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# Level of implementation of guidelines on screening and diagnosis of gestational diabetes: A national survey

Basilio Pintaudi<sup>a,\*</sup>, Raffaella Fresca<sup>b</sup>, Mariagrazia Dalfrà<sup>c</sup>,  
Teresa Marcone<sup>d</sup>, Alessandro Roberto Dodesini<sup>e</sup>, Angela Napoli<sup>f</sup>,  
Matteo Bonomo<sup>a</sup>

<sup>a</sup> SSD Diabetology, Ca'Granda Niguarda Hospital, Milan, Italy

<sup>b</sup> Endocrinology and Diabetes Unit, ASL Salerno, Cava de Tirreni, Italy

<sup>c</sup> Diabetology CSS, Colli-ULSS16, Padua, Italy

<sup>d</sup> SSD Diabetology, University Hospital OORR Foggia, Foggia, Italy

<sup>e</sup> U.S.C. Endocrine Diseases and Diabetes, Papa Giovanni XXIII Hospital, Bergamo, Italy

<sup>f</sup> Department of Clinical and Molecular Medicine, S. Andrea Hospital, Sapienza University, Rome, Italy

## ARTICLE INFO

### Article history:

Received 19 May 2015

Received in revised form

24 October 2015

Accepted 27 December 2015

Available online 28 January 2016

### Keywords:

Gestational diabetes

Screening procedure

Diagnostic test

## ABSTRACT

**Aims:** To describe the degree of diffusion and acceptance of national guideline on screening and diagnosis of gestational diabetes (GDM) among Italian diabetes centers and to detect possible areas for benchmarking.

**Methods:** In 2013 the Italian Diabetes in Pregnancy Study Group structured a national survey, focused on GDM screening and diagnostic procedures, that was administered to diabetologists.

**Results:** Overall, 122 diabetologists of 122 different diabetes centers (21.7% territorial, 78.3% hospital/University) completed the questionnaire. All respondents declared to execute a 75 g-oral glucose tolerance test (OGTT) as diagnostic test. Almost one in five centers preferred a universal screening procedure, the others executing a selective risk factors-based screening. In patients at high risk for GDM the OGTT was performed at 16–18 weeks' gestation in 84.0% of the cases; only 6.5% of respondents preferred to execute it as soon as possible; and 9.5% used to wait until 24–28 weeks' gestation. In the case of fasting plasma glucose (FPG)  $\geq 5.1$  mmol/l (92 mg/dl), two third of respondents used to proceed with the execution of the complete diagnostic OGTT, the others considering sufficient the FPG value for the diagnosis.

**Conclusions:** Good level of reception of national recommendations was documented. The diagnostic procedure was generally accepted and applied. Some criticisms were specifically linked to the choice of universal or risk factor-based screening procedure, and to the right time for executing the OGTT in women at high risk.

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\* Corresponding author. Tel.: +39 0264442464; fax: +39 0264442082.

E-mail address: [basilio.pintaudi@ospedaleniguarda.it](mailto:basilio.pintaudi@ospedaleniguarda.it) (B. Pintaudi).

<http://dx.doi.org/10.1016/j.diabres.2015.12.008>

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## 1. Introduction

In the recent years the debate on screening and diagnosis of gestational diabetes mellitus (GDM) has been very heated [1]. Since O'Sullivan, over 50 years ago, began to investigate a group of women with the aim to evaluate their glucose tolerance status in pregnancy [2], several methods of diagnosing GDM have been proposed [3,4]. Nowadays, a common position is not shared by all international Scientific Societies [5–8]. The use of one-step (glucose tolerance test) or two-steps (screening plus glucose tolerance test) procedure still remains a dilemma. Furthermore, in the case of the two-steps procedure, a selective or universal screening can be adopted, depending on the specific recommendation.

In this variegated scenario, the expectation arising from the publication of the Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study was high [9]. However, no clear indication on GDM diagnostic criteria resulted from the study. A Consensus Panel of the International Association of Diabetes and Pregnancy Study Groups (IADPSG) was then convened in 2010 and diagnostic recommendations were established [10].

Briefly, after overt diabetes was excluded, fasting plasma glucose  $\geq 5.1$  mmol/l (92 mg/dl) but  $< 7.0$  mmol/l (126 mg/dl) was sufficient to diagnose GDM. If fasting plasma glucose was  $< 5.1$  mmol/l, a 75-g oral glucose tolerance test (OGTT) was suggested from 24 to 28 weeks' gestation with glucose cutoffs of 5.1, 10.0 and 8.5 mmol/l for fasting, 1-h and 2-h post-load, respectively.

Nevertheless, the degree of diffusion and acceptance of those criteria was heterogeneous across Countries. Some decided to continue screening and diagnostic procedures for GDM according to their current guidelines [6,11], others fully or partly accepted the IADPSG recommendation [12,13]. In Italy,

for many years, screening and diagnosis of GDM were made according a two-steps procedure consisting first in a risk factors-based evaluation and consequently in a diagnostic 100-g OGTT. After the IADPSG Panel an Italian national conference was held and IADPSG recommendations were accepted. However, in the following months, important criticisms were advanced by the technical and scientific authorities of the Italian National Health Service. Particularly, the lack of strong scientific evidence in determining the glycemic cutoff suggested by IADPSG and the financial consequences in adopting these recommendations related to the increase of GDM prevalence were the major problems recognized by National Health Service. For this reason a committee of experts was designed, including representatives of the two main national diabetes Societies [Associazione Medici Dabetologi (AMD) and Società Italiana di Diabetologia (SID)] and the Italian Public Health Authority, with the purpose of drafting a shared national statement on diagnosis of GDM. So, the “Italian guideline on physiological pregnancy” was written [14]. This document includes specific recommendation on GDM, clearly describing screening and diagnostic procedures. A selective screening, based on the presence of specific risk factors, is recommended after the exclusion of overt diabetes. In particular, a first assessment at the 16–18 weeks' gestation should be performed and in the case of presence of at least one risk factor an early diagnostic 75-g OGTT with the same glucose cut-offs of IADPSG criteria should be executed. If OGTT results are normal, a new OGTT should be repeated for these women at 24–28 weeks' gestation. At this gestational age (24–28 weeks) an OGTT should be offered also to women with the presence of other established risk factors, as showed in Fig. 1. The Italian guideline also recommends not to use FPG, random glycemic values, glucose challenge test, glycosuria or 100-g OGTT for GDM screening and diagnosis.

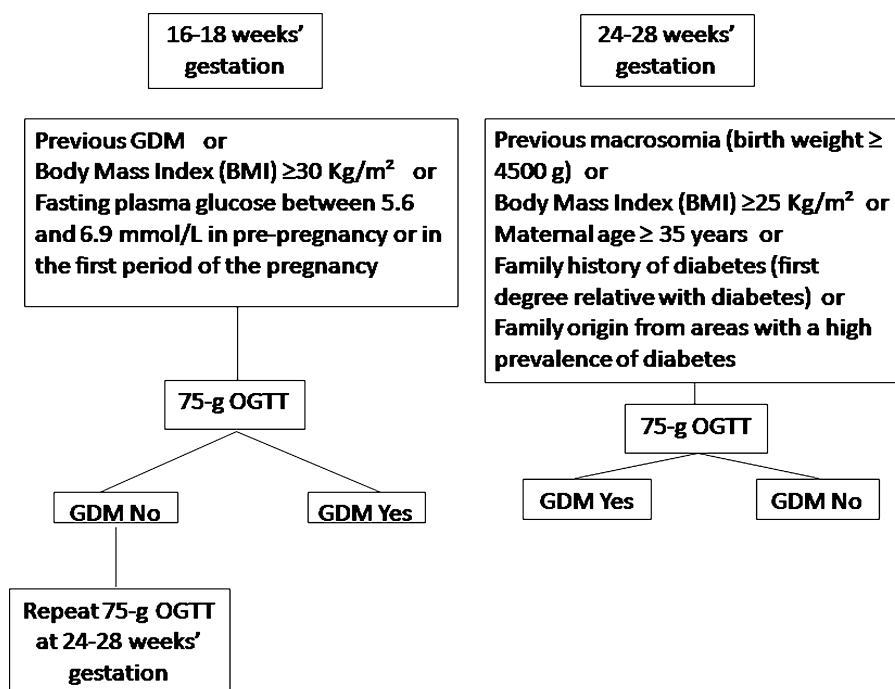


Fig. 1 – Flow chart with screening procedures according to the “Italian guideline on physiological pregnancy”.

Aim of this paper is to describe the degree of diffusion and acceptance of the national guideline among Italian diabetes centers and to detect possible areas for benchmarking.

## 2. Subjects

In 2013 the Italian Diabetes in Pregnancy Study Group structured a national survey, focused on GDM screening and diagnostic procedures. It was administered to diabetologists at conferences, congresses and other scientific events. In addition, Italian Scientific Societies AMD and SID sent it by e-mail to all their members. General information on type of diabetes center (territorial or hospital/university) and number of women with GDM cared for per year was collected. To ensure adequate consistency of data, only diabetes centers caring more than 30 women with GDM per year were considered.

## 3. Materials and methods

Specific questions were asked about the following aspects: type of specialist who manage screening and diagnosis (diabetologist, gynecologist, both diabetologist and gynecologist with the same approach, diabetologist and gynecologist with different approach); diagnostic strategy used (two-steps with glucose challenge test plus OGTT, OGTT alone); screening procedure (selective risk factors-based, universal); type of OGTT performed (100-g glucose, 75-g glucose); gestational age when the OGTT is performed in patients at high risk (as soon as possible, 16–18 weeks' gestation, 24–28 weeks' gestation); diagnostic criteria used for the interpretation of the OGTT (IADPSG, Carpenter and Coustan); attitude to execute the OGTT in the case of FPG  $\geq 5.1$  mmol/l (92 mg/dl) (yes, no). The questionnaire contained one additional open field to be used for comments or problems reporting.

### 3.1. Statistical analyses

Descriptive data were summarized as rates. Comparison between hospital and territorial centers was made by chi-squared tests. A  $p$  value  $<0.05$  was considered for statistical significance. All analyses were performed with SPSS version 17.0 (Chicago, Ill).

## 4. Results

Overall, 122 diabetologists of 122 different diabetes centers of all the Italian regions completed the questionnaire. The majority of centers were hospital/University, only 21.7% being territorial. The specialist who manages screening and diagnostic procedures was a diabetologist in 25.3% of the cases, a gynecologist in 17.2% of the cases, or a diabetologist with the collaboration of a gynecologist in 57.6% of the cases. In the latter case, diabetologists and gynecologist had the same approach in 45.5%, and a different approach in 12.1% of the cases. Most of the specialists adopting the same approach worked in hospitals (86.3%); and only 13.7% were territorial.

All respondents declared to execute only one OGTT as diagnostic test, not considering a two-steps procedure with glucose challenge test plus OGTT. Diagnostic criteria used for OGTT interpretation were those of the IADPSG. Overall, in the case of FPG  $\geq 5.1$  mmol/l (92 mg/dl), two third of respondents used to proceed with the execution of the complete diagnostic OGTT, the others considering sufficient the FPG value for the diagnosis. With respect to this question, the execution of the OGTT was suggested in a greater percentage by diabetologists compared to gynecologists (38.0% vs. 29.0%). Response to others answers are reported in Table 1.

The most common comments reported in the additional open field were: problems with gynecologists (reported by 40% of the respondents) such as the lack of communication between health care professionals, late diagnosis, application of nonuniform diagnostic criteria; problems in managing women with glycemia  $\geq 5.1$  mmol/l (92 mg/dl) but  $<7.0$  mmol/l (126 mg/dl) before the 16th gestational weeks (reported by 26% of the respondents); not sharing of guidelines (reported by 18% of respondents).

## 5. Discussion

### 5.1. Major findings

This survey allowed to give a national picture of the level of application of the Italian recommendations on screening and diagnosis of GDM. Overall, results indicate a good level of reception of the recommendations. In particular, the diagnostic procedure consisting in the execution of a 75-g OGTT, the results of which are interpreted according to IADPSG glycemic cut-off, was generally accepted and applied. The survey also recognized some criticisms, specifically linked to the choice of universal or risk factor-based screening, and to the right time for executing the OGTT in women at high risk.

### 5.2. Comparison with existing literature

Last nationwide data on screening and diagnosis of GDM were reported in the context of the “Mamma serena” study [15]. From that initiative, could be noted that 41% of clinicians declared to execute a universal screening procedure for GDM, and in 66% of the cases a two-steps diagnostic procedure was preferred.

Since 2011, when the national guidelines were published, few studies were performed with the aim to evaluate the impact of the new recommendations [16,17]. They were all retrospective studies that allowed to estimate the theoretical GDM prevalence with the new criteria, by applying them in populations of women diagnosed with previous criteria. The prevalence of GDM they found was not so high as expected. Recently, Di Cianni and colleagues retrospectively studied a population of 2552 pregnant women with the aim to evaluate the time when the screening test for GDM was performed, on the basis of a risk class assessment [17]. They found that the majority of the women performed the diagnostic test at 24–28 weeks gestation. Only to a small percentages of women with indication to perform the OGTT at 16–18 weeks gestation, because of the presence of specific risk factors, was suggested to execute the test at that period of gestation [17].

**Table 1 – Results of the national survey on GDM screening and diagnostic procedures.**

	Overall	Hospital	Territorial	P
N (%)	122 (100)	96 (78.7)	26 (21.3)	
Specialist who manages screening and diagnosis (%)				0.01
Diabetologist	25.3	18.7	45.8	
Gynecologist	17.2	14.7	25.0	
Diabetologist and gynecologist with the same Approach	45.4	53.3	20.8	
Diabetologist and gynecologist with different approach	12.1	13.3	8.4	
Diagnostic strategy (%)				–
Two-steps (glucose challenge test plus OGTT)	0.0	0.0	0.0	
OGTT alone	100	100	100	
Screening procedure (%)				0.03
Selective risk factors-based	82.0	77.7	96.2	
Universal	18.0	22.3	3.8	
Type of OGTT performed (%)				0.87
100-g glucose	3.3	3.2	3.8	
75-g glucose	96.7	96.8	96.2	
Gestational age when the OGTT is performed in patients at high risk (%)				0.75
As soon as possible	6.5	5.3	8.0	
16–18 weeks' gestation	84.0	79.8	84.0	
24–28 weeks' gestation	9.5	14.9	8.0	
Diagnostic criteria used for the interpretation of the OGTT (%)				–
IADPSG	100	100	100	
Carpenter and Coustan	0.0	0.0	0.0	
OGTT execution in the case of FPG $\geq$ 5.1 mmol/l (92 mg/dl) (%)				0.08
Yes	65.8	31.0	50.0	
No	34.2	69.0	50.0	

### 5.3. Implications for clinical practice

This is the first study planned with the aim to explore nationwide the impact of new guidelines in Italy. We decided to include this survey among the activities of the Italian Study Group on Diabetes and Pregnancy because of the need to investigate attitudes of health care professionals in the approach of GDM diagnosis. Different approaches could generate confusion for example in the care of women who have GDM in two different pregnancies and are cared for by two different diabetologists, with two different ways of care. Furthermore, some legal problems may occur in these cases. Importantly, even if the information collected was reported only by diabetologists, this representing a limitation of the study, there was a small percentage (12.1%) of centers in which diabetologists and gynecologist had a different approach in managing GDM screening and diagnosis. This can lead to mistrust for both diabetologists and gynecologists on the part of women. The other significant aspect is that universal screening procedure was preferred by a part of diabetologists, particularly those working in hospitals, although recommendations clearly suggest a selective risk factors-based screening. It should be acknowledged that recent papers have highlighted some limits of current guidelines, compared to universal [16] or to alternative screening approaches [18]. They could have provided clinical elements capable of influencing attitude of clinicians in screening and diagnosing GDM. Particularly, an increased risk of developing GDM was not found to be associated with maternal age  $\geq$  35 years (one of the risk factors established by Italian guidelines) in a retrospective study comparing selective with universal approach [16]. The other study [18] aimed to identify subgroups of women at a higher risk of developing GDM with the use of the RECURSIVE

Partitioning and AMalgamation (RECPAM) method. This led to define as at a high risk those women with the presence of risk factors different from those reported in the guideline (i.e. FPG  $\geq$  4.4 mmol/l or pre-pregnancy BMI  $\geq$  25 kg/m<sup>2</sup> or family history of diabetes or previous GDM). A screening approach based on the RECPAM model was shown to reduce by over 50% the number of undiagnosed GDM cases when compared with the selective screening approach.

However, the greatest heterogeneity in the application of national guidelines could be revealed by two aspects investigating by the survey. The first was the timing for the execution of the OGTT in high risk women: almost one fifth of women were tested in fact in a period of gestation not corresponding to that indicated by guidelines. This could depend on the personal experience of diabetologists and gynecologists in managing the care of GDM. There are specialists that prefer not to wait for the 16–18 weeks' gestation maybe because of much more worries in the clinical management of the women. On the opposite, there could be specialists that do not feel GDM as a very important condition or do not consider only glycemic values sufficient to determine a high risk status. The second aspect was the case of FPG  $\geq$  5.1 mmol/l (92 mg/dl) in the first trimester. According to guidelines, these women should wait for the 16–18 weeks' gestation to execute the OGTT. Also in this case attitudes of specialists could generate a big difference in managing this condition.

### 5.4. Strengths and weaknesses

The major strength of our study was the level of data collection. We were able to collect data of all the Italian regions, this allowing to know the level of application of national guideline both in territorial centers and hospitals/

university. Our major strength was also a weakness because we did not involve in our survey all the Italian centers. Nevertheless, we involved all the diabetes centers which used to care women in large catchment areas, so with a large number of pregnant women tested for GDM. We collected information of all the diabetes centers representing reference centers in the field of diabetes in pregnancy. The other limitation of the study was that only diabetologists were asked, other specialists also dealing with GDM being not explicitly asked about their screening procedures and their adherence to the guideline.

In conclusion, Italian guidelines need to be disseminated and discussed on a local basis in order to be applied in a more extensively way. Differences in their application revealed by this survey must be recognized both by Scientific Societies and by stakeholder. Benchmarking activities could be programmed to avoid heterogeneity in the application of the recommendations. A second national survey could be necessary in the future to re-assess the level of application of these guidelines.

### Conflict of interest statement

None.

### Author's individual contribution

BP and MD wrote the manuscript and performed statistical analyses; AN and MB reviewed the manuscript; RF, TM and RD collected data. All authors have approved the final article.

### Acknowledgments

We want to thank all the participating Colleagues who responded to the survey.

### REFERENCES

- [1] Reece EA, Leguizamón G, Wiznitzer A. Gestational diabetes: the need for a common ground. *Lancet* 2009;373(9677):1789–97.
- [2] O'Sullivan JB, Mahan CM. Criteria for oral glucose tolerance test in pregnancy. *Diabetes* 1964;13:278–85.
- [3] Naylor CD, Sermer M, Chen E, Farine D. Selective screening for gestational diabetes mellitus. Toronto tri-hospital gestational diabetes project investigators. *N Engl J Med* 1997;337:1591–6.
- [4] Buckley BS, Harreiter J, Damm P, Corcoy R, Chico A, Simmons D, et al., DALI Core Investigator Group. Gestational diabetes mellitus in Europe: prevalence, current screening practice and barriers to screening. A review. *Diabetic Med* 2012;29:844–54.
- [5] ADA. Standards of medical care in diabetes. *Diabetes Care* 2015;38(Suppl. 1).
- [6] National Institute for Health and Care Excellence (NICE). Diabetes in pregnancy: management of diabetes and its complications from preconception to the postnatal period; 2015.
- [7] World Health Organization. Diagnostic criteria and classification of hyperglycaemia first detected in pregnancy; 2013.
- [8] Committee on Practice Bulletins—Obstetrics. Practice Bulletin No. 137: Gestational diabetes mellitus. *Obstet Gynecol* 2013;122(2 Pt 1):406–16.
- [9] HAPO Study Cooperative Research Group. Hyperglycemia and adverse pregnancy outcomes. *N Engl J Med* 2008;358:1991–2002.
- [10] International Association of Diabetes Pregnancy Study Groups. Recommendations on the diagnosis and classification of hyperglycemia in pregnancy. International Association of Diabetes and Pregnancy Study Groups consensus panel. *Diabetes Care* 2010;33:676–82.
- [11] Cosson E, Benbara A, Pharisien I, Nguyen MT, Revaux A, Lormeau B, et al. Diagnostic and prognostic performances over 9 years of a selective screening strategy for gestational diabetes mellitus in a cohort of 18,775 subjects. *Diabetes Care* 2013;36(3):598–603.
- [12] Trujillo J, Vigo A, Duncan BB, Falavigna M, Wendland EM, Campos MA, et al. Impact of the International Association of Diabetes and Pregnancy Study Groups criteria for gestational diabetes. *Diabetes Res Clin Pract* 2015;108(May (2)):288–95.
- [13] Wei Y, Yang H, Zhu W, Yang H, Li H, Yan J, et al. International Association of Diabetes and Pregnancy Study Group criteria is suitable for gestational diabetes mellitus diagnosis: further evidence from China. *Chin Med J (Engl)* 2014;127(20):3553–6.
- [14] Linea guida Gravidanza fisiologica, Sistema nazionale per le linee guida dell'Istituto Superiore di Sanita'. Available at: ([http://www.snlg-iss.it/cms/files/LG\\_Gravidanza.pdf](http://www.snlg-iss.it/cms/files/LG_Gravidanza.pdf)) (accessed 10/05/2015).
- [15] Bonomo M, Lapolla A, Mannino D, Arcangeli A, Di Benedetto A, Di Berardino P, et al. Scientific Committee of the 'MAMMA SERENA' Interassociative Study Group. Care of diabetes in pregnancy in Italy: structural and organizational aspects. *Diabetic Med* 2008;25(3):379–80.
- [16] Corrado F, Pintauro B, Di Vieste G, Interdonato ML, Magliarditi M, Santamaria A, et al. Italian risk factor-based screening for gestational diabetes. *J Matern Fetal Neonatal Med* 2014;27(Sep. (14)):1445–8.
- [17] Lacaria E, Lencioni C, Russo L, Romano M, Lemmi P, Battini L, et al. Selective screening for GDM in Italy: application and effectiveness of National Guidelines. *J Matern Fetal Neonatal Med* 2015;28(15):1842–4.
- [18] Pintauro B, Di Vieste G, Corrado F, Lucisano G, Pellegrini F, Giunta L, et al. Improvement of selective screening strategy for gestational diabetes through a more accurate definition of high-risk groups. *Eur J Endocrinol* 2013;170(Nov. (1)):87–93.