THE ANALYSIS STUDY OF ONE-STEP COMPARED WITH TWO-STEP GESTATIONAL DIABETES SCREENING AND PREGNANCY OUTCOMES: A COMPREHENSIVE SYSTEMATIC REVIEW

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ABSTRACT

Background: *Gestational diabetes mellitus (GDM) is a condition of glucose intolerance developed during pregnancy. Many women with GDM experience pregnancy -related complications, which primarily affect the fetus and include macrosomia, congenital malformations, prematurity, neonatal intensive care unit (NICU) admission, and respiratory distress syndrome.*

The aim: *The aim of this study to show about the analysis study of one-step compared with two step gestational diabetes screening and pregnancy outcomes.*

Methods: *By the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) 2020, this study was able to show that it met all of the requirements. This search approach, publications that came out between 2014 and 2024 were taken into account. Several different online reference sources, like Pubmed, SagePub, and Sciencedirect were used to do this. It was decided not to take into account review pieces, works that had already been published, or works that were only half done.*

Result: *Eight publications were found to be directly related to our ongoing systematic examination after a rigorous three-level screening approach. Subsequently, a comprehensive analysis of the complete text was conducted, and additional scrutiny was given to these articles.*

Conclusion: *Patients undergoing one- and two-step testing had equal rates of LGA infants, despite a greater likelihood of GDM diagnosis and treatment with one-step testing. Our findings favor two-step testing to minimize the increased burden of GDM diagnosis resulting from one-step testing. However, understanding the long-term implications of such a strategy across the life course is critically important to inform the public health path forward.*

Keyword: *Diabetes, gestational, screening, one step, two step.*

INTRODUCTION

Gestational diabetes mellitus (GDM) is defined as impaired glucose tolerance first recognized during pregnancy. GDM affects about 7–20% of pregnant women and this value will probably increase in the future, due in particular to maternal obesity. 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. 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.[1–3]

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. 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), the World Health Organization (WHO), the International Federation of Obstetricians and Gynecologists, the Canadian Diabetes Association (CDA) 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.[1,4]

The common approach to detecting gestational diabetes mellitus is the 2-step protocol recommended by the American College of Obstetricians and Gynecologists. A 50 g, 1-hour glucose challenge at 24 to 28 weeks' gestation is followed by a 100 g, 3-hour oral glucose tolerance test when a screening test threshold is exceeded. Notably, 2 or more elevated values diagnose gestational diabetes mellitus. The 2-step screening test is administered without regard to the time of the last meal, providing convenience by eliminating the requirement for fasting. However, depending upon the cutoff used and population risk factors, approximately 15% to 20% of screened women require the 100 g, 3-hour oral glucose tolerance test. The International Association of Diabetes and Pregnancy Study Groups recommends a protocol of no screening test but rather a diagnostic 75 g, 2-hour oral glucose tolerance test. One or more values above threshold diagnose gestational diabetes mellitus.[5,6]

The 1-step approach requires that women be fasting for the test but does not require a second visit and lasts 2 hours rather than 3. Primarily because of needing only a single elevated value, the 1-step approach identifies 18% to 20% of pregnant women as having gestational diabetes mellitus, 2 to 3 times the rate with the 2-step procedure, but lower than the current United States prediabetes rate of 24% in reproductive aged women.[5]

METHODS
PROTOCOL

By following the rules provided by Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) 2020, the author of this study made certain that it was up to par with the requirements. This is done to ensure that the conclusions drawn from the inquiry are accurate.

CRITERIA FOR ELIGIBILITY

For the purpose of this literature review, we compare and contrast the analysis study of one-step compared with two step gestational diabetes screening and pregnancy outcomes. It is possible to accomplish this by researching of the analysis study of one-step compared with two step gestational diabetes screening and pregnancy outcomes. As the primary purpose of this piece of writing, demonstrating the relevance of the difficulties that have been identified will take place throughout its entirety.

In order for researchers to take part in the study, it was necessary for them to fulfil the following requirements: 1) The paper needs to be written in English, and it needs to determine about the analysis study of one-step compared with two step gestational diabetes screening and pregnancy outcomes. In order for the manuscript to be considered for publication, it needs to meet both of these requirements. 2) The studied papers include several that were published after 2014, but before the time period that this systematic review deems to be relevant. Examples of studies that are not permitted include editorials, submissions that do not have a DOI, review articles that have already been published, and entries that are essentially identical to journal papers that have already been published.

SEARCH STRATEGY

We used "the analysis study of one-step compared with two step gestational diabetes screening and pregnancy outcomes." as keywords. The search for studies to be included in the systematic review was carried out using the PubMed, SagePub, and Sciencedirect databases by inputting the words: ((''Diabetes''[MeSH Subheading] OR '' Gestational diabetes''[All Fields] OR ''Pregnancy'' [All Fields]) AND (''Screening''[All Fields] OR '' One step screening''[All Fields]) AND (''Two step screening''[All Fields]) OR (''Screening gestational diabetes'' [All Fields])) used in searching the literature.

DATA RETRIEVAL

After reading the abstract and the title of each study, the writers performed an examination to determine whether or not the study satisfied the inclusion criteria. The writers then decided which previous research they wanted to utilise as sources for their article and selected those studies. After looking at a number of different research, which all seemed to point to the same trend, this conclusion was drawn. All submissions need to be written in English and cannot have been seen anywhere else.
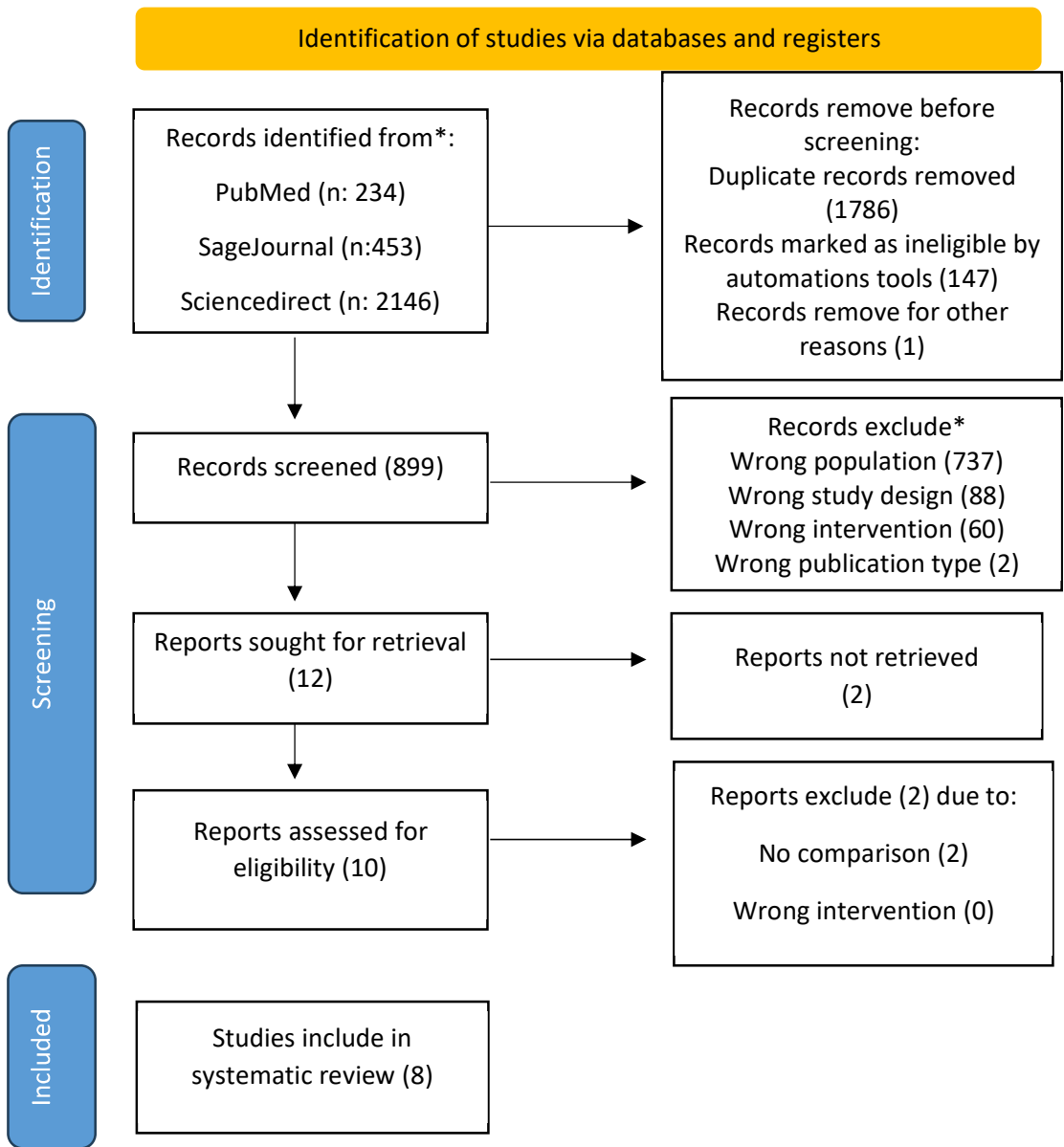

Figure 1. Article search flowchart

Only those papers that were able to satisfy all of the inclusion criteria were taken into consideration for the systematic review. This reduces the number of results to only those that are pertinent to the search. We do not take into consideration the conclusions of any study that does not satisfy our requirements. After this, the findings of the research will be analysed in great detail. The following pieces of information were uncovered as a result of the inquiry that was carried out for the purpose of this study: names, authors, publication dates, location, study activities, and parameters.

QUALITY ASSESSMENT AND DATA SYNTHESIS

Each author did their own study on the research that was included in the publication's title and abstract before making a decision about which publications to explore further. The next step will be to evaluate all of the articles that are suitable for inclusion in the review because they match the criteria set forth for that purpose in the review. After that, we'll determine which articles to include in the review depending on the findings that we've uncovered. This criteria is utilised in the process of selecting papers for further assessment. in order to simplify the process as much as feasible when selecting papers to evaluate. Which earlier investigations were carried out, and what elements of those studies made it appropriate to include them in the review, are being discussed here.

RESULT

Using reputable resources like Science Direct, PubMed, and SagePub, our research team first gathered 2833 publications. A thorough three-level screening strategy was used to identify only eight papers as directly relevant to our ongoing systematic evaluation. Next, a thorough study of the entire text and further examination of these articles were selected. Table 1 compiles the literature that was analyzed for this analysis in order to make it easier to view.

Table 1. The litelature include in this study

Author	Origin	Method	Sample	Result
Luewan, S et al., 2018[7]	Thailand	A prospective study was conducted on singleton pregnancies at low or average risk of GDM. All were screened between 24 and 28 weeks, using the one-step or two-step method based on patients' preference.	648	A total of 648 women were screened: 278 in the one-step group and 370 in the two-step group. The prevalence of GDM was significantly higher in the one-step group; 32.0% versus 10.3%. Baseline characteristics and pregnancy outcomes in both groups were comparable. However, mean birthweight was significantly higher among pregnancies with GDM diagnosed by the two-step approach (3204 ± 555 versus 3009 ± 666 g; p=0.022). Likewise, the rate of large-for-date tended to be higher in the two-step group, but was not significant.
Fuller, KP & Borgida, AF., 2014[8]	USA	This study took place in the Women's Ambulatory Health Services (WAHS) clinic at Hartford Hospital, an inner-city, tertiary care hospital in Hartford, Conn. In July 2011, the WAHS clinic changed its routine GDM screening from the 50-g, two-step process to the 75-g, one-step process.	832	A total of 832 patients delivered during the study period; 10 had preexisting diabetes, 1 had a history of gastric bypass, and 9 were < 18 years of age, leaving 812 patients meeting inclusion criteria. No differences were found between the two groups regarding average BMI, prepregnancy weight, parity, pregnancy weight gain, or race. Of all study patients, 60.4% were overweight or obese, 29.1% were overweight with a BMI of 25–29.9 kg/m^2, and 31.3% were obese with a BMI $\geq$ 30 kg/m^2. The average prepregnancy BMI was 27.7 kg/m^2. The overall distribution of race was Hispanic 74%, African American 16.7%, and Caucasian 7%. The 1-hour, 50-g (two-step) screening was performed in 458 patients, and 75 patients (16.4%) required a 3-hour screening. The 2-hour, 75-g (one-step) screening was performed in 257 patients.
Tehrani, FR et al., 2023[9]	Iran	We conducted a secondary analysis of a randomized community non-inferiority trial of GDM	28771	GDM was diagnosed in 9.3% of the pregnant women who were assigned to the One-step and in 5.4% of those assigned to the Two-step approach with a statistically significant difference between them (p <

		screening in Iran.		0.001). Intention-to-treat analyses showed no significant differences between the One-step and the Two-step group in the unadjusted risks of the adverse pregnancy outcomes of macrosomia, primary cesarean-section, preterm birth, hypoglycemia, hypocalcemia, hyperbilirubinemia, preeclampsia, neonatal intensive care unit admission, birth trauma, low birth weight, and intrauterine fetal death. Results remained unchanged after adjustment for potential confounder variables including gestational age at enrollment and delivery, maternal body mass index, gestational weight gain, type of delivery, treatment modality, and GDM diagnosis in the first trimester.
Goyette, F wt al., 2020[10]	Canada	A retrospective cohort study was performed regrouping all deliveries between 2016 and 2018 in two centers, each using one different screening method.	6188	At interim analysis for the year 2016, a total of 6188 pregnancies, 2664 women in center A (one-step) and 3524 in center B (two-step) were included. The prevalence of GDM was 17.1% in center A (n=456) and 14.8% in center B (n=520). Both populations were comparable in terms of risk factors for LGA except for its ethnic distribution and proportion of obese women (13.1 vs 21.6%). GDM women in center B compared to center A had significant increase in rates of LGA neonates (adjusted OR (OR_a) 2.1, p=0.012); neonatal hypoglycemia (OR_a 2.1, p=0.0001) and neonatal intensive care unit (NICU) admission (2.1, p=0.048). Gestational hypertension's rate was more prevalent in center B (OR_a 2.1, p=0.020) and there was a non statistical trend towards increased rate of caesareans (1.6, p=0.084). Regular prenatal care for borderline women in center B (n=94) compared to GDM care in center A (n=150) resulted in increased rate of LGA babies (OR_a 3.2, p=0.049). Worse maternal outcomes were identified for gestational hypertension (9.7 vs 1.3%, p=0.035) and preeclampsia

				(4.3 vs 0%, p=0.021) in group B vs A, respectively.
Satodiya, M et al., 2016[11]	India	A prospective randomized trial involving screening of 1000 pregnant women for gestational diabetes mellitus was conducted. Women were divided in two groups (500 each).	1000	The incidence of GDM was almost double using one-step versus two-step approach which was 19.2 and 11.8%, respectively. Maternal outcomes were comparable in both the groups except the risk of preterm delivery which was 2.5 times more in group A than group B (odds ratio = 2.43 95% CI 1.01–5.79). Further, fetal outcomes were also comparable except neonatal hypoglycemia which was seen in 29.31% in group A versus 7.4% in group B. In the group B, 15 patients (15.8%) with GDM (based on FBS ≥ 92 mg/dl at first ANC visit) showed clinical symptoms and blood sugars in hypoglycemic range on MNT requiring resumption of normal diet.
Hillier, TA et al., 2021[12]	USA	We performed a pragmatic randomized trial comparing 1-step fasting 75g oral glucose tolerance testing (OGTT) with 2-step screening (non-fasting 50g glucose challenge, followed by 100g OGTT if positive) among all pregnant women treated in 2 health systems.	23792	A total of 23,792 women were randomized. Adherence to randomization was 66% in the 1-step arm and 92% in the 2-step arm. GDM incidence was 16.5% among women randomized to the 1-step approach, versus 8.5% with the 2-step approach [unadjusted relative risk (RR)=1.94, 95% CI 1.79-2.11]. In intention to treat analyses, there were no significant differences between groups in any primary outcome [large for gestational age: 8.9% vs. 9.2%, RR(95%CI) 0.95 (0.87-1.05); perinatal composite: 3.1% vs. 3.0%, 1.04 (0.88-1.23); gestational hypertension/preeclampsia: 13.6% vs. 13.5%, 1.00 (0.93-1.08); primary c-section: 24.0% vs. 24.7%, 0.98 (0.93-1.02)]. Results were materially unchanged in inverse-probability weighted intention-to-treat analyses accounting for differential adherence to screening approaches.
Khalifeh, A et al., 2018[13]	USA	This was a parallel group non-blinded randomized trial conducted at Thomas Jefferson University Hospital	284	284 women agreed to take part in the study and underwent randomization from June 2015 to December 2015. Of them, 249 completed the screening and were followed up for the primary endpoint. Out of the 249 women who completed the screening, 123 were assigned

		(TJUH) in Philadelphia, Pennsylvania from June 2016 to December 2016.		to the one-step group and 126 to the two-step group. GDM occurred in 10 women (8.1%) in the one-step group, and 7 women (5.6%) in the two-step group (p=0.42). Preeclampsia, PTB, induction of labor, mode of delivery, and incidence of OASIS were not significantly different. Perinatal outcomes were similar as well.
Saccone, G et al., 2017[14]	Italy	Electronic databases were searched from their inception until June 2017. We included all randomized controlled trials (RCTs) comparing the one-step with the twostep approaches for the screening and diagnosis of GDM.	2333	Three RCTs (n=2,333 participants) were included in the meta-analysis. 910 were randomized to the one step approach (75gr, 2hr), and 1,423 to the two step approach. No significant difference in the incidence of GDM was found comparing the one step versus 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.

DISCUSSION

Gestational diabetes mellitus (GDM), one of the most common complications of pregnancy, is defined as carbohydrate intolerance of variable severity, with onset or first recognition during pregnancy. According to International Diabetes Federation, prevalence of GDM is approximately 16.7% in 2021, and increases with the presence of risk factors such as obesity and advanced maternal age.[15–17]

Gestational diabetes mellitus is a common chronic disease in pregnancy that impairs the health of several million women worldwide. Formally recognised by O'Sullivan and Mahan in 1964, gestational diabetes mellitus is defined as hyperglycaemia first detected during pregnancy. With the incidence of obesity worldwide reaching epidemic levels, the number of pregnant women diagnosed as having gestational diabetes mellitus is growing, and these women have an increased risk of a range of complications of pregnancy. Quantification of the risk or odds of possible adverse outcomes of pregnancy is needed for prevention, risk assessment, and patient education.[18,19]

In 2014, the U.S. Preventive Services Task Force recommended blood glucose testing for all pregnant women between 24 and 28 weeks of gestation. The American College of Obstetrics and Gynecology (ACOG) supports a two-step approach with a 50 g glucose challenge test (GCT) followed by a diagnostic 100 g oral glucose tolerance test (OGTT). Blood sampling was performed with fasting, and 1, 2, and 3-h after loading of the glucose solution, and diagnosis of GDM was confirmed when more than two values exceeded the National Diabetes Data Group or Carpenter- and Coustan criteria.[15,20]

For well over 50 years, there has been a lack of consensus over the appropriate diagnostic criteria for gestational diabetes mellitus (GDM) and the significance of the diagnosis. Competing diagnostic criteria across the globe have complicated the delivery of healthcare and the design and interpretation of research in GDM. The Hyperglycemia and Adverse

Pregnancy Outcomes (HAPO) study was intended to lead to unification and agreement on the diagnostic criteria for GD. In 2010, the International Association of Diabetes and Pregnancy Study Groups (IADPSG) released their recommendations for a new set of diagnostic criteria, based on the HAPO study outcomes. However, an ongoing global debate continues about when and how to screen and diagnose GDM. A variety of local, regional, and institutional diagnostic criteria continues to be applied in practice, confusing both healthcare delivery and research.[21,22]

Significant time, energy, and resources have been invested in determining optimal diagnostic criteria for gestational diabetes mellitus (GDM). Yet, we are no closer to resolving the one-step versus two-step testing dilemma in 2022 than we were in 2008 when the HAPO study was published. A 2017 Cochrane review concluded there was insufficient evidence to recommend one strategy over the other based on available data. Several studies, including two large randomized controlled trials, published in the interim, advanced our understanding of one- versus two-step testing. The objective of this systematic review and meta-analysis was to use the collective power of pooled data to assess the implications of GDM testing strategy on pregnancy outcomes.[23–25]

CONCLUSION

In conclusion, patients undergoing one- and two-step testing had equal rates of LGA infants, despite a greater likelihood of GDM diagnosis and treatment with one-step testing. Our findings favor two-step testing to minimize the increased burden of GDM diagnosis resulting from one-step testing. However, understanding the long-term implications of such a strategy across the life course is critically important to inform the public health path forward.

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