

Diabetes Drug May Not Help Obese Women Have Normal-Weight Babies

But study says metformin did reduce weight gain, lower risk of dangerously high blood pressure in moms-to-be

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WEDNESDAY, Feb. 3, 2016 (HealthDay News) -- Giving the diabetes drug metformin to obese pregnant women may not help their newborns come into the world at a healthier weight, a new trial finds.

The study, reported Feb. 4 in the *New England Journal of Medicine*, adds to evidence that metformin does not curb obese women's risk of having an abnormally large newborn.

On the other hand, the British researchers found the drug did help control a woman's own weight gain during pregnancy. And it may slash the risk of a potentially dangerous complication called preeclampsia.

"Those findings bring to light some potential benefits of metformin for these women," said Dr. Jerrie Refuerzo, an associate professor of obstetrics and gynecology at the University of Texas Health McGovern Medical School, in Houston.

For now, diet and exercise will remain the mainstay of managing obesity during pregnancy, according to Refuerzo, who was not involved in the study.

But she said researchers should keep looking at a possible role for metformin.

Metformin is an oral drug used to control type 2 diabetes, which causes chronically high levels of blood sugar and insulin -- a hormone that regulates blood sugar.

Metformin is also sometimes given to women who develop pregnancy-related diabetes. One of the main concerns with pregnancy-related diabetes is that the fetus will grow large enough to complicate childbirth or require a cesarean section delivery.

Those newborns are also at increased risk of potentially dangerous blood-sugar lows after delivery, according to the U.S. National Institutes of Health.

But obese moms-to-be often have large newborns, even if they do not have diabetes. And that might be because their blood sugar and insulin are elevated -- but not high enough to be diagnosed with diabetes, explained Dr. Hassan Shehata, the senior researcher on the new study. He is an obstetrician-gynecologist at Epsom and St. Helier University Hospitals, in London.

So going into the trial, Shehata's team hoped that metformin would lower obese moms' odds of having a large baby. It didn't turn out that way.

The trial, which was funded by the Fetal Medicine Foundation, included 450 British women who were between their 12th and 18th weeks of pregnancy. All were severely obese -- with a body mass index topping 35. Half were randomly assigned to take a 3-gram dose of metformin every day; the other half received placebo tablets.

Among the women given metformin, almost 17 percent had a "large for gestational age" baby. That compared with just over 15 percent of women who were given the placebo.

"Large for gestational age" means that the baby's birth weight is at least in the 90th percentile.

Still, Shehata said, metformin did curb women's weight gain: They typically gained nearly 4 pounds less than placebo users did. (Experts recommend that obese women gain a limited amount during pregnancy -- 11 to 20 pounds.)

Women on metformin also had a substantially lower risk of preeclampsia -- with 3 percent developing it, versus 11 percent of placebo users.

Preeclampsia, which occurs after the 20th week of pregnancy, is marked by high blood pressure and other signs that a woman's organs -- such as the kidneys and liver -- are not functioning properly. It can cause preterm delivery and low birth weight, and can raise a woman's risk of seizures and coma.

"Preeclampsia is one of the important pregnancy complications that we've been trying to reduce for decades, with variable success," said Shehata.

He cautioned that this study was not actually "powered" to prove that metformin cuts preeclampsia risk -- meaning there were not enough women in the trial to tell whether the benefit was real or due to chance.

But he said his team hopes to run a future study aimed at answering that question.

According to Refuerzo, the drug's effects on women's weight and preeclampsia risk were "impressive" in light of another recent trial. That study, published last year, suggested metformin had no benefits for women who were obese but diabetes-free.

In this latest study, Refuerzo said, women were given a higher metformin dose and they were more likely to stick with the medication regimen.

Metformin can have side effects that make it difficult to take, Refuerzo pointed out. Stomach pain, nausea and vomiting are among the most common.

But, Shehata said, the drug has long been used for pregnancy-related diabetes, and there is no evidence it carries a risk of birth defects.

It's estimated that 20 percent of pregnant women in the United Kingdom are obese, Shehata noted. In the United States, that figure is around one-third.

SOURCES: Hassan Shehata, M.D., obstetrician-gynecologist, Epsom and St. Helier University Hospitals, London, England; Jerrie Refuerzo, M.D., associate professor, obstetrics and gynecology and reproductive sciences, McGovern Medical School, University of Texas Health Science Center, Houston; Feb. 4, 2016, *New England Journal of Medicine*
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