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Timing of delivery in women with gestational diabetes mellitus: still an open question

Rosamaria Pellegrini¹, Laura Basile^{1,*}, Daniela Menichini², Fabio Facchinetti¹

¹Department of Medical and Surgical Science of the Infant and Adult, University of Modena and Reggio Emilia, Modena, Italy.

²International Doctorate School in Clinical and Experimental Medicine, Department of Biomedical, Metabolic and Neural Sciences, University of Modena and Reggio Emilia, Modena, Italy.

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*Corresponding author: Laura Basile, M.D.
Department of Medical and Surgical Science of the Infant and Adult, University of Modena and Reggio Emilia, via del Pozzo 71, 41125 Modena, Italy.
Email: Laurabaso92@gmail.com.
ORCID: 0009-0003-7500-8103.

ABSTRACT

Gestational diabetes mellitus (GDM) is a pregnancy-related glucose intolerance, and it represents one of the most common metabolic disorders during pregnancy. GDM is associated with serious short- and long-term maternal and foetal morbidity.

The prevalence of both pre-gestational and gestational diabetes mellitus is increasing among women due to older maternal age at childbearing and the growing prevalence of obesity and overweight worldwide.

This review summarizes the recommendations of the main scientific societies on mode and time of delivery in GDM women, highlighting the absence of unique clinical management.

Moreover, analysing the literature, only three randomized clinical trials (RCTs) on this topic are available, and also the largest of these appears underpowered and it does not provide statistically significant data.

In conclusion, the lack of evidence and meta-analyses, suggests the necessity of further studies to draw up guidelines about time and mode of delivery to help clinicians in their decision making.

INTRODUCTION

Gestational diabetes mellitus (GDM) is the most common complication of pregnancy, and it is defined as a glucose intolerance of varying degree that develops in the second or third trimester of pregnancy and it generally resolves after delivery [1].

GDM is associated with an increase of maternal-foetal morbidity as well as short- and long-term complications [2]. Long-term neonatal complications not

only arise from the hyperglycaemia to which foetuses are exposed, but are also a consequence of epigenetic mutations in the offspring, namely in Large for Gestational Age (LGA) newborns [3]. The main complications in GDM pregnancies are caesarean delivery and birth trauma. Little is the available evidence to guides us in the delivery management of these pregnancies. The poorly controlled GDM (elevated BMI, marked insulin resistance as manifested by insulin requirements, polyhydramnios and increased foetal

abdominal circumference) should likely be managed considering earlier induction. In other way, the “low risk” well-controlled primiparous GDM patient with an unfavourable cervix is likely to benefit from expectant management [4].

The Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study showed there is a continuous and graded relationship between maternal hyperglycaemia and risk for adverse perinatal outcome, independent of other risk factors [5].

A large retrospective study [6] evaluated the risk of stillbirth (SB) and infant death stratified by gestational age, in women with GDM; the SB and neonatal death risk for 36-42 week was higher in GDM women compared to the population without diabetes. Such risk displayed a U-shaped curve, highest at 36 weeks, decreasing to a nadir at 39-40 weeks (also in women without GDM), increasing again at 41 and 42 weeks. This result suggested that planning delivery at 39 weeks would be a strategy preventing SB. In a retrospective study, the differences between deliveries with and without iatrogenic intervention in GDM pregnancies were analysed [7]. The incidence of caesarean delivery at ≥ 41 gestational weeks was significantly higher than that at 39^{0/6} weeks. The rate of macrosomia was not significantly different between the different gestational weeks, except that no macrosomia was present at < 37 weeks. The incidences of postnatal hypoglycaemia and vomiting and moaning at < 37 gestational weeks were significantly higher than those in the 39 0/6 gestational weeks group. The results give in this way an indication for the delivery at 39-40 weeks.

PREVALENCE OF GDM IS INCREASING

The prevalence of GDM has increased by more than 30% in several countries, including developing countries Africa, Southeast Asia, the western Pacific regions [8], forming an emerging worldwide epidemic [9]. This increase may be related to the older maternal age, the epidemic of obesity and diabetes, and the reduction in physical activity

with the adoption of the worst western lifestyles in developing countries [10]. According to Emilia Romagna Birth certificates, in 2020 the mean age at delivery was 32 years, there were 10.3% obese and 20.7% overweight women at beginning of pregnancy. The obesity rate has increased compared to 7.7% detected in 2012 in Emilia Romagna [11]. European data shows that the mean age at delivery was 29.5 years and 30-50% of women were obese or overweight at beginning of pregnancy [12].

The growing incidence of GDM consequently increased the interest in this metabolic disorder, leading to the development of more stringent screening. The international Association of Diabetes and Pregnancy Study Groups (IADPSG) developed a consensus statement for a new strategy to diagnose GDM [13] with a reduction of threshold values measured at glucose challenge. These changes were associated with an increased detection rate of GDM, 23.1% according to IADPSG compared with previous values of 17.8% [14]. Similarly, there was an increased prevalence the GDM when the IADPSG criteria were compared with 1999 WHO criteria, respectively 12.4% vs 9.4% respectively [15] (Table 1).

However, easily accessible and systematically organized data on global prevalence estimates of GDM are lacking. Furthermore, lack of consensus and uniformity in the screening standards, definition, and diagnosis criteria of GDM challenges the comparative assessment of the GDM prevalence across countries and regions [9]. At the same time, the need to standardize obstetric management, that appears to be very heterogeneous in terms of mode and timing of delivery, becomes urgent.

TIMING AND MODE OF DELIVERY IN GDM WOMEN

Guidelines

Individual providers, practices, and medical institutions traditionally developed protocols for

Table 1. Summary of the main international diagnostic criteria for GDM.

	IADPSG 2010 (any of one)	NICE 2015 (any of one)	WHO 1999 (any of one)
Fasting glucose, mg/dL	≥ 91.9	≥ 100.9	≥ 109.9
1 h glucose, mg/dL	≥ 180.2	-	-
2 h glucose, mg/dL	≥ 153.2	≥ 140.5	≥ 140.5

Table 2. Summary of the main international guidelines.

	ACOG (2018)	WHO (2011)	NICE (2015)	SOGC (2019)	Polish Gynaecological Society (2017)	Emilia Romagna (2019)
GDM controlled only with diet and exercise	No delivery < 39 wks, unless otherwise indicated. Expectant management up to 40 6/7 wks in the setting of indicated antepartum testing	IOL < 41 wks is not recommended. (Very-low-quality evidence/weak recommendation)	IOL not later than 40 6/7 weeks		Delivery after 39 weeks (Level C)	IOL between 39 0/7 and 40 6/7 weeks
GDM requiring medications	Delivery recommended at 39 0/7 to 39 6/7 weeks	IOL may be necessary	Consider elective birth < 40 6/7 wks with maternal or foetal complications	IOL at 39 wks could be considered		Delivery is recommended from 39 0/7 – 39 6/7 weeks
Poorly controlled GDM	Delivery 37 0/7 to 38 6/7 weeks Delivery from 34 0/7 to 36 6/7 wks if failed in-hospital attempts to improve glycaemic control or with abnormal antepartum foetal testing					IOL is recommended between 37 0/7 and 38 6/7 weeks
Suspected macrosomia	Explain risks and benefits of a scheduled CS when the EFW ≥ 4,500 g	IOL at term is not recommended. (Low-quality evidence/weak recommendation)	Explain risks and benefits of vaginal birth, IOL and CS		EFW > 4,000 g and/or difference between AD and BPD > 2.6 cm, IOL is contradicted	

IOL: induction of labour; EFW: estimated foetal weight; CS: caesarean section.

labour management in women with GDM by incorporating a combination of anecdotal experience, published literature, and recommendations by national clinical organizations. Different scientific associations provided some guidance for labour management of pregnancies complicated by GDM. A summary of the main international guidelines is reported in **Table 2**.

Delivery management options in women with GDM include expectant management, labour induction, elective caesarean sections (CS) [16].

GDM is not by itself an indication for caesarean delivery or for delivery before 38 completed weeks of gestation [17] and is not a contraindication for a vaginal delivery.

The American College of Obstetricians and Gynecologists (ACOG) states that elective CS may be indicated in women with GDM whose estimated foetal weight (EFW) is ≥ 4,500 g. Women with GDM with good glycaemic control (only with diet and exercise) and no other complications are commonly managed expectantly up to 40 6/7 weeks of gestation while for women with GDM that is well controlled by medications, delivery is recommended from 39 0/7 weeks to 39 6/7 weeks of gestation. Expert opinion has supported earlier delivery for women with a poorly controlled GDM. Clear guidance about the degree of glycaemic control that indicates earlier delivery, however is lacking, and the clinical choice must be made on a risk-benefit balance considering the risks of prematurity *vs* the ongoing risks of stillbirth. In such a setting, delivery between 37 0/7 weeks and 38 6/7 weeks of gestation may be justified, on the contrary delivery in the late preterm period from 34 0/7 weeks to 36 6/7 weeks of gestation should be reserved for women with lack of blood glucose control with no others strategy of intervention or with evidence of foetal distress [18].

The World Health Organization (WHO) in 2021 does not recommend induction of labour before 41 weeks for GDM women whose glycaemic level is controlled only with diet and exercise. For GDM women under medication, induction of labour may be necessary, but not in the case of suspected macrosomia, although the quality of the evidence is low, and the recommendation is weak [19].

The National Institute for Health and Care Excellence (NICE) guidance, recommends elective birth (induction of labour or CS) before 40 6/7

weeks in case of maternal or foetal complications [20].

The Society of Obstetricians and Gynaecologists of Canada (SOGC) suggests more frequent foetal assessments, in women with poorly controlled GDM and/or associated with other maternal/foetal diseases. The induction of labour may be offered at 39 weeks with the purpose to reduce the risk of stillbirth and the risk of CS. Earlier or later induction of labour should be considered if GDM is not well controlled or maternal and/or foetal pathologies overlap [21].

According to the Polish Society of Gynaecologists, in the event of an EFW > 4,000 g, induction of labour is contraindicated due to the increased risk of shoulder dystocia. When GDM is well managed, patients are compliant, no other maternal/foetal complications coexist and the estimated foetal weight is between the 10th and 90th percentile, or does not exceed 4,000 g, pregnancy may continue until 39-40th weeks. Individuals with poorly managed GDM, or other maternal and/or foetal pathologies, should be individually assessed [22].

The Emilia Romagna guidelines of 2019 recommend induction of labour between 39 0/7 and 40 6/7 weeks in GDM women managed with diet and exercise, while for women under medication delivery is recommended from 39 0/7-39 6/7 weeks. Poorly controlled GDM women should be induced between 37 0/7 and 38 6/7 weeks [23].

This variety of guidelines on GDM management, underlines that 1) GDM is not a homogenous entity with diverse clinical presentation, and 2) scientific evidences are scanty, based primarily on retrospective studies that summarize individual hospitals' policies. Moreover, each GDM woman faces unique challenges with respect to her ethnicity, biomedical condition, psychological makeup, and social support system and all these factors may potentially impact obstetric decision-making [24].

Randomized controlled trials

Search strategy

To summarize the best evidence on the timing and mode of delivery in GDM women, we carried out a computerized literature search using PubMed. Eligibility criteria were predetermined by reviewers to prevent bias in the inclusion or exclusion of articles and to improve the precision

of the search. We included the most recent experimental studies exclusively published in English until 2021, involving women with GDM randomized to expectant management *versus* induction of labour (IOL). We found only three randomized clinical trials (RCT) available on the timing and mode of delivery in GDM women [25-27]. The first one was conducted by Kjos *et al.* [25] to assess whether the CS rate could be safely reduced by expectant management *versus* induction of labour (IOL) at 38 weeks. It included 200 women with insulin-requiring GDM or uncomplicated pre-gestational diabetes, which were randomly assigned to IOL within 5 days or expectant management (EM), at 38 weeks. The EM group was monitored weekly. The rate of CS was not different between the two arms. However, more cases of shoulder dystocia occurred in EM group (only three cases), with a significant increase in LGA infants compared with IOL. Therefore, the authors concluded that there is no advantage in delaying delivery in women with insulin requiring diabetes past 38 to 39 weeks' gestation. If delivery is postponed, careful monitoring of foetal size and growth must be performed [26] (Table 3).

The GINEXMAL [26] is the largest RCT so far carried out and it has been included in the most recent Cochrane review [28]. The aim of this multicentre open-label RCT was to provide evidence on the best management of women with diagnosis of GDM in terms of maternal and neonatal outcomes [26, 29]. Eligible patients, according to inclusion/exclusion criteria were enrolled and randomized between 38 and 39 weeks of gestation to expectant management or IOL. The main outcomes were the incidence of CS and the rate of operative vaginal delivery, the latter considered risk factor for shoulder dystocia and other adverse outcomes. Secondary outcomes were assessed at the time of delivery and/or during maternal and neonatal admission until discharge. They included mode of delivery, spontaneous or assisted third stage of labour, perineal tears, postpartum haemorrhage, gestational age and weight at birth, shoulder dystocia, neonatal respiratory distress, APGAR score, arterial cord pH, biochemical hypoglycaemia, and hyperbilirubinemia (Table 3). No difference was detected between the two arms both in caesarean section rate and in non-spontaneous delivery rate. A few cases of shoulder dystocia occurred and were solved without significant birth trauma. Mater-

Table 3. Summary of RCTs characteristics.

	Kjos <i>et al.</i> 1993, California	Alberico <i>et al.</i> 2016, Italy, Slovenia and Israel	Worda <i>et al.</i> 2017, Vienna
Participants	200 women with uncomplicated, insulin-requiring gestational or class B pregestational diabetes at 38 weeks' who were compliant with care and whose infants were judged appropriate for GA	425 women with singleton pregnancy, diagnosed with GDM by the IADPSG between 38+0 and 39+0 weeks of gestation, without other maternal or foetal conditions.	100 women with insulin-treated GDM
Interventions	IOL: between 38 and 38+5 weeks EM: weekly monitoring by physical exam and twice a week nonstress tests and amniotic fluid volume estimation until delivery.	IOL between 38+0 and 39 + 0 weeks EM until 41+0 weeks with electronic foetal heart rate monitoring and biophysical profile twice-weekly	IOL at 38 weeks IOL at 40 weeks
Primary outcome	Caesarean section rate	Caesarean section rate Non-spontaneous delivery rate	LGA, neonatal hypoglycaemia and bilirubinaemia, Apgar score at 5 th min, arterial pH-value and rate of NICU admission
Secondary outcomes	GA at delivery, birth weight, and numbers of infants defined as macrosomic (~4,000 g) or LGA. Shoulder dystocia, hypoglycaemia, perinatal death	Assisted 3 rd stage of labour, perineal tears, postpartum haemorrhage, GA and weight at birth, shoulder dystocia, neonatal respiratory distress, Apgar score, arterial cord pH, maternal blood transfusion, ICU admission, hypoglycaemia and hyperbilirubinemia, NICU admission, maternal and perinatal death	Induction to delivery interval, rate of caesarean section
Follow-up	Until discharge from the hospital	Until discharge from the hospital	Until discharge from the hospital

RCT: randomized controlled trial; IOL: induction of labour EM: expectant management; ICU: intensive care unit; NICU: neonatal intensive care unit; GA: gestational age.

nal and neonatal outcomes were similar in the two groups except for hyperbilirubinemia, significantly higher in the IOL group. As expected, gestational age and birthweight were lower in the induction group.

Although this study is the largest published focusing on women affected exclusively by GDM, it resulted underpowered, including low-risk population and having the two arms unbalanced for GDM treatment.

Recently Worda *et al.* planned a RCT [27] to evaluate foetal and maternal morbidity in women with insulin-treated GDM, comparing IOL at 38 weeks *vs* IOL at 40 weeks. Out of 100 randomized women, only 91 were eligible for final analysis focused on neonatal outcomes (LGA newborns, neonatal hypoglycaemia and hyperbilirubinemia, APGAR score at 5th min, cord arterial pH-values and rates of NICU admission). Secondary outcomes IOL to delivery interval and the rate of CS. The main limitation of this study is the sample which makes findings less meaningful. However, although this RCT does not provide statistically significant differences among groups, the authors conclude suggesting routine induction of labour at 40 weeks, considering a lower rate for CS and significantly lower rates of hypoglycaemia and hyperbilirubinemia.

CONCLUSIONS

Given the high incidence of gestational diabetes and the high risk of maternal and perinatal adverse outcomes, the identification of an algorithm for the labour and delivery management for GDM patients is mandatory.

The insufficient quantity of evidences and meta-analyses, highlights the importance of further studies to provide high quality data on optimal terms and modes of delivery in diabetic pregnancies to help guide clinicians in their decision making (Table 4). We recommend a well-designed multicentric RCT comparing expectant management with induction of labour in these women either under diet and exercise or medical treatment. Sample size should be large enough to allow for answers to rare neonatal outcomes, such as perinatal mortality and shoulder dystocia. The enrolled population should represent the general population, in order that the results could be transferable.

Table 4. Summary of RCTs findings.

Outcomes	Kjos et al. 1993 Study arms		Alberico et al. 2016 Study arms		Worda et al. 2017 Study arms	
	IOL (n = 100)	EM (n = 100)	IOL (n = 214)	EM (n = 211)	IOL 38 w (n = 44)	IOL 40 w (n = 47)
Caesarean section (%)	25 (25.0)	31 (31.0)	27 (12.6)	25 (11.8)	7 (15.9)	3 (6.4)
Operative vaginal delivery (%)	NA	NA	18 (8.4)	22 (10.4)	NA	NA
Postpartum haemorrhage (%)	NA	NA	13 (6.1)	11 (5.2)	NA	NA
ICU admission (%)	NA	NA	3 (1.4)	2 (0.9)	NA	NA
Mean GA at birth (wks)	39 ± 2	40 ± 2	NA	NA	NA	NA
GA > 39 weeks (%)	NA	NA	47 (22.0)	157 (74.4)*	NA	NA
Birth-weight (g)	3446 ± 78	3672 ± 77	NA	NA	3246 ± 458	3352 ± 492
Macrosomia/LGA (%)	10 (10)	23(23.0)*	13 (6.1)	24 (11.4)*	3 (6.8)	4 (8.5)
Apgar at 5 th minute < 7 (%)	NA	NA	2 (0.94)	0	NA	NA
Shoulder dystocia (%)	0/100 (0)	3 (3.0)*	3 (1.4)	1 (0.5)	NA	NA
Biochemical hypoglycaemia (%)	0	0	6 (3.0)	8 (4.1)	16 (36.4)	8 (17.0)*
Hyperbilirubinaemia (%)	NA	NA	20 (10.0)	8 (4.1)*	NA	NA
Respiratory distress (%)	NA	NA	3 (1.4)	2 (0.9)	NA	NA
NICU admission (%)	NA	NA	2 (0.9)	2 (0.9)	3/44	4/47
Perinatal death (%)	0	0	0	0	NA	NA

*P-value < 0.05.

COMPLIANCE WITH ETHICAL STANDARDS

Authors contribution

All authors contributed equally to this work.

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Study registration

N/A.

Disclosure of interests

The authors declare that they have no conflict of interests.

Ethical approval

This study is based on secondary data therefore the ethics approval was not required.

Informed consent

N/A.

Data sharing

N/A.

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