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ARTICLE

Pilot study involving the use of point-of-care glycated haemoglobin (HbA1c) testing for screening and monitoring of diabetes mellitus in the public healthcare sector in KwaZulu-Natal

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Background: The diabetes pandemic continues to cause both patient and economic burden. Globally, strategies to improve glycaemic control in patients with diabetes are highly sought after. One such strategy involves the use of point-of-care glycated haemoglobin (POCT HbA1c) testing, which provides clinicians with rapid information on glycaemic control and also may assist with a diagnosis of diabetes in others.
Methods: This pilot study was conducted over three months (December 2019–February 2020) at 21 KwaZulu-Natal (KZN) public healthcare facilities. All patients presenting to the triage units of these facilities had their diabetic history taken and POCT HbA1c, together with their random blood glucose, tested and recorded by nursing staff. These data were forwarded to the Department of Health.
Results: A total of 3 541 patients were included in study, 1 306 with diabetes and 2 235 with no prior diabetes history. The median (+IQR) HbA1c% achieved in the diabetes cohort was 6.0 (5.2–8.1) with 32.39% of these patients not achieving target glycaemic control (HbA1c < 7%). This study revealed that a significant proportion of the patients with no history of diabetes mellitus (DM) had evidence of diabetes (HbA1c > 6.5%) and pre-diabetes (HbA1c 5.7–6.4%) (45.59% vs. 19.5%, respectively). A total of 361 (16.51%) of these asymptomatic patients with no history of DM had random blood glucose levels of ≥ 11.1 mmol/l. There were significant inter-facility differences noted with regard to the number of patients with diabetes achieving target glycaemic control.
Conclusion: This study found that at least one-third of diabetes patients attending these KZN healthcare facilities had sub-optimal control. There was a significant percentage of patients without prior history of DM who had glycaemic levels suggesting dysglycaemia (pre-diabetes and overt diabetes). The Government needs to heed the results of such studies to develop strategies targeting this group of previously undiagnosed diabetes patients. HbA1c point-of-care testing provides one avenue of intervention for both groups of patients.

Keywords: diabetes mellitus, diagnosis, KwaZulu-Natal, monitoring, pre-diabetes, point-of-care HbA1c testing, public healthcare facilities, screening, target glycaemic control

Introduction

Diabetes mellitus (DM) remains one of the leading causes of death globally among non-communicable diseases.[1] Strategies to improve glycaemic control are highly sought after, especially in developing countries where the combination of communicable and non-communicable diseases is wreaking havoc on both patients' health and the economy of these countries.[2] This interaction has been highlighted in the current COVID-19 pandemic where it has been shown that DM as a co-morbidity is a major risk factor for both developing complications and increased overall patient mortality.[3]

Glycated haemoglobin (HbA1c) is a useful test for monitoring of DM. The advantage of glycated haemoglobin testing is that it does not fluctuate considerably and can therefore be performed at any time of the day. This removes the need for pre-test patient fasting or glucose loading as is required for oral glucose tolerance (OGTT) and fasting plasma glucose (FPG) testing. Another benefit of HbAc1 testing is that it provides better reproducibility than glucose testing. Although immediate HbAc1 results are vitally important for both therapeutic and lifestyle interventions, this test is often reviewed only months later in our busy public healthcare facilities, thereby increasing the risks of diabetes-related complications in the form of amputations, kidney failure and blindness. Point-of-care testing (POCT) for HbA1c provides one avenue to help improve overall diabetes care and control. In a previous study conducted by Pillay *et al.* at Edendale Hospital, Pietermaritzburg it was shown that these HbA1c POCT devices correlate well with laboratory results and that patients who have HbA1c POCT had overall better glycaemic control.[4] More recently, a study by Tollanes *et al.* conducted in Norway showed that patients consulting general practitioner offices where HbA1c POCT was done also had improved diabetes control.[5]

The debate on the utility of HbA1c as a tool for diagnosing DM and pre-diabetes is ongoing. Briker *et al.*, in their study conducted with an American immigrant African population, stated that the OGTT was the preferred method for diagnosis of DM but also went on to state that HbAc1 diagnosed significantly more patients with pre-diabetes than OGTT. They, as have other studies, suggested that combining HbAc1 with either a fasting plasma glucose (FPG) or glycated albumin would increase sensitivity for diagnosis of DM.[6–8] Similarly, Kenge *et al.*, in their study conducted in South Africa, concluded that a combination of HbAc1 with either fructosamine or OGTT would improve detection of dysglycaemia.[9] A study conducted by Sumner *et al.* found that the sensitivity of HbAc1 testing

was superior to FPG and that combining these tests would increase sensitivity further in black patients.[7] In contrast, FPG was shown to be superior to HbA1c testing in white American patients in a study conducted by Lorenzo *et al*.[10]

The combination of TB and DM in South Africa presents another management conundrum. Mcebula *et al*. found in their study conducted in Johannesburg that HbA1c testing for DM diagnosis in patients with TB yielded a much higher prevalence of DM than when using OGTT. They recommended that the OGTT be used as the standard for diagnosis of DM in patients infected with TB.[11] Another study conducted in Cape Town by Oni *et al*. found a much higher prevalence of newly diagnosed DM and impaired glucose regulation in patients with TB when utilising HbA1c compared with OGTT or FPG levels They postulated that the HbA1c cut-off level of 6.5% was too high and that a value of 6.0% should be used, as was also suggested by the Durban Diabetes Study.[12,13]

In contrast, Rathod *et al*., in their study conducted in Malawi, concluded that HbA1c as a stand-alone test was highly predictive for diagnosis of type 2 DM but less so for impaired fasting glucose.[14] Other studies from Uganda and South Africa, like those done in East Asia, Europe and the Middle East, have demonstrated that HbA1c is an effective test for DM detection across various ethnic groups.[13,15–18] Results from a metanalysis of studies conducted in 38 countries found that HbA1c had a high specificity but a low-to-moderate sensitivity for detection of DM.[19] The Durban Diabetes Study, conducted with Black South African patients, found that the sensitivity of HbA1c testing for DM detection was higher in their study. They suggested lower cut-off HbAc1 values for diagnosis of DM, which would increase the sensitivity of the test whilst retaining its high specificity. Hird *et al*. further concluded that the prevalence of DM remained similar irrespective of whether the OGTT, FPG or HbA1c testing was being used.[13]

One of the concerns associated with the utilisation of HbA1c testing is the possibility of underlying haemoglobin variants within patients, which could theoretically alter HbA1c values. These variants are usually common in black patients. Sumner *et al*. recently showed in their study conducted with African American patients that neither HbA1c nor two-hour glucose was affected by haemoglobin variants.[7] This bodes well for the use of HbA1c testing in black African patients. Despite having excellent national diabetes guidelines, we are still not achieving optimal diabetes control.[20,21] Pillay *et al*. have also shown in KZN that the bulk of diabetes patients are being diagnosed and have their treatment initiated at their local clinic level.[22] Amongst the Government's key strategic priorities should, then, be to boost diagnosis and treatment at this healthcare level. One such method would be the introduction of HbA1c POCT at this level.

The International Diabetes Federation (IDF) has estimated that over 460 million people have diabetes globally. They have further qualified that this figure does not include the almost 77% of undiagnosed patients with diabetes living in Africa.[1] Late diagnosis of DM almost ensures that these patients already have some or all of the diabetes-related complications. It is these complications that weigh heavily on the economy of any country. Early diagnosis is a must, and point of care HbA1c testing may provide a means to detect and treat diabetes earlier. The current American Diabetes Association (ADA) recommendation for diagnosis of DM is a random HbA1c of > 6.5%.[23] According to local South African diabetes guidelines, two HbAc1 measurements done three months apart would be needed to make a definite diagnosis of DM. This second HbA1c reading was proposed locally, amongst other reasons to counteract the high South African prevalence of HIV infection and the associated rapid red blood cell turnover in these patients.[24] Ekoru *et al*., in their study evaluating DM and its complications in sub-Saharan Africans, pointed out that there is an urgent need for enhanced public healthcare strategies and stressed the importance of early detection of DM.[2]

It is with the above in mind that this pilot study was designed to assess the utility of HbA1c POCT at a far larger scale than Pillay *et al*. undertook at Edendale Hospital to both monitor glycaemic control and screen for DM.[4]

The purpose of this descriptive study was to assess the glycaemic control achieved in patients (both known and unknown with DM) who attended 21 of KZN's public healthcare facilities between December 2019 and February 2020. Although a definite diagnosis of DM could not be made on our patients as these were only single visits, the study aims to highlight the importance of screening patients and then making appropriate referrals for re-testing with a combination of either HbA1c ± FPG or OGTT.

Method

This pilot study was conducted over a period of three months (December 2019–February 2020) within the 21 KwaZulu-Natal public healthcare facilities listed in Table 1.

Relevant nursing staff representatives from these healthcare facilities received in-service training on the use of these handheld portable HbA1c POCT devices and record keeping as illustrated below.

Patients who attended the medical outpatient departments in these facilities had, as part of their routine triage investigations, their HbA1c POCT and random blood glucose (RBG) tested on the BioHermes® handheld POCT device (Wuxi BioHermes Biomedical Technology Co, Jiangsu, China). This machine adopts Boronate Affinity Chromatography to measure the HbA1c level and is National Glycohaemoglobin Standardisation Programme (NGSP) accredited. The HbA1c analysis is traceable to the IFCC reference measurement procedure and the Diabetes Control and Complications Trial (DCTT) reference method. This point-of-care device has a reported coefficient of variation (CV) of < 3%. No significant interference from haemoglobin variants was demonstrated in product analytic comparisons. Results from an analytic comparison between the BioHermes® HbA1c point-of-care testing

Table 1: Healthcare facilities involved in the pilot project

	Name of facilities		Name of facilities
1.	Bruntville CHC	12.	KwaMashu CHC
2.	Caluza Clinic	13.	Mpophomeni Clinic
3.	City Central Clinic	14.	Northdale Clinic
4.	Crammond Clinic	15.	Nxamalala Clinic
5.	East boom Clinic	16.	Pata clinic
6.	Edendale Hospital	17.	Richmond Clinic
7.	Gcumisa Clinic	18.	Sondelani Clinic
8.	Gomane Clinic	19.	Songonzima Clinic
9.	Imbalenhle CHC	20.	Stanger Hospital
10.	Injabulo Clinic	21.	Taylors Clinic
11.	Khan Road Clinic		

device and standard laboratory showed strong correlation for both HbA1c ($r = 0.910$) and glucose ($r = 0.980$) values.

The data collected were recorded in datasheets by nursing staff as reflected below:

Name of clinic/hospital:

- Patient Folder (number)
- Is patient a known diabetic? (Y/N)
- POCT HbA1c (% reading)
- Glucometer reading (mmol/l)

These nurse representatives then faxed the datasheets weekly for the duration of the pilot study to the KZN Office for Non-Communicable Diseases to enable data capture.

Each healthcare facility received one portable HbA1c BioHermes®POCT device together with HbA1c and glucometer strips.

Poor control within the DM cohort was assessed as patients with an HbA1c% of greater than 7% as per South African Diabetes guidelines.[10] Within the cohort of patients without known DM, two categories were established as per the American Diabetes Association (ADA) guidelines. Those with HbA1c between 5.7% and 6.4% were classified as having impaired glucose control (pre-diabetes) and those with an HbAc1 of greater than 6.5% as having overt diabetes.[9]

The results captured were separated into screening (for those who were not known patients with diabetes) and monitoring (in those patients with known diabetes). Once this was done, the monitoring data were interrogated to provide a 'snapshot' of the current diabetes control achieved within these healthcare facilities situated in KZN. The screening data also provided a cursory glimpse into the prevalence of undiagnosed diabetes within our community.

Approval was sought and obtained from the following persons employed by the Department of Health for the conduct of this pilot project:

- Acting Head of Non-communicable diseases;
- Acting Deputy Director of District Health Services;
- Acting Chief Director Executive of Support Services;
- DDG, specialised services and clinical support;
- Chief Director of Infrastructure Development;
- KZN Head of Health in the Department of Health;
- Medical Managers of all relevant healthcare institutions.

Ethics approval was obtained from the University of KwaZulu-Natal Biomedical Research and Ethics Committee (BREC-1267/2020) and the Department of Health.

Categorical and continuous variables were documented as median + interquartile range (25–75% IQR). Numbers (n) and percentages (%) were expressed for categorical variables. Since data were non-parametric in nature, all data were log transformed. The results shown are back-transformed values. A p-value < 0.05 was used as indicator of significance. Data was analysed using the Statistical Package for the Social Sciences (SPSS) version 25 for Windows (IBM Corp, Armonk, NY, USA) and MedCalc (version 19.3.1, Ostend, Belgium).

Analysis and interpretation of the data will be made available to the Department of Health for use in motivating the deployment of these HbA1c POCT machines to all healthcare institutions within KZN and South Africa.

Results

A total of 3 541 patients were included into this study, of whom 1 306 (36.88%) patients were known to have diabetes mellitus (DM) while a further 2 235 (63.12%) patients had no prior history of DM.

Table 2 illustrates the differences in glycaemic levels between the groups of patients with and without DM. Both glycated haemoglobin and RBG levels were significantly poorer in the patients without DM ($p < 0.001$).

Table 3 illustrates that there were significant inter-facility differences in glycaemic levels. Importantly, it also demonstrates that patients with no prior history of DM fared poorer in terms of glycaemic levels in the majority of healthcare facilities.

Within the cohort of patients with DM there were 423 patients (32.39%) who had HbA1c values greater than 7%.

Significant correlation existed between the overall HbA1c and RBG readings (correlation, $r = 0.6953$; $p < 0.0001$) in the patients both with and without diabetes mellitus.

Table 4 demonstrates that in the cohort of patients without a history of DM there were a significant percentage of patients who fulfil the criteria for both pre-diabetes and overt diabetes mellitus when HbA1c was used as a diagnostic criterion.

Table 5 shows that if an RBG of ≥11.1 mmol/l is used as the criterion for diagnosis of DM, a significantly lower percentage (16.15%) of DM is detected.

Table 6 demonstrates that the areas situated around Edendale Hospital, Pata and Sondelani clinics proved to be communities needing targeted intervention strategies.

Among this cohort of 361 patients whose RBG was greater than 11.1 mmol/l, 349 (96.7%) also had an HbA1c ≥ 6.5%. This equated to a statistically significant correlation between HbA1c and RBG of 0.2926 ($p < 0.0001$) within this cohort of patients.

Table 7 provides a breakdown detailing the number and percentage of patients within each healthcare institution who failed to

Table 2: Differences in glycated haemoglobin and random blood glucose levels between the two cohorts

Factor	Patients with DM ($n = 1\,306$)	Patients not known to have DM ($n = 2\,235$)	p-value Mann–Whitney test
Median HbA1c (%) + interquartile range (IQR)	6.0* (5.2–8.1*)	6.3* (5.3–9.1*)	<0.001
Median random blood glucose + IQR	5.4* (4.7–6.7*)	6.0* (5.0–9.1*)	<0.001

* Indicates that data were log transformed and results are shown as back transformation.

Table 3: Numbers of patients and glycaemic levels achieved per healthcare facility

	Patients with no history of DM			Patients with known DM		
Name of healthcare facility	*n*	HbA1c% Median + IQR	Random blood glucose (RBG) (mmol/l) Median + IQR	*n*	HbA1c% Median + IQR	RBG (mmol/l) Median + IQR
1. Bruntville Clinic	106	6.2 (5.6–9.2)	5.45 (4.9–8.9)	16	5.65 (5.15–7.44)	5.35 (4.5–7.12)
2. Caluza Clinic	60	8.4 (6.35–10.1)	6.3 (5.4–10)	152	5.75 (5.1–7.2)	5.55 (4.8–6.85)
3. City Central Clinic	110	6.7 (5.6–8.5)	5.85 (5.1–8.6)	94	5.5 (5.1–6.7)	5.5 (4.8–6.3)
4. Crammond Clinic	111	6.2 (5.43–9.22)	6.1 (5.0–9.28)	24	5.3 (4.15–6.65)	5.45 (4.35–6.85)
5. East Boom Clinic	62	6.7 (5.9–8.0)	6.5 (5.8–8.2)	-	-	-
6. Edendale Hospital	126	10.35 (9.0–12.7)	10.2 (8.9–12.5)	61	6.1 (5.0–8.95)	5.7 (4.8–6.35)
7. Gcumisa Clinic	76	7.35 (5.8–9.9)	6.0 (5.1–9.6)	43	5.6 (5.0.13–7.2)	5.2 (4.82–6.62)
8. Gomane Clinic	141	6.1 (5.28–9.3)	6.1 (5.1–9.4)	27	5.5 (5.1–5.88)	5.0 (4.15–5.6)
9. Imbahlenhle Clinic	155	5.9 (5.0–7.5)	5.2 (4.3–8.28)	75	7.4 (5.4–10.08)	6.6 (5.00–8.95)
10. Injabulo Clinic	80	6.25 (5.6–7.2)	5.6 (4.8–7.65)	77	6.2 (5.3–7.25)	5.2 (4.55–6.2)
11. Khan Road Clinic	11	5.1 (4.15–9.18)	6.3 (5.95–7.1)	1	6.6 (6.6–6.6)	4.3 (4.3–4.3)
12. KwaMashu Clinic	105	5.3 (5.0–5.8)	5.0 (4.28–5.53)	101	5.6 (5.0–7.15)	5.6 (5.0–6.55)
13. Mpopomeni Clinic	63	6.7 (5.4–10.97)	6.4 (5.4–11.18)	-	-	-
14. Northdale Clinic	136	7.55 (5.6–9.85)	6.55 (5.15–9.25)	110	6.9 (5.5–8.8)	6.0 (5.1–9.2)
15. Nxamalala Clinic	60	6.0 (5.4–6.8)	5.85 (5.05–7.89)	27	5.3 (4.85–5.6)	4.9 (4.03–5.58)
16. Pata Clinic	147	8.9 (6.2–10.35)	8.7 (5.7–11.15)	30	7.2 (5.8–8)	5.15 (4.9–6.7)
17. Richmond Clinic	205	6.1 (5.38–7.13)	5.4 (4.8–6.43)	36	5.3 (4.6–5.7)	4.85 (4.3–5.6)
18. Sondelani Clinic	207	5.4 (4.9–6.68)	6.3 (5.0–9.8)	38	6.2 (5.5–8.4)	6.1 (4.9–7.1)
19. Songomiza Clinic	141	5.8 (5.2–7.85)	5.8 (5.0–7.83)	105	5.4 (5.0–6.2)	4.9 (4.3–5.95)
20. Stanger Hospital	2	5.95 (5.8–6.1)	4.2 (4.1–4.3)	237	7.5 (5.8–10.5)	5.6 (4.88–7.13)
21. Taylors Clinic	131	6.1 (5.43–7.3)	5.0 (4.6–6.18)	52	5.4 (5.2–6.1)	5.1 (4.3–5.65)

Table 4: HbAc1 distribution for patients without diabetes mellitus

HbA1c%	*n* (%)
≤ 5.7	781 (34.94)
5.7–6.4	435 (19.46)
≥ 6.5	1 019 (45.59)

Table 5: Random blood glucose distribution for patients without DM

RBG (mmol/l)	*n* (%)
≤ 11.1	1 874 (83.85)
≥ 11.1	361 (16.15)

meet required glycaemic levels in either cohort of patients. Further sub-analysis of all patients with no history of DM who had an HbA1c ≥ 5.7% revealed that the majority of healthcare facilities had more than half of their patients showing dysglycaemia.

Per facility analysis of number and percentage of patients with DM not achieving optimal glycaemic control (Figure 1) revealed the healthcare facilities/districts needing targeted intervention strategies.

Discussion

The cornerstone to decreasing the burden of diabetes-related complications lies in improving glycaemic control.[25] This is especially pertinent in Africa where, according to the 2019 IDF, there has been a 143% increase in the number of patients with DM and where three in every five people with DM remain undiagnosed.[1] In a recent study conducted by Ekoru *et al.* in sub-Saharan Africans, it was that shown that diabetes-related complications are weighing heavily on the African continent.[2] They further went on to conclude that there is an urgent

Table 6: Distribution of patients with RBG ≥ 11.1 mmol/l among the various healthcare facilities

Name of healthcare facility	RBG ≥ 11.1 mmol/l	
	n	%
1. Bruntville Clinic	13	3.6
2. Caluza Clinic	9	2.5
3. City Central Clinic	15	4.2
4. Crammond Clinic	23	6.4
5. East Boom Clinic	8	2.2
6. Edendale Hospital	49	13.6
7. Gcumisa Clinic	17	4.7
8. Gomane Clinic	27	7.5
9. Imbahlenhle Clinic	19	5.3
10. Injabulo Clinic	11	3.0
11. Khan Road Clinic	2	0.6
12. KwaMashu Clinic	5	1.4
13. Mpopomeni Clinic	16	4.4
14. Northdale Clinic	26	7.2
15. Nxamalala Clinic	11	3.0
16. Pata Clinic	37	10.2
17. Richmond Clinic	10	2.8
18. Sondelani Clinic	36	10.0
19. Songomiza Clinic	19	5.3
20. Stanger Hospital	0	0
21. Taylors Clinic	8	2.2

Table 7: Numbers and percentage of patients *not* meeting required glycaemic levels per healthcare facility

Name of healthcare facility	Patients with no history of DM				Patients with known DM	
	HbA1c% 5.7–6.4		HbA1c% > 6.5		HbA1c% > 7	
	n	%	*n*	%	*n*	%
1. Bruntville Clinic	29	6.67	45	42.5	5	31.3
2. Caluza Clinic	9	2.07	44	73.3	41	27.0
3. City Central Clinic	19	4.37	58	52.7	17	18.1
4. Crammond Clinic	19	4.37	51	45.9	5	20.8
5. East Boom Clinic	15	3.45	33	53.2	123	97.6
6. Edendale Hospital	0	0	122	96.8	25	41.0
7. Gcumisa Clinic	14	3.22	16	37.2	9	20.9
8. Gomane Clinic	36	8.28	58	41.1	4	14.8
9. Imbahlenhle Clinic	34	7.82	49	31.6	40	53.3
10. Injabulo Clinic	26	5.98	29	36.3	23	29.9
11. Khan Road Clinic	1	0.23	4	36.4	-	-
12. KwaMashu Clinic	20	4.60	13	12.4	23	22.8
13. Mpopomeni Clinic	10	2.30	33	53.4	75	55.1
14. Northdale Clinic	19	4.37	81	59.6	54	49.1
15. Nxamalala Clinic	15	3.45	20	33.3	2	7.4
16. Pata Clinic	14	3.22	103	70.1	16	53.3
17. Richmond Clinic	50	11.49	81	39.5	3	7.4
18. Sondelani Clinic	36	8.28	54	26.1	14	36.8
19. Songomiza Clinic	29	6.67	49	34.8	19	18.1
20. Stanger Hospital	2	0.46	0	0	131	55.3
21. Taylors Clinic	38	8.74	42	32.1	1	1.9

demand for novel public health measures to address the need for better glycaemic control and thereby decrease diabetes-related complications. Other recommendations made by Ekoru *et al*. for sub-Saharan Africa were, first, that we need earlier diagnosis of type 2 DM (T2DM) and, second, our healthcare systems need strengthening.[2] Point-of-care HbA1c testing might provide one such avenue to help with all of the above-mentioned suggestions made by Ekoru and colleagues for sub-Saharan Africa. Pillay *et al*. have shown previously in a smaller study that HbA1c POCT correlates well to standard laboratory values and patients who had POCT done for HbA1c fared better at three months when compared with those patients who had to wait for their HbA1c results at a later date.[4] In another study conducted at a KZN hospital, Govender *et al*. also suggested POCT HbA1c testing as a possible strategy to improve diabetes control.[26] Using diabetes-related amputations as a surrogate marker for diabetes control, Pillay *et al*. showed that the trend of such amputations was on the increase in KZN and hence it was therefore extrapolated that diabetes control in KZN was sub-optimal.[27]

Poor diabetes control translates into increased risk of diabetes complications.[25] Our study found that approximately one-third of patients with diabetes (32.39%) were not optimally controlled (HbA1c > 7%). Raccah *et al*. have shown that 24–54% of patients with T2DM globally have suboptimal control.[28] Various other studies conducted in both developed and developing countries, in both the public and private healthcare sectors, have shown a higher prevalence of sub-optimal diabetes control than was seen in our patient population.[20,21,26,29,30] Possible explanations for this occurrence would be that no data were collected from our study patients regarding age, duration of DM and race. A younger patient profile with DM for a minimal period of time will have different characteristics from that of older patients with DM for a longer duration. Additionally, these patients were triage patients and not necessarily the complex patients with DM, who are probably followed up at more structured diabetes clinics. Importantly, we also noted that within the entire diabetes population tested in our study that there were inter-facility differences with regard to number and percentage of patients not achieving optimal glycaemic control. In six of these facilities approximately half or more of their tested patients (ranging from 49.1% to 97.6%) were not achieving target HbA1c.

Another possible explanation for our findings of lower rates of sub-optimal control lies in the fact that our 21 healthcare facilities constituted a combination of either rural, semi-rural, urban or semi-urban settings. It has previously been shown that

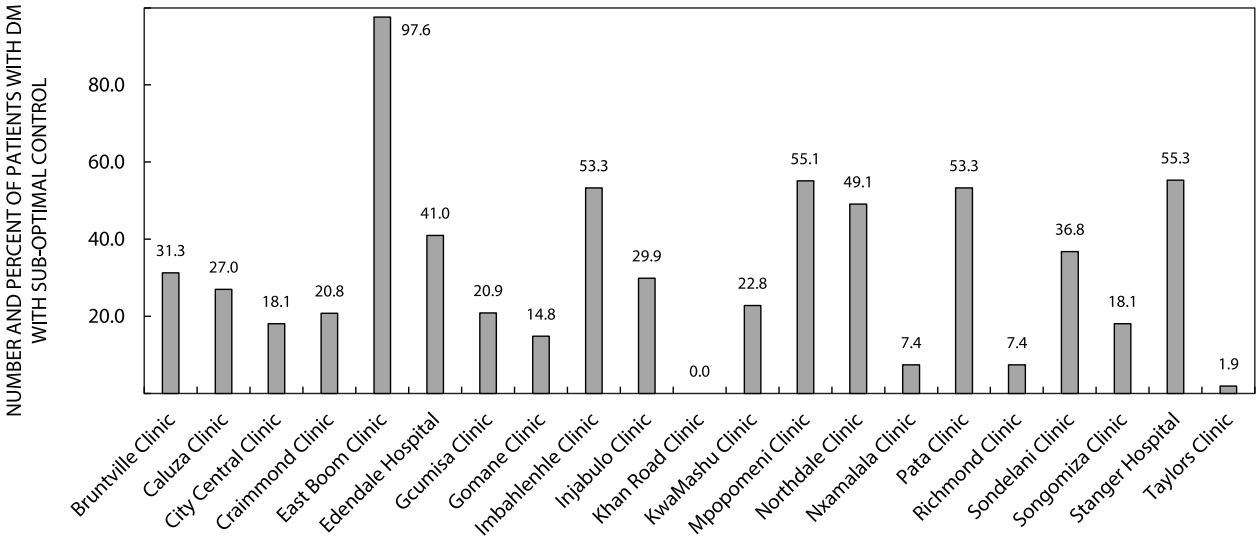

Figure 1: Sub-optimal glycaemic (HbA1c > 7%) control per facility amongst patients with diabetes mellitus.

glycaemic control differs from urban to rural settings. Reisig *et al*. showed in their study that social inequalities are revealed in glycaemic control.[31] Racial differences have also been shown to influence glycaemic control in both diabetics and non-diabetics, and type 1 and type 2 patients with DM globally.[32–34] In our study no record was made of the race of our patients and this could account for the somewhat higher percentage of patients achieving glycaemic control. In an era when improved diabetes control is being striven for, having at least one-third of our patients still being sub-optimally controlled is definitely not an ideal situation.

As mentioned in the introduction, much controversy still exists on the utility of HbA1c as a tool for the diagnoses of DM and pre-diabetes. Within the cohort of patients who had no history of DM we found that a significant proportion of these patients (45.59%) had a POCT HbA1c of greater than 6.5%. This finding is similar to figures supplied in 2019 by the International Diabetes Federation, which stated that one in every two adults with DM remain undiagnosed.[1] The American Diabetes Federation (ADA) uses an HbA1c value of greater than 6.5% as a definite diagnosis of diabetes mellitus.[23] However, South African local guidelines suggest two HbA1c values of greater than 6.5% in order to make a definitive diagnosis of DM. This is done as a precautionary step as South Africa has a high prevalence of HIV infection, a disease that could affect HbA1c readings due to rapid red cell turnover.[24]

When an RBG of ≥11.1 mmol/l was used as a diagnostic criterion for DM, we found that the prevalence of DM in our patients dropped from 45.59% to 16.15%. However, SEMDSA guidelines recommend using RBG ≥ 11.1 mmol/l as a diagnostic criterion only in symptomatic patients. In our study no symptoms were documented, hence using the RBG as a diagnostic criterion would result in inaccuracies. Importantly, it must be noted that 97.6% of the patients who had an RBG ≥ 11.1 mmol/l also had an HbA1c ≥ 6.5%. This demonstrates a strong correlation between the RBG and HbAc1 values in ranges required for diagnosis of DM.

Our study was designed to provide a 'snapshot' of current glycaemic levels in patients both with and without diabetes mellitus and hence is providing us with ample evidence that almost half of our patients without diabetes actually have HbA1c values of greater than 6.5%, thus needing further workup.

A further 19.5% of our patients fell into the pre-diabetes range (HbA1c between 5.7% and 6.4%). Our figure for pre-diabetes is significantly higher than that of the IDF 2019 figure of 8%. One possible explanation for this occurrence is the high prevalence of HIV infection in South Africa (13.4%) compared with Africa and globally.[35] Patients with HIV infection have been shown to have poorer glycaemic control.[36] Added to this cauldron of HIV infection, South Africa has also been recently reported to have the highest prevalence of obesity in females in sub-Saharan Africa.[37] Obesity is another possible reason for this higher rate of pre-diabetes as it is a known risk factor for the development of insulin resistance and ultimately overt diabetes mellitus.[38] Focused strategies need to be directed towards helping curb this phenomenon of undiagnosed pre- and overt diabetes within the South African population. HbA1c POCT provides one such avenue and deserves to be fully explored in larger prospective trials for both monitoring and diagnosis of DM.

Furthermore, per facility sub-analysis revealed that patients from certain facilities or districts fared poorer when compared with others in terms of glycaemic control. HbAc1 POCT devices have the ability to upload data wirelessly to a central database controlled by Department of Health Information Systems. As part of an integrated public healthcare strategy, data of this nature can be used by the Department of Health to identify areas or districts consistently attaining suboptimal control and target these districts or municipalities with focused interventions and thereafter to monitor prospectively the effects of any remedial action taken in these districts both in KZN and nationally.

Limitations of study

No demographics or medical history were collected for this study. The study was aimed at providing a snapshot of glucose control of patients consulting the medical outpatients of these public healthcare facilities. This was intended to mirror a real-life situation where data would be continuously and wirelessly captured via these HBA1c POCT devices if deployed at healthcare facilities throughout the provinces. These data would be used to determine and describe overall glucose control achieved both provincially and nationally. This would enable the Department of Health to identify and monitor poorly performing provinces, districts or municipalities that need intervention plans developed.

Another limitation of this study was that no history was obtained from patients regarding times of consumption of last meal. This offered us no insight into the two-hour postprandial glucose. The glucose readings in this study refer to random blood glucose levels and no fasting plasma glucose levels were done.

Conclusions

Our study demonstrated poor glycaemic control in the diabetes population within these public healthcare facilities. We found that a significant percentage of patients without prior history of DM had glycaemic levels highly suggestive of DM and pre-diabetes. The Government needs to heed results of such studies to develop strategies targeting this group of previously undiagnosed diabetes patients. HbA1c point-of-care testing provides one avenue of intervention.

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