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RESEARCH ARTICLE

Suboptimal control and failure to intensify therapy for South Africans with type 2 diabetes: an audit of diabetes management at primary health care facilities

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Background: The management of people living with type 2 diabetes (T2D) in primary care in a South African district was audited, focusing on glycaemic, cholesterol, and blood pressure (BP) control to identify gaps in care and evidence of clinical inertia.
Methods: A cross-sectional retrospective review was conducted of medical records belonging to patients with T2D seen at 23 primary health care facilities between February and May 2019. Fieldworkers collected patient demographics, BP, laboratory measurements such as HbA1c (two most recent values), total cholesterol (TC) and LDL cholesterol (LDL-C), and which glucose-lowering drug each patient was on, as well as the dosage.
Results: The mean (SD) age of patients was 58 (11.8) years and 64% of them were women. Most patients had hypertension (83%) and were using statins (78%). Most patients (46%) were on second-line therapy and less than a quarter of patients were on insulin (22%). Only 23% (CI: 18.9–27.9%) of patients met the HbA1c target of < 7% with a mean HbA1c of 8.8%. Over half of patients (56%) had achieved the BP target (< 140/90 mmHg) and only 15% (CI: 8.1–23.9%) of the 88 patients with LDL-C values met the LDL target. Healthcare providers failed to intensify oral treatment for most patients who had suboptimal glycaemic control, and most patients who were on maximum oral drugs were not initiated on insulin.
Conclusions: In most patients, diabetes control targets were not met, and treatment was not intensified when needed, suggesting clinical inertia.

Keywords: clinical inertia, cross-sectional audit, glycaemic control, primary care, type 2 diabetes

Introduction

Diabetes mellitus is a complex, metabolic disorder characterised by chronic hyperglycaemia that affects millions of people worldwide. In recent years, the number of people living with type 2 diabetes (T2D) in South Africa has increased. Currently, one in four South Africans older than 45 years has diabetes.[1] The 2021 International Diabetes Federation (IDF) report estimates that 4.2 (1.7–4.6) million South African adults live with diabetes.[2]

Type 2 diabetes is a progressive condition characterised by declining β-cell function and increasing insulin resistance. Most people living with T2D ultimately require intensification of treatment to maintain glycaemic control. Maintaining glycaemic control, as achieved in part by adhering to treatment, is the goal for both patient and healthcare provider alike. Ideally, diabetes management should include regular patient reviews and periodic adjustments of treatment regimens to achieve glycaemic targets. International trials demonstrate that glycaemic control is important for preventing or delaying both acute and long-term diabetes-related complications.[3] With more treatment options becoming available, T2D management is moving away from a "one-size-fits-all" approach and toward individualised treatment regimens based on particular patient needs.[4] International guidelines advocate for early intensive control and the need to individualise both treatment targets and strategies, emphasising person-centred care and shared decision-making.[5,6] Current practice guidelines recommend lifestyle and dietary modifications, usually followed by metformin monotherapy, then adding an increasingly complex array of therapies, including oral and injectable medications.[7] Diabetes management also includes managing cardiovascular disease risk factors such as hypertension and high blood cholesterol with a healthy diet, sufficient physical activity, and appropriate medication.

Despite the large body of evidence supporting intensive blood glucose control, many patients with T2D are not on appropriate therapy and continue to experience suboptimal glycaemic control.[8] Numerous studies have linked suboptimal glycaemic control to healthcare professionals not intensifying therapy when appropriate, also called clinical inertia.[9,10] In South Africa, people living with T2D are often suboptimally managed despite the wide distribution of evidence-based guidelines by the Society for Endocrinology, Metabolism and Diabetes South Africa (SEMDSA).[11,12] Most South Africans with T2D are managed at the primary care level, where the standard of care is inadequate; only 10–30% of patients in the public health system achieve glycaemic control or an HbA1c of < 7.0%.[11,13]

South Africa currently does not have a diabetes registry, making it difficult to measure diabetes outcomes, monitor the quality of diabetes care, and assess the value of therapies and efficacy of treatment models in clinical practice.[14] Without this information, local and national health authorities struggle to

prioritise resources, target interventions, and benchmark progress in scaling up comprehensive diabetes treatment. Cross-sectional studies, despite their limitations, constitute the only source of information in South Africa on the implementation and quality of diabetes care. A previous study in the Tshwane district found that diabetes care and screening for complications was suboptimal and recommended that new models of care be adopted.[13] This study was conducted a decade ago and there are currently no data on whether any progress has been made or whether the gaps in care still exist.

We audited the management of people living with T2D in primary care in the Tshwane district, Gauteng province, South Africa, focusing on glycaemic control and the management of cardiovascular risk factors, hypertension, and hypercholesterolemia to identify gaps in care and evidence of clinical inertia.

Methods

Study design

This study was a descriptive cross-sectional study. We retrospectively reviewed the medical records of patients who attended primary care clinics in the Tshwane district of Gauteng between February and May 2019.

Study setting

We audited the medical files of T2D patients attending 23 primary health care facilities including 20 clinics and 3 community health care centres, approximately a third of the 79 primary care facilities in the Tshwane District. The Tshwane District is situated in the northern part of Gauteng Province in South Africa.

In South Africa, most people with T2D receive routine care at state-funded primary care clinics where they see a health professional at least four times per year. A stepwise approach for managing T2D is outlined in the "Primary Healthcare Standard Treatment Guidelines and Essential Medicines List of South Africa".[15] The guidelines focus on nurse-initiated treatment and recommend that doctors and nurses use the metformin–sulphonylurea–insulin strategy to achieve glycaemic control for their patients. When diagnosed, the person living with T2D starts with metformin (Step 1). An additional oral glucose-lowering drug, namely sulphonylureas, is added to metformin if the haemoglobin A1c (HbA1c) target is not achieved (Step 2). Insulin is introduced in Step 3 with metformin if HbA1c persists above target despite adherence to oral agents, and sulphonylureas are discontinued. The guidelines recommend blood tests to monitor and optimise control, including HbA1c, serum creatinine, and blood lipids (total cholesterol [TC] and LDL cholesterol [LDL-C]).

Data collection

Data were retrospectively extracted from patient medical records. Trained fieldworkers used a data extraction sheet designed in Qualtrics (Qualtrics, Provo, UT, USA) to collect data. Using consecutive sampling, they selected the first 10–15 medical records of adults with T2D at each facility. In our study, a person with T2D was defined as a person older than 18 years old and who had "type 2" written in their records or had evidence of being prescribed an oral glucose-lowering drug or insulin. We only included the files of people with T2D who had attended clinics at least twice in the previous 12 months.

Measurements

Fieldworkers collected patient demographics (age, gender, ethnicity), BP measurements, laboratory measurements such as HbA1c, TC, and LDL-C, and pharmacological treatment prescribed. Where indicated, the fieldworkers also recorded whether the patients had hypertension.

Fieldworkers recorded the two most recent consecutive HbA1c readings, with an average of 12 months between the HbA1c measurements. Fieldworkers also noted the glucose-lowering drug the patient was currently on, as well as the dosage. Fieldworkers noted any treatment adjustments, which were defined as any increase in dosage of a particular drug or addition of a second drug.

Statistical analysis

Data were analysed using STATA version 17BE (StataCorp LLC, College Station, TX, USA). Patient characteristics were summarised using descriptive statistics. Categorical variables are reported with frequencies and percentages. Continuous variables are reported with means and standard deviations or medians and interquartile ranges. The proportion of patients who met the treatment goals is reported with 95% confidence intervals.

To analyse prescription patterns, we considered patients who were on oral medication and their two most recent consecutive HbA1c readings. Any patient whose first HbA1c was greater than 7% was "suboptimally controlled". We then recorded any treatment adjustments, whether healthcare professionals intensified treatment or missed an opportunity to intensify/failed to intensify. We then considered the second HbA1c and recorded if HbA1c decreased, increased, or remained the same.

For reference, we used the targets set out by the 2017 SEMDSA Guidelines for the Management of T2D.[11] The HbA1c target was 7% or lower.[11] The BP target was BP < 140/90 mmHg. Targets for cholesterol were as follows: TC < 4.5 mmol/l; LDL-C < 1.8 mmol/l.[11]

Ethical considerations

The study was approved by the University of Pretoria's Faculty of Health Sciences Research Ethics Committee (Ethics Reference: 496/2018) and the Tshwane Research Committee (NHRD Number: GP_201810_049). Access to medical records was granted by the custodians of the data, namely the district health authorities and facility managers.

Results

We audited 479 medical records of people with T2D at 23 primary health care facilities. The participant characteristics are summarised in Table 1. The mean (SD) age of the patients was 58 (11.8) years with a median duration of T2D of 5.5 years, and 64% were women. Over half of the patients had HbA1c above 8% and a quarter had HbA1c greater than 10%. Hypertension was common (83%) in this sample of patients. A total of 375 (78%) people with T2D were receiving statins for dyslipidaemia. Most patients (46%) were on second-line therapy with sulphonylureas with or without metformin, while less than a quarter of patients (22%) were on insulin.

Of 479 patients, 346 (72%) patients had HbA1c measurements for the previous year (Table 2). Blood pressure was recorded for 99% of patients at their most recent clinic visit. Only 18% of patients had had an LDL-C test in the previous year. Of the

Table 1: Demographics and clinical characteristics of a population of patients with type 2 diabetes in the Tshwane district ($N = 479$), February to May 2019

Patient characteristics	*n* (%)
Gender	
Women	305 (64.0)
Men	174 (36.0)
Age (years)	
Mean (SD)	58.0 (11.8)
28–50	127 (27.0)
51–65	221 (46.0)
> 65	129 (27.0)
Ethnicity	
African	419 (89.0)
Other*	54 (11.0)
Duration of diabetes (years)	
Median (IQR)	5.5 (3.0–9.0)
HbA1c categories	
≤ 8%	167 (48.0)
8–10%	92 (27.0)
> 10%	87 (25.0)
Current glucose-lowering treatment	
Step 1: metformin only	153 (32.0)
Step 2: SU with/without metformin	219 (46.0)
Step 3: Insulin with/without metformin/SU	107 (22.0)
Statins	375 (78.0)
Hypertension	397 (83.0)

Other = White, Coloured, and Asian/Indian; SU = sulphonylureas.

patients who had HbA1c measurements, only 23% (CI: 18.9–27.9%) met the 2017 SEMDSA target of HbA1c < 7% with a mean glycated haemoglobin of 8.8%. Only 56% (CI: 51.5–60.6%) of the patients achieved the BP target; 65% (CI: 60.4–69.2%) and 85% (CI: 81.6–88.2%) met the targets for systolic and diastolic BP, respectively. More than half of the patients met their TC target (59%, CI: 53.7–64.5%), but only 15% (CI: 8.1–23.9%) of the 88 patients with LDL-C values met the LDL-C target.

Of the 479 medical records reviewed, 372 (77.7%) people were on oral glucose-lowering therapy (metformin and/or sulphonylureas). Of those 372, 85 (22.8%) had two recent consecutive HbA1c readings, and 53 of the 85 were suboptimally controlled. In Table 3, we report the treatment adjustments made for those 53 patients, the change in HbA1c, and whether the patients were on maximum oral doses and should have been considered for insulin initiation. In most cases, healthcare providers failed to intensify oral treatment when indicated. Ten patients who had their treatment adjusted and 36 patients (83.7%) who did not have any treatment change had HbA1c > 7%. The second HbA1c reading of most patients remained above the HbA1c target, irrespective of treatment adjustments. Twenty-two patients were on maximum oral doses and their HbA1c readings remained above the target.

Discussion

The results of this audit show that diabetes management in the Tshwane district was suboptimal. Many patients did not meet the targets for blood glucose, BP, and lipid control. Monitoring was satisfactory for BP (99%), HbA1c (72%), and TC (70%), but poor for LDL-C (18%). Patients who were on insulin were less likely to have glycaemic control and therapy was not being intensified when indicated. We identified missed opportunities for insulin initiation in T2D patients who were suboptimally controlled on maximum oral drugs.

Most South Africans with T2D are cared for at the primary health care level. The care received by these patients has historically been sub-standard and falls short of targets.[11] Healthcare providers are known not to implement the recommended processes of care and fail to conduct essential assessments such as HbA1c and lipid testing, especially LDL-C.[12,16] Similar trends were observed in this audit, with the exception of HbA1c testing. Approximately three-quarters of patients in our sample recorded an HbA1c test in the past 12 months. The poor monitoring of LDL-C may denote a lack of awareness among healthcare providers that LDL-C is the primary target of lipid-lowering therapy, e.g. statins, which reduces the risk of major cardiovascular events.[11]

In this audit, only 23% of patients achieved the HbA1c target. This is in line with findings from previous studies conducted in various primary healthcare settings in South Africa, with the lowest proportion of patients who achieved optimal glycaemic control being 8.6% and the highest 27.0%.[1,12,13,16] The mean HbA1c reported in this study was similar to the mean HbA1c reported by Webb *et al.*[13] who audited the quality of diabetes care at 12 primary healthcare clinics in the Tshwane district a decade ago. Recent studies conducted in Cape Town reported similar HbA1c.[1,17] These findings may suggest that a metformin–sulphonylurea–insulin strategy is not effective in the

Table 2: Diabetes control parameters and proportion that reached the SEMDSA targets in a population of patients with type 2 diabetes in the Tshwane district ($N = 479$)

Diabetes control parameters	Tests done, *n* (%)	Proportion reaching target (%)	95% CI (%)	Mean (SD)	Range (Min.–Max.)
HbA1c (%)	346 (72)	23	18.9–27.9	8.8 (2.4)	2.7–18.9
Lipids (mmol/L)					
LDL cholesterol	88 (18)	15	8.1–23.9	2.7 (1.0)	0.7–6.5
Total cholesterol	333 (70)	59	53.7–64.5	4.3 (1.0)	1.31–10.3
Blood pressure BP (mmHG)					
Systolic	476 (99)	65	60.4–69.2	134.4 (18.2)	74–197
Diastolic	476 (99)	85	81.6–88.2	79.5 (11.1)	31–124
Combined	–	56	51.5–60.6		

A greater proportion of people with T2D on insulin (86%, $n = 76$) and on sulphonylureas (83%, $n = 129$) did not meet the SEMDSA target for glycaemic control compared with the proportion of people on metformin only (60%, $n = 61$) ($p < 0.001$).

Table 3: Treatment adjustment and change in HbA1c in suboptimally controlled patients on oral glucose-lowering therapy with two consecutive HbA1c

Factor	Second HbA1c < 7% (*n* = 7)	Second HbA1c ≥ 7.1% (*n* = 46)	*p*-value
Treatment adjustment, n (%)			
Intensified	0	10 (100.0)	0.171
Failed to intensify	7 (16.3)	36 (83.7)	
HbA1c change, *n* (%)			
Decreased	7 (20.0)	28 (80.0)	0.126
Increased	0	16 (100.0)	
Stable	0	2 (100.0)	
Doses, *n* (%)			
On maximum	0	22 (100.0)	0.017
Not on maximum	7 (22.6)	24 (77.4)	

South African primary care setting because many patients do not meet the SEMDSA HbA1c target of < 7%.[11]

The SEMDSA guidelines also stipulate targets for BP, the management of which may be the most critical aspect of diabetes care.[18] Hypertension is common in adults with T2D, with nearly three-quarters either having BP levels > 130/80 mmHg or being on antihypertensive medication.[18] Hypertension is a common cardiovascular comorbidity in South Africans living with T2D,[1,16] as was the case in our study. In our sample, more than half of the participants had controlled BP (< 140/80 mmHg) based on their last clinic measurement. A previous study conducted in 2017 at a community health centre in Johannesburg reported lower achievement rates (22%).[12] In South Africa, suboptimal BP control may be attributed to different factors including poor compliance with guidelines,[19] inadequate treatment,[12] clinical inertia,[20] and patient factors such as low self-efficacy and lack of knowledge.[21]

This audit also revealed that lipid control was suboptimal in this group of patients with T2D. The mean LDL-C was similar to levels reported by Webb *et al*.[13] Even though mean LDL-C was similar, fewer patients in our study achieved their LDL-C target (15%) compared with a decade ago (26%).[13] This finding is unexpected because a large proportion of people in our study were using statins (78%), which was relatively high compared with other settings (25.6%).[12] Previous studies have suggested that LDL-C targets are easier to achieve than HbA1c and BP.[22] Not achieving LDL-C targets has been attributed to not adhering to medication or guidelines, unavailability of drugs due to formulary restrictions or stock shortages, or primary health care providers relying too heavily on lifestyle modifications to treat dyslipidaemia.[23] Dyslipidaemia should be treated aggressively in patients with diabetes.[11] Simvastatin 10 mg is currently the only statin available to patients in South African clinics.[15] Higher doses of statins or the use of more potent statins might be necessary in primary care to ensure that South African patients meet their LDL-C target.

South Africans with T2D are managed by primary health care providers using a stepwise approach.[15] In our sample, three out of 10 patients were on first-line glucose-lowering therapy, namely metformin, five out of 10 were on second-line therapy, and two out of 10 were on insulin therapy. Owolabi *et al*.[24] reported similar figures, with 79.3% of participants on oral medication and 12.6% on insulin. In South Africa, sulphonylureas are commonly prescribed as second-line therapy either alone or in combination with metformin, most likely reflecting limited access to newer and potentially more costly medications.

We found that patients who were on insulin were less likely to have glycaemic control. This has been previously reported in primary care in South Africa.[13,16] This could be explained by various factors including patient, provider, or system factors. Most patients on insulin cannot adjust their insulin doses themselves because they lack training or they do not have the necessary glucose monitoring devices and strips.[25] Suboptimal glycaemic control in these patients may also be caused by poor insulin injecting technique or clinical inertia by primary health care providers, who fail to adjust insulin as necessary.[12]

Our audit suggested a high level of clinical inertia. In our study, healthcare professionals did not intensify oral glucose-lowering therapy despite patients having HbA1c levels well above the target. In South African hospitals, clinical inertia has been posited as a strong driver of suboptimal glycaemic control.[20] In the Tshwane district, an expert panel reviewed the management and care of T2D patients and reported that 69% of patients should have been initiated on insulin but were not, and that 44% of patients stayed on the same dose of insulin despite requiring a higher dose of insulin.[26] Previous South African studies also reported that most people with T2D who require insulin remained at suboptimal glycaemic levels because glucose-lowering medications were rarely changed and insulin was not being prescribed.[27] Patient factors may also play a role in the failure to initiate insulin. Recent studies conducted in the Tshwane district demonstrated that people living with T2D were reluctant to accept insulin for glycaemic control because they were afraid of injecting themselves or not ready to make such a big lifestyle change.[28,29]

Limitations

Healthcare facilities were conveniently selected, but the large sample size and the spread of patients over 23 primary health care facilities can be counted as strengths of this study. The cross-sectional design reflects only a single time point, but these results can be compared with previous studies and act as a baseline for future studies. Primary care facilities did not have electronic data systems, which impeded data collection and limited the number of medical records that could be included in our analysis. Data collection was further limited by the poor quality of medical records, which is common in this setting.[12] We could have underestimated healthcare professionals' compliance, especially if they provided care that was not documented.[16] We did not assess patient non-adherence as a factor of clinical inertia.

Clinical inertia is a multifactorial problem that requires provider-related, patient-related, and health-system-related factors to be addressed together.[30] Further investigations should identify which barriers contribute to clinical inertia in the South African primary care system as well as strategies to overcome it. Patient education concerning the progressive nature of T2D and the risks inherent in long-term suboptimal glycaemic control may reinforce the need for regular treatment reviews, with intensification of therapy when required.[7,18]

Conclusions

In conclusion, we found that the proportion of patients with T2D who achieved recommended HbA1c, BP, and LDL-C levels in the Tshwane district has remained stagnant over the past decades. Patients attend clinic visits regularly, yet they experience prolonged periods of hyperglycaemia and are exposed to potential long-term complications. New strategies could include: (1) adopting individualised patient-centred management with no restriction on the choice of glucose-lowering drugs, (2) addressing clinical inertia and the failure to intensify therapy when indicated, and (3) building a health system that caters for the needs of South Africans with diabetes.

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