

Appendix E1

Hunger Questionnaire

Appetite and satiety questionnaires, which assessed the perceived sensation of hunger, and 3-day food logs were completed by participants at home for 6 consecutive days before bariatric embolization and before each follow-up visit after embolization. The questionnaires included a visual assessment scale incorporating a 100-mm horizontal line representing the rating scale for each response. The analog response for the question “How hungry are you right now?” ranged from “not hungry at all” to “extremely hungry” and was assessed before breakfast, before lunch, at midafternoon, and 2 hours after dinner. Before breakfast, another question was asked: “How hungry have you been generally in the past 3 days?” The visual assessment scale was scored by using a ruler, with the assigned score equal to the number in millimeters from the left end of the scale.

Table E1: Bariatric Embolization of Arteries for the Treatment of Obesity Trial (BEAT Obesity) Study Calendar

Visit	Administrative, Data Collection	Procedures	Tests
Baseline	Informed consent	History and physical examination	CBC
			CMP*, lipids*
			Stool guaiac test
	SF-36 questionnaire	Endoscopy	<i>Helicobacter pylori</i>
	IWQOL questionnaire	Gastric emptying	Meal tolerance test
	Demographic characteristics	3D CTA	Glucose tolerance test
Food log	Pregnancy test**		
Hunger questionnaire			
<i>Weight management intake/initial assessment</i>			
Procedure day		History and physical examination	CBC***
			CMP*, ***
		Bariatric embolization****	Pregnancy test**
<i>Weight management counseling ad lib.</i>			
1 week	SF-36 questionnaire IWQOL questionnaire Food log Hunger questionnaire	History and physical examination	CBC
			CMP*, lipids*
			Hemoccult
			Fasting gastric hormones
2 weeks	Same as 1 week	History and physical examination	CBC
			CMP*, lipids*
		Endoscopy	Hemoccult
			Meal tolerance test
1 month	Same as 1 week	History and physical examination	CBC
			CMP*, lipids*
			Hemoccult
		Gastric emptying	Meal tolerance test
			Pregnancy test**
3 months	Same as 1 week	Same as 2 weeks	Same as 2 weeks

6 months	Same as 1 week	History and physical examination	Same as 1 month
		Gastric emptying*****	
12 months	Same as 1 week	History and physical examination	Same as 2 weeks

3D CTA = three-dimensional computed tomographic angiography, CBC = complete blood count, CMP = comprehensive metabolic panel, IWQOL = impact of weight on quality of life, SF-36 = Short Form-36 Health Survey.

* Performed with participant fasting.

** If applicable.

*** Performed if previous results are > 30 days old.

**** Participants may be admitted to the hospital after the embolization procedure.

***** Only repeated if gastric emptying was abnormal at 1 month. Mandatory for the first five participants.

Table E2: Outcomes (Mean ± SD) of 20 Participants after Undergoing Bariatric Embolization in the Bariatric Embolization of Arteries for the Treatment of Obesity (BEAT Obesity) Trial

Parameter	Raw Baseline Value (n = 20)	Post-Embolization Time Point					
		1 Week	2 Weeks	1 Month	3 Months	6 Months	12 Months
<i>Percentage Change From Baseline (No. of Participants)</i>							
Weight (kg)							
Total	129 ± 20	-3.3 ± 1.4 (20)	-3.6 ± 1.7 (20)	-4.3 ± 2.0 (20)	-6.0 ± 2.8 (18)	-6.7 ± 4.2 (14)	-6.0 ± 5.3 (15)
EWL*	67 ± 12	-6.3 ± 2.8 (20)	-6.8 ± 3.4 (20)	-8.2 ± 3.9 (20)	-12 ± 5.6 (18)	-13 ± 7.7 (14)	-11 ± 10 (15)
BP (mmHg)							
Systolic	125 ± 18	7.8 ± 11 (17)	4.0 ± 11 (18)	-2.0 ± 29 (16)	-0.3 ± 30 (17)	6.1 ± 13 (14)	9.8 ± 16 (13)
Diastolic	77 ± 8.8	-1.3 ± 37 (17)	-0.9 ± 13 (18)	-5.2 ± 30 (16)	-1.4 ± 29 (17)	3.2 ± 16 (14)	4.2 ± 11 (13)
Hunger score	57 ± 2.8	-49 ± 4.8 (17)	-44 ± 5.8 (17)	-51 ± 11 (20)	-45 ± 12 (15)	-37 ± 21 (14)	-26 ± 22 (16)
<i>Absolute Value (No. of Participants)</i>							
SF-36 score							
Physical CS	46 ± 8.0	46 ± 8.9 (17)	47 ± 8.3 (17)	48 ± 9.3 (20)	52 ± 8.2 (15)	53 ± 9.1 (14)	50 ± 9.3 (16)
Mental CS	46 ± 11	48 ± 11 (17)	48 ± 9.8 (17)	49 ± 10 (20)	51 ± 7.3 (15)	46 ± 13 (14)	50 ± 10 (16)
IWQOL score	57 ± 18	62 ± 20 (17)	66 ± 19 (17)	68 ± 21 (20)	75 ± 18 (17)	76 ± 15 (15)	77 ± 18 (16)
Hb A1c (%)	5.8 ± 0.4**	NA	NA	5.7 ± 0.4 (17)	5.8 ± 0.4 (15)	5.8 ± 0.3 (13)	5.7 ± 0.5 (13)
Blood glucose (mg/dL)	95 ± 14	94 ± 12 (19)	94 ± 16 (16)	90 ± 15 (17)	87 ± 11 (17)	85 ± 12 (15)	85 ± 9 (13)
Total cholesterol (mg/dL)	197 ± 35	182 ± 27 (20)	174 ± 34 (16)	181 ± 31 (17)	185 ± 26 (17)	196 ± 40 (13)	199 ± 41 (13)
Triglycerides (mg/dL)	124 ± 69	109 ± 36 (20)	125 ± 61 (16)	104 ± 45 (17)	113 ± 59 (17)	100 ± 26 (13)	112 ± 33 (13)
HDL (mg/dL)	49 ± 14	41 ± 9.4 (19)	43 ± 9.4 (16)	46 ± 13 (17)	48 ± 14 (17)	53.1 ± 16 (13)	56.8 ± 21.3 (13)
LDL (mg/dL)	123 ± 27	120 ± 26 (20)	109 ± 26 (16)	114 ± 25 (17)	114 ± 25 (17)	123 ± 32 (13)	120 ± 29 (13)

BP = blood pressure, CS = Component Summary, EWL = excess weight loss, Hb = hemoglobin, HDL = high-density lipoprotein, IWQOL = impact of weight on quality of life, LDL = low-density lipoprotein, NA = not available, SD = standard deviation.

* As determined by Devine Equation (38).

** Data missing for one participant.

Table E3: Inclusion and Exclusion Criteria for the Bariatric Embolization of Arteries for the Treatment of Obesity (BEAT Obesity) Trial

Type and No. of Criterion	Criterion
Inclusion	
1	Willing, able, and mentally competent to provide written, informed consent
2	Body mass index between 40 and 60 kg/m ²
3	Residence within 25 miles of the enrolling institution
4	Vascular anatomy (including celiac, hepatic, and gastric arteries) that, in the opinion of the interventional radiologist, is amenable to bariatric embolization, as assessed on three-dimensional computed tomographic angiography
5	Suitable for protocol therapy, as determined by the interventional radiology investigator
6	Adequate hematologic, hepatic, and renal function as follows: hematologic neutrophils, > 1.5 × 10 ⁹ /L; platelets, > 100 × 10 ⁹ /L; international normalized ratio, < 1.5; hepatic bilirubin, ≤ 2.0 mg/dL; albumin ≥ 2.5 g/L; renal estimated glomerular filtration rate, > 60 mL/min/1.73 m ²
7	Age ≥ 18 years
Exclusion	
1	Prior gastric pancreatic, hepatic, and/or splenic surgery
2	Prior radiation to the upper abdomen
3	Prior embolization to the stomach, spleen, or liver
4	Portal venous hypertension
5	Prior or current peptic ulcer disease
6	Hiatal hernia
7	Significant risk factors for peptic ulcer disease, including daily nonsteroidal anti-inflammatory drug use and smoking
8	Active <i>Helicobacter pylori</i> infection
9	Weight > 400 lbs
10	Known aortic disease (eg, aneurysm, dissection) and renal insufficiency as evidenced by an estimated glomerular filtration rate of < 60 mL/min
11	Major comorbidity (eg, cancer, clinically significant cardiovascular disease, diabetes, peripheral arterial disease)
12	Complicated arterial anatomic variants (left gastric artery arising from the aorta and/or hepatic arterial supply via a replaced or accessory left hepatic artery arising from the left gastric artery)
13	Pregnancy
14	Preexisting chronic abdominal pain
15	Positive stool occult study
16	Abnormal endoscopic findings
17	Abnormal nuclear gastric motility examination
18	American Society of Anesthesiologists class 4 or 5 (very high-risk surgical candidates: class 4 = incapacitating disease that is a constant threat to life) at the time of screening for enrollment in the study. This exclusion criterion exists because of the possibility that surgical intervention will be needed if the study intervention subsequently leads to severe adverse effects.
19	History of inflammatory bowel disease
20	Autoimmune disease
21	Cirrhosis
22	History of allergy to iodinated contrast media