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The ARMS-D out performs the SDSCA, but both are reliable, valid, and predict glycemic control

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Abstract

Aims—The Adherence to Refills and Medications Scale (ARMS) has been associated with objective measures of adherence and may address limitations of existing self-report measures of diabetes medication adherence. We modified the ARMS to specify adherence to diabetes medicines (ARMS-D), examined its psychometric properties, and compared its predictive validity with HbA_{1C} against the most widely used self-report measure of diabetes medication adherence, the Summary of Diabetes Self-Care Activities medications subscale (SDSCA-MS). We also examined measurement differences by age (<65 vs. ≥65 years) and insulin status.

Methods—We administered self-report measures to 314 adult outpatients prescribed medications for type 2 diabetes and collected point-of-care HbA_{1C}.

Results—One of the 12-item ARMS-D items was identified as less relevant to adherence to diabetes medications and removed. The 11-item ARMS-D had good internal consistency reliability ($\alpha=0.86$), maintained its factor structure, and had convergent validity with the SDSCA-MS ($\rho=-0.52$, $p<0.001$). Both the ARMS-D ($\beta=0.16$, $p<0.01$) and the SDSCA-MS ($\beta=-0.12$, $p<0.05$) independently predicted HbA_{1C} after adjusting for covariates, but this association did not hold among participants ≥65 years in subgroup analyses. There were no differences in ARMS-D

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or SDSCA-MS scores by insulin status, but participants on insulin reported more problems with adherence on two ARMS-D items (i.e., feeling sick and medicine costs).

Conclusions—The ARMS-D is a reliable and valid measure of diabetes medication adherence, and is more predictive of HbA_{1C} than the SDSCA-MS, but takes more time to administer. The ARMS-D also identifies barriers to adherence, which may be useful in research and clinical practice.

Keywords

medication adherence; glycemic control; diabetes; validity; insulin

INTRODUCTION

Many adults with type 2 diabetes mellitus (T2DM) do not take their medications as prescribed [1, 2]; and suboptimal medication adherence has been associated with poor glycemic control [3–6], an increased risk of hospitalization [5, 7–9], early mortality [5, 9], and higher healthcare costs [8]. Improvements in diabetes medication adherence could improve the health outcomes of patients with diabetes [7, 10] and save \$661 million to \$1.16 billion annually [11]. While identifying nonadherence is a logical first step to intervention [12], more scientifically valuable and clinically feasible measures of diabetes medication adherence are needed for this purpose [13, 14].

More “objective” measures of medication adherence (e.g., pill-counts, pharmacy refills, and electronic monitoring systems) may seem to be the most valid and reliable ways to assess adherence, but there is inconsistent evidence to suggest the superiority of one measure over another [13]. Objective measures do not perform consistently better than self-report measures [15, 16] and are costly and often impractical for research and clinical purposes [13]. Self-report measures are more feasible and, though susceptible to social-desirability bias, have been similar to objective measures in their relationship to clinical outcomes, such as glycemic control [3, 17]. However, agreement between self-report measures varies widely and appears to be influenced by a measure’s characteristics [14, 17].

There remains a continued need to identify and evaluate measures of self-reported medication adherence for use with adults with T2DM [14]. Only two self-report measures that are used to assess medication adherence among adults with diabetes have been psychometrically validated against objective measures of refill adherence: the Summary of Diabetes Self-Care Activities medications subscale (SDSCA-MS) [17–19] and the Morisky scale [20]. The SDSCA-MS is the most widely used measure of diabetes medication adherence. However, many studies use only one item from the 2-item subscale [17–19, 21]. Gonzalez et al. [17] recently established the predicative validity of a 1-item version of the SDSCA-MS for HbA_{1C}, but, to our knowledge, predictive validity for the 2-item SDSCA-MS has not been established. The Morisky scale is a brief (4-item) self-report measure of adherence to *all* prescribed medications [20] that has predicted glycemic control among adults with diabetes [3, 6]. Although the SDSCA-MS and the Morisky scale assess adherence to medications quickly, they have limited variability in total scores (0–7 and 0–4, respectively) due to few items and response options. Moreover, they do not provide information on how to intervene once nonadherence is identified.

The identification of specific barriers to adherence may aid in tailoring and targeting adherence promotion interventions and in addressing reasons for nonadherence in clinical practice [12]. The Adherence to Refills and Medications Scale (ARMS) [22] is a longer (12-item) self-report measure of adherence that assesses one’s ability to take and refill medications under different circumstances, and, in turn, identifies barriers not assessed by

the SDSCA-MS or the Morisky scale. The original ARMS was developed to be a measure of adherence to *all* prescribed medications and has been associated with objective measures of refill adherence among a predominately African American, inner-city sample with heart disease. While 45% of the sample in which the ARMS was developed and validated had comorbid T2DM [22], the ARMS' psychometric properties for assessing adherence to diabetes medications, specifically, has not yet been explored.

There is also a lack of standardized and validated measures for patients on insulin for whom adherence may be an even greater problem [2]. Consequently, many studies use the same self-report measures to assess adherence to oral agents and insulin despite the unique challenges associated with insulin adherence. The ARMS may identify barriers to adherence that are more common among insulin users, and may therefore identify insulin nonadherence more effectively, or predict HbA_{1C} differently based on insulin status. In a sample of Japanese patients with T2DM, Mashitani et al. [23] found that self-reported insulin adherence (assessed with one item generated for the study) was only associated with glycemic control for patients younger than 65 years. It remains unclear if this age-related subgroup difference will persist in a different patient population, with validated self-report adherence measures, or if there is an age-related subgroup difference for participants on oral hypoglycemic agents.

To address these gaps and contribute to the literature on self-reported diabetes medication adherence, we modified the ARMS to specify adherence to diabetes medicines (ARMS-D), and then assessed its psychometric properties. First, we examined the ARMS-D's internal consistency reliability. Next, we confirmed a two-factor structure for the ARMS-D and related the ARMS-D to the most widely used measure of diabetes medication adherence (SDSCA-MS) and a measure of diabetes treatment satisfaction (DM-SAT) to establish its construct validity for assessing diabetes medication adherence, specifically. To improve the accuracy of the SDSCA-MS, we administered the instrument for each diabetes medication in the regimen, separately. Then, we compared the predictive validity of the ARMS-D and the SDSCA-MS (2-item and 1-item versions) with HbA_{1C}. Finally, we assessed these measures' performance by age (<65 vs. ≥65 years) and insulin status.

RESEARCH DESIGN AND METHODS

Sample and Recruitment

As part of a larger study testing predictors of medication adherence among adults with T2DM, we recruited outpatients receiving care from a Federally Qualified Health Center (FQHC) in Nashville, TN, USA from July 2010 through November 2012. Eligible patients were English- or Spanish-speaking adults (≥18 years) who were taking prescribed medications for T2DM. Trained research assistants (RAs) worked with clinic personnel each weekday to identify patients with a scheduled clinic appointment and T2DM, approaching patients in the waiting room to describe the study, and advertising the study on flyers in the clinic waiting room.

Data and Procedure

Interested and eligible patients were taken to a private room to complete informed consent and participate before and/or after their clinic appointment. To ensure responses were not confounded by participants' literacy limitations, the RA read all questions and response options aloud. A printed response scale was provided for each instrument and participants could respond verbally and/or point to their response. A bilingual RA recruited and administered the measures to Spanish-speaking patients. Clinic nurses administered a point-of-care HbA_{1C} test, and RAs obtained clinical information from participants' medical

records. Participation lasted approximately one hour and participants were compensated \$20. The Vanderbilt University Institutional Review Board approved all study procedures prior to enrollment.

Demographic and Diabetes Characteristics—We collected self-reported age, gender, race, ethnicity, income, education, insurance status, and duration of diabetes. We collected body mass index (BMI) and the number and type of prescribed diabetes medications from the medical record.

Adherence to Refills and Medications Scale for Diabetes (ARMS-D)—The original ARMS includes two subscales, an 8-item medication taking subscale and a 4-item refill subscale [22]. We modified the ARMS items to specify diabetes medicines (e.g., “How often do you forget to take your *diabetes* medicine(s)?”). Responses range from 1=“none of the time” to 4=“all of the time,” and are summed to produce an overall adherence score ranging from 12–48, with higher scores representing more problems with medication adherence [22]. First, the RA normalized adherence by reading the following statement: “It is common for patients with diabetes to report missing doses of their medicines or take less than the amount prescribed from time to time. Some people find it hard to take their medicines, either because of cost, or they decide to skip doses or reduce the amount to avoid side effects or for other reasons. We are most interested what you are actually doing. Don’t worry about telling us that you don’t take your medicine, or don’t take it all the time. We need to know *what is really happening for you*, not what you think we want to hear. Remember all your answers are confidential and won’t be shared with your doctor.” Next, the RA provided the following instructions before administering the ARMS-D: “I will now ask you how often you actually miss taking your diabetes medicines. If you are taking more than one diabetes medicine, please answer the questions by thinking about your daily experiences, on average, with all of the diabetes medicines you take, not just a certain medicine. There are no right or wrong answers.”

Summary of Diabetes Self-Care Activities medications subscale (SDSCA-MS)

—To improve the accuracy of the 2-item SDSCA-MS [18], the RA administered these items for each diabetes medication in the regimen. The RA used information in participants’ medical chart to help them identify a diabetes medication in their regimen. The participant could identify each diabetes medication by name or appearance (e.g., “the white pill”). Once identified, the RA administered the 2-item SDSCA-MS: (1) “On how many of the last seven days did you take this medication?” and (2) “On how many of the last seven days did you take the correct number of (pills/injections) for this medication?” [18]. Response options ranged from 0–7, with higher scores indicating better adherence. We scored the SDSCA-MS two ways to reflect the recommended scoring [18] and single-item applications we have seen in the literature [17–19, 21]. The SDSCA-MS was calculated as recommended, by averaging responses to both items [18]. However, because we asked these questions for each diabetes medication in the regimen, we calculated the average of the averages (i.e., across medications) to generate the 2-item SDSCA-MS score. Similarly, the 1-item SDSCA-MS was calculated by averaging responses to the first question across medications. In our sample, the 2-item SDSCA-MS had a high inter-item correlation for the first, second, and third diabetes medications queried (mean $r=0.86$; range 0.83–0.92, all $p<0.001$). Only four patients were prescribed more than three diabetes medications.

Diabetes Medication Satisfaction Tool (DM-SAT)—The 16-item DM-SAT (Merck & Co., Inc., 2006) is a reliable and valid measure of patients’ satisfaction with their diabetes treatment regimen [24]. Items ask respondents to rate their satisfaction with their diabetes medication regimen (e.g., “In the past four weeks, how satisfied have you been with...how

the diabetes medication(s) you are taking makes you feel physically?” or “...how much you have to plan your social life around your diabetes medication(s)?”). Response options range from 0=“not at all satisfied” to 10=“extremely satisfied” and a total score is calculated ranging from 0 to 100, with higher scores indicating more diabetes medication satisfaction.

Glycemic Control—A nurse administered a valid and reliable point-of-care HbA_{1C} (%) test [25].

Analyses

All statistical analyses were performed using Stata 12. Data were missing on one variable included in our analyses; five participants (1.6%) said “I don’t know” when asked how long they had diabetes. Casewise deletion can bias estimates [26] and these data were missing at random, so we used multiple imputation using chained equations [27, 28] to impute 10 datasets [29] following Graham’s guidelines [30, 31]. We imputed by insulin status for non-biased estimates of effect modification [31]. We used robust standard errors for all regression models for conservative estimates despite heteroskedasticity [32].

Internal Consistency Reliability—We assessed the internal consistency reliability of the ARMS-D with item-rest correlations (i.e., the correlation between the item and the scale formed from the remaining items) and Cronbach’s α . Item-rest correlations ≥ 0.30 indicate items are conceptually similar to other scale items and Cronbach’s $\alpha \geq 0.70$ indicates good internal consistency reliability [33, 34].

Construct Validity—To verify the ARMS-D’s two factor solution (i.e., medication taking and refill subscales) identified by Kripalani et al. [22], we performed a principal components factor analysis with a forced two-factor solution and Varimax-rotated component matrix. We used polychoric correlations because our data were non-normal and ordinal [35]. Items with loadings ≥ 0.40 were considered to have adequate commonality (i.e., share substantial variance with other scale items) [36]. We examined Spearman’s rho correlations to test whether the ARMS-D was associated with another measure of diabetes medication adherence (i.e., the SDSCA-MS for convergent validity) and a measure of diabetes medication satisfaction (i.e., the DM-SAT for concurrent validity).

Predictive Validity—We explored the predictive validity of the ARMS-D and the SDSCA-MS with HbA_{1C} in steps. First, we examined Spearman’s rho correlations between each measure and HbA_{1C} and obtained confidence intervals with bootstrapping to compare the strength of correlations across measures [37]. Second, we conducted a series of ordinary least squares regression models to assess the relationship between each adherence measure and HbA_{1C}. For each adherence measure, we conducted one bivariate model and four separate models to test if the relationship with HbA_{1C} was moderated by age (continuous), race, education, or income. Next, we used independent samples *t*-tests and Spearman’s rho correlations to test the bivariate relationships between demographic and diabetes characteristics (i.e., age, gender, race, income, education, BMI, diabetes duration, and insulin status) and HbA_{1C}. Those variables significantly related to HbA_{1C} were included as covariates in adjusted regression models assessing both the independent relationship between each adherence measure and HbA_{1C} and the proportion of variance in HbA_{1C} each adherence measure explained.

Differences by Age and Insulin Status—We performed adjusted regression models to assess whether the adherence measures predicted HbA_{1C} differently based on age (<65 vs. ≥ 65 years). Then, we conducted Mann-Whitney U tests to assess whether insulin status was associated with each of the adherence measures. We performed adjusted regression models

with insulin status as an interaction term with each adherence measure, separately, to assess whether the adherence measures predicted HbA_{1C} differently based on insulin status. To understand any significant interaction effects, we conducted post-hoc adjusted regression models with covariates to determine simple slopes for subgroups [38].

RESULTS

Of the 588 patients with T2DM who arrived for a clinic appointment, 86% were approached by a RA. Of those approached, 11% declined participation without being screened for eligibility and 27% were ineligible (74 did not speak English/Spanish, 52 were not prescribed T2DM medications, and 9 were excluded due to an intellectual disability, auditory, or speech impairment, or because a caregiver administered all of their medications, or because they did not have a social security number required for reimbursement). Thus, we consecutively enrolled 314 participants.

Participants had an average age of 51.8±11.7 years; 65% were female; 37% were Caucasian/White, 53% were African American/Black, and 10% reported another race. Eight percent reported Hispanic ethnicity and 11 interviews were conducted in Spanish. Nearly half of the sample (45%) were uninsured; 32% had less than a high school degree; and 45% had incomes less than \$10K. The sample's average HbA_{1C} was 8.2%±2.2% (66±0.5 mmol/mol) and 66% had suboptimal glycemic control (HbA_{1C} ≥7.0% or 53mmol/mol). Almost half (46%) were on insulin (Table 1).

Internal Consistency Reliability

Item 9 on the ARMS-D (“How often do you change the dose of your diabetes medicine(s) to suit your needs?”) had an item-rest correlation of 0.20 with the total and 0.23 with the medication taking subscale. Because patients with diabetes are often advised to adjust their insulin based on blood glucose values or carbohydrate intake [39], we suspected endorsement of this item might reflect adherence rather than nonadherence for certain patients. All other items had an item-rest correlation >0.40. Therefore, we removed item 9 from the scale, resulting in the 11-item ARMS-D (see Table 2 for items). The 11-item ARMS-D had good internal consistency reliability (item-rest correlations 0.41–0.66; Cronbach's α =0.86), and the medication taking and refill subscales had good (α =0.84) and acceptable (α =0.71) internal consistency reliabilities, respectively.

Construct Validity

The ARMS-D items clustered as expected (Table 2). The 7 items on the medication taking subscale [22] loaded onto factor 1 (eigenvalue=6.06) with an average loading of 0.75 and explained 55% of the variance in the ARMS-D total. The 4 items on the refill subscale [22] loaded onto factor 2 (eigenvalue=1.26) with an average loading of 0.77 and explained 11% of the variance in the ARMS-D total. Uniqueness values were low, indicating adequate commonality between items in the ARMS-D total and subscales. Finally, as evidence of convergent and concurrent validity, the ARMS-D total and subscales were each significantly associated, in the expected direction, with the 2-item and 1-item SDSCA-MS and the DM-SAT (Table 3).

Predictive Validity

The proportion of participants reporting less than perfect adherence was: 79% on the ARMS-D total (70% on the medication taking subscale and 57% on the refill subscale), 39% on the 2-item SDSCA-MS, and 27% on the 1-item SDSCA-MS. Each adherence measure was associated with HbA_{1C} in the expected direction (Table 3). Confidence intervals overlapped, indicating no significant differences in correlations between the adherence

measures and HbA_{1C}. In unadjusted regression models, the ARMS-D total explained more than twice the variance in HbA_{1C} than either the 2-item or 1-item SDSCA-MS (5.5% vs. 2.1%; Table 4). Neither age (continuous), race, education, nor income moderated the relationships between the adherence measures and HbA_{1C}.

Age (continuous), race, diabetes duration, and insulin status were each significantly associated with HbA_{1C} and were included as covariates in adjusted regression models. These covariates alone explained 19.2% of the variance in HbA_{1C}. As shown in Table 4, each adherence measure was independently associated with HbA_{1C} in adjusted models, and accounted for a significant amount of unique variance (i.e., incremental R²). The ARMS-D total resulted in a 2.4% increase in R², representing a 12.5% increase in the amount of variance explained by the covariates alone, whereas the 2-item SDSCA-MS resulted in a 1.5% increase in R² and a 7.8% increase in the amount of variance explained by the covariates alone.

Differences by Age and Insulin

Relationships between each adherence measure (i.e., ARMS-D total and subscales, 2-item and 1-item SDSCA-MS) and HbA_{1C} were significant among participants younger than 65 years, but none of the adherence measures were associated with HbA_{1C} among participants who were 65 years or older. Insulin status was unrelated to scores on each of the adherence measures. However, compared to participants on oral agents only, participants on insulin reported more problems with adherence on two ARMS-D items: “How often do you miss taking your diabetes medicine(s) when you feel sick?” ($p<0.05$) and “How often do you put off refilling your diabetes medicine(s) because they cost too much money?” ($p<0.01$). The ARMS-D total predicted HbA_{1C} significantly better for participants on insulin than participants on oral agents only (interaction term $\beta=0.13$, $p<0.05$). The ARMS-D medication taking subscale trended toward a significant interaction effect (interaction term $\beta=0.11$, $p=0.10$). The 2-item and 1-item SDSCA-MS did not predict HbA_{1C} differently based on insulin status.

In post-hoc analyses, the relationship between the ARMS-D total and HbA_{1C} was only significant for participants on insulin. However, most participants on insulin (85%) also had an HbA_{1C} $\geq 7.0\%$ or 53mmol/mol (compared to 51% of participants on oral agents only; $\chi^2=40.62$, $p<0.001$), so we stratified the sample (HbA_{1C} $\geq 7.0\%$ or 53 mmol/mol vs. HbA_{1C} $<7.0\%$ or 53 mmol/mol) and tested whether insulin status remained an effect modifier in either subgroup. Neither interaction was significant, suggesting suboptimal glycemic control may be confounding the insulin status moderation effect in the full sample.

DISCUSSION

In a sample of diverse, low income adults with T2DM, we examined the internal consistency reliability of the ARMS for measuring *diabetes medication adherence* (ARMS-D), and its construct validity with the SDSCA-MS and a measure of diabetes treatment satisfaction (DM-SAT). One of the ARMS-D items was identified, empirically and conceptually, as less relevant to adherence to diabetes medications and removed. The 11-item ARMS-D total and subscales were internally consistent and were each associated with the SDSCA-MS and the DM-SAT. The ARMS-D total and subscales and the 2-item and 1-item SDSCA-MS were each associated with glycemic control after adjustment for demographic and diabetes characteristics also associated with HbA_{1C}. We also examined each measure’s performance by age and insulin status. We found that the adherence measures were associated with HbA_{1C} for participants who were younger than 65 years of age, but not for participants who were 65 years of age or older. We also found that the ARMS-D was more strongly related to HbA_{1C} for participants who were prescribed insulin than for participants who were

prescribed oral hypoglycemic agents only. The ARMS-D total and subscales were each associated with glycemic control, regardless of participants' race, education and income, and each independently predicted glycemic control when adjusting for demographic and diabetes characteristics also associated with HbA_{1C}.

We also replicated and extended psychometric information for the SDSCA-MS. We found a higher inter-item correlation for the 2-item SDSCA-MS than previously reported [18], and a higher correlation between the 1-item SDSCA-MS and HbA_{1C} than previously reported [17], which may be because we administered the SDSCA-MS for each diabetes medication separately. To our knowledge, no published study to date has used this approach. This is also the first study, to our knowledge, to establish predictive validity of the 2-item SDSCA-MS and to show that the 2-item and 1-item SDSCA-MS independently predicted HbA_{1C} after adjusting for covariates.

The respective strengths and weaknesses of the ARMS-D and the SDSCA-MS must be weighed against the goals and challenges of the clinical and research settings in which they will be used. The SDSCA-MS predicts HbA_{1C} and is brief. Both the 2-item or 1-item versions can quickly provide valuable information in busy clinical environments. However, the SDSCA-MS was less sensitive to nonadherence than the ARMS-D (79% reported less-than-perfect adherence on the ARMS-D total and 39% on the 2-item SDSCA-MS). Self-reported adherence measures, such as the ARMS-D and the SDSCA-MS, should only be administered in clinical practice when appropriate responses to nonadherence are in place. Providers must be increasingly proactive in identifying and addressing barriers to medication adherence among adults with diabetes to improve care quality and meet Medicare & Medicaid Services Five-Star Quality Rating benchmarks for patient adherence [12]. In clinical practice, administration of the ARMS-D may allow for identifying the type (i.e., refill or dose) of nonadherence, discussing strategies to overcome barriers to adherence, adjusting the regimen if nonadherence is related to side effects or having to take multiple doses, and/or prescribing more affordable generic medications or leveraging drug assistance programs to overcome cost-related nonuse. In research, the ARMS-D may be more likely to identify relationships between medication adherence and clinical outcomes, as the ARMS-D explained more variance in glycemic control in unadjusted and adjusted analyses than both the 2-item and 1-item SDSCA-MS did. The ARMS-D may also have utility in interventions that attempt to identify and overcome specific barriers to adherence.

The 4-item ARMS-D refill subscale may present an ideal compromise. It is briefer than the 11-item ARMS-D total, but identified more instances of nonadherence than both versions of the SDSCA-MS. The 4-item ARMS-D refill subscale may be a useful screening tool to identify patients with suboptimal adherence, and providers can elect to administer the 7-item ARMS-D medication taking subscale to patients reporting less-than-perfect refill adherence. Moreover, the ARMS-D refill subscale was the most predictive measure of HbA_{1C} in unadjusted analyses. For every 3-point improvement (i.e., 1="none of the time" vs. 4="all of the time" on one item) on the ARMS-D refill subscale there was an associated 0.63% decrease in HbA_{1C} as compared to a 0.17% decrease in HbA_{1C} associated with each 1-point improvement (i.e., one more day adherent) on the 2-item SDSCA-MS. Other studies using self-report measures [3, 6, 40] and objective measures [17, 41] of medication adherence have reported similar relationships between adherence and HbA_{1C}. Seemingly modest correlations reflect the myriad factors affecting glycemic control (e.g., diet, exercise, age, diabetes duration, comorbidities) rather than the limitations of any single measure. Comparatively, Aikens and Piette [6] found that self-reported medication adherence on the 4-item Morisky scale [20] predicted glycemic control 6 months later, even when adjusting for baseline glycemic control and relevant covariates. We did not include the Morisky scale in our analyses, but the bivariate relationship between the 4-item Morisky scale and HbA_{1C}

at baseline [6] was very similar to that reported here for the 4-item ARMS-D refill subscale ($\beta=0.25$, $p<0.001$ and $\beta=0.21$, $p=0.001$, respectively). Finally, we tested whether participants' age (<65 vs. ≥ 65 years) and insulin status affected performance of the ARMS-D and the SDSCA-MS. Our finding that ARMS-D and SDSCA-MS scores were not associated with HbA_{1C} among participants who were 65 years or older replicates and extends Mashitani et al.'s [23] finding with a diverse sample of patients and different medication regimens (i.e., oral agents only, both oral agents and insulin, and insulin only). Future research should explore age-related subgroup differences in the relationship between objective measures of adherence and HbA_{1C} to determine whether this difference is due to inaccurate self-reporting by older patients (as suggested by Mashitani et al. [23]) or if hypoglycemic medications are less effective among older patients. While insulin status was not associated with the ARMS-D total or subscales or the 2-item or 1-item SDSCA-MS, participants on insulin did score higher on two ARMS-D items than participants on oral agents only. In addition, the ARMS-D total predicted HbA_{1C} significantly better for participants on insulin than participants on oral agents only, but we were unable to appropriately assess effect modification of insulin status alone because most participants on insulin also had suboptimal glycemic control. In a sample with less insulin users who had suboptimal glycemic control, Aikens and Piette [6] found that insulin status did not moderate the relationship between self-reported adherence (measured by the 4-item Morisky scale [20]) and HbA_{1C}. Future work is needed to examine insulin status as an effect modifier of ARMS-D performance in a sample with less overlap between insulin status and suboptimal glycemic control. Nonetheless, it is common for individuals with T2DM who have sustained suboptimal glycemic control to be prescribed insulin [42], and the ARMS-D was more strongly associated with HbA_{1C} in this subgroup.

Our cross-sectional design limited our ability to ascertain if the SDSCA-MS and the ARMS-D measures predict future glycemic control. We were also unable to assess test-retest reliability, compare these measures' concordance with objective measures of adherence, or assess the degree of social-desirability bias. Furthermore, results may differ from those presented here if administration of these measures does not include a statement normalizing nonadherence, if the SDSCA-MS is not administered for each medication separately, or if a provider (rather than an RA) administers the measure. Finally, our sample population had low socioeconomic status and these relationships may be different in other patient populations.

Despite these limitations, our findings, along with others' [6, 14, 17, 19], support the utility of self-report measures of diabetes medication adherence. Both the ARMS-D and SDSCA-MS predict glycemic control, and the ARMS-D has the additional benefit of identifying barriers to adherence. In our sample, forgetfulness and carelessness were the most frequently reported barriers to adherence, and feeling sick and the cost of prescriptions were more common barriers among participants on insulin. To identify and effectively address these barriers to adherence for adults with diabetes, researchers and providers require measures, like the ARMS-D and SDSCA-MS, that are reliable, easily-administered, understood by patients with varying levels of education, and predict glycemic control.

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Table 1

Participant characteristics.

<i>N</i> = 314	<i>M</i> ± <i>SD</i> or <i>n</i> (%)
DEMOGRAPHIC CHARACTERISTICS	
Age, years	51.8±11.7
<65 years	277(88.2)
65 years	37(11.8)
Gender	
Male	111(35.3)
Female	203(64.7)
Race	
Caucasian/White	116(36.9)
African American/Black	167(53.2)
Other race	31(9.9)
Hispanic ethnicity	26(8.3)
Education, years	11.9±2.9
Income	
<\$10,000	128(45.1)
\$10,000 – \$20,000	113(39.8)
\$20,000 – \$35,000	33(11.6)
>\$35,000	10(3.5)
Insurance Status	
Private insurance	27(8.6)
Public insurance	145(46.2)
Uninsured	142(45.2)
DIABETES CHARACTERISTICS	
Body mass index	35.6±8.9
Diabetes duration, years	7.7±6.7
Number of diabetes medications	1.6±0.7
Type of diabetes medications	
Oral agents only	170(54.1)
Insulin only	71(22.6)
Both	73(23.3)
MEDICATION ADHERENCE	
ARMS-D total	15.9±5.1
ARMS-D medication taking	10.0±3.5
ARMS-D refill	5.8±2.2
SDSCA-MS (2-item)	6.0±1.8
SDSCA-MS (1-item)	6.2±1.8
DM-SAT	73.4±17.4
GLYCEMIC CONTROL	
HbA_{1C}, % (mmol/mol)	8.2±2.2 (66±0.5)

<i>N</i> = 314	<i>M</i> ± <i>SD</i> or <i>n</i> (%)
Suboptimal (≥ 7.0% or ≥ 53 mmol/mol)	208(66.2)
Optimal (<7.0% or <53 mmol/mol)	106(33.8)

ARMS-D=Adherence to Refills and Medications Scale for Diabetes, DM-SAT=Diabetes Medication Satisfaction Tool, HbA_{1c}=point-of-care hemoglobin A1C, M=mean, SD=standard deviation, SDSCA-MS=Summary of Diabetes Self-Care Activities medications subscale.

Table 2

Principal components factor analysis of 11-item ARMS-D.

Items:	<i>n</i> (%) endorsing	<i>M</i> ± <i>SD</i>	<i>Factor Loadings</i>	
			Medication	Refill
<i>How often do you...</i>	item ^a		Taking	
1. forget to take your diabetes medicine(s)?	167(53.2)	1.6±0.6	0.75	(0.25)
2. decide not to take your diabetes medicine(s)?	82(26.1)	1.4±0.7	0.74	(0.16)
3. forget to get your diabetes prescription(s) filled?	66(20.0)	1.3±0.6	(0.49)	0.68
4. run out of your diabetes medicine(s)?	131(41.7)	1.5±0.7	(0.21)	0.82
5. skip a dose of diabetes medicine(s) before you go to the doctor?	99(31.5)	1.4±0.7	0.76	(0.21)
6. miss taking your diabetes medicine(s) when you feel better?	74(23.6)	1.3±0.6	0.83	(0.26)
7. miss taking your diabetes medicine(s) when you feel sick?	83(26.4)	1.4±0.7	0.73	(0.30)
8. miss taking your diabetes medicine(s) when you are careless?	136(43.3)	1.5±0.7	0.73	(0.40)
9. forget to take your diabetes medicine(s) when you are supposed to take it more than once a day?	122(38.9)	1.5±0.7	0.72	(0.30)
10. put off refilling your diabetes medicine(s) because they cost too much money?	58(18.5)	1.3±0.7	(0.30)	0.78
11. plan ahead and refill your medicine(s) before they run out? (reverse scored)	132(42.0)	1.7±1.0	(0.16)	0.81
Eigenvalue			6.06	1.26
Variance explained			55%	11%

M=mean, SD=standard deviation. Factor loadings in parentheses should not load onto the subscale.

^aIncludes participants who endorsed an item 2="some of the time", 3="most of the time", or 4="all of the time."

Spearman's rho correlations between medication adherence measures, diabetes treatment satisfaction, and glycemic control.

Table 3

	ARMS-D		SDSCA-MS		DM-SAT	HbA _{1C}
	medication					
	total	refill	2-item	1-item		
<hr/>						
ARMS-D total	1.00				-0.46	0.25
ARMS-D medication taking	0.91	1.00			-0.43	0.23
ARMS-D refill	0.77	0.48	1.00		-0.34	0.19
SDSCA-MS (2-item)	-0.52	-0.53	-0.34	1.00	0.27	-0.19
SDSCA-MS (1-item)	-0.46	-0.44	-0.33	0.84	1.00	-0.20

All values significant at $p<0.001$. ARMS-D=Adherence to Refills and Medication Schedules for Diabetes, DM-SAT=Diabetes Medication Satisfaction Tool, HbA_{1C}=point-of-care hemoglobin A_{1C}, SDSCA-MS=Summary of Diabetes Self-Care Activities medications subscale.

Table 4

Predicting HbA_{1c} with the ARMS-D and SDSCA-MS.

Measures	# of items	Unadjusted Models			% variance explained			Adjusted Models ^a		
		b	β	p	(R ²)	b	β	p	Incremental R ^{2†}	% increase in R ^{2‡‡}
ARMS-D total	11	0.10	0.23	0.001	5.5	0.07	0.16	0.005	2.4**	12.5
ARMS-D medication taking	7	0.13	0.21	0.002	4.2	0.09	0.14	0.017	1.9**	9.9
ARMS-D refill	4	0.21	0.21	0.001	4.4	0.14	0.14	0.009	1.9**	9.9
SDSCA-MS	2	-0.17	-0.14	0.024	2.1	-0.15	-0.12	0.030	1.5*	7.8
SDSCA-MS	1	-0.18	-0.15	0.027	2.1	-0.15	-0.11	0.045	1.4*	7.3

ARMS-D=Adherence to Refills and Medication Schedules for Diabetes, b=unstandardized regression coefficients, β=standardized regression coefficients, HbA_{1c}=point-of-care hemoglobin A_{1c}, p=probability value, SDSCA-MS=Summary of Diabetes Self-Care Activities medications subscale.

^aCovariates: age, race, diabetes duration, and insulin status; covariates only R² = 19.2

*** p<0.001,

** p<0.01,

* p<0.05.

[†] Unique contribution of the adherence measure to variance explained in an adjusted model.

^{‡‡} Percent increase in the variance explained by the addition of the adherence measure to the covariates only; [(incremental R²)/(covariates only R²)].