

Cervical Radiculopathy Impact Scale: Translation, cross-cultural adaptation, reliability and validity of the Turkish version

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ABSTRACT

Objectives: The aim of this study was to translate and cross-culturally adapt the English version of the Cervical Radiculopathy Impact Scale (CRIS) and to investigate the validity and reliability of the Turkish version of the CRIS.

Patients and methods: Between October 2021 and February 2022, a total of 105 patients (48 males, 57 females; mean age: 45.4±11.8 years; range, 36.5 to 55.5 years) who were diagnosed with cervical radiculopathy due to disc herniation were included. Disability and quality of life were evaluated with the Neck Disability Index (NDI), Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH), and Short Form-12 (SF-12). Pain severity was evaluated using the Numerical Rating Scale (NRS) in three subscales (neck pain, pain radiating to the arm, and numbness in the finger, hand, or arm). The internal consistency for CRIS was assessed using the Cronbach alpha and test-retest reliability by intraclass correlation coefficients (ICCs). Explanatory factor analyses were performed for construct validity. To examine the content validity, the correlations among the three subgroup scores of CRIS and the other scale scores were analyzed.

Results: The internal consistency of CRIS was found to be high ($\alpha=0.937$). A high reliability was obtained for test-retest reliability for the three subscales of CRIS (Symptoms, Energy and postures, Actions and activities) (ICC: 0.950, 0.941, 0.962, respectively; $p<0.001$). All three subscale scores of CRIS were correlated with the NDI, QuickDASH, SF-12 (physical and mental) and NRS scores ($r=0.358-0.713$, $p<0.001$). Factor analysis showed that the scale had five factors.

Conclusion: The CRIS is a valid and reliable instrument for Turkish patients with cervical radiculopathy due to disc herniation.

Keywords: Cervical radiculopathy, disability evaluation, herniated disc, pain measurement, questionnaire.

Cervical radiculopathy (CR) describes radiating pain in one or both upper extremities caused by compression or inflammation of a spinal nerve root by a cervical herniated disc or by degenerative osteophytes.¹ Neck pain is often present with pain radiating to the extremities. It can be accompanied by motor and/or sensory deficits.^{2,3} The incidence is reported to be up to 100 per 100,000 individuals, with a peak at fourth and fifth decades of life.⁴ The most frequently affected nerve roots are C6 and C7.^{4,5} Diagnosis

is usually made by medical history and physical examination combined with imaging modalities.⁶ The management of CR includes conservative, interventional, and surgical treatments, although the results of comparative studies still remain controversy.^{7,8}

There is a growing interest in cervical disc herniation (CDH) treatment in the literature, and a number of studies have been published, particularly during the recent years.⁹⁻¹¹ Nevertheless, most

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studies are limited due to the fact that a patient-reported comprehensive outcome scoring system approved for CR is not available. Functional and comprehensive outcome measures for CR are essential to depict the effectiveness of different treatment techniques and to choose the most convenient one. The Cervical Radiculopathy Impact Scale (CRIS) was recently developed by Gartner et al.³ which comprises 21 questions divided over three subscales. It is intended to cover the measurement of symptoms and limitations of the arm and neck due to CR and has shown good validity and reliability. However, to date, the Turkish version of the CRIS has not been validated, which impedes a thorough assessment of Turkish patients with CR. In the present study, we, therefore, aimed to translate and cross-culturally adapt the English version of the CRIS and validate the reliability of the Turkish version of the CRIS in patients with CR due to disc herniation.

PATIENTS AND METHODS

This prospective study was conducted at Marmara University Pendik Training and Research Hospital and Gülhane Training and Research Hospital Pain Medicine outpatient clinics between October 2021 and February 2022. A permission was obtained from Anne M. Stiggelbout for the translation of the CRIS into Turkish, adapt it cross-culturally, and investigate the validity and reliability of the Turkish version of CRIS.

A total of 168 patients were screened. Cervical spinal stenosis was detected in 34 patients and these patients were excluded from the analysis. In addition, 12 patients with diabetes, 12 patients with peripheral nerve entrapment, and five patients had cervical spinal surgery were also excluded. The study was carried out with 105 patients (48 males, 57 females; mean age: 45.4±11.8 years; range, 36.5 to 55.5 years) with CDH. The number of participants was calculated as five for each question according to previously published guidelines.¹² Inclusion criteria were as follows: age between 18 and 65 years, having CR due to CDH as confirmed by magnetic resonance imaging, a symptom duration of ≥3 months, at least one of the three criteria (i.e., severity of

neck pain, radiating to the arm, numbness in the finger, hand or arm) based on the Numerical Rating Scale (NRS) ≥4, and patient literacy, on physical examination, presence of sensory deficit and/or motor deficit, or reflex changes in the affected nerve-root distribution. Exclusion criteria were having cervical spinal stenosis, having a neuromuscular and rheumatic diseases, having diabetes mellitus, undergoing cervical spinal surgery, and the presence of upper extremity entrapment neuropathy. The study flowchart is shown in Figure 1.

Demographic data of the patients, age, sex, body mass index (BMI), comorbid diseases, medications used, previous treatments, symptoms duration, and occupational status were collected. All participants were evaluated with the NRS, Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH), Short Form-12 (SF-12), Neck Disability Index (NDI), and CRIS. In addition, the CRIS was re-filled for retest 15 days later.

NRS: The NRS pain scale is used to measure the severity of pain. Scores ranged from 0

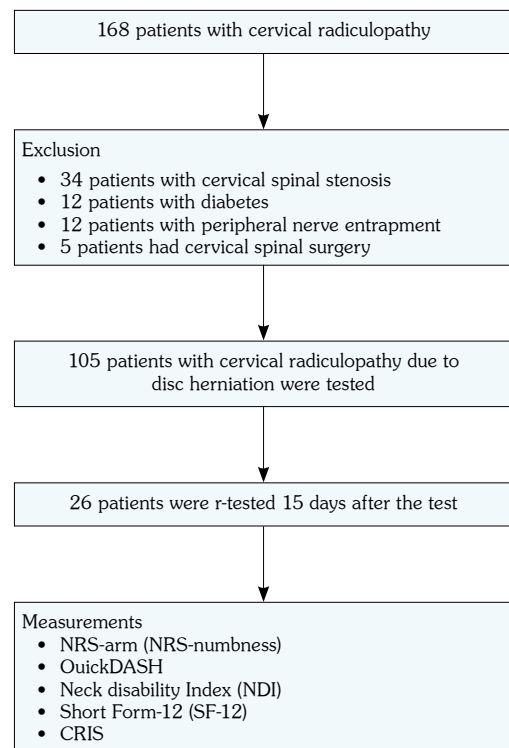


Figure 1. Study flowchart.

NRS: Numerical Rating Scale; DASH: Disabilities of the Arm, Shoulder and Hand; NDI: Neck disability Index; CRIS: Cervical Radiculopathy Impact Scale.

(no pain/numbness) to 10 (worst possible pain/numbness). The patient scores his/her pain between 0 and 10. It is frequently used in clinical studies, as it is an easy-to-understand scale. Three different NRS scores were used in the study: neck pain (NRS-neck), pain radiating to the arm (NRS-arm), and numbness in the finger, hand or arm (NRS-numbness).

QuickDASH: This is an 11-item questionnaire with a five-point response scale for each question that measures patients' perceptions of disability and symptoms associated with any condition that affects the upper extremity. A total score is calculated for participants who complete at least 10 out of 11 items. The total score ranges from 0 (no injury) to 100 (most serious injury).¹³ It has been shown to be valid and reliable in the Turkish population.¹⁴

SF-12: This is a test consisting of seven questions in total, in which the quality of life of the patient is questioned. Two types of scores are calculated in the questionnaire: physical (PCS-12) and mental score (MCS-12). High scores are associated with patient well-being and improved quality of life.¹⁵ It has been shown to be valid and reliable in the Turkish population.¹⁶

NDI: This is a questionnaire that measures disability in patients with neck pain, based on the extent to which disability and pain can participate in the patient's performance and activities of daily living, and it has been validated in Turkish population.¹⁷ The 10-item questionnaire has a six-point response scale ranging from 0 (no disability) to five (total disability), with higher scores indicating a higher degree of disability.

CRIS: This scale focuses on arm and neck symptoms and functionality related to cervical

radicular syndrome. It is a questionnaire that includes the measurement of symptoms and limitations due to neck disability, radiating pain in the arm, numbness and loss of sensation in patients with CR. It is a 21-item questionnaire that consists of three subscales (Symptoms, Energy and postures, and Actions and activities), and it is scored between 0 and 100.³

Translation and cultural adaptation

In the present study, the translation and intercultural adaptation processes were used following previously published guidelines.^{18,19}

Stage 1 (Translation): The questionnaire was translated into Turkish by two translators, who were able to speak Turkish and English fluently, according to the conceptual translation of phrases. One of the translators has no medical/clinical background.

Stage 2 (Synthesis): After the translation, a joint text was prepared with the participation of all translators.

Stage 3 (Back translation): The Turkish version was translated back into English by two native English-speaking translators.

Stage 4 (Clinician's committee): A review group consisting of four pain medicine specialists, two physiatrists, and a health professional was convened. They were asked to comment on points that could be related to cultural differences and cause difficulties in daily life. Finally, a synthesis of the Turkish pre-final version of the index was conducted.

Stage 5 (Face validity, pretest): The pre-final version of the questionnaire was used on 10 patients. The patients were asked to indicate the points they did not understand about the questionnaire questions.

Table 1. Descriptive data of numerical variables

	n	Mean±SD	Median	25 th -75 th percentile
Age (year)	105	45.4±11.7	45	36.5-55.5
Height (cm)	105	167.9±10.4	165	160-177
Weight (kg)	105	76.3±13.2	75	70-83.5
Body mass index	105	27.1±4.3	26.1	24-29.5
Symptom duration (month)	105	20.1±30	12	4.5-24

SD: Standard deviation; n: Sample size.

Stage 6 (Committee evaluation and test): Pretest results were evaluated by the committee. The final version of the questionnaire was prepared based on the opinions of the committee members.

Reliability

The reliability of the scale was evaluated under two headings: internal consistency and test-retest reliability. Internal consistency was evaluated with the Cronbach alpha (α) coefficient, and test-retest reliability was evaluated with the intraclass correlation coefficient (ICC) and 95% confidence interval (CI).

Validity

The validity of the scale was examined under the titles of construct validity and content validity. Explanatory factor analysis was performed for construct validity. To examine the content validity, the correlations among the three subgroup scores of CRIS and the NRS, QuickDASH, SF-12, and NDI scores were analyzed with the Spearman correlation coefficient. The correlation coefficient between 0.91-1.00 was considered perfect, 0.71-0.90 good, 0.51-0.70 moderate, 0.31-0.50 acceptable, and <0.30 weak.²⁰

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 23.0 (IBM Corp., Armonk, NY, USA) and Jamovi version 2.0 software (The Jamovi Project, 2021). Descriptive data were presented in mean \pm standard deviation (SD), median (min-max) or number and frequency, where applicable. The conformity of numerical variables to the normal distribution was examined using the Shapiro-Wilk test, and it was seen that they fit the normal distribution. Relationships between the CRIS subgroup scores and categorical data were analyzed using the one-way analysis of variance (ANOVA), and the relationship between numerical features was analyzed using the Spearman correlation analysis. A p value of <0.05 was considered statistically significant.

RESULTS

The median CR symptom duration was 12 (range, 3 to 240) months. Cervical disc herniation

Table 2. Descriptive data of categorical variables

	n	%
Sex		
Female	57	54.3
Male	48	45.7
Marital status		
Living together	83	79
Single	22	21
Employment status		
Not working	28	26.7
Student	4	3.8
Desk job	21	20
Work that requires physical activity	38	36.2
Retired	14	13.3
Educational status		
Primary school	18	20.9
Secondary school	17	16.2
High school	28	26.7
Vocational school	8	7.6
University	30	28.6
Earlier treatment		
Physical therapy	1	0.09
Pain medication	45	42.8
Interventional pain treatment	5	3.8
None	4	23.8
More than one	50	47.6
Pain medication		
NSAID	61	58.1
Weak opioid	10	9.5
Strong opioid	0	0
Anticonvulsant	5	4.8
Antidepressant	8	7.6
Multiple drug	14	13.3
Not use	7	6.7
Disc herniation level		
C3-4	2	1.9
C4-5	6	5.7
C5-6	32	30.5
C6-7	40	38.1
C7-T1	12	11.4
More than one level	13	12.4
Lateralization		
Right	50	47.6
Left	42	40
Bilateral	13	12.4
Disc herniation type		
Bulging	18	17.1
Protrusion	59	56.2
Extrusion	28	26.7

n: Sample size; NSAID: Non-steroidal anti-inflammatory drug.

Table 3. Scale scores used in the study

	n	Mean±SD	Median	25 th -75 th percentile
NRS-neck	105	7.2±2	8	6-9
NRS-arm	105	6.5±1.9	7	6-8
NRS-numbness	105	5.7±2.3	6	4.5-7
QuickDASH	105	47.9±20.5	47.7	31.8-61.3
SF-12 (PCS-12)	105	35.6±8.3	36.1	30.4-41
SF-12 (MCS-12)	105	42.8±7.1	43.1	38.2-48.3
Neck Disability Index	105	25.4±10.5	26	16-33
CRIS-Symptoms subscale	105	54.6±16.8	53.1	41.6-63.8
CRIS-Energy and postures subscale	105	52±18.1	5	39.5-64.5
CRIS-Actions and activities subscale	105	44.3±22	41.6	29.1-58.3
CRIS-Symptoms subscale (Re-test)	26	52.3±14.6	51.3	38.8-66.6
CRIS-Energy and postures subscale (Re-test)	26	55.3±13.1	54.1	50-66.6
CRIS-Actions and activities subscale (Re-test)	26	47.2±19.4	45.4	33.3-58.3

n: Sample size; SD: Standard deviation; NRS: Numerical Rating Scale; QuickDASH: The Disabilities of the Arm, Shoulder and Hand Score; SF-12: Short Form-12; PCS-12: SF-12 physical score; MCS-12: SF-12 mental score; CRIS: Cervical Radiculopathy Impact Scale.

was detected most frequently at the level of C6-7 (n=40, 38.1%). This was followed by C5-6 (n=32, 30.5%), more than one disc level (n=13, 12.4%) and C7-T1 (n=12, 11.4%) disc herniation, respectively. The numerical demographic and clinical characteristics of the patients are shown in Table 1, and the categorical demographic and clinical characteristics of the patients are shown in Table 2. The mean and median scores of the NDI, QuickDASH, SF-12 subscales, NRS, and CRIS subscales are shown in Table 3.

Reliability

The internal consistency of CRIS was high ($\alpha=0.937$). Twenty-six patients were re-tested.

Test-retest reliability was evaluated for the three subscales of CRIS (Symptoms, Energy and postures, and Actions and activities), and high reliability was obtained (ICC: 0.950, 0.941, 0.962, $p<0.001$) (Table 4).

Content validity

Three subscale scores of the CRIS were correlated with NDI, Quick-DASH, SF-12 (physical and mental), NRS-neck, NRS-arm, and NRS-numbness ($r=0.358-0.713$, $p<0.001$) (Table 5).

Construct validity

Explanatory factor analysis was performed to evaluate internal construct validity. After the

Table 4. Test-retest reliability results (n=26)

CRIS subscales	ICC	95% CI for ICC		p
		Lower	Upper	
Symptoms	0.950	0.890	0.977	<0.001
Energy and postures	0.941	0.873	0.973	<0.001
Actions and activities	0.962	0.916	0.983	<0.001

CI: Confidence interval; ICC: Intraclass correlation coefficients; CRIS: Cervical Radiculopathy Impact Scale.

Table 5. Content validity results

	CRIS-Symptoms		CRIS-Energy and postures		CRIS-Actions and activities	
	r	p	r	p	r	p
NRS-neck	0.561	<0.001	0.589	<0.001	0.358	<0.001
NRS-arm	0.599	<0.001	0.453	<0.001	0.546	<0.001
NRS-numbness	0.625	<0.001	0.584	<0.001	0.578	<0.001
QuickDASH	0.713	<0.001	0.704	<0.001	0.666	<0.001
PCS-12	-0.588	<0.001	-0.551	<0.001	-0.491	<0.001
MCS-12	-0.400	<0.001	-0.469	<0.001	-0.451	<0.001
NDI	0.397	<0.001	0.375	<0.001	0.396	<0.001

CRIS: Cervical Radiculopathy Impact Scale; r: Rho; NRS: Numerical Rating Scale; QuickDASH: The Disabilities of the Arm, Shoulder and Hand Score; PCS-12: Short Form-12 physical score; MCS-12: Short Form-12 mental score; NDI: Neck Disability Index.

Table 6. Rotated component loadings according to explanatory factor analysis

CRIS	Subscales (Factors)				
	1	2	3	4	5
Symptoms subscale Q2	0.584				
Energy and posture subscale Q10	0.618				
Energy and posture subscale Q11	0.526				
Actions and activities subscale Q15	0.694				
Actions and activities subscale Q17	0.813				
Actions and activities subscale Q18	0.724				
Actions and activities subscale Q20	0.749				
Symptoms subscale Q1		0.628			
Symptoms subscale Q6		0.635			
Symptoms subscale Q7		0.679			
Symptoms subscale Q8		0.859			
Symptoms subscale Q9		0.810			
Symptoms subscale Q3			0.740		
Symptoms subscale Q4			0.774		
Symptoms subscale Q5			0.814		
Energy and posture subscale Q14			0.578		
Energy and posture subscale Q12				0.667	
Energy and posture subscale Q13				0.684	
Energy and posture subscale Q21				0.435	
Actions and activities subscale Q16					0.797
Actions and activities subscale Q19					0.680

CRIS: Cervical Radiculopathy Impact Scale; Q: Question.

factor loads were rotated with the Varimax rotation method, five subscales with eigenvalues greater than 1 and explaining 72% of the total variance were obtained. The correlations of each question with the underlying factors are presented in Table 6.

DISCUSSION

In the present study, we investigated the validity and reliability of the CRIS in patients with radiculopathy due to CDH upon translation of the original English version of the scale into

Turkish. The translation procedure was carried out in line with the cross-cultural adaptation guidelines and no difficulties were reported.^{18,19} The results indicated that the CRIS was a valid and reliable instrument that could be used in the future to evaluate the arm and neck symptoms and functionality associated with CR in Turkish populations.

A number of studies have been published in the relevant literature during recent years due to a growing interest in the treatment of CDH.^{9-11,21} The main goal of CR treatment is to reduce radicular pain along with reducing present functional loss. Therefore, studies investigating treatment efficacy should be carried out using comparable, reliable, and verified assessment tools.²² Nevertheless, most studies are limited due to the fact that a patient-reported comprehensive outcome scoring system approved for CR is not available.³ Despite the widespread use in the relevant studies, the NRS and Visual Analog Scale (VAS) are inadequate, as they only assess the severity of pain and do not provide information about disability or functional status. The NDI, which has a Turkish version with proven validity and reliability, only assesses the disability due to neck problems.¹⁷ Similarly, QuickDASH, which also has a Turkish version with proven validity and reliability, only evaluates the disability and symptoms of the upper extremity, and therefore, cannot provide a comprehensive assessment of the CR symptoms.²³ Therefore, CRIS was developed by Gartner et al.³ with an aim to improve the quality of the studies, ensuring a comprehensive assessment of CR symptoms and functional losses caused by CR as a whole. To the best of our knowledge, there is no validity and reliability study in the relevant literature conducted for adapting the CRIS to other languages.

The CRIS development study found the Cronbach α values for the three subscales of the CRIS (symptoms, energy and posture, action, and activities) as 0.927, 0.909, and 0.902, respectively, indicating a high internal consistency.³ Similarly, in the present study, the overall Cronbach α value for the CRIS was 0.937 and, thus, the internal consistency was very high. In the CRIS development study, the ICC scores for the three subscales

were above 0.8, indicating a good test-retest reliability.³ In the present study, the ICC scores for three subscales were 0.950, 0.941, and 0.962 respectively, suggesting a very high reliability. Our results had internal consistency in this respect.

Furthermore, we found that the CRIS subscale scores were acceptable and positively and significantly correlated with the NDI scores. In addition, the symptoms and energy and posture subscales of the CRIS was positively and significantly correlated with QuickDASH, where the action and activities subscale was moderately positively and significantly correlated. In the CRIS development study, all three subscales of CRIS were well, positively, and significantly correlated with the NDI and QuickDASH scores.³ This difference between the correlation of the NDI and CRIS subscale may be due to the difference in patient selection in the respective studies. Only the patients with CR associated with CDH were included in the present study to form a homogeneous patient population. Patients with cervical spinal stenosis and patients who underwent cervical spinal surgery were excluded from the study.

In many studies, the SF-12 was used to measure health-related quality of life (HRQoL) in patients with CR.²⁴⁻²⁶ Unlike the CRIS development study, SF-12 was used instead of SF-36 in the present study to assess the HRQoL, as it was shorter and took less time to complete.^{3,27} The PCS-12 was moderately, negatively, and significantly correlated with the symptoms subscale of CRIS and acceptably, negatively, and significantly correlated with the action and activities subscale of CRIS. The mental health component scale (MCS-12), on the other hand, was acceptably, negatively, and significantly correlated with the three subscales of the CRIS. Bhadra et al.²⁴ reported postoperative improvements in both PCS-12 and MCS-12 in patients with a single-level CR. This result is suggestive of the impaired physical and mental function in patients with CR. The fact that the CRIS is correlated with both physical and mental functionality is important for a comprehensive evaluation of patients with CR who are assessed based on the CRIS.

In the present study, the NRS was preferred over the VAS due to the ease of application

in the assessment of the severity of pain.²⁸ In the CRIS development study, there was a moderately-well, positive, and significant correlation between the three subscales of the CRIS and the VAS scores (neck pain, pain radiating to the arm, and numbness in the finger, hand, or arm), while there was an acceptable-moderate, positive, and significant correlation with NRS scores in the present study. In the current study, the lowest correlation was between the action and activities subscale of the CRIS and NRS neck pain, similar to correlation results for NDI scores. The difference in the number of patients included or the difference in patient inclusion criteria in the respective studies may account for this difference. In addition, although both the VAS and NRS scales are valid, reliable, and suitable for use in clinical practice for the assessment of pain severity, the difference between the two studies, *albeit* minor, may be due to the difference in the way the VAS and NRS were applied.²⁹

While there were three subscales defined in the original scale, five subscales were found during explanatory factor analysis in the present study unlike the original scale.³ As a result of these results, some items were included in the different subscales, where the number of subscales was higher than the original scale. The differences as regards the inclusion criteria in the respective studies may account for the above. In the CRIS development study, patients with a duration of CR symptoms for two months or more were included in the study, where patients with CR during the subacute period were also included in the study. In the present study, patients with CR in the chronic period of three months or more were included. Furthermore, only the patients with CR associated with CDH were included in our study and patients with a history of cervical spinal surgery were excluded. On the contrary, 21% of the patients had a history of surgical operation in the CRIS development study.³ Pursuant to the inclusion criteria of the present study, patients with a score of at least ≥ 4 from three different NRS scores (neck pain, pain radiating to the arm, and numbness in the finger, hand, or arm) were included in the study, where the CRIS development

study required the sum of three different VAS scores to be a minimum of 1. This difference as regards the patient groups might have been associated with a change in CR-related symptoms and functional impairment, thereby resulting in a higher number of subscales as a result of the factor analysis in our study. Therefore, we suggest that the suitability of this weak scale can be increased by further studies, which would separately investigate the acute, subacute, and chronic periods in patients with CR due to a specific diagnostic etiology and standardize the cut off values based on the severity levels for pain and/or numbness.

Nonetheless, this study has certain limitations. First, only the patients with chronic CR were included in this study. The patients with CR in acute and subacute periods were excluded from the study. Second, the reaction of the CRIS scores to post-treatment change were unable to be assessed. Nevertheless, the main strength of the study lies in the fact that it was carried out in two centers and with a homogeneous patient group with a specific diagnosis.

In conclusion, the Turkish version of the CRIS is a valid and reliable instrument that can be used in the future to assess the arm and neck symptoms and functionality in CR associated with disc herniation in the Turkish population. Unlike the other scales that contain general items for the assessment of CR, the CRIS is specific to and objective for CR.

Ethics Committee Approval: The study protocol was approved by the Marmara University Faculty of Medicine Ethics Committee (date: 08.10.2021, no: 1107). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

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

Author Contributions: Contributed to the study conception and design: A.E.Ç., S.Ş.; Material preparation, data collection, and analysis were performed: A.E.Ç., R.S., E.C.Ö.; The manuscript was written: A.E.Ç., S.Ş., R.S., E.C.Ö.; The supervisor: O.H.G.; All authors read and approved the final manuscript.

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