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AOGS SYSTEMATIC REVIEW

Are women positive for the One Step but negative for the Two Step screening tests for gestational diabetes at higher risk for adverse outcomes?

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Abstract

Introduction. The aim of this study was to evaluate if women meeting criteria for gestational diabetes mellitus (GDM) by the One Step test as per International Association of the Diabetes and Pregnancy Study Groups (IADPSG) criteria but not by other less strict criteria have adverse pregnancy outcomes compared with GDM-negative controls. The primary outcome was the incidence of macrosomia, defined as birthweight > 4000 g. *Material and methods.* Electronic databases were searched from their inception until May 2017. All studies identifying pregnant women negative at the Two Step test, but positive at the One Step test for IADPSG criteria were included. We excluded studies that randomized women to the One Step vs. the Two Step tests; studies that compared different criteria within the same screening method; randomized studies comparing treatments for GDM; and studies comparing incidence of GDM in women doing the One Step test vs. the Two Step test. *Results.* Eight retrospective cohort studies, including 29 983 women, were included. Five study groups and four control groups were identified. The heterogeneity between the studies was high. Gestational hypertension, preeclampsia and large for gestational age, as well as in some analyses cesarean delivery, macrosomia and preterm birth, were significantly more frequent, and small for gestational age in some analyses significantly less frequent, in women GDM-positive by the One Step, but not the Two Step. *Conclusion.* Women meeting criteria for GDM by IADPSG criteria but not by other less strict criteria have an increased risk of adverse pregnancy outcomes such as gestational hypertension, preeclampsia and large for gestational age, compared with GDM-negative controls. Based on these findings, and evidence from other studies that treatment decreases these adverse outcomes, we suggest screening for GDM using the One Step IADPSG criteria.

Abbreviations: ACOG, American College of Obstetrics and Gynecologists; C&C, Carpenter and Coustan; CDA, Canadian Diabetes Association; GCT, glucose challenge test; GDM, gestational diabetes mellitus; IADPSG, International Association of the Diabetes and Pregnancy Study Groups; LGA, large for gestational age; NICE, National Institute for Health and Care Excellence; NICU, neonatal intensive care unit; OGTT, oral glucose tolerance test; OR, odds ratio; RCT, randomized controlled trial; SGA, small for gestational age; WHO, World Health Organization.

Introduction

Gestational diabetes mellitus (GDM) is defined as impaired glucose tolerance first recognized during pregnancy (1). GDM affects about 7–20% of pregnant women and this value will probably increase in the future, due in particular to maternal obesity (2). Prompt diagnosis and correct treatment are essential, not only to decrease the risks of maternal and neonatal morbidity and mortality, but also to reduce health costs (1–6). In 2008, the hyperglycemia and adverse pregnancy outcomes (HAPO) study showed strong, continuous associations of maternal glucose levels below those diagnostic for diabetes with increased birthweight (7).

Concerning diagnostic criteria, during the last decades methods and cut-off values have changed several times and complete international consensus about which criteria to adopt has not been reached (1–6). The two most common approaches to screen pregnant women for GDM are the One Step and Two Step tests. Currently, the International Association of the Diabetes and Pregnancy Study Groups (IADPSG) (2), the World Health Organization (WHO) (3), the International Federation of Obstetricians and Gynecologists (4), the Canadian Diabetes Association (CDA) (5) all recommend the 75 g 2 h One Step test, while The American College of Obstetricians and Gynecologists (ACOG) recommends the Two Step approach, with first a 50-g 1-h test, and then, for those with abnormal results, a 100-g 3-h test (6).

The One Step test usually diagnoses more women with GDM than the Two Step test (8). It is unclear if these 'extra' women diagnosed with GDM by the One Step test using IADPSG criteria but not by the Two Step test are at increased risks for GDM complications compared with women without GDM, and also, if they are, if treatment for this 'mild' GDM is beneficial.

Our objective was to evaluate mainly if women meeting criteria for GDM by IADPSG criteria, but not by other less strict criteria, have adverse pregnancy outcomes compared with GDM negative controls, and also if treatment of these women has any potential maternal or perinatal effects.

Material and methods

This is a review of the literature aimed at comparing maternal and neonatal outcomes of women meeting criteria for GDM by IADPSG criteria but not by other less strict criteria, vs. GDM-negative controls. All studies were identified through a review of the literature using PubMed, Ovid, Google Scholar and Cochrane Review. Databases were searched from their inception until May 2017. Search terms used were the following text words: "diabetes", "trial", "screening", "diagnosis", "one-step", "two-step", "guidelines", "review", "randomized" and "clinical trial". No restrictions for language or geographic location were applied. In addition, the reference lists of all identified articles were examined to identify studies not captured by electronic searches. The electronic search and the eligibility of the studies were independently assessed by two authors (GS, CC). Differences were discussed with a third reviewer (VB).

We sought to identify in particular studies including women meeting criteria for GDM based on the One Step test by IADPSG criteria but not by other less strict criteria, and reporting their outcomes compared with GDM-negative controls. We also looked for any information regarding GDM treatment of these (IADPSG-positive only) women, to compare outcomes between those treated vs. those untreated.

We included studies, of any design, identifying pregnant women positive for IADPSG criteria, but negative at the Two Step test as per ACOG Carpenter and Coustan (C&C) criteria (6), WHO 1999 criteria (9), CDA criteria (5), or National Institute for Health and Care Excellence (NICE) Two Step criteria (Table 1) (10). We excluded studies that randomized women to the One Step vs. the Two Step tests; studies that compared different criteria within the same screening method; randomized studies comparing treatments for GDM; studies comparing mainly incidence of GDM in women doing the One Step test vs. other women doing the Two Step test; and studies not reporting clinical outcomes.

Different criteria for GDM are shown in the Supplementary material (Table S1).

We defined different groups of women within these studies (Table 2). We defined the five study groups, all positive for IADPSG criteria, but negative for other less stringent GDM screening tests, as: (1) women who had at least one positive value on the 2-h 75-g oral glucose tolerance test (OGTT) according to IADPSG criteria, but were negative by C&C at the 100-g OGTT test (75-g IADPSG-positive; 100-g C&C-negative); (2) women who had at least one positive value on the 2-h 75-g OGTT according to IADPSG criteria, but were negative by WHO criteria (75-g IADPSG-positive; WHO-negative); (3) women who had at least one positive value on the 2-h 75-g OGTT

Key message

Women meeting criteria for gestational diabetes mellitus by One Step IADPSG criteria, but not by other less strict criteria, have an increased risk of adverse pregnancy outcomes compared with gestational diabetes mellitus-negative controls.

Table 1. Selected studies reporting outcomes of women meeting criteria for gestational diabetes mellitus based on the One Step test but not on the Two Step test.

Author, year (origin) (Ref)	Study design	One Step positive criteria (Study group)	Control group	Two Step screening criteria	Primary outcome
Lapolla, 2011 (Italy) (14)	Retrospective cohort	100-g IADPSG positive; C&C negative (Fasting 92–94 mg/dL; 2 h 153–154 mg/dL; not treated) [*n* = 112]	IADPSG negative (Fasting <92 mg/dL; 1 h < 180 mg/dL; 2 h < 153 mg/dL) [*n* = 1815]	50-g 1 h; if >140 mg/dL: 100-g 3 h GTT 2 abnormal of: Fasting ≥95 mg/dL, or 1 h 180 mg/dl; 2 h 155 mg/dL; 3 h 140 mg/dL[a]	Perinatal outcomes
Bodmer-Roy, 2012 (Canada) (15)	Retrospective cohort	75-g IADPSG positive; CDA negative (Fasting 92–95 mg/dL; 1 h 180–190 mg/dL; 2 h 153–159 mg/dL; not treated) [*n* = 186]	GCT-negative (50-g 1 h < 137 mg/dL) [*n* = 186] or IADPSG-negative (Fasting <92 mg/dL; 1 h < 180 mg/dL; 2 h < 153 mg/dL) [*n* = 186]	50-g 1 h; if 137–184 mg/dL: 75-g 2 h GTT One abnormal of: fasting ≥ 96 mg/dL; 1 h: ≥ 191 mg/dl: 2 h ≥ 160 mg/dL[a]	LGA >90th percentile
Benhalima, 2013 (Belgium) (16)	Retrospective cohort	100-g IADPSG positive; C&C negative (Fasting 92–94 mg/dL; 2 h 153–154 mg/dL; not treated) [*n* = 160]	GCT-negative (50-g 1 h < 140 mg/dL) and IADPSG-negative (Fasting <92 mg/dL; 1 h < 180 mg/dL; 2 h < 153 mg/dL) [*n* = 6345]	50 g 1 h; if ≥140 mg/dL: 100 g 3 h GTT 2 abnormal of: Fasting ≥95 mg/dL, or 1 h 180 mg/dl; 2 h 155 mg/dL; 3 h 140 mg/dL[a]	Pregnancy outcomes
Ethridge, 2014 (USA) (17)	Retrospective cohort	100-g IADPSG positive; C&C negative (Fasting 92–94 mg/dL; 2 h 153–154 mg/dL; not treated) [*n* = 281]	GCT-negative (50-g 1 h < 135 mg/dL) [*n* = 6999] or IADPSG-negative (Fasting <92 mg/dL; 1 h < 180 mg/dL; 2 h < 153 mg/dL) [*n* = 772]	50-g 1 h; if ≥135 mg/dL: 100-g 3 h GTT 2 abnormal of: Fasting ≥95 mg/dL, or 1 h 180 mg/dl; 2 h 155 mg/dL; 3 h 140 mg/dL[a]	Birthweight and neonatal outcomes
Liao, 2014 (China) (18)	Retrospective cohort	100-g IADPSG positive; C&C negative (Fasting 92–94 mg/dL; 2 h 153–154 mg/dL; not treated) [*n* = 1314]	GCT-negative (50-g 1 h < 140 mg/dL) and IADPSG-negative (Fasting <92 mg/dL; 1 h < 180 mg/dL; 2 h < 153 mg/dL) [*n* = 2662]	50 g 1 h; if ≥140 mg/dL: 100-g 3 h GTT 2 abnormal of: Fasting ≥95 mg/dL, or 1 h 180 mg/dl; 2 h 155 mg/dL; 3 h 140 mg/dL	Maternal and neonatal outcomes
Mayo, 2015 (Canada) (19)	Retrospective cohort	75-g IADPSG positive; CDA negative (Fasting 92–95 mg/dL; 1 h 180–190 mg/dL; 2 h 153–159 mg/dL; not treated) [*n* = 155]	GCT-negative (50-g 1 h < 140 mg/dL) [*n* = 4183] or IADPSG negative (Fasting <92 mg/dL; 1 h < 180 mg/dL; 2 h < 153 mg/dL) [*n* = 526]	50-g 1 h; if 140–184 mg/dL: 75-g 2 h GTT One abnormal of: fasting ≥95 mg/dL; 1 h: ≥191 mg/dl: 2 h ≥ 160 mg/dL[a]	Not stated

Table 1. Continued

Author, year (origin) (Ref)	Study design	One Step positive criteria (Study group)	Control group	Two Step screening criteria	Primary outcome
Meek, 2015 (UK) (20)	Retrospective cohort	75-g IADPSG positive; NICE negative (Fasting 92–101 mg/dL, 1 h ≥ 153 mg/dL; not treated) [*n* = 387]	IADPSG negative (Fasting <92 mg/dL; 1 h < 180 mg/dL; 2 h < 153 mg/dL) [*n* = 2406]	50-g 1 h; if >138 mg/dL: 75-g 2 h GTT One abnormal of: fasting ≥110/128 mg/dL; 2 h ≥ 140 mg/dL[b]	Delivery and neonatal outcomes
Tward, 2016 (Canada) (21)	Retrospective cohort	75-g IADPSG positive; CDA negative (Fasting 92–95 mg/dL; 1 h 180–190 mg/dL; 2 h 153–159 mg/dL; not treated) [*n* = 99]	GCT-negative (50-g 1 h < 140 mg/dL [*n* = 1021] or IADPSG negative (Fasting <92 mg/dL; 1 h < 180 mg/dL; 2 h < 153 mg/dL) [*n* = 184]	50-g 1 h; if >140 mg/dL: 75-g 2 h GTT 2 abnormal of: fasting ≥95 mg/dL; 1 h: ≥191 mg/dl: 2 h ≥ 160 mg/dL	Fetal grown in twins

CDA, Canadian Diabetes Association; C&C, Carpenter and Coustan criteria; GCT, glucose challenge test; GTT, glucose tolerance test; IADPSG, International Association of Diabetes Pregnancy Study Group; LGA, large for gestational age; NICE, National Institute for Health and Care Excellence; WHO, World Health Organization.

[a]2008 Canadian Diabetes Association criteria (5).

[b]WHO 1999 criteria until 2007 (fasting 148 mg/dL), than modified WHO 1999 (fasting 130 mg/dL).

according to IADPSG criteria, but were negative by CDA criteria (75-g IADPSG-positive; CDA-negative); (4) women who had at least one positive value on the 2-h 75-g OGTT according to IADPSG criteria, but were negative by NICE criteria (75-g IADPSG-positive; NICE-negative); (5) women who had at least one positive value on the 100-g OGTT according to IADPSG criteria, but were negative by C&C criteria at the 100-g OGTT test (100-g IADPSG-positive; C&C-negative).

We defined the four control groups as: (1) women with negative 50-g 1-h glucose challenge test results (GCT-negative); (2) women GDM-negative by IADPSG criteria on the 75-g One Step test (IADPSG-negative); (3) either (1) or (2), together (GCT-negative or IADPSG-negative); (4) women negative according to WHO criteria (WHO-negative).

We carefully extracted data from all selected papers and we resolved disagreements by discussion.

We planned to compare maternal and neonatal outcomes in study group (1) vs. any controls; study group (2) vs. any controls; study group (3) vs. any controls; study group (4) vs. any controls; study group (5) vs. any controls.

Among the five groups described above, we aimed to compare several outcomes. We identified as our primary outcome the incidence of macrosomia (defined as birthweight ≥ 4000 g).

Secondary outcomes were the following maternal and neonatal outcomes: large-for-gestational-age (LGA) (birthweight > 90th centile), cesarean delivery, shoulder dystocia, maternal gestational hypertension (i.e. blood pressure ≥ 140/90 mmHg occurring during pregnancy in previous normotensive women), preeclampsia, admission to a neonatal intensive care unit (NICU admission), premature delivery (defined as delivery before 37 weeks of gestation), small-for-gestational-age (SGA) (birthweight < 90th centile), clinical neonatal hypoglycemia, live births and stillbirths.

The data analysis was completed independently by two authors (CC, GS) using Review Manager v. 5.3 (The Nordic Cochrane Center, Cochrane Collaboration, 2014, Copenhagen, Denmark). The completed analyses were then compared, and any difference was resolved by discussion with a third reviewer (VB).

Data from each eligible study were extracted without modification of original data onto custom-made data collection forms. For continuous outcomes means ± standard deviation were extracted and imported into Review Manager v. 5.3.

Meta-analysis was performed using the random effects model of DerSimonian and Laird, to produce summary treatment effects in terms of mean difference or odds ratio (OR) with 95% confidence interval (95% CI). Heterogeneity was measured using I-squared (Higgins I^2).

Before data extraction, the review was registered with the PROSPERO International Prospective Register of Systematic Reviews (CRD42017065654).

Results

We identified 73 studies on GDM screening comparison, and these were assessed for eligibility (Figure 1). Sixty-two

Table 2. Study groups and Control groups definitions[a].

Study groups (Ref)	Control groups
1) 75-g IADPSG-positive; 100 g C&C-negative: no studies	1) GCT-negative: 2 studies (16,18)
2) 75-g IADPSG-positive; WHO-negative: no studies	2) IADPSG-negative: 2 studies (14,20)
3) 75-g IADPSG-positive; CDA-negative: 3 studies (15,19,21)	3) GCT-negative or IADPSG-negative: 4 studies (15,17,19,21)
4) 75-g IADPSG-positive; NICE-negative: 1 study (20)	4) WHO-negative: no studies
5) 100-g IADPSG-positive; C&C-negative: 4 studies (14,16–18)	

CDA, Canadian Diabetes Association; C&C, Carpenter and Coustan criteria; GCT, glucose challenge test; IADPSG, International Association of Diabetes Pregnancy Study Group; NICE, National Institute for Health and Care Excellence; WHO, World Health Organization.
[a]For details of criteria, see Supplementary material (Table S1).

were excluded, and therefore 11 studies reporting outcomes of women meeting criteria for GDM based on the One Step test but not on the Two Step test were included. Deerochnawong et al. (11) and Mello et al. (12) were excluded because while women were given both tests (75 g and 100 g), the studies do not compare outcomes. O'Sullivan et al. (13) was excluded because the study and control groups contained overlapping patients. Therefore, finally, eight studies (14–21) were included for final analysis.

We found no study that compared 75-g IADPSG-positive, 100-g C&C-negative women to any of the possible controls. We found no study that compared 75-g IADPSG-positive, WHO-negative women to any of the possible controls, as O'Sullivan et al. (13) had to be excluded. Instead we recognized eight studies that identified women negative at the 75-g CDA, 75-g NICE test, or 100-g C&C tests, but positive for milder GDM criteria (either 75-g or 100-g IADPSG criteria) (14–21).

Three of the included studies considered women positive at 75-g IADPSG criteria, but CDA criteria negative (15,19,21). One study included women meeting criteria for GDM based on 75-g IADPSG criteria, but NICE criteria negative (20). Four of the included studies had as study group women positive for 100-g IADPSG criteria, but negative on C&C criteria (14,16–18).

Regarding control groups, two of the included studies considered women with negative GCT, six studies included as controls women who were IADPSG-negative, four studies considered GCT-negative or IADPSG-negative, and no studies had as control group women who were WHO-negative (Table 2).

Supplementary material (Table S1) reports the recommendations of guidelines used in the eight studies that we included in our analysis. Table 1 shows the characteristics of the included studies. All eight studies were retrospective cohort studies. For the GCT-negative controls, the cut-offs varied between 135 and 140 mg/dL. The study by Tward et al. includes only twin pregnancies, so fetal outcomes are referred to both twins. No study treated for GDM either the study or control groups.

In the three studies of women positive at 75-g IADPSG criteria, but CDA criteria negative, gestational hypertension [17/341 (5.0%) vs. 112/5081 (2.2%); OR 2.55, 95% CI 1.41–4.61], preeclampsia [16/341 (4.7%) vs. 46/5081 (0.9%); OR 2.75, 95% CI 1.38–5.45], hypertensive complications [27/254 (10.6%) vs. 278/5914 (4.7%); OR 1.81, 95% CI 1.19–2.76], cesarean delivery [205/440 (46.6%) vs. 2180/6286 (34.7%); OR 1.68, 95% CI 1.34–2.11] and LGA babies [38/341 (11.1%) vs. 411/5081 (8.1%); OR 1.69, 95% CI 1.15–2.48] were significantly more common; our main outcome, macrosomia, was more frequent in women positive at 75-g IADPSG criteria and CDA criteria negative, but did not reach a statistically significant difference [39/341 (11.4%) vs. 475/5081 (9.3%); OR 1.32, 95% CI 0.90–1.92] (Tables 3 and 4).

In the one study of women positive on 75-g IADPSG criteria, but NICE criteria negative, macrosomia [112/387 (28.9%) vs. 403/2406 (16.8%); OR 2.02, 95% CI 1.59–2.58], LGA babies [115/387 (29.7%) vs. 406/2406 (16.9%); OR 2.08, 95% CI 1.63–2.65] and preeclampsia [39/387 (10.1%) vs. 174/2406 (7.2%); OR 1.44, 95% CI 1.00–2.07], were significantly more common. Other outcomes did not reach a statistically significant difference (Table 5 and 6).

In the four studies of women positive for 100-g IADPSG criteria, but negative on C&C criteria, preeclampsia [27/1474 (1.8%) vs. 66/9011 (0.7%); OR 1.82, 95% CI 1.09–3.05], gestational hypertension [75/1867 (4.0%) vs. 825/1859 (4.4%); OR 1.58, 95% CI 1.21–2.07], cesarean delivery [180/553 (32.5%) vs. 3860/15931 (24.2%); OR 1.46, 95% CI 1.21–1.75], LGA babies [157/1867 (8.4%) vs. 1688/18597 (9.1%); OR 1.36, 95% CI 1.13–1.64], preterm birth [113/1474 (7.7%) vs. 1799/9011 (20.0%); OR 1.67, 95% CI 1.33–2.10], NICU admission [116/1755 (6.6%) vs. 1318/16782 (7.9%); OR 1.32, 95% CI 1.06–1.64], and neonatal hypoglycemia [18/1314 (1.3%) vs. 18/2666 (0.7%); OR 2.04, 95% CI 1.06–3.94] were significantly more common; whereas SGA babies [13/243 (5.3%) vs.

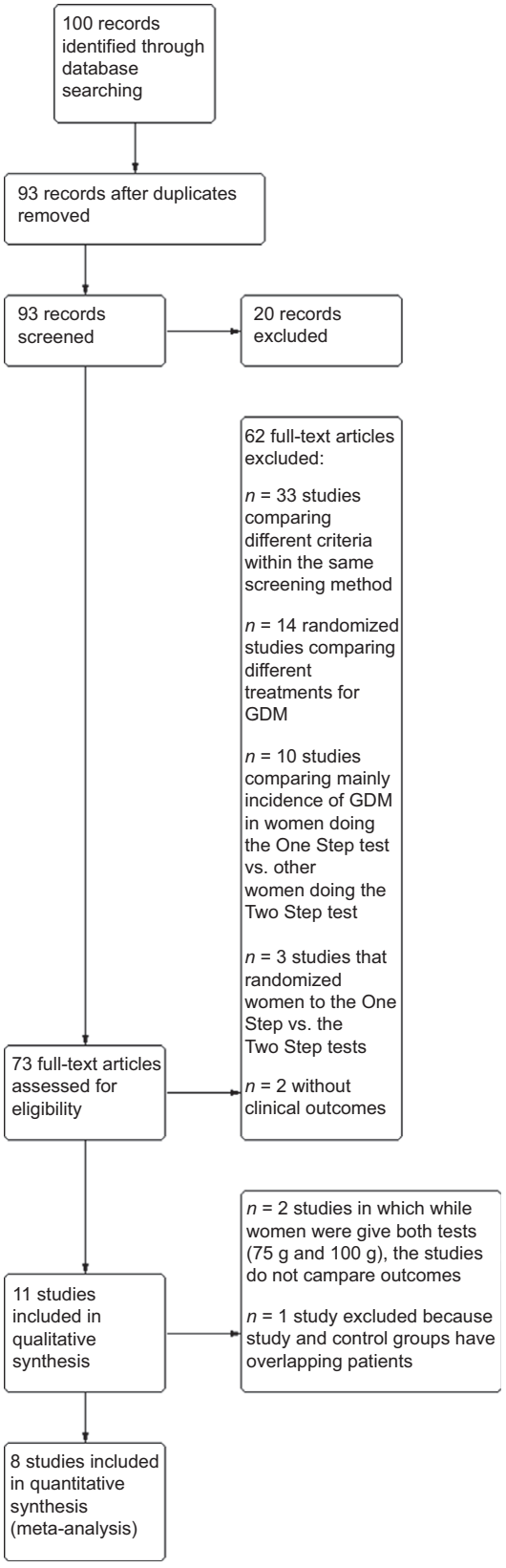

Figure 1. Flow diagram of studies identified in the systematic review.

Table 3. Comparing of maternal outcomes between women who were 75-g IADPSG-positive, CDA-negative (Group 3 in Table 2); vs. any controls.

Author, year (origin) (Ref)	Gestational hypertension	Preeclampsia	Hypertensive complications[b]	Shoulder dystocia	Cesarean delivery
Bodmer-Roy, 2012 (Canada) (15)	8/186 (4.3%) vs. 7/372 (1.9%)	12/186 (6.5%) vs. 10/372 (2.7%)	NR	2/186 (1.1%) vs. 6/372 (1.6%)	69/186 (37.1%) vs. 94/372 (25.3%)
Mayo, 2015 (Canada) (19)	9/155 (5.8%) vs. 105/4709 (2.2%)	4/155 (2.6%) vs. 36/4709 (0.8%)	13/155 (8.4%) vs. 140/4709 (3.0%)	3/155 (1.9%) vs. 88/4709 (1.9%)	57/155 (36.8%) vs. 1247/4709 (26.5%)
Tward, 2016 (Canada)[a] (21),	NR	NR	14/99 (14.1%) vs. 138/1205 (11.4%)	NR	79/99 (79.8%) vs. 839/1205 (69.6%)
Total	17/341 (5.0%) vs. 112/5081 (2.2%)	16/341 (4.7%) vs. 46/5081 (0.9%)	27/254 (10.6%) vs. 278/5914 (4.7%)	5/341 (1.5%) vs. 94/5081 (1.85%)	205/440 (46.6%) vs. 2180/6286 (34.7%)
OR (95% CI)	**2.55 (1.41–4.61)**	**2.75 (1.38–5.45)**	**1.81 (1.19–2.76)**	0.88 (0.34–2.28)	**1.68 (1.34–2.11)**
I^2	0%	0%	50%	0%	78%

IADPSG, International Association of the Diabetes and Pregnancy Study Groups; CDA, Canadian Diabetes Association; NR, not reported; OR, odds ratio; CI, confidence interval.
Bold marking indicates statistically significant results.
[a]For fetal outcomes, data related to twins; [b]Includes gestational hypertension and preeclampsia.

Table 4. Comparing of neonatal outcomes between women who were 75-g IADPSG-positive, CDA-negative (Group 3 in Table 2); vs. any controls.

Author, (origin) (Ref)	Macrosomia	LGA	Preterm birth	NICU admission	Neonatal hypoglycemia
Bodmer-Roy, 2012 (Canada) (15)	20/186 (10.8%) vs. 32/372 (8.6%)	17/186 (9.1%) vs. 22/372 (5.9%)	12/186 (6.5%) vs. 22/372 (5.9%)	12/186 (6.5%) vs. 20/372 (5.4%)	4/186 (2.2%) vs. 16/372 (4.3%)
Mayo, 2015 (Canada) (19)	19/155 (12.3%) vs. 443/4709 (9.4%)	21/155 (13.5%) vs. 389/4709 (8.2%)	NR	11/155 (7.1%) vs. 154/4709 (3.3%)	3/155 (1.9%) vs. 54/4709 (1.1%)
Tward, 2016 (Canada)[a] (21)	NR	NR	NR	89/198 (44.9%) vs. 993/2410 (41.2%)	NR
Total	39/341 (11.4%) vs. 475/5081 (9.3%)	38/341 (11.1%) vs. 411/5081 (8.1%)	12/186 (6.5%) vs. 22/372 (5.9%)	112/539 (20.8%) vs. 1167/7491 (15.6%)	7/341 (2.0%) vs. 70/5081 (1.4%)
OR (95% CI)	1.32 (0.90–1.92)	**1.69 (1.15–2.48)**	1.10 (0.53–2.27)	1.27 (0.98–1.63)	0.79 (0.35–1.78)
I^2	0%	15%	0%	74%	0%

IADPSG, International Association of the Diabetes and Pregnancy Study Groups; CDA, Canadian Diabetes Association; NR, not reported; OR, odds ratio; CI, confidence interval; NICU, neonatal intensive care unit; LGA, large for gestational age.
Bold marking for statistically significant results.
[a]For fetal outcomes, data related to twins.

Table 5. Comparing of maternal outcomes between women who were 75-g IADPSG-positive, NICE-negative (Group 4 in Table 2); vs. any controls.

Author, (origin) (Ref)	Preeclampsia	Polydramnios	Live birth	Intrauterine fetal death	Cesarean delivery.
Meek, 2015 (UK) (20)	39/387 (10.1%) vs. 174/2406 (7.2%)	15/387 (3.9%) vs. 106/2406 (4.4%)	386/387 (99.7%) vs. 2401/2406 (99.8%)	1/387 (0.3%) vs. 5/2406 (0.2%)	147/387 (38.0%) vs. 815/2406 (33.9%)
Total	39/387 (10.1%) vs. 174/2406 (7.2%)	15/387 (3.9%) vs. 106/2406 (4.4%)	386/387 (99.7%) vs. 2401/2406 (99.8%)	1/387 (0.3%) vs. 5/2406 (0.2%)	147/387 (38.0%) vs. 815/2406 (33.9%)
OR (95% CI)	**1.44 (1.00–2.07)**	0.87 (0.50–1.52)	0.80 (0.09–6.90)	1.24 (0.14–10.68)	1.20 (0.96–1.49)
I^2	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

IADPSG, International Association of the Diabetes and Pregnancy Study Groups; NICE National Institute for Health and Care Excellence; OR, odds ratio; CI, confidence interval.
Bold marking for statistically significant results.

Table 6. Comparing of neonatal outcomes between women who were 75 g IADPSG-positive, NICE-negative (Group 4 in Table 2); vs. any controls.

Author, (origin) (Ref)	Macrosomia	LGA	SGA	Premature delivery	NICU admission
Meek, 2015 (UK) (20)	112/387 (28.9%) vs. 403/2406 (16.8%)	115/387 (29.7%) vs. 406/2406 (16.9%)	24/387 (6.4%) vs. 224/2406 (9.6%)	29/387 (7.5%) vs. 127/2406 (5.3%)	22/387 (5.7%) vs. 143/2406 (5.9%)
Total	112/387 (28.9%) vs. 403/2406 (16.8%)	115/387 (29.7%) vs. 406/2406 (16.9%)	24/387 (6.4%) vs. 224/2406 (9.6%)	29/387 (7.5%) vs. 127/2406 (5.3%)	22/387 (5.7%) vs. 143/2406 (5.9%)
OR (95% CI)	**2.02 (1.59–2.58)**	**2.08 (1.63–2.65)**	0.64 (0.42–1.00)	1.45 (0.96–2.21)	0.95 (0.60–1.51)
I^2	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

IADPSG, International Association of the Diabetes and Pregnancy Study Groups; NICE National Institute for Health and Care Excellence; OR, odds ratio; CI, confidence interval; LGA, large for gestational age; NICU, neonatal intensive care unit; SGA, small for gestational age.
Bold marking for statistically significant results.

Table 7. Comparing of maternal outcomes between women who were 100-g IADPSG-positive, C&C-negative (Group 5 in Table 2); vs. any controls.

Author, (origin) (Ref)	Gestational hypertension	Preeclampsia	Polydramnios	Shoulder dystocia	Cesarean delivery	Live birth	Intrauterine fetal death
Lapolla, 2011 (Italy) (14)	9/112 (8.0%) vs. 76/1815 (4.2%)	NR	NR	NR	49/112 (43.6%) vs. 564/1815 (31.1%)	NR	NR
Benhalima, 2013 (Belgium) (16)	3/160 (1.9%) vs. 215/6345 (3.4%)	1/160 (0.6%) vs. 38/6345 (0.6%)	NR	6/160 (3.9%) vs. 89/6345 (1.4%)	49/160 (30.5%) vs. 1478/6345 (23.3%)	NR	NR
Ethridge, 2014 (USA) (17)	23/281 (8.2%) vs. 498/7771 (6.4%)	NR	NR	2/281 (0.71%) vs. 65/7771 (0.84%)	82/281 (29.2%) vs. 1818/7771 (23.4%)	NR	NR
Liao, 2014 (China) (18)	40/1314 (3.0%) vs. 36/2666 (1.4%)	26/1314 (2.0%) vs. 28/2666 (1.1%)	8/1314 (0.61%) vs. 22/2666 (0.81%)	NR	NR	1304/1314 (99.2%) vs. 2654/2666 (99.6%)	10/1314 (0.8%) vs. 12/2666 (0.4%)
Total	75/1867 (4.0%) vs. 825/18597 (4.4%)	27/1474 (1.8%) vs. 66/9011 (0.7%)	8/1314 (0.61%) vs. 22/2666 (0.81%)	8/441 (1.8%) vs. 154/14116 (1.1%)	180/553 (32.5%) vs. 3860/15931 (24.2%)	1304/1314 (99.2%) vs. 2654/2666 (99.6%)	10/1314 (0.8%) vs. 12/2666 (0.4%)
OR (95% CI)	**1.58 (1.21–2.07)**	**1.82 (1.09–3.05)**	0.74 (0.33–1.66)	1.76 (0.86–3.61)	**1.46 (1.21–1.75)**	0.59 (0.25–1.37)	1.70 (0.73–3.94)
I^2	15%	0%	0%	0%	0%	0%	0%

IADPSG, International Association of the Diabetes and Pregnancy Study Groups; C&C Carpenter and Coustan; NR, not reported.
Bold marking for statistically significant results.

Table 8. Comparing of neonatal outcomes between women who were 100-g IADPSG-positive, C&C-negative (Group 5 in Table 2); vs. any controls.

Author, (origin) (Ref)	Macrosomia	LGA	SGA	Preterm birth	NICU admission	Neonatal hypoglycemia
Lapolla, 2011 (Italy) (14)	12/112 (10.8%) vs. 145/1815 (8.0%)	20/112 (18.1%) vs. 272/1815 (15.0%)	3/112 (2.8%) vs. 58/1815 (3.2%)	NR	NR	NR
Benhalima, 2013 (Belgium) (16)	14/160 (8.5%) vs. 577/6345 (9.1%)	17/160 (10.8%) vs. 571/6345 (9.0%)	NR	47/160 (29.2%) vs. 1643/6345 (25.9%)	19/160 (12.0%) vs. 692/6345 (10.9%)	NR
Ethridge 2014 (USA) (17)	27/281 (9.6%) vs. 371/7771 (5.0%)	56/281 (19.9%) vs. 707/7771 (8.8%)	NR	NR	24/281 (8.5%) vs. 520/7771 (6.7%)	NR
Liao, 2014 (China) (18)	22/1314 (1.7%) vs. 60/2666 (2.3%)	64/1314 (4.9%) vs. 138/2666 (5.2%)	10/1314 (0.8%) vs. 48/2666 (1.8%)	66/1314 (5.0%) vs. 156/2666 (5.9%)	73/1314 (5.6%) vs. 106/2666 (4.0%)	18/1314 (0.7%) vs. 18/2666 (0.7%)
Total	75/1867 (4.0%) vs. 1153/18597 (6.2%)	157/1867 (8.4%) vs. 1688/18597 (9.1%)	13/243 (5.3%) vs. 106/4481 (2.4%)	113/1474 (7.7%) vs. 1799/9011 (20.0%)	116/1755 (6.6%) vs. 1318/16782 (7.9%)	18/1314 (1.3%) vs. 18/2666 (0.7%)
OR (95% CI)	1.20 (0.93–1.55)	**1.36 (1.13–1.64)**	**0.49 (0.27–0.89)**	**1.67 (1.33–2.10)**	**1.32 (1.06–1.64)**	**2.04 (1.06–3.94)**
I^2	38%	74%	0%	87%	35%	Not applicable

IADPSG, International Association of the Diabetes and Pregnancy Study Groups; C&C Carpenter and Coustan; NR, not reported; OR, odds ratio; CI, confidence interval; LGA, large for gestational age; NICU, neonatal intensive care unit; SGA, small for gestational age.
Bold marking for statistically significant results.

Table 9. Comparing of maternal outcomes between study groups vs. any controls.

Study groups (Ref)	Gestational hypertension	Preeclampsia	Hypertensive complications[a]	Polydramnios	Live birth	Intrauterine fetal death	Shoulder dystocia	Cesarean delivery
75-g IADPSG positive; CDA negative (Group 3 in Table 1) (15,19,21)	**2.55 (1.41–4.61)**	**2.75 (1.38–5.45)**	**1.81 (1.19–2.76)**	NR	NR	NR	0.88 (0.34–2.28)	**1.68 (1.34–2.11)**
75-g IADPSG positive; NICE negative (Group 4 in Table 1) (20)	NR	**1.44 (1.00–2.07)**	NR	0.87 (0.50–1.52)	0.80 (0.09–6.90)	1.24 (0.14–10.68)	NR	1.20 (0.96–1.49)
100-g IADPSG positive; C&C negative (Group 5 in Table 1) (14,16–18)	**1.58 (1.21–2.07)**	**1.82 (1.09–3.05)**	NR	0.74 (0.33–1.66)	0.59 (0.25–1.37)	1.70 (0.73–3.94)	1.76 (0.86–3.61)	**1.46 (1.21–1.75)**

IADPSG, International Association of Diabetes Pregnancy Study Group; CDA, Canadian Diabetes Association; NICE, National Institute for Health and Care Excellence; C&C, Carpenter and Coustan; NR, not reported.
Bold marking for statistically significant results.
[a]Includes gestational hypertension and preeclampsia.

Table 10. Comparing of neonatal outcomes between study groups vs. any controls.

Study groups	Macrosomia	LGA	SGA	Preterm birth	NICU admission	Neonatal hypoglycemia
75-g IADPSG positive; CDA negative (Group 3 in Table 1) (15,19,21)	1.32 (0.90–1.92)	**1.69 (1.15–2.48)**	NR	1.10 (0.53–2.27)	1.27 (0.98–1.63)	0.79 (0.35–1.78)
75-g IADPSG positive; NICE negative (Group 4 in Table 1) (20)	**2.02 (1.59–2.58)**	**2.08 (1.63–2.65)**	0.64 (0.42–1.00)	1.45 (0.96–2.21)	0.95 (0.60–1.51)	NR
100-g IADPSG positive; C&C negative (Group 5 in Table 1) (14,16–18)	1.20 (0.93–1.55)	**1.36 (1.13–1.64)**	**0.49 (0.27–0.89)**	**1.67 (1.33–2.10)**	**1.32 (1.06–1.64)**	**2.04 (1.06–3.94)**

IADPSG, International Association of Diabetes Pregnancy Study Group; CDA, Canadian Diabetes Association; NICE, National Institute for Health and Care Excellence; C&C, Carpenter and Coustan criteria; LGA, large for gestational age; SGA, small for gestational age; NICU, neonatal intensive care unit; NR, not reported.
Bold marking indicates statistically significant results.

106/4481 (2.4%); OR 0.49, 95% CI 0.27–0.89] were significantly less common. Our main outcome, macrosomia, was more frequent in women positive at 100-g IADPSG criteria and C&C-criteria negative, but did not reach a statistically significant difference [75/1867 (4.0%) vs. 1153/18597 (6.2%); OR 1.20, 95% CI 0.93–1.55] (Table 7 and 8).

We identified no study that evaluated whether treatment of women meeting criteria for GDM by IADPSG criteria but not by other less strict criteria has an effect on adverse pregnancy outcomes compared with no treatment.

Discussion

This meta-analysis showed that women meeting criteria for GDM by IADPSG criteria but not by other less strict criteria have an increased risk of adverse pregnancy outcomes such as gestational hypertension, preeclampsia and LGA, compared with GDM-negative controls. These findings are limited by the risk of bias of the included studies and by the high heterogeneity within the studies.

When analyzing outcomes of all study groups with respect to all control groups for maternal outcomes, we found that gestational hypertension and preeclampsia were consistently significantly more common in women who were GDM positive by more strict IADPSG criteria compared with GDM-negative controls, and cesarean delivery was also more common, with two of three analyses being statistically significant (Table 9). When analyzing outcomes of all study groups with respect to all control groups for neonatal outcomes, we found that LGA was consistently significantly more common in women who were GDM positive by more strict IADPSG criteria compared with GDM-negative controls, and macrosomia and preterm birth were also more common, with only one of the analyses being statistically significant; SGA was less common in the two available analyses, with one of these being statistically significant (Table 10).

Despite continuing controversy over whether the One Step test or the Two Step tests should be used for GDM screening, we identified no study that evaluated if treatment of women meeting criteria for GDM by IADPSG criteria (One Step test) but not by other less strict criteria has an effect on adverse pregnancy outcomes compared with no treatment. Moreover, none of the included studies treated for GDM the study group with milder disease (positive for IADPSG criteria, but negative for less stringent criteria).

We are not aware of such a comprehensive systematic review on maternal and neonatal outcomes in women meeting criteria for GDM by IADPSG criteria but not by other less strict criteria compared with GDM-

negative controls. The first issue in deciding whether to use the One Step or the Two Step for GDM screening and diagnosis is to ascertain if women diagnosed with the One Step, but not the Two Step, are at increased risk for complications compared with GDM-negative controls. The fact that for the first time a comprehensive review finds that gestational hypertension, preeclampsia and LGA, as well as possibly cesarean delivery, macrosomia and preterm birth, are more frequent, and SGA possibly less frequent, in women diagnosed with GDM by the One Step, but not the Two Step, is an important strength of our study. Moreover, none of the studies treated women identified with the One Step, but not the Two Step, so the results are not affected by GDM therapy.

There are also several limitations to our study. In each study group we identified only a few studies, and, importantly, no one was a randomized controlled trial (RCT). We also found a large variety of different criteria (IADPSG, WHO, NICE, CDA, C&C) for screening for GDM used in the literature, as can be seen in the Supplementary material (Table S1). Moreover, some studies used 75-g (IADPSG) criteria in women who instead had the 100-g glucose load. Furthermore, in study group 5 [women who had at least one positive value on the 100-g OGTT according to IADPSG criteria, but were negative by C&C criteria at the 100-g OGTT test (100-g IADPSG-positive; C&C-negative)] the authors applied IADPSG criteria in women who underwent 100-g OGTT rather than 75-g OGTT.

To compare the One Step test to the Two Step tests for GDM screening and diagnosis, several possible study designs have been evaluated in the literature.

Only one RCT has been published in which women underwent both the One Step and the Two Step test. Weiss et al. concluded that, although in metabolically healthy women both different GDM screening approaches lead to statistically different blood glucose levels at 1 and 2 h, in GDM 1-h glucose levels do not differ after a 75-g or 100-g load, and this is due to elevated insulin resistance shown by a low insulin/glucose quotient at 1 h. For comparison of tests in GDM only, 2-h values must be adjusted by 16 mg/dL after different loading (22).

Three RCTs comparing the One Step with the Two Step approaches have been published (7,8,23–28). The meta-analysis of the three RCTs included 2,333 women. No significant difference in the incidence of GDM was found comparing the One Step vs. the Two Step approaches (8.4% vs. 4.3%; RR 1.64, 95% CI 0.77 to 3.48). Women screened with the One Step approach had a significantly lower risk of preterm birth (PTB) (3.7% vs. 7.6%; RR 0.49, 95% CI 0.27 to 0.88), cesarean delivery (16.3% vs. 22.0%; RR 0.74, 95% CI 0.56 to 0.99), macrosomia (2.9% vs. 6.9%; RR 0.43, 95% CI 0.22 to 0.82), neonatal hypoglycemia (1.7% vs. 4.5%; RR 0.38, 95% CI 0.16 to 0.90), and admission to neonatal intensive care unit (NICU) (4.4% vs. 9.0%; RR 0.49, 95% CI 0.29 to 0.84), compared to those randomized to screening with the Two Step approach (29).

Several prospective non-RCTs or retrospective studies comparing the incidence of GDM and/or outcomes between the One Step and Two Step methods have also been published (30–37). Polled data of these studies show that GDM-positive women at One Step test, when treated, have better maternal and neonatal outcomes, compared with treated women GDM positive at Two Step test.

In summary, compared with GDM-negative women, women positive at the One Step test by IADPSG criteria but negative at the Two Step test are at increased risk for gestational hypertension, preeclampsia and LGA, as well as possibly cesarean delivery, macrosomia and preterm birth, while possibly being at decreased risk for SGA. Given the fact that the One Step approach has been often associated in RCTs (7,8,28,38,39) with better maternal and perinatal outcomes, including lower risk of preterm birth, cesarean delivery, macrosomia, neonatal hypoglycemia, admission to NICU and lower mean birthweight, compared with the Two Step approach, consideration should be given to universal adoption of the One Step approach using the IADPSG criteria for GDM screening and diagnosis.

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Supporting information

Additional Supporting Information may be found in the online version of this article:

Table S1. Criteria for gestational diabetes mellitus diagnosis.