Short Communication / Kısa Makale

Examination of Patients Using Paliperidone Palmitate 3-Month Formulation

Paliperidon Palmitat 3 Aylık Formülasyon Kullanan Hastaların İncelenmesi

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ABSTRACT

Adherence problems to oral antipsychotics are common in patients with psychotic disorders. The use of long-acting injectable antipsychotics has been suggested to support adherence management. This study aimed to examine the patients who used paliperidone palmitate 3-month formulation (PP3M). Twenty-one patients (8 females and 13 males) were included in the study. The mean age was 40.90±10.98 years, the age of disorder onset was 18.47±3.64 years, the duration of paliperidone palmitate once-monthly formulation use was 12.38±14.68 months, the duration of PP3M use was 4.66±1.85 months. While 20 patients were diagnosed with schizophrenia, 1 male patient was diagnosed with schizoaffective disorder. Since PP3M does not require long-term continuous drug use and follow-up, its use in patients with adherence problems provides significant benefits.

Key Words: Paliperidone palmitate three-month long-acting injection, Patient compliance, Schizophrenia, Schizoaffective disorder

ÖZ

Psikotik bozukluğu olan hastalarda oral antipsikotiklere uyum sorunları sık görülür. Uyum yönetimini desteklemek için uzun etkili enjekte edilebilir antipsikotiklerin kullanılması önerilmiştir. Bu çalışmada paliperidon palmitat 3 aylık formülasyon (PP3A) kullanan hastaların incelenmesi amaçlandı. Çalışmaya 21 hasta (8 kadın ve 13 erkek) dahil edildi. Ortalama yaş 40,90±10,98 yıl, hastalık başlangıç yaşı 18,47±3,64 yıl, paliperidon palmitat 1 aylık formülasyon kullanım süresi 12,38±14,68 ay, PP3A kullanım süresi 4,66±1,85 ay idi. Yirmi hasta şizofreni tanılıyken, bir erkek hasta şizoaffektif bozukluk tanılıydı. PP3A uzun süreli sürekli ilaç kullanımı ve takibi gerektirmediğinden uyum sorunu olan hastalarda kullanımı önemli faydalar sağlamaktadır.

Anahtar Kelimeler: Paliperidon palmitat üç aylık uzun etkili enjeksiyon, Hasta uyumu, Şizofreni, Şizoaffektif bozukluk

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Introduction

In patients with schizophrenia and other psychotic disorders who do not have sufficient caregiver support and who are left alone, discontinuation of medical treatment is a common problem. Sometimes, even missing a dose in the treatment with oral antipsychotics causes adherence problems and can trigger a psychotic episode. The treatment adherence problems lead to increased hospitalization, long hospitalization periods, persistence of psychotic symptoms, poor prognosis and suicide attempt. Long-acting injectable antipsychotics provide significant benefits in patients with impaired drug adherence.1 In this study, we aimed to examine the clinical and sociodemographic characteristics of patients who were managed by paliperidone palmitate 3-month formulation (PP3M) subsequent to paliperidone palmitate 1-month formulation (PP1M).

Material and Method

This retrospective cohort study was carried out in a mental health and diseases hospital in Turkey. The fifth edition of diagnostic and statistical manual of mental disorders (DSM-5)2 was used for diagnosis and the data between October 01, 2020, and January 01, 2021, were used (Ethics Approval: 2021/01-14). SPSS 22.0 program was used for statistical analysis.

Results

Twenty-one patients were included in the study. Overall, mean age was 40.90±10.98 years (median 42.00 years; minimum 22.00 years; maximum 61.00 years), age of disorder onset was 18.47±3.64 years (median 18.00 years; minimum 14.00 years; maximum 29.00 years), duration of PP1M use was 12.38±14.68 months (median 5.00 months; minimum 3.00 months; maximum 63.00 months), duration of PP3M use was 4.66±1.85 months (median 4.00 months; minimum 3.00 months; maximum 8.00 months). There were 8 (38.09%) female and 13 (61.91%) male patients. The mean age in females is 37.12±12.33 years; mean age in males was 43.23±9.84 years (p=0.257). Age of disorder onset in females was 17.75±3.80 years, duration of paliperidone palmitate 3-month formulation (PP1M) use was 8.87±11.03 months, and duration of PP3M use was 4.12±1.64 months. Age of disorder onset in males was 18.92±3.61 years, duration of PP1M use was 14.53±16.59 months, and duration of PP3M use was 5.00±1.95 months. There was no significant difference between genders in terms of age of disorder onset (p=0.242), duration of PP1M use (p=0.659), duration of PP3M use (p=0.366).

In 20 (95.23%) patients, the diagnosis was schizophrenia, while in one male patient (4.77%), it was schizoaffective disorder. There was no difference between genders in terms of additional medical disease (p=0.154), additional medical drug use (p=0.154), constipation-hemorrhoid history (p=0.920), urinary incontinence history (p=0.091), batting history (p=0.322), diabetes mellitus (p=0.142), hypertension (p=0.854), tinea history (p=0.081), gastrointestinal problems (p=0.284), antidepressant use history (p=0.604), first generation antpsychotic use history (p=0.965), second generation antpsychotic use history (p=0.091), the reason for switching to PP1M (p=0.146), PP1M starting dose (p=0.421), PP1M maintenance dose (p=0.525), PP3M dose (p=0.697), risperidone use history (p=0.091), and clozapine use history (p=0.716). Suture history (p=0.011), hospitalization history (p=0.020), smoking history (p<0.001), and non-PP1M depot antipsychotic use history (p=0.023) were significantly higher in males. Mental retardation (p=0.001) was significantly higher in females (Table 1). There were no patients with alcohol and substance use. Since a female patient with schizophrenia did not want to use PP3M and wanted to use PP1M, she returned to PP1M after a single application. During the use of PP3M, none of the patients required psychiatric hospitalization.

Table 1. Examining Patients in Terms of Some Clinical Variables

		Female n (%)	Male n (%)	p
Diagnosis	Schizophrenia	8 (40.0)	12 (60.0)	0.421
	Schizoaffective Disorder	0 (0.0)	1 (100.0)	
Constipation/ Hemorrhoids	Yes	2 (40.0)	3 (60.0)	0.920
	No	6 (37.5)	10 (42.5)	
Urinary Incontinence	Yes	3 (75.0)	1 (25.0)	0.091
	No	5 (29.41)	12 (70.59)	
Battering	Yes	2 (25.0)	6 (75.0)	0.322
	No	6 (46.15)	7 (53.85)	
Suturing	Yes	0 (0.0)	7 (100.0)	0.011*
	No	8 (57.14)	6 (42.86)	
DM	Yes	0 (0.0)	3 (100.0)	0.142
	No	8 (44.44)	10 (55.56)	
HT	Yes	1 (33.33)	2 (66.67)	0.854
	No	7 (38.88)	11 (61.12)	
Tinea History	Yes	0 (0.0)	4 (100.0)	0.081
	No	8 (47.05)	9 (52.95)	
Hospitalization History	Yes	2 (16.66)	10 (83.34)	0.020*
	No	6 (66.66)	3 (33.34)	
Mental Retardation	Yes	5 (100.0)	0 (0.0)	0.001*
	No	3 (18.75)	13 (81.25)	
Non-PP1M Depot AP Use History	Yes	8 (53.33)	7 (46.67)	0.023*
	No	0 (0.0)	6 (100.0)	
Reason to Switch to PP1M	Ineffectiveness	2 (100.0)	0 (0.0)	0.146
	Non-adherence	2 (25.0)	6 (75.0)	
	Advantage	4 (36.36)	7 (63.64)	
PP1M Starting Dose	100 mg	0 (0.0)	1 (100.0)	0.421
	150 mg	8 (40.0)	12 (60.0)	
PP1M Maintanence Dose	100 mg	6 (42.85)	8 (57.15)	0.525
	150 mg	2 (28.57)	5 (71.43)	
PP3M Dose	350 mg	5 (41.66)	7 (58.34)	0.697
	525 mg	3 (33.33)	6 (66.67)	
Risperidone Use History	Yes	5 (29.41)	12 (70.59)	0.091
	No	3 (75.0)	1 (25.0)	
Smoking	Yes	1 (7.6)	12 (92.4)	<0.001*
	No	7 (87.5)	1 (12.5)	
Clozapine Use History	Yes	1 (50.0)	1 (50.0)	0.716
		7 (36.84)	12 (63.16)	

*p<0.05; Chi-square test was used, Abbreviations: DM=Diabetes Mellitus; HT=Hypertension; AP=Antipsychotic; PP1M = Paliperidone Palmitate Once-Month Formulation; PP3M=Paliperidon Palmitate 3-Month Formulation

Discussion

In this study, patients who had used the long-acting formulation of the active ingredient paliperidone palmitate for approximately seventeen months were examined. Adherence to treatment was determined by the change in hospitalization number. Twelve of the twenty-one patients had a history of hospitalization. Consistent with the literature, our findings

indicated that patients using PP3M after PP1M were clinically stable and there was no need for hospitalization.3 Decreasing the number of hospitalization significantly reduces health expenditures. Jukic et al.4 demonstrated that PP3M, compared with depots of olanzapine and risperidone and oral olanzapine, depot formulation of paliperidone palmitate was the cost-effective atypical LAI for treating chronic schizophrenia in Croatia. According to the results obtained by Debaveye et al.5 with DALY (Disability Adjusted Life Years) and Quality Adjusted Life Years (QALY), PP3M reduces the environmental burden. Although it is not yet available in our country, the palmitate 6-month formulation (PP6M) formulation has been used for some time in various countries. Najarian et al.6 reported that the efficacy of PP6M was noninferior to that of PP3M in preventing relapse in patients with schizophrenia adequately treated with PP1M or PP3M.

In conclusion, PP3M is an effective long-acting antipsychotic that can be used in the treatment of schizophrenia in terms of reducing hospitalization. The relatively small number of patients, the cross-sectional nature of the study, and the lack of support for data with psychometric scales are various limitations of this study. Further studies with fewer limitations are needed.

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KAYNAKÇA

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