Fasting plasma glucose and risk factor assessment: Comparing sensitivity and specificity in identifying gestational diabetes in urban black African women

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Background. Identifying women with gestational diabetes mellitus (GDM) allows interventions to improve perinatal outcomes. A fasting plasma glucose (FPG) level ≥5.1 mmol/L is 100% specific for a diagnosis of GDM. The International Association of Diabetes and Pregnancy Study Groups acknowledges that FPG <4.5 mmol/L is associated with a low probability of GDM.

Objectives. The validity of selective screening based on the presence of risk factors was compared with the universal application of FPG ≥4.5 mmol/L to identify women with GDM. FPG ≥4.5 mmol/L or the presence of one or more risk factors was assumed to indicate an intermediate to high risk of GDM and therefore the need for an oral glucose tolerance test (OGTT).

Methods. Consecutive black South African (SA) women were recruited to a 2-hour 75 g OGTT at 24 - 28 weeks' gestation in an urban community health clinic. Of 969 women recruited, 666 underwent an OGTT, and of these 589 were eligible for analysis. The glucose oxidase laboratory method was used to measure plasma glucose concentrations. The World Health Organization GDM diagnostic criteria were applied. All participants underwent a risk factor assessment. The χ^2 test was used to determine associations between risk factors and a positive diagnosis of GDM. The sensitivity and specificity of a positive diagnosis of GDM were calculated for FPG \geq 4.5 mmol/L, FPG \geq 5.1 mmol/L, and the presence of one or more risk factors.

Results. The prevalence of overt diabetes mellitus and GDM was 0.5% and 7.0%, respectively. Risk factor-based selective screening indicated that 204/589 (34.6%) of participants needed an OGTT, but 18/41 (43.9%) of positive GDM diagnoses were missed. Universal screening using the FPG threshold of ≥4.5 mmol/L indicated that 152/589 (25.8%) of participants needed an OGTT, and 1/41 (2.4%) of positive diagnoses were missed. An FPG of ≥5.1 mmol/L identified 36/41 (87.8%) of GDM-positive participants. The sensitivity and specificity of the presence of one or more risk factors were 56% and 67%, respectively. The sensitivity and specificity of FPG ≥4.5 mmol/L were 98% and 80%, respectively.

Conclusions. Universal screening using FPG ≥4.5 mmol/L had greater sensitivity and specificity in identifying GDM-affected women and required fewer women to undergo a resource-intensive diagnostic OGTT than risk factor-based selective screening. A universal screening strategy using FPG ≥4.5 mmol/L may be more efficient and cost-effective than risk factor-based selective screening for GDM in black SA women.

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The World Health Organization (WHO) estimates that 16% of pregnancies are affected by gestational diabetes mellitus (GDM) globally.[1] Although there is a paucity of data on South African (SA) women, GDM prevalences of 9.1% and 25.8% have recently been reported. [2,3] Identifying affected women allows interventions to improve perinatal outcomes.[4] Both screening strategies and diagnostic thresholds for GDM attract controversy. [5] The International Association of Diabetes and Pregnancy Study Groups (IADPSG) advocates universal screening for GDM, but the WHO recommends that screening strategies be based on disease burden and the availability of resources. [4,6] Risk factor-based selective screening for GDM is currently applied in SA.^[7] A selective screening strategy may fail to identify a high proportion of women affected by GDM.[8-10] In addition to being inadequate, this strategy is difficult to implement and women at risk may not be offered screening, even in well-resourced settings.[11,12]

An alternative to selective or universal application of the oral glucose tolerance test (OGTT) is universal screening using the fasting plasma glucose (FPG) level. According to the WHO 2013 recommendation,^[4] an elevated FPG of ≥5.1 mmol/L is 100% specific for a GDM diagnosis. However, the sensitivity of this diagnostic threshold varies between countries and ethnicities.^[13] The Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study group has suggested that 'in populations in which FPG is diagnostic in more than half of those with GDM, it may be reasonable to perform an accurately measured FPG as an initial step, reserving a full OGTT for those with a non-diagnostic FPG.[13] The IADPSG acknowledges the low probability of GDM and the low risk of adverse outcomes in the HAPO study cohort associated with FPG <4.5 mmol/L.[14] Women with an FPG <4.5 mmol/L are therefore at low risk of GDM and may not require an OGTT. Because women with an FPG ≥4.5 mmol/L are at intermediate to high risk for

GDM, they would require an OGTT. This FPG threshold has been suggested for use in low-resource settings, as it reduces the number of women requiring an OGTT. Use of this threshold would also avoid missed diagnoses in populations where the sensitivity of the FPG may be suboptimal or unknown.[14-16]

Objectives

To compare the utility of this universally applied dual FPG threshold, namely that ≥4.5 mmol/L indicates that formal screening is required and <4.5 mmol/L rules out GDM. The sensitivity and specificity were compared with the current standard practice of risk factorbased selective screening in identifying urban black African women affected by GDM.

Methods

Ethical considerations

The University of the Witwatersrand Human Research Ethics committee reviewed and approved the study protocols (ref. no. M150365). The Johannesburg District Department of Health granted permission to conduct this study in Soweto, Johannesburg (ref. no. 2015–16/031). All participants gave written informed consent.

Design

This cross-sectional, pragmatic, prospective study took place at a single urban community health clinic (CHC) between April 2016 and May 2017. Consecutive women were recruited at their first antenatal clinic visit. Women at <28 weeks' gestation were eligible for inclusion, and we excluded those aged <18 years and those known to have type 1 or type 2 diabetes mellitus. Gestational age was determined by the clinic nurse as part of usual care. There were no ultrasound facilities on site. Study procedures were conducted within the usual functioning of the antenatal service of the CHC.

Participants

Data gathered from all participants included risk factors for GDM as defined by the SA National Department of Health (NDoH).[7] These include maternal obesity (body mass index (BMI) ≥35 kg/m², which is WHO obesity class ≥II), maternal age ≥40 years, previous history of GDM, first-degree relative with diabetes mellitus, previous unexplained intrauterine fetal death, previous macrosomic baby, or complications in the current pregnancy including polyhydramnios, fetus large for gestational age or the presence of repeated glycosuria. [5] All participants in the study were of black African ethnicity, in keeping with this clinic's patient profile, so the NDoH risk factor of being of South Asian descent did not apply. Additional data collected included gestation at the first antenatal visit, parity, cigarette smoking, history of chronic hypertension, and blood pressure and mid-upper arm circumference measurements. [17,18] Participants were frequently unable to recall exact birth weights of their previous babies, so the terms 'small', 'average or 'large' were used instead, as was standard practice at this clinic.

Oral glucose tolerance test

All participants underwent a 2-hour 75 g glucose OGTT in the morning after an overnight fast at 24 - 28 weeks' gestation. Venous blood samples were collected in tubes containing the glycolytic inhibitor sodium fluoride (BD 454297), and samples were kept on ice ex vivo. The use of sodium fluoride tubes is included in the WHO-recommended OGTT procedure. [19] Typically, there are no on-site laboratories at CHCs in SA. All venous blood samples were delivered to the off-site laboratory, which was 14 km away, within an

hour of completion of the OGTTs. This research laboratory used the glucose oxidase method (RX daytona+; Randox Laboratories, USA) to determine plasma glucose concentrations. On request, the laboratory provided us with its quality control results. At mean glucose concentrations of 6.36 mmol/L and 15.80 mmol/L, the analytical coefficients of variation (CVs) were 1.85% and 1.67%, with a bias of 0.35% and 0.31%, respectively. These quality control results are within the recommendation of the American National Academy of Clinical Biochemistry (NACB) for laboratory measurements of plasma glucose (a CV of ≤2.9% and a bias of ≤2.2%). [20] Trained research staff operated independently from the CHC staff.

Clinical diagnostic criteria

The WHO 2013 diagnostic criteria, [4] which were endorsed by the Society of Endocrinology, Metabolism, and Diabetes of South Africa (SEMDSA) in 2017, $^{[21]}$ were used to define OGTT cut-offs for a positive GDM diagnosis. Only one plasma glucose abnormality in the 2-hour OGTT is necessary for a positive diagnosis of GDM. GDM is defined as a plasma glucose concentration of 5.1 - 6.9 mmol/L at fasting, ≥10.0 mmol/L at 1 hour of the OGTT or 8.5 - 10.9 mmol/L at 2 hours. Diagnostic thresholds for overt diabetes in pregnancy, which indicates probable preconception diabetes, are a plasma glucose concentration ≥7.0 mmol/L at fasting or ≥11.0 mmol/L at 2 hours of the OGTT. Participants diagnosed with overt diabetes or GDM were referred for clinical intervention.

Sample size

This analysis was part of a research study to assess the feasibility of implementing a universal screening, diagnosis and GDM lifestyle intervention programme in a low-resource urban setting.[22,23] We intended to identify 100 GDM-positive women for the purpose of participating in the GDM lifestyle intervention. Based on an estimated 16% global prevalence, 625 consecutive participants would need to be recruited.

Statistical analysis

Categorical variables were described as frequencies and proportions (%) and continuous variables as means and standard deviations (SDs). The χ^2 test was used to determine associations between categorical variables, especially between known risk factors and a positive GDM diagnosis. Fisher's exact test was used in cases where expected frequencies were <5. In this analysis, FPG thresholds were retrospectively used to indicate the need for an OGTT, and the categories were low risk (<4.5 mmol/L), meaning no need for an OGTT, and intermediate to high risk (≥4.5 mmol/L), indicating the need for a formal diagnostic OGTT to determine the presence and extent of dysglycaemia. The sensitivity, specificity, positive predictive values (PPVs), negative predictive values (NPVs), positive likelihood ratios (PLRs) and negative likelihood ratios (NLRs) for a positive GDM diagnosis were calculated for FPG ≥4.5 mmol/L and FPG ≥5.1 mmol/L as well as for the presence of one or more NDoHdefined risk factors for GDM. We also evaluated the utility of a modified NDoH-recommended risk score using BMI ≥30 kg/m² (obesity class I) rather than the standard BMI ≥35 kg/m² (obesity class ≥II).[21] A p-value <0.05 was assumed to be statistically significant, and 95% confidence intervals (CIs) are presented where appropriate. Statistical analyses were performed on STATA software version 15 (StataCorp LLC, USA). SAS version 9.4 software (SAS Institute Inc., USA) macro NLEstimate was used to compute modelbased 95% CIs for the likelihood ratios.

Results

Participants

Of the 1 270 women who attended the antenatal clinic over the 12-month recruitment period of the study, 969 (76.3%) were willing and eligible to participate. Of the 666 participants who had an OGTT, 589 had a complete data set that was submitted for analysis. The number of women recruited and the reasons for the attrition of participant numbers before data analysis are presented in Fig. 1. Overt diabetes mellitus was identified in 3/589 participants (0.5%), and GDM was present in 41/589 (7.0%) (95% CI 4.9 - 9.2). The mean (SD) BMI of 26.9 (5.8) kg/m² indicates that, overall, participants in the study were overweight; 57/589 participants (9.7%) had a BMI \geq 35 kg/m² and 16/589 (2.7%) had a BMI \geq 40 kg/m². Six participants were glycosuria-positive on one occasion with no opportunity for repeat glycosuria testing prior to the elective OGTT. Participant characteristics are presented in Table 1.

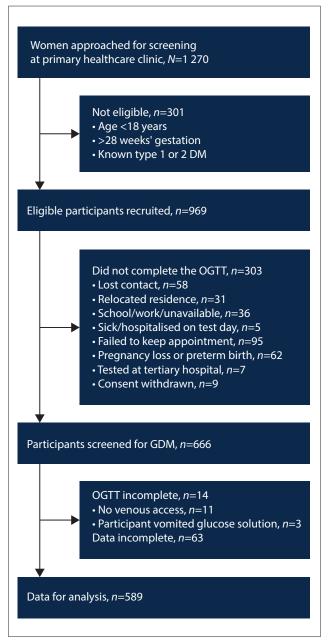


Fig. 1. Consort diagram of participant recruitment. (OGTT = oral glucose tolerance test; GDM = gestational diabetes mellitus.)

Characteristics of GDM-positive women

GDM-positive women were significantly more overweight than their non-GDM counterparts, with 6.1 kg (p=0.017; 95% CI 1.1 - 11.1) heavier body weight and a mid-upper arm circumference that was 2.1 cm (p=0.004; 95% CI 0.7 - 3.4) greater; they were also older (p<0.001), presented later in pregnancy for their first antenatal visit (p=0.001) and had higher diastolic blood pressure (p=0.004). Of the 41 GDM-positive participants, 5 (12.2%) were pregnant for the first time and 27 (63.4%) were pregnant for the third time or more. This higher parity was associated with an increased risk of GDM (p<0.001). Unexpectedly, in this study population, a positive family history of diabetes mellitus was not associated with a positive GDM diagnosis (p=0.591) (Table 1).

Assessment of risk factors

Based on the current NDoH guidelines (which include BMI ≥35 kg/ m2), 204/589 (34.6%) of the participants had one or more risk factors for GDM and would have required an elective OGTT; however, 18/41 GDM-positive cases (43.9%) would have been missed. At a BMI ≥30 kg/m², the number of participants requiring an OGTT would have been 262/589 (44.5%) and the number of missed GDM-positive cases would have been reduced to 12/41 (29.3%) (Table 2). A selective screening strategy based on the presence of two or more NDoH risk factors (including BMI ≥35 kg/m²) had a sensitivity, specificity, PPV, NPV, PLR and NLR of 23% (95% CI 11 - 38), 88% (95% CI 86 - 91), 13% (95% CI 6 - 22), 94% (95% CI 92 - 96), 1.95 (95% CI 1.05 - 3.63) and 0.88 (0.74 - 1.04), respectively. The use of two or more risk factors (including BMI ≥35 kg/m²) would have resulted in 33/41 (80.5%) of GDM-positive cases being missed.

Assessment of laboratory results

The mean plasma glucose concentrations at fasting and 60 and 120 minutes of the OGTT were 4.01 mmol/L (95% CI 3.95 - 4.07), 5.42 mmol/L (95% CI 5.30 - 5.54) and 5.12 mmol/L (95% CI 5.01 -5.23), respectively. The number of abnormalities per time point of the OGTT is presented in a Venn diagram (Fig. 2). The use of FPG ≥5.1 mmol/L as a universal screening strategy for GDM would have required 36 (6.1%) of 589 participants to undergo an OGTT; however, 5 (12.2%) of the 41 GDM-positive participants would have been missed. Based on the dual-threshold screening strategy, if those participants with an FPG <4.5 mmol/L were assumed to be at low risk and so were not formally screened, 152 (25.8%) of 589 participants would have required an OGTT and 40 (97.6%) of the 41 with GDM would have been identified (Table 2).

Discussion

The prevalence of GDM as determined by the glucose oxidase laboratory method in this routine clinical setting in a population of urban black African women attending a single CHC was 7.0%. Our results have similarities to and differences from recent SA reports of GDM prevalence. Macauley et al.[3] reported a 9.1% GDM prevalence in a tertiary hospital setting, using a research laboratory (glucose oxidase method), and their participants had a higher risk profile for GDM than participants at the CHC where this $\,$ study was conducted. [3] A study by Adam and Rheeder [24] possibly overestimated the GDM prevalence at 25.8%, and one reason for this is that the laboratory bias of 3.65%, which is not within the $\leq 2.2\%$ recommended by the NACB,[20] would adversely affect the quality of plasma glucose measures.

Importantly, 87.8% of GDM-positive diagnoses in this study population were based on an elevated FPG. This confirms the

	All participants (N=589)		GDM-positive (N=41)		GDM-negative (N=548)		
Clinical characteristics	N	Variable	N	Variable	N	Variable	<i>p</i> -value
Age (years), mean (SD)	589	27.8 (5.9)	41	31.1 (6.9)	548	27.5 (5.7)	<0.001
History of chronic hypertension, n (%)	588	19 (3.2)	41	1 (2.5)	547	18 (3.3)	1.000‡
Active smoker (cigarettes), n (%)	589	21 (3.6)	41	4 (10.0)	548	17 (3.1)	0.051^{\ddagger}
Family history of diabetes, <i>n</i> (%)	585	99 (16.9)	40	8 (20.0)	545	91 (16.6)	0.591§
Glycosuria (urine dipstick), n (%)	589	6 (1.0)	41	2 (4.9)	548	4 (0.7)	-
MUAC (cm), mean (SD)	589	29.9 (4.4)	41	31.8 (4.3)	548	29.7 (4.4)	0.004^{\dagger}
Body height (cm), mean (SD)	588	162.1 (6.6)	40	160.7 (6.2)	548	162.2 (6.6)	0.152^{\dagger}
Body weight (kg), mean (SD)	589	70.7 (15.7)	41	76.4 (15.3)	548	70.3 (15.7)	0.017^{\dagger}
BMI (kg/m²), mean (SD)	588	26.9 (5.8)	40	29.2 (5.3)	548	26.7 (5.8)	0.009^{\dagger}
Systolic BP (mmHg), mean (SD)	588	122.3 (14.9)	41	122.8 (19.9)	547	122.2 (14.5)	0.2005
Diastolic BP (mmHg)	588	72.6 (11.0)	41	77.4 (9.6)	547	72.2 (11.0)	0.004^{\dagger}
GA at first visit (weeks), mean (SD)	589	19.1 (5.6)	41	22.0 (4.2)	548	18.9 (5.6)	<0.001
Number of pregnancies including current, n (%)							
≥2	589	417 (70.8)	41	35 (85.4)	548	382 (69.7)	0,033§
≥3	589	223 (37.9)	41	27 (65.9)	548	196 (35.8)	<0.001
>3	589	79 (13.4)	41	9 (22.0)	548	70 (12.8)	0,096§
Previous LGA birth, <i>n</i> (%)	588	43 (7.3)	41	6 (14.6)	547	37 (6.8)	0.108°
Previous stillbirth, <i>n</i> (%)	589	32 (5.4)	41	3 (7.5)	548	29 (5.3)	0.481^{\ddagger}
Previous congenital abnormalities, n	588	0	41	0	548	0	-
Previous GDM, n (%)	589	3 (0.5)	41	1 (2.4)	548	2 (0.4)	-

GDM = gestational diabetes mellitus; SD = standard deviation; MUAC = mid-upper arm circumference; BMI = body mass index; BP = blood pressure; LGA = large for gestational age. "Numbers of participants for each characteristic vary slightly owing to missing values. "Student's t-test." I stake text. "Fisher's exact text.

Table 2. Validity measures of GDM screening: universal strategy with FPG ≥5.1 mmol/L, universal strategy with FPG ≥4.5 mmol/L, selective risk factor-based strategy including a BMI \geq 30 kg/m², and selective risk factor-based strategy including a BMI \geq 35 kg/m² and selective risk factor-based strategy including a BMI \geq 35 kg/m² and selective risk factor-based strategy including a BMI \geq 35 kg/m² and selective risk factor-based strategy including a BMI \geq 35 kg/m² and selective risk factor-based strategy including a BMI \geq 35 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy including a BMI \geq 36 kg/m² and selective risk factor-based strategy risk factor-based strategy including a selective risk factor-based strategy risk factor-b

		ning based on dual- v. universal OGTT	Selective screening strategy based on risk factors v. universal OGTT		
			≥1 risk factor(s)	≥1 risk factor(s)	
	FPG ≥5.1 mmol/L	$FPG \geq 4.5 \ mmol/L$	including BMI \geq 30 kg/m 2	including BMI \geq 35 kg/m 2	
Participants, N	589	589	589	589	
True positive, <i>n</i>	36	40	29	23	
False positive, <i>n</i>	0	112	233	181	
True negative, <i>n</i>	548	436	315	367	
False negative, n	5	1	12	18	
Sensitivity, % (95% CI)	88 (74 - 96)	98 (87 - 100)	71 (54 - 84)	56 (40 - 72)	
Specificity, % (95% CI)	100	80 (76 - 83)	57 (53 - 61)	67 (63 - 71)	
PPV, % (95% CI)	100	26 (20 - 34)	11 (8 - 16)	11 (7 - 16)	
NPV, % (95% CI)	99 (98 - 100)	99 (99 - 100)	96 (94 - 98)	95 (93 - 97)	
PLR (95% CI)	Undefined	4.77 (3.95 - 5.60)	1.66 (1.30 - 2.03)	1.70 (1.19 - 2.20)	
NLR (95% CI)	0.12*	0.03 (-0.03 - 0.09)	0.51 (0.26 - 0.75)	0.66 (0.43 - 0.89)	

GDM = gestational diabetes mellitus; FPG = fasting plasma glucose; OGTT = oral glucose tolerance test; PPV = positive predictive value; NPV = negative predictive value; PLR = positive likelihood ratio; NLR = negative likelihood ratio.
*Model did not converge to yield 95% CIs.

findings of Macauley $et\ al.^{[3]}$ and Adam and Rheeder $^{[24]}$ that the majority of GDM diagnoses in SA women screened were based on an elevated FPG. The use of FPG alone to screen for GDM is attractive as it is less expensive than a complete OGTT, avoids the need for multiple punctures, reduces laboratory workload, and avoids exposing pregnant women to the sometimes emesis-inducing oral glucose load.[25,26] There is outcomes-based evidence that an elevated FPG alone is comparable to a complete OGTT in predicting largefor-gestational-age infants, and for indicating the need for insulin

treatment of GDM. $^{[27\text{-}29]}$ Although an FPG $\geq\!5.1$ mmol/L is 100% specific for a diagnosis of GDM, the sensitivity of this diagnostic threshold varies between countries and ethnicities in both lowand high-risk populations. [13,16,30,31] When retrospectively applied to the HAPO study cohort, the mean proportion of GDM-positive diagnoses based on an elevated FPG was 55% (range 24 - 74%), and this figure varied between and within countries. [13] The underlying mechanism responsible for this variability is unknown. Sub-Saharan Africa was not included in the HAPO study. The prevalence of

Mann-Whitney *U*-test.

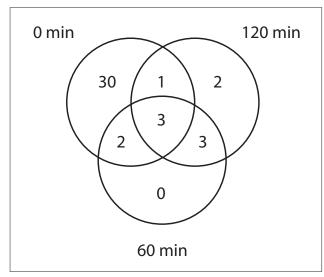


Fig. 2. Venn diagram illustrating the number of positive gestational diabetes mellitus cases identified by the time points of the 2-hour oral glucose tolerance test (World Health Organization 2013 test positivity cut-offs^[4]).

elevated FPG in multiethnic SA, affected by historical undernutrition and a current high burden of obesity, is unknown, and the use of a single value of the OGTT may miss GDM-affected women. The low-cost algorithm of a dual-threshold FPG, with ≥5.1 mmol/L (specificity 100%) used to rule in GDM and <4.5 mmol/L to rule it out, was associated with a reduction in the need for a complete OGTT when applied to the HAPO, United Arab Emirates and Brazilian cohorts. [13,15,16] In order to improve accessibility to screening, it may be possible to screen women for GDM with point-of-care testing, thus reducing the need for more expensive and sometimes inaccessible laboratory services. The use of glucometers to screen for and diagnose DM and GDM is endorsed by the WHO[1] and the International Federation of Gynecology and Obstetrics. [32] The reliable use of selected plasma calibrated glucometers to measure FPG in a universal GDM screening programme in a low-resource SA setting was recently reported.[22]

Maternal obesity was strongly associated with a positive GDM diagnosis in this study. SA has a high prevalence of obesity, which is associated with an increased risk of insulin resistance and dysglycaemia. $^{[33,34]}$ Epidemiologically, the prevalence of GDM increases by 0.9% per one point increase in BMI.[35] In this study, the use of BMI ≥30 kg/m² was associated with an increased sensitivity compared with a BMI \geq 35 kg/m².[36] Based on the current screening strategy of risk factor-based selective screening, a high proportion of SA women may require an OGTT, posing a potentially overwhelming burden to existing healthcare and laboratory services. The low sensitivity and specificity of a risk factor assessment to identify SA women with GDM in this study confirms the findings of Adam and Rheeder. [2] The low reliability of risk factor-based selective screening in SA women is aligned with international findings that almost half of GDM-affected women will be missed by selective screening based on conventional risk factors. [6,32] In 2017, SEMDSA adopted the WHO 2013 diagnostic thresholds for GDM, with a suggestion that a universal screening strategy could be implemented only in wellresourced settings in SA.[21] A previous report suggests that ruraldwelling SA women may be at high risk of diabetes in pregnancy. [38] Ideally, equal access to GDM screening should be available to all pregnant women, whether in a private or state healthcare setting, whether urban or rural dwelling, and regardless of ethnicity.

Prior to the WHO revision of GDM diagnostic thresholds in 2013, there was evidence that plasma glucose concentration abnormalities at all time points of the OGTT could predict the need for insulin therapy.[39] There are no prediction models for which GDM-affected women are likely to need oral hypoglycaemic agents or insulin treatment to restore euglycaemia during pregnancy. In addition, increases in fasting and 2-hour plasma glucose concentrations are associated with an increased risk of developing overt diabetes in later years. [40] For this reason, in the event that a GDM diagnosis is made based on an elevated FPG, it may be necessary to perform a complete OGTT.

Study strengths and limitations

This translational research project was conducted within the usual functioning of a CHC, which equates to routine care rather than a research clinical setting. Our participants were urban black African women attending the antenatal service of a single urban CHC, so our results may not be generalisable beyond this population profile. The sample size and the low GDM prevalence of 7.0% (95% CI 4.9 -9.2) were insufficient to provide robust estimates of the sensitivity of the FPG screening threshold of ≥4.5 mmol/L. Further studies in more diverse patient populations and clinical settings are needed to confirm these results.

Conclusions

A universally applied FPG threshold of ≥4.5 mmol/L, as an indicator of intermediate to high risk of GDM improved sensitivity and reduced the number of women needing to undergo the unpleasant, poorly reproducible and resource-intensive OGTT compared with the current practice of risk factor-based selective screening.

Research highlights

Overt diabetes and gestational diabetes prevalences were 0.5% and 7.0%, respectively.

- Selective risk factor screening indicated that 34.6% of women needed an OGTT, but missed 43.9% of GDM.
- Universally applied FPG ≥5.1 mmol/L identified 87.8% of GDMpositive women.
- Universally applied FPG ≥4.5 mmol/L indicated that 25.8% of women needed an OGTT but missed 2.4% of GDM.

Declaration. This original research article forms part of LMD's PhD thesis.[22,23]

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Author contributions. LMD and EJB are joint senior authors. LMD, EJB, SAN: methodology. LMD: data collection and had full access to all data during the study. LMD, EJB, CJvR, SAN: data analysis. LMD: wrote the manuscript. EJB, CJvR, SAN: reviewed and edited the manuscript.

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Conflicts of interest. None.

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