

Oral Drugs Show Promise in Gestational Diabetes

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SAN FRANCISCO — Two oral medications deserve further investigation as alternative therapies for gestational diabetes, results of separate small studies suggest.

Acarbose or metformin might be helpful additions to the therapeutic armamentarium if additional research supports these preliminary findings, investigators said in separate poster presentations at the annual meeting of the Society for Maternal-Fetal Medicine.

Neither drug is approved for the treatment of gestational diabetes. Both are Food and Drug Administration pregnancy category B. Injected insulin or oral glyburide are approved to treat gestational diabetes.

Having an oral option other than glyburide might allow patients to be managed on one or potentially two oral agents before resorting to injections of insulin, Dr. Jacquelyn Cortez said in an interview at one of the posters.

She and associates conducted a prospective, double-blind trial that randomized 59 women who were diagnosed with gestational diabetes in their second or third trimester, prior to 34 weeks' gestation, to 50 mg acarbose t.i.d. or identical placebo pills taken with meals. All patients had failed diet therapy.

At regular follow-ups, if more than half of the patient's fasting glucose values were above 95 mg/dL, or more than half of her postprandial glucose values were above 135 mg/dL, the dosage was increased to 100 mg t.i.d.

If this did not control blood glucose levels, the patient was considered to have failed single-agent therapy and was started on a second agent.

Fewer patients in the acarbose group failed monotherapy and required a second agent, compared with the placebo group, but the difference did not quite reach statistical significance in this small study.

Women in the acarbose group gained significantly less weight (19 pounds) than did women on placebo (27 pounds), said Dr. Cortez of the department of reproductive medicine at the University of California, San Diego.

Postprandial blood glucose levels were significantly lower on acarbose therapy (122 mg/dL), compared with placebo (130 mg/dL).

There were no differences between groups in perinatal outcomes, including gestational age at delivery, mode of delivery, or rate of macrosomia.

The failure rate with acarbose in this study and failure rates with glyburide in other studies both are high, but women on acarbose in the present study did not develop the hypoglycemia sometimes seen with glyburide, Dr. Cortez noted.

Acarbose is a glycosidase inhibitor that prevents intestinal breakdown of starches to glucose in the upper small bowel.

Metformin, an insulin sensitizer, was the subject of a separate review of data from two randomized trials in which 67 women with gestational diabetes took the drug. Of

these patients, 59 met glycemic goals of fasting glucose values lower than 105 mg/dL and 2-hour postprandial glucose values lower than 120 mg/dL, reported Dr. Lisa E. Moore and associates.

The eight women who did not meet glycemic goals started insulin therapy, said Dr. Moore of the University of New Mexico, Albuquerque.

Macrosomia occurred in four infants (6%), and all were delivered vaginally.

The primary cesarean delivery rate (ex-

cluding elective repeat C-sections) was 15% (10 patients).

There were no cases of fetal anomalies or maternal or fetal hypoglycemia. Eight neonates had hyperbilirubinemia and two had 5-minute Apgar scores that were lower than 5.

The efficacy rate with metformin appeared to be similar to success rates with glyburide in other studies, Dr. Moore commented.

"[Metformin] is certainly better at con-

trolling the fasting blood sugar than glyburide," she added.

Failure of metformin was not predicted by maternal body mass index or by the value of the 1-hour glucose challenge test.

Although metformin is not approved in the United States for this indication, there is a wealth of data from other countries on its use in gestational diabetes, she noted.

Dr. Cortez and Dr. Moore have no financial relationships with the companies that make the medications studied. ■

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Reference: 1. Task Force on Postovulatory Methods of Fertility Regulation. Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet*. 1998;352:428-433.