91	3.05 ± 1.46	**0.053`**
P value*	**<0.001**	**<0.001**	**<0.001**	
Unpleasant taste Pre	6.05 ± 1.23	6.25 ± 1.16	6.35 ± 1.08	**0.77**
Unpleasant taste Post	4.35 ± 1.26	4.00 ± 0.85	3.50 ± 1.76	**0.55**
P value*	**<0.001**	**<0.001**	**<0.001**	
Headache Pre	1.05 ± 0.88	1.00 ± 0.64	0.75 ± 0.71	**0.43**
Headache Post	0.65 ± 0.74	0.45 ± 0.60	0.35 ± 0.48	**0.43**
P value*	**0.097**	**0.005**	**0.033**	
Ability to concentrate Pre	4.50 ± 0.76	4.00 ± 0.79	4.50 ± 0.68	**0.83**
Ability to concentrate Post	5.20 ± 0.76	4.85 ± 0.58	5.10 ± 0.55	**0.28**
P value*	**0.011**	**<0.001**	**0.003**	
Appetite Pre	4.40 ± 0.82	4.25 ± 0.85	4.40 ± 0.59	**0.65**
Appetite Post	6.30 ± 0.80	6.65 ± 0.87	7.05 ± 1.39	**0.08**
P value*	**<0.001**	**<0.001**	**<0.001**	

*Wilcoxon signed rank test, **Kruskal Wallis test (*P* value≤0.05 is considered significant). Bold numers mean statistically significant.

Visual Analogue Scale (VAS) scores showed significant reductions in irritability, calmness, tiredness, anxiety, unpleasant taste, ability to concentrate, and appetite, which was found to be ($P < 0.001$). However, there was a statistically significant increase in headache scores ($P = 0.005$).

In the laser group, post-intervention VAS scores demonstrated significant reductions in irritability, tiredness, anxiety, unpleasant taste, and appetite found to be ($P < 0.001$). Conversely, there were significant increases in the post-intervention scores for calmness ($P = 0.017$), headache ($P = 0.033$), and ability to concentrate ($P = 0.003$).

In the counseling group, post-intervention Visual Analogue Scale (VAS) scores revealed significant reductions in irritability, tiredness, anxiety, unpleasant taste, and appetite found to be ($P < 0.001$). Additionally, there was a significant increase in calmness ($P = 0.004$) and ability to concentrate ($P = 0.011$). However, post-intervention scores for headaches showed a non-significant increase ($P = 0.097$) (Table 5).

Discussion

The study aimed to assess and compare the efficacy of Nicotine Replacement Therapy lozenges, laser therapy, and behavioral counseling on tobacco cessation. Each group consisted of twenty volunteers who underwent interventions for one month. The findings suggest that nicotine lozenges demonstrated marginally superior effectiveness compared to laser therapy and behavioral counseling, as indicated by more significant decreases in both salivary and urinary cotinine levels.

Nicotine dependency was evaluated, revealing a statistically significant decrease in Fagerström Scale Score ($P < 0.001$) across all groups. Similar results were reported by Yavagal et al and Velangi et al who compared laser therapy with behavioral counseling for smoking cessation.[16,17] Both groups exhibited a notable decrease in dependence levels from the pre-intervention to the post-intervention phase. Present research investigating the efficacy of nicotine lozenges as a novel intervention indicates they may be more effective in diminishing nicotine dependence. Preliminary findings suggest that nicotine lozenges may offer a more effective alternative, as significant reductions in dependence levels were observed from pre- to post-intervention. Nevertheless, additional comparison research is necessary to validate their superiority over conventional approaches such as laser therapy and counseling.

The post-intervention differences in salivary and urinary cotinine levels were statistically significant within each group ($P < 0.001$). Hand et al however, reported no significant difference between patients using NRT alone and those who received combined NRT and counseling.[18] While direct comparisons are limited due to differing methodologies, prior studies have contrasted these interventions with a placebo. Brief medical support with NRT has shown effectiveness for motivated smokers, though Dar et al noted only modest efficacy improvements over placebo, even in heavy smokers.[19] Similarly, Pai and Prasad reported favorable placebo responses in individuals with low dependence, with 68% and 47.6% success rates, respectively.[20]

According to Raja et al NRT was most effective in patients with very high dependence (78.7%) and outperformed OHE, with a greater mean score reduction. In this study, comparing nicotine lozenges, laser therapy, and behavioral counseling, the 'Jus Check Kit' results indicated that nicotine lozenges significantly reduced cotinine, highlighting their superior efficacy in reducing nicotine consumption. Although no direct correlation was observed between dependence levels and cotinine, objective data support the greater effectiveness of nicotine lozenges in reducing tobacco use. Participants in the counseling group may have reduced their dependence; however, even minimal tobacco use within the previous 2–3 days can raise cotinine levels due to its 16-hour half-life and 72-hour clearance time.[21]

Patient-reported data are crucial for determining quit rates. In this study, 80% of participants in the NRT-lozenge group, 75% in the laser group, and 70% in the counseling group reported quitting tobacco. Similarly, Yavagal et al observed a greater reduction in daily cigarette/bidi use in the laser group than in counseling, though with lower cessation rates than this study.[16] Kerr et al reported a 55.4% cessation rate in the laser auricular acupuncture group compared to 4.13% in the placebo group, while Lim et al documented an 87.5% cessation rate in the laser cohort.[22,23]

As this study is among the first to compare NRT lozenges with laser therapy and counseling for smokeless tobacco cessation, the findings provide preliminary evidence that lozenges may yield more favorable outcomes than conventional approaches. The lozenges' capacity for controlled nicotine delivery and mitigation of withdrawal symptoms may account for their superior efficacy.

The intergroup comparison of pre-intervention revealed no significant differences across all tested variables. Post-intervention, all tested variables also exhibited non-significant differences, except for irritability, where the laser and nicotine lozenge group demonstrated a significantly improved VAS score compared to the counseling group ($P < 0.001$).

In the Nicotine Lozenge group, the VAS scores for all variables demonstrated a substantial reduction, except the headache VAS score, which exhibited a statistically significant increase ($P = 0.005$).

The VAS ratings for all variables in the laser group showed a significant decrease. Nonetheless, there was a significant increase in post-intervention scores for calmness ($P = 0.017$), headache ($P = 0.033$), and ability to concentrate ($P = 0.003$).

In the counselling group, VAS scores significantly decreased for all variables except for headaches, which showed a non-significant increase ($P = 0.097$). Similarly, studies by Yavagal et al and Velangi et al faced limitations due to their short duration and reliance on self-reported data for nicotine dependency, physical effects, and cessation rates, introducing subjectivity. [16,17]

Nicotine lozenges demonstrated superior efficacy over laser therapy and counselling in this trial, highlighting their potential for tobacco cessation. Despite their promise, prior research has not specifically focused on lozenges in this context, emphasizing the need for further studies to validate these findings.

Limitations

The study's short duration and reliance on self-reported data introduce potential biases, such as recall bias and social desirability bias, which may affect result accuracy. The limited sample size and infrequent follow-ups further constrain the generalizability of the findings and hinder comprehensive data collection, particularly on long-term cessation and relapse. Additionally, the use of subjective measures rather than objective biomarkers limits the precision of the evaluations.

Public Health Significance

Nicotine lozenges offer a promising approach to tobacco cessation. Unlike laser therapy, which provides short-term craving relief, lozenges deliver controlled nicotine doses that help manage withdrawal symptoms and gradually reduce dependence. This pharmacological support, combined with behavioral intervention, enhances their effectiveness for sustained cessation. While further research is needed, current evidence suggests nicotine lozenges may have superior long-term potential.

Future Research Recommendation

This study establishes a foundation for future research by advocating for more follow-ups, longer study durations, and bigger sample sizes to improve the validity and generalizability of the results. Furthermore, integrating additional objective metrics in the evaluation of participants' progress would provide a more exact and accurate assessment of the intervention's effectiveness. This methodology will yield a more thorough comprehension of the long-term effects and the efficacy of nicotine lozenges as a viable tobacco cessation instrument that can support community-based initiatives.

Conclusion

The present study highlights that nicotine lozenges are equally effective as behavioral counseling and low-level laser therapy for smokeless tobacco cessation. Lozenges significantly reduced nicotine dependence, salivary and urinary cotinine levels, quit rates, and physical symptoms. Their effectiveness is further enhanced when combined with behavioral counseling. These findings reject the null hypothesis in the cessation strategy. Larger-scale studies with extended follow-ups are recommended to confirm these results and strengthen their role in mitigating smokeless tobacco use and associated health risks.

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Not Applicable.

Author Contribution

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Writing–review & editing: Jadhav Sachin Kumar, Zainab Akram, Savitha Priyadarsini.

Competing Interests

The authors declare no conflicts of interest.

Ethical Approval

The ethical approval was granted by the Institutional Ethical Committee of the Institute of Medical Sciences, Banaras Hindu University, with ethical clearance No. -Dean/2024/EC/6975.

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