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EDITORIAL COMMENT

Bariatric Arterial Embolization

Are We There Yet?*

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Obesity remains a significant global health crisis; yet, we now have a diverse arsenal of invasive and noninvasive approaches to help combat this epidemic (1). Bariatric surgery and lifestyle modifications have been at the forefront of weight loss therapies for years. Bariatric surgical approaches, although highly effective, are reserved for patients with higher body mass indexes (BMIs), and diet/lifestyle modifications, which are typically reserved for patients who have lower BMIs, often provide limited long-term efficacy (2). There is a need for more aggressive therapies that can provide more robust weight loss outcomes while avoiding postoperative complications. Furthermore, therapies that can modulate underlying metabolic derangements (i.e., diabetes mellitus) in patients with obesity are of interest now that it is known that the hormonal changes after bariatric surgery play a significant role in weight reduction (3). A variety of pharmacological therapies have been introduced to bridge this gap between lifestyle and surgical intervention, as have a series of endoscopic approaches all with variable efficacy and durability.

One of the newest minimally invasive approaches that has been the subject of multiple studies in recent years is bariatric arterial embolization (BAE), referred to by Reddy et al. (4) as transcatheter bariatric embolotherapy (5). This endovascular approach aims to induce localized ischemia in the gastric fundus in theory to modulate the endocrine functions related to appetite, thus inducing weight loss. Multiple studies have yielded exciting results demonstrating appetite suppression and weight loss after BAE with favorable safety profile (5). In this issue of the *Journal*, Reddy et al. (4) present data from the first randomized, sham-controlled trial of BAE. Although the study itself is small, it represents a significant and important contribution to the published data supporting the safety and efficacy of BAE in patients with obesity (4).

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Obese subjects (BMI 33 to 55 kg/m^2) age 21 to 60 years were randomized in a 1 to 1 fashion to either sham or BAE with lifestyle counseling. The sham group was unblinded at the 6-month point and permitted to cross over. BAE was performed via a transfemoral approach targeting the left gastric artery. Embolization was performed using 300- to 500-micron Beadblock microspheres (BeadBlock, Biocompatibles Ltd., Farnham, United Kingdom) to complete stasis. Sham patients received sedation and subcutaneous lidocaine injection without arterial access (4). In total, 37 patients were included in an intent-to-treat (ITT) analysis and 31 patients in a per-protocol (PP) analysis with a 1:1 randomization.

No major/serious adverse events after BAE were reported. Minor adverse events included asymptomatic, superficial ulcerations in 5 patients and nausea, vomiting, and epigastric pain. With regard to the ITT analysis, mean absolute and percentage total weight loss after BAE was 4.4 kg and 3.2% over sham. In the PP analysis, mean absolute and percentage weight loss after BAE was 7.5 kg and 6.5% over sham at 6 months. BAE patients followed to the 12-month time point demonstrated mean absolute and percentage total weight loss of 7.8 kg and 6.5% in the ITT analysis and 9.3 kg and 9.3% in the PP analysis (4).

Secondary analyses of hypertension, quality of life (QOL), hunger scores, and ghrelin levels were

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performed. There was a statistically significant decrease in diastolic blood pressures at 12 months (9.71 ± 15.6 mm Hg); however, a significant decrease in systolic blood pressure was not seen. Quality of life and hunger measures revealed no significant differences between groups though there were improvements in physical function, self-esteem and overall QOL in the BAE group. Ghrelin levels demonstrated a significant decrease (15.5%) in the transcatheter bariatric embolotherapy group at the 12-month mark. Interestingly, 2 BAE patients in this study underwent subsequent bariatric surgery with healthy gastric tissue found during surgery (4).

Findings from this study are concordant with prior single-arm studies including BEAT-Obesity (Bariatric Embolization of Arteries for the Treatment of Obesity), which was a nonrandomized, prospective trial of BAE in severely obese patients, and a recent meta-analysis with regard to safety and efficacy (5,6). In the existing published data, BAE has been shown to be well tolerated. Adverse events after BAE have been minor with the most common being superficial gastric mucosal ulcerations, which resolve rapidly with medical therapy. The most severe complications in the published data are a single instance of gastric perforation and pancreatitis (5,7,8).

Weight loss efficacy in Reddy et al. (4) is also consistent with the current body of single-arm prospective studies of BAE (5). Excess body weight loss at 6 months was 17% in ITT and 22% and PP, similar to the 11% mean excess body weight loss reported in BEAT-Obesity (6) and 17% reported in Syed et al. (9). In their meta-analysis, Hafezi-Nejad et al. (5) performed a pooled analysis of 47 patients treated with BAE finding a mean weight loss at 12 months of 8.85 kg (8.1%) (5). Similar improvements in QOL measures have also been seen in physical function and self-esteem after BAE (6). Finally, other investigations have demonstrated a significant decrease in serum ghrelin after 12 months post-BAE, with some demonstrating a positive trend toward lower ghrelin levels post-BAE (7).

So, where might BAE fit in the paradigm of weight management? Although there is a benefit over diet and lifestyle modifications, BAE does not approach the weight loss efficacy of bariatric surgical approaches (5), but appears to be as effective as many available weight-loss medications (6). However, BAE is not meant to replace bariatric surgery, diet, exercise, and weight-loss medications. Instead, BAE will probably fall somewhere in between lifestyle management and surgery, and hopefully will be part of a multidisciplinary approach to treating patients with obesity. Importantly, preliminary evidence from both the current study and from a handful of case reports suggests that BAE may not preclude future bariatric surgery (4,8,10). Although this is far from proven, this supports the idea that BAE could be included safely in the treatment pathway before bariatric surgery.

Although current data support the concept that BAE may be an exciting new option for the treatment of patients with obesity, many questions remain. It is still unknown whether BAE provides weight loss/maintenance past 12 months. Both the current and previous studies have demonstrated that overall procedural efficacy tends to decline at the 6-month mark (4–6). This inflection point is postulated to occur because of restoration of pre-embolization hormone levels secondary to revascularization of the gastric fundus. With this in mind, the question remains whether re-embolization, either performed empirically or driven by recurrent weight gain, would be of benefit to sustain or improve weight loss. Studies that provide longer-term follow-up of previously treated patients, in addition to larger, multicenter, randomized trials, will be critical to move this procedure into clinical practice.

Despite the fact that it is well known that embolic size, shape, and material composition may influence the safety, efficacy, and durability of an embolization, it is not yet known which embolic is ideally suited to BAE. In the current study, 300- to 500-micron Bead-block microspheres were used for BAE. However, other studies have used embolics of different shapes, sizes, and compositions either alone or in-combination including: 300- to 500-micron embospheres (Merit Medical, South Jordan, Utah), 300- to 500-micron or 500- to 700-micron nonspherical polyvinyl alcohol particles (Boston Scientific, Marlborough, Massachusetts), and even macerated gelfoam (5). Meta-analysis by Hafezi-Nejad et al. (5) found no statistically significant difference in weight loss after embolization based on microsphere size; however, this analysis is underpowered given the small amount of patients' data that were available (5). As well, patient selection warrants further study as male sex was the only characteristic that was associated with greater weight loss in the same meta-analysis (5).

When combined with the previous published data, the data from the current randomized controlled trial from Reddy et al. (4) further demonstrate that BAE is well-tolerated and effective in inducing mild/moderate weight loss up to at least the 12-month timepoint. Although questions remain, BAE remains an exciting, innovative, minimally invasive procedure with the potential to play a significant role in the

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treatment of the patient with obesity. Careful study, with even more careful physician adoption, will allow us to discover the true utility of this procedure.

AUTHOR RELATIONSHIP WITH INDUSTRY

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