Duodenal Mucosal Resurfacing Procedure Improves NASH and Diabetes Markers

The new, minimally invasive outpatient procedure targets a part of the small intestine that plays a key role in diabetes.

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In a recent trial, a new, minimally invasive upper endoscopic procedure called duodenal mucosal resurfacing (DMR) showed promise in improving biomarkers of non-alcoholic steatohepatitis (NASH) and type 2 diabetes in people with the conditions.

The duodenum, which is the first part of the small intestine immediately past the stomach, acts as a key signaling center and a critical regulator of overall balance, or homeostasis, of the metabolism.

Diets high in fat and sugar can cause hyperplasia—overgrowth due to increased cell proliferation—of the lining of the duodenum. This can alter hormone signaling and absorption of nutrients by the organ, which can in turn lead to abdominal obesity, insulin resistance, impaired glucose metabolism, high insulin levels, irregular blood lipids and high blood pressure.

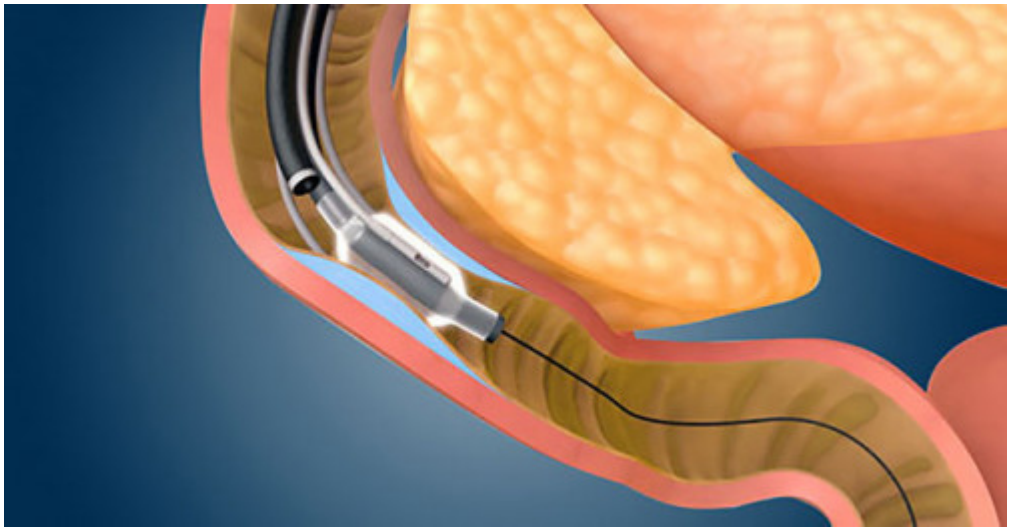
Duodenal bypass surgery can reverse metabolic disease, non-alcoholic fatty liver disease (NAFLD) and its more severe form, NASH, as well as type 2 diabetes and polycystic ovary syndrome.

Consequently, targeting hyperplasia in the mucosal lining of the duodenum could in theory prove beneficial to individuals with metabolic diseases related to insulin resistance.

Arun Sanyal, MD, of the Virginia Commonwealth University School of Medicine in Richmond, presented top-line results from the randomized, double-blind, sham-controlled, prospective multicenter REVITA-2 study of DMR in people with NASH and type 2 diabetes at The Liver Meeting, the Annual Meeting of the American Association for the Study of Liver Diseases, in Boston this month.

In the procedure, clinicians use the Revita DMR catheter to reach the duodenum (a tube is inserted down through the esophagus) to lift the submucosal lining of the organ and use heated liquid to strip away the excessive growth of the mucosal layer. This promotes healthy regrowth of the lining

of the duodenum within 12 weeks with the goal of reducing insulin resistance and excess insulin in the blood.



duodenal mucosal resurfacing (DMR) procedureCourtesy of Fractyl

Previous research has indicated that DMR is well tolerated and associated with only a few side effects, which dissipate over time. The REVITA-1 study previously indicated that the procedure improved liver biomarkers and blood glucose levels through two years among people with type 2 diabetes, which suggested that people with diabetes and NAFLD or NASH might also benefit.

The REVITA-2 study was conducted to analyze liver markers and blood glucose parameters at nine sites in the European Union and two sites in Brazil. Participants needed to be between 28 and 75 years old, have type 2 diabetes with a fasting insulin greater than 7.0 microunits per milliliter, an HbA1c between 7.5% and 10%, a body mass index of at least 24 and below 40 (25 to 29.9 is overweight and 30 or greater is obese). They had to be taking metformin and not have had medication or dose changes for 12 weeks prior to entering the study.

The study excluded people who were currently using insulin or GLP-1 or participating in another ongoing clinical trial of an investigation drug or device as well as those with a history of severe hypoglycemia (low blood sugar), an autoimmune disease, infection with Heliobacter pylori or those who had undergone previous gastrointestinal surgery.

The participants were randomized into two even groups to receive the DMR or a sham treatment (insertion of a catheter without the procedure, performed as a control). After 12 weeks, those who had liver a fat fraction greater than 5% upon entering the study had their liver fat content reassessed. The other key outcomes were assessed at the 24-week mark.

The study divided the participants into two active treatment groups when conducting the analyses. The modified intent-to-treat (mITT) group included the participants in whom the procedure was attempted and who had an initial measurement for at least one of the major outcomes on which the study focused. The per-protocol (PP) group was a subset of the mITT group that included those who received the treatment to which they were randomized but excluded those who had a major deviation from the study protocol. Lastly, the study authors conducted a safety analysis.

One hundred nine people were randomized, including 76 Europeans and 33 Brazilians. Because there were too many differences between the European and Brazilian participants when it came to liver and blood sugar outcomes, the study authors separated the analysis into two parts based on the participants' region.

In the European group, 39 people received DMR and 37 received the sham procedure. In the DMR group, one person discontinued participation in the study. All 39 people were included in all the analyses except for the PP analysis, which included 35 people. In the sham group, two people discontinued, leaving 36 people in both the mITT and PP analysis and 37 people in the safety analysis.

In the Brazilian group, 17 people received DMR and 16 people receive the sham procedure. In the DMR group, no one discontinued; all participants were included in the mITT and safety analyses; and 13 participants were included in the PP analysis. In the sham group, one person discontinued; all were included in all the analyses.

Two people (11.8%) in the Brazilian DMR group experienced serious adverse health events. No one in any of the subgroups experienced unanticipated adverse health events. Adverse health events of special interest were seen in 12 members (33.3%) of the European DMR group, 10 members (27.0%) of the European sham group, 12 members (70.6%) of the Brazilian DMR group and 10 members (62.5%) of the Brazilian sham group. In each of these four respective subgroups, 11 (28.2%), eight (21.6%), eight (47.1%) and three (18.8%) experienced gastrointestinal disorders, including abdominal pain, diarrhea, nausea and vomiting. A respective three (7.7%), three (8.1%), eight (47.1%) and nine (56.3%) people experienced hypoglycemia.

Among the Europeans, the median change in liver fat fraction in those with greater than 5% liver

fat content at the study's outset was a 5.4% decline in the DMR group and a 2.4% decline in the sham group; among the Brazilians, there was a 32.1% decline in the DMR group and an 18.1% decline in the sham group. The differences between these two pairs were statistically significant, meaning they are unlikely to be the result of chance.

Overall, the proportion of participants who experienced a greater than 30% reduction in their liver fat fraction by week 12 was 53.3% among those who received the DMR procedure and 22.2% among those who received the sham procedure—a significant difference.

There was no significant difference between the DMR and sham groups in terms of their ALT or AST liver enzyme changes at week 12.

DMR positively impacted glucose metabolism. At week 24, the median percentage decline in HbA1c was 0.6% in the mITT DMR group and 0.8% in the PP DMR group, compared with 0.3% in the sham group. The proportion of each group that had an Hb1Ac below 7.0 at week 24 was 26.3% in the DMR group and 9.1% in the sham group.

The median percentage decline in liver fat fraction at week 12 was 8.0% in the DMR group and 2.1% in the sham group. The median percentage decrease in HbA1c at week 24 was 1.2% in the DMR group and 0.3% in the sham group.

"DMR is an important new option for patients with [type 2 diabetes with or without] NAFLD/ [or] NASH with a focus on disease reversal rather than management," the study authors concluded. "DMR has a safety and tolerability profile encouraging for broad therapeutic applicability in these disease states."

To read the conference abstract, click here.

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