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Research Article

One-Year Outcomes of Bioresonance Therapy for Smoking Cessation: A Prospective Primary Care Study

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ABSTRACT

Aim: Tobacco use remains a major global health concern. Despite pharmacological advances, many smokers seek non-invasive interventions due to side-effect concerns. This study evaluated the 1-year effectiveness of ~~a~~ standardized biophysical therapy, namely Bioresonance Therapy (BRT), for smoking cessation in a primary care setting.

Material and Methods: In this prospective longitudinal study, 50 adult participants (mean age 44.3 ± 10.4) underwent a standardized BRT protocol. Nicotine dependence was assessed using the Fagerström Test for Nicotine Dependence (FTND). Smoking status was verified via exhaled carbon monoxide (CO) at baseline, 1 month, and 3 months. Continuous abstinence at 12 months was defined as self-reported non-smoking. Factors associated with early relapse, including withdrawal symptoms, were evaluated.

Results: The continuous abstinence rate at the 12-month follow-up was 28.0% (n=14). Early relapse within the first month was significantly associated with depressive mood (p=0.012) and sleep disturbances (p=0.008). Baseline FTND scores were not significantly associated with cessation outcomes (p=0.358). No serious adverse events were reported.

Conclusion: BRT may represent a potentially useful and feasible non-pharmacological option for smoking cessation in primary care settings. Neuropsychiatric withdrawal symptoms were significantly associated with early relapse, suggesting that additional psychological support may be beneficial for patients experiencing mood or sleep-related difficulties during the cessation process. Limitations include the absence of a control group and reliance on self-report at 12 months; randomized controlled trials are warranted.

Keywords: Smoking cessation, nicotine dependence, bioresonance therapy, primary care, complementary therapies, non-pharmacological treatment.

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INTRODUCTION

Tobacco use is a leading cause of preventable morbidity and mortality, including lung cancer and chronic obstructive pulmonary disease (1,2). Pharmacological interventions—Nicotine Replacement Therapy (NRT), bupropion, and varenicline—improve cessation rates but often encounter adherence limitations and side-effect concerns (3-5).

One such alternative gaining prominence is Bioresonance Therapy (BRT), a modality of biophysical therapy. Originally developed in 1977 by the German physician Franz Morell and engineer Erich Rasche (MORA) (6,7), this method operates on the premise that electromagnetic oscillations emitted by the human body can be measured, modulated, and utilized for therapeutic purposes. While BRT was initially applied primarily in the management of allergies, functional gastrointestinal disorders, and chronic pain syndromes (8-10), it has increasingly been integrated into addiction medicine.

The proposed mechanisms underlying BRT remain theoretical and are not yet supported by robust biological evidence. Current hypotheses suggest that electromagnetic signal modulation may influence physiological processes (6,11,12); however, these concepts require further validation through well-designed experimental studies. Proponents suggest that this process may reduce physical cravings by potentially interfering with the biophysical signals associated with nicotine dependence (6,12). This hypothesis is rooted in the principle of neutralizing exogenous frequency patterns to restore physiological electromagnetic balance, a process shown to influence cellular metabolic activities in experimental models (11,13).

The clinical efficacy of BRT in smoking cessation has been investigated in several studies, with a substantial proportion of the research conducted in Türkiye. Available evidence—including studies and observational reports by researchers such as Işık (14), Karadağ et al. (15), Pihtili et al. (16), and Marakoğlu et al. (17)—has reported cessation rates suggesting potential benefit; however, the overall level of evidence remains limited and the absence of high-quality randomized controlled trials continues to restrict broader clinical acceptance. Accordingly, BRT continues to be viewed with skepticism, with critics emphasizing the use of poorly defined theoretical constructs and the lack of rigorous, prospective, and standardized long-term studies (18,19).

In light of the ongoing search for effective tobacco cessation strategies with high patient compliance, there is a clear need for rigorous prospective data. This study aims to describe one-year smoking cessation outcomes following a standardized BRT protocol in a university-based primary care setting.

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MATERIAL AND METHODS

Study Design and Setting

This study was designed as a single-center, prospective longitudinal study evaluating smoking cessation outcomes following BRT. The study was conducted at the Smoking Cessation Outpatient Clinic of Afyonkarahisar Health Sciences University between June 2021 and June 2024. Participant recruitment and subsequent one-year follow-up assessments were completed within this period. The extended study duration primarily reflects the selective nature of participant enrollment and the requirement for complete one-year follow-up for each participant.

Participants

A total of 50 adult volunteers (aged 18–75 years) who presented to the clinic and consented to participate in the BRT program were enrolled in the study. Given the exploratory nature of this study, a formal a priori sample size calculation was not performed; instead, the sample size was determined based on the clinical capacity of the study center. Accordingly, the findings should be interpreted as hypothesis-generating. As participants were self-selected individuals seeking treatment, the potential for selection bias should be considered. Exclusion criteria were defined as: (1) presence of cardiac arrhythmia, (2) use of a cardiac pacemaker, and (3) a history of severe psychiatric disorders (e.g., psychotic disorders or clinically significant anxiety requiring active treatment). Written informed consent was obtained from all participants prior to enrollment. No financial incentives were provided for participation.

Data Collection and Clinical Measurements

Baseline demographic characteristics, smoking history (pack-years), and previous cessation attempts were recorded through face-to-face interviews.

Nicotine Dependence

Nicotine dependence was assessed using the Fagerström Test for Nicotine Dependence (FTND). The validated Turkish version of the FTND was used, as reported by Uysal et al. (20). Scores were categorized as mild (0–4), moderate (5–7), and severe (8–10) dependence, consistent with commonly used classifications in the literature.

Exhaled Carbon Monoxide (CO)

Exhaled CO levels were measured using a portable CO monitor (PICO Smokerlyzer, Bedfont Scientific, UK; sensor sensitivity: 1 ppm, range: 0–150 ppm) to provide objective verification of smoking status at baseline and at the 1st and 3rd month follow-up visits. Biochemical verification was not performed at the 1-year follow-up, and abstinence at this time point was based on self-report. Participants were instructed to hold their breath for 15 seconds before exhaling slowly into the device mouthpiece. Biochemical abstinence was defined as an exhaled CO level of ≤6 ppm, consistent with commonly used thresholds in the smoking cessation literature.

Intervention Protocol (BRT)

All participants underwent a single session of BRT using the Mora-Nova device (Med-Tronik GmbH, Friesenheim, Germany). The intervention was delivered according to a structured protocol that combined the device's standard programs with an additional software module.

Preparation and Application

Prior to the session, participants were asked to smoke cigarettes of their usual brand, after which the material was incorporated into the device setup in accordance with the manufacturer's protocol. Participants were connected to the device via electrodes applied to the hands and feet, and additional electrodes were positioned on specific body regions as required by the device protocol to complete the circuit.

Therapeutic Program

The session began with an audio-based module (Psychobiophonie), administered via headphones, followed by a sequence of standard device programs (EDT-3, EDT-1, and EDT-2) applied in a fixed order. The total duration of the session was approximately 75 minutes. No pharmacological treatment or structured behavioral intervention was provided during the study period.

Post-Intervention and Follow-up

Following the session, participants were provided with adjunct materials, including a wearable chip applied to the abdominal region and oral drops for intermittent sublingual use during craving episodes, to be used during the first month according to the protocol. In addition, all participants received a written post-treatment instruction form together with routine verbal guidance. This form included recommendations for the early post-treatment period, such as avoiding smoking after therapy, resting during the first days, maintaining adequate hydration, avoiding alcohol and caffeine-containing beverages for the first two days, and avoiding smoking environments and smoking-related cues for at least two days after therapy. Participants were also advised to contact the clinic before smoking if they experienced intense craving or difficulty maintaining abstinence, and to contact the clinic during follow-up if smoking urges reappeared, relapse risk increased, or they resumed smoking even occasionally. These recommendations were supportive instructions and were not delivered as a structured or manualized behavioral counseling program. Although the study was designed primarily as a single-session intervention, additional booster sessions were available when clinically indicated. Booster sessions were not routinely scheduled for all participants. They were offered to participants who reported persistent or intense craving, difficulty maintaining abstinence, perceived insufficient treatment response during the early post-treatment period, or increased risk of relapse during follow-up. As part of routine post-treatment monitoring, participants were contacted approximately 72 hours after the initial session, and a short booster session could be offered if the treatment effect was considered insufficient or if severe craving was reported. In exceptional cases, participants with unbearable craving before 72 hours could also receive earlier support. During subsequent follow-up, participants were advised to contact the clinic if smoking urges reappeared, relapse risk increased, or they resumed smoking even occasionally. A maximum of three booster sessions was allowed. Because the timing and indication of booster sessions were individualized rather than standardized, their potential confounding effect on treatment outcomes should be considered. Follow-up assessments were conducted at 1 month, 3 months, and 1 year. Biochemical verification using exhaled CO measurements was performed at baseline, 1 month, and 3 months, whereas 1-year abstinence was based on self-report. The primary outcome was continuous abstinence, defined as self-reported non-

smoking throughout the follow-up period, supported by CO verification at available time points. Secondary outcomes included withdrawal symptoms and self-reported physical and psychological changes. Participants with severe psychiatric disorders or clinically significant anxiety requiring active treatment were not included in the study. Participants with apparent psychological vulnerability or clinically relevant mood or sleep-related symptoms during follow-up were referred for psychiatric or psychological support when clinically indicated; however, this referral process was not protocolized as part of the study and referral outcomes were not systematically recorded.

Statistical Analysis

Data analysis was performed using IBM SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were expressed as mean ± standard deviation (SD) for continuous variables, and as frequencies (n) and percentages (%) for categorical variables. The normality of data distribution was assessed using the Shapiro-Wilk test. Since the continuous variables (e.g., CO levels, pack-years) did not follow a normal distribution, group comparisons were performed using the non-parametric Kruskal-Wallis H test. Categorical variables were compared using Pearson's Chi-square test. To ensure statistical validity, Fisher's Exact test was utilized for categorical variables with expected cell counts less than 5. Correlations between FTND scores and clinical parameters were analyzed using Spearman's rank correlation coefficient (rho). Due to the limited sample size, multivariate modeling was not performed; therefore, the identified associations should be interpreted as exploratory. Given the number of statistical comparisons performed, the potential for type I error should be acknowledged. A p-value of <0.05 was considered statistically significant.

Ethical Considerations

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Scientific Research Ethics Committee of Afyonkarahisar Health Sciences University (Date: 02.10.2020, Decision No: 2020/466). All participants were informed about the purpose and procedures of the study, and written informed consent was obtained from each subject prior to enrollment. This study was supported by the Afyonkarahisar Health Sciences University Scientific Research Projects Coordination Unit under the project number 21.TEMATIK.007.

RESULTS

Demographic and Clinical Characteristics

The study included a total of 50 participants (mean age: 44.3 ± 10.4 years; range: 22–62). The majority of the participants were male (68.0%, n=34), married (80.0%, n=40), and had a university-level education or higher (52.0%, n=26). The clinical smoking history revealed a high level of dependence. The mean age of smoking onset was 18.50 ± 6.26 years, and the mean duration of smoking was 24.85 ± 11.02 years. Participants reported smoking an average of 24.4 ± 11.1 cigarettes per day, with a mean cumulative exposure of 30.8 ± 22.5 pack-years. The mean FTND score was 5.80 ± 2.63, indicating a moderate level of physical dependence. The baseline exhaled CO level was 14.62 ± 6.35 ppm (Table 1).

Table 1. Baseline socio-demographic and clinical characteristics of the participants (n=50).

Variables	n (%) or Mean ± SD
Sociodemographic characteristics	
Age years	44.30 ± 10.40
Gender	
Male	34 (68.0)
Female	16 (32.0)
Marital status	
Married	40 (80.0)
Single	10 (20.0)
Education level	
Primary or secondary school	14 (28.0)
High school	10 (20.0)
University degree or higher	26 (52.0)
Smoking history and dependence	
Age of smoking onset, years	18.50 ± 6.26
Duration of smoking, years	24.85 ± 11.02
Cigarettes per day, n	24.44 ± 11.13
Cumulative exposure, pack-years	30.80 ± 22.50
Baseline exhaled CO level, ppm	14.62 ± 6.35
FTND score	5.80 ± 2.63
Nicotine dependence level	
Mild (0–4)	16 (32.0)
Moderate (5–7)	20 (40.0)
Severe (8–10)	14 (28.0)
Clinical background	
Previous cessation attempts	
None	12 (24.0)
Self-attempt / unaided	20 (40.0)
Pharmacotherapy	18 (36.0)
Chronic disease presence	21 (42.0)
Chronic medication use	17 (34.0)
History of psychiatric disorder	1 (2.0)

Values are presented as n (%) for categorical variables and Mean ± SD for continuous variables; SD: Standard Deviation; FTND: Fagerström Test for Nicotine Dependence; CO: Carbon Monoxide; ppm: parts per million.

Smoking Cessation Outcomes

The primary outcome of the study—continuous abstinence rates—showed a progressive decline over the follow-up period, consistent with the typical nature of addiction relapse curves. The cessation success rates were 60.0% (n=30) at the 1st month, 44.0% (n=22) at the 3rd month, and 28.0% (n=14) at the 1st year.

Regarding supportive care, although the protocol allowed up to three clinically indicated booster sessions, their use remained limited. Most participants (78.0%, n=39) completed the process with only the initial single session, whereas 22.0% (n=11) received at least one booster session due to persistent craving, perceived insufficient early response, difficulty maintaining abstinence, or relapse risk during follow-up. Among the participants who relapsed (n=36), the predominant reasons cited were stressful life events (55.6%) and environmental factors/social pressure (27.8%).

In terms of safety, no serious adverse events were reported during or after the BRT sessions. The most frequently reported withdrawal symptoms were increased appetite/weight gain (52.0%), irritability (46.0%), sleep disorders (38.0%), and restlessness/anxiety (38.0%) (Table 2).

Table 2. Smoking cessation outcomes, withdrawal symptoms, and relapse characteristics.

Outcome Measures	n	%
Smoking Cessation Rates (Abstinence)		
Month 1 (Early Abstinence)	30	60.0
Month 3	22	44.0
Year 1 (Long-term Success)	14	28.0
Reported Withdrawal Symptoms†		
Increased Appetite / Weight Gain	26	52.0
Irritability	23	46.0
Sleep Disorders	19	38.0
Restlessness / Anxiety	19	38.0
Depressive Mood	12	24.0
Oral Aphthae (Mouth Sores)	5	10.0
Supportive Care Utilization		
No booster session (Single session only)	39	78.0
Received booster session(s) (Total)	11	22.0
Primary Reasons for Relapse (Among Relapsed, n=36)		
Stressful life events	20	55.6*
Environmental factors / Social pressure	10	27.8*
Habit / Pleasure / Unknown	6	16.6*

† Multiple responses were allowed; percentages are based on the total study population (n=50). * Percentages for relapse reasons are calculated based on the number of relapsed participants (n=36) to reflect the specific distribution within the failure group.

Factors Associated with Cessation Success

We analyzed the impact of demographic and clinical variables on cessation duration (Table 3).

- ***Demographics:*** Age, gender, marital status, and education level did not show a statistically significant association with smoking cessation success ($p > 0.05$).
- ***Previous Attempts:*** Participants' history of previous quit attempts significantly influenced the outcome ($p = 0.019$). Specifically, participants with a history of pharmacotherapy usage demonstrated higher resistance to early relapse compared to those with no previous attempts or unaided self-attempts. However, despite this early advantage, the long-term (1-year) success rates were comparable between the self-attempt and pharmacotherapy groups.
- ***Withdrawal Symptoms Associated with Early Relapse:*** The analysis of withdrawal symptoms showed that **sleep disorders** ($p = 0.008$) and **depressive mood** ($p = 0.012$) were significantly associated with early relapse. Participants who reported these symptoms were more likely to relapse within the first month than those who did not. However, other common symptoms such as irritability, increased appetite, and anxiety were not significantly associated with cessation duration ($p > 0.05$).

Table 3. Comparison of demographic and clinical characteristics according to smoking cessation duration.

Variables	< 1 Month (n=20)	1–3 Months (n=16)	1 Year (n=14)	p-value
Gender				**0.069**
Male	10 (29.4)	12 (35.3)	12 (35.3)	
Female	10 (62.5)	4 (25.0)	2 (12.5)	
Marital Status				**0.090**
Single	7 (70.0)	2 (20.0)	1 (10.0)	
Married	13 (32.5)	14 (35.0)	13 (32.5)	
Education Level				0.605
Primary/Secondary	6 (42.9)	4 (28.6)	4 (28.6)	
High School	6 (60.0)	2 (20.0)	2 (20.0)	
University or higher	8 (30.8)	10 (38.5)	8 (30.8)	
Previous Cessation Method				**0.019**
No previous attempt	7 (58.3)	3 (25.0)	2 (16.7)	
Self-attempt (Unaided)	11 (55.0)	3 (15.0)	6 (30.0)	
Pharmacotherapy	2 (11.1)	10 (55.6)	6 (33.3)	
Nicotine Dependence (FTND)				**0.358**
Mild	4 (25.0)	7 (43.8)	5 (31.3)	
Moderate	9 (45.0)	4 (20.0)	7 (35.0)	
Severe	7 (50.0)	5 (35.7)	2 (14.3)	
Withdrawal Symptoms (Presence)*				
Irritability	12 (52.2)	7 (30.4)	4 (17.4)	0.190
Increased Appetite / Weight Gain	10 (38.5)	9 (34.6)	7 (26.9)	0.918
Sleep Disorders	11 (57.9)	7 (36.8)	1 (5.3)	**0.008**
Depressive Mood	9 (75.0)	3 (25.0)	0 (0.0)	**0.012**
Mouth Sores (Oral Aphthae)	3 (60.0)	1 (20.0)	1 (20.0)	0.627
Restlessness / Anxiety	9 (47.4)	8 (42.1)	2 (10.5)	0.094

Table 3 (cont.). Comparison of demographic and clinical characteristics according to smoking cessation duration.

Variables	< 1 Month (n=20)	1–3 Months (n=16)	1 Year (n=14)	p-value
Booster Sessions				**1.000**
No booster session	16 (41.0)	12 (30.8)	11 (28.2)	
Received booster session(s)	4 (36.4)	4 (36.4)	3 (27.3)	
Chronic Disease (Presence)	8 (38.1)	6 (28.6)	7 (33.3)	0.766
Medication Use (Presence)	8 (47.1)	3 (17.6)	6 (35.3)	0.291

*Multiple responses were allowed; Values are presented as n (row %); FTND: Fagerström Test for Nicotine Dependence

Biochemical Verification of Abstinence

Objective validation was performed using exhaled CO measurements. As expected, there was a dramatic and statistically significant reduction in CO levels in the successful group at the 1st and 3rd months compared to the non-successful group ($p < 0.001$) (Table 4).

Table 4. Comparison of exhaled CO levels across outcome groups.

Time Point	< 1 Month (n=20) Mean ± SD (Median)	1–3 Months (n=16) Mean ± SD (Median)	1 Year (n=14) Mean ± SD (Median)	p-value
Baseline CO (ppm)	15.75 ± 5.87 (15.0)	13.63 ± 7.17 (12.0)	14.14 ± 6.22 (12.5)	0.465
1st Month CO (ppm)	8.00 ± 3.92 (7.5)	1.63 ± 0.62 (2.0)	1.71 ± 1.07 (2.0)	**< 0.001**
3rd Month CO (ppm)	8.65 ± 5.68 (7.5)	5.38 ± 4.77 (2.0)	1.21 ± 0.43 (1.0)	**< 0.001**

CO: Carbon Monoxide; ppm: parts per million; SD: Standard Deviation

Correlation Analysis and Impact of Addiction Severity

Spearman's rank correlation analysis revealed a strong positive correlation between FTND scores and daily cigarette consumption (rho=0.694, p<0.001), and moderate positive correlations with pack-years (rho=0.401, p=0.004) and baseline CO levels (rho=0.467, p=0.001). These findings confirm the biological validity of the dependence assessment (Table 5). However, age of smoking onset, smoking duration, and the number of previous quit attempts did not correlate with addiction severity ($p > 0.05$). Crucially, as shown in the previous outcome comparisons, baseline nicotine dependence severity was not significantly associated with long-term smoking cessation outcomes ($p > 0.05$, Table 3). Abstinence rates were similar across participants with mild, moderate, and severe nicotine dependence.

Table 5. Spearman's rank correlation analysis between Nicotine Dependence (FTND score) and clinical parameters.

Clinical Parameters	Correlation Coefficient (rho)	p-value
Age of smoking onset	0.106	0.466
Smoking duration (years)	0.038	0.791
Daily cigarette consumption	0.694	**< 0.001**
Pack-years	0.401	**0.004**
Number of previous quit attempts	-0.139	0.335
Baseline CO level (ppm)	0.467	**0.001**
1st Month CO level (ppm)	0.386	**0.006**
3rd Month CO level (ppm)	0.433	**0.002**

FTND: Fagerström Test for Nicotine Dependence; CO: Carbon Monoxide.

DISCUSSION

The present prospective longitudinal study evaluated one-year smoking cessation outcomes following a predominantly single-session BRT protocol in a primary care setting. Tobacco use remains a global epidemic, causing significant morbidity and mortality (1,2). Our findings revealed a continuous abstinence rate of 28.0% at the 1-year follow-up, suggesting that BRT may be a potentially useful non-pharmacological approach within the spectrum of integrative and complementary smoking cessation interventions.

Our findings are consistent with previously reported pilot randomized data by Pihtili et al. (16), who reported an abstinence rate of 28.6% in the active BRT group. Furthermore, recent Turkish retrospective data from Marakoğlu et al. (17) reported a 1-year success rate of 35.3% in a larger cohort. The higher success rate in their study compared with our findings may be related to methodological differences, including study design, participant characteristics, payment status, and session structure. In contrast to studies in which BRT was paid for by patients or delivered through multiple sessions as standard practice, the present study provides prospective observational data on a predominantly single-session protocol delivered free of charge in a primary care setting. Although 78.0% of our participants did not receive booster sessions, this should not be interpreted as evidence of sufficient treatment effect in all cases, because some relapsed individuals may not have requested or accepted further support. Similar findings in local literature (14,15) are consistent with the present results, but the overall evidence base remains limited.

A notable methodological feature of our study is the use of a standardized Mora-Nova-based BRT protocol combined with the Psychobiophonie Therapy Module. While the pilot study by Pihtili et al. (16) used the MORA-Super device, our protocol used the Mora-Nova device. Despite differences in device model and protocol structure, our 1-year abstinence rate remained similar to the findings of Pihtili et al. This suggests that variations in device model or the addition of

supplementary modules should not be assumed to produce higher long-term abstinence rates without direct comparative evidence. Future studies should evaluate whether different BRT protocols, session structures, or individualized parameter settings have measurable effects on smoking cessation outcomes. In the present study, the observed 1-year abstinence rate should be interpreted cautiously because of the small sample size, non-randomized design, and absence of a control group. Although the rate may appear broadly comparable to those reported in some pharmacotherapy trials, no direct comparison can be made due to substantial methodological differences (4,21,22).

BRT should also be interpreted within the broader context of complementary approaches used for smoking cessation. Methods such as acupuncture-related interventions, hypnotherapy, phytotherapy, aromatherapy, homeopathy, cupping therapy, apitherapy, and other non-conventional modalities are frequently sought by smokers who prefer non-pharmacological options or have concerns about medication-related adverse effects. However, the evidence supporting these approaches remains heterogeneous and generally limited. For example, systematic reviews of acupuncture-related interventions have not demonstrated consistent evidence of sustained smoking cessation benefit, and evidence regarding hypnotherapy remains insufficient to establish superiority over other cessation approaches (23,24). Therefore, the present findings should not be interpreted as definitive evidence of efficacy, but rather as prospective observational data contributing to a still limited and methodologically evolving field of complementary smoking cessation research.

Our data revealed that neuropsychiatric symptoms were associated with early treatment failure; notably, none of the participants who experienced depressive mood sustained abstinence for one year, and 75.0% relapsed within the first month ($p=0.012$). Similarly, only 5.3% of those with sleep disorders reached the one-year milestone ($p=0.008$). This finding suggests that mood- and sleep-related symptoms may represent clinically relevant warning signs during the early cessation period. Although BRT is intended to address physical craving, patients with psychological vulnerability may require additional psychological or psychiatric support. This aligns with the EAGLES trial (4), which emphasized the importance of monitoring neuropsychiatric safety and efficacy in smokers. For family physicians, the emergence of depressive symptoms or insomnia after therapy should prompt closer follow-up and consideration of supportive interventions.

Short-term biochemical verification supported abstinence status at the available follow-up points. In the 1-year abstinent group, baseline CO levels decreased from 14.14 ± 6.22 ppm to 1.71 ± 1.07 ppm at the 1st month ($p<0.001$).

The underlying mechanisms of BRT remain hypothetical and are not fully elucidated. While several models have been proposed, their clinical relevance requires further validation (6). Theoretically, BRT has been suggested to involve the modulation of electromagnetic frequency patterns associated with nicotine; however, these concepts remain speculative and are not supported by robust clinical evidence (11,12). In the present study, baseline nicotine dependence severity (FTND) was not significantly associated with cessation outcomes ($p = 0.358$; Table 3), indicating that treatment response did not differ according to initial dependence levels within this sample, and should therefore be interpreted independently from mechanistic assumptions.

Consistent with previous reports (16,17), no serious adverse events were observed. The reported irritability (46.0%) and increased appetite (52.0%) are typical nicotine withdrawal symptoms rather than device-related side effects. The absence of serious adverse events may be clinically relevant for smokers who have concerns about pharmacological adverse effects. Previous qualitative research suggests that concerns about side effects may influence the acceptance of non-invasive interventions, although these findings may not be generalizable across populations (25). Therefore, providing balanced safety information before treatment may help reduce patient anxiety and support informed decision-making.

The primary strength of this study is its prospective design with a 1-year follow-up and partial objective biochemical verification. However, several limitations should be acknowledged. First, the absence of a parallel placebo or control group limits the ability to distinguish the specific effects of the intervention from potential placebo effects. Second, biochemical verification was not performed at the 1-year follow-up, and abstinence at this time point was based on self-report; although earlier CO-confirmed abstinence may partially support the validity of these outcomes, misclassification cannot be excluded. Third, the non-standardized use of booster sessions represents an additional source of variability and may have influenced individual outcomes. Fourth, the relatively small sample size limits the robustness of subgroup analyses. Although all participants received standardized written post-treatment instructions addressing early smoking-related cues and relapse prevention, these recommendations were limited in scope and timing and were not part of a structured behavioral counseling program. Moreover, adherence to these recommendations was not systematically measured; therefore, their independent contribution to smoking cessation outcomes could not be evaluated. Finally, the generalizability of the findings may be constrained by the characteristics of the study population, as participants were self-selected individuals with a potentially higher level of motivation to quit compared to the general smoking population. Future studies involving larger, more diverse populations and controlled designs are needed to confirm these findings and to better define the comparative effectiveness and clinical applicability of BRT in smoking cessation.

CONCLUSION

This prospective observational study suggests that BRT may be a potentially useful, safe, and feasible non-pharmacological smoking cessation option in primary care, with a 28.0% 1-year abstinence rate. Post-therapy sleep disturbances and depressive mood were significantly associated with early relapse, highlighting the potential importance of psychological support during the cessation process. Future adequately powered randomized controlled trials with placebo or active comparator groups and long-term biochemical verification are needed to determine the efficacy and clinical applicability of BRT for smoking cessation.

DECLARATIONS

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