The Question: Is insulin pump therapy safe and effective for maintaining glycemic control in women with gestational diabetes mellitus (GDM) or type 2 diabetes requiring large doses of insulin?

Past Studies: These have shown that insulin pumps have been well tolerated in gravidas with type 1 diabetes. However, there has been no substantial evidence on the use of insulin pumps in patients with GDM or type 2 diabetes. For these gravidas, the current standard of care is to monitor glucose levels 4 times per day and to administer regular insulin injections several times a day, as required.

This Study: Gravidas with GDM or type 2 diabetes were examined over a 4-year period. Parturients on insulin pump therapy were compared to gravidas who did not use an insulin pump. Patients were matched for ethnicity and diabetes type and monitored at a hospital in New Zealand. Of 251 Polynesian, European, and South Asian women, 30 used an insulin pump. None of the patients experienced severe hypoglycemia and 79% had improved glycemic control within 1 to 4 weeks. However, 2 women discontinued pump therapy.

Gravidas using a pump had greater insulin requirements than those not using a pump (median maximum 246 units/day and 130 units/day, respectively) and greater maternal weight gain (10.6 kg and 5.0 kg, respectively). Infants of mothers using insulin pumps were more likely to be admitted to the neonatal care unit, but were neither significantly heavier nor more likely to experience hypoglycemia than control subjects.

Who May Be Affected by These Findings? Parturients with GDM or type 2 diabetes.

Expert Commentary: This study addresses an important clinical issue: Although insulin pumps are safe and effective for use in gravidas with type 1 diabetes, it is not clear whether they should be used in women with GDM or type 2 diabetes. Unfortunately, this study does little to clarify this issue. As the authors point out, this was not a clinical trial, but rather a “service audit.” As such, only 2 conclusions can be reasonably extracted from the reported data. First, there were no serious adverse events in gravidas using the insulin pump. Second, an improvement in glycemic control was evident in all 14 women for whom results of self-glucose monitoring were available before and after initiation of pump therapy. However, it is likely that this improvement was not a result of the pump, but rather of improved overall obstetric care, including more intensive glycemic monitoring and more aggressive insulin dosing.

To consider the use of insulin pumps in gravidas with GDM or type 2 diabetes, researchers must seek to answer the following:

■ Are pumps safe in this population?
■ Do pumps effectively control blood sugar, decrease the incidence of fetal macrosomia and/or cesarean delivery, and prevent such complications as shoulder dystocia?
■ How does pump therapy compare to current regimens of subcutaneous insulin injections?
■ Are patients more or less satisfied?

Potential advantages of the insulin pump over subcutaneous insulin include fewer injections, a continuous insulin infusion, and improved patient satisfaction, which could lead to improved compliance. A possible disadvantage of the pump may be infection at the injection site.

Caveats: This study is marred by several major methodological, statistical, and reporting errors, which include the following:

■ The cases and controls were not correctly assigned. One woman was treated with the insulin pump in 2 pregnancies and included in the analysis twice.
■ Controls included women with “preexisting tablet-treated type 2 diabetes,” whereas all cases were treated with insulin. Seven women with type 1 diabetes also were treated with insulin pumps, but it is not clear from the text whether or not these women were included in the analysis.
■ Gravidas with GDM or type 2 diabetes were seen monthly until 28 weeks’ gestation, fortnightly until 36 weeks’ gestation, and then weekly until term. By U.S. standards, this represents suboptimal antenatal care for high-risk women.
■ There was no power analysis, but it is likely that the study lacked the patient numbers to draw any conclu-
In this study, 4 women stopped taking sildenafil 25 mg, 2 women stopped taking sildenafil 50 mg, and 2 women stopped taking placebo due to vision problems, headaches, and fear of adverse reactions.

**THE BOTTOM LINE:** Physicians may consider prescribing 25 to 50 mg of sildenafil to premenopausal women with normal hormones and libido who experience difficulty with arousal, lubrication, and genital sensation.

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