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Weight Loss after Left Gastric Artery Embolization: A Systematic Review and Meta-Analysis

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Abstract

A systematic review of clinical trials investigating the safety and efficacy of left gastric artery (LGA) embolization as a bariatric procedure was performed. The Methodological Index for Nonrandomized Studies (MINORS) instrument was used for quality assessment. Patient characteristics, weight loss after embolization, and complications were reviewed. Metaregression was performed to assess associations of age, sex, body mass index, and ghrelin and leptin levels with weight change after LGA embolization. The final meta-analysis included 6 nonrandomized prospective trials. Findings of 3 additional studies reporting weight changes after LGA embolization for control of gastrointestinal bleeding were also reviewed. Pooled analysis of 47 subjects with overweight/obesity showed mean \pm SD weight loss after embolization of $8.1\% \pm 1.5\%$ and $8.85 \text{ kg} \pm 1.24 \text{ kg}$ (both $P < .001$) after a mean 12-month follow-up. Male sex ($\beta = 11.36 \pm 5.79$, $P = .049$) was associated with greater weight loss. Transient superficial mucosal ulcers were common after LGA embolization. One major adverse event comprising severe pancreatitis, splenic infarct, and gastric perforation was reported; treatment was supportive care. LGA embolization was associated with statistically significant weight loss and limited complications during short-term follow-up. Given that LGA embolization is an investigative method, it is important for researchers to follow standardized protocols and techniques to avoid complications.

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Obesity is a global epidemic among adults and children in developed and developing countries (1). Initial treatment strategies include diet modification and exercise, which can be coupled with behavioral interventions and pharmacotherapy, but the outcomes of these interventions vary according to patient compliance. Surgical approaches to weight loss have been developed, including Roux-en-Y gastric bypass, sleeve gastrectomy, and gastric banding (2). Bariatric surgery causes weight loss by restricting meal size, inhibiting macronutrient absorption and, importantly, by altering the hormones involved in metabolic homeostasis (2-8). Although effective, surgical approaches carry high risks of patient morbidity and mortality (2,6).

Left gastric artery (LGA) embolization is a minimally invasive, image-guided procedure most commonly used to treat upper gastrointestinal bleeding. Recently, LGA embolization has also been proposed as an alternative method to treat obesity by targeting the appetitestimulating endocrine functions of the gastric fundus (9,10). Specifically, embolic materials are delivered via a transcatheter approach into the LGA, the primary vascular supply to the gastric fundus, with the goal of inducing ischemia (10). The resultant ischemia depresses the production of ghrelin, the only known appetite-stimulating hormone, and suppresses the sensation of hunger (7,8,11,12). Several studies have evaluated the effects of LGA embolization on weight and ghrelin production in both animal models (11-13) and humans (14-18). A systematic review and meta-analysis of the available studies were performed to (i) summarize patient characteristics, embolization techniques, and complications associated with LGA embolization and (ii) determine the amount of weight loss and identify clinical predictors of weight loss associated with LGA embolization.

MATERIALS AND METHODS

This study used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses checklist (19).

Search Strategy and Study Selection

Institutional review board approval was not required for this study. A systematic literature search was performed to identify studies of LGA embolization that reported weight changes after the procedure (Appendix A [available online on the article's Supplemental Material page at [www.jvir.org\]](http://www.jvir.org)). PubMed, Embase, Scopus, and Web of Science were searched using the terms "gastric artery," "bariatric," and "embolization." Titles and abstracts of the identified records were screened using the terms "weight" and "BMI." A total of 47 studies were selected for further evaluation against predetermined inclusion and exclusion criteria.

Original, peer-reviewed studies of human subjects that reported LGA embolization or bariatric embolization as the main procedure of interest were included. To be included, studies had to report weight change (percentages or absolute values) after the procedure. Studies performed for the primary purpose of treating gastrointestinal bleeding or malignancy as well as duplicate studies were excluded. Animal studies, expert opinions, and case reports were also excluded. Of 19 eligible studies, 6 were review articles (no original data), 2 were commentaries, 1 was a case report, and 3 were retrospective reports of

patients with gastrointestinal bleeding. This left 7 reports from 6 individual studies for the meta-analysis (Fig 1).

Data Collection and Data Items

Study data were extracted, including author names, year of publication, study design (prospective vs retrospective), number of patients, indications for embolization, duration of follow-up, and institution where the study was performed. Next, the study populations were analyzed to determine mean patient age, proportion of women versus men, mean baseline weight (kg) and body mass index (BMI) (kg/m²), dietary considerations after the procedure, inclusion of patients with cancer, availability of computed tomography (CT) angiography before the procedure, and treatment setting (inpatient vs emergency department). Baseline levels and changes in ghrelin and leptin were also recorded. Finally, information regarding embolization techniques and complications after the procedure was extracted. Attempts were made to contact the authors for additional information whenever the published report was deemed insufficient.

Study Characteristics

Included studies were published between January 2014 and April 2019. Six nonrandomized prospective trials comprising 47 patients investigating the safety and/or efficacy of LGA embolization for weight loss were included in the meta-analysis (14,16-18,20,21). Two reports were available from the Bariatric Embolization of Arteries for the Treatment of Obesity (BEAT Obesity) Trial, and data from the most recent report were included in the meta-analysis. Significant variation was observed in the duration of follow-up, which ranged from 3 months to 20–24 months (Table 1).

Three additional studies were retrospective evaluations of patients who underwent LGA embolization for gastrointestinal bleeding. Findings from these 3 gastrointestinal bleeding studies (9,15,22) were reviewed but were not included in the meta-analysis. The other 5 studies were included, and each reported on 4–7 eligible patients (14,16-18).

Patient Characteristics

No studies included patients < 18 years of age (Table 2). Mean patient ages ranged from 38 years (20) to 48 years (23). Mean patient weight before the procedure ranged from 79 kg (20) to 160 kg (23). Studies varied according to whether they used dietary recommendations, excluded patients with cancer, and used CT angiography to rule out vascular anomalies before embolization. All studies reported a brief hospitalization period after the procedure (1–3 days) except the study by Syed et al (17), in which patients were not admitted to the hospital for observation (Table El [available online on the article's Supplemental Material page at [www.jvir.org\]](http://www.jvir.org)).

Embolization Procedures

Technical details of the embolization procedure are presented in Table 3. The procedure typically started with obtaining femoral or radial artery access, engaging the celiac trunk, obtaining angiographic imaging of the downstream branches, locating the LGA, inserting a microcatheter into the LGA, and performing embolization of the LGA. After the procedure,

patients were monitored for complications. Proton pump inhibitor therapy (for up to 6 weeks after the procedure) with or without endoscopy (immediately after the procedure and 3 days and 3 months after the procedure) was used to monitor for mucosal ulcers in some studies.

Complications after Procedure

Data were extracted on complications after the procedure, including immediate adverse events and complications that were detected during follow-up examinations. When applicable, complications were classified as major or minor according to the American Society for Metabolic and Bariatric Surgery (24). Follow-up evaluations and treatments were also reviewed.

Summary Measures and Results Synthesis

The 2 primary outcomes of interest were absolute weight change and percentage weight change. Data on weights before and after the procedure were used to calculate mean (and 95% confidence interval) weight change (in kg and %). When only 1 of the 2 primary outcomes was reported, the other outcome was calculated using the baseline weight (assuming similar dispersion and mean \pm SD ratios). For studies with follow-up from multiple time points, data from the latest follow-up visit were used for analysis.

Pooled results were calculated by using random-effects models. Per the methods of Borenstein et al (25), random-effects models were used because the authors could not assume that all included studies were identical. There were considerable variations in patient age, sex distribution, and baseline characteristics among the studies. I^2 values were calculated and used as a relative measure of true statistical heterogeneity to the observed variation. The standard error of the mean was calculated for each study. Standardized mean differences were calculated and pooled. Because baseline values and values following the procedure may not be independent of each other, consistency of pooled estimates was confirmed with multiple pre-post correlation values, following Follmann et al (26). Mean difference in weight loss after the procedure was used as the main outcome of interest.

Sensitivity Analysis.—To assess the robustness of the findings, sensitivity analysis was conducted by excluding each study from the pooled results and recalculating the pooled results. Similarly, the analysis was repeated by excluding studies with < 12 months of follow-up. Finally, multiple meta-regression analyses were used to investigate age, sex, weight, BMI, and ghrelin and leptin levels as predictors of weight loss. Because the purpose of the meta-regression was to identify potential determinants of weight loss after LGA embolization, only obesity-related clinical trials were used for meta-regression. Data regarding ghrelin and leptin were available for 4 and 3 of the obesity-related trials, respectively.

Risk of Bias in Individual Studies

Risk of bias in included studies was assessed by using the Methodological Index for Non-Randomized Studies instrument (27). Two authors (N.H.N., C.R.B.) assessed the potential risk of bias, scoring each item as 0 if not reported, 1 if reported but inadequate, and 2 if reported and adequate. Discrepancies were discussed, and consensus scores were used.

Methodological Index for Non-Randomized Studies consists of 8 items: (a) having a clearly stated aim; (b) including consecutive patients; (c) collecting data prospectively; (d) having appropriate endpoints with regard to the aim of the study; (e) using unbiased assessment of the endpoints; (*f*) having an appropriate follow-up period; (*g*) having $<$ 5% loss to follow-up; and (h) calculating the sample size prospectively. The global ideal score was 16, and studies with total scores of 12 were considered to have a high risk of bias.

Publication Bias.—Potential publication bias was assessed using a quantitative approach to calculate the number of nonsignificant studies that could nullify the observed effect (i.e., classic fail-safe number). Next, effect sizes of the included studies were reviewed and plotted against their standard errors, and Duval and Tweedie's trim-and-fill method was used to identify significant changes in the pooled results (28).

All analyses were performed using Stata 13.0 (StataCorp LLC, College Station, Texas) or CMA Version 2.0 (Biostat, Englewood, New Jersey). P values < .05 were considered significant.

RESULTS

Weight Loss after Embolization

Pooled absolute mean (SE) weight loss was $8.85 \text{ kg} \pm 1.24 \text{ kg}$, ranging from 7.62 kg (21) to 22.00 kg (16) (Table 4). Pooled percentage of mean weight loss was $8.11\% \pm 1.46\%$, ranging from 4.77% (23) to 17.19% (16) (Fig 2). The mean duration of follow-up for the participants included in the final analysis was 12 months (Table 1). No significant statistical heterogeneity was detected (l^2 = 12.35) among pooled studies.

Clinical Variables Associated with Weight Loss

Male sex was associated with absolute weight loss ($\beta = 11.36 \pm 5.79$; $P = .049$). Other clinical variables, including age, weight, and BMI, were not significantly associated with absolute weight loss (Table 5). Likewise, no statistically significant association was found between baseline ghrelin (β = 0.01 ± 0.01; P = .297) or leptin (β = 0.14 ± 0.12; P = .229) and weight loss after procedure.

Embolization Techniques and Complications

Embolization techniques, follow-up evaluations and treatments, and reported complications are summarized in Table 3. Despite variations, major and minor events were used in similar fashion across the included studies. Elens et al (20) defined major complications as adverse events leading to longer hospital stay or intensive care unit admission. Minor complications were complications that were medically managed after discharge. Bai et al (14) used the National Cancer Institute Common Terminology Criteria for Adverse Events (version 4.0), with grade III or above considered major complications (14). Weiss et al (18) used the American Society for Metabolic and Bariatric Surgery recommendations. Syed et al (17) used the Society of Interventional Radiology (SIR) guidelines to categorize procedurerelated complications (29). Per the SIR Standards of Practice Committee recommendation

for classification of complications, major complications included events requiring therapy with hospitalization or resulting in permanent sequelae or death (29).

The most common adverse events were transient abdominal pain and superficial gastric ulcers. Because of variations in the endoscopy protocols, availability of the results, and reports of superficial gastritis, no pooled analysis of adverse events was performed. Superficial gastritis was observed in 8 of 20 patients in the study by Weiss et al (21), 1 of 16 patients in the study by Elens et al (20), 1 of 5 patients in the study by Bai et al (14), and 3 of 4 patients in the study by Syed et al (17). In addition to superficial gastric ulcers, other minor complications included transient subclinical pancreatitis (18,21) and hematoma at the puncture site (14).

Major adverse events were reported in 1 of the patients in the series by Elens et al (20), including severe pancreatitis, splenic infarction, and late gastric perforation. The patient had a total length of hospital stay, including intensive care unit stay, of 1 month. Other obesity clinical trials reported no major complications. Kim et al (15) reported 1 death within 60 days after the procedure, which was unrelated to the procedure.

Sensitivity Analysis

The effects on the pooled weight change data were evaluated by excluding each study in turn. The greatest change (8.24 kg \pm 1.07 kg) occurred when excluding the study by Kipshidze et al (16), but this was not significantly different from the pooled result. Exclusion of studies with < 12 months of follow-up produced no statistically significant differences in the pooled results (Fig 3 and Table E2 [available online on the article's Supplemental Material page at [www.jvir.org\]](http://www.jvir.org)).

Risk of Bias in Individual Studies

The individual scores using the Methodological Index for Non-Randomized Studies tool are summarized in Table E3 (available online on the article's Supplemental Material page at www.jvir.org). Only 2 of the 6 included studies had total scores > 12 and were considered to be at low risk of bias. Absence of prospective sample size calculation and loss to follow-up of > 5% were the most common sources of bias.

Publication Bias

The vulnerability of results to publication bias was investigated by calculating the classic fail-safe number of studies that could potentially nullify this study's findings. Given the Z values of the included studies, number of included studies ($n = 6$), and type I error of .05, 94 additional studies (with a reported effect size of 0) would be required to nullify the findings. Thus, the pooled results are unlikely to be nullified by several unpublished studies with nonsignificant findings. When using the fill-and-trim method to confirm the robustness of the pooled results, the addition of presumed missing studies to the right of the calculated average effect did not produce a statistically significant change in the pooled result (adjusted pooled estimate of 8.05 kg [95% confidence interval 4.99–11.11]).

DISCUSSION

Data on weight change after LGA embolization in 47 patients from 6 studies were collected, and mean weight loss was $8.68 \text{ kg} \pm 1.24 \text{ kg}$ ($P < .001$) after a mean 12 months of follow-up. Men were more likely than women to lose weight after the procedure. This is the first systematic review and meta-analysis elucidating patient characteristics, techniques, and complications related to LGA embolization and pooling the available evidence from bariatric trials to quantify the amount of weight loss that can be expected after LGA embolization.

Weight loss of approximately 8–9 kg (approximately 8% of baseline total body weight) was achieved after a mean follow-up of 12 months (range, 3–24 months), which is superior to the weight loss expected from diet and exercise programs but comparable to other, more invasive interventions. Diet and exercise programs frequently aim for weight loss of 5%– 10% after 12 months (30,31). However, evidence suggests that most patients in diet and exercise programs lose approximately 5% (5 kg) of their baseline body weight (32-36). Significantly less of the initial weight loss is maintained during longer follow-up periods (37-39). In a meta-analysis by Franz et al (38), 80 weight loss–focused randomized trials were reviewed and showed that, on average, 3%–6% (approximately 3–6 kg) of weight loss is maintained after 48 months. From a procediual standpoint, the intragastric balloon device can help patients achieve weight loss of approximately 10%–20% of their baseline weight during short-term follow-up of 3–6 months (40-42). However, up to 50% of patients may be unable to maintain their weight at 12- to 18-month follow-up (40), and approximately 63% may be unsatisfied with the procedure and unwilling to undergo it again (41).

Bariatric surgery is typically reserved for patients with morbid obesity (2,6) and is associated with substantial risk of perioperative death. In a meta-analysis, Buchwald et al (43) pooled the results of 22,094 patients and showed excess body weight loss of 62%–70% after various bariatric surgical procedures. The 30-day mortality rate was 1.1% after biliopancreatic diversion. From a clinical standpoint, weight loss was associated with complete resolution of diabetes, hypertension, hyperlipidemia, and obstructive sleep apnea in 62%–86% of patients (43). The current study shows that bariatric LGA embolization is an effective treatment that is associated with statistically significant weight loss in studies with mean 12-month follow-up. Only 1 case of major complications (severe pancreatitis, splenic infarct, and gastric perforation) after the procedure was reported by Elens et al (20), and the patient was treated with supportive care (20). Given that LGA embolization is an investigative method and is not yet proven to be effective for the management of obesity, it is important for researchers to follow standardized protocols and techniques to avoid unwanted complications. These include detailed technical considerations and stringent inclusion and exclusion criteria. No additional detailed history regarding the patient who developed severe pancreatitis was available. Of note, Elens et al (20) included patients with BMI of 25–35 kg/m². Of their 16 patients, 11 had a BMI < 30 kg/m² (overweight category) (20). In contrast, all US clinical trials of LGA embolization were designed for patients with obesity $(BMI > 30 \text{ kg/m}^2$; most with BMI > 40 kg/m²), resulting in a different risk-benefit balance (16,17,21). All patients with a history of pancreatitis were excluded from the included trials. Risk of gastric perforation, prior gastrointestinal bleeding, and related complications

were assessed before inclusion (14,18,20,21,23). From a technical standpoint, the volume of injected microspheres should be closely monitored; Elens et al (20) restricted volume to \lt 2 mL. Efforts should be made to prevent reflux and avoid potentially related complications, including pancreatitis and splenic infarct. An antireflux device (Surefire Medical, Inc, Westminster, Colorado) was used in select cases by Weiss et al (18,21). Elens et al (20) used Gelfoam (Pfizer, New York, New York) as a liquid suspension mixed with contrast agent in a 3-mL syringe. Finally, prospectively designed randomized clinical trials are needed to determine the efficacy of such considerations in preventing adverse events, including pancreatitis and gastric perforations.

The studies reviewed in this meta-analysis were similar in many ways. All studies included patients who were 18 years of age who underwent gastric artery embolization with or without embolization of additional branches of the celiac trank. The reviewed clinical trials used additional criteria to select appropriate patients. Patients with a history of gastrointestinal surgery, peptic ulcer disease, nonsteroidal anti-inflammatory drag use, major cardiovascular events, psychiatric disorders, or other comorbid conditions (eg, liver or kidney dysfunction) were excluded. Although heterogeneity statistics can be inherently biased in small meta-analyses (44), ℓ^2 values did not show significant heterogeneity among the studies included in this report. Before calculating the pooled results, potential underlying causes of heterogeneity were examined, and the initial objectives of the LGA embolization studies were identified. Among the evaluated studies, embolization was performed for weight loss (6 studies) (14,16-18,20,21) or control of gastrointestinal bleeding (3 studies) (9,15,22). Patient characteristics, embolization techniques, and complications of all eligible reports were systematically reviewed. However, because of considerable risk of bias, only clinical trials of bariatric LGA embolizations were included in the meta-analysis. Variations in study design, duration of follow-up, and population characteristics are further explained in Tables E2 and E3 (available online on the article's Supplemental Material page at www.jvir.org). Significant between-subject variations in the amount of weight loss with regard to follow-up intervals were reported. For example, Weiss et al (21) plotted the amount of excess weight loss over time. Although most of their participants had an upward trend of weight loss over time, significant variations existed, and some patients had partial weight gains (Fig 3). A fitted cubic spline was converged, yielding an approximate excess weight loss of 10% at 12 months of follow-up ($R^2 = .69$). Regarding the size of embolic particles, of the 6 included clinical trials, 4 used 300–500 μm microspheres, and 2 used 500–700 μm microspheres. In the current study, there was no statistically significant difference in weight loss after embolization based on microsphere size. Moreover, in the study by Elens et al (20), 2 patients received 300–500 μm microspheres. In the current study, there was no statistically significant difference in pooled results based on microsphere size. However, this analysis may be underpowered to detect variations among subgroups, and larger studies with patient-level data based on microsphere characteristics are needed for an accurate comparison.

Several technical and statistical considerations with regard to heterogeneity were deliberated while pooling the available data. Availability of weights before and after the procedure was 1 inclusion criterion. In addition to weight change after the procedure, some of the included studies provided more detailed assessment and reporting of their outcomes. For

example, Kipshidze et al (16) included assessments of serum ghrelin changes as one of the primary purposes of their study. Bai et al (14) reported ghrelin and leptin measurements immediately before and 3 months after the procedure. They also measured changes in waist circumference and further assessed the amount of abdominal fat and its distribution by using magnetic resonance imaging both before and after embolization. Weiss et al (18) included an extensive series of assessments, including hormonal panels, appetite/satiety assessments, quality-of-life assessments, hemoglobin A_{1c} levels, and lipid panels. They also reported their results as the percentage of excess weight loss by using the Devine formula for ideal body weight calculation (21,45). The studies by Weiss et al (18,21) and Syed et al (17) also evaluated the technical feasibility of LGA embolization as a bariatric procedure (defined as the ability to perform embolization of the gastric fundus in a severely obese patient). Relevant parameters, including fluoroscopy time, radiation dose, procedure time, and contrast agent dose, were reported. Syed et al (17) also measured changes in satiety hormones and quality of life and reported their results as percentage of excess body weight loss. Because of limitations in the consistency and availability of detailed data on patient outcomes, the outcome of interest in the current study was limited to weight change after the procedure. Likewise, despite the well-known roles of ghrelin and leptin in modulation of appetite, weight loss, and response to bariatric surgery (3,4,8,36), no statistically significant conclusion could be drawn with regard to LGA embolization because of limitations in the number of participants and number of studies with available reports of baseline ghrelin and leptin values. Ghrelin acts as an appetite-stimulating hormone (4,7). In contrast, leptin secretion is associated with decreased appetite, increased energy expenditure, and body weight modulation (46). Increasing leptin levels may act as a signal that orchestrates resistance to obesity (47).

This study is subject to the limitations of the included studies, which should be considered when interpreting the results. These include variations in the indications for LGA embolization, study designs, embolization techniques, follow-up plans, dietary assessments, patient comorbidities, and availability of control subjects. For example, the presence of superficial gastric ulcers may act as a modulator of weight loss following the procedure. Nevertheless, individual-level data regarding the incidence of superficial ulcers (and most complications) were unavailable in the literature. Although pooled results were retrievable from the included trials, individual patient-level data would be needed to compare the amount of weight loss in patients with versus without a complication (e.g., superficial gastriculcer). Larger prospective reports with detailed patient-level data describing clinical characteristics, exposures, and complications are needed to expand these findings and determine other correlates of weight loss after LGA embolization. Finally, because the amount of weight loss after bariatric embolization has been shown to vary over time, static measures of mean weight loss may be less accurate than the mean weight loss at particular time intervals. However, because of limitations in the number of available studies and participants, no detailed time-varying analysis was performed.

CONCLUSIONS

LGA embolization was associated with statistically significant weight loss during short-term follow-up. Male sex was associated with greater weight loss after embolization. Transient

superficial mucosal ulcers were common after LGA embolization. Major complications were uncommon and included severe pancreatitis, splenic infarct, and gastric perforation.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

ABBREVIATIONS

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Flow chart showing study selection. RSNA = Radiological Society of North America.

Mean difference and 95% confidence intervals

Absolute weight change (kg)

Percentage weight change (%)

Figure 2.

Forest plots showing effect sizes and the pooled results.

Mean difference and 95% confidence intervals

Absolute weight change (kg)

Figure 3.

Forest plots of the pooled results for absolute and percentage weight change after excluding each individual study.

Characteristics of LGA Embolization Studies Characteristics of LGA Embolization Studies

 $*$ $\overline{}$ Embolization of additional vessels was performed per individual study protocols.

 $^{\prime\prime}$ BMI criteria was not specified, although mean (± SD) BMI was 42 ± 6.8. BMI criteria was not specified, although mean $(\pm$ SD) BMI was 42 ± 6.8 .

 $\text{BMI} = \text{body}$ mass index; $\text{ED} = \text{energy}$ department; $\text{NA} = \text{not available}$.

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BMI = body mass index; ED = emergency department; NA = not available.

* Of the 16 patients, 14 had portal/venous phase CT, 1 had CT angiography, and 1 had non-contrast CT.

 $t_{\text{Expressed as mean (range)}}$. Expressed as mean (range).

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Table 2.

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Table 3.

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CTCAE = Common Terminology Criteria for Adverse Events; IV = intravenous; LGA = left gastric artery; NA = not available; PVA = polyvinyl alcohol; PPI = proton pump inhibitor. CTCAE = Common Terminology Criteria for Adverse Events; IV = intravenous; LGA = left gastric artery; NA = not available; PVA = polyvinyl alcohol; PPI = proton pump inhibitor.

Table 4.

Table 5.

Associations of Weight Loss with Patient Factors

BMI = body mass index; CI = confidence interval.