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Impact of new diagnostic pathway for gestational diabetes in time of COVID-19

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Abstract

Background: In April 2020, the diagnostic criteria for gestational diabetes mellitus (GDM) changed in Queensland, with the goal of reducing exposure of pregnant women to COVID-19.

Methods: A retrospective clinical audit was conducted at a regional hospital to compare the incidence of GDM, and specific maternal and neonatal outcomes four months before and after the change in guidelines was implemented.

Results: Less than 50% of diagnostic tests were performed according to new guidelines. There was a non-significant increase in the incidence of GDM (13.3% to 15.3%), and pharmacological treatments. Instrumental deliveries ($p = 0.01$) and shoulder dystocia ($p = 0.04$) increased following the change in guidelines. There were no differences in the incidence of elective and emergency caesarean delivery, macrosomia and fetal weight. Maternal pre-pregnancy body mass index (BMI) was higher in the COVID-19 GDM cohort ($p = 0.02$).

Conclusions: Despite the change in guidelines, there was a non-significant increase in the incidence of diagnosis of gestational diabetes.

Keywords

Diabetes, gestational, pregnancy complications, screening

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Introduction

Gestational diabetes mellitus (GDM) is defined as impaired glucose tolerance with onset or first recognition during pregnancy.[1] It affects 12–15% of pregnancies in Australia,[2] and is associated with adverse outcomes including instrumental and caesarean delivery, macrosomia, neonatal hypoglycemia, and type 2 diabetes.[3] Effective treatment minimizes these risks.[4]

The diagnosis of GDM has been subject to controversy. In January 2015, Australasian Diabetes in Pregnancy Society (ADIPS) adopted new diagnostic guidelines proposed by the International Association of Diabetes in Pregnancy Study Groups (IADPSG).[5] The catalyst was the Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study,[6] which demonstrated a linear correlation between maternal blood glucose levels on an Oral Glucose Tolerance Test (OGTT) and pregnancy outcomes. The new 2015 guidelines involved a one-step rather than two-step testing process and a new diagnostic threshold, which aimed to more accurately identify patients at risk of adverse outcomes to improve their glycemic control.

However, analysis of the new guidelines has shown increased incidence of GDM and healthcare costs, with no difference in adverse outcomes.[7–9] A randomized-control-trial comparing patients allocated to one-step versus two-step diagnostic pathway revealed similar trends.[10] Given GDM is associated with negative psychological impacts,[11] the increasing incidence pertaining to guideline changes must be examined in the context of healthcare costs and psychological burden on women.

During the COVID-19 pandemic, temporary changes to GDM screening were implemented in Australia, based on ADIPS advice (updated 07 May 2020).[12] Queensland Health implemented different guidelines (Table 1) on 31 March 2020, changing from a one-step 75 g OGTT at 24–28 weeks, to a two-step process with a fasting blood glucose (FBG) with or without a subsequent OGTT at 24–28 weeks.[13] For women with risk factors, screening in early pregnancy changed from an OGTT to HbA1c (Table 1). The rationale for the changes was to reduce the burden on women and the healthcare system during the pandemic.[14] Avoiding universal OGTT minimizes patient time at pathology centers, but relies on accurate interpretation of results and proactive follow-up.

We hypothesized that the reinstatement of a two-step process for GDM diagnosis, would reduce GDM incidence. This study aimed to investigate the effect of new COVID-19 criteria on the diagnostic incidence and rates of therapeutic interventions for GDM. The secondary aim was to explore rates of adverse pregnancy outcomes, including caesarean sections and macrosomia. Our region was minimally affected by COVID-19 during the study period, therefore we anticipated a low risk of COVID-19 infection confounding these outcomes.

Methods

A retrospective clinical audit was conducted at a regional hospital in Queensland delivering approximately 1300 babies annually. Data were collected for all pregnant women who delivered a singleton fetus

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Table 1. Comparison of pre COVID-19 and COVID-19 GDM guidelines recommended by Australasian Diabetes In Pregnancy Society (ADIPS) and Queensland Health.[5,12–14]

	Early pregnancy strategy (Women at a high risk of GDM)	24–28 weeks strategy (Women not already diagnosed with GDM)	Post-natal strategy
ADIPS and Queensland Health (pre-COVID-19)[5,14]	75 g OGTT GDM diagnosed if OGTT result (mmol/L): - Fasting ≥ 5.1 - 1 h ≥ 10 - 2 h ≥ 8.5 HbA1c (if OGTT not suitable) ≥5.9%	75 g OGTT GDM diagnosed if OGTT result (mmol/L): - Fasting ≥ 5.1 - 1 h ≥ 10 - 2 h ≥ 8.5	OGTT at 6 weeks T2DM diagnosed if FBG is ≥7.0 mmol/L or two-hour plasma glucose is ≥11.1 mmol/L
Queensland Health (COVID-19)[13] Implemented 31/03/2020	HbA1c HbA1c > 5.9% diagnostic of GDM	Step 1: FBG (mmol/L): - ≤4.6—no further testing - 4.7–5.0—proceed to Step 2 - ≥5.1 diagnose GDM. Step 2 75 g OGTT - Fasting ≥ 5.1 - 1 h ≥ 10 - 2 h ≥ 8.5	Delay OGTT for 6–12 months post-partum, or prior to conception or, if concerned about type 2 DM: - Continue self-monitoring - HbA1c at 4–6 months

GDM: Gestational diabetes mellitus; OGTT: Oral glucose tolerance test; FBG: Fasting blood glucose; RBG: Random blood glucose; HbA1c: glycosylated hemoglobin; T2DM: type 2 diabetes mellitus.

between August and November 2019 (IADPSG criteria), and August and November 2020 (Queensland Health COVID-19 criteria). Electronic medical records were used to access maternal and neonatal demographics (including body mass index (BMI); based on pre-pregnancy weight for those diagnosed with GDM), pregnancy, birth and perinatal outcome data. Multiple patient identifiers were used to ensure correct patient-data allocation.

Outcomes recorded were the incidence of GDM, treatment type, rates of caesarean sections, macrosomia (defined as fetal weight greater than 90th centile for gestational age) and median birthweight. The mean HbA1c after 30 weeks' gestation and first fetal blood sugar level (BSL) within 2–3 h of birth were also recorded for women with GDM.

Ethics exemption was granted (HREC: LNR/QTHS/68493). This project was registered with the Townsville Hospital and Health Service Quality Improvement Unit as a quality improvement activity.

Statistical analysis was conducted using Stata version 13.1 (StataCorp LP, College Station, Texas, USA). Categorical data were described using absolute and relative frequencies. Numerical data were described using mean value and standard deviation (SD) if the distribution was symmetrical and median value and inter-quartile range (IQR) if the distribution was skewed. The incidence of GDM was presented with Clopper-Pearson exact binomial 95% confidence intervals (95% CI), excluding women who had pre-existing diabetes (n = 11).

The cohorts were compared using two-sided independent t-test for symmetrical numerical data, Mann-Whitney-U test for skewed numerical data, Fisher's (2 categories) or the Fisher-Freeman-Halton (more than 2 categories) exact test for categorical data. Comparisons were conducted based on intention-to-treat and compliers only analysis.

Multivariable logistic regression analyzes were used for binary outcome variables. Multinomial logistic regression analyzes were applied for categorical outcome variables with more than two categories. Multiple linear regression analyzes were conducted for numerical outcome variables. All multivariable analyzes were adjusted for age and ethnicity of the mother. For women diagnosed with GDM, multivariable analyzes were also assessed for confounding effects of HbA1c, BMI, and obesity (yes/no) separately because of the limited sample size.

Sample size was calculated with power 80% and alpha 0.05. The primary outcome was the incidence of GDM. Based on a prior study at the same hospital, we estimated that the local prevalence of GDM would be 20%, and that with the new guidelines, based on predictive studies, it would decrease to 10%.[9] On this clinical presumption we calculated 219 patients would be required in each group.

Results

A total of 858 women were included; 48.8% (n = 419) delivered their baby prior to the guideline changes. The mean age of women was 28.7 (5.4) years, 11.5% (n = 98) were of Aboriginal and/or Torres Strait Islander ethnicity, and 1.3% (n = 11) had pre-existing diabetes mellitus (DM).

Of 847 women (excluding those with pre-existing DM), 121 (14.3%; 95% CI = [12.0, 16.8]) were diagnosed with GDM. The Queensland Health COVID-19 diagnostic pathway was used in 30 out of 64 (46.9%) patients (Table 2). Women in the COVID-19 GDM cohort had a significantly higher pre-pregnancy BMI (31.3 kg/m^2 vs. 28.5 kg/m^2, $p = 0.020$) and were more likely to be obese (63.6% vs. 37.3%, $p = 0.005$) compared to the pre-COVID GDM cohort (Table 2).

Incidence of GDM diagnosis

There was no difference in the incidence of GDM diagnosis with the COVID-19 criteria (66/432 (15.3%; 95% CI = [12.0, 19.0])) compared to the IADPSG criteria (55/415 (13.3%; 95% CI = [10.1, 16.9])) ($p = 0.433$; adjusted $p = 0.395$).

Treatment

Most women with GDM (47.1%, n = 57) were treated with lifestyle changes (Table 2). Although the proportion of women on metformin and insulin increased in the COVID-19 cohort, this was not significant ($p = 0.726$) and remained non-significant using multinomial logistic regression (data not shown).

HbA1c

Although the mean HBA1c increased in the COVID-19 cohort, this difference was not significant (5.3% vs. 5.2%, $p = 0.10$) (Table 2).

Maternal outcomes

Spontaneous vaginal delivery was the most common form of delivery before (65.9%) and after (60.6%) the guidelines changed (Table 3). There was a non-significant tendency for instrumental deliveries and elective caesarean sections after the guideline changes ($p = 0.055$). Multinomial logistic regression adjusted for age and ethnicity showed a significant increase in instrumental deliveries compared to spontaneous vaginal delivery after changes in guidelines occurred (8.1% vs. 12.8%, $p = 0.012$) (Table 3).

The incidence of shoulder dystocia in the total patient cohort increased after guidelines changed (0.5% vs. 2.2%, $p = 0.036$) and remained significant in multivariable logistic regression analysis ($p = 0.048$) (Table 3). The occurrence of perineal tear remained unaffected by the guideline change ($p = 0.849$) on bivariate and multinomial logistic regression analysis.

For women with GDM, the type of delivery and frequency of complications did not vary significantly due to guideline changes within bivariate and multivariable analyzes (data not shown).

Fetal outcomes

Overall, 47.8% of babies born were female and median birthweight was 3440 g (Table 3). Seven (0.8%) babies died. In both the total patient and

Table 2. Characteristics of patients with GDM, method of diagnosis and treatment.

Characteristic	Total (n = 121)	Pre COVID-19 cohort (n = 55)	COVID-19 cohort (n = 66)	*p*-value*
Mean age (SD)†[years]	29.8 (5.2)	30.5 (5.0)	29.1 (5.3)	$P = 0.135$
% Aboriginal and/or Torres Strait Islander (n = 853)	13.2% (n = 16)	10.9% (n = 6)	15.2% (n = 10)	$P = 0.60$
Mean BMI (SD) (n = 117)	30.1 (6.5)	28.5 (5.8)	31.3 (6.8)	$P = 0.02$
% Obese (n = 117)	52.1% (n = 61)	37.3% (n = 19)	63.6% (n = 42)	$P = 0.01$
Mean HbA1c (SD) [%] (n = 108)	5.3% (0.4)	5.2% (0.4)	5.3% (0.3)	$P = 0.10$
Method of diagnosis		n = 50 ‡	n = 64 ‡	
Early diagnosis				
OGTT		20 (40%)	13 (19.7%)	
FBG		0	5 (7.6%)	
Diagnosis at 24–28 weeks				
OGTT without preceding FBG		29 (58%)	15 (22.7%)	
2 Step FBG > 5.1 (OGTT not required)		1 (2%)	27 (40.9%)	
2 Step FBG, then OGTT		0	3 (4.5%)	
HbA1c		0	1 (1.5%)	
Proportion diagnosed using QLD health guidelines		49 (98.0%)	30 (46.9%)	
%Treatment of GDM				$P = 0.73$
Lifestyle change§	47.1% (n = 57)	52.7% (n = 29)	42.4% (n = 28)	
Metformin	21.5% (n = 26)	18.2% (n = 10)	24.2% (n = 16)	
Insulin dependent	17.4% (n = 21)	16.4% (n = 9)	18.2% (n = 12)	
Insulin & metformin	14.0% (n = 17)	12.7% (n = 7)	15.2% (n = 10)	

*p-values are results of bivariate analyzes; †SD = standard deviation. ‡7 cases with missing information about timing and/or method of diagnosis. §Diet, exercise and other changes.
OGTT: Oral glucose tolerance test; FBG: Fasting blood glucose; RBG: Random blood glucose; HbA1C: glycosylated hemoglobin BMI: body mass index.

Table 3. Comparison of pregnancy outcomes for all patients before and after the change in GDM guidelines.

	Total (n = 858)	Pre Covid-19 cohort (n = 419)	COVID-19 cohort (n = 439)	*p*-value*	*p*-value**
Maternal outcomes					
Median gestation (IQR)† [days]	275 (269, 281)	275 (269, 282)	274 (269, 281)	$P = 0.220$	$P = 0.798$
% Type of delivery				$P = 0.055$	
Vaginal	63.2% (n = 542)	65.9% (n = 276)	60.6% (n = 266)		Base
Instrumental	10.5% (n = 90)	8.1% (n = 34)	12.8% (n = 56)		$P = 0.012$
Elective caesarean	10.3% (n = 88)	8.8% (n = 37)	11.6% (n = 51)		$P = 0.117$
Emergency caesarean	16.1% (n = 138)	17.2% (n = 72)	15.0% (n = 66)		$P = 0.828$
% Shoulder dystocia (n = 831)	1.3% (n = 11)	0.5% (n = 2)	2.2% (n = 9)	$P = 0.036$	$P = 0.045$
% Perineal tear				$P = 0.849$	
None	67.7% (n = 581)	67.8% (n = 284)	67.7% (n = 297)		Base
1st & 2nd degree	29.7% (n = 255)	29.4% (n = 123)	30.1% (n = 132)		$P = 0.731$
3rd & 4th degree	2.6% (n = 22)	2.9% (n = 12)	2.3% (n = 10)		$P = 0.611$
Fetal outcomes					
Median birthweight (IQR)† [g] (n = 854)	3440 (3110, 3751)	3430 (3080, 3758)	3440 (3128, 3750)	$P = 0.552$	$P = 0.296$
% Macrosomic (n = 854)	14.9% (n = 127)	15.3% (n = 64)	14.4% (n = 63)	$P = 0.773$	$P = 0.796$

*p-values are results of bivariate analyzes; **p-values are results of multivariable analyzes; †IQR = inter-quartile range.

GDM cohorts, none of fetal outcomes recorded were significantly affected by the guideline changes (Table 3). Although the mean BSL at 2–3 h of infants born to mothers with GDM was lower in the COVID-19 cohort, this was not significant.

Analysis by "compliers only"

Prior to the guideline change, 98.0% (49 of 50) of women were diagnosed with GDM using the correct Queensland Health guidelines. After the guidelines changed, only 46.9% (30 of 64) women were diagnosed according to the new recommendations. Comparing the women who were diagnosed with GDM using the correct guidelines in each cohort showed no differences in GDM treatment rates or the main outcome characteristics in bivariate and multivariable analyzes.

Discussion

This study found the COVID-19 diagnostic pathway was not associated with an expected decrease in the incidence of GDM, instead we saw a small increase in the incidence from 13.3% to 15.3% over the study period, though this was not significant.

Of the 66 cases of GDM diagnosed during August-November 2020, only 30 were made using the new COVID-19 screening guidelines. This poor uptake of guideline changes may be related to provider confusion, poor dissemination of information. Alternatively, the relatively minimal impact of COVID-19 on the region may have led practitioners to continue using "gold standard" diagnostic testing.

Measurements before and after a change in guidelines are usually not directly comparable because of the 'Will Rogers' phenomenon,[15] an epidemiological paradox whereby changes in the diagnostic criteria for a condition can produce spurious changes in outcomes, though individual patient outcomes have not changed. In our study, we expected fewer women, but with poorer glycemic control, to be identified using the two-step process. However, with a similar incidence of GDM in both groups, we feel that some direct comparison of outcomes in the GDM group can be made, although the true impact of the new guidelines should be based on outcomes in the overall cohort.

Compared to the pre-COVID-19 GDM cohort, the mean booking-in BMI of the COVID-19 GDM cohort was significantly higher. The mean HbA1c (after 30 weeks), and proportion of women treated with metformin or insulin increased, while the mean BSL at 2–3 h of infants was lower in the COVID-19 cohort, though the changes were not statistically significant. These trends may be reflective of poorer glycemic control amongst this population, or could indicate that the two-step process resulted in women at the more severe end of the diabetes spectrum being diagnosed.

We must acknowledge the limitations of our study. Our sample size calculation was based on assumptions from previous research at our hospital that were not supported by the new data. Therefore, we cannot exclude that the increase in instrumental deliveries and shoulder dystocia were not spurious outcomes. This, in combination with poor compliance to the COVID-19 guidelines, means we are underpowered to examine the effect of the new guidelines on outcomes in the overall cohort and adequately address our secondary aim. Post-hoc 'compliers only' analysis of the GDM patients diagnosed using the correct guidelines did not find any difference between GDM treatment or pregnancy outcomes, but was again limited by sample size. Further, we could not retrieve sufficient data for booking weight in the overall cohort, largely due to phone rather than face-to-face appointments, and cannot control for this variable in multivariate analysis. Hence, although the increase in GDM incidence, instrumental deliveries and shoulder dystocia may be related to maternal obesity we are unable to effectively examine this relationship. Overall, this study is limited by the examination of short-term outcomes of a small population, in a single center.

While our finding of increased GDM incidence with the COVID-19 guidelines did not reflect our hypothesis, similar studies of different populations where the incidence of GDM reflects the national incidence may produce different results. It is possible our findings are reflective of the growing obesity epidemic and that the increased GDM incidence may have been exaggerated further if the IADPSG guidelines continued throughout COVID-19. Another explanation is that other factors (including reduced access to healthcare, weight gain, diet and sedentary lifestyle) related to COVID-19 contributed to our findings.

Regardless of explanation, the rising incidence of GDM and maternal obesity is concerning. In this context, given the evolving evidence supporting a two-step GDM screening process, close analysis of future guideline changes has the potential to influence clinical practice, reduce the financial burden on the healthcare system and alter the patient psychological experience.

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Contributorship

CH, KB and LH designed the study. BW and JE conducted data collection. Data analysis was conducted by LH, PB, BW and CH. All authors contributed to the writing of the article and approved the final version.

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Ethical approval

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Informed consent

Not applicable.

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Supplemental material

Supplemental material for this article is available online.

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