

Prepregnancy Diabetes Triples Risk of Birth Defects

BY HEIDI SPLETE
Senior Writer

Women who are diagnosed with diabetes prior to pregnancy are three to four times more likely to have a child with birth defects, compared with women who don't have diabetes prior to pregnancy, based on results from a study of more than 15,000 live births.

Although previous studies have established pregestational diabetes mellitus (PGDM) as a risk factor for several types of birth defects, the prevalence of maternal diabetes in cases of birth defects has not been well quantified, said Dr. Adolfo Correa, an epidemiologist at the Centers for Disease Control and Prevention.

The overall prevalence of pregestational diabetes mellitus was 2.2% in cases of infants with birth defects and 0.5% for the control infants.

Dr. Correa and his colleagues reviewed data from 13,030 cases of infants with birth defects and 4,895 control infants. The data came from the National Birth Defects Prevention Study, an ongoing population-based study that includes birth defect surveillance at 10 locations in the United States (Am. J. Obstet. Gynecol. 2008 [doi:10.1016/j.ajog.2008.06.028]).

The overall prevalence of PGDM was 2.2% in cases of infants with birth defects (283 cases/13,030 births), compared with 0.5% for the control infants (24 cases/4,895 births). In the birth defects group, 138 mothers had type 1 diabetes and 145 had type 2 diabetes. In the control group, 10 mothers had type 1 diabetes and 14 had type 2 diabetes.

Overall, 70% of the cases of isolated birth defects and 90% of cases of multiple birth defects in infants whose mothers had PGDM might be attributed to the mother's diabetes, the researchers noted. The prevalence of both types of diabetes was highest among mothers of infants with multiple defects.

The researchers found significant associations between PGDM and several types of heart defects including aortic stenosis and atrial ventricular septal defects. They also found significant associations between PGDM and other types of birth defects including hydrocephalus, cleft lip (with and without cleft palate), anorectal atresia, and longitudinal limb deficiencies. The associations between PGDM and these defects were seen in isolated cases, but the association was even stronger in cases of multiple defects.

"Our findings of moderate to strong odds ratios for PGDM and a wide range of birth defects are consistent with and expand on previous reports that examined all birth defects as a group or broad categories of birth defects," the researchers said.

The study population included women with known diabetes status prior to pregnancy and delivery dates between Oct. 1, 1997, and Dec. 31, 2003. The researchers excluded cases of birth defects that were linked to a known cause, such as a genetic disorder.

In addition, the prevalence of gestational diabetes mellitus (GDM) was 3.7% among control mothers vs. 5.1% among mothers whose infants had birth defects. But some women who are diagnosed

with gestational diabetes may in fact have had undiagnosed type 2 diabetes prior to pregnancy, the researchers noted.

"We were able to identify overweight and obese women with GDM as a subgroup who may be at increased risk of having offspring with birth defects and in need of closer follow-up examination and evaluation," the investigators wrote.

The study was limited by the use of maternal self-reports of diagnosed diabetes

and by a lack of data on how many pregnancies complicated by PGDM were terminated in the study population.

More research is needed to determine how maternal hyperglycemia affects the developing fetus, the researchers noted. But the range and severity of the defects suggest that diabetes affects the developing embryo in complex and nonspecific ways, they added.

Dr. Correa stated that he had no financial conflicts to disclose. ■



AMITIZA
is now approved for
IBS-C

**IRRITABLE BOWEL SYNDROME
WITH CONSTIPATION
IN WOMEN 18 YEARS AND OVER**

INTRODUCING
a new **8 mcg** dose for IBS-C



BID with food & water
Gelcap shown actual size

Indication

- AMITIZA® (lubiprostone) is indicated for the treatment of Irritable Bowel Syndrome with Constipation (8 mcg) in women ≥18 years old.

Important Safety Information

- AMITIZA is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction. Patients with symptoms suggestive of mechanical gastrointestinal obstruction should be thoroughly evaluated by the treating physician to confirm the absence of such an obstruction prior to initiating AMITIZA treatment.
- The safety of AMITIZA in pregnancy has not been evaluated in humans. AMITIZA should be used during pregnancy only if the benefit justifies the potential risk to the fetus. Women who could become pregnant should have a negative pregnancy test prior to beginning therapy with AMITIZA and should be capable of complying with effective contraceptive measures.
- Patients taking AMITIZA may experience nausea. If this occurs, concomitant administration of food with AMITIZA may reduce symptoms of nausea. Patients who experience severe nausea should inform their physician.
- AMITIZA should not be prescribed to patients that have severe diarrhea. Patients should be aware of the possible occurrence of diarrhea during treatment and inform their physician if the diarrhea becomes severe.
- Patients taking AMITIZA may experience dyspnea within an hour of first dose. This symptom generally resolves within three hours, but may recur with repeat dosing. Patients who experience dyspnea should inform their physician.
- In clinical trials of AMITIZA (8 mcg) in patients with Irritable Bowel Syndrome with Constipation, the most common adverse reactions (incidence >4%) were nausea (8%), diarrhea (7%), and abdominal pain (5%).

Please see Brief Summary of Prescribing Information on adjacent page.

AMITIZA is a registered trademark of Sucampo Pharmaceuticals, Inc.
©2008 Takeda Pharmaceuticals North America, Inc. LUB-01795

Printed in U.S.A.

06/08


amitiza®
lubiprostone

www.amitiza.com