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CLINICAL STUDY DESIGN

WILEY

A cross-sectional study of the prevalence and clinical management of atherosclerotic cardiovascular diseases in patients with type 2 diabetes across the Middle East and Africa (PACT-MEA): Study design and rationale

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Abstract

Aim: To investigate the epidemiology and clinical management of patients with type 2 diabetes (T2D) and established atherosclerotic cardiovascular disease (eASCVD) or high/very high ASCVD risk, defined by the 2021 European Society of Cardiology Guidelines, in seven countries in the Middle East and Africa (PACT-MEA; NCT05317845), and to assess physicians' attitudes and the basis for their decision-making in the management of these patients.

Materials and Methods: PACT-MEA is a cross-sectional, observational study undertaken in Bahrain, Egypt, Jordan, Kuwait, Qatar, South Africa and the United Arab Emirates based on a medical chart review of approximately 3700 patients with T2D in primary and secondary care settings, and a survey of approximately 400 physicians treating patients with T2D.

Results: The primary and secondary objectives are to determine the prevalence of eASCVD and high/very high ASCVD risk in patients with T2D. Current treatment with cardioprotective antidiabetic medication, the proportion of patients meeting the treatment criteria for reimbursement in the study countries where there is an applicable reimbursement guideline, and physician-reported factors in clinical decision-making in T2D management, will also be assessed.

Conclusions: This large cross-sectional study will establish the estimated prevalence and management of eASCVD and high/very high ASCVD risk in patients with type 2 diabetes across the Middle East and Africa.

KEYWORDS

Africa, atherosclerosis, cardiovascular diseases, diabetes complications, epidemiology, Middle East, prevalence, type 2 diabetes

1 | INTRODUCTION

1.1 | Background and rationale

According to the International Diabetes Federation (IDF), in 2021, approximately 10.5% of the world's population had type 2 diabetes (T2D), contributing to more than 6.7 million deaths.[1] The Middle East and North Africa region has the highest regional prevalence of T2D at 16.2%, or 73 million people, and this is projected to increase to 19.3% by 2045, or 136 million people (an 87% increase).[1] A systematic review of the prevalence of T2D in men in the Middle East estimated a pooled prevalence of 19%, with a particularly high prevalence (24%) in the Gulf Cooperation Council (GCC) countries of Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates (UAE) compared with non-GCC (16.0%) countries.[2] Globally, 32%-35% of people with T2D are estimated to have cardiovascular disease (CVD) according to one observational study and a systematic review of the literature[3,4]; however, of the 60 studies included in the review, only five were from the Middle East and Africa.[3] Atherosclerotic cardiovascular disease (ASCVD), defined as coronary artery disease, cerebrovascular disease or peripheral artery disease, is the leading cause of morbidity and mortality for individuals with T2D.[5] A retrospective study of patients with T2D in the United States found that 45% had documented ASCVD, and patients with both conditions had significantly higher healthcare resource utilization and costs than patients with T2D alone.[6]

The optimal treatment of cardiovascular (CV) risk factors in patients with T2D significantly improves ASCVD-related morbidity and mortality.[5,7,8] For CV risk reduction in patients with T2D, global guidelines recommend screening for CVD, lifestyle modification and diabetes education, optimal glycaemic management with antidiabetic medications that have proven CV and kidney benefit (glucagon-like peptide-1 receptor agonists [GLP-1 RAs] and sodium-glucose co-transporter-2 inhibitors [SGLT2is]), lipid management, blood pressure management and antiplatelet management.[5,9] For patients with T2D and established ASCVD (eASCVD)/ASCVD risk, GLP-1 RAs or SGLT2is, both with proven CV benefit, should be considered independent of baseline HbA1c, individualized HbA1c target or metformin use.[10]

A recent observational, multinational, cross-sectional study of CVD prevalence in 9823 adult patients with T2D (CAPTURE) across 13 countries revealed that one in three people (35%) with T2D had CVD and 32% had ASCVD.[11] But few (22%) patients with T2D and ASCVD were taking glucose-lowering medications with proven cardioprotective benefit.[11] The DISCOVER study in 2018 also included 11 countries from the Middle East and Africa (Algeria, Bahrain, Egypt, Jordan, Kuwait, Lebanon, Oman, Saudi Arabia, South Africa, Tunisia and the UAE) with study sites mostly in a primary care setting, with only 3.8% of the centres being cardiology centres. This observational study examined T2D treatment and clinical outcomes among patients initiating second-line treatment for T2D.[12] Only 14% of patients were Middle Eastern (Arabic) and 2% were African (Black).[12] Macrovascular complications were reported in 12.7% of the population. The majority of patients were prescribed metformin and sulphonylurea combinations, largely driven by low cost without regard to CV benefit.[12]

There is a lack of evidence on the prevalence and management of eASCVD and high/very high ASCVD risk in patients with T2D in the Middle East and Africa. This information is critical in identifying deficiencies and supporting optimal management of patients with T2D. By quantifying the proportion of patients with T2D in

these regions who have eASCVD or high/very high ASCVD risk, we will provide a clearer picture of the burden of ASCVD and its risk in patients with T2D. This information will allow us to identify opportunities and barriers to the optimal management of patients with T2D.

1.2 | Objectives

This observational study conducted in 2022 aimed to investigate the epidemiology and clinical management of eASCVD and high/very high ASCVD risk in patients with T2D in primary and secondary care in selected countries (Bahrain, Egypt, Jordan, Kuwait, Qatar, South Africa and the UAE) in a real-world setting. The study focused on generating data from the Gulf region, Middle East and Africa, similar to the IDF classification. The inclusions of a country from northern Africa (Egypt) and one from southern Africa (South Africa) were made to ensure this region was adequately represented.

The primary objective was to estimate the prevalence of eASCVD in patients with T2D across primary and secondary care settings. The secondary objective was to estimate the proportion of patients with T2D at high and very high ASCVD risk according to the European Society of Cardiology (ESC) 2021 guidelines.[13] We also explored the proportion of eligible patients (as per ESC guidelines) receiving cardioprotective glucose-lowering medications (i.e. GLP-1 RAs and SGLT2is) and the number of patients eligible for reimbursement for these medications, according to local treatment criteria for reimbursement per country (where applicable guidelines exist) in the context of widespread availability of these medications in the regions over the last 5 years. Furthermore, we examined the context-specific prescription patterns and physician self-reported drivers in clinical decision-making in the management of patients with T2D and eASCVD or high/very high ASCVD risk. Post hoc analyses will include the proportion of patients achieving guideline-recommended targets with respect to risk factor control, body mass index, exercise and pharmacotherapy.

2 | MATERIALS AND METHODS

2.1 | Study design and ethics

Prevalence and Clinical Management of Atherosclerotic Cardiovascular Diseases in Patients with Type 2 Diabetes Across Countries in the Middle East and Africa (PACT-MEA) (NCT05317845; www.clinicaltrials.gov) is a cross-sectional, observational study comprised of a medical chart review and a physician survey. The chart review estimated the prevalence of eASCVD in patients with T2D and the prevalence of high/very high ASCVD risk in patients with T2D, while the physician survey investigated the clinical decision-making related to the management of these patients.

The study was conducted in accordance with the Declaration of Helsinki[14] and International Society for Pharmacoepidemiology (ISPE) guidelines for Good Clinical and Pharmacoepidemiology Practice (GPP).[15] The study protocol and informed consent form were reviewed and approved by the local Institutional Review Board/Ethics Committee and other regulatory agencies as required for each participating country. IQVIA was the contract research organization (CRO) responsible for data management of the chart review and physician survey. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines.

2.2 | Study setting

This study was conducted in primary and secondary care facilities in Bahrain, Egypt, Jordan, Kuwait, Qatar, South Africa and the UAE (Appendix S1) from a list created by Novo Nordisk, national experts (who were part of the steering committee; Appendix S2) and the CRO. Study investigators were physicians managing T2D in routine clinical practice. They were selected from both primary care (general practitioners, family medicine physicians) and secondary care (endocrinologists, diabetologists, cardiologists, internal medicine) settings. As per local practice in South Africa, diabetologists were classified under primary care. The aim was to capture a sample of patients with T2D that was representative of the target population and the settings where patients receive care. Primary and secondary care sites were selected in a context-dependent manner, considering factors probable to influence the distribution of patients with T2D seen across primary versus secondary care settings such as local scientific or treatment guidelines, reimbursement criteria, referral flows and country-specific regulation governing site involvement in studies of this nature. The ratio of primary care to secondary care facilities varied based on country-specific variables such as local scientific or treatment guidelines, reimbursement criteria and referral flow. Each study site was assessed with a detailed feasibility survey to ensure compliance with all regulatory requirements, and whether they were operationally fit to achieve the recruitment targets by following data collection standards.

2.3 | Study population

2.3.1 | Chart review

Patients were enrolled during a 6-month period in 2022 by their physicians while attending a routine or scheduled visit, after giving informed written consent. Patients were included in the study if they were aged 18 years or older and were diagnosed with T2D 180 or more days prior to study entry. Patients were excluded from the study if they were unwilling to participate, were mentally incapacitated, had language barriers precluding adequate understanding of the study, had type 1 diabetes or had known congenital heart disease. Patients could withdraw consent from the study at any time.

2.3.2 | Physician survey

One investigator (anonymous to the study sponsor) from each participating study site was recruited for the physician survey. Additional healthcare professionals were invited from the CRO's database of

TABLE 1 Information collected from medical records and patients at the chart review visit

Patient and treatment-related assessments
Informed consent
Inclusion/exclusion criteria
Insurance/reimbursement (Y/N)
Medical history
History of established ASCVD
History of diabetes and diabetes complications (nephropathy, retinopathy, neuropathy)
Smoking (including e-cigarettes and water pipe)
Hypertension
Dyslipidaemia
Obesity[a]
Left ventricular hypertrophy (Y/N) (either documented in electrocardiography or echocardiography within the last 3 mo)
Family history of CVD (a positive family history involving first-degree relatives)
Other medical history (as judged relevant by physician)
Demographics
Age
Sex
Ethnicity
Clinical data (most recent data available during last 3 mo including the patient visit)
Physical activity (obtained from patient; number of days in the last week with at least 30 min of moderate activity [0-7 d])
Body weight
Height
Blood pressure (systolic/diastolic)
Laboratory data (most recent data available during last 3 mo including the patient visit)
HbA1c
FPG
Lipids
eGFR or creatinine[b]
Urine ACR[c]
Pharmacotherapy data (current medication or any medication discontinued within the last 3 mo; trade name or generic name, total daily/weekly dose, number of daily/weekly injections [if applicable], starting dose if switched from another medication, start date, stop date)
Diabetes medication
CVD medication

Abbreviations: ACR, albumin-to-creatinine ratio; ASCVD, atherosclerotic cardiovascular disease; BMI, body mass index; CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; CVD, cardiovascular disease; eGFR, estimated glomerular filtration rate; FPG, fasting plasma glucose.

[a]BMI was calculated from height and weight data [kg/m^2] = [body weight (kg)]/[height (m) × height (m)]. Obesity is defined as a BMI of 30 or greater with or without co-morbidities.

[b]If the patient has only creatinine data in their medical records, eGFR was calculated by the CKD-EPI creatinine equation, which is recommended by the 2021 KDIGO Clinical Practice Guidelines for Management of Chronic Kidney Disease.[35]

[c]ACR = moderately increased (ACR: 30-300 mg/g) or seriously increased (ACR > 300 mg/g).

individuals who previously opted in to participate in research studies. Physicians were included after providing informed consent, if they managed patients with T2D in one of the seven participating countries, had been in clinical practice for 2 or more years, and spent at least 50% of their time managing patients in clinical settings. Physicians could withdraw from the survey at any time.

2.4 | Data collection

2.4.1 | Chart review

A medical history, demographic information, clinical data, laboratory data and pharmacotherapy data were collected from the patients' health records by the physician or a trained delegate (Table 1; Appendix S3). If information regarding insurance/reimbursement, medical history of diabetes and diabetes complications, medical history of ASCVD risk factors (smoking, hypertension, dyslipidaemia, obesity), family history of CVD, demographics and physical activity data were not available in the health record, then the physician asked the patient for the relevant information; this was classified as 'referred by the patient'. Any assessment at the enrolment visit was recorded as part of the study. Each laboratory's reference ranges were used for evaluation of the results. Any of the data (medical history, demographics, clinical, laboratory and pharmacotherapy) that are not recorded in the medical chart of a patient within 3 months of the enrolment date will be marked as 'missing' in the forthcoming results.

2.4.2 | Physician survey

After providing informed consent electronically, physicians were asked to complete a single 20-minute online survey on attitudes and behaviours related to management of patients with T2D and eASCVD or those at high/very high ASCVD risk. The survey questionnaire consisted of topics related to medication and patient factors, T2D management decisions and clinical factors (Appendix S4). Incomplete surveys will not be included in the final analysis.

2.5 | Outcomes

2.5.1 | Chart review

The primary outcome of the chart review was the prevalence of eASCVD (coronary artery disease, cerebrovascular disease or peripheral artery disease) in patients with T2D in the study population (across all

countries and within each country). ASCVD was defined according to international guidelines. A patient was counted as having eASCVD if any one of the following variables was recorded in the patient's medical chart (and if present, the 'onset ASCVD date' was also recorded): (a) coronary artery disease[13,16-18]: previous acute coronary syndrome, previous myocardial infarction, previous unstable angina, history of stable angina, past coronary revascularization (percutaneous coronary intervention, coronary artery bypass graft), unequivocally documented ASCVD on imaging (including plaque on coronary angiography or computed tomography angiography); (b) cerebrovascular disease[13,16-18]: history of stroke to be atherosclerotic in origin or history of transient ischaemic attack to be atherosclerotic in origin; and (c) peripheral arterial disease[13,16-20]: (i) extracranial carotid artery disease consisting of unequivocally documented ASCVD on imaging (including plaque on carotid ultrasound or computed tomography angiography) or past arterial revascularization procedure; (ii) lower extremity arterial disease consisting of history of claudication with an Ankle-Brachial Index of 0.90 or less, lesions documented on imaging, past arterial revascularization, or history of non-traumatic minor and major amputation; and (iii) other peripheral arterial diseases of atherosclerotic origin consisting of aortic aneurysm, vertebral artery disease, atherosclerotic upper extremity artery disease, renal artery disease or mesenteric artery disease.

The secondary outcome was the proportion of patients with T2D who were at high/very high ASCVD risk defined according to the ESC 2021 Guidelines on Cardiovascular Disease Prevention in Clinical Practice.[13] Patients will be classified according to the ESC risk categories of moderate, high and very high. Moderate risk is defined as well-controlled short-standing diabetes (e.g. < 10 years), no evidence of target organ damage (TOD) and no additional ASCVD risk factors. High risk is defined as no ASCVD and/or severe TOD, and not fulfilling the moderate risk criteria. The very high-risk category includes patients with T2D with established ASCVD and/or severe TOD.

Two exploratory outcomes were measured by the chart review: (a) the proportion of patients with T2D and eASCVD or high/very high ASCVD risk who were receiving GLP-1 RAs and/or SGLT2is; and (b) the proportion of patients who met the treatment criteria for reimbursement based on local reimbursement guidelines where there was an applicable reimbursement guideline.

2.5.2 | Physician survey

The physician survey evaluated one exploratory outcome: self-reported drivers in clinical decision-making (i.e. treatment, patient, practice and physician factors; engagement in shared decision-making) for the management of T2D based on a series of statements using a five-point Likert scale.

2.6 | Sample size

2.6.1 | Chart review

The targeted chart review sample size for each country is shown in Table 2. The sample sizes included an ~ 10% buffer for missing data.

TABLE 2 Chart review and physician survey sample size targets for each country in the PACT-MEA study

	Chart review			Physician survey
Country	Assumed ASCVD prevalence in patients with T2D (%)	Precision (%)	Targeted sample size (n)	Targeted sample size (n)
Bahrain	30	5	350	30
Egypt	30	4	550	82
Jordan	30	4	550	48
Kuwait	30	5	350	30
Qatar	30	5	350	30
South Africa	30	3	1000	82
United Arab Emirates	30	4	550	48
Total			3700	350

Abbreviations: ASCVD, atherosclerotic cardiovascular disease; T2D, type 2 diabetes.

The total sample size considered was 3700 patients to ensure a precision of ± 3%-5% points. The precision levels for each country reflect a balance between achieving the ideal precision for a cross-sectional study, that is, 2%-3% (same as the precision of the CAPTURE study[11]), and the feasibility of doing so. Thus, for countries where it was feasible to achieve a sample size large enough to allow 3% precision, we targeted a minimum sample size that would achieve this level of precision (i.e. n = 1000). For the other countries, we set a target of the largest feasible sample size, with slightly lower precision.

2.6.2 | Physician survey

The physician survey sample size for each country is shown in Table 2. Given the exploratory nature of the survey, the sample size was based on the margin of error and confidence interval. It was determined that a sample size of 350 physicians was sufficient to address the survey objective based on 5% margin of error and 95% confidence interval. The overall sample size was then distributed across each participating country according to their physician population.

2.7 | Data collection methods and data management

Throughout the study, the CRO conducted at least one remote monitoring visit per study site during the data collection period to ensure that the study was conducted in accordance with the protocol, standard operating procedures, ISPE GPP and applicable regulatory requirements. Specifically, the CRO reviewed the informed consent forms and subject eligibility for all enrolled patients and reviewed/verified the source documentation for 10% of the study sample.

2.7.1 | Chart review

The CRO managed an electronic case record form (eCRF) platform for collection of patient data from the participating study sites. Data were entered into the platform by the study investigators or their delegates trained in eCRF data entry. Encryption was used to protect the identity of patients when transmitting data. The CRO managed the electronic data capture system and maintained an audit trail identifying the personnel entering data into the system and the date and time of data entry. All data were reviewed prior to statistical analysis. Any data excluded at this stage were documented with justifications noted. After conducting quality control checks, the data were locked prior to statistical analysis.

2.7.2 | Physician survey

The CRO contacted physicians by email and informed them about the nature of the survey, including a confidentiality statement. The survey did not collect any personal information from physicians. Physicians were provided with a link to the online survey, which also included the consent form. Participants were able to complete the survey on a personal computer. The survey was conducted using Decipher, a secure survey platform hosted by the CRO that uses a rigorous quality assurance process including manual survey testing, random data generation, data check edits and in-field data checks consisting of reviewing the data for respondent eligibility, survey completion and length of survey. The data were managed in compliance with General Data Protection Regulation; any laws and regulations regarding management of personal data required by participants' country of residence were followed.

2.8 | Statistical analysis

For the chart review, descriptive statistics (mean, standard deviation [SD], median and interquartile range [IQR] for continuous variables and proportion for categorical variables) will be used to describe the study population's demographic, clinical, laboratory and pharmacotherapy characteristics. The overall eASCVD prevalence and ESC risk category estimates will be calculated as weighted estimates to account for the size of the diabetes population in each country. Estimated prevalence rates will be presented with 95% confidence intervals. In addition to overall eASCVD prevalence data, eASCVD prevalence will be stratified by each specific eASCVD condition (coronary artery disease, cerebrovascular disease and peripheral artery disease). Data will also be stratified by country. Missing pharmacotherapy and laboratory data will not be imputed but will be reported with descriptive statistics. Data from the physician survey will be analysed using descriptive statistics (frequency, percentages, means [SD], median [IQR]).

2.9 | Role of the steering committee and sponsor

The PACT-MEA study was overseen by a steering committee, which consisted of the national principal investigators who contributed to the design and conduct of the study alongside the study sponsor (Novo Nordisk) (Appendix S2). The sponsor was responsible for collection and analysis of data, in conjunction with the steering committee. All authors have access to the study results.

3 | DISCUSSION

While there are studies that have established the prevalence of T2D in the Middle East and Africa,[21-26] there is limited information on the prevalence of eASCVD or on high/very high ASCVD risk in patients with T2D in this region.[3,27-31] The CAPTURE study estimated the prevalence of ASCVD among patients with T2D across 13 countries from five continents and showed that one in three adults with T2D have established CVD, of which 9/10 had ASCVD. However, CAPTURE only included Israel, Turkey and Saudi Arabia from the Middle East, with no countries from Africa.[11] The DISCOVER study provided a robust examination of the characteristics and treatment of patients with T2D initiating a second-line glucose-lowering therapy in the Middle East and in two African countries, but was not designed to assess the prevalence of CVD outcomes.[12] The PACT-MEA study has a comparable design to CAPTURE[11] as it aims to identify the prevalence of eASCVD in patients with T2D; additionally, it establishes the prevalence of patients with ASCVD risk according to the ESC 2021 guidelines.[13] However, the key differences between PACT-MEA and CAPTURE are the primary and secondary endpoints: the primary endpoint in CAPTURE was established CVD among patients with T2D and in PACT-MEA, the primary endpoint is eASCVD in patients with T2D. The secondary endpoint in CAPTURE was the proportion of patients with high CVD risk according to the UK Prospective Diabetes Study (UKPDS) risk calculator; the secondary endpoint for PACT-MEA is the percentage of patients at high/very high ASCVD risk, as reflected in current guideline recommendations. The broad study inclusion/exclusion criteria ensure generalizability of the study results to the T2D patient population being managed across the participating countries.

3.1 | Study strengths

A key strength of the PACT-MEA study is that it assesses the proportion of patients receiving GLP-1 RAs and/or SGLT2is as per the current American Diabetes Association[32] and European Association for the Study of Diabetes guidelines recommending GLP-1 RAs and SGLT2is to individuals with T2D and ASCVD as well as patients with T2D and ASCVD risk (or indicators of risk),[33] and the American College of Cardiology.[17]

Additionally, the PACT-MEA study explores the current clinical management paradigms in the Middle East and Africa from the perspective of physicians who encounter T2D complications at different stages of the disease in the participating countries. Understanding the current basis of decisions on the clinical management of patients with T2D and ASCVD or those with high/very high ASCVD risk will allow the identification of key action areas to meet public health needs in the participating countries.

3.2 | Study limitations

Although we aimed to capture a sample of patients with T2D as representative as possible of the target population, the prevalence estimates may not be representative of an entire country because of the small sample size and selection methods. Selection of study participants could be prone to convenience sampling, but this was minimized by (a) enrolling patients over the course of a 6-month period, (b) broad eligibility and (c) selecting study sites that reflect the larger population of patients with T2D seen in primary and secondary settings across the regions. Differences in healthcare delivery systems in the countries participating in the PACT-MEA study limit the validity of direct comparisons between countries. However, if the prevalence is similar across settings and countries, then an overall estimate is appropriate. The mean ASCVD prevalence from the seven countries will be weighted by each country's population size together with prevalence rate. Furthermore, the sample size for Egypt was limited because of logistical issues; however, the sample size of 550 is considered to be the minimum required to ensure generalizability without substantially affecting the precision (± 3.1% for n = 1000 vs. 4.2% for n = 550). The ASCVD prevalence will be estimated among patients attending clinics and may therefore over-represent patients with more co-morbidities because these patients tend to utilize healthcare at a higher rate than patients with fewer co-morbidities. In addition, there may be substantial variation in the availability of tests and procedures for assessing ASCVD in healthcare facilities and countries.

As this is an observational, cross-sectional study, potential unforeseen confounding variables cannot be ruled out. Data collection reflects real-world routine clinical practice rather than mandatory assessments, which may have an impact on the amount of data and its interpretation. The generalizability of results from the physician survey may be limited by the sample selection method of convenience sampling. The physicians who participated in the survey may differ from other physicians in the countries where the PACT-MEA study was conducted. The physician survey relies on self-reported data that can be subject to recall bias.[34]

4 | CONCLUSIONS

The outcomes of the PACT-MEA study will provide the contemporary prevalence of eASCVD and high/very high ASCVD risk in patients with T2D and current clinical management of these conditions in countries from the Middle East and Africa. We believe this will raise awareness of the impact of T2D and ASCVD and inform future disease management strategy in participating countries, and thereby influence policy and practice to improve outcomes.

AUTHOR 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

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EMC is an employee of, and owns stock in, Novo Nordisk. PP is an employee of, and owns stock in, Novo Nordisk. GT is an employee of Novo Nordisk.

PEER REVIEW

The peer review history for this article is available at https://publons.com/publon/10.1111/dom.15011.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article. Once the study results are published, the data that support the findings of this study will be available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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