Gestational diabetes mellitus (GDM) — do the number of fulfilled diagnostic criteria predict the perinatal outcome?

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ABSTRACT

Objectives: The aim of the study was to check whether the number of fulfilled diagnostic criteria of gestational diabetes mellitus (GDM) had any association with patients' characteristics and pregnancy outcomes.

Material and methods: A total of 756 women with single pregnancies and GDM who gave birth at the 2nd Department of Obstetrics and Gynecology of the Medical University of Warsaw between 01.2013–12.2016 were included in a retrospective analysis. Patients were divided into 2 groups: A — 499 patients diagnosed with GDM on the basis of one diagnostic criterion, B — 257 patients diagnosed with GDM on the basis of more than one diagnostic criterion.

Results: Patients from group A had lower pre-pregnancy BMI than those from group B (median 24.9 kg/m² vs. 26.5 kg/m², p = 0.0003). Women from group A were less frequently treated with insulin than women from group B (19.1% vs. 32.7%; p = 0.00002). Group A had lower median OGTT levels than group B (85.9 mg/dL vs. 94.1 mg/dL, p = 0.0001; 160.2 mg/dL vs. 197.6 mg/dL, p = 0.0001; 144.8 mg/dL vs. 167.0 mg/dL, p = 0.0001; respectively). Moreover, in group B the average week of labor was earlier than in group A (mean 38.1 and 38.5 weeks of gestation, p = 0.0006).

Conclusions: Patients who fulfilled more than one diagnostic criterion for GDM may have worse pregnancy outcome. We think that a number of fulfilled diagnostic criteria for GDM may be an important risk factor for insulin therapy during pregnancy and earlier gestational age at delivery.

Key words: gestational diabetes mellitus, oral glucose tolerance test, body mass index, insulin therapy

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INTRODUCTION

Gestational diabetes mellitus (GDM) used to be defined as glucose tolerance disturbance of any degree (abnormal fasting glycemia, glucose intolerance, or diabetes) with onset or first recognition during pregnancy [1]. This population might have included women who had been diabetic, yet undiagnosed before becoming pregnant. According to the newest American Diabetes Association (ADA) guidelines of 2017, GDM is diabetes that is first diagnosed in the second or third trimester of pregnancy and is rather not preexisting type 1 or type 2 diabetes [2].

No unified diagnostic criteria or procedures had been available for GDM for many years. The results of the Hyper-glycemia and Adverse Pregnancy Outcome (HAPO) study were published in 2008 and they attempted to adjust the diagnostic criteria of GDM so as to ensure possibly best identification of women at highest risk of complications [3]. On the basis of these results, new diagnostic criteria of GDM were adopted by most (67.9%) scientific associations in Europe [4].

The GDM criteria as proposed by HAPO study authors [3] are characterized by lowered threshold values and/or allow for GDM diagnosis being made upon a lower number of diagnostic criteria as compared to earlier recommendations from scientific associations. This results in increased GDM diagnosis rates [5–8]. On one hand, this may lead to

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the disorder being over diagnosed while, on the other, resulting in a higher number of patients in need who receive specialist diabetes care.

Due to the change in the definition and the diagnostic criteria of GDM it is difficult to assess its global prevalence; however, it is estimated that 10–25% of all pregnant mothers worldwide [9] and 5.4% of pregnant mothers in Europe [10] either develop GDM or suffer from previously undiagnosed pre-gestational diabetes.

GDM increases the risk of neonatal complications including macrosomia, birth weight above the 90th percentile (large for gestational age, LGA), hypoglycemia, hyperbilirubinemia, polycythemia, respiratory disorders, shoulder dystocia, as well as the risk of obesity and metabolic syndrome in adulthood. In mothers, GDM is associated with an increased risk of GDM in subsequent pregnancies and type 2 diabetes mellitus thereafter.

Objectives

In the face of these changes, a criterion is needed for identification the patients with the likelihood of more severe GDM requiring more medical care. Due to the fact that every patient with GDM had undergone a 75 g oral glucose tolerance test (OGTT), a decision was made to check whether the number of GDM diagnostic criteria associated with the test had any influence on the natural history of pregnancy, the delivery, and post-partum neonatal health.

MATERIAL AND METHODS

A total of 756 women with single pregnancies and diagnosis of GDM who gave birth at the 2nd Department of Obstetrics and Gynecology of the Medical University of Warsaw between 01.01.2013 and 31.12.2016 were included in a retrospective analysis. GDM was diagnosed in accordance with relevant Polish Gynecological Society (PTG) guidelines on the basis of 75 g oral glucose tolerance test results [11, 12].

The conditions of the 75 g OGTT were as follows: the test was performed after nocturnal sleep, 8–14 hours after the last meal; subjects had to receive not less than 150 g of carbohydrates daily for 3 days before the test; the subjects were drinking 75 g of glucose dissolved in 250–300 mL of water within 5 minutes. During the test, the subjects were resting; they did not have any meals or smoke tobacco during that period. The tests were not performed during 72 hours after antenatal steroid treatment in threatened preterm delivery or during intravenous treatment with beta-mimetics. Blood samples were collected in fasting condition as well as 1 and 2 hours after ingestion of glucose solution [11, 12]. Quantitative determination of glucose in venous blood was carried out by means of ultraviolet photometry using hexokinase-catalyzed enzymatic reactions [13].

Preliminary determinations of glucose levels were carried out at the first prenatal visit at the beginning of pregnancy so as to diagnose any potentially previously undiagnosed disturbances in carbohydrate metabolism. If no abnormal fasting blood glucose levels were observed in a risk factor-free patient, the diagnostic test was performed between gestation weeks 24 and 28, or earlier if symptoms suggestive of GDM had been observed. Diagnostic examination performed between gestation weeks 24 and 28 was a single-level determination consisting of the administration of the 75 g OGTT [12]. In women with GDM risk factors, 75 g OGTT was performed already during the first trimester. According to PTG, GDM risk factors include BMI $\geq$ 30kg/m^2 and the history of any carbohydrate metabolism disturbances [12]. According to the Polish Diabetes Association (PTD) risk factors of in-pregnancy diabetes include age above 35 years, history of giving birth to babies with birth weights of > 4000 g or with congenital defects, history of intrauterine fetal demise, arterial hypertension, overweight or obesity status, family history of type 2 diabetes mellitus, history of GDM in previous pregnancies, multiparity, or polycystic ovary syndrome [14]. If normal results of 75 g OGTT were obtained in this group during the first trimester, the test was repeated between weeks 24 and 28.

In June 2014, Polish diagnostic criteria of diabetes were changed to reflect the 2013 WHO guidelines [12, 15] based on the HAPO study results [3]. According to these guidelines, the pregnant patient was qualified for diagnostic examination between gestation weeks 24 and 28, if her fasting blood glucose level was < 92 mg/dL. When the blood glucose level was in the range of 92–125 mg/dL, 75 g OGTT was carried out immediately. When the fasting blood glucose level was $\geq$ 126 mg/dL, the measurement was repeated. In case of a repeated result of $\geq$ 126 mg/dL, the patient was diagnosed with GDM and urgently referred to a clinic of a higher referral order. These patients were not included in the analysis. If a result of < 126 mg/dL was obtained in the second measurement, 75 g OGTT was performed. In cases of random glycemia of $\geq$ 200 mg/dL, patients were urgently referred to a clinic of a higher referral order without the 75 g OGTT being performed. These patients were not included in the analysis.

Patients included in the analysis met one of the following GDM diagnostic criterion: fasting blood glucose level of 92–125 mg/dL; 75 g OGTT 1-hour blood glucose level of $\geq$ 180 mg/dL; 75 g OGTT 2-hour blood glucose level of 153–200 mg/dL [12, 15]. According to this diagnostic regimen, a total of 417 patients in whom 75 g OGTT was performed after June 2014, were diagnosed with GDM.

According to the previous PTG recommendations, the diagnostic criteria of GDM as determined by 75 g OGTT were as follows: fasting blood glucose level of $\geq$ 100 mg/dL,

75 g OGTT 1-hour blood glucose level of ≥ 180 mg/dL, and 75 g OGTT 2-hour blood glucose level of ≥ 140 mg/dL [11]. A total of 339 patients in whom 75 g OGTT was performed by June 2014 were diagnosed with GDM according to this diagnostic regimen.

After the diagnosis of GDM, the management of pregnant patients consisted of diabetic diet and moderate, regular physical exercise. Pregnant patients performed self-assessments with glucometer at least 4 times daily (when fasting and 1 hour after each main meal). Target self-assessment levels were 60–95 mg/dL for the fasting measurements and < 120 mg/dL for 1-hour postprandial measurements [11]. If the blood glucose levels could not be normalized by appropriate dietary management, insulin therapy was initiated at doses being adjusted individually to patients' blood glucose levels. Human insulins approved for use in pregnant women as well as rapid-acting insulin analogs were used.

Patients were divided into 2 groups depending on the number of 75 g OGTT result abnormalities. Group A consisted of 499 patients, in whom GDM was diagnosed on the basis of one diagnostic criterion, while group B consisted of 257 patients, in whom GDM was diagnosed on the basis of more than one diagnostic criterion. Of these, 205 patients met two diagnostic criteria, while 52 patients met all three diagnostic criteria of GDM (Tab. 1).

Both groups were compared in terms of socioeconomic data (age, urban vs. non-urban residence status, education, employment status, marital status), obstetric history (parity, number of vaginal deliveries, history of cesarean sections, miscarriage, delivery of the baby with birth weight of > 4000 g) as well as anthropometric data (pre-gestational BMI, pregnancy weight gain).

With regard to the natural history of pregnancy, the compared variables included the week at which the patients were diagnosed with diabetes, blood glucose levels as measured in 75 g OGTT, the percentage of patients receiving insulin treatment, the percentage of patients diagnosed with pre-pregnancy hypertension (PPH) and pregnancy-induced hypertension (PIH). The course of pregnancy was compared including the week of delivery, the percentage of preterm births, the method of delivery, and the percentage of patients, who had experienced peripartum complications (perineal or cervical tears).

The groups were also compared in terms of neonatal status assessed using the Apgar score 1 minute and 5 minutes after birth, the percentage of neonates with birth weights above the 90th percentile (large for gestational age, LGA) and below the 10th percentile (small for gestational age, SGA) of the overall population [16], the percentage of neonates with hypoglycemia (defined as blood glucose level of < 40 mg/dL), hyperbilirubinemia (defined as serum blood bilirubin concentration of > 12 mg/dL), hypoxia, and peripartum injuries. Moreover, groups were compared in terms of the incidence of intraventricular hemorrhage in neonates, respiratory problems: either mild (i.e. resolving upon passive oxygen therapy), moderate (i.e. treated by continuous positive airway pressure), or severe (i.e. treated by mechanical ventilation), as well as of the percentage of neonates born with congenital defects and the percentage of intra-uterine fetal demise and peripartum death cases.

One-factor analysis was performed with the global significance level of 0.05. Bonferroni correction for multiple testing was applied for the significance levels in individual tests, leading to final down-rounded value of 0.001. In addition, the impact of GDM severity on the frequency of preterm deliveries was tested with the standard statistical significance level of 0.05. Variables were compared by means of Student's t-test, Mann-Whitney's U-test, and chi-squared test. No differences were observed with regard to the impact of old and new GDM diagnostic guidelines on the obtained results.

The study protocol was approved by the Bioethics Committee of the Medical University of Warsaw.

RESULTS

Maternal characteristics is presented in Table 2. The study groups did not differ in terms of maternal age, socioeconomic background, and obstetric history. The majority

Table 1. Grouping strategies for GDM patients based on 75 g OGTT							
	GROUP A n = 499			GROUP B n = 257			
	One criterium			Two criteria n = 205			Three criteria n = 52
Fasting glucose level	↑	N	N	↑	N	↑	↑
1 h glucose level	N	↑	N	↑	↑	N	↑
2 h glucose level	N	N	↑	N	↑	↑	↑

Group A — GDM patients with one abnormal value on the 75 g OGTT; Group B — GDM diagnosed by two or three abnormal values on the 75g OGTT; ↑ — elevated glucose values that meet or exceed the GDM diagnostic criteria; N — normal glucose value; GDM — gestational diabetes mellitus; 75 g OGTT — 75 g oral glucose tolerance test

Table 2. Maternal characteristic and delivery data

Variable [unit]	Group A mean ± SD or n (%)	Group B mean ± SD or n (%)	p
Age [years]	32.69 ± 4.73	32.96 ± 4.79	ns
Urban place of residence	404 (80.9%)	193 (75.1%)	ns
Tertiary educational level	384 (76.9%)	181 (70.4%)	ns
Employed	471 (94.4%)	237 (92.2%)	ns
Married marital status	433 (86.8%)	210 (81.7%)	ns
Multiparas	250 (50.1%)	147 (57.2%)	ns
History of vaginal delivery	194 (38.9%)	96 (37.4%)	ns
1	140 (28.1%)	67 (26.1%)	ns
> 1	54 (10.8%)	29 (11.3%)	ns
History of ceasarian section	68 (13.6%)	61 (23.7%)	ns
History of miscarrage	124 (24.8%)	72 (28%)	ns
History of macrosomia	31 (6.2%)	28 (10,8%)	ns
Pre-pregnancy BMI [kg/m^2]	24.93 ± 4.87	26.45 ± 5.7	< 0.0003
Gestational weight gain [kg]	9.46 ± 5.84	9.23 ± 6.4	ns
GA at diagnosis of GDM [weeks]	23.09 ± 7.38	23.03 ± 7.38	ns
75 g OGTT glucose level [mg/dL]			
FGL	85.93 ± 10.52	94.07 ± 16.46	< 0.0001
1 h	160.22 ± 27.96	197.57 ± 26.17	< 0.0001
2 h	144.78 ± 25.08	167.02 ± 35.1	< 0.0001
GDMG2	95 (19.1%)	84 (32.7%)	0.00002
PPH	42 (8.4%)	29 (11.3%)	ns
PIH	25 (5.0%)	20 (7.8%)	ns
GA at delivery [weeks]	38.5 ±1.4	38.1 ± 1.9	0.0006
Preterm delivery	36 (7.2%)	35 (13.6%)	0.004
Vaginal delivery	310 (62.1%)	142 (55.3%)	ns
Operative vaginal delivery	13 (2.6%)	8 (3.1%)	ns
Maternal injury	44 (8.8%)	18 (7%)	ns
Cervical laceration	33 (6.6%)	16 (6.2%)	ns
Perineal tears	11 (2.2%)	2 (0.78%)	ns
1st degree	6 (1.2%)	2 (0.78%)	ns
2nd degree	2 (0.4%)	0	ns
3rd degree	3 (0.6%)	0	ns

History of macrosomia — birth weight > 4000g; GA — gestational age; OGTT — oral glucose tolerance test; FGL — fasting glucose level; GDMG1 — diet controlled gestational diabetes mellitus; PPH — pre-pregnancy hypertension; PIH — pregnancy induced hypertension, and

of patients were married, multiparous, with higher educational background as well as positive employment and urban residence status. The groups did not differ in the extent of pregnancy weight gain, albeit patients in group B were characterized by BMI values being significantly higher than those in group A (26.5 kg/m^2 vs. 24.9 kg/m^2). In both groups, patients were diagnosed with GDM at similar time points during gestation. In the 75 g OGTT blood glucose levels in group B patients were significantly higher than those in group A; this pertained to both the fasting measurements and to the measurements performed 1 and 2 hours after glucose administration (94.1 mg/dL vs. 85.9 mg/dL; 197.6 mg/dL vs. 160.2 mg/dL; 167.0 mg/dL vs. 144.8 mg/dL, respectively). Insulin treatment was required to normalize blood glucose levels in group B patients significantly more often than in group A patients (32.7% vs. 19.1%). The length of pregnancy was significantly higher in group A patients as compared to group B patients (38.5 vs. 38.1 weeks), with the percentage of premature births being statistically higher in group B patients (13.6% vs. 7.2%). No differences were

Table 3. Neonatal characteristic

Variable [unit]	Group A mean ± SD or n (%)	Group B mean ± SD or n (%)	p
1st min Apgar score			
≤ 7	15 (3%)	6 (2.4%)	ns
8–10	483 (97%)	251 (97.7%)	ns
5th min Apgar score			
≤ 7	4 (0.8%)	2 (0.8%)	ns
8–10	495 (99.2%)	255 (99.2%)	ns
Birth weight [g]	3346.15 ± 516.32	3352.09 ± 595.31	ns
LGA	56 (11.2%)	35 (13.6%)	ns
SGA	41 (8.2%)	17 (6.6%)	ns
Perinatal injuries	9 (1.8%)	7 (2.7%)	ns
Broken collarbone	3 (0.6%)	4 (1.6%)	ns
Brachial plexus palsy	1 (0.2%)	0	ns
Skin abrasion	2 (0.4%)	1 (0.4%)	ns
Subdural hematoma	1 (0.2%)	1 (0.4%)	ns
IVH	3 (0.6%)	2 (0.8%)	ns
Respiratory disorder	37 (7,4%)	28 (10.1%)	ns
Mild	19 (3.8%)	17 (6.6%)	ns
Moderate	14 (2.8%)	9 (3.5%)	ns
Severe	4 (0.8%)	0	ns
Hypoglycemia	30 (6%)	22 (8.6%)	ns
Hyperbilirubinemia	155 (31.1%)	96 (37.4%)	ns
Congenital defects	30 (6%)	13 (5.1%)	ns
Perinatal hypoxia	1 (0.2%)	3 (1.2%)	ns
Stillbirth	1 (0.2%)	0	ns

LGA — large for gestational age; SGA — small for gestational age; IVH — intraventricular hemorrhage

observed between the study groups with regard to the incidence of PIH, PPH, the method of the delivery or the incidence of perinatal injuries.

Neonates born to mothers from both groups did not differ in their Apgar status, birth weight, or incidence of complications (Tab. 3).

DISCUSSION

Most patients in the analysis were diagnosed on the basis of a single GDM diagnostic criterion (499 vs. 256 patients), which was consistent with the results obtained by other authors [17–19].

As shown by the analyses of 100 g OGTT results, pre-gestational overweight status, advanced maternal age (> 35 years), multiparity, and history of GDM had an influence on the higher number of GDM diagnostic criteria being met by the patients [20–22]. In our study group, women who met more than one GDM diagnostic criterion were characterized by higher pre-gestational BMI values. Black et al. concluded that patients meeting only one postprandial criterion of

GDM had lower pre-gestational BMIs than women meeting only the fasting criterion or women meeting both criteria [17]. As shown by numerous analyses, high pre-gestational BMI is associated with higher prevalence of macrosomia, LGA, PIH, and the need to deliver by cesarean section in both GDM-complicated and uncomplicated pregnancies [23–26]. According to Li et al., the risk of neonatal macrosomia is directly proportional to maternal blood glucose levels in gestation weeks 24–28 [27]. In our analysis, no significant difference in the prevalence of these complications could be observed despite significant differences in pre-gestational BMI values.

According to our results, women meeting more than one diagnostic criterion of GDM were characterized by higher blood glucose levels in all three measurements of the 75 g OGTT. Notably, the difference in the 1-hour postprandial results between the study groups was as high as 37 mg/dL. In addition, mean blood glucose levels measured during the 75 g OGTT in patients meeting more than 1 diagnostic criterion of GDM were always higher than the normal levels,

while mean blood glucose levels measured during the 75 g OGTT in patients meeting just 1 criterion were within the normal limits. As shown by the HAPO study, the higher the maternal glucose levels, the higher the risk of GDM; the phenomenon is continuous in nature [3].

According to other authors, high blood glucose levels measured 1 hour after exposure in the 75 g OGTT are associated with higher risks of insulin therapy being required [28, 29]. As concluded by Mirta et al., blood glucose levels of ≥ 173.6 mg/dL as measured 1 hour after exposure in the 75 g OGTT were characterized by the sensitivity of 100% and specificity of 73% as predictors of insulin therapy requirement [29]. In our study women meeting more than one diagnostic criterion more often required insulin therapy to achieve normal blood glucose levels.

According to the results of our study, women who met more than one diagnostic criterion of GDM delivered their babies significantly earlier which might be related to the practice of earlier induction of labor in GDMG2 pregnancies; however, a higher incidence of deliveries before gestation week 37 was also observed. Other authors also confirm that meeting more than 1 criterion of GDM is associated with higher risk of preterm delivery [17, 18].

According to the worldwide literature data, the increase in the number of GDM diagnostic criteria being met is associated with an increase in the risk of GDM-related obstetric and neonatal complications [17, 18], with the nature of these complications depending on the GDM "subtype" defined on the basis of whether the fasting or the postprandial criterion had been met [17]. LGA and shoulder dystocia are associated with the fasting diagnostic criterion while preterm delivery, PIH, and hyperbilirubinemia are associated with the postprandial criteria [17].

Other authors reported that, the higher number of diagnostic criteria met in the 100 g OGTT, the more frequent preterm delivery, PIH and pre-eclampsia, vaginal operative delivery, LGA, shoulder dystocia, and elevated umbilical blood levels of peptide C [20–22]. On the other hand, Kosus et al. were unable to identify any correlation between the number of diagnostic criteria being met in the 100 g OGTT and the neonatal birth weight [30].

In our study, no significant differences were observed between the study groups with regard to the incidence of peripartum complications in mothers or to the incidence of post-partum complications in the neonates, which might have been due to early detection of GDM and initiation of extensive care by diabetologist and appropriate treatment during the pregnancy. Appropriate initiation of anti-GDM treatment prevents the development of complications [3, 31, 32].

In our study, high percentage of children with congenital defects was observed in both study groups. However, our department is a highly specialized clinic admitting patients with pregnancies complicated by congenital fetal defects and thus our study population is not representative of the overall population with this regard.

Limitation of the study

The number of patients meeting all three diagnostic criteria was too small to establish a separate group including these patient only, and therefore patients meeting all three GDM diagnostic criteria were included in a single study group with patients who met two criteria of GDM. The diagnostic criteria of GDM were changed in the course of the study, a

nd therefore different cut-off points were used for different patients in the same groups.

CONCLUSIONS

To sum up, the number of GDM diagnostic criteria being met in 75 g OGTT may be considered a prognostic factor with regard to the natural history of GDM. More than one diagnostic criterion being met in 75 g OGTT may be used to identify a group of patients whose metabolic disorders might have been present before pregnancy and is associated with a higher risk of insulin therapy being initiated in pregnancy as well as with a higher risk of delivery before gestation week 37. As the result of appropriate GDM treatment, the incidence of maternal and neonatal peripartum complications in pregnancies burdened with more than one GDM diagnostic criteria may not exceed that observed in the remaining patients.

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