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Early Gestational Diabetes Mellitus Treatment: A Critical Bioanalytical and Clinical Appraisal of Randomized Trial

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ABSTRACT

Background: Advances in bioanalytical glucose assessment have enabled the identification of gestational diabetes mellitus (GDM) earlier in pregnancy; however, the clinical value of initiating treatment before the conventional 24–28-week screening window remains uncertain. The Treatment of Booking Gestational Diabetes Mellitus (TOBOGM) trial evaluated whether immediate treatment of early-diagnosed GDM improves pregnancy outcomes compared with deferred management.

Objective: To critically appraise the TOBOGM randomized controlled trial, with emphasis on bioanalytical thresholds, trial methodology, outcome validity, and implications for early glycaemic assessment in pregnancy.

Methods: A structured critical analysis of the TOBOGM trial was undertaken, focusing on participant selection, early oral glucose tolerance test (OGTT) criteria, randomisation procedures, intervention fidelity, outcome measurement, and statistical interpretation. Findings were contextualised within current evidence on early pregnancy hyperglycaemia and international screening recommendations.

Results: Immediate treatment of GDM diagnosed before 20 weeks resulted in a modest absolute reduction in a composite neonatal outcome, primarily driven by reductions in non-fatal neonatal morbidities. No significant benefit was observed for maternal hypertensive disorders or neonatal lean body mass. Methodological strengths included rigorous allocation concealment and pragmatic trial design. Key limitations relate to the application of standard late-pregnancy OGTT thresholds in early gestation, phenotypic heterogeneity of early hyperglycaemia, reliance on composite outcomes, and potential overtreatment of women whose glycaemia later normalised.

Conclusion: The TOBOGM trial provides high-quality evidence that early treatment of GDM in selected high-risk pregnancies yields limited neonatal benefit without clear maternal advantage. From a bioanalytical and clinical perspective, the findings support risk-based early glucose assessment rather than universal early screening or treatment. Further research is required to refine early-pregnancy diagnostic thresholds and to distinguish transient dysglycaemia from clinically significant early GDM.

KEYWORDS: TOBOGM trial, gestational diabetes mellitus, early pregnancy hyperglycemia, randomized controlled trial, early treatment, deferred treatment, neonatal outcomes, pregnancy complicationsS.

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BACKGROUND AND RATIONALE

GDM affects an increasing proportion of pregnancies worldwide and is associated with higher risks of large for gestational age (LGA) birth, shoulder dystocia, hypertensive disorders and later cardiometabolic disease in both mother and offspring[1-3]. Recent population data suggests GDM prevalence exceeding 15–20% in many regions when IADPSG thresholds are used[4-6]. Large RCTs in conventional GDM (diagnosed at 24–28 weeks) showed that treatment with diet, glucose monitoring and pharmacotherapy reduces perinatal morbidity, underpinning current international practice [7,8]. However, observational studies indicate that many women already have intermediate hyperglycaemia or even full GDM in the first trimester [9–11]. Early dysglycaemia is associated with later complications in cohorts where hyperglycaemia persists or is only recognised at 24–28

weeks [9–11]. It was noted in TOBOGM, women with early GDM whose glycaemia regressed to normal on repeat OGTT at 24–28 weeks had pregnancy outcomes similar to women who were normoglycaemic throughout pregnancy, indicating that the adverse associations seen in observational cohorts do not apply to this specific regressor subgroup [12].

This raises a critical question. Should we diagnose and treat GDM earlier in pregnancy, and if so, using which thresholds? Prior to TOBOGM, evidence for early treatment consisted mainly of cohort studies and one older systematic review that concluded there was insufficient high-quality trial data to support routine early screening and treatment [13–15].

Against this backdrop, Simmons et al. designed TOBOGM to answer precisely the question that guidelines and clinicians were struggling with. Does initiating standard GDM treatment as soon as early GDM is identified (<20 weeks) improve meaningful pregnancy outcomes, compared with deferring action until the usual 24–28 week screening window? [16,17]

OVERVIEW OF THE TOBOGM TRIAL

2.1 Study Design and Setting

TOBOGM was a controlled, randomized, multicenter trial that took place in Australia, Austria, Sweden and India [16–18]. Pregnant women who had a higher risk of developing GDM, such as those with a history of GDM, obesity, a family history of GDM, or belonging to certain ethnic groups, underwent an early 75 g OGTT before 20 weeks of gestation using the WHO 2013/IADPSG thresholds [16–19].

The experiment was realistic because the care paths were based on how things were done in the area and the locations were typical high-income areas with established diabetes in pregnancy teams [2,16,18].

2.2 Participants and Randomisation

The criteria for inclusion were a singleton pregnancy, a gestational age of under 20 weeks at the commencement of the OGTT, and hyperglycemia that satisfied the GDM standards applicable in the region (typically IADPSG/WHO) [16,18,19]. Women who had early GDM"were put into two groups: those who got treatment right away and those who waited [16,17]. Women with pre-existing diabetes or other significant health conditions were excluded from participation, especially women with overt diabetes, and were treated outside the trial [16,17,19]. Randomization was both central and stratified by study site and by glycaemic range (based on HAPO odds-ratio 1.75 vs 2.0 bands) and early OGTT results were blinded to participants and clinicians (unless very high) to minimise management bias in the deferred treatment group [16–18].

2.3 Interventions and Comparator

The immediate treatment group was provided with lifestyle counseling, blood glucose self monitoring, and insulin and/or metformin according to local norms if their blood glucose levels failed to achieve specified targets after assigning randomly [16–18].

The deferred treatment group received standard prenatal care without gestational diabetes management until a follow up oral glucose tolerance test at 24–28 weeks. Only if GDM persisted were they then managed as GDM for the remainder of pregnancy [16,17].

This design emulates the real world choice clinicians face. Treat early based on early OGTT, or wait for standard timing diagnosis [4,16,20].

2.4 Outcomes

Perinatal mortality, birth trauma, preterm delivery, respiratory support demands, and indications of abnormal fetal growth, such as LGA or newborn overweight status, were the primary outcomes implemented as a composite adverse neonatal outcome [7,8,16]. Secondary outcomes included gestational hypertension (pre-eclampsia), decreased newborn body mass (measured by DXA or equivalent), and other difficulties affecting the mother and infant [16,21,22].

The subsequent articles examined cost effectiveness and breastfeeding results from the same cohort [23–25].

KEY FINDINGS

Immediate treatment of early GDM produced:

• A modest but statistically significant reduction in the primary composite neonatal outcome compared with deferred treatment (driven mainly by fewer infants with neonatal respiratory distress, rather than clear differences in excessive fetal growth) [16,23,26].

• No clear difference in pregnancy related hypertension between groups [16,26,27].

• No meaningful effect on neonatal lean body mass, suggesting that the metabolic programming of fetal lean tissue may be less sensitive to this degree and timing of glycaemic modification [16,21].

The absolute risk reduction for the composite neonatal outcome was around 5.6 percentage points, implying a number needed to treat of 18 to prevent one composite event [16,23].

Economic evaluation using TOBOGM data suggested that early diagnosis and treatment can be cost effective or even cost

saving, especially in women with higher levels of early hyperglycaemia and when diagnosis occurs before 14 weeks [23,28].

METHODOLOGICAL APPRAISAL

4.1 Design and Risk of Bias

TOBOGM is methodologically strong in several respects:

• Randomisation and allocation concealment were clearly described and appear robust, minimising selection bias [16–18]. The use of sham OGTTs and concealment of early OGTT results in the deferred arm is a clever strategy to reduce performance and detection bias and clinicians and participants were less likely to change behaviour based on perceived risk [17,18].

• Outcome assessment for key neonatal endpoints was largely objective (birthweight, gestational age, need for respiratory support), further limiting bias [7,8,16].

However, the trial remained open label regarding treatment allocation once GDM was diagnosed, and the component outcomes of the composite (e.g., respiratory support) can be influenced by clinician thresholds that can vary by centre or by perception of maternal risk [16,23]. This is more about between site heterogeneity than systematic bias in any one direction.

Overall, risk of bias is low to moderate, and certainly lower than in prior observational work on early GDM [13–15].

4.2 Eligibility Criteria and Population

Participants were identified through risk factor based early screening rather than universal early OGTT, which is important for external validity [16–18]. Many guidelines currently support early testing in women with risk factors (e.g., previous GDM, obesity, strong family history), not universal early screening for all pregnancies [3,29,30].

This means:

• TOBOGM's population is enriched for women at higher baseline risk, who may have more to gain from earlier treatment [2,16,26].

• Extrapolating its results to low-risk women identified through future universal early screening is hazardous, so the balance of benefits and harms may differ substantially [13,20,26].

The trial was conducted in well resourced health systems with good access to dietitians, diabetes educators and pharmacotherapy [1,2,16]. Application to lower resource settings, where intensively monitored GDM care is difficult to deliver, is uncertain [2,3,29].

4.3 Intervention Fidelity, Co-interventions and Contamination

The intervention standard GDM care was not strictly protocolised but allowed local variation in dietary support, glucose targets and thresholds for starting medication [16]. This enhances pragmatic relevance but introduces heterogeneity in exposure, which can dilute measured effects [2,3,29].

Use of metformin and insulin followed local practice [16]. Increasingly, oral agents are used first line in GDM, though guidelines remain cautious because of placental transfer and limited long term offspring data [3,31,32]. Different drug choices and titration patterns across centres may have influenced both efficacy and maternal experience [31,32].

Contamination is always a concern in such trials. Clinicians who suspected early GDM in the deferred arm (e.g., based on risk profile or random glucose values) might have tightened general care, partially reducing contrasts between groups. Conversely, label-driven intensification in the immediate treatment arm could have magnified small biochemical differences into clinical action [2,3,20]. This remains speculative but plausible, as TOBOGM did not directly document such behaviour [16].

4.4 Outcome Selection and Measurement

The composite primary outcome blends diverse endpoints with very different severity. Perinatal death sits alongside LGA or need for transient respiratory support. While composite outcomes increase statistical power, they can obscure which components actually drive the effect. In TOBOGM, the benefit appears largely due to reductions in neonatal respiratory distress and some non-fatal morbidities, with little impact on the rarest and most serious events [16,23,26].

From a clinical perspective, reducing LGA and shoulder dystocia is meaningful, but the small absolute risk reduction raises the question of clinical importance versus statistical significance [7,8,13].

Neonatal lean mass was a sophisticated co-primary outcome, reflecting interest in early programming of adiposity versus lean tissue. The absence of variation indicates that slight enhancements in glycaemia during late pregnancy may exert minimal effect on early body composition, or that the measurements did not have sufficient sensitivity [16,21].

4.5 Statistical Analysis and Interpretation

Sample size calculations were based on plausible assumptions about composite event rates and anticipated treatment effect, so the achieved sample provided adequate power for the primary outcome but less so for any single component or maternal outcome [16].

Analytical methods were appropriate:
• Intention-to-treat analysis respected randomisation [16,23].
• Sensitivity analyses explored different definitions and covariate adjustments [16,23,26].
• Prespecified economic and ancillary analyses strengthened the total evidence package [23–25,28].
However, the effect size is modest, and 95% confidence intervals are compatible with both clinically trivial benefits and harms for some secondary outcomes. Interpretation should therefore be cautious. TOBOGM shows that early treatment probably confers a small benefit in high risk women with early GDM, but it does not show that early treatment is dramatically superior to conventional timing [16,23,26].

POSITIONING WITHIN RECENT EVIDENCE

Several recent publications help contextualise TOBOGM:
• A 2025 systematic review and meta-analysis by García-Patterson et al. summarised detection and treatment of early GDM and found that early diagnosis increases GDM prevalence and treatment use, with only modest or inconsistent improvements in hard outcomes. TOBOGM was a major contributor and improved the overall certainty of evidence [33].

• A 2025 systematic review in Cureus similarly concluded that early screening consistently labels more women as GDM and exposes them to treatment, without robust evidence for large clinical gains compared with standard-timing screening [34].

• A 2024 analysis using TOBOGM data showed that early diagnosis and treatment can be cost effective, especially in women with higher early glucose and when intervention starts before 14 weeks, but acknowledged methodological uncertainties and reliance on high-income health system costs [23,28].

• Research from the TOBOGM group indicated that women whose early gestational diabetes mellitus (GDM) regressed to a normal oral glucose tolerance test (OGTT) at 24–28 weeks experienced pregnancy outcomes comparable to those of women who never had GDM. This underscores the risk of potential overtreatment if all instances of early dysglycaemia are managed uniformly [12,26].

Simultaneously, extensive observational cohorts and predictive studies demonstrate that glycaemia in early pregnancy serves as a significant risk marker for subsequent gestational diabetes mellitus and negative outcomes [9–11,35].

Updates to the guidelines illustrate this complex situation:
• The 2024 ADA and other national guidelines advocate for early testing in high-risk women while exercising caution regarding universal early screening. Additionally, they do not uniformly endorse the treatment of all early hyperglycemia based on standard GDM thresholds [3,29,30].

• European and Australasian consensus statements assert that early detection of overt diabetes is essential. However, the criteria and advantages of diagnosing early GDM are still ambiguous and subject to ongoing assessment [1,29,36].

TOBOGM serves as a significant, albeit not conclusive, component of the evidence landscape [1–3,16].

CLINICAL, ETHICAL AND HEALTH SYSTEM IMPLICATIONS

From a clinician's perspective, TOBOGM suggests that, for high-risk women:
• Early GDM treatment yields a small reduction in composite neonatal morbidity, mainly related to neonatal respiratory distress and fetal overgrowth [16,23,26].

• Maternal outcomes such as hypertensive disorders are not clearly improved [16,21].

• Neonatal body composition is unchanged at birth [16,21].

The ethical trade-off revolves around:

1. **Benefit size vs burden**
   Early GDM diagnosis leads to frequent glucose monitoring, dietary restrictions and often pharmacotherapy. For a modest absolute reduction in neonatal composite events, some women will experience anxiety, medicalisation and potential side effects without clear personal benefit [16,23,29].
2. **Overdiagnosis and regression**
   Evidence that a subset of women with early GDM later show normal OGTT and have outcomes similar to non-GDM pregnancies suggests that a one size fits all early diagnostic threshold may overdiagnose and overtreat some women [11,12,26].
3. **Equity and resource implications**
   Widespread early screening and treatment could markedly increase GDM prevalence in some systems, with major implications for clinic capacity, staff workload and costs [4,20]. In settings where basic antenatal care is still under resourced, prioritising early GDM treatment over other interventions (e.g., blood pressure control, anaemia treatment) may not be the most efficient use of limited resources [2,3,16].
4. **Long-term offspring outcome**
   It is unclear how maternal hyperglycemia and its treatment, especially exposure to metformin, may affect

neurodevelopment and metabolism in the long run [5,37,38].

These factors lead to the ensuing logical synthesis. Promote early oral glucose tolerance testing (OGTT) and intervention for high risk women, including those who are obese with a significant family history, display pronounced early hyperglycemia, or possess a history of gestational diabetes mellitus (GDM), particularly in settings equipped for intensive care [1–3,16,29].

A cautious approach is necessary about universal early screening and therapy for all pregnancies until additional evidence on phenotypic and long term consequences are obtained [13,33,36].

STRENGTHS, LIMITATIONS AND FUTURE DIRECTIONS

7.1 Key Strengths of Simmons et al.

• First adequately powered RCT specifically targeting treatment of GDM diagnosed before 20 weeks, directly addressing a long standing evidence gap [16,23].
• Innovative blinding approach using sham OGTTs to reduce performance bias [17,18].
• Pragmatic, multicentre design across several countries, improving external validity within high income contexts [16–18].
• Rich ancillary analyses (economic, breastfeeding, regression of GDM) that expand understanding beyond the primary clinical outcomes [12,23–25,28].

7.2 Important Limitations

• Early GDM was defined using 24–28 week diagnostic thresholds applied earlier in gestation, even though the pathophysiology and risk associations of early hyperglycaemia may differ. This may both over and under diagnose clinically relevant early disease [1,13,20].
• Composite outcome interpretation is challenging. Serious events are rare and the benefit is mainly in intermediate outcomes [16,23,26].
• The trial largely excludes low resource settings and populations with different baseline risks and care structures [2,3,16].
• Treatment algorithms were not uniform. Future trials using standardised glycaemic targets, dietetic input and pharmacotherapy could better isolate the effect of timing rather than of varying care quality [2,3,16].

7.3 Future Research Priorities

Building on TOBOGM, key areas include:
• **Lifespan perspective** such as long term follow up of mothers and children from TOBOGM and similar trials to clarify neurodevelopmental and metabolic consequences of early treatment versus deferred treatment [16,21,38].
• **Phenotype-specific thresholds** differentiating women with transient early hyperglycemia from those with persistent or progressive dysglycemia, perhaps utilizing continuous glucose monitoring (CGM) and machine learning predictive models [10,12,39,40].
• **Alternative management options** encompass trials that compare various glycaemic objectives, the timing of medication commencement, and the incorporation of digital health resources [23,29,41].

CONCLUSION

Simmons et al.'s TOBOGM trial represents a major advance in the evidence base for early GDM management. It demonstrates that, among high risk women diagnosed with GDM before 20 weeks' gestation, immediate treatment yields a small but real reduction in a composite neonatal outcome, with no clear maternal benefit and no effect on neonatal lean mass [16,21,23].
For clinical practice, the results justify targeted early testing and treatment for women at particularly high risk, especially where resources and multidisciplinary teams are available [1–3,16,29]. They do not provide a strong mandate for universal early screening or for labelling all mild early hyperglycaemia as GDM requiring full intensity therapy [13,33,34,36].

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