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## The Effect Of Serotonin Reuptake Inhibitor Use On Restless Legs Syndrome In Children

### Çocuklarda Serotonin Geri Alım İnhibitörü Kullanımının Huzursuz Bacak Sendromu Üzerine Etkisi

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#### Öz

**Amaç:** Bu araştırma, seçici serotonin geri alım inhibitörleri (SSRI'lar) ile depresyon ve/veya anksiyete bozuklukları tanısı alan çocuk ve ergen popülasyonlarında Huzursuz Bacak Sendromu (HBS) görülme oranı arasındaki ilişkiyi incelemeyi amaçlamaktadır.

**Gereç ve Yöntemler:** Bu retrospektif çalışmada, fluoksetin, sertralin veya essitalopram gibi seçici serotonin geri alım inhibitörlerinden (SSRI'lar) birini kullanmış 10-17 yaş arası hastalar incelenmiştir. Dışlama kriterleri arasında demir eksikliği anemisi, diyabet, böbrek hastalıkları, omurilik rahatsızlıkları, antihistaminik veya antipsikotik ilaç kullananlar ve diğer psikiyatrik ya da nörolojik bozukluklara sahip hastalar yer almıştır. Çalışmada, demografik bilgiler, tıbbi geçmiş, ferritin seviyeleri, vitamin B12 seviyeleri ve ailede huzursuz bacak sendromu (HBS) öyküsü kaydedilmiştir. Ayrıca, HBS tanısı konulan hastaların durumunun şiddeti HBS şiddet ölçeği ile değerlendirilmiştir.

**Bulgular:** Analiz edilen 40 çocuk arasında %10'unda HBS gelişmiştir. Sonuçlar, SSRI kullanımının HBS semptomlarının ortaya çıkışıyla potansiyel bir bağlantısı olabileceğini göstermiştir. HBS ile hemoglobin, ferritin veya vitamin B12 seviyeleri arasında anlamlı bir ilişki bulunmamıştır. HBS tanısı alan hastaların yarısında HBS aile öyküsü tespit edilmiştir.

**Sonuç:** Bulgular, SSRI kullanımının çocuk ve ergen popülasyonlarında HBS gelişimi ile olası bir ilişkiyi işaret etmektedir. Daha geniş bir örneklem büyüklüğüyle ek çalışmalar yapılması tavsiye edilmektedir.

**Anahtar kelimeler:** Huzursuz bacak sendromu, çocuklar, serotonin geri alım inhibitörleri, depresyon, anksiyete bozuklukları

#### Abstract

**Objective:** This research intends to investigate the relationship between selective serotonin reuptake inhibitors (SSRIs) and the occurrence rate of Restless Legs Syndrome (RLS) among pediatric and adolescent populations diagnosed with depression and/or anxiety disorders.

**Materials and Methods:** This retrospective study examined patients between the ages of 10 and 17 who had been prescribed one of the following selective serotonin reuptake inhibitors (SSRIs): fluoxetine, sertraline, or escitalopram. Exclusion criteria included patients with iron deficiency anemia, diabetes mellitus, renal disorders, spinal cord conditions, those receiving antihistaminic or antipsychotic medications, and individuals with other

psychiatric or neurological disorders. The study meticulously recorded demographic information, medical histories, ferritin levels, vitamin B12 levels, and a family history of restless legs syndrome (RLS). Furthermore, the severity of RLS was evaluated using a specific scale for patients diagnosed with the condition. **Results:** Among the 40 children analyzed, 10% developed RLS. The results indicated a potential link between SSRI use and the onset of RLS symptoms. No significant relationship was found between RLS and hemoglobin, ferritin, or vitamin B12 levels. Half of the RLS patients had a family history of RLS. **Conclusion:** The results indicate a possible association between the administration of SSRIs and the emergence of RLS in pediatric and adolescent populations. It is advisable to conduct additional studies with an expanded sample size.

**Keywords:** Restless Legs Syndrome, Serotonin Reuptake Inhibitors, Children, Depression, Anxiety Disorders

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## 1. Introduction

Restless Legs Syndrome (RLS), often referred to as Willis-Ekbom disease, is a neurological condition marked by an intense and uncontrollable urge to move the legs which frequently exacerbates during periods of inactivity [1,2]. Pediatric RLS was first recognized in 1994, with the diagnostic criteria undergoing revision in 2013 [3,4]. Children suffering from RLS may exhibit behavioral challenges, including refusal to adhere to bedtime routines or experiencing difficulties with sleep [5]. Restless Legs Syndrome (RLS) is quite common among children and adolescents, with prevalence estimates between 2% and 4% in this age group [6]. Its symptoms are often mild and episodic, also young children may struggle to express leg discomfort, leading to frequent misdiagnosis. However, RLS can be a progressive condition that significantly impacts daily functioning [6,7]. Research has also indicated that children and adolescents with RLS may experience neurocognitive effects, including negative impacts on mood, reduced energy, difficulties with focus and lower academic achievement [8]. Additionally, RLS may play a role in the emergence of parasomnias, especially non-rapid eye movement disorders like sleepwalking and night terrors [9].

There is conflicting evidence regarding the relationship between antidepressant usage and the development of RLS [10]. Some studies suggest that (SSRIs, commonly prescribed for anxiety and depression, might exacerbate RLS symptoms [11]. On the other hand, other investigations propose that these drugs may offer a protective benefit [12]. The exact mechanism by which SSRIs might contribute to RLS is not yet clearly understood. It has been proposed that the blocking of serotonin reuptake could excessively suppress dopaminergic function, potentially triggering RLS symptoms [13].

Iron deficiency is acknowledged as a significant factor in the pathophysiological mechanisms of various neurodevelopmental and sleep-related disorders in the pediatric population [14]. The predominant explanation for the symptoms of RLS is encapsulated in the iron deficiency-metabolic theory. Brain iron deficiency (BID), which arises

from compromised iron transport across the blood-brain barrier, stimulates the hypoxic pathway, predominantly impacting brain regions such as the putamen, thalamus, and substantia nigra. This stimulation enhances dopaminergic activity, resulting in the downregulation of postsynaptic receptors. Furthermore, BID contributes to increased levels of glutamate and a decrease in adenosine, thereby precipitating hyperarousal and sleep disturbances [15].

Secondary RLS may be associated with conditions such as peripheral neuropathy and uremia. For patients suspected of having secondary RLS, it is advisable to screen for underlying causes, including renal disease, thyroid dysfunction and deficiencies in vitamin B12 and folic acid, which may contribute to peripheral neuropathy [16].

This study aimed to assess the prevalence of RLS in children and adolescents receiving treatment with SSRIs. Additionally, it sought to investigate possible correlations between the severity and symptoms of RLS and several blood parameters, such as hemoglobin, ferritin and vitamin B12 levels.

## 2. Material and Method

This study involved a retrospective review of records from children and adolescents aged 10 to 17 years with depression and anxiety disorders, who visited the Child and Adolescent Psychiatry outpatient clinic at Mustafa Kemal University between July and December 2024. The study included children and adolescents who had been exclusively using SSRIs (fluoxetine, sertraline, or escitalopram) for a minimum of one month. To ensure a focused participant group, those with additional psychiatric disorders were excluded. Furthermore, children with neurological conditions such as cerebral palsy or hypothyroidism were not included. Also the presence of iron deficiency anemia, diabetes mellitus, kidney diseases, spinal cord pathologies, antihistaminic or antipsychotic drug use, other psychiatric disorders and neurological conditions were excluded. The study also excluded children who were on other

psychiatric medications, as these could potentially interfere with the outcomes.

Between these dates, 68 patients diagnosed with depression or anxiety disorder visited the outpatient clinic. Twenty-eight of these patients were excluded from the study due to their use of benzodiazepines or antipsychotics alongside SSRIs. In total, the files of 40 patients who met the criteria were retrospectively analyzed.

Patient records were examined to obtain key information for the study. The collected data included demographic details such as the participant's age and gender, along with their medical history, which documented both past and current health conditions. Information on the prescribed SSRIs - fluoxetine, sertraline, or escitalopram - was also gathered. Additionally, laboratory results, including hemoglobin, ferritin and vitamin B12 levels were recorded. Lastly, a family history of restless legs syndrome (RLS) was reviewed to identify any potential hereditary predisposition. Patients diagnosed with RLS were evaluated using the RLS Severity Scale.

### 2.1. Statistical Analysis,

Descriptive statistics, such as means and standard deviations, were calculated for continuous variables. The Mann-Whitney U test was employed to compare continuous variables between groups, while Fisher's Exact test was used for categorical data. A p-value of less than 0.05 was considered statistically significant. Predictors of restless legs syndrome were reported as odds ratios with a 95% confidence interval (CI).

### 3. Results

#### 3.1. Demographic Characteristics

A total of 40 children and adolescents participated in the study. Most of the participants were female. The mean age was  $15.5 \pm 2.0$  years.

**Table 1: Demographic Profile of the Study Population**

Variable	Number	Percentage (%)
Male	6	15.0
Female	34	85.0

#### 3.2. SSRI Usage, RLS Development and Family History

**Table 4: Responses to RLS-Related Questions and Comparison Between Sertraline and Fluoxetine Users**

Question	Response	Total (N=40)	Sertraline Used (n=26)	Fluoxetine Used (n=11)	p-value
	Yes	60.0%	57.7%	63.6%	0.516

The most commonly used SSRI was sertraline (65%), followed by fluoxetine (27.5%) and escitalopram (5%). Among the children who developed RLS, two were using sertraline, one was using fluoxetine and one was using escitalopram. Fifty percent of the RLS patients reported a family history of the condition.

**Table 2: SSRIs Used and RLS Incidence**

SSRI	Number of Users	RLS Cases	Family history
Sertraline	26	2	2
Fluoxetine	11	1	0
Escitalopram	2	1	0

### 3.3. Laboratory Findings

No significant differences were found in hemoglobin, ferritin, or vitamin B12 levels between children with and without RLS.

**Table 3: Hemoglobin, Ferritin, and Vitamin B12 Levels**

Measured Value	Total (Mean $\pm$ SD)	RLS Absent (Mean $\pm$ SD)	RLS Present (Mean $\pm$ SD)	p-value
Hemoglobin	12.4 $\pm$ 2.3	12.7 $\pm$ 14.2	12.8 $\pm$ 1.9	0.557
Ferritin	21.0 $\pm$ 16.8	21.5 $\pm$ 16.8	16.6 $\pm$ 17.7	0.471
Vitamin B12	357.8 $\pm$ 149.9	358.6 $\pm$ 156.7	350.2 $\pm$ 75.1	0.857

Mann-Whitney U Test, SD: Standard Deviation

### 3.4. Evaluation of RLS-Related Questionnaire Responses in Children

To evaluate the diagnosis of RLS in children, responses to four critical questions were recorded and summarized in Table 4. A comparison of responses between the two most frequently used SSRIs -sertraline and fluoxetine- showed no statistically significant differences between the groups (p-values: 0.516, 0.571, 0.091, 0.166).

Do you feel an urge to move your legs?	No	40.0%	42.3%	36.4%	
Do uncomfortable sensations or the urge to move become worse when you're inactive?	Yes	42.5%	42.3%	45.5%	0.571
	No	57.5%	57.7%	54.5%	
Do symptoms improve with activity?	Yes	50.0%	57.7%	72.7%	0.091
	No	50.0%	42.3%	27.3%	
Do unpleasant sensations increase at night?	Yes	30.0%	23.1%	45.5%	0.166
	No	70.0%	76.9%	54.5%	

*Note: Values are presented as column percentages. The p-values were calculated using Fisher's Exact Test.*

**Table 5: The disease severity of four patients diagnosed with Restless Legs Syndrome**

Drugs-Dosage of Drugs Questions-	Patient1	Patient2	Patient3	Patient4
Drugs	Escitalopram	Sertraline	Sertraline	Fluoxetine
Dosage of the drugs	20 mg	50 mg	50 mg	20 mg
Frequency of RLS symptoms	4	4	3	1
Duration of symptoms per night	3	1	2	1
The strength of the compulsion to move your legs	3	2	2	1
Relief from symptoms by movement	2	2	2	1
Sleep disturbance due to RLS	3	2	2	1
Fatigue or drowsiness during the day caused by RLS	4	1	3	0
Impact on the ability to carry out daily activities	4	1	2	0
Mood disturbance caused by RLS	3	1	2	0
How often does RLS disturb overall life quality	4	1	2	1
Overall severity of RLS symptoms	4	2	2	1

*Severity level:0:None, 1:Mild, 2:Moderate, 3:Severe, 4:Very Severe*

#### 4.Discussion

This study underscores the potential link between SSRI use and RLS onset in children. Despite the low incidence, these findings highlight the importance of monitoring pediatric patients prescribed SSRIs. Early identification of RLS symptoms is vital for minimizing its impact on sleep and overall quality of life.

RLS or Willis-Ekbom disease, is a neurological disorder defined by an uncontrollable urge to move the lower limbs, frequently accompanied by

discomfort [17]. Although more commonly observed in middle-aged and elderly individuals, RLS can affect 2-4% of children [6]. The primary symptoms, such as leg discomfort and sleep disturbances, are typically alleviated through voluntary or involuntary leg movements [18]. While the exact cause of RLS remains unclear, iron deficiency is a frequently observed contributing factor [19]. Treatment often involves iron supplementation to reduce symptoms [20]. Our study found no significant differences in hemoglobin, ferritin or vitamin B12 levels between

children with and without RLS. Iron's role in the development of RLS and periodic limb movement disorder has been well-established in both adults and children. The link between low iron levels and these conditions may stem from disruptions in dopamine function, as iron acts as a cofactor in dopamine synthesis. Reduced iron levels in the brain might be linked to impaired iron transport across the blood-brain barrier [21].

Current research identifies several potential mechanisms involved in the development of RLS, including decreased brain iron levels, disruptions in dopaminergic pathways and genetic predisposition [22]. Additionally, stressful environments have been associated with the onset of RLS. Notably, children diagnosed with Post-Traumatic Stress Disorder (PTSD) often experience co-occurring sleep disorders, such as RLS. The stress linked to PTSD can intensify RLS symptoms, creating a cycle of poor sleep quality that negatively impacts both conditions. Sleep disturbances are considered among the most sensitive indicators of PTSD severity in children [23]. The devastating earthquake on February 6, which caused significant loss and trauma in the affected region, had a profound impact on the children in this study, all of whom were diagnosed with RLS and had experienced the earthquake. The DSM-5 outlines several functional consequences of RLS, emphasizing its impact on sleep, including reduced sleep duration, fragmented sleep and overall disruption. RLS is also closely linked to psychiatric disorders such as depression, generalized anxiety disorder, panic disorder, PTSD, and a decline in overall quality of life. A study conducted by Baird et al. investigated sleep disturbances in trauma-exposed Australian Vietnam veterans with and without PTSD (n = 214, including 108 with PTSD). The findings revealed significantly higher rates of restless legs (45% vs. 25%), nightmares (91% vs. 29%), nocturnal screaming (73% vs. 18%), sleep terrors (61% vs. 13%), and dream enactment (78% vs. 11.8%) in veterans with PTSD compared to those without the condition [24]. These findings underscore the heightened prevalence of sleep disturbances, including RLS, among individuals with PTSD.

Psychiatric comorbidities in RLS pose two significant clinical challenges. Firstly, overlapping symptoms between RLS and psychiatric disorders can make diagnosis difficult, requiring careful distinction from conditions that mimic RLS. Secondly, the use of antidepressants and neuroleptic medications can aggravate RLS symptoms, adding complexity to treatment approaches [25].

While the relationship between SSRIs and RLS in children has not been extensively studied, there is growing evidence suggesting that SSRIs may induce RLS symptoms. SSRIs and atypical antidepressants

like mirtazapine have been linked to higher incidences of RLS, likely due to their impact on dopamine and iron pathways in the brain (10). Serotonin, which SSRIs modulate, plays a vital role in regulating mood, sleep, and energy levels. Disruptions in serotonin pathways can lead to neurological and psychiatric disorders, including RLS. Some studies suggest that serotonin receptor gene mutations may further exacerbate these issues [26]. In our study sertraline was the most used SSRI, two of the patients diagnosed with RLS, were using sertraline, and the other SSRIs were fluoxetine and escitalopram.

Attention Deficit Hyperactivity Disorder (ADHD) is among the most commonly diagnosed psychiatric conditions in children, with a significant association observed between ADHD and RLS [6]. Children with ADHD have a higher likelihood of developing RLS, particularly after starting SSRI treatment [7]. Research indicates that RLS symptoms appear in about 40% of children with ADHD before treatment and in up to 80% of children within a year of beginning SSRIs [27]. Psychostimulants used to treat ADHD, such as methylphenidate, have also been associated with nocturnal myoclonus (a condition characterized by sudden twitching during sleep) further complicating the clinical picture [28]. In our study, comorbid psychiatric disease was an exclusion criterion.

Furthermore, the study suggests that the dose-dependent regulation of serotonin transporters by SSRIs may play a role in RLS development [29]. Research on whether increased iron uptake could damage dopamine-producing neurons, thereby contributing to sleep and motor disorders, would be beneficial [30]. Exploring this hypothesis could shed light on the mechanisms through which SSRIs contribute to RLS.

Given the established connection between iron deficiency and RLS, exploring iron supplementation as a preventive or therapeutic strategy for children on SSRIs represents an important area for future research. While pilot studies suggest that iron supplementation may alleviate RLS symptoms in children with ADHD, potentially offering dual benefits in managing both conditions [31]. Our study did not find significant differences in hemoglobin, ferritin or vitamin B12 levels between children with and without RLS.

There are several limitations to this research. As a retrospective study, it relied on existing medical records, which may not have provided comprehensive information on the onset and progression of RLS symptoms. The limited number of patients in the study is also one of its limitations.

Future studies should aim to overcome these limitations by conducting larger, placebo-controlled trials to gain a clearer understanding of the relationship between SSRIs and RLS in children. However, ethical concerns regarding the use of placebos in pediatric populations may pose challenges. Investigating the impact of other antidepressant classes, such as tricyclic antidepressants and serotonin-norepinephrine reuptake inhibitors (SNRIs) on RLS development could also provide valuable insights.

## 5. Conclusion

Healthcare professionals should closely monitor children on SSRIs for early signs of RLS, ensuring timely intervention. The appearance of new symptoms should necessitate a comprehensive assessment and the exploration of alternate therapeutic options. Additional studies involving larger participant pools and extended follow-up durations are essential to validate these results and elucidate the mechanisms involved in SSRI-related RLS. Promoting sleep hygiene and implementing behavioral strategies may also serve to mitigate RLS symptoms and enhance the overall quality of life for

patients. Addressing these research gaps will contribute to a more comprehensive understanding of the risks associated with SSRI use in children and inform better clinical practices.

**Ethics Committee Approval:** The ethical approval was obtained from the Mustafa Kemal University Local Ethics Committee (2024.07.09/19). The study was performed by the principles stated in the Declaration of Helsinki.

**Patient Consent for Publication:** Written informed consent was obtained from all participants.

**Data Sharing Statement:** The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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