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RESEARCH ARTICLE

Relationship between glycaemic control and the severity of erectile dysfunction in men with diabetes attending the diabetic clinic at Kalafong Provincial Tertiary Hospital

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Introduction Erectile dysfunction (ED) is common in men who are in their sixth decade of life and older, particularly those with diabetes. This study aimed to determine whether long-term glycaemic control affects the severity of ED in diabetic male patients attending the diabetic clinic at Kalafong Provincial Tertiary Hospital (KPTH).
Methods This cross-sectional study used data collected at the KPTH Diabetic Clinic, Gauteng, South Africa. Eighty-one male patients aged over 55 years who attended the diabetic clinic in 2017 were selected to participate in this study. The Sexual Health Inventory for Men (SHIM) questionnaire was used to determine the severity of ED, and the mean glycated haemoglobin A1c (HbA1c) over the preceding two years was used to assess glycaemic control.
Results The SHIM distinguished between ED categories among the participants (Cronbach's alpha: 0.964). The HbA1c did not differ significantly between SHIM ED categories ($p = 0.867$). No significant difference was detected between the mean HbA1c in those with ED (8.26%, IQR: 7.2 to 9.4) and those without ED (7.6%, IQR: 6.7 to 8.9) ($p = 0.494$). Multivariate analyses revealed that a longer duration of diabetes, moderate albuminuria, the presence of any peripheral neuropathy, the number of antihypertensive agents used, and smoking history were associated with ED. However, the mean HbA1c of the preceding two years did not significantly contribute to ED ($p = 0.133$).
Conclusion The SHIM reliably distinguished between ED categories in this population, with high internal consistency; however, glycaemic control, as measured by HbA1c over the preceding two years, did not play a significant role in predicting the presence or severity of ED.

Keywords: erectile dysfunction, glycaemic control, sexual health inventory for men, glycated haemoglobin A1c

Background

Erectile dysfunction (ED) is defined as the inability to achieve or sustain an erection sufficient for satisfactory sexual performance.[1] ED commonly affects men as they age, particularly those who have comorbidities. ED is usually underreported by patients and not given as much attention as other medical conditions by healthcare workers. Patients with ED can be treated. The importance of detecting ED is that it is a marker for cardiovascular disease.[2] ED may precede the onset of cardiovascular disease, such as coronary artery disease, by several years.[3]

There must be a paradigm shift to address ED, as it affects patients' self-esteem and overall quality of life, their partners, and the quality of their intimate relationships.[4]

Diabetes mellitus is one of the most common medical conditions at all levels of health care in South Africa. ED in men with diabetes is a common complication of diabetes and occurs in approximately 50% of male patients within 10 years of the diagnosis of diabetes and may be a presenting symptom in as many as 12% of these men.[5]

The discovery of glycated haemoglobin A1c (HbA1c) in the 1960s led to a gradual increase in its use as a marker of glycaemic control. HbA1c is glycated haemoglobin that is formed by the glycosylation of haemoglobin.[6,7] HbA1c values represent average glycaemic control over the preceding 2–3 months and account for both preprandial and postprandial blood glucose levels.[8,9] The HbA1c blood test is available and used extensively at primary, secondary, and tertiary healthcare facilities across South Africa.

Numerous international studies have suggested that glycaemic control in men with diabetes is directly associated with the severity of ED.[5,10,11] The HbA1c test was used to assess glycaemic control in these studies, and the SHIM questionnaire was used to detect and grade the severity of ED.[12]

The SHIM questionnaire is an abridged version of the International Index of Erectile Function questionnaire, which was developed and validated from 1996 to 1997. The SHIM questionnaire, a multidimensional, self-reported instrument for evaluating male sexual function, has been recommended as a primary endpoint for clinical trials of EDs and diagnostic evaluation of ED severity.[13]

In addition to diabetes, ED also has neurologic, psychological, hormonal, and vascular causes, with hypertension, obesity, testosterone deficiency, and chronic medication use being common examples, and lower urinary tract symptoms, including genital pain, prostate disease, and trauma.[1]

The commonly used medications that have been associated with ED include thiazide diuretics, beta-adrenergic receptor blockers, spironolactone, and calcium channel blockers, which are used to treat hypertension; H2 blockers such as cimetidine;

treatments for gastroesophageal reflux disease and peptic ulcer disease; tricyclic antidepressants; and selective serotonin reuptake inhibitors commonly used to treat patients with depression.[14]

Hypogonadism is defined as a clinical and biochemical syndrome characterised by the inability of the testes to produce physiological concentrations of testosterone (T) with or without normal sperm cells.[15] Men with hypogonadism commonly have decreased sexual interest and quality of erections or EDs.[16] Studies have confirmed that ageing men who are obese and have metabolic syndrome have much lower T levels than ageing metabolically healthy men.[17] Testosterone levels, either bioavailable or calculated free, should be considered when investigating patients with sexual dysfunction.[18]

The primary objective of the study was to determine whether glycaemic control, as measured by HbA1c over the preceding 24 months, influenced the severity of ED in male patients with diabetes over the age of 55 who were attending the diabetic clinic at Kalafong Provincial Tertiary Hospital (KPTH). The secondary objective of the study was to investigate the presence of other known causes of ED in our participants and their effect on the severity of ED.

Methods

Study design and setting

This cross-sectional study used data including history, examination findings, anthropometry, and laboratory results, collected as part of routine patient care.

The study took place at the KPTH diabetic clinics in Gauteng, South Africa. These clinics are run by the Department of Internal Medicine. The medical personnel caring for patients in these clinics include at least one consultant physician, medical registrars, medical officers, medical interns, and professional and auxiliary nurses. Health records are captured electronically for all patients by doctors at each clinic visit. There are two diabetic clinics per week. A structured approach is followed for the detection of diabetes-related complications. Patient management is based on the guidelines of the Society for Endocrinology Metabolism and Diabetes of South Africa (SEMDSA). Each patient was followed up at least four times per year.

Patient selection

Male patients over 55 years of age who were attending the diabetic clinic in 2017 were requested to complete the Sexual Health Inventory for Men (SHIM) questionnaire, and appropriate blood samples were taken as part of routine care; where indicated, bioavailable testosterone and sex hormone binding globulin levels were measured.

Measurement variables

The SHIM questionnaire was used to determine the severity of ED. The SHIM has been validated to assess the presence and severity of ED using five questions, each with a potential score ranging from zero to five, depending on the patient's response. A score of 22–25 excludes ED, 17–21 suggests mild ED, 12–16 suggests mild to moderate ED, 8–11 suggests moderate ED, 5–7 suggests severe ED, and 1–4 warrants immediate consultation for ED. Glycaemic control was assessed using the average HBA1c values obtained over the preceding two years. The participants' age, body mass index, blood pressure, duration of diabetes, bioavailable testosterone levels, and chronic medications were extracted from electronically captured health records.

Data management and analysis

The study used patient records captured on the KPTH Diabetes Clinic electronic record system. Paper-based questionnaires were administered to assess the frequency and severity of ED in all patients older than 55 attending the clinic. During the fourth clinic visit of every year (general visit), a sexual health assessment, assessment of injection sites, alcohol use, and skin disease are evaluated in all diabetic patients attending the clinic (male and female) as part of routine comprehensive patient care. As part of sexual health care, all male patients older than 55 completed the Ageing Males Symptoms, SHIM, and International Prostate Symptom Score questionnaires (these questionnaires were captured on paper), and sex hormone levels were measured where indicated. After 2017, an abbreviated sexual functioning assessment was performed, and sex hormone testing was abandoned because of cost, except where clinically indicated. Additional patient information related to diabetes care was extracted from the Diabetic Clinic database.

The principal investigator captured the raw questionnaire data in an electronic spreadsheet format. Google Forms was used for this purpose. Data were analysed using SPSS version 28 (2022; IBM Corp, Armonk, NY, USA). All variables were described appropriately for the type and distribution of the data. The mean HbA1c was compared between patients who reported ED and those who did not, using nonparametric methods. Linear regression for crude SHIM scores and ordinal regression for SHIM ED severity categories were performed to adjust for confounding variables contributing to ED. All appropriate clinical variables were assessed for inclusion in multivariate regression models using univariate linear regression. All variables with a p-value equal to or less than 0.15 in the univariate analysis were included in multivariate modelling, except for mean HbA1c. The most parsimonious linear and ordinal regression models were constructed by removing variables that were highly correlated or were found not to contribute adequately to the models. The mean HbA1c was included in each of these models to assess its contribution to the models.

Ethical considerations

Approval to conduct this study was obtained from the Ethics Committee of the Faculty of Health Sciences of the University of Pretoria (protocol approval number: 562/2022).

Results

Among the male patients attending the KPTH Diabetic Clinic, 82 participated in this study. One patient's clinical data could not be retrieved, and another did not complete the questionnaire adequately and was excluded from the analysis. Fifty-eight (72%) patients had type 2 diabetes, 17 (21%) had type 1 diabetes, 5 (6%) had diabetes of uncertain type, and 1 (1%) had diabetes secondary to chronic pancreatitis. The mean duration of diabetes was 15 (SD 8.63) years, with a mean HBA1c of 8.18 (SD 1.53). The mean age of the participants was 61 years. Most patients were Black ($n = 70$, 86%), followed by four White (5%), four Indian (5%), and two Coloured (3%) individuals (Table 1).

All participants were receiving chronic treatment for diabetes, diabetes complications, and other comorbidities, as reflected in Table 2.

Table 1: Patient demographic information

Variable	*n*	Frequency (%)	Mean (SD)/Median (IQR)
Type of diabetes:			
Type 1	17/81	21	
Type 2	58/81	72	
Secondary	1/81	1	
Uncertain	5/81	6.2	
Hypertension	74/81	91	
Race:			
Black	70/81	87	
Coloured	2/81	3	
Indian	4/81	5	
White	4/81	5	
Smoking status:			
Never smoked	46/81	57	
Currently smoking	11/81	14	
Stopped more than 1 year ago	22/81	27	
Stopped less than 1 year ago	2/81	3	
Snuff use	1/81	1	
Foot ulcers in the last 3 years	6/81	7	
Peripheral neuropathy	32/81	40	
Age	81		62 (IQR 53.5 to 67)
Duration of hypertension (years)	81		12.7 (8.04)
Duration of diabetes (years)	81		15 (8.63)
Mean HbA1c	81		8.18 (1.53)
Urine albumin: creatinine ratio (mg/mmol)	81		3.20 (IQR 0.75 to 15.7)
Lipid profile:			
Total cholesterol (mmol/l)	81		4.05 (1.11)
Low-density lipoprotein (mmol/l)	81		2.07 (0.90)
High-density lipoprotein (mmol/l)	81		1.21 (0.38)
Triglycerides (mmol/l)	81		1.73 (0.87)
Serum creatinine (µmol/l)	81		121.4 (64.11)
Serum potassium (mmol/l)	81		4.29 (0.96)
Thyroid stimulating hormone	18		2.83 (1.99)
Anthropometry			
Body mass index (kg/m^2)	81		29.73 (5.694)
Hip circumference (cm)	81		113.6 (67.402)
Waist circumference (cm)	81		106.41 (17.46)
Laboratory results			
Free testosterone, %	36		1.86 (0.531)
Sex hormone binding globulin (nmol/l)	39		39.62 (20.041)
Calculated free testosterone (nmol/l)	36		0.26 (0.088)
Calculated bioavailable testosterone (nmol/l)	36		6.03 (2.06)
Testosterone (nmol/l) reference range 8.6–23.4	36		14.78 (5.822)
Prostate specific antigen (µg/l)	55		1.86 (2.502)

Severity of ED according to the SHIM questionnaire

According to the SHIM questionnaire, 14 (17%) patients had no ED, 16 (20%) patients had mild ED, 8 (10%) had mild to moderate ED, 9 (11%) had moderate ED, and 33 (41%) had severe ED. Cronbach's alpha for the five items of the SHIM questionnaire was 0.964, suggesting high internal consistency (Tables 3 and 4).

Parametric comparisons of HbA1c across ED categories revealed no significant differences ($p = 0.867$). When HbA1c was compared between patients with any ED (mild to severe) according to the SHIM score, the median HbaA1c was 8.26% (IQR 7.2 to 9.4), and for patients without any ED, the median Hba1c was 7.6% (IQR 6.7 to 8.9). This difference was not significantly different ($p = 0.494$).

Multivariate linear regression modelling was performed to obtain the most parsimonious model with and without the mean HbA1c values. Significant collinearity existed between the Duration of Diabetes (log-transformed), the Duration of Hypertension, and Age; therefore, Duration of Diabetes was selected because it had the best *p*-value in the univariate regression. The individual antihypertensive agents that were indicated by the univariate analysis correlated well with the number of antihypertensive agents, and the less frequently

Table 2: Treatments used by the patients in the study

Drug	*n*	Frequency (%)
Diabetic treatment:		
Combination NPH and regular insulin	52	64
Regular insulin	12	15
NPH insulin	9	11
Metformin	59	73
Glimepiride	4	5
Vildagliptin	1	1
Antihypertensive treatment:		
Enalapril	68	84
Hydrochlorothiazide	60	74
Atenolol	21	26
Alpha-methyldopa	16	20
Hydralazine	15	19
Furosemide	13	16
Amlodipine	12	15
Spironolactone	9	11
Carvedilol	7	9
Doxazocin	5	6
Other treatment:		
Kayexalate	1	1
Simvastatin	65	80
Aspirin	57	70
Amitriptyline	26	32
Paracetamol	22	27
Lansoprazole	12	15
Isosorbide mononitrate	10	12
Carbamazepine	9	11
Atorvastatin	6	7
Isosorbide dinitrate	6	7
Allopurinol	6	7
Other	33	25

Table 3: Sexual Health Inventory for Men (SHIM) scores

Item	Number of responses (*n*)	Median score	Interquartile range (IQR)
1. How do you rate your confidence that you could keep an erection?	81	2.59	1.5 to 4
2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration (entering your partner)?	80	2	0 to 4
3. During sexual stimulation, how often were you able to maintain your erections after you had penetrated (entered your partner)?	80	3	0 to 3.75
4. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?	80	2	0 to 4
5. When you attempted sexual intercourse, how often was it satisfactory for you?	80	2	0 to 5

Table 4: Erectile dysfunction (ED) severity categories

SHIM category of ED	Number of patients	Frequency (%)
No ED	14/80	17
Mild ED	16/80	20
Mild to moderate ED	8/80	10
Moderate ED	9/80	11
Severe ED	33/80	41

used antihypertensive agents indicated more severe hypertension, which explains the strong relationship between the number of antihypertensive agents and the SHIM score. Therefore, the individual agents were dropped in favour of the number of hypertensive agents. The most parsimonious linear regression models with and without mean HbA1c are indicated in Table 5.

The F-change from the model without to the model with the mean HbA1c was 2.315 ($p = 0.133$); thus, the model did not improve significantly with the addition of mean HbA1c. Thus, after adjusting for the urine albumin-to-creatinine ratio (log-transformed), duration of diabetes (log-transformed), number of antihypertensive drugs, ever-smoking status, and presence of peripheral neuropathy, the mean HbA1c was not associated with a significant reduction in the SHIM score (Beta: −0.878 [CI: −2.028 to 0.272]).

Ordinal regression was performed with the ED category identified by the SHIM questionnaire as the dependent variable: severe ED, moderate ED, mild to moderate ED, mild ED and no ED. The same variables used in the linear regression modelling were selected for inclusion in the ordinal regression model.

The ordinal model indicated that the model predicted the ED category well, with a significant chi-square value ($p < 0.001$). In the model, the estimates were as follows: number of hypertensive agents ($p = 0.04$), duration of diabetes ($p = 0.031$), urine albumin to creatinine ratio ($p = 0.028$), ever smoking ($p = 0.164$), and neuropathy ($p = 0.024$). The mean HbA1c did not significantly predict the ED category ($p = 0.175$). The model performed well, with a model fit of $p < 0.001$ (chi-square), Pearson and deviation goodness of fit of $p = 0.884$ and $p = 1.00$, respectively, Nagelkerke $R^2 = 0.353$, and the test for parallel lines $p = 0.995$.

Discussion

The SHIM distinguished well between ED severity categories in this population of over 55-year-old male patients attending the KPTH diabetic clinic. The Cronbach's alpha of the SHIM was 0.964, suggesting high internal consistency, which is in keeping with the findings in the literature.[12,13]

ED was shown to be common in this population, with only 14 out of 81 (17%) patients reporting not having any ED, compared

Table 5: Most parsimonious model with and without mean HbA1c, with SHIM score as the dependent variable

Model	Without mean HbA1c			With mean HbA1c		
Variable	Beta	T	*p*	Beta	T	*p*
Constant	27.638	7.928	< 0.001	35.208	5.812	< 0.001
Log urine albumin to creatinine ratio	−2.838	−2.661	0.010	−2.551	−2.376	0.020
Log duration of diabetes	−7.281	−2.197	0.031	−6.966	−2.117	0.038
Number of anti-hypertensive agents used	−1.250	−1.570	0.120	−1.572	−1.925	0.058
Ever smoked	−2.880	−1.633	0.107	−3.363	−1.893	0.062
Any peripheral neuropathy	−4.215	−2.473	0.016	−3.802	−2.223	0.029
Mean HbA1c				−0.878	−1.521	0.133
	R^2 0.346			R^2 0.367		

with 66 out of 80 patients (82%) who had some degree of ED. Most of the patients who had any ED according to the SHIM questionnaire fell into the severe category (33 out of 66 patients, 50%), followed by mild ED (16 out of 66 patients, 24%), moderate ED (9 out of 66 patients, 14%), and mild to moderate ED (8 out of 66 patients, 13%). These findings highlight the importance of screening elderly male diabetic patients for ED and are consistent with the estimated prevalence of ED reported in the literature.[5] The HbA1c did not differ significantly between SHIM ED categories. When the mean HBA1c levels of the participants in our study over the preceding two years were compared across any ED category (mild to severe ED), no significant difference could be found ($p = 0.867$). There was also no significant difference in the mean HbA1c between those who did and did not have ED ($p = 0.494$). This finding is comparable to that of Rhoden et al., who reported that there was no significant difference in ED severity in the HbA1c subgroups when the duration of DM was less than or equal to five years ($p = 0.87$), but there was a significant difference in those with DM for 6–10 years or more ($p < 0.03$).[11]

Multivariate analyses revealed that a longer duration of diabetes, moderate albuminuria, the presence of any peripheral neuropathy, the number of antihypertensive agents used, and smoking history were the major contributors to ED. This is expected because albuminuria, neuropathy, smoking, and duration of diabetes are known risk factors for microvascular, macrovascular, and neuropathy-related complications of DM, which in turn cause ED.[5] Poor glycaemic control is a significant cause of microvascular complications and neuropathy, and it seems from this study that diabetes-related complications have a much stronger relationship with ED than with HbA1c over the preceding two years.

There is consensus in the literature that antihypertensive treatment classes, such as diuretics (including aldosterone receptor antagonists) and beta blockers, may negatively affect ED. Several studies have suggested that calcium channel blockers and renin-angiotensin system inhibitors have a neutral effect on ED.[19]

Our study suggested that the total number of antihypertensive medications that patients use, as opposed to the individual classes of antihypertensive medications, contributes more to ED. This finding has not been supported or refuted in our literature review. However, patients who are treated with more agents are likely to have long-standing uncontrolled hypertension, with more target organ damage, requiring the addition of second- or third-line antihypertensive treatment. This finding may warrant further investigation.

During questionnaire data collection, some participants were assisted in completing the questionnaire due to poor literacy, poor vision, or language barriers, which could have contributed to observer bias. Some participants might have had difficulty responding fully to intimate questions concerning ED. This discomfort was curbed by using more senior doctors to complete the questionnaire.

HbA1c is a long-term determinant of neuropathy and microvascular and macrovascular disease in diabetic patients, and these complications predispose patients to ED. An earlier assessment of HbA1c in the disease history of male patients may be more related to the presence of ED. There is most likely a delayed effect of poor glycaemic control on ED, and this effect is most likely indirectly mediated by vascular disease and neuropathy. This may validate findings in the literature that focused on patients who have had diabetes for six years or more and reported that HbA1c values are significantly related to the severity of ED.

Conclusion

The SHIM questionnaire reliably distinguished between ED categories in this population, with high internal consistency. Glycaemic control, as measured by HbA1c over the preceding two years, did not play a significant role in predicting either the presence or severity of ED, according to the SHIM questionnaire.

The duration of diabetes, presence of moderate albuminuria, presence of peripheral neuropathy, smoking history, and the use of more antihypertensive agents were shown to be significant risk factors for ED.

ED is more related to the number of antihypertensive agents used than to the use of individual agents; however, this may be an indication of the severity of hypertension and its effect on ED.

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