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Reliability and Validity Study of a Turkish Version of the Sialorrhea Clinical Scale for Parkinson's Disease (SCS-TR)

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ABSTRACT

Introduction: To evaluate the validity and reliability of the Turkish version of the Sialorrhea Clinical Scale for Parkinson's disease (SCS-PD) for use in clinical settings.

Methods: The original English version of SCS-PD has been adapted to Turkish (SCS-TR) in accordance with international guidelines. Forty-one patients with Parkinson's Disease (PD) and 31 healthy people were included in our study. SCS-TR, Movement Disorders Society United Parkinson's Disease Rating Scale (MDS-UPDRS) Part II (functional subscale 2.2 Saliva and drooling), Drooling Frequency and Severity Scale (DFSS) and The Non-Motor Symptoms Questionnaire (NMSQ) (1st question evaluating saliva) were applied to both groups. The adapted scale was re-tested in PD patients 2 weeks later.

Results: A statistically significant relationship was determined between the SCS-TR scale score and all similar scale scores (NMSQ, MDS-UPDRS, DFSS) ($p<0.001$). The correlation between SCS-TR and similar scales scores was high, linear and positive (84.8% for MDS-UPDRS, 72.3% for DFSS and 70.1% for NMSQ). The Cronbach's alpha coefficient for the evaluation of the reliability of the sialorrhea clinical scale questionnaire was found to be 0.881 which indicates a very good internal consistency. Spearman's correlation test evaluating the relationship between the scores of the preliminary test and re-test of SCS-TR showed a high level, linear and positive relationship.

Conclusion: SCS-TR is consistent with the original version of SCS-PD. As its validity and reliability in Turkey have been shown by our study, it can be used for the evaluation of sialorrhea in Turkish PD patients.

Keywords: Drooling, Parkinson's disease, saliva, sialorrhea

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INTRODUCTION

Patients with Parkinson's disease (PD) may experience sialorrhea (drooling) which may result from oropharyngeal dysphagia due to bradykinesia, severe hypomimia and anteflexion posture (1,2). Sialorrhea not only negatively affects both the PD patient's quality of life and social interaction, but also increases the risk of aspiration and infection. (3–8).

Various methods are available for the assessment of saliva production rate and volume including salivary duct cannulation, saliva collection, open suction, a Lashley disc; or placing cotton rolls in the mouth. However, none of these tools address salivation in all its aspects. For instance, these methods do not evaluate the psychosocial impact of sialorrhea. Furthermore, these methods vary in their complexity and are not designed to measure problems with sialorrhea (9–11).

In clinical practice, some examples of the widely-used scales questioning the presence of saliva accumulation and salivation in PD include Movement Disorders Society Unified Parkinson's Disease Rating Scale (MDS-UPDRS), Non-Motor Symptoms Questionnaire (NMSQ), and Drooling Frequency and Severity Scale (DFSS) (12–15). Similar to the abovementioned relatively objective measurement methods, these scales are also not sufficient in terms of evaluating sialorrhea from different dimensions such as affecting speech, eating and social life. Thus, patient-reported scales measuring the sialorrhea's impact on functioning and social interaction appear as a great need. In some countries, scales developed for this purpose such as Radboud Oral Motor Inventory for Parkinson's Disease (ROMP) and Sialorrhea Clinical Scale for Parkinson's Disease (SCS-PD), one of the scales recommended by International Parkinson and Movement Disorders Society, are available as assessment tools for sialorrhea in PD (2,14,16). However, currently, we are unaware of a valid and reliable patient-reported specific scale used to evaluate drooling in PD patients in Turkey. Therefore, we aimed to conduct this study to establish the Turkish validity and reliability of the SCS-PD scale in patients with PD.

Highlights

- **Sialorrhea affects quality of life in PD; increases the risk of aspiration and infection.**
- **The Sialorrhea Clinical Scale (SCS-PD) is recommended to evaluate sialorrhea in PD.**
- **The Turkish validity and reliability of the SCS-PD was established as SCS-TR.**
- **SCS-TR is the first Turkish scale assessing sialorrhea with different aspects in PD.**

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METHODS

Formal authorization for the SCS-PD translations into Turkish was obtained from the original authors (16). The study was conducted in accordance with the Declaration of Helsinki, and it was reviewed and approved by University of Health Sciences, Institutional Review Board (01.10.2021, 21/571). Individuals participating in the study were informed about the aims and procedures of the study in advance, and their written consent was obtained.

The study consists of two phases. The first phase is cross-cultural adaptation of the original English version of SCS-PD in accordance with international guidelines (17). The second phase is testing the validity and reliability of the adapted scale. The first phase of this procedure includes four steps: 1) The original SCS-PD was translated from English to Turkish independently by three native Turkish speakers with good knowledge of English. 2) After discussing inconsistencies, a single consensus version was obtained from three independent translations. 3) The consensus version was back-translated into English by a sworn translator with excellent knowledge of English and Turkish who had never seen the original questionnaire. 4) An expert committee in PD including one Speech and Language Therapist, two neurologists, one physiotherapist, one Audiology and Speech Disorders Specialist, and a professional translator, compared the Turkish translated versions with the originals and finalized the scale (SCS-TR). 5) A pre-test was conducted on the nine PD patients to determine whether there were any words or expressions that were not understood.

Participants population

Forty-one patients with PD who met the diagnostic criteria of the UK Parkinson's Disease Society Brain Bank, and 31 healthy individuals were included in our study (18). The study was carried out at the outpatient neurology clinics at University of Health Sciences, Şişli Hamidiye Etfal Training and Research Hospital..

Inclusion criteria for both groups were as follows: being over 18 years old, being able to cooperate well, having the ability to understand the information sheet, being able to give consent, not having any other medical conditions, not having any psychiatric, neurological, or behavioral pathology other than PD that may prevent the proposed study.

Exclusion criteria were illiteracy, having a native language other than Turkish, and having very serious motor problems that may prevent them from participating in the study. 58/59 was used as MDS-UPDRS part III (motor part) cut-off score to specify 'having very serious motor problems' according to PD severity levels defined by MDS-UPDRS cutoff scores, as previously published by Martinez-Martin et al. (19).

Tools

Sialorrhea Clinical Scale for Parkinson's Disease (as the studied tool), MDS-UPDRS Part II (functional subscale 2.2 saliva and drooling), DFSS and NMSQ (1st question evaluating saliva), and Mini Mental Status Examination (MMSE) were applied to both groups (12,13,15,16,20).

Sialorrhea Clinical Scale for Parkinson's Disease (SCS-PD): It is a seven-item patient-reported clinical scale evaluating the subjective perception of the problems related to sialorrhea. The scale assesses following aspects; (A) diurnal sialorrhea, (B) nocturnal sialorrhea, (C) drooling severity, (D) speech impairment, (E) eating impairment, (F) frequency of drooling and (G) social discomfort (16).

Movement Disorders Society Unified Parkinson's Disease Rating Scale (MDS-UPDRS): This scale consists of four parts: Part I and part II are patient self-administered scales evaluating motor and non-motor aspects of experiences of daily living, respectively. Part III includes motor examination, and motor complications are assessed in part IV. In this study, MDS-UPDRS 2.2 item, which includes the question about saliva and drooling from Part II, was applied to the participants (12,21).

Non-motor Symptoms Questionnaire (NMSQ): It is a 30-item questionnaire with 'yes' and 'no' answers for each item that questions the patient's experiences of the symptoms in the last month. In this study, participants were asked the questionnaire's first question which assesses salivation during daytime (13).

Drooling Frequency and Severity Scale (DFSS): It is a scale evaluating the severity and frequency of saliva by observation or information obtained from family members/caregiver. The severity section is evaluated with a score between 1–5 and the frequency section with a score between 1–4 with higher scores correlating to worse drooling status (15).

Mini Mental Status Examination (MMSE): It is a 30-point questionnaire that is used to assess cognitive status. Any score of 24 or more shows a normal cognition (20).

Protocol

Patients with PD (previously diagnosed by a neurologist) and healthy individuals were assessed by an Audiology and Speech Disorders Specialist to gather demographics and clinical data. Clinical and cognitive status evaluation was performed by a movement disorders expert using the MDS-UPDRS and MMSE. All participants filled out NMSQ, MDS-UPDRS 2.2 item, DFSS in addition to the adapted SCS-PD scale, namely SCS-TR. Family members/caregivers were also invited to assist the patients, but it was emphasized that the scale should mainly include patients' feelings and thoughts. SCS-TR was re-tested in nine PD patients 2 weeks later.

Statistical Methods

For categorical data, n (%) was given as mean, standard deviation, minimum and maximum descriptive value for continuous data. For comparisons between groups, the "Mann Whitney U-Test" was used for the two groups. The relationship between the scale scores was evaluated with the "Spearman's Correlation Test." "Cronbach's Alpha Test" was used for the reliability of the scale.

All analyses were conducted using IBM Statistical Package for the Social Sciences (SPSS) for Windows 23.0 program and p-values less than 0.05 were considered statistically significant.

RESULTS

Demographic Data

Seventy-two individuals (41 PD patients, 31 healthy controls) were included in the study. 54.2% (n=39) of the individuals were male and 45.8% were (n=33) female. The mean age of the participants was 58±14 (min: 23, max: 86) years, the average Hoehn-Yahr score of PD patients was 2.3±0.9 (min: 1, max: 5) and the mean disease duration was 6.3±5.1 (min: 1, max: 25) years.

Table 1. Correlatio n between SCS-TR and similar scales

Spearman's Rank Test		NMSQ	MDS-UPDRS	DFSS
SCS-TR	Correlation Coefficient	0.701	0.848	0.723
	p-value	<0.001*	<0.001*	<0.001*

DFSS: Drooling Frequency and Severity Scale; MDS-UPDRS: Movement Disorders Society Unified Parkinson's Disease Rating Scale; NMSQ: Non-Motor Symptoms Questionnaire; SCS-TR: Turkish version of Sialorrhea Clinical Scale for Parkinson's disease.

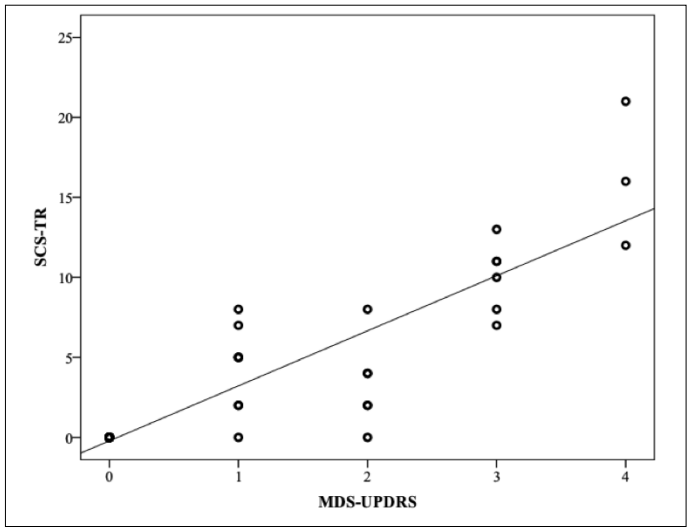

Figure 1. Correlation between MDS-UPDRS and SCS-TR scores.

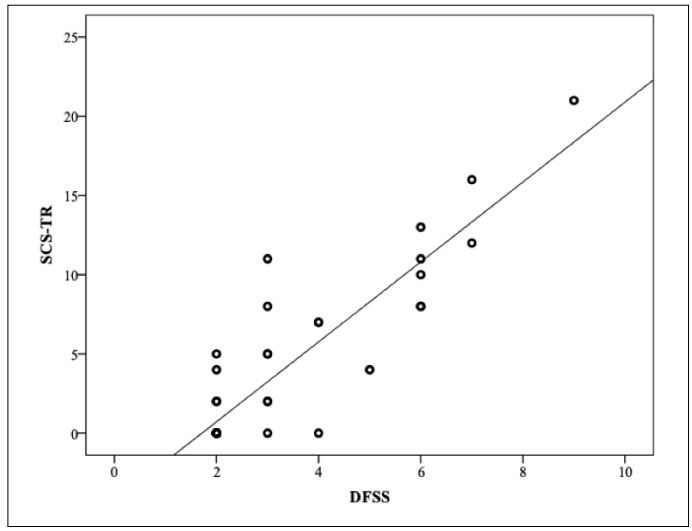

Figure 2. Correlation between DFSS and SCS-TR scores.

Validity and Reliability

As a result of the Spearman's correlation test, a statistically significant relationship was determined between the SCS-TR scale score and all similar scale scores (NMSQ, MDS-UPDRS, DFSS) (p<0.001). The correlation between SCS-TR and similar scales scores was high, linear, and positive (84.8% for MDS-UPDRS, 72.3% for DFSS and 70.1% for NMSQ) (Table 1, Figure 1 and 2).

The Cronbach's alpha coefficient for the evaluation of the reliability of the sialorrhea clinical scale questionnaire was found to be 0.881 which indicates a very good internal consistency.

The correlation between the scores of the preliminary test and re-test of SCS-TR is given in Table 2 (Spearman's correlation test). Each item of the preliminary test and re-test of SCS-TR was evaluated one by one to see

Table 2. The correlation between preliminary test and re-test scores of SCS-TR for each item

Spearman's Rank Test		**Re-test scores**						
Preliminary test scores		**SCS-A**	**SCS-B**	**SCS-C**	**SCS-D**	**SCS-E**	**SCS-F**	**SCS-G**
SCS-A	Correlation Coefficient	0.750						
	p-value	0.020*						
SCS-B	Correlation Coefficient		0.750					
	p-value		0.020*					
SCS-C	Correlation Coefficient			0.992				
	p-value			<0.001*				
SCS-D	Correlation Coefficient				1.000			
	p-value				NA			
SCS-E	Correlation Coefficient					1.000		
	p-value					NA		
SCS-F	Correlation Coefficient						0.750	
	p-value						0.020*	
SCS-G	Correlation Coefficient							1.000
	p-value							NA

NA: Not available; SCS-A, B, C, D, E, F: G, Sialorrhea Clinical Scale for Parkinson's disease items; SCS-TR: Turkish version of Sialorrhea Clinical Scale for Parkinson's disease.

Table 3. The comparison of PD patients and healthy controls in terms of SCS-TR, MDS-UPDRS, DFSS and NMSQ scores

Scales	**Group**	**N**	**Mean**	**Standard deviation**	**Median**	**Min.**	**Max.**	**p-value**
NMSQ	PD	41	0.39	0.49	0.00	0.00	1.00	<0.001*
	Controls	31	0.00	0.00	0.00	0.00	0.00	
MDS-UPDRS	PD	41	1.22	1.35	1.00	0.00	4.00	0.010*
	Controls	31	0.45	0.77	0.00	0.00	2.00	
DFSS	PD	41	3.29	1.86	2.00	2.00	9.00	0.003*
	Controls	31	2.19	0.48	2.00	2.00	4.00	
SCS-TR	PD	41	3.98	5.28	2.00	0.00	21.00	0.003*
	Controls	31	0.65	1.27	0.00	0.00	4.00	

DFSS: Drooling Frequency and Severity Scale; MDS-UPDRS: Movement Disorders Society Unified Parkinson's Disease Rating Scale; NMSQ: Non-Motor Symptoms Questionnaire; SCS-TR: Turkish version of Sialorrhea Clinical Scale for Parkinson's disease.

Table 4. Item-by-item sub-analysis of SCS-TR scale in PD patients and healthy individuals

Scales	Group	N	Mean	Standard deviation	Median	Min.	Max.	p-value
SCS-A	PD	41	0.90	1.10	0.00	0.00	3.00	0.036*
	Controls	31	0.30	0.70	0.00	0.00	2.00	
SCS-B	PD	41	0.90	1.10	0.00	0.00	3.00	0.002*
	Controls	31	0.20	0.60	0.00	0.00	2.00	
SCS-C	PD	41	1.00	1.30	0.00	0.00	3.00	0.001*
	Controls	31	0.00	0.20	0.00	0.00	1.00	
SCS-D	PD	41	0.20	0.60	0.00	0.00	3.00	0.045*
	Controls	31	0.00	0.00	0.00	0.00	0.00	
SCS-E	PD	41	0.10	0.50	0.00	0.00	3.00	0.076
	Controls	31	0.00	0.00	0.00	0.00	0.00	
SCS-F	PD	41	0.50	0.80	0.00	0.00	3.00	0.005*
	Controls	31	0.10	0.20	0.00	0.00	1.00	
SCS-G	PD	41	0.40	0.80	0.00	0.00	3.00	0.006*
	Controls	31	0.00	0.00	0.00	0.00	0.00	

PD: Parkinson disease; SCS-A, B, C, D, E, F, G: Sialorrhea Clinical Scale for Parkinson's disease items; SCS-TR: Turkish version of Sialorrhea Clinical Scale for Parkinson's disease.

Table 5. The distribution of the patients' answers to SCS-TR

	Score			
	0	1	2	3
SCS-A	25 (61.0%)	0 (0.0%)	12 (29.3%)	4 (9.8%)
SCS-B	22 (53.7%)	2 (4.9%)	15 (36.6%)	2 (4.9%)
SCS-C	26 (63.4%)	2 (4.9%)	2 (4.9%)	11 (26.8%)
SCS-D	36 (87.8%)	3 (7.3%)	1 (2.4%)	1 (2.4%)
SCS-E	37 (90.2%)	3 (7.3%)	0 (0.0%)	1 (2.4%)
SCS-F	27 (65.9%)	9 (22.0%)	4 (9.8%)	1 (2.4%)
SCS-G	32 (78.0%)	3 (7.3%)	5 (12.2%)	1 (2.4%)

SCS-A, B, C, D, E, F, G: Sialorrhea Clinical Scale for Parkinson's disease items; SCS-TR: Turkish version of Sialorrhea Clinical Scale for Parkinson's disease.

the relationship between the repeated scale questions and each other. As a result of the evaluation, it was determined that there was a high level, linear and positive relationship between all questions. In other words, it was observed that the results of the re-test were compatible with the results of the preliminary test of SCS-TR.

There was a statistically significant difference between PD patients and healthy controls in terms of SCS-TR, MDS-UPDRS, DFSS and NMSQ scores. (Table 3) ($p<0.05$, Mann Whitney-U test). PD patients had higher SCS-TR scores than healthy controls (3.98 vs 0.65). ($p=0.003$). Item by item sub-analysis of the SCS-TR scale was also performed, and a statistically significant difference was found between PD patients and healthy individuals in terms of A, B, C, D, F, G items (Table 4).

The distribution of the patients' answers to the seven items of SCS-TR is given in Table 5.

DISCUSSION

Patients with PD may experience a wide variety of motor and non-motor symptoms that negatively affects the quality of life and disability (22,23). Among these symptoms, sialorrhea is one of the most disabling. Careful detection of sialorrhea is critical in terms of considering the treatment approaches to improve the PD patient's quality of life. Although several assessment methods for the evaluation of the severity and negative impact on quality of life of sialorrhea are available, PD-specific sialorrhea screening scales which can be easily applied in neurology outpatient clinics is needed. One of the scales used to meet this need is SCS-PD, which was developed by Perez Lloret et al. (16). In this study, the SCS-PD was translated into Turkish as SCS-TR and its Turkish validity and reliability were investigated.

In order to ensure the validity of SCS-TR, we preferred MDS-UPDRS, DFSS and NMSQ as similar scales for comparison purposes. We chose these scales not only because they have Turkish versions, but also because they are widely-used scales in clinical practice. The correlation between scores of SCS-TR and similar scales was high, linear and positive (84.8% for MDS-UPDRS, 72.3% for DFSS and 70.1% for NMSQ). It is not surprising that the relationship was highest in the MDS-UPDRS scale, since this scale, like SCS-TR, includes rating responses from 0 to 4. MDS-UPDRS was also used as a similar scale in a cross-cultural adaptation and validation study of SCS-PD by Cardoso et al. (24). In this Portuguese study, good convergent validity between SCS-PD and the MDS-UPDRS item 2.2 saliva and drooling was found. The relatively lower correlation of the SCS-TR with NMSQ and DFSS in our study is probably due to the fact that the NMSQ is a scale with yes/no responses and the DFSS is not a specific scale for PD.

We did not opt to use the saliva volume assessment method by placing dental cotton rolls in the mouth, which was used as a benchmark in the original validation study by Perez Lloret et al., since it is suggested that this method may not be a reliable method for the evaluation of sialorrhea in PD patients by the authors (16). Perez Lloret et al. found that the SCS-PD score was significantly higher in PD patients, but saliva measurements could not accurately identify PD patients with sialorrhea complaints. It should be noted that sialorrhea in PD may result from several factors including impaired swallowing mechanisms, hypomimia, or anteflexion posture rather than increased saliva production. (4–6,25,26).

We found significant differences between PD patients and healthy individuals in all scales evaluating sialorrhea, from largest to the smallest, in NMSQ, DFSS, MDS-UPDRS and SCS-TR, respectively. In addition to the higher incidence and severity of sialorrhea in PD patients; the impact of sialorrhea on speech and social discomfort was remarkable. The fact that the highest difference was observed in the NMSQ may be due to the fact that unlike the other scales, we evaluated sialorrhea with only one question in this scale, and this question is answered only as yes or no. Although the highest difference was found in this scale; this scale does not assess the severity and frequency of sialorrhea. On the other hand, the relatively small difference found in SCS-TR may be due to the fact that this scale evaluates sialorrhea from different perspectives with more items.

In our study, a significant difference was found between PD patients and the controls in terms of all items except the item related to the impact of

sialorrhea on the eating ability of SCS-TR. This may be related to the fact that the PD patients included in the study were mostly at an early stage and did not yet have sialorrhea at a level that would interfere with eating. Therefore, by applying the scale to PD patients in moderate-to-advanced stages, deterioration in eating ability may also be better determined.

In PD patients, impairment in the domains of eating and speech abilities was found to be lower than the other affected domains in SCS-TR (9.8%, 12.2% respectively). Similarly, in the original study, the rate of eating disorders caused by sialorrhea was lower than the impairment in other domains of SCS-PD (26%) (16). These results confirm that eating ability is the domain least affected by sialorrhea. Indeed, it is not surprising that drooling has a greater impact on patients' speech and interactions in social life. Impaired motor skills, especially in upper limbs and dysphagia seem to play a greater role in the eating ability of PD patients than sialorrhea.

In our study, most of the patients answered the questions in SCS-TR predominantly as 'no' or 'never'. This was also observed in the original study (16). This may be related to the tendency of patients to ignore, deny, neglect, or not wanting to disclose their salivary problems as they may feel embarrassed. Our finding of detecting sialorrhea on the basis of 'items' of SCS-TR supports this, although PD patients did not report sialorrhea as a complaint during routine visits. In addition, PD patients may have overlooked sialorrhea, as all patients were assessed at the 'on' period when they felt better about motor and nonmotor symptoms of PD.

An important aspect that caught our attention while conducting this study was that some PD patients occasionally asked for help from their family members/caregivers while filling out the scale. Therefore, support from family members/caregivers can be obtained when applying such patient-reported scales in PD patients, but they should be informed that the scale should mainly include the patients' feelings and thoughts.

Clearly, our study has several weaknesses. First, all patients were recruited from a specialty clinic at a tertiary referral hospital. Second, a cut-off value for the SCS-TR could not be established, although this was not the main objective in this study. Hence, studies using more stringent methodology in a larger cohort are needed to establish a cut-off value. Third, the majority of our cohort consisted of early stage PD patients. We suggest that for the use of SCS-TR in clinical trials, patients with advanced PD, who are expected to have greater frequency and severity of sialorrhea, should be included to obtain more powerful results. Nonetheless, despite these limitations, our cohort represents a good spectrum of typical PD cases with sialorrhea.

Conclusion

Given that drooling can only be seen with the naked eye clinically in very severe PD cases, evaluation of the impact of sialorrhea on the patients' disability is mainly based on patients' or caregivers' subjective responses to the questions. Therefore, patient-reported sialorrhea scales gain importance in clinical practice.

Our study showed that the validity and reliability of the SCS-TR was ensured for the assessment of sialorrhea in Parkinson's patients in Turkey. The SCS-TR scale is the first patient-reported scale with Turkish validity and reliability that evaluates sialorrhea with different dimensions in PD patients.

Clearly, the use of SCS-TR in combination with other PD scales, including quality of life scales, will better reveal the effects of sialorrhea in PD patients, especially in terms of the impactof sialorrhea on social occasions. A logical approach seems to be to firstevaluate the presence of saliva with the commonly used MDS-UPDRS, followed by SCS-TR for more detailed assessment.

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Ethics Committee Approval: The study was conducted in accordance with the Declaration of Helsinki, and it was reviewed and approved by University of Health Sciences Institutional Review Board (01.10.2021, 21/571).

Informed Consent: Individuals participating in the study were informed about the aims and procedures of the study in advance, and their written consent was obtained.

Peer-review: Externally peer-reviewed

Author Contributions: Concept– MSA, GG; Design– GG, MSA; Supervision– GG; Resources– GG; Materials– MSA; Data Collection and/or Processing– MSA, GG; Analysis and/or Interpretation– GG, MSA; Literature Search– MSA; Writing Manuscript– GG, MSA; Critical Review– GG.

Conflicts of Interest: The authors declared that there is no conflict of interest.

Financial Disclosure: None

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