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Effect of Repetitive Transcranial Magnetic Stimulation (rTMS) on Nicotine Use Disorder in Patients with Schizophrenia: A Randomized Double-Blind Clinical Trial

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Abstract

Background: Schizophrenia is a chronic mental disorder with high nicotine use rates. Despite available interventions, smoking cessation remains challenging due to unique neurobiological and behavioral factors. This study evaluates the efficacy of repetitive Transcranial Magnetic Stimulation (rTMS) using Theta Burst Stimulation (TBS) in reducing nicotine cravings and consumption in schizophrenia.

Methods: A randomized, double-blind controlled trial was conducted with 44 patients with schizophrenia and nicotine use disorder between summer 2022 and summer 2023. The main objective was to assess rTMS effectiveness in reducing cravings and consumption. Secondary objectives included evaluating changes in cravings *via* the Visual Analog Scale (VAS), comparing cigarette use before, immediately after, and one month post-intervention, and assessing effects on positive and negative symptoms (PANSS scale). Participants were randomized to rTMS or sham. Inclusion criteria were DSM-5 schizophrenia and nicotine use disorder. The rTMS group received 10 sessions using the TBS protocol (20 *Hz*, 90% RMT, 20 trains, 30 pulses/train, 1.5 *s* on, 30 *s* off, 750 pulses/hemisphere) over two weeks, targeting the left Dorsolateral Prefrontal Cortex (DLPFC). Key outcomes were measured pre- and post-intervention.

Results: Nicotine cravings and cigarette consumption decreased significantly in the rTMS group versus sham. No significant differences in schizophrenia symptom severity were observed. The intervention was well tolerated with minimal side effects.

Conclusion: rTMS with TBS effectively reduces nicotine cravings and consumption in schizophrenia, representing a promising adjunctive therapy for smoking cessation.

Keywords: Craving, Dorsolateral prefrontal cortex, Humans, Mental disorders, Nicotine, Schizophrenia, Smoking cessation

Introduction

Schizophrenia is a chronic mental illness that affects approximately 21 million people worldwide (1). It is marked by positive symptoms, such as hallucinations and delusions, negative symptoms, like apathy and social withdrawal, and cognitive impairments, including attention deficits (2). This condition often leads to lifelong disability and is frequently complicated by co-occurring substance use disorders, particularly smoking, which is prevalent among patients (2,3). Current treatments, including antipsychotic medications and psychosocial interventions, rarely address smoking (3).

Globally, 1.3 billion people use tobacco, and individuals with schizophrenia are 10 times more likely to develop a smoking disorder than the general population. Around 64.8% of people with schizophrenia are regular tobacco users, which significantly shortens their lifespan due to smoking-related diseases. This high prevalence is linked to genetic and environmental factors, altered brain neurotransmitter systems, and the use of smoking as self-medication for cognitive deficits and side effects of antipsychotic drugs (2,4,5).

Despite public health initiatives, smoking rates among patients with schizophrenia remain high. Imaging studies have identified key brain circuits involved, with higher nicotine absorption and elevated nicotine metabolite levels in these patients. Genetic abnormalities in nicotine receptors and dysfunctions in the frontal cortex also contribute. Additionally, smoking cessation success rates are lower in individuals with schizophrenia compared to the general population (3,6).

Treatment for nicotine addiction includes pharmacological options such as nicotine replacement therapy, varenicline, and bupropion, as well as psychotherapeutic methods (7). However, these approaches often result in only short-term benefits. Behavioral treatments are less effective in this group, and non-nicotine drug treatments can worsen psychiatric symptoms. Effective management of nicotine cravings is critical for successful smoking cessation (3,4).

Evidence on antipsychotics for treating substance use disorders is mixed, though some support exists for naltrexone in reducing alcohol use in schizophrenia. Behavioral interventions show promise during the intervention period but face challenges, such as the exclusion of severely mentally ill patients from clinical trials and difficulty in implementation (8,9). Some addiction treatments may even exacerbate psychotic symptoms (10-12), highlighting the urgent need for new, effective approaches.

Repetitive Transcranial Magnetic Stimulation (rTMS) is a non-invasive technique that uses magnetic pulses to stimulate neurons in the brain's cortex. Depending on the frequency, it can have inhibitory or excitatory effects. Theta Burst Stimulation (TBS), a variant of rTMS, achieves similar results with shorter sessions (13).

Globally, research on rTMS has shown its potential benefits in psychiatric disorders, including schizophrenia (14-37). Early studies, such as Wing *et al* (33) demonstrated that bilateral rTMS reduced smoking inclination in patients with schizophrenia, although it did not significantly increase smoking abstinence rates. Later, Periclinal *et al* (34) found that applying rTMS to the left dorsolateral prefrontal cortex (DLPFC) decreased cigarette consumption, though correlations with symptom improvement were minimal. Huang *et al* (35) observed short-term reductions in smoking without notable changes in cognitive or negative symptoms. Similarly, Kemp *et al* (36) explored long-term outcomes and concluded that while rTMS reduces smoking, its effects on schizophrenia symptoms are limited.

Studies from other countries, such as Kozak-Bidzińska *et al* (1,37) in Poland, have further illustrated rTMS's role in managing co-occurring substance use disorders like cannabis dependency in schizophrenia. These findings suggest a connection between cognitive deficits, negative symptoms, and substance dependence. While nicotine can improve cognitive function in schizophrenia, it may also reinforce dependence. Given the mixed results in previous research, this study adopts a robust methodology to investigate the effects of rTMS on nicotine consumption and schizophrenia symptoms, specifically targeting the left DLPFC for intervention. Given the mixed results of prior studies, this research aims to evaluate the effects of rTMS on nicotine consumption and related symptoms in schizophrenia. By targeting the left DLPFC, a region involved in

cognitive control and addiction pathways, this study seeks to provide a clearer understanding of rTMS's efficacy in addressing nicotine dependence while considering its impact on schizophrenia symptoms. Incorporating robust methodology and addressing the unique needs of this population may help bridge existing gaps in current interventions.

The significance of this study lies in addressing a major treatment gap by exploring the potential of rTMS as a non-invasive and innovative intervention. Current therapies for nicotine dependence in schizophrenia often fail to produce sustained outcomes, highlighting the need for new approaches that target the neural circuits involved in addiction and psychiatric symptoms. By examining rTMS's impact on nicotine consumption and schizophrenia symptoms, this research aims to provide valuable insights into effective treatment strategies that could improve physical and mental health outcomes for this high-risk group.

Materials and Methods

Study design and setting

This randomized, double-blind, sham-controlled trial was conducted at Iran Psychiatric Hospital between summer 2022 and summer 2023.

Participants

Eligible participants were hospitalized patients aged 18-60 years diagnosed with schizophrenia and nicotine use disorder based on DSM-5 criteria. Exclusion criteria included current use of clozapine, alcohol or other substance dependence, recent electroconvulsive therapy, and contraindications to rTMS (*e.g.*, metal implants, pregnancy, seizure history). The participants were enrolled after providing informed consent, and their capacity for informed decision-making was assessed before inclusion.

Intervention protocol

The intervention group received 10 sessions of rTMS over two weeks (five sessions per week). TBS was administered using a Magstim Rapid2 device with a figure-eight coil targeting the left dorsolateral prefrontal cortex (DLPFC). The protocol involved intermittent theta burst stimulation (iTBS): three pulses at 50 *Hz* repeated at 5 *Hz* for 2 *s*, followed by an 8-*s* rest, delivering a total of 600 pulses per session. The additional specifications were as follows: 20 *Hz*, 90% RMT, 20 trains, 30 pulses per train, 1.5 *s* on, 30 *s* off, and 750 pulses per hemisphere. Sham stimulation mimicked the procedure without delivering magnetic pulses.

The biphasic mode was chosen for its ability to deliver balanced magnetic pulses, optimizing stimulation effects while minimizing discomfort and inconsistencies in inducing neuroplasticity. Monophasic stimulation was not utilized due to its association with higher discomfort and less uniform neural activation over repeated sessions (38). These considerations were pivotal in selecting biphasic rTMS for the study.

Scales

Positive and negative syndrome scale (PANSS): The PANSS, developed by Kay *et al* (39), is a widely used instrument for evaluating symptoms in schizophrenia. It comprises 30 items distributed across three domains: positive symptoms, negative symptoms, and general psychopathology. The scale is administered by a trained clinician or psychiatrist.

Visual analog scale (VAS): The VAS is a tool for quantifying an individual's level of agreement or disagreement on a given topic by assigning a numerical value within a specified range (*e.g.,* 0 to 10, where 0 represents complete disagreement and 10 signifies full agreement) (40). The score is self-reported by the participant under study.

Data collection and assessment tools

Data were collected at baseline, immediately post-intervention, and one-month post-intervention. All the assessments were conducted by trained personnel with expertise in administering psychiatric and addiction-related scales, ensuring data reliability. The training of these individuals included workshops on the use of the Positive and Negative Syndrome Scale (PANSS) and Visual Analog Scale (VAS). The outcome measures included:

Primary outcomes: Changes in nicotine cravings (VAS) and daily cigarette consumption logs.

Secondary outcomes: Changes in schizophrenia symptoms measured using the PANSS scale. Positive and negative symptoms were scored using the

validated subscales of PANSS, ensuring accurate quantification.

Sample size calculation

The following formula was used to determine the sample size:

$$n = \frac{2\sigma^2 \left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2}{d^2}$$

where is the variance reported in previous experiments, and is the effect size (the difference between the means of the control group and the intervention group).

Additionally, α and β represent parameters related to the confidence level and test power, respectively. For a 95% confidence level and 80% test power, the required number of participants in each control and case group would be 18. To account for a 20% dropout rate, the final sample size per group was set at 22.

Inclusion criteria

Confirmation of schizophrenia diagnosis based on DSM-5 criteria through clinical interviews conducted by psychiatric faculty members.

Confirmation of smoking disorder diagnosis based on DSM-5 criteria through clinical interviews conducted by psychiatric faculty members.

Non-use of clozapine.

Age between 18 and 60 years.

No alcohol or substance dependence other than nicotine.

Absence of criteria for substance use disorders in the past three months.

No clinical prohibitions for rTMS (*e.g.*, presence of metal, shunt, or implants in the brain, history of brain surgery, increased intracranial pressure, pregnancy or intention to become pregnant, history of seizures in the individual, and the presence of a cardiac pacemaker).

Exclusion criteria

Receipt of electroshock therapy by the patient.

Randomization and blinding

The participants were randomly assigned into two groups of 22 using block randomization with a block size of 4. Randomization was conducted by an independent researcher using sealed, opaque envelopes to ensure allocation concealment. The interventionist was aware of group assignments, but both the patients and the outcome assessors were blinded, minimizing bias. The sham group underwent the same procedural setup as the intervention group but without active magnetic stimulation.

Statistical analysis

Data were analyzed using MATLAB. Paired t-tests were employed to evaluate within-group changes, while independent t-tests were used for between-group comparisons to determine the efficacy of the intervention. Effect sizes were calculated to quantify the magnitude of observed changes. Potential confounding variables, such as baseline nicotine dependency levels and demographic factors, were accounted for using stratification and multivariate regression analyses. These methods ensured the robustness of findings by isolating the effects of the intervention from external influences.

Ethical considerations

The study was registered with the Iranian Registry of Clinical Trials (IRCT20201219049768N1). Ethical approval was obtained from the Ethics Committee of Iran University of Medical Sciences (Ethics code: IR.IUMS.FMD.REC.1399.519). Additionally, informed consent was obtained from all the participants. The purpose of the study was explained to each patient. It was explained to the nurses that their participation in the study was voluntary, and they could withdraw from the study whenever they wished.

Results

Demographic and baseline characteristics

Forty-four participants were enrolled (n=22 per group). Demographic characteristics, including age, sex, and years of smoking, were almost similar between the groups. Initially, 44 individuals, comprising 40 males (91%) and 4 females (9%), entered the study. During the intervention, 8 participants (2 females and 6 males) discontinued participation due to logistical issues and adverse events, with 3 from the case group and 5 from

the control group. A total of 36 participants (19 in the case group and 17 in the control group) completed the study. Flow chart 1 shows how we grouped patients into the Case and Sham groups.

Primary outcomes

Nicotine cravings significantly decreased in the rTMS group (baseline: 7.47±1.07; post-intervention: 5.79±1.44; p<0.001) compared to the sham group (baseline: 7.41±1.62; post-intervention: 7.18±1.33; p=0.19). Daily cigarette consumption also significantly decreased in the rTMS group (baseline: 18.14±29.58; post-intervention: 12.64±19.21; p< 0.001), with no significant changes in the sham group (baseline: 23.16±36.06; post-intervention: 22.72± 35.41; p=0.36). These results are summarized in table 1.

Secondary outcomes

PANSS scores improved in both groups without significant between-group differences, suggesting that the observed improvements were unrelated to the intervention.

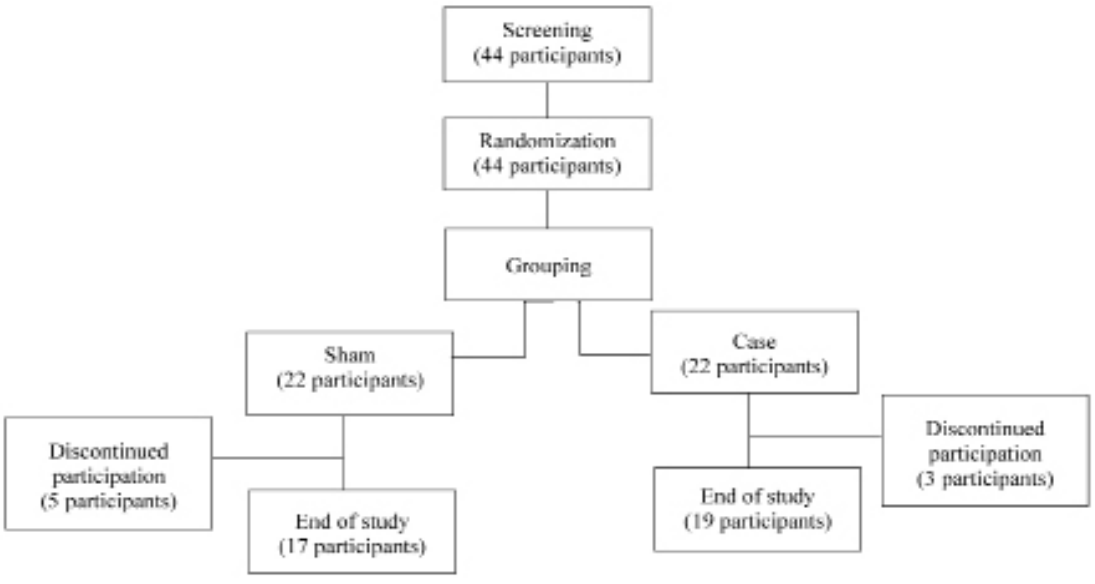
Smoking consumption and cravings

The number of cigarettes consumed decreased significantly in the rTMS group immediately and one-month post-intervention. For the case group, the effect size for consumption changes was 0.66 (p<0.001) immediately post-intervention and 0.65 (p<0.001) at one month. Conversely, no significant changes were observed in the sham group, confirming the targeted impact of rTMS (Figure 1).

Smoking desire also demonstrated a significant reduction in the rTMS group (effect size=1.32, p<

Table 1. Primary results

Variables		68% confidence interval		Effect size
		Case	Control	
Number of cigarettes per day	Before rTMS	29.58±18.14	36.06±23.16	-0.3
	Immediately after rTMS	19±14	35.41±22.74	-0.88
	One month after rTMS	19.21±12.64	34.47±21.08	-0.89
Craving for nicotine	Before rTMS	7.47±1.07	7.41±1.62	0.04
	Immediately after rTMS	5.79±1.44	7.18±1.33	-1
Severity of positive and negative symptoms of schizophrenia	Before rTMS	87.32±16.38	88.76±10.89	-0.1
	Immediately after rTMS	76.79±14.26	75.71±12.47	0.8



Flow chart. The process of grouping patients into Sham and Control groups.

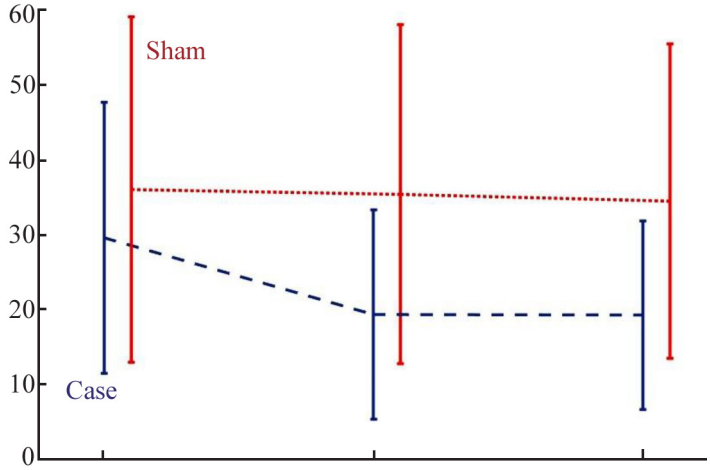


Figure 1. The range of changes in cigarette consumption within one standard deviation from the mean, from left to right: before, immediately after, and one month after the intervention.

0.001) with no notable changes in the sham group. These results highlight the effectiveness of rTMS in reducing nicotine cravings and consumption (Figure 2).

Positive and negative symptoms of schizophrenia

Although PANSS scores for positive and negative symptoms improved in both groups, the changes were not significantly different between the rTMS and sham groups. The findings suggest that these improvements were likely influenced by external factors unrelated to the intervention. Effect sizes for positive and negative symptom changes were calculated as 0.69 for the case group and 1.11 for the control group, both indicating significant within-group changes but no significant between-group differences (Figure 3).

Interpretation of the results

The results underscore the effectiveness of rTMS in reducing nicotine cravings and consumption. However, the lack of significant impact on schizophrenia symptoms indicates that factors other than the intervention may have contributed to these changes. This highlights the need for further studies to investigate the complex interplay of variables influencing these outcomes.

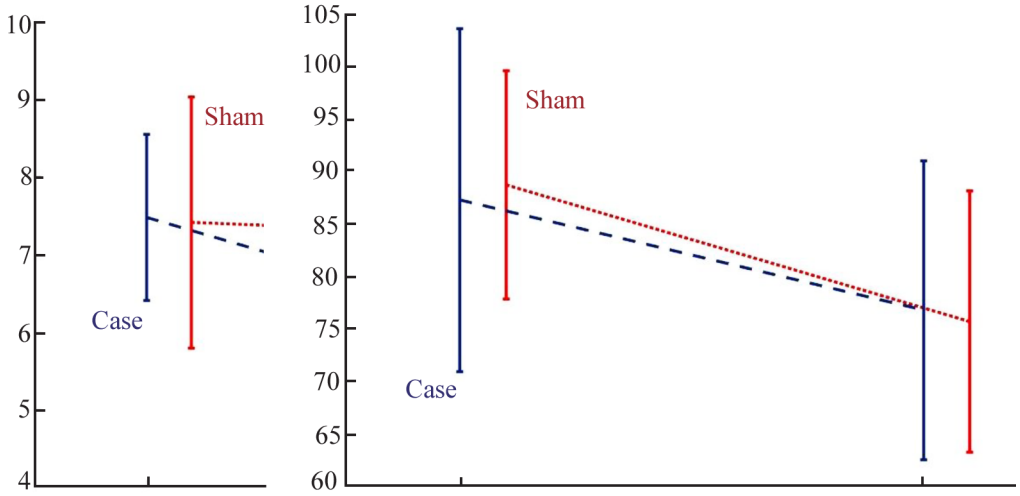


Figure 2. The range of changes in craving consumption within one standard deviation from the mean, from left to right: before and immediately after the intervention.

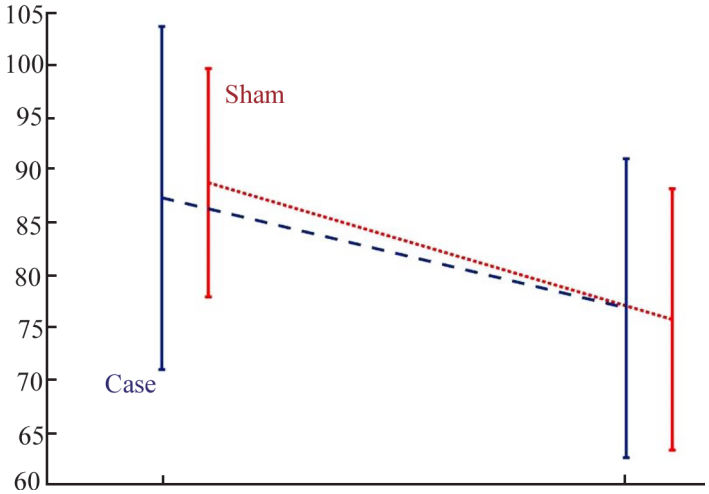


Figure 3. The range of changes in PANSS consumption within one standard deviation from the mean, from left to right: before and immediately after the intervention.

Adverse effects

It is noteworthy that an average of 10 participants in the case group and 8 participants in the sham group reported experiencing headaches following the intervention sessions.

Discussion

This study demonstrates the efficacy of rTMS using TBS in reducing nicotine cravings and consumption among individuals with schizophrenia. The findings align with prior research, supporting the potential of rTMS as an adjunctive therapy for smoking cessation in this population (34-37). However, several limitations should be considered, including a small sample size, short follow-up duration, and the lack of neuroimaging data to confirm mechanistic effects. Future studies should focus on long-term outcomes and evaluate the combination of rTMS with behavioral interventions to enhance efficacy.

Integration with Existing Research

Recent investigations have highlighted the broad applications of rTMS in psychiatric disorders, including major depressive disorder, bipolar disorder, anxiety disorders, and schizophrenia. While significant attention has been given to depression and anxiety, studies exploring the impact of rTMS on nicotine cravings and schizophrenia remain limited (14-37). Cognitive impairments and negative symptoms in schizophrenia have been identified as factors that potentially increase nicotine consumption. Interestingly, nicotine has been shown to temporarily improve cognitive functioning in these patients, which may inadvertently reinforce tobacco dependence (41). Previous studies have suggested a connection between nicotine dependence, reduced dopaminergic activity in the prefrontal cortex, and the severity of cognitive dysfunction. These deficits include impaired working memory and exacerbated negative symptoms (42-45). Additionally, changes in reward-related brain circuits and decreased DLPFC blood flow further illustrate the complex interplay between nicotine use and schizophrenia symptoms (46,47). Stimulation of the prefrontal cortex in individuals without psychiatric disorders has been reported to reduce smoking cravings linked to environmental cues. In patients with schizophrenia, however, responsiveness to neutral cues is diminished, potentially due to negative symptoms (48).

Comparison with similar studies

The current findings align with prior research indicating the effectiveness of rTMS in reducing nicotine consumption. For example, two out of four studies reviewed showed reductions in cigarette use consistent with results of the present study (34,35). Additionally, one of two studies investigating nicotine cravings reported decreases that parallel the present study's findings (33) (Table 2). Unlike some earlier studies that focused on short-term effects, the current research underscores the importance of

Table 2. Main findings from rTMS studies on nicotine craving in patients with schizophrenia

References	Study design	Sample	Stimulation target	Stimulation frequency (Hz)	Number of sessions	Summary of relevant results		
						Number of cigarettes	Craving for nicotine	± symptoms of schizophrenia
Wing *et al* (33)	Counter-balanced, randomized, double blind, parallel, sham-controlled Active= Figure-8 Sham= single wing tilt	SCZ or SCA (n=15, active=6)	Bilateral DLPFC	20	20	No change	Decrease	-
Prikryl *et al* (34)	Double blind, randomized, parallel, sham- controlled Active= Figure-8 Sham= identical coil shape produces sound but no stimulation	SCZ or SCA (n=35, Active=18), M/F=35/0	Left DLPFC	10	21	Decrease	-	-
Huang *et al* (35)	Randomized, double blind, parallel, sham-controlled Active= figure-8 Sham= identical coil shape produces sound but no stimulation	SCZ (n=37, Active=19), M/F=37/0	Left DLPFC	10	21	Decrease	-	-
Kamp *et al* (36)	Double blind, randomized, parallel, sham- controlled Active= figure-8, Sham= distortion of coil 45◦ away from skull	SCZ (n=67, Active=32), M/F=55/12	Left DLPFC	10	15	No change	-	-

exploring long-term outcomes to better understand the sustainability of rTMS benefits.

Given the positive effects of rTMS in reducing substance use, such as cannabis, and improving other psychiatric disorders, it presents itself as a viable option for smoking cessation. However, despite recent research, there is limited evidence confirming the impact of rTMS on psychiatric symptoms and smoking outcomes in patients with schizophrenia. For instance, two studies in 2015 explored the effect of tDCS on smoking cessation in individuals with schizophrenia, showing no significant impact on cigarette consumption (49,50). As a result, short-term rTMS may not be sufficient for modifying cognitive, inclination, and withdrawal symptoms in smoking individuals with schizophrenia. Therefore, long-term, controlled studies are necessary to examine the effects of rTMS on smoking behaviors and cognitive symptoms in this population.

It's also worth noting that the transcranial magnetic stimulation (TMS) method is used as the stimulation protocol, and its effectiveness in smoking cessation has been investigated in individuals without a history of mental illness (51). However, its effect on smoking cessation in patients with schizophrenia has not been examined. It is noteworthy that in 2022, the United States Food and Drug Administration (FDA) introduced dTMS as a method for smoking cessation in adults without mental illness (52).

This study contributes to filling this gap by providing evidence of rTMS's effectiveness in reducing both nicotine consumption and cravings within

this population. However, the lack of significant improvement in schizophrenia symptoms suggests that rTMS's therapeutic effects may be limited to addressing addiction-related outcomes.

Implications and future directions

The findings emphasize the need for more comprehensive approaches that combine rTMS with targeted behavioral interventions to address both addiction and underlying psychiatric symptoms. Long-term, controlled studies incorporating neuro-imaging data are crucial to confirm the mechanistic pathways underlying the observed effects. Furthermore, future research should investigate individualized stimulation protocols to maximize therapeutic outcomes while minimizing variability.

Conclusion

The present study on investigating the effectiveness of rTMS on nicotine craving in patients with schizophrenia has been completed. The results of this study demonstrated significant efficacy of rTMS in reducing the number of cigarettes smoked and nicotine craving, but no significant preference was observed in terms of the severity of positive and negative symptoms of schizophrenia. Given the present study's findings and prior examinations, it can be argued that there is relative evidence supporting the utility of rTMS in treating and improving nicotine addiction.

Acknowledgement

This study was approved by the Ethics Committee of Iran University of Medical Sciences (Ref: IR.IUMS.FMD.REC.1399.519). This clinical trial with the registration number IRCT20201219049768N1 has been registered at https://www.irct.ir/.

Conflict of Interest

Authors declare no conflict of interest.

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