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Research Article

Prevalence and Association of Microvascular Complications with Atherosclerotic Cardiovascular Disease in People with Type 2 Diabetes in The Gulf Region: Results from the PACT-MEA Study

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Abstract

Background and aims: To establish the burden of microvascular complications and their relationship with established Atherosclerotic Cardiovascular Disease (eASCVD) and ASCVD risk in participants with Type 2 Diabetes (T2D).

Methods and results: The study was a sub-analysis of the PACT-MEA study and included data from 1062 adult participants with T2D from Bahrain, Kuwait, and Qatar. Demographic characteristics, clinical profiles, and laboratory measures were extracted from participants' medical records. The overall prevalence of one or more microvascular complications (MC) was 34.9% and did not vary by country: 35.0% in Bahrain, 32.6% in Kuwait and 37.3% in Qatar (p=0.427). The prevalence of MC was 38.9% in participants with eASCVD and 37.3% in those with ASCVD risk. The prevalence of retinopathy and neuropathy was significantly higher in participants with hypertension and dyslipidemia ($p<0.05$).

Conclusion: Microvascular complications are common in individuals with T2D in the Gulf region and are associated with hypertension and dyslipidemia and those at high risk of ASCVD.

Keywords: Type 2 Diabetes; Cardiovascular Disease; Atherosclerotic Cardiovascular Disease; Microvascular Complications; Middle East; Gulf Region; Observational Study

Introduction

Limiting the development and progression of microvascular complications in individuals with Type 2 Diabetes (T2D) is a key goal in diabetes management [1,2]. Prolonged hyperglycemia leads to diabetic nephropathy, retinopathy, and neuropathy, impacting both quality of life and overall life expectancy [3,4]. Microvascular complications start in individuals with impaired fasting glucose and impaired glucose tolerance [5,6] and can result in blindness, amputation, and end-stage kidney disease, with higher healthcare utilization and costs in those with T2D [4-10].

There is an established link between microvascular and macrovascular complications, including coronary artery disease, stroke, heart failure, and atherosclerotic cardiovascular disease (ASCVD) in T2D [11]. Hyperglycemia may act as a common factor in the pathogenesis of both microvascular and macrovascular complications [12]. In a large population-based analysis of patients with T2D from the UK Clinical Practice Research Datalink, the cumulative burden of microvascular complications linearly increased the risk of cardiovascular events [13]. Bartman et al., 2017 showed that the carotid plaque score—a marker for quantifying atherosclerotic plaque burden-was independently associated with retinopathy, neuropathy, and nephropathy in individuals with T2D [14].

Obesity, hypertension, hyperglycemia, and metabolic syndrome increase the risk of developing ASCVD and the risk of heart attack and stroke [15-17]. These risk factors are also closely linked to the development of microangiopathy [18]. Indeed, progression of diabetic retinopathy was associated with a 718% increased risk of ASCVD [19,20]. In a study from Saudi Arabia, the prevalence of diabetic peripheral neuropathy was significantly higher in participants with cardiovascular disease [21]. Improvements in weight, blood glucose, and cardiovascular risk factors have been shown to reduce the incidence of microvascular complications. Thus, the effective management of these ASCVD risk factors may help prevent the progression of microvascular complications and ASCVD in individuals with T2D [22,23].

The Middle East Africa (MEA) Region faces a disproportionate burden of obesity, metabolic syndrome and diabetes, a trend that is expected to worsen in the coming years [24,25]. The Prevalence of Diabetes and Cardiovascular Risk in the Middle East and Africa (PACT-MEA) study found that as many as one in five individuals with T2D in the region has established ASCVD [26]. There is limited data on the prevalence of microvascular complications in this region [24,25]. We have undertaken additional analysis of data from the PACT-MEA study to address this knowledge gap. Our study aims to determine the prevalence of microvascular complications and their relationship with ASCVD in individuals with T2D in Bahrain, Kuwait, and Qatar.

Methods

Study design and objectives

PACT-MEA is a non-interventional, cross-sectional, observational study conducted at 55 centers across seven countries to determine the prevalence of established ASCVD (eASCVD) or high ASCVD risk among participants with T2D in a real-world clinical setting [26]. The overall study sample included 3726 participants from Bahrain (n=366), Egypt (n=550), Jordan (n=576), Kuwait (n=350), Qatar (n=346), South Africa (n=996), and the United Arab Emirates (n=542). The present sub-analysis of the PACT-MEA study draws on data from 1062 participants from Bahrain, Kuwait, and Qatar.

The criteria for identifying eASCVD in study participants include prior diagnosis of coronary artery disease, cerebrovascular disease, or peripheral arterial disease [15,27-29]. High ASCVD risk among participants without eASCVD is defined as patients with T2D duration > 10 years; the presence of target organ damage (retinopathy, neuropathy, nephropathy, left ventricular hypertrophy) [27,28]; or multiple risk factors including age ≥ 55 years [15], current smoker, hypertension (blood pressure ≥ 140/90; antihypertensive therapy or has a history of hypertension), dyslipidemia (LDL ≥ 1.8 mmol/l, statin therapy or history of dyslipidemia), obesity (BMI ≥ 30) [27,28].

Participant recruitment and study setting

Participants were recruited during scheduled clinic visits at 13 centers (primary and secondary care facilities) across the three countries between March and August 2022. Novo Nordisk representatives, national experts (part of the steering committee), and the Contract Research Organization (CRO) created a list of primary and secondary care facilities. The split between care settings was determined at the individual country level based on local treatment dynamics. The study investigators were physicians managing T2D in routine clinical practice and were selected from primary care (general practitioners, family medicine physicians) and secondary care (endocrinologists, diabetologists, cardiologists, internal medicine) settings. Inclusion criteria: Male or female, age ≥ 18 years, diagnosed with T2D ≥ 180 days. Exclusion criteria: Mental incapacity, unwillingness, inability, or language barriers precluding adequate understanding or cooperation; type 1 diabetes mellitus (T1D); congenital heart disease/malformation.

Data collection and outcomes

Participant demographic information, medical history, and laboratory data were obtained from a medical chart review of data recorded in the medical records. The presence of microvascular complications was recorded from the medical history as yes, no, or unknown. The physician or a delegate entered individual patient data into an electronic Case Report Form (eCRF) during the patient's routine clinical visit (and study inclusion). A CRO managed the eCRF platform for the collection of patient data. Encryption was used to protect the identity of patients when transmitting data.

Statistical analysis

Descriptive statistics, with mean and Standard Deviation (SD) for continuous variables and frequencies and proportions (in percentages) with corresponding 95% Confidence Intervals (CIs) for categorical variables, were used to describe the study population's demographic, clinical, and laboratory characteristics. Data were stratified by the presence of ASCVD and the risk thereof. Chi-squared tests were used to compare proportions, with statistical significance considered at p-value < 0.05. Analyses were conducted using complete cases only without imputation of missing data, as the frequency of missing data was minimal across most of the key demographic and clinical variables and unlikely to affect the precision of estimates or introduce bias. Missing laboratory data were reported. Analyses were conducted using SPSS (version 23) [30] and Stata (version 16.1) [31].

Ethics

The local Institutional Review Board (IRB)/Ethics reviewed and approved the study protocol and informed consent form. Approval was obtained from the Kuwait Ministry of Health (regulatory number: 1257, approved on 9 June 2022). In Bahrain, the Mohammed Bin Khalifa Bin Sulman Khalifa Cardiac Center ethics committee (IRB number: CTD-Ij-2022-0085/approved on 8 May 2022), the Research Committee for Government Hospitals (IRB number: 45090522/approved 9 May 2022), the Bahrain Defence Force Hospital IRB (IRB number 2022-667/approved on 6 April 2022) and the IRB for King Hamad University Hospital (IRB number: 22-508/approved on 9 May 2022) issued ethics approval. In Qatar, Weill Cornell Medicine – Qatar IRB (IRB number: 22-0007/approved on 1 June 2022) and Hamad Medical Corporation IRB (IRB number: MRC-02-22-374/approved on 30 June 2022) issued ethics approvals.

Informed consent was obtained prior to any study-related activities. The study was conducted in accordance with the Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Patients [32] and Guidelines for Good Pharmacoepidemiology Practices (GPP) [33]. It followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) [34] reporting guidelines.

Results

Study population

The study recruited 1062 adults diagnosed with T2D in Bahrain, Qatar, and Kuwait from primary care (n=202) and secondary care (n=860), depending on the country setting. The average age of the study participants was 57.9 years (SD=11.3), comprising 53.5% males and 46.5% females. The mean duration of T2D was 13.3 years (SD=8.9), and the mean glycated hemoglobin (HbA_{1C}) was 7.9% (SD=1.9). The estimated prevalence of eASCVD in the study population across the three Gulf Region countries was 26.6% (unweighted %) (**Table 1**), with the highest prevalence in Bahrain (36.6%) and lowest in Kuwait (19.4%). Around two-thirds (65.8%) of the entire study sample were at high risk of ASCVD (**Table 1**).

Characteristics	Overall sample of participants (n=1062)
Age, years. Mean (SD)	57.9 (11.3)
Sex	
Male, %	53.5%
Age, years, mean (SD)	56.7 (11.6)
Female, %	46.5%
Age, years, mean (SD)	58.9 (10.4)
T2D duration, years, mean (SD)	13.3 (8.9)
HbA_{1C}, %, mean (SD), and mmol/mol	7.9 (1.9), 63
Risk factors (%)*	
Obesity	50.7%
Hypertension	67.1%
Dyslipidemia	81.6%
Current smoking	12.2%
Prevalence of eASCVD (%)†	26.6%
High risk of ASCVD (%)	65.8%

[a] HbA_{1c} (Hemoglobin A1C) < 7.0% (53 mmol/mol) is the recommended target in the 2021 European Society of Cardiology (ESC) Guideline on cardiovascular disease prevention in clinical practice[1].
*Regarding risk factors included obesity (BMI ≥ 30 kg/m²; BMI was measured in kg/m², and the categories were assigned according to the World Health Organization classification of obesity [35]), hypertension (at least one of the following: BP over 140 or 90, antihypertensive therapy, history of hypertension), dyslipidemia (at least one of the following: LDL ≥ 1.8 mmol/L, statin therapy, history of dyslipidemia), and current smoking.
†Unweighted prevalence (%) of eASCVD within the overall T2D study population (weighted, %).
Abbreviations: eASCVD, established atherosclerotic cardiovascular disease; HbA_{1C}, glycated hemoglobin; LDL, low-density lipoprotein; SD, standard deviation; T2D, type 2 diabetes.

Table 1: Study Population Characteristics

Prevalence of microvascular complications and relationship with the presence or risk of ASCVD

Microvascular complications were present in 34.9%, n=371 of the total study participants (**Table 2**). The prevalence of complications was comparable by country (p=0.427): 35.0% (95% CI: 30.1 – 40.1) in Bahrain, 32.6% (95% CI: 27.7 – 37.8) in Kuwait and 37.3% (95% CI: 32.2 – 42.6) in Qatar (**Table 2**). Approximately one-quarter (27%) of the participants (n=65/242) had an albumin-to-creatinine ratio (ACR) between 30–300 mg/g, indicative of microalbuminuria. Ten percent of the participants (25/243) had an ACR above 300 mg/g, indicating macroalbuminuria. The prevalence of microvascular complications was 37.3% (95% CI: 33.7–41.0) in participants at high risk of ASCVD and 38.9% (95% CI: 33.2–44.8) in those with eASCVD.

Characteristics	Prevalence of microvascular complications, % (95% CI)	p value[#]
All participants (n=1062)	**34.9% (32.1 – 37.9)**	
Country (n=1062)		
Bahrain (n=366)	35.0% (30.1 – 40.1)	0.427
Kuwait (n=350)	32.6% (27.7 – 37.8)	
Qatar (n=346)	37.3% (32.2 – 42.6)	
With eASCVD (n=283)	38.9% (33.2 – 44.8)	
With high risk of ASCVD (n=699)	37.3% (33.7 – 41.0)	

[#]Chi-squared test of proportions

Table 2: Prevalence of one or more microvascular complications by country, eASCVD status, and ASCVD risk profile.

The presence of retinopathy, neuropathy, and nephropathy was 18.7% (n=198), 17.4% (n=185) and 14.9% (n=158), respectively. Among participants with eASCVD, retinopathy was the most common microvascular complication, at 23.0% (n=75), followed by nephropathy at 22.3% (n=63) and neuropathy at 20.8% (n=59). Among participants at high risk of ASCVD (n=699), retinopathy was also the leading complication at 19.0% (n=133), followed by neuropathy at 18.0% (n=126) and nephropathy at 13.6% (n=95) (**Figure 1**).

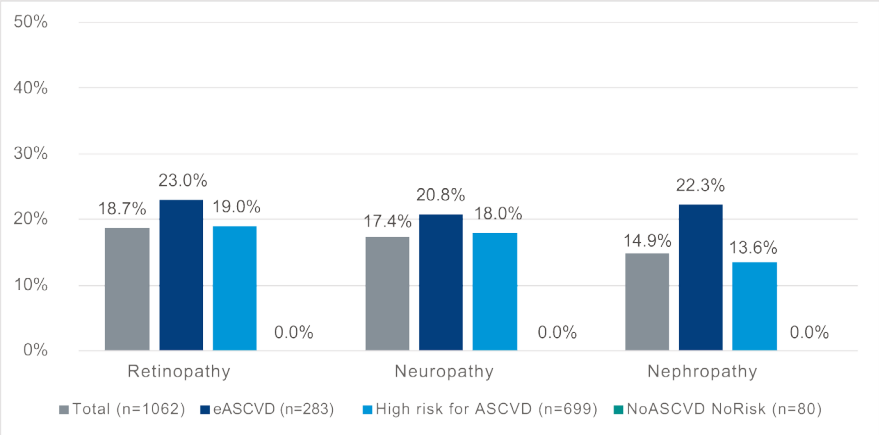

Figure 1: The prevalence of retinopathy, neuropathy, and nephropathy across the three Gulf Region countries among study participants with T2D, eASCVD, at high risk for ASCVD or without ASCVD or risk (%) T2D (Type 2 Diabetes), eASCVD (established atherosclerotic cardiovascular disease), ASCVD (atherosclerotic cardiovascular disease)

In individuals with hypertension compared to those without hypertension, the prevalence of retinopathy (p<0.001), neuropathy (p=0.001) and nephropathy (p<0.001) was significantly higher. In individuals with dyslipidemia compared to those without, the prevalence of retinopathy (p=0.03) and neuropathy (p=0.005) were significantly higher, but with no difference in the prevalence of nephropathy (p=0.142). There was no difference in the prevalence of retinopathy, neuropathy, and nephropathy between those with and without obesity (p>0.05). In current smokers compared to non-smokers, the prevalence of retinopathy (p=0.036) was lower, but with no difference in the prevalence of neuropathy or nephropathy (p>0.05) (**Table 3**)

Risk factor	Retinopathy, % (95% CI)	p value#	Neuropathy, % (95% CI)	p value#	Nephropathy, % (95% CI)	p value#
Obesity (n=1003)						
Yes (n=540)	20.6% (17.2 – 24.2)	0.261	19.3% (16.0 – 22.8)	0.281	15.4% (12.4 – 18.7)	0.382
No (n=463)	17.7% (14.3 – 21.5)		16.6% (13.4 – 20.3)		13.4% (10.4 – 16.8)	
Hypertension (n=1043)						
Yes (712)	22.6% (19.6 – 25.9)	**<0.001**	20.2% (17.3 – 23.4)	**0.001**	19.0% (16.1 – 22.0)	**<0.001**
No (331)	10.9% (7.7 – 14.7)		12.1% (8.7 – 16.1)		6.3% (4.0 – 9.5)	
Dyslipidemia (n=1058)						

Yes (867)	19.8% (17.2 – 22.7)	**0.030**	18.9% (16.4 – 21.7)	**0.005**	15.7% (13.3 – 18.3)	0.142
No (191)	13.1% (8.7 – 18.7)		10.5% (6.5 – 15.7)		11.5% (7.4 – 16.9)	
Current smoking (n=1013)						
Yes (n=130)	12.3% (7.2 – 19.2)	**0.036**	13.8% (8.4 – 21.0)	0.171	13.8% (8.4 – 21.0)	0.618
No (n=883)	20.0% (17.5 – 22.8)		18.8% (16.3 – 21.5)		15.5% (13.2 – 18.1)	

[#]*Chi-squared test of proportions*

Table 3: Prevalence of microvascular complications in relation to obesity, hypertension, dyslipidemia, and smoking status.

Discussion

One-third of participants (34.9%) had one or more microvascular complications in this PACT-MEA study sub-analysis. Previous studies have shown the significant burden of microvascular complications in the region [36-41]. The international, open-label A1chieve study reported a microvascular complications prevalence of 65.8% in the Middle East and Africa (MEA) region [37]. In a study from Saudi Arabia, 55.1% of participants had microvascular complications [36], while in a study in Qatar, the prevalence of one or more microvascular complications was 48.4% [42].

Across the three countries, 17.4% of participants had neuropathy, 18.7% had retinopathy, and 14.9% had nephropathy, which aligns with data from the PACT-MEA study of 3726 individuals across seven countries, which reported rates of 14% for retinopathy, 25% for neuropathy, and 15% for nephropathy [26]. In a previous study, we showed that diabetic neuropathy affected 23.9% of individuals with T2D in Qatar, of whom 82.3% had not been previously diagnosed [43]. Underdiagnosis was also reported in a study from Qatar, Kuwait, and Saudi Arabia, where diabetic neuropathy affected 33.3% of individuals with T2D, and 53.6% of participants with diabetic neuropathy had not been previously diagnosed [44]. Our study relied on information from participants' medical records and from the patient as requested by the physician, which may partly explain the lower prevalence of neuropathy in our current study.

Endothelial dysfunction, chronic inflammation, and hyperglycemia underlie both microvascular and macrovascular complications in T2D [45]. In our study, two-thirds of participants were classified as high risk for ASCVD, and 37.3% were estimated to have microvascular complications. Approximately one in four participants in our study had eASCVD, and 38.9% of these individuals had microvascular complications, supporting the strong association between microvascular complications and ASCVD [45].

Obesity, dyslipidemia, and hypertension were highly prevalent among the participants in this study. The significantly higher prevalence of microvascular complications in participants with hypertension, along with the increased prevalence of retinopathy and neuropathy in those with dyslipidemia, highlights a potential link between macrovascular risk factors and microvascular complications. In the DISCOVER MEA, a three-year observational study, both microvascular and macrovascular complications were significantly associated with older age, male sex, current or former smoking, and history of hyperlipidemia and hypertension [39]. Similarly, in the A1chieve study, multivariate analysis identified age, BMI, diabetes duration, total cholesterol, triglycerides, and systolic blood pressure as key factors associated with microvascular and macrovascular complications [37]. Indeed, the presence of these risk factors collectively increases the likelihood of adverse cardiovascular events, such as myocardial infarction, stroke, and peripheral artery disease, contributing to T2D [46-48].

Around 12% of participants in this study reported being current smokers, and surprisingly, we found that current smoking was linked to a lower prevalence of retinopathy. Separately, a meta-analysis showed that smoking increased retinopathy risk in type 1 diabetes but decreased it in T2D [49]. Indeed, the United Kingdom Prospective Diabetes Study (UKPDS) also identified current smokers with T2D as having a lower risk of retinopathy [50]. However, other studies have shown that smoking is strongly associated with retinopathy progression in T2D [51,52], although Moss et al., 1991 [53] reported no significant risk between diabetic retinopathy and smoking [53]. The relationship between tobacco use and retinopathy is complex [49]. One hypothesis suggests

that a smoking-related reduction in blood pressure may influence retinopathy risk [49]. Overall, the link between smoking and retinopathy remains inconclusive, and further research is needed to better understand these interactions.

Our study observed a significant burden of microvascular complications and an association with ASCVD and risk factors for ASCVD in the Gulf region. Current guidelines recommend assertive management of cardiovascular risk factors in individuals with T2D, including lifestyle modifications, lowering LDL cholesterol and blood pressure, and using cardioprotective glucose-lowering agents [48,54,55]. However, the uptake of these medications remains low across the region, possibly due to insufficient awareness of their potential cardioprotective benefits [15,56,57]. Early intervention and effective management of cardiovascular modifiable risk factors could effectively impact the microvascular and macrovascular complications of T2D [45,58].

Study strengths and limitations

This study adds to the limited knowledge of microvascular complications in the Gulf Region and provides important insights into the relationship between microvascular complications and ASCVD in individuals with T2D. These findings may contribute to informing strategies for screening, mitigating, and managing microvascular and macrovascular complications in the Gulf Region.

The study's limitations include its cross-sectional and retrospective design, making it infeasible to establish any causal relationship between the occurrence of microvascular complications and risk factors in the study sample. Another limitation is that data on microvascular complications were derived from medical charts without any formal screening or validation measure. While the occurrence of missing data was minimal across most of the demographic and clinical variables, missing laboratory data may potentially limit the precision of associated estimates. Lastly, sampling participants within healthcare settings may have been prone to selection bias and may limit the generalizability of findings to populations with limited access to healthcare services.

Conclusion

The study has revealed that microvascular complications are prevalent among individuals with T2D across the Gulf region. The findings highlight the association between traditional macrovascular risk factors and microvascular complications. Understanding the burden of these complications and their link to ASCVD may encourage more targeted screening and management of microvascular complications and ASCVD in individuals with T2D in the Gulf region.

Authors contributions

All authors participated in the study design and take complete responsibility for the integrity of the information provided. All authors participated in the writing, reviewing, and editing of the manuscript and approved the final version of the manuscript for publication.

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Conflict of interest

TE received honoraria from Novo Nordisk as a speaker. Novo Nordisk provided research support and funding to FA and has funded travel expenses for FA. FA is a Novo Nordisk Speakers Bureau member and serves on an Advisory board for Abbott. GS, AS, and UA are Novo Nordisk employees. No other authors have interests to declare.

Data availability statement

Data are available upon reasonable request.

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