

Randomized Study Comparing Two Gestational Diabetes Screening Strategies in a Reference Maternity Hospital in Southern Benin

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Abstract

Objective: The objective of this work is to compare two gestational diabetes screening strategies.

Patients and methods: We conducted a comparative randomized study that screened gestational diabetes on pregnant women who are between 24th and 28th weeks of amenorrhea. We conducted the trials either by measuring fasting glucose values or by a glucose tolerance test performed two hours after oral loading of 75 g glucose (WHO test). The study involved 580 pregnant women (290 for each type of trial) who came for antenatal appointment at the reference maternity hospital in Porto-Novo (Benin) between February 2nd, 2015 and January 31st, 2017.

Results: We detected 26 cases (9%) of gestational diabetes by the "fasting glucose value measurement method" as compared to the 18 cases (6.2%) detected by the WHO test, leading to a p-value of 0.209. The two types of test were equally relevant: Sensitivity (59.09% vs. 40.91%), specificity (50.75% vs. 49.25%), positive predictive value (8.97% vs. 6.21%), and predictive value negative (93.79% vs. 91.03%). All pregnant women tested "negative" between their 24th and their 28th weeks of amenorrhea, were tested again during the 32nd week of amenorrhea, using the WHO test method and no new case of gestational diabetes was detected.

Conclusion: Fasting glucose value measurement method can be an alternative method for gestational diabetes screening in a population where the WHO test is not available.

Keywords: Gestational diabetes screening; Fasting glucose; WHO test

Introduction

Gestational diabetes is a glucose tolerance disorder that leads to different levels of hyperglycemia and is diagnosed for the first time during pregnancy, with blood glucose levels above normal but still below the established thresholds for the diagnosis of diabetes [1-4].

Several screening strategies are proposed in the literature. During the first pregnancy trimester, the French National College of Gynecologists Obstetricians (CNGOF) and the International Association of Diabetes and Pregnancy Study Groups (IADPSG) recommend fasting glucose value measurement for women that present risk factors of gestational diabetes [1,2,4]. Between 24th and 28th weeks of amenorrhea (WA), the screening strategy is usually based on the glucose tolerance test after oral loading of a given amount of glucose [1-5].

This last method is not always available in peripheral maternity hospitals in developing countries, including Benin.

The objective of this work is to compare two gestational diabetes-screening strategies to propose an accessible strategy to a population that has limited resources.

Patients and methods

We conducted the study in the maternity service of the reference hospital of Porto-Novo (southern Benin). We conducted the study between February 2nd, 2015 and January 31st, 2016. It was a randomized analytical study with prospective data collection. It concerned the pregnant patients seen in prenatal consultation between 24th and 28th WA and having agreed to participate at the study. We excluded the patients that were diagnosed with diabetes or a disturbed glycemic profile before or at the beginning of their pregnancy. We formed two groups of patients. The first group referenced as "Group A" was screened using:

Fasting glucose value measurement: Those patients in "Group A" were diagnosed with gestational diabetes when the result of the test was ≥ 0.92 g/l but less than 1.26 g/l. The second group referenced as "Group B" was screened using the WHO test consisting in a glucose tolerance test performed after oral loading of 75 g of glucose. Patients in this group were diagnosed with gestational diabetes when the result of the test was ≥ 1.40 g/l. Two sealed envelopes, each bearing the words "Group A" or "Group B" were put in an urn. At admission, we grouped the patients in pairs. In each pair, the first patient admitted was asked to blindly pick one of the two envelopes. This patient was labeled with the mention on this envelop so that if the 1st patient pick "Group A", the 2nd patient is directly classified in "Group B" and vice versa. All pregnant women of both groups (A and B) who were screened negative between their 24th and 28th weeks of amenorrhea were tested again in their 32nd week of amenorrhea. To compare the results, the Chi-square test was used with a threshold of significance set at 5%. The relevance

of the two tests was assessed by the calculation of the sensitivity, the specificity, and the positive and negative predictive values. Oral consent was obtained for each pregnant woman. The confidentiality of the data and the anonymity of the patients were ensured.

Ethical aspects

The study has been carried out with the approval of administrative authorities at different levels. Pregnant participation was voluntary. A clear explanation was given to pregnant before inclusion and no pregnant was required. Confidentiality and anonymity of the data have been respected.

Results

At the end of the study, 602 pregnant patients were eligible, but 580 met our inclusion criteria, including 290 in each group.

Socio-demographic profile of the patients (pregnant women)

The average age of the patients was 28.47-years-old \pm 5.73 years in "Group A" and 28.18-years-old \pm 5.71 years in group "B". Pregnant women aged 35-years-old and above were the least represented (16.5% in "Group A" vs. 14.5% in "Group B", $p>0.05$).

	Group A (290) Number (%)	Group B (290) Number (%)	p-value
Age (in years)			
(15-25)	78 (26.9)	72 (24.8)	0.305
(25-35)	164 (56.6)	176 (60.7)	
\geq 35	48 (16.5)	42 (14.5)	
Profession			
Tradeswomen	110 (37.9)	120 (41.4)	0.487
Housewives	60 (20.7)	62 (21.4)	
Workers	44 (15.2)	34 (11.7)	
Public servant	54 (18.6)	42 (14.5)	
Student	22 (7.6)	32 (11.0)	
Education			
Schooled	246 (84.8)	252 (86.9)	0.475
Unschoolled	44 (15.2)	38 (13.1)	
Marital status			
Married	230 (79.3)	214 (73.8)	0.113
Divorced	36 (12.4)	38 (13.1)	
Single	24 (8.3)	38 (13.1)	

Table 1: Socio-demographic profile of the patients.

Nearly $\frac{3}{4}$ of the pregnant patients in our sample (73.8% in Group A vs. 74.5% in Group B, $p>0.05$) were from a profession that does not benefit from state health insurance (shopkeepers, homemakers, workers). The two groups were comparable in terms of their socio-demographic profile (Table 1).

Clinical characteristics of the patients (pregnant women)

Gestational diabetes risk factors such as obstetrical history of macrosomia childbirth, stillbirths and more than two spontaneous miscarriages; body mass index \geq 25 kg/m² before pregnancy, a family history of first-degree diabetes and a personal history of hypertension were found to be almost identical between the two groups (Table 2).

	Group A Number (%)	Group B Number (%)	p
Average number of gestations			
Primigravida (1)	44 (15.2)	54 (18.6)	0.733
Gravida 2 or 3 (2-3)	142 (48.9)	146 (50.4)	

Multigravida (≥ 4)	104 (35.9)	90 (31.0)	
Average parity			
Nulliparous (0)/Primiparous (1)	128 (44.1)	126 (43.4)	0.647
Parity 2 to 3 (2-3)	120 (41.4)	118 (40.7)	
Multiparous (≥ 4)	42 (14.5)	46 (15.9)	
Other obstetrical antecedents			
Record of stillbirth	48 (16.6)	38 (13.1)	0.243
Record of more than 2 SM*	78 (26.9)	72 (24.8)	0.569
Record of macrosomia	8 (2.8)	12 (4.1)	0.363
Medical antecedents			
Individual high blood pressure	8 (2.8)	10 (3.4)	0.632
Overweight (BMI** ≥ 25 kg/m ²)	106 (36.6)	104 (35.9)	0.863
1 st degree diabetes in the family	32 (11.0)	42 (14.5)	0.213
Family high blood pressure	24 (8.3)	32 (11.0)	0.261
*Spontaneous Miscarriage; **Body Mass Index			

Table 2: Distribution of patients according to their antecedents.

Strategies for gestational diabetes screening

26 patients (9% of Group A) were tested positive with gestational diabetes in Group A and 18 patients (6.2% of Group B) were tested positive in group B (p=0.209) (Table 3). The 536 pregnant patients for whom the result turned to be negative within their 24th and their 28th week of amenorrhea using both testing methods went through a second screening test in their 32nd week of amenorrhea using the WHO test method. We discovered no new case of gestational diabetes. In total, both methods detected 44 cases of gestational diabetes, an overall prevalence of 7.6% (44/580).

In terms of relevance, the fasting glucose value measurement and the WHO test enabled the detection of gestational diabetes with comparable results: sensitivity (59.09% vs. 40.91%), specificity (50.75% vs. 49.25%), positive predictive value (8.97% vs. 6.21%), and negative predictive value (93.79% vs. 91.03%).

	Fasting blood glucose test n (%)		Test OMS n (%)		p
	Positive	Negative	Positive	Negative	
24-28SA	26 (9.0)	264 (91.0)	18 (6.2)	272 (93.8)	0.209
32 SA	0	--	0	536 (100)	
Total	290		290		

Table 3: Distribution of pregnant patients as per the screening method used.

Discussion

The pregnant patients in our study were in poor socio-economic conditions, which limit access of those women to health care services. It is in light of their poor socio-economic condition that we proposed fasting blood glucose as a screening test in this study. Once considered a rare disease in Africa, gestational diabetes is becoming more and more frequent, probably because of the diet that tends to align with that in developed western countries. The prevalence of gestational diabetes in our series was 7.6%. The difference of the prevalence rates depending on the screening method used was not significant (9% vs. 6.2%, p>0.05). In Africa, the few studies carried out have reported a prevalence ranging from 5% to 17% [6-8]. In France, the prevalence of gestational diabetes ranges from 2% to 6% [1,9].

Strategies of gestational diabetes screening

In the literature, fasting glucose value measurement is the only method that can detect as many cases of gestational diabetes as possible. The “HAPO” international study, which included nearly 24,000 women, made the following findings. Out of the patients diagnosed according to the criteria of the International Association of Diabetes and Pregnancy Study Groups (IADPSG), 55% had an abnormal level of fasting glucose, 55% had an abnormal level of blood glucose at 1 h and 38% had an abnormal level of blood glucose at 2 h [7]. In our study, we used the fasting glucose method to screen 100% of gestational diabetes cases in Group A. In fact, out of the 290 pregnant patients who were subject to fasting blood glucose test, we detected 26 cases of gestational diabetes in-between the 24th and the 28th week of amenorrhea. We tested the remaining patients in their 32nd week of amenorrhea, using the WHO method. We detected no new case.

In the literature, several gestational diabetes-screening strategies are proposed, but there are always reflections on the strategy to adopt for good accessibility and good adherence of the patients.

In the first trimester, in the presence of risk factors, practitioners recommend to use fasting blood glucose screening method.

Between the 24th and the 28th week of amenorrhea, there are two diagnostic methods; the most recommended is currently the WHO test [1-5].

In 2010, the International Association of Diabetes Pregnancy Study Group (IADPSG) proposed an international consensus, on the ground of the data and results provided by the HAPO study [4,10-12]. The IADPSG advocated for an early screening, i.e. performed during the first trimester of pregnancy, and performed to detect pre-gestational diabetes that a fasting blood glucose test, HbA1c or a random blood glucose level check would have missed. Between the 24th and the 28th week of amenorrhea, the IADPSG recommends the fasting blood glucose test (threshold 0.92 g/l) and/or a blood glucose test at 1 h after an oral load of 75 g of glucose (threshold 1.80 g/l) and/or a blood glucose test at 2 h (threshold 1.53 g/l).

For simplicity and compliance reasons a number of African countries such as Cameroon have opted for a 2-step strategy based on the recommendations of the IADPSG [13]:

The first step consists in a fasting glucose test performed between the 24th and the 28th week of amenorrhea:

- If blood glucose <0.80 g/l (4.4 mmol/l, it is unlikely that the patient has developed gestational diabetes; no specific action is to be taken.

- If fasting blood glucose is between 0.80 g/L (4.4 mmol/L) and 0.92 g/L (5.1 mmol/L), it is not possible to come up with a final diagnosis at this stage. A hyperglycemia is induced by oral load of glucose or a second blood glucose test is performed to conclude.

- If the fasting blood glucose >0.92 g/L (5.1 mmol/L), the diagnosis of gestational diabetes can be made.

The 2nd step is indicated if the fasting blood glucose test is between 0.80 g/L (4.4 mmol/L) and 0.92 g/L (5.1 mmol/L). This consists in a glucose tolerance test performed after oral loading of 75 g of glucose over 2 h (according to the WHO).

Out of all international recommendations, the International Association of Diabetes Pregnancy Study Group (IADPSG) and the WHO tests are the benchmark strategies for screening gestational diabetes. Many studies have shown the superiority of IADPSG screening method over the WHO test. This was the case of the Jenum study, which found 30.5% of gestational diabetes with the IADPSG test versus 13% with the WHO test [14]. Even though the IADPSG test is successful, the fact remains that its affordability remains limited in developing countries. To address this situation, some teams have adopted the fasting blood glucose test as a gestational diabetes screening strategy. This was our choice in this study. The reduced number of cases detected in each group, 26 cases in the fasting glucose group and 18 cases in the WHO group, do not allow us to conclude that one method is better than the other.

Fasting blood glucose testing has the advantage of being fairly simple and accessible to all health facilities as well as to populations in a country with limited resources.

Prognosis

Many studies have shown that patients with gestational diabetes are at high risk of developing pre-eclampsia and urinary tract infection [1,6,15-17], as the infection is often related to hyperglycemia. Maternal complications noted in our study were in most of the cases urinary tract infection and pre-eclampsia, but without influence by diagnostic criteria.

Moreover, gestational diabetes is often correlated with perinatal complications such as macrosomia, immediate neonatal distress, early neonatal hypoglycemia, and neonatal death. The latter was related to uncorrected neonatal hypoglycemia due to the “third delay” [1,18-21]. In our series, we also found these complications and without influence by the diagnostic criteria.

Conclusion

The results obtained for gestational diabetes screening were comparable for the two groups of pregnant patients. The fasting blood glucose level of the IADPSG can be an alternative for gestational diabetes screening in a population where the WHO test is not accessible.

Conflict of Interest

None.

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