Nondiabetic Teens Lose Pounds on Metformin

BY TIMOTHY F. KIRN
Sacramento Bureau

CHICAGO — The use of metformin for weight loss in nondiabetic, obese adolescents—a practice that is becoming increasingly popular—produces about a 6- to 7-pound loss over 1 year, according to a study presented at the annual scientific sessions of the American Diabetes Association.

"My conclusion from this study is that metformin XR [extended release] provides a modest weight benefit in obese, nondiabetic adolescents over 1 year of treatment," Dr. Darrell Wilson, chief of pediatric endocrinology at Lucile M. Packard Children's Hospital, Stanford, Calif., said.

The study randomized 77 patients with a body mass index (BMI) above the 95th percentile to either extended-release metformin or placebo. Their average BMI was 36 kg/m^2. Under the study regimen, all patients took placebo for 4 weeks, during which they underwent a lifestyle intervention. Then they were randomized to either the active drug or placebo for 48 weeks. Patients on the metformin took 1 500-mg tablet per day for 2 weeks, then 2 tablets a day for 2 weeks, and finally 4 tablets a day for the rest of the study period.

Seventy percent of the patients (27 in each group) were followed for the entire 52 weeks of the trial.

Over 1 year, the average BMI of the placebo-treated patients rose slightly, while that of the metformin-treated patients decreased. However, there was considerable overlap of weight loss and gain among the subjects in the two groups, and though the study was designed with the assumption that the difference in average BMI between the two groups would be about 1.5 kg/m^2, the actual difference they saw was 1.12 kg/m^2, Dr. Wilson said.

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DR. WILSON

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The trial was conducted by the Glaser Pediatric Research Network at five separate centers, and the medication and placebo were donated by Bristol-Myers-Squibb. ■

Banding May Cut Mortality By 60% in the Morbidly Obese

BY DOUG BRUNK
San Diego Bureau

SAN DIEGO — Morbidly obese patients who underwent gastric banding had a 60% lower risk of death at 5 years than a group of morbidly obese patients who did not undergo any obesity surgery, results from a large Italian study demonstrated.

Dr. Luca Busetto and his associates studied 821 consecutive patients with a body mass index of greater than 40 kg/m^2 who were treated with laparoscopic gastric banding between 1994 and 2001 at the University of Padova (Italy) Center for Medical and Surgery Therapy of Obesity. The reference group consisted of 821 patients matched for body mass index, gender, and age who underwent nonsurgical treatment of obesity at six medical centers in Italy between 1994 and 2001.

The mean age of patients was 25 years, Dr. Busetto reported at the annual meeting of the American Society for Bariatric Surgery. The mean follow-up was 5.6 years in the gastric banding group and 7.2 years in the nonsurgical group. Vital status upon study entry was available for 91% of patients in the gastric banding group and in 97% of patients in the nonsurgical group.

Eight deaths occurred in the gastric banding group, compared with 36 deaths in the nonsurgical group, for a total mortality of about 1% and 4%, respectively.

The rate of revisional surgery in the gastric banding group was 13%. The percent of weight loss in this group peaked at 42% in the second year of follow-up and remained stable up to 6 years after surgery.

Multivariate analysis revealed that gastric banding conferred a 60% reduced risk of death, compared with patients in the nonsurgical group. "The reduction in mortality by [gastric] banding seems to be more pronounced in women than in men, in middle-aged than in younger patients, and in superobese than in morbidly obese patients," Dr. Busetto commented. "However, the number of events observed in the two groups was generally low. Therefore, the results of this subgroup analysis should be interpreted very cautiously."

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DR. BUSETTO

He acknowledged that the differences in mortality between the two groups of patients "may be due to some difference in baseline clinical status that remains undetected in our study, in particular the difference in comorbidities."

Dr. Busetto disclosed that he is a consultant for Allergan and Medtronic. He also is a speaker for Abbott Laboratories. ■

Banding Complication Rates in Teens Mirror Those in Adults

BY MITCHEL L. ZOLER
Philadelphia Bureau

ORLANDO — Sustained weight loss with few complications was achieved after gastric banding placed laparoscopically, according to a single-center series of 73 adolescents after 2 years of follow-up.

"The complication rate in our pediatric patients was about the same as the rate in adults, and the morbidity is milder than with gastric bypass," Dr. Evan P. Nadlerand said at the annual meeting of the American Pediatric Surgical Association.

"Concerns about compliance by adolescents [who undergo gastric banding] seem unfounded, Dr. Nadlerand and colleagues wrote in their poster.

Dr. Nadler and his associates at New York University, New York, began performing laparoscopic gastric banding on morbidly obese teenagers aged 13-17 in September 2001. The average age of their first 73 patients was 15.8 years. Of these patients, 54 were girls, and their average preoperative body mass index (kg/m^2) was 48.

During the first 6 months following gastric banding, average BMI dropped to 40 (with follow-up in 53 patients), and by 1 year after surgery, BMI averaged 34 (with follow-up on 47 patients). By 1 year after surgery, treated patients had lost an average of 57% of their excess weight.

These weight losses were maintained in those followed for longer than 1 year. After 18 months, mean BMI remained at 34 (30 patients followed), and after 2 years the mean BMI was 32 (16 patients followed). At 2 years of follow-up, the average amount lost was 61% of excess weight at baseline.

Of the 73 teenagers who received a gastric band, two later had their bands removed, one because of band slippage and the other because of gastric perforation. An additional five patients with slipped bands had them repositioned.

The most common complications resulted from nutritional deficits: mild hair loss (14 patients), iron deficiency (13 patients), and vitamin D deficiency (4 patients). These patients received nutritional counseling and supplements.

Other complications included three cases of hiatal hernia and three cases of gastroesophageal reflux.

In the first year after band placement, patients had an average of 10 office visits and required an average of six band adjustments.

In addition, 21 of the patients were more intensively evaluated and followed as part of a study for the Food and Drug Administration. These patients had 51 identified, obesity-related comorbidities at baseline. At 1 year after gastric banding, 35 (69%) of the comorbidities had completely resolved, 9 (18%) had improved, 5 (10%) showed no change, and 2 (4%) had worsened. ■

Bariatric Surgery Shown Likely To Resolve Type 2 Diabetes

BY TIMOTHY F. KIRN
Sacramento Bureau

CHICAGO — Two years following bariatric surgery, 73% of patients had remission of their type 2 diabetes, compared with 15% of control patients who did not receive the surgery, according to study findings.

Dr. John B. Dixon of Monash University, Melbourne, presented the findings in a poster at the annual scientific sessions of the American Diabetes Association.

The study enrolled 30 patients in each group, all of whom had a body mass index (BMI) greater than 30 kg/m^2 and less than 40 kg/m^2. Of the 30 randomized to surgery, 1 patient withdrew prior to surgery, and the rest were evaluated for the full 2 years. Patients in the surgery group received laparoscopic, adjustable gastric banding. Patients in the control group received the best available management, including medication if deemed appropriate; four patients in the control group withdrew.

At 2 years, patients who had surgery achieved a mean weight loss of 21% of body weight, compared with 2% for those who did not have surgery. Patients in the surgery group lost a mean of 65% of their excess body weight, compared with 6% in the control group.

At baseline, 23% of the surgically treated patients had a hemoglobin A_{1c} level below 7%, and that percentage rose to 87% at 2 years. In the control group, 37% had an HbA_{1c} level below 7% at baseline, and that rose to 50% at 2 years.

By the trial's end, 10% of the surgically treated patients were using metformin, compared with more than 90% of the controls.

The surgical group had greater improvements in triglyceride levels and HDL cholesterol levels as well.

Adverse events in the surgical group included one patient with a superficial wound infection, two patients who needed nonurgent revision, and one patient who had the band removed after 15 days because of persistent regurgitation.

Further analysis showed that a 10% weight loss provided an 85% sensitivity and an 86% specificity for remission, Dr. Dixon said. ■

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