ORIGINAL RESEARCH

Psychometric Evaluation of Chinese Version of Adherence to Refills and Medications Scale (ARMS) and Blood-Pressure Control Among Elderly with Hypertension

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Objective: This study aimed to develop the ARMS-C and test its psychometric properties in hypertensive patients, to assess the level of medication adherence and to identify associated predictors for medication adherence and blood-pressure control among Chinese hypertensive patients.

Methods: Hypertensive elderly who met inclusion criteria were recruited from an aged-care facility in Henan Province between January 2019 and July 2019. The patients completed the adapted ARMS-C. The scale's factor structure, internal consistency, and construct validity were tested.

Results: Good internal consistency (Cronbach's α=0.89) and test–retest reliability (r=0.86, p<0.01) were obtained. Item-total correlation coefficients for the ten-item ARMS-C were 0.505–0.801. Factor analysis of construct validity identified two factors, explaining a total variance of 63.3%. Binary regression showed that patients with scores at level 2 ($\leq$20 ARMS-10 scores <30) were six times as likely to have blood pressure uncontrolled as those at level 1 (ARMS-10 scores <20, OR 6.6, 95% CI 1.7–25.1; p=0.006), and patients with scores at level 3 (ARMS-10 scores >30) were 115 times as likely to have blood pressure uncontrolled as those at level 1 (ARMS-10 scores <20,OR 115, 95% CI 9–1,470; p=0).

Conclusion: The ten-item ARMS-C is a reliable and valid self-reporting screening tool for adherence to medication and refills in elderly hypertensive Chinese patients.

Keywords: adherence, 10-item ARMS, hypertension, blood-pressure control

Background

Hypertension is a common disease in the elderly, and its prevalence increases with age.[1] It has been calculated that people aged 60 years and over will reach a third of the hypertensive population in Europe and North America in 2030[2] and that nearly half of Chinese adults have hypertension at 35–75 years of age.[3] Hypertension is a key factor in developing cardiovascular disease,[4] and uncontrolled blood pressure (BP) has been observed to be associated with cognitive decline, stroke, renal failure, increased risk of cardiovascular events, and mortality.[5] The benefit of BP lowering has already been proved, and it has been reported that a reduction of 10 mmHg in systolic BP can lower the risk of cardiovascular disease by as much as 20%, stroke by 27%, heart failure by 28%, and all-cause mortality by up to 13%.[6]

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Pharmacotherapy with lifestyle change remains the main component in hypertension management.[7,8] A China-based screening study revealed that less than a third of hypertensive patients were being treated and fewer than one in twelve in control of their BP.[3] Medication nonadherence is the leading cause of inadequate hypertension management and the major patient-related cause of inadequate BP control.[9] Improving medication adherence will increase treatment effectiveness and decrease the burden of health-care usage.[10] Identifying adherence-related behavior is a crucial step in improving medication intake and patient education,[11] and more targeted and specific measures can be developed through this process.

The Adherence to Refills and Medications Scale (ARMS) is a valid and reliable medication-adherence scale specially designed for the chronic-disease population. It is highly correlated with the most commonly used self-reported measure (the Morisky scale) and measures of refill adherence.[12] Currently, the ARMS is available in multiple languages and is used among patients with chronic illness, including diabetes, coronary heart disease, breast cancer, and hypertension.[13–16] However, all studies have been conducted in hospitals, and none have been applied to the elderly in the daily practice setting, especially for the elderly who live alone with a high risk of medication nonadherence.[17] Therefore, this study aimed to validate a Chinese translation and culturally adapted version of the ARMS-10 and to evaluate its psychometric properties among elderly hypertensive Chinese patients. Secondary objectives were to identify demographic and clinical factors that affect levels of medication adherence and BP control.

Methods
Participants
This was a randomized trial conducted in an aged-care facility in Zhengzhou, China. The study was performed between January 2019 and July 2019. Sociodemographic data were obtained from the facility. Patients who met the criteria were invited to participate. After that, questionnaires were administered and collected by staff working there without access to data. Oral explanations and handwriting assistance were offered by these staff. Participants were required to finish the questionnaires after they had signed a written consent form. Participation in the study was voluntary, and patients were free to withdraw from the study at any stage.

Inclusion and Exclusion Criteria
Patients included were aged 65 years or above, had been treated with at least one antihypertensive medicine for 6 months or more, and had been diagnosed with stage I or stage II hypertension (140–159/90–99 mmHg or 160–180/100–110 mmHg, respectively) by a professional physician. Patients who were conscious and able to communicate, took medications by themselves, and were willing to participate in the investigation were included. Exclusion criteria were accelerated hypertension, secondary hypertension, dementia, hemorrhagic stroke in the previous 6 months, estimated life expectancy of <6 months, and a requirement for daily nursing care. For the purposes of this study, the goal of controlled BP was defined in accordance with the 2011 NICE guideline for hypertension in adult patients. Patients' BP was considered controlled if those <80 years old with treated hypertension had BP <140/90 mmHg, those <80 years old with treated hypertension had BP <150/90 mmHg, or those with both hypertension and diabetes mellitus had BP <140/80 mmHg or <130/80 mmHg (in cases of any kidney, eye, or cerebrovascular damage).[18]

Sample Size
In accordance with the recommendation of five to ten participants per questionnaire item for assurance of accuracy[19] in estimating model parameters, a minimum sample of 100 was needed for the ten-item ARMS. A total of 120 participants were selected to participate in this study eventually to allow for a maximum of 20% of missing or incomplete questionnaires.

Ethical Considerations
Ethical approval was obtained from the First Affiliated Hospital of Zhengzhou University (approval 2019-KY-143). The study was performed in accordance with the Helsinki Declaration and the principles of good clinical practice, with respect for the rights and dignity of the participants. All participants provided written informed consent.

Questionnaire
The ARMS was developed by Kripalani et al, and its initial version was developed based on the Morisky and Hill–Bone questionnaires. The 12 items in the original questionnaire comprise two subscales: adherence to taking medications (eight items) and adherence to refilling prescriptions (four items). Each item is structured for response on a Likert scale, with responses of "none", "some", "most", or "all the time", which are given values of 1–4. Item scores are summed to

produce an overall adherence score of 10–40, with lower scores indicating better adherence.[12]

Adaptation of the Scale

The original 12-item ARMS has already been translated into Chinese by Emory University, and both the original English version and translated Chinese version of the instrument (ARMS-C) were deemed equally important for verifying that scale items in the two languages closely resembled each other.[12] A pilot study was conducted to evaluate patients' understanding of the ARMS-C, and 20 hypertensive elderly subjects were included from an aged-care facility in Henan Province, China. The results were reflected in the final version of the questionnaire and some modifications made, given the outpatient nature of the study and target population.[20] Items asking about refill medicine were adjusted: according to our investigation and patient feedback, a doctor's prescription is not required to refill hypertensive medicine and patients can easily get the medicine at a pharmacy with medical insurance. As such, we deleted items 4 and 11 from the original ARMS-12 after obtaining permission from the original author. The final version of the ARMS-10 was used for psychometric testing among elderly hypertensive Chinese patients in this study. A total of ten items in AMRS-C comprised two sub-scales: adherence to taking medication (seven items) and adherence to refilling medication (three items). Each item was structured for response on a Likert scale, with responses of "none", "some", "most", or "all the time", which were given values of 1–4. Item scores were summed to produce an overall adherence score of 10–40. Most items were written so that a lower score indicated better adherence.[12]

Statistical Analysis

Statistical analysis was conducted with SPSS 24. Differences in demographic data and outcome variables were assessed using frequencies and percentages. Internal consistency was assessed by Cronbach's α-coefficient and item-total correlation.[19] In general, items with a correlation of no less than 0.3 on the total scale are considered conceptually similar, and an α-value no less than 0.7 is considered to indicate adequate internal consistency.[21] The structure validity of the questionnaire was analyzed by confirmatory factor analysis with a varimax rotation–component matrix. Test–test reliability was conducted by calculating Spearman's correlation coefficient between the baseline test and retest after 10 days. Correlations of 0.7–0.9 were considered very good. Goodness-of-fit criteria, including χ^2:df ratio, root mean–square error of approximation, and goodness-of-fit index, adjusted goodness-

of-fit index, and comparative fit index, were used to determine the overall data-model fitness.[22] Binary logistic regression analysis using the enter method was conducted to determine factors that could predict medication adherence and BP control. Correlation and Hosmer–Lemeshow goodness-of-fit tests were done to select the best prediction model.[23]

Results
Participant Characteristics

A total of 120 patients were included in the study: 55.8% female with a mean age of 81.9±5.2 years. The majority of the study population were living alone (93.3%) with an

Table 1 Demographic and Clinical Characteristics of Subjects

	n=120 n(%)
Age, years	81.9±5.2
<80	32 (27%)
≥80	88 (73%)
Sex	
Female	67 (56%)
Male	53 (44%)
Marital status	
Single/widow	112 (93%%)
Married	8 (7%)
Education level	
Elementary school	52 (43%)
High school	24 (20%)
College or above	44 (37%)
Monthly medication expense (Chinese RMB)	
<200	58 (48%)
<500	40 (33%)
≥500	22 (18%)
Type of medical payment	
Totally reimbursed	11 (9%)
Partially reimbursed	92 (77%)
Totally self-paid	17 (14%)
Years taking antihypertensive medication	
<10	35 (29%)
10–20	39 (33%)
≥20	46 (38%)
Current types of medication per day	
<5	43 (36%)
5–10	52 (43%)
≥10	25 (21%)
Adverse drug events	
Yes	14 (12%)
No	106 (83%)

elementary education level (43.3%). Demographic and medi-cation-related characteristics of the subjects are shown in Table 1.

Internal Consistency and Reliability

Table 2 shows reliability-analysis results for the ARMS-C questionnaire. Item-total correlation coefficients for the ARMS-C were 0.505–0.801, indicating moderate–strong correlation. Cronbach's α for the ten-item scale was 0.89, which demonstrated good internal consistency.

Validity Analysis

Table 3 shows the results of factor analysis. The Kaiser–Meyer–Olkin test of sampling adequacy and Bartlett's test of sphericity were performed before exploratory factor analy-sis. Results were 0.79 for the Kaiser–Meyer–Olkin test, while Bartlett's test was significant (χ^2=707.3, p<0.001). Through principal-component analysis, two factors were identified, with a total variance of 63.3%. Factor 1 had an an eigenvalue of 1.91 and explained 37.59% of the variance. Factor 2 had an eigenvalue of 1.31 and explained 25.72% of the variance. The rotated factor analysis varied between 0.57 and 0.86. Test–retest reliability of the Chinese ARMS-10 was good at 10 days, with an ICC of 0.86 (p<0).

Risk Factors for Adherence Levels

High levels of adherence were present in 14.3% of the population. Patient sociodemographic characteristics were divided into three adherence categories: level 1 (ARMS-10 scores <20), level 2 (ARMS-10 scores 20–<30), and level 3 (ARMS-10 scores ≥30). Table 4 displays the results of binary logistic regression analysis assessing factors related to medication adherence. This model explained 17% of the change in levels of adher-ence. No variable was found to be an independent pre-dicator of medication adherence (p>0.05).

Blood-Pressure Control

BP was controlled in 33.3% of the study participants. Table 5 shows the results of binary logistic regression analysis identifying factors predicting BP control. About 35% of the change in BP and 73% accuracy of classification was explained by this model. Patients with ARMS-10 scores at level 2 were six times as likely to have BP uncontrolled as those at level 1 (OR 6.6, 95% CI 1.7–25.1; p=0.006), and patients with ARMS-10 scores at level 3 were 115 times as likely to have BP uncontrolled as level 1 (OR 115, 95% CI 9–1,470; p=0).

Table 2 Reliability Analysis for ARMS-10 Items in the Study Group (n=120)

Question	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Item-Total Correlation	Cronbach's α if Item Removed
1. How often do you forget to take your medicine?	22.3	19.5	0.801	0.866
2. How often do you decide not to take your medicine?	22.3	21.7	0.534	0.885
3. How often do you forget to get prescriptions for your medicine?	22.4	21.1	0.607	0.880
5. How often do you skip a dose of your medicine before you go to the doctor?	22.3	21.8	0.515	0.886
6. How often do you miss taking your medicine when you feel better?	22.2	21.8	0.505	0.887
7. How often do you miss taking your medicine when you feel worse?	22.4	20.4	0.699	0.874
8. How often do you miss taking your medicine when you are careless?	22.3	20.0	0.701	0.873
9. How often do you change the dose of your medicine to suit your needs?	22.1	21.5	0.576	0.882
10. How often do you forget to take your medicine when you are supposed to take it more than once a day?	22.3	19.8	0.749	0.870
*12. How often do you plan ahead and refill your medicines before they run out?	22.4	21.0	0.567	0.883

Notes: Questions reduced with permission from Kripalani S, Risser J, Gatti ME, Jacobson TA. Development and evaluation of the Adherence to Refills and Medications Scale (ARMS) among low-literacy patients with chronic disease. *Value Health*. 2009;12(1):118–123. Copyright Emory University. *This item was reverse-coded, ie, 1 = always, 2 = most of the time, 3 = sometimes, 4 = never.
Abbreviation: ARMS, Adherence to Refills and Medications Scale.

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Table 3 Factor Analysis (Varimax-Rotated Component Matrix) for ARMS in the Study Group (n=120)

Questions	Factor 1	Factor 2
1. How often do you forget to take your medicine?	0.800	
2. How often do you decide not to take your medicine?		0.707
3. How often do you forget to get prescriptions for your medicine?	0.662	
5. How often do you skip a dose of your medicine before you go to the doctor?		0.573
6. How often do you miss taking your medicine when you feel better?		0.733
7. How often do you miss taking your medicine when you feel worse?	0.855	
8. How often do you miss taking your medicine when you are careless?	0.824	
9. How often do you change the dose of your medicine to suit your needs?		0.752
10. How often do you forget to take your medicine when you are supposed to take it more than once a day?	0.834	
*12. How often do you plan ahead and refill your medicines before they run out?		0.624
Eigenvalue	1.908	1.305
Variance explained	37.593%	25.723%

Notes: Questions reduced with permission from Kripalani S, Risser J, Gatti ME, Jacobson TA. Development and evaluation of the Adherence to Refills and Medications Scale (ARMS) among low-literacy patients with chronic disease. *Value Health*. 2009;12(1):118–123. Copyright Emory University. *This item was reverse-coded, ie, 1 = always, 2 = most of the time, 3 = sometimes, 4 = never.
Abbreviation: ARMS, Adherence to Refills and Medications Scale.

Discussion

This study focused on the psychometric properties of the ARMS-10 adapted to Chinese and assessed the level of medication adherence among elderly hypertensive patients

Table 4 Binary Logistic Regression Analysis Identifying Factors for ARMS Score

	ARMS-10 Score <20, n=17	ARMS-10 Score ≥20, n=103	OR	95% CI	p
Age, years			1.00	0.90–1.12	0.99
Sex					
Female	12 (21%)	44 (79%)	1		
Male	5 (12%)	37 (88%)	2.55	0.77–8.42	0.13
Education level					
Elementary school or less	7 (19%)	30 (81%)	1		
High school	4 (18%)	18 (82%)	0.25	0.06–1.05	0.06
College or above	6 (15%)	33 (85%)	0.57	0.15–2.19	0.41
Duration, years					
<10	5 (20%)	20 (80%)	1		
10–20	5 (14%)	30 (86%)	0.89	0.19–4.20	0.89
≥20	7 (18%)	31 (82%)	0.77	0.11–5.15	0.78
Number of medications					
<5	8 (22%)	28 (78%)	1		
5–10	3 (7%)	38 (93%)	4.43	0.89–22.11	0.07
≥10	6 (29%)	15 (71%)	0.81	0.13–4.91	0.82

Notes: χ^2=11.80, df=8, n=120, p=0.58; R^2=0.17.
Abbreviations: BP, blood pressure; ARMS, Adherence to Refills and Medications Scale.

at an aged-care facility. The ARMS is one of the best self-reported questionnaires measuring medication adherence in elderly hypertensive patients.[12] It is crucial for both clinicians and health policy-makers to identify patients with poor medication adherence and BP control so that more specific interventions can be designed and implemented.

This study was conducted on elderly hypertensive patients. It demonstrated that the ten-item ARMS-C questionnaire had good psychometric properties and could be used to assess medication adherence in chronically ill patients as well as the original 12-item ARMS. Psychometric analysis revealed high consistency, reliability, and validity. The internal consistency of the ten-item ARMS-C for all levels of education was 0.89 compared to a Cronbach α of 0.75 in the ARMS-7 and 0.82 for a high level of literacy in the original ARMS-12. Item-total correlation coefficients for the ten-item ARMS-C were 0.505–0.801. On the original scale, item-total correlation coefficients were 0.34–0.59, so the ten-item ARMS-C had better psychometric properties than the original ARMS-12 in English and ARMS-7 in Turkish, regardless of patient education.[12,15] Health literacy is an important risk factor affecting adherence to treatment.[24] The original ARMS-12 included only patients with low literacy. In this study, nearly half the participants had no education or only primary education, which extends the original work so that it can be applied to patients with all level of literacy.

For the original English version of the ARMS-12, two factors were identified for factor analysis of construct validity. Factor 1 comprised ten items assessing adherence to taking medication with an eigenvalue of 6.67 and accounted for 55.6% of variance. Factor 2 had two items

Table 5 Binary Logistic Regression Analysis Identifying Factors for BP Control

	Controlled, n=40	Uncontrolled, n=80	OR	95% CI	p
Age, years			0.91	0.83–1.00	0.05*
Sex					
Female	28 (42%)	39 (58%)	1		
Male	12 (23%)	41 (77%)	1.95	0.77–4.96	0.16
Education level					
Elementary or less	16 (32%)	34 (68%)	1		
High school	8 (31%)	18 (69%)	2.25	0.62–8.17	0.22
College or above	16 (36%)	28 (64%)	1.45	0.50–4.23	0.49
Years taking antihypertensive medication					
<10	15 (43%)	20 (57%)	1		
10–20	12 (31%)	27 (69%)	1.86	0.53–6.56	0.34
≥20	13 (28%)	33 (72%)	1.26	0.27–5.85	0.77
Number of medications					
<5	19 (36%)	34 (64%)	1		
5–10	15 (29%)	37 (71%)	1.16	0.36–3.76	0.81
≥10	6 (24%)	19 (76%)	4.42	0.77–25.54	0.10
ARMS score					
<20	12 (71%)	5 (29%)	1		
20–30	27 (33%)	54 (67%)	6.60	1.74–25.08	0.006*
≥30	1 (5%)	21 (95%)	115.06	9.01–1,470.13	0*

Notes: χ^2=34.23, df=10, n=120, p<0.001; R^2=0.35. *Statistically significant.
Abbreviations: BP, blood pressure; ARMS, Adherence to Refills and Medications Scale.

with an eigenvalue of 2.69 and accounted for 22.4% of variance. In the validation of the 10-item ARMS-C, factor 1 (refilling medicine and dosage change) comprised five items, had an eigenvalue of 1.91, and explained 37.59% of the variance. Factor 2 (intentional nonadherence) comprised five items with an eigenvalue of 1.31 and explained 25.72% of the variance. Cronbach's α for factor 1 was 0.90, with an item-total correlation of 0.63–0.82. For factor 2, the item-total correlation was 0.5–0.6 with Cronbach's α of 0.77. Values computed from he ten-item ARMS-C were higher than those from the original version of the ARMS-12 (factor 1, α=0.79; factor 2, α=0.64).

Identifying predictors of poor adherence is crucial for disease management in elderly.[25] In this study, the overall percentage of medication adherence in hypertension was less than studies conducted in Saudi Arabia (22.5%)[23] and Buea, Cameroon (33.3%).[26] One possible explanation for this discrepancy is the existence of cultural differences between China and other countries,[27] and different self-reported adherence scales may also account for this.

We found that the majority of participants had poor medication adherence, while age, sex, education level, duration, and number of medications were not found to be correlated with medication adherence. Previous studies have reported inconsistent results between demographic variables and medication adherence,[23,28–30] while some support age, sex, number of medications, and medical conditions being independent predictors of medication adherence.[23,30,31] In line with our study, a study conducted in China also reported that education level was the only predicator of medication adherence,[27] while another study reported that age was the only factor that correlated with medication adherence among Chinese patients.[32] Age was not statistically significantly related to medication adherence (p=0.05) in this study, and larger samples may be needed to detect an association between age and medication adherence.

Regarding independent predictors for BP control, medication adherence was found to be the only factor related to BP management: patients with higher adherence were more likely to have their BP controlled. Previous studies have reported similar correlations between medication adherence and BP control.[12,23,31] Kripalani et al revealed that higher adherence was in line with better diastolic BP control and more optimal overall BP.

Therefore, the ten-item ARMS-C questionnaire can be regarded as a reliable and powerful self-report instrument in assessing medication adherence.

There were several limitations in this study. Firstly, it was conducted at just one aged-care facility, which may limit application to other settings. Secondly, only one questionnaire was used, so there is a lack of comparison between self-report and other measures, which may affect the reliability of our findings. Thirdly, only patients with hypertension were included, which may restrict the generalizability of these results. Future research should apply these scales to more diverse chronically ill patients.

Conclusion

The results of this study proved the used of the ten-item ARMS-C in Chinese population, which is highly recommended to hypertensive patients as a reliable screening tool for adherence to medication and refills. Future studies are need in Chinese population with other chronic disease, besides, more lager samples are required and its ability to identify predicators that might associate with enhanced adherence.

Acknowledgments

The authors would like to thank the authors of the original ARMS questionnaire for their kind permission, and all the patients in this study.

Disclosure

The authors report no conflicts of interest in this work.

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