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: GIM/FP/GP ★★★★★★☆ Endocrinology ★★★★★☆☆

QUESTION

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

METHODS

Design: Randomized controlled trial (Australian Carbohydrate Intolerance Study in Pregnant Women [ACHOIS]).

Allocation: {Concealed}†.*

Blinding: Blinded {outcome assessors, data analysts, and data safety and monitoring committee; outcome assessors for shoulder dystocia were not blinded}†.*

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- to 30-weeks gestation and ≥ 1 risk factor for GDM on selective screening or a positive 50-g glucose-challenge test (GCT) result, and a 75-g oral glucose tolerance test at 24- to 34-weeks gestation with fasting glucose < 7.8 mmol/L after an overnight fast and 7.8 to 11.0 mmol/L (140 to 198 mg/dL) at 2 hours.

Intervention: A screening and active management intervention (routine screening and treatment for GDM by the obstetric team, dietary counseling, glucose self-monitoring, and insulin therapy as needed to maintain glucose levels within the recommended range) (n = 490), or routine care (women and their caregivers were not aware of the diagnosis of GDM) (n = 510).

Outcomes: Neonatal outcomes included perinatal complications (a composite endpoint of death, shoulder dystocia, bone fracture, and nerve palsy), admission to the neonatal nursery, jaundice requiring phototherapy, components of the composite endpoint, birth weight, large or small for gestational age, and macrosomia (≥ 4 kg). Maternal outcomes included need for induction of labor and cesarean delivery.

Patient follow-up: 100% (women and infants) (intention-to-treat analysis).

MAIN RESULTS

Women gave birth to 1030 infants. The screening and active GDM management group had fewer perinatal complications, more admissions to the neonatal nursery, and more induced labors than the routine-care group (Table). Groups did not differ for cesarean delivery (P = 0.73). Infants in the intervention group weighed less (3335 vs 3482 g, adjusted P < 0.001) than infants in the routine-care group; and fewer were large for gestational age or had macrosomia (P for all comparisons < 0.001). Groups did not differ for components of the composite endpoint and other perinatal outcomes.

CONCLUSION

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

Sources of funding: National Health and Medical Research Council Australia and Queen Victoria Hospital Research Foundation.

For correspondence: Dr. C. Crowther, University of Adelaide, Adelaide, South Australia, Australia. E-mail caroline.crowther@adelaide.edu.au. ■

*See Glossary.

†Information provided by author.

Screening and active management intervention (SAMI) vs routine care for gestational diabetes mellitus at birth to hospital discharge‡

Perinatal and maternal outcomes	SAMI	Routine care	RRR (95% CI)	NNT (CI)
Any serious perinatal complication§	1% (7/506)	4% (23/524)	68% (29 to 86)	34 (19 to 98)
			RRI (CI)	NNH (CI)
Admission to neonatal nursery	71%	61%	15% (5 to 26)	11 (7 to 29)
Induction of labor	39%	29%	31% (10 to 56)	11 (7 to 31)

‡Abbreviations defined in Glossary; RRR, RRI, NNT, NNH, and CI calculated from data in article.

§Deaths (0 vs 1%), shoulder dystocia (1.4% vs 3%), bone fracture (0 vs 0.2%), and nerve palsy (0 vs 0.6%).

COMMENTARY

Finally, the trial by Crowther and colleagues 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. First, the proportion of women who initially met the study eligibility criteria but declined to participate was not mentioned. This has implications for the applicability of the results because enrollment may have included only the most compliant or healthy women. Second, is the primary composite endpoint 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% to 10%. Third, what are the potential harms of dietary counseling with or without insulin therapy? Apart from greater health resource utilization, the availability of an experienced dietitian and inexpensive glucometer testing, as well as a higher rate of induction of labor, few adverse consequences result from treating GDM. Small, remote hospitals caring for Native American 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).

Fourth, 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. Fifth, 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 emphasized, given that it may reduce risk for macrosomia and birth trauma and may have long-lasting positive effects in terms of reducing the risk for type 2 diabetes (2), hypertension (3) and perhaps cardiovascular disease (4).

Joel G. Ray, MD
St. Michael's Hospital, University of Toronto
Toronto, Ontario, Canada

References

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, Grobbee DE, Geleijnse JM.** Hypertension. 2003;42:878-84.
4. **Ray JG.** Fetal Matern Med Rev. 2004;15:1-16.