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Evaluation of Axis I and Axis II Disorders Accompanied by Panic Disorder

Panik Bozukluğa Eşlik Eden Eksen I ve Eksen II Bozuklukların Değerlendirilmesi

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Abstract

Objective: Panic disorder (PD) is a disorder that progresses with relapses and reduces the quality of life. The frequent comorbidity of PD with other psychiatric diseases affects the course and treatment of the disease. In our study, it was aimed to evaluate the axis I and axis II disorders accompanying PD.

Method: The study was conducted in a university hospital psychiatry clinic with patients diagnosed with PD according to the diagnostic criteria of the diagnostic and statistical manual of mental disorders, revised 3rd edition (DSM-III-R) between February 1996 and June 1997. After psychiatric evaluation of 60 patients, socio-demographic and clinical information form, structured clinical interview for DSM-III-R (SCID-I), structured clinical interview for DSM-III-R personality disorders (SCID-II), Hamilton anxiety rating scale and Hamilton depression rating scale were applied. The chi-square (χ^2) and Mann-Whitney U tests were used to evaluate the data. Study groups were formed as pure PD (group 1), PD with comorbid axis I disorder (group 2), and PD with comorbid axis II disorder (group 3).

Results: In the study, 56.6% axis I and 43.3% axis II comorbidities were observed. Major depression, hypochondriasis, generalized anxiety disorder, social phobia, and obsessive-compulsive disorder were the most common Axis I comorbidities, respectively. Avoidant, dependent, obsessive-compulsive and histrionic personality disorders were the most common Axis II comorbidities, respectively.

Conclusion: A high rate of axis I and axis II disorders accompanying PD adversely affects treatment and prognosis. Considering this situation in the treatment and follow-up of patients with PD and adding psychotherapies that also consider personality disorders to pharmacotherapy may increase the success rate in treatment.

Keywords: Panic disorder, personality disorders, psychiatric diagnosis

Öz

Amaç: Panik bozukluğu (PB), tekrarlamalarla ilerleyen ve yaşam kalitesini düşüren bir bozukluktur. PB'nin diğer psikiyatrik hastalıklarla sık birlikteliği hastalığın seyrini ve tedavisini etkilemektedir. Çalışmamızda PB'ye eşlik eden eksen I ve eksen II bozuklukların değerlendirilmesi amaçlanmıştır.

Yöntem: Araştırma, bir üniversite hastanesi psikiyatri kliniğinde, diagnostic and statistical manual of mental disorders, revize 3. baskı (DSM-III-R) tanı kriterlerine göre PD tanısı almış hastalarla Şubat 1996 ile Haziran 1997 tarihleri arasında yürütülmüştür. Altmış hastanın psikiyatrik değerlendirmesinden sonra sosyo-demografik ve klinik bilgi formu, DSM-III-R için yapılandırılmış klinik görüşme (SCID-I), DSM-III-R kişilik bozuklukları için yapılandırılmış klinik görüşme (SCID-II), Hamilton anksiyete derecelendirme ölçeği ve Hamilton depresyon derecelendirme ölçeği uygulandı. Verilerin değerlendirilmesinde ki-kare (χ^2) ve Mann-Whitney U testleri kullanıldı. Çalışma grupları sadece PB (grup 1), eksen I bozukluğu olan PB (grup 2) ve eksen II bozukluğu olan PB (grup 3) olarak oluşturuldu.

Bulgular: Çalışmada %56,6 eksen I ve %43,3 eksen II komorbiditesi izlendi. Majör depresyon, hipokondriyazis, yaygın anksiyete bozukluğu, sosyal fobi ve obsesif-kompülsif bozukluk sırasıyla en sık görülen eksen I eştanılarıydı. Kaçınmacı, bağımlı, obsesif-kompülsif ve histrionik kişilik bozuklukları sırasıyla en sık görülen eksen II eştanılarıydı.

Sonuç: PB'ye eşlik eden eksen I ve eksen II bozukluklarının yüksek oranda olması tedavi ve prognozu olumsuz etkiler. PB hastalarının tedavi ve takibinde bu durumun göz önünde bulundurulması ve farmakoterapiye kişilik bozukluklarını da dikkate alan psikoterapilerin eklenmesi tedavideki başarı oranını artırabilir.

Anahtar kelimeler: Kişilik bozuklukları, panik bozukluk, psikiyatrik tanı

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Introduction

Panic disorder (PD) is an anxiety disorder characterized by recurrent, unpredicted panic attacks (1). Epidemiological studies have reported that the lifetime prevalence of the disorder is 3.4-4.1% (2,3), and the annual prevalence is 1-2% (4). The disorder is more common among women when compared to men (5). The age of onset exhibits a bimodal distribution, where the first peak is observed in the late adolescence and a second peak is observed in the mid-thirties (6).

A panic attack is a unique period where the individual feels intense and sudden anxiety, fear or horror, often accompanied by the ideation of heart attack, suffocation, losing one's mind, or imminent end of life. During these attacks, symptoms such as shortness of breath, palpitation, chest pain, feeling of discomfort in the chest, shortness of breath, sweating, trembling, dizziness, depersonalization, and derealization could be observed (1). The main characteristic of PD is persistent anxiety about having another panic attack for at least one month after the panic attack (anticipatory anxiety), concerns about the possible consequences of the panic attacks, or a significant behavioral change associated with the attacks (avoidance behavior) (1). Although PD has been identified for several years, the associated terminology and diagnostic criteria have significantly changed especially in the last century (2,7). PD was first classified as anxiety neurosis in the diagnostic and statistical manual of mental disorders, second edition (DSM-II) (8) and the International Classification of Disease-9 (9). In DSM-III, PD was discussed as a new disorder in the category of anxiety disorders based on clinical attributes such as with or without agoraphobia (10). PD was categorized in the DSM-IV as two disorders: PD without agoraphobia and PD with agoraphobia (11). In most studies, depression, hypochondriasis and obsessive-compulsive symptoms were found to be the most common comorbidities in patients with PD (12). Agoraphobia was no longer categorized within the PDs in the DSM-5 and considered a separate diagnosis (1). Clinical classifications have attributed a central role to PD and it was considered a distinct disorder. This was due to the observations of comorbidity of other psychiatric diseases. The interest in PD has increased since it was prevalent among individuals of a particular age group who are actively employed, and relapses in prognosis, reduced quality of life and frequent referrals to non-psychiatry outpatient clinics were observed. In recent years, studies on PD have shifted from diagnosis and etiology where the incidence of PD with comorbid anxiety disorders, mood disorders and personality disorders were investigated (12,13). Axis I and axis II comorbid disorders may affect the diagnosis of the PD, the severity of the symptoms, prognosis, and response to treatment (14).

The present study aimed to investigate the comorbid axis I and axis II disorders in PD patients diagnosed based on the diagnostic and statistical manual of mental disorders, revised 3rd edition, (DSM-III-R) diagnostic criteria.

Materials and Methods

The present study was conducted at the faculty of medicine hospital between February 1996 and June 1997 after the approval of the hospital directory was obtained. Informed consent form was read to the patients and all participants signed the form. The study was conducted based on the DSM-III-R criteria, the latest DSM diagnostic classification system at the time of the study (15). The study was conducted with successive outpatients or inpatients who were diagnosed with PD at the emergency department based on in-hospital consultations and psychiatric evaluation by the psychiatry clinic, met the study criteria and volunteered to participate in the study.

Patient Groups

The study group included 60 patients with PD and sub-groups with the following diagnoses:

- Pure PD (1st group)
- PD with comorbid axis I disorder (2nd group)
- PD with comorbid axis II disorder (3rd group)

Inclusion criteria:

- PB diagnosis based on DSM-III-R (15)
- Over the age of 18 years

Exclusion criteria:

- Presence of a physical pathology that may affect the distribution of psychiatric symptoms.
- Educational and language problem that may prevent a psychiatric interview for diagnosis.
- Drug or substances use during the previous two weeks that may affect the distribution of symptoms.

Two PD patients were not included in the study, since they were under the age of 18 years, an exclusion criterion in the study.

Socio-demographic and clinical information form, DSM-III-R structured clinical interview form (SCID-I), personality evaluation form (SCID-II) (16), Hamilton depression rating scale (HDRS) (17), and Hamilton anxiety rating scale (HARS) (18) were applied to the patients after psychiatric evaluation.

Socio-demographic and Clinical Information Form

The form was developed based on the study aim, clinical knowledge, and literature review. The form aimed to collect patient information such as age, gender, marital status, education level, income level, social security, occupation, place of residence, location in the region, age of onset of panic attacks, disease duration, and frequency of the attacks.

DSM-III-R SCID-I

SCID-I is a structured interview form developed for DSM-III and introduced by Spitzer in 1983 (19). In 1987, it was revised and published for DSM-III-R. SCID-I was translated into Turkish language by Sorias et al. (20), and the reliability of the form was confirmed in Turkish language (21). At the beginning of the interview, the clinician was allowed to determine the patient complaints and anamnesis, similar to a conventional interview. Furthermore, SCID-I is an interview model that allows the interviewer to employ all obtained data, and to confront the case with other data if necessary.

DSM-III-R Personality Evaluation Form (SCID-II)

SCID-II was developed by Spitzer for DSM-III and revised for the DSM-III-R in 1987 and has been used for the diagnosis of second axis personality disorders (16). SCID-II is a structured form for individuals, and patients are evaluated based on their responses to the questions in the form and clinical assessments during the interview (16). SCID-II includes items that probe adolescence symptoms for 12 personality disorders, including 3 cluster A personality disorders (paranoid, schizoid, schizotypal personality disorders), 4 cluster B personality disorders (histrionic, borderline, narcissistic, and antisocial personality disorders) and 5 cluster C personality disorders (avoidant, dependent, passive-aggressive, obsessive-compulsive and self-defeating personality disorders). The form was adopted to Turkish language by Sorias et al. (20), and reliability of the form was studied by Coşkunol et al. (22).

HDRS

The HDRS is the most frequently employed depression scale that aims to measure the severity of depression or to determine the symptoms and completed by the interviewer. It was developed by Hamilton and the scale includes 17 items. The scale sub-dimensions include depressive disposition, loss in work and activities, retardation, agitation, gastrointestinal symptoms, general somatic symptoms, hypochondriasis, insight, weight loss, insomnia and anxiety. A total score between 0 and 13 indicates no depressive syndrome. A score between 14 and 27 indicates mild, 28 and 41 indicates moderate, and 42 and 53 indicates severe depressive syndrome (17). The validity and reliability of the scale was determined by Akdemir et al. (23).

HARS

The HARS was developed by Hamilton in 1959 and employed to measure the severity of anxiety (18). It measures depressive symptoms as well as psychological and somatic anxiety. The presence and severity of the 14 scale items are based on the views of the interviewees at the time of the interviews. The scale is scored based on 14 symptoms including anxious mood, stress, fear, insomnia, concentration and memory difficulties, depressive mood, physical, emotional and cardiovascular symptoms, respiratory symptoms, gastrointestinal, genitourinary and autonomic symptoms, behavior during the interview, and each symptom is scored between 0 and 4 points. A total score between 0 and 5 points indicate no anxiety, 6 and 14 points indicate minor anxiety (mild-moderate), 15 points or higher indicate major anxiety (severe). The validity and reliability of the scale was determined by Yazici et al. (24).

Statistical Analysis

Statistical analysis was conducted with SPSS for Windows version 6.0. In data analysis, listing and percentages were presented, and the chi-square (χ^2) and Mann-Whitney U tests were employed in statistical analyses.

Results

The age of the patients in the study group was between 18 and 47 years. The mean age was 31.25±7.19 years. Of the patients, 42 (70%) were female and 18 (30%) were male. The socio-demographic patient data are presented in Table 1.

Participant Socio-demographics

The first study group included 21 patients (35%) with pure PD, the second group included 34 patients (56.6%) with PD and a comorbid axis I disorder, and the third group included 26 patients with PD and a comorbid axis II disorder (43.3%).

The mean patient age was 36.607±5.42 years in the first, 27.91±6.00 years in the second, and 26.92±6.77 years in the third group. The mean age of the second and third groups was statistically significantly lower than that of the first group (p<0.0001).

The male to female ratio was 2/19 in the first group, 14/20 in the second group, and 6/20, in the third group. Female patients were dominant in all study groups. The male to female ratio was statistically significantly lower for patients with pure PD (group 1) when compared to the other groups (p<0.05).

There were significant differences between the marital status, educational level, occupation, place of residence, location in the region, income level, and social security in the group with a comorbid axis I disorder (group 2), and between illiteracy, housemaker, residency in a village, domestic migration, social security (p<0.05) (Table 1). In the group with comorbid axis II disorder (group 3), there were statistically significant differences based on attendance to a university, a school, and domestic migration (p<0.05) (Table 1).

Comorbid Axis I Disorders

Thirty-four (56.6%) out of the 60 patients in the study group had comorbid axis I disorder along with PD. The patients had at least one and at most 4 comorbid disorders. Axis I comorbidity included a single disorder in six cases (17.6%). There was a statistically significant comorbidity of major depression (p<0.05). Moreover, social phobia was second most comorbid pathology. The comorbid axis I disorders to PD are presented in Table 2.

Agoraphobia was comorbid in 38.3% of the study group. Eighth percent of the patients with agoraphobia were female. The presence of agoraphobia was statistically significant in axis I and II comorbidities (p<0.05). The rate of agoraphobia comorbidity in the groups is presented in Table 3.

Table 1. Participant socio-demographics

		Group 1		Group 2		Group 3		Total		χ^2	p
		N	%	N	%	N	%	N	%	-	-
Marital status	Married	11	52.5	24	70	16	61.5	40	66.6	-	-
	Unmarried	6	28.5	8	23.5	8	30.7	14	23.3	-	-
	Widower	2	9.5	1	2.9	1	3.8	3	5	-	-
	Divorced	2	9.5	1	2.9	1	3.8	3	5	-	-
Education	Illiterate	9	42.8	4*	11.7	3	11.5	14	23.3	*13.09	*0.04
	Primary school	10	47.6	12	35.2	6	23	24	40	-	-
	Middle-high school	2	9.5	10	29.4	9	34.6	14	23.3	-	-
	College	0	0	8	23.5	8*	30.7	8	13.5	*16.10	*0.01
Occupation	Housemaker	17	80.9	8*	23.5	10	38.4	30	50	*27.71	*<0.0001
	Worker-civil servant	0	0	15	44.1	7	26.9	15	25	-	-
	Self-employed	2	9.5	2	5.8	0	0	4	6.6	-	-
	Student	0	0	9	26.4	9*	34.6	9	15	*21.52	*0.0002
	Unemployed	2	9.5	0	0	0	0	2	3.3	-	-
Place of residence	Village	3	14.2	0*	0	1	3.8	4	6.6	*12.28	*0.002
	Town	9	42.8	5	14.7	7	26.9	18	30	-	-
	City	9	42.8	29	85.2	18	69.2	38	63.3	-	-
Nativity	Native	19	90.5	27	79.4	20	76.9	51	85	-	-
	Domestic migrant	0	0	7*	20.5	6**	23	7	11.6	*7.75, **7.57	**0.02
	International migrant	2	9.5	0	0	0	0	2	3.3	-	-
Income level	High	3	14.2	2	5.8	1	3.8	5	8.3	-	-
	Medium	12	57.1	24	70.5	20	76.9	40	66.6	-	-
	Low	6	28.5	8	23.5	5	19.2	15	25	-	-
Social security	No	7	33.3	10	29.4	9	34.6	18	30	-	-
	Yes	14	66.6	24*	70.5	17	65.3	42	70	*0.093	*0.04

*p<0.001, **p<0.01

Comorbid Axis II Disorders

Twenty-six (43.3%) out of 60 patients in the study group had comorbid axis II disorders. Axis II disorder comorbidity included at least one and at most 4 personality disorders. One personality disorder comorbidity was determined in 4 cases (15.3%). The most prevalent comorbidities were avoidant, dependent, obsessive-compulsive and histrionic personality disorders, respectively. Comorbid axis II disorders are presented in Table 4.

Hamilton Anxiety and Depression Scores

The mean HARS score was 7.67±3.60, and the mean HDRS score was 19.68±8.02 in the study group. Based on the anxiety and depression scores, there was a statistically significant difference between the 2nd and 3rd groups (groups with comorbid axis I and II disorders) and the 1st group ($p<0.05$). The anxiety and depression scores were lower in the first group. The distribution of anxiety and depression scores by subgroups is presented in the Table 5.

Discussion

Previous studies reported that PD is prevalent in individuals between 18 and 45 years of age and the mean age is between 30 and 33 years (5). The patient age varied between 18 and 47 years and the mean age was 31.25±7.19 years in the present study, consistent with the literature. The mean age was significantly lower in the groups with comorbid axis I and II disorders in the present study, suggesting that young age increased the comorbidity risk. In previous studies, it was reported that patients with PD were predominantly female (75-80%) (5) and PD was 2.5-3.5 times more common in females when compared to males (25). In the present study, consistent with previous reports, 70% of the PD patients were female and the female to male ratio was 2.3. Female patients were dominant in all subgroups. Barlow reported that the higher prevalence of PD in women was associated with cultural factors (26). This is explained by the fact that it is more culturally acceptable for women to report their fears and exhibit avoidance behavior in several situations, while males, who are expected to be strong and brave, could not easily exhibit avoidance behavior, which is an expression of fear. Furthermore, in addition to the biological differences of females, they are more vulnerable to stress due to the historical and psychosocial gender roles assigned to women in Turkish society. This may explain the prevalence of anxiety disorders such as PD among females. The higher number of females with PD when compared to the males could also be associated with the fact that women seek more help and treatment. Consistent with the previous reports, the patients were married, housewives, and with middle income (27). The high number of patients who were urban residents, natives and with social security in the present study could be explained by the fact that the study was conducted in a university hospital in an urban center.

Table 2. Comorbid axis I disorders in the overall study group

	Pre-PD		Post-PD		Total		χ^2	p
	N	%	N	%	N	%		
Major depression	6	25	18	75	24	40		
Hypochondriasis	4	22.2	14	77.8	18	30		
Generalized anxiety disorder	10*	83.3	2	16.7	12	20	*21.24	0.0003
Social phobia	8	80	2	20	10	16.6		
Obsessive compulsive disorder	6	66.7	3	33.3	9	15		

*p<0.001, PD: Panic disorder

Table 3. The agoraphobia rate in the groups

Agoraphobia	Group 1		Group 2		Group 3		χ^2	p
	N	%	N	%	N	%		
No	15	71.4	14	41.1	8	30.7		
Yes	6	28.5	20*	58.8	18**	69.2	4.76, 7.69	0.02, 0.005

Table 4. The rate of personality disorders in the overall study group

Personality disorder	N	%
Paranoid	5	8.3
Schizoid	1	1.6
Schizotypal	2	3.3
Histrionic	9	15
Borderline	1	1.6
Narcissistic	3	5
Antisocial	1	1.6
Dissocial	15	25
Dependent	12	20
Passive-aggressive	1	1.6
Obsessive	11	18.3

Table 5. The mean group anxiety and depression scores

Mean score	1. group	2. group	3. group
Hamilton anxiety	5.7	9*	9.1**
Hamilton depression	11.4	26.1 ***	23.3***

*p<0.001, **p<0.01, ***p<0.0001

In the study, the mean disease duration was 31.15±13.16 months, consistent with the literature (28). It was observed that the duration of disease in groups with comorbid disorders was statistically significantly longer when compared to the group with pure PD, consistent with the findings of Noyes et al. (28). The frequency of events such as trying to adapt to a new region, school, circle of friends, exposure to a turbulent life that includes changes, separation and migration, life decisions, graduation, and further responsibilities among university students increases the PD risk (26).

Agoraphobia is the most common comorbid disorder in PD patients (29). In the literature, it was reported that 1/3-1/2 of the patients with PD also suffered from agoraphobia and the prevalence of the latter was higher among women (30). The National Comorbidity Study reported that agoraphobia comorbidity in PD was around 50% (30). In the present study, agoraphobia comorbidity in PD was 38.3% and 80% of these patients were female. It is known that a typical interpersonal problem associated with agoraphobia is shyness, and most patients with PD have a history of premorbid shyness and introversion (31). In the present study, a statistically significant correlation was determined between the presence of agoraphobia and a comorbid axis II disorder, consistent with the above-mentioned data.

The comorbidity rate in PD patients is high (14). Fifty-seven percent of these patients have a first axis disorder (32). In the literature, it has been reported that 63% of patients with PD experience at least one major depressive episode and 57% have a history of major depressive episodes (33,34). Various studies reported that the rate of comorbid depression in PD was between 31 and 65% (14,35). In the ECA study, it was determined that depression was 10 times more common in patients with PD when compared to those without PD (13). In the present study, the rate of a comorbid major depressive disorder was 40%, consistent with the literature. Previous studies associated the comorbid depressive disorder in PD with narcissistic conflicts, low self-esteem, cognitive distortions, and disability and intimidation due to the chronic and recurrent nature of the disease (29).

Hypochondriasis is the second most common comorbidity in PD, following depressive disorder, excluding agoraphobia. Cognitive reviews suggested similarities between the development mechanisms in these two disorders (36,37). It has been reported that patients with PD and hypochondria consider natural physiological stimuli as a serious physical illness, exhibit hypersensitivity to somatic symptoms, and tend to exaggerate these sensations (36). In different studies, the rate of hypochondriasis comorbidity in PD was reported as 25-50% (38,39). Consistent with the literature, the rate of hypochondriasis comorbidity in PD was 30% in our study. Starcevic, in a study where PD with and without comorbid hypochondriasis were compared, reported that patients with comorbid hypochondriasis exhibited higher levels of agoraphobia, and more severe depressive and obsessive-compulsive symptoms (40).

The rate of comorbid generalized anxiety disorder in PD was reported between 20 and 40% (41,42). In the present study, the comorbid generalized anxiety disorder in PD (20%) was consistent with these reports.

The rate of comorbid social phobia in PD was reported between 15 and 20% (42,43). The comorbid social phobia in PD increases the risk of the development of major depression (42). Clayton (44) reported that the rate of comorbid social phobia and major depression in PD was 94%. Consistent with the literature, the rate of comorbid social phobia was 16.6% in our study, and the correlation between major depression and social phobia was statistically significant. The rate of comorbid obsessive-compulsive disorder in PD was reported as 10-21% (42,45). In the present study, the rate of comorbid obsessive-compulsive disorder was 15%.

In previous studies, the rate of comorbid personality disorder (comorbid axis II disorder) in patients with PD was reported as 27-58% (46-49). It could be suggested that the differences between the rates reported in previous studies were due to research method differences. In the present study, personality disorder was identified in 43.3% of patients with PD, consistent with the literature.

It was reported that the most prevalent comorbid personality disorders in PD patients were avoidant, dependent, histrionic, obsessive-compulsive and borderline personality disorders (46). In the present study, it was determined that avoidant, dependent, obsessive-compulsive and histrionic personality disorders were the most common comorbid personality disorders in PD patients, consistent with the literature.

In the literature, it has been reported that comorbid axis I disorders in PD lead to more severe and several personality disorders, and axis I comorbidities are more common in patients with PD and comorbid personality disorders when compared to patients without comorbid personality disorders (49). Personality disorders may lead to the development of axis I pathologies as well as affect

the severity and prognosis of existing axis I pathology (50). Consistent with the literature, comorbid axis I and II disorders were diagnosed in 21 patients with PD in our study. This group included 61.7% of the patients with comorbid axis I disorders and 80.7% of the patients with comorbid axis II disorders.

It was reported that the comorbid disorders in PD increased anxiety and depression scores (49). In the present study, the anxiety and depression scores of the patients with comorbid disorders were statistically significantly higher, consistent with the literature.

Study Limitations

The present study has certain limitations. The study was conducted in a university hospital, where most patients were urban residents. This socio-demographic limitation may have affected the study findings. The larger the number of participants, the stronger the study findings.

Conclusion

In the study group, 56.6% of the patients had comorbid axis I disorder with PD. The most common axis I disorder was major depression. 43.3% of the study group had comorbid axis II disorders. The most prevalent comorbid disorders were avoidant, dependent, obsessive-compulsive and histrionic personality disorders, respectively. Mild anxiety and depression were observed in the study group. Anxiety and depression were significantly higher in the patients with comorbid axis I and II disorders when compared to those with pure PD. The high rate of comorbid axis I and axis II disorders in PD adversely affects treatment and prognosis. Considering this fact in the treatment and follow-up of patients with PD, and the inclusion of psychotherapies that also consider personality disorders in pharmacotherapy may improve the success of treatment. Future studies with a larger sample and participants with more homogeneous socio-demographic characteristics may contribute further to the literature.

Ethics

Ethics Committee Approval: Ethics committee approval could not be obtained since the formation of local and national ethics committees has not yet taken place at the time of this thesis-based study, but at that time, the study was carried out in Fırat University hospital and in accordance with the Declaration of Helsinki of the World Medical Association.

Informed Consent: Consent of patients received.

Peer-review: Externally peer-reviewed.

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