

ONE- STEP COMPARED WITH TWO-STEP GESTATIONAL DIABETES SCREENING AND PREGNANCY OUTCOMES A SYSTEMATIC REVIEW

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Abstract

Background: Carbohydrate disorders, including gestational diabetes mellitus (GDM) and pregestational diabetes, have significant impacts on maternal, fetal, and neonatal health.

Aim: This study aims to conduct a systematic review and analyze pooled data to evaluate how the choice of GDM testing strategy influences pregnancy outcomes.

Methods: This systematic review adhered to the PRISMA guidelines. The study question and eligibility criteria were defined using the PICOT method, focusing on pregnant patients and comparing IADPSG one-step to Carpenter-Coustan two-step testing in the late mid-trimester

Results: Three randomized controlled trials (RCTs) were included, involving a total of 2,333 participants. The one-step approach demonstrated a non-significant difference in GDM incidence compared to the two-step approach. However, the one-step approach was associated with significantly improved maternal and perinatal outcomes

Conclusion: This systematic review provides insights into the comparison of One Step versus Two Step approaches for gestational diabetes screening and their impact on maternal and perinatal outcomes. While the incidence of GDM did not significantly differ between the two approaches

Keywords: gestational diabetes, two-step approach, systematic review, pregnancy outcomes.

INTRODUCTION

Carbohydrate disorders, such as gestational diabetes mellitus (GDM) and pregestational DM, are common health issues during pregnancy, leading to both short- and long-term effects on mothers, fetuses, and newborns. Approximately 6-18% of pregnancies are affected by diabetes. The International Diabetes Federation (IDF) reported that around 1 in 7 births in 2015 experienced hyperglycemia during pregnancy.¹

Management for women with GDM involves a combination of diet, physical activity, and medication (oral hypoglycemic agents or insulin). The primary goal is to achieve optimal glycemic control while avoiding hypoglycemia, which helps reduce maternal and neonatal complications. However, there is ongoing global debate about the most effective approach and criteria for GDM screening and diagnosis. Several randomized controlled trials (RCTs) have been conducted to compare the one-step and two-step methods for GDM screening and diagnosis. Considerable efforts, both in terms of time and resources, have been devoted to establishing the most effective diagnostic criteria for gestational diabetes mellitus (GDM). However, the ongoing debate between one-step and two-step testing approaches remains unresolved even in 2022, mirroring the situation back in 2008 when the HAPO study was published. Over the years, numerous studies, including two significant randomized controlled trials, have contributed to our understanding of one-step versus two-step testing for GDM.^{2,3}

Management for women with GDM involves a combination of diet, physical activity, and medication (oral hypoglycemic agents or insulin). The primary goal is to achieve optimal glycemic control while avoiding hypoglycemia, which helps reduce maternal and neonatal complications. However, there is ongoing global debate about the most effective approach and criteria for GDM screening and diagnosis. Several randomized controlled trials (RCTs) have been conducted to compare the one-step and two-step methods for GDM screening and diagnosis.⁴

We aim to conduct a systematic review and analyze pooled data to evaluate how the choice of GDM testing strategy influences pregnancy outcomes.

Method

Search Strategy

This study adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) reporting guidelines. The study question and eligibility criteria were defined using the PICOT method. Pregnant patients were included in the review, and the focus was on comparing IADPSG one-step to Carpenter-Coustan two-step testing in the late mid-trimester (targeting 24–28 weeks) with clinically relevant outcomes.

A search strategy was created by a medical librarian to identify studies related to the diagnosis of gestational diabetes using one-step or two-step testing. The search was conducted on various databases without any filters, including Ovid Medline, Embase.com, Scopus, Cochrane Central. All data used in the study were de-identified and publicly available, eliminating the need for Institutional Review Board approval.

Table 1. Literature search strategy

Database	Keywords	Periods	Results
Ovid Medline	"screening" OR "diagnosis" AND "gestational" OR "maternal" AND "diabetes" AND "review" OR "clinical trial" AND "two-step" AND "one-step"	2010-2020	358
Embase.com	"screening" OR "diagnosis" AND "gestational" OR "maternal" AND "diabetes" AND "review" OR "clinical trial" AND "two-step" AND "one-step"	2010-2020	118
Scopus	"screening" OR "diagnosis" AND "gestational" OR "maternal" AND "diabetes" AND "review" OR "clinical trial" AND "two-step" AND "one-step"	2010-2020	599
Cochrane central	"screening" OR "diagnosis" AND "gestational" OR "maternal" AND "diabetes" AND "review" OR "clinical trial" AND "two-step" AND "one-step"	2010-2020	452

Eligibility Criteria

All studies were assessed for eligibility based on the following inclusion and exclusion criteria. Inclusion criteria were: (1) original articles investigating the comparison of one-step and two-step gestational diabetes screening methods and

their impact on pregnancy outcomes; (2) articles published within the last 10 years (2010–2020); (3) full-text articles available; and (4) articles published in English. Exclusion criteria included: articles not indexed by major databases, editorials, reviews, and studies that did not evaluate the specific focus of interest in this systematic review. The research selection was conducted in three phases. Firstly, the titles and abstracts of all search results were screened and evaluated for relevance. Secondly, full access was obtained for all potentially eligible studies. Finally, the systematic review included only those studies meeting the pre-defined inclusion criteria.

Data Extraction and Parameter Measured

Data extraction was conducted by all authors independently. The following information related to the comparison between one-step and two-step gestational diabetes screening methods and their impact on pregnancy outcomes was collected: author, year of publication, study design, sample size, pregnancy outcomes, incidence of gestational diabetes, diagnostic criteria used, and relevant statistical measures (e.g., odds ratios, relative risks, p-values). Any discrepancies in data extraction, article retrieval, or statistical analysis were resolved through consensus among the authors.

Results

The electronic literature search yielded 2,456 citations, out of which 979 duplicates were identified and removed, resulting in 1,477 unique citations (Figure 1). Each title was reviewed for relevance, and 414 abstracts were screened. Ultimately, 80 abstracts or full-text manuscripts were assessed against the inclusion and exclusion criteria. No additional studies were found through the review of selected paper bibliographies against the study criteria. Several studies were excluded for various reasons, such as not including clinical outcomes of interest, not comparing one- to two-step testing, focusing solely on patients with a GDM diagnosis rather than population-level screening, or having stringent exclusion criteria that limited generalizability.

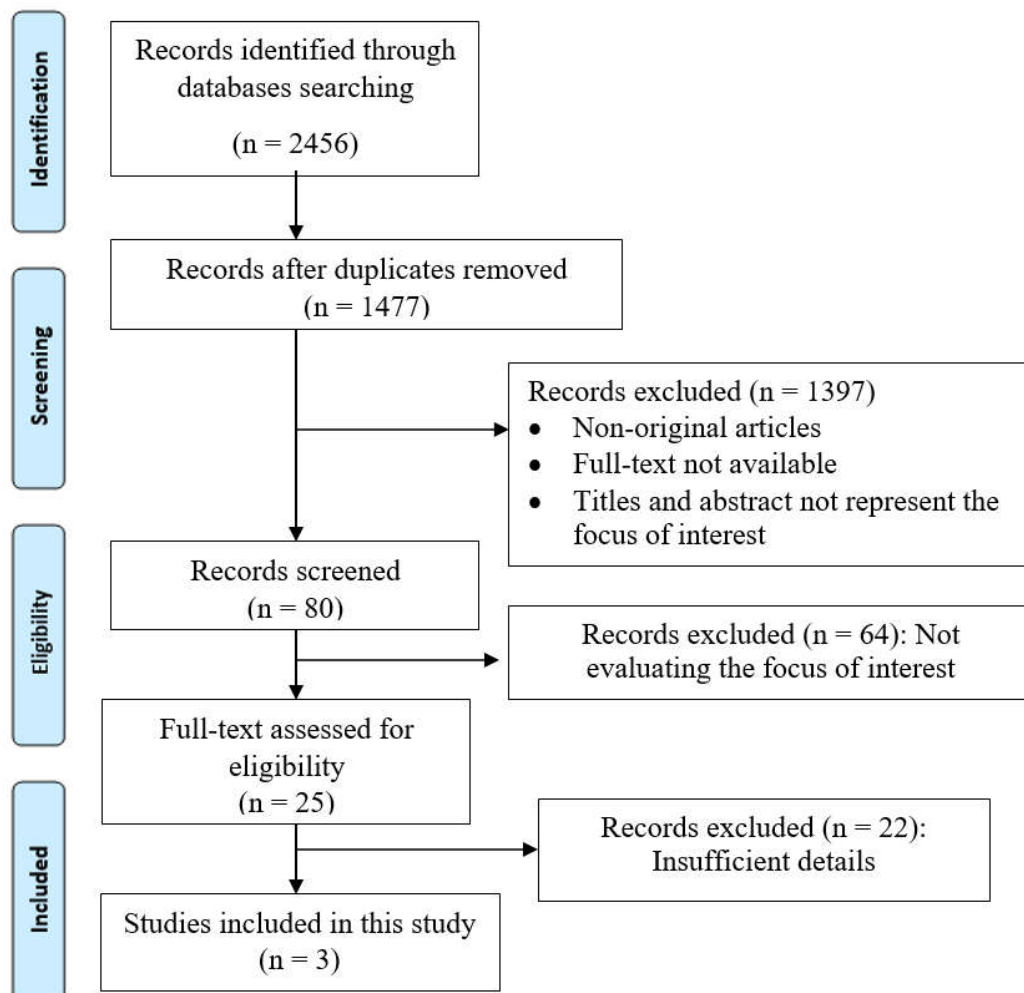


Figure 1. PRISMA flow diagram

Among the 2,333 women included in the systematic review, 910 were randomly assigned to the one-step approach (2hr, 75gr), while 1,423 underwent randomization for the two-step approach (Table 2). For the two-step approach, one trial implemented a 50gr 1hr test followed by a 100gr 3hr test. In another trial, all women underwent a 50gr 1hr test before randomization and were excluded if their glucose levels were ≥ 200 mg/dL. The control group of this trial then underwent a 100gr 3hr test. The third trial had three arms, with two control groups: one with a two-step 50gr 1hr test

followed by a 100gr 3hr test, and the other with a two-step 50gr 1hr test followed by a 75gr 2hr test. Both control groups from the third trial were considered as control groups for this review (Table 3).

Table 2. Characteristics of included trial

Author and year	Population screened	Timing of screening	Risk factor	Fasting	Sample size
Meltzer 2010 ⁵	All pregnant women without pregestational DM	24-28 weeks	Presence of multiple risk factors	Yes	1,500 (500 vs 1,000)
Sevket 2014 ⁶	Singleton gestations without pregestational DM	24-28 weeks	Not stated	Yes	786 (386 vs 400)
Scifres 2015 ⁷	Spontaneous conceived, singleton gestations without pregestational DM	18-24 weeks	Not stated	Yes	47 (24 vs 23)

Table 3. Study design of included trials

Author and year	Study group	Cutoff	1 st Control group	Control group cutoff	2 nd Control group
Meltzer 2010 ⁵	One step (2hr, 75gr)	Fasting 95 mg/dL; 1h 190 mg/dL; 2h 160 mg/dL	Two step (50gr 1hr; 100gr 3hr)	Fasting 105 mg/dL; 1h 190 mg/dL; 2h 165 mg/dL; 3h 145 mg/dL	Two step (50gr 1hr; 75gr 2hr)
Sevket 2014 ⁶	One step (2hr, 75gr)	fasting 92 mg/dL; 1h 180 mg/dL; 2h 153 mg/dL	Two step (50gr 1hr; 100gr 3hr)	Fasting 95 mg/dL; 1h 180 mg/dL; 2h 155 mg/dL; 3h 140 mg/dL	-
Scifres 2015 ⁷	One step (2hr,75gr) pregestational DM	fasting 92 mg/dL; 1h 180 mg/dL; 2h 153 mg/dL	Two step (50gr 1hr; 100gr 3hr)	Fasting 95 mg/dL; 1h 180 mg/dL; 2h 155 mg/dL; 3h 140 mg/dL	-

Discussion

In the realm of gestational diabetes mellitus (GDM) screening and its impact on pregnancy outcomes, our systematic review sought to compare the one-step approach with the two-step approach. We analyzed three randomized controlled trials (RCTs) and found that the one-step approach demonstrated a non-significant difference in GDM incidence when compared to the two-step approach. However, our investigation unveiled compelling evidence that the one-step approach is associated with significantly improved maternal and perinatal outcomes.

Out of three randomized controlled trials (RCTs) analyzed, the one-step approach showed a non-significant difference in GDM incidence compared to the two-step approach. However, the study found that the one-step approach was associated with better maternal and perinatal outcomes, including significantly lower risks of preterm birth (PTB), cesarean delivery, macrosomia, large for gestational age (LGA) babies, neonatal hypoglycemia, admission to the neonatal intensive care unit (NICU), and lower mean birth weight. Although not statistically significant, there was a trend suggesting benefits in other secondary outcomes.^{8,9}

The review identified that the one-step approach (75-gram 2-hour test using IADPSG criteria) led to a higher incidence of GDM compared to the two-step approach (50-gram 1-hour test followed by 3-hour 100-gram test using C&C criteria). Despite the increased GDM incidence, the one-step approach showed significant advantages in various maternal and perinatal outcomes, supporting its potential recommendation. The study highlights the importance of considering these findings in clinical practice and future cost-effectiveness analyses to guide GDM screening strategies. The use of the one-step approach could potentially lead to faster results for GDM diagnosis, although it requires fasting for all women being screened. The different approaches and criteria for GDM screening and diagnosis have been a topic of debate, with varying recommendations from different organizations.¹⁰

The systematic review provides valuable insights into the advantages and disadvantages of each approach, suggesting potential benefits of the one-step approach. However, further research, including more level 1 data and cost-effectiveness analyses, is necessary to establish robust recommendations for GDM screening. This study may be the first to conduct a systematic review of RCTs comparing the one-step and two-step approaches for GDM screening. It is worth noting that a prior Cochrane review by Farrar et al. evaluated different testing strategies for GDM diagnosis, but it did not include any studies comparing the one-step versus two-step approach.¹¹

Our systematic review also explored the use of different criteria for GDM screening. When comparing the one-step approach using the IADPSG criteria with the two-step approach employing the C&C criteria, the former exhibited a significantly higher incidence of GDM (13.9% vs. 5.7%). Nonetheless, the one-step approach proved superior in terms of pregnancy outcomes, supporting its potential recommendation for clinical practice.¹²

The contentious issue of GDM screening approaches has seen varying recommendations from different organizations. The one-step approach using IADPSG criteria has been embraced by FIGO, WHO, and other societies, while ACOG

and ADA have backed the two-step approach. The central argument for the one-step approach is its increased GDM diagnosis rate, albeit with a higher false-positive rate, without substantial improvements in fetomaternal outcomes. However, our systematic review's findings demonstrate that, despite the increased GDM incidence, the one-step approach yields notable benefits in terms of pregnancy outcomes.¹³

Nonetheless, the drawbacks of the IADPSG criteria for GDM diagnosis center on a single value of glucose measurement, potentially leading to higher false-positive GDM diagnoses when compared to the Carpenter and Coustan criteria requiring multiple high glucose values. Lee et al. have shown that IADPSG criteria result in a higher incidence of GDM without clear improvement in perinatal outcomes when compared to the two-step approach. Thus, these considerations highlight the importance of thoroughly evaluating the pros and cons of each screening approach.¹⁴

The systematic review has several strengths, including a comprehensive search strategy, strict inclusion criteria, and a rigorous assessment of the risk of bias of the included studies. The review also used appropriate statistical methods to analyze the data and assess the heterogeneity of the studies. Additionally, the review was registered with the PROSPERO International Prospective Register of Systematic Reviews, which enhances the transparency and credibility of the review. However, the review also has some limitations. Firstly, the number of included studies was small, which may limit the generalizability of the findings. Secondly, the quality of the included studies was moderate, which may affect the validity of the results.

Conclusion

This systematic review aimed to compare the One Step versus Two Step approaches for gestational diabetes mellitus (GDM) screening and evaluate their impact on maternal and perinatal outcomes. The review included three randomized controlled trials with a total of 2,333 participants. The results showed no significant difference in the incidence of GDM between the One Step and Two Step approaches. However, the One Step approach was associated with a lower risk of adverse maternal and neonatal outcomes, such as preterm birth, cesarean delivery, macrosomia, large for gestational age (LGA), neonatal intensive care unit (NICU) admission, and neonatal hypoglycemia.

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