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Validation of diabetes medication adherence scale in the Lebanese population

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ABSTRACT

Aim: To validate the Diabetes Medication Adherence Scale (DMAS-7), determine its concordance with another validated scales and to assess factors affecting medication adherence.
Methods: A cross-sectional study was conducted on a sample of Lebanese patients with diabetes using a questionnaire. The level of adherence was measured using the DMAS-7 and the Lebanese Medication Adherence Scale (LMAS-14). Bivariate and multivariate analyses were conducted, and the scale was validated in terms of reliability, predictive ability, and construct validity using SPSS version 19.
Results: Out of 300 eligible patients, the rate of adherence was 33.7%. Measures of validity showed good reliability (Cronbach alpha = 0.627), and good construct validity with LMAS-14 (Spearman's rho = 0.846; Cohen's kappa = 0.711). DMAS-7 was found to be both correlated with LMAS-14 (ICC average measure = 0.675; p-value <0.001) in addition to possessing a better predictive value. Thus, DMAS-7 showed to have good concordance and increased validity compared to LMAS-14. Having an optimal glycated hemoglobin (HbA1C) (OR = 0.779; p = 0.001) and performing regular physical activity (OR 2.328; p = 0.002) increased medication adherence.
Conclusion: The DMAS-7 showed to be reliable and valid instrument superior to LMAS-14 in predicting adherence levels to oral anti-diabetic medications, and thus can be used to achieve better glycemic outcomes.

1. Introduction

The global burden of diabetes is rapidly emerging throughout the 21th century with increasing prevalence and long lasting complications [1]. This disease remains the 7th leading cause of premature mortality and the most expensive condition in 2017 in the United States [2]. According to the International Diabetes Federation's latest report, the global prevalence of diabetes is estimated to be 8.8% [3]. Lebanon showed to have a higher prevalence of this disease (14.6%) in 2017 [4].

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Glycemic control is based on HbA1c level which is recommended as a standard of care in the management of patients with diabetes [5]. As recommended by the American Diabetes Association (ADA), reasonable HbA1C goal for many non-pregnant adults is 7% [5]. Adequate glycemic control resembled by lifestyle recommendations and glucose lowering agents is associated with significantly decreased rates of development and progression of microvascular and macrovascular complications [6]. Despite an extensive range of available and effective treatments, less than 50% of diabetic patients achieve an optimal glycemic target [7].

Medication non adherence is an important determinant of negative outcomes in patients with diabetes [8]. The World Health Organization defines adherence as "the extent to which a person's medication administration behavior, following a diet, and/or executing lifestyle changes corresponds with agreed recommendations from the health care" [8]. Despite the emphasis put to patients on the importance of appropriate medication use, previous studies found adherence to diabetes treatment generally to be sub-optimal [9]. As a consequence, medication effectiveness is reduced, resulting in increased morbidity and mortality as well as increased societal costs [10]. A study done in United States indicated that patients with diabetes who did not adhere to treatment had significantly worse clinical outcomes compared to patients who did [9].

Since it was recognized as a major problem in patients with diabetes, methods such as pill counts, pharmacological and biochemical markers, medical and dispensing records and self-report were used to measure adherence to medications. At present, there is no gold standard available for measuring medication adherence. Although LMAS-14 scale is one of the validated instruments in Lebanon for measuring medication adherence, it is concerned with chronic diseases and not specific for diabetes [11]. Recently, a study conducted to investigate the factors contributing to non-adherence among patients with Type 2 diabetes mellitus (T2DM) in Lebanon was resulted in development of the DMAS for Lebanese patients with 7 items as indicators of adherence measure. These items evaluated psychological, occupational, economical and annoyance factors affecting adherence [12].

The objective of this study is to validate the DMAS-7 scale developed to evaluate the adherence to oral anti-diabetics in Lebanese population, determine its concordance with other validated scales mainly LMAS-14. The second objective is to assess factors affecting medication adherence.

2. Subjects

Patients were recruited from the outpatient endocrinology clinics of 4 hospitals and 6 private clinics located in Beirut, visited at random dates between the 1st of May and 30th of July 2018. Patients above the age of 18 years diagnosed with T2DM, taking at least one oral anti-diabetic over a period of 6 months or more were invited to participate in the study. Pregnant women, patents receiving only insulin or glucagon-like peptide-1 agonist, and patients with decision impaired illnesses such as mental illness, including schizophrenia, bipolar disorder and dementia, were excluded.

3. Methodology

3.1. Study design, sample size, and procedure

An observational cross-sectional study was conducted. Oral approval by both physician and patient was taken.

A ratio of 20:1 (Number of subjects: Number of items) was used to calculate the sample size [13]. This corresponded to 140 patients for the 7 items of the DMAS scale. To account for a maximum of 20% missing answers or incomplete questionnaires, 300 patients were included.

Data was collected using a structured questionnaire that was pre-tested on 20 patients without being included in the study sample. Trained pharmacists alternated between hospital and private clinics were responsible for face to face interview with patients, data collection and entry. The medical file of each patient included was reviewed to confirm the diagnosis of T2DM, and to obtain accurate data on the patient's medical and medication history. The most recent HbA1c level obtained from the medical file (within less than 1 month) or brought in with the patient was also recorded.

3.2. Variables included in the questionnaire

Sociodemographic characteristics of the patients were assessed. Lifestyle characteristics such as body mass index (BMI), performing regular physical activity defined by at least 30 min of moderate-intensity exercise on most days of the week [14], follow the diet recommended by the physician, smoking status and amount and the consumption of coffee/tea or any other beverage with sugar measured by the frequency of consumption per day. Information concerning diabetes, as disease duration, glycemic control (controlled: HbA1c < 7; uncontrolled: HbA1c ≥ 7), medication, comorbidities, diabetes complications, frequency of physician visits, patient's knowledge, behavior and motivation towards his illness and treatment, DMAS-7 and LMAS-14 scales, were also collected.

3.3. The 7 item DMAS scale

The DMAS-7 is an easy and simple tool for assessment of adherence to oral anti-diabetic medications [12]. The scale measures adherence, both voluntary and involuntary, based on forgetting, neglect and stopping medication when the patient feels better or worse. It was designed to facilitate the identification of patient behaviors and barriers associated with adherence which definitely impedes the way for diabetes control.

The total DMAS-7 consists of 7 questions with response have response choices "yes" or "no". Each "yes" response is rated as "0" and each "no" is rated as "1". The total DMAS scores can range from 0 to 7 with a cutoff point of 7 for adherence based on Receiver Operating Characteristics (ROC) curve and Youden Index. A patient with a value of 7 is considered as adherent and any other value is an indicator of non-adherence (<7) [12]. The DMAS-7 has been shown to have 70.39% sensitivity and 51.47% specificity among Lebanese population (Ayyoub D). The scale was translated to Arabic ver-

sion followed by retranslation back to the English. The two versions were then compared.

3.4. Statistical analysis

Statistical Package of the Social Science (SPSS) version 20 for data entry and analysis was used.

3.4.1. Descriptive analysis

For descriptive analyses, means with standard deviations and medians with interquartile range were reported for normally and non-normally distributed continuous variables, respectively. Proportions were used for categorical variables.

3.4.2. Validation of DMAS-7

To validate DMAS-7, internal consistency was assessed using Cronbach alpha. Taking glycemic control as a reference variable, ROC curves of DMAS-7 and LMAS-14 were drawn and compared to each other. Logistic regression, with glycemic control as a dependent variable, was used to determine which scale was a better predictor glycemic control. Convergent validity was achieved by evaluating the Cohen's kappa and Spearman's' correlation coefficients to measure the agreement between dichotomized and continuous forms respectively of DMAS-7 and LMAS-14 in evaluating the adherence status. Concordance between adherence measures of the two scales was evaluated by the Intra Class Correlation Coefficient (ICC) (considered acceptable > 0.5).

3.4.3. Logistic regression analysis

To determine the factors affecting medication adherence, the dependent variable was adherence as measured by DMAS-7. Bivariate analysis between DMAS-7 and other independent variables was done using Chi square for categorical variables and independent student's t test for dichotomous variables. Variables with p values $\leq$0.2 in this bivariate analysis were included in the logistic regression (forward LR method). A hierarchical method for regression was used due to the large number of independent variables with a p-value $\leq$0.2. Hierarchical Regression refers to the process of adding or removing predictor variables from the regression model in multiple steps [15]. The independent variables thus finally included were: medication cost, physical activity, follow-up diet program, Hb1Ac (%), number of antidiabetic medication per day, knowledge of drug's name by patient, postpone physician visits, neuropathie. In order to illustrate the importance of the developed scale in the prediction of the HbA1c control, another logistic regression was done to see if DMAS-7 is a predictive factor for glycemic control.

4. Results

4.1. Descriptive analysis

A total of 300 patients met the inclusion criteria during the study period. Mean age of patients was 57.99 ± 11.72 years (range 23–87) with 129 patients were males. With respect to the BMI criteria, 37.7% of the patients were overweight and 42% obese.

Only 31% of patients perform regular physical activity and less than the half of them actually follow the diet recommended by their physician (43.6%). More than half of patients had uncontrolled glycemic control (HbA1c $\geq$ 7) (55%) with a mean value of 8.02 ± 2.17%. The total number of medications taken per day by the study patients was 5.23 ± 2.71 and the most common class of oral anti-diabetics taken was biguanides (93.0%), followed by DPP-4 inhibitors (49.0%). The most common reason for discontinuing treatment was the high cost of antidiabetic medication (22.0%) followed by forgetfulness (19.3). One hundred one patients were found to be adherent according to DMAS (33.7%) (Table 1).

4.2. Bivariate analysis

Performing regular physical activity or following a diet recommended by the physician both enhances the adherence rates significantly ($p < 0.001$) compared to patients who don't.

Among patients who have uncontrolled HbA1c, the majority of patients are non-adherent (78.2%) compared to patients who have a controlled HbA1c where the level of non-adherence was lower (51.9%) ($p < 0.001$). The frequency of administration of drugs significantly affects adherence ($p = 0.016$). As the frequency increases from once per day to twice to three times, the level of non-adherence increases from 53.3% to 62.6% to 67.1% respectively. The mean HbA1c in patients who are non-adherent to their medication (8.42% ± 2.34) is significantly higher than in those who are adherent (7.25% ± 1.53) ($p < 0.001$). Additionally, the mean number of anti-diabetic medication per day is slightly higher among non-adherents (1.91 ± 0.83 pills) as compared to adherents (1.55 ± 0.67 pills) ($p < 0.001$) (Table 2).

4.3. Multivariable analysis

As the HbA1c measure increases by 1 unit, the odds of being adherent decreases 22.1% with a p-value of 0.001. Performing regular physical activity (odds ratio: OR = 2.32 p = 0.002) or following diet recommended by the physician (OR = 3.294; p = 0.003) significantly increases the probability of adherence by more than 2 and 3 times respectively. On the other hand, patients who postpone physician's visits are more likely to be non-adherent as predicted by DMAS-7 with a 54.7% lower risk of adherence (p = 0.046) (Table 3: for DMAS-7).

It was significantly demonstrated (p-value = 0.037) that as the patient is adherent to his oral anti-diabetics as shown by DMAS scale, the probability of having a controlled HbA1c increases almost 2 folds (OR = 2.006) (Table 3: for HbA1C controlled).

4.4. Scale validation

In this section, some aspects of the scale have been assessed as steps of validation.

4.4.1. Reliability assessment

Scale reliability is the proportion of variance attributable to the true scale of the latent variable [16]. Cronbach's alpha was measured to determine the scale's reliability. The

Table 1 – Socio-demographic and lifestyle characteristics.

Variable	N (%)	
Sex (N = 300)		
Males	129	(43.0)
Females	171	(57.0)
BMI (N = 300)		
Underweight (<18.5 kg/m^2)	1	(0.3)
Normal (≥18.5 kg/m^2)	60	(20.0)
Overweight (≥25 kg/m^2)	113	(37.7)
Obese (≥30 kg/m^2)	126	(42.0)
Age (Mean ± SD/Range)	57.99 ± 11.72	/23–87
Regular Physical Activity (N = 300)		
Yes	93	(31.0)
No	207	(69.0)
Follow the diet recommended by the physician (N = 300)		
Yes	131	(43.6)
No/Sometimes	169	(56.3)
Glycemic control (N = 300)	8.02 ± 2.17	
Uncontrolled	165	(55.0)
Controlled	135	(45.0)
Total number of medications/day (Mean ± SD)	5.23±	2.71
Pharmacologic class of antidiabetic medication		
Biguanides	279	(93.0)
DPP-4 Inhibitors*	147	(49.0)
Sulfonylureas	105	(35.0)
SGLT-2 Inhibitors*	44	(14.7)
Thiazolidinediones	8	(2.7)
Meglitinides	5	(1.7)
Alpha-glucosidase Inhibitors	1	(0.3)
Main reason for discontinuing treatment (N = 300)		
No drug discontinuation	158	(52.7)
High cost	66	(22.0)
Forgetfulness	58	(19.3)
Experience of unwanted side effects	8	(2.7)
Complexity of treatment regimen	6	(2.0)
Perception of Inefficacy	4	(1.3)
Adherence level (N = 300)		
DMAS-7	101	(33.7)

DPP-4 Inhibitors: Dipeptidyl Peptidase-4 Inhibitors.
SGLT-2 Inhibitors Sodium Glucose Cotransporters-2 Inhibitors.

Cronbach's alpha coefficient for the 7 items was 0.627 and showed to decrease if any item was deleted form the scale (Table 4).

4.4.2. *Receiver Operating Characteristics (ROC) curve*
In order to compare the modality of DMAS-7 to that of LMAS-14, the assessment of area under both ROC curves was done. Results are displayed in Fig. 1. This figure displays the ROC curve of the DMAS scale vs. the glycemic control (HbA1c controlled and uncontrolled). The area under the ROC curve was 0.675 (p-value <0.001, 95% CI: 0.614–0.736) with a sensitivity level of 64.8% and a specificity level of 64.3%, indicating a good predictive value. The area measures discrimination, that is, the ability of the test to correctly classify those with and without the T2DM.

ROC curves of both LMAS-14 and DMAS-7 are very similar and comparable with even a slight superiority of DMAS-7. Area under both ROC curves are significant and close. A good predictive value of adherence in both models was obtained with a tendency for better prediction by DMAS 7.

4.4.3. *Construct validity*
Spearman's rho was used for evaluating the correlation between DMAS-7 and LMAS-14 as continuous scales. A good correlation between both measures was obtained resembled by the correlation coefficient is 0.846 (p-value <0.001). Cohen's kappa was used to measure the agreement between LMAS-14 and DMAS-7 in dichotomized form in classifying non-adherents from adherents. Cohen's kappa was 0.711 indicating there is a good level agreement (P-value = 0.001).

Table 2 – Association between DMAS-7 adherence rates and considered factors.

Variable	Dichotomized DMAS-7		
	Non-adherent N (%)	Adherent N (%)	*p-value*
Regular Physical Activity (N = 300)			
Yes	46 (49.5)	47 (50.5)	**<0.001**[d*]
No	153 (73.9)	54 (26.1)	
Follow diet recommended by physician (N = 300)			
Yes	68 (51.9)	63 (48.1)	**<0.001**[d*]
No/Sometimes	126 (78.8)	38 (21.2)	
Glycemic control (N = 300)			
Uncontrolled	129 (78.2)	36 (21.8)	**<0.001**[d*]
Controlled	70 (51.9)	65 (48.1)	
Frequency of drug administration (N = 300)			
Once per day	16 (53.3)	14 (46.7)	**0.016**[d*]
Twice per day	109 (62.6)	65 (37.4)	
Three times per day	74 (67.1)	22 (22.1)	
Postponing physician visits (N = 300)			
Yes	50 (83.3)	10 (16.7)	**0.002**[d*]
No	149 (62.1)	91 (37.9)	
Monthly medication cost (N = 300)			
<333 US$	179 (64.2)	100 (35.8)	**0.004**[d*]
333US$–666 US$	20 (95.2)	1 (4.8)	
The patient feels his treatment improves his health state (N = 300)			
Yes	168 (63.4)	97 (36.6)	**0.003**[d*]
No	31 (88.6)	4 (11.4)	
Number of anti-diabetic medications/day Mean ± SD	5.47 ± 2.83	4.75 ± 2.40	**0.03**[a*]
HbA1c (%) Mean ± SD	8.42 ± 2.34	7.25 ± 1.53	**<0.001**[b*]

US$: United States Dollar.
Non-significant variables: age, sex, BMI, educational level, family history, presence of medication side effects
[*] Significance level < 0.05.
[a] Student test.
[b] Corrected Student test.
[d] Chi-square test.

ICC showed good concordance between DMAS-7 and LMAS-14 scales (ICC average measure = 0.675; p-value <0.001).

5. Discussion

The level of adherence was found to be 33.7% among Lebanese patients with diabetes. Adherence rates to oral anti-diabetic medications was found to be 39% in France [17], 38.5% in Palestine [18], and 40.6% in Nigeria [19] which are comparable to results obtained by this study. The reported adherence to this study was suboptimal and lower than previous findings reported from Iran with a 74.8% level of adherence [20], 85.1% in Ethiopia [21], 81% in Oregan, United States [22], 71.2% in Tanzania [23], 76.3% in India [24]. The reason for the differences seen may partly be explained by the different methodologies used to estimate adherence rates, socio-economic characteristics, and differences in the health care settings between countries.

Studies have shown that many factors affect adherence to oral anti-diabetic medication ranging from demographic characteristics such as age [8,25,18,26], gender [27], marital state [25,28], and level of education [21,24,28] to clinical and medication factors such as duration of diagnosed diabetes. The findings of this study similarly to another study conducted in a country in southern Africa [29] did not reveal any association to any of these commonly studied variables.

Among lifestyle characteristics, performing physical activity and following a diet recommended by the physician were found to be significantly associated with adherence level. Patients who practice physical activity and follow-up diet were two times more adherent to their medication. Patients who follow lifestyle modifications and non-pharmacologic treatments recommended by their physician are also likely to follow their prescribed pharmacologic treatment [12].

Medication cost was significantly correlated with medication adherence (p = 0.004). Results obtained are confirmed by numerous studies [15,18,22,28] that have proved an association between cost and adherence. A study conducted in Egypt showed that a significantly higher rate of adherence to oral anti-diabetics (57.7%) was observed in patients who exhibited adequate healthcare costs in relation to their income or full coverage health insurance compared with the others who did not have (24.8%) [25].

Table 3 – Logistic regression.

- **For DMAS-7**

Variables	OR	95% CI		p-value
HbA1c (%)	0.779	0.671	0.903	0.001
Performing Physical activity	2.328	1.347	4.024	0.002
Postponing physicians Visit	0.453	0.209	0.985	0.046
Following diet program (Yes vs. No)	3.294	1.483	7.319	0.003

Omnibus test p-value < 0.001 ; Hosmer-Lemshow test p-value = 0.546
Nagelkerke R2 = 0.229 ; Overall predicted percentage = 74.3%
Independent variables: Medication cost, Physical activity, Follow-up diet program, Hb1Ac (%), Number of antidiabetic medication per day, Knowledge of drug's name by patient, Postpone physician visits, Neuropathie.

- **For HbA1c controlled**

Variables	OR	95% CI		p-value
Patient feels medication ameliorates health	2.701	1.113	6.551	0.028
Adherent patient by DMAS	2.006	1.043	3.858	0.037

Omnibus test p-value < 0.001 ; Hosmer-Lemshow test p-value = 0.951.
Nagelkerke R2 = 0.142 ; Overall predicted percentage = 65.3%.
Independent variables: Postpone physician visits, Medication amelioration, Treatment burden, Adherent by DMAS.

Table 4 – Reliability analysis of the DMAS-7.

Questions	Cronbach's Alpha if Item Deleted
Do you sometimes stop taking your medication when feeling well?	0.558
Do you sometimes stop taking your medication when feeling worse?	0.570
Do you skip or double the dose in case of hypo/hyperglycemia?	0.598
Do you sometimes forget taking your medication if travelling or going out?	0.619
Do you skip your medication if fasting?	0.637
Do you sometimes stop taking your medication if there is no medical insurance or enough money?	0.574
Do you feel your treatment is a burden?	0.556

Treatment of T2DM patients comprises the use of multiple medications certainly has a profound influence on adherence. Regimen complexity can involve most importantly the drug count, dose frequency of administration and others. In this study, both the frequency of drug administration and the drug count had significant impact on adherence level. Several retrospective database studies have shown that rates of adherence to polytherapy regimens were 10% to 20% lower than those for monotherapy regimens [30]. The adherence rate for once daily dosing was 79%; those for 2 and 3 times daily dosing decreased to 66% and 38%, respectively [30]. Thus prescribing medications that require fewer dosing frequencies can increase medication adherence [30].

Patients who believe that their treatment improves their health were found to have a significantly higher rate of adherence vs those who don't. Studies emphasize that patients are more likely to adhere to treatments when they have some tangible sense that the prescribed medication is contributing to some positive and relatively immediate outcomes [31], and treatment itself is not difficult or burdensome [31]. It is essential that clinicians help patients understand the short and long term benefits of drugs. Among studied patients, 45% had good glycemic control (HbA1c < 7%). Forty-eight percent of patients were found to have adequate glycemic control in Iran [32] and 41.8% were found in Ethiopia [33]. As described above, medication adherence can play a major role in HbA1c control in addition to other factors such as adherence to a diet or physical activity. Performing regular physical activity or following a diet program was found to increase the adherence to oral anti-diabetic medication measured by DMAS-7. On the other hand, postponing physician's visits and increasing HbA1c levels (%) were associated with a decreased level of adherence.

Patients feeling that their treatment improves their health state were found to be associated with a significantly higher level of adherence. Association between adherence to oral anti-diabetic medication and HbA1c control has been previously demonstrated [22,26,34].

Concerning the DMAS-7, it showed an acceptable internal consistency, stable reliability and concurrent validity. Reliability, which is the extent to which measurements can yield the same results on repeated trials (repeatability), was assessed by Cronbach alpha measure. The value of Cronbach alpha (0.627) shows a good level of reliability of the scale and it tend to decrease when any item was deleted form the scale indicating that all questions in the scale are very important to determine if a patient is adherent or not.

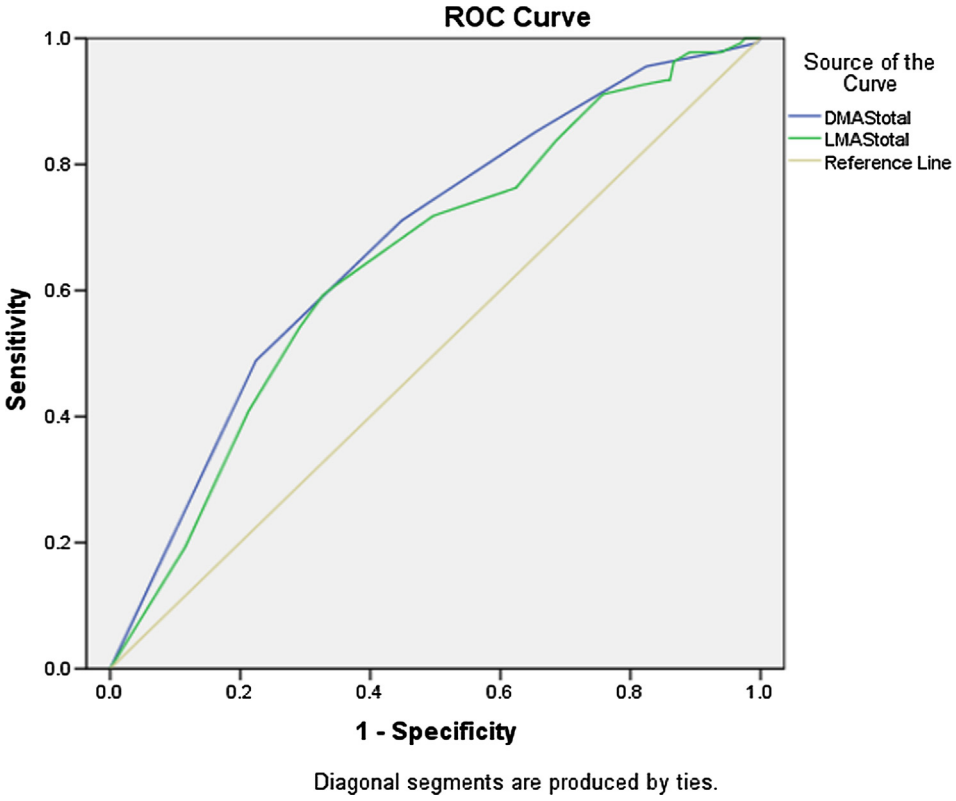

Fig. 1 – ROC curve of DMAS-7 and LMAS-14 vs Glycemic control.

The ROC curve is an important graphical representation of the scales predictive value by AUC calculation. The DMAS-7 scale had a good AUC value of 0.675 ($p < 0.001$) which demonstrates its ability to discriminate and correctly classify those adherent and non-adherent. In fact, the AUC of DMAS-7 is slightly greater than that of LMAS-14 which can show its superiority in predicting adherence levels.

For construct validity, this reveals if the scale is correlated to other measurement parameters and thus measures what it's supposed to measure. The correlation of DMAS-7 and LMAS-14 as quantitative variables was done by Spearman Rho's coefficient and showed that both scales are very well correlated (Spearman Rho = 0.846; p-value < 0.001). This means that there is no great difference in adherence measurement and both scales yield comparable results. For the agreement between DMAS-7 and LMAS-14 as binary variables (adherent-non-adherent), Cohen's kappa was 0.711 ($p < 0.001$) and thus ensures that both measures have a good level of agreement in classifying adherent patients from non-adherent. Most of those classified as adherent by DMAS-7 are also classified adherents by LMAS-14.

The good concordance between the two scales (ICC = 0.675; p-value < 0.001) could be explained by the fact that LMAS-14 and DMAS-7 are assessing adherence among Lebanese population that share thus the same risk factors and predictors for adherence. In addition to that, both scales have similar questions assessing patient forgetfulness, medication cost effects, and subjects willingness to stop medication if feeling good or bad.

The LMAS has 14 questions compared to 7 questions of DMAS. This fact, in addition to those stated above with respect to the superiority in reliability and predictive ability, and its concordance and agreement, DMAS's specificity to Lebanese patients with diabetes, proves that DMAS-7 has superiority to LMAS in assessing adherence to oral anti-diabetic medication. In addition, DMAS-7 which has binary answers (yes/no) is more useful to achieve better glycemic outcomes, easier than that of LMAS-14 (Likert scale) that can be troublesome for the patient and more time consuming.

This implies that the DMAS-7 is a reliable and valid instrument for assessing adherence to oral anti-diabetic medications. The physician has a useful, easily comprehensive, inexpensive and not time consuming instrument to assess his patients' adherence. The evaluation of adherence is a very important step that should be done by all physicians mostly on patients who are not achieving glycemic goals and require intervention. Instead of adding new agents that causes an increase in medication cost, increase number of pills and administrations, burdensome and possibly causing side effects which are all factors that cause the patient to be non-adherent.

Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments. Some measures can be taken to improve patients' adherence to oral anti-diabetic such as prescribing fixed-dose combination drugs, explaining the benefits of these medications for future health protection, and assessing cost-related adherence

issues with patients and offering to change the regimen if appropriate (generics).

Study strengths include adequate sample size, numerous collection sites, controlling for sociodemographic, lifestyle, comorbidities and adherence characteristics. Moreover, factors shown to affect adherence were also defined and were concordant with other studies found in literature which gives a sense of validity to the work. The results obtained concerning validity proved that the developed scale is reliable and can be a clinical tool used to assess adherence among Lebanese diabetic population.

However, some limitations are to be mentioned. A potential selection bias could be due to the recruitment done in endocrinology outpatient clinics in Beirut. An over representation of the Lebanese residing in Beirut was also noted and thus people in other cities or in rural regions were not well represented in this study sample. But this sample could be representative of Lebanon due to the large number of patients from all over the country residing in Beirut, in addition to the great number of patients who come to Beirut from all areas in order to seek medical assistance. Selection bias could happen among primary care patients since those who seek health care are only who care about their health and best. Although the use of self-report method is the simplest and most feasible with regards to cost and time expenditure, they are subjective and have a tendency to overestimate adherence due to information biases (recall) and social desirability, when compared to other methods such as pill counts, prescription claims or biological assays. This study also only emphasize that in addition to the importance of the pharmacotherapy in health management, the other two components of diabetes care; namely physical exercise and dietary modifications; cannot be over stated in their role to enhance glycemic control and improve the outcome of patients with T2DM.

Despite these limitations, a validated scale to assess oral anti-diabetic medication adherence in Lebanon has been successfully achieved. A test-retest reliability to determine the degree to which test results are consistent over time would be useful in enhancing the reliability of the scale in future analysis. This would require filling the questionnaire with a number of patients, and repeating the same questionnaire with the same patients after a period of time.

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Declaration of Competing Interest

There is no conflict of interest.

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