Implementation of new recommendations for the diagnosis of gestational diabetes: a 5-month audit

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Abstract

Background: Recent international recommendations for the diagnosis of gestational diabetes (GD) were implemented in a university hospital. The aim was to audit the appropriateness of use of the new diagnostic approach.

Methods: The same 5-month period, one before [2009, traditional two-step oral glucose tolerance test (OGTT) approach, S1] and one after the implementation of new criteria (2010, S2) were compared.

Results: In the two periods, 256 (S1) and 245 (S2) pregnant women were examined and 298 (50 g, n=195; 100 g, n=103) and 252 (75 g) OGTTs were, respectively, executed. In S1, 54 (27.7%) 50 g OGTTs resulted positive and 36 (66.7%) of those performed the 100 g OGTT. In addition, three (1.5% of total) 50 g OGTT negative women were submitted to 100 g OGTT. Sixty-three women did 100 g OGTT only. In total, 14 (13.6%) 100 g OGTTs were positive. In S2, 38 (15.1%) 75 g OGTTs were positive. In women who did the complete protocol in the hospital, 98.3% in S1 and 77.0% in S2 performed the correct protocol (p<0.0001).

Conclusions: In this hospital new recommendations for GD diagnosis are not correctly applied in 23% of cases. The main issue seems to be the lack of consideration of the new threshold for fasting glycaemia (5.1 mmol/L) as a main decisional driver for performing OGTT.

Keywords: diagnosis; gestational diabetes; new recommendations.

Traditionally, gestational diabetes mellitus (GD) has been defined as any degree of glucose intolerance with onset or first recognition during pregnancy (1). Because of the risks to mother and neonate, screening and early diagnosis of GD are warranted (2). Recently, the Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study has found a significant association between adverse outcomes and concentrations of maternal plasma glucose previously considered as non-diabetic (3). These results indicated the need for reconsidering the diagnostic criteria of hyperglycemia during pregnancy. HAPO study data were translated for diagnosis of GD and plasma glucose concentrations, at which odds for specific outcomes reached 1.75-times the estimated odds at the lowest mean plasma glucose values, were established as new diagnostic threshold values (4). In particular, cut-off values of 5.1 mmol/L for fasting plasma glucose (FPG) and 10.0 mmol/L and 8.5 mmol/L for plasma glucose concentrations 1 and 2 h from a 75 g oral glucose tolerance test (OGTT) has been indicated (4). At least one of these thresholds must be equalled or exceeded to make a diagnosis of GD. These recommendations were implemented in our university hospital on June 2010 after an exhaustive discussion between laboratory specialists and obstetricians. Particularly in the laboratory the 50 g OGTT and the 100 g OGTT were replaced by a new test codifying the 75 g OGTT in pregnancy and the involved physicians, including general practitioners and external obstetricians, were informed about the new recommended protocol by explanatory brochures and by appropriate oral presentations in dedicated meetings. Here, we aimed to audit the impact and the appropriateness of use of the new diagnostic approach after 5 months from its implementation.

Two hundred and fifty-six and 245 pregnant women were examined and 298 and 252 OGTTs were carried out in S1 and S2, respectively. In S1, 54 50 g OGTTs were positive and 36 (66.7%) of those performed the 100 g OGTT for diagnosis confirmation. In addition, 3 (1.5% of total) 50 g OGTT negative women were submitted to 100 g OGTT. In total, 14 100 g OGTTs were positive according to criteria by the American Diabetes Association (1) (see also Table 1). From these positive confirmatory tests, eight women did the complete protocol in our hospital, seven had a positive, while one had a negative screening test. In S2, 38 75 g OGTTs were positive. Of the women who did the complete protocol in our hospital, 98.3% and 77.0% performed the correct diagnostic evaluation in S1 and S2, respectively ($\chi^2=36.7$, p<0.0001). In particular, in S1 for three women a confirmatory test was needlessly requested, while in S2 31 women with a FPG concentration >5.1 mmol/L (all have FPG <7.0 mmol/L) were...
needlessly submitted to the 75 g OGTT. Protocol duplications were requested by physicians for three women in S1 and for five women in S2, without any difference between the two periods ($\chi^2=0.18$, $p=0.68$). The rate of incomplete OGTTs was rather low, with no difference between S1 and S2 ($\chi^2=1.72$, $p=0.19$). Results of the study are summarized in Table 2.

An optimal detection of any level of hyperglycemia in pregnancy is justified not only by the continuous graded relationship between higher maternal plasma glucose and increasing risk of adverse pregnancy outcomes (3), but also by the increasing prevalence of pre-gestational diabetes, which in pregnancies is associated with significant risk of adverse perinatal outcome and also to deleterious long-term effects in infants of these diabetic mothers (5, 6). Furthermore, women with GD have an increased risk of developing type 2 diabetes compared with those with normoglycemic pregnancy, a history of GD therefore providing a natural screening test for future type 2 diabetes (7). Accordingly, the new recommendations by the International Association of Diabetes and Pregnancy Study Groups (IADPSG) Consensus Panel represent a fundamental step in the diagnosis of diabetes in pregnancy. The protocol using FPG at initial visit and a 75 g OGTT at 24–28 weeks, if the screening test is negative, should be able to detect hyperglycemia earlier, in addition to simplifying and unifying the diagnosis of diabetes leading to use the 75 g OGTT in all clinical situations in or outside of pregnancy, while also aiming to reduce patient discomfort (4).

Table 1  Diagnostic criteria of gestational diabetes (GD) in the two evaluated periods, before (S1) and after (S2) the introduction of the new recommendations.

<table>
<thead>
<tr>
<th>Test</th>
<th>Time</th>
<th>Cut-off, mmol/L</th>
<th>Action/diagnosis</th>
<th>Test</th>
<th>Time</th>
<th>Cut-off, mmol/L</th>
<th>Action/diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 g OGTT</td>
<td>2 h</td>
<td>≥7.8</td>
<td>If positive confirm with 100 g OGTT</td>
<td>FPG</td>
<td>≥7.0</td>
<td>Diagnosis of pre-gestational diabetes</td>
<td></td>
</tr>
<tr>
<td>100 g OGTT</td>
<td>0 h</td>
<td>≥5.3</td>
<td>If at least two points are positive diagnosis of GD</td>
<td>75 g OGTT</td>
<td>0 h</td>
<td>≥5.1 and &lt;7.0</td>
<td>Diagnosis of GD</td>
</tr>
<tr>
<td></td>
<td>1 h</td>
<td>≥10.0</td>
<td></td>
<td></td>
<td>1 h</td>
<td>&lt;5.1</td>
<td>Proceed to 75 g OGTT</td>
</tr>
<tr>
<td></td>
<td>2 h</td>
<td>≥8.6</td>
<td></td>
<td></td>
<td>2 h</td>
<td>≥8.5</td>
<td>If at least one point is positive diagnosis of GD</td>
</tr>
<tr>
<td></td>
<td>3 h</td>
<td>≥7.8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The same 5-month period (June–October), one before (2009, S1) and one after the implementation of the new GD criteria (2010, S2), were compared. In S1 the protocol for GD diagnosis (two OGTT approach) consisted of a 50 g OGTT carried out at 24–28 weeks of gestation as a screening test and, in the case of positive results, of the execution of a confirmatory test using a 100 g OGTT (1). In S2, the protocol for GD diagnosis started with a FPG evaluation obtained during the first medical visit in pregnancy. If results were <5.1 mmol/L, a 75 g OGTT was done at 24–28 weeks (one OGTT approach) (4). OGTTs were performed and blood samples were collected in the Obstetrics and Gynaecology Department or in the outpatient clinic of our hospital. Data mining was done using codes encoding 50 g OGTT and 100 g OGTT (S1), 75 g OGTT in pregnancy and FPG (S2) in our laboratory information system. In S2, 75 g OGTT results were first retrieved, then FPG results were searched for every women with 75 g OGTT. As in S1 not all patients with positive screening test were subjected to the confirmatory test in our hospital and, similarly, not every pregnant woman who made the confirmatory test also preformed the screening test in our hospital, the number of women undergoing a complete protocol (screening test + confirmatory test, if needed) was lower than the total number of examined subjects. The same was found in S2, when not every pregnant woman undergoing 75 g OGTT also did FPG at the first visit in our hospital.

Table 2  Summary of data.

<table>
<thead>
<tr>
<th></th>
<th>S1</th>
<th>S2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examined women</td>
<td>256</td>
<td>245</td>
</tr>
</tbody>
</table>
| Performed OGTTs| 298                    | 195 (50 g OGTT) 103 (100 g OGTT) | 252
| Positive OGTTs | 54 (27.7%)             | 14 (13.6%)             | 38 (15.1%) |
| Women with complete protocol in our hospital | 175 (68.4%) | 136 (negative 50 g OGTT) 39 (50 g OGTT+100 g OGTT) | 135 (55.1%) |
| Women with incomplete protocol in our hospital | 81 (31.6%) | 18 (only a positive 50 g OGTT) 63 [only 100 g OGTT (one woman twice)] | 110 (44.9%) (only 75 g OGTT) |
| Women with protocol duplication | 3 (1.2%) | 5 (2.0%) |
| Women with correctly applied complete protocol | 172 (98.3%) | 104 (77.0%) |
| Incomplete OGTTs | 2 (0.7%) | 6 (2.4%) |
With these premises in mind, we recently implemented the new guidelines in our hospital, auditing their application after 5 months. In spite of simplification of the diagnostic approach, our data show that the rate of OGTT per examined woman (1.16 in S1 vs. 1.03 in S2) did not notably decrease, nor did it significantly change the number of protocol duplications. Theoretically, an increase of duplications could be expected in S2 due to the novelty of the diagnostic procedure with consequent more frequent doubtfulness of physicians, while a decrease in number of repeatedly requested protocols could be expected due to simplification of the diagnostic approach. The rate of incomplete OGTTs, due to nausea/emesis causing test suspension, even if very small, did not decrease in S2 that does not support the supposed patient discomfort reducing effect of the new diagnostic approach. Women with incomplete protocol in our hospital were considered outliers as we do not know if they performed the remaining part of the protocol in another center or if they did not complete it at all. Therefore, the correctness of the application of diagnostic approach was considered only in women who did the complete protocol in our hospital. In this subgroup, new recommendations were not correctly applied in 23% of cases. The main issue seems to be the lack of consideration of the new threshold of FPG (5.1 mmol/L) at the first prenatal visit as main decisional driver for ordering OGTT. Even if not directly documented in the audit, the possible doubts of clinicians about the definitive validity of new recommendations, expressed in some recently published editorials (8–10), are aggravated in our country by the existence of different policies supported by national scientific societies, which have introduced the IADPSG recommendations, and national health system, which in its guidelines is still anchored to the traditional World Health Organization (WHO) criteria (11).

Although our study was not conceived to evaluate the impact on the clinical outcome of the introduction of new recommendations and, furthermore, it is only a local experience related to a relatively short time period, we think that our results could be useful for other hospitals considering the introduction of the new IADPSG recommendations for GD diagnosis. Until now, only two Australian studies have been published: a simulation study estimating the impact on workload (12) and a prospective one evaluating the expected prevalence of GD using the current and the newly proposed criteria on the same population (13). Our study is the first examining the appropriateness of the use of new recommendations based on a real experience. From our data, we may conclude that the correctness of use of the new diagnostic approach for GD diagnosis in our hospital should be improved. Further education of ordering physicians about the correct application of the protocol is, therefore, clearly advisable.

Conflict of interest statement

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References