

Impact of diabetic retinopathy on vision-related quality of life: a cross-sectional study in Brazil

Impacto da retinopatia diabética na qualidade de vida relacionada à visão: um estudo transversal no Brasil

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How to cite:

Nunes BF, Reis JS, Barbosa NL, Silva NF, Frango AO, Soares NA. Impact of diabetic retinopathy on vision-related quality of life: a cross-sectional study in Brazil. *Rev Bras Oftalmol.* 2026;85:e0088.

doi:

<https://doi.org/10.37039/1982.8551.20260088>

Keywords:

Diabetes mellitus; Diabetic retinopathy; Sickness impact profile; Quality of life; Laser coagulation; Patient health questionnaire

Descritores:

Diabetes mellitus; Retinopatia diabética; Perfil de impacto da doença; Qualidade de vida; Fotocoagulação a laser; Questionário de saúde do paciente

Received on:
May 17, 2025

Accepted on:
July 22, 2026

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Conflict of interest:
no conflict of interest.

Financial support:
no financial support for this work.

Data availability statement:
the data that support the findings of this study are not openly available but are available from the corresponding author upon reasonable request.

Associated academic work:
This article is derived from the Master's thesis entitled *Impact of Diabetic Retinopathy and Diabetic Macular Edema on Vision-Related Quality of Life*, submitted by Brunelle Francino Nunes in the Professional Master's Program in Diabetes Education at the Santa Casa BH School of Health, Belo Horizonte, Brazil, in 2023.

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ABSTRACT

Objective: To investigate the impact of diabetic retinopathy on vision-related quality of life in patients with type 1 and type 2 diabetes mellitus in a Brazilian population.

Methods: This cross-sectional study included patients aged over 18 years attending the Diabetes Outpatient Clinic of Santa Casa de Belo Horizonte between January and December 2022. Vision-related quality of life was assessed using the National Eye Institute Visual Function Questionnaire. Patients were classified into three groups according to diabetic retinopathy severity: mild or moderate non-proliferative diabetic retinopathy; severe non-proliferative diabetic retinopathy or proliferative diabetic retinopathy, and compensated post-laser status diabetic retinopathy. Comparative analyses and multiple linear regression were performed.

Results: A total of 131 patients were included. Increasing diabetic retinopathy severity was associated with lower vision-related quality of life scores across all domains and in the total score. Patients with compensated post-laser diabetic retinopathy showed significantly higher vision-related quality of life scores compared to those with severe non-proliferative diabetic retinopathy or proliferative diabetic retinopathy. In multivariate analysis, diabetic retinopathy severity and worse visual acuity were independently associated with lower vision-related quality of life scores.

Conclusion: Diabetic retinopathy severity has a substantial impact on vision-related quality of life, underscoring the importance of comprehensive diabetes management. Strategies aimed at preventing diabetic retinopathy progression and ensuring timely therapeutic interventions, such as laser photocoagulation, may contribute to better vision-related quality of life outcomes. Additionally, addressing psychosocial aspects should be considered an integral component of patient care.

RESUMO

Objetivo: Investigar o impacto da retinopatia diabética na qualidade de vida relacionada à visão em pacientes com *diabetes mellitus* tipos 1 e 2 em uma população brasileira.

Métodos: Estudo transversal que incluiu pacientes com idade superior a 18 anos atendidos no Ambulatório de Diabetes da Santa Casa de Belo Horizonte entre janeiro e dezembro de 2022. A qualidade de vida relacionada à visão foi avaliada por meio do *National Eye Institute Visual Function Questionnaire*. Os pacientes foram classificados em três grupos de acordo com a gravidade da retinopatia diabética: retinopatia diabética não proliferativa leve ou moderada; retinopatia diabética não proliferativa severa ou retinopatia diabética proliferativa; e retinopatia diabética *status pós-laser* compensada. Foram realizadas análises comparativas e regressão linear múltipla.

Resultados: Foram incluídos 131 pacientes. A maior gravidade da retinopatia diabética foi associada a menores escores de qualidade de vida relacionada à visão em todos os domínios e no escore total. Pacientes com qualidade de vida relacionada à visão *status pós-laser* compensada apresentaram escores de qualidade de vida relacionada à visão significativamente mais elevados em comparação àqueles com retinopatia diabética não proliferativa grave ou retinopatia diabética proliferativa. Na análise multivariada, a gravidade da retinopatia diabética e a pior acuidade visual foram preditores independentes de pior qualidade de vida relacionada à visão.

Conclusão: A gravidade da retinopatia diabética impacta negativamente a qualidade de vida relacionada à visão, reforçando a importância de uma abordagem abrangente no manejo do diabetes. Estratégias voltadas à prevenção da progressão da retinopatia diabética e à implementação oportuna de intervenções terapêuticas, como a fotocoagulação a laser, podem contribuir para melhores desfechos de qualidade de vida relacionada à visão. Além disso, a abordagem de aspectos psicossociais deve ser considerada componente essencial do cuidado com o paciente.



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INTRODUCTION

Diabetic retinopathy (DR) stands as the most common microvascular complication associated with diabetes mellitus (DM) and constitutes the primary etiology behind acquired vision impairment among individuals in the working-age population, contributing to 5 to 17% of global blindness instances.⁽¹⁻³⁾ It is estimated that one-third of the worldwide diabetic population is afflicted with DR, with approximately one-third of this subgroup manifesting vision-threatening retinopathy.⁽⁴⁾ In Brazil, local studies indicate similar prevalence rates, reinforcing the impact of this condition on the Unified Health System (SUS, acronym from the Portuguese *Sistema Único de Saúde*).

The prevalence of DM is on the rise worldwide, primarily due to the increasing incidence of obesity and sedentary lifestyles, coupled with the global population's longer life expectancy and improved survival of patients with diabetes.⁽⁵⁻⁷⁾ According to the International Diabetes Federation (IDF) Diabetes Atlas,⁽⁸⁾ approximately 537 million people were living with diabetes globally in 2021. Projections indicate that this number will escalate to 643 million by 2030 and 783 million by 2045. Remarkably, about 79% of individuals with diabetes resided in low-and middle-income countries. The future surge in diabetes prevalence is poised to result in a substantial elevation in the number of individuals experiencing visual impairments.⁽⁸⁾

Conventional assessments of DR predominantly concentrate on clinical parameters. The patient's subjective experience and the broader implications on vision-related quality of life (VRQoL) are integral facets often overlooked. Given that a patient's overall health status is known to be determined not only by the disease itself but also by psychological, cultural, professional, and socioeconomic factors,⁽⁹⁾ the assessment of quality of life (QoL) emerges as a particularly important metric for understanding the patient's perspective and the overall impact of the disease on their lives, especially in individuals with chronic conditions, such as DM.^(9,10) It is noteworthy that the compromise of psychological well-being not only detrimentally affects patient adherence to their treatment regimens but also results in a decline in self-care, manifesting in less controlled glycated hemoglobin (HbA1c) levels.⁽¹¹⁾ Hence, a comprehensive approach to effective managing DM should consider not only physical health but also psychological aspects to promote sustainable and successful therapeutic practices.

In the current healthcare landscape, recognizing the significance of patients' VRQoL has become a paramount

objective in the management of DM and its complications.^(10,12) This shift reflects an acknowledgment of the holistic nature of healthcare, emphasizing not only biomedical markers but also the psychosocial well-being of individuals.⁽¹¹⁾

Cross-sectional studies in the populations of the United States, Europe, and Asia have demonstrated that DR is associated with worsening VRQoL.⁽¹³⁻¹⁵⁾ Currently, no studies have been identified that assess the association between the severity of DR and VRQoL in the Brazilian population. This is a critical knowledge gap, as understanding the impact of DR from the patient's perspective is essential for guiding public health and clinical decisions related to the detection, intervention, and long-term management of this visually debilitating disease.⁽¹²⁾

In this context, our study aimed to investigate the impact of DR on VRQoL in patients with type 1 (T1DM) and type 2 diabetes mellitus (T2DM) in a Brazilian population.

METHODS

A cross-sectional observational study was conducted to evaluate all active patients aged 18 years or older who were receiving treatment for T1DM or T2DM at the Diabetes Outpatient Clinic of Santa Casa de Belo Horizonte, in Belo Horizonte (MG), a public healthcare facility operating under SUS. The study included patients who were actively followed at the clinic between January and December 2022. To minimize measurement bias, a standardized ophthalmological assessment protocol was implemented.

Exclusion criteria included individuals unable to communicate or answer questions, as well as those with cataracts exceeding nuclear grade 2, cortical grade 5, or subcapsular grade 3, according to the Lens Opacities Classification System III (LOCS III).⁽¹⁶⁾ Patients with a history of congenital cataract, posterior capsule opacities, intraocular lens opacity, or corneal opacity were also excluded. Additional exclusion criteria comprised the presence of retinal vascular diseases unrelated to DR, such as ischemic ocular syndrome, retinal vein or artery occlusions, and macular telangiectasia, along with retinal dystrophies, prior uveitis-related vision impairment, degenerative myopia, central nervous system-related visual deficits, and optic neuropathies.

A total of 424 individuals were screened, and 131 were included in the final sample (105 T2DM and 26 T1DM). The distribution between diabetes types was unequal (T1DM with $n = 26$; T2DM with $n = 105$), reflecting the epidemiological profile of patients followed in the service. A

post hoc power assessment suggested adequate sensitivity for detecting moderate-to-large effects, while smaller differences between groups should be interpreted with caution.

The remaining individuals were excluded due to non-fulfillment of inclusion/exclusion criteria ($n = 77$), refusal to complete the questionnaires ($n = 41$), or the absence of DR signs ($n = 175$) (Figure 1). Data collection was conducted over a 12-month period, from June 2022 to May 2023.

Participants who consented to take part in the study underwent a detailed ophthalmological examination, followed by an interview-based administration of the VRQoL questionnaire. The visual acuity considered in the analyses corresponded to the eye with the best visual function. Additionally, data on sociodemographic characteristics (age, gender, education level, occupation, and marital status) were collected, along with diabetes-related clinical variables (disease duration, HbA1c levels), the presence of comorbidities (hypertension, dyslipidemia, cardiovascular diseases, nephropathy, and history of stroke), and lifestyle factors, including smoking history.

The study adhered to the ethical principles outlined in the Declaration of Helsinki (1975, revised in 2000) for research involving human participants. The study (CAAE 44367015.1.0000.5138) was approved by the Research Ethics Committee of Santa Casa de Belo Horizonte, under approval number 5,425,090 prior to data collection. All participants provided voluntary written informed consent before enrollment.

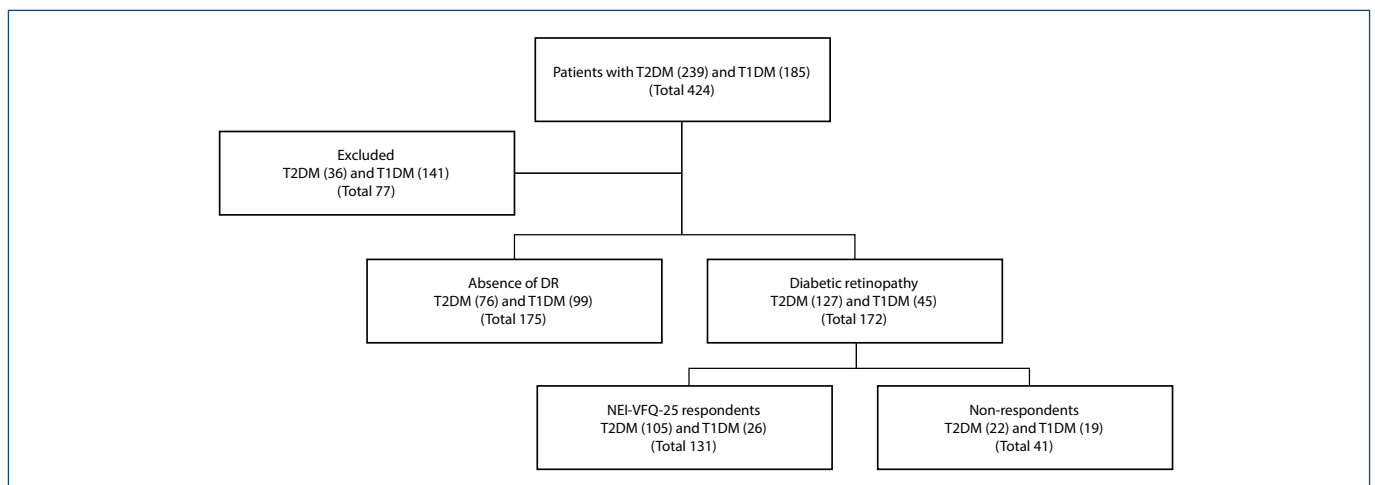
Vision-related quality of life was assessed using the validated Brazilian version of the 25-item National Eye Institute Visual Function Questionnaire (NEI-VFQ-25).⁽¹⁷⁾

Lower scores on this instrument indicate a greater impairment in VRQoL, although no specific cutoff values are established.⁽¹⁸⁾

Diabetic retinopathy severity was systematically categorized into mild non-proliferative diabetic retinopathy (NPDR), moderate NPDR, severe NPDR, and proliferative diabetic retinopathy (PDR) based on the Proposed International Clinical Diabetic Retinopathy and Diabetic Macular Edema Disease Severity Scales.⁽¹⁹⁾ Additionally, patients previously treated with laser photocoagulation without neovascularization, vitreous hemorrhage or pre-retinal hemorrhage were considered as having compensated post-laser status DR. Patients with clinically suspected diabetic macular edema (DME), characterized by visible retinal thickening or hard exudates in the posterior pole,⁽¹⁹⁾ underwent spectral-domain optical coherence tomography (SD-OCT) for confirmation and quantification of macular edema. The criterion adopted to define center-involved DME (CI-DME) was a central retinal thickness of $\geq 275 \mu\text{m}$, as measured by SD-OCT.

Data distribution was assessed using the Shapiro-Wilk test to guide the selection of parametric or non-parametric methods. Continuous variables with normal distribution were expressed as mean $\pm$ standard deviation, while non-normal variables were described using medians and ranges.

Comparisons of VRQoL scores across DR severity groups were performed using one-way analysis of variance (ANOVA) followed by Bonferroni post hoc test for normally distributed variables. When normality assumptions were not met, the Kruska-Wallis test followed by Dunn's post hoc test was applied. Categorical variables were analyzed using the Chi-squared test with Monte Carlo simulation.



T2DM: type 2 diabetes mellitus; T1DM: type 1 diabetes mellitus.

Figure 1. Flowchart of patient selection for the final study sample.

Given the multiple comparisons across NEI-VFQ-25 domains, Bonferroni correction was applied in parametric analyses, while Dunn's test inherently accounts for multiple comparisons in the non-parametric framework.

Bivariate analyses were conducted to identify variables associated with the VRQoL total score. Variables with $p \leq 0.25$ were included in the initial multivariate model.

Multivariate linear regression analysis was performed considering the total VRQoL score as the dependent variable. Independent variables included DR severity, visual acuity, and other relevant clinical and demographic factors. A backward elimination method was used, retaining variables with $p < 0.05$ in the final model. Model fit was assessed using R^2 and root mean squared error (MSE).

Given the limited sample size within individual DR severity subgroups, patients with mild and moderate NPDR were grouped together, as were those with severe NPDR and PDR, based on laser photocoagulation treatment indications.

The reliability and internal consistency of the questionnaire were evaluated using Cronbach's alpha coefficient (α).

For all analyses, the significance level adopted for tests was set at 5% ($p < 0.05$).

RESULTS

The final sample included 105 T2DM and 26 T1DM patients. Among them, 56 (42.7%) exhibited mild or moderate NPDR, 39 (29.7%) had severe NPDR or PDR, and 36 (27.4%) showed compensated post-laser status DR.

The median age of patients with mild or moderate NPDR was 60.5 years, 60 years for patients with severe NPDR or PDR, and 62 years for cases with compensated post-laser status DR. Females were the most frequent among the patients, and the majority of individuals were either illiterate or had only completed primary education. Type 2 DM was the most frequent type of DM, regardless of the retinopathy severity. There was no significant difference between the groups regarding age, sex, education, occupation, marital status, and type of DM ($p > 0.05$).

Regarding DM duration, the compensated post-laser status DR group had the longest disease duration ($p = 0.003$) and the highest frequencies of nephropathy compared to other classifications analyzed in this study ($p = 0.008$). The presence of CI-DME and worse visual acuities were mainly observed in patients with severe NPDR or PDR ($p < 0.05$). No significant differences were observed regarding smoking, hypertension, dyslipidemia, neuropathy, stroke, heart disease, and physical activity practices between the groups ($p > 0.05$).

Analysis of NEI-VFQ-25 scores revealed distinct patterns across DR severity groups. Patients diagnosed with severe NPDR and PDR consistently demonstrated lower scores across 11 domains compared to those with mild or moderate NPDR and compensated post-laser status DR. Particularly impactful domains included general health, mental health, and driving (Table 1).

Within the compensated post-laser status DR subgroup, higher means were observed compared to the severe NPDR or PDR subgroup in domains such as near

Table 1. Scores obtained in each domain of the vision-related quality of life questionnaire, according to the classification of diabetic retinopathy

VRQoL domains	Mild or moderate (n = 56)			Diabetic retinopathy Severe or proliferative (n = 39)			Compensated post-laser status (n=36)			p-value
	Mean	± SD	Min-Max	Mean	± SD	Min-Max	Mean	± SD	Min-Max	
D1 - General health	33.04	± 21.90	0-100	28.85	± 21.10	0-75	33.33	± 18.90	0-75	0.558
D2 - General vision	71.79	± 15.62	20-100	54.36	± 24.26	0-100	62.78	± 17.34	20-100	< 0.001 ^{§*}
D3 - Ocular pain	87.72	± 17.60	25-100	82.69	± 24.60	0-100	90.28	± 20.07	25-100	0.263
D4 - Near activities	79.54	± 19.60	25-100	52.03	± 35.09	0-100	69.68	± 30.53	8.33-100	< 0.001 ^{§†}
D5 - Distance activities	85.12	± 23.12	0-100	50.00	± 34.48	0-100	68.98	± 29.55	0-100	< 0.001 ^{§†‡}
D6 - Social functioning	93.08	± 14.09	37.5-100	76.60	± 29.96	0-100	88.19	± 17.41	37.5-100	0.001 ^{§†}
D7 - Mental health	72.66	± 18.68	6.25-100	45.03	± 31.09	0-100	64.58	± 25.00	0-100	< 0.001 ^{§*†}
D8 - Role difficulties	84.15	± 23.89	12.5-100	56.09	± 33.92	0-100	68.75	± 30.84	0-100	< 0.001 ^{§†}
D9 - Dependency	91.52	± 19.43	16.67-100	51.28	± 40.94	0-100	77.32	± 31.91	0-100	< 0.001 ^{§†}
D10 - Driving	73.21	± 35.38	0-100	50.00	± 46.65	0-100	55.13	± 40.76	0-100	0.331
D11 - Colour vision	98.18	± 8.13	50-100	80.77	± 30.60	0-100	95.14	± 13.12	50-100	< 0.001 ^{§†}
D12 - Peripheral vision	91.52	± 19.23	25-100	70.51	± 34.35	0-100	81.25	± 28.27	25-100	0.001 ^{§*}
Composite score	81.71	± 13.79	42.14-96.96	56.70	± 27.27	11.74-94.42	72.44	± 20.10	25.45-93.7	< 0.001 ^{§*}

SD: standard deviation; min: minimum value; max: maximum value.

* Significant difference between the means obtained by patients with mild or moderate diabetic retinopathy compared to severe or proliferative diabetic retinopathy ($p < 0.05$); † significant difference between the means obtained by patients with severe or proliferative diabetic retinopathy compared to compensated post-laser diabetic retinopathy ($p < 0.05$); ‡ significant difference between the means obtained by patients with mild or moderate diabetic retinopathy compared to compensated post-laser diabetic retinopathy ($p < 0.05$); § significant difference ($p < 0.05$) according to one-way analysis of variance, with Bonferroni post-hoc test for multiple comparisons.

activities, distance activities, mental health, dependency, and color vision.

Table 2 shows the results of the bivariate analysis of categorical and continuous variables, considering the total score obtained in the VRQoL questionnaire. For the composition of the full multivariate linear

Table 2. Bivariate analysis of factors associated with vision-related quality of life; variables used in the initial model

	VRQoL composite score				p-value
	n	Mean	± SD	Min-Max	
Sex					
Female	77	70.32	24.05	11.74-96.96	0.401
Male	54	73.73	20.81	16.3-95.38	
Educational level					
Illiterate or primary education	80	69.61	23.07	11.74-95.65	0.323
Secondary education	38	73.69	22.78	12.62-94.42	
Tertiary education	13	78.92	20.10	41.3-96.96	
Employment					
Retired, unemployed or on health leave	66	70.23	22.23	12.62-94.57	0.453
Active (homemaker, student, or other profession)	65	73.23	23.34	11.74-96.96	
Family status					
Married	65	67.93	22.52	12.62-95.65	0.081*
Single, divorced, widow/widower	64	74.93	22.66	11.74-95.38	
Smoking (current or prior)					
No	85	72.11	23.42	12.62-96.96	0.789
Yes	46	70.99	21.68	11.74-95.65	
Hypertension					
No	17	85.92	16.83	23.48-95.65	0.005*
Yes	114	69.60	22.81	11.74-96.96	
Hypercholesterolemia					
No	21	68.52	24.56	16.30-92.69	0.507
Yes	109	72.14	22.46	11.74-96.96	
Nephropathy					
No	78	71.99	21.44	20.23-95.65	0.897
Yes	50	71.47	23.77	11.74-95.25	
Neuropathy and foot problems					
No	55	74.53	23.36	11.74-96.96	0.290
Yes	74	70.26	22.02	12.62-94.57	
Stroke					
No	122	71.55	23.11	11.74-96.96	0.750
Yes	9	74.06	18.04	42.14-94.23	
Cardiac problem (heart attack, heart failure)					
No	96	73.38	23.34	11.74-96.96	0.167*
Yes	35	67.17	20.68	21.30-92.69	
Retinopathy					
Mild or moderate NPR	56	81.72	13.79	42.14-96.96	< 0.001*
Severe NPR or PDR	39	56.70	27.27	11.74-94.42	
Compensated post-laser status DR	36	72.44	20.10	25.45-93.70	
Retinopathy – 2 groups					
Mild or moderate NPR	56	81.72	13.79	42.14-96.96	< 0.001*
Severe NPR or PDR and compensated post-laser status DR	75	64.26	25.21	11.74-94.42	
Physical activity					
No	77	69.58	23.54	11.74-96.96	0.264
Yes	51	74.22	21.90	12.62-95.65	
Visual acuity					
20/20 a 20/60	96	79.53	16.66	23.48-96.96	< 0.001*
20/70 a 20/400	29	53.10	22.66	12.62-93.91	
Worse than 20/400	5	27.37	12.86	77.74-41.30	

* Variables with p-value less than or equal to 0.25 ($p \leq 0.25$), selected for the full multivariate linear regression model. VRQoL: vision-related quality of life; SD: standard deviation; min: minimum value; max: maximum value; NPR: non-proliferative diabetic retinopathy; PDR: proliferative diabetic retinopathy; DR: diabetic retinopathy.

regression model, variables with a p-value up to 0.25 were considered.

After interpreting the coefficients (β) and excluding variables with non-significant p-values, the results obtained in the final model of linear regression indicated that the variables “severity of DR” and “visual acuity” were considered negative predictors for the VRQoL of these patients ($p < 0.05$) (Table 3). According to these results, patients with severe NPDR or PDR showed a reduction of -15.88 points in the total VRQoL score (95% of confidence interval [95%CI] -23.23-8.53; $p = 0.000$). Regarding visual acuity, patients with acuity of 20/70 to 20/400 showed a reduction of -22.86 points in the total QoL score (95%CI -30.26-15.46; $p = 0.000$), while patients with acuity worse than 20/400 reduced the score by -46.15 points (95%CI -61.80-30.50; $p = 0.000$) (Table 4).

Table 3. Bivariate analysis of factors associated with vision-related quality of life - variables used in the initial model (Pearson correlation)

VRQoL composite score	r-value	p-value
Age, Years	-0.118	0.178*
Duration of diabetes, Years	0.037	0.674
HbA1c, %	-0.153	0.087*
Time since last ophthalmological evaluation, months	0.162	0.067*

VRQoL: vision-related quality of life; HbA1c: glycated hemoglobin.

* Variables with a p-value less than or equal to 0.25 ($p \leq 0.25$), selected for the full multivariate linear regression model.

Table 4. Linear regression (factors associated with vision-related quality of life) – final model

Linear regression (VRQoL composite score)				
Explanatory variables	Final model*			
	Coefficient (β)	Standard error	IC95%	p-value
Retinopathy				
Severe NPR or PDR	-15.88	3.71	-23.23; -8.53	0.000†
Visual acuity				
20/70-20/400	-22.86	3.74	-30.26; -15.46	0.000†
Worse than 20/400	-46.15	7.91	-61.80; -30.50	0.000†

* Root mean squared error = 16.84 / number of observations = 130 / $R^2 = 0.47$; † significant p-values ($p < 0.05$).

VRQoL: vision-related quality of life; 95%CI: 95% of confidence interval; NPR: non-proliferative diabetic retinopathy; PDR: proliferative diabetic retinopathy.

Considering the results obtained in the final model above, a new multivariate linear regression analysis was performed considering only patients with severe NPDR and PDR, and patients with compensated post-laser status RD (multivariate with two groups, considering only cases with indication of laser photocoagulation treatment or previously treated and compensated) (Table 5). The results obtained in this linear regression model indicated again that the variables DR severity and visual acuity were considered positive and negative predictors, respectively, for the VRQoL of these patients ($p < 0.05$) (Tables 6 and 7).

Table 5. Bivariate analysis of factors associated with vision-related quality of life (patients with severe non-proliferative diabetic retinopathy/proliferative diabetic retinopathy and compensated post-laser status diabetic retinopathy status); variables used in the initial model

	n	VRQoL composite score			
		Mean	± SD	Min – Max	p-value
Sex					
Female	41	60.35	26.64	11.74 – 93.70	0.141*
Male	34	68.97	22.89	16.30 – 94.42	
Educational level					
Illiterate or primary education	41	60.48	25.92	11.74 – 92.61	0.289
Secondary education	27	67.30	24.14	12.62 – 94.42	
Tertiary education	7	74.66	23.93	41.30 – 93.70	
Employment					
Retired, unemployed or on health leave	43	64.24	23.57	12.62 – 93.46	0.995
Active (homemaker, student, or other profession)	32	64.28	27.66	11.74 – 94.42	
Family status					
Married	42	61.03	23.97	12.62 – 93.46	0.213*
Single, divorced, widow/widower	33	68.37	26.51	11.74 – 94.42	
Smoking (current or prior)					
No	53	64.76	25.62	12.62 – 94.42	0.792
Yes	22	63.05	24.76	11.74 – 93.46	
Hypertension					
No	6	75.99	26.33	23.48 – 93.46	0.238*
Yes	69	63.24	25.05	11.74 – 94.42	
Hypercholesterolemia					
No	14	67.10	26.46	16.30 – 92.61	0.596
Yes	60	63.10	25.00	11.74 – 94.42	
Nephropathy					
No	38	63.93	24.47	20.23 – 94.42	0.729
Yes	36	65.94	25.35	11.74 – 93.70	
Neuropathy and foot problems					
No	33	69.13	26.37	11.74 – 94.42	0.174*
Yes	40	61.04	23.94	12.62 – 93.46	
Stroke					
No	73	64.33	25.54	11.74 – 94.42	0.876
Yes	2	61.48	8.52	55.45 – 67.50	
Cardiac problem (heart attack, heart failure)					
No	51	65.58	27.12	11.74 – 94.42	0.512
Yes	24	61.45	20.85	21.30 – 92.50	
Retinopathy (2 groups)					
Severe NPR or RDP	39	56.70	27.27	11.74 – 94.42	0.006*
Post-laser compensated status DR	36	72.44	20.10	25.45 – 93.70	
Physical activity					
No	47	61.81	24.97	11.74 – 93.46	0.346
Yes	27	67.59	25.68	12.62 – 94.42	
Visual acuity					
20/20-20/60	46	76.72	18.80	23.48 – 94.42	0.000*
20/70-20/400	24	48.06	21.10	12.62 – 89.76	
Worse than 20/400	5	27.37	12.86	11.74 – 41.30	

* Variables with a p-value less than or equal to 0.25 ($p \leq 0.25$), selected for the full multivariate linear regression model. VRQoL: vision-related quality of life; SD: standard deviation; min: minimum value; max: maximum value; NPR: non-proliferative diabetic retinopathy; PDR: proliferative diabetic retinopathy; DR: diabetic retinopathy.

Table 6. Bivariate analysis of factors associated with vision-related quality of life – variables used in the initial model (Pearson correlation)

VRQoL composite score	r-value	p-value
Age, Years	-0.144	0.218*
Duration of diabetes, Years	0.145	0.217*
HbA1c, %	-0.186	0.117*
Time since last ophthalmological evaluation, months	0.161	0.170*

VRQoL: vision-related quality of life; HbA1c: glycated hemoglobin.

* Variables with a p-value less than or equal to 0.25 ($p \leq 0.25$), selected for the full multivariate linear regression model.

Table 7. Linear regression (factors associated with vision-related quality of life) – final model

Explanatory variables	Linear regression (VRQoL composite score)				
	Coefficient (β)	Standard error	Final model*		p-value
Retinopathy					
Compensated post-laser status DR	13.94	4.18	5.60	22.28	0.001†
Visual acuity					
20/70 a 20/400	-28.07	4.55	-37.15	-18.99	0.000†
Worse than 20/400	-47.95	8.52	-64.94	-30.97	0.000†

* Root mean squared error = 16.84 / number of observations = 130 / $R^2 = 0.47$; † significant p-values ($p < 0.05$). VRQoL: vision-related quality of life; 95%CI: 95% of confidence interval; DR: diabetic retinopathy.

the broader functional and psychosocial impact of the disease.^(9,10) In this context, VRQoL has emerged as a critical outcome, providing a more comprehensive understanding of how visual impairment affects daily functioning and well-being.⁽¹²⁾ In Brazil, however, there is a lack of studies assessing the association between DR severity and VRQoL in patients with T1DM and T2DM mellitus within the public health system. Therefore, this study aimed to evaluate this relationship, contributing to a better understanding of the impact of DR and to the improvement of patient care.

In this study, we found a consistent and significant association between increasing DR severity and worsening VRQoL scores. Both the overall NEI-VFQ-25 score and all domain-specific scores declined progressively with greater disease severity. Notably, the most pronounced differences were observed between patients with mild/moderate NPDR and those with severe NPDR or PDR, suggesting a critical threshold at which disease progression more substantially affects perceived visual function.

Our findings are consistent with those reported by Mazhar et al., who observed progressive deterioration in VRQoL according to DR severity in the Los Angeles Latino Eye Study⁽¹³⁾. Likewise, Ligda et al. and Pereira et al. demonstrated significantly lower QOL scores among patients with advanced DR, reinforcing the impact of disease progression on patient-reported outcomes.^(14,15) In our cohort, the domains most affected were general health, mental health, and driving, highlighting not only the visual but also the psychological and functional burden associated with DR.

DISCUSSION

Diabetic retinopathy remains one of the most relevant microvascular complications of diabetes mellitus, representing a major cause of visual impairment among working-age individuals worldwide.⁽¹⁻³⁾ While its clinical assessment traditionally relies on objective parameters such as visual acuity, these measures do not fully capture

It is noteworthy that the general health domain presented the lowest score among all domains analyzed; although no significant differences were observed across DR severity subgroups. This finding suggests that the presence of DR itself, regardless of severity, negatively influences patients' perception of overall health. Mental health was also significantly affected, with lower scores observed in the severe NPDR/PDR group. The mental health subscale of the NEI-VFQ-25 encompasses concerns, frustration, perceived lack of control, and fear of vision-related embarrassment. In this context, patients with more advanced DR may experience increased psychological burden related to disease progression, the need for ongoing treatment, and uncertainty regarding visual prognosis. These findings reinforce the importance of addressing psychosocial aspects in the care of patients with diabetic retinopathy, as impaired psychological well-being has been associated with poorer treatment adherence.⁽¹¹⁾ The absence of significant differences between the mild/moderate NPDR and compensated post-laser DR groups may suggest a potential attenuation of vision-related concerns following therapeutic intervention. In the driving domain, no significant differences were observed between DR severity groups. However, only 28 of the 131 participants reported currently driving, which may have limited the ability to detect differences between groups. This finding also highlights the potential impact of diabetes and visual impairment on driving status, an important aspect of independence and QoL.

Patients with compensated post-laser DR showed higher mean scores compared to those with severe NPDR/PDR in domains such as near and distance activities, mental health, dependency, and color vision. These findings suggest that appropriate management of advanced DR, including laser photocoagulation when indicated, may be associated with better VRQoL outcomes.

Among the variables analyzed, greater DR severity and worse visual acuity were independently associated with lower VRQoL scores. Multivariate linear regression demonstrated that patients with severe NPDR/PDR and visual acuity worse than 20/70 had substantially lower QoL scores compared to those with milder disease and better visual acuity. These associations remained consistent across different regression models, reinforcing the central role of both structural disease severity and functional visual impairment in determining VRQoL.

While acknowledging the relevance of our findings, certain limitations should be considered. Although this study represents a pioneering effort in evaluating the impact of DR on VRQoL in Brazil, its relatively limited sample

size may restrict the generalizability of the results to the broader population with DM. A larger sample would allow for more precise parameter estimates, providing a more robust understanding of these associations within the Brazilian context. Another important limitation of this study is the imbalance between T1DM and T2DM sample sizes, which reduces statistical power and may increase the likelihood of type II error when comparing these subgroups. The post hoc power analysis supports this limitation, indicating insufficient sensitivity to detect smaller effect sizes. Therefore, the absence of statistically significant differences between diabetes types should be interpreted cautiously. Additionally, the cross-sectional design limits the ability to assess DR progression and its long-term effects on VRQoL. Future research incorporating larger cohorts and longitudinal follow-up could offer deeper insights into the evolving impact of DR on QoL over time. Despite these limitations, we hope that this study contributes to advancing a patient-centered approach to diabetes management, ultimately improving the QoL life and overall well-being of individuals affected by DR.

CONCLUSION

DR severity was significantly associated with worse VRQoL, with advanced disease stages and reduced visual acuity emerging as independent predictors of poorer patient-reported outcomes. These findings reinforce the importance of preventing disease progression through early diagnosis and timely treatment, while emphasizing that the management of DR should extend beyond structural and functional assessment to include patients' perceived visual function and psychosocial well-being.

AUTHOR CONTRIBUTION

Soares AN and Reis JS contributed to the conception and design of the study, as well as to the critical revision of the intellectual content of the manuscript. Nunes BF contributed to data acquisition, analysis and interpretation, manuscript drafting, and critical revision of the manuscript. Barbosa NLC, Silva NE, and Frango AOR contributed to data acquisition. All authors approved the final version of the manuscript and are accountable for all aspects of the work, including ensuring its accuracy and integrity.

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