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Validation of the Turkish version of the DOSE-Nonadherence measure among patients with cardiometabolic conditions

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Abstract

What is known and objective: There are no validated self-report measures to assess extent of and reasons for medication nonadherence in the Turkish language. The aim of this study is to evaluate validity and reliability of the Domains of Subjective Extent of Nonadherence Scale, which assesses extent of and reasons for nonadherence in Turkish patients with hypertension, diabetes mellitus and/or dyslipidaemia in community pharmacy settings.

Methods: The Turkish version of the DOSE-Nonadherence scale was developed through translation and cultural adaption. Psychometric properties of the scale were evaluated in a cross-sectional study among 203 patients who visited six community pharmacies located in Istanbul, Turkey between November 2020 and March 2021. For the extent of nonadherence domain, reliability was estimated through Cronbach's alpha, and convergent validity was evaluated with Spearman's rank correlation with the validated Turkish version of the Medication Adherence Report Scale (MARS). Reasons for nonadherence were characterized among participants reporting nonadherence to the extent of nonadherence items. The measure was administered at baseline and 2 weeks later to 30 patients to estimate stability of extent scores using the Wilcoxon test and intraclass correlation coefficient. $p < 0.05$ was set as the level of statistical significance.

Results: Among the 203 participants (65 male), the median (25th–75th percentiles) age was 59.0 years [51.0–67.0]. Cronbach's alpha for the extent of nonadherence scale was 0.86. A moderate negative correlation ($r = -0.58$; $p < 0.001$) was found between the extent of nonadherence scores and MARS, supporting convergent validity. The most common reasons for medication nonadherence were forgetfulness (22.5%) and mismatch between the patients' daily routine and medication taking (17.5%). The intraclass correlation coefficient was 0.97 for extent of nonadherence scores at baseline and 2 weeks ($p < 0.001$).

What is new and conclusion: The DOSE-Nonadherence Scale could be used to identify nonadherent patients and their reasons for nonadherence in Turkish patients with chronic cardiometabolic conditions. This scale can be used to evaluate clinical pharmacist-led services to reduce medication nonadherence. Nonadherence could be recorded longitudinally in electronic health records to provide a more accurate

picture of medication use. Pharmacists or other providers could administer interventions tailored to patients' reasons for nonadherence.

KEYWORDS
DOSE-Nonadherence, diabetes mellitus, dyslipidaemia, hypertension, medication adherence, nonadherence, validity

1 | WHAT IS KNOWN AND OBJECTIVE

An estimated one in five people have multiple chronic conditions.[1] Yet, adherence to medications is quite low among patients with chronic diseases. A study conducted in community pharmacy settings in Turkey determined that only one-fourth of patients prescribed oral chronic medication regimens were highly adherent to their medications.[2] Another study carried out in community pharmacies in Spain revealed that almost half of the patients with chronic diseases were nonadherent to their medications.[3]

Adherence is defined by WHO as 'the extent to which a person's behaviour (including taking medication, following a diet program, and/or executing lifestyle changes) corresponds with agreed recommendations from a health care provider'.[4,5] Vrijens et al.[5] recently defined medication adherence as 'the process by which patients take their medications as prescribed, composed of initiation, implementation and discontinuation'. Medication-taking behaviour can be assessed with a variety of methods. While some studies use objective measures such as electronic drug monitoring, others utilize validated self-report measures.[6] According to a Delphi study conducted among medication nonadherence experts, self-report tools are preferred for measuring nonadherence behaviours[7] due to their low cost, ability to be administered at the point of care and ability to measure reasons for nonadherence.[8]

Nonadherence to medications is complex to address because it includes many reasons (both intentional and unintentional) and requires a combination intervention to address these problems.[9] Therefore, it is important to select targeted services to address barriers to medication adherence. A first step in this process is to assess, using validated tools, whether patients were nonadherent to medications, and, if they were, the reasons for nonadherence.[9,10] Community pharmacists could play this role because they take accurate, up-to-date lists of medications while dispensing prescribed medications and providing crucial services for preventing, detecting and solving medication adherence problems.[11,12] In Turkey, there is no available valid and reliable self-reported tool to evaluate both the extent of medication adherence and the reasons for nonadherence in the context of pharmacist-led services. The Turkish version of the Medication Adherence Report Scale (MARS) addresses multiple medication taking behaviours (e.g., missing doses, taking doses later than instructed) and confounds extent of missing doses with reasons for missing doses. Furthermore, it does not comprehensively assess all potential reasons for nonadherence in specific patient populations and/or conditions.[13,14]

The Domains of Subjective Extent of Nonadherence Scale (DOSE-Nonadherence) is a self-reported tool developed and validated in the United States in patients with hypertension, dyslipidaemia and hepatitis C to characterize extent of nonadherence and assess reasons for nonadherence.[15–17] Three extent of nonadherence items address both unintentional and intentional missed doses.[15] A comprehensive list addresses both unintentional (such as forgetfulness, being out of routine) and intentional reasons for nonadherence (such as being afraid the medication would interact with other medications). We chose to translate this measure because other measures assess only one of these domains (i.e., extent of or reasons for nonadherence) or confound them, limiting reliability and construct validity.[18] Furthermore, other measures assess a limited number of reasons for nonadherence, limiting content validity. The objectives of this study were: (1) to perform a cultural and linguistic adaption of the measure in the Turkish language and (2) to evaluate the validity and reliability of the scale[15] in Turkish patients with chronic cardiometabolic conditions (including hypertension, diabetes mellitus, and/or dyslipidaemia) in community pharmacy settings. This study is reported based on the recommendations of the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) statement.[19]

2 | METHODS

2.1 | Study setting and design

This study was conducted at six community pharmacies located in Istanbul, Turkey between November 2020 and March 2021. It had two components: (1) a cross-sectional study to evaluate reliability and convergent validity and (2) a sub-study involving assessments at baseline and 2 weeks to evaluate stability of scores over a short time period.

2.2 | Study population

In both parts of the study, patients were eligible if they had at least one chronic cardiometabolic disease (i.e., hypertension, diabetes and/or dyslipidaemia), had been prescribed at least one medication orally for at least a month and were responsible for self-management of their medications. Convenience sampling occurred among patients who usually visiting these six community pharmacies, which are

located close to primary care clinics. Approximately equal numbers of participants were recruited from each pharmacy. A sub-study was conducted in the first 30 eligible participants who did not participate in the psychometric validation study or pilot study.

2.3 | Data collection

Demographic characteristics [age, sex, educational status (classified based on compulsory education year in Turkey before 2012: <8 years and ≥8 years), marital status and employment status] and presence of cardiometabolic disease were self-reported. Medications were self-reported and then confirmed by researchers using the electronic medical record (EMR). ATC codes for the medications were recorded from the EMR. Polypharmacy was defined as having a prescription for four or more medications concurrently.[20] The nonadherence scales were administered either in person or by telephone interview due to the COVID-19 pandemic.

2.4 | DOSE-Nonadherence Scale

This scale consists of two domains: extent of nonadherence and reasons for nonadherence. The first part assesses missed doses using a 7-day recall period. The items were designed to address both intentional and unintentional nonadherence. If patients responded with a score above 1 on any extent of nonadherence item, they were classified as non-adherent and completed the reasons of nonadherence portion of the scale (18 items). Cronbach's alpha values for the English version of the extent of nonadherence items have ranged from 0.78 to 0.94 in previous studies.[15,16,21]

The scale was designed to assess nonadherence to medications for a single disease. In this study, one oral medication for the management of hypertension, dyslipidaemia or diabetes mellitus was randomly selected for each patient, and the patients were asked to respond related to this medication. A 5-point frequency scale (for the extent items: 1 = none of time to 5 = all of the time, and for the reasons items: 1 = never to 5 = always) was used. Higher scores indicate greater extent of nonadherence and greater endorsement of reasons for nonadherence. An open-ended question was included to assess whether participants had other reasons for nonadherence not mentioned in the scale. The Turkish version of the scale is available from the copyright holder, Duke University. A license for use must be obtained from the Duke Office of Licensing and Ventures. After completing the agreement, licensees receive the requested language(s) and a user's guide with scoring instructions.

2.5 | Medication Adherence Report Scale (MARS)

The 5-point Medication Adherence Report Scale (MARS) was used to assess convergent validity. It has a 5-point response scale (1: very often to 5: never) to assess the frequency of adherence to different medication-taking behaviours (including forgetting to take medication, altering the dose, quitting taking medication for a while, taking less than instructed, and missing a dose).[13,14] In a previous study, Cronbach's alpha for the Turkish adaptation was 0.78.[14] Although the scale consists of items related to different nonadherent medication taking behaviours, the total score is calculated by summing the item scores, with the total possible range from 5 to 25; higher scores indicate greater medication adherence.

2.6 | Permissions

The required copyright permission was obtained from Duke University in the United States. The study protocol was approved by Marmara University Health Science Institute Ethical Committee (Date-Number: 14.09.2020-78). Written or electronic informed consent was obtained from participants.

2.7 | Cultural adaption and content validity of the DOSE-Nonadherence Scale

The principles determined by the World Health Organization (WHO) and International Society for Pharmacoeconomics, and Outcomes Research (ISPOR) Task Force for Translation and Cultural Adaption were followed.[22,23] Forward translations were conducted by two Turkish healthcare professionals fluent in English. Back translations were carried out by two English healthcare professionals fluent in Turkish. An expert panel encompassed of a clinical pharmacist and a public health professional came together to resolve discrepancies and finalize the last version. The English translation of the last version was shared with the scale developers to ensure consistency with the intended meaning. Lastly, the back-translation and Turkish version of the scale were reconciled by a Turkish scientist fluent in English.

The Turkish version was pilot-tested by conducting cognitive interviews in 30 participants (aged ≥18 years old, had been prescribed at least one medication during the previous month for their noncommunicable disease, did not participate in the psychometric validation study or substudy) to determine its comprehensibility. The average time to complete the DOSE-Nonadherence Scale (both two domains: extent of nonadherence and reasons for nonadherence) was 3–5 min both in face-to-face and telephone interview.

2.8 | Sample size calculation

We expected a correlation of between the MARS and DOSE-Nonadherence scale of at least −0.50 for convergent validity (negative sign because higher scores on MARS indicate adherence whereas higher scores on DOSE-Nonadherence indicate nonadherence). We also expected an intraclass correlation of at least 0.50 for the two administrations of the extent of nonadherence scale, reflecting stability of behaviour over a short time period. To detect statistical

TABLE 1 Characteristics of patients ($n = 203$) in cross-sectional psychometric study

Characteristics of patients	*n* (%)
Sex	
Male	65 (32.0)
Female	138 (68.0)
Age Median [25th–75th percentiles]	59.0 [51.0–67.0]
<65 years old	140 (69.0)
≥65 years old	63 (31.0)
Education level[a]	
<8 years	112 (55.2)
≥8 years	91 (44.8)
Marital status	
Single	44 (21.7)
Married	159 (78.3)
Employment status	
Yes	151 (74.4)
No	52 (25.6)
Number of chronic diseases Median [25th–75th percentiles]	2 [1.0–2.0]
1	88 (43.4)
2	66 (32.5)
>3	49 (24.1)
Chronic diseases[b]	
Hypertension	163 (80.3)
Diabetes mellitus	97 (47.8)
Dyslipidaemia	63 (31.0)
Number of medications used Median [25th–75th percentiles]	3 [1.0–4.0]
1	62 (30.5)
2	35 (17.2)
3	43 (21.2)
4	27 (13.3)
≥5	36 (17.8)
Polypharmacy[c]	
Yes	63 (31.0)
No	140 (69.0)
Pharmacologic group	
Medications for diabetes mellitus	
Biguanides	30 (14.8)
Sodium-glucose co-transporter 2 (SGLT2) inhibitors	6 (3.0)
Combinations of oral blood glucose lowering drugs	5 (2.5)
Dipeptidyl peptidase 4 (DPP-4) inhibitors	5 (2.5)
Others[d]	3 (1.5)
Medications for hypertension	
Angiotensin II receptor blockers (ARBs) and diuretics	40 (19.7)
Angiotensin II receptor blockers (ARBs)	22 (10.8)
Others[e]	16 (7.9)
Calcium channel blockers	16 (7.9)
Angiotensin-converting enzyme (ACE) inhibitors	16 (7.9)
ACE inhibitors and diuretics	17 (8.4)
ACE inhibitors and calcium channel blockers	7 (3.4)
Beta blocking agents, selective	5 (2.5)
Medications for dyslipidaemia	
HMG CoA reductase inhibitors	12 (5.9)
Others[f]	3 (1.5)

Note: Lipid-modifying agents in combination with other drugs ($n = 1$).
[a]According to obligatory education year in Turkey before 2012.
[b]The patients had more than one chronic disease.
[c]Concurrent use of four or more medications.
[d]Sulphonylureas ($n = 1$), Alpha glucosidase inhibitors ($n = 1$) and Thiazolidinediones ($n = 1$).
[e]Diuretics ($n = 4$), ACE inhibitors, other combinations ($n = 4$), Alpha and beta blocking agents ($n = 2$), Beta-blocking agents, selective and thiazides ($n = 2$), Angiotensin II receptor blockers (ARBs) and calcium channel blockers ($n = 2$), Antiadrenergic agents, centrally acting ($n = 1$), Antiadrenergic agents, peripherally acting ($n = 1$).
[f]Fibrates ($n = 2$), Lipid modifying agents in combination with other drugs (n=1).

significance of a correlation of 0.50–0.70, with an alpha of 0.05 and power of 0.95, the required the sample size was 17–38.

2.9 | Statistical analysis

Normality of extent of nonadherence items was evaluated with the Kolmogorov–Smirnov test. Medians [25th–75th percentiles] and frequencies (percentages) are presented. A mean score was calculated for the three extent of nonadherence items. Internal consistency of the extent of nonadherence scale and the MARS was estimated with Cronbach's alpha coefficient. Convergent validity was evaluated through Spearman's rank correlation between the total scores of the MARS and the extent of nonadherence scales. Reasons for nonadherence items were dichotomized as present (score 2–5) vs. absent (1) due to the non-normal distributions; descriptive statistics were calculated for each item.

Adherent and nonadherent participants according to extent of nonadherence scores were compared by categorical demographic and clinical variables (including sex, older age, education level, marital status, employment status, number and type of chronic diseases, number of medications, polypharmacy and method used for data collection) using the Chi-square test.

Consistency of mean extent of nonadherence scores across 2 weeks was determined with Intraclass correlation coefficient (95% confidence interval [CI]) and Wilcoxon test using scores from the first

TABLE 2 The corrected item-total correlation, squared multiple correction and Cronbach's alpha if item deleted for each extent of nonadherence item of the Turkish DOSE-Nonadherence Scale ($n = 203$, items presented in English)

DOSE-Nonadherence Scale	Corrected item-total correlation	Squared multiple correlation	Cronbach's alpha if item deleted
I missed my medicine	0.606	0.615	0.915
I skipped a dose of my medicine	0.716	0.778	0.823
I did not take a dose of my medicine	0.926	0.866	0.604

TABLE 3 Characteristics of patients by Adherence Status[a]

	Patients with non-adherence ($n = 60$)	Patient with adherence ($n = 143$)	*p* Value
Sex			
Male	16 (24.6%)	49 (75.4%)	0.290
Female	44 (31.9%)	94 (68.1%)	
Age			
<65 years old	44 (31.4%)	96 (68.6%)	0.481
≥65 years old	16 (25.4%)	47 (74.6%)	
Education level[b]			
<8	27 (24.1%)	85 (75.9%)	0.059
≥8	33 (36.3%)	58 (63.7%)	
Marital status			
Single	12 (27.3%)	32 (72.7%)	0.850
Married	48 (30.2%)	111 (69.8%)	
Employment status			
Yes	48 (31.8%)	103 (68.2%)	0.312
No	12 (23.1%)	40 (76.9%)	
Number of chronic diseases			
1	20 (22.7%)	68 (77.3%)	0.46
2	19 (28.8%)	47 (71.2%)	
≥3	21 (42.9%)	28 (57.1%)	
Hypertension			
Yes	49 (30.1%)	114 (69.9%)	0.901
No	11 (27.5%)	29 (72.5%)	
Diabetes mellitus			
Yes	36 (37.1%)	61 (62.9%)	0.024
No	24 (22.6%)	82 (77.4%)	
Dyslipidaemia			
Yes	24 (38.1%)	39 (61.9%)	0.074
No	36 (25.7%)	104 (74.3%)	
Number of medications used			
1	13 (21.0%)	49 (79.0%)	0.140
2	10 (28.6%)	25 (71.4%)	
3	11 (25.6%)	32 (74.4%)	
4	12 (44.4%)	15 (55.6%)	
≥5	14 (38.9%)	22 (61.1%)	
Polypharmacy (concurrent use of four or more medications)			
Yes	26 (41.3%)	37 (58.7%)	0.014
No	34 (24.3%)	106 (75.7%)	
Method used for data collection			
Face to face interview	40 (32.3%)	84 (67.7%)	0.369
Telephone interview	20 (25.3%)	59 (74.7%)	

[a]If patients responded with a score above 1 on any extent of nonadherence item, they were classified as non-adherent.
[b]Based on obligatory education year in Turkey before 2012.

TABLE 4 Reasons for nonadherence among patients reporting nonadherence[a] for a selected medication ($N = 60$; items presented in English)

	N (%)
I forgot	9 (22.5)
I was out of my routine	7 (17.5)
I could not meet the food requirements	4 (10.0)
I did not have my medicines with me	4 (10.0)
I had other medications to take	3 (7.5)
I ran out of medication	3 (7.5)
I was too late with my dose	2 (5.0)
The medication caused side effects	2 (5.0)
I could not afford the medication	1 (2.5)
I was asleep	1 (2.5)
Treatment was hard on my family	1 (2.5)
I was afraid the medication would interact with other medication I take	1 (2.5)
I was feeling too sick to take it	1 (2.5)
I could not get answers to my questions about the medication	1 (2.5)
The medication affected my sex life	–
The medication was not working	–
I did not want others to see my medications	–
There was no one to help me	–

[a]If patients responded with a score above 1 on any extent of nonadherence item, they were classified as nonadherent and completed the reasons for nonadherence items.

and second administration. For all analyses involving the extent of nonadherence domain, $p < 0.05$ was set as the level of statistical significance. Data analysis was performed by IBM® SPSS® 11 software.

3 | RESULTS

Two hundred three patients were invited to participate. No patient was excluded or refused to participate. Participant characteristics are presented in Table 1. The 203 participants (65 male/ 138 female) who completed the psychometric study had a median [25th–75th percentiles] age of 59.0 [51.0–67.0] years.

The corrected item-total correlation, squared multiple correction and Cronbach's alpha if item deleted for each extent of nonadherence item of the Turkish version of the DOSE-Nonadherence Scale are presented in Table 2. Cronbach's alpha for the Turkish version of the DOSE-Nonadherence Scale was 0.861. Cronbach's alpha for the MARS was 0.732. A moderate negative correlation ($r = -0.58$; $p < 0.001$) was found between the extent of nonadherence and MARS scales, supporting convergent validity.

When extent of nonadherence scores was dichotomized, 29.6% of participants were classified as nonadherent. Comparisons of adherent and nonadherent participants by demographic and clinical characteristics are found in Table 3. Patients with three or more chronic diseases, diabetes mellitus and polypharmacy were more nonadherent to their medications ($p < 0.05$ for all). There was no significant difference in extent of nonadherence scores by the method used to administer the scale [face-to-face vs. telephone interview ($p > 0.05$)].

Sixty patients reporting nonadherence to their medications, 18 reasons were endorsed. The most common identified reasons for medication nonadherence were forgetfulness ($n = 9$ [22.5%]) and mismatch between the patients' daily routine and medication-taking ($n = 7$ [17.5%]). No response from the open-ended question was received. Reasons for nonadherence are presented in Table 4.

Among the 30 participants who completed the scale at baseline and 2 weeks later, there was no significant difference between extent of nonadherence scores at the two time points ($p > 0.05$). The intraclass correlation coefficient was 0.97 (95% CI: 0.94–0.99) for extent of nonadherence scores at baseline and 2 weeks ($p < 0.001$). After 2 weeks, 14 participants were still classified as adherent and 15 participants were still nonadherent. One adherent participant was classified as nonadherent after 2 weeks.

4 | DISCUSSION

This study demonstrated that the Turkish version of the DOSE- Nonadherence Scale was a reliable and valid instrument that can be used by telephone or face-to-face administration in patients with cardiometabolic conditions in community pharmacy settings. A previous study showed that the DOSE-Nonadherence Scale produces reliable and valid scores through telephone survey.[16,21] Convergent validity was supported by the moderate correlation between the total scores of the Turkish version of MARS and the extent of nonadherence scale.

Previous studies revealed that the Cronbach's alpha coefficient of the English version of the scale ranged from 0.78 to 0.94.[16,21] Liau et al.[24] evaluated the psychometric properties of different versions (including English, Singaporean Chinese and Malay) of the DOSE-Nonadherence Scale in patients in Singapore with diabetes mellitus and found Cronbach's alpha ranging from 0.65 to 0.73, which is lower than in the present study. They also found a moderate intraclass correlation of 0.52–0.54 between scores assessed at baseline and 14 days later, which is considerably lower than what we observed. Although these scores do not provide indisputable evidence of test–retest reliability due to the comparison of different recall periods, it does suggest stability of nonadherence scores in this population over a short time period. Future work is needed to compare two assessments querying the same recall period to obtain more definitive data about test–retest reliability.

Our rates of nonadherence among different cardiometabolic chronic diseases are similar to previous rates found in US samples. In a cohort study conducted by Voils et al.,[21] the rate of nonadherence in patients prescribed antihypertensive medications in USA was 35.6%, slightly higher than our rate of 30.1%. In a study of patients prescribed statins, 46% were classified as nonadherent in USA,

compared with 38.1% in our study.[17] Liau et al.[24] found the rate of nonadherence in patients with diabetes mellitus as 38.9% (for all languages) in Singapore, lower than our rate of 47.8%.

In our study, having multiple chronic diseases and receiving multiple medications were associated with nonadherence, which is similar to a study of Spanish patients with chronic disease in community pharmacy.[3] In other work, pill burden has been associated with nonadherence in patient with diabetes mellitus and/or hypertension in community pharmacies.[25] Voils et al.[21] determined forgetfulness of medication and being busy as the most common reasons for nonadherence in patients prescribed antihypertensive medications. This is in line with the findings of the present study in Turkey.

This study has some limitations. Patients with nonadherence might be less likely to visit community pharmacy settings for refilling the prescriptions and or less willing to participate, resulting in selection bias. Generalizability of findings is limited due to convenience sampling. This might have led to an underestimation of nonadherent patients and a low rate of stated reasons for nonadherence. Still, the sample size of our study was sufficient to evaluate convergent validity and reliability of the Turkish version of the scale.

Convergent validity was determined using a validated Turkish self-report measure. Future research is needed to obtain additional evidence of convergent validity via objective measures of missed doses (e.g., pill count, electronic medication monitoring) and concurrent validity using constructs related to disease control (e.g., blood glucose, blood pressure, serum lipid panel). Although patients were encouraged to provide reasons for nonadherence not included on the scale, no response was received. This finding needs further assessment, perhaps using qualitative methods. Although Voils et al.[15] suggested conducting focus groups on both patients and healthcare providers, we were unable to do so due to the COVID-19 pandemic. Querying providers could uncover additional reasons for nonadherence that could be added to disease-specific versions of the measure.

5 | WHAT IS NEW AND CONCLUSION

The DOSE-Nonadherence measure is useful to identify patients with nonadherence and assess nonadherence problems specific to patient population and/or conditions in Turkish patients with hypertension, diabetes mellitus and dyslipidaemia. This scale could be useful in research studies and clinically in person or by telephone interview. Nonadherence could be recorded longitudinally in electronic health records to provide a more accurate picture of medication taking. Pharmacists or other providers could administer interventions tailored to patients' personalized reasons for nonadherence.

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CONFLICT OF INTEREST

The authors declare no conflict of interest. The copyright for the DOSE-Nonadherence scale is owned by Duke University.

DATA AVAILABILITY STATEMENT

Data are available from the corresponding author on reasonable request.

PATIENT CONSENT STATEMENT

Written or electronic informed consent was obtained from participants.

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