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Original Research Article

Deep Transcranial Magnetic Stimulation with the H4 Coil for Reducing Smoking Addiction in Patients with Comorbid Psychiatric Illness, Including Depression, Psychosis, and Alcohol Use Disorder.

Name of Author:

Dr. M. Aswin Kumar[1*], Dr. M. S. Reddy[2], Dr. Sailaja Bomma[3], Dr. Balaji Sainath[4], Dr. Swetha Reddy[5], Dr. Deepak Kumar[6].

Affiliation:

[1]MD (Physiology) Head – Academics, Research & Training, Asha Neuromodulation Clinics, Hyderabad, Telangana, India.
[2]MD, DPM Director, Asha Neuromodulation Clinics, Hyderabad, Telangana, India.
[3]MSc Psychology Psychologist, Asha Neuromodulation Clinics, Hyderabad, Telangana, India.
[4]DPM, DNB Psychiatry Consultant Psychiatrist, Asha Neuromodulation Clinics, Hyderabad, Telangana, India.
[5]DNB Psychiatry Consultant Psychiatrist, Asha Hospital, Hyderabad, Telangana, India.
[6]DNB Psychiatry Consultant Psychiatrist, Asha Neuromodulation Clinics, Hyderabad, Telangana, India

Corresponding Author:
Dr. M. Aswin Kumar.

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Abstract: ***Background:*** Tobacco smoking remains a leading preventable cause of morbidity and mortality worldwide. Deep transcranial magnetic stimulation (DTMS) using the H4 coil targets addiction-related circuits within the bilateral insula and prefrontal cortex and has demonstrated safety and efficacy in reducing smoking craving. However, the influence of comorbid alcohol use disorder, depression, and psychosis on smoking-cessation outcomes remains insufficiently studied. ***Aim:*** This study aimed to assess the clinical utility of H4 coil DTMS in reducing nicotine dependence among smokers with alcohol use disorder, depression, or psychosis. ***Materials and Methods:*** This retrospective observational study included 33 nicotine-dependent patients treated with DTMS at a tertiary neuromodulation center. Participants had alcohol use disorder, major depressive disorder (MDD), psychosis, or overlapping comorbidities; all were receiving regular psychiatric treatment and underwent DTMS to reduce smoking craving. High-frequency stimulation (10 Hz) was delivered using the BrainsWay H4 coil at 120% of the resting motor threshold. Patients received two sessions daily for five consecutive days, for a total of 10 sessions, with 1800 pulses delivered over 18 minutes per session. All patients also received Motivational Enhancement Therapy and standard-dose varenicline. Nicotine dependence was assessed before and after treatment using the Fagerström Test for Nicotine Dependence (FTND). ***Results:*** The mean age of participants was 34 ± 10.34 years. Mean FTND score decreased from 7.27 ± 0.96 at baseline to 3.12 ± 1.37 after treatment, representing a mean reduction of 4.15 points and an average improvement of 56.78 ± 18.96%. Alcohol use disorder was present in 24/33 patients (72%), MDD in 14 (42%), and psychosis in 8 (24%). Hypertension and type-II diabetes mellitus were observed in 10 (30%) and 8 (24%) patients, respectively. By day 5, 24/33 patients (72%) achieved ≥50% improvement. Age and smoking duration showed moderate negative correlations with treatment response. ***Conclusion:*** H4 coil DTMS was associated with significant reductions in nicotine dependence in a real-world clinical setting. Outcomes were favourable among smokers with psychiatric comorbidities, supporting DTMS as a useful adjunct to comprehensive smoking-cessation programs. Alcohol use disorder was common, whereas patients with depression showed a lower response than the overall cohort. Controlled studies with long-term follow-up are warranted.

Keywords: Deep Transcranial Magnetic Stimulation, H4 coil, Smoking cessation, Nicotine dependence, Fagerström Test for Nicotine Dependence.

INTRODUCTION

Tobacco smoking is a major preventable cause of cardiovascular disease, chronic respiratory illness, cancer, and premature death. The World Health Organization attributes more than eight million deaths each year to tobacco use, making smoking cessation a global public health priority [1].

Nicotine dependence is a chronic relapsing disorder marked by compulsive tobacco use despite harm. It involves dysregulation of interconnected brain regions, including the prefrontal cortex, insula, anterior cingulate cortex, ventral tegmental area, and nucleus accumbens, which regulate reward, craving, executive control, and reinforcement learning [2,3].

Although nicotine replacement therapy, bupropion, and varenicline are effective, long-term abstinence remains limited, with many patients relapsing within the first year [4,5]. This has increased interest in neuromodulation approaches that directly target addiction-related circuitry.

Transcranial magnetic stimulation (TMS) is a non-invasive technique that modulates cortical excitability through electromagnetic induction. Deep TMS (DTMS) extends conventional repetitive TMS by stimulating broader and deeper cortical regions using specialized coils [6]. The H4 coil targets the bilateral insula and prefrontal cortex, which are key regions involved in nicotine craving and addictive behavior [7].

The insula is central to tobacco addiction. Neuroimaging and lesion studies show that disrupting insular function can reduce craving and support cessation [8,9]. By modulating prefrontal control networks and insular craving circuits, DTMS may reduce cue-induced craving and improve abstinence.

Dinur-Klein et al. reported higher quit rates with active H4 coil DTMS than with sham stimulation, supporting FDA clearance of DTMS for smoking cessation [10]. Subsequent studies have also demonstrated reductions in cigarette use, craving, and dependence severity [11,12].

Psychiatric comorbidities, including depression, psychosis, obsessive-compulsive disorder, and alcohol use disorder, are common among smokers and often worsen nicotine dependence and cessation outcomes [13,14]. Evidence on DTMS effectiveness in such patients remains limited.

This observational study evaluated H4 coil DTMS for reducing nicotine dependence in smokers with and without psychiatric comorbidities in a real-world neuromodulation setting.

MATERIALS AND METHODS

Study Design

This retrospective observational study was conducted at Asha Neuromodulation Clinics, Hyderabad, Telangana, India.

Study Population

Patients with nicotine dependence who received BrainsWay H4 coil DTMS were included. Patients with comorbid MDD, psychosis, or alcohol use disorder were eligible.

Treatment Protocol

DTMS was administered using the BrainsWay H4 coil targeting the bilateral insular and prefrontal cortices. Treatment parameters included:

- Frequency: 10 Hz
- Intensity: 120% resting motor threshold
- Pulses per session: 1800
- Session duration: 18 minutes
- Sessions per day: Two
- Total treatment duration: Five consecutive days

The resting motor threshold was determined from the right hand. From the third or fourth session onward, provocation was introduced according to clinic protocol. Before each Deep TMS session, patients handled a cigarette and/or lighter for two minutes to induce craving. Anxiety was monitored, and provocation was avoided if the anxiety score exceeded 7 on a visual analog scale. Patients were also advised to abstain from smoking for one hour before each session to preserve the craving response.

Adjunctive Treatment

All patients received:

- Motivational Enhancement Therapy: five 30-minute sessions comprising counselling, tobacco self-help guides, craving diary maintenance, and education on tobacco-related harms.
- Standard-dose varenicline for 12 weeks: 0.5 mg once daily on days 1–3, 1 mg daily for the next 4 days, and 2 mg daily thereafter for 12 weeks.

Outcome Measure

Nicotine dependence severity was assessed using the Fagerström Test for Nicotine Dependence (FTND) at baseline and after completion of treatment.

Primary outcome:

- Change in FTND score from baseline to post-treatment.

Statistical Analysis

Paired t-tests were used to compare pre- and post-treatment FTND scores. Independent t-tests compared continuous variables between responder groups, while chi-square tests assessed associations between categorical variables and treatment response. Multiple

linear regression was used to identify predictors of response. Odds ratios with 95% confidence intervals quantified risk factors for low response. Statistical significance was set at $\alpha = 0.05$, and effect sizes were reported using Cohen's d.

RESULTS

Thirty-three patients who received H4 coil DTMS for nicotine dependence were analyzed. The mean age was 34 ± 10.34 years (range: 18–56). Most patients were male, consistent with the clinical profile of individuals seeking treatment for tobacco dependence. All patients were receiving standard treatment for psychiatric comorbidities. Alcohol use disorder was present in 24/33 patients (72%), MDD in 14 (42%), and psychosis in 8 (24%). Hypertension and type-II diabetes mellitus were observed in 10 (30%) and 8 (24%) patients, respectively. DTMS was used specifically for smoking cessation and not for the treatment of psychiatric symptoms.

Table 1. Baseline Characteristics of Study Participants (N = 33)

Variable	Value
Number of participants	33
Mean age (years)	34 ± 10.34
Minimum age	18
Maximum age	56
Treatment sessions	10
Sessions per day	2
Treatment duration	5 days
Stimulation frequency	10 Hz
Intensity	120% resting motor threshold
Pulses per session	1800

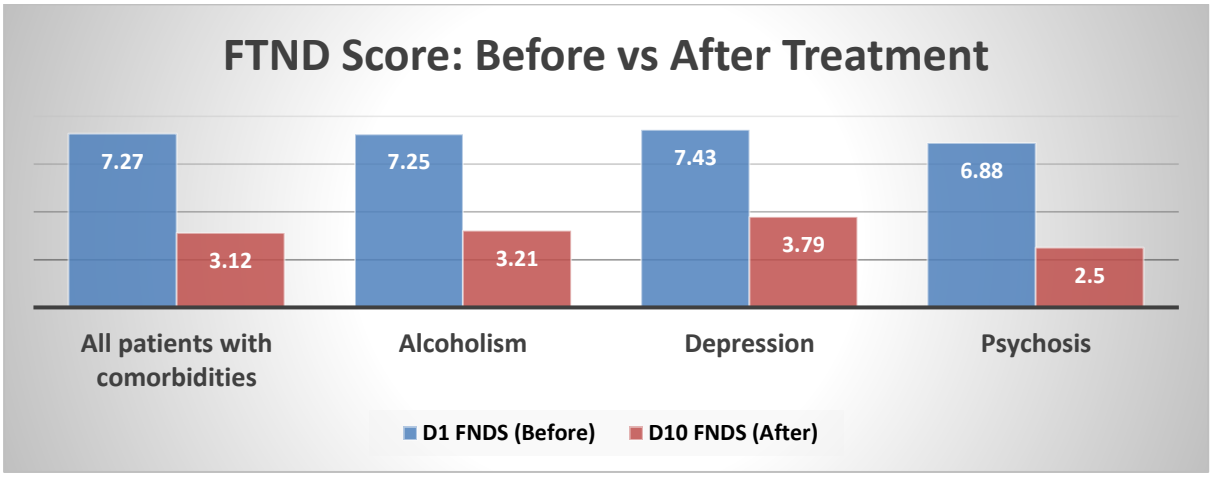

Figure 1. Fagerström Test for Nicotine Dependence Scores Before and After Treatment

DTMS produced a marked reduction in nicotine dependence. Mean FTND score decreased from 7.27 ± 0.96 to 3.12 ± 1.37 (95% CI: 3.81–4.64; $t = 20.65$; $p<0.001$; Cohen's $d = 2.92$), a mean reduction of 4.15 points. By day 5, 24/33 patients (72%) achieved ≥50% improvement, indicating clinically meaningful benefit.

Regression analysis showed that age, baseline FTND score, smoking duration, and number of DTMS sessions did not significantly predict outcome in the multivariable model ($R^2 = 0.182$; F-test $p = 0.056$).

Age emerged as the main significant predictor in subgroup analysis. Patients younger than 35 years showed greater improvement than older patients (63.7% vs. 49.1%; $t = 2.93$, $p = 0.005$). Age was negatively correlated with outcome ($r = -0.39$, $p = 0.006$), with each additional year associated with an approximately 0.73% reduction in response. The greatest improvement was observed in the 18–29-year age group (65.3%), followed by the 40–49-year age group (43.3%).

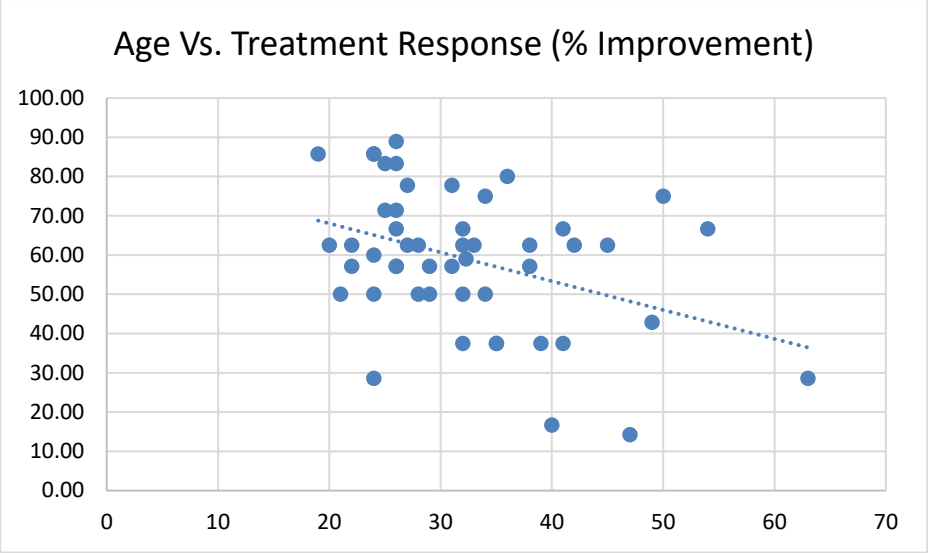

Figure 2. Scatter plot showing the negative correlation between age and treatment response

Smoking duration also showed a moderate negative correlation with outcome ($r = -0.36$, $p = 0.005$). Patients with alcohol use disorder had the longest smoking history, with an average duration of 13.5 years.
All subgroups—MDD ($t = 7.48$, $p<0.001$), psychosis ($t = 11.67$, $p<0.001$), and alcohol use disorder ($t = 12.81$, $p<0.001$)—showed significant improvement, with notable subgroup differences.

Major depressive disorder as a clinically relevant comorbidity:
Fourteen patients (42%) had MDD and were receiving regular treatment. Their improvement was lower than that of patients without depression (48.1% vs. 63.4%; $t = -2.93$, $p = 0.005$). Depression was the only comorbidity significantly associated with low response, conferring 4.8-fold higher odds of poor response (OR = 4.79, 95% CI: 1.24–18.55, $p = 0.018$).

Alcohol use disorder as a coexisting addiction:
Most patients (72%) had comorbid alcohol use disorder. Treatment response did not differ significantly between patients with and without alcohol use disorder (55.5% vs. 62.4%, $p = 0.178$). Alcohol use disorder was not associated with response (OR = 1.08, 95% CI: 0.35–3.32, $p = 0.897$), indicating similar benefit regardless of alcohol history.

Responder profiling:
High and low responders were defined using a 60% FTND improvement cut-off. Patients with MDD had more low responders (43.5%) and fewer high responders (14.8%; $\chi^2 = 5.58$, $p = 0.018$). Among patients with alcohol use disorder, high and low responder proportions were similar (48.1% vs. 47.8%; $\chi^2 = 0.02$, $p = 0.897$), confirming that only depression was significantly associated with response category.

DISCUSSION

This observational study evaluated H4 coil DTMS for nicotine dependence in routine clinical practice. The findings add to growing evidence that DTMS may be a promising intervention for nicotine addiction. Its therapeutic rationale lies in modulation of insular and prefrontal regions involved in craving, reward processing, decision-making, and inhibitory control [2,3]. Neuroimaging studies have shown activation of these regions during craving, suggesting that targeted neuromodulation may reduce addictive behavior [15]. The H4 coil may be particularly useful because it reaches deeper cortical structures than conventional figure-of-eight coils and influences networks involved in craving and executive control [6,7].

A key feature of this study was the inclusion of patients with psychiatric comorbidities. Tobacco dependence is common in mental illness and accounts for a substantial share of cigarette use worldwide [13]. Smokers with depression, schizophrenia spectrum disorders, obsessive-compulsive disorder, or alcohol use disorder often have greater dependence and lower cessation success [14,16].

Despite the presence of psychiatric comorbidities, patients showed clinically meaningful reductions in nicotine dependence. Because DTMS was targeted toward smoking cessation rather than psychiatric symptom reduction, these findings suggest that psychiatric comorbidity does not necessarily preclude responsiveness to H4 coil DTMS.

Age significantly influenced recovery. Patients younger than 35 years had 14.6% better outcomes than older

patients (p = 0.005), consistent with earlier studies [24]. This may reflect shorter smoking exposure in younger adults (5.95 ± 3.71 years vs. 19.69 ± 7.63 years in older patients) and a lower prevalence of depression. Depression was present in 30% of younger patients versus 61% of older patients, increasing the risk of poorer DTMS response.

Depression and smoking have a bidirectional association [25]. In this study, depression was associated with a 15.3% lower improvement compared with patients without depression (p = 0.005). A possible explanation is the overlap between brain regions implicated in depression and smoking addiction. Although H4 coil DTMS stimulates the bilateral insula and prefrontal cortex, altered right-left dorsolateral prefrontal activity in depression may influence treatment response.

Alcohol use disorder did not significantly affect smoking-cessation response. Alcohol and tobacco dependence commonly co-occur through shared genetic, neurobiological, conditioning, and psychosocial mechanisms. Although dual dependence is often associated with poorer outcomes, recent evidence suggests that concurrent treatment may improve results [26]. These findings support the use of DTMS in smokers with alcohol use disorder.

Based on these findings, patients younger than 35 years, without depression, with a smoking history under 10 years, and with or without alcohol use disorder may be more likely to respond well to DTMS for smoking cessation.

Accordingly, the following clinical recommendations may be considered:

1. Screen and treat depression before or during smoking cessation therapy.
2. Expect better outcomes in younger patients.
3. Do not exclude patients with alcohol use disorder, as they respond similarly.
4. Set realistic expectations for older patients with depression.

Integrating pharmacotherapy, behavioural interventions, and neuromodulation may maximize treatment outcomes.

This study has several limitations. Its observational design precludes causal inference, and the absence of a sham-control group limits interpretation of treatment-specific effects. The sample size was modest and drawn from a single center. Follow-up data were unavailable; therefore, long-term abstinence and relapse could not be assessed. Biochemical verification of smoking cessation was also not performed. Larger randomized controlled trials with longer follow-up and biochemical confirmation are warranted.

Overall, the present findings add to the growing evidence supporting H4 coil DTMS as an effective adjunctive intervention for smoking cessation.

CONCLUSION

This study showed that H4 coil DTMS was associated with a significant reduction in nicotine dependence, with mean FTND scores decreasing by 4.15 points and 24/33 patients (72%) achieving ≥50% improvement by day 5. Age was the main predictor of response, with younger patients showing greater improvement. Depression was the only comorbidity significantly associated with reduced response (OR = 4.79, p = 0.018), suggesting that integrated depression management may improve outcomes. Alcohol use disorder was not associated with poorer response; therefore, these patients should not be excluded from DTMS-based smoking-cessation interventions. Larger studies are needed to refine predictors of response and personalize treatment protocols.

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