

IDMPS Wave 7 Africa

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Diabetes is a major economic burden and has rapidly increased worldwide. Type 2 diabetes, which accounts for 90–95% of cases, has increased particularly in the developing world. Early treatment intensification may decrease the morbidity and mortality of diabetes by lowering the risk of related chronic complications. The majority of patients, however, do not achieve glycaemic targets, and consequently suffer from complications secondary to suboptimal glycaemic control. A large number of epidemiological studies or national registers have been analysed at both country and regional levels, particularly in developed countries, in order to assess the quality of care in patients with diabetes, or to determine compliance with national treatment guidelines. There is a paucity of data from the developing world, particularly in Africa, with regard to the quality of care of people with type 2 diabetes. A better understanding of the missing gaps within current diabetes management is therefore required in order to improve the quality of care of these patients.

Keywords: Africa, diabetes, macrovascular, microvascular, standard of care, type 2

Introduction

Diabetes mellitus is a major economic burden because of its negative impact on quality of life and individual productivity,^{1–3} due mainly to the development of microvascular and macrovascular complications.^{4–6} The International Diabetes Federation estimates that, by 2045, there will be 700 million cases of diabetes in adults worldwide.⁴ In Africa, as in other parts of the world, type 2 diabetes also represents over 9 out of 10 diabetes cases.^{7,8} The proportion of undiagnosed diabetes in Africa is over 60%. Furthermore, 44% of deaths due to diabetes in Africa occurred in individuals younger than 60 years of age,⁴ emphasising the magnitude of the diabetes epidemic.

The prevalence of diabetes is rapidly increasing in Africa. Estimates from 2009 by the International Diabetes Federation suggest that the number of adults with diabetes in the world will expand by 54%, from 284.6 million in 2010 to 438.4 million in 2030.^{9,10} Several factors such as the ageing population, economic transition and urbanisation associated with nutrition transition and obesity contribute to the increased diabetes prevalence.^{11–14}

Studies on T2DM show that early intensive treatment of diabetes can decrease the morbidity and mortality of the disease by lowering the risk of related chronic complications.^{15,16} Therefore, a major goal of treatment in the majority of people with diabetes is to achieve near normoglycaemia, thus delaying or preventing the onset of long-term complications. Local and international bodies therefore advocate a target glycated haemoglobin (HbA1c) level below 7% (53 mmol/mol)^{10,17,18} for most people living with diabetes, although this needs to be individualised.

Despite these recommendations, the majority of patients do not achieve glycaemic targets, and consequently suffer from

complications secondary to sub-optimal glycaemic control.¹⁹ One of the barriers to reaching glycaemic targets has been therapeutic inertia, which has been largely attributed to either delayed initiation of insulin therapy or poor insulin titration.²⁰

A large number of epidemiological studies or national registers have been analysed at both country and regional levels, particularly in Westernised countries, in order to assess the quality of care in patients with diabetes, or to check compliance with national treatment guidelines and to guide national programmes for improving the quality of care of these patients.²¹

There is a paucity of data from non-Westernised countries, particularly in Africa, with regard to the quality of care of people with type 2 diabetes. A better understanding of the missing gaps within current diabetes management is therefore required in order to improve the quality of care of these patients.

Methods

The International Diabetes Management Practices Study (IDMPS) is an ongoing multi-centre observational study conducted in waves (one wave per year) with the primary aim of documenting the management of people with type 1 and type 2 diabetes in clinical practice. In addition, data from the registry have been collated in a standardised manner that will reflect current practices in the management of people with type 1 and type 2 diabetes mellitus, and the improvement over time of these practices. The study focuses on diabetes practices and compliance with guidelines by physicians (general practitioners, specialist physicians, diabetologists and endocrinologists) in the low- to middle-income countries in Asia, Eastern Europe, Latin America and the Middle East and Africa.

The objective of the study described was to assess the management of care of patients in Africa with type 2 diabetes in current medical practice.

Participants

Physicians participating in the IDMPS study were requested to enrol the first 10 patients with T2DM visiting their offices during the 2-week recruitment period. A total of 3 225 participants with diabetes were recruited from Africa. Among these, 3 191 met the eligibility criteria for analysis, and 2 403 of these participants had type 2 diabetes.

Procedures

The present study is based on the data recorded during the cross-sectional study of the seventh phase of the study, thus the practices included here represent the wide spectrum of routine care currently available in Africa.

During the cross-sectional period, physicians collected information on the patients' demographic and socioeconomic profiles, relevant medical history (chronic complications, associated cardiovascular risk factors and co-morbidity factors), previous and current treatments for hyperglycaemia and its associated cardiovascular risk factors, disease-related education, and employment conditions and performance.

Outcome measures

Clinical data (bodyweight, height, waist circumference, blood pressure, foot evaluation) were collected at practice visits. Metabolic control measures included HbA1c levels and blood lipid profiles (total cholesterol, high-density lipoprotein cholesterol [HDL-C], low-density lipoprotein cholesterol [LDL-C] and triglycerides). Treatment goals were defined according to ADA guidelines (HbA1c < 7% [53 mmol/mol], blood pressure [BP] < 130/80 mmHg, LDLC < 100 mg/dl).²⁴

The IDMPS study protocol was approved by the appropriate regulatory and ethics committees in all the participating countries and centres. Accordingly, all participants provided written informed consent before entering the study. Implementation was developed under the guidance of a steering committee that also proposed the statistical analyses and reviewed and validated the registry data. The study was coordinated by Sanofi-Aventis and monitored by Sanofi-Aventis staff in each participating country.

Sample size justification

Number of patients

The sample size was determined on a country basis, based on the primary objective, which was to assess the management of care of type 2 DM patients, and on the precision that was expected. Based on the assumption that insulin was the least prescribed therapy in terms of proportions, the sample size was determined in order to establish the frequency of insulin-treated patients. It was estimated to give an estimation of proportions with an absolute precision of 20% and a confidence interval of 95%.

$$n = p(1 - p) \times \left(\frac{\epsilon\alpha}{e}\right)^2$$

with n the per country sample size, p the estimated proportion of type 2 DM patients treated with insulin, $\epsilon\alpha = 1.96$ for $\alpha = 5\%$, e the absolute precision (20%) $\times p =$ the relative precision.

Results

Type 2 diabetes mellitus subset

Study population

The number of participants recruited was similar between North Africa ($n = 1454$; 45%) and sub-Saharan Africa ($n = 1737$; 54%).

Physician data

In Africa, a total of 231 physicians included at least one patient in the study: 138 were self-reported diabetes specialists (endocrinologists or diabetologists). The 91 non-diabetes specialists included primary care practitioners and general internists and cardiologists. The mean age (\pm SD) of all physicians was 50.6 (\pm 9.7) years with 61.9% being male. They had been practising medicine for 22.2 (\pm 10.1) years on average for diabetes specialists and for 23.5 (\pm 9.2) years for non-specialists. The large majority of the physicians (97.8%) declared that they follow clinical practice guidelines, mainly American Diabetes Association (ADA)/European Association for the Study of Diabetes (EASD) (78.6%) consensus statement. Regarding the management of people with diabetes on average, specialists reported that they usually saw 23.5 patients per day and non-diabetic specialists 16.6 patients per day.

Demographic and social data

Of the patients recruited, there was a relatively equal gender split with 48.9% being male and 51.1% being female. The patients' ages ranged from 20 to 95 years with the majority (69.1%) aged between 40 and 65 years (mean \pm standard deviation [SD] 57.7 \pm 10.9 years). Most of the patients with T2DM were mainly of black ($n = 1082$; 45%) or Caucasian ethnicity ($n = 819$; 34.1%) or belonged to either South Asian ($n = 102$; 4.2%), Oriental/Arab/Persian ($n = 321$; 13.4%), East Asian ($n = 2$; 0.1%), South-East Asian ($n = 7$; 0.3%) or other ethnic groups ($n = 72$; 2.3%).

In terms of the patients' socioeconomic profile, our data showed that most of the patients came from both urban and suburban areas (92%). With regard to education level, just over a third of the patients were educated up to secondary or university level (74.7%), with a smaller fraction being educated up to either the primary school level (17.3%) or illiterate (8.1%).

Of the patients with T2DM, 62.4% of them were in either full or part-time employment. The rest were either unemployed (12.4%) or retired (25.3%). In the unemployed group, a total of 291 patients had been unemployed for almost five years (4.68 years; SD 4.32) with 21 of them attributing it to diabetes-related work disability. Amongst patients who were employed either full-time or part-time, 14.4% had to take sick leave during the past three months due to diabetes with median duration of six days.

Glucose lowering therapies

The mean time since diagnosis of T2DM was 9.59 years (SD 7.55) with 63.2% of the patients having health insurance coverage. Despite the health insurance coverage, almost one-third (29.4%) of the patients still required co-payment for their medication.

The majority of patients with T2DM were managed with only oral glucose-lowering drugs ($n = 1497$; 62.3%), whilst the rest were managed with insulin in combination with at least one oral glucose-lowering drug (OGLD; $n = 638$; 26.6%), insulin

alone ($n = 240$; 10%) or lifestyle modifications (diet and exercise) alone ($n = 24$; 1%). In addition, among the 878 insulin-treated T2DM patients, the treatments mainly received were premix alone for 46.4% and basal alone for 29.4%.

Achievement of glycaemic target (HbA1c) (Figure 1)

Overall, our data showed that the HbA1c reading of patients who were on insulin therapy alone was 8.63%, while patients who were managed with both OGLD and insulin had an HbA1c reading of 8.7%. An HbA1c of 7.65% was reported in patients who were managed on OGLDs alone while patients who were not managed by diet, OGLDs or insulin had an HbA1c of 8.13%.

Only 33.1% of the total population reached their glycaemic target (HbA1c < 7%) with episodes of hypoglycaemia (92.6%), discontinuation of insulin (88.6%) and weight gain (86.1%) cited as the top three reasons for the non-achievement of glycaemic target. In addition, HbA1c tests were conducted on average 2.16 times per year in these patients.

The triple targets pooled together HbA1c < 7%, and normal blood pressure (SBP/DBP 130/80 mmHg) and LDL-C < 2.6 mmol/l or 100 mg/dl as per recommendations of international guidelines were reached by only 3.1% of T2DM patients. The non-achievement of the triple targets was due to HbA1c level $\geq 7\%$ in 70.8%, abnormal blood pressure for 84.5% and LDL level ≥ 2.6 mmol/l or 100 mg/dl for 57.4%.

Diabetes-related complications were experienced by 47.2% of T2DM patients, with microvascular complications in 41.9% and macrovascular complications in 11.4% of T2DM patients.

It was found that patients who discontinued their insulin therapy (17.2%) reported having done so for a median period of two months with the most commonly cited reasons for discontinuation of insulin therapy being the cost of the medication/strips (27.5%), and the impact insulin therapy had on their social life (26.2%), followed by the fear of hypoglycaemic episodes (25.5%) as seen in Table 1.

The experience of symptomatic episodes of hypoglycaemia appeared to be higher in patients on insulin therapy compared with patients on OGLD and other therapies (Table 2). In total, 258 of all the patients (73.1%) in whom data regarding hypoglycaemia events were available ($n = 353$) reported having one hypoglycaemic episode at least once a month.

Diabetes-related complications

Diabetes related complications were assessed based on medical history and not during a direct physician consultation. Complications of diabetes were present in 47.2% of patients (data were available from 1 102 patients as indicated in Table 2). The majority, 978 patients (41.9%), had microvascular complications and only 267 patients (11.4%) had at least one documented macrovascular disease.

The most common form of microvascular complication amongst the patients was sensory neuropathy (649 patients; 27.8%), with the least common being renal dialysis (10 patients; 0.4%). Angina was the most commonly reported macrovascular complication (103 patients; 4.4%).

Table 1: Reasons for discontinuation of insulin therapy

Reason	n	%
Lack of efficacy	5	3.4%
Fear of hypoglycaemia	38	25.5%
Occurrence of side effects	8	5.4%
Impact on social life	39	26.2%
Lack of experience in the management of insulin dosing	28	18.8%
Lack of experience in the management of insulin administration	18	12.1%
Cost of medication/strips	41	27.5%
Absence of dose flexibility	7	4.7%
Weight gain	12	8.1%
Lack of support	29	19.5%
Episodes of hypoglycaemia	18	12.1%
Other reasons for discontinuation	40	26.8%

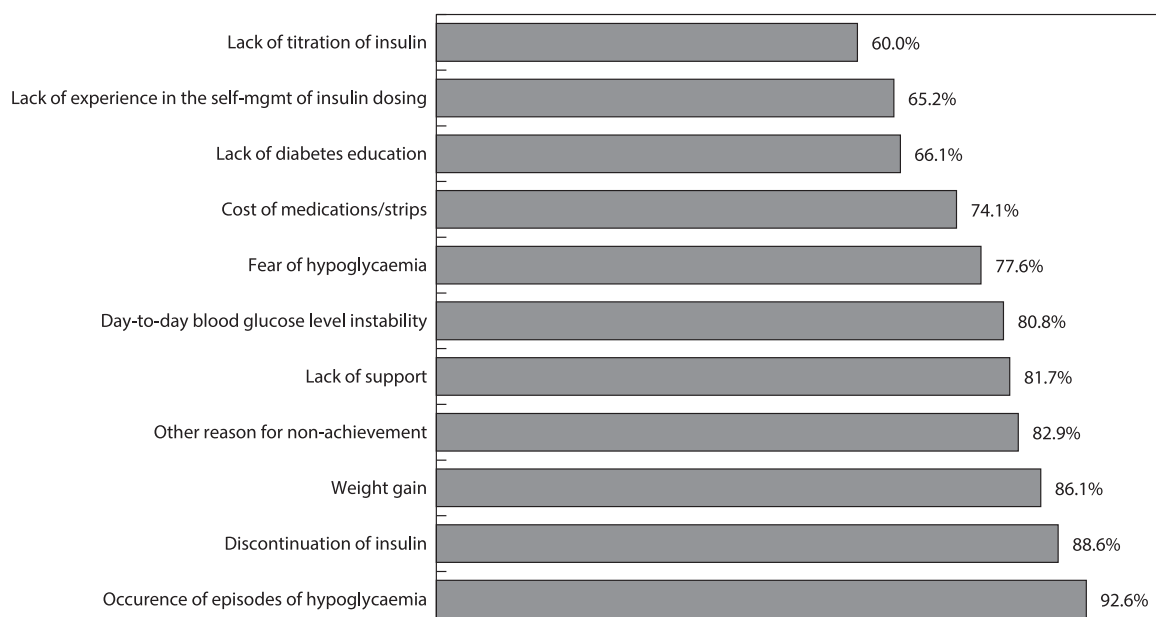


Figure 1: Patients' reasons for non-achievement of HbA1c target.

Table 2: Diabetes-related complications per treatment group

Diabetes-related complications	Diet and exercise alone n (%)	OGLD treatment n (%)	Insulin treatment n (%)	OGLD treatment + insulin treatment n (%)	Other no OGLD—no insulin—no diet n (%)	Total n (%)
Microvascular:						
Retinopathy	0	134 (9.2%)	71 (30.6%)	133 (21.1%)	0	338 (14.5%)
Visual impairment affecting daily living	0	89 (6.1%)	20 (8.6%)	62 (9.9%)	0	171 (7.3%)
Sensory neuropathy	5 (26.3%)	322 (22.2%)	96 (41.4%)	225 (35.8%)	1 (25.0%)	649 (27.8%)
Microalbuminuria	0	110 (7.6%)	37 (15.9%)	80 (12.7%)	0	227 (9.7%)
Proteinuria	0	64 (4.4%)	30 (12.9%)	57 (9.1%)	0	151 (6.5%)
Dialysis	0	1 (0.1%)	8 (3.4%)	1 (0.2%)	0	10 (0.4%)
Amputation	0	5 (0.3%)	11 (4.7%)	5 (0.8%)	0	21 (0.9%)
Active foot ulcer	0	15 (1.0%)	15 (6.5%)	20 (3.2%)	0	50 (2.1%)
History of foot ulcer	0	15 (1.0%)	21 (9.1%)	23 (3.7%)	0	59 (2.5%)
Macrovascular:						
Angina	0	50 (3.5%)	13 (5.6%)	40 (6.4%)	0	103 (4.4%)
History of Myocardial infarction/Acute Coronary Syndrome	0	30 (2.1%)	18 (7.8%)	21 (3.3%)	0	69 (3.0%)
History of heart failure	0	13 (0.9%)	8 (3.4%)	12 (1.9%)	0	33 (1.4%)
History of stroke with partial recovery	0	7 (0.5%)	8 (3.4%)	9 (1.4%)	0	24 (1.0%)
History of stroke with full recovery	0	10 (0.7%)	7 (3.0%)	6 (1.0%)	0	23 (1.0%)
PVD (absent foot pulse or ABI < 0.9)	0	19 (1.3%)	16 (6.9%)	22 (3.5%)	0	57 (2.4%)
History of revascularization (PTCA or CABG)	0	21 (1.4%)	8 (3.4%)	18 (2.9%)	0	47 (2.0%)
Other complications	0	34 (2.3%)	23 (9.9%)	28 (4.5%)	0	85 (3.6%)
Any complication	5 (26.3%)	561 (38.7%)	162 (69.8%)	373 (59.3%)	1 (25.0%)	1102 (47.2%)
At least one microvascular complication	5 (26.3%)	495 (34.2%)	141 (60.8%)	336 (53.4%)	1 (25.0%)	978 (41.9%)
At least one macrovascular complication	0	120 (8.3%)	52 (22.4%)	95 (15.1%)	0	267 (11.4%)

Table 3: Diabetes-related complications per treatment group

Diabetes-related complications	Diet and exercise alone	OGLD treatment	Insulin treatment	OGLD treatment + insulin treatment	Other no OGLD—no insulin—no diet)	Total
Any complication	5 (26.3%)	561 (38.7%)	162 (69.8%)	373 (59.3%)	1 (25.0%)	1102 (47.2%)
At least one microvascular complication	5 (26.3%)	495 (34.2%)	141 (60.8%)	336 (53.4%)	1 (25.0%)	978 (41.9%)
At least one macrovascular complication	0	120 (8.3%)	52 (22.4%)	95 (15.1%)	0	267 (11.4%)

Discussion

At present, nearly half a billion people are living with diabetes, with low- and middle-income countries carrying almost 80% of the disease burden.⁴ Rapid urbanisation, which is associated

with an unhealthy diet and increasingly sedentary lifestyles, has resulted in a growing epidemic in emerging nations. On average, people with diagnosed diabetes have medical expenditures approximately twofold higher than those without

diabetes. It is therefore imperative to determine barriers to treatment goals in order to accurately understand and shape health outcomes in Africa.¹⁰

The majority of patients in the study fell within the 40–65 years age group with a mean diagnosis time of 9.59 years. This follows the trend observed in most developing countries in which the greatest number of individuals with diabetes are aged between 45 and 64 years old.²²

In the wave 7 cohort, the majority of patients were treated with OGLD followed by OGLD and insulin treatment. A smaller percentage of patients were treated exclusively with insulin. The proportion of patients achieving the generally accepted glycaemic target was low, with only 33% of patients achieving an HbA1c level of less than 7% (53 mmol/mol). Suboptimal glycaemic control has been a recurring concern and has been noted in previous IDMPS studies.^{20,23} A lack of adherence to lifestyle changes and a lack of efficacy of drug treatment were previously cited by physicians as barriers to goal attainment.²³

Patients treated exclusively with OGLDs obtained a mean HbA1c of 7.65% (60 mmol/mol) while HbA1c levels were higher in those using insulin either as monotherapy or in combination with OGLDs (8.7%). The apparent reluctance to use insulin therapy in patients using only OGLDs despite suboptimal glycaemic control contrasts with the international guidelines available at the time, which recommended early initiation of insulin therapy in T2DM patients not achieving target HbA1c < 7% (53 mmol/mol).^{2,20} The most commonly used insulin formulation in this IDMPS population was premixed insulin. Among the 878 insulin-treated T2DM patients, 46.4% received a premix alone, and 29.4% received a basal-only regimen. The ADA standards of care recommend the early initiation of basal insulin if HbA1c levels are greater than 10% (86 mmol/mol) or the patient has symptomatic hyperglycaemia¹⁸ with a basal/prandial schedule as a second-line schedule, rather than the alternative but less studied twice-daily premixed insulin strategy.^{18,20} Basal and prandial regimens have additionally been associated with a lower incidence of hypoglycaemia and weight gain.²⁴

Hypoglycaemia (92.6%), discontinuation of insulin (88.6%) and weight gain (86.1%) were cited in this study as the top three reasons for the non-achievement of glycaemic target. Lack of appropriate insulin titration has been reported as a barrier to HbA1c goal attainment; however, this is intricately tied to the fear of hypoglycaemic events by both the physician and patient.²⁵ The fear of hypoglycaemia may also affect the patient's willingness to adhere to prescribed treatment, resulting in discontinuation of insulin and as a result compromising HbA1c goal attainment. It has been reported that 68% of patients who had experienced hypoglycaemia discontinued insulin treatment in the first 12 months.²⁶ Inappropriate insulin dosing and timing were noted as major factors contributing to severe hypoglycaemia. Addressing these factors involves utilisation of treatment with low risk of hypoglycaemia, a multidisciplinary approach to patient education to ensure appropriate patient-level management of insulin therapy.²⁵

With the availability of SGLT-2 inhibitors, DPP-4 inhibitors and GLP-1 agonists, effective therapeutic options with reduced hypoglycaemia are available. In addition, newer generation basal insulin preparations with reduced hypoglycaemia may provide better outcomes with lower HbA1c levels. Cost

however, is a concern—especially in lower income countries. With cost cited as a contributing factor to insulin discontinuation and a third of patients with health insurance coverage still having co-payments on their medication, barriers to patient access remain a concern in Africa.

The lack of HbA1C goal attainment is inherently linked to the high incidence of diabetes-related complications. Diabetes is known to greatly increase the risks of vascular disease and much of the burden of type 2 diabetes is caused by microvascular and macrovascular complications. The microvascular complications of type 2 diabetes are principally nephropathy, retinopathy, neuropathy, and small vessel vasculopathy causing lower extremity amputation.²² Diabetes-related complications were experienced by 47.2% of T2DM patients, with microvascular complications in 41.9% and macrovascular complications in 11.4% of T2DM patients. The most commonly reported microvascular complication was sensory neuropathy while angina was the most commonly reported macrovascular complication. This contrasts somewhat with data observed in the developed world. In the USA, myocardial infarction has been noted as the most common macrovascular complication while chronic kidney disease is the most reported microvascular complication.²⁶

With 29% of patients citing lack of diabetes education and support as a detriment to HbA1c goal attainment, the study highlights the need for in-depth patient education on insulin management.²⁵ This further acknowledges the pivotal role of the diabetes nurse educator as part of a multidisciplinary team in diabetes management.

In 2017, more than 298 160 deaths (6% of all mortality) in Africa were attributed to diabetes, with 77% of these occurring in people under 60 years. With the number of people with diabetes expected to rise by 162.5% by 2045, research and health systems need to increase efforts to combat the looming epidemic. Healthcare expenditure varies greatly between developed and developing regions, with Europe having spent US\$ 166 billion and North America and the Caribbean US\$ 377 billion, contrasting with African expenditure of US\$ 3.3 billion in 2017.¹⁰

Limitations

The information presented in the study is reflective of patients accessing healthcare at the selected study site and may not be representative of the general diabetes population. Due to the descriptive nature of the data, it was not possible to determine the specific impact of variables such as medication change over time. Nevertheless, the data provide some valuable insights into diabetes management in Africa.

Conclusion

With continued urbanisation it is estimated that, by 2045, 40.7 million people will be living with type 2 diabetes in Africa.⁴ With limited resources and a growing epidemic it is therefore imperative that resources are appropriately distributed to early detection and more intensive glycaemic control.

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