Original Research

Cross-cultural adaptation and validation of the Sinhala version of the Hospital Anxiety and Depression Scale (HADS) for patients diagnosed with ischemic heart disease (IHD) in Sri Lanka

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Abstract

Introduction: The Hospital Anxiety and Depression Scale (HADS) is a frequently used instrument to measure depression and anxiety symptoms among patients diagnosed with ischaemic heart disease (IHD). However, a Sinhala version of HADS for Sri Lankan IHD patients has not been validated in Sri Lanka.

Objectives: To translate, cross-culturally adapt and validate the HADS in a Sinhala-speaking Sri Lankan population with IHD

Methods: The Sinhala translation of HADS was conducted in four phases: forward translation, backward translation, patient testing and proofreading with the Mapi Research Trust guidelines. Content and consensual validation of the translated scale was conducted with the Delphi method, and the ratings were evaluated for consensus. The validated scale was administered to a sample selected using systematic sampling of 140 IHD patients attending medical clinics at a base hospital in Sri Lanka. Factor structure was verified with Confirmatory Factor Analysis (CFA) and reliability with internal consistency by Cronbach's alpha.

Results: The HADS Sinhala version showed good content and consensual validity. CFA proved that the uncorrelated two-factor structure was compatible with the original instrument (χ^2=156.98; df=76; p<0.001). The Confirmatory Fit Index (CFI) was 0.89, and the Root Mean Square Error of Approximation (RMSEA) was 0.09. The reliability analysis indicated Cronbach's alpha for depression and anxiety as 0.86 and 0.83, respectively.

Conclusions & Recommendations: The cross-culturally adapted HADS Sinhala version shows similar psychometric properties as the original instrument and can be used in future studies with confidence.

Keywords: *depression, anxiety, ischaemic heart disease, Hospital Anxiety and Depression Scale (HADS)*

Introduction

In Sri Lanka, the prevalence of IHD is increasing, leading to high hospital mortality rates (1). According to the latest WHO data published in 2020, deaths due to IHD in Sri Lanka has reached 22.66% of total deaths (2). Studies conducted in Sri Lanka indicate a concentration of risk factors in metropolitan areas and higher socio-economic groups, with an increasing prevalence among younger individuals (3).

Depression and anxiety are two mental health disorders highly prevalent in IHD patients and it has been identified that both disorders deteriorate the prognosis and quality of life (4). Moreover, it has been identified that symptoms of depression and anxiety can forecast the level of morbidity and mortality of patients with IHD (5). The early detection of these symptoms would facilitate the implementations of necessary interventions to reduce their clinical manifestations (6). A valid tool that determines the symptomatology of depression and anxiety is an excellent investment to reduce the burden of the disease.

The HADS is one of the commonest tools developed for patients admitted to hospitals with somatic illnesses (7). It is a self-administered instrument used to screen symptoms of depression and anxiety in a wide range of patients in general populations (8). HADS is comprised of two subscales; HADS-D and HADS-A which evaluate depression and anxiety symptoms, respectively. The HADS excludes physical symptoms, which can misinterpret the psychic symptoms of severe mood disorders (7). Excluding these physical symptoms is an excellent initiative since the symptoms like dizziness and palpitations can be misinterpreted as symptoms of IHD, not as symptoms of a severe mental disorder (9).

HADS has shown good psychometric properties in various populations such as patients with cardiac disease (9), patients with cancer (10), patients managed in primary care settings (11) , and general populations (12). Previous studies prove that HADS is widely used to detect depression and anxiety among patients with IHD. Further, it was suggested that the symptoms of depression and anxiety are used to predict IHD patients' future morbidity and mortality (5). Even though HADS is an excellent instrument to implement this purpose, a validated Sinhala version of HADS for IHD patients was not found in the Sri Lankan context though literature states that the HADS is validated in different populations in the country (13). Authors of these studies revealed that they have conducted only the judgmental validation and not the construct validity of the scale (14-15). Therefore, a validated HADS Sinhala version would be a good investment to identify symptoms of depression and anxiety among patients with IHD in Sri Lanka. Hence, the present study was carried out to cross-culturally adapt and evaluate the validity and reliability of the HADS for use in patients diagnosed with IHD in Sri Lanka.

Methods

A sample of patients aged 18-60 years who are clinically diagnosed with IHD by a physician with or without angiographic evidence within the last three months, attending medical clinics for treatment at a base hospital in Sri Lanka, were recruited for the study. Eligible patients were selected using systematic sampling till the sample size was fulfilled considering both sexes into the study and feasibility in infrastructure. Patients who had a previous/current clinical history of significant health problems (stroke, HIV/AIDS, cancer, kidney failure, heart failure) or physical disabilities (amputation, arthritis, cerebral palsy, upper limbs, multiple-sclerosis, muscular dystrophy, acquired spinal injury (paraplegia or quadriplegia), post-polio syndrome, spinal bifida) and who were critically ill and pregnant women were omitted to control for potential confounding. The sample size

was determined considering the 1:10 subjects per item (16). Therefore, the calculated sample size was 140 as there are 14 items in the HADS Sinhala version.

The HADS comprises two seven-item subscales; HADS-Depression (HADS-D) and HADS-Anxiety (HADS-A), to assess depression and anxiety, respectively. Each item of the HADS consisted of a four-point Likert response scale (0 to 3), and thereby each scale gets a summed score between 0 and 21. There is no single, generally accepted cut-off score for the HADS. In the original study, Zigmond and Snaith recommended two cut-off scores for both subscales: 7/8 for possible and 10/11 for probable anxiety or depression (7). The cut-off scores to measure depression and anxiety in the current study were obtained from a previous study (17).

Translation of HADS was conducted in four phases: forward translation, backward translation, cognitive debriefing (patient testing), and proofreading according to the Mapi Research Trust institute's guidelines (18). Firstly, in the forward translation phase, the original HADS was translated conceptually equivalent to Sinhala and agreed to a reconciled version by two native local translators who were bilingual. In the backward translation phase, a local professional translator who is a native English speaker translated the forward-translated questionnaire back into English. The backward version was compared with the source instrument to detect any misunderstandings, mistranslations, or inaccuracies in the first version of the scale.

The content and consensual validity of the HADS Sinhala version was evaluated with the Delphi technique (19) by an expert panel comprising mental health experts. It was conducted by rating each of the items on a scale of 0 (total disagreement) to 9 (full agreement) under three dimensions; (i) whether an item's conceptual meaning was retained after it was translated to Sinhala, (ii) whether the items were suitable to be used with patients diagnosed with IHD, and (iii) whether the instrument's items were culturally applicable to the Sri Lankan context. Concerning content validity, the panel of experts rated the instrument again from 0 to 9 under two dimensions: (i) whether each item was a suitable indicator of its scale/sub-scale, and (ii) whether the combination of items in the scale/sub-scale was suitable to test the concept evaluated by the scale/sub-scale. The ratings received from the first round of Delphi were summarized and evaluated for their degree of consensus. Further, a few revisions were made as per the comments received from the mental health experts. The second round of Delphi was conducted for the revised Sinhala version of HADS with the same experts, and the re-ratings were gathered again for a degree of consensus.

A pre-test was conducted among five patients, aged 18-60 years, and diagnosed with IHD. They were native speakers of Sinhala language and were selected from different age groups, and various educational levels, and attended medical clinics in a base hospital, Sri Lanka. Patient feedback was obtained on the ability to understand each of the items, clarity of written instructions, and response alternatives. In this process, some complex words in the items were replaced with simple words with a similar meaning to make them more meaningful for the patients. Proof-reading was conducted to avoid any typing, spelling or grammatical mistakes and it was conducted with a proof-reader whose native language is Sinhala and who is proficient in English. The CFA was performed on the full dataset (n=140) by the R (3.6) and R Studio (1.2) statistical software to assess the instrument invariance, and model-data fit and to verify the factorial structure of the original study by using the Lavaan Package (20) and the reliability by Psych Package (21). In CFA, necessary values were calculated and compared: the ratio of χ^2 to the degree of freedom (χ^2/df), CFI, Incremental Fit Index (IFI), Tucker-Lewis Index (TLI), RMSEA. The model was considered consistent with the experimental data at the values of CFI (22), TLI (23) and IFI $\geq$ 0.9, RMSEA (24)

less than 0.08 and χ^2/df less than five. The reliability of the HADS Sinhala version was verified with internal consistency, with Cronbach's alpha, and the coefficients of ≥0.7 were considered to possess a satisfactory level of internal consistency (25).

Results

The following principles were used in the Delphi process to select the items in the HADS Sinhala version; (i) the item/subscale was removed or replaced with other words to make it more meaningful if 70% or more of the re-ratings were in category 0-3. Further, if the item/ subscale was replaced with other words, another Delphi round was conducted for that item/sub-scale, and (ii) the item/subscale was kept the same if 70% or more of the re-ratings were in categories 4-6 and 7-9 (summative). The Delphi review for all the items/subscales was in the category 7-9. Thus, none of the items was removed and all items were culturally accepted in the HADS Sinhala version. However, according to the experts' suggestions, some items of the HADS Sinhala version were reworded to retain the conceptual meaning when translated into Sinhala.

The study sample population consisted of 140, which represented 39.3% (n=55) males. The average age was 53.87 years (SD=4.1), with the age range of 18-59. All the patients were Sinhalese (100%) and the majority (43.6%) had studied up to the General Certificate of Education (Ordinary Level) (Table 1).

The CFA was performed for the full dataset (n=140) to check the scale dimensionality and validity of the Sinhala version of HADS. The two-factorial structure of the HADS indicated a good model fit according to the CFA. The two-factor model indicated χ^2=156.98; df=76; p<0.001, CFI=0.89, TLI=0.868 and RMSEA=0.09 (90% CI: 0.068, 0.107), which confirmed the two-factor model with the obtained data (Figure 2). Table 4 shows the latent variables, and the significance of the items. The subscales of HADS-D and HADS-A indicated Cronbach alpha values of 0.86 and 0.83, respectively, which proves good internal consistency. Mean inter-item total correlations were identified as 0.475 for depression and 0.423 for anxiety items. Moreover, the values for 'alpha if item deleted' in both subscales of depression and anxiety were not improved (Table 2).

Table 3 shows that 15.7% of the IHD patients had borderline anxiety and 15.7% anxiety. Similarly, 10.0% of the IHD patients had borderline depression and 17.9% had depression. Further, 4.3% of the patients had both depression and anxiety.

Discussion

The HADS is an extensively used instrument to measure depression and anxiety among patients diagnosed with IHD within hospital settings (7). Translation of HADS was conducted as per the recommended 'Mapi Research Trust institute's guidelines. Further, the content and consensual validity of the HADS Sinhala version were evaluated with the Delphi technique by an expert panel comprising mental health experts. There is no agreement on how to modify an instrument for use in a different cultural context. Nevertheless, there is agreement that it is unacceptable to simply translate and apply a questionnaire in a different language setting (26).

CFA was conducted to verify the factorial structure and the two-factor structure of the HADS Sinhala version, which showed a good model fit. Hence, the two-factor model best fits and explains the items in the Sinhala version of HADS in the tested sample. The two-factor structure which was proposed in the original study has been identified as the prominent factor structure in many studies (27-28). Moreover,

some studies have emphasized a three-factor structure (29-30) while some highlighted a one-factor structure as the best-fitting model (31). The reason for these ambiguous factorial conclusions concerns the issues happening in translation (32).

Reliability analysis tested by Cronbach's alpha suggested excellent internal consistency of both HADS-D and HADS-A. These results are similar to previous studies (8, 33) conducted on the validation of HADS. All items in the two subscales' items were shown to be important to be kept, resulting in a reduction in 'alpha', if deleted.

The estimated total cases of depression and anxiety in the general population are as low as 4.1% and 3.4% in Sri Lanka (34). A study conducted among patients attending primary healthcare facilities in the Northern Province using the Patient Health Questionnaire-9 (PHQ-9) estimated a 17.8% prevalence of depression (35). However, there were no specific studies found on the depression and anxiety among patients with IHD in Sri Lanka. In the current study, out of 140 patients, 15.7% of the patients had anxiety and 15.7% had borderline anxiety, whereas 17.9% of patients had depression and 10.0% had borderline depression. Similarly, a study conducted among IHD patients who are registered and attending the outpatient department of Cardiac Centre in Kathmandu, Nepal indicated that 27.4% of the patients had anxiety and 19.6% had borderline anxiety. Similarly, 26.2% of the patients had borderline depression and 23.8% had depression (17). Hence, it is evident that depression and anxiety are common mental health issues in IHD patients who need assessment to improve their prognosis. Therefore, training and sensitization of primary health care staff, as well as strengthening their mental health care ability, are essential for early diagnosis of such mental health conditions. In addition, these primary healthcare personnel should be taught to identify these mental diseases at the level of primary healthcare and to administer first basic management, including counselling. Additionally, the referral mechanism and continuity of treatment must be assessed (35).

Conclusions & Recommendations

The cross-culturally adapted HADS Sinhala version indicates similar psychometric properties as the original instrument among patients with IHD. It can be used as a validated and reliable tool to assess symptoms of depression and anxiety among patients with IHD in clinical settings in the Sri Lankan context.

Table 1: Characteristics of the sample (N=140)

Characteristics		No.	%
Gender	Female	85	60.7
	Male	55	39.3
Race	Sinhala	140	100.0
Level of education	No Schooling	20	14.3
	Primary	55	39.3
	Ordinary Level	61	43.6
	Advanced Level	4	2.9

Table 2: Reliability analysis

Item	Internal consistency
Depression	α = 0.86
1	0.74
2	0.77
3	0.74
4	0.71
5	0.80
6	0.72
7	0.71
Anxiety	α = 0.83
1	0.78
2	0.73
3	0.69
4	0.67
5	0.74
6	0.73
7	0.65

Table 3: Level of anxiety and depression of the participants (N=140)

Level	No.	%
Anxiety		
No anxiety (0-7)	96	68.6
Borderline anxiety (8-10)	22	15.7
Anxiety (11-21)	22	15.7
Depression		
No depression (0-7)	101	72.1
Borderline depression (8-10)	14	10.0
Depression (11-21)	25	17.9
Total	**140**	**100**

Table 4: Latent variables, covariances and variances of anxiety and depression

	Estimate	Std.Err	z-value	P(>|z|)	Std.lv	Std.all
Latent variables:						
Anxiety						
1	0.776	0.078	9.917	0.000	0.776	0.761
2	0.736	0.088	8.372	0.000	0.736	0.671
3	0.652	0.086	7.596	0.000	0.652	0.621
4	0.645	0.101	6.376	0.000	0.645	0.538
5	0.762	0.086	8.856	0.000	0.762	0.700
6	0.606	0.067	9.093	0.000	0.606	0.714
7	0.551	0.085	6.504	0.000	0.551	0.547

Depression						
1	0.633	0.072	8.763	0.000	0.633	0.688
2	0.801	0.086	9.263	0.000	0.801	0.717
3	0.655	0.072	9.144	0.000	0.655	0.710
4	0.616	0.077	7.986	0.000	0.616	0.640
5	0.745	0.072	10.359	0.000	0.745	0.777
6	0.736	0.095	7.789	0.000	0.736	0.628
7	0.496	0.059	8.424	0.000	0.496	0.667
Covariances (Anxiety ~~ Depression):						
	0.277	0.092	3.010	0.003	0.277	0.277
Variances:						
Anxiety						
1	0.436	0.069	6.311	0.000	0.436	0.420
2	0.662	0.092	7.154	0.000	0.662	0.550
3	0.676	0.091	7.438	0.000	0.676	0.614
4	1.025	0.132	7.769	0.000	1.025	0.711
5	0.604	0.087	6.938	0.000	0.604	0.510
6	0.352	0.052	6.817	0.000	0.352	0.490
7	0.711	0.092	7.739	0.000	0.711	0.701
Depression						
1	0.446	0.062	7.233	0.000	0.446	0.527
2	0.606	0.086	7.028	0.000	0.606	0.486
3	0.421	0.059	7.080	0.000	0.421	0.496
4	0.546	0.073	7.492	0.000	0.546	0.590
5	0.364	0.057	6.434	0.000	0.364	0.396
6	0.833	0.110	7.548	0.000	0.833	0.606
7	0.306	0.042	7.354	0.000	0.306	0.555

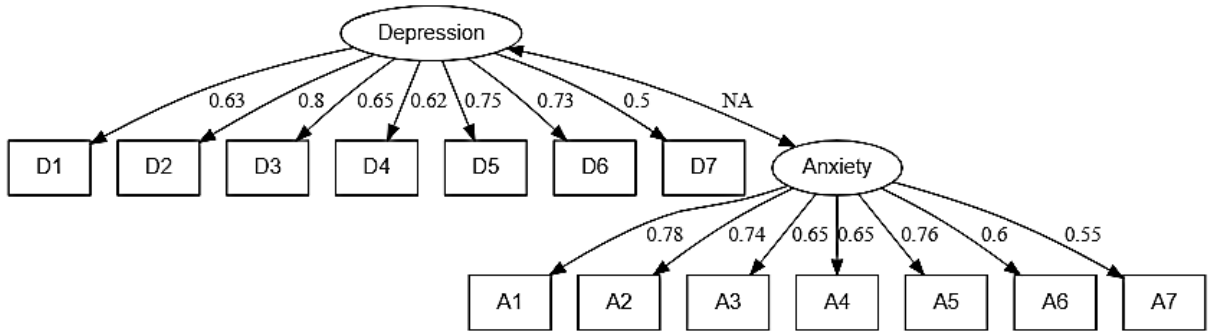

Figure 1: Two-Factor (uncorrelated) path diagram for CFA

Public Health Implications

- The validated HADS can be used to assess the depression and anxiety among the patients with IHD in Sri Lanka. Thereby, it can enhance the treatment adherence and their quality of life.

Author Declarations

Competing interests: The authors declare that they have no competing interests.

Ethics approval and consent to participate: Initially, permission was obtained from the GL-Assessment© and Mapi Research Trust to translate, cross-culturally adapt, and validate HADS into the Sinhala language. The permission to conduct the study was obtained from the Ethics Review Committee, Faculty of Medicine, University of Colombo, Sri Lanka, and the institutional permission was obtained from the Medical Superintendent of Base Hospital, Sri Lanka. Informed written consent was obtained from the patients who participated in the study.

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Author contributions: CG was involved in project implementation, data collection, analysis and preparing the manuscript, PZ, AB, NF & DJ in conceptualization, designing, project implementation, analysis and correcting the draft.

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