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Universal vs. risk-factor-based screening for gestational diabetes—an analysis from a 5-Year Portuguese Cohort

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Abstract

Purpose The criteria to screen for Gestational Diabetes Mellitus are not internationally consensual. In opposition to the universal screening performed in Portugal, certain countries advocate a risk-factor-based screening. We aim to compare obstetric and neonatal outcomes in pregnant women with and without risk factors treated for Gestational Diabetes Mellitus.

Methods Retrospective and multicentric study of 12,006 pregnant women diagnosed with Gestational Diabetes Mellitus between 2011 and 2015, in Portugal. Gestational Diabetes Mellitus was diagnosed according to the International Association of the Diabetes and Pregnancy Study Groups criteria. Risk factors: body mass index $> 30\,kg/m^2$, history of Gestational Diabetes Mellitus, history of macrossomic newborn (birth weight $> 4000\,g$) or first-degree relatives with Type 2 Diabetes Mellitus. Exclusion criteria: lack of data concerning risk factors ($n = 1563$).

Results At least one risk factor was found in 68.2% ($n = 7123$) pregnant women. Pregnant women with risk factors were more frequently medicated with insulin ($p < 0.001$), caesarean section was more commonly performed ($p < 0.001$), their newborns were more frequently large-for-gestational-age ($p < 0.001$) and neonatal morbidity was higher ($p = 0.040$) in comparison to pregnant women without risk factors. The Diabetes Mellitus reclassification test showed an increased frequency of intermediate hyperglycaemia and Diabetes Mellitus in women with risk factors ($p < 0.001$).

Conclusion Almost one-third of pregnant women would have remained undiagnosed if risk-based-factor screening were implemented in Portugal. Women without risk factors presented fewer obstetric and neonatal complications. However, more than one third required insulin therapy.

Keywords Diabetes gestational · Risk factors · Diagnosis · Mass screening

Introduction

Gestational Diabetes Mellitus (GDM) is defined as a sub-type of abnormal glucose tolerance resulting in hypergly-caemia of variable severity with onset during pregnancy. It is associated with an increased risk of adverse maternal, foetal and neonatal outcomes [1]. In Portugal, in 2015, the prevalence of GDM was 7.2% [2]. The criteria to screen for GDM are not internationally consensual [3]. The World

Health Organization (WHO) recommended that local authorities ought to decide on the screening coverage depending on local resources and priorities [4]. In Portugal, screening for GDM is offered to all pregnant women [5]. However, in certain countries, like the United Kingdom, the screening is risk-factor-based [6]. Universal screening allows higher GDM detection rates, but more women are subjected to inconvenient testing, there is additional preg-nancy medical intervention with increased health care costs and further maternal anxiety [7]. Besides, it has been sug-gested that the additional cases detected exhibit a milder to moderate hyperglycaemia [8] and might have less clinical significance [9]. Currently, the scientific evidence available is insufficient to favour a screening method [7]. The National Institute for Health and Care Excellence (NICE) clinical practice recommendations consider that the cost-effectiveness ratios do not support universal screening [6]. The diagnostic criteria for GDM of the International

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Association of the Diabetes and Pregnancy Study Group (IADPSG) [10] is based on the Hyperglycaemia and Adverse Pregnancy Outcome study [11]. These criteria were implemented in Portugal in 2011, lowering the threshold for GDM and subsequently more women have been diagnosed with GDM [2]. Furthermore, more women with GDM are expected due to the obesity epidemic and increased maternal age [12], straining the Portuguese National Health System.

We hypothesised that pregnant women with risk factors (RF) presented worse obstetric and neonatal outcomes compared to women without RF. Thus, we aim to compare obstetric and neonatal outcomes between these two groups, and therefore reflect about risk-factor-based vs. universal screening for GDM.

Materials and methods

Data sources and collection

This is a retrospective cohort study of 12,006 pregnant women based on data from the Portuguese National Registry of Gestational Diabetes. The register is organized by the Portuguese Diabetes and Pregnancy Study Group of the Portuguese Society of Diabetology. The data is collected from 28 hospitals from all regions of Portugal and only includes pregnant women with GDM. The register is voluntary. We included pregnant women with GDM that gave birth from 2011 to 2015. The medical team obtained information about the pregnant women with GDM since the first consultation until the Diabetes Mellitus (DM) reclassification test. The data was anonymised and none of the authors had access to patient identification. We excluded 1563 women due to a lack of data regarding RF. The final sample was constituted by 10,443 pregnant women.

Definitions

The diagnosis of GDM, according to IADPSG, is established by fasting plasma glucose (FPG) at the first pre-natal visit, between the 11th and 13th week plus 6 days gestational age, or by a 2 h 75-g oral glucose tolerance test (OGTT) performed between 24 and 28 weeks of gestation [10]. The diagnostic criteria for GDM are FPG between 92 and 125 mg/dL, or plasma glucose 92–125 mg/dL, superior to 180 mg/dL or 153–199 mg/dL at 0, 60, or 120 min, respectively, with the 2 h 75-g OGTT [5]. All pregnant women diagnosed with GDM were referred to a specialized diabetes care team including a diabetologist, an obstetrician, a dietician, and a nurse. They were instructed to evaluate capillary glycaemia four times a day, at fasting and 1-h after

the beginning of the three main meals. The pregnant women with GDM were seen by the diabetologist every 1–4 weeks. A personalised diet was recommended to all women. The glycaemic targets defined were less than 90 mg/dL at fasting and less than 120 mg/dL 1-h after meals. Pharmaceutical intervention with metformin or insulin was initiated if these glycaemic targets were not accomplished with nutritional therapy and physical activity after one or two weeks. Metabolic control and further therapeutic adjustments were assessed by glycaemic patterns, ultra-sound foetal development, and amniotic fluid changes. The newborns were classified as large-for-gestational-age (LGA) and small-for-gestational-age (SGA) if their weight for gestational age was superior to 90th percentile (P90) or inferior to 10th percentile (P10) respectively, according to Fenton Growth charts. Neonatal morbidity comprised neonatal hypoglycaemia, neonatal hyperbilirubinemia, respiratory distress syndrome, congenital anomalies, and intensive care unit hospitalisation. We considered RF in light of NICE guidelines recommendations: body mass index (BMI) > 30 kg/m^2 (obesity), history of GDM, history of macrossomic newborn (birth weight > 4000 g) or first-degree relatives with Type 2 Diabetes Mellitus (T2DM). The criteria about ethnic family origin was not considered. The type of delivery was divided into eutocic, vaginal instrumented delivery (forceps and ventouse) and caesarean. Six to eight weeks after delivery, all women were invited to undergo the DM reclassification test with 2 h 75-g OGTT. According to the American Diabetes Association (ADA), the diagnostic criteria for DM, impaired glucose tolerance (IGT) and impaired fasting glucose is FPG ≥ 126 mg/dL or 2-h plasma glucose ≥ 200 mg/dL, 2-h plasma glucose between 140 and 199 mg/dL and a FPG between 100 and 125 mg/dL, respectively.

Statistical analysis

Normal continuous variables were described by the mean and standard deviation. Non-normal continuous variables were described by the median and interquartile range (IQR). The normality was verified by the observation of histograms. Categorical variables were described by the absolute and relative frequencies. To compare continuous variables between two independent groups we used the Student t-test (normal distributions) or Mann–Whitney U-test (non-normal distributions). Chi-square test (χ^2) was applied to analyse independence between two categorical variables. Univariate and multivariate logistic regression were performed to study the association of each risk factor with the caesarean. Values of $p \leq 0.05$ were considered statistically significant. Data analysis was performed using IBM SPSS™ software version 25.

Table 1 General characteristics of the total cohort and of pregnant women with and without RF

	Without RF	With RF	Total cohort	p-value
Age, years mean (±SD)	32.6 (5.4)	33.5 (5.2)	33.2 (5.3)	0.001[a]
Non-portuguese	14.2	11	12	0.001[b]
% (n/N)	(361/2547)	(615/5569)	(976/8116)	
Pregravid BMI (kg/m²)	23.7	28.3	26	0.001[c]
Median (IQR)	(21.7–26.3)	(24–33.1)	(22.9-30.9)	
1st degree relatives with T2DM (%)	0	71.8	48.5	0.001[b]
(n/N)	0/3320	(4966/6912)	(4966/10232)	
Previous foetal macrosomia	0	9.2	6.1	0.001[b]
% (n/N)	0/3320	(589/6368)	(589/9688)	
Previous GDM	0	21.1	13.9	0.001[b]
% (n/N)	0/3320	(1354/6404)	(1354/9724)	
Parity, n	0	1	1	0.001[c]
Median (IQR)	(0–1)	(0–1)	(0–1)	

SD standard deviation, *IQR* interquartil range, *BMI* body mass index, *T2DM* type 2 diabetes mellitus, *GDM* gestational diabetes mellitus

[a]*t*-test

[b]Chi-square test

[c]Mann–Whitney test

Results

We analysed data from 10,443 women, with a mean age of 33.2 ± 5.3 years old, of which 68.2% (n = 7123) had at least one RF. The most common RF was first-degree relatives with T2DM (71.8%; n = 4966/6912), followed by obesity (45.9%; n = 3267/7123), history of GDM (21.1%; n = 1354/6404) and history of foetal macrosomia (9.2%; n = 589/6368). From 2011 to 2014, no difference in the proportion of pregnant women with RF was observed. However, in 2015 there was an increase in this group compared to previous years (75.1% vs. 66.2%; p < 0.001).

Women without RF were younger than those with RF (32.6 years vs. 33.5 years; p < 0.001). The detailed characteristics of women with GDM are described in Table 1.

The diagnosis of GDM in both groups was more frequently established by OGTT at the 24–28th gestational week than fasting glycaemia at the first pre-natal visit (60.6 vs. 39.4%; p < 0.001). Nevertheless, women with RF were more frequently diagnosed by fasting glycaemia at the first pre-natal visit in comparison to women without RF (40.2 vs. 37.7%; p = 0.015). The delay from diagnosis to the first consultation with the specialized diabetes care team was 3 weeks (IQR 2.0–6.0) and was similar between groups (p = 0.93). In the pregnant women without RF vs. with RF, insulin therapy was less frequently initiated (38.4 vs. 48.6%; p < 0.001), the starting week of therapy was deferred one week (30th gestational week vs. 29th gestational week; p < 0.001) and total daily doses of insulin were inferior (14 insulin units vs. 18 insulin units; p < 0.001). Moreover, treatment with metformin was less frequently used (5.6 vs. 10.2%; p < 0.001). Regarding obstetric complications, pre-eclampsia occurred more frequently in women with RF (3.4 vs. 2.4%; p = 0.003), whereas no differences in hydramnios or foetal death were observed. Caesarean section was more commonly performed in women with RF (38.4 vs. 30.6%; p < 0.001), although vaginal instrumented deliveries were more frequent in women without RF (18.2 vs. 14.0%; p < 0.001). No differences occurred in eutocic births, in urgent or programmed caesareans, nor gestational age. The detailed characteristics of the obstetric outcomes are described in Table 2.

The pregnant women with first degree relatives with T2DM, previous foetal macrosomia and a BMI > 30 kg/m² presented an increased risk for caesarean section compared to pregnant women without these risk factors (p < 0.001). When adjusting these variables to each other the chance of caesarean section remained elevated (p < 0.001). The univariate and multivariate logistic regression are shown in Tables 3 and 4.

The prevalence of LGA newborns was higher in the group of pregnant women with RF (5.1 vs. 2.3%; p < 0.001), while pregnant women without RF gave birth more frequently to SGA newborns (14.6 vs. 12.3%; p < 0.001). The neonatal morbidity was higher in the newborns of pregnant women with RF (19.3 vs. 17.5%; p = 0.040). No differences in neonatal deaths were observed. Neonatal outcomes are described in Table 5.

The DM reclassification test showed an increased frequency of impaired fasting glycaemia, impaired glucose tolerance and diabetes in women with RF (8.6% vs. 5.2%; p < 0.001).

Table 2 Obstetric outcomes of the total cohort and of pregnant women with and without RF

	Without RF	With RF	Total cohort	*p*-value
Gestational hypertension	7.2	12.7	10.9	0.001[a]
% (n/N)	(226/3157)	(841/6626)	(1067/9783)	
Hydramnios	2.8	3.2	3.1	0.126[a]
% (n/N)	(88/3711)	(213/6616)	(301/9793)	
Pre-eclampsia	2.4	3.4	3	0.003[a]
% (n/N)	(74/3142)	(223/6613)	(297/9755)	
Weight gain, kg (mean ± SD)	10.9 (5.4)	9.1 (6.2)	9.7 (6)	0.001[b]
Therapy with insulin % (n)	38 (1256)	49 (3441)	45.4 (4697)	0.001[a]
Foetal death	0.3	0.4	0.3	0.285[a]
% (n/N)	(8/3092)	(24/6772)	(32/9864)	
Gestational age, weeks median (IQR)	39 (38-39)	39 (38-39)	39 (38-39)	0.101[c]
Induced delivery	35.5	40.2	38.9	0.001[a]
% (n/N)	(319/899)	(941/2343)	(1260/3242)	
Caesarean				
% (n/N)	47.2	46.9	47	
Urgent	(427/905)	(1133/2417)	(1560/3322)	0.453[a]
Elective	52.8	53.1	53	
	(478/905)	(1284/2417)	(1762/3322)	
Type of delivery % (n)				
Eutocic	51.3 (1632)	47.6 (3223)	48.8 (4855)	0.078[a]
Vaginal instrumented delivery	18.2 (578)	14 (946)	15.3 (1524)	0.001[a]
Caesarian	30.6 (973)	38.4 (2602)	35.9 (3575)	0.001[a]

SD standard deviation, *IQR* interquartil range

[a]Chi-square test; Mann–Whitney test

[b]*t*-test

Table 3 Univariate logistic regression

Variables	OR (95% CI)	*p*-value
1st degree relatives with T2DM		
No	Reference	–
Yes	1.248 (1.149 – 1.356)	<0.001
Previous pregnancy with GDM		
No	Reference	–
Yes	1.099 (0.973 – 1.242)	0.130
Previous foetal macrosomia		
No	Reference	–
Yes	1.665 (1.403 – 1.977)	<0.001
BMI	1.036 (1.029 – 1.043)	<0.001

Dependent variable: caesarean

T2DM type 2 diabetes mellitus, *GDM* gestational diabetes mellitus, *BMI* body mass index

Table 4 Multivariate logistic regression

Variables:	OR (95% CI)	*p*-value
1st degree relatives with T2DM		
No	Reference	–
Yes	1.203 (1.101 – 1.314)	<0.001
Previous foetal macrosomia		
No	Reference	–
Yes	1.468 (1.223 – 1.761)	<0.001
BMI	1.035 (1.027 – 1.043)	<0.001

Dependent variable: caesarean

T2DM type 2 diabetes mellitus, *GDM* gestational diabetes mellitus, *BMI* body mass index

Discussion

Universal screening vs. risk-factor based

The IADPSG criteria used in Portugal for GDM screening is currently recommended by the International Federation of Gynaecology and Obstetrics and most international organizations, with some exceptions namely the American College of Obstetricians and Gynaecologists and NICE.

One of the limitations of risk-factor-based screening is the difficulty to ascertain the adequate RF for each population. Interestingly, in our study, the frequency of pregnant women with at least one RF (68.2%) was higher in comparison to other studies [13]. However, if risk-based-factor screening ought to be implemented in Portugal almost a third of pregnant women would have remained undiagnosed. Another limitation of risk-factor-based screening is the fact that previous history of GDM and macrosomia are considered as risk factors, so primiparous that may develop GDM complications during the first pregnancy are excluded. Additionally, age, which is known to be a traditional RF for GDM, is omitted in NICE

Table 5 Neonatal outcomes of the total cohort and of pregnant women with and without RF

	Without RF	With RF	Total cohort	p-value
Neonatal morbidity	17.5	19.3	18.7	0.021[b]
% (n/N)	(525/2993)	(1216/6293)	(1741/9286)	
Neonatal hypoglycaemia	3.2	4	3.7	0.024[b]
% (n/N)	(93/2941)	(248/6174)	(341/9115)	
Neonatal Hyperbilirubinemia	9.9	11.6	11	0.007[b]
% (n/N)	(293/2966)	(723/6235)	(1016/9201)	
Respiratory distress syndrome % (n/N)	2 (59/2960)	2.8 (176/6224)	2.6 (235/9184)	0.019[b]
Weight of newborn, kg Median (IQR)	3110 (2820-3380)	3180 (2870-3480)	3160 (2855-3450)	0.001[c]
Large for gestational age % (n/N)	2.3 (69/3061)	5.1 (335/6535)	4.2 (404/9596)	0.001[b]
Small for gestational age % (n/N)	14.6 (448/3061)	12.3 (803/6535)	13 (1251/9596)	0.001[b]
Adequate for gestational age % (n/N)	83.1 (2544/3061)	82.6 (5397/6535)	82.2 (7941/9596)	0.065[b]
Admission to intensive care unit % (n/N)	5 (149/2972)	6 (375/6239)	5.7 (524/9211)	0.054[b]
Congenital anomalies % (n/N)	2.2 (62/2832)	3.4 (204/6040)	3 (266/8872)	0.001[b]
Neonatal death % (n/N)	0.4 (8/2037)	0.2 (11/4709)	0.3 (19/6746)	0.187[b]

SD standard deviation, IQR interquartil range

[a] t-test

[b] Chi-square test

[c] Mann–Whitney test

screening criteria [14]. Risk-factor-based screening is also more complex than universal screening and requires more attention to previous obstetric history by health professionals, which may result in inadequate screening. The main goal of risk-factor-based screening is to recognise pregnant women at greater risk of complications who would most gain from intensive management, while other pregnant women would be relieved from the burden of further medical interventions. A more rational use of resources would allow, for instance, a reduction of time from diagnosis to the first consultation that in our study was three weeks. Considering that the diagnosis of GDM is mainly established after the 24th week, a 3-week gap until observation and management by the specialized diabetes care team is relevant.

Diagnosis and treatment

The increased frequency of GDM diagnosis by fasting plasma glycaemia and the increased incidence of pre-diabetes and DM at the reclassification test suggest that women with RF suffer a more severe form of abnormal glucose metabolism. However, we emphasise that the diagnosis by fasting plasma glycaemia is not consensual and is not recommended by ADA [15]. Our results showed that women without RF required less frequently therapy with insulin and in a lower dosage. Yet, still, 38% had inadequate metabolic control and initiated insulin therapy. In 2016, a new consensus for GDM treatment was introduced in Portugal and the glycaemic targets were modified to 95 mg/dL when fasting and 140 mg/dL one hour after the meal, instead of 90 and 120 mg/dL in use at the time of this study. Therefore, the proportion of women with GDM in need of pharmacotherapy is expected to decrease.

Obstetric/Neonatal outcomes

The label of "GDM" may prompt higher rates of caesarean section rather than clinical indication [16–18]. On the other hand, Farrar et al. showed that after the transition from risk-factor-based to universal screening and subsequently higher GDM detection rates, caesarean section rates did not rise in their population. However, there was an increase in labour induction [8]. The prevalence of LGA in our cohort was lower than in other studies [19]. One of the possible explanations for this is the use of the Fenton curves for neonatal assessment, that like shown by other authors may underestimate LGA in comparison with other curves [20]. Additionally, these findings are probably related to the adequate glycaemic control attained in both groups. Nevertheless, there were significant differences in LGA between the two groups, strengthening our hypothesis. Our findings showed a high frequency of SGA in the whole cohort and even higher in the group without RF. One of the main goals of the management of women with GDM is to control foetal growth, but tight glucose control may be associated with a higher incidence of SGA and adverse neonatal outcomes [21]. Thus, it is important to avoid over-medicalization of GDM, which we think has been considered in the new glycaemic targets proposed for GDM since 2016.

Reclassification test

The DM reclassification test revealed a higher prevalence of abnormal glucose metabolism in women with RF. However, of the women without any known RF, there were 5% that also had an abnormal result. These women have a higher risk of T2DM in the future, despite being young, non-obese

and with no family history of DM. This is a further concern about selective screening in GDM, as these women would not be identified and there would be no opportunity to intervene longer-term to promote enhanced screening, lifestyle change or early diagnosis of T2DM in the future.

Strengths/Limitations

The strengths of our study are the sample size obtained from several hospitals in all regions in Portugal and by addressing an issue with potential implications on current measures.

The limitations are related to the retrospective nature of the study, loss of data due to incomplete fill of the database, and the international heterogeneity in screening and diagnostic criteria for GDM troubling comparisons between studies. In addition, both groups were treated and the better outcomes observed in the group without RF must be cautiously interpreted. Ideally, comparisons should be established between women diagnosed with GDM with no RF and pregnant women glucose-tolerant in the Portuguese population.

Nevertheless, according to current measures, additional attention is required for pregnant women with GDM and RF.

Conclusion

Pregnant women with RF diagnosed with GDM on universal screening had worse obstetric and neonatal outcomes than those without RF.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study formal consent is not required.

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