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IMPACT OF CENTER-INVOLVED DIABETIC MACULAR EDEMA ON VISION-RELATED QUALITY OF LIFE IN PATIENTS WITH TYPE 2 DIABETES: A CROSS-SECTIONAL STUDY

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Abstract:
Diabetic macular edema (DME), characterized by retinal thickening involving the macula, stems from retinal capillary dysfunction, notably increased vascular permeability due to diabetic retinopathy (DR). It can occur across all severity levels of DR and is a leading cause of vision loss in patients with diabetes mellitus (DM). While management of DM considers DR severity and DME presence/type, conventional DR assessment overlooks the patient's perspective and vision-related quality of life (VRQoL). Addressing VRQoL is crucial in DM management, serving as a significant therapeutic gauge. The objective of this study was to evaluate center-involved DME (CI-DME) impact on VRQoL. We conducted an observational cross-sectional study on patients with DM aged above 18 years at a Brazilian Unified Health

System (SUS) diabetes clinic from June 2022 to May 2023. VRQoL was assessed using the 25-item National Eye Institute Visual Function Questionnaire (NEI-VFQ-25). Patients with apparent DME underwent spectral-domain optical coherence tomography (SD-OCT) for confirmation. CI-DME was defined as central subfield thickness ≥ 275 μm on SD-OCT. NEI-VFQ-25 scores were compared using Kruskal-Wallis test. The final sample included 95 patients, with 72 (75.7%) without DME or non-center-involved DME and 23 (24.2%) with CI-DME. CI-DME patients showed significantly lower mean NEI-VFQ-25 scores across multiple domains, including general vision, distance activities, mental health, functional limitation, and dependency ($p < 0.05$). Total score means also indicated statistically lower values in CI-DME patients ($p < 0.05$). In conclusion, CI-DME was associated with lower VRQoL scores. Effective DME management, alongside DR progression prevention, should be a treatment goal to improve VRQoL for DM individuals.

Keywords: Diabetes mellitus. Diabetic retinopathy. Diabetic macular edema. Vision-related quality of life.

Introduction:

Diabetic macular edema (DME), defined as retinal thickening that involves the macula, arises from dysfunction in retinal capillaries, notably increased vascular permeability resulting from diabetic retinopathy (DR)[1]. It can develop in patients at any severity level of DR, although it is directly related to the increased severity of DR[1]. Higher levels of glycated hemoglobin (HbA1c) (>7%) and disease duration are also associated with an increased risk of DME[2]. DME represents one of the leading causes of vision loss among individuals with diabetes mellitus (DM)[3,4]. An epidemiological study on DR reported that approximately 20% of patients with type 1 DM (T1DM) and 14% to 25% of patients with type 2 DM (T2DM) developed DME over a span of 10 years[5]. Over 25 years, 29% of T1DM patients evaluated in this study developed DME, and 17% developed clinically significant macular edema (CSME)[6]. These wide variations in DME prevalence estimates can be attributed to multiple factors, including adopted diagnostic criteria and available diagnostic technology[7]. Currently, spectral-domain optical coherence tomography (SD-OCT) is considered the gold standard for diagnosing and monitoring treatment response for DME[7]. CSME, a term defined by the Early Treatment Diabetic Retinopathy Study Research Group, describes retinal thickening and/or hard exudates that affect the center of the macula or threat involve it[3]. The definition of CSME arose from the observation that such conditions often lead to reduced visual acuity[3]. CSME can be divided into center-involved macular edema (CI-DME) if there is thickening within a 1 mm diameter of the central retina on SD-OCT; and non-center-involved macular edema, if retinal thickening occurs outside the central retina[7].

The management of patients with DM must take into account the severity of DR, as well as the presence and type of DME[4]. However, conventional assessment of DME does not fully consider the patient's perspective or the impact on vision-related

quality of life (VRQoL). Acknowledging that a patient's overall well-being is affected by not only the disease itself but also by psychological, cultural, professional, and socioeconomic factors[8], evaluating quality of life (QoL) becomes crucial for understanding the patient's perspective and the overall impact of the disease, especially in individuals with chronic conditions like DM[8,9]. Importantly, compromised psychological well-being not only affects patient adherence to treatment regimens but also correlates with poorer self-care practices and less controlled HbA1c levels[10]. Therefore, an effective management approach for DM should encompass not only physical health but also psychological aspects to foster sustainable and successful therapeutic outcomes.

In contemporary healthcare, recognizing the significance of patients' VRQoL has emerged as a primary objective in managing DM and its complications[9,11]. This shift underscores the holistic nature of healthcare, emphasizing the importance of addressing not just biomedical markers but also the psychosocial well-being of individuals[10].
In this context, our study seeks to comprehensively assess the impact of DME on VRQoL in patients with both T1DM and T2DM, shedding light on the intricate interplay between clinical severity and the subjective experiences of those affected.

Objective:
To evaluate the impact of CI-DME on VRQoL. Specific objectives included assessing the clinical and sociodemographic profiles of patients with DM under care at Santa Casa de Belo Horizonte.

Methods:
An observational cross-sectional study was conducted to assess all active patients aged 18 and older undergoing treatment for T1DM or T2DM at the Diabetes Outpatient Clinic of Santa Casa de Belo Horizonte, a public health service, provided by the Brazilian Unified Health System (SUS), between January and December 2022.

The exclusion criteria were patients unable to communicate and respond to questions; cataract worse than nuclear 2, cortical 5, or subcapsular 3, according to the Lens Opacities Classification System III (LOCS III)[12]; history of congenital cataract, posterior capsule opacities, intraocular lens opacity, corneal opacity; retinal vascular diseases other than DR - ischemic ocular syndrome, venous and arterial retinal occlusions, macular telangiectasia; retinal dystrophies; decreased visual acuity related to previous uveitis; degenerative myopia; decreased visual acuity of etiology in the central nervous system; optic neuropathy.

Data collection spanned 12 months, from June 2022 to May 2023.

The patients who agreed to participate in the study underwent ophthalmological evaluation, followed by the completion of the VRQoL questionnaire via interview format. Additionally, they provided sociodemographic information, including age, gender, education level, occupation, marital status; details concerning their diabetic history, such as treatment duration, HbA1c levels; and the presence of comorbidities, including hypertension, dyslipidemia, cardiac conditions, nephropathy, history of stroke; and social history, such as smoking habits.

The study procedures followed the principles established in the Declaration of Helsinki of 1975, which was revised in 2000 regarding research involving human subjects. Approval was obtained from the Institutional Ethics Committee before conducting the study. All participants provided informed consent willingly before participating in the study.

VRQoL was accessed using the Brazilian version of the 25-item National Eye Institute Visual Function Questionnaire (NEI-VFQ-25)[13]. Notably, lower scores on this questionnaire indicate poorer VRQoL[14]. There are no specific cutoff points associated with these scores[14].

Patients with apparently present DME, as per the Proposed International Clinical Diabetic Retinopathy and Diabetic Macular Edema Disease Severity Scales, those with apparent retinal thickening or hard exudates in the posterior pole[15], underwent SD-OCT for confirmation and quantification of macular edema. The criterion used to define the presence of CI-DME was central retinal thickness greater than or equal to 275 µm measured by SD-OCT. This criterion was based on the RISE/RIDE study, a multicenter, randomized trial designed to evaluate the efficacy and safety of intravitreal ranibizumab for DME treatment[16].

NEI-VFQ-25 scores were compared between the groups with and without CI-DME using Kruskal-Wallis test, followed by Dunn's post hoc test, and the Chi-square test via Monte Carlo simulation.

Regarding the assessment of VRQoL using the NEI-VFQ-25 questionnaire, total scores and scores for 11 domains were obtained for each patient. Comparative analysis among mean scores was performed using Unpaired T-tests (for pairwise comparisons) and One-Way ANOVA followed by Bonferroni's post hoc test for multiple comparisons. The reliability and internal consistency of the applied questionnaire were assessed using Cronbach's Alpha coefficient (α). Pearson's Correlation Coefficient was employed for analyzing correlations between VRQoL questionnaire domains. For all analyses, the significance level adopted for tests was set at 5% ($p<0.05$).

Results:
A total of 424 subjects were screened, including 239 patients undergoing treatment for T2DM and 185 for T1DM. The final sample of the study comprised 95 patients, including 72 (75.7%) without DME or with non-center-involved DME and 23 (24.2%) with CI-DME. The remaining patients were excluded due to non-compliance with the inclusion/exclusion criteria (n=77), refusal to complete the questionnaires (n=41), absence of DR signs (n=175), or lack of information regarding the presence of DME on SD-OCT (n=36).

The data obtained demonstrate that patients with CI-DME (n=23) all have T2DM (p=0.013), the highest percentages of severe non-proliferative diabetic retinopathy (NPDR) or proliferative diabetic retinopathy (PDR) (p=0.010), and the worst visual acuity rates (p=0.016). Regarding dyslipidemia, patients with CI-DME presented lower rates compared to patients without this condition (p<0.001) and a shorter time since the last ophthalmological assessment (p=0.024). The other clinical and sociodemographic characteristics did not show statistical significance (p>0.05) (Table 1).

In order to identify significant differences between patients with T1DM and T2DM, considering the diabetes duration and HbA1c levels, a comparative analysis of these parameters was conducted. According to the data presented in Table 2, significant differences were observed regarding the duration of diabetes: patients with T1DM had a median diagnosis time of 22.5 years, while in T2DM patients the median was 17 years (p=0.001). Regarding HbA1c, the median in the total population assessed was 8.45%, and when considering the type of diabetes, a median of 7.3% was observed for patients with T1DM and 8.5% for T2DM. Despite T2DM patients having a higher median value, there was no significant difference compared to T1DM patients (p > 0.05).

Patients with CI-DME demonstrated significantly lower mean scores in multiple NEI-VFQ-25 domains, including general vision, distance activities, mental health, role difficulties, and dependence (p<0.05) compared to patients without this condition. The observed means for the total score also indicated statistically lower values in patients with CI-DME (p<0.05) (Table 3).

Discussion:
In our study, all patients with CI-DME diagnosed by SD-OCT had T2DM. Literature links DME to T1DM, high HbA1c (>7%), and longer diabetes duration[5-7]. Notably, T1DM patients had longer diagnosis times and better glycemic control, though not statistically significant. The effectiveness of this glycemic control may have justified the absence of CI-DME among individuals with T1DM evaluated in this study. This efficacy in glycemic control among patients with T1DM may be attributed, in part, to the fact that these patients receive multidisciplinary care from Endocrinology,

Nutrition, Nursing, Physical Education, Psychology, and Physiotherapy. T2DM patients, with a median diagnosis duration of 17 years, face a substantial diabetes progression period, potentially predisposing them to CI-DME alongside elevated HbA1c levels. Besides, T2DM onset time is often indeterminable[17], leading to potential underestimation of disease duration. Thus, prolonged diagnosis and high HbA1c levels could have impacted study outcomes. Additionally, genetics, lifestyle, treatment adherence, and specific medications, like thiazolidinedione hypoglycemic agents, may influence CI-DME occurrence[4], emphasizing the need for tailored management in this context.

In the CI-DME group, a significant portion (43.48%) had no dyslipidemia, while the majority (56.52%) did, aligning with literature findings[1]. However, among non-CI-DME patients, over 90% had dyslipidemia. This was an intriguing finding of our study, as studies link elevated plasma cholesterol and triglyceride levels with retinal leakage and severity of hard exudates in patients with DM[1]. Possible justifications include the protective role of fenofibrate and statin combination therapy against DR progression, and consequently, the incidence of CI-DME, even with modest changes in plasma lipids, although the exact mechanisms of these effects are not clear[18-20]. Additionally, the pathophysiology of CI-DME is complex and not yet fully understood[1]. Other unexplored factors, like plasma lipid composition and specific medication use, might also play protective roles in dyslipidemic patients without CI-DME.

The presence of CI-DME was associated with poorer scores in all domains and the total score of NEI-VFQ-25. The domains with the most significant impact were general health, mental health, and distant activities. CI-DME led to a significant impact on general health and mental health domains, indicating that patients experience concerns, frustrations, and fears related to their health condition. The presence of CI-DME also had a significant impact on the distant activities domain. This can be explained by the fact that DME generally affects central vision, which is crucial for the ability to recognize and read objects at a distance, navigate safely in low-light environments, and participate in entertainment activities such as cinema and sports events. It's essential to recognize that due to the coexistence of DME and DR in patients with DM, it is challenging to separate the impact of each condition independently.

While recognizing the significance of our study, certain limitations should be mentioned. Our investigation, although a pioneering effort to explore the impact of CI-DME on the VRQoL of patients in Brazil, is constrained by a relatively modest sample size, potentially limiting its representativeness for the broader population. A larger sample would enhance the precision of parameter estimates, offering a more comprehensive understanding of these relationships within the Brazilian context. Moreover, the cross-sectional nature of the research precludes an assessment of CI-DME treatment and its impact on VRQoL over time. Therefore, future studies with

larger samples and longitudinal designs can further deepen the understanding of these complex relationships. It is hoped that this research will foster a patient-centered approach to DM, thereby enhancing the QoL and well-being of this population.

Conclusion:

CI-DME was associated with lower VRQoL scores. Effective management of DME, alongside preventing DR progression, should be a treatment goal to positively impact VRQoL for individuals with DM. Furthermore, adopting a comprehensive approach that encompasses not only biomedical interventions but also psychosocial support is crucial for addressing the complex experiences of these patients. This holistic approach can significantly contribute to improving the care and well-being of individuals with DM.

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Table 1 - Sociodemographic and clinical parameters in diabetic patients with center-involved diabetic macular edema (CI-DME).

	Center-involved diabetic macular edema		
	No (n=72)	Yes (n=23)	*p* valor
Age (years)			
Median	62	62	
(P25 - P75)	(52,5 - 70)	(53 - 70)	0,900 KW
Min - Max	26 - 87	34 - 77	
Duration of diabetes (years)			
Median	17	17	
(P25 - P75)	(12 - 24)	(8 - 20)	0,241 KW
Min - Max	2 - 61	3 - 33	
HbA1c (%)			
Median	8,4	8,05	
(P25 - P75)	(7,3 - 9,3)	(7 - 9,7)	0,756 KW
Min - Max	6,2 - 12,4	6,1 - 11,2	
Time since last ophthalmological evaluation (months)			
Median	6,5	2	
(P25 - P75)	(2 - 12)	(1 - 6)	**0,024* KW**
Min - Max	0,5 - 120	0,5 - 216	
Sex - n (%)			
Female	43 (59,72)	11 (47,83)	0,318 Q
Male	29 (40,28)	12 (52,17)	
Educational level - n (%)			
Illiterate or primary education	42 (58,33)	15 (65,22)	
Secondary education	22 (30,56)	7 (30,43)	0,050 Q
Tertiary education	8 (11,11)	1 (4,35)	
Employement - n (%)			
Retired, unemployed or on health leave	38 (52,78)	8 (34,78)	0,137 Q
Active (homemaker, student, or other profession)	34 (47,22)	15 (65,22)	
Family status - n (%)			
Married	35 (50,00)	15 (65,22)	0,208 Q
Single, divorced, widow/widower	35 (50,00)	8 (34,78)	
Smoking (current or prior) - n (%)			
No	50 (69,44)	14 (60,87)	0,446 Q
Yes	22 (30,56)	9 (39,13)	
Hypertension- n (%)			
No	10 (13,89)	5 (21,74)	0,373 Q
Yes	62 (86,11)	18 (78,26)	
Hypercholesterolemia - n (%)			
No	5 (7,04)	10 (43,48)	**<0,001* Q**
Yes	66 (92,96)	13 (56,52)	
Nephropathy - n (%)			
No	48 (68,57)	15 (68,18)	0,973 Q
Yes	22 (31,43)	7 (31,82)	
Neuropathy and foot problems - n (%)			
No	32 (45,07)	8 (34,78)	0,388 Q
Yes	39 (54,93)	15 (65,22)	
Stroke - n (%)			
No	65 (90,28)	23 (100,00)	0,120 Q
Yes	7 (9,72)	0 (0,00)	
Cardiac problem (heart attack, heart failure) - n (%)			
No	54 (75,00)	16 (69,57)	0,607 Q
Yes	18 (25,00)	7 (30,43)	
Type of DM - n (%)			
Type 1	16 (22,22)	0 (0,00)	**0,013* Q**
Type 2	56 (77,78)	23 (100,00)	

Continuation

	Center-involved diabetic macular edema		
	No (n=72)	Yes (n=23)	*p* valor
Retinopathy - n (%)			
Mild ou moderate NPR	38 (52,78)	5 (21,74)	
Severe NPR or RDP	15 (20,83)	10 (43,48)	**0,010**[*] [Q]
Post-laser compensated status DR	19 (26,39)	8 (34,78)	
Physical activity - n (%)			
No	37 (51,39)	15 (68,18)	0,170 [Q]
Yes	35 (48,61)	7 (31,82)	
Visual acuity - n (%)			
20/20 a 20/60	55 (76,39)	11 (47,83)	
20/70 a 20/400	10 (13,89)	8 (34,78)	**0,016**[*] [Q]
pior que 20/400	7 (9,72)	4 (17,39)	

[n] Absolute frequency; [%] Percentage; [P25] 25th percentile; [P75] 75th percentile; [Min] minimum value; [Max] maximum value.
[HbA1c] Glycated hemoglobin; [NPR] Non-Proliferative Diabetic Retinopathy; [RDP] Proliferative Diabetic Retinopathy; [DR] Diabetic Retinopathy.
[KW] Kruskal-Wallis Test; [Q] Chi-Square Test, via Monte Carlo simulation.
[*] Significant difference ($p < 0.05$). Source: Research data.

Table 2 - Comparative analysis between diabetes duration and HbA1c levels, according to diabetes type.

Type of DM	Mean	± SD	Median	P25 - P75	Min - Max	*p* valor
	Diabetes duration (years) (n=95)					
T1DM (n=19)	26	± 11,65	22,5	18 - 30	13 - 61	**0,001**[*]
T2DM (n=76)	17,81	± 9,16	17	12 - 22	2 – 45	
	HbA1c (%) (n=91)					
T1DM (n=19)	8,12	± 1,52	7,3	6,9 - 9,4	6,3 - 12,1	0,095
T2DM (n=72)	8,62	± 1,54	8,5	7,5 - 9,7	5,6 - 12,4	

[SD] standard deviation; [P75] 25th percentile; [P75] 75th percentile; [Min] minimum value; [Max] maximum value.
[*] Significant p-value ($p < 0.05$), according to the Mann-Whitney test. Source: Research data.

Table 3 - Assessment of scores obtained in each domain of the VRQoL questionnaire in patients with T2DM and CI-DME.

Domínios QVRV	Center-involved diabetic macular edema						*p* valor
	No (n=72)			Yes (n=23)			
	Mean	± SD	Min - Max	Mean	± SD	Min - Max	
D1 - General health	35,76	± 21,73	0 - 100	28,26	± 18,93	0 – 75	0,141
D2 - General vision	69,44	± 17,11	20 - 100	53,91	± 20,39	0 – 80	**<0,001***
D3 - Ocular pain	87,33	± 18,82	25 - 100	84,78	± 25,27	37,5 - 100	0,606
D4 - Near activities	72,11	± 27,98	0 - 100	57,97	± 32,4	0 – 100	0,045
D5 - Distance activities	75,69	± 27,38	0 - 100	53,26	±35,08	0 – 100	**0,002***
D6 - Social functioning	88,89	± 20,07	0 - 100	78,80	± 24,55	25 – 100	0,050
D7 - Mental health	67,36	± 22,79	6,25 - 100	51,36	± 32,14	0 - 93,75	**0,009***
D8 - Role difficulties	74,48	± 30,43	0 - 100	58,15	± 30,53	0 – 100	**0,027***
D9 - Dependency	81,25	± 30,15	0 - 100	61,23	± 38,4	0 – 100	**0,011***
D10 - Driving	57,92	± 42,62	0 - 100	54,54	±44,15	0 – 100	0,836
D11 - Colour vision	93,40	± 18,29	0 - 100	87,50	± 22,82	25 – 100	0,215
D12 - Peripheral vision	84,72	± 25,71	25 - 100	75,00	± 31,08	25 – 100	0,137
Composite score	75,42	± 19,50	12,62 - 96,96	61,30	± 26,05	16,3 – 92,69	**0,006***

SD standard deviation; Min minimum value; Max maximum value.

* Significant difference ($p < 0.05$) according to the Unpaired T-test. Source: Research data.