

Experts debate bariatric surgery as a cure for diabetes

Oct 8, 2009 | Lisa Nainggolan

EASD

Vienna, Austria - Could gastric bypass or banding operations—known as bariatric surgery—for the treatment of obesity also be a potential cure for diabetes? Diabetologists, surgeons, and other doctors debated the idea during a special session at the **European Association for the Study of Diabetes (EASD) 2009 Meeting** last week and at a number of press conferences there.

Use of this type of surgery has conventionally been reserved for those whose body-mass index (BMI) is 35 kg/m² or greater. Trials in these morbidly obese patients confirm the benefits in terms of weight loss and provide evidence that cardiovascular risk factors are improved as a result, and the surgery can result in remission of diabetes in many cases.

Now, given these encouraging results, there appears to be a downward drift in the criteria for which this procedure is being considered, with many advocating it as a reasonable option for diabetics with a lower BMI (<35) who have failed other attempts at therapy. But this approach is severely hampered by a lack of prospective clinical-trials data on bariatric surgery in this group of patients, a situation that does not seem likely to be rectified anytime soon.

Supporter and skeptics



Dr Francesco
Rubino

Surgeon **Dr Francesco Rubino** (Weill Cornell Medical College, New York, NY) told **heartwire** that he does not believe BMI should be the primary determining factor for bariatric surgery in diabetics. BMI, or level of obesity, "is a crude measure on its own. It doesn't reflect the risk from diabetes. And cardiovascular disease in diabetes is predicted by other factors, so if you just use BMI you don't capture the patients who might benefit most."

Endocrinologist **Dr Nick Finan** (University College Hospital, London, UK) is an advocate of bariatric surgery for certain diabetes patients, working in a team with three surgeons at his hospital in London. He told **heartwire**: "Bariatric surgery clearly is established as a highly effective intervention for reducing CV risk and in terms of hard end points—ie, reducing mortality, not just from CV disease but from cancer. And clearly, you can remit 75% or more of patients who have diabetes and you can prevent progression to diabetes."

But there is a major obstacle to making this procedure available to diabetics who are not morbidly obese—a lack of appropriate trials, he says. "Most of the data we have are in those with BMI >35 and diabetes. We do not have long-term studies, large studies, or economic studies on diabetics

who are overweight or obese below a BMI of 35, but there are [increasing] circumstantial data that would suggest that these patients may benefit too."



Dr John Buse

Diabetologist **Dr John Buse** (University of North Carolina School of Medicine, Chapel Hill) remains somewhat skeptical, however. He urged caution at the EASD meeting, telling a press conference: "We do need to remember that surgical approaches to medical problems have been fraught with their fits and starts. Lobotomy was widely viewed as a reasonable therapy for behavioral disorders, and now it's considered an abomination."

To **heartwire**, he added: "The general feeling is that, for people who are morbidly obese, [this surgery] is potentially lifesaving. I do think the heavier the patient, the greater the potential benefit, in part because diabetes is not the only target. But a lot of the operations that are being done now have not been done widely in the less obese patients, which is the area that everybody is sort of advocating, that we need to go lower and lower. But there are consequences; we need a randomized prospective study."

[Gastric bypass] is a mutilating procedure; effectively, they take out your stomach. Mother Nature put your stomach there for a reason.

And Buse warned that gastric bypass—even done laparoscopically as is generally the case these days—"is a mutilating procedure; effectively, they take out your stomach. Mother Nature put your stomach there for a reason, so it does concern me. It may turn out, 15 years from now when all the trials are in, that this was clearly the ideal therapy of the early 21st century. I'm just a little bit afraid that in the year 2025 people will say, 'What were they thinking? How did they ever think it was reasonable to cut out someone's stomach as a treatment, a sort of panacea, for a bad lifestyle?'"

Surgery improves CV risk factors, glycemia, remits diabetes

During the EASD session, Rubino, chief of gastrointestinal surgery and director of the diabetes surgery program at Weill Cornell, highlighted the "remarkable clinical efficacy of bariatric surgery, which is unparalleled by any other form of treatment [for diabetes]. Not only is glycemia improved, but hyperlipidemia, hypertension, all of the CV risk factors are improved by the surgery," he commented.

Other speakers agreed. Cardiologist and internist **Dr Lars Sjöström** (Sahlgrenska University Hospital, Gothenberg, Sweden) spoke about the long-term effects of bariatric surgery, citing a meta-analysis published this year of more than 600 studies, which showed that overall, 78.1% of diabetic patients had complete resolution of the condition, and diabetes was improved or resolved in 86.6% of patients [1].

Insulin levels declined significantly postoperatively, as did HbA_{1c} and fasting-glucose values. "The clinical and laboratory manifestations of type 2 diabetes are resolved or improved in the greater majority of patients after bariatric surgery," the researchers concluded. However, the average BMI in this meta-analysis was 47.9 mg/k².

Here is a treatment that prevents cardiovascular mortality. Why are cardiologists not hammering at the door?

There has been one small, randomized controlled trial done in Australia, published in the *Journal of the American Medical Association* last year, in diabetes patients with a BMI of >30 but <40, comparing adjustable gastric banding with conventional therapy [2]. Remission of type 2 diabetes was achieved in 73% of patients in the surgical group compared with 13% in the conventional-therapy group.

"The take-home message about bariatric surgery is, here we have a treatment that, let's be dramatic, 'cures' many people with diabetes," says Finer. "Why are not the diabetologists hammering at the door to get their patients access to this treatment? Here is a treatment that prevents cardiovascular mortality. Why are cardiologists not hammering at the door? Here is a treatment that cures sleep apnea—why are respiratory physicians still handing out CPAP machines? There is a huge delay behind the evidence, I think, for the adoption and promulgation of surgery. I'm not a surgeon, but I'm a physician who works in the area, and it is very frustrating when a patient has difficulty accessing it."

A relatively safe surgery?

Rubino also told EASD attendees that surgery "is not as dangerous as you think." The mortality rate from bariatric surgery (around 0.3%) is comparable to that for hip replacements and also for laparoscopic removal of the gall bladder. There are also plenty of precedents for using gastric-bypass-type surgeries in the nonobese, he noted, citing the example of gastric-cancer patients: "Patients do tolerate this type of surgery if they are nonobese." In addition, "long-term complications are relatively low and preventable if the patient is instructed on careful follow-up," he says.



Dr Darren
McGuire

Cardiologist **Dr Darren McGuire** (University of Texas Southwestern Medical Center, Dallas), who specializes in treating diabetes, agrees: "Over the years, the procedures have been refined so that the risks—especially for gastric banding—are really quite low, surprisingly low in a pretty otherwise-morbid population. Where complications occur, they are often quite, quite serious, but the complication rates are acceptable in most cohorts that these procedures are being done for. My take is that, like any therapy we have, the more experience we get with it and the more we understand its limitations, the more appropriately we can use it."

But Buse is not convinced. He stresses that there are risks from the procedure: "You can have disability from hypoglycemia, there are excess bone fractures, there are nutritional issues, even a hint, I think . . . about excess suicide, so there are lots of issues that need to be fully examined. There are consequences, and we need a randomized, prospective study," he told **heartwire**.

Surgery effect is about more than weight loss

Rubino says the benefits of bariatric surgery are of a hormonal nature, in addition to the weight loss, because the bowel is an endocrine organ. He points out that other approaches to reducing weight—such as exercise, diet, and even liposuction—have not shown the same benefits in terms of improvement in diabetes as surgery has.

Finer concurs: "There's absolutely no doubt" that this is about more than weight loss, he told **heartwire**. "In these patients, their diabetes remits before they lose weight. This sounds very dramatic, but it is actually true. Patients will wake up from surgery and they will say, 'I've never had this feeling before. I don't want to eat, I'm not hungry. Is this what you call fullness or satiety?' There is no doubt there is a very, very early effect on eating behavior, on food intake, and this has been shown now with MRI studies and PET scans that you completely alter the way the brain responds to food or signals about food."

McGuire is convinced, too: "There is this emerging body of evidence that the gut-hormone axis is dramatically affected [by bariatric surgery] to the point that glucose measures and insulin-sensitivity measures improve even before the weight begins to decline."

Metabolic or diabetes surgery, not bariatric

Buse says the term *metabolic* or *diabetes* surgery is being used, in the US at least, "because diabetes treatments are paid for, but obesity treatments generally are not."



Dr Edward H
Livingston
[Source:
University of
Texas
Southwestern]

Dr Edward H Livingston, who is chair of gastrointestinal and endocrine surgery at University of Texas Southwestern School of Medicine, said: "That is true. That's the attempt of the bariatric-surgery community in this country. Many insurers have an exclusion for treating obesity, but everyone agrees that diabetes should be treated, so the **Association for Bariatric Surgery** changed its name to Metabolic Surgery to try to basically say that they are treating diabetes and not just obesity. I don't think anyone has really been impressed by that, but that's what they've tried to do."

Livingston, however, does appreciate this argument: "It's a legitimate emphasis, because diabetes in most cases is caused by obesity, and the best treatment for that diabetes is not controlling the blood sugar but treating the underlying problem, which is obesity."

He says that in the US, most insurance companies will cover bariatric surgery only for those with a BMI of ≥ 40 , because the US **National Institutes of Health** concluded this was appropriate, "so a lot of insurers have followed those recommendations." For those who are still considered by many

to be technically obese, with BMIs falling between 35 and 40, the easiest option is often to say that the surgery is metabolic or for diabetes, although only around 25% of obese people actually have diabetes, says Livingston.

Finer says that in many parts of the world, "in private-care-dominated systems, such as in Latin America and some parts of Southern Europe, 'metabolic' surgeons abound" and are performing this type of surgery often irrespective of BMI. Buse agrees: "There are even people who are doing this surgery, at least experimentally, in people with normal BMIs," he told **heartwire**.

But is this really a treatment option for simply overweight diabetics?

Rubino said when he first started to advocate that BMI should not be the primary factor in deciding to perform bariatric surgery, "there was a lot skepticism, which is normal, but you can see now this session is very well attended, as was a similar session at the **American Diabetes Association** meeting in June. The diabetologists are starting to realize that this is not something magic or something strange, but it's just one more option."

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However, he remains realistic: "Should we offer this to all diabetic patients, or should we select? The latter is obviously the right answer," he says. "With surgery, you have to give it to selected patients. There is no surgery used as a primary treatment for all the patients who have a certain condition. The goal in the next few years is to identify the patients who will sustain the most benefits."

"My fear is that in the lower-BMI patients there will be people who are not 'pure' type 2 diabetics, for instance, so we really need to find methods and criteria to best select patients," he told **heartwire**.

McGuire said: "I think there's going to be an inevitable drift downward for the criteria for which this procedure should be considered. You can't open a newspaper in Dallas without seeing two or three advertisements for a weight-loss center. We would stop short of recommending this before we had tried really hard with lifestyle interventions, but most of us who work in this metabolic field are considering this a reasonable alternative. Where we are now with this is that a lot of people are fairly enthusiastic but stopping short of saying that we have definitive information."

Finer says: "For type 2 diabetics who meet the UK **NICE** guidelines for bariatric surgery—BMI >35 and have failed all other interventions—I think this is a very real option they should consider. It is not an easy option, but it is an option. There is no point in making those people go on a diet yet again."

But for the ones who are not technically obese (BMI <35), the question "is much harder," says Finer, noting, "They will not be judged a priority."

Finer says he has tried four times, without success, to set up a study of surgery against optimal medical treatment for diabetes in those who are not technically obese. In managed-healthcare systems, such as those in Northern Europe, "there will be no bariatric surgery in diabetics who are not obese until data become available to show the benefits," Finer says.

Livingston agrees, noting that this is a catch-22 situation. To get insurance companies in the US and other countries or national healthcare systems to pay for this surgery will require such studies, "but these will be very hard to do, because they are extremely expensive." He said he tried himself for five years, while working in the **Veterans Affairs** (VA) system in the US, to get funding to do such a study, but quit in frustration when the money was not forthcoming.

There is one small trial ongoing, funded by a company that manufactures a device to staple the stomach, Livingston said, "but this is pretty small, and it won't be too conclusive." And the randomized controlled trial of gastric banding compared with dietary therapy published in the *Journal of the American Medical Association* last year was "good," he says, "but it didn't really get a lot of traction because they were looking at very mild diabetics who could have been treated by a variety of other methods."

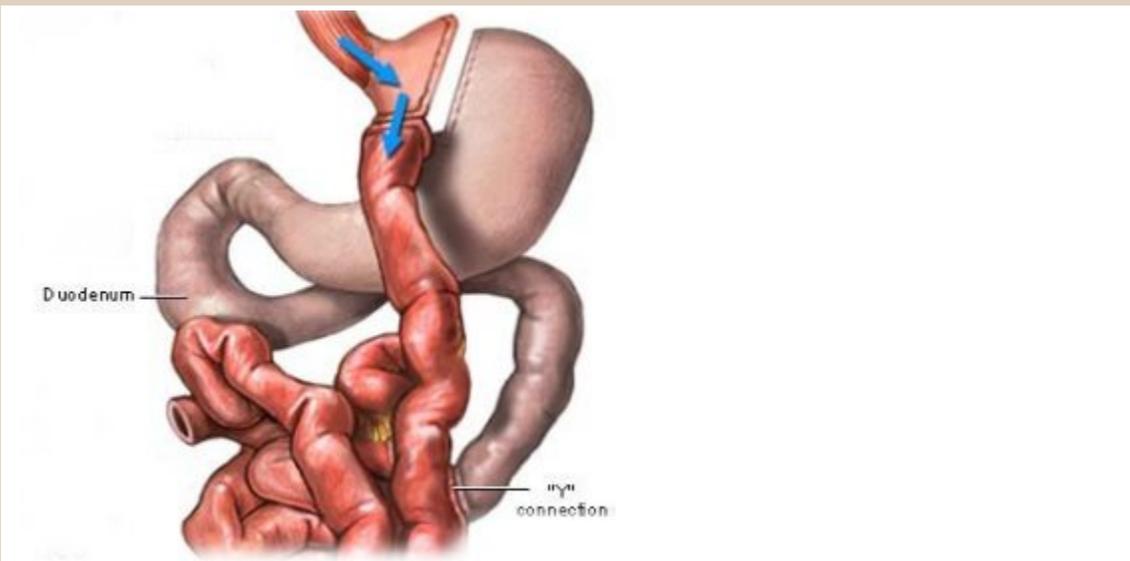
However, there may be a glimmer of hope on the horizon. Finer is optimistic that UK funding will shortly be granted for the establishment of a 10-year bariatric-surgery cohort there.

Our job as endocrinologists is to put the surgeons out of business.

And ultimately, he says, this "gives hope that over the next five or 10 years we can mimic what surgery does with a combination of drugs. And there are already some data showing that by combining various peptide hormones, you can actually achieve substantial weight loss.

"There's a very good parallel as well. In the 1960s we all used to admit patients for milk drips for gastric ulcers, and they all ended up having their stomachs cut out, and then along came H₂ blockers and proton-pump inhibitors and there's not a single surgeon doing surgery now. Our job as endocrinologists is to put the surgeons out of business."

What does the surgery entail?



The diagram illustrates the Roux-en-Y procedure. It shows the stomach at the top, with a blue arrow indicating the path of food. The duodenum is shown as a C-shaped structure. A segment of the small intestine is shown being connected to the duodenum, bypassing the stomach. Labels include 'Duodenum' and 'intestinal connection'.

Roux-en-Y surgery [Source: Medline Plus]

Livingston explained to **heartwire** that "probably the most popular type of bariatric surgery worldwide is the laparoscopic gastric-banding procedure." In this, a plastic band is placed around the top of the stomach and connected to a port placed directly under the skin. A needle is placed in the port and used to adjust the amount of fluid in the band, causing a variable degree of restriction of the stomach. The band is supposed to be left in place permanently, Livingston said, but it can be removed "without consequence," if need be.

In the US, the most popular type of operation remains the laparoscopic Roux-en-Y gastric bypass, during which "nothing is removed, the stomach is stapled closed or divided up toward the top of

the stomach, and a limb of jejunum is brought up to bypass the stomach," he explained.

There is also a procedure called a gastric-sleeve operation, where a portion of the stomach is removed, Livingston said, "but that is not done in any great numbers in the US, as few, if any, insurers will pay for it due to a lack of good outcomes data."

Sources

1. Buchwald H, Estok R, Fahrbach K, et al. Weight and type 2 diabetes after bariatric surgery: systematic review and meta-analysis. *Am J Med* 2009; 122:248-256.

2. Dixon JB, O'Brien PE, Playfair J, et al. Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial. *JAMA* 2008 299:316-323.


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