50,000 Women Aged 18-45 Have Bariatric Surgery Each Year

BY MARY ANN MOON
Contributing Writer

An estimated 50,000 women of childbearing age undergo inpatient bariatric surgery each year, and an unknown number have outpatient bariatric procedures, according to a report in the Journal of the American Medical Association.

Unfortunately, data about the surgery's effects on pregnancy, fertility, and contraception are still so limited that researchers are precluded from drawing firm conclusions and clinicians cannot make informed decisions regarding these patients, said Dr. Melinda A. Maggard of the Rand Corp., Santa Monica, Calif., and her associates.

Risks for maternal complications may be lower following surgically induced weight loss.

DR. MAGGARD

The investigators used data from a national health care sample to assess trends in inpatient bariatric surgeries between 1998 and 2005, the most recent year for which information was available. This sample included data on up to 8 million hospitalizations at approximately 1,000 medical centers.

Outpatient bariatric surgeries were not assessed in this study.

The rate of inpatient bariatric procedures—laparoscopic adjustable gastric banding, vertical-banded gastroplasty, Roux-en-Y gastric bypass, and biliopancreatic diversion/duodenal switch—increased by 800% during this interval, from just more than 12,000 to more than 113,500 cases annually.

From 2003 to 2005, women of childbearing age (ages 18-45) accounted for around half of these surgeries (50,000) annually.

Dr. Maggard and her colleagues also reviewed 75 studies in the literature that compared ob.gyn. data between women who underwent bariatric surgery and those who did not.

"The available evidence suggests that risks for maternal complications, such as gestational diabetes and preeclampsia, may be lower following surgically induced weight loss than the risks in obese women, and may approach community rates," they said (JAMA 2008; 300:2286-96).

However, there have been 20 reports of complications during pregnancy that were directly related to the bariatric surgery, including bowel obstructions, band malfunctions, ulcers, and staple-line stricture. Three mothers and five neonates in these cases died.

Bariatric surgery doesn't appear to strongly influence the rate of cesarean deliveries or that of delivery complications such as blood loss or operative injury.

However, few studies have assessed such outcomes in this patient population, the researchers wrote.

Neonatal complications such as preterm delivery and low birth weight may be less common in pregnancies following bariatric surgery.

Similarly, neonatal outcomes such as macrosomia appear to be less frequent. However, the rate of miscarriage appears to be higher in women who have undergone bariatric surgery than in those who have not.

Moreover, two studies reported higher than expected rates of neural tube defects in neonates of women who had undergone bariatric surgery, possibly related to the mothers' noncompliance with vitamin supplementation.

Nutritional problems during these pregnancies seem to be uncommon and, like neural tube defects, are often attributed to the women's noncompliance with taking the recommended nutritional supplements.

Most studies of fertility after bariatric surgery were small and incomplete, the researchers reported. However, their results suggested that the procedures normalized hormone levels and menstrual irregularities, thus improving fertility.

Dr. Maggard and her associates also reported finding that no randomized trials have yet explored the theoretical possibility that bariatric surgery impairs absorption of oral contraceptives, rendering them less effective. ■

DRUGS, PREGNANCY, AND LACTATION

In Utero Drug Exposure and the Media

Over the past several decades, media coverage of medical journal studies has played a powerful role in perpetuating the bias against the use of certain medications during pregnancy.

As physicians, we read medical journals and other professional materials, but we also pay attention to the media. We may not necessarily have an opportunity to check the veracity and quality of a study we read or hear about, so the message we get may influence some of our perceptions and even our practices.

The impact on the public is enormous. At Motherisk, we are often contacted by pregnant women who are afraid of taking a medication because they heard about a study indicating a drug was not safe during pregnancy. It's not unusual for such reports to lead a woman to seek termination of an otherwise wanted pregnancy.

BY GIDEON KOREN, M.D.

The thalidomide disaster heightened the public's awareness and sensitivity to the concept that every drug is potentially a human teratogen. But the reality is that, almost 50 years later, very few drugs have been shown to be human teratogens. Still, physicians and women are hesitant about the use of medications during pregnancy, even when the drug is highly needed.

The notable examples in the medical literature date back to a study published in the early 1970s that reported an association between prenatal exposure to the hormones in oral contraceptives and congenital malformations (Lancet 1973;1:941-2). At that time, the study caused huge anxiety, resulting in oral contraceptives being labeled as pregnancy category X. But in the 1990s, a large number of studies and two meta-analyses, including one we conducted at Motherisk, failed to show any increased risk of malformations associated with prenatal exposure to OCs, which, by far, are the most common prescription product inadvertently taken by women during pregnancy.

The anxiety created by the initial paper continued until a few years ago, when OCs were switched to category D. It is not possible to estimate how many women may have terminated their pregnancies because of such exposures, but this is clearly an example of how one study in a major journal led to an unwarranted degree of anxiety.

Another important example is the story of spermicidal contraceptives. It made biologic sense that spermicide may not destroy all sperm and that a damaged sperm that fertilizes an egg could possibly cause congenital malformations. In the early 1980s, a study using an HMO database reported finding an association between spermicide prescriptions and malformations (JAMA 1981; 245:1329-32). The number of children with malformations thought to have been exposed to spermicide, although significant, was small. The study used data from the HMO records of women who were prescribed a spermicide. But this information did not prove the women actually took it into pregnancy; some women may have stopped using it before they got pregnant, or may have never taken it at all.

A large number of subsequent studies could not confirm this finding, but this was a positive study in a major journal that caused huge anxiety for many years. Letters to the editor included suggestions to track down the women and confirm whether they took the spermicide into pregnancy; a few years later, one of the original authors indeed interviewed those women and found no association. It turned out that most of the women did not take it into pregnancy. The original study provides a notable example of how anxiety triggered by a poorly conducted study can blow a potential risk out of proportion. (JAMA 1986;256:3095-6; JAMA 1987;258:2066).

Very often major journals that publish studies of positive associations do not publish subsequent studies involving negative findings. While some of these studies are eventually published in less-prominent journals, the biases are perpetuated nonetheless.

A Swedish study published in the 1980s reported cases of dysmorphism and mental retardation in children exposed prenatally to diazepam, which had not been observed previously (Lancet 1987;1:108-9). However, the same journal published another study that used a large database that did not confirm this finding (Lancet 1992; 340:694-6). I believe that the latter study helped resolve the issue because it was given similar prominence.

In animal models, the statins, which decrease cholesterol synthesis, were hypothesized to be the cause of malformations because cholesterol is an important component of cell development. So it makes biologic sense to avoid using these drugs during pregnancy. Several years ago, a letter was published in the New England Journal of Medicine about reports to the FDA of pregnancy outcomes in babies exposed to statins in utero during the first trimester, with an overrepresentation of brain malformations (N. Engl. J. Med. 2004;350:1579-82). There were several responses from investigators who said that they did not find such a tendency in their series. Five studies published in other journals that have systematically collected cases have not confirmed the case reports described in the initial letter.

Physicians should keep in mind that for every positive study published, there also may be negative studies published that may go unnoticed. Moreover, research that we and others have conducted shows that negative studies are less likely to be published than positive studies. At Motherisk, when we evaluate the reproductive safety of a drug, our analysis always includes an attempt to determine whether negative studies exist, and how many unrecognized negative studies could have changed an apparent positive result.

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