Original Article

Cross-cultural adaptation of the Morisky Green Levine medication adherence scale for use in patients with Ischaemic Heart Disease in Sri Lanka

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Abstract

Background

Ischaemic Heart Disease (IHD) is a major constituent of cardiovascular disease in the world at present and has become the leading cause of death in Sri Lanka. Poor adherence to medication in IHD is related to increased re-hospitalisation and mortality. Therefore, continuous assessment of medication adherence is extremely important among these patients. The Morisky Green Levine Medication Adherence Scale (MGLS) is a widely used instrument to evaluate medication adherence in the clinical setting. The study aimed to translate the MGLS into Sinhala and cross-culturally adapt it to the Sri Lankan setting.

Methods

A Delphi process was conducted with a panel of experts where content and consensual validity of the scale was assessed after translation, back translation and pre-testing of the original scale. The ratings received from the first round of the Delphi process were noted and the amended translation re-sent for a second round. The re-ratings were evaluated for the degree of consensus and Items for the MGLS Sinhala version were chosen based on the following criteria: (i) the item was reworded or removed if 70% or more of the re-ratings were in category 0–3. If reworded, the Delphi Process was repeated for that item, (ii) the item was kept with no change if 70% or more of the re-ratings were in categories of 4–6 and 7–9.

Results

No items were removed from the original scale. Some items were reworded according to the experts' suggestions to retain the conceptual meaning when translated into Sinhala. The Sinhala version of the MGLS exhibited adequate content and consensual validity.

Conclusion

The Sinhala version of the MGLS can be used in research, medication adherence evaluations and IHD prevention programmes in Sri Lanka.

Introduction

Ischaemic heart disease (IHD) is considered the foremost cause of mortality in terms of overall diseases, including cardiovascular diseases [1]. The prevalence of IHD among

individuals aged over 18 years, in 2013, was estimated to be 6.4%, 6.1%, 5.3% and 3.7% in Africans, Caucasians, Latinos and Asians respectively [1]. In Southeast Asia, the number of deaths due to IHD were projected to increase from 5.73 million to 8.14 million between 1990 to 2013 [2]. In Sri Lanka, IHD is recognised as the principal cause of morbidity as well as mortality [3]. Recent studies have noted that the incidence of IHD is increasing in the younger generation in Sri Lanka. Further, it was found that urban populations and those in the higher socioeconomic classes were more at risk [3].

Patients who are diagnosed with IHD are prescribed with secondary prevention medicines (SPMs) including aspirin, beta-blockers, angiotensin-converting enzyme inhibitors, statins, oral antiplatelets and angiotensin receptor blockers. National and international guidelines have endorsed the use of SPMs, and their advantages are well recognised [4,5,6]. However, low adherence to medication, especially to SPMs, constitutes an identified barrier to gaining the expected health benefits and non-compliant patients end-up with catastrophic health consequences, a poor quality of life and enhanced demand for health care [7,8,9]. Studies have identified reduced adherence levels, typically in the range of 33% to 50%, among IHD patients [8-13]. Poor adherence to SPMs leads to a 50%–80% increased risk of mortality and a 10%–40% increased risk of cardiac hospitalisation [7,14,15].

Medication adherence is defined as "the extent to which the person's behaviour (including medication-taking) corresponds with agreed recommendations from a healthcare provider" [16]. Medication adherence comprises beginning the medication treatment regime, continuation of a prescribed medication treatment regime and cessation of the prescribed pharmacotherapy [17]. Medication adherence is measured by direct and indirect means [18-21]. Measuring drug concentrations in blood or urine and measuring added biological markers through medications are considered as direct methods. Assessing accessibility of the medication, assessing clinical response, evaluating polycounts, utilising electronic medication monitors, measurement of the refilling prescriptions, patient questionnaires or medication diaries and evaluating physiological markers are considered as indirect methods [22].

Assessing medication adherence using patient questionnaires is one of the commonest, simplest and most economical methods used in clinical settings (18). The Morisky Green Levine Medication Adherence Scale (MGLS) is a frequently utilized, self-reported assessment of medication adherence [23-25]. It consists of four items with a yes/no response option and the scoring system ranges from zero to four. Three levels of medication adherence on MGLS (low, medium and high adherence with 3–4, 1–2 and 0 points respectively) have been suggested by the developers based on this score [25]. A dichotomous explanation of adherence grounded on MGLS is also frequently used with 0 points signifying perfect adherence and 1+ points signifying some level of non-adherence [26]. The concurrent and predictive validity of the original MGLS are

excellent, with an internal consistency reliability of alpha=0.61. This scale, when it is integrated into medical clinics can be used to strengthen adherence to medication [27]. The main focus of the present study was to translate the MGLS into Sinhala and cross-culturally adapt it to the Sri Lankan setting.

Methods

Ethics approval to conduct the study was obtained from the Ethics Review Committee, Faculty of Medicine, University of Colombo and authorisation to cross-culturally adapt the MGLS into Sinhala was obtained from the original authors. The translation process and the cross-cultural adaptation was based on universal guidelines [28]. While one professional translator translated the scale into Sinhala, a second professional translator back-translated it to English. The conceptual equivalence of the two translations was determined by a bilingual professional who determined whether both translations were congruent.

Once the translation process was finished, the first pre-test of the MGLS Sinhala version was conducted on four patients diagnosed with IHD at a Base Hospital. This was carried out in the form of a structured interview and the participants were questioned on the level of difficulty of the items, conceptual understanding of the items, suitable length for the instrument and their comfort level with the items. With feedback from the participants, the scale was revised and pre-tested on another group of patients diagnosed with IHD. Feedback was obtained on the instrument's formatting style, clarity of instructions, response alternatives and the level of difficulty of the items. Feedback obtained from both pre-tests were used to revise the scale.

After amendments based on the pre-tests was completed, a Delphi process was initiated to assess the content and consensual validity of the Sinhala version. The expert panel included two physicians, a cardiologist (clinical and interventional), a clinical psychologist and a registered pharmacist. Consensual validity was conducted to evaluate the relevance of the words used in the Sinhala version. In assessing consensual validity, each item was rated on a scale of 0 (total disagreement) to 9 (total agreement) (i) if its conceptual meaning was retained after translation (ii) if it was appropriate to be used with IHD patients (iii) if it was culturally relevant to Sri Lanka. For content validity, each item was rated on a scale of 0 to 9, as above, considering (i) if each item was an appropriate indicator of its scale and (ii) if the composite of items in the scale was adequate to measure medication adherence. Both the original English and the Sinhala versions were presented for validation. The scale was revised after the first round of the Delphi process and the ratings were repeated using the same panel after presenting the summarised ratings of the first round. The repeat ratings were further assessed for the degree of consensus. Items to be included in the Sinhala version of the MGLS were chosen through a content and consensual validation process, based on the following criteria: the item was reworded or removed if 70% or

more of the re-ratings were in category 0–3. If reworded, the Delphi Process was repeated for that item. The item was kept with no change if 70% or more of the re-ratings were in categories 4–6 or 7–9.

Results

A few discrepancies in the wording, between the Sinhala translation and the original scale were identified during the translation process. For instance, the item "Do you ever forget to take your medicine?" was changed to "Do you forget to take your medicine regularly?" Such discrepancies are common when translating cross-culturally. Pretesting the questionnaire helped to overcome difficulties and discomfort during administration. The proper length and difficulty of the items, any discomfort when responding and ease of understanding of concepts in the items were resolved at this stage.

The Sinhala version of the MGLS showed good content and consensual validity. No items were removed from the original scale but some items were reworded according to suggestions made by the experts so as to retain the conceptual meaning of the original scale.

Discussion

The aim of the study was to cross-culturally adapt the MGLS for a Sinhala speaking population in Sri Lanka. Cultural modifications are essential when adapting a scale to a culture different from that of its origin. Modification of the MGLS was first addressed during the translation process [29] where retaining the conceptual meaning between the original and the Sinhala version was endeavored [30]. Subsequent to the translation, a Delphi process was undertaken, which further enhanced the conceptual equivalence of the original scale and its Sinhala version [31].

A Delphi process was used for content and consensual validation of the Sinhala version of the MGLS. A Delphi process is based on the evaluation of an expert panel where items of a psychometric scale, such as the MGLS, is sent individually to each expert, who then responds in an anonymous and confidential manner [32] on the items' appropriateness to assess the construct under study. The study's expert panel included two physicians, a cardiologist, a clinical psychologist, and a registered pharmacist who provided discipline-specific, subject knowledge regarding the MGLS, while comparing the original with the Sinhala version. Their content and consensual validity ratings were collated into a comprehensive document and shared with the panel. The experts were then asked to reconsider and, if required, modify their initial rating in the light of the ratings given by the other experts. The re-ratings indicated that all the experts agreed on the validity of the Sinhala version of the MGLS. Therefore, the Sinhala version of the MGLS can be used confidently in research, medication adherence evaluations and IHD preventive programmes in the Sinhala speaking population in Sri Lanka. A similar validation study of the MGLS in another Asian country, Indonesia, yielded similar

results [27]. The Indonesian study was on a diabetic population, which indicates that the MGLS could be used in patient populations with diseases other than IHD, in Sri Lanka. Further research is need to validate the Sinhala version of the MGLS in various other treatment groups in Sri Lanka. This study is not without some limitations. For instance, the MGLS was not validated in Tamil nor in niche populations such as the elderly. Future studies may consider such validation.

Acknowledgements

References

1. Global, regional, and national age-sex specific all-cause and cause-specific mortality for 240 causes of death, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. Lancet. 2015 Jan 10;385(9963):117-71. https://doi.org/10.1016/S0140-6736(14)61682-2

2. Roth GA, Forouzanfar MH, Moran AE, Barber R, Nguyen G, Feigin VL, et al. Demographic and epidemiologic drivers of global cardiovascular mortality. N Engl J Med. 2015 Apr 2;372(14):1333-41. https://doi.org/10.1056/NEJMoa1406656

3. Tennakoon SU, Kumar BN, Nugegoda DB, Meyer HE. Comparison of cardiovascular risk factors between sri lankans living in kandy and oslo. BMC Public Health. 2010 Oct 29;10:654. https://doi.org/10.1186/1471-2458-10-654

4. Amsterdam EA, Wenger NK, Brindis RG, Casey DE, Ganiats TG, Holmes DR, et al. 2014 AHA/ACC Guideline for the Management of Patients with Non-ST-Elevation Acute Coronary Syndromes: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2014 Dec 23;64(24):e139-228. https://doi.org/10.1161/CIR.0000000000000134

5. Task Force Members, Montalescot G, Sechtem U, Achenbach S, Andreotti F, Arden C, et al. 2013 ESC guidelines on the management of stable coronary artery disease: the Task Force on the management of stable coronary artery disease of the European Society of Cardiology. Eur Heart J. 2013 Oct;34(38):2949-3003. https://doi.org/10.1093/eurheartj/eht296

6. Overview | Myocardial infarction: cardiac rehabilitation and prevention of further cardiovascular disease | Guidance | NICE [Internet]. [cited 2019 Dec 5].
Available from: https://www.nice.org.uk/guidance/cg17

7. Ho PM, Magid DJ, Shetterly SM, Olson KL, Maddox TM, Peterson PN, et al. Medication non-adherence is associated with a broad range of adverse outcomes in patients with coronary artery disease. Am Heart J. 2008 Apr;155(4):772-9. https://doi.org/10.1016/j.ahj.2007.12.011

8. Overview | Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence | Guidance | NICE [Internet]. [cited 2019 Dec 5]. Available from: https://www.nice.org.uk/guidance/cg76

9. Kolandaivelu K, Leiden BB, O'Gara PT, Bhatt DL. Non-adherence to cardiovascular medications. Eur Heart J. 2014 Dec 7;35(46):3267-76. https://doi.org/10.1093/eurheartj/ehu364

10. WHO | ADHERENCE TO LONG-TERM THERAPIES: EVIDENCE FOR ACTION [Internet]. WHO. [cited 2019 Dec 5]. Available from: https://www.who.int/chp/knowledge/publications/adherence_report/en/

11. Jackevicius, CA, Li P, Tu JV. Prevalence, predictors, and outcomes of primary non-adherence after acute myocardial infarction. Circulation. 2008 Feb 26;117(8):1028-36. https://doi.org/10.1161/CIRCULATIONAHA.107.706820

12. Rathore SS, Mehta RH, Wang Y, Radford MJ, Krumholz HM. Effects of age on the quality of care provided to older patients with acute myocardial infarction. Am J Med. 2003 Mar;114(4):307-15. https://doi.org/10.1016/S0002-9343(02)01531-0

13. Chodick G, Shalev V, Gerber Y, Heymann AD, Silber H, Simah V, et al. Long-term persistence with statin treatment in a not-for-profit health maintenance organisation: a population-based retrospective cohort study in Israel. Clin Ther. 2008 Nov;30(11):2167-79. https://doi.org/10.1016/j.clinthera.2008.11.012

14. Horwitz RI, Viscoli CM, Berkman L, Donaldson RM, Horwitz SM, Murray CJ, et al. Treatment adherence and risk of death after myocardial infarction. Lancet Lond Engl. 1990 Sep 1;336(8714):542-5. https://doi.org/10.1016/0140-6736(90)92095-Y

15. Chowdhury R, Khan H, Heydon E, Shroufi A, Fahimi S, Moore C, et al. Adherence to cardiovascular therapy: a meta-analysis of prevalence and clinical consequences. Eur Heart J. 2013 Oct;34(38):2940-8. https://doi.org/10.1093/eurheartj/eht295

16. ANONIMO, santé O mondiale de la, Organisation WH, Who. Adherence to Long-term Therapies: Evidence for Action. World Health Organization; 2003. 230 p.

17. Vrijens B, De Geest S, Hughes DA, Przemyslaw K, Demonceau J, Ruppar T, et al. A new taxonomy for describing and defining adherence to medications. Br J Clin Pharmacol. 2012 May;73(5):691-705. https://doi.org/10.1111/j.1365-2125.2012.04167.x

18. Osterberg L, Blaschke T. Adherence to medication. N Engl J Med. 2005 Aug 4;353(5):487-97. https://doi.org/10.1056/NEJMra050100

19. Farmer KC. Methods for measuring and monitoring medication regimen adherence in clinical trials and clinical practice. Clin Ther. 1999 Jun;21(6):1074-90; discussion 1073. https://doi.org/10.1016/S0149-2918(99)80026-5

20. Ho PM, Bryson CL, Rumsfeld JS. Medication adherence: its importance in cardiovascular outcomes. Circulation. 2009 Jun 16;119(23):3028-35. https://doi.org/10.1161/CIRCULATIONAHA.108.768986

21. Jimmy B, Jose J. Patient medication adherence: measures in daily practice. Oman Med J. 2011 May;26(3):155-9. https://doi.org/10.5001/omj.2011.38

22. Lars O, Terrence B. Adherence to Medication. N Engl J Med. 2005;11.

23. Unni EJ, Farris KB. Development of a new scale to measure self-reported medication non-adherence. Res Soc Adm Pharm RSAP. 2015 Jun;11(3):e133-143. https://doi.org/10.1016/j.sapharm.2009.06.005

24. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. Med Care. 1986 Jan;24(1):67-74. https://doi.org/10.1097/00005650-198601000-00007

25. Koschack J, Marx G, Schnakenberg J, Kochen MM, Himmel W. Comparison of two self-rating instruments for medication adherence assessment in hypertension revealed insufficient psychometric properties. J Clin Epidemiol. 2010 Mar;63(3):299-306. https://doi.org/10.1016/j.jclinepi.2009.06.011

26. Voils CI, Hoyle RH, Thorpe CT, Maciejewski ML, Yancy WS. Improving the measurement of self-reported medication non-adherence. J Clin Epidemiol. 2011 Mar;64(3):250-4. https://doi.org/10.1016/j.jclinepi.2010.07.014

27. Kristina SA, Putri LR, Riani DA, Ikawati Z, Endarti D. VALIDITY OF SELF-REPORTED MEASURE OF MEDICATION ADHERENCE AMONG DIABETIC PATIENTS IN INDONESIA. Int Res J Pharm. 2019 Aug 2;10(7):144-8. https://doi.org/10.7897/2230-8407.1007234

28. Jones J, Hunter D. Consensus methods for medical and health services research. BMJ. 1995 Aug 5;311(7001):376-80. https://doi.org/10.1136/bmj.311.7001.376

29. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. Spine. 2000 Dec 15;25(24):3186-91. https://doi.org/10.1097/00007632-200012150-00014

30. Coster WJ, Mancini MC. Recommendations for translation and cross-cultural adaptation of instruments for occupational therapy research and practice. Rev Ter Ocupacional Universidade São Paulo. 2015 Apr 24;26(1):50. https://doi.org/10.11606/issn.2238-6149.v26i1p50-57

31. Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. J Clin Epidemiol. 1993 Dec;46(12):1417-32. https://doi.org/10.1016/0895-4356(93)90142-N

32. Williams PL, Webb C. The Delphi technique: a methodological discussion. J Adv Nurs. 1994 Jan;19(1):180-6. https://doi.org/10.1111/j.1365-2648.1994.tb01066.x

33. AlGhurair SA, Hughes CA, Simpson SH, Guirguis LM. A Systematic Review of Patient Self-Reported Barriers of Adherence to Antihypertensive Medications Using the World Health Organization Multidimensional Adherence Model. J Clin Hypertens. 2012;14(12):877-86. https://doi.org/10.1111/j.1751-7176.2012.00699.x

34. Toll BA, McKee SA, Martin DJ, Jatlow P, O'Malley SS. Factor Structure and Validity of the Medication Adherence Questionnaire (MAQ) with Cigarette Smokers Trying to Quit. Nicotine Tob Res. 2007 May 1;9(5):597-605. https://doi.org/10.1080/14622200701239662

35. Pérez-Escamilla B, Franco-Trigo L, Moullin JC, Martínez-Martínez F, García-Corpas JP. Identification of validated questionnaires to measure adherence to pharmacological antihypertensive treatments. Patient Prefer Adherence. 2015 Apr 13;9:569-78. https://doi.org/10.2147/PPA.S76139

36. Tan X, Patel I, Chang J. Review of the four item Morisky Medication Adherence Scale (MMAS-4) and eight item Morisky Medication Adherence Scale (MMAS-8). Innov Pharm [Internet]. 2014 Jan 1 [cited 2019 Dec 9];5(3). https://doi.org/10.24926/iip.v5i3.347

37. Shalansky SJ, Levy AR, Ignaszewski AP. Self-Reported Morisky Score for Identifying Nonadherence with Cardiovascular Medications. Ann Pharmacother. 2004 Sep 1;38(9):1363-8. https://doi.org/10.1345/aph.1E071

38. Wang Y, Lee J, Toh MPHS, Tang WE, Ko Y. Validity and reliability of a self-reported measure of medication adherence in patients with Type 2 diabetes mellitus in Singapore. Diabet Med. 2012;29(9):e338-44. https://doi.org/10.1111/j.1464-5491.2012.03733.x