CAPTURE: A cross-sectional study on the prevalence of cardiovascular disease in adults with type 2 diabetes in Italy

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Abstract  Background and aims: The prevalence of type 2 diabetes (T2D) in Italy is increasing and cardiovascular disease (CVD) represents the leading cause of death in this population. CAPTURE was a multinational, multicentre, non-interventional, cross-sectional study assessing the prevalence of CVD, atherosclerotic CVD (AsCVD) and CVD subtypes among patients with T2D, across 13 countries. Here we report the results from Italy.

Methods and results: Overall, 816 patients with T2D (median age, 69 years [interquartile range: 62–75]; median duration of diabetes, 11.2 years [interquartile range: 5.7–18.7]) were recruited during routine clinical visits at secondary care centres in Italy between December 2018–September 2019. The prevalence of CVD was estimated at 38.8%, largely accounted for by AsCVD (33.1%). The most prevalent CVD subtype was coronary heart disease (20.8%), followed by carotid artery disease (13.2%). Most patients (85.9%) were prescribed oral glucose-lowering agents (GLAs), particularly biguanide (76.7%). Insulin use was higher in patients with CVD (41.3%) than in patients without CVD (32.9%). Sodium-glucose co-transporter-2 inhibitors (SGLT2is) and glucagon-like peptide-1 receptor agonists (GLP-1 RAs) were prescribed to 20.2% vs 14.6%, and 14.5% vs 16.6% of patients with CVD compared to those without CVD, respectively.

Conclusion: The results show that, in Italy, more than one in three patients with T2D attending secondary care centres have CVD, 85% of whom have AsCVD, yet only a minority are treated with SGLT2is and GLP-1 RAs, in discordance with the recommendations of current national and international guidelines.

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Abbreviations: AGi, alpha-glucosidase inhibitor; AsCVD, atherosclerotic cardiovascular disease; BMI, body mass index; CHD, coronary heart disease; CV, cardiovascular; CVD, cardiovascular disease; DPP-4i, dipeptidyl peptidase-4 inhibitor; eGFR, glomerular filtration rate; GLAs, glucose-lowering agents; GLP-1 RA, glucagon-like peptide-1 receptor agonist; IDF, International Diabetes Federation; IQR, interquartile range; SGLT2i, sodium-glucose co-transporter-2 inhibitor; TZD, thiazolidinedione; T2D, type 2 diabetes.

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1. Introduction

Type 2 diabetes (T2D) is a complex cardiometabolic disorder with an enormous clinical, social and economic impact [1,2]. The International Diabetes Federation (IDF) estimates that approximately 463 million people worldwide had T2D in 2019, a figure predicted to increase to over 600 million by 2040 [1]. In Italy, T2D affects almost three million people [1], with an increasing prevalence over time in line with an ageing population, increasing obesity and low socioeconomic status [3]. According to country-specific geographical data, T2D is more prevalent in Southern Italy (6.6%) compared to Northern and Central regions (4.6%) [4].

T2D is associated with an increased risk of micro- and macrovascular complications, which are major causes of disability, reduced quality of life and morbidity in these individuals, as well as contributing to a large burden on healthcare resources [3]. Cardiovascular disease (CVD) is the leading cause of death in people with T2D in Italy, responsible for 42% of mortality according to the Verona Diabetes study population [5]. Joint national (Italian Association of Medical Diabetologists [AMD] [6] and the Italian Society of Diabetology [SID] [2]) and international guidelines have been updated to recommend the use of diabetes medications with proven cardiovascular (CV) benefit, such as sodium-glucose co-transporter-2 inhibitors (SGLT2is) and glucagon-like peptide-1 receptor agonists (GLP-1 RAs), in order to reduce the burden of CVD in patients with T2D [2,7–10].

However, these recommendations have not yet resulted in significant changes to clinical practice, with the latest data from the AMD Annals Initiative (a periodic collection of clinical data extracted from electronic medical records in a specialised care setting) showing that only 9.5% of patients in Italy are treated with an SGLT2i and 5.8% with a GLP-1 RA [6]. Similar figures have been reported by a recent retrospective analysis of the Italian ARNO Diabetes Observatory database, showing that just 5% of patients with diabetes that were prescribed medications were administered either an SGLT2i or a GLP-1 RA, despite a CVD prevalence of 45% in this population [11].

Several epidemiological studies have assessed the prevalence of CVD in patients with T2D in Italy [6,12–14]. However, the data currently available come from studies that vary in design, assessment methods, data sources and timing of collection, highlighting the need for prevalence information that can be compared with those from other countries. Such data are critical in directing the treatment of T2D in Italy and to design preventative strategies to manage the increasing burden of diabetes and associated comorbidities.

CAPTURE was a multinational, multicentre, non-interventional, cross-sectional study assessing the prevalence of established CVD, atherosclerotic CVD (ASCVD) and CVD types among patients with T2D, conducted in 13 selected countries, including Italy [15]. The study showed that the overall prevalence of CVD among 9823 participants with T2D was 34.8%, of which 85.8% were cases of AscVD. In spite of this high prevalence of CVD, fewer than one in four adults with T2D were treated with glucose-lowering agents (GLAs) with proven CV benefit (such as a GLP-1 RA or SGLT2i) in the global population of the CAPTURE study [15].

Here, we report results from the Italian cohort of the CAPTURE study.

2. Methods

Methods of the CAPTURE (NCT03786406, NCT03811288) study have been presented elsewhere [15]. Briefly, CAPTURE gathered data from centres across 13 countries, including 17 sites in Italy; sites were selected to be as representative of the country as possible. The study protocol was first approved by the coordinating centre ethics committee (Istituto Clinico Humanitas, Milan, Italy) and then by the other ethics committees at each site. The study was conducted in accordance with the Declaration of Helsinki, International Society for Pharmacoepidemiology Good Pharmacoepidemiology Practices [16] and local regulations for clinical research [17,18]. All participants provided written informed consent prior to participation in study-related activities.

2.1. Study population

In Italy, diabetes care and treatment are provided by a large network of specialists operating within the National Healthcare System in parallel with general practitioners. Up to 2 million patients with diabetes attend such clinics [19], which accounts for a significant proportion of the T2D population. As such, only secondary care sites were selected to participate in the CAPTURE study.

A target sample size of 800 was calculated to provide a precision of ±2–3% points for the estimated prevalence of CVD in Italy, suggesting that data for this sample could be considered representative of the T2D population treated at secondary care centres in Italy.

Over a 90-day time period, adults aged ≥18 years who were diagnosed with T2D at least 180 days prior to providing informed consent were invited to participate by their specialist. Exclusion criteria included a diagnosis of type 1 diabetes and known congenital heart disease or malformation [15].

2.2. Data collection

Data were collected from participants' medical records during a routine visit to the treating specialist. Participants were asked whether any information was missing from the medical record, and missing information was added with the code 'participant referred'.

Full details of the definitions used for variables in this study have been presented in the supplementary materials (Supplemental Table S1). Briefly, established CVD (including ASCVD, cerebrovascular disease, coronary heart disease [CHD], peripheral artery disease, or carotid artery disease), heart failure, cardiac arrhythmia, or aortic disease...
have been analysed. Patients were stratified by the presence (CVD group) or absence (No CVD group) of established CVD.

Demographic and clinical parameters, including presence of comorbidities (including retinopathy and neuropathy), were collected, along with recent GLAs and CV medications.

2.3. Objectives/endpoints of the study

The primary objective of this analysis of the CAPTURE study was to estimate the prevalence of CVD in patients with T2D in Italy. The secondary objective of this analysis was to characterise the use of glucose-lowering medication and CVD medication in this population.

2.4. Statistical analysis

The prevalence (95% confidence interval [CI]) of CVD, ASCVD and specific CVD subtypes was estimated for Italy. Differences between groups, including the Italian sample versus the global sample, and the CVD group versus the No CVD group, were presented descriptively.

Statistical analyses were carried out using SAS, Version 9.4 (SAS Institute, Cary, North Carolina, USA).

3. Results

3.1. Study population

Overall, 9823 adults with T2D across 13 countries participated in the CAPTURE study, of which 816 were recruited from 17 secondary care centres in Italy between 03 December 2018 and 30 September 2019. Table 1 presents the characteristics and demographics of the Italian cohort. In the Italian cohort, the median (interquartile range, IQR) age was 69 (62–75) years, 38.2% of patients were female, the median (IQR) diabetes duration was 11.2 (5.7–18.7) years and the cohort as a whole demonstrated adequate glucose control (median HbA1c: 7%). The majority (76.7%) of patients had a medical history of hypertension; 77.5% were overweight (body mass index [BMI] ≥ 25).

| Characteristic                          | Study population | By CVD status |               |
|----------------------------------------|------------------|---------------|---------------|
|                                        | N = 816          | CVD n = 317   | No CVD n = 499|
|                                        | n    | Data | n    | Data | n    | Data |
| Female                                 | 816  | 312  (38.2) | 317 | 96  (30.3) | 499 | 216 (43.3) |
| Age, years                             | 816  | 69 [62–75]  | 317 | 71 [65–76] | 499 | 67 [60–74] |
| Race                                   | 816  | 317  | 499  | 499 |
| White                                  | 803  (98.4) | 316 | 99.7 | 487 (97.6) |
| Other                                  | 13 (1.6) | 1 (0.3) | 12 (2.4) |
| Diabetes duration, years               | 816  | 11.2 [5.7–18.7] | 317 | 12.3 [5.9–19.4] | 499 | 10.7 [5.7–17.9] |
| HbA1c, %                               | 799  | 7.0 [6.5–7.9] | 307 | 7.1 [6.5–7.7] | 492 | 7.0 [6.5–7.9] |
| HbA1c, mmol/mol                        | 799  | 53.0 [47.5–62.8] | 307 | 54.1 [47.0–61.0] | 492 | 53.0 [47.5–63.0] |
| FPG, mmol/L                            | 745  | 7.6 [6.4–8.8] | 283 | 7.6 [6.4–8.6] | 462 | 7.4 [6.5–8.9] |
| Body weight, kg                        | 816  | 78.3 [44.0–165.0] | 317 | 79.2 [50.2–143.0] | 499 | 78.0 [44.0–165.0] |
| BMI, kg/m²                             | 816  | 28.4 [25.3–32.5] | 317 | 28.5 [25.6–32.2] | 499 | 28.3 [25.1–32.5] |
| Systolic blood pressure, mmHg          | 816  | 130 [120–140] | 317 | 130 [120–140] | 499 | 130 [120–140] |
| Diastolic blood pressure, mmHg         | 816  | 80 [70–80] | 317 | 75 [70–80] | 499 | 80 [70–80] |
| Total cholesterol, mmol/L              | 739  | 4.1 [3.6–4.8] | 283 | 3.9 [3.4–4.5] | 456 | 4.3 [3.8–4.9] |
| LDL cholesterol, mmol/L               | 681  | 2.2 [1.7–2.7] | 261 | 2.0 [1.5–2.5] | 420 | 2.4 [1.9–2.9] |
| HDL cholesterol, mmol/L               | 721  | 1.2 [1.0–1.5] | 277 | 1.2 [1.0–1.4] | 444 | 1.2 [1.0–1.5] |
| Non-HDL cholesterol, mmol/L           | 267  | 2.7 [2.2–3.3] | 108 | 2.5 [2.0–3.1] | 159 | 2.9 [2.4–3.5] |
| Triglyceride, mmol/L                   | 735  | 1.4 [1.0–1.9] | 279 | 1.4 [1.0–1.9] | 456 | 1.3 [1.0–1.9] |
| eGFR, ml/min/1.73 m²                   | 687  | 257 | 430 |
| >89 (normal)                           | 251  | 36.5 | 79 | 30.7 | 172 | 40.0 |
| >59–89                                 | 286 | 41.6 | 103 | 40.1 | 183 | 42.6 |
| ≤59                                    | 150 | 21.8 | 75 | 29.2 | 75 | 17.4 |
| Albuminuria                            | 652  | 245 | 407 |
| Normal–mildly increased                | 481 | 73.8 | 165 | 67.3 | 316 | 77.6 |
| Micro- and macroalbuminuria            | 171 | 26.2 | 80 | 32.6 | 91 | 22.4 |
| Retinopathy                            | 816  | 317 | 499 |
| Yes                                    | 98 | 12.0 | 43 | 13.6 | 55 | 11.0 |
| Nephropathy                            | 816  | 317 | 499 |
| Yes                                    | 132 | 16.2 | 72 | 22.7 | 60 | 12.0 |
| Neuropathy                             | 816  | 317 | 499 |
| Yes                                    | 90 | 11.0 | 47 | 14.8 | 43 | 8.6 |

Data are n (%), median [interquartile range], or mean ± standard deviation. Differences between CVD and No CVD groups were not compared statistically.

BMI, body mass index; CVD, cardiovascular disease; eGFR, estimated glomerular filtration rate; FPG, fasting plasma glucose; HbA1c, glycated haemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

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3.2. CVD prevalence

In the CAPTURE Italy population, the estimated overall prevalence of CVD was 38.8%, largely accounted for by the prevalence of AsCVD (33.1%; Fig. 1).

The majority of patients with CVD in the Italian cohort had been diagnosed with CHD (20.8%), followed by carotid artery disease (13.2%), cardiac arrhythmia and conduction abnormalities (7.0%) and cerebrovascular disease (5.4%; Fig. 1; Supplemental Table S2). Heart failure was present in 4.2% of patients and was mostly symptomatic (3.4%) (Fig. 1; Supplemental Table S2).

Past revascularisation procedures (12.3%) and myocardial infarction (11.4%) were the most prevalent types of CHD in the Italian cohort, with ischaemic stroke (3.1%) and transient ischaemic attack (2.1%) being the most prevalent forms of cerebrovascular disease, and claudication (1.7%) and asymptomatic peripheral artery disease (1.6%) equally responsible for cases of peripheral artery disease (Supplemental Table S2).

3.3. Characteristics of the study population stratified by CVD status

In this descriptive study, when demographics and clinical characteristics of the Italian cohort were stratified by CVD status, participants with CVD were more likely to be male (69.7% vs 56.7%, respectively), older (median age 71 [IQR: 65–76] vs 67 [IQR: 60–74] years, respectively), and have worse renal function (69.3% vs 60.0% with an eGFR <89 mL/min/1.73 m², respectively; Table 1) than those without CVD. The prevalence of microvascular complications was also higher in the CVD group versus the No CVD group (nephropathy: 22.7% vs 12.0%; neuropathy: 14.8% vs 8.6%). Microalbuminuria, macroalbuminuria and a medical history of hypertension also appeared to be more common in the CVD group compared to the No CVD group (25.3% vs 19.2%, 7.3% vs 3.2% and 86.5% vs 70.6%, respectively).

3.4. GLA use in the study population

Use of GLAs in the CAPTURE Italy population is shown in Table 2. Overall, most patients (85.9%) were prescribed oral GLAs; the majority received biguanide (metformin; 76.7%), followed by dipeptidyl peptidase-4 inhibitor (DPP-4i; 19.6%). Thiazolidinediones (TZDs), alpha-glucosidase inhibitors (AGIs) and glinides were the least prescribed GLAs (2.6%, 2.5% and 2.2%, respectively). Notably, biguanides, DPP-4is, sulphonylureas, glinides, TZDs and AGIs were all more commonly used in the No CVD group than the CVD group. Insulin use was high overall, especially in the CVD group (41.3% in CVD vs 32.9% in No CVD).

In terms of drugs with proven CV benefit, SGLT2is and GLP-1 RAs were prescribed in 16.8% and 15.8% of the population.
CAPTURE Italy population, respectively. SGLT2i treatment was more common (20.2% vs 14.6%, respectively) and GLP-1 RA treatment was slightly less common (14.5% vs 16.6%, respectively) in the CVD group compared with No CVD group. Use of SGLT2is and GLP-1 RAs was similar in the AsCVD group compared with the overall CVD group.

### 3.5. Standard CV medication use in the study population

The use of standard CVD medications in participants with T2D, including antiplatelet, hypolipemic and anti-hypertensive drugs, was also analysed in the CAPTURE Italian cohort (Table 3; Supplemental Table S3). Overall, 65.9% of patients were treated with lipid-lowering medication (mainly statins), 73.0% with anti-hypertensive medication (mainly angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers), 44.0% with antiplatelet drugs, 28.7% with diuretics and a minority (5.5%) received anti-thrombotic drugs. All classes of CVD medication were more commonly used in the CVD group compared with the No CVD group.

### 4. Discussion

In the Italian cohort of the CAPTURE study, the overall prevalence of CVD in adults with T2D attending secondary care outpatient clinics was estimated at 38.8%, of which 85% had AsCVD. CHD and carotid artery disease were major contributing factors. Compared with the weighted prevalence estimates for the global CAPTURE population, the Italian cohort was slightly more likely to have a diagnosis of CVD or AsCVD in general (4% and 1.3% more likely, respectively) [15]. Moreover, when limiting the comparison to the secondary care subpopulation only, the prevalence of CVD and AsCVD in Italy was still slightly higher compared with the global population (4.2% and 1.0% more likely, respectively) [unpublished data].

A greater proportion of patients in the Italian cohort had been diagnosed with CHD, carotid artery disease, cardiac arrhythmia and conduction abnormalities, peripheral artery disease, heart failure and aortic disease compared with the global CAPTURE population; however, a smaller proportion of patients in the Italian cohort had been diagnosed with cerebrovascular disease compared with the global cohort [15]. In particular, the Italian population included over twice as many patients with atrial fibrillation, myocardial infarction or previous revascularisation procedure, and nearly twice as many patients with symptomatic heart failure, compared with the global CAPTURE population [15]. Differences in the demographics of the Italian cohort, such as a lower proportion of women, higher median age and higher proportion of patients with hypertension compared to the global CAPTURE population, may partially explain the higher prevalence of CVD and of specific CVD subtypes in Italy [15]. Another factor that may explain the higher prevalence of CVD subtypes in Italy compared with the global population is the peculiar structure of the Italian healthcare system, in which a large proportion of patients with T2D are treated across a network of secondary and tertiary diabetes care centres [19]. This model of diabetes care is associated with a reduction in all-cause mortality versus primary care [19] and may have led to earlier and more frequent diagnosis of CVD. In addition, the AMD Annals Initiative (implemented by the network since 2006) aimed to improve clinical outcomes in T2D by monitoring patient disease indicators [20,21] and may have also played a part in the higher frequency of CVD diagnosis in Italy.

Contemporary data on the prevalence of CVD and its subtypes observed in the CAPTURE Italy study should also be evaluated in the context of other epidemiological studies that have assessed the prevalence of CVD in patients with T2D recruited from secondary care settings in Italy [8,16–18]. The Diabetes and Informatics study reported a CHD prevalence of 9.9% in people with T2D between 1998 and 1999 [12], whereas the prevalence of CHD in the CAPTURE Italy population was 20.8%. In the more recent Renal Insufficiency And Cardiovascular Events (RIACE) study, 23.2% of people with T2D recruited during 2007–2008 reported major acute CVD events [14]. Patients in the RIACE study with worse renal function and longer diabetes duration were at higher risk of CVD [13,14].

Data for the Italian CAPTURE study were gathered mainly in 2019, in patients with a median diabetes duration of 11 years, and showed a high prevalence of CVD (38.8%) in patients with a median diabetes duration of 20 years [14]. A 2018 analysis of clinical record data from the AMD Annals reported that, of all CVD complications in people with T2D in Italy, myocardial infarction had the highest prevalence, followed by coronary revascularisation, carotid revascularisation, stroke and peripheral revascularisation,
with an overall CVD prevalence of 34.1% in people with a duration of diabetes >20 years [6]. It is possible that the differences in the prevalence of CVD/CHD across these studies are due to a different case mix, determined by the different data collection modalities at different participating sites. However, it is also possible that the CVD prevalence in patients with T2D may have actually increased in Italy over the last decade, potentially due to the increased prevalence of obesity and an ageing population.

In spite of the overall high prevalence of CVD in Italy, local CAPTURE data showed that GLP-1 RAs were used to treat 15.8% of patients with T2D, compared with just 10.1% of the global CAPTURE population, while SGLT2is were used in 16.8%, aligned with the global cohort. The use of GLP-1 RAs was very similar in the CVD and AsCVD subgroups in Italy, compared with the global CAPTURE population (14.5% and 13.7% vs 9.5% and 9.1%, respectively) [15] [unpublished data]. The use of other CV medications such as statins, acetylsalicylic acid, or anti-hypertensive agents was higher amongst the Italian population, especially those with documented CVD, compared with the other countries included in the CAPTURE study [15].

Although the overall use of CV medications and GLAs with proven CV benefit was higher in CAPTURE Italy compared with national data (AMD Annals Initiative [6], ARNO observatory) and other countries included in the CAPTURE study, the data show that their use is still too low to be aligned with current national and international recommendations, especially in light of the high CVD burden in Italy. It may also be that the use of SGLT2is and GLP-1 RAs could be attributed to the sub-optimal persistence of these drugs [22], which was not specifically investigated in the CAPTURE study. In association with this, it is important to underline the high overall use of insulin therapy, especially in participants with established CVD; it is necessary to proceed with further studies to better understand whether this high use of insulin is the result of careful clinical evaluations or rather the consequence of clinical inertia. Differences between the CVD prevalence and use of medications in the Italian and global CAPTURE populations might also reflect variation in the sites selected, healthcare systems (primary or secondary care), genetic or lifestyle factors and CVD screening practices, all of which were not specifically accounted for in the present study.

This analysis has limitations; there was potential for ascertainment bias in the results, as patients with T2D and complications suggestive of CVD may be more likely than the general T2D population to consult their healthcare provider. Another limitation of the study is that differences between groups were not compared statistically due to the descriptive nature of the CAPTURE study. This study relied on the accuracy and completeness of patient medical records, and the protocol did not require additional tests to ascertain diagnoses where medical records were incomplete, thereby limiting the data available for analysis. In this regard, the lack of echocardiographic data collection as well as data on the occurrence of heart failure with reduced ejection fraction or heart failure with preserved ejection fraction, have prevented us from reporting more detailed information on heart failure. Also, since patients with T2D from the Italian cohort were all attending secondary care outpatient clinics, the applicability of our results might not extend to all patients with T2D. Finally, the proportion of ‘other’ races reported was 1.6%, which is not reflective of the wider population demographics found in Italy, implying that the applicability of the results might be limited to the White ethnic group.

In conclusion, the CAPTURE data show that, in Italy, more than one in three participants with T2D who attended secondary care diabetes centres have documented CVD, mostly accounted for by AsCVD; however, only a minority of them are currently treated with GLAs with proven CV benefit. The high burden of CVD in the CAPTURE Italy study and the increasing use of medications with proven CV benefit, in comparison with other countries in the CAPTURE study worldwide, may provide valuable data to help healthcare organisations and policymakers in Italy evaluate strategies to further implement diabetes care with the objective of reducing CVD risk.

Role of the funding source

Novo Nordisk A/S participated in the study design, site selection (in collaboration with the contract research organisation Parexel Ltd.), study coordination, data management, data analysis and study report preparation for the CAPTURE study. Analysis of the Italian data was also funded by Novo Nordisk A/S.

Author contributions

Giuseppina Russo is the lead author of this work and, as such, had full access to all data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. The following authors were study investigators and collected data for the analysis: GR, GC, FA, MGC, EM. All authors confirm that they meet the International Committee of Medical Journal Editors (ICMJE) uniform requirements for authorship and that they have contributed to critical analysis and interpretation of the data, drafting and/or critically revising the article and sharing in the final responsibility for the content of the manuscript, as well as the decision to submit it for publication.

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Data sharing and accessibility

The datasets generated and/or analysed during the current study are available from Giuseppina Russo on reasonable request.
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Declaration of competing interest

GTR: Speakers’ bureau honoraria from and advisory board membership for AstraZeneca, Boehringer Ingelheim, Eli Lilly, Merck Sharp & Dohme, Novartis, Novo Nordisk, Sanofi and Mundipharma.

GC: No conflicts of interest to declare.

FA: Speakers’ fees from Boehringer Ingelheim, Eli Lilly, Merck Sharp & Dohme, Novo Nordisk, Mundipharma and Sanofi, and consultant fees from Boehringer Ingelheim and Eli Lilly.

MGC: Advisory board/speaker for AstraZeneca, Boehringer Ingelheim, Eli Lilly, Novo Nordisk and Sanofi.

CB: Novo Nordisk employee and shareholder.

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Appendix A. Supplementary data

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References

[1] International Diabetes Federation. IDF diabetes atlas. 9th ed. Brussels: International Diabetes Federation; 2019.

[2] Associazione Medici Diabetologi. Società Italiana di Diabetologia. [Standard italiani per la cura del diabete mellito 2018]. 2018. https://www.siditalia.it/pdf/Standard%20di%20Cur%20di%20M&A%20%20SID%202018_protetto2.pdf. [Accessed 23 July 2021].

[3] Tamayo T, Rosenbauer J, Wild SH, Spijkerman AM, Baan C, Forouhi NG, et al. Diabetes in europe: an update. Diabetes Res Clin Pract 2014;103:206–17. https://doi.org/10.1016/j.diabetres.2013.11.007.

[4] Grimacci F, Kanavos P, Cost, outcomes, treatment pathways and challenges for diabetes care in Italy. Glob Health 2014;10:58. https://doi.org/10.1186/1744-8603-10-58.

[5] Brun E, Nelson RG, Bennett PH, Imperatore G, Zoppini G, Verlato G, et al. Diabetes duration and cause-specific mortality in the Verona diabetes study. Diabetes Care 2000;23:1119–23. https://doi.org/10.2337/diacare.23.8.1119.

[6] Associazione Medici Diabetologi. Center for outcomes research and clinical epidemiology. [Annali AMD 2020]. 2020. https://aemmedi.it/wp-content/uploads/2020/10/Annali-nuova-versione-2020_3ok.pdf. [Accessed 23 July 2021].

[7] Arnett DK, Blumenthal RS, Albert MA, Buroker AB, Goldberger ZD, Hahn EJ, et al. 2018 ACC/AHA guideline on the primary prevention of cardiovascular disease: a report of the American college of cardiology/American heart association task force on clinical practice guidelines. Circulation 2019;140:e596–646. https://doi.org/10.1161/CIR.0000000000000678.

[8] American Diabetes Association. Cardiovascular disease and risk management: standards of medical care in diabetes—2020. Diabetes Care 2020;43. https://doi.org/10.2337/dc20-S034.

[9] Buse JB, Wexler D, Tsapas A, Rossing P, Mingerone G, Mathieu C, et al. 2019 update to: management of hyperglycemia in type 2 diabetes, 2018. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care 2020;43:487–93. https://doi.org/10.2337/dc20-0066.

[10] Cosentino F, Grant PL, Aboyans V, Bailey CJ, Ceriello A, Delgado V, et al. 2019 ESC Guidelines on diabetes, pre-diabetes, and cardiovascular diseases developed in collaboration with the EASD. Eur Heart J 2020;41:235–323. https://doi.org/10.1093/eurheartj/ehz486.

[11] Bonora E, Cattaudella S, Marchesini G, Miccoli R, Vaccaro O, Fadini GP, et al. A view on the quality of diabetes care in Italy and the role of Diabetes Clinics from the 2018 ARNO Diabetes Observatory. Nutr Metabol Cardiovasc Dis 2020;30:1945–53. https://doi.org/10.1016/j.numecd.2020.08.018.

[12] The DA1 Study Group. The prevalence of coronary heart disease in Type 2 diabetic patients in Italy: the DA1 study. Diabet Med 2004;21:738–45. https://doi.org/10.1111/j.1464-5491.2004.01230.x.

[13] Solini A, Penno G, Bonora E, Fondelli C, Orsi E, Arosio M, et al. Diverging association of reduced glomerular filtration rate and albuminuria with coronary and noncoronary events in patients with type 2 diabetes: the renal insufficiency and cardiovascular events (RIACE) Italian multicenter study. Diabetes Care 2012;35:143–9. https://doi.org/10.2337/dc11-1380.

[14] Penno G, Solini A, Bonora E, Fondelli C, Orsi E, Zerbini G, et al. Gender differences in cardiovascular disease risk factors, treatments and complications in patients with type 2 diabetes: the RIACE Italian multicentre study. J Intern Med 2013;274:176–91. https://doi.org/10.1111/jim.12073.

[15] Mosenzon O, Alguwailes A, Leon JLA, Bayram F, Darmon P, Davis TME, et al. CAPTURE: a multinational, cross-sectional study of cardiovascular disease prevalence in adults with type 2 diabetes across 13 countries. Cardiovasc Diabetol 2021;20:154. https://doi.org/10.1186/s12933-021-01344-0.

[16] Public Policy Committee, International Society of Pharmacoeconomics and Outcomes Research. Guidelines for Good Pharmacoeconomics practice (GPP). Pharmacoepidemiol Drug Saf 2016;25:2–10. https://doi.org/10.1002/pds.3891.

[17] Ministero della Salute. Circolare ministeriale, vol. 6; 2002 (G.U. n. 214 del 12-09-2002).

[18] Agenzia Italiana del Farnamco. Linee guida per la classificazione e conduzione degli studi osservazionali sui farmaci. 2008. (G.U. n. 78 del 31-33-2008).

[19] Bonora E, Monami M, Bruno G, Zoppini G, Mannucci E. Attending Diabetes Clinics is associated with a lower all-cause mortality. A meta-analysis of observational studies performed in Italy. Nutr Metabol Cardiovasc Dis 2018;28:431–5. https://doi.org/10.1016/j.numecd.2018.02.009.

[20] Nicolucci A, Rossi MC, Arcangeli A, Cimino A, de Bigontina G, Fava D, et al. Four-year impact of a continuous quality improvement effort implemented by a network of diabetes outpatient clinics: the AMD-Annals initiative. Diabet Med 2010;27:1041–8. https://doi.org/10.1111/j.1464-5491.2010.03055.x.

[21] Rossi MC, Candido R, Cerinelli A, Cimino A, Di Bartolo P, Giorda C, et al. Trends over 8 years in quality of diabetes care: results of the AMD Annals continuous quality improvement initiative. Acta Diabetol 2015;52:557–71. https://doi.org/10.1007/s00592-014-0688-6.

[22] Rea F, Cardullo S, Savaré L, Perseghin G, Corrao G. Comparing medication persistence among patients with type 2 diabetes using sodium-glucose cotransporter 2 inhibitors and glucagon-like peptide-1 receptor agonists in real-world setting. Diabetes Res Clin Pract 2021;180:109035. https://doi.org/10.1016/j.diabres.2021.109035.