CLINICAL STUDY

Gastric Artery Embolization Trial for the Lessening of Appetite Nonsurgically (GET LEAN): Six-Month Preliminary Data

Mubin I. Syed, MD, Kamal Morar, MD, Azim Shaikh, MD, MBA, Paul Craig, MD, Omar Khan, MD, Sumeet Patel, and Hooman Khabiri, MD

ABSTRACT

Purpose: To report 6-month safety and efficacy results of a pilot study of left gastric artery (LGA) embolization for the treatment of morbid obesity (ie, body mass index [BMI] $>$ 40 kg/m^2).

Materials and Methods: Four white patients (three women; average age, 41 y [range, 30–54 y]; mean weight, 259.3 lbs [range, 199–296 lbs]; mean BMI, 42.4 kg/m^2 [range, 40.2–44.9 kg/m^2]) underwent an LGA embolization procedure with 300–500–μm Bead Block particles via right common femoral or left radial artery approach. Follow-up included upper endoscopy at 3 days and 30 days if necessary and a gastric emptying study at 3 months. Tracked parameters included adverse events; weight change; ghrelin, leptin, and cholecystokinin levels; and quality of life (QOL; by Short Form 36 version 2 questionnaire).

Results: Three minor complications (superficial gastric ulcerations healed by 30 d) occurred that did not require hospitalization. There were no serious adverse events. Average body weight change at 6 months was −20.3 lbs (n = 4; range, −6 to −38 lbs), or −8.5% (range, −2.2% to −19.1%). Average excess body weight loss at 6 months was −17.2% (range, −4.2% to −38.5%). Patient 4, who had diabetes, showed an improvement in hemoglobin A1c level (7.4% to 6.3%) at 6 months. QOL measures showed a general trend toward improvement, with the average physical component score improving by 9.5 points (range, 3.2–17.2) and mental component score improving by 9.6 points (range, 0.2–19.3) at 6 months.

Conclusions: Preliminary data support LGA embolization as a potentially safe procedure that warrants further investigation for weight loss in morbidly obese patients.

ABBREVIATIONS

BMI = body mass index, CCK = cholecystokinin, IBW = ideal body weight, LGA = left gastric artery, PPI = proton pump inhibitor, QOL = quality of life

Morbid obesity, defined as a body mass index (BMI) of greater than 40 kg/m^2, is a prevalent and deadly public health problem affecting 6.6% of the United States population (1). Bariatric surgery is a commonly used procedure for morbidly obese patients in whom conservative weight loss measures such as diet and exercise have failed (2). However, these surgical treatments have known serious complications, including anastomotic leaks, bowel obstruction, deep vein thrombosis, pulmonary embolism, gastrointestinal bleeding, dumping syndrome, and anesthesia risks resulting in morbidity and mortality (2). The 30-day mortality rate associated with bariatric surgery is approximately 0.31% as of 2014, which is lower than previously reported in 2004 (3). However, the repeat operation rate is 7% and the overall complication rate is 17% (3). It is estimated that only 1% of eligible patients elect to undergo bariatric surgery (4).

Left gastric artery (LGA) embolization may fulfill a role as a minimally invasive alternative to the current surgical treatment of gastric bypass or reduction surgery for morbidly obese patients. The LGA supplies the

From the Department of Radiological Sciences (M.I.S., K.M.), Boonshoft School of Medicine (P.C., O.K.), Wright State University, 3075 Governors Place Blvd., Suite 120, Dayton, OH 45409; Dayton Interventional Radiology (M.I.S., K.M., A.S., S.P.), Dayton, Ohio; and Department of Radiology (H.K.), Wexner Medical Center, The Ohio State University, Columbus, Ohio. Received March 13, 2016; final revision received and accepted July 7, 2016. Address correspondence to M.I.S.; E-mail: mubinsyed@aol.com

None of the authors have identified a conflict of interest.

J Vasc Interv Radiol 2016; XX:■■■–■■■

http://dx.doi.org/10.1016/j.jvir.2016.07.010

fundus of the stomach, where it is known that the hormone ghrelin (one of the hormones responsible for appetite) is produced. Ghrelin is a 28-amino acid hunger-stimulating peptide and hormone that is produced mainly by P/D1 cells lining the fundus of the stomach and epsilon cells of the pancreas (5). Ghrelin is the only known circulating orexigenic, or appetite-enhancing, hormone (6).

The purpose of the present pilot study was to collect safety and efficacy data in patients undergoing LGA embolization for morbid obesity in the United States. As a secondary goal, the pilot study obtained quality-of-life (QOL) data.

MATERIALS AND METHODS

Food and Drug Administration Investigational Device Exemption and institutional review board approval were obtained to perform this study on five patients; however, as a result of recruitment challenges, only four patients underwent the procedure (Fig 1). Inclusion and exclusion criteria for the study are listed on *ClinicalTrials.gov* (*https://clinicaltrials.gov/ct2/show/study/NCT02248688*). A data safety monitoring board was established to monitor this study. Four consecutive patients (three women and one man; average age, 41 y; range, 30–54 y), all of whom were white, with a mean weight of 259.3 lbs (range, 199–296 lbs) and mean BMI of 42.4 kg/m^2 (range, 40.2–44.9 kg/m^2), participated in a single-arm prospective pilot study of LGA embolization with 300–500-μm Bead Block particles (Biocompatibles, Farnham, United Kingdom) for the treatment of morbid obesity. Age, sex, baseline weight, baseline BMI, and comorbidities are shown in Table 1.

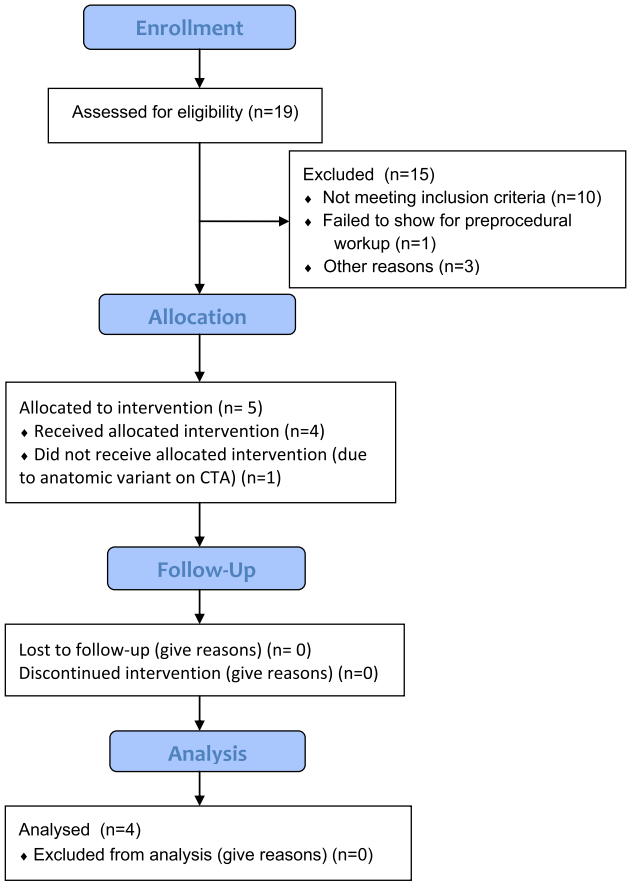

Figure 1. CONSORT flow diagram.

The primary study outcome of this pilot trial was to collect safety data for patients undergoing LGA embolization for morbid obesity in the United States. Secondary study outcomes were efficacy (change in weight and BMI), satiety hormone changes (ghrelin, leptin, and cholecystokinin [CCK] levels), and QOL data.

Patients with morbid obesity (ie, BMI $\geq$ 40 kg/m^2) in whom previous attempts at weight loss through diet, exercise, and behavior modification had failed were recruited for this study. Per the informed consent procedure, patients were allowed to participate only if they were not interested in pursuing bariatric surgery now or in the future. The participants self-reported QOL measures (Short Form 36 version 2 questionnaire), medical records, medications, bariatric histories (weight gain, weight loss attempts), physician and hospital visits, and demographic characteristics. A complete history and physical examination was performed by a clinician specializing in the evaluation and management of obese patients. All patients had dietary consultations for preoperative evaluation and were followed after the procedure by a dietician. Any patient with type II diabetes (n = 1) was evaluated by an endocrinologist before participation in the study. Blood glucose levels were monitored with adjustments of diabetic drugs as needed by the endocrinologist throughout the study. Any female patient of childbearing potential (n = 2) was required to use two forms of contraception during the study (oral and barrier), which was monitored by their primary care provider or gynecologist. An upper endoscopy study was performed at baseline and 3 days after the procedure in all patients. If any patient had any abnormality on 3-day endoscopy (n = 3), upper endoscopy was repeated at 30 days. Fasting morning, plasma ghrelin, leptin, and CCK measurements, in addition to BMI and other baseline and follow-up tests or procedures, were performed at regular intervals (Table 2). Weight loss was calculated as a percentage versus baseline, as well as by percentage excess body weight loss as follows:

$$[(\text{preoperative weight} - \text{follow-up weight})/$$
$$(\text{preoperative weight} - \text{ideal body weight (IBW)}] \times 100.$$

IBW was calculated by using the Devine formula: for men, IBW is 50 kg plus 2.3 kg for each inch in height over 5 feet; for women, IBW is 45.5 kg plus 2.3 kg for each inch in height over 5 feet (7). Treatment with a proton pump inhibitor (PPI) was started 1 week before embolization and continued for 1 month after the pro-