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PSYCHOMETRIC PROPERTIES OF THE SLOVENIAN VERSION OF THE CARDIAC DEPRESSION SCALE

PSIHOMETRIČNE LASTNOSTI SLOVENSKEGA PREVODA LESTVICE DEPRESIVNOSTI ZA SRČNE BOLNIKE

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ABSTRACT

Keywords:

Cardiac Depression Scale, depression, heart disease, reliability, validity **Introduction:** The aim of this study was to translate the Cardiac Depression Scale into the Slovenian language and test its validity and reliability on Slovenian patients with heart disease.

Methods: A total of 272 patients with heart disease who underwent elective coronary angiography at Celje General Hospital participated in this study. We used the Slovenian Cardiac Depression Scale (S-CDS), the Spielberger State Anxiety Inventory (STAI-S), and the Center for Epidemiologic Studies Depression Scale-20 (CES-D) to collect data. An exploratory and confirmatory factor analysis, internal consistency, test-retest reliability, and concurrent validity were performed.

Results: Cronbach's alpha for the total scale was 0.92 and the test-retest reliability was 0.71. Exploratory factor analysis confirmed six factors, accounting for 61% of the total variance. The confirmatory factor analysis indicated that a two- and one-factor solution had acceptable goodness-of-fit measures. However, we kept a more parsimonious one-factor method, given a high correlation between the two factors and the theoretical background in previous studies. Concurrent validation against the CES-D and the STAI-S showed moderate to strong correlations.

Conclusions: The S-CDS is a reliable and valid instrument for screening for depression in Slovenian patients with heart disease.

IZVLEČEK

Ključne besede:

lestvica depresivnosti za srčne bolnike, depresija, bolezni srca, veljavnost, zanesljivost

Namen: Namen raziskave je bil prevesti, validirati in prilagoditi slovenski prevod Lestvice depresivnosti za srčne bolnike (S-CDS) na vzorcu bolnikov z boleznijo srca.

Metode: 272 bolnikov z boleznijo srca, ki so bili vabljeni na elektivno invazivno kardiološko diagnostiko v Splošni bolnišnici Celje, je ustrezalo vključitvenim kriterijem. Uporabili smo S-CDS, Spielbergerjevo lestvico anksioznosti kot stanja (angl. The Spielberger State Anxiety Inventory, STAI-S) in lestvico depresivnosti (angl. The Center for Epidemiologic Studies Depression Scale-20, CES-D). Naredili smo eksploratorno in konfirmatorno faktorsko analizo, ocenili notranjo konsistentnost, časovno stabilnost in sočasno veljavnost.

Rezultati: S-CDS ima dobro notranjo konsistentnost (Cronbach alfa = 0,92) in časovno stabilnost (ICC = 0,71). Z eksploratorno faktorsko analizo smo potrdili šest faktorjev, s katerimi smo pojasnili 61 % celotne variabilnosti. Konfirmatorna faktorska analiza je potrdila dobro prileganje šestfaktorskega modela z eno in dvema dimenzijama, vendar smo se upoštevajoč visoke korelacije med faktorjema in teoretično utemeljene enofaktorske rešitve iz preteklih raziskav odločili za enofaktorsko strukturo. Sočasna veljavnost s CES-D in STAI-S je pokazala precejšnjo do močno povezanost.

Zaključek: S-CDS je zanesljiv in veljaven vprašalnik za merjenje depresivnosti slovenskih bolnikov z boleznijo srca. Potrebne bodo nadaljnje raziskave, ki bodo ocenile senzitivnost in specifičnost S-CDS.

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1 INTRODUCTION

Cardiovascular diseases (CVD) were the cause of 40% of all deaths in Slovenia in 2016, and are the seventh most common cause of visits to the general practitioner (1). The prevalence of depression in people with CVD is high (2) and is a strong predictor of mortality and additional cardiac events (3, 4). In patients with coronary artery disease (CAD), depressive symptoms contribute to a lower quality of life and to physical limitations (5, 6). In the first week after myocardial infarction, the prevalence of depression symptoms in patients is between 30 and 40%, and that of moderate to severe major depressive disorder is between 15 and 30% (6).

The European Society of Cardiology and the American Heart Association recognise depression as a risk factor for CVD and major adverse cardiac events. They recommend routine testing for depression in cardiac patients (4, 6, 7). In Slovenia, we test patients with CVD for depression at the primary care level. The Patient Health Questionnaire-2 (PHQ-2) and the Patient Health Questionnaire-9 (PHQ-9) are administered (8). However, studies have shown that depression in people with CVD differs from major depressive disorder (9). The main symptoms of major depressive disorder are depressed mood and anhedonia (10), whereas patients with CAD complain of fatigue, anxiousness, waking at night, reduced concentration, hopelessness and depressed mood (9, 11). Evidence showed that up to 75% of patients with depression and CVD go undiagnosed, as the somatic symptoms of depression are attributed to cardiac problems and not depression (12, 13). Early identification of depression symptoms is essential for providing optimum management of depression and prevent it from developing into a major depressive disorder. A specific scale for cardiac patients was therefore created in response. The authors used the most frequent responses of cardiac patients and developed the Cardiac Depression Scale (CDS) (9).

Because CVD are highly prevalent in Slovenia and depression affects approximately between 20 and 40% of all patients with cardiac disease (14), the aim of this study was to evaluate the psychometric properties of the Slovenian version of the Cardiac Depression Scale (S-CDS) in Slovenian-speaking cardiac patients.

2 METHODS

2.1 Translation and development of the Slovenian CDS

An independent forward and back translation of the CDS was carried out after consent was obtained from the authors of the original version (9). Three bilingual Slovenian native speakers with medical knowledge produced a forward translation (English to Slovenian). The translators then worked jointly and discussed the three

versions item by item until they reached a consensus. The questionnaire was then back-translated (Slovenian to English) by two independent certified English translators unfamiliar with the original version. The conducting team checked the two back-translated versions until a final version was created. The back-translated version was then compared to the original English version to ensure no loss of meaning or context had occurred. The original authors received the final draft for their approval.

2.2 Study population

This study was conducted at Celje General Hospital between October 2015 and March 2017. The validation study was a part of the 'Evaluating ANxiety in elective coronary anGiography STudy (ANGST)' research project. Its protocol has been described elsewhere (15). To summarise, patients waiting for elective coronary angiography (ECA) were contacted three to four weeks before the procedure with a letter containing information about the study, a written consent form and questionnaires with instructions. The inclusion criteria applied in the S-CDS validation study are as follows:

- diagnosis of CVD (CAD, heart failure, dysrhythmias, cardiomyopathy, valve disease);
- not having a physical/mental disease, with help needed to complete the questionnaires;
- being able to read and understand Slovenian;
- signed written consent; and
- a completed S-CDS two weeks before ECA.

Of the 393 patients, 272 (69.2%) met the inclusion criteria for the ANGST and validation studies. Four weeks after ECA, letters with three questionnaires (S-CDS, the Center for Epidemiologic Studies Depression Scale-20 (CES-D), and the Spielberger State Anxiety Inventory (STAI-S)), and a paid return envelope, were sent to 272 patients. Of the 272 patients, 184 (67.6%) returned completed questionnaires and were included in the test-retest reliability and concurrent validity study. The patient flowchart is presented in Figure 1.

2.3 Instruments

2.3.1 Cardiac Depression Scale

The CDS accurately assesses depression in cardiac patients (9, 16). It has seven reliable and distinct components that include Mood (21, 22, 24, 25, 26), Anhedonia (items 4, 12, 19), Cognition (2, 15, 20, 23), Uncertainty (5, 6, 8, 13, 17, 18), Sleep (items 7, 9), Inactivity (1, 3, 16), and Hopelessness (10, 11, 14). Twenty-six items on the CDS are scored on a 7-point Likert-type scale ranging from 1 ('strongly disagree') to 7 ('strongly agree'). Items 2, 4, 12, 15, 19, 20, 23 are reverse scored. Higher scores on the CDS indicate more severe depression. The total



(ANGST - Evaluating anxiety in elective coronary angiography study; ECA - elective coronary angiography)



CDS score is the sum of all items (additionally recoded where necessary) and ranges from 26 to 182 (9). A cutoff score of 95 had 97% sensitivity and 85% specificity for major depression, as indexed using the Mini International Neuropsychiatric Interview (16). The internal consistency coefficient for the original 26-item scale was 0.9. The authors assessed external validity using correlations with the Beck Depression Inventory and the clinical assessment. The correlations were highly significant (0.73 and 0.67) (9). A validation study of the CDS in the UK population had an acceptable test-retest reliability of 0.79 (17). A systematic review from Chavez and colleagues concluded that the CDS was a reliable measure of depression in patients with CAD (18). The CDS has also been validated and translated into Chinese (19), Persian (13), Arabic (20, 21) and German (22).

2.3.2 Center for Epidemiologic Studies Depression Scale

The CES-D scale is a 20-item self-report scale designed to measure the current severity of depression symptoms that occurred a week before the interview. Each item assesses the intensity of one depression symptom on a scale of 1 to 4. In four of the items, scoring should be reversed. The internal consistency alpha coefficient, as stated by the author, was between 0.85 and 0.9, and test-retest reliability was between 0.45 and 0.7 (23, 24). The CES-D scores correlated well with ratings of symptom severity made by nurse-clinicians before and after patients had received treatment (0.56 and 0.69 to 0.75). Correlations of scores were high between CES-D and other measures of depressive symptoms (Lubin, Bradburn Negative Affect, and Bradburn Balance) and general psychopathology (Langner), rs>0.51 (23). The CES-D has been validated and translated into Tamil, Chinese, Italian, French and Korean

(25-29). It has also been translated into Slovenian and used in different studies, although the translation has not been validated (30-34). The internal consistency coefficient in Slovenian studies was 0.86 (30, 31, 34).

2.3.3 Spielberger State Anxiety Inventory

The STAI-S is a self-report, one-dimensional questionnaire that measures the presence and severity of current anxiety symptoms (state anxiety). It has 20 items. Responses for the STAI-S scale assess the intensity of current feelings 'at this moment' on a scale of 1 to 4. For 10 out of 20 items, scoring should be reversed. The sum of all the items is 20-80; a higher score indicates more severe anxiety. The cut-off point of 39-40 has been suggested to detect clinically significant symptoms. The internal consistency alpha coefficient was relatively high, ranging from 0.86 to 0.94, while test-retest reliability coefficients ranged from 0.34 to 0.62 (35, 36). Convergent validity correlation with the Beck Anxiety Inventory was between 0.47 and 0.64 (37). The STAI-S has been adapted and translated into 48 languages (35), including Slovenian. It has been used in different Slovenian studies with an internal consistency alpha coefficient of 0.7 (38, 39).

2.4 Data analysis

The reliability as internal consistency was estimated using Cronbach's alpha and item-to-total correlation if item deleted. The stability over time (test-retest reliability) was examined six weeks after the first administration of S-CDS using the interclass correlation coefficient (ICC).

The factor structure of the S-CDS was assessed using exploratory and confirmatory factor analysis. As all the items were on the Likert scale, the robust estimator of diagonal weighted least squares (DWLS) was used. The DWLS estimator is based on a polychoric correlations matrix, taking the non-normal nature of data into account. To assess the model fit, the following indicators and recommended criteria were used: chi-square (x2 close to zero; p>.05), root mean square error of approximation (RMSEA≤0.06), comparative fit index (CFI≥0.95), Tucker-Lewis index (TLI 20.95) and standardised weighted root mean square residual (SRMR≤0.08) (40, 41). The concurrent validity of the S-CDS was assessed using the Pearson correlation coefficient. Reliability and concurrent validity analyses were conducted using the IBM SPSS Statistics for Windows, Version 27.0. Statistical analyses for the confirmatory factor analysis were conducted in R 4. 1. 3 (R Foundation for Statistical Computing, Vienna, Austria) with the lavaan (42) and semPlot (43) packages.

3 RESULTS

3.1 Demographics

A total of 272 patients out of 393 included in the ANGST study (69.2%) met the inclusion criteria for the S-CDS validation study. The mean age was 66 (median=66; range=30-87) years. Of the 272 patients, 192 (71%) were male and 80 (29%) were female. The response rate to determine test-retest reliability and concurrent validity was 67.6%. The mean age of this sample was 66 (median=66; range=30-85) years. The characteristics of both samples are listed in Table 1.

Table 1. Characteristics of samples. Sample 1 comprises
all patients included in the validation study, while
Sample 2 comprises patients that meet the criteria
for estimation of stability over time and concurrent
validity study.

Variables	Sample 1 (n=272)	Sample 2 (n=184)
Gender		
Male	192 (71%)	131 (71%)
Medical diagnosis		
Coronary artery disease	7 (3%)	6 (3%)
Dysrhythmias	31 (11%)	23 (12.5%)
Valvular heart disease	14 (5%)	9 (5%)
Heart failure	14 (5%)	12 (6.5%)
Two or more heart diagnoses	206 (76%)	134 (73%)
ECA outcome		
Normal coronary arteries	160 (59%)	111 (60%)
PCI	70 (26%)	49 (27%)
CABG	42 (15%)	24 (13%)

ECA - elective coronary angiography; PCI - percutaneous coronary intervention; CABG - coronary artery bypass graft surgery.

Using the recommended cut-off values of 80 (mild to moderate depression) and 95 (severe depression), 90 (33.1%) patients had severe depression, 74 (27.2%) had mild to moderate depression, and 108 (39.7%) were non-depressed (18, 43). The mean total score for the S-CDS (possible range 26-182) in this test population was 84.6 (SD=24.5, median=84.0, range=31-158).

3.2 Validation

3.2.1 Reliability

Cronbach's alpha for the total scale was 0.92. All item-tototal correlation coefficients if item deleted were positive and ranged from 0.25 to 0.7. The ICC was acceptable for the total scale with a reliability of 0.71.

3.2.2 Validity

Exploratory factor analysis, using the principal axis factoring method and oblimin rotation, extracted six factors, which accounted for 61% of the variance. The six factors, labelled Anhedonia, Mood, Fear, Sleep, Cognition, and Suicidal Ideation, are presented with their respective loadings and internal consistency in Table 2. A factor loading of 0.3 was used according to the original article (9, 16). Out of 26 items, only one failed to reach the factor loading of 0.3, namely 'I can't be bothered doing anything much'. All factors demonstrated acceptable internal consistency ranging from 0.66 (Factor 6-Fear) to 0.84 (Factor 1-Anhedonia).

A confirmatory factor analysis was conducted based on a six-factor model suggested by our exploratory factor analysis. The standardised factor loadings ranged from 0.36 to 0.96 (Figure 2).



Figure 2. Summary of results of confirmatory factor analysis of the Slovenian version of the Cardiac Depression Scale.

Our model showed a good fit, with RMSEA ranging between 0.05 and 0.06. CFI and TLI were 0.99 and 0.98, indicating an acceptable model (Table 3).

ltem no	Item no	Factor 1 Anhedonia	Factor 2 Sleep	Factor 3 Mood	Factor 4 Suicidal Ideation	Factor 5 Cognition	Factor 6 Fear
4	I get pleasure from life at present	0.632	-0.099	-0.023	-0.046	0.017	0.028
12	I feel in good spirits	0.521	-0.012	0.136	-0.068	0.159	-0.212
19	I gain just as much pleasure from my leisure activities as I used to	0.716	-0.076	0.018	0.081	0.116	-0.046
1	I have dropped many of my interests and activities	0.413	0.066	0.17	-0.002	-0.017	0.197
16	I get hardly anything done	0.417	0.059	0.022	-0.223	0.022	0.262
3	I can't be bothered doing anything much	0.204	0.078	0.217	-0.035	0.149	0.036
6	I may not recover completely	0.443	-0.099	0.021	-0.192	-0.026	0.16
8	I am not the person I used to be	0.36	-0.174	0.275	-0.051	0.036	0.11
7	My sleep is restless and disturbed	0.108	-0.721	0.171	0.015	0.018	-0.033
9	I wake up in the early hours of the morning and cannot get back to sleep	0	-0.782	0.072	-0.034	-0.009	0.015
21	I become tearful more easily than before	0.088	-0.004	0.48	-0.098	-0.042	-0.033
22	l seem to get more easily irritated by others than before	-0.082	-0.118	0.827	0.04	0.003	0.027
24	I lose my temper more easily nowadays	-0.043	-0.037	0.765	-0.059	0.098	0.03
25	I feel frustrated	0.03	-0.062	0.684	0.028	0.084	0.06
10	I feel like I am living on borrowed time	0.275	-0.212	-0.06	-0.414	0.043	0.21
11	Dying is the best solution for me	0.007	0.049	0.107	-0.755	-0.011	-0.053
14	There is only misery in the future for me	0.027	-0.182	0.042	-0.6	0.149	0.047
2	My concentration is as good as it ever was	0.044	-0.046	0.018	0.059	0.649	0.05
15	My mind is as fast and alert as always	-0.028	0.072	0.045	-0.184	0.704	0.03
20	My memory is as good as it always was	-0.039	-0.023	0.007	0.079	0.795	-0.027
23	I feel independent and in control of my life	0.278	0.084	-0.033	-0.213	0.349	0.008
5	I am concerned about the uncertainty of my health	0.219	-0.189	0.1	0.186	0.112	0.416
13	The possibility of sudden death worries me	-0.058	-0.166	-0.052	-0.097	0.051	0.465
17	My problems are not yet over	0.196	-0.11	0.044	-0.192	0.128	0.395
18	Things which I regret about my life are bothering me	0.01	-0.07	0.172	-0.229	0.017	0.333
26	I am concerned about my capacity for sexual activity	0.028	0.105	0.11	0.055	0.026	0.367
	Cronbach's alpha	0.84	0.82	0.76	0.82	0.76	0.66

Table 2.Summary of results of factor analysis of the Slovenian version of the Cardiac Depression Scale after the extraction of six
factors and oblimin rotation (factor loadings >0.30 and those <-0.30 are in boldface).</th>

Table 3. Goodness-of-fit measures for the confirmatory factor analyses of the Cardiac Depression Scale (N=272).

Model	X² (df)	RMSEA (90% CI)	CFI	TLI	SRMR
Baseline model (Hare and Davis, 1996)	494.84 (291)	0.051 (0.043-0.058)	0.991	0.990	0.060
6-factor model, 2 dimensions	475.19 (268)	0.053 (0.045-0.061)	0.991	0.990	0.059
6-factor model, 1 dimension	487.25 (269)	0.055 (0.047-0.062)	0.990	0.989	0.060

 χ^2 - chi-square; df - degrees of freedom; RMSEA - root mean square error of approximation; CFI - Comparative Fit Index; TLI - Tucker Lewis Index; SRMR - standardised weighted root mean square residual. A total of 184 patients with cardiac disease were included in the analysis of concurrent validity. The scores of the S-CDS were correlated with the scores of the CES-D and STAI-S to determine the validity of the S-CDS with more generic measures of depression and anxiety. A statistically significantly moderate to high correlation between CES-D (r=0.62, p<0.001) and STAI-S (r=0.82, p<0.001) was found. We present the distributions of scores in this sample in Figure 3.



Figure 3. Scatterplot showing the distribution of the Slovenian Cardiac Depression Scale after elective coronary angiography scores (ECA) vs. the Center for Epidemiologic Studies Depression Scale-20 scores and the Spielberger State Anxiety Inventory scores.

4 DISCUSSION

The findings of our study suggest that the S-CDS is a valid and reliable instrument for measuring depressive symptoms in Slovenian patients with heart disease. The study population included a wide range of ages and a typical spectrum of heart disease diagnoses.

Using the recommended cut-off score of 80 for mild-tomoderate depression and 95 for severe depression (16, 18), the S-CDS demonstrated that 27.2% of the study population had mild-to-moderate depression and 33.1% had severe depression. These findings are comparable to previous studies and underscore the importance of assessing depression in cardiac patients (17, 20, 44, 45). Mean values of individual items ranged from 1.88 to 4.39 on a 7-point Likert scale. The item 'Dying is the best solution for me' had the lowest value. The one with the highest value was 'I am concerned about the uncertainty of my health'. In the S-CDS, the first item operationalises hopelessness and is one of the strongest factors for depression. The second factor operationalises uncertainty. The findings are consistent with the original article (9). To increase the clarity of the construct, the factors Uncertainty and Hopelessness were later relabelled as Fear and Suicidal Ideation (44).

The S-CDS had an acceptable level of internal consistency (Cronbach's alpha 0.92), and the item-to-total correlation coefficients, if item deleted, were positive (ranging from 0.25 to 0.7). According to the literature, we can reason that the S-CDS has good internal reliability (46). The S-CDS also had satisfactory reliability over time (ICC=0.71). All results are similar to those in the original and other CDS translations (9, 17, 19-21, 45, 47).

Factor analysis of the S-CDS recognised six factors that explained 61% of the variance. All the six new factors had acceptable reliability and had been extracted in other research studies (19, 44, 45). In the original study, seven factors were extracted (9). Factor 1-Anhedonia explains 35% of the variance and contains six items with factor coefficients greater than 0.30. A factor from the original scale (Inactivity) loaded on Factor 1, together with two items from Fear. A possible explanation for this result can be that the items from the Anhedonia and Inactivity factors measure similar content since, in the DSM-5, Anhedonia is defined by either a reduced ability to experience pleasure or diminished interest in engaging in pleasurable activities (10). The other five factors in the S-CDS were almost identical to those described originally (Sleep Disturbance, Cognition, Mood, Suicidal Ideation and Fear).

We conducted a confirmatory factor analysis to determine whether to use the S-CDS as a one- or two-dimensional scale. Based on reports from two such studies, we used six factors extracted from the exploratory factor analysis (21, 48). In the baseline model from Hare and Davis, seven factors and two dimensions were extracted (9). According to this model, we divided our six factors into two dimensions. We then re-ran the confirmatory factor analysis on six factors measuring one dimension. The goodness-of-fit measures were acceptable for both models. However, due to a very high correlation (0.93) between the two dimensions, the six-factor model with only one dimension was reasonable (Table 3). Studies conducted to validate the original and translated versions of the CDS also suggested using the scale as a one-dimensional model (17, 19, 44, 45).

We found one item not loading above 0.3 regarding the exploratory factor analysis. The item 'I can't be bothered doing anything much' was removed, as it may not assess potential depression among Slovenian patients with heart disease. The confirmatory factor analysis supported its removal from the S-CDS, showing acceptable goodness-of-fit measures for a six-factor model with 25 items.

We found the high correlation between the S-CDS and the STAI-S scores (r=0.82, p<0.001) stronger than the correlation between the S-CDS and the CES-D scores. The high correlation between the STAI-S and S-CDS suggests high comorbidity between depressive symptoms and anxiety in cardiac patients. A moderate correlation between S-CDS and CES-D suggests that the CDS measures adjustment disorder with depressed mood, while the CES-D is a measurement tool for depression symptoms. Our results are in line with other studies (9, 17, 19, 45, 47, 49, 50).

In our sample, the estimated internal consistency coefficients of the CES-D and the STAI-S were 0.73 and 0.94. The values represent good internal consistency of both questionnaires (51). The questionnaires used for determining concurrent validity were not validated in Slovenian. This is because Slovenia is a small country and we have a limited source of officially translated questionnaires. However, both are widely used in research (30-34, 38, 39). Furthermore, the validation study was a part of the ANGST study, for which we used five different questionnaires (including STAI-S). The CES-D was added for validation because it is in the public domain and is a good tool for measuring depressive symptoms in the general population and in clinical settings (23, 52). Both guestionnaires were previously used in cardiac patients for measuring depressive and anxiety symptoms (12, 45, 47, 53-55).

4.1 Strengths and limitations of the study

Our results are in line with the results published by other authors (9, 16-21). Out of 393 patients included in the ANGST study, only 121 (31%) did not meet the criteria for inclusion in the validation study. The response rate for the test-retest was high and the sample characteristics were similar to the characteristics of 272 patients included in the validation study. However, our study also has some limitations. For an objective assessment of anxiety and depressive symptoms, officially validated Slovenian language scales, specifically designed to assess anxiety and depressive symptoms in the medical population or a clinical evaluation, should be used. Consequently, we did not assess the sensitivity and specificity of the S-CDS.

4.2 Further research

Given that this is the first S-CDS assessment in Slovenian patients with CVD, it is important to assess its psychometric properties on different subsamples of the cardiac disease population, even in cardio-oncology (56). A comparison of the S-CDS with other measurement tools (PHQ-2, PHQ-9, Geriatric Depression Scale, Hospital Anxiety and Depression Scale), and clinical evaluation, would also be of interest. Additionally, the sensitivity and specificity of the S-CDS should be objectively assessed (16, 44) by using clinical evaluation or officially validated scales in the Slovenian language.

5 CONCLUSIONS

This study suggests that the S-CDS with 25 questions is a valid and reliable instrument for measuring depression symptoms in cardiac patients in Slovenia. It could be used in clinical and research settings for the early identification and more efficient management of depression.

CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

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ETHICAL APPROVAL

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