

Screening of GDM during COVID pandemic in an Italian setting: comparison between IADPSG and WHO '99 criteria

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Abstract

Background: During pandemic period, a single fast glycemia value (≥ 92 mg/dl) performed within the recommended time windows for the risk level defined by the Italian guidelines, was considered an acceptable surrogate for GDM diagnosis following Italian Diabetes Association recommendations.

Methods: All pregnant women who performed an OGTT following Italian Guidelines from march 2020 to september 2021 and then delivered at our University Hospital were prospectively enrolled in this study. Primary outcome of the study was the number of women to whom was diagnosed GDM with only the fasting glucose value (≥ 92 mg/dl), following Italian Diabetes Societies recommendations for COVID 19 pandemic period. In the same time, the data of women who became diabetic following the criteria of WHO 1999 was collected too. Secondary outcome was the comparison of risk factors and clinical outcomes between women diagnosed with IADPSG criteria and those diagnosed with WHO '99 criteria.

Results: The number of women with a diagnosis of GDM following Italian guidelines in the 18-month period considered was 161. Only 109 (67.7%) had a fast glucose value ≥ 92 mg/dl. No difference between IADPSG and WHO '99 groups in relation to risk factors, with the exception for overweight and obesity, and clinical outcomes,

Conclusion: Recommendations of Italian Diabetes Societies for COVID 19 pandemic failed to recognize one third of GDM diagnosis.

CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov, www.clinicaltrials.gov, NCT 05026840, August 30, 2021, 'retrospectively registered'.

Background

Gestational Diabetes Mellitus (GDM) is defined as any degree of glucose intolerance that occurs for the first time or is first detected during pregnancy, but does not fulfil the criteria of overt diabetes (1). After the International Association of the Diabetes and Pregnancy Study Groups (IADPSG) published recommendations for the diagnosis and classification of hyperglycemia during pregnancy (2), also Italian guidelines (3) for screening and diagnosis of GDM were published, following IADPSG criteria. GDM affects about 10% of Italian pregnant women, with possible maternal, fetal and neonatal complications in short and long term. Since March 2020, measures for the containment of Coronavirus infection included travel limitations. Considering the risk/benefit ratio, Italian Diabetes Societies published a position statement with recommendations for GDM diagnosis during COVID 19 pandemic (4). The document was a temporary guide for GDM screening when an Oral Glucose Tolerance Test (OGTT) cannot be safely performed. They recommended a two-step testing approach. At first trimester in pregnancy, as reported in Italian guidelines, it is necessary to exclude "overt diabetes" diagnosed with fasting plasma glucose ≥ 126 mg/dl, or random plasma glucose ≥ 200 mg/dl, or glycated hemoglobin $\geq 6.5\%$. Then a single fast glycemia value (≥ 92 mg/dl) performed within the recommended time windows

for the risk level (high or medium risk) defined by the Italian guidelines, was considered an acceptable surrogate for GDM diagnosis (4).

Methods

All pregnant women who performed an OGTT following Italian Guidelines (3) from march 2020 to september 2021 and then delivered at our University Hospital were prospectively enrolled in this study. Primary outcome of the study was the number of women to whom was diagnosed GDM with only the fasting glucose value (≥ 92 mg/dl), following Italian Diabetes Societies recommendations for COVID 19 pandemic period (4). In the same time, we collected the data of women who became diabetic following the criteria of WHO 1999 (fast glucose value ≥ 120 mg/dl, 2 hours later ≥ 140 mg/dl) still in use in some large countries like India. These women, who did not meet IADPSG criteria had no treatment or glycemia monitoring. From the clinical charts, we reported not only general and demographic characteristics (maternal age, pre-gestational BMI, parity), but also the distribution of risk factors for GDM (maternal age ≥ 35 years, family history for diabetes type 2, ethnica, BMI ≥ 25 , previous GDM). Clinical outcomes such as hypertensive disorders, preterm birth, macrosomia, intrauterine growth restriction and Caesarean section rate were compared between those diagnosed with only IADPSG criteria and those diagnosed with only WHO '99 criteria (secondary outcome).

Statistical analysis was performed with IBM SPSS Statistics for Windows (version 22; IBM Corporation, Armonk, NY). Descriptive results of continuous variables are expressed as mean \pm SD or n (%). To compare the two groups, the unpaired t test (parametric distributions) or the Mann–Whitney U test (nonparametric distributions) was used. Categorical variables were compared using the χ^2 test.

Results

The number of women with a diagnosis of GDM following Italian guidelines in the 18-month period considered was 161. Only 109 (67.7%) had a fast glucose value ≥ 92 mg/dl assayed within the recommended time windows for the risk level (high or medium risk). In the same period, pregnant women with a diagnosis of GDM following only WHO '99 recommendations were 62. Of 161 women with GDM, 92 were diagnosed with only IADPSG criteria and 69 were diagnosed with both methods. In table 1, comparison of demographic characteristics between the 2 groups (IADPSG and WHO '99) are reported. There was a statistically significant difference only for nulliparous women (61.3% in the WHO '99 group vs 41.3% in IADPSG group, $P = 0.01$). In table 2, risk factors rate inside each group is reported. A statistically significant difference between groups was shown only for overweight (27.2% vs 11.3%, $p = 0.02$) and obese women (33.7% vs 14.5%, $P = 0.008$) which were more in the IADPSG group. Furthermore, the difference in previous GDM rate was almost al level of significance (8.7% vs 1.6%, $P = 0.06$). There was no statistically significant difference for clinical outcomes (table 3), although the prevalence of preterm birth was 10% in the IADPSG group compared to 1.6% in the WHO '99 group. Also for hypertensive disorders, the cases in the IADPSG group (10.9%) was about triple compared to the WHO '99

group (3.2%). The only statistically significant difference was about insulin treatment (21.7 vs 1.6%), principally because WHO '99 group was neither diagnosed nor carefully monitored.

Discussion

Although with limited numbers, our experience carried out in a single-centre trial demonstrated that performing GDM diagnosis with a single value of fasting glycemia might lose one third of cases. Also in The United Kingdom, the Royal College of Obstetricians and Gynaecologists (RCOG) published guidance relating GDM screening and diagnosis during the COVID 19 pandemic in March 2020 (5). The guidance was similar to that proposed by the Italian Diabetologist Associations with the two-step testing approach, but different with the test used in UK recommended by The National Institute for Health and Clinical Excellence (NICE). A retrospective study (6) performed in a single-centre evidenced that screening GDM with RCOG COVID 19 criteria failed to detect more than half cases who might be diagnosed with NICE recommendations, with a result worse than ours. In relation to comparison between those women with GDM diagnosed with only IADPSG criteria and those diagnosed with only WHO '99 criteria, some considerations can be made. The weakness of this study is the limited number of women enrolled, however it's of interest the comparison of risk factors and clinical outcomes between the 2 groups. In particular, the number of overweight and obese women diagnosed with IADPSG criteria was significantly bigger than the WHO '99 criteria, which seems to identify two different phenotypes in relation to anthropometric measures. This condition has probably a consequence on clinical outcomes; in particular, pre-term birth and hypertensive syndromes did not reach a significant difference only for the limited number of women enrolled. It seems that WHO '99 group experienced the lowest rate of all clinical outcomes considered, even if it was not monitored and not treated. Limited sensitivity of WHO '99 criteria has been reported in a recent meta-analysis on screening and diagnosis of GDM in India, a country in which these criteria are still in use (7). Prevalence of GDM with IADPSG criteria was double (19.19%) than WHO '99 (10.13%) criteria.

Conclusions

In conclusion, recommendations of Italian Diabetes Societies for COVID 19 pandemic failed to recognize one third of GDM diagnosis. The other result of the study is that is very hard to compare western studies performed with IADPSG criteria with those in which WHO '99 criteria are used, this latter method seems to be less sensitive than the other, perhaps also for metabolic and genetic differences between populations considered.

Abbreviations

- GDM: Gestational Diabetes Mellitus;
- IADPSG: International Association of the Diabetes and Pregnancy Study Groups;
- OGTT: Oral Glucose Tolerance Test;

- RCOG: Royal College of Obstetricians and Gynaecologists;
- NICE: National Institute for Health and Clinical Excellence;
- WHO: World Health Organization.

Declarations

All the patients gave written informed consent for publication of the article.

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Availability of data and materials not applicable

No conflict of interest to declare.

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Tables

Tables 1 to 3 are available in the Supplementary Files section.

Supplementary Files

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