CLINICAL & BASIC RESEARCH

Efficacy of Laser Auricular Acupuncture for Smoking Cessation
A randomised controlled trial

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ABSTRACT: ***Objectives:*** The aim of the current study was to compare urinary cotinine levels, nicotine dependence and physical effects related to smoking in smokers before and after laser auricular acupuncture, psychological counselling and a combination of laser treatment with counselling. ***Methods:*** This study was carried out from February to July 2019 in India. A total of 60 smokers were randomly allocated to three interventional groups. Urinary cotinine levels, nicotine dependence and physical effects due to smoking were evaluated using NicAlert strips (Nymox Pharmaceutical Corp., Quebec, Canada) the Fagerström questionnaire and a visual analogue scale, respectively, at baseline and one month post-intervention. Pearson's chi-square, Kruskal Wallis analysis of variance and Wilcoxon sign rank tests were used for statistical analyses. ***Results:*** There was a significant reduction in urinary cotinine levels and nicotine dependence and significant improvement in behaviour and physical effects related to smoking in all groups post-intervention (P <0.05). Reduction in nicotine dependence was significantly higher in the laser group (4.4 ± 1.66) compared to other groups (P <0.01). Reduction in urinary cotinine levels was highest in the laser with counselling group (0.85 ± 0.3) compared to the other groups. There was a significant reduction in irritability, headache, craving for smoking, tiredness and anxiety as well as a substantial increase in calmness, unpleasant taste of smoking, the ability to concentrate and appetite in the laser auricular acupuncture group compared to the other groups (P <0.01) ***Conclusion:*** Laser auricular acupuncture alone and in combination with psychological counselling can reduce nicotine dependence among smokers.

Keywords: Auricular Acupuncture; Laser; Nicotine; Tobacco Dependence; India.

Advances in Knowledge
- *Auricular laser acupuncture alone and in combination with psychological counselling reduces nicotine dependence among smokers.*

Application to Patient Care
- *Low-level laser therapy can be used to stimulate auricular acupoints to reduce nicotine dependence related to smoking. It can also be used as an adjunct therapy along with psychological counselling.*
- *Laser acupuncture is a non-invasive, aseptic and painless therapy which can reduce the withdrawal symptoms associated with smoking cessation.*

Addiction to smoking is a complex condition which can disturb a person's life, leading to health problems, deterioration of vital organs, systemic complications and often premature death.[1] The World Health Organization (WHO) classifies tobacco dependence in the category of 'Diseases, Symptoms or Conditions'. To address this disease, smoking cessation strategies play a pivotal role in saving current smokers from smoking-related mortality and morbidity. The success of such strategies, however, is limited. In a review article based on 633 studies of the most available interventions for smoking cessation, Viswesvaran and Schmidt concluded that the average observed success rate across all methods was just 19% with a 6.4% success rate for placebo controls.[2]

Conventional techniques for smoking cessation have demonstrated a relatively low success rate, quick relapse and unpleasant withdrawal symptoms. Of individuals using conventional approaches to quitting smoking, 20% reported that such treatments had failed in helping them quit smoking.[3] Many smokers, therefore, search for help in complementary and alternative medicine (CAM). In a study by Sood *et al.*, 27% of subjects indicated using CAM as an aid for tobacco cessation, and 67% reported interest in the future use of CAM for smoking cessation.[3]

Studies have shown therapeutic effects of acupuncture, considered a CAM, for tobacco dependence, but further proof of this intervention's efficacy is needed.[4] Stimulating auricular acupoints affects the limbic system of the brain, and specifically the reward centre. This modulation of the reward system is mediated through auricular branches of the trigeminal, the vagus nerve and the superior cervical plexus leading to greater restfulness and sleep management at the supraoptic chiasma. When smokers experience withdrawal systems during smoking cessation, stimulating auricular acupoints leads to modulation of reward pathways and the

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release of dopamine and serotonin, thereby minimising withdrawal effects.[5]

Low-level lasers (defined by wavelengths between 405–904 nm), which are a part of the electromagnetic spectrum, are used in acupuncture treatments and are non-invasive compared to needle acupuncture. Painless non-invasive laser beams directed at specific acupoints for a few minutes per point for 3–5 sessions has been shown to achieve smoking cessation.[6] This form of non-invasive, aseptic and painless therapy has advantages over traditional forms of acupuncture, especially in patients with phobias of needles. The effectiveness of laser acupuncture for smoking cessation, however, needs to be explored further.[6]

Studies conducted on laser acupuncture for smoking cessation have shown inconsistent results due to heterogeneity of subjects' and control groups' ages, wavelength and power of lasers used, duration of treatment and acupoints treated. No studies have been carried out with the Indian population and, most importantly, the majority of the studies have considered only subjective outcomes.[6] This study, therefore, aimed to compare urinary cotinine levels, nicotine dependence and physical effects related to smoking after one month of laser acupuncture treatment with three groups of smokers. One group received only laser acupuncture, one received only counselling and one received a combination of laser acupuncture and counselling.

Methods

The study, a randomised controlled exploratory clinical trial with concurrent parallel design and an active arm trial, had an estimated sample size of 47. The sample size (n) was estimated using the following formula:

$$n = 2 \times (Z\alpha/2 + Z\beta) \times [p1(1 - p1) + p2(1 - p2)] / 2 \times (p1 - p2)$$

[Equation 1]

where $Z\alpha/2 = 1.96$, $Z\beta = 0.84$, p1 = 25% and p2 = 5.6% as expected sample proportions.[7] Considering a 20% dropout rate, 56 smokers (approximated to 60) were recruited to the study.

Inclusion criteria were young adults 18–35 years old who had smoked 100 cigarettes in their lifetime and currently smoked cigarettes daily or on some days (nondaily).[8] Current smokers who consented to participate and who had never been on any form of tobacco cessation therapy were included in the study. Subjects with a known history of cardiac problems; diabetes mellitus (DM); epilepsy; lacking skin sensation near acupuncture points; suffering from undiagnosed fever, severe skin lesions or infection at and around acupuncture points; on psychiatric medications

or unable to attend scheduled appointments were excluded.

Using computer software, a sequence of random numbers was generated to guide subjects' random allocation (i.e. concealed randomisation) to the interventional groups. This allocation was done by a person uninvolved in the study who was given the random numbers within sealed opaque envelopes. Once a patient had been determined to fulfill eligibility criteria and consented to enter the trial, an envelope was opened and the patient was offered the allocated treatment.

All interventions were done by an investigator who was not blinded to the treatment procedure. Group one were treated with only laser auricular acupuncture at days one, three, seven and 14. Group two underwent psychological counselling for smoking cessation, with one session per week for a total of four sessions. Group three were treated with a combination of laser acupuncture and psychological counselling for smoking cessation.

Urinary cotinine levels are widely used biomarkers among tobacco users. These levels have high sensitivity compared to blood cotinine levels, and the test is non-invasive.[9] NicAlert urinary cotinine strips (Nymox Pharmaceutical Corporation, Quebec, Canada) were used for semi-quantitative estimation of cotinine in urine. This validated test determines if an individual has been exposed to tobacco products such as cigarettes within the past 48 hours.[10] A labelled, sterile, disposable container was given to each participant to collect approximately 25 mL of midstream clear urine with aseptic precautions. The sample was tested within four hours of collection by a trained person not involved in the study who was blinded to participants' treatment allocations.

Nicotine dependence was assessed with the help of the widely used standard Fagerström questionnaire.[11] Level of addiction was interpreted as low (scores 0–4), medium (score 4–6) or high (>6). Trained personnel not involved in the study administered the Fagerström questionnaire.

Diode laser equipment (Laboratory Silberbauer, Medical Electronics, Vienna, Austria) with a power output of 36 mW, a wavelength of 660 nm, a beam area of 0.3 cm^2, energy delivered at 7.2 joules per cm^2 per point per session and a point probe contact method was used in continuous wave mode. The dose was calculated based on Litscher's guidelines.[12] The investigator was trained to give laser therapy by a certified laser therapist before the start of the study and used protective eye wear. The National Acupuncture Detoxification Association (NADA) protocol suggests stimulating five auricular acupoints. Acupuncture

points stimulated on each ear included :"Shen Men," "Sympathetic" ("Autonomic"), "Kidney," "Liver," and "Lung".[13] The laser beam was directed at ten acupoints in contact mode. The total treatment duration was 10 minutes (one minute/point) per session. A total of four treatment sessions on days one, three, seven and 14 were given to every subject.

The counselling intervention was done by following a combination of the 5A Framework for interventions and the Transtheoretical Model.[14,15] The subjects were counselled for 30 minutes per week, undergoing four sessions in one month. The stage of change in every subject was assessed at every counselling stage. The stages of change were precontemplation (stage one: not thinking of quitting); contemplation (stage two: ambivalent, but thinking of quitting); preparation (stage three: planning to quit); action (stage four: quit); maintenance (stage five: maintaining cessation) and relapse (stage six: returned from the action or the maintenance stage to an earlier stage).[15] At every stage of change seen, the appropriate component of the 5As was used to bring about and reinforce the tobacco cessation behaviour.

Subjects' physical effects experienced before, after and during the course of treatment were assessed for irritability, tiredness, calmness, anxiety, cravings, unpleasant taste when smoking, headaches, ability to concentration and appetite on a 10-point visual analogue scale (VAS).[16]

Statistical Package for the Social Sciences (SPSS), Version 22 (IBM Corp., Armonk, New York, USA) was used for data analyses. The significance level was fixed at P <0.05. Data distribution was not normal, so non-parametric tests were applied. Pearson's chi-squared, Kruskal Wallis analysis of variance and Wilcoxon sign rank tests were used.

Ethical clearance was obtained from the Institutional Review Board of the college where the study was conducted (BDC/377/2017-18 dated 5-7-2017). The trial was registered under the Clinical Trial Registry of India (CTRI/2017/08/009317). Voluntary written informed consent was obtained from each participant before beginning any intervention and after explaining the intended treatment, the possible outcomes, complications and the need for follow-up.

Results

A total of 60 smokers met the eligibility criteria. Study participants' mean age was 32.93 ± 3.09 years. There were no significant differences in the distribution of participants across groups based on age, socioeconomic status, duration of smoking, nicotine dependence, behavioural stage or urinary cotinine levels (P >0.05). There was a highly significant reduction in urinary cotinine levels, nicotine dependence and the number of cigarettes/bidis smoked per day and a significant improvement in behaviour and physical effects related to smoking in all interventional groups one month post-intervention (P <0.05 each). A post-intervention reduction in nicotine dependence was significantly higher (P <0.01) in the laser group (4.4 ± 1.66) compared to groups two (2.15 ±1.47) and three (2.55 ± 1.23) [Table 1].

The highest reduction in urinary cotinine levels and the number of cigarettes/bidis smoked per day were observed in the laser with counselling group (0.85 ± 0.3) when compared to the other groups (H = 6.08; P = 0.4) [Tables 2 & 3]. Improvements in behavioural changes were similar across different groups. There was a significant reduction (P <0.01) in physical effects associated with smoking, such as irritability, headache, craving smoking, tiredness and anxiety in the laser group compared to the other two interventional groups, and a significant increase (P <0.01) in the physical effects associated with smoking such as calmness, unpleasantness in the taste of smoking, ability to concentrate and appetite in the laser group compared to the other groups [Table 4].

Table 1: Comparison of Fagerström scores between the groups of the current study

Interventional groups	Pre-intervention Fagerström scores		Post-intervention Fagerström scores		Difference between pre- and post-intervention Fagerström scores		
	Mean ± SD	Median (IQR)	Mean ± SD	Median (IQR)	Mean ± SD*	Median (IQR)	*P* value
Group one	6.95 ± 1.63	6.95 (3–9)	2.55 ± 1.39	3 (0–5)	4.4 ± 1.66AB	4 (1–8)	<0.01
Group two	5.3 ± 2.22	5 (2–10)	3.15 ± 1.08	3 (1–5)	2.15 ± 1.47A	2 (0–5)	
Group three	5.65 ± 1.22	6 (3–8)	3.1 ± 1.4	3(1–7)	2.55 ± 1.23B	3 (0–5)	
Kruskal Wallis ANOVA value (*P* value)					18.55 (<0.01)		

SD = standard deviation; IQR = interquartile range; ANOVA = analysis of variance; group one = laser group; group two = counselling group; group three = laser + counselling group.

*Same letters indicate significant differences between groups with post hoc, Mann-Whitney U test, AA groups one and two (P <0.01), BB groups one and three (P <0.01).

Table 2: Comparison of urinary cotinine levels between the groups of the current study

Intervention groups	Pre-intervention urinary cotinine levels			Post-intervention urinary cotinine levels					Difference between pre- and post-intervention	
	L4	L5	L6	L1	L2	L4	L5	L6	Mean ± SD	Median (IQR)
Group one	0	7	13	0	0	5	13	2	0.80 ± 0.6	1 (0–2)
Group two	0	12	8	1	0	4	13	2	0.70 ± 0.3	0 (0–4)
Group three	0	14	16	0	1	2	13	4	0.85 ± 0.3	1 (0–4)
Number of subjects	0	28	37	1	1	11	39	8	Kruskal-Wallis ANOVA value (*P* value)	6.08 (0.4)
Percentage of subjects	0	38	62	1.7	1.7	18.3	65	13.3		
Chi-squared (*P* value)	6.91 (0.032)			6.27 (0.9)						

SD = standard deviation; IQR = interquartile range; 0 = no detectable level of tobacco use; L1 (10–30 ng/mL) and L2 (30–100 ng/mL) = no use of tobacco products; L3 (100–200ng/mL) = cut-off level and positive for tobacco use; L4 (200–500 ng/mL), L5 (500–1000ng/mL) and L6 (>1000ng/ml) = use of tobacco product; group one = laser group; group two = counselling group; group three = laser + counselling group; ANOVA = analysis of variance.

Table 3: Comparison of cigarettes/bidis consumed daily between the groups of the current study

Interventional groups	Pre-intervention cigarettes/bidis smoked per day		Post-intervention cigarettes/bidis smoked per day		Difference between pre- and post-intervention		Intra-group comparison Wilcoxson-sign rank value (*P* value)
	Mean ± SD	Median (IQR)	Mean ± SD	Median (IQR)	Mean ± SD	Median (IQR)	
Group one	18.25 ± 8.35	12.2 (13–24)	9.85 ± 5.86	10 (1–24)	8.4 ± 4.0	6.5 (2–16)	Z = −3.94 (<0.01)*
Group two	15.4 ± 7.95	14.0 (4–36)	8.4 ± 5.08	8 (1–22)	7 ± 4.49	7.0 (0–14)	Z = −3.83 (<0.01)*
Group three	17.4 ± 6.77	17.5 (5–24)	9.95 ± 4.14	10.0 (3–24)	8.05 ± 4.67	8.5 (2–14)	Z = −3.84 (<0.01)*
Intergroup comparison Kruskal-Wallis ANOVA (*P* value)	1.21 (0.51)		1.43 (0.48)		1.51 (0.47)		

SD = standard deviation; IQR = interquartile range; group one = laser group; group two = counselling group; group three = laser + counselling; ANOVA = analysis of variance.
*Statistically significant.

Discussion

Results of the present study revealed that auricular laser acupuncture was effective in reducing nicotine dependence as indicated by a reduction in Fagerström test scores, urinary cotinine levels, number of cigarettes/bidis smoked per day and an improvement in physical effects related to smoking and behavioural stage of quitting smoking at one month post-intervention. Auricular laser acupuncture along with psychological counselling also had the considerable effect of reducing nicotine dependence as compared to only psychological counselling.

The use of laser auricular acupuncture for smoking cessation had been explored earlier in other studies, but no other study to the best of researchers' knowledge had compared it with psychological counselling by assessing urinary cotinine levels, nicotine dependence using the Fagerström test or employing a VAS to measure the physical effects experienced by smokers. Because of these considerations, a direct comparison of the present study with other studies where laser auricular acupuncture was used could not be made for a number of reasons. Laser parameters used in the study were based on standard guidelines stated by Litscher *et al.* and reported based on World Association for Laser Therapy guidelines.[12] Different studies on laser acupuncture, however, have used different wavelengths from those used in the current study.[7,17,18] Additionally, in the current study, interventions were spaced at the first, third, seventh and 14th days so as to compensate for the withdrawal symptoms caused by nicotine deprivation corresponding to a low level of serotonin and dopamine. Spacing of treatments have differed across studies.

Despite these differences in methodology, the results of the current study are similar to some studies of laser acupuncture. Tan *et al.* found that laser stimulation on auricular points produced an overall success rate of over 80% in quitting cigarette smoking; similarly, Lim found it resulted in 87.5% of smokers quitting.[19,20] Kerr *et al.* showed effective results of laser

Table 4: Comparison of physical effects due to smoking based on Visual Analogue Scale scores between interventional groups post intervention

Physical effect related to smoking	Groups	Pretest median VAS score	Post-test median VAS score	Difference between pre- and post-intervention VAS scores		Kruskal Wallis ANOVA test (*P* value)	Post hoc Mann-Whitney U test	
				Mean ± SD	Median (IQR)		Group	Z Value (*P* value)
Irritability	1	6.5	5	1.65 ± 0.74	2 (0–3)	22.76 (<0.01)	1 & 2	62.0 (<0.01)*
	2	6	6	0.35 ± 0.2	0 (-1–2)		2 & 3	170 (0.37)
	3	7	7	0.5 ± 0.4	0.5 (0–1)		1 & 3	50 (<0.01)*
Tiredness	1	7	5	2.0 ± 1.25	2 (0–6)	22.76 (<0.01)	1 & 2	62 (<0.01)*
	2	6.5	5.5	1.05 ± 0.05	1 (-1–4)		2 & 3	170 (0.3)
	3	7	7	0.40 ± 0.28	0 (-1–2)		1 & 3	50 (<0.01)*
Calmness	1	7	5	1.85 ± 1.08	2 (0–4)	19.20 (<0.01)	1 & 2	3.6 (<0.01)*
	2	6.5	6	0.6 ± 0.49	0.5 (-1–3)		2 & 3	-1.97 (0.04)*
	3	7	7	0.40 ± 0.08	0 (0–2)		1 & 3	-2.27 (0.023)*
Anxiety	1	7	5	1.75 ± 0.91	2 (1–5)	22.86 (<0.01)	1 & 2	27.5 (<0.01)*
	2	6	5	0.8 ± 0.32	1 (0–3)		2 & 3	110 (0.01)*
	3	7	7	0.15 ± 0.04	0 (0–3)		1 & 3	132 (0.04)
Cravings	1	7.5	3	4.4 ± 1.66	4 (1–8)	18.55 (<0.01)	1 & 2	62 (<0.01)*
	2	5	3	2.15 ± 1.42	2 (0–5)		2 & 3	160 (0.2)
	3	6	3	2.55 ± 1.23	3 (0–5)		1 & 3	73 (<0.01)*
Unpleasant taste while smoking	1	7	3.5	2.6 ± 1.42	3 (0–4)	16.86 (<0.01)	1 & 2	79 (0.001)*
	2	6	5.5	0.60 ± 1.69	0 (-3–4)		2 & 3	181.5 (0.6)
	3	7	6	0.70 ± 1.17	1 (-2–2)		1 & 3	64.5 (<0.01)*
Headache	1	7	5	1.6 ± 1.5	1 (-2–4)	11.52 (0.003)	1 & 2	118.3 (0.002)*
	2	6.5	6	0.35 ± 0.06	1 (-2–4)		2 & 3	179 (0.5)
	3	7	7	0.25 ± 0.06	0 (-1–2)		1 & 3	78.5 (0.001)*
Ability to concentrate	1	7	5.5	1.55 ± 0.6	1.5 (-2–5)	10.55 (0.005)	1 & 2	121.5 (0.02)*
	2	6.5	6	0.55 ± 0.1	1 (-2–2)		2 & 3	162 (0.2)
	3	7	7	0.4 ± 0.06	0 (0–2)		1 & 3	90 (0.002)*
Appetite	1	7	5	2.1 ± 1.41	2 (0–6)	22.51 (<0.01)	1 & 2	73.5 (<0.01)*
	2	6.5	6	0.6 ± 0.3	1 (-2–2)		2 & 3	146 (0.11)
	3	7	7	0.3 ± 0.2	0 (-1–2)		1 & 3	47 (<0.01)

VAS = Visual Analogue Scale; SD = standard deviation group 1 = laser group; group 2 = counselling group; group 3 = laser + counselling group.
*Statistically significant.

acupuncture for smoking cessation compared to a sham acupuncture group.[7] Mostyn *et al*. also arrived at similar results, but the trial was uncontrolled.[17] A Cochrane meta-analysis, in contrast, demonstrated no superior effects of laser acupuncture over control groups which received placebo treatments, or groups that received sham and conventional acupuncture (i.e. with needles).[6] According to another study, body acupuncture in combination with auricular acupuncture was not more effective than auricular acupuncture alone.[2]

The first two days are crucial during the smoking cessation period during which an increase in serotonin level in the brain tissue mediated by acupuncture can help reduce withdrawal symptoms.[21] There was

significant improvement (*P* <0.05) in physical effects related to smoking in the current study. The reason for this improvement could be the stimulation of the sympathetic auricular point and liver points, which are associated with relaxation of internal organs and resolving aggression, respectively, thereby leading to positive effects such as increased levels of endorphins secretion.[22]

Subjects who underwent laser therapy (i.e. groups one and three) experienced an increased unpleasant taste for smoking post-intervention. Similar findings have been observed in other studies, with participants reporting that, because cigarettes came to taste like burnt ash and were associated with malodoar, they had a decreased urge to smoke.

In the present study, very few subjects reported headaches. These headaches were ill-defined and coupled with irritability. Headaches are recognised symptoms of smoking withdrawal due to an inability in smokers to build-up their own endorphin levels. Similar experiences have been noted in other studies.[7,19]

The current study had a few limitations. The sample size was small, and observations were made one month post-intervention, limiting the generalisability of the study results and long-term effects of the intervention. Urinary cotinine values, which determine tobacco exposure within the past 48 hours, were expressed as a range and were therefore not very sensitive to changes in nicotine levels. Participants met the same mentor for the duration of the intervention possibly leading to exaggerated reports of good results. In short, social desirability bias could have influenced the results. It is recommended that researchers undertake longterm studies with large sample sizes in which sensitive objective measures of nicotine dependence are used such as gas chromatography. Assessment of changes in the serotonin and dopamine levels in the body after laser auricular acupuncture could lead to insights on its mechanism of action. It is recommended to further test the efficacy of laser acupuncture along with alternative aids to reduce nicotine dependence.

Conclusion

Auricular laser acupuncture alone and in combination with psychological counselling reduced nicotine dependence among smokers.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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