

Screening and active management reduced perinatal complications more than routine care in gestational diabetes

Crowther CA, Hiller JE, Moss JR, *et al.* Effect of treatment of gestational diabetes mellitus on pregnancy outcomes. *N Engl J Med* 2005;**352**:2477–86.

Clinical impact ratings GP/FP/Primary care ★★★★★☆☆ IM/Ambulatory care ★★★★★☆☆ GP/FP/Obstetrics ★★★★★☆☆ Obstetrics ★★★★★☆☆ Endocrine ★★★★★☆☆

Q In women with gestational diabetes mellitus (GDM), does a screening and active management intervention reduce serious perinatal complications more than routine care?

METHODS

-  **Design:** randomised controlled trial (Australian Carbohydrate Intolerance Study in Pregnant Women [ACHOIS]).
-  **Allocation:** {concealed*}†.
-  **Blinding:** blinded {outcome assessors (except for shoulder dystocia), data analysts, and monitoring committee}†.*
-  **Follow-up period:** birth to hospital discharge.
-  **Setting:** 16 hospitals in Australia.
-  **Patients:** 1000 women (mean age 30 y) with a singleton or twin pregnancy at 16–30 weeks' gestation and ≥1 risk factor for GDM on selective screening or a positive 50 g oral glucose challenge test (GCT) result, and a 75 g oral glucose tolerance test at 24–34 weeks' gestation with fasting glucose <7.8 mmol/l after an overnight fast and 7.8–11.0 mmol/l [140–198 mg/dl] at 2 hours.
-  **Intervention:** a screening and active management intervention (routine screening and treatment for GDM, dietary counselling, glucose self monitoring, and insulin therapy as needed) (n = 490), or routine care (diagnosis of GDM unknown) (n = 510).
-  **Outcomes:** neonatal outcomes: perinatal complications (a composite of death, shoulder dystocia, fracture, and palsy), admission to the neonatal nursery, jaundice requiring photo therapy, birth weight, and macrosomia (≥4 kg). Maternal outcomes: need for induction of labour and caesarean delivery.
-  **Patient follow-up:** 100% (intention to treat analysis).

*See glossary.
†Information provided by author.

MAIN RESULTS

1030 infants were born. The intervention, relative to routine care, led to fewer perinatal complications, more admissions to the neonatal nursery, more induced labours (table), lower birth weight (3335 v 3482 g, adjusted p<0.001), and fewer infants who were large for gestational age (p<0.001) or had macrosomia (p <0.001). Groups did not differ for caesarean delivery, components of the composite end point, or other perinatal outcomes.

CONCLUSION

In women with gestational diabetes, screening and active management reduced perinatal complications more than routine care.

Abstract and commentary also appear in ACP Journal Club.

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Commentary

Finally, the trial by Crowther *et al* offers high quality evidence to answer the question about the efficacy of treating (and therefore screening for) GDM. The approach used in this well designed RCT stands to principally benefit the newborn infant.

I address 5 issues about the current study. Firstly, the proportion of women who initially met the study eligibility criteria but refused to participate was not mentioned. This has implications for the applicability of the results because enrolment may have included only the most compliant or healthy women. Secondly, is the primary composite end point relevant? It seems that this outcome was a realistic reflection of the expected benefits of GDM therapy, in which the rate of infant macrosomia was also reduced from 21–10%. Thirdly, what are the potential harms of dietary counselling with or without insulin therapy? Apart from greater health resource use, the availability of an experienced dietician and inexpensive glucometer testing, as well as a higher rate of induction of labour, few adverse consequences result from treating GDM. Small, remote hospitals caring for Native women for whom the rate of GDM is high should also be equipped to deal with GDM especially if dietary changes are not possible.¹ Fourthly, should we screen all pregnant women for GDM based on a 50 g GCT, or by individual risk factors? For now, the former seems necessary if one applies these study results to clinical practice because 93% of women were designated as having GDM based on a GCT result. Fifthly, because only 20% of women in the intervention group received insulin therapy but all received dietary advice, which is more important? Dietary modification should be most emphasised, given that it may reduce risk of macrosomia and birth trauma, and may have long lasting positive effects in terms of reducing the risk of type 2 diabetes,² hypertension,³ and, perhaps, cardiovascular disease.⁴

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- 1 Gray-Donald K, Robinson E, Collier A, *et al.* *CMAJ* 2000;**163**:1247–51.
- 2 Knowler WC, Barrett-Connor E, Fowler SE, *et al.* *N Engl J Med* 2002;**346**:393–403.
- 3 Neter JE, Stam BE, Kok FJ, *et al.* *Hypertension* 2003;**42**:878–84.
- 4 Ray JG. *Fetal Matern Med Rev* 2004;**15**:1–16.

SAMI v routine care for gestational diabetes at birth to hospital discharge*

Perinatal and maternal outcomes	SAMI	Routine care	RRR (95% CI)	NNT (CI)
			RRI (CI)	NNH (CI)
Any serious perinatal complication†	1%	4%	68% (29 to 86)	34 (19 to 98)
Admission to neonatal nursery	71%	61%	15% (5 to 26)	11 (7 to 29)
Induction of labour	39%	29%	31% (10 to 56)	11 (7 to 31)

*SAMI = screening and active management intervention. Other abbreviations defined in glossary; RRR, RRI, NNT, NNH, and CI calculated from data in article.

†SAMI = 7/506; routine care = 23/524. Deaths (0% v 1%), shoulder dystocia (1.4% v 3%), bone fracture (0% v 0.2%), and nerve palsy (0 v 0.6%).