RESEARCH ARTICLE

Yale-Brown Obsessive Compulsive Scale modified for neurotic excoriation: Validity and reliability study of Turkish version

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ABSTRACT

Objective: The Yale-Brown Obsessive Compulsive Scale Modified for Neurotic Excoriation (NE-YBOCS) is a valid and reliable scale used to evaluate the severity of skin picking disorder (SPD). This was a validity and reliability study of a Turkish version of the NE-YBOCS.

Method: Eighty patients diagnosed with SPD according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition criteria were included the study. The patients completed a sociodemographic data form, as well as the Beck Depression Inventory, the Beck Anxiety Inventory, the Skin Picking Impact Scale, the Barratt Impulsiveness Scale, the Eysenck Personality Questionnaire Revised-Short Form, and a Turkish version of the NE-YBOCS for analysis of the findings.

Results: Exploratory factor analysis and confirmatory factor analysis determined that a 3-factor structure explained 74.7% of the variance and that the factor loads of 10 items were sufficient and had good fit index values. Criterion validity analysis verified the correlation between the NE-YBOCS and the other scales. The internal consistency of the scale, subdimensions, and item-total correlation coefficients were sufficient.

Conclusion: The results indicated that the Turkish NE-YBOCS can be used as reliable and valid instrument to assess SPD.

Keywords: Rating scale, reliability, skin picking disorder, validity

INTRODUCTION

Skin picking disorder (SPD) was first defined as neurotic excoriation (NE) by Erasmus Wilson in 1875. Historically, NE has also been referred to as compulsive skin picking, acne excorieé, dermatillomania, and psychogenic excoriation. In 1898, the case of a young patient who repeatedly picked at his acne was presented

by a French dermatologist, M.L. Bronq. Early literature on NE reported that it was observed frequently in people with suppressed anger, or a personality described as sensitive, arrogant, nervous, or vindictive (1). It was first included in the text revision of the Diagnostic and Statistical Manual of Mental Disorders (DSM), Fourth Edition in the category of impulse control disorders not otherwise specified (NOS) (2). It was subsequently

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classified with obsessive-compulsive disorder (OCD) and related disorders in the DSM-5 with the establishment of diagnostic criteria (3). The diagnostic criteria are i) repetitive skin picking that results in skin lesions, ii) repeated attempts to stop or decrease skin picking, iii) picking causes clinical distress or impairment in functioning, (iv) picking cannot be explained by the use of a substance or another medical condition, and v) picking cannot be explained by the symptoms of another psychiatric disorder.

Difficulty controlling a compulsion or impulse to pick at the skin as well as an experience of transient relief after the behavior in both SPD and OCD suggest a similarity in these disorders. However, while OCD is driven by intrusive thoughts, this is not necessarily observed in SPD (4). The repetitive behavior is typically motivated by efforts to reduce tension. Some patients have demonstrated an obsession with roughness of the skin and making it feel smooth, and thus, can meet the diagnostic criteria for body dysmorphic disorder (BDD). Skin picking usually begins in response to itching or other skin sensations, such as burning, dryness, stinging, warmth, tingling, or pain, or in response to increasing stress throughout the day, as in impulse control disorder (5-7). Therefore, Arnold et al. (4) suggested that NE is a heterogeneous disorder and should be divided into subtypes of impulsive, compulsive, and mixed.

Although SPD can occur at any age, the onset is usually observed during adolescence (7). The disorder becomes chronic, with a severity that can vary based on factors such as comorbidities (8,9), impulsivity (10,11), coping with stress (11), emotion regulation skills (12), and the premenstrual phase (13). Psychological comorbidities are common in SPD, particularly depression, anxiety disorders, and body-focused repetitive behaviors (1), as well as OCD and borderline and avoidant personality disorders (7,14).

Several scales may be used to determine the severity of the disorder and response to treatment. These include the Yale-Brown Obsessive Compulsive Scale Modified for Neurotic Excoriation (NE-YBOCS) (15) and the Skin-Picking Treatment Scale (SPTS) (16) as clinician-administered assessments, as well as self-report instruments, such as the Skin-Picking Symptom Assessment Scale (SP-SAS) (17); the Skin-Picking Scale (SPS) (18); the Skin-Picking Impact Scale (SPIS), used to determine the effect on psychosocial functioning (19); and the Milwaukee Inventory for the Dimensions of Adult Skin Picking (MIDAS) (20), used to determine subtypes of the disorder. The NE-YBOCS was first

adapted by Arnold et al. (15) from the original YBOCS (21) to include an examination of treatment response and has been used in several treatment trials to evaluate the severity of disorder and the response to treatment (17,22-25). Although studies have reported that the NE-YBOCS has good validity and reliability, factor analysis has not yet been performed. At the time of writing, to our knowledge, there are no scales in Turkish to measure the severity of SPD. This research was designed to perform a validity and reliability study of a Turkish version of the NE-YBOCS scale.

METHOD

Sample

A total of 80 patients who presented consecutively at the University of Health Sciences, Şişli Hamidiye Etfal Training and Research Hospital Psychodermatology Outpatient Clinic and were diagnosed with SPD according to the DSM-5 diagnostic criteria were enrolled. The exclusion criteria were a diagnosis of mental retardation or psychotic disorder, current diagnosis or history of dementia, or illiteracy. Of the group, 22 had comorbid onychophagia, 17 had OCD, 9 had trichotillomania, 4 had BDD, and 3 of the patients had hoarding disorder.

The participants were advised of the purpose and design of the study, and informed consent was provided by all of those enrolled. The study was approved by the University of Health Sciences, Sisli Hamidiye Etfal Training and Research Hospital Ethics Committee (No: 1490, Date: 04.04.2017).

Means of Data Collection

All of the participants completed a sociodemographic data form, the Beck Depression Inventory (BDI), the Beck Anxiety Inventory (BAI), the SPIS, the Barratt Impulsiveness Scale (BIS-11), the Eysenck Personality Questionnaire Revised-Short Form (EPQR-SF), and a Turkish version of the NE-YBOCS.

Sociodemographic Data Form: A data form was designed for the study to record details of patient age, gender, educational status, employment status, family history of psychiatric disorders, age of onset of SPD, duration of disorder, sites of picking, time spent skin picking per day, and the frequency of skin picking.

Yale-Brown Obsessive Compulsive Scale Modified for Neurotic Excoriation: The NE-YBOCS is a modification developed by Arnold et al. (15) to measure the severity of NE. It is a semi-structured, clinician-administered scale that evaluates the severity of the disorder over the previous week using 10 items. Each

item is scored 0-4, yielding a total score of 0-40. The first 5 items of the original YBOCS, which assess obsession, are also used in the NE-YBOCS to evaluate the time devoted to urges/thoughts of skin picking, the effect of these urges/thoughts on functioning, the resulting distress, and resistance to/control of these urges/thoughts. The second half of the instrument examines picking behavior (time spent picking, interference and distress due to the behavior, ability to control the behavior). Though no validity and reliability studies of the NE-YBOCS have been conducted, treatment trials frequently use it to evaluate the treatment response and have reported that it has good psychometric properties (17,23-25). Bloch et al. (23) reported a good correlation between the NE-YBOCS and the Clinical Global Impression (CGI) scale (r=0.65), the SPTS (r=0.74), and the Massachusetts General Hospital Skin Picking Scale (MGH-SPS) (r=0.41). Also, Grant et al. (17) determined good test-retest reliability (r=0.83) and good structural validity for the NE-YBOCS. A randomized, double-blind treatment trial conducted by Grant et al. (24) demonstrated good test-retest reliability (r=0.747), a strong correlation with CGI during follow-up from week 1 to week 7 (r=0.698-0.851), and good scale validity for the NE-YBOCS. Treatment trials have also studied both dimensions of the NE-YBOCS (impulse/thought and behavior) and a decrease of ≥35% from pre-treatment values has been used to indicate a clinically meaningful response (22,24).

Skin Picking Impact Scale: The SPIS was developed by Keuthen et al. (19) to evaluate the psychosocial outcomes of repetitive skin picking. A 5-point Likert-type scale is used to score the severity of 10 statements as experienced over the preceding week. The total score ranges 0-50; a higher score indicates greater severity. Scores ≥ the cut-off point of 7 distinguish patients with self-destructive skin picking from those with milder skin picking. The SPIS has a high internal consistency value (Cronbach's alpha=0.93) and good structural validity. A validity and reliability study of a Turkish version was conducted by Kenar et al. (26)

Beck Depression Inventory: The BDI is a 21-item, self-report scale used to determine the presence and severity of depressive symptoms. Each item is rated on a 4-point Likert-type scale of 0-3 to describe the respondent's experience in the previous 2 weeks, and a higher score indicates greater severity. A reliability and validity study for a Turkish adaptation was performed by Hisli (27).

Beck Anxiety Inventory: The BAI is a 21-item, self-report scale designed to differentiate between anxiety

and depression with items related to common anxiety symptoms, such as feelings of anger, fear, and fear of death. Responses are scored using a 4-point Likert scale of 0 (not at all) to 3 (severely). A higher score reflects greater anxiety. A reliability and validity study for a Turkish version of the instrument was performed by Ulusoy et al. (28).

Barratt Impulsiveness Scale: The BIS is a 30-item self-assessment scale developed to measure 3 subfactors of impulsiveness: attentional impulsiveness, motor impulsiveness, and non-planning impulsiveness. Attentional impulsiveness reflects the inability to concentrate, motor impulsiveness relates acting suddenly without thinking, and non-planning impulsiveness describes a lack of forethought. Higher scores indicate a greater level of impulsiveness. A validity and reliability study of a Turkish version of the BIS was performed by Gulec et al. (29).

Eysenck Personality Questionnaire Revised-Short Form: The EPQR-SF is a 24-item questionnaire used to evaluate 3 primary factors of the personality: extraversion, neuroticism, psychoticism, and also includes a lie scale. Each factor is evaluated using 6 items answered Yes (1) or No (0). A validity and reliability study of a Turkish adaptation was performed by Karanci et al. (30).

Procedure

Permission to adapt the NE-YBOCS scale was obtained from the original authors via e-mail. The scale was translated into Turkish and the draft modified version was reviewed by 2 psychiatrists who have conducted research on this topic. The scale was modified and finalized according to their recommendations.

Statistical Analysis

IBM SPSS Statistics for Windows, Version 20.0 software (IBM Corp., Armonk, NY, USA) was used to perform the statistical analysis. Descriptive statistics were expressed as mean, SD, minimum, and maximum for numerical variables, and as number and percentage for categorical variables. Cronbach's alpha coefficient and item-total correlation were examined for consistency with the reliability of the SPIS. A Cronbach's alpha value of ≥0.70 indicates the good internal consistency of the scale. Exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) were used to examine the factor structure of the scale. The Kaiser-Meyer-Olkin (KMO) test was performed to evaluate the suitability of the sample size and the data set for factor analysis and Bartlett's test of sphericity was used to test

the null hypothesis that the variables in the population correlation matrix were uncorrelated. A KMO value of >0.60 indicates adequate sampling, and the Bartlett's test chi-squared value should be statistically significant. The factor loading was expected to explain at least 40% of the total variance of the scale (31). In addition, parallel analysis was performed (32). The number of random correlation matrices was set at 100. In this analysis, the eigenvalues of the sample correlation matrix are compared with the eigenvalues obtained from a random correlation matrix for which no factors are assumed, and the number of factors to retain will be the number of eigenvalues generated from the dataset that are larger than the corresponding random eigenvalues. Model fit was evaluated using the IBM SPSS AMOS Version 22.0 program (IBM Corp., Armonk, NY, USA). The goodness-of-fit of the model tested using CFA was evaluated with several fit indices: chi-square divided by the degrees of freedom (χ^2/df), the root mean squared error of approximation (RMSEA), comparative fit index

Table 1: Sociodemographic data of the study patients with skin picking disorder

	SPD (n=80)		
	Mean±SD	Min-Max	
Age (years)	32.7±14.9	16-66	
	n	%	
Gender			
Male	22	27.5	
Female	58	72.5	
Marital status			
Married	32	40	
Single	40	50	
Divorced	5	6.3	
Widowed	3	3.8	
Education status			
Literate	7	8.8	
Primary school	15	18.8	
Middle school	10	12.5	
High school	22	27.5	
University	26	32.5	
Employment status			
Employed	33	41.3	
Unemployed	11	13.8	
Retired	3	3.8	
Housewife	14	17.5	
Student	19	23.8	

SPD: Skin picking disorder

(CFI), the Tucker–Lewis index (non-normed fit index) (TLI [NNFI]), normed fit index (NFI), and the standardized root mean square residual (SRMR) (33). The validity of the scale was examined using Pearson's correlation analysis when there was normal distribution, and Spearman's correlation analysis was used in instances of non-normal distribution. The statistical alpha significance level was p<0.05.

RESULTS

Sociodemographic and Clinical Characteristics of the Patients

The sociodemographic data of the study participants are provided in Table 1. The mean number of sites of skin picking was 2.6±1.3. The mean age of onset was 21.4±15.1 years, and the duration of the disorder was 108.0±130.8 months. The mean picking frequency per day was 4-6 times in 27.5% (n=22), 7-10 times in 23.8% (n=19), >20 times in 20% (n=16), 1-3 times in 17.5% (n=14), and 11-20 times in 11.3% (n=9) of the patients. The time spent skin picking per day was 1-3 hours in 32.5% (n=26), 31-60 minutes in 32.5% (n=26), 16-30 minutes in 25% (n=20), 6-15 minutes in 7.5% (n=6), and >4 hours in 2.6% (n=2). The NE-YBOCS, SPIS, BDI, BAI, EPQR-S, and BIS-11 clinical scores of the patients are provided in Table 2.

Table 2: Clinical scale scores of the study patients

	SPD (n=80)		_
	Mean	SD	Min-Max
NE-YBOCS-Urge	7.9	4.4	0-15
NE-YBOCS-Behavior	5.4	2.1	1-10
NE-YBOCS-Control	6.4	1.7	2-8
NE-YBOCS-Total	19.7	6.2	6-31
SPIS	15.6	12.9	0-48
BAI	17.5	14.1	0-57
BDI	15.7	10.7	0-46
BIS-11-Attentional	30.7	6.5	18-48
BIS-11-Motor	12.5	3	8-22
BIS-11-Non-planning	21	4.6	12-31
BIS-11-Total	64.3	11.8	41-101
EPQR-S-Neuroticism	4.1	1.6	1-6
EPQR-S-Extraversion	3.5	2.1	0-6
EPQR-S-Psychoticism	1.5	1.2	0-5
EPQR-S-Lie	4	1.7	0-6

BAI: Beck Anxiety Inventory, BDI: Beck Depression Inventory, BIS-11: Barratt Impulsiveness Scale, EPQR-SF: Eysenck Personality Questionnaire Revised-Short Form, NE-YBOCS: Yale-Brown Obsessive Compulsive Scale Modified for Neurotic Excoriation, SPD: Skin picking disorder, SPIS: Skin Picking Impact Scale

Table 3: Three-factor solution according to exploratory factor analysis based on criterion of an eigenvalue greater than one and parallel analysis based on random data

Factors	Random data mean eigenvalues	Real eigenvalues	% Variance explained
1	1.594	3.295	39.652
2	1.404	2.196	21.964
3	1.258	1.313	13.135
4	1.134	0.635	6.345
5	1.022	0.488	4.876

	r¹	Cα	r²
		<u> </u>	<u>r</u> -
Factor 1			
Item 1. Time spent on urges/thoughts	0.76	0.947	0.614
Item 2. The effect of these urges/thoughts on functioning	0.66	0.95	0.575
Item 3. Distress related to urges/thoughts	0.766	0.945	0.642
Item 4. Resisting urges/thoughts	0.791	0.944	0.885
Item 5. Ability to control urges/thoughts	0.887	0.94	0.906
Factor 2			
Item 6. Time spent on behavior	0.851	0.943	0.756
Item 7. The effect of this behavior on functioning	0.827	0.944	0.763
Item 8. Distress related to behavior	0.875	0.94	0.79
Factor 3			
Item 9. Resisting behavior	0.828	0.943	0.903
Item 10. Ability to control behavior	0.861	0.943	0.873

C_α: Cronbach alfa (if item deleted), r¹: Adjusted item-total score correlation, r²: Factor loading

Validity Results

Exploratory Factor Analysis: The analysis of the KMO and Bartlett's tests used to evaluate the data fit for factor analysis resulted in a KMO value of 0.762, and χ^2 =407.307, p<0.001 in the Bartlett's test, indicating suitability. Principal component analysis was performed using all 10 items of the scale. EFA resulted in a factor 1 eigenvalue of 3.965 (items 1, 2, 3, 4 and 5), a factor 2 eigenvalue of 2.196 (items 6, 7 and 8), and a factor 3 eigenvalue of 1.313 (items 9 and 10). This 3-factor structure explained 74.7% of the variance and was supported by the parallel analysis. The first 3 eigenvalues of real data from this study were greater than those derived from the random data. Thus, the 3-factor solution was accepted (Table 3).

The analysis demonstrated an acceptable factor loading of 0.58-0.88 for each item (Table 4).

Confirmatory Factor Analysis: The 3-factor structure determined with EFA was tested using CFA. The primary analysis revealed the following values: χ^2/df =3.331, CFI=0.806, GFI= 0.800, RMSEA=0.172, and

NFI=0.752. Due to the poor model fit, modifications were considered. The recommendations suggested that errors in items 4 and 5 were associated with each other. Secondary analysis resulted in the following values: $\chi^2/df=1.519$, CFI=0.958, RMSEA=0.081, TLI=0.940, SRMR=0.08, and NFI=0.890. The analysis was repeated because the NFI value was not at an acceptable level. Errors in items 1 and 3 were associated with each other according to the modification indices. A third analysis resulted in the following values: $\chi^2/df=1.509$, CFI=0.960, GFI=0.910, RMSEA=0.080, TLI=0.940, SRMR=0.08, and NFI=0.900, which represented an acceptable level (Figure 1). The loading values of the 3-factor structure were 0.872-0.999.

Validity of Scale: Correlations between the NE-YBOCS score and the frequency of skin picking per day, the duration of skin picking per day, the number of sites picked, and the SPIS, BDI, BAI, BIS-11, and EPQR-S scores were examined to determine the validity of the scale. There was a good correlation between the NE-YBOCS and the number of sites

Table 5: Correlation between subscale scores and total NE-YBOCS score

	1	2	3	4
(1)NE-YBOCS-Urge		0.509*	0.105	0.887*
(2) NE-YBOCS-Behavior			0.294*	0.766*
(3)NE-YBOCS-Control				0.427*
(4) NE-YBOCS-Total				

*p<0.001. NE-YBOCS: Yale-Brown Obsessive Compulsive Scale Modified for Neurotic Excoriation

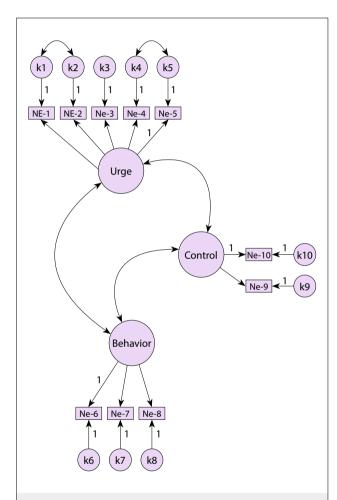


Figure 1. Confirmatory factor analysis model for the Yale-Brown Obsessive Compulsive Scale Modified for Neurotic Excoriation.

(r=0.485, p<0.001), the duration per day (r=0.620, p<0.001), the frequency of skin picking per day (r=0.239, p=0.039), and the SPIS score (r=0.509, p<0.001).

No significant correlations were detected between the NE-YBOCS total score and the BDI score (r=0.044, p=0.701); the BAI score (r=-0.006, p=0.958); the neuroticism (r=-0.074, p=0.513), psychoticism (r=0.166, p=0.141), or extraversion (r=-0.045, p=0.690) subscale

scores of the EPQR-SF; the attentional impulsiveness (r=0.056, p=0.619), motor impulsiveness (r=-0.110, p=0.333), or non-planning impulsiveness (r=0.073, p=0.522) subscales of the BIS-11, or the BIS-11 total score (r=0.023, p=0.841).

Reliability Results

The Cronbach's alpha internal consistency coefficient of the NE-YBOCS was 0.949. The Cronbach's alpha coefficients were 0.809 for factor 1, 0.831 for factor 2, and 0.910 for factor 3. The item-total correlation coefficient of all of the questions was 0.660-0.887 (Table 4). Correlations between the subscale scores and the total score are shown in Table 5. The analysis indicated that the scale was highly reliable.

DISCUSSION

This study was a validity and reliability analysis of a Turkish version of the NE-YBOCS, which was developed by Arnold et al. (15), and reported to have good psychometric properties by Grant et al. (17). Psychometric measures of a Turkish version of the 10-item scale suggested that it is a valid and reliable instrument.

The factor structure of the scale was first examined using EFA. The KMO and Bartlett's test values obtained indicated that the study data were sufficient for factor analysis. Our research yielded a 3-factor structure with an eigenvalue of >1 that explained 74.7% of the variance. The items 1, 2, 3, 4, and 5 correspond to factor 1, items 6, 7 and 8 reflect factor 2, and items 9 and 10 represent factor 3. A good model fit was observed for 2 subscales to measure the severity of obsession in the first 5 items and the severity of compulsion in the final 5 items, similar to the original (34) and Turkish versions (35) of the YBOCS scale to examine OCD symptoms. Treatment trials have studied the 2 dimensions of urge/ thought and behavior of the NE-YBOCS (24,25). However, the factor structure of the NE-YBOCS scale has not yet been studied. Based on the contents of the scale items, the first, second, and third subscales are considered to evaluate the severity of the thought/urge for skin picking, the severity of behavior, and control of picking behavior, respectively. Factor loading values of ≥0.60 and 0.30-0.59 can be considered to provide highand intermediate-magnitude, respectively, and these values are taken into account in variable extraction (31). Based on these data, it appears that the 3-factor structure adequately explained the variance and the item loadings determined in our study were sufficient.

We used CFA to test the 3-factor structure. When acceptable CFI, GFI, RMSEA, and NFI fit index values were not seen in the primary CFA analysis, modifications were made. A third analysis resulted in an acceptable model fit (χ^2 /df=1.509, CFI=0.960, TLI=0.940, RMSEA=0.080, NFI=0.900, TLI=0.940, and SRMR=0.08). The goodness-of-fit of the model tested in CFA was evaluated using several fit indices: χ^2 /df, RMSEA, CFI, NFI, NNFI (TLI), and SRMR. The values of χ^2 /df=0-3, 0.0 \leq RMSEA \leq 0.05, 0.95 \leq CFI \leq 1, 0.95 \leq NNFI \leq 1, 0.0 \leq SRMR \leq 0.05 indicate perfect fit, and the values of χ^2 /df=3-5, 0.05 \leq RMSEA \leq 0.1, 0.90 \leq CFI \leq 0.95, 0.90 \leq NFI \leq 0.95, 0.90 \leq NFI \leq 0.95, and 0.05 \leq SRMR \leq 0.08 indicate acceptable fit (33).

Our results demonstrated acceptable reliability for a 3-factor scale. The internal and overall consistency of the scale was considered to be sufficient in terms of reliability since the Cronbach's alpha level was >0.70 and the item-total correlations and subscale-total correlations were >0.30 (36).

Our investigation of the validity of the scale revealed that the Turkish NE-YBOCS demonstrated significant correlation with SPIS scores, and the items related to the number of sites of picking, the duration of skin picking per day, and the frequency of skin picking per day on the sociodemographic data form. Correlation coefficients of 0.10-0.29, 0.30-0.49, and 0.50-1.00 indicate low, intermediate, and high validity, respectively (37). Consistent with other studies, we also observed significant correlations between the NE-YBOCS and scales used to assess the severity of SPD, such as the CGI, MGH-SPS, and SPTS (23,24).

Our study has some limitations. First, our sample group was limited to patients applied to the outpatient clinic. Therefore, illness severity and comorbidity rates were high in the majority of patients. Thus, the psychometric properties presented for the scale may not be generalized. The validity and reliability study of the scale is needed to be repeated in a population-based sample. Second, our sample size was limited as the patients with SPD rarely applied to outpatient clinics, and thus, the results should be interpreted with caution.

In conclusion, the NE-YBOCS is a clinician-administered scale that can be used to determine the initial severity of SPD and in patient follow-up. Our study revealed that a 10-item scale consisting of 3 subscales is a valid and reliable tool for use in Turkish population. Future studies can establish the cut-off point of the scale for determination of treatment response.

Contribution Categories		Author Initials
	Concept/Design	E.P.A., J.G.K.
Category 1	Data acquisition	E.P.A., J.G.K., I.K.A.
Data analysis/Interpretation		E.P.A.
C-t	Drafting manuscript	E.P.A.
Category 2	Critical revision of manuscript	O.A.O., K.O.K.
Category 3	Final approval and accountability	E.P.A., J.G.K., O.A.O., I.K.A., K.O.K.
Technical or material support		E.P.A., J.G.K.
Other	Supervision	O.A.O., I.K.A., K.O.K.

Ethics Committee Approval: Study was approved by the Ethics Committee of University of Health Sciences, Sisli Hamidiye Etfal Training and Research Hospital (No: 1490).

Informed Consent: Participants were instructed on the purpose and design of the study, and the informed consents were obtained.

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