IMPROVEMENT OF SELECTIVE SCREENING STRATEGY FOR GESTATIONAL DIABETES THROUGH A MORE ACCURATE DEFINITION OF HIGH RISK GROUPS.

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ABSTRACT

**Objective:** To assess the predictive value of the risk factors (RF) for gestational diabetes (GDM) considered by the selective screening (SS), and to identify subgroups of women at higher risk for GDM.

**Design:** Retrospective, single-center study.

**Methods:** Data of 1015 women, screened for GDM at 24-28 weeks gestation and diagnosed according to IADPSG criteria, were evaluated. Information on the RF considered by SS was also collected, and their association with GDM was tested. To identify distinct and homogeneous subgroups of patients at higher risk, the RECPAM (RECursive Partitioning and AMalgamation) method was used.

**Results:** Overall, 113 (11.1%) women were diagnosed as having GDM. The application of SS would lead to the performance of an OGTT in 58.3% of women, and 26 (23.0%) cases of GDM would not be detected due to the absence of any RF. RECPAM analysis identified high risk subgroups characterized by fasting plasma glucose >5.1mmol/L (OR=26.5;95%CI 14.3-49.0) and pre-gestational BMI (OR=7.0;95%CI 3.9-12.8 for overweight women). In a final logistic model including RECPAM classes, previous macrosomia (OR=3.6;95%CI 1.1-11.6) and family history of diabetes (OR=1.8;95%CI 1.1-2.8), but not maternal age, were also associated with an increased risk of GDM. A screening approach based on the RECPAM model would reduce by over 50% (23.0% vs. 10.6%) the number of undiagnosed GDM cases as compared with the current SS approach, at the expense of 50 additional OGTTs needed.

**Conclusions:** A screening approach based on our RECPAM model allows a significant reduction of undetected GDM cases compared to current SS procedure.
INTRODUCTION

Gestational Diabetes Mellitus (GDM) is defined as any degree of glucose intolerance with onset or first recognition during pregnancy (1). In the last years, many screening and diagnostic criteria were proposed (2, 3, 4, 5), this representing the main reason for the very different GDM prevalence worldwide (6). GDM is an important factor in determining adverse maternal and neonatal outcomes (7, 8, 9), and long-term consequences for both baby and mother, such as predisposition to obesity, metabolic syndrome, cardiovascular diseases and diabetes (10, 11, 12). For those reasons it necessitates an early detection and a proper treatment. In 2010, the International Association of Diabetes and Pregnancy Study Groups (IADPSG) Consensus Panel (3), reconsidering the results of the HAPO Study (13), proposed new diagnostic criteria, based on universal diagnostic approach, which have been accepted by American Diabetes Association (14). According to universal screening all pregnant women not previously known to have diabetes have to screen for GDM at 24-28 weeks of gestation, using a 75-g 2-h oral glucose tolerance test (OGTT), regardless of the presence of any risk factor. Moreover, several International Diabetes Scientific Societies, including British National Institute for Health and Clinical Excellence (NICE) and the Italian Guideline of Physiological Pregnancy (5, 15), established to execute a selective screening for GDM, based on the presence of specific risk factors. According to universal screening all pregnant women not previously known to have diabetes have to screen in a first step for the presence of defined risk factors.

Traditional risk factors such as maternal age, pre-pregnancy Body Mass Index (BMI), fasting plasma glucose (FPG), previous GDM, previous macrosomia, family history of diabetes and ethnicity were considered. In case of presence of even only one risk factor women have to screen for GDM using a 75-g 2-h OGTT. However, there is still a debate about which risk factors should be taken into account in order to make screening and diagnostic procedures cost-effective.
Aim of this study was to assess, in a Caucasian population, the independent predictive value of the risk factors for GDM considered by the selective screening, and to identify subgroups of women at higher risk for GDM.

In particular, we applied retrospectively the selective screening criteria to our population, to estimate the number of OGTTs that would have been required by these criteria and the proportion of diagnoses of GDM that would have been missed, as compared to a universal screening approach. We also compared the yield of the selective screening criteria strategy with that of an alternative approach, based on risk stratification derived from the application of tree-growing regression techniques.

MATERIALS AND METHODS

This is a retrospective study approved by the local Ethics Committee, involving a total of 1015 Caucasian pregnant women consecutively referred to the Clinic of Diabetes and Pregnancy of the University of Messina, Italy, from May 1st, 2010 to October 31st, 2011. All the participant patients gave informed consent.

All the patients underwent a 75 g-2 h oral glucose tolerance test (OGTT) between 24 and 28 weeks of gestation and the diagnosis of GDM was made according to the IADPSG recommendations (3). Briefly, IADPSG suggests to perform a 75-g OGTT, with plasma glucose measurement fasting and at 1 and 2 h, at 24–28 weeks of gestation in women not previously diagnosed with overt diabetes. The diagnosis of GDM is made when any of the following plasma glucose values are exceeded: fasting: ≥ 5.1 mmol/L, 1 h: ≥ 10.0 mmol/L, 2 h: ≥ 8.5 mmol/L. First trimester FPG and information on the risk factors established by selective screening (13) was also collected from clinical chart records. The risk factors considered were: maternal age ≥ 35 years, pre-pregnancy Body Mass Index (BMI) ≥ 25 Kg/m², fasting plasma glucose (FPG) between 5.6 and 6.9 mmol/L in pre-pregnancy or in the first period of the pregnancy, previous GDM, previous macrosomia (birth weight ≥ 4500 g), family history of diabetes (first degree relative with diabetes), family origin from areas with a high
prevalence of diabetes. Data of 1028 singleton consecutive pregnancies in the study period were evaluated. Twelve of them had no complete information on the risk factors or the first trimester FPG; one was diagnosed as pre-pregnancy diabetes on the basis of the first trimester FPG value. Therefore, 13 patients were excluded from the study.

Statistical Analyses

Data were reported as means ± SD for continuous variables and percentages for categorical variables. Characteristics of the study population were categorized by GDM (Yes/No) and were compared using $\chi^2$ statistic for categorical variables and Mann-Whitney U test for continuous variables.

Multivariate logistic regression analysis was performed to evaluate the association between the risk factors considered in the selective screening and GDM. The following baseline covariates were tested: FPG between 5.6-6.9 mmol/L (yes or no), previous macrosomia (birth weight ≥4500g) (yes or no), pre-pregnancy BMI ≥ 25 Kg/m2 (yes or no), family history of diabetes (yes or no), maternal age ≥ 35 years (yes or no). Results of the logistic models are expressed as adjusted odds ratios (aORs) with their 95% confidence intervals (CIs).

Furthermore, to identify distinct and homogeneous subgroups of patients at higher risk of developing GDM, the RECPAM (RECursive Partitioning and AMalgamation) method was used (16, 17, 18). This tree-based method integrates the advantages of main effects of standard logistic regression and tree-growing techniques. At each partitioning step the method chooses the covariate and its best binary split to maximize the difference in the risk of developing GDM. The algorithm stops when user defined conditions (stopping rules) are met. In our RECPAM analysis a minimum set of 20 GDM cases and 50 women per node was considered. We tested in the RECPAM model the same set of variables used in the multivariate logistic regression analysis, without categorizing continuous variables, to allow the algorithm to choose the natural cutoff points. A final backward logistic regression with the RECPAM classes forced in was performed to highlight the role of
additional variables that play a role as global correlates. A sensitivity analysis comparing selective screening criteria, and risk factor-based screening (according to our RECPAM model) criteria with respect to universal screening criteria was performed. Number of OGTTs to be performed and of undetected GDM cases resulted from the application of current and RECPAM-based selective criteria, as compared to universal screening, were calculated. A p value < 0.05 was considered for statistical significance. Analyses were performed using SAS version 9.2 (SAS Institute Inc.).

RESULTS

Overall, 1015 pregnant women were evaluated and GDM was diagnosed in 113 cases (11.1%). Applying to our study population the selective screening criteria, only 591 patients (58.3%) would have undergone the diagnostic OGTT because of the presence of at least one risk factor. The number of patients with GDM according to IADPSG criteria but not having any risk factor, and therefore not considered for selective screening, was of 26 women. When compared with women having a normal glucose tolerance (NGT) at the OGTT, women with a GDM diagnosis made by universal screening were older, had higher pre-pregnancy BMI, higher BMI at the OGTT and higher FPG at first trimester; furthermore, they had more often a family history of diabetes, previous GDM and previous macrosomia (Table 1). Women with GDM did not differ from NGT women for gestational age, parity, weight gain during pregnancy and percentage of women aged ≥ 35 years (Table 1). Results of logistic regression analysis showed a higher risk of developing GDM in presence of FPG between 5.6-6.9 mmol/L (aOR 66.3; 95%CI 8.0-548.1), previous macrosomia (aOR 6.1; 95%CI 2.1-17.3), pre-pregnancy BMI ≥ 25 Kg/m² (aOR 2.2; 95%CI 1.4-3.4) and family history of diabetes (aOR 2.0; 95%CI 1.3-3.1). An increased risk was not associated with maternal age ≥ 35 years (aOR 1.0; 95%CI 0.6-1.6).

RECPAM Analysis
RECPAM analysis led to the identification of 4 classes at different risks for developing GDM (Figure 1). The reference category was represented by the subgroup of women with the lowest prevalence of GDM. Thus, the odds ratios (ORs) for all the other subgroups were estimated with respect to the reference class. The most important variable in discriminating the risk of GDM was represented by FPG, with the lowest prevalence in patients with FPG ≤ 4.4 mmol/L. Therefore, this group served as the reference category. On the opposite side of the regression tree, patients with a FPG > 5.1 mmol/L represented the subgroup with the highest prevalence of GDM (OR 26.5; 95%CI 14.3-49.0). In women with FPG between 4.5-5.1 mmol/L the prevalence of GDM was further discriminated on the basis of pre-gestational BMI values. Women with a pre-pregnancy BMI > 24.4 Kg/m² showed a 7-fold higher risk of developing GDM compared to the reference class (OR 7.0; 95%CI 3.9-12.8) and a double risk compared to women with a pre-pregnancy BMI ≤ 24.4 Kg/m² (class 3). Other risk factors considered did not contribute in identifying distinct subgroups at increased risk for GDM. When examining the clinical characteristics of the RECPAM classes, the class at higher risk for GDM (class 1) showed higher and statistically significant percentages of women with a family history of diabetes and women with previous macrosomia, as compared with women of the other classes (Figure 1). A final logistic regression model with RECPAM classes forced in, performed to highlight the role of additional covariates, identified RECPAM classes 1, 2 and 3, previous macrosomia and a family history of diabetes as predictive variables associated with an increased risk of GDM. Maternal age was not associated with an increased risk (Table 2).

As shown in Table 3, applying the most predictive risk factors detected by RECPAM model can diagnose with higher sensitivity GDM women, as compared to current selective screening criteria.

Following the application of universal screening recommendations, all the women in our study underwent the diagnostic OGTT (i.e. 1015 OGTTs). Considering a screening strategy based on the most predictive risk factors suggested by the RECPAM model, 641 women would be considered at risk, having at least one of these risk factors. The use of OGTT only in women at risk would result in the execution of 641 OGTTs, thus leading to a saving of 1015-641=374 OGTTs (36.8%), as
compared to universal screening. On the other hand, the application of current selective screening recommendations would imply the execution of an OGTT in 591 women, because of the presence of at least one risk factor. Therefore, the application of the RECPAM approach would increase by only 50 the number of OGTTs (641 vs. 591), as compared with current selective screening.

DISCUSSION

Our study allowed us to detect the independent predictive role of the suggested individual risk factors for GDM in a Caucasian population of pregnant women. We also identified subgroups of women at higher risk of developing GDM.

Our approach was similar to that of several studies designed with the scope to identify the best diagnostic approach for GDM (19, 20, 21, 22, 23). In the European Countries the nonconformity of screening and diagnosis procedures for GDM is responsible of its different reported prevalence (6). The attempt of the IADPSG Consensus Panel recommendations to establish a common strategy, triggered a still current international debate on its validity (24, 25). In the various National contexts a divergence in acceptance of the IADPSG recommendations was therefore seen, and in some cases a reworking of the same was made. The Italian Institute of Health elaborated a specific Guideline, that established, according to the NICE criteria, a two-steps risk factor-based procedure for the detection of GDM (15).

Our study aimed, for the first time, to evaluate the real relevance of each risk factor through the RECPAM model, whose algorithm allowed to choose the natural cutoff points of the continuous variables included in the model. Thus, the cutoff values chosen by the model are not defined a priori, but they represent the split effect that maximizes the difference in the risk of GDM. The big advantage of the RECPAM model, as compared with classical multivariate analysis, is to not identify the risk of GDM associated with a specific variable but to define subgroups of patient at higher risk, according to the factors most capable of determining a high predictive value for GDM.
We tested in the RECPAM model a set of variables made of the suggested risk factors for GDM. FPG was confirmed to be the most important factor in differentiating the risk of GDM. It is interesting to observe that the highest risk of developing GDM was present in the subgroup of women with FPG > 5.1 mmol/L and this is exactly in line with the FPG diagnostic cutoff value proposed by IADPSG. This could support the IADPSG Panel recommendation to consider a FPG value ≥ 5.1 mmol/L to diagnose GDM. Furthermore, the reference class we identified was characterized by a FPG ≤ 4.4 mmol/L, the same FPG cutoff value for which in the HAPO study the risks of some adverse outcomes was low (3, 13).

In addition to the FPG, it is important to underline the role of pre-pregnancy BMI, further differentiating the risk of GDM among women with intermediate levels of FPG. This confirms the recent acquisition of a perhaps overly glucocentric approach that could change in a vision considering more the BMI as an equally important risk factor (26). Therefore, even in the lack of a clear FPG impairment, pre-pregnancy BMI was per se a parameter capable of causing an increased risk for GDM (Figure 1).

Among the considered risk factors we showed that maternal age was not associated with an increased risk of developing GDM, as shown by the multivariate analysis, and it did not define a subgroup of women at higher risk at the RECPAM analysis. Even when performing the final logistic regression model, with RECPAM classes forced in, maternal age was not detected as a globally predictive variable associated with an increased risk of GDM. This is certainly an interesting point because among the scientific Societies that provide a similar two-step procedure with selective screening, there is still a discrepancy on the definition of the risk factors to be considered, specifically concerning maternal age (5, 27). The Australasian Diabetes in Pregnancy Society (ADIPS) recommends universal screening for GDM. However, it advises that where resources are limited selective screening based on risk factors may be appropriate (27) and among the considered risk factors there is age > 30 years. NICE Guidelines (5) decided not to consider
mother’s age as a risk factor. The predictive value of maternal age in the development of GDM was evaluated in several studies and the risk associated was shown higher with increasing age (20, 21, 28, 29). However, other Authors have reported no very higher risk for older women (30, 31). A recent study, examining the individual association between maternal age, BMI and racial origin with the development of GDM, found different associated risks in relation to the GDM prevalence of the specific racial group considered. In particular the most important findings implied that maternal age was more important in the development of GDM in Black Africans and South Asians than in White Europeans (20). This could explain the possibility of considering older maternal age as a strong risk factor for GDM in populations other than the White European population.

Limits of our study are primarily its retrospective design, which also determines the lack of cases of women with previous GDM who did not develop GDM in the second pregnancy. However, it is widely accepted that previous GDM is one of the best predictors of GDM, as reported in many studies (30). Furthermore, having no information on the maternal and fetal outcomes makes no possible an assessment on the predictive role of individual risk factors for GDM on the occurrence of these outcomes.

In conclusion, the current selective screening based on risk factors led to sparing more than 40% of the OGTTs, as compared to universal screening, but at the cost of the lack of identification of about one-fourth of women with GDM without established risk factors. In the light of our results it is clear that some women have distinct characteristics that place them at greater risk of developing diabetes. In particular, a FPG value > 5.1 mmol/L and pre-pregnancy overweight are the two factors associated with the highest risk for GDM, while an increased risk seems not to be associated with maternal age ≥ 35 years. The screening we suggest consists of a selective risk factor-based approach. As shown by the performed sensitivity analysis it could determine a significant reduction in undetected cases of GDM, in the face of minimum increase of the number of OGTTs to be performed.
Even though what is an acceptable percentage of missing cases of GDM is difficult to establish, considering our results, a revaluation of the risk factors used in the screening procedures for the detection of GDM could be useful. This could make the procedures more cost-effective and, above all, could relieve stressful conditions and unnecessary medicalization of healthy women in their pregnancies. However, it is desirable to conduct further studies, with a greater number of participants of different ethnicities, that correlate the risk factors to maternal-fetal outcomes.

**DISCLOSURE**

Authors declare that there is no conflict of interest that could be perceived as prejudicing the impartiality of the research reported.

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Nothing.
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FIGURE LEGEND

Figure 1. Identification of subgroups at different risks for GDM: results of RECPAM analysis.

REPCAM analysis identified patients’ subgroups at different risks for GDM. The tree-growing algorithm modeled odds ratios (ORs) following a logistic regression with age, familiarity history of diabetes, fasting plasma glucose (FPG), pre-pregnancy Body Mass Index (BMI), previous macrosomia as global variables. Splitting variables are shown between branches, whereas a condition sending patients to left or right sibling is on a relative branch. Class 4 with lowest risk for GDM was the reference category (OR=1). Circles indicate subgroups of patients; squares indicate the patient subgroup REPCAM class. Numbers inside circles and squares represent the number of events (top) and the number of nonevents (bottom), respectively. An odds ratio (OR) with the corresponding 95% CI (in parentheses) is attached to each class. The table placed at the bottom of the figure shows patients’ characteristics within each RECPAM class.
Figure 1
Table 1. Clinical characteristics of the women according to their glucose tolerant status.

<table>
<thead>
<tr>
<th></th>
<th>NGT (n=902)</th>
<th>GDM (n=113)</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>30.5±5.4</td>
<td>32.0±4.8</td>
<td>0.0076</td>
</tr>
<tr>
<td>Women aged ≥ 35 years [n (%)]</td>
<td>212 (23.5)</td>
<td>35 (31.0)</td>
<td>0.0811</td>
</tr>
<tr>
<td>Gestational age (weeks)</td>
<td>25.9±1.8</td>
<td>25.6±2.0</td>
<td>0.128</td>
</tr>
<tr>
<td>Pre-pregnancy BMI (kg/m²)</td>
<td>23.7±6.8</td>
<td>25.7±4.7</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Women with pre-pregnancy BMI ≥ 25 (kg/m²)</td>
<td>243 (26.9)</td>
<td>56 (49.0)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Women with pre-pregnancy BMI ≥ 30 (kg/m²)</td>
<td>68 (7.5)</td>
<td>19 (16.8)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>BMI at the OGTT (kg/m²)</td>
<td>26.6±9.4</td>
<td>28.6±4.2</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Family history of diabetes [n (%)]</td>
<td>199 (22.1)</td>
<td>46 (40.7)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Parity &gt;1 [n (%)]</td>
<td>429 (47.6)</td>
<td>49 (43.4)</td>
<td>0.399</td>
</tr>
<tr>
<td>Previous GDM [n (%)]</td>
<td>0 (0)</td>
<td>10 (8.8)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Previous macrosomia [n (%)]</td>
<td>11 (1.2)</td>
<td>7 (6.2)</td>
<td>0.0002</td>
</tr>
<tr>
<td>FPG between 5.6 and 6.9 mmol/L [n (%)]</td>
<td>1 (0.1)</td>
<td>12 (10.6)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>FPG at first trimester (mmol/L)</td>
<td>4.3±0.4</td>
<td>4.8±0.6</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Glycemia T0 at the OGTT (mmol/L)</td>
<td>4.3±0.4</td>
<td>4.9±0.5</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Glycemia T60 at the OGTT (mmol/L)</td>
<td>6.8±1.4</td>
<td>9.8±1.6</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Glycemia T120 at the OGTT (mmol/L)</td>
<td>5.8±1.2</td>
<td>7.8±1.4</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Weight gain during pregnancy (Kg)</td>
<td>7.1±3.9</td>
<td>7.5±3.8</td>
<td>0.246</td>
</tr>
</tbody>
</table>

NGT=Normal Glucose Tolerance; GDM=Gestational Diabetes Mellitus.

* Mann-Whitney U test for continuous variables and $\chi^2$ for categorical variables.
Table 2. Backward logistic regression with the RECPAM classes forced in: Odd Ratio (OR) and 95% confidence interval (CI) of the risk factors considered.

<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>RECPAM class 3 vs. 4</td>
<td>3.9</td>
<td>2.1-7.0</td>
</tr>
<tr>
<td>RECPAM class 2 vs. 4</td>
<td>6.4</td>
<td>3.52-11.7</td>
</tr>
<tr>
<td>RECPAM class 1 vs. 4</td>
<td>22.0</td>
<td>11.7-41.2</td>
</tr>
<tr>
<td>Previous macrosomia (birth weight ≥4500g)</td>
<td>3.6</td>
<td>1.1-11.6</td>
</tr>
<tr>
<td>Family history of diabetes</td>
<td>1.8</td>
<td>1.1-2.8</td>
</tr>
</tbody>
</table>

Variables included in the model were: RECPAM classes, previous macrosomia, family history of diabetes, maternal age.
Table 3. Comparison between GDM screening procedures according to the current selective criteria or the risk factors suggested by RECPAM model, as compared to universal screening.

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
<th>OGTTs needed</th>
<th>Undetected GDM cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current selective screening</td>
<td>80%</td>
<td>44%</td>
<td>85%</td>
<td>94%</td>
<td>591</td>
<td>26 (23.0%)</td>
</tr>
<tr>
<td>FPG &gt; 4.4 mmol/L</td>
<td>80%</td>
<td>66%</td>
<td>77%</td>
<td>96%</td>
<td>399</td>
<td>23 (20.3%)</td>
</tr>
<tr>
<td>FPG &gt; 4.4 mmol/L or pre-pregnancy BMI ≥ 25kg/m²</td>
<td>87%</td>
<td>50%</td>
<td>82%</td>
<td>96%</td>
<td>550</td>
<td>15 (13.3%)</td>
</tr>
<tr>
<td>FPG &gt; 4.4 mmol/L or pre-pregnancy BMI ≥ 25kg/m² or family history of diabetes</td>
<td>89%</td>
<td>40%</td>
<td>84%</td>
<td>97%</td>
<td>641</td>
<td>12 (10.6%)</td>
</tr>
</tbody>
</table>

PPV, positive predictive value; NPV, negative predictive value.