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ORIGINAL ARTICLE

Cytisine Use in a Smoking Cessation Clinic: The Case of Türkiye

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Abstract

Introduction: Smoking is a major public health concern worldwide. However, smoking cessation significantly reduces the negative outcomes associated with tobacco use. Therefore, smoking cessation treatments play a crucial role in public health. The two primary approaches to smoking cessation are psychotherapy and pharmacotherapy. In this study, we aim to share our experience with cytisine-based smoking cessation treatment in our outpatient clinic, which has recently been introduced in our country.

Methods: This is a retrospective cohort study conducted on individuals presenting to the Smoking Cessation Outpatient Clinic of Balıkesir Atatürk City Hospital between June 1, 2024, and December 31, 2024. Patients received cytisine treatment for one month, and their demographic data, smoking cessation status, and any reported side effects were recorded.

Results: A total of 754 patients presented to the Smoking Cessation Outpatient Clinic during the study period. After applying the exclusion criteria, the final study population included 557 patients. The smoking cessation rate among participants was 55.3% (n=308). Additionally, 124 out of 557 patients (22.3%) reported experiencing at least one side effect, with a total of 158 side effects recorded. Smoking cessation success was higher among patients who did not experience side effects.

Discussion and Conclusion: For a drug to be deemed appropriate for clinical use, it must be both effective and have minimal side effects. Previous studies have demonstrated the efficacy of cytisine, and its side-effect profile has been well documented in the literature. Our findings indicate that data from our country are generally consistent with existing literature. In our study, the most commonly reported side effects were nausea, dry mouth, and insomnia. We shared our experience with the use of cytisine, which has been recently introduced in our country. Our findings indicate that cytisine is effective in smoking cessation and is associated with mild, tolerable side effects.

Keywords: Cytisine; smoking addiction; smoking cessation.

Tobacco use is a significant public health concern and the leading preventable cause of morbidity and mortality worldwide. In the United States, an estimated 16 million adults currently live with a smoking-related disease [1]. Globally, smoking accounts for more than 7 million deaths annually. Long-term smokers have an average reduction in life expectancy of 10 to 11 years [2]. Furthermore, half of all smokers lose approximately 20 years of healthy life expectancy before succumbing to a smoking-related disease [3].

Smoking plays a significant role in the pathophysiology of various types of cancer, including lung, stomach, and colon cancers. It is also linked to numerous other diseases, such as chronic obstructive pulmonary disease (COPD), pulmonary infections, myocardial infarction, stroke, peripheral arterial disease, hypertension, and atherosclerosis [1]. Additionally, smoking imposes a substantial economic burden on societies. The economic costs associated with smoking include expenses related to the treatment of diseases

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in both active and passive smokers, loss of workforce productivity, premature mortality, and the environmental damage caused by smoking [4].

Fortunately, quitting smoking reverses much of the damage caused by smoking. Quitting before age 35 can prevent almost all premature deaths. Quitting smoking by age 60 increases life expectancy by three years. Quitting smoking after age 60 reduces mortality, cardiovascular disease, and cancer risk [2]. For these reasons, smoking cessation is crucial for reducing the associated health risks. Both psychotherapy and pharmacological treatments are employed in smoking cessation. Psychotherapy may involve individual therapy, group therapy, or behavioral interventions. Individual therapy can be delivered through brief physician consultations or telephone counseling. Pharmacological treatments include nicotine replacement therapies, varenicline, bupropion, and cytisine. Nicotine replacement therapies are available in various forms, such as patches, gum, inhalers, oral sprays, and lozenges [1,5].

Smokers often struggle to quit without assistance, primarily due to the development of addiction. The mechanism underlying this addiction and the subsequent chronic and repeated use of tobacco is rooted in the pharmacodynamics of nicotine. Nicotine binds to specific acetylcholine receptors in the central nervous system, predominantly subtypes of neuronal nicotinic acetylcholine receptors, and stimulates the release of neuromodulators, primarily dopamine. This release promotes pleasure, which reinforces the desire for continued consumption, ultimately leading to addiction [6].

To address nicotine addiction, nicotine replacement therapies have been developed, offering various forms of treatment. Varenicline, a partial agonist selective to α4β2 nicotinic acetylcholine receptors (nAChR)—receptors involved in dopamine release following nicotine binding—helps alleviate cravings and withdrawal symptoms. Consequently, varenicline supports smoking cessation by maintaining moderate dopamine levels in the brain, thereby preventing withdrawal symptoms [7].

Bupropion is believed to exert its pharmacological effects by weakly inhibiting the reuptake of both dopamine and norepinephrine, thereby prolonging the duration of dopamine activity in the synapse. When used for smoking cessation, bupropion inhibits the dopamine reuptake associated with nicotine use. It offers both anti-craving and anti-withdrawal effects by antagonizing the nicotinic acetylcholine receptors [8].

Cytisine, a natural alkaloid found in plant genera such as Cytisus laburnum and Sophora tetraptera, acts similarly to varenicline. It is a selective partial agonist of the α4β2 nicotinic acetylcholine receptors, which mediate nicotine's effects. Cytisine prevents nicotine binding, thereby reducing rewarding effects, withdrawal symptoms, and cravings [9].

In this study, we aimed to investigate the effectiveness of cytisine, which has recently been introduced as a smoking cessation treatment in our country. Our article is the first study reporting the results of cytisine use in smoking cessation in our country.

Materials and Methods

Study Designand Participants

This retrospective cohort study was conducted on individuals who presented to the Smoking Cessation Outpatient Clinic of Balıkesir Atatürk City Hospital. Patients who visited the clinic between June 1, 2024, and December 31, 2024, were included in the study. Demographic data included age, gender, and comorbidities such as cardiovascular disease (ischemic heart disease, heart failure, arrhythmia), pulmonary disease (COPD, asthma, pulmonary fibrosis, bronchiectasis, atelectasis), hypertension, diabetes, thyroid disease, and peripheral arterial disease.

Smoking history was categorized based on daily cigarette consumption (0–10, 11–20, 21–30, and >30 units/day) and smoking duration (0–10, 11–20, 21–30, and >30 years). Vital signs recorded at the time of presentation included blood pressure, pulse rate, body temperature, respiratory rate, and oxygen saturation. Educational status was classified as high school or lower, associate degree, undergraduate, or graduate. Additionally, smoking cessation status and reported side effects following cytisine use were documented. Our study is a descriptive study.

All data were obtained from patient files, which were created separately for each individual during their initial visit to the Smoking Cessation Outpatient Clinic, as well as from patient follow-up forms and the hospital automation system.

Inclusion Criteria:

- Age between 18 and 65 years
- Presentation to the Smoking Cessation Outpatient Clinic and initiation of cytisine treatment

Exclusion Criteria:

- Patients for whom cytisine was deemed inappropriate by the physician

- Patients who refused medication
- Patients who did not adhere to the prescribed smoking cessation treatment or discontinued the medication
- Patients who did not attend follow-up visits
- Patients with incomplete or inaccurate data in their records
- Pregnant or breastfeeding individuals
- Patients with a known allergic reaction to cytisine

Procedure

The study data were obtained from patient files, which were completed separately for each individual, and from the hospital automation system. Patient files are documented by physicians for every patient who presents to the Smoking Cessation Outpatient Clinic. The clinic is staffed by physicians authorized by the Ministry of Health of the Republic of Türkiye, and all treatments are administered by certified physicians.

During the study, all patients received cytisine (Nikitabs® 1.5 mg, 100 tablets; Nobel Pharmaceuticals) following a standardized medical treatment protocol (Table 1). The duration and dosage of treatment were identical for all patients. Smoking cessation status was recorded at the end of the treatment period. After completing the pharmacological intervention, patients were scheduled for follow-up visits, during which they were assessed for any side effects associated with cytisine use. These follow-ups were conducted through face-to-face interviews by the physician, and all reported side effects were documented.

All reported side effects were evaluated by the coordinator physician of the study. The classification of side effects was conducted using the method described by Courtney et al. [10] For an adverse event to be considered a side effect, the patient must have received at least one dose of cytisine. All side effects were categorized according to the Medical Dictionary for Regulatory Activities (MedDRA) terminology, and causalities were evaluated using the criteria defined by the World Health Organization. Patients were permitted to report more than one side effect. Side events were documented one month after the initiation of treatment.

Table 1. Cytisine treatment regimen

Days	Cytisinea
1 to 3	One capsule every 2 hours. Maximum of 6 capsules a day
4 to 12	One capsule every 2.5 hours. Maximum of 5 capsules a day
13 to 16	One capsule every 3 hours. Maximum of 4 capsules a day
17 to 20	One capsule every 5 hours. Maximum of 3 capsules a day
21 to 28	1-2 capsules a day

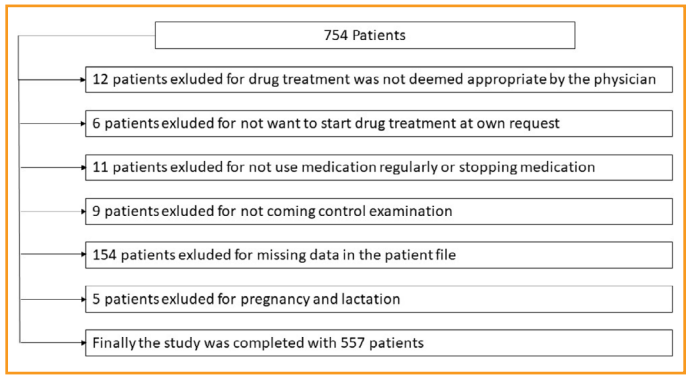

Figure 1. Flow Chart.

The study was approved by the local ethics committee and conducted in accordance with the principles of the Declaration of Helsinki (Balıkesir Atatürk City Hospital Ethics Committee, Date: 26.12.2024, Decision No: 2024/12/85).

Statistical Analysis

Statistical analyses were conducted using SPSS version 23 (IBM). Data were presented as number and percentage. Categorical variables were analyzed using the chi-square test. A p-value of <0.05 was considered statistically significant.

Results

This study was conducted on patients who presented to the Smoking Cessation Outpatient Clinic. During the study period, 754 patients visited the clinic; however, after applying the exclusion criteria, the final analysis included 557 patients. The study flowchart is presented in Figure 1.

Table 2. Distributions of Side Effects in Our Study

	n	%	Total (n)
Nausea	34	6,1	557
Dry Mouth	18	3,2	557
Insomnia	17	3,1	557
Headache	16	2,9	557
Weakness	15	2,7	557
Dizziness	15	2,7	557
Stomach Ache	10	1,8	557
Skin Rash	8	1,4	557
Chest Pain	6	1,1	557
Diarrhea	5	0,9	557
Constipation	5	0,9	557
Palpitation	4	0,7	557
Anorexia	4	0,7	557
Sweating	1	0,2	557

The patients included in the study were between 18 and 65 years of age, with a mean age of 48.94±12.23 years. Of the participants, 370 (66.4%) were male.

The distribution of comorbidities among the study population was as follows: 129 patients (23.2%) had cardiovascular disease, 115 (20.6%) had pulmonary disease, 140 (25.1%) had hypertension, 62 (11.1%) had diabetes, 40 (7.2%) had thyroid disease, and 18 (3.2%) had peripheral vascular disease.

The number of cigarettes smoked per day was categorized as follows: 1–10 cigarettes/day in 23 patients (4.1%), 11–20 cigarettes/day in 147 patients (26.4%), 21–30 cigarettes/day in 295 patients (53%), and >30 cigarettes/day in 92 patients (16.5%). Smoking duration was classified as follows: 0–10 years in 124 patients (22.3%), 11–20 years in 149 patients (26.7%), 21–30 years in 183 patients (32.9%), and >30 years in 101 patients (18.1%).

Regarding educational status, 378 patients (67.9%) had a high school education or lower, while 179 patients (32.1%) had an associate, undergraduate, or graduate degree. The smoking cessation rate at the end of the one-month treatment period was 55.3% (n=308).

Among the 557 patients included in the study, at least one side effect was reported by 124 patients (22.3%). A total of 158 side effects were reported by these 124 patients. The reported side effects are presented in Table 2.

In our study, among the 308 patients who successfully quit smoking, 223 did not report any side effects, while 85 experienced at least one side effect. This difference was statistically significant ($p<0.05$).

Discussion

This is the first study on cytisine use for smoking cessation in our country. The use of cytisine for smoking cessation treatment was introduced in our country for the first time in April 2024. In this article, we present the initial national data on cytisine.

Cytisine was first developed in Bulgaria in the 1960s for the treatment of tobacco addiction and was marketed under the trade name Tabex. It was derived from the plant Cytisus laburnum L. (Golden Rain) [11]. Similar to varenicline, cytisine acts as a partial agonist of nicotinic acetylcholine receptors [12]. Notably, cytisine is approximately ten times more affordable than both nicotine replacement therapies and varenicline [13].

Clinical studies have demonstrated that cytisine more than doubles the likelihood of smoking cessation success compared to placebo. Additionally, it has been reported to be more effective than nicotine replacement therapy. When compared with varenicline, another pharmacological smoking cessation agent, cytisine was found to be at least equally effective. Furthermore, in terms of side effect profile, cytisine has been shown to cause fewer side effects than varenicline [12,14].

In July 2021, varenicline was withdrawn from the market due to the detection of high levels of N-nitroso-varenicline, a potentially harmful compound [15]. Given these factors, cytisine has emerged as a promising alternative for smoking cessation treatment. However, for a pharmacological agent to be widely adopted in smoking cessation therapy, it must demonstrate both high efficacy and a favorable safety profile with minimal side effects.

In a study evaluating the efficacy of cytisine, the experimental group received both cytisine and smoking cessation counseling, while the control group received only smoking cessation counseling. The smoking cessation rate was 32.1% in the cytisine group and 7.3% in the control group [15]. A 2014 study on cytisine's effectiveness for smoking cessation found a 40% cessation rate at the end of one month [12]. Tinghino et al. [16] reported a smoking cessation success rate of 50.5% with cytisine in their study. In our study, the smoking cessation success rate with cytisine treatment was 55.3%. These results highlight cytisine as a viable treatment option for smoking cessation.

Regarding its side effect profile, cytisine has generally been reported to have no serious side effects. In a study by Pastorino et al., [15] cytisine was administered to 470 patients, with 41.7% (n=196) reporting a total of 399 side effects. The most commonly reported side effects included sleep disturbances (12.1%), nausea and vomiting (8.5%), and increased appetite and weight gain (4.0%). In another study, 71.4% (n=482) of 675 patients receiving cytisine reported at least one side effect. A total of 997 side effects were reported, with the most common being abnormal dreams (16.6%, n=120), nausea (10.9%, n=79), sleep disturbances (18.6%, n=135), and headaches (9.2%, n=67) [10].

Rigotti et al. [17] conducted a study with 269 patients, where 64% (n=172) reported side effects after using cytisine for six weeks. In total, 459 side effects were reported, with the most common being insomnia (9%, n=23), abnormal dreams (8%, n=22), headaches (7%, n=18), nausea (6%, n=16), constipation (6%, n=16), anxiety (3%, n=7), and diarrhea (4%, n=10).

In a study by Walker et al. [12] comparing cytisine and nicotine replacement therapy (NRT), 31% (n=204) of the total 655

patients in the cytisine group experienced side effects. The most common side effects included nausea and vomiting (4.6%, n=30), sleep disorders (4.3%, n=28), circulatory and respiratory symptoms (1.4%, n=9), depressive disorder (2%, n=8), colitis and diarrhea (1.2%, n=8), headache (1.2%, n=8), dizziness (1.2%, n=8), weakness and fatigue (0.9%, n=6), and somnolence (0.8%, n=5).

In the efficacy and safety study conducted by Phusahat et al. [18] in Thailand, 67 patients received cytisine, and side effects were reported in 37 of these patients (55.22%). The reported side effects included insomnia (11.94%, n=8), drowsiness (7.46%, n=5), dizziness (5.97%, n=4), abdominal distension (4.48%, n=3), headache (4.48%, n=3), dry mouth (4.48%, n=3), and sore throat (4.48%, n=3).

A study conducted in New Zealand on 313 participants receiving cytisine for smoking cessation found that 111 patients (35.46%) reported a total of 297 side effects. The most common side effects were headache (18.5%, n=55), nausea (10.1%, n=30), insomnia (6.4%, n=19), fatigue (3.4%, n=10), stomach pain (3.4%, n=10), vivid dreams (3%, n=9), and dry mouth (3%, n=9) [19].

In our study, the incidence of side effects was 22.3%. It is important to consider that genetic, environmental, and cultural factors may influence the occurrence of drug side effects. The most commonly reported side effects in our study were nausea, dry mouth, and insomnia, which were consistent with the findings in the literature.

In our study, a high success rate in quitting smoking was achieved with the use of cytisine, in line with the literature. Four systematic reviews reported that cytisine was superior to placebo in short- and long-term smoking cessation [20]. Studies in the literature show that cytisine is a proven drug for smoking cessation. Therefore, in our country, the Ministry of Health recommends that patients who want to quit smoking start cytisine within the indication.

Although cytisine is used almost exclusively as a smoking cessation drug, it has been tried in a few other cases. In these trials, it has been reported to increase appetite and to be a potential chemotherapeutic because it induces apoptosis [21,22].

Cytisine is generally regarded as a safe drug, which may be attributed to its relatively short half-life (4.8 hours) compared to other smoking cessation medications [12]. Furthermore, cytisine is excreted unchanged through the kidneys without undergoing hepatic metabolism, thereby reducing the risk of drug interactions [23]. This characteristic contributes to its safety profile. It is well established that smoking cessation success is negatively impacted by the occurrence of side effects, as these can lead to discontinuation of the treatment. In our study, we observed that fewer side effects were associated with higher rates of smoking cessation.

Among the patients who successfully quit smoking, 89% (with 2 missing cases) of those who experienced side effects after 1 week recommended cytisine to other individuals attempting to quit smoking [12]. Additionally, it has been reported that the use of cytisine does not negatively impact quality of life. In a study comparing cytisine with a placebo, no significant differences in quality of life were observed [18]. These findings suggest that cytisine does not cause severe side effects and that any side effects experienced are generally mild and tolerable.

Conclusion

Cytisine is a recently introduced smoking cessation medication in Türkiye, demonstrating significant potential in this domain. This article shares our experiences regarding its efficacy and side effect profile. Our findings indicate that cytisine is effective in promoting smoking cessation in our country. The side effect profile was also evaluated, revealing that the most common side effects include nausea, dry mouth, and insomnia. Consequently, cytisine has proven to be an affordable and effective smoking cessation option in Türkiye, with mild, tolerable side effects.

Ethics Committee Approval: The study was approved by Balıkesir Atatürk City Hospital Ethics Committee (No: 2024/12/85, Date: 26.12.2024).

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