糖尿病管理目的の肥満手術の持続的効果

STAMPEDE：肥満手術は肥満糖尿病患者の血糖コントロールに対する強化薬物療法に勝る

STAMPEDE: Bariatric surgery beats intensive medical therapy for glycemic control in obese diabetics

過剰体重または肥満患者のコントロール不良2型糖尿病の管理において、胃バイパス術および胃スリーブ切除術は強化薬物療法よりも有効であるとの研究結果が第63回American College of Cardiology学会で発表され、*New England Journal of Medicine*オンライン版に掲載された。STAMPEDEは、血糖コントロール達成（スタディにおいて3か月の平均HbA1cレベル6%以下と定義）の補助として、肥満手術と強化薬物療法の効果を比較した最大のランダム化コントロールトライアルである。3年間のフォローアップにおいて、この一次エンドポイントを満たしたのは薬物療法では5%に過ぎなかったが、胃バイパス術患者では37.5%であり、胃スリーブ切除術群では24.5%であった。手術群患者では薬物療法のみの患者と比較し、ボディーマスインデックス、体重コントロール、中性脂肪および高密度リポ蛋白コレステロールなどの心血管系リスクファクターにおいてもまた、有意に改善した。薬物療法群では血糖コントロールにおいて1年以内の早期の改善を認めたが、これは3年以内には元のレベルに戻った。手術群では血糖値が平均2.5%低下し（ベースライン9.3%、3年後胃バイパス術および胃スリーブ切除術群でそれぞれ6.7%および7.0%）、維持された。

Full Text

Gastric bypass and sleeve gastrectomy – two of the most commonly used bariatric surgeries – are more effective than intensive medical therapy alone when it comes to managing uncontrolled type 2 diabetes in overweight or obese patients after three years, according to research presented at the American College of Cardiology's 63rd Annual Scientific Session and published online in the *New England Journal of Medicine*.

STAMPEDE is the largest randomized controlled trial with one of the longest follow-ups to compare the effect of these two procedures to intensive medical therapy in helping patients achieve glycemic control, defined in this study as a three-month average blood glucose level of 6 percent or lower – a more aggressive target than the American Diabetes Association recommendation of 7 percent. At the three-year follow up, only 5 percent of patients in the medical therapy group met this primary endpoint compared with 37.5 percent of gastric bypass and 24.5 percent of sleeve gastrectomy patients. Surgical patients also had a significant improvement in key cardiovascular risk factors including body mass index, weight control, triglycerides and high-density lipoprotein cholesterol compared to those receiving medical therapy alone.

"Both surgical options maintain their supremacy over standard intensive medical therapy at the three-year mark," said Philip Schauer, M.D., professor of surgery, director of the Bariatric and Metabolic Institute, Cleveland Clinic, and lead investigator of the study. "There is this notion that if we keep adding medications and pushing patients to lose weight on their own, they will eventually achieve the same type of results as those undergoing surgery, but that wasn't the case here."

While the medical group showed an initial improvement in glycemic control within the first year, they were almost back to baseline by year three. "Their [blood glucose level] went from 9.5 at the start of the study and dropped as low as 7.5 and then back up to 8.4 percent," he said. In contrast, the surgical groups were able to maintain a lower glucose level with an average 2.5 percent reduction (9.3 at baseline and 6.7 and 7.0 for gastric bypass and sleeve gastrectomy at year three).

A total of 150 patients, age 41 to 57, were randomly assigned to one of three treatment groups: intensive medical therapy only, which includes a combination of counseling, lifestyle changes and medications, medical therapy plus Roux-en-Y gastric bypass, or medical therapy plus sleeve gastrectomy. Nearly all patients, 91.3 percent, completed 36 months of follow up. At the start of the trial, the average patient had an average blood glucose level of 9.2 percent, was living with uncontrolled diabetes for eight or more years and was taking three or more anti-diabetic medications and three or more cardiovascular medications. All patients had some degree of obesity. The sample was 66 percent female.

After three years, weight loss was five to six times greater for patients who underwent gastric bypass or sleeve gastrectomy on average compared with those in the intensive medical therapy group. On average the gastric bypass group lost 24 percent of their body weight, sleeve gastrectomy patients lost 21percent of their weight, and those on medical therapy alone lost 4 percent.

Quality of life measures were evaluated using a validated questionnaire and were significantly improved across multiple domains in both of the surgical groups. There was no improvement among those in the intensive medical therapy group.

Reliance on cardiovascular and glucose-lowering medications was drastically reduced in the surgery groups. At three years, 5 percent to 10 percent of these patients were using insulin compared to 55 percent of those in the medical therapy group.

New data considered kidney function as measured by the amount of albumin in the urine – a marker of kidney damage due to diabetes. Albumin was significantly lower in the gastric bypass group at year three, a trend that was not seen in either of the other groups.

Even those patients who are not severely obese, those with a body mass index of 27 to 35, appear to benefit from surgery in much the same way as those with a higher body mass index, a finding that Schauer hopes will encourage insurance companies to lower the threshold for covering such procedures.

Sleeve gastrectomy involves removing part of the stomach to reduce its volume by 75 to 80 percent; gastric bypass involves two operations, the first to reduce the stomach to 2 to 3 percent of its usual volume (going from the size of a football to a golf ball when expanded) and the second to connect the new gastric pouch directly into the intestine to bypass the stomach.

Roughly 80 percent of the 23 million American adults living with type 2 diabetes are overweight or obese, so these findings may apply to a significant percentage of patients with diabetes, according to researchers. People with uncontrolled diabetes have a much higher risk of cardiovascular complications, including myocardial infarction, stroke and the development of secondary complications like neuropathy, retinopathy and amputation.

"Three years ago, top endocrinologists were curious about these surgeries, but due to the lack of randomized controlled trials and data, were reluctant to include it as a legitimate therapy," Schauer said. "But now the evidence is mounting and we see the benefits of surgery over medical therapy for these patients."

Bariatric surgery is not without risks and can cause complications such as bleeding, infection or blood clots. However, researchers report no major late surgical complications. The most common issues were reported at 12 months and included short-term dehydration, bleeding and one leak. Four out of 100 surgical patients needed operative intervention to manage complications occurring within the first year.

Schauer and his team will conduct long-term follow-up of these patients. Multicenter studies are needed to evaluate the effect of surgery and medical therapy on clinical outcomes such as heart attack, stroke, renal failure and blindness. Several studies have been published since STAMPEDE's one-year results and show similar findings.

This study was funded by Ethicon Endo-Surgery, Inc., a subsidiary of Johnson & Johnson. Dr. Schauer is a consultant with Ethicon.

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