Health literacy in diabetes: psychometric properties of a new scale and effect on biochemical parameters

Letramento em saúde no diabetes: propriedades psicométricas de uma nova escala e efeito em parâmetros bioquímicos

Letramiento en salud en la diabetes: propiedades psicométricas de una nueva escala y efecto en parámetros bioquímicos

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Abstract

This study evaluated the health literacy (HL) competencies (access, understand/appraise and apply) using a new developed scale and the association with biochemical profile among people living with diabetes. For the diagnosis of diabetes, biochemical parameters were used. Exploratory Factor Analysis (EFA) and Confirmatory Factor Analysis (CFA) estimated the construct validity of the scale. Statistical models estimated the association of HL with socioeconomic, biochemical, anthropometric and cognitive parameters. This study included 341 people living with diabetes. The results showed that 91.9% received information related to diabetes. EFA demonstrated a proper factorial fit (KMO = 0.919) and the items were loaded in three factors: access, understand/appraise and apply. CFA confirmed the fit of the model (λ^2 /df of 2.09; RMSEA of 0.061). High levels of access to information related to diabetes led to a higher apply level self-reported. However, a high apply level was not associated with better biochemical profile (p < 0.05), including the dosage of glycated hemoglobin. Moreover, regression models showed that some characteristics were associated with high HL in all its domains, such as skin color and cognitive condition. Furthermore, a higher proportion of men had high access to information related to diabetes, compared to women. These results show that different factors must be considered in the HL process to achieve proper self-management behavior to control the disease or prevent its complications. Health information for people living with diabetes should focus on specific risk factors or behaviors that modulate biochemical parameters.

Keywords: Health literacy; Health education; Diabetes Mellitus; Health promotion; Psychometrics.

Resumo

Este estudo avaliou as competências (acesso, compreensão/avaliação e aplicação) do Letramento em Saúde (LS), utilizando uma nova escala desenvolvida e sua associação com o perfil bioquímico entre pessoas que vivem com diabetes. Para diagnóstico do diabetes, foram utilizados parâmetros bioquímicos. Para validação de constructo da escala, foram utilizadas Análise Fatorial Exploratória (AFE) e Análise Fatorial Confirmatória (AFC). Análises estatísticas estimaram a associação do LS com parâmetros socioeconômicos, bioquímicos, antropométricos e cognitivos. O estudo incluiu 341 pessoas com diabetes. Os resultados mostraram que 91,9% receberam informações relacionadas ao diabetes. AFE demonstrou adequado índice de ajuste (KMO = 0,919) e os itens foram agrupados em 3 fatores: acesso, compreensão/avaliação e aplicação. AFC confirmou o ajuste do modelo (λ^2 /df = 2.09; RMSEA =

0.061). Altos níveis de acesso à informação relacionada ao diabetes implicaram em altos níveis autorrelatados de aplicação. Entretanto, elevado nível de aplicação não foi associado com melhor perfil bioquímico (p < 0,05), incluindo a dosagem de hemoglobina glicada. Modelos de regressão mostraram que características, como cor da pele e cognição, foram associadas com alto nível de LS em todos os domínios. Ademais, uma proporção maior de homens teve maior acesso à informação relacionada ao diabetes, quando comparado às mulheres. Estes resultados demonstram que diferentes fatores devem ser considerados no processo do LS para atingir adequado autocuidado no controle da doença e na prevenção de complicações. Informações de saúde para pessoas que vivem com diabetes devem focar em fatores de risco ou comportamentos que modulam os parâmetros bioquímicos.

Palavras-chave: Letramento em saúde; Educação em saúde; Diabetes Mellitus; Promoção da saúde; Psicometria.

Resumen

Este estudio evaluó las competencias (acceso, comprensión/evaluación y aplicación) del Letramiento en Salud (LS), utilizando una nueva escala desarrollada y su asociación con el perfil bioquímico entre personas que viven con diabetes. Para diagnóstico de la diabetes, fueron utilizados parámetros bioquímicos. Para validación de constructo de la escala, fueron utilizadas Análisis Factorial (AFE) y Análisis Factorial Confirmatoria (AFC). Análisis estadísticas estimaron la asociación del LS con parámetros socioeconómicos, bioquímicos, antropométricos y cognitivos. Los resultados muestran que 91,9% recibieron informaciones relacionadas a la diabetes. AFE demostró adecuado índice de ajuste (KMO = 0,919) y los ítems fueron agrupados en 3 factores: acceso, comprensión/evaluación y aplicación. AFC confirmó el ajuste del modelo ($\lambda^2/df = 2.09$; RMSEA = 0.061). Altos niveles de acceso a la información relacionada a diabetes implicaron en altos niveles autoinformados de aplicación. Sin embargo, elevado nivel de aplicación no fuera asociado con mejor perfil bioquímico (p < 0,05), incluyendo la dosis de hemoglobina glicosilada. Modelos de regresión mostraron que rasgos, como color de piel y cognición, fueron asociados con alto nivel de LS en todos los dominios. Además, una proporción mayor de hombres tuvo mayor acceso a la información relacionada a diabetes, cuando comparado a las mujeres. Estos resultados demuestran que diferentes factores deben ser considerados en el proceso del LS para lograr adecuado autocuidado en el control de la enfermedad y en la prevención de complicaciones. Informaciones de salud para personas que viven con diabetes deben focar en factores de riesgo o comportamientos que modulan los parámetros bioquímicos.

Palabras clave: Alfabetización en salud; Educación en salud; Diabetes Mellitus; Promoción de la salud; Psicometría.

1. Introduction

The increasing burden of noncommunicable chronic diseases worldwide is the main cause of morbidity and mortality currently (Wang, 2016) and, therefore, it is a threat to global health. Among them, diabetes, a chronic disease triggered by genetic and environmental factors characterized by the progressive loss of pancreatic beta cell mass and/or function which shows clinically as a hyperglycemia condition (American Diabetes Association [ADA], 2018; International Diabetes Federation [IDF], 2019), affects more than 460 million people worldwide (IDF, 2019). Although diabetes diagnosis, treatment, and prevention have advanced significantly (Nathan, 2015), this disease is still among the top 10 causes of death globally and its prevalence is projected to increase drastically more than 50% until 2045 (IDF, 2019). Diabetes has been related to poor quality of life (Jing et al., 2018), high need for medical care (Jiang et al., 2003), complications and it also has been associated with others chronic diseases, such as cardiovascular problems (Matheus et al., 2013).

Interestingly, type 2 diabetes, which represents approximately 90% of cases, is preventable since its main risk factors are related to body conditions, such as physical inactivity, inadequate diet and overweight (Chatterjee et al., 2018; IDF, 2019). Even among diagnosed patients, these conditions need to be controlled as part of treatment to avoid complications related to diabetes (IDF, 2019). Therefore, it is expected that people living with diabetes have access to information about the disease to develop skills and abilities to may change harmful behaviors and apply self-care/self-management (Chatterjee et al., 2018), which is described by the health literacy concept.

Health literacy (HL) has been described as individual abilities to access information related to health and critically understand/appraise it and applies on own situation, making appropriate health decisions (Skyes et al., 2013). Therefore, HL considers multiple personal skills and not only simple abilities, such as reading or numeracy (Schonlau et al., 2011). In fact, a previous systematic review suggested that a proper HL conceptual model should consider the following types of competencies: Access, ability to obtain information regarding health; understand and appraise, ability to comprehend and evaluate the health

information and apply, ability to use this information and improve health conditions or behavior (Sørensen et al., 2012). Therefore, it is expected that evaluations regarding HL related to diabetes consider these competencies.

Since inadequate HL may lead to reduce adherence to the treatment and increase mortality rates (Baker et al., 2007), self-management skills among people living with diabetes (i.e., adequate diet and physical activity) are expected as part of diabetes care to control complications/outcomes related to the disease (Chatterjee et al., 2018). In fact, HL and, consequently, enhanced self-care have been associated with improved medication adherence (Lee et al., 2016) and glycemic control (Ueno et al., 2019). Previous studies evaluated the HL among people living with diabetes and a high variation on HL prevalence between 7-80% has been reported (Abdullah et al., 2019; Lee et al., 2016; Pashaki et al., 2019), which may be explained by the differences in the tools used (Abdullah et al., 2019). Moreover, there is no consensus about the use of low HL as a suitable screening to improve self-management and health behavior related to diabetes (Al Sayah et al., 2013), but it could be enhanced by HL scales that consider properly its competencies. Some HL related to diabetes scales have been developed with properly psychometric properties, but it has considered mainly the access of information and "understand/appraise" factor (Ishikawa et al., 2008; Kang et al., 2018; Lee et al., 2018) or confirmatory factor analysis, which is used to check the 'fit' of developed model (El-Den et al., 2020), was not considered (Ishikawa et al., 2008). Additionally, since health professionals should improve access to information and high HL (Xu et al., 2018), the different sources/professionals that provide information about diabetes has not been widely considered by previous scales.

Moreover, although an enhanced biochemical profile has been associated with HL among people living with diabetes (Lee et al., 2016), a systematic review suggested that this relationship is still a gap in the knowledge and needs to be better understood (Caruso et al., 2018). Therefore, we evaluated the construct validity of a new HL related to diabetes scale that was developed (Martins et al., 2018) considering proper competencies: access, understand/appraise, and apply. Additionally, the association of high HL level with a better biochemical profile among people living with diabetes was estimated. It is expected that people with high HL levels show improved biochemical parameters as a consequence of proper self-management.

2. Methodology

2.1 Ethical aspects

The study was carried out respecting the ethical principles of National Health Council Resolution 196/96, in accordance with the Helsinki Declaration. The survey was approved and registered by the National Commission for Research Ethics (CONEP) (protocol / CAAE: 54417616.1.0000.5146).

2.2 Design, sampling and diabetes diagnosis

A cross-sectional study was carried out among people diagnosed with diabetes and attended by the public health service of a medium-sized municipality (estimated population: 400,000 inhabitants) in the southeastern region of Brazil.

The participants were selected by sampling for infinite population considering a p value of 0.5, q = 0.5, E = 0.053, Z value = 1.96, non-response rate of 10% and confidence level of 10 (n = 341). For this, two health care centers from the primary health care in the city were randomly selected among the 73 centers. These two centers represent 7 health teams from public health system in the city. Then, individuals (more than 18 years) from these centers were invited to participate in the study until achieve the sample number previously established.

Diabetes diagnosis was conducted according to the American Diabetes Association, using one of the following tests: fasting plasma glucose \geq 126 mg/dL, 2 hours of plasma glucose (PG) \geq 200 mg/dL during an oral glucose tolerance test (OGTT), glycated hemoglobin (A1C) \geq 6.5%, or in patients with classic symptoms of hyperglycemia or hyperglycemic crisis a random plasma glucose \geq 200 mg/dL (ADA, 2010).

All individuals eligible were interviewed by a researcher, examined and blood draw executed.

2.3 Health Literacy related to diabetes scale

The Health Literacy in Diabetes (HLD) scale (known as "Alfabetização em Saúde para Diabéticos") was developed based on the Health Literacy theoretical model (Sørensen et al., 2012) to evaluate the access, understand/appraise and apply of information related to diabetes. The developed scale considered 10 questions and some psychometric properties were evaluated previously showing a suitable content validity and reliability (Kappa \geq 0.60) (Martins et al., 2018).

The following three initial overall questions were considered/applied but not included in the scale: "Have you received any information about diabetes?"; "When was the last time that you received information about diabetes?"; and "How is the frequency that you receive information about diabetes?". These three questions were used to characterize the overall access of information about diabetes (Table S1).

The HLD developed scale initially considered the different characteristics of information related diabetes. First the individuals were asked about who provided information about diabetes (doctor, dentist, nurse, health care agent and others). Then, they were asked about the topic of information, considering factors that affect diabetes (diabetes, complications, medicines/drugs, physical activity, nutrition, tobacco and alcohol). Moreover, questions about the source of information were considered (television, internet, radio, billboard, flyer, newspaper, magazine, poster, medicine leaflet and medical prescription). Thus, all these questions were used to develop three main questions about the access: information provider, topic of information and source of information. Therefore, the questions of each category were summed and categorized according to quintile. The following questions – 7 questions – in the scale were developed to measure understand/appraise and application of information. These questions asked about the understanding of the information, the possibility of classifying it as more or less important, the possibility of identifying the quality and veracity of the information, the evaluation of the advantages and the disadvantages of different treatments for diabetes and if the interviewee incorporated information into practice on a daily basis, maintaining an appropriate behavior considering the information received about diabetes.

2.4 Factor analysis

The factorial structure of the HLD scale was analyzed by Exploratory Factor Analysis (EFA) and Confirmatory Factor Analysis (CFA). Initially, EFA was conducted to check the latent dimensions of scale. Since HL theoretical model (Sørensen et al., 2012) considering the access, understand/appraise and apply factors was used to develop the scale, it was also considered to define the number of factors in the EFA. Initially, matrix correlation was analyzed to identify any correlation (p < 0.05) among the items in the scale. The Bartlett test and the Kaiser–Meyer–Olkin (KMO) measure were used to check whether the items were adequate to perform factor analysis. Then, the communalities were analyzed to identify the variance of each item in relation to the all scale (> 0.5). Varimax orthogonal rotations were used to check the factors considered and the variance explained by the selected components was evaluated to identify the items in each factor (higher values grouped). Cronbach's Alpha was used to check the internal consistency of each factor and the total scale.

After that, CFA was conducted to confirm and establish the factorial model. For this, the quality of model was evaluated by the ratio between chi-square (χ 2) value and the number of degrees of freedom – values lower than 5 mean a suitable model. The goodness of factorial model was evaluated using the following parameters: Root Mean Square Error of Approximation (RMSEA) (suitable when lower than 0.05), Goodness-of-Fit (GFI) (> 0.90 means a suitable model), Comparative Fit Index (CFI) and the Tucker–Lewis Index (TLI) (> 0.90 indicate a good fit).

To evaluate each factor (latent variable) identified separately all items (questions) attributed in each factor (according with variances) were summed to determine a score (cut-off) for each one. For this, each factor constructed was dichotomized

according with the lower limit of confidence interval as cutoff and categorized as "low" and "high" level of condition (outcome). Therefore, it can be used in any sample considering the lower limit of confidence interval. The overall HL considering the 10 items was also summed and categorized as mentioned above.

2.5 Individuals profile – socioeconomic, biochemical and psychological/physical measures

Considering each factor generated by factor analysis as dependent variable (outcome), the associated factors with the "high" (better) condition were identified to determine the profile of individuals with HL related to diabetes. The following socioeconomic and diabetes description variables were considered as independent variables: gender, age, skin color / ethnicity, civil status, schooling, number of people with diabetes at home and speeding money with medication.

Biochemical parameters were also evaluated. For this, a blood draw was conducted after 8 hours of fasting to determine serum levels of: HDL (high density lipoproteins), LDL (low density lipoproteins), glucose, glycated hemoglobin, insulin, triglycerides and urea levels. All analyses were performed at the same laboratory. Glucose measurement was performed using the enzymatic colorimetric method, with values between 70 and 99 mg/dL as reference. The measurement of glycated hemoglobin was performed by high-performance liquid chromatography. Insulin level was checked by chemiluminescence method. HLD, LDL, glucose, triglycerides and urea were measured by enzymatic method (Wiener CB350i). Data were expressed as mean and standard deviation.

Physical condition was evaluated by waist circumference and expressed as mean and standard deviation. The quality of life of people living with diabetes was evaluated by the scale Diabetes-39 (Queiroz et al., 2009). All items of scale were summed and the impact of at least one item was considered as impact in the quality of life. Cognitive function was evaluated by the Mini-Mental State Examination (MMSE) (Almeida, 1998), which evaluate five areas of cognitive function: orientation, immediate memory, attention and calculation, language and verbal construction. The total score ranges from 0 (impaired) to 30 (normal) and the variable was considered quantitatively. The gender differences in terms of HL factors were also considered.

The evaluation of literacy in terms of nutritional habits was done through the application of an instrument (questionnaire) called Nutritional Literacy among people with Diabetes (NLD) whose interpretability is made by identifying and counting the correct answers for 24 combinations of 3 words each. For each combination of words, the individual should indicate the right one related to diabetes. All right questions were summed and considered quantitatively (Eleutério et al., 2018).

Same approach was used for HL regarding the practice of physical activity, using the "Health Literacy on the Practice of Physical Activities Among Diabetics" (HLPPA-D) questionnaire (Martins et al., 2018), and drug adherence among people living with diabetes, using the "Health Literacy Regarding Drug Adherence Among Diabetics" (HLDA-D) questionnaire, each one with 18 questions (Cardoso et al., 2019; Crespo et al., 2020).

2.6 Statistics

SPSS 25.0 (IBM) software was used for EFA, descriptive, bivariate and multiple analyses. AMOS SPSS (IBM) software was used for CFA. Initially, descriptive analysis was conducted to estimate absolute frequency (n), the relative frequency (%) and average and standard deviation for quantitative variables. Bivariate analyses were carried out using the $\chi 2$ -test. Variables with p value equal or lower than 0.2 were considered in multiple models. Subsequently, the adjusted multilevel model was estimated by logistic regression, and only variables with a significance level of 5% (p \leq 0.05) were maintained. *Odds ratio* and 95% confidence interval were estimated. Pearson's correlations were conducted to evaluate the relation between each factor of HL scale, as well physical activity, nutritional status and drug adherence HL with biochemical

parameters. Factor analysis and parameters were described above. For CFA, all individuals with any missing information were excluded and this sample was also considered for bivariate and multiple analysis.

3. Results

341 individuals were diagnosed with diabetes and included in the study. Socioeconomic characteristics of the sample were described in the Table 1. Among them, the most of individuals received information related to diabetes (91.9%) (Table S1). Interestingly, the sample evaluated mainly who has had access to this type of information frequently, every month (31.5%) or 6 months (31.1%). It is may explained by the characteristic of sample that was recruited from a health care center from the Brazilian health system which is mainly based on the prevention of diseases. In overall, a good pattern of HL was identified among the individuals evaluated, with higher prevalence to the best conditions for all questions used to develop the HL scale.

Table 1 - Multiple analyses of independent variables associated (p < 0.05) to high level of health literacy related to diabetes scale considering each factor (access, understand/appraise and apply).

| Variables | High Access | | High Understand/Ap raise | op | High Apply | | High total HI | _ |
|-------------------------------|----------------|-------|--------------------------------|---------|----------------|-------|----------------|---------|
| | OR (95% CI) | p | OR (95% CI) | p | OR (95% CI) | p | OR (95% CI) | p |
| Skin color | , <u> </u> | | | | | | | |
| White | 1 | | | | | | | |
| Black/Brown/ | 2.69 | 0.004 | | | | | | |
| Asian/Indigenous | (1.41-4.26) | | | | | | | |
| Civil status | | | | | | | | |
| In a relationship | 1 | | | | | | | |
| Single | 0.42 | 0.005 | | | | | | |
| | (0.23-0.77) | | | | | | | |
| Schooling (years) | 1.13 | 0.002 | 1.16 | < 0.001 | | | 1.18 | < 0.001 |
| | (1.04-1.22) | | (1.08-1.26) | | | | (1.09-1.27) | |
| Spending money wit medication | th | | | | | | | |
| No | | | | | 1 | | | |
| Yes | | | | | 1.88 | 0.021 | | |
| | | | | | (1.09-3.24) | | | |
| HDL | 0.97 | 0.005 | | | | | | |
| | (0.95-0.99) | | | | | | | |
| LDL | | | | | 0.99 | 0.016 | | |
| | | | | | (0.98-1.00) | | | |
| Insulin | | | | | 0.96 | 0.050 | | |
| | | | | | (0.93-1.00) | | | |
| Cognitive condition | 1.15 | 0.019 | 1.24 | < 0.001 | | | 1.14 | 0.009 |
| | (1.02-1.29) | | (1.11-1.39) | | | | (1.03-1.27) | |

OR – odds ratio. 95% IC – 95% confidence interval. Source: Authors (2022).

3.1 Access, understand/appraise and apply competencies identified by factor analysis

The developed HL related to diabetes scale was evaluated regarding factor analysis considering the conceptual model proposed by Sørensen et al. (2012). Therefore, in the EFA was checked whether the three factors proposed (access, understand/appraise and apply) and the factor loading of each item could be identified as designed. The 10 items of scale and considering 3 conceptual factors showed a KMO value of 0.919 and *Bartlett* test with p-value < 0.001, showing a properly factorial fit for the matrix data. Cronbach's Alpha test for the scale considering all items was of 0.936, suggesting an optimal internal consistency. The Varimax rotation showed that three items (1, 2, 3) were loaded (variance > 0.6) on the first factor (access); five items (4, 5, 6, 7, 8) loaded on the second factor (understand/appraise); and two items (9, 10) on the third factor

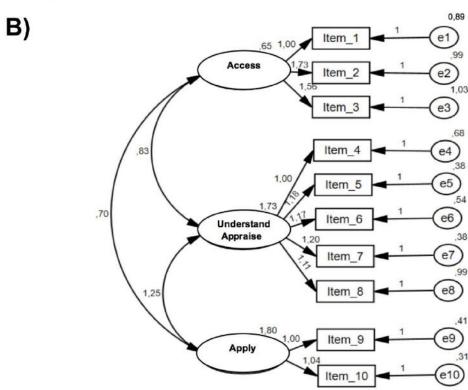
(apply) and it explained 81.2% of cumulative variance that means (Fig. 1A). Therefore, the items in the developed HL related to diabetes scale were loaded in the right factor, and the scale was able to explain 81.2% of the conceptual model to evaluate the access, understand/appraise and apply. Moreover, each factor showed a good internal consistency with Cronbach's Alpha test between 0.7 - 0.9 and communalities among the items between 0.5 - 0.9 (Fig. 1A).

Then, CFA was conducted to confirm the factorial structure identified by EFA using 3 factors (Fig. 1B). CFA confirmed the fit of model by the following results: |2/df of 2.09; RMSEA of 0.061 (95% confidence interval 0.04 - 0.08); CFI of 0.986; TLI of 0.980; and GFI of 0.955. All these tests confirmed an optimal fit of proposed factor model. Therefore, the items in the developed HL related to diabetes scale were in fact loaded in three factors to evaluate the access, understand/appraise and apply of HL.

Figure 1 - (A) Exploratory factor analysis (EFA) of health literacy related to diabetes scale according with factors identified (n = 341). **(B)** Confirmatory factor analysis (CFA) of health literacy related to diabetes scale according with factors identified (latent variables) and items/questions.

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| | Factor 1 | Factor 2 | Factor 3 | Communalities | Cronbach's alpha |
|--|-------------|-------------|-------------|---------------|------------------|
| ACCESS | | | | | • |
| 1 – Quantity of professionals/people who provided information related to diabetes. | 0.674 | 0.225 | 0.154 | 0.528 | |
| 2 – Quantity of topics discussed in the information related to diabetes. | 0.751 | 0.318 | 0.335 | 0.778 | |
| 3 – Quantity of sources used to obtain information related to diabetes. | 0.848 | 0.297 | 0.116 | 0.820 | 0.788 |
| UNDERSTAND/APPRAISE | | | | 97027335456 | |
| 4 - Did you understand the information received related to diabetes? | 0.294 | 0.692 | 0.461 | 0.778 | |
| 5 - Are you able to classify the importance of information received related to diabetes? | 0.326 | 0.831 | 0.281 | 0.875 | |
| 6 - Are you able to judge the quality of information received related to diabetes? | 0.280 | 0.819 | 0.323 | 0.853 | |
| 7 – Are you able to evaluate if the information received related to diabetes is true or false? | 0.334 | 0.842 | 0.256 | 0.886 | |
| 8 – Are you able to evaluate the advantages and disadvantages of information received related to diabetes? | 0.267 | 0.828 | 0.205 | 0.799 | 0.947 |
| APPLY | | | | | |
| 9 - Do you apply in you daily life the information received related to diabetes? | 0.203 | 0.319 | 0.874 | 0.906 | 20_00000000 |
| 10 - Can you keep a properly behavior considering the information received related to diabetes? | 0.241 | 0.323 | 0.861 | 0.904 | 0.910 |



Source: Authors (2022).

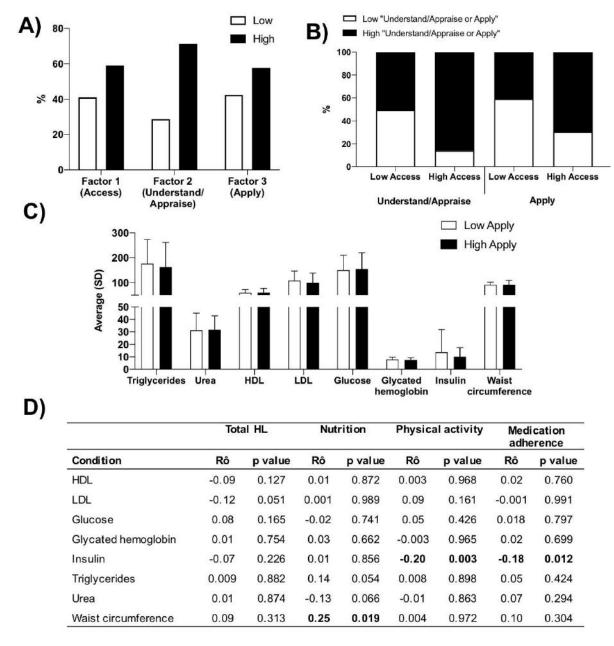
3.2 High access to information promotes understand/appraise and apply factors self-reported but better HL profile did not change biochemical profile

The items in each factor considered (access, understand/appraise and apply) were grouped (summed) and dichotomized according with lower limit of 95% confidence interval as "low" and "high" level. 60 - 70% of individuals had a

high level of access to information, understand/appraise and apply (Fig. 2A). Therefore, a high level of HL related to diabetes was identified in the sample evaluated, since the information received was understood and applied, according with individuals' answers. In fact, people living with diabetes who had high access to information also reported a higher understand/appraise and apply (Fig. 2B). Considering the components of "access" factor where the questions were formed considering different providers and sources, a higher number of sources to information can lead to a higher understand/appraise and apply and, therefore, should be considered by HL scales.

Although a high prevalence of HL was found among people living with diabetes, the results suggest that it did not change biochemical profile related to diabetes. No difference was identified for all biochemical and physical parameters among people considered with low and high HL apply factor (Fig. 2C). These results suggest that some information may not have been properly applied in the daily life to change harmful behaviors or the information were focused in others topics. However, higher HL related to physical activity and medication adherence was significantly correlated to lower insulin level (Fig. 2D). Despite the significance of this finding, insulin dosage has a minor relevance for patients who already have a diagnosis of diabetes and their values vary according to the duration of the disease and the use of medications for the treatment of diabetes, especially exogenous insulin and insulin secretagogues (Rodacki et al., 2008).

Figure 2 - (A) Percentage of low and high level of health literacy related to diabetes in each factor identified (access, understand/appraise and apply). **(B)** Percentage of low and high levels of understand/appraise and apply factor among individuals with low and high access of information (factor) related to diabetes. **(C)** Average (SD) of biochemical parameters and physical/cognitive conditions of individuals evaluated. SD - standard deviation. LDL - Low Density Lipoproteins; HDL - High Density Lipoproteins. Cognitive condition was evaluated by Mini-Mental State Examination; the average represent the number of right answers (0 - 30 questions). **(D)** Correlation between biochemical and physical parameters with total HL related to diabetes scale and HL related to nutritional status, physical activity and medication adherence.



Source: Authors (2022).

3.3 Patient profile with high level of HL related to diabetes

Considering the total HL scale and factors identified (access, understand/appraise and apply), we also evaluated the variables associated with the high HL level to identify the profile of people living with diabetes and high HL. In the bivariate analysis, independent variables related to socioeconomic conditions, characterization of diabetes costs, biochemical

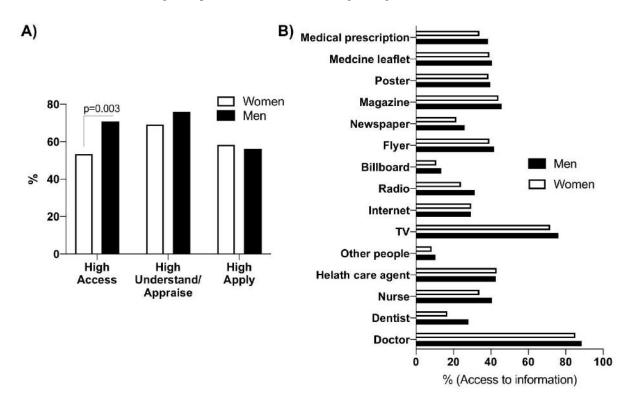
parameters, physical/cognitive conditions and quality of life were considered; and variables with p value lower than 0.2 were considered in the multiple models.

In the multiple model (logistic regression) was identified that high access was associated (p > 0.05) with: skin color / ethnicity, schooling, HDL level and cognitive condition (Table 1). The high understand/appraise was associated (p > 0.05) with schooling and cognitive condition (Table 1). Additionally, the high apply was associated with spending money with medication, LDL and insulin levels (Table 1). With regard to the elderly, medical societies have defined the establishment of goals for glycemic control in patients in this age group. According to the American Geriatrics Society (AGS), a glycemic target with A1C between 7.5% and 8.0% should be sought in healthy elderly people with a life expectancy greater than 10 years, which can be reduced to 7.0% to 7.5% depending on the clinical and social conditions of each person. However, for those who have a higher number of complications related to diabetes, disabilities, longer illness time and shorter life expectancy, the target can be raised to levels between 8.0% and 9.0% of A1C (AGS, 2013). The International Diabetes Federation and the American Diabetes Association defined glycemic targets depending on individual characteristics and other associated risk factors (ADA, 2017; IDF, 2019). Therefore, in our sample, although the statistical significance of HL as a way of increasing glycemic control by reducing A1C levels is not evident, most patients presented A1C values according to their therapeutic goals within reference limits recommended by relevant medical societies. The high total HL level was associated (p > 0.05) with: schooling and cognitive condition (Table 1). In summary, these results suggest that educational status and cognitive condition may favor a better HL level, showing higher access to information and understanding/appraising, which was expected. Moreover, high apply level was higher among people which spending money with medication and, therefore, it may suggest the adherence to medication.

3.4 Gender differences in the level of HL related to diabetes

Since previous systematic review highlighted the needed to evaluate gender differences in the levels of HL related to diabetes (Caruso et al., 2018), it was considered. A higher proportion of men had high access factor level, compared to women (p = 0.003, by chi-square test) (Fig. 3A). However, a similar proportion of high understand/appraise and apply was identified for both genders (Fig. 3A). Considering the better level of high access among men, the specific source/provider of information between the genders was characterized. In overall, men showed higher levels of access to information in all sources/providers, compared to women (Fig. 3B), except for health care agent provider. Altogether, these data suggest a higher HL related to diabetes level for men, compared to women, and mainly in relation to access to information.

Figure 3 - (A) Distribution of high level of health literacy related to diabetes in each factor according with gender. **(B)** Level of access to information considering each provider or source according with gender.



Source: Authors (2022).

4. Discussion

Although HL concept still been debated in the literature, it is mainly described as individual cognitive skills and abilities applied in a medical context in relation the access to information which, when understood, is applied to promote health outcomes (Sørensen et al., 2012). Since diabetes treatment is mainly based on self-care to avoid complications and to reduce risk factors (Chatterjee et al., 2018), HL context is extremely important to improve quality of life and life expectancy of people living with diabetes. We show a new diabetes-specific scale developed to measure HL, which consider as factorial structure the following competencies: access, understand/appraise and apply. The validity construct conducted by EFA and CFA confirmed the optimal fit of proposed model according with the items loaded in each factor. Interestingly, as novelty, in our scale the "access" factor was developed considering the different sources of information, as well professionals/people who could provide any information related to diabetes and topics discussed in this information. In fact, people who reported high levels of access also reported high understand/appraise and apply. Therefore, to achieve a high HL on diabetes it may be necessary to increase the quantity of sources and professionals/people responsible for providing this information and, consequently, this may lead to an enhanced understand/appraise and apply profile. However, high apply did not led to a better biochemical profile which suggest that HL self-reported may not affect directly clinical outcomes or the quality and content of information needs to be enhanced according with patients' needs. Even for individuals that received information about diabetes, understood and evaluated it as important (appraise), it is a personal choice to apply on a daily basis. Moreover, contextual determinants and social context may not favor the application of some behavior to change health outcomes. Results from multiples analysis showed that different variables are associated to a high HL on diabetes considering each factor, and it could be considered to enhance this process (i.e., cognitive condition associated to access and understand/appraise factors).

Clinical trials have shown that educational interventions to improve self-care among people living with diabetes affect positively health outcomes (Ghoreishi et al., 2019; Thoolen et al., 2007; van Puffelen et al., 2019), such as physical activity and vegetable intake (Thoolen et al., 2007). Moreover, these interventions also require knowledge, emotional adaptation and self-efficacy to overcome barriers (Ghoreishi et al., 2019). In this context, HL is a properly indicator of how these interventions are understood and applied in the daily life. For this, HL scale should consider all these factors (access, understand/appraise and apply). Although previous scales have considered mainly a wide evaluation of understand/appraise process (Ishikawa et al., 2008; Lee et al., 2018), the apply factor is necessary to identify whether the information received has been used to improve self-care and health outcomes. Additionally, educational interventions, which also consider frequent contact with the individuals and increased number of sessions to provider information, can reduce significantly the incidence of diabetes complications (Diabetes Prevention Program Research, 2002). Therefore, whether an increased number of providers (professionals/people) and sources of information is considered, a higher HL related to diabetes is expected. Then, as novelty we considered in the access factor different sources of information which could provide any information related to diabetes; and we also included among overall questions in the developed scale a specific one to evaluate the frequency that this type of information has been received.

The factor analysis is used to determine the factorial structure of scale, exploring the characteristics of instrument and whether the items support the theoretical model considered (El-Den et al., 2020). Our scale was developed based on HL conceptual model proposed by Sørensen et al. (2012), and competencies suggested by the model (access, understand/appraise and apply) were confirmed as factors in the developed scale in an optimal fit. Therefore, the proposed scale is able to collect information related to access, understand/appraise and apply of HL on people living with diabetes.

The multiple models evaluated here by regression logistic analysis may suggest the profile of patients with high HL related to diabetes. In fact, educational interventions have to be designed to fit patients' profile, such as resources, culture and lifestyle (Sørensen et al., 2012). Even socio-cultural environment affects the implementation of self-care in diabetes and, therefore, there is interplay between individual and contextual determinants to promote HL (De Man et al., 2019). Considering these aspects, professionals could promote patient empowerment, which describes the ability to help patients to discover their capacities and to be responsible on own health decisions (Funnell & Anderson, 2004). Interestingly, the high access level was higher among people with skin color or ethnicity black/brown/Asian/indigenous. Although some racial inequalities related to diabetes prevalence and rates of complications have been reported (Peek et al., 2007), our results suggest that a high level of access to information has been provided for this group, but it could be affected by Brazilian health system context which is based on reduced inequalities related to health care. In contrast, high level of access and understand/appraise was associated with better schooling (years) and cognitive condition. Since low literate people has reported difficulties to understand/appraise the decision process (Storms et al., 2017) and poor cognitive condition has been associated to inadequate HL (Federman et al., 2009), we expected that both conditions could be improved by the access and, mainly, the understand/appraise factor and it needs to be further investigated by interventional studies.

HL related to diabetes has been associated with higher medication adherence (Ueno et al., 2019). In fact, high apply was associated with spending money with medication. This result suggests the association between the apply in participants with high levels of HL and medication adherence. Therefore, information related to diabetes should also focus on others factors which affect diabetes treatment and to avoid complications, such as diet and physical activity. These results also highlight that HL related to diabetes should consider the complex factors that affect the disease and the quality of information is necessary to achieve a properly HL profile. Although LDL and insulin level were associated with high apply, OR values (± 1.0) show that these biochemical factors do not affect apply and it was significantly confirmed. Surprisingly, in relation to gender difference the access to information was higher for men. Although women experience more health issues than men

(Regitz-Zagrosek, 2012), even for diabetes (Kautzky-Willer et al., 2016), a higher access to health care is expected for women (Merzel, 2000). Therefore, we expected a better profile for women compared to men. However, this result suggests that HL related to diabetes must be improved among women to promote self-care and these gender differences for HL need to be better evaluated considering health care characteristics.

5. Conclusion

The evaluation of the Health Literacy Diabetes scale's psychometric properties in people living with diabetes collaborates to emphasize the importance of using instruments as tools for the elaboration of strategies for disease prevention, minimization of complications, and health promotion. The statistical analysis demonstrated the instrument construct reliability and validity in the studied population, inferring suitability for application in research, and health services that assist people living with diabetes. The developed scale to measure HL related to diabetes showed an optimal fit considering as factors the access, understand/appraise and apply by factor analysis. As novelty the access factor was developed considering the different sources of information, topics discussed and professionals/people who provided the information. Moreover, high access to information showed a trend for a better profile of understand/appraise and apply. Interestingly, high HL profile considering each factor (access, understand/appraise and apply) was associated with socioeconomic conditions. Some gender differences were found with a higher access to information among men. Meanwhile, a high HL level was not associated with a better biochemical profile. Health information for people living with diabetes should focus on specific risk factors for the disease or behaviors that modulate biochemical parameters. In clinical and research scenarios, valid and reliable instruments may contribute to the identification of modifiable risk factors that, by acting bidirectionally, feedback the limitation of HL, from which complexity needs to be the target of studies that support public health policies.

We conclude that the Health Literacy in Diabetes (HLD) is a potentially effective and feasible instrument to detect patients at risk for inadequate health literacy in diabetes. Further researches involving valid and reliable health literacy measurement instruments and new evidence-based interventions are important to provide patients and healthcare professionals with the necessary tools to reduce health inequities attributed to low health literacy.

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