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Original Research

## Predictive Validity of Self-Reported Measures of Adherence to Noninsulin Antidiabetes Medication against Control of Glycated Hemoglobin Levels



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### ABSTRACT

**Objective:** To assess and compare the predictive validity of 4 self-reported adherence measures.

**Methods:** A convenience sample of 153 patients with type 2 diabetes completed a self-report with 4 items (SR-4) and a French version of the Morisky Medication Adherence Scale with 8 items (MMAS-8), reported the proportion of pills missed, and answered a single-item scale regarding their antidiabetes drug treatments. They also provided measures of glycated hemoglobin (A1C) taken between 3 and 6 months after the adherence measurements. We examined the relationship between self-reported adherence and glycemic control using the area under the receiver operating characteristics curve (AUC) and linear regression analyses.

**Results:** AUCs were 0.51, 0.52, 0.53 and 0.52 for the SR-4, MMAS-8, self-reported proportion of pills missed and single-item scale, respectively. AUCs stratified according to median duration of diabetes ranged from 0.55 to 0.63. Based on linear regression analyses adjusted for diabetes duration, the association measured in the total sample between adherence measures and A1C levels was not statistically significant. When regression analyses were performed among participants with A1C levels  $\geq 7\%$  only, SR-4, MMAS-8 and the single-item scale scores were significantly associated with A1C levels, and beta coefficients were associated with a 1-unit increase in adherence scores of  $-0.46$ ,  $-0.20$  and  $0.38$ , respectively.

**Conclusion:** The results support the predictive validity of all measures except the self-reported proportion of missed pills.

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### R É S U M É

**Objectif:** Évaluer et comparer la validité prédictive de 4 mesures d'observance autodéclarées.

**Méthodes:** Un échantillon de commodité de 153 patients souffrant du diabète de type 2 ont rempli une échelle autodéclarée de 4 questions (SR-4) et l'échelle modifiée Morisky Medication Adherence Scale de 8 questions (MMAS-8), déclaré la proportion de comprimés omis et répondu à une échelle à question unique au sujet de leurs traitements antidiabétiques. Ils ont également fourni les mesures de l'hémoglobine glyquée (A1c) prises de 3 à 6 mois après les mesures d'observance. Nous avons examiné la relation entre l'observance autodéclarée et la maîtrise de la glycémie à l'aide de l'aire sous la fonction d'efficacité du récepteur (courbe ROC) et des analyses de régression linéaire.

**Résultats:** Les aires sous la courbe ROC de la SR-4, de la MMAS-8, de la proportion autodéclarée de comprimés omis et de l'échelle à question unique ont respectivement été de 0,51, 0,52, 0,53 et 0,52. Les aires sous la courbe ROC stratifiées en fonction de la durée médiane du diabète ont varié de 0,55 à 0,63. À partir des analyses de régression linéaire ajustées selon la durée du diabète, l'association mesurée dans l'ensemble de l'échantillon entre les mesures de l'observance et les concentrations d'A1c n'a pas été statistiquement significative. Lorsque les analyses de régression ont été réalisées parmi les participants ayant des concentrations d'A1c  $\geq 7\%$  seulement, la SR-4, la MMAS-8 et les scores à l'échelle à

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question unique ont été significativement associés aux concentrations d'A1c, et les coefficients bêta ont été associés à une augmentation respective de 1 unité dans les scores d'observance de  $-0,46$ ,  $-0,20$  et  $0,38$ .

*Conclusion:* Les résultats confirment la validité prédictive de toutes les mesures, excepté la proportion autodéclarée de comprimés omis.

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## Introduction

Poor adherence to antidiabetes drug treatment is a major barrier to achieving clinical targets in type 2 diabetes (1). Unfortunately, adherence to antidiabetes drug treatment is suboptimal (1,2). Therefore, there is a need in clinical practice to identify nonadherent patients in order to help them to manage their treatments better and to benefit from better health outcomes.

Many methods are available to measure adherence to drug treatment. They all come with strengths and limitations (3). In clinical practice, the advantages of self-reported measures over other methods include simplicity, ease of administration, cost-effectiveness (3) and capacity to identify underlying issues contributing to non-adherence (4).

There are 3 general types of self-reported measures: 1) medication-taking habits; 2) general adherence tendencies and 3) specific quantities of pills missed over an identified period of time, expressed as a proportion (5). On one hand, medication-taking habit measures are usually multiple-item scales. They can help to distinguish between intentional and unintentional nonadherence, which have different underlying causes and, therefore, require differing interventions (6). However, characteristics of the item questions and literacy issues could influence their validity (3). On the other hand, measures of general adherence tendency are usually single-item scales that can be used in busy clinical settings. Unfortunately, as a single-item scale, those measures have little value in identifying reasons for nonadherence. Finally, by their nature, self-reported measures of the proportion of pills missed do not provide reasons that can explain nonadherence. Their accuracy can also be influenced by the number of drugs being used and by the length of the recall time period (5,7).

The validity of those 3 types of measures, when used to assess adherence to antidiabetes drug treatment, has been evaluated (8–10). However, little is known about their comparative validities. In one study (8), a self-reported general adherence tendency measure was compared to a self-reported proportion of pills missed. The former measure was more strongly correlated than the latter with glycaemic control and with adherence measured by using an electronic medication-monitoring system (8). To our knowledge, a head-to-head assessment of the validity of the 3 types of self-reported measures of adherence to antidiabetes drugs treatment has never been conducted.

The present study was designed to assess and compare the sensitivity and specificity of 3 different types of self-reported antidiabetes drug-adherence measures in predicting control of glycated hemoglobin (A1C) levels in patients with type 2 diabetes.

## Methods

### Study design

We carried out a validation study in which self-reported adherence was measured at baseline, and A1C levels were measured between 3 and 6 months later. The following self-reported measures were assessed: 1) 2 medication-taking habits measures, i.e. a 4-item self-report (SR-4) and the 8-item Morisky Medication Adherence Scale (MMAS-8); 2) a self-reported proportion of pills missed measure developed by Godin et al (7); and 3) a single-item

scale (i.e. a general tendency measure) developed by our team. The versions of the 4 self-reported measures used are available in Appendix Tables A1–A4.

### Population

The source population was drawn from the Diabète Québec membership file. Diabète Québec is the Quebec provincial advocacy association for patients with diabetes. The association contacted those of its members ( $n=6258$ ) who were 18 years of age or older, had in-file valid e-mail addresses and had received notification that they had type 2 diabetes. They were asked for their participation in a cross-sectional web survey that was conducted to assess factors associated with adherence to noninsulin antidiabetes drugs. Our source study population consisted of the 901 persons who completed the survey. The study population is a random sample of individuals in the source population whom we contacted after the survey to obtain A1C measurements (our validation criterion).

### Data collection

Self-reported adherence and participants' sociodemographics and diabetes-related variables were measured through the above-mentioned web survey. Individuals who consented to participate in the web survey received by e-mail personalized secure links to reach the questionnaire. The survey took place between January 14 and February 4, 2013, for participants included in the current analysis.

### Variables

*A1C levels.* A1C levels were measured between 3 and 6 months after the participants' noninsulin antidiabetes drug adherence self-assessment. Because A1C levels reflect the average plasma glucose in the period of 3 to 4 months preceding its measurement (11), a minimum of 3 months after self-assessment of adherence was required to ensure that we would be measuring the predictive relationship between adherence to treatment and A1C levels. The maximum of 6 months between the adherence and the A1C measures was based on the results of a previous study that indicated that baseline self-reported adherence is associated with 6-month glycaemic control (12).

A personalized invitation to participate was sent by e-mail to each individual in the random sample. Those interested in participating were sent informed consent forms by mail. Finally, individuals who returned signed consent forms were sent A1C tests by mail (i.e. the A1C Now SelfCheck [Bayer HealthCare, Diabetes Care, Tarrytown, New York, USA]). It is a fully integrated, hand-held device for the quantification of percentage of A1C in capillary (finger-stick) whole blood (13). The validity of this test has been established (13), and it is currently being certified by the Canadian National Glycohemoglobin Standardization Program for A1C measurement.

Participants were instructed to perform the test in the week following its receipt, according to instructions included on the label and in a tutorial video. They were also told to contact the research team by phone or e-mail for any questions related to the test or if they faced difficulty in performing the test. They were asked to communicate the results (by phone or e-mail) with the research team.

The A1C measurements were dichotomized as being 7% or lower or above 7% (poor glycaemic control) based on the Canadian Diabetes Association 2013 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada (11).

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