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Cross-cultural adaptation and psychometric validation of the Turkish version of Paper and Pencil Test in patients with multiple sclerosis

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Abstract

Background & Objective: Multiple Sclerosis (MS) is a chronic neurological disease that impairs patients' cognitive abilities and motor functions, making it difficult to maintain independent living. This condition leads to significant challenges in complex self-care tasks such as clean intermittent catheterization (CIC). The aim of this study was to adapt the Paper and Pencil Test (PP-Test) into Turkish and evaluate its psychometric properties, thereby providing a reliable tool for assessing CIC skills in patients with MS. *Methods:* This methodological study was conducted between June and December 2023 at a university hospital with 61 MS patients who perform CIC. Data were collected using the PP-Test, Clean Intermittent Catheterization Learning Scale, Expanded Disability Status Scale (EDSS), and Functional Independence Measure (FIM). Reliability was assessed using Cronbach's alpha and interrater agreement (Cohen's kappa), and validity was analyzed through content validity index (CVI) and predictive validity based on the relationships between PP-Test, EDSS, and FIM scores. *Results:* Cronbach's alpha was 0.97 for female and 0.74 for male participants. Interrater reliability was excellent ($\kappa = 0.87$). The CVI was 0.85. PP-Test scores were negatively correlated with EDSS ($r = -0.50$) and positively correlated with both FIM and CIC ability scores ($r = 0.60$).
Conclusion: The Turkish version of the PP-Test is a valid and reliable instrument for assessing CIC proficiency in patients with MS. It can be effectively used in clinical and educational settings to evaluate and monitor catheterization learning.

Keywords: Multiple sclerosis, Clean Intermittent Catheterization, Paper and Pencil Test, validity, reliability

INTRODUCTION

Multiple sclerosis (MS) is a chronic disease that affects the central nervous system and is one of the most common neurological disorders in young adults.[1-3] MS leads to motor and cognitive impairments in patients, significantly reducing their quality of life.[4-8] A significant proportion of patients with MS experience lower urinary tract symptoms, with urinary retention being one of the most common. One of the most effective methods of managing this problem is clean intermittent catheterization (CIC).[9-11]

CIC is a method that helps patients to empty their bladder regularly and is effective in preventing urinary retention. Correct and consistent use of CIC improves patients' quality of life and reduces complications such as urinary tract infections.[10,12,13] However, for CIC to succeed, patients must have certain cognitive and motor skills. Given the prevalence of cognitive and motor impairments in people with MS, it is recommended that these skills be assessed. In this context, an accurate assessment of patients' ability to perform CIC is of great importance.[9] Current guidelines strongly emphasize the evaluation of

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these functions before CIC training but do not specify a recommended tool for such assessments.

Various tools have been developed to identify psychological barriers to CIC implementation[14,15] or to assess potential challenges, satisfaction, and compliance after learning and applying CIC.[16-18] However, only one instrument has been developed specifically to assess the cognitive and physical barriers to the acquisition of the CIC technique.[19] The Paper and Pencil Test (PP-Test) is a simple and quick tool used to assess the ability of neurological patients to perform CIC. This test assesses various cognitive and physical abilities that are essential for the CIC process, such as attention, memory, motor coordination, strategic planning, and learning ability. The test includes basic CIC maneuvers such as opening the catheter package, grasping the catheter correctly, directing it to the urethral orifice, inserting it into the urethra, and withdrawing it. The test takes only four minutes to administer and objectively assesses the patient's ability to learn and apply these techniques through movements that simulate various steps of the CIC maneuver. The original version of the PP-Test has shown high reliability and validity in different neurological populations.[19-21] However, the validity and reliability studies of the Turkish version of this test have not yet been conducted. The aim of this study was to adapt the PP-Test into Turkish and evaluate its psychometric properties, thereby providing a reliable tool for assessing CIC skills in patients with MS. In addition, the study aimed to examine the associations between the PP-Test and other clinical outcome measures, such as the Expanded Disability Status Scale (EDSS) and the Functional Independence Measure (FIM), to evaluate the predictive validity of the adapted tool. It is of great importance to have a valid and reliable tool to assess CIC abilities in people with MS in Turkey.

This study contributes to international literature by supporting the standardization and validation of neurological tools across languages and cultures. It enhances the methodological depth of adaptation processes and broadens tool applicability to similar populations. Additionally, it offers a valuable perspective on improving self-management and quality of life in individuals with chronic neurological conditions, providing a theoretical foundation for similar research globally.

METHODS

Study design

This cross-sectional methodological study was conducted on MS patients at a university hospital's outpatient clinic between June and December 2023. The adaptation process followed the Guidelines for Reporting Reliability and Agreement Studies (GRRAS), developed by the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) Network, which provide consensus-based standards for the selection and reporting of health measurement instruments[22] (Supplementary Material 1).

Participants

In cultural adaptation studies of scales, it is recommended that the sample size should be at least five times the number of items in the scale to conduct psychometric analysis.[23] Based on the number of items in the scale, 61 patients with MS aged 18 years and older, without a psychiatric diagnosis, who agreed to participate in the study and who had lower urinary tract symptoms and urinary retention were included. Patients with sufficient upper limb function and truncal control to perform CIC, as determined by the EDSS assessment, were included in the study. Patients with severe upper limb dysfunction or truncal instability (EDSS ≥7) were excluded, as these conditions would prevent CIC performance.

Outcome measures and procedure

Forms were administered by the researchers to patients who met the inclusion criteria. The data collection tools included a descriptive characteristics information form, the PP-Test, the CIC learning scale, the Expanded Disability Status Scale (EDSS), and the Functional Independence Measure (FIM). All patients underwent a CIC learning period after the PP-Test and before the CIRCLES assessment. The CIC training was delivered by two members of the research team in an outpatient clinic for over 2-3 hours. This training included anatomical and physiological explanations, indications and benefits of CIC, methods and materials, a video demonstration of the technique, and practical application of the technique. The ability to learn and apply CIC was assessed immediately after the first training session.

Descriptive Characteristics Information Form: This form includes descriptive characteristics of patients such as age, sex, education level, socio-economic status, disease duration, and medication use.

Paper and Pencil (PP) Test: The PP-Test is the first tool specifically designed to predict an individual's ability to perform CIC.[19] The test can be completed in less than 4 minutes and requires only a piece of paper and a pencil. It is a short and simple test that includes common movements that mimic the maneuvers used during CIC and require the same cognitive and physical resources as this technique. Each item of the PP-Test is scored as follows 0: impossible; 1: not completed; 3: completed but difficult; and 5: possible and easy. The total PP-Test score ranges from 0 to 15**.**

*CIC Skill Assessment Form***:** In this study, the CIC Skill Assessment Form developed by Amarenco and colleagues[19] was used to assess the ability to perform CIC. This form assesses the patient's learning of CIC on a scale from 0 to 5. A score of 5 indicates that the patient learned CIC easily and completed the technique, while a score of 0 indicates that learning was impossible. Notably, a score of 3 reflects that although CIC was completed, it was achieved with significant difficulty and may have problematic durability over time.[19]

Functional Independence Measure (FIM): The FIM assesses physical and cognitive disability, assistance needs, and care burden in daily activities. It includes 18 items across six areas: self-care, sphincter control, mobility, locomotion, communication, and social cognition—divided into motor (13 items) and cognitive (5 items) sections. Each item is rated on a 7-point scale (1 = total assistance, 7 = total independence). The assessment is observational and takes about 20 minutes.[24] The FIM has been adapted into Turkish.[25]

Expanded Disability Status Scale (EDSS): The EDSS is used to determine disability in patients with MS Developed by Kurtzke, the EDSS evaluates changes in MS by categorizing them in terms of pyramidal, cerebellar, brainstem, sensory, bowel/bladder, visual, cerebral/mental, and other functions. A total score is given based on the scoring of each functional system and the assessment of the patient's mobility. The scoring ranges from 0 (no symptoms) to 10 (death due to MS); a score of 4.5 indicates that the patient is fully mobile, while a score of 5 or above indicates difficulty in performing daily activities.[26,27] The EDSS has been adapted into Turkish.[27,28]

Adapting the scale

Obtaining permission

As a first step, written authorization was obtained from the original developers of the PP test and other scales to be used.

Linguistic validity

The original English version of the scale was translated into Turkish by two independent language experts. These Turkish versions were then translated back into English by two further independent language experts. Consistency between the translations was assessed and linguistic equivalence was ensured. During this process, any possible differences in meaning between the original and back-translated versions were checked.

Expert opinion and content validity

The content validity of the scale translated into Turkish was assessed by five experts (two urologists and three neurologists). The experts rated the appropriateness of the scale items to Turkish culture and the extent to which the items accurately reflected the concepts they were intended to measure using a four-point scale. As a result of these evaluations, the majority of the items had high Content Validity Index (CVI) values; 16 out of 20 items received a CVI of 0.80 or above, while 4 items had CVI values between 0.70 and 0.79. The overall average CVI was calculated to be 0.85, indicating that the scale has strong content validity and adequately covers all important aspects of the target concept. Adjustments were made to the items with lower CVI values to improve the overall validity of the scale**.**

Pilot testing

The scales adapted to Turkish were piloted with people with MS to assess their comprehensibility and applicability. During this process, the scales were administered to 20 MS patients and necessary adjustments were made to the items based on the feedback received. The pilot testing showed that the scale was well understood and applicable to the patients.

Validity and reliability studies

The reliability of the scale was assessed using internal consistency (Cronbach's alpha reliability coefficient) and inter-rater reliability. The scale's validity was assessed by content validity (content validity indices) and predictive validity (correlation tests). A significance level of 0.05 was used.

Data analysis

Data were analyzed using SPSS 23.0 (SPSS Inc., Chicago, IL). Descriptive statistics (percentage, frequency, median, min–max, mean, SD) were used for socio-demographic data. Scale reliability was assessed via Cronbach's alpha and interrater reliability (κ) based on evaluations by two nurses. Validity was examined through content validity indices and predictive validity using correlation analysis. Correlation analyses between PP-Test, EDSS, and FIM scores were performed using Pearson's correlation coefficients. Predictors of PP-Test scores were analyzed using linear regression. The significance level was set at 0.05.

Ethical considerations

Ethical approval was obtained from the university ethics committee Approval No: 26.05.2023-1781544), and permission for scale adaptation was granted by the original developer. Written informed consent was obtained from all participants. Data confidentiality and participant privacy were ensured, and the study complied with the Declaration of Helsinki.

RESULTS

Participants

A total of 61 participants were included in the study; 57.4% were female and 42.6% were male, with a mean age of 49.5 ± 11.2 years. The educational level was as follows: 59% had completed primary school, 24.6% had completed high school and 16.4% had a university degree. In addition, 90.2% of the participants were not employed and the mean disease duration was 17.7 ± 8.3 years. (Table 1).

In the analysis of FIM, PP-Test, and CIC ability scores, no significant differences were found between female and male participants in terms of age and disease duration. The mean EDSS score was 6.1 ± 1.9 EDSS scores also did not differ between the sexes. The mean EDSS score was 6.1 ± 1.9. FIM scores were similar between women and men for both motor and cognitive components. However, women scored significantly higher on the paper-and-pencil test (12.1 ± 3.0) compared with men (7.1 ± 2.2) ($p < 0.001$). Although women also scored higher on the CIC Skill scores (4.2 ± 0.9) compared to men (3.9 ± 1.3), this difference was not statistically significant ($p = 0.153$) (Table 2).

Table 3 shows that the majority of participants (44.3%) found the learning process easy and successfully completed CIC. This group included 42.9% of women and 46.2% of men. Meanwhile, 29.5% of participants - 37.1% of women and 19.2% of men - experienced minor difficulties but were still able to complete CIC Those who experienced significant learning difficulties but completed CIC accounted for 14.8%, with 14.3% of women and 15.4% of men in this group. The proportion of those who encountered serious difficulties and made technical errors was 9.8%, with 5.7% of women and 15.4% of men falling into this category. The percentage of participants who found it almost impossible to learn and could only perform intermittent catheterization was 1.6%, all of whom were men. There were no participants in the group where learning was considered impossible. These results suggest that while the majority of participants were successful

Table 1: Sociodemographic characteristics of the patients

Characteristics	n	%
Gender		
Female	35	57.4
Male	26	42.6
Educational Level		
Primary School	36	59
High School	15	24.6
University	10	16.4
Employment Status		
Employed	6	9.8
Unemployed	55	90.2
Income Level		
High	2	3.3
Medium	47	77
Low	12	19.7
Marital Status		
Single	18	29.5
Married	43	70.5
People Living With		
Spouse	43	70.5
Parents	14	23
Alone	4	6.5

Table 2: Mean of Functional Independence Measure, Pencil and Paper Test, and Clean Intermittent Catheterization Skill Scores

Characteristics	Female	Male	Total	Test value	P value
	Mean ± SD	Mean ± SD	Mean ± SD		
Age	49.5 ± 12.3	49.46 ± 9.7	49.5 ± 11.2	0.037	0.485
Disease Duration	49.5 ± 12.3	49.46 ± 9.7	17.6 ± 8.2	- 0.110	0.458
EDSS	6.0 ± 1.8	6.23 ± 2.0	6.1 ± 1.9	- 0.433	0.333
FIM					
Motor	63.6 ± 20.4	59.9 ± 21.9	62.0 ± 20.9	0.666	0.254
Cognitive	25.9 ± 7.2	25.2 ± 7.0	25.6 ± 7.1	0.399	0.346
Total	89.5 ± 26.3	85.1 ± 27.3	87.7 ± 26.6	0.632	0.265
Pencil and Paper Test	12.11 ± 2.98	7.0 ± 2.20	9.9 ± 3.6	7.572	<0.001
CIC skill score	4.17 ± 0.89	3.8 ± 1.27	4.0 ± 1.0	1.035	0.153

EDSS: Expanded Disability Status Scale, FIM: Functional Independence Measure, CIC: Clean Intermittent Catheterization, SD: Standard Deviation

in the learning process, men may experience more serious difficulties.

Table 4 shows the completion status of the PP-Test tasks. The tasks are categorized as "impossible", "incomplete", "complete but difficult" and "complete + easy". In the first task (holding the pencil with the index finger and thumb and placing it in the ear canal), 45.9% of the participants completed the task as 'Complete + Easy', 44.3% as 'Complete But Difficult', and 9.8% left it as 'Incomplete'. Similar trends can be seen in other tasks. For example, in the task 'Hold pencil horizontally between legs', 51.4% of participants completed it as 'Full + Easy' and 40% as 'Full But Difficult'. Overall, most of the tasks were successfully completed by the participants, with a distribution between ease and difficulty. There were no tasks that were considered 'Impossible' and the rate of 'Incomplete' tasks remained generally low.

Reliability

The internal consistency of the scale was assessed using Cronbach's alpha reliability coefficient. The Cronbach's alpha value for the paper-and-pencil test was 0.97 for female patients and 0.74 for male patients. The interrater reliability of the PP-Test was assessed using the κ test, which was applied by two nurses involved in the assessment of each patient. The κ test showed excellent interrater reliability (κ = 0.87) (Table 4).

Validity

Correlations between patients' PP-Test scores and their EDSS, CIC ability scores, and FIM total and subscale mean scores were examined for predictive validity analysis. A moderate negative correlation (r = -0.5) was found between the EDSS score and the PP-Test scores, indicating that as

Table 3: Distribution of Clean Intermittent Catheterization Skill Assessment outcomes among patients

Clean Intermittent Catheterization Skill Assessment	Female		Male		Total	
	n	%	n	%	n	%
Learning easy + CIC complete	15	42.9	12	46.2	27	44.3
Learning with minor difficulty + CIC complete	13	37.1	5	19.2	18	29.5
Learning with important difficulty but CIC complete + without problematic durability	5	14.3	4	15.4	9	14.8
Learning with important difficulty, problematic durability + CIC incomplete with many technical errors	2	5.7	4	15.4	6	9.8
Learning almost impossible, CIC incomplete with patient just able to help caregivers achieve intermittent catheterization	0	0	1	3.8	1	1.6
Learning impossible	0	0	0	0	0	0

Table 4: Distribution of Pencil and Paper Test outcomes among patients

Pencil and Paper Test		Impossible		Incomplete		Full But Difficult		Full+Easy		Cronbach's Alpha	ICC (κ)
		n	%	n	%	n	%	n	%		
F+M	Pencil clasped with index + thumb, then positioned in the ear canal (dominant hand)	0	0	6	9.8	27	44.3	28	45.9	F: 0.97	0.87
M	Pencil clasped with palm + fingers, then kept vertical (nondominant hand)	0	0	4	15.4	10	38.5	12	46.2	M: 0.74	
F	Pencil positioned horizontally between thighs	0	0	3	8.6	14	40	18	51.4		
F	Pencil laid on thumb + index finger moved apart	0	0	3	8.6	15	42.9	17	48.6		
F	Pencil laid + kept up on chair between thighs	0	0	3	8.6	15	42.9	17	48.6		
F+M	Paper folded, torn + given	0	0	6	9.8	26	42.6	31	47.5		

ICC: Interrater correlation coefficient, F: Female, M: Male.

the level of disability increases, test performance decreases. This finding suggests that disease severity has a negative impact on cognitive and motor skills, which is reflected in test scores. In addition, positive correlations were observed between FIM-Motor, FIM-Cognitive, and FIM-Total scores and test scores, suggesting that higher levels of functional independence improve test performance. A strong positive correlation (r = 0.6) was found with CIC ability scores (Table 5).

According to the results of the linear regression analysis presented in Table 6, the strongest predictor of the PP-Test scores is "CIC Skill" and the effect of this variable is statistically significant (B = 2.1, p < 0.001). Other variables such as FIM-Motor, FIM-Cognitive, and EDSS do not have a significant effect on PP-Test scores. These results suggest that performance on the PP-Test is largely related to CIC ability.

DISCUSSION

This study was conducted to adapt the PP-Test into Turkish and to examine the psychometric properties of this adaptation. The results indicate that the Turkish version of the test is valid and reliable. It was found that the Turkish PP-Test can accurately assess the ability of MS patients to perform CIC and highlights the importance of cognitive and motor skills in this process.

Our study demonstrated high content validity for the Turkish version of the PP-Test, consistent with the original study conducted in France, where the PP-Test was first developed and validated. This high CVI value indicates that the scale adequately reflects the concepts it aims to measure and

Table 5: Correlations of Pencil and Paper Test scores with some variables

Pencil and paper test	r	p-value
Age	-0.2	0.052
Disease Duration	-0.4	0.706
EDSS	-0.5	<0.001
FIM-Motor	0.3	0.001
FIM- Cognitive	0.4	<0.001
FIM-Total	0.4	<0.001
CIC skill score	0.6	<0.001

CIC: Clean Intermittent Catheterization; FIM: Functional Independence Measure, EDSS: Expanded Disability Status Scale

Table 6: Linear regression analysis

Model	Unstandardized Coefficients		Standardized Coefficients	t-test value	p value	95.0% Confidence Interval	
	B	Standard Error	Beta			Lower Bound	Upper Bound
(Constant)	0.995	4.885		0.204	0.839	-8.791	10.781
CIC skill score	2.115	0.447	0.619	4.727	<0.001	1.219	3.011
FIM-Motor	0.009	0.030	0.054	0.308	0.759	-0.051	0.070
FIM-Cognitive	0.013	0.083	0.025	0.154	0.878	-0.153	0.179
EDSS	-0.082	0.377	-0.043	-0.217	0.829	-0.838	0.674

CIC: Clean Intermittent Catheterization, FIM: Functional Independence Measure, EDSS: Expanded Disability Status ScaleIf

comprehensively assesses all important aspects of the targeted concept.[29] The PP-Test is effective in predicting the ability to perform CIC in studies conducted with MS and different neurological disease groups.[19-21]

This finding supports the content validity of the PP-Test items. To assess the predictive validity of the scale, this study examined correlations between the PP-Test scores and the EDSS, CIC ability scores, and FIM total and subscale mean scores. A moderate negative correlation (r = -0.5) was found between the EDSS score and the PP-Test scores. As the EDSS score measures the level of physical disability in patients, this finding suggests that as the level of disability increases, cognitive and motor skills are negatively affected and this effect is reflected in the PP-Test scores. Particularly in neurological diseases such as MS, this finding supports the expected decline in cognitive and motor function as the disease progresses. Other studies have also found a relationship between EDSS scores and CIC learning skills and adherence, which supports our findings.[21,30]

The positive correlations between FIM total and subscale scores (FIM-Motor and FIM-Cognitive) and PP-Test scores indicate that higher levels of functional independence have a positive effect on test performance. These correlations suggest that the level of independence in activities of daily living may be related to cognitive and motor performance. Functional independence requires individuals to use both their motor and cognitive skills effectively. The PP test assesses several cognitive and physical abilities that are critical to the CIC process, such as attention, memory, motor coordination, strategic planning, and learning ability.[20,21,30] Therefore, it is an expected outcome that an increase in functional independence levels would improve performance on the PP-Test. In a study of people with MS, the sensitivity of the FIM and the PP-Test in predicting CIC ability was found to be similar.[20]

The study found a strong positive correlation (r = 0.6) between CIC Skill scores and PP-Test scores in people with MS. In addition, the results of linear regression analysis indicated that the strongest predictor of PP-Test scores was CIC Skill scores. The original study of the scale and other studies have also found a strong correlation between PP-Test scores and CIC Skill scores in people with neurological conditions.[19] These findings suggest that the PP-Test has high predictive validity and is an effective tool for assessing CIC skills.

In the study, the reliability of the scale was assessed through internal consistency and interrater agreement. The satisfactory level of Cronbach's alpha coefficient (0.97 for women, 0.74 for men) indicates that the test has high internal consistency and can be considered a reliable measurement tool. However, it was noted that, as in the original scale study, gender differences were reflected in the test scores, with more accurate scores for women than for men. This suggests that there may be differences in the movements required to perform CIC procedures between women and men. The observed gender differences in PP-Test scores may not only reflect physical differences in the movements required

to perform CIC procedures but could also be influenced by other factors. These may include differences in prior experience with similar tasks, levels of confidence, fine motor skills, and sociocultural factors that affect task performance. In our study, we also evaluated whether any of the PP-Test tasks were perceived as culturally unfamiliar or uncomfortable during the pilot phase and data collection. No negative feedback was reported by participants regarding cultural appropriateness. However, we acknowledge that cultural perceptions and attitudes may still subtly influence task performance. Future studies are recommended to explore potential cultural factors in more detail when applying the PP-Test in different settings.

In the study, when the use of the PP-Test was evaluated in terms of interrater reliability, the satisfactory level of Cronbach's alpha coefficient ($\kappa = 0.87$) indicates that the test has high internal consistency. Interrater reliability is an important indicator of whether a test or measurement tool produces similar results when used by different observers.[31] In this context, the high Cronbach's alpha value indicates that there is good agreement between observers and that the test can be applied consistently.

Among the limitations of the study, the most important is the size of the sample. Only 61 patients with MS were assessed in the study, which may limit the generalisability of the results. Research on larger populations is important to validate the findings. The study also found differences in consistency between male and female populations on the PP-Test. The fact that women scored higher on the test than men suggests that the test produces different results for men and women. Further research is needed to investigate the reasons for these differences and how the test could be adapted to suit different genders.

In conclusion, the Turkish adaptation of the PP-Test demonstrated strong validity and reliability. The scale exhibited high content validity and robust predictive validity. Notably, a negative correlation was found between EDSS scores and PP-Test scores, while positive correlations were observed with both FIM scores and CIC ability scores. The test proved to be an accurate predictor of CIC skills and can be effectively employed to assess CIC learning in patients. The significantly higher PP-Test scores observed in female participants compared to their male counterparts indicate the potential influence of gender differences, suggesting that women may be more successful in CIC application skills.

DISCLOSURE

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Conflicts of interest: None

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