

Role of HbA1c in Gestational Diabetes screening: NICE versus RCOG Covid-19 guidance.

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Background

Gestational diabetes mellitus (GDM) is any degree of glucose intolerance identified during pregnancy with normal or abnormal glycaemia after pregnancy (*O’Sullivan, 1961; Bhavadharini et al, 2016*). An exponential increase in the prevalence of GDM has been observed worldwide over the years with improved screening uptake and increase in maternal risk factors (*Zhu and Zhang, 2016; Claesson et al, 2017; Saravanan P, 2020; Zhou et al, 2022; Pintaudi et al, 2022*).

National Institute for Health and Care Excellence (NICE) in England, United Kingdom recommends targeted screening for women ‘at risk’ of GDM with 75g-oral glucose tolerance test (OGTT). Fasting plasma glucose (FPG) ≥ 5.6 mmol/l and 2-hour plasma glucose (2hr-PG) ≥ 7.8 mmol/L on OGTT would categorise women as GDM. During the Covid-19 pandemic the Royal College of Obstetricians and Gynaecologists (RCOG) in the UK proposed alternatives to OGTT to reduce risk of Covid-19 transmission and suggested an HbA_{1c} ≥ 39 mmol/mol (5.7%) or FPG ≥ 5.6 mmol/l or random plasma glucose ≥ 9 mmol/l or above as the criteria for diagnosis of GDM (*RCOG, 2020*).

We explored any variability in identification of GDM using the RCOG criteria during COVID-19 pandemic, from the conventional NICE guidelines, and assessed the utility of HbA_{1c} in GDM screening and evaluated key pregnancy outcomes (pre-term delivery, still birth and birth weight [>4500 g]).

Methods

- Of all the deliveries from 2009 (n=40,740) at our tertiary hospital, excluding women with pre-existing diabetes, utilising NICE recommended risk stratification, n=8,542 were categorised as “high risk” for GDM and had simultaneous OGTT and HbA_{1c} estimations for GDM screening.
- At our hospital, HbA_{1c} has always been routinely undertaken along with OGTT for several years.
- Data was analysed retrospectively to explore variation in GDM diagnosis using the two criteria, and also to analyse and explore the variation in proportion of women diagnosed as GDM using the traditional NICE criteria and the RCOG guidance suggested during the pandemic.
- The differences between frequencies and proportions were analysed by Chi-square test.
- Binary logistic regression was used to determine the association, correcting for significant demographic and biochemical factors, with key pregnancy outcomes.
- P-value of <0.05 was used for statistical significance.
- This quality improvement project was registered and approved by the Audit Committee at the University Hospitals of North Midlands NHS Trust, Stoke-on-Trent, UK (Reference: O&G-73/19-20).

Results

Of the 8,542 women deemed ‘high risk’ who had GDM screening, the proportion diagnosed as GDM using NICE criteria and RCOG guidance, were 11.3% (n=965) and 15.3% (n=1,307) respectively, with 6.4% (n=545) women meeting both criteria for GDM diagnosis (Table 1). HbA_{1c} ≥ 39 mmol/mol was observed in 13.5% and FPG ≥ 5.6 mmol/L in 4.5%.

RCOG guidance if used in isolation, would have diagnosed more women as GDM, however missing the diagnosis in 43.5% of women diagnosed with NICE (OGTT) criteria (4.9% of ‘high-risk’ cohort) ($\chi^2=1423$, $P<0.001$), suggesting different cohorts diagnosed with GDM using these two recommendations. 8.9% (n=762) women with normal OGTT would have been diagnosed GDM with RCOG guidance.

The proportion of Asians diagnosed with GDM were higher in the cohort with RCOG criteria compared to those diagnosed with OGTT alone (26.2% vs. 18.1%, $\chi^2=1,170$, $P<0.001$) (Table 2). The glycaemic parameters in women diagnosed with GDM using NICE criteria vs. RCOG guidance were (mean $\pm$ sd): FPG 5.3 ± 1.0 vs. 5.1 ± 1.0 mmol/L, 2hr-PG 8.6 ± 1.9 vs. 7.0 ± 2.3 mmol/L ($P<0.001$) and HbA_{1c} 37.9 ± 5.9 vs. 40.6 ± 4.6 mmol/mol ($P<0.001$) respectively. The key pregnancy outcomes in the cohorts using NICE criteria vs. RCOG guidance: fetal macrosomia 1.2% vs. 2.6%; preterm delivery 9.4% vs. 9.5%; and still birth rate 0.3% vs. 0.7% (Table 3).

On logistic regression analysis HbA_{1c} (Exp(B)[95%CI] 1.03[1.01-1.05], $P=0.011$) and 2hr-PG (1.06[1.00-1.02], $P=0.035$), but not FPG, were independent predictors of preterm birth. HbA_{1c}, but not FPG or 2hr-PG, was a significant variable in predicting still-birth (1.06[1.01-1.11], $P=0.024$). HbA_{1c} was not associated with macrosomia that was predicted independently by FPG & 2hr-PG.

NICE criteria	RCOG guidance			
		No GDM	GDM	Total
	No GDM	6815 (79.8%)	762 (8.9%)	965 (11.3%)
	GDM	420 (4.9%)	545 (6.4%)	
	Total		1307 (15.3%)	

Table 1. Proportion diagnosed GDM using NICE criteria and RCOG guidance

	NICE criteria			RCOG guidance		
	Non GDM	GDM		Non GDM	GDM	
Age (years)	28.3 $\pm$ 5.8	30.4 $\pm$ 5.6	$P<0.001$	28.2 $\pm$ 5.7	30.15 $\pm$ 5.8	$P<0.001$
Proportion Caucasians, Asians	74%, 13%	66%, 21%	$P<0.001$	75%, 12%	60%, 27%	$P<0.001$
(FPG (mmol/l))	4.4 $\pm$ 0.41	5.3 $\pm$ 1.0	$P<0.001$	4.4 $\pm$ 0.4	5.1 $\pm$ 1.0	$P=0.001$
2hr-PG (mmol/l)	5.3 $\pm$ 1.1	8.6 $\pm$ 1.9	$P<0.001$	5.5 $\pm$ 1.3	7.0 $\pm$ 2.3	$P<0.001$
HbA1c (mmol/mol)	33.6 $\pm$ 3.8	37.9 $\pm$ 5.9	$P<0.001$	32.9 $\pm$ 3.1	40.6 $\pm$ 4.6	$P<0.001$

Table 2. Demographics and glycaemic parameters in the cohorts diagnosed GDM by the two criteria

	NICE (OGTT) criteria			RCOG guidance		
	Non GDM	GDM		Non GDM	GDM	
Pre-term delivery	6.7%	9.4%	$P=0.002$	6.6%	9.5%	$P<0.001$
Still birth	0.3%	0.3%	NS	0.3%	0.7%	$P=0.018$
Birth weight (g)	3396	3267	$P<0.001$	3389	3336	$P=0.019$
Birth weight >4500 g	2.7%	1.2%	$P=0.026$	2.5%	2.6%	NS

Table 3. The key pregnancy outcomes in the cohorts diagnosed with GDM using the two criteria

Discussion

The RCOG guidance and NICE criteria utilised in isolation for GDM screening identified different populations with GDM. Although there was a higher prevalence of GDM based on the RCOG guidance, there remains a risk of missing the diagnosis of GDM in a proportion of women, when RCOG criteria is solely applied. The key strengths of our study are inclusion of a large cohort with women of diverse ethnicity, all considered ‘high risk’ applying the NICE risk-stratification. This quality improvement study is distinctly unique, having simultaneous HbA_{1c} estimations undertaken with OGTT during GDM screening enabling a direct comparison between NICE criteria and the RCOG guidance in the same cohort wherein we were able to establish the variation in the prevalence rates of women identified as GDM.

Other studies have similarly explored the impact of implementation of the criteria for GDM screening during the pandemic (*McIntyre et al, 2020; McLennan et al, 2024; Liyanage et al, 2024*). In a multi-centre study comparing multiple sites adopting the emergency screening criteria during the pandemic, with single site using the traditional OGTT for GDM screening, higher GDM prevalence using the emergency criteria with different demographics and similar maternal and neonatal outcomes was observed (*McLennan et al, 2024*). Nonetheless, in our study we have demonstrated similar increased prevalence of GDM when using RCOG guidance in the cohort prior to the pandemic, indicating such increased prevalence could be due to incorporation of HbA_{1c} in GDM screening. Utilising data from the Hyperglycaemia and Adverse Pregnancy Outcome study, a significant reduction in GDM prevalence using the RCOG criteria was noted, emphasising the risks of ‘missed GDM’ and potential impact on pregnancy outcomes (*McIntyre et al, 2020*).

To compare the pregnancy outcomes, a limitation of our study was its retrospective nature and women meeting the RCOG criteria did not have the intensive standard antenatal care that women with GDM receive. Nevertheless, we demonstrated the supplementary role of HbA_{1c} to the OGTT in ‘high-risk’ women, i.e. in both GDM and those ‘high risk’ women who had normal OGTT, to identify women at higher risk of preterm delivery and still-birth. Identifying this at-risk cohort, not diagnosed as GDM utilising the NICE criteria, could potentially help in offering intensive antenatal management to reduce maternal-fetal complications.

In conjunction, the association of third-trimester HbA_{1c} with key pregnancy outcomes is well-recognised in women with pre-existing diabetes (*Maresh et al, 2015*). However, HbA_{1c} has not been widely used in GDM screening and not been incorporated in various national or international guidelines. There is increasing evidence for the role of HbA_{1c} in early pregnancy (*Hannah et al, 2022; Saravanan et al, 2024*), and in assisting risk stratification for GDM screening. This would facilitate identification and early intensive intervention to the cohort with the highest risk, in our efforts at attempting to improve GDM screening rates and it could likely reduce the need for OGTT (*Saravanan et al, 2024*). Further studies are warranted to explore the neonatal and maternal outcomes of such a stepwise approach and to support the timing and use of HbA_{1c} in GDM screening in improving pregnancy outcomes.

Conclusion

The criteria of screening for gestational diabetes mellitus (GDM) using the Royal College of Obstetricians and Gynaecologists’ (RCOG) recommendations during Covid-19 pandemic and the National Institute of Clinical Excellence (NICE) guidance identify different populations, with a risk of missing the diagnosis of GDM in a proportion of women when RCOG guidance is solely applied.

HbA_{1c} could have a supplementary role when used in addition to oral glucose tolerance test, in ‘high-risk’ women, to identify and to potentially reduce maternal-fetal complications through intensive antenatal management.

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