Original Article

Comparative Evaluation of the Effect of Laser Therapy and Behavioral Counseling in Tobacco Cessation: A Randomized Controlled Trial

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Abstract

Background: Laser auricular acupuncture is a form of therapy that is non-invasive, aseptic, and painless, thus advantageous over the traditional form of acupuncture for tobacco cessation. The objective of the study is to evaluate and compare nicotine dependence, urinary cotinine level, physical effects, and quit rate among tobacco chewers before and one month after laser therapy and behavioral counseling, and to evaluate and compare extrinsic stains one month post-intervention.

Methods: The present study was a randomized controlled trial, with laser therapy and behavioral counseling as the test and control interventions, respectively. The laser was focused on both ears once a week for four weeks. Counseling sessions were held once a week for four weeks. Nicotine dependence, urinary cotinine level, physical effects, as measured using the Visual Analog Scale, and quit rate were recorded before and after the intervention.

Findings: The results showed significant reductions in nicotine dependence in both laser and counseling groups post-intervention ($P<0.001$). Urinary cotinine levels increased significantly in the counseling group post-intervention ($P=0.010$). Inter-group comparison revealed significant differences in pre- and post-intervention cotinine levels ($P<0.05$). Adjusted analysis confirmed significant post-intervention differences between the groups ($P=0.048$).

Conclusion: This study demonstrates that combining laser auricular acupuncture therapy with behavioral counseling yields superior outcomes for smokeless tobacco cessation compared to behavioral counseling alone. The combined approach results in greater reductions in nicotine dependence, lower urinary cotinine levels, slightly higher quit rates, and significant improvements in various physical effects associated with tobacco use.

Keywords: Tobacco use cessation, Laser, Counseling, Nicotine, Cotinine

Introduction

Tobacco refers to various plants from the *Nicotiana* genus, part of the Solanaceae family. The addictive substances in tobacco, particularly nicotine, stimulate brain synapses, triggering addictive reinforcement.[1] Nicotine also activates the dopaminergic system, raising dopamine levels in the nucleus accumbens, which plays a key role in reinforcing behavioral changes and promoting nicotine dependence.[2]

The prevalence of tobacco use in India is currently 28.6%, with 42.4% of men and 14.2% of women being tobacco users.[3,4] Among minors aged 15 to 17, 4% are reported to use tobacco.[5] Tobacco addiction can severely impact an individual's life, leading to serious health issues, damage to vital organs, incurable diseases, and ultimately, premature death.[6] Tobacco consumption is recognized as a significant risk factor for numerous diseases.

Individuals struggling with tobacco addiction can be supported through various cessation methods, including behavioral counseling, pharmacological treatments like Nicotine Replacement Therapy (NRT), and laser therapy.

Behavioral counseling is a commonly used method for tobacco cessation, but it carries a higher risk of relapse, often showing low success rates, rapid relapse, and uncomfortable withdrawal symptoms. Among individuals using conventional methods to quit smoking, 20% report relapsing after quitting tobacco.[7] As a result, supportive pharmacotherapies, such as nicotine replacement therapies (NRTs) and first-line medications like bupropion and varenicline, have been explored to complement traditional behavioral counseling.

Nicotine replacement therapy (NRT) is often not affordable for individuals from lower socioeconomic

backgrounds and can also lead to nicotine dependence.[8] To reduce both financial strain and the risk of NRT dependence, alternative methods for tobacco cessation are needed. According to the neurohumoral theory, acupuncture promotes the release of various neurochemical substances that provide analgesic effects and induce overall relaxation, offering a potential alternative approach to pain management.[9]

Research suggests that acupuncture has been used to curb the urge to consume tobacco. A novel, non-invasive form of acupuncture, low-level laser therapy, is now being utilized to stimulate acupoints associated with tobacco cessation. The light emitted by the probe, with wavelengths of 660 nm and 880 nm, is absorbed by the cell's mitochondria and chromatophores, thereby enhancing cellular activity.[10] While previous studies have assessed the effectiveness of lasers in smoking cessation, none have focused on tobacco chewers. Additionally, most studies have not employed quantitative variables to measure smoking cessation outcomes, except one. The absence of sufficient quantitative evidence and a lack of research on laser auricular acupuncture for smokeless tobacco cessation highlight the need for a study to evaluate the combined effect of laser therapy and behavioral counseling in helping individuals quit smokeless tobacco.

The primary objective of the study was to evaluate and compare nicotine dependence, urinary cotinine levels, quit rate, and extrinsic stains among tobacco users before and one month after laser therapy and behavioral counseling. The secondary objective was to evaluate and compare the physical effects of tobacco use before and one month after laser therapy and behavioral counseling. The null hypothesis stated 'there is no difference in the efficacy of laser auricular acupuncture and behavioral counseling in tobacco cessation'.

Methods
Trial design
The present study employed a Randomized controlled trial with a concurrent parallel design, in which participants were randomly divided into two groups: the laser group(Group A) and the Counseling group (Group B).

Ethical Clearance
The study protocol was approved by the Institutional Ethical Committee (Ref. No. Dean/2022/EC/3456, dated August 20, 2022). The protocol was registered on Clinical Trial Registry India (registration number: CTRI/2023/03/050311).

Study setting
The study was conducted at the Unit of Public Health Dentistry, a dental institute. The study was conducted from March 2023 to February 2024.

Sample size determination
The sample size was calculated based on the results of the study conducted by Velangi et al using the G Power software version 3.1.9.7.[11] An effect size of 0.933 was estimated from the mean scores of the previous study. A minimum of 20 samples per group was needed at 80% power, with a 5% α error. Considering the length of follow-ups and a dropout 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 between 18 and 70 years old who were current tobacco users with low to moderate nicotine dependence and were willing to quit tobacco were included in the study. Patients with known diabetes mellitus, cardiac problems, or epilepsy, people lacking skin sensation, immunocompromised individuals, patients with autoimmune diseases or severe skin lesions, people suffering from undiagnosed fever or infection at and around the acupuncture points, pregnant females and lactating mothers, people who were taking psychiatric medication or were unable to comply with scheduled appointments, people who had used Roaccutane at any time with in the last six months, and subjects who had underwent TCC/NRT previously were excluded.

The nicotine dependence was assessed using the Fagerström test for nicotine dependence as per the Fagerström Test for Nicotine Dependence-Smokeless Tobacco (FTND-ST)[12], and dependence levels were categorized as low, moderate, or high. Table 1 shows the details of the Fagerström Test for Nicotine Dependence-Smokeless Tobacco.

Random sequence generation
Randomization was performed using the Clinical Trial Randomization Tool made available by the National Cancer Institute. [13]

Allocation concealment mechanism
The codes generated after randomization were concealed in sequentially numbered, opaque, sealed envelopes by a person who was not a part of the main study.

Masking
The participants were masked, as they were unaware of their group allocation and the type of treatment they received. Participants in the laser group received laser therapy and behavioral counseling, and participants in the counseling group received behavioral counseling along with sham therapy, i.e, all the setup was similar to the laser group, and the laser probe was kept at the four points on the ear for one minute, but the probe was switched off. This would give participants a feeling that the laser was irradiating them. The outcome was assessed by a third

person who was unaware of the group allocation.

A total of 50 eligible participants were randomly divided into the following intervention groups (Figure 1):

Group A
consisted of 25 participants who received laser auricular acupuncture with behavioral counseling. Laser therapy was given once weekly for four weeks, and then behavioral counseling was provided. Diode laser equipment (low-level laser) with the following parameters was used:

- Power output: 100 MW
- Beam area: 0.62 cm²
- Wavelength: 660 nm
- Mode of usage: continuous wave mode
- Energy delivered: 7.2 joules per cm² per point per session
- Method of usage: point probe (contact method) with protective eyewear.

The locations of these points on the external ear were standardized as per the WHO guidelines.[14] Each point on each ear was irradiated for one minute. As the total duration of laser therapy was one minute per point, four minutes for each side (four points), the overall treatment time was eight minutes. During the treatment, protective measures were taken to ensure the safety of both the participants and the investigator.

Group B
consisted of 25 participants who received behavioral counseling with a sham laser treatment.

Participants of group B were under behavioral counseling as they showed a willingness to quit tobacco, and sham laser therapy was given with a switched-off laser probe. The counseling was given once per week for four weeks, and sham laser therapy was given on the same follow-ups, based on the 5 As and 5 Rs.

The urinary cotinine levels were assessed before and four weeks after the intervention. The urine sample was collected in a sterile 30 mL container. The samples were centrifuged at 1500 g for 10 minutes. The supernatant was collected in a 1.5 mL microcentrifuge tube, sealed well, and stored at −80 ℃. The cotinine level was determined through an ELISA test using human cotinine GENLISA™.

Modified lobene stain index
The participants were assessed for extrinsic stains using the Lobene stain index[15,16]. Eight index teeth were assessed for extrinsic stains, specifically 11, 12, 21, 22, 31, 32, 41, and 42.

Physical effects determined by the 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 were asked to rate it from 0 to 10 according to the intensity they felt. The FTND ST format is provided in Table 1.

Statistical analysis
The statistical analysis was done using SPSS version 21. The level of significance was 5%. The normality of the data distribution was assessed using the Shapiro-Wilk test. The Wilcoxon signed-rank test, the Mann-Whitney *U* test, and paired and unpaired *t*-tests were used. As the intervention cotinine levels differed significantly between the two groups at baseline, the adjusted analysis was performed using the ANCOVA test, considering the baseline cotinine values as the covariate, the two intervention groups as the independent variables, and post-intervention cotinine

Table 1. FTND ST format for recording questionnaire

Please tick one box 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 waking up 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
	Test score	
A score of 5 or more indicates significant dependence, while a score of 4 or less shows low to moderate dependence.		

levels as the dependent variable.

Results

Table 2 shows the demographic details of the study participants. In the laser group, 19 out of 20 participants were males and 1 was female. In the counseling group, all 20 participants were male (Table 2).

Table 3 presents the inter- and intra-group comparison of nicotine dependence levels using the Fagerström scale. The post-intervention Fagerström score was significantly lower than the pre-intervention Fagerström score in each group ($P < 0.001$). The intergroup comparison showed that the pre-intervention nicotine dependence in the laser group was almost similar to that of the counseling

group ($P = 0.783$). Additionally, the post-intervention Fagerström score in the laser group was nearly identical to that of the counseling group ($P = 0.566$) (Table 3).

Table 4 presents the inter- and intra-group comparisons of urinary cotinine levels. There was no significant difference between the pre- and post-intervention urinary cotinine levels in the laser group ($P = 0.135$), whereas in the counseling group, the post-intervention urinary cotinine levels were significantly higher than the pre-intervention levels ($P = 0.010$). The intergroup comparison of urinary

Table 2. Demographic characteristics of the participants of the laser and counseling groups

| Group | Gender | | Mean age (years) |
	Male *n* (%)	Female *n* (%)	
Laser	19 (95%)	1 (5%)	41.3 ± 12.22
Counseling	20 (100%)	0	40.3 ± 15.41

Table 3. Inter and intra-group comparison of nicotine dependence level through the Fagerström scale

Group	Pre-intervention Fagerström score (mean ± SD)	Post-intervention Fagerström score (mean ± SD)	*P* value*
Laser	4.80 ± 2.21	1.10 ± 1.86	<0.001
Counseling	5.05 ± 1.79	1.45 ± 1.99	<0.001
Effect size (95% CI)	0.124 (−0.497 to 0.744)	0.182 (−0.440 to 0.802)	
P-value**	0.783	0.566	

*Wilcoxon signed rank test; **Mann-Whitney *U* test; (*p*-value ≤ 0.05 is considered significant)
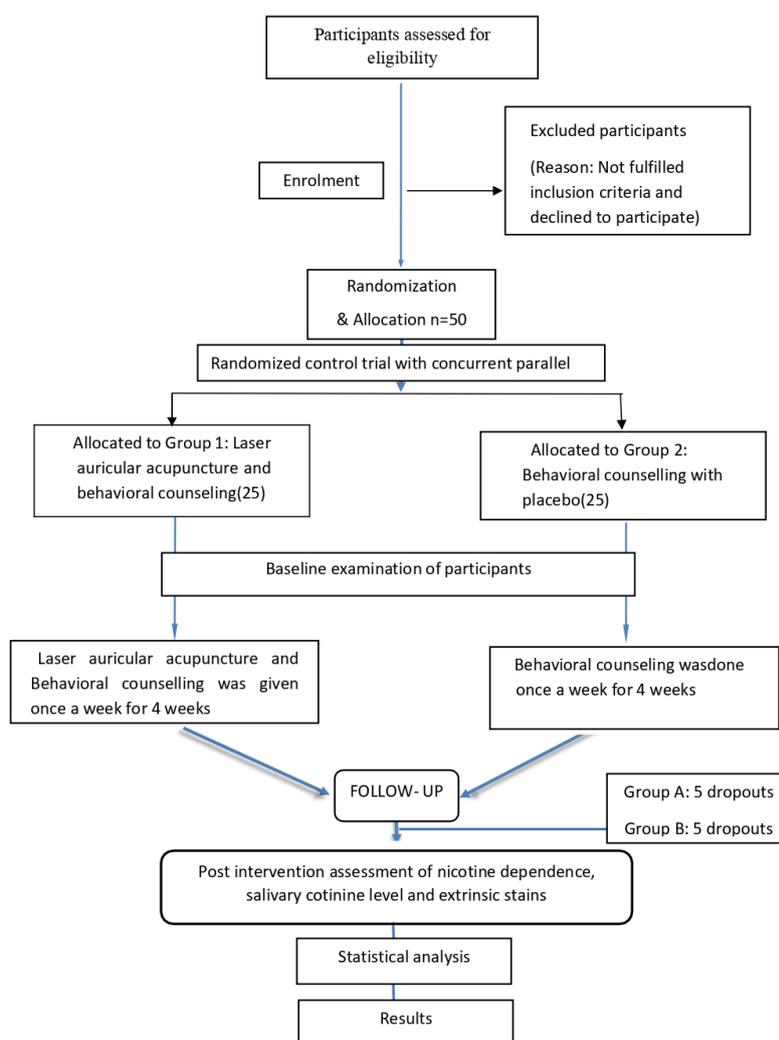

Figure 1. Flow chart of the present study

cotinine levels revealed that the pre-intervention levels in the laser group were significantly higher than those in the counseling group ($P = 0.024$). Post-intervention urinary cotinine levels in the laser group were significantly lower than those of the counseling group ($P = 0.013$). The adjusted analysis was performed due to the significant difference at baseline between the two groups. The adjusted mean value was found to be 5.96 for the laser group and 7.72 for the counseling group. There was a significant difference in post-intervention cotinine levels between the two groups, even after adjusting for baseline data ($P = 0.048$) (Table 4).

Table 5 shows the comparison of quit rates between the two groups. In the laser group, 15 (75%) participants claimed that they had quit tobacco use, and 5 (25%) had continued, whereas in the counseling group, 12 (60%) participants quit tobacco use, and 8 (40%) continued. The difference in quit rate was statistically nonsignificant (Table 5).

Table 6 shows the inter-group comparison of the Lobene stain index level after the intervention. The stains in both groups were evaluated using the Lobene stain index method. Intergroup comparison showed that the post-intervention scores in the laser group were significantly lower than those of the counseling group ($P = 0.034$). Scaling was done for all the participants, so the pre-intervention stain index was not compared (Table 6).

The intergroup comparison of pre-intervention values showed no significant difference for any of the tested variables. The intergroup comparison of post-intervention values showed no significant difference for all tested variables, except for the ability to concentrate. In contrast, the laser group showed a significant improvement in the VAS score ($P = 0.018$).

In the laser group, the post-intervention VAS scores of irritability ($P = 0.001$), tiredness ($P = 0.003$), anxiety ($P = 0.003$), and unpleasant taste ($P = 0.001$) were significantly reduced. For headaches, the VAS score showed a nonsignificant reduction. However, there was a significant increase in post-intervention scores of calmness ($P = 0.005$), ability to concentrate ($P = 0.002$), and appetite ($P = 0.001$). In the counseling group, post-intervention, the VAS scores of irritability, ($P = 0.001$), tiredness ($P = 0.002$), anxiety ($P = 0.001$), and headache ($P = 0.005$) were significantly reduced, and there was a significant increase in calmness ($P = 0.004$), ability to concentrate ($P = 0.005$), and appetite ($P = 0.039$). The post-intervention scores of unpleasant taste showed a nonsignificant increase ($P = 0.474$).

Discussion

The study was conducted to evaluate and compare the effect of laser therapy and behavioral counseling on tobacco cessation. Twenty participants in each group received interventions over a one-month period. The results showed that the laser was more effective than behavioral counseling, as evidenced by significantly lower urinary cotinine levels in the laser group than in the counseling group.

The conventional method of behavior counseling for tobacco cessation has certain limitations, such as relapse and failure; hence, newer modalities such as acupuncture, low-level laser therapy (LLLT), etc., have been evaluated for tobacco cessation. The available literature suggests that LLLT is effective in tobacco cessation[17,18]. Despite over two decades of research into the benefits of low-level laser therapy (LLLT) for tobacco cessation, its precise mechanism of action remains unclear. Proponents of LLLT believe that laser acupuncture therapy can work similarly to traditional needle acupuncture therapy in reducing tobacco addiction by releasing feel-good hormones.

Nicotine dependence was assessed, and a statistically significant reduction in FSS ($P < 0.001$) was noted in both

Table 4. Inter and intra-group comparison of urine cotinine level

Group	Pre-intervention cotinine level (mean ± SD)	Post-intervention cotinine level (mean ± SD)	P value*	Adjusted post cotinine level (mean ± SE)
Laser	6.82 ± 2.4	5.79 ± 2.44	0.135	5.96 ± 0.58
Counseling	5.52 ± 1.18	7.90 ± 2.64	0.010*	7.72 ± 0.58
Effect size (95% CI)	0.746 (0.099 to 1.383)	0.826 (0.175 to 1.468)		
P value**	0.024*	0.013*		0.048*

*Paired *t*-test; ** Unpaired *t*-test; (*P* value ≤ 0.05 is considered significant)

Table 5. Comparison of quit rate with respect to the laser and counseling groups

Group	Quit		Effect size OR (95% CI)	P value*
	Yes *n* (%)	No *n* (%)		
Laser	15 (75%)	5 (25%)	2.000 (0.518 to 7.721)	0.311
Counseling	12 (60%)	8 (40%)		

*Chi-square; (*P* value ≤ 0.05 is considered significant)

Table 6. Inter-group comparison of the Lobene stain index level after intervention

Group	Post-intervention stain score	Effect size (95% CI)	P value*
Laser	0.071 ± 0.226	0.497 (0.136 to 1.12)	0.034
Counseling	0.216 ± 0.345		

*Mann-Whitney *U*-test; (*P* value ≤ 0.05 is considered significant)

groups. A similar result was observed in studies conducted by Yavagal et al[17] and Velangi et al [11], where lasers were compared with behavioral counseling in smoking cessation. A significant decrease in the dependence level was observed from the pre-intervention to the post-intervention phase in both groups.

Urinary cotinine was assessed, and post-laser therapy cotinine levels in the urine were found to be lower than pre-intervention levels; however, the difference was not statistically significant ($P = 0.135$). In contrast, cotinine levels in the counseling group increased post-intervention, and this difference was statistically significant ($P = 0.01$). The pre-intervention urinary cotinine level differed significantly ($P = 0.024$); therefore, the adjusted analysis was performed. Contrary to the results of the present study, Yavagal et al [17] reported a significant reduction in cotinine levels in all the intervention groups. The reason for the increased cotinine level of the Counseling group in the present study may be the consumption of tobacco in the past two to three days by the participant. In the present study, there was a decrease in nicotine dependence level in the counseling group, but there was an increase in the urinary cotinine level. The dependence level is subjective and is measured through the Fagerström scale, so we need to rely on the information provided by the patient. The patient may have answered inaccurately, resulting in the social desirability bias. To mitigate the effect of social desirability bias, an objective ELISA test was conducted to measure the amount of cotinine in the participants' urine. This method helps verify the accuracy of the information provided by the patients. However, the dependence level and the cotinine level in the body are not dependent upon each other. The dependence may have been genuinely reduced in the participants of the counseling group, but the consumption of even a small amount of tobacco two to three days before may have resulted in an increased cotinine level in the urine. As the half-life of cotinine is 16 hours, it takes at least 72 hours to clear the body completely.

The investigator must rely entirely on the information provided by the patient for the quit rate. In the present study, 75% of the participants in the laser group and 60% in the counseling group claimed to have quit their tobacco habit. Similar results were obtained in the study done by Yavagal et al., [17] where there was a larger reduction in the number of cigarettes/bidis smoked per day in the laser group compared to the counseling group. The quit rate was lower compared to the present study. Kerr et al[18] made a comparison of laser auricular acupuncture and placebo in tobacco cessation and found the quit rate was higher in the laser group (55.4%) compared to the placebo group (4.13%). A study conducted by Tan et al[19] employed three laser units with differing power outputs (2, 2.5, and 3 mW). Tan et al[19] reported a superior quit rate (80%) in the laser group compared to the control group among smokers. Rhonda Mostyn et al[20] conducted a single-group study and obtained similar results to those above. In a study conducted by Yiming et al[21] it was observed that in the laser group, there was complete cessation in 21.9% of participants and a reduction in 82.1% of participants (which also included complete cessation) immediately after the intervention. After three months, there was a complete cessation in 24.8% of cases, and 74.3% reported reduced smoking. In the control group, there was complete cessation in 21.4% and a reduction in 80.7% (which included complete cessation) immediately after intervention. After three months, 26.2% showed complete cessation, and 72.9% reported a reduction in smoking. In a study conducted by Lim et al,[22] a 87.5% quit rate was reported in the laser group. In contrast, a meta-analysis by Cochrane described that the laser group had no superior effects as compared to the placebo control group.

The stain index was evaluated using the Lobene stain index. This variable was assessed due to the staining nature of the smokeless tobacco. At the start of the study, scaling was done for all the participants, and the baseline scores were set to zero to facilitate easy comparison. After completing the four follow-ups, scaling was performed again, and the results were compared. It was found that participants in the laser group had significantly lower stain scores compared to those in the counseling group ($p = 0.034$). The reason for the lower stain on the teeth of the laser group participants may be due to a higher quit rate and decreased tobacco consumption. This parameter was not recorded in any other previous studies, so it could not be compared.

Intergroup comparison for the physical effects of the post-intervention values revealed a nonsignificant difference for all tested variables, except for the ability to concentrate, where the laser group showed a significantly better VAS score compared to the control group ($P = 0.018$).

In the laser group, the VAS scores for all variables showed significant improvement, except for headache ($P = 0.059$). In the counseling group, all the variables showed significant improvement except for unpleasant taste ($P = 0.474$). Similar results were obtained regarding physical effects in the studies conducted by Yavagal et al.[17] and Velangi et al[11] The duration of the present study was relatively short. Variables such as nicotine dependence, physical effects, and quit rate were subjective, i.e., we had to rely on the information provided by the patient. Patient follow-up was difficult as it depends on the participant's willingness. The sample size of the study was small, which means fewer follow-ups. Further research on this topic is necessary.

Public Health Significance

Laser auricular acupuncture offers a promising approach for those who want to quit but are unable to because of

cravings. It can be helpful for those who have been seeking treatment via behavioral counseling but have experienced relapse. Laser therapy suppresses the cravings and reduces withdrawal symptoms. Besides, patients are more willing to undergo treatment, respond more sincerely to the clinicians, and take the therapy more seriously.

Recommendation

The present study paves the way for further research with more follow-ups, longer study durations, and larger sample sizes. Additionally, more objective variables can be considered to accurately evaluate the participants.

Conclusion

Laser auricular acupuncture therapy in combination with behavioral counseling is more effective than behavioral counseling alone for smokeless tobacco cessation. Both of these methods reduce the nicotine dependence level equally among tobacco chewers. Laser auricular acupuncture, along with behavioral counseling, reduced the urinary cotinine levels, but behavioral counseling alone showed a slight increase in the cotinine level among the tobacco chewers. The reduced tobacco staining in the laser group indicates lower tobacco consumption and, consequently, less staining. Therefore, the evaluation of nicotine dependence levels, urinary cotinine levels, quit rates, improvement in the physical effects, and stains on the teeth shows that laser auricular photodynamic therapy is more effective in combination with behavioral counseling as compared to behavioral counseling alone for tobacco cessation. Thus, the null hypothesis was rejected.

Authors' Contribution
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Methodology: Naveen Kumar PG, Mahesh Khairnar, and Jyotsna Kailashiya.
Project administration: Naveen Kumar PG and Mahesh Khairnar.
Resources: Zainab Akram and Naveen Kumar PG.
Software: Mahesh Khairnar and Jadhav Sachin Kumar.
Supervision: Naveen Kumar PG and Mahesh Khairnar.
Validation: Naveen Kumar PG and Mahesh Khairnar.
Visualization: Naveen Kumar PG and Mahesh Khairnar.
Writing – original draft: Zainab Akram and Savitha Priyadarsini S.
Writing – review & editing: Naveen Kumar PG and Mahesh Khairnar.

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/2022/EC/3456.

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