



Critique on Adverse Effects of Gestational Diabetes Mellitus: Improvement of Maternal and Perinatal Outcomes

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Abstract: Background: Background: A systematic review and meta analysis was conducted by Luo et al. based on the PRISMA 2020 recommendations, to clarify whether induction of labour at term in women with gestational diabetes mellitus (GDM) improves maternal and perinatal outcomes as compared with expectant care. **Method:** The researchers conducted a meticulous search of four major databases starting from inception until June 2021. They found 11 studies (three randomized controlled trials (RCTs) and 8 observational cohorts, 13,617 women) that compared induction at term (between 38 to 40 weeks) versus ongoing pregnancy in women with GDM and singleton pregnancies. Primary outcomes were caesarean section (CS) and macrosomia. Secondary outcomes included instrumental birth, severe perineal lacerations and a range of maternal and neonatal morbidities. Induction was associated with reduced odds of macrosomia and, in observational studies, severe perineal trauma. However, there was no significant difference in CS, instrumental birth, large for gestational age (LGA) infants or serious neonatal outcomes. This critique argues that Luo et al. address an important and controversial question at the interface of diabetes in pregnancy and labour management. Methodological strengths include protocol registration, comprehensive search strategy, duplicate screening, separate synthesis of RCTs and observational studies, and GRADE assessment of evidence certainty. However, the evidence base underpinning the meta analysis is heterogeneous and dominated by older, moderate quality observational studies, where expectant management is variably defined and confounding by indication is likely. Adjustment for glycaemic control, GDM phenotype and obesity is limited, and patient centred outcomes are absent. **Conclusion:** When interpreted alongside contemporary data on GDM epidemiology, timing of delivery and neonatal risk, Luo et al.'s findings support guideline recommendations that routine induction for well controlled GDM at term should aim primarily to reduce macrosomia and birth trauma, and is unlikely to substantially lower CS or perinatal mortality. The review therefore strengthens but does not definitively resolve the case for individualized timing of birth in GDM based on glycaemic control, maternal BMI and local induction capacity.

Keywords: Gestational diabetes, neonatal risk, maternal outcome, perinatal outcome, macrosomia,

1. Background and Rationale

GDM affects roughly 14% of pregnancies worldwide (1). There is a rise in prevalence due to maternal obesity, advanced age and changing diagnostic thresholds with recent meta analytic data showing substantial variation in prevalence depending on criteria used (1–3). Short term risks emphasised by contemporary reviews include hypertensive disorders, cesarean section, shoulder dystocia, neonatal hypoglycaemia and NICU admission while long term risks are type 2 diabetes and cardiovascular disease for both mother and child (4–6).

Induction of labour (IOL) at term has become increasingly common and in many high income settings, about a quarter of women now deliver following induction (7,8). Following large randomized studies such as ARRIVE, which suggested that elective induction at 39 weeks does not increase cesarean section rates and may reduce some adverse outcomes in low risk nulliparas, induction rates at 39 weeks rose further (8,9). However, extrapolating these findings to women with GDM is problematic given their distinct pathophysiology and risk profile (3,6).

Professional bodies such as the Society of Obstetricians and Gynaecologists of Canada/Diabetes Canada, NICE and ACOG broadly recommend offering induction between 38 and 40 weeks for GDM pregnancies, while acknowledging that many recommendations rest on expert consensus and limited high quality RCT data (10–12). Contemporary reviews stress that optimal timing of delivery in GDM must balance reduction in stillbirth, macrosomia and shoulder dystocia risk against the higher neonatal respiratory and metabolic morbidity observed with birth before 39 weeks (6,13,14).

Historically, observational data and smaller trials in GDM populations yielded conflicting results regarding whether planned induction reduces cesarean section or serious perinatal complications (15). In this context, Luo et al. sought to strengthen the evidence base by synthesising RCTs and observational studies comparing induction versus expectant management specifically among women with singleton term GDM pregnancies (15).

2. Overview of Luo et al.'s Study

2.1 Objectives and Design

Luo et al. performed a systematic review and meta analysis according to PRISMA 2020, followed by protocol registration in PROSPERO (16,17). The researchers examined various sources such as

MEDLINE, EMBASE, the Cochrane Library and Web of Science from inception till June 2021, including trial registry searches and reference screening (15). Research qualifying for eligibility was randomized controlled trials (RCTs) or comparative observational studies comprising prospective or retrospective cohorts and case control studies (15). The studies included women with singleton GDM pregnancies ≥ 37 weeks undergoing induction of labor and compared induction with expectant care, as well as reported on maternal and/or neonatal outcomes (15).

2.2 Data and Outcomes

The authors included 11 studies (3 RCTs, 8 observational) from 4,791 citations. 13,617 women were involved (3,633 induction versus 9,984 expectant management) (15).

The primary outcomes were cesarean section and macrosomia. The secondary outcomes included instrumental birth, severe perineal lacerations, ICU admission, LGA, shoulder dystocia, NICU admission, 5 min Apgar score less than 7, neonatal acidemia and perinatal mortality (15). This review did not include any of its outcomes on hypoglycaemia and pre eclampsia (15).

According to the Mantel Haenszel method, a random effect meta analysis yields the odds ratios (ORs) separately for RCTs, observational studies, and all studies (18). The Cochrane Risk of Bias tool was used to assess study quality for RCTs while to assess study quality for observational designs the Newcastle Ottawa Scale (NOS) was used (19,20). GRADE was used to evaluate the overall certainty of evidence for each outcome (21).

2.3 Main Findings

Following were the key findings (15):

- **Cesarean Section:** The overall likelihood of cesarean section was similar in both induced and expectant groups. This was true across all 11 studies. RCTs and observational subset had similar null estimates OR 1.02 (95% CI 0.82–1.27) (15).
- **Macrosomia:** The odds were reduced with induction in all studies. RCTs represented 0.49 with Confidence Interval 0.30–0.81, 0% I^2 . Observational studies represented 0.64 with Confidence Interval 0.54–0.77, I^2 12%. Overall was 0.64 with Confidence Interval 0.55–0.74, I^2 0% (15).
- **Severe perineal lacerations:** The odds were lower with induction in observational studies OR 0.59 (95% CI 0.39–0.88, I^2 0%). A small RCT was underpowered and non significant (15,22).

The results were not significantly different between the groups for LGA, shoulder dystocia, NICU admission, low Apgar, neonatal acidemia, perinatal

mortality, and confidence intervals were wide for the more rare outcomes (15). The researchers found that term induction may prevent macrosomia and severe perineal trauma in gestational diabetes without increasing caesarean section. However, they emphasized the need for stronger and newer studies (15).

3. Methodological Appraisal

3.1 Strengths of the Review Methods

Adherence to PRISMA and protocol registration
The review adhered to PRISMA 2020 and was registered prospectively on PROSPERO (16,17). This reduces selective outcome reporting and increases transparency and aligns with current best practice for evidence synthesis and is a clear methodological strength (16).

Comprehensive search strategy

Four major databases were searched from inception with a librarian assisted strategy, and trial registries and reference lists were screened (15). Due to the scarcity of large RCTs in this area including both RCTs and observational studies was appropriate (15).

Clear inclusion criteria and PICOS framework

Eligibility criteria follow the PICOS framework, specifying term singleton GDM pregnancies as the population, induction as the intervention, expectant management as the comparator and clinically relevant maternal and neonatal outcomes (CS, macrosomia) (15).

Duplicate screening, extraction and risk of bias assessment

Two reviewers conducted the study selection, data extraction and quality appraisal independently. A third reviewer resolved the disagreements, which strengthens internal validity (15).

Use of GRADE

Luo et al. applied GRADE to rate certainty of evidence, generally as low or very low and details were presented in a supplementary table (15,21).

3.2 Limitations of the Evidence Base

Despite robust review methods, the underlying primary studies limit interpretability.

Dominance of observational studies and risk of confounding

Eight of the 11 included studies are observational, contributing the majority of the 13,617 participants (23–25). Luo et al. noted risks of selection bias e.g. non concurrent control groups and residual confounding by indication, glycaemic control, BMI and comorbidities (15). Women selected for earlier induction may have worse glycaemic control, higher BMI or suspected macrosomia, while expectantly managed women may have milder disease and more

favourable obstetric histories (15). Additional observational studies contributing to the evidence base include cohorts evaluating timing of delivery and outcomes in GDM (26,27) and earlier comparative studies around induction policies in diabetic pregnancies (28,29). Contemporary cohort work confirms that poorer glycaemic control and obesity strongly predict macrosomia, shoulder dystocia and NICU admission (3,30,31). Without consistent individual level adjustment, the net direction of bias remains uncertain.

Heterogeneous definitions of exposure and comparator

“Induction” spans prostaglandins, mechanical methods and oxytocin, at different gestational ages (37–40 weeks) and varying cervical favourability (23,26,28). “Expectant management” generally includes women who deliver later, sometimes after subsequent induction or pre labour CS for emerging indications (23,26,28). One study (Sutton et al.) includes spontaneous vaginal birth at the same week as induced women in the expectant group (24). This undermines a simple “induction vs no induction” contrast and complicates causal inference for outcomes such as CS (15).

Temporal and contextual heterogeneity

The studies span more than three decades (1983–2014), over which diagnostic criteria (e.g. adoption of IADPSG/WHO 2013), glucose targets, thresholds for induction and intrapartum practices have changed substantially (2,13,14). Modern cohorts also distinguish early onset and insulin requiring GDM from late onset, diet controlled GDM with different risk profiles (6,32). Pooling across such heterogeneous eras and populations, without robust stratification, may mask effect modification (23).

3.3 Risk of Bias Assessment and Reporting

Luo et al. used the Cochrane Risk of Bias tool for RCTs while the NOS was used for observational studies and summarised quality in a table (19,20). However:

- Two of the three RCTs (including Kjos 1993, and Singh 2013) have unclear risk of bias (22,33). The third (Alberico 2017) is rated high risk, mainly due to limitations in blinding and attrition (34).
- Several observational studies score only 4–6/9 on NOS, which reflects issues in selection and comparability (15,20).
- While GRADE is applied, its implications for clinical interpretation are mainly in the supplement rather than integrated into the main text (15,21).

3.4 Statistical Methods and Heterogeneity

Random effects Mantel Haenszel models are appropriate given clinical and methodological

diversity (18). RCTs and observational studies are analysed separately. However:

- Pooled estimates for CS show substantial heterogeneity among cohort studies (I^2 70%). Heterogeneity is explored only by study design. Meta regression on gestational age at induction, insulin treatment or BMI is not reported (15).
- Only crude ORs are pooled, even when some primary studies present adjusted estimates; residual confounding is therefore likely (15).
- Absolute risk differences and numbers needed to treat/harm are not presented which limits clinical interpretability of relative effects for outcomes like macrosomia or perineal lacerations (18).
- Funnel plots are used to explore publication bias, but with ≤ 11 studies, power to detect asymmetry is limited (35).

4. Interpretation of Findings

4.1 Caesarean Section

Luo et al. found no significant difference in caesarean section odds between induction and expectant management across all studies, with similar null results when RCTs and observational data were analysed separately (15). This broadly accords with newer evidence in low risk populations suggesting that well managed induction at 39–40 weeks need not increase CS and may reduce it in some contexts (8,9). However, in this review, “expectant management” typically involves later induction or caesarean section for evolving indications thus the comparison is “earlier planned birth vs later planned or unplanned birth” rather than induction versus spontaneous labour alone (15). The null finding can be interpreted as bringing birth forward by induction at term does not substantially change overall caesarean section risk in GDM compared with allowing pregnancy to continue under current practice (15).

Given that caesarean section risk is strongly influenced by cervical favourability, fetal size and intrapartum management, Luo et al.’s findings suggest that timing policy alone is unlikely to dramatically alter caesarean section rates in GDM; optimisation of intrapartum care for suspected macrosomia and labour progress may be more influential (15).

4.2 Macrosomia and Birth Trauma

The most robust signal in Luo et al.’s meta analysis is the reduction in macrosomia with induction. All contributing studies show lower macrosomia rates with induction, with a pooled OR around 0.64 (15). This is biologically plausible under the Pedersen hypothesis and its modern refinements, whereby ongoing maternal hyperglycaemia leads to fetal hyperinsulinaemia, increased nutrient storage and accelerated fetal growth (30,36).

Luo et al. also report a reduction in severe perineal

lacerations in observational studies (15). This likely reflects fewer vaginal births of very large infants, consistent with contemporary evidence linking macrosomia to shoulder dystocia, anal sphincter injury and CS for obstructed labour (31,32,37). Two nuances are important:

Magnitude in absolute terms

The ORs are favourable, but Luo et al. did not consistently provide baseline risks, limiting calculation of absolute risk reduction (15). In contemporary GDM populations with macrosomia rates of approximately 10–20%, the number needed to induce to prevent one case may be substantial especially in low risk, well controlled women with GDM (1,6).

Interaction with glycaemic control and obesity

Modern studies show that macrosomia risk varies markedly with HbA1c, fasting glucose, BMI and early vs late onset GDM (3,30,31). Without stratification by these factors, the pooled macrosomia benefit may obscure genuine heterogeneity, overestimating benefit in well controlled, normal BMI women and underestimating it in high risk phenotypes (4,10).

4.3 Neonatal Morbidity and Mortality

For LGA, shoulder dystocia, NICU admission, 5 min Apgar <7, neonatal acidemia and perinatal mortality, Luo et al. found no statistically significant differences between induction and expectant management, with wide confidence intervals and low GRADE ratings (15). Several RCTs report zero perinatal deaths in both arms, and rare events in observational studies require continuity corrections (15).

This aligns with more recent literature suggesting that in well controlled GDM at term, the main trade off of earlier delivery is between reduced macrosomia/birth trauma and potential increases in early term respiratory and metabolic morbidity (11,15,30). Robust evidence for mortality benefit with routine early term delivery in GDM remains lacking (11).

5. Positioning Luo et al. Within the Recent Literature

More recent narrative reviews and guidelines emphasise nuanced, phenotype specific timing of birth in GDM (12–14). Data from large cohorts indicate that early onset or insulin treated GDM carries higher stillbirth and neonatal risk, potentially justifying earlier delivery (around 38–39 weeks), whereas late onset, diet controlled GDM may safely continue to 39–40 weeks if glycaemic control is good (26,27,38).

Luo et al.'s synthesis, pooling older RCTs and more recent observational data, updates prior systematic reviews that were hampered by very few studies and inconsistent results (15,39). Their conclusion that induction at term reduces macrosomia and severe perineal trauma without altering CS or serious neonatal outcomes fits with contemporary conceptions of induction as a strategy primarily to reduce fetal macrosomia and birth trauma rather than CS or mortality (23,26,39).

However, because most included studies lack detailed reporting on GDM phenotype, glycaemic control or BMI, Luo et al. cannot fully reflect the more personalised, risk stratified approach now advocated (3,6,38).

6. Clinical and Guideline Implications

Luo et al.'s review supports several aspects of current practice.

Induction as a tool to reduce macrosomia and birth trauma rather than a primary means to lower CS or perinatal death (15).

Flexible timing within 38–40 weeks for most well controlled GDM pregnancies, tailored to maternal and fetal risk factors and local resources (10–12).

However, several nuanced practice questions are unresolved by Luo et al.:

How should timing be individualised by GDM phenotype?

Early onset or insulin requiring GDM (class A2) may benefit from earlier delivery compared to late onset, diet controlled GDM (class A1) (10,14,27). Luo et al. cannot address this due to lack of stratified data by GDM subtype (15).

How important is the method and quality of induction?

Success and CS risk with induction depend on cervical status, method of induction, protocol and staffing (7,9). The review does not stratify by these factors, which may limit applicability across settings with different induction resources (15).

What about patient centred outcomes and health system capacity?

Induction at scale affects labour ward workload and women's experiences (7). Recent qualitative and mixed methods work suggests that women with GDM fears about macrosomia and shoulder dystocia against concerns about increased intervention (39,40). None of the primary studies in Luo et al. discuss about patient reported outcomes or economic data which is a notable gap for making shared decision (15).

7. Strengths and Limitations

7.1 Strengths

- **Clinically important, relevant question** aligned with international guideline controversies.
- **Rigorous methodology** involving protocol registration, adherence to PRISMA, comprehensive search, duplicate screening and extraction (16–18).
- **Including both RCTs and observational studies**, with separate analyses (15).
- **Clear primary and secondary outcomes** with focus on CS, macrosomia and severe perineal trauma which are outcomes with direct relevance to women and clinicians (15).
- **Explicit risk of bias assessment** and use of GRADE (19–21).
- **Transparent discussion of limitations**, including selection bias, residual confounding and potential publication bias (15).

7.2 Limitations

From a critical perspective:

- The evidence base is largely observational, old and **moderate to low quality**, with incomplete control for confounding and variable definitions of induction and expectant management (15,23,26).
- There is **limited stratification** by GDM phenotype, glycaemic control, BMI and treatment modality, now known to be major modifiers of risk (3,6,38).
- **Pooled effects** are expressed mainly as ORs without absolute risks or numbers needed to treat, limiting bedside decision making (18).
- **Patient reported outcomes and economic implications** are not mentioned, although they are important in an era of rising induction rates and constrained resources (8,40).

8. Conclusions and Future Directions

Luo et al.'s systematic review and meta analysis make a meaningful contribution to the debate on optimal timing of delivery in GDM. In aggregate, the review suggests, induction of labour at term:

- Reduces macrosomia and, in observational data, severe perineal trauma (15,37).
- Does not clearly change CS rates or serious neonatal outcomes (24,34).
- It argues that induction should be used mainly to limit fetal macrosomia and birth trauma rather than to reduce operative birth or mortality (15,27,39).

In current practice, the decision to induce these women with GDM at term should be based on a woman's individual glycaemic control, body mass index, obstetric history and local service capacity,

rather than a blanket policy (3,15). The key findings of Luo et al. strengthen guideline recommendations that routine induction between 38–40 weeks is reasonable for many GDM pregnancies (13,14). The findings also underscore the strong need for modern, adequately powered RCTs and high quality prospective cohorts which

- Stratify by GDM phenotype and metabolic control (15,30).

- Incorporate patient centred outcomes and cost effectiveness (30,40).

- Use rigorous methods to adjust for confounding by indication (24,39).

In an era where the diagnosis of gestational diabetes mellitus (GDM) encompasses a more heterogeneous population than ever before, well designed studies are essential to determine the optimal timing and mode of delivery (10,15,24).

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