A Case-Control Study to Assess Vision-Related Quality of Life in Patients With and Without Diabetic Retinopathy from a Multiethnic Population in Malaysia

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ABSTRACT

INTRODUCTION: Diabetic patients are exposed to information regarding diabetic eye complications and may therefore be aware of visual function problems even when diabetic retinopathy (DR) is absent or minimal. Hence, it is important to assess vision-related quality of life (VRQL) even in patients with no or minimal DR and preserved visual acuity. **MATERIAL AND METHODS:** This observational, matched case-control study involved diabetic patients aged above 45 years. The VRQL was measured by the 25-item National Eye Institute Visual Function Questionnaire (NEI VFQ-25, version 2000). Multiple linear regression analysis was performed to compare VRQL between cases and controls after adjusting for age and gender. **RESULTS:** After adjustment for age and gender, cases had a significantly lower general health score than controls (mean difference -16.33; 95% CI -19.99 to -13.45; $p<0.001$). Near-activity scores were also significantly lower among cases (mean difference -5.32; 95% CI -8.23 to -2.41;) $p<0.001$). Although cases demonstrated a lower composite VRQL score, the difference was not statistically significant (b -0.71, 95% CI -3.57 to 2.15;$p>0.05$). **CONCLUSION:** This study showed VRQL is more strongly associated with visual acuity than with the stage of diabetic retinopathy. Hence, we recommend comprehensive counselling regarding vision-related issues to all patients with diabetes.

KEYWORDS: diabetic retinopathy, vision-quality of life, population

INTRODUCTION

Vision plays an important role in allowing people to process information from their environment and to participate in activities such as reading, working, walking, driving, and interacting with others. People with visual impairment face challenges in completing these activities, which may lead to depression, social isolation, and difficulties at home, in school, or at work.[1,2] Many studies have reported impaired vision-related functioning and quality of life in major eye diseases, including diabetic retinopathy (DR) in its vision-threatening stages.[3] Diabetic patients are generally counselled about diabetic eye complications and may be alerted to problems with visual function, even when DR is absent or minimal.[4] Hence, it is important to assess vision-related quality of life (VRQL) even in patients with no or minimal DR and no loss of visual acuity.[4] VRQL is related to, but not identical to, visual function. The VRQL represents the degree to which vision impacts an individual's ability to complete activities of daily living and their social, emotional, and economic well-being. VRQL can be assessed by measuring the degree of impairment experienced in activities of daily living that rely on sight, i.e., impaired daily function secondary to visual difficulties is a proxy for visual function.[5]

Globally, the number of people with diabetes has increased sharply and is projected to increase by over 80% in upper-middle-income countries.[5] In Malaysia, the prevalence of diabetes is also on an upward trend, with the prevalence of type 2 diabetes escalating to 20.8% in adults above the age of 30, affecting 2.8 million individuals.[6] Chronic diseases like diabetes may affect a person's quality of life in many ways. Although better glycaemic control is associated with a higher quality of life, the complexity of regimens aimed at achieving glycaemic control may hurt the patients' quality of life. The negative impact of insulin injections on the patients' quality of life is often overlooked.[7] Newer modalities of insulin delivery, such as non-invasive insulin inhalers, could address this shortcoming and help improve quality of life.[8]

Visual impairments secondary to DR present a major public health problem. Legal blindness accounts for 83% of visual impairment among people with youth-onset diabetes and 33% among people with age-related diabetes.[6] Diabetes alone can increase the risk of blindness up to 25-fold.[6] DR occurs in approximately 7-29% of patients attending general medical practices. Approximately two-thirds of diabetic patients have an increased risk of visual impairment after 35 years of suffering from the condition. Moreover, they are 25 times more likely to go blind, compared with other health conditions.[7]

Evaluation of quality of life was included in the EUROCONDOR trial (European Consortium for the Early Treatment of Diabetic Retinopathy).[4] This was to verify whether subtle changes in some of the subscales, explored by the NEI VFQ-25 questionnaire, could be detected at baseline and possibly modified as a result of either disease progression or changes in visual function (intervention-induced or not). Evidence for impaired vision, specific mental health and role difficulties in patients with mild non-symptomatic DR may highlight aspects of discomfort in everyday life, despite preserved BCVA (best corrected visual acuity).[4] Many studies have reported impaired vision-related functioning and quality of life in major eye diseases, including DR in its vision-threatening stages (diabetic macular oedema and proliferative DR). [1] Diabetic patients are often counselled regarding diabetic eye complications and may therefore be aware of perceived visual difficulties even in the absence of clinically significant diabetic retinopathy. Hence, it is important to assess vision-related quality of life (VRQL) even in patients with no or minimal DR and no loss of visual acuity. Although there are a few studies in other parts of the world, like Europe [4] and India[6] assessing VRQL in patients with diabetes, to the best of our knowledge, no such study has been done in Malaysia. The study aimed to analyse visual impairment and the associated effect on quality of life in diabetic patients with or without diabetic retinopathy (DR).

MATERIAL AND METHODS

This was an observational, matched case-control study. All patients with diabetes above 45 years of age, who had given informed written consent to participate in this research, were included in this study. Patients who were not willing to be examined, who were terminally ill, and who had severe behavioural problems were excluded from the study. Other associated ocular disorders contributing to poor visual acuity were also excluded. All cases were examined through detailed slit lamp examinations of both anterior & posterior segments. Controls were individuals without diabetes or any ocular disorder that could decrease vision. Each control was matched with its corresponding case according to age and gender. The sample size was calculated by using the Raosoft® software from the website www.raosoft.com/samplesize.html. The required sample size was estimated at the 95% confidence level with an estimated 50% response distribution and a

margin of error of 5%. The calculated sample size was 230 cases and 260 controls. All participants received full explanations about the research and written informed consent was obtained. The patients' data were recorded in a form. After collecting the demographics and reports of medical tests of the patient, visual acuity, slit lamp examination, dilated fundus examination, and fundus photography were done. The retinopathy was classified according to the ETDRS classification. The patients were then given the questionnaire, and it was completed with the help of the interviewer. Vision-related quality of life (VRQL) was measured by the 25-item National Eye Institute Visual Function Questionnaire (NEI VFQ-25, ver 2000). VFQ-25 was developed by RAND and funded by the NEI.[9,10] It is a validated tool specifically developed to measure self-reported vision-related aspects of health status that are most significant to individuals with chronic eye diseases. The questionnaire includes 25 items grouped into 12 subscales; i) general health: 1 item, ii) general vision: 1 item, iii) ocular pain: 2 items, iv) difficulty with near-vision activities: 3 items, v) difficulty with distance-vision activities: 3 items, vi) vision-specific social functioning: 2 items, vii) vision specific mental health: 4 items, viii) vision specific role difficulties: 2 items, ix) visual specific dependency: 3 items, x) driving difficulties: 2 items, xi) difficulty with colour vision: 1 item, xii) difficulty with peripheral vision: 1 item.[11] The scoring of the items and subscales was done by scoring instructions provided in the VFQ-25 Manual.[12] Patients were informed about the need to complete the short questionnaire and it was made clear to them that this assessment would not affect their treatment. A female attendant was present during interviews with female participants.

Data processing and data analysis

The scoring of the items and subscales was done by scoring instructions provided in the VFQ-25 Manual.[12] Microsoft Excel was used for data entry, and SPSS version 12 was used for data analysis. Descriptive statistics such as frequency and percentage were calculated for categorical variables, and mean and standard deviation were calculated for quantitative variables. Multiple linear regression was performed to determine the VRQL between cases and controls after adjusting for age and gender. A regression coefficient and its 95% confidence interval were calculated. Unpaired t-test and ANOVA were used to determine the association between gender, diabetic treatment, cataract, maculopathy, diabetic retinopathy, health-related, and VRQL among diabetic patients. All statistical tests were two-sided, and $p<0.05$ was considered statistically significant. Association between age, duration of diabetes, fasting blood glucose, HbA1C with visual acuity and VRQL among diabetic patients was done by using Pearson's correlation. Pearson Correlation coefficient (r) was calculated, and $p<0.05$ was considered statistically significant.

RESULTS

From the case group, there were 49.1% male, whilst in the control group, there were 49.2% male. Table I shows the demographic characteristics and the diabetic eye disease manifestation of the diabetic study participants.

Table I: Demographic characteristics of cases (diabetes mellitus) (n=230) and control (n=260).

Variable	Cases n (%)	Control n (%)
Age[a]	59.7 (11.7)	60.1 (11.6)
Gender		
Male	113 (49.1)	128 (49.2)
Female	117 (50.9)	132 (50.8)
Duration of diabetes[a]	9.9 (6.5)	n/a
Fasting blood glucose[a]	8.4 (2.2)	n/a
HbA1C[a]	8.4 (1.9)	n/a
Diabetes retinopathy (Right)		n/a
None	119 (52.0)	
Mild	24 (10.5)	
Moderate	35 (15.3)	
Severe	8 (3.5)	
PDR	33 (14.4)	
ADED	10 (4.4)	
Diabetes retinopathy (Left)		n/a
None	121 (52.8)	
Mild	23 (10.0)	
Moderate	35 (15.3)	
Severe	8 (3.5)	
PDR	34 (14.8)	
ADED	8 (3.5)	
Treatment		n/a
Diet alone	4 (1.7)	
Diet+Oral	111 (48.3)	
Diet+Insulin	32 (13.9)	
Diet+Oral+Insulin	83 (36.1)	
Maculopathy		n/a
Present	43 (18.7)	
Absent	187 (81.3)	
Cataract		n/a
Present	96 (43.2)	
Absent	126 (56.8)	

results shown in mean (SD)

The multiple linear regression analysis of VRQL between cases and controls is shown in Table II. The analysis (after adjusting for age and gender) showed that the cases had a general health score that was on average 16.33 lower than the controls (95% CI -19.99, -13.45) ($p<0.001$). Cases had on average significantly lower near activities score of 5.32 (95% CI -8.23, -2.41) ($p<0.001$), and demonstrated a lower composite VRQL score (b -0.71, 95% CI -3.57, 2.15) ($p>0.05$). There was no significant difference in ocular pain, distance activities, vision-specific social functioning, vision-specific mental health, vision-specific role difficulties, vision-specific dependency, driving, colour vision, or peripheral vision scores between cases and controls ($p>0.05$) after adjusting for age and gender.

Table II: Multiple linear regression analysis of all vision-related quality of life (VRQL) subscales between case and control

Variable	b	(CI =95%)[b]	SE	p value
General health	-16.33	(-19.19, -13.46)	1.458	<0.001
General vision	3.45	(1.73, 5.18)	0.879	<0.001
Ocular pain	-2.48	(-5.05, 0.09)	1.307	0.059
Near activities	-5.32	(-8.23, -2.41)	1.481	<0.001
Distance activities	0.71	(-2.19, 3.60)	1.475	0.633
Vision specific: Social functioning	1.54	(-0.64, 3.72)	1.108	0.165
Vision specific: Mental health	-1.18	(-4.23, 1.87)	1.553	0.448
Vision specific: Role difficulties	3.35	(-1.19, 7.89)	2.311	0.148
Vision specific: Dependency	4.60	(-0.18, 9.38)	2.433	0.059
Driving	2.08	(-3.18, 7.34)	2.668	0.436
Colour vision	-0.50	(-2.77, 1.77)	1.154	0.663
Peripheral vision	2.48	(-0.80, 5.75)	1.667	0.138
Composite score VRQL	-0.71	(-3.57, 2.15)	-0.490	0.625

Among diabetic patients, females had a significantly higher mean score of general vision, ocular pain, and role difficulties ($p<0.05$). There was a significant association between stages of diabetic retinopathy (DR) of both left and right eyes and VRQL. Proliferative diabetic retinopathy and advanced diabetic eye disease (ADED) had lower mean scores of VRQL than other stages ($p<0.05$). There was no significant difference in VRQL between different diabetic treatments ($p>0.05$). Diabetic patients who had maculopathy were found to have a significantly low mean score of VRQL ($p<0.05$) except for the driving component.

Diabetic patients who had cataracts were found to have a significantly low mean score of VRQL ($p<0.05$) except for social functioning, colour vision, and peripheral vision. Table III shows the association between gender, diabetic treatment, cataract, maculopathy, diabetic retinopathy, and all VRQL subscales among diabetic patients reported in mean (SD).

The association between age, duration of diabetes, fasting blood glucose level, HbA1C, visual acuity and VRQL among diabetic patients is shown in Table IV. There was a significant positive correlation between VRQL and age amongst diabetic cases ($p<0.05$) in all subscale analyses except for general vision, colour vision, and driving. However, there was a significant correlation between the duration of diabetes and VRQL ($p>0.05$). There was a significant negative correlation between general health, ocular pain, distance activities, mental health, role difficulties, and dependency scores with fasting blood glucose level and HbA1C level ($p<0.05$). A significant negative correlation was also found between VRQL and visual acuity among diabetic cases ($p<0.001$).

Table III: Association between gender, diabetic treatment, cataract, maculopathy, diabetic retinopathy, and all vision-related quality of life (VRQL) subscales among diabetic patients reported in mean (SD).

Variables	General health	General vision	Ocular pain	Near activities	Distance activities	Social functioning	Mental health	Role difficulties	Dependency	Colour vision	Peripheral vision	Driving	VRQoL score
Gender[b]													
Male	61.8 (17.2)	46.7 (7.2)	84.2 (18.1)	78.6 (20.7)	84.8 (17.5)	92.7 (13.2)	82.8 (18.3)	79.0 (23.8)	81.9 (25.2)	94.9 (12.6)	88.8 (18.6)	81.4 (18.2)	83.0 (10.0)
Female	62.4 (19.1)	48.8 (7.8)*	90.5 (15.4)*	83.3 (18.2)	88.1 (14.8)	95.2 (11.3)	86.2 (18.2)	85.8 (22.8)*	87.7 (22.6)	96.8 (9.6)	92.1 (16.3)	78.8 (19.6)	84.6 (10.5)
Diabetes retinopathy (right) [c]													
None	63.8 (18.5)	49.9 (7.9)	90.9 (13.9)	87.7 (12.9)	93.7 (8,3)	98.5 (4.3)	89.3 (14.6)	89.6 (15.7)	92.5 (14.2)	99.4 (4.0)	95.6 (12.5)	85.7 (17.9)	86.6 (7.9)
Mild	69.6 (17.4)	46.9 (6.0)	96.3 (7.8)	78.3 (16.2)	85.5 (10.5)	94.8 (9.1)	93.1 (7.63)	90.9 (15.2)	94.8 (11.9)	94.8 (10.4)	91.7 (12.0)	77.5 (11.7)	86.3 (5.3)
Moderate	58.0 (18.0)	45.0 (5.1)	82.5 (19.9)	78.8 (23.9)	82.0 (16.5)	91.4 (14.4)	82.3 (16.8)	78.6 (24.3)	79.8 (26.6)	92.9 (14.3)	87.9 (18.6)	78.9 (19.6)	81.7 (10.4)
Severe	62.8 (13.9)	47.5 (6.0)	75.0 (18.9)	77.1 (16.4)	85.4 (13.2)	91.7 (11.8)	79.4 (18.8)	76.6 (24.7)	78.1 (30.3)	93.8 (11.6)	87.5 (13.4)	76.2 (19.5)	78.9 (10.5)
PDR	55.2 (16.6)	45.2 (8.1)	79.2 (19.7)	68.8 (21.8)	73.4 (19.7)	85.1 (16.2)	68.8 (24.0)	63.4 (30.7)	64.0 (32.5)	91.7 (13.5)	80.3 (23.2)	73.4 (21.0)	76.2 (13.3)
ADED	61.3 (18.4)*	43.5 (6.7)†	77.5 (24.2)†	60.4 (32.3)†	65.0(30.8)†	79.2 (26.4)†	71.0 (20.9)†	57.5 (33.4)†	62.5 (33.3)†	82.5 (26.5)†	72.5 (29.9)†	76.7 (25.3)	82.8 (13.5)*
Diabetes retinopathy (left) [c]													
None	63.3 (18.3)	49.7 (7.9)	90.1 (15.1)	87.4 (13.6)	93.3 (8.6)	98.2 (5.1)	88.9 (14.7)	89.0 (16.0)	92.0 (14.2)	99.2 (4.5)	95.2 (13.1)	87.3 (15.8)	86.9 (7.4)
Mild	72.5 (16.2)	47.0 (6.0)	97.8 (6.1)	76.1 (15.6)	85.4 (11.4)	94.9 (9.3)	93.5 (9.8)	90.5 (18.0)	95.7 (12.3)	95.7 (9.7)	92.4 (11.8)	74.0 (15.8)	84.5 (8.3)
Moderate	57.8 (18.1)	45.3 (5.4)	83.2 (17.1)	80.1 (23.5)	82.4 (16.7)	91.7 (14.1)	83.0 (16.1)	81.3 (23.3)	81.1 (26.9)	92.1 (14.6)	87.9 (17.5)	75.9 (18.9)	81.7 (9.9)
Severe	57.5 (15.4)	46.3 (5.2)	75.0 (18.9)	79.7 (16.0)	85.4 (14.8)	92.7 (11.3)	74.4 (21.3)	73.4 (26.5)	69.5 (34.6)	96.9 (8.8)	87.5 (18.9)	73.8 (18.9)	77.2 (13.8)
PDR	56.3 (16.7)	45.9 (8.1)	80.9 (20.7)	69.1 (21.7)	73.6 (20.4)	85.0 (16.5)	70.6 (24.2)	64.2 (30.2)	67.3 (31.2)	91.2 (13.6)	80.1 (22.8)	78.3 (19.0)	79.5 (10.8)
ADED	62.5 (19.2)*	41.3 (6.4)*	73.4 (22.6)†	55.7(33.5)†	63.0 (30.7)†	78.1 (28.1)†	68.8 (21.0)†	51.6 (33.5)†	53.1 (35.8)†	81.3 (29.1)†	71.9 (31.2)†	61.7 (29.8)*	73.9 (19.4)*
Treatment[c]													
Diet alone	71.3 (17.9)	51.3 (4.8)	100.0 (0.0)	95.8 (0.0)	100.0 (0.0)	100.0 (0.0)	97.5 (5.0)	100.0 (0.0)	95.3 (6.0)	100.0 (0.0)	100.0 (0.0)	0.0 (0.0)	0.0 (0.0)
Diet+Oral	63.1 (17.8)	48.3 (7.6)	88.0 (16.8)	81.9 (18.6)	87.6 (14.4)	94.6 (11.1)	86.2 (17.8)	84.2 (22.5)	86.3 (23.0)	96.6 (9.9)	91.4 (18.4)	81.1 (18.6)	83.6 (10.1)
Diet+insulin	62.3 (17.1)	46.9 (6.4)	91.0 (13.9)	80.3 (23.3)	83.5 (18.1)	92.4 (11.9)	82.6 (18.9)	81.3 (24.0)	82.2 (16.2)	93.8 (11.0)	89.8 (17.8)	79.7 (21.7)	83.9 (10.6)
Diet+Oral+ insulin	60.4 (19.1)	47.2 (7.9)	84.6 (18.5)	79.2 (19.8)	85.6 (17.9)	93.4 (14.1)	82.4 (18.8)	79.6 (24.9)	83.3 (25.2)	95.5 (13.0)	89.2 (16.7)	80.1 (17.8)	83.1 (10.3)

[b]Unpaired t-test; [c]ANOVA; *p<0.05; †p<0.001

DISCUSSION

The general health score in our study was 62.13±18 which is significantly lower compared to the controls (p<0.001) after adjusting for age and gender during multiple linear regression analysis. The values we obtained were higher than Akkaya et al[13] (45.99±16.46), Klein et al[14] (40.6±10.7) and Cusick et al[15] (50.0±2.0). This might be attributable to the study population originating from a middle-income country with relatively better health awareness and access to care. The general health score is significantly lower in advanced diabetic retinopathy, Clinically Significant Macular Oedema (CSME), and patients with poor glycaemic control (fasting blood

glucose and HbA1C levels) and low visual acuity (p<0.05 in all). Akkaya et al also reported that a low general health score was seen in patients with advanced diabetic retinopathy, CSME and duration of diabetes.[13]

Table IV: Association between age, duration of diabetes, fasting blood glucose, HbA1C, visual acuity and all vision-related quality of life (VRQL) subscales among diabetes patients

General health (r)	General vision (r)	Ocular pain (r)	Near activities (r)	Distance activities (r)	Social functioning (r)	Mental health (r)	Role difficulties (r)	Dependency (r)	Colour vision (r)	Peripheral vision (r)	Driving (r)	VRQoL score (r)
Age												
0.100	0.124	0.165*	0.173*	0.210†	0.184†	0.261†	0.239†	0.220†	0.117	0.189*	0.164	0.207*
Duration of diabetes												
-0.102	-0.016	-0.058	0.052	0.020	0.004	-0.050	-0.035	-0.073	0.021	0.059	0.042	0.027
Fasting blood glucose												
-0.213*	-0.081	-0.147*	-0.141	-0.202*	-0.203*	-0.261†	-0.287†	-0.293†	-0.118	-0.048	-0.179	-0.122
HbA1C												
-0.187*	-0.104	-0.188*	-0.137*	-0.196*	-0.176*	-0.246†	-0.280†	-0.285†	-0.110	-0.043	-0.122	-0.068
Visual acuity (right)												
-0.163*	-0.194†	-0.262†	-0.380†	-0.443†	-0.427†	-0.362†	-0.369†	-0.369†	-0.392†	-0.310†	-0.124	-0.299†
Visual acuity (left)												
-0.072	-0.257†	-0.174†	-0.397†	-0.376†	-0.354†	-0.314†	-0.329†	-0.364†	-0.231†	-0.283†	-0.426†	-0.406†

Pearson's correlation coefficient (r); **P<0.05; †P<0.001

Although Pereira et al reported that a general health score is inversely proportional to the duration of diabetes, our study did not find any association with the duration of diabetes.[16]

In our study, the general vision score was 47.77±7.54; significantly lower than the controls (p<0.001). It was lower in females, patients with cataracts and CSME (p<0.05) but it was significantly lower in patients with advanced diabetic retinopathy (DR) and low visual acuity (p<0.001). General vision scores were found to be lower than general health scores in our study. In the study by Klein et al[14] the general vision score was 79.0±16.1 and in Akkaya et al[13] the general vision score was 53.96±17.96. This could be explained by the fact that our study participants were literate enough to gather more evidence-based information on visual progress in the long run. Colour vision, peripheral vision, and ocular pain scores were 95.83±11.21, 90.50±17.52 and 87.39±17.08 respectively in our study. Like other studies, all three scores are high unlike general vision scores showing that these patients do not face the problems of colour vision, peripheral vision, and ocular pain. These problems are mostly related to glaucoma. The near vision activities score was 80.92±19.60 in our study, which was statistically significant (p<0.001) and associated with the presence of CSME, cataract (p<0.05) and advanced DR (p<0.001). Our findings correlate with another study by Akkaya et al[13], which reported a near vision activities score of 75.71±23.28 and it was associated with CSME, cataracts, advanced DR and decreased visual acuity. The distance activity score was 86.48±16.25 in our study. It was associated with advanced age, low visual acuity in advanced diabetic retinopathy, CSME, cataracts (p<0.001) and low glycaemic control (p<0.05). This also correlates with a study by Akkaya et al.[13]

The social functioning score was 93.98±12.31, the mental health score was 84.51±18.29, the role difficulty score was 82.41±12.52, and the dependency score was 84.81±24.08. In comparison to the control group, this was not significant. It was associated with age, glycaemic control, visual acuity, cataract, CSME and advanced DR ($p<0.001$). These associations are similar to studies by Klein et al[14] and Akkaya et al [13,] which stated a strong association of mental health with visual acuity. The only difference was that in our study there was no association with the duration of diabetes, which was found in other studies.[17] The higher social functioning score in our study could be a reflection of the cultural setting, as the study was conducted at a facility that is multi-ethnic.

The driving score of 80.58±18.61 in this study was not associated with common variables like age, duration of diabetes, glycaemic control, visual acuity, cataract, CSME and advanced diabetic retinopathy. It might be related to the fact that at the time of completing the questionnaire, 45.4% of patients were not driving, out of which 80% never drove whilst 20 % gave up driving with the diminution of vision and advancing age.

The VRQL composite score in the present study was 83.49±10.14 ($p<0.05$), which is higher than the reported score in a couple of studies. Akkaya et al[13] reported it as 76.39±18.63 and Pereira et al[16] as 73.93±25.55. However, other studies found results similar to ours; Klein et al[11] reported it as 88.9±13.7 and Cusick et al[15] as 82. In our study, the score was dependent on visual acuity and the presence of cataract, CSME and advanced DR ($p<0.001$). This correlates with other studies by Klein et al[14] and Akkaya et al[13] who also stated that VRQL is more related to visual acuity than to the stage of DR.

This study was done in a multi-ethnic patient community with a good sample size (230 cases vs 260 controls) indicating the strength of our study. However, we could not explore the confounding effect of other ocular co-morbidities like glaucoma and age-related macular degeneration on the VRQL. This will be taken up in further research.

CONCLUSION

General vision scores were found lower than general health scores in our study. This study demonstrated that VRQL is more closely related to visual acuity than to the stage of diabetic retinopathy. Hence, we recommend that all diabetic patients be counselled in detail regarding vision-related problems. The high social score is indicative of the cultural setting of our community.

INSTITUTIONAL REVIEW BOARD (ETHICS COMMITTEE)

The study was registered with the National Medical Research Register [NMRR – 18-1080-41544 (IIR)] of Malaysia. Permission for the research work was approved by the Medical Research and Ethics Committee (Ref No.KKM.NIHSEC P18-1181),[9] a Malaysian government body, the Clinical Research Centre, Hospital Melaka and Institutional Research Board of Manipal University College Malaysia (MUCM) bearing approval number: MMMC/FOM/Research Ethics Committee – 9/2018.

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