Original Article

New Guidelines for Diagnosis of Gestational Diabetes: Pathology-Based Impact Assessment

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Abstract

Background: A recent study indicated an average of 19.5% abnormal oral glucose tolerance in antenatal clients per year. **Aim:** The purpose of this study was to determine the impact on gestational diabetes cases due to new guidelines for diagnosis and classification of hyperglycaemia in pregnancy. **Materials and Methods:** This study reviewed the archived clinical pathology data on oral glucose tolerance tests performed between January 1999 and December 2008 on antenatal clients ($N = 615$). The cases were reviewed to determine changes if any in percentage of gestational diabetes due to new guidelines. **Results:** Over the 10 years period, a yearly average of additional 10.8% antenatal cases suggestive of gestational diabetes was observed due to the new recommended thresholds. Further, the average yearly incidence would have increased from 8.8 cases to 16.2 cases, which translates to almost 46% increase in the prospective numbers of gestational diabetes. **Conclusions:** This report presents the extent of how the new recommended guidelines for diagnosis and classification of hyperglycaemia in pregnancy could increase the prevalence of gestational diabetes. It also provides pathology-based evidence for the epidemiology of gestational diabetes mellitus and allows for planning the costs that would be attendant to the full implementation of the new guidelines.

Keywords: Gestational diabetes, Impact evaluation, New guidelines, Oral glucose tolerance test, Pathology-based evidence

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Introduction

A report from Norway published in 1994 in the Scandinavian Journal of Primary Health Care indicated a prevalence of up to 45% abnormal oral glucose tolerance test (OGTT).[1] Although OGTT is highly criticized as inconsistent, inconvenient and poorly reproducible,[2] it still adds predictive advantage to the use of fasting blood glucose level alone. Thus, it is still the gold standard,[2,3] especially to make gestational diabetes diagnoses. However, 18 years since the Norwegians' report, corroborative data from other countries are lacking, including pathology-based evidence regarding the actual prevalence of gestational diabetes.

In 2010, the International Association of Diabetes and Pregnancy Study Groups issued new guidelines for diagnosis and classification of hyperglycaemia in pregnancy. That is, diagnosis of gestation diabetes mellitus (GDM), which is defined in this report as any degree of glucose intolerance with onset or first recognition during pregnancy.[4] A concern is that there is a subpopulation of overt diabetics in antenatal patients who are at risk of adverse pregnancy outcomes, but there seems to be no clear correlation to hyperglycaemia.[4,5] Thus, the new guidelines introduced a brand set of thresholds and recommendations. Since the recommendations, there have been series of comments,[5-9] especially on the potential increase in number and the associated cost of management of gestational diabetes.[10-12] However, pathology-based data indicating the extent of the increase is yet to be reported. Such a study would be a contribution to the epidemiology on the impact of the new guidelines in terms of quantity of laboratory reports of abnormal OGTT suggestive of gestational diabetes.

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Materials and Methods

Study setting

This work was done at the South West Pathology Service

of New South Wales (NSW) Health Australia, as part of a Translational Biomedical Science Research initiative. The pathology operates a Laboratory Information System (LIS) that could only be access by permission and with a password. The Ethics Committee of the Area Health Service approved the acquisition and use of de-identified database from the LIS. The database comprises 10 years of archived clinical pathology data from January 1999 to December 2008. All OGTT (glucose load 75 g) performed in the 10 years period were audited. This included 5126 cases, of which 615 were antenatal. The OGTT results from the 10 years under review, including all those selected as GDM, had blood glucose levels for the three points (fasting, as well as 1 h and 2 h postprandial).

Source of information and definition on gestational diabetes

As this study was based on de-identified data, and no immediate benefit for the study clients was envisaged, no personal contact was made or letter from clinicians solicited ($N = 615$). OGTT were performed on antenatal patients. There was no record indicating previous diabetes or pre-diabetes on these clients. The source of information about GDM for this evaluation was from the de-identified OGTT reports in the LIS. The definition of GDM was based on the clinical pathology reports sent out to the clinicians, i.e. cases that were reported as indicating gestational diabetes were evaluated as percentage of the 615 antenatal subpopulations.

Analyses

To assess the impact of the new guidelines on potential increase in number of GDM, the same antenatal subpopulation ($N = 615$) was further reviewed. Based on the recommended threshold, data were sorted as follows:

1. First, by the diagnostic report sent to clinicians: for each year, those reported as suggestive of GDM were ranked on top. The counts were evaluated as percentage of antenatal subpopulations to determine the prevalence of GDM diagnosis (% Dx).
2. Second, by the new threshold: those not reported as suggestive of GDM, but had fasting blood glucose level of 5.1 mmol/L (92 mg/dL), 1-h postprandial glucose level of 10.0 mmol/L (180 mg/dL) and/or a 2-h postprandial glucose level of 8.5 mmol/L (153 mg/dL) were identified.[4] The counts were evaluated as percentage of antenatal subpopulations to determine the prevalence of "DM diagnosis based on new guideline" (% other).
3. The absolute numbers that made up "% Dx" and "% other," from (i) and (ii), respectively, were then pooled together to determine the might-have-been prevalence or prospective GDM diagnosis (% Pro) by the new guidelines. Lastly, the fraction of the "other" in the "Pro" for the 10 years period is expressed as the potential impact of the new guidelines.

Results

The summary statistics of the results is presented in table. The yearly average of 19.5% was reported as gestational diabetes [Table 1]. The focus of evaluations is the "normal" reports; how many of them would have been reported as GDM based on the new recommended guideline or threshold. Using the new guidelines, the results show an additional yearly average of 10.8%, and the 10 years additive of 12% (74 out of 615) would have been reported as GDM. That is, the incidence or number of GDM cases would have increased from 88 to 162 [Table 2], which translates to approximately 46% impact [Figure 1].

Discussion

The main focus of this study was to investigate and quantify the potential impact of the new

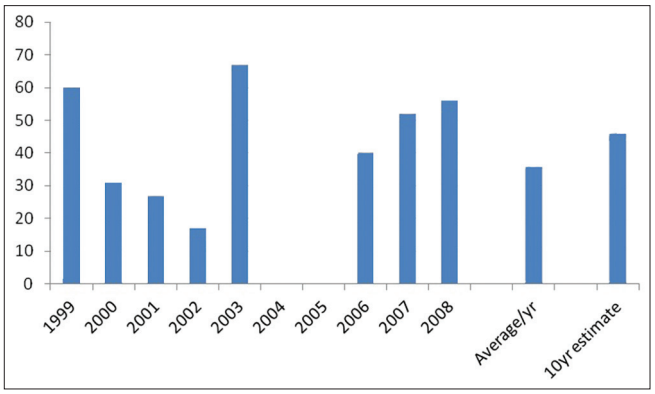

Figure 1: Percentage* impact of the new guidelines on number of gestation diabetes mellitus cases

Table 1: Summary statistics of all oral glucose tolerance test reports for antenatal subpopulation

Parameters	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
N	9	42	33	32	14	13	15	24	129	304
GDM	2	11	8	10	1	4	3	3	12	34
Normal	7	31	21	20	13	9	10	21	114	269
TNC	0	0	4	2	0	0	2	0	3	1
% Pos	22.2	26.2	24.2	31.3	7.1	30.8	20.0	12.5	9.3	11.2

GDM: Gestation diabetes mellitus; TNC: Test not completed; *N*: Total number; Pos: Abnormal

Table 2: Yearly incidence of gestation diabetes mellitus cases with and without considering the new guidelines

Year	*N*-test	Old guideline		New threshold*		Total %	
		N_{old}	%	N_{new}	%	N_{total}	%
1999	9	2	22.22	3	33.33	5	55.56
2000	42	11	26.19	5	11.90	16	38.10
2001	33	8	24.24	3	9.09	11	33.33
2002	32	10	31.25	2	6.25	12	37.50
2003	14	1	7.14	2	14.29	3	21.43
2004	13	4	30.77	0	0.00	4	30.77
2005	15	3	20.00	0	0.00	3	20.00
2006	24	3	12.50	2	8.33	5	20.83
2007	129	12	9.30	13	10.08	25	19.38
2008	304	34	11.18	44	14.47	78	25.66

*Abnormality based on new recommended threshold: Fasting glucose level>5.1 mmol/L (92 mg/dL), 1-h postprandial glucose level>10.0 mmol/L (180 mg/dL), and/or a 2-h postprandial glucose level>8.5 mmol/L (153 mg/dL)–the sum of N_{new}=74 cases would was observed. This amount to an increase of N_{old}=88 to N_{total}=162 over the ten year period

guideline thresholds for diagnosis or classification of hyperglycemia in pregnancy. Initial review shows that by the pathology's protocol, yearly average of 19.5% of antenatal OGTT tests were reported as gestational diabetes.[13] A further review of the case reports that were classified as normal [Table 1], but this time using the new recommended thresholds, revealed that an additional yearly average of 10.8% would have been reported as gestational diabetes [Table 2].

A cursory look at the descriptive statistics or the information on Table 2 may not reveal the full impact of the new recommendations on prospective incidence of GDM. For instance, it could be hastily translated to be "10.8/(19.5 + 10.8) ×100 = 35.6%." Another potential hasty translation could be to take only 1 or 2 years, but the results show unevenness in the yearly impact. A critical evaluation shows that the increase in number from 88 to 162 translates to 45.7% [Figure 1].

It is pertinent to note one of the reviews of the new criteria that the total incidence of gestational diabetes in the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) population was 17. 8%,[7] which is less than half of what is being reported here. This is probably a reflection of the different populations studied. Nevertheless, the significance comes to bear in estimating and planning for the management of GDM in the population, and reinforces the call to study local populations because of geographical and social impacts among others.

Conclusion

We report a level of prevalence of abnormal OGTT that has yet to be fully appreciated. We also report pathology-based evidence that the new guidelines for diagnosis and classification of hyperglycaemia could increase the GDM cases by as much as 46%. The importance of this report is in the epidemiological information necessary for estimating the cost of adopting criteria.

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