



Contents available at ScienceDirect

Diabetes Research
and Clinical Practice

journal homepage: www.elsevier.com/locate/diabres



International
Diabetes
Federation



Incidence, risk factors, and pregnancy outcomes of gestational diabetes mellitus using one-step versus two-step diagnostic approaches: A population-based cohort study in Isfahan, Iran

Elham Hosseini, Mohsen Janghorbani*, Ashraf Aminorroaya

Isfahan Endocrine and Metabolism Research Center, Isfahan University of Medical Sciences, Isfahan, Iran

ARTICLE INFO

Article history:

Received 6 August 2017

Received in revised form

12 March 2018

Accepted 4 April 2018

Available online 10 April 2018

Keywords:

Gestational diabetes

Screening

Incidence

Risk factor

Pregnancy outcomes

Iran

ABSTRACT

Aims: To study the incidence, risk factors, and pregnancy outcomes associated with gestational diabetes mellitus (GDM) diagnosed with one-step and two-step screening approaches.

Methods: 1000 pregnant women who were eligible and consented to participate underwent fasting plasma glucose testing at the first prenatal visit (6–14 weeks). The women free from GDM or overt diabetes were screened at 24–28 weeks using the 50-g glucose challenge test (GCT) followed by 100-g, 3-h oral glucose tolerance test (OGTT) (two-step method). Regardless of the GCT result, all women underwent a 75-g, 2-h OGTT within one-week interval (one-step method).

Results: GDM incidence using the one-step and two-step methods was 9.3% (95% CI: 7.4–11.2) and 4.2% (95% CI: 2.9–5.5). GDM significantly increased the risk of macrosomia, gestational hypertension, preeclampsia, and cesarean section and older age and family history of diabetes significantly increased the risk of developing GDM in both approaches. In two-step method, higher pre-pregnancy body mass index and lower physical activity during pregnancy along with higher earlier cesarean section also increased significantly the risk of developing GDM.

Conclusions: Despite a higher incidence of GDM using the one-step approach, more risk factors for and a stronger effect of GDM on adverse pregnancy outcomes were found when using the two-step approach. Longer follow-up of women with and without GDM may change the results using both approaches.

© 2018 Elsevier B.V. All rights reserved.

Abbreviations: ACOG, American College of Obstetrician and Gynecologists; BMI, body mass index; CI, confidence interval; FPG, fasting plasma glucose; GCT, glucose challenge test; GDM, gestational diabetes mellitus; IADPSG, International Association of the Diabetes and Pregnancy Study Groups; MET, Metabolic Equivalent of Task; NICU, neonatal intensive care unit; NIH, National Institute of Health; NRD, neonatal respiratory distress; OGTT, oral glucose tolerance test; OR, odds ratio; SD, standard deviation; WHO, World Health Organization

* Corresponding author.

E-mail address: janghorbani@hlth.mui.ac.ir (M. Janghorbani).

<https://doi.org/10.1016/j.diabres.2018.04.014>

0168-8227/© 2018 Elsevier B.V. All rights reserved.

1. Introduction

Gestational diabetes mellitus (GDM) is a common condition of glucose intolerance associated with adverse maternal and fetal outcomes [1–3]. Several risk factors are known to contribute to this condition [4–6]. Depending on the diagnostic methods and criteria used to find, its prevalence varies widely around the world [7–9]. Debate and discussion continue regarding the best screening and diagnostic method for GDM. The American College of Obstetrician and Gynecologists (ACOG) recommends that all pregnant women be screened for GDM by patient history, clinical risk factors, or a 50-g, 1-h glucose challenge test (GCT) [10]. If GCT result is positive, it should be followed by a 100-g, 3-h oral glucose tolerance test (OGTT) to diagnose GDM. This two-step approach has been the most commonly used screening approach to diagnosing GDM. The International Association of the Diabetes and Pregnancy Study Groups (IADPSG) and the American Diabetes Association (ADA) recommends that pregnant women should be screened for GDM by the one-step process using a 75-g, 2-h OGTT [11]. The rate of GDM would increase up to two to three times the rate using the two-step screening process [12]. In 2013, both the World Health Organization (WHO) and the Endocrine Society revised their guidelines and recommend that the IADPSG criteria should be used for the diagnosis of GDM [13]. In March 2013, The National Institute of Health (NIH) held a Consensus Development Conference, which concluded that there is insufficient evidence to recommend the one-step method [14,15]. Later the same year, in contrast to NIH and ACOG, the Endocrine Society recommended the one-step method [16]. Despite facts to support each strategy, there still is debate and discussion about an optimal strategy for detection or diagnosis of GDM. The latest ADA recommendations specify that further research is needed to prove a uniform approach to diagnosing GDM and leave open the options of using the one-step or the two-step screening strategy [17]. Therefore, the aims of this study were to evaluate the prevalence of GDM based on fasting plasma glucose screening at the first prenatal visit and the incidence of GDM using different diagnostic strategies (one-step vs. two-step approach). Our secondary objectives were to identify risk factors and pregnancy outcomes associated with GDM using one-step screening versus two-step screening method.

2. Subjects and methods

A prospective cohort study from October 2015 to January 2017 was done at 10 community health care centers in different areas of Isfahan city, Iran. The primary outcome of interest was the incidence of GDM using one-step and two-step methods. Consecutive sampling was used to get data for 1000 pregnant women who were eligible. We enrolled women aged 18–45 years and data from all singleton pregnancies were obtained from prenatal records and/or from the patient at first prenatal visit (6–14 weeks) [11,18]. It included demographic information, anthropometric and clinical measurements; weight, height, and systolic and diastolic blood

pressure, drug consumption, any anti-diabetic agent use, maternal or paternal family history of diabetes, current pregnancy complications, history of earlier pregnancy complications (e.g., earlier diagnosis of GDM, macrosomia, stillbirth, neonatal death, recurrent abortion ≥ 2 , polyhydramnios, eclampsia/preeclampsia, and cesarean section), and blood testing. We used a 24 h questionnaire to assess physical activity of subjects which was given to them at their first or second prenatal visit (6–14 or 16–20 weeks) [11,18]. For viable pregnancies, delivery records including preterm delivery, birth-weight, 1 and 5-min apgar scores, preeclampsia, gestational hypertension, stillbirth, neonatal death, type of labor [cesarean section and vaginal (natural or instrumental) delivery], were obtained from hospital records. We excluded women with known diabetes, non-viable pregnancy (miscarriage), chronic medical condition such as high blood pressure, severe heart disease, liver disease, infections such as HIV and hepatitis, bariatric surgery, any surgery to change glucose absorption rate, twin pregnancy, and women who were unavailable or incompliant to follow during the study if present.

2.1. Diagnosis of GDM; one-step versus two-step approach

Women were universally screened for overt diabetes and GDM at their first prenatal visit (6–14 weeks) [11,18]. A positive result of fasting plasma glucose (FPG) ≥ 126 mg/dl indicated the presence of overt diabetes [11,18]. Women with FPG 92–125 mg/dl were considered as GDM [11]. Women without diabetes or GDM in early pregnancy were screened at 24–28 weeks and underwent a non-fasting 50-g oral GCT and a later plasma glucose measurement at 1-h post glucose taking. A result of plasma glucose level < 140 mg/dl was considered to be normal and the value ≥ 140 mg/dl was considered as abnormal for GCT. Regardless of the result of GCT, each subject underwent a later 75-g, 2-h OGTT within one week. IADPSG criteria used to diagnose GDM with 75-g, 2-h OGTT were as following: FPG ≥ 92 mg/dl or; 1 h plasma glucose ≥ 180 mg/dl or; 2 h plasma glucose ≥ 153 mg/dl [11]. For women whose GCT result was abnormal, an extra 100-g, 3-h OGTT was performed. Diagnostic tests were performed in few days interval. The presence of GDM with 100-g, 3-h OGTT was based on the criteria of Carpenter-Coustan as following: FPG: ≥ 95 mg/dl; 1 h: ≥ 180 mg/dl; 2 h ≥ 155 mg/dl; 3 h ≥ 140 mg/dl and if two out of four plasma glucose levels were abnormal, diagnosis of GDM was confirmed [12].

2.2. Management approach

Management of women diagnosed as having gestational diabetes in either one-step or two-step method did not differ. Women with GDM in both methods received similar therapeutic interventions including, nutrition counseling and lifestyle modification according to the National Protocol for Pregnancy [18]. A dietitian instructed participants about a 3-meal, 2 to 4-snack standard daily meal plan. Caloric restriction was prescribed for obese women based on 25 kcal/kg

for actual maternal weight in pregnancy, and 35 kcal/kg for non-obese subjects. Approximately 40% to 45% of calories were derived from carbohydrates. If glycemic control was poor by nutrition counseling and lifestyle modification within two weeks, physicians would consider insulin or oral hypoglycemia agents to treat GDM. Patients were advised to carry out self-monitoring of their blood glucose. The objective for all patients was to reach the same metabolic goals according to the recommendation from the Fifth International Workshop-Conference on Gestational Diabetes Mellitus [19] that is the following targets for maternal capillary glucose concentrations: fasting plasma glucose ≤ 95 mg/dl and either one-hour post-meal ≤ 140 mg/dl or two-hour post-meal ≤ 120 mg/dl.

2.3. Definitions

Pre-pregnancy body mass index (BMI) was calculated as a self-reported pre-pregnancy weight of mother divided by height squared (kg/m^2). Physical activity assessment was done using a 24 h questionnaire [20]. Women were asked to write every single activity that they do over a 24 h and time spent on it. Further, we assigned each activity a Metabolic Equivalent of Task (MET) score multiplying its time (in an hour). Energy expenditure of participants was further calculated by summing the MET-hour values. Gestational age at the time of delivery was calculated based on last normal menstrual period or ultrasonography. Macrosomia was defined as birth-weight >4000 g. Low birth-weight was defined as birth-weight <2500 g. Preeclampsia was defined as systolic blood pressure ≥ 140 mmHg and/or diastolic blood pressure ≥ 90 mmHg on two or more occasions with proteinuria $\geq 1+$ on dipstick [18]. Preterm delivery was defined as delivery prior to 37 weeks of gestation. Stillbirth was defined as fetal death after 20 weeks of pregnancy resulting in a baby born without signs of life [18].

2.4. Statistical analysis

At the beginning of the study prevalence rate of GDM was assessed based on FPG result given at the first prenatal visit. For the prevalence calculation, the denominator was the total number of viable pregnancies for which FPG result was available. The numerator was the total number of pregnancies for which the criteria for being GDM was met [11,12]. Excluding women with overt diabetes or GDM at the first prenatal visit, univariate and multiple logistic regression analysis were used to assess firstly, the association between the potential risk factors and GDM at 24–28 weeks, and secondly the association of GDM with pregnancy outcomes. The results of logistic regression are presented as unadjusted and adjusted odds ratios (ORs) (95% CIs). Chi-square or Fisher's exact tests (for categorical variables) and independent-samples t-tests (for continuous variables) were used for the comparisons. The SPSS version 18 for Windows (SPSS Inc., Chicago, IL, USA) was used. Reported P-values were two-tailed and P-values < 0.05 were considered to be statistically significant.

3. Results

3.1. Characteristics

We enrolled 1000 pregnant women who were eligible and consented to participate in the study. Excluding women with known diabetes ($n = 11$), ones who had miscarriage ($n = 18$) or twin-pregnancy ($n = 7$), and women who were unable or incompliant to follow the protocol ($n = 35$), a total of 929 patients meeting our inclusion criteria delivered during the study period. Of all study women 32.5% (302) were overweight (BMI 25–29.9 kg/m^2), and 10.4% (97) were obese (BMI ≥ 30 kg/m^2). The average (SD) pre-pregnancy BMI was 24.6 (4.2) kg/m^2 . The mean (SD) age was 29.2 (4.7) (range 18–44) year. The years of education varied from 0 to 23 years with the mean (SD) of 12.5 (3.6) year. The mean (SD) gestational age at the time of delivery was 38.6 (1.5) (ranged 24.6–42.3) weeks.

3.2. Prevalence and incidence of GDM

A total of 929 pregnant women were included in our analysis. Ninety-three had GDM at baseline (6–14 weeks) based on FPG. The overall prevalence of GDM was 10.0% (95% CI: 8.1–11.9). The others with no GDM at baseline ($n = 836$) were screened at 24–28 weeks for GDM incidence.

The 50-g, 1-h GCT (two-step screening) was performed in 836 pregnant women and 94 women (11.2%) required a 100-g, 3-h OGTT. Of them, 35 (37.2%) ultimately tested positive for GDM after the 3-h OGTT. Of the same pregnant women who had the 75-g, 2-h OGTT (one-step screening), 78 were diagnosed as GDM when using IADPSG criteria of which 35 (44.9%; 95% CI: 33.6–56.6) had GDM using the two-step approach. 758 (90.7%) women were diagnosed with no GDM in both approaches. All women without GDM in the one-step approach were diagnosed with no GDM using the two-step approach.

The overall incidences of subsequent GDM were 9.3% (95% CI: 7.4–11.2) and 4.2% (95% CI: 2.9–5.5) in one-step and two-step approaches, respectively.

3.3. Risk factors

Table 1 represents the group means (SD) and proportions for those women who did and did not develop GDM by one-step and two-step methods. Those who developed GDM had higher FPG and plasma glucose values at 1 h, 2 h, and 3 h ($P < 0.001$), higher pre-pregnancy BMI ($P < 0.001$), and lower physical activity and were older in both approaches ($P < 0.001$). Those who developed GDM had a higher proportion of family history of diabetes, higher history of cesarean section, and history of polyhydramnios in both approaches (Table 1). Using one-step method, those who developed GDM had slightly higher systolic blood pressure (Table 1), a higher proportion of pre-existing hypertension (6.4% vs. 2.2%, $P < 0.05$), and history of neonatal death (2.6% vs. 0.4%, $P < 0.05$). Using two-step method, those who developed GDM had higher proportion of history of macrosomia (2.9% vs.

Table 1 – Selected prenatal risk factors, maternal characteristics, and pregnancy outcomes by diabetes diagnosed in one-step and two-step approaches.

Variable	One-step approach		Two-step approach	
	GDM (n = 78)	Normal (n = 758)	GDM (n = 35)	Normal (n = 801)
Age >35 years	21.8	7.4 ^{***}	25.7	8.0 ^{***}
Pre-pregnancy BMI ≥ 30 kg/m ²	16.7	8.8 [*]	20.0	9.1 [*]
Education <12 years	63.6	61.9	55.9	62.4
Family history of diabetes	43.6	29.6 [*]	57.1	29.7 ^{***}
Previous gestational diabetes	1.3	1.5	2.9	1.4
History of cesarean section	41.0	29.0 [*]	48.6	29.3 [*]
History of polyhydramnios	3.8	0.8 [*]	8.6	0.7 ^{***}
FPG at first prenatal visit (mg/dl)	85.5 (5.2)	82.8 (6.4) ^{***}	85.5 (5.3)	82.9 (6.4) [*]
Systolic BP (mmHg)	105.0 (9.8)	102.0 (9.6) [*]	105.3 (10.5)	102.6 (9.6)
Diastolic BP (mmHg)	67.1 (8.8)	65.6 (8.6)	68.0 (9.6)	65.6 (8.6)
Physical activity (met-hr/day)	33.3 (4.3)	34.9 (6.0) [*]	31.6 (4.0)	34.9 (5.9) ^{***}
Gestational age (week)	38.5 (1.3)	38.7 (1.6)	38.3 (1.3)	38.7 (1.6)
Birth-weight (g)	3216.9 (465.6)	3112.6 (435.2) [*]	3276.4 (484.1)	3115.6 (435.9) [*]
Birth-height (cm)	49.8 (2.2)	49.8 (2.4)	50.3 (2.1)	49.8 (2.4)
Head circumference (cm)	34.7 (1.3)	34.6 (1.5)	34.9 (1.4)	34.6 (1.4)
Chest circumference (cm)	33.4 (1.8)	33.3 (1.7)	33.7 (1.9)	33.3 (1.7)
Apgar Score (5 min)	9.86 (0.42)	9.93 (0.34)	9.80 (0.41)	9.93 (0.34) [*]
Apgar Score (1 min.)	8.77 (1.10)	8.88 (0.59)	8.89 (0.47)	8.87 (0.66)

Data are percentages or means (SD). *P < 0.05, **P < 0.01, ***P < 0.001; GDM, gestational diabetes mellitus; BMI, body mass index; FPG, fasting plasma glucose; BP, blood pressure.

0.4%, $P < 0.05$), preeclampsia (8.6% vs. 1.9%, $P < 0.01$), infertility treatment (20.0% vs. 7.7%, $P < 0.01$), and stillbirth (5.7% vs. 0.6%, $P < 0.001$).

To determine the influence of potential risk factors on GDM, univariate analysis was first performed. Crude OR (95% CI) showed that maternal age (3.5 (1.9–6.4), $P < 0.001$; 3.9 (1.8–8.8), $P < 0.001$), pre-pregnancy BMI (2.1 (1.1–3.9), $P < 0.05$; 2.5 (1.1–5.9), $P < 0.05$), family history of diabetes (1.8 (1.1–2.9), $P < 0.05$; 3.1 (1.6–6.3), $P < 0.001$), history of cesarean section (1.7 (1.1–2.7), $P < 0.05$; 2.3 (1.2–4.5), $P < 0.05$) and polyhydramnios (5.0 (1.2–20.5), $P < 0.05$; 12.4 (2.9–51.9), $P < 0.001$), and physical activity (0.95 (0.89–0.99), $P < 0.05$; 0.88 (0.80–0.97), $P < 0.01$) were significantly associated with the risk of developing GDM in one-step and two-step methods, respectively. Women with a history of stillbirth (9.6 (1.8–51.6), $P < 0.01$), infertility treatment (3.0 (1.2–7.1), $P < 0.05$), and preeclampsia (4.9 (1.3–17.8), $P < 0.05$) were more likely to develop GDM in the two-step method, while women with pre-existing hypertension (2.9 (1.1–8.3), $P < 0.05$) and history of neonatal death (6.6 (1.1–40.2), $P < 0.05$) were more likely to develop GDM in the one-step method.

To determine the independent predictors of the incidence of GDM a multiple logistic regression analysis was performed. Older age and family history of diabetes significantly increased the risk of developing GDM in both approaches. In the two-step method, higher pre-pregnancy BMI and physical inactivity along with higher earlier cesarean section also increased significantly the risk of developing GDM. No other variables were significant (Table 2).

3.4. Pregnancy outcomes

Those who developed GDM in both approaches delivered to neonates with higher birth-weight. In the two-step method,

apgar score at 5-min was slightly higher in normal subjects compared to GDM group (Table 1).

To determine the association of GDM with maternal and neonatal outcomes univariate analysis was first performed. Crude OR (95% CI) showed that GDM significantly increased the risk of macrosomia (5.6 (2.0–15.7), $P < 0.01$; 10.9 (3.6–33.0), $P < 0.001$), cesarean section (2.1 (1.2–3.4), $P < 0.01$; 6.6 (2.3–18.9), $P < 0.001$), and gestational hypertension (2.3 (1.1–4.7), $P < 0.05$; 3.1 (1.2–7.8), $P < 0.05$) in one-step and two-step methods, respectively. In the two-step approach, GDM also increased significantly the risk of preeclampsia (6.6 (1.2–10.8), $P < 0.05$).

In multiple logistic regression analysis, GDM was found to be an independent predictor of macrosomia and cesarean section in both approaches. We found no association of GDM with pregnancy outcomes including low birth-weight, preeclampsia, gestational hypertension, and preterm delivery after adjusting for potential confounders (Table 2).

4. Discussion

The present study indicated an incidence rate of 9.3% for GDM using one-step approach which was more than double compared with that of 4.2% using two-step approach. The later incidence is very close to earlier studies done in Iran with the rates assessed 4.7% and 4.8% [21,22]. It is also in the middle range of findings from other studies using the same diagnostic method in which GDM incidence ranged from 2.5% to 6.9% [23–25]. Several studies have examined the use of one-step vs. two-step approach for GDM diagnosis [23,26–28]. The increased incidence of GDM using one-step method has been associated with adverse pregnancy outcomes compared with women without GDM [23,27]. It was also associated with increased rates of cesarean delivery and macrosomia

Table 2 – Adjusted odds ratio (95% CI) of the association of risk factors and maternal and neonatal outcomes with GDM diagnosed in one-step and two-step approaches using multiple logistic regression analysis.

Characteristics	One-step approach	Two-step approach
<i>Risk factors</i>		
Maternal age >35 (year)	3.5 (1.6–8.1)**	3.6 (1.1–12.0)*
Pre-pregnancy BMI ≥ 30 (kg/m ²)	1.6 (0.7–3.8)	3.1 (1.1–9.4)*
Family history of diabetes	2.2 (1.2–4.0)**	3.9 (1.5–9.7)**
History of cesarean section	1.7 (0.9–3.5)	4.9 (1.5–15.9)**
History of polyhydramnios	0.43 (0.03–6.69)	0.20 (0.01–7.34)
Pre-existing hypertension	0.8 (0.1–11.9)	2.0 (0.1–48.8)
History of preeclampsia	3.3 (0.2–46.3)	4.7 (0.2–121.6)
History of infertility treatment	0.9 (0.3–2.5)	0.9 (0.2–3.6)
History of stillbirth	2.0 (0.1–28.2)	3.9 (0.2–78.3)
Previous gestational diabetes	1.1 (0.1–9.6)	1.8 (0.2–20.6)
History of macrosomia	2.5 (0.2–39.5)	4.5 (0.2–88.8)
Physical activity (met-hr/day)	0.95 (0.89–1.01)	0.88 (0.79–0.98)*
<i>Maternal and neonatal outcomes</i>		
Macrosomia (>4000 g)	4.9 (1.7–14.2)**	13.3 (3.2–55.9)***
Low birth-weight	0.49 (0.15–1.65)	0.48 (0.06–3.83)
Cesarean section	1.8 (1.1–3.1)*	4.7 (1.2–18.5)*
Preeclampsia	1.5 (0.6–4.3)	2.8 (0.5–14.5)
Gestational hypertension	1.9 (0.9–4.1)	2.4 (0.6–9.2)
Preterm delivery	0.96 (0.41–2.25)	0.65 (0.14–3.10)

*P < 0.05, **P < 0.01, ***P < 0.001; BMI, body mass index; Odds ratios of maternal and neonatal outcomes were adjusted for maternal age and family history of diabetes in one-step method and maternal age, pre-pregnancy BMI, family history of diabetes, physical activity, and history of cesarean section in two-step method.

compared to women with GDM diagnosed in two-step method [26,28].

In the present study, we found more risk factors associated with GDM diagnosed in the two-step method while, determinants of GDM were only maternal age and family history of diabetes using the one-step method. On the other hand, except for maternal age, we found no significant difference in prenatal risk factors and pregnancy outcomes in women who were diagnosed only by the one-step method, but not with the two-step method (n = 43) compared to women without GDM. This is consistent with studies in which the increased women with GDM using one-step method did not differ in the prevalence of outcomes compared to women without GDM [29]. In our study, no requirement of insulin therapy was found in these women and 92.1% were treated based on lifestyle modifications and only 3 (7.9%) treated with metformin. Of women diagnosed with GDM using both approaches (n = 35), 4 (11.4%) required insulin, 10 (28.6%) metformin, 1 (2.9%) insulin + metformin, and 20 (57.1%) treated with lifestyle modifications. The information above may reflect the potential over-diagnosis towards one-step strategy and that the increased rate of GDM in one-step method results from using IADPSG criteria with lower threshold values to find GDM and not really reflects women with the higher risk for developing GDM. We also found a positive association of GDM with short-term pregnancy outcomes in both approaches. GDM independently increased the risk of macrosomia and cesarean section, the association was stronger for both outcomes using two-step approach. Macrosomia has been the principal pregnancy complication affected by GDM which resulted in higher rates of preterm delivery and operative delivery in other studies [30]. The reason for a higher rate

of the cesarean section would be partially related to the general tendency of Iranian women and that they frequently request elective cesarean section and also depends upon gynecologist decision. This can be considered as a limitation of our study when comparing the rate of cesarean section in GDM and non-GDM women. Our study has several strengths and limitations. Its strengths include population-based evaluation for GDM. We only included pregnant women from one academic institution in one geographic area. This can be considered as strength of the study in that pregnancy management was fairly consistent during the study period although, it may also be considered a limitation because our findings are not necessarily generalized to pregnant women in other regions. While the sample size was believed to be adequate for analysis as a whole, the sample size limited our ability to detect potentially clinically meaningful differences in some risk factors and pregnancy outcomes between GDM and healthy groups, as judged by wide 95% CI. Although pregnant women express concern about the complexity of one-step and two-step screening and diagnosis of GDM, they seemed to tolerate the inconvenience of both diagnostic tests in our study. This is the first report of GDM incidence using one-step and two-step diagnostic approaches in routine care in a Middle-East country and provides new data from Iran which has been under-represented in past studies.

In summary, despite a higher incidence of GDM using the one-step approach, more risk factors for and a stronger effect of GDM on adverse pregnancy outcomes were found when using the two-step approach. We found no significant difference in the prevalence of risk factors and pregnancy outcomes in women who were diagnosed only by the one-step, but not with the two-step method. So, these data address

concerns in the literature that the one-step screening guideline may identify lower-risk women as having GDM, increasing their anxiety and health care costs with more visits, more ultrasounds, additional laboratory testing, and no clear indication of the benefit in short term. Moreover, longer follow-up of women with and without GDM may change the results using both approaches.

Acknowledgements

The authors thank M. Abyar for his technical computer assistance, Dr. Z. Shahshahan for her support, the midwifery sections of Isfahan health care centers, and the medical record section of the hospitals for providing us with the prenatal and delivery records of the participants for their support during data collection.

Conflict of interest

None declared.

Author's contributions

EH, recruited samples, performed statistical analyses, and contributed to interpreting the data and drafted the manuscript. MJ, designed the study, and interpreted the data and revised the manuscript. AA, contributed to interpretation of results and revised the manuscript. All authors approved the final version submitted for publication.

Details of ethics approval

This study approved by the Isfahan University of Medical Sciences ethical committee. All participants gave written informed consent.

Funding

This study was partly supported by the research deputy of Iranian Ministry of Health and Medical Education, Iran.

REFERENCES

- [1] Oster RT, King M, Morrish DW, Mayan MJ, Toth EL. Diabetes in pregnancy among First Nations women in Alberta, Canada: a retrospective analysis. *BMC Pregnancy Childbirth* 2014;14:136.
- [2] Meek CL, Lewis HB, Patient C, Murphy HR, Simmons D. Diagnosis of gestational diabetes mellitus: falling through the net. *Diabetologia* 2015;58:2003–12.
- [3] Jain R, Pathak RR, Kotecha AA. Gestational diabetes: perinatal and maternal complication in 24–28 weeks. *Int J Med Sci Public Health* 2014;3:1283–8.
- [4] Cheng YW, Chung JH, Kurbisch-Block I, Inturrisi M, Shafer S, Caughey AB. Gestational weight gain and gestational diabetes mellitus: perinatal outcomes. *Obstet Gynecol* 2008;112:1015–22.
- [5] Jenum AK, Mørkrid K, Sletner L, Vange S, Torper JL, Nakstad B, et al. Impact of ethnicity on gestational diabetes identified with the WHO and the modified International Association of Diabetes and Pregnancy Study Groups criteria: a population-based cohort study. *Eur J Endocrinol* 2012;166:317–24.
- [6] Kautzky-Willer A, Bancher-Todesca D, Weitgasser R, Prikoszovich T, Steiner H, Shnawa N, et al. The impact of risk factors and more stringent diagnostic criteria of gestational diabetes on outcomes in central European women. *J Clin Endocrinol Metab* 2008;93:1689–95.
- [7] Ben-Haroush A, Yogev Y, Hod M. Epidemiology of gestational diabetes mellitus and its association with Type 2 diabetes. *Diabet Med* 2004;21:103–13.
- [8] Hollander MH, Paarlberg KM, Huisjes AJM. Gestational diabetes: a review of the current literature and guidelines. *Obstet Gynecol Surv* 2007;62:125–36.
- [9] Reece EA, Leguizamón G, Wiznitzer A. Gestational diabetes: the need for a common ground. *Lancet* 2009;373:1789–97.
- [10] American College of Obstetricians and Gynecologists. Practice bulletin no. 137: gestational diabetes mellitus. *Obstet Gynecol* 2013;122:406–16.
- [11] International Association of Diabetes and Pregnancy Study Groups Consensus Panel. International association of diabetes and pregnancy study groups recommendations on the diagnosis and classification of hyperglycemia in pregnancy. *Diabetes Care* 2010;33:676–82.
- [12] American Diabetes Association. Standards of Medical Care in Diabetes. *Diabetes Care* 2015;38(Suppl 1):S1–S94.
- [13] Benhalima K, Van Crombrugge P, Verhaeghe J, Vandeginste S, Verlaenen H, Vercammen C, et al. The Belgian Diabetes in Pregnancy Study (BEDIP-N), a multi-centric prospective cohort study on screening for diabetes in pregnancy and gestational diabetes: methodology and design. *BMC Pregnancy Childbirth* 2014;14:226.
- [14] Vanderstien JP, Dodson WC, Espeland MA, Grobman WA, Guise JM, Mercer BM, et al. NIH consensus development conference: diagnosing gestational diabetes mellitus. *NIH Consens State Sci Statements* 2012;29:1–31.
- [15] Donovan L, Hartling L, Muise M, Guthrie A, Vandermeer B, Dryden DM. Screening tests for gestational diabetes: a systematic review for the US Preventive Services Task Force. *Ann Intern Med* 2013;159:115–22.
- [16] Blumer I, Hadar E, Hadden DR, Jovanovic L, Mestman JH, Murad MH, et al. Diabetes and pregnancy: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab* 2013;98:4227–49.
- [17] American Diabetes Association. Standards of medical care in diabetes. *Diabetes Care* 2017;40:S4–5.
- [18] Jafari N, Valafar S, Radpouyan L. National protocol for pregnancy. 8th ed. Tehran: The Iranian Ministry of Health and Medical Education; 2016 (In Persian).
- [19] Metzger BE, Buchanan TA, Coustan DR, De Leiva A, Dunger DB, Hadden DR, et al. Summary and recommendations of the fifth international workshop-conference on gestational diabetes mellitus. *Diabetes Care* 2007;30: S251–S60.
- [20] Ainsworth BE, Haskell WL, Whitt MC, Irwin ML, Swartz AM, Strath SJ, et al. Compendium of physical activities: an update of activity codes and MET intensities. *Med Sci Sports Exerc* 2000;32:S498–504.
- [21] Keshavarz M, Cheung NW, Babae GR, Moghadam HK, Ajami ME, Shariati M. Gestational diabetes in Iran: incidence, risk factors and pregnancy outcomes. *Diabetes Res Clin Pract* 2005;69:279–86.
- [22] Hossein-Nezhad A, Maghbooli Z, Vassigh A-R, Larijani B. Prevalence of gestational diabetes mellitus and pregnancy outcomes in Iranian women. *Taiwan J Obstet Gynecol* 2007;46:236–41.
- [23] Benhalima K, Hanssens M, Devlieger R, Verhaeghe J, Mathieu C. Analysis of pregnancy outcomes using the new IADPSG recommendation compared with the Carpenter and Coustan

- criteria in an area with a low prevalence of gestational diabetes. *Int J Endocrinol* 2013;2013:1–6.
- [24] Weijers RNM, Bekedam DJ, Smulders YM. Determinants of mild gestational hyperglycemia and gestational diabetes mellitus in a large Dutch multiethnic cohort. *Diabetes Care* 2002;25:72–7.
- [25] Xiong X, Saunders LD, Wang FL, Demianczuk NN. Gestational diabetes mellitus: prevalence, risk factors, maternal and infant outcomes. *Int J Gynaecol Obstet* 2001;75:221–8.
- [26] Feldman RK, Tieu RS, Yasumura L. Gestational diabetes screening: the international association of the diabetes and pregnancy study groups compared with carpenter-coustan screening. *Obstet Gynecol* 2016;127:10–7.
- [27] Waters TP, Dyer AR, Scholtens DM, Dooley SL, Herer E, Lowe LP, et al. Maternal and neonatal morbidity for women who would be added to the diagnosis of GDM using IADPSG criteria: a secondary analysis of the Hyperglycemia and Adverse Pregnancy Outcome Study. *Diabetes Care* 2016;39:2204–10.
- [28] Ethridge Jr JK, Catalano PM, Waters TP. Perinatal outcomes associated with the diagnosis of gestational diabetes made by the international association of the diabetes and pregnancy study groups criteria. *Obstet Gynecol* 2014;124:571–8.
- [29] Liao S, Mei J, Song W, Liu Y, Tan YD, Chi S, et al. The impact of the International Association of Diabetes and Pregnancy Study Groups (IADPSG) fasting glucose diagnostic criterion on the prevalence and outcomes of gestational diabetes mellitus in Han Chinese women. *Diabet Med* 2014;31:341–51.
- [30] He X-J, Qin F-y, Hu C-L, Zhu M, Tian C-Q, Li L. Is gestational diabetes mellitus an independent risk factor for macrosomia: a meta-analysis? *Arch Gynecol Obstet* 2015;291:729–35.