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# A Comparison of Short and Long-Term Acting Dopamine Agonists in the Treatment of Parkinson's Disease with Respect to the Side Effects of Impulse Control Disorder

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## ABSTRACT

**Objective:** Impulse control disorders are thought to emerge as a result of the pulsatile stimulation of dopamine D3 receptors in the limbic-ventral striatum with dopamine treatment. According to this pathophysiology, it is argued that the use of long-acting dopamine agonists leads to fewer impulse control disorders than the use of short-acting dopamine agonists. This study aimed to compare short and long-acting dopamine agonists with respect to impulse control disorders in patients with Parkinson's disease.

**Materials and Methods:** Seventy-five patients with Parkinson's disease were examined with respect to impulse control disorders. All the patients were administered the Barratt Impulsivity Scale Short Form to determine impulsivity and the Movement Disorder Society-Unified Parkinson's Disease Rating Scale to evaluate disease severity.

**Results:** There was no significant difference between the patient groups using short and long-acting dopamine agonists for impulsivity (p=0.966, p=0.052, respectively). The Barratt Impulsivity Scale scores were seen to be higher in the patients who were illiterate compared to the other educational level groups (p<0.001), and there was no significant difference in respect of other demographic data (p>0.05). Male gender (odds ratio [OR]: 4.000, 95% CI: 1.164–13.745, p=0.028) and a high score on the Movement Disorder Society- Unified Parkinson's Disease Rating Scale (OR: 3.636, 95% CI: 1.394–9.484, p=0.008) were found to be associated with impulse control disorders.

**Conclusion:** The results of this study showed no difference between short and long-acting dopamine agonists with respect to the development of impulse control disorders.

**Keywords:** Dopamine agonist, dopamine replacement therapy, impulse control disorder, impulsivity, Parkinson's disease.

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## INTRODUCTION

Parkinson's disease (PD) is a neurodegenerative disease that develops due to neuron loss in the nigrostriatal dopaminergic pathway in the brain and progresses slowly.[1]

The general treatment recommendations for PD, the treatment of each patient should be adjusted according to individual characteristics.[2]

Dopamine agonists (DA) act on post-synaptic dopaminergic D2 receptors and mimic dopamine.[3]

The side effects of DAs include leg oedema, orthostatic hypotension, nausea and impulse control disorders (ICD) such as hypersexuality, gambling, over-organization, excessive shopping, and over-eating.[4]

Dopamine replacement therapy used for PD can lead to behavioral side effects such as ICD. This non-motor side-effect is thought to emerge as a result of the pulsatile stimulation of D3 dopamine receptors (D3R) in the limbic-ventral striatum with dopamine treatment.[5]

As the disease duration prolongs, there is an increased risk of the development of at least one ICD. Behavioral disorders in this impulsive-compulsive spectrum are seen in PD patients, especially in those with disease onset at a young age, those who use dopaminergic drugs at a high dose, have a history of depression, alcohol, or substance use and those who exhibit personality traits of impulsivity or continually searching for innovation.[6,7]

The relationship between ICD and the dopaminergic medications used has been determined in several previous studies. This non-motor side-effect is thought to emerge as a result of the pulsatile stimulation of D3R in the limbic-ventral striatum with dopamine treatment.[5] The pathogenesis of peak dose dyskinesia and the high rate of association between peak dose dyskinesia and ICD support this mechanism.[8]

Chronic use of dopaminergic drugs may interfere with the phasic and tonic activity of dopaminergic neurons and develop adaptive mechanisms in receptor and transporter density.[9] Animal studies have shown the mechanisms of this adaptation, upregulation, and downregulation of dopamine receptors. Acute pramipexole treatment reduced mean firing activity at dopamine receptors in the ventral tegment.[10]

Pulsative stimulation of D3R by dopaminergic drugs leads to up-regulation of these receptors, which in turn leads to ICD.[8]

According to this pathophysiology, it is argued that the use of long-acting DAs leads to less ICD than the use of short-acting DAs.[7] However, there are not enough studies in the literature that have compared these two types of DA with respect to ICD development.

We aimed to compare short and long-acting DAs with respect to ICD in patients with PD.

**KEY MESSAGES**

- Since the social and psychological effects of impulse control disorder, it is important to follow up and manage it well.
- There are hypotheses that this side effect is related to the result of the pulsatile stimulation of D3 dopamin receptors in the limbic-ventral striatum with dopamine treatment.
- The results of this study showed no difference in ICD between the PD patients using short and long-acting DAs.

## MATERIALS AND METHODS

### Patient Population

Seventy-five patients who were diagnosed with idiopathic PD according to the United Kingdom Brain Bank criteria11 and followed up in the Kahramanmaraş Sütçü İmam University, Neurology department's outpatient clinic for movement disorders were evaluated between September 2021 and July 2023. All patients gave written informed consent. KSÜ Non-Interventional Clinical Research Ethics Committee approval has been obtained (dated: 14.09.2021). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patients' inclusion criteria;

- Use of the same dose of DA for the last 6 months
- Age >18 years
- No dementia was determined in the clinical evaluation and anamnesis
- Patients using levodopa, rasagiline were also included in the study, but they were required to use the same treatment for the last 6 months.

Patients'exclusion criteria;

- The presence of dementia
- Patients receiving device-supported treatment such as deep brain stimulation, apomorphine infusion, Duodopa intestinal gel infusion
- Patients on two or three types of DAs.

### Evaluation of Patients

In the first stage of the study, gender, age, education level, duration of PD, drugs used for PD, smoking status, use of Maras powder (smokeless tobacco), alcohol consumption, family history of PD, gambling and drug use, parental consanguinity, and history of head trauma of patients were asked and recorded.

In the second stage of the study, the Barratt Impulsivity Scale Short Form (BIS-11-SF) was administered to determine impulsivity.[11–13]

In the third stage of the study, the Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) was administered to evaluate disease severity.[14]

### Scales used in the study

The Barratt Impulsivity Scale Short Form is a patient self-reported form to evaluate impulsivity. The Barratt Impulsivity Scale 11 (BIS-11) is one of the most frequently used scales for assessing impulsivity in both normal and clinical samples. When examined in relation to electrophysiological and neuropsychological parameters, it shows sensitivity to the prefrontal region, which is particularly associated with orbitofrontal functions. The BIS-11 is a 30-item self-report scale that assesses the manifestation of impulsivity. Items are rated on a 4-point Likert scale: 1=rarely/never; 2=occasionally; 3=often; 4=almost always/always. There are three reliable and non-overlapping subscales: Plan Making (PM), Motor Impulsivity (MI), and Attention Impulsivity (AI). High BIS-11-SF values indicate a high level of impulsivity. Reliability and validity studies of the BIS-11-SF in Turkish were conducted by Güleç et al.[13] Taking that study as reference, since the average score for the Turkish version was determined to be 26.5, the cutoff value was set at 26.5. The PD patients in the current study were evaluated as "no ICD" for a score <26.5 and as "ICD present" for a score >26.5.

MDS-UPDRS is the most frequently used scale in the evaluation of PD severity. Patients are evaluated through examination and the administration of this scale, which consists of a total of 42 items in 4 sections. The first section (4 items) evaluates mental functions, behavior and mood, the second section (13 items) daily activities, the third section (16 items) motor examination, and the fourth section (3 items) treatment complications.[14]

### Statistical Analysis

Study data were analyzed statistically using IBM SPSS Statistics for Windows, Version 22.0 (Armonk, NY: IBM Corp.) and GraphPad Prism (v.9.4.0) software. Conformity of the data to normal distribution was tested with the Kolmogorov-Smirnov test and skewness-kurtosis tests. Continuous variables were stated as mean±standard deviation (SD) or median (minimum-maximum) values, and categorical variables as number (n) and percentage (%). In the comparisons between groups, the independent samples t-test was applied to two groups and the one-way ANOVA test to three or more groups. Following one-way ANOVA, post hoc Bonferroni correction was used for multiple comparisons. In the evaluation of relationships between variables, the parametric test of Pearson correlation analysis was used.

**Table 1.** Demographic data of Parkinson's disease patients

| Demographic datas | n (%) |
|---|---|
| Age (years), mean±SD | 64.3±10.9 |
| Gender | |
| Male | 58 (77.3) |
| Female | 17 (22.7) |
| Use of cigarette | |
| Yes | 24 (32) |
| No | 51 (68) |
| Use of Maras powder (smokeless tobacco) | |
| Yes | 13 (17.3) |
| No | 62 (82.7) |
| Alcohol consumption | |
| Yes | 10 (13.3) |
| No | 65 (86.7) |
| History of head trauma | |
| Yes | 23 (30.7) |
| No | 52 (69.3) |
| Educational level | |
| Illiterate | 15 (20) |
| Elementary school | 42 (56) |
| Middle school | 3 (4) |
| High school | 5 (6.7) |
| University | 10 (13.3) |
| Parental consanguinity | |
| Yes | 19 (25.3) |
| No | 56 (74.7) |
| Family history of gambling and/or drug abuse | |
| Yes | 3 (4) |
| No | 72 (96) |
| Family history of Parkinson's disease | |
| Yes | 20 (26.7) |
| No | 55 (73.3) |

SD: Standard deviation.

Multiple binary and univariate logistic regression analyses were used to identify risk factors for patients with impulse control disorder. All variables (age, gender, disease duration, cigarette, alcohol, Maras powder, family history, gambling and/or drug abuse, and MDS-UPDRS score) with p-values <0.1 in binary univariate logistic regression analysis were entered into forward stepwise multiple binary logistic regression analysis. A value of $p<0.05$ was accepted as the level of statistical significance.

**Table 2.** Demographic and clinical findings of patients using short-acting and long-acting DA

| | Patients short- acting DA n (%) | Patients long-acting DA n (%) | p |
|---|---|---|---|
| | 34 (45.3) | 41 (54.7) | |
| Age, mean±SD | 63.8±12.3 | 64.6±9.8 | 0.762 |
| Gender | | | 0.695* |
| Female | 7 (20.6) | 10 (24.4) | |
| Male | 27 (79.4) | 31 (75.6) | |
| Use of cigarette | 14 (41.2) | 10 (24.4) | 0.121 |
| Maras powder | 9 (26.5) | 4 (9.8) | 0.057 |
| Alcohol consumption | 2 (5.9) | 8 (19.5) | 0.084 |
| History of head trauma | 12 (35.3) | 11 (26.8) | 0.429 |
| Educational level | | | 0.952** |
| Illiterate | 7 (20.6) | 8 (19.5) | |
| Elementary | 19 (55.9) | 23 (56.1) | |
| Middle school | 2 (5.9) | 1 (2.4) | |
| High school | 2 (5.9) | 3 (7.3) | |
| University | 4 (11.8) | 6 (14.6) | |
| Parental consanguinity | 11 (32.4) | 8 (19.5) | 0.203 |
| Family history of gambling and/or drug abuse | 2 (5.9) | 1 (2.4) | 0.449 |
| Family history of Parkinson's disease | 9 (26.5) | 11 (26.8) | 0.972 |

DA: Dopamin agonist; SD: Standard deviation; *: Chi-square test (data were shown as number and percentages); **: One-Way NOVA test.

## RESULTS

The patients comprised 58 (77.3%) males, 17 (22.7%) females. The mean age of male patients was 65.7±10.3 years and the mean age of females was 59.4±12.1 years. The demographic characteristics of the patients and patients' family history are presented in Table 1.

The demographic and clinical findings of patients using short-acting and long-acting DA are presented in Table 2.

Mean disease duration was determined to be 4 years (range, 2–7 years). Short-acting DAs were used by 34 (45.3%) patients and long-acting DAs by 41 (54.7%). The mean DA dose was 2.25mg (range, 0.25–200mg). The BIS-11-SF score of the whole patient group was 28±84, and the mean MDS-UPDRS score was 58.6±30 (Table 3).

No statistically significant difference was determined between the patient groups using short and long-acting DAs in respect of the BIS-11-SF and MDS-UPDRS scores (p=0.966, p=0.052, respectively) (Table 4).

When the BIS-11-SF scores and demographic data were compared, the BIS-11-SF scores were seen to be higher in the patients who were illiterate compared to the other educational level groups (p<0.001), and there was no significant difference with respect of other demographic data (p>0.05) (Table 5).

**Table 3.** Disease duration, treatment, BIS-11 SF and MDS-UPDRS scores

| | |
|---|---|
| Disease duration (year), median, min–max | 4 (2–7) |
| Number of patients using dopamine agonist, n (%) | 75 |
| Short acting dopamine agonist | 34 (45.3) |
| Long acting dopamine agonist | 41 (54.7) |
| BIS-11 SF score, mean±SD | 28±8.4 |
| MDS-UPDRS score, mean±SD | 58.6±30 |

Min: Minimum; Max: Maximum; SD: Standard deviation; BIS-11 SF: Barratt Impulsivity Scale- Short Form; MDS- UPDRS: Movement Disorder Society-Unified Parkinson's Disease Rating Scale.

A positive but not statistically significant correlation was determined between disease duration and the BIS-11-SF scores (r=0.020, p=0.867) (Fig. 1).

Risk factors for ICD were evaluated with logistic regression analysis.

**Table 4.** Comparison of BIS-11 SF and UPDRS scores of patients using short- and long-acting dopamine agonists

| | Patients using short-acting DA (n=34) | Patients using long-acting DA (n=41) | p |
|---|---|---|---|
| BIS-11 SF score, mean±SD | 28.1±8.6 | 28.0±8.3 | 0.966 |
| UPDRS score, mean±SD | 66.0±33.1 | 52.5±26.0 | 0.052 |

SD: Standard deviation; BIS-11 SF: Barratt Impulsivity Scale- Short Form; MDS- UPDRS; Movement Disorder Society-Unified Parkinson's Disease Rating Scale.

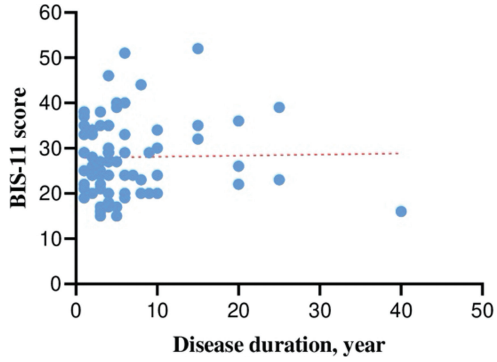


**Figure 1.** Association between disease duration and BIS-11 SF scores.

In the univariate logistic regression analysis, male gender (odds ratio [OR]: 4.000, 95% CI: 1.164–13.745, p=0.028), the use of Maras powder (OR: 6.679, 95% CI: 1.365–32.668, p=0.019), and a high MDS-UPDRS score (OR: 3.636, 95% CI: 1.394–9.484, p=0.008) were found to be associated with ICD.

In the multivariate logistic regression analysis, male gender (OR: 6.480, 95% CI: 1.710–24.555, p=0.006), the use of Maras powder (OR: 10.127, 95% CI: 1.894–54.149, p=0.007), and a high MDS-UPDRS score (OR: 3.415, 95% CI: 1.171–9.958, p=0.024) were found to be associated with ICD (Table 6).

The results of the logistic regression analyses of the risk factors of patients with ICD are presented in Table 6.

## DISCUSSION

In this study, 75 patients were examined in detail and the use of short-acting and long-acting DAs was investigated with respect of ICD. The results showed no difference between the PD patients using short and long-acting DAs.

Mean disease duration was determined to be 4 years (range, 2–7 years). A positive but not statistically significant correlation was determined between disease duration and the BIS-11-SF scores (r=0.020, p=0.867). A longer disease duration (>7.8 years for pathological gambling, >9.6 years for hypersexuality) has been previously suggested to be a risk factor for ICD in some studies,[15,16] whereas in a 2010 study

**Table 5.** The relationship between BIS-11 SF scores and demographic data

| | BIS-11 SF score Mean±SD | p |
|---|---|---|
| Gender | | 0.103 |
| Male | 27.1±8.7 | |
| Female | 30.9±6.8 | |
| Use of cigarette | | 0.508 |
| Yes | 28.9±9.3 | |
| No | 25.6±8.0 | |
| Use of Maras powder (smokeless tobacco) | | 0.065 |
| Yes | 31.9±8.1 | |
| No | 27.1±8.3 | |
| Alcohol consumption | | 0.846 |
| Yes | 28.5±7.1 | |
| No | 27.9±8.6 | |
| History of head trauma | | 0.899 |
| Yes | 27.8±8.6 | |
| No | 28.1±8.4 | |
| Educational level | | **<0.001*** |
| Illiterate | 35.1±9.3 | |
| Elementary school | 27.8±7.1 | |
| Middle school | 24.6±9.5 | |
| High school | 20.2±5.6 | |
| University | 23.0±5.9 | |
| Parental consanguinity | | 0.457 |
| Yes | 29.2±7.5 | |
| No | 27.6±8.7 | |
| Family history of gambling and/or drug abuse | | 0.731 |
| Yes | 29.6±6.4 | |
| No | 27.9±8.5 | |
| Family history of Parkinson's disease | | 0.277 |
| Yes | 26.2±8.8 | |
| No | 28.6±8.2 | |

SD: Standard deviation; BIS-11 SF: Barratt Impulsivity Scale- Short Form; *: One-way ANOVA was uesd for analysis and Bonferroni's multiple comparison test was applied.

**Table 6.** Results of logistic regression analysis of risk factors for patients with impulse control disorder

| Variables | Binary univariate logistic regression | | | Multiple binary logistic regression | | |
|---|---|---|---|---|---|---|
| | OR | 95% CI | p | OR | 95% CI | p |
| Age (≥64 vs. <64 year) | 1.158 | 0.466–2.878 | 0.752 | | | |
| Gender (male vs. female) | 4.000 | 1.164–13.745 | **0.028** | 6.480 | 1.710–24.555 | **0.006** |
| Disease duration (≥4 vs. <4 year) | 1.598 | 0.633–4.031 | 0.321 | | | |
| Cigarette (yes vs. no) | 1.456 | 0.547–3.879 | 0.452 | | | |
| Alchol (yes vs. no) | 1.455 | 0.375–5.641 | 0.588 | | | |
| Maras powder (yes vs. no) | 6.679 | 1.365–32.668 | **0.019** | 10.127 | 1.894–54.149 | **0.007** |
| Family history of gambling and/or drug abuse (yes vs. no) | 1.892 | 0.164–21.804 | 0.609 | | | |
| MDS- UPDRS score (≥58 vs. <58) | 3.636 | 1.394–9.484 | **0.008** | 3.415 | 1.171–9.958 | **0.024** |

OR: Odd ratios; CI: Confidence interval; MDS- UPDRS: Movement Disorder Society-Unified Parkinson's Disease Rating Scale.

by Evans et al.,[17] no significant difference was determined between the disease durations of patients with and without ICD. In a longitudinal study, treatment of Parkinson's patients with dopamine agonists was found to have a cumulative increase in risk at the end of 5 years. In a multicenter study conducted in Europe with a large patient population, the incidence of ICD was found to be lower with the long-acting rotigotine patch compared to short-acting agonists. In this study, the disease duration was 7.5 years. The reason why we did not find a positive correlation between disease duration and BIS-11-SF scores in our study may be that the mean disease duration was shorter than 5 years.[18–20]

Of the 75 patients, 15 (20%) were illiterate, 42 (56%) had an educational level of primary school, 3 (4%) had of middle school level, 5 (6.7%) had of high school level, and 10 (13.3%) were university graduates. The mean BIS-11-SF scores were determined to be 35.1±9.3 for those who were illiterate, 27.8±7.1 for those at the primary school level, 24.6±9.5 for those at the middle school level, 20.2±5.6 for those at the high school level, and 23.0±5.9 for university graduates. When the BIS-11-SF scores were compared with the demographic data, the BIS-11-SF scores of the patients who were illiterate were determined to be statistically significantly higher than those of patients in the other education level groups (p<0.001). Although ICD was detected more frequently in illiterate individuals in our study, one study found no association between educational level and ICD[19], while another study detected ICD more frequently in the group with higher education.[21] Although it is unclear whether educational level poses a risk in terms of ICD development, a well-organized study on this subject could be beneficial.

No statistically significant difference was determined in the BIS-11-SF scores when compared with the other demographic data examined in the study of gender, smoking, use of Maras powder, alcohol consumption, history of head trauma, parental consanguinity, family history of gambling and/or drug use, and family history of PD (p>0.05). The reason why young age at the onset of the disease, motor fluctuations, male gender, apathy, depression, smoking were found to be risk factors in many previous studies but not in our study may be due to the small number of patients in our study.[22–24]

According to the literature, ICD prevalence is affected by gender and it is seen more often in males. The current study population comprised 58 (77.3%) males and 17 (22.7%) females. The mean BIS-11-SF scores were 27.1±8.7 for males and 30.9±6.8 for females. In a study by Gallagher et al.[25] ICD prevalence was high in males and pathological gambling was determined at the rate of 75% in males. In the study by Torres et al,[24] hypersexuality was found to be more common in males and money-related impulse disorders were found to be more common in females. Since our number of patients was not very high, we did not analyze impulse control disorders separately; we evaluated them globally.

Of the current study patient population, 24 (32%) were smokers and 51 (68%) were non-smokers. The BIS-11-SF scores were 28.9±9.3 for smokers and 25.6±8.0 for non-smokers. Maras powder was used by 13 (17.3%) patients with a mean BIS-11 SF score of 31.9±8.1, and was not used by 62 (82.7%) with a mean BIS-11 score of 27.1±8.3. Alcohol consumption was reported by 10 (13.3%) patients and not by 65 (86.7%), with respective BIS-11 scores of 28.5±7.1 and 27.9±8.6. In the univariate analysis of the current study, male gender (odds ratio [OR]: 4.000, 95%

CI: 1.164–13.745, p=0.028), the use of Maras powder (OR: 6.679, 95% CI: 1.365–32.668, p=0.019), and a high (>58) MDS-UPDRS score (OR: 3.636, 95% CI: 1.394–9.484, p=0.008) were found to be statistically significantly associated with ICD. This relationship with ICD was maintained at a significant level in the multivariate analysis; male gender (OR: 6.480, 95% CI: 1.710–24.555, p=0.006), the use of Maras powder (OR: 10.127, 95% CI: 1.894–54.149, p=0.007), and a high MDS-UPDRS score (OR: 3.415, 95% CI: 1.171–9.958, p=0.024).

"Maras powder" is a form of smokeless tobacco that is commonly used in the South and Southeastern parts of Türkiye. Although sometimes it is used as an alternative to quitting smoking, it is often used as an independent substance due to its higher addictive properties.[26] Since the use of Maras powder is common in our province, we examined the use of Maras tobacco alongside addictive substances such as cigarettes and alcohol. Increasing or new substance dependence, like tobacco, alcohol, has been reported in PD patients with ICD-27.[27]

In the DOMINION I study, independent demographic and clinical variables contributing to the development of ICD were determined. These included age <65 years, smoking, family history of gambling, and the use of DA and levodopa.[23] The results of the univariate logistic regression analysis in the current study showed no statistically significant effect on the development of ICD of age, disease duration, smoking, alcohol consumption, and family history of gambling and/or drug use. However, the limitations of the relatively low number of samples and the parameters that could be adapted to the regression analysis prevented evaluation of stronger independent variables, such as DA doses.

For the whole study population, the BIS-11-SF scores were 28±8.4 and the MDS-UPDRS scores were 58.6±30. The BIS-11 scores were determined to be 28.1±8.6 for patients using short-acting DAs and 28.0±8.3 for those using long-acting DAs. The MDS-UPDRS scores were 66.0±33.1 for patients using short-acting DAs and 52.5±26.0 for those using long-acting DAs. No statistically significant difference was determined between the patient groups using short and long-acting DAs in respect of the BIS-11-SF and MDS-UPDRS scores (p=0.966, p=0.052, respectively). It is currently unknown whether the risk of ICD is similar in different DAs. In a study by Perez-Lloret et al.,[28] there was shown to be an increasing risk of ICD was shown in all DAs, and this supported the class effect. As stated by Weintraub et al.,[21] studies aiming to analyze ICD in the context of anti-Parkinson's drug treatment are especially difficult for various reasons. The first of these is that many patients do not report severe side effects even to neurologists, because of embarrassment or because of a suspected association with the PD treatment, and this is especially true for ICD. A second reason is that many patients do not see various aspects of ICD, such as compulsive shopping and overactivity of hobbies, as abnormal behavior, and partially for these reasons, ICD is generally not sufficiently identified.[28]

Another problem is that over time, most PD patients change from one drug to another, including different DAs,[29] and in some cases can use a combination of Das,[30] which makes it difficult to establish a link between individual drugs, especially individual DAs, and ICD.

The limitation of our study is that the mean disease duration is short (4 years). Increased duration of drug use may increase the risk of impulse control disorder, which may better reveal the difference between the two drug groups.

## CONCLUSION

The results of this study showed no difference in ICD between the PD patients using short and long-acting DAs, and that illiterate patients developed ICD more than the other educational level groups. Patients with male gender, the use of Maras powder, a longer disease history, and a higher MDS-UPDRS score were found to be at higher risk of developing ICD. Therefore, whenever dopaminergic treatment is considered, individuals at risk should be identified, the treatment scheme should be planned according to these risks, there must be an awareness of the non-motor symptoms and psychiatric problems that could emerge in the continuation of the treatment, and when identified, the first step must be to terminate the DA in use. Nevertheless, there is a need for further, more extensive epidemiological studies to support all the information and links established.

**Ethics Committee Approval:** The KSÜ Non-Interventional Clinical Research Ethics Committee granted approval for this study (date: 14.09.2021, number: 2021/30).

**Informed Consent:** Written informed consent was obtained from patients who participated in this study.

**Conflict of Interest:** The authors have no conflict of interest to declare.

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