Glyburide was as safe and effective as insulin in gestational diabetes


QUESTION: Is glyburide as effective and safe as insulin in women with gestational diabetes mellitus?

Design
Randomised (allocation concealed), unblinded, controlled trial.

Setting
Maternal health clinics in San Antonio, Texas, USA.

Patients
404 women (mean age 29.5 y) who were between 11 and 33 weeks of gestation with a singleton pregnancy and who had gestational diabetes and fasting blood glucose concentrations ≥5.3 mmol/l and < 7.8 mmol/l. Follow up was 100%.

Intervention
404 women were allocated to receive glyburide (n = 201) or insulin (n = 203). Glyburide was started at an oral dose of 2.5 mg and increased to 20 mg as needed. Insulin was started at a dose of 0.7 U/kg of actual body weight, given subcutaneously 3 times/day, and increased as needed. All women were given standard nutritional instructions for 3 meals and 4 snacks daily.

Main outcome measures
The primary outcome was the achievement of prespecified levels of glycaemic control. Secondary outcomes were maternal and neonatal complications.

Main results
Analysis was by intention to treat. At a mean of 10.5 weeks of testing, the glyburide and insulin groups did not differ for mean daily blood glucose concentrations (5.9 ± 5.9 mmol/l, p = 0.99) or mean glycated haemoglobin (5.5% ± 5.4%, p = 0.12). The glyburide and insulin groups did not differ for the rate of infants who were large for gestational age (12% ± 13%, p = 0.76), had macrosomia defined as a birth weight ≥4000 g (7% ± 4%, p = 0.26), or had hypoglycaemia (9% ± 6%, p = 0.25) or for those who had cord serum insulin concentrations (15 ± 15 μU/ml, p = 0.84). 8 women in the glyburide group (4%) were switched to insulin therapy because the maximal glyburide dose failed to produce good glycaemic control.

Conclusion
Glyburide was as safe and effective as insulin in the treatment of women with gestational diabetes mellitus. *See glossary.