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Extended Research Article

Glycaemic control in labour with diabetes: GILD, a scoping study

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Scientific summary

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Scientific summary

Background

Diabetes in pregnancy affects 5–10% of pregnant women. For most women, this is gestational diabetes mellitus (GDM) (87.5%), but 12.5% of women have pre-existing type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM). There is evidence that 'tight' glycaemic control in pregnancy reduces the risk of adverse outcomes for the mother and the baby. Maternal hyperglycaemia results in increased fetal insulin production because of excess placental transfer of glucose and can lead to neonatal hypoglycaemia. The ideal intrapartum glucose target level is unknown. Traditionally 'tight' glucose control (target 4–7 mmol/l) is recommended in labour. Treatment with intravenous insulin may be needed during labour to maintain 'tight' control; however, this may be unnecessary, and this increases the risk of maternal hypoglycaemia in labour, which carries a risk to the mother. Hourly intrapartum testing is also intrusive for women and time-consuming for healthcare professionals (HCPs). Conversely, accepting more permissive glucose levels in the mother may be detrimental to the baby.

Objective

To determine the feasibility of a randomised trial to compare the clinical and cost-effectiveness of permissive versus intensive intrapartum glycaemic control in labour in women with pregnancies complicated by diabetes.

Methods

A mixed-methods scoping study of four work packages:

Work package 1: Assessment of current practice determined by:

a. review of clinical guidelines on intrapartum glycaemic control in pregnant women with diabetes and neonatal hypoglycaemia in UK maternity units
b. survey of practice, training and experience of HCPs involved in caring for women with diabetes in labour in the UK
c. survey of women who have/had diabetes in pregnancy to hear their views on glucose monitoring in labour and the birth outcomes that are important to them
d. a national service evaluation of intrapartum care in pregnant women with diabetes exploring practice and adherence to clinical guidelines on maternal glycaemic control.

Work package 2: Delphi survey followed by a consensus meeting to agree important components of a future trial (types of diabetes, glucose levels in control and intervention arm, frequency of monitoring, maternal and neonatal outcomes).

Work package 3: Design a clinical trial of permissive versus intensive intrapartum glycaemic control in labour for women with diabetes, including consideration of an economic evaluation.

Work package 4: One-to-one virtual interviews with women with diabetes who have experienced labour and HCPs who look after them to understand facilitators or barriers to conducting the trial.

Results

Work package 1a

We collected local unit guidelines of diabetes care in labour from a total of 48 units in England, Wales and Scotland with a further 12 in a joint regional guideline and unit guidelines on neonatal hypoglycaemia covering 55 trusts. There is

significant variation in recommended frequency of testing for GDM in labour, technologies used to test glucose levels in labour and administer insulin in T1DM, and in the operational definition of neonatal hypoglycaemia.

Work packages 1b and 1c

The online surveys were completed by 174 HCPs and 159 women. Confidence of HCPs ranged from 57% reporting feeling fairly or extremely confident in management of T1DM in labour, through to 62% for T2DM and 72% for GDM. Education and training were therefore considered important for successful trial conduct. Of the women surveyed, 66% would be willing to participate in a future trial, with 23% unsure without further information.

Work package 1d

The service evaluation included 594 women from 33 obstetric units. Only 7 women (9%) with T1DM, 7 women (14%) with T2DM and 34 (7%) with GDM had a glucose measurement taken within an hour of admission to Labour Suite (8% overall). Once glucose testing had commenced, it was repeated in 1 hour in 18% overall (34% for T1DM, 14% for T2DM and 16% for GDM). Results for 2 hours was 38% overall (52% for T1DM, 35% for T2DM and 36% for GDM) and for 4 hours 45% overall (58% for T1DM, 50% for T2DM and 42% for GDM) of women re-tested.

The incidence of neonatal hypoglycaemia (defined as glucose < 2.6 mmol/l) was 47% in T1DM, 45% in T2DM and 16% in GDM. The rates of other maternal and neonatal complications were low.

Work package 2

The Delphi survey was conducted in three rounds between February 2022 and March 2022. Round 1 was completed by 133 from 150 registered participants (20 obstetricians, 19 midwives, 5 endocrinologists, 4 neonatologists, 102 parents; 89%), round 2 by 40 participants (12 HCPs and 28 women) and round 3 by 23 (7 HCPs and 16 women). The consensus meeting was attended by 30 participants including obstetricians (7), endocrinologists (4), neonatologists (3), midwives (6), trialists/methodologists (2), health economists (2), health psychologist (1) and women with lived experience of labour with diabetes (5). Consensus was gained on key outcomes for a future trial, with agreement that all types of diabetes should be studied with a permissive glucose target range of 4–10 mmol/l. Neonatal hypoglycaemia should be the primary outcome. Maternal satisfaction was considered an important maternal outcome.

Work package 3

Based on data from previous work packages, a randomised trial using an umbrella design and master protocol has been designed, with an aim to include women with all types of diabetes. The trial will evaluate if a permissive monitoring strategy is non-inferior to a tight control strategy, with a primary outcome of neonatal hypoglycaemia (defined as blood glucose level < 2.6 mmol/l). Key components were identified to conduct a within-trial economic evaluation to estimate the incremental cost per neonatal hypoglycaemia prevented at birth.

Work package 4

Nineteen women and 16 HCPs participated in a 1:1 virtual interview. There was support for the trial, but participants outlined important aspects including the timing of approach and consent and ensuring a multidisciplinary approach to conducting the trial within the hospital.

Patient and public involvement

This study was co-designed from the outset with a patient and public involvement (PPI) co-applicant with a funded PPI advisory group who influenced and guided the development of this project into its final submission.

Conclusions

Data from all work packages have been used to determine the most appropriate design for a future trial. There is eagerness from women with lived experience of diabetes during labour, and HCPs (obstetricians, neonatologists, endocrinologists and midwives) to conduct a randomised clinical trial. An umbrella trial design will enable efficiencies in conduct to minimise burden at participating sites, while allowing women with any type of diabetes to be included. This was considered important by all stakeholders. We also consider it feasible to conduct a within-trial economic evaluation

to estimate the incremental cost per neonatal hypoglycaemia prevented at birth. The trial we have designed was considered necessary, acceptable and feasible by the women and HCPs who took part in interviews.

We therefore recommend that a clinical trial comparing glucose-monitoring strategies in labour, for women with diabetes, is conducted, including an internal pilot phase to test key aspects of trial conduct, given the challenges we have identified during this scoping study.

Study registration

This study is registered as researchregistry6832.

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