The Clinical and Financial Effects of Replacing the 1 h 50 g Screening Test for Gestational Diabetes Mellitus by the Stick Method

Abstract

Background. Gestational diabetes is connected with fetal macrosomia and higher perinatal mortality and morbidity rates. The usually quoted literature, which causes so much anxiety among pregnant women and an increased number of cesarean sections, is often dated, from the times when pregnancy monitoring methods were not as highly developed as they are now, comes from heterogeneous populations, and does not take into consideration the age and ethnicity of women. Screening for gestational diabetes mellitus (GDM), diagnostic tests, and special programs for diabetic pregnant women are very expensive and time consuming. It is worthwhile then to try to evaluate their cost and see if reducing it would affect the clinical results.

Objectives. The aim of this study was to identify the real cost reduction and clinical advantages/disadvantages of replacing the 1−hr 50−g glucose challenge test (GCT) with the glucometer (stick method).

Material and Methods. Two hundred and two pregnant women from the population of this clinic attended screening for GDM by both enzymatic and stick method. The criteria for both measurements were the same. The positively screened women received a one−step diagnostic test and only they participated in the clinic’s diabetic program.

Results. The results showed that replacing the enzymatic method by the stick method would reduce the total cost of screening for GDM by 90%. It was also calculated that the total cost of screening by this method followed by the diagnostic test would be 9.5 times lower than screening by the enzymatic method. It would have no harmful effects on perinatal outcome and would even make it possible to shorten the time between screening and treatment of GDM by about 7 days.

Conclusions. Although identifying GDM is important because of possible perinatal complications, the same aim can be achieved by replacing the GCT with the glucometer (Adv Clin Exp Med 2009, 18, 6, 601–607).

Key words: gestational diabetes mellitus, pre-gestational diabetes mellitus, glucometer, stick method, glucose challenge test, oral glucose tolerance test, cesarean section rate, shoulder dystocia.

Streszczenie

Wprowadzenie. Od dawna wiadomo, że cukrzycy ciąży mogą prowadzić do powikłań u płodów w postaci makrosomii, obrażeń okołoporodowych dużych płodów, czy nawet śmierci okołoporodowej. Często jednak powielane dane statystyczne są nieaktualne, nie uwzględniają wielu dodatkowych danych zmieniających znaczenie statystykę, jak np.: wieku badanych kobiet, pochodzenia etnicznego, a nawet liczby wad letalnych wpływających na śmiertelność okołoporodową, czy liczby nierozpoznanych cukrzyc przedciążowych. Dane takie wywołują strach u kobiet i mimo ogólne dostępnych badań okołoporodowych dla wszystkich ciężarnych czynią z cukrzycy ciążyowych nadspodziewanie kosztowną grupę ciężarnych.

Cel pracy. Zbadanie możliwości ograniczenia kosztów badań przesiewowych cukrzycy ciążyowej i sprawdzenie, czy może to mieć wpływ na liczbę rozpoznawanych potem w testach diagnostycznych cukrzycy ciążyowych oraz powikłań okołoporodowych.

Material i metody. U 202 ciężarnych poddanych 1h-50g GCT wykonano jednoczesny pomiar stężenia glukozy sposobem enzymatycznym w osoczu krwi żyłnej i sposobem paskowym z użyciem glukometru. Zachowano te sa-
Diabetes mellitus (DM) is divided into four types: type-1, type-2, gestational, and other forms caused by other conditions [1]. If carbohydrate intolerance is recognized for the first time during the pregnancy, it is defined as gestational diabetes mellitus (GDM) [2]. Therefore, regardless of the severity of the illness and the method of treatment, use of the term GDM is determined solely by the time when it is diagnosed. There is a practical side to this as the situation during pregnancy is unique: the fetus is also under the influence of DM. It is thus out of concern for the fetus that GDM was identified as a separate type. However, the present authors’ more than 20 years of experience indicates that with the present diagnostic methods, pregnancies with GDM should be treated either like all other pregnancies with pre-gestational DM or like pregnancies in which some specific complications may be expected with similar probability to that in the whole population. In short, there is usually no reason for a pregnant woman to give up her normal daily activities. This is important because the need to perform frequent glucose controls and additional tests, even in mild GDM, becomes so time consuming and tiring that the pregnant woman quits work and even refrains from taking care of her children at home. At present, screening and special care of a GDM-pregnant woman very often lead to excessive and unnecessary stress and cost.

Are the fetuses of GDM pregnant women exposed to the same kinds of complications as those of women with DM diagnosed before pregnancy? Can these complications be prevented by means of special programs, which originated in the times of insufficient monitoring methods? It is these questions that the present series of articles, based on the authors’ research and everyday clinical practice, addresses.

In the USA there are 1.5 million new cases of diabetes mellitus diagnosed every year among persons ≥ 20 years old [3]. In 2005, the total prevalence of DM in the USA was 7% of the population and it is considered highly probable that a large part remained undiagnosed [3]. Of all diabetics, 5–10% are type-1 DM and 9–95% type-2 [3]. GDM occurs in about 3–5% of all pregnant women [4]; according to the Fifth International Workshop-Conference on GDM, even in 5–10% [5]. The rate also depends on ethnicity [6] and even on the diagnostic criteria assumed; for example, there were 3.2–3.21% diagnosed by the NDDG and 4.8–4.95% diagnosed by the Carpenter and Coustan criteria [7, 8]. The rate of DM is increasing and this increase is greater in developing countries [3]. The prevalence and incidence of GDM have also been rising over recent years [9]. At the same time, in many countries the number of pregnancies complicated by type-2 diabetes is currently exceeding those complicated by type-1 [9]. The prevalence of GDM depends on age and ethnicity [6, 10]; thus, for example, among Asians it is 5.0% by the NDDG and 7.4% by the Carpenter and Coustan criteria, among Hispanics these are 3.9% and 5.6%, among African-Americans 3.0% and 4.0%, and among whites 2.4% and 3.8% [7]. In the present authors’ hospital, GDM is recognized in 3.5% of pregnancies according to the NDDG and in 4.2% according to the Carpenter and Coustan criteria. About 0.5% of them go on insulin therapy. In Poland there is obligatory screening for GDM between the 24th and 28th week of pregnancy. The percentage of recognized GDM in Lower Silesia keeps rising. It is suspected that it may be connected with a growing percentage of obesity among young women, a sedentary life style from the early years, a greater number of late first pregnancies (the percentage of first pregnancies at ages ≥ 40 years is growing), and the growing number of pregnancies as a result of assisted reproductive technology.

As the authors hope this article will also be useful to students, who often ask for help with understanding of screening, diagnosing, and treating GDM, the authors decided to present these findings in a form that would also serve such educational purposes.
According to ADA guidelines for GDM risk [11]:

1. All pregnant women should be assessed for GDM risk at their first prenatal visit.
2. If there are risk factors for GDM (obesity, personal history of GDM, a previous birth with birth weight ≥ 4500 g, a history of two or more fetal deaths, neonatal death, congenital anomalies, hypertension, proteinuria, glycosuria, a strong family history of DM), the pregnant woman should immediately undergo glucose testing.
3. A pregnant woman has GDM on the early screening when she has either of the following:
   - FPG > 7.0 mmol/l (126 mg/dl); causal plasma glucose ≥ 11.1 mmol/l (200 mg/dl)
4. These results need to be confirmed on a subsequent day unless unequivocal symptoms of hyperglycemia are present.
5. Women at high risk for GDM who do not meet the requirements for a diagnosis of GDM at the initial screening and average-risk women should be retested between the 24th and 28th week of gestation.
6. The tests that should be performed to diagnose GDM: A 100-g oral glucose tolerance test (OGTT) and two of the following must be met for a positive diagnosis. In this university hospital it is advised to repeat this test when there is one altered result; FPG (fasting plasma glucose) ≥ 95 mg/dl (5.3 mmol/l); 1-hour glucose level ≥ 180 mg/dl (10 mmol/l); 2-hour glucose level ≥ 155 mg/dl (18.6 mmol/l); 1-hour glucose level ≥ 140 mg/dl (7.8 mmol/l).

In the present authors’ opinion (about 20 years experience with pregnant diabetic women from the whole southwest of Poland), this is the best and verified method of screening and diagnosing GDM in this population and should be applied in the whole province.

For the initial screening, the plasma or serum glucose concentration 1 hour after a 50-g load is checked (i.e. the glucose challenge test, GCT) in women between the 24th and 28th week of pregnancy followed by a 100-g OGTT in women who exceed the glucose threshold value on the GCT. The glucose cut-off of 140 mg/dl (7.8 mmol/l) identifies approximately 80% of women with GDM. A lower cut-off of 130 mg/dl (7.2 mmol/l) identifies 90% [11]. OGTTs are aimed at confirming the diagnosis in suspected subjects and leaving as few undiagnosed GDM patients as possible.

OGTTs used to diagnose diabetes mellitus [4]:

A. 100-g 3-h OGTT
   1. Carpenter and Coustan values (plasma or serum):
      - norm: fasting 95 mg/dl (5.3 mmol/l)
      - 1 h 180 mg/dl (10.0 mmol/l)
      - 2 h 155 mg/dl (8.6 mmol/l)
      - 3 h 140 mg/dl (7.8 mmol/l)
   2. O’Sullivan and Mahan/NDDG values:
      - Fasting 105 mg/dl (5.8 mmol/l)
      - 1 h 190 mg/dl (10.5 mmol/l)
      - 2 h 165 mg/dl (9.2 mmol/l)
      - 3 h 145 mg/dl (5.3 mmol/l)
      - Fasting 95 mg/dl (5.3 mmol/l)
      - 1 h 180 mg/dl (10.0 mmol/l)
      - 2 h 155 mg/dl (8.6 mmol/l)
      - 3 h 140 mg/dl (7.8 mmol/l)
   4. FIWC-GDM
      Two-step testing
      Screen using a 50-g load utilizing either O’Sullivan and Mahan or Carpenter and Coustan’s values
      Definitive diagnosis using 100-g glucose utilizing Carpenter and Coustan’s values

B. One-step diagnostic test, 75-g glucose load in a fasting state (2-h 75-g OGTT):
   1. FIWC-GDM
      - Fasting 95 mg/dl (5.3 mmol/l)
      - 1 h 180 mg/dl (10.0 mmol/l)
      - 2 h 155 mg/dl (8.6 mmol/l)
   2. WHO/FIGO/ASEAN: A Study Group on Diabetes in Pregnancy (ASGODIP)
      - 2-h post-glucose value >140 mg/dl (7.8 mmol/l)

C. WHO
   - no screening or testing is needed if:
      - random FBS >140 mg/dl (7.8 mmol/l)
      - 2 h PPBS>200 mg/dl (11.1mmol/l)
   - FBS (fasting blood sugar)
   - PPBS (postprandial blood sugar)

Screening tests of GDM [4]:

1. Carpenter and Coustan screening test:
   - Fasting is not needed before a 50-g anhydrous glucose load
   - 1 hour later, plasma glucose determination with a cut-off of 130 mg/dl (7.2 mmol/l)
   > 130 mg/dl indicates the need for diagnostic test of 100-g 3-h (OGTT)
2. NDDG/ADA (National Diabetes data Group/American Diabetes Association)
   - Fasting is not needed before a 50-g anhydrous glucose load
   - 1 hour later, plasma glucose determination with a cut-off of 140 mg/dl (7.8 mmol/l)
   > 140 mg/dl indicates the need for a 100-g 3-h OGTT diagnostic test.

A review of GDM statistics in the literature on the subject is presented in Table 1.

The accepted definition of GDM is too gener-
al [10] and, from the clinical point of view, not sufficiently precise. One might expect that fetal and neonatal complications that may occur in GDM pregnancies would be similar to those in pre-gestational diabetic pregnancies [10]. However, it is more complex than that. For example, the perinatal mortality rate in diabetic pregnancies can be as much as twice the rate in non-diabetic pregnancies [14], but this is largely due to the fact that there is a higher rate of lethal malformations among all diabetic pregnancies.

Apart from that, fetal loss is also the result of other factors, for example the age of the pregnant woman. Fetal loss occurs more often in older women than in younger women with GDM. It may seem that some authors do not give the age of the sample in order to make their findings more attractive to the reader [15, 16]. Today the difference in perinatal mortality between diabetic and non-diabetic pregnancies is very similar, almost negligible [14]. This is confirmed by the present authors’ own observations. It seems that perinatal mortality is more often due to other complications occurring in diabetic pregnancies, such as preeclampsia [6, 10, 13], or it may be connected with substandard obstetrical care in general rather than the lack of some special care that should be offered to pregnant women with GDM.

“The goal of blood glucose diagnostic test is to find out whether you have a very large amount of glucose in your blood” [17], but for obstetricians it is equally important to know how it influences the fetus. The information given most often by physicians to a GDM pregnant woman is that “the most frequent and significant morbidity is fetal macrosomia, which in turn is associated with increased risk of birth injuries and asphyxia” [10]. Therefore one of the aims of this study was to check if the incidence of macrosomia (birth weight ≥ 4500 g) in gestational diabetic and non-diabetic pregnancies is different and whether it could be true that shoulder dystocia occurs in 21% of infants weighing in excess of 4000 g [18]. The main aim of this study was to calculate the advantages and disadvantages of using a glucometer (the stick method) instead of the enzymatic method in screening for GDM. If in the 1-h 50-g GCT a glucometer instead of venous plasma blood (the enzymatic method) is used, how many more women will have an additional OGTT and what would its consequences be for the pregnant women and for the hospital?

### Material and Methods

The prospective study conducted between 2006 and 2008 included 202 pregnant women, both outpatients and hospitalized. They were screened for GDM between the 24th and 28th week of gestation. The women were in the age bracket of 17 to 41 years. All of them were screened in the same way, i.e. the 1-h 50-g GCT. Simultaneously with venous blood, finger capillary blood samples were taken (for the stick method). The patients with a venous or capillary blood glucose level of > 140

### Table 1. A review of GDM statistics [6, 8, 12, 13].

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<tr>
<td><strong>Perinatal mortality</strong></td>
<td>24.3%</td>
<td>5.0%</td>
<td>1.1%</td>
<td>49.2/1000</td>
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<td><strong>Perinatal mortality in background population</strong></td>
<td></td>
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<td>11.6/1000</td>
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<td><strong>Infant mortality</strong></td>
<td>31.4%</td>
<td>7.5%</td>
<td>4.6%</td>
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<td><strong>Emergency c.s.</strong></td>
<td></td>
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<td>1.6 x greater</td>
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<td><strong>Preeclampsia</strong></td>
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<td>8%, 2 x greater</td>
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<td><strong>Hypertension</strong></td>
<td>7.3%</td>
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<td><strong>Macrosomia (≥ 4500 g)</strong></td>
<td>2–3 x greater</td>
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<td>2.91%</td>
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<td><strong>&gt; 4200 g or ≥ 4000 g</strong></td>
<td>6.7%</td>
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<td>16.9–17.9%</td>
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<td><strong>Fetal malformation</strong></td>
<td>9.8%</td>
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<td><strong>Fetal malformation in background population</strong></td>
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<td>2.2%</td>
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<td><strong>Asphyxia</strong></td>
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<td>2–3 x greater</td>
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<td><strong>Shoulder dystocia</strong></td>
<td>0.15–0.6% (of all deliveries)</td>
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<td><strong>Erb’s palsy</strong></td>
<td>0.7 or 5% (&lt; 4500 g, ≥ 4500 g)</td>
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<tr>
<td><strong>Primary c.s</strong></td>
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<td>22.3–35.3%</td>
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mg/dl went for a FIW-GDM (one-step) diagnostic test (2-h 75-g OGTT). All patients diagnosed with GDM went on a 2-h PPS control in this hospital. Then the decision was made as to the kind of treatment they were to receive. Glycemic control and its evaluation through self-monitoring of blood glucose level were done 2-3 times a week (before breakfast and 2 hours after each meal) until delivery (the routine way here) and 4 or 6 times a day every day if the patients were on insulin therapy. For years, also in this hospital, this program has been producing optimal pregnancy outcome [19, 20].

Patient management was according to the venous plasma glucose results, not the stick test results. The information about the way of the delivery, the number of macrosomic infants and the cesarean section rate were obtained from the records. After allocating the patients to both groups (by both methods of measuring the glucose level in the screening test), the outcome data were compared. For easier comparison, the results obtained from venous plasma (by the oxidase method) is called the “enzyme group” and those obtained from the glucometer the “stick group”.

**Results**

Of the 202 patients in the screening groups, 7 (~3.5%) from the enzyme group and 9 (~4.5%) from the stick group underwent the diagnostic test for GDM. After the diagnostic test, a diagnosis of GDM was made in 85.7% of those from the enzyme group and 66.7% of those from the stick group (the same 6 patients were diagnosed as having GDM in both groups). After the diagnostic test, about 16.6% went on insulin therapy and about 83.3% went on diet only. The glucometer readings differed from the enzymatic readings by about 7.2 mmol/l.

The average age of the pregnant women with GDM was 36.2 years and of the non-diabetic women 27.8 years. On average, the patients picked up their test results after 4 days. The average time between the screening and the OGTT was 2 days in the stick group and 9 days in the enzyme group. In the enzyme group there was only 1 infant heavier than 4000 g (4200 g), from a diabetic mother who was on diet only. In the stick group there was another newborn weighing > 4000 g (4100 g). In the GDM-diagnosed population there was one case of macrosomia (1/6, i.e. about 16.7%). In the non-diabetic population the incidence of macrosomia was 7.7% (15/196).

No shoulder dystocia in these GDM pregnancies was found for the simple reason that the only infant weighing 4200 g was born by c.s. All fetuses > 4000 g from non-GDM pregnancies were born vaginally, without shoulder dystocia symptoms. Macrosomia (> 4000 g) in the background population was 7.4%. The c.s. rate among the GDM patients was about 66.7% and the causes were prematuritas and GDM (50%), severe hypertension and GDM (25%), and breech presentation (25%). Of the 196 non-GDM women, the rate of cesarean section was about 26% and the main cause was asphyxia (~51%).

Using the glucometer, the authors had to do two more diagnostic tests, i.e. 28.6% of all diagnostic tests. The cost of enzymatic blood testing in this laboratory is 4 PLN (ca. EUR 1). The cost of one glucometer measurement is about 0.4 PLN (ca. EUR 0.10, i.e. 10% of the cost of the enzymatic blood test). The total cost for screening in the study population was 80.8 PLN in the stick group and 808 PLN in the enzyme group. Given that each year there are about 1600 births in this hospital, if all of the women were screened at the current prices for the tests, the cost of screening by the enzymatic method would be 6400 PLN (EUR 1600) and by the stick method 640 PLN (EUR 160), i.e. 10 times less. The cost of one diagnostic test (one-step test, three measurements) is (commercially calculated) 12 PLN (EUR 3).

Recall that these results show that the GTT had to be carried out in 3.5% of the women screened by the enzymatic method and 4.5% of those screened by the stick method. Matched with the average number of births in this hospital (1600), this means 56 pregnant women for the enzymatic method and 72 women for the stick method. The respective yearly costs of the OGGT and GCT together are then 6568 PLN for the enzymatic method and 856 PLN for the stick method. This means that by using the stick method, 5712 PLN a year are saved.

**Discussion**

The incidence of patients who underwent the diagnostic test for GDM was 3.5% in the enzyme group and 4.5% in the stick group. Both values are between the NDDG criteria (1.4%) and the WHO criteria (15.7%) [21]. Therefore the reduction in the cost of screening may depend on the criteria and on the laboratory method.

Screening with a glucometer does not produce any harmful clinical effects because the diagnosis of GDM is done only after the diagnostic test, which is enzymatic. In short, both screening methods indicated the same patients as suspected GDM, and among these were the same patients
later diagnosed as having GDM. After the screening, the patients are always (in the case of this region) directed for diagnosis and treatment to this clinic or to another center specializing in the treatment of diabetes. It is therefore not possible that a patient will be treated for diabetes on the basis of screening alone. The only disadvantage of the stick method is that because of the higher incidence of cases in which the result of the screening is not confirmed by the diagnostic test, there will be a few more women without GDM who will experience the stress connected with waiting for the results of the diagnostic test. However, the stick method also offers the advantage of a shorter screening time, which results in a shorter time to the diagnostic test if it proves necessary and, consequently earlier diagnosis and treatment. Another advantage of the stick method is the lower cost of nationwide screening. The money saved in this way can be directed to the treatment of other patients.

According to these results, when the glucometer was used in screening, the specificity was about 98.5% and the positive predictive value was 66.7%, assuming that the diagnostic test diagnosed 100% of GDM. The literature says that it discovers about 90.4% [22]. In comparison, the specificity of the 1-h 50-g GCT (enzymatic method) is 99.6% and sensitivity 66.7% [7, 15].

Macrosomia among the infants of the GDM mothers was about twice as frequent as among the non-GDM mothers in this study, which is similar to results given by other authors (16.9%) [8]. It should be noted that changing the criteria for GDM (for example by replacing NDDG with the Carpenter and Coustan criteria) and using diet did not change the prevalence of infants ≥ 4000 g (17.15% vs. 16.9%) or the prevalence of infants ≥ 4500 g (2.95% vs. 2.91%) [8]. The present authors’ research does not confirm that shoulder dystocia occurs so often among fetuses > 4000 g [18]. The GDM patients had about 2.5 times more primary c.s. than non-diabetic patients, which is much more than that reported in other sources [6, 13].

The number of c.s. in this clinic confirms the statement by some other authors that “screening for gestational diabetes may color the clinical judgment, influencing further management e.g. more unjustified caesarean sections” [23]. The perinatal mortality rate was 0 for the GDM and non-GDM women.

Reducing the cost of screening by 90% through the use of the stick method would make it possible to reduce the cost of medical care in GDM pregnancies, which is already huge due to the great number of tests and c.s. In Australia, the treatment for mild GDM, in addition to routine obstetric care, costs about $6521 and rises if there is hospitalization or if induction of labor must be included [24]. The cost per insulin-treated patient was estimated at $3596–3700 [25], so reducing the cost of even one step in diagnosing GDM is important.

It should be considered how to optimize the cost of medical care of pregnant GDM women if the treatment is by diet, as in most cases (16.6% vs. 83.3%), and this depends on the responsibility and self-discipline of the patient herself [26].

The present authors’ observations show that most women want to have and are ready to pay about 150 PLN (EUR 40) for 4-D USG, even when this is not required by the obstetrical situation. Why then should they not agree to pay for the sticks and insulin, if this is only for a relatively short time of treatment?

As an additional outcome, the present results show that investing in the treatment of GDM brought considerable benefits, but it also brought about a more widespread feeling of being seriously ill among the pregnant women as well as an increase in the number of cesarean sections.

Some authors have already suggested that in order to reduce the cost of screening, only FBS with risk factors should be performed [5, 27].

In the last decade it has become clear that GDM is a clinical entity associated with perinatal mortality and morbidity. As attention to and management of gestational diabetes during pregnancy are mandatory, the present authors do not propose abandoning screening the whole population of pregnant women in Poland, but to make the screening cheaper, self-control more rational, and the c.s. rate lower. The authors are aware that the level of glycemic control and its evaluation through self-monitoring of blood glucose are the foundation for assuring optimal pregnancy outcome [20], but this mainly depends on the patient [28].

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