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Italian national guidelines for the screening of gestational diabetes: Time for a critical appraisal?

C. Bianchi [a,*], G. de Gennaro [b], M. Romano [c], L. Battini [c], M. Aragona [a], M. Corfini [a], S. Del Prato [b], A. Bertolotto [a]

[a] Department of Medicine, University Hospital of Pisa, Italy
[b] Department of Clinical and Experimental Medicine, University of Pisa, Italy
[c] Maternal-Infant Department, University Hospital of Pisa, Italy

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Abstract *Background and aim:* In 2011, the Italian National Health System guidelines introduced a selective screening for gestational diabetes (GDM) based on risk factors, recommending early evaluation in high risk women. The present study examined to which extent guidelines are applied, and analyzed the effectiveness of GDM diagnosis according to risk profile.
Methods and results: We analyzed 1338 pregnant women, consecutively screened for GDM with a 75 g OGTT between January 2013 and December 2015, according to national guidelines. Diagnosis of GDM was based on IADPSG/WHO 2013 criteria.

As many as 14.4% of screened women was at high risk, 64% at medium, 21.6% did not have any risk factor. Only 50% of high-risk women were appropriately screened at 16th–18th gestational weeks; 28% of them repeated the OGTT due to NGT. The overall prevalence of GDM was 39.9%, higher in high risk women (67% vs. 40% medium risk vs. 22% low risk; $p < 0.0001$). An early GDM diagnosis was performed in 40.7% of high-risk women. In low risk women, gestational weight gain at the screening time was independently associated with GDM.
Conclusions: The recommendations for the screening of GDM are still insufficiently implemented, especially for early evaluation in high risk women. Considering the high proportion of early GDM diagnosis, the poor adherence to screening recommendation may result in late diagnosis of GDM. Finally, our finding of a 22% prevalence of GDM among low risk women suggests the need to consider additional risk factors, such as excessive weight gain during pregnancy.

Introduction

Criteria for diagnosis of gestational diabetes (GDM) have been a matter of continuous debate [1]. The first diagnostic criteria were developed more than 40 years ago [2]. Since then many different diagnostic criteria, mainly based on expert opinion, have been used. In 2010, in an attempt to develop evidence-based GDM diagnostic criteria, conferees from 40 countries reviewed the results of the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) Study [3], along with results of other studies assessing the association of maternal glycemia with perinatal and long-term outcomes [4]. The meeting, held under the auspices of the International Association of Diabetes and Pregnancy Study Groups (IADPSG), recommended new diagnostic

* Corresponding author. Department of Clinical and Experimental Medicine, Section of Metabolic Diseases and Diabetes, Nuovo Ospedale Santa Chiara, Via Paradisa 2, 56124 Pisa, Italy. Fax: +39 050 541521.
E-mail address: c.bianchi@ao-pisa.toscana.it (C. Bianchi).

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criteria for GDM, endorsed by various bodies, including the World Health Organization [5].

In addition to the controversy over the GDM diagnostic criteria, there is considerable uncertainty about the optimal screening strategy for identification of women with GDM. One approach claims for a universal screening with an Oral Glucose Tolerance Test (OGTT). Alternatively, selective screening with a 2-h 75 g OGTT involving women with identifiable risk factors, or a two-step screening strategy with an initial 50 g glucose challenge test, followed by 3-h 100 g OGTT using the Carpenter & Coustan diagnostic criteria [1] have been proposed. These selective screening approaches have the advantage of being less expensive and to be of inconvenience to a fewer women, but it cannot identify GDM among unscreened pregnant women.

In Italy, for many years, the two-steps procedure has been widely used until IADPSG Panel recommendations have been accepted. However, in the following months, criticisms were raised since adoption of the new criteria resulted in a rapid increase of GDM prevalence [6,7]. To explore the matter, a national committee of experts was established and in 2011 the Italian National Health System introduced a selective screening for GDM based on risk factors recommending early screening in high risk women. According to those guidelines [8,9], high risk women are those with previous GDM (pGDM), pre-pregnancy BMI $\geq$30 kg/m^2, fasting plasma glucose 100–125 mg/dl in the first trimester of pregnancy; while at medium risk are those aged $\geq$35 years, pre-pregnancy BMI 25–29.9 kg/m^2, family history of type 2 diabetes, previous macrosomia, and of an ethnic group at GDM risk. Based on this risk stratification, high risk women should be screened between 16th–18th gestational week to be repeated at 24th–28th week in case of normal glucose tolerance, whereas for women with medium risk only the 24th–28th week screening is recommended (Fig. 1). In all cases the diagnosis of GDM is based on the IADPSG/WHO 2013 criteria.

Although this approach may sound rational, there is scanty information about the effective implementation of these recommendations, in particular for the early screening. This survey was then planned to ascertain to which extent current national guidelines are implemented and to analyze the effectiveness of GDM diagnosis based on risk profile.

Methods

This is a retrospective study including 1338 pregnant women referred to the Diabetic Clinic of the University Hospital of Pisa through January 2013 and December 2015 to perform the selective OGTT screening for GDM, according to the Italian National Guidelines (8–9; Fig. 1).

A standardized medical history was obtained in all women at the time of evaluation of glucose tolerance. Data about maternal age, parity, last menstruation date, pregestational weight, history of GDM (pGDM), hypertension and macrosomia, family history of diabetes mellitus, educational level and employment were recorded. Fasting plasma glucose (FPG) levels during the first trimester were obtained. Body weight and height were measured in all women. Blood pressure was measured with a standard electronic sphygmomanometer with patient on a recumbent position and blood pressure reported as the mean value of two independent measurements. Pre-pregnancy (pp) BMI (kg/m^2) was calculated from height and self reported pre-pregnancy body weight. Based on pp-BMI, women were stratified as Normal-Weight (NW), Over-Weight (OW), Obese (OB) [10]. Gestational weight gain (GWG) was calculated as the difference between body weight at the time of OGTT and referred pre-pregnancy weight.

Statistical analysis was performed using the StatView program. Continuous measures are expressed as mean $\pm$ standard deviation (SD), while discrete variables are reported as count and/or percentage. Statistical significance was tested by ANOVA, LSD Fisher's test and Fisher exact test or χ^2 test as appropriate. To explore which is the independent contribution of each risk factor to GDM, a logistic regression analysis has been performed in all women, including all traditional risk factors as categorical variable and GWG as continuous variable. To investigate the independent contribution of risk factors to GDM in women at medium risk, a logistic regression analysis including age, pp-BMI, family history of diabetes, ethnicity, previous macrosomia, parity (all as categorical variables) and GWG at the screening time (as continuous variable) has been performed. To explore which factors might contribute GDM in women at low risk, a logistic regression analysis was performed including some known factors associated to GDM as maternal age, pp-BMI, parity and GWG at the screening time as covariates. In the Model 1 all factors have been included as continuous variable, while in the Model 2 GWG has been included as quartiles of GWG at the screening time; parity has been considered always as categorical variable. Results from logistic analysis are presented as odds ratio (OR) with 95% confidence intervals (CI). To assess the accuracy of GWG as a risk factor for GDM in low risk women, a ROC curve analysis has been performed. Result from ROC analysis is presented as area under the curve (95%CI). For all calculations p values < 0.05 were considered statistically significant.

Results

Of the 1338 women included in the study, 14.4% (point estimate 0.144; 95%CI 0.126–0.164) were at high risk, 64% (point estimate 0.639; 95%CI 0.613–0.665) at medium risk, and 21.6% (point estimate 0.216; 95%CI 0.195–0.239) have no risk factors for GDM. Characteristics of study population are shown in Table 1, while the distribution of risk factors is shown in Table 2. A history of pGDM was present in the 8.5% of the screened women, while a 56.8% of them were $\geq$35 years old. The overall prevalence of GDM was 39.9%. As expected the prevalence of GDM was higher among high risk women (67% *vs.* 40% in medium risk *vs.* 22% in low risk group; $p < 0.0001$). The contribution of all risk factors and GWG at the screening time to GDM in the whole cohort is presented in Table 3. In the attempt to