Aspiration Therapy Leads to Weight Loss in Obese Subjects: A Pilot Study

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BACKGROUND & AIMS: Obese patients rarely achieve long-term weight loss with only lifestyle interventions. We evaluated the use of endoscopic aspiration therapy for obesity. Aspiration therapy involves endoscopic placement of a gastrostomy tube (A-Tube) and the AspireAssist siphon assembly (Aspire Bariatrics, King of Prussia, PA) to aspirate gastric contents 20 minutes after meal consumption. **METHODS:** We performed a pilot study of 18 obese subjects who were randomly assigned (2:1) to groups that underwent aspiration therapy for 1 year plus lifestyle therapy (n = 11; mean body mass index, 42.6 ± 1.4 kg/m^2) or lifestyle therapy only (n = 7; mean body mass index, 43.4 ± 2.0 kg/m^2). Lifestyle intervention comprised a 15-session diet and behavioral education program. **RESULTS:** Ten of the 11 subjects who underwent aspiration therapy and 4 of the 7 subjects who underwent lifestyle therapy completed the first year of the study. After 1 year, subjects in the aspiration therapy group lost 18.6% ± 2.3% of their body weight (49.0% ± 7.7% of excess weight loss [EWL]) and those in the lifestyle therapy group lost 5.9% ± 5.0% (14.9% ± 12.2% of EWL) ($P < .04$). Seven of the 10 subjects in the aspiration therapy group completed an additional year of therapy and maintained a 20.1% ± 3.5% body weight loss (54.6% ± 12.0% of EWL). There were no adverse effects of aspiration therapy on eating behavior and no evidence of compensation for aspirated calories with increased food intake. No episodes of binge eating in the aspiration therapy group or serious adverse were reported. **CONCLUSIONS: In a pilot study, aspiration therapy appears to be a safe and effective long-term weight loss therapy for obesity. ClinicalTrials.gov, Number: NCT00773903.**

Keywords: Obesity; Endoscopic Bariatric Therapy; Overweight; Percutaneous Endoscopic Gastrostomy.

Obesity is a major global health problem because of its high prevalence, causal relationship with a large number of medical comorbidities, adverse effect on quality of life, and considerable economic consequences.[1,2] In all persons, obesity is caused by ingesting more energy than is expended over a long period. Accordingly, the principle of obesity therapy is to have patients consume less energy than expended, which mobilizes endogenous adipose tissue triglyceride stores for use as fuel. The current therapeutic approaches for obesity include lifestyle therapy to change eating and physical activity behaviors, pharmacotherapy to reduce food intake or energy absorption, and bariatric surgery to reduce food intake and, in some procedures, also cause malabsorption.[3]

Although many patients lose 5% to 10% of their body weight with intensive lifestyle therapy,[4–6] long-term weight loss maintenance is rarely achieved, with most people regaining lost weight over time.[7–9] Pharmacotherapy can provide additional weight loss when used as an adjunct to lifestyle intervention.[10,11] Bariatric surgery is the most effective available therapy for obesity, but it is expensive, is associated with serious complications, and can only be performed on a small number of patients per year relative to the number of eligible patients.[12–14] The limitations of current obesity treatment options have led to an increased interest in developing endoscopic therapies for obesity. Endoscopic therapy could have several advantages over existing therapies by being more effective than pharmacotherapy and less expensive, safer, and potentially more available than bariatric surgery.

The purpose of this study was to conduct a 1-year clinical randomized controlled trial (RCT) with an additional 1 year of follow-up to evaluate the safety and efficacy of a novel endoscopic therapy for obesity. This approach takes advantage of percutaneous endoscopic gastrostomy (PEG) tube technology to induce weight loss by aspirating a portion of ingested meals from the stomach.

Patients and Methods

Trial Design

This was a 12-month RCT performed at a single center with 2:1 randomization (aspiration therapy plus lifestyle therapy [AT]/lifestyle therapy only [LT]) conducted at the Washington University School of Medicine (St Louis, MO). After completion of the 12-month RCT, subjects in the AT group were allowed to continue participating in the study for an additional 12 months if they lost at least 25% of their excess body weight. Excess body weight was determined as current body weight (in kilograms) minus calculated body weight (in kilograms) at a body mass index (BMI) of 25 kg/m^2. The primary study end point was percent absolute weight loss. Secondary study end points were (1) percentage of excess weight loss (EWL) and (2) percentage of

Abbreviations used in this paper: ALT, alanine aminotransferase; AT, aspiration therapy plus lifestyle therapy; BDI-II, Beck Depression Inventory; BMI, body mass index; EDE, Eating Disorder Examination; EWL, excess weight loss; LT, lifestyle therapy only; PEG, percutaneous endoscopic gastrostomy; RCT, randomized controlled trial.

0016-5085/$36.00
http://dx.doi.org/10.1053/j.gastro.2013.08.056

subjects achieving ≥25% EWL. All authors had access to the study data and reviewed and approved the final manuscript.

Participants

Eighteen obese adults (BMI between 40.0 and 50.0 kg/m^2 or between 35.0 and 39.9 kg/m^2 with comorbidities) recruited between February and October 2009 participated in this study (Table 1). The flow of study participants is shown in Supplementary Figure 1. All subjects completed a comprehensive medical examination, which included a history and physical examination, blood tests, and a 12-lead electrocardiogram. All subjects also completed a careful psychological assessment, including the Eating Disorder Examination (EDE),[15,16] Stunkard Eating Inventory,[17] and Beck Depression Inventory (BDI-II).[18,19] The EDE is a structured interview–based assessment of disordered attitudes and behaviors related to eating, body shape, and weight that has items designed to diagnose eating disorders based on Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria.[15] The Stunkard Eating Inventory is a self-administered questionnaire that assesses 3 behavioral traits that can affect control of body weight: cognitive dietary restraint (deliberate control of intake), disinhibition (loss of control over food intake), and perceived hunger (awareness of and susceptibility to hunger). The BDI-II is a self-administered 21-item questionnaire that assesses the existence and severity of symptoms of depression. Potential subjects were excluded if they had evidence of an eating disorder or major depression, history of gastrointestinal disease or previous gastric surgery that would increase the risk of A-Tube placement, uncontrolled hypertension, sleep apnea, fasting serum glucose level ≥105 mg/dL, diabetes, or serum triglyceride level >400 mg/dL or were pregnant/lactating. In addition, women of childbearing potential were required to be on at least one form of birth control. All subjects were weight stable (<3% change in self-reported weight for at least 3 months before the study). All subjects provided written informed consent before participating in this study, which was approved by Washington University's Institutional Review Board (protocol no. 201111076). This study was registered at ClinicalTrials.gov (NCT00773903).

Table 1. Baseline Subject Characteristics

	LT group	AT group	*P* value
No. (male/female)	4 (1/3)	10 (0/10)	
Age (*y*)	45.3 ± 2.8	38.7 ± 2.3	.129
Weight (*kg*)	105.3 ± 2.5	112.2 ± 4.6	.384
BMI (*kg/m^2*)	39.3 ± 1.1	42.0 ± 1.4	.155
Total cholesterol (*mg/dL*)	192.3 ± 13.1	189.2 ± 6.1	.813
Low-density lipoprotein cholesterol (*mg/dL*)	116.0 ± 13.0	112.8 ± 6.9	.818
High-density lipoprotein cholesterol (*mg/dL*)	48.5 ± 4.1	53.6 ± 2.9	.354
Total triglyceride (*mg/dL*)	139.3 ± 12.8	113.4 ± 18.8	.425
Glucose (*mg/dL*)	86.8 ± 3.4	83.9 ± 1.9	.448
ALT (*IU/L*)	26.8 ± 7.3	20.6 ± 2.6	.325
Magnesium (*mEq/L*)	1.6 ± 0.03	1.6 ± 0.03	.395
Calcium (*mg/dL*)	9.2 ± 0.17	9.2 ± 0.08	.749
Iron (*μm/dL*)	83.8 ± 8.9	68.9 ± 8.1	.308
25-Hydroxyvitamin D (*nmol/L*)	45.2 ± 11.4	65.3 ± 3.6	.128
Vitamin B_{12} (*pg/mL*)	465.3 ± 110.6	395.6 ± 60.8	.567

NOTE. Values are expressed as means ± SEM.

Randomization

Eligible subjects were randomized to the AT group or LT group using a 2:1 computer-generated randomization scheme developed by an independent statistician who did not participate in subject enrollment. Randomization allocations were sealed in envelopes, which were opened sequentially by study coordinators as subjects were enrolled in the study.

AspireAssist Components

The device used to perform AT, AspireAssist (Aspire Bariatrics, King of Prussia, PA), consists of the following (Figure 1):

1. The A-Tube, which has holes in the intragastric portion to allow aspiration of gastric contents.
2. The Skin-Port, which is a flange 3.5 cm in diameter and 0.9 mm in height that connects to the external end of the A-Tube, contains a valve that is normally closed to prevent gastric leakage and is opened by engaging the connector.
3. The connector, which mates with the Skin-Port and opens the Skin-Port valve to allow aspiration of gastric contents. In addition, the connector contains a "counter" that tracks the number of times the connector is attached to the Skin-Port. When the count reaches 115 aspiration cycles (approximately 5–6 weeks of therapy), the connector locks and the Skin-Port can no longer be accessed for aspiration. The connector provides an additional safety measure against long-term unsupervised use, and the subject must return to the clinic to obtain a new connector to continue aspiration therapy.
4. The companion, which is a siphon that allows 2-way flow of fluids (draining stomach contents and infusing water into the stomach).
5. The reservoir, which is a 600-mL soft water bottle that allows subjects to flush tap water into the stomach to facilitate aspiration.

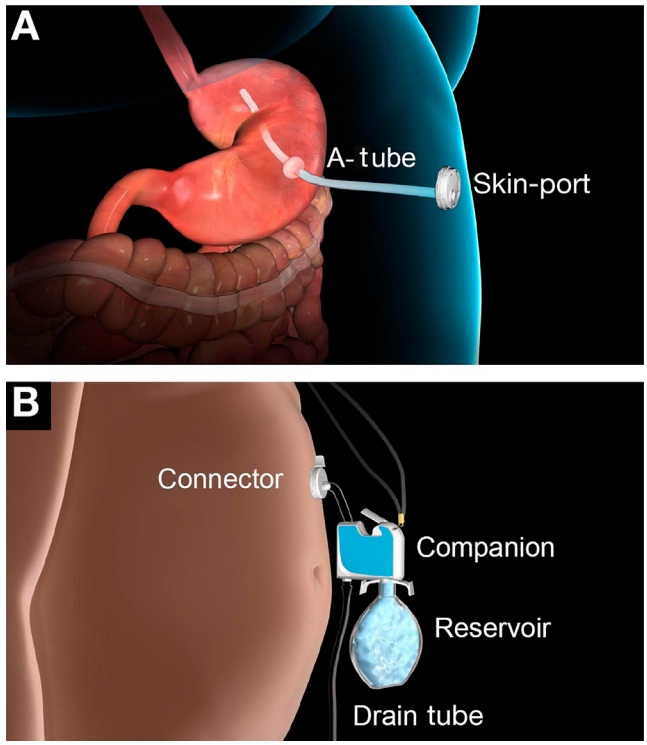

Figure 1. Components of AT. (*A*) Internal components and Skin-Port and (*B*) external components.