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Health literacy and cardiovascular complications in people with type 2 diabetes

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A – Study Design, **B** – Data Collection, **C** – Statistical Analysis, **D** – Data Interpretation, **E** – Manuscript Preparation, **F** – Literature Search, **G** – Funds Collection

Summary **Background.** Cardiovascular complications are the main causes of death for type 2 diabetes. Their relationship to socio-economic factors, such as health literacy, is not well known.
Objectives. To study the relationship between health literacy and cardiovascular complications (acute myocardial infarction, cerebrovascular accident, transient ischemic attack and ischemic heart disease) in type 2 diabetes patients and to understand the relationship of type 2 diabetes mellitus associated cardiovascular disease with empowerment and therapy adherence.
Material and methods. A cross-sectional study with a convenience sample of people with type 2 diabetes in central Portugal. Socio-demographic and clinical characteristics (blood pressure, LDL cholesterol, hemoglobin A_{1c} and history of cardiovascular diseases) were collected, and validated scales were applied to assess health literacy, adherence to therapy, empowerment and quality of life. Bivariate inferential analysis between literacy, other variables and cardiovascular diseases, with subsequent Logistic Regression, was performed.
Results. A sample of $n = 202$, mean age 68.11 ± 10.19 years, $n = 116$ (57.4%) males was studied. Higher health literacy was significantly associated with a lower prevalence of cardiovascular diseases ($p = 0.015$). This relationship was independent of the remaining variables (OR = 0.947; 95% CI: 0.913–0.982; $p = 0.003$). Significant relationships were demonstrated between cardiovascular disease and quality of life ($p = 0.001$), adherence to total therapy ($p = 0.045$), general diet ($p = 0.002$), physical activity ($p = 0.027$), age ($p = 0.004$) and LDL cholesterol ($p = 0.036$).
Conclusions. The independent relationship between health literacy and cardiovascular disease in people with type 2 diabetes, when confirmed, will indicate that health literacy promotion acts as an important health policy measure to be adopted.
Key words: diabetes mellitus type 2, health literacy, self care, quality of life, empowerment, treatment adherence and compliance.

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Background

Diabetes mellitus (DM) is an important public health problem causing premature disability and death. These are mainly due to a wide spectrum of complications [1], of which Cardiovascular Disease (CVD) and kidney disease stand out as the main causes of death in diabetic people worldwide [2].

Literacy, "people's ability to make informed daily decisions at home, in the community and in the work-place in the use of health services" is a enablement strategy to increase people's control over their own health, to seek for information and to assume responsibilities" [3]. It is also considered an empowerment strategy, patients so acquiring the necessary influence on the achievement of health out-comes, their behavior, self-caring, critically thinking in autonomy [4]. The mechanisms underlying the relationship between Health Literacy (HL), self-care and clinical outcomes of DM are poorly understood [5]. Some studies show that low HL is associated with poor glycemic control [6, 7], while others show that low literacy is associated with poorer knowledge about the disease, as well as with less adherence to self-care, but it is not associated with poor control of glycaemia. Literature is still relatively scarce and ambiguous regarding the relationship between HL and macrovascular complications in DM [8, 9].

Considering the HL potential for health promotion and disease prevention and the uncertain relationship between HL and the outcomes of DM, as well as the great impact of CVDs on DM's morbimortality, this study aimed to understand the relationship between HL and cardiovascular diseases (CVD) [Acute Myocardial Infarction (AMI), Cerebrovascular Accident (CVA), Transient Ischemic Accident (TIA) and Ischemic Heart Disease (IHD)] in people with Type 2 Diabetes Mellitus (T2DM). It also aimed at understanding the relationship between the occurrence of cardiovascular complications and empowerment, adherence to therapy and quality of life in people with T2DM.

Material and methods

Study design, setting and participants

A cross-sectional, quasi-randomized study was performed using questionnaires in a representative sample of people with T2DM from four primary care units in central Portugal between

07/01/2018 to 07/17/2019. The selection criteria for primary health care units were being situated in an influence area of both medical schools in central Portugal, receiving medical students for the last two years and being coordinated by a PhD doctor. From the T2DM patients attending specific primary care diabetes consultations in randomized days, those who agreed to participate and signed the informed consent were included in a convenience manner. Exclusion criteria were those not willing to participate, not having the ability to understand the questions and those suffering from mental diseases. Anonymity and confidentiality were guaranteed. Ethics approval was obtained from the Ethics Committee of ARS Centro, and questionnaires author's gave permission to this specific use.

Variables

The questionnaire included:

Socio-demographic variables: gender, age, schooling level (number of years completed), living conditions and monthly income (higher, equal or lower than the national minimum wage) were used to determine the Socio-Economic Deprivation Index (SEDI) [10].

T2DM variables: time of disease evolution (years), CVA for stroke, HbA_{1c} level (%), blood pressure (BP, mm Hg) and LDL cholesterol (mg/dL) were recorded by the general practitioners.

HL: a specific scale, known as the Medical Term Recognition Test (METER), was used [11].

Adherence to pharmacological and non-pharmacological therapy: completed using the Diabetes Self-Care Activities Measure (DSCA) [12].

Empowerment: analyzed with the Diabetes Empowerment Scale – Short Form (DES-SF) [13].

Health-related quality of life: recorded using EQ-VAS [14].

Data source/measurement

The socio-demographic variables were calculated form the questionnaires answers. The Socio-Economic Deprivation Index (SEDI) was calculated giving a score of 1 to each of the following responses: receives less than the minimum wage; attended 4 or less years of schooling and living alone. In the absence of this, a score of 0 was given, so the total score for this index ranged from 0 to 3. The lower the person's socio-economic index, the higher the SEDI.

As for variables related to T2DM, the "time of disease evolution" and "history of cardiovascular complications" were verified in the respective medical record, as well as the most recent values of HbA_{1c}, BP and LDL cholesterol.

HL evaluation was performed using the METER scale (Medical Term Recognition Test), previously validated in Portugal [11]. This scale consists of a list of 40 real health-related words and 30 "non-words" [11]. The participant was asked to read the list and mark only the words he was sure were real. When the patient reported having difficulties with vision, this questionnaire was answered through an interview. In this study, the scale was scored adding the selected real words (Cronbach's α = 0.92). The greater the number of real terms marked, the greater the respondent's HL.

The "Diabetes Self-Care Activities Measure" (DSCA), validated in Portugal (Cronbach's α between 0.36 and 0.68) [12], assesses the adherence to pharmacological and non-pharmacological therapy. The DSCA consists of questions organized by seven dimensions. The first six dimensions cover diabetes care over the last seven days, to which the person responds from 0 to 7, according to the number of days on which a certain behavior was adopted. The coding was only inverted (7 days = 0; 0 days = 7) in dimension two ("Specific Diet"), in which the questions refer to behaviors to be avoided [11]. Regarding "Smoking habits", in this study, we chose to only evaluate question 7.1 "Did you smoke a cigarette, even if only one drag, during the last seven days?" (no = 7; yes = 0). The analysis of adherence to pharmacological therapy was limited to the question "Over the last seven days, how many days did you actually take your diabetes medications as indicated?". Due to the difficulty the participants showed in understanding what was intended with certain questions in the questionnaire, a decision was made that if the patient asked for it, the interviewers would make the questions, explain them and mark the answer [12].

Empowerment was measured using the "Diabetes Empowerment Scale – Short Form" (DES-SF), validated in Portugal (Cronbach's $\alpha \geq 0.90$). This scale consists of eight items that address the patient's psychosocial self-efficacy in relation to T2DM [13]. Answers range from 1 to 5, and the greater the user's empowerment, the higher the score obtained. We opted to apply DES-SF through an interview, given the participants' difficulty in understanding the meaning of the items.

Finally, QdVRS was assessed using the "European Quality of Life - Visual Analogic Scale" (EQ-VAS). This scale is an integral part of the generic instrument for measuring quality of life, "European Quality of Life - 5 Dimensions" (EQ-5D), the use of which is validated in Portugal. The EQ-VAS is described to the patient as a thermometer, whose values range from 0 to 100, with 0 being the worst health condition imaginable and 100 the best. The user was asked to indicate on this "thermometer" a number that reflected his health status at that time [14].

Bias

To avoid possible biases in social desirability, the anonymity and confidentiality of the participants in this study was guaranteed, and the questionnaires were applied by researchers identified as medical students and not by the health professionals of each unit. Regarding the variable "cardiovascular complications", for statistical analysis, preference was given to patients' assessments of medical records by the assistant family doctors to avoid possible information and memory bias. The family doctor did not have access to the patients' answers from the questionnaires.

Study size

Minimal sample size was calculated as of n = 196, for an error margin of 7% and a confidence interval of 95% using ["Raosoft – Sample Size Calculator" (http://www.raosoft.com/samplesize.html)], considering the population with T2DM in the studied primary health care units of ARS Centro [14, 15]. A sample of n = 202 was collected.

Statistical methods

SPSS version 23.0 software (Statistical Package for the Social Sciences) for MacOs (SPSS Inc, Chicago, IL, USA) was used for statistical analysis. Descriptive and inferential statistics were performed after checking the non-normality of the data using the Kolmogorov–Smirnov test ($n \geq 30$). Thus, the Mann–Whitney test was used to study the relationship between HL and CVDs and between CVDs and empowerment, adherence to therapy, quality of life and socio-demographic and clinical-laboratory variables. Logistic regression analysis was performed in forward conditional mode, and for the variables with significant relationship to the presence or absence of cardiovascular disease using bivariate analysis. Relative risks and 95% confidence intervals were calculated, considering $p < 0.05$ as significant.

Results

The calculated sample was n = 196, and the study sample consisted of 202 persons: 97 (48%) from UCSP Covilhã [Personalized Health Care Units (PHCU)], 51 (25.2%) from USF Coimbra Centro [Family Health Unit, (FHU)], 24 (11.9%) from USF Topázio [FHU] and 30 (14.9%) from UCSP Mealhada [PHCU].

The average age was 68.11 ± 10.19 years (minimum 28 and maximum 87 years). Table 1 shows the distribution by gender, age groups and schooling level.

Regarding the schooling level, described by classes in Table 1, the minimum was 0, the maximum was 15 years, and the average was 6.10 ± 3.13 years.

Table 1. Sample by gender and age (*n* = 202) and its correspondence with the Portuguese population with type 2 diabetes. The distribution of schooling level (*n* = 197) by class is also shown

		n (%)	Portuguese population with diabetes (%) [16, 17]
Gender	male	116 (57.43)	58.66
	female	86 (42.57)	41.34
Age groups (years)	25–34	1 (0.50)	2.69
	35–44	3 (1.49)	2.11
	45–54	16 (7.92)	17.67
	55–64	46 (22.77)	38.58
	≥ 65	136 (67.33)	38.94
Schooling level (years) (*)	≤ 4th year	113 (57.36)	N/A
	5th–8th year	24 (12.18)	
	9th–11th year	39 (19.80)	
	12th year	17 (8.63)	
	higher education	4 (2.03)	

* 5 people did not fill in this information, N/A – not available.

The length of T2DM was of 9.92 ± 7.81 years, with a minimum of 0 and maximum of 51.

Regarding the history of CVD, IHD was the most frequent complication (*n* = 28 (13.86%)), followed by CVA for stroke (*n* = 19 (9.41%)) and AMI (*n* = 8 (3.96%)). As for TIA, there was only one case. For 7 of the 49 individuals, there were 2 cardiovascular complications, thus the total was 56 (Table 2).

Table 2. Frequency of cardiovascular complications detected in patients' medical records

Cardiovascular disease		*n* (total of cases)	*n* (total of complications) (%)
IHD	only IHD	22	28 (50.00)
	AVC and IHD	3	
	AMI and IHD	3	
CVA	only CVA	15	19 (33.93)
	CVA and IHD	3	
	CVA and AMI	1	
AMI	only AMI	4	8 (14.29)
	AMI and IHD	3	
	CVA and AMI	1	
TIA		1	1 (1.79)
Total		49	56 (100)

The relative frequency (%) was calculated with the sum of the total complications (*n* = 56).

IHD – Ischemic Heart Disease, CVA for stroke – Cardiovascular Accident, AMI – Acute Myocardial Infarction, TIA – Transient Ischemic Accident

As for the METER questionnaire, 28.30 ± 9.13 real terms were recognized, with a minimum of 0 and a maximum of 40. Only 52 individuals (25.74%) indicated 35 or more real terms out of the existing 40.

The self-care activity showed greater adherence related to pharmacological therapy. The activity with lowest level of adherence was physical activity (Table 3).

Table 3. Characterization of the answers given in the DSCA measure by the sample under study (*n* = 202)

	Average ± SD	Min	Max	*n* (%)
Adherence to non-pharmacological therapy	4.27 ± 0.98	1.67	6.90	201 (99.50)
General diet	4.70 ± 1.66	0	7	202 (100.00)
Specific diet	4.50 ± 1.28	0	7	201 (99.50)
Physical activity	2.44 ± 2.25	0	7	202 (100.00)
Glucose monitoring	3.29 ± 2.61	0	7	202 (100.00)
Foot care	6.36 ± 1.12	0	7	202 (100.00)
Adherence to pharmacological therapy	6.96 ± 0.33	3	7	202 (100.00)
Total average adherence (pharmacological and non-pharmacological)	4.63 ± 0.80	2.53	6.82	201 (99.50)
Smoking habits	5.87 ± 2.56	0	7	202 (100.00)

For the "Diabetes Empowerment Scale – Short Form" (DES-SF), the average was 4.03 ± 0.68, with a minimum of 2.25 and a maximum of 5, and for the HRQoL, an average of 66.48 ± 19.19 was obtained, with a minimum of 6 and a maximum of 100.

The average HbA_{1c} was 6.98 ± 1.20 (minimum 5% and maximum 12% for the latest result). The systolic BP was 138.93 ± 17.37 mm Hg on average, with a minimum of 75 mm Hg and a maximum of 176 mm Hg. The diastolic BP was, on average, 75.02 ± 11.53 mm Hg, with a minimum of 33 mm Hg and a maximum of 105 mm Hg. LDL cholesterol was 94.79 ± 36.70 mg/dL on average, with a minimum value of 29.8 mg/dL and a maximum of 256.0 mg/dL.

Regarding HL (real terms) and cardiovascular complications, a statistically significant relationship was found (*p* = 0.015), with individuals with a history of cardiovascular complications recognizing fewer real terms than those with no such past. For isolated cardiovascular complications, IHD (*p* = 0.007), CVA for stroke (*p* = 0.031) and AMI (*p* = 0.009) were equally found. Individuals with CVA and/or IHD presented the same pattern of lesser HL as those with cardiovascular diseases. However, those with AMI recognized a greater number of real terms than those who did not have AMI (Table 4).

Table 4. Characterization of the relationship between the real terms identified in METER and cardiovascular disease

Average of selected real terms ± SD		*p**
With CVD	without CVD	0.015
24.16 ± 11.99	29.63 ± 7.58	
With IHD	without IHD	0.007
21.82 ± 12.55	29.35 ± 8.02	
With CVA	without CVA	0.031
23.95 ± 10.67	28.75 ± 8.86	
With AMI	without AMI	0.009
35.25 ± 3.69	28.02 ± 9.17	
With TIA	without TIA	0.733
28.00 ± 0.00	28.30 ± 9.15	

* Mann–Whitney U Test, CVD – Cardiovascular Disease; SD – Standard Deviation.

According to Table 5, cardiovascular complications were statistically related to worse HRQoL ($p = 0.001$), lower adherence to total therapy ($p = 0.045$), as well as lower adherence to "General diet" ($p = 0.002$) and "Physical activity" ($p = 0.027$) (Table 6). Cardiovascular complications were significantly related to more advanced age ($p = 0.004$). Total cardiovascular complications were significantly related to LDL cholesterol levels ($p = 0.034$) being smaller.

Table 5. Relationship between total cardiovascular complications and empowerment, HRQoL, adherence to therapy, sociodemographic variables, time of evolution of T2DM and clinical laboratory variables

	Total cardiovascular diseases		
	With CVD	Without CVD	p*
	Average ± SD		
Empowerment (DES-SF)	4.03 ± 0.63	4.02 ± 0.70	0.815
HRQoL (EQ-VAS)	**59.00 ± 18.79**	**68.83 ± 18.77**	**0.001**
Adherence to non--pharmacological therapy (no. of days during the last week)	4.07 ± 0.94	4.02 ± 0.70	0.083
General diet	**4.14 ± 1.41**	**4.88 ± 1.70**	**0.002**
Physical activity	**1.88 ± 2.17**	**2.62 ± 2.60**	**0.027**
Adherence to pharmacological therapy (no. of days during the last week)	6.92 ± 0.57	6.97 ± 0.20	0.958
Adhesion to total therapy (no. of days during the last week)	**4.42 ± 0.86**	**4.70 ± 0.77**	**0.045**
Age (years)	**71.67 ± 9.72**	**66.97 ± 10.11**	**0.004**
Schooling level (years)	6.10 ± 3.45	6.08 ± 3.04	0.945
SEDI	4.07 ± 0.94	4.33 ± 0.98	0.599
T2DM evolution time (years)	11.04 ± 6.87	9.56 ± 8.07	0.077
BP systolic (mm Hg)	142.00 ± 18.48	138.53 ± 16.09	0.164
BP diastolic (mm Hg)	73.98 ± 10.15	75.37 ± 11.88	0.249
LDL (mg/dL)	**83.49 ± 29.92**	**98.36 ± 37.99**	**0.036**
HbA_{1c} (%)	6.76 ± 1.24	7.05 ± 1.18	0.054

* Mann–Whitney U Test, CVD – Cardiovascular Diseases, SD – Standard Deviation.

Logistic regression analysis was performed to predict the "presence/absence of total cardiovascular complications". Table 6 shows the variables independently related and significantly contributing to the forecast of the complications under study.

Table 6. Variables included in the final logistic regression model that allows for the prediction of total cardiovascular complications

	Relative Risk (RR)	$CI_{95\%}$	p
Constant	14.645	–	0.002
HL (real terms)	0.947	[0.913; 0.982]	**0.003**
Cholesterol LDL	0.987	[0.976; 0.999]	**0.029**
Average general diet	0.770	[0.624; 0.950]	**0.015**
R^2 Nagelkerke = 0.162; correct global classification = 78.4%			

CI – Confidence Interval.

They were HL ($p = 0.003$), LDL cholesterol ($p = 0.029$) and average general diet ($p = 0.015$). For each additional day of adherence to a good general diet, the risk of developing cardiovascular complications decreases by about 23%, and for each extra real term recognized on the METER scale, the probability of having cardiovascular complications decreases by 5.3%.

Discussion

Key results

The relationship between HL and total cardiovascular complications proved to be significant, and less literacy was associated with such complications. Conversely, people with AMI showed a superior HL. Adherence to total therapy, general diet, physical activity, age, LDL levels and HRQoL were significantly related to total CVDs. HL, adherence to general diet and levels of LDL were independently related to total cardiovascular complications.

Limitations of the study

As a main limitation of this study, METER only evaluates the knowledge of vocabulary, having been validated in Portugal in a young health professional's sample. Thus, we used the continuous levels of the scale, as suggested in the original validation [18]. The questionnaires applied may have suffered a social desirability bias, as they were applied in a health unit by researchers identified as medical students. People with reduced visual acuity were not excluded, which may have skewed some results. Only one person had TIA, so the isolated assessment of this complication is limited. For a cross-sectional, quasi-randomized study, causal inferences are limited. However, the fact that the sample was obtained on pre-specified days by the interviewers allows for some degree of confidence. So no interference in the choice of days or of patients to be questionned by the responsible doctors was achieved.

Interpretation

In a sample consisting of 202 people with T2DM, 74.3% had inadequate HL. DM is a complex chronic disease, demanding monitoring and therapeutic management due to its outcomes [7]. These facts could support the statistically significant relationship between HL and cardiovascular complications ($p = 0.015$), as less literacy is associated with less ability to manage all the complexity inherent to the underlying disease and consequently lead to greater metabolic deregulation and the occurrence of complications. The present study found that this relationship remains statistically significant for each of the cardiovascular complications (IHD, $p = 0.007$; CVA for stroke , $p = 0.031$ and AMI, $p = 0.009$). The present results are partially in line with those of existing studies reporting significant relationships between HL and CVA for stroke [9] but not with Ischemic Heart Disease (IHD) [6, 7]. In the present study, there was a significant relationship between HL and IHD. Other studies did not show any relationship between HL and macrovascular complications of DM [8, 9]. It should be noted that the non-standardization of HL scales in the different studies makes it difficult to compare the results.

People with a history of AMI showed higher HL on average. The INTERHEARTH study reported psychosocial stress to be associated with a higher risk of AMI [19]. On the other hand, this result may reflect the limitations of the METER. Although with adequate HL, numeracy and practical application of the information obtained [9] may not be as developed.

Regarding self-care activities, physical activity was the lowest scored item. These results are in line with those already described by other studies [20] and reinforce the importance of promoting healthy lifestyles.

People with a history of cardiovascular complications reported significant lower quality of life (59.00 ± 18.79) compared to people without complications (68.83 ± 18.77), as did previous studies [21]. Diabetes and its complications imply greater therapeutic and economic burdens and have a negative impact on patients' autonomy and physical and psychosocial well-being.

The level of LDL was, on average, lower in people with CVDs. These values are far from recommended by the most recent guidelines [22]. The fact that LDL is lower in people with cardiovascular complications is probably due to closer monitoring and the awareness of diabetic patients about the importance of therapeutic compliance after the occurrence of cardiovascular events.

Lower HL has been shown to be independently related to the occurrence of total CVDs and thus reinforces the role of HL as an important non-clinical factor with the potential to reduce the risk of diabetes complications [9]. This potential is supported in the present study, because for each extra real term most recognized on the METER scale, the probability of having cardiovascular complications decreases by about 5.3%. The scarcity/ /inexistence of studies specifically proving the direct relationship between low HL and the occurrence of CVDs in people with T2DM [23, 24] makes comparison difficult, confirming this study's originality. Still, a recent investigation argues that inadequate HL is an independent predictor of poor glycemic control and the presence of diabetes complications (previous hospitalizations related to DM, neuropathy and retinopathy) [23]. All this data reinforce the need for more research in this area.

The "*Average General Diet*" also showed a direct relationship with total cardiovascular complications, as it was verified that for each additional day of adherence to a healthy diet, the risk of developing cardiovascular complications decreases by about 23%. Promotion of healthy eating is one of the pillars of diabetes management and plays a significant role in limiting the incidence of associated CVDs [25]. Finally, LDL also showed an independent relationship with total CVDs, reinforcing the importance of its control in reducing cardiovascular risk [26].

Generalizability

Being a quasi-randomized study, this study has some characteristics to be valued, namely being multicenter in rural and urban areas, with an age and gender distribution close to the one found in 2015 in the Portuguese population with DM [17] and demonstrating the representativeness of the sample studied. Two researchers performed the collection of field data in two different time sets and regions, using the same approved protocol. Thus, the results can be cautiously generalized. According to more recent data, people under the second basic cycle of studies, 6 years, was of 19.9% in 2020, and as this study found out they are a main target of concern for increasing HL [27].

Conclusions

Low HL was significantly associated with cardiovascular complications in people with T2DM (p = 0.015), IHD (p = 0.007) and CVA for stroke (p = 0.031). For AMI, HL is significantly higher (p = 0.009). For T2DM associated cardiovascular complications, significant differences with lower HL were found for HRQoL (p = 0.001), General diet (p = 0.002), Physical activity (p = 0.027), Adhesion to total therapy (p = 0.045), Age (p = 0.004) and for LDL levels (p = 0.036).

HL significantly and independently contributed to the prediction of cardiovascular complications, and for each extra real term recognized on the literacy scale, the risk of developing CVD decreased by about 5.3%.

HL promotion must be considered in the first line of diabetes treatment.

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