Research Article

VALIDITY OF SELF-REPORTED MEASURE OF MEDICATION ADHERENCE AMONG DIABETIC PATIENTS IN INDONESIA

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ABSTRACT

Medication non-adherence in patient with diabetes has been associated with poor blood glucose control. A self-reported questionnaire consisted of 4 items Morisky Green Levine Adherence Scale (MGLS) has been developed and validated as well as widely used because of its convenience for patients. The objectives to the study were to examine the psychometric properties including internal consistency, test-retest reliability, convergent validity, and known-groups validity of the MGLS among patients with diabetes in Indonesia. A cross sectional study was conducted to collect the data, using a convenience sampling. A total of 250 patients with diabetes at four primary health centers in Yogyakarta Province were recruited and interviewed, during September to December 2017. Four items MGLS, sociodemographic data, and medical records were reviewed for data analysis. Internal consistency reliability was moderate (*Cronbach's* α = 0.651), as well as the test-retest reliability of the MGLS was moderate (*Spearman's* rank correlation = 0.425; $p < 0.001$). Regarding convergent validity, the MGLS had a moderate correlation with the 5 items Medication Adherence Report Scale ($r = 0.58$, $p < 0.01$). MGLS had excellent score in known group validity, showed a significant association between MGLS and fasting blood glucose level ($p < 0.001$). The sensitivity, specificity, positive predictive value, and negative predictive value of the MGLS were 65.5%, 46.7%, 46% and 63.5% respectively. The four items MGLS is satisfactory tool in measuring medication adherence among patients with diabetes in Indonesia, but future research could target the reasons of non-adherence and investigating its use in other chronic disease populations.

Keywords: Morisky Green Levine Adherence Scale; diabetes type 2; validation; Indonesia.

INTRODUCTION

Diabetes type 2 or called diabetes is a major health problem worldwide. Prevalence and high economic burden due to morbidity and mortality is gradually increasing¹. It has been predicted that around 380 people with diabetes will be occurred in 2025, mostly happened in developing countries². In Indonesia, based on National Health Survey data 2013 showed that the prevalence of diabetes among adults was as amount as 6.8%, the fourth rank in the world, after India, China, and United States³. Effective blood glucose control requires the adherence on medication taking behavior, as many studies highlighted that medication non adherence has been associated with poor blood glucose control^{4,5}. Micro and macro vascular complications of diabetes are caused by poor glycemic control^{6,7}. On average, the adherence rate of diabetes treatment ranges from 36% to 93%⁸⁻¹⁰.

Numerous direct and indirect tools have been proposed to assess and evaluate adherence on medication include pill counts, pharmacokinetics drug profile using blood and urine concentration, medication record, and self-reported instrument¹¹⁻¹³. However, no tool has been identified as the gold standard and appropriate for every patient adherence status and healthcare setting. A self-reported questionnaire has frequently been used¹⁴⁻¹⁶ because of its advantages such as inexpensive, most convenience, and ease of scoring.

The Morisky, Green, Levine Adherence Scale (MGLS) consisted of 4 items has been developed by Morisky, Green, and Levine which is exhibit adequate psychometric properties^{11,17}. The psychometric properties and the concurrent and predictive validity of a structured four-item self-reported adherence were good, with alpha reliability of 0.61. The MGLS therefore can be easily integrated into the medical daily visit and able to reinforce positive adherence behavior¹¹.

Because of the easy use of the MGLS as a medication adherence tool, we were interested in examining the reliability and validity in Indonesian setting among diabetic patients. The main objective of this study was to validate an Indonesian version of the MGLS and to examine its psychometric properties in patients with diabetes.

MATERIALS AND METHODS

A non-experiment cross sectional study design was used. The study was conducted in primary health centers as the first health referral for the community in Yogyakarta Province, Indonesia. A sample size of 250 patients attending the outpatient unit was participated, between September and December 2017.

Ethics and Informed Consents

The study was approved by an ethics committee (UGM Ethical Committee) no KE/FK/256/EC/2016. The study procedure was

explained to all eligible patients attending the outpatient diabetic unit. Inclusion was validated after written informed consent was signed by the patient.

Patients who fulfill criteria: have been diagnosed with type 2 diabetes at least one month, used hypoglycemic drug, completed medical record for clinical measurement, and able to communicate in Indonesian language were included in the study. Patients were excluded if they had complications affected the feelings or could not complete interviews.

The translated four-item MGLS, followed by five-item Medication Adherence Report Scale (MARS) were administered using face-to-face interview. Medical records of patients were reviewed for fasting blood glucose levels, number of hypoglycemic drugs, and presence of comorbidities including hypertension, hypercholesterolemia, hyperuricemia, and cardiovascular disease⁷.

Translation of MGLS

The four-item MGLS and the five-item MARS were translated followed the international guidelines^{12, 18}: (1) The forward translation of the original English version of the four-item-MGLS into Indonesian was undertaken by two qualified independent linguistic translators, who were both native speakers of Indonesian and proficient in English. Researchers reviewed the two primary versions and take a consensus on Indonesian draft version, (2) A bilingual expert then translated the draft version back into English. Translators and researchers compared the backward-translated English version with the original one in the terms of conceptual equivalence, (3) The translated questionnaire was piloted to 20 Indonesian diabetic patients. The questionnaire was completed and the questions were commented. The patients' comments were discussed by the researchers, and a final Indonesian version was completed and made available for the psychometric properties.

Statistical analysis

Descriptive statistics were used to explain demographic and patients characteristics as well as the MGLS adherence scores, using percentage and frequencies for the categorical variables and means, SD for the continuous variables. The level of adherence was categorized based on response of four items, with "yes" answer. If patients answer "yes" for 4 items, then they were categorized as low adherence. Those who answer "yes" for 1-3 items were categorized as medium adherence. High adherence was obtained when patients answer "yes" for 0 items. The *Chi-square* test was employed for categorical variables and *Kruskal-wallis* test was used to evaluate the differences between adherence groups.

Internal consistency was assessed using *Cronbach's alpha*, and *Spearman rank* correlation was used to assess test-retest reliability. Convergent validity was assessed using *Spearman rank* correlation between four-item MGLS scores and the scores on the five-item MARS. Known group validity was assessed through the association of MGLS categories and fasting blood glucose level using *Chi-square* test. Known group validity was assessed by using *Kruskal wallis* test, assuming that patients with poor blood glucose control also reported lower level of adherence. All analysis was performed using SPSS version 15.0. The significance level was set at $p < 0.05$.

RESULTS

Sociodemographic characteristics of the population

Of 250 respondents, majority of them was aged 60 years old, female (63%), low level of education (87%), and had been diagnosed of diabetes mellitus more than one year (90%). Most of patients got combination therapy of metformin and glimepiride (31%) and had comorbid of hypertension (87%) (Table 1).

Reliability

Regarding the internal consistency reliability, *Cronbach's alpha* test was 0.651 for the four items in MGLS, which is lower than acceptable value 0.7, indicates moderate reliability. Item 1 to 4 to total correlation coefficient ranged from 0.428 to 0.624 (Table 2). The test-retest reliability of four items MGLS indices moderate stability and reliability of the instrument with *Spearman rank* correlation coefficient of 0.425 ($p < 0.001$).

Convergent validity

A positive correlation between the MGLS and the five-item MARS was found ($r = 0.58$ ($p < 0.001$)). The moderate correlation indices moderate to good correlation between the two scores.

Known group validity

The *Chi-square* test shows a significant relationship between MGLS categories and blood glucose control ($p < 0.001$). About 64.5% of the low adherence patients were in the poor blood glucose control group, while 75.2% of those in the high adherence group were in the good blood glucose level. Table 3 shows the distribution of the three adherence groups according to poor and good blood glucose control.

Sensitivity and Specificity

To determine how good the MGLS performance to identify patients with poor blood glucose control and to provide information in clinical practice, sensitivity and specificity were evaluated. For the sensitivity and specificity analysis, only two groups of adherence scores were used, low adherence patients as one group, and medium and high adherence patients together as the second group. The MGLS sensitivity and specificity were 65.5 % and 46.7 %, respectively. The positive and negative predictive values were 46 % and 63.5 %.

Table 1. Characteristics of patients based on the groups of adherence

Characteristics	Total sample N=250	Low adherence N = 62(24.8%)	Medium adherence N = 79 (31.6%)	High adherence N = 109 (43.6%)	p
Age, Mean $\pm$ SD	60,42 $\pm$ 8,87	58.38 $\pm$ 9.10	60.26 $\pm$ 8.93	61.70 $\pm$ 8.55	0.169
Gender N (%)					
• Male	92 (36.8)	24 (9.6)	33 (13.2)	35 (14)	0.374
• Female	158 (63.2)	38 (15.2)	46 (18.4)	74 (29.6)	
Education level N (%)					0.253
• No education	30 (12)	5 (2)	14 (5.6)	11 (4.4)	
• Primary	60 (24)	18 (7.2)	17 (6.8)	25 (10)	
• Secondary	63 (25.2)	13 (5.2)	21 (8.4)	29 (11.6)	
• Tertiary	63 (25.2)	13 (5.2)	18 (7.2)	32 (12.8)	
• Vocational	15 (6)	6 (2.4)	3 (1.2)	6 (2.4)	
• Bachelor	17 (6.8)	5 (2)	6 (2.4)	6 (2.4)	
• Magister	2 (0.8)	2 (0.8)	0	0	
Employment status N (%)					0.972
• Not employed	172 (68.8)	42 (16.8)	55 (22)	75 (30)	
• Employed	78 (31.2)	20 (8)	24 (9.6)	34 (13.6)	
Diabetic duration N (%)					0.597
• Less than 3 months	4 (1,6)	1 (0.4)	2 (0.8)	1 (0.4)	
• 3-6 months	10 (4)	5 (2)	2 (0.8)	3 (1.2)	
• 7-12 months	12 (4,8)	3 (1.2)	3 (1.2)	6 (2.4)	
• > 1 year	224 (89.6)	53 (21.2)	72 (28.8)	99 (39.6)	
Blood glucose status N (%)					0.000
• Uncontrolled	106 (42.4)	40 (16)	39 (15.6)	27 (10.8)	
• Controlled	144 (57.6)	22 (8.8)	40 (16)	82 (32,8)	
Fasting blood glucose Mean $\pm$ SD					0.174
	152.74 $\pm$ 63,81	167.40 $\pm$ 68.84	171.73 $\pm$ 75.28	130.63 $\pm$ 41.71	
MARS 5 item score N(%)					0.000
• Low (5-10)	41 (16,4)	41 (16,4)	0	0	
• Medium (11-20)	78 (31,2)	21 (8,4)	56 (22,4)	1 (0,4)	
• High (21-25)	131 (52,4)	0	23 (9,2)	108 (43,2)	
Comorbid N (%)					0.379
• Hypertension	104 (87.4)	23 (19.3)	27 (22.9)	54 (45.4)	
• Hyperuricemia	3 (2.5)	1 (0.8)	1 (0.8)	1 (0.8)	
• Hypercholesterol	11 (9.5)	3 (2.5)	3 (2.5)	5 (4.2)	
• Heart disease	1 (0.8)	1 (0.8)	0	0	
Medication N (%)					0.805
• Metformin	99 (26.8)	24 (6.5)	32 (8.6)	43 (11.6)	
• Glimepiride	10 (2.7)	1 (0.3)	4 (1.1)	5 (1.3)	
• Metformin + Glimepiride	114 (30.8)	31 (8.4)	32 (8.6)	51 (13.8)	
• Metformin + Glibenclamide	27 (7.3)	6 (1.6)	11 (2.9)	10 (2.7)	
• Number of medication					
• 1	109 (43.6)	25 (10)	36 (14.4)	48 (19.2)	0.817
• >1	141 (56.4)	37 (14.9)	43 (17.2)	61 (24.4)	

Table 2. Reliability test of four items MGLS

Question no	Corrected item-total correlation	Cronbach's alpha if item deleted
1	0.458	0.572
2	0.437	0.564
3	0.595	0.637
4	0.450	0.663

Table 3. The relationship between adherence categories and blood glucose control groups

Blood glucose control (mg/dl)	Low adherence	Medium adherence	High adherence	Total (n)	p
Controlled (≤ 130)	22 (35.4)	40 (50.6)	82 (75.2)	144	0.000
Uncontrolled (>130)	40 (64.5)	39 (49.3)	27 (24.7)	106	
Total (n)	62 (100)	79 (100)	109 (100)	250	

DISCUSSION

To our knowledge, this study was the first to translate and validate the four-item MGLS in patients with diabetes in Indonesian setting. Our study was also attempt to assess medication adherence profile in diabetic patients using MGLS instrument.

Our study showed that the 4 items MGLS had good correlation between items as well as test-retest reliability achieved acceptable values. Moreover, our study resulted that four items MGLS had a moderate correlation with 5 items MARS resulting good convergent validity and good known group validity in Indonesian people with diabetes. Regarding the sensitivity and specificity, our results also found that the 4 items MGLS had good sensitivity (65%) but moderate in specificity (46%). Beyhaghi *et.al* tested the psychometric properties of their 4 items MGLS in atherosclerosis patients. They found that the 4 items MGLS was moderate reliability, with good concurrent and predictive validity and had good sensitivity¹⁷.

The MGLS had adequate test retest reliability (*Spearman rank r* = 0.425), in addition to good score of the internal consistency reliability (*Cronbach's α* >0.6). Our result is similar to the Beyhaghi *et.al*, that they reported the *Cronbach's α* of 0.45¹⁷. The previous study among Singaporean patients with diabetes showed that the four items MGLS had good test retest reliability (0.62) with good convergent validity and sensitivity (77.61%) but lower specificity (45.37%)¹⁸. Thai study also revealed that the self-reported adherence score was moderately reliable (0.61), with excellent test-retest reliability (ICC 0.83) and good convergent validity ($r=0.77$)¹⁹.

Our study resulted the specificity, specificity, positive predictive value, and negative predictive value of the MGLS were 65.5%, 46.7%, 46% and 63.5% consecutively. The study found high sensitivity but moderate in specificity and positive predictive value. Malaysia's study showed the similar result with our study, with scores of sensitivity and specificity were 77.6% and 45.4%, and positive and predictive values were 46.8% and 76.5%¹⁵. Again, our study is in accordance with the Thailand study with the same patient group shows that their sensitivity was high and specificity a bit lower¹⁹. This may be due to similarity of Malay and Southeast Asian culture and perception regarding their diseases and medication behavior. However, Morisky *et. al* showed that the original MGLS yielded a higher sensitivity and specificity than our study¹⁷. This may be due to the differences of Asian and western culture and the way of thinking of their population. The high sensitivity resulted in our study is useful in clinical practice, where health practitioners are more attention in detecting patients with poor blood glucose control and low adherence than controlled patients with high adherence²⁰.

In addition, moderate or lower sensitivity in our study could be caused by the dichotomous response on all items of the MGLS scale¹². Moreover, the choice of wording is using 'sometimes', which is not specific word and can be interpreted by patient as rarely missed a few doses or frequently forgot to take medication.

Our study did not measure the outcome using HbA1C due to HbA1C is not used on regular basis because of its high cost and

did not covered by universal coverage in Indonesia. HbA1C is the average blood glucose level achieved in the past 3 months that more accurate than the fasting blood glucose only²¹. Nevertheless, fasting blood glucose level is usual measures in Indonesia, but it is not related to medication adherence as HbA1C do. In this study, fasting blood glucose levels were significantly associated with MGLS scores (Table 3). Morisky *et. al* have stated that each item of the MGLS is measuring a medication taking behavior and related to health outcome¹¹. This statement in accordance with our study found that there was a good relationship between the MGLS and blood glucose level, as shown in known group validity ($p < 0.001$), highlighted the MGLS scores indirectly predict the blood glucose level.

Based on our study, the 4 items MGLS can be a useful tool to help in assessing adherence in any Indonesian setting where HbA1C is not available, since it is easy and simple to use and yielded acceptable reliability and validity. As for patients with high medication adherence and good blood glucose control, the MGLS can also be used to remind patients of the importance of continued adherence and the benefits of controlled blood glucose level.

Our results may limit the generalizability the findings to other patient groups and diseases. Therefore, more study to explore the adapted MGLS in Indonesian people with other clinical conditions is needed. In addition, further research on responsiveness and predictive validity properties is needed, since this study cannot conducted such measurement due to the cross-sectional study design.

CONCLUSION

The Indonesian version of the MGLS proved to be acceptable to patients as it is a non-complicated questionnaire can be face to face interviewed. In conclusion, the findings from this validation study indicate that the Indonesian version of the MGLS is reliable and valid instrument of medication adherence.

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