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CONTROVERSIAL CARE

To Heal Diabetes, Doctors Push Weight-Loss Surgery

Studies Suggest Benefit For Bariatric Procedure; Debate on Cost, Science

By RON WINSLOW
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Doctors who have turned surgery into a popular treatment for obesity are setting their sights on a burgeoning new market: diabetes patients.

A growing amount of research suggests that bariatric surgery, which shrinks the stomach and sometimes reroutes the intestines, has a lasting effect on the most common form of diabetes, and not just because patients lose weight. Studies have found that more than 75% of patients with this type of diabetes who undergo the surgery see their disease disappear. They can go on to live diabetes-free without insulin or other medicines.

Controversial Care

Studies suggest bariatric or gastric-bypass surgery can alleviate diabetes and other obesity-related problems

Percentage of patients in which:

Type 2 diabetes resolved	76.8%
Abnormal cholesterol improved	70.0
High blood pressure normalized	61.7
Obstructive sleep apnea resolved	85.7

Source: Analysis of 136 studies involving 22,094 patients who underwent bariatric surgery, published in the Journal of the American Medical Association, 2004.

Even advocates of bariatric surgery say it's too early to recommend it for the broad mass of diabetics. Bariatric surgery can lead to serious complications such as nutritional deficiency. The death rate from the procedure is estimated to be between one in 100 and one in 1,000. An array of medicines, plus better diet and exercise, can treat diabetes effectively without invasive procedures.

Still, some doctors behind the research believe surgery could be a new weapon against a disease that affects some 20 million Americans and 250 million people world-wide. "The idea that you could induce long-term remission in diabetic patients without medication is unprecedented," says Francesco Rubino, a surgeon at Catholic University in Rome who is one of the leaders in the field. "Clearly there's something big going on here that can't be ignored."

Studies into bariatric surgery's impact on diabetes are shedding light on little-understood hormones that reside in the small intestine and help keep the body's sugar levels in balance. Researchers theorize that in diabetic patients, food causes these

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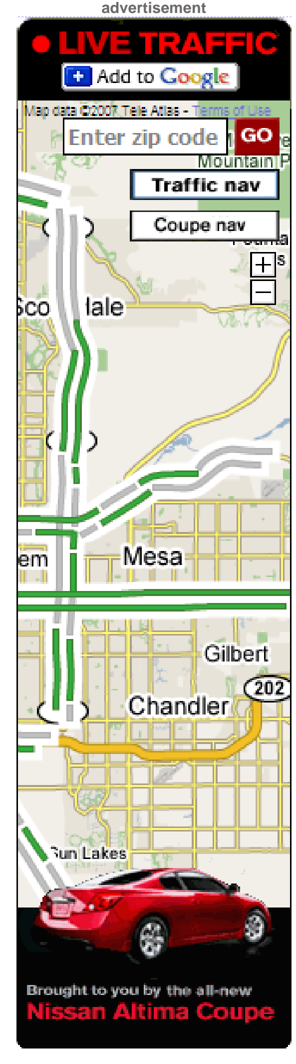

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hormones to go awry, but when surgery alters the intestinal tract and diverts food away from them, the disease can quickly recede. Understanding how this happens could lead to new medicines and nonsurgical strategies to fight diabetes.

Bariatric surgery usually costs about $25,000 and is a big profit center for some hospitals. If even a small percentage of diabetics chose to undergo surgery, it would bring a gusher of new business for the profession. Over the short term, at least, the cost of surgery exceeds the estimated $10,000 a year needed for conventional care of diabetics.

"As a primary treatment for diabetes, it simply doesn't measure up very well," says Richard Hellman, president of the American Association of Clinical Endocrinologists, specialists who treat diabetes.

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Treating Obesity

Bariatric surgery is currently recommended only for patients considered "morbidly obese" -- those who are at least 100 pounds overweight or about 75 pounds overweight and also have diabetes or other related conditions. In medical parlance, this corresponds to a body mass index, or BMI, of 40 and 35 respectively, according to a calculation based on height and weight. Obesity is defined as a BMI of 30 or higher. A 5-foot-10-inch person who weighs 245 pounds has a BMI of 35.

Health insurers generally cover bariatric surgery for the severely obese, though sometimes reluctantly. It is unlikely that less-obese patients would receive broad coverage without a significant body of research proving the surgery's benefits in such cases.

Death rates from bariatric surgery have fallen in recent years, partly reflecting new minimally invasive techniques and efforts to improve quality. But a few patients still die on the operating table or shortly afterward. Others suffer ill effects later, such as vitamin deficiency. Also, the surgery isn't foolproof as a weight-loss strategy. Some patients gain lost weight back.

Daniel B. Jones, director of bariatric surgery at Beth Israel Deaconess Hospital in Boston, is among doctors who think diabetics with moderate obesity may benefit from surgery. "If you have type 2 diabetes and your BMI is 35, we absolutely intervene," says Dr. Jones, referring to the more common type of diabetes that typically strikes adults. "Maybe we should be looking at BMIs of 30. Maybe we're not being aggressive enough with the amount of health impact we can have."

Barbara Brennan, who has diabetes, was more than 100 pounds overweight when Dr. Jones operated on her July 2. Within a couple of weeks, she became light-headed and had other signs of low blood sugar. That is the reverse of the usual problem with diabetics, who experience high blood sugar because their bodies aren't producing enough insulin or aren't properly using the insulin that gets made. Ms. Brennan expects that she will soon be able to drop her diabetes medicine. She has lost 34 pounds since the procedure.

"I can see the medical benefit already and it's not even two months," says the 60-year-old, who retired as a property manager at Boston's Logan Airport. "Taking less medication plus having my sugar levels being more stable has really made me feel a lot better."

However, she says, "I don't know if I'd ever recommend someone have the surgery just for diabetes."

Last year, 177,600 patients underwent bariatric surgery, according to the American Society of Bariatric Surgery,

Popular Procedure 200,000

nearly four times the figure five years earlier. Reflecting the
potential for growth from expanding the business to diabetes patients, the society plans to announce today a name change to the American Society of Metabolic and Bariatric Surgery.

Following a meeting in Rome earlier this year, the society is part of an effort to publish a consensus paper on when the surgery is appropriate in diabetes patients and what further research needs to be done.

The prevalence of diabetes is growing at 5% a year, according to data from the U.S. Centers for Disease Control and Prevention. Diabetics are at especially high risk for heart attacks as well as such ailments as stroke, kidney disease, blindness, infertility and a clogging of blood vessels in the legs and feet that can lead to amputations. Studies indicate that just 35% to 55% of diabetics are able to keep their blood sugar under control. A treatment that could reduce this toll would be a major advance and an economic boon to the health-care system.

Aggressive Marketing

Aggressive marketing and a gold-rush atmosphere sparked a surge in bariatric surgery for the severely obese early in this decade, resulting in variable results for patients and a tarnished reputation for the procedure.

"We don't want to make the same mistake twice," says Dr. Rubino, who will move from Rome in October to head a new program for diabetes-surgery research at New York-Presbyterian Hospital's Weill Cornell Medical Center in Manhattan. He says it could be a "disaster" if thousands of patients were urged to get the procedure before further studies show who is likely to get the most benefit from it.

Evidence of bariatric surgery's impact on diabetes has been building for two decades. In 1995, Walter Pories, a surgeon at East Carolina University, Greenville, N.C., and colleagues published a paper in the Annals of Surgery titled, "Who Would Have Thought It?"

The report, based on 608 patients who had undergone the procedure over a 14-year period, found not only weight loss but also long-term blood-sugar control in 83% of the patients who had diabetes and 99% of patients with a prediabetic condition called glucose impairment. "No other therapy has produced such durable and complete control of diabetes," the researchers reported.

'Radical Departure'

Few diabetes specialists noticed the article in the surgical journal. "It was such a radical departure from how diabetes is treated, it didn't get much recognition by thought leaders in the diabetes world," says Philip R. Schauer, head of bariatric surgery at the Cleveland Clinic.

In 2003, Dr. Schauer, then at the University of Pittsburgh, and colleagues reported in Annals of Surgery on a five-year study of 1,160 diabetics who had the surgery. Their finding was nearly identical: In 83% of the patients, blood sugar returned to normal, and it was markedly improved in the others.

Results from both papers suggested patients with milder forms of diabetes and those who lost the most weight after surgery were most likely to experience remission of the disease.

Recent papers point to another phenomenon. Among several variations of bariatric surgery, there are two principal strategies. One of the strategies, marketed by Allergan Inc. and known as the Lap-Band procedure, involves an adjustable band that is cinched around the stomach to reduce its size. It is reversible and doesn't involve any rearrangement of the intestines.

The other strategy both shrinks the stomach and reroutes the passage of food to avoid upper portions of the small intestine known as the duodenum and some of the jejunum. One specific example of this strategy is a procedure known as Roux-en-y gastric bypass.

Some doctors in the field say that although both forms of the surgery lead to weight loss, patients who get the intestinal rerouting see faster improvement in their diabetes. That suggests weight loss alone isn't a full explanation for how surgery might help diabetics.

Testing Surgery

While training as a surgeon at Mount Sinai Hospital in New York in the late 1990s, Dr. Rubino became curious about whether surgery could address diabetes without shrinking the stomach. He came up with a procedure that would bypass the duodenum and the upper portion of the jejunum but leave the stomach intact, in contrast to the Roux-en-y procedure. Then he tested it on a strain of laboratory rats that had type 2 diabetes but weren't obese. They were able to eat normally. The procedure resulted in a dramatic reduction of diabetes. A report on the experiment was published in the Annals of Surgery in 2004.

"That was the first evidence that the surgery could have a direct effect on diabetes that wasn't related to losing weight," Dr. Rubino says.

Doctors are beginning to test the idea of intestines-only surgery in humans. Dr. Rubino says about 100 patients, all of them outside the U.S., have been treated with that approach, with encouraging early results.

Fabrizio Michelassi, surgeon in chief at Weill Cornell, says such surgery could be a valuable innovation. The standard forms of bariatric surgery typically leave patients with stomachs the size of an egg. "They are condemned to meals that are little purees for the rest of their lives," says Dr. Michelassi. It may be, he says, that with Dr. Rubino's procedure, "you can still eat your steak and potatoes and your diabetes gets controlled."

Other doctors say the stomach-reduction part of the traditional surgery plays an important role in the antidiabetes effect. It may help by curtailing how quickly food flows into the intestine, they say.

"It looks as if there are rogue cells in the intestine that are causing diabetes," says Dr. Pories, the surgeon from East Carolina University. "The surgery either reduces the amount of food that comes down to these cells or detours the food around them."

Studies Show Promise

Small studies of moderately obese diabetics in Brazil, India and Mexico show promise for surgery, but the numbers are too small and the length of the studies too short to reach solid conclusions.

Dr. Schauer at the Cleveland Clinic has started a five-year study of diabetics with BMIs ranging from 30 to 40. Two groups of patients in the study will receive forms of bariatric surgery. A third group will get only drugs and other noninvasive therapies. Dr. Schauer wants to discover which group sees the greatest effect on diabetes.

"When you get a gastric bypass, things are dramatically changed in your favor," says Dr. Jones in Boston. "We don't know what it is. We know it's real and it's reproducible. If we can tease it out, it will be a huge advance."

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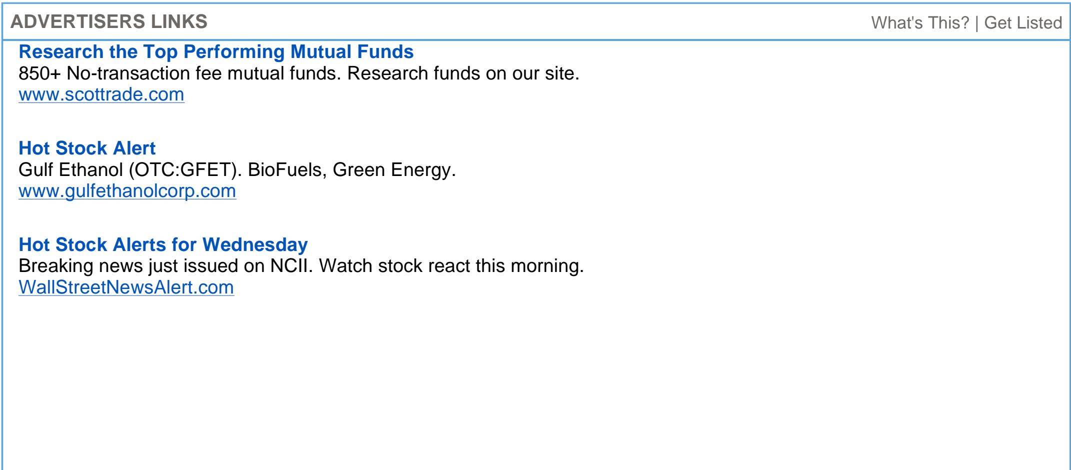

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