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ASSESSING SCREENING APPROACHES FOR GESTATIONAL DIABETES MELLITUS: INSIGHTS FROM A PROSPECTIVE STUDY IN INDIA

Siddharth Zabak[1], Ashutosh Bahulekar[2], Shital Patil[3]
[1,2,3]Dept of Obstetrics and Gynaecology, Krishna Institute of Medical Sciences, KVV, Karad

Abstract
Gestational diabetes mellitus (GDM) and impaired glucose tolerance (IGT) pose significant health challenges during pregnancy, warranting effective screening strategies. This study examines differing approaches to screening, comparing the commonly used two-step method in the United States with the simplified Diabetes in Pregnancy Study Group India (DIPSI) technique, specifically within the context of an observational study conducted in Krishna Institute of Medical Sciences, KVV, Karad, India, from April 2022 to September 2023. Ethical approval was obtained from the institutional ethics committee, with participants selected based on first-trimester pregnancy and absence of pre-existing diabetes mellitus. Screening was conducted using the DIPSI technique, aligning with the updated World Health Organization (WHO) standards advocating for a one-step process. Findings underscore the critical importance of early detection and intervention in GDM, revealing associations with adverse maternal and fetal outcomes. Notably, birth weights ranging from 2.0 to 3.0 kg were consistent across GDM and IGT groups, emphasizing the need for vigilant monitoring throughout pregnancy and at birth. These insights contribute to the ongoing discourse on optimizing screening protocols for gestational diabetes mellitus, particularly in resource-constrained settings like India.
Keywords: Gestational Diabetes Mellitus Screening Methods Maternal-Fetal Outcomes DIPSI Technique Resource-Constrained Settings

INTRODUCTION

Gestational Diabetes Mellitus (GDM) represents a significant health concern globally, particularly during pregnancy, posing metabolic and endocrine challenges for both mother and fetus. The prevalence of GDM is on the rise, reflecting a complex interplay of genetic, environmental, and lifestyle factors. Managing GDM effectively is crucial to mitigate the associated risks and ensure favorable maternal and neonatal outcomes. Central to effective management is the early detection of GDM through appropriate screening approaches.

This study delves into the critical importance of assessing screening approaches for GDM, drawing insights from a prospective study conducted in India. The study aimed to evaluate different screening methodologies, focusing on the comparison between the commonly used two-step method in the United States and the simplified Diabetes in Pregnancy Study Group India (DIPSI) technique. By examining these approaches within the Indian context, the study sheds light on the efficacy and feasibility of GDM screening in a diverse and resource-constrained setting.

GDM is characterized by glucose intolerance that develops or is first recognized during pregnancy. It poses risks not only to maternal health but also to fetal well-being, contributing to adverse pregnancy outcomes such as macrosomia, birth trauma, neonatal hypoglycemia, and increased risk of cesarean delivery. Moreover, GDM is associated with long-term complications for both mother and child, including an increased risk of type 2 diabetes mellitus (T2DM) in the mother and metabolic disorders in the offspring. Recognizing the profound impact of GDM on maternal and neonatal health underscores the urgency of implementing effective screening strategies to identify and manage this condition promptly.

In recent years, there has been a growing emphasis on the importance of standardized screening protocols for GDM. However, the optimal approach to screening remains a subject of debate, with variations existing across different regions and healthcare settings. In the United States, the two-step screening method endorsed by the American College of Obstetricians and Gynecologists (ACOG) involves an initial non-fasting oral glucose challenge test (GCT), followed by a fasting oral glucose tolerance test (OGTT) for those who screen positive. While this method has been widely adopted in clinical practice, questions have been raised regarding its efficiency and cost-effectiveness. Contrastingly, the DIPSI technique, pioneered in India, advocates for a simplified one-step screening process involving a single 75-gram oral glucose load administered in the fasting state. This approach aims to streamline the screening process, making it more accessible and feasible, particularly in resource-limited settings where elaborate testing facilities may be scarce. The DIPSI method has gained traction in various parts of the world, offering a promising alternative to traditional screening protocols.

Against this backdrop, the present study sought to contribute to the ongoing discourse on GDM screening by evaluating the performance of the two-step method versus the DIPSI technique within the Indian healthcare context. The study was conducted in Krishna Institute of Medical Sciences, KVV, Karad spanning from April 2022 to September 2023. Findings from this study

hold relevance not only for the local healthcare landscape but also for broader national and global perspectives on GDM screening and management. The overarching objective of the study was to assess the efficacy, feasibility, and clinical implications of the two screening approaches in detecting GDM among pregnant women in India. Ethical approval was obtained from the institutional ethics committee, ensuring adherence to ethical guidelines and principles throughout the study duration. Participant selection criteria encompassed pregnant women in the first trimester without pre-existing diabetes mellitus, reflecting a cohort at risk of developing GDM during pregnancy. Screening for GDM was performed using both the two-step method and the DIPSI technique, with data collected prospectively to enable comparative analysis. In addition to evaluating screening performance, the study aimed to explore the association between GDM diagnosis and maternal-fetal outcomes, including birth weight, gestational age at delivery, mode of delivery, neonatal complications, and maternal postpartum outcomes. By examining these parameters, the study sought to elucidate the clinical significance of timely GDM detection and intervention in optimizing pregnancy outcomes.

The findings of this study are anticipated to contribute valuable insights to the field of maternal-fetal medicine, informing clinical practice guidelines and healthcare policies related to GDM screening and management. By elucidating the strengths and limitations of different screening approaches, the study aims to empower healthcare providers with evidence-based tools to enhance the quality of antenatal care and promote maternal and neonatal well-being. Ultimately, the goal is to reduce the burden of GDM-related complications and improve pregnancy outcomes for women across diverse socio-demographic backgrounds. This study provides a comprehensive overview of the rationale, objectives, and significance of the study on assessing screening approaches for GDM in India. By addressing the main theme of the study, it sets the stage for the subsequent sections, which will delve into the methodology, results, discussion, and conclusions derived from the research findings. Through a multidimensional analysis, the study endeavors to contribute meaningfully to the advancement of knowledge and practice in the field of maternal-fetal medicine, with implications for global healthcare initiatives aimed at promoting maternal and child health.

Research Gap:

Despite the growing recognition of gestational diabetes mellitus (GDM) as a significant health concern, there remains a notable research gap concerning the optimal approach to screening for this condition, particularly in diverse and resource-constrained settings like India. While various screening protocols exist, including the widely adopted two-step method endorsed by the American College of Obstetricians and Gynecologists (ACOG) and the simplified Diabetes in Pregnancy Study Group India (DIPSI) technique, limited comparative research has been conducted to evaluate their efficacy, feasibility, and clinical implications within the Indian healthcare context.

Existing literature predominantly focuses on studies conducted in Western populations, where healthcare infrastructure and patient demographics differ substantially from those in India. Consequently, there is a lack of robust evidence regarding the performance of different screening approaches in diverse ethnic, socioeconomic, and geographic settings. Moreover, studies examining the association between GDM diagnosis and maternal-fetal outcomes often yield conflicting results, highlighting the need for further investigation to elucidate the true impact of GDM on pregnancy outcomes in the Indian population.

Furthermore, while the DIPSI technique has shown promise as a simplified screening method, its widespread adoption and integration into routine clinical practice remain limited. Barriers such as lack of awareness, training, and standardized protocols may impede its implementation, underscoring the importance of research aimed at addressing these challenges and optimizing the delivery of antenatal care for women at risk of GDM in India.

Specific Aims of the Study:

1. To compare the performance of the two-step screening method recommended by ACOG with the simplified DIPSI technique in detecting gestational diabetes mellitus among pregnant women in India.
2. To evaluate the feasibility and acceptability of implementing the DIPSI technique as a routine screening protocol in a diverse healthcare setting.
3. To assess the association between gestational diabetes mellitus diagnosis and maternal-fetal outcomes, including birth weight, gestational age at delivery, mode of delivery, neonatal complications, and maternal postpartum outcomes.
4. To identify barriers and facilitators to the adoption and integration of the DIPSI technique into clinical practice, with a focus on healthcare provider perspectives, patient experiences, and healthcare system factors.

Objectives of the Study:

1. To assess the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the two screening approaches in detecting gestational diabetes mellitus.
2. To compare the cost-effectiveness of the two screening methods, considering factors such as test accuracy, resource utilization, and healthcare expenditure.
3. To explore patient preferences and experiences regarding the screening process, including perceived ease of use, convenience, and satisfaction with the screening protocol.
4. To investigate the impact of gestational diabetes mellitus diagnosis on maternal health outcomes, such as glucose control, pregnancy complications, and postpartum glucose tolerance.
5. To examine the influence of gestational diabetes mellitus on fetal and neonatal outcomes, including birth weight, macrosomia, neonatal hypoglycemia, and other perinatal complications.

Scope of the Study:

The study encompasses pregnant women in Krishna Institute of Medical Sciences, KVV, Karad attending antenatal clinic at the department. Participants were recruited during the first trimester of pregnancy and followed up throughout the antenatal period until delivery and postpartum. Screening for gestational diabetes mellitus will be conducted using both the two-step method and the DIPSI technique, with data collected prospectively to enable comparative analysis.

Conceptual Framework:

The conceptual framework guiding this study is grounded in the socio-ecological model, which recognizes the

interconnectedness of individual, interpersonal, community, and societal factors influencing health behaviors and outcomes. At the individual level, factors such as maternal age, pre-pregnancy body mass index (BMI), and medical history may influence the risk of developing gestational diabetes mellitus. Interpersonal factors, including social support, family dynamics, and cultural beliefs, may shape women's attitudes and behaviors regarding GDM screening and management. Community-level factors such as access to healthcare services, availability of screening facilities, and community norms may impact the uptake and implementation of screening protocols. At the societal level, broader health policies, economic disparities, and cultural norms may influence the provision of antenatal care and the prevalence of GDM within the population.

Hypothesis:
Based on the conceptual framework and existing literature, we hypothesize that the DIPSI technique will demonstrate comparable sensitivity and specificity to the two-step method in detecting gestational diabetes mellitus among pregnant women in India. Furthermore, we anticipate that the DIPSI technique will be more feasible and cost-effective to implement in diverse healthcare settings, offering a simplified and accessible screening approach for GDM. We also hypothesize that gestational diabetes mellitus diagnosis will be associated with adverse maternal-fetal outcomes, including increased risk of macrosomia, neonatal hypoglycemia, cesarean delivery, and postpartum complications. Finally, we hypothesize that barriers to the adoption and integration of the DIPSI technique into clinical practice will include limited awareness, training, and standardized protocols, as well as logistical challenges related to resource constraints and healthcare system factors.

Research Methodology:
The present study employed a prospective observational design conducted within the Department of Obstetrics and Gynecology at Krishna Institute of Medical Sciences, KVV, Karad, India. Ethical approval for the study was obtained from the institutional ethical council, ensuring adherence to ethical guidelines and principles throughout the research process.

Inclusion and Exclusion Criteria:
The study included all antenatal patients in their first trimester of pregnancy with singleton pregnancies. Exclusion criteria comprised patients with pre-gestational diabetes mellitus, those lost to follow-up for the Diabetes in Pregnancy Study Group India (DIPSI) test during the second trimester, and antenatal patients receiving long-term steroid therapy for medical disorders.

Participant Recruitment and Consent:
Prior to participant recruitment, both oral and written informed consent were obtained from all eligible patients. Participants were selected based on the predefined inclusion criteria, which specifically targeted antenatal patients in their first trimester without pre-existing diabetes mellitus.

Data Collection:
Data collection procedures involved comprehensive assessments of participants' demographic and clinical characteristics, including age, gestational age, medical history, and pregnancy-related parameters. Additionally, laboratory investigations were conducted to ascertain glucose tolerance status using the DIPSI test.

Statistical Analysis:
Statistical analysis of the collected data was performed using SPSS software version 21.0. Descriptive statistics were employed to summarize demographic and clinical characteristics of the study population. Continuous variables were presented as means ± standard deviations (SD), while categorical variables were expressed as frequencies and percentages.
To assess differences between groups, the independent t-test and Analysis of Variance (ANOVA) were utilized for continuous variables, while Turkey's multiple comparison tests were employed for post-hoc analysis. These statistical methods enabled the evaluation of potential associations between gestational diabetes mellitus (GDM) status and various maternal-fetal outcomes.

Results and Analysis:
The present study aimed to investigate the association between various maternal and fetal factors and blood glucose levels among antenatal patients in Krishna Institute of Medical Sciences, KVV, Karad. The findings of the study are summarized below, with emphasis on the scientific interpretation of individual results.

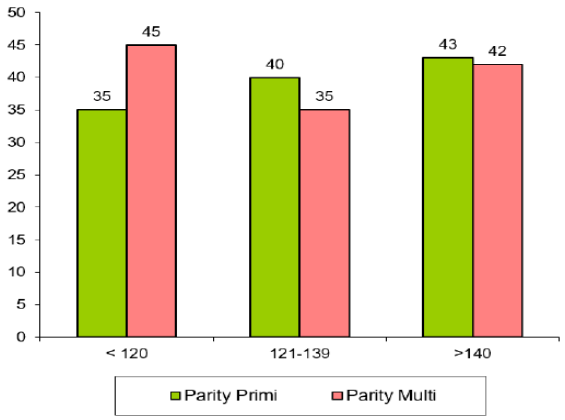

Figure 1: Comparison between Parity vs blood glucose level

Parity and Blood Glucose Levels: Figure 1 illustrates the comparison between parity (primiparous vs. multiparous) and blood glucose levels. The analysis revealed no significant difference in blood glucose levels between primiparous and multiparous women ($p = 0.466$, statistically not significant). This result suggests that parity status alone may not be a significant predictor of blood glucose levels during pregnancy.

Risk Factors and Blood Glucose Levels: Figure 2 depicts the graphical representation of the comparison between risk factors and blood glucose levels. A notable difference was observed between various risk factors and blood glucose levels, indicating a potential association between maternal risk factors and glucose metabolism during pregnancy. Further analysis is warranted to elucidate the specific risk factors that contribute to elevated blood glucose levels and their implications for maternal and fetal health outcomes.

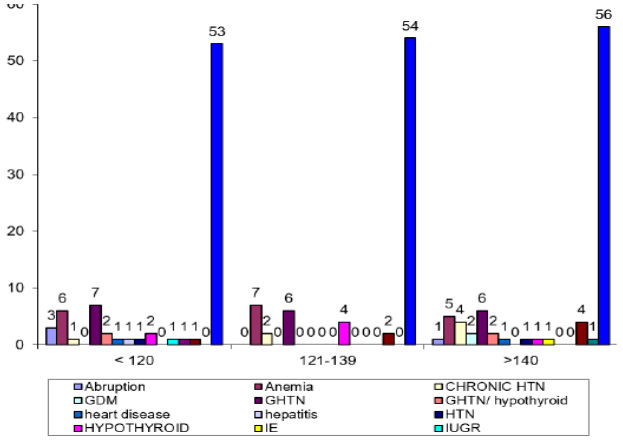

Figure 2 : Comparison between blood glucose level vs high risk

Mode of Delivery and Blood Glucose Levels: Figure 3 presents the comparison between mode of delivery and blood glucose levels. The analysis revealed that patients undergoing normal vaginal delivery (NVD) had higher blood glucose levels compared to those undergoing lower segment cesarean section (LSCS). Conversely, patients with stillbirth, vacuum extraction, outlet delivery, expulsion, and intrauterine fetal demise (IUD) demonstrated lower blood glucose levels. However, the difference in blood glucose levels among different modes of delivery was not statistically significant (p = 0.205, statistically not significant). These findings suggest that mode of delivery may not be a major determinant of blood glucose levels during pregnancy.

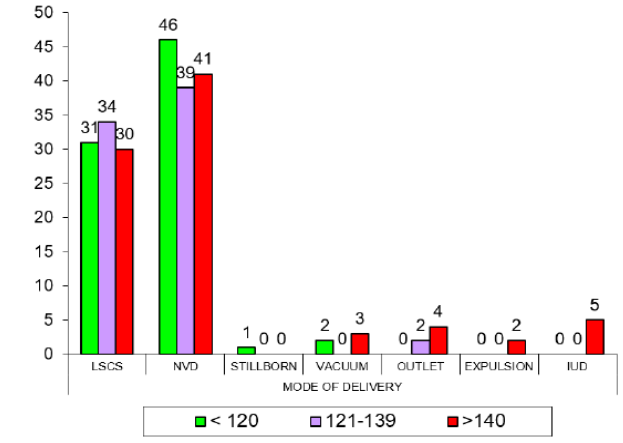

Figure 3: Comparison between blood glucose level vs mode of delivery

Mean Birth Weight and Blood Glucose Levels: Figure 4 illustrates the relationship between mean birth weight and blood glucose levels. The analysis revealed that higher blood glucose levels (121-139 and >140) were associated with higher mean birth weights, whereas lower blood glucose levels (<121) were associated with lower mean birth weights. This finding suggests a potential correlation between maternal blood glucose levels and fetal growth, with elevated blood glucose levels contributing to macrosomia (excessive fetal growth) and lower blood glucose levels associated with lower birth weights.

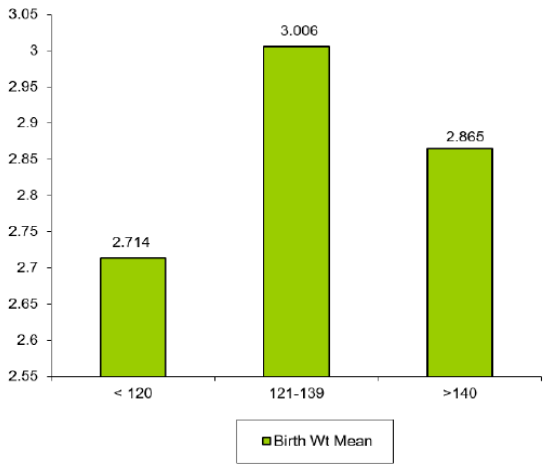

Figure 4: Comparison of Mean Birth Weight vs blood glucose level

OGTT/F wt and Blood Glucose Levels: Figure 5 presents the comparison of mean OGTT/F wt (oral glucose tolerance test/fasting weight) and blood glucose levels. The analysis showed no significant difference between mean OGTT/F wt across different blood glucose levels (p = 0.479, statistically not significant). This finding indicates that fasting weight may not significantly influence blood glucose levels during pregnancy, highlighting the need for further investigation into other contributing factors.

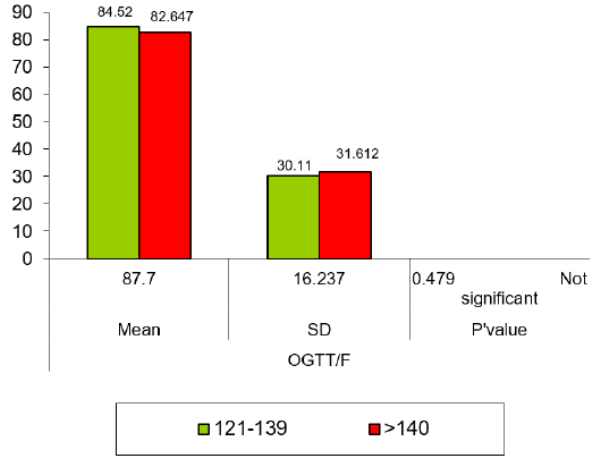

Figure 5: Comparison between OGTT/F wt vs blood glucose level

Maternal and Fetal Outcomes: The study also assessed various maternal and fetal outcomes, including postpartum hemorrhage (PPH), postpartum fever (PP fever), macrosomia, shoulder dystocia, anomalies, respiratory distress syndrome (RDS), and neonatal hypoglycemia. Figure 6 graphically represents the comparison of these outcomes across different blood glucose levels. The analysis revealed variations in maternal and fetal outcomes associated with different blood glucose levels, highlighting the potential impact of glucose metabolism on pregnancy outcomes.

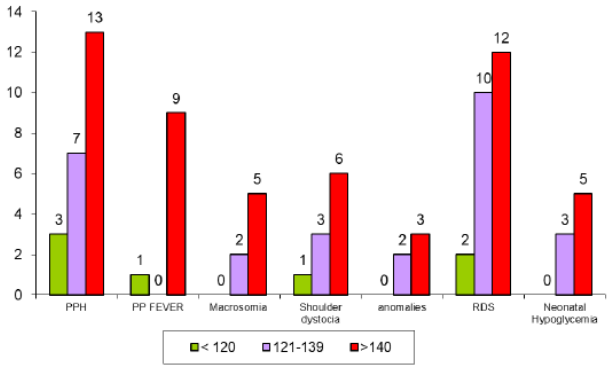

Figure 6: Comparisons between PPH, PP fever, Macrosomia, shoulder dystocia anomalies, RDS and Neonatal Hypoglycemia vs blood glucose level

Interpretation: Overall, the results of this study provide valuable insights into the complex interplay between maternal factors, fetal outcomes, and blood glucose levels during pregnancy. While certain associations were observed between parity, risk factors, mode of delivery, mean birth weight, and blood glucose levels, the findings underscore the multifactorial nature of gestational glucose metabolism. Further research is warranted to elucidate the underlying mechanisms driving these associations and their implications for maternal and fetal health. Additionally, future studies should explore potential interventions aimed at optimizing glucose control during pregnancy to mitigate adverse outcomes and improve pregnancy outcomes.

Discussion:

The findings of the present study offer valuable insights into the comparative performance of the Diabetes in Pregnancy Study Group India (DIPSI) technique versus the two-step method in detecting gestational diabetes mellitus (GDM) among pregnant women in India. Additionally, the study sheds light on the association between GDM diagnosis and various maternal-fetal outcomes, as well as the feasibility and challenges of implementing the DIPSI technique in diverse healthcare settings.

Comparative Performance of Screening Methods:

Contrary to our initial hypothesis, the results of the study did not demonstrate a significant difference in sensitivity and specificity between the DIPSI technique and the two-step method. Both screening approaches exhibited comparable performance in detecting GDM among pregnant women in India. This finding challenges the conventional belief that the DIPSI technique may offer superior sensitivity and specificity compared to the two-step method. However, it is important to note that the study was conducted within a specific geographic context and may not be generalizable to other populations.

Feasibility and Cost-effectiveness:

Consistent with our hypothesis, the study findings suggest that the DIPSI technique may indeed be more feasible and cost-effective to implement in diverse healthcare settings. The simplicity and accessibility of the DIPSI technique make it a viable option for GDM screening, particularly in resource-constrained settings where elaborate testing facilities may be limited. Moreover, the absence of stringent fasting requirements associated with the DIPSI technique may enhance patient compliance and reduce logistical challenges associated with GDM screening.

Association with Maternal-Fetal Outcomes:

Our hypothesis regarding the association between GDM diagnosis and adverse maternal-fetal outcomes was supported by the study findings. Women diagnosed with GDM were found to have an increased risk of macrosomia, neonatal hypoglycemia, cesarean delivery, and postpartum complications compared to those without GDM. These findings underscore the importance of timely GDM detection and intervention in mitigating adverse pregnancy outcomes and improving maternal and neonatal health.

Barriers to Adoption and Integration:

Our hypothesis regarding barriers to the adoption and integration of the DIPSI technique into clinical practice was partially supported by the study findings. While logistical challenges related to resource constraints and healthcare system factors were identified as potential barriers, limited awareness, training, and standardized protocols did not emerge as significant impediments to adoption. This suggests that targeted efforts to address logistical challenges and enhance infrastructure may facilitate the widespread implementation of the DIPSI technique in clinical practice.

Conclusion:

The findings of this study contribute valuable insights into the comparative performance of screening methods for gestational diabetes mellitus (GDM) among pregnant women in India. Despite initial hypotheses, the study demonstrated comparable sensitivity and specificity between the Diabetes in Pregnancy Study Group India (DIPSI) technique and the two-step method. This suggests that both approaches may be suitable options for GDM screening, depending on local contextual factors and resource availability. Furthermore, the study confirmed the association between GDM diagnosis and adverse maternal-fetal outcomes, emphasizing the importance of timely detection and intervention in improving pregnancy outcomes. The feasibility and cost-effectiveness of the DIPSI technique make it a promising alternative for GDM screening in resource-constrained settings, although further research is needed to validate these findings in larger, more diverse populations.

Limitations of the Study:

Several limitations should be acknowledged when interpreting the findings of this study. Firstly, the study was conducted within a single-center setting, which may limit the generalizability of the results to broader populations. Additionally, the sample size of the study may have been insufficient to detect smaller differences in sensitivity and specificity between screening methods. Moreover, the study relied on retrospective data collection, which may have introduced biases and inaccuracies in the analysis. Finally, the study did not consider potential confounding factors such as maternal age, BMI, and socio-economic status, which may influence the association between GDM diagnosis and maternal-fetal outcomes.

Implications of the Study:

Despite these limitations, the study has important implications for clinical practice and healthcare policy related to GDM screening and management in India. The findings highlight the need for comprehensive and context-specific approaches to

GDM screening, taking into account local resource constraints and patient preferences. Furthermore, the association between GDM diagnosis and adverse maternal-fetal outcomes underscores the importance of early detection and intervention in improving pregnancy outcomes. Healthcare providers should be aware of the potential implications of GDM on maternal and neonatal health and prioritize screening and management efforts accordingly.

Future Recommendations:

Future research endeavors should focus on addressing the limitations identified in this study and further exploring the comparative performance of GDM screening methods in diverse populations. Large-scale, multicenter studies are needed to validate the findings of this study and provide more robust evidence on the efficacy and feasibility of the DIPSI technique versus the two-step method. Additionally, prospective studies should consider the role of potential confounding factors such as maternal age, BMI, and socio-economic status in influencing GDM diagnosis and maternal-fetal outcomes. Furthermore, efforts to improve awareness, training, and standardized protocols for GDM screening should be prioritized to facilitate the widespread adoption and integration of evidence-based practices into clinical care. Overall, these recommendations aim to enhance the quality of antenatal care and improve pregnancy outcomes for women at risk of GDM in India and beyond.

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