**The Effect of Pramipexole on Impulse Control and Other Behavioral Disorders in Idiopathic Restless Legs Syndrome**

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**Abstract**

Restless legs syndrome (RLS) is characterized by unpleasant sensations in the legs that occur or worsen during rest and/or in the evening. Pramipexole is an effective treatment option for RLS. While dopamine agonists are associated with impulse control and other behavioral disorders (ICBD) in Parkinson’s disease, there is limited consensus on their relationship with such disorders in RLS. This study aimed to evaluate the association between pramipexole treatment and ICBD in RLS patients.

In this case-control cross-sectional study, ICBD were assessed using the PD-QUIP questionnaire and the Barratt Impulsivity Scale-11 Short Form (BIS-11 SF). Patients diagnosed with idiopathic RLS using the International Restless Legs Syndrome Study Group diagnostic criteria, aged over 18, without psychiatric disorders, and treated with pramipexole for at least one month, were included. Untreated RLS patients served as controls. The study included 108 patients, with 50.9% receiving pramipexole treatment. The BIS-11 SF total score was 31.79 ± 7.32 in the pramipexole-treated group and 30.35 ± 6.73 in the untreated group (p=0.324). No significant differences were found in total or subscale scores (attention: p=0.232, non-planning: p=0.695, motor impulsivity: p=0.498). Based on PD-QUIP results, ICBD were detected in 37% (N=40) of patients, with punding in 12 (11.1%), compulsive eating in 9 (8.3%), and hypersexuality in 1 patient (0.9%). The frequency of ICBD did not differ significantly between groups (p=4.90). These findings suggest that pramipexole treatment in RLS does not significantly affect ICBD development. Large-scale studies are warranted to further explore the impact and causality of pramipexole on ICBD.

**Keywords:** Restless legs syndrome, pramipexole, impulse control disorders, punding, BIS-11 SF

**Introduction**

Restless legs syndrome (RLS) is a sensorimotor disorder characterized by an urge to move the legs accompanied by uncomfortable sensations. Symptoms typically occur in the evening, during rest, and tend to improve with movement [1]. RLS significantly impacts patients' quality of life and psychosocial well-being and is associated with a high risk of depressive symptoms and suicidal thoughts [2]. In addition to genetic susceptibility, environmental factors contribute to the etiology of RLS. While it can occur idiopathically, conditions such as pregnancy, iron deficiency anemia, chronic renal insufficiency, diabetes mellitus, and neurological and rheumatological disorders are recognized as additional risk factors [3, 4].

Hypotheses regarding the pathophysiological mechanisms suggest that, in addition to iron deficiency, dysfunction in central dopaminergic and nociceptive pathways, as well as disruptions in adenosine and glutamatergic pathways in the brain, contribute to the underlying pathology [3]. Non-ergot dopamine agonists, such as ropinirole, pramipexole, and rotigotine, given in low doses, are considered effective treatment options for RLS. However, long-term use of these drugs may result in complications, including augmentation, increased symptom severity, reduced therapeutic efficacy, and the emergence of impulse control and other behavioral disorders [5].

Impulse control and other behavioral disorders represent a series of heterogeneous neuropsychiatric dysfunctions. Impulse control disorder is defined as the inability to resist certain repeatedly performed activities. It is characterized by behaviors that are rewarding, evoke pleasure, and are driven by efforts to prevent or reduce anxiety [6-8]. Prominent disorders within the spectrum of impulse control and related behavioral disorders (ICBD) include pathological lying, hypersexuality, compulsive shopping, and compulsive eating. Punding involves stereotypical and repetitive purposeless behaviors. ICBD has been reported under dopamine agonist therapies in conditions such as Parkinson's disease (PD), RLS, fibromyalgia, and hyperprolactinemia [9]. Overstimulation of the dopaminergic reward systems and dopamine (D3) receptors in the mesolimbic pathways is believed to play a role in the underlying mechanisms [7, 8, 10].

Impulse and behavioral disorders, including pathological gambling, hypersexuality, compulsive shopping, and compulsive eating, have been observed at varying incidence rates (7-16%) during dopaminergic treatment for RLS [9, 10, 11]. This study aims to evaluate the frequency of ICBD associated with pramipexole treatment in RLS patients in Turkey.

**Materials & Methods**

This study was approved by Ankara Etlik City Hospital and designed as a cross-sectional study conducted in a movement disorders clinic in Turkey. Patients who presented to our clinic and were diagnosed with idiopathic RLS according to the International Restless Legs Syndrome Group (IRLSSG) diagnostic criteria were evaluated face-to-face by a neurology specialist [12]. The inclusion criteria were as follows: having a diagnosis of idiopathic RLS, being aged 18 or older, and having no history of psychiatric illnesses or substance use. Demographic data for all participants were recorded after obtaining their written informed consent in accordance with the Declaration of Helsinki.

During meetings with the patients and their relatives, the following assessments were conducted: the International Restless Legs Syndrome Study Group Severity Scale, the short form of the Barratt Impulsiveness Scale (BIS-11 SF), a survey based on the Questionnaire for Impulsive-Compulsive Disorders in Parkinson’s Disease (PD-QUIP) to evaluate impulsive and behavioral disorders, the Patient Global Impression of Change (PGIC) scale, and the Beck Depression Inventory (BDI).

The International Restless Legs Syndrome Study Group Severity Scale consists of 10 questions in total. While the first five questions assess the severity of symptoms, the remaining five assess daily life activities and quality of life. Each question is scored on a scale from 0 to 4, corresponding to “none,” “mild,” “moderate,” “severe,” and “very severe,” respectively. The total score reflects disease severity, with a score of 1-10 classified as mild, 11-20 as moderate, 21-30 as severe, and 31-40 as very severe [12, 13]. The validity and reliability of the Turkish version were confirmed in 2019 [14].

Weintraub et al. developed the Questionnaire for Impulsive-Compulsive Disorders in Parkinson’s Disease (PD-QUIP) in 2009 to identify impulsivity and its various forms in Parkinson’s disease patients [15, 16]. In this study, we used the short version of this questionnaire, which included six questions assessing the following behaviors that persisted for at least four weeks: pathological gambling, hypersexuality, compulsive shopping, compulsive eating, other behaviors (punding, taking up a new hobby, or purposeless/excessive walking), and compulsive medication use. Responses were recorded as “yes” or “no” for each behavior.

The PGIC scale reflects patients’ beliefs about the efficacy of the treatment. It is a clinically relevant tool to evaluate the perceived impact of disease management. The PGIC rates overall well-being on a 7-point scale, where scores range from 1 (worst) to 7 (best) [17].

The BDI, developed by Beck, measures the level and severity of depressive symptoms. The validity and reliability of the Turkish version were established by Hisli [18]. According to the total score, scores of 1-10 are categorized as normal, 11-16 as mild mood disturbance, 17-20 as borderline clinical depression, 21-30 as moderate depression, 31-40 as severe depression, and 41-63 as extreme depression.

To evaluate impulsivity, the standardized tool selected was BIS-11 SF, a 30-item self-report measure to assess personality and behavioral characteristics [19]. The BIS-11 SF consists of 15 items divided into three subscales: attention (attention impulsivity, cognitive instability), motor (motor impulsivity, impatience), and non-planning (lack of forethought, difficulty tolerating cognitive complexity). Four sub-scores are generated: total score, non-planning, attention, and motor impulsivity scores. Higher total scores indicate greater levels of impulsivity [20]. The Turkish validity and reliability of the BIS-11 SF were established by Tamam et al. [21]. There are no established cut-off scores for the scale or its subscales. In this study, it was used to evaluate the severity of impulsivity and its components.

**Statistical Analysis**

Quantitative variables were described using measures of central tendency and variance: mean ± standard deviation. Fisher’s Exact Test (for small sample sizes) and the Chi-square test were used to evaluate differences in ratios and relationships between categorical variables. To compare group means, the student’s t-test was applied when the assumptions of normality and equal variances were met. When these assumptions were not satisfied, the Mann-Whitney U-test was used.

To assess the correlation between two numerical variables, the non-parametric Spearman’s Rank Correlation test was employed, as the data did not follow a normal distribution. Statistical significance was set at p = 0.05. All statistical computations were performed using IBM SPSS Statistics software (Version 21.0, Armonk, NY, IBM Corp.).

**Results**

A total of 108 idiopathic RLS patients were assessed face-to-face over a three-month period. Among the participants undergoing pramipexole treatment, the medication dose (mg), treatment duration, and responses to treatment efficacy (recorded as "yes" or "no") were evaluated. The gender distribution showed a predominance of females, comprising 68.5% (n=74) of the participants. The demographic characteristics of the participants are listed in Table 1.

Of the study group, 50.9% (n=55) were undergoing pramipexole treatment, with treatment durations ranging from 1 to 180 months. Patients receiving pramipexole treatment had longer disease durations and were older (p<0.001, p=0.045). The RLS severity score was significantly higher in patients receiving pramipexole treatment compared to those not receiving treatment (p=0.045) (Table 2). When asked about treatment efficacy, 60% of patients reported a favorable ("yes") response. The PGIC score, as a more objective evaluation of treatment efficacy, was significantly higher in this group (Mean ± SD: 4.28 ± 2.1) compared to those reporting a negative ("no") response (p=0.035).

The BDI score (Mean ± SD: 14.11 ± 10.45) in the pramipexole treatment group showed no statistically significant difference compared to the untreated group (p=0.534) (Table 2). A tendency to increase the pramipexole dose was observed in 21.8% of patients, and their PGIC scores (Mean ± SD) were 2.91 ± 2.17. When comparing the PGIC score and the pramipexole treatment duration, a statistically significant weak negative correlation (inverse relationship) was found (p=0.016) (Table 4).

In terms of impulsivity levels, groups (receiving pramipexole or not) were compared using the BIS-11 SF. The mean scores and statistical data are shown in Table 3. No statistically significant differences were found between the groups in total impulsivity, attention, motor impulsivity, or non-planning subscale scores. The overall mean BIS-11 SF score for all patients was 31.09 ± 7.03. Among patients receiving pramipexole, the BIS-11 SF total was 30.86 ± 4.15 in males and 32.25 ± 8.51 in females (p=0.229).

According to the PD-QUIP questionnaire, impulsive and behavioral disorders were identified in 37% of all RLS patients (23 females and 17 males). The ages of these patients ranged from 21 to 76, and 55% of them were receiving pramipexole treatment. Within the pramipexole-treated group, punding was observed in 12 patients (11.1%), compulsive eating in 9 patients (8.3%), and hypersexuality in 1 patient (0.9%). In the untreated group, punding was detected in 8 patients (7.4%), compulsive eating in 7 patients (6.4%), and hypersexuality in 3 patients (2.7%) (Figure 1). No significant differences were found between the pramipexole-treated and untreated groups in terms of impulsive and behavioral disorders (p=4.90).

**Discussion**

Restless legs syndrome (RLS) is known to have significant psychological and behavioral impacts on patients. Treatments are expected to improve symptoms while also addressing psychiatric conditions associated with the disease. However, it is also well-recognized that treatments themselves may contribute to such complications. In Parkinson’s disease (PD), the relationship between dopaminergic therapies and the emergence of impulsive and other behavioral disorders has been widely investigated. The prevalence of impulsive-compulsive behavioral disorders (ICBD) due to the use of dopamine agonists in PD is approximately 13.6%, compared to 0.5–1% in the general population. Yet, the dosages used for RLS treatment are considerably lower than those used for PD [7, 24]. It has been suggested that impulsive and behavioral disorders may be inherent to RLS itself. On the other hand, some studies indicate that these disorders may emerge or be exacerbated by dopaminergic therapies [10, 23].

In this study, the association between pramipexole treatment in RLS and ICBD was investigated. Compared to previous studies, we utilized BIS-11 SF concurrently in a larger cohort from Turkey and evaluated patients face-to-face with their relatives [16, 18, 24]. The prevalence of ICBD in RLS patients has been previously reported as at least 2.76% [24].

In a study that used surveys and phone interviews to evaluate ICBD in RLS patients, a frequency of 17% for any ICBD was found, which was higher than in patients with obstructive sleep apnea (6%) and RLS patients not using medication (8%) [9]. In our study, we did not find a significant relationship between pramipexole use and the risk of impulsive and behavioral disorders in RLS patients in Turkey. Impulsive and other behavioral disorders were present in 37% of all patients (with or without pramipexole treatment), with 40% of the pramipexole-treated group. This was in accordance with the findings of Heim et al., who reported a prevalence of 39.7% [11].

Considering the sociocultural differences and dependencies of ICBD in pramipexole users, we found that punding was more frequent among the entire patient group (with or without pramipexole treatment) in this small sample of RLS patients from Turkey. Punding is defined by pointless, complex, and stereotypical behaviors, such as constantly holding objects or disassembling them, manipulating technical equipment, excessive grooming or cleaning, and hoarding [25]. In contrast with the findings of Cornelius et al., punding was more common in the pramipexole-treated group (11.1%), and compulsive eating ranked second in our study [9]. Although high doses of pramipexole in RLS can induce ICBD, some studies have identified changes related to ICBD in much lower doses of pramipexole [26]. In our study, ICBD occurred at pramipexole doses lower than those used for PD, and we did not observe an association between pramipexole dose and the frequency of ICBD or other behavioral disorders.

Unlike previous studies, pathological gambling was not observed in our study. This may be attributed to cultural factors in Turkish society, where binge eating and gambling are perceived negatively, and access to gambling is highly restricted [9, 27]. However, behavioral disorders like addictions can vary across different cultures and societies, and we did not conduct an objective, standardized assessment for gambling addiction.

RLS symptoms become more severe in the evening, whereas active daytime hours are linked to improved well-being and less reliance on medication, and it is likely that impulsivity may also decrease in states of well-being. Based on this, we suggest that pathological gambling, compulsive shopping, hypersexuality, and compulsive eating may be less prevalent in RLS patients compared with PD [28]. Furthermore, the relationship between the need for repetitive limb movements and purposeless actions can be interpreted as a relieving mechanism. Beyond all these hypotheses, we support that circadian dopaminergic cycles or clinical states of well-being and distress may be the mechanisms behind the co-occurrence of RLS and impulse and other behavioral disorders [28, 29]. Disarrangement in mesolimbic and mesostriatal dopaminergic systems and the sensitization of cortico-striatal pathways have been hypothesized to play a pathogenic role in punding caused by dopaminergic treatments in PD and RLS [30].

We did not detect a correlation between BIS-11 SF total and subscale scores, similar to the findings of Dang et al. [24]. Consistent with previous research, the presence of ICBD and other behavioral disorders in RLS patients without pramipexole treatment may reflect a predisposing nature of the disease itself [22]. The causality of this relation may stem from personality traits irrespective of the pramipexole treatment. Functional imaging could offer further insights into this causality in the future.

Several limitations should be acknowledged. First, the surveys were conducted within a limited timeframe. Additionally, our study did not include a control group. The restricted scope of the surveys may also have been insufficient for comprehensive psychiatric and neuropsychological evaluations. We lacked detailed information on the patients’ personality characteristics and psychiatric histories. While relatives were included in the assessment of impulsivity, we could not investigate the psychiatric family history. Lastly, the study included a small sample size. Since the sample is thought to represent a specific cultural context, expanding the sample size and adopting a multicultural and regional approach could yield more generalizable results. From a critical perspective on previous studies, cultural differences may influence addictions, and distinctions between “well-being” and “distress” periods in RLS have not been adequately explored in prior research.

Despite its limitations, face-to-face and separate evaluation of pramipexole-treated and untreated groups, application of the BIS-11 SF scale, and investigation of impulsive and other behavioral disorders in collaboration with patient relatives can be highlighted as the notable strengths of our study. We hypothesize that pramipexole, beyond being a treatment option, may also pose a risk for ICBD and other behavioral disorders. However, our findings are correlational and do not reveal causality.

In general, ICBD and other behavioral disorders in RLS patients may not be initially questioned, recognized, or perceived as pathological by clinicians. While this study did not statistically associate ICBD and other behavioral disorders with pramipexole treatment, it emphasizes the importance of considering the potential presence of ICBD and other behavioral disorders in pramipexole-treated and untreated RLS patients during treatment selection and follow-up. Regarding the extent to which ICBD and other behavioral disorders identified are harmful, we remain uncertain. There is a need for larger cohorts with broader perspectives to address these questions.

**Conclusion**

Impulse control and other behavioral disorders in RLS may be associated with the nature of the disease, dopaminergic treatments such as pramipexole, or both. Considering and addressing this possibility is crucial in treatment planning. Timely interventions for atypical changes during the treatment process can help prevent the potential debilitating effects of impulsive and other behavioral disorders.

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**Conflict of Interest Statement**

The authors declare that they have no conflict of interest.

**Author Contributions**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Contributor | Concept | Study Design | Data Collection | Statistical Analysis | Literature Overview | Discussion | Fund Generation |
| Zehra Yavuz | ✓ | ✓ | ✓ | - | ✓ | ✓ | - |
| İlknur Topal Yarat | - | ✓ | - | ✓ | - | ✓ | - |
| Ayşenur Gençalp | - | ✓ | - | - | ✓ | ✓ | - |
| Selim Selçuk Çomoğlu | ✓ | - | ✓ | - | - | ✓ | - |

**Data Availability**

All data generated or analysed during this study are included in this article. Further enquiries can be directed to the corresponding author.

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**Ethics Statement**

This study was approved by the Ethics Committee of Etlik City Hospital, Written informed consent was obtained from all participants.

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**Abbrevations:** BDI, Beck Depression Inventory; BIS-11 SF, the short form of the Barratt Impulsiveness Scale; ICBD, impulse control and related behavioral disorders; IRLSSG, International Restless Legs Syndrome Group; PD, Parkinson's disease; PD-QUIP, Questionnaire for Impulsive-Compulsive Disorders in Parkinson’s Disease; PGIC, Patient Global Impression of Change; RLS, Restless legs syndrome.

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**Figure-1:** ICBD and Other Behavioral Disorder Types Between Groups

**Table-1:** Demographic and Clinical Characteristics of RLS Patients

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| Parameters | Value  (N, Mean ± SD / Median (Min-Max)) |
| Sex | Male: 31,4% (n=34)  Female: 68,5% (n=74) |
| Age (years) | 52.88 ± 14.18  53 (19-85) |
| Age at disease onset (years) | 45.77 ± 13.85  46 (10-80) |
| Disease duration (months) | 28 ± 7.05  5 (1-40) |
| Marrital status | Married: 89,8% (n=97)  Single: 10,2% (n=11) |
| Presence of family history | 31,5% (n=34) |
| RLS severity score | 27.84 ± 6.31  28 (12-44) |
| Patients receiving pramipexole treatment | 50,9% (n=55) |
| Pramipexole dose (mg) | 0.52 ± 0.47  0.25 (0.25-3) |
| Pramipexole treatment duration (months) | 3-41.98 ± 55.06  15 (1-180) |
| Presence of augmentation | 25% (n=27) |
| Tendency to increase pramipexole dose | 11,1% (n=12) |
| Treatment response | Yes: 30,6% (n=33)  No: 20,4% (n=22) |
| PGIC score | 3.75 ± 1.96 4 (1-7) |
| BDI | 14.44 ± 10.15  12 (0-42) |

Abbrevations: RLS, restless legs syndrome; PGIC, Patient Global Impression of Change; BDI, Beck Depression Inventory

**Table-2:** Comparison of Demographic Data Between Groups

|  |  |  |  |
| --- | --- | --- | --- |
| Parameters | Pramipexole  Group (N=55) | Non-Pramipexole  Group (N=53) | P-value |
| Sex | Male: %50,0 (n=17) | Male: %50,0 (n=17) | 1 |
| Female: %51,4 (n=38) | Female: %48,6 (n=36) |
| Age (years) | 55.6 ± 13.91 | 50.06 ± 14.03 | 0.593(s) |
| Age at disease onset (years) | 46.47 ± 14.84 | 45.04 ± 12.83 | 0.593(s) |
| Disease duration (months) | 9.6 ± 7.07 | 4.87 ± 6.21 | 0.001(m) |
| RLS severity | 29.04 ± 5.37 | 26.6 ± 6.99 | <0.045 |
| BDI | 14.11 ± 10.45 | 14.77 ± 19.93 | 0.534 (m) |

Stats: n, Mean ± SD/Median (Min–Max); (m) Mann Whitney U Test-, (s) Student’s T- tes

**Table-3:** Comparison of BIS-11 SF Impulsivity Scores Between Groups

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| BIS-11 SF | Total RLS | Pramipexole Group (N=55) | Non-Pramipexole Group (N=53) | P-value |
| Attention | 8.71 ± 3.0 | 9.1 ± 3.37 | 8.3 ± 2.52 | 0.232(s) |
| Motor Impulsivity | 8.71 ± 3.64 | 9.17 ± 3.79 | 8.23 ± 3.45 | 0.498(m) |
| Non-Planning | 13.62 ± 4.21 | 13.43 ± 4.15 | 13.83 ± 4.31 | 0.695(m) |
| Total Impulsivity | 31.09 ± 7.03 | 31.79 ± 7.32 | 30.5 ± 6.73 | 0.324(m) |

Stats: Mean ± SD/Median (Min–Max), (m) Mann Whitney U Test-,(s) Student’s T- test

**Table-4:** Correlations Between BIS-11 Subscales, RLS Severity Score, BDI and Age, Disease Duration, and Treatment Parameters

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameters | Age (years) | Disease Duration (months) | Pramipexole Dose (mg) | Treatment Duration (months) |
| BIS-11 SF Total Impulsivity | r:0.133  p:0.402 | r:0.033  p:0.837 | r:0.023  p:0.888 | r:0.087  p:0.589 |
| BIS-11 Attention | r:0.003  p:0.985 | r:0.129  p:0.417 | r:0.068  p:0.672 | r: 0.265  p:0.094 |
| BIS-11 Motor Impulsivity | r:-0.122  p:0.44 | r:- 0.249  p:0.11 | r:-0.143  p:0.371 | r:-0.042  p:0.794 |
| BIS-11 Non-Planning | r:0.292  p:0.061 | r:0.154  p:0.329 | r:0.006  p:0.15 | r:0.001  p:0.994 |
| RLS Severity Score | r:-0.12  p:0.382 | r:0.135  p:0.326 | r:0.259  p:0.058 | r:0.128  p:0.357 |
| Beck Depression Inventory | r:0.133  p:0.332 | r:0.12  p:0.384 | r:0.258  p:0.06 | r:0.223  p:0.105 |
| PGIC | r:0.038  p:0.793 | r:-0.163  p:0.259 | r:-0.227  p:0.117 | r:-0.343  p:0.016 |

Spearman's Correlation Test