

Influence of new criteria for the diagnosis of gestational diabetes mellitus on its expected frequency of occurrence and complications

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Review article

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Summary

Gestational diabetes mellitus (GDM) is the most common glucose tolerance disorder diagnosed during pregnancy. It is associated with complications for the mother, fetus and the child in the future. A prospective multicenter study, called HAPO, demonstrated a linear relationship between glycemia in OGTT in pregnant patients and macrosomia, the frequency of cesarean sections, the level of c-peptide in the umbilical blood and neonatal hypoglycemia. Based on its results, the International Association of Diabetes and Pregnancy Study Group (IADPSG) and the World Health Organization (WHO) have proposed new criteria for GDM diagnosis. The Polish Gynecologic Society (*Polskie Towarzystwo Ginekologiczne*, PTG) accepted them in 2014.

According to the previous criteria, a fasting glucose level ranged from 95 to 126 mg/dl and increased to 140 mg/dl after 2 hours (ADA criteria from 2004, WHO from 1999 and PTG from 2011) [1–3]. Due to lower fasting glucose limit values in a OGTT test (to 92 mg/dl) and increased level after 2 hours (up to 153 mg/dl), a question arises concerning the influence of these new criteria on the frequency of GDM and complications during pregnancy and in the fetus (4–6).

A considerable number of studies conducted so far indicate an increase in diagnoses of gestational diabetes mellitus compared with the previous criteria. It is also suggested that the number of labor inductions and cesarean sections has also increased. It is estimated that the treatment of mild hyperglycemia would reduce the percentage of macrosomia, shoulder dystocia and the need for hospitalization of newborns at neonatal intensive care units [7]. It is still postulated that the new criteria should be verified in large, prospective randomized trials.

Key words: gestational diabetes mellitus; GDM diagnostic criteria; obstetric outcomes; diabetes complications

INTRODUCTION

Gestational diabetes mellitus (GDM) is defined as impaired glucose tolerance with onset or first recognition during pregnancy. It is estimated that it accounts for over 90% of all cases of impaired carbohydrate tolerance that complicate pregnancy [5,8,9]. The remaining conditions are type 1 and 2 diabetes as well as impaired glucose tolerance which were not detected before pregnancy. GDM-associated complications in-

clude an increased risk of: pre-eclampsia, pregnancy-induced hypertension (PIH), macrosomia, perinatal trauma, hyperinsulinemia, hypoglycemia, hyperbilirubinemia and carbohydrate metabolism disorders in the mother as well as future obesity in the child [10,11].

O'Sullivan and Mahan were the first to propose diagnostic criteria for gestational diabetes mellitus in 1964 [12]. Since then, the methods for diagnosing carbohydrate metabolic disorders during pregnancy

have been debated. The discussion has involved the use of screening tests, doses of glucose in glucose tolerance testing and the limits of cut-off values. The results of the HAPO study, published in 2008, set the grounds for the introduction of new criteria proposed, among others, by IADPSG in 2010, WHO in 2013 and PTG in 2014 (Tab.1) [5–7].

The aim of this article is to evaluate the consequences of the introduction of the new criteria for gestational diabetes mellitus in terms of its frequency of occurrence and complications during pregnancy and in the neonatal period.

PREDICTED CONSEQUENCES OF THE INTRODUCTION OF NEW GDM DIAGNOSTIC CRITERIA

Frequency of gestational diabetes mellitus

In the HAPO trial, gestational diabetes mellitus was diagnosed in about 17.8% of 23,957 patients treated in 15 centers in 9 countries [13]. The percentage of diagnosed GDM cases varied depending on the center and ranged from 9.3% to 25.5%. In OGTT, the following types of increased glycemia prevailed: fasting glucose in 55% of patients, after 1 hour in 33% of women and after 2 hours in 12% of patients. It is estimated that following the introduction of the IADPSG criteria, the percentage of patients with GDM in the United States may even triple [14,15].

Nwose et al. [16] analyzed women who had undergone OGTT in 1999–2008. They compared the frequency of diagnosing gestational diabetes mellitus based on the previous and new criteria. The authors concluded that the introduction of the IADPSG criteria in 2010 will result in an increase in the number of diagnosed gestational diabetes mellitus by 12% over 10 years. Mayo et al. [17] analyzed how the new IADPSG criteria affected the percentage of GDM diagnoses in patients who had OGTT interpreted according to the recommendations of the Canadian Diabetes Association (CDA) from 2008. The percentage of diagnosed GDM increased from 3.2% to 10.3%. Moreover, Kalter-Leibovici et al. [18] studied data of 3,345 patients from Israel who participated in the HAPO trial. The number of patients who met the GDM criteria proposed by IADPSG was 50% greater than the one estimated so far (9% vs 6%). Furthermore, Bodmer-Roy et al. [19] conducted a retrospective study and analyzed OGTT results in pregnant patients from 2008–2010 assessed according to the CDA 2008 criteria. The introduction of the new IADPSG criteria nearly doubled the percentage of diagnosed GDM (from 14.18% to 27.51%).

Agarwal et al. [15] assessed the results of OGTT in 10,283 patients who reported for routine examinations during pregnancy in 2003–2008. They compared the number of GDM diagnoses based on the then criteria of the American Diabetes Association (ADA) are the IADPSG criteria from 2010. The percentage of newly diagnosed GDM nearly tripled: from 12.9% to

37.7%. Leng et al. [20] conducted a prospective study in 2010–2012 in which they assessed the frequency of gestational diabetes mellitus in China (Tianjin). OGTT results were analyzed according to the WHO criteria from 1999 and compared with the IADPSG criteria from 2010. The authors noted an increase in the percentage of diagnosed GDM from 8.3% (WHO) to 9.1% (IADPSG). The change in the percentage of diagnosed GDM is not only caused by the new criteria. For instance, Yew et al. [21] conducted OGTT in 855 pregnant patients and interpreted the results in accordance with the WHO 1999 criteria and recommendations from 2013. The percentage of diagnosed GDM was found to decrease from 28.8% to 21.1%. Depending on the investigated population, the introduction of the new IADPSG criteria can result in a double or even triple increase in the number of patients with a GDM diagnosis.

Complications during pregnancy

The primary aim of the HAPO study was to assess the influence of abnormal glucose values (lower than those recommended so far) on complications during pregnancy and in the neonate [22]. Abnormal glucose levels in mothers indicated a strong relationship with the occurrence of pre-eclampsia (fasting glucose OR 1.21, 95% CI; after 1 h OR 1.28, 95% CI, after 2 h OR 1.28, 95% CI) [7]. A statistically significant relationship was also found between abnormal glucose levels after 1 and 2 h and preterm labor (fasting glucose OR 1.05, 95% CI; after 1 h OR 1.18, 95% CI, after 2 h OR 1.16, 95% CI). Moreover, a relationship was observed between increased glucose levels and the need for a cesarean section (fasting glucose OR 1.11, 95% CI; after 1 h OR 1.10, 95% CI, after 2 h OR 1.08, 95% CI).

The literature suggests that an increase in new GDM diagnoses will increase the number of cesarean sections and complications associated with this procedure. It is also estimated that the number of labor inductions without evident indications will rise [14,23,24]. Mayo et al. [17] analyzed obstetric outcomes in patients who met the CDA criteria from 2008 and the IADPSG criteria from 2010, and compared them with the outcomes of patients with normal pregnancies. Pregnancy-induced hypertension and pre-eclampsia were significantly more frequent in patients who met the new IADPSG criteria compared with the controls (8.4% vs 3.0%). Cesarean sections were conducted significantly more frequently in patients who met both the IADPSG and CDA criteria (36.8% and 34% vs 26.1%). The percentage of preterm childbirths, labor inductions and duration of hospitalization was not significantly different between the patients with GDM diagnosed with the IADPSG criteria and healthy women. Such a difference, however, was observed in patients who met the CDA criteria (7.8% vs 5.0%, 20.5% vs 11.0% and 25.7% vs 20.5%, respectively). Nayak et al. [25] also studied pregnant patients in whom OGTT was assessed based

Tab. 1. Recommendations concerning the criteria of gestational diabetes mellitus [32–40]

Recommendations	Year of introduction	Method of glucose tolerance assessment	Method of glucose tolerance assessment
O'Sullivan and Mahan [32]	1964	100 g OGTT	At least two criteria met: fasting glucose ≥ 90 mg/dl (5.0 mmol/l) after 1 h ≥ 165 mg/dl (9.2 mmol/l) after 2 h ≥ 143 mg/dl (8.1 mmol/l) after 3 h ≥ 127 mg/dl (6.9 mmol/l)
Carpenter-Coustan [32]	1982	100 g OGTT	At least two criteria met: fasting glucose ≥ 95 mg/dl (5.2 mmol/l) after 1 h ≥ 180 mg/dl (10.0 mmol/l) after 2 h ≥ 155 mg/dl (8.6 mmol/l) after 3 h ≥ 140 mg/dl (7.8 mmol/l)
WHO [33]	2006	75 g OGTT	At least one criterion met: fasting glucose ≥ 126 mg/dl (7.0 mmol/l) after 2 h ≥ 200 mg/dl (11.1 mmol/l)
WHO [6]	2013	75 g OGTT	At least one criterion met: fasting glucose ≥ 92 –125 mg/dl (5.1–6.9 mmol/l) after 1 h ≥ 180 mg/dl (10.0 mmol/l) after 2 h ≥ 153 –199 mg/dl (8.5–11.0 mmol/l)
PTG [34]	2005	50 g GCT ≥ 140 –199 mg/dl (7,8–11,06 mmol/l) 75 g OGTT	GCT ≥ 200 mg/dl (11.1 mmol/l) At least one criterion met in OGTT: fasting glucose ≥ 100 mg/dl (5.5 mmol/l) after 1 h ≥ 180 mg/dl (10 mmol/l) after 2 h ≥ 140 mg/dl (7.8 mmol/l)
PTG [3]	2011	75 g OGTT	At least one criterion met: fasting glucose ≥ 100 mg/dl (5.5 mmol/l) after 1 h ≥ 180 mg/dl (10.0 mmol/l) after 2 h ≥ 140 mg/dl (7.8 mmol/l)
PTG [5]	2014	75 g OGTT	At least one criterion met: fasting glucose ≥ 92 mg/dl (5.1 mmol/l) after 1 h ≥ 180 mg/dl (10.0 mmol/l) after 2 h ≥ 153 mg/dl (8.5 mmol/l)
PTD [35]	2013	75 g OGTT	At least one criterion met: fasting glucose ≥ 100 mg/dl (5.5 mmol/l) after 2 h ≥ 140 mg/dl (7.8 mmol/l)
PTD [36]	2014	75 g OGTT	At least one criterion met: fasting glucose ≥ 92 –125 mg/dl (5.1–6.9 mmol/l) after 1 h ≥ 180 mg/dl (10.0 mmol/l) after 2 h ≥ 153 –199 mg/dl (8.5–11.0 mmol/l)
CDA [37]	2008	50 g GCT ≥ 140 –184 mg/dl (7,8–10,2 mmol/l) 75 g OGTT	GCT ≥ 185 mg/dl (10.3 mmol/l) At least two criteria met in OGTT: fasting glucose ≥ 95 mg/dl (5.3 mmol/l) after 1 h ≥ 191 mg/dl (10.6 mmol/l) after 2 h ≥ 160 mg/dl (8.9 mmol/l)
CDA [38]	2013	50 g GCT ≥ 140 mg/dl (7,8 mmol/l) 75 g OGTT	GCT ≥ 200 mg/dl (11.1 mmol/l) At least one criterion met in OGTT: fasting glucose ≥ 95 mg/dl (5.3 mmol/l) after 1 h ≥ 191 mg/dl (10.6 mmol/l) after 2 h ≥ 162 mg/dl (9.0 mmol/l)
ADA [39]	2004	50 g GCT ≥ 130 –140 mg/dl (7,2–7,8 mmol/l) 100g OGTT 75g OGTT*	At least two criteria met in OGTT: fasting glucose ≥ 95 mg/dl (5.3 mmol/l) after 1 h ≥ 180 mg/dl (10.0 mmol/l) after 2 h ≥ 155 mg/dl (10.6 mmol/l) after 3 h ≥ 140 mg/dl (7.8 mmol/l) – in the case of 100 g OGTT

Tab. 1. Cont.

Recommendations	Year of introduction	Method of glucose tolerance assessment	Method of glucose tolerance assessment
ADA [40]	2013	75 g OGTT	At least one criterion met: fasting glucose ≥ 92 mg/dl (5.1 mmol/l) after 1 h ≥ 180 mg/dl (10 mmol/l) after 2 h ≥ 153 mg/dl (8.5 mmol/l)
IADPSG [4]	2010	75 g OGTT	At least one criterion met: fasting glucose ≥ 92 mg/dl (5.1 mmol/l) after 1 h ≥ 180 mg/dl (10.0 mmol/l) after 2 h ≥ 153 mg/dl (8.5 mmol/l)
* alternatively GDM (<i>Gestational Diabetes Mellitus</i>); GCT (<i>Glucose Challenge Test</i>); OGTT (<i>Oral Glucose Tolerance Test</i>); WHO (<i>World Health Organization</i>); PTG (<i>Polish Gynecologic Society [Polskie Towarzystwo Ginekologiczne]</i>); PTD (<i>Polish Diabetes Association [Polskie Towarzystwo Diabetologiczne]</i>); CDA (<i>Canadian Diabetes Association</i>); ADA (<i>American Diabetes Association</i>); IADPSG (<i>International Association of Diabetes and Pregnancy Study Groups</i>)			

on the IADPSG criteria. They found that polyhydramnios was significantly more common in patients with GDM (6.0% vs 0.5%). Generally, PIH, PROM and preterm delivery were more common in patients with gestational diabetes mellitus. The number of labor inductions and cesarean sections was not different between the groups. The gestational age at the conclusion of pregnancy was significantly higher in healthy patients (38.83 ± 1.23 vs 38.45 ± 1.36 , $p=0.02$). The study of Bodmer-Roy et al. [19] did not show statistical significance with respect to the percentage of pre-eclampsia and cesarean sections between patients who met the criteria of IADPSG and healthy women.

Complications in newborns

In studies on the influence of gestational diabetes mellitus on the course of the neonatal period, the following parameters are assessed: birth weight, hypertrophy and complications such as: hypoglycemia, hyperinsulinemia, hyperbilirubinemia, the need for hospitalization and duration of hospitalization at intensive care units.

The HAPO study conducted among women with diabetes revealed a strong relationship between glucose levels measured in OGTT and birth weight (fasting glucose OR 1.38, 95% CI, after 1 h OR 1.46, 95% CI, after 2 h OR 1.38, 95% CI) as well as C-peptide level in the umbilical blood >90 th percentile (fasting glucose OR 1.55, 95% CI, after 1 h OR 1.46, 95% CI, after 2 h OR 1.37, 95% CI) [7]. A positive relationship was observed between increasing glycemia and: shoulder dystocia, perinatal trauma, hyperbilirubinemia, hypoglycemia and the need for hospitalization at the neonatal intensive care unit (NICU).

A retrospective study from Toronto compared the outcomes in patients with OGTT interpreted on the basis of the CDA criteria from 2008 and the IADPSG criteria. The group that met the CDA criteria presented

a higher rate of newborn hospitalization at the NICU (7.3% vs 4.1%), hyperbilirubinemia (9.4% vs 6.4%) and hypoglycemia (7.3% vs 1.1%) compared with healthy pregnant patients [17]. Hypertrophy and birth weight >90 th percentile were more often observed in the group of patients with diabetes mellitus diagnosed on the basis of both CDA and IADPSG criteria (7.8% and 12.3% vs 9.3% 11.7% and 13.5% vs 8.1%). There were no significant differences between the groups in terms of: the occurrence of shoulder dystocia, perinatal trauma or respiratory distress syndrome. Nayak et al. [25] found a significant difference in the percentage of neonates hospitalized at NICUs (>24 hours) born of patients with GDM assessed according to the IADPSG criteria compared with healthy patients (10.8% vs 4.1%). The average birth weight and the percentage of hypertrophy did not differ between the groups. Furthermore, there were no significant differences concerning the percentage of respiratory distress syndrome, hyperbilirubinemia and perinatal mortality.

Bodmer-Roy et al. [19] did not find any significant differences concerning the number of newborns with body weight >90 th percentile between the group of mothers who met the IADPSG criteria and healthy women (9.1% vs 5.9%, $p=0.19$). Respiratory distress syndrome was more common in newborns of mothers with GDM (8.6% vs 3.8%, $p=0.06$). When the manner of delivery (natural vs cesarean section) was included, the differences were not statistically significant. Moreover, no statistically significant differences were observed in terms of the percentage of hypoglycemia (2.2% vs 4.3%, $p=0.24$), hyperbilirubinemia (2.2% vs 5.6%, $p=0.08$) and duration of hospitalization >24 hours at the NICU (6.5% vs 5.4%, $p=0.7$).

With the previous GDM diagnostic criteria, GDM-associated complications included: increased risk of future type 2 diabetes, arterial hypertension and obe-

sity in the child [6,26]. Currently, there is no evidence concerning the type and rate of these complications with respect to the new criteria. In 2010, Gillman et al. [27] assessed the influence of treating mild forms of hyperglycemia during pregnancy on BMI of children aged 4–5 years. The values \geq 85th percentile were noted in 33% of children born of mothers who were treated for gestational diabetes mellitus and in 27.6% of children of untreated mothers (macrosomia diagnosed in 5.3% vs 21.9% of newborns, respectively).

Despite the positive influence of treating benign hyperglycemic state on lowering the rate of macrosomia, such a therapy was not found beneficial when BMI in children at the age of 4–5 was assessed. Pirkola et al. [28] studied the influence of obesity and gestational diabetes mellitus in the pregnant on BMI of their children at the age of 16. The highest risk of overweight and abdominal obesity was noted in children of patients with BMI \geq 25 kg/m² and GDM (overweight OR 4.05, abdominal obesity OR 3.82). In the case of mothers with normal pre-pregnancy body weight and GDM, there was no risk of obesity in their children (OR 0.73 and OR 1.22). Pre-pregnancy overweight is an independent risk factor of both complications (OR 2.56 i OR 2.6).

Furthermore, Hung Tam et al. [29] noted in 2010 that children of mothers with diagnosed gestational diabetes mellitus carry a higher risk of metabolic syndrome and overweight in adolescence (control at the age of 15) compared with children of healthy women (7.1% vs 3.4%, $p=0.35$). There were no relationships between birth weight and BMI at the age of 15.

CONCLUSION

Despite being accepted by renowned Diabetes Associations, the new diagnostic criteria for gestational diabetes mellitus still cause controversy. Their introduction is justified by: the reference of the cut-off points to complications typical of gestational diabetes mellitus (such as macrosomia, C-peptide level >90 percentile), randomized studies indicating that the treatment of mild hyperglycemia during pregnancy has an impact on lowering the number of GDM complications, financial advantage resulting from the protection of mothers and children from the complications of gestational diabetes mellitus in the future and easier GDM treatment [24,30,31].

Arguments against the introduction of the new criteria include: a considerable increase in the number of patients diagnosed with gestational diabetes mellitus, limited repeatability of oral glucose tolerance test (up to 30% of negative diagnoses in patients previously classified as having GDM), overload of the health care system with the need of engaging interdisciplinary teams in the therapeutic process (gynecologists, dietitians, endocrinologists), stigmatizing patients (higher-risk pregnancy) and increased percentage of obstetric interventions (labor induction, cesarean sections) [14,24,30].

In order to verify the actual influence of the new criteria, it is necessary to collect data on complications during pregnancy and in children as well as the percentage of women who need insulin treatment. It also needs to be verified whether increasing the cut-off point for glycemia two hours after glucose intake can influence the number of diagnosed cases of macrosomia and shoulder dystocia in children of patients classified as healthy.

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