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RESEARCH

Patterns of diabetes management in South Africa: baseline and 24-month data from the South African cohort of the DISCOVER study

A Kok[a], A Hariram[b], D Webb[c*] and A Amod[d]

[a]*Union Hospital, Alberton, South Africa*
[b]*AstraZeneca, Johannesburg, South Africa*
[c]*Pattacus Medical, Johannesburg, South Africa*
[d]*Department of Diabetes and Endocrinology, Nelson R Mandela School of Clinical Medicine, University of KwaZulu-Natal, Durban, South Africa*
**Correspondence: dawebb@mweb.co.za*

Objectives: To describe disease management patterns and associated outcomes in patients with type 2 diabetes initiating a second-line glucose-lowering therapy in routine clinical practice in South Africa.
Design: Non-interventional observational study.
Setting: General and specialist private practices.
Subjects Patients with diabetes initiating second-line glucose-lowering therapy.
Outcome measures: Variables collected at baseline and at 6-, 12- and 24-month follow-up visits included sociodemographics, first- and second-line glucose-lowering treatments and other medications, reasons for change in diabetes therapy, HbA1c target set by the attending clinician at the time of change, comorbidities and health-related quality of life (HRQoL).
Results: Baseline data were collected for 519 patients (69% female). Mean age was 54.6 years and mean time since initial diagnosis was 7.5 years. Mean HbA1c at baseline was 9.0% and the most common second-line treatment approach was to combine metformin with a sulphonylurea. Median HbA1c and median fasting glucose measurements were marginally lower at 24 months than at baseline (8.0% vs. 8.4%, and 8.5 mmol/l vs. 8.8 mmol/l, respectively). Only approximately 5% of patients had had their diabetes medication changed at any time after the baseline visit.
Conclusions: Management of type 2 diabetes mellitus in private practice in South Africa is suboptimal.

Keywords: observational study, outcomes, real-world evidence, treatment patterns, type 2 diabetes

Introduction

Diabetes mellitus is one of the largest global health emergencies of the twenty-first century and among the top 10 causes of death worldwide.[1] In Africa the number of people with diabetes is approximately 19 million and, with an ageing population, economic development, increasing urbanisation, declining dietary standards and physical activity, that is expected to increase to more than 40 million in 2045.[1,2]

South Africa has one of the highest prevalence rates of diabetes in sub-Saharan Africa. The International Diabetes Federation estimates that there are approximately 4.6 million South African adults with diabetes, about half of whom remain undiagnosed.[1,2]

Poorly managed diabetes leads to serious complications, disability, poor quality of life and early death. It is a leading cause of cardiovascular disease, blindness, kidney failure and lower limb amputation.[1] In South Africa, diabetes is the second leading cause of death and in 2019 almost 90 000 South Africans died from diabetes-related causes.[1,3]

The most effective way to prevent or reduce diabetes-related morbidity and mortality is meticulous control of glycaemia, blood pressure and dyslipidaemia, and regular examinations to facilitate timeous intervention for complications.[2] However, glycaemic control remains poor worldwide.[4,5] Studies from Europe, Australia, China and the USA report that approximately 40% of people receiving treatment for diabetes fail to achieve the recommended target of HbA1c < 7%.[6–11] In Africa, India and the Middle East control rates are reportedly even lower, with 60% to > 80% not achieving target HbA1c.[12–22] In South Africa, even in tertiary centre specialist clinics, the proportion of people with diabetes whose blood glucose is well controlled is alarmingly low. At best, only approximately 1 out of every 4 patients with type 2 diabetes achieves HbA1c < 7%.[23–34]

However, currently, there are few or no data on usual prescribing practices for patients with diabetes in South Africa.

DISCOVER is a worldwide study to investigate management patterns for type 2 diabetes in everyday clinical practice across different regions and countries. The objectives are to describe clinical evolution in patients with type 2 diabetes who are starting a second-line glucose-lowering therapy (defined as adding a glucose-lowering agent or switching between therapies) after failure of first-line oral treatment with a monotherapy, dual therapy or triple therapy; determinants of treatment patterns at baseline and thereafter; and the associations between treatment patterns and a broad range of outcomes, including glycaemic control, changes in bodyweight, blood pressure (BP) and lipid profile, hypoglycaemic episodes, incidence of diabetes-related complications, patient-reported outcomes and healthcare resource utilisation.[35] Here we report the baseline characteristics and 24-month outcomes for the South African cohort of DISCOVER.

Table 1: Baseline demographics and vital data

Factor	Data	
Male (%)	31.4	
Female (%)	68.6	
Age (years):		
Mean ± standard deviation	54.6 ± 11.4	
Median (interquartile range)	55.1 (47.5; 62.6)	
Ethnic distribution (self-reported):		
Black (%)	45.3	
Caucasian (%)	2.7	
Mixed ancestry (%)	17.5	
Asian (%)	34.1	
Tobacco smoking:		
Non-smoker (%)	79	
Ex-smoker (%)	9.6	
Current smoker (%)	11	
Education status:		
No formal education (%)	6.4	
Primary (1–6 years' education) (%)	22.1	
Secondary (7–13 years' education) (%)	55.9	
University/higher education (≥ 13 years) (%)	15.7	
Employment status:		
Employed (%)	33.9	
Not working (%)	43.4	
Retired (%)	16.5	
Clinical measurements	Mean ± standard deviation	Median
Body weight (kg)	82.8 ± 18.7	80
Body mass index (kg/m^2)	31.5 ± 6.8	30.9
Waist circumference (cm)	104.6 ± 13.2	104
Systolic BP (mmHg)	137 ± 20	135
Diastolic BP (mmHg)	83 ± 11	82
Resting pulse rate	84 ± 13	84
Vascular pathology:		
Coronary artery disease	8.7%	
Myocardial infarction	5.8%	
Angina	3.1%	
Coronary artery bypass graft	1.5%	
Percutaneous coronary intervention	1.3%	
Heart failure	1.2%	
Amputation	1.0%	
Peripheral arterial disease	0.6%	
Stroke	0.4%	
Diabetic foot	0.4%	
Peripheral neuropathy	3.5%	
Erectile dysfunction	2.9%	
Retinopathy	1.7%	
Chronic kidney disease	1.5%	
Albuminuria	1.2%	
Nonvascular pathology:		
Urinary tract infection	8.3%	
Genital infection	6.4%	
Minor hypoglycaemic event	5.9%	
Depression	4.6%	
Arthritis	4.0%	
Respiratory disease	3.7%	
Thyroid disease	2.9%	
Tuberculosis	1.5%	
Cancer	1.3%	
Major hypoglycaemic event	1.2%	
HIV	0.8%	

Study design

The design of the DISCOVER study has been described in detail elsewhere.[35] It is a multinational, prospective, 3-year, observational, longitudinal, non-interventional study involving 15 992 patients in 38 countries across six continents. Eligible patients are adults (age ≥ 18 years) with type 2 diabetes initiating a second-line glucose-lowering treatment (add-on or switching) after a first-line oral treatment. Eligible patients were invited to participate by their doctor (primary care physicians, diabetologists, endocrinologists, cardiologists and other specialists). Exclusion criteria include type 1 diabetes, pregnancy, initiation of dual therapy after having previously received two different lines of monotherapy, first-line treatment with insulin or another injectable agent, other illness or condition that would compromise three-year follow up.

Data were collected at baseline (initiation of second-line therapy) using a standardised electronic case report form and transferred to a central database via a web-based data capture system. Some data were collected retrospectively from medical records. Variables collected included sociodemographics, first- and second-line glucose-lowering treatments and other medications, reasons for change in diabetes therapy, HbA1c target set by the attending clinician at the time of change, and comorbidities. Health-related quality of life (HRQoL) was assessed using the Short-Form version 2 (SF-36v2) Health Survey. The SF-36 consists of 36 items comprising 8 domains that measure the extent to which physical and/or mental health problems affect physical, emotional and social aspects of quality of life. Each domain yields a percentage ranging from 0 (worst possible health) to 100 (best possible health), such that higher scores indicate better HRQoL.[36]

In accordance with the observational nature of the study, methods to measure HbA1c and glucose were those routinely used by the individual practices and diagnosis of complications and comorbidities was dependent on the attending clinician. There was no external independent adjudication of events.

Results

Baseline data

Baseline data for the South African cohort were collected from 519 patients enrolled by a general practitioner/family doctor (72.2%), endocrinologist/diabetologist (11.1%), specialist physician (internist) (5.6%) or cardiologist (5.6%). The majority of enrolled patients were being treated in the private healthcare sector (94%). Data collection was variable and the majority of patients had incomplete data. Demographic and other baseline characteristics are shown in Tables 1 and 2 and Figures 1–3.

Table 2: Metabolic parameters at baseline and during follow-up

Factor	Follow-up time point			
	Baseline ($n = 519$)	6 months' follow-up ($n = 343$)	12 months' follow-up ($n = 474$)	24 months' follow-up ($n = 466$)
HbA1C (%)				
Mean ± SD	9.0 ± 2.1	8.2 ± 1.9	8.4 ± 1.7	8.3 ± 1.9
Median (IQR)	8.4 (7.5, 10.1)	7.8 (7.0, 9.0)	8.1 (7.4, 9.2)	8.0 (7.1, 9.4)
Missing Rate	334 (64.4%)	256 (74.6%)	358 (75.5%)	352 (75.5%)
Fasting glucose (mmol/l)				
Mean ± SD	9.9 ± 4.0	9.5 ± 3.8	9.5 ± 3.2	8.7 ± 3.3
Median (IQR)	8.8 (7.1, 11.7)	8.0 (6.7, 11.0)	9.0 (7.3, 10.5)	8.5 (6.2, 9.8)
Missing Rate	440 (84.8%)	299 (87.2%)	408 (86.1%)	425 (91.2%)
Casual/random glucose (mmol/l)				
Mean ± SD	16.0 ± 5.9	10.2 ± 3.8	10.1 ± 3.6	10.0 ± 2.9
Median (IQR)	15.2 (12.0, 19.7)	9.5 (7.4, 12.1)	9.8 (7.4, 12.5)	9.4 (8.4, 11.6)
Missing Rate	447 (86.1%)	291 (84.8%)	418 (88.2%)	423 (90.8%)
HDL (mmol/l)				
Mean ± SD	1.2 ± 0.6	1.1 ± 0.3	1.2 ± 0.3	1.1 ± 0.3
Median (IQR)	1.1 (0.9, 1.3)	1.1 (0.9, 1.3)	1.2 (1.0, 1.3)	1.0 (0.9, 1.2)
Missing Rate	406 (78.2%)	296 (86.3%)	430 (90.7%)	418 (89.7%)
LDL (mmol/l)				
Mean ± SD	2.8 ± 1.0	2.9 ± 1.0	2.8 ± 1.1	2.7 ± 1.1
Median (IQR)	2.7 (2.1, 3.5)	2.7 (2.2, 3.6)	2.7 (1.9, 3.4)	2.5 (1.9, 3.1)
Missing Rate	395 (76.1%)	294 (85.7%)	426 (89.9%)	417 (89.5%)
Total cholesterol (mmol/l)				
Mean ± SD	4.8 ± 1.1	4.7 ± 0.9	4.8 ± 1.2	4.7 ± 1.4
Median (IQR)	5.0 (4.2, 5.7)	4.6 (4.0, 5.2)	4.7 (3.7, 5.7)	4.3 (3.8, 5.3)
Missing Rate	390 (75.1%)	282 (82.2%)	420 (88.6%)	400 (85.8%)
Triglycerides (mmol/l)				
Mean ± SD	2.1 ± 1.6	1.8 ± 0.9	2.1 ± 1.1	2.0 ± 1.4
Median (IQR)	1.9 (1.3, 2.4)	1.8 (1.2, 2.2)	1.9 (1.1, 2.7)	1.8 (1.1, 2.6)
Missing Rate	417 (80.3%)	297 (86.6%)	430 (90.7%)	417 (89.5%)

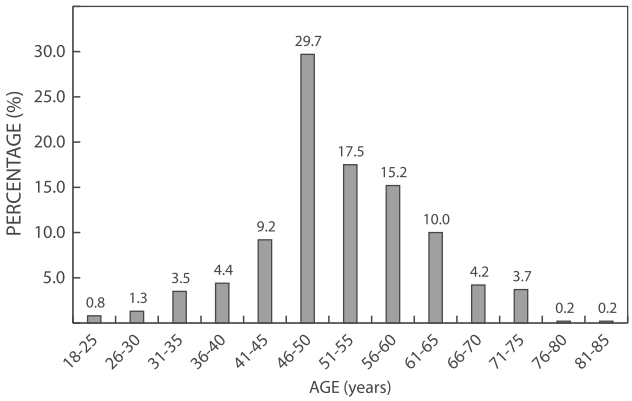

Figure 1: Baseline age distribution.

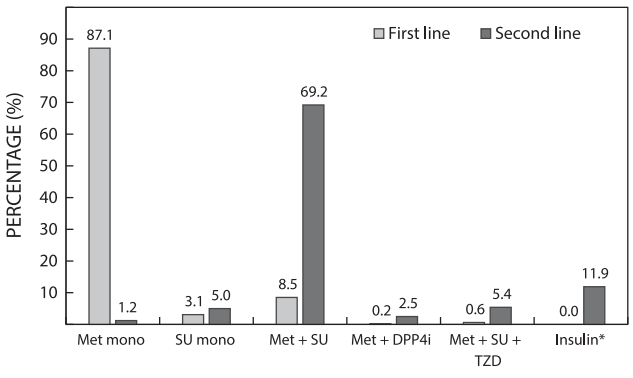

Figure 2: First-line and second-line diabetes medications at baseline visit. Met: metformin; SU: sulphonylurea; DPP4i: dipeptidyl peptidase-4 inhibitor; TZD: thiazolidinedione. *Patients on insulin may also have received oral therapy.

The mean time since initial diagnosis of diabetes mellitus was 7.5 (±6.0) years. Mean baseline HbA1c was 9.0% ± 2.1, with a median value of 8.4% (interquartile range, IQR 7.5% to 10.1%). Macrovascular and microvascular pathologies were reported in 24% and 10.8%, respectively, and nonvascular pathologies were reported in 24%. In total, 67% of patients had a prior diagnosis of hypertension and 51% had a prior diagnosis of hyperlipidaemia. Previous episodes of major and minor hypoglycaemic events were reported in 1% and 6% of patients, respectively.

Overall, including monotherapy or combination therapy, 96% of patients were receiving metformin as first-line therapy and approximately 11% were receiving a sulphonylurea (SU). The most common second-line approach was to combine metformin with an SU (Figure 2).

The most common reasons given for changing first-line glucose-lowering therapy were lack of efficacy (96%), weight gain or other side effect (2%), patient convenience (2%) and

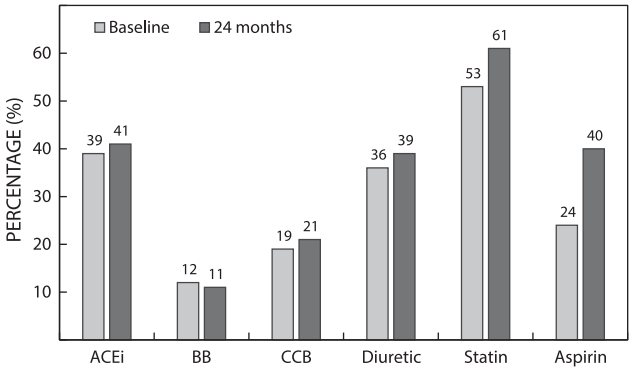

Figure 3: Most common co-prescribed medications at baseline and at 24-month follow-up. ACEi: angiotensin converting enzyme inhibitor; BB: beta blocker; CCB: calcium channel blocker.

affordability (2%). At initiation of a new therapy, 67% of patients had an HbA1c target set, of whom 43% were specifically aware of their HbA1c target.

Mean scores (out of a total of 100) across the subdomains of SF-36 ranged from 44 to 53.

24-month data

At 24 months, data were available for 466 (88%) patients. Eleven patients had died, including 4 from cardiovascular causes, 2 from infection, 1 from kidney disease and 4 unspecified.

In the remaining patients, body mass index, waist circumference, and systolic and diastolic blood pressures remained largely unchanged from the values recorded at baseline. From baseline to 24 months, incident hypertension and hyperlipidaemia were diagnosed in a further 135 (26%) and 83 (16%) patients, respectively.

Mean HbA1c, mean fasting glucose and random glucose measurements were lower at 24 months than at baseline (8.3% vs. 9%, 8.7 mmol/l vs. 9.0, and 10 mmol/l vs. 16 mmol/l, respectively) (Table 2).

Despite failing to meet treatment targets, at each of the 6-, 12- and 24-month follow-up visits only approximately 5% of patients had had their diabetes medication changed at any time after the baseline visit. At the 24-month follow-up, the most common treatment discontinuations were a sulphonylurea (0.9%), sulphonylurea plus thiazolidinedione (0.9%) or basal or premix insulin (0.6%), whereas the most common treatment addition was basal insulin (2.8%). The most common reasons given for changing treatment regimen were efficacy (70%), poor adherence (9%), weight issues (9%), hypoglycaemia or side effects (9%), affordability (4%) and physician preference (4%).

A single major hypoglycaemic event was reported for only one patient at each of the follow-up visits. Minor hypoglycaemic events were reported for 13 patients (3.8%) at 6 months and 11 patients (2.5%) each at 1 and 2 years. There were few other incident diabetes complications. At the 24-month follow-up, recorded events included 51 patients with urinary tract infections, 18 with depression, 13 with peripheral neuropathy, 4 with chronic kidney disease, 4 with retinopathy and 1 with coronary artery disease.

Physical functioning and mental health summary scores on the SF-36v2 remained unchanged from baseline at 24 months (45.7 vs. 46.4 and 48.2 vs. 47.2, respectively).

Discussion

The South African DISCOVER population represents a diverse group of individuals from different ethnic groups and educational backgrounds being treated mainly in the private healthcare sector. Over two-thirds of the study population is female, which is disproportionately high in comparison with other South African studies of people being treated for diabetes and also in the DISCOVER population overall, in which 46% of the patients are female.[4,24–27,34]

At baseline, the majority of patients had at least one comorbidity, predominantly hypertension and/or hyperlipidaemia, and those prevalences are similar to those reported previously.[24–27,29,30,32,34,37] The prevalence of hypertension and hyperlipidaemia was consistent with the proportion of patients receiving any antihypertensive medication and statins, suggesting that pharmacotherapy is usually prescribed to manage these conditions when they are diagnosed.

Compared with previous published reports of South African patients, the baseline prevalence of macro- and microvascular complications in this DISCOVER population, with a mean time since diagnosis of 7.5 years, was low. However, since no specific tests were conducted to establish these findings, which were documented from history only, it is possible that the actual prevalence of complications may have been underestimated. In patients with a mean age of 63 years attending a state outpatient clinic (duration of diabetes not specified) the prevalence of coronary artery disease was 14.3%, nephropathy 11.7%, neuropathy 7.1% and retinopathy 6.3%.[24] In patients with a mean duration of diabetes of 12 years being treated at outpatient clinics in the State sector (mean age 58 years), and private sector (mean age 63 years) nephropathy was reported in 9.7% and 8.9%; neuropathy in 11.8% and 17.8%; retinopathy in 13.9% and 18.5%; and cardiovascular disease in 16% and 15.8%, respectively.[38]

In a cross-sectional study of 50 institutional/private clinics, in patients with a mean time since diagnosis of 9 years and mean age 56 years, the prevalence of diabetic peripheral neuropathic pain was 30%, autonomic neuropathy 5%, nephropathy 11% and retinopathy 12%.[37] Furthermore, in the DISCOVER population, incident complications, including hypoglycaemia, were extremely uncommon during the two years' follow-up. Data were relatively complete for these outcomes. Reasons for these discrepancies are unclear, except that the South African DISCOVER population was younger than that in the first study and had a shorter mean time since diagnosis in comparison with those in the second and third studies. Ethnicity may also play a role. It is notable that approximately 97% of the DISCOVER population self-reported being of either Black, Asian (Indian) or mixed ancestry and fewer than 3% were Caucasian (White). Pinchevsky reported that there are considerable differences between South African ethnic groups in the prevalence and incidence of diabetes-related complications (Table 3).[27] In his cohort, with a mean time since diagnosis of approximately 10–14 years, diabetes-related complications were considerably less common at baseline and after 4 years' follow-up among the Black and mixed-ancestry groups (which together comprised 63% of the South African DISCOVER population).

In line with current South African diabetes management guidelines, metformin was the most commonly prescribed first-line oral therapy.[2] At baseline almost all of the patients were being treated with metformin (96%), whereas approximately

Table 3: Prevalence of diabetes-related complications by ethnic group in patients attending the Charlotte Maxeke Johannesburg Academic Hospital in 2009 (data from Pinchevsky et al.)[27]

Factor	Black African (*n* = 112)	Caucasian (*n* = 66)	Asian/Indian (*n* = 68)	Mixed ancestry (*n* = 15)
Duration of diabetes (years)	9.6	13.9	12.3	10.4
Cardiovascular disease (%)	2.7	24.2	22.1	0
Stroke (%)	1.8	3.0	2.9	0
Retinopathy (%)	2.7	13.6	5.9	13.3
Neuropathy (%)	3.6	10.6	7.4	0
Nephropathy (%)	5.4	10.6	13.2	13.3

11% were receiving an SU, either as monotherapy or in combination with metformin. In almost all cases the reason for change to second-line therapy was poor glycaemic control. The most common second-line approach, which included 70% of patients, was to combine metformin with an SU. Basal insulin was prescribed to 12%. Although both of these approaches are supported by recent South African diabetes treatment guidelines, adding a sulphonylurea to metformin is the preferred approach and insulin is not recommended unless HbA1c target is not achievable with other agents.[2]

In contrast to algorithmic sequential treatment, more recent guidelines recommend an individualised approach to diabetes therapy, with particular attention to comorbidities. Because they have been shown to reduce morbidity and/or mortality in these patients, glucagon-like peptide-1 receptor agonists (GLP1RA) and sodium-glucose co-transporter 2 inhibitors (SGLT2i) are recommended as early add-on therapies to metformin where there is established cardiovascular disease, high or very high cardiovascular risk and in patients with chronic kidney disease.[39,40] A considerable proportion of DISCOVER patients had more than two cardiovascular risk factors and coronary artery disease was reported in almost 10%, suggesting that a not insignificant proportion might have been candidates for one of these add-on therapies. Although the SGLT2i class has only recently been introduced to South Africa and would not have been available during the course of the study, a GLP1RA had been prescribed to only one patient in the entire cohort. Nevertheless, these medications are unavailable in the public sector and in the private sector access to them is limited by cost.

During follow-up, the most common reason for changing therapy was lack of efficacy. However, although glucose control improved during follow up, mean HbA1c remained above the usual target value of 7% and diabetes therapy was changed in only 5% of patients. It is worrying that only 43% of patients were aware of their HbA1c target and 75% of patients had missing data for glycaemic control, suggesting that clinicians are making treatment decisions without proper expectations or monitoring. Therapy is unlikely to be adjusted or to be appropriate if, at minimum, there is no monitoring of glycaemic control.

Considering the long duration of type 2 diabetes (> 7 years), mean HbA1c at which second-line treatment was started and prevailing HbA1c levels over the following 24 months, it appears that diabetes management in South African patients is, at present, suboptimal.

The SF-36 HRQoL summary scores for both physical and mental health in the South African DISCOVER patient population are low. Although there are no published normative data for SF-36 in a South African population, these scores are lower than normative scores reported for various general populations in other countries.[36] However, they are similar to those reported for South African adults 12 months after discharge from a surgical intensive care unit.[41] These patients perceived their emotional and physical health to negatively affect their social interactions with family and friends, they perceived themselves to be more nervous and depressed than calm and happy, and they regarded themselves as generally sicker than other people they knew.[41]

Conclusions

The South African cohort in the multinational DISCOVER study has revealed that diabetes management in private practice in South Africa is suboptimal. While poor glycaemic control among people with diabetes has been consistently recorded across the world, DISCOVER suggests that South Africans are neither being sufficiently monitored nor having their medication adjusted appropriately or timeously. Despite a high level of comorbidities, many patients are still managed exclusively at the general practitioner level, when referral to a specialist physician or diabetologist would be appropriate. It is unsurprising that HRQoL among this patient group remains low.

Results from the 3-year follow-up in DISCOVER will be available later this year.

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ORCID

D Webb http://orcid.org/0000-0002-6017-485X

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